H10

Finger Oximeter

Version 1.5

User Manual

CE 0123

EDAN

About this Manual

P/N: 01.54.109755
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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.

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

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

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

EDAN will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by EDAN as

repairable by service personnel.

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

1 Intended use/Indications for Use

The device is a small, lightweight, portable device intended for use in measuring and displaying functional oxygen saturation of arterial haemoglobin (%SpO_2) and pulse rate (PR). The oximeters are intended for use by trained healthcare professionals in hospital environments. It is intended for spot-checking of adult and pediatric patient.

2 Precautions for Use

WARNING

1 Do not use the device in an MRI or CT environment.

2 Do not use the device in situations where alarms are required. The device has no alarms.

3 Explosion hazard: Do not use the device in an explosive atmosphere.

4 The oximeter is intended only as an adjunct in patient assessment. It must be used with other methods of assessing clinical signs and symptoms.

WARNING

5 Do not stretch the adhesive tape while applying the oximeter sensor. This may cause inaccurate readings or skin blisters.

6 Carefully read the manual and check the device before using it.

7 In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.

8 The presence of a defibrillator may affect the performance of the device.

9 Only recommended batteries can be used for oximeter.

WARNING

10 Significant concentration of dysfunctional hemoglobins (such as carbonxy-hemoglobin or methemoglobin) may affect the accuracy of the SpO_2 measurement.

11 Intravascular dyes such as indocyanine green or methylene blue may affect the accuracy of the SpO_2 measurement.

12 Batteries may leak or explode if used or disposed of improperly.

13 Patients with hypotension, severe vasoconstriction, severe anemia, or hypothermia may have inaccurate SpO_2 readings.

WARNING

14 Don’t use different types of batteries at the same time. Don’t mix fully charged and partially charged batteries at the same time. These actions may cause batteries to leak.

15 Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.

16 Patients in cardiac arrest or in shock may have inaccurate SpO_2 readings.

17 The presence of high ambient light may cause inaccurate SpO_2 measurements.

WARNING

18 Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

19 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

20 To protect eyes from damage, don't look directly at the light emitting parts (Infrared light is invisible).

21 Dispose of batteries in accordance with local ordinances and regulations.

WARNING

22 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.

23 Before using the device, the equipment and accessories should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.

24 The materials with which the patient or any other person can come into contact conform to the standard of ISO10993-1: 2013.

WARNING

25 Ensure that the environment in which the oximeter is used is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.

26 As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation. It is especially important for children.

27 Please avoid inhalation or swallowing of small parts.

28 The device should keep away from pets, pests or children.

WARNING

29 Periodically check the battery for corrosion. Remove the batteries from the battery tray if the oximeter will not be used for a long time.

30 The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC Information provided in this user manual.

31 The oximeter is a prescription device to be operated only by trained personnel. The oximeter is for attended monitoring only.

WARNING

32 The equipment 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.

33 Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in Appendix A2 EMC Information.

34 The oximeter can only be used on one patient at a time.

WARNING

35 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 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.

36 When serious arrhythmia is present, the SpO_2 pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO_2) value.

37 Do not service or maintain the oximeter or any accessory which is in use with the patient.

WARNING

38 Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the equipment to another site. Change the application site at least every four hours.

39 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 oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

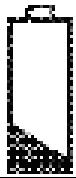
40 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.

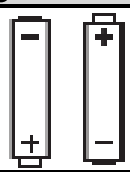
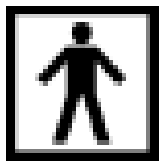
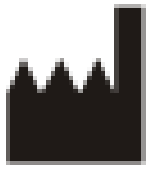
41 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.

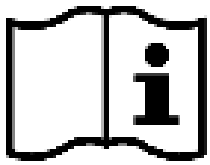
NOTE:

The device is calibrated to display functional oxygen saturation.

