

129-850/810 Vital Signs Monitor
Operating Manual



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Service Information

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Service Contact

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Product information

Product model: 129-850 /810
Product name: Vital Signs Monitor

Version information

This version is subject to change or upgrade without notice.
This version is suitable for 129-850 and 129-810. 129-810 is only with SpO2
parameter. Pls refer to relative SpO2 operations.
Version: 1.2
Issue date: 2017-7

Preface

This operating manual introduces the monitor's performance, operation methods and safety information. This manual is intended for professional healthcare personnel and those who have experience in operating monitoring equipment. 129-850 Vital Signs Monitor provides:

- SpO₂ monitoring
- Pulse rate (PR) monitoring
- End tidal carbon dioxide (EtCO₂) monitoring
- Fraction of Inspiration CO₂ (FiCO₂) monitoring
- Respiration rate (RR) monitoring
- CO₂ and SpO₂ waveform display
- Audible and visual physiological and technical alarms
- Trend graph and trend table review
- Alarm event records review
- History data storage
- Rechargeable battery
- External power supply and charger

The monitor is intended for monitoring patients in clinical environments where healthcare is provided by healthcare professionals.

NOTES

- This manual is for all possible configurations. The monitor you use may not have all parameters as above mentioned.
- United States Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

Explanation of Symbols

Symbols	Description
	Attention! Consult accompanying documents (This manual)
	BF Type Defibrillation
	Collect Separately
	Date of Manufacture
	Manufacturer
	Serial number
	Electrostatic sensitive device
IPX2	Drip proof
Rx ONLY	Prescriptive device, operated by qualified personnel only!

1. Safety

1.1 Safety Information

This chapter includes warnings, cautions, and basic safety information of 129-850 Vital Signs Monitor (hereinafter referred to as “monitor”). In addition, the manual includes significant information relevant to the monitor display and operating instructions.

Important! Read carefully before using. All notes and precautions of important information are highlighted in the manual.

- **“Warning”**: Advice against certain actions or situations that could result in personal injury or death.
- **“Caution”**: Advice against actions or situations that could damage the equipment, produce inaccurate data, or invalidate a procedure.
- **“Note”**: Provides useful information that may be neglected.

WARNINGS

- Electric Shock Hazard. The cover should 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.
- When alarms happen, the exact date and time on event table depends on the precision of date and time that the user has set in the monitor.
- Explosion hazard. The monitor is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Contacting the chemical substance from a cracked LCD display can cause poisoning. Please handle with caution when the display is broken.
- Please check the patient periodically to ensure that the monitor is working well and the correct positioning of SpO₂ and CO₂ sensors.
- CO₂ readings, respiratory rate, pulse oximetry readings, and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.
- High frequency surgery device or electrosurgery device may cause inaccurate measurement.
- The use of unspecified accessories, transducers, sensors and cables may result in increased emission and/or decreased immunity of the equipment.
- DO NOT silence the audible alarm if patient safety may be compromised.
- Make sure that the speaker is not covered by any slipcover; otherwise the alarm may not be heard.
- Always respond immediately to a system alarm since the patient may not be monitored during certain alarm conditions.
- Before using the monitor, verify that the alarm limits are appropriate for the patient to be monitored.
- Do not use airway adapter if the package is broken during transport.
- To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, such as rain.

- The SpO₂ sensor must be moved to a new site at least every 4 hours. Due to the fact that individual skin conditions may affect the ability to tolerate sensor placement, it may be necessary to change the sensor site more frequently for some patients. If the skin integrity changes, move the sensor to another site.
- DO NOT use the monitor during magnetic resonance imaging (MRI) scanning. Induced current could cause burns. The monitor may affect the MRI image and the MRI unit may affect the accuracy of monitor's measurements.
- The monitor has no defibrillation synchronization, so it cannot be connected to defibrillators.
- 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.
- Please place sensor on right position mentioned in the manual to reduce burnable damage when use with high frequency surgery device.
- If the accuracy of any measurement appears questionable, check the patient's vital signs by alternate means, and then make sure the monitor is functioning correctly.
- 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, shut down the monitor normally or when in low voltage. Do not take battery out abruptly when the monitor is working or in the process of shutting down to avoid data loss.
 - (2) When using external an AC adapter for power supply, if there is LI battery, you can take battery out when the monitor is working or in the process of shutting down. If there is no battery, you can only unplug the adapter only after the monitor is shut down normally. You can not unplug the adapter when it is working to avoid data loss.
- Using SpO₂ sensor incorrectly may do harm to patient's skin. Check whether the SpO₂ sensor is applied correctly according to the sensors instructions for use.
- Loss of pulse signal can occur if a blood pressure cuff is inflated on the same extremity as the one to which a SpO₂ sensor is attached.
- DO NOT alter or modify SpO₂ and CO₂ sensor. Alterations or modifications may affect performance or accuracy.
- Using the SpO₂ sensor in the presence of excessive illumination may result in inaccurate measurements. In such cases, cover the sensor site with an opaque material.
- DO NOT use SpO₂ and CO₂ sensor if the sensor or the sensor cable appears damaged.
- DO NOT lift the monitor by SpO₂ sensor or CO₂ 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 (SpO₂ sensor and CO₂ sensor) to reduce the possibility of patient entanglement or strangulation.
- Be sure to follow local regulations and recycling instructions regarding disposal or recycling of battery.
- This monitor's electrical isolation part is centralized in AC adapter. When using external power supply or charging the battery, please use only the medical grade AC adapter provided by the manufacturer. If the integrity of the main supply connection appears questionable, operate the monitor from its internal battery pack.

- Reuse, disassemble, cleaning, disinfecting or sterilizing the single patient use CO₂ airway adapters may compromise functionality and system performance leading to user or patient hazards. Performance is not guaranteed if a disposable single patient use sensor is reused.
- If the SpO₂ and CO₂ Sensor fails to respond as described in this manual, DO NOT use it until it's approved for use by qualified personnel.
- The CO₂ 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 necessary isolation.
- The monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.
- DO NOT reuse disposable accessories.
- DO NOT cross use SpO₂ and CO₂ sensors between epidemical and unepidemical patients before sterilization.
- DO NOT connect the monitor, sensor and AC adapter to any other equipment.

CAUTIONS

- Aimed to ensure patients' safety, please use the appointed accessories in this manual. Otherwise, it may make device can not work normally.
- Must set and dispose monitor or accessories according to local law or hospital rules when they will be overt time limit of use. Please contact us whenever you have a doubt.
- All equipment connected to the monitor must comply with IEC 60601-1.
- All SpO₂ sensors, cable and other accessories of this monitor corresponds secure requirements. It only allow uses appointed accessories.

NOTES

- Changes or modifications not approved by the manufacturer could void the user's rights to operate the equipment.
- Ambient light, movement, electromagnetic interference, artifacts, dysfunctional hemoglobin, and intravascular dyes, etc. may cause inaccurate SpO₂ measurements.
- DO NOT sterilize any sensor by irradiation steam, or ethylene oxide. Do not immerse cables or sensors completely in liquid or cleaning solutions.

1.2 Product Label

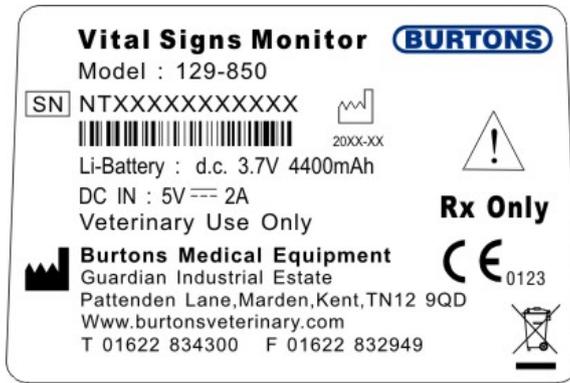


Figure1-1: Product label

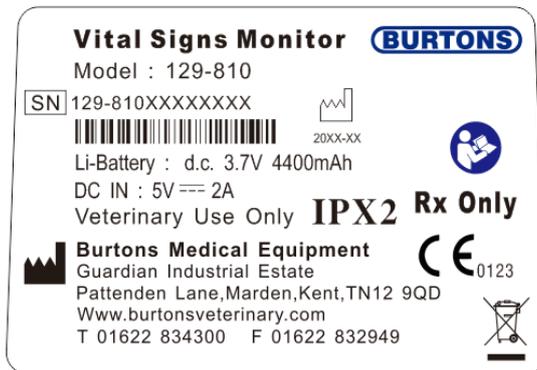


Figure1-2: Product label

2. Introduction

2.1 Product Introduction

129-850 is a handheld vital signs monitor that continuously monitors end tidal carbon dioxide (EtCO₂), respiratory rate (RR), oxygen saturation (SpO₂), Fraction of inspiration CO₂ (FiCO₂) and pulse rate. The unit is intended for monitoring only and must be used in the continuous presence of a qualified healthcare provider. It is 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 dogs, cats or similar size patients.

The product is composed of monitor, SpO₂ sensor, Mainstream/Sidestream CO₂ sensor.

The product has input and output ports:
Input: SpO₂ sensor port, CO₂ sensor port;

NOTE

- Using the monitor with excessive movement may cause inaccurate saturation measurements.

2.2 Features

- SpO₂ monitoring
- Pulse rate (PR) monitoring
- EtCO₂ monitoring
- Fraction of Inspiration CO₂ (FiCO₂) monitoring
- Respiration rate (RR) monitoring
- CO₂ and SpO₂ waveforms display
- Audible and visual physiological and technical alarms
- Trend graph and table review
- Alarm event records review
- History data storage
- English language interface
- Internal battery
- External power supply

2.3 Basic Theory of Operation

● SpO₂ theory 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 SpO₂ 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 light-emitting 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 SpO₂ 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.

