DRE Waveline EZ

User Manual

DRE

DRE Waveline EZ

Patient Monitor

USER'S MANUAL

STANDARDS AND CLASSIFICATIONS

The manufacturer of this product maintains a quality management system that fulfills the requirements of Annex II of Directive 93/42/EEC (CE 0297).

The manufacturer fulfills the requirements of the following standard: DIN EN ISO 13485:2003.

CE 0297 UL

***Caution*:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

CONTENTS

SAFETY INFORMATION

This section contains important safety information related to general use of the Waveline EZ monitor. Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Read all text surrounding all precautionary information.

The Waveline EZ monitor can be powered by an internal battery pack that provides 3 hours of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

A warning message appears on the screen and an audible alarm sounds when the remaining battery power is only enough for 10 minutes of operation. The user should connect the monitor to an external power source to avoid loss of patient monitoring action.

External power sources may be connected, disconnected and reconnected without interrupting the monitoring action.

The integrity of the external protective conductor in the installation or its arrangement is in doubts; equipment shall be operated from its INTERNAL ELECTRICAL POWER SOURCE.

Important! Before use, carefully read this manual and its accessory directions.

WARNING: The Waveline EZ monitor is defibrillator proof. It may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter.

WARNING: The Waveline EZ monitor is a prescription device and is to be operated by qualified personnel only.

WARNING: Occasionally, electrical signals at the heart do not produce a peripheral pulse. If a patient's beat-to-beat pulse amplitude varies significantly (for example, pulsus alternans, atrial fibrillation, rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic and an alternate measuring method should be used for confirmation.

WARNING: Explosion hazard. Do not use the Waveline EZ monitor in the presence of flammable anesthetics or gases.

WARNING: Do not lift the Waveline EZ monitor by the sensor cable, blood pressure hose, or power cord because the cable, lead, or cord could disconnect from the monitor, causing the monitor to drop on the patient.

WARNING: The Waveline EZ monitor may not operate effectively on patients who are experiencing convulsions or tremors.

WARNING: The user must check the equipment prior to use and ensure its safe and proper use.

WARNING: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING: Do not use the Waveline EZ monitor to monitor patients who are linked to heart/lung machines.

WARNING: Enclosure leakage current is less than 100 microamperes (μA); however, always consider additional leakage current that can be caused by other equipment used on the patient at the same time as these monitors.

WARNING: To ensure that the leakage current protection remains within the specifications, use only the patient cables supplied with, or specifically intended for use with the Waveline EZ Monitors.

WARNING: Do not autoclave, ethylene oxide sterilize, or immerse these monitors in liquid. Unplug the monitors before cleaning or disinfecting.

WARNING: Connection of non-isolated devices to the RS-232 connector may cause chassis leakage to exceed the specification standards.

WARNING: To prevent electrical hazards to all personnel, these monitors must be properly grounded. The chassis grounding assembly, Universal Switching Power Supply, and the power cord supplied with the equipment provides for this protection. Do not attempt to defeat this protection by modifying the cords or using ungrounded adapters.

WARNING: Liquid crystal is poisonous. Do not put it in your mouth. If liquid crystal touches your skin or clothes, wash it off immediately by using soap and water.

CAUTION:
When connecting the Waveline EZ monitor to any instrument, verify proper operation before clinical use. Both the Waveline EZ monitor and the instrument connected to it must be connected to a grounded outlet. Accessory equipments connected to this patient monitor must be certified according to the respective IEC standards (e.g. IEC 60950 for information technology equipment and IEC 60601-1 for medical electrical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input or signal output is responsible to ensure the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, contact our company or customer service.

To ensure accurate readings, consider the environmental conditions that are present and the condition of the patient. See the appropriate sections of the manual for specific safety information related to these conditions.

CAUTION:
To touchscreen:
- Clean and soft clothes with neutral detergent and with isopropyl alcohol may be used for cleaning.
- Do not use any chemical solvent, acidic or alkali solution.
- The panel is designed with air groove. Insulation and cushioning pads should be designed around the edges of the panel to prevent water and dust.
- Use a plastic stylus (tip R0.8 or over) or finger. Sharp edged or hard articles are prohibited.
- The gathering of dew in the panel may occur with abrupt temperature or humidity changes. A stable environment condition is recommended.
- Keep the surface clean. No adhesives should be applied.
- Avoid high voltage and static charge.

INTRODUCTION

INTENDED USE
ABOUT THIS MANUAL

INTENDED USE

The Waveline EZ monitor is a comprehensive monitoring system with two or three traces compiling, processing, analyzing and displaying data from up to eight different patient parameters. It integrates parameter measuring modules, display and recorder in one device, featuring in compactness, lightweight and portability. Built-in battery facilitates transportation of patient.

The purpose and function of the Waveline EZ monitor is to monitor ECG, heart rate, NIBP (systolic, diastolic, and mean arterial pressures), SpO_2, respiration, temperature, and $EtCO_2$ for adult, neonate and pediatric patients in all hospital areas and hospital-type facilities. It may be used during hospital transport and in mobile, land-based environments, such as ambulances.

The Waveline EZ monitor offers advanced features such as an intuitive touchscreen with clinical measurements, one-touch commands, crisp and clear display.

WARNING: The Waveline EZ monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

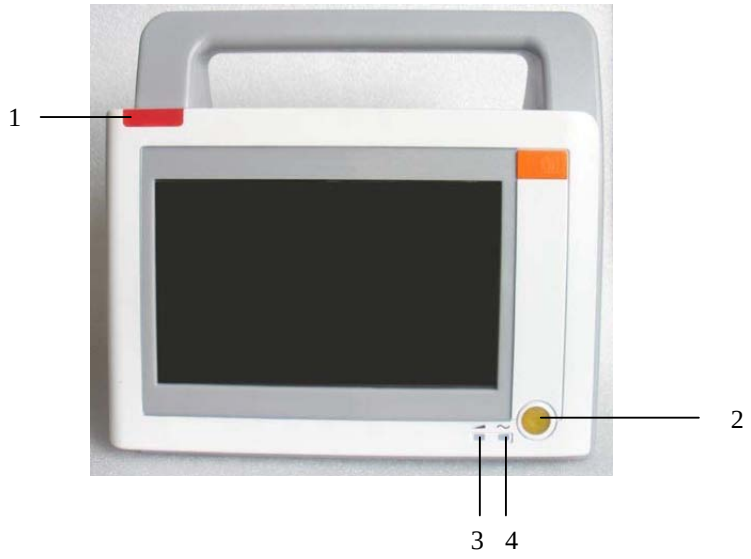
ABOUT THIS MANUAL

This manual explains how to set up and use the Waveline EZ monitor. Important safety information relating to general use of the Waveline EZ monitor appears before this introduction. Other important safety information is located throughout the text where applicable. **Read the entire manual including the *Safety Information* section before you operate the monitor.**

CONTROLS, INDICATORS AND SYMBOLS

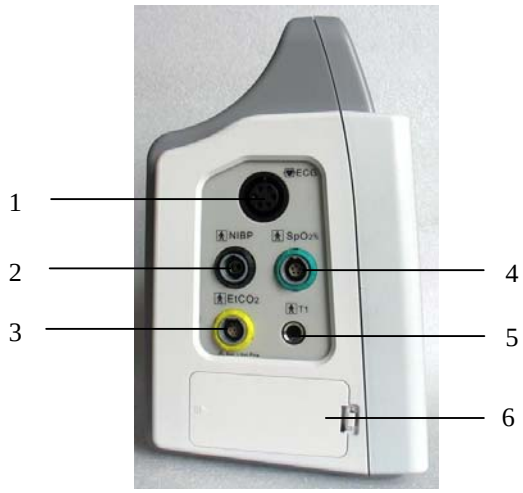
FRONT PANEL
LEFT SIDE PANEL
RIGHT SIDE PANEL
REAR PANEL
SYMBOLS

FRONT PANEL



No.	FUNCTION	Icon
1	Alarm Indicator In normal mode, no indicator lights. In alarm mode, the alarm indicator flashes.	
2	On/Standby Switch This toggle switch turns the secondary power from on to off from the monitor. The monitor will continue to charge the battery as long as the AC cable is plugged in, even if the power switch is in the off station.	
3	DC ON This LED indicates that the monitor is powered by battery.	
4	AC ON This LED indicates that the monitor is powered by AC.	

LEFT SIDE PANEL



No.	FUNCTION
1	Six cores, AAMI ECG lead socket
2	NIBP port for the connection with the blood pressure cuff hose
3	$EtCO_2$ input port (Option)
4	Oxygen saturation sensor port
5	Temperature port
6	Battery access

RIGHT SIDE PANEL

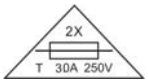
No.	FUNCTION
1	Recorder (Option)

REAR PANEL

No.	FUNCTION	Icon
1	Protection earth (ground) To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	
2	AC Input The AC power connection is where facility line power is connected to this monitor, the AC power fuses must be replaced with the same type and rating fuse.	100-240V ~ 50/60Hz, 150VA
3	Ethernet port Connect to the central monitoring system via wired networking.	
4	RS-232 I/O This digital interface connector provides serial data to most RS-232 devices	RS232
5	Wireless Transmitter For wireless central monitor system	
6	$EtCO_2$ Module(option)	

SYMBOLS

The following symbols may appear on the packaging, monitor or in user's manual:

	Type BF applied part
	Defibrillation-proof type CF applied part To identify a defibrillation-proof type CF applied part complying with IEC 60601-1. Note 1 - C = Cardial. Note 2 - F = Floating applied part.
	Rechargeable battery To indicates the positioning of the cells.
SN	Manufacture's serial number
	Fuse information
	Date of manufacture
	Manufacturer
	FRAGILE Contents of the transport package are fragile therefore it shall be handled with care.
	THIS WAY UP Indicates correct up right position of the transport package.
	KEEP AWAY FROM RAIN Transport package shall be kept away from rain.
	STACKING LIMIT BY NUMBER Maximum number of identical packages which may be stacked on one another is six.
	General warning, caution, risk of danger Please read the instructions carefully before operating the product.

DISPLAY SCREEN PARTITION

All TFT display screen is divided into four areas:

PARAMETER AREA

This area is used for display monitoring parameters, such as HR, RESP, SPO2, TEMP, NIBP (SYS, DIA, and MAP) and ETCO2.

WAVEFORMS AREA

This area is used for displaying waveforms and menu setup interface. The user can use the menu to distribute the combination of window waveform and NIBP data list.

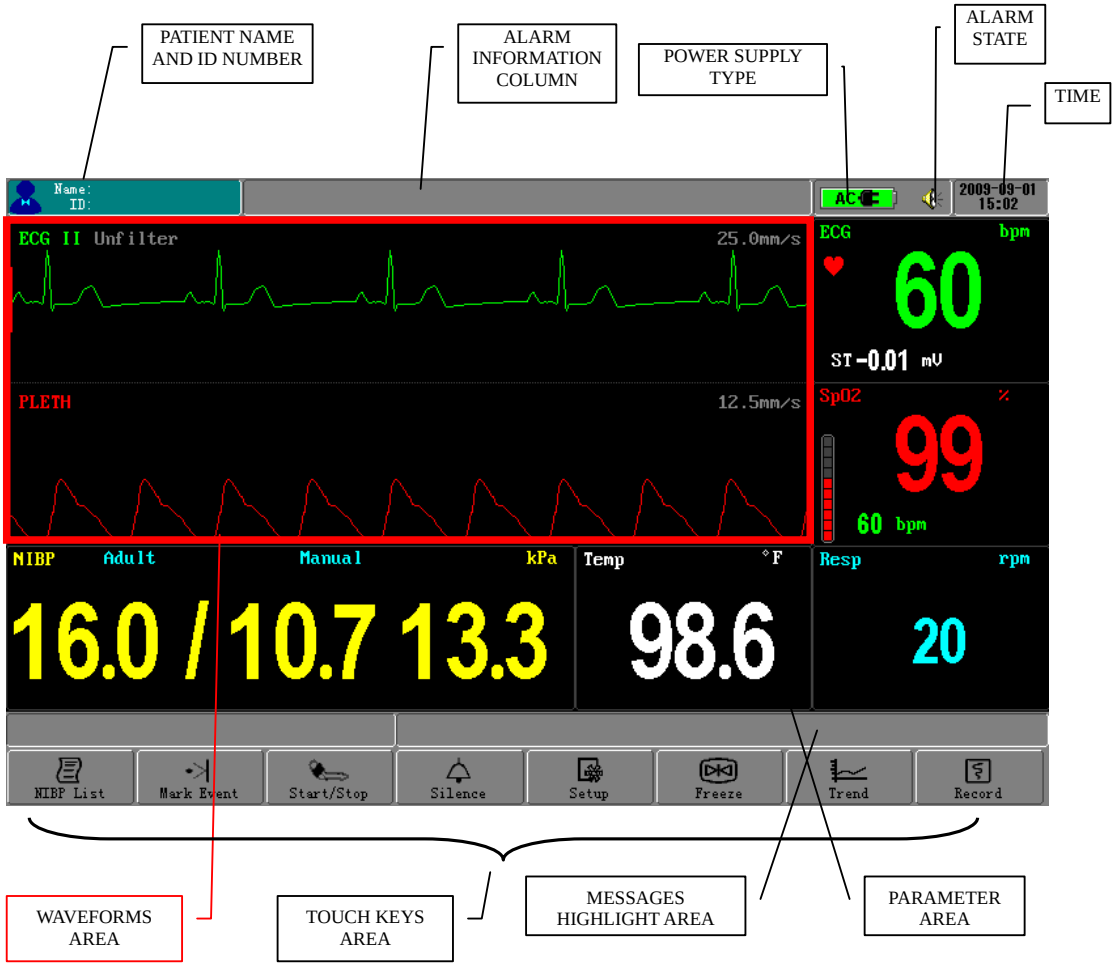
MESSAGE AREA

This area states messages of time, patient types and other correlated information.

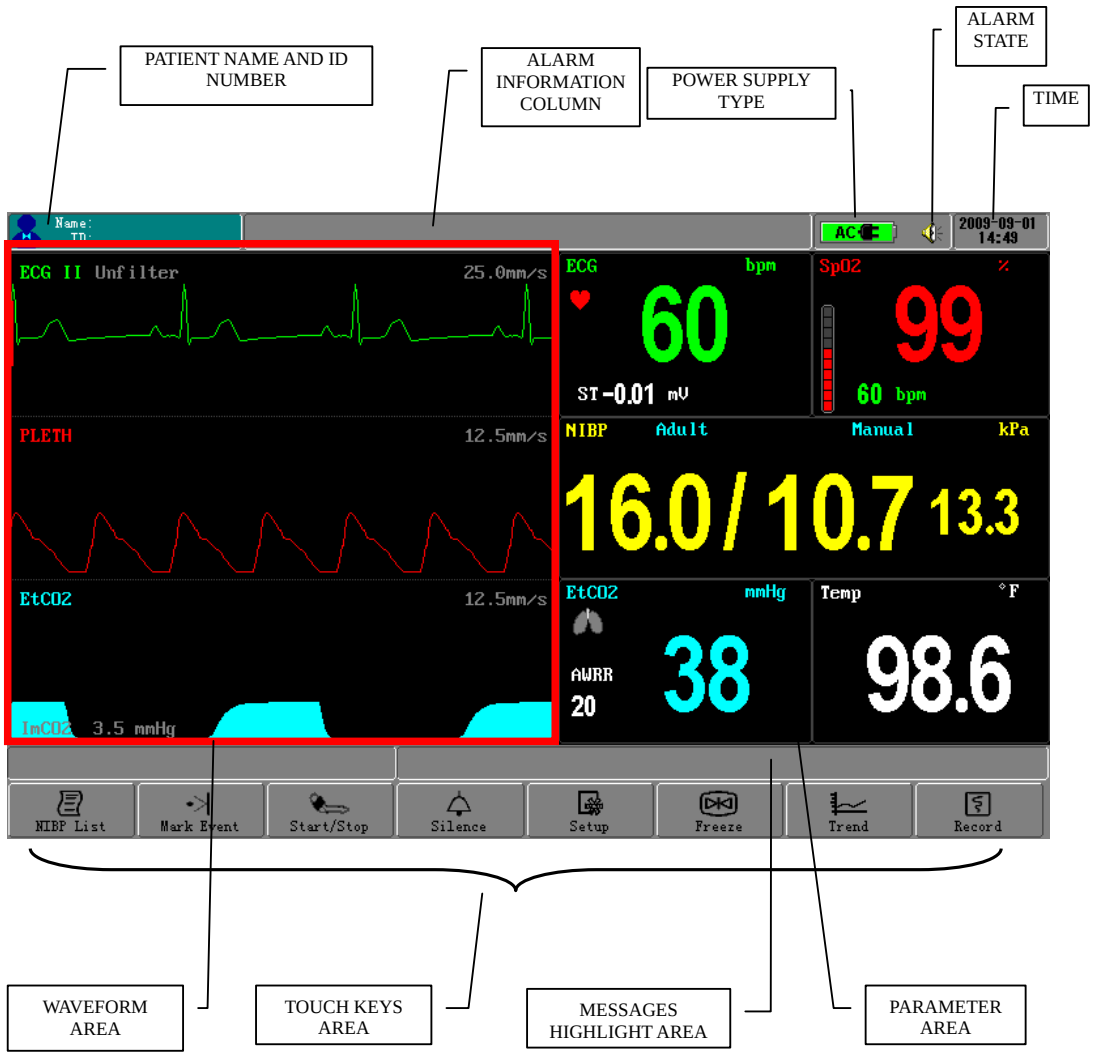
TOUCH KEYS AREA

This area lists the main function touch keys. The user can touch and click any of them to enter relevant function.

