OMNI(K)

Patient Monitor

USER'S MANUAL

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SAFETY INFORMATION

This section contains important safety information related to general use of the OMNI (K) 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 OMNI (K) monitor can be powered by an internal battery pack that provides 2 hours of monitoring from fully charged batteries. The batteries are continuously recharged when AC power is connected to the monitor.

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

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

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

Important! Before use, carefully read this manual, accessory direction for use.

WARNING: The OMNI (K) 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 OMNI (K) 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 OMNI (K) monitor in the presence of flammable anesthetics or gases.

WARNING: Do not lift the OMNI (K) 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 OMNI (K) monitor may not operate effectively on patients who are experiencing convulsions or tremors.

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

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

WARNING: For pacemaker patients, the OMNI (K) may continue to count pacemaker rate during occurrences of cardiac arrest or some arrhythmias. To reduce the likelihood of this, ensure that the Pacer Detect setting is ON in the ECG menu when monitoring such patients. Do not rely entirely upon the OMNI (K) alarms. Keep pacemaker patients under close surveillance.

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 OMNI (K) Monitors.

WARNING: Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Such transients may be minimized by proper electrode and cable placement, as specified in this manual and electrode directions for use.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING: Disconnect the OMNI (K) monitor and sensors during magnetic resonance imaging (MRI) scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy. Also, to avoid burns, remove the sensors from the patient before conducting MRI.

WARNING: ECG cables may be damaged if they are connected to a patient during defibrillation. Cables that have been connected to a patient during defibrillation should be checked for functionality before using again.

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 OMNI (K) monitor to any instrument, verify proper operation before clinical use. Both the OMNI (K) 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.

WARNING:
Defibrillation and Electrosurgery: Do not touch the patient, or table, or instruments, during defibrillation.
After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied in accordance with the manufacturer's instructions.
ECG cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again.
According to AAMI specifications the peak of the synchronized defibrillator discharge should be delivered within 60 ms of the peak of the R wave. The signal at the ECG output on the OMNI (K) patient monitors is delayed by a maximum of 30 ms. Your biomedical engineer should verify that your ECG/Defibrillator combination does not exceed the recommended maximum delay of 60 ms.
When using electrosurgical (ES) equipment, never place ECG electrodes near to the grounding plate of the ES device, as this can cause a lot of interference on the ECG signal.

INTRODUCTION

INTENDED USE
ABOUT THIS MANUAL

INTENDED USE

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

The purpose and function of the OMNI (K) monitor is to monitor ECG, heart rate, NIBP (systolic, diastolic, and mean arterial pressures), SpO_2, respiration, *dual temperature, $EtCO_2$, anesthetic gas (AG) and dual IBP*for adult, neonate and pediatric patients in all hospitals and hospital-type facilities such as clinics and emergency room facilities.

The OMNI (K) monitor offers advanced features such as an intuitive touchscreen with clinical measurements, one-touch commands, and a crisp, clear display.

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

WARNING: This OMNI (K) Monitor is intended to only be used under the supervision of clinical personnel. Using this outside the supervision of clinical personnel could be hazardous.

ABOUT THIS MANUAL

This manual explains how to set up and use the OMNI (K) monitor. Important safety information relating to general use of the OMNI (K) 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 AND LEFT SIDE PANEL
REAR PANEL AND RIGHT SIDE PANEL
SYMBOLS

FRONT PANEL

Figure 1: Front View for Main Unit

Table 1: Description for controls on front panel of OMNI (K)

No.	FUNCTION	Icon
1	ALARM INDICATOR In normal mode, no indicator lights. In alarm mode, the alarm indicator flashes.	
2	POWER SWITCH This toggle switch turns the secondary power from on to off from the monitor. The monitor will continue to charge the battery as long as the AC cable is plugged in, even if the power switch is in the off station.	
3	DC ON This LED indicates that the monitor is powered by battery.	
4	AC ON This LED indicates that the monitor is powered by AC.	
5	START/STOP Start or stop NIBP measurements	
6	SILENCE Silence all alarm sounds	
7	SETUP If no menu is displayed on the screen, pressing it will enter the main menu. If there is a menu displayed on the screen, pressing it will close that menu.	
8	FREEZE Freeze or unfreeze waveforms	
9	TREND Start or stop to review the history data	

10	RECORD Start or stop recordings	
11	ROTARY KNOB Rotate the Knob clockwise or anti-clockwise. With each click, the highlight jumps to the neighboring item. When you reach your desired item, press the Knob to select it.	

LEFT SIDE PANEL

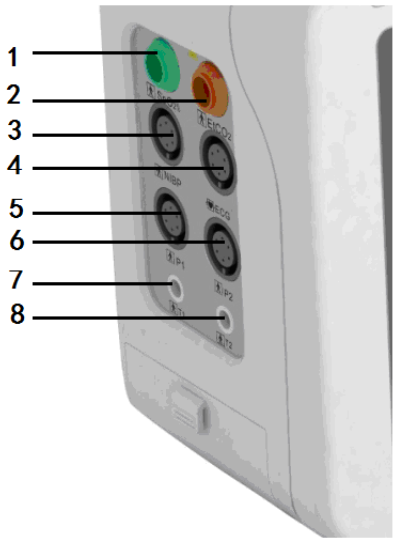


Figure 2*: Left Side Panel for Main Unit*

Table 2: Description for controls on side panel of OMNI (K)

No.	FUNCTION
1	Oxygen saturation sensor port
2	$EtCO_2$ input port (Option)
3	NIBP port for the connection with the blood pressure cuff hose
4	AAMI ECG lead socket
5	IBP port for channel 1 (Option)
6	IBP port for channel 2 (Option)
7	Temperature port for channel 1
8	Temperature port for channel 2

REAR PANEL AND RIGHT SIDE PANEL

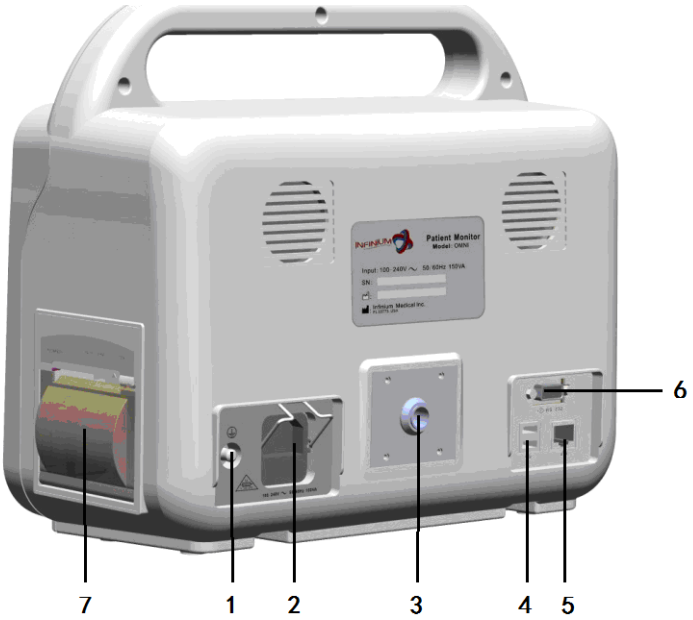


Figure 3*: Rear View for Main Unit*

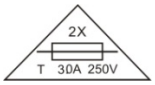
Table 3: Description for controls on rear and side panel of OMNI (K)

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	Fixed support for $EtCO_2$ module (option)	
4	USB port	
5	Network Interface	
6	RS-232 I/O This digital interface connector provides serial data to most RS-232 devices	RS232
7	Recorder (option)	

SYMBOLS

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

Table 4: Description for Symbols

	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.

DISPLAY SCREEN PARTITION

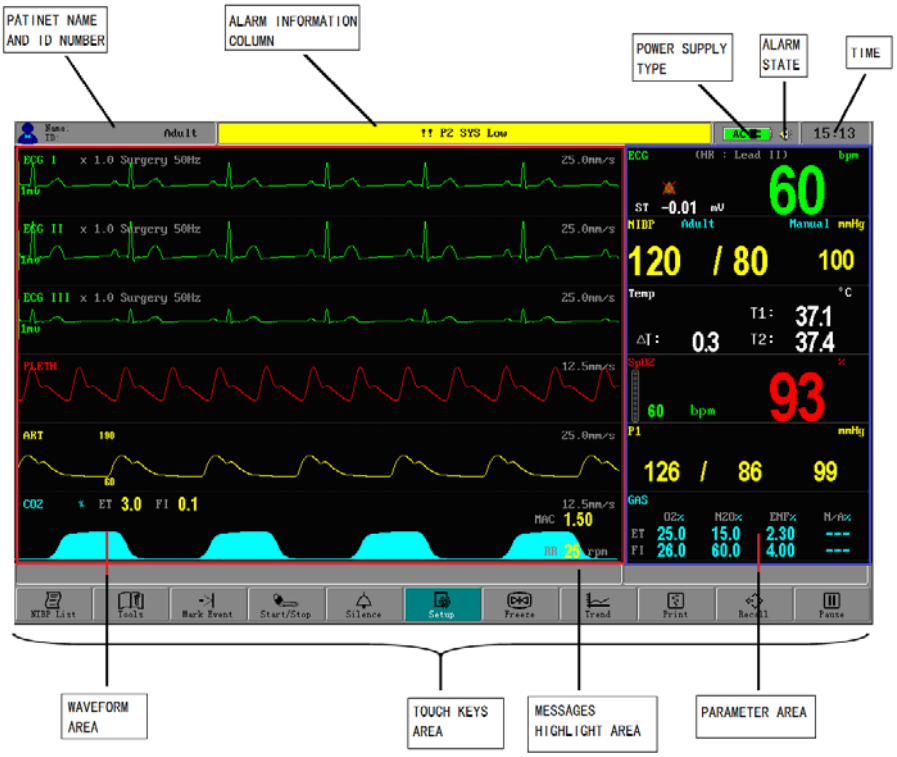


Figure 4: Display Screen Partition Diagram

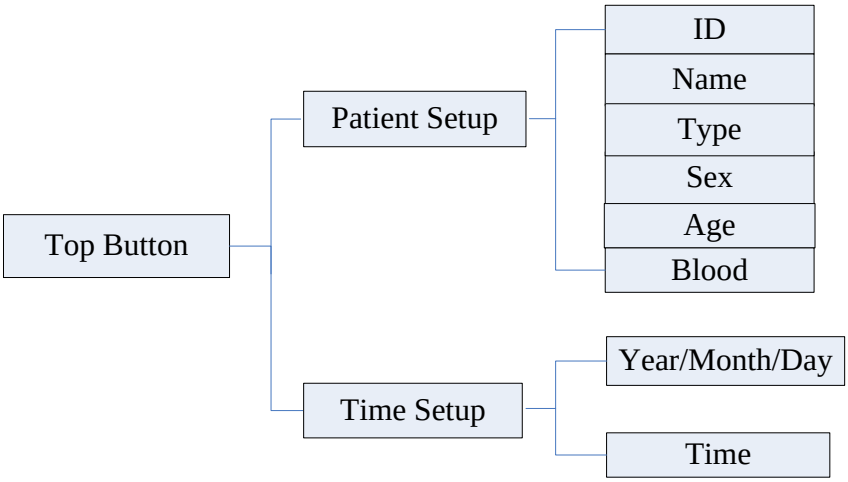


Figure 5: Tree Diagram for Top Button

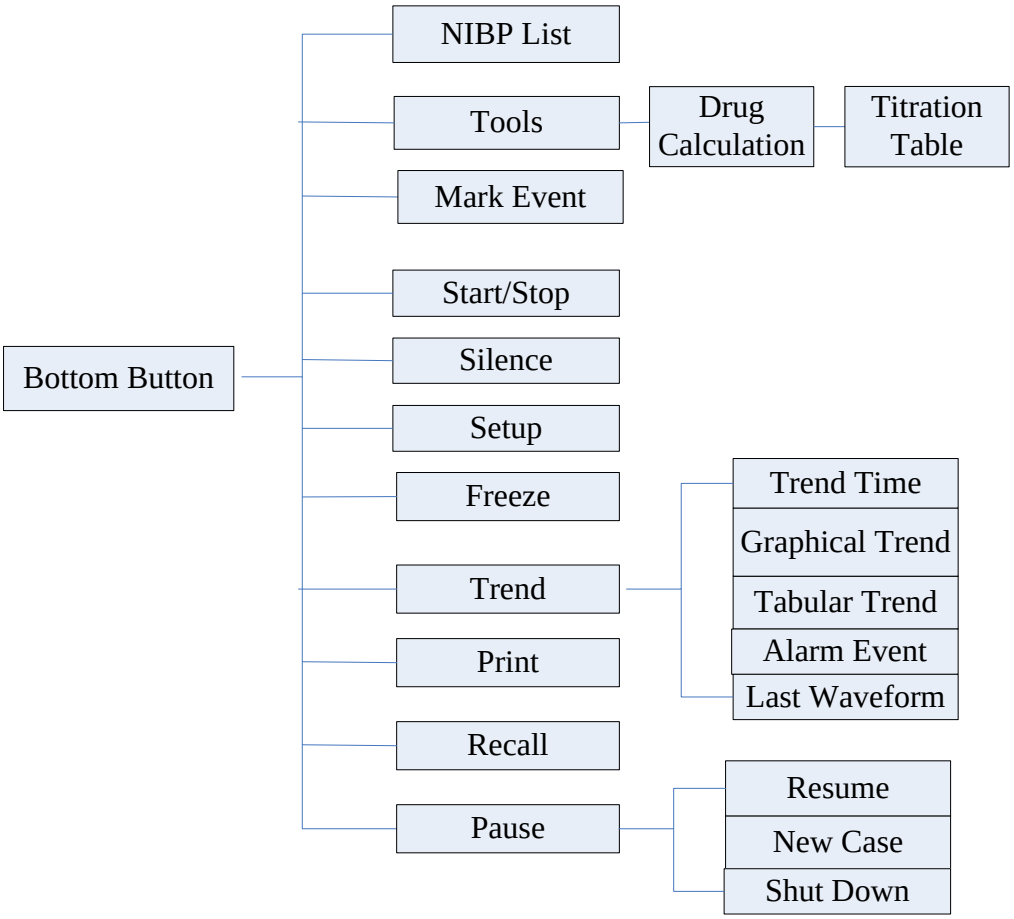


Figure 6: Tree Diagram for Bottom Button

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, GAS 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.

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.

MESSAGE AREA

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

TOUCH KEYS AREA

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

MENU AREA

Menu Area is in the waveform area, see below:

SYSTEM SETUP

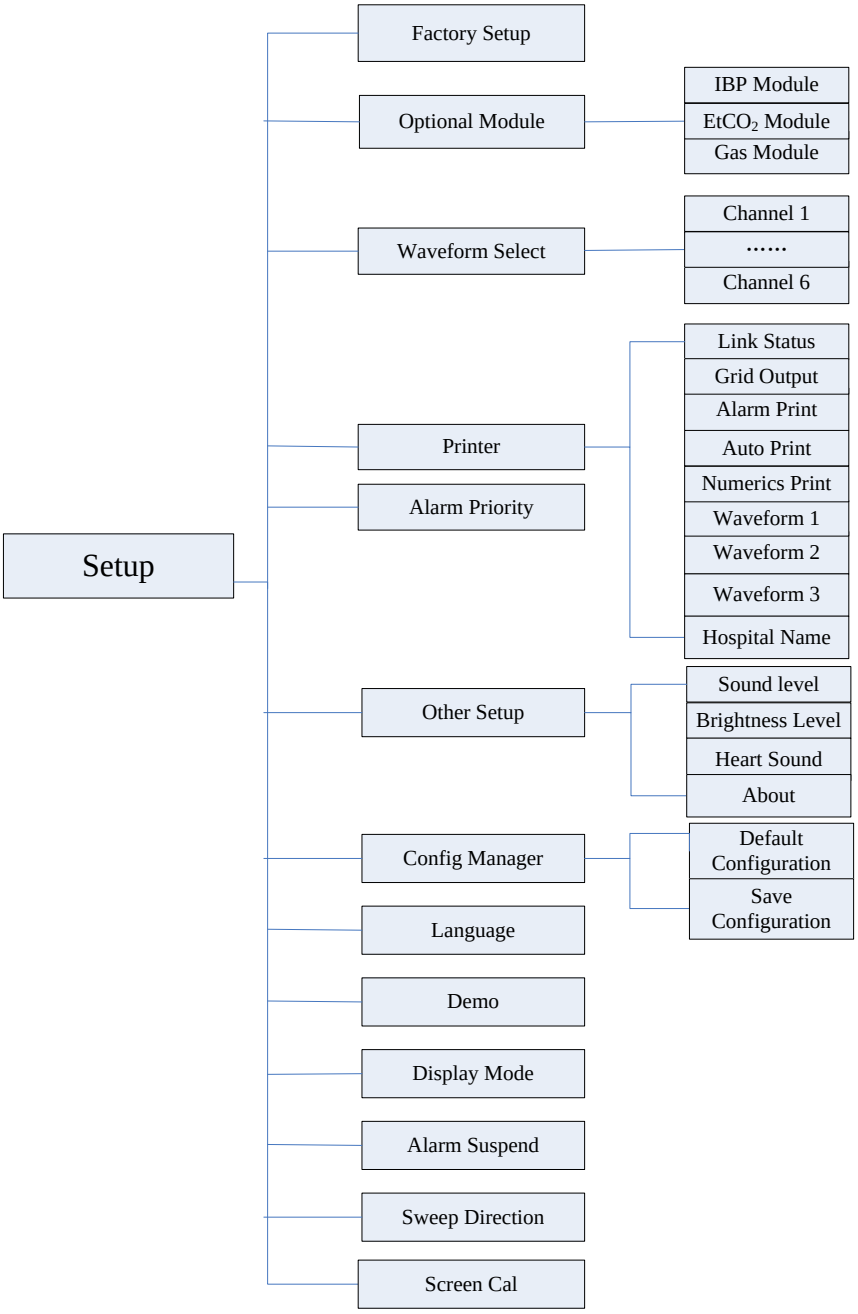


Figure 7: Tree Diagram for System Setup Menu

FACTORY SETUP

Click **Factory Setup** in the **SYSTEM SETUP** menu to call up the **Input the Password** menu.

