CREATIVE MEDICAL

Sleep Screener

AP-20

User Manual

Shenzhen Creative Industry Co., Ltd

Instructions to User

Dear Customer,

Thank you for purchasing this quality product. Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the Sleep Screener.

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Notes:

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Instructions for Safe Operation

- Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. It is recommended that the device should be inspected minimally before each use. If there is obvious damage, stop using the device.

- Necessary service must be performed only by qualified technicians. Users are not permitted to service this device.
- The Sleep Screener must not be used with the devices and accessories not specified in User Manual.

Cautions

- Explosive hazard—DO NOT use the Sleep Screener in environment with inflammable gas such as some ignitable anesthetic agents.
- **DO NOT** use the Sleep Screener while the Patient is under MRI or CT scanning. This device is NOT MRI Compatible.

Warnings

- Discomfort or pain may occur if using the sensor of this device

continuously on the same location for a long time, especially for the patients with poor microcirculation.

- Misapplication of a SpO_2 probe with excessive pressure for prolonged periods can induce pressure injury.
- Place the SpO_2 probe on the finger tightly will cause venous pulse and effect blood circulation, and lead to interstitial edema, hypoxia and inaccurate measurement.
- Biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do not apply to those who have anaphylaxis.
- For the individual patients, there should be a more prudent inspecting in the placing process.

The sensor can not be placed on the edema and tender tissue.

- The local law should be followed when disposing of the expired device or its accessories.
- DO NOT operate in the environment where strong electro-magnetic interference exists, such as radiogram, television, radiophone, etc.
- Please pay attention to the SpO_2 probe cable and oral-nasal cannula while using to avoid strangulating patient.

Attentions

- Keep the Screener away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the Screener gets wet, please stop operating it and do not resume

operation until it is dry and checked for correct operation. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately. Allow at least 15 minutes for the Screener to reach ambient temperature.

- **DO NOT** operate the button on the front panel with sharp materials or sharp point.
- DO NOT use high temperature or high pressure steam disinfection on the Screener and probes. Refer to related chapter for instructions regarding cleaning and disinfection.
- The intended use of this device is not for therapy purpose.
- The equipment is IP22 with protection against harmful solid foreign objects and ingress of liquid.

So that means the equipment is protected against solid foreign objects of 12.5mm and greater, and protected against vertically falling water drops when enclosure tilted up to 15°.

- Please pay attention to the effects of lint, dust, light (including sunlight), etc.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1:2005+A1: 2012, IEC60601-1-2:2014, IEC60601-1-11:2010, ISO 80601-2-61:2017 and follows the provisions of the council directive MDD93/42/EEC.

Table of Contents

1 Overview

1.1 Appearance

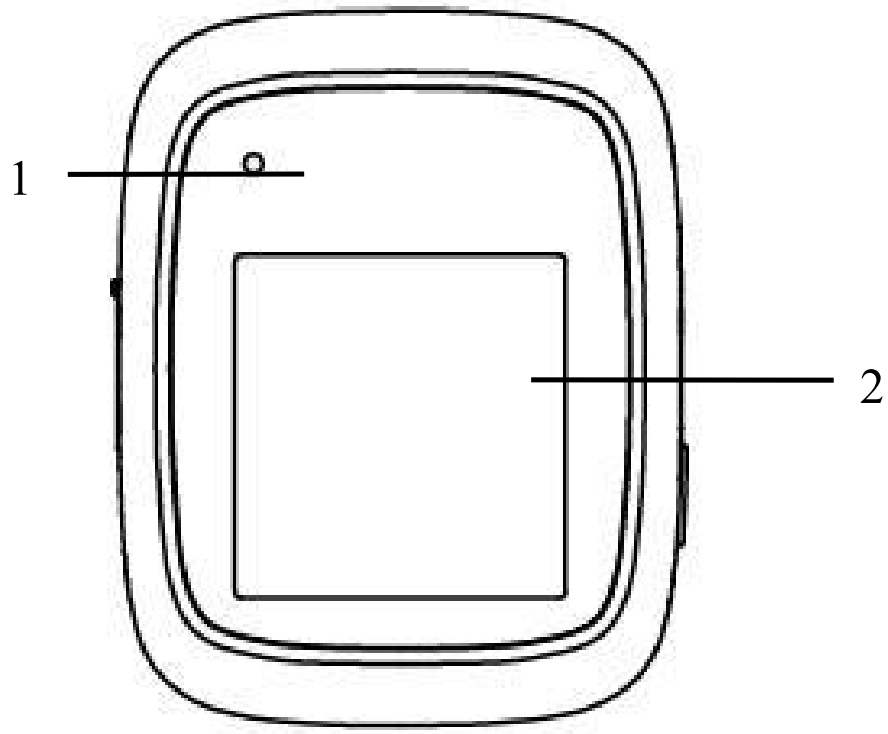


Figure 1A Front view

1. Working status indicator.

2. LCD display screen: Display measurement result, waveform.

Note: Two kinds of appearance for optional, please refer to the device you've purchased.