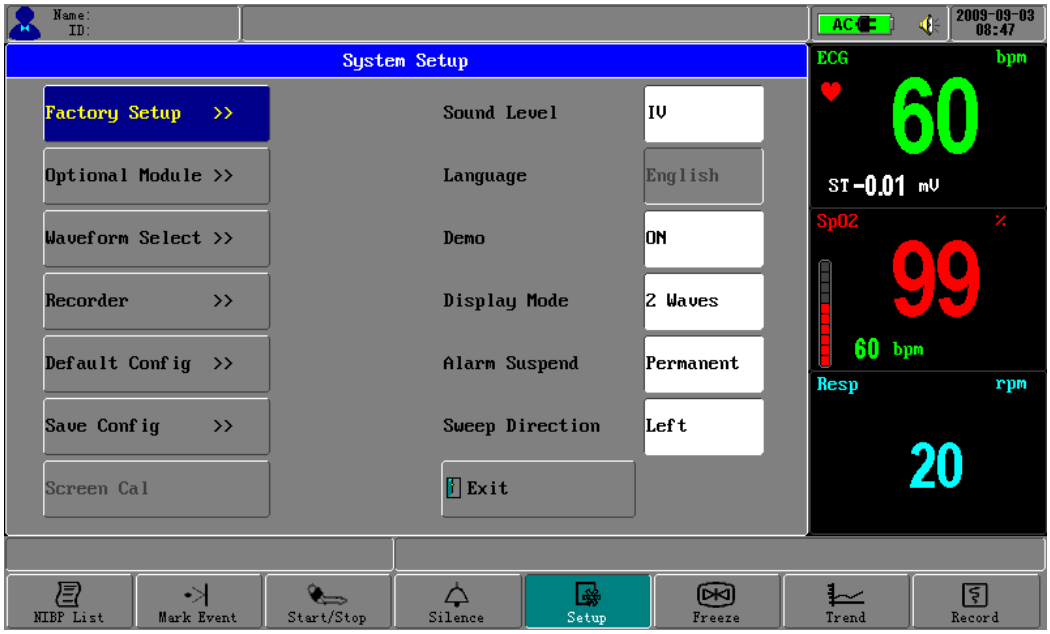
Two waveforms display mode:



Three waveforms display mode:



MENU AREA



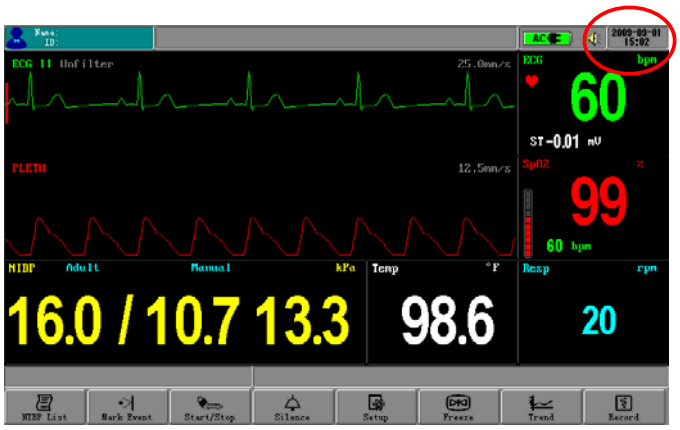
On the main screen display, clicking a parameter area will open the correlated menu. Clicking the SILENCE,TREND and SETUP etc. function buttons can also open the correlated menu or access the choosing item (enter submenu if available). If you want to exit from menu, just click the menu item of EXIT or OK (or CANCEL).

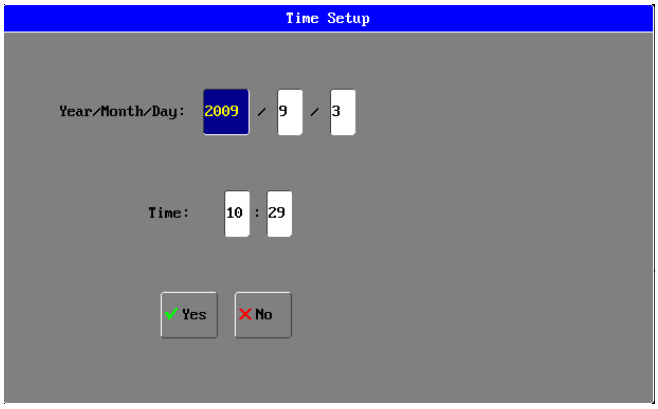
SYSTEM SETUP

SYSTEM SETUP includes: time setup, recorder setup, factory setup, waveform setup, default setting selection, system setup save, sound level, language setup, etc.

TIME SETUP

Click the time display area to pop the Time Setup Menu (see graph below):





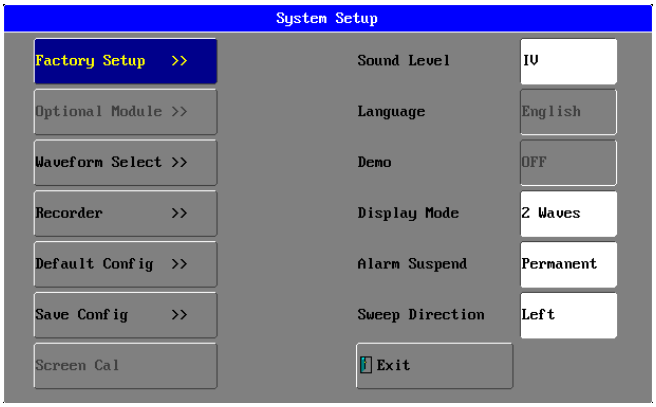
The value of year, month, hour and minute can be set. Then system will amend the internal clock according to the new settings. When the time menu opens, the system shows the right time when entering this menu. If you click the **NO** item to exit from the menu, the system will not change internal clock.

Once the system time realigned, the trend data will renew correspondingly.

On entering the master screen, please checks whether the monitor time and the current time are consistent, if not, please correct them.

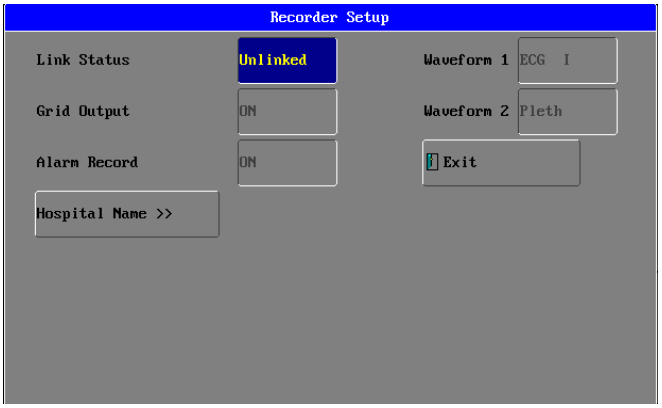
SYSTEM SETUP

Click the **SETUP** function button to open up the menu as below:



RECORDER SETUP

Click **RECORDER** item in the SYSTEM SETUP menu to call up the following menu:



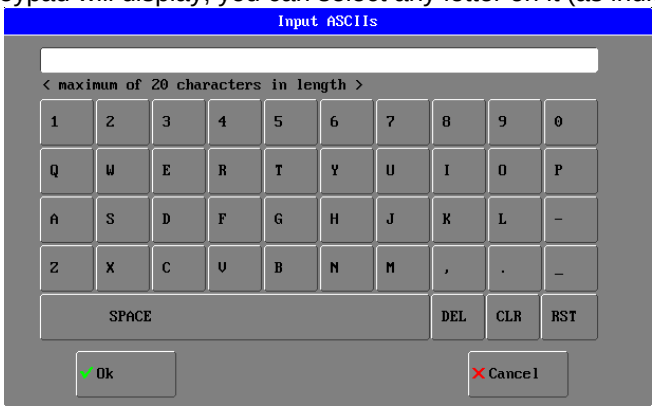
RECORDER LINKING STATUS
Use to display or set the connecting state of recorder.

RECORDER GRID OUTPUT
Open the setup to make waveforms and parameters' printouts have a grid background, just like recording paper—contrary when closed.

ALARM RECORD
If this item set to be **ON**, It can record a slip of waveform of 10 seconds (the preceding 4 seconds before the recording till the current 4 seconds) when an alarm

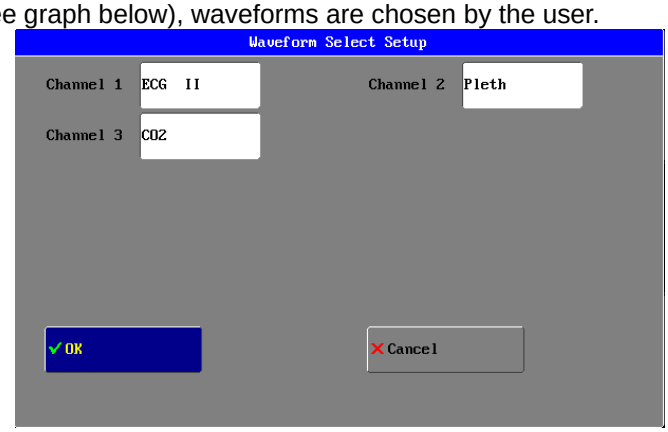
is triggered.

HOSPITAL NAME
Click this item to input or change the hospital name. When the input name location is clicked, a keypad will display; you can select any letter on it (as indicated below):



WAVEFORM SELECT

Select **WAVEFORM SETUP** item in system Setup menu to open up the waveform select setup menu (see graph below), waveforms are chosen by the user.



The waveforms from top to bottom can be selected from ECG I, ECG II, ECG III, ECG AVR, ECG AVF, ECG AVL, ECG V, PLETH and ETCO2. Only when a relative module is set to be **ON**, its waveform can be selected.

SOUND LEVEL

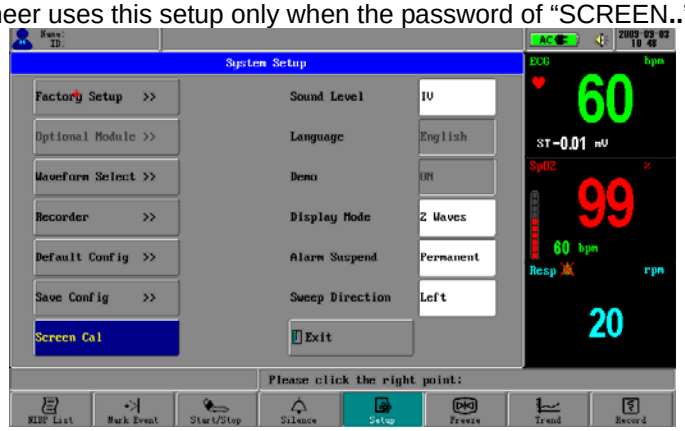
Mainly used to adjust the sound to four volumes. They are I, II, III and IV from low-to-high separately.

LANGUAGE SETUP

Used to select language for the monitor system. The language can be switched only after inputting the correct password of "language."

SCREEN CALIBRATE SETUP

Servicing engineer uses this setup only when the password of "SCREEN**..**" is inputted.

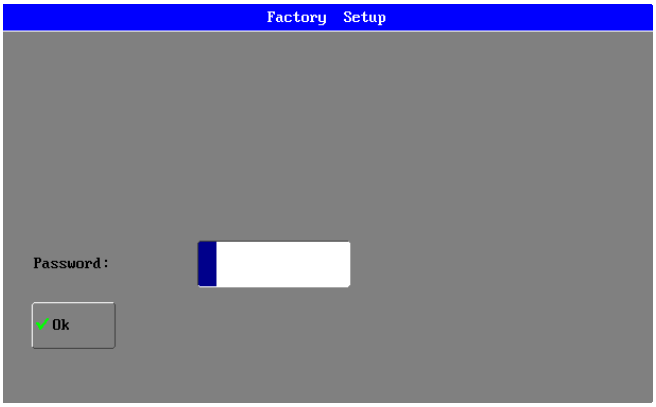


Click the button of **Screen Cal** in the above figure, the system enters screen calibration mode. At this time user actions are invalidated except for calibration actions.

Four steps need be followed according to information in the message highlight area. The first three steps are for calibration that has the user click the red cross icon accurately to calibrate the touch screen.

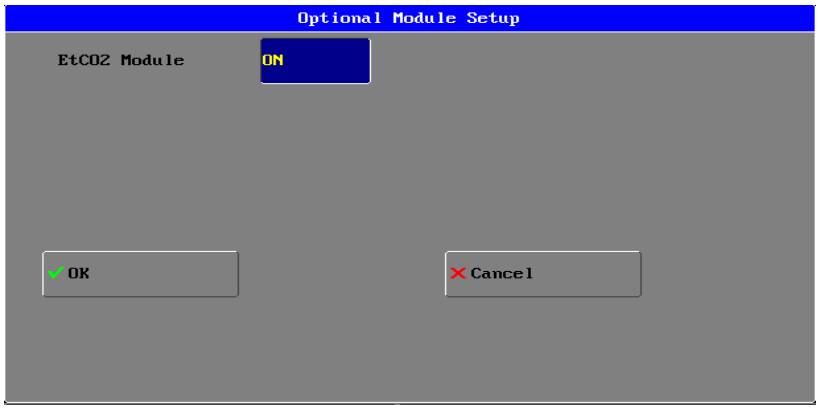
The fourth step is calibration verification. The user will click the red cross icon accurately to verify touch screen calibration result.

After finishing the screen calibration, the system will return to the normal mode if the calibration validate is successful, otherwise the system will return to the first step of calibration if calibration is failed.



OPTIONAL MODULE SETUP

Sets the function module for the ETCO2 module to be switched on or off.
This item is for servicing engineer use only.



SWEEP DIRECTION SETUP

There are two options of "right" and "left".

DISPLAY MODE SETUP

There are two options of "2 waveforms" and "3 waveforms".

ALARM SUSPEND SETUP

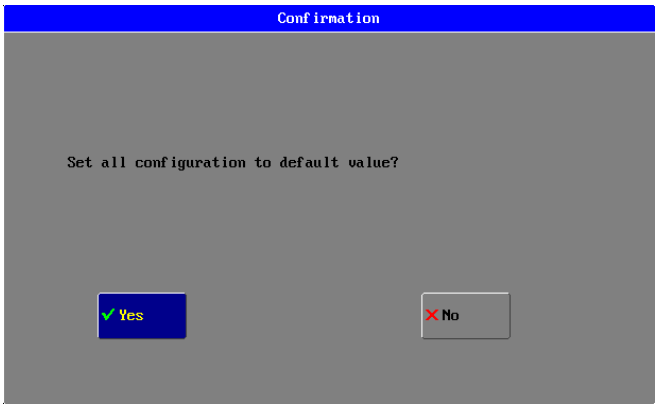
There are four options of 1 minute, 2 minutes, 3 minutes and Permanent.
If select "Permanent" item, there is a warning message of "warning: alarm suspend permanently" displaying on the top message area. And alarm indicator will not flash, there are no any alarm messages and alarm sounds.

DEMO DISPLAY

Use to display demonstration interface. This can be available only after inputting the correct password of "DEMO**….**"

DEFAULT CONFIG SETUP

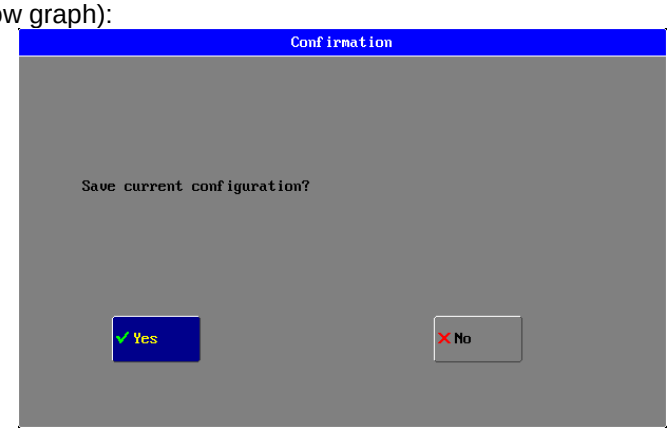
You can apply the default settings by clicking this item to open up the below menu, then click **Yes** or **No** to confirm.



After return the above confirmation menu, a message of "LOAD DEFAULT CONFIG DATA SUCCESS!" will display in the message highlight area, showing that the system has begun to use the default settings.

SAVE CONFIG SETUP

Saving current config settings allows the system to call up the saved settings on the next time of use. Click this item and the screen will display a menu to let you confirm the setup (see below graph):



After returning from the above confirmation menu, a message will display "SAVE DATA SUCCESS!" showing that the system and all monitoring parameter settings have been saved (see each chapter).

HOW TO MONITOR

1. According to the parameter needed, connect the correlated sensors to the sockets on the left panel;
2. Connect with the power supply, press the power switch in the front panel;
3. Power indicator is bright, the display screen enters the main screen after 5 seconds;
4. Connect corresponding sensors with the patient;
5. Set monitoring parameters (see chapters below) ;
6. Enter the monitoring state.

CAUTION: If the Waveline EZ is to be stored for a period of 2 months or longer, notify service personnel to remove the battery from the monitor prior to storage. Recharge the battery when the battery has not been recharged for 2 or more months.

CAUTION: Follow local government ordinances and recycle instructions regarding disposal or recycling of device components, including batteries.

SOUND & ALARM

SOUND ASSORTMENT

ALARM SOUND

The mild sound of BEEP. There are four items of , , and for alarm levels in turn from low to high.

HEART-BEAT (PULSE-TONE)

The heart-beat or pulse-tone is a sound of RUB-A-DUB. In the ECG setup menu, there are the QRS, PULSE and OFF choices. When the choice is QRS, the system will sound by heart-beat sound. When the choice is PULSE, the system will sound by pulse-tone sound. When the choice is OFF, the system will close the heart-beat sound or pulse-tone.

KEY BEEPS

The key beep sounds come along with clicking function items.

SILENCE

Click this function button to disable all sounds except for the key beeps. A symbol of  displays in the message area, click this button again to restore all sounds except for the key beeps.

ALARM SWITCH

When any alarm switch is set to be **OFF**, the alarm indicator will not light, the relative alarm parameter will not flash and relative parameter area will appear an icon of  .

ALARM EXPLAINATION

If a certain parameter is above the higher alarm limit or below the lower alarm limit (sees each chapter of monitoring), there will appear some alarm information on the top screen. There are shining parameters at the correlated zone. The alarm indicator flashes and alarm sound will be active.

WARNING: Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

WARNING: Each time the monitor is used, check alarm limits to ensure that they are appropriate for the patient being monitored.

