

DRE Waveline Touch
User Manual



***Waveline Touch
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.



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

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SAFETY INFORMATION

This section contains important safety information related to general use of the Waveline Touch 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 Touch monitor can be powered by an internal battery pack that provides 1 hour 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 these manual, accessory directions for use.

WARNING: *The Waveline Touch 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 Touch 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 Touch monitor in the presence of flammable anesthetics or gases.*

WARNING: *Do not lift the Waveline Touch 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 Touch 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 Touch monitor to monitor patients who are linked to heart/lung machines.*

WARNING: *Enclosure leakage current is less than 100 microamperes (μ A); 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 Touch 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.*

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.*

CAUTION:

When connecting the Waveline Touch monitor to any instrument, verify proper operation before clinical use. Both the Waveline Touch 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.

INTRODUCTION

- **INTENDED USE**
- **ABOUT THIS MANUAL**

INTENDED USE

The Waveline Touch monitor is a comprehensive monitoring system with four, six or eight traces compiling, and 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 Touch monitor is to monitor ECG, heart rate, NIBP (systolic, diastolic, and mean arterial pressures), SpO₂, respiration, temperature, dual temperature, EtCO₂ and dual IBP 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 Touch monitor offers advanced features such as an intuitive touchscreen with clinical measurements, one-touch commands, crisp and clear display.

<p>WARNING: <i>The Waveline Touch monitor is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.</i></p>

ABOUT THIS MANUAL

*This manual explains how to set up and use the Waveline Touch monitor. Important safety information relating to general use of the Waveline Touch 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

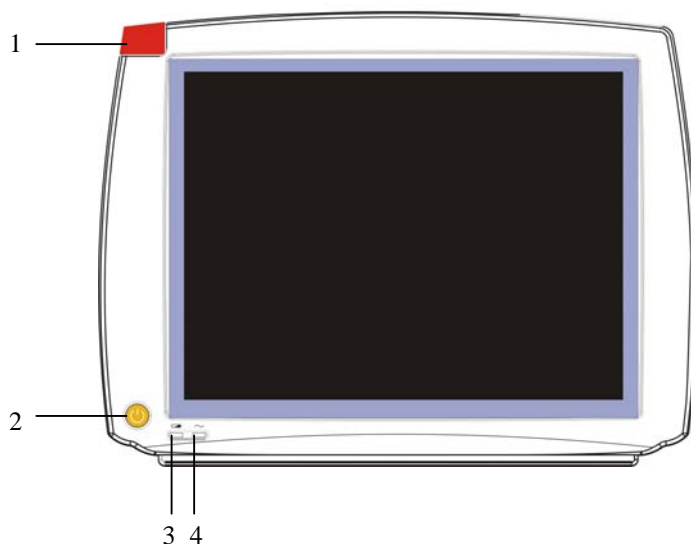
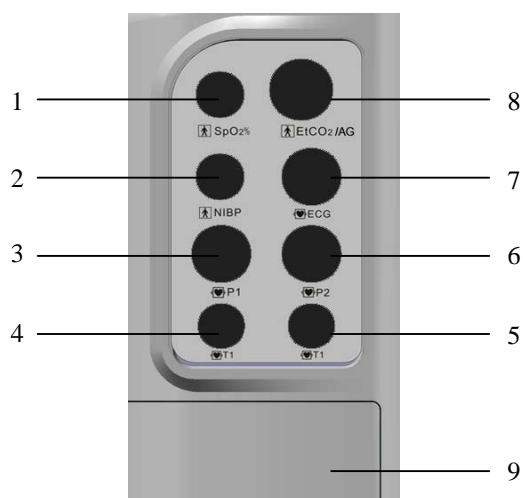


Figure-1 Front Panel

No	FUNCTION	Icon
1	ALARM INDICATOR <i>In normal mode, no indicator lights. In alarm mode, the alarm indicator flashes.</i>	
2	POWER SWITCH <i>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.</i>	
3	DC ON <i>This LED indicates that the monitor is powered by battery.</i>	
4	AC ON <i>This LED indicates that the monitor is powered by AC.</i>	

LEFT SIDE PANEL



No	FUNCTION
1	Oxygen saturation sensor port
2	NIBP port for the connection with the blood pressure cuff hose
3	IBP port for the channel 1 (Option)
4	Temperature port for temperature channel 1
5	Temperature port for temperature channel 2
6	IBP port for the channel 2 (Option)
7	Six cores, AAMI ECG lead socket
8	EtCO ₂ or AG input port (Option)
9	Battery access



RIGHT SIDE PANEL



No	FUNCTION
1	Recorder (Option)













REAR PANEL



No.	FUNCTION	Icon
1	Equipotentiality Ground	
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	RS-232 I/O This digital interface connector provides serial data to most RS-232 devices	 RS232
4	Wireless Transmitter For wireless central monitor system	
5	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 eight.
	General warning, caution, risk of danger Please read the instructions carefully before operating the product.
	Stand-by To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition.

DISPLAY SCREEN PARTITION

All TFT display screen is divided into five areas:

PARAMETER AREA

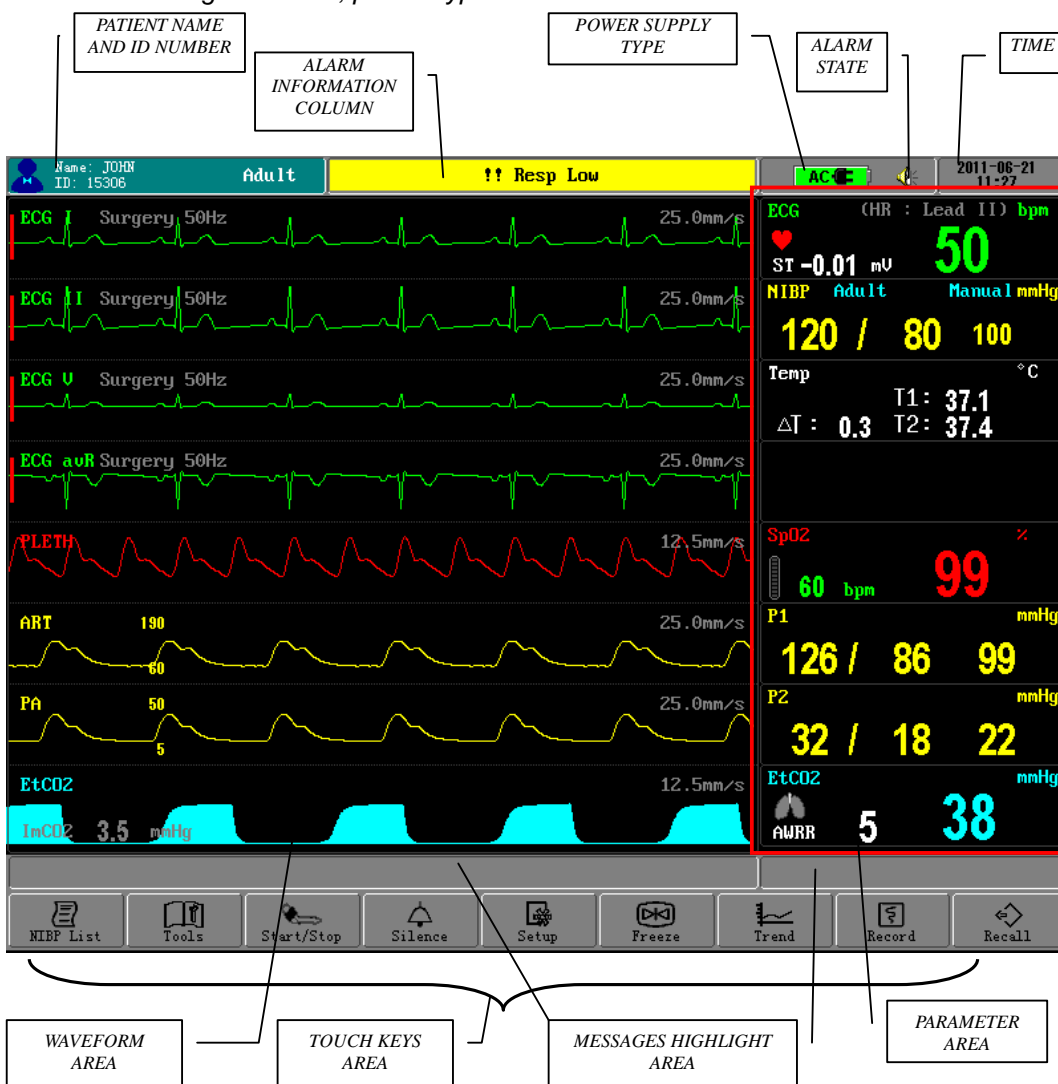
This area is used for display monitoring parameters, such as HR, RESP, SPO2, TEMP, NIBP(SYS、DIA、MAP), P1,P2, ETCO2 and so on.

WAVEFORM AREA

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

MESSAGE AREA

The state messages of Time, patient types and correlated information are list here.

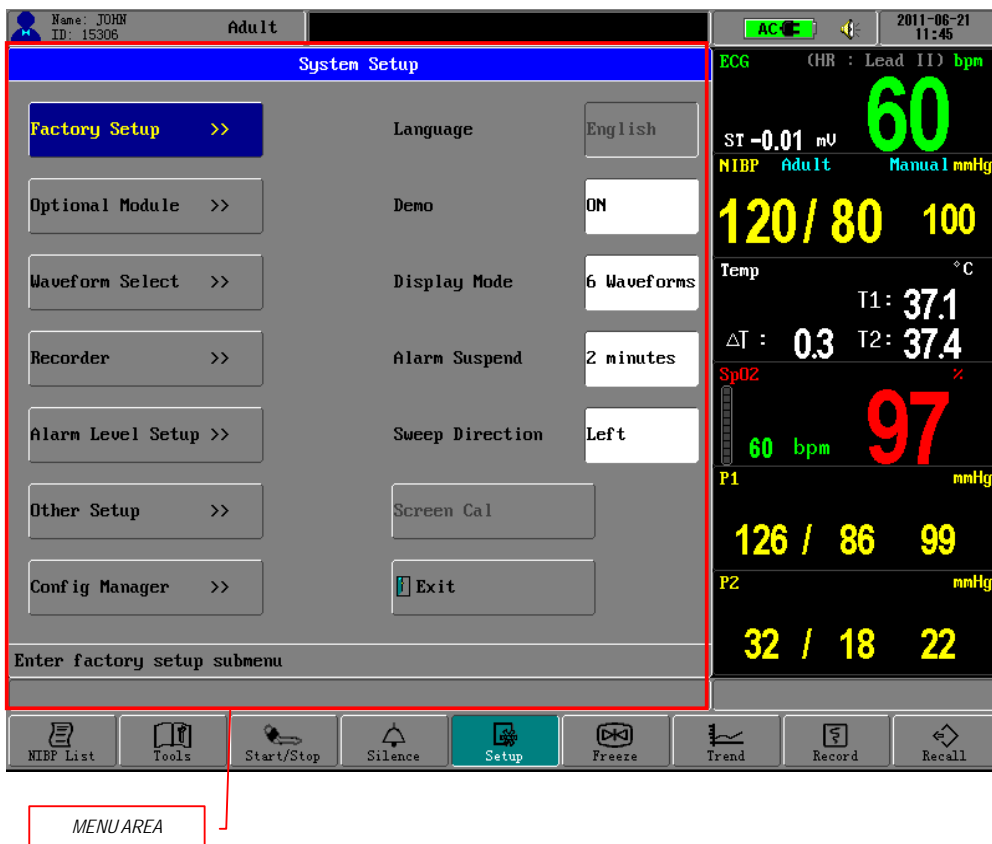


TOUCH KEYS AREA

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

MENU AREA

Menu Area is in the waveform area, see below:



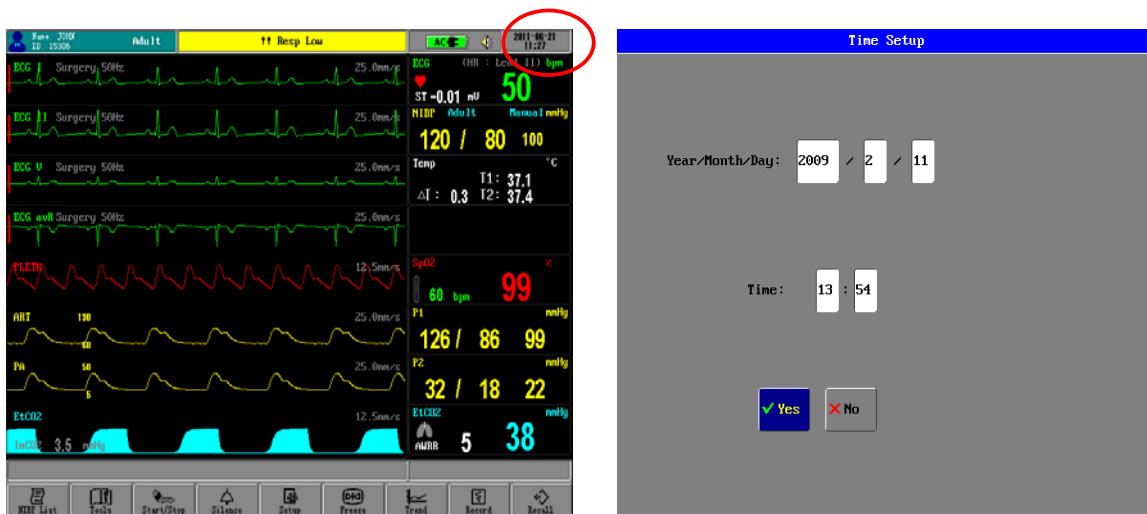
On the condition of main screen displaying, click a parameter area to pop the correlated menu, click the function buttons of SILENCE, TREND and SETUP etc. button also can pop up the correlated menu or access the choosing item (enter submenu if available). If you want to exit from menu, just click the 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):



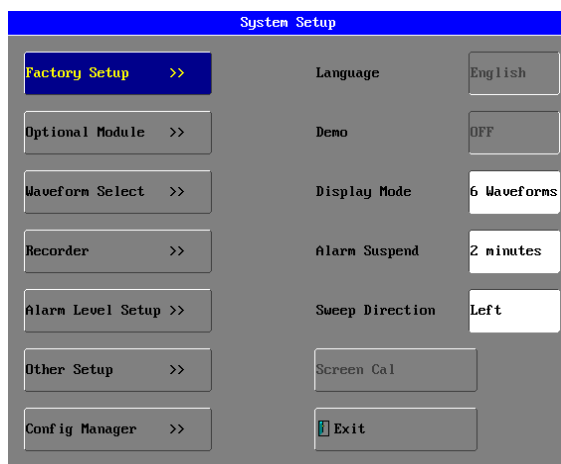
*The value of year, month, hour and minute can be set. Then system will amend the internal clock according to the new settings. On the pop of the time menu, the system shows the right time of entering this menu. If you click the **NO** item to exit from the menu, the system will not change internal clock.*

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 function button of **SETUP** to pop up the menu as below:

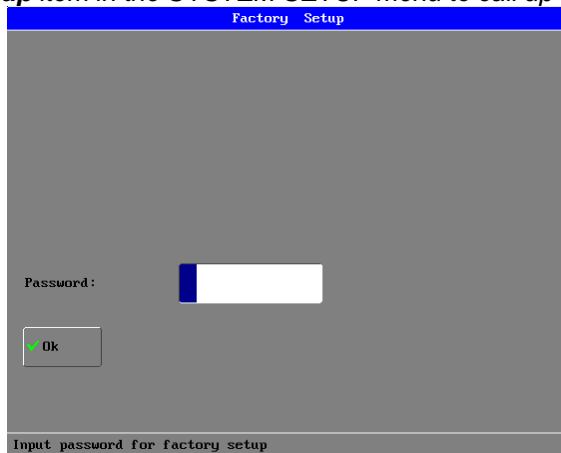


The screenshot shows the 'System Setup' menu with a blue header. It contains two columns of settings. The left column has buttons for 'Factory Setup >>', 'Optional Module >>', 'Waveform Select >>', 'Recorder >>', 'Alarm Level Setup >>', 'Other Setup >>', and 'Config Manager >>'. The right column has settings for 'Language' (English), 'Demo' (OFF), 'Display Mode' (6 Waveforms), 'Alarm Suspend' (2 minutes), 'Sweep Direction' (Left), 'Screen Cal', and an 'Exit' button with a red icon.

