PROFESSIONAL MEDICAL PRODUCTS

SLEEP APNEA SCREEN METER

REF **RS01 (GIMA 33676)**

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CE 0123

LATEX MD STERILE EO

60°C -40°C 1060hPa 500hPa 95% 0% %

IPX1
IP22

M33676-EN-Rev.8-10.26

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 MDR 2017/745/EU 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 2 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 cannulas, 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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- RS01 should only be configured by trained and qualified personnel.

Contents

1 Overview 1

1.1 Features 1

1.2 Intended use 2

1.3 Environment requirements 2

1.4 Precautions 2

2 Principle 6

3 Functions 6

4 Appearance and structure 7

4.1 Appearance 7

4.2 Interface introduction 8

4.3 Structure, accessories and software description 11

5 Operating 13

5.1 Operation and use of the instrument 13

5.2 Operating instruction of PC software....29
6 Maintain, Transport and Storage....47
6.1 Cleaning and disinfection....47
6.2 Maintenance....48
6.3 Transport and Storage....48
7 Troubleshooting....49
8 Symbols....50
9 Specification....52
Appendix 1: EMC....54

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 Intended use

The device is intended to collect and record respiration and SpO_2 data for patient self-measuring.

Intended users:

It is intended for use by or on the order of a physician.

Intended environment:

It is intended for use in a supervised (hospital) or unsupervised (home) environment.

Patient population:

Adult

Medical indications:

The device is especially suitable for patients with suspected sleep inefficiency, such as patients with heart disease, asthma and OSAHS. And it is also suitable for people without previous diseases, such as who want to measure respiration and SpO_2, or show symptoms that the measured values are different from the normal values.

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 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 can contact 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 service life of Pulse Oximeter Probe is two years.Disposable nasal cannulas are disposable accessories.See the packaging label for the production date.
- 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.

1.4.2 Clinical 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, 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

SpO_2 measurement: according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in red light & near-infrared light zones, the device adopts Lambert-Beer Law to establish an empirical formula for data processing. On the basis of the principle of Photoelectric Oxyhemoglobin Inspection Technology and Photoplethysmography technology, it uses two beams of light with different wavelengths to irradiate the human fingertip to obtain the measurement information from the photosensitive element, after processed by the electronic circuits and microprocessor, displays the measured results on the screen.
Nasal airflow measurement: the pressure signal of the human respiratory airflow is collected by the pressure sensor, after processed by the electronic circuits and microprocessor, it displays the measured nasal airflow waveform on the screen.

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

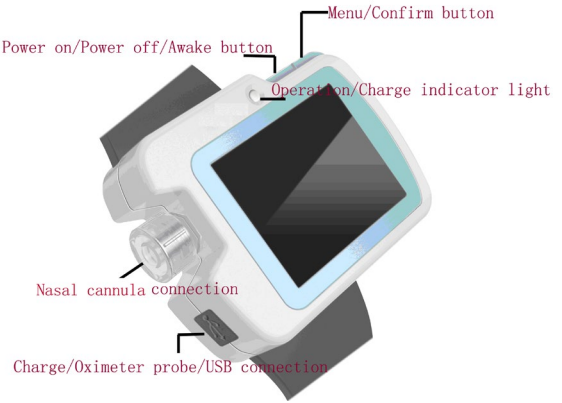
J.PR sound and prompt tone function

K.Charging function

L.Quantity of electricity indication

4 Appearance and structure

4.1 Appearance



The device is consisted of main unit, nasal cannulas, SpO_2 probe, power adapter（optional）, USB data line and PC software.No detachable parts for main unit itself, applied parts: the nasal cannulas and SpO_2 probe, they are detachable parts.

4.2 Interface introduction

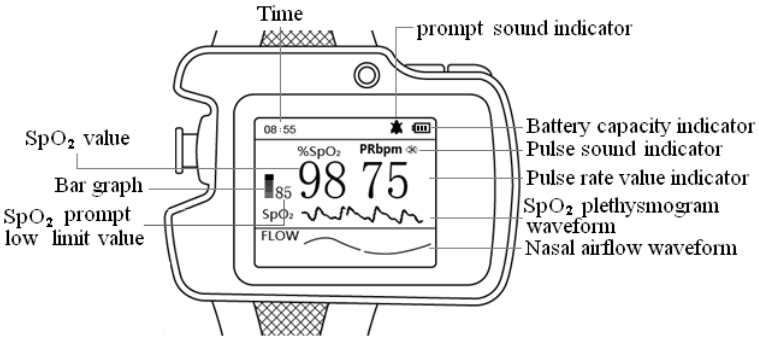


Figure 4.1 Measurement interface

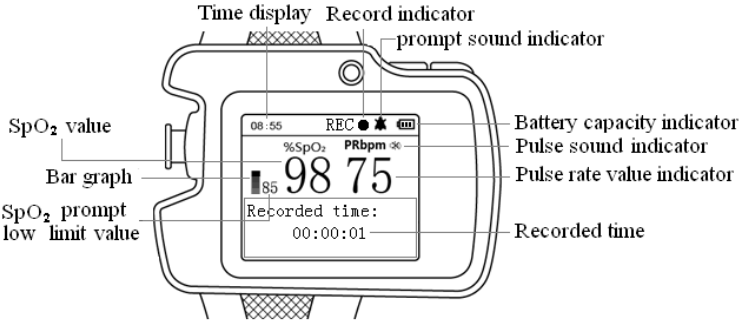


Figure 4.2 Record interface

(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.