The password allows you to input a total of 8 characters. For less than 8 characters you can add a period to fill in the space. The following table shows all the passwords you can set:

1."**DEMO....**": Open/close the demonstration mode for the system;
2."**MAKE....**": Switch on/off for "make" item for the SPO2 function;
3."**LANGUAGE**": Set the language;
4."**SCREEN..**": Open/close the calibration mode for the touch screen;

5."**IP SETUP**": Set Ethernet IP address;
6."**FORMAT..**": 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, then save patient data again.

PRINTER SETUP

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

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

ALARM PRINT
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.

AUTO PRINT
5 minutes, 10minutes, 20minutes, 30 minutes and 60 minutes are for choice, if the "Numerics Print" menu is set to on, after related interval, it will only print parameters' value automatically. If it is set to off, it will print Waveform and Parameters' value automatically. Also, you can choice "OFF", and then the print should be executed by manual.

NUMERICS PRINT
If this item set to be ON, It can record the parameters' value. For example HR, NIBP, RR, SpO2, IBP1, IBP2, T1, T2, EtCO2, nN2O, inENF and expENF and so on.

HOSPITAL NAME
Click this item to input or change the hospital name.

ALARM PRIORITY
It is used to set the alarm priority to be medium or high.

DEFAULT CONFIG SETUP
You can call the default settings by clicking this item.
After returning the above confirmation menu, a message of "LOAD DEFAULT CONFIG DATA SUCCESS!" will display in the message highlight area showing that the system has begun to use the default settings.

SAVE CONFIG SETUP
Save current config settings so the system can call up these settings the next time you open it.

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

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

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

DISPLAY MODE
It is used to set the display mode to be "6 waveforms", "3 waveforms", "Large font", or "OxyCRG".

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

SCREEN CALIBRATE SETUP
Servicing engineer uses this setup only after inputting the correct password of "SCREEN**..**".

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

Four steps need be followed according to information in the message highlight area. The first three steps are calibration steps where the user clicks the red cross icons accurately in order to calibrate the touch screen.

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

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

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 OMNI (K) 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 OMNI (K) 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 OMNI (K) has at least 10 minutes of operating time remaining) and communications errors for modules.

VISUAL ALARM INDICATORS

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

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

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 OMNI (K) 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 above or low 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 OMNI (K).

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 OMNI (K). A non-flashing 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

A mild BEEP sound. There are four items of Ⅰ, Ⅱ, Ⅲ and Ⅳ for alarm levels in order 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 refer to relative musical pitches and C is one octave above 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 are the options, 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 SETUP
ERROR MESSAGES OF ECG MONITORING
MAINTENANCE AND CLEANING

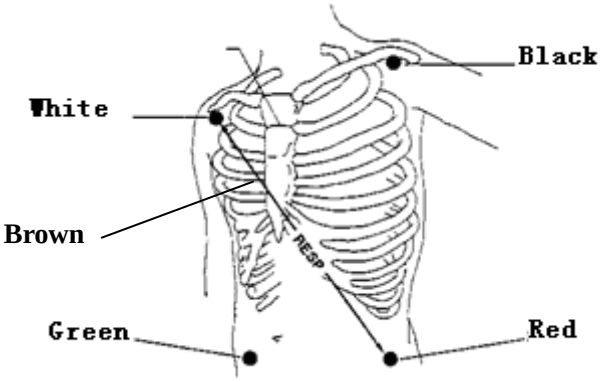
ELECTRODE INSTALLATION

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

5-Leadwire Electrode Placement

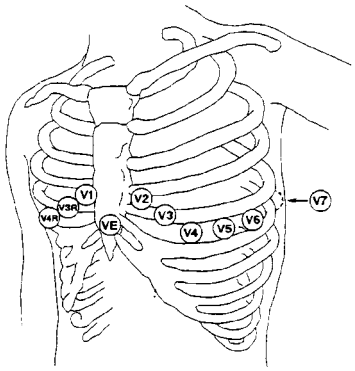
Follow the methods below to place these 5 –lead electrodes;



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

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

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



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

WARNING:
□When using electrosurgical units (ESU), patient leads should be placed in a position that is equal distance from the Electrosurgery electrotome and the grounding plate to avoid burns to the patient. Never entangle the ESU cable and the ECG cable together.
□When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.

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 PARAMETER SETUP

The ECG setup can be popped out by click the parameter area of ECG.

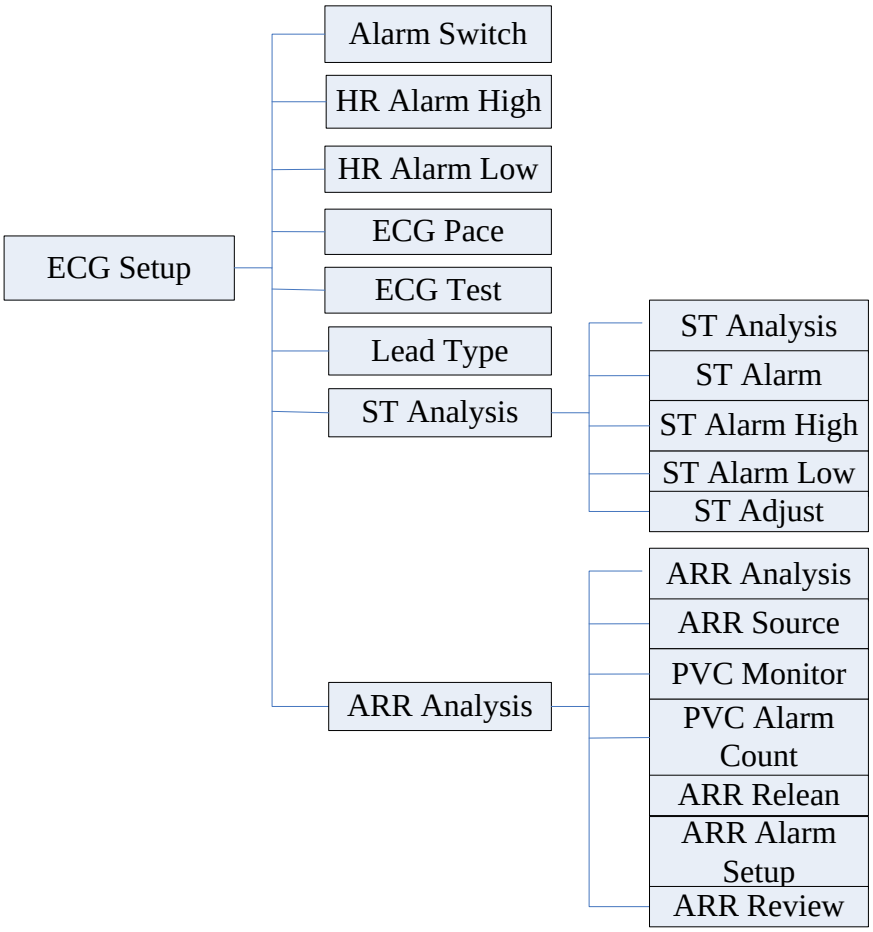


Figure 8: Tree Diagram for ECG Setup Menu

ALARM SWITCH

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

HR ALARM UPPER-LIMIT

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

LEAD TYPE

3 leads, 5 leads for choice, the factory- set is 5 leads.

ST-SEGMENT ANALYSES MENU

It is used to complete Automatic ST-segment analysis function.

ARRHYTHMIA ANALYSIS

It is used to complete Automatic arrhythmia analysis function.

ECG WAVEFORM SETUP

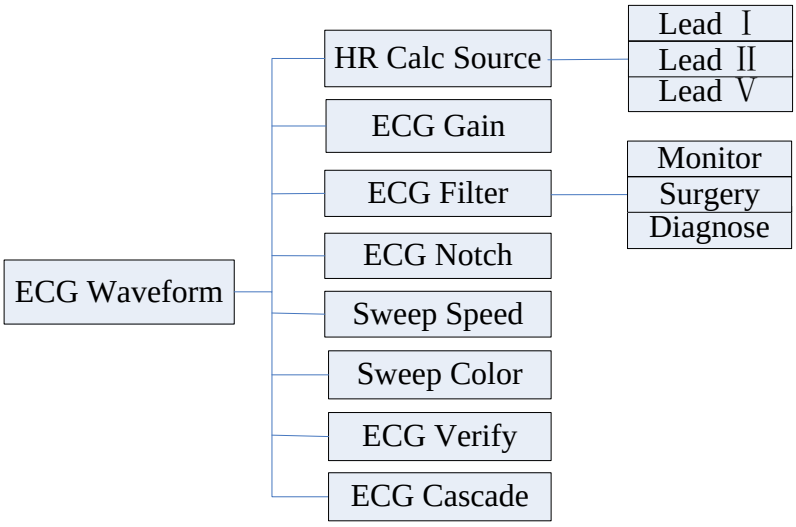


Figure 9: Tree Diagram for ECG Waveform Setup Menu

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.

ECG GAIN
The user can freely choose one from items of X0.25, X0.5, X 1.0, and X 2.0. Gain adjustment can change the value of ECG waveform and ECG STAFF, and the factory-set is X 1.0.

ECG FILTER
Freely select three different modes which are Surgery, Monitor or Diagnose. The factory-set is Monitor.

ECG NOTCH
It provides 50Hz or 60Hz which can be chosen. The factory-set is 60Hz

SWEEP SPEED
From 12.5mm/s, 25mm/s, 50mm/s *and 100mm/s* for choice, the factory-set is 25mm/s.

SWEEP COLOR
From White, Gray, Red, Yellow, Green, Cyan, Blue, and Magenta for choice, the default-set is Green.

ECG CASCADE
ON or OFF, if choose on, it will display a waveform at two channels.

ERROR MESSAGES OF ECG MONITORING

Sometimes messages will display above the ECG waveform：

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

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℃(167F) and higher temperature. If there is dirt on the material surface, you can use the abluent which will not leave remainder to clean. Any metal grinding medium, like floss, is forbidden. The storing temperature should be -20℃ to 75℃(-68F to 167F). Hang or place them flat so as not to be damaged.

ADDING POINTS

1. HR calculating stability has a process. ECG lead switching sometimes affects HR which will stabilize after a while. The change of gain and filter may influence the HR calculating stability too. Another factor which affects HR calculation is the QRS waveform. If T wave is too high, HR will be incorrect too. Arrhythmia sometimes influences HR calculation as well.
2. Choosing suitable ECG waveform range and complete QRS waveform has an important effect in the accuracy of HR calculation.

RESP MONITORING

RESP ELECTRODE INSTALLATION
RESP SETUP
MAINTENANCE AND CLEANING

RESP ELECTRODE INSTALLATION

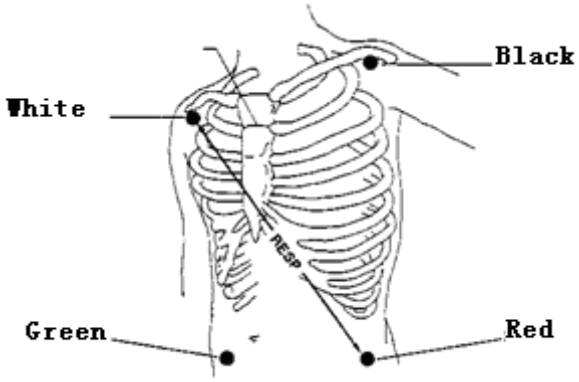
The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

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 the 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 follows:



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

RESP PARAMETER SETUP

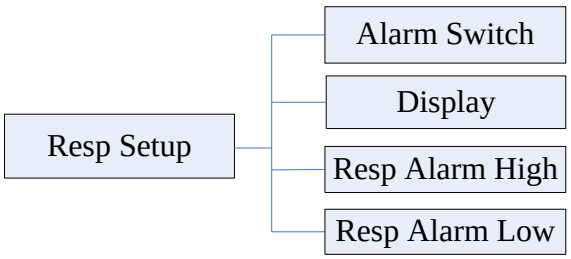


Figure 10: Tree Diagram for Resp Setup Menu

ALARM SWITCH
ON and **OFF** are the options, the default is **ON**.

DISPLAY PARAMETER
ON and **OFF** are the options**.** selecting **ON** can display RESP rate, selecting **OFF** would not display the RESP, but this does not influence 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 default is **12.5mm/s**.

RESP ALARM HIGHER-LIMIT
The RESP alarm upper-limit, the range is from **8** to **120** bpm， and the default 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 **6** to **100** bpm，and the default is **8** bpm，the single-step adjustable step-length is **1** bpm.

RESP WAVEFORM SETUP

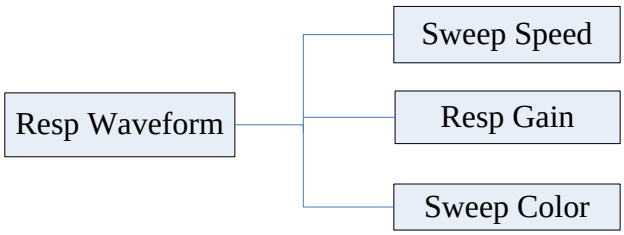


Figure 11: Tree Diagram for Resp Waveform Setup Menu

The menu can finish settings as below:

SWEEP SPEED
Choose from 6.25mm/s,12.5mm/s and 25.0mm/s, and the factory-set is 6.25mm/s.

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.

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

MAINTENANCE AND CLEANING

It is the same as the ECG monitoring.

SPO2 MONITORING

SPO2 MONITORING PRINCIPLE

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through the patients tissue (such as a finger or an ear), to a receiver on the other side.

The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.

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

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

SPO2 SENSOR INSTALLLATION

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

SPO2 PARAMETER SETUP

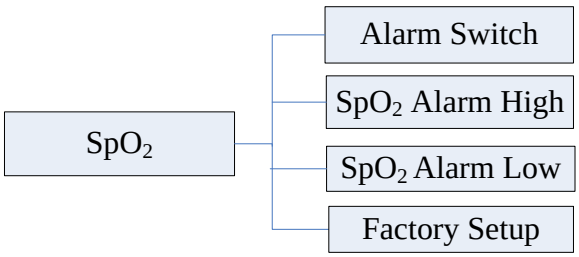


Figure 12: Tree Diagram for SPO2 Setup Menu

ALARM SWITCH
ON and **OFF** are the options, the default is **ON**.

SPO2 ALARM UPPER-LIMIT
The SPO2 alarm upper-limit, the range is from **50** to **100**%，and the default is **100%**，the single-step adjustable step-length is **1** %.

SPO2 ALARM LOWER-LIMIT
The SPO2 alarm lower-limit, the range is from **50** to **100**%， and the default is **85%**， the single-step adjustable step-length is **1**%.

