

USER NOTICE

Dear users, thanks for purchasing the Multi-functional Visual Stethoscope.

This Manual is written and compiled in accordance with the council directive IEC60601-1 for medical devices and harmonized standards. The Manual is written for the current product. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

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

Please read the Manual carefully before using this equipment. These instructions describe the operating procedures to be followed strictly; This manual will tell you the operating procedures, possible abnormal operation, possible damage to this instrument and danger to personal injury which must be noticed during using this product. Our company is not responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

This product is medical device, which can be used repeatedly.

Attention

This manual is compiled by our company, the copyright belongs to our company.No part of this document may be photocopied,reproduced or translated to another language without prior written consent of the manufacturer.

The manufacturer assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing,performance or use of this material. The information contained in this document is subject to change without prior notice.

Our company reserves the final elucidative right.



WARNING: This device can't be used as normal ECG machine,it's ECG function only be used to detect the ECG waveform.



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

The label instruction of 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.

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Chapter1 Safety Guidance

1.1 Safe Operation


To avoid any possible danger,please operate the device according to safety guidance as following:


- ✧ 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 the device.
- ✧ Necessary maintenance must be performed by qualified service engineers ONLY.Users are not permitted to maintain it by themselves.
- ✧ The device cannot be used together with devices not specified in User's Manual.Only the accessory that is appointed or recommendatory by manufacture can be used with this device.
- ✧ This product is calibrated before leaving factory.

1.2 Warning

 The infrared is harmful to eyes,so the user and the maintenance man should not stare at the light part of the SpO₂ probe (the infrared is invisible).

 The SpO₂ probe can not be clipped on the edema and tender tissue.

 Please don't use this device when charging.

 Explosive hazard: Do not use this device in environment with inflammable gas such as

some ignitable anesthetic.



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



The person who is allergic to rubber can not use this device.



The user must use the accessory which is provided by our company, don't use the parts which are not manufactured by our company.



Don't break the hang rope, or it will not be hanged in the neck, or the device will be broken for the broken rope. The person who is allergic to rope can not use this device.



The device doesn't suit all users, if you can't get steady value, please stop using it.



The device is not intended for treatment.



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












Please don't measure this device with functional tester for the device's related information.



The device can not be transported mixed with toxic, harmful, corrosive material.

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 actual device as standard.
-  The device is designed for continuous operation and is 'ordinary'. If the device gets wet or freezing, please stop operating it.
-  Keep the device away from dust, vibration, corrosive substances.
-  When it is carried from cold environment to warm or humid environment, please do not use it immediately.
-  DO NOT operate keys on front panel with sharp materials.
-  The device has normal useful life for three years since the first electrified use.
-  After the service life, please return the products to the manufacture or disposal the products according to local regulations.
-  Please refer to text for else notice proceeding.

Chapter2 Brief Introduction

2.1 Overview

This device is a kind of multi-functional visual stethoscope. It integrates the functions of auscultation, ECG collection, SpO₂ and PR inspection.

The product is applicable for hospital, community medical treatment, oxygen station, family, sport health care (it is advised to be used before and after sport, and it is not suggested to be used in the process of sport), etc.

STH_Sync visible stethoscope synchronized software (STH_Sync for short) is the special software for this device, STH_Sync, which is connected with this device by USB interface, can receive case data sent by this device, and can also analyze and show case data.

2.2 Features

- ◇ Operation of the product is simple and convenient.
- ◇ Light weight, compact size, easy to carry.
- ◇ Low power consumption.
- ◇ Multi-function, know more physiological information.

2.3 Main Function

- ◇ Three-mode choices: heart sound mode, lung sound mode and combination mode;
- ◇ ECG waveform display;
- ◇ Heart rate(HR)display;

- ✧ SpO₂ monitor through connecting with an external oximeter probe;
- ✧ ECG and SpO₂ data record, waveform review and upload;
- ✧ Pulse rate, pulse waveform and bar graph display;
- ✧ The alarm of SpO₂ and PR data's going beyond the limits;
- ✧ Battery power display and the alarm of low-voltage;
- ✧ Clock display.

2.4 Accessories

- (1) An User Manual
- (2) An Earphone
- (3) A Power adapter
- (4) A data line
- (5) An oximeter probe
- (6) A CD

Chapter3 Technical Specifications



Product name: Multi-functional Visual Stethoscope.

Safety:Complies with IEC 60601-1

Classification:

EMC: Group I Class B.

Anti-electroshock Type: Internally powered equipment.

Anti-electroshock Degree: type B applied part  .(The oximeter probe is type BF applied part )

Harmful Liquid Proof Degree: IPX0.

Degree of Safety in Presence of Flammable Gases: Equipment is not suitable for use in presence of flammable gases.

Mode: Continuous work.

Physical Characteristics

Size: 110 (length) × 60 (width) × 14 (height) mm

Weight: 100g(including battery)

Environment

Transport and storage

Temperature: -10°C~+50°C

Relative Humidity: 10%~95%

Atmospheric pressure: 50kPa~106kPa

Working environment

Temperature: 5 °C~ 40 °C

Relative Humidity: 20%~80%

Atmospheric pressure: 70kPa~106 kPa

Battery type: charging lithium battery

Working-voltage:DC3.6V ~ DC4.2V

Power: ≤120mA

LCD display:2.4" TFT,320*240 pixels

Continuous running time: 7 hours

Main Parameters:

(1) Measurement of auscultation volume

heart sound range:20Hz~230Hz

lung sound range:100Hz~800Hz

heart&lung combination sound range:20Hz~800Hz

(2) Measurement of Heart Rate

range: 30bpm~300bpm;

resolution:1bpm;

accuracy: ±2 bpm or ±2% (select larger).

(3) Measurement of SpO₂

range:0%~100%;

resolution:1 %;

accuracy: When the SpO₂ measurement range is 70%~100%,the permission of absolute error is $\pm 2\%$. below 70% unspecified.

(4) Measurement of pulse rate

range: 30bpm~250bpm;

resolution : 1bpm;

accuracy: ± 2 bpm or $\pm 2\%$ (select larger).

(5) Measurement Performance in Weak Filling Condition:

SpO₂ and pulse rate can be shown correctly when pulse-filling ratio is 0.4%.SpO₂ error is $\pm 4\%$, pulse rate error is ± 2 bpm or $\pm 2\%$ (select larger).

(6) Resistance to surrounding light:

The deviation between the value measured in the condition of man-made light and indoor natural light and that of darkroom is less than $\pm 1\%$.