4.3 Structure, accessories and software description

A. Main unit,nasal cannulas,SpO_2 probe,power adapter (optional),USB data line,PC software

B.Accessories:Accessories:nasal cannulas,SpO_2 probe and power adapter(optional).

Please check the device and accessories according to the list to avoid that the device can not work normally.

Table 4.3

Name	Model	Supplier
Pulse Oximeter Probe	ESB0059	Contec Medical Systems Co., Ltd.
Pulse Oximeter Probe	GSE0032	Contec Medical Systems Co., Ltd.
Nasal cannulas	EM08-003	Excellentcare Medical (Huizhou) Ltd.
Power adapter(optional)	CMS0105-5EU	Contec Medical Systems Co., Ltd.

C.Software description

PC software name: ResMonPlus PC software model: No

PC software version: V3.0

Software version naming rules: VX.Y. Z. B

V: the first letter of"Version", represents the prefix of the version number.

X: represents the major enhancive updates and/ or major cybersecurity updates, with a maximum value of 9.

Y: represents the major enhancive updates and/ or major cybersecurity updates, with a maximum value of 9. When the maximum value is reached, Y resets and X is changed.

Z: represents the minor enhancive updates and/ or minor cybersecurity updates, with a maximum value of 999.

B: representes corrective and/ or build updates, with a maximum value of 999.

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.

D.System requirements for running Resmon Software

Environmental operation requirement:

Windows 10 and compatible versions

Assess Database

Office 2003 and above

Computer hardware minimum requirements:

CPUCeleron2.0G

1GB RAM

250GB HDD

USB 2.0

19''TFT monitor（1600x1200）

Colored Printer

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

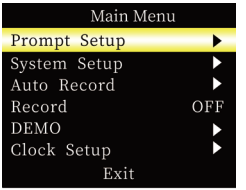


Figure 5.1 Main menu

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

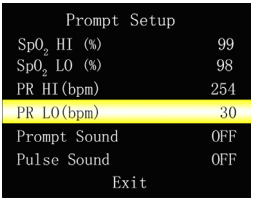


Figure 5.2 Prompt setting menu

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:

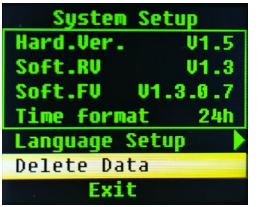


Figure 5.3 System menu

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

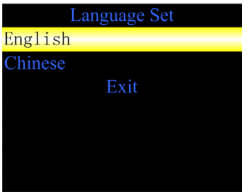


Figure 5.4 Language setting menu

Table5.4

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.

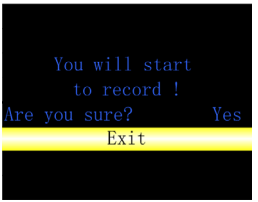


Figure 5.6 Record setting menu

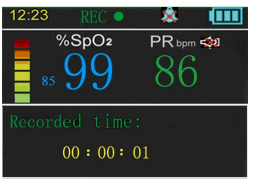


Figure 5.7 Recorded time interface

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.

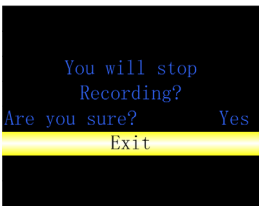


Figure5.8Stop recording menu

6．Time setting

The time setting menu is shown as Figure 5.9:

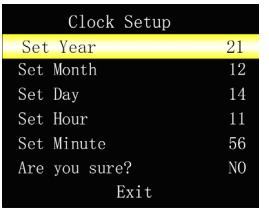


Figure 5.9 Time setup menu

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.

5.1.3 Connection of application parts

1. Nasal airflow monitoring

Unpack the packaging of nasal cannulas, unscrew the screw cap following Figure 5.10, then insert the nasal cannulas 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 cannulas is shown as Figure 5.11, and the overall wearing mode is shown as Figure 5.12.