System Setup	
Factory Setup >>	Language: English
Optional Module >>	Demo: OFF
Waveform Select >>	Display Mode: 6 Waveforms
Recorder >>	Alarm Suspend: 2 minutes
Alarm Level Setup >>	Sweep Direction: Left
Other Setup >>	Screen Cal
Config Manager >>	Exit

FACTORY SETUP

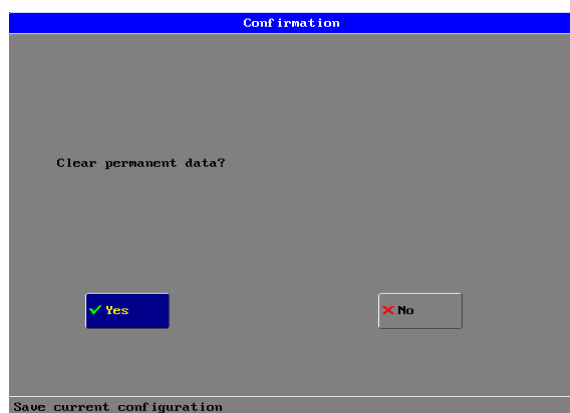
Click **Factory Setup** item in the **SYSTEM SETUP** menu to call up the following menu:



The screenshot shows the 'Factory Setup' menu with a blue header. It contains a 'Password:' label followed by a text input field. Below the input field is a button with a green checkmark and the text 'Ok'. At the bottom of the screen, there is a status bar that reads 'Input password for factory setup'.

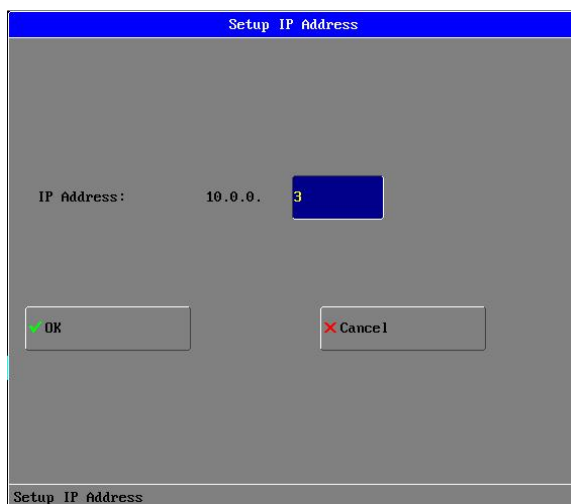
Factory Setup	
Password: <input type="text"/>	
<input type="button" value="Ok"/>	
Input password for factory setup	

1. If input **FORMAT..** for the password, the window for confirming clear permanent data will pop out as following:



If click **YES** item, the system will format the NAND flash. This function is used for clear all data which for the patient data is too much in order to vacate space in NAND flash, and then save patient data again.

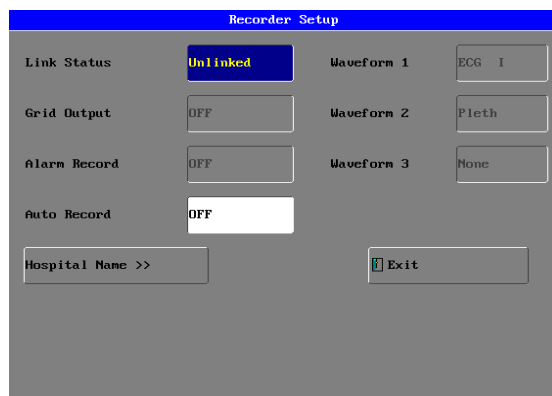
2. If input **IP SETUP** for the password, the window for Ethernet IP address setup of the patient monitor will pop out as following:



If click **OK** item, the Ethernet IP address setup of the patient monitor is set and saved. This IP address is available only when the patient monitor is re-powered on.

RECORDER SETUP

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



The Recorder Setup menu is displayed with a blue title bar. It contains the following settings:

Parameter	Value
Link Status	Unlinked
Grid Output	OFF
Alarm Record	OFF
Auto Record	OFF
Hospital Name >>	[Input Field]
Waveform 1	ECG I
Waveform 2	Pleth
Waveform 3	None

Buttons: Exit

RECORDER LINKING STATUS

Use to display or set the connecting state of recorder.

RECORDER GRID OUTPUT

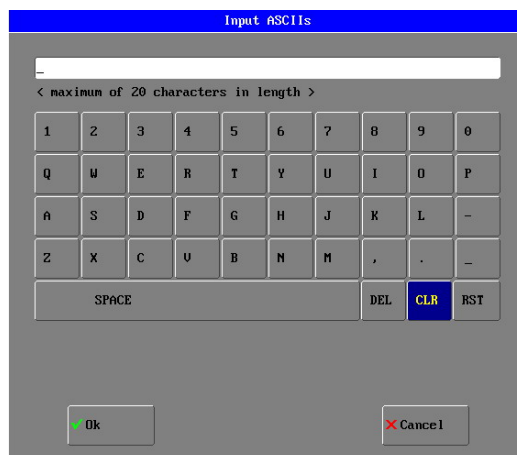
Open the setup to make waveforms and parameters printout has a grid background, just like record paper. Contrary when closed.

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 happened.

HOSPITAL NAME

Click this item to input or change the hospital name. When click the input name location, a keypad will display, you can select any word on it as following picture:



The Input ASCII keypad is displayed with a blue title bar. It contains the following layout:

< maximum of 20 characters in length >

1	2	3	4	5	6	7	8	9	0
Q	W	E	R	T	Y	U	I	O	P
A	S	D	F	G	H	J	K	L	-
Z	X	C	V	B	N	M	,	.	_
SPACE							DEL	CLR	RST

Buttons: Ok, Cancel

WAVEFORM SELECT

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

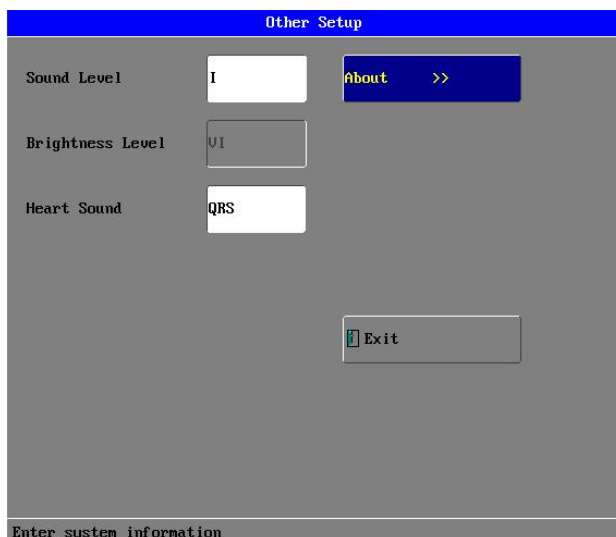
The image shows a 'Waveform Select Setup' screen with a blue header. It contains six channels arranged in two columns. Channel 1 is set to 'ECG I' (highlighted in blue). Channel 2 is set to 'ECG II'. Channel 3 is set to 'ECG III'. Channel 4 is set to 'Pleth'. Channel 5 is set to 'IBP 1'. Channel 6 is set to 'IBP 2'. At the bottom, there are two buttons: 'OK' with a green checkmark icon and 'Cancel' with a red X icon.

Channel	Waveform
Channel 1	ECG I
Channel 2	ECG II
Channel 3	ECG III
Channel 4	Pleth
Channel 5	IBP 1
Channel 6	IBP 2

OK Cancel

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, IBP1, IBP2 and ETCO2. Only a relative module is set to be **ON**, its waveform can be selected.

OTHER SETUP

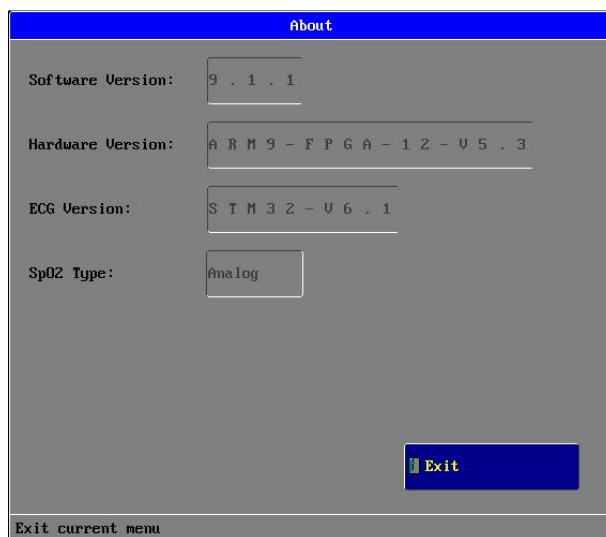


Sound Level: I, II, III, . . . (From lowest to highest)

Brightness Level: from I to X, ten levels. (From lowest to highest)

Heart Sound: QRS, Pulse, IBP1 or IBP2

About: It provides the version of software, hardware and ECG, even for the type of SPO2 as below figure shown.

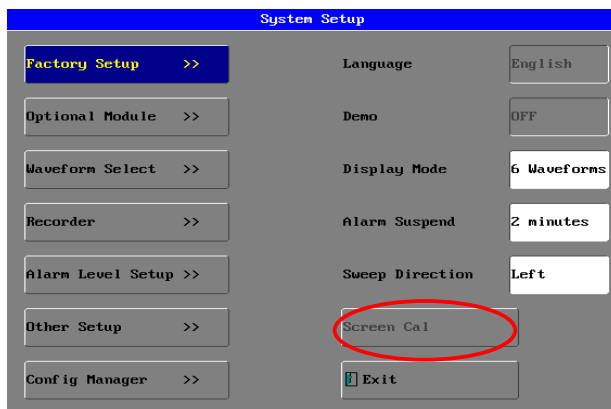


LANGUAGE SETUP

Use 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 input the correct password of "SCREEN.."



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

Four steps need be followed according to information in the message highlight area. The first threes steps are calibration steps that user click the Red Cross icon accurately to calibrate touch screen.

The fourth step is calibration verification step that user 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 when calibration validate is successful or return to the first step of calibration when calibration is failed.

OPTIONAL MODULE SETUP

The Waveline Touch monitor provides three optional functional modules which are ETOC2, IBP and GAS. Each of optional modes is basing on the S/N of the monitor to generate the separate password.

Input correct password to open the function module for the ETCO2 module, IBP or GAS module.

- ETCO2 mode provides two modules as choice: Philips Respironics module or PHASEIN module

Note: If chosen PHASEIN module, more details please see the following chapter of Anesthetic Agent monitoring.

If chosen Philips Respironics module, more details please see the following chapter of ETCO2 monitoring.

- GAS mode provides PHASEIN module

More details of this, please contact with local distributor or servicing engineer.

This item is for servicing engineer use only.

SWEEP DIRECTION SETUP

There are two options of “right” and “left”.

DISPLAY MODE SETUP

There are three options of “4 waveforms”, “6 waveforms” and “8 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 call the default settings by clicking this item to pop 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 for work.

SAVE CONFIG SETUP

Save current config settings so that system can call up these settings on the next time of open by clicking this item, then the screen will display a menu to let you confirm the setup (see below graph):



After return the above confirmation menu, a message of will display the message of "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 enter the main screen after 25 seconds;*
4. *Connect corresponding sensors with the patient;*
5. *Set monitoring parameters (see chapters below) ;*
6. *Enter the monitoring state.*

CAUTION: *If the Waveline Touch 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.*

ALARM & SOUND

ALARM

When the monitor detects certain conditions that require user attention, the Waveline Touch monitor enters an alarm state. The monitor response is indicated by:

- *Visual alarm indicators*
- *Audible alarm indicators*
- *Print-on-alarm (if printer installed)*
- *Identification of out-of-limit vital signs in trend data*

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

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

ALARM PRIORITY

The monitor's visual and audible responses to a detected alarm depend on the priority of the alarm; High, Medium, or Low.

A higher priority alarm will supersede a lower priority alarm.

The three categories of alarms are summarized in the following paragraphs. The text indicates the message shown on the screen.

High Priority:

Indicating that immediate OPERATOR response is required:

Asystole (4 seconds have passed with no heart beats from ECG, preceded by detecting valid ECG-derived heart rate data.)

Loss of Pulse from SpO2 (and no valid ECG)

Medium Priority:

Indicating that prompt OPERATOR response is required:

High/Low numeric value limits violated (such as High/Low SpO2 limits violated, High/Low Sys./Dia. blood pressure limits violated, High/Low Respiration Rate limits violated, High/Low Temperature limits violated, etc.)

Low Priority:

Indicating that OPERATOR awareness is required:

Senor or leads off (such as ECG Leads Off, SpO2 Cable/Sensor Disconnect, Temperature Probe Disconnect, etc.), Low Battery (alarm commences when the Waveline Touch has at least 10 minutes of operating time remaining) and communications errors for modules.

VISUAL ALARM INDICATORS

When an alarm occurs, the monitor responds with visual alarm indications. The flashing rates for the three categories of alarms are shown. The monitor uses flashing colors to indicate high and medium priority alarm as following Flashing Rates.

<i>Alarm Category</i>	<i>Flashing Rate</i>
<i>High Priority</i>	<i>Two flashes in 1 second</i>
<i>Medium priority</i>	<i>One flash in 2 seconds</i>
<i>Low priority</i>	<i>Constant (on) (non-flashing)</i>

When a low priority alarm occurs, a non-flashing alarm message appears in the message area. If more than one low priority alarm is present, the alarm messages “rotate” . On the Waveline Touch numeric frame background color will change to a solid yellow for a low priority alarm.

When a medium priority alarm is activated, because a parameter is outside its alarm limits, the out-of-limit numeric value and the bell icon in the corresponding Numeric Frame flash at the medium priority rate. Only the numeric frame background color will flash yellow for a medium priority alarm in the Waveline Touch.

When the high-priority Asystole alarm occurs, the heart rate numeric value and the corresponding bell icon flash at the high priority rate. Only the numeric frame background color will flash red for a high priority alarm in the monitor. A nonflashing Asystole message appears in the message area and will override any other messages which may be present (there is no message “rotation” in this instance).

ALARM SUSPEND

If the Alarm Silence switch is depressed, the Alarm Suspend condition is initiated. Pressing the Alarm Silence switch terminates the Alarm Suspend condition.

When Alarm Suspend is initiated, ALL audible alarms and print-on-alarm functions are disabled. Visual alarms and identification of out-of-limits vital signs in trend memory continue to function.

During Alarm Suspend, monitoring continues for all parameters; the numeric values and the top Graphic Frame (typically ECG waveform) continue to operate normally. Trend memory operates normally. The single-function buttons continue to operate normally. No Level 1 or 2 menus may be invoked while in Alarm Suspend State. Access to the Big Numbers screen is denied while in the Alarm Suspend condition.

SOUND

ALARM SOUND

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

The following encoded auditory alarm signals categorized by alarm condition and priority:

Alarm Category	Encoded Auditory
High Priority	c c c-c c
Medium priority	c c c
Low priority	e C
Note1: The characters c, e refers to relative musical pitches and C is one octave c.	
Note2: A high priority alarm signal is generated with the five pulses shown; repeat once, for total of 10 pulses.	


HEART-BEAT (PULSE-TONE)

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

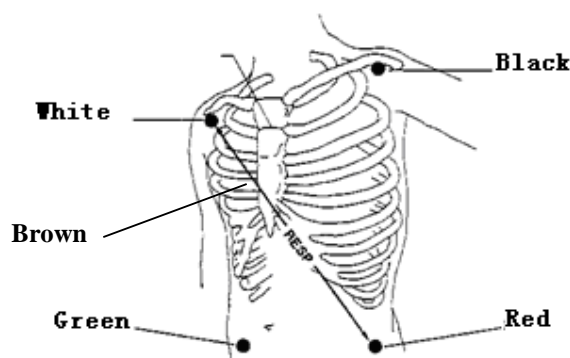
ECG MONITORING

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

ELECTRODE INSTALLATION

Some points should be paid attention to in ECG monitoring:

1. Check the lead and cable, the 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 that whether they are contact well.
4. Follow the methods below to place these 5 –lead electrodes, it can be set by the ECG menu.