Chapter4 Appearance and Structure

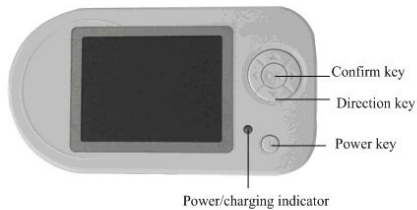


Fig.4-1 Front panel view



Fig.4-2 Rear panel view


4.1 Front Panel Instruction


4.1.1 Display Screen

LCD: 2.4"TFT

Pixel: 320*240


4.1.2 Keys

(1)  : Power key

Function: long press "" to turn on/off the device and short press it to freeze the wave for observe when measuring ECG.


(2)  : Confirm/Menu key

Function: 1. In any monitor interface, short press  to enter the main menu.

2. In any monitor interface, long press  to record or halt.

3. Press the key to activate the selected operation, enter corresponding interface.

(3) Direction key

 : Up key

Function: 1. In ECG interface, change the direction of display .

2. In menu interface, move the selection bar up.

 : Down key

Function: 1.In ECG interface,select auscultation mode(Heart,Lung,Heart&Lung).

2.In menu interface,move the selection bar down.



: Left key

Function: 1.In ECG interface,descend the volume in auscultation function.

2.Move selection bar on "YES" or "NO" when you need to confirm your operation.



: Right key

Function: 1.In ECG interface,raise the volume in auscultation function.


2.Move selection bar on "YES" or "NO" when you need to confirm your operation.

4.1.3 Power/Charging Indicator

Function: The indicator shows green when turning on.

It is orange in charging state and it is green when the charge has finished.


4.2 Side Panel Instruction

(1) USB socket : 

Function: 1.Connect SpO₂ probe to measure SpO₂;

2.The socket for charge;

3.Upload the recorded data with data line.

(2) Earphone socket: 

Function:monitor the auscultation sound.

(3) Hole for hanging rope

Function: Connect the hanging rope, and it is convenient for auscultation.

4.3 Rear Panel Instruction

(1) Stethoscope Probe

Function: Collect heart-beat, lung-beat and ECG signal.

(2) Electrode


Function: Collect electrical signal of the body.

Chapter5 Operating Guide

5.1 Monitor Operation

5.1.1 Auscultation Monitor


(1) Let the patient keep calm.


(2) Press " " long to turn on the device.


(3)Set the device into the auscultation measurement interface.(traditional areas of auscultation: 1.Cardiac apex area 2. Puimonic area 3. Aortic area 4. The second intercostal of aortic area 5.the ricuspid area)


(4) Select auscultation mode(heart sound,lung sound and heart&lung combination sound.) and the auscultation volume.

Attention:

 Please check the device before using,and confirm that it can work normally.

 When monitoring the auscultation function,keep the device in tranquil environment.

 If only to auscultate the sound,medical conductive paste is not needed,you can measure directly through the stethoscope probe which connects with the body thoroughly and stably.

 Acute sport will affect the measure result.

5.1.2 ECG Measurement

(1) Let the patient keep calm.

(2) Daub some medical conductive paste to the surface of the three electrodes well-proportioned.

- (3) Press "⏻" long to turn on the device, and it will enter the ECG monitor interface (do not connect the oximeter probe to the device), see Fig.5-1.
- (4) Hold the device and stick to the chest of patient. All the three electrodes should stick to the skin upon heart. It can display the real-time ECG. (User can adjust the wave scale according to the system settings, see chapter 5.2).
- (5) When monitoring, short press "⏻" to halt the wave. Then operators observe the wave carefully, short press "⏻" again to continue monitor after observing.
- (6) Press "⏻" long to turn off the device after measuring.

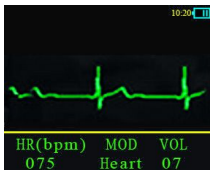


Fig.5-1 ECG monitor interface

Attention:

- 🔔 Please check the device before using, and confirm that it can work normally.

- 🔔 Let the patient use the device in quiet environment, and not speak during monitoring.
- 🔔 The device should be in a proper position, or else it may result in inaccurate measure.
- 🔔 When monitoring the ECG, the electrodes must be assured to connect with the body thoroughly and stably.

5.1.3 SpO₂ Measurement

- (1) Insert the oximeter probe to the USB socket. long press "🔌" to enter the SpO₂ monitor interface automatically.
- (2) Put the finger into the oximeter probe monitor as Fig.5-2..
- (3) Press "🔌" long to turn off the device after measuring.



Fig.5-2 SpO₂ monitor interface


⚠ Warning: The probe is limited to be collocated by our company, never replace it with the


similar types.


Attention:

- 🔔 The fingernails of the testee should not be too long.
- 🔔 Testee can not use enamel or other makeup.
- 🔔 As to the fingers which are too thin or too cold,it would probably affect the normal measure value,please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- 🔔 Do not shake the finger and keep the patient in a stable state during using process.
- 🔔 Fingernails and the luminescent tube should be on the same side.
- 🔔 Excessive ambient light may affect the measuring result.It includes fluorescent lamp,dual ruby light,infrared heater,direct sunlight and etc.
- 🔔 There shouldn't be rubber fabric and so light barrier on the way of light,or else it may result in inaccurate measure.
- 🔔 The photoelectric receiving tube of the SpO₂ sensor and luminescence tube should be arranged in a way with the subject's arteriole in a position there between.
- 🔔 Avoid to be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
- 🔔 Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
- 🔔 If some abnormal conditions appear on the screen during monitor process,pull out the

finger and reinsert to remeasure.

 The update period of data 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 equally and steady-going. This measured value is optimal value. And the waveform at the moment is the standard one.

 The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this.

●Clinical restrictions

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 SpO₂ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

b. 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 SpO₂ determination by this monitor may be inaccurate.

c. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO₂ measure.

d. As the SpO₂ value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO₂ measurement.

Notice :

For the details of correlative clinic restriction and contraindications, please refer to the related medical literatures.

5.2 Menu Operation

Under any monitor condition, press "OK" to enter main menu interface. The diagram is showed as Fig.5-3.

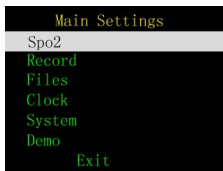


Fig.5-3 Main menu

Press " \triangle " or " ∇ " to move the selection bar, and press "OK" to enter. The concrete functions are showed in table5.1

Table5.1 The main menu function

No	Option	Function
1	SpO ₂	Enter SpO ₂ Settings
2	Record	Record settings
3	File	File operations
4	Clock	Clock settings
5	System	System Settings
6	Demo	Optional:ECG,SpO ₂
7	EXIT	Exit main menu,back to monitor interface

5.2.1 SpO₂ Settings

SpO₂ settings menu is showed as Fig.5-4.