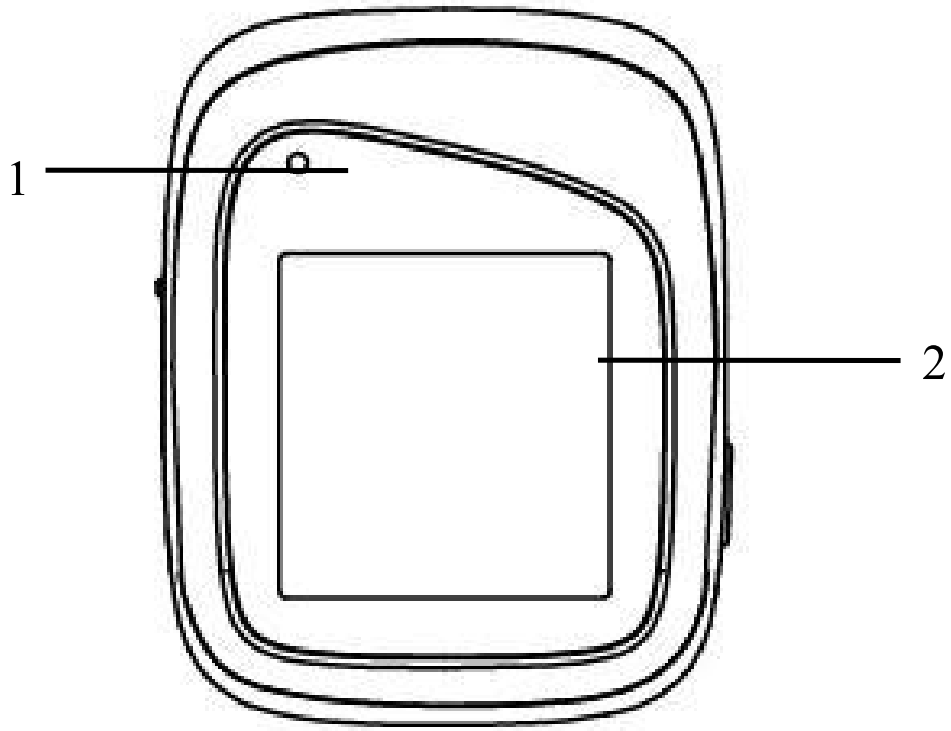


Figure 1B Front view

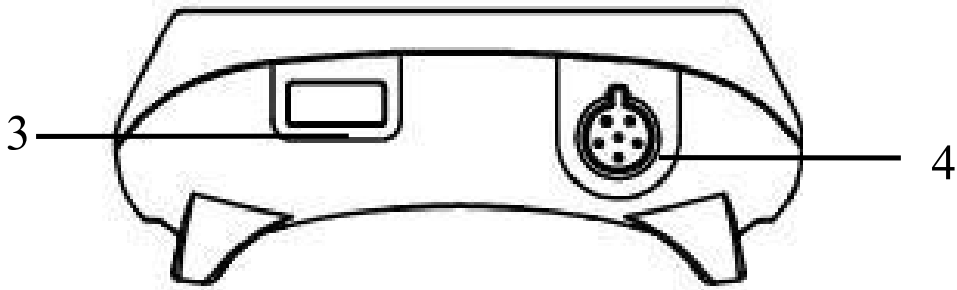


Figure 2 Right side view

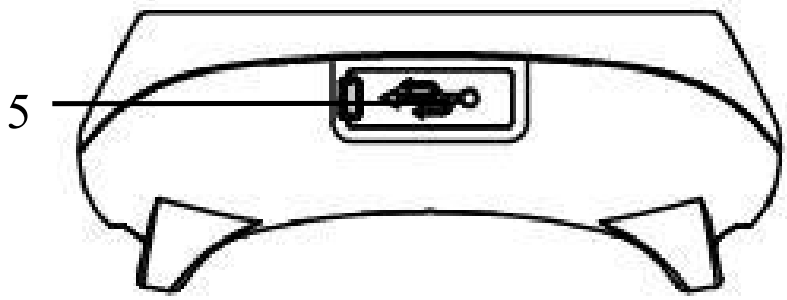


Figure 3 Left side view

3. Power on/off key: Power on/off the device by

long pressing.

4. SpO_2 probe connector.

5.  Data interface: For charging, data uploading and connecting air-flow measuring module.

1.2 Product Name and Model

Name: Sleep Screener

Model: AP-20

1.3 Structure

It consists of main unit, SpO_2 probe, air-flow module, acceleration sensor, oral-nasal cannula, data interface as well as the bluetooth module (optional).

1.4 Features

- ✧ It’s a smart wearable Sleep Screener, lightweight, small in size and easy to wear;
- ✧ 1.44 inch color LCD to display parameters, plethysmogram, oral/nasal air flow and

snore waveform;

- ✧ Body activity recording and analysis function is available;
- ✧ Setting menu is available;
- ✧ Over-limit alert by vibration of the device. The over limits can be adjusted via the provided PC software .
- ✧ Convenient to measure and record SpO_2, pulse rate, respiration rate, oral/nasal air flow and snore signals in long-term while sleeping;
- ✧ Up to 72 hours data storage (500 pieces of record at most).
- ✧ Data can be uploaded to PC for review and analysis.

1.5 Intended Use

This Sleep Screener is intended for measuring and recording the functional oxygen saturation (SpO_2), pulse rate (PR), respiration rate (RR), oral/nasal air flow, snoring and so on. It’s applicable for

long-term tracking of SpO_2, PR, RR, oral/nasal air flow and snoring of adult or pediatric while sleeping in hospital, clinics or home. This device is not intended for continuous monitoring.

1.6 Working Environment

Operating temperature: 0~40℃

Operating humidity:

10%~90% (non-condensing)

Atmospheric pressure: 70kPa~106kPa

2 Preparation

2.1 Power Supply

- Internal power supply: built-in lithium battery 3.7V/500mAh.
- External power supply for charging via USB cable: the power source from USB cable should produce the capacity of 5V DC/1.2A.

2.2 Connection

The illustration of connection among SpO_2 probe, oral-nasal cannula, air-flow module and Sleep Screener is shown in figure 2.1.

Note: Two kinds of SpO_2 probes are for optional (L-type with wrapper and finger rubber), please refer to the probe you've optioned.