3 Symbols

No.	Symbol	Definition of Symbol
1		SERIAL NUMBER
2		Caution
3		Disposal method
4		No SpO_2 Alarms
5		Low battery indication
6	%SpO2	Hemoglobin saturation
7	BPM	Heart rate(BPM)

No.	Symbol	Definition of Symbol
8		Battery orientation
9		TYPE BF APPLIED PART
10		Date of manufacture
11		MANUFACTURER
12	CE 0123	CE marking
13	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14	P/N	Part Number

No.	Symbol	Definition of Symbol
15		Warning (Background: yellow; Symbol and outline: black)
16		Operating instructions
17		Refer to User Manual (Background: blue; Symbol: white)
18		General symbol for recovery/recyclable
19		This way up
20		Fragile

No.	Symbol	Definition of Symbol
21		Keep away from rain
22	IP22	Ingress Protection IP22 (Protected against access to hazardous parts with a finger; Protected against solid foreign objects of 12.5 mm Ø and greater; Protected against vertically falling water drops when enclosure tilted up to 15)

NOTE:

The user manual is printed in black and white.

4 Installing Batteries

When the batteries are low, the low battery indication flashes once per second. Replace low batteries as soon as possible, following the instructions below.

1. Hold the device as shown below, press upward and then pull outward slightly with your thumb to release the device’s battery tray.
2. Remove the battery tray and the old batteries, dispose of the batteries properly.
3. Insert two 1.5 volt AAA -size alkaline batteries. Follow the polarity marks (+ and -) as illustrated.

4. Carefully guide the battery tray back onto the device, press downward and push inward slightly to re-secure the battery tray.

