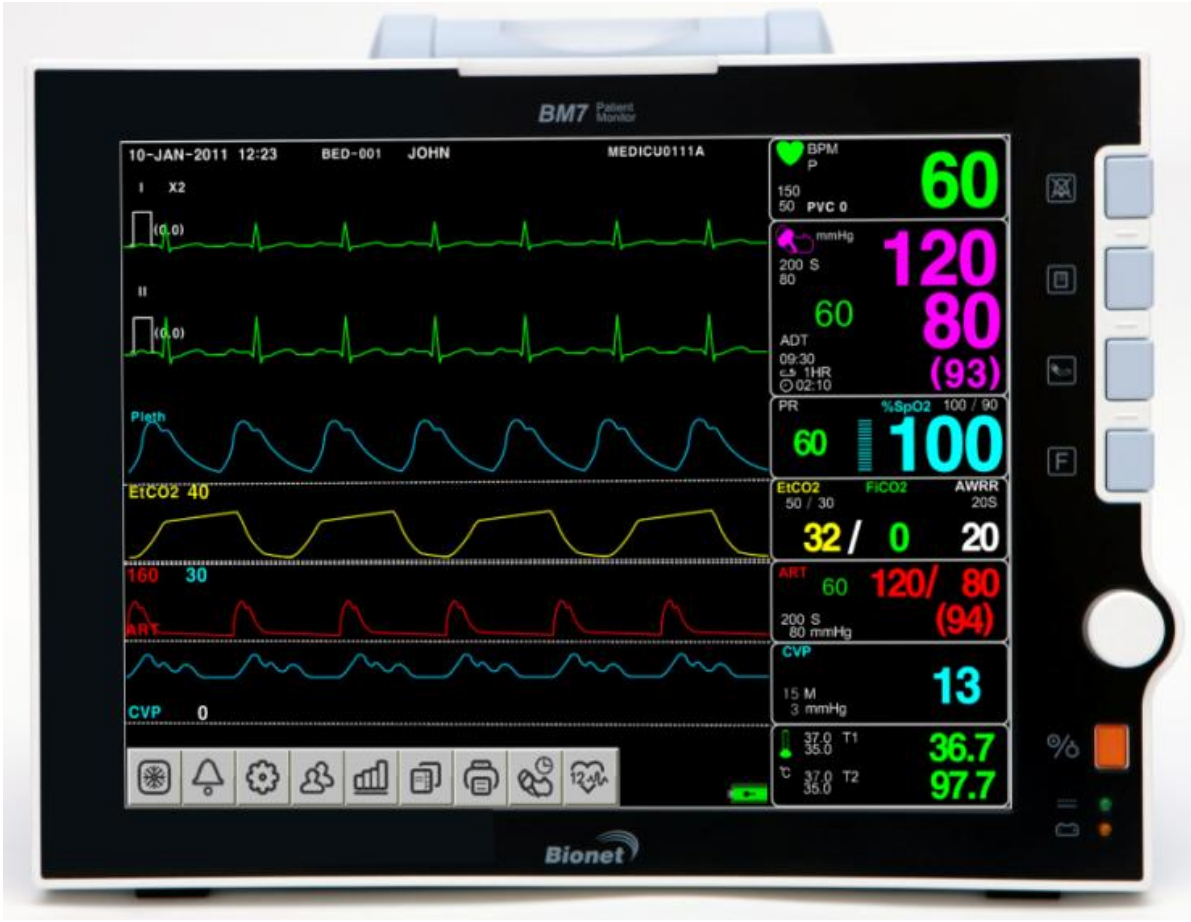
BM7 User’s Manual

Patient Monitor

Rev. 1.6



Bionet

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1.1 CE Standard Information

Electromechanical safety standards met:

Information supplied by the manufacturer of medical devices

1. **IEC/EN 60601-1 3rd. Edition 3.0**

   Medical electrical equipment Part1: General requirements for safety and essential performance

2. **IEC/EN 60601-1-2 3rd Edition**

   Medical electrical equipment Part 1: General requirements Electromagnetic Compatibility Requirement and tests

3. **IEC/EN 60601-1-6 Edition 3.0**

   Part 1-6 : General requirements for basic safety and essential performance – Collateral Standard: Usability

4. **IEC/EN 60601-1-8 Edition 2.1**

   Part 1-8 : General requirements for safety Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

5. **IEC/EN 60601-2-26 Edition 3.0**

   Part 2-26 : Particular requirements for the safety and essential performance of electroencephalographs.

6. **IEC/EN 60601-2-27 Edition 3.0**

   Part 2-27 : Particular requirements for the safety and essential performance of electrocardiographic monitoring equipment.

7. **IEC/ISO 80601-2-30 Edition 1.0**

   Part 2-30 : Particular requirements for safety and essential performance of automated non-invasive sphygmomanometers.

8. **IEC/EN 60601-2-34 Edition 3.0**

   Part 2-34: Particular requirements for the safety and essential performance of invasive blood monitoring equipment.

9. **IEC/EN 60601-2-49 Edition 2.0**

   Part 2-49 : Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment.

10. **ISO 80601-2-55 Edition 1.0**

    Part 2-55 : Particular requirements for the basic safety and essential performance of respiratory gas monitors

11. **ISO 80601-2-56 Edition 1.0**

    Part 2-56 : Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.

12. **ISO 80601-2-61 Edition 1.0**

    Part 2-61 : Particular requirements for the basic safety and essential performance of pulse oximeter equipments.

1.2 Read before Use

BIONET services are always available to you.
The followings are address and phone number for contacting information, services, and product supplies.

How to Contact Us

Product Supply Information	**Bionet Ltd. – Sales Department** Address #11F, E&C DREAM TOWER Ⅲ, 197-33, Guro-dong, Guro-gu, Seoul, South Korea (ZIP 08376) or #1101 11F E&C Venture Dream Tower3 38-21, Digital-Ro, 31-Gil, Guro-Gu, Seoul 08376, REPUBLIC OF KOREA Overseas sales dept. Tel:++82-2-6300-6418 Fax : ++82-2-6499-7799 E-mail : sales@ebionet.com URL : http:// www.ebionet.com

※ In the event of malfunction or failure, contact us along with the model name, serial number, and product name of the equipment.

※ If you need the supply circuit diagram, component list, description and calibration instruction etc. you can contact us we will provide you with it.

Warranty Period

- This product is manufactured and passed through strict quality control and through inspection.

- Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's protection law" noticed by Korea Fair Trade Commission.

- Warranty period is 1 year.(Two years in Europe).

- We will repair or replace any part of the BM7 found to be defective in usual operating circumstance for free to you.

- This warranty does not apply to any defect caused by improper abuse, misuse or exposure to poor management.

Warning, Caution, Note

For special emphasis on agreement, terms are defined as listed below in user's manual. Users should operate the equipment according to all the warnings and cautions.

Indicated in this manual In order to improve the product specifications and features are subject to change without notice.

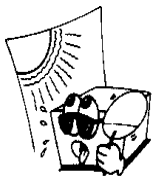
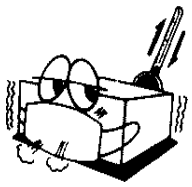
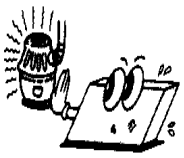
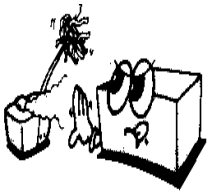
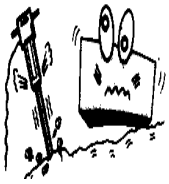
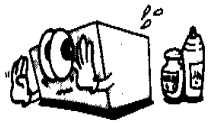
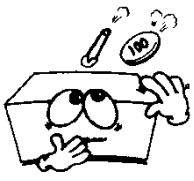
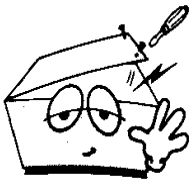
Warning
To inform that it may cause serious injury or death to the patient, property damage, material losses against the "warning" sign

Caution
To inform that it may cause no harm in life but lead to injury against the "caution" sign

Note
To inform that it is not dangerous but important "note" sign for proper installation, operation, and maintenance of the equipment.

General Precaution on Environment

- Do not keep or operate the equipment in the environment listed below.

	Avoid placing in an area exposed to moist. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10(C to 40(C. Operating humidity ranges from 30% to 85%.		Avoid in the vicinity of Electric heater
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is danger of gas leakage.		Avoid being inserted dust and especially metal material into the equipment
	Do not disjoint or disassemble the equipment. We take no responsibility for it.		Power off when the equipment is not fully installed. Otherwise, equipment could be damaged.

CAUTIONS

Before Installation

Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

Defibrillator Precaution

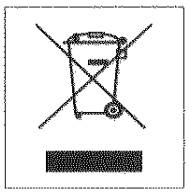
Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and lead wires.

Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

Disposables

Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

Disposal of your old appliance



1. When this crossed out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.
2. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.
3. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.
4. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.

Electrocute Precautions

To prevent skin burns, apply electrocute electrodes as far as possible from all other electrodes, a distance of at 15 cm/6 in. is recommended.

EMC

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are possible source of interference as they may emit higher levels of electromagnetic radiation.

Also, keep cellular phones to other telecommunication equipment away from the monitor.

CAUTIONS

Instruction for Use

For continued safe use of this equipment, it is necessary that the instructions are followed. However, instructions listed in this in no way supersede established medical practices concerning patient care.

Loss of Data

Should the monitor at any time temporarily lose patient data, the potential exists that active monitoring is not being done. Close patient observation or alternate monitoring devices should be used until monitor function is restored.

If the monitor does not automatically resume operation within 60 seconds, power cycle the monitor using the power on/off switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

Maintenance

Regular preventive maintenance should be carried out annually (Technical inspections). You are responsible for any requirements specific to your country.

MPSO

The use of a multiple portable socket outlet (MPSO) for a system will result in an enclosure leakage current equal to the sum of all individual earth leakage currents of the system if there is an interruption of the MPSO protective earth conductor. Do not use an additional extension cable with the MPSO as it will increase the chance of the single protective earth conductor interruption.

Negligence

BIONET does not assume responsibility for damage to the equipment caused by improperly vented cabinets, improper or faulty power, or insufficient wall strength to support equipment mounted on such walls.

NOTES

Power Requirements

Before connecting the device to the power line, check that the voltage and frequency. Ratings of the power line are the same as those indicated on the unit's label. If this is not the case, do not connect the system to the power line until you adjust the unit to match the power source. In U.S.A, if the installation of this equipment will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

Restricted Sale

U.S.A federal law restricts this device to sale by or on the order of a physician.

Supervised Use

This equipment is intended for use under the direct supervision of a licensed health care practitioner.

Ventilation Requirements

Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the technical specifications must be ensured at all times.

·Put the monitor in a location where you can easily see the screen and access the operating controls.

·This product is protected against the effects of cardiac defibrillator discharges to ensure proper recovery, as required by test standards. (the screen may blank during a defibrillator discharge but recovers within second as required by test standards.)

Reference Literature

Medical Device Directive 93/42/EEC

EN 60601-1/1990 +A1: 1993 +A2 : 1995 : Medical electrical equipment.

General requirements for safety

EN 60601-1-1/9. 1994 +A1 12.95: General requirements for safety.

General Precaution on Electric Safety

Warning
Check the item listed below before operating the equipment.

1. Be sure that AC power supply line is appropriate to use. (AC100 - 240V)
2. Be sure that the power source is the one supplied from Bionet. (DC18V,2.8A,BPM050 Made in BridgePower Co., Ltd.)
3. Be sure that the entire connection cable of the system is properly and firmly fixed.
4. Be sure that the equipment is completely grounded. (If not, there might be the problem occur in the product.)
5. The equipment should not be placed in the vicinity of electric generator, X-ray, broadcasting apparatus to eliminate the electric noise during operation. Otherwise, it may cause incorrect result.

Note
The Equipment should be placed far from generator, X-ray equipment, broadcasting equipment or transmitting wires, so as to prevent the electrical noises from being generated during the operation, When these devices are near the Equipment, it can produce inaccurate measurements. For BM7 both independent circuit and stable grounding are essentially required. In the event that the same power source is shared with other electronic equipment, it can also produce inaccurate output. **This unit uses a common isolation path for the ECG leads and the Invasive Pressure Channels. Ensure that conductive parts of the ECG electrodes do not contact other conductive parts including earth ground. Do not connect any non-isolated accessories to the unit or to the ECG or invasive pressure channel inputs when connected to a patient. Insure that the total chassis leakage currents of all connected units does not exceed 100µA in normal conditions and does not exceed 300µA in a single fault condition. Use an IEC 60601-1 approved isolation / separation transformer if required. Do not operate the equipment with any cover removed. Do not simultaneously touch the patient and any piece of electrical equipment if any cover has been removed from the equipment.**

Warning
Do not contacts with the patient while operate the machine It may cause serious danger to the users. Use only the provided cable. A warning that other cables and accessories may negatively affect EMC performance

Warning
In case the Equipment does not operate as usual or damaged, do not use on patient, and contact to the medical equipment technician of the hospital or the equipment supply division.

Note
BM7 is classified as follows: - BM7 classifies as Class **I,** BF **&** CF concerning electric shock. It is not proper to operate this Equipment around combustible anesthetic or dissolvent. - Noise level is B class regarding IEC/EN 60601-1 and the subject of Nose is B level concerning IEC/EN60601-1-2.

Equipment Connection

For measurements in or near the heart we recommend connecting the monitor to the potential equalization system. Use the green and yellow potential equalization cable and connect it to the pin labeled with the symbol  .

Manufacturer's declaration - Electromagnetic emission

The Model **BM7** is intended for use in the electromagnetic environment specified below.

The customer or the user of the Model **BM7** 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 common mode	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3.0 A/m	3.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in 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 (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 0240031000 requires continued operation during power mains interruptions, it is recommended that the Model 0240031000 be powered from an uninterruptible power supply or a battery

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

The Model **BM7** is intended for use in the electromagnetic environment specified below.

The customer or the user of the Model **BM7** should assure that it is used in such an environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Model **BM7**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	**Recommended separation distance** $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined 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) U_T is the A.C. mains voltage prior to application of the test level.

Note 2) At 80 MHz and 800 MHz, the higher frequency range applies.

Note 3) 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 m obile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with a ccuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey s hould be considered. If the measured field strength in the location in which the EUT is used exceeds the applicabl e RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the **BM3** System.

The **BM7** system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the **BM7** system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **BM7** system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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 max imum 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 an d reflection from structures, objects, and people.

Immunity and Compliance Level

Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	3 Vrms
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	3 V/m

Guidance and manufacturer's declaration - electromagnetic immunity

The **BM7** is intended for use in the electromagnetic environment specified below.

The customer or the user of the **BM7** should assure that it is used in such an environment

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment –guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80 MHz	The **BM7** must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.**a** Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

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 outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

Caution
In the hospital, doctors and patients are exposed to dangerous, uncontrollable compensating currents. These currents are due to the potential differences between connected equipment The safety solution to the problem is accomplished with EN60601-1;2005

Biocompatibility

When used as intended, the parts of the product described in this operator manual, including accessories that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions about this matter, please contact BIONET or its representatives.

Maintenance and Washing Equipment Connection

Using various methods can clean BM7 and its accessories. Please follow the methods mentioned below to avoid unnecessary damage or contamination to the Equipment.

We do not repair with free of charge regardless of warranty period if it is contaminated or damaged with using dangerous material not designated for washing.

Cleaning Applied Parts

Do not permit any liquid to enter the monitor case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning solution to enter the connectors of jack cover.

Recommended cleaning agents:

Alcohol (Ethanol 70%, Iosopropanol 70%, Window cleaner)

Ammonias (Dilution of ammonia <3%, Window cleaner)

Tensides (dishwasher detergents) (Edisonite schnellreiniger®, Alconox®)

Cables and Lead wires

CAUTION
Do not use acetone or keytone solvents for cleaning; do not use an autoclave or steam cleaner.

Cables and lead wires can be cleaned with a warm, damp cloth and mild soap, or isopropyl alcohol wipes. For more intensive disinfecting (near sterile) Ethylene Oxide (ETO) is acceptable but will reduce the useful lifetime of the cable or lead wire.

CAUTION
The decision to sterilize must be made per your institution's requirements with an awareness of the effect on the integrity of the cable or lead wire.

Note
The Equipment needs safety inspection once a year. Please refer to user's guide or service manual for the examine objects.

Please check carefully both frame and sensor, after cleaning the Equipment, Do not use the equipment that is worn out or damaged.

At least once a month, clean and wipe off the frame by using the soft cloth after wetting it with water and alcohol. Do not use lacquer, thinner, ethylene, and oxidizer which may leads damage to the equipment.

Make sure both cables and accessories are free of dust or contaminants, and wipe them off with soft cloth wetted with warm water (40°), and at least once a week, clean them by using the clinical alcohol.

Do not submerge the accessories under any liquid or detergent. Also, make sure any liquid not to penetrate into the Equipment or probe.

Disinfecting

Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

Clean equipment before disinfecting.

Recommended disinfecting agents:

Aldehyde based (Cidex® activated dialdehyde solution, Gigasept)

Alcohol base (Ethanol 70%, Isopropanol 70%, Spitacid®, Streilium fluid®, Cutasept®, Hospisept®, Tinktur forte, Sagrosept®, Kodan®

Caution
Do not dispose single use probe to any hazard place, Always think about environmental contamination.

Caution
There is back-up battery on board inside system. When users dispose this battery, Please waste proper place for environmental protection.

Warning
Check the electrodes of batteries before changing them.

· Operate BM7 with internal electric power supply when unsure of external ground connection or installation occur.

· Remove the 1st Battery when not using equipment for a while without any damage.

For other applied parts such as temperature sensors, pulse oximetry probes, and NBP cuffs, you must consult the manufacturer for cleaning, sterilization, or disinfecting methods.

1.3 Product Components

Product Outline

BM7 monitor is a product used for monitoring biological information and occurrence of a patient. Main functions of the product include displaying information such as ECG, respiration, SpO2, NIBP, IBP, Gas monitoring, Cardiac Output, CSM and temperature on its LCD screen and monitoring parameter, and alarming. It also prints out waves and parameters via a printer. Bionet monitor offers a monitoring solution optimized for surgical, cardiac, neonatal care environments with patient surveillance and data managements.

Principal Characters of Product

BM7 is small-size multifunctional monitoring equipment for a patient designed to an easy usage during movement. It features DC power supply (Bridgepower,BPM050S18F02,DC 18V,2.8A) as well as installing its handle to the patient's bed. The equipment also measures major parameters such as ECG, respiration rate, SpO2, pulse rate, NIBP, IBP, Gas monitoring, Cardiac Output, CSM and temperature, displaying them on a 12.1-inch color LCD screen. It also enables users to check waves and parameters and other vital signs of a patient via the 58mm thermal printer and monitor the patient by the remote-controlled alarm system. It also enables to build a central monitoring system by linking devices used for separate patients so that one can monitor several patients at a time. USB/SDCARD slot is used to copy the stored trend data or read the patient id using a barcode reader. It is space to insert an additional battery to use if you need to maintain the battery for an extended period of time, an extra battery.

Warning
Use only the supplement accessories provided by us. Otherwise, patient and user may exposed to danger.

Warning
BEFORE USE — Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately. Before using the system, the operator must verify that it is in correct working order and operating condition. Periodically, and whenever the integrity of the product is in doubt, test all functions.

Product Configuration

1. Main body of BM7 Monitor	1 EA
2. 5-Lead patient Cable	1EA
3. Disposable electrodes	10 EA
4. NIBP extension horse	1EA
5. Reusable Adult NIBP Cuff	1EA
6. SpO2 extension cable	1EA
7. Reusable Adult SpO_2 Probe	1 EA
8. DC Adaptor (BPM050S18F02 made in Bridgepower Co., Ltd.)	1 EA
9. Operator`s Manual	1 EA
10. Thermal roll Paper	2ROLL

Option Product

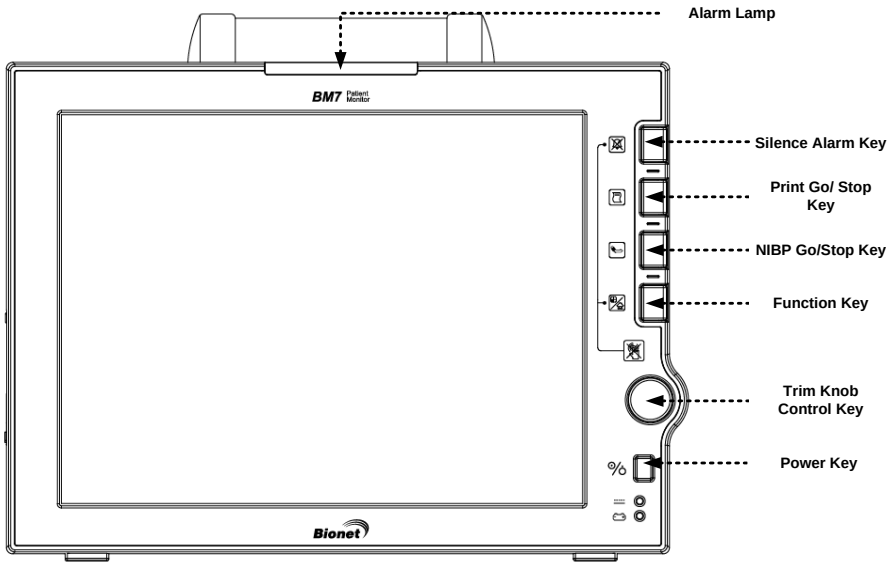
1. Reusable Temperature Probe (Surface/Skin, TEMPSENS-430)	1 EA
2. IBP Transducer Set (Disposable/Reusable)	1 SET
3. Sidestream EtCO2 Module (Respironics)	1 SET
4. Mainstream EtCO2 Module (Respironics)	1 SET
5. Sidestream EtCO2 airway adapter sampling kit	1 EA
6. Mainstream EtCO2 airway adapter	1 EA
7. 3-Lead Patient Cable (MECA3-US, MECA3-EU)	1 EA
8. 10-Lead Patient Cable (MECA10-US, MECA10-EU)	1 EA
9. Sidestream Multigas Module (Masimo Sweden)	1 EA
10. Mainstream Multigas Module (Masimo Sweden)	1 EA
11. Sidestream Multigas Nomoline	1 EA
12. Sidestream Multigas Nomoline adapter	1 EA
13. Sidestream Multigas Nomo Extension	1 EA
14. Sidestream Multigas T-adapter	1 EA
15. Mainstream Multi-gas IRMA Airway Adapter (Adult/ Pediatric)	1 EA
16. Mainstream Multi-gas IRMA Airway Adapter (Infant)	1 EA
17. CSM 3lead electrode cable	1 EA
18. CSM Procedure pack (electrode for CSM)	1 EA
19. Swan-Ganz Thermodilution Catheter kit	1 EA
20. AVA introducer catheter	1 EA
21. Interface Cable (PAT-ICO-CABLE)	1 EA
22. Bath Temperature Probe	1 EA

Warning
In order to avoid electrical shock, do not open the cover. Disassembling of the equipment should be done only by the service personnel authorized by BIONET

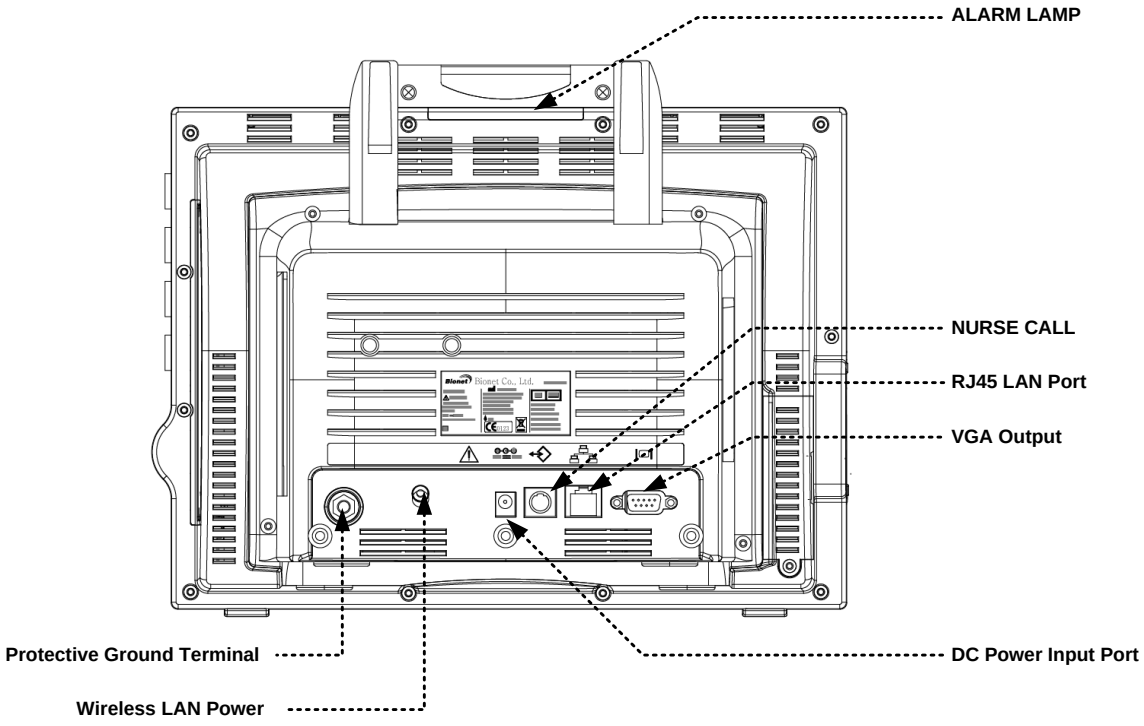
Warning
Users must pay attention on connection any auxiliary device via LAN port or nurse calling. Always consider about summation of leakage current, please check if the auxiliary device is qualified by IEC 60601-1, or consult your hospital biomedical engineer.

Features of Main Body

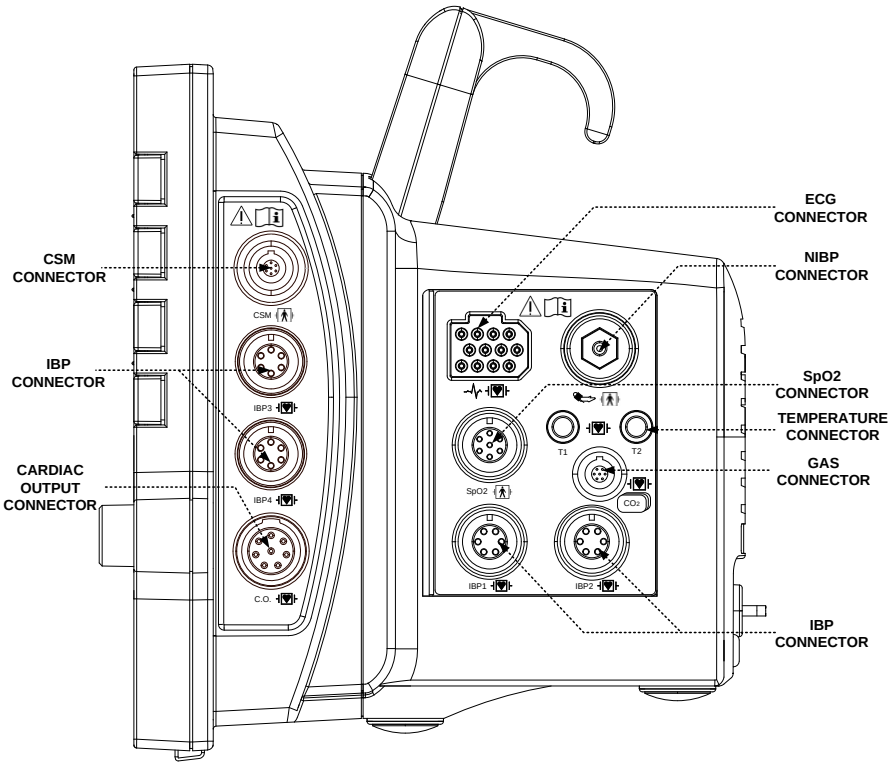
FRONT



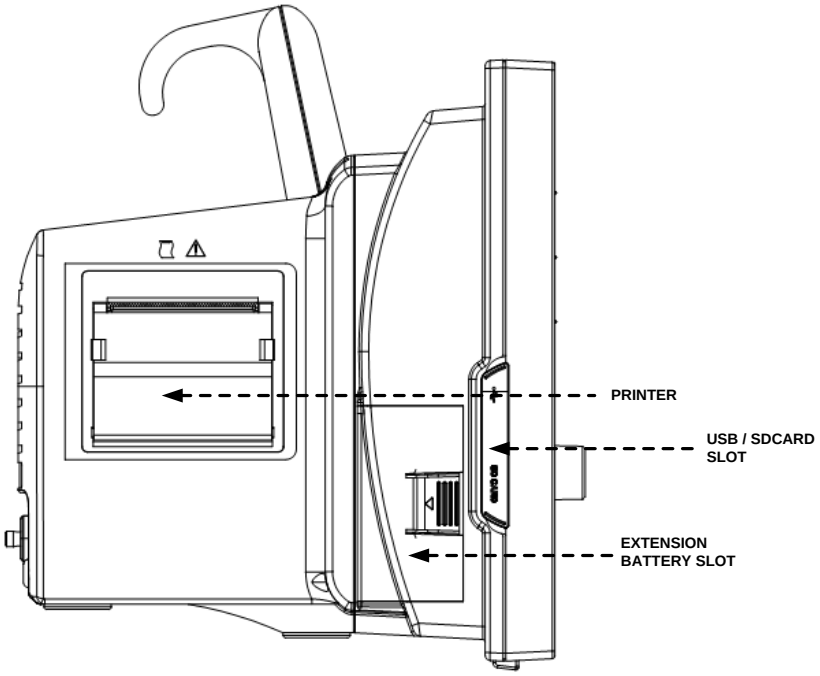
BACK



Right Side



Left Side



Accessories

ECG Cable

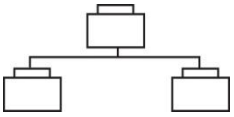
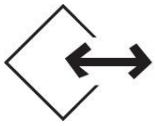
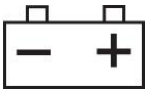
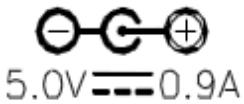
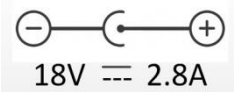
SpO_2 Cable +
Extension Cable

NIBP Cuff+
Extension cable

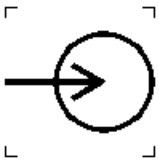
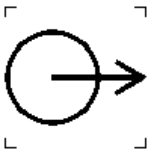
Temperature
sensor (Option)

Equipment Sign

	ATTENTION : Consult accompanying documents
	General prohibition sign And Template for constructing a prohibition sign NOTE Background color: white Circular band and slash: red Symbol or text: black
	TYPE CF APPLIED PART : Insulated (floating) applied part suitable for intentional external and internal application to the patient including direct cardiac application. "Paddles" outside the box indicate the applied part is defibrillator proof. Medical Standard Definition : F-type applied part(floating/insulated) complying with the specified requirements of IEC 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide a higher degree of protection against electric shock tan that provided by type CF applied parts.
	TYPE BF APPLIED PART : Insulated (floating) applied part suitable for intentional external and internal application to the patient excluding direct cardiac application. "Paddles" outside the box indicate the applied part is defibrillator proof. Medical Standard Definition : F-type applied part (floating/insulated) complying with the specified requirements of IEC 60601-1/UL 2601-1/CSA 601.1 Medical Standards to provide a higher degree of protection against electric shock than that provided by type BF applied parts.

	**Ground**
	**Printer**
	**Serial Port**
	**LAN Port**
	**AUX Connector Port**
	**DC Input Indicator**
	**DSUB 15pin external VGA port**
	**Battery Operation Indicator**
	**WIRELESS LAN power output Port**
	**DC Input Connector**

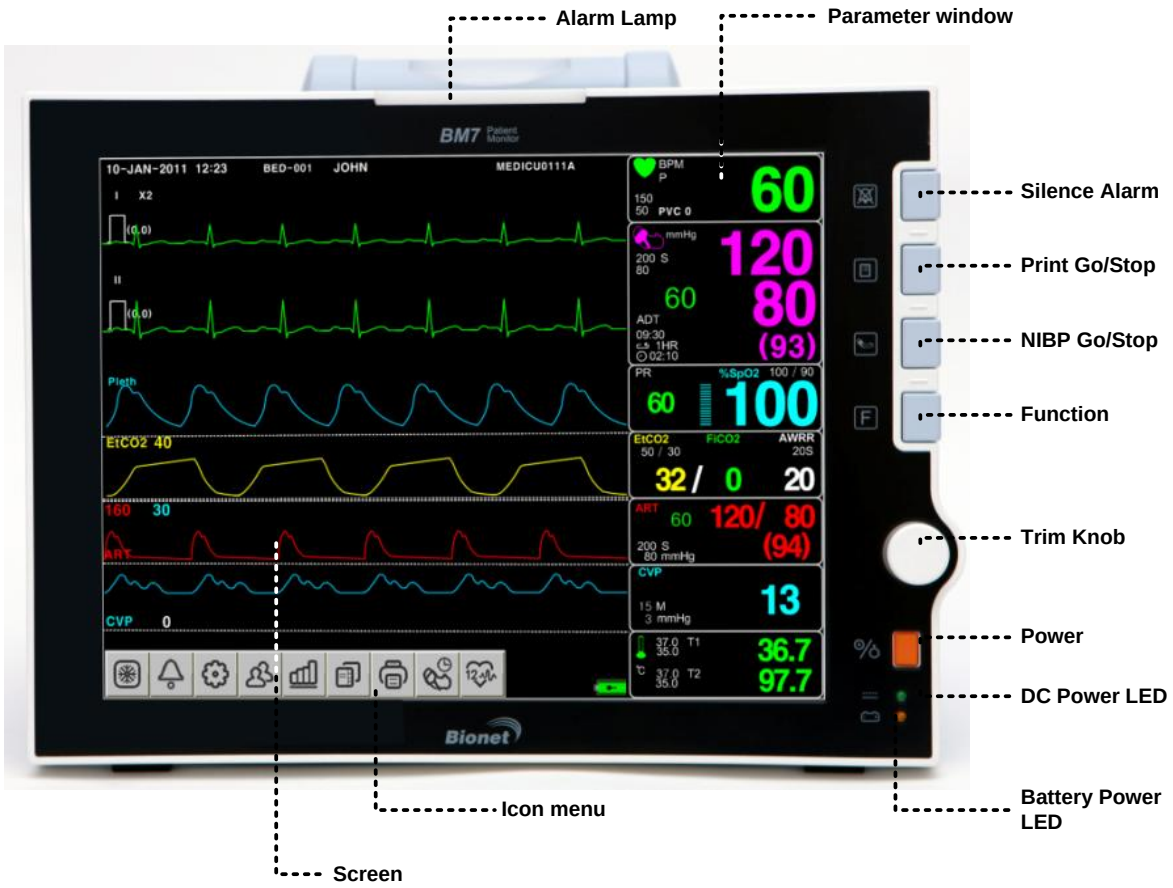
	**USB PORT**
SD CARD	**SD CARD PORT**
	**SCREEN Swap / HOME Return**
	**TOUCH SCREEN LOCK**
	**NIBP**
	**Temperature**
	**Function**
	**Power on**
	**Power off**
	**Respiration**
	**ECG**
	**Heart Pulse**

	To identify an input terminal when it is necessary to distinguish between inputs and outputs.
	To identify an output terminal when it is necessary to distinguish between inputs and outputs.
	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell.

1.4 Function and Key

External Function

The front panel of this product consists of an LCD screen and five function keys and one trim knob.



Operation Key

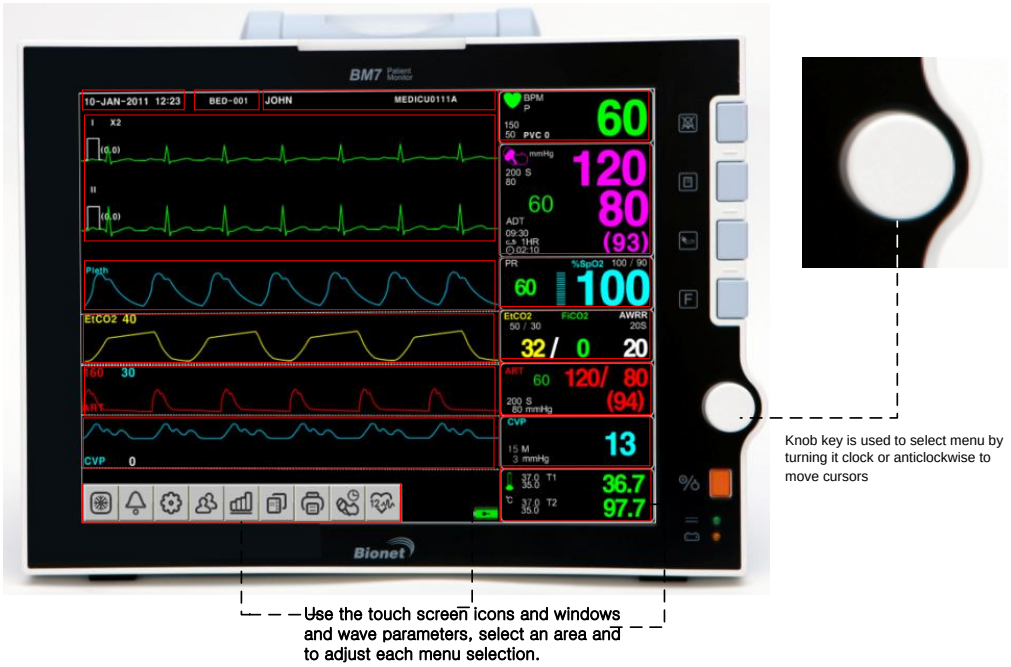
1. Power：Switches on and off the Power.
2. Function Key
3. Blood Pressure：Manually completes measuring blood pressure.
4. Printer：Prints out the waves selected from the menu until the key is pressed to stop.
5. Alarm： Stop alarm sound and lamp.
   First press stops the current alarm for one minute
   Second press stops the all alarm for two minutes.
   Third press will continue to stops the all alarm.
   Forth press makes the alarm back to the original setting.
6. Trim Knob：This key is used to select menu by turning it clock or anticlockwise to move cursors.
7. Alarm + Function: Touch screen, key, rotary wheel lock function on and off.

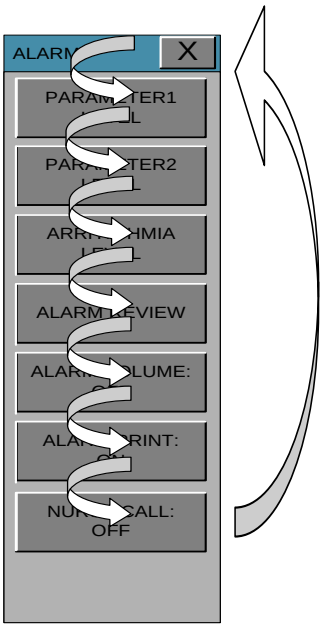
Lock : Press the alarm and function key at the same time until lock icon is displayed.

Unlock : Press the alarm and function key at the same time until Unlock icon is displayed.

Lock icon

Unlock icon





1.5 Standard Power Supply Application

DC Power

- Product information

Manufacture: Bridgpower corp.

Model name: BPM050S18F02

Input power:

Rated Voltage 100 – 240V

Rated Line Frequency 50 – 60 Hz

Current 1.5A Max at 100 VAC input

Protection Internal primary current Fuse (2.0A)

Output power:

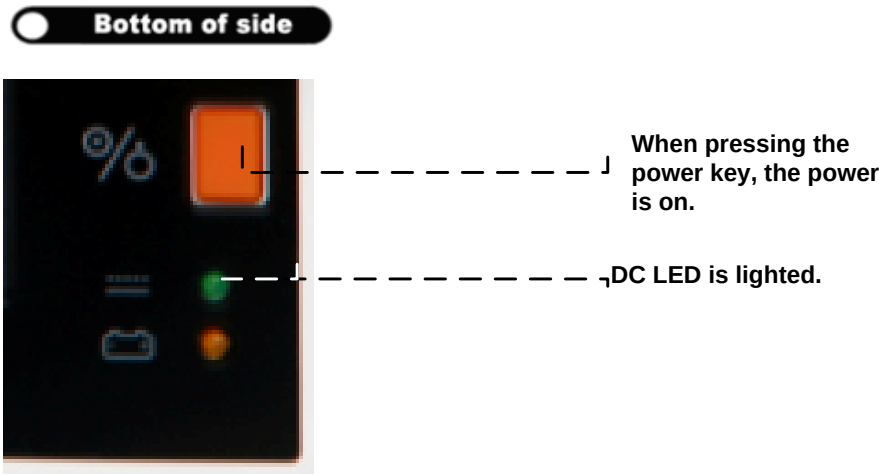
Capable of supplying +18VDC at 2.8A

Voltage +18VDC +/- 5%

Over current Protection 3.36 – 5.6A

DC Power LED is lighted on when the DC Power is plugged into the inlet at the back of the product.

A press of power key makes the machine ready for use.

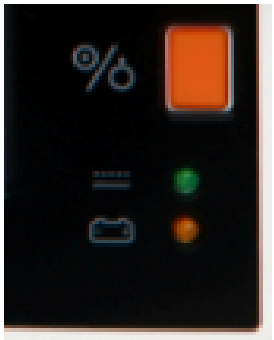


Warning
This equipment must only be connected to supply mains with protected earth. Noise or distortion of signals using non-off-the-shelf products rather than adapters supplied by our company may be caused. Also dangerous to the safety related isolation and protection by using the adapter supplied by our company in order to give

1.6 Battery Power Supply Application

Battery power can be supplied for enabling a portable use or a use during DC power failure.
Further expansion equipment is mounted on the bottom of the battery; the battery is connected to the left side.

Operation



1. Battery Power LED is lighted on when the machine is in use.

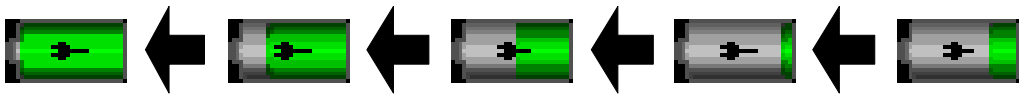
2. The DC/battery power is only sustainable for 2 hour and half.

3. Battery is automatically charged when the machine is connected to DC Power Supply. Battery LED is lighted on after blinking.

4. The charging status of the batteries is displayed with 5 green boxes, each indicating a different charging. (0% -> 25% -> 50% -> 75% -> 100%)

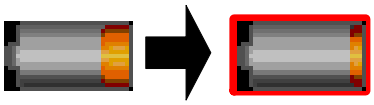
- Battery code: 151900-009003 (10.8V - 4400mA, Li-ion)

The Lithium-Ion battery is a rechargeable battery containing Lithium-Ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.



5. The discharge condition of battery is indicated with on of 5 yellow boxes, each box showing a different level of charge available.
   (100% -> 75% -> 50% -> 25%)

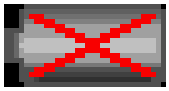
When remained battery is less than 25%, the battery icon box is turned to red one with blink. The device will be turned off automatically after 5 minutes from that warning sign. In case of that warning sign with red and blink at icon box, charge the device immediately with DC power adaptor which is provided from BIONET.



- Battery charging time: More than 6 hours/ include extension battery 10hours
- Continuous battery use time: Lowest 1 hour to highest 2 hours continuous use (buffering)
- Using additional battery Continuous use time: at least 3 hours up to 4 hours or more (when fully charged)

Warning
Check the electrodes of batteries before charging them.

6. Battery status indication: When battery is apart from equipment and out of order, it is shown by a red `X' as shown below.



7. Low power supply: When an low power uses less than 16V, the battery indication disappears and

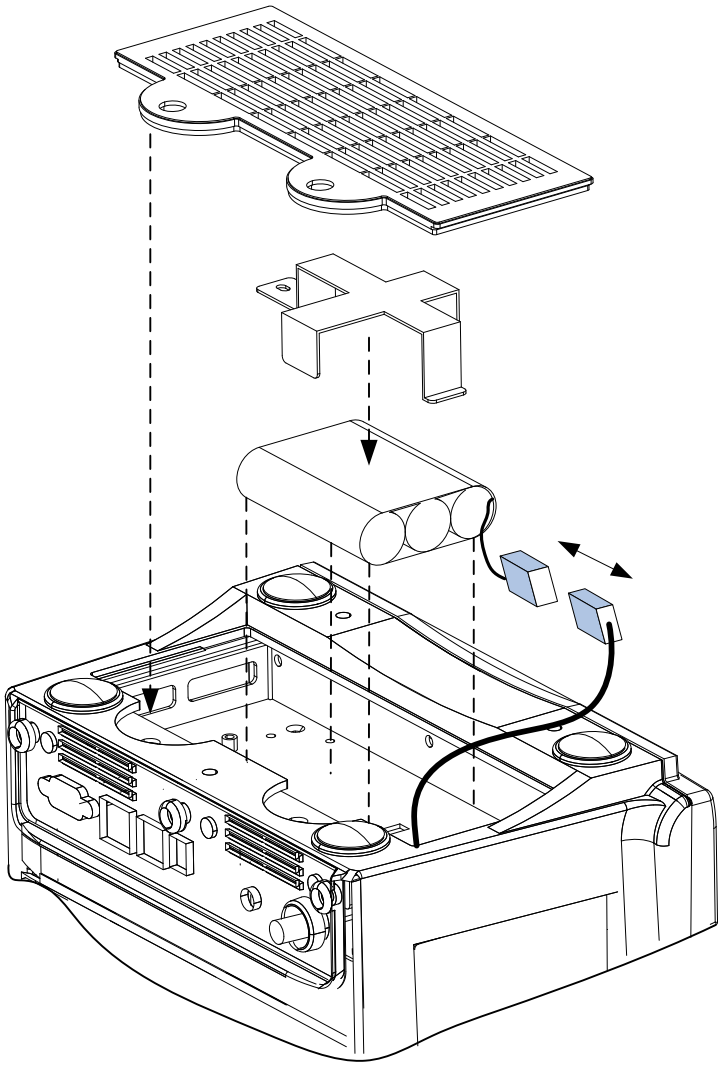
the ”LOW” indication is active.

Display of low power

Note
Battery is not charged when the automobile power is used. It cannot be used if the 24V automotive power. When the batteries are replaced, remove and replace the DC adapter.

Insert and remove of the battery pack.

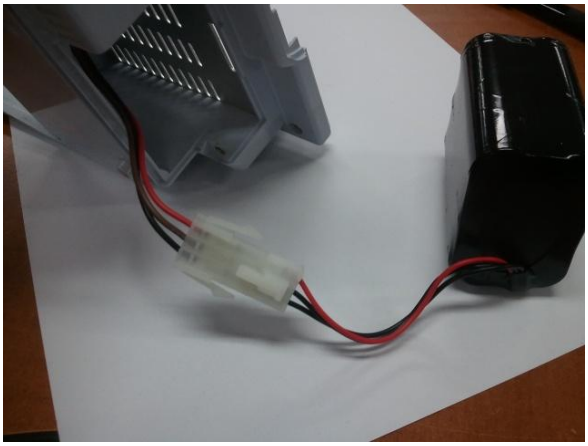
It is assembly or replacement, as shown in the figure below.



The Extra Lithium-Ion Battery Information, and How to replace

Additional battery module is available as an option, as shown below for extended battery life.

Battery code: 151900-044300 (10.8V - 4400mA, Li-ion)

	
1. Open the battery cover screws using (+)screwdriver on the left side of BM7	2. While pressing the battery cover by sliding back and opens.
	
3. Connect the connector located on the inside of the battery cover and the battery connector.	4. Puts in the battery housing.

	
5. Close the back cover.	6. Using (+) screwdriver to close the screw

The Impact of Lithium-Ion Battery Technology on the Battery

The following are the key points you should know about Lithium-Ion battery technology:

The battery will discharge on its own, even when it is not installed in a monitor. This discharge is the result of the Lithium-Ion cells and the bias current required for the integrated electronics.

By the nature of Lithium-Ion cells, the battery will self-discharge.

The self-discharge rate doubles for every 10°C (18°F) rise in temperature.

The capacity loss of the battery degrades significantly at higher temperatures.

As the battery ages, the full-charge capacity of the battery will degrade and be permanently lost. As a result, the amount of charge that is stored and available for use is reduced.

Conditioning Guideline

the battery in the monitor full charged and discharged every six months and condition it using the battery charger.

Storage Guideline

Store the battery outside of the monitor at a temperature between 20°C to 25°C (68°F to 77°F).

When the battery is stored inside a monitor that is powered by an AC power source, the battery cell temperature increases by 15°C to 20°C (59°F to 68°F) above the room's ambient temperature. This reduces the life of the battery.

When the battery is stored inside a monitor that is continuously powered by an AC power source and is not powered by battery on a regular basis, the life of the battery may be less than 12 months. BIONET recommends that you remove the battery and store it near the monitor until it is needed for transport.

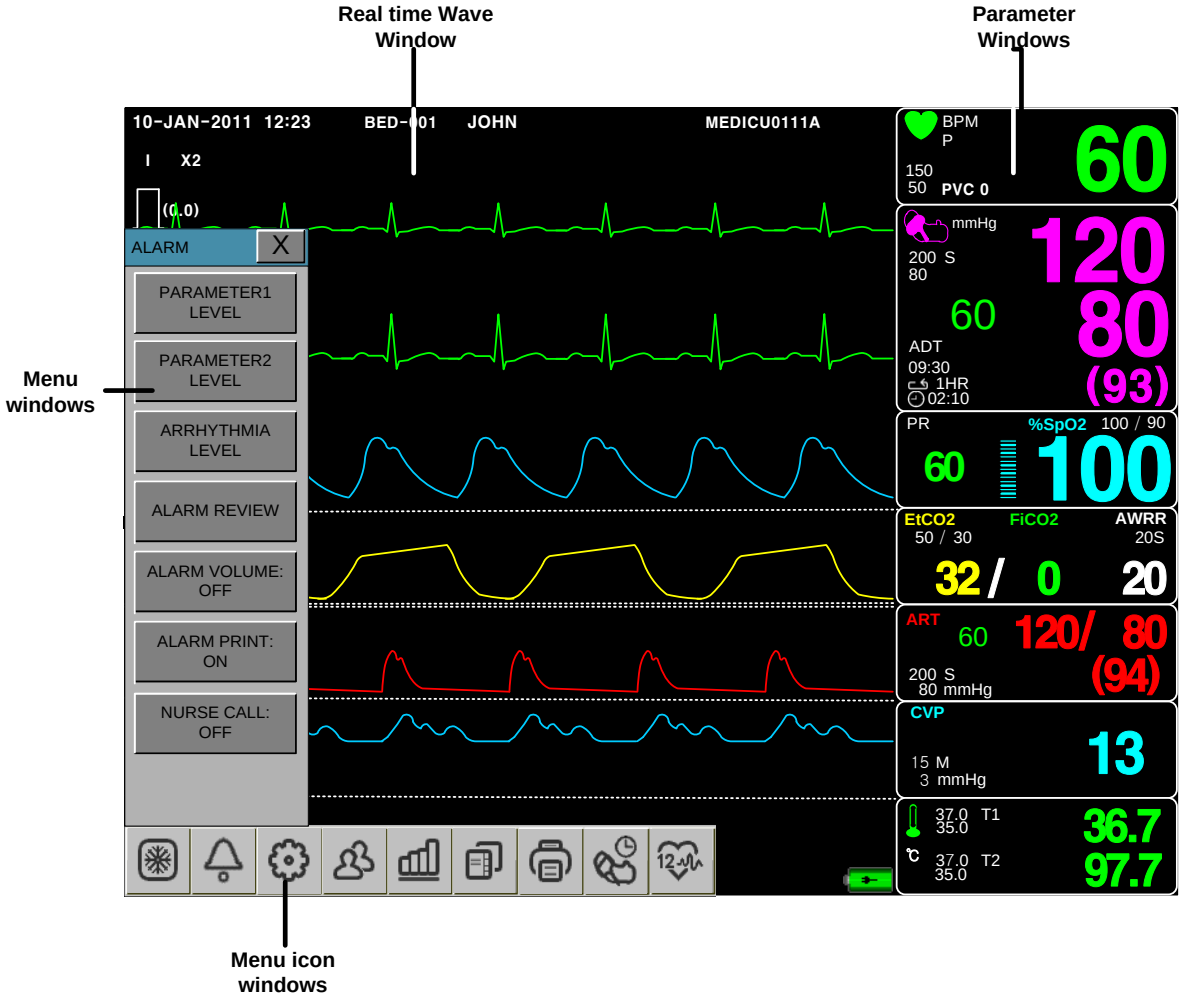
How to Recycle the Battery

When the battery no longer holds a charge, it should be replaced. The battery is recyclables. Remove the old battery from the monitor and follow your local recycling guidelines.

WARNING
EXPLOSION HAZARD — DO NOT incinerate the battery or store at high temperatures. Serious injury or death could result.

1.7 General Manu Operation

Screen Composition



Real Time Wave Window : Displays measured results by up to seven waves.

Menu icon windows: A menu displays icons for each function.

Menu Select Window : Menus appear when they are activated..

Parameter Window : Measured and setup data are displayed in five windows.

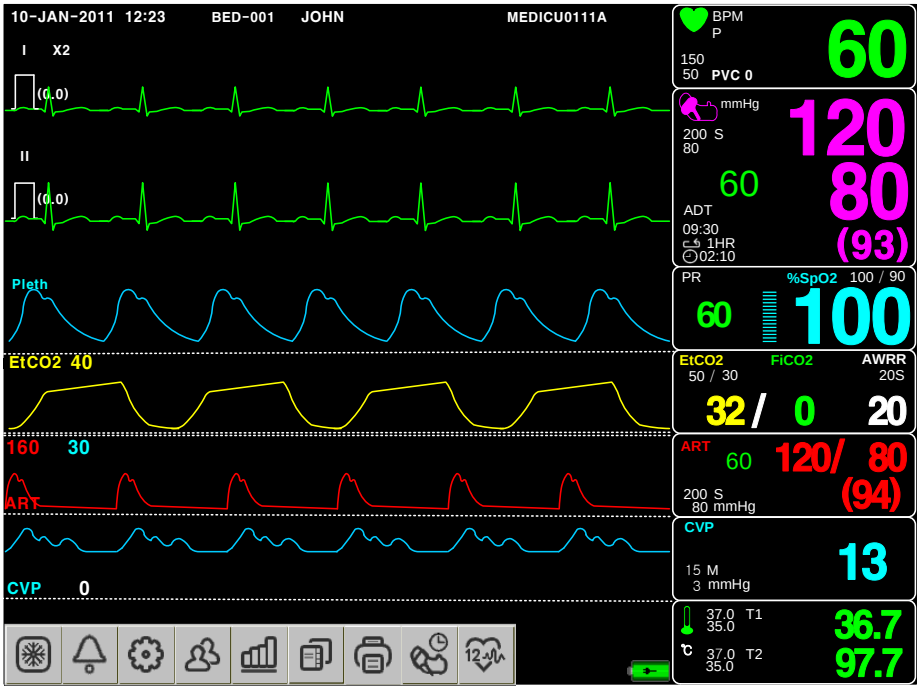
12CH diagnostic menu icon is supported on 12ch ECG select models only.

The screen consists of a total of two modes

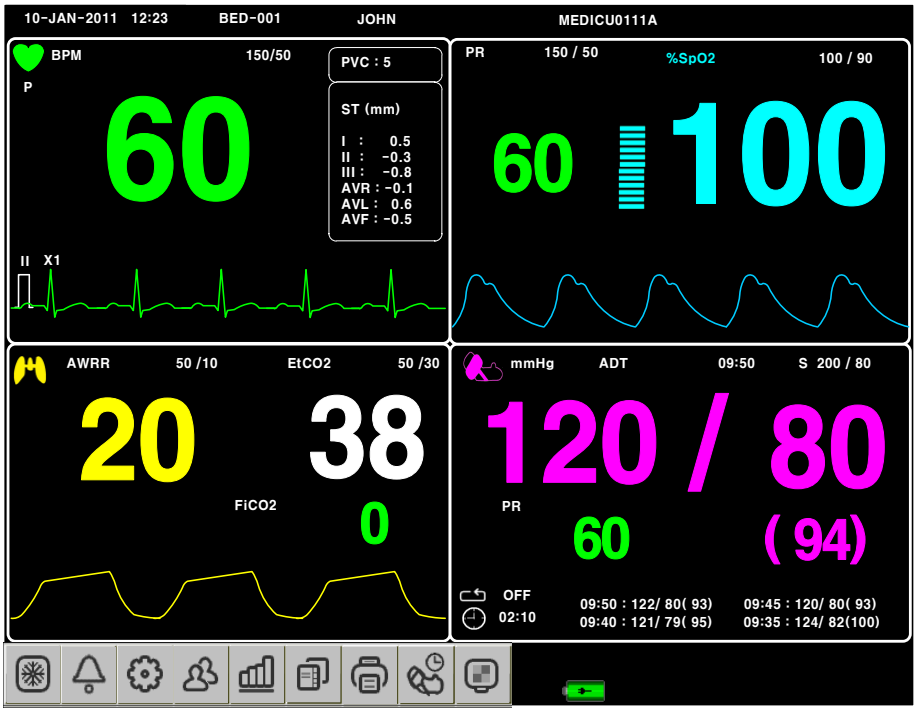
NORMAL MODE: As the figure shows the waveform parameters of the screen

PARAMETER MODE: Selected figures show only the 4 parameters of the screen

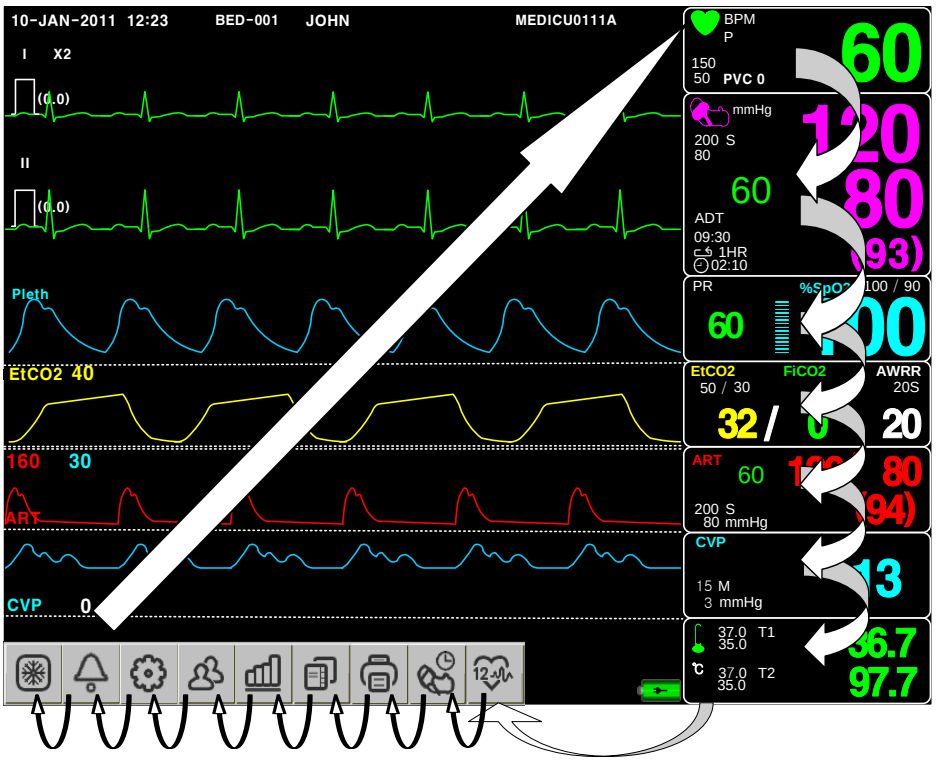
NORMAL MODE



PARAMETER MODE



Menu Selection



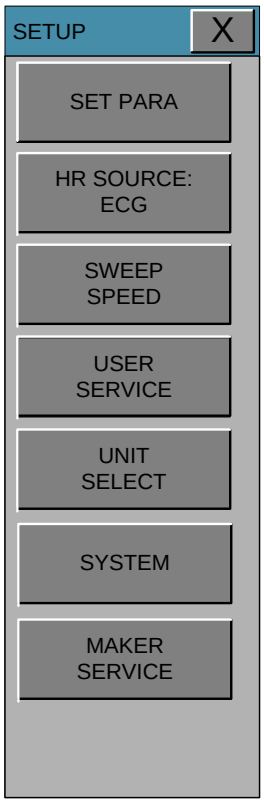
Turn or press the knob .

When the Trim Knob Key is turned, menus are selected in the order indicated above. The above screen shows that the MORE menus is selected. The menus move to the right in the order of MORE MENU → ECG → NIBP →SpO_2 → RESP (EtCO2) → IBP1 → IBP2 → TEMP. An inactivated window is jumped off.

Menu Composition

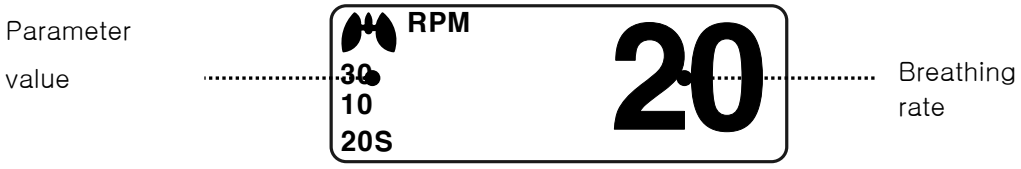
More Menu Window

When the additional menu is selected it will set and cancel the functions.



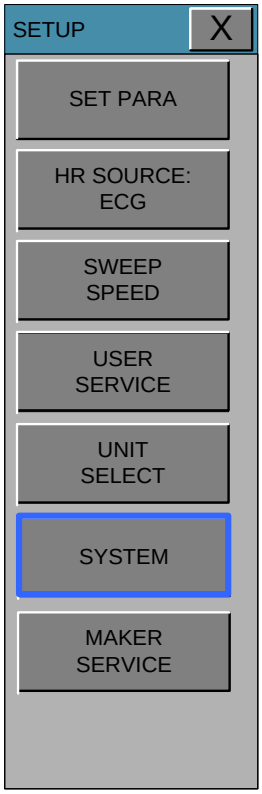
Numerical value sign widow

This window displays a measured parameter, function setup, and the boundary of parameter values.



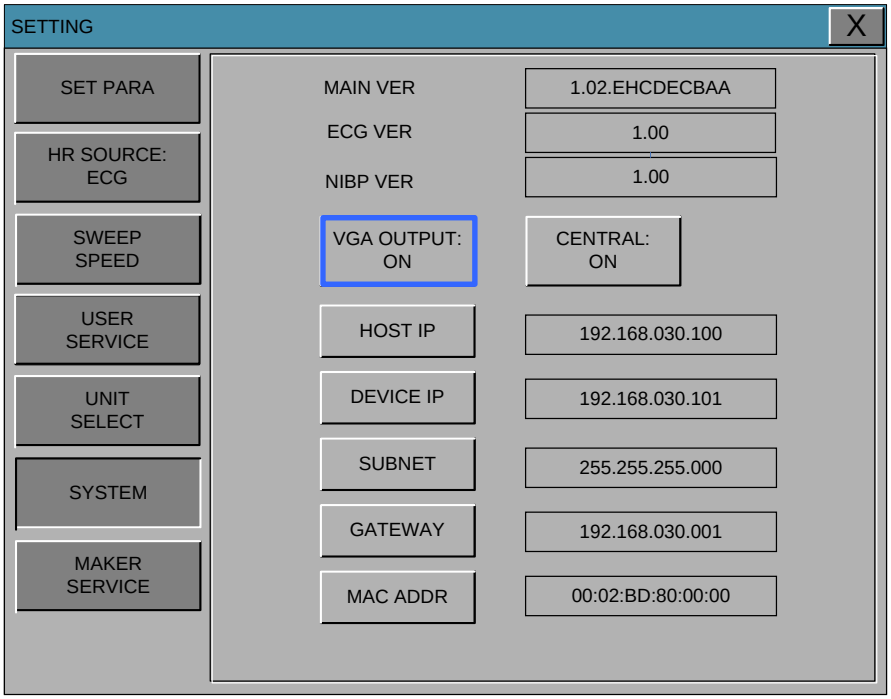
Menu selection by using Trim Knob key

As the key is turn to the right, the menu selection moves clockwise. As the key is turn to the left, the menu selection moves counterclockwise. The menu selection is activated when you depress Trim Knob key.



Menu selection with touch keys

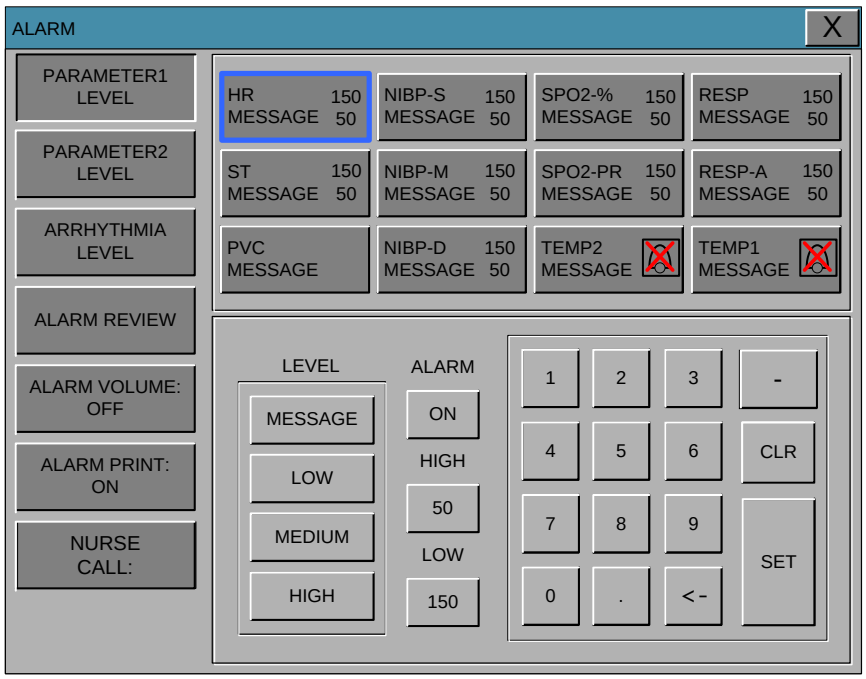
Touch the desired menu, the menu can be selected.



Word feature menu

The following figure shows the screen where the word sequence menu is activated within the word sequence correction menu. Here, the cursor moves over the words when the Trim Knob key is turned in the clockwise direction.

Touch the desired menu box, select the menu is available

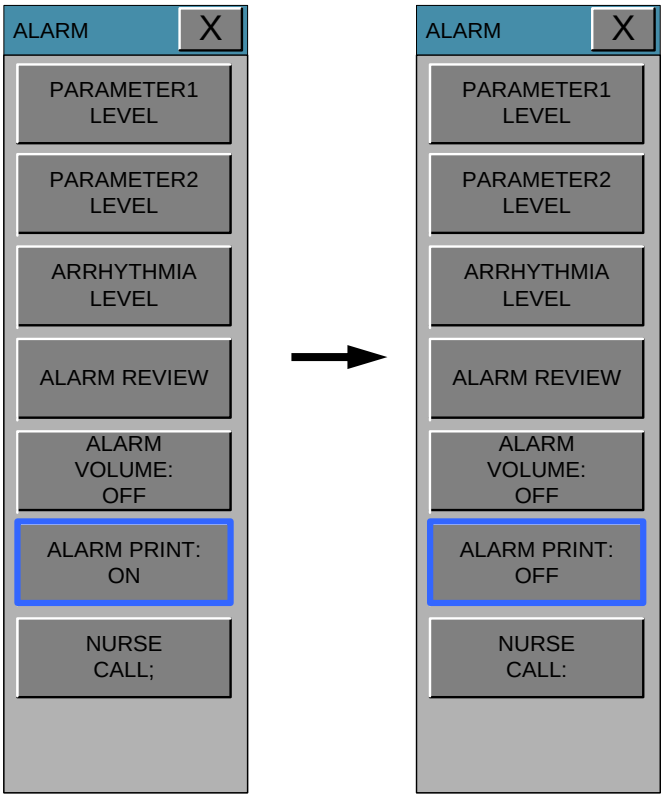


Word feature menu

The following figure shows the screen where the word sequence menu is activated within the word sequence correction menu. Here, the cursor moves over the words when the Trim Knob key is turned in the clockwise direction. To enter letters and numbers at the touch of their letters and numbers after the 'SET' button is pressed

Operation menu

The setup value changes without a selection when the menu is moved.



Networked Monitoring

You can connect your monitor to an Information Center on a network, using one of the optional interfaces:

• Standard wired LAN

• Wireless LAN

• in the monitor info line, select the bed label.

Be aware that some network-based functions may be limited for monitors on wireless networks in comparison to those on wired networks.

Warning
Do not connect patient monitors to the standard hospital network

2. PATIENT/DATA MANAGEMENT

2.1 ADMIT

ADMIT/DISCHARGE

ADMIT TYPE

CHANGE ADMIT INFO

DEFAULT SETTING

WEIGHT UNIT

HEIGHT UNIT

DRUG CALL

2.2 ALARM

PARAMETER1 LEVEL

PARAMETER2 LEVEL

PARAMETER3 LEVEL

ARRHYTHMIA LEVEL

ALARM REVIEW

ALARM VOLUME

ALARM PRINT

NURSE CALL

Additional setups are made for each parameter function. One can make an overall setup for the entire monitor system.

2.1 ADMIT

ADMIT / DISCHARGE

ADMIT TYPE

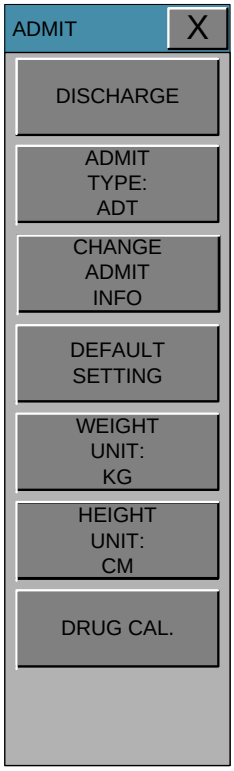
CHANGE ADMIT INFO

DEFAULT SETTING

WEIGHT UNIT

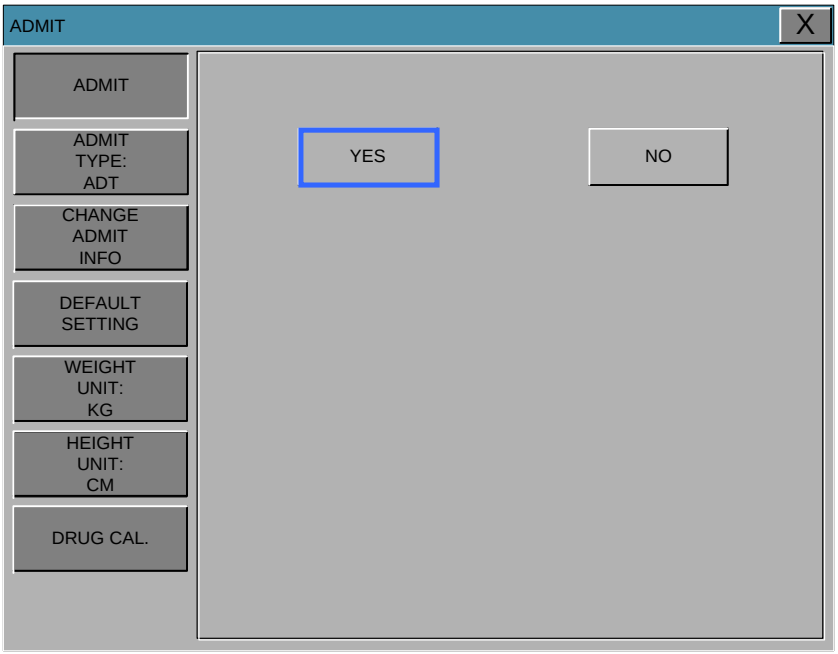
HEIGHT UNIT

DRUG CAL.