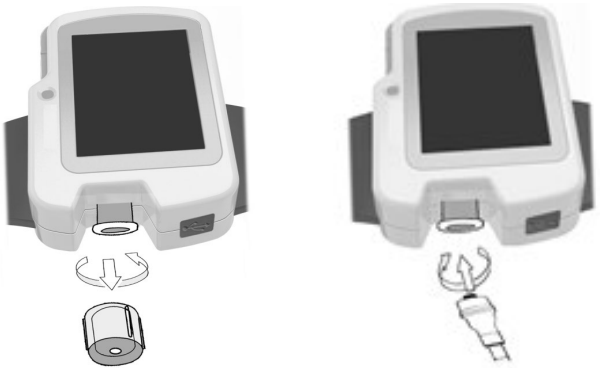


Figure 5.10 Connection of nasal cannulas

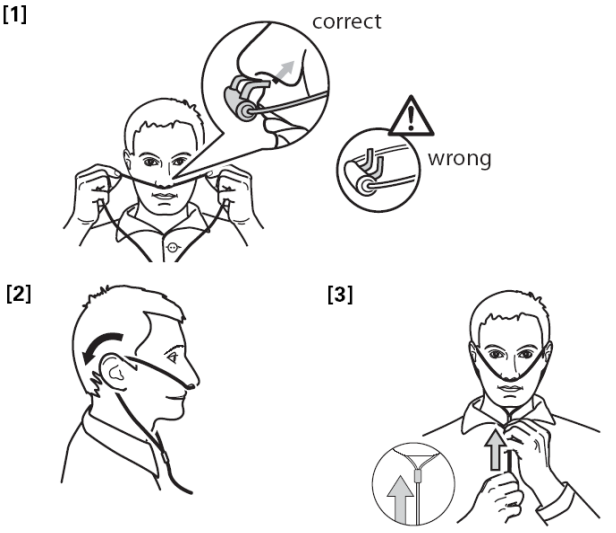


Figure 5.11 Wearing mode of nasal cannulas

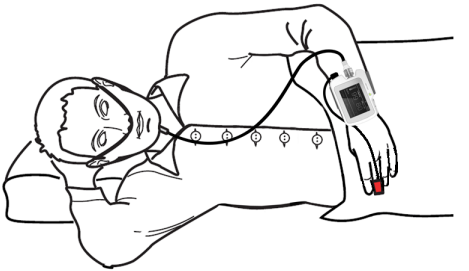


Figure 5.12 Sketch map of overall wearing

Attention:

- Wear the nasal cannulas according to the regulations, or it will affect the collection effect.
- If the non-screwing nasal cannulas is used, then use the Luer male plug to connect.
- The nasal cannulas is disposable, repeated use may cause infection.
- Refer to the packaging of nasal cannulas 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	Specification and model	Quantity	Length (cm)	Whether shielding
1	Digital fingerstall SpO_2 probe	ESB0059	1	35	No
2	Non-woven adult SpO_2 probe	GSE0032	2	35	No

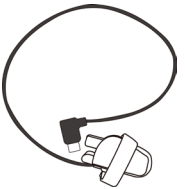


Figure 5.13 Digital fingerstall SpO_2 probe

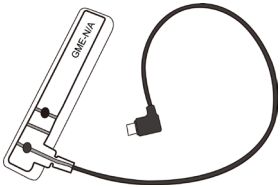


Figure 5.14 Non-woven adult SpO_2 probe

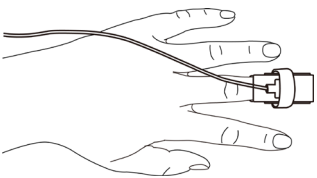


Figure5.15Wearing mode of probe

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).

5.1.5 Automatic 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).

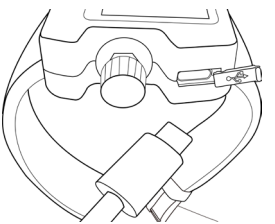


Figure 5.16 Sketch map for connection between Sleep apnea screen meter and USB data line

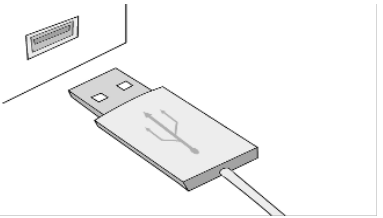


Figure 5.17 Sketch map for connection between PC and USB data line

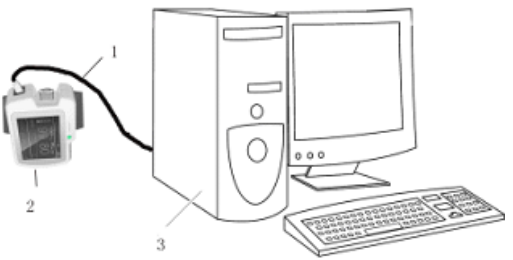


Figure 5.18 Sketch map for connection between device and computer

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.
- When launching the software, a password is required. The default password is "654321".Please change your password before using.