ECG MONITORING

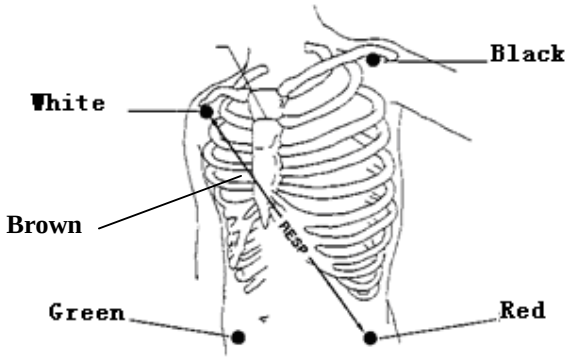
ELECTRODE INSTALLATION
SENSOR INSTALLATION
ECG PARAMETER SETUP
ERROR MESSAGES OF ECG MONITORING
MAINTENANCE AND CLEANING

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the monitor as a waveform and a numeric.

ELECTRODE INSTALLATION

Some points should be paid attention to in ECG monitoring：

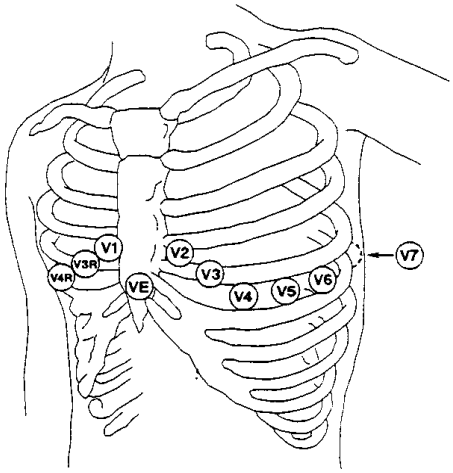
1. Check the lead and cable; a damaged or ruptured one cannot be used.
2. Link up the lead set and cable, and connect the electrode to the lead.
3. Choose the suitable skin at which the electrode should be pasted. Use alcohol to clean the skin and remove the skin grease. Paste the electrode on the patient and check whether it contacts well.
4. Follow the methods below to place these 5-lead electrodes; it can be set by the ECG menu.



□ WHITE (RIGHT ARM) ELECTRODE (RA)—is placed near the right shoulder, directly below the clavicle.
□ BLACK (LEFT ARM) ELECTRODE (LA)—is placed near the left shoulder, directly below the clavicle.
□ GREEN (REFERENCE) ELELCTEODE (RL)—is placed on the right hypogastrium.
□ RED (LEFT LEG) ELELCTEODE (LL)—is placed on the left hypogastrium.
□ BROWN(CHEST)ELECTRODE(V or C)-be placed on the chest as illustrated below:

NOTE:
□ Only the ECG cable presented by our factory can be used.
□ To ensure patient safety, all leads must be attached to the patient.

For 5-lead set, attach the C-electrode to one of the indicated positions as below:



☐ **V1** is on the 4th intercostal space at the right sterna margin.
☐ **V2** is on the 4th intercostal space at the left sterna margin.
☐ **V3** is at the midway between V2 and V4 electrodes.
☐ **V4** is on the 5th intercostal space at the left clavicular line.
☐ **V5** is on the left anterior axillary line, horizontal with V4 electrode.
☐ **V6** is on the left middle axillary line, horizontal with V4 electrode.
☐ **V3R-V7R** is on the right side of the chest in positions corresponding to those on the left.
☐ **VE** is over the xyphoid. As for the V-lead position on the back, it should be placed at one of the positions below.
☐ **V7** is on the 5th intercostals space at the left posterior axillary line of back.
☐ **V7R** is on the 5th intercostals space at the right posterior axillary line of back.

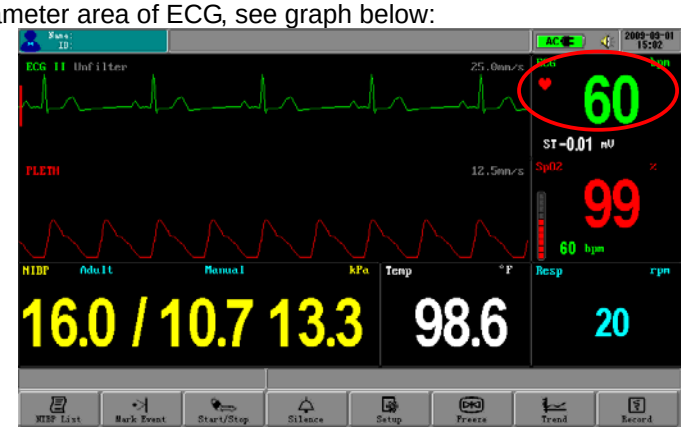
5. The electrodes must be moved away to check the skin every 24 hours, if the skin is found inflamed or damaged, substitute a new electrode to another position.
6. The gain choice of ECG is 0.5, 1.0 and 2.0.
7. Make sure no conductive part of electrodes is in contact with the ground and the other conductive ones.

CONNECTING ECG CABLES

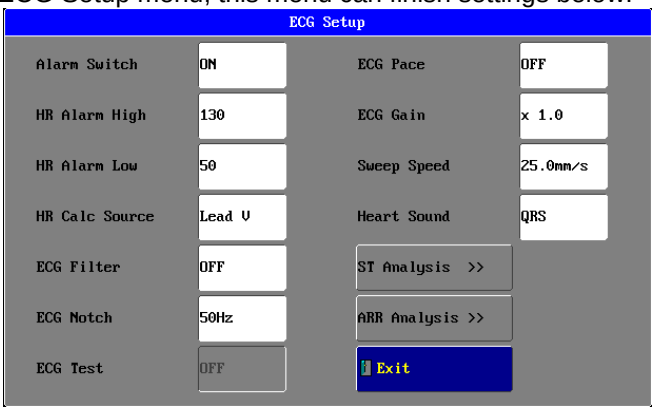
1. Attach the clips or snaps to the electrodes before placing them. If you are not using pre-gelled electrodes, apply electrode gel to the electrodes before placement.
2. Place the electrodes on the patient according to the lead placement you have chosen.
3. Attach the electrode cable to the patient cable.
4. Plug the patient cable into the white ECG connector on the left panel of monitor. An ECG waveform and numeric appear on the monitor display.

ECG PARAMETER SETUP

Click the parameter area of ECG, see graph below:



Then open the ECG Setup menu, this menu can finish settings below:



ALARM SWITCH

ON and **OFF** for choice, the factory-set is **OFF.**

HR ALARM UPPER-LIMIT

The range is from **80** bpm to **400** bpm，the factory-set is **130** bpm，the single-step adjustable step-length is **5** bpm.

HR ALARM LOWER-LIMIT

The range is from **20** bpm to **150** bpm，the factory-set is **50** bpm，the single-step adjustable step-length is **5** bpm.

HR CALCULATE SOURCE

Select between **lead I, lead II** and **V**, and the factory-set is **lead II**.

FILTER SWITCH

Select between **ON** and **OFF**, and the factory-set is **OFF**.

NOTE: On conditions that the interference to ECG waveform is too large or using at operating room, FILTER SWITCH is suggested to set to be **ON.**

ECG NOTCH
Select between **50Hz** and **60Hz**, and the factory-set is **50Hz**.

FILTER TEST
Select between **ON** and **OFF**, and the factory-set is **OFF**.

ECG GAIN
The user can freely choose one from items of **X0.5**, **X 1.0**, **X 2.0**. Gain adjustment can change the value of ECG waveform and ECG STAFF, and the factory-set is **X 1.0**.
– Size x0.5 to halve the waveform size
– Size x1.0 to display the waveform without zoom
– Size x2.0 to double the waveform size

SWEEP SPEED
From **12.5mm/s, 25mm/s** and **50mm/s** for choice, the factory-set is **25mm/s**.

HEART SOUND
There are QRS, PULSE and **OFF** choices, the factory-set is **QRS**.
There are QRS, PULSE and OFF choices; when the choice is QRS, the system will sound by heart-beat sound. When the choice is PULSE, the system will sound by pulse-tone sound. When the choice is OFF, the system will close the heart-beat sound or pulse-tone.

ST-SEGMENT ANALYSIS
It is used to complete Automatic ST-segment analysis function. Refer to the below detailed chapter.

ARRHYTHMIA ANALYSIS
It is used to complete Automatic arrhythmia analysis function. Refer to the below detailed chapter.

ERROR MESSAGES OF ECG MONITORING

Sometimes messages will display above the ECG waveform：

PROMPTS	EXPLANATION
Lead off	ECG leads fall off the skin or the monitor
ECG Signal Weak	ECG Signal is Weak

ECG LEAD PLACEMENTS

The labels and colors of the ECG electrodes differ according to the standards that apply for your hospital. The electrode placement illustrations in this chapter use the AAMI labels and colors.

Electrode labels			Electrode color	
AAMI	**EASI**	**IEC**	**AAMI**	**IEC**
RA	I	R	White	Red
LA	S	L	Black	Yellow
LL	A	F	Red	Green
RL	N	N	Green	Black
V	E	C	Brown	White
V1		C1	Brown/Red	White/Red
V2		C2	Brown/Yellow	White/Yellow
V3		C3	Brown/Green	White/Green
V4		C4	Brown/Blue	White/Brown
V5		C5	Brown/Orange	White/Black
V6		C6	Brown/Violet	White/Violet

MAINTENANCE AND CLEANING

PATIENT CABLE AND LEAD

After every use, the cable must be cleaned by using the following methods below:

1. Clear the paste on body and the remainder of electrolyte on the electrode. The paste-eradicator can be used when removing the adhesive tape remainder, but acetone, alcohol, ammonia, chloroform and other strong solvents are not suggested because they would finally damage the vinyl cable.
2. Use a sponge moistened in mild soap liquid or other suitable detergent solution to clean the cable and then dry them. Do not submerge the cable into the water.
3. Check each cable to see whether they are corroded, damaged or degenerated. Do not use autoclave to disinfect the cable and electrode or heat them to 75 (167F) and higher temperature. If there is dirt on the material surface, you can use a non-corrosive disinfectant. The storing temperature should be -20 till 75 (-68F till 167F). Hang or place them flat so as not to be damaged.

ADDING POINTS

1. HR calculating stability has a process; ECG lead switching sometimes affects HR, which will become stable after a while. The change of gain and filter may influence the HR calculating stability, as well. Another factor that affects HR calculation is the QRS waveform: if T wave is too high, HR will possibly make errors. Arrhythmia sometimes influences HR calculation.
2. Choosing suitable ECG waveform range and complete QRS waveform has important effects in the accuracy of HR calculation.

RESP MONITORING

RESP ELECTRODE INSTALLATION
RESP PARAMETER SETTING
MAINTENANCE AND CLEANING

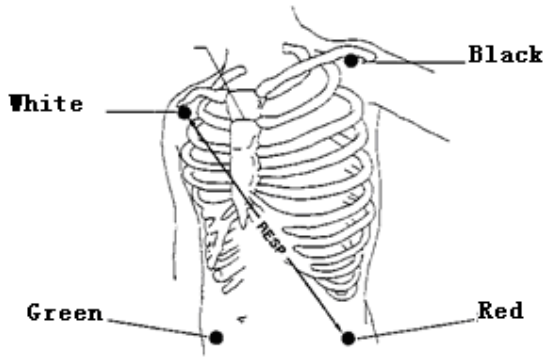
RESP ELECTRODE INSTALLATION

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.
For RESP monitoring, it is not necessary for additional electrodes, however, the placing of electrodes is important.

Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.
The sensor of RESP ELECTRODE's installation is same as ECG's.

NOTE:
The RESP monitoring is not recommended to be used on patients who are very active, as this can cause **false alarms**.

The scheme picture for placing the 5 Electrodes for respiratory monitoring is seen as followings:

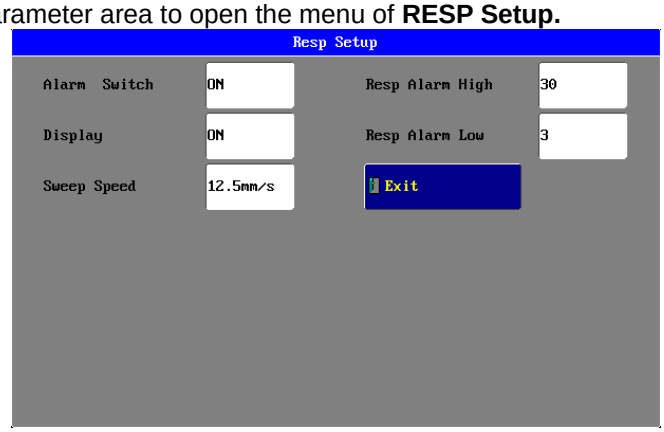


NOTE:
Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

RESP PARAMETER SETTING

Click and choose the **WAVEFORM SELECT** item in the SYSTEM SETUP menu to enter

the WAVEFORM SELECT SETUP menu. Open the RESP monitoring function. Click the RESP parameter area to open the menu of **RESP Setup.**



The menu can finish settings as below:

ALARM SWITCH

ON and **OFF** for choice, the factory –set is **OFF**.

DISPLAY PARAMETER

The **ON** and **OFF** for choice**.** Select **ON** can display RESP rate, select **OFF** would not display the RESP, but this do not influent the actual data of trend.

NOTE: When the patient's thorax or abdomen is subjected to too much interference, the RESP monitoring is not accurate. It is suggested to close the RESP rate display.

SWEEP SPEED

Choose from **12.5mm/s** to **25.0mm/s**, and the factory-set is **12.5mm/s**.

RESP ALARM HIGHER-LIMIT

The RESP alarm upper-limit, the range is from **6** to **120** bpm，and the factory-set is **30** bpm，the single-step adjustable step- length is **1** bpm.

RESP ALARM LOWER-LIMIT

The RESP alarm lower-limit, the range is from **3** to **120** bpm，and the factory-set is **3** bpm，the single-step adjustable step- length is **1** bpm.

MAINTENANCE AND CLEANING

It is the same as the ECG monitoring.

RESP SAFETY INFORMATION

WARNING:
Respiration detection level If you do not set the detection level for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the detection level too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.

Apnea The respiration measurement does not recognize obstructive and mixed apneas — it only indicates an alarm when a pre-adjusted time has elapsed since the last detected breath.

The safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

Interference If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3V/m), field strengths above 1V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

Resp Accessories To monitor respiration use only the non-OR ECG accessories listed in the Resp section of the accessories chapter. You cannot measure respiration if you are using an orange OR ECG cable set. This is because of the higher internal impedance of the OR cable set, required for use if electro-surgery is being performed.

SPO2 MONITORING

SPO2 MONITORING PRINCIPLE

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.
The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.

About SpO_2、SaO_2、$SjvO_2$
□**SpO_2：** It is the arterial blood oxygen saturation lever measuring by oximeter.
□**SaO_2：** It is the oxygen saturation of arterial blood
□**$SjvO_2$：** It is the oxygen saturation of the jugular blood.

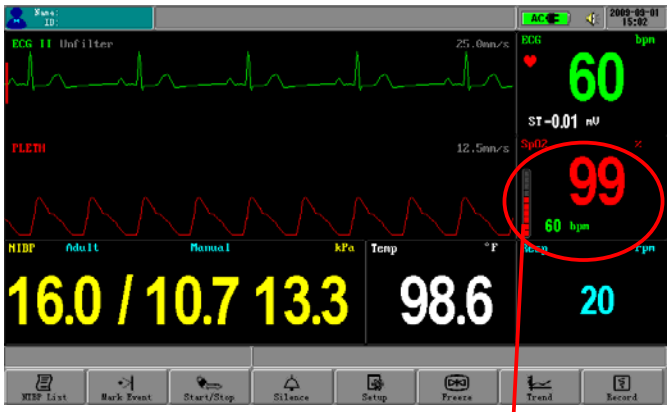
WARNING: Pulse oximeter can overestimate the SPO2 value in the presence of HB-CO, Met-HB or dye dilution chemicals.

SPO2 SENSOR INSTALLLATION

1. Insert the plug of SPO2 sensor into the **SPO2** socket on the left panel of monitor. Make sure that the salient of plug must direct to the notch of socket when inserting of unplugging, otherwise the measurement will not be reliable and the sensor connector will be damaged.
2. Wear the finger-probe on the finger; make sure that the finger tip is the same direction as the finger direction indicated on the probe.

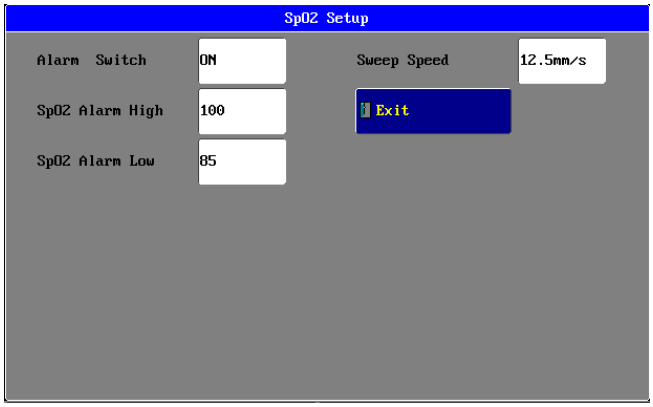
SPO2 PARAMETER SETUP

Click the SPO2 parameter area as graph below:



PULSE BARGRAPH:
Use red bargraph to express the intensity of the pulse of patient.
Pulse bargraph is throbbing upon with the pulse.

Open the menu of SPO2 Setup, see graph below:



The menu can finish settings as below:

ALARM SWITCH

ON and **OFF** for choice, the factory-set is **OFF**.

ALARM RECORD

ON and **OFF** for choice, the factory-set is **OFF**.

If set to **ON** choice, the recorder can automatically print the current wave and each parameter value when occurring parameter alarm.

WAVEFORM SPEED

Choose from **12.5mm/s** to **25.0mm/s**, and the factory-set is **12.5mm/s**.

SPO2 ALARM UPPER-LIMIT

The SPO2 alarm upper-limit, the range is from **70** to **100**%，and the factory-set is **100%**，the single-step adjustable step- length is **1** %.