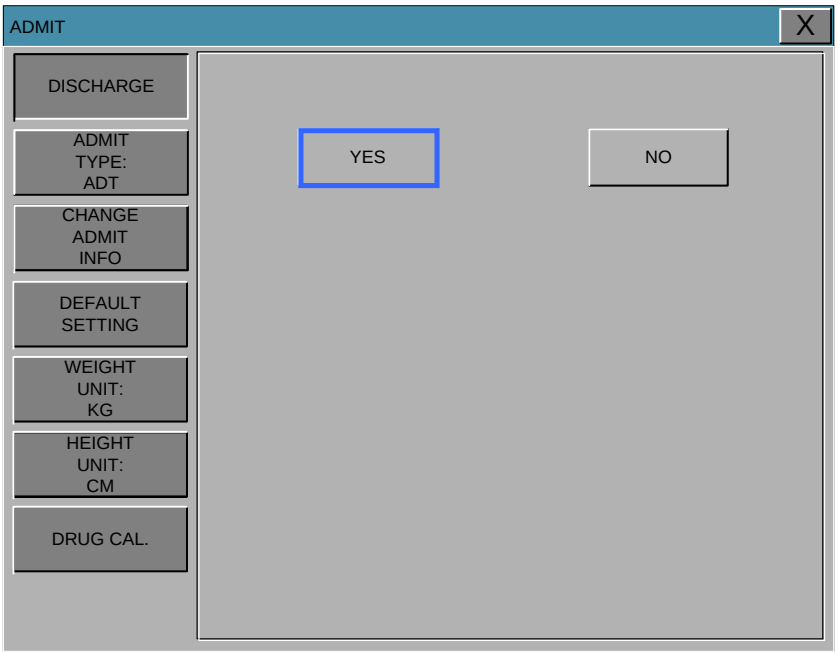
ADMIT

Data set of patients who Trent to start saving, and apply the appropriate settings.



DISCHARGE

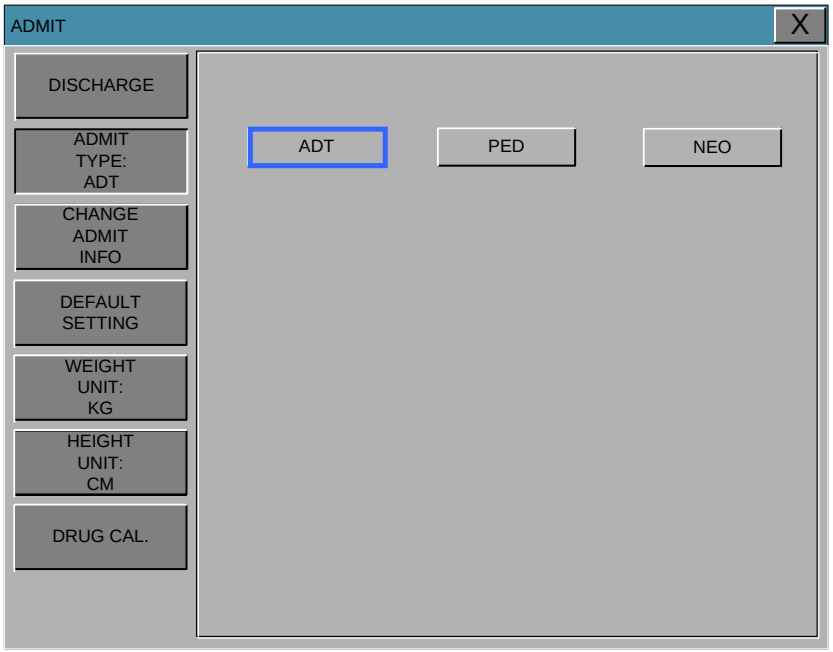
Patient information and all numbers change to standard, and the screen displays, "ALL ALARMS OFF ADMIT PATIENT TO ACTIVE ALARMS."



ADMIT TYPE

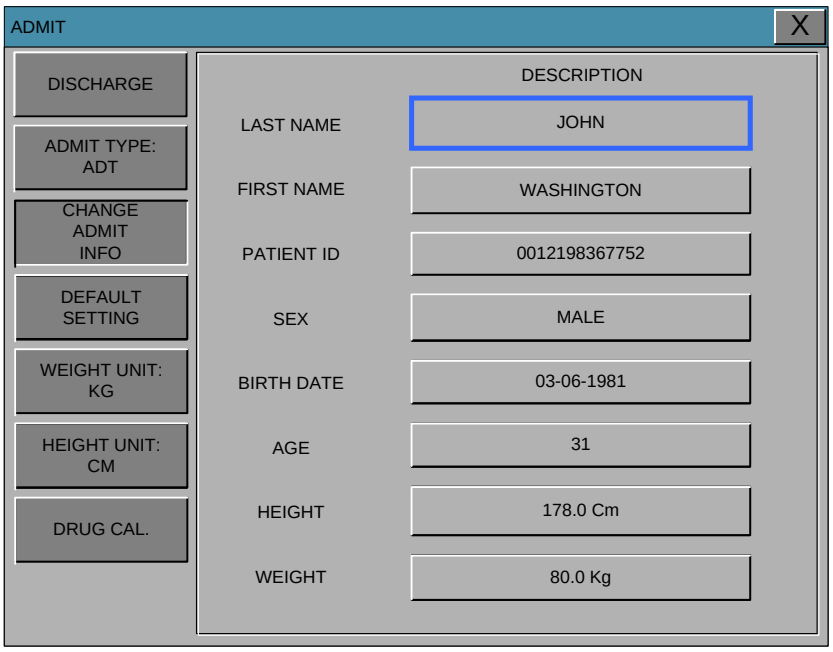
Set the exercise environment of equipment in discharge status.

ADU : ADULT // PED: PEDIATRIC // NEO : NEONATE



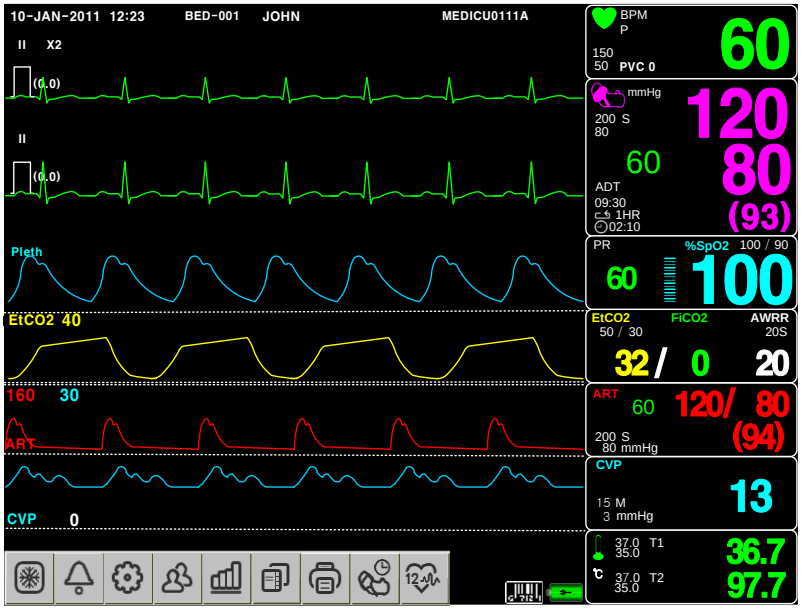
CHANGE ADMIT INFO

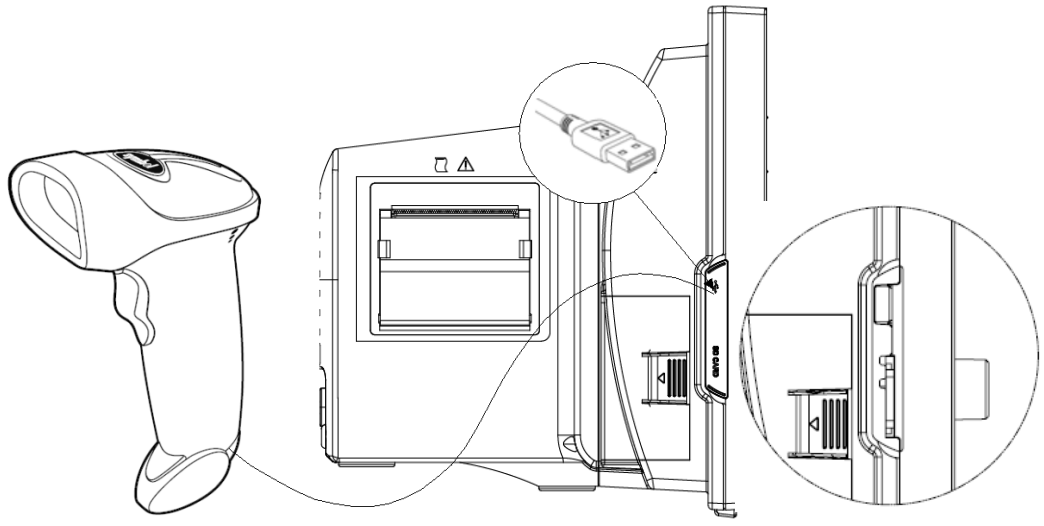
Last and first name (11 letters for each), sex (male or female), date of birth, weight, height, and patient ID (11 characters)



Using barcode PATIENT ID Registration

This product, you can enter the PATIENT ID in the form of a barcode using a USB barcode scanner to monitor Connect a barcode scanner to the USB HOST connector on the left side of the first, as shown in the figure below, BEEP sound after the equipment at the bottom of the screen appears barcode icon ( ) marked barcode available.



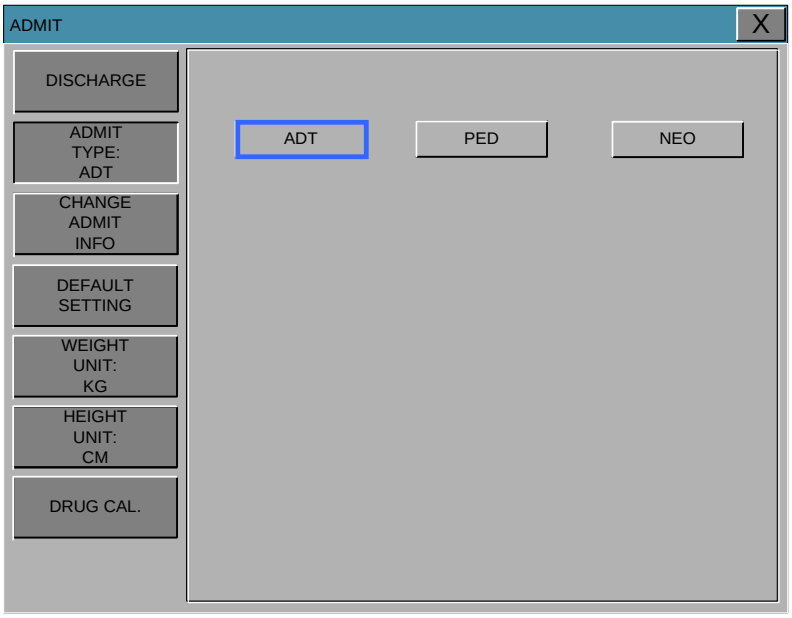


You want to input from a barcode scanner to index LED well focused, the corresponding button is pressed, the input ID and sends it to the monitor. Sender ID is displayed in the upper portion of the center of the screen.

ADMIT TYPE

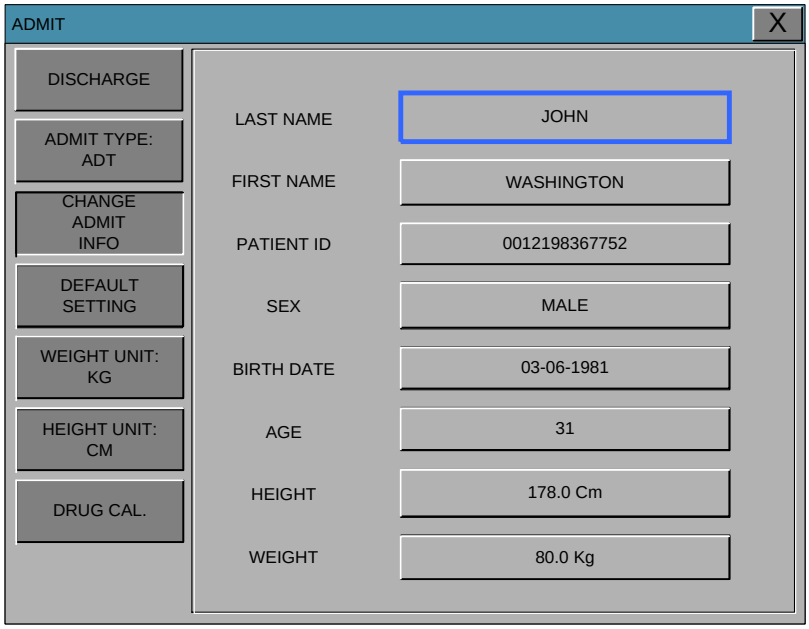
DISCHARGE set up the environment to use of the equipment in the state.

ADT: ADULT ICU // PED: PEDIATRIC ICU // NEO : NEONATE ICU



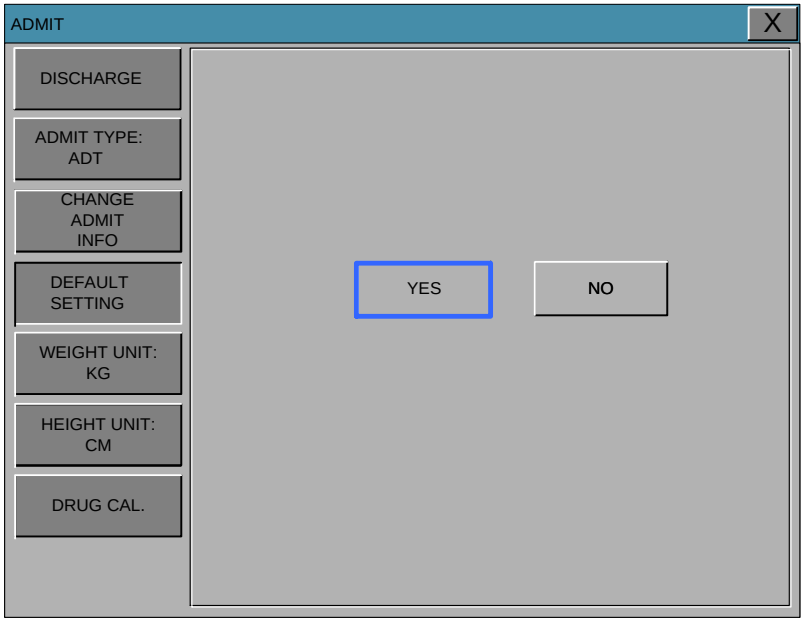
CHANGE ADMIT INFO

LAST FIRST name (each 11 digits), SEX (MALE, FEMALE), date of birth, weight, height, PATIENT ID (11 digits), AGE (age), each can be set.



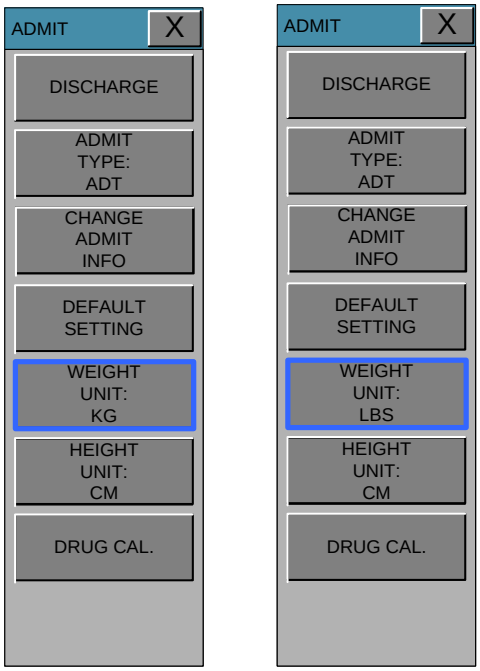
DEFAULT SETTING

Parameter range settings, alarm settings and patient specific initialization settings are initializing.



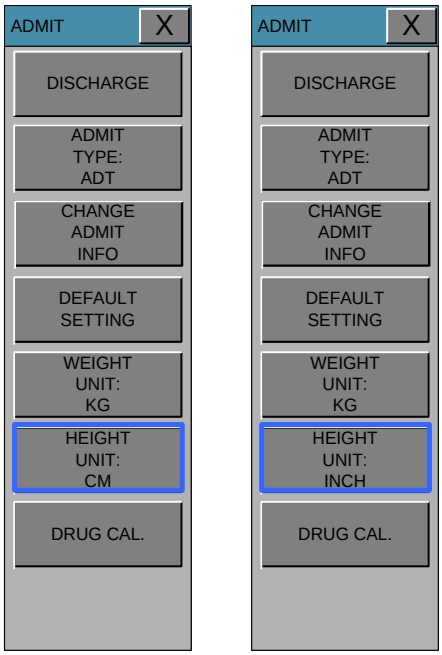
WEIGHT

Unit of weight is set as Kg / LBS.



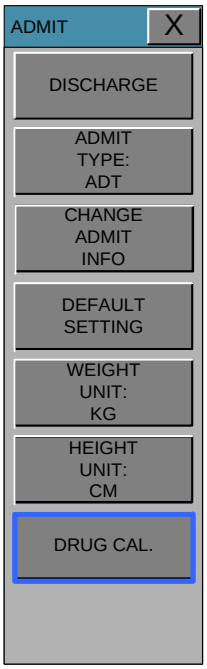
HEIGHT

Unit of height is set as Cm / Inch.



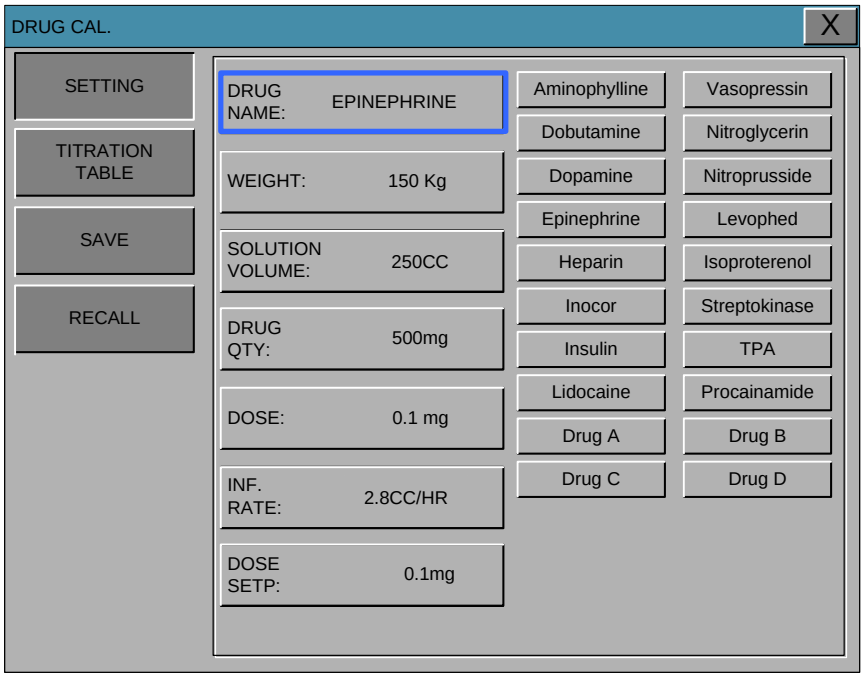
DRUG CAL.

The amount of the drug to the patient to inject a menu that automatically calculated.



SETTING

Medicine and the patient's weight is input by the input and calculate the amount to be injected is the menu. Menu to set parameters for calculating drug dosage: drug name, weight, solution volume, drug QTY, INF. Rate (DOSE/MIN, DOSE/HR, DOSE/KG/MIN, INF RATE, DIRP RATE, DROP SIZE, and INF TIME), etc.



Dosage Unit	Drug Name	Equation
mg/hr	AMINOPHYLLINE TPA	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mg/hr)} \times \text{SolutionVolume(ml)}}{\text{Drug QTY(mg)}}$
mg/min	BRETYLIUM LIDOCAINE PROCAINAMIDE	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mg/min)} \times \text{SolutionVolume(ml)} \times 60}{\text{Drug QTY (mg)}}$
mcg/min	EPINEPHRINE LEVOPHED ISOPROTERENOL	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mcg/min)} \times \text{SolutionVolume(ml)} \times 60}{\text{Drug QTY (mg)} \times 1000}$
Mcg/kg/min	DOPAMINE DOBUTAMINE NITROGLYCERINE NITROPRUSSIDE INOCOR	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mcg/kg/min)} \times \text{Weight(kg)} \times \text{SolutionVolume(ml)} \times 60}{\text{Drug QTY (mg)} \times 1000}$

units/hr	HEPARIN INSULIN	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(units/hr)} \times \text{SolutionVolume(ml)}}{\text{Drug QTY(units)}}$
IU/hr	STREPTOKINASE	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(IU/hr)} \times \text{SolutionVolume(ml)}}{\text{Drug QTY (IU)}}$

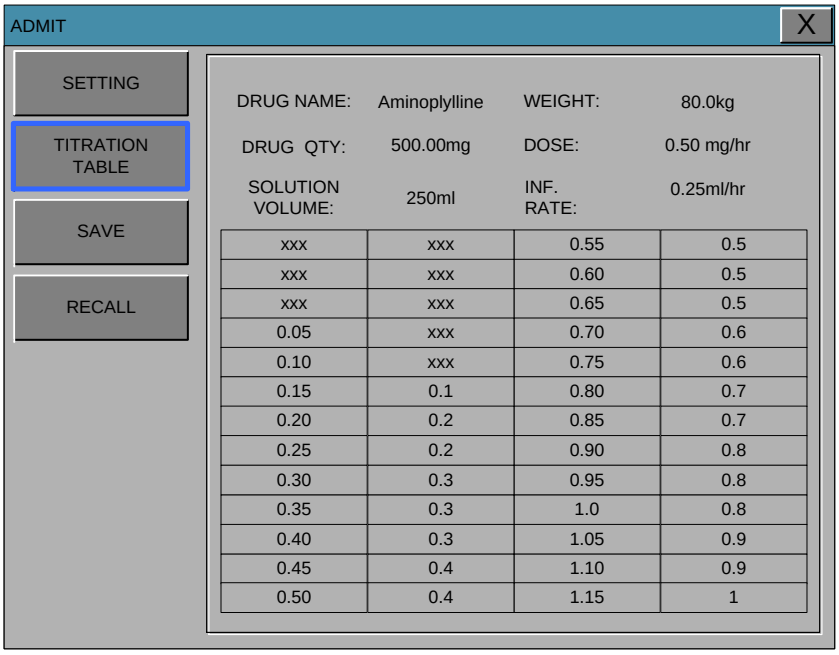
Dose		**Drug QTY**	
Unit	Setting range	Unit	Setting range
mg/hr	0.01 to 500	mg	0.01 to 2000
mg/min			
mg/kg/hr			
mg/kg/min			
mcg/hr			
mcg/min			
mcg/kg/hr			
mcg/kg/min			
units/hr	10 to 15000	Units	100 to 150000
IU/hr	1000 to 1500000	IU	1000 to 1500000

Item	**Unit**	**Drug QTY unit**
Solution Volume	mL	1 to 1000
Weight	Kg	0 to 300
Flow Rate	ml/hr	0.1 to 600

Note
If you see the value of the results outside the range displayed in the table above are marked "OUT OF RANGE"

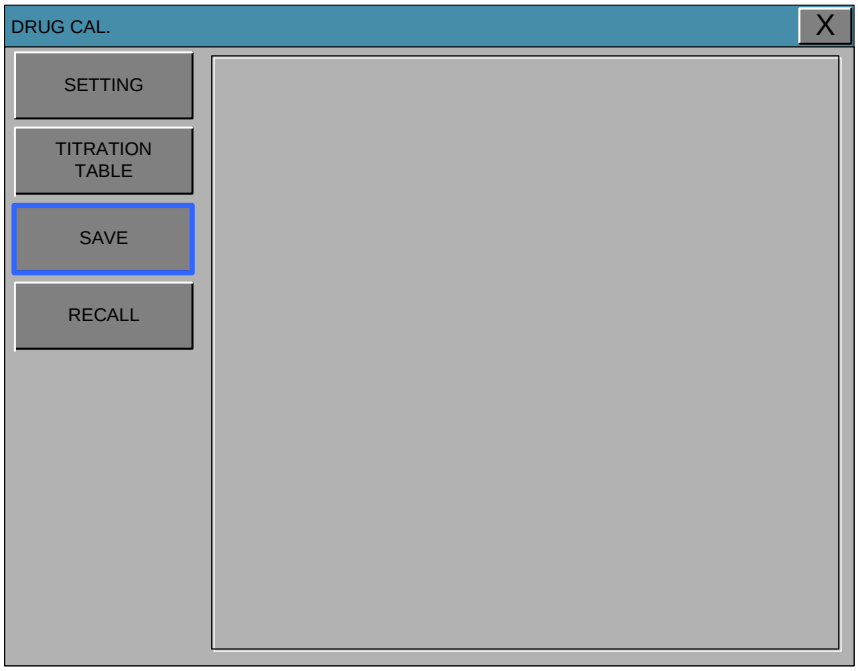
TITRATION TABLE

Display calculated drug dosage in a titration table using parameters such as drug name, weight, solution volume, drug QTY, INF. rate(DOSE/MIN, DOSE/HR, DOSE/KG/MIN, INF RATE, DIRP RATE, DROP SIZE, INF TIME), etc.



SAVE

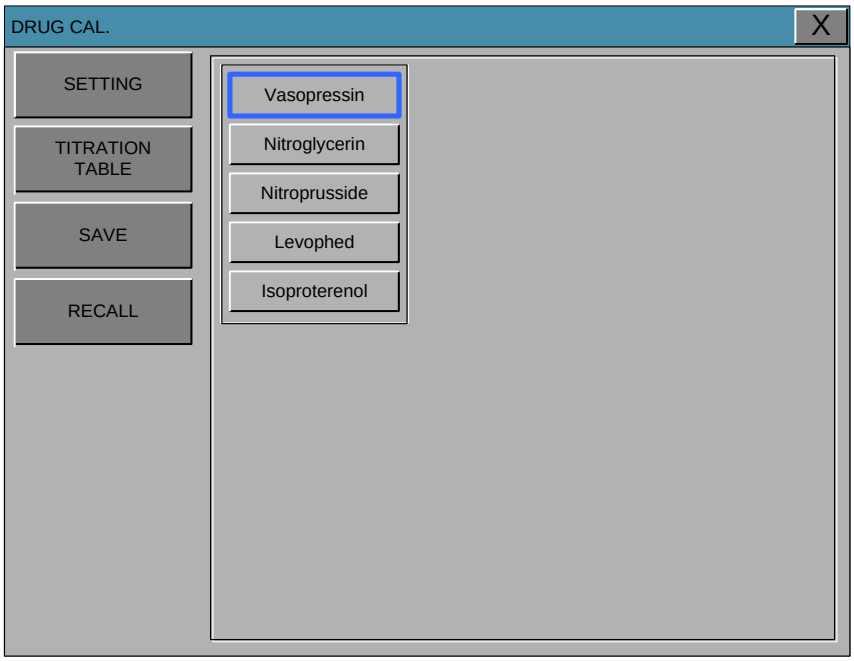
Medicinal dose is calculated to save the menu.



RECALL

Loading dose of medicine is stored in the menu.

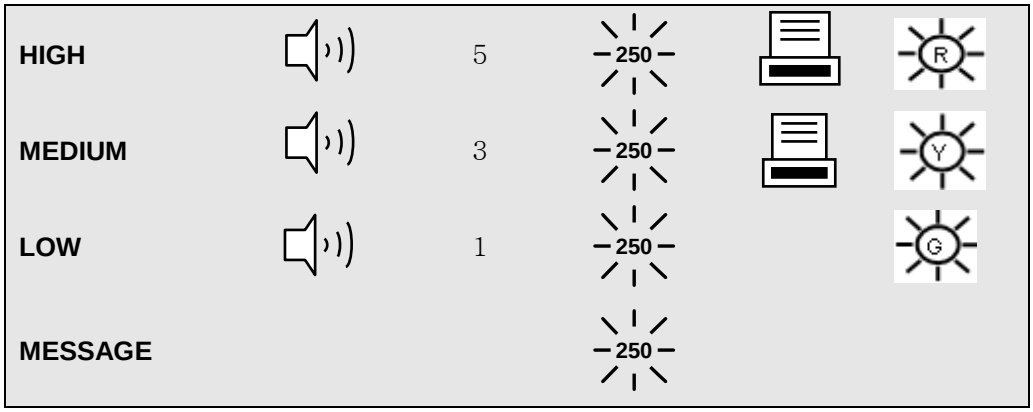
You can delete the saved settings.



2.2 ALARM

Alarm is divided into two, alarm for the patient's condition and for the product's condition.

The patient's alarm sounds when the diagnostic functions (ASYSTOLE, VTAC/VFIB, and VTAC) are detected. Each alarm sound differs in order in order and volume according to the levels of HIGH, MEDIUM, LOW and MESSAGE.



: Alarm sounds

: Number flashes

: Waves are printed out

: Blinking and flashing red alarm lamp on the front of the handle of the red alarm lamp.

: Blinking yellow alarm lamp on the front panel.

: Blinking green alarm lamp on the front panel.

Alarm Behavior

The BM7 uses alarms to send notification when a patient's physiological status change, a patient has a specific technical issue, or when there is a system warning. When a patient is first admitted, the default system alarm settings are in effect. Individual patient alarm settings can be modified by using the accessing the Alarms menu in the individual parameter setup. By default, alarm settings send notification using:

• Visual indicators

• Audible indicators

The three alarm types used in this system include physiological, technical, and system.

Alarm Behaviors

The visual and audio indicators associated with a physiological alarm are:

Visual Indicators

Visual indicators provide visual notification when an alarm threshold is violated. When a physiological alarm condition is triggered, the digital data portion of the upper waveform flashes (if the alarm priority is set to high or medium), a text message displays in the digital tile, and, if configured, the alarm light indicators flash, unless it is a low level alarm, in the corresponding alarm response color. The physiological alarm behavior varies depending on the parameter, and on the alarm priority associated with the parameter.

Audio Indicators

Audio indicators provide audible notification when an alarm threshold is violated. Audio indicators may vary depending on the alarm severity, alarm type, system setup and configuration. Audio alarms are triggered by:

• The onset of an alarm condition provided the alarm delay is not active.

• A configured alarm delay, if alarm delay is active.

Once the alarm condition is resolved and/or acknowledged, the audible alarm stops, unless the alarm is latched.

Alarm Levels

The BM7 supports four alarm levels. When an alarm level is turned on, the choices available are high, medium, low, and message. Alarms may be turned off by selecting the All Off button in the respective parameter alarms menu. All parameters can be modified. The alarm level used to configure a parameter defines the alarm severity. When a parameter is assigned to off, there are no visual or audio alarm indicators associated with the alarm event.

High Level Alarms

High level alarms are the most severe alarm type. Lethal-arrhythmia alarms (Asystole, VTAC, and VFIB) are configured as high level alarms. High level alarm conditions cause the applicable parameter digital tile to flash in red, display a red text message in the parameter tile message area, use a high level alarm sound, and if configured, the alarm light indicator flashes in the corresponding alarm response color. A parameters' alarm limit is configured in the respective parameter Alarms menu.

Medium Level Alarms

Medium level alarms are less severe than high level alarms, and have different visual and audio indicators. Medium level alarm conditions cause the applicable parameter digital tile to flash in yellow (for a physiological alarm), display a yellow text message in the parameter tile message area (if alarm delay is not enabled), use a low level alarm sound, and if configured, the alarm light indicator flashes in the corresponding alarm response color. A parameters' alarm limit is configured in the respective parameter Alarms menu.

Low Level Alarms

Low level alarms are the least severe of the three alarm levels. Low level alarm conditions cause the applicable parameter digital tile to flash in cyan (for a physiological alarm), display a cyan text message in the parameter tile message area (if alarm delay is not enabled), use a low level alarm sound, and if configured, the alarm light indicator flashes in the corresponding alarm response color.
A parameters' alarm limit is configured in the respective parameter Alarms menu.

All Alarm Off

Any alarm levels can be turned off, including lethal alarms. Parameters configured to use All Off do not have any visual or audio alarm indicators.

Audio Alarm Delay

Audio Alarm Delay is the configurable time period required before alarm sound triggers. Alarm Audio Delay does not affect the Apnea Alarm, ST Alarms, the non-lethal arrhythmia alarms, or the lethal arrhythmia alarms. When permitted, this option can be enabled or disabled in the Alarm Setup

Alarm for the Product

The machine gives alarm sounds for its system with a related message flashing.

LOW  -1 

PARAMETER LEVEL：The machine enables one to see and change the limits and level(priority) of alarm for all parameter functions.

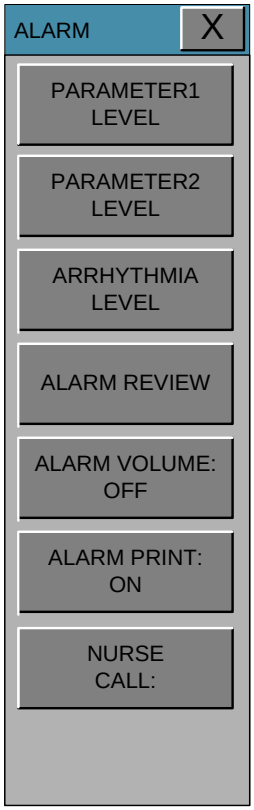
ARRHYTHMIA LEVEL: The machine enables one to see and change the level (priority) of Arrhythmia.

ALARM REVIEW： Shows the priority order information for all alarms of each measurement.

ALARM VOLUME：volume of each alarm can be adjusted in 10 step.

ALARM PRINT：with an ON/OFF setup, the related information is printed out whenever an alarm is given.

NURSE CALL： Set the feature of the NURSE CALL.

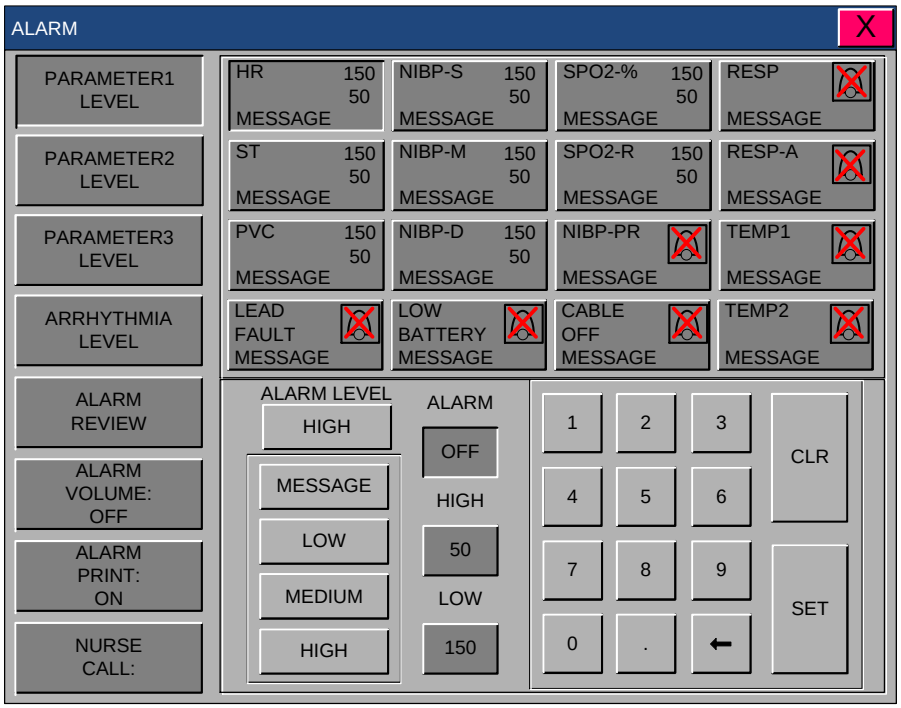


It is able to see all the alarm range and change of measurement function.

Warning
• Be aware that the monitors in your care area may each have different alarm settings, to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring. • Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

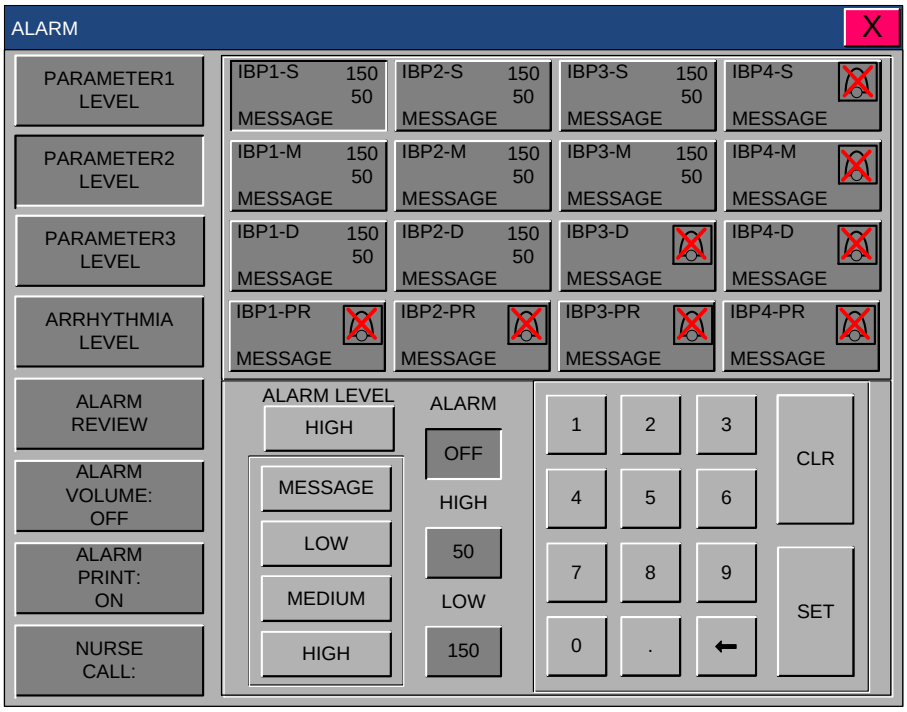
PARAMETER1 LEVEL

ECG, NIBP, SpO2, RESP, TEMP and LEAD FAULT information about all of the alarm is set.



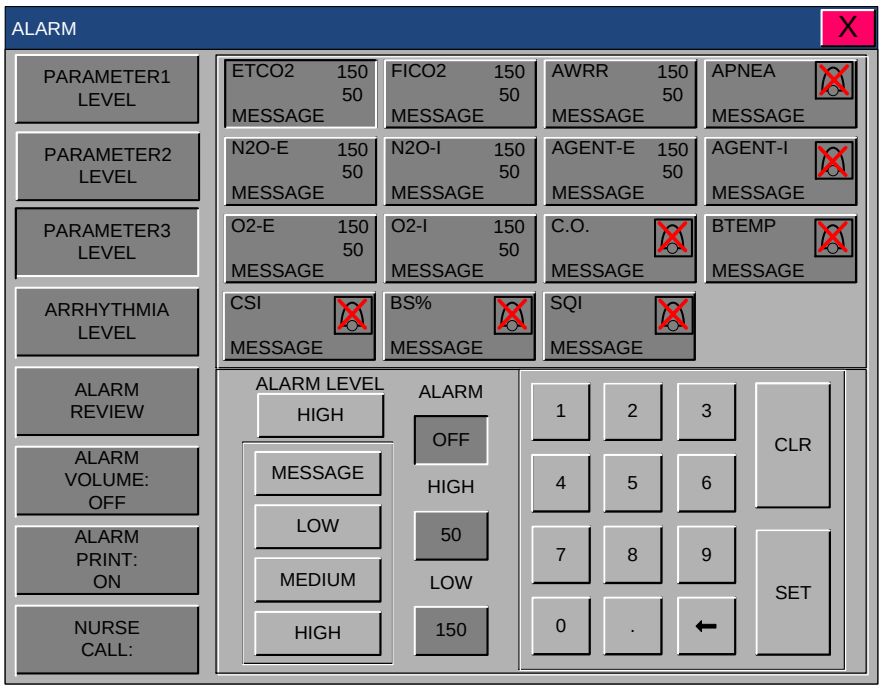
PARAMETER2 LEVEL

IBP information about all of the alarm is set.



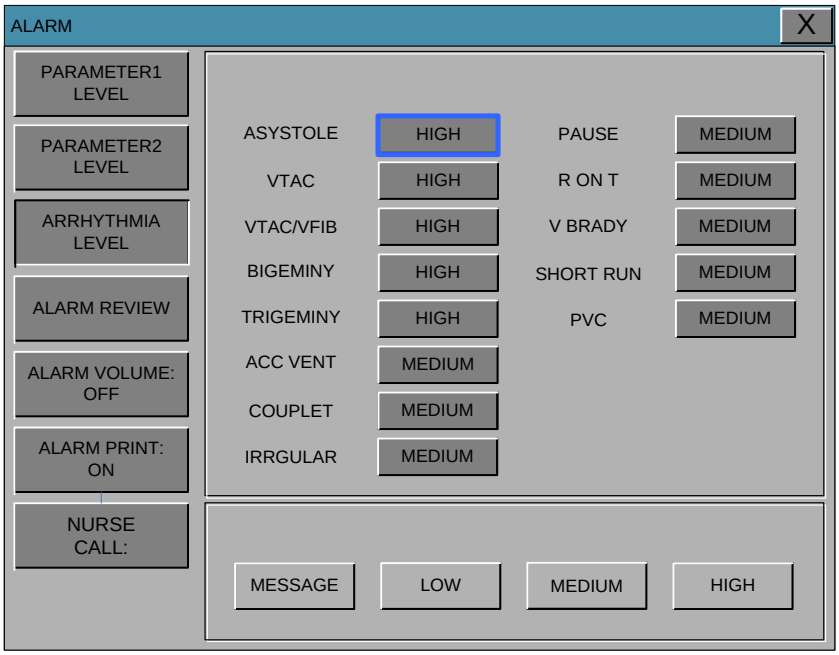
PARAMETER3 LEVEL

EtCO2, Multi-gas, C.O. and CSM information about all of the alarm is set.



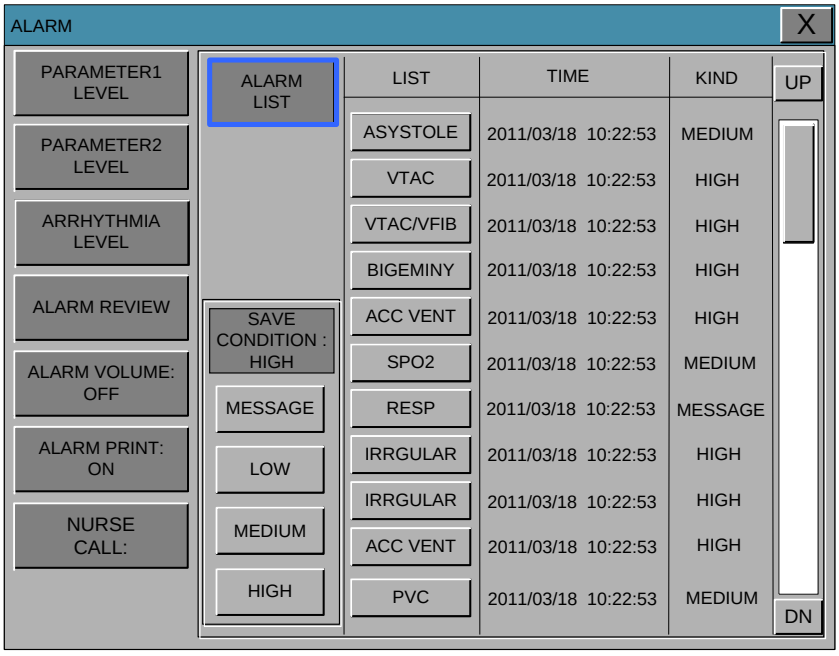
ARRHYTHMIA LEVEL

Diagnostics when the alarm is set to the priority of the alarm is set.



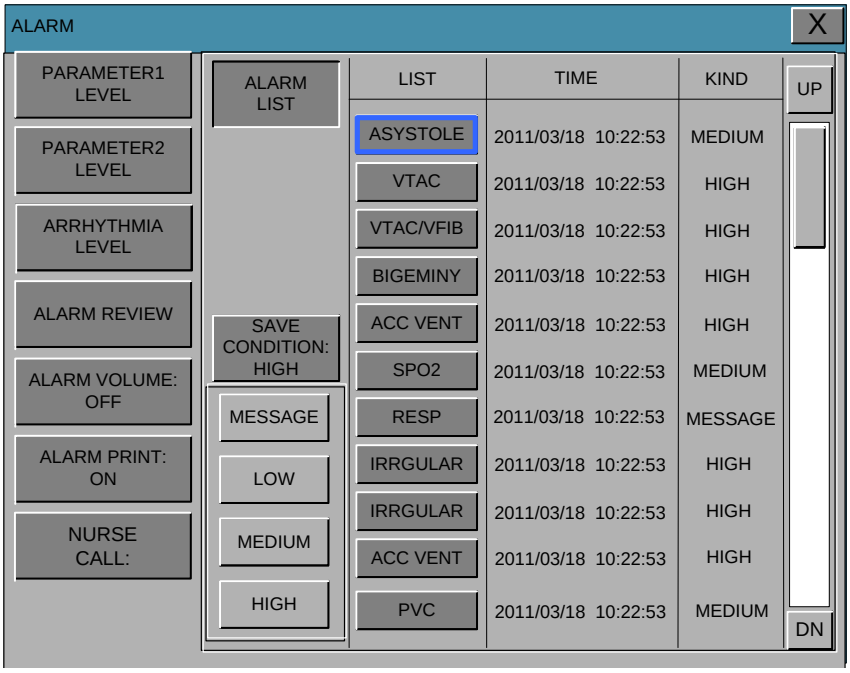
ALARM REVIEW

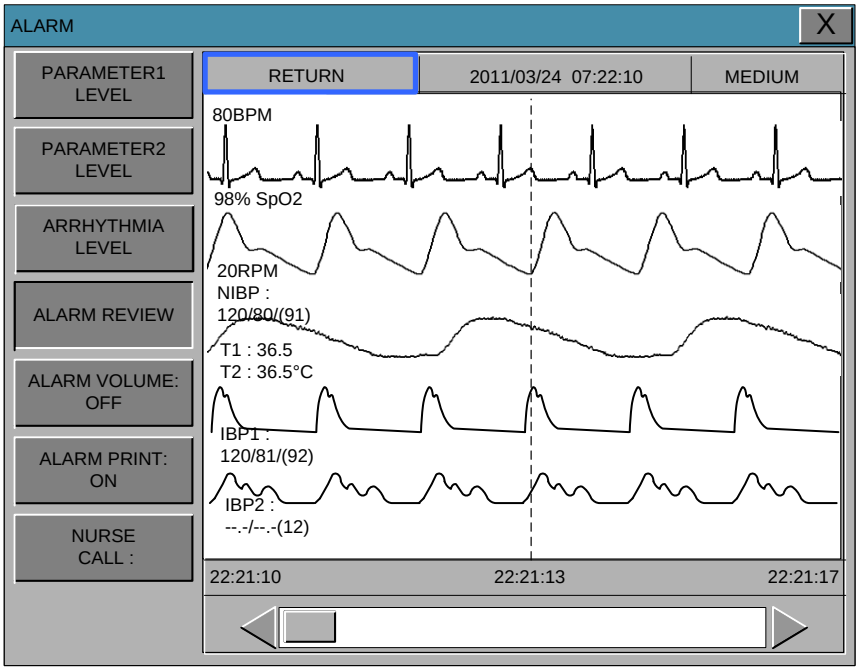
After an alarm is triggered the alarms and data wave pattern can be reviewed. Set up for priority of each parameter alarm.



ALARM LIST

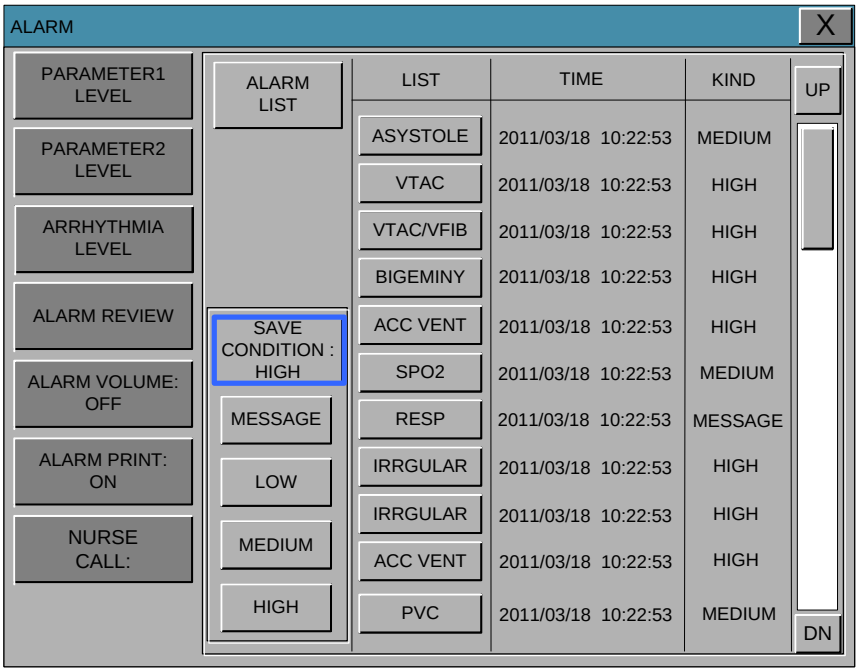
When an alarm activates, this shows the order of the alarms. The alarm can be stored up to 20 cases.





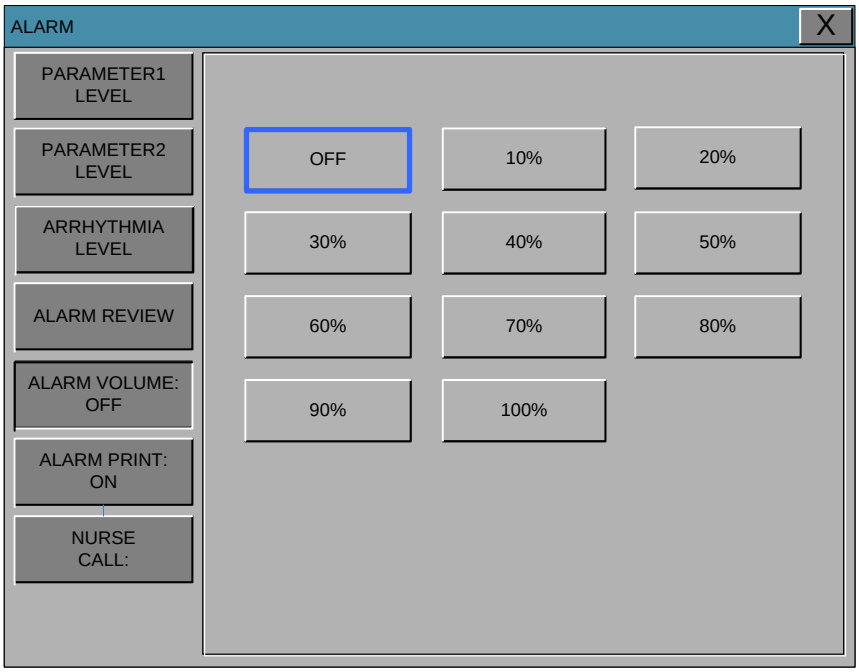
SAVE CONDITION

This determines the alarm level of parameters which are saved in the alarm list, when alarm occurs. If the higher level of alarm only occurs than the previously determined alarm level, data would be saved in the alarm list.



ALARM VOLUME

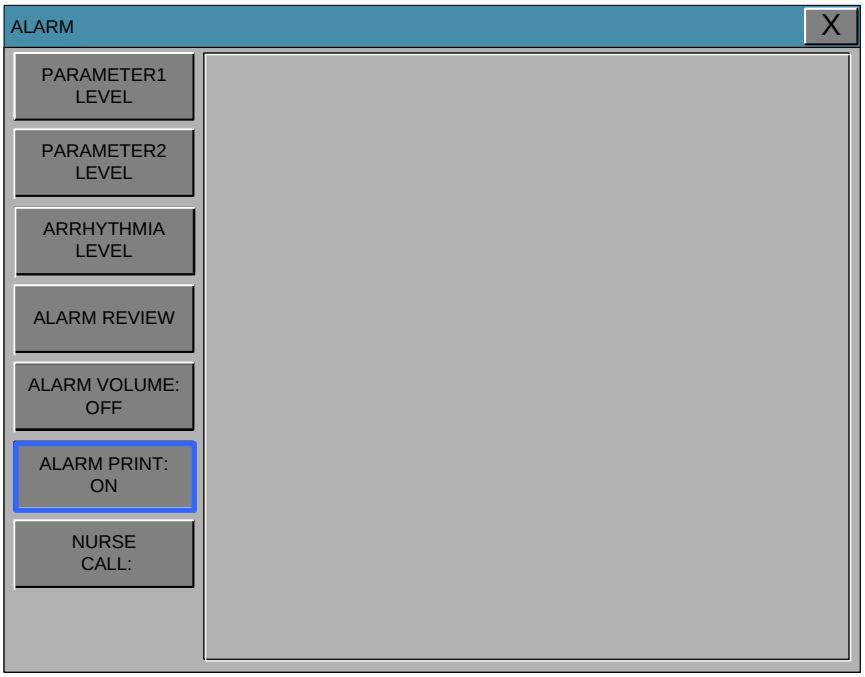
Set the alarm volume to be set at 10 grades.



ALARM PRINT

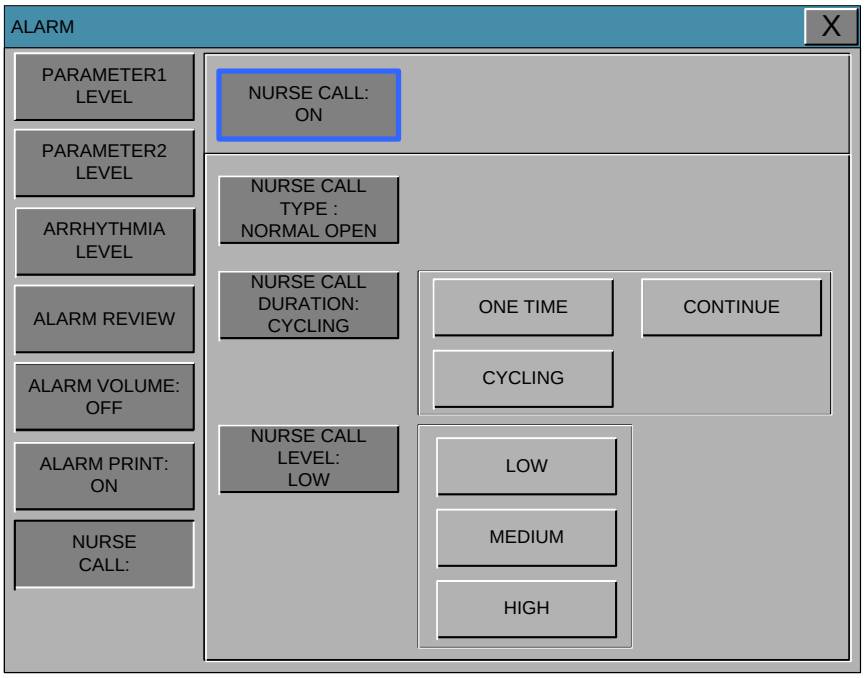
ON / OFF settings for when the alarm sounds are printed on thermal paper.

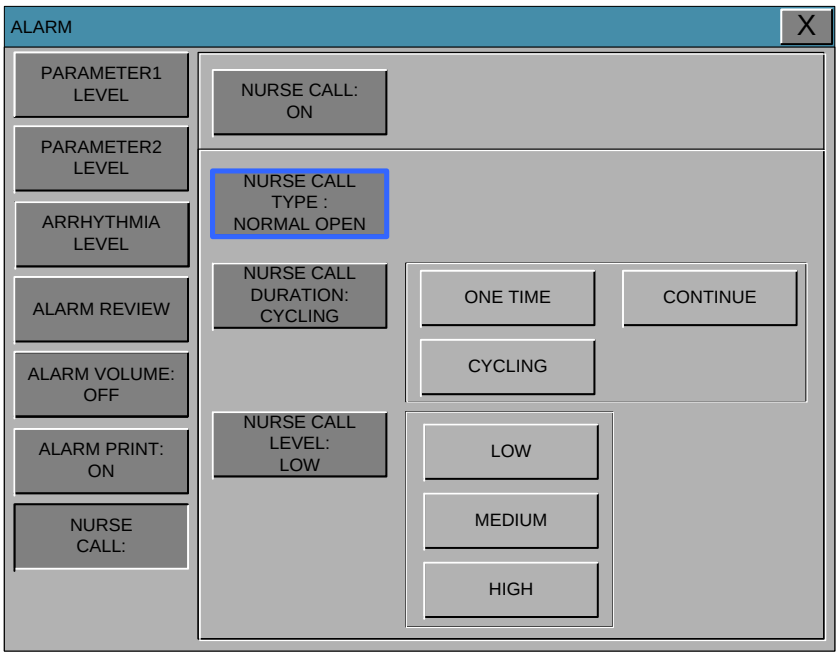
MEDIUM alarm level is greater than if only the printer output.



NURSE CALL

When an alarm is triggered, this activated the NURSE CALL function.



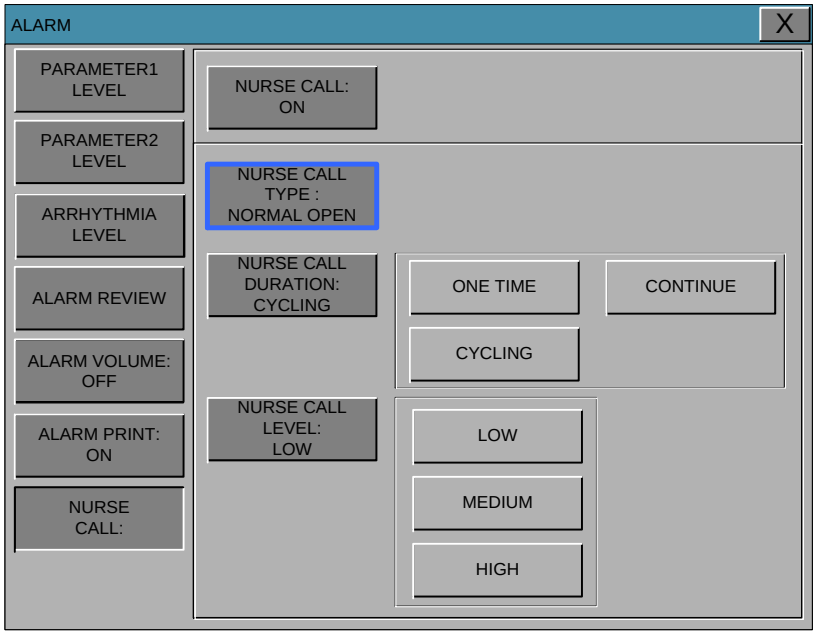


NURSE CALL TYPE

NURSE CALL function calls when an alarm condition is set way.

NORMAL OPEN: RELAY OPEN when ALARM does not ring, CLOSE when ALARM does ring.

NORMAL CLOSE: RELAY CLOSE when ALARM does not ring, OPEN when ALARM does ring.



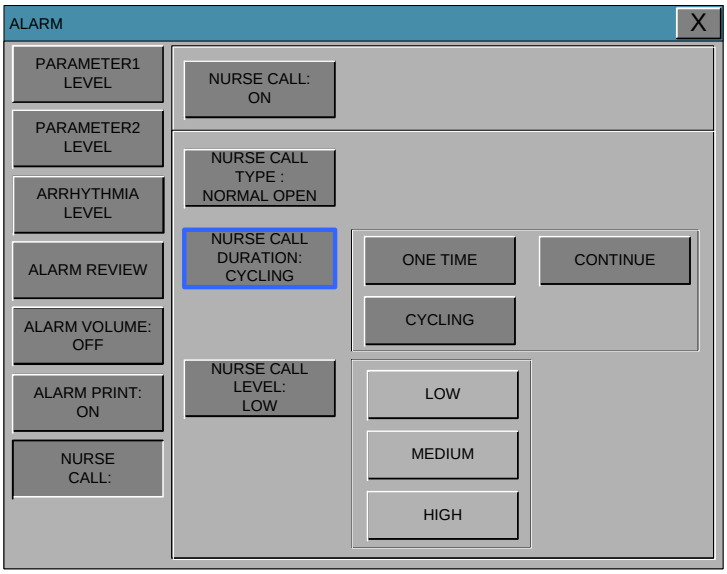
NURSE CALL DURATION

NURSE CALL alarm calls when the situation is set to output mode.

ONE TIME: After ALARM occurs, set the RELAY to be ON for 3 seconds then OFF

CYCLING: Relay will cycle between ON and OFF in every 1-second interval.

CONTINUE: After ALARM occurs, set the RELAY to be ON for 60 seconds then OFF.



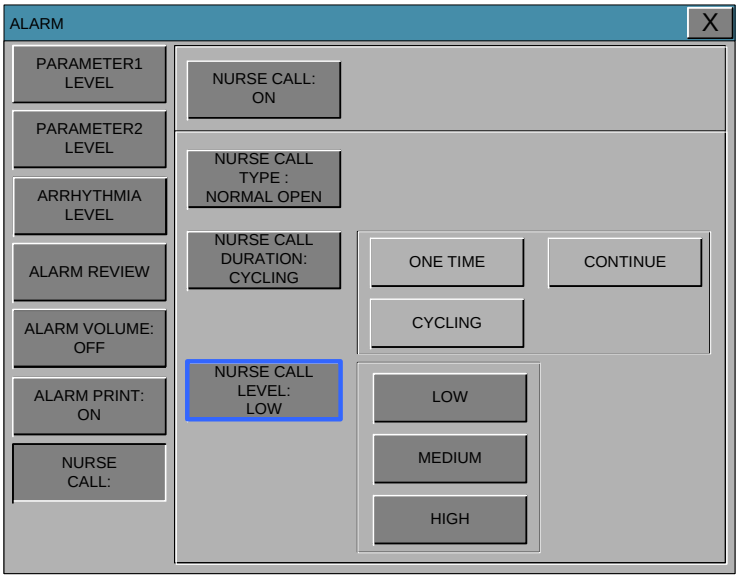
NURSE CALL LEVEL

NURSE CALL alarm level is set to operate.

LOW : If the alarm is raised above the LOW level NURSE CALL call.

MEDIUM: If the alarm is raised above the MEDIUM level NURSE CALL call.

HIGH: If the alarm is raised above the HIGH level NURSE CALL call.



3. SETUP

3.1 SETUP

SET PARA

HR SOURCE

SWEEP SPEED

USER SERVICE

UNIT SELECT

SYSTEM

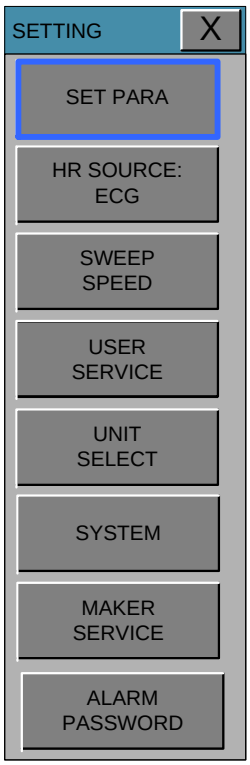
MAKER SERVICE

ALARM PASSWORD

3.1 SETUP

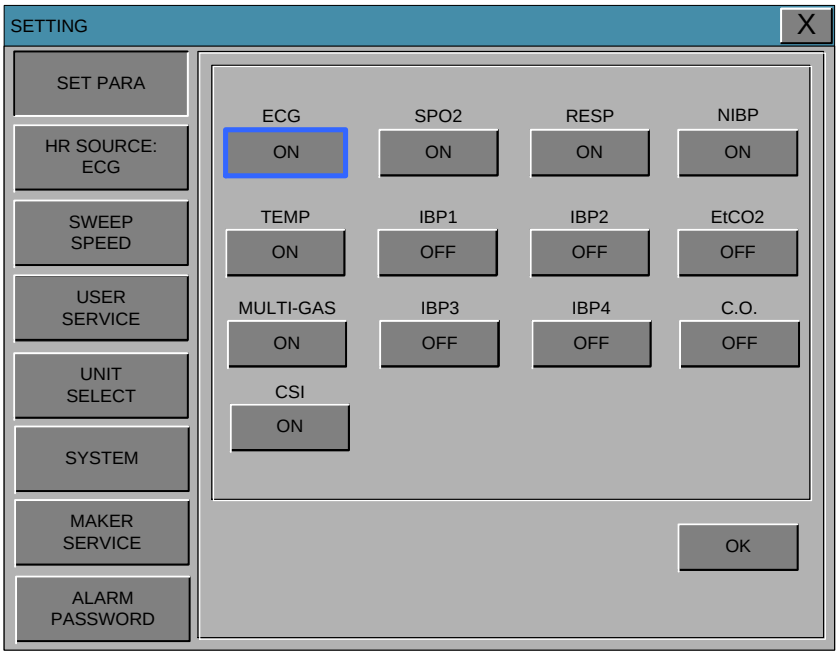
The Settings menu, the following window is displayed, pressing the icon shown above.

SET PARA	: Measurement function selected.
HR SOURCE	: Set and select HR/PR source. It can choose between ECG and SPO2.
SWEEP SPEED	: Set speed of Waveform display.
USER SERVICE	: This is the menu to set the connection used to interface with an external computer.
UNIT SELECT	: The setup menu to change the parameters of the unit.
SYSTEM	: System able to change and verify Equipment version information and system information.
MAKER SERVICE	: This is the basic adjustment menu used to adjust the features of this product.
ALARM PASSWORD	: This is the setting menu for alarm management settings of security. Set the alarm password and sound settings menu.



SET PARA

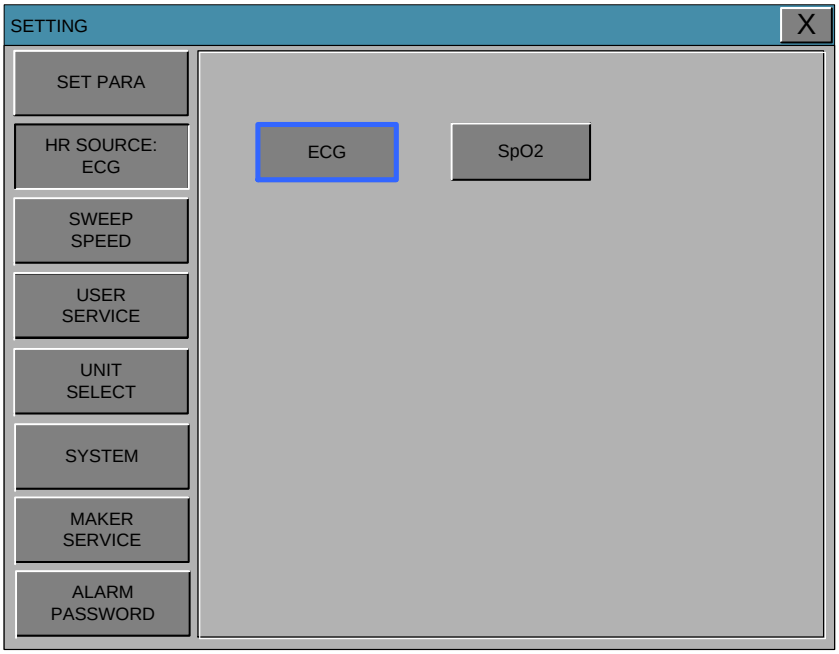
Select measurement function to use. IBP3, IBP4, C.O. and CSI are an optional feature.



HR/PR SOURCE

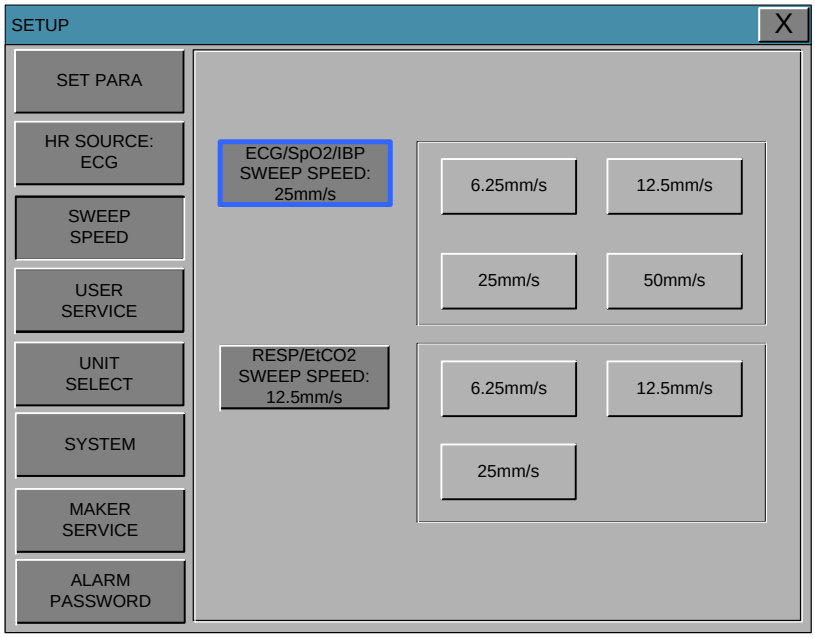
This menu is used to set the source that detects heart and pulse rate.

The source can select among ECG and SPO2.



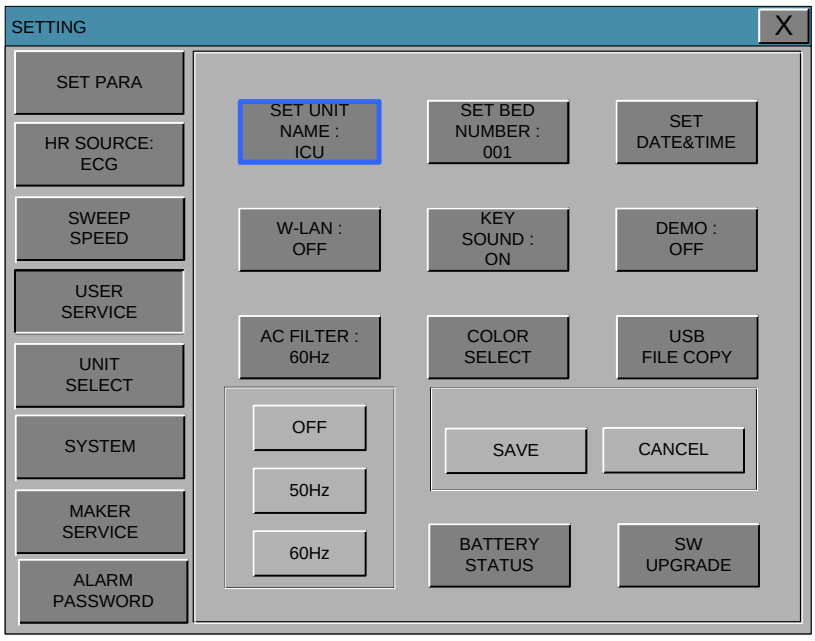
SET SWEEP

Set speed of drawing wave signal pattern in this widow.



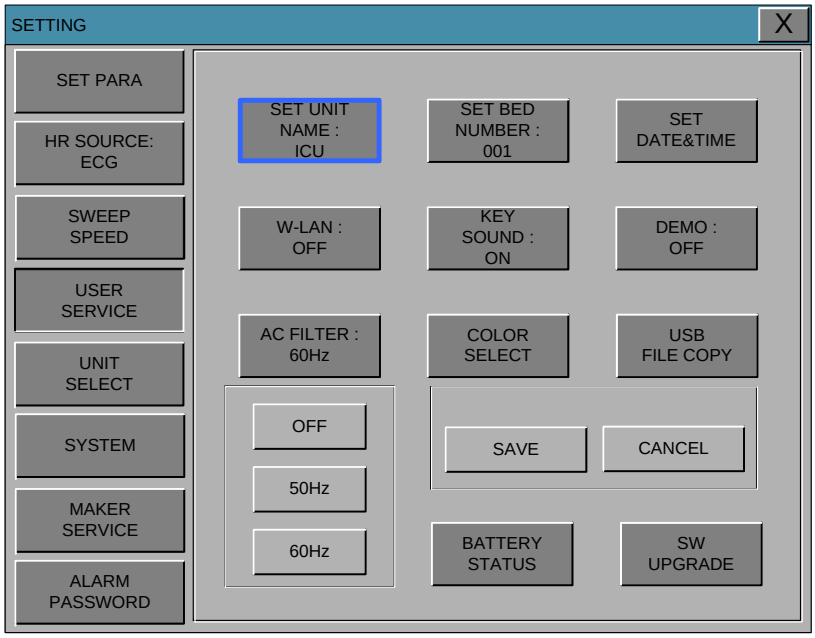
USER SERVICE

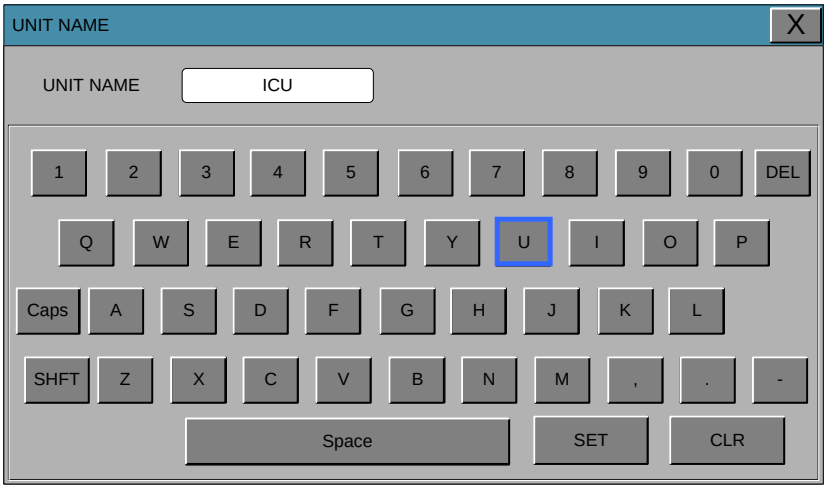
The user is able to set the communication parameters, power supply filter.



