

iM50/iM60/iM70/iM80/M50/M80
Patient Monitor
Version 1.7

User Manual

CE₀₁₂₃



About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) cannot be held liable.

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The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Table of Contents

Chapter 1 Intended Use and Safety Guidance	1
1.1 Intended Use/Indications for Use.....	1
1.2 Safety Guidance	2
1.3 Explanation of Symbols on the Monitor	7
Chapter 2 Installation	13
2.1 Initial Inspection.....	13
2.2 Mounting the Monitor	13
2.3 Connecting the Power Cable	13
2.4 Checking the Monitor	13
2.5 Checking the Recorder	14
2.6 Setting Date and Time	14
2.7 Handing Over the Monitor	14
2.8 FCC Statement	15
2.9 FCC RF Radiation Exposure Statement.....	15
Chapter 3 Basic Operation	16
3.1 System Components.....	16
3.1.1 Front View.....	16
3.1.2 Rear View	19
3.1.3 Side View	23
3.2 Operating and Navigating	25
3.2.1 Using Keys.....	26
3.3 Operating Mode	28
3.3.1 Demo Mode.....	28
3.3.2 Standby Mode	28
3.3.3 Night Mode	29
3.3.4 Privacy Mode	29
3.3.5 NFC Mode.....	29
3.4 Changing Monitor Settings	30
3.4.1 Adjusting Screen Brightness	30
3.4.2 Changing Date and Time.....	30
3.5 Adjusting Volume	31
3.5.1 Adjusting Key Volume	31
3.5.2 Adjusting Alarm Volume	31
3.5.3 Adjusting Beat Volume.....	31
3.6 Checking Your Monitor Version	31
3.7 Setting Languages	31
3.8 Setting Keyboard Languages	32
3.9 Calibrating Screens	32
3.10 Disabling the Touch Screen.....	32
3.11 Using the Barcode Scanner	32
3.12 Resolving IBP Label Conflicts.....	33
Chapter 4 Networked Monitoring	34
4.1 Cybersecurity Measures	34

4.1.1 Personal Information Safety.....	34
4.1.2 Network Security	35
4.2 Connecting the Wireless Network.....	36
4.3 Network Disconnected Alarms	38
4.4 Connecting the Monitor to MFM-CMS	38
4.5 Connecting the Monitor to CMS-LITE.....	39
4.6 Connecting the Monitor to Gateway	39
4.7 HL7 Communication.....	40
Chapter 5 Alarms	41
5.1 Alarm Category	41
5.1.1 Physiological Alarms	41
5.1.2 Technical Alarms.....	41
5.1.3 Prompts	41
5.2 Selecting Alarm Tone Type	41
5.3 Alarm Levels	41
5.4 Controlling Alarm	43
5.4.1 Setting Parameter Alarm	43
5.4.2 Audio Alarm Paused.....	44
5.4.3 Audio Alarm off	45
5.4.4 Alarm Reset.....	45
5.5 Latching Alarms	45
5.6 Disabling Sensor Off Alarms	46
5.7 Testing Alarms.....	46
Chapter 6 Alarm Information.....	47
6.1 Physiological Alarm Information.....	47
6.2 Technical Alarm Information	54
6.3 Prompts	70
6.4 Adjustable Range of Alarm Limits.....	75
Chapter 7 Managing Patients	79
7.1 Confirming a Patient	79
7.2 Admitting a Patient.....	79
7.2.1 Patient Category and Paced Status	80
7.3 Quick Admit.....	80
7.4 Barcode Admit	80
7.5 Managing Patient Information	81
7.5.1 Editing Patient Information.....	81
7.5.2 Obtaining Patient Information from the Network Server	81
Chapter 8 User Interface.....	83
8.1 Setting Interface Style	83
8.2 Selecting Display Parameters.....	83
8.3 Changing Waveform Position	83
8.4 Changing Interface Layout.....	83
8.5 Viewing Trend Screen	84
8.6 Viewing OxyCRG Screen	84
8.7 Viewing Large Font Screen.....	84

8.8 Viewing the Vital Screen.....	85
8.9 Viewing the Bed View Window	85
8.9.1 Opening the Bed View Window.....	86
8.9.2 Settings of the Bed View Window	86
8.10 Changing Parameter and Waveform Colors.....	86
8.11 Displaying the Timer.....	86
8.12 Profile.....	87
8.13 Neonatal Configuration*	87
Chapter 9 Monitoring ECG	88
9.1 Overview.....	88
9.2 ECG Safety Information	88
9.3 ECG Display	90
9.3.1 Changing the Size of the ECG Wave.....	90
9.3.2 Changing the ECG Filter Settings.....	91
9.4 Selecting Calculation Lead	91
9.5 Monitoring Procedure	92
9.5.1 Preparation	92
9.5.2 Connecting ECG Cables	92
9.5.3 Selecting Electrode Type.....	92
9.5.4 Installing Electrodes.....	93
9.6 ECG Menu Setup	97
9.6.1 Setting Alarm Source	97
9.6.2 Setting Beat Source.....	98
9.6.3 Smart Lead Off.....	98
9.6.4 ECG Screen Layout.....	98
9.6.5 Setting Pace Status	99
9.6.6 ECG Calibration.....	100
9.6.7 ECG Waveform Settings	100
9.7 12-Lead ECG Monitoring	100
9.7.1 Activating 6/10 Electrodes ECG Monitoring.....	101
9.7.2 Analysis Function.....	101
9.7.3 Waveform Durations and Isoelectric Segments	101
9.8 ST Segment Monitoring.....	102
9.8.1 Setting ST Analysis	103
9.8.2 ST Display.....	103
9.8.3 About ST Measurement Points.....	103
9.8.4 Adjusting ST and ISO Measurement Points.....	104
9.8.5 ST Alarm Setup	104
9.8.6 ST View.....	104
9.9 Arrhythmia Monitoring.....	105
9.9.1 Arrhythmia Analysis.....	105
9.9.2 ARR Analysis Menu.....	110
9.10 QT Analysis.....	112
9.10.1 Measurement Limitations.....	112
9.10.2 Switching QT Analysis On and Off	113

9.10.3 QT Display	113
9.10.4 Selecting QT Analysis Lead	113
9.10.5 Selecting Calculation Formula	113
9.10.6 Setting QT Baseline	114
9.10.7 QTc Alarm Setup	114
9.10.8 QT View	114
Chapter 10 Monitoring RESP	115
10.1 Overview	115
10.2 RESP Safety Information	115
10.3 Electrode Placement for Monitoring RESP	116
10.4 Cardiac Overlay	116
10.5 Chest Expansion	116
10.6 Abdominal Breathing	117
10.7 Selecting RESP Lead	117
10.8 Changing Hold Type	117
10.9 Changing the Size and Speed of the Respiration Wave	117
10.10 Changing the Apnea Alarm Time	117
Chapter 11 Monitoring SpO₂	118
11.1 Overview	118
11.2 SpO ₂ Safety Information	118
11.3 Measuring SpO ₂	119
11.4 Measurement Limitations	121
11.5 Assessing the Validity of a SpO ₂ Reading	122
11.6 SpO ₂ Alarm Delay	123
11.7 Perfusion Index (PI)*	123
11.8 Measuring SpO ₂ and NIBP Simultaneously	123
11.9 Setting Pitch Tone	124
11.10 Setting Sensitivity	124
11.11 SatSeconds Alarm Management*	124
11.11.1 Describing SatSeconds	124
11.11.2 SatSeconds “Safety Net”	125
11.11.3 Setting SatSeconds Duration	125
Chapter 12 Monitoring PR	126
12.1 Overview	126
12.2 Setting PR Source	126
12.3 Setting PR Volume	126
12.4 Selecting the Active Alarm Source	126
Chapter 13 Monitoring NIBP	127
13.1 Overview	127
13.2 NIBP Safety Information	127
13.3 Measurement Limitations	128
13.4 Measurement Methods	129
13.5 Measurement Procedures	130
13.5.1 Operation Prompts	131
13.5.2 Correcting the Measurement if Limb is not at Heart Level	131

13.6 NIBP Multi-Review Window	132
13.7 Resetting NIBP.....	132
13.8 Calibrating NIBP.....	132
13.9 Leakage Test.....	132
13.10 Setting Inflation Mode	133
13.11 Cleaning Mode	134
13.12 Assisting Venipuncture.....	134
Chapter 14 Monitoring TEMP.....	135
14.1 Overview	135
14.2 TEMP Safety Information	135
14.3 Selecting TEMP Sensor Type.....	135
14.4 Switching T1/T2 On/Off	135
14.5 TEMP Monitoring Setup	135
14.6 Selecting a Temperature for Monitoring	136
14.7 Calculating Temp Difference	136
Chapter 15 Monitoring Quick TEMP	137
15.1 Overview	137
15.2 Quick TEMP Safety Information	137
15.3 Measuring Procedure	138
15.3.1 Measurement for Oral Temperature	138
15.3.2 Measurements for Rectal Temperatures	139
15.3.3 Measurements for Axillary Temperatures	139
15.4 Changing Temp Unit	140
Chapter 16 Monitoring IBP	141
16.1 Overview	141
16.2 IBP Safety Information	141
16.3 Monitoring Procedures.....	142
16.3.1 Selecting a Pressure for Monitoring.....	142
16.3.2 Zeroing the Pressure Transducer.....	143
16.3.3 Troubleshooting the Pressure Zeroing (Taking Art for Example).....	143
16.3.4 IBP Calibration.....	143
16.4 Changing the IBP Waveform Ruler.....	144
16.5 IBP Waveform Overlapping.....	144
16.6 Measuring PAWP	144
16.6.1 Measurement Procedures	144
16.7 Calculating CPP	145
16.7.1 Measurement Procedures	145
16.8 Calculating PPV	146
Chapter 17 Monitoring CO₂.....	147
17.1 Overview	147
17.2 CO ₂ Safety Information.....	147
17.3 Monitoring Procedures.....	148
17.3.1 Zeroing the sensor	148
17.3.2 Sidestream CO ₂ Module.....	149
17.3.3 Mainstream CO ₂ Module	157

17.4 Setting CO ₂ Corrections.....	159
17.5 Setting Apnea Alarm Time.....	160
17.6 Setting CO ₂ Waveform.....	160
17.7 Intubation Mode.....	160
Chapter 18 Monitoring C.O.....	162
18.1 Overview.....	162
18.2 C.O. Safety Information.....	162
18.3 C.O. Monitoring.....	162
18.4 Blood Temperature Monitoring.....	166
Chapter 19 Monitoring AG.....	167
19.1 Overview.....	167
19.2 Safety Information.....	167
19.2.1 Safety Information for G7 Module.....	167
19.2.2 Safety Information for Masimo ISA Analyzer.....	168
19.2.3 Safety Information for Dräger Minimodule.....	170
19.2.4 Safety Information for Masimo IRMA Module.....	172
19.3 Monitoring Steps.....	173
19.3.1 Monitoring Steps for G7 Module.....	173
19.3.2 Monitoring Steps for Masimo ISA Module.....	175
19.3.3 Monitoring Steps for Dräger Minimodule.....	178
19.3.4 Monitoring Steps for Masimo IRMA Module.....	179
19.4 Setting Apnea Alarm Time.....	182
19.5 O ₂ Compensations.....	182
19.6 Effects of Humidity.....	183
Chapter 20 Freeze.....	184
20.1 Entering/Exiting Freeze Status.....	184
20.1.1 Entering Freeze Status.....	184
20.1.2 Exiting Freeze Status.....	184
20.2 Reviewing Frozen Waveform.....	185
Chapter 21 Review.....	186
21.1 Trend Graph Review.....	186
21.2 Trend Table Review.....	187
21.3 NIBP Review.....	188
21.4 Alarm Review.....	188
21.5 ARR Review.....	188
21.6 12-lead Analysis Review.....	189
21.7 ST Segment Review.....	189
Chapter 22 Calculation.....	190
22.1 Drug Calculation.....	190
22.1.1 Calculation Procedures.....	190
22.1.2 Calculation Unit.....	191
22.1.3 Titration Table.....	191
22.2 Hemodynamic Calculation.....	192
22.2.1 Calculation Procedure.....	192
22.2.2 Input Parameters.....	192

22.2.3 Output Parameters.....	192
22.3 Oxygenation Calculation.....	193
22.3.1 Calculation Procedure.....	193
22.3.2 Input Parameters.....	194
22.3.3 Output Parameters.....	194
22.4 Ventilation Calculation.....	195
22.4.1 Calculation Procedure.....	195
22.4.2 Input Parameters.....	195
22.4.3 Output Parameters.....	195
22.5 Renal Function Calculation.....	196
22.5.1 Calculation Procedure.....	196
22.5.2 Input Parameters.....	196
22.5.3 Output Parameters.....	197
Chapter 23 Warning-Score System.....	198
23.1 Warning-Score Interface.....	198
23.2 Warning-Score Method.....	198
23.3 Warning-Score Criteria.....	198
23.4 Warning-Score Result.....	200
23.5 Warning-Score Trend Table.....	200
Chapter 24 Recording.....	201
24.1 Performance of the Recorder.....	201
24.2 Starting and Stopping Recording.....	202
24.3 Recorder Operations and Status Messages.....	203
24.3.1 Record Paper Requirement.....	203
24.3.2 Proper Operation.....	204
24.3.3 Paper Out.....	204
24.3.4 Replacing Paper.....	204
24.3.5 Removing Paper Jam.....	204
Chapter 25 Printing Patient Reports.....	206
25.1 Printer Settings.....	206
25.2 Starting and Stopping Report Printing.....	206
Chapter 26 Other Functions.....	208
26.1 Nurse Call.....	208
26.2 Analog Output and Defibrillator Synchronization.....	208
26.3 Storing Data in the Storage Device.....	208
26.3.1 Data Stored in the Storage Device.....	208
26.3.2 Activating/ Deactivating Data Storing.....	209
26.3.3 Selecting a Storage Device.....	209
26.3.4 Reviewing Data Stored in the Storage Device.....	210
26.3.5 Deleting Data Stored in the Storage Device.....	210
26.3.6 Exporting Data Stored in the Internal Storage Device.....	210
26.3.7 Formatting the Internal Storage Device.....	211
26.3.8 Ejecting a Removable Device.....	211
Chapter 27 Using Battery.....	212
27.1 Battery Safety Information.....	212

27.2 Battery Power Indicator	213
27.3 Battery Status on the Main Screen	213
27.4 Checking Battery Performance	213
27.5 Replacing the Battery	214
27.6 Recycling the Battery	214
27.7 Maintaining the Battery	214
Chapter 28 Care and Cleaning	216
28.1 General Points	216
28.2 Cleaning	216
28.2.1 Cleaning the Monitor	217
28.2.2 Cleaning the Reusable Accessories	217
28.3 Disinfection	218
28.3.1 Disinfecting the Monitor	219
28.3.2 Disinfecting the Reusable Accessories	219
28.4 Cleaning and Disinfecting Other Accessories	220
Chapter 29 Maintenance	221
29.1 Inspecting	221
29.2 Maintenance Task and Test Schedule	221
Chapter 30 Warranty and Service	223
30.1 Warranty	223
30.2 Contact Information	223
Chapter 31 Accessories	224
31.1 ECG Accessories	224
31.2 SpO ₂ Accessories	228
31.3 NIBP Accessories	229
31.4 TEMP Accessories	231
31.5 Quick Temp Accessories*	231
31.6 IBP Accessories	231
31.7 CO ₂ Accessories	232
31.8 C.O. Accessories*	235
31.9 AG Accessories*	235
31.10 Other Accessories	236
A Product Specification	238
A.1 Classification	238
A.2 Physical Specifications	238
A.2.1 Size and Weight	238
A.2.2 Environment Specification	238
A.2.3 Display	239
A.2.4 Battery Specification	239
A.2.5 Recorder	240
A.2.6 Data Management	240
A.3 Wi-Fi	241
A.3.1 Wi-Fi Technical Specifications	241
A.3.2 Wi-Fi Performance Specifications	242
A.4 ECG	244

A.5 RESP	250
A.6 NIBP	250
A.7 SpO ₂	255
A.8 PR	256
A.9 TEMP	256
A.10 Quick TEMP	257
A.11 IBP	258
A.12 CO ₂	259
A.13 C.O.	269
A.14 AG	269
A.14.1 Sidestream	269
A.14.2 Mainstream	278
A.15 Interfaces	283
A.15.1 Analog Output	283
A.15.2 Defibrillator Synchronization	284
A.15.3 Nurse Call	284
A.15.4 USB Interfaces	284
A.15.5 VGA Interface	285
A.15.6 RS232 Interface	285
A.15.7 Wired Network Interface	285
B EMC Information	286
B.1 Electromagnetic Emissions	286
B.2 Electromagnetic Immunity	286
B.3 Electromagnetic Immunity	288
B.4 Recommended Separation Distances	291
C Default Settings	292
C.1 Patient Information Default Settings	292
C.2 Alarm Default Settings	292
C.3 ECG Default Settings	292
C.4 RESP Default Settings	295
C.5 SpO ₂ Default Settings	295
C.6 PR Default Settings	296
C.7 NIBP Default Settings	296
C.8 TEMP Default Settings	297
C.9 Quick TEMP Default Settings	297
C.10 IBP Default Settings	297
C.11 CO ₂ Default Settings	298
C.12 C.O. Default Settings	299
C.13 AG Default Settings	299
D Abbreviations	301

Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

The monitors are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The iM50 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO₂), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO₂ and Quick Temperature (Quick TEMP).

The iM60 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO₂), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP) and Expired CO₂.

The iM70 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO₂), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO₂ and Anesthetic gas (AG).

The iM80 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO₂), Invasive or noninvasive blood pressure (2/4 channels IBP, NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO₂ and Anesthetic gas (AG).

The M50 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO₂), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO₂ and Quick Temperature (Quick TEMP).

The M80 monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO₂), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (C.O.), Temperature (dual-TEMP), Expired CO₂ and Anesthetic gas (AG).

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The monitors are not intended for MRI environments.

1.2 Safety Guidance

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

WARNING

- 1 To ensure that the monitor works properly, please read the user manual and follow the steps before using the monitor.
 - 2 Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.
 - 3 Medical technical equipment such as these monitor/monitoring systems must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.
 - 4 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
 - 5 SHOCK HAZARD-To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.
 - 6 Do not come into contact with the patient, table, or the monitor during defibrillation.
 - 7 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.
 - 8 Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
 - 9 Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.
 - 10 Route all cables carefully to avoid possible entanglement, apnea, or electrical interference. For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.
 - 11 Devices connecting with monitor should be equipotential.
 - 12 If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by internal power only.
-

WARNING

- 13 Do not rely exclusively on the auditory alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
 - 14 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.
 - 15 The monitor is equipped with wireless AP/Wi-Fi to receive RF electromagnetic energy. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.
 - 16 Only patient cable and other accessories supplied by EDAN can be used. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable or sterilized accessory is intact. Do not use it if its casing is damaged.
 - 17 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
 - 18 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.
 - 19 During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off. The settings configured by the user can be stored, and settings not configured by user keep no change. That is, the last settings used will be recovered when the power is restored.
 - 20 If leakage or foul odor is detected, ensure that there's no fire around.
 - 21 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test, before installation and any time new medical equipment is added to the Wireless LAN coverage area.
 - 22 The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.
-
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WARNING

- 23 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.
 - 24 After defibrillation, the ECG display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.
 - 25 Clinical decision making based on the output of the device is left to the discretion of the provider.
 - 26 This equipment is not intended for home usage.
 - 27 Do not service or maintain the monitor or any accessory which is in use with the patient.
 - 28 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.
 - 29 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.
 - 30 The monitors are MR Unsafe. The monitors are not intended for use in an MRI environment.
 - 31 Only recommended batteries can be used for the monitor.
 - 32 Additional multiple socket-outlets or extension cords can't be connected to the system.
 - 33 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.
 - 34 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:
 - a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and
 - b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.
 - 35 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.
 - 36 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.
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WARNING

- 37 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in this user manual.
 - 38 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.
 - 39 The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.
 - 40 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously, such as USB connector, VGA connector or other signal input/output connectors.
 - 41 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.
 - 42 SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.
 - 43 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.
 - 44 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only EDAN-approved accessories.
 - 45 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
 - 46 To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by EDAN.
 - 47 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
 - 48 Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
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WARNING

- 49 The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.
 - 50 Make sure networking function is used in a secure network environment.
-
-

CAUTION

- 1 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.
 - 2 Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dust area, high temperature and humid environment.
 - 3 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.
 - 4 Do not use autoclave or gas to sterilize the monitor, recorder or any accessories.
 - 5 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.
 - 6 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.
 - 7 Remove a battery whose life cycle has expired from the monitor immediately.
 - 8 Avoid liquid splashing on the device.
 - 9 To ensure patient safety, use only parts and accessories manufactured or recommended by EDAN.
 - 10 Before connecting the monitor to the AC power, make sure the voltage and the power frequency are consistent with the requirements indicated on the device label or in this user manual.
 - 11 Protect the device against mechanical damage resulting from falls, impacts, and vibration.
 - 12 Do not touch the touch screen with a sharp object.
 - 13 A ventilated environment is required for monitor installation. Do not block up the ventilation grille at the back of the device.
 - 14 The device must be connected to the ground to avoid the signal interference.
 - 15 Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.
 - 16 To protect eyes from damage, don't look directly at supplementary light for long time.
 - 17 Extremely frequent clicking on the screen within a short period of time may result in temporary discontinuous data.
-
-







CAUTION










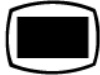

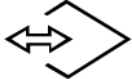



- 18 When multiple parameters are simultaneously displayed and one of the parameter values is close to the limit value, the waveform might get non-smooth, please take the parameter value as the reference.
- 19 If the touch screen fails, use the rotary knob and keys and contact the service personnel.















NOTE:













- 1 Position the device in a location where the operator can easily see the screen and access the operating controls.
- 2 The monitor can only be used on one patient at a time.
- 3 If the monitor gets damp or liquid pours on the monitor, please contact the service personnel of EDAN.
- 4 This monitor is not a device for treatment purposes.
- 5 The pictures and interfaces in this manual are for reference only.
- 6 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.
- 7 When there's measurement beyond range, invalid measurement or no measurement value, it will display -?-.
- 8 In normal use, the operator shall stand in front of the monitor.











1.3 Explanation of Symbols on the Monitor





1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
3		Caution
4		MR Unsafe - Keep away from magnetic resonance imaging (MRI) equipment
5		Equipotentiality
6		Alternating Current

7		Power Supply switch
8		Serial Number
9		Network port
10		USB (Universal Serial Bus) Connection
11		Bell cancel
12		NIBP measurement
13		Trend
14		Screen or video image, freeze
15		Graphical recorder
16		Menu
17		Video output
18		RS-232 port
19		Nurse call port
20		Write data into store
21		Defibrillator synchronization/Signal output port

22		Output
23		CE marking
24		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
25		Date of manufacture
26		Manufacturer
27	P/N	Part Number
28		General symbol for recovery/recyclable
29		Disposal method
30		Operating instructions
31		Refer to instruction manual/booklet (Background: Blue; Symbol: White)
32		Warning (Background: Yellow; Symbol & outline: black)
33		Anti-theft lock
34		Gas inlet
35		Gas outlet (evac)
36		ISA equipped to measure CO ₂ only.

37		ISA equipped to measure multiple gases.
38	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
39	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
40		Non-ionizing electromagnetic radiation
41	Contains FCC ID	Federal Communications Commission: Contains FCC ID: SMQV1102EDAN
42		DO NOT RE-USE
43		Catalog number/model number) (for Masimo module)
44		Lot code (for Masimo module)
45		Not made with natural rubber latex (for Masimo module)
46		Use by date [YYYY-MM] (for Masimo module)
47		Storage temperature range (for Masimo module)
48		Atmospheric pressure limitation (for Masimo module)
49		Storage humidity limitation (for Masimo module)
50		Do not use if package is damaged (for Masimo module)
51		Biohazardous waste (for Masimo module)

52		Patient body weight range (for Masimo module)
53		Number of units (for Masimo module)
54		CE marking (for Masimo module)
55		ETL Intertek certification (for Masimo module)
56	IPX4	Protection against water splashed from all directions (for Masimo AG sidestream module)
57	IP34	Protection from ingress of particulates ≥ 2.5 mm and against splashing water from all directions (for Masimo CO ₂ sidestream module)
58	IP44	IP classification indicating degree of protection against ingress of solid foreign objects and water (for Masimo mainstream module)
59		Class II Equipment (for Masimo module)
60		China Restriction of Hazardous Substances (for Masimo module)
61		Instructions/Directions for Use/Manuals are available in electronic format @ http://www.Masimo.com/TechDocs Note: eIFU is not available in all countries. (for Masimo module)
62		This way up
63		Fragile, handle with care
64		Keep dry

65		Stacking limit by number
66		Handle with care
67		Do not step on
68		Use-by date

NOTE:

The user manual is printed in black and white.

Chapter 2 Installation

NOTE:

The monitor settings must be configured by the authorized hospital personnel.

2.1 Initial Inspection

Before unpacking, check the packaging and ensure that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove the monitor and accessories. Check that the contents are complete and that the correct options and accessories have been delivered.

If you have any question, please contact your local supplier.

2.2 Mounting the Monitor

Place the monitor on a flat, level surface, hang it on the bed rail, or mount it on a wall. For detailed information about how to install the wall mount for the monitor, please refer to the *Wall Mounting Bracket Assembly Instruction*.

WARNING

The wall mounting bracket can be fixed only on a concrete wall.

2.3 Connecting the Power Cable

Connection procedure of the AC power line is listed below:

1. Make sure the AC power supply complies with the following specifications: 100 V-240 V~, 50 Hz/60 Hz.
2. Connect the power cord provided with the monitor. Connect the power cord to connector of the monitor. Connect the other end of the power cord to a grounded power outlet.

NOTE:

1. Connect the power cable to the socket specialized for hospital use.
2. Only use the power cable supplied by EDAN.

2.4 Checking the Monitor

Make sure there is no damage on the measurement accessories and cables. Then turn on the monitor, check whether the monitor can start normally. Make sure all alarm lamps light up and the alarm sound is heard when turning on the monitor. Please refer to chapter *Testing Alarms*.

WARNING

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact Customer Service Center immediately.

NOTE:

- 1 Check all the functions of the monitor and make sure that the monitor is in good status.
- 2 If rechargeable batteries are provided, charge them after using the device every time, to ensure the electric power is enough.
- 3 After long-time continuous running, please restart the monitor to ensure the monitor's steady performance and long lifespan.

2.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder's door to check if paper is properly installed in the slot. If no paper exists, refer to Chapter *Recording* for details.

2.6 Setting Date and Time

To set the date and time:

1. Select **Menu > Maintenance > User Maintain > Date/Time Setup**.
2. Adjust the **Date Format** and **Clock Format** based on the user's habit.
3. Set the correct time of year, month, day, hour, min and sec.

NOTE:

- 1 If the system is not used for a longer period of time, its system time may be inaccurate. In this case, readjust the system time after powering on.
- 2 If the system time cannot be saved and resumes the default value after restart, contact the service department of EDAN to replace the button cell in main board.
- 3 The default clock format is 24 hours. When **Clock Format** is set to **12 Hours**, please select AM or PM according to actual situation.

2.7 Handing Over the Monitor

If you are handing over the monitor to the end-users directly after configuration, make sure that it is in normal working status and let user know the status.

The users must be adequately trained to use the monitor before monitoring a patient. To achieve this, they should have access to, and read, the following documentation delivered with the monitor:

- User Manual (this book) - for full operating instructions.
- Quick Reference Card - for quick reminders during use.

2.8 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

2.9 FCC RF Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

Chapter 3 Basic Operation

This manual is for clinical professionals using the iM50/iM60/iM70/iM80/M50/M80 patient monitors. Unless otherwise specified, the information here is valid for all the above products.

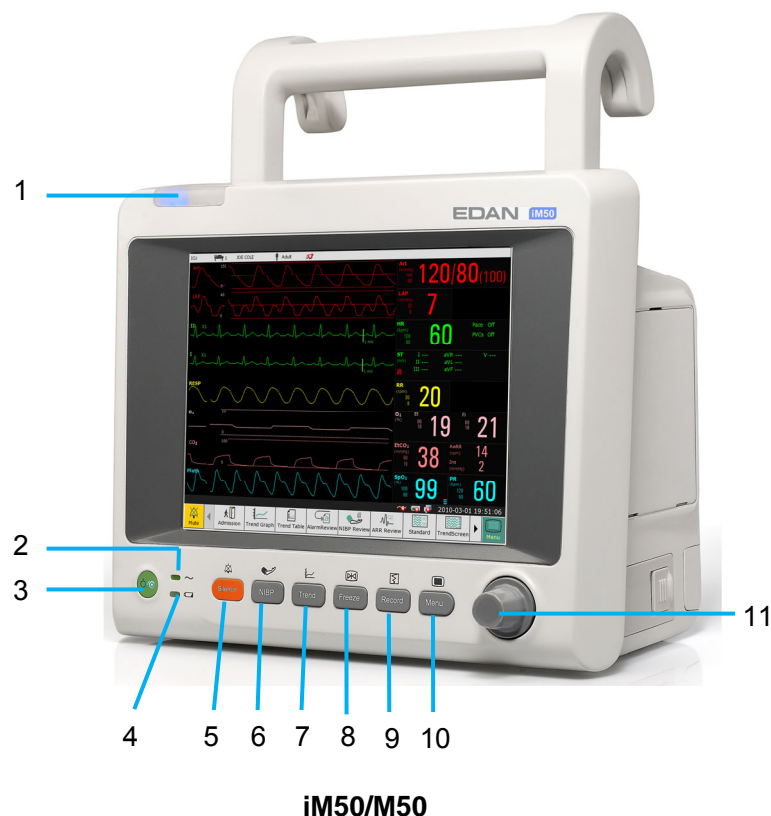
This user manual describes all features and options. Your monitor may not have all of them; they are not all available in all geographies. Your monitor is highly configurable. What you see on the screen, how the menus appear and so forth, depend on the way it has been tailored for your hospital and may not be exactly as shown here.

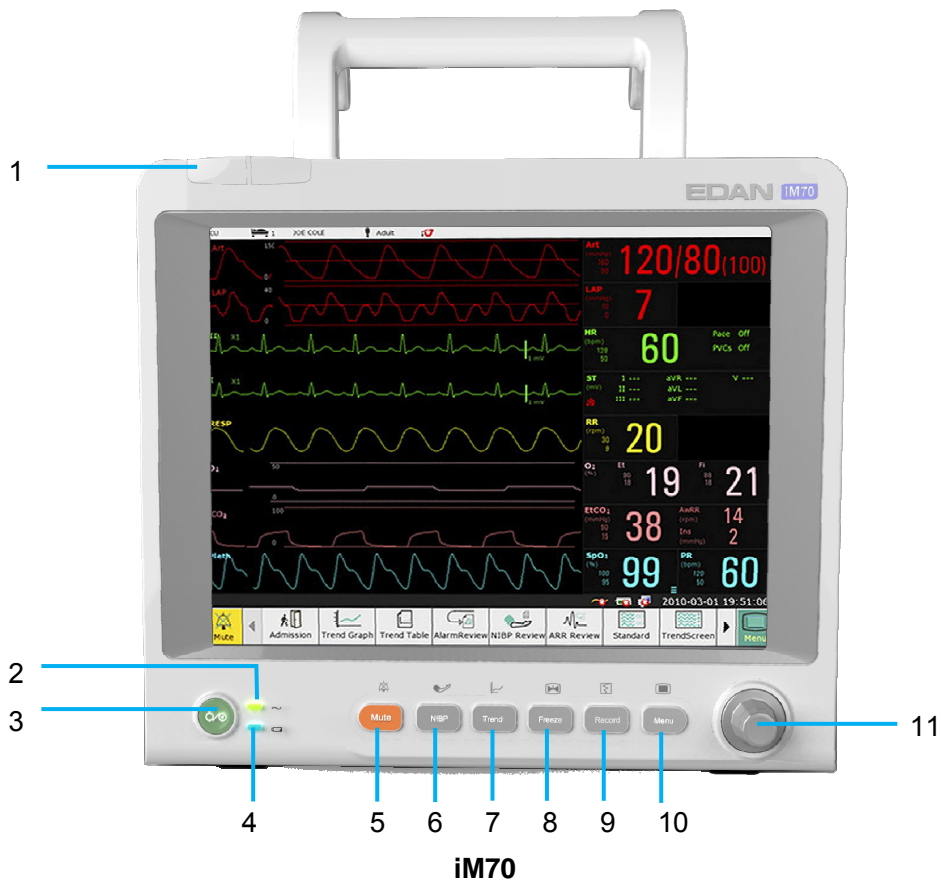
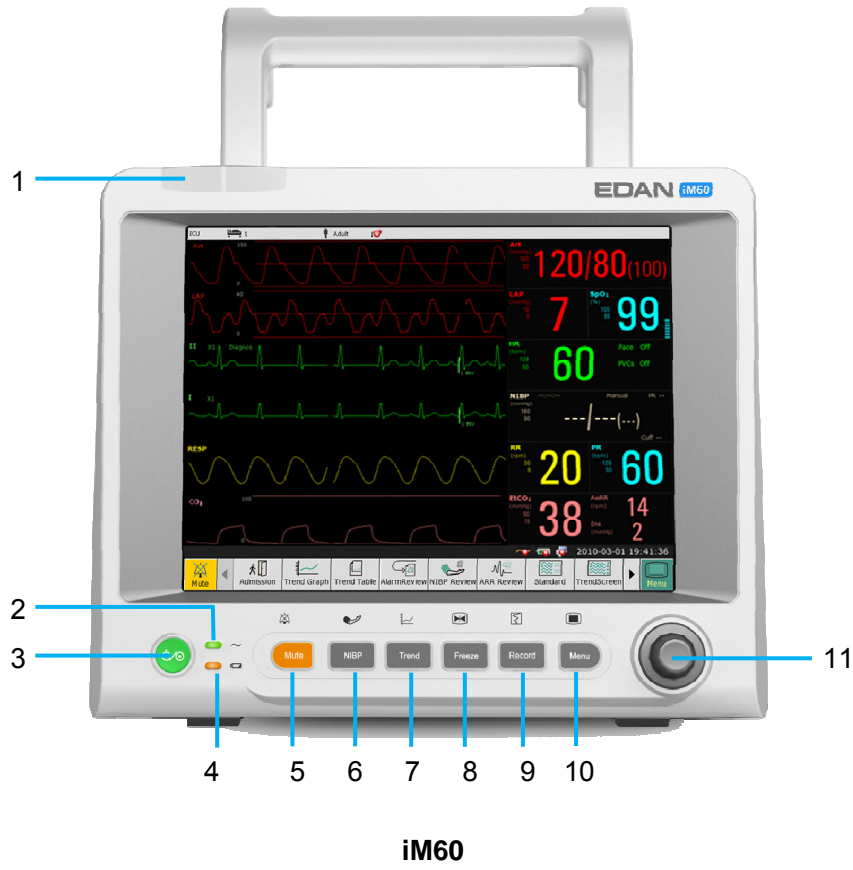
You may frequently use the follow functions:

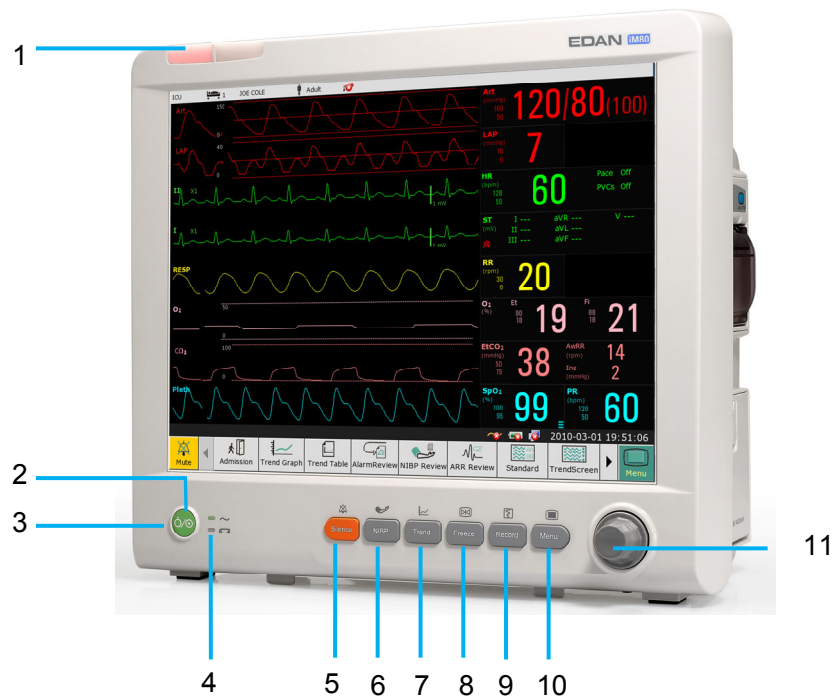
- ◆ ECG monitoring (Refer to *Monitoring ECG* for more information.)
- ◆ SpO₂ monitoring (Refer to *Monitoring SpO₂* for more information.)
- ◆ PR monitoring (Refer to *Monitoring PR* for more information.)
- ◆ NIBP monitoring (Refer to *Monitoring NIBP* for more information.)
- ◆ Alarm (Refer to *Alarms* for more information.)

3.1 System Components

3.1.1 Front View





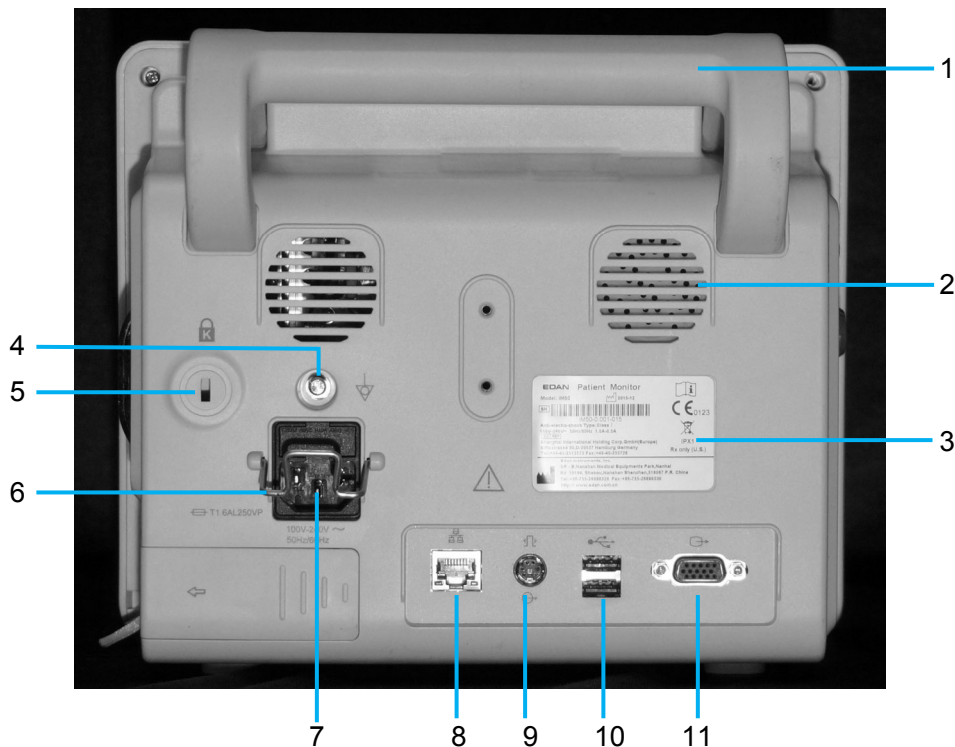


iM80/M80

1	Alarm indicator — when an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level. High level alarm: flashes red; Medium level alarm: flashes yellow; Low level alarm: constantly yellow for physiological alarm and constantly blue for technical alarm.
2	Alternating current indicator— On: AC power is connected; Off: AC power is not connected.
3	Power supply switch — Press it to turn the monitor on when the monitor is connected to the AC power supply, or press the key to turn the monitor off when the monitor is on.
4	Battery indicator, refer to Section <i>Battery Power Indicator</i> for details.
5	Mute — Press it to suspend the output of all audible alarm signals. Upon the configuration, pressing this button to pause or turn off the audio alarm. Further information can be found in the section <i>Audio Alarm Paused</i> and section <i>Audio Alarm Off</i> .
6	Start/Stop NIBP measurement — Press this button to inflate the cuff and start blood pressure measurement. During the measurement, press the button to stop the measurement.
7	Trend Key — Press this button to enter trend table review interface.
8	Freeze/Unfreeze — In normal mode, press this button to freeze all the waveforms on the screen. In Freeze mode, press this button to restore the waveform refreshing.
9	Start/Stop Recording — Press this button to start a real-time recording. During

	the recording, press this button again to stop recording.
10	Menu — Press this button to return to the main interface when there is no menu open. Press it again to exit.
11	Rotary Knob (hereinafter called knob) — The user can rotate the knob clockwise or anticlockwise. This operation can make the highlighted item shift up, down, left or right to choose the desired item. Remember, when using the knob, rotate this button to highlight, and press it to select the item.

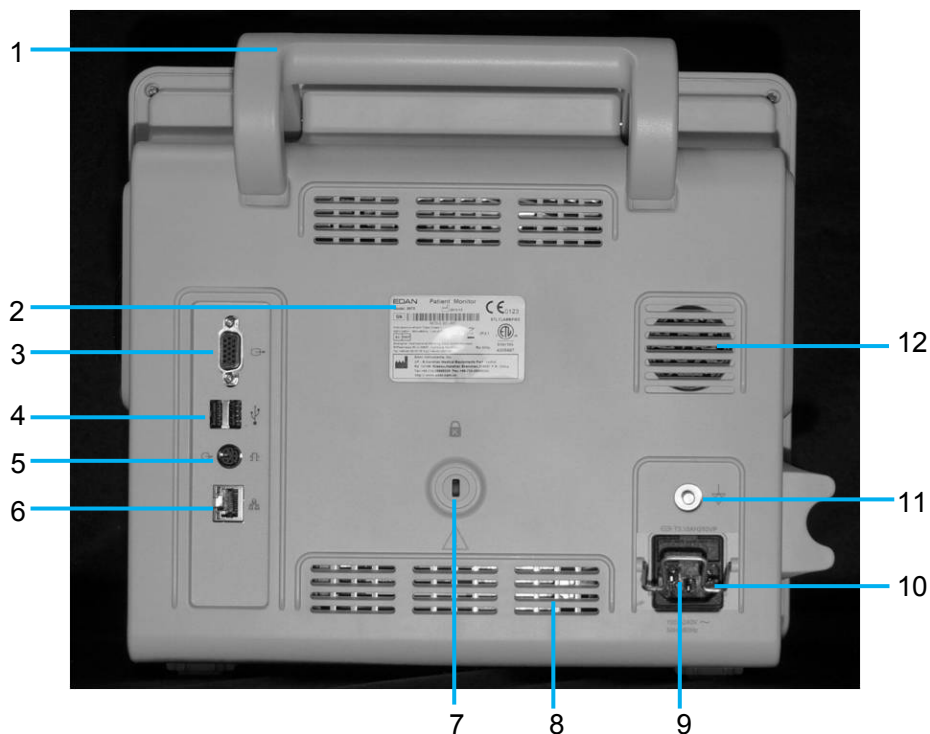
3.1.2 Rear View



iM50/M50

1	Handle: for lifting or moving the monitor, which is convenient, comfortable and fast.
2	Speaker
3	Label
4	Equipotential grounding terminal, if the monitor or other processing unit are used in internal examinations on the heart, ensure that the room incorporates an equipotential grounding system to which the monitor and other processing unit have separate connection.
5	Anti-theft lock interface
6	Power cable safety latch, used to prevent the power cable from losing or falling. Place the latch on the power cable and press it down firmly to ensure that it

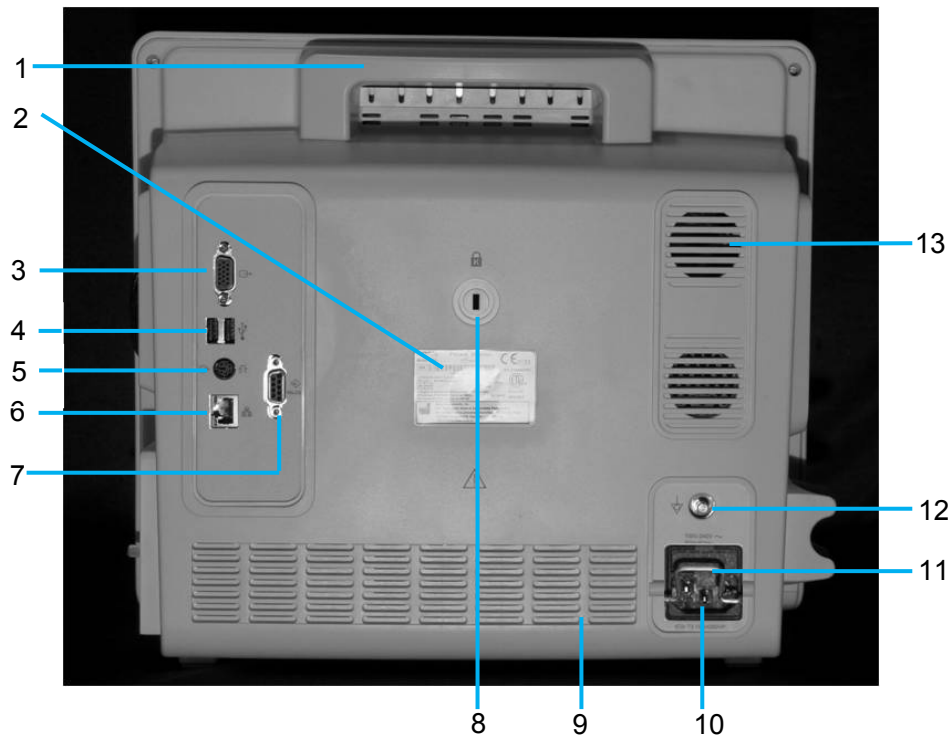
	secures the power cable.
7	Power supply interface: for connecting AC power cable.
8	Network interface. It connects the monitor to the central monitoring system (also named as MFM-CMS), CMS-LITE or gateway via standard network cable, which enables MFM-CMS or gateway to achieve bidirectional communication with the monitor.
9	Multifunctional port: Nurse call port/analog output/defibrillator synchronization. Nurse call port: it connects the monitor to the hospital's nurse call system. Alarms indications are alerted through the nurse call system if configured to do so. Analog output: the monitor outputs the waveform through the port. Defibrillator synchronization: the monitor outputs the defibrillator synchronization signal through the port.
10	USB interfaces: supports USB 2.0 output. It connects approved USB devices, for example, USB flash disk, barcode scanner, mouse and keyboard.
11	VGA output: it enables the VGA video output.



iM60/iM70

1	Handle: for lifting or moving the monitor, which is convenient, comfortable and fast.
2	Label
3	VGA output: it enables the VGA video output.

4	USB interfaces: supports USB 2.0 output. It connects approved USB devices, for example, USB flash disk, barcode scanner, mouse and keyboard.
5	Multifunctional port: Nurse call port/ analog output/ defibrillator synchronization. Nurse call port: it connects the monitor to the hospital's nurse call system. Alarms indications are alerted through the nurse call system if configured to do so. Analog output: the monitor outputs the waveform through the port. Defibrillator synchronization: the monitor outputs the defibrillator synchronization signal through the port.
6	Network interface. It connects the monitor to MFM-CMS, CMS-LITE or gateway via standard network cable, which enables MFM-CMS or gateway to achieve bidirectional communication with the monitor.
7	Anti-theft lock interface
8	Heat sink: Adopt No-fan design, which is dust-free, low noise and low consumption.
9	Power supply interface: for connecting AC power cable.
10	Power cable safety latch, used to prevent the power cable from loosening or falling. Place the latch on the power cable and press it down firmly to ensure that it secures the power cable.
11	Equipotential grounding terminal, if the monitor or other processing unit are used in internal examinations on the heart, ensure that the room incorporates an equipotential grounding system to which the monitor and other processing unit have separate connection.
12	Speaker

**iM80/M80**

1	Handle: for lifting or moving the monitor, which is convenient, comfortable and fast.
2	Label
3	VGA output: it enables the VGA video output.
4	USB interfaces: supports USB 2.0 output. It connects approved USB devices, for example, USB flash disk, barcode scanner, mouse and keyboard.
5	Multifunctional port: Nurse call port/ analog output/ defibrillator synchronization. Nurse call port: it connects the monitor to the hospital's nurse call system. Alarms indications are alerted through the nurse call system if configured to do so. Analog output: the monitor outputs the waveform through the port. Defibrillator synchronization: the monitor outputs the defibrillator synchronization signal through the port.
6	Network interface. It connects the monitor to MFM-CMS, CMS-LITE or gateway via standard network cable, which enables MFM-CMS or gateway to achieve bidirectional communication with the monitor.
7	RS232 interface. Connect it to communicate with other devices.
8	Anti-theft lock interface
9	Heat sink: Adopt No-fan design, which is dust-free, low noise and low consumption.
10	Power supply interface: for connecting AC power cable.

11	Power cable safety latch, used to prevent the power cable from loosening or falling. Place the latch on the power cable and press it down firmly to ensure that it secures the power cable.
12	Equipotential grounding terminal, if the monitor or other processing unit are used in internal examinations on the heart, ensure that the room incorporates an equipotential grounding system to which the monitor and other processing unit have separate connection.
13	Speaker

3.1.3 Side View



iM50/M50

1	Sensor interface: enables the parameter measurement.
2	CO ₂ module holder: for holding the CO ₂ module.
3	Recorder: refer to Section <i>Recording</i> for details.
4	Battery door: for fixing and replacing the battery.



iM60/iM70

1	Sensor interface: enables the parameter measurement.
2	CO ₂ module holder: for holding the CO ₂ module.
3	Recorder: refer to Section <i>Recording</i> for details.
4	Battery door: for fixing and replacing the battery.



iM80/M80

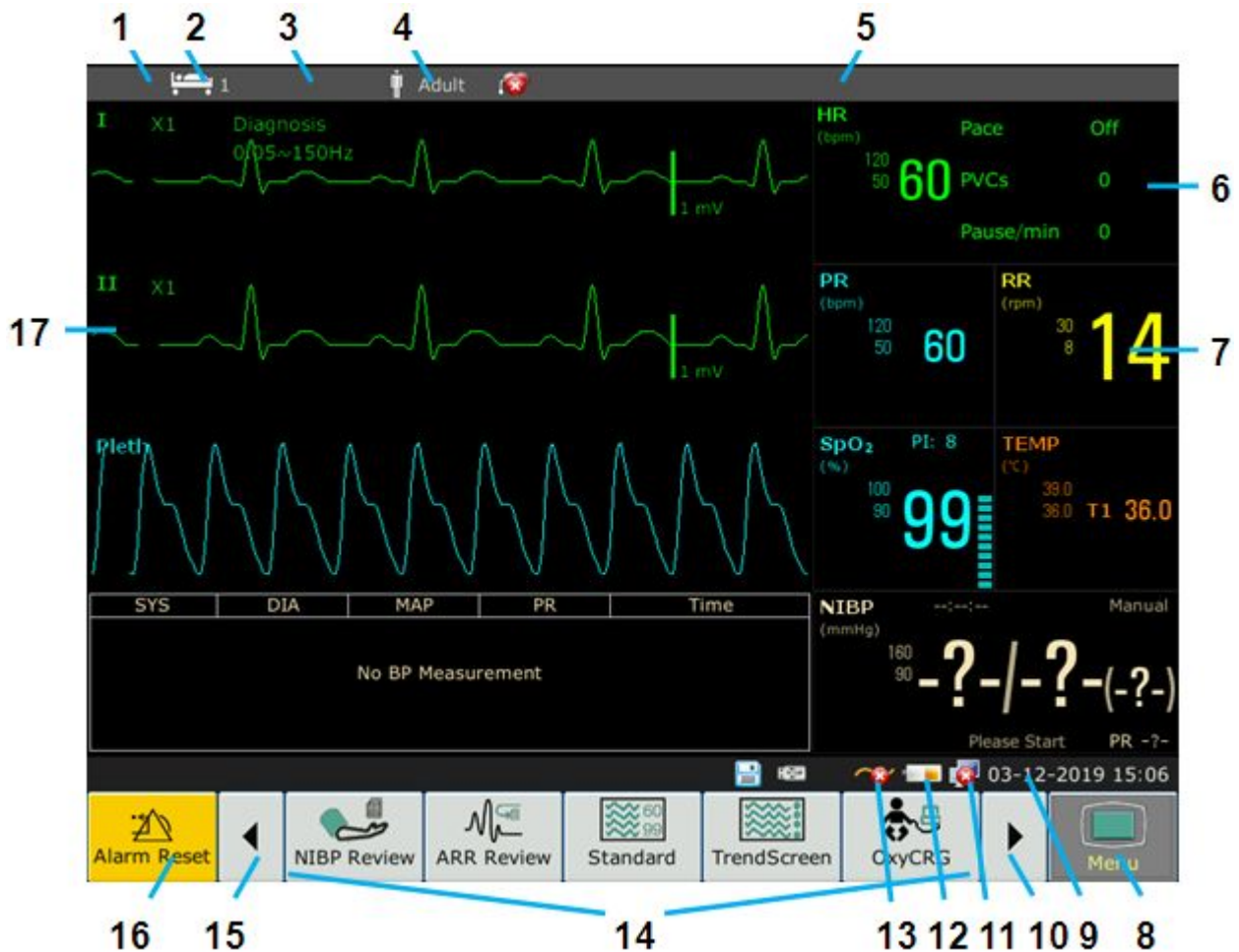
1	Sensor interface: enables the parameter measurement.
2	AG module holder: for holding the AG module.
3	Recorder: refer to Section <i>Recording</i> for details.
4	Battery door: for fixing and replacing the battery.

NOTE:

To avoid blocking and affecting NIBP measurement, the user can open the battery compartment door to clean the dustproof vent periodically. Do not use wet cotton swab to clean the vent. If NIBP measurement is still affected after cleaning, contact the service personnel of EDAN.

3.2 Operating and Navigating

Everything you need to operate the monitor is contained on its screen. Almost every element on the screen is interactive. Screen elements include measurement data, waveforms, screen keys, information fields, alarms fields and menus. The configurability of the monitor means that often you can access the same element in different ways. For example, you might be able to access an item through its on-screen setup menu, via a hard key, or via a shortcut key. The User Manual always describes how to access items via an on-screen menu. You may use whichever way you find most convenient.



1	Department
2	Bed number
3	Patient name
4	Patient type
5	Alarm area
6	Alarm off
7	Measurement value
8	Menu
9	Date and time
10	Scroll right to display more shortcut keys
11	Networking symbol
12	Battery status symbol
13	AC power supply symbol
14	Shortcut key area
15	Scroll left to display more shortcut keys
16	Alarm reset key
17	Parameter waveform

3.2.1 Using Keys

The monitor has four different types of keys. If the key sound is enabled, the monitor gives a normal key sound when the operation is valid.

3.2.1.1 Permanent Keys

A permanent key is a graphical key that remains on the screen all the time to give you fast access to functions.









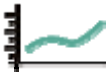











To display the main setup menu.



To reset the alarm.

3.2.1.2 Shortcut Keys

A shortcut key is a configurable graphical key, located at the bottom of the main screen. It gives you fast access to functions. The selection of shortcut keys available on your monitor depends on your monitor configuration and on the options purchased. You can select the shortcut keys those need to be displayed on the main screen through **Menu > Maintenance > User Maintain > Shortcut Setup**. You can adjust the shortcut key sequence as need.

	Perform a 12-lead analysis		Switch to the standard screen
	Exit from 12-lead analysis		Switch to the OxyCRG screen
	Access the 12-lead review		Switch to the large font screen
	Perform 12-lead record (in 12-lead interface)		Set the module switch
	Admit a patient		Change the key volume
	Review the trend graph		Adjust the screen brightness
	Review the trend table		Zero the IBP sensor
	Review the alarm event		Alarm setup
	Access the NIBP review		Change the beat volume
	Access the ARR review		Enter standby mode
	Switch to the trend screen		Enter night mode
	Switch to the vital screen		Select this item by the rotary knob to enable the touch screen operation
	Printer Setup		Enter warning score interface
	Enter privacy mode		Start or stop NIBP measurement
	Audio alarm paused/off		Freeze or unfreeze waveforms
	Start or stop recording		

3.2.1.3 Hardkeys

A hardkey is a physical key on a monitoring device, such as the recording key on the front panel. Refer to the illustration in *Front View* for more information.

3.2.1.4 Pop-up Keys

Pop-up keys are task-related graphical keys that appear automatically on the screen when required. For example, the confirmation pop-up key appears only when you need to confirm a change.

3.3 Operating Mode

3.3.1 Demo Mode

To change the operating mode into the demo mode, please refer to the following procedure:

Select **Menu > Common Function**, then choose **Demo Mode** from the popup interface and input password **3045**.


To exit **Demo Mode**, select **Menu > Common Function > Demo Mode**.

WARNING

Demo Mode is for demonstration purposes only. You must not change into Demo Mode during monitoring. In Demo Mode, all stored trend information is deleted from the monitor's memory.

3.3.2 Standby Mode

To enter into standby mode, select **Menu > Common Function > Standby**, or press the shortcut

key  on the screen directly, the monitor enters into standby mode after user's confirmation.

In standby mode:

1. The monitoring data are stored.
2. The monitor won't respond to all alarms and prompts, except Battery Low alarm.
3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.
4. All recording and printing tasks will stop.
5. MFM-CMS won't update monitoring data, and will display monitor's standby mode. If network is disconnected, monitor will make request for connection.

The monitor exits standby mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).
2. Battery Low alarm occurs.
3. The monitor is connected to MFM-CMS.

After exiting standby mode, the monitor resumes alarm; users need to press Record button or

shortcut key  to restart recording.

NOTE:

The monitor is unable to enter into standby mode when exporting data.

3.3.3 Night Mode

To switch to night mode, you may:


- Select the shortcut key  on the main screen, or
- Select **Menu > Common Function > Night Mode**.

NOTE:

In night mode, the sound of key, heart beat and pulse is muted; the alarm volume and screen brightness are down to their minimum; the settings including key volume, beat volume, PR volume, alarm volume and screen brightness are unavailable.

