**GIMA**

PROFESSIONAL MEDICAL PRODUCTS

# *SLEEP APNEA SCREEN METER*

**REF** **RS01 (GIMA 33676)**

CONTEC MEDICAL SYSTEMS CO., LTD
No 112 Qinhuang West Street,
Economic & Technical Development Zone,
Qinhuangdao, Hebei Province, 066004,
PEOPLE'S REPUBLIC OF CHINA
Made in China

**MD**   **CE** **0123**

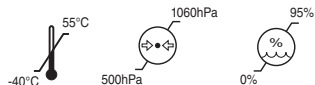**EU** **REP** Prolinx GmbH Brehmstr. 56,
40239 Duesseldorf Germany

55°C
-40°C

1060hPa
500hPa

95%
0%

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**IP22**

**User Notice**

Dear Users, thank you very much for purchasing the Sleep apnea screen meter.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

It is a medical device, which can be used repeatedly.

The User Manual contains use and technical descriptions.The Manual describes, in accordance with the device's features and requirements, main structure, functions, specifications, correct methods for transportation, assembly, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and device. Refer to the respective chapters for details.

Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, device damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and device damage due to users' negligence of the ope ration instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

Our company has the final interpretation to this manual. The content of this manual is subject to change without prior notice.

**Warnings**

**Remind that it may cause serious consequences to tester, user or environment.**

- ☛ Explosive hazard—DO NOT use the device in environment with inflammable gas such as anesthetic.
- ☛ DO NOT use the device while examining by MRI or CT, as the induced current may cause burn.
- ☛ Do not take the information displayed on the device as the sole basis for clinical diagnosis. The device is only used as an auxiliary means in diagnosis. And it must be used in conjunction with doctor's advice, clinical manifestations and symptoms.
- ☛ The maintenance to the device or replacement of the battery can only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire or explosion) may occur when replacing the battery by the personnel not fully trained. Users are not permitted to maintain or refit

the device by themselves.

- ☛ Uncomfortable or painful feeling may appear if using the blood oxygen probe ceaselessly, especially for the microcirculation disturbance users. It is not recommended that the sensor is used on the same finger for more than 6 hours.
- ☛ For some special users who need a more careful inspection on the test site, please don't place the device on the edema or tender tissue.
- ☛ Please do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the device, including the maintenance staff, as it may be harmful to the eyes.
- ☛ Each part of the device is firmly fixed,if accidental falling leads to the small parts such as a button to fall off,avoid swallowing of these parts,it may cause suffocation.
- ☛ The device contains silicone, PVC, TPU, TPE and ABS materials, whose biocompatibility has been tested in accordance with the requirements in ISO 10993-1, and it has passed the recommended biocompatibility test. The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.
- ☛ Do not wrap the nasal oxygen tube, SpO2 probe or USB cable around neck to avoid an accident.
- ☛ Be careful to avoid tying or wrapping senor, tube, wire and cable to the patient, avoiding accidents to the patient.
- ☛ The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. The equipment and packaging materials must be placed in the region where the children are out of reaching.
- ☛ The device can not be used with the equipment not specified in the Manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device.
- ☛ The $SpO_2$ probe is only suitable for using with the device. The device can only use the $SpO_2$ probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the $SpO_2$ probe before using, incompatible accessories may cause device performance degradation, device damage or patient injury.
- ☛ Do not reprocess the accompanying $SpO_2$ probe.
- ☛ Check the device before use to make sure that there is no visible damage that may affect user's safety and device performance. When there is obvious damage, please replace the damaged parts before use.

- When the message "Sensor Off" or "Sensor Fault" appears on the screen, it indicates that the SpO2 probe is disconnected or line fault occurs. Check the connection of the $SpO_2$ probe and whether there is damage for the probe, if necessary, please replace the probe to avoid risks. The probe fault will not result in a safety hazard.
- Functional testers can not be used to assess the accuracy of the $SpO_2$ probe and Pulse Oximeter.
- Some functional testers or patient simulators can be used to verify whether the device works normally, for example, INDEX-2LFE Simulator (software version: 3.00), please refer to the Manual for the detailed operation steps.
- Some functional testers or patient simulators can measure the accuracy of the device copied calibration curve, but they can not be used to evaluate the device accuracy.
- When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- When storing the device, keep it away from children, pets and insects to avoid affecting its performance.
- Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, to avoid affecting its performance.
- The measured accuracy will be affected by the interference of electrosurgical equipment.
- When several products are used on the same patient simultaneously, danger may occur which is arisen from the overlap of leakage current.
- CO poisoning will appear excessive estimation, so it is not recommended to use the device.
- This device is not intended for treatment.
- The intended operator of the device may be a patient.
- Avoid maintaining the device during using.
- The device can not be used during charging.
- Do not damage the wristband,in order to avoid affecting the use;or the wristband is not fastened,causing the instrument to fall and damage in the process of use.
- Shock，coma patients should be under the guidance of the hospital and professional nursing staff can be used.

**Contents**

**1 Overview**

The oxygen saturation is the percentage of $HbO_2$ in the total Hb in the blood, so-called the $O_2$ concentration in the blood, it is an important physiological parameter for the respiratory and circulatory system. A number of diseases related to respiratory system may cause the decrease of $SpO_2$ in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' $SpO_2$ is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field.

Insert the finger when measuring, the device will directly display the $SpO_2$ value measured, it has a higher accuracy and repeatability.

