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H10 Series Finger Oximeter User 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 user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.
EDAN holds the rights to modify, update, and ultimately explain this manual.

【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.

【1 Intended Use/Indications for Use】

The finger oximeter is intended for spot checking of functional oxygen saturation of arterial haemoglobin (SpO_2) and pulse rate (PR) for both adult and pediatric patients. It is indicated for use in medical institution and home environments.

【2 Contraindications】

None.

【3 Precautions for Use】

WARNING

1 **The oximeter is a prescription device to be operated by clinical professionals or under their guidance. It should only be used by personnel who have received adequate training in their use.**
2 **Carefully read the manual and check the device before using it.**
3 **The device is not intended for treatment purpose.**
4 **Do not use the device in an MRI or CT environment.**
5 **Do not use the device in situations where alarms are required. The device has no alarms.**
6 **EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.**
7 **The physiological data displayed on the device are for reference only and cannot be directly used as the sole basis for medical decisions. The device must be used in conjunction with clinical signs and symptoms.**
8 **In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.**
9 **This device is not intended to be used with the defibrillator.**
10 **The device is not suitable for use in the presence of electrosurgery.**
11 **Only recommended batteries can be used for oximeter.**
12 **Batteries may leak or explode if used or disposed of improperly.**

WARNING

13 **Do not use different types of batteries at the same time. Don't mix new and old batteries at the same time. These actions may cause batteries to leak.**
14 **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.**
15 **The device is to be disposed of according to local regulations after its useful life. Alternatively, it 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.**
16 **To protect eyes from damage, don't look directly at the light emitting parts (Infrared light is invisible).**
17 **Before using the device, the equipment should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.**
18 **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.**
19 **As with all medical equipment, carefully route the string to reduce the possibility of patient entanglement or strangulation. It is especially important for children.**
20 **Please avoid inhalation or swallowing of small parts.**
21 **The device should keep away from pets, pests or children.**
22 **To avoid safety risks, do not use batteries with signs of damage, otherwise short circuit may be caused.**
23 **Periodically check the battery for corrosion. Remove the batteries from the battery tray if the oximeter will not be used for a long time.**
24 **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.**
25 **The oximeter is a prescription device to be operated only by trained personnel. The oximeter is for attended monitoring only.**
26 **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.**
27 **Portable and mobile RF communications equipment can affect medical electrical equipment; refer to the recommended separation distances provided in Appendix A2 EMC Information.**
28 **Correct and proper oximeter application: if the oximeter is too loose, it might compromise the optical alignment, and even cause the oximeter to fall off. If the oximeter 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.**
29 **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.**
30 **Do not service or maintain the oximeter which is in use with the patient.**
31 **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.**
32 **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.**
33 **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.**
34 **Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.**

CAUTION

1 **Do not squeeze the silicone pad with your finger when using the device. Otherwise, it may cause the deviation of measurement values due to the excessive squeezing of the finger.**
2 **Patients with hypotension, severe vasoconstriction, severe anemia, or hypothermia may have inaccurate SpO_2 readings.**
3 **Patients in cardiac arrest or in shock may have inaccurate SpO_2 readings.**

NOTE:

1 **The device is calibrated to display functional oxygen saturation.**
2 **The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1.**
3 **During normal use, the operator is expected to face the screen of the device.**
4 **The illustrations in this manual are for reference only.**

【4 Symbols】

No.	Symbol	Definition of Symbol
1	SN	Serial Number
2		Caution
3		The products marked with this symbol apply to the European WEEE directive. This symbol Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.
4		No SpO_2 Alarms
5		Low battery indication
6	%SpO2	Hemoglobin saturation
7	♥BPM	Heart rate (BPM)
8	%PI	Perfusion Index (PI)
9		Battery orientation
10		TYPE CF APPLIED PART
11		Date of manufacture
12		Manufacturer
13	CE 0123	CE marking
14	EC REP	Authorized representative in the European Community
15	P/N	Part Number
16		Consult instruction for use
17		Refer to instruction manual/booklet (Background: blue; Symbol: white)
18		General symbol for recovery/recyclable
19		This way up
20		Fragile, handle with care
21		Keep dry
22	12	Stacking limit by number
23		Handle with care
24		Do not step on
25	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°)
26		Apply the oximeter as illustrated
27	+55℃ -20℃	Temperature limit
28	MD	Medical Device
29	UDI	Unique Device Identifier

NOTE:
The user manual is printed in black and white.

【5 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.

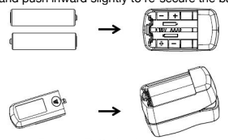

Figure 1 Batteries Installation

WARNING

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

【6 Operation Instructions】

Figure 2 Front Panel

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 10 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. Press the switch button on front panel to turn on the device.
3. Nip the clamp.
4. Insert one of your fingers; nail side up, into clamp of the oximeter until the fingertip touches the built-in stop guide.