Spo2 Settings		
Spo2	ALM HI	100
Spo2	ALM LO	085
PR	ALM HI	120
PR	ALM LO	030
Alarm		off
Pulse Sound		on
	Exit	

Fig.5-4 SpO₂ settings

Press "△" or "▽" to move the selection bar, and press "◀" and "▶" to adjust the value of the parameters. The corresponding function and the adjustable ranges are shown in table 5.2

Table5.2 The SpO₂ settings function

No	Option	Adjustable Ranges
1	SpO ₂ ALM HI	Optional:high limit of alarm HI~100%
2	SpO ₂ ALM LO	Optional:lower limit of alarm 0%~LO
3	PR ALM HI	Optional:high limit of alarm HI~250,the unit is bpm
4	PR ALM LO	Optional:lower limit of alarm 0~LO,the unit is bpm
5	Alarm	Optional:Turn on or turn off the alarm function.
6	Pulse Sound	Optional:Turn on or turn off the pulse sound.
7	EXIT	Exit SpO ₂ setting,back to main menu interface

5.2.2 Data Record Settings

The device can store the measured data.Users can review the waveform or upload recorded data

to the computer with data line to display and analyse.

(1) ECG recording

Start recording in the ECG monitor interface

a. Short press "OK" to enter main menu, move the selection bar to "Record" to enter data record interface, select "YES" to record, "NO" to back to main menu.

b. Long press "OK" to enter record mode.

Stop recording in the ECG monitor interface

a. Short press "OK" to enter menu in record mode, move the selection bar to "Record", press "OK" to stop recording menu, "Yes" to stop recording, "NO" to back to main menu and keep recording.

b. Long press "OK" to exit the record mode

If the record mode is open, the monitor interface will show a symbol of "REC" and a flicker dot, which indicates in the storage state.

(2) SpO₂ recording

Start recording in the SpO₂ monitor interface

a. Short press "OK" to enter main menu, move the selection bar to "Record" to enter data record

interface,select "YES" to record, "NO" to back to main menu .

b.Long press "OK" to enter record mode.

Stop recording in the SpO₂ monitor interface

a.Short press "OK" to enter main menu, move the selection bar to "Record"to stop recording menu, "YES" to stop recording, "NO" to back to main menu and keep recording.

b.Long press "OK" to exit the record mode

If the record mode is open,the monitor interface will show a symbol of "REC" and a flicker dot,which indicates in the storage state.

5.2.3 File Operations

Select "Files" in main menu to enter file interface as Fig.5-5 to operate the ECG file,SpO₂ file and delete all files.

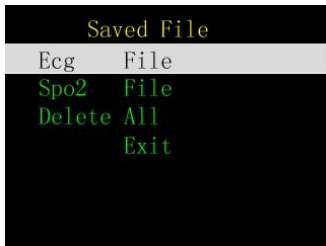


Fig.5-5 File interface

(1) ECG file


Select “Ecg File” in file interface,press "  " to enter ECG listed files as Fig.5-6 to operate ECG file.



Fig.5-6 Ecg File interface

a. ECG wave review


Select "01.ECG 10/01/08 00:03" in ECG file interface, press "OK" to enter its menu as Fig.5-7, select "Review" to enter ECG review interface which shows a symbol of "REV" and a flicker dot, it indicates it is reviewing wave.


Exit the "Review" interface automatically after finishing review wave. Press "OK" to halt reviewing during reviewing, and to exit "Review" interface.



Fig.5-7 Ecg File Operate

b. ECG data upload

Select "01.ECG 10/01/08 00:03" in ECG file interface, press "  " to enter its menu as Fig.5-7, select "Upload" to start uploading, then the interface shows a symbol of "uploading".

Exit the "Upload" interface automatically after finishing uploading. Press "  " to halt upload during uploading, and exit "upload" interface.

c. Delete


Select "01.ECG 10/01/08 00:03" in ECG file interface, press "  " to enter its menu as

Fig.5-7,select“Delete”to enter delete file interface,“Yes”to delete file,"No" to quit deleting.

(2) SpO₂ Files

Select“SpO₂ Files” in file interface,press "OK" to enter)listed files as Fig.5-8 to operate SpO₂ files.



Spo Files			
04.	SPO	10/01/08	01:35
03.	SPO	10/01/08	01:34
02.	SPO	10/01/08	01:33
01.	SPO	10/01/08	01:32
00.	SPO	10/01/08	01:31
Exit			

Fig.5-8 SpO₂ Files

a. Wave review

Select“00.SPO 10/01/08 01:31”in SpO₂ Files interface,press"OK" to enter its menu as Fig.5-9,select“Review”to enter ECG review interface which shows a symbol of "REV" and a

flicker dot,it indicates it is reviewing wave.

Exit the "Review" interface automatically after finishing review wave.Press "OK" to halt review during reviewing,and to exit "Review" interface.



Fig.5-9 SpO₂ File Operate

b. SpO₂ data upload

Select "00.SPO 10/01/08 01:31" in SpO₂ file interface,press "OK" to enter its menu as Fig.5-9,select "Upload" to start uploading,then the interface shows a symbol of "uploading".

Exit the "Upload" interface automatically after finishing uploading. Press "OK" to halt upload during uploading, and exit "upload" interface.

c. Delete

Select "00.SPO 10/01/08 01:31" in SpO₂ file interface, press "OK" to enter its menu as Fig.5-7, select "Delete" to delete file interface, "Yes" to delete files, "No" to quit deleting.

(3) Delete all files

Select "Delete All" in file interface, press "OK" to enter its menu, "Yes" to delete all files, "No" to quit deleting.

5.2.4 Clock Settings

Select "Clock" in main menu, press "OK" to enter its menu, press "△" or "▽" to select the selection bar which required to be changed, press "◀" or "▶" to change the time value.

5.2.5 System Settings



Select "System" in main menu, Press "OK" to enter system settings interface as Fig.5-10 to operate key sound, time settings, wave scale, wave speed, auto poweroff, then press "◀" or "▶" in

sub-menu to system settings.



System Settings		
Key Sound		off
Wave Scale		1
Wave Speed		1
Auto Poweroff		off
Version		
	Exit	

Fig.5-10 System settings



(1) Key sound

Press "Key Sound",press " "or " ", "On" to turn on the key sound, "Off" to turn off the key sound.

(2) ECG wave scale



Select "Wave Scale",press " "or " " to change the ECG wave scale.wave scale is setted for three grades,1 is the lowest grade,3 is the highest one.