● CO₂ theory of operation

The CO₂ Sensor is used for continuous measurement of CO₂ and respiratory rate. The sensor measures CO₂ by using the infrared absorption technique. The principle is based on the fact that CO₂ molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO₂ concentration. When an IR beam is passed through a gas sample containing CO₂, 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 CO₂ concentration in the sample. The CO₂ Sensor's response to a known concentration of CO₂ 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.

● Working theory of monitor

Signals from a patient are checked and magnified through various sensors and then transferred by extended cable to parameter module for data processing, and then communicate with monitor's control board to show the result of measurement. The result will be displayed on the screen in the form of a waveform and figures. It can save up to 72 hours per parameter for up to 99 patients.

WARNINGS

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

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

2.4 Terminology

SpO₂	Oxygen saturation value	PR	Pulse Rate
Pleth	Blood dimension	RR	Respiration rate
EtCO₂	End tidal carbon dioxide value		
FiCO₂	Fraction of inspiration carbon dioxide value CO ₂		

2.5 Electrical safety classification

This device is Class II of Electrical safety, common device built in

battery or use internal battery. Anti-electric shockparts is BF type. Mark



means: Note, please check manual.

Please note all part with mark  in this manual. Users must pay more attention during using to ensure safety of patient, user or device.

WARNINGS

- One patient only uses one monitor. Attention Leakage current superposition when several monitors used for patient at same time.
- Do not dismantle monitor shell, avoid electronic shock. Any maintaining and upgrade must do by trained and authorized service person.
- Monitor can not use with electosurgery at same time as it's no flame-proof protector. Avoided burn and endanger patient.
- Must use appointed accessories on this monitor.
- Keep monitor being dry. Avoid moistening and collision.
- Do not use this monitor during MRI or CT test.
- Do not use this monitor under inflammable anesthetic gas.

3. Unpacking and Installing

3.1 Unpacking

Open the package according to the marks on the box. Remove the monitor and accessories carefully.

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

If any problem is detected, contact your local representative immediately.

Friendly Reminder: The packing material should be saved for future transportation and storage.

WARNINGS

- Keep the packaging materials from children. Follow local regulations or hospital policies to dispose packaging materials.
- The equipment may be infected by microorganism during transportation. Check the packaging before using the monitor. Do not use it if damaged is present.
- Do not use other unspecified extension cords or adapters unless they are provided along with the monitor. Power cord and plug must be intact, not damaged.
- To ensure patient safety and to prevent electric shock, please do not touch the metal patch at the bottom of the monitor during the charging process.

3.2 Installing Battery

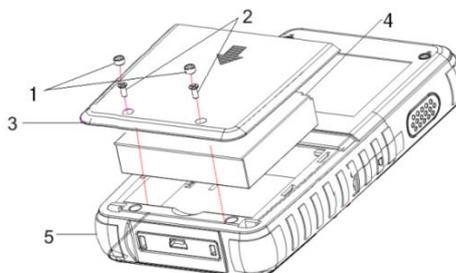


Figure 3-1 Installing Battery

- | | | |
|---------------------|----------------------------|------------------|
| 1. Screw hole plugs | 2. Countersunk head screws | 3. Battery cover |
| | 4. Li battery pack | 5. Monitor |

Operation:

1. First remove the screw hole plugs from the battery cover, then use a screwdriver to take the screws out; use both hands to pull down the battery cover.

2. Align the battery positive and negative connector while putting the battery pack into the battery slot. Push the battery cover into place and then snap back the screws and put back the screw hole plugs (as shown in Figure 3-1)

This monitor is using Li battery and can be recharged with an external power adaptor.

 **WARNINGS**

- Never operate the device without the battery cover in place.
 - DO NOT use any other battery without recommendation.
-

- **Use of Li Battery**

DO NOT immerse the battery pack in liquid.

DO NOT heat the battery or leave it close to the fire source; avoid heat and scratching to prevent short circuits.

Please only use the power cable and Li battery pack provided along with the monitor.

Please use the Li battery in environments suitable for use of the monitor.

If the Li battery is not used for a long time, please fully recharge the battery before use.

- **Battery Replacement**

Before installing or removing the battery pack, make sure the AC power cord is unplugged. Remove the patient lead wire connection when replacing the battery.

- **Storage of Li Battery**

Short-term storage (within one month): The battery pack has an automatic discharge feature. Check the battery capacity periodically.

Long-term storage (6 months or more): The battery pack must be stored in a cool, dry area, remove the battery if not use for a long time.

- **Disposal of Li Battery**

DO NOT dispose the battery pack in fire; or it may explode.

Be sure to follow local regulations and recycling instructions regarding disposal or recycling of battery.

 **WARNINGS**

- The monitor is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.
- To ensure patient electrical isolation, connect only to authorized AC adapters that provide patient electrical isolation. Do not use unauthorized AC adapters.
- Use accompanying battery only.
- DO NOT allow Child to touch battery.
- DO NOT charging battery with broken charger.
- DO NOT disassemble the battery.
- Only allow qualified personnel to install and remove the battery.
- Except for replacing the battery, do not remove the monitor housing. Users can only perform maintenance procedures described in this manual. Please only allow monitor to be serviced by equipment maintenance personnel who have been trained to service this monitor.

NOTES

- Check the battery periodically for corrosion. Replace battery if corrosion is present, otherwise it may cause damages to the monitor.
- Take out the battery if the monitor has not been used for a long time.
- When the battery needs to be charged, continue charging the battery until the battery icon is showing full grid. Normal charging time is 8 hours.
- To avoid corrosion of the contacts, remove battery from the battery compartment, if you do not intend to use the monitor for an extended period of time.
- DO NOT leave the battery in sun exposure, or throw the battery in fire or immersion in water.

- Avoid shaking and shocking battery.
- Battery capacity will decrease when the battery is used for a long time. Therefore battery run time during low power depends on the battery life.

3.3 Installing Power Adapter

WARNINGS

- Use the appointed power adapter to charge Li Battery. DO NOT use any other power adapter.
- Avoid squeezing the power adapter cable as such squeezing may break the cable outer insulation.

NOTES

- DO NOT damage the power cable by putting too much pressure on the cable for too long.
- When the monitor is not used, please take off the power adaptor.
- Power adapter should be used in compliance with the product work environment. It should be examined once every three months by checking the cable for damage or leakage, and whether the output voltage is normal.

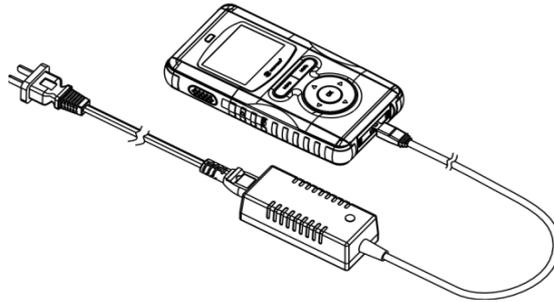
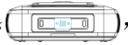


Figure 3-2 Installing Power Adapter

1. As shown in Figure 3-2, connect the power adaptor to the monitor. Before inserting the USB connector side into the monitor, move the slide at the bottom of the monitor “” to the right “”, Move the slide to its original

place when the battery is full.

2. Connect the AC adapter to the monitor power socket.
3. If the monitor is off, Press the On button, it will start up and display the charging screen. Press the On button again to start monitoring.
If the monitor is working, the battery icon will flash.

3.4 Sensor Placement

WARNINGS

- Read the sensor instructions before use, including warnings, cautions, and instructions.
- Do not use a damaged sensor.
- Do not immerse or wet the sensor in liquid.
- Do not use a sensor with exposed electronic components.

NOTES

- Use only recommended sensors and cables for SpO₂ and CO₂ measurements. Other sensors may cause inaccuracy.
- Do not lift the monitor by the sensor cable or it may cause the monitor to fall on the patient.
- Use the appointed SpO₂ and CO₂ sensors to ensure the monitor's working conditions.
- Do not connect anything other than a SpO₂ sensor to the SpO₂ sensor socket (for example, do not attempt to connect a PC to the monitor through SpO₂ sensor socket).
- Do not connect anything other than a CO₂ sensor to the CO₂ sensor socket.

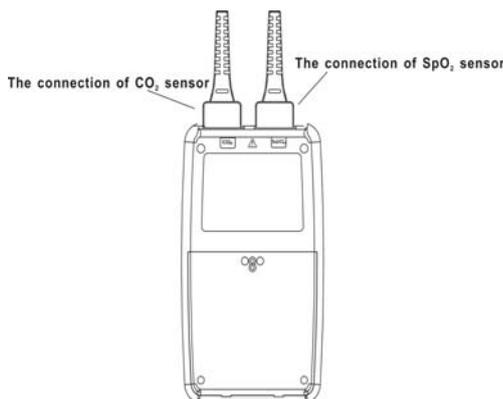


Figure 3-3: Installing sensors

● **Installing the SpO₂ sensor**

1. Select an appropriate Clip for the patient.
2. Refer to Figure 3-3, Connect the sensor to the monitor socket.
3. Attach the probe with the light to the patient. Be sure to put the sensor at a applicable site.
4. Apply the sensor following the instructions supplied with the sensor.

● **Installing CO₂ sensor**

1. Insert the CO₂ Sensor into the monitor socket. To remove the sensor, grasp the connector and pull back.
2. Figure 3-4 shows how to connect mainstream or Sidestream CO₂ sensor.