3.3.4 Privacy Mode

Only if the monitor is connected and admitted by MFM-CMS, the privacy mode can be activated. To enter into privacy mode, you can select **Menu > Maintenance > User Maintain > Shortcut**

Setup > Privacy Mode (it is defaulted to be off). Press the shortcut key  on the screen, the monitor enters into privacy mode after user's confirmation.

In privacy mode:

1. The screen displays message: **Privacy mode and Patient is in monitoring without audio alarm and alarm indicator lighting. Please click screen or hard key to exit.**
2. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.
3. Audio alarm paused status discontinues. Audio alarm off, alarm off, alarm reset and alarm latch status are not influenced.

The monitor exits privacy mode in any of the conditions:

1. The user clicks anywhere on the screen or presses any key (except Power ON/OFF key).
2. Battery Low alarm occurs.
3. The monitor is disconnected with MFM-CMS.

NOTE:

The monitor is unable to enter into privacy mode when exporting data.

3.3.5 NFC Mode

NFC mode is designed when users need to constantly observe HR physiological alarm. In NFC

mode, the HR physiological alarm is automatically or always switched on, and user cannot turn off it. To configure NFC mode, select **Menu > Maintenance > User Maintain > Alarm Setup** and choose **NFC Mode** which can be set to **On** or **Off**. NFC mode is off by default.

In NFC mode:

1. The HR physiological alarms are always on and can't be set to off by the user.
2. The user can't turn off the audio alarm permanently.
3. The audio alarm off status will be finished and the monitor enters normal alarm response status. **Pause Time** will automatically switch to **120 s**, which can be set to **60 s**, **120 s**, or **180 s** manually.
4. The audio alarm paused status is not affected by entering NFC mode.
5. Symbol **NFC** is displayed in the HR parameter area.
6. Monitoring data, alarm information, stored data and monitor status are transmitted to MFM-CMS.

NOTE:

NFC mode and standby mode can't coexist. When the monitor enters the standby mode, the NFC mode will automatically pause. After exiting the standby mode, the monitor will automatically resume the NFC mode.


After exiting NFC mode:

1. The HR physiological alarms are still on and can be set to off by the user.
2. **Pause Time** keeps no change and the user can set it to **Permanent**.
3. Symbol **NFC** gets disappeared.

3.4 Changing Monitor Settings

3.4.1 Adjusting Screen Brightness

To change the screen brightness:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > Common Function > Brightness**, and select the appropriate setting for the screen brightness. **10** is the brightest, **1** is the least bright.

3.4.2 Changing Date and Time

To change the date and time, please refer to Section *Setting Date and Time*.


WARNING

Change to date and time will influence the storage of trend data.

3.5 Adjusting Volume


3.5.1 Adjusting Key Volume

The key volume is the volume you hear when you select any field on the monitor screen or when you turn the knob. To adjust the key volume:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > System Setup > Key Volume**, then select the appropriate setting for the key volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the key volume will be off.


3.5.2 Adjusting Alarm Volume

To change the alarm volume:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > Alarm Setup** and select the desired setting for the **Alarm Volume** item: five bars represent the maximum volume and one bar represents the minimum volume.

3.5.3 Adjusting Beat Volume

Beat volume is from HR or PR, depending on your setting of the beat source. To change the beat volume:

1. Select the shortcut key  on the screen directly, or
2. Select **ECG Setup > Beat Volume**, then select the appropriate setting for the beat volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the beat volume will be off. Beat frequency has positive correlation with measurement value.

3.6 Checking Your Monitor Version

To check the monitor version, please select **Menu > Common Function > About** to check the monitor software revision.

3.7 Setting Languages

To change the language, please:

1. Select **Menu > Maintenance > User Maintain**, then type the correct password into the displayed interface.
2. Select the **Language** option on the popup interface to open the language list.
3. Select the desired language from the list. To make the change validate, please restart the monitor.

3.8 Setting Keyboard Languages



The monitor is equipped with Chinese keyboard, English keyboard and Russian keyboard. To change the keyboard language, select **Menu > Maintenance > User Maintain > Keyboard Language**, then select the desired language from the list.

NOTE:

The keyboard language will restore to the default language when the system language changes. User can change the keyboard language as needed.

3.9 Calibrating Screens




To calibrate the screen, please refer to the following steps:

1. Select **Menu > Maintenance > User Maintain**, input the user password, and select **TouchScr Calibration** on the **User Maintain** menu. User can also enter into calibration interface through pressing shortcut key F9 in connected keyboard.
2. The symbol  appears on the screen.
3. Click on the central point of the symbol .

NOTE:

- 1 If calibration file is lost or damaged, the monitor will automatically enter into screen calibration interface.
- 2 In the screen calibration interface, the screen turns gray and no measurement data can be displayed.

3.10 Disabling the Touch Screen

The user can disable touch screen operation by selecting and holding the permanent key  for three seconds. A message of **Screen Locked** and the symbol  will be displayed at the bottom of screen. To enable the touch screen operation, select the symbol  by using the knob.

3.11 Using the Barcode Scanner

To enter the barcode setup menu, please select **Menu > Maintenance > User Maintain**. After entering the required password, select **Other Setups > BarCode Setup**. Then the user can set MRN, last name, first name and so on.

User can also check relevant scanner device information or delete certain barcode scanner in **User Maintain > Scanner Management**.

If the scanner is connected for the first time, the monitor will pop up a confirmation message to ask user whether the new USB device is added as scanner. Choose **Scanner** to add the barcode scanner to the scanner management list and enable the barcode scanning. Choose **Keyboard** to enable the keyboard entry. Please refer to Chapter *Accessories* for the recommended scanner.

NOTE:

- 1 In order to correctly read and input barcode information, set the barcode scanner to USB PC Keyboard. For detailed settings, please refer to the user manual of the scanner.
- 2 The start and end code should be set before using scanner to update patient, otherwise the barcode can't be recognized normally. After setting start and end code, user should also set male code and female code to distinguish the gender.

3.12 Resolving IBP Label Conflicts

Each label must be unique and can only be assigned once. The measurement labels are stored in the measurement modules. If you try to use two IBP channels that have identical labels, this causes a label conflict in the monitor.

For example, an IBP channel (channel A) has already been loaded and the label Art is used for channel A. Then another IBP channel (channel B) is loaded and the label Art is also used for channel B. In this case, a label conflict will be triggered. A prompt indicating IBP label conflict will appear on the left of the screen. Additionally, at the corresponding measurements area, a label flickers to indicate a label conflict. The flickering label is the default one assigned by the system.

The IBP channel with a label conflict will not provide any measurement data; besides, the functions of setup, zeroing and calibrating are unavailable. To resolve the label conflict, you have to change the conflicting label into a non-conflicting one via the following method:

1. Select the IBP channel with a label conflict on the screen and open the **Options** menu.
2. Choose another label among the options from the **Alias** pull-down list to resolve the label conflict.

Chapter 4 Networked Monitoring

Your monitor can be connected to the wired network and the wireless network. If the monitor is networked, a network symbol is displayed on the screen.

NOTE:

- 1 Be aware that some network-based functions may be limited for monitors on wireless networks in comparison to those on wired networks.
- 2 When selecting dynamic IP mode, please check the IP address from MFM-CMS.

4.1 Cybersecurity Measures

4.1.1 Personal Information Safety

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. EDAN recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement security practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the monitor.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

CAUTION

- 1 The access/operation of the monitor is restricted to authorized personnel only. Assign only staff with a specific role the right to use the monitor.
 - 2 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
 - 3 Ensure that the data are deleted after the patient is discharged. (Refer to Section *Deleting Data Stored in the Storage Device*).
 - 4 Ensure that the monitor is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported monitors within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.
 - 5 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the **Factory Maintain** settings.
-

CAUTION

- 6 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
 - 7 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against DoS and DDoS attacks, and keep it up to date.
 - 8 DoS and DDoS protection of the router or switch must be turned on for defending against attacks.
 - 9 When the monitor is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the monitor. (Refer to Section *Deleting Data Stored in the Storage Device*).
 - 10 When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the monitor to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, monitor and MFM-CMS are into the same VLAN, and isolate it from other VLANs.
 - 11 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the monitor.
 - 12 To avoid malicious tampering and theft of data transmitted by the network, it is recommended to switch on the encryption function. After the encryption function is turned on (it is set to on by default), the monitor will authenticate the accessed MFM-CMS devices and encrypt the transmitted data to ensure the security.
-
-

NOTE:

Log files generated by the monitor are used for system troubleshooting and do not contain protected medical data.

4.1.2 Network Security

For more security operations, select **Menu > User Maintain** and input user maintain password > **Security**. In this menu:

- Select **Modify User Password**, the user can change the password according to the prompts. For safety considerations, change the password periodically, and a combination of words and numbers is recommended. If **Old Password** is forgotten, contact Service personal for help.
- Click **Firewall Rules** to check rule details.
- Set **Auto Login** to On/Off.

When it is set to **On**, the monitor can enter the normal working interface after start-up; when it is set to **Off**, after start-up, a password window will be displayed, and the monitor can enter the normal working interface until correct password is input. Default setting is **On**.

- Select the minutes in **User login Timeout**. If there are no any operations to the monitor for XX minutes (**5, 15, 30, 60** and **Never**), the screen will enter into the screensaver status. User Maintain password should be correctly input before user operates the monitor again. The selection **Never** means the monitor will never enter into screensaver status and still in the normal working status. Default setting is **Never**.
- Set **Firewall** to **On** to protect against hacker attacking.
- Set **Packets Limit** value for traffic monitoring. If the data traffic per minute exceeds the preset threshold, the monitor will trigger the alarm “**Network Traffic Abnormity**” to remind the user, and at the same time, the network will disconnect for 5 minutes. After 5 minutes, the network will be re-connected and alarm disappears.
- Set **CMS/Gateway Encryption** to **Off, TLS** or **AES** (default) when user connects the monitor with network server (MFM-CMS/Gateway).
- Set **HL7** to **On/Off**. The monitor supports HL7 protocol to upload data. To avoid hacker attacking, setting HL7 to **Off** is normally recommended.

User can also set **HL7 IP** address of client-side in **User Maintain > Network Maintain**.

- Set **HL7 Encryption** method to **Off** or **TLS** (default).
- Click **Import Certificate** to install/upgrade the **Certificate** via USB flash drive. The certificate issued by Certificate Authority (CA) is recommended and self-signed certificate should be avoided. For detailed steps of importing certificates, please refers to service manual.




NOTE:

- 1 When the monitor is turned on for the first time, modify the **User Maintain** password according to the prompts. The default initial **User Maintain** password is **ABC**. After modifying the password, please keep it safe.
- 2 When any password is continuously input incorrectly for more than 5 times, the monitor will display the information: **More than five consecutive password errors**.





4.2 Connecting the Wireless Network


Wi-Fi modules are optional to be configured in the monitors. And you should configure the settings on the monitor following the steps below before connecting the monitor to a wireless network:



1. Select **Menu > Maintenance > User Maintain**, and input the password.
2. In the **User Maintain** menu, select **Network Maintain**.
3. In the **Network Maintain** menu, select **Wi-Fi** from the **Network Type** list. And click **Config** to open the **Wi-Fi Setup** window. The available networks will be listed in this window.

4. Choose a network from the window, in which the user can check the network’s encryption information (**Security**). The user will be prompted to enter the password of that network if a password is required. After entering the password and setting the IPv4 address, the user can click  to connect the network.
5. Or select  to connect the hidden networks. After entering **Network Name**, **Security**, password and setting the IPv4 address, the user can click  to connect the hidden network.











If the monitor is successfully connected to the selected network, it will be indicated by the message **Connected**, and the local IP address of the monitor will be displayed in the **Wi-Fi Setup** window. Also, a symbol indicating the networking state will be displayed on the lower portion of the main screen. The meanings of the networking state symbols are explained below:

	Wi-Fi signal intensity: Level 4
	Wi-Fi signal intensity: Level 3
	Wi-Fi signal intensity: Level 2
	Wi-Fi signal intensity: Level 1

Click  to review the historically connected networks. After choosing certain network, the user can select **Forget This Network** or **Join This Network**.

If the encryption information of the currently connected network is modified, the network will automatically disconnect and attempt to reconnect. At this time, click  first to ignore this network and then connect manually. For an unconnected network, if the encryption information or SSID is modified and the user attempts to connect it, the user needs to disconnect the currently connected network and click  to select the updated network.

The following symbols may appear when configuring Wi-Fi:

Symbol	Description	Symbol	Description
	Connect to hidden networks		Insecure network (not recommended). Icon color is red.
	View historically connected networks		Hide password
	Refresh network list		Show password
	Turn the page left and right. to view more networks		Connect the network
	Secure network		Disconnect the network

NOTE:

- 1 Be aware that some network-based functions may be limited for monitors on wireless networks in comparison with those on wired networks.
- 2 The obstacle may interfere with data transmission and even cause data loss.
- 3 If the monitor fails to connect to any wireless network or no available wireless network

is in the **Wi-Fi Setup** window, switch the **Network Type** from **Wi-Fi** to **Wired** and then to **Wi-Fi** again. Then retry to connect to a wireless network. If the wireless network still fails to be connected, please try to restart the monitor and connect again.

- 4 Use the wireless device recommended by EDAN, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.
- 5 The wireless driver is compatible with channels 1-11 only.
- 6 When signal intensity is level 2 or less, signal may be unstable and quality of the signal transmission may be degraded.
- 7 When the monitor is connected to MFM-CMS/Gateway via the wireless network, the user should set the router to a secure encryption/authentication and use the non-dictionary password.
 - ◆ Recommended options: WPA/WPA2 Personal (supports AES/TKIP);
 - ◆ Other options: none or WPA/WPA2 Enterprise (includes TLS/TTLS /PEAP).
- 8 The storage path for certificate related to EAP-TLS enterprise-level encryption method: root directory of USB flash drive\certs\wlan\.

WARNING

- 1 Before monitoring patient, **Network Type (Wired or Wi-Fi)** should be selected and is not allowed to switch during monitoring. Otherwise, Wi-Fi may be unavailable.
 - 2 If Wi-Fi is unavailable, please restart the monitor to restore Wi-Fi function under the precondition of ensuring patient's safety.
-

4.3 Network Disconnected Alarms

To configure the network disconnected alarms, select **Menu > Maintenance > User Maintain > Alarm Setup** and choose **Disconnect Alarm** which can be set to **On** or **Off**. The alarm is off by default.

NOTE:

1. When the monitor is connected with the central monitoring system, you must set **Disconnect Alarm** to **On**.
2. If **Disconnect Alarm** occurs during audio alarm paused or audio alarm off status, the monitor will prompt a sounding alarm with information of **NetWork Disconnect**. During the network disconnected status, activating audio alarm paused or audio alarm off function can disable the audio alarm signal of **Disconnect Alarm**.

4.4 Connecting the Monitor to MFM-CMS

The monitor can be connected to the central monitoring system (V2.65 and above). Through the network:

1. The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.

2. The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, receiving patient, discharging patient and so forth.

For detailed information, please refer to *MFM-CMS Central Monitoring System User Manual*.

And the monitor supports HL 7 protocol.

NOTE:

- 1 Use wired instead of wireless networking when connecting the monitor to central monitoring system in the operating room because the ESU will interfere with a wireless network, which may cause networking failure.
- 2 Make sure the network connection between the monitor and MFM-CMS is in good condition when the time synchronization function on the monitor is active. (Default setting is on. Setting path: **Menu > Maintenance > User Maintain > Date/Time Setup > Sync Time**). If the setting is on, the monitor will accept time synchronization from MFM-CMS.
- 3 The time synchronization function might not be available to all software versions of MFM-CMS. Consult our technical service department or your local distributor for more information.
- 4 When deploying the network of the monitor and MFM-CMS, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.

4.5 Connecting the Monitor to CMS-LITE

The monitor can be connected to the CMS-LITE Data Management Software. Through the network:

1. The monitor sends patient information, monitoring or measurement data to the CMS-LITE Data Management Software.
2. The real-time monitoring information is displayed on the CMS-LITE Data Management Software as the same to the monitor.

For detailed information, please refer to *CMS-LITE Data Management Software User Manual*.

4.6 Connecting the Monitor to Gateway

The monitor can be connected to the Gateway (V1.1 and above), which provides clinicians with the capability of viewing and collecting patient data remotely and the data exchange of selected clinical and administrative information between iM series Network and the hospital network.

To set the monitor server IP address, select **User Maintain > Network > Server IP**. Make sure the monitor share the same server IP with the computer in which the MFM-CMS software is installed.

For more information about Gateway communication, refer to *GW1 Gateway User Manual*.

4.7 HL7 Communication

The monitor supports HL7 protocol to upload data. Select **Menu > User Maintain** and input user maintain password > **Security**. In this menu:

- Set **HL7** to **On/Off**. To avoid hacker attacking, setting HL7 to **Off** is normally recommended.
- Set **HL7 Encryption** method to **Off** or **TLS** (default).

To set HL7 IP address of the client-side, select **User Maintain > Network Maintain**.

Click **Import Certificate** to install/upgrade the **Certificate** via USB flash drive. The certificate issued by Certificate Authority (CA) is recommended and self-signed certificate should be avoided. For detailed steps of importing certificates, please refer to service manual.

For more information about HL7 communication, refer to *HL7 Communication Protocol Service Manual*.

Chapter 5 Alarms

WARNING

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.

5.1 Alarm Category

The monitor provides two types of alarms: physiological alarms and technical alarms. Also, the monitor provides prompts.

5.1.1 Physiological Alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, the monitor will give an alarm, and this type of alarm is called physiological alarms. About the detailed alarm information, please refer to the Section *Physiological Alarm Information*.

5.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, the monitor will give an alarm. And this type of alarm is called technical alarms. Technical alarms can't be disabled. About the detailed alarm information, please refer to Section *Technical Alarm Information*.

5.1.3 Prompts

The monitor can give the character indication of monitoring process or other functions. And this character is called prompts. About the detailed alarm information, please refer to Section *Prompts*.

5.2 Selecting Alarm Tone Type

The user can select the alarm tone type as desired.

1. Select **Menu > Maintenance > User Maintain**, and enter the required password.
2. If configured, select **Alarm Setup**, and set **Alarm Tone** to **Standard** or **Mode 1**.
 - ◆ **Standard**: Standard alarm sound according to IEC 60601-1-8.
 - ◆ **Mode 1**: User customized alarm sound according to clinical applications.

5.3 Alarm Levels

In terms of severity, the device's alarm levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

1. High level alarms

A high level alarm intensively warns the operator of a high priority alarm condition which

requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

2. Medium level alarms

A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

3. Low level alarms

A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

The high/medium/low-level alarms are indicated by the system in following different ways:

Standard

Alarm level	Prompt
High	Mode is “DO-DO-DO-----DO-DO, DO-DO-DO-----DO-DO”, which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz ~ 2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.
Medium	Mode is “DO-DO-DO”, which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz~0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.
Low	Mode is “DO-”, which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

Mode 1

Alarm level	Prompt
High	Mode is “Di-Di-Di-----Di-Di”, which is triggered once every 10 seconds. The alarm indicator flashes in red, with frequency of 1.4 Hz~2.8 Hz. The alarm message flashes with red background, and the symbol *** is displayed at the alarm area.
Medium	Mode is “Di-Di-Di”, which is triggered once every 25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz~0.8 Hz. The alarm message flashes with yellow background, and the symbol ** is displayed at the alarm area.



Alarm level	Prompt
Low	Mode is “Di-”, which is triggered once every 30 seconds. When physiological alarm is triggered, the alarm indicator is constantly yellow. While for technical alarm, the alarm indicator is constantly blue. The alarm message flashes with yellow background, and the symbol * is displayed at the alarm area.

The sound pressure range for standard audible alarm signals is from 45 dB to 85 dB, and for Mode 1 is from 30 dB to 85 dB.

When different level alarms occur at the same time, alarm sound and alarm indicator prompt the highest level alarm, alarm messages display in turn.

The parameter area has two flash methods to prompt alarms: background flash and text flash. User can select one method from **Menu > Alarm Setup > Visual Effect**:

1. **Text Flash**: text flashes with frequency of 1 Hz.
2. **Background Flash**: background flashes with frequency of 1 Hz.


Meanwhile, the alarm level icon is displayed in the parameter area.  stands for medium or low level alarm and  for high level alarm.


WARNING

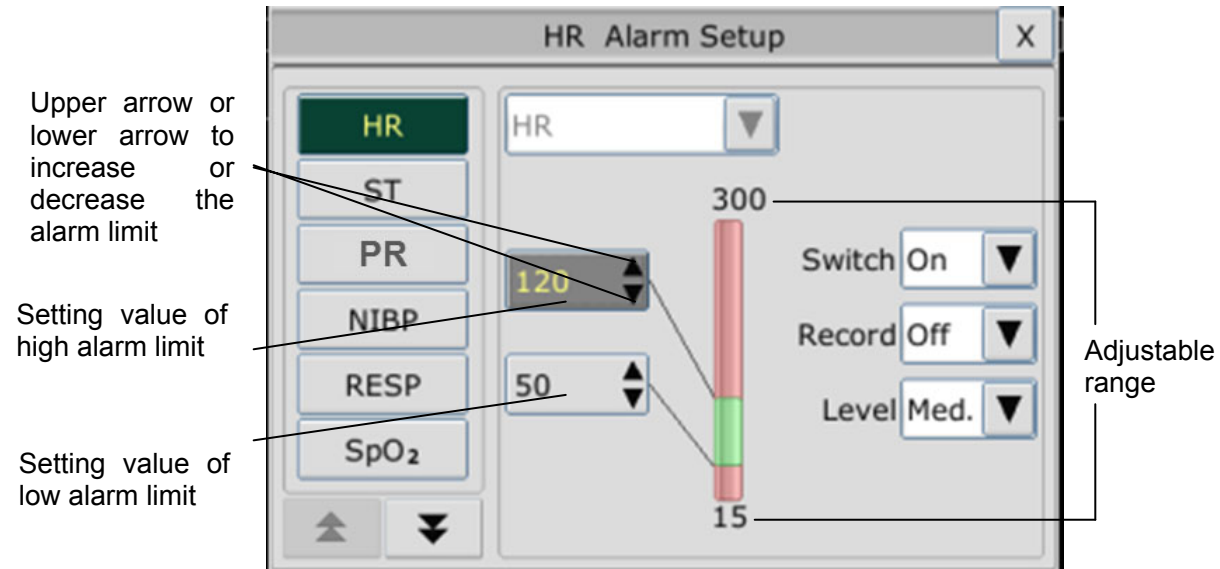
- 1 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
- 2 Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.

5.4 Controlling Alarm

5.4.1 Setting Parameter Alarm

Parameter alarm settings including alarm switch, alarm record, alarm level and alarm limit are available on the respective alarm setup menu for each parameter. To access the menu for parameter alarm settings, use the shortcut key  or select **Menu > Alarm Setup**, and then click **Alarm Options** to open the menu shown below for alarm settings of each parameter. Also, you can access this menu via the respective parameter setup menu.



When alarm switch is off, the parameter alarm off icon  will be displayed in the corresponding parameter area.



WARNING

- 1 When the alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.
- 2 Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
- 3 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.



5.4.2 Audio Alarm Paused

You can temporarily prevent alarms from sounding by pressing the hardkey  on the front panel or pressing shortcut key  on the screen.

You can set the alarm pause time as desired. The default alarm pause time is 120 s.

1. Select **Menu > Maintenance > User Maintain**, and enter the required password.
2. Select **Alarm Setup**, and set **Pause Time** to **60 s**, **120 s**, or **180 s**.

When alarms are paused,

- ◆ The audio alarm is turned off, and no alarms are sounding.
- ◆ The visual alarm indications are still displayed.
- ◆ The monitor displays the audio alarm paused icon .
- ◆ The monitor displays the remaining pause time in seconds with red background.
- ◆ The hardkey  on the front panel flashes in yellow.

When the alarm pause time expires, the audio alarm paused status is automatically terminated and alarm is sounding. You can also terminate the alarm paused status by pressing the hardkey





or pressing shortcut key




NOTE:

If a new alarm occurs during the audio alarm paused period, the new alarm will not be sounding.

5.4.3 Audio Alarm off

Set **Pause Time** to **Permanent**, press hardkey  or shortcut key , the monitor displays information: **please confirm whether to activate audio alarm off function?** Click **Yes**, the monitor will enter into audio alarm off status. Click **No**, the monitor will keep current status.

- The audio alarm is turned off, and no alarms are sounding.
- The visual alarm indications are still displayed.
- The hardkey  on the front panel flashes in yellow.

Remind signal: Audio alarm off symbol  and **Audio Alarm off** on a red colored background are displayed with an interval of 2 s during the audio alarm off status.

Pressing the hardkey



or shortcut key




again can resume the audio alarm.

NOTE:

If a new alarm occurs during the audio alarm off period, the new alarm will not be sounding.

5.4.4 Alarm Reset

Select the shortcut key  on the screen directly. When the alarm is reset,

- ◆ No alarms are sounding until a new alarm occurs.
- ◆ As for the active alarms, the visual alarm indications are still displayed.
- ◆ All latching alarms are cleared. If the alarm condition is no longer present, all alarm indications stop and the alarm is reset.
- ◆ It will not influence the configuration of physiological alarm off, audio paused, and audio off status.


NOTE:

If a new alarm occurs after the alarm is reset, the new alarm will be sounding.





5.5 Latching Alarms

To configure the alarm latching setting, select **Menu** > **Maintenance** > **User Maintain** > **Alarm**

Setup and choose **Alarm Latch** which can be set to **On** or **Off**. When it is set to **Off**, alarm indications end when the alarm condition ends. When it is set to **On**, the visual and audio alarm indication are still displayed after the alarm condition ends; meanwhile, the alarm time is also displayed for the latched alarm for your reference. The indication lasts until you acknowledge the alarm.

You can use the permanent key  on the screen to acknowledge the latched alarm.

5.6 Disabling Sensor Off Alarms

To set sensor off alarm, please select **Menu > Maintenance > User Maintain** and enter the required password. Then select **Alarm Setup** and set **Sensor Off Alm** from the pull-down list. If it is set to **On**, and a sensor off alarm occurs, after pressing the hardkey  or permanent key  the user can disable the audio alarm signal, however, the visual alarm indications are still displayed. If it is set to **Off**, and a sensor off alarm occurs, after pressing the hardkey  or permanent key , sensor-off status will be announced with a prompt message. It means there's no audio alarm signal and alarm indicator, but prompt information displayed.

In **Menu > Maintenance > User Maintain > Alarm Setup**, **SpO₂ Sensor Off** and **ECG Lead Off** alarm level can be adjusted as **High**, **Med.** or **Low**. These alarm levels are set to **Low** by default.

5.7 Testing Alarms

When you switch the monitor on, the monitor will prompt a “Di-Di” tone that means the audio in selftest is normal. Meantime, you must check that the alarm indicator lights are normal. This indicates that the visible and auditory alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

NOTE:

The patient monitor will reboot in 3 seconds due to self-test failure.

Chapter 6 Alarm Information

6.1 Physiological Alarm Information

WARNING

The physiological alarms including **ASYSTOLE (Asystole)**, **Sustain VT**, **RESP APNEA**, **SpO₂ No Pulse**, **SpO₂ Desat**, **CO₂ APNEA**, **AG FiO₂ Low**, and **AG APNEA** cannot be turned off.

Message	Cause	Alarm level
ECG		
HR High	HR measuring value is above the upper alarm limit.	User-selectable
HR Low	HR measuring value is below the lower alarm limit.	User-selectable
ST-X High	ST measuring value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
ST-X Low	ST measuring value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6)	User-selectable
QTc High	QTc measuring value is above upper alarm limit.	User-selectable
ΔQTc High	ΔQTc measuring value is above upper alarm limit.	User-selectable
Advanced ARR		
Asystole	No QRS is detected for 4 consecutive seconds	High
V-Fib/V-Tach	4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR ≥100 bpm.	High
Couplet	2 consecutive PVCs	User-selectable
Run PVCs	$3 \leq$ the number of consecutive PVCs < 5	User-selectable
PVC Bigeminy	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
PVC Trigeminy	A dominant rhythm of N, N, V, N, N,V	User-selectable
R on T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable

Message	Cause	Alarm level
PVC	Single PVC detected in normal heartbeats, and the number of consecutive single PVC ≥ 4 within 30 s.	User-selectable
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.	User-selectable
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.	User-selectable
Missed Beat	Basic: If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second; or no valid QRS wave is detected within 3 s or longer. Advanced: If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.	User-selectable
Irr Rhythm	Consistently irregular heart rhythm	User-selectable
Pacer not Capture	No QRS complex detected in 300ms after a pace pulse.	User-selectable
Pacer not Pacing	No pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
Vent Brady	Basic: 5 consecutive ventricular beats, and ventricular HR < 40 bpm. Advanced: 5 consecutive ventricular beats, and ventricular HR < 20 bpm.	High
Vent Rhythm	Basic: 5 consecutive ventricular beats, and $40 \text{ bpm} \leq$ ventricular HR < 100 bpm. Advanced: 5 consecutive ventricular beats, and $20 \text{ bpm} \leq$ ventricular HR < 40 bpm.	User-selectable
Sustain VT	The duration of ventricular tachycardia rhythm $>$ the threshold value that has been set.	High

Message	Cause	Alarm level
ExtremeTachy	HR > Extreme Tachycardia threshold value that has been set.	High
ExtremeBrady	HR < Extreme Bradycardia threshold value that has been set.	High
V-Tach	5 consecutive ventricular beats and ventricular HR \geq 100 bpm.	High
Wide QRS Tachy	Meet tachycardia conditions, and QRS wave width \geq 160 ms.	User-selectable
Non-Sustain VT	$3 \leq$ The number of consecutive ventricular beats < 5, and ventricular HR \geq 100 bpm.	User-selectable
Afib	Atrial fibrillation alarm should meet below two conditions for 1 minute: the RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.	User-selectable
Acc. Vent Rhythm	5 consecutive ventricular beats, and $40 \text{ bpm} \leq$ ventricular HR < 100 bpm.	User-selectable
Pause	No QRS is detected within the heartbeat pause threshold value that has been set.	User-selectable
Pauses/min High	The measurement value of Pause/min is greater than high alarm limit that has been set.	User-selectable
PVCs High	The measurement value of PVCs is greater than high alarm limit that has been set.	User-selectable
VEB	The delayed ventricular beats detected in normal heartbeats occur more than or equal to 3 2 times within 30 s.	User-selectable
Multiform PVCs	Different forms of ventricular premature beats are detected in 15 beats.	User-selectable
IPVC	The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.	User-selectable
PAC Bigeminy	The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).	User-selectable
PAC Trigeminy	The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.	User-selectable

Message	Cause	Alarm level
Low Voltage(Limb)	None of the signal amplitudes of I, II and III leads exceeds that of the alarm threshold that has been set. PS: this alarm is available for 5 or 12 leads only, not available for 3 leads.	User-selectable
Basic ARR		
PVCs High	PVCs measuring value is above the upper alarm limit.	User-selectable
ASYSTOLE	No QRS is detected for 4 consecutive seconds	High
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.	High
VT > 2	$3 \leq$ the number of consecutive PVCs < 5	User-selectable
COUPLET	2 consecutive PVCs	User-selectable
BIGEMINY	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
TRIGEMINY	A dominant rhythm of N, N, V, N, N,V	User-selectable
R ON T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Single PVC detected in normal heartbeats.	User-selectable
TACHY	Adult: RR interval for 5 consecutive QRS complex \leq 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex \leq 0.375 s.	User-selectable
BRADY	Adult: RR interval for 5 consecutive QRS complex \geq 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex \geq 1 s.	User-selectable
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR \geq 120 bpm, no beats are detected for one second.	User-selectable
IRR	Consistently irregular heart rhythm	User-selectable
PNC	PACER NOT CAPTURE: no QRS complex detected in 300ms after a pace pulse.	User-selectable

Message	Cause	Alarm level
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.	User-selectable
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.	User-selectable
RESP		
RESP APNEA	RESP waveform cannot be detected within the set apnea alarm delay time.	High
RR High	RR measuring value is above upper alarm limit.	User-selectable
RR Low	RR measuring value is below lower alarm limit.	User-selectable
SpO₂		
SpO₂ High	SpO ₂ measuring value is above upper alarm limit.	User-selectable
SpO₂ Low	SpO ₂ measuring value is below lower alarm limit.	User-selectable
SpO₂ No Pulse	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High
SpO₂ Desat	SpO ₂ measuring value is below the SpO ₂ Desat Limit.	High
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable
TEMP		
T1 High	Measuring value of T1 channel is above upper alarm limit.	User-selectable
T1 Low	Measuring value of T1 channel is below lower alarm limit.	User-selectable
T2 High	Measuring value of T2 channel is above upper alarm limit.	User-selectable
T2 Low	Measuring value of T2 channel is below lower alarm limit.	User-selectable
TD High	Measuring value of TD channel is above upper alarm limit.	User-selectable
NIBP		
SYS High	SYS measuring value is above upper alarm limit.	User-selectable
SYS Low	SYS measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm level
DIA High	DIA measuring value is above upper alarm limit.	User-selectable
DIA Low	DIA measuring value is below lower alarm limit.	User-selectable
MAP High	MAP measuring value is above upper alarm limit.	User-selectable
MAP Low	MAP measuring value is below lower alarm limit.	User-selectable
PR (NIBP) High	PR measuring value from the NIBP module is above upper alarm limit.	User-selectable
PR (NIBP) Low	PR measuring value from the NIBP module is below lower alarm limit.	User-selectable
IBP		
Art SYS High	Art SYS measuring value is above upper alarm limit.	User-selectable
Art SYS Low	Art SYS measuring value is below lower alarm limit.	User-selectable
Art DIA High	Art DIA measuring value is above upper alarm limit.	User-selectable
Art DIA Low	Art DIA measuring value is below lower alarm limit.	User-selectable
Art MAP High	Art MAP measuring value is above upper alarm limit.	User-selectable
Art MAP Low	Art MAP measuring value is below lower alarm limit.	User-selectable
PA SYS High	PA SYS measuring value is above upper alarm limit.	User-selectable
PA SYS Low	PA SYS measuring value is below lower alarm limit.	User-selectable
PA DIA High	PA DIA measuring value is above upper alarm limit.	User-selectable
PA DIA Low	PA DIA measuring value is below lower alarm limit.	User-selectable
PA MAP High	PA MAP measuring value is above upper alarm limit.	User-selectable
PA MAP Low	PA MAP measuring value is below lower alarm limit.	User-selectable
CVP MAP High	CVP MAP measuring value is above upper alarm limit.	User-selectable
CVP MAP Low	CVP MAP measuring value is below lower alarm limit.	User-selectable
ICP MAP High	ICP MAP measuring value is above upper alarm limit.	User-selectable
ICP MAP Low	ICP MAP measuring value is below lower alarm limit.	User-selectable
LAP MAP High	LAP MAP measuring value is above upper alarm limit.	User-selectable
LAP MAP Low	LAP MAP measuring value is below lower alarm limit.	User-selectable
RAP MAP High	RAP MAP measuring value is above upper alarm limit.	User-selectable
RAP MAP Low	RAP MAP measuring value is below lower alarm limit.	User-selectable
P1 SYS High	P1 SYS measuring value is above upper alarm limit.	User-selectable
P1 SYS Low	P1 SYS measuring value is below lower alarm limit.	User-selectable
P1 DIA High	P1 DIA measuring value is above upper alarm limit.	User-selectable
P1 DIA Low	P1 DIA measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm level
P1 MAP High	P1 MAP measuring value is above upper alarm limit.	User-selectable
P1 MAP Low	P1 MAP measuring value is below lower alarm limit.	User-selectable
P2 SYS High	P2 SYS measuring value is above upper alarm limit.	User-selectable
P2 SYS Low	P2 SYS measuring value is below lower alarm limit.	User-selectable
P2 DIA High	P2 DIA measuring value is above upper alarm limit.	User-selectable
P2 DIA Low	P2 DIA measuring value is below lower alarm limit.	User-selectable
P2 MAP High	P2 MAP measuring value is above upper alarm limit.	User-selectable
P2 MAP Low	P2 MAP measuring value is below lower alarm limit.	User-selectable
CO₂		
EtCO₂ High	EtCO ₂ measuring value is above upper alarm limit.	User-selectable
EtCO₂ Low	EtCO ₂ measuring value is below lower alarm limit.	User-selectable
FiCO₂ High	FiCO ₂ measuring value is above alarm limits.	User-selectable
CO₂ APNEA	In the set apnea alarm delay time interval, no RESP can be detected using CO ₂ module.	High
AwRR High	AwRR measuring value is above upper alarm limit.	User-selectable
AwRR Low	AwRR measuring value is below lower alarm limit.	User-selectable
AG		
EtCO₂ (AG) High	EtCO ₂ (AG) measuring value is above upper alarm limit.	User-selectable
EtCO₂ (AG) Low	EtCO ₂ (AG) measuring value is below lower alarm limit.	User-selectable
FiCO₂ (AG) High	FiCO ₂ (AG) measuring value is above alarm limits.	User-selectable
AwRR (AG) High	AwRR (AG) measuring value is above upper alarm limit.	User-selectable
AwRR (AG) Low	AwRR (AG) measuring value is below lower alarm limit.	User-selectable
EtO₂ High	EtO ₂ measuring value is above upper alarm limit.	User-selectable
EtO₂ Low	EtO ₂ measuring value is below lower alarm limit.	User-selectable
FiO₂ High	FiO ₂ measuring value is above upper alarm limit.	User-selectable
FiO₂ Low	FiO ₂ measuring value is below lower alarm limit.	User-selectable
EtN₂O High	EtN ₂ O measuring value is above upper alarm limit.	User-selectable
EtN₂O Low	EtN ₂ O measuring value is below lower alarm limit.	User-selectable
FiN₂O High	FiN ₂ O measuring value is above upper alarm limit.	User-selectable
FiN₂O Low	FiN ₂ O measuring value is below lower alarm limit.	User-selectable

Message	Cause	Alarm level
EtHAL High	EtHAL measuring value is above upper alarm limit.	User-selectable
EtHAL Low	EtHAL measuring value is below lower alarm limit.	User-selectable
FiHAL High	FiHAL measuring value is above upper alarm limit.	User-selectable
FiHAL Low	FiHAL measuring value is below lower alarm limit.	User-selectable
EtENF High	EtENF measuring value is above upper alarm limit.	User-selectable
EtENF Low	EtENF measuring value is below lower alarm limit.	User-selectable
FiENF High	FiENF measuring value is above upper alarm limit.	User-selectable
FiENF Low	FiENF measuring value is below lower alarm limit.	User-selectable
EtISO High	EtISO measuring value is above upper alarm limit.	User-selectable
EtISO Low	EtISO measuring value is below lower alarm limit.	User-selectable
FiISO High	FiISO measuring value is above upper alarm limit.	User-selectable
FiISO Low	FiISO measuring value is below lower alarm limit.	User-selectable
EtSEV High	EtSEV measuring value is above upper alarm limit.	User-selectable
EtSEV Low	EtSEV measuring value is below lower alarm limit.	User-selectable
FiSEV High	FiSEV measuring value is above upper alarm limit.	User-selectable
FiSEV Low	FiSEV measuring value is below lower alarm limit.	User-selectable
EtDES High	EtDES measuring value is above upper alarm limit.	User-selectable
EtDES Low	EtDES measuring value is below lower alarm limit.	User-selectable
FiDES High	FiDES measuring value is above upper alarm limit.	User-selectable
FiDES Low	FiDES measuring value is below lower alarm limit.	User-selectable
AG FiO₂ Low	FiO ₂ measure value is extremely low.	High
AG APNEA	In the set apnea alarm delay time interval, no breath can be detected using AG module.	High
C.O.		
TB High	TB measuring value is above upper alarm.	User-selectable
TB Low	TB measuring value is below lower alarm.	User-selectable

6.2 Technical Alarm Information

NOTE:

The ECG alarm information listed in the below table describes the electrode names in America. For the corresponding electrode names in Europe, please refer to the section *Installing Electrodes*.

Message	Cause	Alarm Level	Action Taken
ECG			
ECG Lead Off	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LL Lead Off	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	Low	
ECG LA Lead Off	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	Low	
ECG RA Lead Off	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	Low	
ECG RL Lead Off	When electrode type is AUTO, ECG electrode RL falls off the skin or the ECG cable RL falls off the monitor, 5/6/10 electrodes switches to 3 electrodes.	Low	
ECG V Lead Off	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	Low	
ECG V1 Lead Off	ECG electrode V1 falls off the skin or the ECG cable V1 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG V2 Lead Off	ECG electrode V2 falls off the skin or the ECG cable V2 falls off.	Low	
ECG V3 Lead Off	ECG electrode V3 falls off the skin or the ECG cable V3 falls off.	Low	
ECG V4 Lead Off	ECG electrode V4 falls off the skin or the ECG cable V4 falls off.	Low	
ECG V5 Lead Off	ECG electrode V5 falls off the skin or the ECG cable V5 falls off.	Low	

Message	Cause	Alarm Level	Action Taken
ECG V6 Lead Off	ECG electrode V6 falls off the skin or the ECG cable V6 falls off.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG Signal Exceeded	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition
ECG Comm Fail	ECG module failure or communication failure	High	Stop measuring function of ECG module, and notify biomedical engineer or manufacturer's service staff.
ECG Noise	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition
RESP			
RESP Comm Fail	RESP module failure or communication failure	High	Stop measuring function of RESP module, and notify biomedical engineer or the manufacturer's service staff.
RESP Cardiac Artifact	No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact.

Message	Cause	Alarm Level	Action Taken
RESP Noise	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.
RR Exceed	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.
SpO₂			
SpO₂ Sensor Off	SpO ₂ sensor may be disconnected from the patient measuring site.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.
SpO₂ Comm Fail	SpO ₂ module failure or communication failure	High	Stop using measuring function of SpO ₂ module, and notify biomedical engineer or manufacturer's service staff.
SpO₂ Sensor Err	Malfunction in the SpO ₂ sensor or in the extension cable.	Low	Replace the SpO ₂ sensor or the extension cable.
SpO₂ No Sensor	No SpO ₂ sensor was connected to the monitor.	Low	Make sure the monitor and sensor are well connected, reconnect the sensor.

Message	Cause	Alarm Level	Action Taken
SpO₂ Low Perfusion (EDAN SpO ₂ module)	The pulse signal is too weak or the perfusion of the measurement site is too low. The SpO ₂ value and PR value might be inaccurate then.	Low	Reconnect the SpO ₂ sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO₂ Noisy Signal (EDAN SpO ₂ module)	There is interference with SpO ₂ measurement signals due to patient movement, ambient light, electrical interference or else.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
SpO₂ Light Interference (EDAN SpO ₂ module)	Ambient light around the sensor is too strong.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
NIBP			
NIBP Comm Fail	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, and notify biomedical engineer or manufacturer's service staff.
NIBP Leak	NIBP pump, valve, cuff or tube has a leakage.	Low	Check the connections and the wrapped cuff to see whether they are all prepared well. If failure persists, please notify biomedical engineer or manufacturer's service staff.

Message	Cause	Alarm Level	Action Taken
NIBP Excessive Pressure	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Init Pressure High	The initial pressure is too high during measuring	Low	
NIBP Aux Excessive Pressure	Pressure has exceeded the second safety limit as specified.	High	Notify biomedical engineer or manufacturer's service staff.
NIBP Time Out	Measuring time has exceeded the specified time.	Low	Measure again or use other measuring method.
NIBP Self Test Error	Sensor or other hardware errors.	High	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP Pressure Airway Abnormality	Atmospheric pressure or system pressure is abnormal. The valve is occluded so that deflation is failed.	Low	Check whether the airway is occluded or pressure sensor works properly. If the problem still exists, contact your service personnel.

Message	Cause	Alarm Level	Action Taken
NIBP System Failure	NIBP is not calibrated.	High	Contact your service personnel.
NIBP Weak Signal	Cuff is too loose or patient pulse is too weak.	Low	Use other methods to measure blood pressure.
NIBP Exceeded Range	All of the SYS, DIA and MAP value are beyond the measurement range.	High	Use other methods to measure blood pressure.
SYS(NIBP) Overrange	SYS (NIBP) value is beyond the measurement range.	High	Use other methods to measure blood pressure.
DIA(NIBP) Overrange	DIA (NIBP) value is beyond the measurement range.	High	
MAP(NIBP) Overrange	MAP (NIBP) value is beyond the measurement range.	High	
NIBP Loose Cuff	Cuff is not properly wrapped or no cuff is connected.	Low	Properly wrap the cuff.
NIBP Interference	Signal noise is too large or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.
NIBP Leak Test Error (EDAN NIBP module)	Fail to deflate normally during the leak test, so NIBP leak test cannot be finished.	Low	Test again. If the problem still exists, contact your service personnel.
NIBP Pressure Low (Omron NIBP module)	Maybe pre-inflation pressure can't block the vessel.	Low	Check if the cuff leak or cuff is properly wrapped.
NIBP Pulse Abnormal (Omron NIBP module)	Arrhythmia is serious or pulse rate is not regular due to the patient movement.	Low	Make sure that the patient under monitoring is motionless.

Message	Cause	Alarm Level	Action Taken
NIBP Pulse Signal Weak (Omron NIBP module)	Pulse is too weak, and the detected signal is too weak.	Low	Check if the cuff leak or cuff is properly wrapped.
TEMP			
TEMP T1 Sensor Off	Temperature cable of TEMP channel may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
TEMP T2 Sensor Off	Temperature cable of TEMP channel2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
Excessive T1	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
Excessive T2	TEMP2 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
TEMP Comm Fail	TEMP module failure or communication failure.	High	Stop measuring function of TEMP module, and notify biomedical engineer or Manufacturer's service staff.
T1 Calibration Failed	T1 calibration failed.	High	Please check whether the module works properly.
T2 Calibration Failed	T2 calibration failed	High	Please check whether the module works properly.
IBP			
YY Sensor Off (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP sensor falls off.	Medium	Check the sensor connection and reconnect the sensor.

Message	Cause	Alarm Level	Action Taken
IBP Catheter Off	IBP catheter falls off due to patient movement.	High	Check the catheter connection and reconnect it.
IBP Sensor Err	Malfunction in the IBP sensor or in the extension cable.	Medium	Replace the IBP sensor or the extension cable.
YY Comm Fail (YY stands for the IBP label name: Art, PA, CVP, RAP, LAP, ICP, P1 and P2)	IBP module failure or communication failure	High	Stop measuring function of IBP module, and notify biomedical engineer or Manufacturer's service staff.
C.O.			
C.O. Comm Fail	C.O. module failure or communication failure	High	Stop measuring of C.O. module, or notify biomedical engineer or Manufacturer's service staff.
C.O. TI Sensor Off	C.O. TI sensor not connected	Low	Insert injective temperature sensor.
C.O. TB Sensor Off	C.O. TB sensor not connected	Low	Insert TB sensor.
C.O. TEMP Out Of Range	TI/TB measuring value is beyond measuring range.	High	Please check TI/TB sensor.
AG			
AG Comm Fail	AG module failure or communication failure.	High	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
CO₂ Out Of Range	The CO ₂ concentration exceeds the accuracy range of AG module.	High	
N₂O Out Of Range	The N ₂ O concentration exceeds the accuracy range of AG module.	High	

Message	Cause	Alarm Level	Action Taken
AA Out Of Range	The anesthesia gas concentration exceeds the accuracy range of AG module.	High	
O₂ Out Of Range	The O ₂ concentration exceeds the accuracy range of AG module.	High	
AG Baro Press Out Of Range (Masimo AG module)	The barometric pressure exceeds the specified working barometric pressure range.	High	Make sure the AG module is used within the specified barometric pressure range.
AG Mixed Agents MAC<3	Two types of anesthetic agents are present in the gas mixture, and the concentration is low.	Low	Adjust the concentration of the anesthetic agents if necessary.
AG Mixed Agents MAC≥3	Two types of anesthetic agents are present in the gas mixture, and the concentration is high.	Medium	Adjust the concentration of the anesthetic agents if necessary.
AG AA Id Unreliable (Masimo AG module)	<p>1) Mainstream: The airway adapter was replaced without a zeroing.</p> <p>2) More than 2 anesthetic agents are present in the breathing circuit.</p> <p>3) High concentrations of solvents, cleaning agents or other interfering gases are present in the breathing circuit.</p>	Medium	<p>1) Perform a zeroing after replacing the adapter.</p> <p>2) Reduce the number of anesthetic agent types.</p> <p>3) Replace the sampling tube or reduce the interfering gases.</p>
AG Zero Required (Masimo AG module)	Zeroing of AG module is required.	Medium	Perform zero calibration.
AG Replace O₂ Sensor (Masimo AG module)	Replacement of the O ₂ sensor is required.	Medium	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
AG Motor Error (Masimo AG module)	Malfunction in the AG motor.	High	

Message	Cause	Alarm Level	Action Taken
O₂ Cali Required (Masimo AG module)	O ₂ sensor requires calibration.	Medium	
AG Software Error (Masimo AG module)	Malfunction in the AG software.	High	
AG Hardware Error (Masimo AG module)	Malfunction in the AG hardware.	High	
AG Uncalibrated (Masimo AG module)	AG module calibration is not completed.	High	
AG Calibration Fail (Masimo AG module)	Calibration of the sidestream AG module fails.	Medium	
AG Replace Adapter (Masimo AG module)	Replacement of the adapter is required.	Medium	Replace the adapter.
AG TEMP Out Of Range (Masimo AG module)	The temperature of the AG module exceeds the specified working temperature range.	High	Make sure the AG module is used within the specified temperature range.
Sample Line Occluded	The sampling tube is occluded.	Medium	Replace the sampling tube.
O₂ Sensor Error (Masimo AG module)	Malfunction in the O ₂ sensor inside the sidestream AG module.	High	Stop measuring function of AG module, and notify biomedical engineer or Manufacturer's service staff.
AG No Adapter (Masimo AG module)	No adapter is connected.	Medium	Connect the adapter correctly.
No Sample Line (Masimo AG module)	No sampling tube is connected.	Medium	Connect the sampling tube correctly.
AG Occlusion	AG module sample line occluded	High	Replace the sampling line.

Message	Cause	Alarm Level	Action Taken
Check Watertrap/Sample Line (Dräger AG module)	Watertrap or sample line falls off.	Low	1) Check whether water trap is installed normally. 2) Check whether sample line is installed normally.
AG Change Watertrap (Dräger AG module)	Malfunction in watertap	Medium	Replace the watertrap.
Watertrap will be full (Dräger AG module)	Watertrap will be full.	Medium	Replace the watertrap.
AG Agent Mixture (Dräger AG module)	Mixture agents are detected, but the monitor cannot calculate MAC because of low concentration.	Medium	Check agents' concentration ratio.
CO₂			
CO₂ Comm Fail	CO ₂ module failure or communication failure	High	Check if the water tray has been fixed.
CO₂ Zero Required	Zero calibration failure	Low	Disconnect the sampling cannula or adapter from the airway; initiate the zeroing before making sure that no expired air is inside the sampling cannula and adapter.

Message	Cause	Alarm Level	Action Taken
CO₂ Check Adapter	<p>1) For the Respiration CO₂ module: The cannula is off or disconnected.</p> <p>2) For the EDAN CO₂ module: The water trap is disconnected or not properly connected.</p>	Low	<p>1) For the Respiration CO₂ module: Check whether the adapter is properly connected or replace the adapter.</p> <p>2) For the EDAN CO₂ module: Properly connect the water trap.</p>
CO₂ Sensor Over Temp	CO ₂ sensor temperature exceeds +40 °C.	High	Stop using measuring function of CO ₂ module, notify biomedical engineer.
CO₂ Out Of Range	The CO ₂ concentration exceeds the accuracy range of CO ₂ module.	High	Reduce CO ₂ concentration.
EtCO₂ Overrange	The EtCO ₂ concentration exceeds the measurement range.	High	Please check the monitor or patient status and adjust the gas concentration accordingly.
FiCO₂ Overrange	The FiCO ₂ concentration exceeds the measurement range.	High	
CO₂ Sensor Faulty	CO ₂ module failure	High	Stop measuring function of CO ₂ module, notify biomedical engineer.
CO₂ Occlude	Water trap of SideStream is occluded.	High	Make sure the gas exhaust works well
CO₂ Replace Adapter	Replacement of the adapter is required.	Medium	Replace the adapter.

Message	Cause	Alarm Level	Action Taken
CO₂ Hardware Error	Hardware error of CO ₂ module	High	Stop measuring function of CO ₂ module, and notify biomedical engineer or Manufacturer's service staff.
CO₂ Software Error	Software error of CO ₂ module	Medium	
CO₂ Motor Error	Malfunction in the CO ₂ motor.	High	
CO₂ Factory Calibration Data Lost	Ex-factory calibration data of CO ₂ module is lost.	Medium	
CO₂ Air Pressure Overrange	The barometric pressure exceeds the specified working barometric pressure range.	High	Make sure the CO ₂ module is used within the specified barometric pressure range.
CO₂ No Sample Line	No sampling tube is connected.	Medium	Connect the sampling tube correctly.
CO₂ No Adapter	No adapter connected	Medium	Connect the adapter correctly.
CO₂ Occlusion	CO ₂ module sample line occluded.	High	Replace the sampling line.
CO₂ Noisy Signal	The CO ₂ signal is interfered by ambient or electromagnetic interference	Low	Check interference sources around the device.


Message	Cause	Alarm Level	Action Taken
QuickTemp			
QuickTemp Comm Fail	TEMP module failure or communication failure.	High	Stop measuring function of TEMP module, and notify biomedical engineer or manufacturer's service staff.
Temp exceed limit	The TEMP value is beyond the range of +25 °C ~ +45 °C.	Medium	Put the sensor into the sensor bracket, take it out and measure again.
No Temp Sensor	TEMP sensor is not connected to the TEMP module.	Low	Connect the sensor and the monitor well, and measure again.
Ambient temp too high	The Sensor temperature is higher than +40 °C.	Low	Put the sensor into the sensor bracket, measure again after the ambient temperature reaches normal value.
Ambient temp too low	The Sensor temperature is lower than +10 °C.	Low	
Probe temp too high	The original temperature of sensor $>+33\text{ °C}$ & $\leq+40\text{ °C}$.	Low	
Probe data error	Offline: NTC resistance $>R\text{ °C}$; Short: NTC resistance $<R+100\text{ °C}$.	Medium	Put the sensor into the sensor bracket, take it out and measure again. If the problem persists, stop using measuring function of TEMP module, and notify biomedical engineer or manufacturer's service staff.
Probe heater error	Single failure	Medium	
Temp Sensor Off	After the sensor temperature reaches Predict value, it descends to the value lower than Predict value.	Medium	Reconnect the sensor and make sure that the cable is properly connected.

Message	Cause	Alarm Level	Action Taken
Others			
Battery Low	Battery Low	High	Please change the battery or charge the battery.
Battery1 Error	Malfunction in Battery 1	Low	Replace the battery and restart the monitor. If the problem persists, notify the manufacturer's service staff.
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper
Recorder Probe Overheated	The probe of recorder is overheated.	Low	Stop recording and retry after the probe cools.
Printer Unavailable	The selected printer is not available.	Low	Check whether the network connection is in good condition and whether the printer is malfunctioning.
Insufficient storage space	Less than 10M space is left in the storage device.	Low	Delete some data in the storage device or use another storage device.
Read-only storage device	The storage device is read-only.	Low	Repair the storage device or replace it with a new one.
Storage device damaged	Storage device is damaged.	Low	

Message	Cause	Alarm Level	Action Taken
Network Disconnect	In distributed alarm system, the monitor's network is disconnected.	Low	<p>1) Check if the network cable is well connected.</p> <p>2) Check if the MFM-CMS is turned on.</p> <p>3) Check if the IP of bedside monitor and MFM-CMS are on the same network segment.</p>
Network Traffic Abnormity	Abnormal network traffic has been detected. The data traffic exceeds the limit.	High	Disconnect the network to make the monitor work properly, and then contact the professionals authorized by manufacturer to check the network problem.

6.3 Prompts

Message	Cause
ECG ARR Learning	The QRS template building required for Arr. Analysis is in process.
Unable to analyze ST	The ST algorithm cannot produce valid ST value, which may be caused by the large change in the measured value of connected cardiogram ST or ventricular pacing.
Unable to analyze QT	QT algorithm cannot generate valid QT for more than 10 minutes (or 1 minute during startup).
QT Baseline Overrange	After modifying the calculation formula, the QTc parameter value exceeds the range.
Unable to analyze ECG	The arrhythmia algorithm cannot analyze ECG data reliably.
V-Fib/V-Tach (VFIB/VTAC) Off	V-Fib/V-Tach (VFIB/VTAC) alarm is set to Off .
ExtremeTachy Off	Extreme Tachycardia alarm is set to Off .

Message	Cause
ExtremeBrady Off	Extreme Bradycardia alarm is set to Off .
V-Tach Off	V-Tach alarm is set to Off .
Vent Brady Off	Vent Brady alarm is set to Off .
Key ARR Alarm Off	One of Key ARR alarms is set to Off .
Electrode Contact Poor	The electrode has bad contact with patient's body.
SpO₂ Search Pulse	SpO ₂ module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
Manual Measuring	In manual measuring mode
Continual Measuring	In continuous measuring mode
Auto Measuring	In automatic measuring mode
Sequence Measuring	In sequence measuring mode.
Measurem. Canceled	Press the "Start/stop NIBP measurement" button or shortcut key  to stop the measurement.
Calibrating	During calibrating
Calibrat. Canceled	Calibration is over.
Leak. Test Running	The leakage test is in process.
Leak.Test Canceled	Pneumatic test over
Module Self Test	The module is self-testing.
Manometer Mode	Calibrate in this mode.
Please Switch To Maintain Mode (Omron NIBP module)	Need to calibrate in this mode.
Please Switch To Normal Mode (Omron NIBP module)	Need to measure in normal mode.
Leakage Test Ok	There is no leak.
Resetting	NIBP module in resetting
Please Start	NIBP module is in idle status.
Done	NIBP measurement is completed.
Venipuncture Starting	Start the assisting venipuncture and the cuff begins to inflate.

