CE 0123

NT1D Vital Signs Monitor

Operating Manual

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Preface

This operation manual introduces the monitor's performance, way of operation and others safety information and so on. This is the best start for new user to use the monitor. This manual is intended for readers who are family with contacting various measurement and who have experience in operating monitoring equipment.

Monitor's features:

- Combines a capnograph and pulse oximeter in a small, portable, lightweight monitor.
- Measures and displays SpO_2 in one graphic and one digital displays.
- Measures and displays pulse rate one digital displays.
- Measures and displays $EtCO_2$ in one graphic and one digital displays.
- Measures and displays respiration rate one digital displays.
- Displays CO_2 and SpO_2 waveforms and trends in one interface
- Employs audible and visual alarm warnings for monitored parameters and instrument malfunctions.
- Displays current trend line and trend table.
- Displays table of alarm events.
- Stores history data.
- Provides user selectable language options: English and Chinese.
- Uses internal batteries pack to supply power.
- Provides external power supply.
- Transfers history data wireless.
- Equips with wireless USB adapter and PC software.

The monitor is intended for monitoring adult, pediatric, and neonatal patients in clinical environments where healthcare is provided by healthcare professionals, i.e. doctors, nurse, or technicians.

NOTE

- This manual includes the maximal configuration. The monitor you use may have not some functions.
- Federal Law in the United States restricts this device to sale, distribution and use by or on the order of a physician.

Symbols

The following symbols appear on the monitor:

Symbols	Description
	Attention! Consult the accompanying document (This manual)）
	BF Type Defibrillation
	Complies with the European Medical Device Directive 93/42/EEC
	Disposal requirement
	Manufacturer date
	Manufacturer
	Serial number
	Static sensitivity mark!
IPX1	Drip proof
R_X ONLY	Prescriptive device, operated by qualified personnel only!

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CONTACT

Address:	R1-B1, Hi-Tech Park, NanShan District, Shenzhen, Guangdong 518057 P.R. China
Postcode:	518057
Tel:	86-755-26525910
Fax:	86-755-26525912
Web cite:	Http://www.sznewtech.com
E-mail:	sales@sznewtech.com

Authorised Representative

Name:	Shanghai International Holding Corp. GmbH（Europe）
Address:	Eiffestrasse 80, 20537 Hamburg Germany
Tel:	0049 – 40 – 2513175
FAX:	0049 – 40 – 255726

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1.Safety

1.1 Safety Information

This chapter lists warnings, attentions, and basic safety information when using NT1D Vital Signs Monitor. Similar or related and other safety information can be found in appropriate chapters.
Important! To use the monitor correctly and safely, carefully read this operator's manual. Use of the monitor requires full understanding and strict observance of these instructions, the precautionary information in boldface type, and the specifications.

- "Warning": Indicates a potentially harmful condition that can lead to personal injury.
- "Caution": Indicates a condition that may lead to equipment damage or malfunction.
- "Note": A point of particular interest or emphasis intended to provide more effective or convenient.

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⚠ WARNINGS

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- To protect against electric shock hazard, the monitor's cover is to be removed only by qualified service personnel. There are no user-serviceable parts inside.
- The monitor is a prescription device and is to be operated by qualified healthcare personnel only.
- The exact time and date of the table of events depends on the precision of time and date what you have set in the monitor, when alarms happened.
- The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide. Use of SpO_2 and CO_2 Sensor in such environment may present an explosion hazard.
- Sucking the chemic matter came from cracked LCD display will cause poisoning. Please take yourself carefully when the monitor's display was broken.
- Please check the patient periodically, insure the monitor runs well and place SpO_2 sensor and CO_2 sensor rightly.
- CO_2 readings, respiratory rate, pulse oximetry readings, and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.
- The use of accessories, transducers, sensors and cables other than those specified may result in increased emission and/or decreased immunity of the equipment and/or system.
- DO NOT silence the audible alarm if patient safety may be compromised.
- Mark sure that the speaker and speaker's pore are not covered by any slipcover; otherwise the alarm maybe can not be heard.
- Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.
- Before each use, verify that the alarm limits are appropriate for the patient being monitored.
- To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.
- The SpO_2 sensor must be moved to a new site at least every 4 hours. Because individual skin condition affects the ability of the skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.
- DO NOT use oximetry sensors during magnetic resonance imaging (MRI) scanning. Conducted current could cause burns. The sensors may affect the MRI image and the MRI unit may affect the accuracy of oximetry measurements.
- Monitor has no defibrillation synchronization, so it cannot be connected to defibrillation

instruments.

- Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
- To ensure patient electrical isolation, connect only to other equipment with circuits that are electrically isolated.
- If uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.
- The danger of losing data: this monitor can save current patient's data only when it is shut down normally or in low voltage, therefore:

  1）when using internal power supply, only allow to shut down the monitor normally or in low voltage. Do not take batteries down abruptly when the monitor is working or in the progress of shutting down. To do this can avoid losing data.

  2）when using external AC adapter or the pedestal to supply power, if there are four Ni-MH batteries, you can take batteries down when the monitor is working or in the progress of shutting down. If there aren't batteries, you can only pull the adapter out or break the pedestal away only after monitor shut down normally, you can not pull the adapter out or break the pedestal away when it is working. To do this can avoid losing data.

- Using SpO_2 sensor incorrectly may do harm to patient's skin. Please check whether the SpO_2 sensor is placed following the instructional way and position.
- DO NOT use NIBP or other constructing instruments on same appendage as sensor as blood flow interrupted by NIBP cuff or circulatory patient condition will result in no pulse found or loss of pulse.
- DO NOT alter or modify SpO_2 and CO_2 sensor. Alterations or modifications may affect performance or accuracy.
- Using the SpO_2 sensor in the presence of bright lights may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
- DO NOT use SpO_2 and CO_2 sensor if the sensor or the sensor cable appears damaged.
- DO NOT lift the monitor by the SpO_2 sensor or CO_2 sensor cable as they could disconnect from the monitor, causing the monitor to fall on the patient.
- To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.
- Carefully route patient cabling (SpO_2 sensor and CO_2 sensor) to reduce the possibility of patient entanglement or strangulation.
- Be sure to follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.
- Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2 airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.
- If the SpO_2 and CO_2 Sensor fails to respond as described in this user guide; DO NOT use it until approved for use by qualified personnel.
- The CO_2 Sensor is not patient isolated. Use of the sensor does not require direct patient contact. If isolation is desired or required, it is the responsibility of the Host system to provide the necessary isolation.
- This monitor's electrical isolation part is centralized in the AC adapter. When using external power supply or charging the batteries, please use only the medical grade AC adapter provided by the manufacturer. If in doubt about the integrity of the mains supply connection, operate the monitor from its internal battery pack.

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- The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Please do not repeat to use one-off accessories.
- Do not use SpO_2 and CO_2 sensor across between epidemical and unepidemical patients before sterilized.
- Do not connect the host monitor, sensor, AC adapter and pedestal to any other equipment mutually.

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CAUTIONS

- All equipment connected to the monitor must conform to EN60601-1.
- Use only approved sensors, pulse oximetry and CO_2 cables. Other sensors or oximetry cables may cause improper monitor performance.

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NOTE

- Changes and modifications not expressly approved by the manufacturer responsible for compliance could void the user's authority to operate the equipment.
- Ambient light, movement, electromagnetic interference, artifacts, dysfunctional hemoglobin, and certain dyes, etc may be interfere in the pulse oximeter's function.
- Do not sterilize by irradiation steam, or ethylene oxide.

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1.2 Product Label

Figure1-1: Product label

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2.Introduction

2.1 Product Introduction

NT1D is a portable handheld vital signs monitor that continuously monitors end tidal carbon dioxide ($EtCO_2$), respiratory rate (RR), oxygen saturation (SpO_2), and pulse rate. The unit is indicated for monitoring only and must be used in the continuous presence of a qualified healthcare provider, and transfer history data to PC through USB adapter. It is intended for use in any environment where continuous, noninvasive monitoring of these parameters is desired, including hospital and hospital type facilities. The monitor is intended for use on adult, pediatric, and neonatal patients.
Our product is composed of host monitor, SpO_2 sensor, mainstream CO_2 sensor, pedestal, wireless USB adapter and PC software.
Our product has input and output ports:
Input: SpO_2 sensor port, CO_2 sensor port;
Output: Sends data to USB adapter wirelessly.

NOTE

- Using the monitor in excessive movement will affect the accuracy of saturation measurements

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2.2 Monitor Features

- Combines a capnograph and pulse oximeter in a small, portable, lightweight monitor.
- Measures and displays SpO_2 in one graphic and one digital display.
- Measures and displays pulse rate one digital displays.
- Measures and displays $EtCO_2$ in one graphic and one digital display.
- Measures and displays respiration rate one digital displays.
- Displays CO_2 and SpO_2 waveforms and trends in one interface
- Employs audible and visual alarm warnings for monitored parameters and instrument malfunctions.
- Displays current trend line and trend table.
- Displays table of alarm events.
- Stores history data.
- Provides user selectable language options: English and Chinese.
- Uses internal batteries pack to supply power.
- Provides external power supply.
- Transfers history data wireless.
- Equips with wireless USB adapter and PC software.

2.3 Basic Principles of Operation

- SpO_2 principles of operation

Pulse oximetry is based on two principles: 1) oxyhemoglobin and deoxyhemoglobin, which differ in their absorption of red and infrared light (spectrophotometry), and 2) changes in the volume of arterial blood in tissue during the pulse cycle (plethysmography), and hence, light absorption by that blood. A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and

measures changes in light absorption during the pulsatile cycle. Red and infrared low power lightemitting diodes (LEDs) in the oximetry sensor serve as light sources; a photodiode serves as the photodetector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of *arterial* hemoglobin, the monitor uses the pulsatile nature of arterial flow.
During systole, a new pulse of arterial blood enters the vascular bed and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point.
The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). The focus of light absorption by pulsatile arterial blood eliminates the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

- CO_2 principles of operation

The CO_2 Sensor is used for the continuous measurement of CO_2 and respiratory rate. The sensor measures CO_2 by using the infrared absorption technique. The principle is based on the fact that CO_2 molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR beam is passed through a gas sample containing CO_2, the electronic signal from the photo detector (which measures the remaining light energy) is measured. This signal is then compared to the energy of the IR source and adjusted to accurately reflect CO_2 concentration in the sample. The CO_2 Sensor's response to a known concentration of CO_2 is stored at the factory in the sensor's memory. A reference channel accounts for optical changes in the sensor, allowing the system to remain in calibration without user intervention.

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- Host monitor's principles of operation

Patient's signal is checked and magnified through various sensors and then transported to parameter module to disposal data by extended cable, and then communicate with host monitor's control board to show the measuring result. The results will be shown on the screen in the form of waveform and figure. It can save every parameter for 99 patients, 72 hours per capita, and can transfer data to PC wirelessly.

⚠ WARNINGS

- Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, probe application errors, and certain patient conditions.

Specific information about ambient environmental conditions, probe application, and patient conditions, is contained throughout this manual.

2.4 Terms' Explanations

SpO_2	Oxygen saturation value	PR	Pulse Rate
Pleth	Blood dimension	$EtCO_2$	End tidal carbon dioxide value
RR	Respiration rate		

3. Unpacking and Installation

3.1 Unpacking

Open the package according to the marks on the box. Carefully remove the monitor and its accessories.

- Count the accessories according to the packing list.
- Check the monitor and accessories for any physical damage.

If there are any problems, contact the distributor immediately.

Friendly reminder: The packaging material should be saved for future transportation and storage.

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WARNINGS

- Customers should put the wrappers somewhere that child couldn't touch. When disposaling the wrappers, you should follow local governing ordinances or hospital instructions.
- The equipment may be polluted by microorganism when deposit and transportation. Please check the packaging before using. Do not use it if it is damaged.

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This monitor is equipped with Ni-MH rechargeable Batteries as well as alkaline batteries. When using Ni-MH Batteries, we can use external AC adapter or the pedestal to charge to the host monitor. But when using alkaline batteries, we can not use external AC adapter or the pedestal to charge to the host monitor.

WARNINGS

- Never operate the device without the battery cover in place.
- This monitor only sustain "AA" size Ni-MH Batteries and alkaline batteries，do not use any type of batteries that have no admission.
- when using alkaline batteries，do not use external AC adapter or the pedestal to charge to the host monitor.
- DO NOT use Ni-MH Batteries and alkaline batteries together！

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- Ni-MH Batteries' handling
  - Do not immerse the battery pack in water; it may malfunction.
  - Only recharge the battery pack in the monitor, provided by your local representative, to avoid possible overheating, burning or rupture of the battery pack.
- Ni-MH Batteries' storage
  - Short-term storage (one month or less): The battery pack has an automatic discharge feature. You must periodically check the charge level of the battery pack.
  - Long-term storage (6 months or more): The battery pack must be stored in a cool, dry area. Its charge decreases over time. To restore the battery pack to full power, charge and discharge it three times before use. Long-term storage, without charging the battery, may degrade the battery capacity.