SET UNIT NAME

Set up for Equipment name

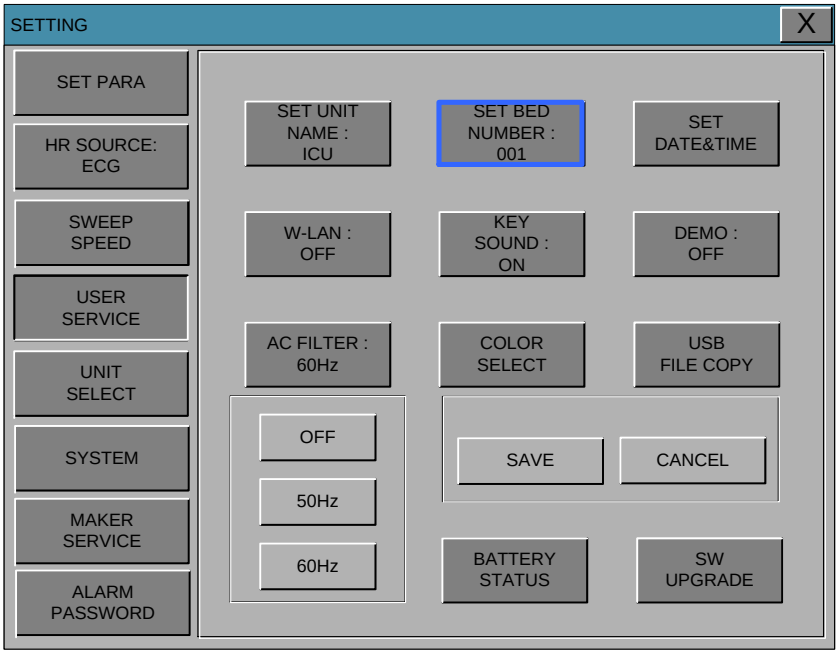




SET BED NUMBER

Set up for patient bed number.

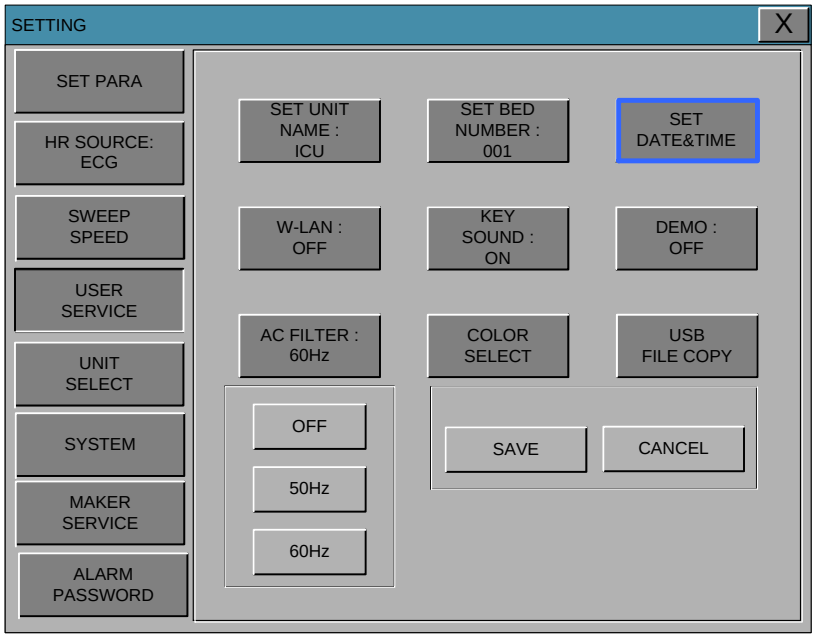
Allowable setters are from 1 to 255.

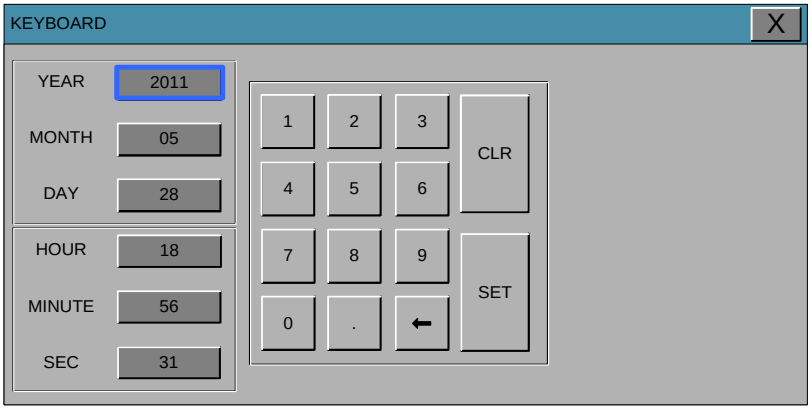


SET DATE & TIME

Set date and time of equipment.

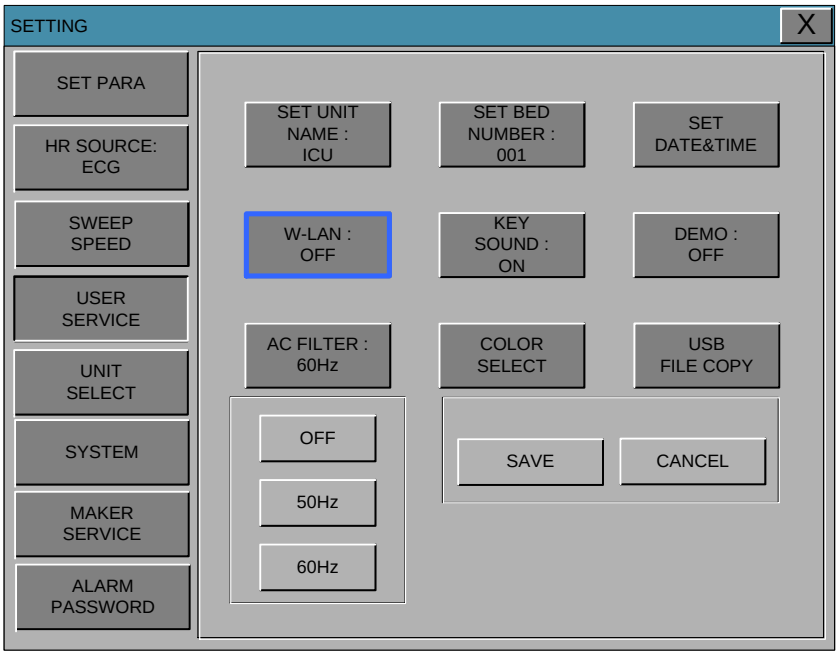
Press the SET button after each input change you want to change the year, month, day, hour, minute, and second item during the setting will be entered.





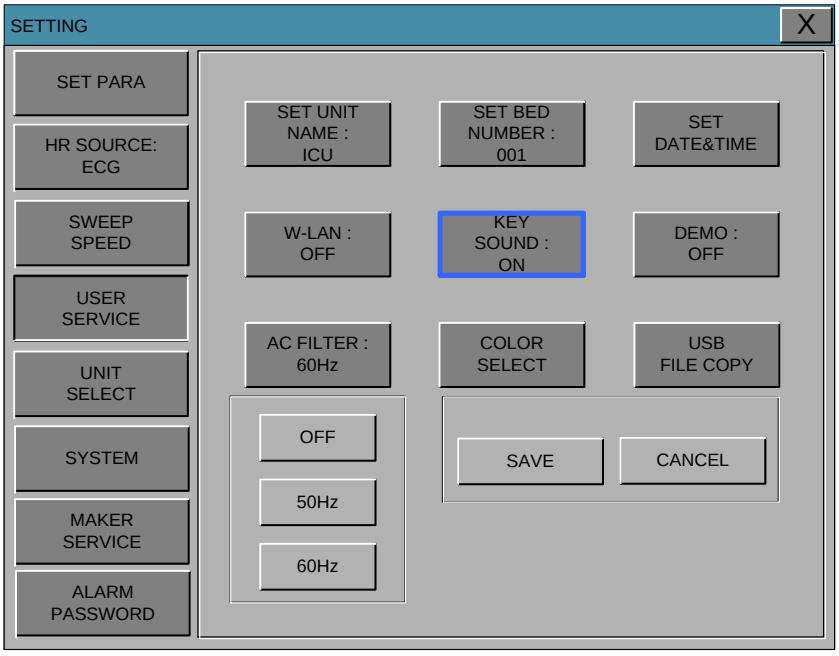
W-LAN

Power supplying of W-LAN module could be adjusted with this function



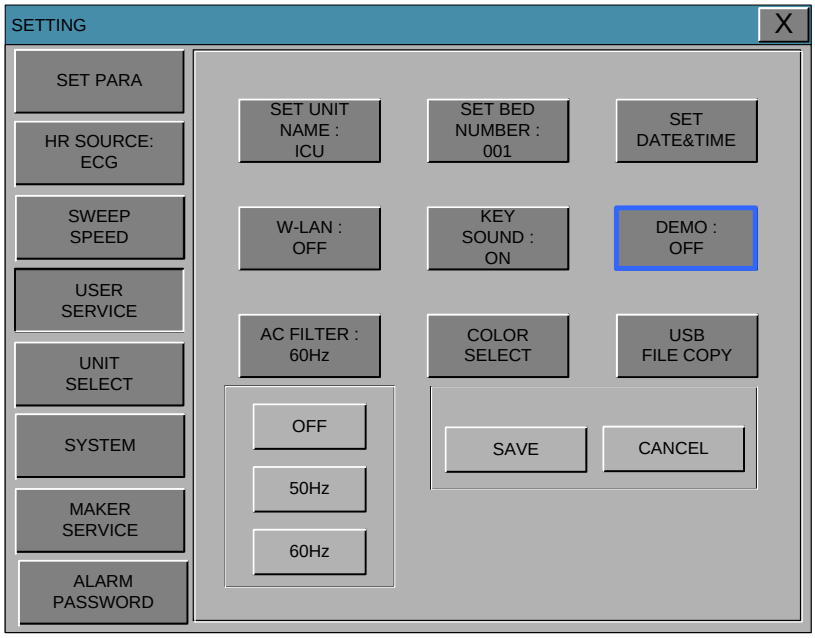
KEY SOUND

This is the menu for KEY SOUND to ON/OFF.



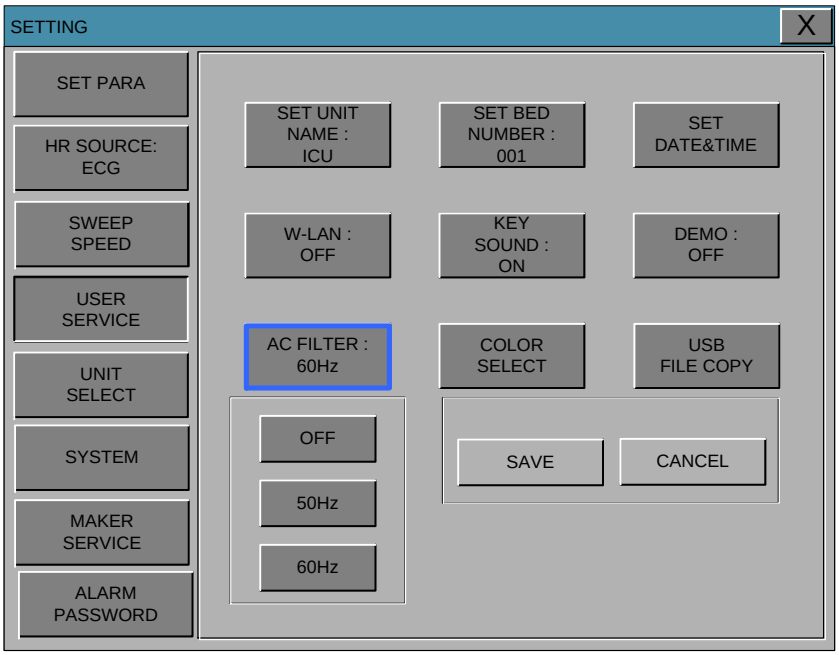
DEMO

Set ON/OFF DEMONTRATION of equipment.



AC FILTER

AC FILTER is function where you can set power supply frequency. This feature is required because power supply frequency can be different from one country to another. (The selectable frequencies are 50Hz and 60Hz, OFF.)

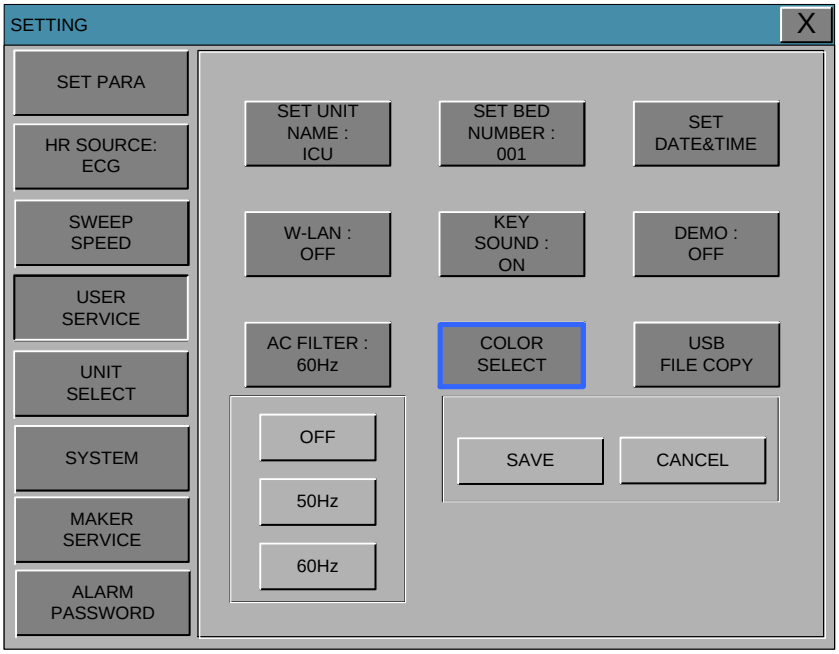


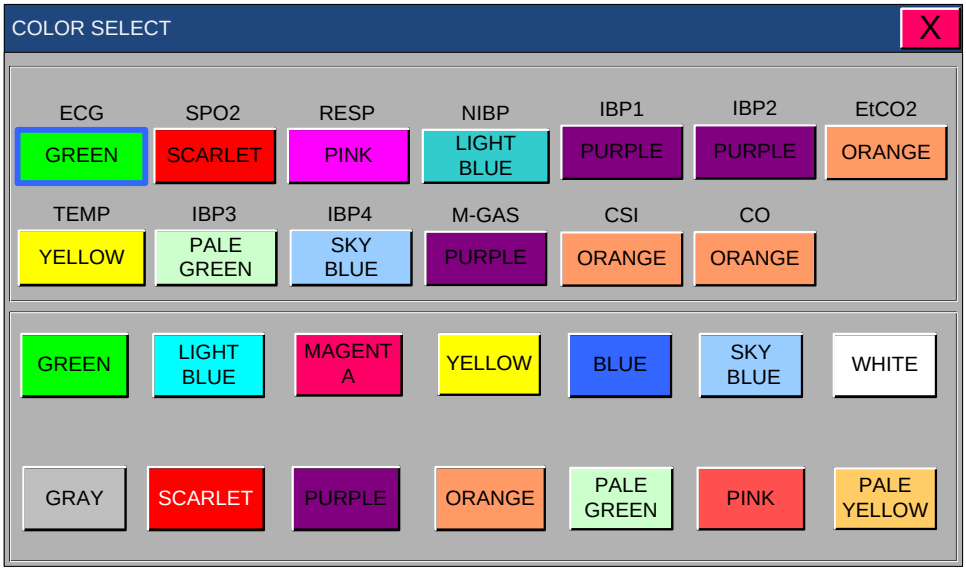
COLOR SELECT

This is the menu to set the waveform and parameter color selection.

It has ten colors below table.

The color of parameter could be changed in ten colors from following table.



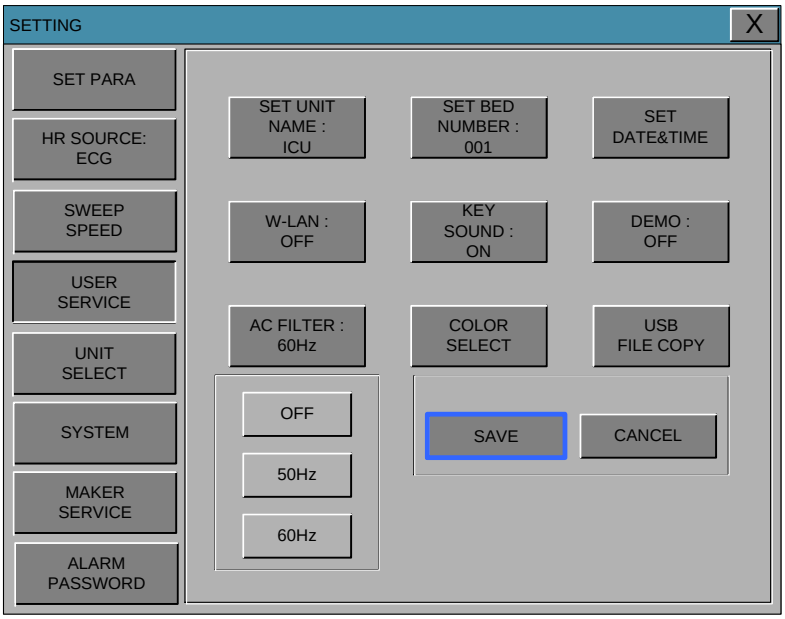


USB FILE COPY

There is menu to save the file on the USB.

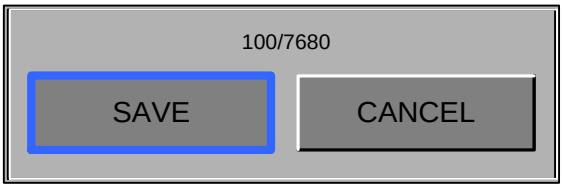
SAVE: command to save TREND DATA in the USB memory.

CANCEL: command to cancel TREND DATA in the USB memory.

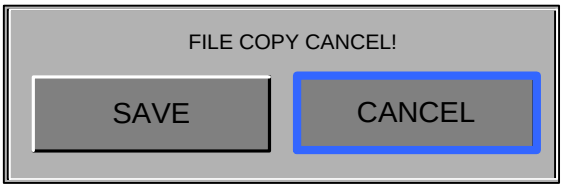


Display the progress of the file data stored.

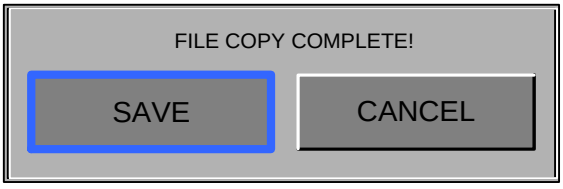
The number on the left is a number of stores, and the number on the right displays the number of the total number.



Data is stored cancel the message display.



Data is stored upon completion message displays.

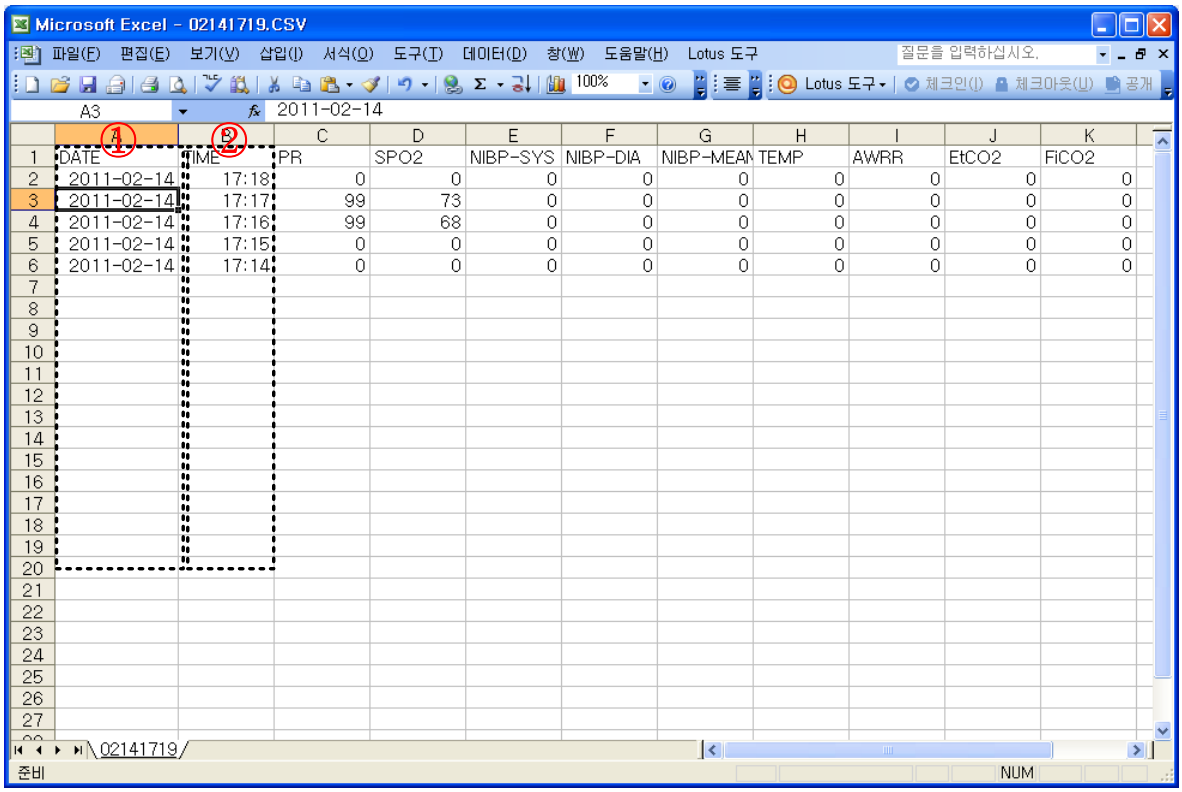


Save the date-hour-minute format. CSV file is stored.

The figure below Microsoft Excel program to open the files that are stored on this screen is.

Date data items and to properly view the data in this column, the cell format is set to "day-month-year".

Patient data entry, normally view the data in this column is set to a cell formatted as "h: mm: ss".



DATE	TIME	PR	SPO2	NIBP-SYS	NIBP-DIA	NIBP-MEAN	TEMP	AWRR	EtCO2	FiCO2
2011-02-14	17:18	0	0	0	0	0	0	0	0	0
2011-02-14	17:17	99	73	0	0	0	0	0	0	0
2011-02-14	17:16	99	68	0	0	0	0	0	0	0
2011-02-14	17:15	0	0	0	0	0	0	0	0	0
2011-02-14	17:14	0	0	0	0	0	0	0	0	0

Note

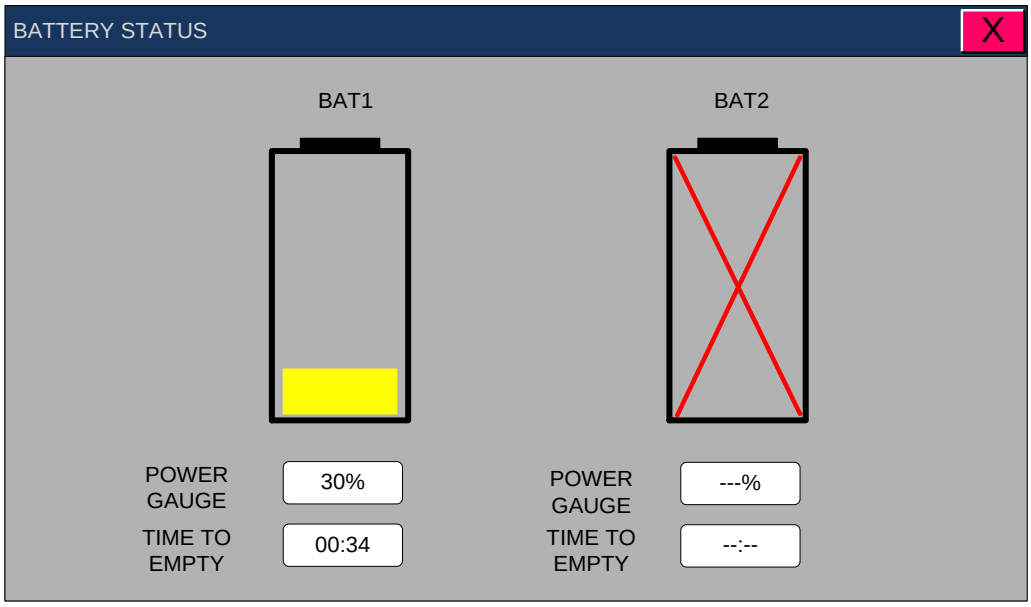
USB cannot work if you remove the USB while stored in USB.

Can not perform normal when no storage space on the USB storage.

BATTERY STATUS

This is the menu for battery status information of BM7.

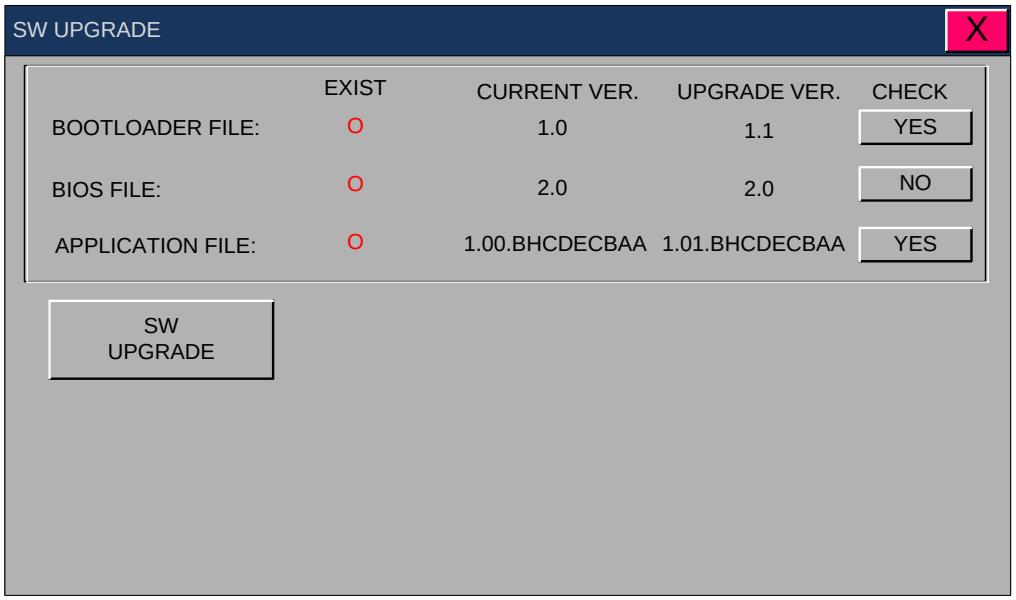
It provides current battery status information.



SW UPGARDE

This is menu for software upgrade of BM7.

Put the upgrade file in USB memory stick connected to the monitor.



UNIT SELECT

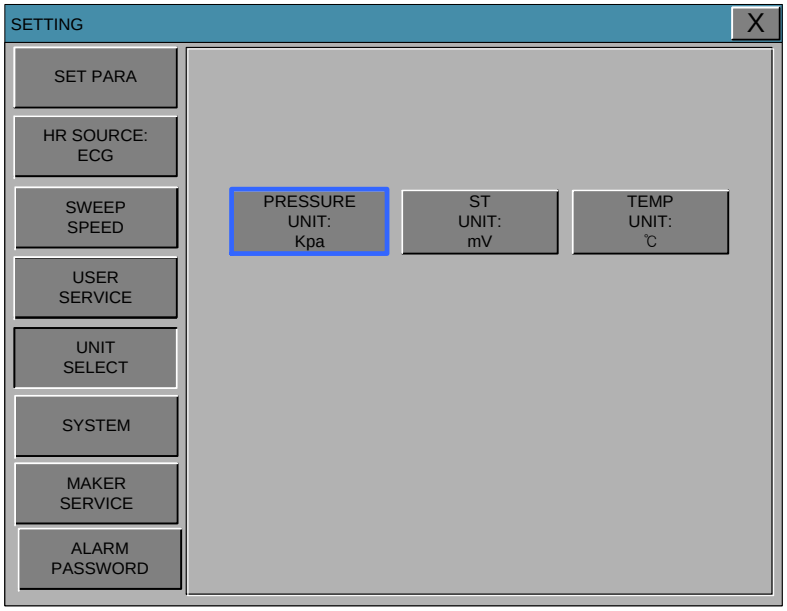
This is the menu for converting the units of BM7.

The units of parameters for pressure, ST LEVEL, Temperature are able to convert

Pressure: kPa ← → mmHg

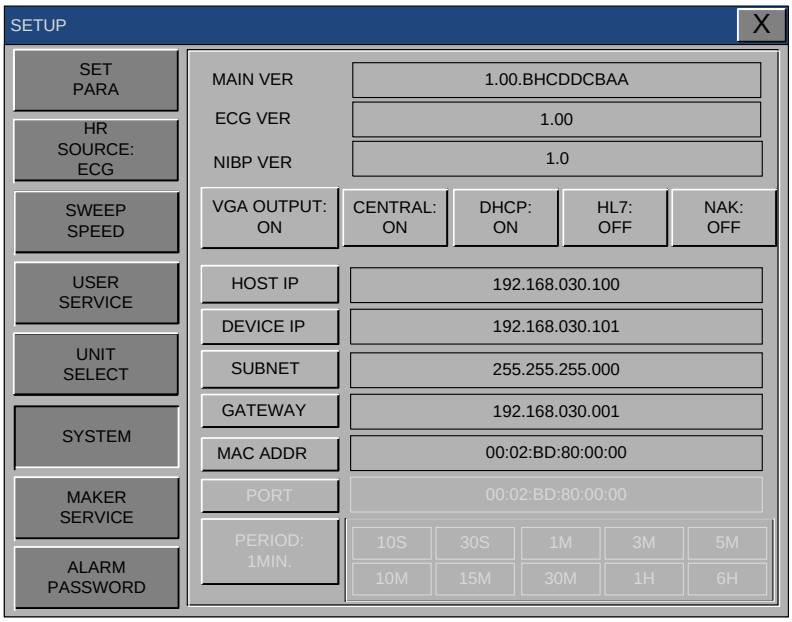
ST mm ← → mV

Temperature: ℃ ← → ℉



SYSTEM

System menu is able to change and verify equipment version information and system information.



VGA OUTPUT: VGA output on the output board provides.

CENTRAL: ON / OFF function of the network system used to set.

Will turn ON after setting the equipment off and connected to the Central system.

DHCP: ON/OFF function of allocation IP address automatically.

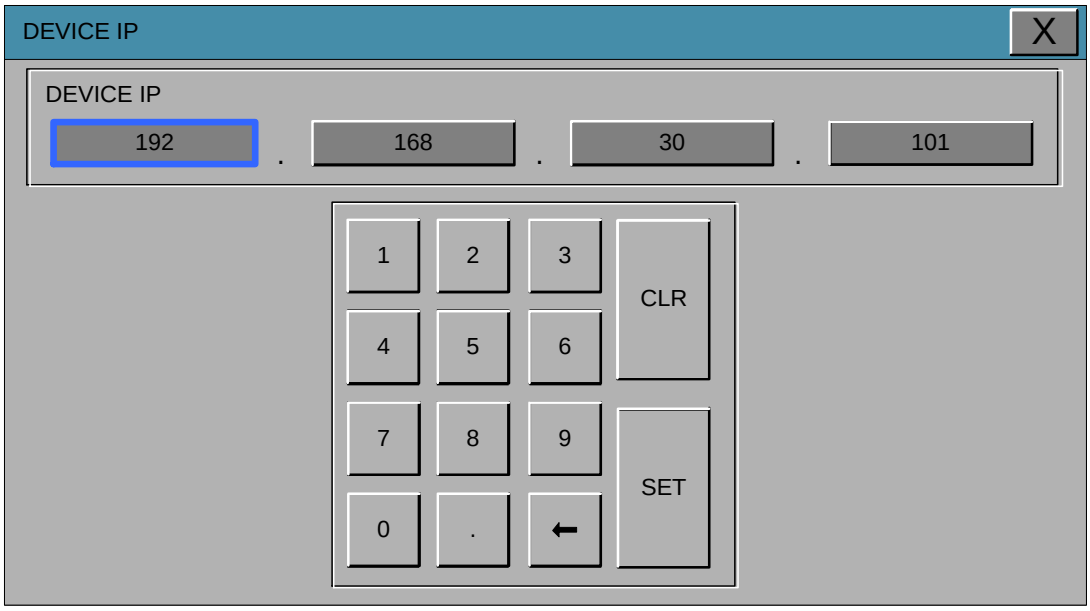
HL7: ON/OFF function of HL7 network protocol.

NAK: ON/OFF function of transmission control of HL7 protocol

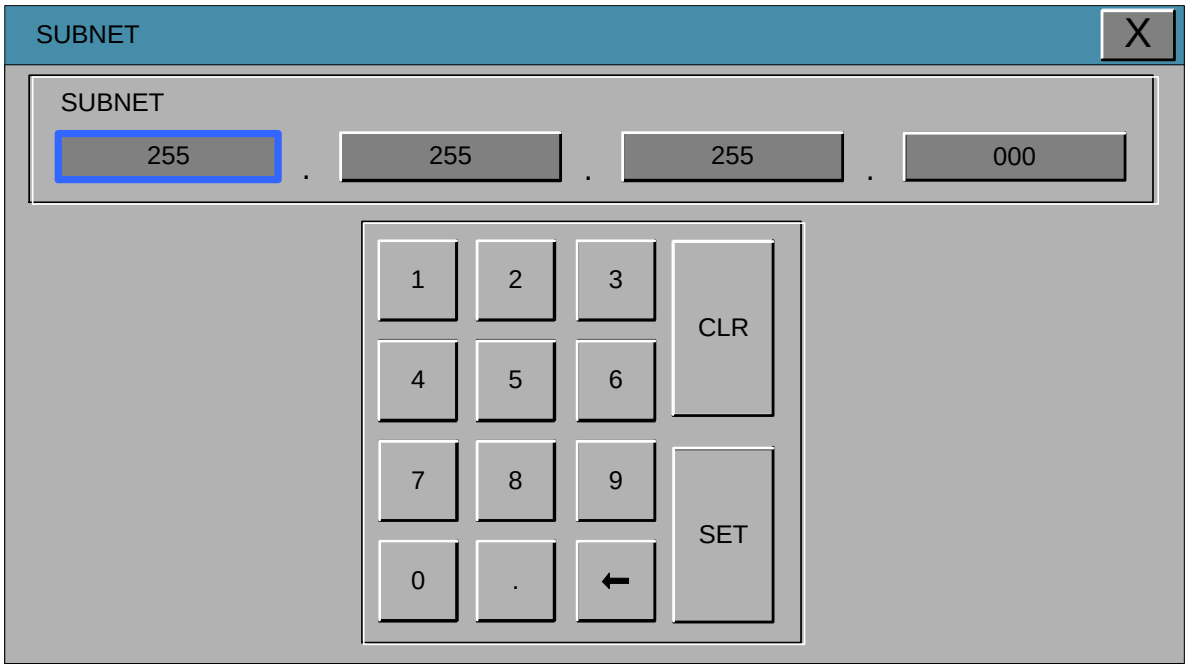
HOST IP, DEVICE IP, SUBNET and GATEWAY: Set the information for connecting to the Central system.

HOST IP: Press the SET button to set the address of the remote sites to send and receive data.

DEVICE IP: Press the SET button to set the address of the sending and receiving equipment.

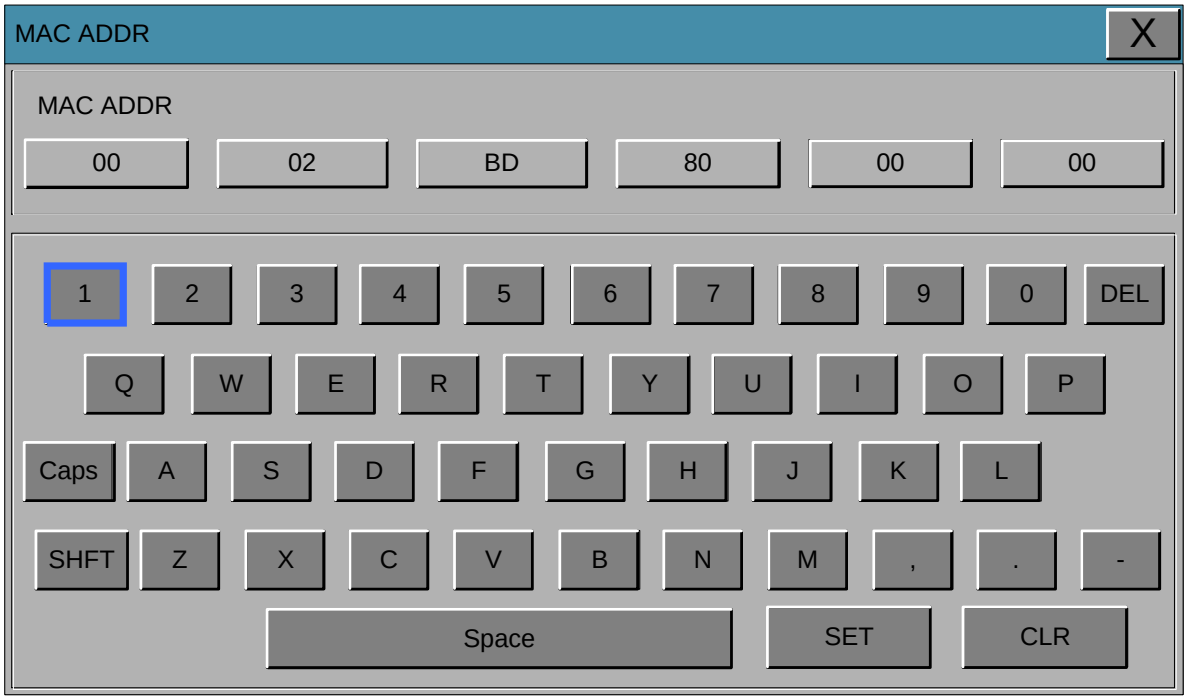


SUBNET: Bit address that set which need to see when the network settings, press the SET button to set.



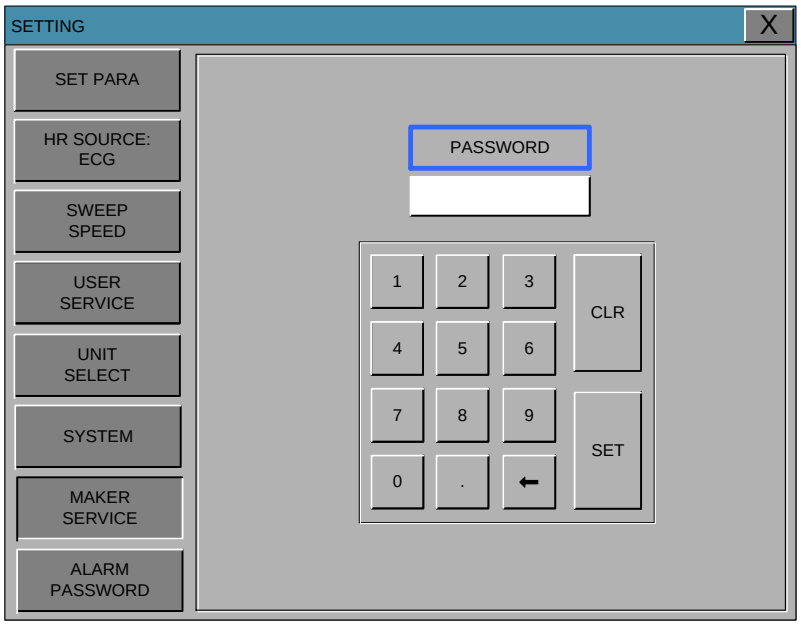
GATEWAY: Press the SET button to set the address that set up a connection at the network settings window.

MAC ADDR: Press the SET button to set the hardware address for the network settings.
(MAC ADDR cannot be modified by the user.)



MAKER SERVICE

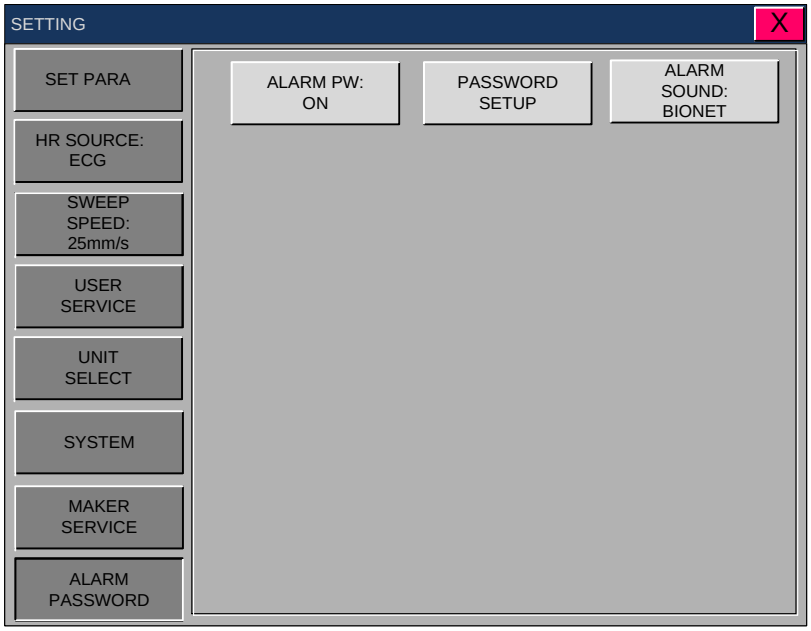
Maker service is a menu is used by manufacturers.

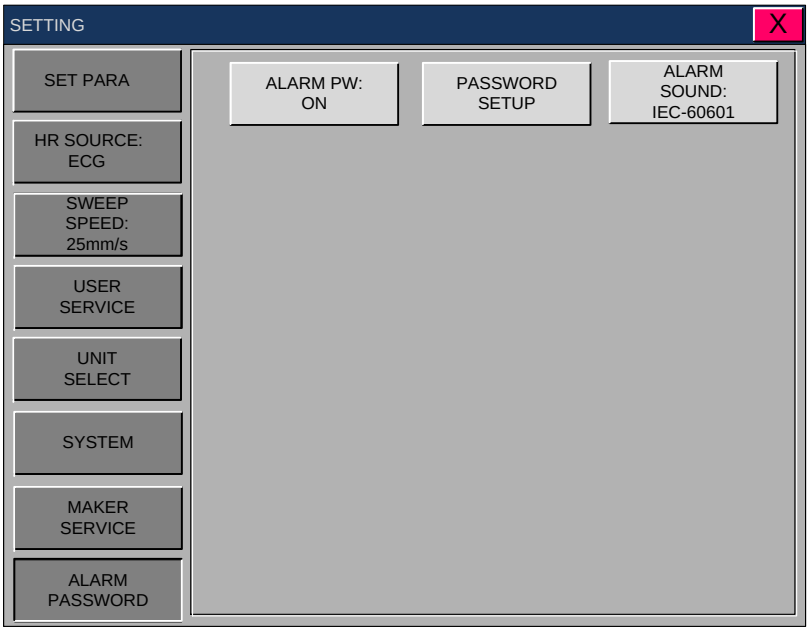


ALARM PASSWORD

This is the setting menu for alarm management settings of security.

Set the alarm password and sound settings menu.





FREEZE MENU

If you select the icon which is located in the far left in the icon menu with controlling a rotary switch, the wave window is held and is maintained as the previous status, at the same time the parameter windows is normally showing the current patient's status.

Whenever selecting the FREEZE menu, the FREEZE and RELEASE are repeated by turns.

The FREEZE is released by the following two conditions.

1. 3 minutes after selecting FREEZE menu.
2. Selection of the releasing FREEZE menu
3. Off screen pause function key if you selected (function/ home key  and rotary key)

Note
Unlike regular screen freeze screen prints during waveform output parameters of the state and its parameters. ECG 7CH/12CH selection followed by ECG waveforms at the output.

4. TREND

4.1 TREND

TABULAR TREND

GRAPHIC TREND

TREND WINDOW SETUP

OxyCRG TREND

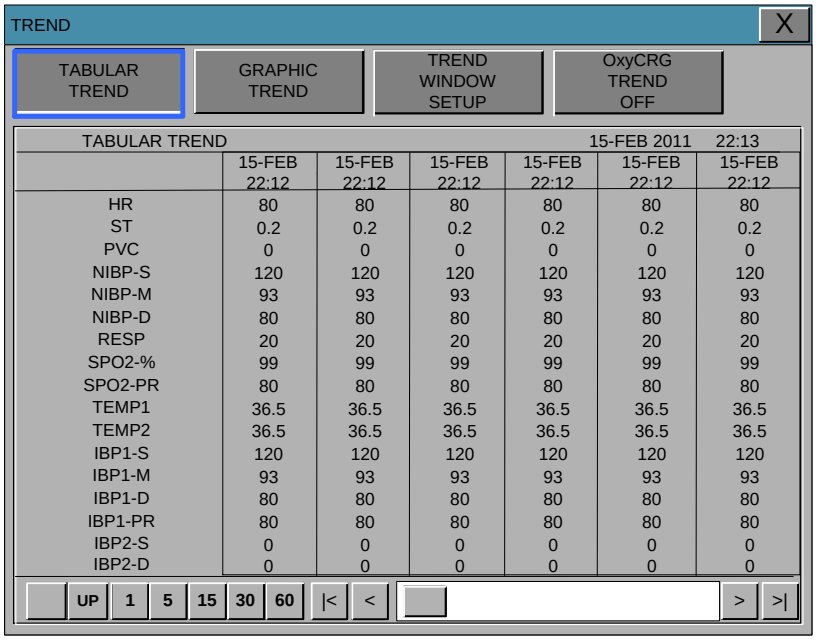
4.1 TREND

TREND shows saved data graphically displayed with numeric values.

Real-time data recording duration is 1 minute. Amount of saving time is for this data will be saving for 168hours.

The following entries are stored.

- Standard Feature : HR,ST,PVC,NIBP(S/M/D),RESP,SPO2%,SPO2-PR, TEMP1, TEMP2, IBP1(S/M/D), IBP1-PR, IBP2 (S/M/D), IBP2-PR, EtCO2, FiCO2, AWRR, AG-EX, AG-INS,AG2- EX,AG2-INS,N2O-EX,N2O-INS, O2-EX,O2-INS, Alarm
- Optional Feature : IBP3(S/M/D),IBP3-PR,IBP4(S/M/D),IBP4-PR C.O, BTEMP, CSI, BS%, SQI



X : Move to main screen.

1 : Move within the tables.

UP : Move to other analysis function.

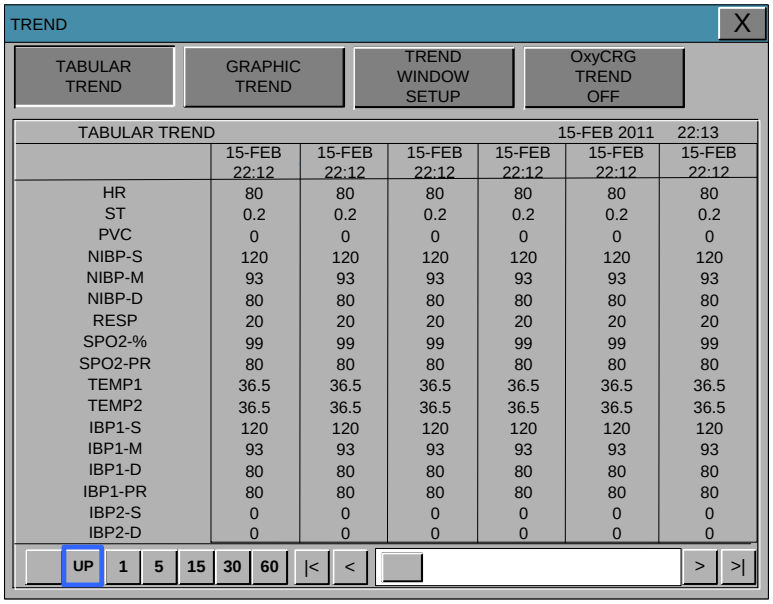
0.5 1 1.5 3 6

1 5 15 30 60

: Time period set menu

TABULAR TREND

One can see the stored data at the time previously set up.

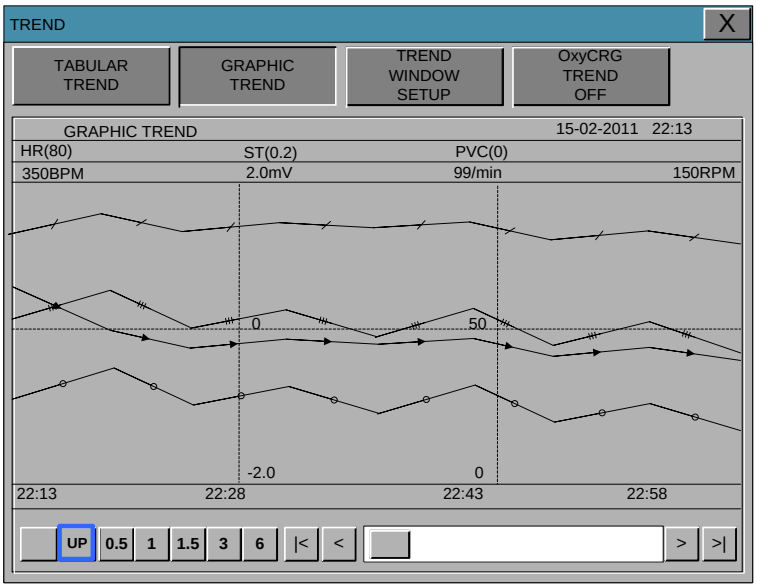


TIME INTERVAL

One can store data and set up time.

GRAPHIC TREND

Wave Data can be stored and seen according to section.

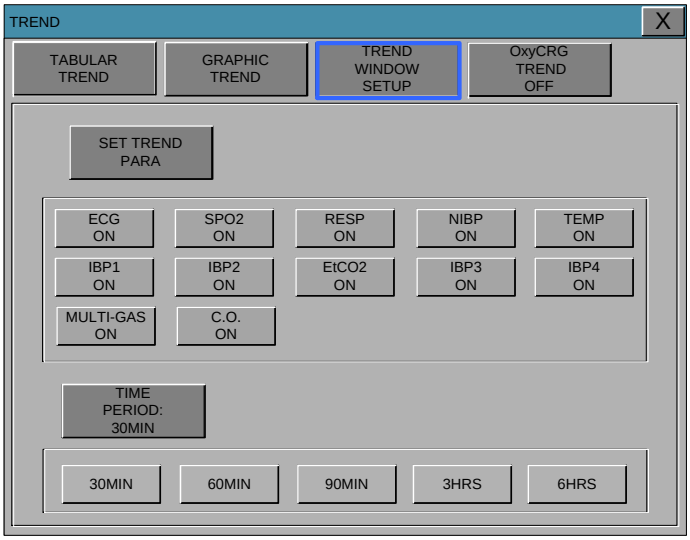


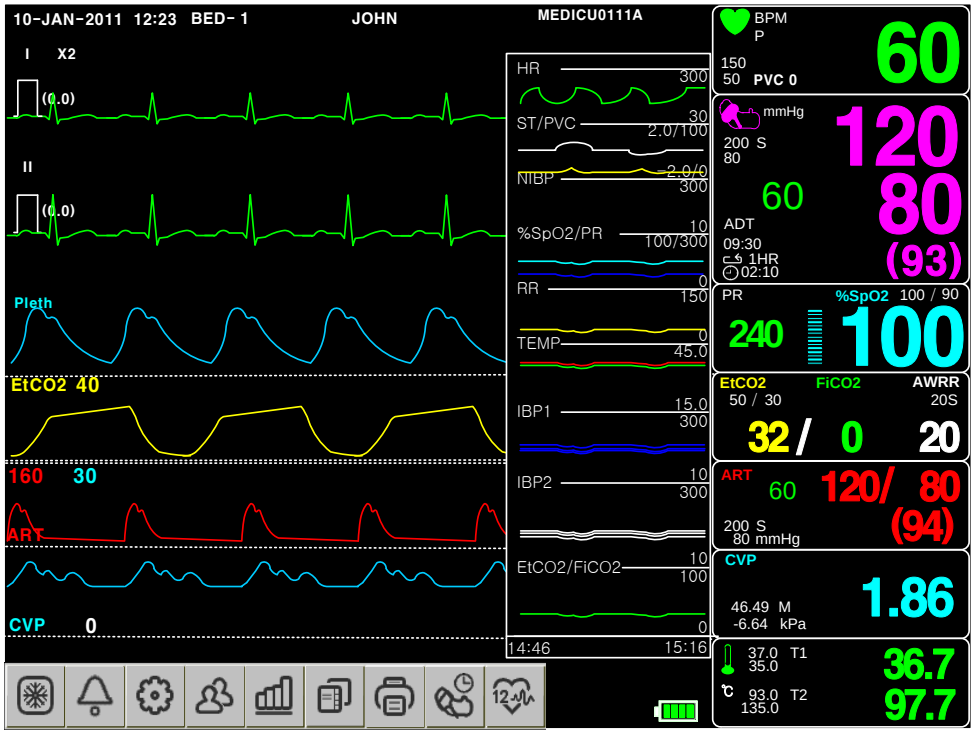
TIME PERIOD

One can set up and store data and time that one can see in a screen.

TREND WINDOW SETUP

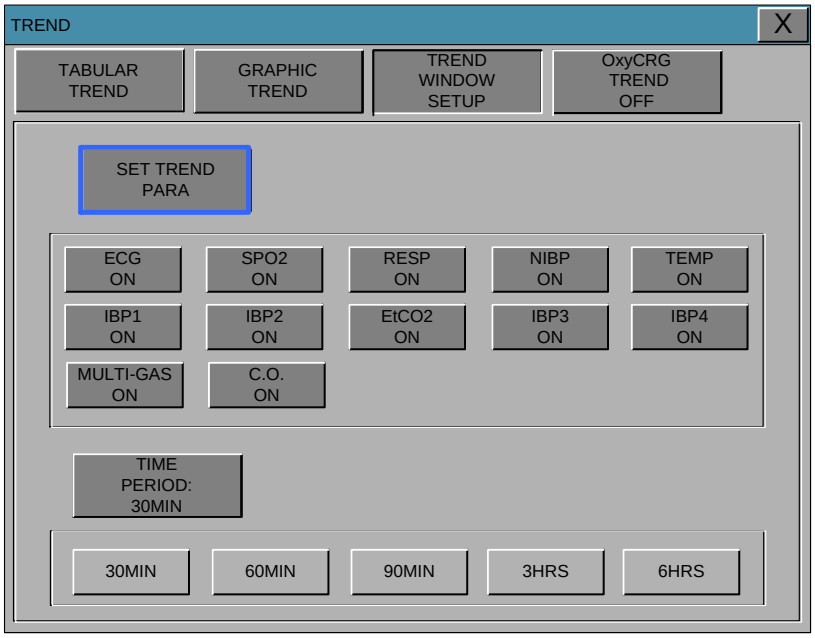
Set the trend display window that will show the real time wave window.





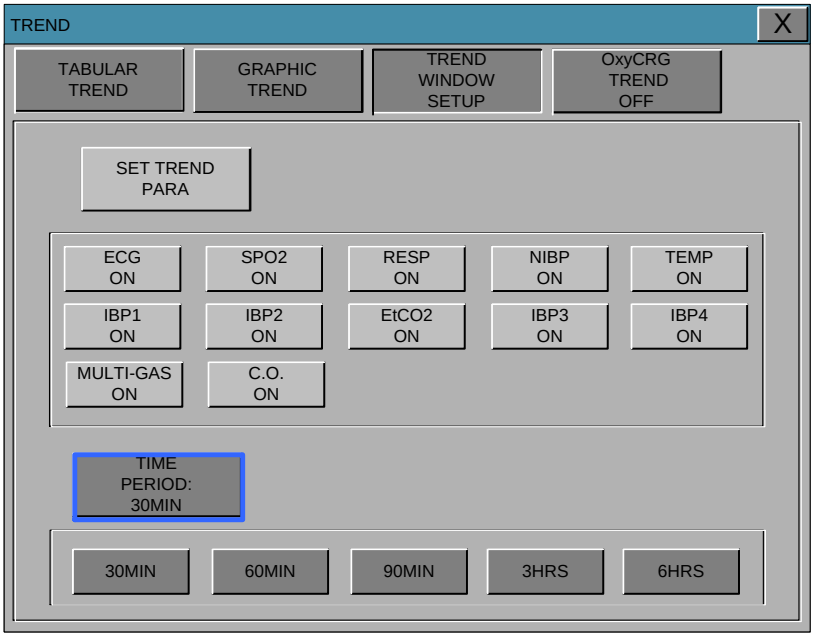
SET TREND PARA

Set visible parameter in a screen.



TIME PERIOD PARA

Set visible time period in a screen.



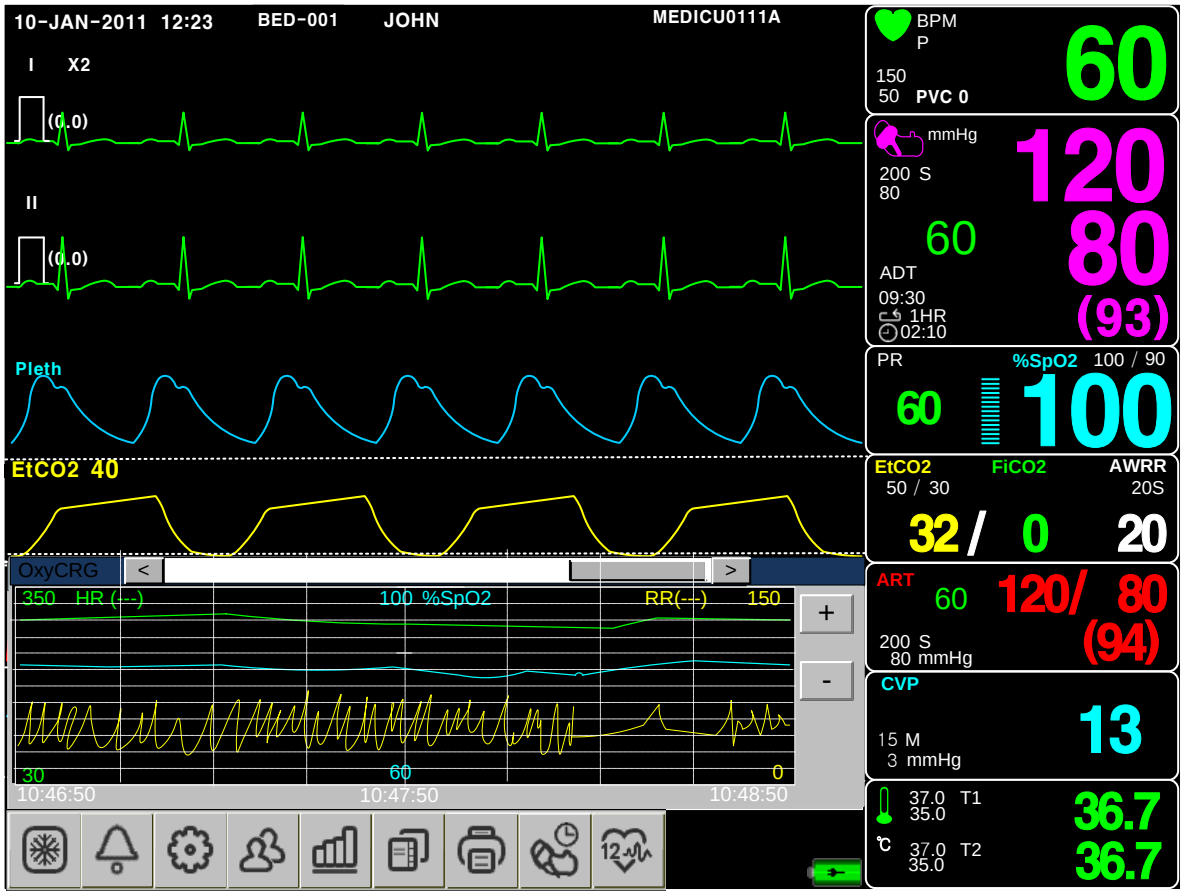
TREND PRINT

Graphic: select the number which selects a graphic trend and press print to prints the selected trend.

Table: select the table number to be print and press print to receive print all the data in the selected patient admit (Admit) table.

OxyCRG TREND

When selecting ON heart rate, respiration and oxygen saturation trend on the screen.



Note
ECG 7CH/12CH when selecting an automatic OFF the screen after switching ON OxyCRG trend.

5. ECG

5.1 Outline

Color and Name for Each Cable Size

ECG Connector Location and Measurement Cable

10 Lead Electrode Attached Location

5 Lead Electrode Attached Location

3 Lead Electrode Attached Location

Method to Attach Electrode to Baby

5.2 ECG Data Window

5.3 ECG Data Setup

ALARM

LEAD SELECT

QRS VOLUME

DISPLAY

ARRHYTHMIA SETTING

ST/PVC

PACE MAKER

12 ECG ANALYSIS

5.1 Introduction

It calculates the heart rate with 3 or 5 leads or10 leads ECG signal acquisition and perform the alarm according to the setting value.

Colors and Standards of Cables

AHA：American Heart Association (U.S.A. Certification)

IEC：International Electro technical Commission (Europe Certification)

3LEAD / 5LEAD

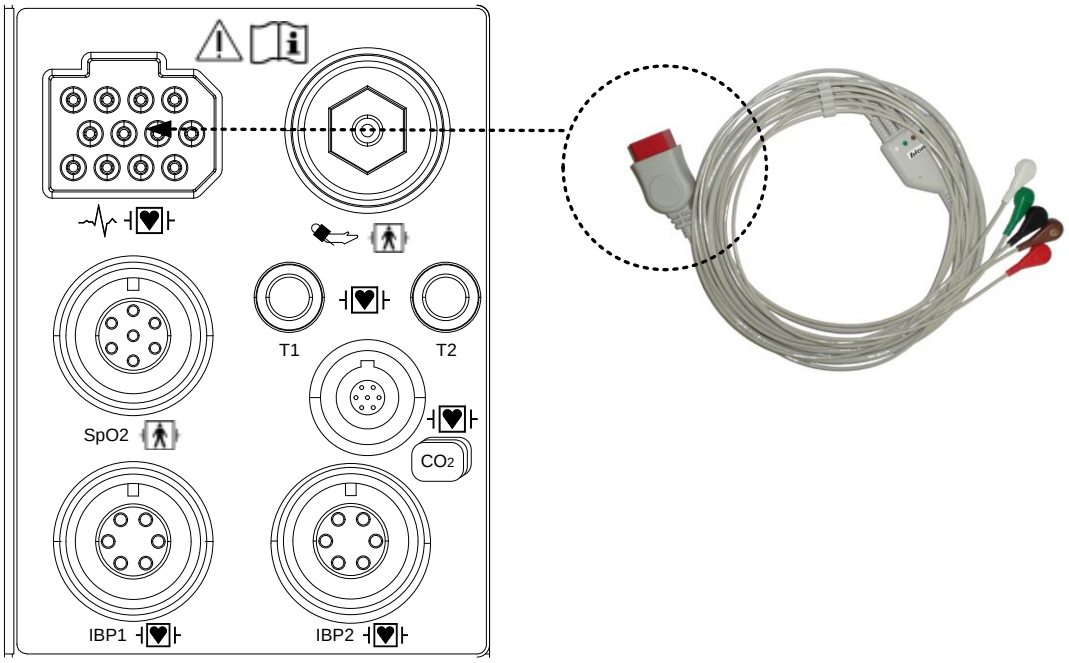
Leadwire	AHA Color code	AHA Label	IEC Color code	IEC Label
Right arm	White	RA	Red	R
Left arm	Black	LA	Yellow	L
Right leg	Green	RL	Black	N
Left leg	Red	LL	Green	F
V1(precordial)	Brown	V1	White	C1

10LEAD

Leadwire	AHA Color code	AHA Label	IEC Color code	IEC Label
Right arm	White	RA	Red	R
Left arm	Black	LA	Yellow	L
Right leg	Green	RL	Black	N
Left leg	Red	LL	Green	F
V1(precordial)	Brown(Red)	V1	White(Red)	C1
V2	Brown(Yellow)	V2	White(Yellow)	C2
V3	Brown(Green)	V3	White(Green)	C3
V4	Brown(Blue)	V4	White(Brown)	C4
V5	Brown(Orange)	V5	White(Black)	C5
V6	Brown(Purple)	V6	White(Purple)	C6

Position of ECG Connector and Measuring Cable

- **ECG connecter + detect cable**



Attaching Electrodes to the Patient

1. Shave excess hair. With a piece of cotton pad moistened with alcohol, clean the patient's skin where the electrodes should be mounted. Avoid wrinkled or uneven skin areas. Wipe off the alcohol with a dry cotton pad.

2. Open the electrode package and take out the electrode.

3. Remove the backing paper from the electrode. Be careful not to touch the adhesive side.

4. Attach the disposable electrode to the previously cleaned skin. Avoid wrinkled and uneven skin areas.

5. The electrode lead which is connected to the monitor onto the electrode.

6. Fasten the electrode lead to the skin with surgical tape with an extra length of wire between the tape and the electrode. This prevents body movement from moving the electrode lead.

Note
✓ To maintain good contact between the electrode and skin, check that the paste of the disposable electrode is not dry. ✓ When contact of the disposable electrode becomes poor, replace the electrode with a new one immediately. Otherwise, contact impedance between the skin and electrode increase and the correct ECG cannot be obtained. ✓ If the contact is bed before the expiration date on the package, replace the electrode with a new one. ✓ To obtain a stable ECG wave form rub the skin with "skin Pure" skin preparation gel or tincture of Benzion. ✓ Shall use only the CE certified disposable electrode.

Choosing an ECG lead for Arrhythmia Monitoring

It is very important to select a suitable lead for arrhythmia monitoring.
Guidelines for non-paced patients:

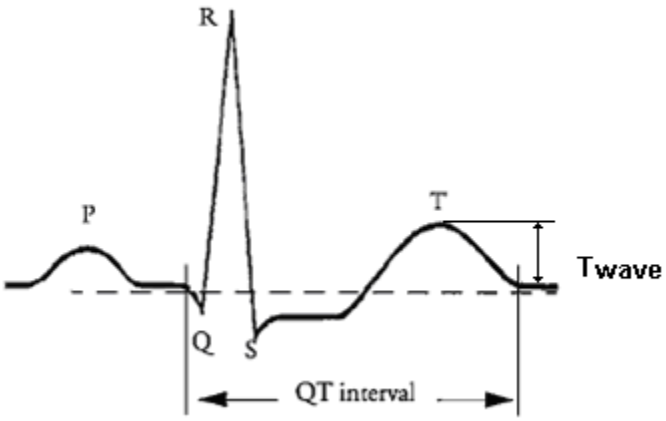
- ✓ QRS should be tall and narrow(recommended amplitude > 0.5mV)
- ✓ R wave should be above or below the baseline (but not bi-phasic)
- ✓ T wave should be smaller than 1/3 R-wave height.
- ✓ The P-wave should be smaller than 1/5 R-wave height.

For paced patients, in addition to the above,:

- ✓ Not wider than the normal QRS
- ✓ The QRS complexes should be at least twice the height of pace pulses.
- ✓ Large enough to be detected, with no re-polarization.

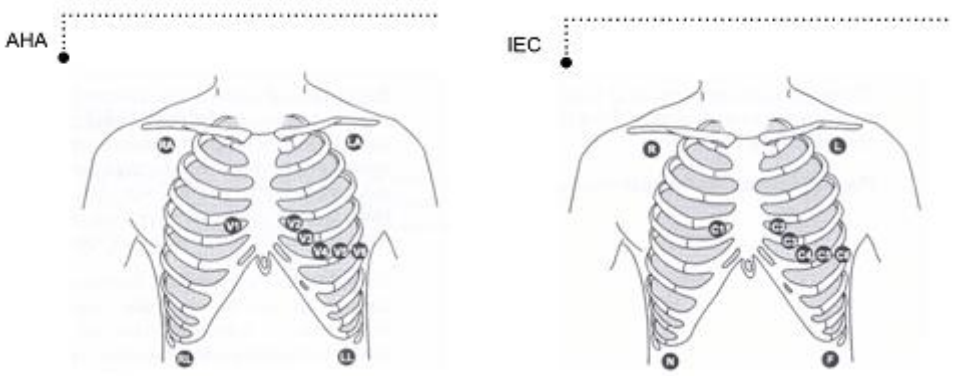
To prevent detection of P-waves or baseline noises as QRS complexes, the minimum detection level for QRS complexes is set at 0.15mV. Adjusting the ECG wave size on the monitor display (gain adjustment) does not affect the ECG signal which is used for arrhythmia analysis. If the ECG signal is too small, you may get false alarms for asystole.

Information on the ECG waveform

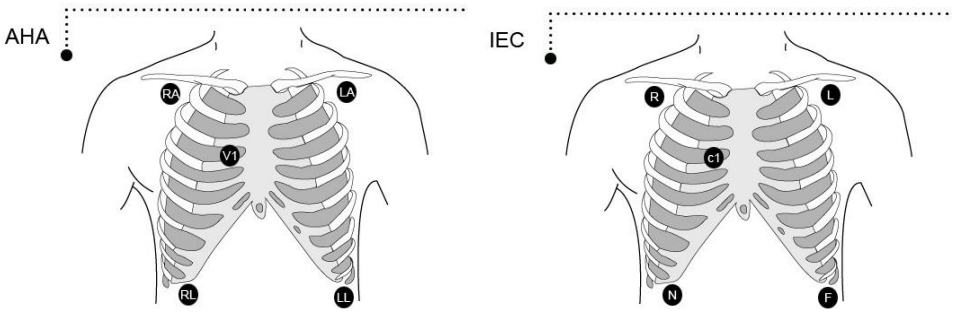


When ECG signal is 80bpm T-wave duration is 180ms, and the QT interval is 350ms.