SPO2 ALARM LOWER-LIMIT

The SPO2 alarm lower-limit, the range is from **70** to **150**%， and the factory-set is **85%**，

the single-step adjustable step- length is **1%**.

MEASUREMENT LIMITATIONS

1. The measurement is decided by the pulsating characteristic of blood stream in artery or arterial blood vessel. The arterial blood stream may decrease to a level which cannot be measured in conditions below:
   - □ Shock
   - □ Hypothermia
   - □ Vasoactive medicines are applied
   - □ Anemia
2. The measurements are also decided by the condition how the oxyhemoglobin and reduced-hemoglobin absorb the light of special wave-length. If there are other material can absorb the same wave-length light, they can cause the measurement to be false or lower than the actual value of SPO2, for example:
   - □ Carboxyhemoglobin
   - □ Methemoglobin
   - □ Methylene blue
   - □ Carmine indigo
3. The strong light in the environment can also influence measurement. Use some suitable light-tight material to cover the sensor to improve the measurement quality.

WARNING:

- □ Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important for neonate and patient of poor perfusion or immature dermogram to check the sensor placement by light collimation and proper attaching strictly according to changes of the skin .Check regularly the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.
- □ Setting the SpO2 upper alarm limit to 100% is equivalent to switching off the alarm on upper limit. High oxygen levels may predispose a premature infant to retrolental fibroplasias. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

SPO2 ERROR MESSAGES

The PLETH Waveform may display messages as below:

PROMPTS	EXPLAINATION
Search Too Long	Search-time of SPO2 is too long
Searching For Pulse. . .	On searching for pulse signal
Sensor Off	Sensor falls off or the finger fails to insert into the finger-probe

SpO_2 Com Error	SPO2 board has communication error with the mainboard

NIBP MONITORING

SUMMARY ON NIBP MONITORING

The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method.
It is applicable for **adult**, **pediatric** and **neonatal** usage.
There are three modes of measurement available: **manual**, **automatic** and **continuous**.
Each mode displays the diastolic, systolic and mean blood pressure.

WARNING:

- You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.
- For a thrombasthenia patient, it is important to determine whether measurement of the blood pressure shall be done automatically. The determination should be based on the clinical evaluation.
- Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric or neonate). Ensure that the correct setting is selected when performing measurements on neonate, because the higher adult BP level is not suitable for neonate; it may be dangerous for the neonate to use a high pressure level.
- Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

NIBP CUFF FITTING

1. Choosing the suitable cuff that matches the arm of the patient heavily influences the accuracy of NIBP measurement. The cuff width recommended by the **AMERICA HEART SOCIETY** is 40% of upper arm circumference or 2% of the upper arm length.
2. Apply the blood pressure cuff to the patient's arm:

□ Make sure that the cuff is completely deflated.
□ Apply the appropriate size cuff to the patient, and make sure that the symbol "**φ**" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual isocheimal of the extremities.

3. Make sure that the cuff has not been twisted.
4. Insert the air pipe into the **NIBP** socket on the left panel of monitor. Ensure that the spring block on the left side of the socket has been pressed when inserting or unplugging the pipe, otherwise measurement process will be irregular and the sensor connector will be damaged.

WARNING:

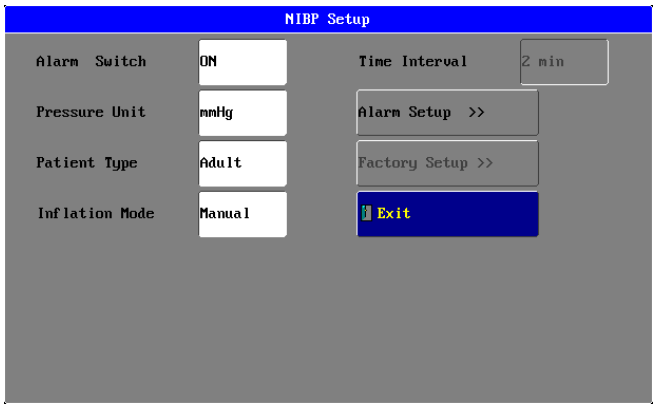
- ☐ The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.
- ☐ Make sure that the cuff edge falls within the range of 〈-〉. If does not, change a more suitable cuff.
- ☐ Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:
  If the cuff is placed higher than the heart level, add 0.9mmHg (0.12kPa) for each inch of difference.
  If it is placed lower than the heart level, deduct 0.9mmHg (0.12kPa) for each inch of difference.

NIBP MONITORING INITIALIZATION

After opening the host machine, check the information indicating area before NIBP monitoring. If there is a message of "NIBP MODULE SELF-CHECK OK," it shows that the NIBP module operates well. Begin NIBP monitoring; the NIBP monitoring before this information is invalid; if there is a message of "NIBP MODULE SELF-CHECK ERROR," it shows that the NIBP module cannot proceed. Click the **START/STOP** button to give another attempt of self-checking or machine-opening, and contact a servicing engineer.

NIBP MONITORING SETUP

Click the NIBP Parameter Area to open the NIBP Setup menu (see graph below), this menu can complete settings below:



ALARM SWITCH

ON and **OFF** for choice, the factory-set is **OFF**

PRESSURE UNIT

mmHg or **kPa**，the factory-set is **mmHg**.

PATIENT TYPE

ADULT TYPE：

Applies to the adult mode. In the initiated measurement, inflate the cuff to 180mmHg (24kPa). If the NIBP value cannot be measured, then inflate the cuff to higher than the form value by 50mmHg (6.7kPa)—the maximum value cannot exceed 280mmHg (37.3kPa), and the enduring pressure range is 50-280mmHg.

PEDIATRIC/NEONATE TYPE
Applies to the **PEDDIATRIC or NEONATE** mode. In the initiated measurement, inflate the cuff to 60mmHg (8kPa). If the NIBP value cannot be measured, then inflate the cuff to higher than the form value by 30mmHg (4kPa)—the maximum value cannot exceed 150mmHg (20kPa), and the enduring pressure range is 50-150mmHg.

If this setup is before the NIBP module initiation, information indicating area will give a message of "PATIENT TYPE SET ERROR."

The factory-set is **ADULT TYPE.**

If the inflating range above has been realized on NIBP, NIBP will use this inflation range to make sure of the safety of patient.

INFLATION TYPE
MANUAL MODE, AUTOMATICAL MODE and **STAT MODE**

MANUAL MODE:
Click the **START/STOP** button to begin inflation and the information indicating area display "MANUAL MEASURING…" This shows that it is currently measuring.
If the NIBP value has been measured, NIBP parameter area will display it and the information indicating area will give a message of "MANUAL MEASURING END!" then the measurement process is finished.
If the NIBP value cannot be measured, NIBP parameter area will display error messages and automatically begin three more attempts of measurement again. If the value still cannot be measured, the information indicating area will give a message of "RETRY OVER!" and will stop measuring.
During the measurement, click the **START/STOP** button again to stop the NIBP measurement process. The information indicating area will give a message of "STOP MANUAL MEASURING."

AUTOMATICAL MODE:
NIBP parameter area will display the countdown of "Auto measuring..." (TIME INTERVAL) until it reaches the zero point. Machine will automatically precede inflating measurement again and again until the mode is changed.
If the NIBP value has been measured, NIBP parameter area will display accordingly and the information indicating area will give a message of "AUTO MEASURING END!" which shows measurement process is finished and automatically begins another measurement until the mode is changed.
If the NIBP value cannot be measured, NIBP parameter area will display error messages and the first measurement will automatically begin three more measurements again.

The information indicating area will give a note of "RETRY OVER!" and automatically go on the next measurement until the mode is changed.
If **START/STOP** is activated during any period of countdown, it immediately begins inflation measurement.
During the measurement, clicking the **START/STOP** button again will stop this

period of NIBP measurement process and the information indicating area will give a message of "STOP AUTO MEASURING." The automatic measurement period is continuous.

WARNING:

- Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, isocheimal and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

STAT MODE:

Click the **START/STOP** button to begin inflation; the information indicating area displays "STAT MEASURING..." which shows that it is currently measuring; if the NIBP value has been measured, NIBP parameter area will display accordingly and the information indicating area well give a message of "STAT MEASURING END."

If the NIBP value cannot be measured, the NIBP parameter area will display error messages and automatically begin three attempts at measurement again. If the value still cannot be measured, the information indicating area will show a message of "RETRY OVER!" and then continue one last attempt at measurement which lasts 5 minutes and then stops.

During the measurement, if **START/STOP** is activated again, the information indicating area will give a note of "STOP STAT TEST" to stop the NIBP measurement and exit from this mode.

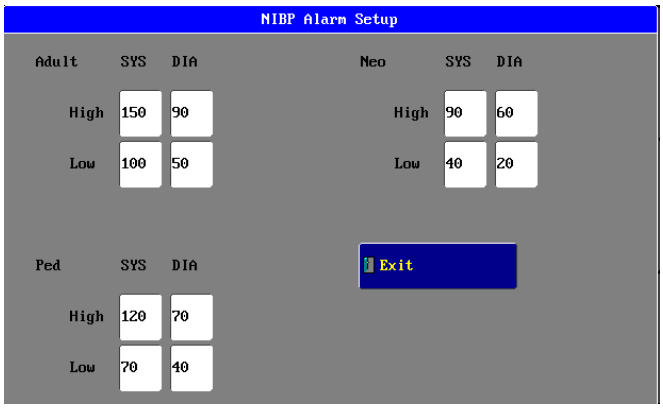
NOTE:

- The value measured will display on the NIBP parameter area for 240 minutes unless a new measurement begin during this period. On the appropriate trend graph and trend table, the parameter will exist for correlated time length.

TIME INTERVAL

There are 2/3/4/5/10/20/30/40/50/60/120/180/240 minutes as choices. This setting is used supported by **automatic** inflation mode, and the factory-set is **2** minutes.

ALARM LIMIT SETUP



PRESSURE	ADULT	PEDIATRIC	NEONATE

SYS upper limit	range	30-240(mmHg) 4.0-32.0(kPa)	30-240(mmHg) 4.0-32.0(kPa)	30-240(mmHg) 4.0-32.0(kPa)
	factory-set	150mmHg 20.0kPa	120mmHg 16.0kPa	90mmHg 12.0kPa
SYS low limit	range	30-240(mmHg) 4.0-32.0(kPa)	30-240(mmHg) 4.0-32.0(kPa)	30-240(mmHg) 4.0-32.0(kPa)
	factory-set	100mmHg 13.3kPa	70mmHg 9.3kPa	40mmHg 5.3kPa
DIA upper limit	range	15-180(mmHg) 2.0-24.0(kPa)	15-180(mmHg) 2.0-24.0(kPa)	15-180(mmHg) 2.0-24.0(kPa)
	factory-set	90mmHg 12.0kPa	70mmHg 9.3kPa	60mmHg 8.0kPa
DIA lower limit	range	15-180(mmHg) 2.0-24.0(kPa)	15-180(mmHg) 2.0-24.0(kPa)	15-180(mmHg) 2.0-24.0(kPa)
	factory-set	50mmHg 6.7kPa	40mmHg 5.3kPa	20mmHg 2.7kPa

FACTORY SETUP

Servicing engineer uses this function only.

MEASUREMENT LIMITATIONS

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

PATIENT MOVEMENT

Measurements will be unreliable or impossible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

CARDIAC ARRHYTHMIA'S

Measurements will be unreliable or impossible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time will be prolonged.

HEART-LUNG MACHINE

Measurements will not be possible if the patient is connected to a heart-lung machine.

PRESSURE CHANGES

Measurements will be unreliable or impossible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

SEVERE SHOCK

If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

HEART RATE EXTREMES

Measurements cannot be made at a heart rate of less than 40 bpm and greater than 240 bpm.

NIBP ERROR MESSAGES

Message indicating area may display messages like below：

Patient moving !
Pressure < 10 mmHg !
Pressure < 1.3 kPa !
Pressure > 325 mmHg !
Pressure > 43.3 kPa!
Serial overtime !
Reset error !
Zero reset error !
Serial error
NIBP renew selfcheck...
NIBP selfcheck...
NIBP selfcheck error !
NIBP inter error !
Patient type error !
Setup patient...
NIBP selfcheck ok!

MAINTAINENCE AND CLEANING

NOTE：Do not squeeze the rubber tube on the cuff.

REUSABLE BLOOD PRESSURE CUFF

The cuff can be sterilized by means of conventional autoclaving, gas or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned. The cuff can also be machine-washed or hand-washed; the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, and then reinsert the rubber bag.

To replace the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

TEMP MONITORING

THEORY OF OPERATION

The monitor provides an isolated temperature measurement channel. When inserting one temperature sensor to the port, the channel's test temperature value will display.

The monitor utilizes a temperature probe with a thermistor to give continuous electronic temperature readings of either core body temperature via rectal/esophageal probe or skin temperature via an external sensor.

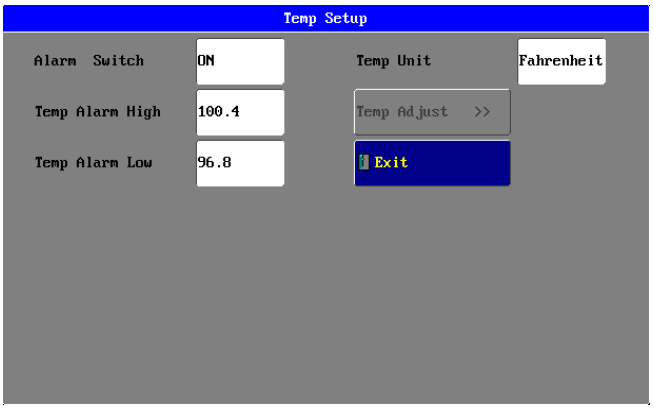
TEMP SENSOR INSTALLATION

1. Select the correct type and size of probe for your patient.
2. If you are using a disposable probe, connect the probe to the temperature cable.
3. Plug the probe or temperature cable into the temperature connector socket on the left panel of monitor.
4. Apply the probe to the patient. You are advised to use a protective rubber cover on rectal probes.
5. Select an appropriate temperature label.
6. Check that the alarm settings (on or off, high and low limits) are appropriate for this patient and this type of temperature measurement.

WARNING:
Make sure you set alarm limits for the correct label. The alarm limits you set are stored for that particular label only. Changing the label may change the alarm limits.

TEMP PARAMETER SETUP

Click the TEMP Parameter Area to open the TEMP Setup menu, see graph below:



The menu can finish settings as below:

ALARM SWITCH
ON and **OFF** for choice, the factory-set is **OFF**.

TEMP UNIT
FAHRENHEIT or **CELSIUS** for choice, the factory-set is **CELSIUS**.

TEMP ALARM UPPER-LIMIT
The range is from **10** to **50** ， and the factory-set is **38.0** , the single-step adjustable step- length is **0.1** .

TEMP ALARM LOWER-LIMIT
The range is from **10** to **50** ， and the factory-set is **36** ， the single-step adjustable step- length is **0.1** .

TEMP ERROR MESSAGES

TEMP SENSSOR OFF: the TEMP probe falls off the monitor.

MAINTAINENCE AND CLEANING

REUSABLE TEMP PROBES

1. The TEMP probe should not be heated above 100℃(212^{o}F). It should only be subjected, briefly, to temperatures between 80℃(176^{o}F) and 100℃(212^{o}F).
2. The probe must not be sterilized in steam.
3. To clean the probe, use alcoholic detergent solution.
4. To clean the probe, hold the tip with one hand and with the other hand rubbing the probe down in the direction of the connector using a moist lint-free cloth.

ETCO2 MONITORING (OPTION)

THEORY OF OPERATION

Carbon dioxide monitoring is used to monitor continuous carbon dioxide and report the End Tidal carbon dioxide ($EtCO_2$), inspired CO_2 and respiratory rate values of the intubated and non-intubated adult, pediatric, infant and neonatal patient.

There are two methods for measuring carbon dioxide in the patient's airway:

• Mainstream measurement uses a CO2 sensor attached to an airway adapter directly inserted into the patient's breathing system.

• Sidestream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO2 sensor. Two variations of this method, with different sensors, are available as options on the monitor. They are referred to here as sidestream CO2 and Microstream CO2.

In both cases, the measurement principle is infrared transmission, where the intensity of infrared light passing the respiratory gas is measured with a photo detector. As some of the infrared light is absorbed by the CO2 molecules, the amount of light passing the gas probe depends on the concentration of the measured CO2.

Carbon dioxide monitoring system is a sidestream sampling system with a 50 ml/minute low sampling rate that is used to measure the CO_2 of non-intubated and intubated neonate, infant, pediatric and adult patients using specially designed sampling cannula and on-airway adapter kits. These kits incorporate a filter and the sample cell that provides maximum filtration of fluids and contaminants and protects the system from aspiration of these fluids.

In carbon dioxide monitoring system, infrared light is generated by the sensor and beamed through the sample cell to a detector on the opposite side. CO_2 from the patient that is aspirated into the sample cell absorbs some of this infrared energy. The monitor determines CO_2 concentration in the breathing gases by measuring the amount of light absorbed by these gases. $EtCO_2$ is displayed as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO_2 waveform (capnogram) may be displayed which is a valuable clinical tool that can be used to assess patient airway integrity and proper endotracheal tube (ETT) placement. Respiration rate is

calculated by measuring the time interval between detected breaths.