Message	Cause
In venipuncture process	Venipuncture in process
Venipuncture Ending	Finish the assisting venipuncture and the cuff begins to deflate.
Be sure the cuff is disconnected from monitor	In Cleaning Mode, the user clicks the Start Cleaning button.
Cleaning succeeded	Cleaning finished successfully.
Cleaning failed	Abnormal air pressure in cleaning mode.
Cleaning in progress	The monitor is in cleaning progress.
Quick TEMP Is Warming Up	Quick TEMP Is Warming Up.
Place Probe On Measure Place	Probe isn't placed on the measurement site.
CO₂ Standby	Turn from measuring mode to standby mode, making the module in energy-saving status.
CO₂ Sensor Warms Up	The CO ₂ module is in warm-up state.
CO₂ Zero Start	CO ₂ module starts zero calibration.
CO₂ Zero OK	CO ₂ module completes zero calibration.
Please Press 'Zero'.	Enter the IBP zeroing menu, and zeroing is not performed yet.
Zero OK	IBP completes zeroing.
Pulsatile Pressure Zero Fail.	During the zeroing process, pressure fluctuation is excessive.
Pressure out of normal range,Fail.	During the zeroing process, pressure value is beyond the zeroing range.
Sensor Off, Fail!	Perform zeroing when the sensor is off.
Invalid Time,Zero Fail.	Time is not set up prior zeroing.
Unable to Calibrate in Demo Mode	Perform zeroing in Demo Mode.
Zeroing...	Zeroing is in progress.
Please Press 'Calibrate'.	Enter the Calibration menu, and Calibration is not performed yet.
Calibration OK	Calibration is completed.
Pulse Pressure Calibration Failed	During the Calibration process, pressure fluctuation is excessive.
Pressure out of range	During the Calibration process, pressure value is beyond the Calibration range.

Message	Cause
Zeroing and Calibration Failed	Zeroing is not performed prior calibration.
Sensor Off,Fail.	Perform calibration when the sensor is off.
Invalid Time,Calibration Fail.	Time is not set up prior calibration.
Unable to Calibrate in Demo Mode	Perform calibration in Demo Mode.
Calibrating...	Calibration is in progress.
CO₂ Self-Testing	CO ₂ module is performing a power-on self-test.
IBP alias collision	The same IBP label appears.
C.O. Lack Param	Parameter is not configured for C.O. measurement.
AG Self-Testing..... (Masimo AG module)	AG module is performing a power-on self-test.
AG Span Calib In Progress (Masimo AG module)	The calibration of AG module is in progress.
MultiGas Zero in Progress	The zeroing of AG module is in progress.
AG Is Starting (Dräger AG module)	AG module is starting.
AG Standby (Dräger AG module)	User sets Work Mode to Standby .
AG Zero In Progress (Dräger AG module)	The zeroing of Scio module is in progress.
AG Is Warming Up (Dräger AG module)	Scio module is warming up and is operating at reduced accuracy.
AG Changing to Standby (Dräger AG module)	Work Mode is switching to Standby from Measure .
AG Changing to Meas. (Dräger AG module)	Work Mode is switching to Measure from Standby .
AG Agent Low Concentration (Dräger AG module)	Measured agent concentration is low.
AG Agent Overflow (Dräger AG module)	The gas concentration has increased above the maximum threshold.
AG Agent Calculate (Dräger AG module)	Usually it comes up if no single agent history is available and a mixture situation occurs.

Message	Cause
AG Agent Estimated (Dräger AG module)	The AG module cannot identify the present agent(s) but only give an estimation of one of the present agents. The reason is the presence of either a mixture or too many anesthetic.
AG Interference	AG module is interfered by external device when working.
Warm-up over	The monitor displays this message after taking the sensor out of the bracket and warm-up is over.
Measure over	After the Predict measuring is over, the data and message display on the interface.
Measure time out	No measuring result after the module entering Predict state for 30 s.
Printer Busy	The monitor is performing a print job.
No Default Printer	No default printer has been set.
Incomplete parameter input, unable to score	In Warning-Score System interface, parameters are not completely input.
No WIFI module detected	No Wi-Fi module is detected.
SpO₂ Noisy Signal (Nellcor SpO ₂ module)	There is interference with SpO ₂ measurement signals due to patient movement, ambient light, electrical interference or else.
Recorder Setup Needed	The user presses the RECORD button or shortcut key Record when Recorder is not configured.
NIBP Simul	NIBP Simul function is turned on.
The space in U disk is less than 300 M. Please clean it up.	The remaining space of U disk is less than 300 M.
Please input user password first. Attention! Private information included in the data.	When user exports data from the internal storage device.
More than five consecutive password errors	Continuously enter the wrong password for more than 5 times.

6.4 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows: unit (bpm)

	Patient Type	Adjustable Range
HR	ADU	15~300
	PED/NEO	15~350

ST analysis alarm limits are listed as follows: unit (mV)

	Adjustable Range
ST	-2.0~2.0

QTc and Δ QTc alarm limits are listed as follows: unit (ms)

	Adjustable Range
QTc	200~800
Δ QTc	30~200

RESP alarm limits are listed as follows: unit (rpm)

	Patient Type	Adjustable Range
RESP	ADU	6~120
	PED/NEO	6~150

SpO₂ alarm limits are listed as follows: unit (%)

	Adjustable Range
SpO ₂	20~100

SpO₂ Desat Limits are listed as follows: unit (%)

	Adjustable Range
SpO ₂ Desat Limit	20~99

NOTE:

User can set the range through **User Maintain > Alarm Setup > SpO₂ Desat Limit**, SpO₂ Desat Limit should be less than or equal to SpO₂ alarm low limit.

PR alarm limits are listed as follows: unit (bpm)

		Adjustable Range
PR(SpO ₂)	EDAN	30~300
	Nellcor	30~300

PR(NIBP)	EDAN	40~240
	Omron	Adult/pediatric: 40~200 Neonate: 40~240
	SunTech	30~220
PR (IBP)	EDAN	30~300

NIBP alarm limits are listed as follows: unit (mmHg)

Patient Type		Adjustable Range		
		EDAN	Omron	SunTech
ADU	SYS	25~290	60~250	40~260
	DIA	10~250	40~200	20~200
	MAP	15~260	45~235	26~220
PED	SYS	25~240	60~250	40~230
	DIA	10~200	40~200	20~160
	MAP	15~215	45~235	26~183
NEO	SYS	25~140	40~120	40~130
	DIA	10~115	20~90	20~100
	MAP	15~125	30~100	26~110

TEMP alarm limits are listed as follows:

	Adjustable Range
T1	0 °C (32 °F)~50 °C (122 °F)
T2	0 °C (32 °F)~50 °C (122 °F)
TD	High limit: 0.1 °C (32.18 °F)~50 °C (122 °F)

IBP alarm limits are listed as follows: unit (mmHg)

	Adjustable Range
Art	0~300
RAP/LAP/CVP/ICP	-10~40
PA	-6~120
P1/P2	-50~300

CO₂ alarm limits are listed as follows:

	Adjustable Range
EtCO ₂	0 mmHg~150 mmHg
FiCO ₂	High limit: 3 mmHg~50 mmHg

AwRR	Sidestream: 2 rpm ~150 rpm (EDAN, Respironics) 0 rpm ~150 rpm (Masimo) Mainstream: 0 rpm~150 rpm
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C.O. alarm limits are listed as follows:

	Adjustable Range
TB	23 °C (73.4 °F)~43 °C (109.4 °F)

Quick Temp alarm limits are listed as follows:

	Patient Type	Adjustable Range
Quick Temp	ADU	35.5 °C (95.9 °F)~42 °C (107.6 °F)
	PED	35.5 °C (95.9 °F)~42 °C (107.6 °F)

AG alarm limits are listed as follows:

EDAN Module

	Adjustable Range
EtCO ₂ /FiCO ₂	0.0%~15.0%
EtO ₂ / EtN ₂ O/FiN ₂ O	0.0%~100.0%
FiO ₂	18.0%~100.0%
EtHAL/EtENF/EtISO/FiHAL/FiENF/FiISO	0.0%~8.0%
EtSEV/FiSEV/	0.0%~10.0%
EtDES/FiDES	0.0%~22.0%
AwRR	0 rpm~150 rpm
Apnea Time	20 s~40 s

Masimo Module

	Adjustable Range
FiCO ₂	0.1%~25.0%
EtCO ₂	0.0%~25.0%
FiO ₂	18.0%~100.0%
EtO ₂	0.0%~100.0%
FiN ₂ O/EtN ₂ O	0.0%~82.0%
EtDes/FiDes	0%~18%
EtIso/FiIso/EtHal/FiHal/EtEnf/FiEnf	0%~5.0%
EtSev/FiSev	0%~8%
AwRR	0 rpm~150 rpm
Apnea Time	20 s~40 s

Dräger Minimodule

	Adjustable Range
FiCO ₂ /EtCO ₂	0%~13.6%
FiO ₂	18.0%~100.0%
EtO ₂ /FiN ₂ O/EtN ₂ O	0%~100.0%
EtDes/FiDes	0%~20.0%
EtIso/FiIso/EtHal/FiHal	0%~8.5%
EtSev/FiSev/EtEnf/FiEnf	0%~10.0%
AwRR	0 rpm~100 rpm

Chapter 7 Managing Patients

7.1 Confirming a Patient

After the user switches the monitor on, the monitor will prompt “**Continue monitoring the current patient or admit new patient?**”. Select **Current Patient** to use the current configuration; Select **New Patient** to admit new patient.

NOTE:

If the user does not make a selection within 1 minute, **Current Patient** is selected by default.

7.2 Admitting a Patient

The monitor displays physiological data and stores it in the trends as soon as a patient is connected. This allows you to monitor a patient who is not yet admitted. It is however important to admit patients properly so that you can identify your patient on recordings, reports, and networked devices.


During admission you enter data that the monitor needs for safe and accurate operation. For example, the patient category setting determines the algorithm the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.

To admit a patient, please:

1. Select the **Admission** key on the screen or.
2. Select **Menu > Patient Setup > New Patient**, then a message is displayed to ask the user to confirm to update patient.
3. Click on **No** to cancel this operation; click on **Yes**, the **Patient Info** window is displayed.
4. Enter the patient information:
 - **MRN:** Enter the patient’s medical record number.
 - **Last Name:** Enter the patient’s last name (family name).
 - **First Name:** Enter the patient’s first name.
 - **Bed No.:** Supports up to 8 characters. Chinese, English, Russian, numbers and special characters can be input.
 - **Doctor:** Enter the attending doctor for the patient.
 - **Gender:** **Male**, **Female** and **N/A**.
 - **Type:** Choose the patient type, either **Adult**, **Pediat**, or **Neonat**.
 - **BloodType:** **N/A**, **A**, **B**, **AB** and **O**.
 - **Pace:** Choose **On** or **Off** (You must select **On** if your patient has a pacemaker).
 - **Date of Birth:** Enter the patient’s date of birth.
 - **Date of Admission:** Enter the patient’s date of admission.

- **Height:** Enter the patient's height, with unit: **cm** or **inch**.
- **Weight:** Enter the patient's weight, with unit: **kg** or **lb**.

NOTE:

- 1 For Bed No., user can select English, Chinese, Russian through switching keyboard language, and select special characters through .
- 2 Creating new patient and updating patient will clear the history data in the monitor associated with the patient.

7.2.1 Patient Category and Paced Status

The patient category setting determines the algorithm which the monitor uses to process and calculate some measurements, the safety limits that are applied for some measurements, and the alarm limit ranges.


The paced setting determines whether the monitor shows pacemaker pulses or not. When **Pace** is set to **Off**, pace pulses are filtered and therefore do not show in the ECG wave.

WARNING

- 1 Changing the patient category may change the arrhythmia and NIBP alarm limits. Always check alarm limits to make sure that they are appropriate for your patient.
 - 2 For paced patients, you must set **Pace** to **On**. If it is incorrectly set to **Off**, the monitor could mistake a pace pulse for a QRS and fail to give an alarm during asystole.
-

7.3 Quick Admit

If you do not have the time or information to fully admit a patient, you can use Quick Admit to quickly admit a patient and complete the rest of the patient information later. To quickly admit a patient, please:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > Patient Setup > Quick Admit**, then a message is displayed to ask the user to confirm to update patient.
3. Click on **No** to cancel this operation; click on **Yes** to continue and the **Quick Admit** window is displayed.
4. Configure **Type** and **Pace** to the correct setting and click **Yes** to finish the quick patient admission operation. If you want to quit the operation, click **No**.

7.4 Barcode Admit

Barcode scanner can recognize patient information directly and quickly, which can provide convenience and reduce mistakes for users.

To admit a patient by barcode,

1. The user can scan the barcode through scanner, then a message is displayed to ask the user to confirm the patient update.
2. Click **No** to cancel this operation; click **Yes**, the **Patient Info** window is displayed and the corresponding patient information is updated according to the identified MRN. If the monitor is connected with the network server through the gateway, the monitor will automatically inquire for patient information from the network server via MRN. As soon as the MRN is successfully found on the network server, the corresponding patient information will be updated to the monitor. Otherwise, prompt information will be displayed to notify the user that network is not available or no patient information is matched. If patient information is modified on the network server, prompt information will also be sent to inform the user of the update.


NOTE:

- 1 When the monitor is in keyboard interface and patient information interface, admitting patient via barcode scanner is not available.
- 2 The start and end code should be set before using scanner to update patient, otherwise the barcode can't be recognized normally.
- 3 Patient information obtained from network server cannot be edited.

7.5 Managing Patient Information

7.5.1 Editing Patient Information

To edit the patient information after a patient has been admitted, select **Menu > Patient Setup > Patient Info.**, and make the required changes on the popup interface.


If the monitor is equipped with a barcode scanner, the user can scan the patient's barcode to enter the patient's medical record number (MRN). When patient's MRN is modified, the user can click on  to obtain the patient information from network server. Otherwise, only MRN is updated.

NOTE:

Switching patient type will change the current configuration.

7.5.2 Obtaining Patient Information from the Network Server

The user can obtain patient information from the network server to the monitor. To obtain patient information from the network server,

1. Select **Menu > Patient Setup > Network Admit**.
2. Input the query conditions (**Department, Date of Admission**), and then click . A list including all the patients that meet the query conditions is displayed.
3. Select a patient from the patient list, and click **Admit**. The corresponding patient information in the monitor will be updated after user's confirmation. Click **View** to display the detailed

patient information.

NOTE:

The user can load patient information from the network server only when **ADT Query** is enabled. Default setting is off. Setting path: **Maintenance > User Maintain > Network Maintain > ADT Query**.

Chapter 8 User Interface

8.1 Setting Interface Style


The user can set the interface based on the requirement, and the set options include the following:

- Sweep of the waveform.
- Parameters needing to be monitored.

Changing some settings may have the risk, so only the authorized person can change them. After changing the settings, please notify the operator.

8.2 Selecting Display Parameters

The user can select the display parameters based on the monitoring and measurement requirements. To select the parameter, please:

1. Select the shortcut key  on the screen directly, or
2. Select **Menu > System Setup > Module Switch**.
3. Select the required parameters from the popup interface.
4. Exit the menu and the screen will adjust the parameters automatically.

8.3 Changing Waveform Position

The user can exchange the waveform positions of parameter A and parameter B with the following method:


1. Select waveform A and open the setup menu of waveform A.
2. Select **Change** from the popup menu and select the desired label name of waveform B from the pull-down list.

8.4 Changing Interface Layout

Select **Menu > Display Setup** to open the **Display Setup** menu on which you can

- Select a function screen based on the clinical requirements by configuring **View Selection**.
- Select the maximum number of waveforms displayed on the screen by configuring **Wave. Num.**.
- Decide whether the control bar is displayed or not displayed on the screen by setting **Control Bar** to **On** or **Off**.


8.5 Viewing Trend Screen

To view the trend screen, the user can press the shortcut key  on the screen directly or select **Menu > Display Setup > View Selection > TrendScreen**.



Select short trend to open **Short Trend Setup** menu, the user can set:

1. **Parameter**.
2. **Interval**: set the interval to **30 min**, **1 h** and **2 h**.

8.6 Viewing OxyCRG Screen


To view the OxyCRG screen, the user can press the shortcut key  on the screen directly or select **Menu > Display Setup > View Selection > OxyCRG**. This interface is always used in NICU because the SpO₂, HR and Resp of the neonate are different from those of adults. OxyCRG is in the bottom half part of wave area; it consists of HR trend, SpO₂ trend and RR trend or compressed respiration waveform.

Select OxyCRG waveform to open **OxyCRG Setup** menu, you can set:

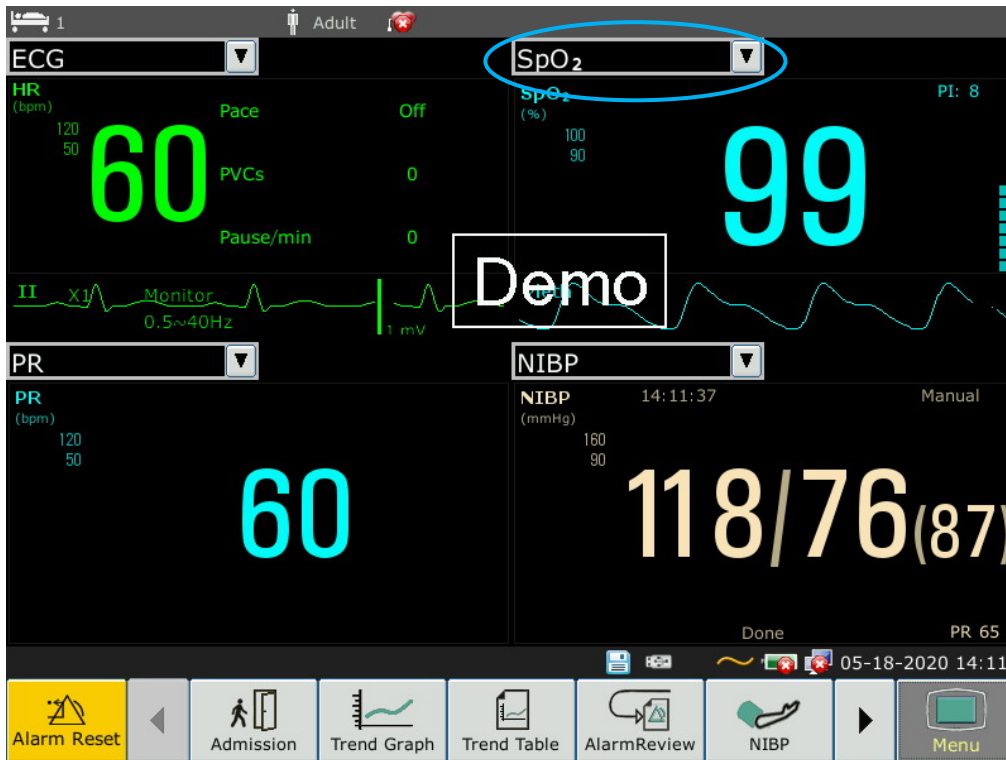
1. **Interval**: set the interval to **1 min**, **2 min** and **4 min**.
2. **Parameter**: to select **RESP** or **RR**.
3. **OxyCRG Review**: user can review the 24 hours OxyCRG parameters including HR, SpO₂, RR. Clicking  or  to left or right move the screen for viewing OxyCRG. Click **Exit** to exit the review interface.

8.7 Viewing Large Font Screen


To open the large font screen, please refer to the following steps:

1. Select the shortcut key  on the screen directly or.
2. Select **Menu > Display Setup > View Selection > Large Font** to open this interface.

You can view any available parameter by selecting the parameter from the pull-down list on each section.



8.8 Viewing the Vital Screen

To view the vital screen, the user can press the shortcut key  on the screen directly or select **Menu > Display Setup > View Selection > Vital**.

8.9 Viewing the Bed View Window

The **Bed View** window allows you to view one waveform, numeric information of all parameters and alarm information from another bed on the same network. The monitor enables a maximum of eight beds to be viewed.

NOTE:



- 1 The IP addresses of the monitors configured with bed view function should share the same network segment. The IP addresses of the monitors on the same LAN should be unique from each other; you cannot use the bed view function in the monitors in which an IP address conflict exists.
- 2 In order to use the bed view function without impediment, you need to restart the monitor after you change its IP address.
- 3 To use the bed view function smoothly, make sure the network connection is in good condition.
- 4 In the **Bed View** window, you cannot view the over-limit alarms of physiological parameters occurring on other beds. Besides, arrhythmia alarms and vital alarms will be indicated only by alarm icons.
- 5 The bed view results are for reference only.

8.9.1 Opening the Bed View Window

Before opening the **Bed View** window, make sure the bed view function is configured on your monitor. To open the **Bed View** window, select **Menu > Display Setup** and choose **Bed View** in the **View Selection** list.

8.9.2 Settings of the Bed View Window

Click on the **Bed View** window to open the **ViewBed Setup** menu on which you can


- Assign a bed to be viewed by selecting the bed No. in the **Bed No.** list.
- Select the waveform to be displayed on the window in the **Wave Type** list.
- Use the buttons  and  to view more numeric information of parameters in the window.

8.10 Changing Parameter and Waveform Colors

The user can set the display colors of parameter and waveform as desire. To change the display color, please select **Menu > Maintenance > User Maintain**, enter the required password. Then select **Color Setup** to make color changes on parameter and waveform.

8.11 Displaying the Timer

The monitor has the timer function to notify you when a preset time period is expired. To display the timer on the main interface,

1. Select the shortcut key  on the screen directly, or select **Menu > System Setup > Module Switch**.
2. Select **Timer** from the popup interface. Exit the menu and the screen will adjust the parameters automatically.

In the timer displaying area, the user can set the timer counting direction. Select **Timer Setup > Timing Direction**.

- **Count Down:** to display the remaining time. When the user selects **Count Down**, **Timing Duration** shall be set simultaneously. The timing duration can be set between 0 and 120 hours. Default setting is 5 min. When the remaining time is 30 seconds, the time turns red, prompting you that the timing duration is to expire. When the timing duration expires, the monitor issues a reminder tone. To set the reminder tone volume, select **Menu > System Setup > Reminder Volume**.
- **Count Up:** to display the elapsed time.

When the **Timing Direction** is **Count Down**, the user can select **Start/Pause/Resume** or **Cancel** to start/pause/resume or end the timer; When the **Timing Direction** is **Count Up**, the user can select **Start** or **Cancel** to start or clear the timer.

To turn off the timer displaying, the user can remove the timer in the module switch menu.

NOTE:

- 1 The user cannot change timer settings when a timer is running.
- 2 Do not use the timer to schedule critical patient-related tasks.
- 3 The timer function is not available in privacy mode or standby mode.

8.12 Profile

Select **Menu > Maintenance > User Maintain > Profile**, enter the required password, users can save the current monitor's configuration, delete the saved user configuration and rename it. Three pieces of user configuration can be saved in the monitor. User can select as desire.

To set default configuration, select **Menu > Profile**. On the **Profile** menu, users can choose a factory configuration (adult, pediatric or neonate) based on the patient category.

The one labeled with ● is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.

8.13 Neonatal Configuration*

* Only applicable to iM50 and M50.

Neonatal configuration is exclusively designed for neonate. When it is set to **On**, the patient type is defaulted to be neonate and cannot be changed.

Neonatal configuration is not set by user. Contact the professionals authorized by the manufacturer if needed.

Chapter 9 Monitoring ECG

9.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the monitor as a waveform and a numeric. This chapter also tells you about arrhythmia monitoring and ST monitoring.

9.2 ECG Safety Information

WARNING

- 1 Only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.
 - 2 When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.
 - 3 Place the electrode carefully and ensure a good contact. Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.
 - 4 Store the electrodes in room temperature. Open the electrode package immediately prior to use. Never mix electrode types or brands. This may lead to problem due to impedance difference. When applying the electrodes, avoid bones close to skin, obvious layers of fat and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of thorax, may lead to erroneous arrhythmia alarm due to excessive muscle movement.
 - 5 Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message “ECG LEAD OFF” and the audible alarm is activated.
 - 6 If the ECG signal exceeds the measuring range, the monitor will indicate it by a message “ECG Signal Exceeded”.
 - 7 In order to avoid being burnt, please keep the electrodes far away from the radio knife while using electrosurgical equipment.
 - 8 When using Electrosurgery (ES) equipment, do not place an electrode near the grounding plate of the Electrosurgery device: otherwise there will be a great deal of interference with the ECG signal.
 - 9 The electrodes should be made of the same metal materials.
 - 10 ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.
-

WARNING

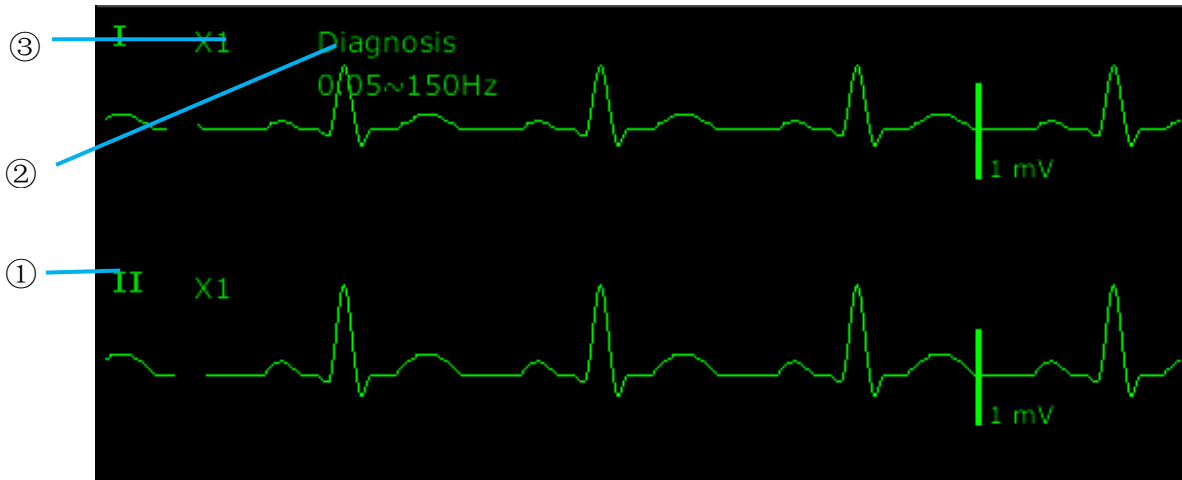
- 11 According to AAMI specifications the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The synchronization pulse output on the patient monitors is delayed by a maximum of 35 ms from the R wave peak. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.
 - 12 Before outputting signals with defibrillator synchronization or ECG, check if the output is functioning normally.
 - 13 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION. (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION.)
 - 14 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. When the electrode or lead is loose or fallen, the monitor is easily affected by the transient response of certain types of insulation monitors. The transient monitor signal produced by poor insulation of the line may be very similar to the actual heart waveform, which will prevent the monitor from prompting a heart rate alarm. In order to avoid this, user should check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.
 - 15 The monitor can only be used on one patient at a time. Monitoring more than one patient simultaneously may result in hazards to the patient.
 - 16 Pacemaker Failure: During a complete cardiac block or when pacemaker is unable to pacing/capture, high P-wave (greater than 1/5 of the average height of the R-wave) may be incorrectly counted by the monitor, which leads to a missing asystole.
-
-

NOTE:

- 1 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.
- 2 IEC/EN60601-1-2 (protection against radiation is 3 v/m) specifies that the electrical field density exceeding 3 v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.
- 3 If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.
- 4 In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the waveform area.
- 5 For measurements in or near the heart we recommend connecting the monitor to the potential equalization system.
- 6 For protecting environment, the used electrodes must be recycled or disposed of properly.

9.3 ECG Display

The figure below is for reference only.



The symbol “①” indicates lead name of display waveform: there are several options, such as **I**, **II**, **III**, **aVR**, **aVF**, **aVL**, **V** (for 5 Electrodes). If you want to change the lead, please refer to section *Selecting Calculation Lead*.

The symbol “②” indicates Filter setting, there are six options: **Monitor**, **Surgery**, **Diagnosis**, **Enhanced**, **Diagnosis 1**, and **Customized**. If you want to change it, please refer to section *Changing the ECG Filter Setting*.

The symbol “③” indicates waveform gain: there are several options, such as **X0.125**, **X0.25**, **X0.5**, **X1**, **X2**, **X4** and **AUTO**. If you want to change it, please refer to section *Changing the Size of the ECG Wave*.

9.3.1 Changing the Size of the ECG Wave

If any of the displayed ECG waveform is too small or clipped, you can change the size of it on the screen. First select **ECG Waveform Setup > ECG Gain**, then select an appropriate factor from the pop-up box to adjust the ECG waveform.

X0.125: make the size of 1 mV ECG waveform signal become 1.25 mm;

X0.25: make the size of 1 mV ECG waveform signal become 2.5 mm;

X0.5: make the size of 1 mV ECG waveform signal become 5 mm;

X1: make the size of 1 mV ECG waveform signal become 10 mm;

X2: make the size of 1 mV ECG waveform signal become 20 mm;

X4: make the size of 1 mV ECG waveform signal become 40 mm;

AUTO let the monitor choose the optimal adjustment factor for all the ECG waves.

NOTE:

The effect of ECG wave gain is subject to the size of the wave area. Whichever wave gain is chosen, the ECG wave has to be displayed within the wave area, the exceeded part is clipped.

9.3.2 Changing the ECG Filter Settings

The ECG filter setting defines how ECG waves are smoothed. An abbreviation indicating the filter type is shown underneath the lead label on the monitor display. Filter settings do not affect ST measurement.

To change the filter setting, in the **ECG Setup** menu, select **Filter** and then select the appropriate setting.

- **Monitor**: Use this mode under normal measurement conditions.
- **Surgery**: The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts and interference from electro-surgical units. Under normal measurement conditions, selecting **Surgery** may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the monitor.
- **Diagnosis**: Use when undistorted quality is required and its own characteristics can be maintained. The waveform filtered by the bandwidth of 0.05 Hz~150 Hz is displayed so that the actual changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.
- **Enhanced**: It should be used if the signal is distorted by strong interference from high frequency or low frequency. If there is still obviously interference in the signals when select surgery filter mode, it is recommended to choose the enhanced mode. In this mode, QRS wave rhythm information is emphasized, its shape information cannot be considered as diagnostic criteria. Under normal measurement conditions, the selection of this mode may inhibit QRS wave group and interfere ECG analysis.
- **Diagnosis 1**: To meet the filtering requirements of ST analysis, it is used when ST analysis is turned on or when ST analysis results are concerned.
- **Customized**: User can set **High-pass Filter** and **Low-pass Filter** as needed. Cutoff frequency of **High-pass** can be selected as: **0.01 Hz, 0.05 Hz, 0.15 Hz, 0.25 Hz, 0.32 Hz, 0.5 Hz** and **0.67 Hz**. Cutoff frequency of **Low-pass Filter** can be selected as: **25 Hz, 35 Hz, 45 Hz, 75 Hz, 100 Hz**, and **150 Hz**. After **High-pass filter** and **Low-pass Filter** are set, the bandwidth range of high - pass bandwidth to low - pass bandwidth can be formed.

9.4 Selecting Calculation Lead

To set the calculation lead, select **ECG Setup > Calc. Lead**, or on the **Normal** display interface, click on the calculation lead waveform area, select **Calc. Lead** from the popup interface to make the appropriate setting. For 3 Electrodes, II, I, and III are selectable; For 5 Electrodes, II, I, III, aVR, aVL, aVF, and V are selectable; For 6 Electrodes, II, I, III, aVR, aVL, aVF and leads corresponding to Va and Vb are selectable; For 10 Electrodes, II, I, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6 are selectable. Normal QRS complex should be:

- The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of

pace pulses.

- The QRS should be tall and narrow.
- The P-waves and the T-waves should be less than 0.2 mV.

NOTE:

Make sure you have selected the best lead with the best waveform amplitude and highest signal-to-noise ratio. Choosing the best lead is important for heart beat test, heart beat classification and ventricular fibrillation detection.

9.5 Monitoring Procedure

9.5.1 Preparation

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Select sites with intact skin, without impairment of any kind.
- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

9.5.2 Connecting ECG Cables

1. Attach clip or snap to electrodes prior to placement.
2. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
3. Connect the electrode lead to the patient's cable.
4. Plug the patient cable into the ECG connector on the monitor.

CAUTION

To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by EDAN.

9.5.3 Selecting Electrode Type

To change the electrode type, please:

1. Select the ECG parameter area, open the **ECG Setup** menu;
2. Set **Electrode Type** to **3 Electrodes**, **5 Electrodes**, **6 Electrodes**, **10 Electrodes** or **AUTO** based on the lead used.

9.5.4 Installing Electrodes

NOTE:

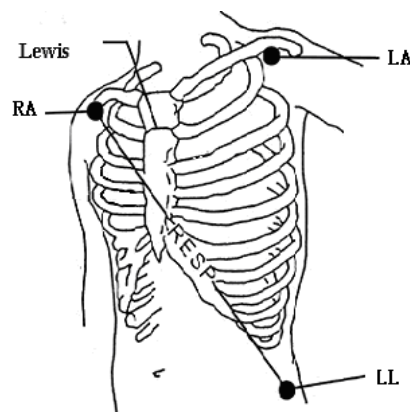
The following table gives the corresponding electrode names used in Europe and America respectively. (Electrode names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding electrode names in America are RA, LA, LL, RL, V, V1-V6.)

AHA (American Standard)		IEC (Europe Standard)	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/Blue	C4	White/ Brown
V5	Brown/Orange	C5	White/ Black
V6	Brown/Purple	C6	White/ Purple

3 Electrodes Placement

Take the American standard for example, see the following figure:

- RA placement - directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement - on the left hypogastrium.

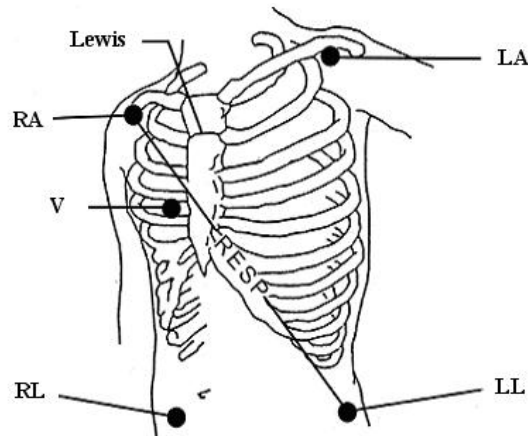


3 Electrodes Placement

5 Electrodes Placement

Take the American standard for example, see the following figure:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right hypogastrium.
- LL placement: on the left hypogastrium.
- V placement: on the chest, the position depends on your required electrode selection.

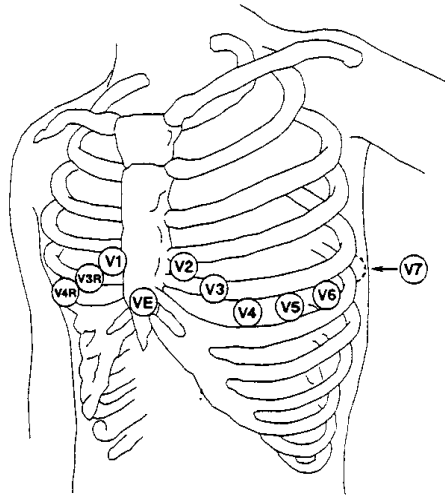


5 Electrodes Placement

NOTE:

To ensure the patient safety, all electrodes must be attached to the patient.

- For 5 electrodes, attach the V electrode to one of the indicated positions as below:
- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R On the right side of the chest in positions corresponding to those on the left.
- VE Over the xiphoid position.
- V7 On the 5th intercostal space at the left posterior axillary line of back.
- V7R On the 5th intercostal space at the right posterior axillary line of back.

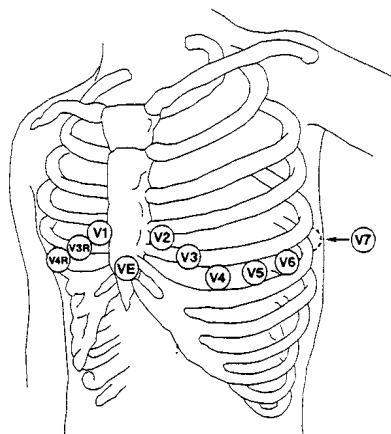


V-Electrode Placement for 5 Electrodes

6 Electrodes Placement

For the placement of 6 electrodes, please use the position of 5 electrodes in the schematic diagram to remove the two thoracic leads. The two thoracic leads Va and Vb can be placed at any two positions from V1 to V6, as shown in the following thoracic leads. To ensure that the label is correct, the selected Va and Vb placements must be set simultaneously in **ECG Setup**.

- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.



V-Electrode Placement for 6 Electrodes

10 Electrodes Placement

In 12-Lead ECG monitoring, the 10 electrodes are placed on the patient's four limbs and chest. The limb electrodes should be placed on the soft skin according to the physician's preference.

The picture below shows the conventional 10 electrodes placement.

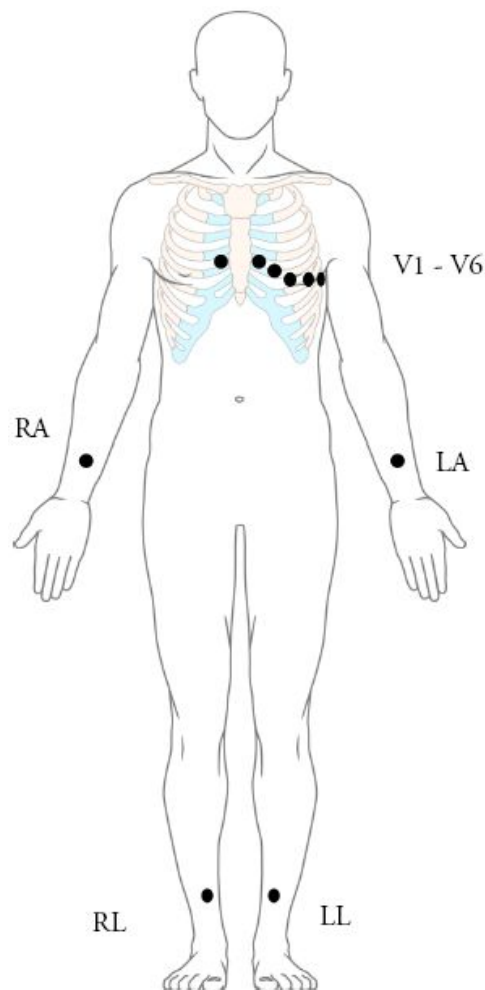
Take the American standard for example; the 10 electrodes should be placed as follows:

Limb electrodes:

- RA and LA: Place arm electrodes on the inside of each arm, between the wrist and the elbow.
- RL and LL: Place leg electrodes inside of each calf, between the knee and the ankle.

Chest electrodes:

- V1: On the 4th intercostal space at the right sterna margin.
- V2: On the 4th intercostal space at the left sterna margin.
- V3: Midway between V2 and V4 electrodes.
- V4: On the 5th intercostal space at the left clavicular line.
- V5: On the left anterior axillary line, horizontal with V4 electrode.
- V6: On the left middle axillary line, horizontal with V4 electrode.



10 Electrodes Placement

Recommended ECG Electrode Placement for Surgical Patients

WARNING

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small.

WARNING

ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

NOTE:

- 1 If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the leads displayed on the screen.
- 2 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

9.6 ECG Menu Setup

9.6.1 Setting Alarm Source

To change the alarm source, please select **ECG Setup > Alarm Source**, then a pop-up box is displayed:

HR: the monitor considers the HR as HR/PR alarm source;

PR: the monitor considers the PR as HR/PR alarm source;

AUTO: If the alarm source is set to **AUTO**, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical condition. The monitor will automatically switch

to PR as the alarm source if:

- a valid ECG lead can no longer be measured and
- a PR source is switched on and available.

The monitor then uses the pulse rate from the measurement currently active as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

9.6.2 Setting Beat Source


To change the beat source, select either **ECG Setup > Beat Source** or **PR Setup > Beat Source**. Select from the following options:

HR: HR is HR/PR beat source;

PR: PR is HR/PR beat source;

AUTO: If the Beat Source is set to **AUTO**, the monitor will use HR as the beat source whenever the ECG measurement is switched on, and at least one ECG lead can be measured. The monitor will automatically switch to PR as the beat source if:

- a valid ECG lead can no longer be measured and
- a PR source is switched on and available.

If an ECG lead becomes available again, the monitor automatically uses HR as beat source and the monitor gives a “Di” tone with a blinking heart  displaying in the HR parameter box when one heartbeat is detected. While a pulse is detected, the monitor gives a “Da” tone.

9.6.3 Smart Lead Off

When **Electrode Type** is **5 Electrodes**, **6 Electrodes** or **10 Electrodes** and **Smart LeadOff** is set to **On**, if the current selected calculation lead cannot detect ECG signal, the monitor automatically switches the corresponding lead as calculation lead, and switches the waveform display of calculation lead at the same time. When ECG electrode is re-connected, and the original calculation lead recovers its signals, the monitor automatically switch to the original calculation lead.

To change the smart lead off setting, select **ECG Setup > Smart LeadOff**, and select the desired setting.

NOTE:

When **Electrode Type** is set to **AUTO**, the smart lead off function will be automatically turned on and cannot be turned off.

9.6.4 ECG Screen Layout


It varies with **Electrode Type**. When **Electrode Type** is set to **3 Electrodes**, **Screen Layout** can be set to **Normal**, and it can display one ECG waveform on the main screen.

When **Electrode Type** is set to **5 Electrodes** or **6 Electrodes**, **Screen Layout** can be set to **Normal**, **Full-Scr** and **Half-Scr**. Select **Normal** to display two ECG waveforms on the main screen; In 5 electrodes, select **Full-Scr** to display seven ECG waveforms which occupy the area of seven waveforms on the main screen; In 6 electrodes, select **Full-Scr** to display eight ECG waveforms which occupy the area of eight waveforms on the main screen; In 5 electrodes, select **Half-Scr** to display seven ECG waveforms on the screen, occupying the area of four waveforms; In 6 electrodes, select **Half-Scr** to display eight ECG waveforms on the screen, occupying the area of four waveforms.

When **Electrode Type** is set to **10 Electrodes**, **Screen Layout** can be set to **Normal** and **12 Leads**. Select **Normal** to display two ECG waveforms on the main screen; select **12 Leads** to display 13 ECG waveforms.

When **Electrode Type** is set to **AUTO**, the monitor can automatically identify the electrode type according to the actual connection condition of the electrodes, and provide as much lead data as possible when the condition of the lead signal is satisfied.

NOTE:

- 1 If **3 Electrodes** is selected in the **ECG Setup** menu, only **Normal** can be selected for **Screen Layout** in the sub-menu.
- 2 In **10 Electrodes** display interface, the filter can only be set to **Diagnosis**.
- 3 If **6 Electrodes** is selected in the **ECG Setup** menu, Va and Vb can be respectively set to either Lead V1 ~ V6, but cannot be set to the same lead, Va is Lead V2 by default, Vb is Lead V5 by default.
- 4 If **AUTO** is selected in the **ECG Setup** menu, when the electrodes connected to patient is reduced from 10 electrodes to 3/5/6 electrodes, user can click **Update Lead Setup** button to enable the monitor to perform lead off alarm according to actual electrodes.
- 5 If **AUTO** is selected in the **ECG Setup** menu, Va and Vb cannot be set when the monitor recognizes the 10 electrodes system automatically. Va is fixed as V1 and Vb is fixed as V2.
- 6 **Full-Scr** and **Half-Scr** settings in **Screen Layout** can be stored after restarting. The user needs to press  shortcut key to switch to the standard screen.

9.6.5 Setting Pace Status

It is important to set the paced status correctly when you start monitoring ECG. To change the paced status in the ECG Setup menu, select **Pace** to toggle between **On** or **Off**. When **Pace** is set to **On**:

- Pace Pulse Rejection is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.
- Paced symbol is displayed as ^l on the main screen. At this time, the artifact is displayed on the screen instead of the actual pacemaker crest. All pacemaker crests are the same, so do not give a

diagnostic explanation about the size and shape of the pacemaker crest.

NOTE:

When monitoring a patient with a pacemaker, set **Pace** to **On**. If monitoring a patient without a pacemaker, set **Pace** to **Off**.

WARNING

- 1 Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Be sure to check the paced symbol on the display screen has correctly detected the pacing pulse. Keep pacemaker patients under close observation.
 - 2 For patients with pacemakers, the pace must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected. When changing settings and admitting patients, please make sure the pace mode is always correct.
 - 3 External pacing electrodes: When using pacemakers with external pacing electrodes on the patient, the quality of arrhythmia is severely degraded due to the high energy level in the pacemaker pulse. This can cause arrhythmia algorithms cannot detect the pacemaker without capturing or asystole.
-

9.6.6 ECG Calibration

This item is used to calibrate ECG waveform. When you select this item from **ECG Setup** menu again, the ECG waveform calibration ends.

NOTE:

The patients can't be monitored during ECG calibration.

9.6.7 ECG Waveform Settings

To change the speed, select **ECG Waveform Setup > Sweep (mm/s)**, then select an appropriate setting from the pop-up list. The bigger the value is, the wider the waveform is.

Select **ECG Waveform Setup > Cascade**: Turn on or off ECG cascade. **Cascade** means the ECG waveforms displayed on the screen all occupy the area of two waveforms. This function is valid only when **Screen Layout** is set to **Normal**.

9.7 12-Lead ECG Monitoring

In 12-lead display mode, 12 ECG waveforms and one rhythm lead waveform will be shown at the waveform area on the screen. The rhythm lead is for ECG calculation before entering 12-lead display mode. Also, in this mode, the filter mode is set to **Diagnosis** and cannot be changed.

NOTE:

- 1 The 12-lead analysis results are for reference only and the analysis significance must be determined by the physician.
- 2 If the ECG signal is too weak, the 12-lead analysis results might be affected.
- 3 SEMIP algorithm is a 12-lead ECG automatic measurement and analysis algorithm. Regarding to the standards' instructions for ECG measurement and analysis of the monitor, please refer to *Smart ECG Measurement and Interpretation Programs User Manual_EDAN2*.
- 4 For 12-lead analysis, the gain selection contains: 1.25 mm/mV ($\times 0.125$), 2.5 mm/mV ($\times 0.25$), 5 mm/mV ($\times 0.5$), 10 mm/mV ($\times 1$), AUTO gain.

9.7.1 Activating 6/10 Electrodes ECG Monitoring


Select **Menu** > **Maintenance** > **User Maintain** > **Other Setups** > **Activate 6/10 Electrodes** in order to get the SN number which is supposed to be supplied to EDAN for a corresponding password. Enter the password on the above-mentioned interface and restart the monitor, and the 6/10 Electrodes ECG monitoring function will be activated.

NOTE:

If the 6/10 Electrodes ECG monitoring fails to be activated, users can reenter the password and try to activate this function again.

9.7.2 Analysis Function

If your monitor is configured with the 12-lead ECG monitoring function, the monitor can perform automatic analysis function. To perform 12-lead analysis:

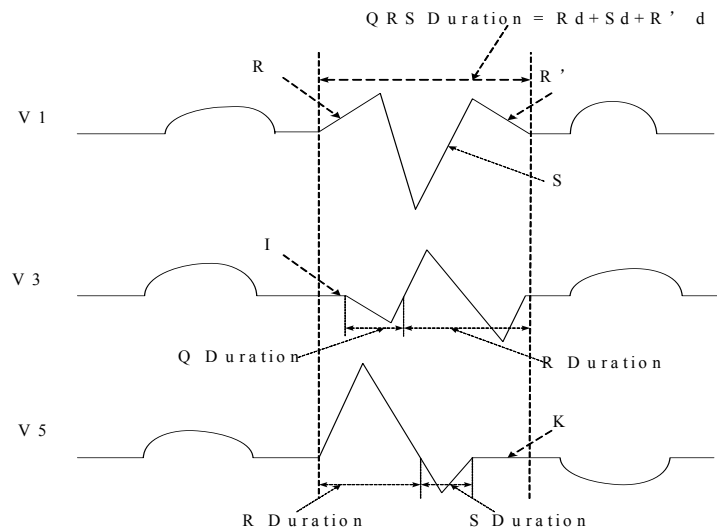
1. In the **ECG Setup** menu, set **Electrode Type** to **10 Electrodes** and set **Screen Layout** to **12 Leads**.
2. Select the shortcut key  on the screen directly.
3. The analysis results will be provided in the **Analysis Review** window after approximately 10 seconds.

The measurement function provides the automatic measurement of the common parameters, such as heart rate, PR interval, QRS duration, QT/QTc interval, P/QRS/T axis, RV5/SV1 amplitude and RV5+SV1 amplitude. The interpretation function provides the automatic analysis of hundreds of abnormal cases, such as arrhythmia, AV block, IVCD (Intraventricular Conduction Block), myocardial infarction, ventricular hypertrophy and atrial enlargement, ST-T abnormality and electrical axis deviation.

9.7.3 Waveform Durations and Isoelectric Segments

Between the global onset and offset of the QRS-complex, signal parts with a duration of more than 6 ms and amplitude not exceeding 20 μV should be defined as isoelectric segments.

Because the duration of the Q-, R- or S-wave of 12 leads is respectively detected by the ECG algorithm, isoelectric parts (I-waves) after global QRS-onset or before global QRS-offset (K-wave) are excluded in the measurement duration of the respective adjacent waveform.



9.8 ST Segment Monitoring

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics and ST templates on the monitor.

ST segment monitoring function is shut off by default. You can switch it to **On** when necessary. When using the ST analysis function, the ST analysis results will be displayed on the right of the main screen.

NOTE:

- 1 ST-segment analysis is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended and default setting for ST analysis in neonatal and pediatric modes is Off.
- 2 In ST analysis, the obtained ST value and ST template are all unaffected by the selected filter mode. ST algorithm itself uses a dedicated linear filter to ensure the signal is not distorted, and to better ensure the consistent and accurate measurement value and ST template can be obtained in different filter modes. If the doctor wants to observe the waveform to evaluate ST segment result, it is recommended to use the ST template for observation, as it is not affected by the filter mode. If the real-time waveform displayed on the interface is used to evaluate ST segment result, it is recommended to select **Diagnosis** mode.
- 3 Reliable ST monitoring may be influenced in following situations:
 - You are unable to get a lead with low noise.
 - If there is arrhythmia such as atrial fibrillation/flutter, the ECG baseline may be irregular.

- The patient is continually performing ventricular paced.
- The dominant template cannot be obtained for a long time.
- The patient has left bundle branch block.

When any of above situations happens, ST monitoring should be switched off.

- 4 The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.
- 5 If you use ST analysis, you must adjust the ST measurement point when you start the monitor. If the patient's heart rate or ECG waveform changes significantly, this will affect the size of the QT interval, so the ST point must be placed. If the equipotential or ST points are not set correctly, the ST fragments of the artifacts may be depressed or raised. Always ensure that the ST measurement point is suitable for your patient.
- 6 ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.
- 7 ST is calculated with a fixed delay from the R position. Changes in heart rate or the width of QRS may affect ST.
- 8 If the algorithm triggers self-learning (either manually or automatically), the calculation of ST segment will be reinitialized.

9.8.1 Setting ST Analysis

To change ST analysis, please select **ECG Setup** > **ST Analysis**, then select **On** or **Off** from the pop-up list.

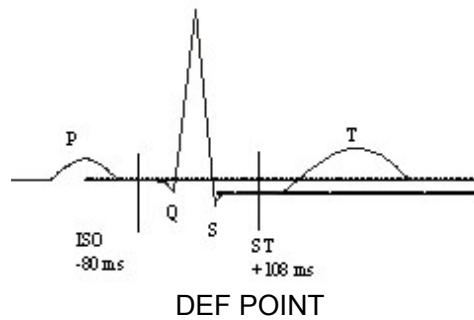
9.8.2 ST Display

Your monitor screen may be configured to look slightly different from the illustrations.

ST	I	0.08	aVR	-0.09	V	0.04
	II	0.10	aVL	0.03		
	III	0.02	aVF	0.06		

9.8.3 About ST Measurement Points

The ST value for each beat complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, and the ST point is at the midpoint of the ST segment. The J point is where the QRS complex changes its slope; as it is a fixed distance away from the ST point, it can be useful to help you position the ST point correctly.



The ST and ISO measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly. Always ensure that ST measurement points are appropriate for your patient. Abnormal QRS complex is not considered in ST segment analysis.

NOTE:

In DEMO mode, the **Analysis Point Setup** button is unavailable.

9.8.4 Adjusting ST and ISO Measurement Points

Depending on your monitor's configuration, the ST point can be positioned, too.

These two points can be adjusted by turning the knob. When adjusting ST measurement point, the system will show the ST Measurement Point Window. The system displays the QRS complex template in the window. It is adjustable for the highlight bar in the window. You may select ISO or ST, switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

9.8.5 ST Alarm Setup

Select **ECG Setup > ST Analysis > ST Alarm Setup** to change the ST Alarm Mode:

Real Time: The user can set the alarm switch, alarm level, alarm limit and alarm record separately for each ST or all ST.

Differential: The monitor triggers the alarm according to the change of ST. The user does not need to set alarm for each ST separately, but only need to set alarm switch, alarm level and alarm difference value (-0.1~0.1) for all ST.

When **ST Alarm Mode** is differential, the user needs to select **Delay** to set the ST alarm delay time. **3 seconds** and **5 seconds** are optional, and the default is **3 seconds**. Besides, the Difference and baseline value shall be set, the difference range is 0.01 mv ~0.1 mv, and the baseline range is -1.90 mv ~1.90 mv.

9.8.6 ST View

The ST View displays a complete QRS segment for each ST lead. The color of current ST segment and ST value are consistent with the color of HR. The color of baseline and ST value are yellow. To enter ST view, please select **ST View** in **ST Analysis**.

In the ST View interface, the user can save ST baseline through clicking **Save as Base** when ST values gets stable. If no ST baseline is saved, the monitor automatically saves the baseline when

the first valid and complete ST waveform appears.

In the ST View interface, the user can display the current waveform, baseline waveform, or the both by selecting **Real**, **Baseline** or **Real+Base**. The user can also hide or display ST points by selecting **Hide Points** or **Show Points**. Besides, the user can record and print the ST view.

In the ST View interface, the user can save ST segment through clicking **Save ST SEG**. Up to 20 groups of ST segments can be saved. When the 21st ST segment is saved, the earliest ST segment will be deleted.

NOTE:

The ST baseline and ST segment will be cleared in following situations:

- 1) Turning off the monitor;
- 2) Changing the electrode type;
- 3) Changing the calculation lead in 3 electrodes;
- 4) Entering or exiting Demo mode;
- 5) Changing the patient type;
- 6) Admitting new patients;

In order to view the ST value situation of each lead more intuitively, the user can enter into the ST Histogram. The horizontal axis shows the lead name while the vertical axis shows the ST value. And the bar graph is used to display the ST value result. The ST histogram refreshes with ST View synchronously.

9.9 Arrhythmia Monitoring

9.9.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarm information. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

The monitor can support 2 configurations for ARR analysis, basic ARR or advanced ARR (also called Basic or Advanced). The default is advanced ARR. For configuration selection, please contact service personnel of the manufacturer.

NOTE:

- 1 Advanced ARR is not available in USA.
- 2 The measured **PVCs** and **Pause/min** will be displayed in main interface. **Pause/min** is only applicable to advanced ARR.
- 3 Advanced ARR is intended to be used with MFM-CMS 2.65 or above version.

ARR Alarms	Occurring Condition
Advanced ARR	
Asystole	No QRS is detected for 4 consecutive seconds
V-Fib/V-Tach	4 consecutive seconds' fibrillation wave occurs; Or 5 consecutive ventricular beats, and ventricular HR ≥ 100 bpm.
Couplet	2 consecutive PVCs
Run PVCs	$3 \leq$ the number of consecutive PVCs < 5
PVC Bigeminy	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
PVC Trigeminy	A dominant rhythm of N, N, V, N, N, V
R on T	A type of single PVC under the condition that HR < 100 , R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
PVC	Single PVC detected in normal heartbeats, and the number of consecutive single PVC ≥ 4 within 30 s.
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
Missed Beat	Basic: If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second; or no valid QRS wave is detected within 3 s or longer. Advanced: If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.
Irr Rhythm	Consistently irregular heart rhythm
Pacer not Capture	No QRS complex detected in 300 ms after a pace pulse.
Pacer not Pacing	No pace pulse detected in 1.75 times RR interval after a QRS complex.
Vent Brady	Basic: 5 consecutive ventricular beats, and ventricular HR < 40 bpm. Advanced: 5 consecutive ventricular beats, and ventricular HR < 20 bpm.

ARR Alarms	Occurring Condition
Vent Rhythm	Basic: 5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$. Advanced: 5 consecutive ventricular beats, and $20 \text{ bpm} \leq \text{ventricular HR} < 40 \text{ bpm}$.
PVCs High	The measurement value of PVCs is greater than high alarm limit that has been set.
Sustain VT	The duration of ventricular tachycardia rhythm $>$ the threshold value that has been set.
ExtremeTachy	$\text{HR} >$ Extreme Tachycardia threshold value that has been set.
ExtremeBrady	$\text{HR} <$ Extreme Bradycardia threshold value that has been set.
V-Tach	5 consecutive ventricular beats and ventricular $\text{HR} \geq 100 \text{ bpm}$.
Wide QRS Tachy	Meet tachycardia conditions, and QRS wave width $\geq 160 \text{ ms}$.
Non-Sustain VT	$3 \leq$ The number of consecutive ventricular beats < 5 , and ventricular $\text{HR} \geq 100 \text{ bpm}$.
Afib	Atrial fibrillation alarm should meet below two conditions for 1 minute: the RR interval of normal beats must be irregular, and it can be seen that the obvious f or P waves do not exist.
Acc. Vent Rhythm	5 consecutive ventricular beats, and $40 \text{ bpm} \leq \text{ventricular HR} < 100 \text{ bpm}$.
Pause	No QRS is detected within the heartbeat pause threshold value that has been set.
Pauses/min High	The measurement value of Pause/min is greater than high alarm limit that has been set.
VEB	The delayed ventricular beats detected in normal heartbeats occur more than or equal to 3 2 times within 30 s.
Multiform PVCs	Different forms of ventricular premature beats are detected in 15 beats.
IPVC	The single ventricular premature beat between 2 sinus beats with normal interval occurs more than or equal to 3 times within 30 s.
PAC Bigeminy	The dominant rhythm of N, A, N, A, N, A, and the rhythm number exceeds the number of threshold value that has been set (N = supraventricular beat, A = atrial beat).
PAC Trigeminy	The dominant rhythm of N, N, A, N, N, A, N, N, A, and the rhythm number exceeds the number of threshold value that has been set.
Low Voltage(Limb)	The signal amplitudes of I, II and III leads shall not exceed alarm threshold value that has been set. PS: this alarm is available for 5 or 12 leads only, not available for 3 leads.