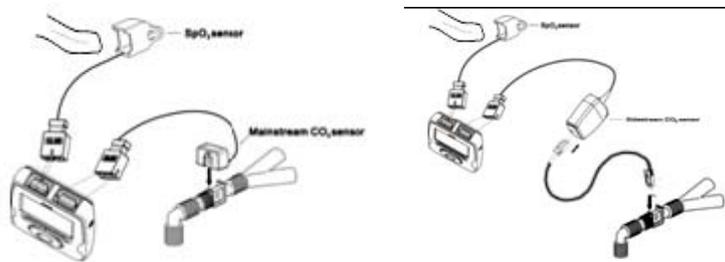


Figure 3-4: Installing Mainstream or Sidestream CO₂ sensor

● **3.C300 sidestream CO₂ sensor connection**

- Please connect sample line with dehumidification tube .
- Please connect sample line with Airway Adapter with Luer. **Figure 3-5**
- Please connect airway adapter into the ventilation circuit .(Generally the position of tee-junction is connected to the anaesthetic mask or intubation tube that is near-end of human body)

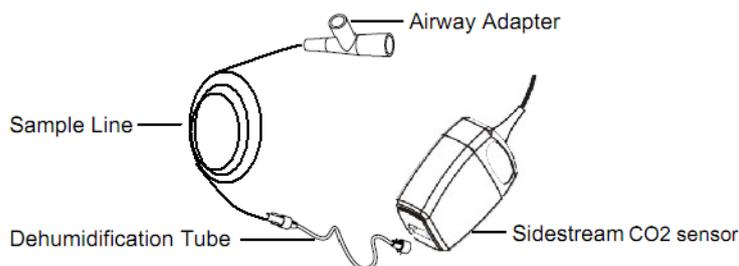


Figure 3-5: Connection C300 Sidestream CO₂ sensor

⚠ WARNINGS

- Do not make sensor cable or sample line under state of tangling or muzzling. Put up Respiratory tract transverter to sample line pressure.

- Functionally or system damage may make by Reusing, dismantling, cleaning, disinfecting disposable sample line and adapter.
- Check sidestream adapter and sample line before using. Do not use it if broken.
- Please change sidestream adapter and sample if there is too much secreta.
- Do not do any operation if CO₂ sensor id wed or there is condensing.
- Do not connect exit pipe with ventilation circuit.
- Do not block exhaust part on side of C300 sensor(black part)

NOTES

- Please dispose used disposable accessories according hospital program.
- Dehumidification tube is PFSIEM. It can reuse for 1 year.
- Do not soak or disinfect C300 sensor.
- Do not reuse or disinfect sample line.
- Ensure nasal cannula, sample line is clean, dry and undamaged before use. Please change new one if necessity.
- Do not block reset hole(Zero hole)
- Please take sample line out from sensor and connected system when do not use it.
- Ensure sidestream adapter connect with sample line when insert with breath pipe for anesthesia or ventilator monitor patient.
- Take out sidestream adapter from breath pipe before take out sample line.
- Do not stick anything on sample line.

For starting CO₂, monitoring, refer to chapter 5 for more information.

Note: Do not remove the sensor by pulling the cable.

4. Powering Up

4.1 Main Structure

The monitor is composed of main unit, SpO₂ Sensor and CO₂ Sensor.

4.2 General Description

Figures 4-1 to 4-3 are the pictures of the monitor, front panel, display screen and rear/top views of the monitor.

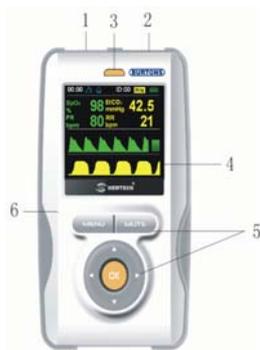


Figure 4-1: Front Panel

Number	Description	Function
1	SpO ₂ Socket	Connects to SpO ₂ Sensor
2	CO ₂ Socket	Connects to CO ₂ Sensor
3	Power Indicator	Indicates the monitor is power on
4	Display Window	Displays measurements
5	Button	Operation buttons
6	Front Cover	Protects the internal components

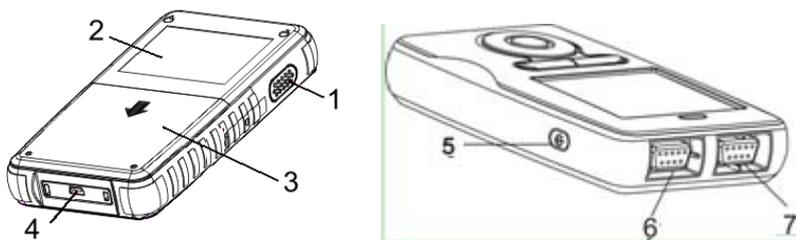


Figure 4-2: Rear/top View

Number	Description	Function
1	Speaker	For pulse tone and alarm sound
2	Rear Panel	Protects inner components
3	Battery Door	Opens/closes to install or unload battery
4	Power Socket	Connects to AC power
5	On/Off Button	Turns on/off the monitor
6	CO ₂ Sensor Socket	Connects to CO ₂ Sensor
7	SpO ₂ Sensor Socket	Connects to 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 cable because it might 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 highlighted precaution information and all specifications.

NOTES

- The monitor is intended to use 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 film that covers the screen. This film is to protect the screen during transportation. Keeping it on during monitoring can make it difficult to read measurement results.

4.3.1 Buttons

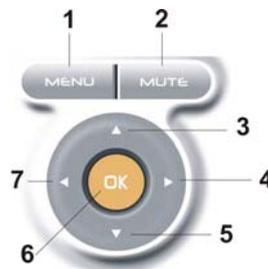


Figure 4-3: Buttons

Number	Description	Function
--------	-------------	----------

Powering Up

1	Menu	Enters or exits submenu.
2	Mute	Turns off current alarm or enables all alarm sound.
3	Up	Moves the cursor upwards or increases values.
4	Right	Moves the cursor to the right or increases volume.
5	Down	Moves the cursor downwards or decreases values.
6	OK	Confirms your selections.
7	Left	Moves the cursor to the left or decreases volume.

4.3.2 Powering Up

● Installing battery

When the monitor is off, press On/Off button shortly to turn on the monitor if it is powered by battery.

NOTES

- You will see the startup screen and then the monitor turns off automatically if the battery is low. The monitor will have no response if the battery is too low. Check the battery capacity.
- 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.

● Self Test

The power indicator is on if the monitor is turned on. It will conduct self test during startup and display below contents:

- (1) Software version.
- (2) Self test in progress showing status check of the disk, power indicator and speaker below the software version number.
- (3) If you hear “dee” sound and the power light is on, the self test is completed successfully. If not, do not continue to use this monitor, contact your representative or manufacturer.

There is a pop-up screen to set up system time manually if there is no time set up in the system or the time is lost. See Figure 4-5.



Figure 4-4: Setting System Time

⚠ WARNINGS

- Make sure that you can hear “dee” sound and the power light is on. If not, do not 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 that the speaker is not blocked or covered. Otherwise, you may not hear alarm sound.

4.3.3 SpO₂ and CO₂ Monitoring

SpO₂ measuring is initiated automatically after turning on the monitor. Follow below procedures to start monitoring:

- (1) Apply SpO₂ sensor correctly and place patient's tongue in position.
- (2) The monitor will search pulse for 10 seconds.
- (3) If pulse search is successful, values of %SpO₂ and PR will display in % SpO₂ and PR areas. Pulse indicator will change together with the pulse. Speaker will generate "dee dee" sound with the pulse.

Terminology:

- % SpO₂: Percent oxygen saturation
- PR: Pulse beats per minute (bpm)

Initiating CO₂ monitoring:

- (1) Connect the CO₂ sensor to the monitor and adapter correctly. Green light in the module is shining, when C500 and C300 working in the normal operating situation.
- (2) Press MENU to enter the setup option and turn on CO₂ switch. "-- --" will appear in EtCO₂, FiCO₂ and RR display area if CO₂ sensor has already been connected without CO₂ input.
- (3) If there is CO₂ input, patient end tidal carbon dioxide value and respiration rate will be displayed in the EtCO₂, FiCO₂ and RR display area.

Terminology:

- EtCO₂: end tidal carbon dioxide value, and has three Units: %, kPa, mmHg (default).
- FiCO₂: indicate fraction of inspiration CO₂ carbon dioxide value. There are 3 units: %, kPa, mmHg (Default).
- RR: respiration rate per minute (bpm).

4.3.4 Information Bar

The information bar displays as shown in figure 4-6, from left to right: time, alarm and mute status, full disc, patient ID and type and battery capacity.



Figure 4-5: Information bar

Item	Icon	Description
		General alarm is on, but single parameter alarm may be turned off.

Alarm		General alarm is off. No alarms other than low battery alarm is available.
Mute		Alarm for all parameters is on.
		Alarm for one or more parameters is turned off.
Data Recording		Saving history data of current user.
Memory Full		Memory full. Saving data stopped.

4.3.5 Status Bar



Item	Icon	Description
Sensor unplugged		Sensor is not plugged in the socket.
Sensor off tongue		Sensor is not attached to tongue.
Search pulse		Pulse searching in progress.
Weak signal		It will be displayed if the patient signal is low.

4.3.6 Pulse Tone Volume



Press Left/Right arrow buttons to adjust pulse volume any time except in trend graph screen.

4.3.7 Battery Capacity Indicator and Recharge

WARNINGS

- Be sure to follow local regulations and recycling instructions regarding disposal or recycling of battery.
- Low battery alarm is high priority alarm which cannot be disabled.

NOTES

- The remaining battery time is estimated according to battery types. This indicator icon  will display when the battery capacity is less than 15 minutes. Remaining battery time may differ from different types of batteries.
- Check the battery periodically for corrosion. Remove the battery if you don't intend to use the monitor for more than three months.

- **Battery Capacity Indicator**

The battery icon in the information bar indicates the remaining battery capacity in a working mode. It will flash and the low battery alarm will be on if the remaining battery time is less than 15 minutes. See Figure 4-7.



Figure 4-6: Low Battery Icon

If the battery is too low, the monitor will pop up a warning message and the monitor will turn off itself as shown in Figure 4-8.