5.1.6 Delete data

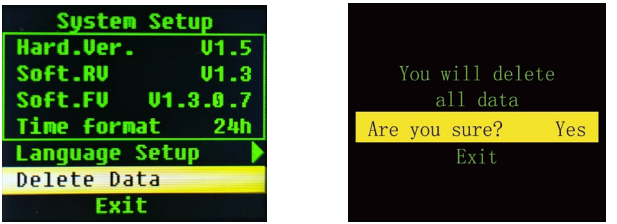


Figure 5.19 Delete date interface

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.

5.2 Operating instruction of PC software

5.2.1 Data importing and case management

1：Import case data

Double-click the desktop icon to enter the software, the initial interface shown as Figure 5.19appears.

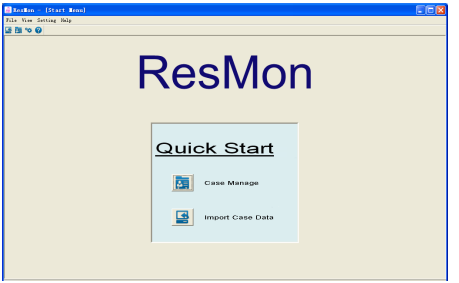


Figure 5.19

Import data after starting the software. Click "Import Case Data" in "File" menu, then the interface shown as Figure 5.20appears.

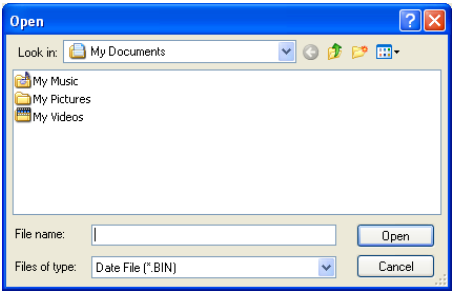


Figure 5.20

Click "Open" after selecting the case to enter the interface as shown in Figure 5.21. Note: “Name” in “Import Case” must be filled in, otherwise the system will give corresponding prompts after clicking “Import Case”. If patient’s name has been filled in, it will enter its waveform display interface (as Figure 5.22) of the case data after clicking “Import Case”, then the case information is stored in case library.

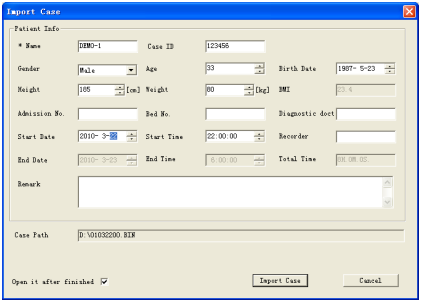


Figure 5.21

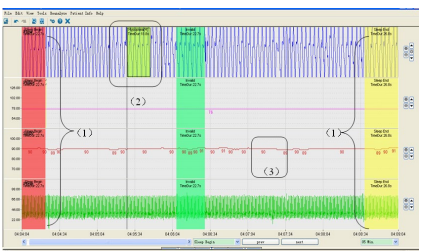


Figure 5.22

2：Case management

Click "Case Manage" in "File" menu to its sub-menu as Figure 5.23:

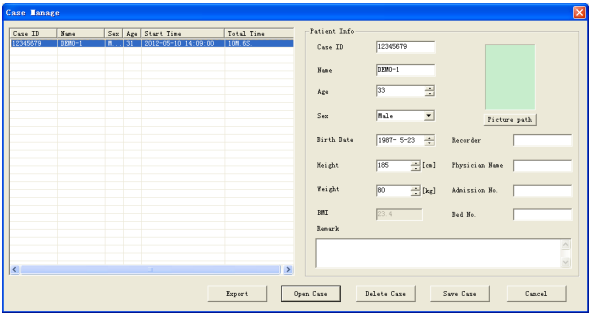


Figure 5.23

All cases in case library displays on left of the interface, after selecting one case, the corresponding patient's information display on right of the interface, including basic information and collected information, and physician name, recorder name, and the identification made by the doctor can be added here.

Click "Picture path" to select the patient's picture, then click "Save Case" to save the picture into the report.

The case information can be modified and deleted. Modification method: select the case to be modified on left of the interface, then modify the information on right, click "Save Case" to finish modifying. Deleting method: select the case to be deleted on left of the interface, click "Delete Case", then the prompt interface shown as Figure 5.24appears, the case will be deleted after clicking "OK", and the case deleted can not be resumed. Double-click the case on left of "Case Manage" interface or click "Open Case" to enter the waveform display interface (as Figure 5.23) of corresponding case. it will enter its waveform display interface (as Figure 5.22) of the case data

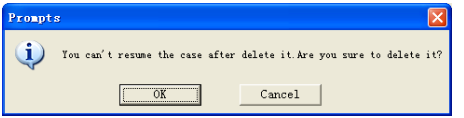


Figure 5.24

5.2.2 System setting

Select “Global Setting” in “Setting” menu to enter the interface shown as Figure 5.25:

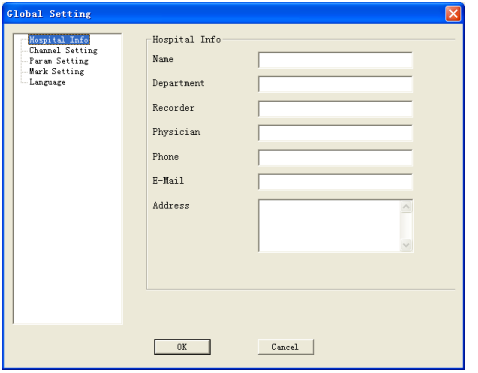


Figure 5.25

1) Fill in basic information of hospital in “Hospital Info” interface.

2) Set waveform color of each lead (click the color bar to change), display / hide state of waveform display in “Channel Setting” interface, as shown in Figure 5.26.

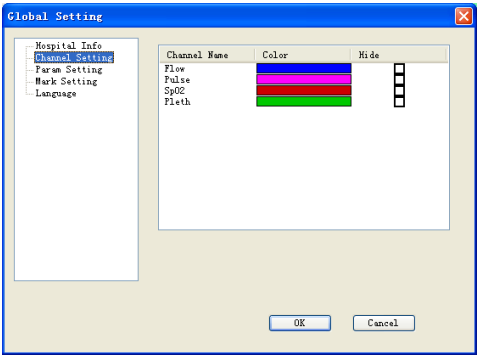


Figure 5.26

3) “Param Setting” contains two setting interfaces: “SpO2 Param” and “Flow Param”, the corresponding parameter value can be set in each interface, as shown in Figure 5.27.

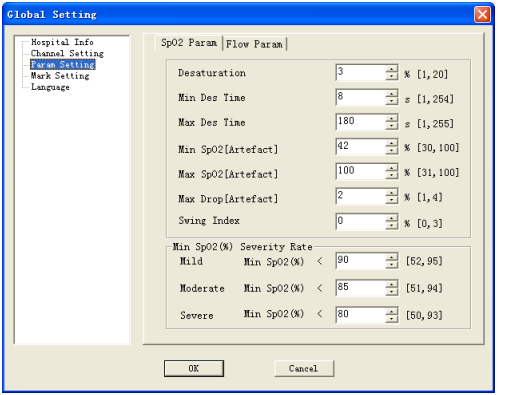


Figure 5.27

4) Marks can be added, edited and deleted in “Mark Setting” interface, as shown in Figure 5.28.

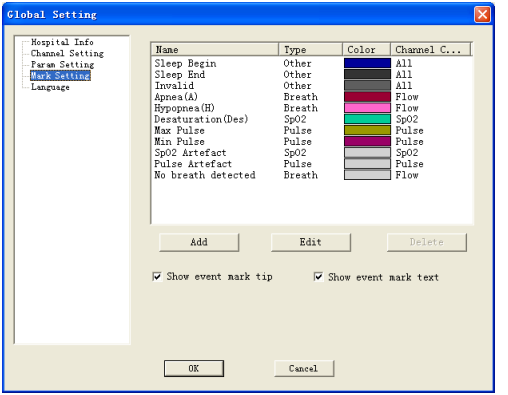


Figure 5.28

Click “Add” to enter its sub-menu as shown in Figure5.29, the customized mark will be added to the mark list after setting and clicking “OK”. If a mark need to be edited, select the mark name in the list, click “Edit” or double-click the mark name to enter its sub-menu as shown in Figure 5.30 (the front eight items in the mark list are default, they can not be deleted and edited, but their color can be modified). After selecting a mark, click “Delete” to delete the customized mark. Refer to 5.2.3for the use of mark.

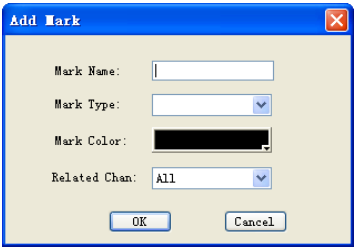


Figure 5.29

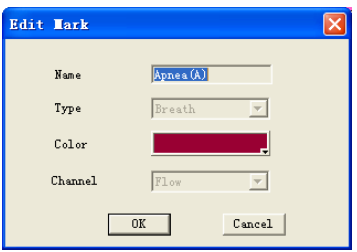


Figure 5.30

5) Set language in “Language” menu, as shown in Figure 5.31.