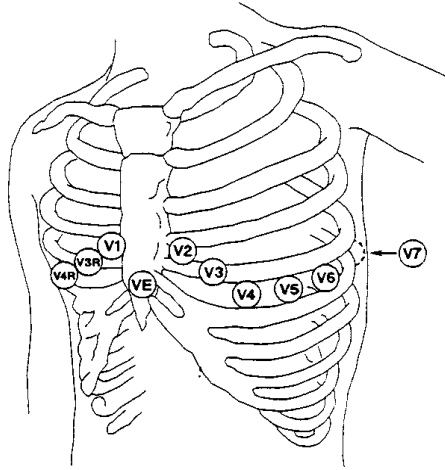


- ☐ WHITE (RIGHT ARM) ELECTRODE (RA)—is placed near the right shoulder, directly below the clavicle.
- ☐ BLACK (LEFT ARM) ELECTRODE (LA)—is placed near the left shoulder, directly below the clavicle.
- ☐ GREEN (REFERENCE) ELECTEODE (RL)—is placed on the right hypogastrium.
- ☐ RED (LEFT LEG) ELECTEODE (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:



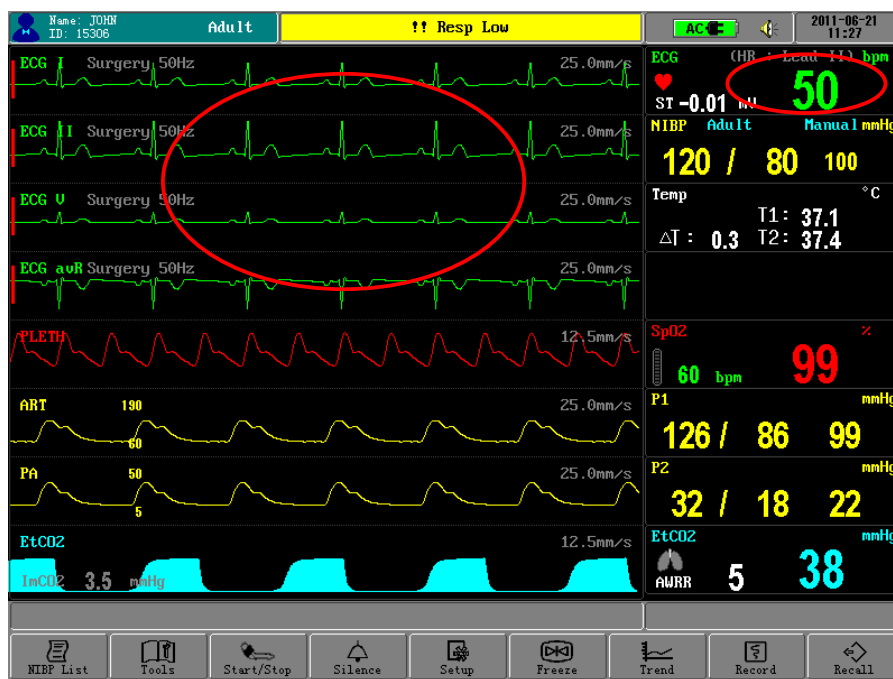
- ☐ **V1** is on the 4th intercostal space at the right sterna margin.
 - ☐ **V2** is on the 4th intercostal space at the left sterna margin.
 - ☐ **V3** is at the midway between V2 and V4 electrodes.
 - ☐ **V4** is on the 5th intercostal space at the left clavicular line.
 - ☐ **V5** is on the left 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 xiphoid. 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 evidently, substituted 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 other conductive.

SENSOR INSTALLATION

1. Insert the plug of ECG into socket on the left panel of monitor, make sure that the salient of plug must direct to the notch of socket when inserting.
2. Connect the electrode lead to the patient's cable.

ECG WAVE AND ECG SETUP

Click the parameter and waveform area of ECG, see graph below:



Then pop up the ECG Setup and ECG Wave Setup menu, this menu can finish settings below:

ECG Wave Setup			
HR Calc Source	Lead II	Sweep Speed	25.0mm/s
ECG Gain	x 1.0	Sweep Color	Default
ECG Filter	Surgery	ECG Verify	OFF
ECG Notch	50Hz	Exit	

Select HR calculating source

The screenshot shows the 'ECG Setup' menu with the following settings and options:

- Alarm Switch:** ON
- Lead Type:** 5 Leads
- HR Alarm High:** 130
- HR Alarm Low:** 50
- Ecg Pace:** OFF
- ECG Test:** OFF
- Buttons:** ST Analysis >>, ARR Analysis >>, Exit
- Footer:** Enable/disable ECG alarm

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**.

ECG NOTCH

It provides 50Hz or 60Hz which can be chosen.

ECG FILTER

Freely select three different modes which are Surgery, Monitor or Diagnose.

HR CALCULATE SOURCE

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

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 **Surgery**.

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**.

SWEEP SPEED

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

ST-SEGMENT ANALYSES MENU

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
<i>Lead off</i>	<i>ECG leads fall off the skin or the monitor</i>
<i>ECG Signal Weak</i>	<i>ECG Signal is Weak</i>

MAINTENANCE AND CLEANING

PATIENT CABLE AND LEAD

After every times of using, the cable must be cleaned and following the 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 solvent 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 pressure cooker to disinfect the cable and electrode or heat them to 75 °C (167°F) and higher temperature. If there is dirt on the material surface, you can use the abluent which will not left remainder to clean and any metal grinding medium like floss is forbidden. The storing temperature should be -20 °C till 75 °C (-68°F till 167°F). 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 influent the HR calculating stability too. Another factor which affecting HR calculation is the QRS waveform, if T wave is too high, HR will be make mistake too. Arrhythmia sometimes influent HR calculation too.
2. Choosing suitable ECG waveform range and complete QRS waveform has important effect 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.

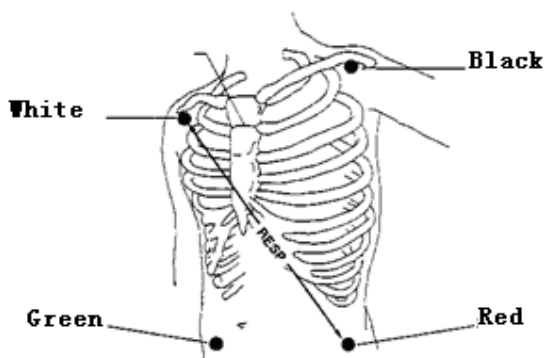
Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the 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 white and red 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. Then click the **RESP** parameter area to pop up the menu of **RESP Setup and RESP Wave Setup**.

The menu can finish settings as below:

ALARM SWITCH

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

RESP GAIN

The user can freely choose one from items of **X0.25**, **X 0.5**, **X1.0**, **X 2.0**. Gain adjustment can change the value of ECG waveform and ECG STAFF, and the factory-set is **X 1.0**.

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 too much interference, the RESP monitoring is not accurate, so 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.

SPO2 MONITORING

- SPO2 MONITORING PRINCIPLE
- SPO2 SENSOR INSTALLATION
- SPO2 PARAMETER SETUP
- SPO2 PARAMETER SETUP
- MEASUREMENT LIMITATIONS
- SPO2 ERROR MESSAGES

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 SpO₂, SaO₂, SjvO₂

- **SpO₂**: It is the arterial blood oxygen saturation lever measuring by oximeter.
- **SaO₂**: It is the oxygen saturation of arterial blood
- **SjvO₂**: It is the oxygen saturation of the jugular blood.

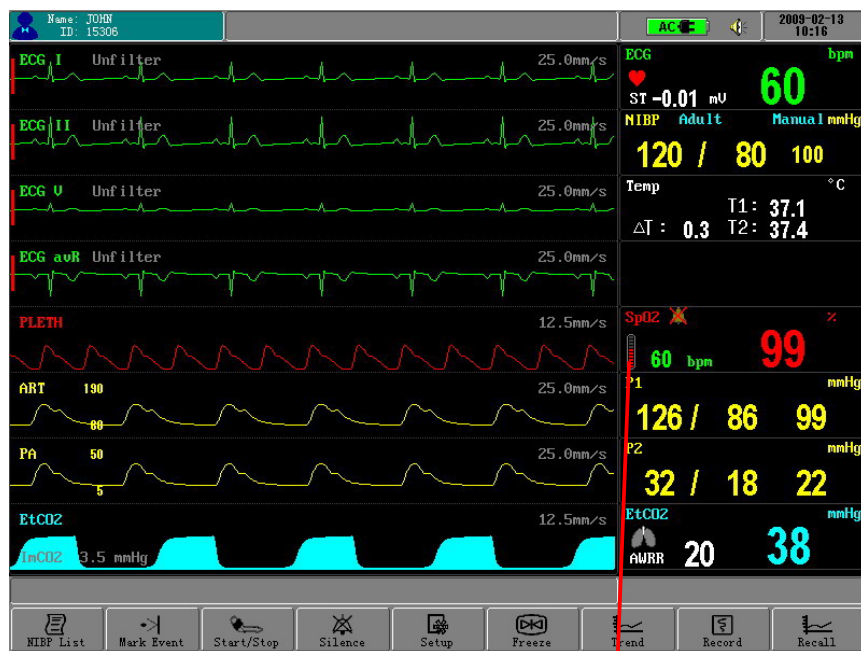
WARNING: Pulse oximeter can overestimate the SPO2 value in the presence of HB-CO, Met-HB or dye dilution chemicals.

SPO2 SENSOR INSTALLATION

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 or 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:

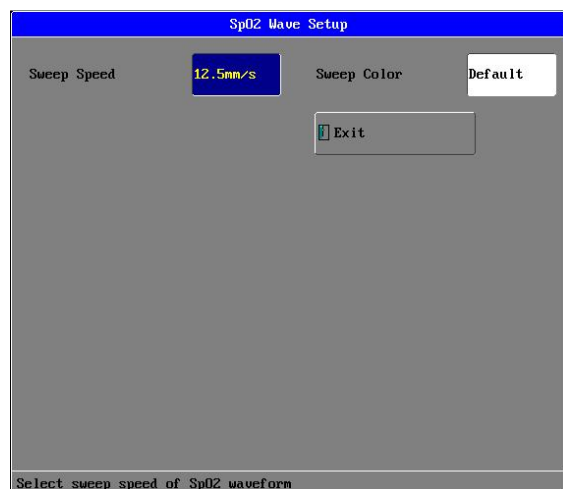
Use red bargraph to express the intensity of the pulse of patient.
Pulse bargraph is throbbing upon with the pulse.

Pop up the menu of SPO2 Setup and SPO2 Wave Setup, see graph below:

The screenshot shows the 'SpO2 Setup' menu. It includes the following options and settings:

- Alarm Switch: **ON**
- SpO2 Alarm High: 100
- SpO2 Alarm Low: 85
- Factory Setup >>
- Exit

At the bottom, it says 'Enable/disable SpO2 alarm'.



The menu can finish settings as below:

ALARM SWITCH

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

SWEEP SPEED

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

SPO2 ALARM UPPER-LIMIT

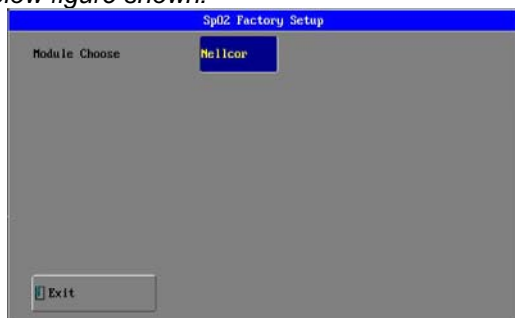
The SPO2 alarm upper-limit, the range is from **70** to **100%**, and the factory-set is **100%**, the single-step adjustable step- length is **1 %**.

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%**.

SPO2 FACTORY SETUP

Clicking **Factory Setup** and input “SPO2....”password into **SPO2 Setup**→ **SpO2 Factory Setup** as below figure shown:



*It can choose Nellcor SpO2 module or BCI Compatible.
More detail please contact with local distributor or service engineer
This item is for servicing engineer use only.*

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 decreased to the level which cannot be measured in conditions below:*
 - ☐ Shock
 - ☐ Hypothermia
 - ☐ Vasoactive medicines are applied
 - ☐ Anemia
2. *The measurement 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 false or lower than the actual value of SPO2, for example:*
 - ☐ Carboxyhemoglobin
 - ☐ Methemoglobin
 - ☐ Methylene blue
 - ☐ Carmine indigo
3. *The strong light in the environment also can influent measurement. Some suitable light-tight material to cover the sensor which can improve the measure 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

PLETH Waveform may display messages as below:

PROMPTS	EXPLANATION
<i>Search Too Long</i>	<i>Search-time of SPO2 is too long</i>
<i>Searching For Pulse. . .</i>	<i>On searching for pulse signal</i>
<i>Sensor Off</i>	<i>Sensor falls off or the finger fails to insert into the finger-probe</i>
<i>SpO₂ Com Error</i>	<i>SPO2 board has communication error with the mainboard</i>

NIBP MONITORING

- SUMMARY ON NIBP MONITORING
- NIBP CUFF FITTING
- NIBP MONITORING INITIALIZATION
- NIBP MONITORING SETUP
- MEASUREMENT LIMITATIONS
- NIBP ERROR MESSAGES
- MAINTAINENCE AND CLEANING

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 an over 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. Whether choosing the suitable cuff which match the arm of patient influent much on the accuracy of NIBP measurement. The cuff width recommend by **AMERICA HEART SOCIETY** is the 40% of upper arm circumference or the 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 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 note of NIBP MODULE SELF-CHECK OK, it shows that the NIBP module operate well, then begin NIBP monitoring, and the NIBP monitoring before this information is invalid; if there is NIBP MODULE SELF-CHECK ERROR, it shows that the NIBP module cannot be proceeded, click the button of **START/STOP** to give another time of self-checking or machine-opening, if it is also this information, contact with servicing engineer.

NIBP MONITORING SETUP

Click the NIBP Parameter Area to pop up the NIBP Setup menu (see graph below), this menu can finish settings below:

The screenshot shows the 'NIBP Setup' menu with the following settings:

NIBP Setup	
Alarm Switch	ON
Time Interval	2 min
Pressure Unit	mmHg
Patient Type	Adult
Inflation Mode	Manual
Alarm Setup >>	
Factory Setup >>	
Exit	

Enable/disable NIBP alarm

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

It can apply 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 AND NEONATE TYPE

*It can apply to the **PEDIATRIC** 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**.*

Inflating range showing above has been realized on NIBP, NIBP use this inflation range to make sure the safety of patient.

INFLATION TYPE

MANUAL MODE, AUTOMATICAL MODE and STAT MODE

MANUAL MODE:

*Click the button of **START/STOP** to begin inflation, the information indicating area display “MANUAL MEASURING...” which shows that it is on measurement just the moment.*

If the NIBP value been measured, NIBP parameter area will display it and the information indicating area will give a note of “MANUAL MEASURING END!”, then the measurement process finished.

If the NIBP value cannot be measured, NIBP parameter area will display error messages and automatically begin three times of measurement again, if the value cannot be measured also, the information indicating area will give a note of “RETRY OVER! ” and never measure again.

*During the measurement, click the button of **START/STOP** again will stop the NIBP measurement process and the information indicating area will give a note of **STOP MANUAL MEASURING**.*

AUTOMATICAL MODE:

NIBP parameter area will display the countdown of “Auto measuring...” (TIME INTERVAL), so long as reaching the zero point, machine will automatically precede inflating measurement again and again until the mode be changed.

If the NIBP value been measured, NIBP parameter area will display it and the information

indicating area will give a note of "AUTO MEASURING END ! ", which show 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 automatically begin three times of measurement again, if the value cannot be measured.

also, the information indicating area will give a note of "RETRY OVER ! " and automatically go on the next measurement until the mode is changed.

If click the button of **START/STOP** during any period of countdown, it is immediately begin inflation measurement.

During the measurement, click the button of **START/STOP** again will stop this period of NIBP measurement process and the information indicating area will give a note of "STOP AUTO MEASURING", but 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 button of **START/STOP** to begin inflation, the information indicating area display "STAT MEASURING.." which shows that it is on measurement just the moment; If the NIBP value been measured, NIBP parameter area will display it and the information indicating area well give a note of "STAT MEASURING END".

If the NIBP value cannot be measured, NIBP parameter area will display error messages and automatically begin three times of measurement again, if the value cannot be measured also, the information indicating area will give a note of "RETRY OVER ! ", and then continue another time of measurement which lasts 5 minutes and then stop.

During the measurement, if click the button of **START/STOP** 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 having been 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

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

ALARM SETUP

SYS UPPER LIMIT (SYS)

The range is from 50 to 240 mmHg (6.7~32.0 kPa), and the factory-set is 200 mmHg.

SYS LOWER LIMIT (SYS)

The range is from 50 to 240 mmHg (6.7~32.0 kPa), and the factory-set is 90 mmHg.

DIA UPPER LIMIT (DIA)

The range is from 15 to 180 mmHg (2.0~24.0 kPa), and the factory-set is 100 mmHg.

DIA LOWER LIMIT (DIA)

The range is from 15 to 180 mmHg (2.0~24.0 kPa), and the factory-set is 50 mmHg.

The single-step adjustable length of alarm limit above is 5 mmHg

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 may not be possible 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 and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus 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 and may not be possible 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:

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

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
- TEMP SENSOR INSTALLATION
- TEMP PARAMETER SETUP
- TEMP ERROR MESSAGES
- MAINTAINENCE AND CLEANING
-

THEORY OF OPERATION

The monitor provides one or two isolated temperature measurement channels (T1 and T2). When inserting one temperature sensor to any port of T1 or T2, the relative channel's test temperature value will display. If the second temperature channel is installed, the temperature difference between the two channels is an available option. Temperature difference is displayed as " ΔT " (delta temperature).

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. Insert the plug of **T1 or/and T2** sensor into the sensor socket on the left panel of monitor.
2. Put the probe on the patient according to the explanation of probe usage (lacuna and body).

WARNING:

Inspect the probe for wear or splitting after every disinfection/sterilization process is complete. If wearing or splitting of the probe is found upon visual inspection, a new probe should be used.

TEMP PARAMETER SETUP

Click the TEMP Parameter Area to pop up the menu of TEMP Setup, see graph below:

Temp Setup			
Alarm Switch	ON	Temp Unit	Celsius
T1 Alarm High	38.0	T2 Alarm High	38.0
T1 Alarm Low	36.0	T2 Alarm Low	36.0
Temp Adjust >>		Exit	
Enable/disable temperature alarm			

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**.