- Ni-MH Batteries' disposal

  • Do not dispose of the battery pack in fire; it may explode.

  • Be sure to follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.

⚠ WARNINGS

- The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- When using alkaline batteries, do not charge them.
- To ensure patient electrical isolation, connect only to appointed AC adapter with circuits that are electrically isolated. Do not use unauthorized AC adapter.
- To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.
- If the batteries happen to leak liquid, break the external safeguard or run out of charge, please stop using these batteries and follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.
- Carefully route cables to reduce the possibility of patient entanglement or strangulation
- To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.
- DO NOT use Ni-MH batteries and alkaline batteries together. When exchanging batteries, you should replace all depleted batteries by fresh ones.
- Please use accompanying batteries only!

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NOTE

- Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the monitor may occur.
- Insert the (-) terminal of each battery first, compressing the battery terminal spring until the (+) terminal clears the positive spring, and pressing the battery downward into place.
- To remove the batteries, reverse the installation process, removing the positive end of each battery first.
- To avoid corrosion of the contacts, remove batteries from the battery compartment, if you do not intend to use the monitor for an extended period of time.

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3.2 Installing Pedestal

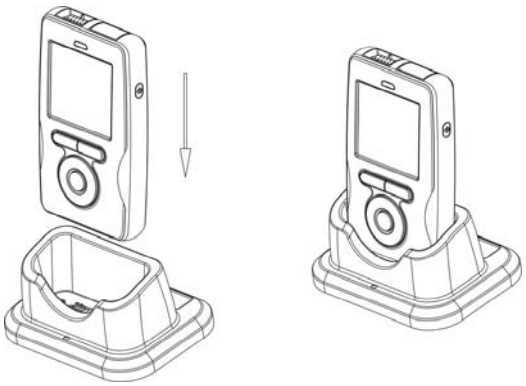

Figure: 3-1 Install pedestal

1. Plug the AC adapter into the faucet of the pedestal, as shown in Figure 3-1.
2. Put the monitor into the pedestal following the right orientation to insure the contact of metal point and shrapnel.
3. Connect AC adapter to electrical outlet.
4. If the monitor is shut down, it will set up and display the charging interface, pressing the On/Off key will enter into normal operating mode.
5. If the monitor is working, it will display the movement of battery icon.

⚠ WARNINGS

- Do not plug the monitor into the pedestal at wrong orientation.
- Make sure equip the monitor with Ni-MH batteries, do not charge alkaline batteries or any other type of batteries. Do not mix different kinds of batteries to use!
- When there are no batteries in the monitor and use the pedestal to supply power, you have danger of losing data. So please make sure shut the monitor down before taking the pedestal away.

3.3 Installing AC adapter

1. Plug the AC adapter into the chargeable faucet which on the bottom of the host monitor.
2. Connect AC adapter to electrical outlet.
3. If the monitor is shut down, it will set up and display the charging interface, pressing the On/Off key will enter into working interface.
4. If the monitor is working, it will display the movement of battery icon.

3.4 Installing Wireless USB Dongle

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment dose cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the main device.

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2. Increase the separation between the equipment and receiver.
3. Consult the dealer or an experienced technician for help.

Figure 3-2: Install wireless USB Dongle

Installing steps:

1. Install driver and software at PC.
2. Plug wireless USB Dongle into PC's USB faucet, The USB Dongle receive data from monitor via wireless, as shown in Figure 3-2.
3. Open the monitor in 2 meters around the PC, the monitor will send the data to USB Dongle via wireless.
4. Press MENU key, enter into "sending data" dialog.
5. Choose "connect" button to open the ward software.
6. The software will show historical data of patient's ID which have stored in the host monitor at the side column, if it's connected successfully.

NOTE

- In order to insure the quality of the transporting signal, please let the monitor close to the USB wireless adapter plugged in PC as possible and make sure there is no barrier between them.
- This monitor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
  (1) This device may not cause harmful interference.
  (2) This device must accept any interference received, including interference that may cause undesired operation.
- The monitor used for this transmitter must be installed with providing a separation distance of at least 20cm from all persons.

3.5 Sensor Connections

⚠ WARNINGS

- Before use, carefully read the sensor directions for use, including all warnings, cautions, and instructions.
- Do not use a damaged sensor.
- Do not immerse or wet the sensor.
- Do not use a sensor with exposed electronic components.

NOTE

- Use only sensors and its cable suited to this monitor for SpO_2 and CO_2 measurements. Other

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带格式的: 缩进: 左侧: 0 厘米, 悬挂缩进: 3.6 字符, 项目符号 + 级别: 1 + 对齐位置: 0 厘米 + 制表符后于: 0.74 厘米 + 缩进位置: 0.74 厘米, 制表位: 1.71 字符, 列表制表位 + 不在 2 字符

sensors may cause the monitor improper performance.

- Do not lift the monitor by the sensor cable because the cable could disconnect from the monitor, causing the monitor to drop on the patient.

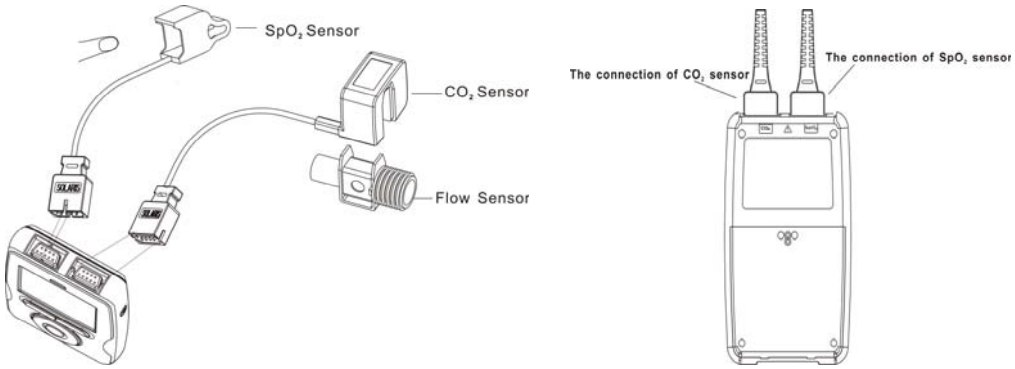

Figure 3-3: Installing sensors

● Installing SpO_2 sensor

1. Select the appropriate sensor for the patient.
2. Refer to Figure 3-3, Connect the oximeter plug to pulse oximeter convex interface.
3. The probe is finger of tip oximeter probe. Attach the finger probe with the light to the patient. Be sure to fully insert the patient's finger into the probe.
4. Apply the sensor following the instructions supplied with the sensor.

● Installing CO_2 sensor

1. Insert the CO_2 Sensor connector into the receptacle of the host monitor. To remove the connector, grasp the body portion of the connector back and remove.
2. Shown below is the CO_2 Sensor connection to a CO_2 adapter

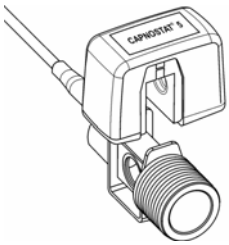

Figure 3-4: Installing CO_2 sensor

3. Open the function of measuring CO_2. Please see chapter 5 for more information.

Note: Do not remove by pulling cable.

带格式的： 缩进：左侧： 0 厘米，悬挂缩进：3.6 字符，项目符号 + 级别：1 + 对齐位置： 0.63 厘米 + 制表符后于： 1.38 厘米 + 缩进位置： 1.38 厘米，制表位： 1.71 字符，列表制表位 + 不在 3.71 字符

带格式的： 缩进：左侧： 0 厘米，悬挂缩进：3.6 字符，项目符号 + 级别：1 + 对齐位置： 0.63 厘米 + 制表符后于： 1.38 厘米 + 缩进位置： 1.38 厘米，制表位： 1.71 字符，列表制表位 + 不在 3.71 字符

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4. Initial Setup

4.1 Main Structure

The monitor is composed by host monitor, SpO_2 Sensor, CO_2 Sensor and pedestal.

4.2 Description Crust

Figure 4-1 through 4-4 show the crust, display, pedestal and rear/top view of the monitor.

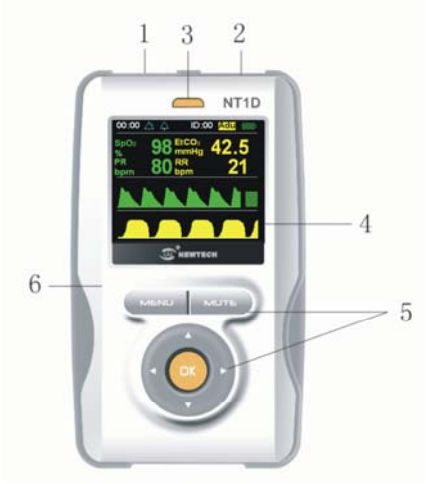


Figure 4-1: Crust

The function of each numbered label in Figure 4-1 is described below:

Label	Description	Function
1	SpO_2 Connector	Connect the host monitor and SpO_2 Sensor
2	CO_2 Connector	Connect the host monitor and CO_2 Sensor
3	Power indicator light	Indicate the state of host monitor
4	Display Window	Display the user's interface
5	Keys	Operate the host monitor
6	Crust	Protect the internal parts of host monitor

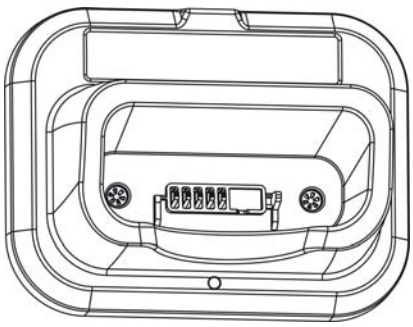


Figure 4-2：Pedestal View

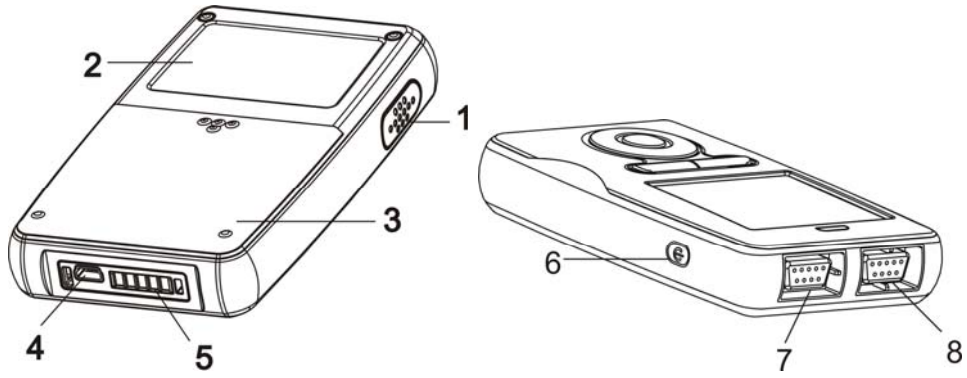


Figure 4-3：Rear/top view

The function of each numbered label in Figure 4-3 is described below:

Label	Description	Function
1	Speaker	Emit sounds of pulse and alarm
2	Rear shuck	Protect the internal parts of host monitor
3	Battery door	Open it can install or unload batteries
4	Electrical outlet	Connect the host monitor and AC adapter
5	Pedestal connector	Connect the host monitor and pedestal
6	On/Off key	Open and close the host monitor
7	CO_2 Connector	Connect the host monitor and CO_2 Sensor
8	SpO_2 Connector	Connect the host monitor and SpO_2 Sensor

4.3 Basic Operation

WARNINGS

- The monitor is a prescription device and is to be operated by qualified personnel only.
- Do not lift the monitor by the probe cable because the cable could disconnect from the monitor, causing the monitor to drop on the patient.
- Prior to using the monitor, carefully read the manual and accessory directions for use, all precautionary information in boldface type, and all specifications.

带格式的： 缩进：左侧： 0 厘米，悬挂缩进：3.6 字符，项目符号 + 级别：1 + 对齐位置： 0 厘米 + 制表符后于： 0.74 厘米 + 缩进位置： 0.74 厘米，制表位：1.71 字符，列表制表位 + 不在 2 字符

NOTE

- The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- Before using the monitor, remove the plastic protective sheet that covers the display. This sheet is only on the display to protect it during shipping. Leaving it on during monitoring could make it difficult to read displayed measurements.

4.3.1 Keys Operation

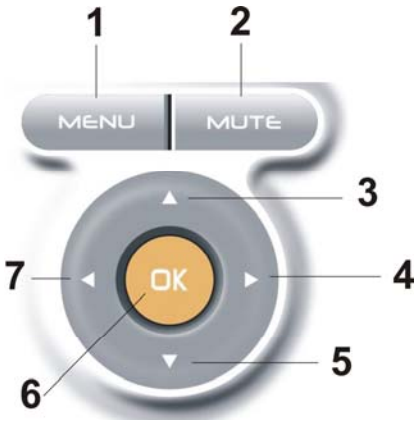


Figure 4-4: keys

The function of each numbered label in Figure 4-4 is described below:

Label	Description	Function
1	MENU key	Press this bottom to enter submenu.
2	MUTE key	Press this bottom to shut down the alarm of this parameter or restart all alarms.
3	Up key	Move menu and cursor upwards or increase number.
4	Right key	Move menu and cursor rightwards.
5	Down key	Move menu and cursor upwards or decrease number.
6	OK key	Use to choose menu or number.
7	Left key	Move menu and cursor leftwards.