The device is intended to provide sleep test for patients with sleep apnea - hypopnea syndrome, a basis for whether a comprehensive sleep examination is necessary, and a reference to the effectiveness of treatment for patients who are receiving treatment, it can be used in family, community medical institution and hospital.

Humanized ON / OFF design: manual and automatic ON / OFF. The patient can adopt manual power-on to record or auto power-on in accordance with the sleep time estimated to record, to reduce patient's psychological burden and test easily. After setting auto power-on, the device will save the cases automatically.

Adopt a large capacity SD card to store many cases, upload case by USB to PC or computer for saving directly. By the PC software, personal information can be edited to save the case for a long time, the case collected can be analyzed to help doctor to diagnose quickly, which meets the requirements of respiration department, sleep center and internal medicine, etc. in hospital.

The patient can also invite expert to diagnose remotely via network, which is convenient for patient to have a physical examination at home.

**1.1 Features**

A.LCD display.

B.Easy to operate.

C.Wrist design, small in volume and light in weight.

**1.2 Applied range**

be applicable for monitoring sleep respiration and $SpO_2$.

**1.3 Environment requirements**

Storage Environment

a) Temperature: -40 ℃ ~ + 55 ℃

b) Relative humidity: ≤ 95%

c) Atmospheric pressure: 500 hPa ~ 1060 hPa

Operating Environment

a) Temperature: 10 ℃~ 40 ℃

b) Relative Humidity: ≤ 75%

c) Atmospheric pressure: 700 hPa ~ 1060 hPa

**1.4 Precautions**

**1.4.1 Attention**

**Point out conditions or practices that may cause damage to the device or other properties.**

- Before using the device, make sure that it locates in normal working state and operating environment.
- In order to get a more accurate measurement, it should be used in a quiet and comfortable environment.
- When the equipment from the cold or hot environment to normal room temperature, please do not use it immediately,wait four hours at least is recommended.
- If the device is splashed or coagulated by water, please stop operating.
- DO NOT operate the device with sharp things.
- The device is suitable for children and adult.
- The device may not be suitable for all users, if you can't get a satisfactory result, please stop using it.
- Data averaging and signal processing have a delay in the upgrade of $SpO_2$ data values. When the data update period is less than 30 seconds, the time for obtaining dynamic average values will increase, which is arisen from signal degradation, low perfusion or other interference, it depends on the PR value.
- The device has 5-year service life, date of manufacture: see the label.
- The device does not provide over-limit alarm function for $SpO_2$ and PR, so it is inapplicable for using in the place where need such function.
- The maximum temperature at the $SpO_2$ probe -tissue interface should be less than 41℃ which is measured by the temperature tester.
- During measuring, when abnormal conditions appear on the screen, please pull out your finger and

reinsert it to measure again.

⚠ If some unknown error appears during measuring,the product can be connected to the adapter through the

date line,long press "⏻"button about 10 seconds for reset and then shut down to terminate the operation of the

product.

⚠ Do not contort or drag the wire of the device.
⚠ The plethysmographic waveform is not normalized, as a signal inadequacy indicator, when it is not smooth and stable, the accuracy of the measured value may degrade. When it tends to be smooth and stable, the measured value read is the optimal and the waveform at this time is also the most standard.
⚠ The device can not be used during charging.
⚠ If necessary, please visit our official website to get the information about $SpO_2$ probe that can be used with this device.
⚠ If the device or component is intended for single-use, then the repeated use of these parts will pose risks on the parameters and technical parameters of the equipment known to the manufacturer.
⚠ If necessary, our company can provide some information (such as circuit diagrams, component lists, illustrations, etc.), so that the qualified technical personnel of the user can repair the device components designated by our company.
⚠ Operators cancontact our company to obtain the modified Bland and Altman plot.
⚠ The measured results will be influenced by the external colouring agent (such as nail polish, colouring agent or color skin care products, etc.), so don't use them on the test site.
⚠ Do not fix the SpO2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO2 and pulse rate.
⚠ As to the fingers which are too cold or too thin or whose fingernail is too long, it may affect the measured results, so please insert the thicker finger such as thumb or middle finger deeply enough into the probe when measuring.
⚠ The finger should be placed correctly (see picture 5.15), otherwise,the measurement may be inaccurate.
⚠ The light between the photoelectric receiving tube and the light-emitting tube of the device must pass

through the subject's arteriole. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate results.

⌂ Excessive ambient light may affect the measured results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure to place the sensor properly and cover the sensor with opaque material.

⌂ requent movement (active or passive) of the subject or severe activity can affect the measured accuracy.

⌂ The $SpO_2$ probe should not be placed on a limb with the blood pressure cuff, arterial ductus or intraluminal tube.

⌂ The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as it has not defibrillation function.

⌂ The device has been calibrated before leaving factory.

⌂ The device is calibrated to display functional oxygen saturation.

⌂ The equipment connected with the Oximeter interface should comply with the requirements of IEC 60601-1.

⌂ Please select medical power adapter to charge it, when connecting the special adapter with the socket, make sure there is no shelter near the socket and it is easy to plug and unplug, otherwise the power will not be cut off in time when necessary, causes damage.

⌂ The actual product may be slightly different from the picture in the manual ,please refer to the actual product.

⌂ The expected service life of the attached parts or accessories of the equipment is two year.See the packaging label for the production date.

