

EDAN Agile PLM Electronic Signature Information

--Signatures related to this document and performed in EDAN Agile PLM.

文件名称(Document Name) : H10 系列说明书_英文

文件编号(Number) : 01.54.458951

版本(Version) : 1.3

产品型号(Product Model) : H10

项目编码(Project Code) : 2131I001

签批信息(Signature):

作者(Originator) : 洪 珊艳 (hongshanyan) 2022-09-21 21:40:27

审核人(Reviewers) : 程 亮 (chengliang) 2022-09-22 09:18:29

审核人(Reviewers) : 夏 欢欢 (xiahuanhuan) 2022-09-21 22:17:44

审核人(Reviewers) : 欧阳 亮 (ouyangliang) 2022-09-23 09:42:22

批准人(Approvers) : 史 洪华 (shihonghua) 2022-09-26 14:00:18

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:

- Switch off the oximeter and take out the batteries.
- 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.
- Use a clean cotton swab dampened with the cleaning solution to wipe the surface apertures of the oximeter until no visible contaminants remain.
- Use a soft clean cloth dampened with the cleaning solution to wipe the entire exterior surface of the oximeter until no visible contaminants remain.
- Wipe the patient contact area of the oximeter with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
- After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
- Dry the oximeter in a ventilated and cool place.
- If the oximeter still has stains or residues after cleaning, please repeat step 3 to step 7.
- 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

- 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.
- 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.

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:

- Switch off the oximeter and take out the batteries.
- Clean and dry the oximeter according to the methods in section *Cleaning the Oximeter* prior to disinfection.
- Prepare the disinfectant solution.
- 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.
- 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.
- Wipe the patient contact area of the oximeter with the cotton swab dampened with the disinfectant solution.
- After disinfection, wipe off the disinfectant solution with a new sterile cloth dampened with sterile water.
- Dry the oximeter for at least 30 minutes in a ventilated and cool place.
- 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
	Critical low battery	Please replace batteries Please reinstall batteries
Device can't be powered on	Batteries might be installed incorrectly Device might be damaged	Please contact local customer service centre Please contact local customer service centre
"ERR 1" displayed on OLED screen	Excessive driving current.	Please contact local customer service centre
	Abnormal driving voltage	Please check the photoelectric sensor and remove the shielding or contact local customer service centre
"ERR 2" displayed on OLED screen	Abnormal SpO ₂ reception signal.	
"No finger" displayed on OLED screen	No finger is detected by the system. The oximeter is applied incorrectly. There is very bright light	Re-apply the oximeter 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 can't be shown normally	Patient is in low perfusion or Patient's oxyhemoglobin is too low to be measured	Re-apply the oximeter Please keep quiet
SpO ₂ or PR value is unstable	Finger might not be inserted deep enough Finger is trembling or patient is moving	

[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:

- damage caused by handling during shipping.
- subsequent damage caused by improper use or maintenance.
- damage caused by alteration or repair by anyone not authorized by EDAN.
- damage caused by accidents.
- 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

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 ±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 network 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 test level	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 interruption s, and voltage variations on power supply input lines IEC/EN61000-4-11	0 % U _r ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U _r ; 1 cycle and 70 % U _r ; 25/30 cycles) Single phase: at 0°	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
----------------	-------------------------	------------------	---------------------------------------

Test frequency (MHz)	Band (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity test level (V/m)
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 KHz to 80 MHz 6 Vrms ^c in ISM bands between 0.15 MHz and 80 MHz	N/A	/	10 V/m 80 MHz to 2.7 GHz	80 MHz to 800 MHz 800 MHz to 2.7 GHz	
Radiated RF IEC/EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz	Comply with Table 1				
See Table 1						

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 (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 ±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

Test frequency (MHz)	Band (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	Immunity test level (V/m)
810						
870	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0.3	28
930						
1720						
1845	170 0-19 90	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0.3	28
1970						
2450	240 0-25 70	Bluetooth , WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0.3	28
5240	510 0-58 00	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.

- For some services, only the uplink frequencies are included.
- The carrier shall be modulated using a 50 % duty cycle square wave signal.
- 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 SaO₂ vs SpO₂ 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.