4.3.2 Start Up

- Enclosing butteries

If the monitor is turned off, when you have enclosed batteries, press On/Off key can turn on the monitor. The start interface is shown in Figure 4-5 below:

Figure4-5: Initialization Screen

NOTE

- If the battery were insufficient to operated, you maybe can see the opening of the system. And then, the monitor turns itself off automatically. If the batteries are less or installing the batteries is

failure, this monitor may have no response. Then, Please make sure the batteries have enough energy.

- The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- This monitor is a prescription device and is to be operated by qualified personnel only.
- Do not connect anything other than a SpO_2 sensor to the SpO_2 sensor port (for example, do not attempt to connect a PC to the monitor at the sensor port).
- Do not connect anything other than an CO_2 sensor to the CO_2 sensor port

---

- Self Test

When turned on, the monitor automatically performs a Self Test. The screen will display the followings in turn:

1) It will display the software's version number at all the test times.
2) The self test progress of magnetic disk, power indicator light and speaker is displaying below the version number.
3) Make sure that you can hear "dee" sound and the power light is on. That means finishing the self test successfully. If not, do not continue to use this monitor, contact your provider or manufacturer.

After self testing, if you haven't set the system time or the right has lost, a dialog box will come out to hint you set the system time manually.(Refer to Figure 4-6).

Figure 4-6 Setting system time

⚠ WARNINGS

- Make sure that you can hear "dee" sound and the power light is on. If not, do not continue to use this monitor.
- Do not lift the monitor by the sensor cable because the cable could disconnect from the monitor, causing the monitor to drop on the patient.
- Make sure there is no any barrier in the front of the speaker and the speaker's pores aren't covered. Otherwise, you may not hear alarms.

CAUTIONS

- When adjust any menu's parameter, the screen will display partially but still record data.

4.3.3 Running Mode

After turning on the monitor, the SpO_2 testing is opened automatically. Steps are as follows:

1) Install the SpO_2 sensor correctly and put patient's finger in it.
2) The monitor will search for pulse in 10 seconds.
3) If pulse search is successful, in $\%SpO_2$ and PR area will display the patient's $\%SpO_2$ and PR. Pulse indicator will jump together with the pulse jumping. Speaker will generate "dee dee" with the pulse jumping. Feature as follows:

- $\%SpO_2$: Express percent oxygen saturation
- PR: In pulse beats per minute (bpm)

Steps of opening CO_2 measuring mode:

1) Attach the CO_2 sensor to the monitor and adapter correctly.
2) Press MENU key to enter the setting menu, open CO_2 switch. The SpO_2 sensor has already been inserted, but doesn't input, $EtCO_2$ and RR display area displays "- - -".
3) If there is CO_2 flowing the flow sensor, patient's end tidal carbon dioxide value and respiration rate will be shown at the $EtCO_2$ and RR display area.
   - $EtCO_2$ means end tidal carbon dioxide value, and has three units:%, KPa, mmHg (default).
   - RR means the respiration times of every minute (bpm）.

4.3.4 Information Column

From left to right ,the information column displays: time, the state of alarm and mute, remaindering full of magnetic disk, patient's ID and type and batteries' charge level. As shown in figure 4-7.

Figure 4-7: Information column

The function of partial icons in Figure 4-7 is described below:

Name	State	Description
State of alarm		It means the general alarm switch is turn on, but one or more sub-switch maybe have already turn off。
		It means the general alarm switch is turn off. At this state, the monitor can generate any alarms except low voltage alarming.
State of silence		It means all alarming sound is turn on.
		It means one or more alarming sound is turn off.
Hint of recording data		It means recording historical data for present patient.
Hint of full memory		It means full memory for present patient and stopping recording data.

4.3.5 Status Bar

Name	State	Function
Loss of sensor icon		It will be displayed when the sensor is off.
Loss of finger icon		The SpO_2 sensor has already been inserted, but the sensor not attached to the finger, the icon will be shown.
Search pulse icon		When the monitor is search pulse, the icon will be shown.
Low signal icon		It will be displayed if the patient's signal is low.

4.3.6 Adjust the Volume of Pulse

You can adjust the volume of pulse by using the right/left key in all interfaces except trend graph interfaces.

4.3.7 Indicating Batteries' Charge and Recharging

WARNINGS

- Be sure to follow local governing ordinances and recycling instructions regarding disposal or recycling of batteries.
- Do not recharge alkaline batteries.

NOTE

- The system use AA alkaline batteries to estimate remainder time. The icon  appears when there is only approximately 15 minutes of using time remains. The remainder time will be different if use other kinds of batteries.
- Check the batteries periodically for corrosion. If don't use the monitor for three months or more time, please take all batteries away.

- Indicating batteries charge

  When the monitor is working, the battery-shaped icon in information column will show remainder charge. When approximately 15 minutes of charge time remains,  will wink and begin low battery voltage warning, as shown in figure 4-8.

Figure 4-8: low charge icon

If the voltage is excessive low, the monitor will come out a window to reminder user that the monitor must be shut down and the progress can not be terminable, as shown in figure 4-9.

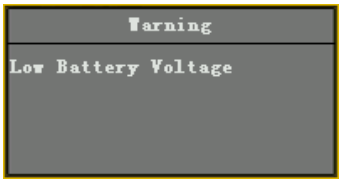


Figure 4-9: low voltage warning screen

- Internal Recharge Function

  When the monitor is connected to an external power source (even if the monitor is turned off), the battery pack charges automatically. When charging, the battery-shaped icon displays a dynamic pattern, press On/Off key to enter double waveform interface. After charging, the battery-shaped icon will show filling pattern, press On/Off key to enter main monitoring interface. If user pulls the charger out or breaks the pedestal away when the monitor is closed, it will turn off automatically. The charging screen is shown in figure 4-10.

带格式的: 缩进: 左侧: 0 厘米, 首行缩进: 0 厘米, 项目符号 + 级别: 1 + 对齐位置: 0.63 厘米 + 制表符后于: 1.38 厘米 + 缩进位置: 1.38 厘米, 制表位: 不在 3.71 字符

带格式的: 缩进: 左侧: 0 厘米, 首行缩进: 0 厘米, 项目符号 + 级别: 1 + 对齐位置: 0.63 厘米 + 制表符后于: 1.38 厘米 + 缩进位置: 1.38 厘米, 制表位: 不在 3.71 字符

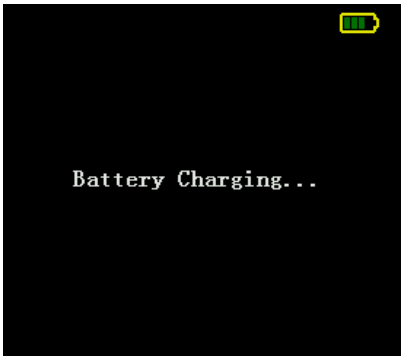


Figure 4-10: Charging screen

When the monitor is working, if you connect it to AC adapter or put it on pedestal, the battery-shaped icon at information column displays a dynamic pattern from 1 to 4 panes. You can continue using the monitor if user pulls the charger out or breaks the pedestal away in working mode.

4.3.8 Shut Down

1） Shut down normally

Press the On/Off key for full gauge to shut down the monitor when it's working. The monitor will come out a window, as shown in figure 4-11.

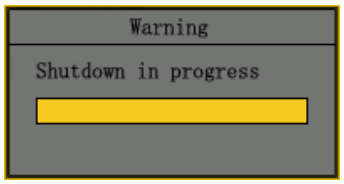


Figure 4-11: Shut down normally

2） Shut down in low voltage

The monitor turns itself off automatically when batteries are depleted.

The system enters into the state of low voltage, when approximately 15 minutes of charge time remains. The icon  will wink and stored trend data is saved in memory. After that, the historical data can't be saved, so please shut it down normally and change batteries.

If the voltage is excessive low, the monitor will come out a window to reminder user that the monitor must be shut down and the progress can not be terminable, as shown in figure 4-9.

NOTE

- You can stop shutting the monitor down if it closed automatically because of low voltage.
- The low voltage is distinguished by alkaline battery. That is different for Ni-MH battery, but it doesn't matter with using the monitor.
- If you press On/Off key when the AC adapter is inserted, the system will enter the state of dormancy after full gauge.

WARNINGS

- In order to keep optimal performance of the equipment, please open the monitor at least 30 seconds after being shut down or cut power.
- The historical data can be saved as the battery-shaped icon winking. After that the data won't be saved even if shut down the monitor normally.

4.4 Storage

Remove the batteries from the instrument before long-term storage, or if the device won't be used for 6 months or more. This protects the device from damage due to batteries leaking acid.

Store the device in its original shipping carton and packing materials to help protect the device from damage during storage.

4.5 Environment of Protection

For minimizing risks, discard the used-up batteries and this monitor according to your local government organization rules, ROHS（2002/95/EC）and WEEE（2002/96/EC）.

4.6 Impact of Performance Consideration

Inaccurate SpO_2 measurements can be caused by:

- Prolonged and/or excessive patient movement;
- Anaemia;
- Venous pulsations;
- Intravascular dyes, such as indocyaninegreen or methylene blue;
- Significant levels of dysfunctional hemoglobins;
- Defibrillation.

The affects of electromagnetic interference on oximetry reading is discussed in the Troubleshooting and Maintenance section of this manual.

Inaccurate CO_2 measurements can be caused by:

- Trachea's entanglement or strangulation.
- Reuse, disassembly, cleaning, disinfecting or sterilizing the single patient use CO_2 airway adapters
- Air flow adapter is damaged.
- CO_2 Sensor is damaged.
- CO_2 Sensor is wet or has exterior condensation.
- Nitrous oxide, elevated levels of oxygen, helium and halogenated hydrocarbons can influence the CO_2 measurement.
- Air flow adapter windows are dirty.
- CO_2 Sensor windows are dirty.
- Patient's secretion.
- CO_2 Sensor is forgotten to reset the air flow adapter.
- CO_2 Sensor did not be set and compensated according to the environment.

Ambient environmental conditions and sensor application errors, which can affect pulse oximetry and CO_2 readings, are discussed in the Probe section of this manual and in the probe directions for use.

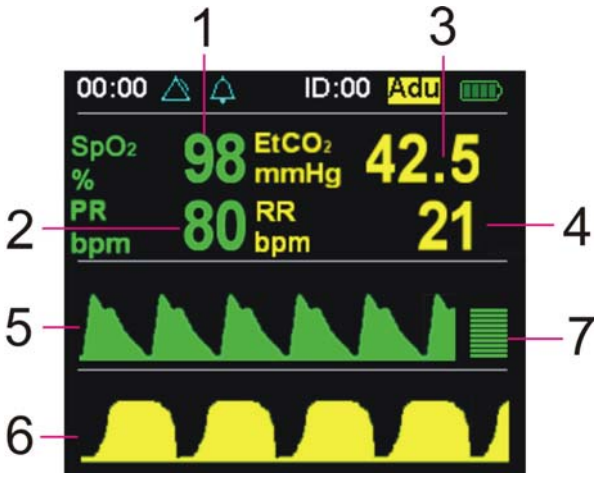
带格式的：缩进：左侧： 0 厘米，悬挂缩进：3.6 字符，项目符号 + 级别：1 + 对齐位置： 0.63 厘米 + 制表符后于： 1.38 厘米 + 缩进位置： 1.38 厘米，制表位： 1.71 字符，列表制表位 + 不在 3.71 字符

带格式的：缩进：左侧： 0 厘米，悬挂缩进：3.6 字符，项目符号 + 级别：1 + 对齐位置： 0.63 厘米 + 制表符后于： 1.38 厘米 + 缩进位置： 1.38 厘米，制表位： 1.71 字符，列表制表位 + 不在 3.71 字符

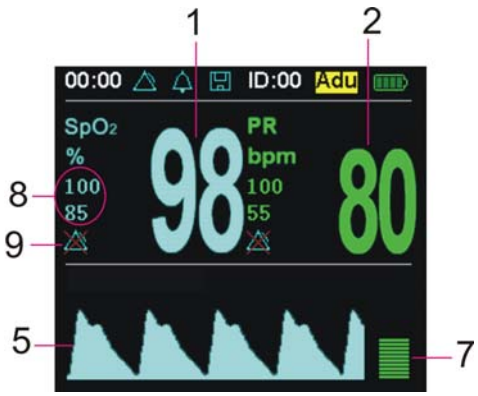
5. Interface and Function

5.1 Main Monitoring Interface

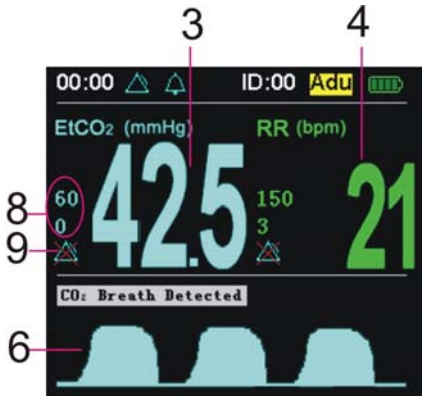
After turning on the monitor, you will enter into the main monitoring interface. Its function is displaying parameter of patient's vital signals. Refer to figure 5-1.