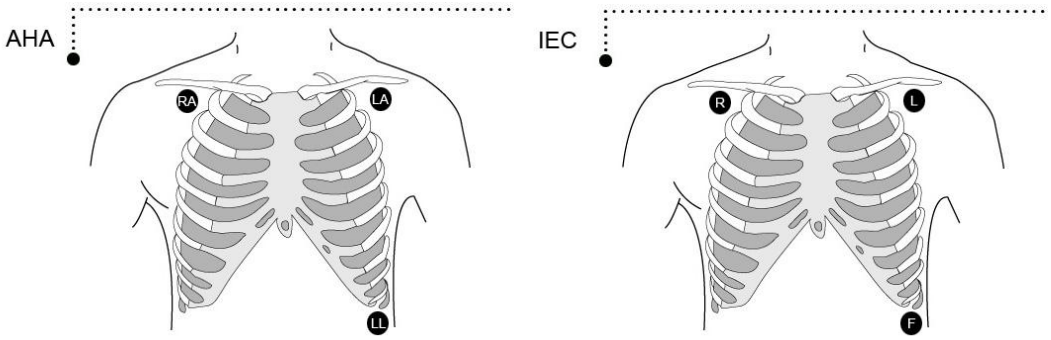
Position of 10-Lead Wires Electrode



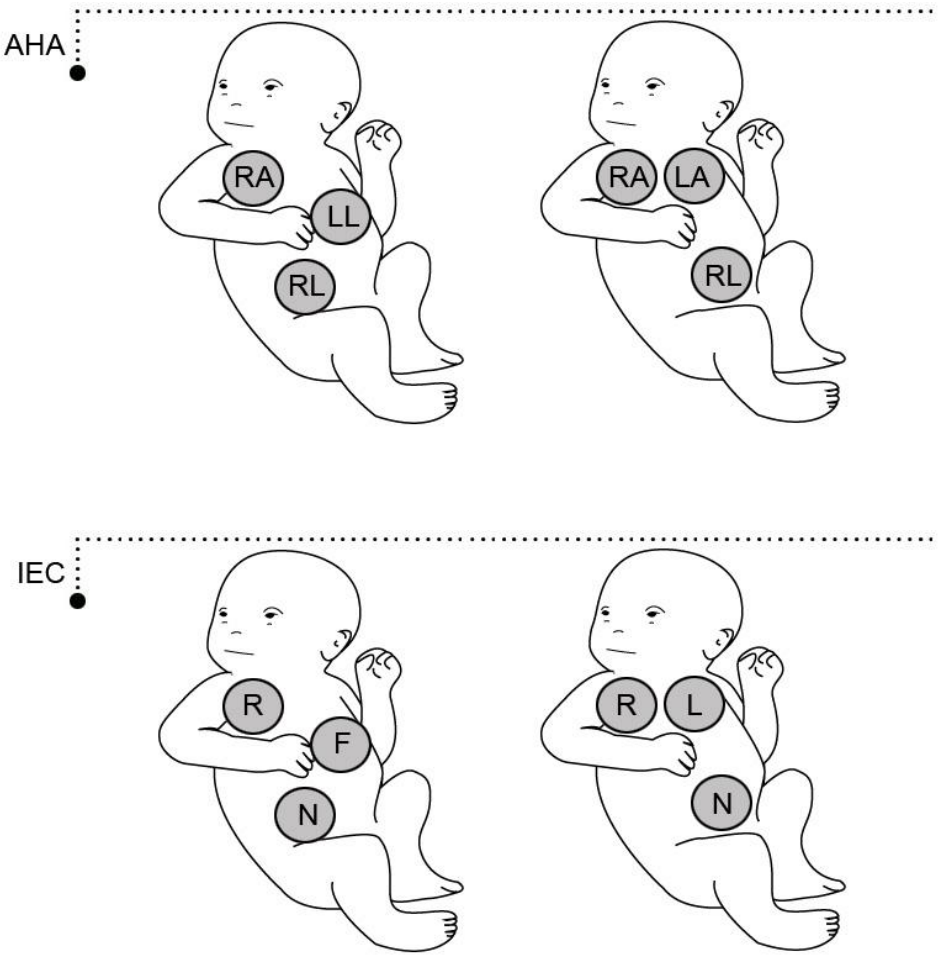
Position of 5-Lead Wires Electrode



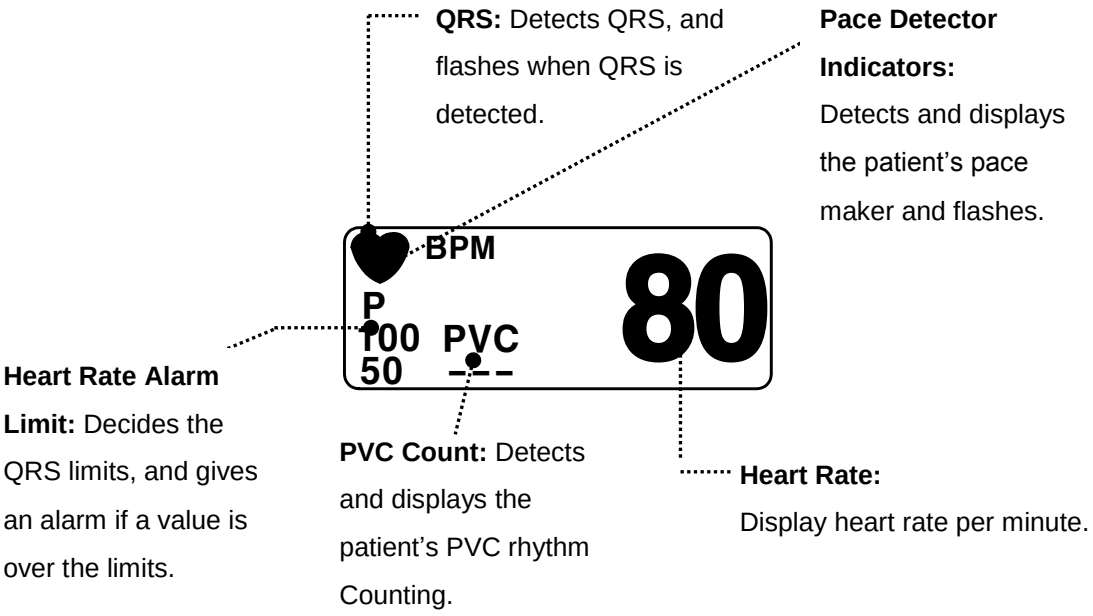
Position of 3-Lead Wires Electrode



How to Attach the NEONATE Electrode



5.2 ECG Data Window



Note
ECG Wave Display is always on when the cable is connected.

The heart rate is calculated by a moving average. The monitor detects 8 consecutive beats, averages the R-R intervals of the latest 8 beats and uses this average to calculate the current heart rate. When a new beat is detected, the heart rate is recalculated using the latest 8beats. The heart rate display is updated every 3 seconds.

Heart rate meter updates a new heart rate for a step increase or decrease in 10 seconds maximum. When ventricular tachycardia is detected, the alarm set in 5 seconds maximum.

Check that the delay time of the output signal (alarm trigger 80ms maximum) is within the range of the connected equipment.

Safety Precautions

Warning
CABLES — Route all cables away from patient's throat to avoid possible strangulation. **CONDUCTIVE CONNECTIONS** — Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground. **DEFIBRILLATION** — Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result. To avoid the risk of serious electrical burn, shock, or other injury during defibrillation, all persons must keep clear of the bed and must not touch the patient or any equipment connected to the patient. After defibrillation, the screen display recovers within 10seconds if the correct electrodes are used and applied in accordance with the manufacturer's instructions. Patient cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again. The peak of the synchronized defibrillator discharge should be delivered within 60ms of the peak of the R wave. The signal at the ECG output on the patient monitors is delayed by a maximum of 30ms. If the ECG waveform on the screen is too unstable to synchronize with the patient's heart beat because of the following reason, remove the cause of an alarm, message, or unstable ECG, and then use a stable ECG lead for synchronization. ✓ ECG electrode is detached or broken. Lead wire is detached or broken. ✓ Lead wire moves. AC interference, EMG noise or noise from ESU is superimposed. ✓ Connection cable is broken or has a short circuit. Connector has poor contact. **INTERFACING OTHER EQUIPMENT** — Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical engineering

personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable Manufacturer's instructions for use and system standards IEC 60601-1-1/EN 60601-1-1 must be complied with.

Electro surgery Unit

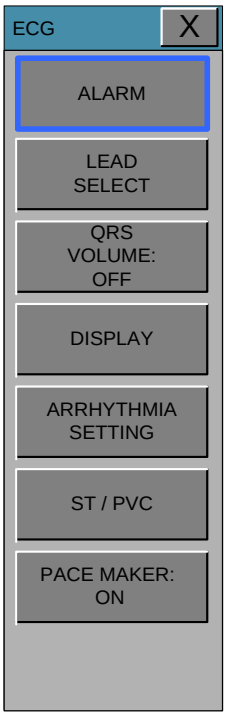
- ✓ Electrosurgical unit (ESU) emits a lot of RF interference. If the monitor is used with an ESU, RF interference may affect the monitor operation.
- ✓ Locate the monitor as far as possible from the ESU. Locate them on opposite sides of the operating table, if possible.
- ✓ Connect the monitor and ESU to different AC outlets located as far as possible from each other.
- ✓ When using this monitor with an electrosurgical unit, its return plate and the electrodes for monitoring must be firmly attached to the patient. If the return plate is not attached correctly, it may burn the patient's skin where the electrodes are attached.

During surgery:

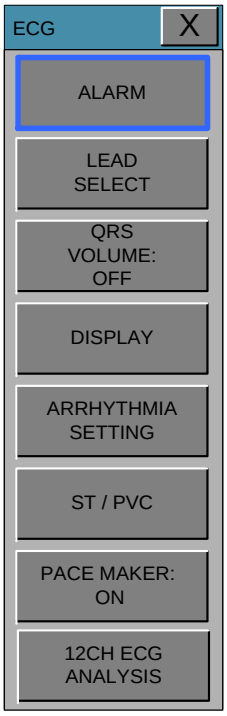
Use the appropriate orange electrode ECG safety cable, or lead cable with an red connector, for measuring ECG in the operating room. These cables have extra circuitry to protect the patient from burns during cautery, and they decrease electrical interference. This also reduces the hazard of burns in case of a defective neutral electrode at the HF device. These cables cannot be used for measuring respiration.

5.3 ECG Data Setup

A setup window appears at lower part of the screen when the Trim Knob Key is pressed in the ECG Parameter Window. Selection is made by pressing the Trim Knob Key, while movement across the menu is performed by turning the key either clock or anticlockwise.

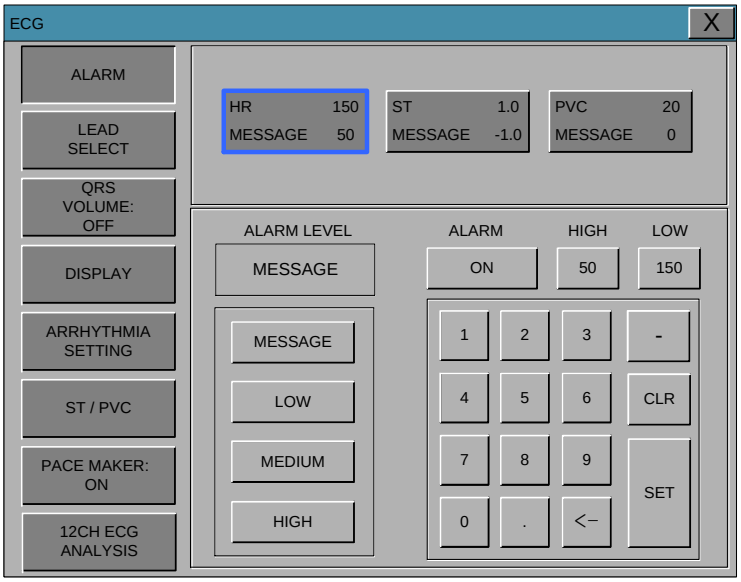


*12 LEAD ECG ANALYSIS menu (optional).



ALARM

Alarm Limit is 0 ~ 350BPM.
ECG alarm feature ON / OFF and the menu is set to LEVEL.

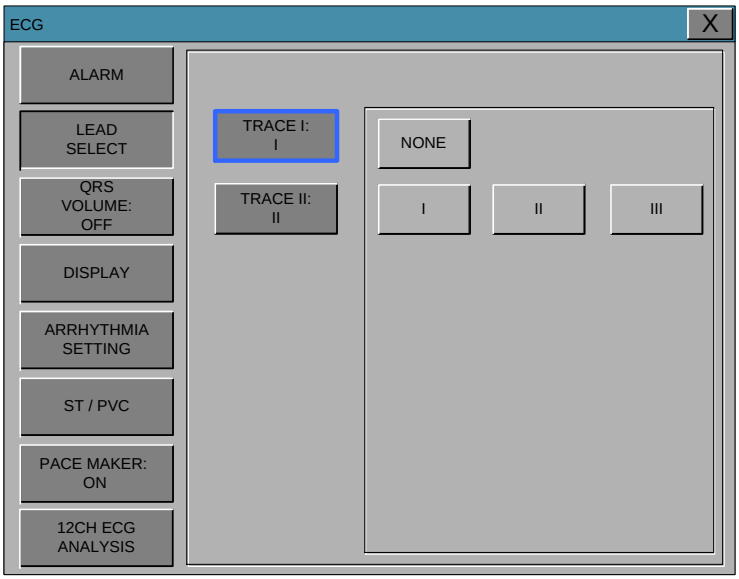


LEAD SELECT

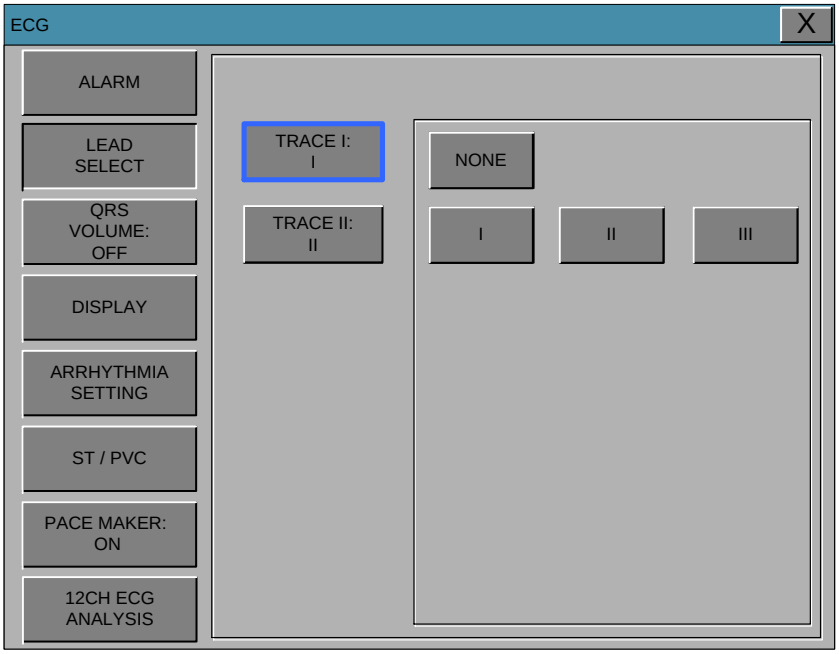
Select channels from I to V in ECG

Lead I, II, III show up in case of connecting 3-Leads patient Cable.

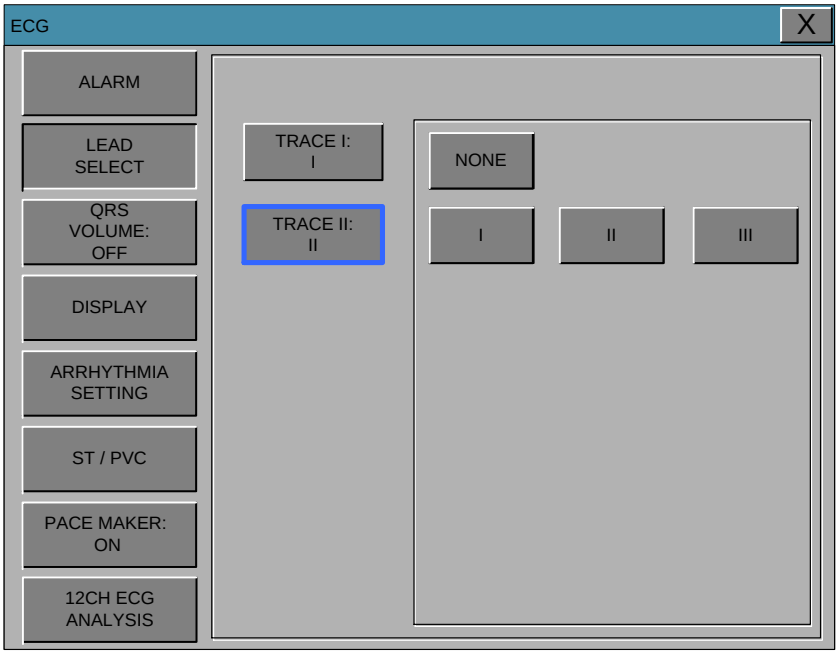
Lead I, II, III, aVR, aVL, aVF, V show up in case of connecting 5-Leads patient Cable.



TRACE I SELECT MENU



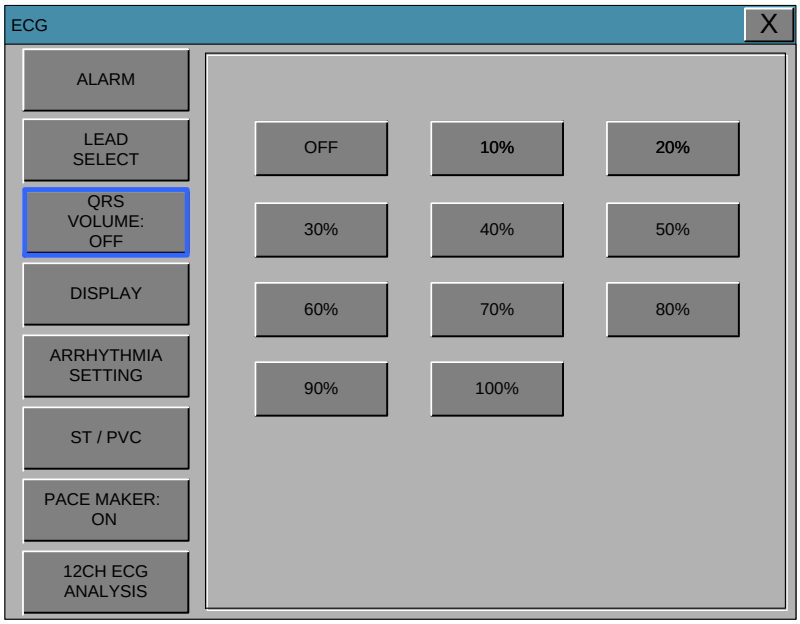
TRACE II SELECT MENU



QRS VOLUME

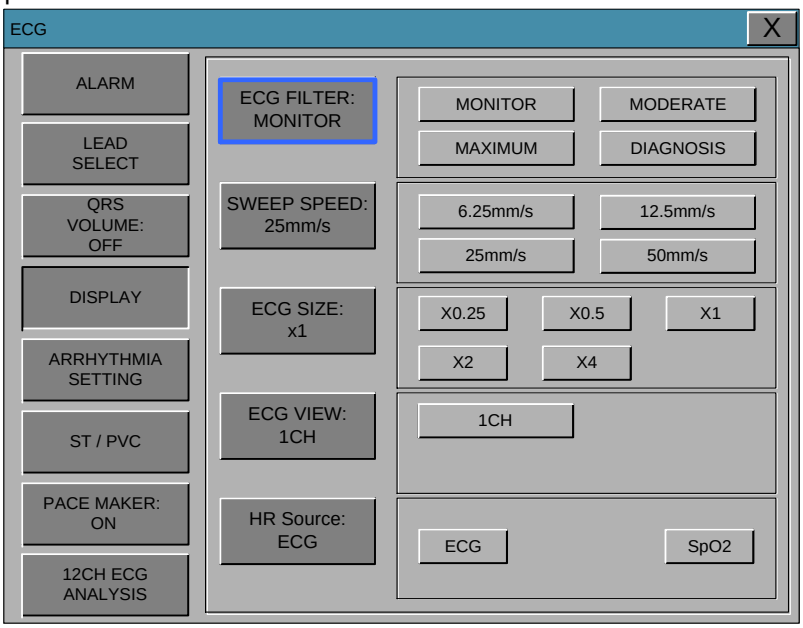
Move the Key to select a volume rate from OFF, 10% to 100%.

SpO2 volume setting is set OFF automatically.



DISPLAY

Set the sweep speed and waveform size.

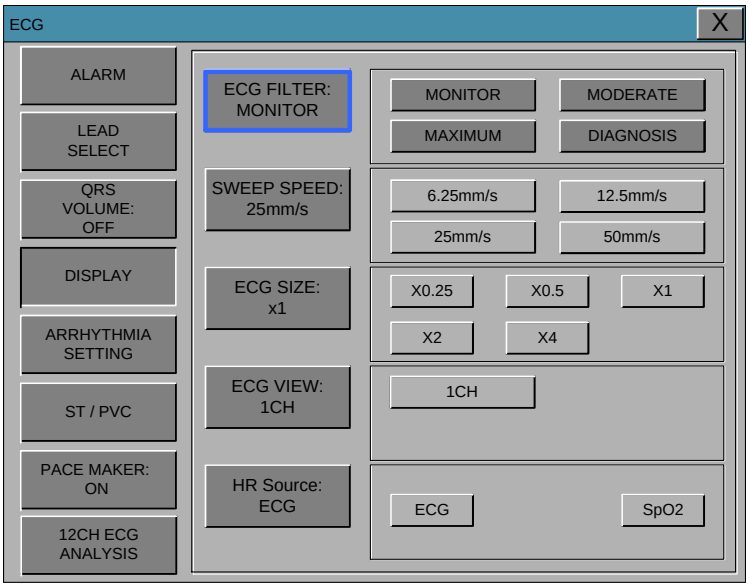


ECG FILTER

One may select from three frequency types for WAVE FILTER.

MONITOR 0.5Hz ~ 40Hz , MODERATE 0.5Hz ~ 25Hz

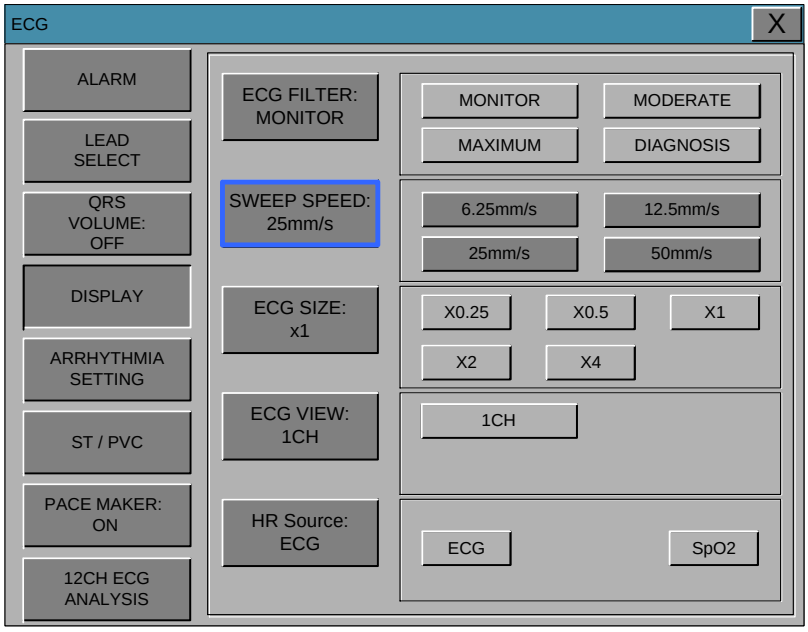
MAXIMUM 5Hz ~ 25Hz , DIAGONOSIS 0.05Hz ~ 150Hz



ECG **SWEEP** SPEED

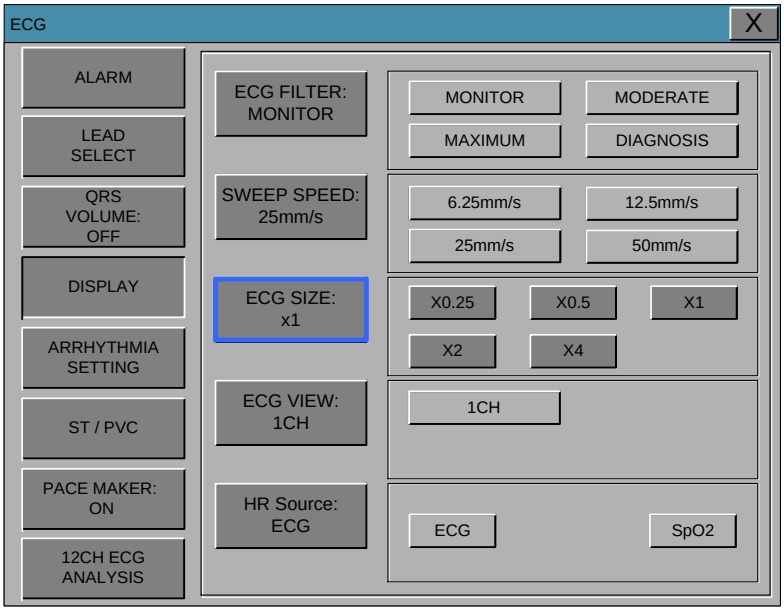
ECG speed on the LCD is 25 mm/s.

Speed is changeable to 6.25, 12.5, 25, 50mm/s.



ECG SIZE

The size is changeable to X0.25, X0.5, X1, X2, X4.

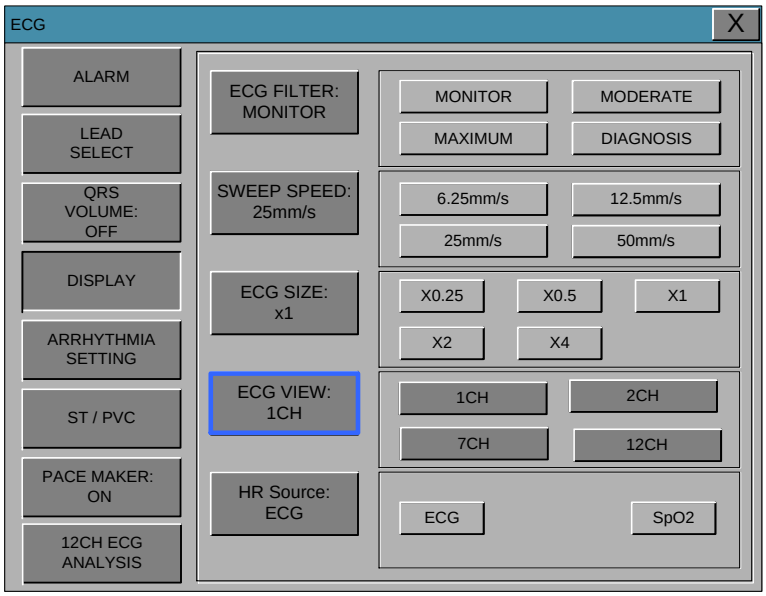


ECG VIEW

The number of ECG wave could be configured with this function.

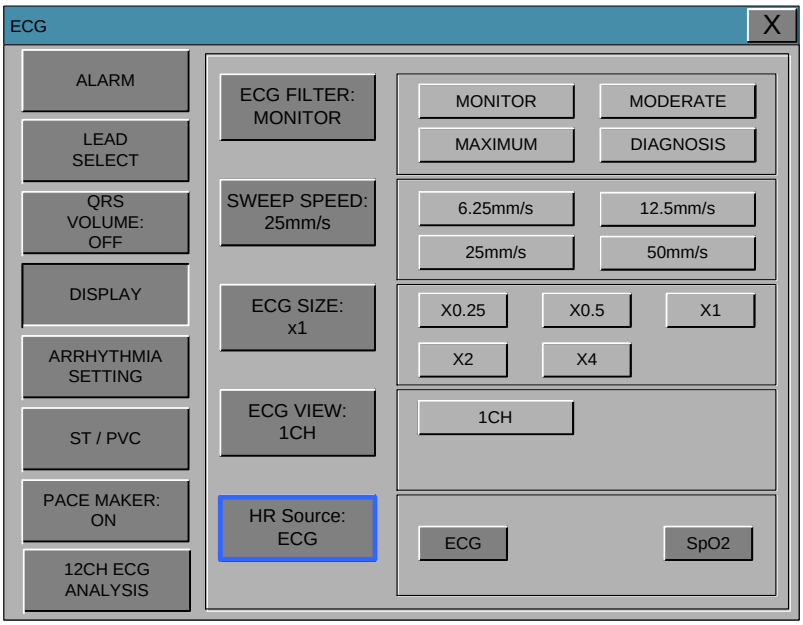
In case of 1 CH, there are 2 traces of 1 CH data at the ECG wave.

- 3LEAD : 1CH
- 5LEAD : 1CH, 2CH, 7CH
- 10LEAD : 1CH, 2CH, 7CH, 12CH



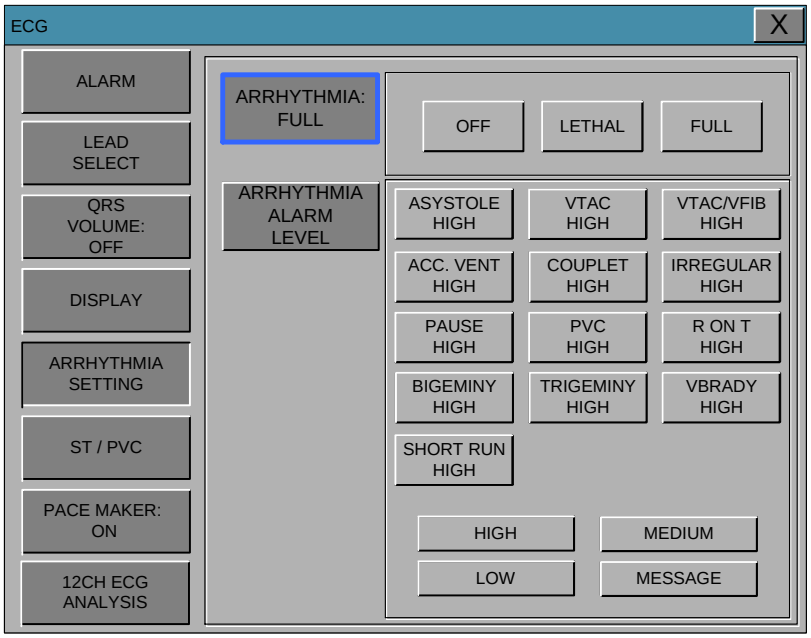
HR Source

ECG or SpO2 and heart rate in the source can be selected.



ARRHYTHMIA SETTING

Analysis setting is divided to 3 menus.



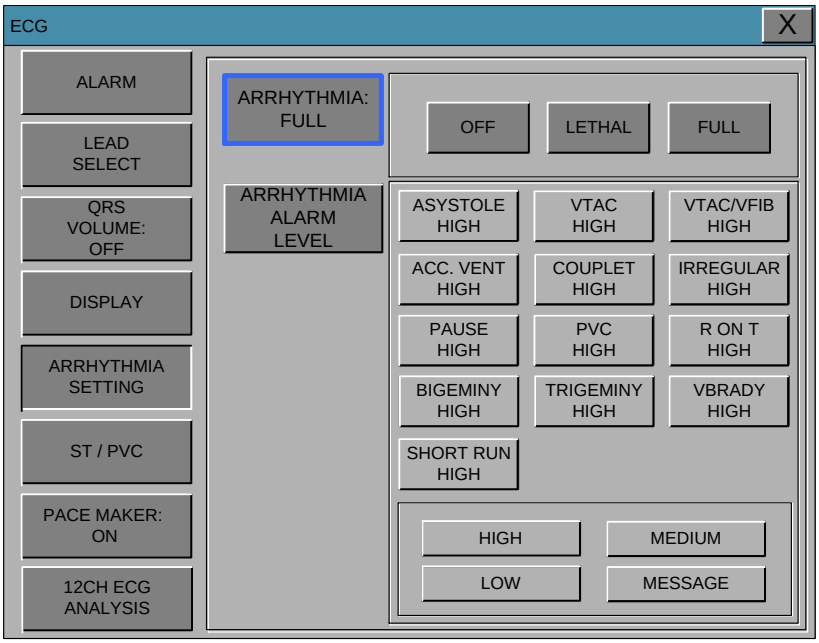
ARRHYTH : Sets up ON/OFF to indicate detection of diagnosis (Asys, VTAC/VFIB and VTAC).

OFF: Do not perform arrhythmia diagnosis.

LETHAL: Performs the detection of Asys, VTAC/VFIB, and VTAC at the selected lead

FULL: Performs the detection of all 13 arrhythmia.

The Analysis algorithm simultaneously uses leads I, II, III, and the V lead for ECG and arrhythmia analysis.



ACC VENT

Adult— Accelerated ventricular occurs when six or more ventricular beats are detected with an average heart rate for the ventricular beat between 50 and 100 beats per minute.

0-2 years—Occurs when six or more ventricular beats are detected with an average heart rate for the ventricular beat between 60 and 160 beats per minute.

3-10 years—Occurs when six or more ventricular beats are detected with an average heart rate for the ventricular beat between 60 and 140 beats per minute.

11-13 years—Occurs when six or more ventricular beats are detected with an average heart rate for the ventricular beat between 60 and 130 beats per minute.

ASYSTOLE

Ventricular asystole occurs whenever the displayed heart rate drops to zero.

BIGEMINY

Occurs when two or more bigeminal cycles (a ventricular beat followed by a non-ventricular beat) are detected.

BRADY

Bradycardia is the average of the most recent eight R-to-R intervals at a heart rate less than the set low heart rate limit.

NOTE
The Brady limit matches the low heart rate limit. If the low heart rate limit is changed, the Brady limit changes.

COUPLET

Occurs when two ventricular beats are detected and have non-ventricular beats before and after the couplet. The coupling interval must be less than 600 milliseconds.

IRREGULAR

Occurs when six consecutive normal R-to-R intervals vary by 100 milliseconds or more.

PAUSE

Occurs when the interval between two consecutive beats exceeds three seconds.

PVC

Isolated premature ventricular complexes occur when a premature ventricular beat is Detected and has non-ventricular beats before and after.

R ON T

Occurs when a ventricular complex is detected within the repolarization period of a Non-ventricular beat.

TACHY

Tachycardia is four R-to-R intervals at a heart rate greater than the set high heart rate limit.

NOTE
The Tachy limit matches the high heart rate limit. If the high heart rate limit is changed, the Tachy limit changes.

TRIGEMINY

Occurs when two or more trigeminal cycles (a ventricular beat followed by two non-Ventricular beats) are detected.

V BRADY

Adult—Ventricular bradycardia occurs when a run of three or more ventricular beats is detected with an average heart rate that is less than or equal to 50 beats per minute.

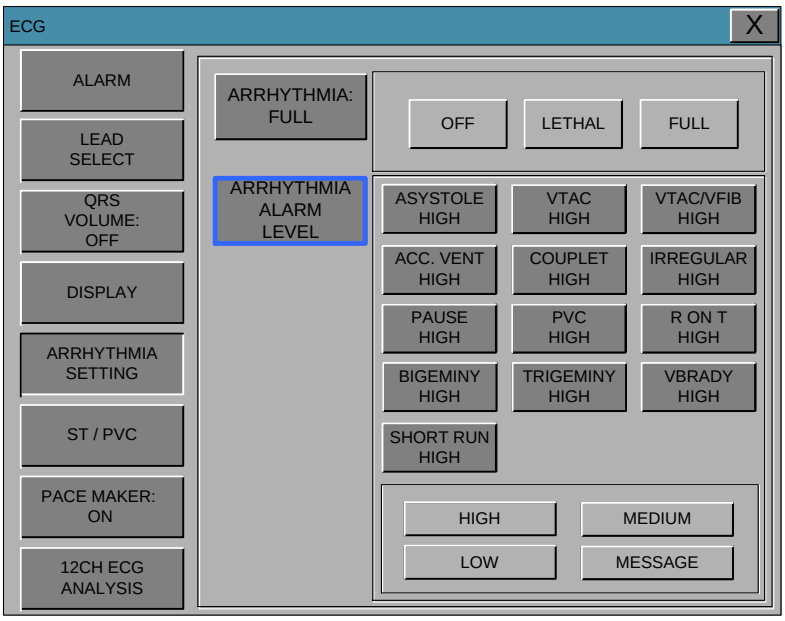
0-2, 3-10, and 11-13 years—Occurs when a run of three or more ventricular beats is detected with an average heart rate that is less than or equal to 60 beats per minute.

VFIB/VTAC

Ventricular fibrillation occurs when the ECG waveform indicates a chaotic ventricular arrhythmia.

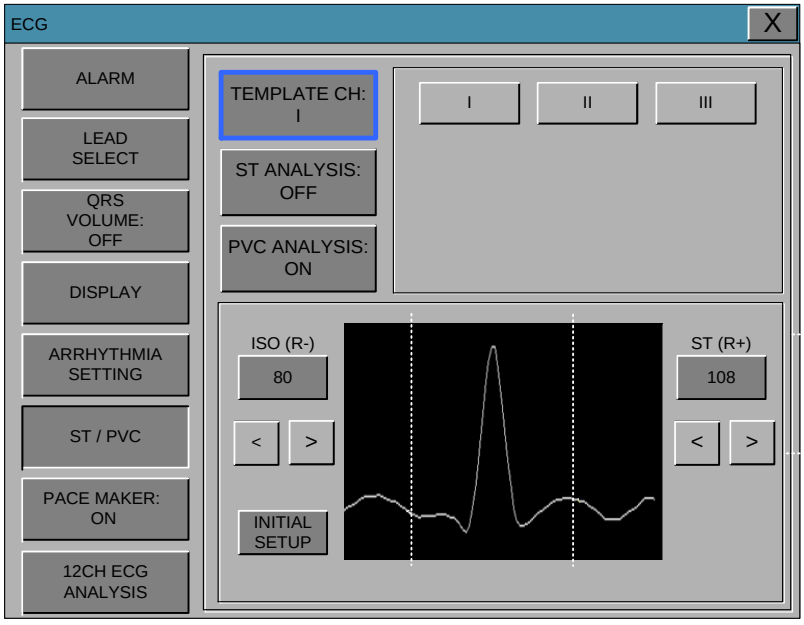
ARRHYTHMIA ALARM LEVEL

Diagnostic alarm level is set.



ST/PVC

ST signal and setting related ST menu and PVC menu.

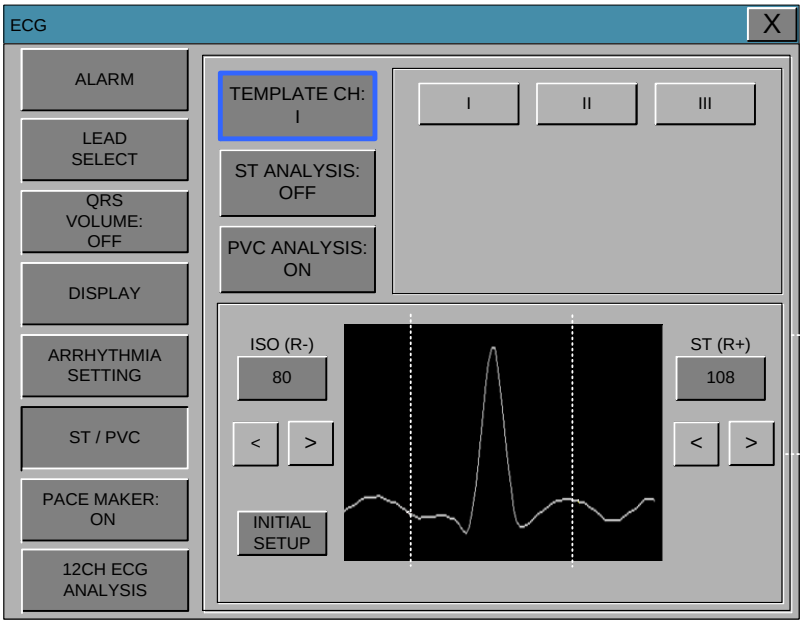


TEMPLETE CH:

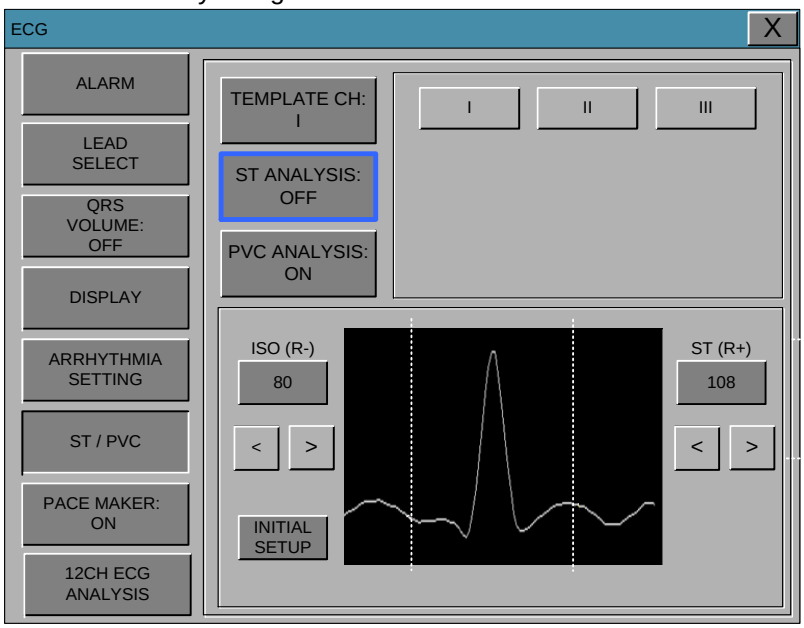
TEMPLETE SELECT: Select a Representative Lead of ST LEVEL.

The trace of the selected LEAD shows up at ST Window of POPUP TREND WINDOW

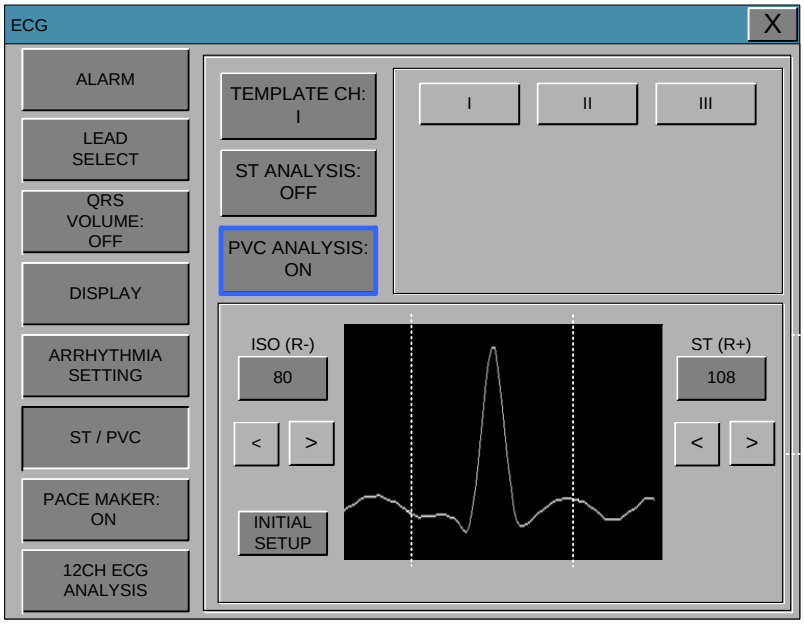
* 3lead is fixed in lead II



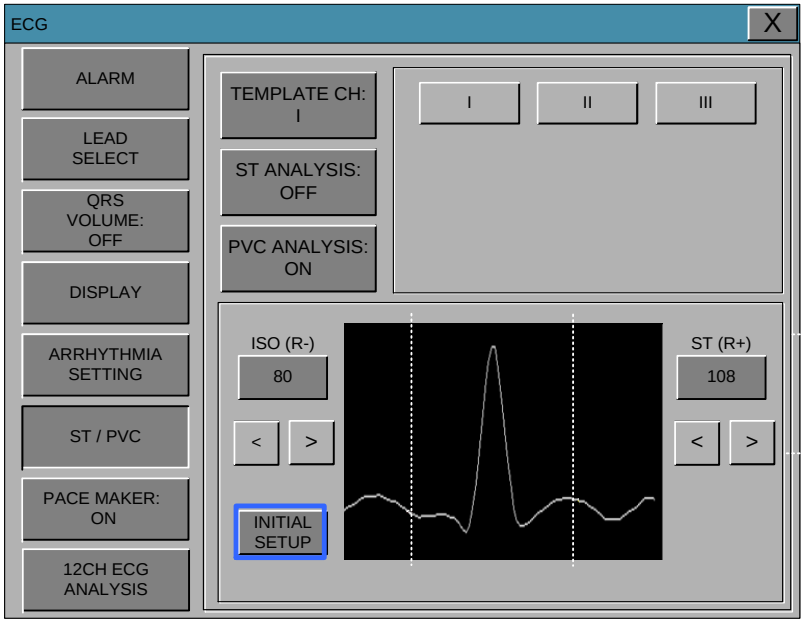
ST ANALYSIS: ON/OFF ST analysis signal.



PVC ANALYSIS: Decision maker to display PVC value sign with ON/OFF

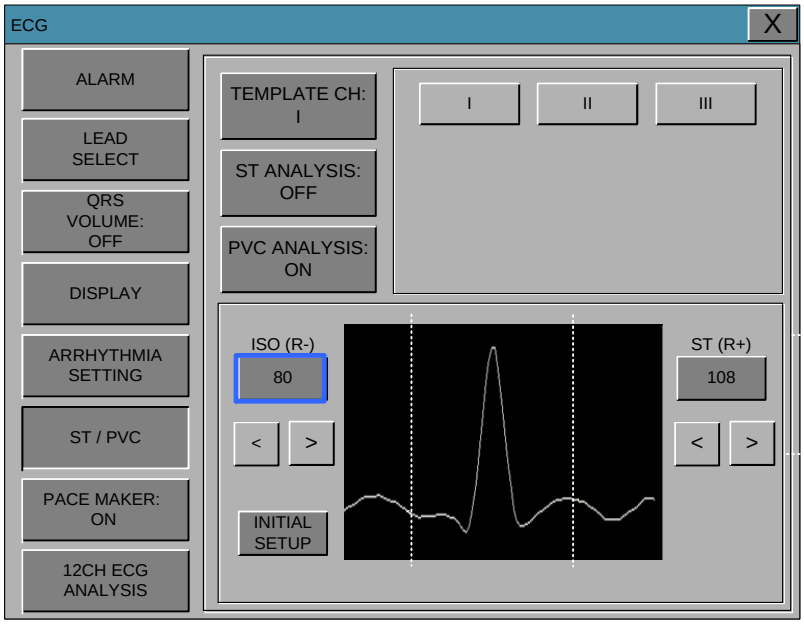


INITIAL SETUP: ST measurements to factory settings (ISO R-: 80, ST R +: 108)



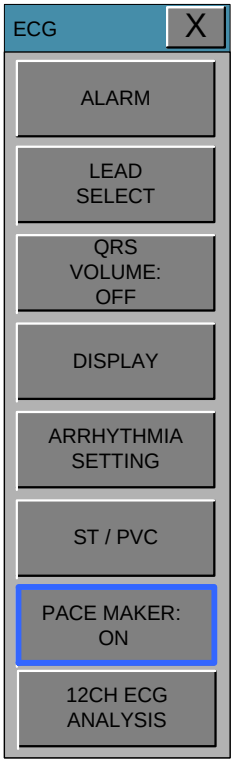
ST MEASUREMENT CONDITION fine-tune the ISO and ST in order to position the cursor keys to select the rotary and then to be adjusted and controlled at ISO and ST TOUCH button arrow and then fine-tuning is possible when TOUCH.

MEASUREMENT CONDITION: ST measurement condition setting



PACE：Sets up ON/OFF to indicate that the patient has PACE.

The PACE menu option enables/disables the pacemaker detection program.



Be aware of the following when monitoring a patient with a pacemaker.

Warning

FALSE CALLS—False low heart rate indicators or false asystole calls may result with certain pacemakers because of electrical overshoots.

MONITORING PACEMAKER PATIENTS—Monitoring of pacemaker patients can only occur with the pace program activated.

PACEMAKER SPIKE—An artificial pacemaker spike is displayed in place of the actual pacemaker spike. All pacemaker spikes appear uniform. Do not diagnostically interpret pacemaker spike size and shape.

PATIENT HAZARD—A pacemaker pulse can be counted as a QRS during asystole in either pace mode. Keep pacemaker patients under close observation.

PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon ratemeter ALARMS. Keep pacemaker patients under close surveillance.

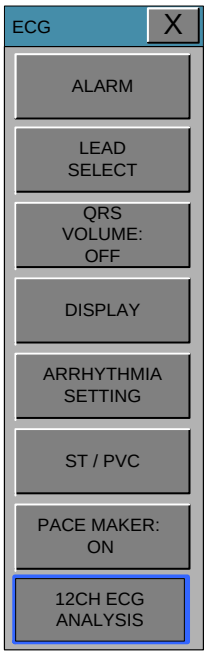
Pacemaker failure:

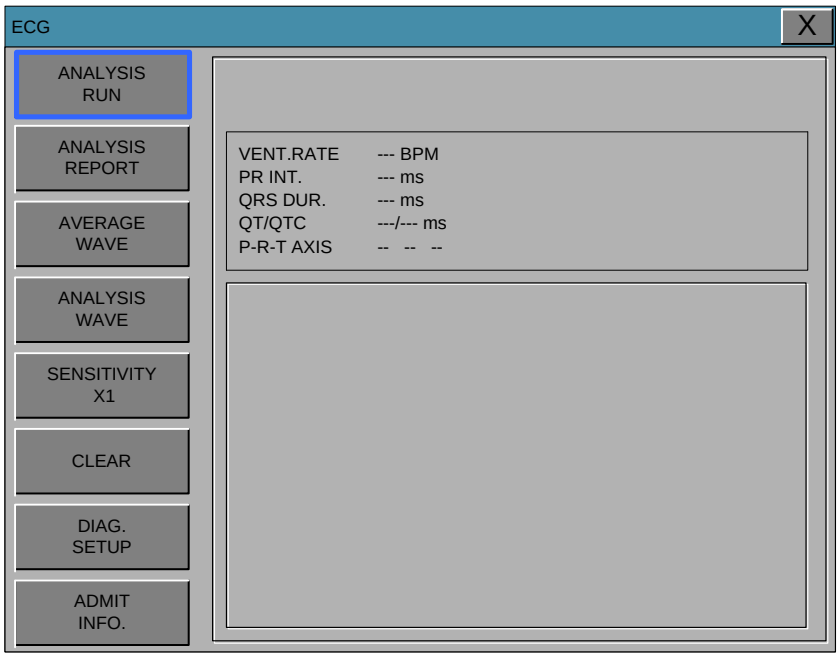
During complete heart block or pacemaker failure to pace/capture, tall P-waves (greater than 1/5 of the average R-wave height) may be erroneously counted by the monitor, resulting in missed detection of cardiac arrest.

12 CH ECG ANALYSIS (Optional Function)

There are 8 sub-menus for 12 CH ECG ANALYSIS menu as following.

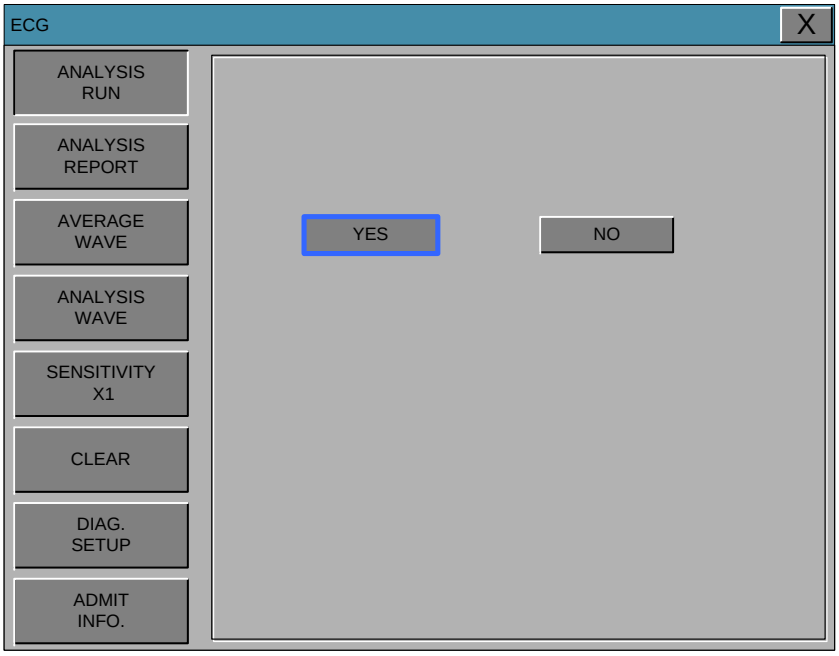
The appropriate menu option applies 12CH ECG equipment can be used in





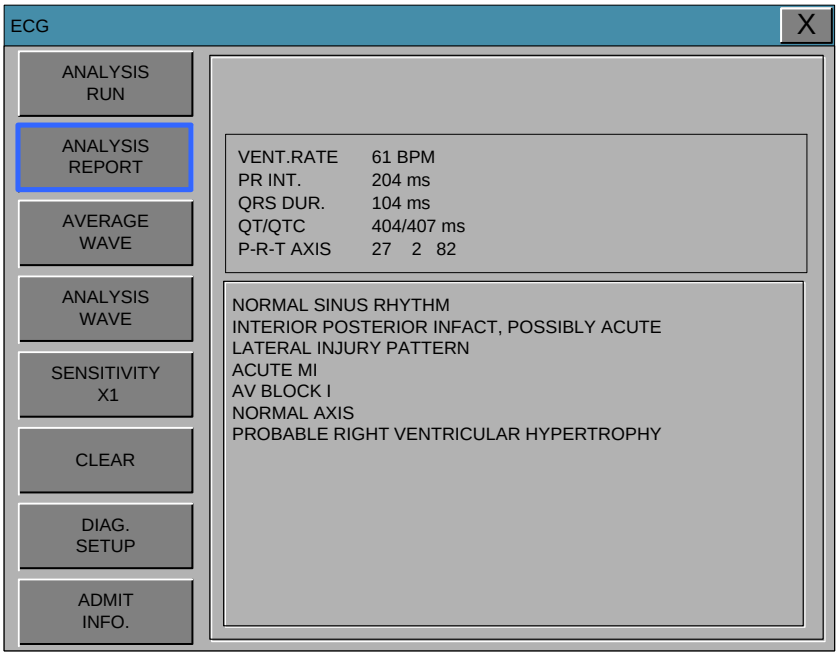
12LEAD ANALYSIS RUN

This is the start command of 12 CH ECG ANALYSIS.



ANALYSIS REPORT

Showing AVERAGE WAVE of each ECG channel when the module interprets them.



If ECG Board sends diagnosis code to BM7, it will display the interpretation of following table at the report and the screen.

NUMBER	CODE	DESCRIPTION
Sinus Node Rhythms and Arrhythmias		
1	111	Normal Sinus Rhythm
2	112	Sinus Bradycardia (HR : 50-59)
3	113	Sinus Bradycardia (HR < 50)
4	115	Sinus Tachycardia (HR : 100-130)
5	116	Sinus Tachycardia (HR > 130)
6	121	Sinus Arrhythmia
7	131	Sinus Pause (pause <= 3.0sec)
8	132	Sinus Pause(pause > 3.0sec)
9	135	SA Block
Other Supraventricular Arrhythmias		
10	211	Atrial Rhythm
11	212	Atrial Tachycardia (HR : 100-130)
12	213	Atrial Tachycardia (HR > 130)

13	214	Wandering Pacemaker
14	215	Multifocal Atrial Tachycardia
15	216	Nonsustained Atrial Tachycardia
16	217	Atrial Flutter
17	218	Atrial Fibrillation
18	219	(possible) Atrial Flutter with 2:1 AV conduction
19	221	Junctional Rhythm
20	222	Supraventricular Tachycardia(AV node dependent Tachycardia)
21	223	Nonsustained Supraventricular Tachycardia
22	231	PAC(Premature Atrial Contraction)
23	232	Bigeminy PAC
24	233	Trigeminy PAC
25	234	short run of PAC
26	241	PJC
27	242	Bigeminy PJC
28	243	Trigeminy PJC
29	244	short run of PJC
30	251	EAB(Escape Atrial Beat)
31	252	EAR (Escape Atrial Rhythm, HR : 50-54)
32	253	EAR (Escape Atrial Rhythm: HR < 50)
33	261	EJB (Escape Juncational Beat)
34	262	EJR (Escape Junctional Rhythm)
Ventricular Arrhythmias		
35	311	Ventricular Rhythm
36	312	Ventricular Tachycardia
37	313	Slow Ventricular Tachycardia
38	314	Nonsustained Ventricular Tachycardia
39	315	Ventricular Flutter
40	316	Nonsustained Ventricular Flutter
41	321	PVC(Premature Ventricular Contraction)
42	322	Bigeminy PVC
43	323	Trigeminy PVC
44	324	short run of PVC

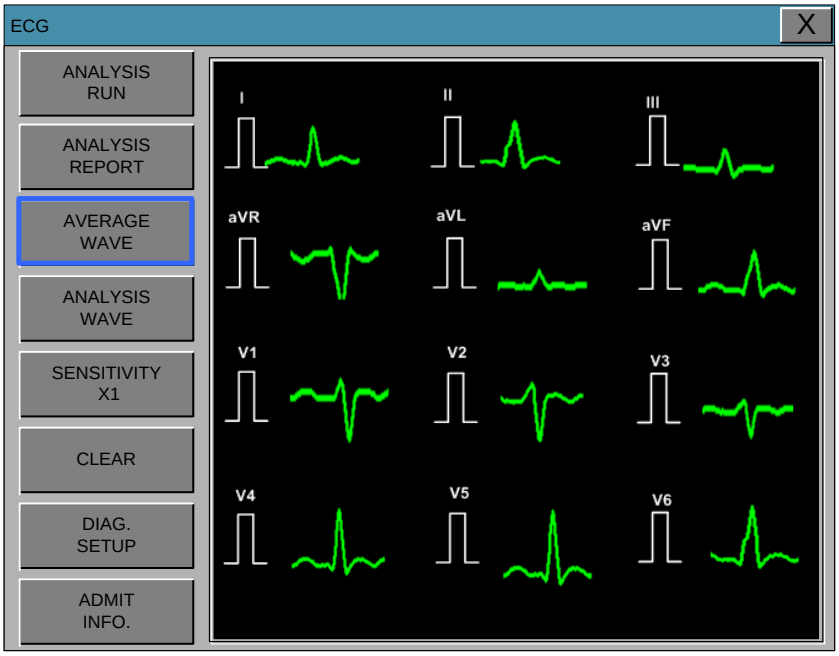
45	331	EVB (Escape Ventricular Beat)
46	332	EVR (Escape Ventricular Rhythm)
AV and Intraventricular Conduction		
47	411	AV Block I
48	412	AV Block II-1
49	413	AV Block II-2
50	414	2:1 AV Block
51	415	AV Block III
52	421	ICRBBB (Incomplete Right Bundle Branch Block)
53	422	CRBBB (Complete Right Bundle Branch Block)
54	423	Bifascicular Block (RBBB + LPFB)
55	424	Bifascicular Block (RBBB + LAFB)
56	425	LBBB (Left Bundle Branch Block)
57	431	Nonspecific Intraventricular Conduction Delay
58	441	WPW (Ventricular Preexcitation)
QRS axis and Voltage		
59	511	Normal Axis
60	512	Right Axis Deviation (Posterior Fascicular Block)
61	513	Left Axis Deviation (Anterior Fascicular Block)
62	514	Northwest Axis
63	521	Low Voltage QRS
64	522	Low Voltage (Limb Leads)
65	523	Low Voltage (Chest Leads)
Chamber Hypertrophy or Enlargement		
66	611	BAE (Biatrial Enlargement)
67	621	RAE (Right Atrial Enlargement)
68	631	LAE (Left Atrial Enlargement)
69	641	BVH (Biventricular Hypertrophy)
70	650	probable RVH
71	651	RVH (Right Ventircular Hypertrophy)
72	661	LVH (Left Ventricular Hypertrophy)
Repolarization Changes		
73	710	ST abnormality, possible subendocardial ischemia
74	711	ST abnormality, possible subendocardial ischemia (Anteroseptal)

75	712	ST abnormality, possible subendocardial ischemia (Anterolateral)
76	713	ST abnormality, possible subendocardial ischemia (Anterior)
77	714	ST abnormality, possible subendocardial ischemia (High Lateral)
78	715	ST abnormality, possible subendocardial ischemia (Inferior)
79	720	ST abnormality, possible transmural injury
80	721	ST abnormality, possible transmural injury (Anteroseptal)
81	722	ST abnormality, possible transmural injury (Anterolateral)
82	723	ST abnormality, possible transmural injury (Anterior)
83	724	ST abnormality, possible transmural injury (High Lateral)
84	725	ST abnormality, possible transmural injury (Inferior)
85	730	T wave inversion (possible Myocardial Ischemia)
86	731	T wave inversion in Anteroseptal (possible Myocardial Ischemia)
87	732	T wave inversion in Anterolateral (possible Myocardial Ischemia)
88	733	T wave inversion in Anterior (possible Myocardial Ischemia)
89	734	T wave inversion in High Lateral (possible Myocardial Ischemia)
90	735	T wave inversion in Inferior (possible Myocardial Ischemia)
91	741	Prolonged QT
Myocardial Infarction		
92	810	Anterior Extensive MI
93	811	Anteroseptal MI
94	812	possible Anteroseptal MI
95	813	Anterior MI
96	814	High Lateral MI
97	815	Lateral MI
98	816	Anterolateral MI
99	817	Inferior MI
100	818	Posterior MI
Pacemaker		
101	911	Pacemaker Rhythm
102	912	paced Atrial Rhythm
103	913	paced Ventricular Rhythm

Warning
This device uses a computerized 12-lead ECG analysis program which can be used as a tool in ECG tracing interpretation. This computerized interpretation is only significant when used in conjunction with clinical findings. All computer-generated tracings should be overread by a qualified physician. The intended use of this device is to record electrocardiograms and vector cardiograms from surface ECG electrodes, not for positioning (floating) temporary pacemaker lead wires, performing pericardiocentesis, or other internal applications

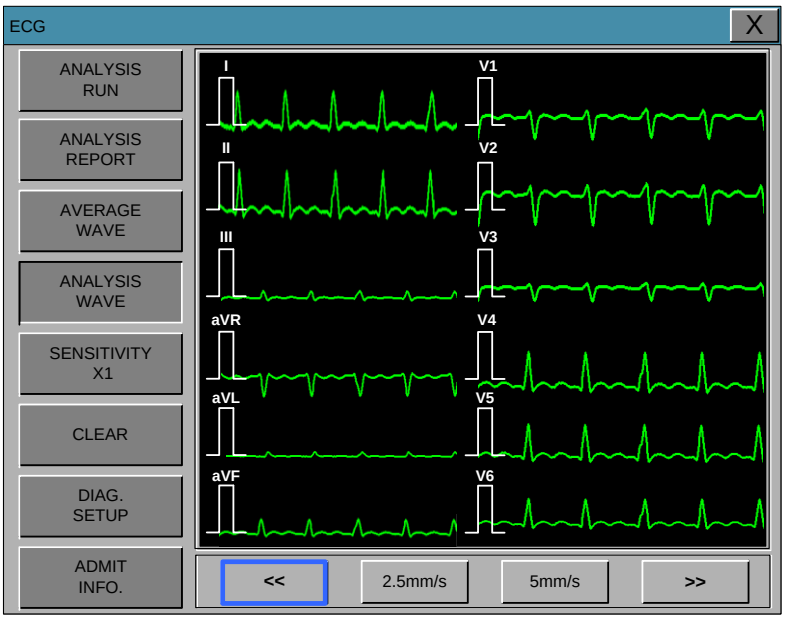
AVERAGE WAVE

Showing AVERAGE WAVE of each ECG channel when the module interprets them.



ANALYSIS WAVE

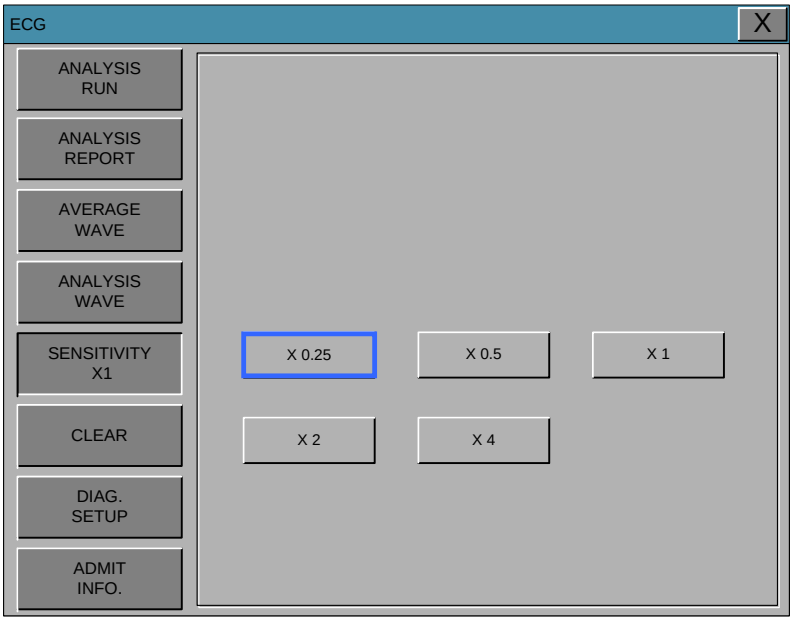
Showing interpreted ECG wave for 2.5 seconds period of each 3 channels in total 10 seconds from starting Interpretation. For example, each channel shows each time period as CH I, II, III show for 0~2.5 second section, CH aVR, aVL, aVF show in 2.5~5 second section, CH V1, V2, V3 show in 5~7.5 second section and CH V4, V5, V6 show in 7.5~ 10 second section. Under this window, all the ECG channels are printed out



SENSITIVITIY

This is the adjustment menu for amplitude of 12CH ECG wave.

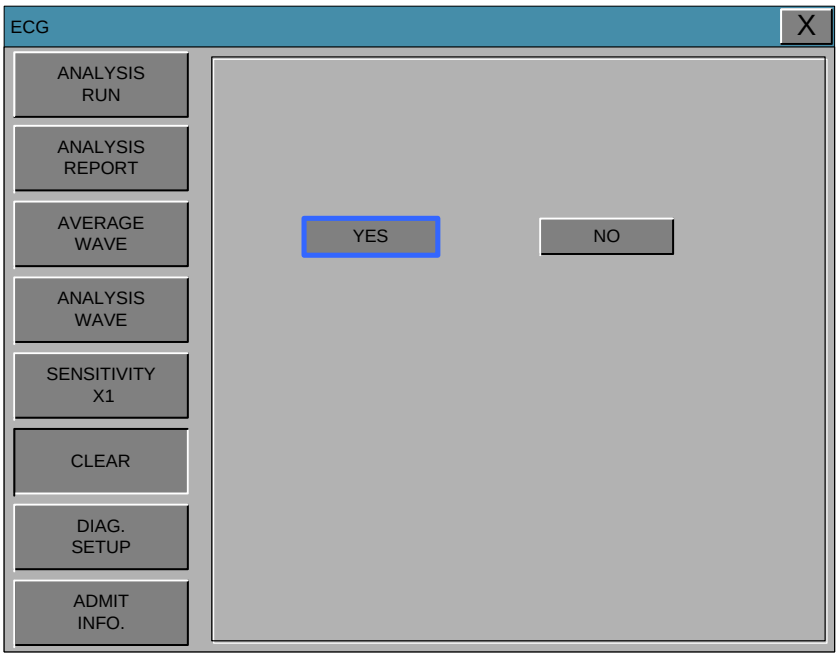
There are 5 kinds of gain from x0.25 to x4 as following.



CLEAR

This is the deleting function for result of interpretation.

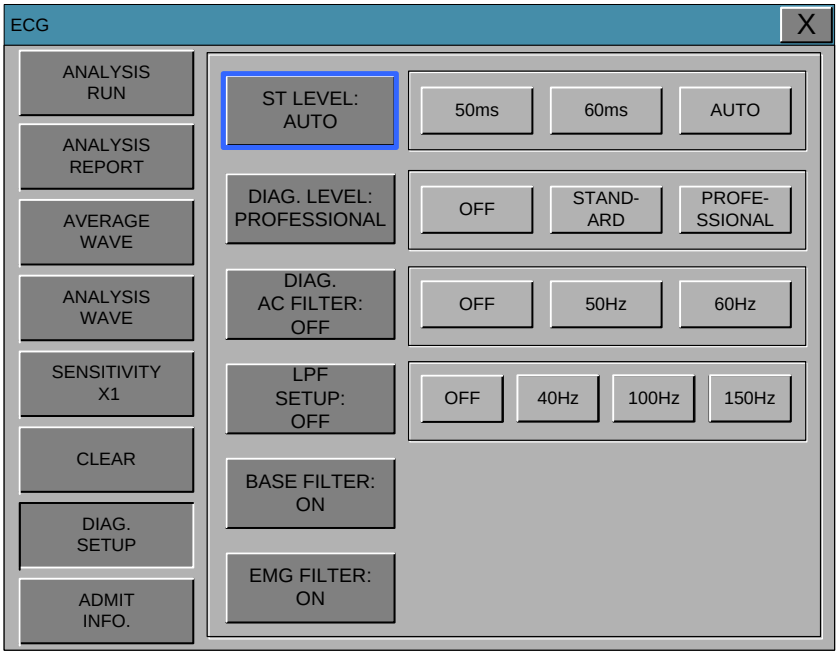
The results of analysis report, average wave and analysis wave are deleted if this menu is selected.



DIAG. SETUP

Diagnosis is related to the setup menu.

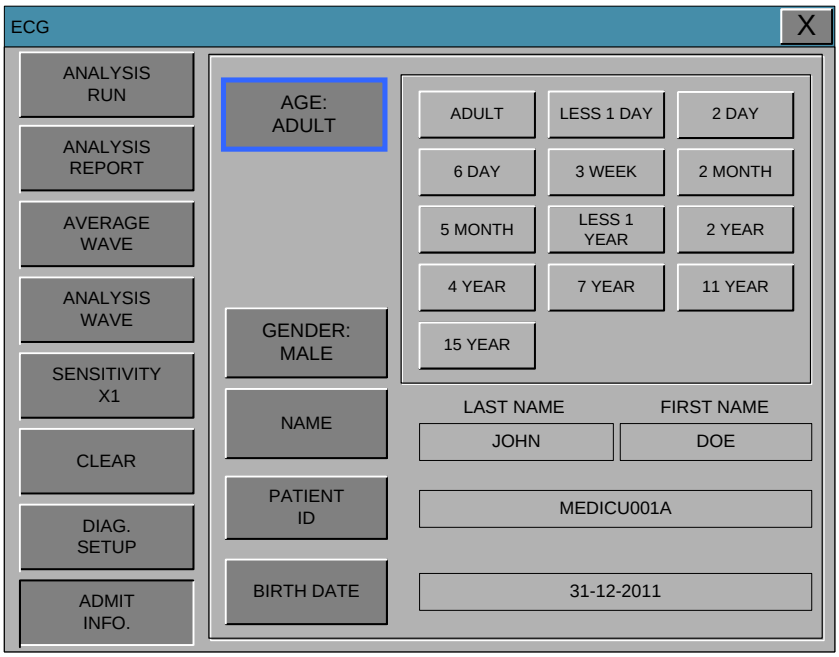
The filter used in the diagnosis and level can be set up to do.



ADMIT INFO

This is a menu for setup the configuration of interpretation.

This is made up with 3 sub-menus.



Warning
Display Heart Beat Equipment Signal Hart Beat equipment signal displays when the PACE mode is. the signal appears series form. The signal size or form are meaningless clinically **Number Of Heart Beat** Attention to the patient with heart beat equipment. The heart beat equipment can show heart beat even during arrhythmia continuously. Therefore, do not depend on heart beat alarm excessively.

Trouble shooting

Problem:

Inaccurate heart rate and/or false asystole.

Solution:

Check ECG signal from patient:

1. Check/adjust lead placement.
2. Check/perform skin preparation.
3. Check/replace electrodes.

Check amplitude of ECG waveform:

1. Select ECG parameter label.
2. Select DISPLAY LEAD,
3. Scroll through all ECG leads and check for 0.5mV amplitude at normal (1X) size. (at least 0.5mV amplitude is required for QRS detection.) for borderline signals, validate on a graph.
4. If amplitudes are low, electrodes may need to be repositioned or replaced.

Problem:

False ventricular calls.

Solution:

Check ECG signal from patient: (the chest lead may exhibit polarity changes which may occasionally cause an inaccurate call.)

1. Check/adjust lead placement.
2. Check/perform skin preparation.
3. Check/replace electrodes. (if chest lead is a problem, move the chest lead to another chest position or leg position.)

Problem:

Inaccurate pacemaker detection

Solution:

Use pacemaker processing:

1. Select ECG parameter label.
2. Display the lead of ECG with the greatest amplitude in the top waveform position.
3. Select ANALYSIS SETTINGS.
4. SELECT DETECT PACE.

6. SpO_2

6.1 Outline

SpO_2 Connector Location and Measuring Cable

6.2 SpO2 Data Window

6.3 SpO2 Data Setup

ALARM

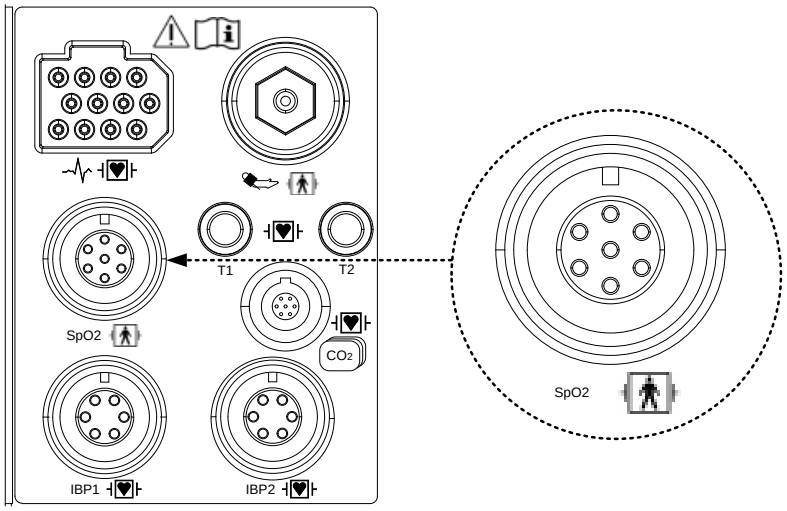
RATE VOLUME

6.1 Outline

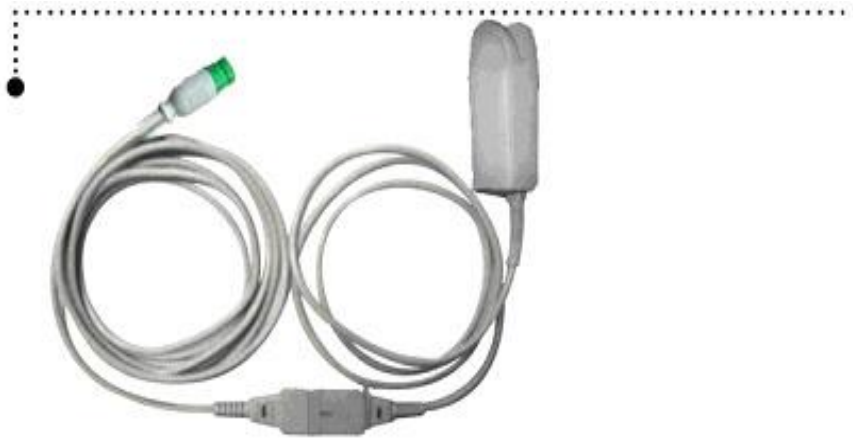
SPO2 monitoring is a noninvasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into an electrical signal by the photo detector in the probe. The monitor processes the electrical signal and displays on the screen a waveform and digital values for SpO2 and pulse rate. It detects SpO2 in the way of transmitting the red and infrared rays into the capillary vessel to take the pulsation. Also perform the alarm function according to the setting value.