WARNING

- DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation. Support the carbon dioxide monitoring system airway adapter to prevent stress on the ET tube.
- Reusing, disassembling, cleaning, disinfecting or sterilizing the single patient use cannula kits and on-airway adapters may compromise functionality and system performance leading to a user or patient hazard. Performance is not guaranteed if an item labeled as single patient use is reused.
- Inspect the sidestream on-airway adapters and sidestream sampling kits for damage prior to use. DO NOT use the sidestream on-airway adapters and sidestream sampling kits if they appear to be damaged or broken.
- Replace the sidestream on-airway adapters and sidestream sampling kits if excessive secretions are observed.
- Monitor the CO_2 check waveform (Capnogram). If you see changes or abnormal appearances check the patient and the sampling line. Replace line if needed.
- Do not apply excessive tension to any cable.
- DO NOT use device on patients that cannot tolerate the withdrawal of 50 ml/min +/- 10 ml/min from the airway or patients that can not tolerate the added dead space to the airway.
- Do not connect the exhaust tube to the ventilator circuit.
- DO NOT stick appendage into sample receptacle.
- Always insert sample cell before inserting the on-airway adapter into the ventilated circuit.
- Always remove the on-airway adapter from the ventilated circuit before removing the sample cell.
- Nitrous oxide, elevated levels of oxygen, helium, Xenon, halogenated hydrocarbons, and barometric pressure can influence the CO_2 measurement.
- **Correlation:** The EtCO2 readings do not always correlate closely with paCO2, especially in neonatal patients and patients with pulmonary disease, pulmonary embolism or inappropriate ventilation.
- **Pharmaceuticals in aerosols:** Do not measure CO_2 in the presence of pharmaceuticals in aerosols.
- **Explosion Hazard:** Do not use in the presence of flammable anesthetics or gases, such as a flammable anesthetic mixture with air, oxygen or nitrous oxide. Use of the devices in such an environment may present an explosion hazard.
- **Failure of operation:** if the measurement or a sensor fails to respond as described, do not use it until the situation has been corrected by qualified personnel.
- **Low $EtCO_2$ values:** Leakages in the breathing system or sampling system may cause the displayed $EtCO_2$ values to be significantly too low. Always connect all components securely and check for leaks according to standard clinical procedures. Displacement of the nasal or combined nasal oral cannulas can cause lower than actual $EtCO_2$ readings. Even with combined nasal oral cannulas, the EtCO2 readings may be slightly lower than actual in patients breathing through the mouth only.

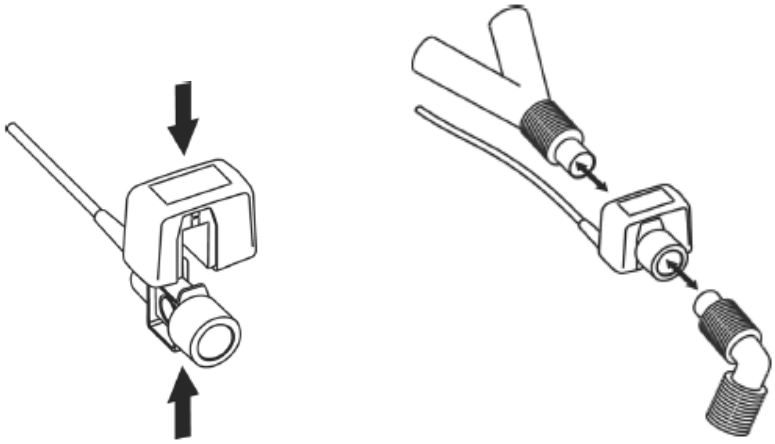
ABBREVIATIONS AND TERMINOLOGY

$EtCO_2$	End tidal carbon dioxide
INSP CO_2	Inspired minimum CO_2

AWRR Air-way respiration rate
BARO Barometric Pressure

PREPARING TO MEASURE MAINSTREAM CO2

You must perform a zero as described in this procedure each time you use a new airway adapter.



1. Attach the sensor connector to the CO2 connector on the monitor.

2. Wait 2 minutes, allowing the sensor to reach its operating temperature and a stable thermal condition.

3. Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.

4. To zero the sensor:
The sample cell zero allows the CO_2 Module to adjust to the optical characteristics of the sample cell only when requested.

Whenever the type of adapter being used with the CO_2 Module is changed, for optimal accuracy, a CO_2 module zero should also be performed whenever the CO_2 Module is connected to the patient monitor.

Before performing a CO_2 Module zero, the CO_2 Module should be removed from the patient monitor and the airway adapter type to be used in the circuit should be inserted into the CO_2 Module. Care should be taken to ensure that the airway adapter is clear of any residual CO_2 gas. The maximum elapsed time for a CO_2 Module zero is 30 seconds. The typical time for a zero is 15 – 20 seconds.

Several CO_2 Module conditions may also request that a zero be performed. These requests stem from changes in the airway adapter that may indicate that the sensor is not in optimal measuring condition. When this occurs, the airway adapter should be checked to ensure optical occlusions such as mucus have not obscured the adapter window. If occlusions are found, the airway adapter should be cleaned or replaced.

5. Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.

NOTE:
- System does not allow adapter zero for 20 seconds after the last breath is detected.
- System does not allow adapter zero if temperature is not stable.
- An adapter zero cannot be performed if a sample cell is not connected to the module.

WARNING: To prevent stress on the endotrachial tube, support the sensor and airway adapter.

Position sensor cables and tubing carefully to avoid entanglement or potential strangulation. Do not apply excessive tension to any cable.

Replace the airway adapter if excessive moisture or secretions are observed in the tubing or if the CO2 waveform changes unexpectedly without a change in patient status.

To avoid infection, use only sterilized, disinfected or disposable airway adapters.

Inspect the airway adapters prior to use. Do not use if airway adapter appears to have been damaged orbroken. Observe airway adapter color coding for patient population.

PREPARING TO MEASURE SIDESTREAM CO2

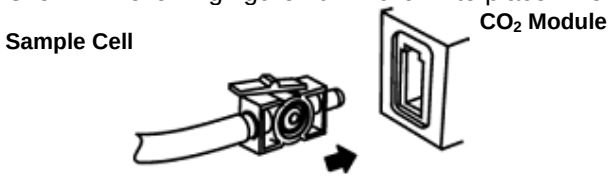
1. MODULE MOUNTING

a. Put the CO_2 module into the bracket of the rear panel of the monitor.
b. Check that the monitor is switched off. Insert the plug of CO_2 sensor into the corresponding sensor socket marked with appropriate **$EtCO_2$** icon on the left panel of monitor. Allow the sensor two minutes of warm up time.

WARNING: Don't plug into hot $EtCO_2$ module. Make sure that the Waveline EZ is powered off before inserting the connector of CO_2 sensor into $EtCO_2$ socket. Otherwise, the CO_2 module may be damaged by power supply from $EtCO_2$ socket of Waveline EZ.

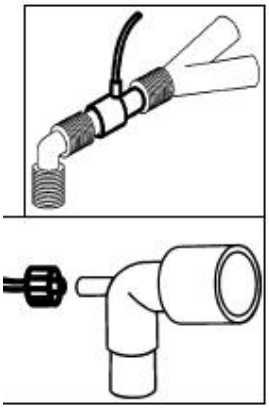
2. CONNECTING THE SAMPLE KIT

a. The sample cell of the sampling kit must be inserted into the sample cell receptacle of the CO_2 Module as shown in following figure. It will click into place when seated correctly.



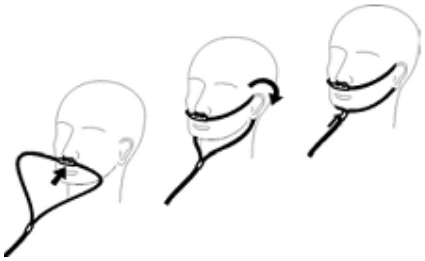
b. To zero the sensor.

c. For intubated patients requiring an airway adapter: Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y section.



For intubated patients with an integrated airway adapter in the breathing circuit: connect the male lure connector on the straight sample line to the female port on the airway adapter.

For non-intubated patients: Place the nasal cannula onto the patient.

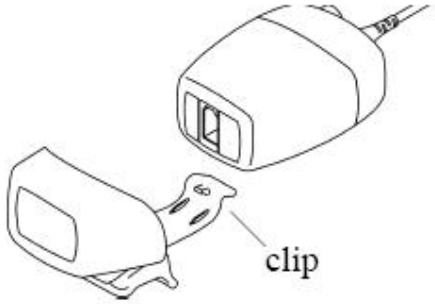


For patients prone to mouth breathing, use an oral-nasal cannula.

For nasal or oral-nasal cannulas with oxygen delivery, place the cannula on the patient as shown then attach the oxygen supply tubing to the oxygen delivery system and set the prescribed oxygen flow.

WARNING: Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.

USING THE SIDESTREAM SENSOR HOLDER



The holder delivered with the sensor can be used to clamp the sensor onto an IV pole or a shelf.

1. Push the sensor into the holder until it clicks into position.

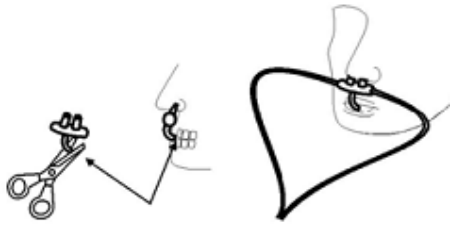
2. Clamp the holder onto an IV pole, a shelf or another appropriate location.

To remove the sensor from the holder, release the clip and pull the sensor out of the holder.

DIRECTIONS FOR USE OF SINGLE PATIENT USE NASAL AND NASAL/ORAL SIDESTREAM KITS

CAUTION: The Nasal and Nasal/Oral Cannula kits are intended for single patient use. Do NOT reuse or sterilize the cannula kit, as system performance will be compromised.

1. Verify that the cannula kit is clean, dry and undamaged. Replace the cannula kit if necessary.
2. Insert the sample cell into the sample cell receptacle as shown in above figure on Connecting the Sample Kit section. A "click" will be heard when properly inserted.
3. Perform a sample cell zero if prompted by the host system.
4. Place the nasal cannula kits onto the patient.
5. Some patients are prone to mouth breathing. The Oral/Nasal sampling cannula should be used on these patients, as most, if not all of the CO_2 is exhaled through the mouth. If a standard nasal CO_2 sampling cannula is used with these patients, the $EtCO_2$ number and capnogram will be substantially lower than actual.
6. When using the Nasal or Oral/Nasal CO_2 sampling kits with oxygen delivery, place the cannula on the patient as shown in Figure 3 and then attach the oxygen supply tubing to the oxygen delivery system and set the prescribed oxygen flow.
7. If the oral/nasal cannula is used, the oral sampling tip may need to be trimmed to adequately fit the patient (see following figure). Place the cannula onto the patient as shown in above figure. Observe the length of the oral cannula tip. It should extend down past the teeth and be positioned in the mouth opening. Remove the cannula from the patient if the tip needs to be trimmed.



CAUTION: Do NOT cut the oral cannula tip when the cannula is on the patient.

CAUTION: Remove the sampling kit sample cell from the CO_2 Module Inlet Port when not is use.

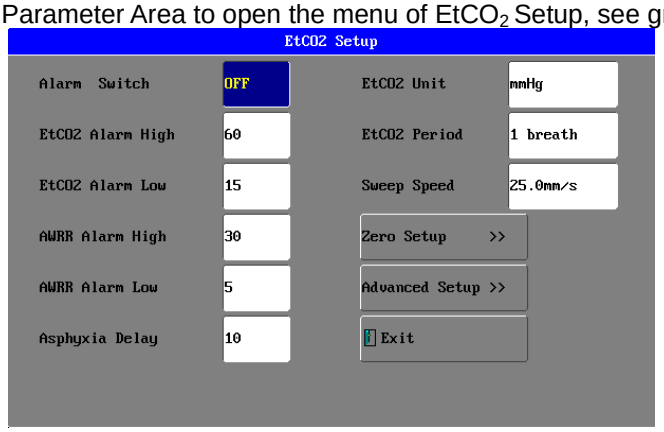
REMOVING EXHAUST GASES FROM THE SYSTEM

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

WARNING Anesthetics: When using the sidestream CO_2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, to avoid exposing medical staff to anesthetics.

ETCO2 SETUP

Click the $EtCO_2$ Parameter Area to open the menu of $EtCO_2$ Setup, see graph below:



ALARM SWITCH
ON and **OFF** for choice, the factory-set is **OFF**.

ETCO2 ALARM HIGH
The range is from **20** to **100 mmHg**，and the factory-set is **20mmHg**.

ETCO2 ALARM LOW
The range is from **10** to **95 mmHg**，and the factory-set is **40mmHg**.

AWRR ALARM HIGH
The range is from **10** to **150 mmHg**，and the factory-set is **30mmHg.**

AWRR ALARM LOW
The range is from **5** to **100 mmHg**，and the factory-set is **20mmHg**. The single-step adjustable length of alarm limit above is **5mmHg**.

ASPHYXIA DELAY

This setting is used to set the no breaths detected time-out. This time-out is the time period in seconds following the last detected breath at which the CO_2 module will signal no breaths detected.

The setting range is from **10** to **60 seconds**，and the factory-set is **20 seconds**.

ETCO2 UNIT

mmHg, kPa or **percent (%)**，the factory-set is **mmHg**.

ETCO2 PERIOD

This setting is used to set the calculation period of the $EtCO_2$ value. The end-tidal CO_2 value is the highest peak CO_2 value of all end of expirations (end of breaths) over the selected time period. If less than two breaths exist in the selected time period, the value will be the maximum $EtCO_2$ value for the last two breathes.

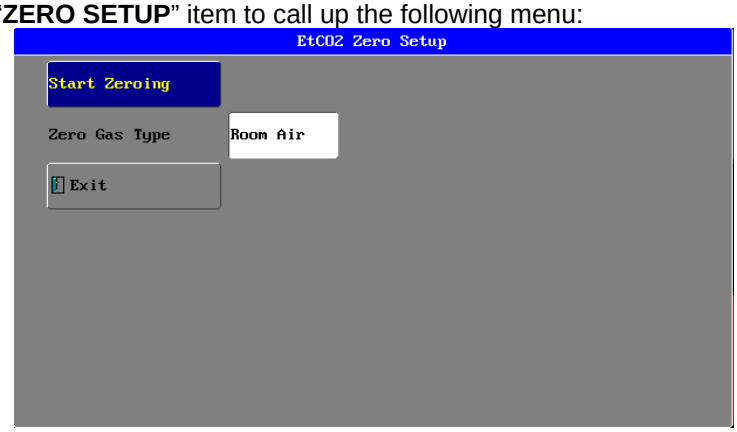
This setting has 1 breath, 10 seconds and 20 seconds for choice, the factory –set is **20 seconds**.

SWEEP SPEED

From **12.5mm/s** and **25mm/s** for choice, the factory-set is **25mm/s**.

ZERO SETUP

Pick up "**ZERO SETUP**" item to call up the following menu:



Zero steps refer to "Zeroing the CO_2 Module" section detailed.

In above menu, complete the zero procedure by clicking the button **"Start Zeroing."** During zeroing, a message of "$EtCO_2$ Zero Started" will be displayed on the message area.

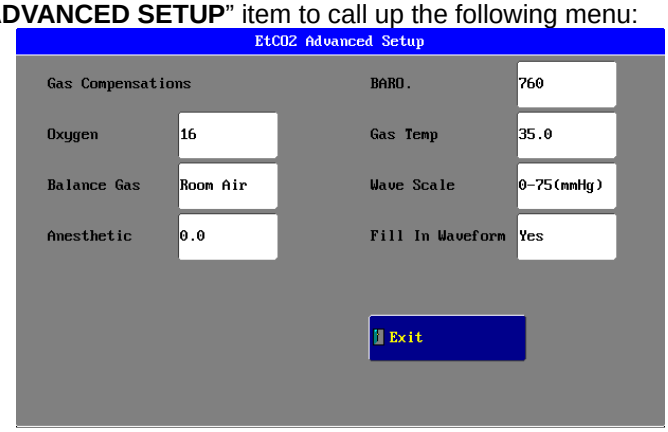
NOTE: During the CO_2 module warmup period after the monitor is powered on, the monitor will perform an automatic zero calibration. The maximum elapsed time for a CO_2 Module zero is 30 seconds. The typical time for a zero is 15 – 20 seconds.

ZERO GAS TYPE

When performing a zero on room air, this setting should be set to room air (the default). Only change to nitrogen (N_2) when performing a zero on 100% N_2 gas; this is provided for use in a laboratory environment.

ADVANCED SETUP

Click the "**ADVANCED SETUP**" item to call up the following menu:



SET GAS COMPENSATIONS

The measurement of CO_2 is affected by temperature, pressure, and gas compensations. The barometric pressure as well as the presence of O_2 , N_2O, helium, and anesthetic agents in the gas mixture needs to be compensated for by the CO_2 module in order to achieve its stated accuracy. The instrument settings for these parameters should be set when initially connecting to the CO_2 module and whenever there is a change in the conditions at the patient airway.
In the CO_2 module, the temperature of the gas in the airway also effects the CO_2 measurement. It is necessary to adjust the instrument setting for the gas temperature to achieve the maximum accuracy for the CO_2 module.

BAROMETRIC PRESSURE

This setting is used to set current Barometric Pressure.
The setting range is from **400** to **850 mmHg**. The factory-set is **760 mmHg**.

GAS TEMPERATURE

This setting is used to set temperature of the gas mixture. This setting is useful when bench testing using static gasses where the temperature is often room temperature or below.
The setting range is from **0** to **50**℃. The factory-set is **35**℃.

OXYGEN COMPENSATION

The setting range is from **0** to **100%**. The factory-set is 1**6%**.

BALANCE GAS

There are room air, N_2O and Helium items to choose.

ANESTHETIC AGENT

Use this setting to correct for the compensation of the gas mixture administered to the patient. Anesthetic agent is ignored when the balance gas is set to helium.
The setting range is from **0.0** to **20.0%**. The factory-set is **0.0%**.

NOTE: At 700mmHg of pressure, the correct CO_2 value is 35.0 mmHg.

WAVEFORM SCALE

Use this setting to adjust the amplitude measurement (size) of the displayed $EtCO_2$

waveform scale manually.
There are two items to choose: 0～75 mmHg, 0～150 mmHg.

FILL IN WAVEFORM
Use this setting to fill in the bottom portion of the waveform on any channel of the display; the "fill in" can be canceled by choosing NO item.

CALIBRATION

No routine user calibration required.

Safety lock-outs:

- System does not allow sample cell zero for 20 seconds after the last breath is detected.
- System does not allow sample cell zero if temperature is not stable.
- An adapter zero cannot be performed if a sample cell is not connected to the module.