(a) Double waveform interface



(b) Single SpO_2 module monitoring interface



(c) Single CO_2 module monitoring interface

Figure 5-1: Main monitoring interface

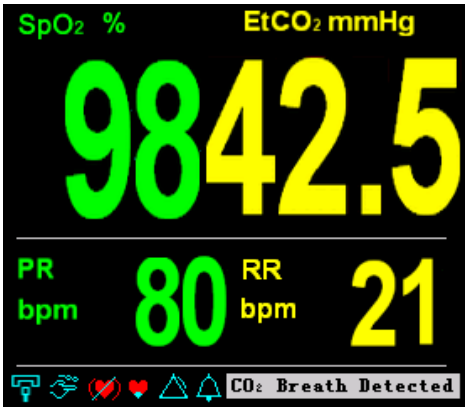
Label	Description	Function
1	SpO_2 Numeric Field	Display the current SpO_2 value. If it doesn't measure SpO_2, it will display"- - -"
2	PR Numeric Field	Display the current value. If it doesn't measure PR it will display"- - -".
3	$EtCO_2$ Numeric Field	Display the current value. If it doesn't measure $EtCO_2$ it will display"- - -".
4	RR Numeric Field	Display the current value. If it doesn't measure RR it will display"- - -".
5	SpO_2 waveform	When it is measuring SpO_2, it displays SpO_2 waveform. It

		shows a beeline when it doesn't.
6	$EtCO_2$ waveform	When it is measuring $EtCO_2$, it displays $EtCO_2$ waveform. It shows a beeline when it doesn't.
7	Pulse histogram	Display the intension of pulse.
8	Alarm Limits	It shows the high and low limit of the parameter.
9	Alarm Switch	When it is displaying means the alarm of this parameter is closed.

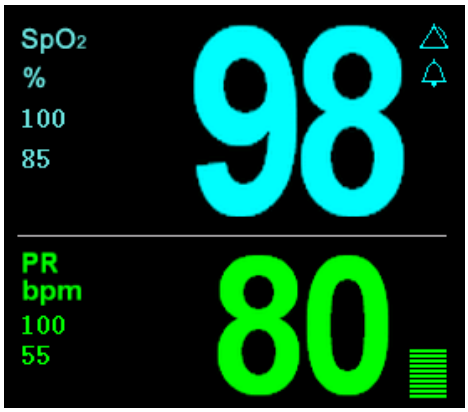
Note: Press the up and down key to switch the main monitoring interface, big chart mode, trend plot interface, trend table and event table circularly.

5.2 Big Chart Mode

Press down key to switch real-time monitoring interface to big chart mode, as shown in figure 5-2.



(a) Big chart mode of SpO_2 and CO_2 module



(b) Big chart mode of single SpO_2 module

(c) Big chart mode of single CO_2 module

Figure 5-2: big chart mode

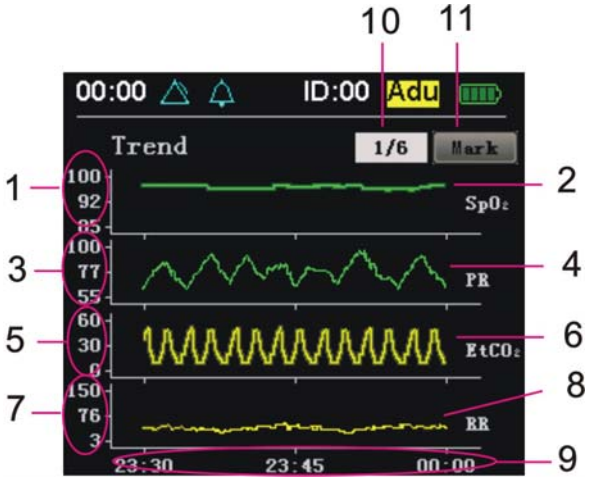
At monitoring interface, press MUTE key can shut down the sound of alarming or resume all alarms.

5.3 Real-time Trend Interface

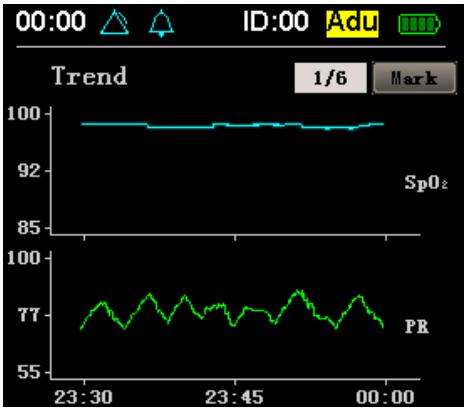
5.3.1 Trend Graph Interface

Press down key to enter into real-time trend interface. It displays trends of the parameters such as

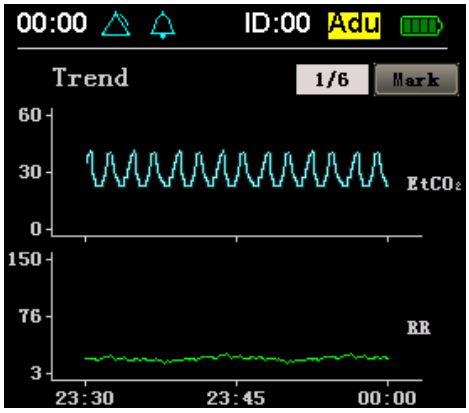
SpO_2 and PR. It records 1 point every 10 seconds acquiescently in 6 pages. Shut down the monitor, change date, ID and precision will cause losing the current data and the new real-time trend will be shown. As shown in figure 5-3. Press right/left key to switch every single parameter's trend graph screen.



(a) Trend graph interface of Spo_2 and CO_2 module



(b) Trend graph interface of single SpO_2 module



(c) Trend graph interface of single CO_2 module

Figure 5-3: Trend graph interface

Label	Description	Function
1	SpO_2 scale ruler	Mark SpO_2 trend graph's value range and range of alarm limits.
2	SpO_2 trend graph	In order to analyze data, protract SpO_2 trend in a period of time according SpO_2 historical data.
3	PR scale ruler	Mark PR trend graph's value range and range of alarm limits.
4	PR trend graph	In order to analyze data, protract PR trend in a period of time according PR historical data.
5	$EtCO_2$ scale ruler	Mark $EtCO_2$ trend graph's value range and range of alarm limits.
6	$EtCO_2$ trend graph	In order to analyze data, protract $EtCO_2$ trend in a

		period of time according $EtCO_2$ historical data.
7	RR scale ruler	Mark RR trend graph's value range and range of alarm limits.
8	RR trend graph	In order to analyze data, protract RR trend in a period of time according RR historical data.
9	Time scale	Mark the time scale of this page and time.
10	Selective frame for turning pages over	Select the page you want to see trends.
11	Marked button	Mark trend of current time.

In the trend graph interface, press OK key to enter operation mode, use right and left key to move focus and press the MENU key to exit operated mode:

◆selective frame for turning pages over: Move focus to the selective frame, press OK key and then press the right and left key to select the page you want to see its trend circularly. Press OK key to drop out operation mode.

◆ Mark button: move focus on mark button, press OK key to set a mark of current time at trend graph. The mark will move leftwards at the trend graph with time.

NOTE

- The real-time trend data will be cleared when open the monitor or change patient's ID every time. Pictures are protracted step by step from the right side of the screen until it fills in the whole screen and then the whole waveform will move leftwards. If there no measured patient, the picture still move leftwards.
- The time to display current trend is different because of different precision. The longest is 18 hours. The historical trends will covered by the new ones if the monitoring time exceeds the displaying time.
- Shutting down the monitor will cause the losing of real-time trend data.

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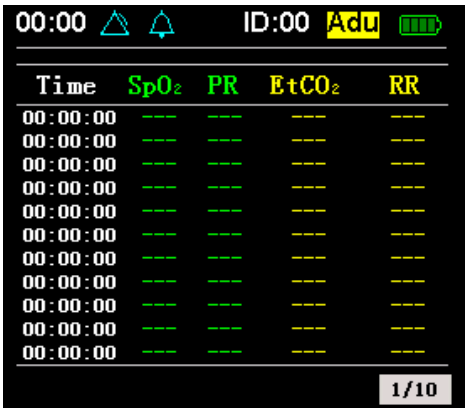
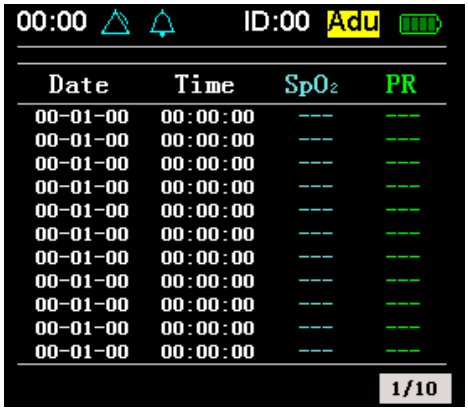
5.3.2 Trend Table Interface

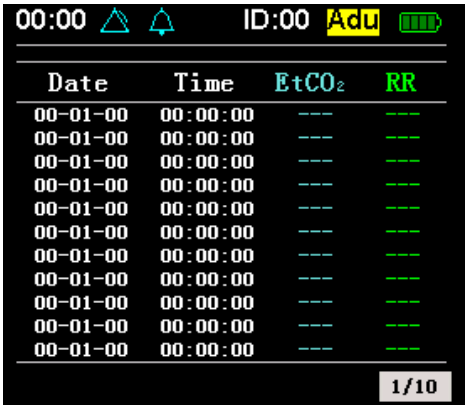
Press down key to enter into trend table interface. Every line of the table will display the data of every parameter in every time which is recorded in the trend plot interface. As shown in figure 5-4.



(a) Trend table interface of SpO_2 and CO_2 module



(b) Trend table interface of single SpO_2 module



(c) Trend table interface of single CO_2 module

Figure 5-4: Trend table interface

5.3.3 Saving Historical Trend

Historical trend will be saved in magnetic disk with the following ways:

- When patient's ID number is 00, it does not save historical trend data.
- When patient's ID number is 01~99, it can save historical trend data in recent 72 hours. If there is no enough room for present user, the icon in the status bar will wink to remind you that the data won't be save from now on.
- The historical data is saved every 10 seconds acquiescently. The recorded data include the value of SpO_2, PR, CO_2, RR.

NOTE

- Historical trend data will be saved if the monitor shut down normally. But if batteries are taken away abruptly, the data will lose.
- Historical trend data will be saved at the moment of changing patient's ID.
- Historical trend data will be saved if there is a low voltage alarm. And then the monitor enters into the status of low voltage. Please replace batteries in time. At the status of low voltage, it will no longer save data even if it shut down normally.

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5.4 Event Table Interface

Press down key to enter into event table interface. The event table will show the alarm records of SpO_2, PR or $ETCO_2$, RR or all the four parameters. Refers to figure 5-5.

Figure 5-5: Event table

Operation:

1. You can use the right and left key to turn over pages circularly after pressing OK key when the focus is on the selective frame. Press OK key again to drop out turning pages.

NOTE

- The event table will only record alarms happened recently in 10 pages.

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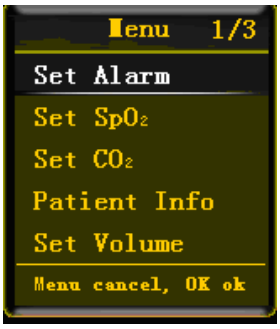
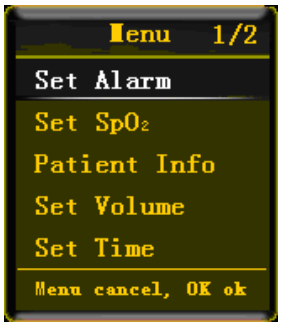
5.5 Setting Menu Interface

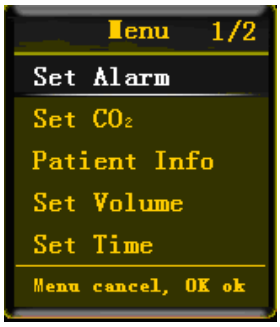
At the real-time monitoring interface, big chart mode, trend interface and event table interface, press MENU key to enter menu interface. As shown in figure 5-6.



(a) Menu of SpO_2 and CO_2 module



(b) Menu of single SpO_2 module



(c) Menu of single CO_2 module

Figure 5-6: Menu interface

Operation:

1. In the menu, press MENU key can exit.
2. Use up and down key to select different option.
3. Press OK key to affirm your option.
4. After that, a dialog box will come out.