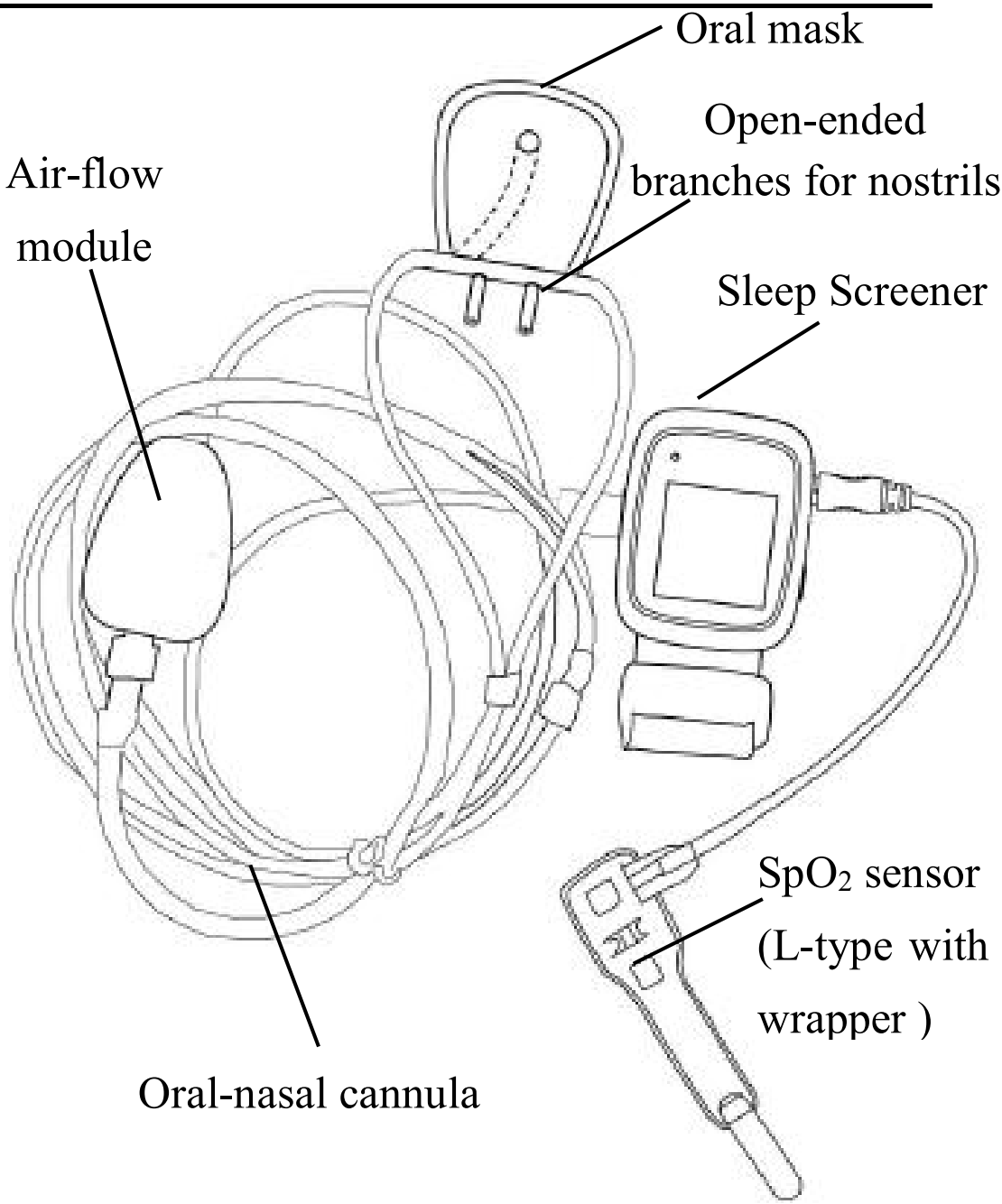


Figure 2.1A Device and accessories connection

----- L-type SpO_2 sensor with wrapper

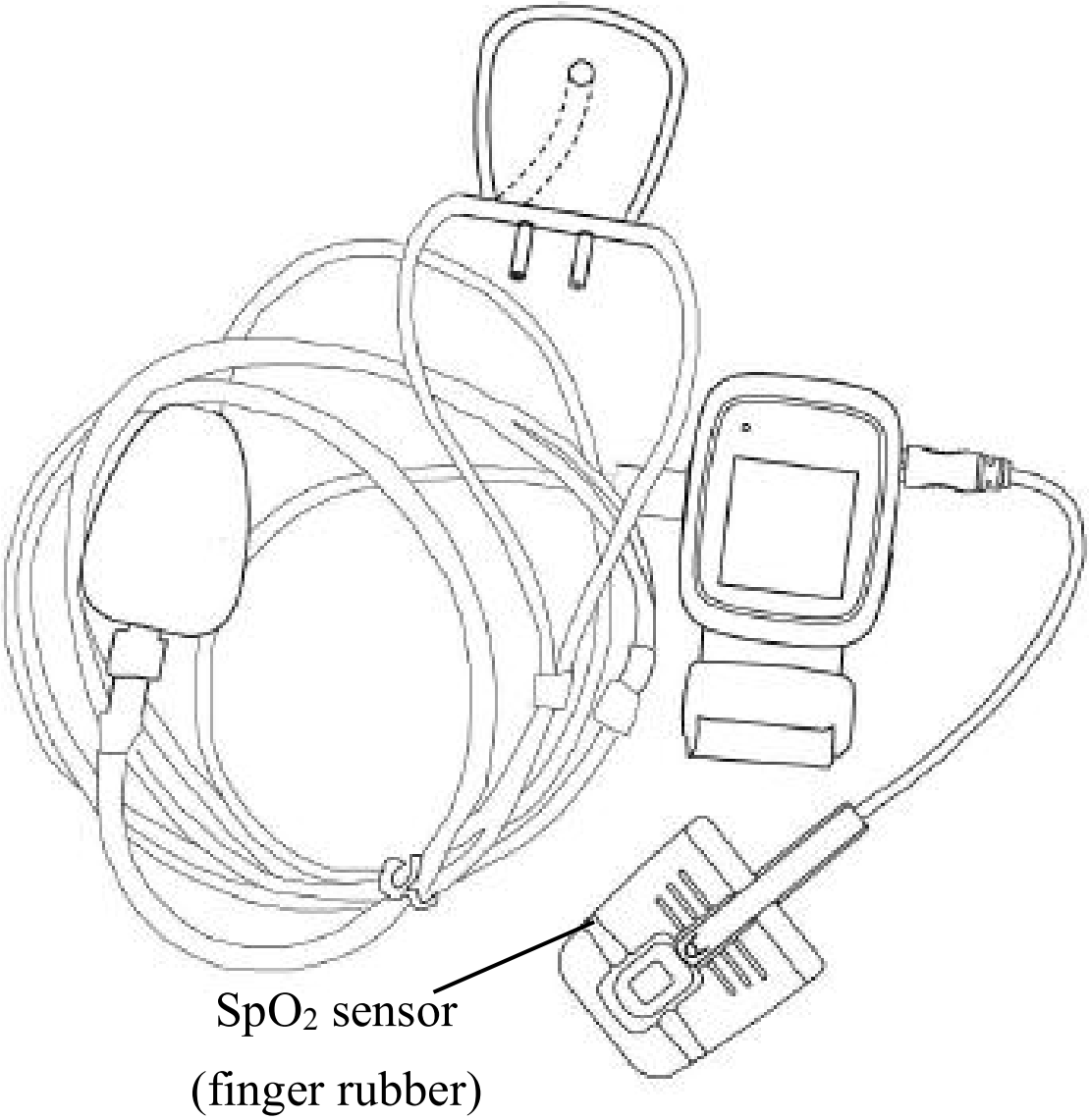


Figure 2.1B Device and accessories connection

----- Finger rubber SpO_2 sensor

3 Make measurement

3.1 SpO_2 Measurement

1. Long press power on/off key to turn on the device.

2. Connect the SpO_2 probe to the connector "  " on the side of the device, the red blinking light from the probe indicates a successful connection. (Note: When disconnecting the connector, be sure to hold the head of the connector firmly and pull).