(3) ECG wave speed

Select "Wave Speed",select " "or " " to change the ECG wave speed.wave speed is setted for

three grades,1 is the lowest grade,3 is the highest one.


(4) Auto poweroff

Select "Auto Poweroff",press " "or " " to select,"ON" to open it,"OFF" to close it.
The time of Auto Poweroff is setted twenty minutes for no operation.

(5)Version

The "Version" describes the device's hard and soft version,this menu can't be selected.

5.2.6 Demo Interface

Choose "Demo" and select the required monitor interface:ECG,SpO₂,press " "to enter the corresponding interface;choose "Exit"to quit demo.

5.2.7 Exit

Move the selection bar to"Exit",press "OK" to exit the interface.

5.3 Alarm Operation

5.3.1 Alarm PRI

Alarm including the alarm of measure data's going beyond the limits,the alarm of low-voltage,the alarm of finger's out of position.

Alarm PRI:the alarm of low-voltage> the alarm of finger's out of position= the alarm of measure data's going beyond the limits.

5.3.2 Alarm Recognised Methods

(1) Low voltage alarm:battery power is draining away and flashing incessantly.When the battery

power is not enough for supplying the apparatus normal work,the screen shows "Low Power" and turn off automatically;

(2) Finger out alarm:sound alarm and at the same time the screen shows "Finger Out";

(3) Except for above sound alarm,the others are considered as the tested value exceed the limit alarm.

5.4 Charging Operation

There are two kinds of charging methods:

(1) Connect the device with computer by data line,the indication light is on— then the device should be under charging state.

(2) Connect one end of the adapter to power socket,the other end to the device by data line.

The indicator prompts:The indicator shows orange in charging state and shows green when the charge has finished.

NOTICE:

To ensure measure exactly,when the battery power is low, the battery should be charged.

Chapter6 Software Operating Guide

STH_Sync is mainly used with this device produced by our company. And it can analyze ECG data and SpO₂ data of case, and show and print it. STH_Sync can be used to do daily check of ECG and SpO₂ by common family, and it can also be used to general check for common patient by doctors of hospitals. It can support reference for doctors, but can not be used for diagnosis.

6.1 Install and Start

6.1.1 System Configuration Required:

CPU: Pentium PIV, above2.0G

Memory: above 128M

Main board: support USB2.0, main board having Intel chips group is recommended.

Hard disk: 10G or above

Display chip: with more than 16M memory.

Printer: 600dpi laser printer

Display: above 15 inch

CD ROM: CD-ROM with 24 times speed or above (or CD memory System)

Operating System: Microsoft Windows 2000/xp/vista/7 (Windows xp is recommend)

Resolution: above 1024*768

Color: 24 bit color or above

Font: normal font

Printer: 300dpi or above

Interface: USB2.0

The setting can be modified at display attribute in Windows operating system. If you have any question of modifying the system setting, you can refer to the help of Windows operating system.

6.1.2 Software Installation

First, put the CD of STH_Sync into the CD-ROM. Then run STH_Sync_EN_V1.2.exe. (Fig.6-1)

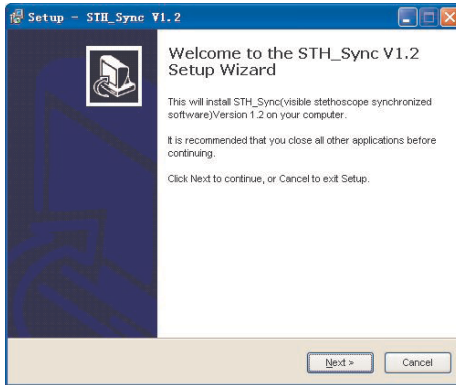


Fig.6-1

Press button “Next”, and dialog as shown in Fig.6-2 will be popped up.

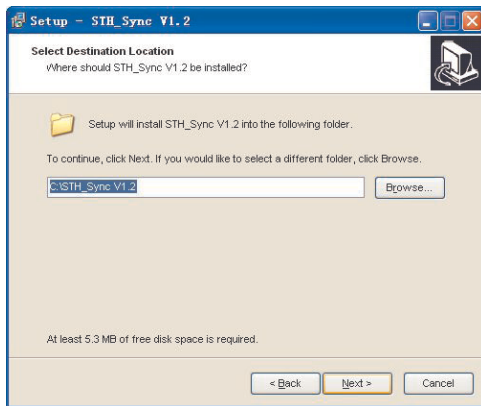


Fig.6-2

Press button "Browse" to select the destination folder you wish to install. We suggest don't select C disk(or system disk) to avoid so many documents on the system disk that affect the speed of the system.

After installation completed, the dialog box will appear as shown in Fig.6-3, click "Finish" to complete the installation.

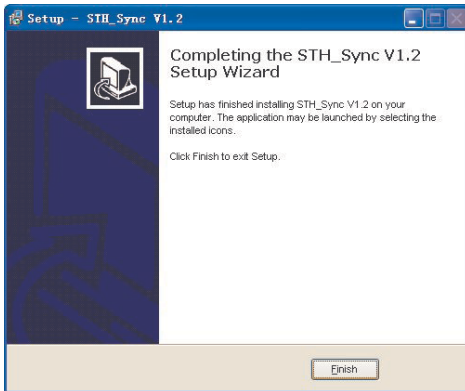


Fig.6-3

After installation finished, please set the system configuration of your computer as above-mentioned. Restart the computer.

6.1.3 Install Driver

After installing the software, connect Device and computer host by USB line. And computer will prompt finding new hardware. (Fig.6-4):



Fig.6-4

Select "No, not this time", and click "Next" button (Fig.6-5):

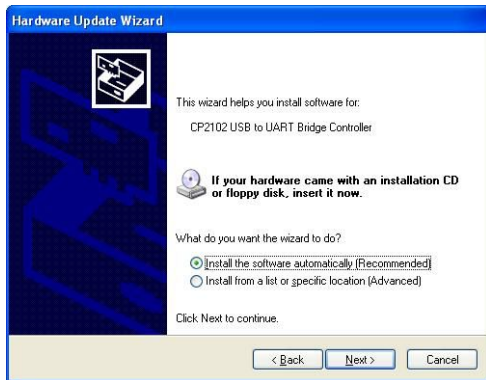


Fig.6-5

Choose "Install the software automatically", then click "Next" button to install the driver. In the proceeding of installation, there will be dialog as following. Choose "Continue Anyway". (Fig.6-6).