5.5.1 Setting Alarm Limits

WARNINGS

- The monitor's alarm function will be affected by environmental light, EMC and noise and so on.
- The sounds of alarms and the wink of monitoring data on the screen must be audible and visual by operator.

(a) Set alarm for SpO_2 and CO_2 module

(b) Set alarm for single SpO_2 module

(c) Set alarm limits for single CO_2 module

Figure 5-7: Set alarm limits

Operation:

1. Use up, down, right, left key to move focus. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then the dialog box will disappear. Pressing MENU key is equal to choosing Cancel button.
2. Press OK key to enter compiling state, and use right and left key to change limits, then press OK to exit.
3. When the focus moves to CO_2 option, press OK key to switch to set alarm limit of $EtCO_2$ and RR. (Only for SpO_2 and CO_2 module).

NOTE

- If alarm default limit is changed, a decimal point appears behind the displayed value during monitoring. The decimal point remains on display until the limit is returned to its default value.

⚠ WARNINGS

- It should be only the professional to adjust the alarm high/low limit. Alarm high limit can not lower than alarm low limit.
- The alarm system will be invalid if set alarm high/low limit out of the range of alarm limit.
- When patient needs to be looked after specially, inadequacy alarm limit will cause the delay or invalidation of alarm signal.
- Make sure that the monitor default alarm settings are appropriate for the specific patient being monitored.

5.5.2 Setting SpO_2

In the setting menu, you can choose "Set SpO_2" option. As shown in figure 5-8.

Figure 5-8: Set SpO_2 (Not suitable for single CO_2 module)

Operation:

1. Use up, down, right, left key to move focus. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then the dialog box will disappear. Pressing MENU key is equal to choosing Cancel button.
2. Move the focus to "Pleth Speed" , "Average Pulse" or " Discolor Time", press OK key first and then use up and down key to change the value, press OK to affirm your setting.

NO.	Name	Option
1	Pleth Speed	High, Low
2	Average Pulse	4,8,16
3	Discolor Time	1, 10, 30. It means the interval to change the color of Spo_2 waveform according alarming level when alarm occurs.

5.5.3 Setting CO_2

In the setting menu, you can choose "Set CO_2" option. As shown in figure 5-9.

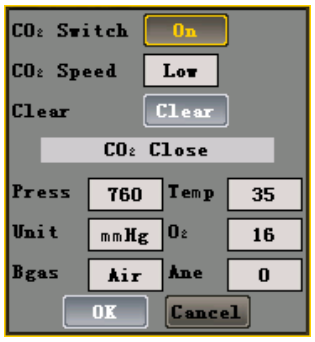


Figure 5-9: Set CO_2 (Not suitable for single SpO_2 module)

Operation:

1. Use up, down, right, left key to move focus. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then the dialog box will disappear. Pressing MENU key is equal to choosing Cancel button.
2. User can move focus to switch CO_2, set the speed of waveform, zeroing, parameters of CO_2.

NO.	Name	Description	NO.	Name	Description
1	Press	barometric pressure	4	O_2	O_2 compensation
2	Temp	gas temperature	5	Bgas	balance gas
3	Unit	current CO_2 units	6	Ane	anesthetic agent

5.5.4 Setting Patient's Information

In the setting menu, you can choose "Patient Info" menu to set patient's ID, sex and type. As shown in figure 5-10.

Figure 5-10: Set patient's information

Operation:

1. Use up, down, right, left key to move focus. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then the dialog box will disappear. Pressing MENU key is equal to choosing Cancel button.
2. You can change patient's ID from 0 to 99.The types of patient are adult, pediatric and neonate and the sexes are male and female.
3. When you choose the New button, the system will auto-generate a new ID. You can't use the New button, if there no available ID.
4. If you choose an ID that has never been used, press OK key can change ID number and then the dialog box will exit. If the ID you choose is existing, it will remind you to substitute the former ID or cancel your operation.
5. If you choose to substitute the ID, the historical data of this ID will be cleared, and the restart to record new data, then the dialog box will disappear. If you choose to cancel your setting, then return to setting ID interface with the disappearance of the dialog box.

5.5.5 Setting Volume

⚠ WARNINGS

- Do not turn off the audible alarm or decrease the audible alarm volume if patient safety could be compromised.

Figure 5-11: Set volume

Operation:

1. Use up, down, right, left key to move focus. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then the dialog box will disappear. Pressing MENU key is equal to choosing Cancel button.
2. Adjust the volume with the right and left and press the up and down key to move the focus, and then press OK to confirm your setting.

5.5.6 Setting Time and Date

Figure 5-12: Set time and date

Operation:

1. Use right and left key to move focus, and press OK to enter compiling state, press OK again to exit.
2. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then exit from the dialog box.

5.5.7 Setting Trend

Select the “Set trend “submenu in the setting menu and you can adjust the trend record step. As shown in Figure 5-13.

WARNINGS

- If you change the steps, the data have saved will be lost.

Figure 5-13: Set trend

Operation:

1. Use up, down, right, left key to move focus. When the focus is on OK or Cancel button, press OK key can save or give up saving settings, then the dialog box will disappear. Pressing MENU key is equal to choosing Cancel button.
2. User can move focus to step, press the up/down key to change step. The default value is 10 seconds.

NO.	Name	Option
1	Runtime Trend Step	1, 5,10,30,60. It means the trend data saving interval in the monitor.
2	History Trend Step	1, 5,10,30,60. It means the trend data saving interval you can watch on PC.

5.5.8 Data Output

In the setting menu, you can choose “data output” option to enter data output interface. As shown

in figure 5-14.

Figure 5-14: Data output

Operation:

1. Open the “data output “interface in the setting menu.
2. Plug wireless USB Dongle into USB port in PC, and then run the historical data analytical software. Choose the “Connect instrument” of the software.
3. If it has found instrument, the software will remind you to choose the patient’s ID which you want to upload to PC. After that, you can upload patient’s data to PC. You can also delete appointed patient’s data.
4. At the process of sending data, you can press Stop button to stop it. Then the dialog box will disappear.

5.5.9 Set Module

Figure 5-15: Set Module

There are three modules of the monitor including the SpO_2 and CO_2 Module, the Single SpO_2 Module and the Single CO_2 Module. You can choose one of these to run after entering “Set Module” submenu.

5.5.10 Resume Settings

Entering into the “Reset setting “submenu can resume all settings you have changed. As shown in figure 5-16.

Figure 5-16: Resume settings

5.5.11 System Information

System information includes the information of hardware, software and product and so on. The interface is tolerant and can not to be changed. As shown in figure 5-17.

Figure 5-17: System information

Operation:

1. Press OK key to exit the dialog box.

5.6 Audible and Visual Indication

The following audible indications do not change with symbols, key board or visual indication:

Label	Description	Visual indication	Audible indication
1	Setup	When self testing, the indicator will wink red, green and yellow color once.	One sound ,“dee”
2	Pulse sound	/	One sound ,“dee”
3	Sensor falls off	The red light will wink and the icon  will be displayed.	Dee,dee,dee-dee,dee Dee,dee,dee-dee,dee Period: 10s
4	Loss of finger	The red light will wink and the icon  will be displayed.	Dee,dee,dee-dee,dee Dee,dee,dee-dee,dee Period: 10s
5	Loss of pulse	The red light will wink and the icon  will be displayed.	Dee,dee,dee-dee,dee Dee,dee,dee-dee,dee Period: 10s
6	Poor signal	The icon  will be displayed.	Dee,dee,dee-dee,dee Dee,dee,dee-dee,dee Period: 10s
7	Low voltage	The red light and the icon  will wink.	Dee,dee,dee-dee,dee Dee,dee,dee-dee,dee Period: 10s
8	Alarm sound	The red light will wink in high priority. The yellow light will wink in medium priority. And the related parameter values will wink at the same time.	Dee,dee,dee Period of high priority:10s Period of medium priority:25s

6. Monitoring SpO_2

6.1 Overview

SpO_2 measures functional blood oxygen saturation. It measures the percentage of oxyhemoglobin. It does not measure carboxyhemoglobin or methemoglobin. For example, if 97% of red blood cells in the artery are oxygenated, then blood has 97% blood oxygen saturation. The monitor SpO_2 value reading would be 97.

SpO_2 measurement is a non-invasive, continuous measurement through a SpO_2 sensor attached to a patient's finger. The sensor is connected directly to the SpO_2 module. There are three types of display for SpO_2: percentage (%), pulse rate, and SpO_2 waveform.

6.2 Principles of Measurement

Pulse oximetry is based on two principles: 1.That oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., Spectrophotometry), and 2.that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry probe serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light Absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation .To identify the oxygen saturation of arterial bemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood volume and light absorption increase.

During diastole, blood volume and light absorption reach their lowest point .The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (i.e., Measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

The Pulse oximeter determines SpO_2 and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue to a photodetector. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the probe placement, The intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissue. (Refer To Figure 6-1)

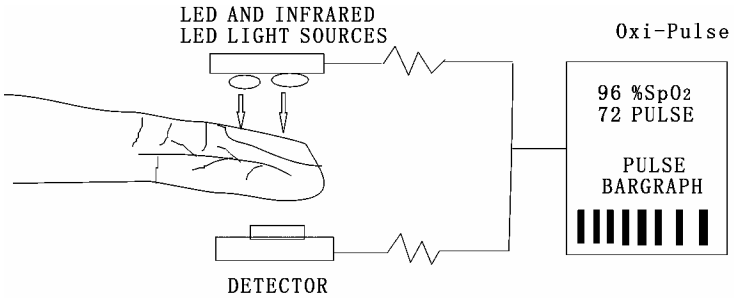


Figure 6-1: SpO_2 theory of operation

The Pulse Oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO_2) to identify the pulse rate and calculateoxygen saturation. Oxygen saturation

calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

6.2 Abnormal State of SpO_2 Measurement:

After turning on the monitor, if the sensor is installed incorrectly or there are other wrong operations, the following situation may happen:

1) The SpO_2 sensor has already been inserted, but the sensor not attached to the finger, the icon "  " will wink and SpO_2 and PR display area has display"- - -"，At the same time, the monitor will generate lost reminder sound in every 10 seconds.
2) Pulse search mode: If patient is connected with the sensor, the monitor attempts to search pulse. The icon "  " will wink. At the same time, display shows display"- - -"in %SpO_2 and PR areas. Normally the search mode process is approximately 10 seconds. If the pulse search is failed, the monitor generates high alarm.
3) The sensor falling off. The icon "  " will be displayed.
4) Hinting poor signal. The icon "  " will displayed.

6.4 Directions for SpO_2 Sensor Use

Single patient use SpO_2 sensor and SpO_2 saturation monitor compose the system to use to examine the adult, pediatric's blood oxygen degree of saturation (SpO_2) and (or) the arteries rate (PR) physiological parameter and so on. The use situation is not restricted in the specialized medical establishment the patient guardianship room, the operating room, the first-aid room, the emergency room and the technique the observation room. Its use cycle generally is 7days to 15 days for a person in hospitalized.

NOTE

- The sensor isn't suitable for continuous and long term SpO_2 monitoring. Continuous and long term monitoring may cause skin to become irritated, reddening, blistering or necrosis.
- The SpO_2 sensor has passed biologic compatibility experiments like cell's toxicity, stimulative test under skin and scratch test and so on.

Steps:

1） Hold the sensor with its opening towards the patient's index finger (A). The sensor should be oriented in such a way that the sensor side with a cable is positioned on the top (B). If an index finger cannot be positioned correctly, or is not available, other fingers can be used.

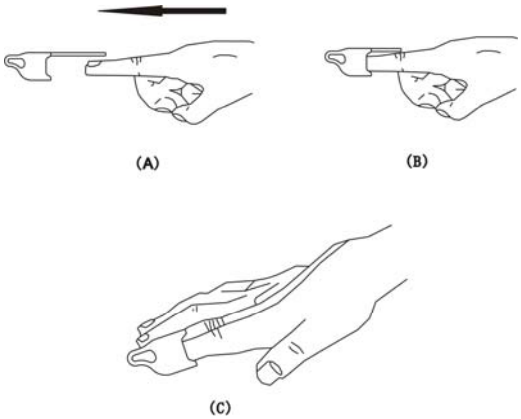


Figure 6-2: Placement of sensor

2） Insert the patient's index finger into the sensor until the fingernail tip touches the end of the sensor. Adjust the finger to be placed evenly on the middle base of the sensor (C).

3） Plug the sensor into the monitor and verify proper operation as described in the monitor operator's manual.

4） Inspect the monitoring site every 4 hours for skin integrity.

5） Before each use, surface-clean sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution.

NOTE

- Do not sterilize by irradiation steam, or ethylene oxide.
- Do not use a blood pressure cuff or arterial blood pressure measurement device on the same limb as the sensor.