⌂ The shelf life shall prevail if the accessory or part has a shelf life that is shorter than its intended service life.

⌂ The device should be operated by medical personnel via professional training,or non-medical personnel who have been guided.

⌂ This device has the function of prompting, users can check on this function according to chapter 5.1.2 as a reference.

⌂ The device has the function of limits prompting, when the measured data is beyond the highest or lowest limit, the device would start prompting automatically on the premise of the prompting function is on.

- The device has the function of prompting, this function can either be paused, or closed (default setting) for good. This function could be turned on through menu operation if you need. Please check the chapter 5.1.2 as a reference.
- Please check the package before use.Do not use if the package is damaged.
- Please refer to the body for other matters needing attention.

**1.4.2Clinical restriction**

A. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, Raynaud's syndrome, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the $SpO_2$ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

B. The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.

C. The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin(such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulfhaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.

D. Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia patients still show better pulse oxygen measured valued.

E. Contraindication:

a. The person who is allergic to silicone, PVC, TPU TPE or ABS.

b. The damaged skin tissue.

c. During cardiopulmonary resuscitation.

d. When the patient is hypovolemic.

e. For assessing the adequacy of ventilatory support.

f. For detecting worsening lung function in patients on a high concentration of oxygen.


**2 Principle**

The product makes a preliminary judgment on whether the user has sleep apnea - hypopnea syndrome and the severity of the disease by recording and analyzing the changes of respiration and $SpO_2$ during a sleep.

**3 Functions**

A.It can collect the signals of nasal airflow,oxygen saturation and pulse in real time,and display the waveform and data in real time.

B.Multi case storage function

C.Card reading function

D.Storage function of case database

E.PC software case data and analysis results display function

F.Report output function

G.Continuous recording time

H.Real-time clock

I.Timing recording function

J.PR sound and prompt tone function

K.Charging function

L.Quantity of electricity indication

## 4 Appearance and structure

### 4.1 Appearance



Menu/Confirm button

Power on/Power off/Awake button

Operation/Charge indicator light

Nasal cannula connection

Charge/Oximeter probe/USB connection

The device is consisted of main unit, nasal oxygen cannula, SpO$_2$ probe, power adapter（optional）, USB data line and PC software.No detachable parts for main unit itself, applied parts: the nasal oxygen cannula and SpO$_2$ probe, they are detachable parts.

**4.2 Interface introduction**
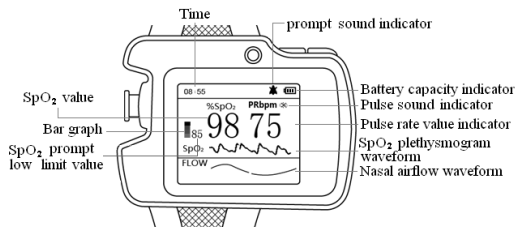


Figure4.1 Measurement interface
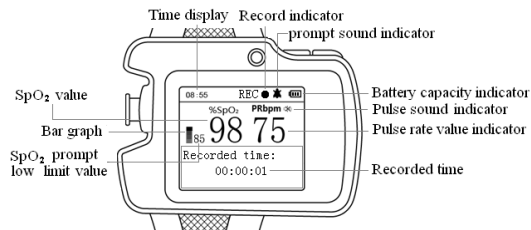


Figure 4.2 Record interface

(1)SpO$_2$ value display

Sign: %SpO$_2$

Description: it displays SpO$_2$ value after inserting the finger into the SpO$_2$ probe.

(2)Pulse rate value display

Sign: PRbpm

Description: it displays PR value after inserting the finger into the SpO$_2$ probe.

(3)Bar graph display

Sign:



Description: it displays the pulse beat after inserting the finger into the SpO$_2$ probe.

(4 )Nasal airflow waveform

Sign: flow

Description: real-time display of nasal airflow waveform

(5)SpO$_2$ plethysmogram waveform display

Sign: SpO$_2$

Description: real-time display of PLETH waveform

(6) Pulse sound indication

Sign: 

Description: : ON, : OFF

(7) Prompt (over-limit of SpO$_2$ or PR value) sound indication

Sign:

Description: ⌂: ON, ⌂: OFF

(8)Battery capacity indication

Sign: ▮▮▮, ▮▮, ▮, ☐

Description: it indicates low battery when ☐ flickers.

(9)Real-time clock display
 Sign: 08:55
 Description: it displays real-time clock
(10)Lower limit of $SpO_2$ prompt
 Sign: 85
 Description: the current lower limit value is "85".
(11)Record indication
 Sign: REC ●
 Description: ● flickers under record state
(12)Recorded time display
 Sign: 00:00:01
 Description: the time that the device has recorded, format: hour:minute:second
(13)Prompt functions for finger out, sensor off, sensor fault
 It will give corresponding prompts when $SpO_2$ measurement is abnormal:
  "Finger out": no finger detected;
  "Sensor off": no $SpO_2$ probe detected;
  "Sensor fault": the probe is damaged.
**4.3Structure, accessories and software description**
A. Main unit,nasal oxygen cannula,$SpO_2$ probe,power adapter (optional),USB data line,PC software
B.Accessories:Two Luer male adapter,One User Manual
Please check the device and accessories according to the list to avoid that the device can not work normally.

C.Software description

PC software name: ResMonPlus          PC software model: No

PC software version: V3.0

Naming rule for version: VX.Y. Z. B

X,Y: major enhancive software upgrade

Z: minor enhancive software upgrade

B: improvement software upgrade

Obtain PC software version from "Help" in PC software.