Fig.6-6

When the installation finished, please click “Finish”(Fig.6-7)




Fig.6-7



When the installing guide is popped up again, please be reassurance. It doesn't mean the first installing is unsuccessful, but may shows there are other hardwares in the sampling case need installing.

6.1.4 Startup the Software

First, make sure that you have installed the hardware driver of the Device. Distinguish rate needs setting as 1024*768, and the font of Windows appearance needs setting normal.

Double click  icon on the desktop, and the STH_SyncV1.2 is started. You can access to the interface shown as Fig.6-8.

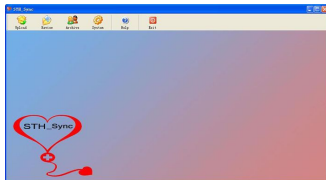


Fig.6-8

If you first use the software ,you should set the edition of the Device .How to set the edition of the Device,Please refer to "**sampling setting**".

There are “Upload”,“Review”,“Archive”,“System Settings”,“Help” and “Exit” buttons in toolbar. Now I will introduce the characteristics of these features to you briefly.

The "Upload" allows you to enter the patient information interface before uploading, and start

the data upload interface, and receive case data from Device, and display wave data dynamically. "Review" can help you to view data and information of case saved, and modify case information and print report.

You can not only use the "Database Management" to find, edit, delete, update etc database operation, but also to review the case.

The "System Settings" provides you with a series of humanized options. By simple set, you can use and operate the software with the way you need or familiar.

"Help" provides the help system of this software.

"Exit": Exit and close this system.

Well, so much introduction of the main interface. Let's begin to learn how to operate the software and the use of each item of the software.

6.2 Uninstall the Software

Choose "start"-> "program"-> "STH_Sync V1.2", and then click "Uninstall STH_Sync V1.2"; or run "Uninstaller.exe" in the installation list. Then dialog will be popped up. (Fig.6-9)

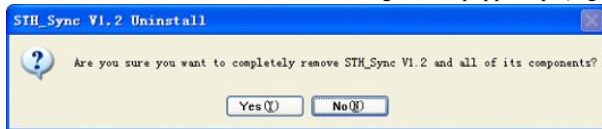


Fig.6-9

Click "Enter" button, and the program will delete all components. Then the dialog as Fig.6-10

will be shown up, click "OK" to complete uninstall.




Fig.6-10

6.3 Operating Guide

6.3.1 Upload

You can use our product after installing the software and hardware, know how to operate it. And then you can upload data.

6.3.1.1 Input New Patient Information

Before Press the "Upload"  button,you must make sure to set the edition of the Device. The dialog of "Patient Information" will be shown. (Fig.6-11)

The image shows a software dialog box with a blue title bar that reads "Please input case information" and a close button (X) in the top right corner. The dialog box has a light beige background and contains the following fields and controls:

- Name:** A text input field.
- Sex:** A dropdown menu currently showing "Male".
- Height:** A text input field followed by the unit "cm".
- Tel.:** A text input field.
- Age:** A text input field.
- Weight:** A text input field followed by the unit "kg".
- Case NO.:** A text input field.
- Phy:** A dropdown menu.
- Device:** A dropdown menu currently showing "Without Blue".
- Address:** A large text input area.
- Remark:** A large text input area.
- Buttons:** Two buttons at the bottom, labeled "ok" and "cancel".

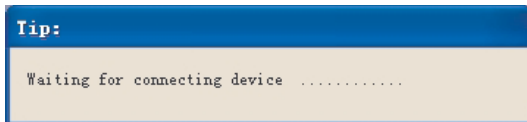
Fig.6-11

You can input patient information in this dialog, which will make it convenient to manage and inquiry the case. You can also input the items you want, or input nothing, and enter the uploading module directly. Some important information associated with the printing, which will print in the table header. After you fill out, click "OK" button, and you can enter the uploading interface.

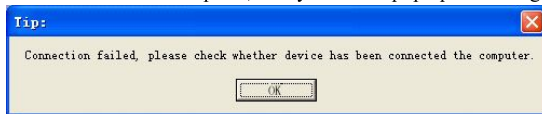
Note: After the start of the upload, you can not maximize or minimize. Please set it in advance.

6.3.1.2 Tips and the Corresponding Operation

Fill out the information and click "OK", If the version of the Device is With Blueth, the system will enter the state of wait for connecting thedevice, the system will pop up the dialog box as follows:



If the Device has not connected the computer, the system will pop up the dialog box as follows:



If the Device has been connected the computer, the system will enter the state of wait for uploading, as shown in Fig.6-12, If the version of the Device is Without Blueth, the system will directly enter the state of wait for uploading, as shown in Fig.6-12:

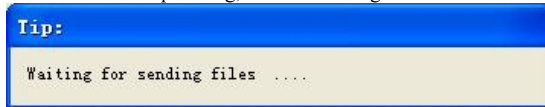


Fig.6-12

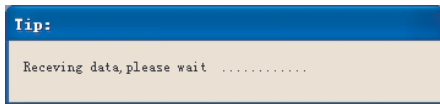
At this point you should operate the stethoscope to upload the files of case history as soon as possible.

- If you do not have time to upload files during the process of waiting, the system will pop up the dialog box as shown in Fig.6-13 in the end.



Fig.6-13

- If you had done the uploading operation during the process of waiting, but it still pop-up dialog box shown as Fig.6-13, then you should check whether the connect line between equipment and the computer is correct, after checked, you can try to reconnect the device, and then operate it according to the above introduction.
- If the version of the Device is Without Blueth and the connection is successful, system will directly enter the uploading interface, as shown in Fig.6-14 (ECG cases) and Fig.6-15 (SpO₂cases).
- If the version of the Device is With Blueth, the system will pop up the dialog box as follows. Finish rececing data, system will directly enter the uploading interface, as shown in Fig.6-16 (ECG cases) and Fig.6-17 (SpO₂cases)



