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PROFESSIONAL MEDICAL PRODUCTS

SLEEP APNEA SCREEN METER

User manual

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

REF 33676 / RS01

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

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

-40°C 55°C CE 0123

IP22

500hPa 1060hPa 0% 95%

M33676-GB-Rev.1-01.20

USER NOTICE

Announce

Owing to the forthcoming renovation or error contained in the manual, 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 reserves the final elucidative right.

Manufacture's Responsibility
Our company is responsible for safety, reliability and performance of this product only in the condition that: all installing and repairs of this product are conducted by our company's authorized personnel; and this product is operated under strict observance of this manual.

⚠ **Warning: This device is not intended for treatment. If the result is distrustful, please use other methods to verify immediately.**

Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by manufacturer. We warrant that each product we sell you is free from defects in labour and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it for free charge. Misuse, improper maintenance may void from the warranty.

Explanation of label in the manual

⚠ **Warning:** the information that should be noted to avoid injury to the patient and the operator.

Attention: important information that you should know.

- **Item:** item message.

Contents

1 Safety

1.1 Safety Instructions

- Test at regular period to verify there is not evident damage that may affect safety and monitor performance. The period is recommended to be less than one month. If there is any damage, stop using it immediately.
- The maintenance of the device should only be carried out by personnel authorized and specified by our company, and the user shall not maintain it by himself.
- The device should not be used with other devices that not specified in this manual. Especially for those accessories specified or recommended by manufacture.
- The device has been calibrated before leaving factory.

1.2 Warnings

⚠ The infrared is harmful to the eyes, so the user and the maintenance man should not stare at the light part of the SpO_2 probe (the infrared is invisible).

⚠ For the special patients, there should be a more prudent inspecting in the placing process. The SpO_2 probe can not be clipped on the edema and tender tissue.

⚠ Please don't use this device when charging.

⚠ Explosive hazard—DO NOT use the device in environment with inflammable gas such as some ignitable anesthetic.

⚠ DO NOT use the device while the patient is being scanned by MRI or CT.

⚠ Protect the wrist band for normal use; and wear it tightly to avoid dropping to broken in the operation; the user who is allergic to rubber shall not use the wrist band.

⚠ Please use the accessories and probe that the manufacture specifies or recommends to avoid damage to this device.

⚠ The disposal of scrap instrument and its accessories and packings (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

⚠ Please do not test the related information of this device with function tester.

⚠ Do not transport this device with poisonous, deleterious or mordant substances.

⚠ No modification of this equipment is allowed.

⚠ **When the equipment was used in home, patients might be expected, and the patient should pay attention to the specifications of 1.2 on the operator's warning and note 1.3**

⚠ **The equipment is prohibit from repairing or vindicating during it is using.**

⚠ Moreover, the external computer, CD or Type with recording cable which connected with the Sleep apnea screen meter must be certificated according to the relevant IEC standards (such as: IEC 60601-1). For the requirements that are applicable to an ME SYSTEM, the RESPONSIBLE ORGANIZATION shall be referred to this standard.

1.3 Attention

⚠ Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

⚠ The device may be a little different from the picture of manual, please make the actual device as standard.

⚠ Keep a operation environment without dust, vibration, flammable or mordant substances.

⚠ When moved from a place cold to another warm and wet one, do not use it at once.

⚠ Do not operate the buttons with sharp tools.

⚠ Do not disinfect this device with high temperature and pressure or gas.

⚠ Do not immerse this device in liquid. When cleaning its surface with medical alcohol, do not spoil it directly on the device.

⚠ This device has prompt sound function, if it is not necessary, you can choose to silence it.

⚠ The mode of operation for this device is continuous, and it is common equipment, if splashed and coagulated, stop operation.

⚠ The service life of this device is five years.

⚠ At the end of this device's service life, return it to your manufacture for circle use or dispose it in compliance with local regulations.

⚠ Please refer to respective chapter for more notes.

2 Brief Introduction

2.1 Overview

The device is applied for the persons who have Sleep apnea-hypopnea syndrome (SAHS). It can be used in hospital and home.
The device's SpO_2 is based on anti-movement-interference design, applied for routine sports and exercise, displayed with LCD, monitors real-time SpO_2, pulse rate and nose air flow, and also with setupable alarm function.
Human power on/off design: manual and time power on/off two modes.
The patient can either adopt manual power on/off mode to store or set up time power on/off, having estimated his sleep time, which can decrease patient's mental burden and make patient take monitor easy. After time power on, the device will save cases automatically.
The device has large capacity SD card, which can save multiply cases, and uploads or directly stores cases to PC though USB data line. The strong PC software can edit personal information for case long storage, analyze cases gathered to help doctor diagnose quickly, and will be to the requirements of such aspects as respiration, clinical, E.N.T. departments and sleep center, etc.
The patient can also invite expert to diagnose remotely via network, which helps patient with physical examination at home.

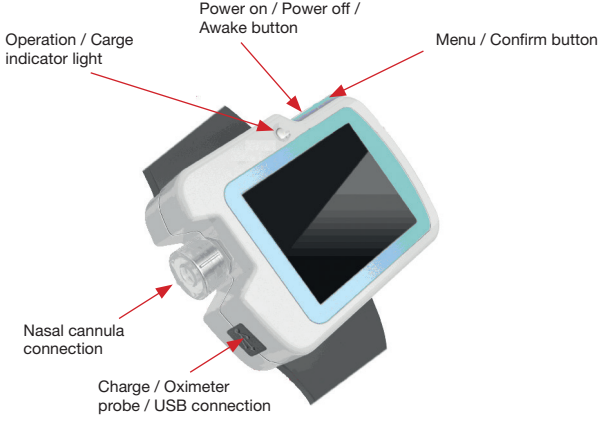
2.2 Main Functions and Features

- LCD display screen
- Convenient operation
- Wrist-design,tiny and light
- Multiple functions in one device,supplying more vital information
- SpO_2 and pulse rate(hereinafter referred to as "PR") value display
- Pulse sound and indicator bar
- Pulse and nose flow waveform display
- Such alarms as low power, finger out and exceeding limits can be set up
- Real-time clock
- Auto-power on/off
- Multi-case record
- Continuous 12 hours data record
- Uploading Data via USB port
- Powerful PC analysis software

2.3 Accompanying Accessories

- A power adaptor
- An USB data line
- Two kinds of SpO_2 probes
- A Nasal cannula
- A CD (PC software)
- An user manual

3 External Appearance and Structure



3.1 Buttons and Connections

 : Power on / Power off /Awake button

 : Menu / Confirm button

 : Nasal cannula connection

 : Charge / SpO_2 probe / USB connection

3.2 Instructions for Front Panel

The measurement interface is showed as Figure3-2-1.