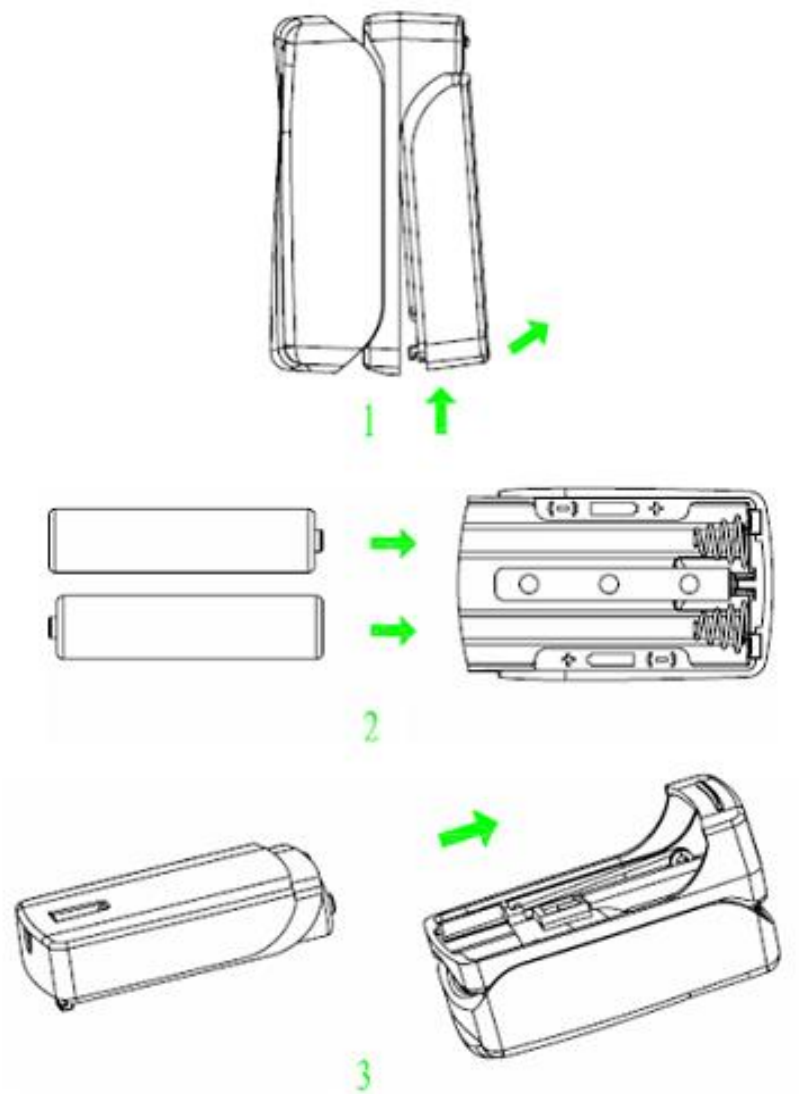


Figure 1 Batteries Installation

WARNING

Battery polarities must be correctly installed. Otherwise, the device might be damaged.