T1 AND T2 ALARM UPPER-LIMIT

The T1 or T2 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** .

T1 AND T2 ALARM LOWER-LIMIT

The T1 or T2 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 ADJUST

This item is for servicing engineer use only.

TEMP ERROR MESSAGES

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

MAINTAINENCE AND CLEANING

REUSABLE TEMP PROBES

1. The TEMP probe should not be heated above 100 °C(212°F). It should only be subjected briefly to temperatures between 80 °C(176°F) and 100 °C(212°F).
2. The probe must not be sterilized in steam.
3. To clean the probe with alcohol 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
- WARNINGS
- ABBREVIATIONS AND TERMINOLOGY
- ZEROING THE CO₂ MODULE
- PATIENT AND TUBING PREPARATION
- ETCO₂ SETUP
- ADVANCED SETUP
- CALIBRATION
- STATUS/ERROR MESSAGES

THEORY OF OPERATION

Carbon dioxide monitoring is used to monitor continuous carbon dioxide and report the End Tidal carbon dioxide (EtCO₂), inspired CO₂ and respiratory rate values of the intubated and non-intubated adult, pediatric, infant and neonatal patient.

Carbon dioxide monitoring system is a sidestream sampling system with a 50 ml/minute low sampling rate that is used to measure the CO₂ 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. CO₂ from the patient that is aspirated into the sample cell absorbs some of this infrared energy. The monitor determines CO₂ concentration in the breathing gases by measuring the amount of light absorbed by these gases. EtCO₂ is displayed as a numerical value in millimeters of mercury (mmHg), percent (%), or kilopascals (kPa). In addition, a CO₂ 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.*
- ♦ *Reuse, disassembly, 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 CO₂ check waveform (Capnogram). If you see changes or abnormal appearance 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 can not 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 CO₂ measurement.*

ABBREVIATIONS AND TERMINOLOGY

EtCO₂	<i>End tidal carbon dioxide</i>
INSP CO₂	<i>Inspired minimum CO₂</i>
AWRR	<i>Air-way respiration rate</i>
BARO	<i>Barometric Pressure</i>

ZEROING THE CO₂ MODULE

The sample cell zero allows the CO₂ Module to adjust to the optical characteristics of the sample cell only when requested.

Whenever the type of adapter being used with the CO₂ Module is changed. For optimal accuracy, a CO₂ Module zero should also be performed whenever the CO₂ Module is connected to the patient monitor.

Before performing a CO₂ Module zero, the CO₂ Module should be removed from the patient monitor and the airway adapter type to be used in the circuit should be inserted into the CO₂ Module. Care should be taken ensure that the airway adapter is clear of any residual CO₂ gas. The maximum elapsed time for a CO₂ Module zero is 30 seconds. The typical time for a zero is 15 – 20 seconds.

Several CO₂ 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.

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.

PATIENT AND TUBING PREPARATION

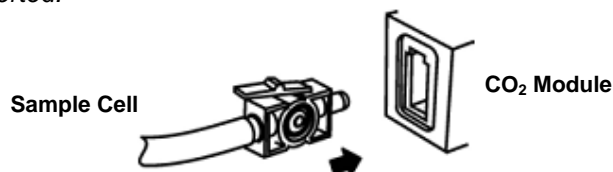
1. MODULE MOUNTING

- a. Put the CO₂ module into the bracket of the rear panel of the monitor.
- b. Check that monitor is switched off. Insert the plug of CO₂ sensor into the corresponding sensor socket marked with **EtCO₂** icon on the left panel of monitor.

WARNING: Don't hot plug EtCO₂ module, that is make sure that the Waveline Touch is powered off before Insert the connector of CO₂ sensor into EtCO₂ socket. Otherwise the CO₂ module may be damaged by power supply from EtCO₂ socket of monitor.

2. CONNECTING THE SAMPLE KIT

- a. The sample cell of the sampling kit must be inserted into the sample cell receptacle of the CO₂ Module as shown in following figure. A "click" will be heard when the sample cell is properly inserted.

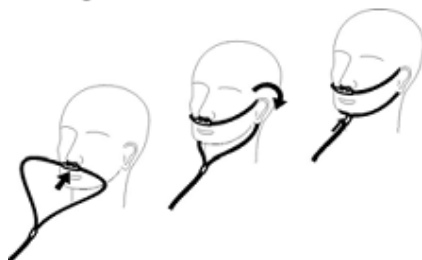


- b. Connect the CO₂ tubing to Nasal And Nasal/Oral Sidestream Kits.
- c. Inserting the sample cell into the receptacle automatically starts the sampling pump. Removal of the sample cell turns the sample pump off.
- d. to remove the sampling kit sample cell from the sample cell receptacle, press down on the locking tab and pull the sample cell from the sample cell receptacle.

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 as shown in following figure.



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 CO₂ is exhaled through the mouth. If a standard nasal CO₂ sampling cannula is used with these patients, the EtCO₂ number and capnogram will be substantially lower than actual.
6. When using the Nasal or Oral/Nasal CO₂ 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 CO₂ Module Inlet Port when not in use.

ETCO2 SETUP

Click the EtCO₂ Parameter Area to pop up the menu of EtCO₂ Setup and EtCO₂ Wave Setup, see graph below:

The image shows two screenshots of the ETCO2 Setup and ETCO2 Wave Setup screens. The top screen, titled 'ETCO2 Setup', contains the following settings: Alarm Switch (ON), EtCO2 Unit (mmHg), EtCO2 Alarm High (60), EtCO2 Alarm Low (15), AWRR Alarm High (30), AWRR Alarm Low (5), Asphyxia Delay (10), EtCO2 Period (1 breath), Sweep Speed (12.5mm/s), Zero Setup (>>), Advanced Setup (>>), and an Exit button. The bottom screen, titled 'ETCO2 Wave Setup', contains the following settings: Wave Scale (0-75(mmHg)), Sweep Speed (12.5mm/s), Fill In Waveform (Yes), Sweep Color (Default), and an Exit button. At the bottom of the bottom screen, there is a text label 'Select CO2 wave scale'.

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 CO₂ 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 EtCO₂ value. The end-tidal CO₂ value is the highest peak CO₂ value of all ends 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 EtCO₂ value for the last two breaths.

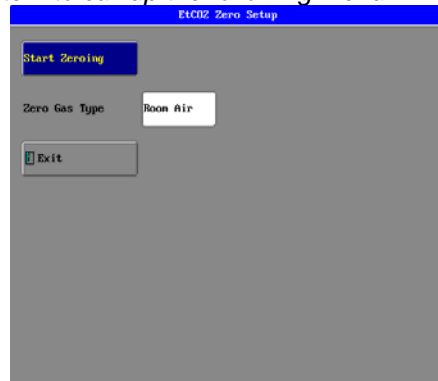
This setting has 1 breath, 10 seconds and 20 seconds for choice, the factory –set is **20 seconds**.

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 CO₂ Module” section detailed.

In above menu, complete the zero procedure by clicking the button “**starting zeroing**”.

During zeroing, a message of “EtCO₂ Zero Started” will display on the message area.

NOTE: During the CO₂ module warmup period after the monitor is powered on, the monitor will perform an automatic zero calibration the maximum elapsed time for a CO₂ 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 (N₂) when performing a zero on 100% N₂ gas; this is provided for use in a laboratory environment.

ADVANCED SETUP

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

EtCO2 Advanced Setup		
Gas Compensations	BARO.	760
Oxygen	16	Gas Temp
Balance Gas	Room Air	Wave Scale
Anesthetic	0.0	Fill In Waveform
		Yes
Exit		

SET GAS COMPENSATIONS

The measurement of CO₂ is affected by temperature, pressure, and gas compensations. The barometric pressure as well as the presence of O₂, N₂O, helium, and anesthetic agents in the gas mixture needs to be compensated for by the CO₂ module in order to achieve its stated accuracy. The instrument settings for these parameters should be set when initially connecting to the CO₂ module and whenever there is a change in the conditions at the patient airway.

In the CO₂ module, the temperature of the gas in the airway also effects the CO₂ measurement. It is necessary to adjust the instrument setting for the gas temperature to achieve the maximum accuracy for the CO₂ 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 °C**. The factory –set is **35 °C**.

OXYGEN COMPENSATION

The setting range is from **0** to **100%**. The factory –set is **16%**.

BALANCE GAS

There are room air, N₂O 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 CO₂ value is 35.0 mmHg.

WAVEFORM SCALE

Use this setting to adjust the amplitude measurement (size) of the displayed EtCO₂ 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 CO ₂ 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 CO₂ 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 CO₂ 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.

IBP MONITORING (OPTION)

- THEORY OF OPERATION
- INTRODUCTION
- WARNING
- PREPARATION FOR MONITORING
- INSTRUCTIONS FOR USE OF TRANSDUCER MONITORING KIT
- IBP SETUP
- SET TRANSDUCER ZERO
- PROMPT MESSAGE
- MAINTAINENCE AND CLEANING

THEORY OF OPERATION

There are two ways of measuring blood pressure: Direct (Invasive Pressure or IP) and Indirect (Non-invasive Blood Pressure or NIBP) method. The indirect method uses simple equipment but provides limited physiological information. The direct or invasive method (IP) provides accurate pressure measurements in regions of the cardiovascular system that are inaccessible to the indirect method.

To measure blood pressure by the invasive method, a catheter is inserted in a blood vessel and taken to the point of interest. The catheter has a transducer that provides electrical signals, which are then processed and analyzed by the monitor. Measurement of blood pressure by the invasive method gives the systolic (maximum), diastolic (minimum) and means pressure.

The invasive pressure range is from -30 to 300 mmHg, allowing the operator to use the monitor for measuring arterial pressure, pulmonary artery pressure and central venous pressure.

INTRDUCTION

When an invasive pressure is selected to be displayed on a waveform channel, the monitor will default to the label P1 or P2, which indicates a general "Invasive Pressure". In addition, the monitor allows the selection of a pressure channel label that more clearly identifies a measurement. The choices for invasive arterial pressures are:

ART	Arterial Blood Pressure
PA	Pulmonary Artery Pressure
CVP	Central Venous Pressure
RAP	Right Arterial Pressure
LAP	Left Arterial Pressure
ICP	Intracranial Pressure

WARNING:

- ♦ *For invasive pressure monitoring, routinely inspect the catheter and/or pressure line for leaks after zeroing. Always follow the pressure transducer/catheter manufacturer's use recommendations.*
- ♦ *Always zero the pressure transducer(s) prior to patient use.*
- ♦ *Non-physiological pulsatile invasive pressure waveforms (e.g., such as found during intra-aortic balloon pump use) can lead to inaccurate blood pressure readings. If questionable value is observed, re-check patient's pressures by alternate means before administering medication or therapy.*
- ♦ *The operator should avoid contact with the conductive parts of the appurtenance when being connected or applied.*
- ♦ *Disposable IBP transducer or domes should not be reused.*
- ♦ *Use only the pressure transducer designated by our company.*
- ♦ *Verify transducer cables fault detection before beginning of monitoring phase. Unplug the transducer of the channels from the socket, the screen will display the error message and audible alarm is activated, the other channel is the same.*
- ♦ *If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or may enter the transducer or inside the monitor, contact the hospital service center immediately.*
- ♦ *If there are air bubbles in the pressure line or the transducer, you should flush the system with solution to be infused.*
- ♦ *Calibrate the instrument either whenever a new transducer is used, or as frequently as indicated by your hospital procedures policy.*

PREPARATION FOR MONITORING

Preparing for invasive pressure monitoring requires the following steps:

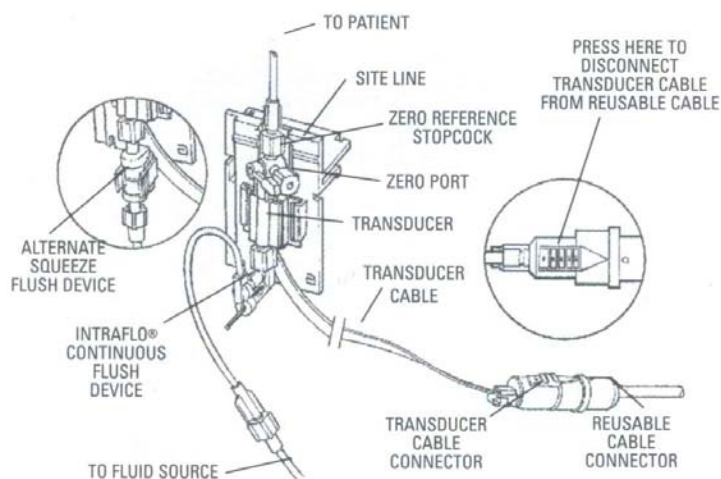
- Installation of transducer cable
- Kit set up
- Purging air from the Lines
- Zeroing, leveling and calibration
- Connecting monitoring system to patient
- Set IP channel and label
- Rescale the IP waveform
- Set the alarm limits
- Select printer option

INSTRUCTIONS FOR USE OF TRANSDUCER MONITORING KIT

INSTALLATION OF TRANSDUCER CABLE

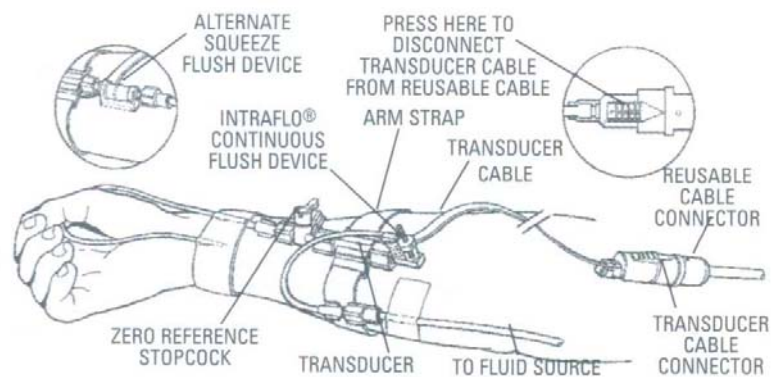
1. Insert the plug of IBP transducer cable into the corresponding sensor socket on the left panel of monitor and check that monitor is switched on.
2. Prepare the pressure tubing and transducer by flushing through the system with normal saline solution. Ensure the system is free of air bubbles.
3. Connect that patient catheter to the pressure line; making sure that there is no air present in the catheter of pressure line.
4. Position the transducer so that it is the level with the patient's heart, approximately midaxillary line.
5. Check if you have selected the correct label.
6. Zero the transducer.

KIT SET UP



This section detail refers to relate to content detailed of instructions for use for disposable transducer monitoring kit.

PATIENT MOUNT



This section detail refers to relate to content detailed of instructions for use for disposable transducer monitoring kit.

IBP SETUP

Click the P1 Parameter Area to pop up the menu of IBP Setup, see graph below:

P1 Setup		
Alarm Switch	ON	Zero Set >>
Set Label	ART	Wave Scale >>
Sweep Speed	25.0mm/s	Alarm Setup >>
		Exit

ALARM SWITCH

Click the **alarm switch** item to pop up the IBP1 or IBP2 alarm setup menu as following:

	HI	LO		HI	LO
ART (SYS)	150	75	CVP (MAP)	30	10
ART (DIA)	90	60	RAP (MAP)	30	10
PA (SYS)	90	60	LAP (MAP)	30	10
PA (DIA)	75	45	ICP (MAP)	30	10
OK				CANCEL	

The alarm setup range for high or low is from 0 to 300mmHg for ART label. The factory-set for high limit is 150 mmHg. The factory-set for low limit is 75 mmHg.

The alarm setup range for high or low is from -10 to 120mmHg for PA label. The factory-set for SYS high limit is 90 mmHg. The factory-set for SYS low limit is 60 mmHg. The factory-set for DIA high limit is 75 mmHg. The factory-set for DIA low limit is 45 mmHg.

The alarm setup range for high or low is from -10 to 40mmHg for CVP, RAP, LAP and ICP label. The factory-set for MAP high limit is 30 mmHg. The factory-set for MAP low limit is 10 mmHg.

ALARM SETUP

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

SET LABEL

ART, **PA**, **CVP**, **RAP**, **LAP** and **ICP** are selectable.

SWEEP SPEED

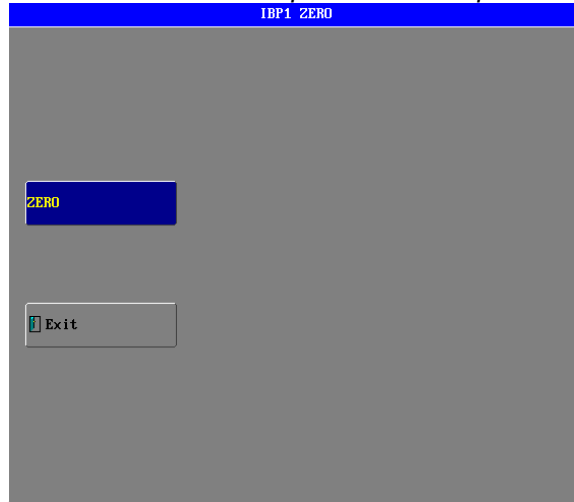
From **12.5mm/s**, **25mm/s** and **50mm/s** for choice, the factory-set is **25mm/s**.