ARR Alarms	Occurring Condition
Basic ARR	
ASYSTOLE	No QRS is detected for 4 consecutive seconds
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.
VT > 2	$3 \leq$ the number of consecutive PVCs < 5
COUPLET	2 consecutive PVCs
BIGEMINY	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
TRIGEMINY	A dominant rhythm of N, N, V, N, N, V
R ON T	A type of single PVC under the condition that HR < 100, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
PVC	Single PVC detected in normal heartbeats.
TACHY	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
BRADY	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.
IRR	Consistently irregular heart rhythm
PNC	PACER NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.
NOTE: Arrhythmia monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients. For this reason, the recommended setting for arrhythmia monitoring in neonatal and pediatric modes is Off .	

Selecting an ECG lead for Arrhythmia:

In arrhythmia monitoring, it is important to select the appropriate lead.

For non-paced patients, the guidelines are:

- QRS should be tall and narrow (recommended amplitude > 0.5 mV)
- R wave should be above or below the baseline (but not biphasic)
- T wave should be smaller than 1/3 of the R wave height
- P wave should be smaller than 1/5 of the R wave height.

For paced patients, in addition to above guidelines, the pacemaker signal should also:

- not wider than normal QRS
- The QRS complexes should be at least twice the height of the pacing pulse
- large enough to be detected, without repolarization signal

According to Standard ISO60601-2-27, the minimum detection level of the QRS complex is set to 0.15 mV, to prevent the detection of P-wave or baseline noise as QRS complexes. Adjusting ECG displayed waveform size (gain adjustment) won't influence ECG signals which are used for arrhythmia analysis. If the ECG signal is too small, a false asystole alarm may occur.

Aberrantly-Conducted Beats:

As not recognizing the P waves, the monitoring system is difficult to distinguish between aberrantly-conducted beats and ventricular heartbeat. If the aberrantly-conducted beat is similar to ventricular tachycardia, it may be classified as ventricular. Make sure to select such a lead, the aberrantly-conducted beats have an R wave that is as narrow as possible to minimize the incorrect calls. The ventricular should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

Intermittent bundle branch block: bundle branch block or other bundle obstruction phenomenon is a challenge for arrhythmia algorithm. If the QRS wave during the block has a considerable change in morphology compared to the normal QRS of learning, the blocked heartbeat may be misclassified as ventricular tachycardia, resulting in an incorrect chamber alarm. Make sure to select such a lead, which blocks the heartbeat of the R wave as narrow as possible to minimize the wrong classification. Ventricular heartbeat should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

NOTE:

- 1 Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.
- 2 Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.
- 3 The ventricular HR mentioned above refers to:
 - In basic ARR, when the consecutive PVCs number ≥ 5 , the algorithm calculates ventricular HR with the average of 4-8 RR intervals.
 - In advanced ARR, when the consecutive PVCs number ≥ 3 , the algorithm calculates ventricular HR with the average of 2-8 RR intervals.

The methods are different from the HR Averaging Method of the monitor. Therefore, the ventricular HR values calculated by basic/advanced ARR algorithm may be different from the HR values calculated by HR Averaging Method. The ventricular HR is for judging arrhythmias and is not exactly equal to the HR displayed on the interface.

- 4 The ARR analysis results and HR values obtained during ARR analysis and HR calculation are not affected by the selected filter mode. The algorithm itself has independent data-flow processing, which can better ensure the consistent and accurate results in different filter modes.
- 5 Atrial fibrillation alarm should meet below two conditions for 1 minute:
 - The RR interval of normal beats must be irregular,
 - It can be seen that the obvious f or P waves do not exist.
- 6 Atrial fibrillation analysis is only applicable to adult patients and should not be performed for PVC or pacing fluctuations.
- 7 Atrial flutter cannot be detected by the atrial fibrillation algorithm because most of their RR intervals are regular.
- 8 In following situations, atrial fibrillation alarm detection error may occur:
 - Sinus arrhythmia
 - Atrioventricular block
 - Frequent ventricular premature beats
 - Myoelectric interference
 - Electrode motion artifact

9.9.2 ARR Analysis Menu

9.9.2.1 Switching ARR Analysis On and Off

To switch ARR Analysis on or off, in the **ECG Setup** menu, select **ARR Analysis** to toggle between **On** and **Off** from the popup interface.

9.9.2.2 ARR Alarm Setup

Select **ECG Setup > ARR Analysis > ARR Alarm Setup** to change the following ARR alarm settings:

- Separately switch on or off each arrhythmia alarm and set the alarm level/record.
- Select **All Alarms On/All Alarms Off** to switch on or off all arrhythmia alarms except key ARR alarms.
- Set the threshold of certain arrhythmia alarms. When an arrhythmia exceeds its threshold, an alarm will be triggered.
- Select **Default** to restore the ARR alarm settings to factory defaults.

Confirm the changes to make the settings effective.

V-Fib/V-Tach (VFIB/VTAC), ExtremeTachy, ExtremeBrady, V-Tach and Vent Brady are key ARR alarms and they are preset to be on. The user can switch on/off those key ARR alarms only when **Key ARR Alarm Switch Authority** is enabled. To enable the authority,

1. Select **Menu > Maintenance > User Maintain**, and enter the required password.
2. Select **Alarm Setup** and set **Key ARR Alarm Switch Authority** to **On**. If any of key ARR alarms is switched off, the bottom information area will prompt **Key ARR Alarm Off**. Clicking the prompts can view the details.

Asystole (ASYSTOLE) and **Sustain VT** alarms are key ARR alarms as well and they are preset to be on and cannot be turned off.

WARNING

When the ARR alarm is set to **Off**, the monitor won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.

NOTE:

Pacer not Capture (PNC) and **Pacer not Pacing (PNP)** alarms are available only when **Pace** is set to **On**.

9.9.2.3 Adjustable Range of ARR Alarm Threshold

ARR Alarm	Range
PVCs High	1/min to 99/min
Pauses/min High	1/min to 20/min
Pause	2 s, 2.5 s, 3 s
Sustain VT	15 s to 45 s
ExtremeTachy	Adult: 120 bpm to 300 bpm; Pediatric/neonatal: 120 bpm to 350 bpm
ExtremeBrady	15 bpm to 60 bpm
PAC Bigeminy PAC Trigeminy	3/min to 50/min
Low Voltage(Limb)	0.3 mV to 0.8 mV

NOTE:

Both the ARR alarm information and threshold value are displayed when the above ARR alarms are triggered.

9.9.2.4 ARR Selflearning

Pick this item **ARR Selflearn** to start a learning procedure, and **ECG ARR Learning** is displayed on the screen.

The ARR selflearning will start automatically in the following status:

- Switching the ARR Analysis from Off to On;
- Changing patient type or electrode type;
- Connecting or switching calculation leads;
- Changing pacemaker status;
- Exiting DEMO or Standby mode;
- Admitting a patient;
- Switching calibration mode into normal measurement mode;
- Switching the ECG parameter on.
- Changing-over between basic ARR and advanced ARR.

NOTE:

- 1 During the relearning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor the patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.
- 2 Take care to initiate ARR selflearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If ARR selflearning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.
- 3 If ARR selflearning is performed during ventricular rhythm, ventricular heartbeats may be erroneously identified as normal QRS complexes. This may lead to missed ventricular tachycardia and ventricular fibrillation events.

Due to this reason, you should:

- 1) Take care that ARR selflearning may start automatically;
- 2) Response to lead off information;
- 3) Always check the correctness of arrhythmia alarm.

9.10 QT Analysis

The QT interval is the time from the beginning of Q wave to the end of T wave. It measured the total duration of the depolarization (QRS duration) and repolarization (ST-T) phases of ventricular action potential. QT analysis can help detect extended QT interval syndrome.

9.10.1 Measurement Limitations

The following clinical status of the patient may affect the QT analysis, and the inaccurate measurement may but is not limited to the following reasons:

- The T-wave is very flat;
- Atrial flutter and atrial fibrillation make T wave is difficult to define;
- The end of the T-wave is difficult to define because of the presence of U-waves;
- A high heart rate causes the P-wave to encroach on the end of the previous T-wave;

- Noise or the QRS wave variation is too big.

In these cases, the user should choose a lead with good T wave amplitude and no visible oscillations, and without a dominant U wave or P wave.

In some conditions, such as left or right bundle branch block or cardiac hypertrophy causes broaden QRS complex. If long QTc is observed, verify it to ensure that it is not caused by QRS broadening.

Since normal beats followed by ventricular beats are not included in the analysis, QT measurement could not be carried out when there was bigeminy rhythm.

When the heart rate changes, it may take several minutes for the QT interval to stabilize. In order to obtain reliable QTc calculations, it is important to avoid areas where the heart rate changes.

NOTE:

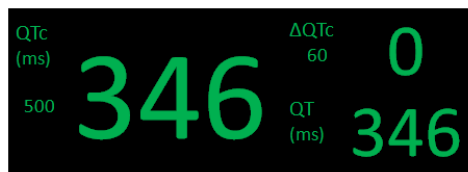
QT/QTc measurements should always be validated by a qualified clinician.

9.10.2 Switching QT Analysis On and Off

To switch QT Analysis on or off, in the **ECG Setup** menu, select **QT Analysis** to toggle between **On** and **Off** from the popup interface.

9.10.3 QT Display

The following figure is QT display for your reference only. The graphics on your monitor may be slightly different.



9.10.4 Selecting QT Analysis Lead

There are two modes for selection:

All lead: Use all available leads (except pressurized the limb lead) to produce an overall QT measurement, user can select **ALL** through **ECG Setup > QT Analysis > Analysis Lead**.

Single lead: QT measurements were performed using all available single leads (except the pressurized limb lead). User selects any lead in **Analysis Lead** menu to enter into single lead mode.

9.10.5 Selecting Calculation Formula

The monitor uses Bazett formula to correct QT values by default. There are four alternative formulas: **Bazett**, **Fridericia**, **Framingham** and **Hodges**.

$$\text{Hodges: } QTc = QT + 1.75 \times (HR - 60)$$

$$\text{Bazett: } QTc = QT \times \left(\frac{HR}{60} \right)^{\frac{1}{2}}$$

$$\text{Fridericia: } QT_c = QT \times \left(\frac{HR}{60} \right)^{\frac{1}{3}}$$

$$\text{Framingham: } QT_c = QT + 154 \times \left(1 - \frac{60}{HR} \right)$$

9.10.6 Setting QT Baseline

To quantitatively express the QT_c values change, the user can set a QT_c baseline, the baseline is used for calculating ΔQT_c value. The user can set the baseline through **ECG Setup > QT Analysis > Save Baseline**, and the monitor displays **The Baseline is saved at: (Time)**. If no baseline has been set, the first five minute QT_c value after the QT measurement begins will be automatically set as the baseline. If a new baseline is set, the previous baseline is discarded. Because ΔQT_c alarm is based on the difference of the baseline with the current values, inappropriate baseline settings may lead that no ΔQT_c alarm is generated.

NOTE:

The QT baseline will be cleared in following situations:

- 1) Turning off the monitor;
- 2) Changing the electrode type;
- 3) Changing the calculation lead in 3 electrodes;
- 4) Changing the patient type;
- 5) Admitting new patients;
- 6) Enters or exits Demo mode.

If QT analysis is needed, please reset the baseline.

9.10.7 QT_c Alarm Setup

Select **ECG Setup > QT Analysis > Alarm Setup** to change the following QT alarm settings:

- Separately switch on or off QT_c alarm and ΔQT_c alarm and set the alarm level.
- Set the thresholds of QT_c alarm and ΔQT_c alarm. When QT_c value or ΔQT_c value exceeds the preset thresholds, an alarm will be triggered.

9.10.8 QT View

To enter QT view, please select **ECG Setup > QT Analysis > QT View**. In the QT View interface, the color of current QT segment and QT value are consistent with the color of HR. The color of baseline and QT value are yellow.

In the QT View interface, the user can save QT baseline through clicking **Save as Base** when QT values gets stable. If no QT baseline is saved, the monitor automatically saves the baseline when the first five minutes value appears. Besides, the user can record and print the QT view.

Chapter 10 Monitoring RESP

10.1 Overview

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

10.2 RESP Safety Information

WARNING

- 1 If you do not set the **Hold High** and **Hold Low** for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the **Hold High** and **Hold Low** too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.
 - 2 Respiration measurements cannot detect all underexposure sudden events, nor can they distinguish between central, obstructive and mixed respiratory asphyxial events. It only prompts alarm in a predetermined time if the last breath is detected and the next breath is not detected, so it cannot be used for diagnostic purposes.
 - 3 If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.
 - 4 Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as etCO₂ and SpO₂.
 - 5 For the diagnosis of apnea, especially in premature infants and infants, the safety and effectiveness of respiration measurements have not been validated.
 - 6 To monitor the respiration, only non-ESU-proof accessories can be used. This is because the internal impedance of the ESU-proof accessories required to be used for electrosurgical operation is too large.
 - 7 Some implantable pacemakers can adjust their triggering frequency according to the "minute ventilation rate." Impedance respiration measurements may cause these pacemakers to react incorrectly. To prevent this, turn off the respiration measurement.
 - 8 In manual detection mode, after changing the gain of the respiration wave, be sure to check the setting of hold high and hold low.
-

WARNING

- 9 When ECG electrode is placed on patient's limb, the impedance respiration may be unreliable.
- 10 Respiration measurement cannot be performed when ESU is used.
- 11 RESP Apnea alarm is based on inadequate thoracic impedance change.
- 12 RESP Apnea alarm should not be used or relied upon while the patient is unattended.

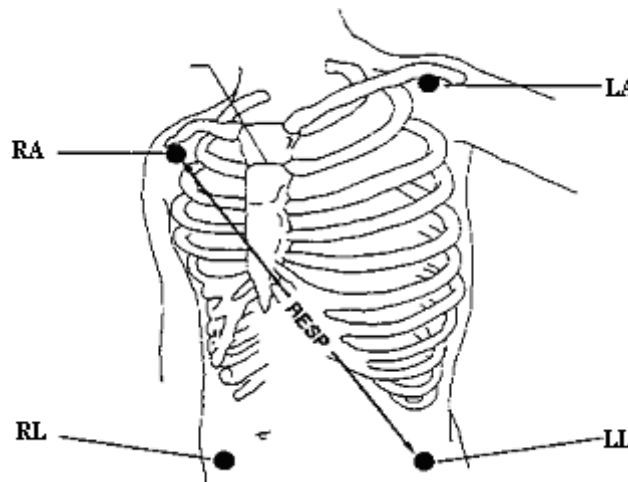
NOTE:

The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

10.3 Electrode Placement for Monitoring RESP

Correct patient skin preparation techniques for electrode placement are important for RESP measurement: you will find this information in the chapter on ECG.

The RESP signal is always measured between two of the ECG electrodes. There are two standard ECG leads for selection: I lead (RA and LA) and II lead (RA and LL).



Electrodes Placement for 5 Electrodes

10.4 Cardiac Overlay

Cardiac activity that affects the RESP waveform is called cardiac overlay. It happens when the RESP electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.

10.5 Chest Expansion

Some patients, especially neonates, expand their chests laterally. In these cases it is best to place

the two respiratory electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

10.6 Abdominal Breathing

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

NOTE:

Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

10.7 Selecting RESP Lead

To change RESP lead, in the **RESP Setup** menu, select **RESP Lead** to pick up the appropriate lead from the pop-up list.

10.8 Changing Hold Type

To change the calculation mode, in the **RESP Setup** menu, set **Hold Type** to **Manual** or **AUTO**. When it is set to the **AUTO** mode, **Hold High** and **Hold Low** are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to the **Manual** mode, you can adjust the broken lines in RESP area by the **Hold High** and **Hold Low** items.

10.9 Changing the Size and Speed of the Respiration Wave

Select the RESP waveform area to open the **RESP Waveform Setup** menu:

- Select **AMP**, and choose an appropriate value. The bigger the value is, the higher the waveform amplitude will be.
- Select **Sweep**: select an appropriate setting from the pop-up list.

10.10 Changing the Apnea Alarm Time

The apnea alarm is a high priority red alarm used to detect apneas. The apnea alarm delay time defines the time period between the point where the monitor cannot detect any respiration activity and the indication of the apnea alarm. Users should set it cautiously.

1. In the **RESP Setup** menu, select **Apnea Alm**.
2. Select the appropriate setting from the popup list.

Chapter 11 Monitoring SpO₂

11.1 Overview

SpO₂ is used to measure arterial blood oxygen saturation, which is the percentage of oxyhemoglobin in the arterial blood. SpO₂ parameter can also provide pulse rate (PR) and a plethysmogram wave (Pleth).

11.2 SpO₂ Safety Information

WARNING

- 1 Do not use the SpO₂ sensors if the packaging or the sensor is damaged and return them to the vendor.
 - 2 If the SpO₂ sensor cannot work properly, please reconnect the sensor or change a new one.
 - 3 Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect the if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.
 - 4 Use only EDAN permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.
 - 5 High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.
 - 6 When serious arrhythmia is present, the SpO₂ pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO₂) value.
 - 7 Misapplied sensor or sensor that becomes partially dislodged may cause either over or under reading of actual arterial oxygen saturation.
-

NOTE:

- 1 Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line, or inflated NIBP cuff. When measuring SpO₂ on the limb with

- inflated NIBP cuff, please turn on the **NIBP Simul** function.
- 2 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.
 - 3 SpO₂ waveform is not directly proportional to the pulse volume.
 - 4 The device is calibrated to display functional oxygen saturation.
 - 5 A Functional tester or simulator cannot be used to assess the SpO₂ accuracy. However, it can be used to demonstrate that a particular monitor reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.
 - 6 If the surrounding temperature increases, the operator should pay attention to the site of poor perfusion, and increase the frequency of checking the skin and changing the measurement site to prevent burns. If the initial skin temperature is less than 35°C, the temperature of all the listed sensors on the skin will not exceed 41°C during working.
 - 7 The cumulative use time for the SpO₂ sensor in a single patient should be less than 30 days.

11.3 Measuring SpO₂

1. Select the correct patient category setting (adult/pediatric and neonatal), as this is used to optimize the calculation of the SpO₂ and pulse numerics.
2. During measurement, ensure that the application site:
 - has a pulsatile flow, ideally with a good circulation perfusion.
 - has not changed in its thickness, causing an improper fit of the sensor.

Measurement Procedure

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient.

Before Applying the Sensor:

Be sure to understand all warnings listed in the previous section before applying any sensor to a patient. Also, check the sensor as follows:

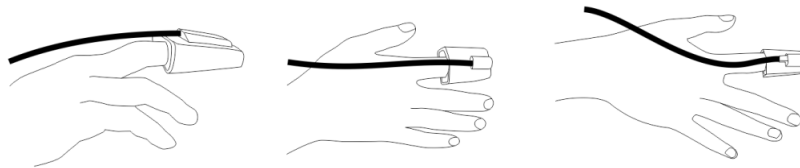
- ◆ Check the sensor outside and inside. To inspect the inside, gently open the sensor cavity and check splits on or next to the transparent silicone that covers the optical elements.
- ◆ Any sensor showing signs of damage or alteration must not be used for further patient monitoring; instead, dispose of it using proper disposal procedures.

Applying Finger/Soft-tip Sensors:

- ◆ Nip the clamp, and choose a site that is well perfused and restricts a conscious patient's movements least. The ring finger of the non-dominant hand is preferred. Alternatively, the

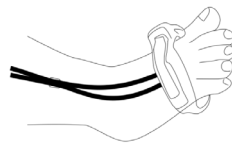
other fingers on the non-dominant hand may be used.

- ◆ The big toe or long toe (next to the big toe) may be used on restrained patients or patients whose hands are unavailable.
- ◆ Place the finger into the sensor according to the direction of the symbol on the sensor. Adjust the finger to ensure that the pad of the finger completely covers the sensor detection window.
- ◆ Orient the sensor so that the cable will be running towards the top of the patient's hand.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



Applying Neonatal Finger (or Toe) Wrap Sensors:

- ◆ When you perform the measurement, position the sensor over the hand or foot with optical components opposite each other.
- ◆ Hold the sensor, and insert stretched strap into slot, hold it there while threading end through latch. If strap is too long, thread it through second latch.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



Applying Adult/Pediatric Ear Clip Sensor:

- ◆ When you perform the measurement, clip the plastic fixing part on top of the ear; reinforce it to prevent falling off or getting loose.
- ◆ Clip the probe onto fleshy part of the lobe with optical components opposite to each other.
- ◆ Connect the sensor with the monitor (or with the extension cable if needed).



3. Plug the connector of the sensor extension cable into the SpO₂ socket.

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. For neonate, change the measuring site every 20 minutes.

NOTE:

- 1 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.
- 2 Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. The sensor cable should be placed on the back of the hand.
- 3 Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

11.4 Measurement Limitations

Certain patient conditions can affect the measurements or cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- incorrect sensor application
- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight
- failure to cover the sensor with opaque material in high levels of ambient light conditions
- dysfunctional hemoglobins
- low peripheral perfusion
- excessive or violent patient movement
- venous pulsations
- intravascular dyes, such as indocyanine green or methylene blue
- externally applied coloring agents (nail polish, dye, pigmented cream)
- defibrillation
- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- electromagnetic interference

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly

- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached
- there is arterial occlusion proximal to the sensor
- low peripheral perfusion

NOTE:

- 1 To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.
- 2 Adjacent SpO₂ sensors may interfere with each other (eg, multiple SpO₂ measurements in the same patient). Be sure to cover the sensor with opaque material to reduce cross-interference.
- 3 Move the sensor to a less active site, and keep the patient still, if possible.
- 4 For Nellcor SpO₂ module, the algorithm automatically extends the amount of data required for measuring SpO₂ and PR depending on the measurement conditions. During normal measurement conditions the averaging time is 6 to 7 seconds. During conditions such as those caused by low perfusion, interference (e.g., external interference such as ambient light or patient movement), or a combination of these, the algorithm automatically extends the amount of data required beyond 7 seconds. If the resulting dynamic averaging time exceeds 20 seconds, the screen will display prompt message “SpO₂ Search Pulse” and SpO₂ and PR will continue to be updated every second. As these conditions extend, the amount of data required continues to increase. If the dynamic averaging time reaches 40 seconds, the screen will display high-level alarm message “SpO₂ No Pulse” indicating a loss-of-pulse condition.

11.5 Assessing the Validity of a SpO₂ Reading

You can check the quality of the pleth wave and the stability of the SpO₂ values to assess whether the sensor functions properly and whether the SpO₂ readings are valid. Always use these two indications simultaneously to assess the validity of a SpO₂ reading.

Generally, the quality of the SpO₂ pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO₂ values also reflects the signal quality. Different from varying SpO₂ readings caused by physiological factors, unstable SpO₂ readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO₂ readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

- 1 The SpO₂ accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO₂ measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies are composed of healthy men and women from

age 19 to 37 (for EDAN SpO₂ module), from 18 to 50 (for Nellcor SpO₂ module), with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

- 2 The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).
- 3 During monitoring, if the monitor's reading differs significantly from the patient's physiological condition, it indicates that the signal may be disturbed, resulting in an inaccurate reading. In this case, the artifact can disguise as a similar reading, causing the monitor to fail to send an alarm. In order to ensure reliable monitoring, it is necessary to regularly check whether the sensor is wearing properly and the signal quality is good.

11.6 SpO₂ Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

11.7 Perfusion Index (PI)*

* Only applicable to the EDAN SpO₂ module.

PI is a numeric value indicating perfusion level. It reflects the perfusion level at the monitoring site.

As the measurement of SpO₂ is based on the pulsation caused by the blood flow through the vessel, PI is in relation to the strength of the pulse. Also, you can use PI as a signal quality indicator for the measurement of SpO₂.

PI is indicated by a value ranging from 0 to 10. The bigger the value is, the better the perfusion and the signal quality will be. The perfusion level and the signal quality are at their maximum when the value reaches 10. When PI is below 2, it indicates the low perfusion and the poor signal quality at the monitoring site; you need to reposition the sensor or find a better site.

The PI value will be displayed in the SpO₂ parameter area.

11.8 Measuring SpO₂ and NIBP Simultaneously

While measuring SpO₂ and NIBP on the same limb simultaneously, the user can set **NIBP Simul** to **On** in **SpO₂ Setup** menu to lock the SpO₂ alarm status until the NIBP measurement ends. If

NIBP Simul is set to **Off**, low perfusion caused by NIBP measurement may lead to inaccurate SpO₂ readings and therefore cause false physiological alarms.

11.9 Setting Pitch Tone

If tone modulation is on, the PR sound lowers when the SpO₂ level drops. In the **SpO₂ Setup** menu, select pitch tone to toggle between **On** and **Off**.

11.10 Setting Sensitivity

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO₂ value is the most frequent. To change the sensitivity, please follow the steps:

- 1 Select the **SpO₂ Setup** menu;
- 2 Select **Sensitivity** on the interface and select the desired sensitivity from the popup list.

11.11 SatSeconds Alarm Management*

* Only applicable to the Nellcor SpO₂ module.

11.11.1 Describing SatSeconds

With traditional alarm management, upper and lower alarm limits are set for monitoring oxygen saturation. During monitoring, as soon as an alarm limit is violated by as little as one percentage point, an alarm is immediately triggered. When the SpO₂ level fluctuates near an alarm limit, the alarm is triggered each time the limit is violated. Such frequent alarms can be distracting.

With the SatSeconds technique, upper and lower SpO₂ alarm limits are set in the same way as traditional alarm management. However, you can also set a SatSeconds limit that allows monitoring of SpO₂ below the selected lower alarm limit and above the selected upper alarm limit for a period of time before an alarm is triggered.

The method of calculation is as follows:

The number of percentage points that the SpO₂ falls outside the alarm limit is multiplied by the number of seconds that the SpO₂ level remains outside that limit. This can be stated as an equation:

$$\text{Points} \times \text{Seconds} = \text{SatSeconds}$$

Where:

Points = SpO₂ percentage points outside of the limit

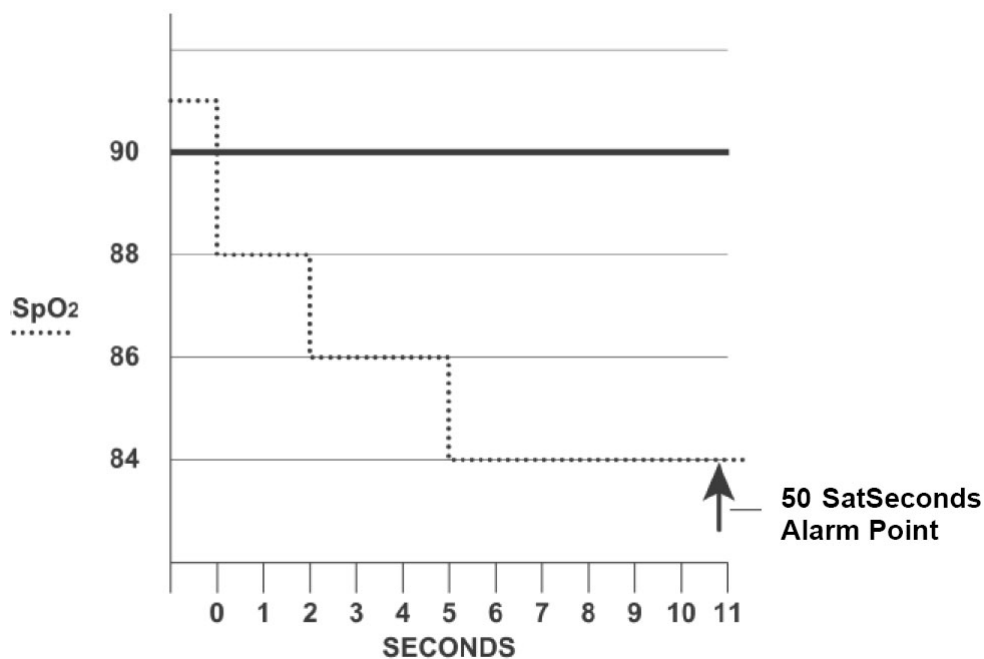
Seconds = number of seconds that SpO₂ remains at that point outside of the limit

The alarm response time, assuming a SatSeconds limit set at 50 and a lower alarm limit set at 90, is described and illustrated below.

In this example, the SpO₂ level drops to 88 (2 points below the limit) and remains there for a period of 2 seconds (2 points × 2 seconds = 4 SatSeconds). The SpO₂ then drops to 86 for 3 seconds and then to 84 for 6 seconds. The resulting SatSeconds values are shown below:

SpO ₂		Seconds	=	SatSeconds
2	×	2	=	4
4	×	3	=	12
6	×	6	=	36
Total SatSeconds			=	52

After approximately 10.7 seconds, a SatSeconds alarm will be triggered, because the limit of 50 SatSeconds has been exceeded. See arrow (↑) in the following figure.



Alarm Response with SatSeconds

Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient SpO₂ may fluctuate above and below the alarm limit, re-entering the non-alarm range several times. During such fluctuation, the monitor integrates the number of SpO₂ points, both positive and negative, until either the SatSeconds limit is reached, or the patient SpO₂ returns within a normal range and remains there.

11.11.2 SatSeconds “Safety Net”

The SatSeconds “Safety Net” is for patients whose saturation makes frequent excursions below or above the SpO₂ limit but does not remain in violation long enough for the SatSeconds limit to be reached. If three or more SpO₂ alarm limit violations occur within a 60-second period, an alarm will be triggered even if the SatSeconds limit has not been reached.

11.11.3 Setting SatSeconds Duration

You can set **SatSeconds** to **Off** or to the duration among **10**, **25**, **50** and **100**. To configure the SatSeconds settings, enter the **SpO₂ Setup** menu and select the desired SatSeconds setting from the **SatSeconds** list.

Chapter 12 Monitoring PR

12.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can obtain a pulse from any measured SpO₂ signal or any arterial pressure.

12.2 Setting PR Source

The monitor provides PR source options. You can select SpO₂ or arterial pressure labels as the PR source in the **PR Source** list on the **PR Setup** menu.

NOTE:

In the **PR Source** list, an arterial pressure label accompanied with a label with brackets indicates this label is in conflict. Do not select a conflicting label as the PR source.

12.3 Setting PR Volume

Select **PR Setup > PR Volume**, then select the appropriate setting for the PR volume: five bars represent the maximum volume and one bar represents the minimum volume. If none of bars are selected, the PR volume will be off. Beat frequency of pulse has positive correlation with measurement value.

12.4 Selecting the Active Alarm Source

In most cases, the HR and PR numerics are identical. In order to avoid simultaneous alarms on HR and PR, the monitor uses either HR or PR as its active alarm source. To change the alarm source, select either **ECG Setup > Alarm Source** or **PR Setup > Alarm Source**, then select:

- **HR:** if you want HR to be the active alarm source.
- **PR:** if you select PR as the active alarm source, the monitor will prompt you to confirm your choice. Be aware that if you select PR as the alarm source, ECG HR alarms are switched off.
- **AUTO:** If the alarm source is set to AUTO, the monitor will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical alarm condition. The monitor will automatically switch to PR for the alarm source if:
 - a valid ECG lead can no longer be measured and
 - a PR source is switched on and available.

The monitor uses the pulse rate from the currently active measurement as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the monitor automatically uses HR as alarm source.

NOTE:

Pulse alarms are only generated when the active alarm source is set to **PR**, a pulse source is set as system pulse and pulse alarms are switched on.

Chapter 13 Monitoring NIBP

13.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients. It is also intended for use with pregnant, including pre-eclamptic patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ISO 81060-2:2013) in relation to mean error and standard deviation. In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine adult diastolic pressure, and the fourth Korotkoff sound was used to determine pediatric diastolic pressure. The invasive blood pressure is used to determine the neonate pressure in clinical investigation, and the arterial reference sites include umbilical artery, arteria cruralis, axillary artery, brachial artery, dorsalis pedis, and radial artery.

13.2 NIBP Safety Information

WARNING

- 1 Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
 - 2 Do not measure NIBP on the arm of the same side with a mastectomy.
 - 3 Use clinical judgement to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
 - 4 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
 - 5 Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient.
 - 6 Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
 - 7 Ensure that the correct patient type is selected before performing measurements. Do not apply the higher adult inflation, overpressure limits and measurement duration for neonatal patients. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
 - 8 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
 - 9 Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.
-

WARNING

- 10 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
 - 11 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
 - 12 Verifying the calibration is only applicable for adults, and it cannot be operated in automatic measuring interval. Continuous measuring cannot be operated in automatic measuring interval either.
-
-

NOTE:

- 1 It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.
- 2 If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.
- 3 Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient. Continuous measuring and automatic measuring in neonatal or pediatric mode may result in tissue damage or ischemia to the patient.
- 4 NIBP measurement can be affected by extremes of temperature, humidity and altitude.
- 5 NIBP measurement value should be explained by qualified professionals.
- 6 The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.
- 7 The cumulative use time for the NIBP cuff in a single patient should be less than 30 days.

13.3 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

- A regular arterial pressure pulse is hard to detect.
- Patients with cardiac arrhythmias.
- Patients with excessive and continuous movement such as shivering or convulsions.
- Patients with rapid blood pressure changes.
- Patients with severe shock or hypothermia that reduces blood flow to the peripheries.
- Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations

coming from the artery.

- Patients on an edematous extremity.

13.4 Measurement Methods

There are four methods of measuring NIBP:

- **Manual** - measurement on demand.
- **Auto** - continually repeated measurements (between 1 and 480 minute adjustable interval). The interval can be user defined, and the default interval of user defined is 2.5 minutes. After the first measurement starts manually, the monitor will automatically measure NIBP as preset interval. When the measurement interval is set to 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 180 min, 240 min, 360 min and 480 min, the system will automatically adjust the next measurement time. Here's an example.

Auto Measurement Interval	Current Time	Next Measurement Time
5 min	12:02	12:05, 12:10, 12:15, 12:20, and so forth.
10 min	12:02	12:10, 12:20, 12:30, 12:40, and so forth.
15 min	12:02	12:15, 12:30, 12: 45, 13:00, and so forth.
30 min	12:02	12:30, 13:00, 13:30, 14:00, and so forth.
60 min	12:02	13:00, 14:00, 15:00, 16:00, and so forth.
90 min	12:02	13:00, 14:30, 16:00, 17:30, and so forth.
120 min	12:02	13:00, 15:00, 17:00, 19:00, and so forth.
180 min	12:02	13:00, 16:00, 19:00, 22:00, and so forth.
240 min	12:02	13:00, 17:00, 21:00, 1:00, and so forth.
360 min	12:02	13:00, 19:00, 1:00, 7:00, and so forth.
480 min	12:02	13:00, 21:00, 5:00, 13:00, and so forth.

When the completion time of manual measurement to the first hourly time is less than or equal to 30 seconds, the measurement will not be performed at the first hourly time, and the first automatic measurement will be delayed to the next hourly time.

- **Continuous** - the measurement will run consecutively in five minutes, then the monitor enters manual mode.
- **Sequence**- after the first measurement starts manually, NIBP measurements run automatically according to the preset phase and interval. The phase can be selected as **4, 5** and **6**. The interval can be set as **1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90 min, 120 min, 180 min, 240 min, 360 min,** and **480 min**. The user can also set the measurement times in each phase, there are several selections: **Off, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30** and **Continuous**.

WARNING

Prolonged non-invasive blood pressure measurements in Auto, Continuous or Sequence mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

13.5 Measurement Procedures

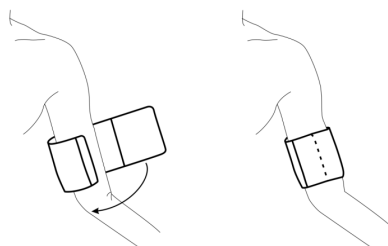
To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including
 - ◆ Comfortably seated or lie flat, legs uncrossed;
 - ◆ Feet flat on the floor;
 - ◆ Back and arm supported;
 - ◆ Relax as much as possible, neither talking nor applying external pressure against the cuff. Rest for five minutes in a quiet environment.
2. Connect the air hose and switch on the monitor.



Apply the blood pressure cuff to the patient's arm or leg and follow the instructions below.

-Ensure that the cuff is completely deflated.

-Apply the appropriate size cuff to the patient (About the cuff size selection, please refer to Section *NIBP accessories*), and make sure that the symbol "Φ" is over the artery. Ensure that the middle of the cuff is at the level of the right atrium of the heart and the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.



Cuff Usage

3. Check whether the patient type is appropriately selected. Access the **Patient Setup** menu from **Menu**. Turn the knob to select the required patient **Type** in the **Patient Info.** menu.
4. Select a measurement mode and NIBP Unit (mmHg, kPa or cmH₂O, 1 mmHg=0.133 kPa, 1 mmHg=1.36 cmH₂O) in the **NIBP Setup** menu. Refer to Section *Operation Prompts* for details.
5. Press the  button on the front panel or shortcut key  on the main screen to start a measurement.



6. Wait until the first reading is taken.

NOTE:



- 1 The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80%-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.
- 2 If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.
- 3 Please make sure the cuff is well connected. A leak of air may cause measurement error.
- 4 Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.
- 5 Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.

13.5.1 Operation Prompts

1. Manual Measuring

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Manual**. Then press the  button on the front panel or shortcut key  on the main screen to start a manual measurement.

2. Automatic Measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Auto**, select time interval as need, then press the  button on the front panel or shortcut key  on the main screen.



3. Continuous measurement

Access the **NIBP Setup** menu and pick the **Continuous** item to start a continuous measurement. The continuous measurement will last 5 minutes.

4. Sequence measurement

Access the **NIBP Setup** menu and set the **Measure Mode** item to **Sequence**, then click **Sequence**. In **Sequence Measurement Setup**, set the **Phase Counts**, **Times** and **Interval** to start a sequence measurement.

5. Stopping continuous measurement

During continuous measurement, press the  button on the front panel or shortcut key  on the main screen at any time to stop measurement.

13.5.2 Correcting the Measurement if Limb is not at Heart Level

To correct the measurement if the limb is not at heart level to the displayed value:

Add 0.75 mmHg (0.10 kPa) for each centimeter higher or	Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower or
Add 1.9 mmHg (0.25 kPa) for each inch higher	Deduct 1.9 mmHg (0.25 kPa) for each inch lower

13.6 NIBP Multi-Review Window

To set the display of NIBP measurements, select **NIBP Setup > Review**:

- ◆ When it is set to **On**, a window for NIBP measurements will be displayed at the waveform area on the main interface, and the size of this window varies depending on the numbers of displayed waveforms.
- ◆ When it is set to **Off**, the window is unavailable on the screen.

13.7 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem, pick **Reset** in the **User Maintain > NIBP Maintain** menu to activate self-test procedure, and thus restore the system from abnormal performance.

13.8 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated, if necessary, at least once every two years by a qualified service professional. See the Service Manual for details.

13.9 Leakage Test

Leakage test is used to detect the air tightness of the NIBP pump, valve, and trachea. If not, the system will display NIBP leakage. NIBP leak detection should be performed at least once every two years or when you think the measurement is inaccurate.

WARNING

This leakage test other than being specified in the ISO 81060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of Leakage Test

1. Connect the cuff securely with the socket for NIBP air hole.
2. Wrap the cuff around the cylinder of an appropriate size, don't wrap the cuff around limbs.
3. Make sure the patient type has been set to **Adult**.
4. Access **User Maintain > NIBP Maintain**.

5. Select **Leakage Test**. Then the prompt **Leak. Test Running** will appear indicating that the system has started the leakage test.

For iM70/iM80/M80 with the Omron module:

The system will automatically inflate the pneumatic system to 285 mmHg. After 4 minutes, the system will automatically open the deflating valve, which marks the completion of a pneumatic measurement.

For iM50/iM60/iM70/iM80/M50/M80 with the EDAN module:

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates **NIBP Leak**. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

For iM60/iM70/iM80/M80 with the SunTech module:

NOTE:

When applying high pressures; take special care to increase the pressure at a rate that will not cause unwanted overpressure errors (300mmHg).

Manually inflate the pneumatic system to approximately 250 mmHg. Start the timer and wait 60 seconds for the pneumatic system to reach its pressure equilibrium point. After the waiting period, record the pneumatic pressure level (P1) and wait another 60 seconds and record the pneumatic pressure level again (P2). Safety circuitry on the module only allows the pressure in the pneumatic system to remain above 10mmHg for 180 seconds. When this safety time limit is exceeded, the valves will open releasing the pressure. Subtract P2 from P1 and this is the leak rate per minute.

6. If the alarm information **NIBP Leak** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the leakage test. If the failure prompt still appears, please contact the manufacturer for repair.

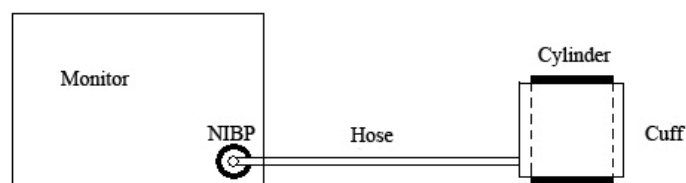


Diagram of NIBP Air Leakage Test

13.10 Setting Inflation Mode

To change the inflation mode:

1. Select **NIBP Setup > Inflation Mode**;
2. Choose **Manual** or **AUTO** from the pull-down list.

- ◆ If **Manual** is chosen, the preset value by users will be adopted as the inflation value when measuring blood pressure.
- ◆ If **AUTO** is chosen, the default value will be adopted as the inflation value when measuring blood pressure.

13.11 Cleaning Mode

The cleaning mode can remove the dust and foreign matters in the air valve to ensure the accuracy of NIBP measurement. To start the cleaning mode, please select **User Maintain > NIBP Maintain > Cleaning Mode**, the monitor displays: **Be sure the cuff is disconnected from monitor**, after confirmation and clicking **Start Cleaning** button, cleaning mode starts. The cleaning mode lasts three minutes. In this mode, the monitor displays **Cleaning in progress**, the remaining time of cleaning mode and cuff value are also displayed. When the countdown finishes, the monitor exits cleaning mode automatically, if the user needs to exit the cleaning mode in advance, please click **Stop** button.

When the air pressure is abnormal, the monitor will automatically turn off the cleaning mode and display the prompt message: **Cleaning failed**.

NOTE:

Cleaning mode is only available when the patient type is adult.

13.12 Assisting Venipuncture

The user can use the NIBP cuff to cause a pressure close to diastolic pressure, so as to block the venous blood vessel and therefore help venipuncture. To assist venipuncture:

1. Select **NIBP Setup > Venipuncture**;
2. Select the appropriate **Cuff Pressure** according to the patient type;
3. Select **Start**, the monitor displays: **Venipuncture Starting**;
4. Wait until the monitor prompts **In venipuncture process**. If an abnormal alarm occurs before it, no follow-up operation can be carried out. Restart the procedure after checking if necessary;
5. Puncture vein and draw blood sample;
6. Select **Stop** to deflate the cuff. If you do not deflate the cuff, the cuff automatically deflates when the venipuncture time expires (170 seconds for adult and pediatric patient, 85 seconds for neonatal patient).

During venipuncture, pay attention to the cuff pressure and the countdown displayed in the NIBP numerics area. When the remaining time is 30 seconds, the monitor issues a reminder tone and the countdown displays in red, prompting the user that the venipuncture time is to expire.

NOTE:

- 1 Only when the monitor exits **Venipuncture** menu, the user can do other operations.
- 2 When the monitor is in DEMO mode, continuous measurement process, manual measurement process, sequence measurement process or auto measurement process, Assisting Venipuncture function is not available.

Chapter 14 Monitoring TEMP

14.1 Overview

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin or to the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values and get the temperature difference. The standard configuration is skin probe for adult.

14.2 TEMP Safety Information

WARNING

- 1 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable of the channel1 from the socket, and then the screen will display the error message **TEMP T1 Sensor Off** and the auditory alarm is activated. It is the same to the other channel.
 - 2 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
 - 3 Temperature probes do not need any probe covers; Please remember to disinfect the probe after each use on a patient.
-

NOTE:

- 1 The reference body site temperature is the same as the temperature of the measuring site.
- 2 The cumulative use time for the oral or rectal temperature probe in a single patient should be less than 24 hours.

14.3 Selecting TEMP Sensor Type

The user can choose the TEMP sensor type as the temperature signal source.

To configure the TEMP sensor type, select **Menu > Maintenance > User Maintain > Other Setups**, and set **TEMP Sensor** to **YSI-10K** or **YSI-2.252K**.

14.4 Switching T1/T2 On/Off

In **Menu > System Setup > Module Switch**, T1 or T2 can be switched on/off separately and won't be affected by each other.

14.5 TEMP Monitoring Setup

- With a reusable TEMP probe you can plug the probe directly into the TEMP connector on the monitor.
- Apply the TEMP probes securely to the patient.
- Switch on the monitor.

It takes 5 minutes for the temperature measurement to stabilize.

14.6 Selecting a Temperature for Monitoring

Select the temperature label according to the measurement site. The label is a unique identifier for each type of temperature.

To select the label,

1. Click the TEMP parameter area to enter **TEMP Setup** menu.
2. Select the appropriate label from the list for **T1** and **T2**.

Label	Description
Tskin	Skin temperature
Trect	Rectal temperature
Tcore	Core temperature

NOTE:

Tcore is only available when **TEMP Sensor** is **YSI-2.252K**.

14.7 Calculating Temp Difference

The monitor can calculate and display the difference between two temperature values by subtracting the second value from the first. The difference is labeled TD.

Chapter 15 Monitoring Quick TEMP

15.1 Overview

Quick temperature measurement is to establish thermal balance between probe and human body. When the probe is placed on the measurement site until a steady reading is available - after approximately three minutes for oral and rectal measurements and five minutes for axillary measurements. And the measurement temperature is the monitoring temperature. The temperature curve in this process has a certain discipline. The approximately actual temperature curve can be simulated by temperature data sampled earlier. The temperature at thermal balance is calculated through the specific algorithm based on the curve.

The monitor can only measure temperature of adult and pediatric patients. If the user measures temperature of neonatal patient, the monitor will not display data. The oral/axillary sensor and rectal sensor are of standard configuration.

15.2 Quick TEMP Safety Information

WARNING

- 1 To ensure optimal accuracy, always confirm that the correct mode and alarm limit are selected. Changing the measure position may lead to the change of alarm limit.
 - 2 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable from the socket, and then the screen will display the error message TEMP SENSOR OFF and the auditory alarm is activated.
 - 3 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.
 - 4 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.
 - 5 Patient actions may interfere with accurate oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum or mints, brushing teeth, smoking or performing strenuous activity may affect temperature readings for up to 20 min after activity has ended.
 - 6 Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.
 - 7 Biting the sensor tip while taking a temperature may result in damage to the sensor.
-

WARNING

- 8 Make sure disposable TEMP sensor covers are used to limit patient cross-contamination. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.
- 9 Quick Temp measurement isn't suitable for use during defibrillation.

NOTE:

- 1 After one measurement, the user should put the sensor well to the sensor bracket and then take it out for starting a new measurement.
- 2 To ensure optimal accuracy, always confirm that the correct measurement position is selected.
- 3 The reference body site temperature is the same as the temperature of the measuring site.

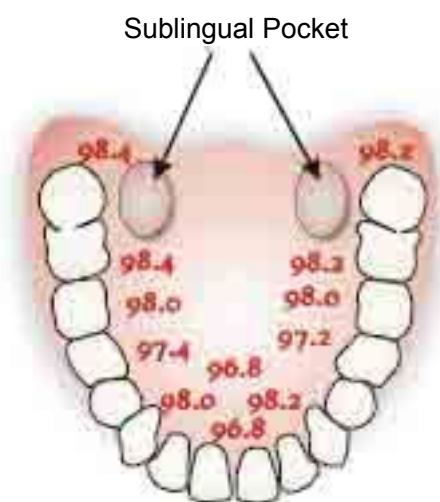
15.3 Measuring Procedure

15.3.1 Measurement for Oral Temperature

1. Ensure the oral probe (white probe) and probe are well installed.
2. Remove the probe from the probe well.
3. Observe the oral mode indicator on the screen (flashing head icon).

If this icon is not flashing, press the **Measure Pos** button and set it to **Oral** until the head icon appears.

4. Load the probe cover.
5. Place the probe tip deep into the patient's sublingual pocket as shown in the following figure.



Measuring Position in Mouth

6. Do not hand the probe to the patient to place in his or her own mouth.
7. Always hold the probe in place, maintaining tissue contact until temperature is complete.

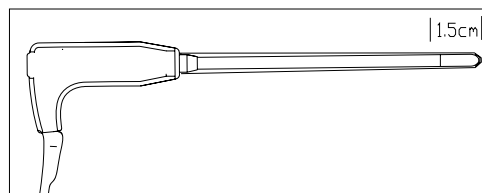
If necessary, repeat the measurement procedure shown above.

When the monitor enters prediction mode, “- - -” will display in the TEMP parameter area. After prediction measuring is over, the measuring value displays on the interface.

If the prediction measuring is successfully finished, the monitor enters **Monitor Mode** after 30s; otherwise the monitor enters **Monitor Mode** immediately after the prediction measuring. The monitoring state lasts for 10 min, and then the monitor enters waiting state. “-?-” displays in the TEMP parameter area. Or you can directly enter **Monitor Mode** by selecting **TEMP Setup > Monitor Mode**.

15.3.2 Measurements for Rectal Temperatures

1. Ensure that the rectal probe (red probe) and probe well are installed.
2. Remove the red probe from the probe well.
3. Observe the Rectal Mode indicator on the display (flashing lower body icon).
4. Load a probe cover. Apply lubricant if desired.
5. Separate the buttocks and gently insert the probe only 1.5cm (5/8 inch), less for infants and children.



Measuring Position in Rectal

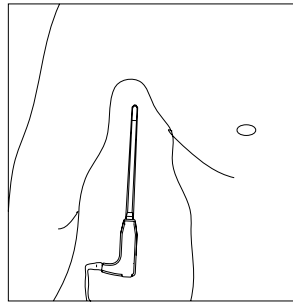
WARNING

Incorrect insertion can cause bowel perforation.

15.3.3 Measurements for Axillary Temperatures

1. Ensure that the white probe and probe well are installed.
2. Remove the probe from the probe well.
3. Press **TEMP Setup > Measure Pos** and select the Axillary mode.
4. Observe the axillary mode indicator on the display (flashing axillary icon).
5. Load a probe cover.
6. Adjust clothing to visualize the axilla.
7. Avoid folds in the axilla and place the probe tip vertically as high as you can as shown.
8. Place the arm at the patient's side. Hold in this position without movement of the arm or probe

during the measurement cycle.



Measuring Position in Axillary

NOTE:

Do not take an axillary temperature through the patient's clothing. Direct contact between the patient's skin and the probe is required.

To obtain accurate rectal temperature, use the white temperature probe.

15.4 Changing Temp Unit

To change **Temp Unit**, please:

- 1 Select the **TEMP Setup** menu to open it and select **Unit** on the interface.
- 2 Select the appropriate unit from the popup list.

Chapter 16 Monitoring IBP

16.1 Overview

IBP is measured by means of a catheter inserted directly into the circulatory system. A pressure transducer connected to the catheter converts the mechanical force exerted by the blood into an electrical signal, which is displayed graphically as pressure versus time on a monitor screen or numerically on digital display.

The monitor measures direct blood pressure of one selected blood vessel through two channels or four channels, and displays waveforms and pressure of measured direct blood pressure (SYS, DIA and MAP).

16.2 IBP Safety Information

WARNING

- 1 The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.
 - 2 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.
 - 3 Disposable IBP transducer or domes should not be reused.
 - 4 If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.
 - 5 All invasive procedures have risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.
 - 6 Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero and calibration, and then cause erroneous readings.
 - 7 The longest duration of IBP arterial catheterization is 7 days.
-
-

NOTE:

- 1 Use only the pressure transducer listed in the IBP Accessories.
- 2 If measuring intracranial pressure (ICP) on a sitting patient, adjust the transducer on the same level with the top of the patient's ear. Incorrect leveling may lead incorrect values.
- 3 Confirm you set correct alarm limit for labels, the alarm limit you set are stored for its label only. Changing label may change the alarm limit.
- 4 Don't perform IBP calibration when a patient is being monitored.
- 5 When using high frequency ventilation, make sure that the ventilator catheter is not

connected to or indirectly connected to the arterial catheter at zero pressure. This can lead to less pressure variations, thus interfere the zeroing process.

16.3 Monitoring Procedures

Preparatory steps for IBP measurement:

1. Plug the pressure cable into the IBP socket and switch on the monitor.
2. Prepare the flush solution.
3. Flush through the system, exhaust all air from the tube, ensure that the transducer and stopcocks are free of air bubbles.
4. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.
5. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.
6. For the label name selection, please refer to *Selecting a Pressure for Monitoring*.
7. To zero the transducer, please refer to *Zeroing the Pressure Transducer*.

WARNING

If there are air bubbles in the tube system, you should flush the system with the solution again. The bubbles may cause erroneous pressure readings.

16.3.1 Selecting a Pressure for Monitoring

Tell the monitor which pressure you want to monitor by selecting its pressure label. The label is a unique identifier for each type of pressure. When you choose a label, the monitor uses that label's stored settings, for example color, wave scale and alarm settings. The label also determines which algorithm is used to process the pressure signal, so an incorrect label can lead to incorrect pressure values. To select the label, please refer to the following table:

Label	Description
ART	Arterial blood pressure
PA	Pulmonary artery pressure
CVP	Central venous pressure
ICP	Intracranial pressure
LAP	Left atrial pressure
RAP	Right atrial pressure
P1-P2	Alternative non-specific pressure labels

NOTE:

The pressure option is only valid when the label is P1/P2 and does not take effect under other labels.

16.3.2 Zeroing the Pressure Transducer

To avoid inaccurate pressure readings, the monitor requires a valid zero. Zero the transducer in accordance with your hospital policy (at least once per day). You must perform a zero:

- When you use a new transducer or tubing;
- Every time you reconnect the transducer cable to the monitor;
- If you think the monitor's pressure readings are not correct.

When using a pressure module, the zero information is stored in the module.

The zeroing procedure is listed as below:

1. Turn off the stopcock to the patient.
2. Vent the transducer to atmospheric pressure, to compensate for the static and atmospheric pressure exerted on the transducer.
3. In the setup menu for the pressure, select **Zero Channel: XX** or **Zero All**. (**XX** stands for the IBP label name). After confirmation, the user can zero the pressure of certain channel or pressure of all channels. After zeroing, the interface displays the result and last calibration time.
4. When you see the message **Zero Ok**, please close the stopcock to atmospheric pressure, and open the stopcock to the patient.

16.3.3 Troubleshooting the Pressure Zeroing (Taking Art for Example)

The status message lists the probable cause of an unsuccessful calibration.

Message	Corrective Action
Art ZERO FAIL	Make sure that the transducer is not attached to the patient.
Art SENSOR OFF, FAIL	Make sure that transducer is not off, and then proceed zeroing.
IN DEMO, FAIL	Make sure that the monitor is not in DEMO mode. Contact service technician if necessary.
PRESSURE OVER RANGE, FAIL	Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician.
PULSATILE PRESSURE ZERO FAIL	Make sure that the transducer is vented to air, not connected to a patient, and try again.

16.3.4 IBP Calibration

IBP is not user-calibrated. Calibration should be performed by a qualified service professional as

frequently as dictated by your Hospital Procedures Policy.

16.4 Changing the IBP Waveform Ruler

The top, middle and bottom rulers are available for each channel of IBP waveform. Users can adjust the top, middle or bottom rulers manually:

1. Open the menu **Wave Setup** of IBP by clicking on the IBP waveform area.
2. Select a suitable ruler from the options **TopRuler**, **MidRuler** and **BotRuler**.

16.5 IBP Waveform Overlapping

The monitor can display IBP overlapped waveforms. To set IBP waveform overlapping:

1. Select **Menu > Maintenance > User Maintain > Other Setups**, and set **IBP Wave Overlapping** to **On** or **Off**.
2. Click the IBP waveform area to show the **IBP Wave Setup** menu.
3. Select **Add IBP Waves** and then select the IBP waves for overlapping from the pop-up list. A maximum of four overlapping waveforms can be displayed.
4. After exiting the interface, the main screen will display the overlapped IBP waves. The flashing label is the main label of the waveform area.

Click the IBP overlapping waveform area on the main screen, and then select **Setup Rulers**. The user can select a suitable ruler for the overlapped waveforms from the options **TopRuler** and **BotRuler**.

16.6 Measuring PAWP

PAWP, Pulmonary Artery Wedge Pressure, used to assess the cardiac function, is obtained by introducing a balloon-tipped pulmonary artery flotation catheter into the pulmonary artery. When the catheter is in one of the smaller pulmonary arteries, the inflated balloon occludes the artery allowing the monitor to record changes in the intrathoracic pressures that occur throughout the respiration cycle. The user can view the PAWP measurement result via connected MFM-CMS.

16.6.1 Measurement Procedures

Pulmonary Artery Wedge Pressure (PAWP) values are affected by fluid status, myocardial contractility, valve and pulmonary circulation integrity. The most accurate PAWP values are obtained at the end of the respiration cycle when the intrathoracic pressure is fairly constant. You can use the respiration waveform as a reference when assessing the PAWP waveform, to ensure constant measurement timing relative to the respiratory cycle.

To start the measurement:

1. On the standard screen interface, select the PA parameter window to enter its setup menu. Then, select **Setup > PAWP Activate** to open the PAWP measurement window.
2. Prepare and check the accessories according to your hospital policy.
3. Wedge the flotation catheter into the pulmonary artery. Then inflate the balloon and pay

attention to PA waveform changes on the screen.

4. After obtaining a stable PAWP waveform, press **Freeze** to freeze the waveform. In freeze status, you can adjust the PAWP scale to an appropriate position by selecting **Measure** and moving the cursors up and down according to the clinical experience. Select **Confirm** to store the PAWP, CVP, HR values. To review the frozen waveform, press **s Browse** and rotate the rotary knob clockwise or counter-clockwise as desired. If you need to review the stored PAWP, CVP, HR values, select **PAWP Review**.
5. Deflate the balloon when the monitor prompts you “**Please deflate the balloon!**”.
6. If you need to start a new measurement, select **Remeasure**.
7. Click on **Exit** or select **Setup > PAWP Exit** to exit.