5 Operation Instructions

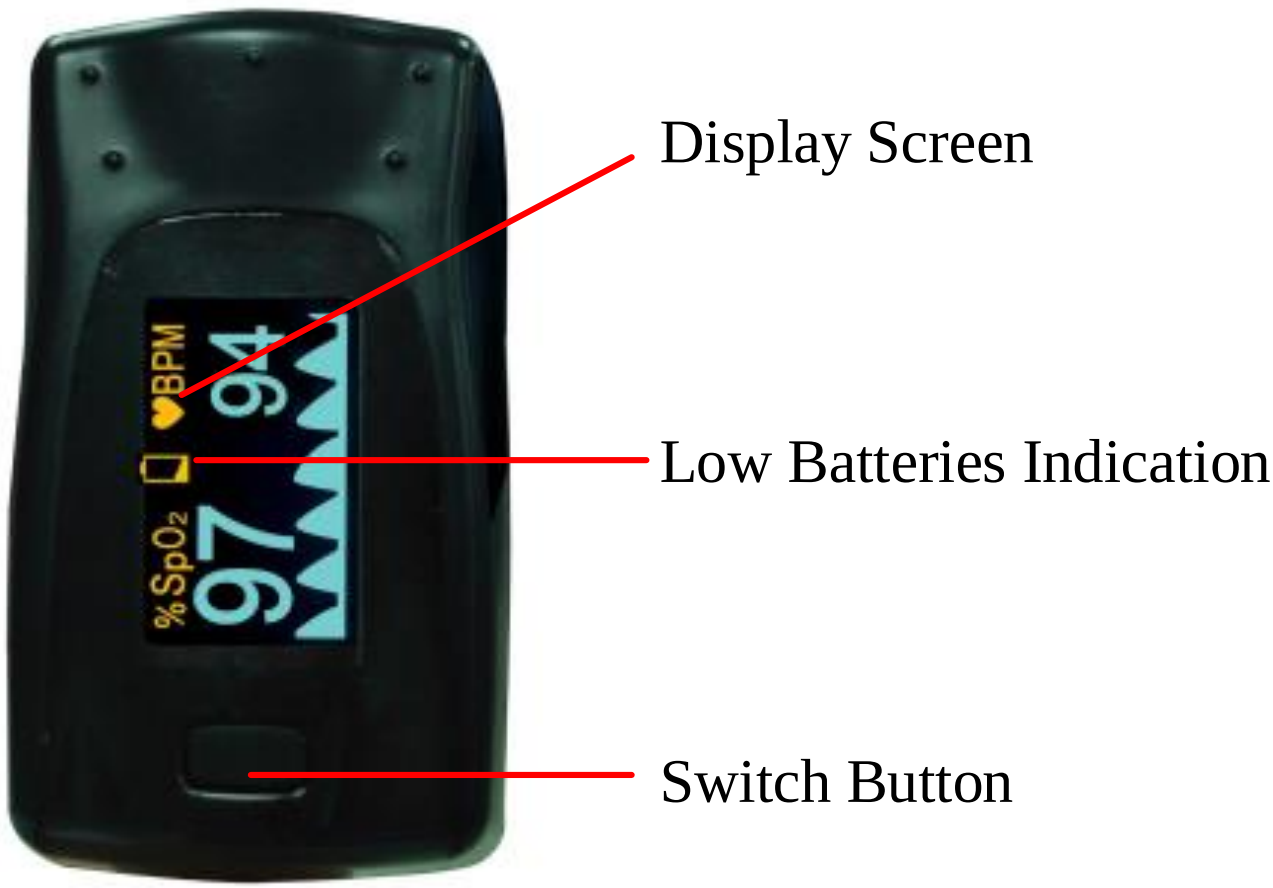


Figure 2 Front Panel Instruction

The OLED display screen of the device displays blood oxygen saturation (SpO_2) and

pulse rate (BPM) and provides a visual indication of the pulse signal. The displayed results of SpO_2 and PR are refreshed every second. Stable measurement is obtained in approximately 30 seconds. The values of SpO_2 and pulse rate can be displayed properly when pulse saturation is at 0.6%.

1. Insert two 1.5V AAA-size alkaline batteries into battery tray. Follow the polarity marks (+ and -) as illustrated. Carefully guide the battery tray back into the device.
2. Nip the clamp.
3. Insert one of your fingers; nail side up, into clamp of the oximeter until the fingertip touches the built-in stop guide.

4. Press the switch button on front panel to turn on the device (The device will automatically shut off if the screen displays “ERR1” or “ERR2” signal for more than three seconds).
5. Movement is not recommended during measurement.
6. When the signals are stable, read corresponding data from OLED display screen.
7. The device has six display modes shown in figure 3. If you press the switch button twice after turning on the oximeter, the device will change to another display mode.

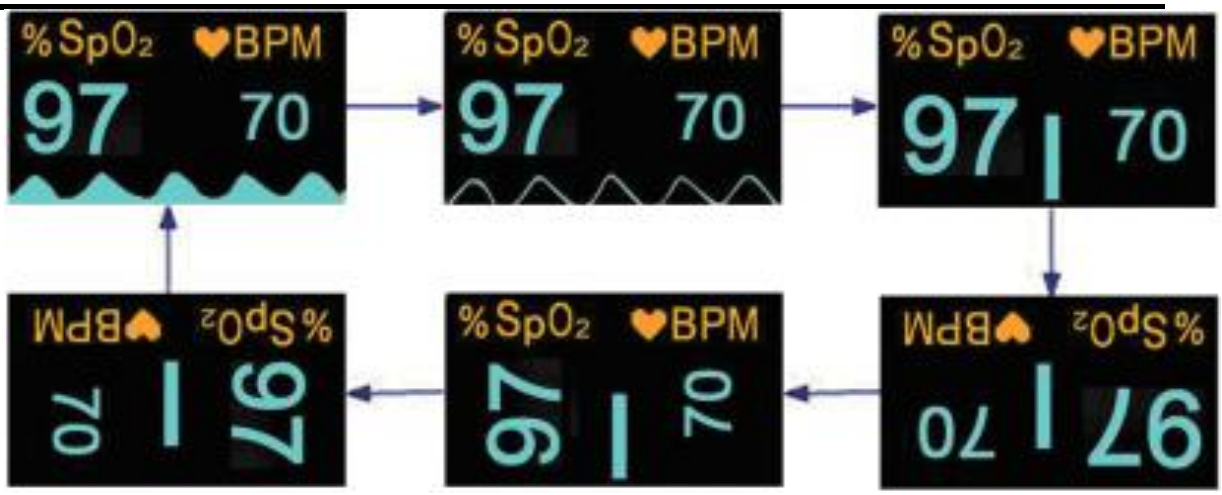


Figure 3 Six Display Modes

8. You can press the switch button to turn on/off the PR tone in every display mode.
9. When you press and hold the switch button for more than one second, the brightness of the device will change gradually. There are 10 levels of brightness; the default level is level five.
10. When the device is removed from your finger, the screen will display

"No Finger". The device will automatically shut off when the signal of "No Finger" lasts for more than eight seconds.