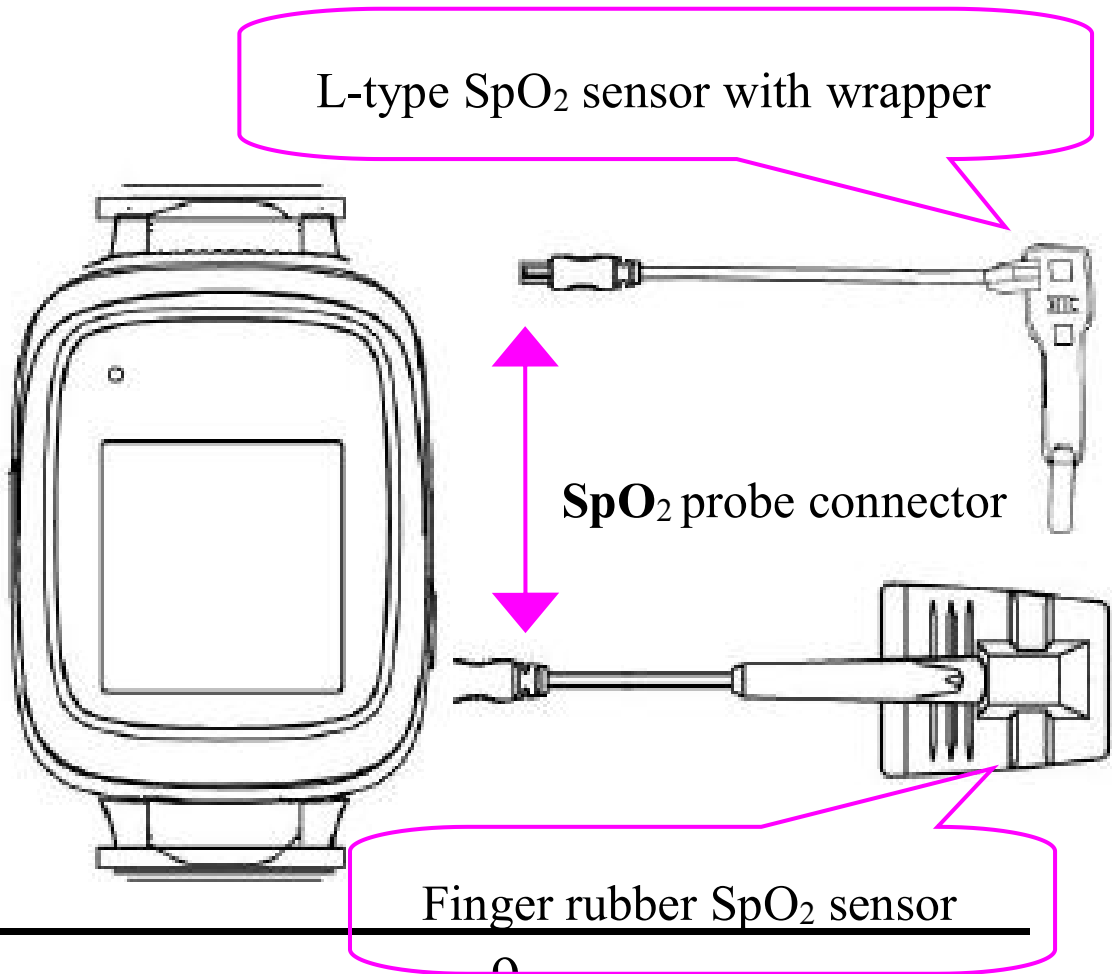


Figure 3.1 SpO_2 probe connection

3. Wear the Screener on your left hand.

4. ① For L-type SpO_2 sensor with wrapper: Wrap it upon the finger (index finger is preferred) with the disposable wrapper (the light emitter should aim at the light receiver), refer to figure 3.2A for placement illustration.

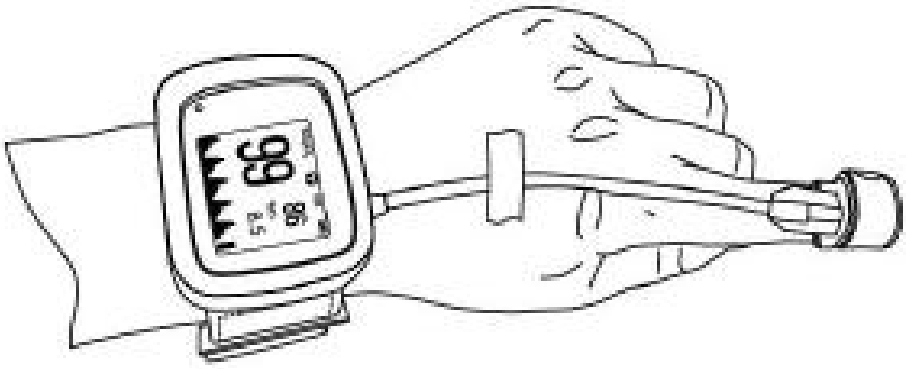


Figure 3.2A Placement illustration

--- For L-type SpO_2 sensor with wrapper

② For Finger rubber SpO_2 sensor: Insert the finger (index finger is preferred, the nail should be not too long) into the probe until the fingernail tip rests against the stop at the end of the probe (figure3.2B). Adjust the finger to be placed evenly on the middle base of the sensor (make sure the finger is in the right position).

Note: If the index finger cannot be positioned correctly, or is not available, other finger can be used.

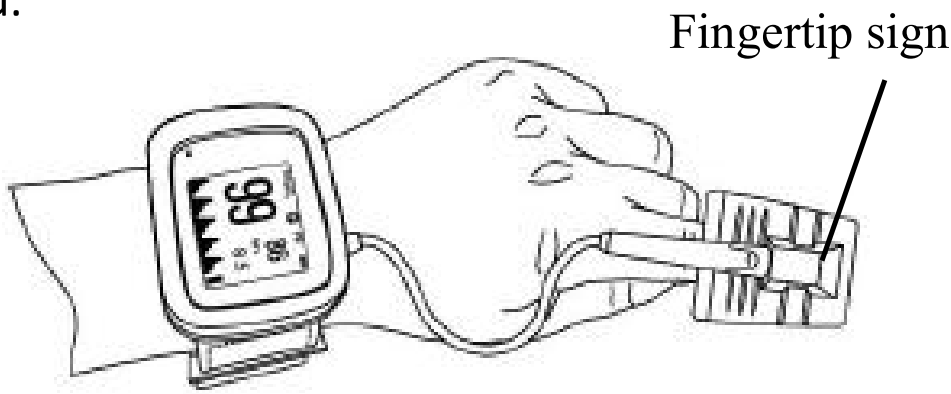


Figure 3.2B Placement illustration

--- For Finger rubber SpO_2 sensor

The right placement of probe is as shown in figure3.3A.

Figure 3.3A

The wrong placement of probe is as shown in figure3.33B/3.3C.

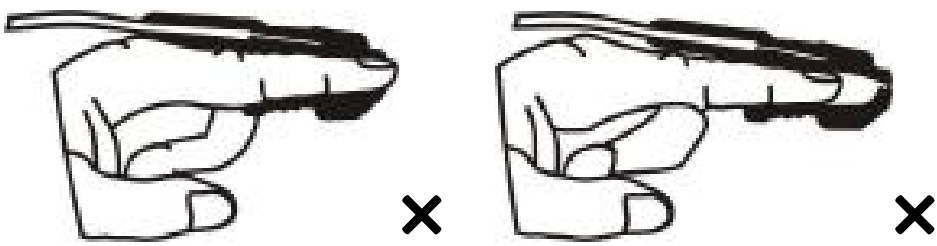


Figure 3.3B Figure out Figure 3.3C Not deep enough

5. The Screener will automatically start measurement in 2 seconds, and then recording the measured data automatically. The display screen is as shown in figure 3.4. User can read the values and view the waveform form the display screen.