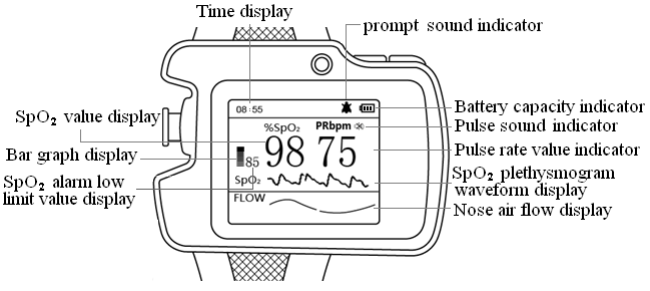


Figure 3-2-1 measurement interface

The record interface is showed as Figure3-2-2.

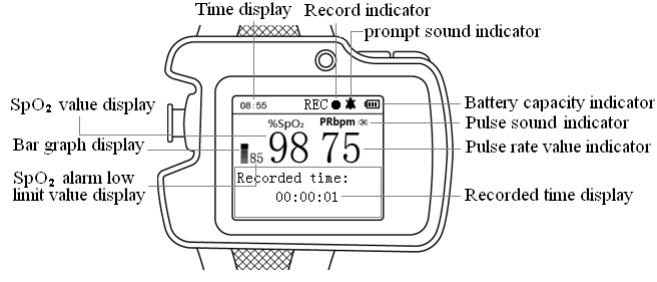


Figure3-2-2 record interface

(1) SpO_2 value display
Indicator: %SpO_2
Instruction: Put the finger into the SpO_2 probe,and the corresponding SpO_2 value will be displayed here.

(2) Pulse rate value display
Indicator: PRbpm
Instruction: Put the finger into the SpO_2 probe,and the corresponding pulse rate value will be displayed here.
(3) Bar graph display
Indicator: 
Instruction: Put the finger into the SpO_2 probe, and pulse beat will be displayed here.
(4) Nose air flow display
Indicator: FLOW
Instruction: Real-time display nose air flow waveform.
(5) SpO_2 plethysmogram waveform display
Indicator: SpO_2
Instruction: Real-time display SpO_2 plethysmogram waveform.
(6) Pulse sound indicator
Indicator: 
Instruction: The former indicates pulse sound is on, while the later indicates it is off.
(7) Prompt sound indicator
Indicator: 
Instruction: The former indicates prompt sound is on, while the later indicates it is off.
(8) Battery capacity indicator
Indicator: 
Instruction: It indicates battery capacity, it indicates that the power is low when  appears and flickers.
(9) Time display
Indicator: 08:55
Instruction: Here it indicates real-time clock.
(10) Record indicator
Indicator: REC ●
Instruction: ● flash indicates it is saving data.
(11) Recorded time display
Indicator: Recorded time: 00:00:01
Instruction: The device is recording the record time (hour:minute:second).
(12) SpO_2 alarm low limit value display
Indicator: 85
Instruction: SpO_2 alarm low limit value.

4 Device Operation Explanation

4.1 Button Operation

Power on / Power off / Awake button:

Powering on operation: Long press the button ⏻, then the green indicator light is on, LOGO is displayed and enter the measurement interface.

Powering off operation: Long press the button ⏻ without recording, the screen displays “Bye-Bye!”, and then the work indicator light is off.

Screen awaking operation: In recording status, if there is no button operation for 60 seconds,the screen will be shut up automatically to enter power-saving status. Short press the button ⏻ to awake the LCD to display.

Menu / Confirm button:

In measurement interface,long press button “M” to enter the main menu.

You can look through the menu by short pressing button “M”,and access the submenu or set up the selected item by long pressing.

4.2 Menu Operation

4.2.1 Main Menu

In measurement interface, long press button “M” to enter the main menu, as Figure 4-2-1.

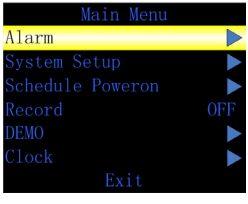


Figure 4-2-1 Main menu

Callout	Function	Instruction
1	Alarm	Alarm setup,long press “M” button to access alarm setup menu.
2	System Setup	Long press “M” button to access system setup menu.
3	Schedule Power on	Auto poweron Setup, long press “M” button to access Auto poweron Setup menu.

4	Record	Record setup, long press “M” button to access record setup menu.
5	DEMO	Long press “M” button to enter DEMO interface.
6	Clock	Time setup, long press “M” button to access time setup menu.
7	Exit	Exit to the measurement interface.

Table 4-2-1

4.2.2 Alarm Setup

Alarm setup menu is showed as Figure 4-2-2.

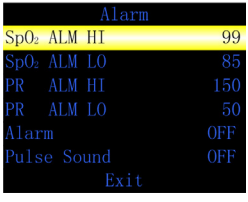


Figure 4-2-2 Alarm setup menu

Callout	Function	Instruction
1	SpO_2 ALM HI	SpO_2 alarm high limit, setup range is 1~100, default is 99(unit:%).
2	SpO_2 ALM LO	SpO_2 alarm low limit, setup range is 0~99, default is 85(unit:%).
3	PR ALM HI	Pulse rate alarm high limit, setup range is 1~254, default is 150 (unit:bpm).
4	PR ALM LO	Pulse rate alarm low limit,setup range is 0~253, default is 50 (unit:bpm).
5	Alarm	Alarm setup, ON or OFF can be selectable, default is OFF.
6	Pulse Sound	Pulse sound setup, ON or OFF can be selectable, default is OFF.
7	Exit	Exit to the upper-level menu.

Table 4-2-2

With alarm function on, when measurement value exceeds limit, the device gives audio prompt. With pulse sound on, it will give pulse prompt.

4.2.3 System Setup

System setup menu is showed as Figure 4-2-3.