STATUS/ERROR MESSAGES

Messages	Descriptions
Sensor Off	The CO_2 sensor is not connected
Sensor Warm Up	One of the following conditions exist: Sensor under temperature Temperature not stable Source Current unstable
Sensor Over Temp	Make sure sensor is not exposed to extreme heat (heat lamp, etc.). If error persists, return sensor to factory for servicing.
Sensor error	Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing.
Sensor Zeroing. . .	A zero is currently in progress.
Zero Required	To clear, check airway adapter and clean if necessary. If this does not correct the error, perform an adapter zero. If you must adapter zero more than once, a possible hardware error may exist.
Check Sampling Line	To clear, clean if sampling line mucus or moisture is seen. If the sampling line is clean, perform a zero.
CO_2 Out of Range	The value being calculated is greater than the upper CO2 limit (150 mmHg, 20.0 kPa, or 19.7 %). The maximum value output is the upper CO_2.
Check Airway Adapter	To clear, clean airway adapter if mucus or moisture is seen. If the adapter is clean, perform a zero.
Pump Life Exceed	The manufacturer stated pump life has been exceeded. Service may be required if Pneumatic System Error is present and can no longer be cleared.
Sensor Setup. . .	The CO_2 sensor is setting process.
$EtCO_2$ Zero Error: Sensor Not Ready.	The CO_2 sensor is not ready for a $EtCO_2$ Zero
$EtCO_2$ Zero Error: Breath Detected.	Breaths have been detected by the CO_2 module within the last 20 seconds while a CO_2 module zero was attempted.

MAINTENANCE AND CLEANING

SCHEDULE

The CO_2 Module flow rate accuracy should be verified by direct measurement using a calibrated flow meter every 12 months.

CLEANING

Cleaning the CO2 Module case, Cable and connector:

1. Use a cloth dampened with isopropyl alcohol 70%, a 10% aqueous solution of sodium hypochlorite (bleach), a 2% gluteraldehyde solution, ammonia, mild soap or disinfectant spray cleaner such as Steris Coverage® Spray HB.
2. Wipe down with a clean water-dampened cloth to rinse and dry before use. Make certain that the sensor windows are clean and dry before reuse.

NOTE： Do not immerse or sterilize the CO_2 Module.

Cleaning the Sidestream On-Airway Adapters and Sidestream Sampling Kits:

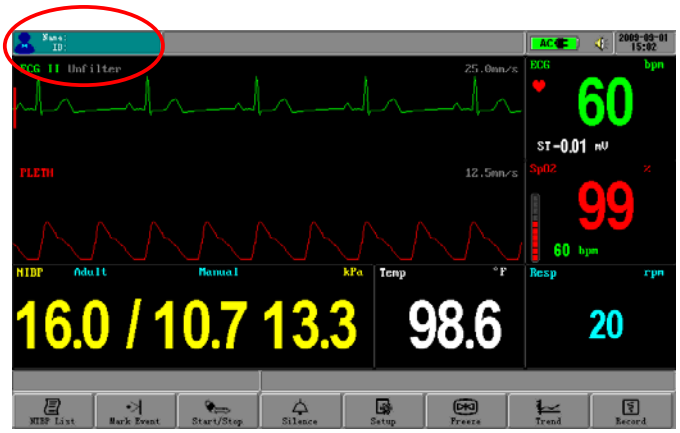
Sidestream on-airway adapters and sidestream sampling kits are single patient use. Treat in accordance with hospital protocols for handling single patient use devices.

PATIENT INFORMATION ADMINISTRATION

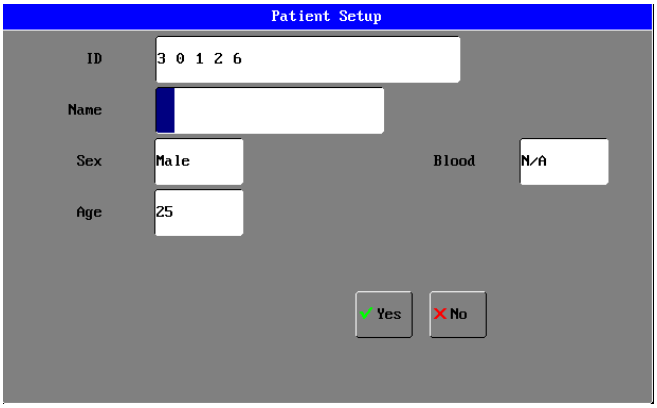
PATIENT BASIC INFORMATION SETUP
MARK EVENT SETUP
NIBP DATA LIST OBSERVATION
TREND GRAPH ANALYSIS
TREND ANALISIS
TRANSFERRING TRENDS VIA RS-232

PATIENT BASIC INFORMATION SETUP

Click the patient information area as following:



Open the menu of Patient Information Setup (see graph below). The menu can set up the following patient record:



ID
Set the ID number of the patient.

NAME

Move the cursor box to the correlated position and press it, turning the ROTARY KNOB after choosing can input the English alphabet or Chinese phonetic letters, the range is: uppercase A-Z, point (.) and blank character.
Patient name supports the display method of English and phonetic letters, but does not support the Chinese characters input. The user can input 9 characters at most.

SEX
Set the patient gender, the default setting is **MALE**.

BLOOD
Set the blood type of the patient. It can be：**N/A**(unknown type) , **A** , **B** , **O** , **AB** , **RH+** , **RH-** and so on, the default setting is **N/A**.

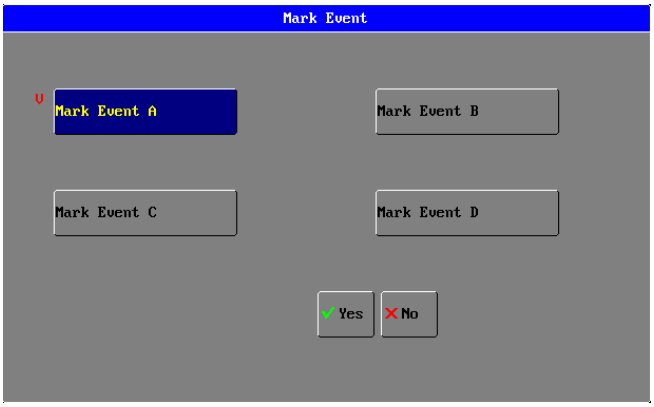
AGE
Set the age of the patient, the default setting is **20**.

NOTE: Once the user chooses **YES** to exit from the Patient Information Setup, all information of patient will be refreshed and the trend data will be renovated.

MARK EVENT SETUP

Click the **Mark Event** button in the Touch Keys Area. There are four types of events that you can define. The user can freely define the implication of each type.

The menu is like the chart below:



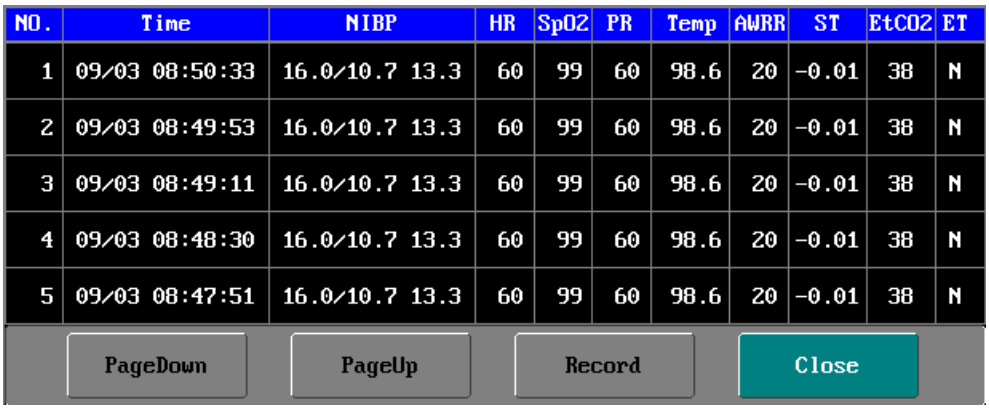
MARK EVENT
To mark the event: click and select one from A, B, C and D. There is a red **V** mark signal for the one selected.

Choose the **YES** button to exit, and the event marked will become effective immediately upon the exit, or else it will not become effective.

IMPORTANCE OF EVENT MARKING:
It can classify the circumstances which influence the parameter monitoring on patient, for example: medicines taken, injection and other treatment. These events, displaying on NIBP list, trend graph or table, are very important to the parameter analysis.

NIBP LIST OBSERVATION

Click the **NIBP LIST** button in the Touch Keys Area to open the NIBP LIST menu, see chart below:



NO.	Time	NIBP	HR	SpO2	PR	Temp	AWRR	ST	EtCO2	ET
1	09/03 08:50:33	16.0/10.7 13.3	60	99	60	98.6	20	-0.01	38	N
2	09/03 08:49:53	16.0/10.7 13.3	60	99	60	98.6	20	-0.01	38	N
3	09/03 08:49:11	16.0/10.7 13.3	60	99	60	98.6	20	-0.01	38	N
4	09/03 08:48:30	16.0/10.7 13.3	60	99	60	98.6	20	-0.01	38	N
5	09/03 08:47:51	16.0/10.7 13.3	60	99	60	98.6	20	-0.01	38	N

NIBP LIST MOVING

Click the choice item to the correlated button position as indicated on chart to complete relevant operation, including in page down, page up, and record.

The NIBP list can save 256 groups of data.

NOTE:
Only after the NIBP value has been measured can it be added to the NIBP Data List. NIBP list can save 256 groups of data at all, if exceed, the new data will kick the most former data out of the list and be added to the list automatically.

TREND OBSERVATION

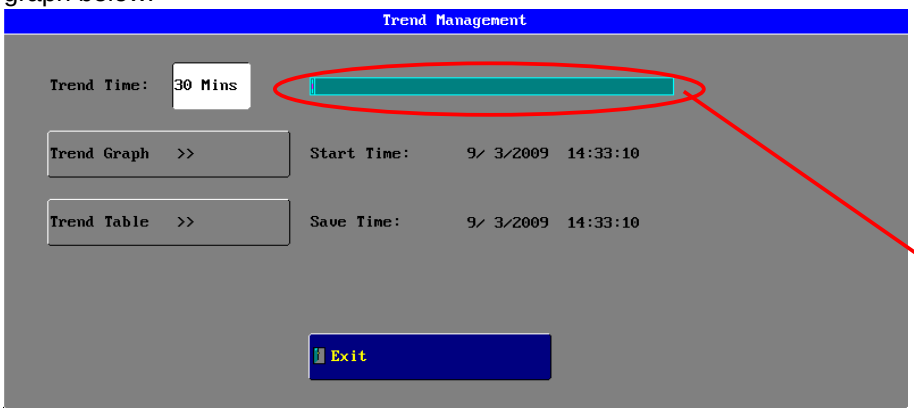
PARAMETER FOR TREND OBSERVATION

The monitoring system will save and trace the trend of parameters below:
HR (HEART RATE)
SPO_2 (OXYGEN SATURATION)
NONTRAUMATIC BLOOD PRESSURE (NIBP-SYSTOLIC BLOOD PRESSURE (SYS, DIASTATIC BLOOD PRESSURE (DIA)
TEMP (TEMPERATURE)
PR (PULSE RATE)
RESPIRATION RATE (RESP)
ETCO2

ST
ET (EVENT)

TREND OBSERVATION ADMITTANCE

Click the function button of **TREND** button in the Touch Keys Area to open the graph below:



Data-recording Status Bar: It is used to show the current data-recording length. For example, the user sets a trend of 15 minutes, if the color of bar right moment is red, it means that the data-recording time is shorter than 15 minutes, i.e. the data-recording length is smaller than the time-length choosing by user; if the color is light-blue, it means that the data-recording is equal to the choosing time-length; if the bar presents the light-blue and green alternately, it means that the data-recording length is larger than the setup time length, and the light=blue part is the proportion of data-recording length covered by the time-length, and the green part is the proportion of data-recording length covered by time-length which has not been chosen.

TREND TIME CHOOSING

Trend time is the time length before current time.

There are eleven items for trend time choosing: 15 minutes, 30 minutes, 60 minutes, 90 minutes, 3 hours, 6 hours, 12 hours, 18 hours, 24 hours, 36 hours, 48 hours, 60 hours, and 72 hours. For instance, if 30 minutes is chose as the reference trend time, then we can recall the trend change of 30 minutes before current time.

TREND TIME INTERVAL

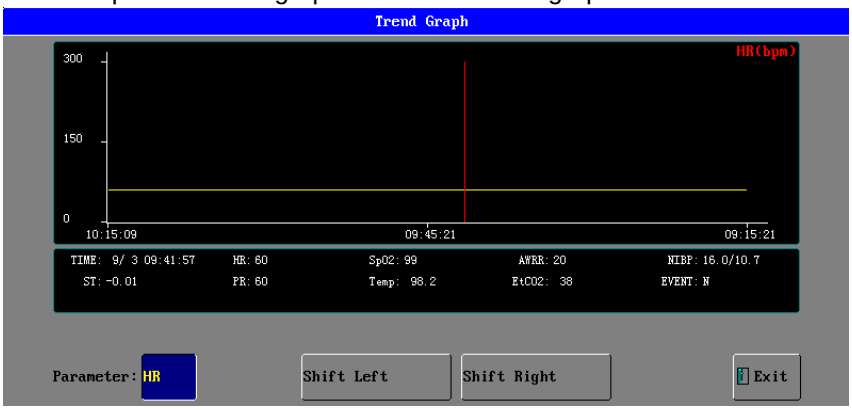
Trend Time Interval means how often the system stores a trend data. Different trend reference time has its correlated trend time interval, the relation between them are show below:

15 minutes:	3 seconds
30 minutes:	6 seconds
60 minutes:	12 seconds
90 minutes:	18 seconds
3 hours:	36 seconds
6 hours:	72 seconds
12 hours:	144 seconds
18 hours:	216 seconds
24 hours:	288 seconds
36 hours:	432 seconds
48 hours:	576 seconds
60 hours:	720 seconds
72 hours:	864 seconds

TREND GRAPH ANALYSIS

TREND GRAPH ANALYSIS ADMITTANCE

To choose the Trend Graph Analysis on the trend management menu, click the **trend graph** button to open the trend graph interface like the graph below:



Each page displays the trend chart of one parameter; the user can change it by clicking the **PARAMETER** item. The selection order is as below:
HR, SPO2, RESP, NIBP, ST, PR, TEMP, ETCO2.

The newest data is on the right side of the graph. Time is displayed on the bottom of the graph at the scale of 24 hours; the upper and lower limit of parameter is displaying on the left side of graph.

TREND STAFF

On the trend graph, the number by each side of parameter is the trend graph staff; it shows the valid range of trend data. The trend staff of each parameter is below:

HR：10～300 bpm
SPO_2：50～100 %
RESP：3～150 bpm
NIBP：10～255 mmHg
ST：-2.5～+2.5mV
PR： 10～300 bpm
TEMP：5～50
ETCO2：0 to 150 mmHg

CURSOR BAR

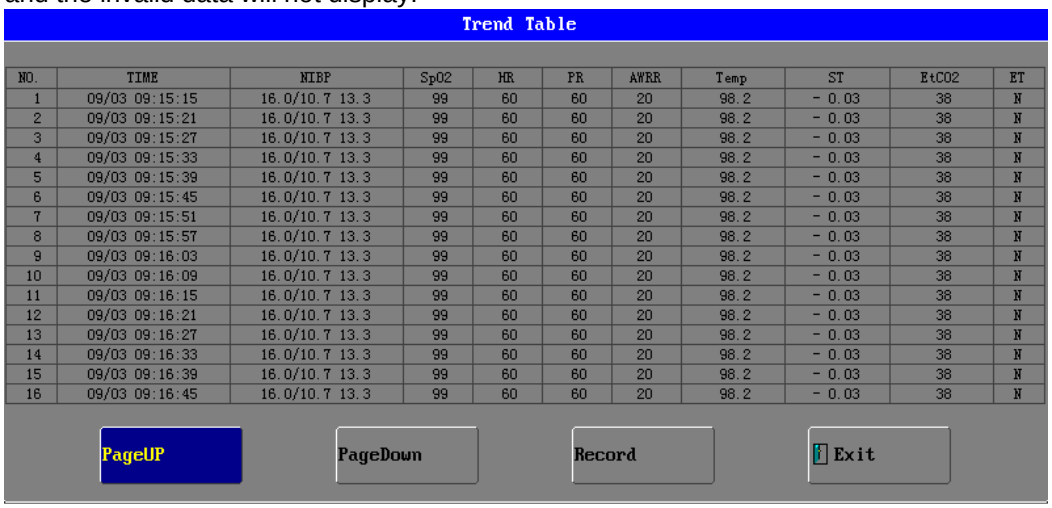
It is the red vertical line on the trend graph, used for indication.
Click the **shift left** or **shift right** buttons to move the red cursor bar. Click the **EXIT** button to exit from the cursor operation.

TREND TABLE ANALYSIS

TREND TABLE ADMITTANCE

If **Trend Table** is clicked on the trend management menu, the trend Table menu will display in the waveform area on the screen. Sixteen groups of parameters are listed every

one page. These data will list by following the order of from new to former and the time is displaying at the scale-of-24 hours. The parameter name is displayed on the top of chart and the invalid data will not display.



TREND TABLE MOVING

Click the choice item to the correlated button position as indicated on chart to complete relevant operation, including in page down, page up, and record.

NOTE: The trend table can save total 300 groups of data.

ST SEGMENT MONITORING

The monitor performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numeric and snippets on the monitor.

All available leads can be monitored continuously. The ECG waveform does not need to be displayed on the monitor for ST Segment analysis.

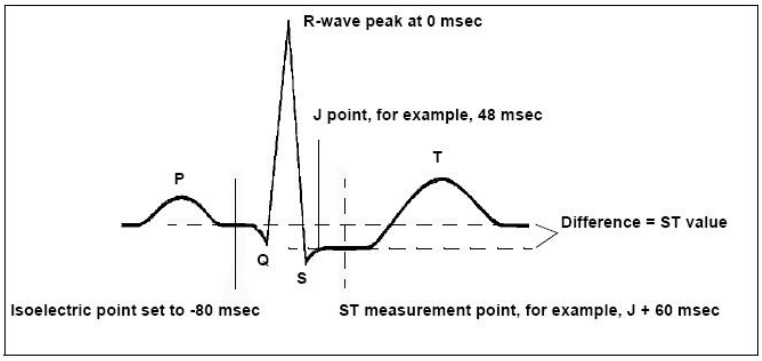
ST analysis is always performed using a dedicated filter which ensures diagnostic quality. If you are monitoring ECG using an ECG filter mode other than Diagnostic, the ST segment of the ECG wave may look different from the ST segment of the ST snippet for the same wave. For diagnostic evaluation of the ST segment, always switch to Diagnostic filter mode or use the ST snippet.