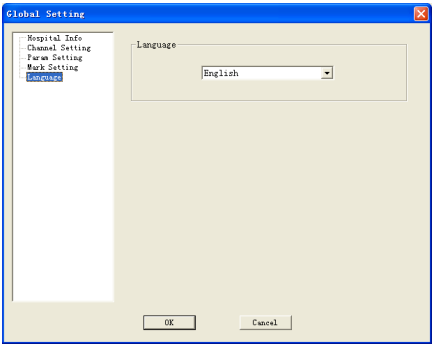


Figure 5.31

After setting, click “OK” in “Global Setting” interface, the modifications will be saved.

5.2.3 Waveform display

The waveform display area is shown in Figure5.22, the display area can display two waveform charts, or one event chart and one waveform chart, or only event or waveform chart. Window adjustment button can change the amount of charts and size of the area, as shown in Figure 5.32:



Figure 5.32

One chart display area displays the data waveform of Flow, SpO_2, Pulse and Pleth, as shown in Figure5.33. Drag the border line of the waveform area to change the size of display area of each waveform, convenient to observe. Use the values (as Figure 5.33) in front of display area to determine the values of waveform.

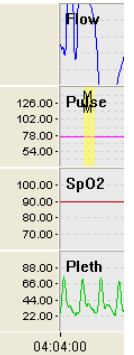


Figure 5.33

The buttons (as Figure 5.34) on right of waveform display area can be used to adjust the size and baseline position of the waveform. Click ⊕ to increase the amplitude of the waveform, ⊖ to decrease the amplitude, ▲ to move up the baseline position, ▼ to move down the baseline position. Meanwhile, when adjusting the amplitude, the values in Figure5.33 will change correspondingly. When adjusting the amplitude of the lead without specific values, the waveform gain multiple behind the lead name will increase or decrease.



Figure 5.34

Drag the right button of the mouse on one waveform of the waveform display area to enter the interface as shown in Figure 5.35 the identification will be marked on the corresponding position (as Figure 5.22) after clicking “OK”, place the mouse to the border of identification area, when the editable identification appears, drag the mouse to change the size of identification area (new identification can not cover the existed one). When selecting one identification on waveform, please “Delete” on keyboard or click the right button to delete the identification.

“Sleep Begin” and “Sleep End” time can be dynamically marked, drag the right button of the mouse to enter the identification interface of the waveform, as shown in Figure5.35, select “Sleep Begin” and “Sleep End” time to mark the sleep period, as shown in Figure 5.22.

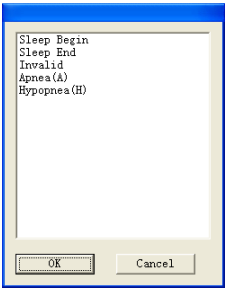


Figure 5.35

The display area of time axis is shown as Figure5.36. Drag the scroll bar or roll the mouse wheel to browse the waveform. Press "PgUp" and "PgDn" to switch the waveform display between previous and next screen. Press "Home" and "End" to return to the start and end position of the waveform. The time axis displays the beginning and end time of data record, set a time coordinate every five seconds. When the position of the scroll bar changes, the time of the time axis will change correspondingly.

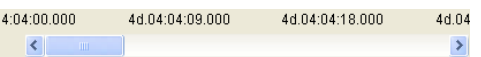


Figure 5.36

Time selections are shown as Figure 5.37, the time interval of screen display can be set. The different time interval in display area of upper and nether charts can be set, convenient to observe simultaneously.

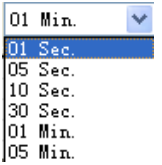


Figure 5.37

The buttons for browsing event are shown as Figure 5.38, select the event name to be browsed in the dropdown list, click the left and right arrowhead button to browse the event one by one, convenient to observe. The system will give prompts if there is no matched identification event.



Figure 5.38

5.2.4 Function menu

The function menus in waveform display interface are as following:

1) Click "Import Case" in "File" menu to enter the interface as shown in Figure 5.20, the data of the other patient can be imported while observing the waveform, which is convenient for doctor to comprehensively observing, as shown in Figure 5.39.

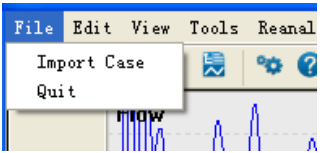


Figure 5.39

2) It contains “Undo Ctrl+Z” and “ReDo Ctrl+Y” in “Edit” menu, as shown in Figure5.40, click the option to undo or restore the waveform identification.

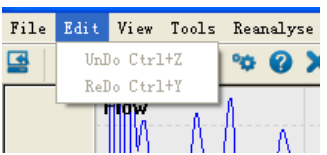


Figure 5.40

3) It contains “Report View” and “EventList View” in “Edit” menu, as shown in Figure 5.41, "Report View" menu is used to print reports, when clicking this option, the print preview interface as Figure5.42will appear, including such functions as Zoom In, Zoom Out, Next Page and Prev Page.