CAUTION

1 The loss of pulse signal may occur when the patient has poor peripheral perfusion, and the screen will display "---". When there's measurement beyond range, invalid measurement or no measurement value, it will display "---".

2 SpO_2 waveform is directly not proportional to the pulse volume.

CAUTION

3 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously.

4 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.

NOTE:

1 The pictures and interfaces in this manual are for reference only.

2 A Functional tester or simulator can not be used to assess the SpO_2 accuracy. However, it can be used to demonstrate that a particular oximeter reproduces a calibration curve that has been independently demonstrated to meet a particular accuracy.

3 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

4 Avoid placing the sensor on extremities with an arterial catheter,

intravascular venous infusion line, or inflated NIBP cuff.

5 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.

6 When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.

7 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.

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
- Low perfusion

Loss of pulse signal can occur for the following reasons:

- 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 SpO_2 sensors may interfere with each other (eg, multiple SpO_2 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.

6 SpO_2 Functional Test

This test checks the function of the SpO_2 measurement.

Tools required: SpO_2 simulator (Provided with a calibration curve approved by EDAN).

Procedure:

1. Connect the device and the SpO_2 simulator.
2. Switch on the device and the simulator.
3. Set the simulator to the following configuration:
   - SpO_2 = 85%.
4. Check the displayed SpO_2 value against the simulator configuration. The value should be 85% ±2%.

7 Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

Generally, the quality of the SpO_2 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 SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors,

unstable SpO_2 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 SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1 The SpO_2 accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. SpO_2 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, 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 oximeter'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 oximeter 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.

8 Installing String

A string and a carrying case are provided for convenience. The device will function with or without these accessories.

If the string use is desired, thread the string as shown below.

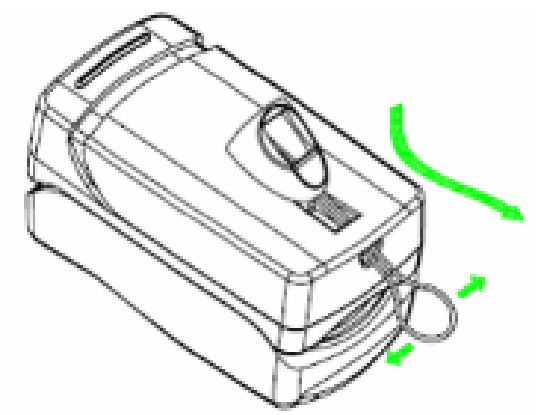


Figure 4 String Installation

WARNING

Only the string provided by EDAN can be used. Other or longer ones may have risks for users, especially for children.

9 Maintenance

The oximeter does not require calibration. Maintenance shall be carried out at least once every two years, or as specified by local regulations.

If service is necessary, contact qualified service personnel or your local EDAN representative.

Before using the oximeter, do the following:

- Check if there is any mechanical damage;
- Check all the functions of the oximeter to make sure that the oximeter is in good condition.

If you find any damage on the oximeter, stop using the oximeter on patient, and contact the biomedical engineer of the hospital or customer service immediately.

The overall check of the oximeter, including the safety check, should be performed only by qualified personnel once every 6 to 12 months, and each time after fix up.

Periodic Safety Checks

It is recommended that the following checks should be performed every 24 months:

- Inspect the devices for mechanical and functional damage
- Inspect the relevant labels for legibility

All the checks that need to open the oximeter should be performed by qualified customer service technician. The safety and maintenance check can be conducted by personnel from this company. You can obtain the material about the customer

service contract from the local company's office.

If the hospital or agency that is responding to using the oximeter does not follow a satisfactory maintenance schedule, the oximeter may become invalid, and the human health may be endangered.

WARNING

The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service professionals.

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 oximeter and 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.

Cleaning the Oximeter:

WARNING

Before cleaning the oximeter, make sure that the oximeter is switched off and batteries are taken out.