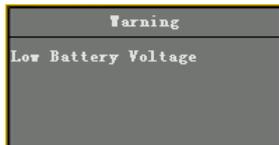


Figure 4-7: Low Battery Warning Message

● **Recharge**

If the monitor is connected to a power cable when the monitor is off, Press the On button , it will start up automatically and display charging screen with the battery icon flashing. The battery icon will appear full after the charging is completed. Press on/off button to enter real-time monitoring screen. If you unplug the power cable when the monitor is off, the monitor turns off automatically. See Figure 4-9.

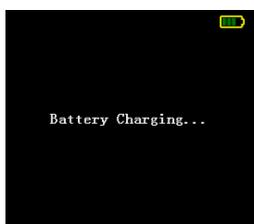


Figure 4-8: Charging Screen

If the monitor is connected to a power cable when it is working, the bars inside the battery icon will flash. Four full bars mean the battery is fully charged. You may continue to use the monitor after you disconnect the power cable.

4.3.8 Powering off

(1) Normal shutdown

Press and hold On/Off button until the progress bar is full to turn off the monitor. The message below displays shutdown in progress. Figure 4-10.

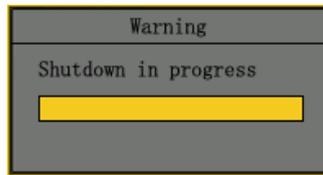


Figure 4-9: Normal Shutdown

(2) Shutdown in Low Battery

The monitor turns itself off automatically when battery is depleted.

The system enters into the state of low voltage status at least 15 minutes before shutdown. The battery icon will flash and history data of current ID will be saved. Change or recharge battery after normal shutdown.

NOTE: No more data will be saved when the battery icon is flashing.

The monitor pops up a message during low battery shutdown, see Figure 4-8, and the shutdown progress can not be terminated.

NOTES

- You can not terminate shutdown progress in low battery status.
- The low battery capacity is estimated by LI battery.
- Press On/Off button with AC adapter in use, the monitor will enter standby mode after the progress bar is full.

⚠ WARNINGS

- In order to keep optimal performance of the equipment, re-start the monitor at least 30 seconds after the last shutdown or power off.
- The history data can be saved only once when the battery icon is flashing. After that the data won't be saved again even if the monitor is normally shut down.

4.4 Device Storage

Remove the battery from the monitor before long-term storage, or if the device won't be used for more than 6 months. This will protect the device from any damage due to possible battery leaking acid.

Keep the device in the original shipping carton and packing materials to protect it from any damage during storage.

4.5 Environmental Protection

To ensure minimum environmental pollution, make sure to dispose the battery appropriately in accordance with your local regulations, ROHS (2002/95/EC) and WEEE (2002/96/EC).

4.6 Performance-related Factors

Inaccurate SpO₂ measurements can be caused by:

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

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

Inaccurate CO₂ measurements can be caused by:

- Filter line entanglement or strangulation.
- Reuse, disassemble, cleaning, disinfecting or sterilizing the single patient use CO₂ airway adapters
- Air flow adapter is damaged.
- CO₂ sensor is damaged.
- CO₂ sensor is wet or has exterior condensation.
- Nitrous oxide, elevated levels of oxygen, helium and halogenated hydrocarbons can influence the CO₂ measurement.
- Air flow adapter windows are dirty.
- CO₂ Sensor windows are dirty.
- Patient's discharges.
- CO₂ sensor has not been zeroed for airway adapter.
- Environment configuration has not been set up for the CO₂ sensor

Environmental conditions and sensor application errors may affect SpO₂ and CO₂ measurements and readings. Refer *Sensor Application* of the manual, as well as Sensor Application Guidance.

5. Displays and Functions

5.1 Main Monitoring Screen

After turning on the monitor, you will enter the main monitoring screen. Its basic function is to display parameters of the patient's vital signals. See Figure 5-1.

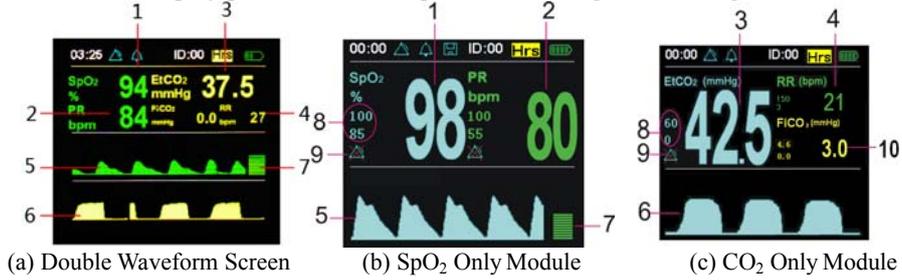


Figure 5-1: Main Monitoring Screen

Item	Description	Function
1	SpO ₂ Value	Displays current SpO ₂ value. Or displays “- - -” without SpO ₂ measurement.
2	PR Value	Displays current PR value. Or displays “- - -” without PR measurement.
3	EtCO ₂ Value	Displays current EtCO ₂ value. Or displays “- - -” without EtCO ₂ measurement.
4	RR Value	Displays current RR value. Or displays “- - -” without RR measurement.
5	SpO ₂ waveform	Displays SpO ₂ waveform. Or displays a straight line without SpO ₂ measurement.
6	EtCO ₂ waveform	Displays EtCO ₂ waveform. Or displays a straight line without EtCO ₂ measurement.
7	Pulse graph	Displays the strength of pulse.
8	Alarm Limits	Upper and lower limits of current parameter.
9	Alarm Switch	The alarm of current parameter is off if the icon is displayed.
10	FiCO ₂ Value	Displays current FiCO ₂ value. Or displays “- - -” without FiCO ₂ measurement.

Note: Press the Up/Down key to switch among the main monitoring screen, the big chart screen, the trend graph screen, and the trend table and event table.

5.2 Big Chart Screen

Press the Down button to enter real-time big chart screen, see Figure 5-2.



(a) SpO₂ and CO₂ Module (b) SpO₂ Only (c) CO₂ Only

Figure 5-2: Big Chart Mode

In the monitoring screen, press MUTE button to disable current alarm or enable all alarms.

5.3 Real-time Trend Screen

5.3.1 Trend Graph Screen

Press the Down button to enter real-time trend graph screen, displaying parameters trend graph of SpO₂, PR, EtCO₂, FiCO₂ and RR. It records 1 event every 10 seconds, 30 minutes per page and a total 6 pages. To shut down the monitor, modify ID, change time and interval will clear any current data and the new real-time trend graph will display. See Figure 5-3. Press Right/Left buttons to select single parameter trend graph screen.

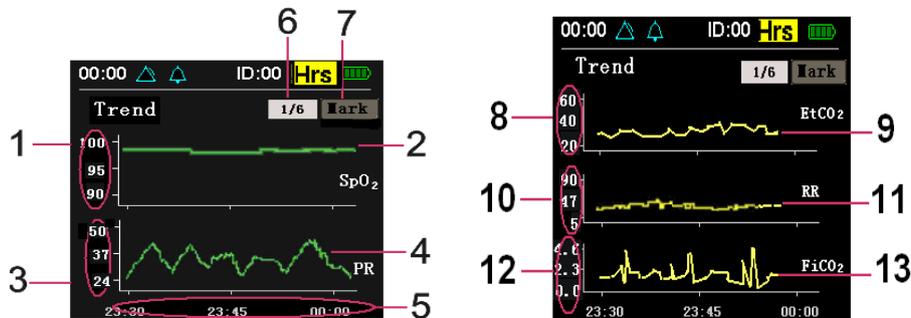


Figure 5-3: SpO₂ and CO₂ Trend Graph Screen

Item	Description	Function
1	SpO ₂ scale bar	Marks the range of SpO ₂ trend graph alarm limits.
2	SpO ₂ trend graph	Draws SpO ₂ trend graph of a time span according to history data for analysis.
3	PR scale bar	Marks the range of PR trend graph alarm limits.
4	PR trend graph	Draws PR trend of a time span according to PR history data for analysis.
5	Time span	Marks the time span according to setup.

6	Page Up/Down	Selects the page of trend required.
7	Marker button	Marks on the trend graph, Maximum 2 marks.
8	EtCO ₂ scale bar	Marks the range of EtCO ₂ trend graph alarm limits.
9	EtCO ₂ trend graph	Draws EtCO ₂ trend in a time span according to EtCO ₂ history data for analysis.
10	RR scale bar	Marks the range of RR trend graph alarm limits.
11	RR trend graph	Draws RR trend in a time span according to RR history data for analysis.
12	FiCO ₂ scale bar	Marks the range of FiCO ₂ trend graph alarm limits.
13	FiCO ₂ trend graph	Draws FiCO ₂ trend in a time span according to FiCO ₂ history data for analysis.

In the trend graph screen, press OK key to enter operation mode. Press Right/Left buttons to move the cursor. Press MENU to exit:

- Page Up/Down: Move the cursor on it and press OK. Press Right/Left buttons to select the desired page.. Press OK key to exit.
- Marker Button: Move the cursor on it and press OK to place a mark of current time on trend graph. The mark will move leftward at the trend graph with time.

NOTES

- The real-time trend data will be cleared when you start up the monitor or change patient ID every time. Graphs are protracted step by step from the right side of the screen to the left until it fills the screen and then the waveform will move leftward. If there is no monitored patient, the trend graph still moves leftward.
- The time span of the current trend is different according to different interval setup. The maximum span can be 18 hours. The history trends will be covered by a new trend if the monitoring time exceeds the limits.
- Shutting down the monitor will cause the real-time trend data to be cleared.

5.3.2 Trend Table Screen

Press Down button to enter trend table screen. See Figure 5-4:



Figure 5-4: SpO₂ and CO₂Trend Table Screen

Operations:

1. Press Right/Left buttons to turn the pages after pressing OK when the cursor is on the page up/down frame. Press OK again to exit.