NOTE: The pressure unit is displayed in accord with setup of NIBP menu.

SET TRANSDUCER ZERO

After the system has been primed and mounted , zero the transducer. The following procedure should be completed periodically .

1. Turn zero reference stopcocks "off" to the patient and remove yellow nonvented cap from the side port that opens the zero reference stopcock to air.
NOTE: The air-fluid interface of the zero reference stopcocks should be at or near the right atrial (mid-axillary) level.
2. Click the button of "zero set" in IBP setup menu to call up the following menu:



Upon connection of an invasive pressure transducer, the monitor will seek a steady pressure for zeroing. A sequence of on-screen status messages will be displayed.

- a. As soon as the power switch is turned on, "SENSOR OFF!" will be displayed on the screen in the message highlight area.
 - b. When an invasive pressure transducer is inserted into the IP receptacle on the left side panel of the monitor, the initial waveform may be visible immediately based upon the most recently selected scale. The waveform scale numbers are not shown until transducer is zeroed. If the pressure transducer or interconnect cable is defective, the on-screen message "SENSOR OFF, UNABLE TO ZERO!" will remain on the screen. In this case, try another transducer or another cable.
3. Turn zero reference stopcock "off" to the side port. Replace nonvented yellow cap.

NOTE:

It is the responsibility of the user to ensure that a zero procedure has recently been done on the transducer, otherwise there will be on recent, valid zero value for the instrument to use, which may result in inaccurate measurement results.

- ◆ *Turn off patient 3-way stopcock before you start the zero procedure.*
- ◆ *The transducer must be vented to atmospheric pressure before the zero procedure.*

WAVEFORM SCALE

Click the button of "waveform scale" to call up the following menu:

LABEL	HI	LO	LABEL	HI	LO
ART	150	0	PA	150	0
CVP	50	0	RAP	50	0
LAP	50	0	ICP	50	0

OK CANCEL

The waveform and corresponding scale values will be displayed in the IBP waveform area. These scales can be set according to the table given below:

HI: IBP value of High Limit scale;

LO: IBP value of Low Limit scale.

Labels	High	Low
ART	50-300	0-100
PA	20-150	-10-50
CVP	0-150	-10-150
RAP	0-150	-10-150
LAP	0-150	-10-150
ICP	0-150	-10-150

PROMPT MESSAGE

Messages	Descriptions
OVERANGE, ZERO FAIL!	Make sure that the stopcock is vented to

	<i>atmosphere. If the problem persists, contact service representative if necessary.</i>
<i>TIMED OUT, ZERO FAIL!</i>	<i>Make sure that monitor is not in DEMO mode. Contact service representative if necessary.</i>
<i>SENSOR OFF, UNABLE TO ZERO!</i>	<i>Make sure that channel 1 or channel 2 transducer is not off, and then proceed zeroing.</i>
<i>ZERO IN PROCESS!</i>	<i>A zero is currently in progress.</i>
<i>ZERO OK!</i>	<i>The zero procedure is completed.</i>

MAINTAINENCE AND CLEANING

WARNING:

Make sure that the device is switched off and disconnected from the power cable before cleaning the monitor or the transducer.

NOTE:

The disposable transducers or caps is a single use kit, must not be re-sterilized or re-used.

ANESTHETIC AGENT MONITORING (OPTION)

- THEORY OF OPERATION AND DESCRIPTIONS
- INTRODUCTION
- SAFETY AND CLEANING
- SYSTEM ASSEMBLY INSTRUCTION
- ZEROING PROCEDURE & ROOM CALIBRATION OF OXYGEN SENSOR
- ANESTHETIC AGENT PARAMETER AND DISPLAY
- ANESTHETIC AGENT PARAMETER SETUP
- CALIBRATION

THEORY OF OPERATION AND DESCRIPTIONS

The Anesthetic Agent Module (AAM) incorporates the latest design techniques and solid-state technology to redefine compactness and reliability. Miniaturization and performance advancements lead to an extremely cost-effective measuring of all five relevant anesthetic agents, as well as carbon dioxide and nitrous oxide. Ingenious solid-state design means that there are no moving parts to wear out.

The result is a solution that is highly shock-proof, while featuring low power consumption and an exceptional degree of integration flexibility into the finished product.

The infrared technology consists of a multi-spectral detector that operates according to the principles of absorption measuring and ray mixture. During each use, the infrared light is reflected in four directions after which it passes through a filter. The filters are laid out so that they are only permeable for a small wave length bandwidth in which the analyzed gas shows a particular absorption characteristic. Consequently, it is possible to determine the concentration of the gas, based on the light intensity measured by a sensor. And unlike other sensors, the AAM is not susceptible to cross-sensitivities due to gases like water vapour, ethanol or acetone.

A rapid response time of less than 350ms for CO₂ and less than 500 ms for other gases enables the AAM to differentiate between inhaled and exhaled gas concentrations. Plus, the functional range of the AAM provides automatic identification of the agent, including identifying and quantifying a mixture of two different anesthetic gases. Yet both sensors are lifetime calibrated and require only minimal maintenance.

INTRODUCTION

The monitor adopts the module of PHASEIN IRMA™ mainstream multi-gas probe is intended for gas monitoring of adults, pediatric. It made by PHASEIN AB.

PHASEIN IRMA™ mainstream multi-gas probe is intended for gas monitoring of adults, pediatric and infant patients in anesthesia, intensive care and emergency care.

The IRMA probe comprises a state-of-the-art, single path, nine-channel non-dispersive

infrared(NDIR) gas bench, an ultra rapid galvanic oxygen sensor, a barometric pressure sensor, a power regulator, a CPU and a RS-232 digital interface. The unit weighs less than 25 g (less than 38 g with oxygen sensor).

The probe is available in various configurations for different clinical applications. Concentrations of carbon dioxide, nitrous oxide, Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane in different combinations are determined together with derived parameters such as respiration rate, waveform data and inspired/expired concentrations of all gases.

The IRMA probe snaps in place on the IRMA airway adapter that includes PHASEIN's XTP™ windows. The airway adapter is inserted between the endotracheal tube and the breathing circuit, and the gas measurements are obtained through the XTP windows in the sides of the adapter.

The oxygen measurements are obtained through an oxygen port at the top of the airway adapter.

Running on a standard low voltage DC, the IRMA probe is designed with portability in mind and has low power consumption, typically less than one watt. It has been specially designed to be extremely easy to integrate in any host device for display of real time and derived breathing gas data.

The IRMA main stream multi-gas probe is intended to be connected to other medical devices for display of real time and derived monitoring data of CO₂, N₂O, O₂, and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane. It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and emergency medicine settings for adult, pediatric and infant patients.

It is not intended to be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition. The IRMA probe is intended to be used by trained and authorized health care professionals only.

SAFETY AND CLEANING

Warning

- *Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds*
- *6 ml dead space to the patient circuit.*
- *Replace the adapter if rainout/condensation occurs inside the airway adapter.*
- *Use only PHASEIN manufactured IRMA airway adapters.*
- *Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.*
- *The host equipment shall have adequate protection against contact with live parts.*
- *Use only adapter cables approved by PHASEIN AB.*
- *There must be a warning implemented in the host equipment to indicate when demo data is being displayed.*
- *The host equipment shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's*

state of health.

- *Alarm messages corresponding to each bit in the IRMA Status summary field must be implemented in the host equipment.*
- *The IRMA probe is not intended to be in patient contact.*
- *Incorrect probe zeroing will result in false gas readings.*
- *The IRMA probe is intended for use by authorized and trained medical personnel only.*
- *The IRMA probe must not be used with flammable anesthetic agents.*
- *Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.*
- *Used airway adapters shall be disposed of in accordance with local regulations for medical waste.*
- *Use only PHASEIN manufactured oxygen sensor cells. Depleted oxygen sensors shall be disposed of in accordance with local regulations for batteries.*
- *Do not try to open the oxygen sensor assembly. The oxygen sensor in the IRMA probe is a disposable product and contains a caustic electrolyte and lead.*
- *The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.*
- *Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.*
- *To keep secretions and moisture from pooling on the windows or oxygen sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.*
- *Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.*
- *Incorrect agent selection by the user for IRMA OR (no automatic agent identification) will result in false agent readings.*
- *Using IRMA OR (no automatic agent identification) with gas mixtures containing more than one agent will result in false agent readings.*

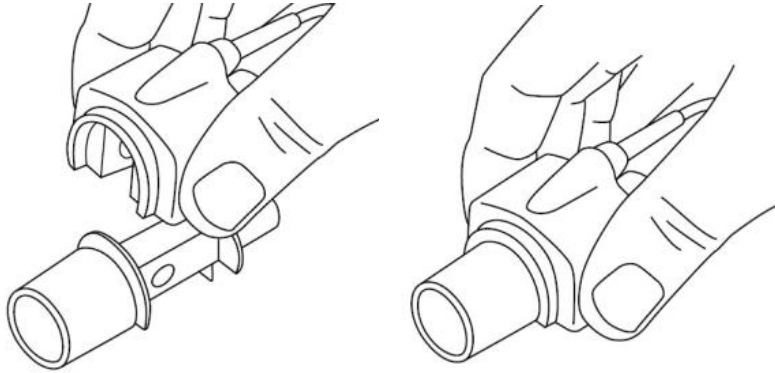
CAUTION

- *Never sterilize or immerse the IRMA probe in liquid.*
- *The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices.*
- *Do not autoclave the devices as this will damage them.*
- *Do not leave depleted oxygen sensors mounted in the IRMA probe, even if the probe is not in use.*
- *Do not apply tension to the sensor cable. 5.10*
- *Do not operate the device outside the temperature environment*
- *(U.S.): Federal law restricts this device to sale by or on the order of a physician.*

SYSTEM ASSEMBLY INSTRUCTION

Set-up

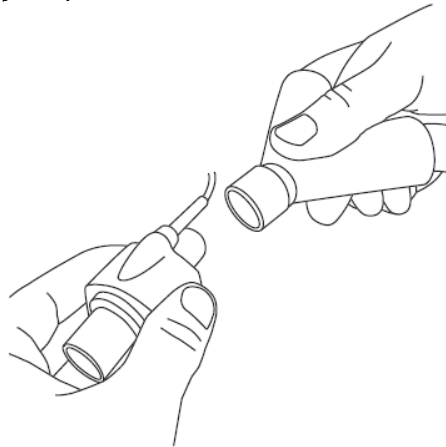
1. Plug the IRMA connector into the IRMA input of <host device> and switch the power on.
2. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.



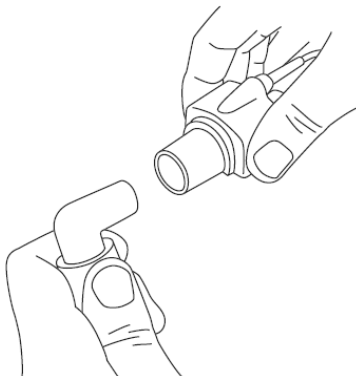
3. A green LED indicates that the IRMA probe is ready for use.



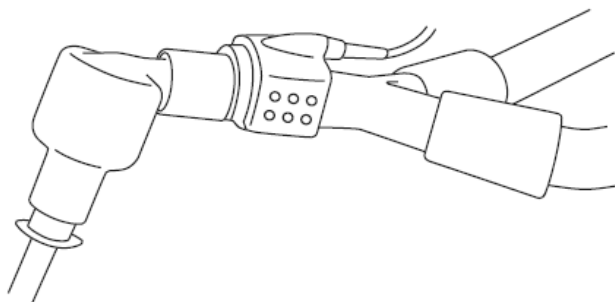
4. Connect IRMA/airway adapter 15 mm male connector to the breathing circuit Y-piece.



5. Connect the IRMA/airway adapter 15 mm female connector to the patient's endotracheal tube.



Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing an HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.



6. Unless the IRMA probe is protected with an HME always position the IRMA probe with the status LED pointing upwards



Placement of IRMA Probe

When connecting IRMA probe to an infant patient circuit it is important to avoid a direct contact between the IRMA probe and the infant's body.

If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.

WARNING: *The IRMA probe is not intended to be in patient contact*

Pre-use check

Prior to connecting the IRMA airway adapter to the breathing circuit, verify the O₂ calibration by checking that the O₂ reading on the monitor is correct (21%). See Section 5.4 for instructions on how to perform room air calibration.

Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

ZEROING PROCEDURE

Warning: *Incorrect probe Zeroing will result in false gas readings.*

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air (21% O₂ and 0% CO₂) in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a "ZERO_REQ" alarm should appear directly after a Zeroing procedure, the procedure has to be repeated. Always perform a pre-use check after Zeroing the probe.

IRMA CO₂ probes:

Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed.

Allow 10 seconds for warm up of the IRMA CO₂ probe after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

IRMA OR probes:

*Zeroing should be performed **every time the IRMA airway adapter is replaced**, or whenever an offset in gas values or an unspecified gas accuracy message is displayed. Allow 15 minutes for warm up of the IRMA OR probe after power on before proceeding with the Zeroing Procedure.*

Allow the IRMA probe to warm up for at least 1 minute after changing the IRMA airway adapter before transmitting the Zero reference command.

IRMA AX+/OR+ probes:

Zeroing should be performed **every time the IRMA airway adapter is replaced**, or whenever an offset in gas values or an unspecified gas accuracy message is displayed. Allow 30 seconds for warm up of the IRMA AX+/OR+ probes after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

Room calibration of oxygen sensor

Room air calibration of the oxygen sensor will be performed automatically at regular intervals whenever the IRMA probe is disconnected from the IRMA airway adapter.

If the IRMA probe is kept in operation for a long time period without being disconnected from the airway adapter the IRMA probe will indicate that a new room air calibration is required and a message will appear on the <host instrument>.

Use the following procedure to perform a room air calibration of the oxygen sensor:

1. Disconnect the IRMA probe from the airway adapter.
2. Wait until the LED starts blinking with red light.
3. Snap the IRMA probe back on the IRMA airway adapter.
4. Check that the LED turns green.
5. While not connected to the breathing circuit, check that the O₂ reading on the monitor is 21%.

Alarms

Include a description of the host alarm system, including the gas reading alarm limit range and its discrimination, and the implementation of alarm and status information transmitted by the IRMA probe.

Include a description of the status LED situated on the IRMA probe:

Steady green light	System OK
Blinking green light ¹⁾	Zeroing in progress
Steady blue light ²⁾	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

Note 1: Not valid for IRMA OR

Note 2: Valid for IRMA multi-gas probes only

Cleaning

The IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA probe.

Caution: The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

Caution: Never sterilize or immerse the IRMA probe in liquid.

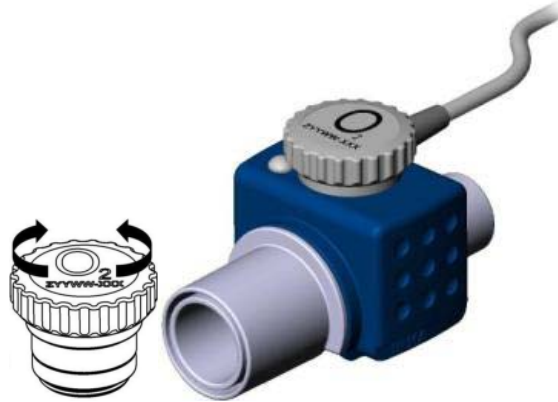
Preventive maintenance**Oxygen sensor replacement**

Replace the oxygen sensor XL every six (6) months or whenever the oxygen readings are questionable.

Oxygen sensors for replacement should be stored in a cold environment (+2 °C - +8 °C).

The IRMA O2 Sensor XL lifetime of > 100 000 oxygen hours is calculated based on cold storage for maximum 3 months. Storage in less cold environment or storage a longer time than 3 months will reduce the operating life time. For further information regarding life time of the IRMA O2 Sensor XL,

To replace the IRMA O2 Sensor XL, remove the depleted oxygen sensor by turning the sensor by hand in a counter-clockwise direction. Remove the depleted sensor and carefully screw the new oxygen sensor into position while slightly pressing it down.