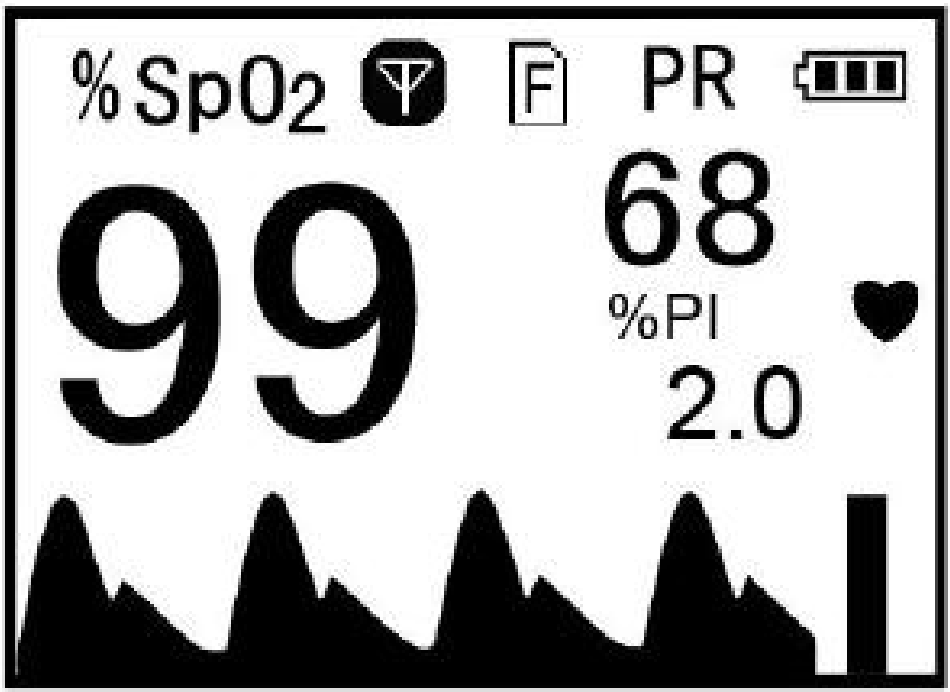


Figure 3.4 SpO_2 measuring screen display

Screen description:

- ✧ **"%SpO_2":** SpO_2 label; "99": current SpO_2 value.
- ✧ "**PR**": Pulse rate label; "68"： current PR value.

- “%PI”: Perfusion index label; “2.0”: current PI value.
- “  ”: Pulse beat icon.
- “  ”: Pulse strength bar-graph.
- The displayed waveform is plethysmogram.
- “  ”: Battery voltage icon.
- “  ”: Wireless icon. If the wireless (bluetooth communication) link is setup successfully, the icon will be displayed on the screen; if the icon is flashing, it means a failure connection. If there is no wireless icon, it means the device is not configured withe the wireless function.
- “  ”: Full memory icon. During measurement, if the memory is full, then icon”  ” will appear on the screen for prompt; if the memory is fail to store (eg. the Screener is unexpected power off), then icon “  ” will be displayed on screen. If the memory is full, it’s recommended that the user export the stored data from the device

then delete the data, and the device can continue storing data.

3.2 Oral-nasal Air Flow Monitoring

1. Connect the oral-nasal cannula to one end of the air-flow module, and insert the cable of air-flow module to the connector “  ” on the side of the device.
2. When the device shows “FL————” and “SN ————”, it indicates that the air-flow module is linked with the device successfully.
3. Then insert the the open-ended branches of the cannula into the nostrils, and put the oral mask cover the mouth (refer to the figure 3.5).
4. The oral-nasal air flow and snore waveform changes according to the patient’s breath.
5. The oral-nasal air-flow monitoring screen is as shown in figure 3.6.

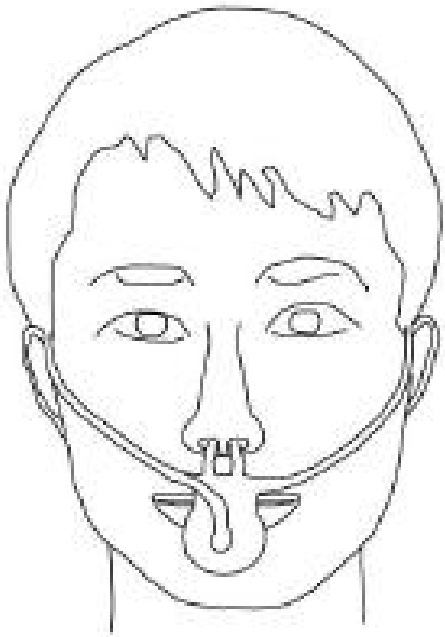


Figure 3.5

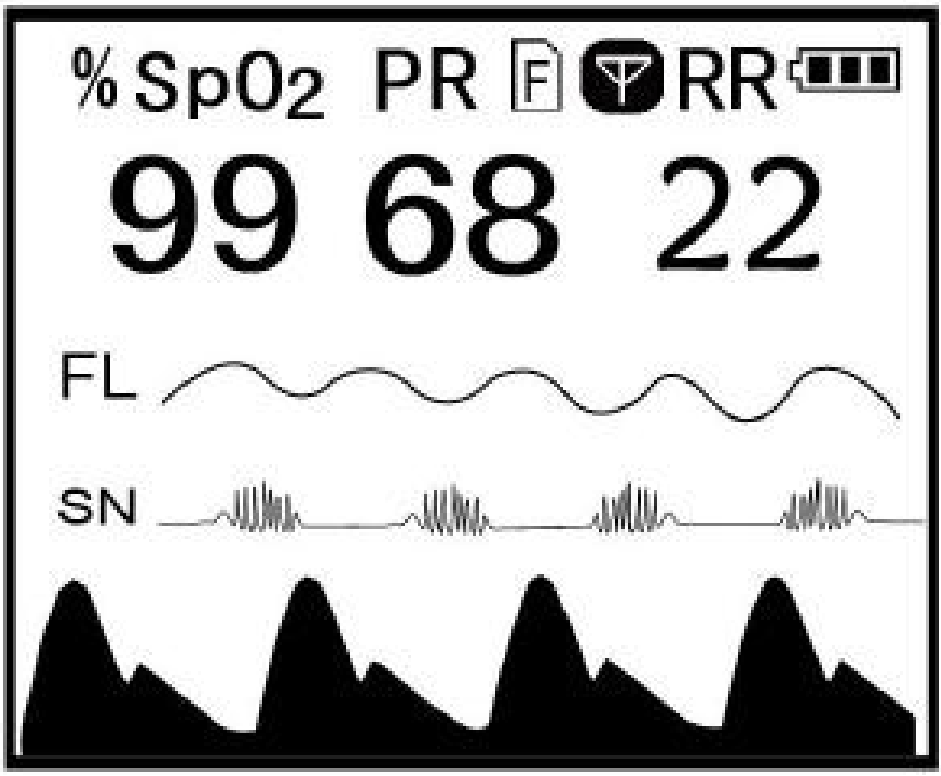


Figure 3.6 Oral-nasal air flow monitoring screen

Screen description:

- ✧ RR： Respiration rate icon; “22”: current respiration rate.
- ✧ FL：Oral-nasal air flow waveform.
- ✧ SN：Snore waveform.

Key Operation:

Long press: press and hold the key for over 1 second.

Short press: press the key for less than 1 second

Description for Power indicator:

1) The power indicator is always on during charging.

2) When the screen display is on, the indicator is off.

3) During measuring, short press the power on/off key, then the device enter into power saving mode (backlight is off), and the power indicator keeps on.

Short press the power on/off key again, the power indicator off and device screen display is on.

Activate the device during standby status:

1). Short press power on/off key “[redacted]”.

2). Insert the air-flow module into the Screener.