5. Movement is not recommended during measurement.
6. When the signals are stable, read corresponding data from OLED display screen.
7. The device has four display modes shown in figure 3. If you press the switch button after turning on the oximeter, the device will change to another display mode.

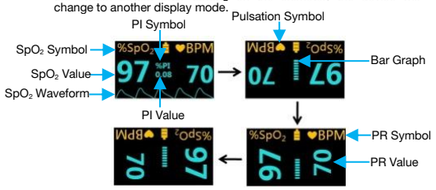

Figure 3 Four Display Modes

8. You can press the switch button twice to turn on/off the pulse 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 of H10, H10A and H10B is level one, level five and level 10 respectively.
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.**
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 oximeter 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 cannot 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 **Avoid placing the oximeter on extremities with an arterial catheter, intravascular venous infusion line, or inflated NIBP cuff.**
4 **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 the oximter on the skin will not exceed 41°C during working.**
5 **When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.**
6 **Inspect the oximeter to ensure that the light emitter and receiver are aligned with each other and there is no gap between the oximeter 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 oximeter 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 oximeter 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 oximeter 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 oximeter attached
- there is arterial occlusion proximal to the oximeter
- low peripheral perfusion

NOTE:

1 **To prevent interference from ambient light, ensure that the oximeter is properly applied, and cover the oximeter site with opaque material.**
2 **Adjacent oximeters may interfere with each other (eg, multiple SpO_2 measurements in the same patient). Be sure to cover the oximeter with opaque material to reduce cross-interference.**
3 **Move the oximeter to a less active site, and keep the patient still, if possible.**

【7 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%.

【8 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 oximeter 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 oximeter. 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 oximeter's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong oximeter placement or oximeter malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the oximeter, measure another site or replace the oximeter.
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 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 oximeter is wearing properly and the signal quality is good.**

【9 PI (Perfusion Index)】

PI gives a percentage for the pulsatile signal to the non-pulsatile signal at the monitoring site. PI reflects the perfusion level at the monitoring site, which can also indicate arterial pulse signal strength. PI below 0.1% indicates the low perfusion at the monitoring site. Reposition the oximeter or find a better site.

【10 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

1 **The maintenance operations like software upgrade of the device can only be completed by EDAN-qualified service professionals.**
2 **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.**

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.

Safety Instructions

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

► Follow the infection prevention policies and reprocessing regulations of the health-care facility.

► Follow the national infection prevention policies and reprocessing regulations.

► Use validated procedures for reprocessing.

► Reprocess reusable products after every use.

► Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices. Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

► Check the products for signs of wear and replace them if necessary.

Keep your oximeter 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 in liquid.
- Do not pour liquid onto the device.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the oximeter after it is cleaned and disinfected.

CAUTION

If you spill liquid on the device, or it is accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

NOTE:

Automated cleaning/disinfection to the device is prohibited.

Cleaning

If the device 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 are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. Refer to the cleaning agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

Cleaning the Oximeter:

WARNING

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

To clean the oximeter, follow these steps:

1. Switch off the oximeter and take out the batteries.
2. Remove all residual foreign matters from the surface of the oximeter using sterile cloth or paper towel immediately after examination until the surface is visually clean.
3. Use a clean cotton swab dampened with the cleaning solution to wipe the surface apertures of the oximeter until no visible contaminants remain.
4. Use a soft clean cloth dampened with the cleaning solution to wipe the entire exterior surface of the oximeter until no visible contaminants remain.
5. Wipe the patient contact area of the oximeter with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
6. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
7. Dry the oximeter in a ventilated and cool place.
8. If the oximeter still has stains or residues after cleaning, please repeat step 3 to step 7.
9. Inspect the oximeter to ensure no signs of damage.

Disinfection

For devices that have been in contact mucosal surface, High Level disinfection must occur, for others, low level disinfection is appropriate. Clean the oximeter before disinfecting. The validated disinfectants for disinfecting the oximeter are:

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

Disinfecting agents should be applied and removed by using a clean cotton swab or a clean, soft, non-abrasive cloth or paper towel each time. Refer to the disinfecting agent manufacturer's instruction for use with reference to concentration, temperature and contact time.

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.**

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

WARNING

The oximeter 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. Clean and dry the oximeter according to the methods in section *Cleaning the Oximeter* prior to disinfection.
3. Prepare the disinfectant solution.
4. Use a clean cotton swab dampened with the disinfectant solution to wipe the surface apertures of the oximeter. Follow the contact time and method recommended by the disinfectant manufacturer.
5. Use a soft clean cloth dampened with the cleaning solution to wipe the entire exterior surface of the oximeter until no visible contaminants remain. Follow the contact time and method recommended by the disinfectant manufacturer.
6. Wipe the patient contact area of the oximeter with the cotton swab dampened with the disinfectant solution.
7. After disinfection, wipe off the disinfectant solution with a new sterile cloth dampened with sterile water.
8. Dry the oximeter for at least 30 minutes in a ventilated and cool place.
9. Inspect the oximeter to ensure no signs of damage.

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.