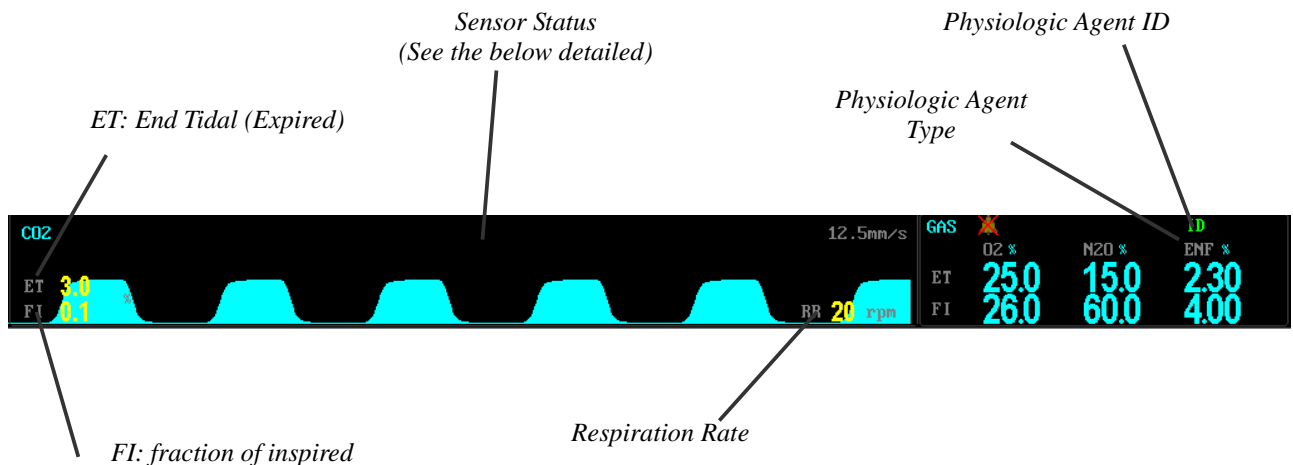
The oxygen sensor contains chemical substances and shall be disposed according to local regulations for batteries.

Caution: Do not leave depleted oxygen sensors mounted in the IRMA probe, even if the probe is not in use.

ANESTHETIC AGENT PARAMETER AND DISPLAY

CALLING UP THE DISPLAY MENU

Turn the ROTARY KNOB and move the white box to the parameter area of GAS, see graph below:



Sensor Status:

- Sensor Off
- Check Watertrap/Sample Line
- Hardware Failure
- Occlusion
- Zero in Progress
- Sensor Standby (See the menu setup below)
- Sensor Warm Up

The Zero Procedure has the purpose to maintain proper accuracy of the measurements.

Zero requests typically occur after the warm-up phase (a couple of minutes or so after start-up) of a sensor component and then again in regular time intervals (every two hours). Under certain circumstances the module will indicate extraordinary zero requests (e.g. after returning from Standby Mode or Switched Off mode). Most AAM have an internal zero management that schedules the regular zero requests in an intelligent way, such that zero requests for several individual parameters are synchronized with each other. By this, zero requests will occur less frequent, and also the zeroing process can be conducted for several gas parameters at the same time. As a consequence, zeroing will consume less of the operation time and the availability of measured data is improved.

The time needed for conducting a Zero Procedure varies between different sensor heads. Typically, it will require between ca. 20 seconds and 1 minute. In the course of the Zero Procedure, the setting of the valve and the pump change temporarily. When the Zero Procedure is finished, the module will automatically restore the valve and pump settings prior to the procedure.

Physiologic Agent Status:

ID: *The AAM has identified an agent. In this state, the corresponding ID indicates one of the 5 anesthetic agents.*

CALC: *Calculate..., The Patient Gas Module is currently busy with identifying the present agent(s). This status typically lasts for a couple of seconds.*

"Calculate" is a condition in which the agent mixture algorithm is not sure about the detected agents. Usually it comes up if no single agent history is available and a mixture situation occurs. Then it may stay for a few seconds.

OVER: *Overflow*

The gas concentration has increased above the maximum threshold.

MIX: *Mixture*

The Patient Gas Module can not identify the present agent(s). The reason is the presence of

- *Either a mixture of too many anesthetic agents*
- *or other unidentifiable gases*

FORCE:

Forced mode is used for the non-automatic Identification.

These sensors are not able to identify which of the volatile anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane or Desflurane is contained within the patient gas. This type of sensor is always operated in "Forced Mode".

In this mode the monitor will specify the type of anesthetic agent for the AAM with the command "Select Anesthetic Agent". The ID of the Physiologic Agent then reflects the forced agent.

EST: Estimated

The AAM can not identify the present agent(s) but only give an estimation of one of the present agents. The reason is the presence of

- Either a mixture of too many anesthetic agents
- Or other unidentifiable gases

Anesthetic Agent Type:

HAL: Halothane

ENF: Enflurane

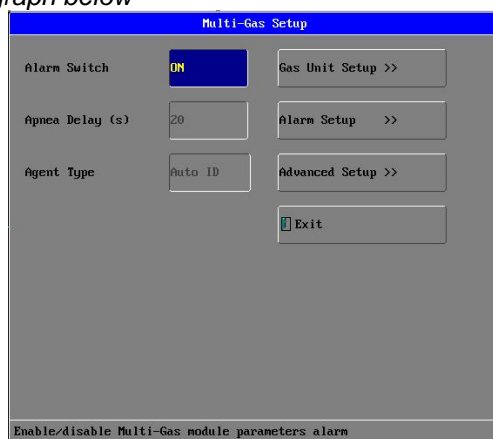
ISO: Isoflurane

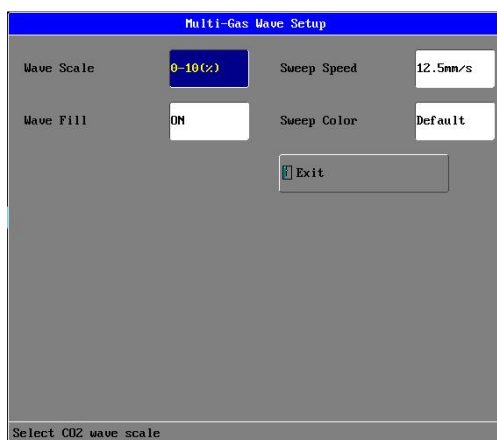
SEV: Sevoflurane

DES: Desflurane

ANESTHETIC AGENT PARAMETER SETUP

Click the Anesthetic Agent Waveform and Parameter Area to pop up the menu of Multi-Gas Setup, see graph below





ALARM SWITCH

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

SWEEP SPEED

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

WAVEFORM SCALE

“0-10%” and **“0-20%”** for choice, the factory-set is **“0-10%”**. Use this setting to adjust the amplitude measurement (size) of the displayed EtCO₂ waveform scale manually.

WAVE FILL

Use this setting to fill in the bottom portion of the waveform on any channel of the display,

SWEEP COLOR

It provides white, red, green, cyan, blue, yellow, gray and magenta which can be chosen.

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 CO₂ module will signal no breaths detected.

The setting range is 10~60 seconds, and the factory-set is 10 seconds.

AGENT TYPE

“Auto ID”, **“Halothane”**, **“Enflurane”**, **“Isoflurane”**, **“Sevoflurane”** and **“Desflurane”** for choice.

If the AAM has no **“Auto ID”** function, the anesthetic agent type needs to be selected manually.

GAS UNIT SETUP

“mmHg”, **“kPa”** and **“%”** for choice, the factory-set is **%**

ALARM SETUP

The range of alarm limits are as following:

*FI Agt: 0~20.0%
ET Agt: 0~20.0%
FI CO2: 0~10.0%
ET CO2: 0~10.0%
FI N2O: 0~100.0%
ET N2O: 0~100.0%
FI O2: 0~100.0%
ET O2: 0~100.0%
RR (rpm): 0~100*

ADVANCED SETUP

ZERO GAS TYPE

"Scrubbed Air/N2/O2", "Room Air" and "100% O2" for choice, the factory-set is "Room Air".

MANUAL ZERO

A Zero Procedure is required for any of the measured gas parameters manually. Normally the AAM has an internal zero management that schedules the regular zero requests in an intelligent way, when the user's find the measurement is not accurate, the manual zero will be requested.

O2 COMPENSATIONS

The anesthetic agents in the gas mixture need to be compensated in order to achieve its stated accuracy. The instrument settings for this parameter should be set when the O2 sensor is unconnected. But when install the O2 sensor, this function isn't available.

RESET MODULE

When the AAM module has a malfunction, this setup can try to reset this module for working. The reset sequence is equal to that after power-on.

CLEAR APNEA ALARM

This setting is used to clear the apnea alarm.

Usually, the AAM is powered up and started before the patient monitor (or anesthesia machine) is actually applied to the patient. Before the AAM is not fed with the actual patient gas, from a medicinal point of view, the apnea alarm will now be triggered as soon as the absence of breathing is detected (always taking the time-out into account). The monitor could make use of this feature by generating an audible and/or visible alarm signal to catch the operator's attention.

STANDBY MODE

When measurements are temporarily not needed, the monitor can switch the AAM from 'Operation Mode' into 'Standby Mode'. During standby, some internal components of the module are switched off, which increases the lifetime of the module. When measurements are needed again, the device must be switched back into 'Operation Mode'. The latter transition will usually take less than 30 seconds. After returning from Standby Mode, the Patient Gas Module may request a Zero Procedure; this may depend on the duration of the standby period.

CALIBRATION

The gas module doesn't require calibration.

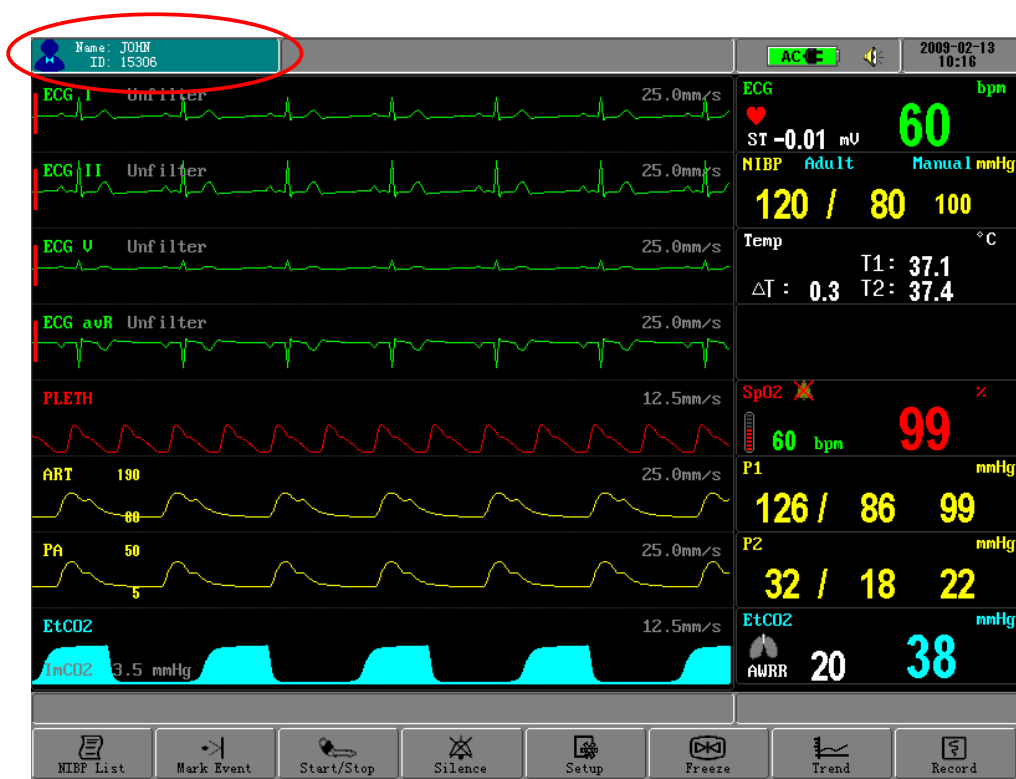
The gas module is calibrated once in the factory during production and this calibration is valid for the complete lifetime of the module. During operation, to compensate for drifts, the module will request a Zeroing Procedure in regular intervals. After a zeroing command from the host the module conducts the Zero Procedure automatically.

PATIENT INFORMATION ADMINISTRATION

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

PATIENT BASIC INFORMATION SETUP

Click the patient information area as following:



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

Patient Setup

ID

Name

Type Age

Sex Blood

Hint : If not input the patient's ID, you couldn't recall the patient's data in future.

Input patient ID

ID

Set the ID number of the patient.

NAME

Move the cursor box to the correlated position and press it, turn 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 support the display method of English and phonetic letter, and do not support the Chinese character input. The user can input 9 characters at most.

TYPE

It provides patient type as following: neonatal, pediatric and adult

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**.

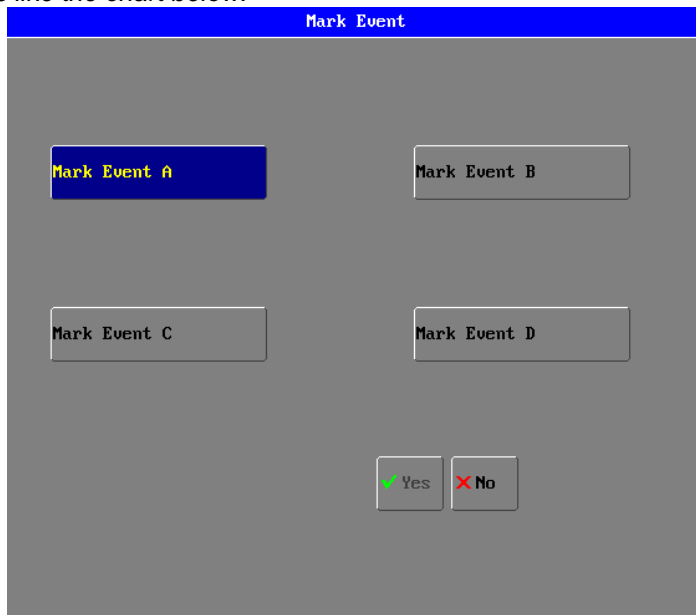
NOTE:

Once the user choose the method of **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

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:

The image shows a screenshot of a 'Mark Event' menu. At the top is a blue header bar with the text 'Mark Event' in white. Below the header, on a grey background, are four rectangular buttons arranged in a 2x2 grid. The top-left button is blue with the text 'Mark Event A' in yellow. The top-right button is grey with the text 'Mark Event B' in black. The bottom-left button is grey with the text 'Mark Event C' in black. The bottom-right button is grey with the text 'Mark Event D' in black. At the bottom center of the screen are two small buttons: one with a green checkmark and the text 'Yes', and another with a red 'X' and the text 'No'.

MARK EVENT

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

*Choose the button of **YES** to exit, and the event marked is 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, medicine taking, 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 button of **NIBP LIST** to pop up the menu of NIBP LIST, see chart below:

NO.	Time	NIBP	HR	SpO2	PR	T1/T2	RR	ST	ET
1	03/11 14:27:38	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
2	03/11 14:27:11	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
3	03/11 14:26:46	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
4	03/11 14:26:21	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
5	03/11 14:25:55	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
6	03/11 14:25:30	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
7	03/11 14:25:05	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
8	03/11 14:24:40	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
9	03/11 14:24:14	120/80 100	60	99	60	37.1/37.4	20	-0.01	N
PageDown		PageUp		Record		Close			

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:

HEART RATE (HR)、OXYGEN SATURATION (SPO₂)

NONTRAUMATIC BLOOD PRESSURE (NIBP-SYSTOLIC BLOOD PRESSURE (SYS, DIASTATIC BLOOD PRESSURE (DIA)

TEMPERATURE (TEMP)

PULSE (PULSE)

RESPIRATION RATE (RESP)

ETCO2

IBP1

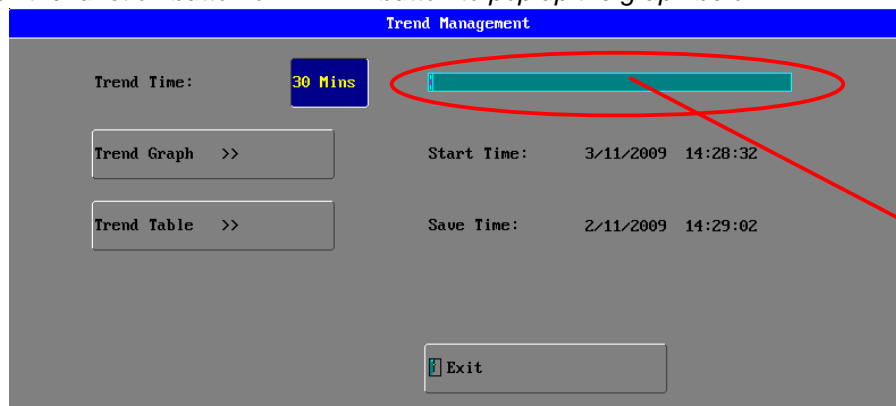
IBP2

ST

EVENT

TREND OBSERVATION ADMITTANCE

Click the function button of **TREND** button to pop up the graph below:

**Data-recording Status Bar:**

It is used to show the current data-recording length. For example, the user set 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、3hours、6 hours、12 hours、18 hours、24 hours、36 hours、48 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

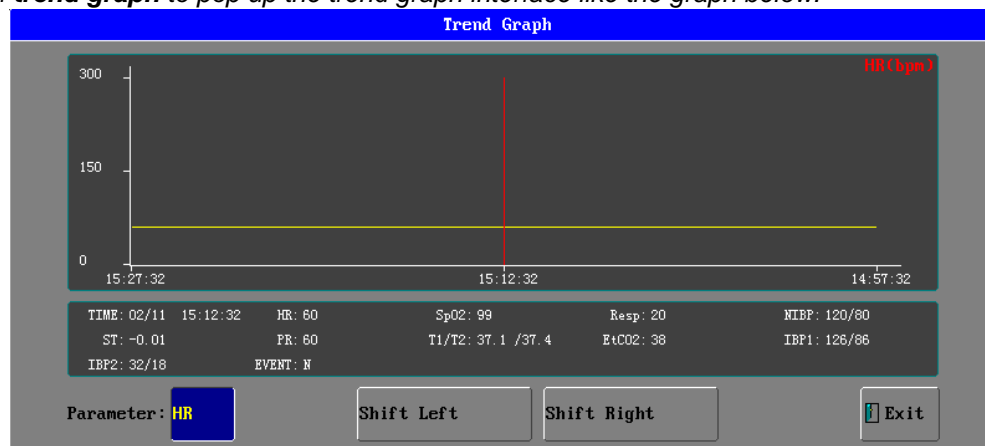
Trend Time Interval means how often the system stores a trend data. Different trend reference time has its correlated trend time interval, the relation between them are show below:

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:	16 seconds
2 hours:	288 seconds
36 hours:	432 seconds
48 hours:	576 seconds

TREND GRAPH ANALYSIS

TREND GRAPH ANALYSIS ADMITTANCE

If want to choose the Trend Graph Analysis on trend management menu, click the button of **trend graph** to pop up the trend graph interface like the graph below:



Each page display the trend chart of one parameter, the user can change it by clicking the item of **PARAMETER**, and the selection order is as below:

HR, SPO2, RESP, NIBP, ST, PR, TEMP, ETCO2, IBP1, IBP2.