SpO2 Connector Location and Measuring Cable

- **SpO_2 connector**

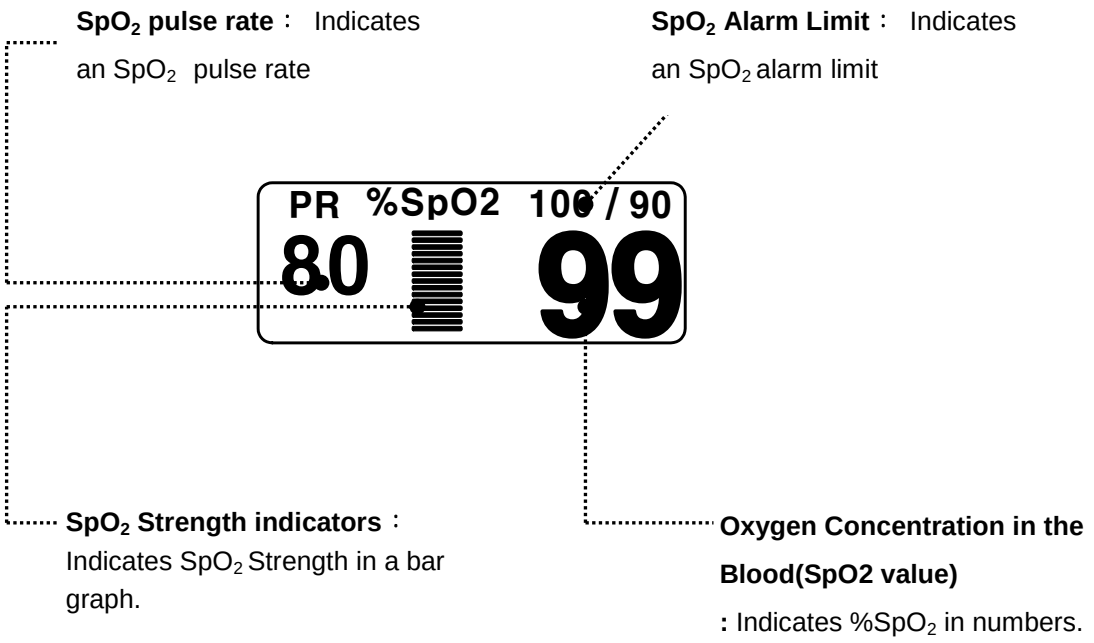


SpO_2 Measuring Cable



Note
The signal input is a high-insulation port and it is defibrillator proof ( )   The insulated input ensures patient safety and protects the device during defibrillation and electro surgery.

6.2 SpO_2 Data Window



The current SPO2 value and the derived pulse rate (RATE) are displayed. The block sets indicate the strength of the signal (twenty block bars indicate the strongest signal). The SPO2 measurements are averaged over a 6-second period of time.

The monitor display is updated every second.

The SPO2 monitoring features are found in the SPO2 menu. These features include alarm limit adjustment, display of RATE, and RATE volume.

Note
SpO_2 WAVE SIZE is changed automatically.

Signal and Data Validity

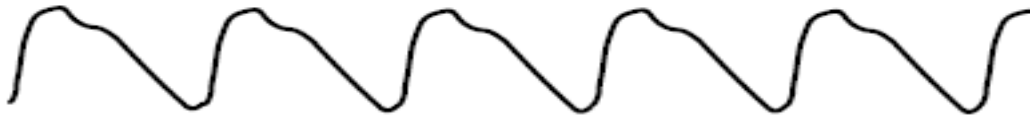
It is extremely important to determine that the probe is attached to the patient correctly and the data is verifiable. To make this determination, three indications from the monitor are of assistance—signal strength bar, quality of the SPO2 waveform, and the stability of the SPO2 values. It is critical to observe all three indications simultaneously when ascertaining signal and data validity.

Signal Strength Bar

The signal strength bar is displayed within the SPO2 values window. This bar consists of 20 blocks set depending on the strength of the signal. Proper environmental conditions and probe attachment will help to ensure a strong signal.

Quality of SPO2 Waveform

Under normal conditions, the SPO2 waveform corresponds to (but is not proportional to) the arterial pressure waveform. The typical SPO2 waveform indicates not only a good waveform, but helps the user find a probe placement with the least noise spikes present. The figure below represents an SPO2 waveform of good quality.



Good Quality SPO2 Waveform

If noise (artifact) is seen on the waveform because of poor probe placement, the photo detector may not be flush with the tissue. Check that the probe is secured and the tissue sample is not too thick. Pulse rate is determined from the SPO2 waveform which can be disrupted by a cough or other hemodynamic pressure disturbances. Motion at the probe site is indicated by noise spikes in the normal waveform. (See the figure below.) It has been noted that letting the patient view the SPO2 waveform enables them to assist in reducing motion artifact.

SPO2 Waveform with Artifact

Stability of SPO2 Values

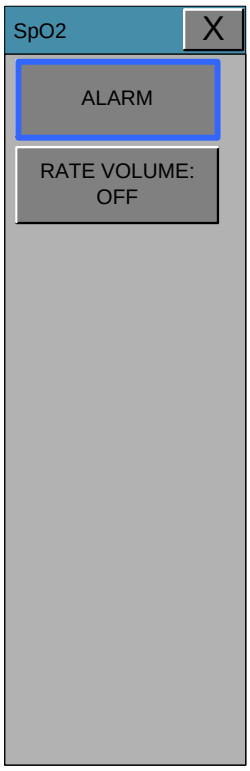
The stability of the displayed SPO2 values can also be used as an indication of signal validity. Although stability is a relative term, with a small amount of practice one can get a good feeling for changes that are artifactual or physiological and the speed of each. Messages are provided in the SPO2 values window to aid you in successful SPO2 monitoring.

WARNING
In the monitoring of patients the coincidence of adverse conditions may lead to a disturbed signal going unnoticed. In this situation artifacts are capable of simulating a plausible parameter reading, so that the monitor fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

6.3 SpO_2 Data Setup

ALARM ： Menu in which SpO_2 limits are set up.

RATE VOLUME：Menu in which RATE VOLUME is set up



ALARM

Two menus: ALARM LIMIT, ALARM provided in the alarm menu

Number setting of alarm value of %SpO_2 is 0 ~ 100

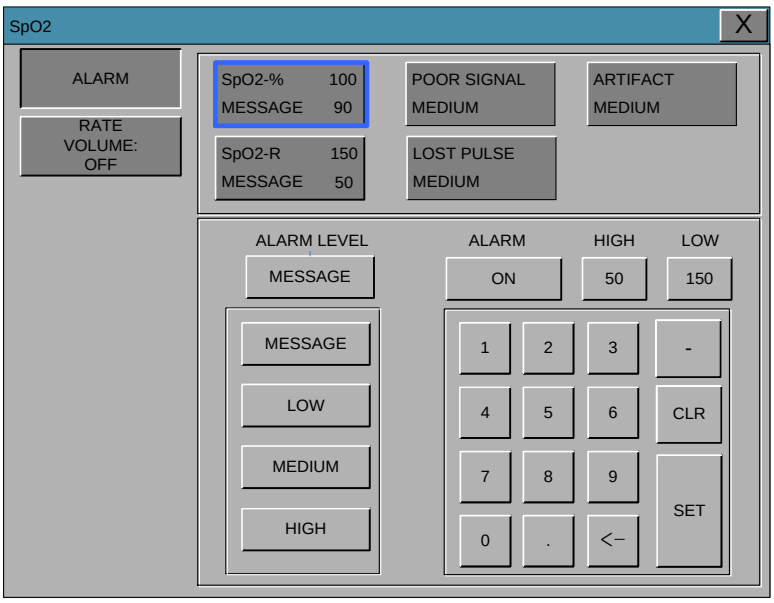
Warning sound or message displays configuration menu when an alarm is triggered.

1. Move the ▶ mark to select from alarm, SpO_2 or SpO_2-R or Poor signal, Artifact, Lost pulse, and press.
2. After pressing at SpO_2, move the cursor right or left to LOW, and press.
3. Once the color is changed, move the cursor again to the selected value and press.
4. Place the cursor to HIGH and press, when the color changes, move the cursor again to select the targeted value, and press. Finally move to SpO_2 and press.

(You may decide to perform the process in the opposite order, LOW to HIGH, to have the same result.)

5. After pressing at SpO_2-R, move the cursor right or left to LOW, and press.
6. Once the color is changed, move the cursor again to the selected value and press.

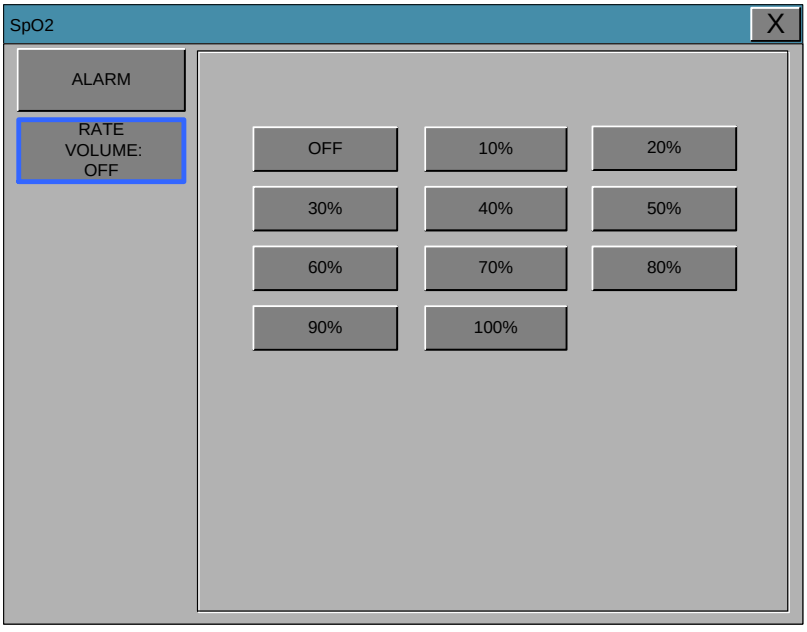
7. Place the cursor to HIGH and press, when the color changes, move the cursor again to select the targeted value, and press. Finally move to SpO2-R and press.
8. With the selection of alarm the user gets out of the menu.



RATE VOLUME

Move the KEY to select the volume from OFF to 100%.

The SpO2 volume setting turn on a tone which sounds each time an SpO2 pulse is detected. This is a variable pitch tone which changes as the patient's saturation level changes.



LEAD FAULT Condition

When using a reusable finger probe, there is a system alarm to alert you when the probe is off the Monitor. The monitor defaults this "LEAD FAULT" condition as a System Warning alarm. However, you can set it as a System ALARM LEVEL in Monitor Defaults.

SPO2 Messages

Below is a list of system status alarm messages which may be displayed in the SPO2 parameter window during monitoring.

CHECK PROBE

Reusable finger probe is off the patient. Check the probe. *The factory default for this alarm is MESSAGE ALARM.*

PULSE SEARCH

Detection by the monitor of a repeatable pulse has ceased. Check the patient and the probe site.

POOR SIGNAL

The SPO2 signal is too low. No SPO2 data is displayed. This can be due to a low patient pulse, patient motion, or some other interference. Check the patient and the probe.

LOST SIGNAL

SPO2 data continues to be displayed, but the quality of the signal is questionable. Check the patient and the probe.

ARTIFACT

It indicates that something happened to the pulses; determine if the artifact to be abnormal and irregular

Cleaning

- Do not autoclave, pressure sterilizes, or gas sterilizes this oximeter.
- Do not soak or immerse the monitor in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.
- Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with anything that could scratch the panel.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attack the device's materials and device failure can result.

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and the check the MS board pulse oximeter for proper functioning.
Inaccurate measurements may be caused by:
Incorrect sensor application or use
Significant levels of dysfunctional hemoglobins. (e.g., carboxyhemoglobin or methemoglgbin)
Intravascular dyes such as indocyanine green or methylene blue.

Operating Principals

The board pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).
2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse. (plethysmography).
3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance(AC) to the mean absorbance(DC) at each of two wavelengths, 660nm and 905nm:

S(660) = AC(660)/ DC(660)
S(905) = AC(905)/ DC(905)

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

R = S(660) / S(905)

This value of R is used to find the saturation SpO2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major components of noise during the pulse. MS board decomposes S(660) and S(905) into an arterial signal pulse a noise component and calculates the ratio of the arterial signals without the noise.

S(660) = S1 + N1
S(905) = S2 + N2
R = S1/S2

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N`) is determined:
N` = S(660) – S(905) x R
If these is no noise N` = 0: then S(660) = S(905)xR which is the same relationship for the traditional pulse oximeter.

A pulse oximeter should NOT be used as an apnea monitor

WARNING

- To be operated by qualified personnel only Intended use of the instrument
- A pulse oximeter should NOT be used as an apnea monitor
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- A pulse oximeter is an early warning device. Use lab co-oximeter to completely understand the patient's condition.

CAUTION

- Do not use Bionet oximetry sensors during MRI scanning as it could potentially cause burns.

  Grounding
- Patient isolation
- Cabling entanglement/strangulation
- Inaccurate measurements may be caused by incorrect application or use.
- Inaccurate measurements may be caused by significant levels of dysfunctional hemoglobins (HbCO or MetHb).
- Inaccurate measurements may be caused by intravascular dyes such as indocyanine green or methylene blue.
- Inaccurate measurements or loss of pulse signal may be caused by excessive illumination.

7. RESPIRATION

7.1 Outline

Respiration Connector and Measuring Cable

7.2 RESPIRATION Data Window

7.3 RESPIRATION Data Setup

ALARM

APNEA DETECT

LEAD SELECT

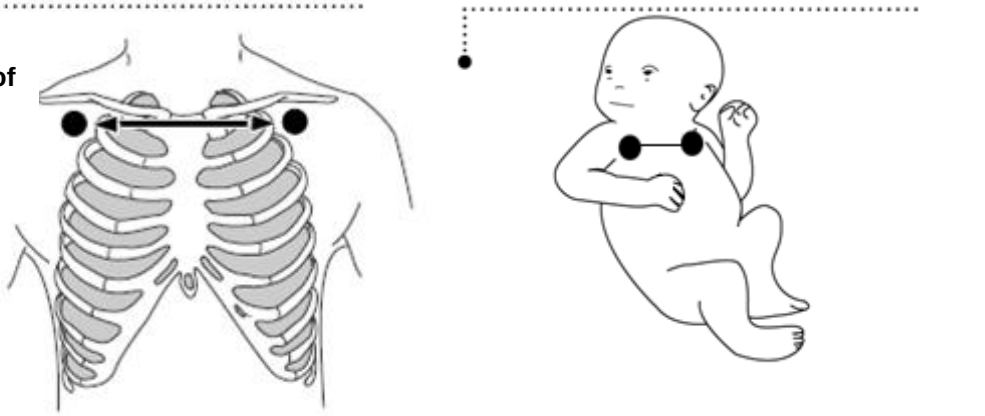
SWEEP SPEED

RESP SIZE

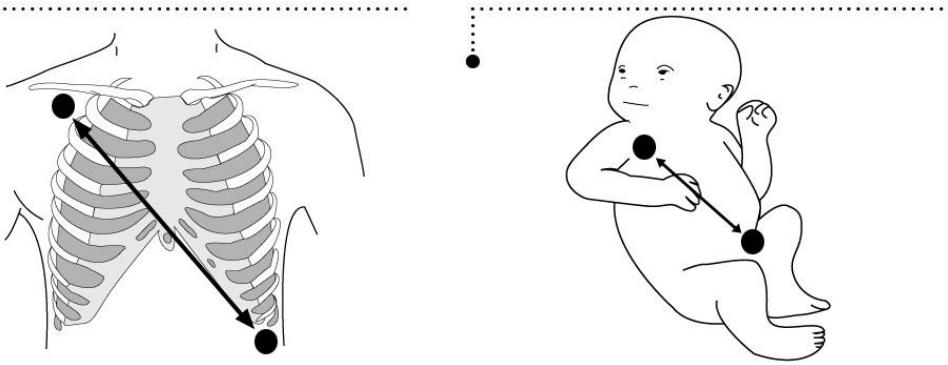
7.1 Outline

Respiration via ECG Lead I or Lead II electrode makes the skin area of the chest enlarged, causing changes in the resistance of skin. Through this it calculates respiration value per minutes and performs the alarm function according to limit value.

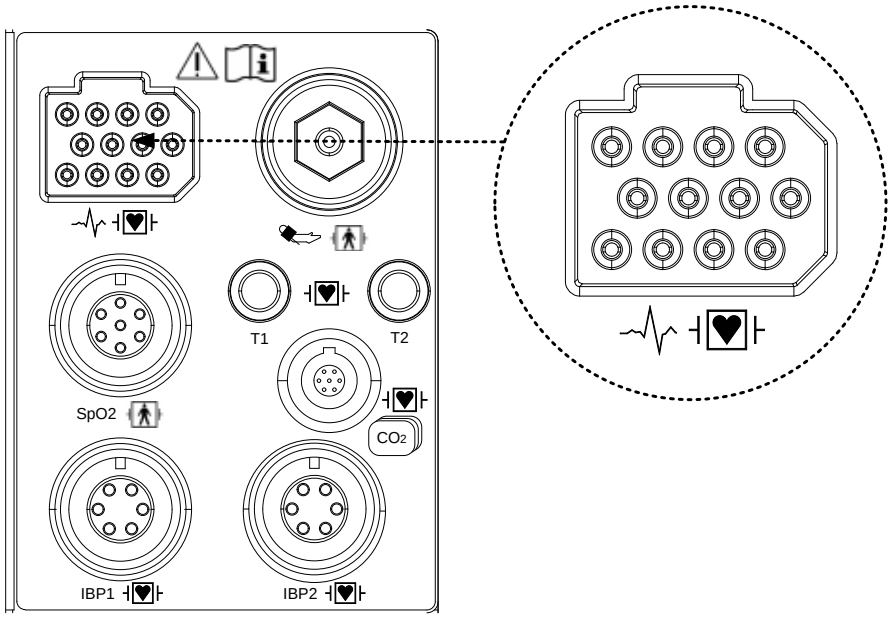
Position of Detected Lead Ⅰ



Position of Detected Lead Ⅱ



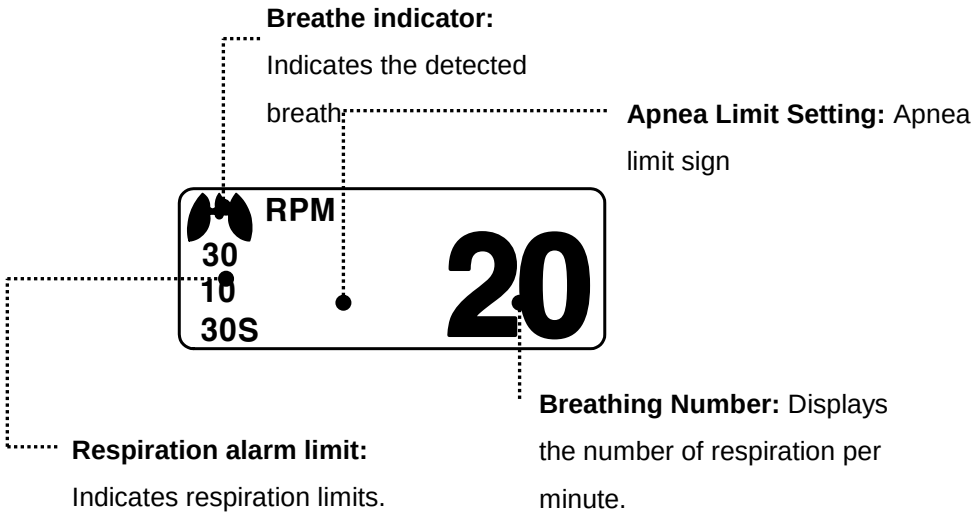
- **Respiration Connector and Measuring Cable**



Respiration Measuring

Note
Respiration Rate measures the cable and connector will be used as the ECG and common.

7.2 Respiration Data Window



7.3 Respiration Data Setup

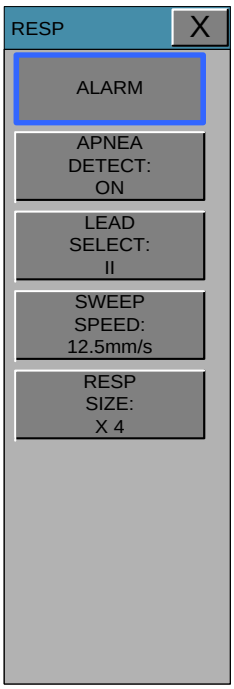
ALARM: Respiration alarm setting menu

APNEA DETECT: A menu to setup APNEA alarm display

LEAD SELECT : This is for changing the reference LEAD for respiration

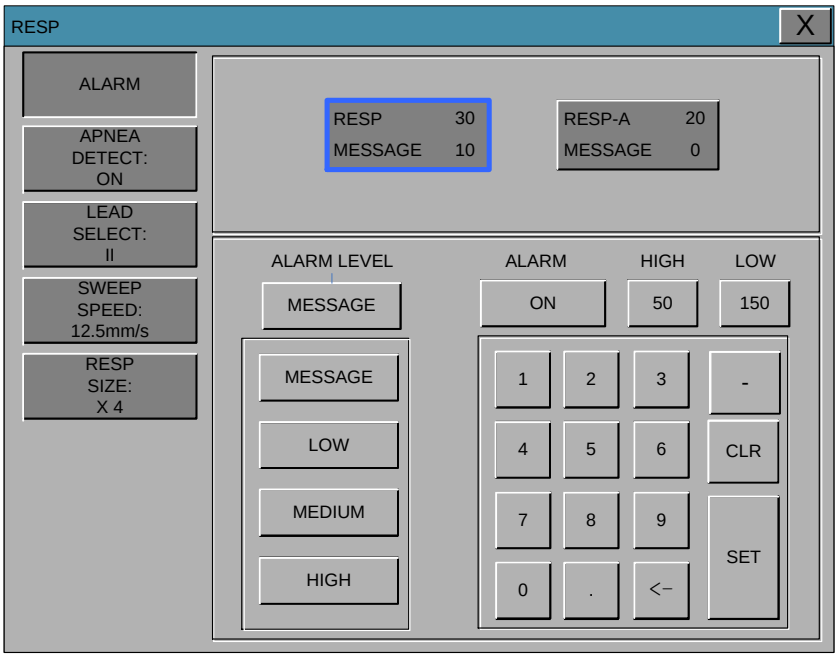
SWEEP SPEED: A menu to setup Wave Display of speed

RESP SIZE: A menu to setup Wave Display



ALARM

Alarm menu provide ALARM LIMIT and ALARM SOUND .



Alarm Limit of Respiration Numeric Value is 5 ~ 150bpm

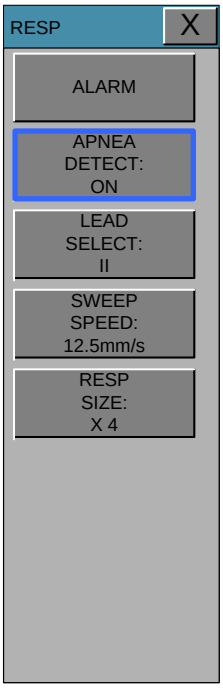
Alarm Limit of RESPIRATION APNEA Numeric Value is 3 ~ 30sec.

Warning sound or message displays activation setting when Respiration ALRAM occurs.

1. Move the ▶ mark to select RETURN, RESP or RESP-A, and press.
2. After a press in RESP, move the cursor right or left to LOW, and press.
3. After the color changed, move the cursor right or left to the selected value, and press.
4. Place the cursor to HIGH, and press. When the color has changed, move the cursor again to select the value and press. Move to the RESP and press again. (You may decide to perform the process in the opposite order, LOW to HIGH, to have the same result.)
5. Once RESP-A is pressed, move to LOW and press.
6. When the color has changed, move the cursor to select the value, and press.
7. A press in the HIGH position, the color changes. Then move the cursor to select the value and press. Move again to RESP-A, and press.
8. Select RETURN to get out of the window.

APNEA DETECT

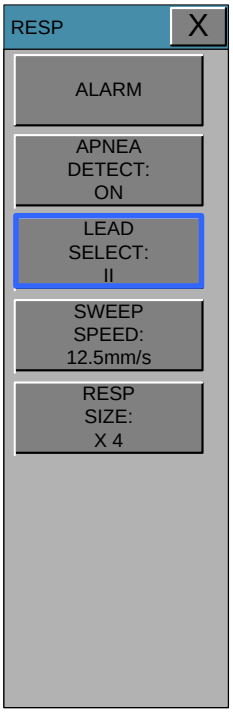
Deciding function of activating Apnea Alarm



LEAD SELECT

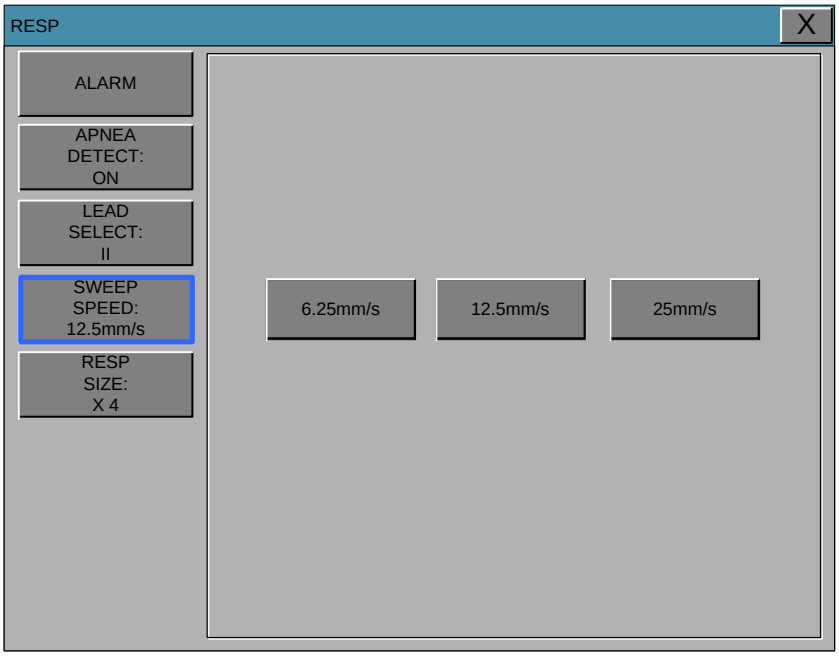
This is for changing the reference LEAD for respiration

LEAD I or LEAD II can be selected.



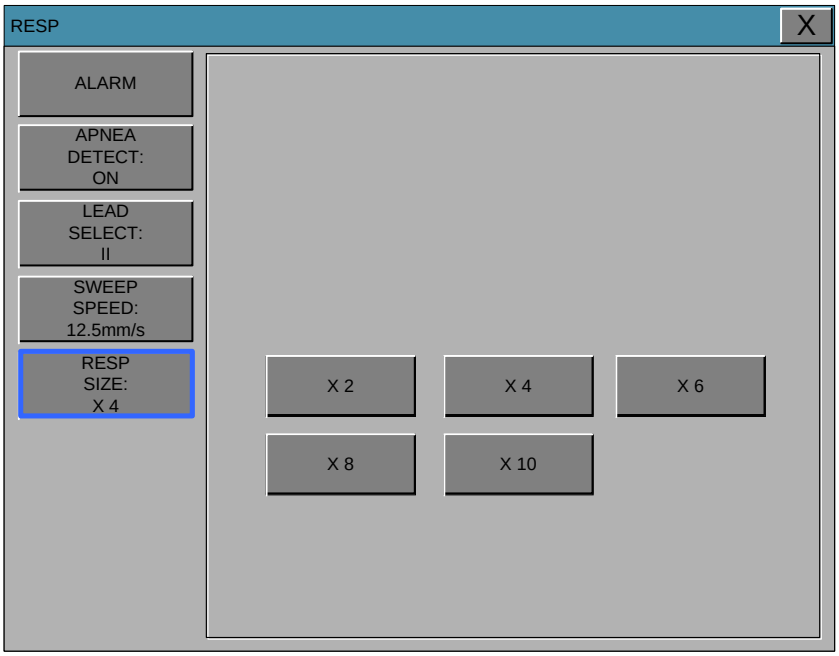
RESPIRATION SWEEP SPEED

Wave pattern speed is 6.25 , 12.5 , 25 mm/s.



RESPIRATION SIZE

Set wave pattern size X2~ X10.



8. NIBP

8.1 Outline

NIBP Connector Location and Cuff

8.2 NIBP Data Window

8.3 NIBP Data Setup

ALARM

CUFF SIZE

INFLATION

INTERVAL

NIBP STAT

NIBP VITAL SIGN

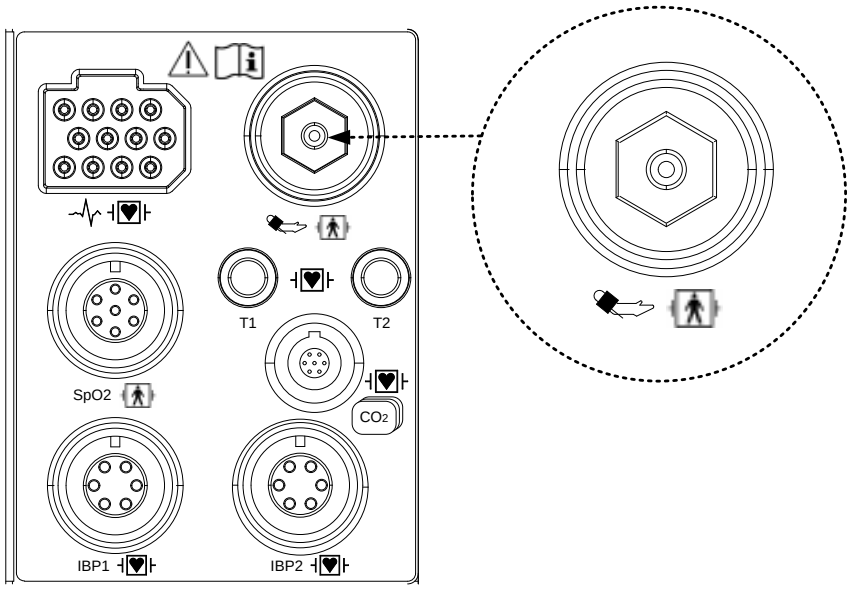
UNIT SELECT

8.1 Outline

This function is to measure minimum, Maximum and average blood pressure by using Oscillometric method. In adult and pediatric mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to intra-arterial or auscultatory measurements (depending on the configuration) in a representative patient population. In neonatal mode, the blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI SP10-1992) in relation to mean error and standard deviation, when compared to intra-arterial measurements in a representative patient population.

The NBP measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC/ISO80601-2-30 A physician must determine the clinical significance of the NBP information

- **Position of NIBP Connecter and cuff**



- **ADULT CUFF**

Introducing the Oscillometric NBP Measurement

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish. Studies show that, especially in critical cases (arrhythmia, vasoconstriction, hypertension, shock), oscillometric devices are more accurate and consistent than devices using other noninvasive measuring techniques. Optional accessory list

Big Adult		**Big Adult NIBP Cuff** Cuff Size : 458 * 143 Arm circumference : 31 to 40 Cm Option
Child		**Child NIBP Cuff** Cuff Size : 430 * 108 Arm circumference : 18 to 26 Cm Option
Pediatric		**Pediatric NIBP Cuff** Cuff Size : 313 * 88 Arm circumference : 12 to 19 Cm Option
Infant		**Infant NIBP Cuff** Cuff Size : 210 * 60 Arm circumference : 8 to 13 Cm Option
Neonate		NIBP Disposable Cuff Neonate 1 (3.3~5.6cm) Option
		NIBP Disposable Cuff Neonate 2 (4.2~7.1cm) Option
		NIBP Disposable Cuff Neonate 3 (5.0~10.5cm) Option
		NIBP Disposable Cuff Neonate 4 (6.9~11.7cm) Option

WARNING

Noninvasive blood pressure monitoring is not recommended for patients with hypotension, hypertension, arrhythmias or extremely high or low heart rate. The software algorithm cannot accurately compute NIBP or patients with these conditions.

Patient Category: Select the correct patient category setting for your patient. Do not apply the higher adult inflation, overpressure limits and measurement duration to neonatal patients.

Intravenous infusion: Do not use the NBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

Skin Damage: Do not measure NBP in cases of sickle-cell disease or any condition where skin damage has occurred or is expected.

Note

As the value of NIBP can vary according to the age and sex of a patient, the user needs to set up right data in parameter Menu before measurement. Tubes between the cuff and the monitor are not kinked or blocked.

Pay attention to not to block connecting hose when you put cuff on patient.
Cuff or hose connection for leaks periodically. Measurements can be inaccurate if air leaks.

The air pad should be exactly over the branchial artery. Tubing is immediately to the right or left of the branchial artery to prevent kinking when elbow is bent.

Try to measure infants when they are calm. A kicking or crying baby may disturb or jiggle the cuff, causing noise within the system and resulting in unstable blood pressure readings. If necessary, hold the cuffed limb steady, without impeding circulation. Do not hold onto the cuff and do not pat the cuffed limb to comfort the child.

NIBP cannot be taken under all conditions. Even manual methods, employing a sphygmomanometer and stethoscope, will not work on unstable or active patients.

Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb

The need to check that operation of the NIBP does not result in prolonged impairment of the circulation of the blood of the PATIENT

The maintenance is performed every 2 years.
Check the following list devises to operates properly and safety at all times.

1. Check for proper cuff size.
2. Check for residual air left in the cuff from a previous measurement.
3. Make sure cuff is not too tight or too loose.
4. Make sure cuff and heart are at same level, otherwise hydrostatic pressure will offset the NIBP value.
5. Minimize patient movement during measurement.
6. Watch for pulses paradox us.
7. Check for leak in cuff or tubing.
8. Patient may have a weak pulse.

It recommended PATIENT position in NORMAL measurement, as below;
1) Comfortably seated
2) Legs uncrossed
3) Feet flat on the floor
4) Back and arm supported
5) Middle of the CUFF at the level of the right atrium of the heart

a recommendation that 5 min should elapse before the first reading is taken

Measurement Limitations

Measurements are impossible with heart rate extremes of less than 40 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

• With excessive and continuous patient movement such as shivering or convulsions

• if a regular arterial pressure pulse is hard to detect

• With cardiac arrhythmias

• With rapid blood pressure changes

• With severe shock or hypothermia that reduces blood flow to the peripheries

• With obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery

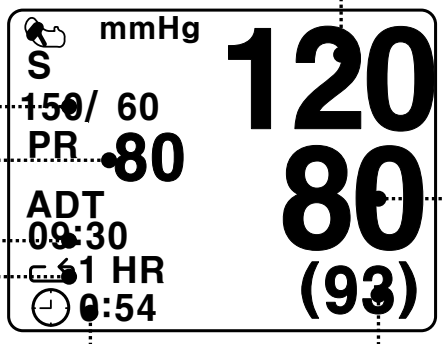
• On an edematous extremity.

The effectiveness of this sphygmomanometer has not been established in pregnant, including preeclamptic patients.

8.2 NIBP Data Window

Alarm Limit：Indicates alarm limit of blood pressure.

Systolic pressure：Indicates the maximum limit of blood pressure



Pulse Rate
Indicates pulse rate

Diastolic blood pressure：Indicates the minimum limit of blood pressure

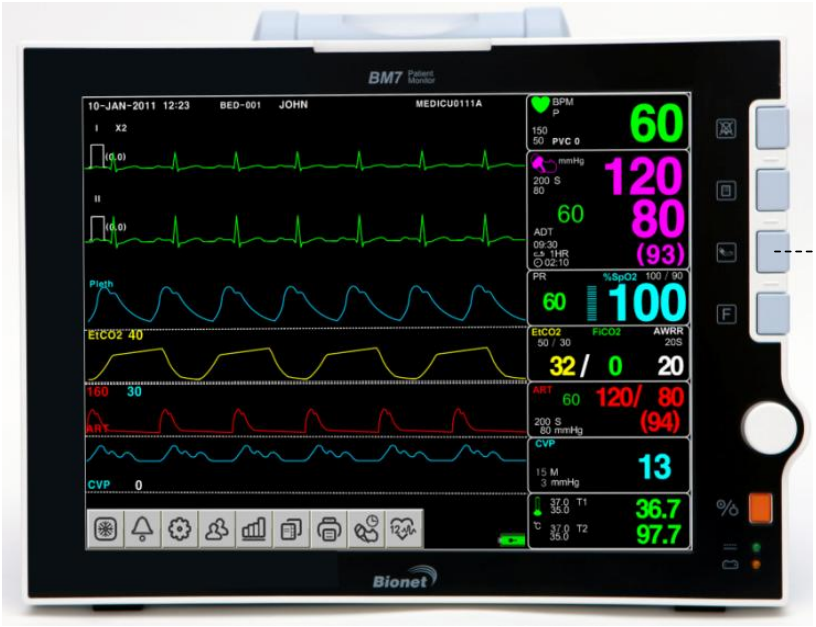
Measurement time
Indicates the completion time of measuring

Interval Time: Indicates Interval time when measures the blood pressure periodically

Measure time:
Indicates the schedule counter time of measuring

Mean Value： Indicates mean blood pressure

NIBP KEY



Manually operated keys NIBP start / stop can be.

POWER OFF

When power is cut off during pressure, air runs out of the CUFF automatically.

8.3 NIBP Data Setup

ALARM： A menu to set the Alarm

CUFF SIZE：A menu to select cuff size

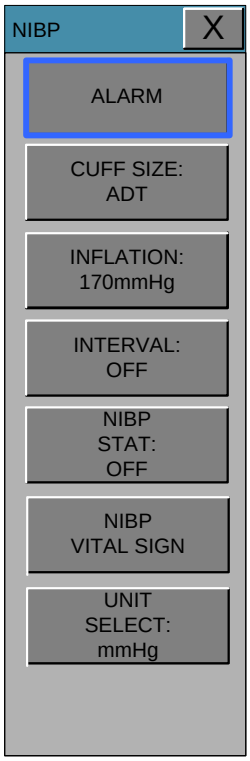
INFLATION: Initial Pressurization setting menu

INTERVAL ：A menu to set Interval time when measures the blood pressure periodically

NIBP STAT : 5 minutes to continuous measurement mode.

NIBP VITAL SIGN : 15 recently measured blood pressure values and pulse rate are recorded.

UNIT SELECT: A menu to select the pressure unit



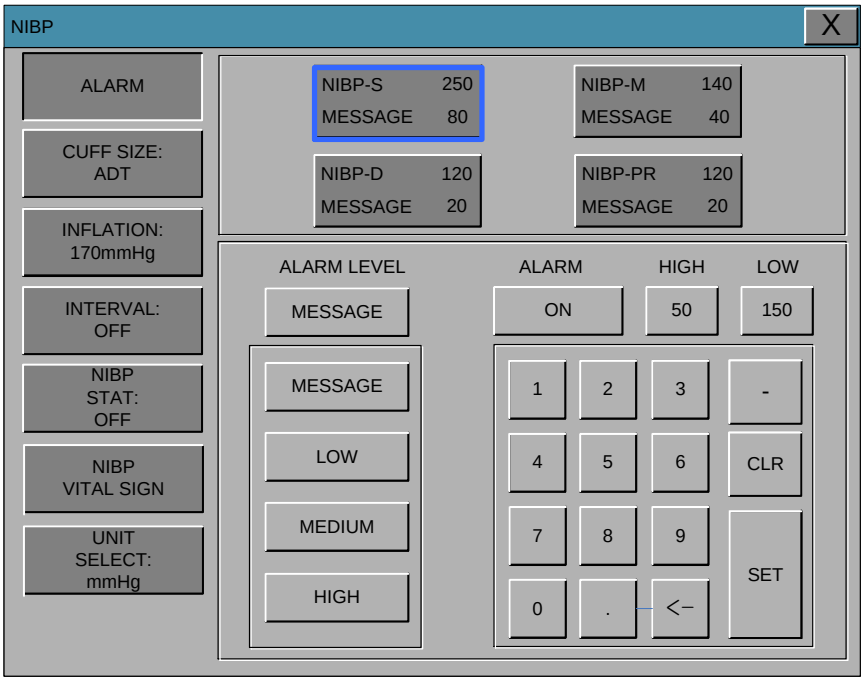
ALARM

The alarm provides ALARM LIMIT and ALARM SOUND.

Alarm setting Numeric Value of Systolic, Diastolic, and mean pressure is 10 ~ 360mmHg.

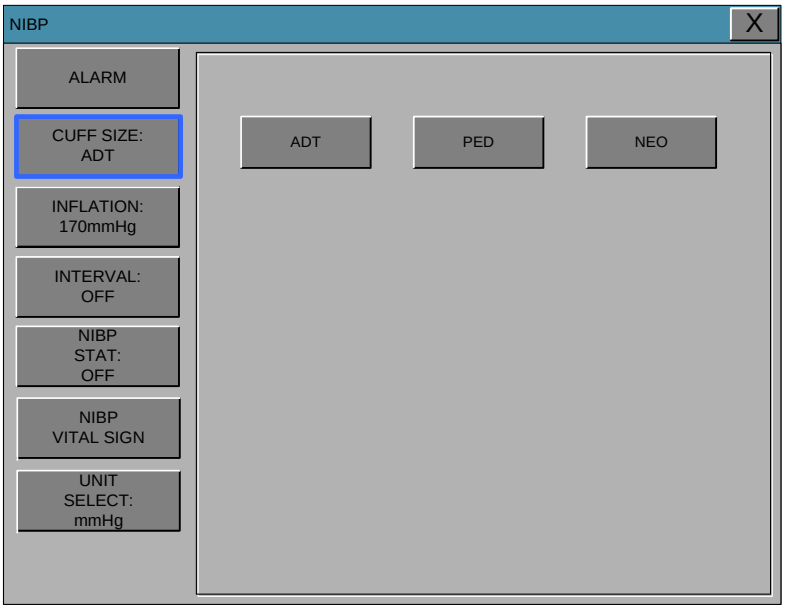
The menu which decide activate of warning sign and message display when the respiration alarm is on.

1. Move the ▶ mark to select one from RETURN, NIBP-S, NIBP-M, or NIBP-D, and press.
2. Press the key at NIBP-S, and move to LOW, and press again.(The user gets the same result regardless of the LOW-HIGH, or HIGH-LOW order.)
3. When the color has changed, move it again to select a target value, and press.
4. Press the key at HIGH. When the color has changed, move to the right to select a target value, and press.
5. Set up or revise the values of NIBP-M and NIBP in the same way as above.
6. With the selection of RETURN, the user can get out of the window.



CUFF SIZE

The user can select a CUF between ADULT , PEDIATRIC and NEONATAL.



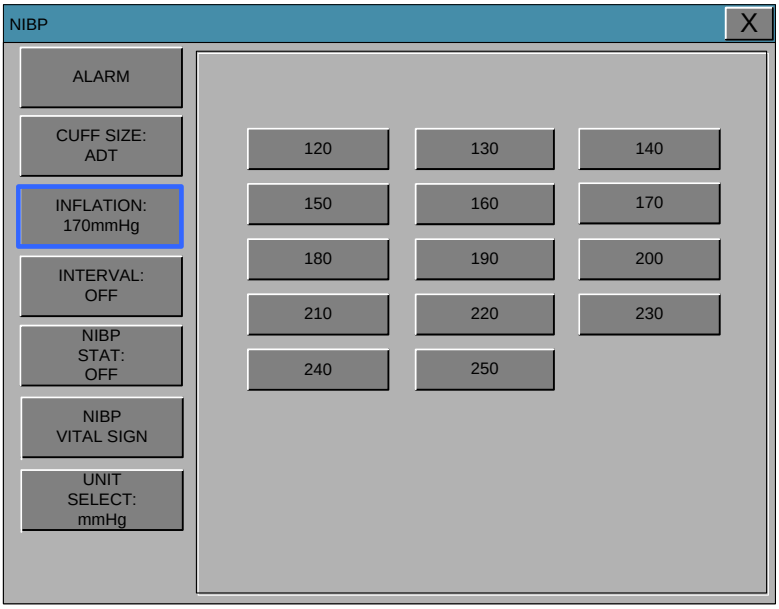
INFLATION

It is a function for set the maximum initial inflation pressure value.

The range of initial inflation pressure value of BM7 is as follows.

ADT/PED : Numeric value is 120, 130 ,140,150 ~ 240, and 250.

NEO : Numeric value is 60, 70, 80, 90, 100, 110, and 120. 130, 140

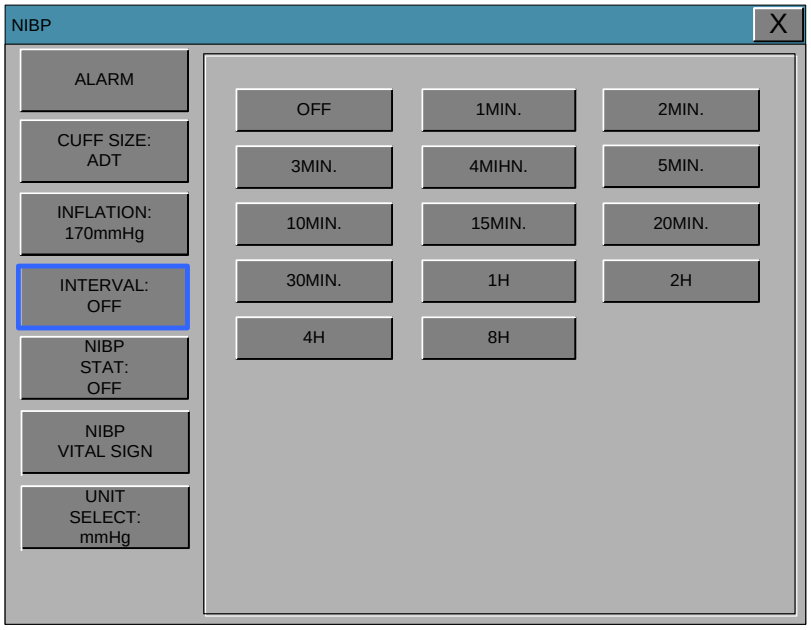


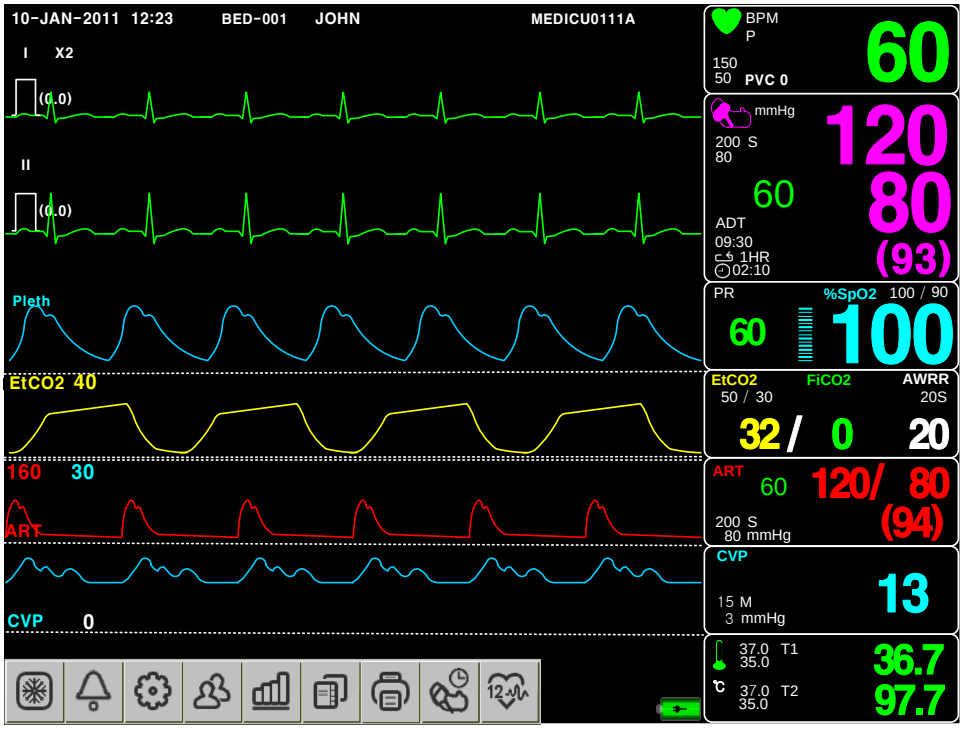
INTERVAL

This menu is used for selecting intervals when measures the blood pressure automatically.

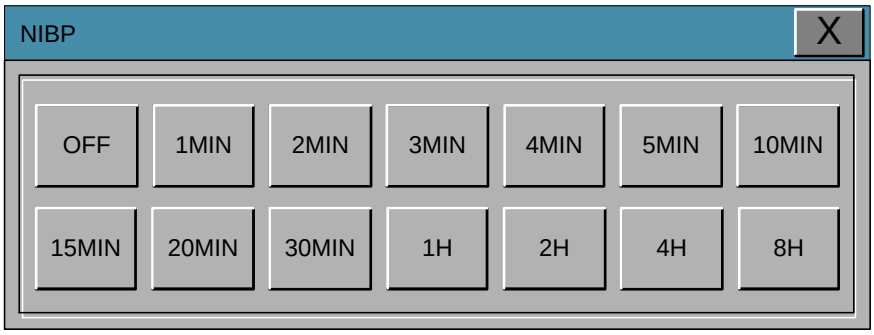
Select a target interval from 1min, 2, 3, 4, 5, 10, 15, 20, 30, 1hour, 2, 4, 8.

INTERVAL is set after the start, press the NIBP START NIBP KEY periodically.





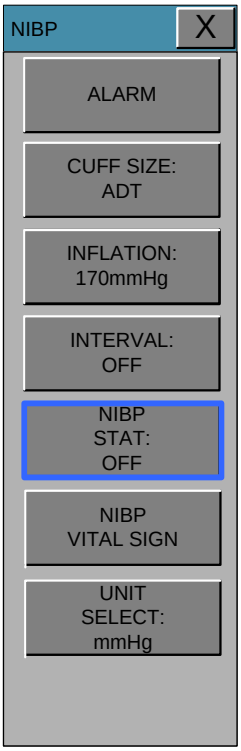
If you select the icon  from the main screen of the equipment to the fast cycle setting from the following menu window you can select the measurement cycle.



Warning
Periodically check patient limb circulation distal to the cuff. Check frequently when using auto NBP in 1 and 2 minute intervals. Intervals below 10 minutes are not recommended for extended periods of time.

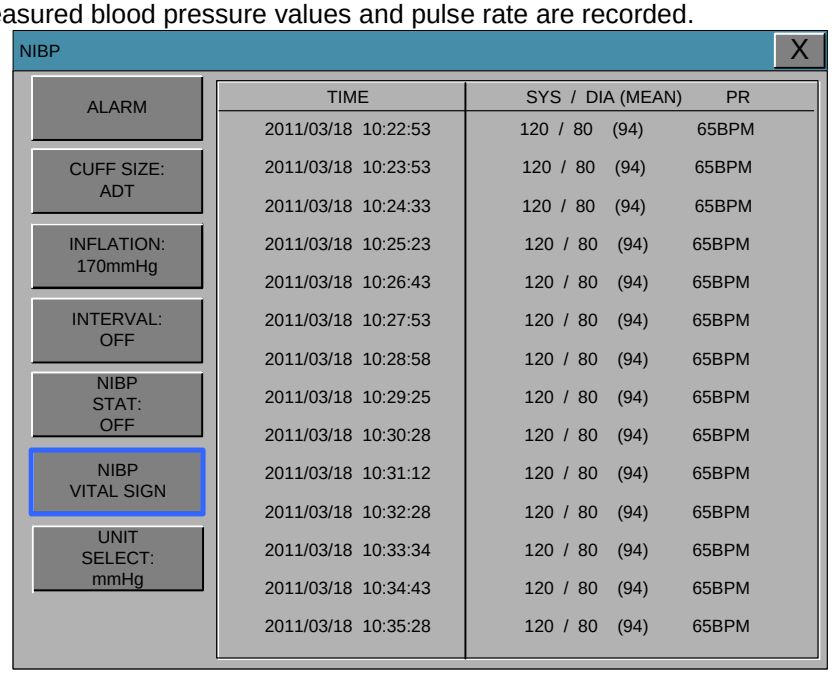
NIBP STAT

5 minutes to continuous measurement mode.



NIBP VITAL SIGN

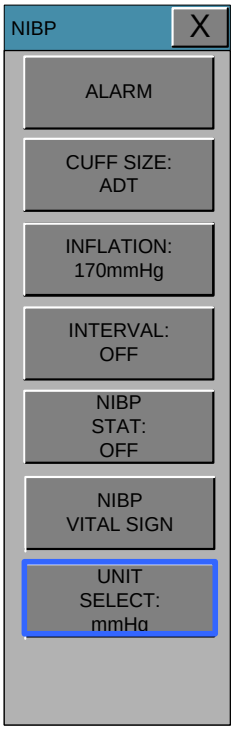
15 recently measured blood pressure values and pulse rate are recorded.



TIME	SYS / DIA (MEAN)	PR
2011/03/18 10:22:53	120 / 80 (94)	65BPM
2011/03/18 10:23:53	120 / 80 (94)	65BPM
2011/03/18 10:24:33	120 / 80 (94)	65BPM
2011/03/18 10:25:23	120 / 80 (94)	65BPM
2011/03/18 10:26:43	120 / 80 (94)	65BPM
2011/03/18 10:27:53	120 / 80 (94)	65BPM
2011/03/18 10:28:58	120 / 80 (94)	65BPM
2011/03/18 10:29:25	120 / 80 (94)	65BPM
2011/03/18 10:30:28	120 / 80 (94)	65BPM
2011/03/18 10:31:12	120 / 80 (94)	65BPM
2011/03/18 10:32:28	120 / 80 (94)	65BPM
2011/03/18 10:33:34	120 / 80 (94)	65BPM
2011/03/18 10:34:43	120 / 80 (94)	65BPM
2011/03/18 10:35:28	120 / 80 (94)	65BPM

UNIT SELECT

It is a function to set blood pressure measurement unit.
The blood pressure measurement unit provides mmHg and kPa.


NIBP
X
ALARM
CUFF SIZE:
ADT
INFLATION:
170mmHg
INTERVAL:
OFF
NIBP
STAT:
OFF
NIBP
VITAL SIGN
UNIT
SELECT:
mmHg

9. IBP

9.1 Description

IBP Connectors & Accessories

9.2 IBP Data Window

9.3 IBP Data Setting

CHANGE NAME (Configuration of measuring position)

SCALE (Configuring size of measurement waveform)

ALARM LIMITS (Maximum / Minimum Alarming Values)

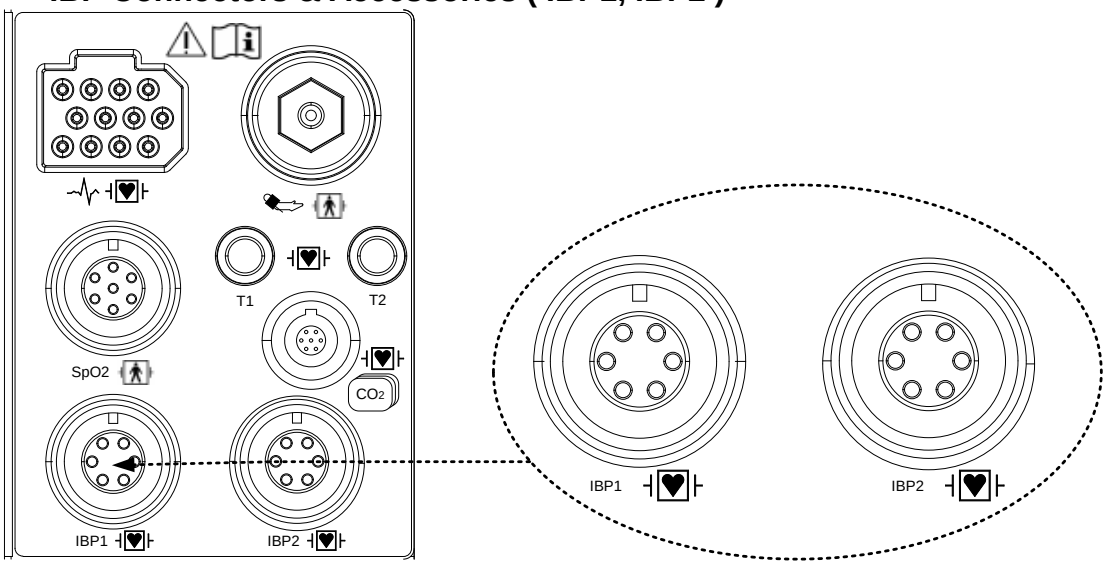
SETTINGS (Various Settings)

ZERO (Zero-Point Setting)

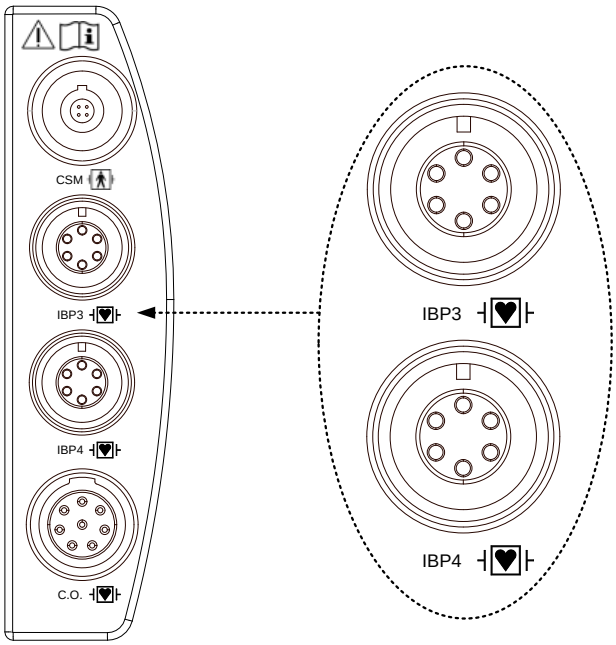
9.1 Description

IBP has an alarming function based on the maximum & minimum alarming values configured by measuring the systolic, diastolic and mean blood pressure values with signal processing of electric signals which are transformed from changes in impedance components according to the changes of blood flow in vessels.

- **IBP Connectors & Accessories (IBP1, IBP2)**



Extended Connector (IBP3 , IBP4 , Optional)

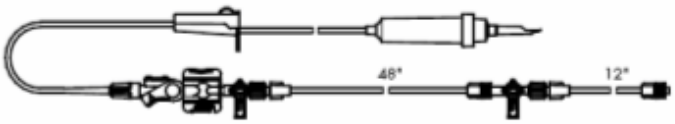


IBP ACCESSARY

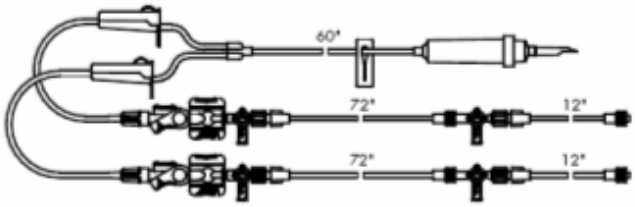
MEDEX Kit is used for IBP MONITORING KIT.

LogiCal Disposable Pressure Transducers Cartridges and Monitoring kit

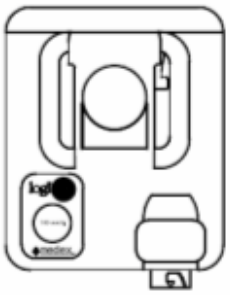
MX9604A LogiCal® 60" (152cm) single line monitoring kit.



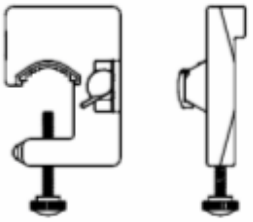
MX9602A LogiCal® double line monitoring kit.



MX960 LogiCal® transducer mounting plate.

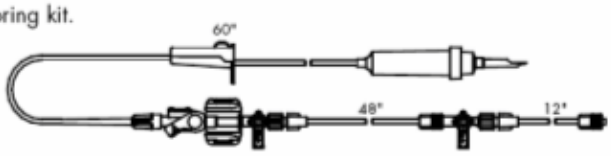


MX261 LogiCal® clamp for transducer bracket.

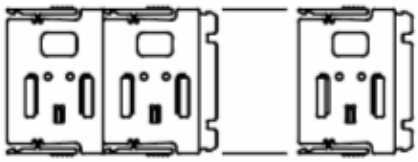


TranStar Disposable Pressure Transducers Cartridges and Monitoring kit

MX9504T TranStar® 60" single line monitoring kit.

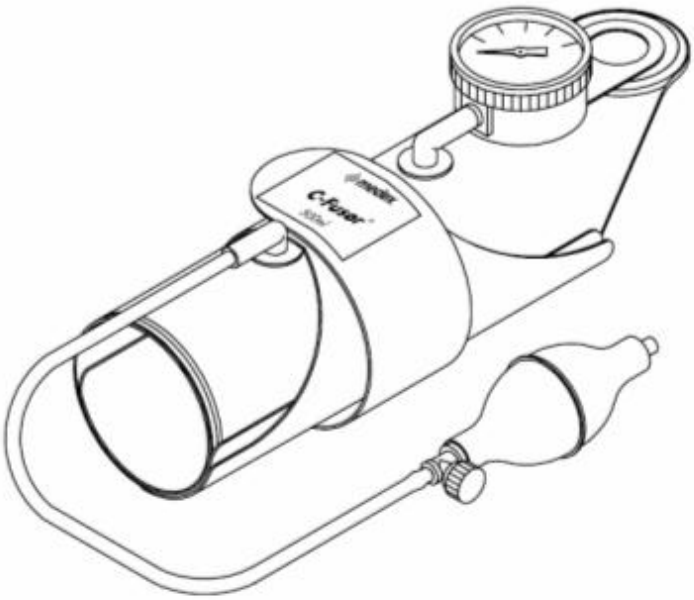


MX800 Modular transducer mounting plate.



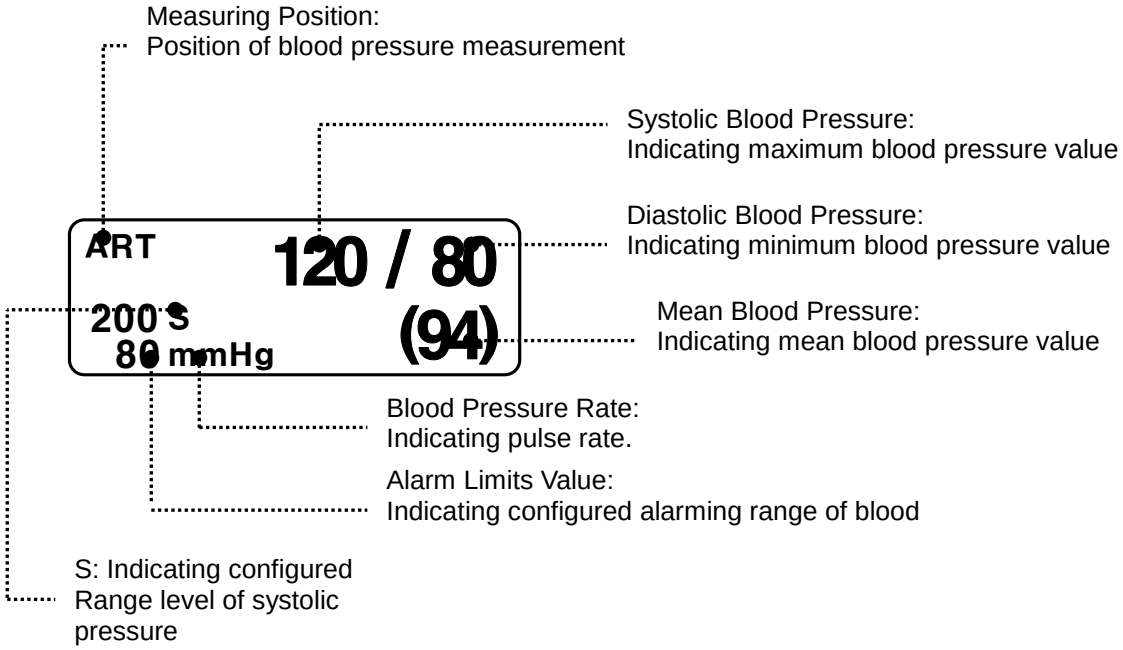
MX240 Pole clamp for mounting a transducer plate (fits 3/4" to 1-1/2" I.V. pole).

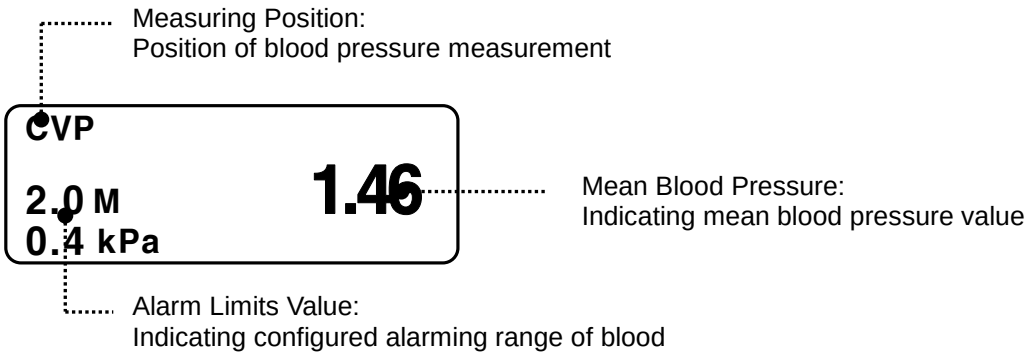
MX4810 C-Fusor® 1000ml Pressure Infusor complete unit with squeeze bulb and pressure gauge.



9.2 IBP Data Window

Different data windows are displayed on the screen according to the measuring positions.





9.3 IBP Data Setting

Labels for measuring positions are described on each menu.

ALARM: Menu to set alarming range.

BP FILTER : Menu to set the filter to be applied when measuring.

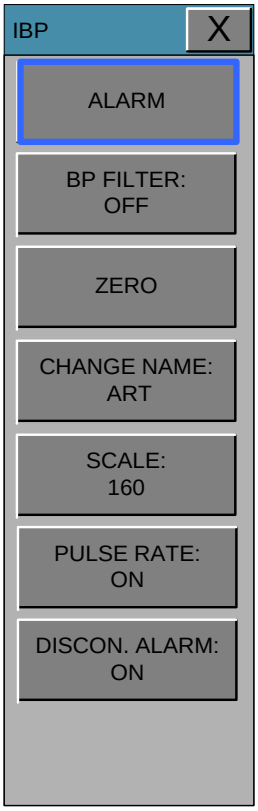
ZERO: Menu to set zero-point of Transducer.

CHANGE NAME: Menu to set measuring position

SCALE: Menu to set size of measurement waveform on screen.

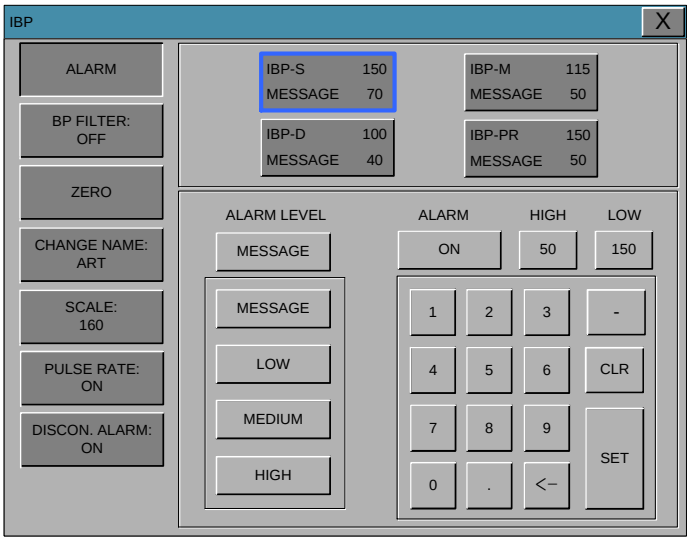
PULSE RATE: Menu to Set display of blood pressure pulse. (ART, FEM, UAP LABEL)

DISCON. ALARM: Menu for Alarming functions for disconnection. (ART, FEM, UAP LABEL)



ALARM LIMIT

Alarming limits vary according to measuring positions. The settable alarming range for systolic pressure, diastolic pressure and mean pressure is - 50 ~ 350mmHg.



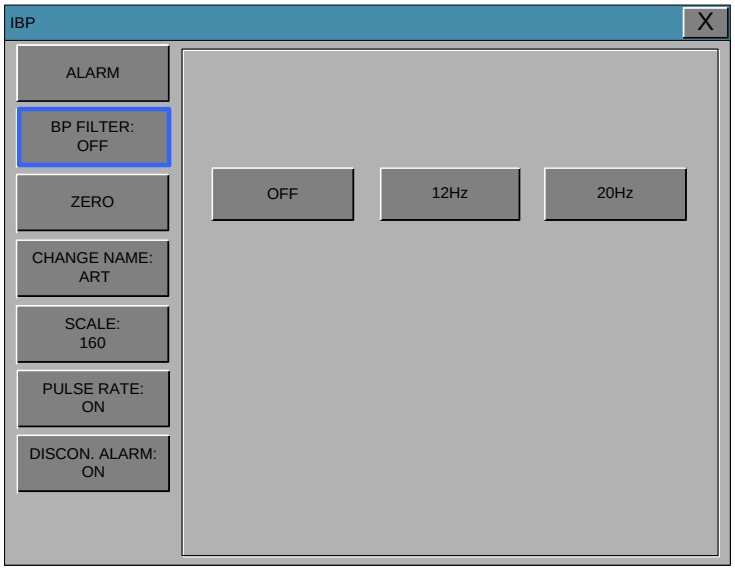
BP FILTER:

It filters waveforms by selecting three frequency bands.

OFF : 0Hz ~ 40Hz

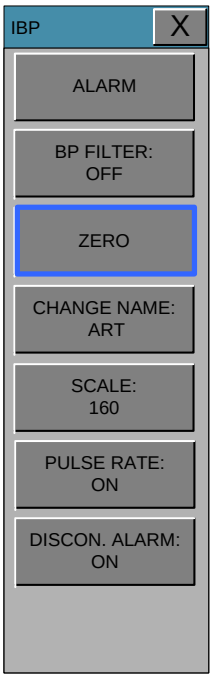
12Hz : 0Hz ~ 12Hz Generally recommended for monitoring

20Hz : 0Hz ~ 20Hz Used for processing waveform components of higher frequency. Pressure value can be increased with this filter.



ZERO ART: (Zero-point Adjustment)

Use ZERO option to set the zero-point of Transducer.



Procedures (Zero reference)

1) Close the transducer stopcock on the patient's side.
2) Open the venting stopcock on the air side.
3) Press the knob switch on the monitor panel.
4) Draw a line with the current input data in IBP area of WAVE WINDOW according to the Wave Base Line. And accord the wave line with the data.
5) Set the data as '0' on the parameter screen.
6) Check if Zero reference is carried out. (Check the pressure parameter on the message window.)
7) Close the venting stopcock on the air side.
8) Open the transducer stopcock on the patient side. The pressure value should be displayed on the pressure parameter screen in a few seconds.