Involved algorithm：

Name: a method for judging respiratory wave of human respiratory monitoring system

Type: mature arithmetic

Purpose: be used for preliminary breathing screening in patients with sleep-disordered breathing.

Clinical function: the algorithm analyzes the breathing digital signal of patients with sleep-disordered breathing to form an effective and clear respiratory waveform.

**5 Operating**

**5.1 Operation and use of the instrument**

**5.1.1 Button operation**

**ON / OFF / Awake button**

Power on: the green indicator is light after long pressing "⏻", then it enters to the measurement interface after displaying the time.

Power off: under non-record state, long pressing "⏻"to power off.

under record state, it is disable to power off,you need to stop recording before you operate.

Screen awaking: under record state, if there is no button operation within 60 seconds, it will automatically enter power-saving state. Short press "⏻" to awake the LCD to display.

Menu / Confirm button

Under measurement interface, long press "M" button to enter the main menu, then short press "M" button in main menu to browse the menu, long press it to enter the next menu or set the menu option selected.

**5.1.2 Menu operation**
**1.Main menu**
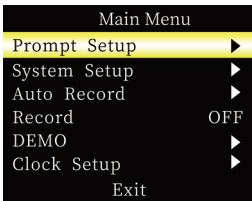Under the measurement interface, long press "M" button to enter the main menu, as shown in Figure 5.1

```
               Main Menu
  Prompt  Setup              ▶
  System  Setup              ▶
  Auto  Record               ▶
  Record                   OFF
  DEMO                       ▶
  Clock  Setup               ▶
             Exit
```

Figure 5.1 Main menu

Table 5.1

| No. | Function | Description |
|-----|----------|-------------|
| 1 | Prompt | Select it to enter its setting menu |
| 2 | System Setup | Select it to enter its setting menu |
| 3 | Schedule Poweron | Select it to enter its setting menu |
| 4 | Record | Select it to enter its setting menu |
| 5 | DEMO | Select it to enter DEMO interface |
| 6 | Clock | Select it to enter its setting menu |
| 7 | Exit | Select it to return to measurement interface |

**2. Prompt setting**

The prompt setting menu is shown as Figure 5.2



Figure 5.2 Prompt setting menu

When the "prompt" is "ON", the device will give a sound prompt when over-limit or low battery appears. When "Pulse Sound" is "ON", it can give a pulse sound prompt.

Table 5.2

| No. | Function | Description |
|-----|----------|-------------|
| 1 | SpO$_2$ HI (%) | Setting range: 1 ~ 100, default: 99 (unit: %) |
| 2 | SpO$_2$ LO (%) | Setting range: 0 ~ 99, default: 85 (unit: %) |
| 3 | PR HI (bpm) | Setting range: 1 ~ 254, default: 150 (unit: bpm) |
| 4 | PR LO (bpm) | Setting range: 0 ~ 253, default: 50 (unit: bpm) |
| 5 | Prompt Sound | "ON" / "OFF", default: "OFF" |
| 6 | Pulse Sound | "ON" / "OFF", default: "OFF" |
| 7 | Exit | Select it to return to previous menu. |

**3. System menu**

1)    The system menu is shown as Figure 5.3:



Figure 5.3 System menu

Table 5.3

| No. | Function | Description |
|-----|----------|-------------|
| 1 | Hard.ver | Hardware version number, which can not be set by user. |
| 2 | Soft.RV | Release software version number, which can not be set by user. |
| 3 | Soft.FV | Full software version number, which can not be set by user. |
| 4 | Time format | 24-hour format, which can not be set by user. |
| 5 | Language setup | Select it to enter language setting interface |
| 6 | Delete Data | Delete data stored by the device |
| 7 | Exit | Select it to return to previous menu. |

2)    The language setting menu is shown as Figure 5.4

Figure 5.4 Language setting menu

Table 5.4

| No. | Function | Description |
|-----|----------|-------------|
| 1 | English | Set language to English and return to the main menu displayed in English. |
| 2 | Chinese | Set language to Chinese and return to the main menu displayed in Chinese. |
| 3 | Exit | Select it to return to previous menu. |

**4.Auto Record**

Auto Record setting menu is shown as Figure 5.5:



Figure 5.5 Auto Record menu

Table 5.5

| No. | Function | Description |
|-----|----------|-------------|
| 1 | Set Month | Setting range: 1 ~ 12 |
| 2 | Set Day | Setting range: 1 ~ 31 |
| 3 | Set Hour | Setting range: 0 ~ 23 |
| 4 | Set Minute | Setting range: 0 ~ 59 |
| 5 | Record Length(h) | Setting range: 1~10, default: 8, unit: hour |
| 6 | Auto Record? | "NO"/"YES", YES: confirm, No: cancel |
| 7 | Exit | Select it to return to previous menu, "YES": exit this interface, the settings take effect. |

Attention: "Auto poweron" can not be set during recording.

Attention: when it reaches the set time and under "OFF" state, the device will turn on and record automatically.