6.3.1.3 The Process of Data Upload

1. ECG data upload interface is as shown in Fig.6-14:

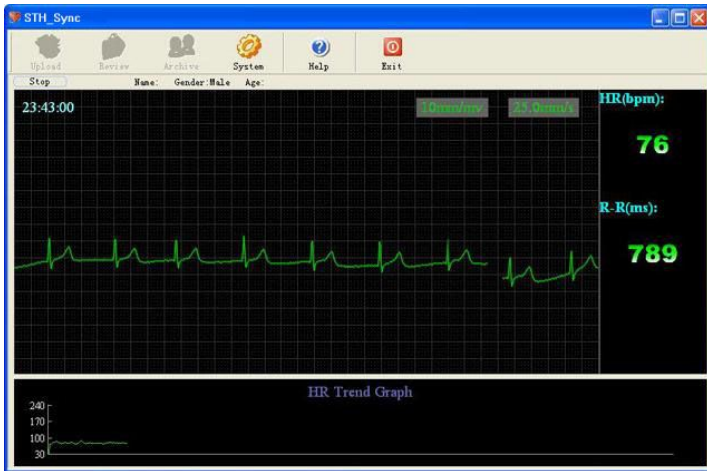


Fig.6-14

2. SpO₂ data upload interface is as shown in Fig.6-15.

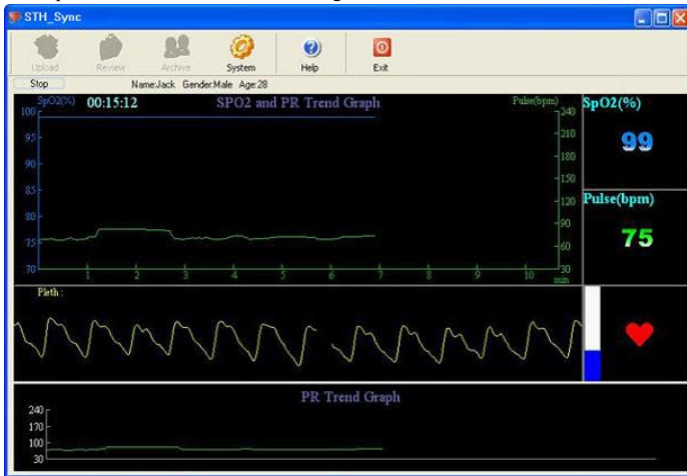


Fig.6-15

3. Operations in uploading

1) System setting

Function:

- ◆ If there's much noise in the wave, you can set "Filter Settings" in "Sample Setting" to get calm and clear ECG.
- If there's much noise when sampling, you are supposed to select "PF Filter" in "Sample Setting".
- Keep off interference, refer to "Filter Settings" to solve noise and baseline drift.
- If myoelectrical noise is serious you can select "myoelectrical Filter".
- ◆ You can use the "Alarm Settings" to set the scope of heart rate, when alarm the font will become red.

2) Stop

Function: Stop the ongoing data uploading.

Gain and speed



Function: You can adjust the waveform gain and walking speed.

Amplitude: 5mm/mv ,10mm/mv ,20mm/mv

Velocity: 12.5mm/s ,25mm/s ,50mm/s

Note: After uploading, the computer and devices can be disconnected.

6.4 Review

You can review the local case info and print report by this function.

The main interface of "Review" is shown as Fig.6-16(ECG Case) or Fig.6-17(SpO₂ Case).



Fig.6-16

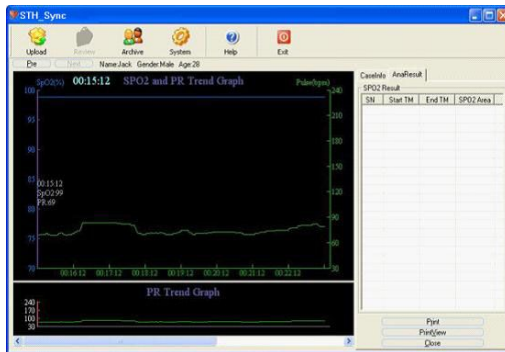


Fig.6-17

Function:

1. Waveform and Trend graph Display:

The display modes can be divided into two by case type.

- ◆ ECG Case: It shows the ECG wave and the heart rate trend graph (Fig.6-15). The red vertical line in heart rate trend graph, which is as shown in Fig.6-15, shows the current enabled QRS wave (The QRS wave which is shown by two vertical lines in ECG wave). You can select the QRS wave by clicking left button of mouse in heart

rate trend graph, or by using "←" or "→" in keyboard.



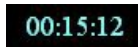
Means the start time of current screen wave;



The gain and speed of ECG wave buttons. You can

change the gain and the speed of ECG wave by clicking the buttons.

- ◆ SpO₂ Case: Shows SpO₂ and PR Trend (Fig.6-17)



Means the start time of current screen wave;

As Fig.6-16 shows, the white horizontal line in "SpO₂ and PR trend " is the identifier of desaturation event. And the dashed shows the enabled desaturation event. As to the display of desaturation event, we will introduce it in "Event Statistics".

2. Query Case Info

Enter your conditions in the "Query Condition" column and then press the "Search" button, all cases that meet the conditions will be displayed in the table. You can query by name, sex, age, sample type, case NO., date and remark. The name and the remark support fuzzy query, which

means you just need to input one of the characters, all eligible cases will be listed.

3. Modify Case Info

First, click the case you want to modify in the case table, and then the case info will be displayed in the "Case Info" column below. You can modify the name, gender, age, case ID or remark of patients' here. Click the button "save" to save the case info.

4. Quickly Switch Case


You can quickly open the case you want to review by clicking the button "Pre" or "Next" if there are multiple cases in the case table. Or just double-click the case by left key to do this.

5. Event Statistics

The SpO₂ events table shows the desaturation event of the current case(Fig.6-16). If you click an event in the SpO₂ events table, it will be marked with white dotted line in the SpO₂ and PR Trend Graph. Also, if you click an event in the SpO₂ and PR Trend Graph, the event will be marked in the SpO₂ events table.

Note: Event statistics is only for cases of SpO₂.

6.5 Archive Management

Press the button  in the toolbar above,the interface is as Fig.6-18:

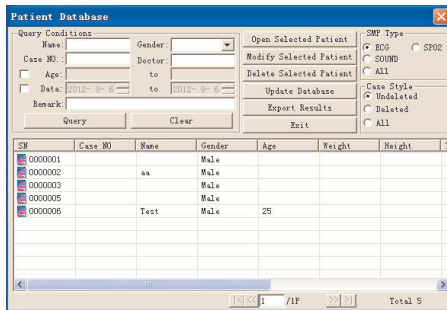


Fig.6-18

This function offers you a way to save every patient's data automatically, and archive management allows you to view patient info and modify, delete or query patient info according compound condition, and query results can be exported to the excel table.

In the area where the history cases are shown, we list the recent 100 cases in order for convenience and shortcut looking up. User can change the page by press the button at the underside.

See case information, and change case style to display.

The icons displayed in front of the cases indicate the type of the cases:



An icon indicates that the case has only ECG case file or Sound case file;



An icon indicates that the case has only SpO₂ case file;



An icon indicates the case has been deleted;

You can double click the case items in the table to view them.