After Reprocessing

- After reprocessing, the equipment should be checked to ensure there are no signs of aging, wear, cracks, deformation, discoloration or peeling, etc. Replacement should be taken or contact the service personal of the manufacturer if necessary.
- Assembling and attaching device-specific components.

Prerequisite:

All components have been reprocessed and are dry.

- Preparation before next use of device

Assembling and fitting patient-specific device.

Storage and Transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:

– Store dry and free of dust

– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

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

【11 Accessories】

Part Number	Accessories
01.21.064426	Two 1.5V AAA-size alkaline batteries
01.54.458951	One user manual

NOTE:

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

【12 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	Excessive driving current.	Please contact local customer service centre
"ERR 2" displayed on OLED screen	Abnormal driving voltage; Abnormal SpO_2 reception signal.	Please contact local customer service centre Please check the photoelectric sensor and remove the shielding object or contact local customer service centre
"No Finger" displayed on OLED screen	No finger is detected by the system.	Re-apply the oximeter
SpO_2 or PR value can't be shown normally	The oximeter 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 oximeter 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 oximeter Please keep quiet

【13 Warranty and Service Policy】

13.1 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.

13.2 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 cannot 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.

【Appendix I Product Specification】

A1.1 Classification

Type of Protection	Internally powered equipment (two 1.5 V AAA alkaline batteries)
Degree of Protection	Type CF-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, EN 60601-1 IEC 60601-1-2, EN 60601-1-2 ISO 80601-2-61

A1.2 Specification

A1.2.1 Size and Weight

Size	61 (L)×33 (W)×34 (H) (mm) (±1 mm)
Weight	<59 (g) (Including battery)

A1.2.2 Environment

Temperature	
Working	0 °C ~ 40 °C (32 °F~104 °F)
Transport and Storage	-20 °C ~ 55 °C (-4 °F~131 °F)
Humidity	
Working	15%RH ~ 95%RH (non-condensing)
Transport and Storage	15%RH ~ 95%RH (non-condensing)
Atmospheric pressure	
Working	50 kPa ~ 106 kPa
Transport and Storage	50 kPa ~ 106 kPa
The time required for the oximeter to warm from the minimum storage temperature between uses until it is ready for intended use is at least 2 hours; the time required for the oximeter to cool from the maximum storage temperature between uses until it is ready for intended use is at least 2 hours.	

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 1.5 V AAA -size alkaline Batteries
Life-span of battery	approximately 24 hours of operation with two 1.5V AAA -size alkaline batteries (Condition: In a laboratory environment, continuous measurement, screen brightness is set to 1, pulse tone off)

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.)

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	0 ~ 100%
PR	25 BPM ~ 300 BPM
PI	0-20%, invalid PI value is -.--
Accuracy	
SpO_2	70%~100%, ±2% 0~69%, unspecified
PR	±2 BPM or ±2%,whichever is greater
Resolution	
SpO_2	1%
PR	1 BPM
PI	0.1% (10% to 20%) 0.01% (0 to 9.99%)
Accuracy in low perfusion	
When PI is 0.2%, the accuracy of SpO_2 is ±4%; the accuracy of PR is ±2 BPM or ±2%,whichever is greater.	

【 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/H10A/H10B is intended for use in the electromagnetic environment specified below. The customer or the user of H10/H10A/H10B should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR11	Group 1	H10/H10A/H10B 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/H10A/H10B 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/H10A/H10B 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	±2 kV for power supply lines ±1 kV for input/output lines (>3 m)	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN61000-4-5	± 1 kV for line to line	N/A	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC/EN61000-4-11	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)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

A2.3 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity

H10/H10A/H10B is intended for use in the electromagnetic environment specified below. The customer or the user of H10/H10A/H10B should assure that it is used in such an environment.

Emissions test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment- guidance

Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 Vrms 150 KHz to 80 MHz 6 Vrms[c] in ISM bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz See Table 1	N/A 10 V/m 80 MHz to 2.7 GHz Comply with Table 1	Portable and mobile RF communications equipment should be used no closer to any part of H10/H10A/H10B, including cables, than the recommend separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** / $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d=6\sqrt{P}/E$ 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:

NOTE 1 At 80MHz and 800MHz, the 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.

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/H10A/H10B is used exceeds the applicable RF compliance level above, H10/H10A/H10B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating H10/H10A/H10B.

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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	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
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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

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/H10A/H10B

H10/H10A/H10B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of H10/H10A/H10B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and H10/H10A/H10B 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

【Appendix III Accuracy Results in Clinical Studies】

The table below shows Arms values measured with the investigational device in a clinical study.

SaO_2 Range	Arms
90%-100%	1.01
80%-90%	2.01
70%-80%	2.01
70%-100%	1.68

The figure below shows the Bland-Altman Plot of SaO_2 vs SpO_2 measured with the investigational device. In the plots, the upper and lower dotted lines represent the upper and inferior limits of the 95% consistency, and the middle dotted line represents the average of the bias.