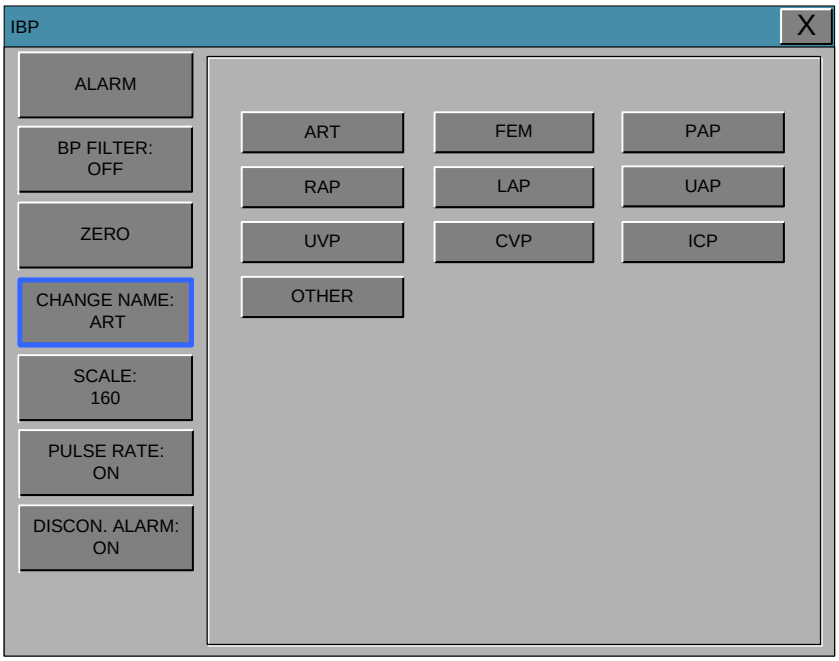
Troubleshootings for a case that blood pressure value is not displayed on screen

Description	Action to Take
In case of 'out of measurement range' situation	Check the measurement conditions.
In case blood pressure transducer is damaged	Replace the damaged transducer with new one

CHANGE NAME (Setting Measuring Position)

It performs the name changing function for a measuring position to monitor.

The setting positions are **ART, FEM, PAP, RAP, LAP, UAP, UVP, CVP, ICP** and **OTHER.**



List & Description of IBP Measurement Parameter Label

Parameter Window, Scales Menu Window or **Alarm Limits Pop-up Menu** will appear according to the Labels.

IBP displays the measuring positions based on 10 labels shown in the below table.

The below table shows the names for each label and the descriptions to be displayed on the **Parameter Window**.

Select **'OTHER'** for a measuring position not in the listed positions.

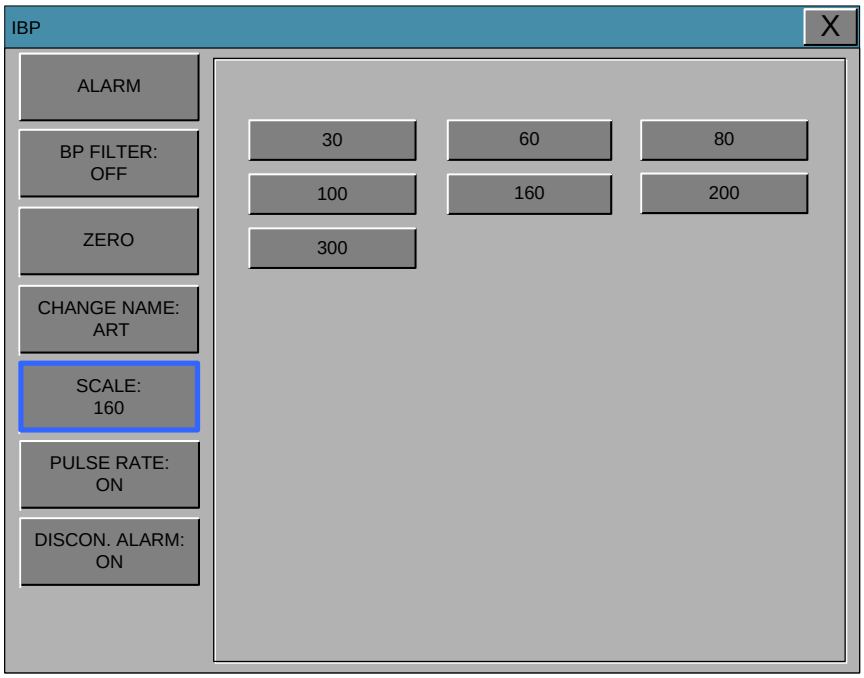
LABEL	DESCRIPTION	DISPLAY VALUE
ART	Arterial Pressure	- Systolic, Diastolic and Mean
FEM	Femoral Pressure	- Systolic, Diastolic and Mean
PAP	Pulmonary Artery Pressure	- Systolic, Diastolic and Mean
CVP	Central Venous Pressure	- Mean
LAP	Left Arterial Pressure	- Mean

RAP	Right Arterial Pressure	- Mean
ICP	Intracranial Pressure	- Mean
OTHER	Other (IBP1, IBP2)	- Mean
UAP	Umbilical Artery Pressure	- Systolic, Diastolic, and Mean
UVP	Umbilical Venous Pressure	- Mean

SCALE (Setting size of measurement waveform)

You can set the pressure range for measurement waveform on this menu.

The selectable values mean the maximum blood pressure range value that can be shown in a waveform.

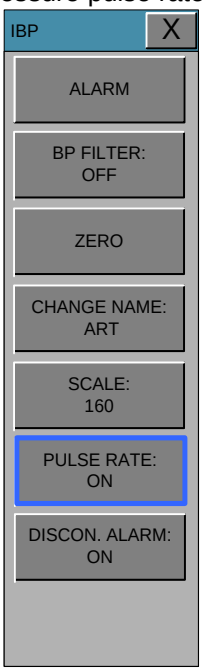


The below table show the settable values of standard alarm limits and scales of parameters for label setting.

Parameter	Adult			Neonatal		
	Low	High	Scale	Low	High	Scale
ART-S	70	150	160	40	100	100
ART-D	40	100		20	50	
ART-M	50	115		30	70	
ART-PR	50	150		50	170	
FEM-S	70	150	160	40	100	100
FEM-D	40	100		20	50	
FEM-M	50	115		30	70	
FEM-PR	50	150		50	170	
UAP-S	70	150	160	40	100	100
UAP-D	40	100		20	50	
UAP-M	50	115		30	70	
UAP-PR	50	150		50	170	
PAP-S	20	50	60	40	100	60
PAP-D	5	30		20	50	
PAP-M	10	40		30	70	
PAP-PR	50	150		50	170	
CVP-S	0	300	30	0	300	30
CVP-D	3	15		3	15	
CVP-M	0	300		0	300	
CVP-PR	50	150		50	170	
RAP-S	0	300	30	0	300	30
RAP-D	3	15		3	15	
RAP-M	0	300		0	300	
RAP-PR	50	150		50	170	
LAP-S	0	300	30	0	300	30
LAP-D	3	15		3	15	
LAP-M	0	300		0	300	
LAP-PR	50	150		50	170	
UVP-S	0	300	30	0	300	30
UVP-D	3	15		3	15	
UVP-M	0	300		0	300	
UVP-PR	50	150		50	170	
ICP-S	0	300	30	0	300	30
ICP-D	3	15		3	15	
ICP-M	0	300		0	300	
ICP-PR	50	150		50	170	
BP1(BP2)-S	0	300	30	0	300	30
BP1(BP2)-D	3	15		3	15	
BP1(BP2)-M	0	300		0	300	
BP1(BP2)-PR	50	150		50	170	

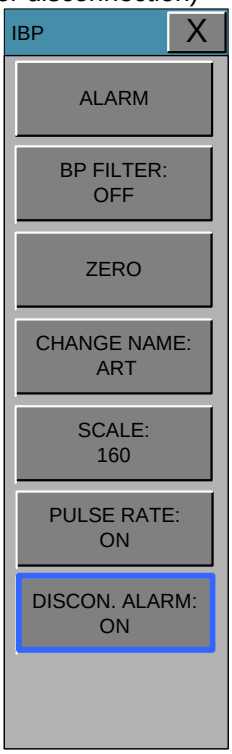
PULSE RATE

PULSE RATE: Setting display of blood pressure pulse rate.



DISCONN. ALARM

DISCONN ALARM: (Alarming function for disconnection)



DISCONN ALARM MENU will be displayed when measurement label is set for ART, FEM and UAP. This function will be activated upon the following two conditions.

1. In case MEAN PRESSURE is not higher than 25mmHg.
2. In case the Disconnect Alarm is set 'ON'.

Medium alarming sound will be generated when the **DISSCONNECTED ALARM** is activated, and the alarming message "DISCONNECTED" will be displayed on the parameter screen.

Trouble shootings for a case the measured value is different from the expected value

Description	Action to Take
In case there are air bubbles in tubes	Remove the air bubbles
In case an extension tube is connected	Remove the extension tube
In case of using blood pressure transducer with a different sensitivity	Check position of transducer
For other cases	Perform zero-point adjustment

CAL. TRANSDUC: A function to adjust a Transducer error on the monitor

A function to adjust an error value based on the other index manometer.

How to Adjust

1. Select a menu by pressing the knob switch key.
2. Measure blood pressure along with another index manometer.
3. Compare the measured values of 'mmHg' for both manometers.
4. Adjust the error value on the parameter menu screen by turning knob switch.
5. Terminate the menu by pressing the knob switch key again.

Warning
All parts, except Transducer, should not be conductive. Otherwise discharge energy may induce a shock to operators during cardioversion. single-use ACCESSORIES are not to be reused

Note
● Check if there is a scratch on the catheter balloon before using. ● Do not reuse disposal parts and accessories. ● Do not use saline packs with passed expiration dates. ● Does not use pressure measurement kits in torn packages. ● Remove all air in the saline pack by squeezing it. Otherwise it may cause errors in blood pressure band and may go into the blood vessels.

10. EtCO2

10.1 INTRODUCTION

Position of $EtCO_2$ Connector and Accessory

$EtCO_2$ ACCESSORY

10.2 $EtCO_2$ Parameter Window

10.3 $EtCO_2$ Parameter Setting Menu

ALARM

WAVE SCALE

SWEEP SPEED

APENEA DETECT

MODULE SETUP

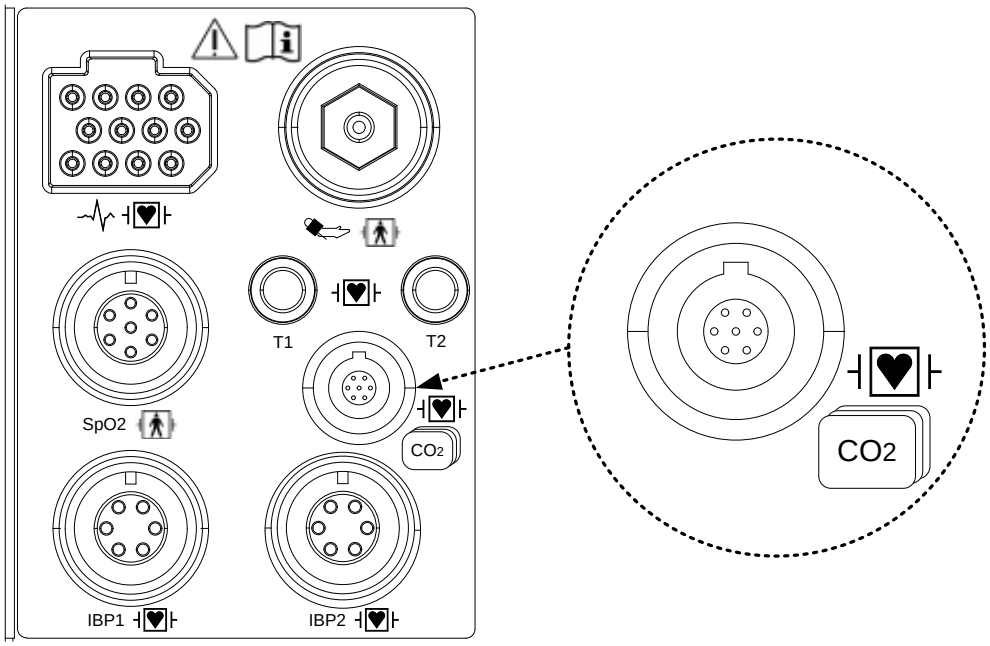
ZERO

MODULE RESET

10.1 Introduction

ETCO2(End-Tidal CO2) is a device to see the concentration of end-tidal carbon dioxide, which uses a method of measurement based on the non-dispersed IR absorption of CO2 using IR ray by sampling a certain part of respiration through pipe during respiration.

- **EtCO2 connector position and accessory (Sidestream, Respironics)**



LoFlo sidestream CO2 sensor and connector

Sidestream sensor

Sidestream sensor connector

EtCO2 accessories for sidestream applications

EtCO2 monitoring accessory uses the accessories for LoFlo™ sidestream module of Respironics Company.

The airway adapters for sidestream intubated applications			
3473ADU-00		Airway Adapter Kit w/ Dehumidification Tubing	Weight: 4.5 grams Dead space – adds approximately 7 cc of dead space **Intended for use when monitoring patients with ET Tube sizes >4.0 mm**
3473INF-00		Airway Adapter Kit w/ Dehumidification Tubing	Weight: 5.8 grams Dead space – adds approximately 1 cc of dead space **Intended for use when monitoring patients with ET Tube sizes <=4.0 mm**

Connecting the LoFlo Sample Kit

1. The sample cell of the sampling kit must be inserted into the sample cell receptacle of the LoFlo CO_2 Module as shown in Figure 1. A "click" will be heard when the sample cell is properly inserted.

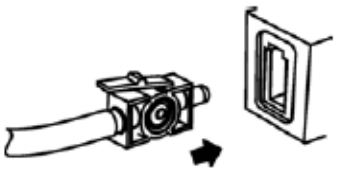


Figure 1

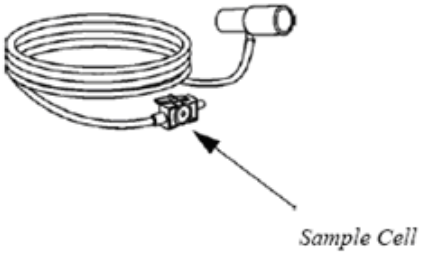
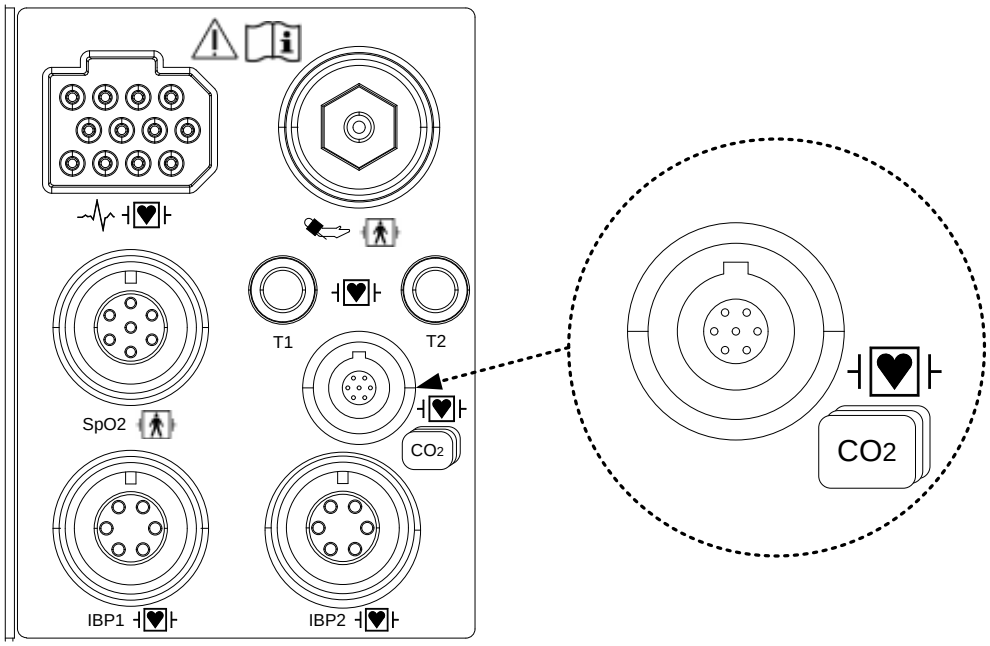


Figure 2

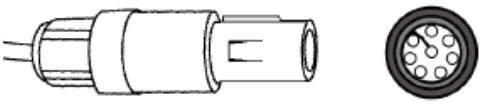
2. Inserting the sample cell into the receptacle automatically starts the sampling pump. Removal of the sample cell turns the sample pump off.
3. To remove the sampling kit sample cell from the sample cell receptacle, press down on the locking tab and pull the sample cell from the sample cell receptacle.

- **EtCO2 connector position and accessory (Mainstream, Respironics)**



CAPNOSTAT 5 mainstream CO2 sensor and connector

Mainstream sensor



Mainstream sensor connector

EtCO2 accessories for mainstream applications

EtCO2 monitoring accessory uses the accessories for CapnoStat5 microstream sensor of Respironics Company.

The airway adapters for mainstream intubated applications		
6063-00		Single-Patient Use Airway Adapter
6312-00		Single-Patient Use Airway Adapter
7007-00		Reusable Airway Adapter
7053-00		Reusable Airway Adapter

Connecting the CAPNOSTAT® 5 CO2 Sensor to the Host System

1. Insert the CAPNOSTAT 5 CO_2 Sensor connector into the receptacle of the host monitor as shown in Figure 1.

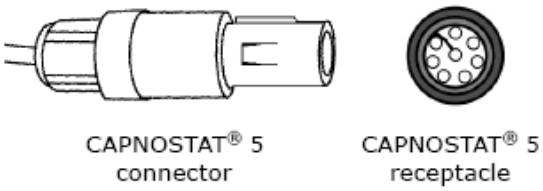


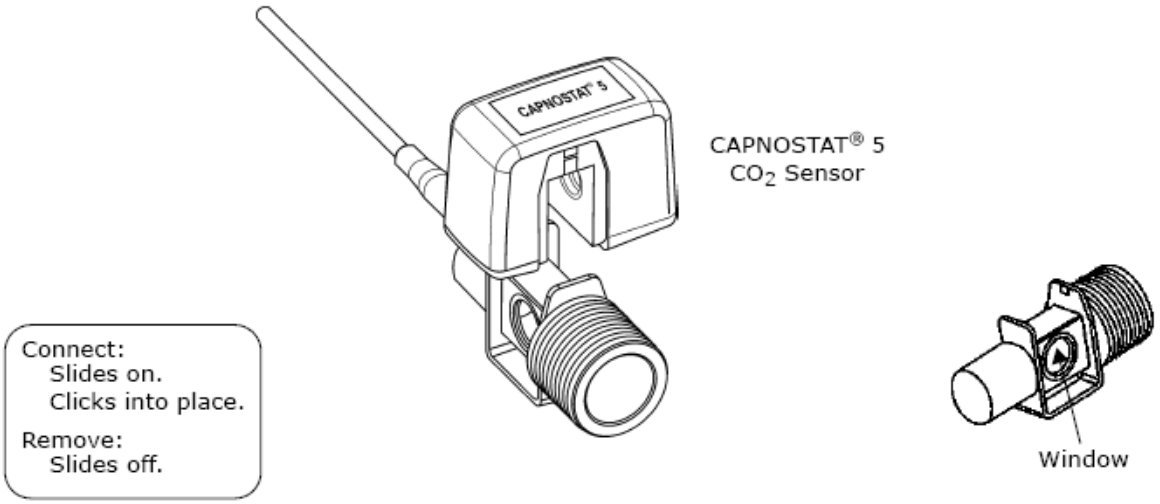
Figure 1

2. Make sure the arrows on the connector are at the top of the connector and line up the two keys of the connector with the receptacle and insert.

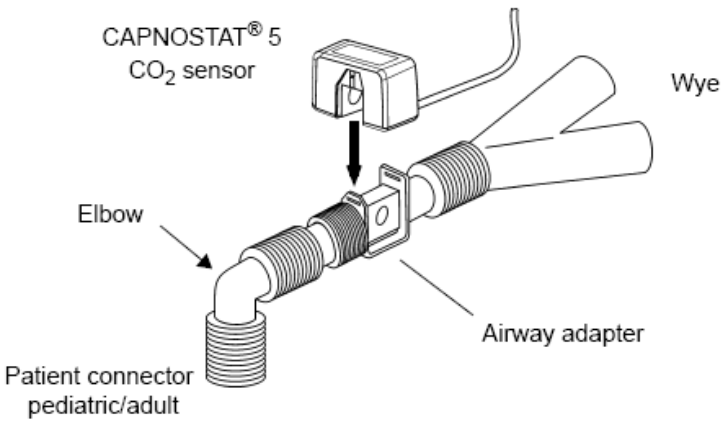
3. To remove the connector, grasp the body portion of the connector back and remove.

Note: Do not remove by pulling cable.

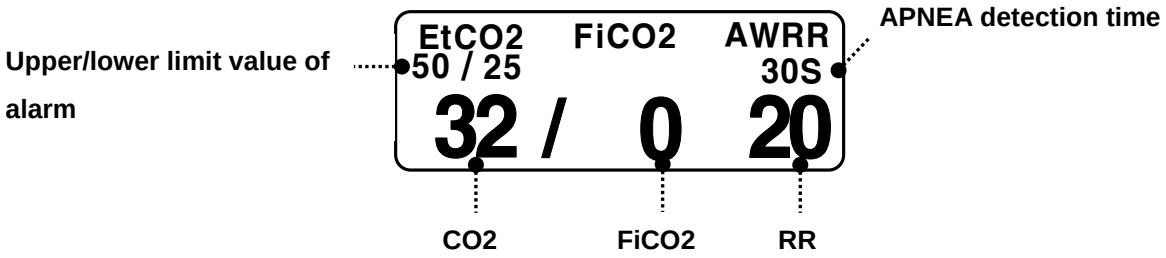
Shown below is the CAPNOSTAT 5 CO_2 Sensor connection to a Respironics Novametrix CO_2 adapter



Shown below is the CAPNOSTAT 5 CO_2 Sensor with a patient circuit:



10.2 EtCO2 Parameter Window



S: Display of apnea setting time in second unit

Upper/lower limit value of alarm: Display of alarm setting range value for concentration of CO_2

EtCO$_2$: Display of concentration value of carbon dioxide

AWRR: Display of the number of respirations per minute

FICO2: Display of concentration value of carbon dioxide during inspiration

Note
$EtCO_2$ waveform is always displayed if cable is connected.

10.3 EtCO2 Parameter Setting Menu

ALARM: A menu to set the alarm limit

WAVE SCALE: menu to set the size of waveforms of the on-screen

SWEEP SPEED: Speed is set to draw the signal waveform. (6.25mm/s, 12.5mm/s, 25mm/s)

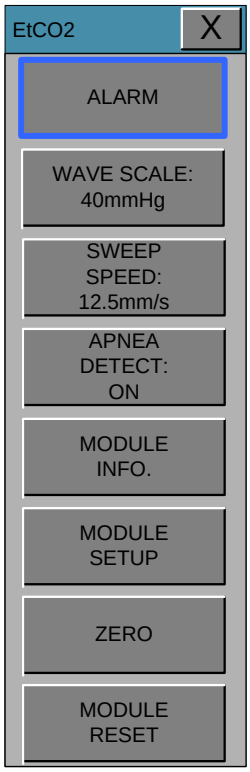
APNEA DETECT: Menu for the detection of apnea

MODULE INFO.: Menu where you can see the MODULE information

MODULE SETUP: Menu to set module of the information.

ZERO: Atmospheric pressure and zero adjustment menu to run

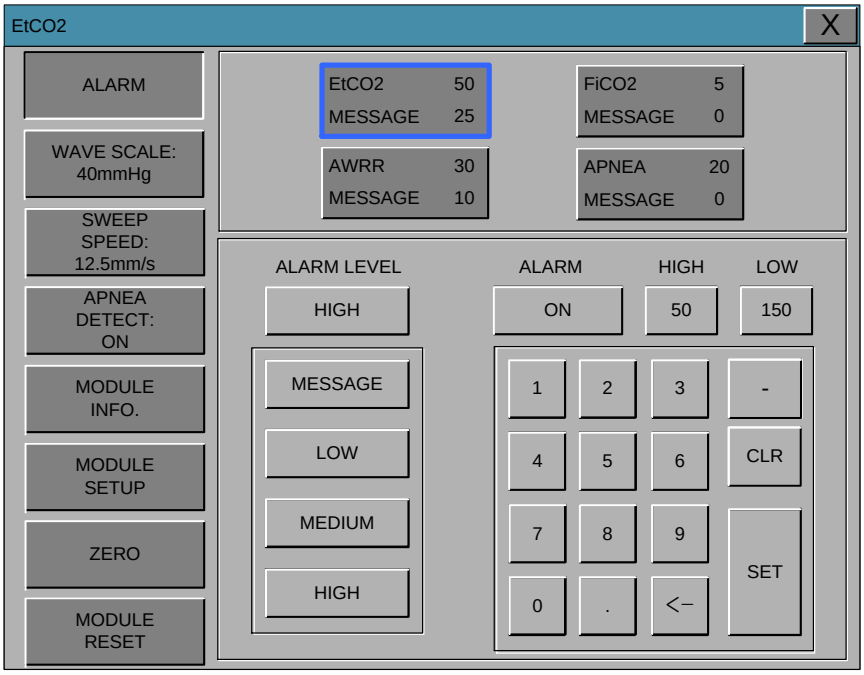
MODULE RESET: EtCO2 MODULE menu to initialize the run



ALARM LIMIT (Upper/lower limit value of alarm)

Upper/lower limit value of alarm differs depending on the position of measurement.

The basic setting range is alarm setting value for EtCO2, FiCO2, AWRR, APNEA.



The following table shows standard alarm limit of parameter and setting value of scale when setting the label.

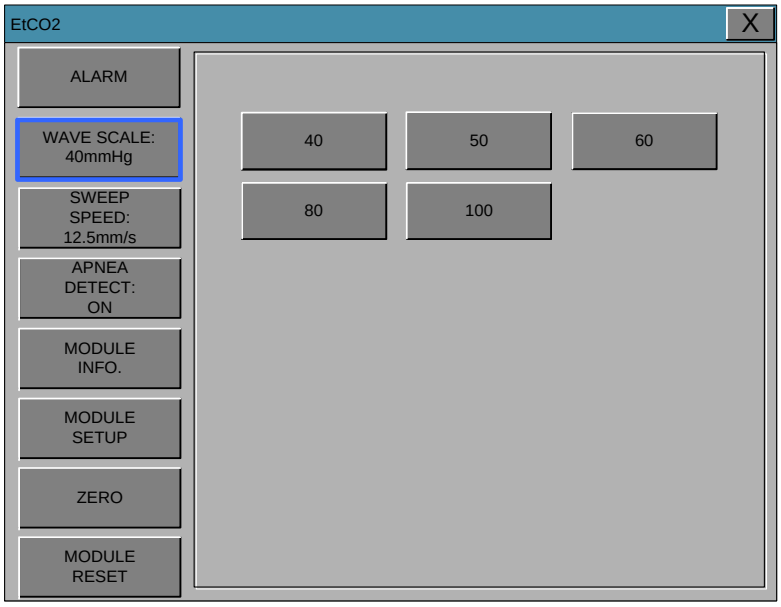
Parameter	Adult			Neonatal		
	Low	High	Scale	Low	High	Scale
EtCO2	0	98	40	0	98	40
FiCO2	0	20		0	20	
AWRR	0	100		0	100	
APNEA	0	40		0	40	

WAVEFORM SCALE (Measured waveform scale setting)

This sets the range of measured waveform versus pressure.

Selectable numerical value means the maximum pressure range value that is shown with waveform.

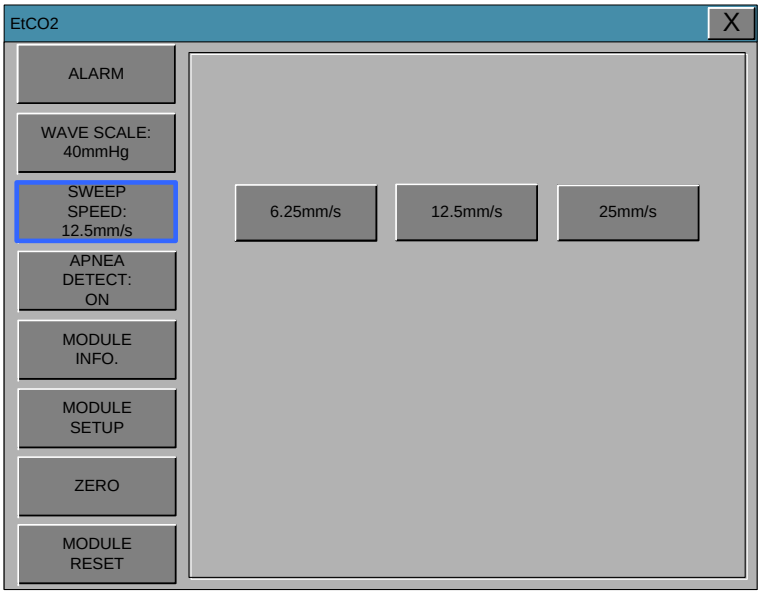
Pressing the knob switch key and then selecting the desired range value displays the selected pressure range value below the upper dotted line among two dotted lines in the left middle of wave window.



EtCO2 SWEEP SPEED

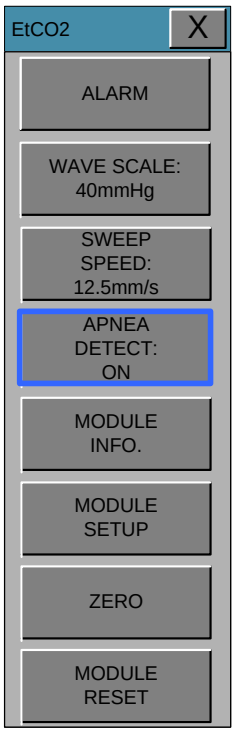
EtCO2 speed is 6.5mm/s.

Speed is changeable to 6.25, 12.5, 25mm/s.



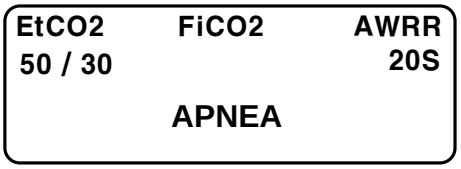
APNEA DETECT

Turn the APNEA detection alarm off and on

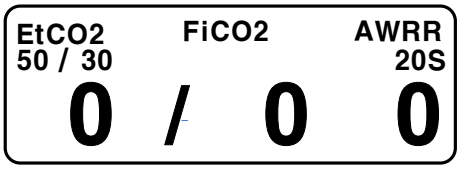


APNEA ALARM: This performs a function to set the display of apnea message alarm.

This displays a "apnea" message at the center of parameter window as shown in the figure below with apnea alarm on in case of apnea until the set apnea period is passed through.

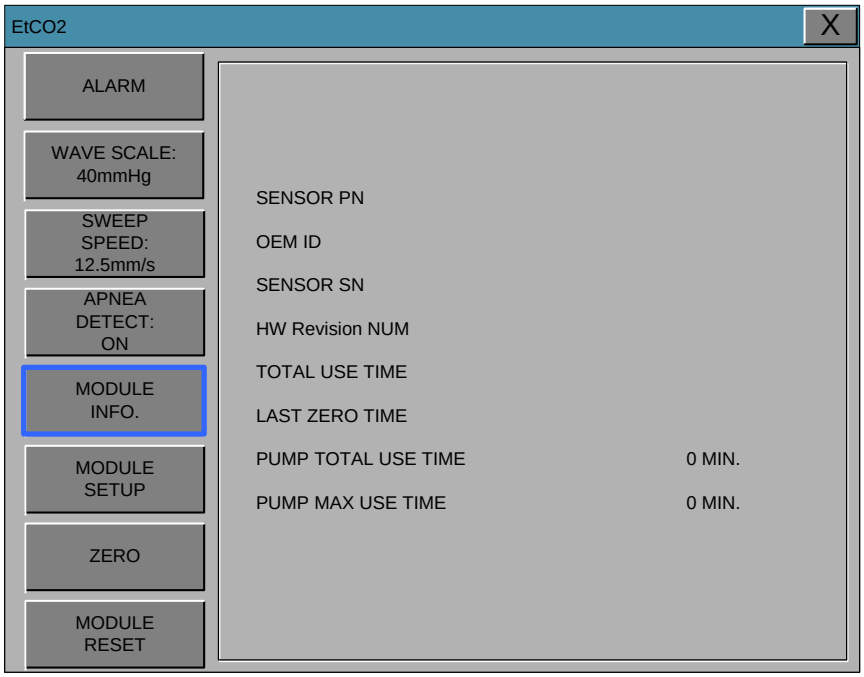


With apnea alarm off, measured values are displayed instead of message.



MODULE INFO

This is information for handling the EtCO2 module.



SENSOR PN (part number): The sensor part number

OEM ID: The id is a 7bit identifier which is set at the factory to a unique value for each OEM.

SENSOR SN: The serial number of the module.

HW REVISION NUM: The hardware version number of the module.

TOTAL USE TIME: Total use time of the module.

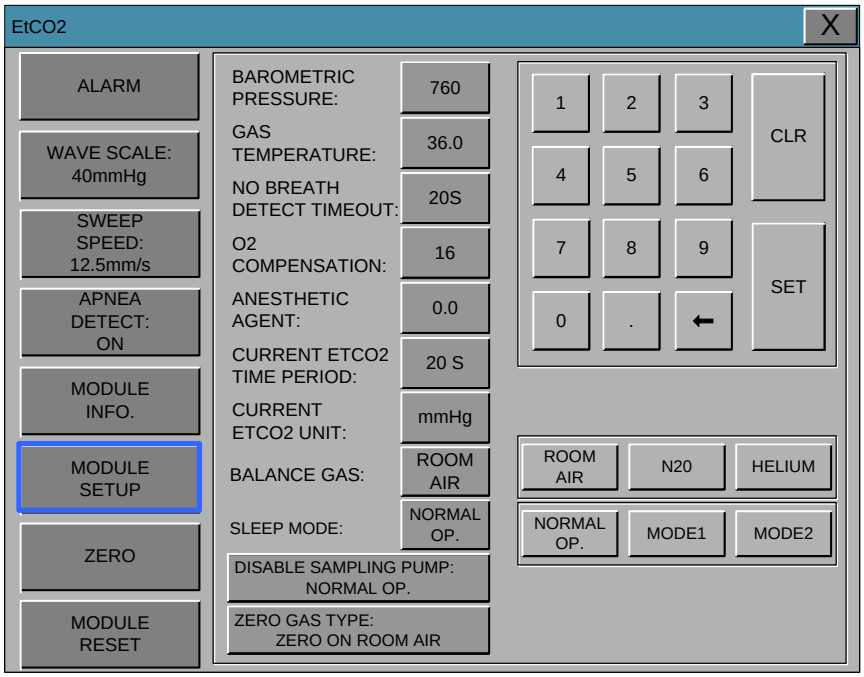
LAST ZERO TIME: This is the total time that has elapsed with the sensor in service the last zero.

PUMP TOTAL USE TIME: This is the total time the pump has been on.(LoFlo only)

PUMP MAX USE TIME: This value indicates the maximum rated lifetime of the sampling pump. (LoFlo only)

MODULE SETUP

This is information for handling the EtCO2 module.



BAROMETRIC PRESSURE: This setting is used to set current Barometric Pressure.

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.

NO BREATH DETECT TIMEOUT: 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 Capnostat will signal no breaths detected.

O2 COMPENSATION

ANESTHETIC AGENT

BALANCE GAS: 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.

CURRENT ETCO2 TIME 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 breaths.

CURRENT CO2 UNIT: Continuous waveform mode commands (the CO_2 Waveform Mode command [command 80h] and the CO_2/O_2 Waveform Mode command [command 90h]) MUST NOT be active when this command is used otherwise this command will be ignored and the setting will remain unchanged.

SLEEP MODE: Sleep mode is used to save power when the host monitor is in standby mode. There are two sleep modes available for the Capnostat. Using Sleep Mode 1 maintains the heaters so the Capnostat is able to run immediately after exiting the sleep mode. Mode 2 will require the Capnostat to go through its warm up sequence when exiting this mode and a delay will be introduced until the system has stabilized.

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.

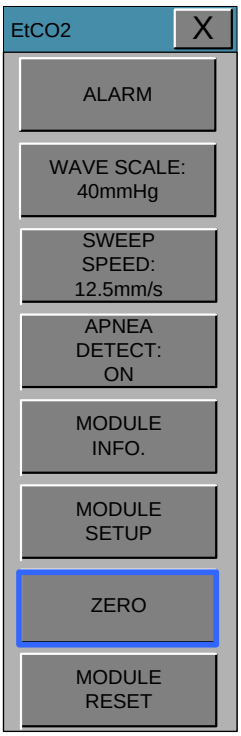
DISABLE SAMPLING PUMP: This setting allows the pump to be forced off. In Normal Operating Mode, the pump will be turned on when the sampling cell is connected and no pneumatic system errors are detected. In Pump Disabled Mode, the pump will remain off in all circumstances.

ZERO

This function is used to initiate a Capnostat zero.

A zero is used to correct for differences in airway adapter types.

The Capnostat zero must be performed free of any CO2.

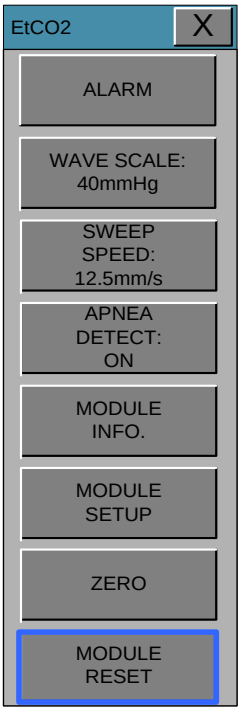


1. Set the Host to the zeroing function.
2. Connect the CAPNOSTAT 5 CO2 Sensor
3. Place the CAPNOSTAT 5 CO2 Sensor onto a clean and dry CO2 adapter that is exposed to room air and away from all sources of CO2, including the ventilator, the patient's breath and your own.
4. Start the adapter zero. The maximum time for a CAPNOSTAT zero is 40 seconds. The typical time for a zero is 15~20 seconds.

Note
For best result, connect the CAPNOSTAT 5 CO2 Sensor to an adapter and wait 2 minutes before performing the Adapter Zero procedure.

MODULE RESET

This performs a function to reset handling the EtCO2 module.



Warning
If defibrillation is performed while doing CO2 monitoring, remove the CO2 FilterLine from patient Getting in touch with sensor cable without removing the FilterLine can result in serious electrical burn, shock, or injury due to electric discharge energy.

Note
In the following monitoring conditions, the measured values may be inaccurate. Read the measured values carefully. 1. When using this in an environment of using nitrous oxide gas of high concentration 2. When using this in an environment where abrupt temperature change takes place 3. When using this in an environment with severely high humidity.

Caution
● The measured values may be inaccurate when using this equipment for patients who have very fast or irregular respiration. ● When measuring CO2 from the patient under the anesthesia, check it when gas mixture comes in. Otherwise, the measured result values may be inaccurate. ● When using a anesthesia machine that uses a volatile anesthetic, CO2 values may be inaccurate.

10.4 TROUBLESHOOTING

Following is a list of some of the message that may appear on the monitor when monitoring CO2. The message should clear when normal operating criteria are met or a solution is found.

*** SENSOR OVER TEMP**

- Cause : The sensor temperature is greater than 40'C
- Solution : Make sure sensor is not exposed to extreme heat(heat lamp,etc.)

*** SENSOR FAULTY**

- Cause: One of the following conditions exist : Capnostat Source Current Failure
  EEPROM Checksum Faulty , Hardware Error
- Solution : Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary.

*** SENSOR WARM UP**

- Cause : Sensor under temperature , Temperature not stable, Source Current unstable
- Solution : This error condition is normal at startup. This error should clear when the warm up is complete.

*** CHECK SAMPLING LINE**

- Cause : This error occurs whenever the pneumatic pressure is outside the expected range.
- Solution : Check that the sampling line is not occluded or kinked. Replace the sample line

*** ZERO REQUIRED**

- Cause : Zero Required , Zero Error
- Solution : 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.

*** CO2 OUT OF RANGE**

- Cause : The value being calculated is greater than the upper CO2 limit(150mmHg)
- Solution : If error persists, perform a zero.

*** CHECK AIRWAY ADAPTER**

- Cause: Usually caused when the airway adapter is removed from the Capnostat or when there is an optical blockage on the windows of the airway adapter. May also be caused by failure to perform Capnostat zero to when adapter type is changed.
- Solution: To clear, clean airway adapter if mucus or moisture is seen. If the adapter is clean, perform a Capnostat zero.

11. TEMPERATURE

11.1 Outline

Temperature Connector and Measuring Cable

11.2 Temperature Data Window

11.3 Temperature Data Setup

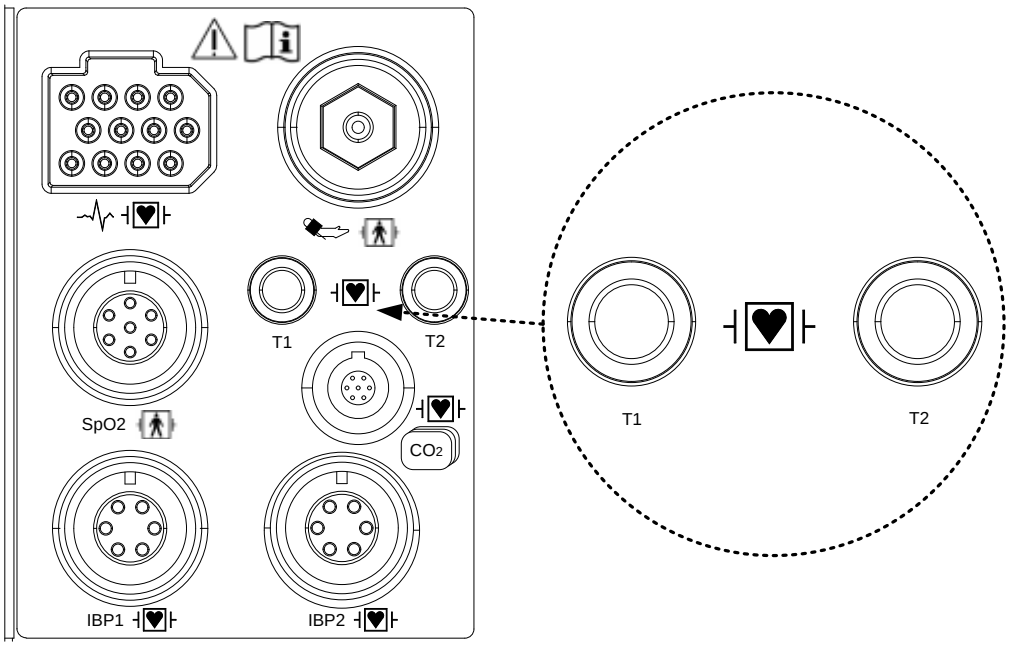
ALARM

TEMP UNIT

11.1 Outline

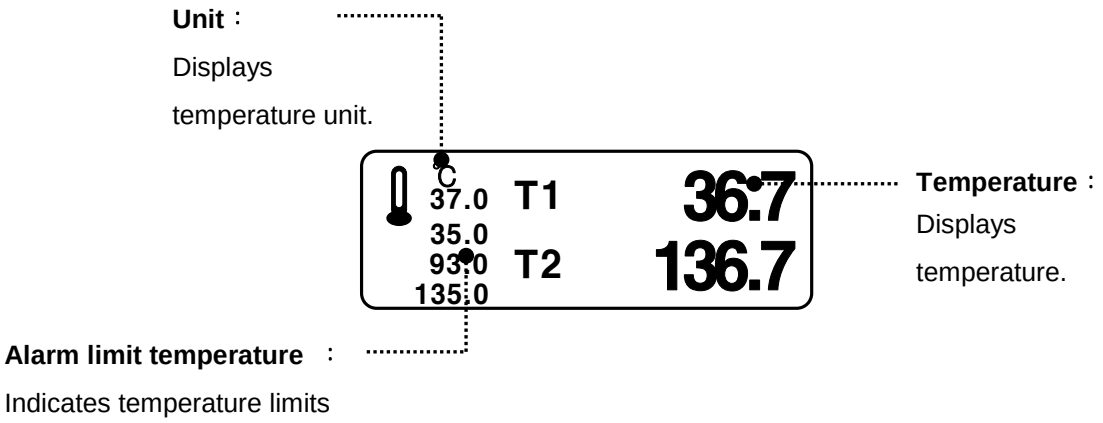
This function is used to indicate the changes of resistance generated by the changes of temperature in numbers. The function involves the process of transferring the changes into electric signals.

- **Temperature Connector and Measuring Cable**



Note
Temperature probe is correctly positioned and fixed to do not disconnect on the patient. Temperature cable is attached to the monitor.

11.2 Temperature Data Window

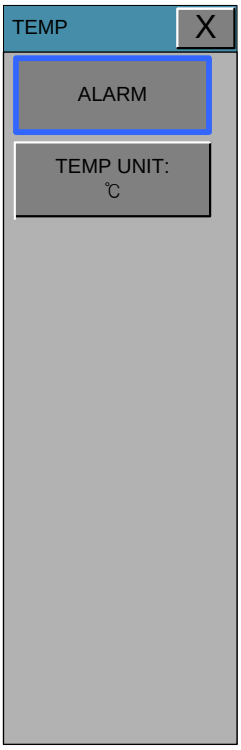


Note
The minimum measuring time required to obtain accurate readings at the specific body site is at least 3 minutes.

11.3 Temperature Data Setup

ALARM: Temperature measurement alarm set

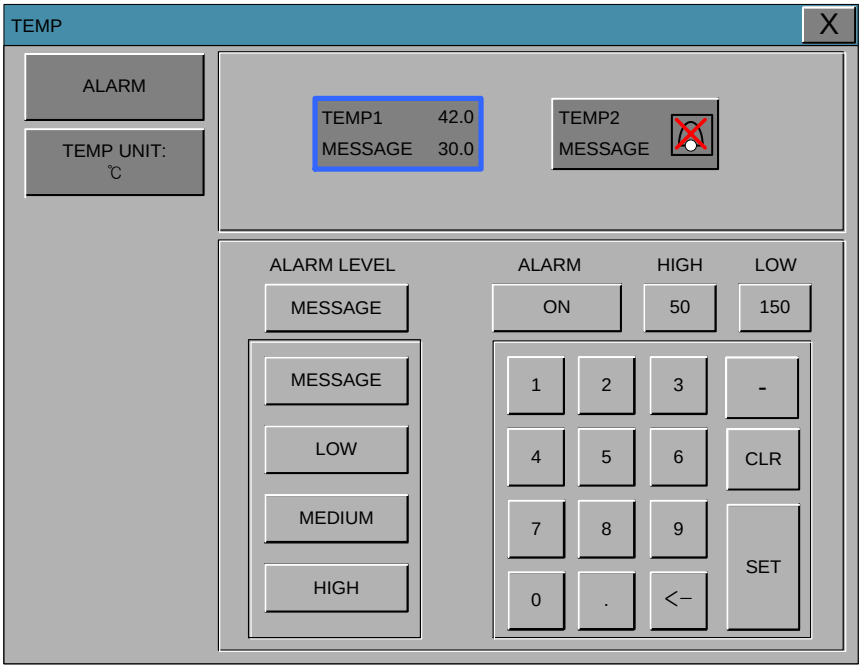
UNIT: Temperature measurement unit set



ALARM

Alarm menu provide ALARM LIMIT and ALARM.

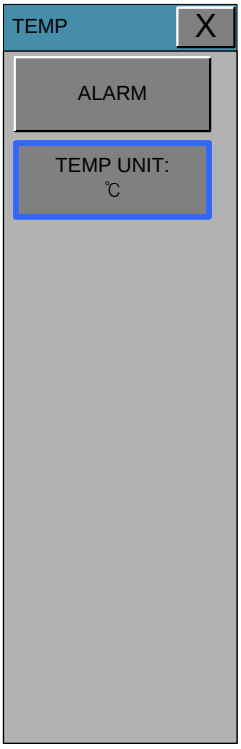
Setting numeric value is 0℃ ~ 50.0℃.



1. Move the ▶ mark to select either RETURN or TEMP, and press.
2. After pressing the cursor at TEMP, move it to LOW, and press.
3. When the color has changed, move the cursor again to select a target value, and press.
4. Move the cursor to HIGH and press. After the color has changed, move the cursor again to select a target value, and press. (One may choose HIGH first to get the same result.)
5. Select RETURN to get out of the menu.

TEMP UNIT

It is able to select unit with °C, °F.



Warning
To measure the peripheral temperature, attach the probe to the ankle or palm. If the patient sweats heavily or moves violently, fasten the pad with surgical tape.

Note
When the measuring site is exposed directly to air, the temperature may be lower than normal. It take about 20 to 30 minutes to reach the equilibrium temperature after attaching the sensor.

12. CARDIAC OUTPUT

12.1 Outline

Cardiac Output Connector and Measuring Cable

12.2 Cardiac Output Data Window

12.3 Cardiac Output Data Setup

ALARM

CATHETER

DELETE CO TRIALS

START

STOP

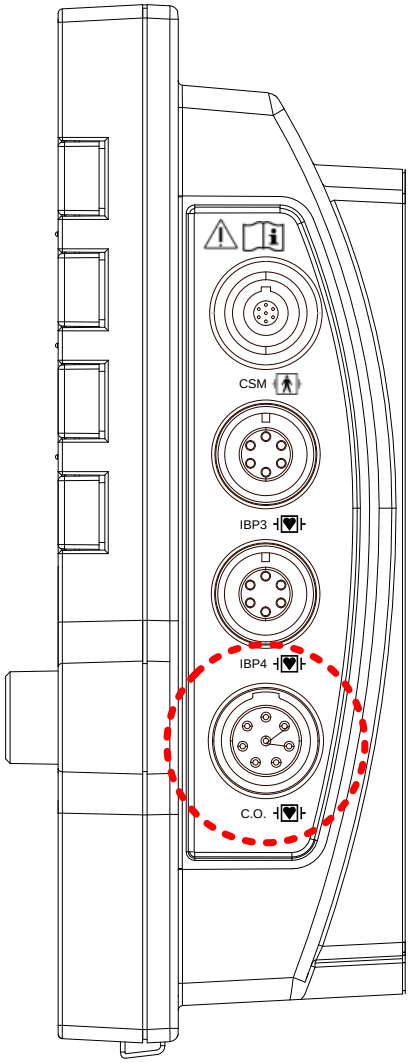
CANCEL

CALC.

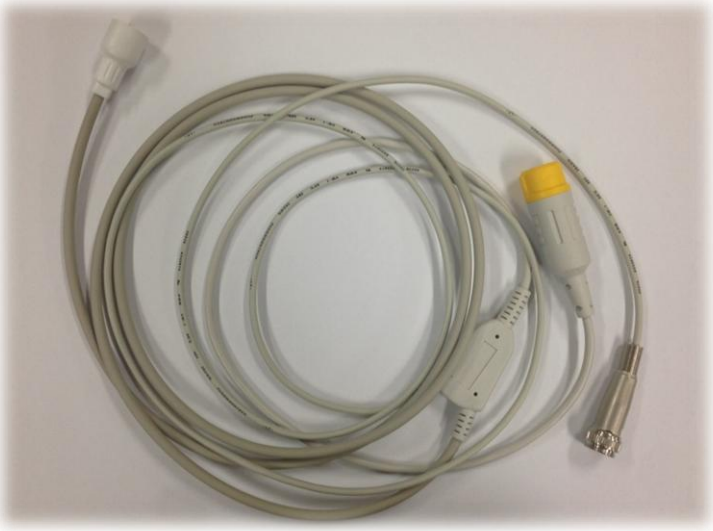
12.1 Outline (Optional Function)

This function allows measurement of cardiac output by using of a thermodilution catheter with information processed by the monitor. A numeric value and, during measurement, a real-time cardiac output washout curve are displayed on the monitor's screen. It allows you to perform multiple measurements and to delete those not wanted. Up to four measurements are retained. It will automatically average these and, when saved, enter the averaged values into cardiac calc. and vital signs.

Cardiac Output Connector and Measuring Cable

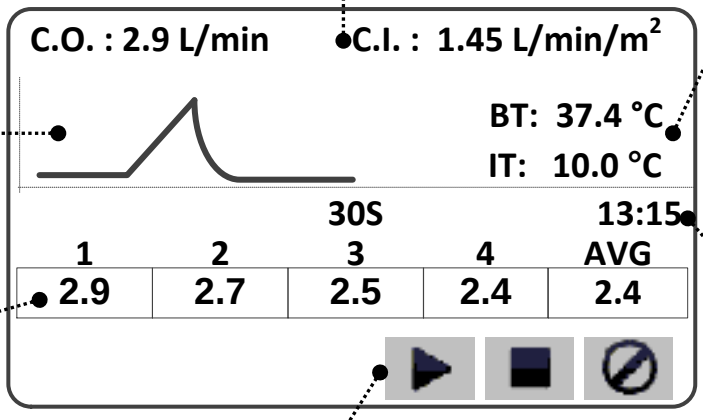


Cardiac Output Measuring Cable



Note
The signal input is a high-insulation port and it is defibrillator- proof (⊣♥⊢). The insulated input ensures patient safety and protects the device during defibrillation and electrosurgery.

12.2 Cardiac Output Data Window (Optional Feature)



Value：
Displays C.O. and C.I. value.

Temperature：
Displays blood temperature and injectate temperature waveform.

Washout Curve：
Displays temperature curve waveform .

C.O. Average Table：
Displays four measurement C.O. data and Average data.

Time：
Displays current time.

C.O. setup menu ：
Setup the module start, stop and cancel.

Note
The minimum measuring time required to obtain accurate readings at the specific body site is at least 3 minutes.

12.2 Cardiac Output Data Window

ALARM: A menu to set the alarm limit

CATHETHER: menu to set the catheter type.

DELETE CO TRIALS: Delete those trials not adaptable.

START: Menu for the measurement start

STOP: Menu for the measurement stop

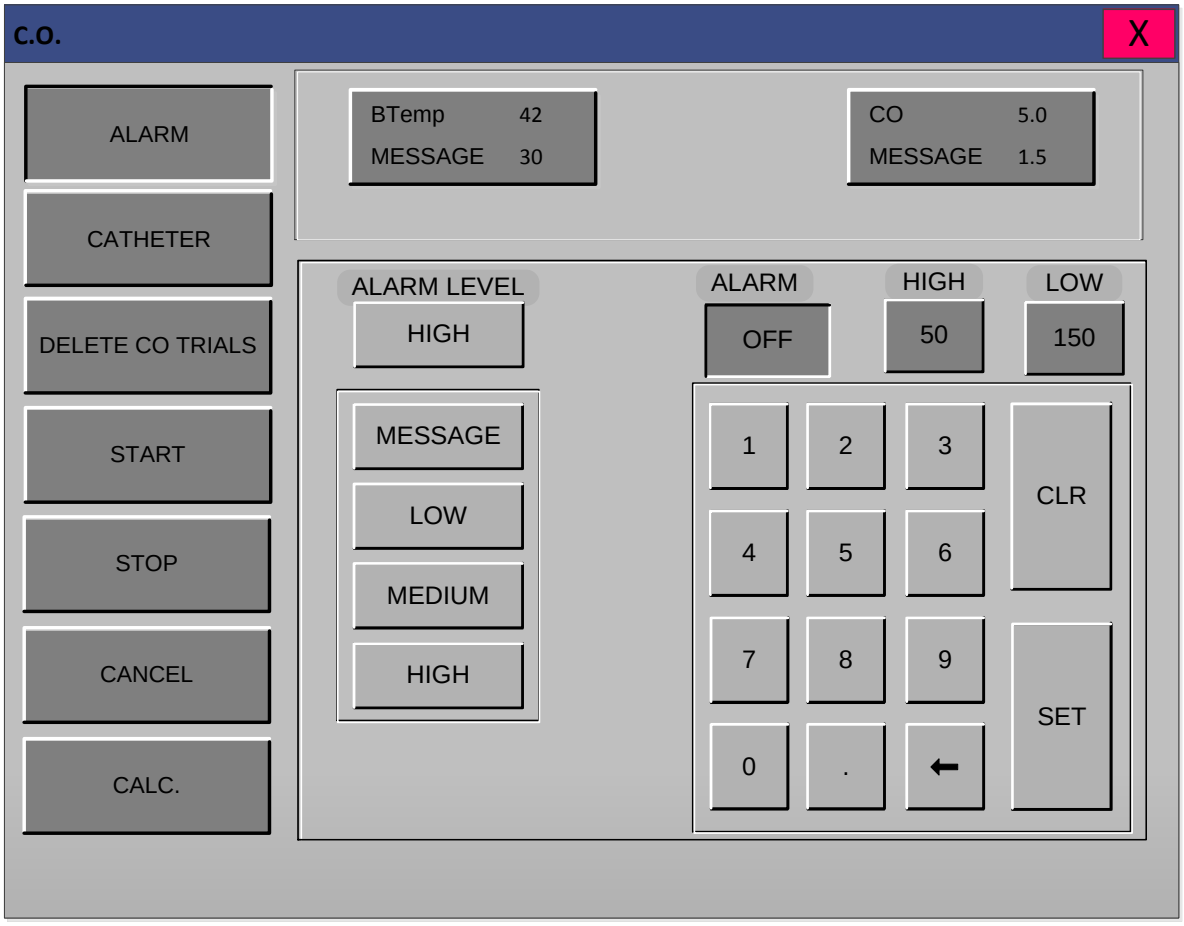
CANCEL: Menu for the measurement cancel.

CALC.: Menu to set the cardiac calculation program.

ALARM

Upper/lower limit value of alarm differs depending on the position of measurement.

The basic setting range is alarm setting value for Blood Temp, CO.
Alarm priority and On/Off settings.



The following table shows standard alarm limit of parameter and setting value of scale when setting the label.

Parameter	Adult			Neonatal		
	Low	High	Scale	Low	High	Scale
BTEMP	0	98	40	0	98	40
CO	0	40		0	40	

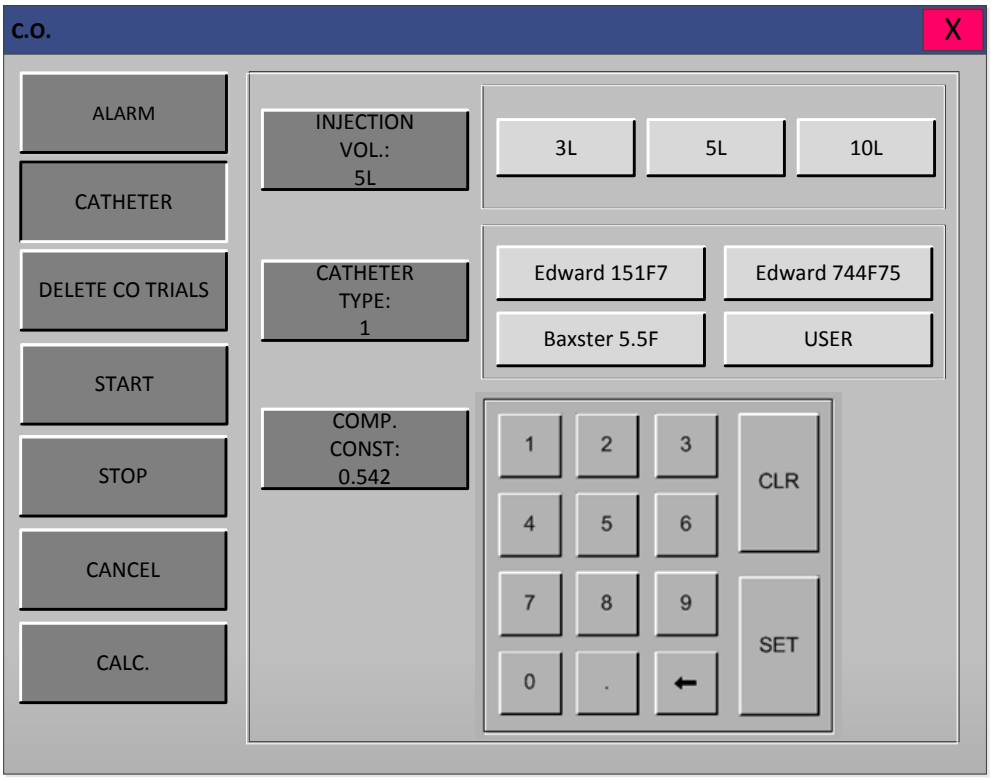
CATHETER

Use this option to change catheter types. Selecting another catheter type causes the monitor to automatically guide you through INJECT TEMP and INJECT VOL options to assure that your setup is the one you want. You do not need to enter a computation constant as the software calculates one based on the manufacturer selected and the temp, size and volume settings.

INJECT VOL: Adjust the injectate volume.

CATHETER TYPE: Select the catheter type.

COMPUTATION CONSTANT: Enter a different computation constant.



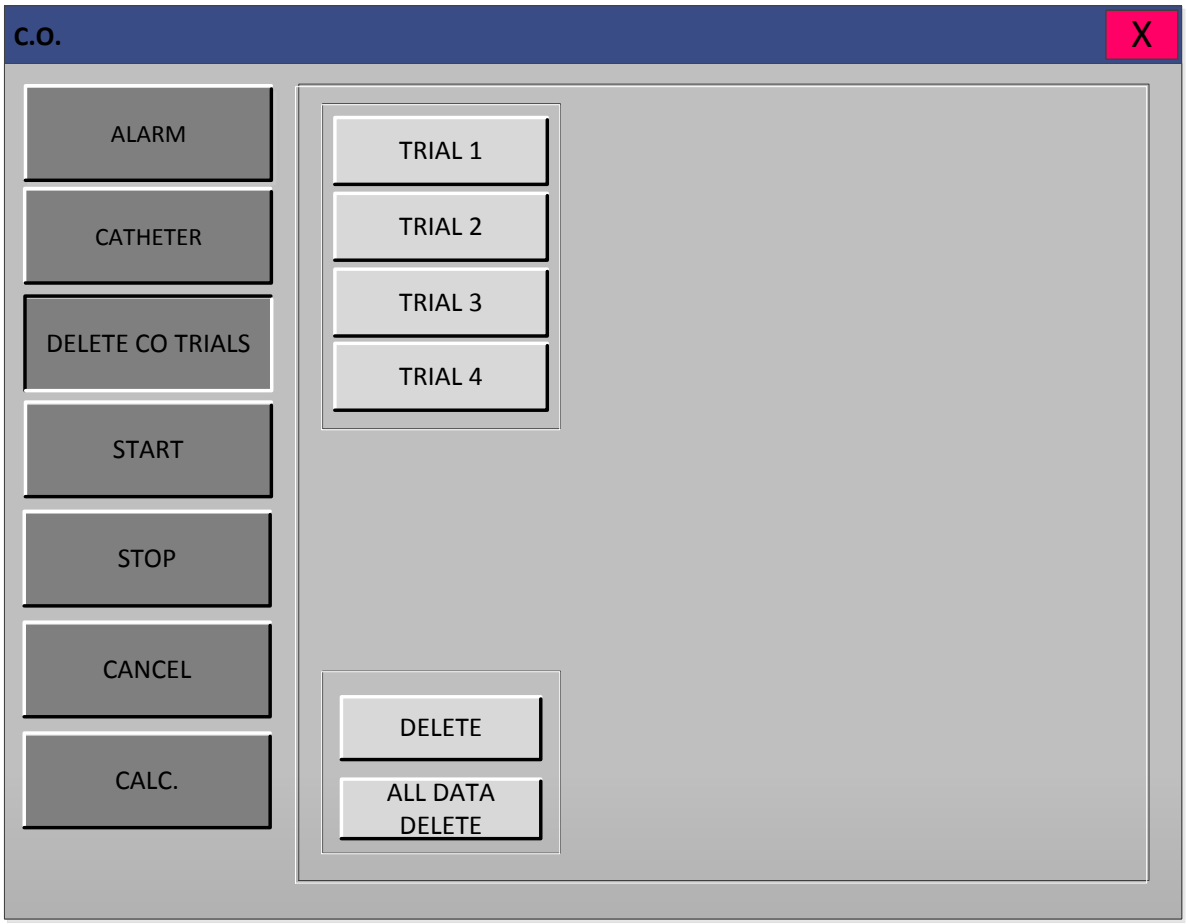
NOTE: It is recommended that a catheter change be made *before* an injection is begun. If you select this option and make a change *after* one or more cardiac output trials have been done, the trials will be deleted. This does not affect any calculations already saved.

NOTE: Selecting USER in catheter type. You will have to manually enter the computation constant found in the literature for the catheter you are using.

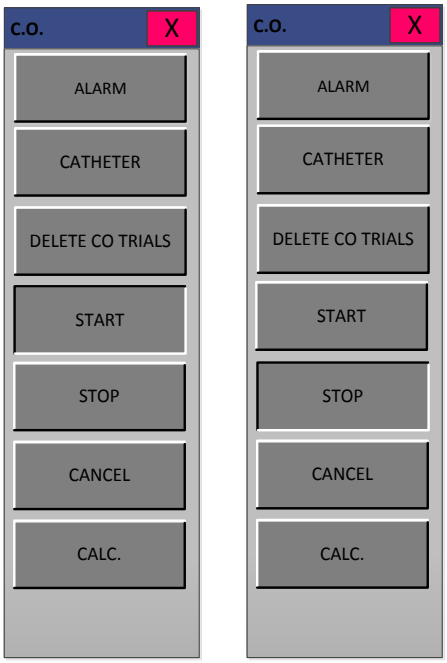
DELETE CO TRIALS

EtCO2 speed is 6.5mm/s.

Speed is changeable to 6.25, 12.5, 25mm/s.



START / STOP



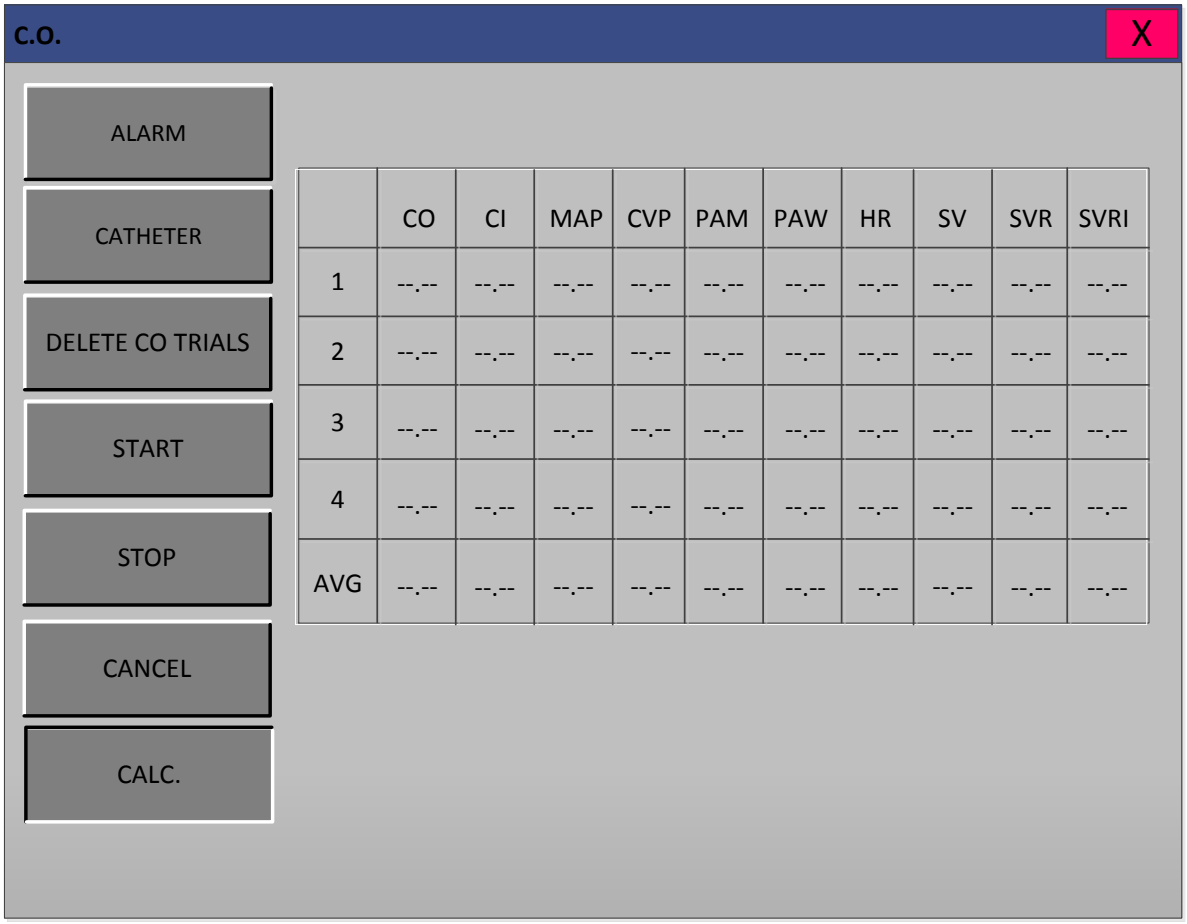
CANCEL

CALC. (CALCULATION)

The cardiac calculations program displays important hemodynamic parameter values. These parameters are separated into two classifications: monitored parameters and calculated parameters. A menu is provided to change or enter a monitored parameter value.

The monitored parameter values are obtained from available monitored patient data. Only two values must be entered manually: weight and height.

The chart below shows the monitored parameters, the labels used to identify these parameters on the screen, and the units of measure.



Monitored Parameters

Parameter	Label	Units
Cardiac Output	CO	L/MIN

Heart Rate	HR	BPM
Mean Arterial Pressure	MAP	mmHg
Central Venous Pressure	CVP	mmHg
Pulmonary Artery Mean	PAM	mmHg
Pulmonary Artery Wedge	PAW	mmHg
Pulmonary Artery Diastolic	PAD	mmHg
Left Atrial	LA	mmHg
Weight	WEIGHT	KG or LBS
Height	HEIGHT	CM or INCHES

Calculated Parameters

The calculated parameter values are figured automatically. The chart below shows the calculated parameters, the labels used to identify these parameters on the screen, the units of measure, and the formulas used.

Calculated Parameters

Parameter	Label	Units	Formula
Body Surface Area	BSA	m^2	$Height^{0.725} \cdot Weight^{0.425} \cdot 0.007184$
Cardiac Index	CI	$L/min/m^2$	CO/BSA
Stroke Volume	SV	mL/beat	CO/HR • 1000
Systemic Vascular Resistance	SVR	$dyn \cdot sec \cdot cm^{-5}$	[(MAP–CVP) • 79.92]/CO
Systemic Vascular Resistance Index	SVRI	$dyn \cdot sec \cdot cm^{-5} \cdot m^2$	SVR • BSA

13. Multi-Gas

13.1 Outline

Multi-Gas Connector position and accessory

13.2 Theory and design

13.3 Multi-gas Parameter Window

13.4 Multi-gas Parameter Setting Menu

ALARM

DISPLAY

APNEA DETECT

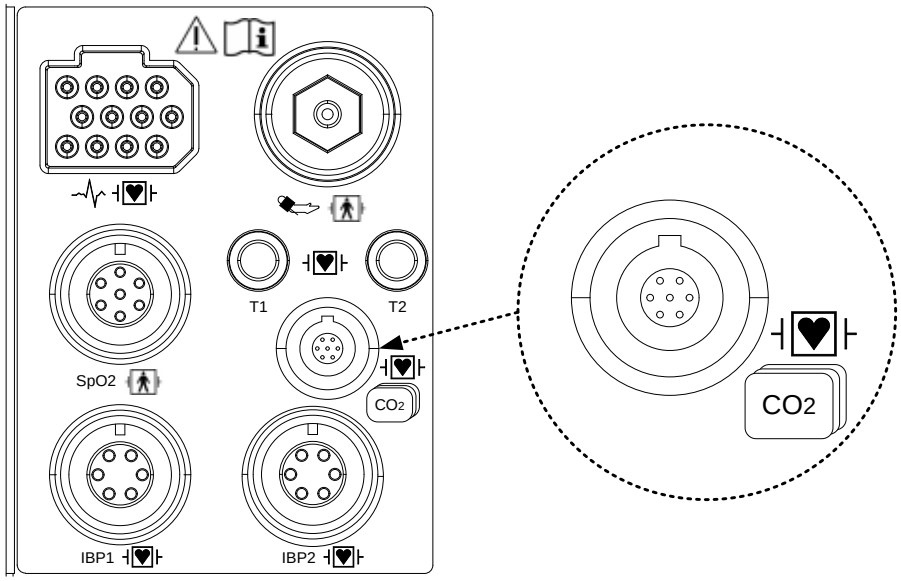
ZERO

MODULE SETUP

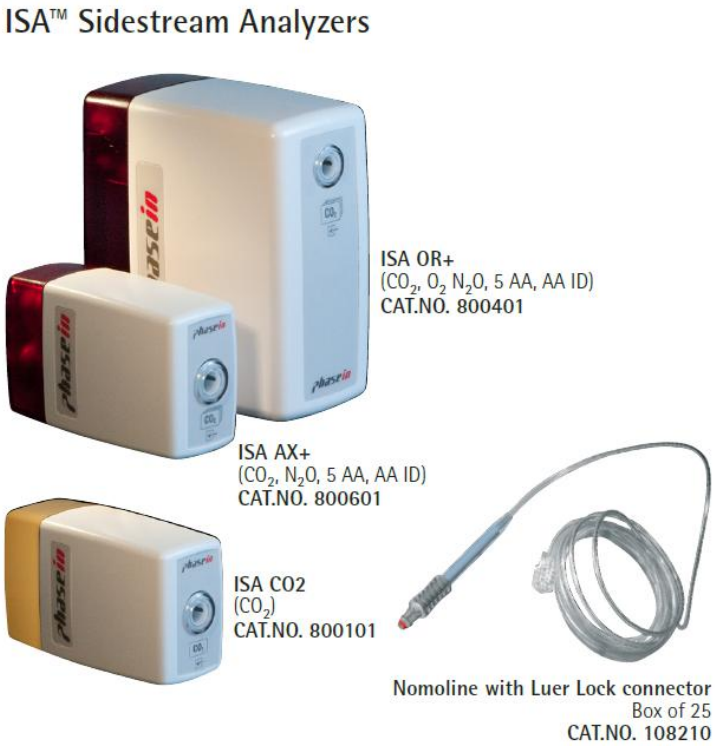
MODULE INFO.