Function:

◆ **Query:** Enter your conditions and then press the "Query" button, all cases that meet the conditions will be displayed in the table. You can view the case ID, and the age, name, sex, and date of examination of patients' and so on.

◆ **Clear query conditions:** Clear all previously entered conditions.

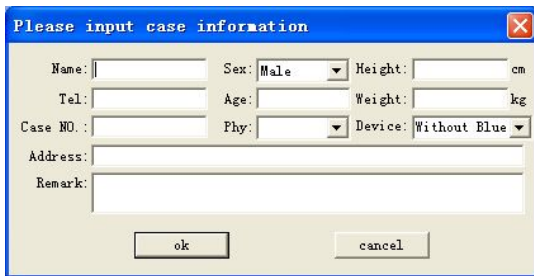
◆ **View a case:** Select the case you want to view, and press "Open Selected Patient" button, then you can view the waveform of the case. Or just double click this case item in the table to do all these things.

◆ **Delete current case:** Select the cases that you want to delete, and then press "Delete Selected Patient" button.

Notice: The cases can't be recovered once you deleted, but the patient information will be kept with a deleted flag in database.

◆ **Case Style:** "ECG" indicates ECG sampling mode, "SpO₂" shows SpO₂ sampling mode, and "ECG&SpO₂" means both ECG sampling mode and SpO₂ sampling mode.

- ◆ **Case type:** You can choose whether the table display the deleted cases or not, or display all the cases.
- ◆ **Modify patient information of current case:** Select the case, of which you want to modify the patient information. Then press the button of "Modify Selected Patient". After modification, click "OK" button, as shown in Fig.6-19.



The image shows a dialog box titled "Please input case information" with a blue title bar and a close button (X) in the top right corner. The dialog contains several input fields and dropdown menus:

- Name: [text input]
- Sex: [dropdown menu, currently set to "Male"]
- Height: [text input] cm
- Tel: [text input]
- Age: [text input]
- Weight: [text input] kg
- Case NO.: [text input]
- Phy: [dropdown menu]
- Device: [dropdown menu, currently set to "Without Blue"]
- Address: [text input]
- Remark: [text input]

At the bottom of the dialog, there are two buttons: "ok" and "cancel".

Fig.6-19

- ◆ **Update the Database:** Resume database files or some other operations may cause the actual database files and the actual case records not matched. Click "update database" button, and it can help you check the database information, and match the database of case records and

documents to show the correct query results.

◆ **Export results:** You can export the query results to excel file by clicking the button "Export results". The system pops up the following dialog (Fig.6-20). You should select the export path and the excel file name and then click the button "Save".

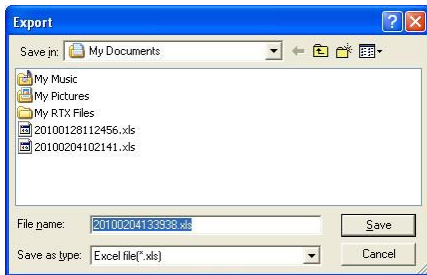



Fig.6-20

6.6 System Setting

Press the system setting button  in the toolbar above, the interface is as Fig.6-21.

Function:

◆ The interface of hospital is as Fig.6-21. You can set the name, phone, fax and address of

hospital in Hospital property page, and hospital name will be displayed in print report.

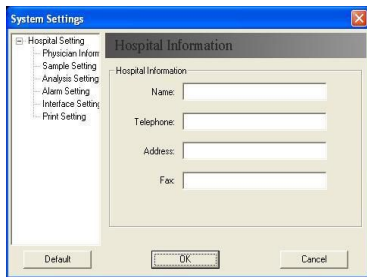


Fig.6-21

◆ The doctor interface is as Fig.6-22.

You can set the name, telephone and address of doctors in this interface. You can input and record 10 doctor names at most, and it relates with the diagnosis doctor item of input case dialog box.

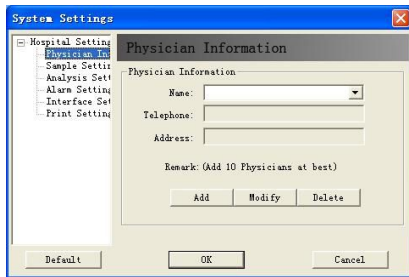


Fig.6-22

- ◆ In the "**sampling setting**" (Fig.6-23), you can set the power frequency filter parameters, EMG Filter, Base Line Filter ,Device Type and so on.

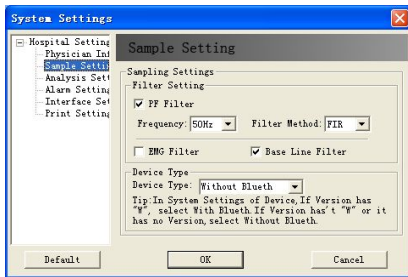


Fig.6-23

Set the power frequency filter parameters. The "Frequency" item must be set to the power frequency of your country or region. And it is 50 Hz in China. If "Base Line Filter" and "EMG Filter" are selected, the ECG wave will be better, but at the same time they will affect the ECG signal to some extent. So we propose to choose them cautiously.

Set the device version. The "Device Type" item must be set to the version of your device. And the default version is "Without Blueth".

The choices you set will be applied to actual sampling automatically and regarded as the default, but it does not mean that we can't change the settings during sampling. You can also change

them manually before or after sampling.

- ◆ "Analysis Setting" includes SpO₂ analysis setting and heart rate analysis setting (Fig.6-24).

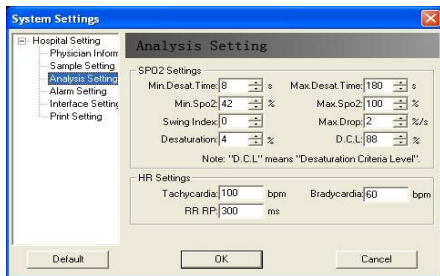


Fig.6-24

During the process of uploading, the system analyzes according to the chosen channel. The analyzing channel can also be modified at any time.

- ◆ The interface of "Alarm Setting" is as Fig.6-25. The alarm items include heart rate, pulse rate and SpO₂.

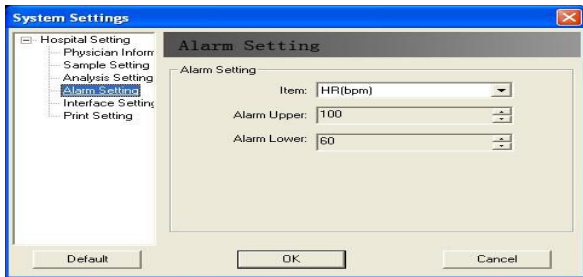


Fig.6-25

When the alarm conditions are met during uploading, it begins to alarm. And the font color of heart rate, pulse rate, SpO2 and RR distance will turn red.