WARNING: Some clinical conditions may make it difficult to achieve reliable ST monitoring, for example:
• If you are unable to get a lead that is not noisy.
• If arrhythmias such as atrial fib/flutter are present, this may cause an irregular baseline.
• If the patient is continuously ventricularly paced.
• If the patient has left bundle branch block.

You should consider switching ST monitoring off if these conditions are present.
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

ABOUT THE ST MEASUREMENT POINTS

The ST value for each beat complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, the ST point is at the midpoint of the ST segment. The J point is where the QRS complex changes its slope; as it is a fixed distance away from the ST point, it can be useful to help you position the ST point correctly.

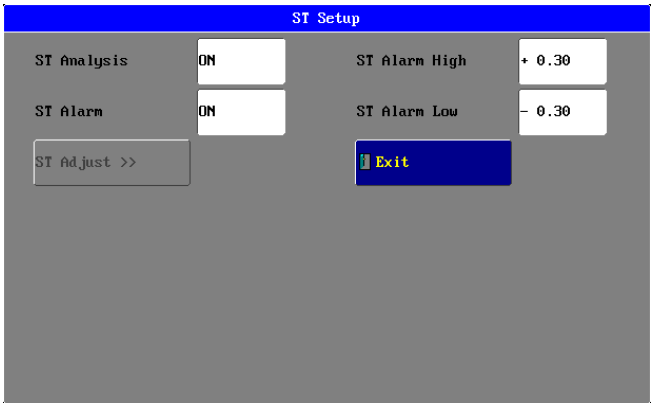


CAUTION: The ST measurement points need to be adjusted when you start monitoring, and if the patient's heart rate or ECG morphology changes significantly, this may affect the size of the QT interval and thus the placement of the ST point. Artifactual ST segment depression or elevation may occur if the isoelectric point or the ST point is incorrectly set.

Always ensure that ST measurement points are appropriate for your patient.

OPERATON SEQUENCE

Click the **ST Analysis** button in the ECG setup menu to open the ST setup menu as below:



ST ANALYSIS SWITCH

The default value is **OFF**; only with the choice of **ON** can the user operate the ST Segment Monitoring. The ST Segment result measured on the lead appointed by the user is the digital form when appearing on the ST Parameter Area. Meanwhile, the **TREND GRAPH** or **TREND TABLE** can be opened by the button of **TREND** to see the tendency displaying on the graph or table.

ST ALARM SWITCH

The default value is **OFF**. The alarm is triggered when the ST measurement value exceeds the alarm limits. If the ST Alarm is **ON**, the ST value blinks, the alarm sounds and the alarm indicator flashes, and the information column will give the note that **ST HIGHER** or **ST LOWER**.

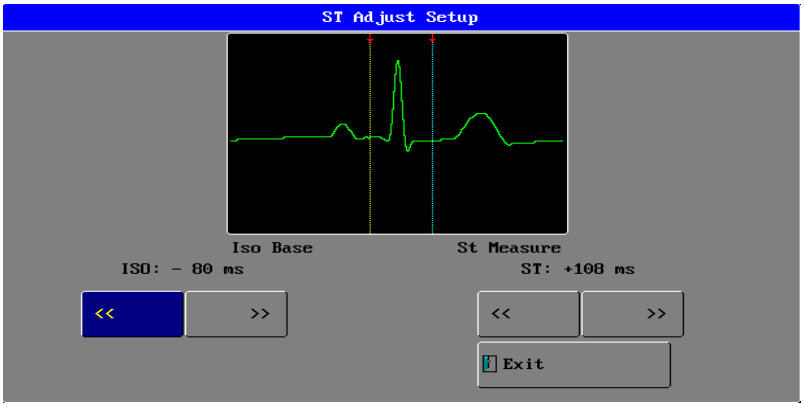
ST ALARM LIMIT

Set the ST alarm upper limit and lower limit separately. The default upper limit is+0.30，The default lower limit is -0.30.

	The Most High Limit	the Most Low Limit	Single Adjustment
ST	2.00mV	-2.00mV	0.02 mV

ST ADJUST

After choosing, this menu below will appear (the graph is the obtained ST Segment module):



ISO（Base Point）

Set the baseline point, its adjustable range is –508ms～–4ms, the default value is –80ms, it shows that the reference point is the position 80ms before the peak of R-wave locates.

ST（Measurement Point）

Set the measuring point, its adjustable range is +508ms～+8ms, the default value is +108ms, it shows that the reference point is the position 108ms after the peak of R-wave locates.

These two points can be adjusted by clicking the button of **<<** or **>>.** The value and the indicating line will change simultaneously. The ST measurement for each beat complex is the vertical difference between the two measurement points.

NOTE: The ST measurement point should be adjusted if the patient's HR or ECG morphology changes significantly.

ATTENTION POINTS

1. **ST Segment Measurement Value：**

   Unit：mV

   Implication：The positive number means the ST SEGMENT is elevating, and the negative number means depressing.

   Measurement Range：-2.0mV～+2.0mV

2. **Indicating Information Explanation：**

   ST SEGMENT TOO HIGH: means that the ST value is above the upper limit of alarm.

   ST SEGMENT TOO LOW: means that the ST value is below the lower limit of alarm.

3. **Other Points:**

   Abnormal QRS complex is not considered in ST segment analysis.

   If the ST Segment Calibration cannot be entered, it means that there is no ST module for use.

   It only appears when the ECG signal doesn't exist.

ARRHYTHMIA ANALYSIS

ABOUT ARRHYTHMIA MONITORING

Arrhythmia analysis provides information on your patient's condition, including heart rate, PVC rate, rhythm and ectopics. The monitor uses the user-selected primary and secondary ECG leads for single lead arrhythmia analysis. During arrhythmia analysis, the monitor continuously:

• Optimizes ECG signal quality. This is important for arrhythmia analysis. The monitor continuously filters the ECG signal to remove baseline wander, muscle artifact, and signal irregularities. Also, if the Patient Paced status is set to Yes, pace pulses are filtered out to avoid processing them as QRS beats.
• Detects beats, for example, QRS complexes, identifying them for further analysis.
• Measures signal features such as R-wave height, width, and timing.
• Creates beat templates, and classifies and labels beats to aid in rhythm analysis and alarm detection.
• Examines the ECG signal for ventricular fibrillation, asystole, and noise.

CHOOSING AN ECG LEAD FOR ARRHYTHMIA MONITORING

It is important to select a suitable lead for arrhythmia monitoring.
Guidelines for non-paced patients are:
– QRS complex should be tall and narrow (recommended amplitude > 0.5 mV).
– R-Wave should be above or below the baseline (but not bi-phasic).
– T-wave should be smaller than 1/3 R-wave height.
– The P-wave should be smaller than 1/5 R-wave height.

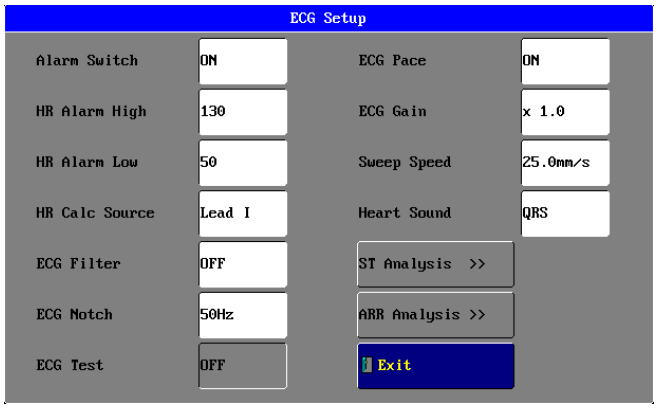
For paced patients, in addition to the above, the pace pulse should be:
– Not wider than the normal QRS.
– The QRS complexes should be at least twice the height of pace pulses.
– Large enough to be detected, with no re-polarization.
To prevent detection of P-waves or baseline noises as QRS complexes, the minimum detection level for QRS complexes is set at 0.15 mV, according to AAMI-EC 13 specifications. Adjusting the ECG wave size on the monitor display (gain adjustment) does not affect the ECG signal which is used for arrhythmia analysis. If the ECG signal is too small, you may get false alarms for pause or asystole.

Arrhythmia analysis can monitor 13 kinds of arrhythmias:
ASY ---- Asystole
FIB ---- Fibrillation
VTA ---- Ventricular tachycardia
ROT ---- R ON T
RUN ---- Ventricular Run
TPT ---- Ventricular Triplet
CPT ---- Ventricular Couplet
VPB ---- Ventricular prematare beat
BGM ---- Bigeminy
TGM ---- Trigeminy
TAC ---- Tachycardia
BRD ---- Bradycardia
MIS ---- Miss beat
The monitoring system supports the self-relearn function to accommodate itself to new conditions, such as different patients. The user can edit the arrhythmia type. For each type, the system saves 8 items arrhythmia and totally saves 104 items.

ECG PACE

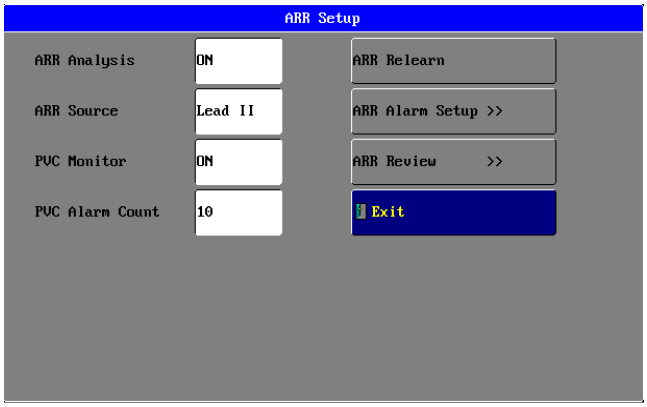
Set the ECG Pace on or off. The factory-set is **OFF**,

If ECG Pace is set to be **on**, the arrhythmia analysis is off to avoid invalid arrhythmia analysis.



OPERATION SEQUENCE

Click the **ARR Analysis** button in the ECG setup menu to open the ARR setup menu as below:



ARR ANALYSIS

Set arrhythmia analysis to be **ON** or **OFF**. The factory-set is **ON**,

ARR SOURCE

Select between **lead I, lead II** and **V**, and the factory-set is **lead II**. The user can switch the ECG lead if the current lead's signal is weak.

PVC MONITOR

Set PVC monitor to be **ON** or **OFF**. The factory-set is **ON.** If the premature ventricular contraction times exceed the PVC ALARM COUNT, the system will alarm.

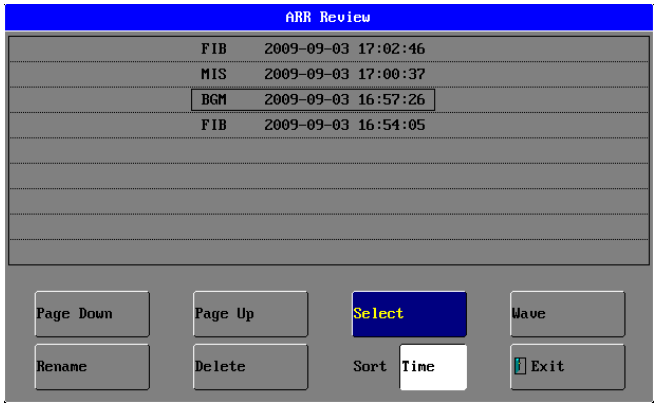
PVC ALARM COUNT

Its set range is from 1 to 10. The factory-set is 10.

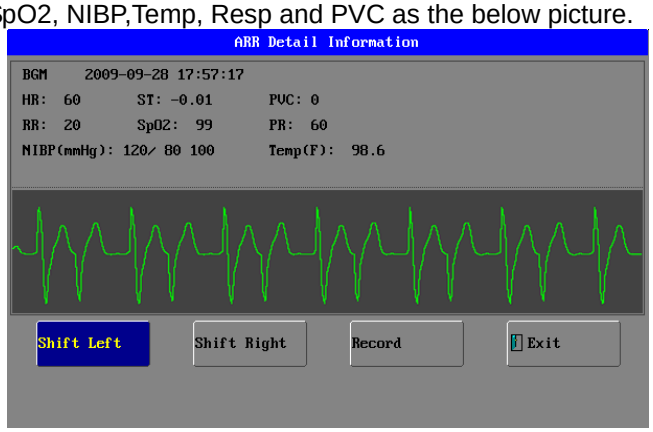
ARR RELEARN

To initiate Arrhythmia Relearning Manually:

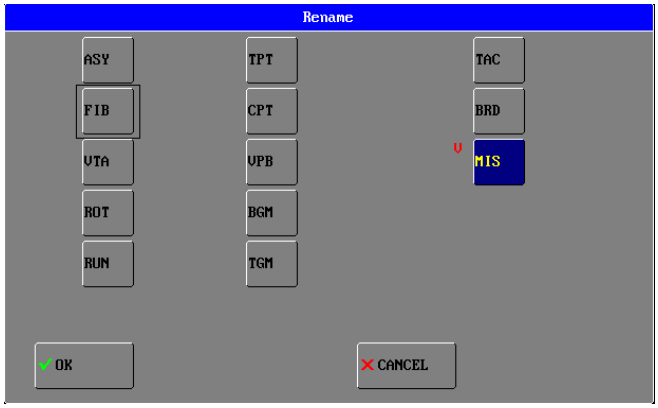
– While the monitor is learning, the delayed arrhythmia wave displays the beat label L and

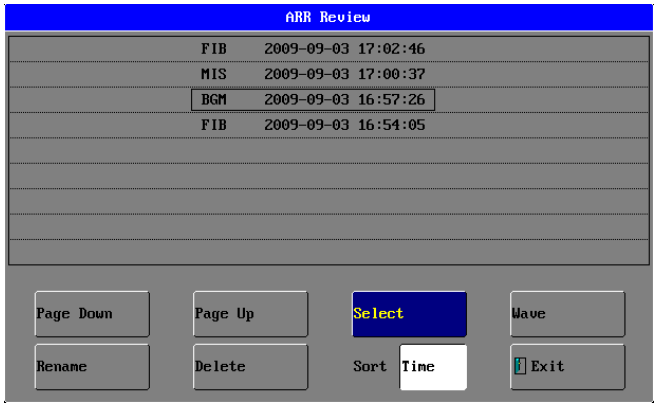


Click the **Select** button to choose an arrhythmia item.
Click the **Delete** button to delete a selected ARR item.
Click the **Sort** button to sort the arrhythmia items by **time** or **type**.
Choose the **Sort** type. The factory-set is by **Time**.
Click the **Wave** button to review the detailed for a selected arrhythmia item includes items of HR, ST, PR, SpO2, NIBP,Temp, Resp and PVC as the below picture.

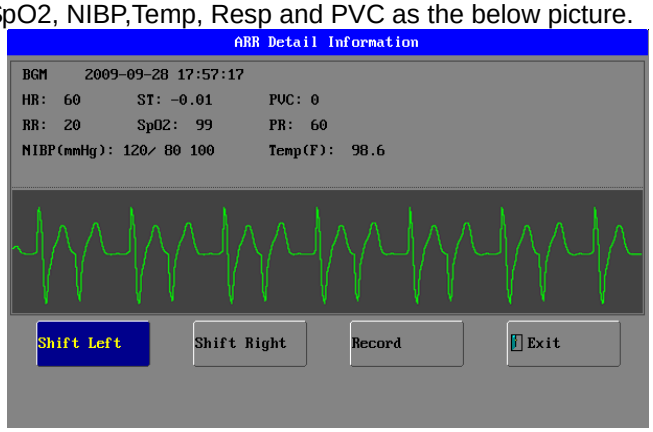


Click the **Rename** button to rename a selected ARR item.

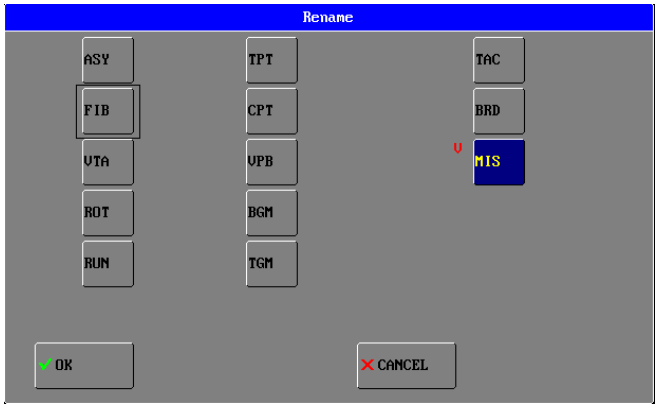




Click the **Select** button to choose an arrhythmia item.
Click the **Delete** button to delete a selected ARR item.
Click the **Sort** button to sort the arrhythmia items by **time** or **type**.
Choose the **Sort** type. The factory-set is by **Time**.
Click the **Wave** button to review the detailed for a selected arrhythmia item includes items of HR, ST, PR, SpO2, NIBP,Temp, Resp and PVC as the below picture.



Click the **Rename** button to rename a selected ARR item.



RECORDING（OPTION）

NOTE: This is a thermal recorder which must use the thermal recording paper (the specification is 48mm on width).