13.1 Outline

Multi gas connector position and accessory (Mainstream, Sidestream, Masimo Sweden AB)



ISA Sidestream Analyzers



ISA Analyzers

Product	Description	Catalog No.
ISA AX+	CO_2, N_2O, 5 AA, AA ID	800601
ISA OR+	CO_2, O_2, N_2O, 5 AA, AA ID	800401

Options

Product	Description	Catalog No.
Servomex Pm1116	Paramagnetic O_2 Sensor (will be discontinued)	100835
Servomex Paracube® Sprint	Paramagnetic O_2 Sensor	100836

Consumables

Product	Description	Catalog No.
Nomoline, Box of 25	Sampling line with male luer lock connector, Adult/Pediatric/Infant, 2.0m. Intubated patients. Single patient use.	108210
Nomoline Adapter, Box of 25	Sampling line with female luer lock connector. Adult/Pediatric/Infant, 0.15m. Intubated/spontaneous breathing patients. Multi patient use.	108220
Nomoline Airway Adapter Set, Box of 20	Sampling line with straight airway adapter, Adult/Pediatric, 2.0m. Intubated patients. Single patient use.	108230
Nomo Extension, Box of 25	Sampling line with male luer lock connector, 2.0 m. Connects to Nomoline Adapter. Single patient use.	108240
T-adapter, Box of 25	Straight airway adapter with female luer lock connector. Adult/Pediatric. Single patient use. Connects to Nomoline and Nomo Extension.	108250

Accessories

Product	Description	Catalog No.
ISA Analyzer Clamp Adapter	Adapter for mounting a "plug-in and measure" gas analyzer to a standard clamp or ISA Modura Holder	100845
ISA Analyzer Modura Holder	Adapter for mounting a "plug-in and measure" gas analyzer to a standard rail clamp	100840
ISA Module Tubing	5 meter polyurethane tube, ID 1.6 mm / OD 3.2	100801

	mm. (Tygothane C210-A 1.6/3.2). Pneumatically connects the ISA build-in module to the O2 sensor. Does also connect the ISA build-in module with the "ISA Gas Outlet Kit" 100803 and the "ISA Reference Gas Inlet Fitting" 100804	
ISA Gas Outlet Kit	Each bag is sufficient for 25 ISA built-in modules. The outlet barb (including mounting nut and o-ring) used on all ISA "plug-in and measure" analyzers to connect an ID 2.4 mm (3/32") tube for returning the gas to the breathing circuit or to the scavenger. To connect the outlet to the ISA build-in module, "ISA Module Tubing" 100801 could be used.	100803
ISA Reference Gas Inlet Fitting	Comes in pack of 25. For ISA built-in modules only. The fitting should be used to ensure that the reference air needed for the ISA's zeroing is taken from the outside of the housing that ISA is mounted in. To remove particulates and avoid water or cleaning fluids from entering the ISA, the "ISA Reference Gas Inlet Filter" 100805 should be used in combination with the fitting. To connect the reference gas inlet fitting to the ISA build-in module, "ISA Module Tubing" 100801 could be used.	100804
ISA Reference Gas Inlet Filter	Comes in pack of 25. For ISA built-in modules only. The filter should be used in combination with the "ISA Reference Gas Inlet Fitting" 100804 to remove particulates and avoid water or cleaning fluids from entering the ISA during the zeroing procedure.	100805
RS-232-M, open end cable,	Adapter cable; male RS-232 to open-end.	100270

Box of 25	Cable length 30 cm. Delivered in boxes of 25	
IRMA/ISA USB serial converter	Integration tool, used to connect and power the IRMA/ISA RS232 connector to a compatible USB port. Comes with driver routines and extension cable. Not for clinical use.	100310
Calibration Gas Regulator Kit	Gas regulator kit for ISA/IRMA/EMMA. Fits PHASEIN´s calibration gas bottles 900170, 900470; Philips´s calibration gas bottle M1662A; GE Healthcare´s calibration gas bottles REF 755583, REF 755580	900910
Calibration Gas, CO_2	For ISA CO2, IRMA CO2 and EMMA Content: 5% CO_2, 20.9% O_2 bal N_2	900170
Calibration Gas, AX+/OR+	For ISA AX+/OR+ and IRMA AX+ Content: 5% CO_2, 2% DES, 42% N_2O, 51% O_2	900470

SA sidestream gas analyzers

ISA sidestream gas analyzers are intended for the monitoring of intubated as well as spontaneously breathing adult, pediatric and infant patients. The ISA analyzers are available in various configurations, ranging from capnography (CO_2) only to multigas analyzers measuring carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2) and five anesthetic agents with dual agent identification capabilities. The ISA analyzers have been specially designed to be extremely easy to integrate in any host device for display of real time and derived breathing gas data.
The ISA sidestream analyzers are available as stand-alone "plug-in and measure" analyzers or build-in modules.

ISA CO_2

The ISA CO_2 analyzers are low-flow sidestream gas analyzers, designed for routine clinical use in environments that place special demands on the product's ruggedness. Its low power consumption and fast rise-time makes the ISA CO_2 ideal for any application, ranging from the OR and ICU to transport monitoring of adult, pediatric and infant patients.

ISA AX+ and ISA OR+

The ISA AX+ are low-flow sidestream multigas analyzers designed to monitor respiratory concentrations of CO_2, N_2O and gas mixtures containing any two of the five anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane in the OR and the ICU. Its low

sampling flow and low agent identification threshold makes the ISA AX+ a perfect choice for adult and pediatric applications, as well as for the monitoring of infant patients with low tidal volumes and high respiratory rates.
ISA OR+ sidestream analyzer offers the same features as ISA AX+, with the addition of oxygen measurement capabilities by means of an integrated paramagnetic O_2 sensor.

Nomoline Family sampling lines

Nomoline Family sampling lines incorporate a unique water separation (**NO MO**isture) section, which removes condensed water. The NOMO section also incorporates a bacteria filter which protects the gas analyzer from water intrusion and cross contamination.
The design of the Nomoline Family sampling lines ensures a smooth, uninterrupted sample gas flow resulting in gas measurements with short response times.

13.2 Theory and design

Gas measurement

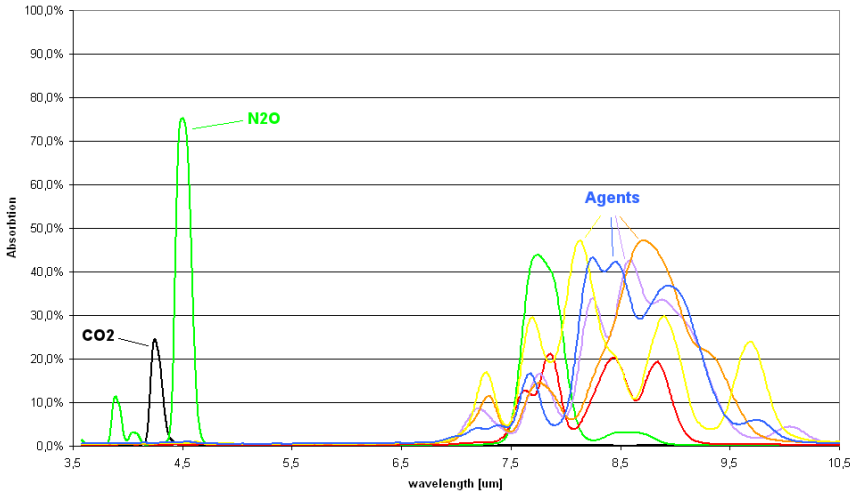
The measurement of CO_2, N_2O and anesthetic agents is based on the fact that different gases absorb infrared light at specific wavelengths. The analysis of respiratory gases by the ISA gas analyzers are therefore performed by continuously measuring the infrared light absorption in the gas flow through an infrared spectrometer. Oxygen, on the other hand, does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods.

The gas analysis

The heart of any ISA gas analyzer is the SIGMA spectrometer. The SIGMA spectrometer uses a proprietary broadband infrared radiation source to transmit light through the gas sample. Before reaching the gas sample, the light path is intersected by narrowband optical filters that only allow light corresponding to selected wavelength peaks of the measured gases to pass. At the other end of the light path, a sensor detects the portion of the light that is not absorbed by the gas.
The amplitude of the detector output is an inverse function of the gas concentration. Thus, at a concentration of zero, the amplitude is at its maximum.

If the gas sample is a mixture of several components that absorb light at the same wavelength, such as a mixture of two anesthetic agents, the absorbed radiation will be the sum of the absorption of the agents. To determine the concentration of each of the individual gases, several filters have to be used. The ISA gas analyzers therefore uses the SIGMA spectrometer, which contains up to nine different narrowband filters to facilitate simultaneous measurement of CO_2, N_2O and a mixture of any

two of the five anesthetic agents.



Gas absorption spectra.

The selection of the optical filters within the spectrometer is crucial to the characteristics and performance of the gas analyzers. The SIGMA spectrometer uses the strong absorption peaks at 4.2 and 4.5 µm for CO_2 and N_2O measurements and five wavelengths in the 8 to 10 µm long wave infrared range (LWIR) for the anesthetic agent calculations. The LWIR contains strong absorption peaks for the anesthetic agents and negligible interference from other common respiratory gases, such as alcohol and acetone, which could degrade measurement accuracy. In addition to the measurement filters, two optical filters appropriately located within the 4 to 10 µm range are used as references.

Oxygen measurement

Oxygen does not absorb infrared light to the same extent as other breathing gases and is therefore measured using alternative methods. The ISA OR+ analyzer is fitted with a paramagnetic oxygen sensor, and the ISA AX+ module is designed to be fitted with an optional oxygen sensor.

Paramagnetic oxygen analysis

Paramagnetic oxygen analysis is based on measurements of the attractive force exerted by a strong magnetic field applied to the oxygen molecules in a gas mixture. The paramagnetic analyzer distinguishes oxygen from other gases as a function of their magnetic susceptibility.

Due to its paramagnetic nature, oxygen is attracted into the magnetic field, while most other gases are not. On a scale, where oxygen is assigned the value 100, most other gases have a magnetic

susceptibility of close to zero.

The Servomex sensors

Two oxygen sensors well suited for the ISA gas analyzer is the Pm1116 and the Paracube® Sprint paramagnetic oxygen sensor from Servomex. In these sensors, a symmetrical nonuniform magnetic field is created. If oxygen is present, it will be attracted into the strongest part of this field. Two nitrogen-filled glass spheres are mounted on a rotating suspension within the magnetic field. Centrally on this suspension, a mirror is mounted. A light beam projected on the mirror is reflected onto a pair of photocells. Oxygen attracted into the magnetic field will push the glass spheres from the strongest part of the magnetic field, causing the suspension to rotate.
When this rotation is detected by the photocells, a signal is generated and passed to a feedback system. The feedback system will pass a current around a wire mounted on the suspension, causing a restoring torque that keeps the suspension in its original position. The current flowing around the wire is measured. This current is directly proportional to the oxygen concentration.
The most important benefits of the paramagnetic oxygen sensor are:

- Fast rise time
- High stability and accuracy
- No chemicals to replace or renew
- Low maintenance requirements

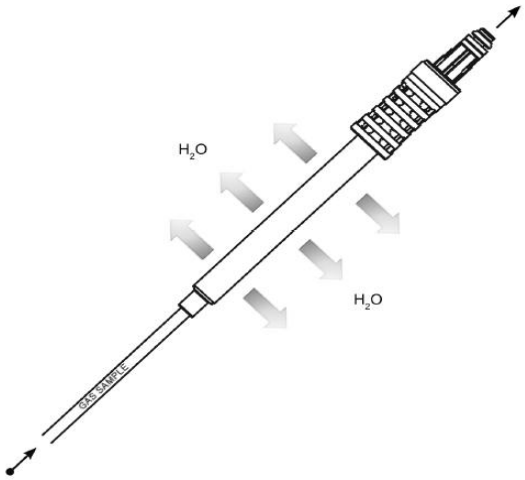
Sampling

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 MO**isture) 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 sml/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 CO_2, N_2O 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:

Figure .The Nomoline Family sampling lines; Nomoline Airway Adapter Set with integrated airway adapter, Nomoline with male Luer Lock connector 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). See section 11 for ordering details.

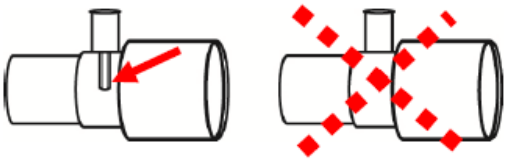


Figure . For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left in the figure above.

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).

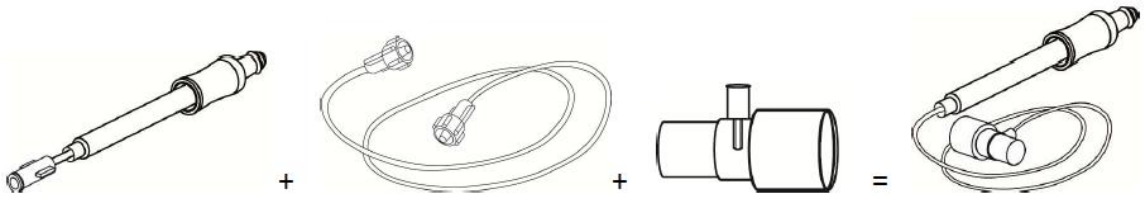


Figure . Combining Nomoline Adapter with the Nomo Extension and T-adapter results in a similar product as the Nomoline Airway Adapter Set.

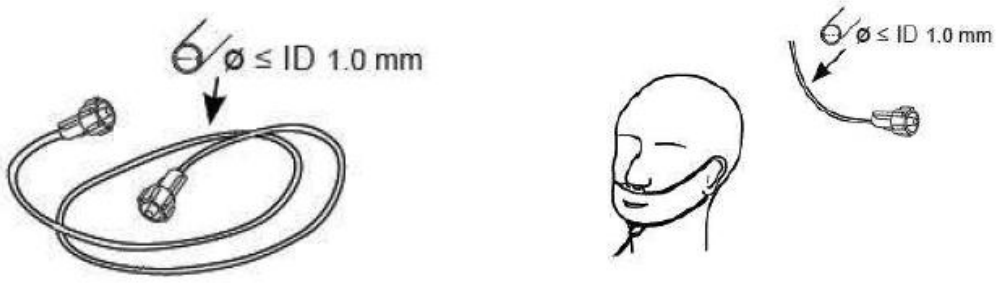


Figure . If using third-party sample tubes or cannuals, make sure that the inner diameter does not exceed 1 mm since this will increase the ISA's total system response time.

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

IRMA Mainstream Analyzers

The entire IRMA Mainstream Analyzer, weighing only 25 grams, is as small as a pulse oximeter sensor. It is designed using the latest ad-vances in miniaturized components and microprocessor technology to provide a complete mainstream monitoring system with unique versatility and design. The complete system is housed in the sensor head which does not require any hardware modifications of the host device. A clinically diverse selection of disposable airway adapters is available for all your applications.

Gas measurement and identification

The IRMA probe snaps in place on the top of the IRMA airway adapter. The IRMA airway adapter is, for example, inserted between the endotracheal tube and the Y-piece of the breathing circuit.
The respiratory gas measurements are obtained by continuously measuring the infrared light absorption, through the XTP windows, in the gas flow through the adapter. To measure the concentrations and identify the gases, absorption of up to nine different wavelengths of infrared light is measured.

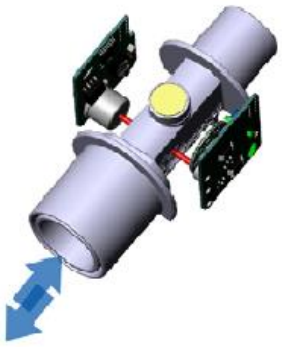
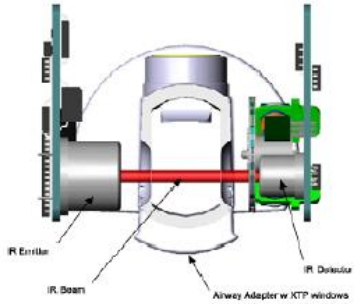


Figure . *Masimo IRMA IR light path through the IRMA airway adapter.*

The measurement of CO_2, N_2O and anesthetic agents in the breathing gas mixture is based on the fact that the different gas components absorb infrared light at specific wavelengths.
A microprocessor continuously calculates the CO_2, N_2O and anesthetic agent concentrations from the infrared light absorption measurements, using matrix calculations to automatically identify which anesthetic agents are present in the gas mixture. Mixtures of maximum two anesthetic agents are automatically identified and both agents are measured.

Infrared measurement technology

The absorption spectra for CO_2, N_2O and the five anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane are shown in the figure(Gas absorption spectra) above.
Masimo IRMA uses the absorption peaks at 4.2 and 4.5 µm for the measurement of CO_2 and N_2O respectively and five different wavelengths in the 8–10 µm range for anesthetic agent measurements. Two additional wavelengths beside the absorption peaks are used as references.
To measure the absorption of light at these wavelengths, a broadband infrared radiation source is used. The light transmitted from the infrared source passes through the XTP windows in the airway adapter and is then filtered using a set of narrow optical band pass filters. The individual filters are mounted in a rapidly rotating filter wheel that intersects the light path before the light reaches the infrared detector.



IRMA XTP™ airway adapter

The IRMA disposable airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP windows in the sides of the adapter.

As the airway adapter is positioned directly in the airway, its performance can be affected by water vapor, patient secretions or nebulized medications that can accumulate on the adapter's windows. The use of metered dose inhalers can also affect the adapter. The water vapor can condense on the surface of the adapter windows in the format of small discrete water droplets. This condensation can affect the light absorption through the windows thus affecting the precision of the measurement. The design and material technology of the XTP windows have special features that prevent a decrease in performance when water vapor is present.

The root cause of water droplet formation is the difference in surface tension between the plastic and water. This mismatch means that the water condenses into discrete droplets with a high contact angle. Figure 3-8 illustrates a water droplet with various contact angles showing the effects of condensed water on light transmission.

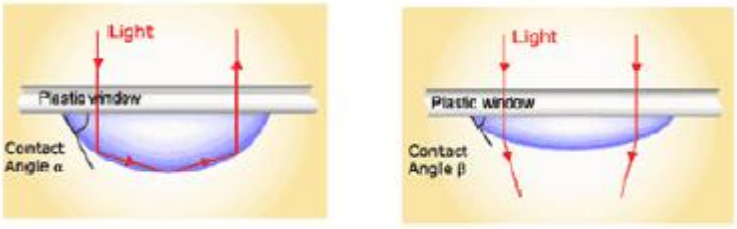


***Figure**. Effect of condensed water on light transmission.*

The XTP windows are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission. Figure 3-9 illustrates the light transmission in a XTP window

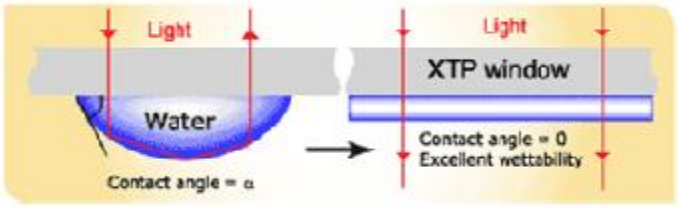


***Figure.** Light transmission through a XTP window.*

For optimal results, the airway adapter shall not be placed between an endotracheal tube and an

elbow, as this may allow patient secretions to block the adapter windows. The IRMA airway adapter shall be positioned with its windows in a vertical position to help keep patient secretions from pooling on the windows.

The IRMA airway adapter is designed as a non sterile single patient use disposable for both Adult/Pediatric and Infant applications.

Figure. *IRMA airway adapters: Adult/Pediatric and Infant adapter*

The IRMA Infant airway adapter has specially designed connectors for minimizing the dead space and can be used even for very small patients.

MAC (Minimum Alveolar Concentration) Calculation

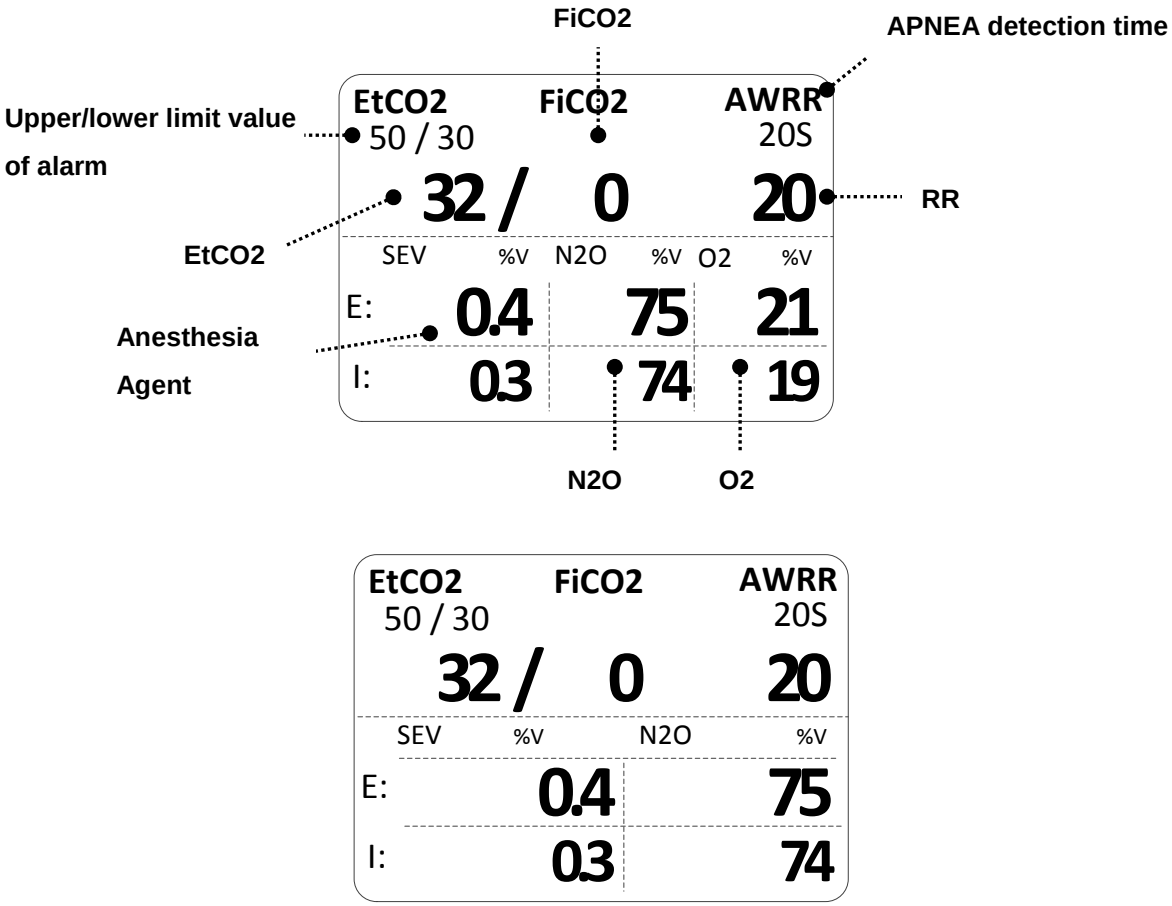
The MAC value may be calculated and displayed by using end-tidal (ET) gas concentrations according to the following formula:

MAC = $\%ET(AA_1)/X(AA_1) + \%ET(AA_2)/X(AA_2) + \%ET(N_2O)/100$

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

Note: The altitude and the patient age as well as other individual factors are not taken into account in the above described formula.

13.3 Multi-gas Parameter Window



S: Display of apnea setting time in second unit

Upper/lower limit value of alarm: Display of alarm setting range value for concentration of $EtCO_2$

$EtCO_2$: Display of concentration value of carbon dioxide

AWRR: Display of the number of respirations per minute

FICO2: Display of concentration value of carbon dioxide during inspiration

Anesthesia Agent: Display of concentration value of Anesthesia agent during inspiration and expiration

N2O: Display of concentration value of Nitrous oxide during inspiration and expiration

O2: Display of concentration value of oxygen during inspiration and expiration

13.4 Multi gas Parameter Setting Menu

ALARM: A menu to set the alarm limit

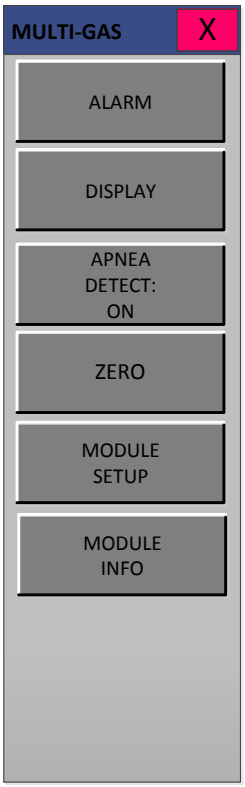
DISPLAY: menu to set the display of waveforms and units of the on-screen

APNEA DETECT: Menu for the detection of apnea

ZERO: Atmospheric pressure and zero adjustment menu to run

MODULE SETUP: Menu to set module of the information.

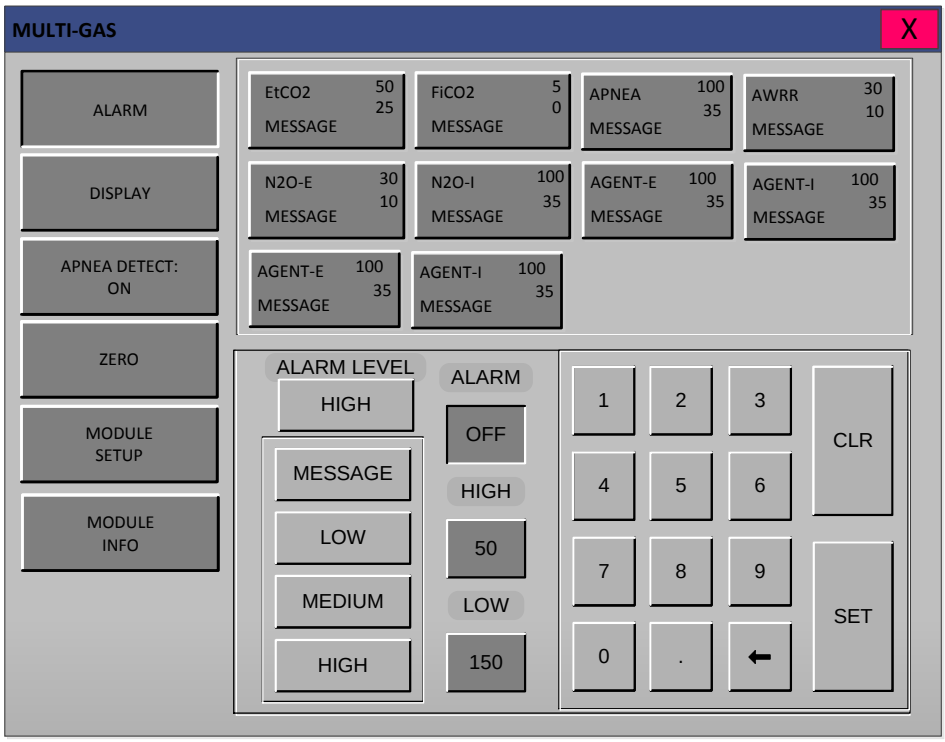
MODULE INFO.: Menu where you can see the MODULE information



ALARM

Upper/lower limit value of alarm differs depending on the position of measurement.

The basic setting range of alarm setting value for EtCO2, FiCO2, AWRR, APNEA,AG-E,AG-I,N2O-E,N2O-I,O2-E,O2-I.



The following table shows standard alarm limit of parameter and setting value of scale when setting the label.

Parameter	Adult			Neonatal		
	Low	High	Scale	Low	High	Scale
EtCO2	0	98	40	0	98	40
FiCO2	0	20		0	20	
AWRR	0	100		0	100	
APNEA	0	40		0	40	
AG-E	0	5		0	5	
AG-I	0	6		0	6	
N2O-E	0	80		0	80	
N2O-I	0	80		0	80	
O2-E	0	100		0	100	
O2-I	0	100		0	100	

DISPLAY (Measured waveform scale setting)

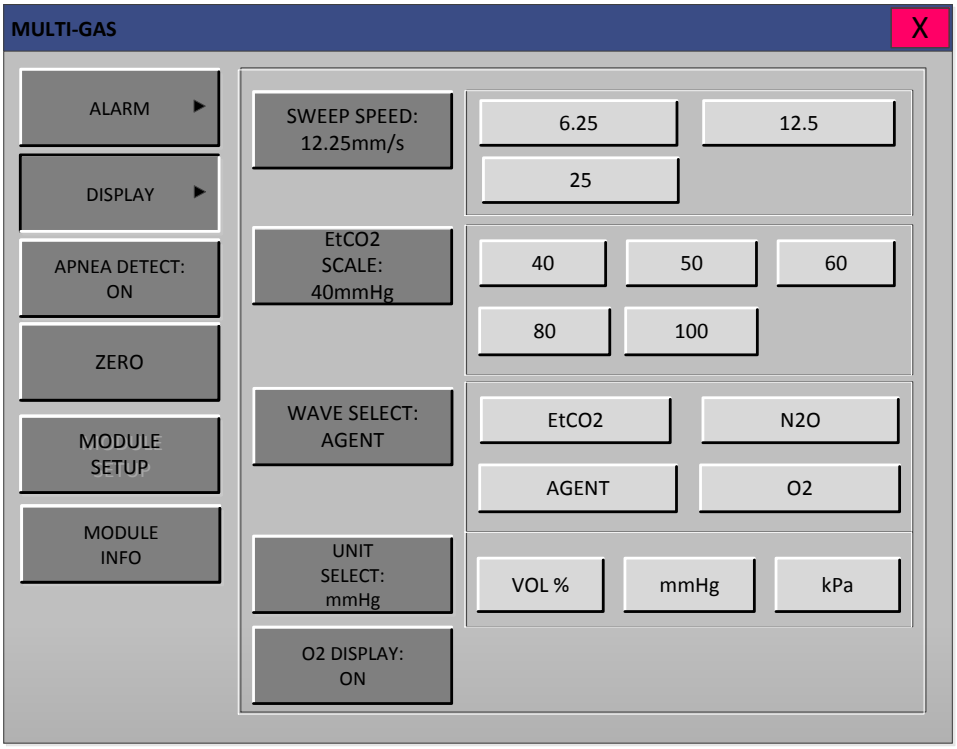
Sweep Speed : Speed is changeable to 6.25, 12.5, 25mm/s.

Scale: Scale is changeable to 40, 50, 60, 80, 100 (mmHg or kPa).

Wave Select: Select the waveform of each gas to display in parameter windows.

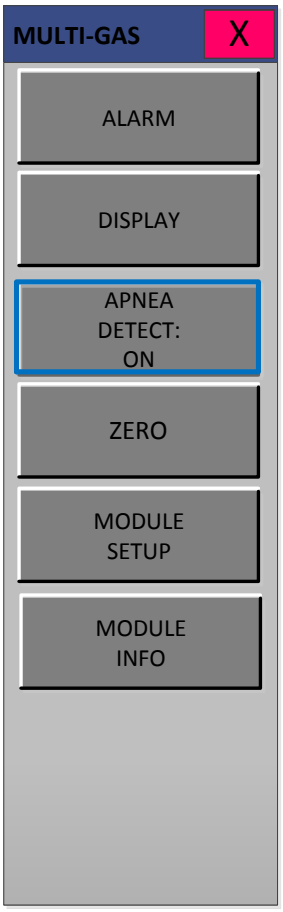
Unit Select: A menu to select the gas unit.

O2 Display: Menu to set parameter display of O2 value.



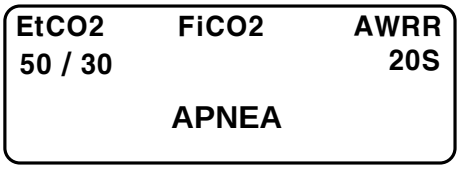
APNEA DETECT

Turn the APNEA detection alarm off and on

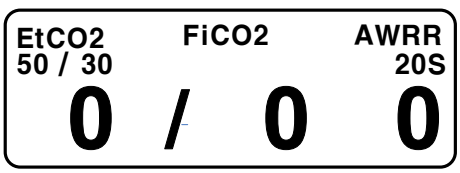


APNEA ALARM: This performs a function to set the display of apnea message alarm.

This displays a "apnea" message at the center of parameter window as shown in the figure below with apnea alarm on in case of apnea until the set apnea period is passed through.



With apnea alarm off, measured values are displayed instead of message.

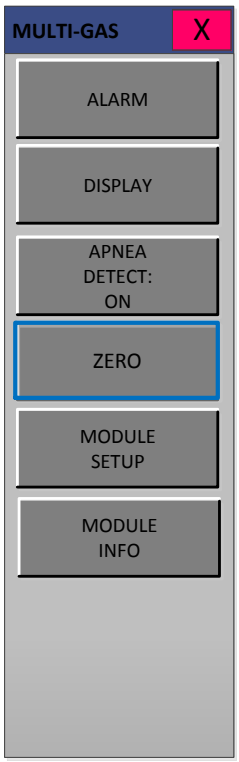


ZERO

This function is used to initiate a IRMA / ISA zero.

A zero is used to correct for differences in airway adapter types.

The IRMA / ISA zero must be performed free of any CO2 and Agent Gas.

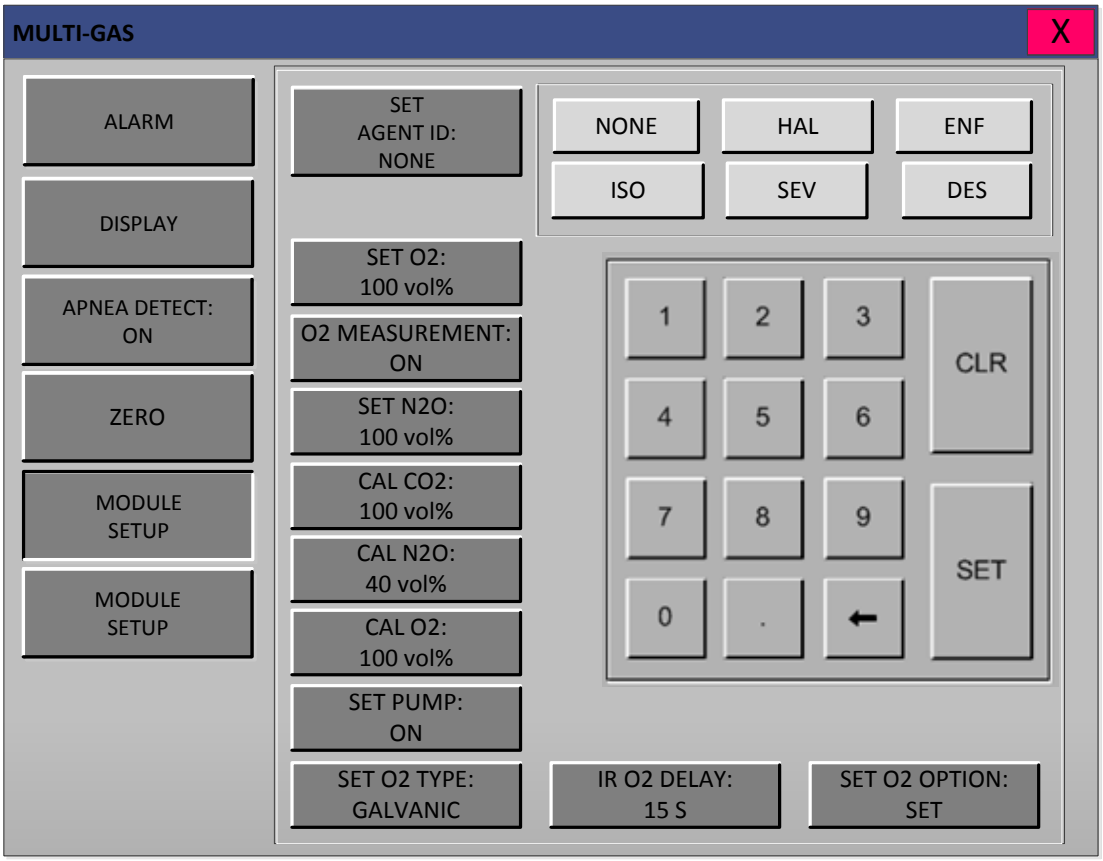


1. Set the Host to the zeroing function.
2. Connect the IRMA / ISA Sensor
3. Place the IRMA / ISA Sensor onto a clean and dry IRMA adapter that is exposed to room air and away from all sources of CO2, including the ventilator, the patient's breath and your own.
4. Start the adapter zero. The maximum time for a IRMA / ISA zero is 40 seconds. The typical time for a zero is 15~20 seconds.

Note
For best result, connect the IRMA / ISA Sensor to an adapter and wait 2 minutes before performing the Adapter Zero procedure.

MODULE SETUP

This is information for handling the IRMA / ISA module.



SET AGENT ID: Set primary Agent ID.

SET O2 : Set O_2 concentration from host Disable O_2 measurement / Enable O_2 measurement.

O2 MEASUREMENT: Set O2 measurement on/off.

SET N2O: Calibrate the concentration of N2O in the settings.

CAL CO2: Performs CO2 span calibration Reset SpanCalCO2.

CAL N2O : Performs N2O span calibration Reset SpanCalN2O

CAL O2: Performs O2 span calibration

SET PUMP: Sets the pump on/off.

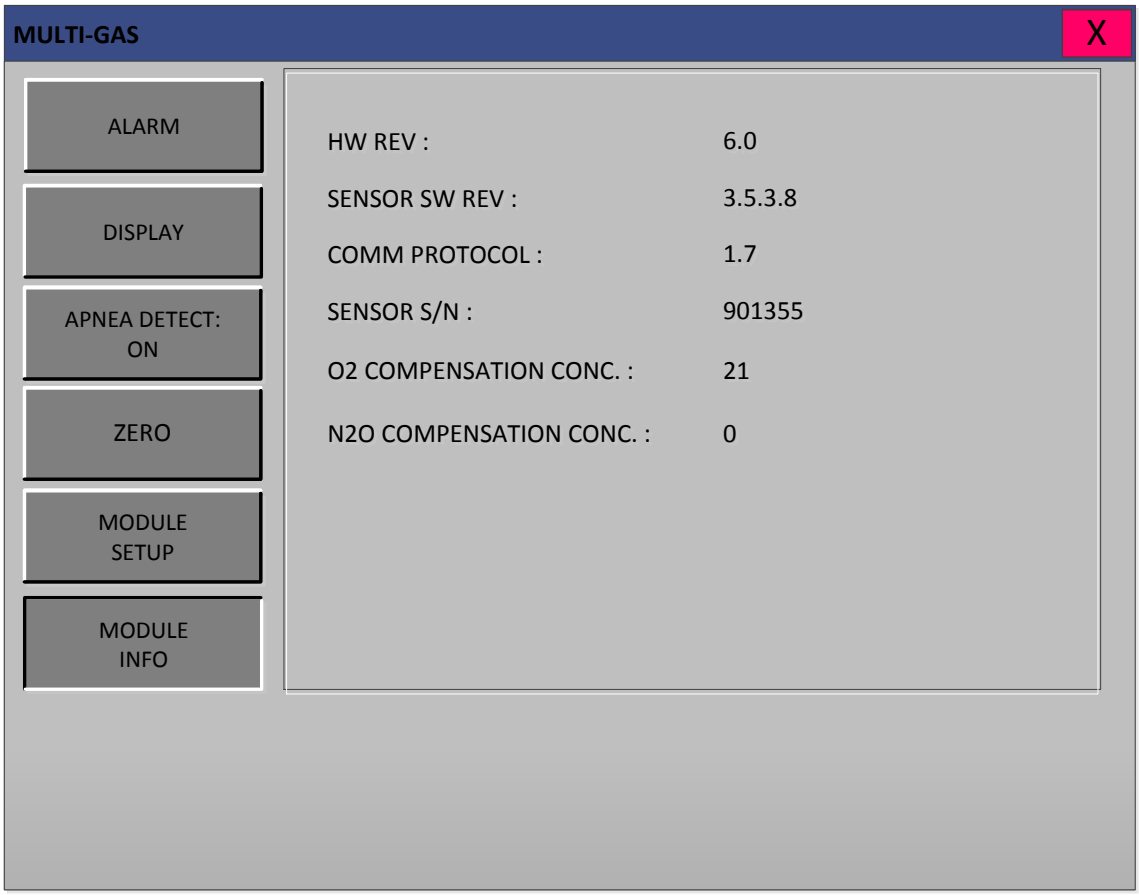
SET O2 TYPE : Set O2 sensor type bits in sensor configuration register 1. (galvanic / Servomex)

IR O2 DELAY: Sets the delay time between the IR and O2 measurements.

SET O2 OPTION: Set/Clear O2 option bit in sensor configuration register 0.

MODULE INFO

This is information for handling the IRMA / ISA module.



HW REVISION: The hardware version number of the module.

SENSOR SW REV: The software revision number of the module.

COMM PROTOCOL: The sensor communication protocol number

SENSOR S/N: The serial number of the module.

O2 COMPENSATION CONCENTRATION: The compensation concentration of the module.

N2O COMPENSATION CONCENTRATION: The compensation concentration of the module.

13.5 Maintenance

The ISA sidestream gas analyzers are permanently factory calibrated and requires no routine user calibration. For all ISA sensor fitted with an O_2 sensor, O_2 gas span calibration instructions described in this sections.

Calibration gas

The gas span check and calibration requires the use of a suitable calibration gas mixture. A cylinder containing such mixture may be acquired from the vendor of your choice, provided the following gas concentrations and accuracy. Depending on your application, multi-gas calibration gas mixture shall be used:

ISA Multigas	
Gas	**Gas Concentration**
CO_2	4.0 to 11.0 %
N_2O	30 to 100 %
DES	2.0 to 12.0 %
O_2	45 to 100 %

Accuracy for all gases: ±0.03 vol% or ±(0.02 vol% + 0.1% of reading), whichever is greatest.
For convenience, the appropriate calibration gas can be ordered from.

Maintenance tasks

PHASEIN Gas Master can be used to complete the maintenance task.

Leak test

1. Connect Nomoline to the ISA gas analyzer, with the analyzer connected to PHASEIN Gas Master.
2. Tightly block the gas inlet of the Nomoline sampling line.
   The cuvette pressure ("Atm press - Cuvette press [kPa]" in PHASEIN Gas Master) will start to rapidly decrease, until the internal pump stops when the cuvette pressure is decreased to about 15 kPa below atmospheric pressure.
3. When the internal pump stops, quickly block the exhaust port tightly.
   When blocked, the cuvette pressure shall be 15 - 23 kPa below atmospheric pressure.
4. Stop the pump by sending parameter "Stop pump" under "Installation & maintenance" in PHASEIN Gas Master.
5. Wait about 10 seconds until the cuvette pressure value as shown by the PHASEIN Gas Master is stable. Note the value.

6. Wait additional 10 seconds.
7. Check that the cuvette pressure value has not changed more than 3 kPa in 10 seconds.
8. If the cuvette pressure value changes more, troubleshoot tubing and fittings. If the problem persists, return the analyzer to PHASEIN.

Note: In step 5, if the cuvette pressure is less than 15 kPa below atmospheric pressure repeat steps 1 to 3 blocking the exhaust port quicker.

Gas span check

Confirm the gas measurements values by performing the following sequence

1. Connect a *new* Nomoline sampling line to the ISA gas analyzer.
2. Warm up for at least 1 min.
3. Connect the calibration gas to the ISA gas analyzer. The calibration gas shall have an accuracy of at least ±0.03 vol% or ±(0.02 vol% +0.1% of reading), whichever is greater.
4. Supply the calibration gas.
5. Check that the displayed gas concentration readings correspond to the calibration gas values.
6. The gas readings shall be within the following ranges:
   a. CO_2 ±(0.3 vol% + 4% of reading)
   b. N_2O ±(2 vol% + 5% of reading)
   c. Agents ±(0.2 vol% + 10% of reading)
   d. O_2 ±(2 vol% + 2% of reading)
7. If the gas readings are outside the specified range, perform a gas span calibration for the failing gases. If failing on Agents the span calibration shall always be performed using DES.

Gas span calibration

Only perform the gas span calibration if the gas span check fails repeatedly.

Before performing the gas span calibration, ensure that the SETO2 and SETN2O values are set (if applicable for your gas analyzer model) correctly to match the corresponding calibration gas.

Span calibration can be performed using gases within the ranges:

4.0% ≤ CO2 ≤ 11.0%

45% ≤ O2 ≤ 100% - for ISA Multigas with Servomex only

30% ≤ N2O ≤ 100% - for ISA Multigas only

2.0% ≤ DES ≤ 12.0% - for ISA Multigas only

The accuracy of the individual components of the calibration gas mixture shall each have an accuracy of at least +/-0.03 vol% or +/-(0.02 vol% +0.1% of reading), whichever is greater.

Note: DES shall be used for span calibration of all 5 agents (HAL, ENF, ISO, SEV, DES).

Note: Do only perform span calibration for gases that failed in the Gas span check**.**

1. Warm up the ISA gas analyzer for at least 1 min
2. Send "Pre span calibration zeroing" and make sure that the surrounding gas is normal air (21% O_2 and 0% CO_2).
3. For each gas that failed the Gas span check, perform step 4 to 7. Always perform the span calibration with the gases in order O2, N2O, DES and CO2

   Example*: Span calibration of O2 and CO2 only, start with O2 then CO2.*
4. Supply the calibration gas and wait for at least 30 seconds.
5. Send the corresponding span calibration command.
6. Wait until the gas span calibration is no longer in progress. The calibration gas can be turned off when "*span calibration is in progress"* no longer is set, but the O2 span calibration continues for about 40 s with a special zeroing during which the Servomex paramagnetic O_2 sensor is sensitive to mechanical movements.
7. Verify the gas readings.

   Note: If the calibration process fails, the flag SPAN_ERR is set, and will stay active until the next successful calibration is passed.

14. CSM

(CELBRAL STATE MACHINE)

14.1 Introduction

14.2 CSM Parameter Window

14.3 SKIN preparation and Sensor Positioning

14.4 CSM Parameter

14.5 Principle of Operation

14.6 CSM Setup

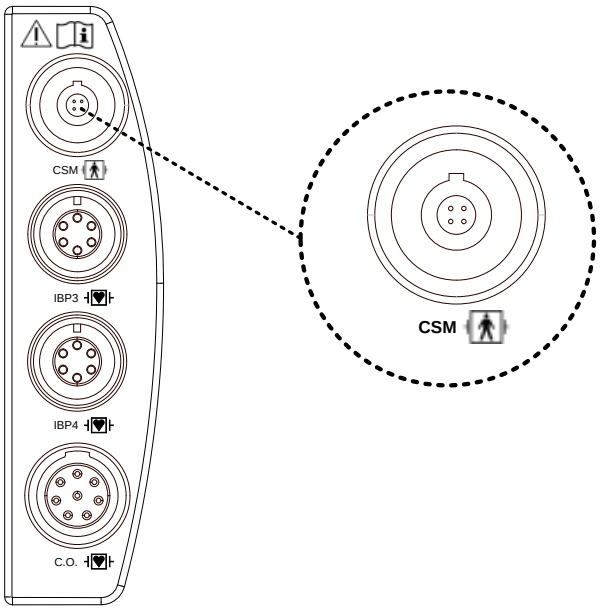
ALARM

DISPLAY

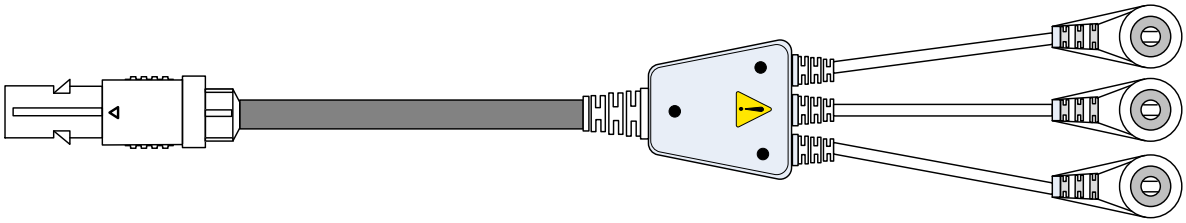
14.1 Introduction (Optional Function)

The module is intended for use in monitoring the hypnotic state of the brain by data acquisition of EEG signals of the anaesthetized or sedated patient in all areas of the hospital. The module is a non-invasive measurement tool to be used by a trained professional to measure the level of consciousness during general anesthesia and sedation by use of variation in the frequency content of the spontaneous EEG. It analyses the frequency shifts that take place in the EEG signal as the level of consciousness changes. Based on this principle, the module calculates the Cerebral State Index(CSI), which is used to estimate the level of consciousness of the patient.

- **CSM connector position and accessory (Danmeter)**

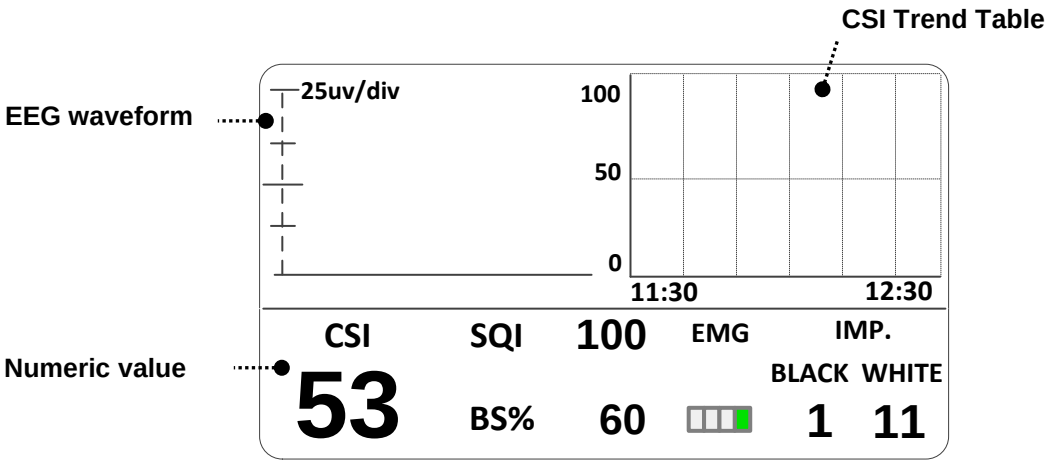


CSM sensor and connector



Note
The CSM module's EEG acquisition performance, and its processing and calculating of the CSM parameters and waveform are ONLY guaranteed by the manufacture.

14.2 CSM Parameter Window (Optional Feature)



CSI TREND Table: Display of CSI Trend data with Operation time and CSI wave. The time scale for the trend curve is selected by CSI LOG INTERVAL SETUP MENU.

EEG waveform: Displays 1 second of EEG waveform. EEG scales are ±100uV, ±50uV, ±25uV, ±10uV, ±5uV.

CSI: The CSI mean value of the patient behavior.

SQI: Display of the number of the quality of the acquired EEG signal.

BS%: Display of the amount of Burst Suppression (very low-amplitude or "flat" EEG)

EMG: Display of level as EMG measurement.

IMP.: Display of impedance of the white and black sensor.

Note
$EtCO_2$ waveform is always displayed if cable is connected.

14.3 Skin Preparation and Sensor Positioning

To ensure low sensor impedance, cleanse skin using mild soap and water.

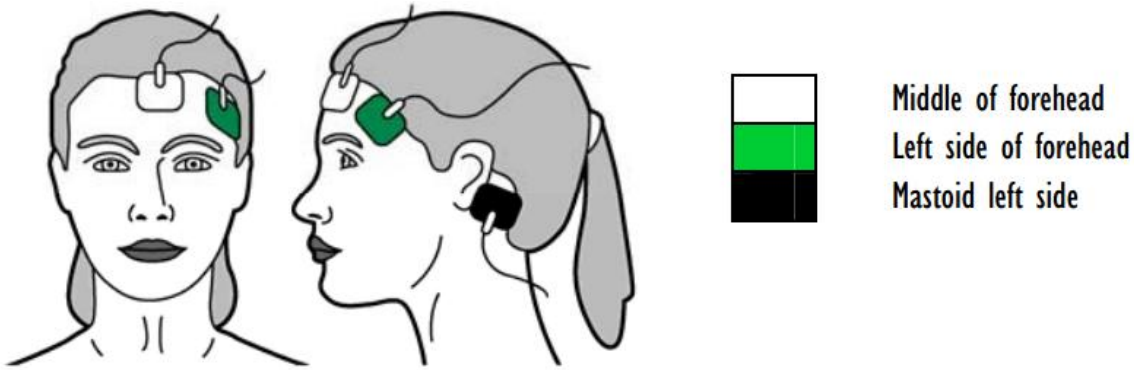
Note
Alcohol is not recommended as a skin cleanser, it leaves a film layer that may cause high sensor impedance. If alcohol is used, ensure 30 seconds drying time.

The CSM module contains a skin preparation product and 3 neuro sensors.

Dry-abrade the skin gently using the skin prep product or with a dry wash cloth or gauze, to remove the nonconductive skin layer. See diagram below

Caution
- Make sure no part of the sensors is in contact with any other conductive parts including earth / ground. - If skin rash or other unusual symptoms develop, remove sensors from patient. - Change sensors every 24 hours to check skin integrity.

Position the three sensors from your CSM module Pack according to the diagram below:



The diagram above shows a left-sided setup; right-sided is also acceptable. Place sensors at the side furthest from the surgical area.

The advanced signal processing of the module ensures that a deviation in the positioning of the sensors up to 2cm (0.78in) has no significant influence on the index. However, it is recommended to place the sensors on an area of the skull where only a few muscle fibers are present in order to achieve the best quality signal.

Note
Once the sensors have been secured to the skin, attach the color-coded wires on the patient cable to the appropriate sensor.

14.4 CSM Parameter

BS% Indicator

The amount of Burst Suppression (very low-amplitude or "flat" EEG) is displayed at the bottom center side. Please refer to next Section for further information on the BS% measurement.

EMG bar

The EMG level is displayed graphically as a bar at the lower hand side in parameter window.

Signal Quality Indicator (SQI%)

SQI% measures the quality of the acquired EEG signal. The calculation is based on a number of artifacts during the last minute. The electrode-to-skin impedance is included in the SQI% calculation. Higher electrode-to-skin impedances reduce the SQI%. Only electrode-to-skin impedances at 1 kΩ and 1 kΩ will result in a SQI% of 100. This quantity is displayed numerically as a percentage (0-100%, 100% equals best signal quality) If the impedance of the white or black sensors exceeds 1kΩ, the SQI will fall gradually. Poor impedance conditions may cause the SQI to fall to 50%.

Sensor Impedance

The impedance of the white and black sensors is continuously measured and displayed in parameter window. Low sensor impedance values (typically between 1 and 3 kΩ) are essential for good monitor operation. A "<1kΩ" readout means that sensor impedance is optimal.

14.5 Principle of Operation

High Quality Amplifier

An instrumentation amplifier collects ongoing EEG with a high Common Mode Rejection Ratio ensuring a high quality EEG acquisition. Special artifact detection algorithms are used to eliminate their effects on subsequent CSI calculations.

Measurement Principle

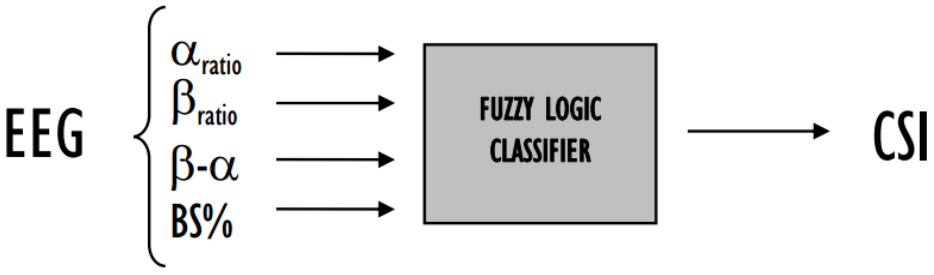
The performance of the CSI is based on the analysis of the frequency content of the EEG signal.

The energy of the EEG is evaluated in specific frequency bands. These are used to define two energy ratios called alpha (α) and beta (β). Both of these show a shift in energy content from the higher to the lower frequencies during anesthesia. The relationship between these quantities is also analyzed as a separate parameter (β-α).

$$\alpha_{ratio} = \ln \frac{E_{30-42.5Hz}}{E_{6-12Hz}} \qquad \beta_{ratio} = \ln \frac{E_{30-42.5Hz}}{E_{11-21Hz}}$$

The module also on-line evaluates the amount of instantaneous burst suppression (BS) in each thirty-second period of the EEG. This measurement quantifies the amount of "silent" or "flat" EEG periods characteristic of the deepest levels of hypnosis.

These four parameters are used as input to a fuzzy logic classifier system that calculates the Cerebral State Index.



CSI Scale

The CSI is a unit-less scale from 0 to 100, where 0 indicates a flat EEG and 100 indicates EEG activity corresponding to the awake state. The range of adequate anesthesia is designed to be between 40 and 60. All values in the table are approximate values based on the mean values of the patient behavior.

The relationship between the CSI, the clinical state and the OASS score is shown in the table below:

CSI	Clinical State	OASS
90 – 100	Awake	5
80 – 90	Drowsy	4
60 – 80	Light anesthesia or sedation	3
40 – 60	Range considered as adequate for surgical anesthesia	2-1
10 – 40	Deep anesthesia, in most cases accompanied by burst suppression.	1
0 – 10	Close to coma, BS (burst suppression) larger than 75. When CSI is below 3, the EEG is practically iso-electric.	< 1

The prediction probability (Pk) between the CSI and the OAAS was 0.92.

The OASS score correspond to:

OASS	Clinical State
5	Responds readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Responds only after name called loudly and /or repeatedly
2	Does not respond to mild prodding or shaking
1	Does not respond to noxious stimulus

EMG

High levels of facial muscular or electromyographic (EMG) activity can interfere with the CSI under certain circumstances. The monitor incorporates an EMG filter that most of the potential interfering EMG activity. The EMG bar shows the energy of the EMG level in the 75-85Hz frequency band (0-100 logarithmic). The bar is located on the right side of the display.

EMG activity is expected to be present when the patient is awake. When the patient is asleep, EMG activity can increase due to:

Reflex reactions to painful stimuli during surgery.

Lack of muscular relaxation.

Muscular rigidity caused by some opioids (analgesics)
Presence of large external electrical fields, e.g. diathermy

The EMG bar should be checked frequently, especially in case of a sudden increase in the CSI. If the increase in CSI is accompanied by an increase in muscular activity, there is a risk that EMG is causing interference. When this happens, attention must be paid to the stimuli received by the patient during surgery. In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent will cause the CSI to decrease. Since patients receiving neuromuscular blocking agents cannot exhibit movement as a sign of arousal, the CSI is a valuable tool in their anesthetic management.

Burst Suppression Indicator

The monitor includes a Burst Suppression Indicator to show periods when the EEG is iso-electric or "flat". The indication appear in the lower center of the graph window in the display and shows the percentage of burst suppression over the last 30 seconds of the EEG signal. A BS% = 20 readouts means that the EEG has been iso-eletric during 20% of the last 30 seconds.

Artifact and Noise Control

The artifact rejection algorithm ensures that the incoming EEG is not contaminated with noise. When excessive noise is detected, the signal quality index is reduced reflecting the disturbance. The artifact rejection algorithm will be active especially when diathermy and equipment creating external interference is used.

Trouble Shooting

Sensor impedance too high
If sensor impedance is >5kohm the CSI , BS and EMG will be blanked
Check that sensors are not dry.
Check that the skin has been cleaned properly.

Signal Quality Index (SQI) low

If the impedance of the white or black sensors exceeds 1kohm, the SQI will fall gradually.
Poor impedance conditions may cause the SQI to fall to 50%.
Artifacts can have many causes: diathermy, EMG, etc. are typical causes.
If SQI falls because of extensive use of diathermy, it will rise as soon as the diathermy is stopped.
Check that all sensors and cable connections are correctly connected.

Has the use of any mechanical device that could generate high frequency activity (e.g. patient warmer) been initiated or is any such device in close proximity to the CSM sensors?
If possible move disturbing device away from the sensors.
Check grounding of disturbing device.

CSI is higher than expected

Check anesthetic delivery systems: IV lines and status of vaporizers.
Some patients require a higher dose of drugs due to interpatient variability.
Adequate dosing for maintenance may not be sufficient for increased stimulation.

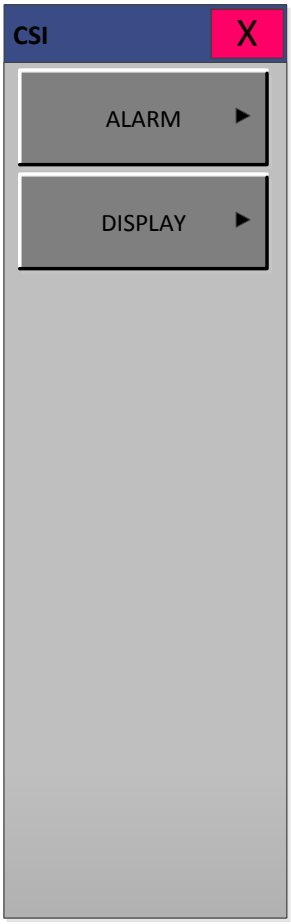
CSI rise along with EMG

High levels of facial muscular or electomyographic (EMG) activity can elevate the CSI under certain circumstances. When this happens, attentions must be paid to the stimuli received by the patient during surgery. When the patient is asleep, EMG activity can increase due to reflex reactions to painful stimuli during surgery, lack of muscular relaxation or muscular rigidity cuasued by some opioids (analgesics). In the presence of hypnotically unrelated EMG, administration of a neuromuscular blocking agent may cause the CSI to decrease.

14.6 CSM Setup

ALARM： CSM measurement alarm set

DISPLAY: CSM measurement display set



ALARM

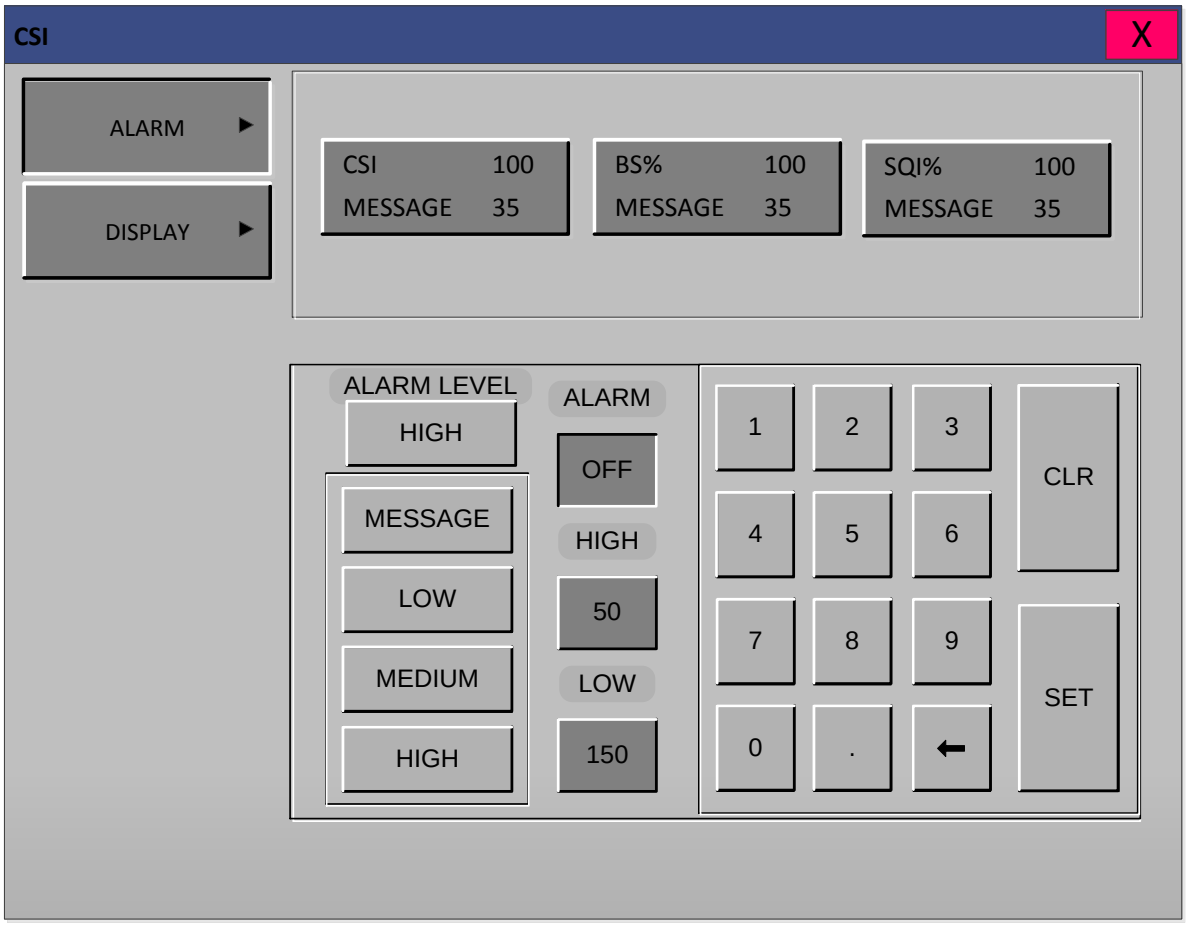
Alarm menu provide ALARM LIMIT and ALARM.

Setting numeric values

CSI is 0 ~ 100.

BS% is 0 ~ 100%.

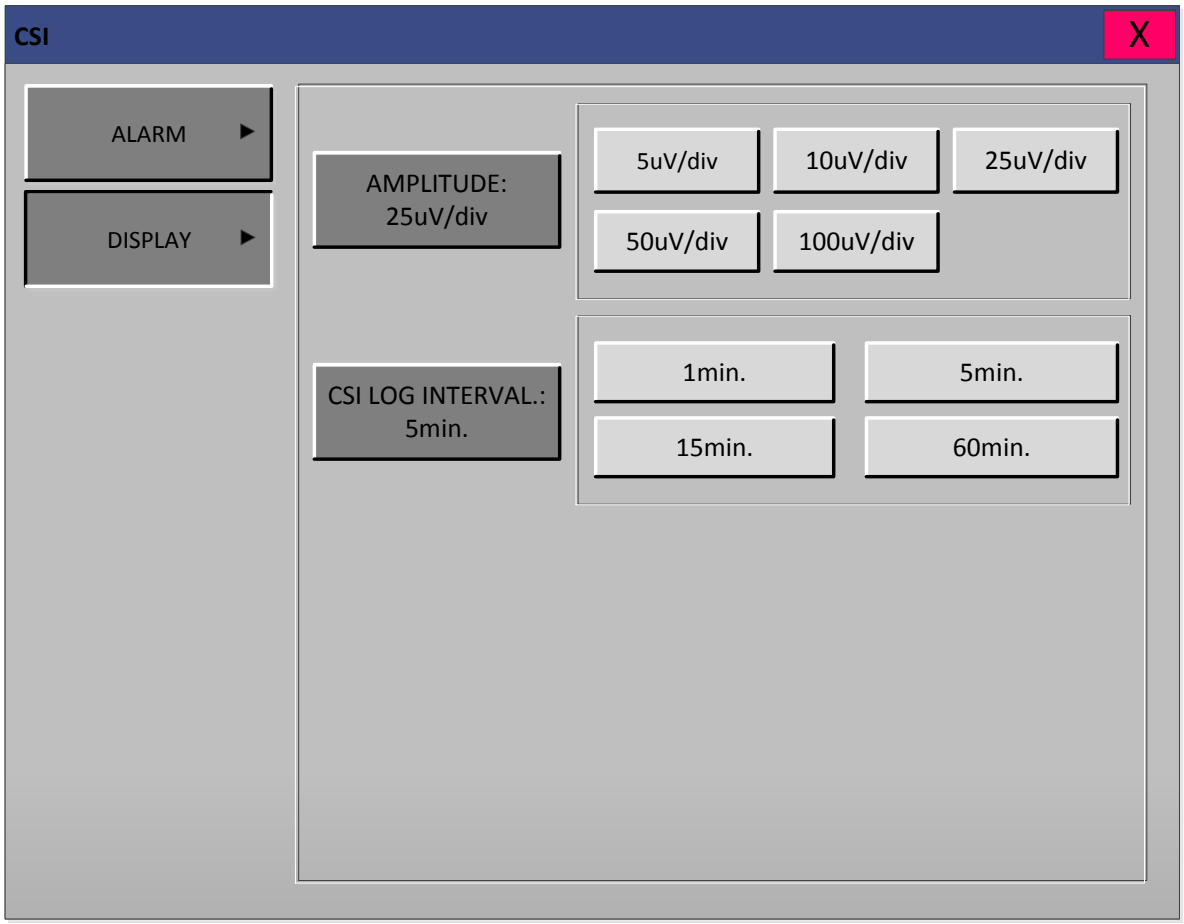
SQI% is 0 ~ 100.



1. Move the ▶ mark to select either ALARM or CSI, and press.
2. After pressing the cursor at HIGH, move it to LOW, and press.
3. When the color has changed, move the cursor again to select a target value, and press.
4. Move the cursor to HIGH and press. After the color has changed, move the cursor again to select a target value, and press. (One may choose HIGH first to get the same result.)
5. Select ALARM to get out of the menu.

DISPLAY

It is able to select Amplitude and LOG interval menu.



Amplitude

The amplitude is changeable to 5, 10, 25, 50, 100uV/div.

CSI log interval

It can set up and display data and time that one can see in a screen.

It can be 1 , 5, 15, 60 minutes.

15. PRINT

15.1 Print

Printer and Heat Sensitivity Paper

Function and Setup Menu

15.2 Paper Change

15.1 Print

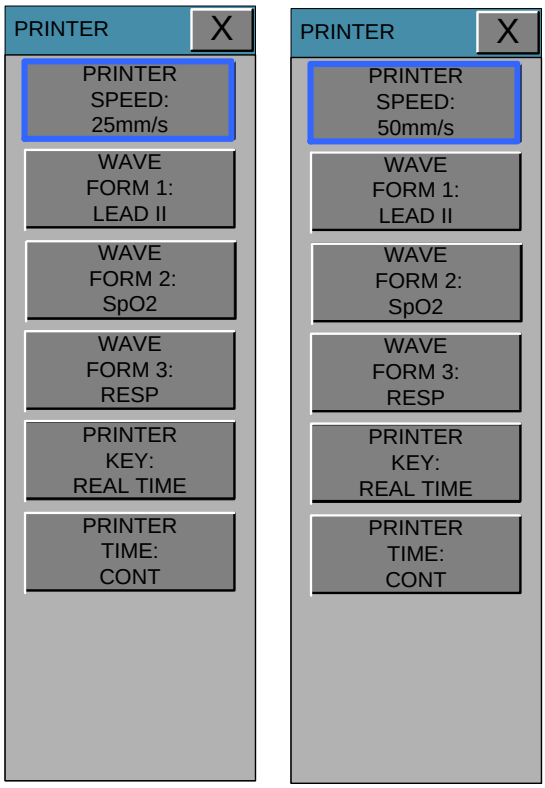
Printer and Heat Sensitivity Paper

A printer used to print data onto thermal paper.

Size of the thermal paper roll: 58mm wide x 38mm in diameter any thermal paper of same size can be used for the printer.

Side View of Printer

Function and Setup Menu



1. Press the PRINT Key for continuous printing.
2. Select Printing Speed 25, 50 mm/s.
3. Set up ALARM PRINT in the MORE menu to activate ALARM during printing.

⇨ **ALARM** ⇨ **ALARM PRINT** ⇨ **ON**

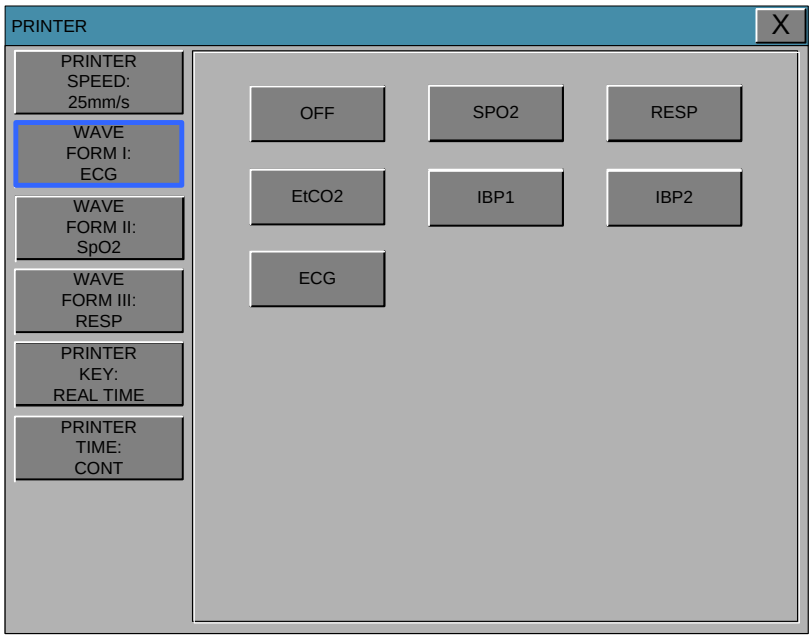
Medium less than the alarm level set alarm print output is not.