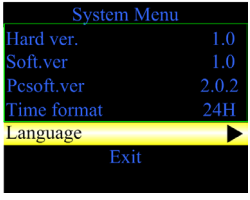


Figure 4-2-3 System setup menu

Callout	Function	Instruction
1	Hard.ver	Hardware version number, user can not set up.
2	Soft.ver	Software version number, user can not set up.
3	PCsoft.ver	PC software version number, user can not set up.
4	Time format	24-hour format,user can not set up.
5	Language	User can switch languages between English and Chinese.
6	Exit	Exit to the upper-level menu.

Table 4-2-3

4.2.4 Auto poweron Setup

Auto poweron Setup menu is showed as Figure 4-2-4.

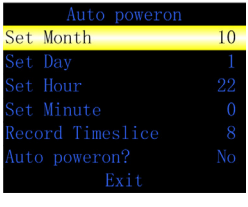


Figure 4-2-4 Time powering on setup menu

Callout	Function	Instruction
1	Set Month	Month setup, 1~12 can be selected.
2	Set Day	Day setup, 1~31 can be selected.
3	Set Hour	Hour setup, 0~23 can be selected.
4	Set Minute	Minute setup, 0~59 can be selected.
5	Record	Record duration setup, 1~10 can be selected and default is 8, unit:hour.
6	Are you sure?	Confirming information, NO/YES can be selected, YES: confirm NO: cancel
7	Exit	Exit to the upper-level menu. When exit in YES status, the setup you have done takes effect.

Table 4-2-4

Note: You shall not set up time powering on when the device is in record status.

4.2.5 Record Setup

1) Not in record status,the record setup menu is showed as Figure 4-2-5-1.
It prompts whether to begin record or not. Select YES to exit, it access the record interface (as Figure 4-2-5-2) to save and the record indicator REC dot flashes, the “Recorded Times” records the recorded time.
Select NO to exit, it will not record.

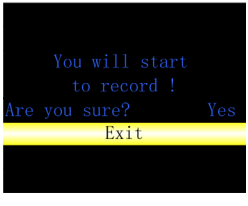


Figure 4-2-5-1 Starting record menu

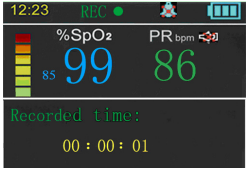


Figure 4-2-5-2 Record interface

Note:
In record status, the interface prompts “TF Card is full!”, it indicates the remaining capacity of SD card is lack and the user shall not do record operation. And the user needs to displace previous cases by computer.
Manual power off can not be performed in record status, please stop recording before power off.

Suggestion:
Termly copy the cases to the computer in case of losing the cases when the SD card is damaged. Do not store any file except the cases.

2) In record status,the record setup menu is showed as Figure 4-2-5-3. It prompts whether to stop record or not, select YES to exit,stop record. Select NO to exit, it will still record.

Figure 4-2-5-3 Stop record menu

4.2.6 Demo Interface

Demo interface is showed as Figure 4-2-6,and in DEMO mode prompt sound and pulse sound are off, it can not be switched on, Long press “M” to exit.

Figure 4-2-6 Demo interface

4.2.7 Time Setup

Time setup menu is showed as Figure 4-2-7.

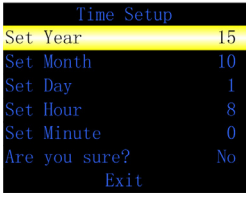


Figure 4-2-7 Time setup menu

Callout	Function	Instruction
1	Set Year	Year setup, 2010~2099 can be selected.
2	Set Month	Month setup, 1~12 can be selected.
3	Set Day	Day setup, 1~31 can be selected.
4	Set Hour	Hour setup, 0~23 can be selected.
5	Set Minute	Minute setup, 0~59 can be selected.
6	Are you sure?	Confirming information, NO/YES can be selected, YES: confirm NO: cancel
7	Exit	Exit to the upper-level menu. When exit in YES status, the setup you have done takes effect, at the same time display the effected time.

Table 4-2-7

Note: You shall not set up time when the device is in record status.

4.3 Sensor Connection

4.3.1 Nose Air Flow Monitoring

Unpack the Nasal cannula,wrest down the screw cap following Figure 4-3-1-1, then insert the Nasal cannula in its upper-right jack and screw down.
Insert the tie-in in sleep apnea screen meter, and the oxygen-absorbing apparatus in the nose, with oxygen-dividing connection tube round between the nose and chin. Adapt orientation circle to a comfortable position, then power on, and after serval seconds, the waveform is stable and you can examine respiration status.

The method of wearing the Nasal cannula is as showed in Figure 4-3-1-2, and that of the entire sensor wearing is as Figure 4-3-1-3.

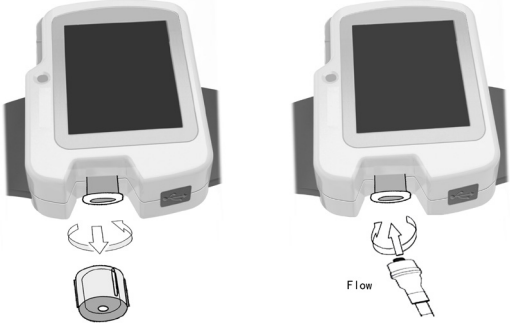


Figure 4-3-1-1 Interface icon

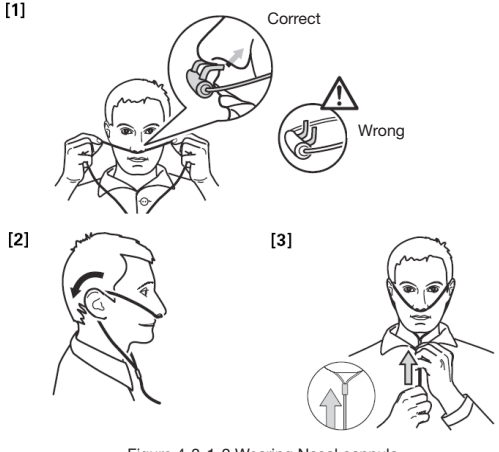


Figure 4-3-1-2 Wearing Nasal cannula

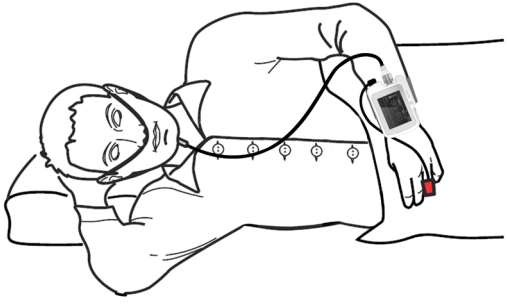


Figure 4-3-1-3 The entire wearing of sensor

Note:
Wear the Nasal cannula according to the regulations, or it will affect the gathering effect.