SPO2 PARAMETER SETUP

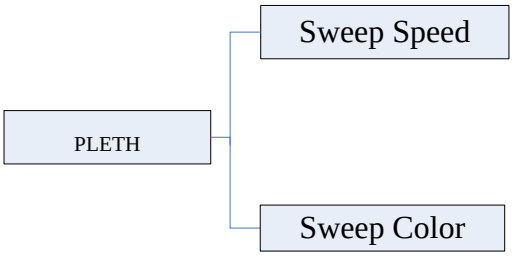


Figure 13: Tree diagram for SPO2 setup menu

SWEEP SPEED
Choose from **12.5mm/s** to **25.0mm/s**, and the default is **12.5mm/s**.

SWEEP COLOR
From White, Gray, Red, Yellow, Green, Cyan, Blue, and Magenta for choice, the default-set is Red.

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 the conditions below:
   - □ Shock
   - □ Hypothermia
   - □ Vasoactive medicines are applied
   - □ Anemia

2. The measurements are also decided by how the oxyhemoglobin and reduced-hemoglobin absorb the light of the special wave-length. If there are other materials that can absorb the same wave-length of light, they can cause the measurement to be false or lower than the actual value of SPO2. For example:
   - □ Carboxyhemoglobin
   - □ Methemoglobin
   - □ Methylene blue
   - □ Carmine indigo
3. Strong light in the environment also can influence measurements. Some suitable light-tight material to cover the sensor can improve the measure quality.

WARNING:

- □ Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important for neonate and patients of poor perfusion or immature dermogram to check the sensor placement by light collimation and properly attaching according to changes of the skin. Check sensor placement regularly 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:

Table 5: SPO2 Error Messages

PROMPTS	EXPLAINATION
Search Too Long	Search-time of SPO2 is too long
Searching For Pulse. . .	On searching for pulse signal
Sensor Off	Sensor falls off or the finger fails to insert into the finger-probe
SpO_2 Com Error	SPO2 board has communication error with the mainboard

NIBP MONITORING

SUMMARY ON NIBP MONITORING

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

WARNING:

- □ You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.
- □ For a thrombasthenia patient, it is important to determine whether measurement of the blood pressure shall be done automatically. The determination should be based on the clinical evaluation.
- □ Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult, pediatric, or neonate.) Ensure that the correct setting is selected when performing measurements on neonate since 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. Choosing a suitable cuff to match the arm of patient greatly influences the accuracy of NIBP measurement. The cuff width recommend by the **AMERICA HEART SOCIETY** is 40% of upper arm circumference or 2% of the upper arm length.
2. Apply the blood pressure cuff to the patient's arm:

□ Make sure that the cuff is completely deflated.

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

3. Make sure that the cuff has not been twisted.。
4. Insert the air pipe into the **NIBP** socket on the left panel of monitor. Ensure that the spring block on the left side of socket has been pressed when inserting or unplugging the pipe. Otherwise, the 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 is operating well and you may begin NIBP monitoring. If there is an NIBP MODULE SELF-CHECK ERROR, it shows that the NIBP module cannot be performed. Click **START/STOP** to give another time of self-checking or machine-opening. If you still get the error, contact your servicing engineer.

NIBP SETUP

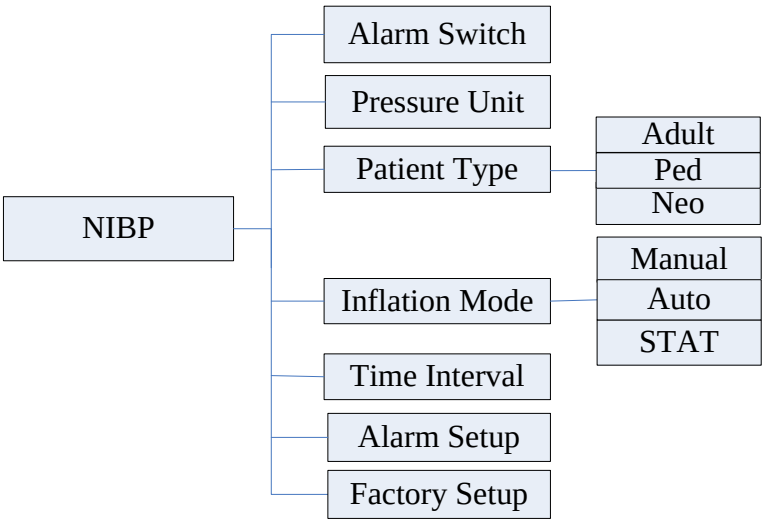


Figure 14: Tree Diagram for NIBP Setup Menu

ALARM SWITCH
ON and **OFF** are the options, the default is **ON**.

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

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

The default is **ADULT TYPE.**

If the inflating range shown above has been realized on NIBP, use this inflation range to ensure the safety of patient.

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

MANUAL MODE:
Click **START/STOP** to begin inflation, the information indicating area display "MANUAL MEASURING… " which shows that it is measuring.
If the NIBP value been measured, the NIBP parameter area will display it and the information indicating area will give a note of "MANUAL MEASURING END!", indicating that the measurement process is finished.
If the NIBP value cannot be measured, the NIBP parameter area will display error messages and automatically begin three times of remeasurement. If the value still cannot be measured, the information indicating area will give a note of "RETRY OVER！" and will not measure again.
During the measurement, clicking **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. The machine will automatically repeat the inflating measurement until the mode is changed.
If the NIBP value has been measured, the NIBP parameter area will display it and the information indicating area will give a note of "AUTO MEASURING END！", which shows the measurement process is finished and automatically begins another measurement until the mode is changed.
If the NIBP value cannot be measured, the NIBP parameter area will display error messages and will automatically begin three followup attemepts. If it still cannot measure the value, the information indicating area will give a note of "RETRY OVER！" and automatically go on to the next measurement until the mode is changed.
If you click **START/STOP** during any period of the countdown, it will immediately begin the inflation measurement.
During the measurement, clicking **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 will continue.

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 **START/STOP** to begin inflation, the information indicating area will display "STAT MEASURING..." which shows that it is measuring. If the NIBP value been measured, the 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 followup attempts. If the value still cannot be measured, the information indicating area will give a note of "RETRY OVER!", and then do one more 5-minute measurement before stopping.
During the measurement, if you click **START/STOP** again, the information indicating area will give a note of "STOP STAT MEASURING" to stop the NIBP measurement and exit from this mode.

NOTE:
- □ Values will display on the NIBP parameter area for 240 minutes unless a new measurement begins 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 are the options. This setting is supported by **automatic** inflation mode, and the default is **2** minutes.

ALARM SETUP

Limits / *Patient Type*	***SYS UPPER LIMIT(mmHg)***	***SYS LOWER LIMIT(mmHg)***	***DIA UPPER LIMIT(mmHg)***	***DIA LOWER LIMIT(mmHg)***
ADULT	*30~240 Factory-set:150*	*30~240 Factory-set:100*	*15~180 Factory-set:90*	*15~180 Factory-set:50*
NEO	*30~240 Factory-set:90*	*30~240 Factory-set:40*	*15~180 Factory-set:60*	*15~180 Factory-set:20*
PED	*30~240 Factory-set:120*	*30~240 Factory-set:70*	*15~180 Factory-set:70*	*15~180 Factory-set:40*

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

FACTORY SETUP
Servicing engineer uses 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 making it take 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：

Table 6: NIBP Error Messages

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

MAINTAINENCE AND CLEANING

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

REUSABLE BLOOD PRESSURE CUFF

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

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

TEMP MONITORING

THEORY OF OPERATION
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

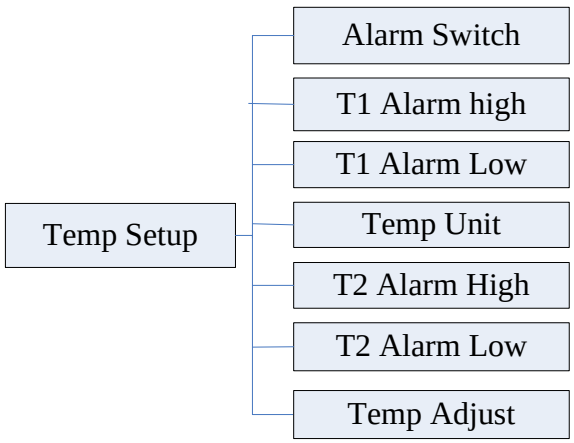


Figure 15: Tree Diagram for Temp Setup Menu

ALARM SWITCH
ON and **OFF** are the options, the default is **ON**.

T ALARM UPPER-LIMIT
The T1 or T2 alarm upper-limit, the range is from **10** to **50℃**，and the default is **38.0℃**, the single-step adjustable step-length is **0.1℃**.

T ALARM LOWER-LIMIT
The T1 or T2 alarm lower-limit, the range is from **10** to **50℃**， and the default is **36℃**，the single-step adjustable step-length is **0.1℃**.

TEMP UNIT
FAHRENHEIT or **CELSIUS** are the options, the default is **CELSIUS**.

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℃(212^{o}F). It should only be subjected briefly to temperatures between 80℃(176^{o}F) and 100℃(212^{o}F).
2. The probe must not be sterilized in steam.
3. To clean the probe use 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, Not Cleared for US Sales)

THEORY OF OPERATION

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

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

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

WARNING

- DO NOT position the sensor cables or tubing in any manner that may cause entanglement or strangulation. Support the carbon dioxide monitoring system airway adapter to prevent stress on the ET tube.
- 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 CO_2 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 CO_2 measurement.

ABBREVIATIONS AND TERMINOLOGY

$EtCO_2$	End tidal carbon dioxide
INSP CO_2	Inspired minimum CO_2
AWRR	Air-way respiration rate
BARO	Barometric Pressure

ZEROING THE CO2 MODULE

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

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

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

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

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 CO_2 module into the bracket of the rear panel of the monitor.

b. Check that monitor is switched off，Insert the plug of CO_2 sensor into the corresponding sensor socket marked with **$EtCO_2$** icon on the left panel of monitor.

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

2. CONNECTING THE SAMPLE KIT

a. The sample cell of the sampling kit must be inserted into the sample cell receptacle of the CO_2 Module as shown in following figure. A "click" will be heard when the sample cell is properly inserted.

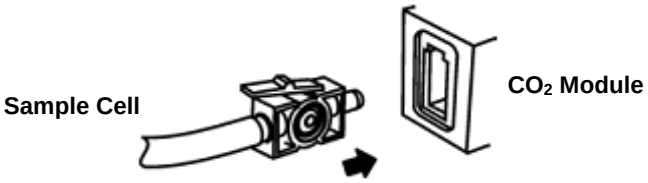


Figure 16: Connecting Diagram for Sample Kit

b. Connect the CO_2 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.

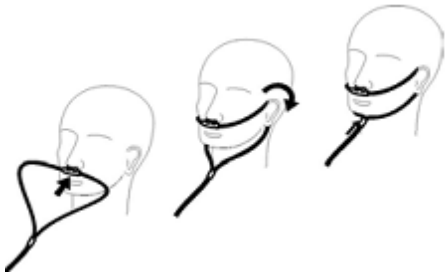


Figure 17: Placing Method for the Nasal Cannula Kits

5. Some patients are prone to mouth breathing. The Oral/Nasal sampling cannula should be used on these patients, as most, if not all of the CO_2 is exhaled through the mouth. If a standard nasal CO_2 sampling cannula is used with these patients, the $EtCO_2$ number and capnogram will be substantially lower than actual.
6. When using the Nasal or Oral/Nasal CO_2 sampling kits with oxygen delivery, place the cannula on the patient as shown in Figure 14 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.

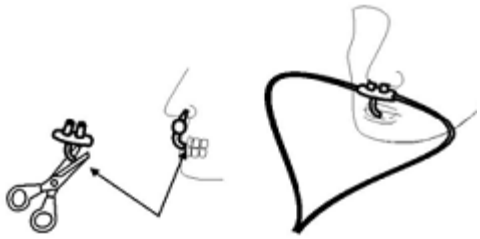


Figure 18: Placing Method for Oral Sampling Tip

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

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

ETCO2 WAVEFORM SETUP

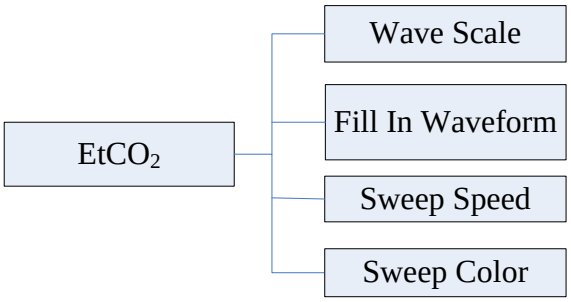


Figure 19: Tree Diagram for ETCO2 Waveform Setup Menu

WAVE 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.

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

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

ETCO2 PARAMETER SETUP

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

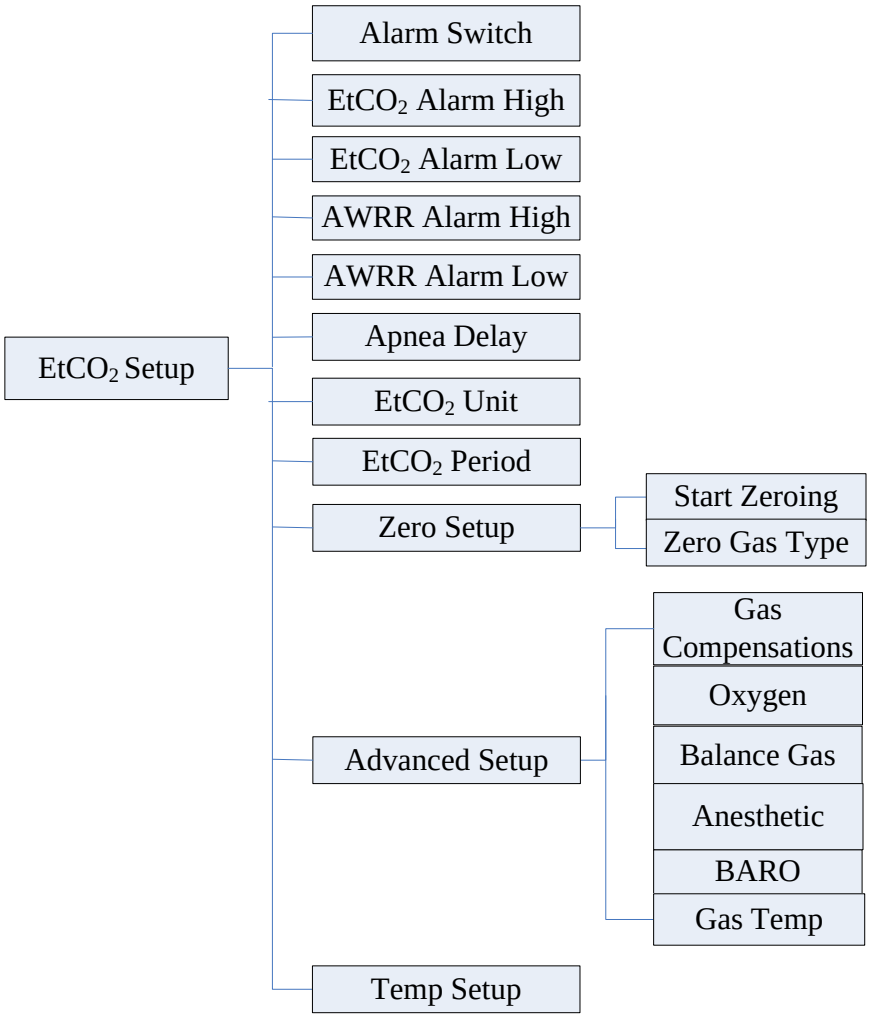


Figure 20: Tree Diagram for ETCO2 Setup Menu

ALARM SWITCH

ON and **OFF** are the options, the default is **ON**.

ETCO2 ALARM HIGH

The range is from **20** to **100 mmHg**，and the default is **60mmHg**.

ETCO2 ALARM LOW

The range is from **10** to **95 mmHg**，and the default is **15mmHg**.

AWRR ALARM HIGH

The range is from **10** to **150 mmHg**，and the default is **30mmHg.**

AWRR ALARM LOW

The range is from **5** to **100 mmHg**，and the default is **5mmHg**. The single-step adjustable length of alarm limit above is **5mmHg**.

ASPHYXIA DELAY

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

The setting range is from **10** to **60 seconds**，and the default is **10 seconds**.

ETCO2 UNIT

mmHg, kPa or **percent (%)**，the default is **mmHg**.

ETCO2 PERIOD
This setting is used to set the calculation period of the $EtCO_2$ value. The end-tidal CO_2 value is the highest peak CO_2 value of all end of expirations (end of breaths) over the selected time period. If less than two breaths exist in the selected time period, the value will be the maximum $EtCO_2$ value for the last two breathes.
This setting has 1 breath, 10 seconds and 20 seconds are the options, the default is **1 breath**.