3.3 Setting Menu

Double short time press the power on/off key “[redacted]” to enter into Menu Setting Screen, as shown in figure 3.7.

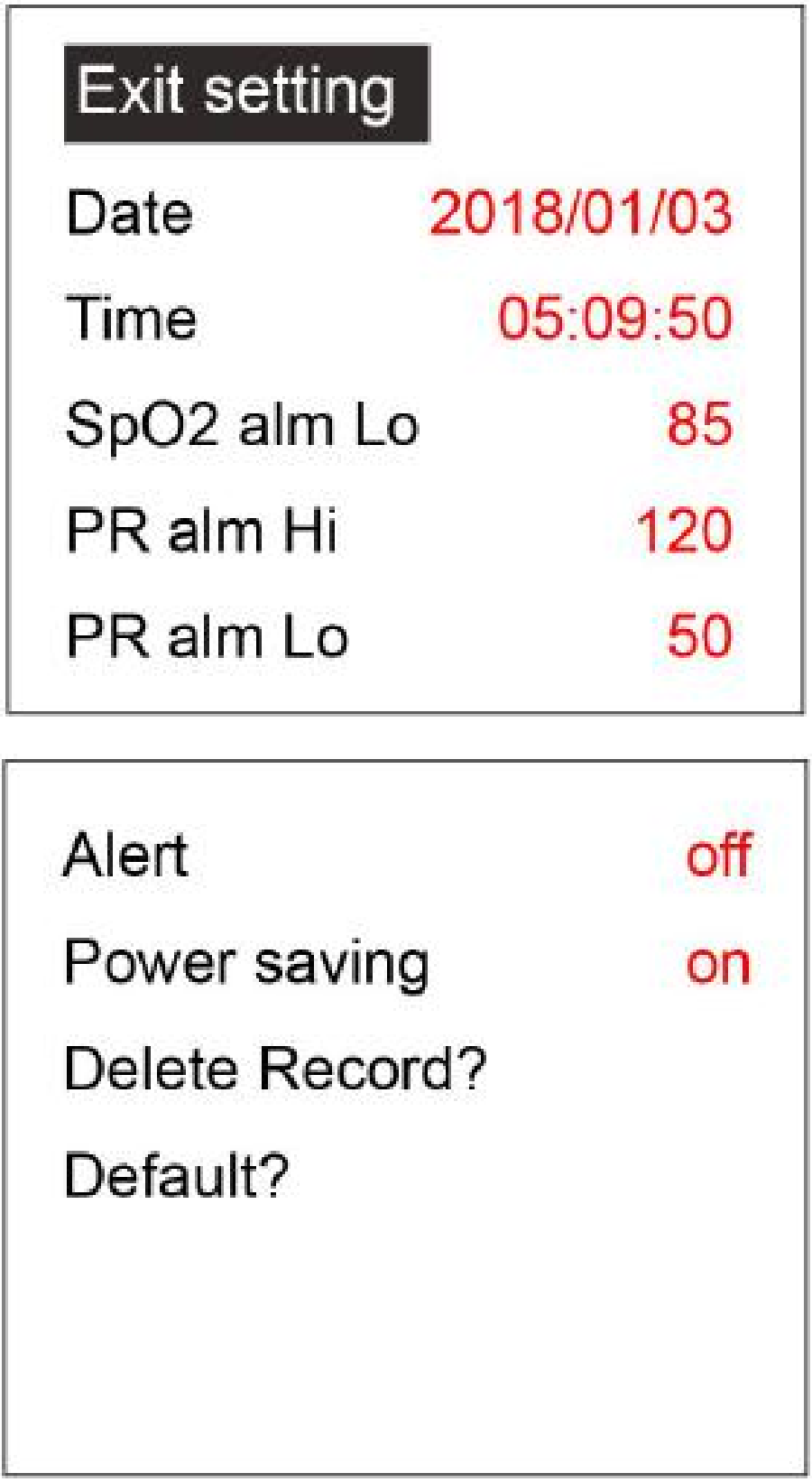

Exit setting
Date 2018/01/03
Time 05:09:50
SpO2 alm Lo 85
PR alm Hi 120
PR alm Lo 50
Alert off
Power saving on
Delete Record?
Default?

Figure 3.7

- ✧ Date: set current date;
- ✧ Time: set current time;
- ✧ SpO2 alm Lo: set SpO2 low limit; Setting range: 85%~100%, default setting: 85%;
- ✧ PR alm Lo: set pulse rate low limit; Setting range: 25bpm~99bpm, default setting: 50bpm;
- ✧ PR alm Hi: set pulse rate high limit; Setting range: 100bpm~250bpm, default setting: 120bpm;
- ✧ Alert: enable/disable the function of over-limit indication by vibration of the Screener, factory default is “off”.
- ✧ Power saving: turn on/off the power saving mode, factory default is “on”.
- ✧ Delete record: select “Delete record” and long press “ ■■■■ ” key to enter into Deletion Confirmation screen. Then, select “Yes” with

“ [redacted] ” key (short time press), and long pressing “[redacted]” key to carry out the deleting action.

✧ Default: select “Default” and long press “[redacted]” key to enter into Default Setting screen. Then select “Yes” with “[redacted]” key (short time press), and long pressing “[redacted]” key to carry out the action of resuming all items to factory setting.

Menu setting operation:

Short time press “[redacted]” to move the cursor to the item you need to set, and longtime press “[redacted]” to activate the setting item, then short time press it to modify the setting parameter; Next, longtime press “[redacted]” to confirm the modification and exit from this setting item. At last, move the setting item to “Exit setting” to exit from the setup menu.

3.4 Body Movement Detection

Wearing the Screener and making measurement, if you rotate your wrist, then the screen enter into the time indicating screen, as shown in figure 3.8.

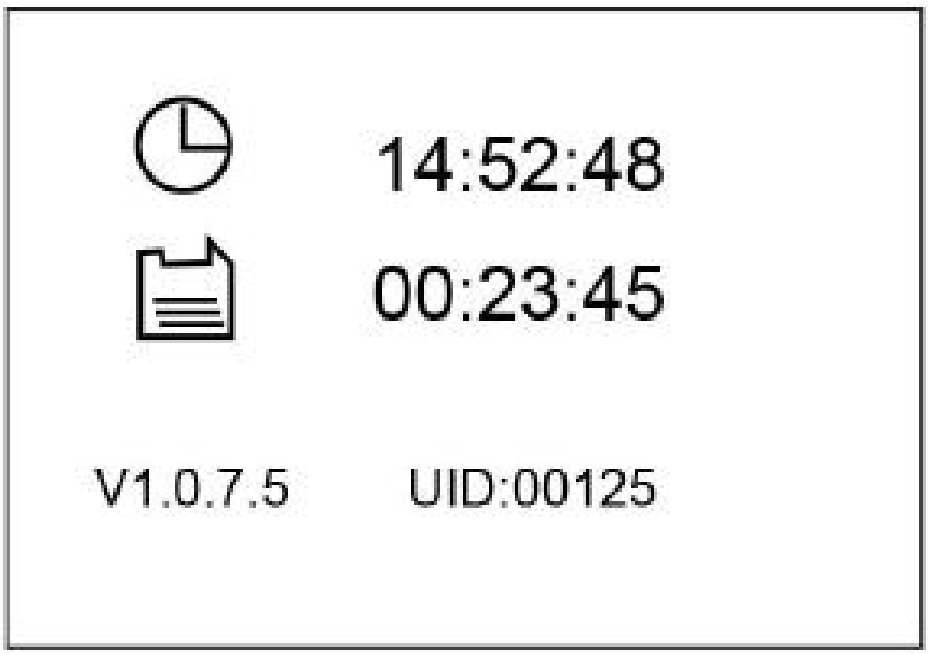
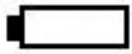


Figure 3.8

- “14:52:48”: the current time.
- “00:23:45”: the measuring duration up to now.
- “V1.0.7.5”: the software version.
- “UID 00125”: unique ID for the device.