**5. Record setting**

1) When "Record" is "OFF", select it to enter record setting menu shown as Figure 5.6. The prompt information "You will start to record! Are you sure?" displays on the interface, select "Exit" after setting to "Yes" to enter the record interface, under record interface, record sign is "REC ●", it indicates that it is recording when "●" flickers, recorded time displays on the interface shown as Figure 5.7. Select "Exit" after setting to "No" to enter the interface which will not record.
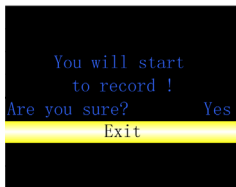


Figure 5.6 Record setting menu
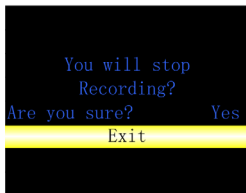
Figure 5.7 Recorded time interface

Attention:

If the interface prompts "TF card is full" during recording, it indicates that the remaining capacity of the built-in SD card is insufficient, then the user can not record, the user need to transfer previous cases via computer.

Manual poweroff can not be performed during recording, please exit the record mode firstly, then power off.

**Advice:**

✧ Regularly back up the recorded cases by computer to prevent the loss of case due to damage to the built-in SD card.

✧ Do not store any file except the cases.

Attention:

The device interface prompt "TF card error"when the card is damaged.

2) When "Record" is "ON", select it to enter the stop recording menu shown as Figure 5.8. The prompt information "You will stop recording? Are you sure?" appears on the interface, select "Exit" after setting to "Yes" to exit the stop recording interface to enter the measurement interface; select "Exit" after setting to "No" to enter the interface which will continue recording.

3)
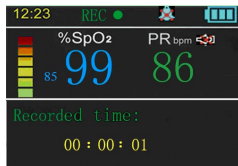
Figure 5.8 Stop recording menu

**6．Time setting**

The time setting menu is shown as Figure 5.9:



Figure 5.9 Time setup menu

Table 5.6

| No. | Function | Description |
|-----|----------|-------------|
| 1 | Set Year | Setting range: 10 ~ 99, represents 2010 ~ 2099 |
| 2 | Set Month | Setting range: 1 ~ 12 |
| 3 | Set Day | Setting range: 1 ~ 31 |
| 4 | Set Hour | Setting range: 0 ~ 23 |
| 5 | Set Minute | Setting range: 0 ~ 59 |
| 6 | Are you sure? | "No" / "Yes", "Yes": confirm, "No": cancel |
| 7 | Exit | Select it to return to previous menu, select "Exit" after setting to "Yes", an effective time interface appears. |

Attention: the time can not be set during recording.

**5.1.3Connection of application parts**

1. Nasal airflow monitoring

Unpack the packaging of nasal oxygen cannula, unscrew the screw cap following Figure 5.10, then insert the Nasal oxygen cannula into its jack and tighten it. Insert the oxygen breathing apparatus into the nostril, wind the oxygen-dividing connecting tube from ear to the lower jaw. Turn on the device after adjusting the locating ring to a comfortable state, after a few seconds, check the respiration state after stable waveform appears. Wearing mode of nasal oxygen cannula is shown as Figure 5.11, and the overall wearing mode is shown as Figure 5.12.
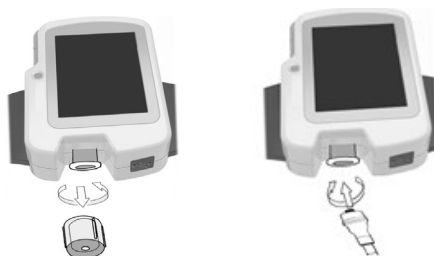
Figure 5.10Connection of nasal oxygen cannula

[1]



correct

wrong
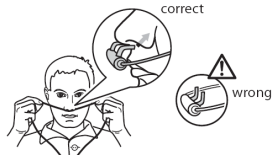
[2]                    [3]



Figure 5.11 Wearing mode of nasal oxygen cannula
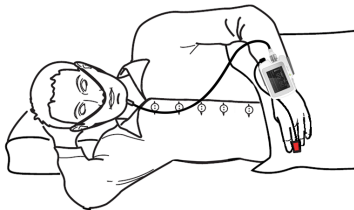
Figure 5.12 Sketch map of overall wearing

**Attention:**

🔔       Wear the nasal oxygen cannula according to the regulations, or it will affect the collection effect.

🔔       If the non-screwing nasal oxygen cannula is used, then use the Luer male plug to connect.

🔔       The nasal oxygen cannula is disposable, repeated use may cause infection.

🔔       Refer to the packaging of nasal oxygen cannula for its use.

**2.** Monitoring of $SpO_2$ and PR

The device equips with the two $SpO_2$ probes as table 5.7

Table 5.7

| No. | Name | Quantity | Length (cm) | Whether shielding |
|-----|------|----------|-------------|-------------------|
| 1 | Digital fingerstall $SpO_2$ probe | 1 | 35 | No |
| 2 | Disposable non-woven adult probe | 2 | 35 | No |
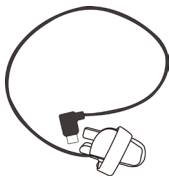
Figure 5.13 Digital fingerstall SpO$_2$ probe     Figure 5.14 Disposable non-woven adult probe
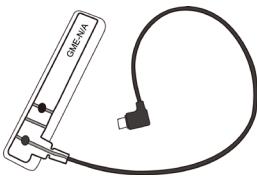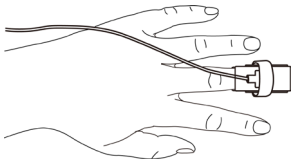


Figure 5.15 Wearing mode of probe

Insert the SpO$_2$ probe into USB interface, the wearing way is shown in Figure5.15.