6.5 Measuring Restriction

6.5.1 The following may affect the accuracy of SpO_2 measurement:

- High frequency electrical interference from the monitor itself or from ambient electrical instruments connected to the system.
- Patient's excess movements.
- Inductive current generated from MRI can cause burn.
- Outside light radiation.
- Incorrect sensor placement.
- Sensor temperature (suitable temperature range should be 28℃ - 41℃)
- The same limb used for sensor, NTBP cuff, artery tube or inner tube.
- Presence of COHb, MetHb and dyestuff.
- Low signal.
- Bad perfusion on sensor site.
- Coma, anemia, low temperature and insufficient blood flow caused by drugs.

NOTE

- The maximum time duration for one sensor site in use should not be over 4 hours. The sensor surface temperature should not be higher than 41ºC, or it may cause burn.
- During continuous monitoring, sensor site should be cleaned at least every 12 hours. Otherwise it may result in inaccurate measurements.

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6.5.2 Inaccurate measurements can be caused by:

- Incorrect application of the sensor;
- Patient's finger is too big or its blood cycle doesn't well;
- Failure to cover the sensor site with opaque material in high or ambient light conditions;
- prolonged and/or excessive patient movement;
- Intravascular dyes, such as indocyaninegreen or methylene blue;
- Interavascular dyes or externally applied coloring, such as nail polish or pigmented cream;
- Venous pulsations;
- Significant levels of dysfunctional hemoglobins
- Lack of supplying blood.

6.5.3 Loss-of-pulse signal can occur for the following reasons:

- The sensor is applied too tightly;
- Defibrillation;
- A blood pressure cuff is inflated on the same extremity as the one with the sensor attached;
- There is arterial occlusion proximal to the sensor;
- Poor peripheral profusion;
- Losing of pulse or stopping of heart.

Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor. Clean and remove any substances such as nail polish from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material.

If patient movement presents a problem, try one or more of the following remedies:

- Verify that the sensor is properly and securely applied;
- Move the sensor to a less active site;
- Use an adhesive sensor that tolerates some patient motion;
- Use a new sensor with fresh adhesive backing;
- Try to keep patient quiet.

NOTE

- Failure to cover the sensor site with opaque material in high ambient light conditions may result in

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inaccurate measurements.

- You can select and use sensor to realize how to deal with patient and environment.
- Do not sterilize by irradiation steam, or ethylene oxide. Wipe the monitor with cloth dampened with soft suds and then wipe surfaces dry. Wipe the sensor with cloth with alcohol if necessary. Note: Do not spray or pour any liquid directly on the monitor, accessories or consumables.

⚠ WARNINGS

- Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and patient conditions.
- Tissue damage can be caused by incorrect application or inappropriate duration of use of a SpO_2 sensor. Inspect the sensor site as directed in the sensor Directions for Use.
- Inspect the monitoring site every 4 hours for skin integrity.

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7. Monitoring CO_2

7.1 Overview

The CO_2 Sensor is used for the continuous measurement of CO_2 and respiratory rate. The sensor measures CO_2 by using the infrared absorption technique. The principle is based on the fact that CO_2 molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR beam is passed through a gas sample containing CO_2, the electronic signal from the photo detector (which measures the remaining light energy) is measured. This signal is then compared to the energy of the IR source and adjusted to accurately reflect CO_2 concentration in the sample. The CO_2 Sensor's response to a known concentration of CO_2 is stored at the factory in the sensor's memory. A reference channel accounts for optical changes in the sensor, allowing the system to remain in calibration without user intervention.

7.2 Principles of Measurement

CO_2 monitoring is to monitor the respiration of a patient by detecting the concentration of CO_2 generated during respiration. The maximum concentration of CO_2 at the end of exhalation is called *End-Tide* CO_2 ($EtCO_2$). The minimum concentration of CO_2 at the end of inspiration is called *Inspiration* CO_2 ($FiCO_2$). CO_2 is generated by cells in the body during metabolizing, and is breathed out via breathing system. The concentration of CO_2 breathed out from the lung reflects directly the situation of metabolizing and breathing system. If the concentration of CO_2 is high, it means that metabolism is over active, such as blood poisoning or acute fever. If the concentration of CO_2 is low, it is commonly due to a weak output ability of the heart, or the heartbeat stopped, or insufficient blood flow with less oxygen. Monitoring CO_2 is used to warn the doctor of the abnormal breathing and metabolizing during anaesthesia.

The concentration of CO_2 is represented as a pressure level, with 'mmHg' or % as its unit. Generally, the acceptable value is 38mmHg (5%) when air pressure is 760mmHg. The concentration of CO_2 varies rapidly from 0% to 5%. To detect the concentration of CO_2 accurately, the monitor needs to be very sensitive.

The monitor is used to measure the $EtCO_2$ and respiration rate of adult, infant and neonatal patient

7.3 Medical Use of CO_2 Sensor

- The CO_2 Sensor is used to continuously monitor carbon dioxide and report $ETCO_2$, inspired CO_2 and respiratory rate of the intubated and non-intubated adult, pediatric, and neonatal patient.
- The CO_2 Sensor is indicated for use in care areas such as, but not limited to critical care, intensive care, anesthesia, medical/surgical units, LTAC units, emergency department, sleep labs and during intra-hospital transport and inter-hospital transport.
- For use in monitoring patients in respiratory distress, respiratory arrest or that have asthma, COPD or other disorders where the patient's $ETCO_2$ and capnogram will benefit the caregiver in the treatment of the patient.
- For use in monitoring patients pre- and post-intubation.
- To assist in the setup, management and weaning of the patient that is connected to a "conventional" mechanical ventilator.

7.4 CO_2 Sensor Adapter Zero

The sensor is compatible only with appointed CO_2 airway adapters. Each airway adapter has a unique set of optical characteristics. The adapter zero allows the CAPNOSTAT to adjust to the optical characteristics of each of the different adapter types. An “Adapter Zero” is a quick process that allows the Host system to adjust to the special characteristics of a particular CO_2 Sensor; it is necessary only when requested. Such a request may occur the first time a particular CO_2 Sensor is connected to a particular Host, or if a change is detected in the CO_2 Sensor.

To perform an Adapter Zero:

1）Connect the CO_2 Sensor to the Host.

2）Open the Host’s CO_2 switch. If it is the first time you open the CO_2 switch , Place the CO_2 sensor onto a clean and dry CO_2 adapter that is exposed to room air and away from all sources of CO_2, including the ventilator, the patient’s breath and your own. Do not conduct any operation in 20 minutes.

3）Open the MENU and select ”Set CO_2” option.

4）Choose “clear” and the CO_2 information column will display “ CO_2 Zeroing” and “ CO_2 Zero OK” in turn. At the progress of zeroing, do not conduct any operation including breathing, key-press and so on. Otherwise, the zeroing operation will fail. The time for a zero is 15-20 seconds. If failed, the information column will hint “CO_2 needs zeroing”, choose “Clear” can zero the adapter again.

NOTE

- For optimal results, connect the CO_2 Sensor to an adapter and wait 2 minutes before performing the Adapter Zero procedure.

⚠ WARNINGS

- CO_2 readings and respiration rate can be affected by certain ambient environmental conditions, sensor application errors, and patient conditions.
- Check whether CO_2 adapter is damaged or not. Do not use damaged CO_2 adapter.
- If the CO_2 waveform (Capnogram) appears abnormal, inspect the CO_2 airway adapters and replace if needed.
- Replace the CO_2 airway adapters if excessive secretions are observed.
- Monitor the CO_2 waveform (Capnogram) for elevated baseline. Elevated baseline can be caused by sensor or patient problems.

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8. Data Output

8.1 Driver Installations and Copy of Data Analysis Software

Install the driver “F32x Express USB Driver” and copy the tool folder ” History Data Viewer” from the enclosed CD to PC before transmitting of data derived from the monitor to PC.

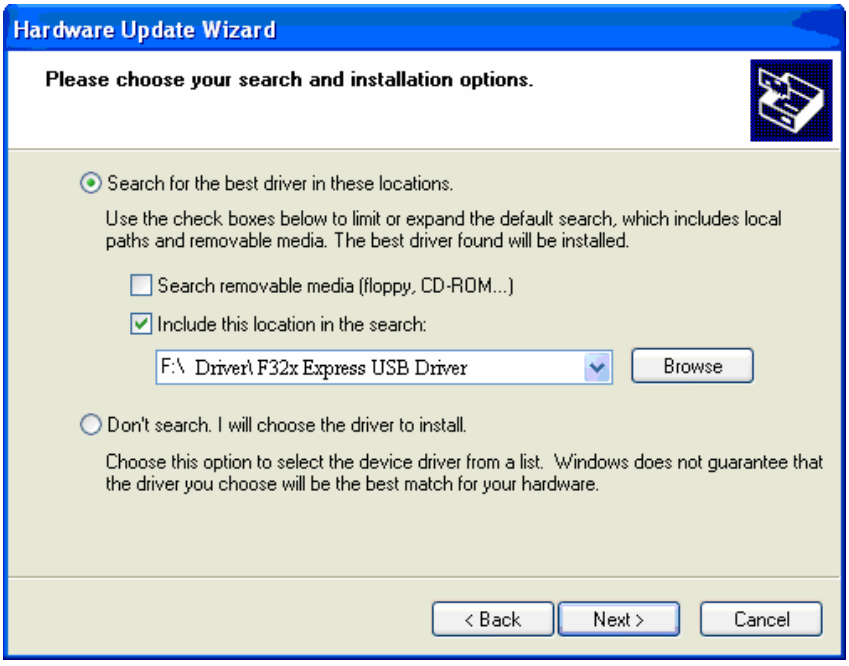
8.1.1 Install USB Drivers

F32x Express USB Drivers is used to drive USB dongle, to install as follows:

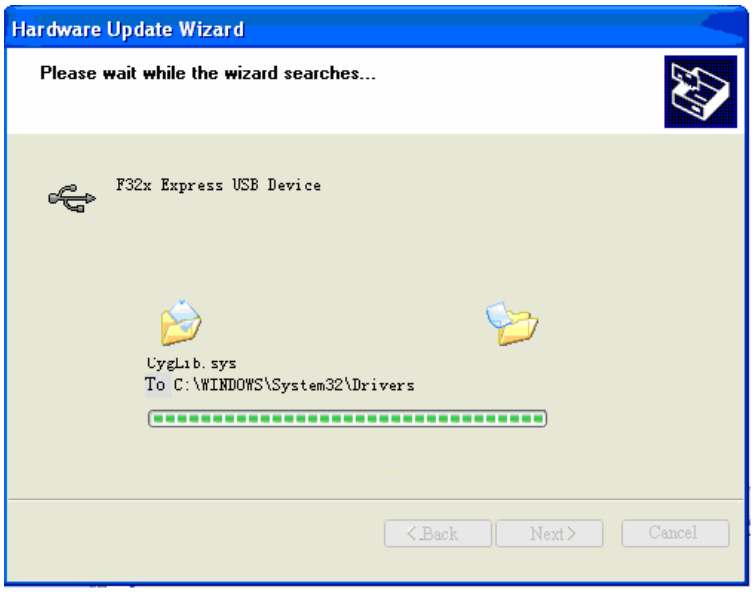
1）Insert the enclosed CD into your computer.

2）Plug the USB dongle into the USB faucet in PC, and you will see an automatic popup window “Welcome to the Found New Hardware Wizard”. Choose “Install from a list or specific location”. Note: If there is no automatic window, you may double left click the icon  on the bottom right corner of the desktop.

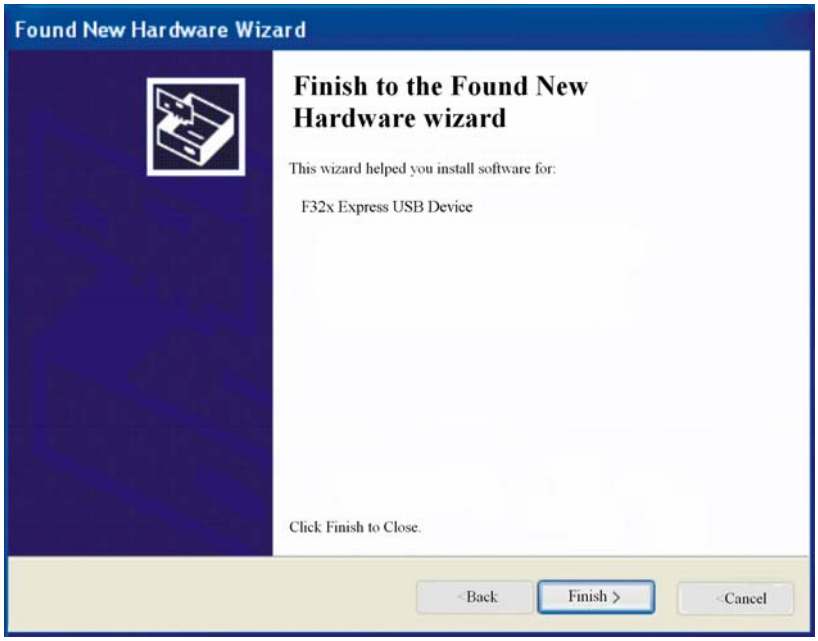
3）Click “Next” and see “Hardware Update Wizard” window as below.