5.3.3 History Trend

History trend will be stored in three ways as below:

- No data will be stored in disk if patient ID is 00.
- The latest 72-hour data will be stored if patient ID is from 01 to 99. If the disk is full, the full disk icon will display in the status bar and no more data will be recorded.
- The history data is saved every 10 seconds. The recorded data includes the values of SpO₂, PR, CO₂, FiCO₂ and RR.

NOTES

- History trend data will be saved if the monitor shuts down normally. But if the battery is taken out without powering off first during data recording, it may cause data loss or disk damage.
- History trend data will be saved during shutdown process.
- History trend data will be saved if there is a low voltage alarm. Then the monitor enters the low voltage status. Replace battery immediately. No data will be stored in low voltage status, even if the monitor is turned off normally.

5.4 Event Table Screen

Press the Down button to enter event table screen. The event table displays alarm records of SpO₂, PR or EtCO₂, FiCO₂, RR or all these parameters. Refer to figure 5-5.

Date	Time	Type	Des
1/10			

Figure 5-5: Event Table

Operations:

1. Press Right/Left buttons to turn the pages after pressing OK when the cursor is on the selective frame. Press OK again to exit.

NOTE

- The event table will only record alarms of recent 10 pages.
- Events recorder table will not be saved when monitor outage or suddenly

shutdown.

5.5 Menu Options

Press MENU key to access menu options, as shown in figure 5-6.



Figure 5-6: Menu Screen

Operations:

1. Use Up and Down keys to scroll through different options. Note: You may scroll past the options shown to reach additional options.
2. Press OK to select your option.
3. Press MENU to exit.

5.5.1 Setting Alarm

WARNINGS

- The monitor alarm function will be affected by environmental light, EMC, noise, etc.
- The alarm sound and data flashing on the screen must be audible and visual to the operator.
- If careless disconnect sensor, shut alarm main switch will close technical alarm indication.



Figure 5-7: SpO₂ and CO₂ Set Alarm limits

Operations:

1. Use Up, Down, Right and Left buttons to move the cursor. When the cursor is on OK or Cancel, press OK on device to save or cancel, and exit. You may also press MENU to exit.
2. Press OK button to edit the fields you wish to change. Use Up/Right buttons to increase the value. Use Left/Down buttons to decrease the value. Press OK to save and exit.
3. When the cursor moves to CO₂ option, press OK button to switch to set alarm limit of EtCO₂ and RR. (Only for SpO₂ and CO₂ module).

NOTE

- If the alarm limits are different from default values, there is a dot displaying next to the limit values. The dot will not disappear until the limits are resumed to default.
- User to restore the factory default setting to default alarm limits.

⚠ WARNINGS

- No one other than trained personnel shall set up alarm limits. Upper limits should not be lower than lower limits.
- The alarm system will be invalid if you set alarm upper/lower limits out of the range of alarm limits.
- If the patient needs special care, improper alarm limits setting will cause the delay or invalidation of alarm signals.
- When monitor is suddenly outage and open it again, the alarm setting is same as before. And History trend data will be saved.
- Make sure that the default alarm settings are appropriate for the specific patient being monitored.

5.5.2 Setting SpO₂

In the setting menu, you can choose “Set SpO₂” option, as shown in Figure 5-8.



Figure 5-8: Set SpO₂ (Not valid for CO₂ only module)

Operations:

1. Use Up, Down, Right or Left buttons to move the cursor. When the cursor is on OK or Cancel button, press OK to save or cancel, and exit. Alternatively, you may press MENU to exit.
2. Move the cursor to “Pleth Speed”, “Averaging Time” or “Pleth Visual Alert”, press OK button first and then use Up/Down buttons to change the values. Press OK to

confirm your setting.

No.	Name	Option
1	Pleth Speed	High, Low
2	Average Pulse Rate	4,8,16 indicate get SpO ₂ value from average of 4/8/16 waveforms
3	Pleth Visual Alert	1s, 10s, 30s. This setting determines how quickly the color of the waveform changes during an alarm condition to provide a visual alert. (Red for high priority alarm and yellow for middle priority alarm.)

5.5.3 Setting CO₂

In the setting menu, you can choose “Set CO₂” option which is the same for both mainstream and sidestream CO₂.

Operations:

1. Connect CO₂ sensor to the monitor first. (See Chapter 3 for details)
2. Press MENU and select “Set CO₂”. Press OK to see the following:

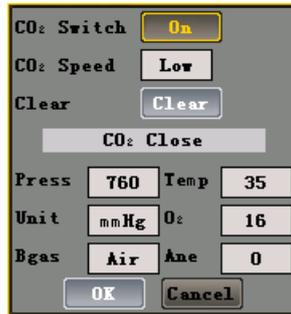


Figure 5-9: Set CO₂ (Not valid for SpO₂ only module)

Note: The parameters shown in this screen are factory default values.

3. Open the “CO₂ Switch”. Press OK to activate CO₂. The main screen will show message saying “CO₂ is opening”, “Sensor warm up” and “CO₂ Compensations Required”, “CO₂ is opening”, “CO₂ Compensations Required”, “CO₂ need zeroing” are displayed in the screen when opening the C500 module. C300 module has Auto Zero function. The interface displays “Zero in Progress”.
4. Press MENU again to select “Set CO₂”. Press OK to change CO₂ waveform speed and CO₂ configuration parameters according to operating environment (i.e. air pressure, temperature).
5. Use Up, Down, Right or Left buttons to move the cursor. When the cursor is on OK or Cancel, press OK to save or cancel and exit. Pressing MENU button will also exit the screen.
6. Calibration: The unit will perform auto calibration with the data put in. When the operating environment changes, the current carbon dioxide value needs to be

entered through the following:

- (1) Input the barometric pressure to the “Press” field, the unit is kPa;
- (2) Input the room temperature to the “Temp” field, the unit is °C;
- (3) O₂ Compensation Range: 0 to 100%, Resolution: 1%, Default: 16%.
- (4) Balance Gas is Air.

NOTE

- According to the configuration and accessories in Chapter 9, different module is configured different accessories. And when plugged in and opening different CO₂, the messages on the screen is different.
- C300 module has Auto Zero function .It is normal that device show “Zero in Progress”during working.

No.	Parameter	Description	No.	Parameter	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 Set Patient Information

In the setting menu, you can choose “Patient Info” menu to set patient ID, gender and type, as shown in Figure 5-10.

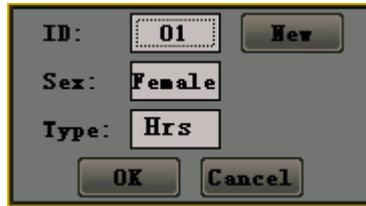


Figure 5-10: Set Patient Information

Operations:

1. Use Up, Down, Right, or Left buttons to move the cursor. When the cursor is on OK or Cancel button, press OK to save or cancel, and exit. Pressing MENU will also let you exit the screen.
2. You can set up patient ID from 0 to 99, patient gender, and patient types (dog or cat).
3. When you choose the “New” button, the system will auto-generate a new ID. The New button is not valid if there is no available ID.
4. If you choose an ID that has never been used, pressing OK button will change ID number and then exit. If the ID you choose is in use, 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. If you choose to cancel, you will return to setting ID screen.

5.5.5 Adjust Volume

WARNINGS

- Do not pause an audible alarm or decrease its volume if it could compromise patient safety.



Figure 5-11: Adjust Volume

Note: When the device is in operation, you may change the volume of the audible pulse beep simply by pressing the Right (increase) or Left (decrease) buttons. The steps below allow you to change the default setting that will be in place upon power-up.

Operations:

1. Use Up, Down, Right, or Left buttons to move the cursor. When the cursor is on OK or Cancel, press OK to save or Cancel, and exit. You may also press MENU to exit.
2. Adjust the volume with the Right and Left button. Press the Up or Down key to move the cursor, and then press OK to confirm. Note: Monitor will power-up with the last confirmed alarm volume setting.

5.5.6 Setting Date and Time



Figure 5-12: Set Date and Time

Note: Date format is yyyy-mm-dd.

Operations:

1. Use Right and Left buttons to move the cursor. Press OK to change values. Press OK again to exit.
2. When the cursor is on OK or Cancel button, press OK to save or cancel and exit.

5.5.7 Setting Trend

Select the “Set Trend” submenu in the setting menu and you can adjust the trend record steps, as shown in Figure 5-13.

⚠ WARNINGS

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



Figure 5-13: Set Trend

Operations:

1. Use Up, Down, Right, or Left buttons to move the cursor. When the cursor is on OK or Cancel, press OK to save or cancel and exit. Pressing MENU can also exit.
2. Move the cursor to step, press the Up/Down key to change the step value. The default value is 10 seconds.

Item	Name	Option
1	Runtime Trend Step	1s, 5s, 10s, 30s, 60s. It means the trend data saving intervals in the monitor.
2	History Trend Step	1s, 5s, 10s, 30s, 60s. It means the trend data saving intervals you can watch on a PC.

Note: Any adjustment of trend intervals or date/time will cause the current run time trend date being collected to be erased.

5.5.8 Module Options



Figure 5-14: Set Module

There are three modules: SpO₂ and CO₂, SpO₂ Only and CO₂ Only. You can choose any of these to run after entering “Set Module” submenu.

5.5.9 Resume Settings

Enter “Reset Setting” submenu to resume all settings you have changed, as shown in Figure 5-15.



Figure 5-15: Resume Settings

5.5.10 System Information

System information includes the information of hardware and software, see Figure 5-16.