(1) Connect the probe with the device.

(2) Insert the finger into the probe.

(3) Under the measurement interface, read the related data directly from the LCD.

**Attention:**

When inserting the finger, the light emitting from the sensor must be directly irradiated to the side of the fingernail.

**5.1.4 Auto poweron function**

After setting the time of auto poweron, turn off the device, when it reaches the time set, it will turn on and record automatically. After "Record Timeslice" time, it will turn off automatically (refer to 5.1.2).

**5.1.5Automatic sync clock and USB data upload**

Long press "⏻" to turn on the device to enter to the main interface, insert one end of the USB data line into USB interface as Figure5.16, the other end to the USB interface of PC as Figure 5.17, the connection mode from the device to PC is shown as Figure5.18. If connection is built at the initial interface of the PC software, the device will automatically synchronize with the PC. After synchronization, it will enter card read state. If fails to build connection at the initial interface, clock can not be synchronized. After entering this mode, a new disk will appear in the computer.After a new drive letter appears in computer, double-click it to open it to find the data recorded, which can be copied from the device and saved to any disk in my computer. Open the file recorded by the PC software to analyze the patient's sleep information.Note that the drive letter recognized by the device when connected to the computer is write -protected to prevent malware from   implanting viruses

  (power on - insert the USB data line - open my computer - open the device drive letter - copy the data file generated to PC hard disk to avoid data missing).



Figure 5.16 Sketch map for connection between Sleep apnea screen meter and USB data line
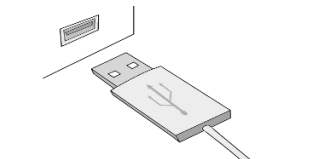
Figure 5.17 Sketch map for connection between PC and USB data line
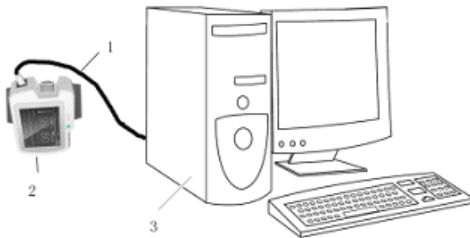


Figure 5.18 Sketch map for connection between device and computer
1. USB data line    2. Sleep apnea screen meter    3. PC

**Attention:**
- The data can not be uploaded until stop recording.
- If "Device drive letter" can not be recognized, unplug the USB data line and insert it again.

**5.1.6 Delete data**
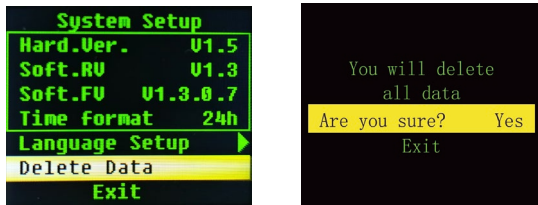


Figure 5.19    Delete date interface

As shown in the figure,when the data stored in the device needs to be deleted,the system settings interface in the menu is entered.Select the "Delete Data" option,When the "delete all data?"Select "Yes".The date in the device is then completely delete.

**5.1.7 Charging**

Connect one end of the power adapter to power socket, the other end to the device by the data line.
Charging indicator: it is orange when the battery is being charged, and it is green after fully charged.

**Attention:**

🖰        To ensure enough operation time, please fully charge the battery before measuring.

🖰        Please charge the device under "OFF" state.

**6 Maintain, Transport and Storage**

**6.1Cleaning and disinfection**

Do not immerse it into liquid.Use 75% alcohol to wipe the device enclosure and the nail pad, and use liquid soap or isopropanol to wipe the watchband for disinfection nature dry or clean it with clean and soft cloth. Do not spray any liquid on the device directly, and avoid liquid penetrating into the device.

**Attention:**

🖰  Please turn off the device before cleaning.

- Do not use strong solvent as acetone.
- Do not use abrasive materials as steel wire or silver polishing agent.
- The water used to clean the device should be below 60 ℃.
- Do not allow any liquid to enter the device, and do not immerse any part of the device into any liquid.
- Do not leave any cleaning solution on the surface of the device.

**6.2 Maintenance**

A.This device is a sophisticated electronic device, please handle with care. Maintain this device according to the measures listed below, which will prolong this device life.

B.Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.

C.  Please clean and disinfect the device before/after using it according to the User Manual (6.1).

D.Please charge the battery in time when low battery appears.

E.Recharge the battery soon after over-discharge. The device should be recharged every three months when it is not used for a long time. It can extend the battery life following this guidance.

F.This product does not need to be calibrated during maintenance.

G.The accuracy of the device is controlled by the equipment, which can not be adjusted by user. If the result is distrustful, please use other methods to verify immediately or contact local distributor or manufacturer to get help.

**6.3 Transport and Storage**

A.The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, corrosive material.

B.The packed device should be stored in room with no corrosive gases and good ventilation.

**Attention:**

- If the instrument is not used for a long time,it should be kept in the packaging box after cleaning and disinfection,and placed in a room with no corrosive gas and good ventilation.