4.3.2 SpO_2 and Pulse Rate Monitoring

The scheme of the following three probe could be chose by user, as table 4-3-2.

Appellation	Quantity	Scheme
One-off adhesive SpO_2 probe	2	Standard (Figure 4-3-2-1)
Adult fingertip SpO_2 probe	1	Standard (Figure 4-3-2-2)
Binding SpO_2 probe	1	Optional (Figure 4-3-2-3)

Table 4-3-2

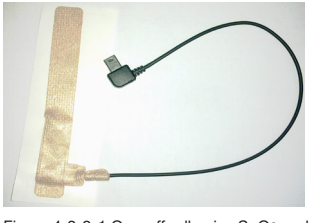


Figure 4-3-2-1 One-off adhesive SpO_2 probe

Figure 4-3-2-2 Adult fingertip SpO_2 probe

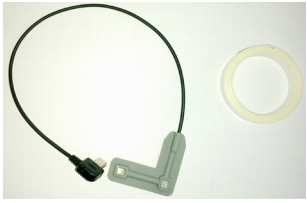


Figure 4-3-2-3 Binding SpO_2 probe

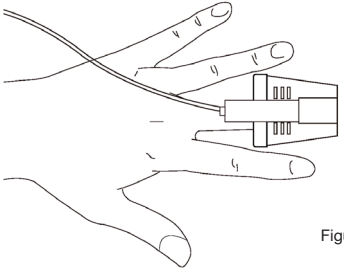


Figure 4-3-2-4 Placing SpO_2 probe

Plug the SpO_2 probe into USB interface, as Figure 4-3-2-4.

1) Connect the probe with the device.
2) Put the finger into the probe.
3) In measurement interface,you can directly read corresponding data from display screen.

⚠ **Warning:** Use the SpO_2 probe specified by our company,and other SpO_2 probes are forbidden.

Notes:

- Testee's fingernail shall not too long.
- Testee shall not use enamel or other makeup.
- The finger too cold or too thin may affect the measurement; when measuring, please insert the thicker finger fully into the probe (thumb or middle finger recommended).
- In operation, the finger tested shall not tingle and the testee shall not be in movement.
- When inserting the finger, fingernail and the luminescent tube should be on the same side

- Excessive ambient light may affect the measuring result,including fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
- There should not be such light barrier as rubber fabric on the way of light, or it may result in incorrect measure results of SpO_2 and pulse rate.
- The SpO_2 probe and photoelectric receiving tube should be arranged in a way with the testee's arteriole in a position there between.
- The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
- Acute testee movement or electrosurgical interference can affect the accuracy.
- Data update period is less than 5 seconds, which is changeable according to different individual pulse rate.
- Please read the measured value when the waveform on screen is equable and steady-going, of which the value is optimal. And the waveform at the moment is the standard one.
- The problem of overrating would display when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.
- The finger shall be put correctly (refer to the related Figure 4-3-2 in the manual) or the measurement results may be incorrect.

4.4 Clinical Restrictions

SpO_2

1) 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.

2) For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.

3) The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.

4) As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

⚠ **Warning:** Please refer to corresponding medical literature for details about clinical limits and tabu illness.

Nasal cannula

⚠ **Warning:** Shock,conk patient shall be monitored directed by medical stuff or professional paramedics.

4.5 Time Powering on Function

(Refer to **4.2.4 Time powering on setup**)
After having set up the time for powering on,you can power off, and when the clock arrives to the time set,the device will power on automatically and save. After the set duration operation,the device will power off automatically.

4.6 USB Data Uploading

Long press ⏻ key to power on and access the main interface, plug one port of the USB data line into USB connection as Figure 4-6-1, the other into PC's "USB" port as Figure 4-6-2, the connection method between the device and PC is shown as Figure 4-6-3. then the PC begins to read SD card.
In my computer,double-click the new disk symbol newly occurring to search for the record data,copy the data from SD card, and save it in any disk of my computer,and open the saved file via PC software to analyse patient's sleep information. ("Power on" ---- "Plug in USB data line" ---- "Open my computer" ------- "Search for the device disk symbol" ----- "Copy the .bin file to PC hard disk to avoid data missing").

Figure 4-6-1 Connection between sleep apnea screen meter and USB data line

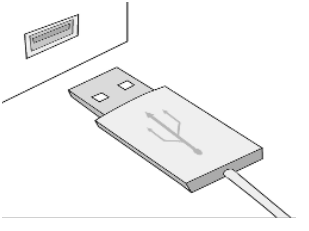


Figure 4-6-2 Connection between PC and USB data line

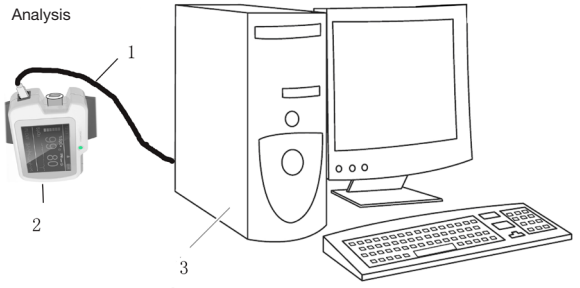


Figure 4-6-3 Connection between PC and the device

1. USB data line
2. The device
3. PC

Notes:

- Data can not be uploaded during recording. To upload data, please stop recording.
- If the computer can not identify the disk symbol, connect USB data line repeatedly.

4.7 Charging Operation

Two methods for charging:

1) Connect one end of the data line to PC, the other to the device, and the battery is then charged.

2) Connect one end of the power adapter to power receptacle, and the other to the device with data line.

Charging indicator light: when the battery is being charged, the light is orange; while the battery is full power, the light is green.

Note:

- To ensure enough operation time,charge the battery to full power before measuring.

5 PC Software Operation Explanation

Double click Shortcuts to enter the operation system (hereinafter referred as “this system”) as shown in Figure 5-1.