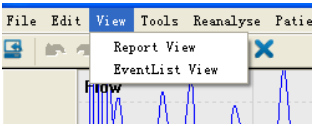


Figure 5.41

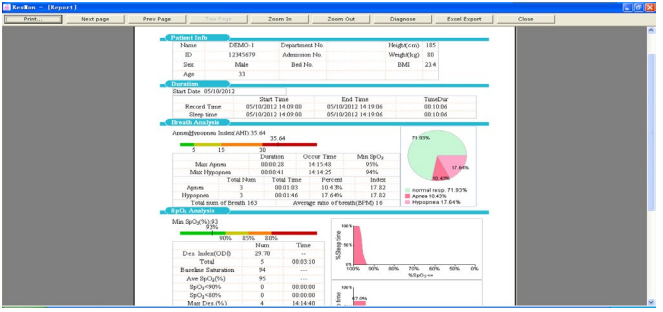


Figure 5.42

4) Under the print preview interface, the diagnosis information can be edited and filled into the report. Click “Diagnose” to enter the interface as Figure 5.43, fill the report name into “Report Name” and the diagnosis results into “Diagnosis Result”. Click “OK” to fill the report name and diagnosis information into the report.

Click “Excel Export”, the system will export the first page of report in a form of Microsoft Excel to the folder specified.
Note: to use Excel export function, Microsoft Office 2003 or above is required to be pre-installed.

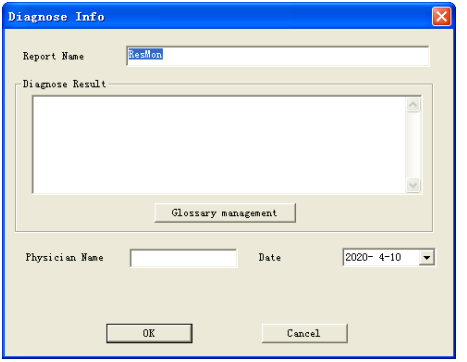


Figure 5.43

When selecting "EventList View" option, the interface as Figure5.44 will appear. The types of all events display on left of the interface, it contains four types: Other, SpO_2, Breath and Pulse. Event name, Start Time, End Time and Time duration display on right of the interface. Click “All Events”, then the identifications of all events will be displayed on right list.

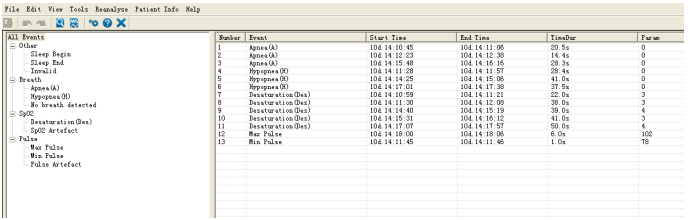


Figure 5.44

5) Click "Reanalyse", the dialogue box as Figure 5.45 will appear, click "Yes(Y)" to remove all old data analyzed manually and re-analyse; click “No(N)” to reanalyse but not remove the manual analysis data; click "Cancel" to cancel the reanalyse operation.

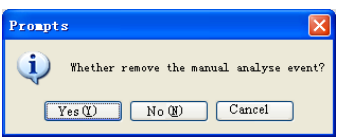


Figure 5.45

6) Click"Patient Info", the interface will display the current patient information.

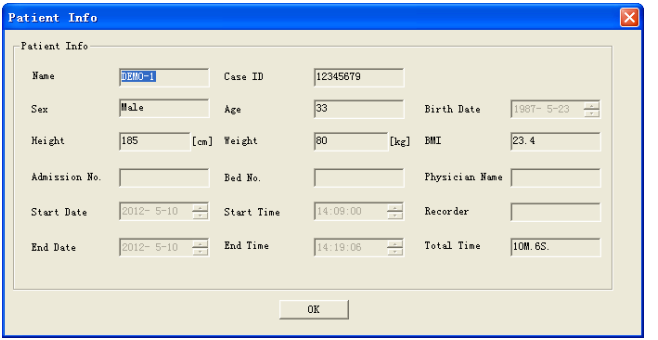


Figure 5.46

7) Click “Help”, the help document of this software will appear.

6 Maintain, Transport and Storage

6.1 Cleaning and disinfection

Before cleaning, ensure good room ventilation, remove the inflammable and combustible materials around it, and avoid open flame and electrical power source, etc.

Please turn off the device, then wipe the host and pulse oximeter probe respectively with a medical gauze dipped in medical alcohol (75 %，note：medical alcohol produced by any formal company can be used.) for about 1 minute. Dry them naturally or clean them with a clean and dry cloth.

Determine whether the cleaning is adequate by visual inspection. If stains are found, please repeat the above steps.