**7 Troubleshooting**

| Trouble | Possible Reason | Solution |
|---|---|---|
| The values can not be displayed normally or stably. | 1.The finger is not properly inserted.<br>2.The finger is shaking or the patient is moving.<br>3.The device is not used in environment required by the manual.<br>4.The device works abnormally. | 1.Please insert the finger properly and measure again.<br>2.Let the patient keep calm.<br>3.Please use the device in normal environment.<br>4.Please contact the after-sales. |
| The display of nasal airflow is unstable. | 1.Connection problem.<br>2.Wearing mode problem.<br>3.The patient is moving. | 1. Connect correctly.<br>2. Wear in correct mode.<br>3. Let the patient keep calm. |
| The device can not be turned on. | 1.Low battery or the battery is drained away.<br>2.The device works abnormally. | 1.Please charge the battery.<br>2.Please contact the after-sales. |
| The display disappears suddenly. | 1.The device enters into the energy saving mode.<br>2.Low battery.<br>3.The device works abnormally. | 1.Normal.<br>2.Please charge the battery.<br>3.Please contact the after-sales. |
| PC can not identify SD card drive letter. | 1. Poor connection of USB interface.<br>2.SD card is damaged. | 1.Connect the USB data line repeatedly.<br>2.Contact local service center. |
| The device can not be used for full time after charge. | 1.The battery is not charged fully.<br>2.The device works abnormally. | 1.Please charge the battery.<br>2.Please contact the after-sales. |
| The battery can not be fully charged even after 10-hour charging time. | The device works abnormally. | Please contact the after-sales. |

**8 Symbols**

Your device may not contain all the following symbols.

| Symbol | Meanings | Symbol | Meanings |
|--------|----------|--------|----------|
| %SpO$_2$ | Oxygen saturation (unit: %) | PRbpm | Pulse rate (unit: bpm) |
| 🔔̸ | Sound prompt: OFF | 🔋 | Fully charged |
| 🔔 | Sound prompt: ON | 🔋 | Two grid of power |
| 🔊̸ | Pulse sound: OFF | 🔋 | One grid of power |
| 🔊 | Pulse sound: ON | 🔋 | Low battery |
| REC ● | Record mark | ⚠ | Caution: read instructions (warnings) carefully |
| 🧍 | Type BF applied part | ⌧ | No prompt system |
| SN | Serial number | 🏭 | Manufacturer |
| ♻ | Recyclable | ⏳ | Use-by date |
| **IP22** | Covering Protection rate | 🗑 | WEEE disposal |

| | | | |
|---|---|---|---|
| (symbol) | Date of manufacture | (symbol) | USB |
| P/N | Material code | REF | Product code |
| (symbol) | Not made with natural rubber latex | LOT | Lot number |
| (symbol) | For indoor use only | EU REP | Authorized representative |
| (symbol) | Temperature limit | (symbol) | Class II applied |
| (symbol) | Atmospheric pressure limit | (symbol) | Follow instructions for use |
| (symbol) | Fragile, handle with care. | (symbol) | Humidity limit |
| Sensor Off | The probe is disconnected. | (symbol) | This side up. |
| Sensor Fault | Probe failure | (symbol) | Keep in a cool, dry place |
| CE 0123 | Medical Device compliant with Directive 93/42/EEC | Finger Out | The finger is not inserted. |
| (symbol) | Stacking limit by number | MD | Medical device |
| UDI | Unique device identifier | (symbol) | Imported by |

**9 Specification**

| SpO$_2$ [see note 1] | |
|---|---|
| Display range | 0% ~ 99% |
| Measured range | 0% ~ 100% |
| Accuracy [see note 2] | 70%~100%: ±2%;<br>0%~69%: unspecified |
| Resolution | 1% |
| PR | |
| Display range | 30 bpm ~ 250 bpm |
| Measured range | 30 bpm ~ 250 bpm |
| Accuracy[see note3] | ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm. |
| Resolution | 1 bpm |
| Nasal airflow | |
| Measured range | 0 bpm～40bpm |
| Accuracy | ±2 bpm |
| Resolution | 1 bpm |
| Light interference | Under normal and ambient light conditions, the SpO2 deviation ≤ 1% |
| Pulse intensity | Continuous bar graph display, the higher display indicates the stronger pulse. |
| Optical sensor [see note 4] | |
| Red light | Wavelength: about 660 nm, optical output power: < 6.65 mW |
| Infrared light | Wavelength: about 905 nm, optical output power: < 6.75 mW |
| Recording function | The continuous recording time of fully charged battery shall not be less then 12 |

| | |
|---|---|
| | hours.(During normal data storage) |
| Safety class | Internally powered equipment, type BF applied part |
| International Protection | IP22 |
| Working voltage | DC3.6 V—4.2 V |
| Working current | ≤100 mA |
| Power supply | A rechargeable lithium battery (3.7V) .The red wire on the battery denotes anode, the black wire on the battery denotes cathode. |
| Battery life | Charge and discharge: no less than 500 times. |
| Adapter specification | Output voltage: DC 5V<br>Output current: 1000 mA |
| Dimension and Weight | |
| Dimension | 69 mm(L) × 50 mm(W)×17.3 mm(H) |
| Weight | About 100 g (including a lithium battery) |
| Compatibility | Group I,Type B |
| The degree of safety of application in the presence of flammable gas | Not usable in the presence of flammable gas. |
| The mode of operation | continuous operation |
| Display | color LCD |

Note 1: the claims of $SpO_2$ accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % $SpO_2$, compare the $SpO_2$ values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which are used for the accuracy analysis.(It is applicable for the probes equipped)
There are 12 healthy volunteers (male: 6. female: 6; age: 18~45; skin color: black: 2, light: 8, white: 2) data in the

clinical report.