To surface-clean the oximeter, follow these steps:

1. Switch off the oximeter and take out the batteries.
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 oximeter in a ventilated and cool place.

Disinfecting

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 oximeter and

accessories before disinfecting. The validated disinfectants for cleaning the oximeter and accessories are:

- Ethanol (75%)
- Isopropanol (70%)

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 quanternary ammonium salt.

CAUTION

2 Although the oximeter chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, different cleaners or disinfectants are not recommended and may stain the oximeter, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

WARNING

The oximeter and accessories shall be disinfected to avoid patient cross infection.

Disinfecting the Oximeter:

WARNING

Before disinfecting the oximeter, make sure that the oximeter is switched off and batteries are taken out.

To disinfect the oximeter, follow these steps:

1. Switch off the oximeter and take out the batteries.
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 oximeter for at least 30 minutes in a ventilated and cool place.

WARNING

Sterilization may cause damage to the equipment and is therefore not recommended for this oximeter unless otherwise indicated in your hospital's servicing schedule.

Production date can be found on labels. The service life for main machine (not including replaceable accessories or parts) is 5 years when working time is 8 hours per day.

10 Accessories

Part Number	Accessories
01.50.109744	One hang string
01.21.064111	Two 1.5V AAA-size alkaline batteries
01.54.109755	One user manual

NOTE:

The part name may vary depending on context, but the part number is constant.

11 Troubleshooting

Problems	Possible Reason	Solutions
Device can't be powered on	Critical low battery Batteries might be installed incorrectly Device might be damaged	Please replace batteries Please reinstall batteries Please contact local customer service centre
"ERR 1" displayed on OLED screen	Drive circuit might be damaged	Please contact local customer service centre

Problems	Possible Reason	Solutions
“ERR 2” displayed on OLED screen	Drive circuit might be damaged	Please contact local customer service centre
	Photoelectric sensor might be damaged or shielded	Please check the photoelectric sensor and remove the shielding object or contact local customer service centre

Problems	Possible Reason	Solutions
SpO_2 or PR value can't be shown normally	The sensor is applied incorrectly. There is very bright light Patient is in low perfusion or Patient's oxyhemoglobin is too low to be measured	Re-apply the sensor Don't use the device in the environment with high ambient light Go to a hospital for diagnosis
SpO_2 or PR value is unstable	Finger might not be inserted deep enough Finger is trembling or patient is moving	Re-apply the sensor Please keep quiet

12 Warranty and Service Policy

12.1 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 period begins on the date the products are shipped to distributors.

The warranty is void in cases of:

a) damage caused by handling 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.

12.2 Service Policy

All repairs on products must be performed or approved by EDAN. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall be exclusively be performed by EDAN certified service personnel.

If the product fails to function properly or if you need assistance, service, or spare parts, contact EDAN's service center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone or Email, avoiding potential unnecessary returns.

In case a return can not be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) form that includes the appropriate return address and instructions. An RMA form must be obtained prior to any return.

Freight policy:

Under warranty: the service claimer is responsible for freight & insurance charges when a return is shipped to EDAN for service including custom charges. EDAN is responsible for freight, insurance & custom charges from EDAN to service claimer.

Out of warranty: the service claimer is responsible for any freight, insurance &

custom charges for product.

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.

Appendix I Product Specification

A1.1 Classification

Type of Protection	Internally powered equipment (two 1.5V AAA alkaline batteries)
Degree of Protection	Type BF-Applied part
Mode of operation	Continuous working
Enclosure Degree of ingress Protection	IP22
Degree of Safety in Presence of Flammable Gases	Not suitable for use in presence of flammable gases
Compliant with Safety Standards	IEC 60601-1: 2005+A1:2012 EN 60601-1: 2006+A1:2013 IEC 60601-1-2: 2014 EN 60601-1-2: 2015