WARNING

- 1 Prolonged inflation can cause pulmonary hemorrhage, infarction or both. Inflate the balloon for the minimum time necessary to get an accurate measurement.
 - 2 If the PAWP (mean) is greater than the PA (systolic), deflate the balloon and report the incident in accordance with hospital policy, because the pulmonary artery could be accidentally ruptured, and the PAWP value derived will not reflect the patient’s hemodynamic state, but will merely reflect the pressure in the catheter or balloon.
 - 3 The pressure receiver in the catheter records the pressure change that occurs only at the front of the obstruction.
 - 4 Due to the short measurement delay, do not use sidestream CO₂ as a direct reference to determine the end point of the breath in the pressure curve.
 - 5 If the balloon is not inflated but the pulmonary artery floating catheter enters the wedge position, the pulmonary artery pressure waveform becomes wedge-shaped. Follow the standard steps to take appropriate action to correct this situation.
 - 6 PAWP measurement is not applicable to pediatric and neonate patients.
-

16.7 Calculating CPP

CPP is calculated by subtracting MAP and ICP, it means: $CPP=MAP-ICP$.

16.7.1 Measurement Procedures

To start CPP calculation:

1. Click the ICP parameter area to enter into **ICP Options** interface, select **Setup** to enter into **ICP Setup > CPP Source**; CPP source is defaulted as the currently opened artery, it can be selected as **Art**, **P1** or **P2**. If there is more than one arterial pressure at the same time, the priority level should be: $Art > P1 > P2$.
2. Take P1 as example: if P1 is selected as CPP Source, when MAP and ICP are both measured, ICP area will display CPP and its value as below picture, unit is same as ICP. Invalid CPP will display “-?-”. CPP will be closed if exit ICP parameter.



16.8 Calculating PPV

Pulse Pressure Variation (PPV) is calculated from the specific arterial pressure values, which reflects the variation between the maximal pulse pressure and the minimum pulse pressure in 30 seconds. Pulse pressure is affected by left ventricular-stroke volume, arterial resistance and arterial compliance.

WARNING

- 1 The clinical value of the derived PPV information must be determined by a physician. According to recent scientific literature, the PPV information is restricted to sedated patients who receive controlled mechanical ventilation and without arrhythmia. Whether the calculation results in other situations are clinically significant, applicable and reliable must be determined by a physician.
- 2 In below situations, the calculated PPV value may be inaccurate:
 - the respiration rate is lower than 8 rpm
 - the tidal volume during ventilation is lower than 8 ml/kg
 - patients have acute right ventricular functional disorder (pulmonary heart disease)
- 3 PPV measurement has been validated only for adult patients.

PPV is calculated according to the following equation:

$$\text{PPV} = (\text{PPmax} - \text{PPmin}) / (\text{PPmax} + \text{PPmin}) / 2 * 100\%$$

To select an arterial pressure as PPV source:

1. Click the PPV parameter area to enter **PPV Setup** menu.
2. Select **Art**, **P1**, **P2**, or **AUTO** as **PPV Source**.

Only when P1 and P2 are arterial pressure can they be selected as PPV source. When it is set to **AUTO** and if there is more than one arterial pressure at the same time, the priority level should be: Art > P1 > P2.

NOTE:

PPV results will not be recorded.

Chapter 17 Monitoring CO₂

17.1 Overview

The monitor provides the sidestream and mainstream methods for CO₂ monitoring. EDAN EtCO₂ module, Masimo Sidestream CO₂ module and Respironics Sidestream CO₂ module are used for sidestream measuring; Masimo Mainstream CO₂ module and Respironics Mainstream CO₂ module is are used for mainstream measuring. Respironics CO₂ module is plug-and-play and the monitor can automatically identify its sidestream and mainstream modules.

The principle of CO₂ measurement is primarily based on the fact that CO₂ molecule can absorb 4.3µm infrared ray. Absorption intensity is proportional to CO₂ concentration of patient sample, the CO₂ concentration will compute according to the detecting CO₂ absorption intensity of patient sample.

- Sidestream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a CO₂ sensor. You can measure Sidestream CO₂ using the monitor's built-in CO₂ measurement. Respiration rate is calculated by measuring the time interval between detected breaths.
- Mainstream measurement uses a CO₂ sensor attached to an airway adapter directly inserted into the patient's breathing system.

17.2 CO₂ Safety Information

WARNING

- 1 Do not use the device in the environment with flammable anesthetic gas.
 - 2 The device should be used by trained and qualified medical personnel authorized by EDAN.
 - 3 Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO₂ measurement.
 - 4 The monitor will be damaged if any pipeline from the CO₂ module's air tube /the air inlet /the air outlet is plugged by water or other materials.
 - 5 The accuracy of the CO₂ measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.
 - 6 Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
 - 7 Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.
 - 8 When using mechanical ventilation, gas compensation should be well set. Inappropriate setting may cause incorrect measurement result.
-

WARNING

- 9 Respiration module is not equipped with automatic air pressure compensation, before you start the CO₂ measurement for the first time, you must set the correct altitude. Incorrect altitude settings can cause incorrect CO₂ readings. EDAN EtCO₂ module is equipped with automatic air pressure compensation, and manual setting is not required.
 - 10 Leakage in the respiratory system or sampling system may result in a significant low display of the EtCO₂ value. Always keep all components connected firmly and check for leaks according to standard clinical procedures.
 - 11 The EtCO₂ reading is not always closely related to the paCO₂ value, especially in neonatal patients, and patients with pulmonary disease, with pulmonary embolism or inappropriate ventilation.
 - 12 Don't measure CO₂ while nebulized medications are being delivered.
 - 13 The CO₂ module temporarily stops measuring during zeroing.
 - 14 Do not use the EtCO₂ monitor for diagnostic purpose.
 - 15 CO₂ APNEA alarm is based on prolonged over-the-threshold EtCO₂ concentration.
 - 16 CO₂ APNEA alarm should not be used or relied upon while the patient is unattended.
-
-

NOTE:

- 1 After the low battery alarm appears, please do not start the CO₂ measurement, or the monitor may turn off for the low capacity of battery.
- 2 For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.
- 3 If the measurement or sensor fails, stop measurement before the qualified service personnel solves the problem.
- 4 The cumulative use time for the sampling line in a single patient should be less than 30 days.

17.3 Monitoring Procedures

17.3.1 Zeroing the sensor

For the EDAN EtCO₂ module:

EDAN EtCO₂ module itself has automatic zero function, only when the measurement is abnormal or measurement results are doubtful, the user can perform manual zero as following steps:

1. Wait until the monitor's warm-up message disappears; keep the monitor away from CO₂ source.
2. In the **CO₂ Setup** menu, set **Work Mode** to **Measure**.

3. Select **Zero Calibration** in **CO₂ Setup** menu.
4. After the zeroing calibration is completed, the zeroing message disappears, and the CO₂ monitoring can be performed.

For the Respironics Sidestream CO₂ Module:

1. Connect the sample line to the module correctly, wait until the monitor's warm-up message disappears, keep the inlet of sample line away from CO₂ source.
2. In the **CO₂ Setup** menu, set **Work Mode** to **Measure**.
3. Select **Zero Calibration** in **CO₂ Setup** menu.
4. After the zeroing calibration is completed, the zeroing message disappears, and the CO₂ monitoring can be performed. If the monitor displays **Breath Detected** or **Zero Required**, zeroing has failed. Zero calibration must be performed again.

For the Masimo Sidestream CO₂ module:

The highly stable Masimo Sidestream CO₂ module requires no regular zeroing. A room air reference measurement is performed when the NomoLine is disconnected from the gas inlet, provided that CO₂ measurements are stable. This zeroing procedure is indicated by the blinking green.

For the Respironics Mainstream CO₂ Module:

1. Wait until the monitor's warm-up message disappears; correctly install the mainstream CO₂ sensor to airway adaptor and remove it from breathing circuit, keep the monitor away from CO₂ source.
2. In the **CO₂ Setup** menu, set **Work Mode** to **Measure**.
3. Select **Zero Calibration** in **CO₂ Setup** menu.
4. After the zeroing calibration is completed, the zeroing message disappears, and the CO₂ monitoring can be performed. If the monitor displays **Breath Detected** or **Zero Required**, zeroing has failed. Zero calibration must be performed again.

Note: CO₂ source includes ventilator, patient's and operator's breath.

For Masimo Mainstream CO₂ Module:

The user can click **Zero** button in **CO₂ Setup**, during the zeroing progress, the monitor displays prompt information of "**Zeroing**".

Zeroing needs to be performed only when an offset in gas value is observed, or when an unspecified accuracy message is displayed.

17.3.2 Sidestream CO₂ Module

17.3.2.1 Measurement Steps

For the EDAN EtCO₂ Module:

1. Fix the water trap to the water trap holder on the left side of the monitor, confirm it is well

fixed.

2. Connect the sampling cannula or the sampling line to the water trap.
3. Set **Work Mode** to **Measure**.
4. For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.

CAUTION

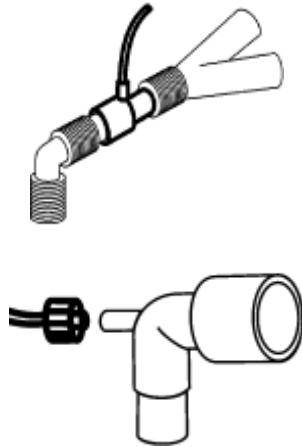
- 1 The water trap collects water drops condensed in the sampling line and therefore prevents them from entering the module. If the water trap is nearly filled, you should replace it to avoid blocking the airway.
 - 2 Based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100%, the water trap will be filled after approximately 90 hours with the flowrate of 100 ml/min and approximately 130 hours with the flowrate of 70 ml/min. In clinical practice, the water trap can be used for a longer time before it is filled. It is recommended to replace the water trap once every month.
 - 3 When replacing the water trap or suspecting the measurement value, please check if the O-rings of the water trap holder are normal and well installed. If the O-rings get damaged or loose, contact EDAN's service staff.
 - 4 To prevent the module from abnormal work, please ensure the water trap detection button is not mistakenly touched.
 - 5 Please replace and discard the water trap when blocking. Don't reuse it, otherwise the reading is not accurate and even the device may be damaged.
-

NOTE:

- 1 Disconnect the water trap from the holder or set **Work Mode** to **Standby** when the module is not in use. Setting path: **CO₂ Setup > Work Mode > Standby**.
- 2 To avoid patient cross infection, do not connect the exhaust tube to the ventilator circuit. If the sampled gas is returned to the breathing system, always use the bacterial filter of the sample gas return kit.

For the Respironics Sidestream Module:

1. Plug the sensor cable into the monitor's CO₂ input connector. Allow the sensor two minutes for warm-up.
2. Appropriately connect the cannula, airway adapter or sample line to the sensor. It will click into place when seated correctly.
3. To zero the sensor, please refer to *Zeroing the Sensor*.
4. For intubated patients, an airway adapter is required;



Air adapter

For non-intubated patients: Place the nasal cannula onto the patient.



Place the nasal cannula

NOTE:

- 1 You must perform a zero calibration as described in this procedure each time the ambient temperature changes more than 10°C (for example during transport).
- 2 Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.
- 3 Always disconnect the cannula, airway adapter or sample line from the sensor when the sensor is not in use.
- 4 To extend the lifetime of the module, set **Work Mode** to **Standby** when the module is not in use.
- 5 The sidestream CO₂ module continuously extracts a quantity of gas from the patient's airway per minute. Please do not use this module in any patient who will be affected by this sampling rate.
- 6 If the catheter falls off during the measurement, it is necessary to re-zero after the catheter is well connected, and then measurement can be performed.

For Masimo Sidestream Module:**WARNING**

- 1 To avoid water condensation inside the module and the connecting tubings, ensure that the surrounding temperature of the module and the connecting tubings does not fall below the ambient temperature of the Sampling line.
- 2 The fulfillment of the EMC requirement is the responsibility of the integrator.
- 3 The Masimo sidestream CO₂ module's exhaust gas is not intended to be returned to the patient circuit.
- 4 The host power supply shall employ current limiting, whereby current is reduced or cut-off under overload conditions.
- 5 The host power supply shall provide 2 MOPP of isolation to Mains according to IEC 60601-1.
- 6 Alarm messages corresponding to each bit in the status summary field of the software interface protocol must be implemented in the host equipment.
- 7 The host equipment shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
- 8 Make sure that Masimo sidestream CO₂ module is used in the electromagnetic environment specified in this manual.
- 9 Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Masimo sidestream CO₂ module, including the cable. Otherwise, degradation of the performance of the Masimo sidestream CO₂ module could result.
- 10 Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
- 11 Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 12 Do not use the module if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.
- 13 Do not adjust, repair, open, disassemble, or modify the module. Damage to the device may result in degraded performance and/or patient injury.
- 14 Do not start or operate the module unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.

WARNING

- 15 Do not place the module or accessories in any position that might cause it to fall on the patient.
 - 16 Only use Masimo authorized devices with the module. Using unauthorized devices with the module may result in damage to the device and/or patient injury.
 - 17 Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
 - 18 Do not lift the module by the NomoLine capnography sampling line as it could disconnect from the module, causing the device to fall on the patient.
 - 19 Do not use the module during magnetic resonance imaging (MRI) or in an MRI environment.
 - 20 Only use sample lines intended for anesthetic agents if N₂O and/or anesthetic agents are being used.
 - 21 Do not re-use disposable single-patient use NomoLine Family sampling lines due to the risk of cross contamination.
 - 22 Do not use the NomoLine Infant/Neonate Airway Adapter Sets for adults/pediatrics as they may cause excessive flow resistance (0,7 ml dead space).
 - 23 Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the airway adapter adds 6 ml dead space.
 - 24 Do not apply negative pressure to remove condensed water from the NomoLine Family sampling line.
 - 25 The module is not intended to be used for returning exhaust gases to the patient circuit. Exhaust gases should be returned to a scavenging system.
 - 26 Disconnect the device from AC mains by removing the device cable connection from the host device.
 - 27 The module should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
 - 28 Use of high-frequency electrosurgical equipment in the vicinity of the module may produce interference and cause incorrect measurements.
 - 29 Do not use the module with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
 - 30 Properly apply sampling lines according to the sampling lines directions for use. Misapplied sampling lines that become partially dislodged may cause no or incorrect readings.
 - 31 Replace the sampling line if the sampling line input connector starts flashing red, or host device displays a check sampling line type of message.
-
-

WARNING

- 32 Too strong positive or negative pressure in the patient circuit might affect the sample flow.
 - 33 Strong scavenging suction pressure might affect the sample flow.
 - 34 To avoid electric shock, always physically disconnect the module and all patient connections before cleaning.
 - 35 Do not attempt to remanufacture, recondition or recycle the module as these processes may damage the electrical components, potentially leading to patient harm.
-
-

CAUTION

- 1 Masimo sidestream CO₂ module does not contain any user-serviceable parts.
 - 2 Anyone not properly trained and certified must not attempt to perform any service or maintenance of the Masimo product.
 - 3 Only use existing mounting holes. Drilling additional holes will void the warranty.
 - 4 Do not operate the module outside of the specific operating environment.
 - 5 The module should be mounted securely to avoid risk of damage.
-
-

NOTE:

Use and store the module in accordance with specifications. See the Specifications section in this manual.

NomoLine Sampling Lines

Masimo Sidestream CO₂ module samples gas from the respiratory circuit through the NomoLine Family sampling line at a rate of 50 sml/min, making measurements of CO₂ possible for adult, pediatric, infant and neonatal patients. The NomoLine Family of sampling lines are designed for optimal performance and measurement fidelity when used with the Masimo Sidestream CO₂ module.

NomoLine sampling lines include nasal and nasal/oral cannulas for non-intubated patients with and without supplementary oxygen delivery and airway adapter sets for intubated patients.



As long as no sampling line is connected, the Masimo Sidestream CO₂ module remains in a low-power sleep mode. Once the sampling line is connected, the Masimo Sidestream CO₂ module switches to measuring mode and starts delivering gas data.

For ordering information about NomoLine sampling lines, cannulas, and related consumables, visit www.masimo.com.

Sampling Line Replacement

NomoLine sampling lines should be replaced between each patient or when the sampling line becomes occluded. Occlusion occurs when water, secretions etc. are aspirated from the respiratory circuit to such an extent that NomoLine capnography cannot maintain the normal 50 ml/min sample flow. This is indicated by a red flashing LEGI indicator and an alarm message; replace the sampling line and wait until the LEGI indicator switches to green, indicating that the Masimo Sidestream CO₂ module is again ready for use.

For ordering information about NomoLine sampling lines and related consumables, visit www.masimo.com.

Setting up

1. Remove the temporary plug from the NomoLine Capnography input connector.
2. Securely mount the Masimo sidestream CO₂ module.

Note: A bracket designed to mount the module is available, visit www.masimo.com.

3. Connect the gas sample exhaust port on the rear of the module to a scavenging system if intended to be used in combination with N₂O and/or anesthetic agents.
4. Connect the module cable to the connection port of the monitor.
5. Connect a NomoLine sampling line to the module input connector.
6. Check that the monitor is powered up and correctly configured.
7. Set **Work Mode** to **Measure**.
8. Check that the gas inlet indicator shows a steady green light, indicating that the Masimo sidestream CO₂ module is ready for use.

Note: Without a sampling line connected, the gas inlet indicator does not illuminate.

9. Attach a NomoLine sampling line to the patient for monitoring. Refer to the NomoLine sampling line Directions for Use.
10. Following connection of the NomoLine sampling line, check that CO₂ values appear on the monitor screen.

Operation

The information in this section assumes that Masimo sidestream CO₂ module is set up and ready for use. This section provides necessary information for proper operation of the device. Do not operate Masimo sidestream CO₂ module without completely reading and understanding these instructions.

The Light Emitting Gas Inlet (LEGI) Indicator provides visual indications of capnography status.

The LEGI Indicator (3) is located around the capnography connector on the front of the device.

The LEGI indicator illuminates in different colors depending on the state of the device as described in the table:

LEGI Indicator	Status
Steady green light	Capnography monitoring in operation and OK
Blinking green light	Zeroing in progress. Refer to <i>Zeroing the sensor</i>
Steady red light	Sensor error
Blinking red light	Check the sampling line (possible occlusion)

Note: Without a NomoLine sampling line connected, the LEGI Indicator does not illuminate.

With no sampling line connected, the Masimo sidestream CO₂ module stays in a low-power, sleep mode. Once a sampling line is connected, the Masimo sidestream CO₂ module switches to measuring mode and starts delivering gas data.

Capnography Display

Parameters and measurements display on the screen of the monitor that the Masimo Sidestream CO₂ module is connected to.

Cleaning

Cleaning of the Masimo sidestream CO₂ module should be performed at regular intervals or in accordance with hospital, as well as local and governmental regulations.

WARNING

To avoid electric shock, always physically disconnect the modules and all patient connections before cleaning.

CAUTION

To avoid permanent damage to the module, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.

NOTE:

To prevent cleaning liquids and dust from entering the NomoLine capnography gas analyzer through its sampling gas inlet connector, keep the sampling line fitted while cleaning the module.

The surfaces of the module may be cleaned with the following solution(s):

- 70% ethyl alcohol
- 70% isopropyl alcohol
- Glutaraldehyde Solution

- Quaternary Ammonium Chloride Wipe
- 0.5% Sodium Hypochlorite/Water Solution
- Accelerated Hydrogen Peroxide

Maintenance

Once every year it is recommended to perform maintenance on the module. A NomoLine ISA CO₂ Maintenance Kit containing all required components and instructions to perform maintenance procedures is available through www.masimo.com.

17.3.2.2 Removing Exhaust Gases from the System

WARNING

Do not connect the exhaust tube to the ventilator circuit, connect the outlet to a scavenging system, cross infection can occur if sampling gas is returned to the breathing system. When using the sidestream CO₂ measurement on patients who are receiving or have recently received anesthetics, please avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

17.3.3 Mainstream CO₂ Module

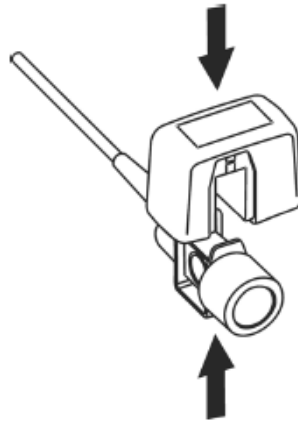
For Respronic Module:

NOTE:

You must perform a zero calibration as described in this procedure each time you use a new airway adapter.

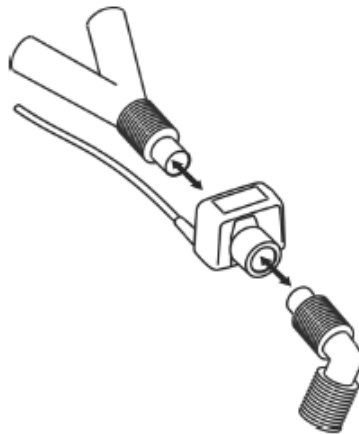
17.3.3.1 Measurement Steps

- 1 Attach the sensor connector to the CO₂ connector on the monitor.
- 2 Wait two minutes, allowing the sensor to reach its operating temperature and a stable thermal condition.
- 3 Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.



Connecting Sensor

- 4 To zero the sensor, please refer to *Zeroing the Sensor*.
- 5 Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.



Connecting Airway Adapter

WARNING

- 1 No routine user calibration is required.
 - 2 Accuracy is affected by temperature and barometric pressure.
-

NOTE:

- 1 If the catheter falls off during the measurement, it is necessary to re-zero after the catheter is well connected, and then measurement can be performed.
- 2 Replace the airway adapter, if excessive moisture or secretions are observed in the tubing or if the CO₂ waveform changes unexpectedly without a change in patient status.
- 3 To avoid cross infection, use only sterilized, disinfected or disposable airway adapters.
- 4 Inspect the airway adapters prior to use. Do not use it if airway adapter appears

- damaged or broken. Observe airway adapter color coding for patient population.
- 5 Periodically check the flow sensor and tubing for excessive moisture or secretion buildup.
 - 6 Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.
 - 7 To avoid dead space, place the sensor as close to the patient as possible.

For Masimo Mainstream Module:

WARNING

- 1 The connection circuit in the host device shall be separated from live parts with double or reinforced insulation.
 - 2 The host power supply shall employ current limiting, whereby current is reduced or cut-off under overload conditions.
 - 3 The host equipment shall be equipped with appropriate alarm system to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.
 - 4 Alarm message corresponding to each bit in the status summary field must be implemented in the host equipment.
 - 5 Incorrect probe zeroing will result in false gas readings.
 - 6 Measurements can be affected by mobile and portable RF communications equipment. It should be assured that the probe is used in the electromagnetic environment specified in this manual.
-

For the monitoring procedures, please refer to Section *Monitoring Steps for IRMA Module*.

17.4 Setting CO₂ Corrections

Temperature, water vapor in the patient's breath, barometric pressure, and the proportions of O₂, N₂O and Helium in the mixture all influence CO₂ absorption. If values seem inaccurately high or low, check that the monitor is using the appropriate corrections.

For the EDAN sidestream module, the following items are available in the **CO₂ Other Setup** menu: **N₂O Compens.**, **O₂ Compens.**, **Anest. Agent**, **Vapor Compens.** and **Pump Rate**. The concentration of compensated gas should be set based on the current gas concentration which is supplied for patient. As for O₂ and N₂O, make the supplied gas concentration multiply to its volume to get the concentration. For instance, supply 100% O₂, and its volume is 60%, then O₂ compensation is: 100%*60%=60%. AG concentration is decided by anaesthesia apparatus.

For the Respironics CO₂ modules, there are **Baro Press**, **O₂ Compens**, **Anes Agent** and **Balance Gas** in the **CO₂ Other Setup** menu. The concentration of compensated gas (including O₂ and AG) should be set based on the current gas concentration which is supplied for patient. The selection

of balance gas depends on actual situation. For instance, N₂O should be selected as balance gas if the real balance gas is N₂O.

For the Masimo CO₂ modules, there are **N₂O Compens** and **O₂ Compens** in the **CO₂ Other Setup** menu. The **N₂O Compens** includes two options: low and high, default is **Low**. **Low** refers to N₂O concentration is 0~30%, and **High** refers to N₂O concentration is 30%~70%. **O₂ Compens** includes three options: low, medium and high, default is **Low**. **Low** refers to O₂ concentration is 0~30%, **Medium** refers to O₂ concentration is 30%~70%, and **High** refers to O₂ concentration is 70%~100%.

After settings, the interface will display a dialog box: **Confirm to change the settings?** And the detailed settings are displayed under the warning. Click **Yes** to confirm, and click **No** to cancel the settings.

NOTE:

Make sure compensation value is correctly set, otherwise the measurement accuracy may be affected.

17.5 Setting Apnea Alarm Time

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

1. Select **CO₂ Setup > Apnea Alm**;
2. Choose the apnea alarm time from the pop-up list.

WARNING

Safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

17.6 Setting CO₂ Waveform

Open the menu **CO₂ Waveform Setup** by clicking on the CO₂ waveform area:

- ◆ Choose **Mode** and set it to **Curve** or **Filled** from the pop-up list;
- ◆ Choose **Sweep** and select a suitable setting from the pop-up list. The bigger the value is, the wider the waveform will be.

17.7 Intubation Mode

Intubation mode is suitable for CO₂ monitoring. During general anesthesia, the monitor can be set to intubation mode to eliminate unnecessary alarms. In intubation mode, CO₂-related physiological alarm (including **CO₂ APNEA**) will be turned off, and the user is unable to enter the CO₂ setup interface for related settings.

To enter intubation mode, follow these steps:

1. Click **Intubation Mode** in **CO₂ Setup**;

2. Select **Duration** in **Intubation Mode**, there are two selections: **3 min** and **5 min**. The default setting is **3 min**.
3. Click **Start**, the monitor will start the intubation mode. During the intubation mode, the monitor will display the intubation mode and remaining time in the form of text.

When countdown finishes or clicking **End** in **Intubation Mode** menu, the monitor will exit the intubation mode; After exiting intubation mode, the monitor will respond the physiological alarm related to CO₂.

NOTE:

The intubation mode is not available when CO₂ module is in Standby mode.

Chapter 18 Monitoring C.O.

18.1 Overview

The cardiac output (C.O.) measurement invasively measures cardiac output and other hemodynamic parameters by using the Thermodilution method. The Thermodilution method is to inject a cold solution into the blood circulation system and measure the temperature changes caused by the cold solution through the thermistor of the pulmonary artery floating catheter, and the C.O. value is calculated by using the temperature dilution curve.

As C.O. is a variable value, a series of measurements must be carried out to obtain a reliable and average C.O. value. Always use the average of multiple measurements for therapy decisions. The monitor can save a maximum of 6 measurement results.

18.2 C.O. Safety Information

WARNING

- 1 Make sure that appurtenance applied is in conformity with relevant Medical Device Safety Requirements.
 - 2 Appurtenance should be avoided from contact with conductive metal body when being connected or applied.
 - 3 All invasive procedures involve risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.
 - 4 The C.O. measurement results may be incorrect during electrosurgery.
 - 5 C.O. floating catheter shall be removed or reinserted after 3 days.
-

NOTE:

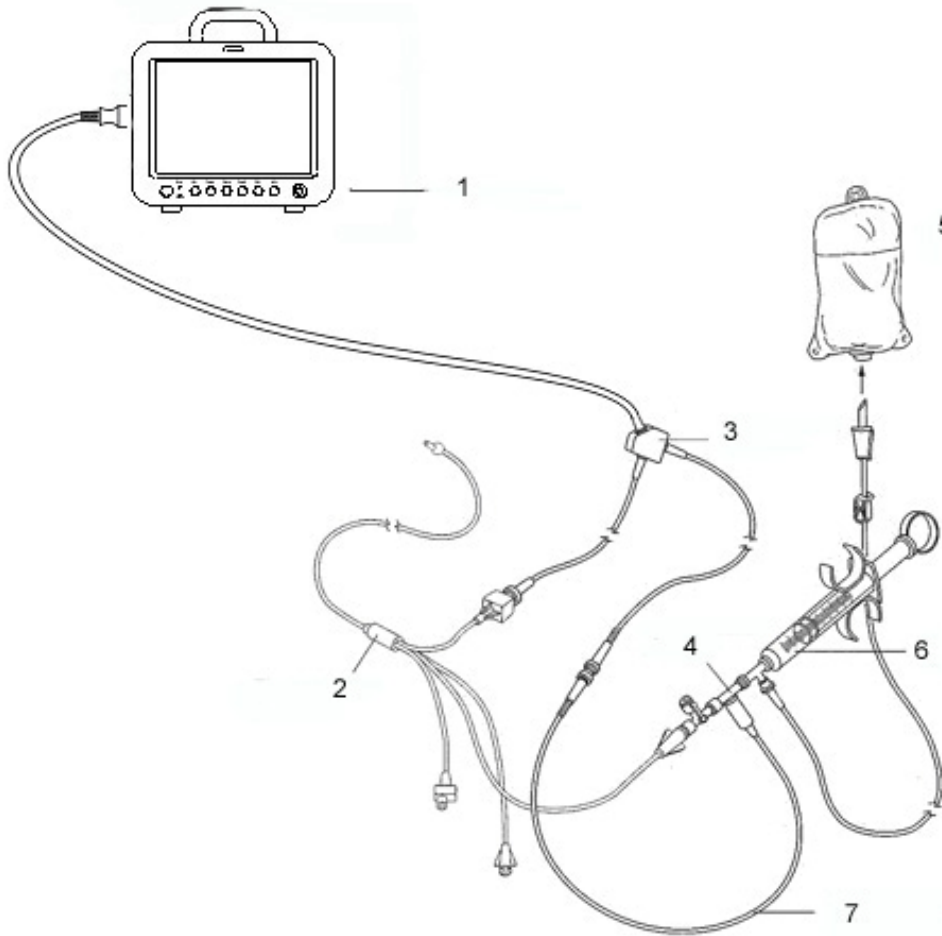
- 1 To replace the catheter thermistor, please enter the catheter computation coefficient into the **Constant** item according to the instruction.
- 2 Please set injection switch well. The calculation of the cardiac output is based on the state of the injection switch at the end of the measurement. Therefore, after the selection of the injection switch is completed, don't change until the measurement is completed.
- 3 Please start C.O. measurement after blood temperature is stable, otherwise the measurement may fail.

18.3 C.O. Monitoring

Preparing Measurement

1. Plug the C.O. cable into the C.O. socket and turn on the monitor.

2. Attach the injective probe connector and catheter thermistor connector to the appropriate parts of the cardiac output interface cable.



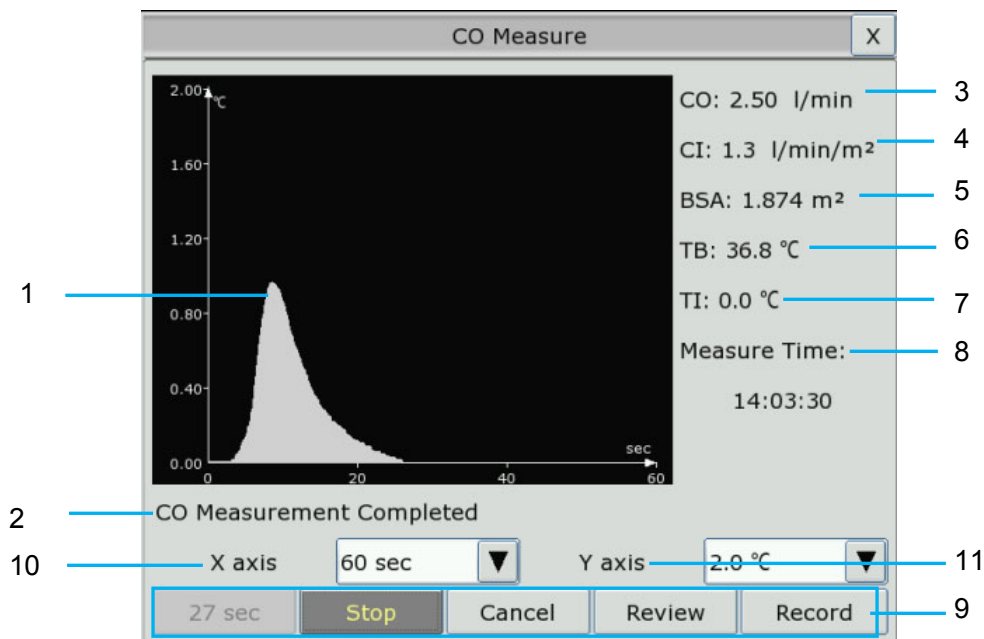
- 1: Monitor; 2: Thermodilution Catheter; 3: Cardiac Output Cable; 4: Injectate Sensor Housing; 5: Injectate; 6: Delivery System; 7: In-line injectate Temperature probe.

C.O. Sensor Connection

3. Open the patient information window to confirm the patients' height and weight.
4. In C.O. Setup menu, set:
 - **C.O. Constant:** The computation constant is associated with catheter and injectate volume. When the catheter is changed, please adjust **Constant** in the **C.O. Setup** menu based on product description provided by the manufacturer. After user's confirmation, the setup takes effect.
 - **INJ. TEMP Source:** Select **Auto** or **Manual** from the list, when set as **Manual**, the system directly displays the injectate temperature from INJ. TEMP. Ensure INJ. TEMP is correct, otherwise the C.O. measurement may be affected. When set as **Auto**, the system obtains the injectate temperature through sampling.

Performing C.O. Measurement

1. Pick the **C.O. Measure** item in the **C.O. Option** menu. The C.O. Measure menu displays as below:



C.O. Measure Window

1	Measurement curve	10	X axis: Change the Scale X (time) value. Two modes are available: 0 s to 30 s, 0 s to 60 s. If you start measurement in the 0 s to 30 s mode, it will be switched to 0 s to 60 s mode automatically if the measurement cannot finish within 30 seconds. After the switch, no further adjustment can be made to the Scale X.
2	Prompt message area		
3	Cardiac Output		
4	Cardiac Index		
5	Body Surface Area		
6	Blood Temperature	11	Y axis: Change the scale Y (temperature) value. Three modes are available: 0 °C to 0.5 °C, 0 °C to 1 °C, 0 °C to 2.0 °C. Adjust the scale by the temperature differences. A smaller scale results in a larger curve.
7	Injectate Temperature		
8	Start time of the measurement		
9	Function keys		

The functional keys on the C.O. measure window are explained in the following table:

Start	Start a measurement
Stop	If the blood temperature cannot resume in a considerably long time, the measurement could not stop automatically. Use this button to stop the measurement and display the C.O., CI calculation result.
Cancel	Cancel the processing measurement or cancel the result after measurement.
Record	Print out the curve.
Review	Enter the Review window

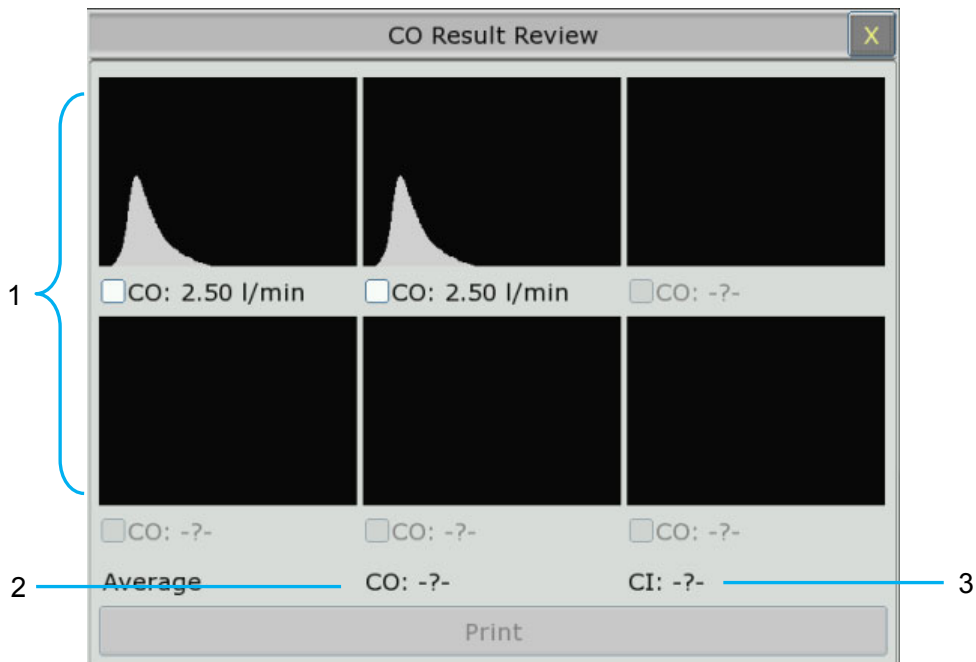
2. Measurement should be taken when the message “**Ready for new measurement**” appears on the screen. Press the **Start** button, and then start injection. The thermodilution curve, current blood temperature and the injective temperature are displayed during the measurement. Curve drawing will stop automatically when the measurement finishes, and the C.O. and CI (3 and 4 in the above figure) will be calculated and displayed on the screen. The monitor will display C.O. in the parameter area and the start measurement time (8 in the above figure).

To ensure the accuracy of the measurement, it is suggested that a reasonable interval should take place between two consecutive measurements. The length of the interval can be set in the C.O. Setup menu (Time unit: second). The interval time counter is displayed on the screen. The next measurement cannot be performed until the time reduces to zero and a message **Ready for new measurement** appears. The adjustable range of **Interval** is: 5 to 300 seconds.

Repeat this procedure until you have completed the measurements you want.

A maximum of six measurements can be saved. If you perform additional measurements, the earliest measurement will be automatically deleted when a seventh curve is saved.

In C.O. review window, select required curves from the 6 measurement curves, and the monitor will automatically calculate and respectively display the average values of C.O. and CI as following:



Contents displayed in the window:

1	Six curves of the six measurements and C.O. value
2	Average value of C.O.
3	Average value of CI

WARNING

- 1 Make sure that the computational constant for the measurement is appropriate to the catheter used.
- 2 Before a C.O. measurement is initiated, check the accuracy of patient setup. The calculation of C.O. is related to the patient height, weight, and catheter computation coefficient; therefore, incorrect input will lead to error in calculation.

NOTE:

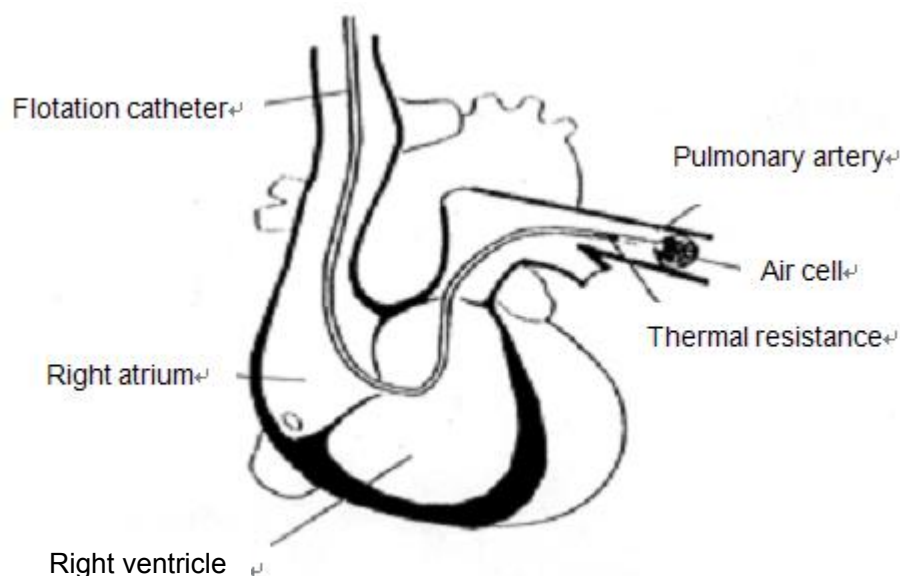
- 1 The blood temperature alarm will not function during C.O. measurement. It will resume automatically when the measurement is over.
- 2 It is strongly recommended that the user must push the injector within four seconds after pressing the **Start** button.
- 3 It is strongly recommended that you wait at least 1 minute (or longer depending on the patient's clinical condition) before starting the next measurement.

18.4 Blood Temperature Monitoring

Blood temperature monitoring can function when C.O. measurement is not taken. The blood temperature is measured by the thermistor situated in the distal end of the flotation catheter in the pulmonary artery.

The blood temperature alarm function will not work during the C.O. measurement. When the measurement ends, the function will automatically resume.

The current blood temperature is displayed in the C.O. parameter area.



Thermodilution Catheter Site

Chapter 19 Monitoring AG

19.1 Overview

The monitor uses ISA sidestream gas analyzer (hereinafter called ISA analyzer), Dräger AG sidestream Minimodule (hereinafter called Dräger Minimodule), EDAN G7 sidestream (hereinafter called G7 Module) and IRMA mainstream module (hereinafter called IRMA module) to monitor the anesthetic gas which can be used to measure the gases of adult, pediatric and neonatal patients during anesthesia, recovery and respiratory care. And the anesthetic gas includes Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), N₂O, and O₂ (Optional). The user can view the AG measurement result via connected MFM-CMS.

19.2 Safety Information

19.2.1 Safety Information for G7 Module

WARNING

- 1 G7 Module is not designed for MRI environments.
 - 2 Do not use the device in the environment with flammable anesthetic gas.
 - 3 The device should be used by trained and qualified medical personnel authorized by EDAN.
 - 4 Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the AG measurement.
 - 5 The monitor will be damaged if any pipeline from the AG module's air tube /the air inlet /the air outlet is plugged by water or other materials.
 - 6 The accuracy of the AG measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.
 - 7 Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
 - 8 The use of authentic EDAN anesthesia sample lines is strongly recommended, as other sample lines with an incorrect length and/or diameter may lead to erroneous agent concentration readings.
 - 9 Since a successful zeroing requires the presence of ambient air (21% O₂ and 0% CO₂), ensure that the module is placed in a well-ventilated place. Avoid breathing near the module before or during the zeroing procedure.
 - 10 The module is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
 - 11 Exhaust gases should be returned to the patient circuit or a scavenging system.
 - 12 Too strong positive or negative pressure in the patient circuit might affect the sample flow.
-

WARNING

- 13 When the monitor is working, do not insert or unplug G7 module (with O₂) to prevent inaccurate O₂ measurement.
 - 14 Do not place the module in any position that might cause it to fall on the patient.
 - 15 Do not immerse sampling lines in liquid.
 - 16 It is recommended to use two agents maximally at the same time.
-
-

CAUTION

- 1 Do not operate the module outside the specified operating temperature environment.
 - 2 The sidestream AG module with O₂ is fragile and should be handled with care.
 - 3 The module should be securely mounted in order to avoid the risk of damage to the module. The module should be handle with care and it cannot be fallen or thrown.
-
-

19.2.2 Safety Information for Masimo ISA Analyzer

WARNING

- 1 The ISA sidestream gas analyzer is intended for use by authorized healthcare professionals only.
 - 2 Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
 - 3 Do not lift the ISA sidestream gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA sidestream gas analyzer to fall on the patient.
 - 4 Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.
 - 5 Use only airway T-adapters with the sampling point in the center of the adapter.
 - 6 Do only use sample lines intended for anesthetic agents if N₂O and/or anesthetic agents are being used.
 - 7 Do not use the T-adapter with infants or neonates, as this adds 7 ml dead space to the patient circuit.
 - 8 Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
 - 9 Since a successful zeroing requires the presence of ambient air (21% O₂ and 0% CO₂), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.
 - 10 Never sterilize or immerse the ISA sideateam gas analyzer in liquid.
-
-

WARNING

- 11 The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
 - 12 Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.
 - 13 Replace the sampling line if the sampling line input connector starts flashing red, or the monitor displays "Sample Line Occluded" message.
 - 14 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
 - 15 The ISA sidestream gas analyzers are not designed for MRI environments.
 - 16 During MRI scanning, ISA must be placed outside the MRI suite.
 - 17 Use of high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.
 - 18 Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.
 - 19 Too strong positive or negative pressure in the patient circuit might affect the sample flow.
 - 20 Strong scavenging suction pressure might affect the sample flow.
 - 21 Exhaust gases should be returned to the patient circuit or a scavenging system.
 - 22 Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.
 - 23 Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.
 - 24 Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.
 - 25 Do not sterilize or immerse Nomoline Family sampling lines in liquid.
 - 26 Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.
 - 27 Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the adult/pediatric airway adapter adds 6 ml dead space.
 - 28 Do not use the NomoLine Infant/Neonate Airway Adapter Sets for adults/pediatrics, as they may cause excessive flow resistance (0.7 ml dead space).
 - 29 Disconnect the module from the gas inlet or set **Work Mode** to **Standby** when the module is not in use. Setting path: **AG Setup > Work Mode > Standby**.
-

CAUTION

- 1 The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.
 - 2 Do not operate the ISA sidestream gas analyzer outside the specified operating environment.
 - 3 (US Only) Caution: Federal law restricts this device to sale by or on the order of a physician. For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.
-

19.2.3 Safety Information for Dräger Minimodule

WARNING

- 1 Dräger Minimodule is intended to be used by trained and authorized health care professionals only.
 - 2 Dräger Minimodule must not be used in areas where combustible or explosive gas mixtures are likely to occur.
 - 3 Modifications to the module may lead to malfunctions.
 - 4 It's recommended to use accessories approved by Dräger. If other, incompatible accessories are used, there is a risk of patient injury due to module failure.
 - 5 Do not use the module near magnetic resonance imagers (MRI, NMR, NMI).
 - 6 During warm-up, reported values may not be accurate.
 - 7 If the gas sensors are not ready for operation, the patient will not be adequately monitored. Before using the medical device, ensure a suitable substitute monitoring.
 - 8 Misdiagnosis or misinterpretation of the measured values or other parameters can endanger the patient. Do not make therapeutic decisions based solely on individual measured values and monitoring parameters. Therapeutic decisions must be made solely by qualified users.
 - 9 When using three anesthetic agents, the oxygen measurement may be inaccurate. Only use two agents at a time.
 - 10 The use of authentic Dräger sample lines is strongly recommended, as other sample lines with an incorrect length and/or diameter may lead to erroneous agent concentration readings and waveforms or water trap/sample line alarms.
 - 11 Never use standard pressure-sensor tubing or IV lines (PVC) because it absorbs anesthetic agents, which are released later (degassing) resulting in erroneous agent concentration readings.
-

WARNING

- 12 The sample flow diverted by the module may reduce the breathing system volume in case of low-flow anesthesia. Compensate by increasing the fresh-gas flow of the anesthesia machine accordingly. In some anesthesia systems, the sample flow may influence the measurement of the expiratory minute volume.
- 13 The liquid in the water trap could be contaminated and must be handled and disposed of with care. Dispose of the liquid in an adequate way and in compliance with local regulations.
- 14 Disconnect sample line before removing the water trap from the medical device. Contaminated liquid could be pushed out of the water trap when removing it without disconnecting the sample line.
- 15 Do not spray the O-rings of the water trap holder with silicon spray. Silicon can get into the measuring cuvette and influence the gas measurement permanently.
- 16 Connect the sample line properly, otherwise faulty gas measurements may result.
- 17 Used sample lines may be infectious due to the breathing gases that passed through them. Sampling lines are not reusable and must be replaced after each patient unless a bacterial filter is in place between sample line and patient.
- 18 Always connect the gas exhaust of the medical device and anesthesia machine to the scavenging system.
- 19 Ensure proper ventilation of the place where the medical device is located.
- 20 Negligent placement of sample line, cables, and similar device components can endanger the patient. Use particular diligence when establishing connections to the patient.
- 21 To avoid temporary influence on the gas measurement and prevent damage to the water trap and measuring system do not use nebulizers/aerosols in the breathing system, when the medical device is connected.
- 22 Do not wash or disinfect the inside of the sample line or water trap to avoid temporary influence on the gas measurement and prevent damage to the water trap and measuring system. Do not sterilize the sample line or water trap.
- 23 Disconnect the water trap from the holder or set Work Mode to Standby when the module is not in use. Setting path: **AG Setup > Work Mode > Standby**.

CAUTION

- 1 Strictly observe the requirements in the user manual while using the module.
 - 2 Do not operate the medical device without water trap.
 - 3 If the water trap is nearly filled, you should replace it to avoid blocking the airway.
-
-

CAUTION

- 4 Do not apply excessive pressure (e.g., syringe, or compressed air) to the inlet, exhaust port, or the water trap of the medical device.
 - 5 To avoid temporary influence on the gas measurement and prevent condensation and resulting failure of electrical components, do not switch on the medical device after significant temperature changes for 1 to 2 hours (e.g., after storage in unheated rooms).
-
-

19.2.4 Safety Information for Masimo IRMA Module

WARNING

- 1 The IRMA probe is intended for use by qualified medical personnel only.
 - 2 The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessment of clinical signs and symptoms.
 - 3 Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.
 - 4 Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.
 - 5 Do not use the IRMA Adult/Pediatric adapter with infants as the adapter adds 6 ml dead space to the patient circuit.
 - 6 Do not use the IRMA Infant airway adapter with adults/pediatrics as this may cause excessive flow resistance.
 - 7 Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.
 - 8 The IRMA probe is not designed for MRI-environments.
 - 9 Do not place the IRMA Airway Adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.
 - 10 To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.
 - 11 Do not use the IRMA Airway Adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.
 - 12 Incorrect probe zeroing will result in false gas readings.
 - 13 Replace the airway adapter if rainout/condensation occurs inside the airway adapter.
 - 14 Use only Masimo manufactured IRMA Airway Adapters.
 - 15 The IRMA probe is not intended to be in patient contact.
-
-

WARNING

- 16 If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.
 - 17 No modification of this equipment is allowed.
 - 18 Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.
 - 19 Disconnect the module from the airway adapter or set **Work Mode** to **Standby** when the module is not in use. Setting path: **AG Setup > Work Mode > Standby**.
-
-

CAUTION

- 1 Never sterilize or immerse the IRMA probe in liquid.
 - 2 The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
 - 3 Do not apply tension to the probe cable.
 - 4 Do not operate the IRMA probe outside the specified operating temperature environment.
 - 5 (US Only) Caution: Federal law restricts this device to sale by or on the order of a physician. For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.
-
-

NOTE:

For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

19.3 Monitoring Steps

19.3.1 Monitoring Steps for G7 Module

19.3.1.1 Zeroing the Sensor

EDAN G7 module itself has automatic zero function, only when the measurement is abnormal or measurement results are doubtful, the user can perform manual zero as following steps:

1. Wait until the monitor's warm-up message disappears; keep the monitor away from AG source.
2. In the **AG Setup** menu, set **Work Mode** to **Measure**.
3. Select **Zero Calibration** in **AG Setup** menu.

19.3.1.2 Measurement Steps

1. Fix the water trap to the water trap holder on the left side of the monitor, confirm it is well fixed.
2. Connect the sampling cannula or the sampling line to the water trap.
3. Set **Work Mode** to **Measure**.
4. For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.

CAUTION

- 1 The water trap collects water drops condensed in the sampling line and therefore prevents them from entering the module. If the water trap is nearly filled, you should replace it to avoid blocking the airway.
- 2 When replacing the water trap or suspecting the measurement value, please check if the O-rings of the water trap holder are normal and well installed. If the O-rings get damaged or loose, contact EDAN's service staff.
- 3 To prevent the module from abnormal work, please ensure the water trap detection button is not mistakenly touched.
- 4 Based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100%, the water trap will be filled after approximately 60 hours with the flowrate of 150 ml/min. In clinical practice, the water trap can be used for a longer time before it is filled. It is recommended to replace the water trap once every month.
- 5 Please replace and discard the water trap when blocking. Don't reuse it, otherwise the reading is not accurate and even the device may be damaged.

NOTE:

To avoid patient cross infection, do not connect the exhaust tube to the ventilator circuit. If the sampled gas is returned to the breathing system, always use the bacterial filter of the sample gas return kit.

19.3.1.3 MAC Calculation

The MAC value is calculated and displayed by using end-tidal (Et) gas concentrations according to the following formula:

$$MAC = \frac{EtAA1}{MAC_{standard1}} + \frac{EtAA2}{MAC_{standard2}} + \frac{EtN2O}{MAC_{standardN2O}}$$

EtAA1 is the concentration of the main anesthetic gas at the end of the breath.

EtAA2 is the concentration of the secondary anesthetic gas at the end of the breath.

EtN₂O is N₂O concentration at the end of the breath.

MAC_{standard1} is the MAC_{standard} value of the main anesthetic gas.

$MAC_{standard2}$ is the $MAC_{standard}$ value of the secondary anesthetic gas.

$MAC_{standardN_2O}$ is the $MAC_{standard}$ value of N_2O .

$MAC_{standard}$ value is as following:

	$MAC_{standard}$
HAL	0.77%
ENF	1.7%
ISO	1.15%
DES	6.0%
SEV	2.1%
N_2O	105%

19.3.2 Monitoring Steps for Masimo ISA Module

NomoLine Sampling Lines

Masimo Sidestream CO_2 module samples gas from the respiratory circuit through the NomoLine Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric, infant and neonatal patients. The NomoLine Family of sampling lines are designed for optimal performance and measurement fidelity when used with the Masimo Sidestream CO_2 module.

NomoLine sampling lines include nasal and nasal/oral cannulas for non-intubated patients with and without supplementary oxygen delivery and airway adapter sets for intubated patients.



As long as no sampling line is connected, the Masimo Sidestream CO_2 module remains in a low-power sleep mode. Once the sampling line is connected, the Masimo Sidestream CO_2 module switches to measuring mode and starts delivering gas data.

For ordering information about NomoLine sampling lines, cannulas, and related consumables, visit www.masimo.com.

Working Status of ISA analyzer

Working status of the ISA analyzer can be indicated by the indicator. For the detailed information, please refer to the following table.

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress

Indication	Status
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check sampling line

Remark: the blue light is applicable to ISA AX+ and ISA OR+.

19.3.2.1 Performing a Pre-use Check

Before connecting the Nomoline sampling line to the breathing circuit, do the following:

1. Connect the sampling line to the ISA gas inlet connector (LEGI).
2. Check that the LEGI shows a steady green light (indicating that the system is OK).
3. For ISA OR+ and ISA AX+ module with O₂ option fitted: Check that the O₂ reading on the monitor is correct (21%).
4. Breathe into the sampling line and check that valid CO₂ waveforms and values are displayed on the monitor.
5. Occlude the sampling line with a fingertip and wait for 10 seconds.
6. Check that an occlusion alarm is displayed and that the LEGI shows a flashing red light.
7. If applicable: Perform a tightness check of the patient circuit with the sampling line attached.

19.3.2.2 Leakage Check

1. Connect a new Nomoline sampling line with male luer lock to the ISA LEGI and check that the LEGI shows a steady green light.
2. Connect a short silicon tubing with an inner diameter of 3/32" (2.4 mm) to the Nomoline male luer.
3. Exhale a long breath into the silicon tubing until the CO₂ concentration is greater than 4.5 vol% or 34 mmHg.
4. Quickly connect the silicon tubing tightly to the exhaust port.
5. Wait 1 minute until the CO₂ concentration has stabilized. Note the value.
6. Wait 1 minute and check that the CO₂ concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

19.3.2.3 System Setup for Analyzer

If your system is using the plug-in and measure ISA analyzer, please follow the setup instructions below:

1. Connect the ISA analyzer interface cable to the monitor.
2. Connect a Nomoline sampling line to the ISA analyzer input connector.
3. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient

circuit.

4. Power up the monitor.
5. A green LED indicates that the ISA analyzer is ready for use.
6. Perform a pre-use check as described in section Perform a pre-use Check.

19.3.2.4 Zeroing

The infrared module needs to establish a zero reference level for the CO₂, N₂O and anesthetic agent gas measurement. This zero calibration is here referred to as "zeroing".

ISA analyzer performs zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 10 seconds for ISA analyzer.

If the ISA analyzer is fitted with an oxygen sensor, the automatic zeroing will also include room air calibration of the oxygen sensor.

WARNING

Since a successful zeroing requires the presence of ambient air (21% O₂ and 0% CO₂), ensure that the ISA analyzer is placed in a well ventilated place. Avoid breathing near the ISA analyzer before or during the zeroing procedure.

19.3.2.5 Cleaning

The ISA sidestream gas analyzers and Nomoline Adapter can be cleaned using a cloth moistened (not wet) with max 70% ethanol or isopropyl alcohol.

To prevent cleaning liquids and dust from entering the ISA gas analyzer through its LEGI connector, keep the Nomoline Family sampling line connected while cleaning the analyzer.

CAUTION

Never immerse the ISA sidestream gas analyzer in liquid.

19.3.2.6 Maintenance

Once every year, or whenever gas readings are questionable, perform a leakage check according to section *Leakage Check* and verify gas readings with a reference instrument or with calibration gas.

WARNING

The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any parts of the sampling line.

19.3.2.7 Replacement of Consumables

The Nomoline and Nomoline Airway Adapter Set are single-patient use products.

The Nomoline Adapter is a multiple-patient use product.

The T-adapter and Nomo Extension are single-patient use products.

Nomoline Family sampling lines and all consumables mentioned above should be replaced according to good clinical practice or when the sampling line gets occluded. Occlusion occurs when water, secretion etc. is aspirated from the respiratory circuit to such extent that ISA cannot maintain the normal 50 ml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

19.3.2.8 MAC Calculation

The MAC value is calculated and displayed by using end-tidal (Et) gas concentrations according to the following formula:

$$MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N_2O)}{100}$$

X (AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

NOTE:

Altitude, patient age and other individual factors are not considered in the formula above.

19.3.3 Monitoring Steps for Dräger Minimodule

1. Fix the water trap to the water trap holder.
2. Connect the sampling cannula or the sampling line to the water trap.
3. Set **Work Mode** to **Measure**.
4. For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.

Upon start-up, the module passes through an initialization (status message **MultiGas Initialization** appears) and warm-up period (status message **MultiGas Warming Up** appears). During this time, concentrations for certain gases may not be available and the anesthetic agent may not be identified. After the warm-up period, the module will have achieved full ISO-accuracy.

19.3.3.1 Zeroing

The module purges and zeroes itself and does not need any interaction by the user. Waveforms flatline and parameter box values blank from the screen during this cycle.

19.3.3.2 MAC Calculation

Standard MAC values

1 standard MAC is equal to the alveolar anesthetic concentration at one atmosphere (760 mmHg) at which 50% of all patients no longer respond to noxious stimuli. The integrated MAC algorithm

is based on the MAC values shown in the following table. The values specified in the table apply to a patient age of 40 years and are guiding values only.