Figure 5-1

5.1 Data Importing and Case Management

1: Import Case Data

Startup this software and import data. Click “Import Case Data” in “File” menu, then the following Figure 5-1-1 will appears:

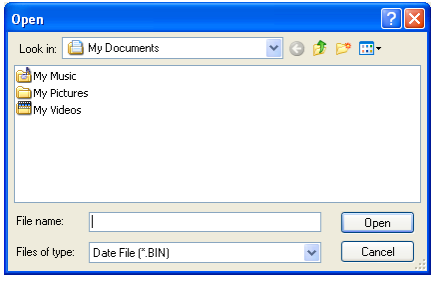


Figure 5-1-1

Click the button “Open”, then the data importing interface appears, as Figure 5-1-2. Find the saving path of the case, and click “Import Case”. You must firstly fill in the name of the patient, then click “Import Case” to enter the interface of waveform display as Figure 5-1-3, and the case information is saved in the case library. If the patient’s name is empty, this system will prompt.

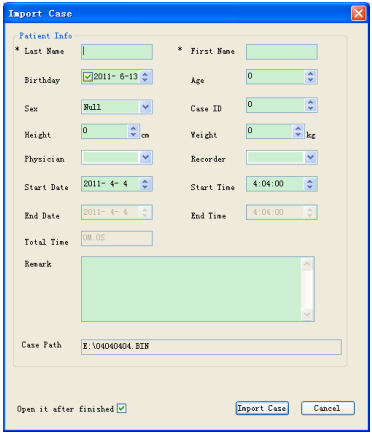


Figure 5-1-2

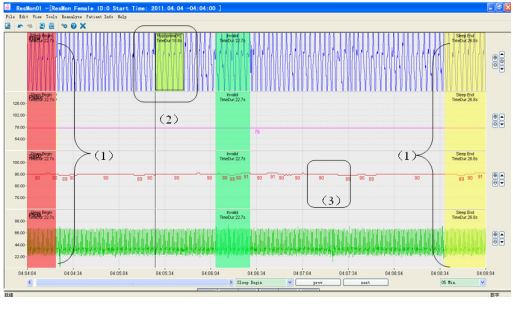


Figure 5-1-3

2. Case Management

Click “Case Manage” in “File” menu to its sub-menu as Figure 5-1-4:

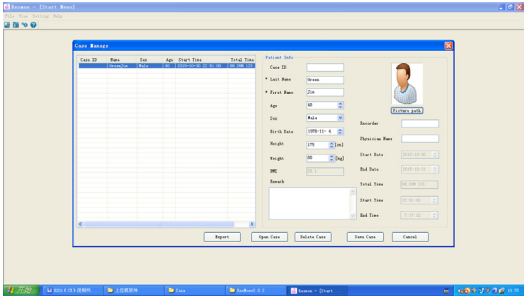


Figure 5-1-4

The left of the interface are all cases in the case library. When selecting any case, the relative patient information will display on the right of the interface, including patient's basic information and gathered information, you also can add the name of the physician, recorder, and the marks the doctor made.
Click "Picture Path" to choose the patient's picture, next click "Save", the picture will be displayed in the report.
This system has the functions of modifying and deleting patient's information, if you want to modify some case information, first, select the patient on the left, and then modify the information as you like on the right, click "Save Case" to complete modifying patient's information; if you want to delete some case information, first select it, then click "Delete Case", the system will prompt to verify whether to delete or not(as Figure 5-1-5), click "OK" to delete the case forever from the case library. Double click the case in case management interface to enter corresponding case waveform display interface (as Figure 5-1-3).

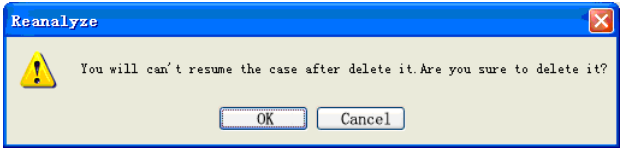


Figure 5-1-5

5.2 System Setting

Select “Global Setting” in “Setting” menu, the global setting dialogue box will pop up as shown in Figure 5-2-1.

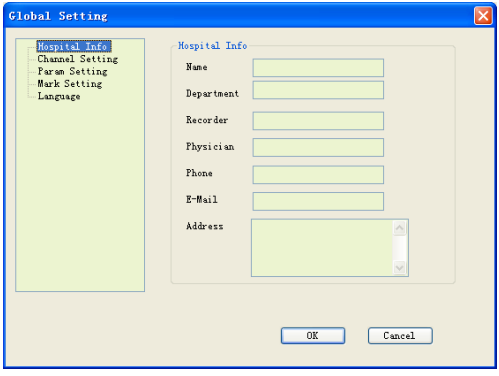


Figure 5-2-1

1) Fill in the basic hospital information in the “Hospital Info” interface.
2) Set the waveform color or the waveform state of each lead in “Channel setting” interface, as shown in Figure 5-2-2:

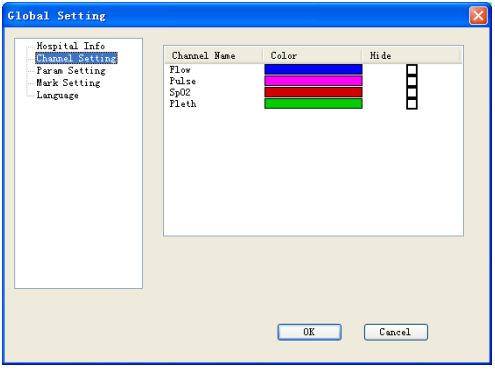


Figure 5-2-2

3) There are two interfaces (SpO_2 and flow) in “Param Setting”, you can set up the parameter value in the respective interface (as Figure 5-2-3).

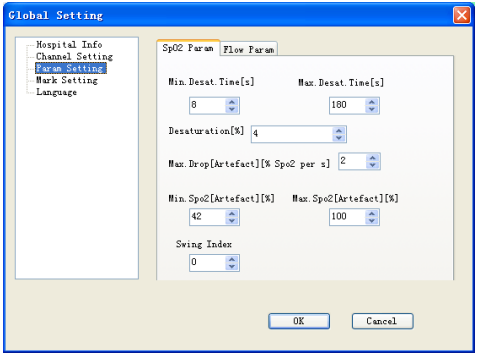


Figure 5-2-3

4) You can add, edit and delete marks in “Mark” interface, as shown in Figure 5-2-4:

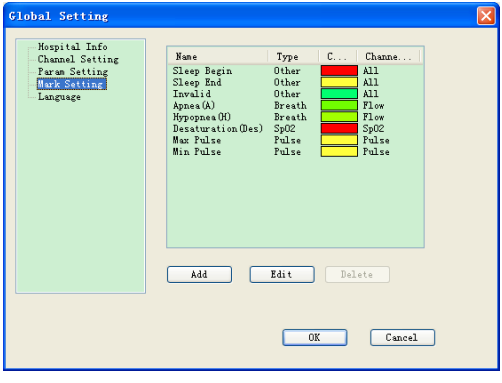


Figure 5-2-4

Click “Add” to enter “Add Mark” dialogue box (as Figure 5-2-5). Click “OK”, the new mark will display in the mark list. If you want to edit some mark, first, select mark name in the mark list, click “Edit” or double click mark name, the “Edit Mark” dialogue box will appear (as Figure 5-2-6). (The front eight items in the mark list are default, they can not be deleted or edited, but their color can be modified) Select some mark and click “Delete” to delete user-defined mark. (Refer to chapter 5.3 for details)

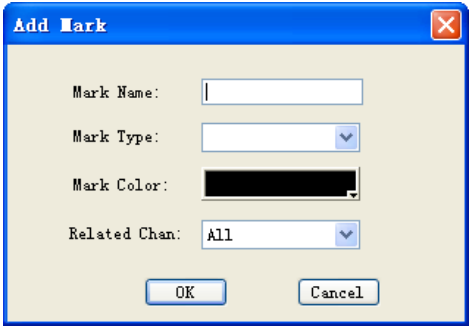


Figure 5-2-5

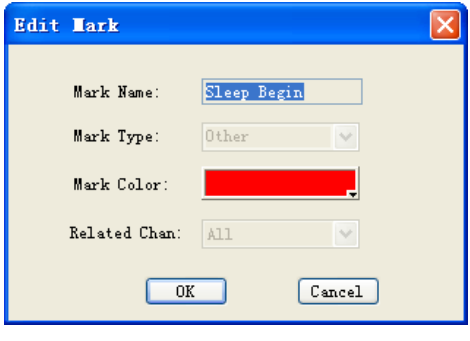


Figure 5-2-6

5) You can set up the display language through “Language” option (as Figure 5-2-7).

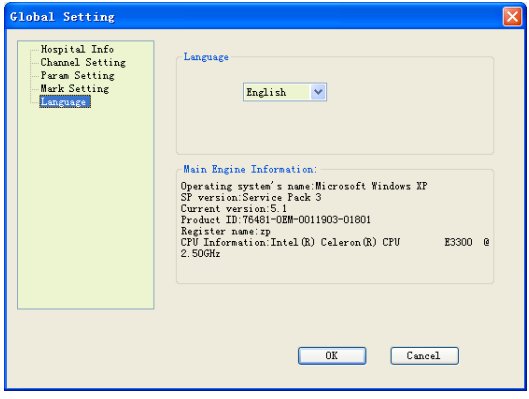


Figure 5-2-7

When clicking “OK” button in “Global Setting” dialogue box, the setup you have done will be saved in system setting.

5.3 Waveform Display

The waveform display area is shown in Figure 5-1-3, the display area can display two waveform charts, or one event chart and one waveform chart, or only event or waveform chart. Window adjusting button can change the amount of charts and size of the area, shown as Figure 5-3-1:

Figure 5-3-1

Four-lead data waveform for Flow, SpO_2, Pulse, Pleth will be displayed in chart display area, (as Figure 5-3-2). Drag the borderline of each waveform to change the size of display area, which is convenient for observing. Some data marks displayed in the front of each lead can use to confirm corresponding value, as Figure 5-1-3(3):

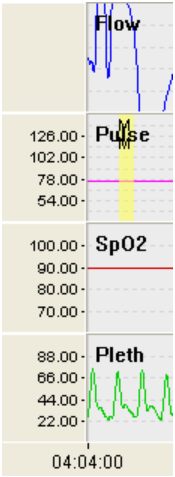


Figure 5-3-2

The buttons on the right of the waveform display area are showed in Figure 5-3-3, here, you can adjust the size and the baseline position of the waveform. When clicking ⊕ , the amplitude will get bigger; when clicking ⊖ , the amplitude will get smaller; when clicking ▲ , the baseline will move up; when clicking ▼ , the baseline will move down. Meanwhile,when adjusting the amplitude, the data mark in Figure 5-3-2 will change correspondingly, while for the leads without data mark, the waveform gain back of the waveform name will change bigger or smaller.

Figure 5-3-3

Drag the mouse on some waveform while clicking the right button and the mark dialogue box in Figure 5-3-4 will pop up, select the mark type, click “OK” to mark in corresponding position (as Figure 5-1-3(2)), put the mouse on the borderline of the marked area, when the editing sign occurs, you can drag the mouse to adjust the marked area size. (New marks can not cover old ones.)
Select some mark on the waveform and click “Delete” in the keyboard or clicking the right button to delete the mark.

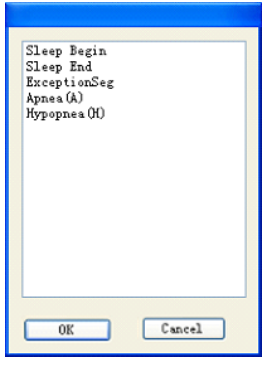


Figure 5-3-4

Drag the left button of the mouse, then the corresponding dialog box will appear (as Figure 5-3-4), “Sleep Begin” and “Sleep End” marks can be set as Figure 5-1-3(1):

The time axes display area is showed as Figure 5-3-5. Dragging the scroll bar or rolling the mouse wheel to browse the waveform. Meanwhile, 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 axes displays the beginning and end time of data record and set up a time coordinate every five seconds. When the position of the scroll bar changes, the time of the axes will change correspondingly.

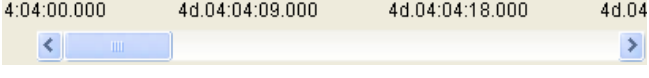


Figure 5-3-5

Time selections are showed as Figure 5-3-6, you can set the time interval of a screen, also set different time intervals of the upper and netherchart display areas and synchronously view.

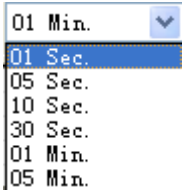


Figure 5-3-6

The buttons for browsing events are showed as Figure 5-3-7, you can select the event name you want to browse in the list, click the left and right arrowhead buttons to browse the event marks one by one, which is convenient for observing. If there is no suited mark event, this system will give prompt.