The newest data is on the right side of the graph, time is displaying 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

SPO₂: 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

IBP1/IBP2: -10~300mmHg

CURSOR BAR

It is the red vertical line on the trend graph for indication.

Click the button of **shift left** or **shift right**, we can move the red cursor bar. Click the button of **EXIT** to exit from the cursor operation.

TREND TABLE ANALYSIS

TREND TABLE ADMITTANCE

Clicking the item of **Trend Table** on the trend management menu, the trend Table menu displays 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 display on the top of chart and the invalid data will not display.

Trend Table													
NO.	TIME	MLBP	SpO2	HR	PR	RR	T1	T2	ST	EtCO2	IBP1	IBP2	ET
1	2/11 15:11:06	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
2	2/11 15:11:12	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
3	2/11 15:11:18	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
4	2/11 15:11:24	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
5	2/11 15:11:30	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
6	2/11 15:11:36	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
7	2/11 15:11:42	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
8	2/11 15:11:48	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
9	2/11 15:11:54	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
10	2/11 15:12:00	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
11	2/11 15:12:06	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
12	2/11 15:12:12	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
13	2/11 15:12:18	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
14	2/11 15:12:24	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
15	2/11 15:12:30	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N
16	2/11 15:12:36	120/80	99	60	60	20	37.1	37.4	- 0.01	38	126/86	32/18	N

PageUP
PageDown
Record
Exit

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.

RECALL PATIENT HISTORY DATA

Recall patient history data in graphical or tabular format can be displayed on the screen or transferred to on the computer for analysis via RS232 interface, and printed if a recorder is installed.

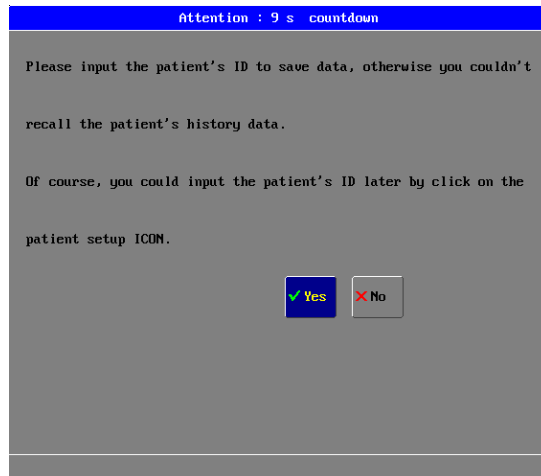
The recall patient history data for all parameters is the average of a 6-second sample of the data. Seventy two (72) hours of recall data is stored in a nonvolatile memory, and remain in storage when the monitor is in Standby. The memory can save the data, alarm events and the latest waveforms for up to 8 patients in the index of the patient ID.

A new record of recall data is started each time the monitor is turned on. A recall data record is defined as the data from one power on event to the Standby power event. A date/time annotation is included at the start of each new record (up to eight patients') and the record can be correlated with the patient. Once the recall memory has stored 72 hours of data, the oldest recall data will be overwritten by new data.

OPERATION DESCRIPTIONS

Input patient ID for recall

After you power on the monitor, there is a window pop out on the screen to remind you input the patient ID as following:



The above window will be automatically closed in count down 10 seconds.

Note: *If you want recall data for a patient at any time, you must input his/her ID number, otherwise you couldn't recall this patient's history data. Of course, you could input this patient ID later by click the patient setup icon.*

*If click **YES** item, enter the following Patient Setup menu, refer to the detailed in the section of "PATIENT BASIC INFORMATION SETUP".*

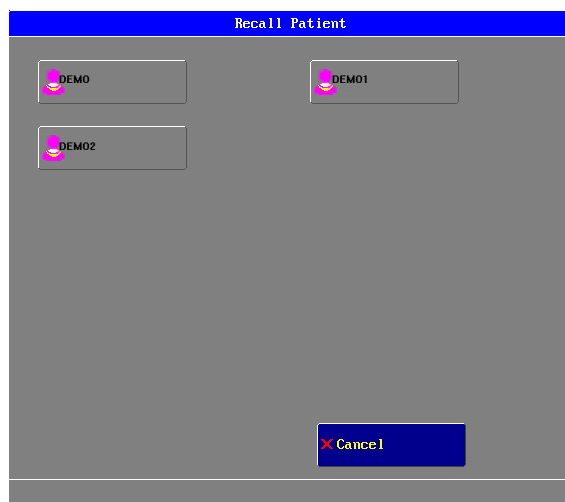
Recall Operation

1. Click the **Recall** icon on the bottom right corner the function keys to open the recall function for up to 8 patients:

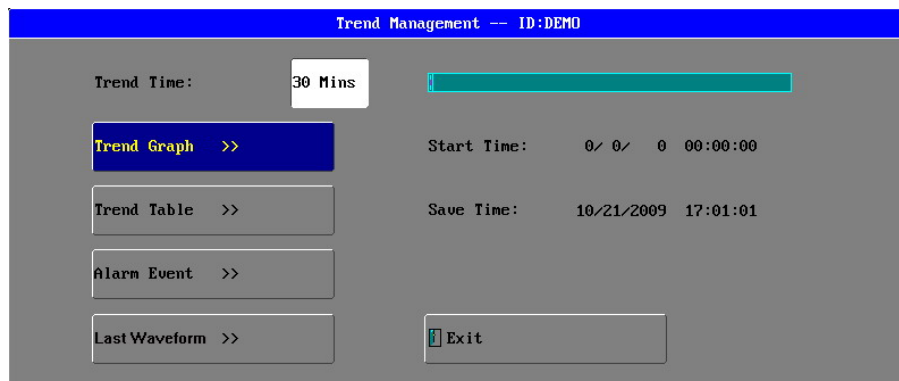


2. Select the patient ID for recall:

Complete step 1, enter the following Select patient ID menu:



3. On the **Recall Patient** window, select one ID for a patient, then enters the following **Trend Management** window with Patient ID as following:

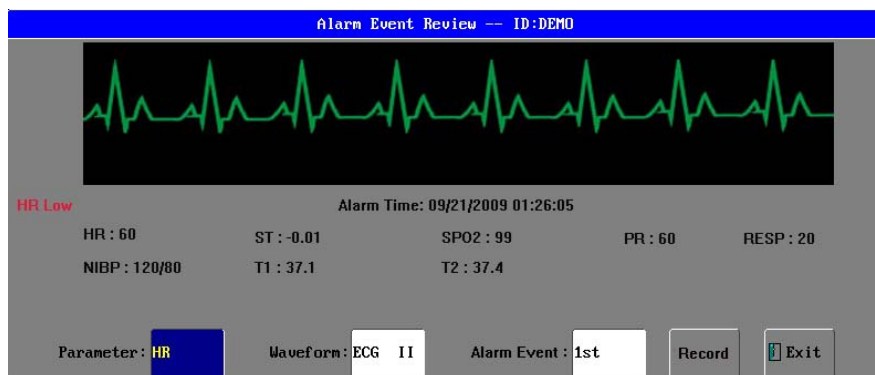


The detailed descriptions for the trend graph and trend table are see in sections of "TREND GRAPH ANALYSIS" and "TREND TABLE ANALYSIS".

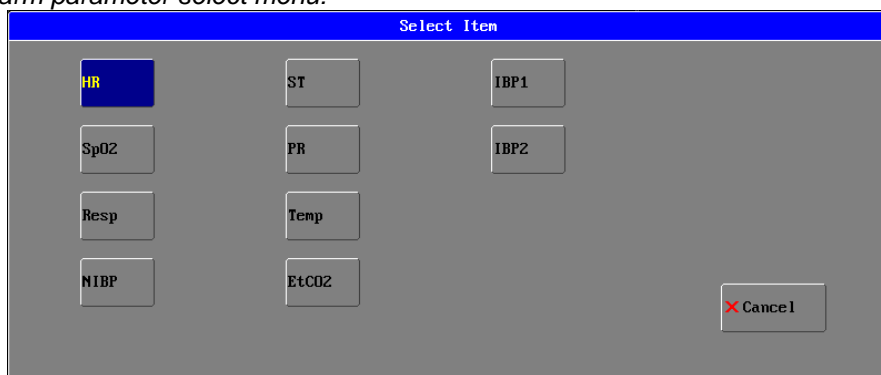
RECALL ALARM EVENTS

The alarm events record all parameter values, happened time and waveforms from 8 seconds before the recording to 8 seconds after the recording when the alarm happens for 4 seconds. The memory saves the latest 8 alarm events for each parameter and can record the current alarm event.

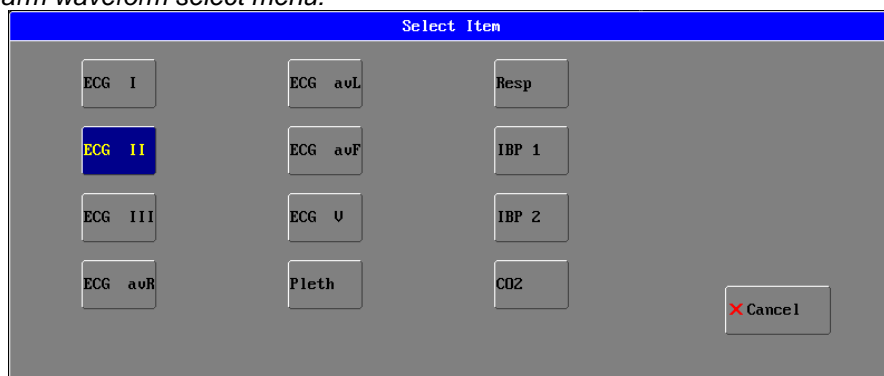
Click the item of **Alarm Event** on the trend management menu, the Alarm Event Review window will display in the waveform area on the screen. In this window you can select the alarm parameter (10 parameters), alarm waveform (12 waveforms) and alarm times (8 times).



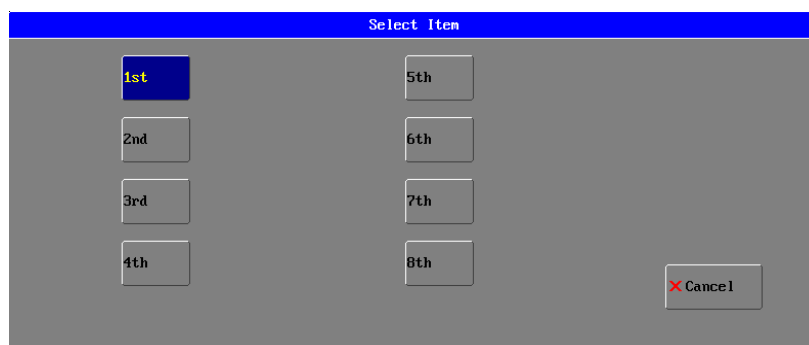
1. Alarm parameter select menu:



2. Alarm waveform select menu:



3. Alarm times select menu:



THE LAST WAVEFORM REVIEW

Click the item of **Last Waveform** to pop up the last waveform review window like the graph below:



When there are waveforms display for demonstration or realtime measurement, the system only save data for the last 8 seconds and display two selectable waveforms, the happened time for the late waveforms will display on the title bar in the window as below.



ST SEGMENT MONITORING

OPERATION SEQUENCE

Click the button of **ST Analysis** in the ECG setup menu to pop up the ST setup menu as below:

ST ANALYSIS SWITCH

The default value is **OFF**, only the choice of **ON** can operate the ST Segment Monitoring. The ST Segment result been 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**.

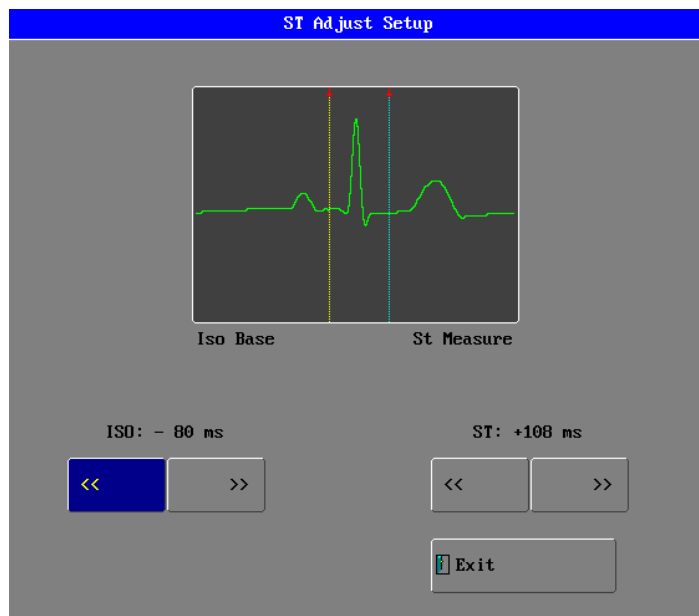
ST ALARM LIMIT

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

**ISO (Base Point)**

Set the baseline point, its adjustable range is $-508\text{ms} \sim -4\text{ms}$, 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 $+508\text{ms} \sim +8\text{ms}$, the default value is $+108\text{ms}$, 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 \ll or \gg . 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: $-2.0\text{mV} \sim +2.0\text{mV}$

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 no ST module for use.

It only appears when the ECG signal isn't existed.

RECALL DATA

- **RECALL DATA STORAGE**
- **RECALL DATA DISPLAYS**

RECALL DATA STORAGE

Recall Data in graphical or tabular format can be displayed on the screen or transferred to on the computer for analysis via RS232 interface, and printed if a printer is installed.

The recall data for all parameters is the average of a 6-second sample of the data. Seventy two (72) hours of recall data is stored in a nonvolatile memory, and remain in storage when the monitor is in Standby.

A new record of recall data is started each time the monitor is turned on. A recall data record is defined as the data from one power on event to the Standby power event. A date/time annotation is included at the start of each new record (up to eight patients') and the record can be correlated with the patient. Once the recall memory has stored 72 hours of data, the oldest recall data will be overwritten by new data.

RECALL DATA DISPLAYS

The Recall data are displayed in graphical or tabular format. The recall information in graphical format for a selected parameter is shown as a line connecting each of the points representing the stored 6-second average.

The information stored for each recall episode can include:

- *Numeric vital signs for all the measurements monitored*
- *Waveforms for up to 12 measurements of alarm events for your choice*

You can navigate through the recall database to view events retrospectively, and you can document recalls on a recording or report marked with the patient name, patient ID, the data and time.

RECALL OPERATION DESCRIPTIONS

Input ID and name of a patient for recall

After you power on the monitor, there is a window pop out on the screen to remind you input the patient's ID as following:

The above window will be automatically closed in count down 10 seconds.

Note: If you want recall data for a patient at any time, you must input his/her ID number, otherwise you couldn't recall this patient's history data. Of course, you could input this patient's ID later by click the patient setup icon.

If click **YES** item, enter the following Patient Setup menu:

ID

Set the ID number of the patient.

NAME

Move the cursor box to the correlated position and press it, turn 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 support the display method of English and phonetic letter, and do not support the Chinese character 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 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 patient, the default setting is **20**.*

ARR ANALYSIS

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 premature 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 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.