4）Click “Browse” and choose the path G:\Driver\ F32x Express USB Driver. Click “Next” and start installation.



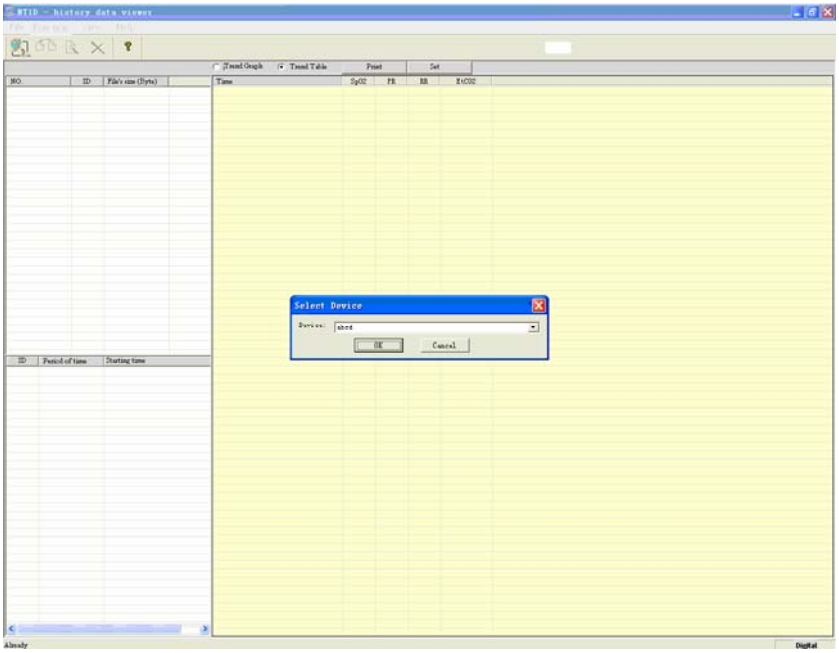
5）After installation, you will see the window “Completing the Found New Hardware Wizard”.



Click “Finish” to complete the installation of F32x Express USB Drivers. Once the driver is installed on PC, there is no need to install for the second time.

8.1.2 Copy the Folder “History Data Viewer”

The software in this folder has the functions of data output, data analysis and printing report. Copy the folder” History Data Viewer” from CD to PC and enter into it.， dbclick the icon “  ” to start the main interface of the History Data Viewer software. Click “OK” to start it.



8.2 Transmit and Delete Data

NOTE

- At the process of data transmitting and deleting, please don't chose the History Data View software or pull the USB adapter out, otherwise the process will be failure.
- After data transmitting and deleting, please pull out the USB adapter firstly, and then chose the History Data View software.

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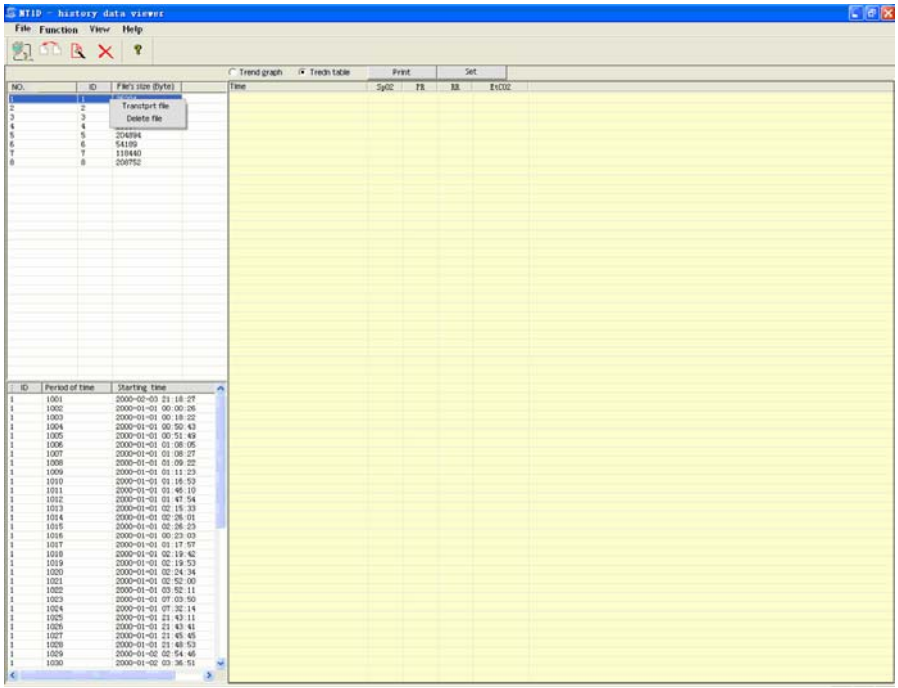
1）Put the monitor into 2 meters around the PC, and open it.

2）Press the MENU key to enter into the dialog box of "Data Output ". The monitor will stick on the dialog box as shown in the following picture:

3）Open the history data viewer software and click the button "  " at the top left corner can connect the monitor and PC wirelessly. If connected successfully, patient's history data which have stored in the monitor will be displayed at the left side column of the monitoring software. Select one patient's ID, click with the right key and choose "Transmit data" or "Delete data" to send this ID's data to PC or delete the stored trend data of the ID in monitor. As shown below:



9. Accessories

9.1 Standard Configure of NT1D

1）Host monitor	one	
2）SpO_2 Sensor	one	Solaris medical technology company SpO_2 Sensor, Model: D400AL-160108.
3）CO_2 Sensor	one	Respironics company Capnostat 5 mainstream CO_2 sensor
4）Charging pedestal	one	
5）Chargeable batteries	four	4xAA,2400mAh,Ni-MH chargeable batteries.
6） AC adapter	one	Input a.c.100-240V,50/60Hz，output d.c. 9V, (operation power) and 6.0V（Recharging power）.（Confirm to EN 60601-1）
7） Safeguard jacket	one	
8） Wireless USB Dongle	one	
9） Driving CD	one	
10）Operation Manual	one	
11）Maintenance card	one	
12）Package bill	one	

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9.2 Optional Accessories of NT1D

User can buy accessories from the local agent if necessary. The following are the accessories:

Num	Type	Description	Manufacturer
1	D400A-160108	Digital One Adult SpO_2 Sensor	Solaris
2	D400P-160108	Digital One Pediatric SpO_2 Sensor	Solaris
3	Y400N -160108	Digital Y-type Neonatal SpO_2 Sensor	Solaris
4	DP400A-160108	Digital One Use Only SpO_2 Sensor-Adult	Solaris
5	DP400N/A-160108	Digital One Use Only SpO_2 Sensor-Neonate/Adult	Solaris
6	DP400P-160108	Digital One Use Only SpO_2 Sensor-Pediatirc	Solaris
7	DP400I-160108	Digital One Use Only SpO_2 Sensor-Infant	Solaris
8	S400A-160108	Digital Adult Finger SpO_2 Sensor	Solaris
9	S400P-160108	Digital Pediatric Finger SpO_2 Sensor	Solaris

10	T400A-160108	Adult Soft-Finger SpO_2 Sensor	Solaris
11	T400P-160108	Pediatric Soft-Finger SpO_2 Sensor	Solaris
12	W400AN-160108	Digital Wrapped and tied SpO_2 Sensor-Neonate/Adult	Solaris
13	WP400PI-160108	Digital Wrapped and tied SpO_2 Sensor- Pediatirc / Infant	Solaris
14	/	LoFlo sidestream CO_2 sensor	Respironics

10. Troubleshooting and Maintenance

⚠ WARNINGS

- If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.
- The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

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NOTE

- Do not spray or pour any liquid directly on the monitor, accessories or consumables. Otherwise may cause damage to the monitor.

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If you experience a problem while using the monitor and are unable to correct it, contact qualified service personnel or representative. The monitor service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

10.1 Troubleshooting Guide

1. Monitor does not turn on after pressing the power switch.

◆ Check power cable connection.
◆ Replace or recharge the battery pack, or connect to AC power.
◆ Be sure the battery pack is in the monitor and inserted properly.

2. One or more showed elements or indicatory icons do not bright when self testing.

◆ Do not use the monitor and contact technical services department.

3. Indicatory icon of searching pulse is winking more than 10 seconds.

◆ Check whether sensor is suitable or connected correctly following SpO_2 using direction. Check sensor and its cable connection. Chang other patient to use the sensor. Use another sensor or its prolonged cable.
◆ Lacking of blood supply may cause the failure of tracing pulse, so check the patient or monitor operator. Replace if necessary, move the sensor to a new site.
◆ Patient's movement may interfere in the failure of tracing pulse. Keep patient still. Check whether the sensor is firm. Replace if necessary, move the sensor to a new site.
◆ The probe may be emplaced too tight. Environmental light may also affect monitoring. A blood pressure cuff is inflated on the same extremity as the one with the sensor attached, Replace sensors if necessary.
◆ EMI, Remove disturbing equipment.

4. No pulse shown on the bar-graph.

◆ Check sensor connections to the patient cable and to the monitor.
◆ Reposition the sensor.
◆ Try a new sensor or connect your authorized repair center for help.

5. PR, SpO_2, $EtCO_2$, RR Pulse rate is erratic, intermittent, or incorrect. (May caused by EMI)

◆ Reposition the SpO_2 and CO_2 sensor.
◆ Patient must remain still to obtain an accurate measurement.
◆ Close nearby equipment and then open it to find interferential equipment out.
◆ Change the orientation and position of interferential equipment.

- Let interferential equipment far away from this monitor.

6. The monitor switches off automatically.

- Replace or recharge battery.
- Check connections and correct problem.
- If previous actions are not effective, contact authorized service representative.

10.2 Technical Assistance

If you need technical information and sustain or ordered parts and operation manual, please contact your local representative, and tell them is software's version number of this monitor.

10.3 Factory Default Alarm Range Values

This monitor has default values when it is shipped to leave factory. technician has described how to change default values in detail at the operation manual.
Factory default alarm range values:

Alarm parameter(unit)	Default value of alarm high limit			Default value of alarm low limit		
	Adult	Pediatric	Neonate	Adult	Pediatric	Neonate
$EtCO_2$（mmHg）	60	60	60	0	0	0
RR（BPM）	150	150	150	3	12	12
SpO_2（%）	100	95	95	85	80	80
PR（BPM）	100	200	200	55	100	100

10.4 Returning the Monitor

If it is necessary to return the monitor for repairs, call the local representative for shipping instructions.

To repack the monitor, disconnect the accessories from the instrument and wrap each item separately. Pack them in the original shipping carton. If the original carton is unavailable, use a suitable box filled with the appropriate amount of packing material.

If the monitor malfunctions, carefully package the monitor with the consumable used at the time of malfunction and return it with the monitor for inspection.

10.5 Maintenance and Cleaning

WARNINGS

- The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.
- Turn the monitor off before cleaning.
- Do not spray or pour any liquid directly on placket of the monitor, accessories, connector, switch or

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crack. Otherwise it will dose damage to them.

- Do not autoclave, or immerse the monitor in liquid.
- If disinfection is required, wipe the monitor's surfaces with a soft cloth moistened with commercial nonabrasive cleaner. Do not allow any liquid to enter any of the monitor's opening.
- Do not touch or rub the display window with abrasive, apparatus, brush, shaggy material or any other stuff that may do damage to the display window.
- If there are any internal parts of the monitor exposed, please contact qualified service personnel to deal with it. Please follow your local governing ordinances regarding disposal monitor when it dosen't run.
- Dispose or recycle of batteries and retired sensors and the monitor's accessories according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
- This monitor can use disabled batteries, please install new ones.

You can clean and disinfect the surface of monitor and sensor. (Sensor is the only part that contacts to patient, so you should clean it every time after use.)

10.5.1 Cleaning and Disinfecting the Monitor

- To clean the monitor's surface: To clean the monitor's surfaces, dampen a soft cloth with a commercial, non-corrosive cleaner or alcohol 70%,and wipe the top, bottom, and front surfaces lightly.
- To disinfect the monitor: Use a cloth dampened with a 10% aqueous solution of hypochlorite (bleach).

10.5.2 Cleaning and Disinfecting SpO_2

- You can use a tampon or soft cloth dampened with alcohol 70% to wipe the SpO_2 sensor, and then dry it completely with dry cloth. The same to SpO_2 sensor's LED and receiver. Clean and disinfect reusable SpO_2 sensor. Read SpO_2 sensor's direction carefully before cleaning. Every kind of SpO_2 sensor has its own way to clean.
- If low-level disinfection is required, use a 1:10 bleach solution.

10.5.3 Disinfecting Cable

- Clean and disinfect cables with 3% hydrogen peroxide, or 70% isopropyl alcohol.

10.5.4 Cleaning and Disinfecting CO_2 Sensor

- Cleaning and Disinfecting
- Use a cloth dampened with isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), disinfectant spray cleaner such as Steris Coverage® Spray HB, ammonia, or mild soap.
- Wipe down with a clean water-dampened cloth to rinse and dry before use. Make certain that the sensor windows are clean and dry before reuse.