3.5 Additional Information

- During measurement, if the memory is full, then icon “  ” appears on the screen, and the device will not store the following measured data again.
- If “  ” appears on the screen, it indicates that battery power is not enough, please charge for the battery. If you keep on using it, after a while the Screener will be off.
- Do not make measurement when the Screener is charging.
- Avoid shaking finger as possible as you can during measurement.
- Do not wrap wet finger or put wet finger directly into sensor.
- Do not let anything block the emitting light from device.
- Using enamel or other makeup on the nail may affect the measuring accuracy.
- If the first readings appear with poor plethysmogram (irregular or not smooth),

then the readings are unlikely true, the more stable values are expected by waiting for a while.

4 Technical Specification

A. Display Mode: 1.44 inch color LED display

B. SpO_2 measurement

Transducer: dual-wavelength LED

LED wavelength:

Red light: 660nm, Infrared light: 905nm

Maximal optical output power: less than 2mW maximum average

Measuring range: 0~100%

Display range: 0~100%

Measuring accuracy: *Arms* value (defined in ISO 80601-2-61) is not greater than 3% for SpO_2 range from 70% to 100%.

Data update: <10s

C. Pulse Rate measurement

Measuring range: 30bpm~250bpm

Measuring accuracy: ±2bpm or ±2%

(whichever is greater)

Resolution: 1bpm

D. Perfusion Index Display

Range: 0.2%~20%

E. Preset alert limits

SpO_2 Low alert limit: 85%

PR high alert limit: 120bpm

PR low alert limit: 50bpm

F. Oral-nasal air flow measurement (with air-flow module)

Measuring principle: Oral/nasal air flow pressure measuring method.

Parameters:

1) Oral/nasal air flow waveform: sampling rate of 100Hz, data storage rate of 25Hz

2) Snore waveform: sampling rate of 1000Hz, data storage rate of 25Hz

3) Respiration Rate:

Range: 6-60rpm

Accuracy: ±2rpm or ±5% which is greater

G. Power Supply:

Built-in lithium battery: 3.70V/500mAh

Operating current: ≤90mA

Continues working time (display is off and measuring SpO_2 Only): about 13 hours

H. Operating environment

Operating temperature: 5~40℃

Operating humidity:

15%~93% (non-condensing)

Atmospheric pressure: 70kPa~106kPa

I. Performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meets the specification described above when the modulation amplitude is as low as 0.6%.

J. Resistance to ambient light interference:

The accuracy of SpO_2 and PR measurement still meets the specification described above when the device is tested by SpO_2 simulator (Fluke Biomedical Index 2 series) while setting the emulating interference of sun light and 50Hz/60Hz fluorescent light.

K. Over-limit alert by visible display: If the measured SpO_2, PR, RR exceeds the preset alert limit value, then visible alert should be available.

L. Dimensions: D 56mm× W 44mm×H 16mm

Net Weight: about 45g

M. Bluetooth function

Frequency band: 2.4GHz

Working profile: BLE V4.0

5 Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied part.

The degree of protection against harmful ingress of liquids: IP22.

Electro-Magnetic Compatibility:

Group I, Class B

6 Packing List

1. SpO_2 probe.....One
   （L-type with wrapper or Finger Rubber）
2. Air-flow module..... .....One
3. Oral-nasal cannula..... .....One
4. Wristband .....One
5. AC power adapter.....One
6. Data cable... .....One（Optional）

Note: the accessories are subject to change, please refer to the items in your package.

7 Repair and Maintenance

7.1 Maintenance

The service life (not a warranty) of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please charge the device when low battery voltage indicator lightens.
- Please clean the surface of the device before using. Use cloth with alcohol to wipe the device first, and then let it dry in air or wipe it dry.
- The recommended storage environment of the device:
  ambient temperature: -20ºC ~60ºC, relative humidity 10%~95%, atmospheric pressure: 50kPa~107.4kPa.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle. However, if it is necessary to verify its precision routinely, the

user can do the verification by means of SpO_2 simulator, or it can be done by the local third party test house.

⚠ **High-pressure /high temperature sterilization cannot be used on the device.**

⚠ **Do not immerse the device in liquid.**

7.2 Cleaning and Disinfection

- Surface-clean sensor with a soft gauze by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution. Then surface-clean with a damp cloth and dry with a piece of cloth.
- Clean the wristband with soapy water. Please detach the wristband from the oximeter firstly.(Refer to Appendix for detailed disassembly method)

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the sensor if it is damaged.

7.3 Storage and Transportation

If the device will not be used for long period of time, wipe it clean and keep it in the packaging, which shall be kept in a dry and good ventilation place free from dust and corrosive gases.

Storage environment:

Ambient temperature: -20~60℃

Relative humidity: 10%~95% (non-condensing)

Atmospheric pressure: 50kPa~107.4kPa

Transportation:

The device should be transported by land (vehicle or railway) or air in accordance with the contractual terms.

Do not hit or drop it with force.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate display instable	1. The finger is not placed far enough inside. 2. The finger is not wrapped correctly	1. Place the finger correctly inside and try again. 2. Wrap the finger properly and make the emitter focus on receiver
Can not turn on the device	1. Low battery voltage 2. The device is malfunctioning.	1. Please charging. 2. Please contact the local service center.
Fragmental SpO_2 waveform	1. Your finger is out of proper location in the probe. 2. Blood flow in the finger blocked. 3. Extreme movement	1. Adjust your finger location properly. 2. Make sure there is no object may occlude the blood flow. 3. Extreme movement may cause invalid measuring result.