ECG Setup			
Alarm Switch	OFF	ECG Pace	OFF
HR Alarm High	130	ECG Gain	x 1.0
HR Alarm Low	50	Sweep Speed	25.0mm/s
HR Calc Source	Lead II	Heart Sound	QRS
ECG Filter	OFF	ST Analysis >>	
ECG Notch	50Hz	ARR Analysis >>	
ECG Test	OFF	Exit	

OPERATION SEQUENCE

Click the button of **ARR Analysis** in the ECG setup menu to pop up the ARR setup menu as below:

The screenshot shows the 'ARR Setup' menu with the following settings and buttons:

ARR Setup	
ARR Analysis	ON
ARR Source	Lead II
PVC Monitor	ON
PVC Alarm Count	10

Buttons on the right side of the menu:

- ARR Relearn
- ARR Alarm Setup >>
- ARR Review >>
- Exit

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

Self relearn to accommodate itself to new conditions. Such as different patients, cardiograph changes a lot.

ARR ALARM SETUP

Label	Status
ASY	ON
TPT	ON
TAC	ON
FIB	ON
CPT	ON
BRD	ON
VTA	ON
UPB	ON
MIS	ON
ROT	ON
BGM	ON
SPB	ON
RUN	ON
TGM	ON
ALL_ALM	ON

Buttons: OK, Default, CANCEL

Set all kinds of arrhythmia alarm to be **ON** or **OFF**. The all factory-sets are **ON**.

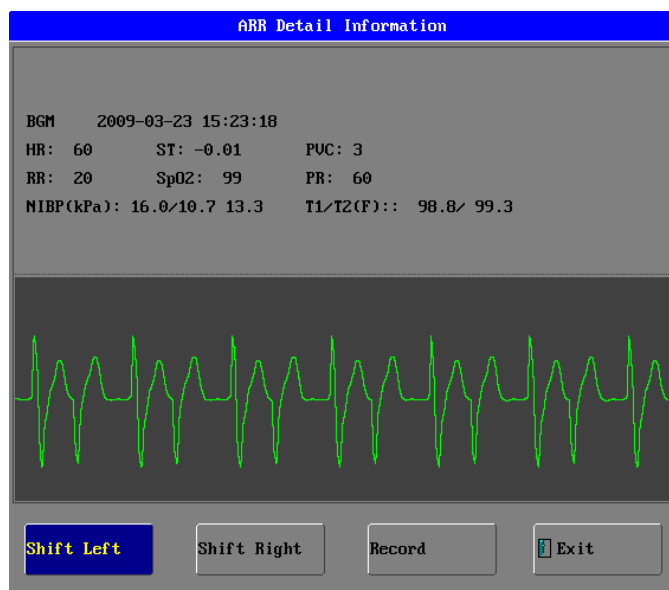
ARR REVIEW

Label	Time
MIS	2009-03-11 14:04:47
BGM	2009-03-11 14:04:20
FIB	2009-03-11 14:04:02

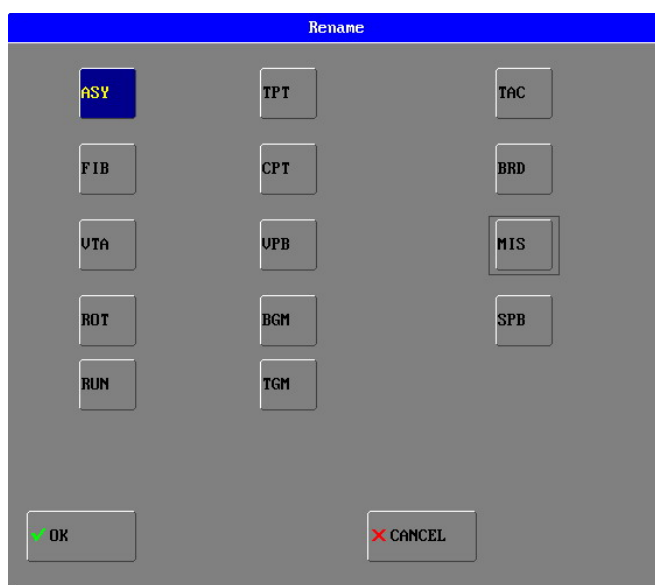
Buttons: Page Down, Page Up, Select, Wave, Rename, Delete, Sort Time, Exit

Click the button of **Select** to choose an arrhythmia item.

Click the button of **Wave** to review the selected arrhythmia item includes items of HR, ST, PR, SpO2, NIBP, Temp, Resp and PVC.



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



Click the button of **Delete** to delete a selected ARR item.
Click the button of **Sort** to sort the arrhythmia items by **time** or **type**.
Choose the type of **Sort**. The factory-set is by **Time**.

RECORDING (OPTION)

NOTE: This is thermal recorder which must use the thermal record paper with 48mm on width.

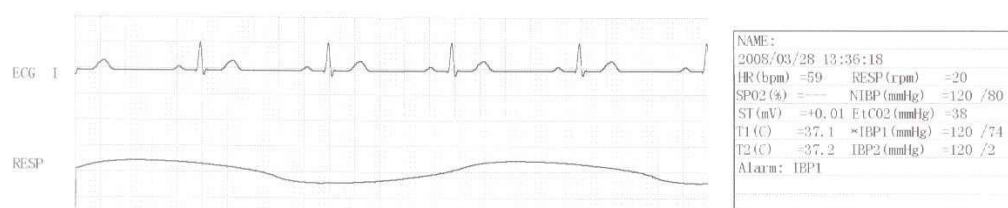
REAL-TIME WAVEFORM RECORDING

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) Record the parameter report simultaneously which include:

Patient Name, Hospital name, Recording Time, LEAD, HR, RESP, SPO2, T1, T2, ETCO2, IBP1, IBP2, ST Segment, the latest NIBP's Blood Pressures of SYS and DIA (mmHg), see graph below:



2. RECORDER SETUP

3. OPERATION SEQUENCE

Click the function button of **RECORD** on the screen → The statement of **START RECORDING** appear on the bottom of screen, which shows that the print process is going on; If want to terminate print during the printing process, just press the button of **RECORD** again, the recorder stop immediately as the statement of **BREAK RECORDING** will appears on the bottom of screen.

NOTE: Each time of pressing the button of **RECORD** will either carry out **REAL-TIME RECORDING** or terminate **CURRENT RECORDING TASK**.

TREND TABLE RECORDING

1. CONTENTS

Record 11 groups of parameter report, include seven items of DATE, TIME, HR, ST SECTION, RESP, SPO2, T1/T2, SYS/DIA, ETCO2, IBP1, and IBP2, see table below:

Date	2008/03/03	2008/03/03	2008/03/03	2008/03/03	2008/03/03	2008/03/03	2008/03/03	2008/03/03
Time	10:30:17	10:30:14	10:30:11	10:30:08	10:30:05	10:30:02	10:29:59	10:29:56
NIBP	120 / 80	120 / 80	120 / 80	120 / 80	120 / 80	120 / 80	120 / 80	120 / 80
SPO2	100	100	100	100	100	100	100	100
HR	59	59	59	59	59	59	59	59
PR	59	59	59	59	59	59	59	59
RESP	20	20	20	20	20	20	20	20
T1/T2	37.1/37.2	37.1/37.2	37.1/37.2	37.1/37.2	37.1/37.2	37.1/37.2	37.1/37.2	37.1/37.2
ST	+0.00	+0.00	+0.00	+0.00	+0.00	+0.00	+0.00	+0.00

2. RECORDING SEQUENCE

Click the function button of **TREND** on the screen → **TREND MANAGEMENT** menu appears on screen → click the button of **TREND TABLE** → **XX TIME TREND TABLE** menu appears on screen → click the button of **RECORD** → **START RECORDING.....** If want to stop record, click the button of record again or choose the soft button of **RECORD** again → **BREAK RECORDING**.

ALARM RECORD

1. CONTENTS

- (1) It can record a burst of waveform of 10 seconds (the preceding 4 seconds before the recording till the current 4 second), after the alarm, includes Gain and Paper Advance Speed.
- (2) One paper of alarm report, includes Alarm Begin Time, Alarm Lead, HR, RESP, SPO2, T1/T2, ST SECTION, Alarm Type, the latest NIBP's SYS and DIA(mmHg) value, Alarm Types are explained as below:

HR ALM	Heart Rate Alarm
SYS ALM	Systolic Pressure Alarm
DIA ALM	Diastolic Pressure Alarm
ST ALM	ST Segment Alarm
SPO2 ALM	SPO2 Alarm
TEMP ALM	Temperature Alarm
RESP ALM	Respiration Alarm

2. RECORDING SEQUENCE

Click the button of **TREND** on the screen→TREND MANAGEMENT menu appears on screen→ click the item of ALARM EVENT→ALARM EVENT menu appears on screen→click button of RECORD→START RECORDING, If want to stop printing, click the button of RECORD again or click the soft button of RECORD again→BREAK RECORDING.

If there is several parameters alarm simultaneously, click and choose them on ALARM menu, parameter alarms indicated by red sigh can be record 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.

[NOTE] : "-----"means invalid parameter.

RECORDING EXPLANATION

1. INSERTING PAPER

Press the button of the catch 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 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 button of RECORD 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 button of RECORD been pressed again during the process of printing, so it can 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:

Showing that record paper has been installed well

(6) NO PAPER

Record paper has been use up.

(7) RECORDER READY

Showing that recorder has been connected well.

(8) RECORDER NOT READY

Showing that recorder hasn't been connected well.

GRID OUTPUT

Some recording paper without grid, in order to observe the waveform easily, you can set the grid form. The set method is as below:

*Click the function button of **SETUP**→the menu of SYSTEM SETUP→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

Waveline Touch type patient monitor is equipped with a rechargeable battery. The monitor through 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 1 hour of monitoring time under the following conditions: no audible alarms, no analog or serial output devices attached, and no backlight.

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 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: *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.*

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.

CAUTION: *If the Waveline Touch 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.*

WARNING: *The batter need to be charged before use. Please note the inserting direction, insert the battery rightly according to the instruction on the label attaching on the battery. Otherwise it will damage the inner structure of the batery housing.*

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.*

CLEANING

WARNING: *Do not spray, pour, or spill liquid on Waveline Touch, its accessories, connectors, switches, or openings in the chassis. Do not immerse the monitor or its accessories in liquid or clean with caustic or abrasive cleaners.*

To clean the Waveline Touch, dampen a cloth with a commercial, nonabrasive cleaner and wipe the exterior surfaces lightly. Do not allow any liquids to come in contact with the power connector or switches. Do not allow any liquids to penetrate connectors or openings in the instrument. For cables, sensors, and cuffs, follow the cleaning instructions in the directions for use that accompany these accessories.

SPECIFICATIONS

SAFETY	
Meet the requirement of EN60601 series, CE marking according to MDD93/42/EEC	
Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide	
Type of Protection:	Class I (on AC power) , Internally powered (on battery power)
Degree of Protection:	Type BF, defibrillation-proof CF - Applied part
Sterilization or Disinfection methods:	70% isopropyl alcohol solution or a nonstaining disinfectant.
Operation Mode:	Continuous Operation
Protection Against Ingress of Liquid's:	IPX0
APPLICATION	
Neonatal, pediatric and adult patients	
Physical Dimensions & Weight	
Base Unit:	555x335x235mm
Weight:	4.5kgs
PERFORMANCE SPECIFICATIONS	
Display:	12.1 " color TFT
Resolution:	800x600
Trace:	4, 6 or 8 waveforms
Waveforms	ECG(I, II, III, aVR, aVL, aVF, V1-V6), PLETH, RESP, IBP1, IBP2, 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:	5/3-lead ECG cable and standard AAMI line for connection
Lead Choice:	I, II, III, aVR, aVF, aVL, V
Gain Choice:	x0.5, x1.0, x2.0
Frequency Characteristic:	0.5~40 Hz (+3dB)
ECG Waveforms:	7 channels
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: ± 5 mmHg 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 (°C)
Accuracy:	± 0.2 °C (25.0~34.9 °C) ± 0.1 °C (35.0~39.9 °C) ± 0.2 °C (40.0~44.9 °C) ± 0.3 °C (45.0~50.0 °C)
Display Resolution:	0.1 °C
Alarm Upper-lower Limit:	Upper limit 0~50 °C, Lower limit 0~50 °C
Channel:	2 channels
Alarm Limit:	10~50 (°C)
SPO2	
ASpO ₂ :	Anti-motion SpO ₂
SpO ₂ % Range:	0~100%
SpO ₂ Accuracy:	$\pm 2\%$ (70~100%, non-motion) $\pm 3\%$ (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 \pm 5nm Infrared light LED wavelength 940nm \pm 10nm
IBP(OPTION)	
Measurement Range:	-10~300mmHg
Channel:	2 channels
Pressure transducer:	Sensitivity, 5 μ V/V/mmHg

Impedance range:	300~3000Ω																				
Transducer sites:	ART, PA,CVP, RAP, LAP, ICP																				
Resolution:	1mmHg																				
Accuracy:	±1mmHg or ±2%, whichever is greater																				
Alarm range:	-10~300mmHg																				
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																				
ANESTHETIC AGENTS(OPTION)																					
Description	Ultra-compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.																				
Measurement Range:	<table><tr><th>Gas</th><th>Range³</th><th>Accuracy</th></tr><tr><td>CO₂</td><td>0 to 15 vol% 15 to 25 vol%</td><td>±(0.2 vol% + 2% of reading) Unspecified</td></tr><tr><td>N₂O</td><td>0 to 100 vol%</td><td>±(2 vol% + 2% of reading)</td></tr><tr><td>HAL, ENF, ISO</td><td>0 to 8 vol% 8 to 25 vol%</td><td>±(0.15 vol% + 5% of reading) Unspecified</td></tr><tr><td>SEV</td><td>0 to 10 vol% 10 to 25 vol%</td><td>±(0.15 vol% + 5% of reading) Unspecified</td></tr><tr><td>DES</td><td>0 to 22 vol% 22 to 25 vol%</td><td>±(0.15 vol% + 5% of reading) Unspecified</td></tr></table>	Gas	Range ³	Accuracy	CO ₂	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified	N ₂ O	0 to 100 vol%	±(2 vol% + 2% of reading)	HAL, ENF, ISO	0 to 8 vol% 8 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified	SEV	0 to 10 vol% 10 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified	DES	0 to 22 vol% 22 to 25 vol%	±(0.15 vol% + 5% of reading) Unspecified		
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	³ All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.																				
	<table><tr><th>Gas</th><th>Accuracy</th></tr><tr><td>CO₂</td><td>±(0.3 kPa + 4% of reading)</td></tr><tr><td>N₂O</td><td>±(2 kPa + 5% of reading)</td></tr><tr><td>Agents ¹⁾</td><td>±(0.2 kPa + 10% of reading)</td></tr><tr><td>O₂</td><td>±(2 kPa + 2% of reading)</td></tr></table>	Gas	Accuracy	CO ₂	±(0.3 kPa + 4% of reading)	N ₂ O	±(2 kPa + 5% of reading)	Agents ¹⁾	±(0.2 kPa + 10% of reading)	O ₂	±(2 kPa + 2% of reading)										
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	Note 1: The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set.																				
NETWORKING																					
Wired Networking	Industry standard: 802.11b/g wired network Connected bedside number: Up to 32 bedside monitors																				
Wireless Networking	Up to 100m indoors Frequency Range: 2.412~2.484 GHz Industry standard 802.11b/g wireless Supports TCP/IP and UDP/IP Protocols																				
POWER																					

Source:	External AC power and internal battery
AC Power:	100~240VAC, 50/60Hz, 150VA
Battery:	Built-in and rechargeable
Charge Time:	4 hours
Operating Time:	1 hour
ENVIRONMENTAL SPECIFICATIONS	
Temperature:	Operating: 5~40 °C Storage: -10~45 °C
Humidity Range:	Operating: ≤80 % Storage: ≤80 %
BATTERY	
Manufacturer:	Pilot Battery Co.,Ltd.
Type:	FB 1223 12v-2.3Ah
Operating time under the normal condition:	1 hour
Operating time after the first alarm of low battery:	10 minutes
RECORDER (OPTION)	
Record Width:	48 (mm)
Paper Speed:	25 (mm/s)
Trace:	2
FUSE	
Fuse	T 3.0A
LCD SPECIFICATIONS	
Display Type:	TFT color LCD
Size (diagonal):	31cm (12.1")
Active Area:	246.0 H x 184.5 V
Pixel Format	800 H x 600 V (1 pixel=R + G + B dots)
Pixel Pitch (W x H) :	0.3075 x 0.3075 mm
Number of Colors(number of gray scale level):	262,144 colors(64 gray scales per color)
Display Mode:	Normally white
Surface Treatment:	Anti-glare and hard-coating 3H
TOUCHSCREEN SPECIFICATIONS	
Type:	Four-Wire Analog Resistive Touch Panel
Input Mode:	Stylus Pen or Finger
Connector:	FPC
Frame Size:	268.50±0.30x201.50±0.30(mm)
View Area:	253.50±0.20x189.00±0.20(mm)
Active Area:	245.00±0.20x183.00±0.20(mm)
Total Thickness:	2.25±0.20(mm)
Tail Length:	80.00±1.00(mm)
Transparency:	≥78% ± 3% (Measured by BYK-Gardner)
Haze:	Antiglare Finish ≤10% ± 3%
Knock Test:	1,000,000 times

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