Note 2: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

Note 3:PR accuracy has been verified using signals from the patient simulator .The difference between the measured PR and the set value of the patient simulator is used to calculate the RMS to indicate the accuracy of the PR.

Note 4: optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.For example, photodynamic therapy operated by clinician.

**Appendix 1: EMC**

This equipmen is suitable for professional healthcare facility environments and home healthcare environments

**Attention :**

- The device is subject to special EMC precautions and it must be assemblied and used in accordance with these guidelines.

- The electromagnetic field can affect the device performance, so other equipment used near the device must meet the corresponding EMC requirements. Mobile phones, X-rays or MRI devices are possible interference source, as they can emit high-intensity electromagnetic radiation.

- The use of ACCESSORIES and cables other than those specified, with the exception of cables sold by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM. Including but not limited to power cord.

- Devices or systems should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.

- Devices or systems may still be interfered by other equipment, even if other equipment meets the requirements of the corresponding national standard.

- Accessories must be used to ensure compliance with interference radiation and immunity stands

- Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic

resonance imaging, where the intensity of EM DISTURBANCES is high.

**Note**：

- This equipment needs special precautions regarding EMC and needs to be assemblied and put into service according to the EMC information provided below.
- The basic performance:. SpO$_2$ measured range: 70% ~ 100%, absolute error: ±2%; PR measured range: 30 bpm ~ 250 bpm, accuracy:±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.Nasal airflow measured range: 0 bpm～40bpm，accuracy:±2 bpm;
- When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.
- Other devices may affect this device even though they meet the requirements of CISPR.

**Product configuration**

| Serial number | name | Cable length |
|---|---|---|
| 1 | SpO2 probe | 0.35m |
| 2 | USB cable | 1m |

Table 1

| Guidance and Declaration - Electromagnetic Emissions | |
|---|---|
| Emissions test | Compliance |
| Conducted and radiated RF EMISSIONS CISPR 11 | Group 1 |
| Conducted and radiated RF EMISSIONS CISPR 11 | Class B |
| Harmonic distortion IEC 61000-3-2 | Class A |
| Voltage fluctuations and flicker    IEC 61000-3-3 | Complies |

Table 2

| Guidance and Declaration - Electromagnetic Immunity | | |
|---|---|---|
| Immunity Test | IEC 60601<br>Test level | Compliance level |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±15 kV air | ±8 kV contact<br>±15 kV air |
| Electrical fast<br>transient/burst<br>IEC 61000-4-4 | ±2 kV for power<br>supply lines<br>±1 kV for input/ output lines | ±2 kV for power supply lines |
| Surge<br>IEC 61000-4-5: | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth |
| Voltage dips and<br>Voltage interruptions<br>IEC 61000-4-11 | 0 % UT;<br>0,5 .cycle .At0°,45°,90°,135°,180°,225°,<br>270°and315°.<br>0 % UT; 1 cycle and<br>70 % UT ; 25/30<br>cycles ;Single phase:at 0°.<br>0 % UT ; 250/300 cycle | 0 % UT;<br>0,5 .cycle .At0°,45°,90°,135°,180<br>°,225°,270°and315°.<br>0 % UT; 1 cycle and<br>70 % UT ; 25/30<br>cycles ;Single phase:at 0°.<br>0 % UT ; 250/300 cycle |
| Power frequency<br>(50/60Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz |
| Conduced RF<br>IEC61000-4-6 | 3 V<br>0,15MHz - 80 MHz<br>6 V in ISM and amateur radio bands<br>between<br>0,15MHz to 80 MHz<br>80%AM at 1kHz | 3 V<br>0,15MHz - 80 MHz<br>6 V in ISM and amateur radio<br>bands between<br>0,15MHz to 80 MHz<br>80%AM at 1kHz |

| Radiated RF IEC61000-4-3 | 10V/m<br>80 MHz-2,7GHz<br>80%AM at 1kHz | 10V/m<br>80 MHz-2,7GHz<br>80%AM at 1kHz |
|---|---|---|
| NOTE UT is the a.c.mains voltage prior to application of the test level | | |

Table 3

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | | | |
|---|---|---|---|---|---|---|
| | Test Frequency (MHz) | Band (MHz) | Service | Modulation | IEC60601-1-2 Test level (V/m) | Complian ce level (V/m) |
| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | 385 | 380 –390 | TETRA 400 | Pulse modulation b) 18 Hz | 27 | 27 |
| | 450 | 430-470 | GMRS 460, FRS 460 | FM c) ± 5 kHz deviation 1 kHz sine | 28 | 28 |
| | 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation b)217 Hz | 9 | 9 |
| | 745 | | | | | |
| | 780 | | | | | |
| | 810 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation b)18 Hz | 28 | 28 |
| | 870 | | | | | |
| | 930 | | | | | |
| | 1720 | 1700 – 1990 | GSM 1800; CDMA 1900; | Pulse modulation b)217 | 28 | 28 |
| | 1845 | | | | | |

| | 1970 | | GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Hz | | |
|---|---|---|---|---|---|---|
| | 2450 | 2400 – 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation b)217 Hz | 28 | 28 |
| | 5240 | 5100 – 5800 | WLAN 802.11 a/n | Pulse modulation b)217 Hz | 9 | 9 |
| | 5500 | | | | | |
| | 5785 | | | | | |



*Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment*

**GIMA WARRANTY TERMS**

The Gima 12-month standard B2B warranty applies