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

Zero steps refer to "Zeroing the CO_2 Module" section detailed.
In above menu, complete the zero procedure by clicking the button **"start zeroing "**. During zeroing, a message of "$EtCO_2$ Zero Started" will be display on the message area.

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

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

ADVANCED SETUP

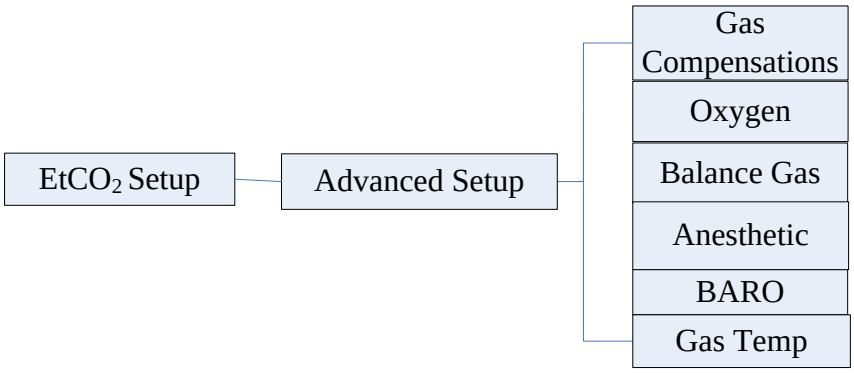


Figure 21: Tree Diagram for ETCO2 Advanced Setup

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.

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.

BAROMETRIC PRESSURE
This setting is used to set current Barometric Pressure.
The setting range is from 400 to 850 mmHg. The factory –set is 760 mmHg.

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

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

Table 7: Staus/Error Messages for ETCO2

Messages	Descriptions
Sensor Off	The CO_2 sensor is not connected
Sensor Warm Up	One of the following conditions exist: Sensor under temperature Temperature not stable Source Current unstable
Sensor Over Temp	Make sure sensor is not exposed to extreme heat (heat lamp, etc.). If error persists, return sensor to factory for servicing.
Sensor error	Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing.
Sensor Zeroing. . .	A zero is currently in progress.
Zero Required	To clear, check airway adapter and clean if necessary. If this does not correct the error, perform an adapter zero. If you must adapter zero more than once, a possible hardware error may exist.
Check Sampling Line	To clear, clean if sampling line mucus or moisture is seen. If the

	sampling line is clean, perform a zero.
CO_2 Out of Range	The value being calculated is greater than the upper CO2 limit (150 mmHg, 20.0 kPa, or 19.7 %). The maximum value output is the upper CO_2.
Check Airway Adapter	To clear, clean airway adapter if mucus or moisture is seen. If the adapter is clean, perform a zero.
Pump Life Exceed	The manufacturer stated pump life has been exceeded. Service may be required if Pneumatic System Error is present and can no longer be cleared.
Sensor Setup. . .	The CO_2 sensor is setting process.
$EtCO_2$ Zero Error: Sensor Not Ready.	The CO_2 sensor is not ready for a $EtCO_2$ Zero
$EtCO_2$ Zero Error: Breath Detected.	Breaths have been detected by the CO_2 module within the last 20 seconds while a CO_2 module zero was attempted.

MAINTENANCE AND CLEANING

SCHEDULE

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

CLEANING

Cleaning the CO2 Module case, Cable and connector:

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

NOTE：Do not immerse or sterilize the CO_2 Module.

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

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

IBP MONITORING(OPTION)

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 mean 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.

INTRODUCTION

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 lable.
6. Zero the transducer.

KIT SET UP

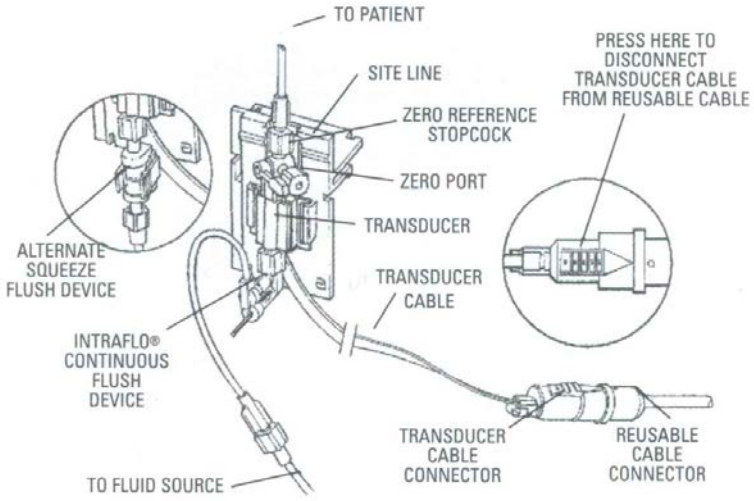


Figure 22: Diagram for ETCO2 Transducer Setup

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

PATIENT MOUNT

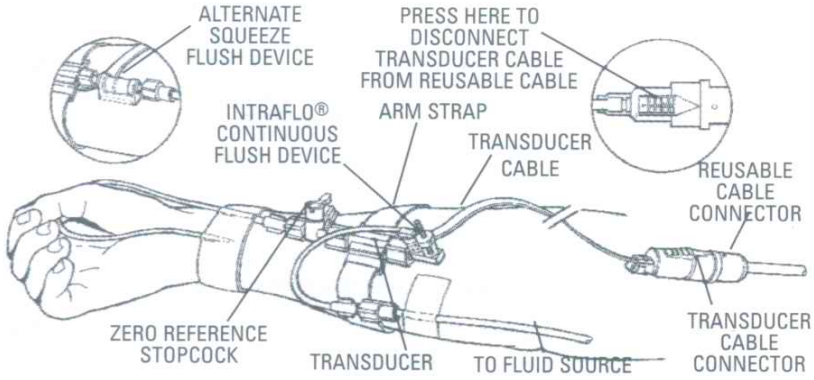


Figure 23: Patient Mount for ETCO2 Transducer

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:

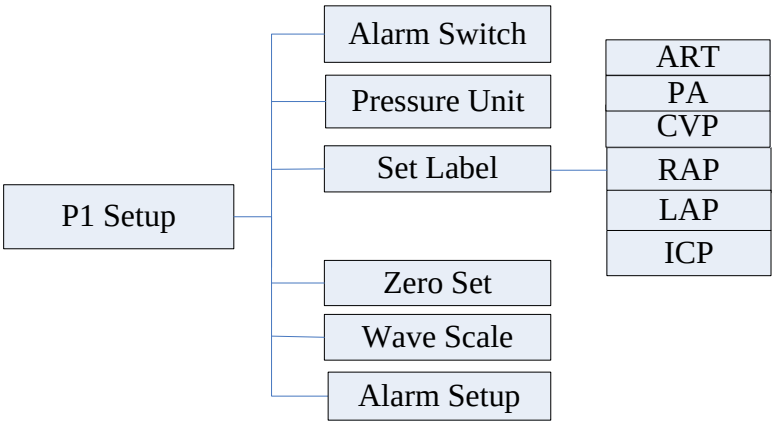


Figure 24: Tree Diagram for IBP Setup Menu

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

PRESSURE UNIT
mmHg and KPa for choice, the factory-set is mmHg.

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

SET LABEL
ART, PA, CVP, RAP, LAP and ICP are selectable. *The factory-set is ART.*

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 stopcock "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 stopcock should be at or near the right atrial (mid-axillary) level.
2. Click "zero set" in IBP setup menu to call up the zero 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.

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.

3. Turn zero reference stopcock "off" to the side port. Replace non-vented yellow cap.

WAVEFORM SCALE

Click "waveform scale" to call up this menu.

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.

Table 8: Limits for Waveform Scale for IBP

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

ALARM SETUP

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

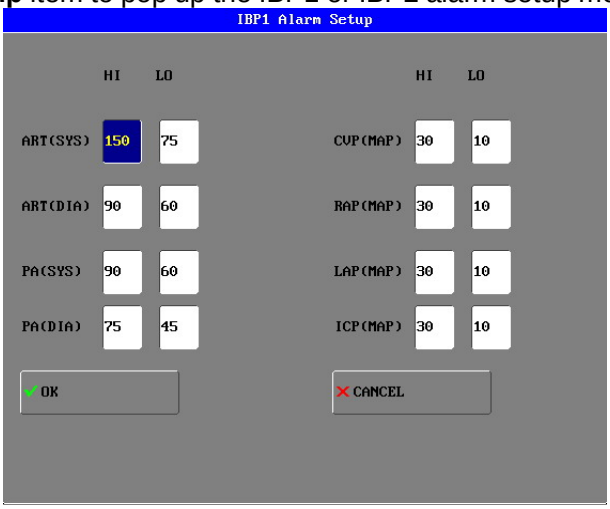


Figure 25: Window for IBP1 or IBP2 Alarm Setup

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.

IBP WAVEFORM SETUP

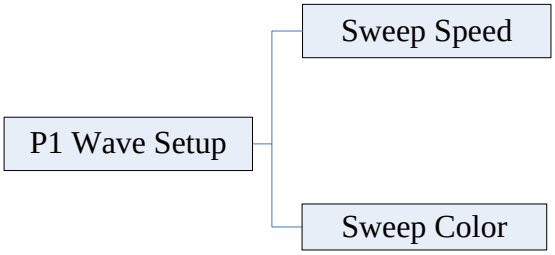


Figure 26: Tree Diagram for IBP Waveform Setup Menu

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

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

PROMPT MESSAGE

Table 9: Prompt Message for IBP Measure

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

MAINTAINENCE AND CLEANING

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

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

ANESTHETIC AGENT MONITORING（OPTION, PHASEIN）

PHASEIN IRMA™ MAINSTREAM PROBE

- *INTRODUCTION*
- *SAFETY*
- *SYSTEM ASSEMBLY INSTRUCTION*
- *ZEROING PROCEDURE*
- *ALARMS*
- *CLEANING*
- *MAINTENANCE*

PHASEIN ISA™ SIDESTREAM ANALYZER

- *INTRODUCTION*
- *SAFETY*
- *SYSTEM SETUP*
- *PRE-USE CHECK*
- *CONSUMABLE*
- *AUTOMATIC ZEROING*
- *ALARMS*
- *CLEANING*
- *MAINTENANCE*

- *MAC CALCULATION*
- *SYMBOLS*
- *ADVERSE EFFECTS ON PERFORMANCE*
- *ANESTHETIC AGENT PARAMETER AND DISPLAY*
- *ANESTHETIC AGENT PARAMETER SETUP*

PHASEIN IRMA™ MAINSTREAM PROBE

INTRODUCTION

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, a barometric pressure sensor, a power regulator, a CPU and a RS-232 digital interface. The unit weighs less than 25 g

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.

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, 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 WARNINGS

- 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 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.
- 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,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.

CAUTIONS

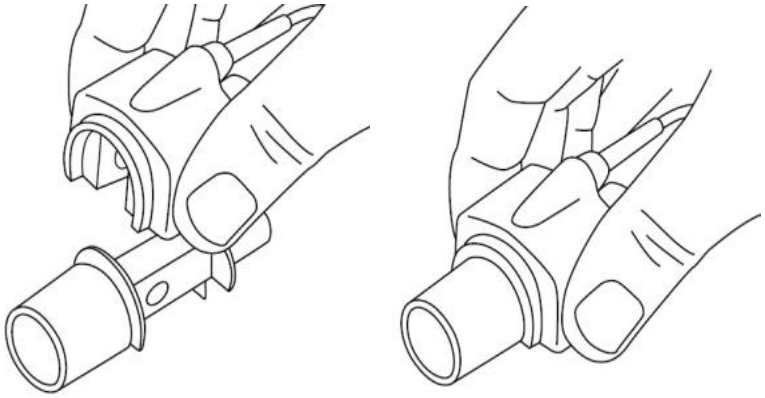
- Never sterilize or immerse the IRMA probe in liquid.
- Do not autoclave the devices as this will damage them.
- Do not apply tension to the sensor cable.
- Do not operate the device outside the temperature environment
- (U.S.): Federal law restricts this device to sale by or on the order of a physician.

SYSTEM ASSEMBLY INSTRUCTION

Set-up

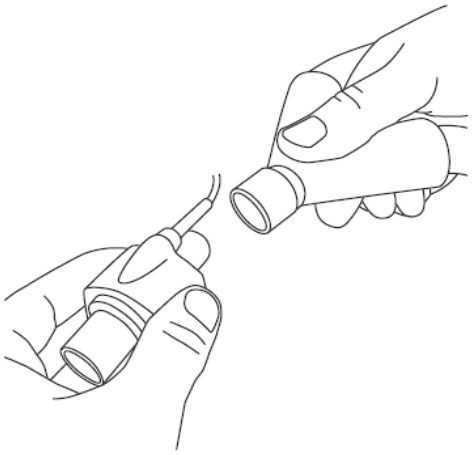
1. Plug the IRMA connector into the IRMA input of OMNI (K) and switch the power on.

2. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.

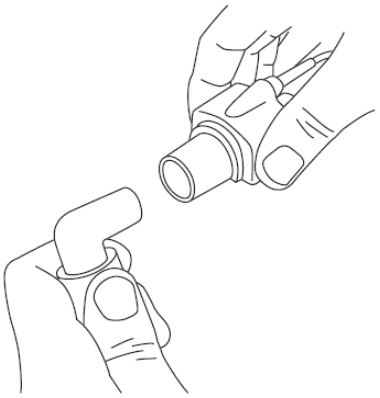


3. A green LED indicates that the IRMA probe is ready for use.

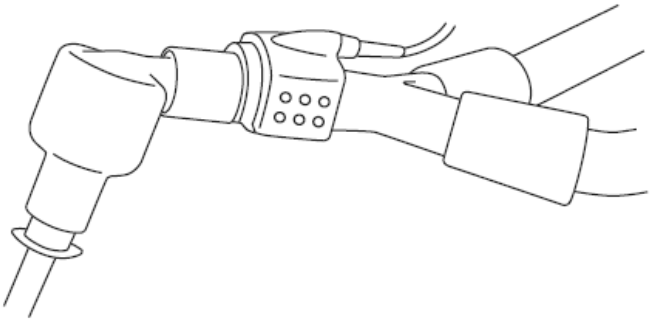
4. Connect IRMA/airway adapter 15 mm male connector to the breathing circuit Y-piece.



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 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 OMNI (K) 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. 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 AX+ 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+ 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.

Zero by using monitor
After install the PHASEIN gas module, and Click the Anesthetic Agent Waveform and Parameter Area to pop up the menu of Multi-Gas Setup→Advanced setup→ manual zero, OMNI (K) will conduct a zero procedure and "zero in progress" message will be displayed.

ALARMS

Gas Alarm limit in %:

Gas type	HIGH	LOW
FIAGT	5	0
ETAGT	5	0
FICO2	0.5	0
ETCO2	8	2
FIN2O	100	0
FIO2	100	18
ETO2	100	5

Status LED on 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: 2) Valid for IRMA AX+ 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: Never sterilize or immerse the IRMA probe in liquid.

MAINTENANCE

Gas readings should be verified at regular intervals with a reference instrument or with calibration gas. The recommended interval is once every year.

PHASEIN ISA™ SIDESTREAM ANALYZER

INTRODUCTION

The ISA product family consists of three types of sidestream gas analyzers (ISA CO2, ISA AX+ and ISA OR+), which are intended to be connected to OMNI (K) for monitoring of breath rate and the following breathing gases:
ISA CO2: CO2
ISA AX+: CO2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane
ISA OR+: CO2, O2, N2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane
ISA CO2, ISA AX+ and ISA OR+ are intended to be connected to a patient breathing circuit for the monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. ISA CO2 is also intended to be used in road ambulances. The intended patient population is adult, pediatric and infant patients.

Note 1: An ISA sidestream gas analyzer should never be used as the only means of monitoring a patient.
Note 2: An ISA sidestream gas analyzer shall only be connected to medical devices approved by PHASEIN.

Patents
PHASEIN AB holds the following patents regarding products described in this manual: SE519766; SE519779; SE523461; SE524086. Other patents pending.
Trademarks
PHASEIN IRMA™, PHASEIN ISA™, PHASEIN XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, PHASEIN Gas Master™ and PHASEIN Gas Master™ are trademarks of PHASEIN AB.

SAFETY

Classification:

- According to the degree of safety of application in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE:

  The ISA is not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE.

- According to the degree of protection against harmful ingress of water:IPX4

- According to sterility:The ISA system contains no sterile parts.