- ◆ **"Interface Setting"** includes language setting and smooth line setting.(Fig.6-26):

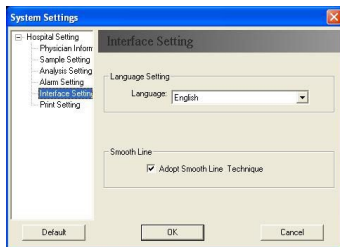


Fig.6-26

"Language setting" provides multi-language displaying.

If you choose "Adopt Smooth Line Technique" of "Smooth Line", then the ECG wave will become more smooth (Fig.6-27,6-28).



Fig.6-27 Adopt Smooth Line Technique

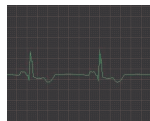


Fig.6-28 Not Adopt Smooth Line Technique

- ◆ In "**Print Setting**", you can choose the paper type(A4 or B5), printing arrangement style, and ECG print type.(Fig.6-29)

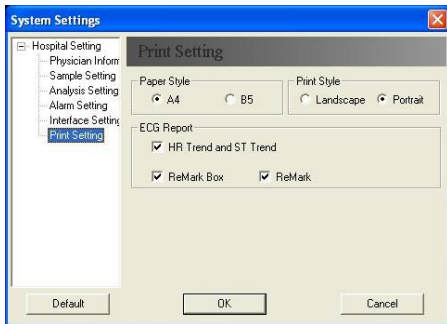


Fig.6-29

6.7 Help



Run the help system of this software.

6.8 Exit










Exit and shut down this software.

Chapter7 Cleaning Disinfecting and Maintenance

7.1 Cleaning

Keep the outside surface of the device clean and free of dust and dirt, and clean exterior surface of the device (including LCD screen) with a dry, soft cloth. If necessary, clean the chassis with a soft cloth soaked in a solution of soap or water, and wipe dry with a clean cloth immediately.


Attention:


-  Before cleaning, switch off the power.
-  Don't use the strong solvent, such as acetone.
-  Never use an abrasive such as steel wool or metal polish.
-  The temperature of the water which is used for cleaning the device should be below 60°C.
-  Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.
-  Avoid pouring liquids on the device while cleaning.
-  Don't remain any cleaning solution on the surface of the device.

7.2 Disinfecting

After cleaning the device, wipe the surface of device with ethanol, self-air dry (or clean with a clean, dry cloth).

Attention:

 Never try to sterilize the equipment by low pressure steam or high temperature sterilizing process.

 Do not use E-beam or gamma radiation sterilization or other methods.

7.3 Maintenance

The user must check that the equipment does not have visible evidence of damage that may affect patient safety or device capability before using. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before using.

Please put the device lightly as it is precise electronic equipment. Taking the following methods to maintain it can prolong the life of the unit.

(1) Please recharge the battery when the battery power shows shortage.

(2) Recharge the battery soon after the over-discharge. The device should be recharged every six months when it is no regular used. It can extend the battery life following this guidance.

(3) Please clean and disinfect the device before using according to the user manual.

(4) Please clean and disinfect the device after using to avoid infection.

(5) The device needs to be calibrated once a year (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

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

Attention:














The device should be maintained by the eligible engineers who have been accredited by our company.



If the device is not used for a long time, please put it in the casing after cleaning and disinfecting.

Chapter8 Symbol Meanings

Symbol	Meanings
%SpO ₂	Pulse oxygen saturation(%)
PR	Pulse rate (bpm)
HR	Heart rate (bpm)
	Full-voltage
	Battery sign,it indicates the voltage is lack when flickering.
	Alarm-sound "off"
	Alarm-sound "on"
	Close the pulse sound indication
	Open the pulse sound indication

SN	Serial number
 and 	Waiting for measuring data
IPX1	Ingress of liquids rank
	Warning
	WEEE (2002/96/EC)
	Attention, consult ACCOMPANYING DOCUMENTS

Chapter9 Trouble Shooting

Trouble	Possible Reason	Solution
1.The SpO₂ and Pulse Rate can not be displayed normally	<ol style="list-style-type: none">1. The finger is not properly positioned.2. The patient's SpO₂ value's going beyond the limits.	<ol style="list-style-type: none">1. Place the finger properly and try again.2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
2.The SpO₂ and Pulse Rate are not displayed stably	<ol style="list-style-type: none">1. The finger is not placed inside deep enough.2. The finger is shaking or the patient is moving.	<ol style="list-style-type: none">1. Place the finger properly and try again.2. Let the patient keep still.
3.ECG display astatically	<ol style="list-style-type: none">1. Electrodes do not connect with skin very well.2. The device is shaking.3. The patient is shaking or moving.	<ol style="list-style-type: none">1. Recoat gel and press electrodes.2. Keep the device on the body still.3. Keep the patient in a stable state.

<p>4.The device can not be turned on</p>	<p>1. The battery is drained away or almost drained away. 2. The malfunction of the device.</p>	<p>1. Recharge battery. 2. Please contact the local service center.</p>
<p>5.Noise</p>	<p>Here is disturbance sources.</p>	<p>Remove the disturbance sources and other electrical instruments.</p>
<p>6.The device can not be used for full time after charge or the battery can not be full charged even after 10 hours charging time.</p>	<p>The battery is broken.</p>	<p>Please contact the local service center.</p>

<p>7. Software interface shows insufficiency</p>	<p>The monitor did not be conduct appropriate settings.</p>	<p>In accordance with the specification requirements will be adjusted to monitor resolution 1024 * 768 and above.</p>
<p>8. Print failure or incorrect reporting format</p>	<p>1. Computer has not connected printer or has not installed printer driver correctly. 2. Printers did not be conduct appropriate settings.</p>	<p>Please let professional and technical personnel to reinstall printers, and printers will set to 600 dpi in accordance with the specification requirements of precision</p>

<p>9.Connect equipment failure</p>	<ol style="list-style-type: none"> 1.After the last use of software, did not normally close 2.The computer is from sleep in the recovery, dormant state will cut off all equipment and computer to connect the power 3.Data lines damaged 4.Acquisition device driver was not installed correctly 	<ol style="list-style-type: none"> 1.Device will be re-connected with the computer and restart the software. 2.Inspection and replacement of data lines 3.According to specification content reinstalled the hardware
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Note:



If the trouble is still not got rid of, please contact warrant service agent as soon as possible.



For the damage aroused by client dismantling and mending, our company does not assume any responsibility.