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. 2.The finger is shaking or the patient is moving. 3.The device is not used in environment required by the manual. 4.The device works abnormally.	1.Please insert the finger properly and measure again. 2.Let the patient keep calm. 3.Please use the device in normal environment. 4.Please contact the after-sales.
The display of nasal airflow is unstable.	1.Connection problem. 2.Wearing mode problem. 3.The patient is moving.	1. Connect correctly. 2. Wear in correct mode. 3. Let the patient keep calm.
The device can not be turned on.	1.Low battery or the battery is drained away. 2.The device works abnormally.	1.Please charge the battery. 2.Please contact the after-sales.
The display disappears suddenly.	1.The device enters into the energy saving mode. 2.Low battery. 3.The device works abnormally.	1.Normal. 2.Please charge the battery. 3.Please contact the after-sales.
PC can not identify SD card drive letter.	1. Poor connection of USB interface. 2.SD card is damaged.	1.Connect the USB data line repeatedly. 2.Contact local service center.
The device can not be used for full time after charge.	1.The battery is not charged fully. 2.The device works abnormally.	1.Please charge the battery. 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
	Type BF applied part		No prompt system
SN	Serial number		Manufacturer
	Recyclable		Use-by date
IP22/IPX1	IP22: It means this Sleep apnea screen meter is protection against ingress of solid foreign objects of 12.5mm and greater protection against ingress of water dripping when device tilted up to 15°. IPX1: Protected against vertically falling water drops	CE 0123	Medical Device compliant with Regulation (EU) 2017/745

	Date of manufacture		USB
P/N	Material code	REF	Catalogue number
	Later free	LOT	Batch No.
	For indoor use only	EU REP	European Representative
	Temperature limitation.		CLASS II equipment
	Atmospheric pressure limitation.		Caution,consult accompanying documents
	Fragile, handle with care.		Humidity limitation.
Sensor Off	The probe is disconnected.		This way up.
Sensor Fault	Probe failure		Keep away from rain.
UDI	unique device identification	**Finger Out**	The finger is not inserted.

	Stacking limit by number	MD	Medical device
	Do not reuse	STERILE EO	Sterilized using ethylene oxide
	Imported by		WEEE disposal

9 Specification

SpO_2 [see note 1]	
Display range	0% ~ 100%
Measured range	0% ~ 100%
Accuracy [see note 2]	70%~100%: ±2%; 0%~69%: unspecified
Resolution	1%
PR	
Display range	30 bpm ~ 250 bpm
Measured range	30 bpm ~ 250 bpm
Accuracy[see note3]	±2 bpm or ±2%, whichever is greater.
Resolution	1 bpm
Nasal airflow	
Measured range	0 bpm～40bpm
Accuracy	±2 bpm
Resolution	1 bpm
Measurement Performance in	SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%.

weak Filling Condition	SpO_2 error is ±4%,pulse rate error is ±2bpm or ±2%(select larger).
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 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)
Safety	comply with IEC 60601-1
Compatibility	Group I,Type B
Storage card space	8G
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

Attention :

- The device is subject to special EMC precautions and it must be assembled 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

Guidance and manufacturer's declaration – electromagnetic emissions

Table 1

Guidance and manufacturer's declaration-electromagnetic emission		
The Sleep apnea screen meter is intended for use in the electromagnetic environment specified below. The purchaser or the user of the Sleep apnea screen meter should assure that it is used in such an environment.		
Emission test	**compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Sleep apnea screen meter 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 CISPR 11	Class B	The Sleep apnea screen meter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Applicable	

Guidance and manufacturer's declaration

Table 2

Guidance and manufacturer's declaration-electromagnetic immunity
The Sleep apnea screen meter is intended for use in the electromagnetic environment specified below. The purchaser or the user of Sleep apnea screen meter should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m	

Guidance and manufacturer's declaration

Table 3

Guidance and manufacturer's declaration-electromagnetic immunity			
The Sleep apnea screen meter is intended for use in the electromagnetic environment specified below. The purchaser or the user of Sleep apnea screen meter should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3V (effective value) 150 kHz-80 MHz 3V/m 80 MHz- 2.5 GHz	3V (effective value) 3 V/m	Portable and mobile RF communication equipment should be used no closer to any part of the Sleep apnea screen meter including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz-800 MHz $d=2.3\sqrt{P}$ 800 MHz-2.5 HGz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, 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.			
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 the Sleep apnea screen meter is used exceeds the applicable RF compliance level above, the Sleep apnea screen meter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sleep apnea screen meter. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Sleep apnea screen meter

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Sleep apnea screen meter
The Sleep apnea screen meter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The purchaser or the user of the Sleep apnea screen meter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sleep apnea screen meter as recommended below, according to the maximum output power of the communications equipment.

Rated power of transmitter (W)	Separation distance according to power of transmitter (m)		
	150 k Hz – 80 MHz $d=1.2\sqrt{P}$	80 MHz – 800 MHz $d=1.2\sqrt{P}$	800 MHz – 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (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.



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