- According to the model of operation:CONTINUOUS OPERATION

- According to the degree of protection against electric shock:
  Nomoline Family sample lines are classified as DEFIBRILLATION PROOF TYPE BF APPLIED PART
- The combination of OMNI (K) and ISA shall be considered a ME SYSTEM.

Warnings:

- The ISA sidestream gas analyzer is intended for use by authorized and trained medical personnel only.
- Use only Nomoline sampling lines manufactured by PHASEIN.
- The ISA sidestream gas analyzer must not be used with flammable anesthetic agents.
- Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
- Do not re-use disposable sampling lines.
- Do not lift the ISA/OMNI (K) by the sampling line as it could disconnect from the ISA/ OMNI (K) >, causing the ISA/ OMNI (K) to fall on the patient.
- Used disposable sampling lines shall be disposed of in accordance with local regulations for medical waste.
- Do not use adult/pediatric type sampling line configurations with infants, as this may add dead space to the patient circuit.
- Do not use infant type sampling line configurations with adults, as this may cause excessive flow resistance.
- Do not use the ISA sidestream gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Check that the gas sample flow is not too high for the present patient category.
- Since a successful zeroing requires the presence of ambient air (21% O2 and 0% CO2) in the gas analyzer, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.
- The Nomoline sampling line and its interfaces are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid.
- Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.
- ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It

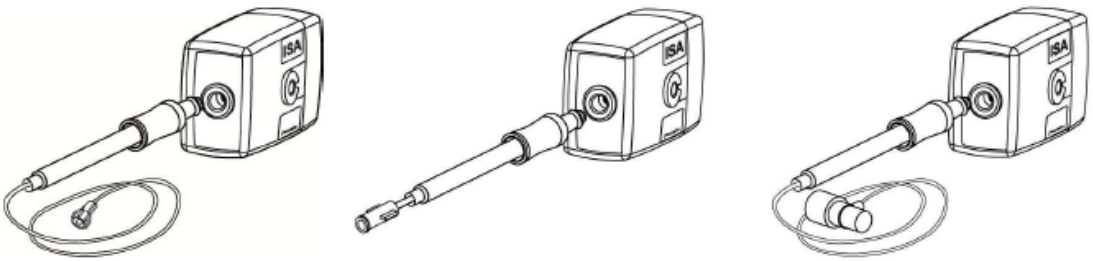
must be used in conjunction with other assessments of clinical signs and symptoms.
- Replace the sampling line if the sampling line input connector starts flashing red, or a Nomoline occlusion message is displayed on the OMNI (K).
- No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- ISA sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, the OMNI (K) must be placed outside the MRI suite.
- Use of high frequency electrosurgical equipment in the vicinity of the ISA/OMNI (K) may produce interference and cause incorrect measurements.
- Do not use external ambient cooling of the ISA device.
- Do not apply negative pressure to the Nomoline (i.e. by a syringe) to remove condensed water.
- Too strong positive or negative pressure in the patient circuit might affect the sample flow.
- Strong scavenging suction pressure might affect the sample flow.
- Exhaust gases should be returned to the patient circuit or a scavenging system.
- Always use a bacteria filter on the evac side if sampled gas is intended to be re-breathed.
- Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

Cautions:
- The ISA "plug-in and measure" analyzers should be securely mounted in order to avoid the risk of damage to the ISA.
- Do not apply tension to the ISA sidestream gas analyzer cable.
- Do not operate the ISA sidestream gas analyzer outside the specified operating temperature environment.
- (US Only) Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

ANALYZER SYSTEM SET-UP

1. Securely mount the ISA analyzer.

2. Connect the ISA analyzer interface cable to the OMNI (K).
3. Connect a Nomoline Family sampling line to the ISA analyzer input connector.



4. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit to prevent pollution of the operation room when N2O and/or anesthetic agents are being used.
5. Power up the OMNI (K).
6. A green LED indicates that the ISA analyzer is ready for use.
7. Perform a pre-use check as described in section "Pre Check".

PRE-USE CHECK

Before connecting the Nomoline sampling line to the breathing circuit, do the following:
1. Connect the sampling line to the ISA gas inlet connector (LEGI)
2. Check that the LEGI shows a steady green light (indicating that the system is OK)
3. For ISA AX+ module with O2 option fitted:
   Check that the O2 reading on the monitor is correct (21%).
4. Breathe into the sampling line and check that valid CO2 waveforms and values are displayed on the OMNI (K).
5. Occlude the sampling line with a fingertip and wait for 10 seconds.
6. Check that an occlusion alarm is displayed and that the LEGI shows a flashing red light.
7. If applicable:
   Perform a tightness check of the patient circuit with the sampling line attached.

CONSUMABLE

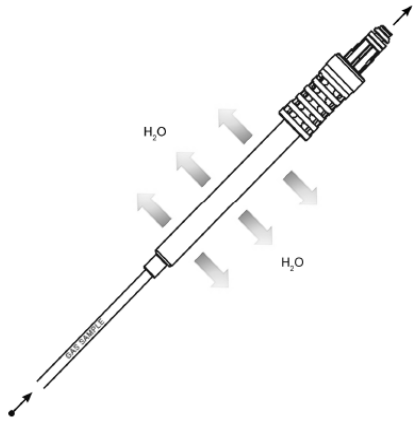
Sampling
A sidestream gas analyzer continuously removes a gas sample flow from the respiratory circuit,for example a nasal cannula, a respiratory mask or the Y-piece of an intubated patient. The gas sample is fed through a sampling line to the gas analyzer. The sampled gas is usually warm and humid, and cools down in contact with the wall of the sampling line. Water therefore condenses in form of droplets on the inner wall of the sampling line. These droplets could potentially occlude the sampling line and interfere with the gas measurement.

The Nomoline Family
To overcome the shortfalls of current gas sampling solutions, the Nomoline Family sampling lines have been developed for the ISA sidestream gas analyzers.

Unlike traditional solutions that remove water vapor and collect water in a container, the Nomoline Family sampling lines incorporates a unique water separation (NO MOisture)

section, which removes condensed water. The NOMO section also has a bacteria filter which protects the gas analyzer form water intrusion and cross contamination.

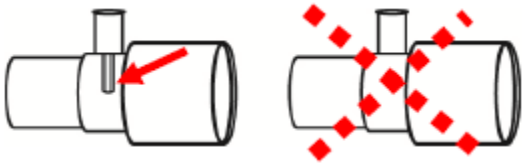
The Nomoline Family sampling lines are specially designed for 50 ml/min low sample flow applications. The Nomoline Family sample lines have a very low dead space that results in an ultra-fast rise time, making measurements of CO2, N2O and anesthetic agents possible even at high respiratory rates. ISA sidestream gas analyzers are therefore suitable for adult, pediatric and infant patients.



The Nomoline Family sampling lines are available in the following versions:

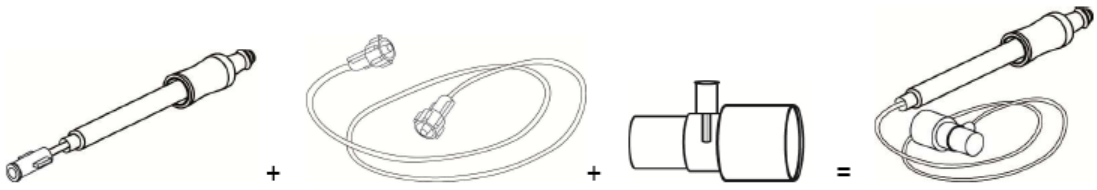
(The Nomoline Family sampling lines; Nomoline with male Luer Lock connector, Nomoline Airway Adapter Set with integrated airway adapter and the Nomoline Adapter with female Luer Lock connector.)

The Nomoline Airway Adapter Set with integrated airway adapter can be used with intubated patients.
The Nomoline with a male Luer Lock type connector is compatible with any normal configuration that uses a female Luer Lock connector. When connecting to a T-adapter, be sure to use a PHASEIN T-adapter that samples the gas from the center of the T-adapter (see below).

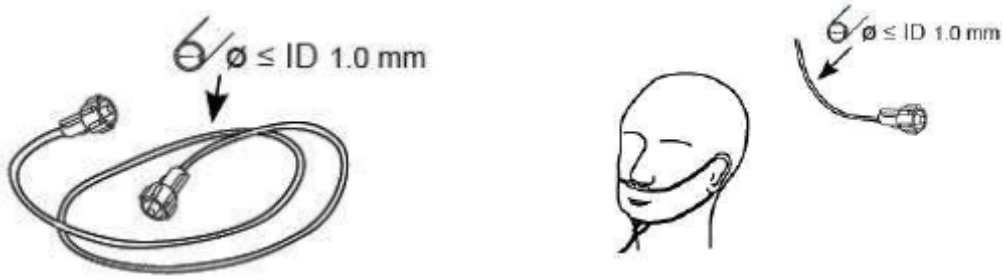


(For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left in the figure above.)

The Nomoline Adapter with female Luer Lock connector connects to a standard male Luer to Luer sample line (Nomo Extension) as well as to different kinds of third-party cannulas for oral and nasal sampling. Combining the Nomoline Adapter with the Nomo Extension and T-adapter results in a similar product as the Nomoline Airway Adapter Set (see below).



(Combining Nomoline Adapter with the Nomo Extension and T-adapter results in a similar product as the Nomoline Airway Adapter Set.)



(If using third-party sample tubes or cannuals, make sure that the inner diameter does not exceed 1 mm since this will increase the ISA's total system response time.)

Note: Using sample tubes or cannuals with larger inner diameter than 1 mm will increase ISA's total system response time.

Warning: Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

Warning: Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.

Warning: Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.

Warning: Use only airway T-adapters with the sampling point in the center of the adapter.

Warning: Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.

Warning: Do not sterilize or immerse Nomoline Family sampling lines in liquid.

Warning: Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.

Warning: Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.

Replacement of Nomoline and Nomoline Airway Adapter Set

The Nomoline and Nomoline Airway Adapter Set are single-patient use products.
They should be replaced according to good clinical practice or when an occlusion message appears. Occlusion occurs when the sample flow is too low. This is indicated by

a flashing red LEGI together with a message on OMNI (K).

Replacement of Nomoline Adapter

The Nomoline Adapter is a multiple-patient use product.
The Nomoline Adapter should be replaced according to good clinical practice or when an occlusion message appears. Occlusion occurs when the sample flow is too low. This is indicated by a flashing red LEGI together with a message on OMNI (K).

Replacement of T-adapter and Nomo Extension

The T-adapter and Nomo Extension are single-patient use products.
They should be replaced according to good clinical practice or when an occlusion messageappears. Occlusion occurs when the sample flow is too low. This is indicated by a flashing red LEGI together with a message on OMNI (K).

ALARMS

Gas Alarm limit in %:

Gas type	HIGH	LOW
FIAGT	5	0
ETAGT	5	0
FICO2	0.5	0
ETCO2	8	2
FIN2O	100	0
FIO2	100	18
ETO2	100	5

Status indicated by ISA LEGI:

Indication	**Status**
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check sampling line

AUTOMATIC ZEROING

The infrared gas analyzer needs to establish a zero reference level for the CO2, N2O and anesthetic agent gas measurement. This zero calibration is here referred to as "zeroing".
ISA sidestream gas analyzers perform zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds for ISA CO2 gas analyzers and less than 10 seconds for ISA multigas analyzers.

If the ISA sidestream gas analyzer is fitted with an oxygen sensor, the automatic zeroing will also include room air calibration of the oxygen sensor.

Warning: Since a successful zeroing requires the presence of ambient air (21% O2 and 0%CO2) in the gas analyzer, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

CLEANING

The "plug-in and measure" ISA sidestream gas analyzers should be cleaned on a regular basis.
Use a cloth moistened with max 70% ethanol or isopropyl alcohol to clean the analyzer.
To prevent cleaning liquids and dust from entering the ISA gas analyzer through its LEGI connector, keep the Nomoline sampling line connected while cleaning the analyzer.
Warning: The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.
Warning: Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

MAINTENANCE

Once every year, or whenever gas readings are questionable, perform a leakage check as below and verify gas readings with a reference instrument or with calibration gas.
Calibration gas can be ordered from PHASEIN AB (www.phasein.com).

■ Leakage check

1. Connect a new Nomoline sampling line with male luer lock to the ISA LEGI and check that the LEGI shows a steady green light.
2. Connect a short silicon tubing with an inner diameter of 3/32" (2.4 mm) to the Nomoline male luer.
3. Exhale a long breath into the silicon tubing until the CO2 concentration is greater than 4.5 vol% or 34 mmHg.
4. Quickly connect the silicon tubing tightly to the exhaust port.
5. Wait 1 minute until the CO2 concentration has stabilized. Note the value.
6. Wait 1 minute and check that the CO2 concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

MAC (MINIMUM ALVEOLAR CONCENTRATION) CALCULATION

Minimum alveolar concentration (MAC) is a standard for comparing the potency of inhalation anesthetics. 1 MAC represents the end-tidal concentration of an agent (at sea level) that, in 50 percent of a tested population, prevents gross muscular movement in response to a painful, standardized stimulus.
The MAC value may be calculated and displayed by using end-tidal (Et) gas concentrations according to the following formula:

$$MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N2O)}{100}$$

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

Note: Altitude, patient age and other individual factors are not considered in the formula above.

SYMBOLS

Symbol	Title	Explanation
	Instructions for use	Consult instructions for use
	Catalog number	
	Serial number	
	Batch code	
	Year of manufacture	
	Use by date [YYYY-MM-DD]	The device should not be taken into operation after the date accompanying the symbol.
	Temperature limitation	
	Pressure limitation	
	Humidity limitation	
	Do not re-use	Nomoline and Nomoline Airway Adapter Set are intended for single patient use
	Biohazardous waste	Nomoline Family sampling lines shall be disposed as biohazardous waste
	For EU only: Waste Electrical and Electronic Equipment (WEEE)	For EU only: Electrical and electric equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)

Symbol	Title	Explanation
	ETL Listing Mark	Conforms to ANSI/AAMI 60601-1:2005 Cert. to CAN/CSA-C22.2 No.60601.1:2008.
	Conformité Européenne	Complies with 93/42/EEC Medical Device Directive when connected to medical devices approved by PHASEIN AB.
	IP classification indicating level of water protection	"Splash-proof"
	Rx only	(US Only) Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	CO_2	ISA equipped to measure CO_2 only
	Multigas (AX+ or OR+)	ISA equipped to measure multiple gases
	Sigma Multigas Technology	The product is fitted with PHASEIN Sigma Multigas Technology
	Gas Inlet	See sections 7.1 (build-in module) or 7.2 ("plug-in and measure" analyzer)
	Gas Outlet	See sections 7.1 (build-in module) or 7.2 ("plug-in and measure" analyzer)
	Defibrillation-proof type BF applied part	The applied part of ISA is the Nomoline Family sampling line

ADVERSE EFFECTS ON PERFORMANCE

Effects of humidity

The partial pressure and the volume percentage of CO2, N2O, O2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure. 20.8 vol% O2 corresponds to the actual O2 concentration in room air with 0.7 vol% H2O concentration (at 1013 hPa this equals for example 25°C and 23% RH).

The measurement of CO2, N2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.
In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).
When the breathing gas flows through the sampling line, the gas temperature will adapt to ambient before reaching the gas analyzer. As the NOMO section removes all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.
If CO2 values at BTPS are required, the following equation can be used:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

where:
EtCO2 = EtCO2 value sent from ISA [vol %]
Pamb = Ambient pressure sent from ISA [kPa]
3.8 = Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]
EtCO2(BTPS) = EtCO2 gas concentration at BTPS [vol%]
O2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H2O.