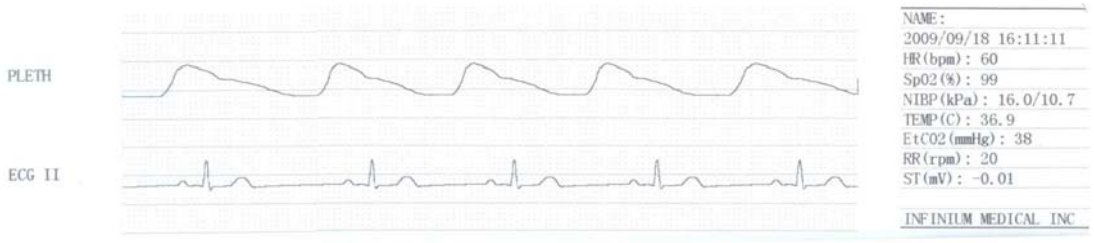
REAL-TIME WAVEFORM RECORDING

1. CONTENTS:

（1） From the preceding 8 seconds before the recording, it can record a burst of two waveforms, Gain and Paper Advance Speed.

（2） Records the parameter report simultaneously which includes:

Patient Name, Hospital name, Recording Time, LEAD, HR, RESP, SPO2, TEMP, ETCO2, RR, ST Segment, the latest NIBP's Blood Pressures of SYS and DIA (mmHg), see graph below:



2. OPERATION SEQUENCE

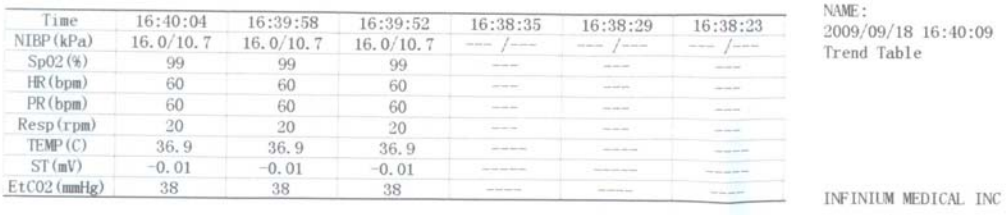
Click the **RECORD** function button on the screen —→The statement of "START RECORDING" appears on the bottom of screen, which shows that it is currently printing.

NOTE: Each time the RECORD button is pressed, it will either carry out REAL-TIME RECORDING or terminate CURRENT RECORDING TASK.

TREND TABLE RECORDING

1. CONTENTS

Records 11 groups of parameter reports, including seven items of DATE, TIME, HR, ST SECTION, RESP, SPO2, TEMP, PR, AWRR,SYS/DIA and ETCO2, see table below:



2. RECORDING SEQUENCE

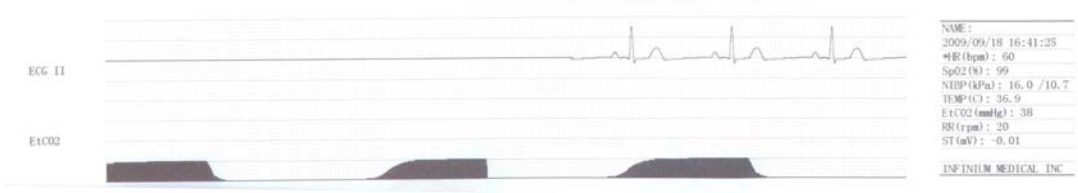
Click the **TREND** function button on the screen —→ TREND MANAGEMENT menu appears on screen—→click the TREND TABLE button—→XX TIME TREND TABLE menu appears on screen—→click the RECORD button—→START RECORDING…….

ALARM RECORDING

1. CONTENTS

(1) It can record a burst of waveforms of 10 seconds (the preceding 4 seconds before the recording till the current 4 seconds) after the alarm, including Gain and Paper Advance Speed.

(2) One alarm report paper includes Alarm Begin Time, Alarm Lead, HR, RESP, SPO2, RR, TEMP, ST SECTION, Alarm Type, the latest NIBP's SYS and DIA(mmHg) value. Alarm Types are explained as below (The alarm parameter is marked with the letter of "*"):



2. RECORDING SEQUENCE

Click the **TREND** button on the screen—→TREND MANAGEMENT menu appears on screen—→ click the ALARM EVENT item—→ALARM EVENT menu appears on screen —→click RECORD button—→START RECORDING

If there are several parameter alarms simultaneously, click and choose them on ALARM menu, parameter alarms indicated by red sign can be recorded simultaneously. The same parameter alarm can only record one sequence from the alarm state into the normal state; it can only be refreshed until the next state of alarm.

NIBP LIST RECORDING

1. CONTENTS

Records 11 groups of parameter reports, including seven items of DATE, TIME, HR, ST SECTION, RESP, SPO2, TEMP, PR, AWRR,SYS/DIA and ETCO2, see table below:

Time	16:21:25	16:21:05	16:20:46	16:20:27	16:20:08
NIBP(kPa)	16.0/10.7	16.0/10.7	16.0/10.7	16.0/10.7	16.0/10.7
HR(bpm)	60	60	60	60	60
Sp02(%)	99	99	99	99	99
PR(bpm)	60	60	60	60	60
TEMP(C)	36.9	36.9	36.9	36.9	36.9
AWRR(rpm)	20	20	20	20	20
ST(mV)	-0.01	-0.01	-0.01	-0.01	-0.01
EtCO2(mmHg)	38	38	38	38	38

NAME:
2009/09/18 16:39:55
NIBP List

INFINIUM MEDICAL INC

2. RECORDING SEQUENCE

Click the **NIBP List** function button on the screen —→ NIBP List menu appears on screen—→click the Record button—→START RECORDING…….

【**NOTE**】: **"-------"**means invalid parameter.

RECORDING EXPLANTION

1. INSERTING PAPER

Press the catch button on the recorder, open the catch and take the old paper roll out and insert a new one into the paper cassette. Pay attention that the paper is turning swiftly. Pull a small length of paper out of the catch from the lower end of the roll (If it is the upper end, the paper reel is installed conversely), close the catch, and make sure that the paper is just in the groove, or else paper advance will not be orderly.

2. ATTENTIONS

(1) The time of continuous print cannot exceed 2 minutes.

(2) Do not press the RECORD button when there is no paper, or the recorder head will be damaged.

(3) Only thermal record paper can be used.
(4) If there is too much dust, use a sponge lightly moistened with alcohol to clean the correlated parts.

3. RECORDING INDICATING MESSAGES

（1）START RECORDING
Recording process is going on
（2）BREAK RECORDING: The RECORD button has been pressed again during the process of printing; press the button once again to re-start it.
（3）DOOR OPEN
Recorder's door is opened.
（4）DOOR CLOSE
Recorder's door has been closed.
（5）PAPER OK:
Shows that record paper has been installed properly.
（6）NO PAPER
Record paper has been use up.
（7）RECORDER READY
Showing that recorder has been connected properly.
（8）RECORDER NOT READY
Showing that recorder hasn't been connected properly.

GRID OUTPUT
Some recording paper is without a grid—in order to observe the waveform easily, you can set the grid form. The set method is as below:
Click the **SETUP** function button—→the SYSTEM SETUP menu—→recorder setup —→RECORDER SETUP MENU—→RECORDER GRID is set to ON (default value is OFF, then the waveform being recorded is in the grid form.

BATTERY OPERATION

One rechargeable Lithium Ion battery must be inserted into the battery compartment on the right side of the monitor to use the Waveline EZ monitor with battery power.

You can switch between battery-powered and mains-powered (AC) operation without interrupting monitoring.

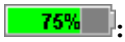
The battery normally recharges automatically when the monitor is connected to mains power.

The Waveline EZ type patient monitor is equipped with a rechargeable battery. The monitor uses the AC INPUT socket to recharge the battery until it is full. A symbol is displayed in the upper right quarter of the screen to indicate the status of recharging, in which the color part represents the electric energy of the battery.

A new, fully charged battery will provide about 3 hour of monitoring time under the following conditions: no audible alarms, no analog or serial output devices attached, and no backlight.

Battery Status on the Main Screen

Battery status information can be configured to display permanently on all Screens. It shows the status of the battery, with the battery power remaining and, when the battery is not charging, an estimate of the monitoring time this represents.

Battery power gauge 

: This shows the remaining battery power. As in this example, this indicates that 75% battery power remains. If no battery is detected, the battery gauge is grayed-out. If no data is available from the battery, question marks are shown in the gauge.

When operating on battery, the monitor will prompt alarm and shut off automatically when the electric energy is low. When the electric energy is lower than 25% of total power capacity, the alarm will be active, at the same time the message of "Battery Power Low" will display in the message area in the top of the screen. The battery signal will change red. Connect the monitor to AC power at this moment can recharge the battery while operating. If keep operating on the battery, the monitor will shut off automatically upon exhaustion of the battery.

NOTE: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter.

If the backlight is turned off during a low battery condition, it cannot be turned back on. It is recommended that the internal battery is replaced by qualified service personnel every 24 months.

NOTE: Whenever the monitor is connected to AC power, the battery is being charged. Therefore, it is recommended that the monitor remain connected to AC power when not in use. This will make available a fully charged battery for use at any time.

Replacing a Battery

To replace the battery,
1. Press the battery compartment latch to open the battery compartment door.
2. Push the release clip in the compartment.
3. Grasp the battery and pull it out fully.
4. Slide the new battery into position, making sure that the battery contacts are facing in the correct direction, as outlined on the inside of the battery compartment.
5. Close the battery compartment door.

WARNING: The battery needs to be charged before use. Please note the inserting direction, insert the battery according to the instructions on the label attached to the battery. Otherwise it will damage the inner structure of the batery housing.

Battery Safety Information

Do not open batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak or heat up, causing personal injury.

Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements.

CAUTION Do not disassemble, heat above 100°C (212°F) or incinerate the batteries, to avoid the risk of fire and burns. Keep batteries out of the reach of children and in their original package until you are ready to use them.

If battery leakage should occur, use caution in removing the battery. Avoid contact with skin. Refer to qualified service personnel.

CAUTION: If the Waveline EZ is to be stored for a period of 2 months or longer, notify service personnel to remove the battery from the monitor prior to storage. Recharge the battery when it has not been charged for 2 or more months.

DISPOSAL OF DEVICE COMPONENTS

Follow local governing ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

PERIODIC SAFETY CHECKS

It is recommended that the following checks be performed every 24 months.
• Inspect the equipment for mechanical and functional damage.
• Inspect the safety relevant labels for legibility.

CARE AND CLEANING

WARNING: If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or DRE service engineer. Do not operate the equipment before it has been tested and approved for further use.

CAUTION: To clean the touch-enabled display, disable the touch operation by switching off the monitor during the cleaning procedure, or by selecting and holding the Main Screen key until the padlock symbol appears on it, indicating that touch operation is disabled. Select and hold again to re-enable touch operation.

Use only the DRE-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

DRE makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital's Infection Control Officer or Epidemiologist. For comprehensive details on cleaning agents and their efficacy refer to "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health Care and Public- Safety Workers" issued by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia, February 1989. See also any local policies that apply within your hospital, and country.

General Points

Keep your monitor, cables and accessories free of dust and dirt. After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to DRE, decontaminate it first.

Observe the following general precautions:
• Always dilute according to the manufacturer's instructions or use lowest possible concentration.
• Do not allow liquid to enter the case.
• Do not immerse any part of the equipment or any accessories in liquid.
• Do not pour liquid onto the system.
• Never use abrasive material (such as steel wool or silver polish).
• Never use bleach.

Cleaning the Monitor

Clean with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap, a diluted non-caustic detergent, tenside, ammonia- or alcohol-based cleaning agent. Do not use strong solvents such as acetone or trichloroethylene.

Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing. Do not permit any liquid to enter the monitor

case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning solution to enter the measurement connectors. Wipe around, not over, connector sockets.

Disinfecting the Monitor

CAUTION Solutions: Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
Hospital policy: Disinfect the product as determined by your hospital's policy, to avoid long term damage to the product.

Sterilizing the Monitor

Sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.

Cleaning, Sterilizing and Disinfecting Monitoring Accessories

To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessory.

Cleaning Batteries and the Battery Compartment

Wipe with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap. Do not use strong solvents. Do not soak the battery.

SPECIFICATIONS

APPLICATION	
Neonatal, pediatric and adult patients	
PHYSICAL DIMENSIONS & WEIGHT	
Base Unit:	229(W)×133(D)×210(H)mm
Weight:	2.5kgs
PEFORMANCE SPECIFICATIONS	
Display:	7.0 inch (Diagonal) color TFT
Resolution:	800 × 3(RGB) × 480
Trace:	2 or 3 waveforms
Waveforms	ECG(I, II, III, aVR, aVL, aVF, V1-V6), PLETH, ETCO2
Indicator:	Alarm indicator Power indicator QRS beep and alarm sound
Trend time:	From 1 to 48 hours
Recorder:	Built-in, thermal array, 2 channels Record width: 48mm Recorder paper: 50mm Record speed: 25mm/s, 50mm/s
ECG	
Input:	5-lead ECG cable and standard AAMI line for connection
Lead Choice:	I，II，III，aVR，aVF，aVL，V
Gain Choice:	×0.5，×1.0，×2.0
Frequency Characteristic:	0. 5～40 Hz （+3dB）
ECG Waveforms:	7 channels
Penetration Voltage:	4000VAC 50/60Hz
Sweep Speed:	12.5, 25 and 50 mm/s
HR Display Range:	30～300bpm
Accuracy:	±2bpm
Alarm Limit Range	Upper limit:80～400bpm Lower limit: 20～150bpm
RESPIRATION	
Measure Method:	RA-LL impedance
Range:	0～120 rpm
Accuracy	± 3 rpm
Alarm Upper-lower Limit	Upper limit: 6～120 rpm， Lower limit: 3～120 rpm
Sweep Speed:	12.5 and 25mm/s
NIBP	
Measuring Technology:	Automatic oscillating measurement
Cuff Inflating:	<30s（0～300 mmHg，standard adult cuff）
Measuring Period:	AVE<40s
Mode	Manual, Auto, STAT
Measuring Interval in AUTO Mode	2 min～4 hrs
Pulse Rate Range:	30 bpm～250 bpm
Measuring Range:	Adult/Pediatric Mode SYS 40～250 (mmHg) DIA 15～200 (mmHg) Neonatal Mode

	SYS 40～135 (mmHg) DIA 15～100 (mmHg)
Resolution:	1mmHg
Pressure Accuracy:	Maximum Mean error: ±5mmHg Maximum Standard deviation: 8mmHg
Overpressure Protection:	Adult Mode 280(mmHg) Neonatal Mode 150 (mmHg)
Alarm Limit:	SYS 50～240 mmHg DIA 15～180 mmHg
TEMPERATURE	
Range:	25～50（℃）
Accuracy:	± 0.2℃（25.0～34.9℃） ± 0.1℃（35.0～39.9℃） ± 0.2℃（40.0～44.9℃） ± 0.3℃（45.0～50.0℃）
Display Resolution:	0.1℃
Alarm Upper-lower Limit:	Upper limit 0～50℃， Lower limit 0～50℃
Alarm Limit:	10～50（℃）
SPO2	
ASpO_2:	Anti-motion SpO_2
SpO_2% Range:	0～100%
SpO_2 Accuracy:	± 2%（70～100%,non-motion） ± 3%（70～100%, motion）
Pulse Rate Range:	30-250 bpm
Pulse Rate Accuracy:	±2 bpm(non-motion) ±3 bpm (motion)
Alarm Upper-lower Limit:	Upper limit 70～100%， Lower limit 70～100%
SpO_2 Probe:	Red light LED wavelength 660nm±5nm Infrared light LED wavelength 940nm±10nm
EtCO_2(OPTION)	
Mode of Sampling:	Sidestream or Mainstream
Principle of Operation:	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts.
CO_2 measurement Range:	0 to 150 mmHg (0 to 19.7%, 0 to 20 kPa)
CO_2 Calculation Method:	BTPS (Body Temperature Pressure Saturated)
CO_2 Resolution:	0.1mmHg(0-69mmHg), 0.25mmHg(70-150mmHg)
CO_2 Accuracy:	0～40 mmHg ± 2 mmHg 41～70 mmHg ± 5% of reading 71～100 mmHg ± 8% of reading 101～150 mmHg ± 10% of reading Above 80 breath per minute ± 12% of reading
Sampling rate:	100Hz
Respiration Rate:	2～150 bpm
Respiration Rate accuracy:	±1 breath
Response Time:	<3 seconds - includes transport time and rise time
Inspired CO_2 measurement Range:	3～50 mmHg

NETWORKING	
Wired Networking	Industry standard: 802.11b/g wired network Frequency Range: 2.412～2.484 GHz Connected bedside number: Up to 16 bedside monitors
Wireless Networking	Up to 100m indoors Industry standard 802.11b/g wireless Supports TCP/IP and UDP/IP Protocols
POWER	
Source:	External AC power or internal battery
AC Power:	100～240VAC, 50/60Hz，60VA
Battery:	Built-in and lithium Ion rechargeable, 12.6V/5Ah
Charge Time:	8 hours
Operating Time:	3 hour
ENVIRONMENTAL SPECIFICATIONS	
Temperature:	Operating: 5～40 °C Storage: -10～45 °C
Humidity Range:	Operating: ≤80 % Storage: ≤80 %
RECORDER (OPTION)	
Record Width:	48 (mm)
Paper Speed:	25 (mm/s)
Trace:	2
FUSE	3.15A/250V
LCD SPECIFICATIONS	
Display Type:	TFT color LCD
Size (diagonal):	7.0 inch
Active Area:	152.4 (W) × 91.44 (H) mm
Color arrangement:	RGB-stripe
Dot pitch:	0.0635(W) × 0.1905(H) mm
Display Mode:	Normally white, Transmissive
Interface:	Digital(TTL)
Surface Treatment:	Anti-Glare
TOUCHSCREEN SPECIFICATIONS	
Type:	Four-Wire Analog Resistive Touch Panel
Input Mode:	Stylus Pen or Finger
Connector:	FPC
Insulation resistance:	25MΩ
Voltage:	7VDC
Chattering:	10ms
Transparency:	80%
Surface hardness:	3H
Durability-surface scratching:	Write 100,000
Active force:	80gf
Knock Test:	1,000,000 times

TECHNICAL SUPPORT

DRE, Inc.
Website: www.dremed.com
Address: 1800 Williamson Court
Louisville, KY 33773 USA
Toll Free (US call only): 502-244-4444

To obtain information about a warranty, if any, for this product, contact DRE Technical Services or your local DRE representative.


DRE