Figure 5-3-7

5.4 Function Menus

There are some function menus in the waveform display interface (as Figure 5-4-1).

1. Click “Import Case” in “File” menu, then the case information interface will appear as Figure 5-1-1, which can help doctors import the other patient’s data when observing one patient’s waveform.

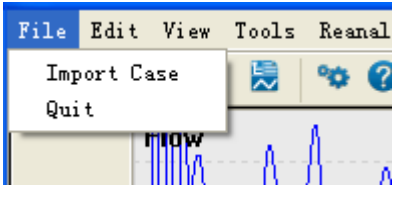


Figure 5-4-1

2. There are two menu options in the “Edit” menu: “Undo Ctrl+Z” and “Redo Ctrl+Y” (as Figure 5-4-2). Click the options to undo and redo the waveform mark.

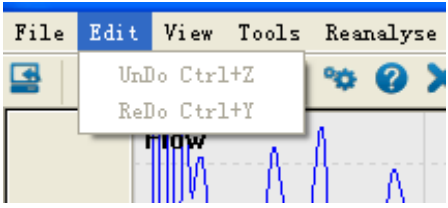


Figure 5-4-2

3. There are two menu options in the “View” menu, “Report View” and “EventList View” (as Figure 5-4-3). “Report View” menu is used to print reports, when clicking this option, the print preview interface will appear as Figure 5-4-4: there are such functions as zooming in, zooming out and paging-up and paging-down functions, when all have been done, click “Print” and the case report will be printed out.

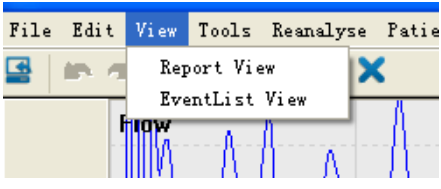


Figure 5-4-3

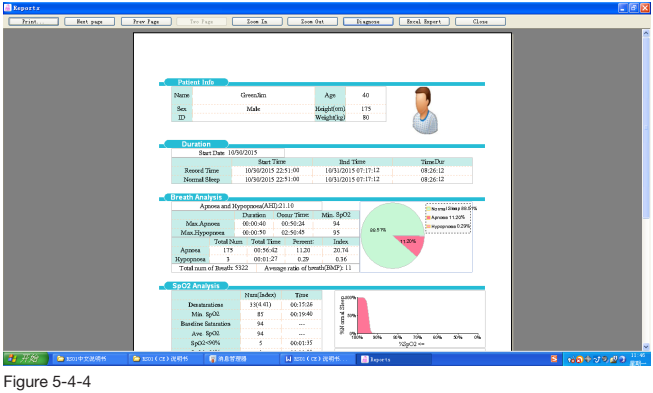


Figure 5-4-4

It also has such functions as editing the diagnosis information and filling it into the report, click “Diagnose” and the Diagnose info interface will appear, as Figure 5-4-5, then you can fill in the diagnosis information and report name. 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 as a form of Excel spreadsheet to the file that user specified.

Note: The Excel export function can be applied only preinstalled with Microsoft Office 2003 or higher version.

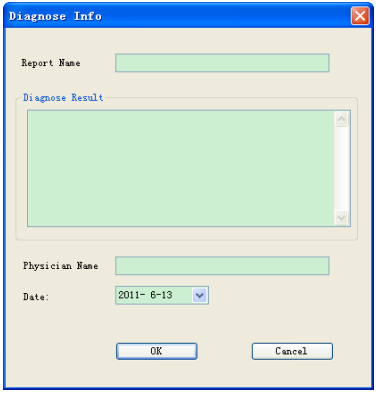


Figure 5-4-5

4. When selecting “EventList View” option, the interface as Figure 5-4-6 will appear. event type is displayed on the left, this system are divided into four types: Other, SpO_2, Breath and pulse. Mark name, the start and end time of mark and interval will be displayed on the right of the event list.
   Click “All events”, then the mark of all events will be displayed in the right list.

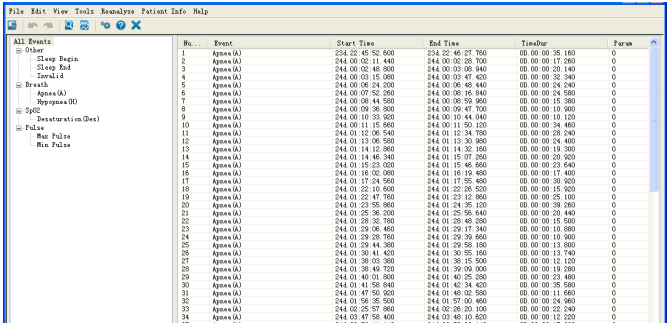


Figure 5-4-6

5. Click “Reanalyse”, the dialogue box as Figure 5-4-7 will appear, click “OK”, you will remove the old data and reanalyse; click “No” to reanalyse but not remove the manual analyse data; click “Cancel” to cancel the reanalyse operation.

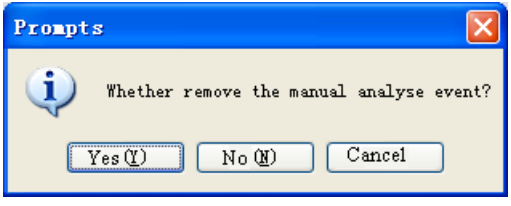


Figure 5-4-7

6. Click “Patient info”, and the current patient information will appear which is convenient for the doctor to analyse the patient’s case.

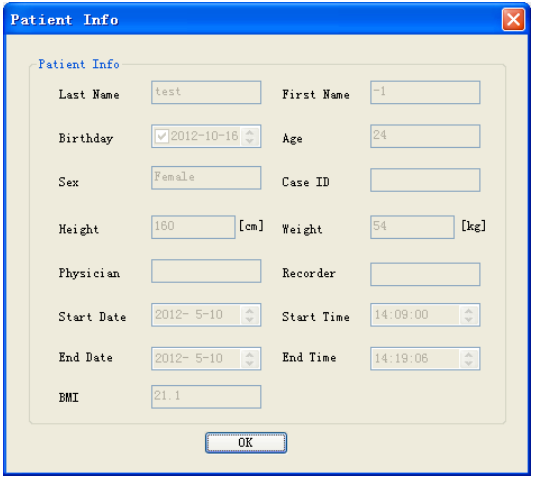


Figure 5-4-8

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

6 Product Specification

Product name: Sleep apnea screen meter
Safety: complied with the standard IEC 60601-1
Classification:
Compatibility: Group I,Type B
Power type: internal powered equipment
The degree of protection against electric shock: BF applied part.
The degree of protection against entry liquids: IP22 grade, SpO_2 probe IPX1.
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
Physical characteristic:
Size: 69(L)× 50(W)×17.3 (H)mm
Weight: 100g
Environment requirements:
(1) Transportation and record:

Environment temperature range: - 40°C~+55°C
Relative humidity range: ≤95 %
Atmospheric pressure range: 500 hPa~1060 hPa
(2) Operation:
Environment temperature range: 10°C~40°C
Relative humidity range: ≤75%
Atmospheric pressure range: 700 hPa~1060 hPa
Battery type: 3.7V Chargeable lithium battery
Operation voltage: 3.6 V DC ~ 4.2V DC.
Operation current: :≤100 mA
Display screen: LCD display screen
Performance parameters
(1) Nose air flow measurement:
Measurement range: 0rpm~40rpm
Resolution: 1rpm
Accuracy: ±2rpm
(2) SpO_2 measurement:
Measurement range: 0%~100%
Resolution: 1%
Accuracy: 70%~100%, ±2%; <70% unspecified
(3) Pulse rate measurement:
Measurement range: 30bpm~250bpm
Resolution: 1bpm
Accuracy: ±2 bpm and ±2% (selecting larger)
(4) Resistance to surrounding light:
The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

7 Cleaning, Disinfection and Maintenance

7.1 Cleaning

Keep the exterior surface of the device clean, without dust and dirt.
The exterior surface of the device shell may be cleaned with a clean and soft cloth, if necessary,with soap water or dampened soft cloth, and remember to dry it with dry cloth at once. Nasal cannula is one-off, of which the connection may be cleaned with medical alcohol,then air-dry it, or with a dry cloth.

Notes:
- Power off the device before cleaning.
- Never use such acute solutions as acetone.
- Never use worn materials (like steel wire or silver polishing reagent)

- The temperature of the device cleaning water is below 60°C.
- Never permit any liquid run into the device,nor submerge the device into any liquid.
- Never spoil liquid on the device when cleaning.
- Never remain any solution on the surface of the device.

7.2 Disinfection

After cleaning the device with the methods above, disinfect it with medical alcohol, then air-dry (or with dry cloth).

Notes:

- Never disinfect the device with the method of low temperature steam or high temperature.
- Never use electron shoot bind or other methods to disinfect.

7.3 Maintenance

Before using the device,check it for evident damages which may possibly affect patient's safety. We recommend the check period is once a month (or shorter period). In case of evident damage,it is recommended to replace the damage parts before using.

The device is precise electrical equipment,take and put it carefully. For a longer service life, take the following measures to maintain the device.

1) When the battery is in low power, recharge it in time.

2) After fully discharged,the battery should be recharged as soon as possible. If the device is not used for long, you shall make entire charge/discharge operation every 6 months.

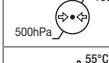
3) Please clean and disinfect the device before using it on patient.

4) Disinfect the device after use in case not cause cross infection in use again. The device determines its accuracy, which can not adjusted by user. If there is any doubt about the measurement result, use other methods to verify, or contact your local agent or manufacturer for help.

Notes:

- Maintaining this device must be carried out by our company's authorized and qualified engineer.
- If not in use for long,clean, disinfect this device and save it in the packing case, then put it in a draughty place without caustic gas.

8 Symbol Meanings

Symbol	Meaning
	Follow instructions for use
% SpO_2	SpO_2 value (unit: %)
PR bpm	Pulse rate (unit: bpm)
	Full power
	Leak power
	Audio prompt off
	Audio prompt on
	Pulse sound off
	Pulse sound on
REC ●	Record indicator
	Type BF applied part
	WEEE disposal
	USB data connection
	Medical Device complies with Directive 93/42/EEC
	Atmospheric pressure limitation
	Store between 10 and 40°C

Symbol	Meaning
	Humidity limitation
	Disposable device, do not re-use
REF	Product code
LOT	Lot number
SN	Serial number
	Caution: read instructions (warnings) carefully
	Manufacturer
EC REP	Authorized representative in the European community
	Date of manufacture
	Keep in a cool, dry place
	Keep away from sunlight
	Fragile, handle with care
IP22	Covering Protection rate

9 Trouble Shootings

Trouble	Possible cause	Solution
SpO_2 or Pulse rate is displayed abnormally.	1.The finger is not put in correctly. 2.Patient SpO_2 value is beyond the measurement range. 3.The deepness of the finger putting in is not enough. 4.The finger wobbles or the patient is in movement.	1.Try again with the finger correctly put in. 2.Try repeatedly,if you are sure the product performance is normal,go to hospital for diagnose. 3.Try again with the finger correctly putting in. 4.Please keep calm.
Nose air flow waveform display is instable.	1.Connection problem. 2.Wearing method problem. 3.The patient is in movement.	1.Correctly connect. 2.With correct wearing method. 3.The patient shall keep calm.
Powering on disabled	1.Battery capacity lack or no power. 2.Device failure.	1.Charge the battery at once. 2.Contact your local service center
PC can not identify SD card disk symbol.	1.The USB connection has been worn and in bad connection. 2.SD card is damaged.	1.Try to connect the USB data line repeatedly. 2.Contact your local service center.
In full power,the operation time is too short or the charging time is already over 10 hours, the battery is still not full.	The battery is damaged.	Contact your local service center

The device may not meet your intended purpose owing to operation or other problems, and consult the following troubleshooting to solve the problems you have met.

Appendix 1

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	1s	20ms
SpO_2 alarm	330ms	20ms
Pulse rate alarm	330ms	20ms
Probe error alarm	16ms	20ms

Appendix 2

Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The RS01 is intended for use in the electromagnetic environment specified below. The customer of the user of the RS01 should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The RS01 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 RS01 is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The RS01 is intended for use in the electromagnetic environment specified below. The customer or the user of RS01 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 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	3A/m	Class B	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The RS01 is intended for use in the electromagnetic environment specified below. The customer or the user of RS01 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RS01, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz - 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz - 2,5 GHz 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 metres (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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 RS01 is used exceeds the applicable RF compliance level above, the RS01 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the RS01.
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 EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the RS01

The RS01 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RS01 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RS01 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150KHz to 80MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

***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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.
The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.