ANESTHETIC AGENT PARAMETER AND DISPLAY

Calling up the display menu

Click the white box to the parameter area of GAS, see graph below:

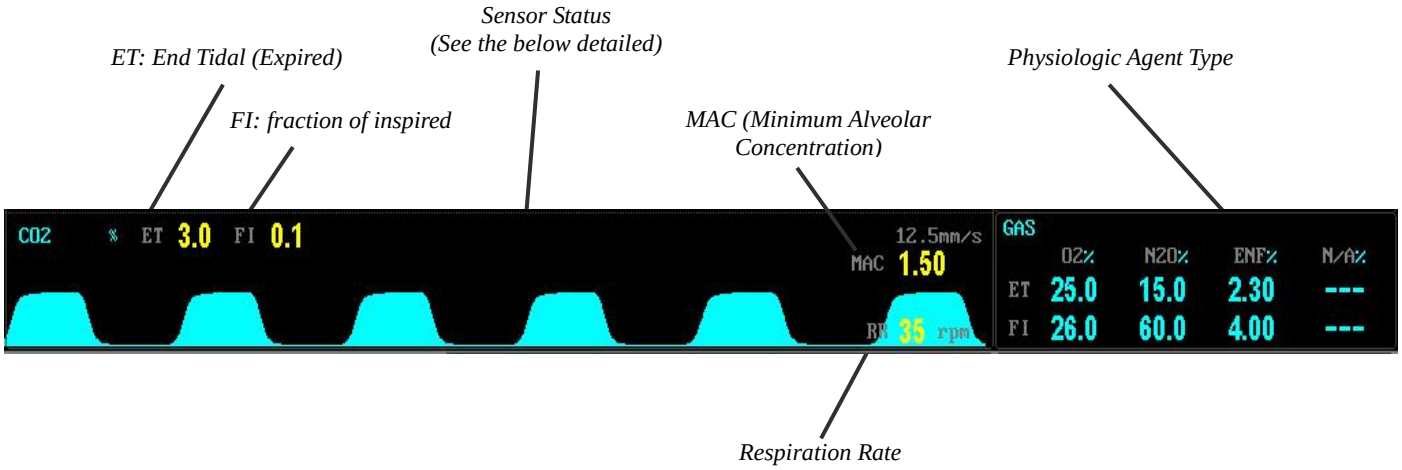


Figure 27: Display Graph for Multi-Gas

Sensor Status:

- Sensor Off
- Check Sample Line
- Sensor error
- Zero in Progress
- Unspecified accuracy

Physiologic Agent Status：

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

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

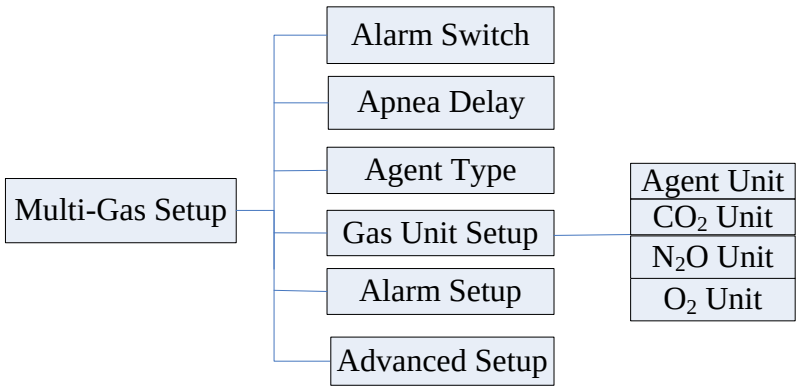


Figure 28: Tree Diagram for Multi-Gas Setup Menu

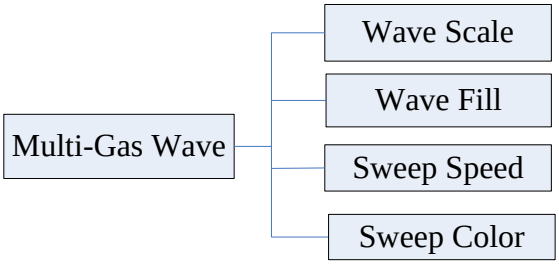


Figure 29: Tree Diagram for Multi-Gas Wave Menu

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

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 $EtCO_2$ 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 CO_2 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

	High	**LOW**
FI Agt	0.0-20.0 factory-set：5.0(%)	0.0-20.0 factory-set：0.0(%)
ET Agt	0.0-20.0 factory-set：5.0(%)	0.0-20.0 factory-set：0.0(%)
FI CO2	0.0-10.0 factory-set：0.5(%)	0.0-10.0 factory-set：0.0(%)
ET CO2	0.0-10.0 factory-set：8.0(%)	0.0-10.0 factory-set：2.0(%)
RR	0-100 factory-set：30(rpm)	0-100 factory-set：5 (rpm)
FI N2O	0-100 factory-set：100(%)	0-100 factory-set： 0(%)
ET N2O	0-100 factory-set：100(%)	0-100 factory-set： 0(%)
FI O2	18-100 factory-set：100(%)	18-100 factory-set：18(%)
ET O2	0-100 factory-set：100(%)	0-100 factory-set：5(%)

ADVANCED SETUP

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

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.

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.

OXYCRG DISPLAY

The OxyCRG diagram is used to quickly evaluate the patient status based on SpO2, HR and RESP.

The OxyCRG diagram will display the following three graphs simultaneity :
1. Heart rate (HR) data trend;
2. SPO2 data trend
3. Respiration rate or Constringent the respiration waveform
The information displayed for the above three parameters is 1 minute, 2 minutes, 4 minutes or 8 minutes newly.

Select "OxyCRG" item in the System Setup menu → Display Mode to change to the OxyCRG display mode as following picture:

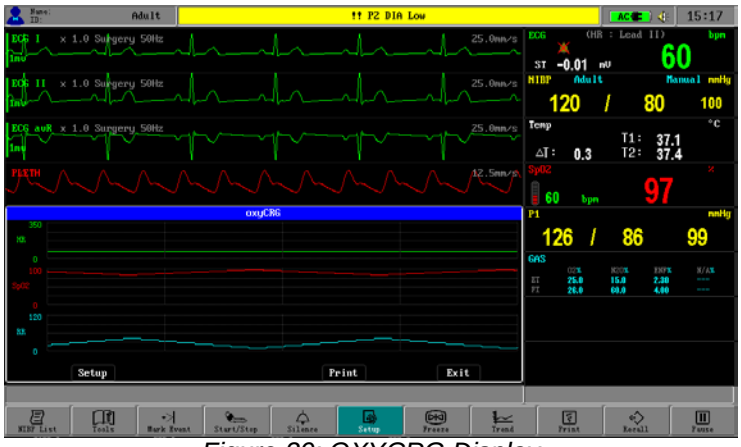


Figure 30: OXYCRG Display

Note:

1. The OxyCRG dynamic view display appears in the below area of the screen and overlaps on the realtime waveforms area. At this time all monitoring is processing in and the alarm will still active.
2. The OxyCRG display speed is too slow to have effect on displaying when pressing down the waveform freeze button.
3. The number for the realtime waveforms display which is along with the OxyCRG diagram at the same time is determined by the Max. waveforms display number in the system. This detailed is seen as follows:

"OxyCRG" display is OFF	"OxyCRG" display is ON
6 channels realtime waveforms	"OxyCRG" diagram + 3channels realtime waveforms
8 channels realtime waveforms	"OxyCRG" diagram + 4channels realtime waveforms

DRUG DOSE CALCULATIONS

DESCRIPTIONS

The drug dose calculations function is used to calculate the Drug-perfusion ratio, dosage, amount or volume. The titration table for each drug can be displayed or printed.

Normally there are up to 24 sorts of drugs which can be calculated as following: Aminophylline, Amrinone,Bretylium, Dobutamine， Dopamine, Epinephrine, Heparin, Hydrocortisone, Inocor, Insulin, Isuprel, Levophed, Lidocain, Morphine, Neostigmine, Neosynephrine, Nipride, Nitroglycerine, Pronestyl and Versed.

OPERATING INSTRUCTIONS

1. Enter Tools → Drug Calculation >> on the bottom menu bar.

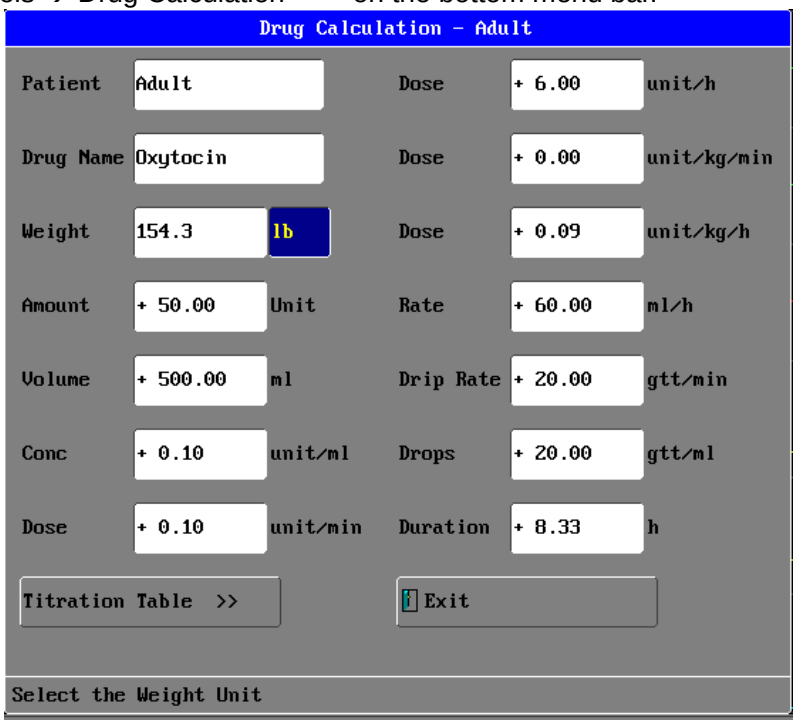


Figure 31: Drug Calculation Menu

2. Choose patient type and drug name. Fifteen drugs below, including user defined drugs Drug A, B, C, D, E:
   - Drug A, B, C, D, E
   - Oxytocin
   - Nitroglycerin
   - Nipride
   - Lidocaine
   - Isoproterenol
   - Heparin
   - Adrenaline
   - Dopamine
   - Dobutamine
   - Aminophylline

   Default values will be given, These are not the useful results. Doctor will provide known parameters' value.
3. Input the patient's weight (kg or lb) and the known parameters' value.

Unit:

Drug A, B, C: Nitroglycerin, Nipride, Lidocaine, Isoproterenol, Adrenaline, Dopamine, Dobutamine and Aminophylline use units g, mg, mcg.
Drug D: Oxytocin and Heparin use units Unit, KU, MU.
Drug E: use unit mEq.
Choose user defined drugs by the drug's unit.
Titration Table:

Click Titration Table >> to open the titration table.

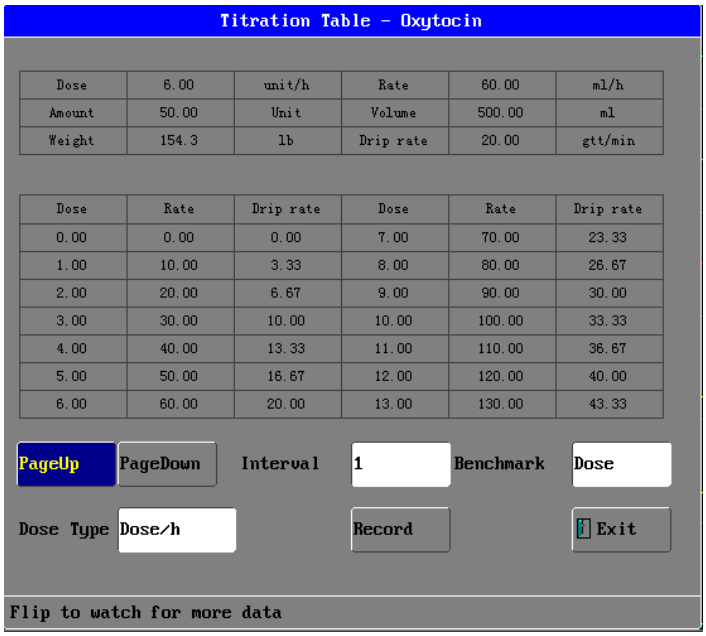


Figure 32: Titration table-oxytocin diagram

Interval, Becnchmark, and Dose Type can be changed. Click PageUp or PageDown to choose the required table. Click Record to print currently displayed table.

PATIENT INFORMATION ADMINISTRATION

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

PATIENT BASIC INFORMATION SETUP

Click the patient information area as following:

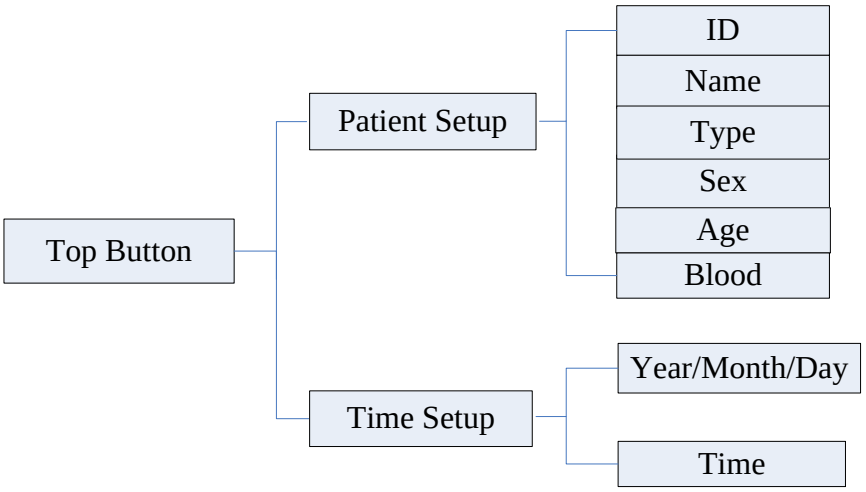


Figure 33: Tree Diagram for Top Button

Pop up the menu of Patient Information Setup. The menu can set up the following patient record:

ID
Set the ID number of the patient.

NAME
Move the cursor box to the correlated position and press it. Turning the ROTARY KNOB after choosing can input the English alphabet or Chinese phonetic letters, the range is: uppercase, A-Z, point(.) and blank character.
Patient name supports the display method of English and phonetic letter, and does 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 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.

TOOLS SETUP

There are four types of events that you can define. The user can freely define the implication of each type by select **Tools→ Mark event**.

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 **YES** to exit, and the event marked becomes effective immediately upon 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 **NIBP LIST** to pop up the menu of NIBP LIST, see chart below:

Table 10: NIBP List

NO.	Time	NIBP	HR	SpO2	PR	T1/T2	RR	ST	ET
1	05/22 14:23:57	120/80 100	60	97	60	37.1/37.4	10	-0.01	N
2	05/22 14:23:38	120/80 100	60	91	60	37.1/37.4	25	-0.01	N
3	05/22 14:23:19	120/80 100	60	87	60	37.1/37.4	35	-0.01	N
4	05/22 14:23:00	120/80 100	60	95	60	37.1/37.4	15	-0.01	N
5	05/22 14:22:41	120/80 100	60	95	60	37.1/37.4	15	-0.01	N
6	05/22 14:22:23	120/80 100	60	89	60	37.1/37.4	35	-0.01	N
7	05/22 14:22:04	120/80 100	60	89	60	37.1/37.4	30	-0.01	N
8	05/22 14:21:45	120/80 100	60	97	60	37.1/37.4	10	-0.01	N
9	05/22 14:21:26	120/80 100	60	93	60	37.1/37.4	20	-0.01	N

PageDown PageUp Print 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 group 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 in all. If exceeded, the new data will kick the oldest data out of the list and take its place.