	ISO 80601-2-61: 2011

A1.2 Specification

A1.2.1 Size and Weight

Size	57 (L)×32 (W)×31 (H) (mm)
Weight	57 (g) (Including battery)

A1.2.2 Environment

Temperature	
Working	5 ℃ ~ 40 ℃ (41 ℉~104 ℉)
Storage	-25 ℃ ~ 70 ℃ (-13 ℉~158 ℉)
Humidity	
Working	15%RH ~ 95%RH (non-condensing)
Storage	15%RH ~ 95%RH (non-condensing)

Atmospheric pressure	
Working	70 kPa ~ 106 kPa
Transport and Storage	70 kPa ~ 106 kPa

A1.2.3 Display

SpO_2	OLED display
PR	OLED display
Bar graph	10-segment, OLED display
Data update period	one second

A1.2.4 Batteries

Power supply	two 1.5V AAA -size alkaline Batteries
Life-span of battery	approximately 22 hours of operation with two 1.5V AAA

	-size alkaline batteries

Battery status symbols on screen

Battery power level	symbol
High level	
Medium level	
Low level	 (Batteries are almost depleted and need to be replaced immediately. The device will turn off after 40 s when battery low symbol appears.)

A1.2.5 Measurement Wavelengths

Red light	660 nanometers
Infrared light	905 nanometers

Emitted light energy	<15 mW

NOTE:
The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A1.3 Displayed Parameters Specification

Displayed range	
SpO_2	35% ~ 99%
BPM	30 BPM ~ 240 BPM
Accuracy	
SpO_2	80%~99%, ±2% 70%~80%, ±3% Less than 70%, unspecified
PR	±2 BPM or ±3% (larger)

Resolution	
SpO_2	1%
BPM	1 BPM

Appendix II

EMC Information-Guidance and Manufacture's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC/EN 60601-1-2.

A2.1 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
H10 is intended for use in the electromagnetic environment specified below. The customer or the user of H10 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment -guidance

RF emissions CISPR11	Group 1	H10 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	H10 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply net work that supplies buildings used for domestic purpose.
Harmonic emissions IEC/EN61000 -3-2	N/A	
Voltage fluctuations /flicker emissions IEC/EN61000 -3-3	N/A	

A2.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
H10 is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC/EN61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/ Burst IEC/EN61000-4-4	±2kV for power supply lines ±1kV for input/output lines (>3m)	N/A	Mains power quality should be that of a typical commercial or hospital

Surge IEC/EN61 000-4-5	±1 kV for line to line	N/A	environment.
Voltage dips, short interruptio ns, and voltage variations on power supply input lines IEC/EN61 000-4-11	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	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz)Magne tic Field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of

IEC/EN 61000-4-8			a typical location in a typical commercial or hospital environment

A2.3 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
H10 is intended for use in the electromagnetic environment specified below. The customer or the user of H10 should assure that it is used in such an environment.			
Emissions test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of H10, including cables, than the recommend

			separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC/EN 61000-4-6	3Vrms 150KHz to 80MHz 6Vrms[c] in ISM bands between 0.15 MHz and 80 MHz	N/A	**Recommended separation distance** /
Radiated RF IEC/EN 61000-4-3	10 V/m 80MHz to 2.7 GHz See Table 1	10 V/m 80 MHz to 2.7 GHz Comply with Table 1	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$

			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 oximeter, including cables specified by the manufacturer). where p is the maximum output power

			rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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. Interference may occur in the vicinity of

			equipment marked with the following symbol: 

NOTE1 At 80MHz and 800MHz, the frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 H10 is used exceeds the applicable RF compliance level above, H10 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating H10.

b. 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.

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.

A2.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and H10			
H10 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of H10 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and H10 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)		
	/	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**	**0.23**
0.1	/	**0.38**	**0.73**
1	/	**1.2**	**2.3**
10	/	**3.8**	**7.3**
100	/	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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

P/N: 01.54.109755
MPN: 01.54.109755015

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