	1 MAC corresponds to: (in 100 % O₂)
Halothane	0.77 Vol%
Enflurane	1.7 Vol%
Isoflurane	1.15 Vol%
Desflurane	6.65 Vol%
Sevoflurane	2.10 Vol%
N ₂ O	105 Vol%

For gas mixtures, the respective multiples for N₂O and anesthetic agents are added according to the following equation.

$$\text{MAC}_{\text{standard, total}} = \frac{\text{exp. conc. Anesth.}_1}{\text{MAC}_{\text{standard Anesth.}_1}} + \frac{\text{exp. conc. Anesth.}_2}{\text{MAC}_{\text{standard Anesth.}_2}} + \frac{\text{exp. conc. N}_2\text{O}}{\text{MAC}_{\text{standard N}_2\text{O}}}$$

NOTE:

Age and other factors are not taken into account for standard MAC value calculation.

Age-corrected MAC values

The equation applies to patients older than 1 year.

$$\text{MAC}_{\text{age corrected}} = \text{standard MAC} \times 10^{(-0.00269 \times (\text{age} - 40))}$$

For gas mixtures, the respective multiples for N₂O and anesthetic agents are added according to the following equation.

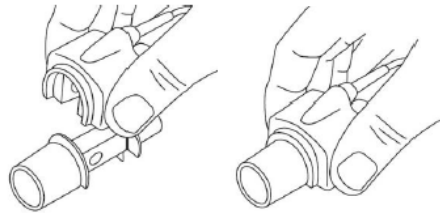
$$\text{MAC}_{\text{age corrected, total}} = \frac{\text{exp. conc. Anesth.}_1}{\text{MAC}_{\text{age corrected Anesth.}_1}} + \frac{\text{exp. conc. Anesth.}_2}{\text{MAC}_{\text{age corrected Anesth.}_2}} + \frac{\text{exp. conc. N}_2\text{O}}{\text{MAC}_{\text{age corrected N}_2\text{O}}}$$

CAUTION

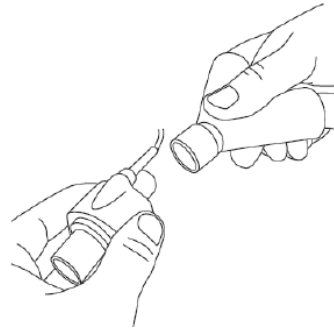
- 1 Always set patient age correctly. Incorrect settings can lead to inappropriate MAC values and therefore to inappropriate anesthetic gas delivery.
- 2 Age-based MAC values only apply if the patient's age is ≥ 1 year. An aged-based MAC of 1 year is used if the patient's age is < 1 year.
- 3 If patient age is not entered, the default age-based MAC of 40 years is used.

19.3.4 Monitoring Steps for Masimo IRMA Module

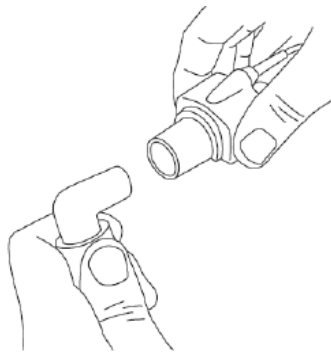
- 1 Plug the IRMA connector into the IRMA input and switch the power on.
- 2 Snap the IRMA sensor head on the top of the IRMA airway adapter. It will click into place when properly seated.



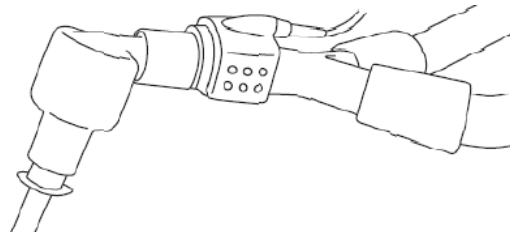
- 3 A green LED indicates that the IRMA probe is ready for use.
- 4 Connect IRMA /airway adapter 15mm male connector to the breathing circuit Y-piece.



- 5 Connect the IRMA /airway adapter 15mm female connector to the patient's endotracheal tube.



Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing an HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.



- 6 Unless the IRMA probe is protected with an HME always position the IRMA probe with the status LED pointing upwards.

Working Status of IRMA Module

The working status of the IRMA module can be transmitted by the IRMA probe. For the detailed information, please refer to the following table.

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

Remark: the blue light is applicable to IRMA AX+ only.

19.3.4.1 Placement of IRMA Probe

When connecting IRMA probe to an infant patient circuit, it is important to avoid a direct contact between the IRMA probe and the infant's body. If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body, an insulation material shall be placed between the IRMA probe and the body.

WARNING

The IRMA probe is not intended to be in long term skin contact.

19.3.4.2 Performing a Pre-use Check

Prior to connecting the IRMA airway adapter to the breathing circuit, verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

19.3.4.3 Zeroing

WARNING

Incorrect probe zeroing will result in false gas readings.

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the zeroing procedure. The presence of ambient air (21% O₂ and 0% CO₂) in the IRMA airway adapter is of crucial importance for a successful zeroing. If a “**Zero Required**” appears directly after a zeroing procedure, the procedure has to be repeated.

Always perform a pre-use check after zeroing the probe.

Zeroing for IRMA AX+ probes:

Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

Allow 30 seconds for warm up of the IRMA AX+ probes after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

19.3.4.4 Cleaning

The IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA airway adapter prior to cleaning the IRMA probe.

CAUTION

- 1 The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
- 2 Never immerse the IRMA probe in liquid.

19.3.4.5 Maintenance

Gas readings should be verified at regular intervals with a reference instrument or by conducting the gas check. The suggested interval is once every year.

19.3.4.6 MAC Calculation

The MAC value may be calculated and displayed by using end-tidal (ET) gas concentrations according to the following formula:

$$\text{MAC} = \% \text{ET}(\text{AA}_1) / \text{X}(\text{AA}_1) + \% \text{ET}(\text{AA}_2) / \text{X}(\text{AA}_2) + \% \text{ET}(\text{N}_2\text{O}) / 100$$

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

19.4 Setting Apnea Alarm Time

This determines the time limit after which the monitor gives an alarm if the patient stops breathing.

- 1 Select the **CO₂ (AG) Setup > Apnea Alm;**
- 2 Choose the apnea alarm time from the pull-down list.

19.5 O₂ Compensations

The following models need O₂ compensation: IRMA AX+, ISA AX+, G7+ and G7S+. For the compensation details, please refer to the following.

For the Masimo AG modules, the following table is for your reference:

O ₂ Range	Set O ₂ Range
0 to 30 vol%	Low
30 to 70 vol%	Med.
70 to 100 vol%	High

For G7 module, the following items are available in the **AG Other Setup** menu: **O₂ Compens.** and **Vapor Compens.**. The concentration of compensated gas should be set based on the current gas concentration which is supplied for patient. As for O₂, Make the supplied gas concentration multiply to its volume to get the concentration. For instance, supply 100% O₂, and its volume is 60%, then O₂ compensation is: 100%*60% = 60%. AG concentration is decided by anaesthesia apparatus. For G7 with O₂ module, the O₂ compensation is automatic; for G7 without O₂ module, the O₂ compensation is manual. After settings, the interface will display a dialog box: **Confirm to change the settings?** And the detailed settings are displayed under the warning. Click **Yes** to confirm, and click **No** to cancel the settings.

19.6 Effects of Humidity

The partial pressure and the volume percentage of CO₂, N₂O, O₂ and anesthetic agents depend on the amount of water vapor in the measured gas. The O₂ measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O₂ corresponds to the actual O₂ concentration in room air with 0.7 vol% H₂O concentration (at 1013 hPa this equals for example 25°C and 23% RH). The measurement of CO₂, N₂O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas flows through the sampling line, the gas temperature will adapt to ambient before reaching the gas analyzer. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO₂ values at BTPS are required, the following equation can be used:

$$EtCO_2(BTPS) = EtCO_2 * \left(1 - \left(\frac{3.8}{P_{amb}} \right) \right)$$

where:

$EtCO_2$ = EtCO₂ value sent from ISA [vol %]

P_{amb} = Ambient pressure sent from ISA [kPa]

3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]

EtCO₂ (BTPS) = EtCO₂ gas concentration at BTPS [vol%]

O₂ is assumed to be room air calibrated at a humidity level of 0.7 vol% H₂O.





Chapter 20 Freeze

When monitoring a patient, the user may freeze the waveforms and examine them. Generally, the user can review a frozen waveform of a maximum of 120 seconds. The freeze function of this monitor has the following features:

- Freeze status can be activated on any operating screen.
- Once entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms on the Full Lead ECG interface (if any). Nevertheless the Parameter area refreshes normally.
- The frozen waveforms can be reviewed and recorded.



20.1 Entering/Exiting Freeze Status

20.1.1 Entering Freeze Status



In the Non-Freeze status, press the  button on the control panel of the monitor or select the shortcut key  to exit the current menu. Press the  button or select the shortcut key  again, freeze status is entered and the popup **Freeze** menu is displayed. In Freeze status, all waveforms are frozen and will no longer be refreshed.

20.1.2 Exiting Freeze Status



In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

- Exit the **Freeze** menu;
- Press the  button on the control panel or select the shortcut key  again;
- Execute any operation that may trigger the adjustment of the screen or the display of a new menu.

After exiting Freeze status, the system will clear screen waveforms and resume displaying real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from left to right in the Waveform Area.

Press the  button on the control panel or select the shortcut key , and the **Freeze** menu will appear on the bottom part of the screen. At the same time, the system freezes the waveforms.

NOTE:

Pressing the  button or select the shortcut key  repeatedly over a short period of time may result in discontinuous waveforms on the screen.

20.2 Reviewing Frozen Waveform

By moving the frozen waveform, you may review a waveform of 120 seconds before it is frozen. For a waveform of less than 120 seconds, the remaining part is displayed as a straight line. Select **Time** on the **Freeze** menu and use the up/down arrow keys to move the frozen waves so that you can review the other parts of the frozen waves not displayed on the current screen.

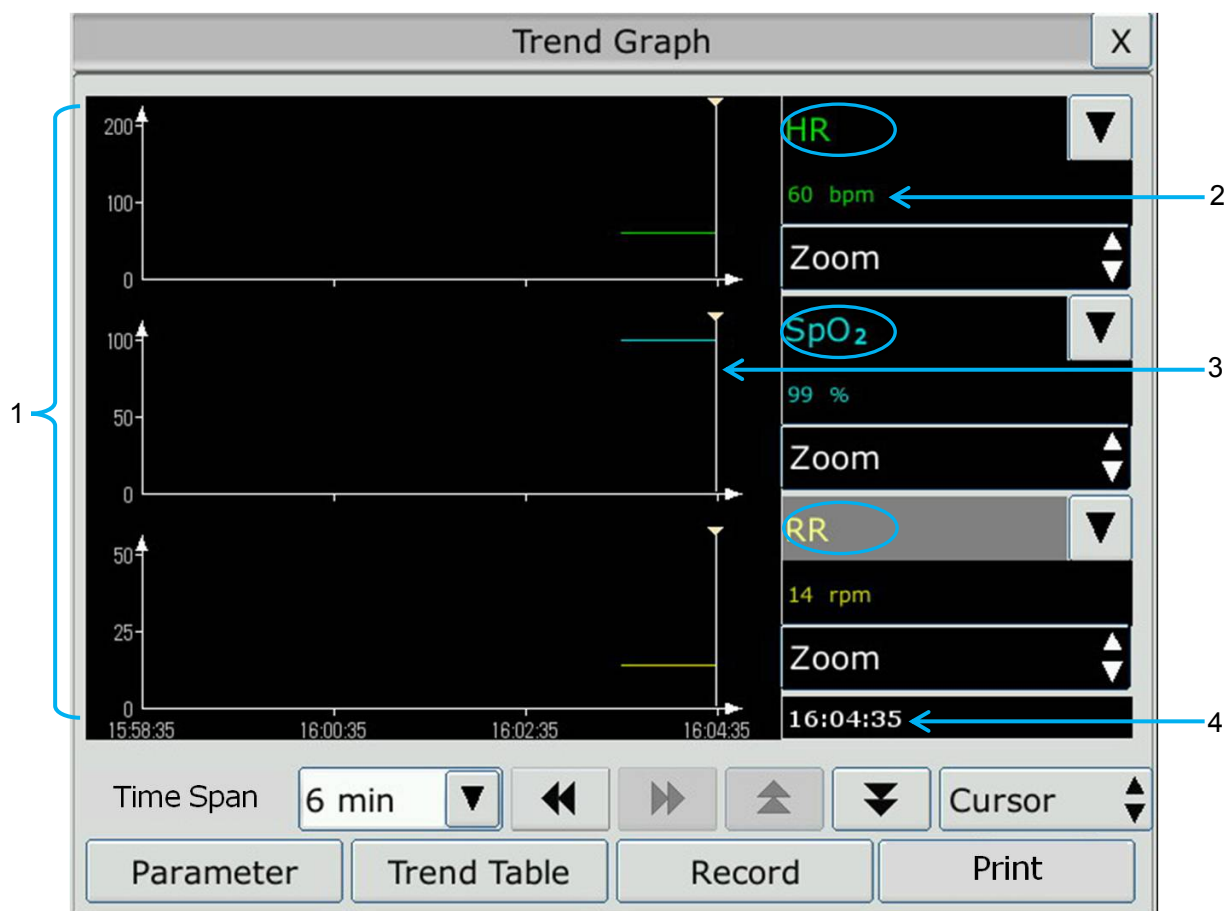
Chapter 21 Review

The monitor provides 120-hour trend data of all parameters, storage of 1200 NIBP measurement results, 200 alarm events, 200 arrhythmia events, 24 hours OxyCRG and 50 sets of 12-lead analysis results. This chapter gives detailed instruction for review of all data.

21.1 Trend Graph Review

To review the trend graph, please press the **Trend Graph** key  on the screen or select **Menu > Review > Trend Graph**.







In the trend graph, the y-axis stands for the measurement value and x-axis stands for the time. With the exception of NIBP, other trends are displayed as continuous curves.



- 1 Trend curve area
- 2 Trend data: displays measurement values at the cursor indicated time.
- 3 Cursor
- 4 Cursor time

In the trend graph review window:





- Select **Parameter** and you can choose the required parameters to be displayed in the trend graph.

- To display a different parameter's trend, you can either:
 - ◆ Select  beside the parameter name and choose the desired parameter from the pop-up list (as shown in red circle above).
 - ◆ Press the symbols  and  to switch parameters in batch.
- Select **Zoom** to adjust the trend scale. Once the trend scale on the trend graph review interface is adjusted, the trend scale of the corresponding parameter in **TrendScreen** of the main interface will also change.
- Select **Time Span** to change the length of trend data displayed on the current screen. **6 min**, **12 min**, **30 min**, **1 h**, **2 h**, **4 h**, **6 h**, **12 h**, **24 h**, **36 h** and **48 h** are optional.
- Select  beside **Cursor** to move the cursor left or right.
- Select  and  to scroll the screen left and right manually to browse the trend graph.
- Select **Trend Table** to switch to the trend table interface.
- Select **Record** to print out the currently displayed trends by the recorder.
- Select **Print** to print out the trend graph report by the printer.

21.2 Trend Table Review

To review the trend table, please press the **Trend Table** key  on the screen or select **Menu > Review > Trend Table**.


In the trend table review window:

- Select **Parameter** and you can choose the required parameters to be displayed in the trend table.
- Select **Interval** to change the interval of the trend data. **1 s**, **5 s**, **30 s**, **1 min**, **3 min**, **5 min**, **10 min**, **15 min**, **30 min**, **60 min** and **NIBP** are optional. Select **NIBP** to view the trend data according to the NIBP measurement time.
- Select , ,  and  to scroll the screen manually to browse the trend table.
- Select **Trend Graph** to switch to the trend graph interface.
- Select **Record** to print out the currently displayed trends by the recorder.
- Select **Record All** to enter the setup menu. Click **Record All** after setting **Start Time** and **End Time**, then all the trends for that period will be printed out by the recorder.
- Select **Print** to print out the trend table report by the printer.



NOTE:

When the interval is selected as **3 min**, **5 min**, **10 min**, **15 min**, **30 min** or **60 min**, the latest measurement values are displayed in the right of the trend table.

21.3 NIBP Review

To review the NIBP measurement data, please press the **NIBP Review** key  on the screen or select **Menu > Review > NIBP Review**.



In the NIBP review window:

- Select **Unit** to change the pressure unit.
- Select  and  to browse more NIBP measurement data.
- Select **Record** to print out the NIBP measurement data by the recorder.
- Select **Print** to print out the NIBP review report by the printer.

21.4 Alarm Review

To review the alarm event, please press the **Alarm Review** key  on the screen or select **Menu > Review > Alarm Review**.


In the alarm review window:



- Select **Event Type** to choose the required parameter from the popup list and the user can review alarm event of the specific parameters.
- Select **Time Index** to set end time of alarm review.
 - ◆ **Current Time**: the alarm events occurring before the current time are displayed on the alarm event review interface.
 - ◆ **User Define**: the user can define the review time by setting time box displayed on the interface. The alarm events occurring before the **User Define** option are displayed on the alarm event review interface.
- Select  and  to browse more alarm events.
- Select **Record** to print out the alarm events by the recorder.
- Select **Print** to print out the alarm event report by the printer.

NOTE:

The monitor can store a maximum of 200 alarm events. As soon as the alarm event storage is full, the earliest alarm event will be replaced by the latest one.

21.5 ARR Review

To review the ARR alarm event, please press the **ARR Review** key  on the screen or select **ECG Setup > ARR Analysis > ARR Review** or **Menu > Review > ARR Review**.

In the ARR review window, the latest arrhythmia events are displayed. Select  and  to


browse more ARR alarm events. You may select an alarm event and access the alarm review interface to get more information. On the alarm review interface, you can:

- ◆ Right or left shift the waveform to review the complete 8-second waveform.
- ◆ Select **Record** and output the arrhythmia waveform by the recorder.
- ◆ According to the actual clinical needs, select another name from the pull-down list of **Rename** for the arrhythmia event. Confirm the changes to make the settings take effect.
- ◆ Select **Delete** to remove a specific arrhythmia event.
- ◆ Select **Alarm List** or exit to get back to the arrhythmia review interface.



NOTE:

- 1 If there are more than 200 arrhythmia events, the monitor will only keep the recent ones.
- 2 The name of arrhythmia event will be shown on the alarm status area.
- 3 The renaming is only available for the ARR alarm event of the current patient, not for that of the history patient.

21.6 12-lead Analysis Review

To review the 12-lead analysis result, please press the **Analysis Review** key  on the screen or select **Menu > Review > Analysis Review**.

In the 12-lead analysis review window:

- The user can switch between results and waveforms. Select **Waveform** to review the analysis waveforms and **Result** to review the analysis results.
- Select **Delete** to delete the analysis results displayed on the current screen.
- Select  and  to browse more analysis results or waveforms.
- Select **Record** to print out the analysis results by the recorder.
- Select **Print** to print out the analysis report by the printer.

21.7 ST Segment Review

To review the ST segment, please press the **ECG Setup > ST Analysis > ST Segment Review**.

In the ST segment review window,

- The user can select the lead waveform that want to review.
- The user can select the ST segment to review. There are 20 groups of segments at the most, user can review one ST segment, and can also review all overlapped ST segments.
- The color of ST waveform is consistent with the color of ECG. When only one ST segment is reviewed, this segment is highlighted, the ST value and saved time of the ST Segment is displayed, at the same time, the color of other segments becomes dark.

Chapter 22 Calculation

The monitor provides calculation and record function and titration table. Calculations are patient data that are not directly measured but calculated by the monitor.

The monitor can perform drug calculation, hemodynamic calculation, oxygenation calculation, ventilation calculation and renal function calculation, and also support record function.

NOTE:

- 1 The drug calculation function acts only as a calculator. The patient weights in Drug Dose menu and in Patient Information menu are independent of each other. Therefore changing the Weight in Drug Dose menu will not change the weight in the Patient Information menu.
- 2 The calculation results are for reference only and the calculation significance must be determined by the physician.

WARNING

The correctness of the input parameters and the suitability of the calculated results should be carefully verified. EDAN is not liable for any consequences arising from input or operation errors.

22.1 Drug Calculation

22.1.1 Calculation Procedures

1. The drug calculation window is displayed by selecting **Menu > Common Function > Calculation > Drug Dose**.
2. Select the right pull-down box of the **Drug** option and select the required drug name among the 15 drugs which are listed as follows. And the drug name of **Drug A, Drug B, Drug C, Drug D** and **Drug E** can be defined by the user.
 - Drug A, Drug B, Drug C, Drug D and Drug E
 - Aminophylline
 - Dobutamine
 - Dopamine
 - Epinephrine
 - Heparin
 - Isuprel
 - Lidocaine
 - Nipride
 - Nitroglycerin
 - Pitocin

3. The system generates values that can't be treated the calculation results. The user must enter the correct parameter value based on the doctor's instruction.
4. Manually enter the value of patient weight or directly obtain the value from the monitor by selecting **Get Info**.
5. Enter the correct parameter value.
6. Confirm whether the calculation result is correct.

The following formulas are applied to dose calculation:

$$\text{Concentration} = \text{Amount} / \text{Volume}$$

$$\text{Inf. Rate} = \text{Dose} / \text{Concentration}$$

$$\text{Duration} = \text{Amount} / \text{Dose}$$

$$\text{Dose} = \text{Inf. Rate} \times \text{Concentration}$$

$$\text{Dose (weight based)} = \text{Inf. Rate} \times \text{Concentration} / \text{Weight}$$

$$\text{Drip Rate} = \text{Inf. Rate} / 60 \times \text{Drop Factor}$$

22.1.2 Calculation Unit

Each drug has the fixed unit or unit series to calculate. Among the same unit series, the unit binary varies with the entered parameter value.

The calculation units of the drugs are listed as follows:

Drug	Unit
Drug A, Drug B, Drug C, Aminophylline, Dobutamine, Dopamine, Epinephrine, Isuprel, Lidocaine, Nipride, Nitroglycerin	g, mg, mcg
Drug D, Pitocin, Heparin	Ku, mu, Unit
Drug E	mEq

When defining a drug, select Drug A, Drug B, Drug C, Drug D, and Drug E based on the unit series.

NOTE:

- 1 The drug calculation is displayed as invalid value before the user edits the drug name and patient weight, and the user can't enter any value.
- 2 Drip Rate and Drop Factor are invalid in the neonatal mode.

22.1.3 Titration Table



After completing the drug calculation, the user can open the **Titration** on the **Drug Dose** interface.

The user can change the following items in the titration table:

- Basic
- Step

- Dose Type

The data in the titration table will vary with the changes above. And the user can perform the following:

- Select  and  to observe more data.
- Record the data displayed in the current window by selecting **Record**.

22.2 Hemodynamic Calculation

22.2.1 Calculation Procedure

1. The hemodynamic calculation interface is displayed by selecting **Menu > Common Function > Calculation > Hemodynamics**.
2. Manually enter the values required on this interface. You can also directly obtain the values of HR, C.O., PA MAP, CVP, and PAWP if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

22.2.2 Input Parameters

Items	Unit	English Full Name/Description
PAWP	mmHg	Pulmonary artery wedge pressure
CVP	mmHg	Central venous pressure
C.O.	L/min	Cardiac output
HR	bpm	Heart rate
EDV	ml	End-diastolic volume
AP MAP	mmHg	Mean Artery Pressure
PA MAP	mmHg	Pulmonary artery mean pressure
Height	cm	/
Weight	kg	/

22.2.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
CI	L/min/m ²	Cardiac index	$CI (L/min/m^2) = C.O. (L/min)/BSA (m^2)$
BSA	m ²	Body surface area	$BSA (m^2) = Weight^{0.425} (kg) \times Height^{0.725} (cm) \times 0.007184$
SV	ml	Stroke volume	$SV (ml) = C.O. (L/min)/HR (bpm) \times 1000$
SVI	ml/m ²	Stroke volume index	$SVI (ml/m^2) = SV (ml)/BSA (m^2)$

Items	Unit	English Full Name/Description	Formula
SVR	DS/cm ⁵	Systemic vascular resistance	$SVR (DS/cm^5) = 80 \times [AP \text{ MAP (mmHg)} - CVP (mmHg)] / C.O. (L/min)$
SVRI	DS·m ² /cm ⁵	Systemic vascular resistance index	$SVRI (DS \cdot m^2/cm^5) = SVR (DS/cm^5) \times BSA (m^2)$
PVR	DS/cm ⁵	Pulmonary vascular resistance	$PVR (DS/cm^5) = 80 \times [PA \text{ MAP (mmHg)} - PAWP (mmHg)] / C.O. (L/min)$
PVRI	DS·m ² /cm ⁵	Pulmonary vascular resistance index	$PVRI (DS \cdot m^2/cm^5) = PVR (DS/cm^5) \times BSA (m^2)$
LCW	kg·m	Left cardiac work	$LCW (kg \cdot m) = 0.0136 \times [AP \text{ MAP (mmHg)} - PAWP (mmHg)] \times C.O. (L/min)$
LCWI	kg·m/m ²	Left cardiac work index	$LCWI (kg \cdot m/m^2) = LCW (kg \cdot m) / BSA (m^2)$
RCW	kg·m	Right cardiac work	$RCW (kg \cdot m) = 0.0136 \times [PA \text{ MAP (mmHg)} - CVP (mmHg)] \times C.O. (L/min)$
RCWI	kg·m/m ²	Right cardiac work index	$RCWI (kg \cdot m/m^2) = RCW (kg \cdot m) / BSA (m^2)$
LVSW	g·m	Left ventricular stroke work	$LVSW (g \cdot m) = 0.0136 \times [AP \text{ MAP (mmHg)} - PAWP (mmHg)] \times SV (ml)$
LVSWI	g·m/m ²	Left ventricular stroke work index	$LVSWI (g \cdot m/m^2) = LVSW (g \cdot m) / BSA (m^2)$
RVSW	g·m	Right ventricular stroke work	$RVSW (g \cdot m) = 0.0136 \times [PA \text{ MAP (mmHg)} - CVP (mmHg)] \times SV (ml)$
RVSWI	g·m/m ²	Right ventricular stroke work index	$RVSWI (g \cdot m/m^2) = RVSW (g \cdot m) / BSA (m^2)$
EF	%	Ejection fraction	$EF (\%) = SV (ml) / EDV (ml) \times 100$

22.3 Oxygenation Calculation

22.3.1 Calculation Procedure

1. Select **Menu > Common Function > Calculation > Oxygenation**.
2. Manually enter the values required on this interface. You can also directly obtain the values of patient height, patient weight, C.O. and FiO₂ if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

22.3.2 Input Parameters

Items	Unit	English Full Name/Description
FiO ₂	%	Percentage fraction of inspired oxygen
PaO ₂	mmHg	Partial pressure of oxygen in the arteries
PaCO ₂	mmHg	Partial pressure of carbon dioxide in the arteries
SaO ₂	%	Arterial oxygen saturation
PvO ₂	mmHg	Partial pressure of oxygen in venous blood
SvO ₂	%	Venous oxygen saturation
Hb	g/L	Hemoglobin
RQ	/	Respiratory quotient
ATMP	mmHg	Atmospheric pressure
C.O.	L/min	Cardiac output
Height	cm	/
Weight	kg	/

22.3.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
BSA	m ²	Body surface area	$BSA (m^2) = Weight^{0.425} (kg) \times Height^{0.725} (cm) \times 0.007184$
VO ₂	ml/min	Oxygen consumption	$VO_2 (ml/min) = Ca-vO_2 (ml/L) \times C.O. (L/min)$
Ca-vO ₂	ml/L	Arteriovenous oxygen content difference	$Ca-vO_2 (ml/L) = CaO_2 (ml/L) - CvO_2 (ml/L)$
O ₂ ER	%	Oxygen extraction ratio	$O_2ER (\%) = VO_2 (ml/min)/DO_2 (ml/min) \times 100$
DO ₂	ml/min	Oxygen transport	$DO_2 (ml/min) = CaO_2 (ml/L) \times C.O. (L/min)$
PAO ₂	mmHg	Partial pressure of oxygen in the alveoli	$PAO_2 (mmHg) = [ATMP (mmHg) - 47 mmHg] \times FiO_2 (\%)/100 - PaCO_2 (mmHg) \times [FiO_2 (\%)/100 + (1 - FiO_2 (\%)/100)/RQ]$
AaDO ₂	mmHg	Alveolar-arterial oxygen difference	$AaDO_2 (mmHg) = PAO_2 (mmHg) - PaO_2 (mmHg)$
CcO ₂	ml/L	Capillary oxygen content	$CcO_2 (ml/L) = Hb (g/L) \times 1.34 + 0.031 \times PAO_2 (mmHg)$
Qs/Qt	%	Venous admixture	$Qs/Qt (\%) = [CcO_2 (ml/L) - CaO_2 (ml/L)]/[CcO_2 (ml/L) - CvO_2 (ml/L)] \times 100$

Items	Unit	English Full Name/Description	Formula
AaDO ₂ /PaO ₂	/	AaDO ₂ /PaO ₂	$AaDO_2/PaO_2 = [PAO_2 \text{ (mmHg)} - PaO_2 \text{ (mmHg)}]/PaO_2 \text{ (mmHg)}$
DO ₂ I	ml/min/m ²	Oxygen delivery index	$DO_2I \text{ (ml/min/m}^2\text{)} = DO_2 \text{ (ml/min)}/BSA \text{ (m}^2\text{)}$
VO ₂ I	ml/min/m ²	Oxygen consumption index	$VO_2I \text{ (ml/min/m}^2\text{)} = VO_2 \text{ (ml/min)}/BSA \text{ (m}^2\text{)}$
CaO ₂	ml/L	Arterial oxygen content	$CaO_2 \text{ (ml/L)} = 100 \times 1.34 \times Hb \text{ (g/L)} \times SaO_2 \text{ (\%)} / 100 + 0.031 \times PaO_2 \text{ (mmHg)}$
CvO ₂	ml/L	Venous oxygen content	$CvO_2 \text{ (ml/L)} = 100 \times 1.34 \times Hb \text{ (g/L)} \times SvO_2 \text{ (\%)} / 100 + 0.031 \times PvO_2 \text{ (mmHg)}$

22.4 Ventilation Calculation

22.4.1 Calculation Procedure

1. Select **Menu > Common Function > Calculation > Ventilation**.
2. Manually enter the values required on this interface. You can also directly obtain the values of FiO₂, RR, PIP and PEEP if they are available from the monitor by selecting **Get Info**.
3. Select **Calculate** to output parameter value.

22.4.2 Input Parameters

Items	Unit	English Full Name/Description
FiO ₂	%	Percentage fraction of inspired oxygen
RR	rpm	Respiration rate
VT	ml	Tidal volume
PaCO ₂	mmHg	Partial pressure of carbon dioxide in the arteries
PaO ₂	mmHg	Partial pressure of oxygen in the arteries
RQ	/	Respiratory quotient
PeCO ₂	mmHg	Partial pressure of mixed expiratory CO ₂
ATMP	mmHg	Atmospheric pressure

22.4.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
PAO ₂	mmHg	Partial pressure of oxygen in the alveoli	$PAO_2 \text{ (mmHg)} = [ATMP \text{ (mmHg)} - 47 \text{ mmHg}] \times FiO_2 \text{ (\%)} / 100 - PaCO_2 \text{ (mmHg)} \times [FiO_2 \text{ (\%)} / 100 + (1 - FiO_2 \text{ (\%)} / 100) / RQ]$

Items	Unit	English Full Name/Description	Formula
AaDO ₂	mmHg	Alveolar-arterial oxygen difference	$AaDO_2 \text{ (mmHg)} = PAO_2 \text{ (mmHg)} - PaO_2 \text{ (mmHg)}$
AaDO ₂ /PaO ₂	/	AaDO ₂ /PaO ₂	$AaDO_2/PaO_2 = [PAO_2 \text{ (mmHg)} - PaO_2 \text{ (mmHg)}] / PaO_2 \text{ (mmHg)}$
MV	L/min	Minute volume	$MV \text{ (L/min)} = VT \text{ (ml)} \times RR \text{ (rpm)} / 1000$
VD	ml	Volume of physiological dead space	$VD \text{ (ml)} = [(PaCO_2 \text{ (mmHg)} - PeCO_2 \text{ (mmHg)}) \times VT \text{ (ml)}] / PaCO_2 \text{ (mmHg)}$
VD/VT	%	Physiological dead space in percent of tidal volume	$VD/VT \text{ (%) } = [PaCO_2 \text{ (mmHg)} - PeCO_2 \text{ (mmHg)}] / PaCO_2 \text{ (mmHg)} \times 100$
VA	L/min	Alveolar volume	$VA \text{ (L/min)} = [VT \text{ (ml)} - VD \text{ (ml)}] \times RR \text{ (rpm)} / 1000$

22.5 Renal Function Calculation

22.5.1 Calculation Procedure

1. Select **Menu > Common Function > Calculation > Renal Function**.
2. Manually enter the values required on this interface.
3. Select **Calculate** to output parameter value.

22.5.2 Input Parameters

Items	Unit	English Full Name/Description
URK	mmol/L	Urine potassium
URNa	mmol/L	Urinary sodium
Urine	ml/24h	Urine
Posm	mOsm/kgH ₂ O	Plasm osmolality
Uosm	mOsm/kgH ₂ O	Urine osmolality
SerNa	mmol/L	Serum sodium
SCr	umol/L	Serum creatinine
UCr	umol/L	Urine creatinine
BUN	mmol/L	Blood urea nitrogen
UUN	mmol/L	Urine urea nitrogen

22.5.3 Output Parameters

Items	Unit	English Full Name/Description	Formula
URNaEx	mmol/24h	Urine sodium excretion	$URNaEx \text{ (mmol/24h)} = URNa \text{ (mmol/L)} \times \text{Urine (ml/24h)}/1000$
URKEx	mmol/24h	Urine potassium excretion	$URKEx \text{ (mmol/24h)} = URK \text{ (mmol/L)} \times \text{Urine (ml/24h)}/1000$
Na/K	%	Sodium potassium ratio	$Na/K \text{ (%) } = URNa \text{ (mmol/L)}/URK \text{ (mmol/L)} \times 100$
CNa	ml/24h	Clearance of sodium	$CNa \text{ (ml/24h)} = URNa \text{ (mmol/L)} \times \text{Urine (ml/24h)}/SerNa \text{ (mmol/L)}$
CCr	ml/min	Creatinine clearance rate	$CCr \text{ (ml/min)} = UCr \text{ (}\mu\text{mol/L)} \times \text{Urine (ml/24h)}/[SCr \text{ (}\mu\text{mol/L)} \times 24 \times 60]$
CUUN	ml/min	Urine urea nitrogen clearance rate	$CUUN \text{ (ml/min)} = UUN \text{ (mmol/L)} \times \text{Urine (ml/24h)}/[BUN \text{ (mmol/L)} \times 24 \times 60]$
FENa	%	Fractional excretion of sodium	$FENa \text{ (%) } = [URNa \text{ (mmol/L)} \times SCr \text{ (}\mu\text{mol/L)}]/[UCr \text{ (}\mu\text{mol/L)} \times SerNa \text{ (mmol/L)}] \times 100$
FEUr	%	Fractional Excretion of Urea	$FEUr \text{ (%) } = [SCr \text{ (}\mu\text{mol/L)} \times UUN \text{ (mmol/L)}]/[UCr \text{ (}\mu\text{mol/L)} \times BUN \text{ (mmol/L)}] \times 100$
Cosm	ml/min	Osmolar clearance	$Cosm \text{ (ml/min)} = [Uosm \text{ (mOsm/kgH}_2\text{O)} \times \text{Urine (ml/24h)}]/[Posm \text{ (mOsm/kgH}_2\text{O)} \times 24 \times 60]$
CH ₂ O	ml/24h	Free water clearance	$CH_2O \text{ (ml/24h)} = \text{Urine (ml/24h)} - Uosm \text{ (mOsm/kgH}_2\text{O)} \times \text{Urine (ml/24h)}/Posm \text{ (mOsm/kgH}_2\text{O)}$
U/Posm	/	Urine to plasma osmolality ratio	$U/Posm = Uosm \text{ (mOsm/kgH}_2\text{O)}/Posm \text{ (mOsm/kgH}_2\text{O)}$
BUN/SCr	/	Blood urea nitrogen creatinine ratio	$BUN/SCr = [BUN \text{ (mmol/L)}/SCr \text{ (}\mu\text{mol/L)}] \times 1000$
U/SCr	/	Urine-serum creatinine ratio	$U/SCr = UCr \text{ (}\mu\text{mol/L)}/SCr \text{ (}\mu\text{mol/L)}$

Chapter 23 Warning-Score System

User can use warning-score system to get an early warning score based on measurement value or input value of each vital sign. Warning-score system includes NEWS (National Early Warning Score System) and MEWS (Modified Early Warning Score) system.

NOTE:

- 1 The score results are for reference only and the score significance must be determined by the physician.
- 2 MEWS and NEWS are applicable to adults only.

23.1 Warning-Score Interface

The interface includes NEWS and MEWS sub-interface.

To enter the interface: 1. By shortcut key. Click **Menu > Maintenance > User Maintain > Shortcut Setup** to select **Score**. Then click **Score** shortcut key to enter; 2. By menu. Click **Menu > Common Function > Score** to enter.

To exit the interface: 1. By shortcut key. Click **Score** shortcut key to exit; 2. By menu. Click X button on the top right of the interface.

Before exiting interface, if selected **Method** is score calculator, the monitor can exit not only this interface, but also this function; if selected **Method** is auto score, the monitor can only exit this interface instead of this function.

The above rule is also applicable to the switchover between sub-interface. (e.g., if selected **Method** is auto score, sub-interface is switched over from MEWS to NEWS, however, MEWS function is still in working.)

NOTE:

Operations, including power-off, updating patient and entering standby or Demo mode, will stop current warning-score, and also monitor will exit this function.

23.2 Warning-Score Method

Warning-Score method includes score calculator (default) and auto score. If score calculator is selected, user needs to input **HR/PR, TEMP, RR, SYS, SpO₂, Oxygen, Age** and **Consciousness** manually, if auto score is selected, user only needs to input **Consciousness** manually, **HR/PR, TEMP, SYS, RR** and other value will be obtained automatically, and then click **Start to Score**. The monitor will calculate and display score result.

NOTE:

If any of above information is not completely input, the monitor will prompt information: **Incomplete parameter input, unable to score**.

23.3 Warning-Score Criteria

In NEWS interface, select **Criteria** to check score criteria as following:

Value							
	3	2	1	0	1	2	3
RESP (rpm)	≤8		9~11	12~20		21~24	≥25
SpO ₂ (%)	≤91	92~93	94~95	≥96			
TEMP (°C)	≤35.0		35.1~36.0	36.1~38.0	38.1~39.0	≥39.1	
SYS (mmHg)	≤90	91~100	101~110	111~219			≥220
HR (bpm)	≤40		41~50	51~90	91~110	111~130	≥131
Consciousness				A			V/P/U
Oxygen		Yes		No			

In MEWS interface, select Criteria to check score criteria as following:

Value							
	3	2	1	0	1	2	3
HR (bpm)		<40	41~50	51~100	101~110	111~129	≥130
SYS (mmhg)	<70	71~80	81~100	101~199		≥200	
RESP (rpm)		<9		9~14	15~20	21~29	≥30
TEMP (°C)		<35.0		35.0~38.4		≥38.5	
Consciousness				A	V	P	U

Note: (1) HR=40, value is 2; (2) SYS=70, value is 3.

The relationship between consciousness level and its display result is as below:

Consciousness	Displayed Result
Sober	A
Responsive to Voice	V
Responsive to Pain	P
Unresponsive	U

23.4 Warning-Score Result

Warning-Score results include parameter value, score value, time and severity level. The relation for value and severity level is as following:

NEWS	Severity Level	Color
NEWS=0	Non-urgent	Green
1<NEWS<4	Observing	Yellow
5<NEWS<6	Warning	Amber
One single parameter's score value=3 points		
NEWS≥7	Critical	Red

MEWS	Severity Level	Color
0	Non-urgent	Green
1≤MEWS≤3	Observing	Yellow
4≤MEWS≤6	Warning	Amber
One single parameter's score value=3 points		
MEWS>7	Critical	Red

NOTE:

The score result can be displayed on the main screen through ticking the **Display on Main Screen** in **Score** Interface.

23.5 Warning-Score Trend Table

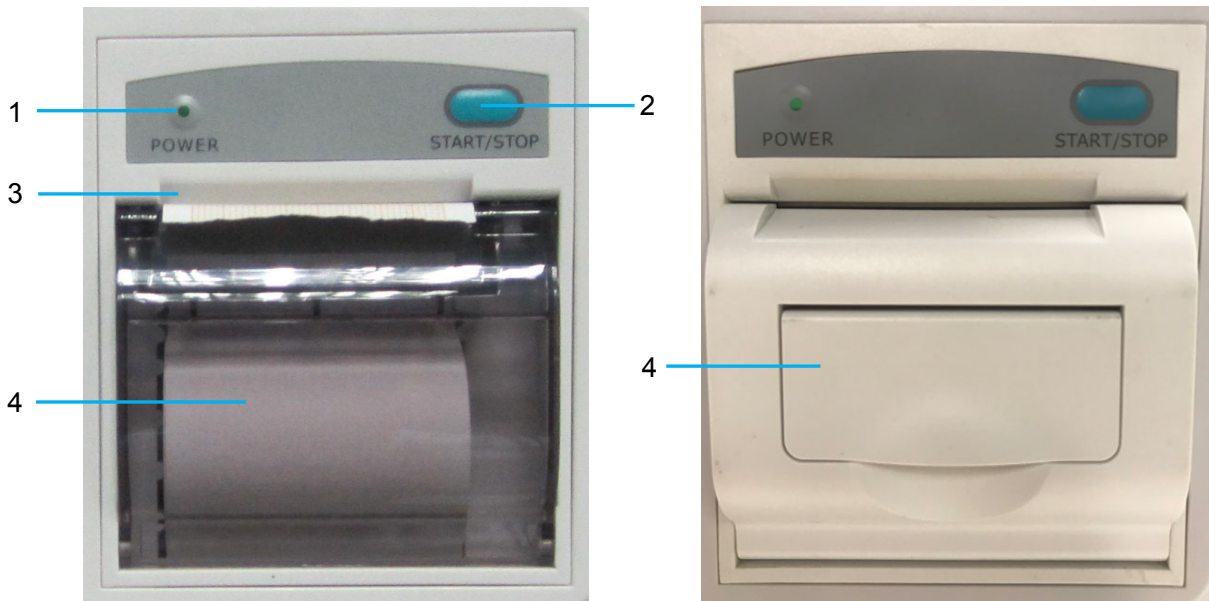
Trend table provides the monitored patient's scores during a period of time; it includes score time, score parameters and value, score. To check the trend table, click **Trend Table** button in Warning-Score interface. NEWS and MEWS can respectively support 1200 groups of trend review at least.

NOTE:

Trend table is cleared after admitting new patients, entering or exiting Demo mode.

Chapter 24 Recording

A thermal dot matrix recorder is used for the monitor and can support many recording types and output patient information, measurement data, review data waveform and so forth.



1	Recording indicator
2	Paper feeding key: press this key to start or stop feeding recording paper without outputting anything on the paper
3	Paper outlet
4	Recorder door

NOTE:

If the blank recording paper is insufficient after recording is stopped, the user can press the paper feeding key on the recorder to feed more paper.

24.1 Performance of the Recorder



- Waveform record is printed at the rate of 12.5 mm/s, 25 mm/s or 50 mm/s.
- 48 mm record width and 50 mm record paper width.
- It can record up to three waveforms.
- User-selectable real-time recording time and waveform.
- Auto recording interval is set by the user, and the waveform is in accordance with the real time recording.

NOTE:

It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

24.2 Starting and Stopping Recording

The monitor provides several types of stripe recording. You can start recording following the procedure below:

Recording Type	Description/ Procedure
Continual real-time recording	Select at least one Rec waveform in Recorder Setup (A maximum of three waveforms can be selected), select Continual in R-T Rec Time . Press the Record button on the front panel or select shortcut key  to start the recording. Press the button again to stop recording.
8-second real-time recording/20-second real-time recording	Select at least one Rec waveform in Recorder Setup (A maximum of three waveforms can be selected), select 8 s or 20 s in R-T Rec Time , set Record Interval as needed, press the Record button on the front panel or select shortcut key  to start the recording. Press the button again to stop recording or when R-T Rec time ends, the monitor stops recording automatically. The runtime for each wave is 8 seconds or 20 seconds. The record Interval can be set as: Off, 10 min, 20 min, 30 min, 40 min, 50 min, 1 h, 2 h, 3 h, 4 h . The default recording time is 8 s .
Trend graph recording	Select Menu > Review > Trend Graph , click Record to start recording.
Trend table recording	Select Menu > Review > Trend Table , click Record to start recording.
NIBP review recording	Select Menu > Review > NIBP Review , click Record to start recording.
Arrhythmia review recording	Select Menu > Review > ARR Review , select one arrhythmia alarm and click Record to start recording.
Alarm review recording	Select Menu > Review > Alarm Review , select one alarm and click Record to start recording.
Drug calculation titration recording	Select Menu > Common Function > Calculation > Drug Dose > Titration , click Record to start recording.
Hemodynamic Calculation result recording	Select Menu > Common Function > Calculation > Hemodynamics , click Record to start recording.
Oxygenation Calculation result recording	Select Menu > Common Function > Calculation > Oxygenation , click Record to start recording.



Recording Type	Description/ Procedure
Ventilation Calculation result recording	Select Menu > Common Function Calculation > Ventilation , click Record to start recording.
Renal Function Calculation result recording	Select Menu > Common Function > Calculation > Renal Function , click Record to start recording.
12-lead analysis recording	Select ECG Setup > 12-L Review , click Record to start recording.
C.O. measurement recording	Select C.O. Option > C.O. Measure , click Record to start recording.
Frozen waveform recording	In the Freeze window, click Record to start recording.
ST View recording	In the ST View window, click Record to start recording.
QT View recording	In the QT View window, click Record to start recording.

To manually stop recording, click **Record** again in the related windows.

The recorder will stop recording in the following situations:

- The recording task is finished.
- No paper in the recorder.
- Malfunction stops the recorder from running properly.
- The monitor enters into standby mode.

NOTE:

- 1 You can also use the button  on the front panel or select shortcut key  to manually start or stop recording.
- 2 For waveforms with sweep of 6.25 mm/s, after entering freeze status, the recording speed will automatically be adjusted to 12.5 mm/s. Users can modify the recording speed according to their actual needs. The options are 12.5 mm/s, 25 mm/s and 50 mm/s.
- 3 In DEMO mode, the waveform amplitude does not change with the adjustment of gain in CO₂ and IBP real-time recording.

24.3 Recorder Operations and Status Messages

24.3.1 Record Paper Requirement

Only standard thermosensitive record paper can be used: otherwise the recorder may not function, the recording quality may be poor, and the thermosensitive print head may be damaged.

24.3.2 Proper Operation

- When the recorder is working, the record paper goes out steadily. Do not pull the paper outward with force: otherwise the recorder may be damaged.
- Do not operate the recorder without record paper.

24.3.3 Paper Out

When the **Recorder Out OF Paper** alarm is displayed, the recorder cannot start. Please insert record paper properly.

24.3.4 Replacing Paper

1. Pull outwards the upper arc part of the recorder casing to release the casing, shown in the following figure.



2. Insert a new roll of paper into the paper cassette, printing side facing upwards.
3. Ensure proper position and tidy margin.
4. Pull about 2 cm of the paper out, and close the recorder casing.

NOTE:

Be careful when inserting papers. Avoid damaging the thermo-sensitive print head. Unless when inserting papers or shooting troubles, do not leave the recorder catch open.

24.3.5 Removing Paper Jam

When the recorder functions or sounds improperly, you should open the recorder casing to check for a paper jam. Remove the paper jam in the following way:

- Cut the record paper from the feeding edge.
- Open the recorder casing.
- Re-insert the paper.

NOTE:

- 1 If the monitor is not configured with the recorder function, it will indicate **Recorder**

Setup Needed after the **Record** button is pressed.

- 2 Do not touch the thermo-sensitive print head when performing continuous recording.


Chapter 25 Printing Patient Reports

Patient reports can be printed out by an HP series laser printer connected with the monitor.

NOTE:

Use the printer HP Laser Jet P2055dn, HP LaserJet Pro 400 M401n and HP LaserJet 600 M602, which are tested to be compatible with the monitor.

25.1 Printer Settings

You can configure the printer settings on the monitor before printing out patient reports. Click the shortcut key  or select **Menu > System Setup > Printer Setup**, and you can

- Assign a locally networked printer by selecting it from the **Printer** list.
- Search all available printers networked with the monitor by clicking **Search Printer**.
- Enable or disable double side printing by setting **DoubleSide Print** to **On** or **Off**.

The reports will be printed out on A4 paper and with single side by default.

NOTE:

- 1 You need to search all available printers on the local network for the first time you use a networked printer.
- 2 Make sure the IP of the printer and the IP of the monitor share the same network segment.
- 3 Do not click **Search Printer** during printing patient reports, or the printer might stop the current print job.
- 4 When a printer simultaneously received print jobs from several networked monitors, a print job conflict may occur. Check the use status of the monitors and the printers on the same network prior to use and avoid print job conflicts.
- 5 Make sure there is no lack of paper before printing patient reports, or the alarm **Printer Unavailable** will be triggered.

25.2 Starting and Stopping Report Printing

You can print out ten types of patient reports following the procedure below:

Report Type	Procedure
Trend graph report	In the Trend Graph window, click Print to start printing.
Trend table report	In the Trend Table window, click Print to start printing.
Alarm waveform report	In the Alarm Review window, click Print to start printing.
NIBP review report	In the NIBP Review window, click Print to start printing.
Arrhythmia review report	In the ARR Review window, click Print to start printing.

Report Type	Procedure
12-lead analysis report	In the Analysis Review window, click Print to start printing.
12-lead analysis waveform report	In the 12-Lead Analysis Waveform Review window, click Print to start printing.
Drug calculation titration report	In the Titration window, click Print to start printing.
Oxygenation calculation report	In the Oxygenation window, click Print to start printing.
Ventilation calculation report	In the Ventilation window, click Print to start printing.
Renal function calculation report	In the Renal Function window, click Print to start printing.
C.O. measurement report	In the C.O. Measure window, click Print to start printing.
Hemodynamics report	In the Hemodynamics window, click Print to start printing.
ST View	In the ST View window, click Print to start printing.
QT View	In the QT View window, click Print to start printing.

To stop the current print job, click **Stop Printing** in the windows mentioned above.

NOTE:

You can only start one print job at a time. Before starting a new print job, you have to stop the current print job or wait until the current print job is completed.

Chapter 26 Other Functions

26.1 Nurse Call

The monitor provides dedicated nurse call port which is connected to nurse call system through the nurse call cable to perform the nurse call function. You should activate the function following the steps below:

1. Select **Menu > Maintenance > User Maintain**, and input the password;
2. Select **Other Setups > Aux Output**;
3. Choose **On** in the **Nurse Call** list.

NOTE:

Before using nurse call function, please check whether it is functioning normally.

26.2 Analog Output and Defibrillator Synchronization

The monitor provides analog output signals to accessory equipment. Also, if a defibrillator is connected to the monitor, a defibrillator synchronization pulse can be output. You should activate the function following the steps below:

1. Select **Menu > Maintenance > User Maintain**, and input the password;
2. Select **Other Setups > Aux Output**;
3. Choose **Analog Output** or **Defibrillation** in the **Aux Output** list.

26.3 Storing Data in the Storage Device

26.3.1 Data Stored in the Storage Device

Refer to Section *Data Management* for more information about single patient data volume.

You can choose to **Keep Storing** or **Stop Storing** by selecting **Menu > Common Function > Data Store > if one patient data full**. When the single patient data reach the maximum, the monitor will keep storing or stop storing as selected.

If you choose **Keep Storing**, as soon as the single patient data is full, the earliest data will be replaced by the latest one. When the remaining storage space is less than 15 M, the earliest patient data in the storage space will be deleted in order to store the latest data.

If you choose **Stop Storing**, the monitor will stop data storing and the latest data cannot be stored when the single patient data reach the maximum. For instance, if all the patient data (such as the trend graph, trend table, NIBP measurements, arrhythmia event, alarm event and 12-lead analysis) except waveforms reach the maximum, the monitor will stop storing, while only the waveforms keep storing until they are full. When the remaining storage space is less than 10 M, the monitor will stop storing new data, prompting insufficient storage space. The default setting of **if one patient data full** is **Stop Storing**.

The monitor can detect the storage space threshold. Select **Menu > Common Function > Data Store** and set **Threshold Detection** to **On**. When the removable device is newly inserted and selected as storage device, and its remaining storage space is less than 300 M, the monitor will not store data, prompting **The space in U disk is less than 300 M. Please clean it up**. The user needs to clean up the space manually till the remaining space is more than 300 M, thus the monitor will keep storing data. When this removable device is read-only and its space is insufficient, the monitor only provides alarm of **Read-only storage device**.

NOTE:

- 1 The storage time varies according to the patient's parameter data volume. When the single patient data store reaches 240 hours, the monitor will automatically create a new folder for continuous data store. If you chose **Keep Storing**, when the storage space is insufficient, the earliest folder will be deleted and new folder will be created.
- 2 **Threshold Detection** is only applicable to the removable devices.
- 3 Without use of data store function, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.

26.3.2 Activating/ Deactivating Data Storing

To activate/ deactivate the data storing function, select **Menu > Maintenance > User Maintain > Other Setups**, and set **Data Store** to **On** or **Off**.



The monitor will stop storing data in the storage device under the following circumstances:

- No storage devices are selected.
- There is no enough space in the storage device for storing data.
- The removable device is read-only.
- The storage device is damaged.
- The data storing function is deactivated.
- The monitor is switched off.
- The power supply is off.

26.3.3 Selecting a Storage Device

To configure the storage device, select **Menu > Common Function > Data Store**. The initial default storage device is **Internal Storage**. When the monitor has no internal storage device, the storage device displays **null**.

When user switches the storage device from an internal device to a removable device or switches from one removable device to another removable device, the user password is required.

After you configure the appropriate storage device, click exit. If the storage device is successfully starting data storing, the monitor will be indicated by the symbol . If there is no enough space in storage device, or the storage device is read-only/damaged, the symbol  will be displayed.

CAUTION

- 1 Not all the removable devices are compatible with the monitor, Use the removable devices recommended by EDAN.
 - 2 Do not set the read-only switch on the removable device to on when the removable device is inserted in the monitor.
 - 3 It is recommended to format the USB flash drive to the FAT file type via PC prior to use.
-
-

26.3.4 Reviewing Data Stored in the Storage Device

To review data stored in the storage device, select **Menu > Review > History Patient**. You can choose to review the storage device as desired from the pop-up list. Choose a patient from the list to review the data including patient information, trend graph, trend table, NIBP measurements, arrhythmia event, alarm event, 12-lead analysis and waveform.

26.3.4.1 Reviewing Full Disclosure Waveform

Select **Menu > Review > History Patient > Full Wave**, to enter the full disclosure review interface. Select **Wave Setup** to set the desired waveform (Maximum: 1) to be displayed on the full disclosure review interface.

26.3.5 Deleting Data Stored in the Storage Device

To delete data of one patient, choose the patient from the list after selecting **Menu > Review > History Patient**, and then click **Delete data** on the **Review** menu. Further confirmation of deletion is required.

To delete data of all patients, select **Menu > Review > History Patient** and click **Delete all data** on the **History Patient Review** menu. Further confirmation is required.

26.3.6 Exporting Data Stored in the Internal Storage Device

To export data of one patient from the internal storage device to the removable device, choose the patient from the list after selecting **Menu > Review > History Patient**, and then click **Export Current Data** on the **Review** menu.

To export data of all patients, select **Menu > Review > History Patient** and click **Export all data** on the **History Patient Review** menu.

NOTE:

When you export data from the internal storage device, the user password is required, and there is a prompt message in the password inputting interface: **Please input user password first. Attention! Private information included in the data.** If password is correct, the data will be successfully exported into the selected removable device, otherwise, the data export fails, and the interface displays: **Password Error.**

26.3.7 Formatting the Internal Storage Device

To format the internal storage device, select **Menu > Maintenance > User Maintain > Other Setups > Format internal storage device**. Further confirmation is required. After Formatting, the monitor displays result including **Format Succeeded** or **Format Failed, Please Retry!**

NOTE:

- 1 As soon as the internal storage device is formatted, all the data will be cleared.
- 2 You have no need to restart the monitor after formatting is successful. The internal storage device can be identified and loaded automatically.
- 3 If formatting is failed, try again. Restart the monitor and retry the formatting, or contact the service personnel of the manufacturer if formatting is failed repeatedly.

26.3.8 Ejecting a Removable Device

Before unplugging a removable device from the monitor, you need to select **Menu > Removable Device** and click **Eject** to uninstall the removable device. In this menu, you can also check the remaining capacity of the storage device.

CAUTION

Do not remove the removable device without ejecting it during data storing, or the removable device might be damaged.

Chapter 27 Using Battery

This monitor can run on battery power, which ensures its uninterrupted operation even when AC power supply is interrupted. The battery recharges whenever the monitor is connected to the AC power source. During monitoring, if the AC power is interrupted, the monitor will take power from the internal battery. If the monitor is powered by battery, the monitor will switch off automatically before the battery is completely depleted.

27.1 Battery Safety Information

WARNING

- 1 Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.
 - 2 The service life of the battery depends on the service frequency and time. The service life of the battery is about three years if the battery is well maintained and stored. The service life of the battery may shorten if it is used inappropriately. If the battery life is exhausted and not replaced in time, it may cause damage or heat to the device.
 - 3 Periodic checks on the battery performance are required. Change the battery if necessary.
 - 4 Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal objects, which can result in short circuits.
 - 5 Do not unplug the battery when the monitor is working.
 - 6 Do not heat or throw the battery into a fire.
 - 7 Do not use, leave the battery close to fire or other places where temperature may be above 60°C.
 - 8 Do not immerse, throw, or wet the battery in water/seawater.
 - 9 Do not destroy the battery: do not pierce the battery with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the battery.
 - 10 The recommended battery can only be used for this monitor.
 - 11 Do not solder the leading wire and the battery terminal directly.
 - 12 If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the battery splash onto your skin or clothes, wash well with fresh water immediately.
 - 13 Keep away from fire immediately when leakage or foul odor is detected.
 - 14 Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.
 - 15 Do not use a battery with serious scratch or deformation.
-

WARNING








- 16 Use the battery with similar performance, which can extend the service life of the battery. If one of the two batteries is malfunctioning, it is recommended to change both of the two batteries.
 - 17 When the monitor is running on battery power, do not replace the battery during monitoring patients; or the monitor will be powered off, which may result in patient injury.
 - 18 Do not place battery in the monitor with the (+) and (-) in the wrong way.
-

27.2 Battery Power Indicator

The indicator labeled Battery on the front panel of the monitor illuminates in green when the monitor is battery powered and illuminates in yellow when battery is being charged. The indicator is not illuminated when the monitor is not powered or when AC power is applied.