TREND OBSERVATION

PARAMETER FOR TREND OBSERVATION

The monitoring system will save and trace the trend of parameters below:
HEART RATE (HR), OXYGEN SATURATION（SPO_2）
NONTRAUMATIC BLOOD PRESSURE （NIBP-SYSTOLIC BLOOD PRESSURE （SYS, DIASTATIC BLOOD PRESSURE（DIA）
TEMPERATURE（TEMP）
PULSE（PULSE）
RESPIRATION RATE（RESP）
ETCO2
IBP1
IBP2
GAS
EVENT

TREND OBSERVATION ADMITTANCE

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

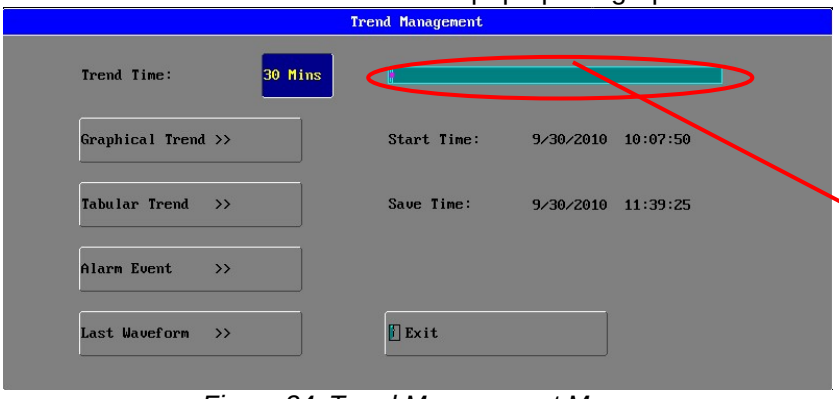


Figure 34: Trend Management Menu

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

TREND TIME INTERVAL

Trend Time Interval means how often the system stores a trend data. Different trend reference time has its correlated trend time interval, the relation between them are show below:
30 minutes： 6 seconds
60 minutes： 12 seconds

90 minutes:	18 seconds
3 hours:	36 seconds
6 hours:	72 seconds
12 hours:	144 seconds
18 hours:	216 seconds
24hours:	288 seconds
36 hours:	432 seconds
48 hours:	576 seconds
60 hours:	712 seconds
72 hours:	864 seconds

TREND GRAPH ANALYSIS

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

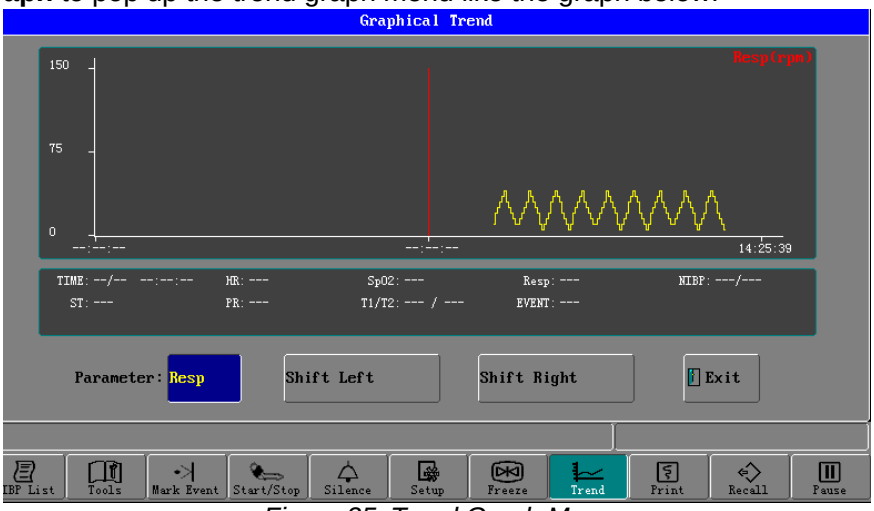


Figure 35: Trend Graph Menu

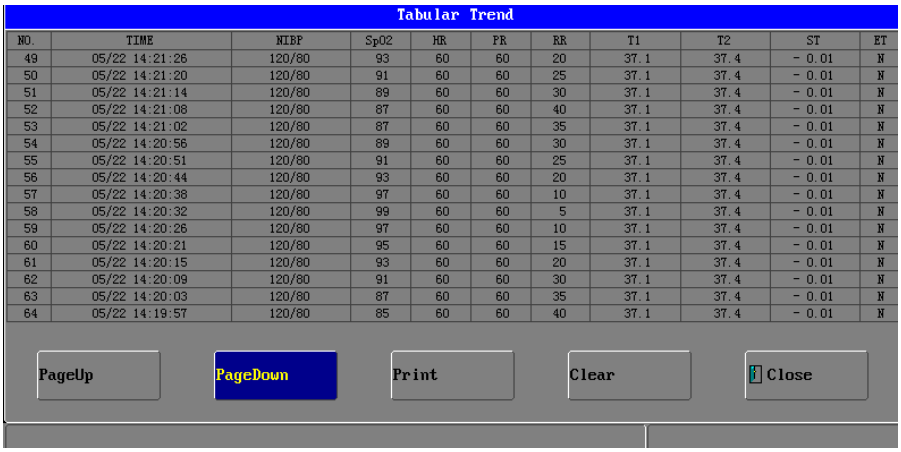
Each page displays the trend chart of one parameter, and the user can change it by clicking **PARAMETER**.

TREND TABLE ANALYSIS

TREND TABLE ADMITTANCE

Click **Trend Table** on the trend management menu and the trend table menu will display in the waveform area on the screen. Sixteen groups of parameters are listed on each page. The data will list from new to old and the time is displayed using the 24-hour clock. The parameter name is displayed on the top of chart and the invalid data will not display.

Table 11: Trend Table



TREND TABLE MOVING

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

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

ALARM EVENTS RECALL

If clicking **Alarm Events** 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).

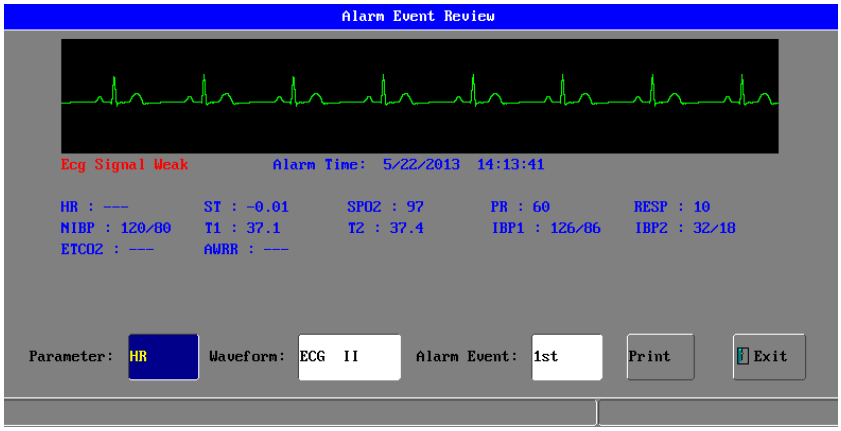
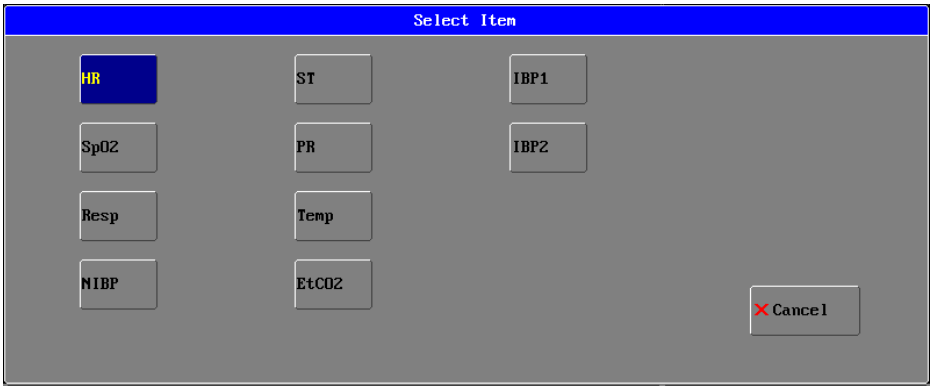
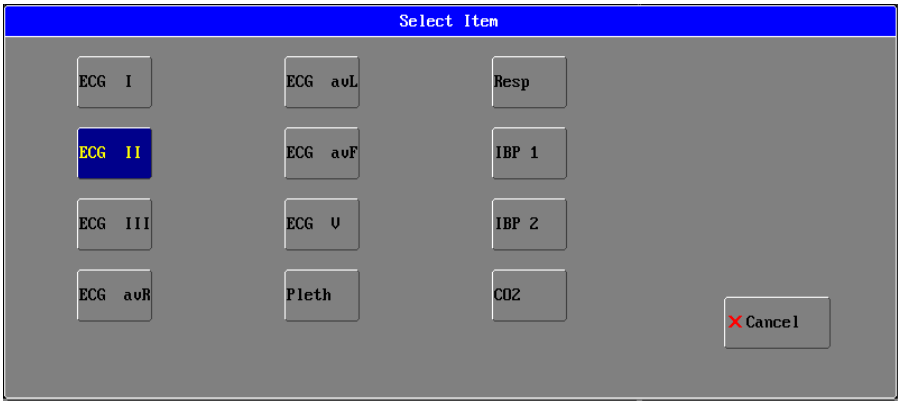


Figure 36: Windows for Alarm Event Recall

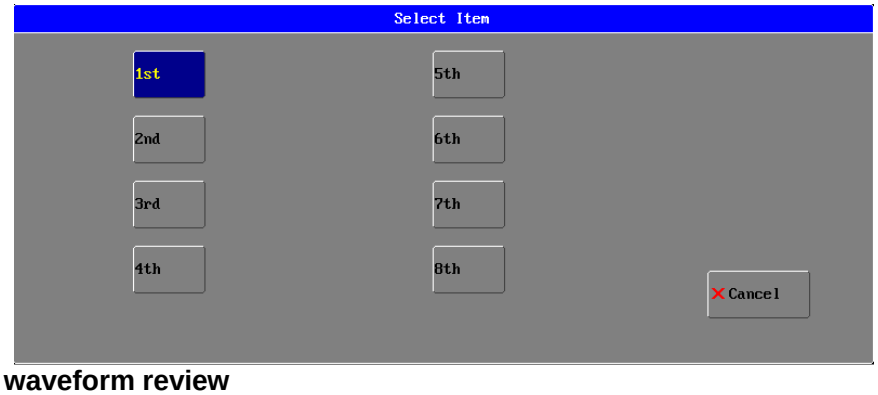
1. Alarm parameter select menu:



2. Alarm waveform select menu:



3. Alarm Event select menu:



The last waveform review

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

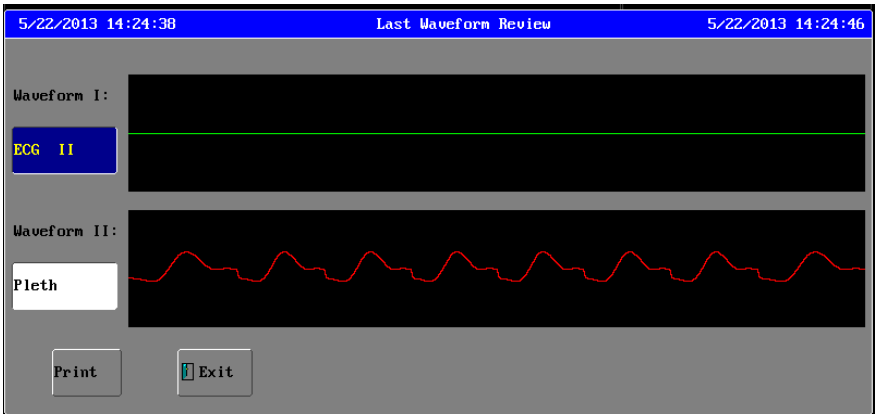


Figure 37: Last Waveform Review

When there are waveforms displayed for demonstration or realtime measurement, the system only saves data for the last 16 seconds and displays two selectable waveforms. The time for the late waveforms will display on the title bar in the window as below.

Figure 38: Recent Waveform Review

DATA RECALL

Data Recall Storage
Data Recall Displays
Recall Operation Descriptions

DATA RECALL STORAGE

Data Recall 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 data recall 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 remains in storage when the monitor is in Standby.

A new record of data recall is started each time the monitor is turned on. A data recall 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 data recall 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:

Figure 39: Prompt Window for Input Patient ID

The above window will be automatically closed in 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 you click **YES,** enter the Patient Setup menu.

Recall Operation

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

2. Select the patient's ID for recall:
Complete step 1, select patient's ID.

3. Complete step 1 and step 2, enter the following **Trend Management** window with Patient ID as figure 24.

Note: This trend management-default window is for a patient which has no ID number.

RECORDING（OPTION）

NOTE: This is thermal recorder which must use the thermal record paper (the specification is
48mm on width). The waveforms can be printed by 2 or 3 traces.

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 includes:

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

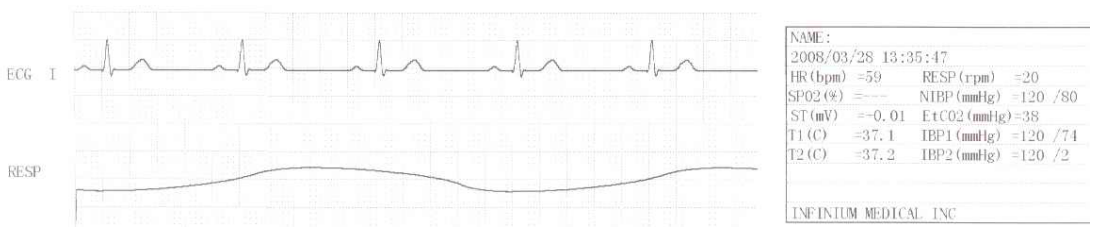


Figure 40: Printout Sample for 2 Traces

2. RECORDER SETUP

3. OPERATION SEQUENCE

Click the function button of **RECORD** on the screen —→The statement of START RECORDING appears on the bottom of screen, which shows that the print process is going on. To terminate printing, press RECORD again, and the recorder will stop immediately as the statement BREAK RECORDING appears on the bottom of screen.

NOTE: Each time you press RECORD will either carry out REAL-TIME RECORDING or terminate the CURRENT RECORDING TASK.

TREND TABLE RECORDING

1. CONTENTS

Record 11 groups of parameter report, include seven items of DATE, TIME, HR, 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
SP02	---	---	---	---	---	---	---	---
HR	---	59	59	59	59	59	59	59
PR	---	---	---	---	---	---	---	---
RESP	---	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
ST	-----	+0.00	+0.00	+0.00	+0.00	+0.00	+0.00	+0.00

Table 12: Printout Sample for Trend Table

2. RECORDING SEQUENCE

Click the function button of **TREND** on the screen —→ TREND MANAGEMENT menu appears on screen—→click TREND TABLE—→XX TIME TREND TABLE menu appears on screen—→click RECORD—→START RECORDING……If want to stop recording, click 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, 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
SPO2 ALM SPO2 Alarm
TEMP ALM Temperature Alarm
RESP ALM Respiration Alarm

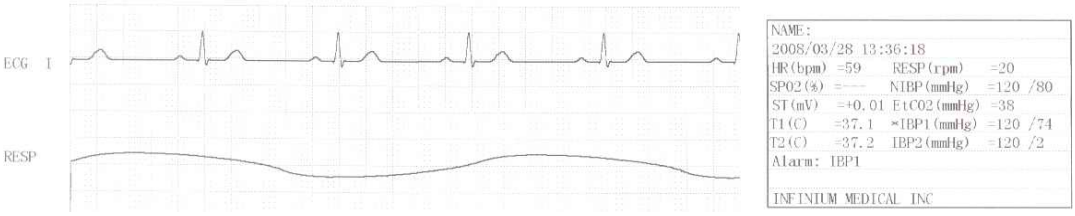


Figure 41: Printout Sample for Alarm Record

2. RECORDING SEQUENCE

Click **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 RECORD again or click the soft button of RECORD again—→BREAK RECORDING.

If there are several parameter alarms simultaneously, click and choose them on ALARM menu. Parameter alarms indicated by a red sign 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 EXPLANTION

1. INSERTING PAPER

Press 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 will not advance correctly.

2. ATTENTIONS

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

(2) Do not press 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: 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

OMNI (K) 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 to 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 a fully charged battery available 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 OMNI 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: Do not attempt to recharge battery outside of the recommended operating limits of 5～40 °C. This could result in damage to the battery or the monitor.

WARNING: The battery needs to be charged before use. Please note the inserting direction. Insert the battery according to the instruction on the label attached to the battery. Otherwise, it will damage the inner structure of the battery 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 OMNII, its accessories, connectors, switches, or openings in the chassis. Do not immerse the OMNI or its accessories in liquid or clean with caustic or abrasive cleaners.

To clean the OMNI (K), 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:	145(D) × 300(W) × 270(H) mm
Weight:	4.4kgs

PEFORMANCE SPECIFICATIONS

Display:	10.4 inch color TFT-LCD
Resolution:	800 x R.G.B. x 600
Trace:	3 or 6 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 30 minutes to 72 hours

ECG

Input:	*5 or 3 ECG cable and standard AAMI line for connection*
ECG standard	AHA, IEC
Lead Choice:	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V
Gain Choice:	×0.25，×0.5，×1.0，×2.0
CMRR (common mode rejection ratio):	>100 dB at 50 Hz or 60 Hz
Frequency Characteristic:	0.67～40 Hz （+3dB attenuation）
ECG Waveforms:	7 channels
Sweep Speed:	12.5, 25 , 50 and 100mm/s
HR Display Range:	30～300bpm
Accuracy:	±1bpm or ±1%, whichever is greater
Alarm Limit Range	Upper limit:80～400bpm Lower limit: 20～150bpm
Input Dynamic Range:	±5 mV AC
Defibrillator Discharge:	<5 sec
Differential Input Impedance:	>5 MΩ
Bandwidth(-3dB):	Diagnostic Mode: 0.05 Hz~130 Hz Monitor Mode: 0.5 Hz~40 Hz Surgical Mode: 1 Hz~20 Hz
Electrode Offset Potential Tolerance:	±300 mV
Input Signal Range:	±5 mV
Recovery:	<8 sec

Standards:

Meets the performance standards of ANSI/AAMI EC13:2002. Instead of a 1 mV standardization voltage (section 4.2.2.9), a fixed, 1 cm reference bar is always present in the ECG display, along with the ECG size setting expressed in mV/cm. The following

references particular sections of ANSI/AAMI EC13:2002.