Figure 5-16: System Information

5.6 Audible and Visual Indications

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

No.	Description	Visual indication	Audible indication
1	Startup	During self test, the indicator light will flash red, yellow and green.	“dee”
2	Pulse Sound	/	“dee”
3	Sensor Unplugged	The red light will blink and the icon  will be displayed.	Dee dee dee - dee dee Dee dee dee - dee dee Every 10s
4	Sensor Off	The red light will blink and the icon  will be displayed.	Dee dee dee - dee dee Dee dee dee - dee dee Every 10s
5	No Pulse	The red light will blink and the icon  will be displayed.	Dee dee dee - dee dee Dee dee dee - dee dee Every 10s
6	Poor Signal	The icon  will be displayed.	Dee dee dee - dee dee Dee dee dee - dee dee Every 10s
7	Low Voltage	The red light and the icon  will blink.	Dee dee dee - dee dee Dee dee dee - dee dee Every 10s
8	Alarm Sound	The red light blinks in high priority. The yellow light blinks in medium priority. The related parameter values will blink at the same time.	Dee dee dee Every 10s for high priority; Every 25s for medium priority

6. Monitoring SpO₂

6.1 General

SpO₂ 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 monitoring SpO₂ value reading would be 97.

SpO₂ measurement is a non-invasive, continuous measurement through a SpO₂ sensor attached to a patient tongue. The sensor is connected directly to SpO₂ module. There are three types of display for SpO₂: percentage (%), pulse rate, and SpO₂ waveform.

6.2 Theory of Measurement

Pulse oximetry is based on two principles: 1. The oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e. Spectrophotometry), and 2. 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 SpO₂ 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 hemoglobin, 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 SpO₂ 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 non-pulsatile absorbers such as tissue, bone, and venous blood.

The Pulse oximeter determines SpO₂ 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)

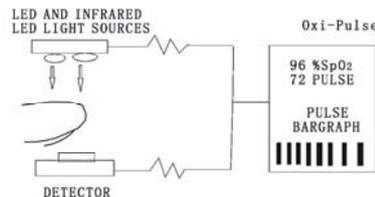


Figure 6-1: SpO₂ Theory of Operation

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 SpO₂) to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

6.3 Abnormal Conditions of SpO₂ Measurement

After turning on the monitor, the following may occur due to the wrong sensor placement or other operations:

- (1) Sensor off tongue: The SpO₂ sensor has already been inserted into the monitor, but not attached to the patient, the icon " " will blink and "- - -" will display in SpO₂ and PR area with high priority alarm sound every 10 seconds.
- (2) Pulse search mode: If the patient is connected with the sensor, the monitor attempts to search pulse. The icon " " will blink. At the same time, "- - -" will display in %SpO₂ and PR areas. Normally the search lasts approximately 10 seconds. If the pulse search fails, the monitor generates high priority alarm.
- (3) Sensor unplugged. The icon " " will display.
- (4) Weak signal. The icon " " will display.

6.4 Applying SpO₂ Sensor

SpO₂ sensors and a SpO₂ saturation module are the components to monitor blood oxygen level of saturation (SpO₂) and/or the pulse rate (PR) and other physiological parameters of patients. The device is for use in (but not limited to) specialized medical facilities, patient wards, operation rooms, first-aid rooms, emergency rooms and observation rooms.

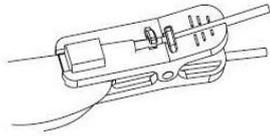
NOTES

- The sensor is not suitable for continuous and long term SpO₂ monitoring which may cause skin to become irritated, reddening, blistering or necrosis.
- The SpO₂ sensor has passed biological compatibility tests such as cytotoxic test, intracutaneous stimulation and scratch test.

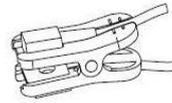
Procedures:

Normally, SpO₂ monitoring is performed with a SpO₂ Y-type sensor affixed to the animal's tongue. Other well-vascularized areas are optional sites.

- (1). Choose the sensor and clips appropriate for the patient. Inspect them carefully to make sure they are not damaged;



Veterinary sensor with large clips



Veterinary sensor with small clips

(Applicable sites: tongue, paws and well-vascularized areas)

Figure 6-2: Placement of the Sensor

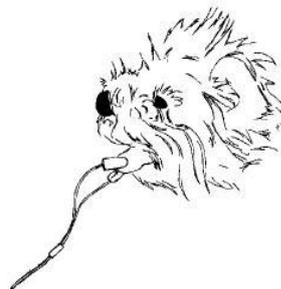
(2). Connect the sensor to the monitor, Before each use, clean the surface of the sensor and cable with a soft gauze pad by saturating it with a solution such as 70% isopropyl alcohol. If low-level disinfection is required, use a 1:10 bleach solution;

(3). Attach the sensor to the proper site of the patient.

(4). Power on the monitor.

If necessary, the lingual clips may also be positioned on toe, lip, cheeks, ear, prepuce or vulva of the animals. Moisten the area with isopropyl alcohol, water, and clip hair if needed. To get better reading on the smaller tongues, fold the tongue up and pass the light through both layers. Do not fold the tip of the tongue back because you will restrict blood flow to the tongue.

The small clips prove effective on the small breeds and especially on smaller cats' tongue. The small clips also work well on larger animals.



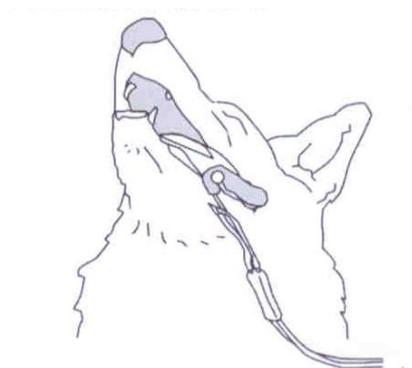
Sensor with small clips

In order to protect the animal from injury by clipping, Burtons has two sizes of cushions for its clips as shown below.



Large & Small clips with cushions

Lingual sensor placement



Lingual sensor placement

NOTES

- 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 to which the sensor is applied.

6.5 Measurement Restrictions

6.5.1 Inaccurate SpO₂ measurements may be caused by:

- High frequency electrosurgical interference from a monitor or ambient electrical instruments connected to the system.

- Excessive patient movement.
- Inductive current generated from MRI may cause burn.
- Outside light radiation.
- Incorrect sensor application or use.
- Sensor temperature (suitable temperature range should be 28°C - 41°C)
- The same limb is used for sensor, NIBP cuff, artery tube or infusion tube.
- Presence of COHb, MetHb and dyestuff.
- Weak signal.
- Bad perfusion on sensor site.
- Coma, anemia, low temperature and insufficient blood flow caused by drugs.

NOTES

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

6.5.2 Inaccurate measurements can also be caused by:

- Incorrect application of the sensor;
- 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
- Insufficient blood supply.

6.5.3 Loss-of-pulse signal can occur with any of the following:

- The sensor is too tight;
- Defibrillation;
- A blood pressure cuff is inflated on the same extremity as the one to which an SpO₂ sensor is attached;
- There is arterial occlusion next to the sensor;
- Peripheral insufficient blood supply;
- Loss of pulse or heart arrest.

Select an appropriate sensor, apply it as directed, and read all warnings and cautions presented in the directions for use of 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 lamps (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight

can interfere with the performance of a SpO₂ 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:

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

NOTES

- Failure to cover the sensor site with opaque material in high ambient light conditions may result in inaccurate measurements.
- You can select sensor types to determine 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 wipe the surface dry. Wipe the sensor with cloth with alcohol if necessary. Note: Do not spray or pour any liquid directly onto 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 continuous measurement of SpO₂. Inspect the sensor site as directed in the sensor Directions for Use.
- Inspect the monitoring site every 4 hours for skin integrity.

7. Monitoring CO₂

7.1 General Description

The CO₂ Sensor is used for continuous measurement of CO₂, FiCO₂ and respiratory rate. The sensor measures CO₂ by using the infrared absorption technique. The principle is CO₂ molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO₂ concentration. When an IR beam is passed through a gas sample containing CO₂, 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 CO₂ concentration in the sample. The CO₂ Sensor's response to a known concentration of CO₂ 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 Theory of Measurement

CO₂ monitoring is to monitor the respiration of a patient by detecting the concentration of CO₂ generated during respiration. The maximum concentration of CO₂ at the end of exhalation is called *End-Tide* CO₂ (EtCO₂). The minimum concentration of CO₂ at the end of inspiration is called *Inspiration* CO₂ (FiCO₂). CO₂ is generated by cells in the body during metabolizing, and is breathed out via breathing system. The concentration of CO₂ breathed out from the lung reflects directly the situation of metabolizing and breathing system. If the concentration of CO₂ is high, it means that metabolism is over active, such as blood poisoning or acute fever. If the concentration of CO₂ 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 CO₂ is used to warn the doctor of the abnormal breathing and metabolizing during anaesthesia.

The measurement value of CO₂ is represented by a pressure level, with the unit: "mmHg" or "%". Generally, the maximum acceptable value is 38mmHg (5%) when air pressure is 760mmHg. The concentration of CO₂ varies rapidly from 0% to 5%. To detect the concentration of CO₂ accurately, the monitor needs to be very sensitive.

The monitor is used to measure EtCO₂ and respiration rate of dog and cat patients.

7.3 Applying the CO₂ Sensor

- The CO₂ Sensor is used to continuously monitor carbon dioxide and report EtCO₂, inspired CO₂ and respiratory rate of intubated and non-intubated patients.
- The CO₂ Sensor is intended for use in, but not limited to, intensive care units, anesthesia/medical/surgical units, LTAC units, emergency rooms, sleep labs, intra-hospital and inter-hospital transportation.
- For use in monitoring patients in respiratory distress, respiratory arrest asthma, COPD or other disorders where the patient's EtCO₂ and capnogram will be helpful in the treatment of the patient.
- For use in monitoring patients pre- and post intubation.
- To assist the patient in the management of "mechanical" ventilator.