27.3 Battery Status on the Main Screen

Battery status symbols show the status of each battery detected and the combined battery power remaining.

-  Remaining battery power: 76%~100%.
-  Remaining battery power: 51%~75%
-  Remaining battery power: 26%~50%
-  Remaining battery power: 4%~25%
-  Batteries are almost depleted and need to recharge immediately.
-  No battery is installed.
-  Battery malfunction

27.4 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

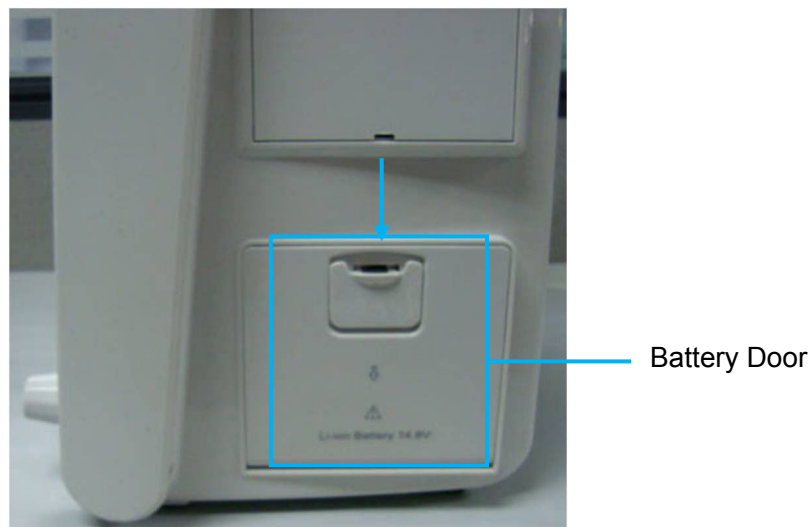
1. Disconnect the patient from the monitor and stop all monitoring and measurement.
2. Switch the monitor power on and fully charge the battery.

3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.
4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel. If the running time meets the specification, fully charge the battery again for use or charge it to 40%-60% for storage.

27.5 Replacing the Battery

To install or replace the battery, please follow the procedure:



1. Pull the battery door according to indication on it to open it.
2. Pull the plastic retainer until the battery can be removed.
3. Insert the new battery into the battery compartment.
4. Pull the metal retainer downward to fix the battery and close the battery door.

27.6 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

WARNING

Do not disassemble batteries, put them into fire or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

27.7 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time.

It is recommended to check and maintain the batteries regularly every 3-6 months if they are not

in use for a long time. And recharge the batteries to 40%-60% at a minimum of every 3-6 months when they are stored. Refer to the steps in section *Checking Battery Performance*. If the running time meets the specification, fully charge the battery again for use or charge it to 40%-60% for storage.

Chapter 28 Care and Cleaning

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

EDAN Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

28.1 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

28.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

28.2.1 Cleaning the Monitor

WARNING

Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Dry the monitor in a ventilated and cool place.

28.2.2 Cleaning the Reusable Accessories

28.2.2.1 Cleaning the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the cable assembly to air dry.

28.2.2.2 Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

1. Take out the air bladder before cleaning.
2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth.
5. Air dry the cuff thoroughly after cleaning.

Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.

2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.
3. Adjust the bladder until it is in position.

28.2.2.3 Cleaning the SpO₂ Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth.
5. Leave the sensor to air dry.

28.2.2.4 Cleaning the IBP/C.O. Cables

1. Wipe the cables with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the cables to air dry.

28.2.2.5 Cleaning the TEMP Sensor/Quick TEMP Probe

1. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the sensor/probe to air dry.

28.3 Disinfection

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)
- Cidex OPA (High level disinfection of intracavitary temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

CAUTION

- 1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
 - 2 Although the monitor is chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, different cleaners or disinfectants are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.
-
-

WARNING

The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

28.3.1 Disinfecting the Monitor

WARNING

Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

28.3.2 Disinfecting the Reusable Accessories

28.3.2.1 Disinfecting the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the cable assembly to air dry for at least 30 minutes.

28.3.2.2 Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

1. Take out the air bladder before disinfection.

2. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
3. Leave the cuff and air bladder to air dry for at least 30 minutes.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to Section *Cleaning the Blood Pressure Cuff* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

28.3.2.3 Disinfecting the SpO₂ Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth after disinfection.
4. Leave the sensor to air dry for at least 30 minutes.

28.3.2.4 Disinfecting the IBP/C.O. Cables

1. Wipe the cables with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the cables to air dry for at least 30 minutes.

28.3.2.5 Disinfecting the TEMP Sensor

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the sensor to air dry.

28.4 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

Chapter 29 Maintenance

WARNING

- 1 Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- 2 If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.
- 3 The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service professionals.
- 4 Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

29.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- If the recorder can work properly and the paper meets the requirement.
- Battery performance
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

29.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for EDAN-qualified service professionals only. Contact an EDAN-qualified service provider if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

Chapter 30 Warranty and Service

30.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) damage caused by alteration or repair by anyone not authorized by EDAN.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

30.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Chapter 31 Accessories

You can order accessories from EDAN supplies at www.edan.com.cn or consult your local EDAN representative for details.

WARNING

- 1 Never reuse disposable transducers, sensors, accessories and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance and cause a potential hazard.
- 2 Use only EDAN-approved accessories. Using non-EDAN-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by EDAN with patient monitors by other manufacturers.
- 3 IBP and C.O. sterilized accessories are already sterilized, refer to the package labeling for detailed method. Do not use a sterilized accessory if its packaging is damaged.

NOTE:

Transducers and sensors have a limited shelf life. Refer to the package labeling.

The following cables may not all be available in all countries. Please check availability with your local EDAN supplier.

31.1 ECG Accessories

Part Number	Accessories
01.57.471381	3-lead, 6-pin, Defib-proof, IEC, Clip
01.57.471382	3-lead, 6-pin, Defib-proof, AHA, Clip
01.57.471383	3-lead, 6-pin, Defib-proof, IEC, Snap
01.57.471384	3-lead, 6-pin, Defib-proof, AHA, Snap
01.57.471389	3-lead, 6-pin, ESU-proof, IEC, Clip
01.57.471390	3-lead, 6-pin, ESU-proof, AHA, Clip
01.57.471391	3-lead, 6-pin, ESU-proof, IEC, Snap
01.57.471392	3-lead, 6-pin, ESU-proof, AHA, Snap
01.57.471380	3-lead, 12-pin, Defib-proof, AHA, Snap
01.57.471388	3-lead, 12-pin, ESU-proof, AHA, Snap

Part Number	Accessories
01.57.471378	3-lead, 12-pin, Defib-proof, AHA, Clip
01.57.471386	3-lead, 12-pin, ESU-proof, AHA, Clip
01.57.471379	3-lead, 12-pin, Defib-proof, IEC, Snap
01.57.471387	3-lead, 12-pin, ESU-proof, IEC, Snap
01.57.471377	3-lead, 12-pin, Defib-proof, IEC, Clip
01.57.471385	3-lead, 12-pin, ESU-proof, IEC, Clip
01.57.471230	5-lead, 6-pin, ESU-proof, Adult/pediatric
01.57.471231	5-lead, 6-pin, ESU-proof, Adult/pediatric, Extended
01.57.471232	5-lead, 6-pin, Defib-proof, Adult/pediatric
01.57.471233	5-lead, 6-pin, Defib-proof, Adult/pediatric, Extended
01.57.471226	5-lead, 12-pin, ESU-proof, Adult/pediatric
01.57.471227	ECG trunk cable, 5-lead, 12-pin, ESU-proof, AHA/IEC, 5.0 m, reusable
01.57.471228	5-lead, 12-pin, Defib-proof, Adult/pediatric
01.57.471229	5-lead, 12-pin, Defib-proof, Adult/pediatric, Extended
01.13.036620	5-lead, Clip, AHA, Adult/pediatric, Extended
01.13.036621	5-lead, Clip, AHA, Adult/pediatric
01.13.036622	5-lead, Snap, AHA, Adult/pediatric, Extended
01.13.036623	5-lead, Snap, AHA, Adult/pediatric
01.13.036624	5-lead, Clip, IEC, Adult/pediatric, Extended
01.13.036625	5-lead, Clip, IEC, Adult/pediatric
01.13.036626	5-lead, Snap, IEC, Adult/pediatric, Extended
01.13.036627	5-lead, Snap, IEC, Adult/pediatric
01.57.040203	12-lead, Snap, IEC, Adult/pediatric
01.57.471163	12-lead, Clip, IEC, Adult/pediatric
01.57.109101	12-lead, Snap, AHA, Adult/pediatric

Part Number	Accessories
01.57.471169	12-lead, Clip, AHA, Adult/pediatric
01.57.471072	12-lead, 12-pin, Defib-proof, AHA, Adult/pediatric
01.57.471168	12-lead, 12-pin, Defib-proof, IEC, Adult/pediatric
01.57.471461	3-lead, Clip, IEC, 1.0m, Reusable
01.57.471462	ECG limb wires, 3-lead, Snap, IEC, 1.0m, Reusable
01.57.471463	3-lead, Clip, AHA, 1.0m, Reusable
01.57.471464	ECG limb wires, 3-lead, Snap, AHA, 1.0m, Reusable
01.57.471465	5-lead, 12-pin, Defib-proof, Clip, IEC, 3.4m, Reusable
01.57.471466	5-lead, 12-pin, Defib-proof, Clip, AHA, 3.4m, Reusable
01.57.471467	5-lead, 12-pin, Defib-proof, Snap, IEC, 3.4m, Reusable
01.57.471468	5-lead, 12-pin, Defib-proof, Snap, AHA, 3.4m, Reusable
01.57.471469	5-Lead, 6-pin, Defib-proof, Clip, IEC, 3.4m, Reusable
01.57.471470	5-lead, 6-pin, Defib-proof, Clip, AHA, 3.4m, Reusable
01.57.471471	5-Lead, 6-pin, Defib-proof, Snap, IEC, 3.4m, Reusable
01.57.471472	5-Lead, 6-pin, Defib-proof, Snap, AHA, 3.4m, Reusable
01.57.471473	5-lead, 12-pin, ESU-proof, Clip, IEC, 3.4m, Reusable
01.57.471474	5-Lead, 12-pin, ESU-proof, Clip, AHA, 3.4m, Reusable
01.57.471475	5-Lead, 12-pin, ESU-proof, Snap, IEC, 3.4m, Reusable
01.57.471476	5-lead, 12-pin, ESU-proof, Snap, AHA, 3.4m, Reusable
01.57.471477	5-lead, 6-pin, ESU-proof, Clip, IEC, 3.4m, Reusable
01.57.471478	5-lead, 6-pin, ESU-proof, Clip, AHA, 3.4m, Reusable
01.57.471479	5-lead, 6-pin, ESU-proof, Snap, IEC, 3.4m, Reusable
01.57.471480	5-lead, 6-pin, ESU-proof, Snap, AHA, 3.4m, Reusable
01.57.471481	3-lead, 12-pin, ESU-proof, AHA/IEC, 2.7m, Reusable
01.57.471482	3-lead, 12-pin, ESU-proof, AHA/IEC, 5.0m, Reusable

Part Number	Accessories
01.57.471483	3-lead, 12-pin, Defib-proof, AHA/IEC, 2.7m, Reusable
01.57.471484	3-lead, 12-pin, Defib-proof, AHA/IEC, 5.0m, Reusable
01.57.471485	3-lead, 6-pin, ESU-proof, AHA/IEC, 2.7m, Reusable
01.57.471486	3-lead, 6-pin, ESU-proof, AHA/IEC, 5.0m, Reusable
01.57.471487	3-lead, 6-pin, Defib-proof, AHA/IEC, 2.7m, Reusable
01.57.471488	3-lead, 6-pin, Defib-proof, AHA/IEC, 5.0m, Reusable
01.57.471196	3-lead, Snap, AHA, Neonate
01.57.471198	3-lead, Clip, AHA, Neonate
01.57.471195	3-lead, Snap, IEC, Neonate
01.57.471197	3-lead, Clip, IEC, Neonate
01.57.471193	3-lead, 6-pin, Defib-proof, Neonate
01.57.471194	3-lead, 12-pin, Defib-proof, Neonate
01.57.471979	6-lead, 12-pin, Defib-proof, Adult/pediatric
01.57.471980	6-lead, Clip, AHA, Adult/pediatric
01.57.471981	6-lead, Snap, AHA, Adult/pediatric
01.57.471982	6-lead, Clip, IEC, Adult/pediatric
01.57.471983	6-lead, Snap, IEC, Adult/pediatric
01.57.471276	ECG CONDUCTIVE ADHESIVE ELECTRODES
01.57.471056	ECG Electrodes, adult, disposable, 30 pieces
01.57.471060	ECG Electrodes, adult, disposable, 100 pieces
01.57.471057	ECG Electrodes, child, neo disposable, 50 pieces
01.57.471897	Disposable ECG Electrodes
01.57.471898	Disposable ECG Electrodes
01.57.471858	Disposable ECG Electrodes
01.57.471859	Disposable ECG Electrodes

Part Number	Accessories
01.57.471861	Disposable ECG Electrodes
01.57.471862	Disposable ECG Electrodes

31.2 SpO₂ Accessories

Part Number	Accessories
For EDAN Module	
02.01.210119	SH1 Adult Reusable SpO ₂ Sensor (Lemo)
02.01.210120	SH1 Adult Reusable SpO ₂ Sensor (DB9)
02.01.210673	SH3 Neonate Wrap SpO ₂ Sensor
02.01.210122	SH4 Adult Silicone Soft-tip SpO ₂ Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO ₂ Sensor
01.13.210001	SpO ₂ adapter cable, standard (Lemo to DB9)
02.57.225000	SpO ₂ Sensor, Ear Clip, Adult/Pediatric, 1m, reusable
01.13.036336	SpO ₂ adapter cable, standard (Lemo to DB9) 4.0m
01.57.471235	SHD-A SpO ₂ Sensor, adult, disposable
01.57.471236	SHD-P SpO ₂ Sensor, pediatric, disposable
01.57.471237	SHD-I SpO ₂ Sensor, Infant, disposable
01.57.471238	SHD-N SpO ₂ Sensor, Neonate, disposable
For Nellcor Module	
01.15.30043	Nellcor Reusable Adult SpO ₂ Sensor (DS-100A OxiMax)
01.15.40096	Nellcor Reusable Adult/Neonate SpO ₂ Sensor (OXI-A/N OxiMax)
01.57.471069	Nellcor SpO ₂ Extension cable (Compatible with Nellcor OXI-Max SpO ₂ module and Nellcor sensor)
01.57.040436	Nellcor forehead sensor, Adult/Pediatric, > 10 kg, MAX-FAST
01.57.040437	Nellcor strip winding sensor, Pediatric/Infant, 3 kg-40 kg, hand/foot, OXI-P/I
01.57.040438	Nellcor multisite sensor, > 1 kg, hand, D-YS

Part Number	Accessories
01.57.040440	Nellcor sticking sensor, Adult, > 30 kg, hand, MAX-A/MAX-AL
01.57.040441	Nellcor sticking sensor, Neonatal/Adult < 3kg or > 40 kg, foot, MAX-N
01.57.040442	Nellcor sticking sensor, Infant, 3 kg-20 kg, foot, MAX-I
01.57.040445	Nellcor sticking sensor, Pediatric, 10 kg-50 kg, hand, MAX-P

31.3 NIBP Accessories

Part Number	Accessories
For EDAN Module	
01.57.471326	NIBP Cuff, E5, Infant,10-15cm, reusable
01.57.471327	NIBP Cuff, E6, Small child,13-17cm, reusable
01.57.471328	NIBP Cuff, E7, Child,16-21.5cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult,20.5-28cm, reusable
01.57.471330	NIBP Cuff, E9, Adult,27-35cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult,34-43cm, reusable
01.57.471005	NIBP Hose, Quick Connect to Quick Connect
01.57.471323	NIBP Cuff, Neonate, 10cm-15cm, reusable
01.57.471324	NIBP Cuff, Neonate, 6cm-11cm, reusable
01.57.471157	NIBP Cuff, neonatal #1, 3-6cm,disposable
01.57.471158	NIBP Cuff, neonatal #2, 4-8cm,disposable
01.57.471159	NIBP Cuff, neonatal #3, 6-11cm,disposable
01.57.471160	NIBP Cuff, neonatal #4, 7-13cm,disposable
01.57.471161	NIBP Cuff, neonatal #5, 8-15cm,disposable
01.57.471303	NIBP Tube, 3m
01.57.471291	NIBP Tube, 3m
For Omron Module	
01.59.102099	OMRON NIBP Tube (3.5 m)/CUFF HOSE(NO.1) length3.5 m

Part Number	Accessories
01.57.471457	HXA-GCUFF-SSLA, REF 9520668-3, SS 12 cm-18 cm, reusable, Omron
01.57.471458	HXA-GCUFF-SLA, REF 9520669-1, S 17 cm-22 cm, reusable, Omron
01.57.471459	HXA-GCUFF-MLA, REF 9520670-5, M 22 cm-32 cm, reusable, Omron
01.57.471460	HXA-GCUFF-LLA, REF 9520671-3, L 32 cm-42 cm, reusable, Omron
01.57.471081	OMRON Neonatal disposable cuff/CUFF(NO.10) arm 3.5 cm-6 cm, width 2.5 cm
01.57.471082	OMRON Neonatal disposable cuff/CUFF(NO.11) arm 5 cm-7.5 cm, width 3 cm
01.57.471083	OMRON Neonatal disposable cuff/CUFF(NO.12) arm 7.5 cm-10.5 cm, width 4 cm
01.57.471084	OMRON Neonatal disposable cuff/CUFF(NO.13) arm 8.5 cm-13 cm, width 5 cm
01.59.473003	OMRON NIBP Tube (3.5 m)/CUFF HOSE(NO.3) length 3.5 m (Only compatible with Neonatal Disposable and NIBP Tube)
For SunTech Module	
01.57.471157	NIBP Cuff, neonatal #1, 3 cm-6 cm, disposable
01.57.471158	NIBP Cuff, neonatal #2, 4 cm-8 cm, disposable
01.57.471159	NIBP Cuff, neonatal #3, 6 cm-11 cm, disposable
01.57.471160	NIBP Cuff, neonatal #4, 7 cm-13 cm, disposable
01.57.471161	NIBP Cuff, neonatal #5, 8 cm-15 cm, disposable
01.57.471494	APC Cuff, Child (Green), Range: 12 cm–19 cm
01.57.471495	APC Cuff, Small Adult (Royal Blue), Range: 17 cm–25 cm
01.57.471496	APC Cuff, Adult (Navy Blue), Range: 23 cm–33 cm
01.57.471497	APC Cuff, Large Adult (Burgundy), Range: 31 cm–40 cm
01.57.000974	OPC Cuff, Child, range: 12 cm-19 cm
01.57.000976	OPC Cuff, Small Adult, range: 17 cm-25 cm
01.57.000977	OPC Cuff, Adult, range: 23 cm-33 cm
01.57.000978	OPC Cuff, Large Adult, range: 31 cm-40 cm

31.4 TEMP Accessories

Part Number	Accessories
01.15.040257	Temperature Probe, Skin, Neonate/Infant, 6.3 mm plug (2.252K/25 °C)
01.15.040258	Temperature Probe, rectal/oral, Neonate/Infant, 6.3 mm plug (2.252K/25 °C)
01.15.040422	Neonatal/pediatric Skin Temperature Probe (10K)
01.15.040423	Neonatal/pediatric Rectal/Oral Temperature Probe (10K)
01.15.040185	Temperature Probe, skin, adult, 3 m, reusable
01.15.040184	Temperature Probe, rectal/oral, adult, 3 m, reusable
01.15.040420	Skin Temperature Probe (10K)
01.15.040421	Rectal/Oral Temperature Probe (10K)

31.5 Quick Temp Accessories*

Part Number	Accessories
02.01.110130	Temperature Probe, Rectal, FT20
02.01.110131	Temperature Probe, Oral/Axillary, FT10
01.57.110159	Probe Covers

* Only applicable to iM50 and M50.

31.6 IBP Accessories

Part Number	Accessories
02.57.471280	ICP transfer cable
01.57.471014	Pressure transducer interface cable, BD
01.57.471013	Pressure transducer interface cable, EDWARD
01.57.471027	Pressure transducer interface cable, Hospira
01.57.471028	Pressure transducer interface cable, Utah
01.57.471835	IBP Pressure transducer interface cable/6pin, B.Braun type interface
01.57.40121	IBP Pressure transducer kit, BD, disposable(BD DT-4812)
01.57.471664	Disposable Pressure transducer PT161103, compatible with BD

Part Number	Accessories
01.57.471665	Disposable Pressure transducer PT151103, compatible with Edward
01.57.471666	Disposable Pressure transducer PT141103, compatible with Abbott
01.57.471880	Reusable pressure transducer
01.57.471881	Disposable dome

31.7 CO₂ Accessories

Part Number	Accessories
For EDAN Module	
02.01.210520	Dewatering Cup(Single Patient Use, Adult/Pediatric 10 ml)
01.57.471275	CO ₂ Sampling Line with Male Luer Lock, 2.0 m
01.57.471282	All Purpose Sampling Cannula without filter (Non Sterile). Size: Adult
01.57.471283	All Purpose Sampling Cannula without filter (Non Sterile). Size: Infant
01.57.471284	All Purpose Sampling Cannula without filter (Non Sterile). Size: Neonate
01.57.471285	Duo Flow O ₂ +CO ₂ Sampling Cannula (Non Sterile). Size: Adult
01.57.471286	Duo Flow O ₂ +CO ₂ Sampling Cannula (Non Sterile). Size: Child
01.57.471287	Capnomask O ₂ +CO ₂ Sampling Cannula (Non Sterile). Size: Adult
01.57.471288	Capnomask O ₂ +CO ₂ Sampling Cannula (Non Sterile). Size: Child
For Respironics Module	
02.08.078137	Respironics EtCO ₂ module/(Side-stream) 1022054
01.15.040143	Respironics CAPNOSTAT 5 EtCO ₂ (Main-stream) Module 1015928
01.57.078139	Disposable CO ₂ Nasal Cannula - Adult (Respironics 3468ADU-00)
01.57.078151	Adult/Pediatric Airway adapter kit with dehumidification tubing(Respironics 3473ADU-00)
01.57.078154	Disposable Sampling Line Kit with Dehumidification Tubing (Respironics 3475-00)
01.57.471019	Reusable Adult/Pediatric Airway Adapter (7007-01)
01.57.471020	Reusable Neonate/Infant Airway Adapter (7053-01)
01.59.078155	CO ₂ Airway Adapter, Adult, disposable (6063-00)
01.59.078156	CO ₂ Airway Adapter, Neonatal (infant/pediatric)(6312-00)

Part Number	Accessories
01.57.078142	Adult Nasal CO ₂ with O ₂ delivery sampling cannula(Respironics 3469ADU-00)
01.57.078143	Pediatric Nasal CO ₂ with O ₂ delivery sampling cannula(Respironics 3469PED-00)
01.57.078144	Infant Nasal CO ₂ with O ₂ delivery sampling cannula(Respironics 3469INF-00)
01.57.101019	Adult Nasal/Oral CO ₂ sampling cannula(Respironics 3470ADU-00)
01.57.101020	Pediatric Nasal/Oral CO ₂ sampling cannula(Respironics 3470PED-00)
01.57.101021	Adult Nasal/Oral CO ₂ with O ₂ delivery sampling cannula(Respironics 3471ADU-00)
01.12.031598	Adult/Pediatric Airway adapter kit(Respironics 3472ADU-00)
01.57.078140	Disposable CO ₂ Nasal Cannula - Pediatric (Respironics 3468PED-00)
01.57.078141	Disposable CO ₂ Nasal Cannula - Infant (Respironics 3468INF-00)
01.57.078152	Pediatric/Infant Airway adapter kit with dehumidification tubing(Respironics 3473INF-00)
01.57.078158	Pediatric mask/mainstream 9960PED-00
01.57.078159	Adult standard mask /mainstream 9960STD-00
01.57.078160	Adult large mask /mainstream 9960LGE-00
01.57.078161	Band/mainstream 8751-00
01.12.078162	Card Slot /Mainstream 6934-00
For Masimo Module	
01.57.471086	GAS Module Extension cable, 0.3 m
01.57.472058	CO ₂ mainstream module
01.57.472071	CO ₂ sidestream module
02.08.208216	Nomoline IRMA CO ₂ , DB9, 200101
02.08.208217	Nomoline ISA CO ₂ , DB9, 4410
01.51.412962	Masimo CO ₂ external sidestream holder
01.57.471043	Nomoline with Luer Lock connector, Box of 25, CAT.NO. 108210
01.57.471042	IRMA Airway Adapter, Adult/Pediatric, Box of 25, CAT.NO. 106220
01.57.471189	Nomoline Adapter
01.57.471190	Nomoline Airway Adapter Set

Part Number	Accessories
01.57.471191	Nomo Extension
01.57.471192	T-adapter
01.57.472072	NomoLine LH Adult/Pediatric Airway Adapter Set, 25/box 3814 2 m
01.57.472073	NomoLine LH Adult/Pediatric Airway Adapter Set, 25/box 3815 3 m
01.57.472074	NomoLine LH Infant Airway Adapter Set, 25/box 3816 2 m
01.57.472075	NomoLine LH Infant/Neonatal Airway Adapter Set, 25/box 4369 2 m
01.57.472076	NomoLine HH Adult/Pediatric Airway Adapter Set, 25/box 3827 2 m
01.57.472077	NomoLine HH Adult/Pediatric Airway Adapter Set, 25/box 3828 3 m
01.57.472078	NomoLine HH Infant Airway Adapter Set, 25/box 3829 2 m
01.57.472079	NomoLine HH Infant/Neonatal, Airway Adapter Set, 25/box 4367 2 m
01.57.472080	NomoLine LH Adult Nasal CO ₂ Cannula with O ₂ , 25/box 3820 2 m
01.57.472081	NomoLine LH Pediatric Nasal CO ₂ Cannula with O ₂ , 25/box 3821 2 m
01.57.472082	NomoLine LH Adult Nasal/Oral CO ₂ Cannula with O ₂ , 25/box 3824 2 m
01.57.472083	NomoLine LH Pediatric Nasal/Oral CO ₂ Cannula with O ₂ , 25/box 3825 2 m
01.57.472084	NomoLine HH Adult Nasal CO ₂ Cannula with O ₂ , 25/box 3833 2 m
01.57.472085	NomoLine HH Pediatric Nasal CO ₂ Cannula with O ₂ , 25/box 3834 2 m
01.57.472086	NomoLine HH Adult Nasal/Oral CO ₂ Cannula with O ₂ , 25/box 3837 2 m
01.57.472087	NomoLine HH Pediatric Nasal/Oral CO ₂ Cannula with O ₂ , 25/box 3838 2m
01.57.472088	NomoLine LH Adult Nasal CO ₂ Cannula, 25/box 3817 2 m
01.57.472089	NomoLine LH Pediatric Nasal CO ₂ Cannula, 25/box 3818 2 m
01.57.472090	NomoLine LH Infant Nasal CO ₂ Cannula, 25/box 3819 2 m
01.57.472091	NomoLine LH Adult Nasal/Oral CO ₂ Cannula, 25/box 3822 2 m
01.57.472092	NomoLine LH Pediatric Nasal/Oral CO ₂ Cannula, 25/box 3823 2 m
01.57.472093	NomoLine LH Adult Single Nasal Prong CO ₂ Cannula, 25/box 3826 2 m
01.57.472094	NomoLine HH Adult Nasal CO ₂ Cannula, 25/box 3830 2 m
01.57.472095	NomoLine HH Pediatric Nasal CO ₂ Cannula, 25/box 3831 2 m

Part Number	Accessories
01.57.472096	NomoLine HH Infant Nasal CO ₂ Cannula, 25/box 3832 2 m
01.57.472097	NomoLine HH Adult Nasal/Oral CO ₂ Cannula, 25/box 3835 2 m
01.57.472098	NomoLine HH Pediatric Nasal/Oral CO ₂ Cannula, 25/box 3836 2 m
01.57.472099	NomoLine HH Adult Single Nasal Prong CO ₂ Cannula, 25/box 3839 2 m

31.8 C.O. Accessories*

Part Number	Accessories
01.57.471663	C.O. cable, 3.0 m
01.13.40119	In-line Injection temperature probe (BD 684056-SP4042)
01.57.40120	In-line Injection temperature probe housing (BD 680006-SP5045)
01.57.100175	Control Syringe (Medex MX387)

*Not applicable to iM50 or M50.

The Thermodilution Catheter is required when measuring C.O.. Swan-Ganz catheter (Type 131HF7 and 741HF7), manufactured by Edwards Lifesciences Corporation, has been validated to be compatible with the monitor. Refer to Edwards for more details.

31.9 AG Accessories*

Part Number	Accessories
For EDAN G7 Module	
02.01.210520	Dewatering Cup (Single Patient Use, Adult/Pediatric 10 ml)
01.57.472055	Anaesthetic gas sampling line
For Masimo Module	
01.57.471043	Nomoline with Luer Lock connector, Box of 25, CAT.NO. 108210
01.57.471042	IRMA Airway Adapter, Adult/Pediatric, Box of 25, CAT.NO. 106220
01.57.471189	Nomoline Adapter
01.57.471190	Nomoline Airway Adapter Set
01.57.471191	Nomo Extension
01.57.471192	T-adapter
02.08.208005	ISA™ Sidestream Analyzers, ISA AX+, CAT.NO.800601 (CO ₂ , N ₂ O, 5AA, AAID)
02.08.208006	IRMA™ Mainstream Analyzers, IRMA AX+,CAT.NO.200601 (CO ₂ , N ₂ O, 5AA, AAID)

Part Number	Accessories
02.08.208007	ISA™ Sidestream Analyzers, ISAOR+, CAT.NO.800401 (CO ₂ , O ₂ ,N ₂ O, 5AA, AAID)
01.13.113617	GAS Module Extension cable
For Dräger Minimodule	
01.57.471489	Water trap
01.57.471492	Sample line

* EDAN G7 module and Masimo module are applicable to iM70, iM80 and M80. Dräger Minimodule is only applicable to iM80 and M80.

31.10 Other Accessories

Part Number	Accessories
01.57.471048	Assembly board for iM80 gas module
01.21.064142	Rechargeable Lithium-Ion Battery/TWSLB-002, 14.8V, 2500mAh
01.21.064143	Rechargeable Lithium-Ion Battery/TWSLB-003, 14.8V, 5000mAh
02.04.241047	EPRT-48mm recorder, Serial/parallel port
02.01.109592	Pole clamp, 1 set /package
02.01.109636	Pole clamp, 4 sets/package
01.57.78035	Recorder paper
01.18.052245	Netac USB flash disk (U208, 4G, USB2.0)
01.23.068023	Linear Barcode Scanner
02.04.241690	Patient monitor mounting arm assembly kit (M3/iM50)
02.04.241688	Patient monitor mounting arm assembly kit (iM60/iM70)
02.04.241689	Patient monitor mounting arm assembly kit (iM8/iM9/iM80)
83.60.261083	MT-206 Trolley (iM60&iM70), metal caster
83.60.261118	MT-206 Trolley (iM60&iM70), plastic caster
02.04.101976	Rolling Stand Basket (in the bottom)
83.60.261069	MT-206 Trolley (M3/iM50), metal caster
83.60.261116	MT-206 Trolley (M3/iM50), plastic caster
83.60.261084	MT-207 Trolley (iM80), metal caster

Part Number	Accessories
83.60.261119	MT-207 Trolley (iM80), plastic caster
83.60.261648	MT-206 (S) Trolley (iM50)
83.60.261720	MT-206 (S) Trolley (iM60&iM70)
01.13.037122	Power cable, length 1.8 m, American standard, medical grade
01.13.036638	Power cable, length 1.8 m, VDE
01.13.114214	Ground Cable
01.17.052452	SD Memory Card (8GB, Class4)

NOTE:

The part name may vary depending on context, but the part number is constant.

A Product Specification

NOTE:

The performance of the equipment with ☆ mark is determined to be essential performance.

A.1 Classification

Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	CF: ECG (RESP), TEMP, IBP, C.O., Quick Temp BF: SpO ₂ , NIBP, CO ₂ , AG
Ingress Protection	IPX1
Disinfection/sterilization method	Refer to Chapter Care and Cleaning for details.
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2015; IEC 60601-2-49: 2011

A.2 Physical Specifications

A.2.1 Size and Weight

Product	Size	Weight (standard configuration, without battery)
iM50/M50	261 mm (W) × 215 mm (H) × 198 mm (D)	< 3.6 kg
iM60	303 mm (W) × 254 mm (H) × 161 mm (D)	< 3.8 kg
iM70	328 mm (W) × 285 mm (H) × 158 mm (D)	< 4.5 kg
iM80/M80	370 mm (W) × 320 mm (H) × 175 mm (D)	< 7 kg

A.2.2 Environment Specification

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature	
Working	+0 °C to +40 °C(32 °F~104 °F)

Transport and Storage	-20 °C to +55 °C(-4 °F~131 °F)	
Humidity		
Working	15%RH ~ 95%RH (non-condensing)	
Transport and Storage	15%RH ~ 95%RH (non-condensing)	
Altitude		
Working	86 kPa ~ 106 kPa	
Transport and Storage	70 kPa ~ 106 kPa	
Power Supply	100 V-240 V~, 50 Hz/60 Hz	
	iM50/M50	Current=1.0 A-0.5 A; Fuse: T3.15AH, 250VP
	iM80/M80	Current=1.4 A-0.7 A; Fuse: T3.15AH, 250VP
	iM60/iM70	Current=1.4 A-0.7 A; Fuse: T3.15AH, 250VP

A.2.3 Display

Product	Display	Messages
iM50/M50	Display screen: 8.4 inch color TFT, supporting touch screen Resolution: 800×600	A maximum of 13 waveforms One power LED Two alarm LED One charge LED
iM60	Display screen: 10.4 inch color TFT, supporting touch screen Resolution: 800×600	
iM70	Display screen: 12.1 inch color TFT, supporting touch screen Resolution: 800×600	
iM80/M80	Display screen: 15 inch color TFT, supporting touch screen Resolution: 1024 × 768	

A.2.4 Battery Specification

Operating Time	iM50/iM60	2500 mAh	≥ 3.5 h
	iM70/M50	5000 mAh	≥ 7 h
		iM80/M80	One battery (5000 mAh)
			Two batteries (2*5000 mAh)

Condition	At 25~30 °C, with (a) new fully charged battery/batteries, EDAN module in use, continuous SpO ₂ measurement and NIBP automatic measurement mode at interval of 15 minutes, ECG/TEMP module connected, recording at interval of 10 minutes, brightness set to “1”.		
Charge Time	iM50/iM60 iM70/M50	2500 mAh	≤ 3.5 h, 100% charge ≤ 3.15 h, 90% charge
		5000 mAh	≤ 6.5 h, 100% charge ≤ 5.85 h, 90% charge
	iM80/M80	One battery (5000 mAh)	≤ 6.5 h, 100% charge ≤ 5.85 h, 90% charge
		Two batteries (2*5000 mAh)	≤ 13 h, 100% charge ≤ 11.7 h, 90% charge
Condition	Environment temperature: 25±2 °C. iM50/M50 is powered off.		
Charge/Discharge Cycle	300 times		

A.2.5 Recorder

Record Width	48 mm
Record Paper Width	50 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Trace	3
Recording types	Continual real-time recording, 8-second real-time recording, 20-second real-time recording, trend graph recording, trend table recording, NIBP review recording, arrhythmia review recording, alarm review recording, drug calculation titration recording, Hemodynamic Calculation result recording, Oxygenation Calculation result recording, Ventilation Calculation result recording, Renal Function Calculation result recording, 12-lead analysis recording, C.O. measurement recording, frozen waveform recording, ST view recording, QT view recording

A.2.6 Data Management

Data Review

Trend Data	3 hours, resolution: 1 s 120 hours, resolution: 1 min
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Alarm Events	Up to 200 sets
NIBP Measurement Data	1200 sets
Arrhythmia Events	Up to 200 sets
12-lead Analysis Result	Up to 50 sets
OxyCRG	24 hours

Refer to Chapter *Review* for more information about data review.

Data Storage

A single piece of patient data maximally contains the following information:

Patient information	MRN, name, date of birth, date of admission, gender, type, height, weight, blood type, pace, doctor, bed No., department
Trend graph and trend table	240 hours, resolution: 1 min
NIBP measurement review	1200 sets
Alarm review	200 sets
Arrhythmia event	200 sets
12-lead analysis review	50 sets
Full disclosure waveforms	48 hours

The following storage capacity for standard extended space is for reference:

Continuous parameter data	5400 hours, resolution: 1 min
NIBP data	At least 510000 sets
Physiological alarm event	At least 33750 sets
Arrhythmia event	At least 33750 sets
Full disclosure waveforms	225 hours

Refer to Section *Storing Data in the Storage Device* for more information about storing data in the storage medium.

A.3 Wi-Fi

A.3.1 Wi-Fi Technical Specifications

IEEE	802.11a/b/g/n
Frequency Band	2.4 GHz ISM band & 5 G ISM band
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS

Maximum Typical Transmit Power (\pm 2 dBm)	<p>2.4 G:</p> <p>17 dBm for 802.11b DSSS</p> <p>17 dBm for 802.11b CCK</p> <p>17 dBm for 802.11g OFDM</p> <p>16 dBm for 802.11n OFDM</p> <p>5 G:</p> <p>10 dBm for 802.11a OFDM</p> <p>9 dBm for 802.11n OFDM</p>
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A.3.2 Wi-Fi Performance Specifications

System Capacity and Resistance to Wireless Interference	<p>When the following conditions are present,</p> <ul style="list-style-type: none"> ■ Quantity of the monitors supported by a single AP: \leq 8. ■ Each monitor can communicate with MFM-CMS. ■ Each monitor supports bed view function, which allows users to view its information from another bed or view other bed's information from its screen. ■ The AP signal strength of the monitor should be stronger than -65 dBm. ■ When the distance between the interfering devices and the monitor is more than 30 cm, and there are a co-channel interference Wi-Fi network (at least -85 dBm weaker than the monitor's network) and an adjacent-channel Wi-Fi network (at least -50 dBm weaker than the monitor's network) at the same time. Note: Excluding the Wi-Fi devices, the interfering devices include but are not limited to: <ul style="list-style-type: none"> ◆ 2.4 G or 5G wireless devices (excluding Wi-Fi devices) ◆ Cellular mobile communication networks ◆ Microwave ovens ◆ Interphones ◆ Mobile phones
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	<p>◆ ESU equipment</p> <p>The wireless network function of all monitors works normally and meets the following requirements:</p> <ul style="list-style-type: none"> ■ Total delay time for data transmission from the monitors to MFM-CMS: ≤ 2 s. ■ Total delay time of data transmission from one monitor to other monitors: ≤ 2 seconds. ■ Effective time of alarm reset configured on another monitor ≤ 2 s. ■ Effective time for monitor-related settings configured on the MFM-CMS: ≤ 2 s. ■ No communication loss between all the monitors.
Wi-Fi Network Stability	<p>When the following conditions are present,</p> <ul style="list-style-type: none"> ■ Quantity of the monitors supported by a single AP: ≤ 8. ■ Each monitor can communicate with MFM-CMS. ■ Each monitor supports bed view function, which allows users to view its information from another bed or view other bed's information from its screen. ■ The AP signal strength of the monitor should be stronger than -65 dBm. <p>The following requirements must be met:</p> <ul style="list-style-type: none"> ■ Within 24 hours, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.1%. When the connected 8 monitors roam for 30 times, the time percentage of failing to transmit data from any monitor to the MFM-CMS does not exceed 0.1%.
Distinct Vision Distance	<p>The distinct vision distance between the monitor and the AP: ≥ 50 meters.</p>

A.4 ECG

Complies with IEC 60601-2-25: 2011, IEC 60601-2-27: 2011.

Lead Mode	<p>3 Electrodes: I, II, III</p> <p>5 Electrodes: I, II, III, aVR, aVL, aVF, V</p> <p>6 Electrodes: I, II, III, aVR, aVL, aVF, and leads corresponding to Va Vb.</p> <p>10 Electrodes: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6</p>
Electrode Standard	AHA, IEC
☆Display Sensitivity (Gain Selection)	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), , 40 mm/mV (×4), AUTO gain
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Bandwidth (-3dB)	<p>Diagnosis: 0.05 Hz to 150 Hz</p> <p>Diagnosis 1: 0.05 Hz to 40 Hz</p> <p>Monitor: 0.5 Hz to 40 Hz</p> <p>Surgery: 1 Hz to 20 Hz</p> <p>Enhanced: 2 Hz ~18 Hz</p> <p>Customized: High-pass Filter and Low-pass Filter (Refer to <i>Changing the ECG Filter Settings</i>)</p>
☆CMRR (Common Mode Rejection Ratio)	<p>Diagnosis: > 95 dB</p> <p>Diagnosis 1: > 105 dB (when Notch is turned on)</p> <p>Monitor: > 105 dB</p> <p>Surgery: > 105 dB</p> <p>Enhanced: > 105 dB</p> <p>Customized: > 105 dB (Low-pass Filter < 40 Hz) > 95 dB (Low-pass Filter > 40 Hz)</p>
Hum Filter	In diagnosis, Diagnosis 1, monitor, surgery, enhanced and customized modes: 50 Hz/60 Hz (Hum Filter can be turned on or off manually)
☆ Differential Input Impedance	> 5 MΩ
☆Input Signal Range	±10 mV PP

☆ Accuracy of Signal Reproduction	An error of $\leq \pm 20\%$ of the nominal value of the output or $\pm 100 \mu\text{V}$, whichever is greater. The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.
☆ Electrode Offset Potential Tolerance	$\pm 800 \text{ mV}$
Auxiliary Current (Leads off detection)	Active electrode: $< 100 \text{ nA}$ Reference electrode: $< 900 \text{ nA}$
☆ Recovery Time After Defibrillation	$< 5 \text{ s}$ (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Leakage Current of Patient	$< 10 \mu\text{A}$
Scale Signal	1 mV PP , accuracy is $\pm 5\%$
☆ System Noise	$< 30 \mu\text{VPP}$
☆ Multichannel Crosstalk	$\leq 5\%$ of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.
☆ Frequency and Impulse Response	Frequency response: Input a 5 Hz , 1 mV sine wave signal, and the output signal amplitude remains within the range of 71% to 110% at 0.67 Hz and 40 Hz . Input a 1 Hz , 1.5 mV 200 ms triangular wave input signal, and the output shall be within $11.25 \text{ mm} \sim 15 \text{ mm}$. Impulse response: Displacement value: $\leq 0.1 \text{ mV}$ Slope: $\leq 0.3 \text{ mV/s}$ following the end of the pulse. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.
Sampling Frequency	1000 Hz
Sampling Channel Switch Time	$< 80 \mu\text{S}$
A/D Precision	24 Bits (Minimum resolution: $0.077 \mu\text{V/LSB}$)
☆ ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: $\leq 10 \text{ s}$
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.
Minimum Input Slew Rate (Lead II)	$> 2.5 \text{ V/s}$
☆ Baseline Reset Time	$< 3 \text{ s}$

Pace Pulse	
☆Pulse Indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ± 2 mV to ± 700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μ s to 100 μ s
☆Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ± 2 mV to ± 700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μ s to 100 μ s
Pace Pulse Detecting Lead: one among I, II, III, AVR, AVL, AVF, V1, V2, V3, V4, V5, V6	
Heart Rate	
HR Calculation	
☆Range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
☆Accuracy	$\pm 1\%$ or 1 bpm, whichever is greater
Resolution	1 bpm
Sensitivity	≥ 300 μ VPP
☆QRS Detection Range	The detection range has exceeded the requirement described in the standard: Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate. Amplitude: 0.5 mv~5 mv In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.
PVC	
Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
Resolution	1 PVCs/min
Pause/min	
Range	ADU/PED/NEO: (0 to 30) pauses/min

Resolution	1 pause/min
ST value	
Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ± 0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
QT measurement	
Range	200 ms ~ 800 ms
Resolution	4 ms
Accuracy	± 30 ms
QTc measurement	
Range	200ms ~ 800 ms
Resolution	1 ms
Δ QTc measurement	
Range	-600 ms ~ 600 ms
Resolution	1 ms
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200 ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Normal	Adult: 0.5 s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric/neonatal: 0.375 s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.

Range of Ventricular Rhythm	
V-Tach (Ventricular Tachycardia)	Advanced: 5 consecutive ventricular beats and ventricular HR \geq 100 bpm. Basic: The interval of 5 consecutive ventricular beats is less than 600 ms
Vent Rhythm (Ventricular Rhythm)	Advanced: 5 consecutive ventricular beats, and 20 bpm \leq ventricular HR < 40 bpm. Basic: The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms
Vent Brady (VBRADY)	Advanced: 5 consecutive ventricular beats, and ventricular HR < 20 bpm. Basic: The interval of 5 consecutive ventricular beats is more than 1000 ms
Acc. Vent Rhythm	5 consecutive ventricular beats, and 40 bpm \leq ventricular HR < 100 bpm.
Maximum Start-up Alarm Time for Tachycardia	
V-Tach (Ventricular Tachycardia) 1 mV 206 bpm	Gain 0.5: 10 s Gain 1.0: 10 s Gain 2.0: 10 s
V-Tach (Ventricular Tachycardia) 2 mV 195 bpm	Gain 0.5: 10 s Gain 1.0: 10 s Gain 2.0: 10 s
Response Time of Heart Rate Meter to Change in HR	HR range: 80 bpm to 120 bpm Range : Within 11 s HR range: 80 bpm to 40 bpm Range : Within 11 s
☆Tall T-wave Rejection	Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude

Accuracy of Heart Rate Meter and Response to Irregular Rhythm	Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy: 80 bpm±1 bpm Slow alternating ventricular bigeminy: 60 bpm±1 bpm Rapid alternating ventricular bigeminy: 120 bpm±1 bpm Bidirectional systoles: 91 bpm±1 bpm		
Time to Alarm for Heart Rate alarm conditions	Asystole alarm: ≤ 10 s HR low alarm: ≤ 10 s HR high alarm: ≤ 10 s		
Arrhythmia analyses (Advanced)	Asystole	V-Fib/V-Tach	Couplet
	Vent Rhythm	PVC Bigeminy	PVC Trigeminy
	Tachy	R on T	PVC
	Irr Rhythm	Brady	Missed Beat
	Pacer not Pacing	Vent Brady	Pacer not Capture
	VEB	Run PVCs	Acc. Vent Rhythm
	IPVC	Non-Sustain VT	Multiform PVCs
	Pauses/min High	Pause	Afib
	PAC Bigeminy	PVCs High	Low Voltage(Limb)
	ExtremeBrady	PAC Trigeminy	Wide QRS Tachy
Arrhythmia analyses (Basic)	Sustain VT	ExtremeTachy	V-Tach
	ASYSTOLE	VFIB/VTAC	COUPLET
	VT > 2	BIGEMINY	TRIGEMINY
	VENT	R on T	PVC
	TACHY	BRADY	MISSED BEATS
	IRR	VBRADY	PNP
12-Lead ECG Synchronization Analysis	Average parameters of heart beat		
	Heart rate (bpm)		
	Time limit of P wave (ms)		
	PR interval (ms)		
	QRS interval (ms)		

	QT/QTC (ms)
	P-QRS-T AXIS

A.5 RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual, Automatic
Baseline Impedance Range	200 Ω to 2500 Ω (with ECG cables of 1 K Ω resistance)
Measuring Sensitivity	Within the baseline impedance range: 0.3 Ω
Waveform Bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
Respiration Waveform	Excitation Sinusoid, 45.6 kHz ($\pm 10\%$), < 350 μ A
☆RR Measuring Range	
☆Adult	0 rpm to 120 rpm
☆Neo/Ped	0 rpm to 150 rpm
Resolution	1 rpm
☆Accuracy	
☆Adult	6 rpm to 120 rpm: ± 2 rpm 0 rpm to 5 rpm: not specified
☆Neo/Ped	6 rpm to 150 rpm: ± 2 rpm 0 rpm to 5 rpm: not specified
☆Gain Selection	$\times 0.25$, $\times 0.5$, $\times 1$, $\times 2$, $\times 3$, $\times 4$, $\times 5$
☆Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
☆Apnea Alarm Time Setup	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

A.6 NIBP

Complies with IEC 80601-2-30: 2009+A1: 2013.

EDAN Module

Technique	Oscillometry
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Mode	Manual, Auto, Continuous, Sequence
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define
Continuous	5 min, interval is 5 s
Measuring Parameter	SYS, DIA, MAP, PR
Pressure Unit	kPa, mmHg, cmH ₂ O
☆Measuring Range	
☆Adult Mode	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
☆Pediatric Mode	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
☆Neonatal Mode	SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg
☆Alarm Type	SYS, DIA, MAP
☆ Cuff Pressure Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1 mmHg
☆Maximum Mean Error	±5 mmHg
☆Maximum Standard Deviation	8 mmHg
Maximum Measuring Period	
Adult/Pediatric	120 s
Neonate	90 s
Typical Measuring Period	20 s to 35 s (depend on HR/motion disturbance)
Dual Independent Channel Overpressure Protection	
Adult	(297±3) mmHg
Pediatric	(245±3) mmHg
Neonatal	(147±3) mmHg
Pre-inflation Pressure	

Adult	Default: 160 mmHg Range: 80/100/120/140/150/160/180/200/220/240 mmHg
Pediatric	Default: 140 mmHg Range: 80/100/120/140/150/160/180/200 mmHg
Neonatal	Default: 100 mmHg Range: 60/70/80/100/120 mmHg
Venipuncture pressure	
Adult	Default: 60 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg, 90 mmHg, 100 mmHg, 110 mmHg, 120 mmHg
Pediatric	Default: 40 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg, 60 mmHg, 70 mmHg, 80 mmHg
Neonatal	Default: 30 mmHg Options: 20 mmHg, 30 mmHg, 40 mmHg, 50 mmHg

Omron Module

Not applicable to iM50, iM60 or M50.

Method	Oscillometric
Mode	Manual, Auto, Continuous, Sequence
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define
Continuous	5 min, interval is 5 s
☆Measuring Parameter	SYS, DIA, MAP
Pressure Unit	kPa, mmHg, cmH ₂ O
☆Measuring Range	
☆Adult/ Pediatric Mode	SYS: 60 mmHg to 250 mmHg DIA: 40 mmHg to 200 mmHg MAP: 45 mmHg to 235 mmHg
☆Neonatal Mode	SYS: 40 mmHg to 120 mmHg DIA: 20 mmHg to 90 mmHg MAP: 30 mmHg to 100 mmHg

Alarm Type	SYS, DIA, MAP			
Cuff pressure Measuring Range	0 mmHg to 300 mmHg			
Pressure Resolution	1 mmHg			
Measuring Accuracy				
☆ Maximum Mean Error	±5 mmHg			
☆ Maximum Standard Deviation	8 mmHg			
	Adult/Pediatric		Neonate	
	Normal Condition	Single Fault Condition	Normal Condition	Single fault Condition
Maximum Cuff Pressure	300 mmHg	330 mmHg	150 mmHg	165 mmHg
Maximum Measuring Period	Less than 160 s	Less than 180 s	Less than 80 s	Less than 90 s
Pre-inflation Pressure				
Adult/ Pediatric Mode	Default: 180 mmHg Range: 120/140/150/160/180/200/220/240/260/280 mmHg			
Neonatal Mode	Default: 120 mmHg Range: 80/100/120/140 mmHg			
Dual Independent Channel Overpressure Protection				
Adult/Pediatric	< 300 mmHg			
Neonatal	< 150 mmHg			

SunTech Module

Not applicable to iM50 or M50.

Method	Oscillometric
Mode	Manual, Auto, Continuous, Sequence
Measuring Interval in AUTO Mode (unit: minute)	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 and User Define
☆Measuring Parameter	SYS, DIA, MAP, PR
Pressure Unit	kPa, mmHg, cmH ₂ O
☆Measuring Range	

☆Adult Mode	SYS: 40 mmHg ~ 260 mmHg DIA: 20 mmHg ~ 200 mmHg MAP: 26 mmHg~ 220 mmHg
☆Pediatric Mode	SYS: 40 mmHg~ 230 mmHg DIA: 20 mmHg~ 160 mmHg MAP: 26 mmHg~ 183 mmHg
☆Neonatal Mode	SYS: 40 mmHg – 130 mmHg DIA: 20 mmHg~ 100 mmHg MAP: 26 mmHg – 110 mmHg
☆Alarm Type	SYS, DIA, MAP
Pressure Resolution	1 mmHg
☆Maximum mean error	±5 mmHg
☆Maximum standard deviation	8 mmHg
Maximum measuring period	
Adult	130 s
Pediatric	90 s
Neonate	75 s
Overpressure protection	
Adult/Pediatric	< 300 mmHg
Neonate	< 150 mmHg
Pre-inflation Pressure	
Adult Mode	Default: 160 mmHg Range: 120/140/150/160/180/200/220/240/260/280 mmHg
Pediatric Mode	Default: 140 mmHg Range: 80/100/120/140/150/160/180/200/220/250 mmHg
Neonatal Mode	Default: 90 mmHg Range: 60/70/80/90/100/120/140 mmHg

A.7 SpO₂

Complies with ISO 80601-2-61: 2017.

EDAN Module

Measuring Range	0% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
☆Adult /Pediatric	±2% (70% to 100% SpO ₂)
	Undefined (0% to 69% SpO ₂)
☆Neonate	±3% (70% to 100% SpO ₂)
	Undefined (0% to 69% SpO ₂)
Sensor	
Red Light	(660±3) nm
Infrared Light	(905±10) nm
Emitted Light Energy	< 15 mW
PI	
Measuring Range	0-10, invalid PI value is 0.
Resolution	1

Nellcor Module

Measuring Range	1% to 100%	
Resolution	1%	
☆ Data Update Period	1 s	
☆Accuracy	DS-100A, OXI-A/N(Adult) D-YS (Adult and Pediatric) OXI-P/I (Pediatric)	± 3% (70% to 100% SpO ₂)
	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±2% (70% to 100% SpO ₂)

	MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	$\pm 3\%$ (60% to 80% SpO ₂)
	If sensor is used for neonate as recommended, the accuracy will be larger than adult by ± 1 .	
Sensor	Wave length: approximately 660 nm and 900 nm	
	Emitted light energy: < 15 mW	

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A.8 PR

		Measuring range	Accuracy	Resolution
☆PR (SpO ₂)	EDAN	25 bpm to 300 bpm	± 2 bpm	1 bpm
	Nellcor	20 bpm to 300 bpm	± 3 bpm (20 bpm to 250 bpm)	1 bpm
☆PR (NIBP)	EDAN	40 bpm to 240 bpm	± 3 bpm or 3.5%, whichever is greater	1 bpm
	Omron	Adult/Pediatric mode: 40 bpm to 200 bpm Neonatal mode: 40 bpm to 240 bpm	± 2 bpm or 2% of the readings	1 bpm
	SunTech	30 bpm to 220 bpm	± 3 bpm or $\pm 2\%$, whichever is greater	1 bpm
☆PR (IBP)	EDAN	20 bpm to 300 bpm	30 bpm to 300 bpm: ± 2 bpm or $\pm 2\%$, whichever is greater; 20 bpm to 29 bpm: undefined	1 bpm

A.9 TEMP

Complies with ISO 80601-2-56: 2018.

Technique	Thermal resistance
Position	Skin, oral cavity, rectum

Measure Parameter	T1, T2, TD(the absolute value of T2 minus T1)
Channel	2
Sensor Type	YSI-10K and YSI-2.252K
Unit	°C, °F
Measuring Range	0 °C to 50 °C(32 °F to 122 °F)
Resolution	0.1 °C (0.1 °F)
☆Accuracy ¹	±0.3 °C
Refresh Time	Every 1 s to 2 s
Temperature Calibration	At an interval of 5 to 10 minutes
Measuring Mode	Direct Mode
Transient Response Time	≤ 30 s

Note 1: The accuracy consists of two parts, as following:

- Accuracy (not including sensor): ± 0.1 °C
- Sensor accuracy: ≤ ±0.2 °C

A.10 Quick TEMP

Only applicable to iM50 and M50.

Measuring Range	25 °C ~ 45 °C(monitored mode) 35.5 °C~42 °C (prediction mode)
Operating Temp	10 °C ~ 40 °C
Sensor Type	Oral/Axillary sensor, Rectal sensor
Resolution	0.1 °C
Accuracy ¹	±0.3 °C
Response time	< 60 s
Update time	1 s ~ 2 s
Warm-up time	Less than 10 seconds
Prediction time	Less than 30 seconds
Measuring Mode	Direct Mode/Adjusted Mode
Transient Response Time	≤ 30 s
Clinical Bias	(-0.2 to -0.4)°C
Limits of Agreement	0.49

Repeatability	0.14 °C
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Note 1: The accuracy consists of two parts, as following:

- Accuracy (not including sensor): ± 0.1 °C (25 °C ~ 45 °C) (monitoring mode)
- Sensor accuracy: $\leq \pm 0.2$ °C

NOTE:

The direct mode refers to monitor mode, while adjusted mode refers to predict mode.

A.11 IBP

Complies with IEC 60601-2-34: 2011.