Appendix

A Common Knowledge for SpO_2 Measurement

1 Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$\mathbf{SpO_2 = HbO_2 / (HbO_2 + Hb) \times 100\%}$$

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with

certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these characteristics, SpO_2 can be determined. SpO_2 measured by this oximeter is the functional oxygen saturation -- a percentage of the hemoglobin that can transport oxygen. In contrast, hemoximeters report fractional oxygen saturation – a percentage of all measured hemoglobin, including dysfunctional hemoglobin, such as carboxyhemoglobin or metahemoglobin.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 measurement used in clinical becomes more popularly, such as monitoring the patient with

serious respiratory disease, the patient under anesthesia during operation, premature and neonate. The status of SpO_2 can be determined in time by measurement and find the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Factors affecting SpO_2 measuring accuracy (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methylene blue.
- ✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- ✧ Vascular dyes or external used color-up product such as nail enamel or color skin care
- ✧ Excessive patient movement
- ✧ Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or

intravascular line

- ✧ Exposure to the chamber with High pressure oxygen
- ✧ There is an arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

4 Factors causing low SpO_2 Measuring value (pathology reason)

- ✧ Hypoxemia disease, functional lack of HbO_2
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough

B Knowledge for Oral-nasal Air flow and Snoring detection

The principle of measurement for oral-nasal air flow and snoring is by means of the air flow pressure sensor within the measuring module to detect the pressure variation of the air flow which comes from patient's mouth/nose via the cannula. Oral/Nasal air flow is one of the important indicators to identify apnea which is meaningful for those suffering from sleep apnea and suddenly breath suspending.

Snoring is one of the main clinical performance from sleep apnea syndrome. Serious snoring may cause the oxygen lack in cerebrum, and result in hypoxaemia. Consequently, it may induce hypertension, arrhythmia, MI (myocardia infarction)

and stenocardia. Seriously, if breath suspending for over 120 seconds at night, sudden death may occur in the early morning.

C Wristband Installation and Disassembly

Introduction:

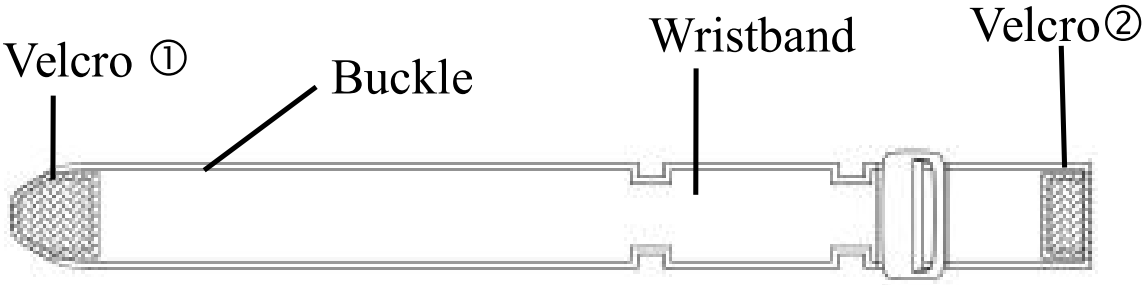


Fig. A

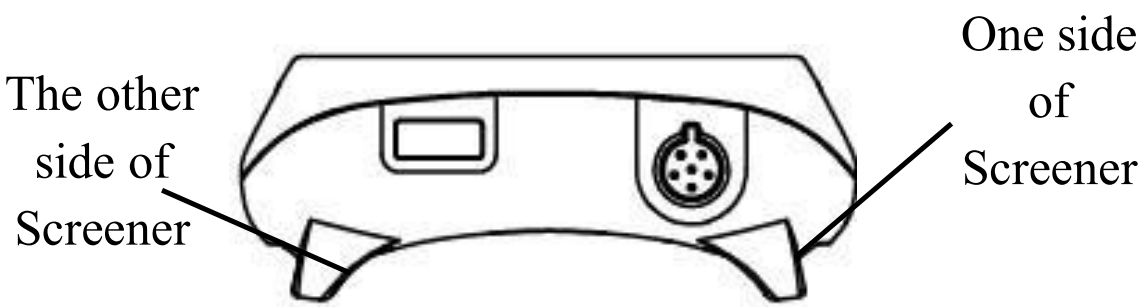


Fig. B Sleep Apnea Screener

Installation Procedure:

Step 1: Insert the wristband to the Screener from one side to the other side, as shown in Fig.C.

Fig. C

Step 2: Put the Screener on the wrist, and stick the Velcro ① to the inner side of wristband, press the wristband to make the Velcro ① stick to the inner side of wristband firmly, as shown in Fig.D.

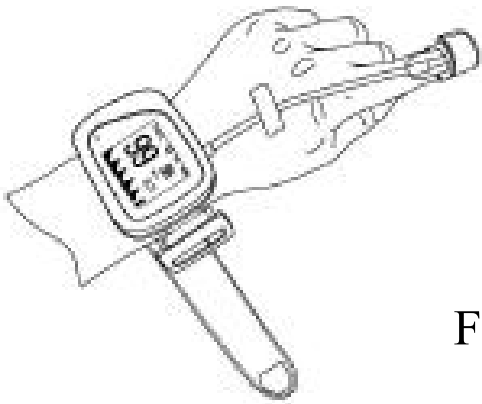


Fig. D

Step 3: Bring the wristband out from the buckle, and fold back the wristband, as shown in Fig.E. Then press the Velcro ② to make it stick to the outer side of wristband firmly, as shown in Fig.F.

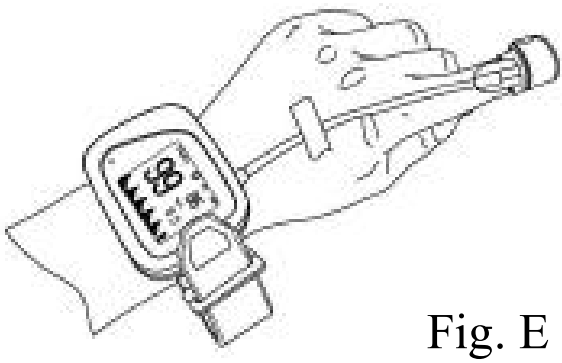
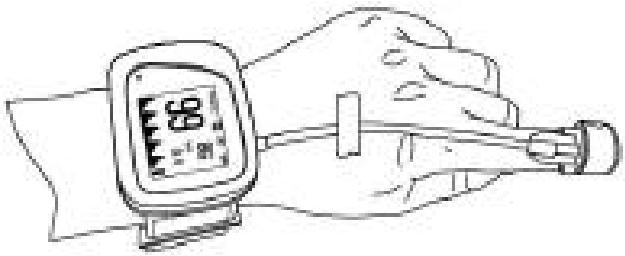


Fig. E



Disassembly: The process of wristband disassembly is similar to the installation method, but with reverse procedure.

⚠ **Note: Please detach the wristband from the Screener before cleaning the wristband.**

D Key of Symbol

Symbol		Description
Symbols on the enclosure		With Type BF applied part
		See User Manual
		Data interface
	SN	Serial number
		No alarm
		Do not litter at will
		Life span
Symbols on the screen	**%SpO_2**	The oxygen saturation
	%PI	Perfusion Index
	PR	Pulse rate
	RR	Respiration rate

		Pulse beat
		Wireless
		Pulse strength bar-graph
		Low battery voltage
		Memory full
		Memory error

Note: the above symbol may appear on your device.

Quality Certificate

Name: Sleep Screener

Model: AP-20

Date: _____

QA: _____

This prosuct has been inspected in accordance with the standards specified in the User Manual.

Shenzhen Creative Industry Co., Ltd

CE 0123

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