7.4 CO₂ Sensor Adapter Zeroing

The sensor is compatible only with appointed CO₂ airway adapters. Each airway adapter has its own optical characteristics. The adapter zeroing allows the CAPNOSTAT to adjust to the optical characteristics of each different adapter types. Zeroing request may occur for the first time when a particular CO₂ Sensor is connected to a particular Host or plugged in/off, or if a change is detected by CO₂ Sensor. When the message “CO₂ need zeroing” appeared, please zero the module manually.

Procedures of Adapter Zeroing:

- (1) Connect the CO₂ Sensor to the Monitor.
- (2) Turn on the monitor. If it is the first time you switch on CO₂, place the CO₂ adapter into a clean and dry CO₂ sensor that is exposed to air and away from the sources of CO₂, including ventilator, patient and your own breath. Do not operate within 20 seconds.
- (3) Press MENU and select “Set CO₂” option. Set “On” for “CO₂ Switch”.
- (4) Choose “Clear” and CO₂ information column will display “CO₂ Zeroing” and “CO₂ Zero OK”. In the process of zeroing, do not make any operation (e.g. breathing or key-pressing). Otherwise, the zeroing operation will fail. The time for zeroing is 15-20 seconds. CO₂ information note field will disappear after Completing Zeroing, “setup CO₂” shows operational status, it means zeroing process is completed. Press “MENU” key turn back to main window.

Main window “CO₂ waveform” will change to thick lines when occur following:

- 1) Check Airway Adaptor
- 2) CO₂ Compensations Required
- 3) Sensor warm-up
- 4) NO breaths Detected
- 5) Zero in Progress

Completing above process, CO₂ waveform will turn back to original baseline.

NOTE

- For optimal performance, connect CO₂ Sensor to an adapter and wait for 20 seconds before the Adapter Zeroing procedure.
- Unplug adaptor, this monitor main window will hint checking CO₂ adaptor and occur high level alarm.
- There is indicator light in C500 and C300 module. The green light is shining in normal operating situation, and no light in plug-off situation. But there is no indicator light in Capnostat 5 EtCO₂ module.

⚠ WARNINGS

- CO₂ readings and respiration rate can be affected by certain ambient environmental conditions, sensor application errors, and patient conditions.
- Check whether the CO₂ adapter is damaged or not. Do not use damaged CO₂ adapters.
- If CO₂ waveform (Capnograph) appears abnormal. Inspect the CO₂ airway adapters and replace if necessary.
- Replace CO₂ airway adapters if excessive discharge is observed.
- Monitor CO₂ waveform (Capnograph) for elevated baseline. Elevated baseline can be caused by sensor or patient.

8. Configuration and Accessories

8.1 Maximum Configuration of 129-850

No.	Model	Description	Quantity	Unit
1	129-850	Monitor	1	pc
2	Y100V	SpO ₂ Sensor	1	pc
3	Capnostat 5 or LoFlo	Mainstream CO ₂ Sensor Or sidestream CO ₂ Sensor	1	pc
4	NT655548-1S2P	Rechargeable Battery	1	pc
5	FW7401M/05	AC Adapter	1	pc
6	/	Protective Jacket	1	pc
7	129-850	Operating Manual	1	pc
8	/	Maintenance Card	1	pc

Note: This maximum configuration is just suitable for the SpO₂ and CO₂ Module, not for SpO₂ only module or CO₂ only Module.

8.2 Optional Accessories for 129-850

No.	Model	Description	Manufacturer
1	7007-01	Reusable Airway Adapter for animals more than 40kg	/
2	7053-01	Reusable Airway Adapter for animals less than 40kg	/
3	LH900	Mainstream CO ₂	Prior care
4	C300	Sidestream CO ₂ Sensor	National
5	C500	Mainstream CO ₂ Sensor	National

9. Troubleshooting and Maintenance

WARNINGS

- If accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternative means and then with this monitor to make sure it is working properly.
- The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside.

NOTES

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

If you discover a problem while using the monitor, do not continue to use or try to fix it. Contact qualified service personnel or representative. The monitor service manual, which is for use by qualified service personnel, provides additional troubleshooting information.

9.1 Errors and Solutions

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 displayed parameters or indicator icons do not light up during self test.
 - Do not use the monitor and contact technical service department.

3. Indicator icon of searching pulse is blinking more than 10 seconds.
 - Check if the sensor is suitable or connected correctly following sensor directions for use. Check the sensor and its cable connection. Try this sensor on another person. Try another sensor or another extension cable.
 - Blood insufficient supply may cause failure of detecting pulse. Check the patient or try the monitor on yourself. Replace the sensor or try another sensor.
 - Interference from patient movement may affect pulse searching. Keep the patient quiet. Check the sensor placement. Replace the sensor if necessary or move the sensor to a new site.
 - The probe may be placed too tight. Ambient 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.
 - Remove disturbing equipment.

4. No pulse shown on the indicator bar.
 - Check sensor connections with the patient cable as well as the monitor.
 - Replace the sensor.
 - Try a new sensor or contact your local service group for help.

5. PR, SpO₂, EtCO₂, RR, FiCO₂ or Pulse rate is erratic, intermittent, or incorrect. (May caused by EMI)

- Reposition the SpO₂ and CO₂ sensor.
- Patient must remain still to obtain an accurate measurement.
- Power off nearby equipment and then power up again to locate the interfering equipment.
- Change the orientation and position of the interfering equipment.
- Keep the interfering equipment far away from this monitor.

6. Sudden shutdown of the monitor.

- Replace or recharge battery.
- Check power cable connection.
- If the above remedies are not effective, contact authorized service representative.

7. Instrument halts or has no response for the monitor.

- Remove the battery.
- Reinstall the battery and start it manually .
- If the above remedies are not effective, contact authorized service representative.

8. CO₂ setting interface is zero upon powering the unit on.

- Restore factory default value.

9.2 Technical Assistance

If you need technical information and support or to order accessories and operating manuals, please contact your local representative, and specify the software's version number and the serial number of this monitor.

9.3 Factory Default Values

Alarm parameter (unit)	Default upper alarm limit		Default lower alarm limit	
	dog	cat	dog	cat
EtCO ₂ (mmHg)	60	60	0	0
FiCO ₂ (mmHg)	4.6	4.6	0	0
RR (bpm)	150	150	3	12
SpO ₂ (%)	100	95	85	80
PR (bpm)	100	200	55	100

9.4 Product Return

For return or repair of the monitor, call the local representative for a RMA number and shipping instructions.

To pack the monitor for return, disconnect all cables. It is not necessary to return accessories. Pack the monitor to be returned in its original shipping carton, if available. If not, use a suitable carton with appropriate packing materials to protect the monitor during transportation.

9.5 Maintenance and Cleaning

WARNINGS

- Covers 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 onto the monitor or accessories. Otherwise it will cause damage.
- Do not immerse the monitor in liquid or use caustic or abrasive cleaners.
- If disinfection is required, wipe the monitor surface with a soft cloth moistened with commercial nonabrasive cleaner. Do not allow any liquid to enter any of the monitor's openings.
- Do not touch or rub the display window with abrasive apparatus, brush, shaggy material or any other stuff that may cause damage to the display screen.
- If there are any internal parts of the monitor exposed, please contact qualified service personnel. Follow your local regulations regarding disposal of hospital waste.
- Dispose or recycle of battery and retired sensors and the monitor accessories according to standard operating procedures or local regulations for the disposal of contaminated medical waste.
- This monitor cannot use disabled battery. Install new ones.

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

9.5.1 Cleaning and Disinfecting the Monitor

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

9.5.2 Cleaning and Disinfecting SpO₂ Sensor

- You can use a soft cloth dampened with 70% alcohol to wipe the SpO₂ sensor, and then dry it completely with dry cloth. The same for cleaning SpO₂ sensor LED and receiver. Clean and disinfect reusable SpO₂ sensor. Read SpO₂ sensor directions carefully before cleaning. Every type of SpO₂ sensor has its own way to clean.
- If low-level disinfection is required, use a 1:10 bleach solution.

9.5.3 Disinfecting Cable

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

9.5.4 Cleaning and Disinfecting CO₂ Sensor and Adapter

A. Cleaning and Disinfecting CO₂ Sensor

- Use a cloth dampened with isopropyl 70% alcohol, 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 connector is cleaned and dried before reuse.

B. 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 procedures.):

- Clean by rinsing in a warm soapy solution followed by soaking in a liquid disinfectant such as 70% isopropyl alcohol, a 10% aqueous solution of sodium hypochlorite (bleach), a 2.4% glutaraldehyde solution such as Cidex®, Steris System 1® or ammonia. It should be rinsed out with sterile water and dried.
- Can be disinfected by means listed below:
 - (1) Steam Autoclave - adult adapter only;
 - (2) Immerse and soak in Cidex® or equivalent 2.4 glutaraldehyde solution for 10-hour soak.
 - (3) Immerse and soak in Perasafe® or equivalent 26% peracetic acid solution for a 10-minute soak.
 - (4) Cidex® OPA - follow the manufacturer instructions for use.

Disposable adapter:

- 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 CO₂ airway adapter. Irreparable damage may occur to the CO₂ windows.

C. Maintenance Schedule

CO₂ Sensor should be compared against calibration gas every 12 months.

NOTE: Accuracy is affected by temperature and barometric pressure.

D. CO₂ Accuracy Check

The following procedures are recommended to be performed as part of a periodic maintenance schedule to check CO₂ accuracy of the sensor.

- (1) Zeroing. Refer to chapter 7.4 *CO₂ Sensor Adapter Zeroing*.
- (2) Calibration. Open the MENU and select "Set CO₂". Set up values of all parameters (pressure, temperature, unit, oxygen compensation, etc.) according to the actual environment. Press OK key to confirm your calibration.