Technique		Direct invasive measurement
Channel		iM80/M80: 4 channels iM50/iM60/iM70/M50: 2 channels
IBP Measure	☆Measuring Range	Art (0 to +300) mmHg
		PA/PAWP (-6 to +120) mmHg
		CVP/RAP/LAP/ICP (-10 to +40) mmHg
		P1/P2 (-50 to +300) mmHg
	Resolution	1 mmHg
☆Accuracy (not including sensor)		$\pm 2\%$ or ± 1 mmHg, whichever is greater ICP: 0 mmHg to 40 mmHg: $\pm 2\%$ or ± 1 mmHg, whichever is greater; -10 mmHg to -1 mmHg: undefined
Pressure Unit		kPa, mmHg, cmH ₂ O
Pressure sensor		
Sensitivity		5 μ V/V/mmHg
Impedance Range		300 Ω to 3000 Ω
Filter		DC~ 12.5 Hz; DC~ 40 Hz
Zero		Range: ± 200 mmHg
Pressure Calibration Range	IBP (excluding ICP)	80 mmHg to 300 mmHg
	ICP	10 mmHg to 40 mmHg
Volume Displacement		7.4×10^4 mm ³ /100mmHg

A.12 CO₂

Complies with ISO 80601-2-55: 2011.

EDAN G2 Sidestram Module

Intended Patient	Adult, pediatric, neonatal		
Measure Parameters	EtCO ₂ , FiCO ₂ , AwRR		
Unit	mmHg, %, kPa		
☆ Measuring Range	EtCO ₂	0 mmHg to 150 mmHg (0 % to 20%)	
	FiCO ₂	0 mmHg to 50 mmHg	
	AwRR	2 rpm to 150 rpm	
Resolution	EtCO ₂	1 mmHg	
	FiCO ₂	1 mmHg	
	AwRR	1 rpm	
☆ Accuracy	EtCO ₂	± 2 mmHg, 0 mmHg to 40 mmHg	Typical conditions: Ambient temperature: (25± 3) °C Barometric pressure: (760± 10) mmHg Balance gas: N ₂ Sample gas flowrate: 100 ml/min
		± 5% of reading, 41 mmHg to 70 mmHg	
		± 8% of reading, 71 mmHg to 100 mmHg	
		± 10% of reading, 101 mmHg to 150 mmHg	
	±12% of reading or ± 4 mmHg, whichever is greater	All conditions	
AwRR	± 1 rpm		
Drift of Measure Accuracy	Meets the requirements of the measure accuracy		
Sample Gas Flowrate	70 ml/min or 100 ml/min (optional), accuracy: ±15 ml/min		
Warm-up Time	Display reading within 20 s; reach to the designed accuracy within 2 minutes.		
Rise Time	< 400 ms (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)		
	< 500 ms (with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)		
Response	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)		

Time	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)	
Work Mode	Standby (default), measure	
O ₂ Compensation	Range: 0% to 100% Resolution: 1% Default: 16%	
N ₂ O Compensation	Range: 0% to 100% Resolution: 1% Default: 0%	
AG Compensation	Range: 0% to 20% Resolution: 0.1% Default: 0%	
Humidity Compensation Method	ATPD (default), BTPS	
Barometric Pressure Compensation	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)	
Zero Calibration	Support	
Calibration	Support (It is recommend to be operated by trained personal.)	
☆ Alarm	EtCO ₂ , FiCO ₂ , AwRR	
☆ Apnea Alarm Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	
Data Sample Rate	100 Hz	
EtCO ₂ Change ¹	AwRR ≤ 80rpm, meet the accuracy mentioned above; AwRR > 80 rpm, EtCO ₂ descends 8%; AwRR > 120 rpm, EtCO ₂ descends 10%	with 2 m gas sampling tube, sample gas flowrate: 100 ml/min)
	AwRR ≤ 60rpm, meet the accuracy mentioned above; AwRR > 60 rpm, EtCO ₂ descends 8%; AwRR > 90 rpm, EtCO ₂ descends 10%; AwRR > 120rpm, EtCO ₂ descends 15%;	with 2 m gas sampling tube, sample gas flowrate: 70 ml/min)

Note 1: Use a test device equivalent to EN ISO 80601-2-55 fig 201.101 to measure at 1:2 I/E ratio. Respiration rate accuracy is determined by frequency of device, and end-tidal reading change refers to the nominal value.

Interfering Gas Effects:

Gas	Gas Level (%)	Quantitative Effect/Comments
Nitrous oxide	60%	None

Halothane	4%	None
Enflurane	5%	None
Isoflurane	5%	None
Sevoflurane	5%	None
Xenon	Not applicable	Not applicable
Helium	Not applicable	Not applicable
Metered dose inhaler propellants	Not applicable	Not applicable
Desflurane	15%	None
Ethanol	0.1%	None
Isopropanol	0.1%	None
Acetone	0.1%	None
Methane	1%	None

Respironics Sidestream and Mainstream Modules

Applicable Patient Type	Adult, pediatric and neonatal patients	
Technique	Infra-red Absorption Technique	
Measure Parameters	EtCO ₂ , FiCO ₂ , AwRR	
Unit	mmHg, %, Kpa	
☆ Measuring Range		
☆ EtCO ₂	0 mmHg to 150 mmHg	
☆ FiCO ₂	3 mmHg to 50 mmHg	
☆ AwRR	0 rpm to 150 rpm (Mainstream) 2 rpm to 150 rpm (Sidestream)	
Resolution	EtCO ₂	1 mmHg
	FiCO ₂	1 mmHg
	AwRR	1 rpm
☆ EtCO ₂ Accuracy	± 2 mmHg, 0 mmHg to 40 mmHg	
	± 5 % of reading, 41 mmHg to 70 mmHg	
	± 8 % of reading, 71 mmHg to 100 mmHg	
	± 10 % of reading, 101 mmHg to 150 mmHg	
	± 12% of reading, RR is over 80 rpm (sidestream)	
There will be no degradation in performance due to		

	Respiration Rate. (mainstream)	
☆AwRR Accuracy	± 1 rpm	
Operation Mode	Measure, standby	
Sample Gas Flowrate (sidestream)	(50 ±10) ml/min	
O ₂ Compensation		
Range	0% to 100%	
Resolution	1%	
Default	16%	
Barometric Compensation	Pressure	User setup
Anesthetic Gas Compensation		
Range	0% to 20%	
Resolution	0.1%	
Default	0.0%	
Balance Gas Compensation	Room air, N ₂ O, helium	
Stability		
Short Term Drift	Drift over 4 hours < 0.8 mmHg	
Long Term Drift	120 hours	
Zero Calibration	Support	
☆Alarm Type	EtCO ₂ , FiCO ₂ , AwRR	
☆Apnea Alarm Delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	
Data Sample Rate	100 Hz	
CO ₂ Rise Time/Response Time (mainstream)	Less than 60 ms	
Sensor Response Time (sidestream)	< 3 seconds, including transport time and rise time	

Interfering Gas and Vapor Effects on EtCO₂ Measurement Values:

Gas or Vapor	Gas Level (%)	Quantitative Effect/Comments
Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	(0 – 40) mmHg: ± 1 mmHg additional error

Enflurane	5	(41 – 70) mmHg: $\pm 2.5\%$ additional error
Isoflurane	5	(71 – 100) mmHg: $\pm 4\%$ additional error
Sevoflurane	5	(101 – 150) mmHg: $\pm 5\%$ additional error
Xenon	80	<p>*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.</p> <p>Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.</p> <p>Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg.</p>
Helium	50	
Desflurane	15	

Barometric Pressure on EtCO₂ Measurement Values:

Quantitative Effect
<p>Ambient Barometric, Operational</p> <p>(0 – 40) mmHg: ± 1 mmHg additional error</p> <p>(41 – 70) mmHg: $\pm 2.5\%$ additional error</p> <p>(71 – 100) mmHg: $\pm 4\%$ additional error</p> <p>(101 – 150) mmHg: $\pm 5\%$ additional error</p> <p>*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.</p>

NOTE:

Respiration Rate accuracy was verified by using a solenoid test setup to deliver a square wave of known CO₂ concentration to the device. 5% and 10% CO₂ concentrations were used. Respiration rate was varied over the range of the device. Pass/Fail criteria was comparison of the respiratory rate output from the sensor to the frequency of the square wave.

Masimo Sidestream Module

Dimensions	91 mm × 60 mm × 37 mm (3.6 × 2.4 × 1.4), excluding cable, tubing and Nomoline.
Weight	≤ 98 g, excluding cable, tubing and Nomoline.
According to the degree of protection against harmful ingress of water	IP34

Transient operating Temperature	The device operates according to specification when exposed to -20 °C to 0 °C (-4 °F to 32 °F) for 20 minutes.
Warm up time after storage at -40 °C	A warm up period of 10 minutes is required for the NomoLine ISA CO ₂ module to fulfill the accuracy specification if immediately put into use after being stored at -40 °C (A power on reset is required if a hardware error is generated during the warm up period after being stored at -40 °C).
Ambient CO ₂	≤ 800 ppm (0.08 vol%)
Mechanical robustness	Meets the shock and vibration requirements for transport of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.2 and EN 60601-1-12: 2015 clause 10.1.3
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Water handling	NomoLine Family sampling lines with proprietary water removal tubing.
Sampling flow rate	(50 ± 10) sml/min Note: 1. Volumetric flow rate of air corrected to standardized conditions of temperature and pressure. 2. Flow accuracy specification for the extended temperature range (-20 to 0 °C) is +15/-10 sml/min.
Breath detection	Adaptive threshold, minimum 1 vol% change in CO ₂ concentration.
Respiration rate	0 to 150 ± 1 breaths/min. (Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.)
Fi and ET	FiCO ₂ and EtCO ₂ are displayed after one breath and have a continuously updated breath average. The following method is used to calculate end-tidal (ET) values: - The highest concentration of CO ₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. EtCO ₂ will typically decrease below nominal value (ET _{nom}) when respiration rate (RR) exceeds the RR threshold (RR _{th}) according to the following formula: $Et = Et_{nom} \times \sqrt{95/RR} \text{ for } RR > 95$ (with NomoLine HH Adult/Pediatric Airway Adapter Set - REF 3827) Measured according to EN ISO 80601-2-55.
Sensor head	Dual channel NDIR type gas analyzer measuring at 3.5 to 4.5 μm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel).

Compensations	Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO ₂ .		
Calibration	No span calibration is required.		
Warm-up time	< 10 seconds (Concentrations reported and full accuracy)		
CO ₂ rise time at 50sml/min sample flow	≤ 200 ms (Measured according to EN ISO 80601-2-55.)		
NomoLine ISA CO ₂ system response time	< 3 seconds		
☆AwRR	0 rpm to 150 rpm		
☆AwRR Accuracy	± 1 rpm		
☆ Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO ₂	(0 to 15) vol%	±(0.2 vol% + 2% of reading)
		(15 to 25) vol%	Unspecified
The accuracy specifications above are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.			
☆Accuracy- All Conditions	CO ₂	±(0.3 kPa + 4% of reading)	
The accuracy specification above is valid for all specified environmental conditions except for interference specified in Section <i>Effects From Water Vapor Partial Pressure On Gas Readings</i> and Section <i>Interfering Gas Effects</i> .			

Effects from Water Vapor Partial Pressure on Gas Readings:

When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The CO₂ measurement will always show the actual partial pressure at the current humidity level in the gas sample. As the NomoLine sampling line removes all condensed water, no water will reach NomoLine ISA CO₂ system. However at an ambient temperature of 37 °C and a breathing gas with a relative humidity of 95% the CO₂ reading will typically be 6% lower than corresponding partial pressure after removal of all water.

Interfering Gas Effects:

Gas	Gas Level	Effect on CO ₂
N ₂ O ¹⁾	60 vol%	- ²⁾
HAL ¹⁾	4 vol%	- ³⁾
ENF, ISO, SEV ¹⁾	5 vol%	+8% of reading ⁴⁾
DES ¹⁾	15 vol%	+12% of reading ⁴⁾
Xe (Xenon) ¹⁾	80 vol%	-10% of reading ⁴⁾
He (Helium) ¹⁾	50 vol%	-6% of reading ⁴⁾

Gas	Gas Level	Effect on CO ₂
Metered dose inhaler propellants ¹⁾	Not for use with metered dose inhaler propellants	
C ₂ H ₅ OH (Ethanol) ¹⁾	0.3 vol%	– ³⁾
C ₃ H ₇ OH (Isopropanol) ¹⁾	0.5 vol%	– ³⁾
CH ₃ COCH ₃ (Acetone) ¹⁾	1 vol%	– ³⁾
CH ₄ (Methane) ¹⁾	3 vol%	– ³⁾
CO (Carbon monoxide) ⁵⁾	1 vol%	– ³⁾
NO (Nitrogen monoxide) ⁵⁾	0.02 vol%	– ³⁾
O ₂ ⁵⁾	100 vol%	– ²⁾

Note 1: According to the EN ISO 80601-2-55:2011 standard.

Note 2: Negligible interference with N₂O / O₂ concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.

Note 3: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 4: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO₂ readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO₂ and 50 vol% Helium, the actual measured CO₂ concentration will typically be $(1-0.06) * 5.0 \text{ vol\%} = 4.7 \text{ vol\% CO}_2$.

Note 5: In addition to the EN ISO 80601-2-55:2011 standard.

Masimo Mainstream Module

Dimensions (W × D × H)	38 mm × 37 mm × 34 mm (1.49” × 1.45” × 1.34”)
Weight	≤ 25 g (cable excluded)
According to the degree of protection against harmful ingress of water	IP44
Mechanical robustness	Withstand repeated 1.8 m drops on a hard surface. Complies with requirements for shock and vibration for professional transportation according to EN ISO 80601-2-55:2011 and requirements for road ambulances according to EN1789:2007 (clause 6.4).
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Surface temperature (at ambient temp. 23 °C)	Max 39 °C / 102 °F
Airway adapters	Disposable adult/pediatric:

	<ul style="list-style-type: none"> - Adds less than 6 ml deadspace - Pressure drop less than 0.3 cm H₂O @ 30 LPM Disposable infant: <ul style="list-style-type: none"> - Adds less than 1 ml deadspace - Pressure drop less than 1.3 cm H₂O @ 10 LPM (Infant Airway Adapter recommended for Tracheal Tube ID size ≤ 4 mm)		
Breath detection	Adaptive threshold, minimum 1 vol% change in CO ₂ concentration.		
Respiration rate	0 to 150 ± 1 bpm. The respiration rate I displayed after three breaths and the average value is updated every breath. (Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.)		
Fi and ET	FiCO ₂ and EtCO ₂ are displayed after one breath and have a continuously updated breath average. The following method is used to calculate end-tidal (ET) values: <ul style="list-style-type: none"> - The highest concentration of CO₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. EtCO ₂ will be within specification for all respiration rates up to 150 bpm. (Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.)		
Probe	2-9 channel NDIR type gas analyzer measuring at 4-10 μm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel). Pressure, temperature and full spectral interference correction.		
Calibration	No span calibration required for the IR bench.		
Warm-up Time	< 10 seconds (full accuracy)		
Rise time (@ 10 l/min)	≤ 90 ms (measured @10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas)		
Total system response time	< 1 second (Measured according to EN ISO 80601-2-55)		
☆AwRR	0 rpm to 150 rpm		
☆AwRR Accuracy	± 1 rpm		
☆ Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO ₂	(0 to 15) vol%	±(0.2 vol% + 2% of reading)
The accuracy specifications above are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.			
☆Accuracy- All Conditions	CO ₂	±(0.3 kPa + 4% of reading)	
The accuracy specification above is valid for all specified environmental conditions except for interference specified in Section <i>Effects From Water Vapor Partial Pressure On Gas Readings</i>			

and Section <i>Interfering Gas Effects</i> .
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Interfering Gas Effects:

Gas	Gas Level	CO ₂	Agents	N ₂ O
N ₂ O ⁴⁾	60 vol%	- ^{1&2)}	- ¹⁾	- ¹⁾
HAL ⁴⁾	4 vol%	- ¹⁾	- ¹⁾	- ¹⁾
ENF, ISO, SEV ⁴⁾	5 vol%	+8% of reading ³⁾	- ¹⁾	- ¹⁾
DES ⁴⁾	15 vol%	+12% of reading ³⁾	- ¹⁾	- ¹⁾
Xe (Xenon) ⁴⁾	80 vol%	-10% of reading ³⁾	- ¹⁾	- ¹⁾
He (Helium) ⁴⁾	50 vol%	-6% of reading ³⁾	- ¹⁾	- ¹⁾
Metered Dose Inhaler Propellants ⁴⁾	Not for use with metered dose inhaler propellants			
C ₂ H ₅ OH (Ethanol) ⁴⁾	0.3 vol%	- ¹⁾	- ¹⁾	- ¹⁾
C ₃ H ₇ OH (Isopropanol) ⁴⁾	0.5 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CH ₃ COCH ₃ (Acetone) ⁴⁾	1 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CH ₄ (Methane) ⁴⁾	3 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CO (Carbon monoxide) ⁵⁾	1 vol%	- ¹⁾	- ¹⁾	- ¹⁾
NO (Nitrogen monoxide) ⁵⁾	0.02 vol%	- ¹⁾	- ¹⁾	- ¹⁾
O ₂ ⁵⁾	100 vol%	- ^{1&2)}	- ¹⁾	- ¹⁾

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: For probes not measuring N₂O and/or O₂ the concentrations shall be set from host according to the instructions. (IRMA CO₂ measures neither N₂O nor O₂.)

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO₂ readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO₂ and 50 vol% Helium, the measured CO₂ concentration will typically be $(1-0.06) * 5.0 \text{ vol\%} = 4.7 \text{ vol\% CO}_2$.

Note 4: According to the EN ISO 80601-2-55:2011 standard.

Note 5: In addition to the EN ISO 80601-2-55:2011 standard.

A.13 C.O.

Not applicable to iM50 or M50.

Technique	Thermodilution Technique
Measure Parameters	C.O., TB, TI
Measuring Range	
C.O.	0.1 L/min to 20 L/min
TB	23 °C to 43 °C(73.4 °F to 109.4 °F)
TI	-1 °C to 27 °C(30.2 °F to 80.6 °F)
Resolution	
C.O.	0.1 L/min
TB, TI	0.1 °C (+0.1 °F)
Accuracy	
C.O.	±5% or ± 0.2 L/min, whichever is greater
TB	±0.1 °C (not including sensor)
TI	±0.1 °C (not including sensor)

NOTE:

At least 90% of the C.O. data should reside inside the bounded region, and the lower 95% confidence interval should not exceed 85%.

A.14 AG

Complies with ISO 80601-2-55: 2011.

EDAN G7 module and Masimo module are applicable to iM70, iM80 and M80. Dräger Minimodule is only applicable to iM80 and M80.

A.14.1 Sidestream

EDAN G7 Module

Intended Patient	Adult, pediatric, neonatal	
Measure Parameters	Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), CO ₂ , O ₂ , N ₂ O, AwRR, and MAC	
Unit	HAL, ISO, ENF, SEV, DES, N ₂ O: %; CO ₂ , O ₂ : mmHg, %, kPa, default is %; AwRR: bpm;	
☆ Measuring	CO ₂	0~15 vol%

Range	N ₂ O	0~100 vol%	
	Halothane/ Enflurane/ Isoflurane	0~8 vol%	
	Sevoflurane	0~10 vol%	
	Desflurane	0~22 vol%	
	O ₂ ¹	0~100%	
Resolution	N ₂ O, O ₂ ¹	1%	
	CO ₂ , AG	0.1%	
AwRR	Measurement range	2 ~ 150 rpm	
	Measuring accuracy	±1 bpm (120 bpm and below), Not specified (120 bpm above)	
	Resolution	1 rpm	
☆Accuracy	CO ₂	± (0.2vol% + 2% of reading)	Typical conditions: Ambient temperature: (25 ± 3) °C Barometric pressure: (760 ± 10) mmHg Balance gas: N ₂ Sample gas flowrate: 100 ml/min
	N ₂ O	± (2vol% + 2% of reading)	
	Hal, Enf, Iso, Sev, Des	± (0.15vol% + 5% of reading)	
	O ₂ ¹	± (1vol% + 2% of reading)	
	CO ₂	± (0.3vol% + 4% of reading)	Claimed working environment
	N ₂ O	± (2vol% + 5% of reading)	
	Hal, Enf, Iso, Sev, Des	± (0.2vol% + 10% of reading)	
	O ₂ ¹	± (2vol% + 2% of reading)	
Anesthetic gas identification method	Manually set anesthetic gas ¹ Automatic identification of an anesthetic gas ² Automatic identification of two anesthetic gases ³		
Anesthetic	1 st gas identification concentration ²	> 0.2vol%	

gas identification concentration	2 nd gas identification concentration ³	> 0.3vol% When the concentration of DES in the mixed gas is greater than 3%, the identification concentration of the second anesthetic gas should be greater than 10% of the DES concentration.
Sample Gas Flowrate	150 ml/min, accuracy ± 15 ml/min	
Warm-up Time	Display reading within 20 s; reach to the designed accuracy within 2 minutes.	
Rise Time	CO ₂ / N ₂ O/ DES/ SEV/ ISO/ ENF	< 400ms
	HAL/ O ₂	< 500 ms
	with 2 m gas sampling tube, sample gas flowrate: 150 ml/min	
Response Time	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 150 ml/min)	
Work Mode	Standby, measure	
O ₂ Compensation	Manual: without O ₂ module Range: 0% to 100% Resolution: 1% Default: 16% Auto: with O ₂ module	
Humidity Compensation Method	ATPD (default), BTPS	
Zero Calibration	Auto, Manual	
☆ Alarm	EtCO ₂ , FiCO ₂ , AwRR, EtAA, FiAA, EtO ₂ , FiO ₂ , EtN ₂ O, FiN ₂ O	
☆ Apnea Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	
Data Sample Rate	100 Hz	
Drift of Measure Accuracy	Meets the requirements of the measure accuracy	
Barometric Pressure Compensation	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)	

Note 1: This function is available in O₂ module.

Note 2: This function is available in G7, G7+ modules.

Note 3: This function is available in G7A, G7A+, G7S, and G7S+ modules.

Note 4: This function is available in G7S and G7S+ modules.

Interfering Gas Effects:

Gas	Gas Level (%)	Quantitative Effect/Comments
Xenon/Helium/Metered dose inhaler propellants	Not applicable	Not applicable
Ethanol/Isopropanol/Acetone	0.1%	None
Methane	1%	None

Masimo ISA analyzer

Module Type	ISA AX+	Displaying the concentration of CO ₂ , N ₂ O, and two anaesthesia agent and identifying the anaesthesia agent automatically (built-in module)
	ISA OR+	Displaying the concentration of CO ₂ , O ₂ , N ₂ O, and two anaesthesia agent and identifying the anaesthesia agent automatically (built-in module)
Measurement Parameters	CO ₂ , N ₂ O, O ₂ , Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), AwRR, MAC	
Measurement Principle	CO ₂ , N ₂ O, Anaesthesia Agent: infra-red absorption characteristic; O ₂ : Paramagnetic method	
Dimensions (W × D × H)	ISA AX+: 33 mm × 78 mm × 49 mm (1.3" × 3.1" × 1.9") ISA OR+: 49 mm × 90 mm × 100 mm (1.9" × 3.5" × 3.9") Excluding cable, tubing and Nomoline.	
Weight	ISA AX+: < 130 g (cable included) ISA OR+: < 420 g (cable included)	
According to the degree of protection against harmful ingress of water	IPX4	
Ambient CO ₂	≤ 800 ppm (0.08 vol%)	
Mechanical robustness	Meets the shock and vibration requirements EN ISO 80601-2-55:2011 clause 201.15.3.5.101.1	
Recovery time after defibrillator test	Unaffected	
Drift of measurement accuracy	No drift	

Water handling	NomoLine Family sampling lines with proprietary water removal tubing.
Sampling flow rate	(50 ± 10) sml/min Note: Volumetric flow rate of air corrected to standardized conditions of temperature and pressure.
Breath detection	Adaptive threshold, minimum 1 vol% change in CO ₂ concentration.
Respiration rate	0 to 150 ± 1 breaths/min. (Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.)
Fi and ET	<p>Fi and ET are displayed after one breath and have a continuously updated breath average.</p> <p>The following methods are used to calculate end-tidal (ET) values:</p> <ul style="list-style-type: none"> - CO₂: The highest concentration of CO₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. - O₂: The highest/lowest concentration of O₂ during the expiratory phase (depending on whether ETO₂ is higher or lower than FiO₂). - N₂O and anesthetic agents: The momentary gas concentration at the time point where ETCO₂ is detected. <p>ET will typically decrease below nominal value (ET_{nom}) when respiration rate (RR) exceeds the RR threshold (RR_{th}) according to the following formulas:</p> <p>CO₂ $ET = ET_{nom} \times \sqrt{(70/RR)}$ for RR_{th} > 70</p> <p>N₂O, O₂, DES, ENF, ISO, SEV $ET = ET_{nom} \times \sqrt{(50/RR)}$ for RR_{th} > 50</p> <p>HAL $ET = ET_{nom} \times \sqrt{(35/RR)}$ for RR_{th} > 35</p> <p>NOTE: Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101</p>
Automatic agent identification	Primary and secondary agents
Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 μm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel). O ₂ measurements by Servomex's paramagnetic sensor.
Compensations	Automatic compensation for pressure, temperature and broadening effects on CO ₂ .
Calibration	No span calibration is required for the IR bench. An automatic Zeroing is performed typically 1 to 3 times per day.
Warm-up Time	< 20 seconds (Concentrations reported, automatic agent identification enabled and full accuracy)

Rise time (@ 50 sml/min sample flow)	$\text{CO}_2 \leq 300 \text{ ms}$ $\text{N}_2\text{O}, \text{O}_2, \text{ENF}, \text{ISO}, \text{SEV}, \text{DES} \leq 400 \text{ ms}$ $\text{HAL} \leq 500 \text{ ms}$ (Measured according to EN ISO 80601-2-55)		
Primary Agent Threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.		
Secondary Agent Threshold	0.2 vol% + 10% of total agent concentration		
Agent Identification Time	< 20 seconds (typically < 10 seconds)		
Total system response time	< 4 seconds (with 2 m Nomoline Airway Adapter Set sampling line)		
Work Mode	Measure		
Data Update Period	1 s		
Measurement Range	CO_2 : 0 to 25 vol% O_2 : 0 to 100 vol% N_2O : 0 to 82vol% HAL, ENF, ISO, SEV, DES: 0 to 25 vol% AwRR: 0 rpm to 150 rpm		
Resolution	CO_2 : 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N_2O : 1% O_2 : 1% AwRR: 1 rpm		
☆ Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO_2	0 to 15 vol%	$\pm(0.2 \text{ vol}\% + 2\% \text{ of reading})$
		15 to 25 vol%	Unspecified
	N_2O	0 to 82 vol%	$\pm(2 \text{ vol}\% + 2\% \text{ of reading})$
	HAL, ENF, ISO	0 to 8 vol %	$\pm(0.15 \text{ vol}\% + 5\% \text{ of reading})$
		8 to 25 vol %	Unspecified
	SEV	0 to 10 vol %	$\pm(0.15 \text{ vol}\% + 5\% \text{ of reading})$
10 to 25 vol %		Unspecified	
DES	0 to 22 vol %	$\pm(0.15 \text{ vol}\% + 5\% \text{ of reading})$	
	22 to 25 vol %	Unspecified	

	O ₂	0 to 100 vol %	±(1 vol% + 2% of reading)
The accuracy specifications above are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.			
☆ Accuracy- All Conditions	Gas	Accuracy	
	CO ₂	±(0.3 kPa + 4% of reading)	
	N ₂ O	±(2 kPa + 5% of reading)	
	Agents	±(0.2 kPa + 10% of reading) (The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set)	
	O ₂	±(2 kPa + 2% of reading)	
The accuracy specification above is valid for all specified environmental conditions except for interference specified in Section <i>Effects From Water Vapor Partial Pressure On Gas Readings</i> and Section <i>Interfering Gas Effects</i> .			
☆ AwRR Accuracy	±1 rpm		
☆ Apnea Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.		
☆ Alarm	Providing alarms of EtCO ₂ , FiCO ₂ , EtO ₂ , FiO ₂ , EtN ₂ O, FiN ₂ O, EtAA, FiAA, AwRR		
Exhaust Emission	Interface for exhaust collection is available		
Support:			
<ul style="list-style-type: none"> ◆ Zero calibration ◆ O₂ compensation ◆ N₂O compensation 			

Effects from Water Vapor Partial Pressure on Gas Readings:

When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. However at an ambient temperature of 37 °C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.

Interfering Gas Effects:

Gas	Gas Level	CO ₂	Agents	N ₂ O
		ISA AX+ ISA OR+		

N ₂ O ⁴⁾	60 vol%	- ¹⁾	- ¹⁾	- ¹⁾
HAL ⁴⁾	4 vol%	- ¹⁾	- ¹⁾	- ¹⁾
ENF, ISO, SEV ⁴⁾	5 vol%	- ¹⁾	- ¹⁾	- ¹⁾
DES ⁴⁾	15 vol%	- ¹⁾	- ¹⁾	- ¹⁾
Xe (Xenon) ⁴⁾	80 vol%	-10% of reading ³⁾	- ¹⁾	- ¹⁾
He (Helium) ⁴⁾	50 vol%	-6% of reading ³⁾	- ¹⁾	- ¹⁾
Metered Dose Inhaler Propellants ⁴⁾	Not for use with metered dose inhaler propellants			
C ₂ H ₅ OH (Ethanol) ⁴⁾	0.3 vol%	- ¹⁾	- ¹⁾	- ¹⁾
C ₃ H ₇ OH (Isopropanol) ⁴⁾	0.5 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CH ₃ COCH ₃ (Acetone) ⁴⁾	1 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CH ₄ (Methane) ⁴⁾	3 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CO (Carbon monoxide) ⁵⁾	1 vol%	- ¹⁾	- ¹⁾	- ¹⁾
NO (Nitrogen monoxide) ⁵⁾	0.02 vol%	- ¹⁾	- ¹⁾	- ¹⁾
O ₂ ⁵⁾	100 vol%	- ²⁾	- ¹⁾	- ¹⁾

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: Negligible interference with N₂O / O₂ concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO₂ readings by 6%. This means that if measuring on a mixture containing 5.0vol% CO₂ and 50vol% Helium, the actual measured CO₂ concentration will typically be $(1-0.06) * 5.0\text{vol}\% = 4.7\text{vol}\% \text{CO}_2$.

Note 4: According to the EN ISO 80601-2-55:2011 standard.

Note 5: In addition to the EN ISO 80601-2-55:2011 standard.

Dräger Minimodule

Method	Sidestream gas measurement Infrared measurement: CO ₂ , N ₂ O, anesthetic agents Paramagnetic measurement: O ₂
Barometric Compensation	Pressure Automated compensation

Gas Sampling Rate	200 mL/min \pm 20 mL/min
Maximum time until water trap requires draining	41 hrs (sample gas under BTPS conditions, ambient air 23 °C)
Total System Response Time	< 3 s
Drift Compensation (zeroing)	Automated cyclical zeroing, once per day (in error-free operation)
Zeroing Duration	< 20 s
Cross Sensitivity	None concerning alcohol (< 3000 ppm blood conc.), acetone (< 1000 ppm), methane, water vapor, NO, and CO
☆O ₂	
☆Range	(0 to 100) Vol%
☆Accuracy ¹	\pm (2.5 Vol% + 2.5 % rel.)
Rise Time (t _{10...90}) ⁴	< 500 ms
Time to Specified Accuracy ³	< 450 s
☆CO ₂	
☆Range	(0 to 13.6) Vol%
☆Accuracy ¹	\pm (0.43 Vol% + 8% rel.)
Rise Time (t _{10...90}) ⁴	< 350 ms
Time to availability ²	< 60 s
Time to Specified Accuracy ³	< 450 s
☆N ₂ O	
☆Range	(0 to 100) Vol%
☆Accuracy ¹	\pm (2 Vol% + 8% rel.)
Rise Time (t _{10...90}) ⁴	< 350 ms
Time to Specified Accuracy ³	< 450 s
☆Anesthetic Gases Range	
☆Halothane	(0 to 8.5) Vol%
☆Isoflurane	(0 to 8.5) Vol%
☆Enflurane	(0 to 10) Vol%
☆Sevoflurane	(0 to 10) Vol%
☆Desflurane	(0 to 20) Vol%

☆Accuracy ¹	$\pm(0.2 \text{ Vol}\% + 15 \% \text{ rel.})$
Rise Time (t10...90) ⁴	< 450 ms
Time to Specified Accuracy ³	< 450 s
Automatic Detection	
Primary Gas	At the latest at 0.3 Vol%
Secondary Gas	At the latest at 0.4 Vol% With a Desflurane concentration greater than 4 Vol%, mixture detection occurs at the latest when the concentration of the second anesthetic gas rises above 10% of the Desflurane concentration.
☆Respiratory Rate	
☆Range	0/min to 100/min (Respiratory rate is derived from the CO ₂ value)
☆Accuracy	0/min to 60/min: ± 1 /min > 60 /min: not specified
Resolution	1 /min

Note 1: In accordance to ISO 21647:2004 and ISO 80601-2-55:2011, for respiratory rates from 0...60 ¹/min with I:E ratio of 1:1.

Note 2: Duration from power on at 10 °C module temperature to transmission of measurements with unspecified accuracy

Note 3: Duration from power on at 10 °C module temperature to transmission of measurements with specified accuracy

Note 4: With Dräger sample line and water trap

A.14.2 Mainstream

Masimo IRMA module

Module Type	IRMA AX+	Displaying the concentration of CO ₂ , N ₂ O and two anaesthesia agent and indentifying two anaesthesia agent
Measurement Parameters	CO ₂ , N ₂ O, HAL, Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), AwRR, MAC	
Measurement Principle	CO ₂ , N ₂ O, anaesthesia agent: infra-red absorption characteristic	

Dimensions (W × D × H)	38 mm × 37 mm × 34 mm (1.49" × 1.45" × 1.34")
Weight	≤ 25 g (cable excluded)
According to the degree of protection against harmful ingress of water	IP44
Mechanical robustness	Withstand repeated 1.8 m drops on a hard surface. Complies with requirements for shock and vibration for professional transportation according to EN ISO 80601-2-55:2011 and requirements for road ambulances according to EN1789:2007 (clause 6.4).
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Surface temperature (at ambient temp. 23 °C)	Max 46 °C / 115 °F
Airway adapters	Disposable adult/pediatric: <ul style="list-style-type: none"> - Adds less than 6 ml deadspace - Pressure drop less than 0.3 cm H₂O @ 30 LPM Disposable infant: <ul style="list-style-type: none"> - Adds less than 1 ml deadspace - Pressure drop less than 1.3 cm H₂O @ 10 LPM (Infant Airway Adapter recommended for Tracheal Tube ID size ≤ 4 mm)
Breath detection	Adaptive threshold, minimum 1 vol% change in CO ₂ concentration.
Respiration rate	0 to 150 ± 1 bpm. The respiration rate I displayed after three breaths and the average value is updated every breath. (Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.)

Fi and ET	<p>IRMA AX+: CO₂, N₂O, primary and secondary agents (HAL, ENF, ISO, SEV, DES)</p> <p>Fi and ET are displayed after one breath and have a continually updated breath average.</p> <p>The following method is used to calculate end-tidal (ET) values:</p> <ul style="list-style-type: none"> - CO₂: The highest concentration of CO₂ during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. - N₂O and anesthetic agents: The momentary gas concentration at the time point where ET_{CO₂} is detected. <p>ET-values for anesthetic agents and N₂O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm. The maximum decrease is described by the formula $ET = 80 * ET_{nom} / RR$.</p> <p>ET_{CO₂} will be within specification for all respiration rates up to 150 bpm. (Measured at I/E ratio 1:1 using breath simulator according to EN ISO 80601-2-55 fig. 201.101.)</p>
Automatic agent identification	Primary and secondary agents
Probe	2-9 channel NDIR type gas analyzer measuring at 4-10 μm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel). Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter. No span calibration required for the IR bench.
Warm-up Time	< 20 seconds (agent identification enabled and full accuracy)
Rise Time (@ 10 l/min)	<p>CO₂ ≤ 90 ms</p> <p>N₂O ≤ 300 ms</p> <p>HAL, ISO, ENF, SEV, DES ≤ 300 ms</p> <p>(Measured @ 10 l/min with gas concentration steps corresponding to 30% of total measuring range for each gas.)</p>
Primary Agent Threshold	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.
Secondary Agent Threshold	0.2 vol% + 10% of total agent concentration
Agent Identification Time	< 20 seconds (typically < 10 seconds)
Total System Response Time	< 1 second (Measured according to EN ISO 80601-2-55.)

Barometric Pressure Compensation	Automatic		
Data Update Period	1 s		
Measurement Range	CO ₂ : 0 to 25 vol% N ₂ O: 0 to 82 vol% HAL, ENF, ISO, SEV, DES: 0 to 25 vol% AwRR: 0 to 150 rpm		
Resolution	CO ₂ : 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N ₂ O: 1% AwRR: 1 rpm		
☆Accuracy- Standard Conditions	Gas	Range	Accuracy
	CO ₂	0 to 15 vol%	±(0.2 vol% + 2% of reading)
	N ₂ O	0 to 82 vol%	±(2 vol% + 2% of reading)
	HAL ISO ENF	0 to 8 vol%	±(0.15 vol% + 5% of reading)
	SEV	0 to 10 vol%	±(0.15 vol% + 5% of reading)
	DES	0 to 22 vol%	±(0.15 vol% + 5% of reading)
The accuracy specifications above are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.			
☆Accuracy- All Conditions	Gas	Accuracy	
	CO ₂	±(0.3 kPa + 4% of reading)	
	N ₂ O	±(2 kPa + 5% of reading)	
	Agents	±(0.2 kPa + 10% of reading) (The accuracy specification for IRMA AX+ is not valid if more than two agents are present in the gas mixture)	
The accuracy specification above is valid for all specified environmental conditions except for interference specified in Section <i>Effects From Water Vapor Partial Pressure On Gas Readings</i> and Section <i>Interfering Gas Effects</i> .			
☆AwRR Accuracy	±1 rpm		
☆Apnea Alarm Delay	20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.		
Work Mode	Measure		

☆ Alarm	Providing alarms of EtCO ₂ , FiCO ₂ , EtN ₂ O, FiN ₂ O, EtAA, FiAA, AwRR
Support:	
<ul style="list-style-type: none"> ◆ Real-time gas concentration monitoring ◆ Zero calibration 	

Interfering Gas Effects:

Gas	Gas Level	CO ₂	Agents	N ₂ O
		IRMA AX+		
N ₂ O ⁴⁾	60 vol%	- ^{1&2)}	- ¹⁾	- ¹⁾
HAL ⁴⁾	4 vol%	- ¹⁾	- ¹⁾	- ¹⁾
ENF, ISO, SEV ⁴⁾	5 vol%	- ¹⁾	- ¹⁾	- ¹⁾
DES ⁴⁾	15 vol%	- ¹⁾	- ¹⁾	- ¹⁾
Xe (Xenon) ⁴⁾	80 vol%	-10% of reading ³⁾	- ¹⁾	- ¹⁾
He (Helium) ⁴⁾	50 vol%	-6% of reading ³⁾	- ¹⁾	- ¹⁾
Metered Dose Inhaler Propellants ⁴⁾	Not for use with metered dose inhaler propellants			
C ₂ H ₅ OH (Ethanol) ⁴⁾	0.3 vol%	- ¹⁾	- ¹⁾	- ¹⁾
C ₃ H ₇ OH (Isopropanol) ⁴⁾	0.5 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CH ₃ COCH ₃ (Acetone) ⁴⁾	1 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CH ₄ (Methane) ⁴⁾	3 vol%	- ¹⁾	- ¹⁾	- ¹⁾
CO (Carbon monoxide) ⁵⁾	1 vol%	- ¹⁾	- ¹⁾	- ¹⁾
NO (Nitrogen monoxide) ⁵⁾	0.02 vol%	- ¹⁾	- ¹⁾	- ¹⁾
O ₂ ⁵⁾	100 vol%	- ^{1&2)}	- ¹⁾	- ¹⁾

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: For probes not measuring N₂O and/or O₂ the concentrations shall be set from host according to the instructions. (IRMA AX+ does not measure O₂)

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO₂ readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO₂ and 50 vol% Helium, the measured CO₂ concentration will typically be $(1-0.06) * 5.0 \text{ vol\%} = 4.7 \text{ vol\% CO}_2$.

Note 4: According to the EN ISO 80601-2-55:2011 standard.

Note 5: In addition to the EN ISO 80601-2-55:2011 standard.

A.15 Interfaces

A.15.1 Analog Output

Bandwidth (-3 dB; reference frequency: 10 Hz)	Monitor: 0.5 Hz to 40 Hz Diagnosis: 0.5 Hz to 40 Hz Diagnosis 1: 0.05 Hz to 40 Hz Surgery: 1 Hz to 20 Hz Enhanced: 2 Hz ~18 Hz Customized: When Low-pass Filter < 40 Hz, Bandwidth is High-pass Filter ~ Low-pass Filter; When Low-pass Filter > 40 Hz, Bandwidth is High-pass ~40 Hz.
Maximum Transmission Delay (Diagnosis Mode)	500 ms
Sensitivity	1 V/1 mV ±10%
PACE Rejection/ Enhancement	No PACE rejection or enhancement
Waveform Display	Consistent with the calculation leads.
Compliant with Standard and Directive	Complies with the requirements in terms of short circuit protection and leakage current in EN60601-1.
Output Impedance	< 500 Ω
Interface Type	PS2 connector

NOTE:

While using analog output, set the calculation lead as following:

- 1) In 3 Electrodes mode, set to Lead I, Lead II, or Lead III.
- 2) In 5 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V.
- 3) In 6 Electrodes mode, set to I, II, III, and leads corresponding to Va, Vb.
- 4) In 10 Electrodes mode, set to Lead I, Lead II, Lead III or Lead V1~V6.

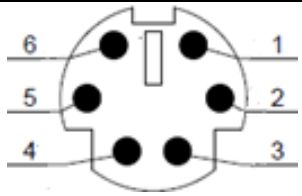
A.15.2 Defibrillator Synchronization

Output Impedance	< 500 Ω
Maximum Time Delay	35 ms (R-wave peak to leading edge of pulse)
Waveform	Rectangular wave
Amplitude	High level: 3.5 V to 5.5 V, providing a maximum of 1 mA output current; Low level: < 0.5 V, receiving a maximum of 5 mA input current
Minimum Required R-wave Amplitude	0.3 mV
Pulse Width	100 ms \pm 10%
Limited Current	15 mA rating
Rising and Falling Time	< 1 ms
Interface Type	PS2 connector

A.15.3 Nurse Call

Drive Mode	Voltage output
Power Supply	\leq 12.6 VDC, 200 mA Max.
Interface Signal	12 V power supply and PWM waveform
Interface Type	PS2 connector

PS2 connector Definition for Analog Output/Defibrillator Synchronization/Nurse Call

	PIN.NO.	Signal name	Signal Description
	1	ANALOG_OUT	Analog out signal
	2	GND	Ground
	3	SYS_OUT	Defibrillator Synchronization signal
	4	+12V	Nurse call power
	5	GND	Ground
	6	NURSE_OUT	Nurse call control signal

A 15.4 USB Interfaces

Number of USB Interfaces	Standard:2
Drive Mode	HOST interface, USB1.0/2.0 protocol

Power Supply	5 VDC±5%, 500 mA Max.
Interface Type	USB A-type port

A.15.5 VGA Interface

Number of VGA Interface	1
Horizontal Refreshing Rate	(30-94) KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

A.15.6 RS232 Interface

Applicable to iM80 and M80.

Level	RS232
Output Voltage Range	-13.2 V~+13.2 V
Interface Type	DB-9 female receptacle

A.15.7 Wired Network Interface

Specification	100-Base TX (IEEE802.3)
Interface Type	Standard RJ-45 network interface

B EMC Information

- Guidance and Manufacture's Declaration

B.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
iM50, iM60, iM70, iM80, M50 and M80 are intended for use in the electromagnetic environment specified below. The customer or the user of iM50, iM60, iM70, iM80, M50 and M80 should assure that they are used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	iM50, iM60, iM70, iM80, M50 and M80 use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	iM50, iM60, iM70, iM80, M50 and M80 are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

NOTE:

The EMISSIONS characteristics of iM50/iM60/iM70/iM80/M50/M80 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) iM50/iM60/iM70/iM80/M50/M80 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

B.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity
iM50, iM60, iM70, iM80, M50 and M80 are intended for use in the electromagnetic environment specified below. The customer or the user of iM50, iM60, iM70, iM80, M50 and M80 should assure that they are used in such an environment.

Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV for line to line ±2 kV for line to ground	±1 kV for line to line ±2 kV for line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles) Single phase: at 0° 0 % U_T ; 250/300 cycle	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 cycles) Single phase: at 0° 0 % U_T ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of iM50, iM60, iM70, iM80, M50 and M80 requires continued operation during power mains interruptions, it is recommended that iM50, iM60, iM70, iM80, M50 and M80 be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

B.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
iM50, iM60, iM70, iM80, M50 and M80 are intended for use in the electromagnetic environment specified below. The customer or the user of iM50, iM60, iM70, iM80, M50 and M80 should assure that they are used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC/EN 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms} 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of iM50, iM60, iM70, iM80, M50 and M80, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150KHz to 80MHz
Radiated RF IEC/EN 61000-4-3	6V _{rms} ^c in ISM bands between 0.15 MHz and 80 MHz	6V _{rms} ^c in ISM bands between 0.15 MHz and 80 MHz	
	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz
	See Table 1	Comply with Table 1	$d = 6\sqrt{P} / E$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer). Where P is the maximum output


			<p>power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which iM50, iM60, iM70, iM80, M50 and M80 are used exceeds the applicable RF compliance level above, iM50, iM60, iM70, iM80, M50 and M80 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iM50, iM60, iM70, iM80, M50 and M80.</p> <p>^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.</p> <p>^c The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.</p>			

Table 1 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

B.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and iM50 iM60 iM70 iM80 M50 M80			
iM50, iM60, iM70, iM80, M50 and M80 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iM50, iM60, iM70, iM80, M50 and M80 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iM50, iM60, iM70, iM80, M50 and M80 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

C Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

NOTE:

If your monitor has been preconfigured according to your requirements, the settings at delivery will be different from the default settings listed here.

C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

C.2 Alarm Default Settings

Alarm Settings	
Pause Time	120 s
Sensor Off Alarm	Off
Alarm Latch	Off

C.3 ECG Default Settings

ECG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
ARR Analysis Threshold Value			
Low Voltage(Limb)	0.5 mV		
Pause	3 s		
Sustain VT	30 s		
PAC Bigeminy	8/min		
Pauses/min High	8/min		
PVCs High	10/min		

PAC Trigeminy	16/min		
ExtremeTachy	160	180	200
Extreme Brady	30	50	60
Pace	Off		
Electrode Type	5 Electrodes		
Screen Layout	Normal		
Filter	Monitor		
Smart Lead Off	Off		
Heart Volume	3		
ST Analysis	Off		
Alarm Switch	Off		
Alarm Level	Medium		
Alarm Record	Off		
Alarm High Limit (ST-X)	0.2		
Alarm Low Limit (ST-X)	-0.2		
QT Analysis	Off		
QTc	500	480	460
Δ QTc	60		
X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.			
	ADU	PED	NEO
ARR Analysis	On	Off	Off
ARR Alarm Settings	Alarm Switch	Alarm Level	Alarm Record
Advanced ARR			
Asystole	On(non-adjustable)	High(non-adjustable)	Off
V-Fib/V-Tach	On	High(non-adjustable)	Off
R on T	On	Medium	Off
PVC	Off	Low	Off
Couplet	On	Low	Off
Run PVCs	On	Low	Off
PVC Bigeminy	On	Medium	Off

PVC Trigeminy	On	Low	Off
Tachy	On	Medium	Off
Brady	On	Medium	Off
Missed Beat	Off	Low	Off
Irr Rhythm	Off	Low	Off
Pacer not Capture	On	Medium	Off
Pacer not Pacing	On	Medium	Off
Vent Brady	On	High(non-adjustable)	Off
Vent Rhythm	On	Medium	Off
Sustain VT	On(non-adjustable)	High(non-adjustable)	Off
ExtremeTachy	On	High(non-adjustable)	Off
ExtremeBrady	On	High(non-adjustable)	Off
V-Tach	On	High(non-adjustable)	Off
Wide QRS Tachy	On	Medium	Off
Non-Sustain VT	On	Medium	Off
Afib	On	Medium	Off
Acc. Vent Rhythm	On	Low	Off
Pause	On	Medium	Off
Pauses/min High	On	Medium	Off
PVCs High	On	Medium	Off
VEB	Off	Low	Off
Multiform PVCs	Off	Low	Off
IPVC	Off	Low	Off
PAC Bigeminy	Off	Low	Off
PAC Trigeminy	Off	Low	Off
Low Voltage(Limb)	Off	Low	Off
Basic ARR			
ASYSTOLE	On	High (non-adjustable)	Off
VFIB/VTAC	On	High (non-adjustable)	Off
R ON T	On	Medium	Off
VT > 2	On	Medium	Off
COUPLET	On	Medium	Off

PVC	On	Medium	Off
BIGEMINY	On	Medium	Off
TRIGEMINY	On	Medium	Off
TACHY	On	Medium	Off
BRADY	On	Medium	Off
MISSEDBEATS	On	Medium	Off
IRR	On	Medium	Off
PNC	On	Medium	Off
PNP	On	Medium	Off
VBRADY	On	Medium	Off
VENT	On	Medium	Off

C.4 RESP Default Settings

RESP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	30	30	100
Alarm Low Limit	8	8	30
Apnea Alarm Time	20 s		
Calculation Type	Auto		
Resp Type	II		
Sweep	12.5 mm/s		
Amplitude	1		

C.5 SpO₂ Default Settings

SpO ₂ Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	100	100	95

Alarm Low Limit	90	90	88
Pitch Tone	On		
Sensitivity	Medium		
SatSeconds (Nellcor Module)	Off		
Sweep	12.5 mm/s		
SpO ₂ Desat Limit	80%		

C.6 PR Default Settings

PR Settings	ADU	PED	NEO
PR Source	SpO ₂		
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pulse Volume	3		
Alarm Source	Auto		

C.7 NIBP Default Settings

NIBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (SYS)	160	120	90
Alarm Low Limit (SYS)	90	70	40
Alarm High Limit (Map)	110	90	70
Alarm Low Limit (Map)	60	50	30
Alarm High Limit (Dia)	90	70	60
Alarm Low Limit (Dia)	50	40	20
Venipuncture pressure	60	40	30

Inflation value	EDAN Module	160	140	100
	Omron Module	180	180	120
	SunTech Module	160	140	90
Unit		mmHg		
Measure Mode		Manual		

C.8 TEMP Default Settings

TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	39.0
Alarm Low Limit (T1)	36.0	36.0	36.0
Alarm High Limit (T2)	39.0	39.0	39.0
Alarm Low Limit (T2)	36.0	36.0	36.0
Alarm High Limit (TD)	2.0	2.0	2.0
Unit	°C		

C.9 Quick TEMP Default Settings

Quick TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	/
Alarm Low Limit (T1)	36.0	36.0	/
Unit	°C		

C.10 IBP Default Settings

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		

Unit	mmHg		
Filter	12.5 Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	120, 70, 90	90, 60, 70
Alarm Low Limit (ART, P1, P2)	90, 50, 70	70, 40, 50	55, 20, 35
Alarm High Limit (PA)	35, 16, 20	60, 4, 26	60, 4, 26
Alarm Low Limit (PA)	10, 0, 0	24, -4, 12	24, -4, 12
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	4	4
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

C.11 CO₂ Default Settings

CO ₂ Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea Time	20 s		
O ₂ Compensation	16% (EDAN G2 Module and Respirationics Module) Low (Masimo Module)		
N ₂ O Compensation	0% (EDAN G2 Module and Respirationics Module) Low (Masimo Module)		
Anes Agent	0%		
Alarm High Limit (EtCO ₂)	50	50	45
Alarm Low Limit (EtCO ₂)	25	25	30
Alarm High Limit (FiCO ₂)	4	4	4
Alarm High Limit (AwRR)	30	30	100
Alarm Low Limit (AwRR)	8	8	30
Sweep	6.25 mm/s		

Amplitude	Low
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C.12 C.O. Default Settings

C.O. Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (TB)	40	40	40
Alarm Low Limit (TB)	30	30	30
Injective Temperature Source	Auto		
Temperature Unit	°C		
Interval	30		
Constant	0.542		

C.13 AG Default Settings

AG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Measure		
Apnea Time	20s		
Unit	%		
O ₂ Compensation	16% (EDAN G7 Module) Low (Masimo Module)		
N ₂ O Compensation	Low (Masimo Module)		
Anes Agent	HAL		
Alarm High Limit (EtCO ₂ AG)	6.6	6.6	5.9
Alarm Low Limit (EtCO ₂ AG)	3.3	3.3	3.9
Alarm Low Limit (FiCO ₂ AG)	0.5	0.5	0.5

Alarm High Limit (AwRR AG)	30	30	100
Alarm Low Limit (AwRR AG)	8	8	30
Alarm High Limit (EtO ₂)	100	100	100
Alarm Low Limit (EtO ₂)	0	0	0
Alarm High Limit (FiO ₂)	100	100	100
Alarm Low Limit (FiO ₂)	18	18	18
Alarm High Limit (EtN ₂ O)	55	55	55
Alarm Low Limit (EtN ₂ O)	0	0	0
Alarm High Limit (FiN ₂ O)	53	53	53
Alarm Low Limit (FiN ₂ O)	0	0	0
Alarm High Limit (EtHAL, EtENF, EnISO)	3	3	3
Alarm Low Limit (EtHAL, EtENF, EnISO)	0	0	0
Alarm High Limit (FiHAL, FiENF, FiISO)	2	2	2
Alarm Low Limit (FiHAL, FiENF, FiISO)	0	0	0
Alarm High Limit (EtSEV)	6	6	6
Alarm Low Limit (EtSEV)	0	0	0
Alarm High Limit (FiSEV)	5	5	5
Alarm Low Limit (FiSEV)	0	0	0
Alarm High Limit (EtDES)	8	8	8
Alarm Low Limit (EtDES)	0	0	0
Alarm High Limit (FiDES)	6	6	6
Alarm Low Limit (FiDES)	0	0	0
Sweep	6.25 mm/s		
Amplitude	2		

D Abbreviations

Abbr	English Full Name/Description
AC	Alternating Current
Acc. Vent Rhythm	Accelerated Idioventricular Rhythm
Adu	Adult
Afib	Atrial Fibrillation
AG	Anaesthesia Gas
Art	Arterial
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
AwRR	Airway Respiration Rate
BP	Blood Pressure
Brady	Bradycardia
BTPS	Body temperature and pressure, saturated
CI	Cardiac Index
C.O.	Cardiac Output
CISPR	International Special Committee on Radio Interference
CMS	Central Monitoring System
CO ₂	Carbon Dioxide
COHb	Carboxyhemoglobin
Couplet	Ventricular Couplets
CVP	Central Venous Pressure
DC	Direct Current
DDoS	Distributed Denial of Service
Des	Desflurane
Dia	Diastolic
DoS	Denial of Service
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic Compatibility

Abbr	English Full Name/Description
EMI	Electromagnetic Interference
Enf	Enflurane
ESU	Electrosurgical Unit
Et	End-tidal
EtCO ₂	End-tidal Carbon Dioxide
EtN ₂ O	End-tidal Nitrous Oxide
Eto	Ethylene Oxide
EtO ₂	End-tidal Oxygen
ExtremeTachy	Extreme Tachycardia
ExtremeBrady	Extreme Bradycardia
Fi	Fraction of Inspired
FiCO ₂	Fraction of Inspired Carbon Dioxide
FiN ₂ O	Fraction of Inspired Nitrous Oxide
FiO ₂	Fraction of Inspired Oxygen
Hal	Halothane
Hb	Hemoglobin
Hb-CO	Carbon Mono-xide Hemoglobin
HR	Heart Rate
IBP	Invasive Blood Pressure
ICP	Intracranial Pressure
ICU	Intensive Care Unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IPVC	Inserted Premature Ventricular Contraction
Irr Rhythm	Irregular Rhythm
Iso	Isoflurane
LA	Left Arm
LAP	Left Atrial Pressure
LCD	Liquid Crystal Display
LED	Light Emitting Diode

Abbr	English Full Name/Description
LL	Left Leg
Low Voltage(Limb)	Low QRS Voltage
MAP	Mean Arterial Pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic Resonance Imaging
Multiform PVCs	Multiformed Premature Ventricular Contractions
N/A	Not Applied
N ₂	Nitrogen
N ₂ O	Nitrous Oxide
Neo	Neonate
NIBP	Non-invasive Blood Pressure
Non-Sustain VT	Nonsustained Ventricular Tachycardia
O ₂	Oxygen
oxyCRG	Oxygen Cardio-respirogram
PA	Pulmonary Artery
PAC Bigeminy	Premature Atrial Contraction (PAC) Bigeminy
PAC Trigeminy	Premature Atrial Contraction (PAC) Trigeminy
PAWP	Pulmonary Artery Wedge Pressure
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse Rate
PVC	Premature Ventricular Contraction
PVC Bigeminy	Premature Ventricular Contraction Bigeminy
PVC Trigeminy	Premature Ventricular Contraction Trigeminy
R	Right
RA	Right Arm
RAP	Right Atrial Pressure
Resp	Respiration
RHb	Reduced Hemoglobin
RL	Right Leg

Abbr	English Full Name/Description
RR	Respiration Rate
Run PVCs	Run premature Ventricular Contractions
Sev	Sevoflurane
SpO ₂	Pulse Oxygen Saturation
Sustain VT	Sustained Ventricular Tachycardia
SYS	Systolic Pressure
Tachy	Tachycardia
TB	Blood Temperature
TD	Temperature Difference
TEMP	Temperature
USB	Universal Serial Bus
VEB	Ventricular Escape Beat
Vent Brady	Ventricular Bradycardia
Vent Rhythm	Ventricular Rhythm
V-Fib/V-Tach	Ventricular Fibrillation/Ventricular Tachycardia
V-Tach	Ventricular Tachycardia
Wide QRS Tachy	Wide QRS Tachycardia

P/N: 01.54.457239

MPN: 01.54.457239017



EDAN INSTRUMENTS, INC.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District, 518122 Shenzhen, P.R.China

Email: info@edan.com.cn

TEL: +86-755-2689 8326 FAX: +86-755-2689 8330

Website: www.edan.com.cn



EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH
Eiffestrasse 80, 20537 Hamburg Germany

TEL: +49-40-2513175

E-mail: shholding@hotmail.com