Respiration, leads-off sensing waveform.	Sinusoidal signal, 260 μA, 40.5 kHz
Noise suppression 4.1.2.1(b)	Noise Suppression: RL drive gain 44 dB max., max. voltage 1.8 Vrms
Tall T-wave rejection. 4.1.2.1(c)	Exceeds ANSI/AAMI EC 13 Sect. 4.1.2.1(c) , Recommended less than 1.2 mV T-Wave amplitude
Heart Rate Averaging Method 4.1.2.1(d)	Normally, heart rate is computed by averaging the 12 most recent RR intervals. For runs of PVCs, up to 8 RR intervals are averaged to compute the HR. If each of 4 consecutive RR intervals is greater than 1200 ms (that is, rate less than 50 bpm), then the 4 most recent RR intervals are averaged to compute the HR. Thereafter computing by increasing 1 RR interval till recover 12 RR intervals. The fresh rate for displaying HR value is 1 second.
Response to irregular rhythm. 4.1.2.1(e)	a) Ventricular bigeminy - 80 BPM b) Slow alternating ventricular bigeminy - 60 BPM. c) Rapid alternating ventricular bigeminy - 120 BPM d) Bi-directional systoles - 90 BPM
Heart rate meter response time. 4.1.2.1(f)	HR change from 80 to 120 bpm: Average: 10 seconds HR change from 80 to 40 bpm: Average: 10 seconds

Heart rate meter response time. 4.1.2.1(g)

0.5 mV	Average Time to Alarm
1 mV	10 sec
2 mV	10 sec
Waveform 4(b), Amplitude	10 sec
1 mV	Average Time to Alarm
2 mV	10 sec
4 mV	10 sec
	10 sec

Pacemaker pulse rejection. 4.1.4.1, 4.1.4.3	With the exceptions noted below, the monitor will reject all pacemaker pulses having amplitudes of ±2 to ±700 mV and pulse widths from 0.1 to 2.0 ms.
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs
Pace pulse rejection	When tested in accordance with the ANSI/AAMI EC13-2002: Sections 4.1.4.1 and 4.1.4.3, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs

RESPIRATION

Measure Method:	RA-LL impedance
Range:	0～120 rpm
Accuracy	± 3 rpm
Alarm Upper-lower Limit	Upper limit: 8～120 rpm， Lower limit: 6～100 rpm
Sweep Speed:	6.25,12.5 and 25mm/s
Lead:	II

NIBP	
Measuring Technology:	Automatic oscillating measurement
Cuff Inflating:	<30s（0～300 mmHg，standard adult cuff）
Measuring Period:	AVE<40s
Mode	Manual, Auto, STAT
Measuring Interval in AUTO Mode	2 min～4 hrs
Pulse Rate Range:	30 bpm～250 bpm
Measuring Range:	Adult/Pediatric Mode SYS 40～250 (mmHg) DIA 15～200 (mmHg) Neonatal Mode SYS 40～135 (mmHg) DIA 15～100 (mmHg)
Resolution:	1mmHg
Pressure Accuracy:	Maximum Mean error: ±5mmHg Maximum Standard deviation: 8mmHg
Overpressure Protection:	Adult Mode 280(mmHg) Neonatal Mode 150 (mmHg)
Alarm Limit:	SYS 30～240 mmHg DIA 15～180 mmHg
TEMPERATURE	
Scale:	Selectable ℃ or °F
Channel:	2 channels
Range:	T1 and T2 : 25℃～50℃/77°F～122°F Delta T: 0℃～5.5℃/ 0°F～9.9°F
Accuracy:	± 0.2℃（25.0℃～34.9℃）/（77°F ~94.8°F） ± 0.1℃（35.0℃～39.9℃）/（95°F ~103.8°F） ± 0.2℃（40.0℃～44.9℃）/（104°F ~112.8°F） ± 0.3℃（45.0℃～50.0℃）/（113°F ~122°F）
Display Resolution:	0.1℃（0.2°F）
Alarm Limit:	Upper limit 10℃～50℃/50°F ~122°F) Lower limit 10℃～50℃/50°F ~122°F)
SPO2	
$ASpO_2$:	Anti-motion SpO_2
SpO_2% Range:	0～100%
SpO_2 Accuracy:	± 2%（70～100%,non-motion） ± 3%（70～100%, motion）
Pulse Rate Range:	30-250 bpm
Pulse Rate Accuracy:	±2 bpm(non-motion) ±3 bpm (motion)
Alarm Upper-lower Limit:	Upper limit 50～100%， Lower limit 50～100%
SpO_2 Probe:	Red light LED wavelength 660nm±5nm Infrared light LED wavelength 940nm±10nm
IBP(OPTION)	
Measurement Range:	-50～300mmHg
Channel:	2 channels
Scale:	-10 to 50, 0–100, 0–150, -10–150,20–150, 50–300mmHg
Zero Range:	±120 mmHg
Excitation:	5V DC ±2%
Pressure transducer:	Sensitivity, 5μV/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:	50ml/min±10ml/min
Respiration Rate:	0～150 bpm
Respiration Rate accuracy:	±1 bpm
Response Time:	<3 seconds - includes transport time and rise time
Inspired CO_2 measurement Range:	3～50 mmHg

C.O. (CARDIAC OUTPUT)

Measurement Method	Measurement Method	
Measurement Range	C.O.	0.1 to 20 L/min
	TB	23 to 43℃
	TI	0 to 27℃
Resolution	C.O.	0.1 L/min
	TB, TI	0.1℃
Accuracy	C.O.	±5% or ±0.1 L/min, whichever is greater, as measured using electronically generated flow curves.
	TB, TI	±0.1℃(without sensor)
Alarm Range	TB	23 to 43℃
Repeatability	C.O.	±2% or ±0.1 L/min, whichever is greater, as measured using electronically generated flow curves.

Alarm limit	Range	Step
TB High	(low limit + 1) to 43℃	0.1℃
	(low limit + 1.8) to 109.4 °F	0.1 °F
TB Low	23 to (high limit - 1) ℃	0.1℃
	73.4 to (high limit - 1.8) °F	0.1 °F

ANESTHETIC AGENTS(OPTION, PHASEIN)

Operating environment:	IRMA CO2:	IRMA AX+:
	0–40°C / 32–104°F	10–40°C / 50–104°F
	10–95% RH, non-condensing	
	525–1200 hPa	
	(525 hPa corresponding to an altitude of 4 572 m / 15 000 feet)	
Primary agent threshold:	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol% as long as apnea is not detected.	
Secondary agent threshold:	0.2 vol% + 10% of total agent concentration	
Total system response time:	< 1 second	

Interfering gas and vapor effects

Interfering gas and vapour effects

Gas or vapour	Gas level	CO_2		Agents	N_2O
		IRMA CO_2	IRMA AX+		
N_2O [4]	60 vol%	– [1 & 2]	– [1 & 2]	– [1]	– [1]
HAL [4]	4 vol%	– [1]	– [1]	– [1]	– [1]
ENF, ISO, SEV [4]	5 vol%	+8% of reading [3]	– [1]	– [1]	– [1]
DES [4]	15 vol%	+12% of reading [3]	– [1]	– [1]	– [1]
Xe (Xenon) [4]	80 vol%	-10% of reading [3]		– [1]	– [1]
He (Helium) [4]	50 vol%	-6% of reading [3]		– [1]	– [1]
Metered dose inhaler propellants [4]	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) [4]	0.3 vol%	– [1]	– [1]	– [1]	– [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	– [1]	– [1]	– [1]	– [1]
CH_3COCH_3 (Acetone) [4]	1 vol%	– [1]	– [1]	– [1]	– [1]
CH_4 (Methane) [4]	3 vol%	– [1]	– [1]	– [1]	– [1]
CO (Carbon monoxide) [5]	1 vol%	– [1]	– [1]	– [1]	– [1]
NO (Nitrogen monoxide) [5]	0.02 vol%	– [1]	– [1]	– [1]	– [1]
O_2 [5]	100 vol%	– [1 & 2]	– [1 & 2]	– [1]	– [1]

Accuracy(standard conditions)

Accuracy specifications – during standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5°C and 1013 ± 40 hPa.

	Range[1]			
Gas	**CO2**		**AX+**	**Accuracy**
CO_2	0 – 15 15 – 25		0 – 10 10 – 15 15 – 25	±(0.2 vol% + 2% of reading) ±(0.3 vol% + 2% of reading) Unspecified
N_2O	-		0 – 100	±(2 vol% + 2% of reading)
HAL, ISO, ENF	-		0 – 8 8 – 25	±(0.15 vol% + 5% of reading) Unspecified
SEV	-		0 – 10 10 – 25	±(0.15 vol% + 5% of reading) Unspecified
DES	-		0 – 22 22 – 25	±(0.15 vol% + 5% of reading) Unspecified

Note 1: The accuracy specification is valid for the operating temperature and humidity conditions specified, except for interference specified in the table "Interfering gas and vapour effects" below.

Note 2: The accuracy specification is not valid if more than two agents are present in the gas mixture.

ISA sidestream gas analyzer

Operating environment:

IRMA CO2: 0–40°C / 32–104°F

IRMA AX+: 10–40°C / 50–104°F

10–95% RH, non-condensing

525–1200 hPa

(525 hPa corresponding to an altitude of 4 572 m

/ 15 000 feet)

Mechanical robustness ISA CO2: Meets the shock and vibration requirements for transport of SS-EN ISO 21647:2004 clause 21.102 and SS-EN 1789:2007 clause 6.3.4.2.

ISA OR+/AX+: Meets the shock and vibration requirements of SS-EN ISO 21647:2004 clause 21.101

Primary agent threshold: 0.15 vol%. When an agent is identified,concentrations will be reported even below 0.15 vol% as long as apnea is not detected.

Primary agent threshold (ISA OR+/AX+): 0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%.

Secondary agent threshold (ISA OR+/AX+): 0.2 vol% + 10% of total agent concentration

Total system response time: < 3 seconds (with 2 m Nomoline sampling line)Interfering gas and vapor effects

Gas or vapor	Gas level	CO_2		Agents	N_2O
		ISA CO_2	ISA AX+ ISA OR+		
N_2O [4]	60 vol%	– [2]	– [1]	– [1]	– [1]
HAL [4]	4 vol%	– [1]	– [1]	– [1]	– [1]
ENF, ISO, SEV [4]	5 vol%	+8% of reading [3]	– [1]	– [1]	– [1]
DES [4]	15 vol%	+12% of reading [3]	– [1]	– [1]	– [1]
Xe (Xenon) [4]	80 vol%	- 10% of reading [3]		– [1]	– [1]
He (Helium) [4]	50 vol%	- 6% of reading [3]		– [1]	– [1]
Metered dose inhaler propellants [4]	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) [4]	0.3 vol%	– [1]	– [1]	– [1]	– [1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	– [1]	– [1]	– [1]	– [1]
CH_3COCH_3 (Acetone) [4]	1 vol%	– [1]	– [1]	– [1]	– [1]
CH_4 (Methane) [4]	3 vol%	– [1]	– [1]	– [1]	– [1]
CO (Carbon monoxide) [5]	1 vol%	– [1]	– [1]	– [1]	– [1]
NO (Nitrogen monoxide) [5]	0.02 vol%	– [1]	– [1]	– [1]	– [1]
O_2 [5]	100 vol%	– [2]	– [2]	– [1]	– [1]

Note 1: Negligible interference, effect included in the specification "Accuracy, all conditions" above.

Note 2: Negligible interference with N_2O / O_2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO_2.

Note 4: According to the EN ISO 21647:2004 standard.

Note 5: In addition to the EN ISO 21647:2004 standard.

Accuracy(standard conditions)

Gas	Range[1]	Accuracy
CO_2	0 to 15 vol% 15 to 25 vol%	±(0.2 vol% + 2% of reading) Unspecified
N_2O	0 to 100 vol%	±(2vol% + 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
O_2	0 to 100 vol%	±(1 vol% + 2% of reading)

Accuracy(all conditions)

Gas	Accuracy
CO_2	±(0.3 kPa + 4% of reading)
N_2O	±(2 kPa + 5% of reading)
Agents [1)]	±(0.2 kPa + 10% of reading)
O_2	±(2 kPa + 2% of reading)

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: IEEE 802.3 wired network Connected bedside number: Up to 16 bedside monitors RJ45 interface or RS232 serial port
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:	Rechargeable Lithium Battery Type: KXD1243 11.1V-4.3Ah Operating time after the first alarm of low battery: 10 minutes Number of Batteries: 1 Charge Time: 4 hours Operating Time: 2 hours
ENVIRONMENTAL SPECIFICATIONS	
Temperature:	Operating: 5～40 °C Storage: -10～45 °C
Humidity Range:	Operating: ≤80 % Storage: ≤80 %
RECORDER (OPTION)	
Record Width:	48 (mm)
Paper Speed:	25 (mm/s)
Trace:	2 or 3
FUSE	T 3.0A, self-recovery

EMC

The product is in radio-interference protection class A in accordance with EN55011. The product complies with the requirement of standard EN60601-1-2:2007 "Electromagnetic Compatibility - Medical Electrical Equipment".

ELECTROMAGNETIC IMMUNITY

This section constitutes the guidance and OMNI (K)'s declaration regarding electromagnetic immunity. The OMNI (K) Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the OMNI (K) Patient Monitor should assure that it is used in such an environment.

Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	*±6 kV contact ±8 kV air*	*±6 kV contact ±8 kV air*	*Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.*
Electrical fast transient/burst IEC 61000-4-4	*±2 kV for power supply lines ±1 kV for input/output lines*	*±2 kV for power supply lines ±1 kV for input/output lines*	*Mains power quality should be that of a typical commercial or hospital environment.*
Surge IEC 61000-4-5	*±1 kV differential Mode ±2 kV differential Mode*	*±1 kV differential Mode ±2 kV differential Mode*	*Mains power quality should be that of a typical commercial or hospital environment.*
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	*<5 % U_T[1] (>95 % dip in U_T) for 0.5 cycle* *40 % U_T (60 % dip in U_T) for 5 cycles* *70 % U_T (30 % dip in U_T) for 25 cycles* *<5 % U_T (>95 % dip in U_T) for 5 sec*	*<5 % U_T[2] (>95 % dip in U_T) for 0.5 cycle* *40 % U_T (60 % dip in U_T) for 5 cycles* *70 % U_T (30 % dip in U_T) for 25 cycles* *<5 % U_T (>95 % dip in U_T) for 5 sec*	*Mains power quality should be that of a typical commercial or hospital environment. If the user of the OMNI (K) Patient Monitor requires continued operation during power mains interruptions, it is recommended that the OMNI (K) Patient Monitor be powered from an uninterruptible power supply or a battery.*
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	*3 A/m*	*3 A/m*	*Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.*

Note: *U_T is the a. c. mains voltage prior to application of the test level.*

Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***
			Portable and mobile RF communications equipment should be used no closer to any part of the OMNI (K) Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ***Recommended separation distance:*** $d = [\frac{3.5}{V_1}]\sqrt{P}$
Conducted RF *IEC 61000-4-6*	*3 Vrms* *150 kHz to 80 MHz*	*3 Vrms*	$d = [\frac{3.5}{V_1}]\sqrt{P}$ *80 MHz to 800 MHz*
Radiated RF *IEC 61000-4-3*	*3 V/m* *80%AM@2Hz* *80 MHz to 2.5 GHz*	*3 V/m*	$d = [\frac{7}{E_1}]\sqrt{P}$ *800 MHz to 2.5 GHz*
Only ISA CO2 is tested at 20 V/m	*20 V/m* *80%AM@1kHz* *80 MHz to 2.5 GHz*	*20 V/m*	*where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).* *Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:* 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OMNI (K) Patient Monitor is used exceeds the applicable RF compliance level above, The OMNI (K) Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary,such as reorienting or relocating the OMNI (K) Patient Monitor.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the OMNI (K) Patient Monitor

The OMNI (K) Patient Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the OMNI (K) Patient Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OMNI (K) Patient Monitor as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter [W**]**	**Separation distance according to frequency of transmitter [**m**]**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{V_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.