NOTES

- Do not autoclave, ethylene oxide sterilize, or immerse the monitor and its accessories in liquid.
- Turn off the monitor before cleaning.
- Do not immerse SpO₂ and CO₂ sensors in liquid.

 **WARNINGS**

- If there is any internal part of the SpO₂ and CO₂ sensor exposed, please contact qualified service personnel for disposal.

9.6 Periodic Safety Checks

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

- Inspect the equipment for mechanical and functional performance, e.g. speaker, indicator light, button response.
- 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.

9.7 Guarantee

The manufacture provides one-year-warranty for the monitor and CO₂ sensor and three-month quality warranty for SpO₂ sensor.

The warranty does not cover the followings:

- The monitor label of serial number is torn off or can not be recognized.
- Monitor damage caused by misconnection with other devices.
- Monitor damage caused by accidents.
- Changes performed by users without prior written authorization of the manufacturer.

Appendix A: Specifications

A.1 Basic parameters

SpO₂, PR, EtCO₂, RR, FiCO₂

A.2 Mean Time Between Failures

≥1000 hours

A.3 Normal Working Environment

- Environment temperature range: (5~40) °C,
- Relative Humidity: ≤ 95 %,
- Atmospheric Pressure: (700~1060) hPa,
- Power Voltage: AC 100V-240V,
- Power Frequency: 50/60 Hz,
- Battery type: Li battery.

A.4 Safety Requirements and Classifications

- Electric shock type: Type II equipment with internal power supply.
- Electric shock degree: All application parts are BF type.
- Harmful liquid material proof degree: IPX2
- Disinfection: Follow manufacturer's recommended methods.
- Safety on flammable gas: Not suitable to use where flammable gas is present.
- The monitor has applicable parts.
- Power supply:
 - Li battery:
 - Internal power supply: 3.7~4.2V
 - II type power adapter : Input AC100-240V, 50/60Hz, Output DC 5V, (operation power) .
- The monitor has signal input and output parts, i.e., buttons, LCD, wireless interface.
- When using external power supply, the monitor is a continuous working system. When using battery, working time is about 3.5 hours for SpO₂ and CO₂.

A.5 SpO₂

- Measurement range: (0-100)%.
- Measurement accuracy: (70-100)% , ±2%,
(0-69)% , not required

A.6 PR

- Measurement range: (30~450)bpm
- Measurement accuracy: (30~300) bpm , 1 bpm or ±2%, whichever is greater,
(301~450) bpm, not required

A.7 EtCO₂

- Measurement range: 0~150mmHg.
- Resolution: 0.1mmHg (0~69mmHg),
0.25mmHg (70~150mmHg).

- Measurement accuracy: ± 2 mmHg (0~40mmHg)
 $\pm 5\%$ (41~70mmHg)
 $\pm 8\%$ (71~100mmHg)
 $\pm 10\%$ (101~150mmHg)

A.8 FiCO₂

- Measurement range: 3~50mmHg.
- Measurement accuracy: ± 2 mmHg (3~40mmHg)
 $\pm 5\%$ (41~50mmHg)

A.9 RR

- Measurement range: 0~150 bpm
- Measurement accuracy: ± 1 bpm

A.10 Alarms

- Alarm Priorities:

Priority Alarms	High	Medium
Technical alarm	Low voltage, Loss of pulse, Sensor off, Cable off, CO ₂ sampling line off, No breath.	/
Physiological alarm	Parameter's value exceeds limits(The priority can be adjusted to high or medium)	
Audible alarm	Dee,Dee,Dee -Dee,Dee Every 10s	Dee,Dee,Dee Every 25s
Figures	Displays "- - -" with related icon indication. Refers to chapter 5.1.	Numeric blinking Frequency 0.625Hz
Indicator light	Blinking, Red Frequency 2Hz	Blinking, Yellow Frequency 0.5Hz
Event	Record the event, such as the date, time, parameters, etc.	

- Alarm Types:

- Physiological alarm: Patient's physiological parameters exceed limits.
- Technical alarm: System failure to lead wrong results, i.e., sensor off.
- General alarm: No harm to patient health but needs attention, i.e. Battery low voltage.

A.11 Factory Default Values of Alarm Parameter

Alarm Parameter (unit)	Default Upper Alarm Limit		Default Lower Alarm Limit	
	dog	cat	dog	cat
EtCO ₂ (mmHg)	60	60	0	0
FiCO ₂ (mmHg)	4.6	4.6	0	0
RR (bpm)	150	150	3	12
SpO ₂ (%)	100	95	85	80
PR (bpm)	100	200	55	100

A.12 Limits Setting and Tolerance of Upper/Lower Limits

Alarm Parameter	Range of Upper Limit	Range of Lower Limit
SpO ₂	21%~100%	20%~99%
PR	35 bpm~300 bpm	30 bpm~245bpm
EtCO ₂	5~100mmHg	0~99mmHg
FiCO ₂	0.8~50mmHg	0~49mmHg
RR	1~150bpm	0~149bpm

A.13 Continuous Working Time

Power supply: Li battery or external power source. The monitor switches to external power source immediately when connected to AC power.

Internal power continuous working time: SpO₂ & CO₂ about 3.5 hours.

A.14 Trend Data Storage

- Memory of trend data: Up to 99 patient IDs, 72h trend data per ID
- Stored parameters of trend data: SpO₂, PR, EtCO₂, RR, FiCO₂Time etc.

A.15 Dimensions and Weight

Item	Dimensions L x W x H (mm)	Net Weight (kg)	Gross Weight (kg)
Monitor	125x73x23	0.137	0.23 (with battery)
Charging Adapter(Li battery)	92 x40x27.5	0.153	-

A.16 Packing, Transportation and Storage

■ Packing

Place the monitor in a plastic bag, and place it in a corrugated carton filled with 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: $-20^{\circ}\text{C} \sim +55^{\circ}\text{C}$;
- b. Relative humidity range: $\leq 95\%$;
- c. Air pressure range: $500\text{hPa} \sim 1060\text{hPa}$.

■ Storage

The monitor should be stored indoors with a temperature range: $-20^{\circ}\text{C} \sim +55^{\circ}\text{C}$, relative humidity $\leq 95\%$, no corrosive gas, and with good ventilation.

A.17 Compliance Standards

Standards of 129-850

Requirement	Standards	
General Safety	EN60601-1:2006	Medical electrical equipment-Part1: General requirements for basic safety and essential performance
	EN60601-2-49:2006	Particular requirements for the safety of multifunction Patient monitoring equipment
EMC conformity	EN60601-1-2:2007	Medical equipment-Part1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
Usability requirement	EN 60601-1-6:2007	Medical electrical equipment Part 1-6: general requirements for basic safety and essential performance collateral standard: usability
Software requirement	EN62304: 2007	Medical device software-Software life cycle processes
Alarm conformity	IEC60601-1-8:2007	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
SpO ₂ Particular standard	EN ISO9919:2009	Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
CO ₂ Particular standard	EN ISO 21647:2004	Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors
Biological compatible requirement	ISO 10993-1: 2009	Biological evaluation of medical devices part-1:Evaluation and testing ISO 10993-1
Risk management requirement	ISO 14971:2007	Medical devices—Application of risk management to medical devices
Label and symbol	EN:980:2008	Graphical symbols for use in the label of medical devices
Information supplied by the manufacturer	EN 1041:2008	Information supplied by the manufacturer with medical devices
	EN ISO 14155-1:2009	Clinical investigation of medical devices for human subjects –General requirements

Appendix A

Clinical requirement	ENISO 14155-2:2009	Clinical investigation of medical devices for human subjects –Clinical investigation plans
	Guidance of clinical evaluation Med dev 2.7.1V3	Evaluation of clinical data: a guide for manufacturers and notified bodies

Appendix B: EMC (Electro-Magnetic Compatibility)

Caution: The monitor complies with the limits for medical devices to EN60601-1-2: 2007, Medical Device Directive 93/42/EEC, and this monitor has been tested for CISPR 11 class A.

Guidance & Manufacturer's Declaration-Electromagnetic Emissions for All EQUIPMENT and SYSTEMS

Guidance and Manufacturer's Declaration-Electromagnetic Emission		
The 129-850 is intended for use in the electromagnetic environment specified below. The user of 129-850 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The 129-850 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 129-850 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 129-850 is intended for use in the electromagnetic environment specified below. The user of 129-850 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 floors 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 atypical 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 129-850 is intended for use in the electromagnetic environment specified below. The user of 129-850 should assure that it is used in such an environment.		
Immunity test	Conducted RF IEC 61000-4-6	Radiated RF IEC 61000-4-3
IEC 60601 test level	3 Vrms 150 kHz to 80 MHz	3 V/m 80 MHz to 2.5 GHz
Compliance level	3 Vrms	3 V/m
Electromagnetic environment – guidance	<p>Portable and mobile RF communications equipment should be used no closer to any part of the 129-850 including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:</p> $d = \left[\frac{3.5}{V1} \right] \sqrt{P};$ $d = \left[\frac{3.5}{E1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz};$ $d = \left[\frac{7}{E1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}.$ <p>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: </p>	
NOTE1 At 80 MHz. 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.		
<p>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 129-850 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 129-850.</p> <p>b. Over the frequency range 150 kHz to 80MHz. Field strengths should be less than 3 V/m.</p>		

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the EQUIPMENT or SYSTEM -For EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Monitor			
The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the 129-850 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 129-850 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 $d = \left[\frac{3.5}{fV} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{fV} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{fV} \right] \sqrt{P}$
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 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 the equipments in the vicinity of the monitor off and on to locate the source of the interference.
- Reorient or relocate other interfering devices.

- Set up/ increase the isolation measures between the interfering equipment and this monitor.