Cleaning adapter

Reusable adapters (Before reusing the adapter, ensure the windows are dry and residue free and that the adapter has not been damaged during handling or the cleaning/disinfecting process.):

- Clean by rinsing in a warm soapy solution followed by soaking in a liquid disinfectant such as isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), a gluteraldehyde 2.4% solution such as Cidex®, Steris System 1® or ammonia. It should then be rinsed out with sterile water and dried.
- May be disinfected using the methods listed below:
  1）Steam Autoclave - adult adapters only;

2）Immerse and soak in Cidex® or equivalent 2.4 glutaraldehyde solution for a 10 hour soak.

3）Immerse and soak in Perasafe® or equivalent peracetic acid. 26% solution for a 10-minutes soak.

4）Cidex® OPA - follow the manufacturer's instructions for use.

Disposable adapters:

- Treat all single patient use airway adapters in accordance with institutional protocol for single patient use items.
- DO NOT insert any object, such as a brush, into the CO_2 airway adapter. Irreparable damage may occur to the CO_2 windows.

- Maintenance Schedule

CO_2 Sensor should be compared against calibration gas every 12 months.

NOTE: Accuracy is affected by temperature and barometric pressure.

- CO_2 Accuracy Check

The following procedure should be performed to check the CO_2 accuracy of the Sensor. It is recommended that this procedure be included as part of a periodic maintenance schedule.

1）Zeroing. Refers to chapter 7 "7.4 CO_2 sensor adapter zero".

2）Calibration. Open the MENU and select "set CO_2" option. You can adjust all parameter's value (Pressure, temperature, unit, oxygen compensation and so on) according to the actual environment. Press OK key can confirm your calibration.

NOTE

- Do not autoclave, ethylene oxide sterilize, or immerse the monitor and its accessories in liquid.
- Turn off the monitor before cleaning.

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⚠ WARNINGS

- If there are any internal parts of the SpO_2 and CO_2 sensor exposed, please contact qualified service personnel to deal with it.

10.6 Periodic Safety Checks

The following safety checks should be performed every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment for mechanical and functional.
- Inspect the safety relevant labels for legibility.
- Verify that the device functions properly as described in this operator's manual.

If the monitor is not functioning properly or fails any of the above tests, do not attempt to repair the monitor. Please return the monitor to the manufacturer or to your distributor for any required repairs.

10.7 Guarantee

The company warrants the monitor at the time of its original purchase and for the subsequent time period of twelve months for the original purchaser. The company warrants SpO_2 Sensor free of defects at the time of its original purchase and for the subsequent time period of three months.

The warranty does not cover the followings:

- The monitor serials number of the label is teared off or can not be recognized.
- Damage to the monitor resulting from misconnection with other devices.
- Damage to the monitor resulting from accidents.
- Changes performed by users without the prior written authorization of the company.

Customer Service Department Tel: 86-755-26520739

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Appendix A: Specifications

A.1 Basic parameter

SpO_2, PR, $EtCO_2$, RR.

A.2 Average operation time

≥1000 hours.

A.3 Normal operation time

a) Environment temperature range:（0 ～ 50）℃,

b) Relative Humidity range: ≤ 95 %,

c) Atmospheric pressure range:（700～1060）hPa,

d) Power Voltage: AC 100V-240V,

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e) Power frequency: 50/60 Hz,

f) Battery type: 4xAA size Ni-MH rechargeable battery or alkaline battery (Forbidden to charge alkaline battery).

A.4 Safety requirements and classifications

a) Electric shock type: Type II equipment with internal power supply.

b) Electric shock degree: All application parts are BF type.

c) Harmful liquid material proof degree: Liquid proof.

d) Disinfection: follow manufacturer's recommended methods.

e) Safety on flammable gas: not suitable to use where flammable gas is present.

f) The monitor has applicable.

g) Power supply:

Internal power supply:4.4～6.0V（4xAA size battery）,

II type power adapter: input a.c.100-240V,50/60Hz，output d.c. 9V, (operation power) and 6.0V（Recharging power）.

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h) The monitor has signal input and signal output parts, i.e., keypad, LCD, wireless interface.

i) Using external power supply, the monitor is a continuous working system.

A.5 Trend data transfer

1) Wireless, via USB dongle for PC end

2) RF frequency: 2.440GHz

3) Modulate mode: GFSK

4) Effective transfer distance（clear area without interferential source or barrier）: ≤10m

5) Transfer speed: ≤ 40kbps

6) Transfer time: ≤ 40secs per ID

7) Power consumption: Rx or Tx Peak ≤13mA

A.6 SpO_2

■Measurement range:(0 ～ 100）%.

■Measurement accuracy:(70 ～ 100)%,±2 %,

(0 ～ 69)%, not required.

A.7 PR

■Measurement range: (30 ～ 250)bpm,

■Measurement accuracy: 1 bpm or ±2%, take the bigger one.

A.8 $EtCO_2$

■Measurement range: 0~150mmHg.

■Resolution: 0.1mmHg (0~69mmHg), 0.25mmHg (70~150mmHg).

■Measurement accuracy:

±2mmHg (0~40mmHg)

±5% (41~70mmHg)

±8% (71~100mmHg)

±10% (101~150mmHg)

A.9 RR

■Measurement range: 0~150 BPM

■Measurement accuracy: ±1 BPM

A.10 Alarm

■Alarm Mode:

Priority / Mode	High	Medium
Technical alarm	Low voltage, Pulse lost, Sensor off, Cable off, CO_2 sampling line off, No breath.	/
Physiological alarm	Parameter's value exceed limits(The priority can be adjusted)	
Audible alarm	Dee,Dee,Dee -Dee,Dee Period: 10secs	Dee,Dee,Dee Period: 25secs
Digital alarm	Display "- - -", related value will wink, refers to chapter 5.1.	Numeric Blinking Frequency 0.625Hz
Light alarm	Blinking, Red Frequency 2Hz	Blinking, Yellow Frequency 0. 5Hz
Event	Record the event, such as the date, time, parameters, etc.	

■Alarm Object：

- Physiological alarm: Indicate patient's physiological parameters exceed limits.
- Technical alarm: Indicate system failure to lead wrong results, i.e., sensor off.
- Normal alarm: In normal range, no harm to patients' health, .i.e. Battery low voltage.

A.11 Factory default value of alarm parameter

Alarm parameter(unit)	**Default value of alarm high limit**	**Default value of alarm low limit**

	Adult	Pediatric	Neonate	Adult	Pediatric	Neonate
$EtCO_2$（mmHg）	60	60	60	0	0	0
RR（BPM）	150	150	150	3	12	12
SpO_2（%）	100	95	95	85	80	80
PR（BPM）	100	200	200	55	100	100

A.12 Setting range and allowable tolerance of alarm high/low limits

Alarm parameter	Setting range of alarm high limit	Default value of alarm low limit
SpO_2	21%～100%	20%～99%
PR	35 bpm～250 bpm	30 bpm～245bpm
$EtCO_2$	5～100mmHg	0～99mmHg
RR	1～150bpm	0～149bpm

A.13 Continuous operation time

Power supply: Internal 4xAA alkaline or Ni-MH battery or external wall-power. Capable of charging when connect to external wall-power or power stack. Be capable of charging Ni-MH batteries only. (DO NOT to charging alkaline batteries).

Internal power continuous operation time:SpO_2 ≥ 10h，SpO_2 & CO_2 ≥ 3.5h.

A.14 Trend data storage

■ Store time of trend data:

Total 99 patients' ID，72h trend data per ID

■ Store parameters of trend data:

Include SpO_2, Pulse Rate, $EtCO_2$, Respiration Rate, time etc.

A.15 Dimensions and weight

Model	Dimensions（mm）L*W*H	Net weight（kg）	Gross weight（kg）
Host	125x73x23	0.137	0.233（with batteries）
Wireless USB Dongle	61.8x18.2x9.0	0.0075	-
Charger adapter	95x57x32	0.260	-

A.16 Packing, transportation, storage

■Packing

Place the monitor in a plastic bag, place it in a corrugated carton filled with the foam or other fillers. Seal the carton.

■Transportation

The monitor can be transported by airplane, train or automobile. Prevent fierce collision during transportation. Do not keep it with perishables. The transportation environment should be:

a)Environment temperature range: -20℃～＋70℃;

b) Relative humidity range: ≤95%;

c) Air pressure range: 500hPa～1060hPa.

■Storage

The monitor should be stored indoors with a temperature range: -10℃~+40℃, relative humidity≤80%, no corrosive gas, and with good ventilation.

A.17 Explanations of interface

Connector type	Description
Wireless（PC end）	Connected PC via wireless USB dongle（2.440GHz ISM band）
Wireless(handheld end）	Built-in RF IC to communicate with wireless USB Dongle，with data rate up to 40kbps.（2.440GHz ISM band）
DB9 SpO_2 Connector	Standard DB9-F Connector
DB9 CO_2 Connector	Standard DB9-F Connector

A.18 Compliance standards

CE Applied Standard of NT1D

Requirement	CE(MDD 93/42/EEC)	
General Safety	EN 60601-1:1990+A1:1993 +A2:1995+A13：1996	Medical electrical equipment-Part1: General requirements for basic safety and essential performance
	EN 60601-2-49:2001	Particular requirements for the safety of multifunction Patient monitoring equipment
EMC conformity CE R&TTE(99/5/EC)	EN60601-1-2:2001	Medical equipment-Part1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
	ETSI EN 301 489-1 V1.6.1(2008-04)	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

	ETSI EN 301 489-17 V1.3.2(2008-04)	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for 2,4 GHz wideband transmission systems, 5 GHz high performance RLAN equipment and 5,8 GHz Broadband Data Transmitting Systems
	ETSI EN 300 328 V1.7.1(2006-10)	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
Software validation requirement	IEC 60601-1-4:2000	General requirements for safety - Collateral Standard: Programmable electrical medical systems
Usability requirement	IEC 60601-1-6:2007	Medical electrical equipment Part 1-6: general requirements for basic safety and essential performance collateral standard: usability
Alarm conformity	IEC60601-1-8:2005	Medical electrical equipment—Part 1-8：General requirements for safety-Collateral Standard：General requirements，tests and guidance for alarm systems in medical electrical equipment and medical systems in medical electrical equipment and medical electrical systems
Spo2 Particular standard	EN ISO9919:2005	Medical electrical equipment—Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
CO2 Particular standard	EN ISO 21647:2004/AC:2006	Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors
Biological compatible requirement	ISO 10993-1: 2003	Biological evaluation of medical devices part-1:Evaluation and testing ISO 10993-1
	ISO 10993-5:1999	Biological evaluation of medical devices –test for in vitro cytotoxicity

	ISO 10993-10:2002	Biological evaluation of medical devices – tests for irritation and delayed-type hypersensitivity
Risk management requirement	ISO 14971:2007	Medical devices－Application of risk management to medical devices
Label and symbol	EN:980：2003	Graphical symbols for use in the label of medical devices
Information supplied by the manufacturer	EN 1041:1998	Information supplied by the manufacturer with medical devices
Clinical requirement	EN ISO 14155-1:2003	Clinical investigation of medical devices for human subjects –General requirements
	EN ISO 14155-2:2003	Clinical investigation of medical devices for human subjects –Clinical investigation plans
	Guidance of clinical evaluation Meddev 2.7.1	Evaluation of clinical data: a guide for manufacturers and notified bodies

Appendix B: EMC (Electro-Magnetic Compatibility)

Caution: The monitor complys with the limits for medical devices to IEC601-1-2: 1993, EN60601-1-2: 1994, Medical Device Directive 93/42/EEC, and this monitor has been tested for CISPR 11 class A.

Guidance and manufacturer's declaration-electromagnetic emissions-

for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic emission		
The *NT1D* is intended for use in the electromagnetic environment specified below. The customer of the user of *NT1D* should assure that it is used in such environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The *NT1D* 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 emission CISPR 11	Class A	The *NT1D* 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 manufacture's declaration-electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The *NT1D* is intended for use in the electromagnetic environment specified below. The customer or the user of *NT1D* 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 (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a

			typical location in 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 *NT1D* is intended for use in the electromagnetic environment specified below. The customer or the user of *NT1D* 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *NT1D*. Including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = $\left[\frac{3.5}{V1}\right]\sqrt{P}$ d = $\left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz d = $\left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 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 transmitter as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol:

			

NOTE 1 At 80 MHz. 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 *NT1D* is used exceeds the applicable RF compliance level above, the *monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *NT1D*.

b Over the frequency range 150 kHz to 80MHz. Field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF 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 *monitor*

The *monitor* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *NT1D* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *NT1D* 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)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHZ $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$
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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (for example, cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

The monitor generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference with other devices in the vicinity. Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning .If this occurs, the site of use should be surveyed to determine the source of this disruption, and actions taken to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the offending equipment
- Reorient or relocate the other receiving device
- Increase the separation between the interfering equipment and this equipment