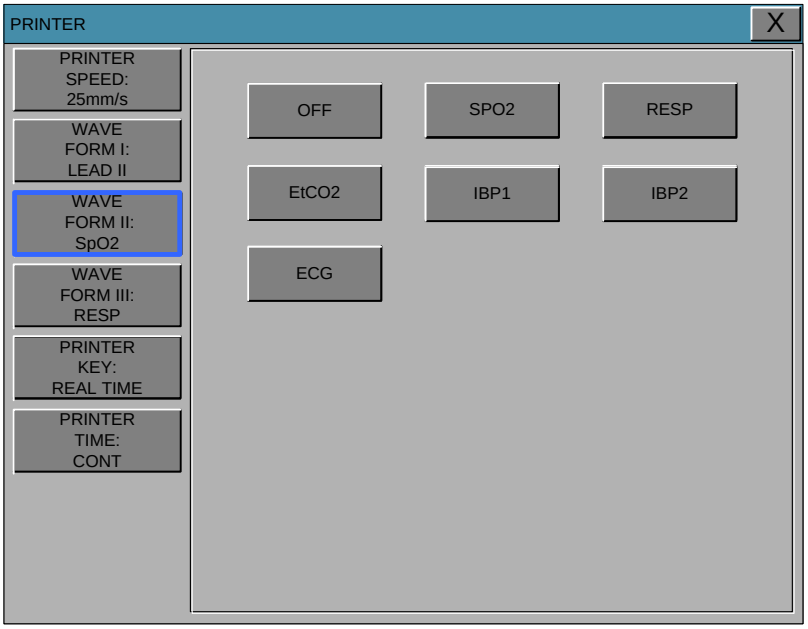
Lead fault alarm the alarm does not print the output.

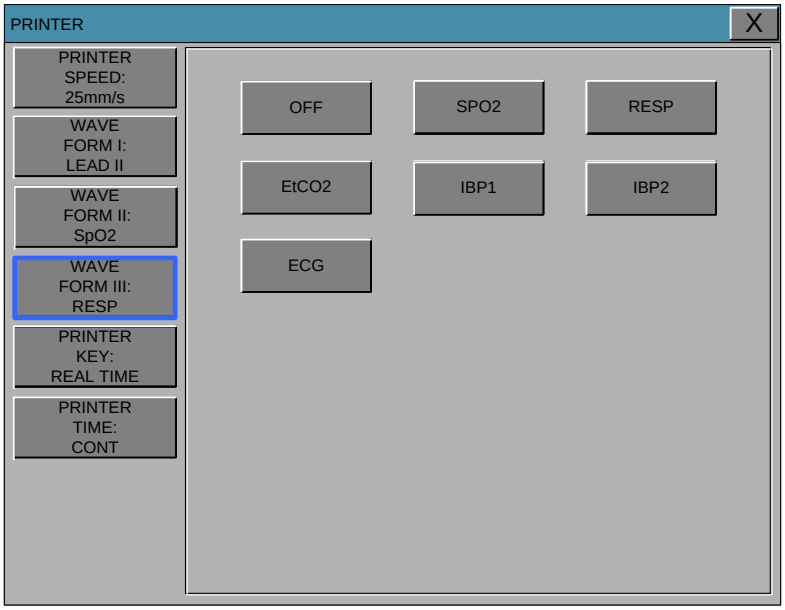
4. Data is printed in a selected wave form along with personal information of the patient.

   3 channels select 3 parameters to print.

⇨ **PRINTER** ⇨ **ECG, RESP, SPO2, IBP1, IBP2, EtCO2**


PRINTER
X
PRINTER SPEED: 25mm/s
WAVE FORM I: ECG
WAVE FORM II: SpO2
WAVE FORM III: RESP
PRINTER KEY: REAL TIME
PRINTER TIME: CONT
OFF
SPO2
RESP
EtCO2
IBP1
IBP2
ECG


PRINTER
X
PRINTER SPEED: 25mm/s
WAVE FORM I: LEAD II
WAVE FORM II: SpO2
WAVE FORM III: RESP
PRINTER KEY: REAL TIME
PRINTER TIME: CONT
OFF
SPO2
RESP
EtCO2
IBP1
IBP2
ECG



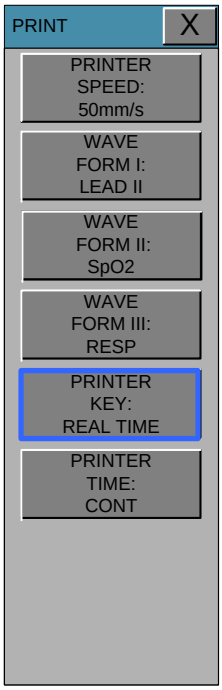
PRINTER KEY

This menu is setup printing time delay in normal printing.

There are two menus for time configuration. One is Real-time, another is Delayed Time.

Real-time: This configuration makes printing out the newest data when the Printer Key is pushed.

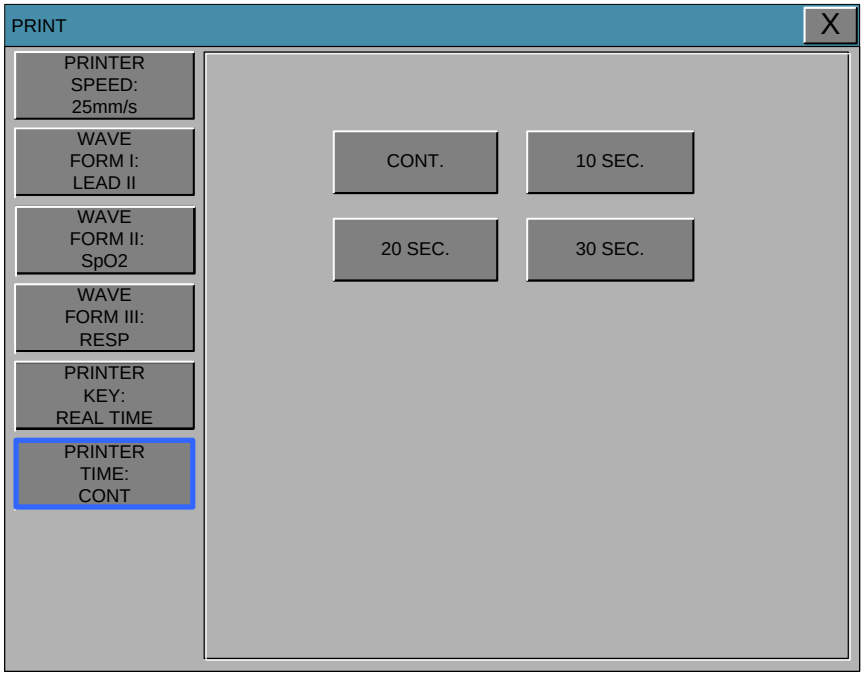
Delayed time: This configuration makes printing out the data after 5 seconds from the Printer Key is pushed.



PRINTER TIME

This is configuration of printed time in normal printing.

If the print out is not stopped in manual by PRINTER KEY, BM7 print out for setup time after starting print out with PRINTER KEY. The configuration of time could be setup with 4 types in CONTINUOUS, 10 sec, 20 sec and 30 sec. The configuration of PRINTER KEY(Real-time/Delayed time) is applied at print out with PRINTER TIME configuration.



If there is no print sheet, no paper icon of  appears.

Thermal Paper Storage

To avoid fading of traces or deterioration, follow these precautions:

Note
These precautions apply to both unused paper as well as paper that has already been run through the printer.

• Store in cool, dark locations. Temperature must be below 27°C (80°F). Relative humidity must be between 40% and 65%.

• Avoid exposure to bright light or ultraviolet sources such as sunlight, fluorescent, and similar lighting which causes yellowing of paper and fading of tracings.

• AVOID CONTACT WITH: cleaning fluids and solvents such as alcohols, ketones, esters, ether, etc.

• DO NOT STORE THERMAL PAPER WITH ANY OF THE FOLLOWING:

  • Carbon and carbonless forms.

  • Non-thermal chart papers or any other products containing tributyl phosphate, dibutyl phthalate, or any other organic solvents. Many medical and industrial charts contain these chemicals.

  • Document protectors, envelopes, and sheet separators containing polyvinyl chloride or other vinyl chlorides.

• DO NOT USE: mounting forms, pressure-sensitive tapes or labels containing solvent-based adhesives.

To assure MAXIMUM TRACE IMAGE LIFE, thermal paper should be stored separately in: manilla folders, polyester or polyimide protectors.

Plastic document protectors, envelopes, or sheet separators made of polystyrene, polypropylene, or polyethylene will not degrade thermal traces in themselves. However, these materials afford no protection against fading from external causes.

Paper manufacturers advise us that these thermal products should retain their traces when properly imaged and stored for about 3-5 years.

If your retention requirements exceed these guidelines, we recommend you consider alternate image storage techniques.

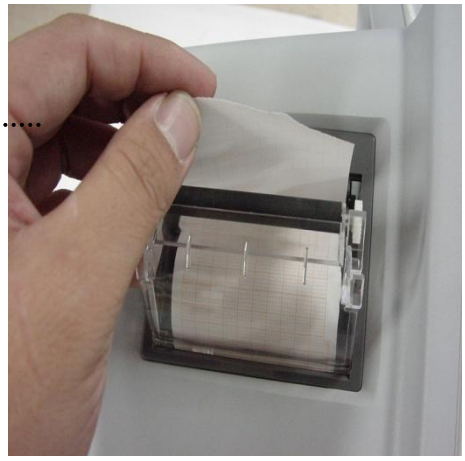
15.2 Paper Change

1

Open the window of the printer.

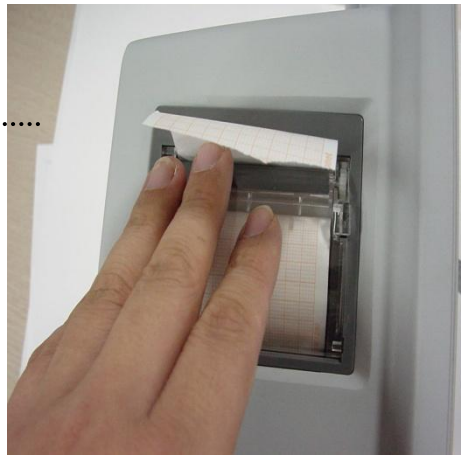
2

Insert the paper roll offered with the product into the printing unit. Place the roll in a proper way so that the printed paper can roll out upwards.



3

Press the printer window until it is properly shut. Inaccurate shutting may cause failure in printing.



16. MESSAGE LIST

Function	Message	Details
ECG	LEAD FAULT	Cable is not properly connected.
SpO_2	CHEK PROBE	Patient's finger is off the probe.
	LEAD FAULT	Cable is not properly connected.
RESP	LEAD FAULT	Cable is not properly connected.
	APNEA	APNEA gives an alarm.
NIBP	INFLATION FAILURE CHECK CUFF	Cuff hose is not properly connected.
	OVER PRESSURE	Cuff pressure is putting on excessively.
	DEFLATION FAILURE CHECK CUFF	Cuff is bent, preventing deflation.
	OVER TIME CUFF PRESSURE	Measure time exceeds the preset Level.
	MEASUREMENT ERROR	Measure signal absent
	PULSE TOO WEAK	
IBP	CHECK SENSOR	Cable is not properly connected.
	DISCONNECTED	Cable is not properly connected.
	IMBALANCE	Zeroing procedure when necessary.
EtCO2	MODULE OFF	Module is not properly connected.
	SENSOR WARMUP	Sensor is initializing
	CHECK ADAPTOR	Adaptor is not properly connected.
	CHECK LINE	Tube is not properly connected.
	APNEA	APNEA gives an alarm.
	ZERO IN PROGRESS	Zeroing procedure when necessary.
	SENSOR FAULTY	Sensor is not properly measured
TEMP	LEAD FAULT	Cable is not properly connected.
MULITI GAS	MODULE OFF	Module is not properly connected.
	CHECK ADAPTOR	Adaptor is not properly connected.
	CHECK LINE	Tube is not properly connected.
	MOTOR ERROR	Motor is not properly operated.
	HW ERROR	Hardware is not working.
	SW ERROR	Software is not properly operated.
	FACTORY CAL LOST	Factory calibration value is lost.

	O2 SENSOR ERROR	O2 Sensor is not properly operated.
	REPLACE ADAPTOR	Adpater needs to change new.
	O2 PORT FAIL	O2 Sensor is not properly connected.
	SLEEP MODE	Module is sleep mode.
CSM	LEAD FAULT	Cable is not properly connected.
	ARTIFACT	Signal is some noise.
	SQI LOW	SQI value is lower.
	IMP. HIGH	Impedance value is high.
C.O.	IT LEAD FAULT	IT Cable is not properly connected.
	BT LEAD FAULT	BT Cable is not properly connected.
	BTIT LEAD FAULT	BTIT Cable is not properly connected.
	WAIT	Waiting for Injection operation.
	UNSTABLE	Temperature is unstable.
	INJ. NOW	Injection operation is now.
	COMPUTE	Cardiac Output is calculation.
	COMPLETE	Algorithm is done.
ALARM	ALARM VOL.OFF	Alarm volume is off.
	SILENCED	Alarm key is pressed once
	ALARM PAUSE 2MIN	Alarm key is pressed twice
TREND	NO PATIENT DATA	No patient's data input.

17. DEFAULT SETTING VALUE

17.1 Adult-ICU Mode

Alarm level

	High	Medium	Low	Message
Asystole	0			
VTAC/VFIB	0			
VTAC	0			
SHORT RUN	0			
ACC VENT	0			
BIGEMINY	0			
COUPLET	0			
IRREGULAR	0			
PAUSE	0			
R ON T	0			
TRIGEMINY	0			
V BRADY	0			
PVC			0	
ST			0	
HR		0		
NIBP - S		0		
NIBP - M		0		
NIBP - D		0		
SpO_2			0	
SpO_2-Rate				0
RR				0
RR-Apnea				0
T1(° C)				0
T2° C)				0
IBP1(S/M/D)			0	
IBP2(S/M/D)			0	
IBP3(S/M/D)			0	
IBP4(S/M/D)			0	

EtCO2			**0**	
FiCO2				**0**
AWRR			**0**	
APNEA				**0**
AG-E		**0**		
AG-I		**0**		
AG2-E		**0**		
AG2-I		**0**		
N2O-E			**0**	
N2O-I			**0**	
O2-E			**0**	
O2-I	**0**			
CSI			**0**	
BS%			**0**	
SQI			**0**	
BTemp			**0**	
C.O.			**0**	
LEAD FAULT				**0**
CABLE OFF				**0**
LOW BATTERY				**0**

Parameter Limits

	Low	High
HR	**50**	**150**
NIBP-S	**80**	**200**
NIBP-M	**40**	**140**
NIBP-D	**20**	**120**
SpO_2	**90**	**100**
SpO_2-Rate	**50**	**150**
RR(RESP)	**10**	**30**
RR-Apnea	**0**	**20**
T1 ℃/℉	**30.0/86.0**	**42.0/107.6**

ST	**-0.4**	**0.4**
PVC	**0**	**20**
T2 C/℃ F	**30.0/86.0**	**42.0/107.6**
IBP1-S(ART)	**80**	**200**
IBP1-M(ART)	**40**	**140**
IBP1-D(ART)	**20**	**120**
IBP2-S(CVP)	**0**	**300**
IBP2-M(CVP)	**3**	**15**
IBP2-D(CVP)	**0**	**300**
IBP3-S(PAP)	**20**	**50**
IBP3-M(PAP)	**10**	**40**
IBP3-D(PAP)	**5**	**30**
IBP4-S(LAP)	**0**	**300**
IBP4-M(LAP)	**0**	**300**
IBP4-D(LAP)	**3**	**15**
IBP1/2/3/4-PR	**50**	**150**
AWRR	**10**	**30**
EtCO2	**25**	**50**
FiCO2	**0**	**5**
APNEA	**0**	**20**
AG-E	**0.0**	**20.0**
AG-I	**0.0**	**20.0**
AG2-E	**0.0**	**20.0**
AG2-I	**0.0**	**20.0**
N2O-E	**0**	**100**
N2O-I	**0**	**82**
O2-E	**18**	**100**
O2-I	**18**	**100**
CSI	**35**	**100**
BS%	**35**	**100**
SQI	**35**	**100**
BTemp	**30.0**	**42.0**
C.O.	**1.50**	**5.00**

Display

Patient Age	**Adult**
Primary ECG	**II**
Arrhythmia	**LETHAL**
Detect Pace	**Off**
Print Waveform1	**LEAD II**
Print Waveform2	**SpO2**
Print Waveform3	**Resp**
Alarm Print	**Off**
NIBP Interval	**Off**
NIBP Cuff Size	**Adult**
RR(RESP) Lead	**II**
Alarm Volume	**Off**
QRS Volume	**Off**
Pulse Volume	**Off**
ECG Lead Fault	**Message**
SpO_2 Check Probe	**Low Alarm**
Units for Height	**cm**
Units for Weight	**kg**
Temperature Units	**°C**
NIBP Limit Type	**Systolic**
ECG Filter	**Monitor**
PVC	**ON**
ST	**ON**

17.2 Neonate-ICU Mode

Alarm level

	High	Medium	Low	Message
Asystole	0			
VTAC/VFIB	0			
VTAC	0			
SHORT RUN	0			
ACC VENT	0			
BIGEMINY	0			
COUPLET	0			
IRREGULAR	0			
PAUSE	0			
R ON T	0			
TRIGEMINY	0			
V BRADY	0			
PVC			0	
ST			0	
HR		0		
NIBP - S		0		
NIBP - M		0		
NIBP - D		0		
SpO_2			0	
SpO_2-Rate				0
RR				0
RR-Apnea				0
T1(℃)				0
T2℃)				0
IBP1(S/M/D)			0	
IBP2(S/M/D)			0	
IBP3(S/M/D)			0	
IBP4(S/M/D)			0	
EtCO2			0	
FiCO2				0
AWRR			0	

APNEA				**0**
AG-E		**0**		
AG-I		**0**		
AG2-E		**0**		
AG2-I		**0**		
N2O-E			**0**	
N2O-I			**0**	
O2-E			**0**	
O2-I	**0**			
CSI			**0**	
BS%			**0**	
SQI			**0**	
BTemp			**0**	
C.O.			**0**	
LEAD FAULT				**0**
CABLE OFF				**0**
LOW BATTERY				**0**

Parameter Limits

	Low	High
HR	**50**	**170**
NIBP-S	**40**	**100**
NIBP-M	**30**	**70**
NIBP-D	**20**	**60**
SpO_2	**88**	**100**
SpO_2-Rate	**50**	**170**
RR(RESP)	**15**	**100**
RR-Apnea	**0**	**15**
T1 ℃/℉	**30.0/86.0**	**42.0/107.6**
ST	**-0.4**	**0.4**
PVC	**0**	**20**
T2 C/℉	**30.0/86.0**	**42.0/107.6**

IBP1-S(ART)	**40**	**100**
IBP1-M(ART)	**30**	**70**
IBP1-D(ART)	**20**	**60**
IBP2-S(CVP)	**0**	**300**
IBP2-M(CVP)	**3**	**15**
IBP2-D(CVP)	**0**	**300**
IBP3-S(PAP)	**40**	**100**
IBP3-M(PAP)	**30**	**70**
IBP3-D(PAP)	**20**	**50**
IBP4-S(LAP)	**0**	**300**
IBP4-M(LAP)	**0**	**300**
IBP4-D(LAP)	**3**	**15**
IBP1/2/3/4-PR	**50**	**170**
EtCO2	**25**	**50**
FiCO2	**0**	**5**
AWRR	**15**	**100**
APNEA	**0**	**20**
AG-E	**0.0**	**20.0**
AG-I	**0.0**	**20.0**
AG2-E	**0.0**	**20.0**
AG2-I	**0.0**	**20.0**
N2O-E	**0**	**100**
N2O-I	**0**	**82**
O2-E	**18**	**100**
O2-I	**18**	**100**
CSI	**35**	**100**
BS%	**35**	**100**
SQI	**35**	**100**
BTemp	**30.0**	**42.0**
C.O.	**1.50**	**5.00**

Display

Patient Age	**NEONATE**
Primary ECG	**II**
Arrhythmia	**LETHAL**
Detect Pace	**Off**
Print Waveform1	**LEAD II**
Print Waveform2	**SpO2**
Print Waveform3	**Resp**
Alarm Print	**Off**
NIBP Interval	**Off**
NIBP Cuff Size	**NEONATE**
RR(RESP) Lead	**II**
Alarm Volume	**Off**
QRS Volume	**Off**
Pulse Volume	**Off**
ECG Lead Fault	**Message**
SpO_2 CHECK Probe	**Low Alarm**
Units for Height	**cm**
Units for Weight	**kg**
Temperature Units	**°C**
NIBP Limit Type	**Systolic**
ECG Filter	**Monitor**
PVC	**ON**
ST	**ON**

17.3 Pediatric-ICU Mode

Alarm level

	High	Medium	Low	Message
Asystole	0			
VTAC/VFIB	0			
VTAC	0			
SHORT RUN	0			
ACC VENT	0			
BIGEMINY	0			
COUPLET	0			
IRREGULAR	0			
PAUSE	0			
R ON T	0			
TRIGEMINY	0			
V BRADY	0			
PVC			0	
ST			0	
HR		0		
NIBP - S		0		
NIBP - M		0		
NIBP - D		0		
SpO_2			0	
SpO_2-Rate				0
RR				0
RR-Apnea				0
T1(℃)				0
T2(℃)				0
IBP1(S/M/D)			0	
IBP2(S/M/D)			0	
IBP3(S/M/D)			0	
IBP4(S/M/D)			0	
EtCO2			0	
FiCO2				0
AWRR			0	

APNEA				**0**
AG-E		**0**		
AG-I		**0**		
AG2-E		**0**		
AG2-I		**0**		
N2O-E			**0**	
N2O-I			**0**	
O2-E			**0**	
O2-I	**0**			
CSI			**0**	
BS%			**0**	
SQI			**0**	
BTemp			**0**	
C.O.			**0**	
LEAD FAULT				**0**
CABLE OFF				**0**
LOW BATTERY				**0**

Parameter Limits

	Low	High
HR	**50**	**160**
NIBP-S	**60**	**160**
NIBP-M	**40**	**120**
NIBP-D	**30**	**100**
SpO_2	**90**	**100**
SpO_2-Rate	**50**	**160**
RR(RESP)	**10**	**50**
RR-Apnea	**0**	**20**
T1 ℃/℉	**30.0/86.0**	**42.0/107.6**
ST	**-0.4**	**0.4**
PVC	**0**	**20**
T2 ℃ /℉	**30.0/86.0**	**42.0/107.6**

IBP1-S(ART)	**60**	**140**
IBP1-M(ART)	**40**	**100**
IBP1-D(ART)	**30**	**90**
IBP2-S(CVP)	**0**	**300**
IBP2-M(CVP)	**3**	**15**
IBP2-D(CVP)	**0**	**300**
IBP3-S(PAP)	**20**	**50**
IBP3-M(PAP)	**10**	**40**
IBP3-D(PAP)	**5**	**30**
IBP4-S(LAP)	**0**	**300**
IBP4-M(LAP)	**0**	**300**
IBP4-D(LAP)	**3**	**15**
IBP1/2/34/-PR	**50**	**160**
AWRR	**10**	**50**
EtCO2	**25**	**50**
FiCO2	**0**	**5**

Display

Patient Age	**PEDIATRIC**
Primary ECG	**II**
Arrhythmia	**LETHAL**
Detect Pace	**Off**
Print Waveform1	**LEAD II**
Print Waveform2	**SpO2**
Print Waveform3	**Resp**
Alarm Print	**Off**
NIBP Interval	**Off**
NIBP Cuff Size	**PEDIATRIC**
RR(RESP) Lead	**II**
Alarm Volume	**Off**
QRS Volume	**Off**
Pulse Volume	**Off**

ECG Lead Fault	Message
SpO_2 Probe Off	Low Alarm
Units for Height	cm
Units for Weight	kg
Temperature Units	℃ C
NIBP Limit Type	Systolic
ECG Filter	Monitor
PVC	ON
ST	ON

18. MAINTENANCE and TROUBLE SHOOTING

18.1 Inspection Equipment

You should perform a visual inspection before every use, and in accordance with your hospital's policy. With the monitor switched off:

- Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids and that there are no signs of abuse.
- If the EtCO2 and Multi-gas module are mounted on the monitor, make sure that they are locked into place and do not slide out without releasing the locking mechanism.
- Inspect all accessories (cables, transducers, sensors and so forth). If any show signs of damage, do not use.
- Switch the monitor on and make sure the backlight is bright enough. Check that screen is at its full brightness. If the brightness is not adequate, contact your service personnel or your supplier

18.2 Inspection Cables

- Examine all system cables, the power plug for damage. Make sure that the prongs of the plug do not move in the adaptor. If damaged, replace it with an appropriate Bionet power cord and adaptor.
- Inspect the parameter cable and ensure that it makes good connection with the Monitor. Make sure that there are no breaks in the insulation.
- Apply the transducer or electrodes to the patient, and with the monitor switched on, flex the
  patient cables near each end to make sure that there are no intermittent faults.

WARNING
To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the monitor appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

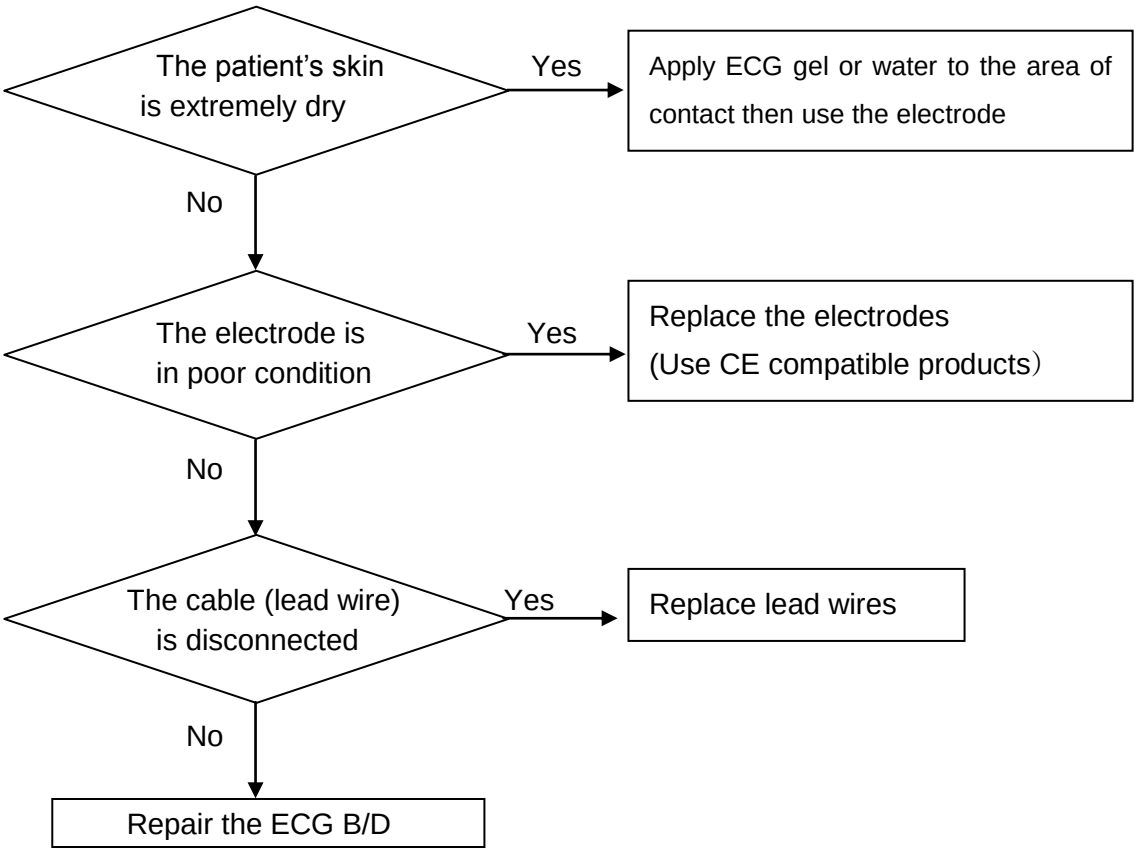
18.3 Maintenance Task and Test Schedule

All maintenance tasks and performance tests are documented in detail in the service documentation

Maintenance and Test Schedule	Frequency
Monitor Tests	
Safety checks. Selected tests on the basis of IEC 60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped
Monitor Maintenance	
Check ECG synchronization of the monitor and defibrillator (only if hospital protocol requires use of monitor during defibrillation)	At least once every two years, or as needed.
Replace backlight (integrated displays only)	35,000 - 40,000 hours (about four years) of continuous usage, or as needed.
Parameter Module Tests	
Performance assurance for all measurements not listed below.	At least once every two years, or if you suspect the measurement values are incorrect.
Parameter Module Maintenance	
NBP calibration	At least once every two years, or as specified by local laws.
Mainstream and sidestream CO_2 calibration check	At least once a year, or if you suspect the measurement values are incorrect.
Battery Maintenance	
Battery	See the section on Maintaining Batteries in chapter 1.

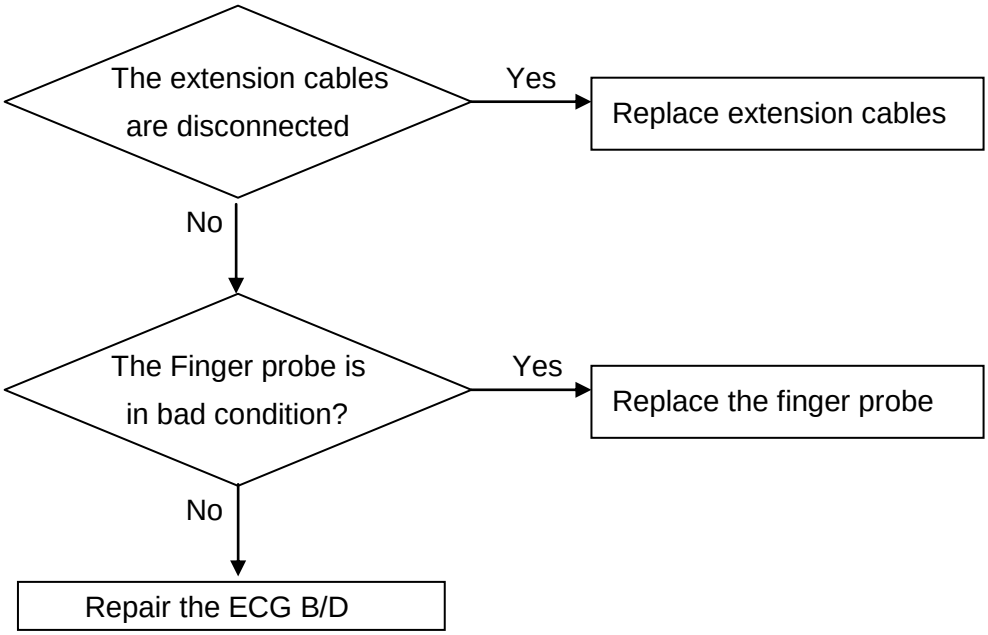
18.4 Noise in ECG

- Gel is dry
- Electrodes does not stick well to skin

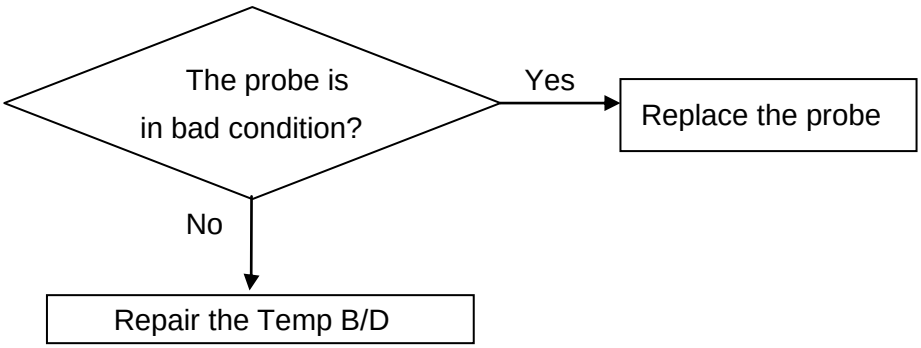


18.5 SpO_2 malfunction

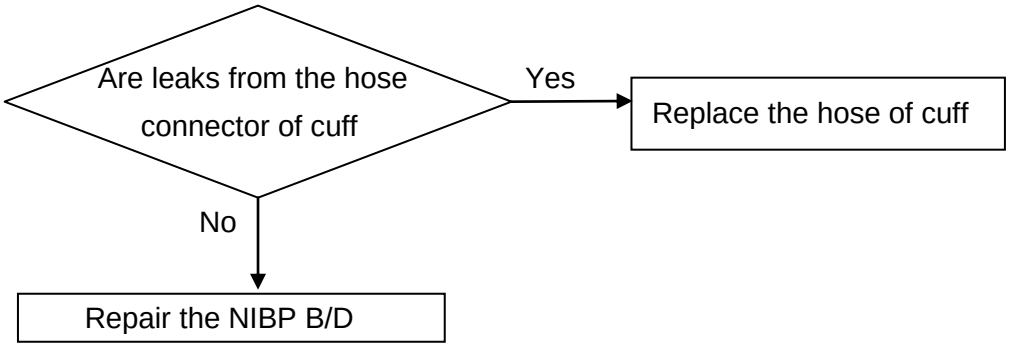
Connectors of the equipments are in bad condition?



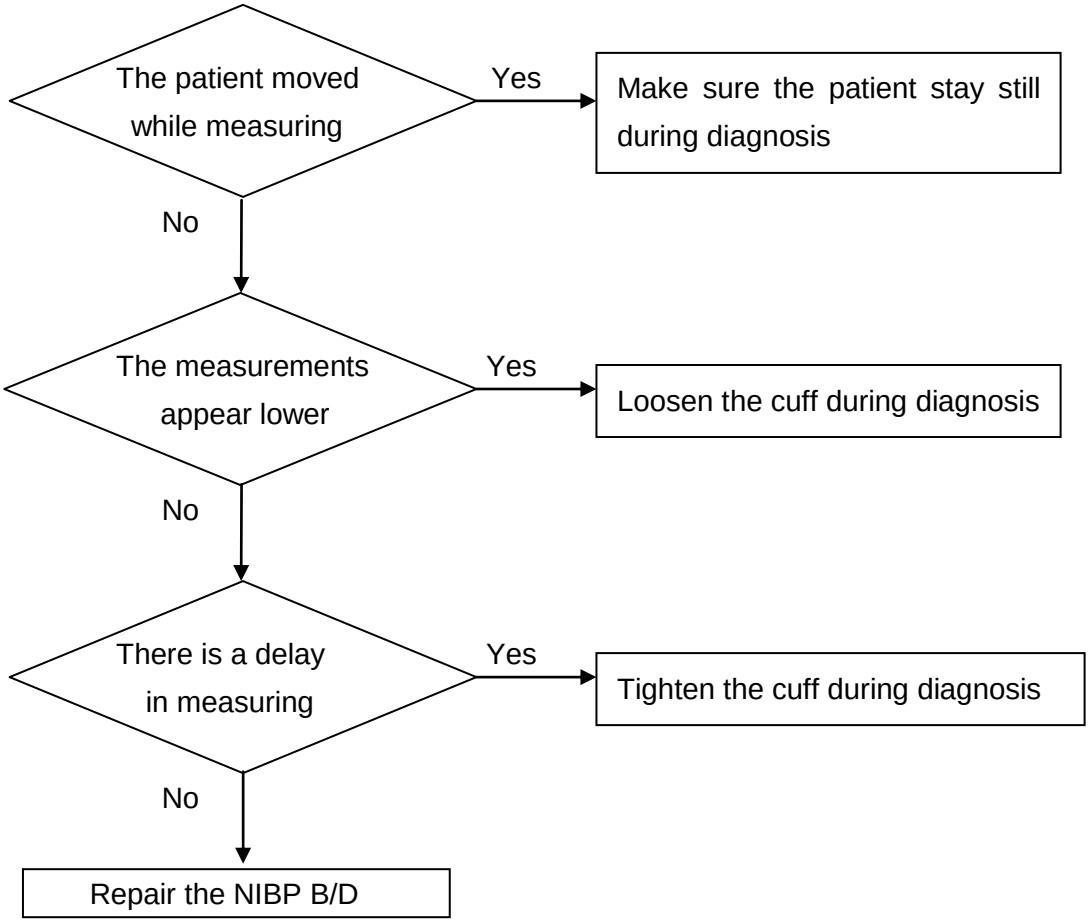
18.6 Temp malfunction



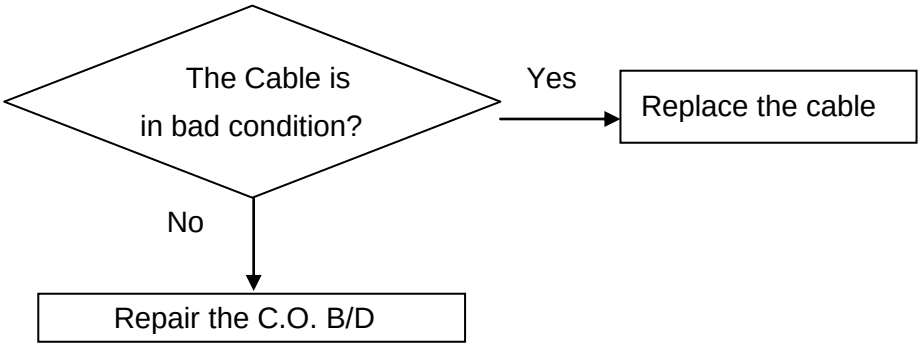
18.7 NIBP malfunction



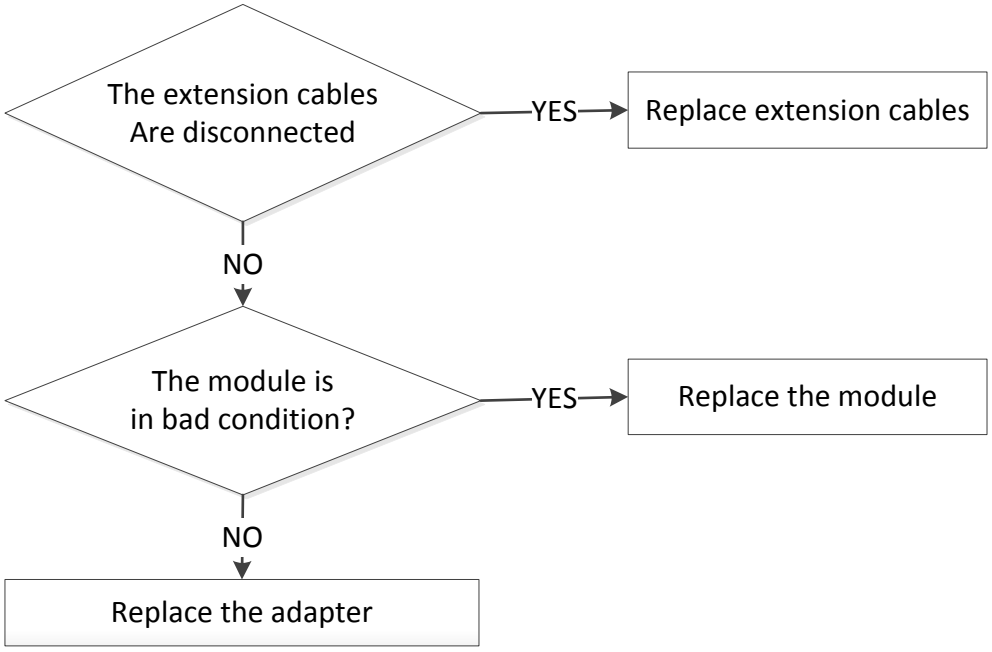
18.8 Abnormality in NIBP measurements



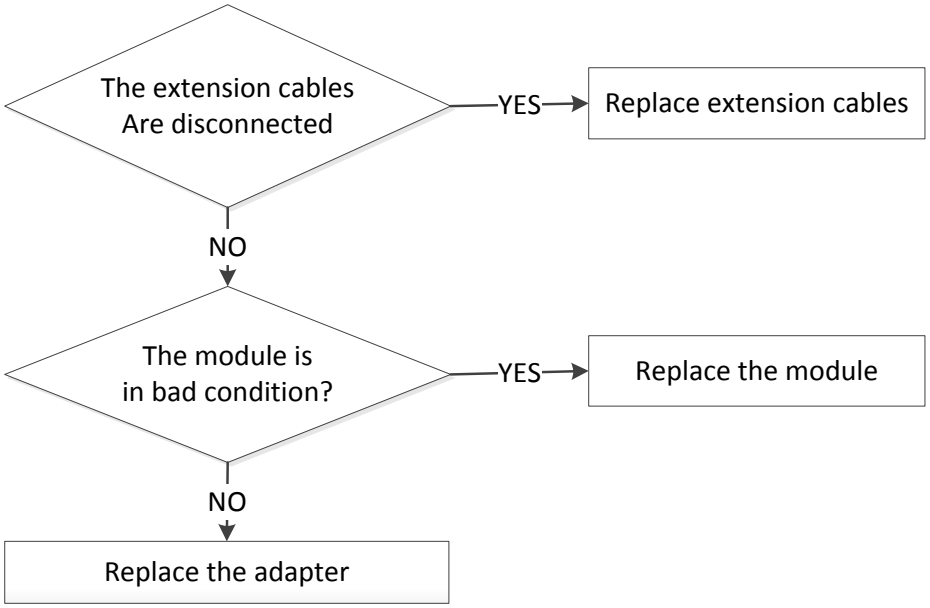
18.9 Cardiac Output malfunction



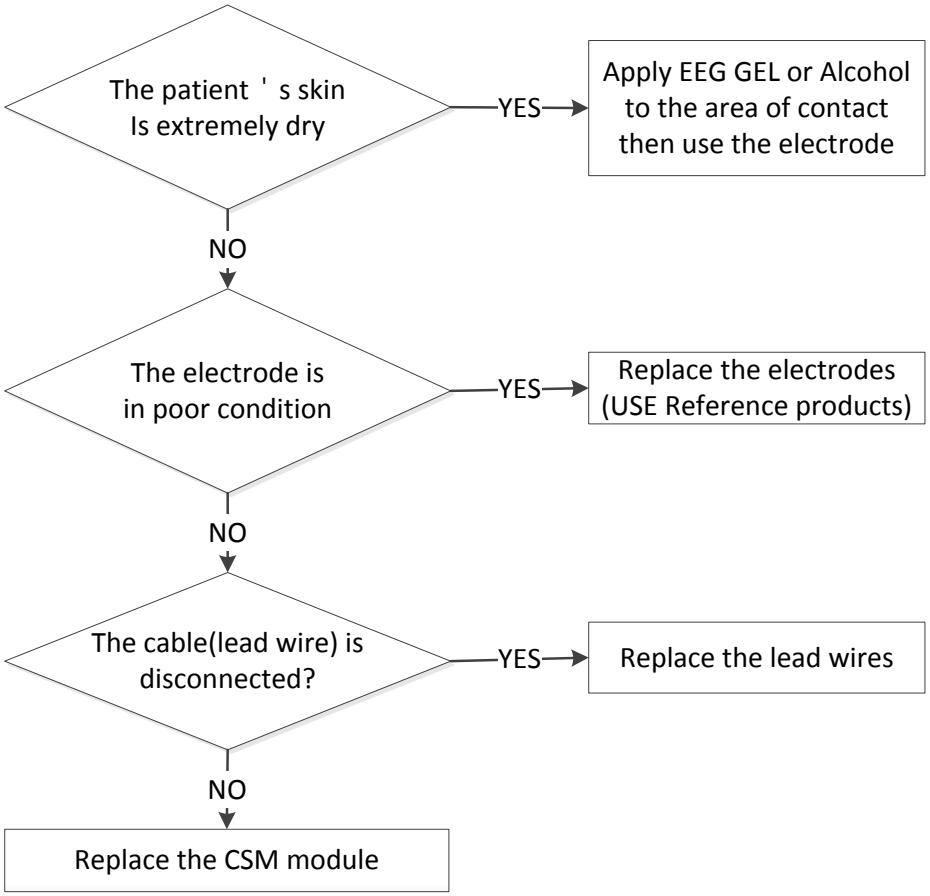
18.11 Multi-gas malfunction



18.12 EtCO2 malfunction

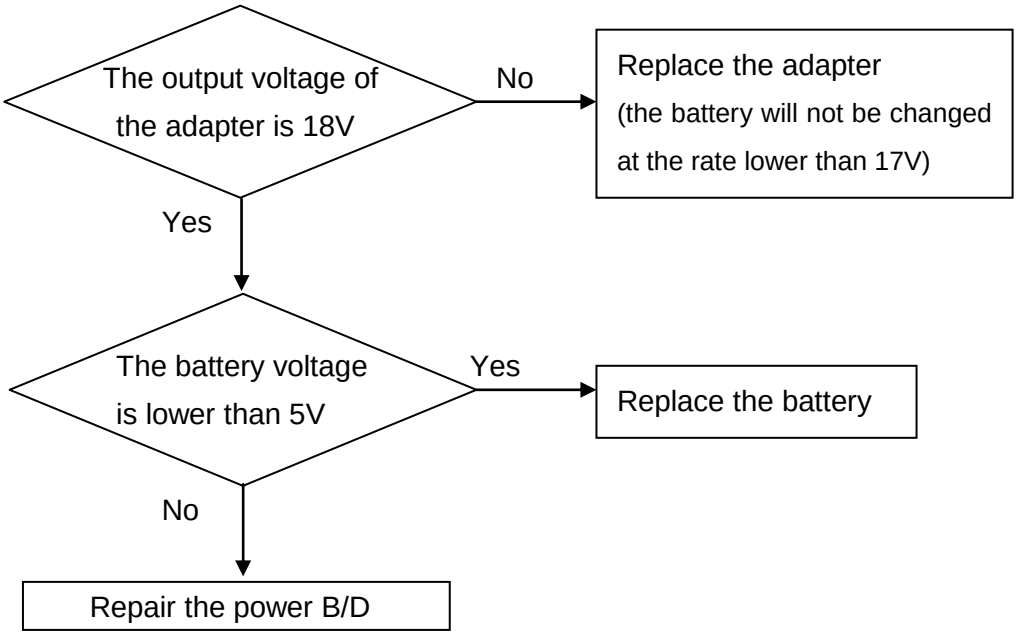


18.13 CSM malfunction

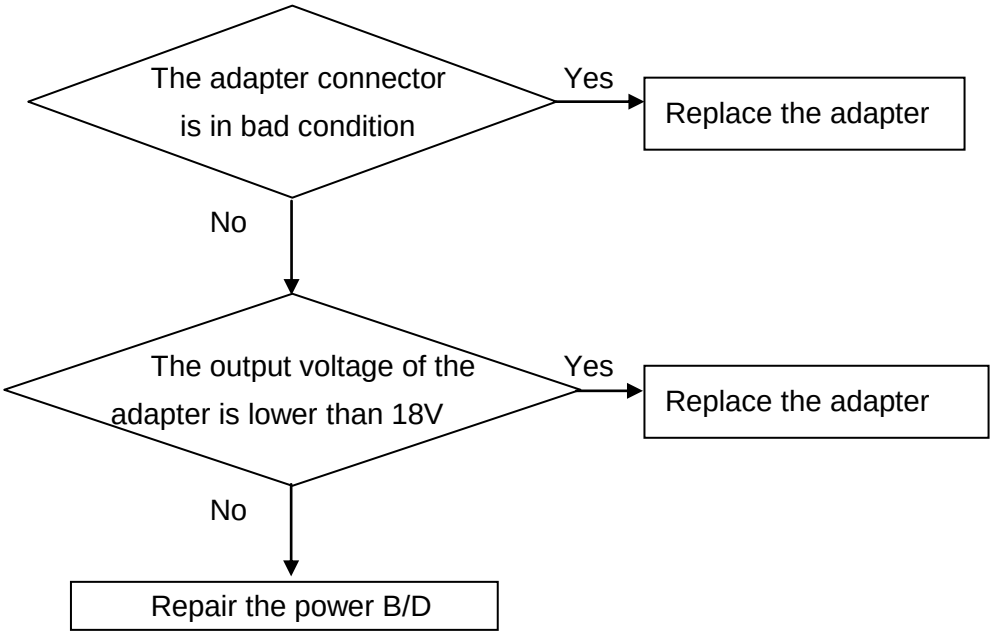


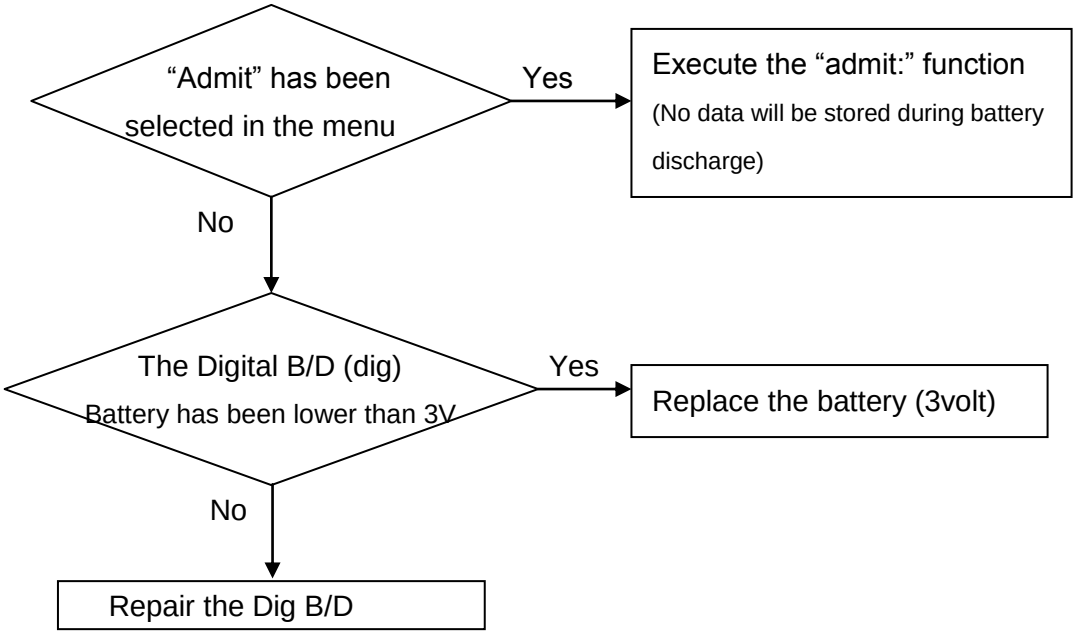
18.14 Failure in battery recharge

(the battery does not fully recharge in 6 hours or more)

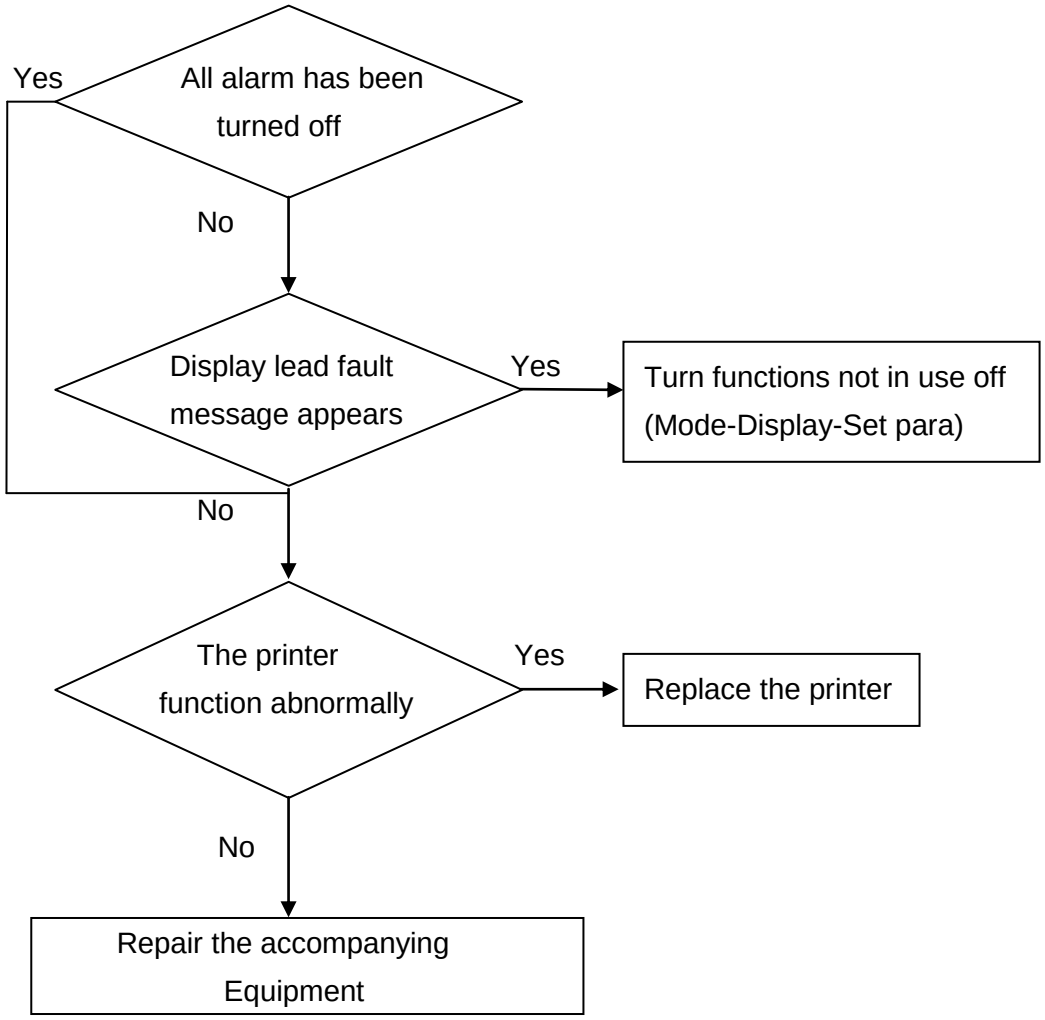


18.15 Power failure

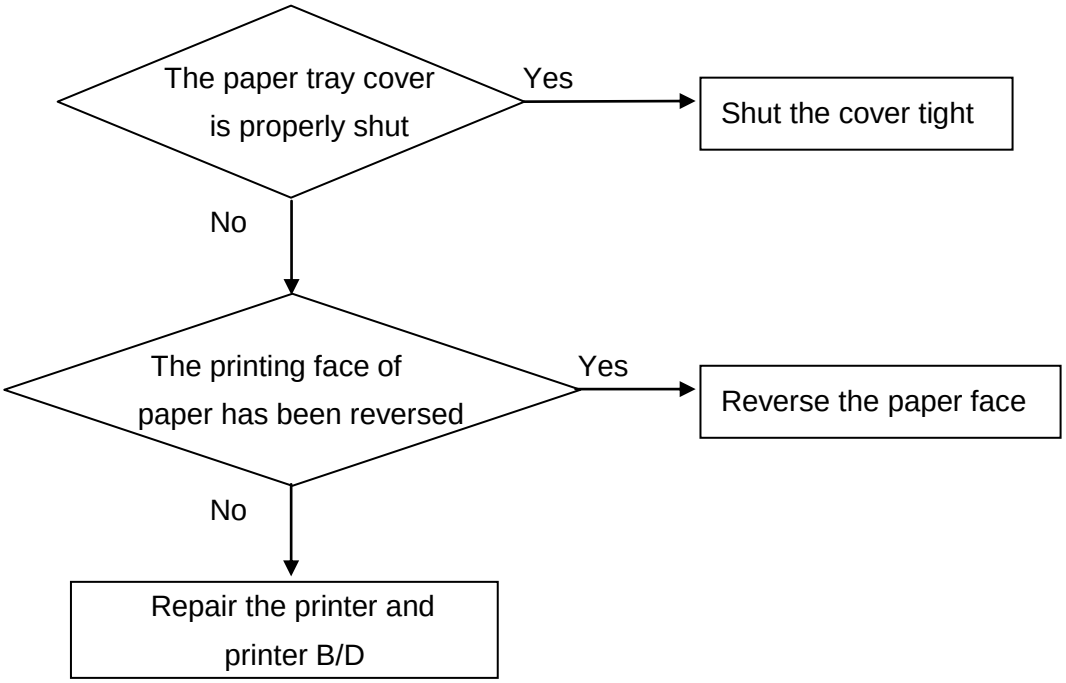




18.16 Periodic noises



18.17 Print failure



19. SPECIFICATION

Ease of use

Customization

Special Features

Monitor Environmental Specifications

Power adaptor

Monitor Performance Specifications

Graphical and Tabular Trends

SpO2 Performance Specifications

Respirations Performance Specifications

NIBP Performance Specifications

ECG Performance Specifications

Temperature Unit Performance Specifications

Accessories included

OPTION

Intended Use

The monitor is not user installable. It must be installed by qualified service personnel.

The monitor is intended to be used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities. The device is to be used by trained health care professionals.

The monitor is intended for use in health care facilities; the BM7 Monitor is additionally intended for use in transport situations within the hospital setting.

The monitor is only for use on one patient at time. It is not intended for home use.

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes.

The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates.

The monitors are intended for use by trained healthcare professionals in a hospital environment.

The BM7 monitors are additionally intended for use in transport situations within hospital environments.

The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices.

The monitors are for prescription use only.

The BM7 Patient Monior is not intended for use during MRI.

The BM7 Patient Monior monitors and displays ECG (including arrhythmia and ST segment analysis), heart/pulse rate, oscillometric non-invasive blood pressure(systolic, diastolic and mean arterial pressure), invasive blood pressure, end-tidal carbon dioxide, respiration rate, temperature with a electronic thermometer for continual monitoring Esophageal/Nasopharyngeal/Tympanic/Rectal/Bladder/Axillary/Skin/Airway/Room/Myocardial/Core/ Surface temperature, and functional oxygen saturation (SpO2) and pulse rate via continuous monitoring, including monitoring during conditions of clinical patient motion or low perfusion.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes.

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

The gas measurement is restricted to neonatal patients only.

CSM is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use.

It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The CSM may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of CSM monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Indication for Use

The monitor is indicated for use by health care professionals whenever they need monitoring the physiological parameters of patients.

Monitoring, recording and/or alarming of patients including with arrhythmias in ICU, OR, Post-OP and others. The target populations are adult, pediatric and neonate with the exception of:

- Arrhythmia detection and ST segment analysis, for which the target populations are adult and pediatric only.
- Drug Calculations for which the target population is adult only, and Cardiac Output for which the target population is adult only.

Operator Position

The operator of the device should be positioned in front of the BM7 display at a distance of no more than 1 meter.

Ease of use

- Battery operation
- Attached printer
- Table and graphic trend

Additional Function

- LAN Connection

Monitor Environmental Specifications

- Operating Temperature： 15°C to 40°C (59°F to 104°F)
- Storage Temperature： - 10°C to 60°C (14°F to 140°F)
- Humidity： 20% to 95% RH
- Operating Attitude： 70(700) to 106Kpa(1060mbar)

Power

- AC 100-240V (50/60Hz)
- Adapter 18 V, 2.8 A

Specification

Display, Resolution	**12.1" color TFT, 800 x 600 pixels**
Dimension, Weight	322(W) x 257.4(H) x 224.8(D) mm, Approx. 4.7kg
Parameter	ECG, Heart Rate, Respiration Rate, SpO2, Pulse Rate, Systolic BP, Diastolic BP, Mean BP, **2 x Temperature, 4 x IBP, EtCO2, FiCO2, Airway Respiration Rate, AG-Ex, AG-Ins, AG2-Ex, AG2-Ins, N2O-Ex, N2O-Ins, O2-Ex, O2-Ins, CSI, BS%, C.O, BTemp**
Trace	**8 waveforms : 2*ECG, SpO2, RR or EtCO2(MultiGas), 4*IBP** Sweep speed : 6.25, 12.5, 25, 50 mm/sec
Indicators	Categorized alarms (3 priority levels), Visual alarm lamp handle QRS beep & SpO2 pulse beep, Percent(%) SpO2 pitch tone Battery status, External power LED, Touch screen, Rotary knob
Interfaces	DC input connector : 18VDC, 2.8A Defibrillator Sync. Output : - Signal Level : 0 to 5V pulse LAN digital output for transferring data, Nurse call system connection -0.3A at 125VAC – 1A at 24VDC DC output : 5VDC, 0.9A Max USB Barcode Scanner, USB & SD memory data storage
Battery	Rechargeable Li-ion battery, 2hours for continuous working
Thermal Printer (option)	Speed : 25, 50mm/sec, Paper width : 58mm
Data Storage	168hours trends, 20cases of 10sec alarm waveform
Language	English, French, Spanish, Italian, Germany, Chinese, Russian, Czech, Bulgarian, Portuguese, Romanian, Hungarian, Turkish, Polish, Korean
ECG Performance	
Lead type	3-lead, 5-lead, 10-lead(option)
Lead Selection	3-lead : I, II, III 5-lead : I, II, III, aVR, aVL, aVF, V 10-lead: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
ECG waveforms	3-lead : 1 channel 5-lead : 2/7 channels 10-lead: 1/2/7/12 channels
Heart Rate Range	Adult : 30 ~ 300 bpm Neonate/Pediatric : 30 ~ 350 bpm
Heart Rate Accuracy	±1bpm or ±1%, whichever is greater
Sweep speed	6.25, 12.5, 25, 50 mm/sec
Filter	-Diagnosis : 0.05Hz ~ 150Hz -Monitoring : 0.5 ~ 40 Hz -Moderate: 0.5 ~ 25Hz -Maximum : 5 ~ 25 Hz
S-T segment detection range	-2.0 to 2.0 mV
Arrhythmia analysis	ASYSTOLE,VTACH,VFIB,BIGEMINY,ACCVENT, COUPLET,IRREGULAR, PAUSE,PVC,RONT,TRIGEMINY,VBRADY, SHORTRUN
Pacemaker Detection Mode	Indicator on waveform display (user selectable)
Protection	Against electrosurgical interference and defibrillation
Differential Input	>5 MΩ at all other leads

Impedance	
Common Mode Rejection Ratio	>86 dB at 50 or 60Hz
Input Dynamic Range	±5 mVac , ±300 mVdc
Respiration Performance	
Method	Thoracic impedance
Channel selection	RA-LA or RA-LL
Measurement range	5 – 120 Breath per minute
Accuracy	±1 Breath per minute
Apnea alarm	Yes
SpO2 Performance	
Saturation range	0 to 100%
Saturation accuracy	70 to 100% ±2 digits 0 to 69% unspecified
Pulse rate range	30 to 254 bpm
Pulse rate accuracy	±2 bpm
NIBP Performance	
Method	Oscillometry with linear deflation
Operation Mode	Manual/Automatic/Continuous
Measurement range	**Systolic:** ADULT 40 – 260mmHg PEDIATRIC 40 – 230mmHg NEONATE 40 – 130mmHg **MAP(Mean Aterial Pressure):** ADULT 26 – 220mmHg PEDIATRIC 26 – 183mmHg NEONATE 26 – 110mmHg **Diastolic:** ADULT 20 – 200mmHg PEDIATRIC 20 – 160mmHg NEONATE 20 – 100mmHg **Pulse Rate:** ADULT 30 – 220BPM PEDIATRIC 30 – 220BPM NEONATE 30 – 220BPM
Accuracy	Meets accuracy requirements of ANSI/AAMI SP10:1992 and 2002
Temperature Performance	
Measurement range	15 to 45℃ (59 to 113˚F)
Accuracy	±1℃
Compatibility	YSI Series 400 temperature probes
IBP Performance (Option)	

Channels	4
Measurement range	-50 to 300mmHg
Accuracy	<100mmHg : ±1mmHg >=100mmHg : ±1% of reading
Pulse rate measurement range	0 to 300bpm
Zero balancing	Range : ±200mmHg Accuracy : ±1mmHg Drift : ±1mmHg over 24hours
Transducer sensitivity	5μV/mmHg
Pulse rate measurement range	0 to 300bpm
Sidestream CO2 (Option)	
Measurement range	0 to 150 mmHg, 0 to 19%
Accuracy	0-40mmHg ±2 mmHg, 41-70mmHg ±5% of reading 71-100mmHg ±8% of reading, 101-150mmHg ±10% of reading
Respiration rate	2 to 150 breath per minute
Respiration accuracy	±1breath per minute
Mainstream CO2 (Option)	
Measurement range	0 to 150 mmHg, 0 to 19%
Accuracy	0-40mmHg ±2 mmHg, 41-70mmHg ±5% of reading 71-100mmHg ±8% of reading, 101-150mmHg ±10% of reading
Respiration rate	0 to 150 breath per minute
Respiration accuracy	±1breath per minute
Anesthetic GAS/O2 *- Phasein (Option)*	
Method	Infra-red absorption characteristic
Gas	CO2, O2, N2O, Des, Iso, Enf, Hal, Sev
Warm-up time	Main stream (IRMA AX+) Iso accuracy mode: 45s Full accuracy mode : 60s Side stream (ISA OR+/ AX+) : <20s
Sample flow rate (for ISA OR+/AX+)	50 ± 10 ml/min
Measuring Range	CO2 : 0 ~ 15 % N2O: 0 ~ 100% Hal/Iso/Enf: 0 ~ 8% Sev: 0~10% Des: 0 ~ 22% O2: 0 ~ 100%(ISA OR+/AX+)
Respiratory Rate	0 ~ 150bpm ± 1bpm

C.O. (Optional)	
Method	Thermodilution Technology
Measuring Range	C.O. : 0.1 ~ 20L/min TB : 23 ~ 45℃ TI : 0 ~ 27℃ Alarm range 23 ~ 45℃
CSM (Optional)	
EEG sensitivity	±400μV
Noise	< 2μVp-p, < 0.4μV RMS, 1–250 Hz
CMR	>140dB
Input impedance	>50MOhm
Sample rate	2000 samples/sec. (14 bits equivalent)
CSI and update	0-100. Filter 6-42 Hz, 1 sec. update
EMG	0-100 logarithmic. Filter 75-85 Hz, 1 sec. update
BS%	0-100%. Filter 2-42 Hz, 1 sec. update
Artifact rejection	Automatic
Sensor impedance range	0-10kOhm / measurement current 0.01μA

ECG supplemental Information as required by IEC 60601-2-27		
Respiration Excitation Waveform		Sinusoidal signal, 260 μA, 64.2 kHz
Time to Alarm for Tachycardia	Vent Tachycardia 1 mVpp,200 bpm	Gain 0.5, Range 6.8 to 8.9 seconds, Average 7.8 seconds
		Gain 1.0 Range 6.4 to 7.3 seconds, Average 6.8 seconds
		Gain 2.0, Range 6.1 to 6.9 seconds, Average 6.5 seconds
	Vent Tachycardia 2 mVpp,185 bpm	Gain 0.5, Range 5.8 to 6.6 seconds, Average 6.2 seconds
		Gain 1.0, Range 6.0 to 6.8 seconds, Average 6.4 seconds
		Gain 2.0, Range 5.7 to 6.4 seconds, Average 6.0 seconds
Tall T-Wave Rejection Capability		Minimum recommended 1.2 mV T-Wave amplitude
Heart Rate Averaging Method		Normally, heart rate is computed by averaging the 8 most recent RR intervals. For runs of PVCs, up to 8 RR intervals are averaged to compute the HR. If each of 3 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.
Response Time of Heart Rate to Change in Heart Rate		HR change from 80 to 120 bpm: Range: [6.4 to 7.2 seconds] Average: 6.8 seconds HR change from 80 to 40 bpm: Range: [5.6 to 6.4 sec] Average: 6.0 seconds
Heart Rate Accuracy and Response to Irregular Rhythm		Ventricular bigeminy: 80 bpm Slow alternating ventricular bigeminy: 60 bpm Rapid alternating ventricular bigeminy: 120 bpm Bidirectional systoles: 90 bpm

Pacemaker Pulse Rejection Performance	Rejection of pacemaker pulses with amplitudes from ±2mV to ±700mV and widths from 0.1 ms to 2.0ms

ECG Sync Output		
General	Connector	PS2 with ring
	Isolation	Functional isolation
Digital Pulse Output	Output low voltage level	<0.4 V @ I=-1 mA
	Output high voltage level	>2.4 V @ I=1 mA
	Pulse Width	100 ms±10 ms (active high)
	Pulse Rise Time	<1 ms (from 0.4 V to 2.4 V)
	Signal delay	< 35ms per 60601-2-27

Accessories Included:

1. Main body of BM7 Monitor	1 EA
2. 5-Lead Patient Cable (MECA5-US, MECA5-EU)	1 EA
3. Disposable electrodes	10 EA
4. NIBP extension horse	1 EA
5. Reusable Adult NIBP cuff	1 EA
6. SpO_2 extension cable	1 EA
7. Reusable Adult SpO_2 probe	1 EA
8. DC Power Adaptor with Power Cord (18VDC/2.8A, BPM050S18F02)	1 EA
9. Operator's Manual	1 EA
10. Thermal roll Paper	2 Roll

Option

1. Reusable Temperature Probe (Surface/Skin, TEMPSENS-430)	1 EA
2. IBP Transducer Set (Disposable/Reusable)	1 SET
3. Sidestream EtCO2 Module (Respironics)	1 SET
4. Mainstream EtCO2 Module (Respironics)	1 SET
5. Sidestream EtCO2 airway adapter sampling kit	1 EA
6. Mainstream EtCO2 airway adapter	1 EA
7. 3-Lead Patient Cable (MECA3-US, MECA3-EU)	1 EA
8. 10-Lead Patient Cable (MECA10-US, MECA10-EU)	1 EA
9. Sidestream Multigas Module (Masimo Sweden)	1 EA
10. Mainstream Multigas Module (Masimo Sweden)	1 EA
11. Sidestream Multigas Nomoline	1 EA
12. Sidestream Multigas Nomoline adapter	1 EA
13. Sidestream Multigas Nomo Extension	1 EA
14. Sidestream Multigas T-adapter	1 EA
15. Mainstream Multi-gas IRMA Airway Adapter (Adult/ Pediatric)	1 EA
16. Mainstream Multi-gas IRMA Airway Adapter (Infant)	1 EA
17. CSM 3lead electrode cable	1 EA
18. CSM Procedure pack (electrode for CSM)	1 EA
19. Swan-Ganz Thermodilution Catheter kit	1 EA
20. AVA introducer catheter	1 EA
21. Interface Cable (PAT-ICO-CABLE)	1 EA
22. Bath Temperature Probe	1 EA

Abbreviations and Symbols

Abbreviations and symbols which you may encounter while reading this manual or using the monitor are listed below with their meanings.

Abbreviations

	A
A	amps
AC	alternating current
ADT	adult
ARRYTHM	arrhythmia
ASYS	asystole
Auto, AUTO	automatic
AUX	Auxiliary
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
	B
BPM	beats per minute
	C
C	Celsius
CAL	calibration
cm, CM	centimeter
	D
D	diastolic
DC	direct current
DEFIB, Defib	defibrillator
DIA	diastolic
	E
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
ESU	electrosurgical cautery unit
	F
F	Fahrenheit
	G
g	gram
	H
HR	heart rate, hour
Hz	hertz
	I
ICU	intensive care unit
IBP	invasive blood pressure
Inc	incorporated

K

kg, KG	kilogram
kPa	kilopascal

L

L	liter, left
LA	left arm, left atrial
LBS	pounds
LCD	liquid crystal display
LED	light emitting diode
LL	left leg

M

M mean,	minute
m	meter
ME	Medical Device
MIN,	min minute
MM, mm	millimeters
MM/S	millimeters per second
MMHG, mmHg	millimeters of mercury
mV	millivolt

N

NIBP	noninvasive blood pressure
NEO, Neo	neonatal

O

OR	operating room

P

PED	pediatric
PVC	premature ventricular complex

Q

QRS	interval of ventricular depolarization

R

RA	right arm, right atrial
RESP	respiration
RL	right leg
RR	respiration rate

S

S	systolic
sec	second
SpO2	arterial oxygen saturation from pulse oximetry
SYNC, Sync	synchronization
SYS	systolic

T

Temp, TEMP	temperature

U

V

V	precordial lead
V	volt

V-Fib, VFIB	ventricular fibrillation
VTAC	ventricular tachycardia

W

X

X	multiplier when used with a number (2X)

Symbols

&	and
°	degree(s)
>	greater than
<	less than
–	minus
#	number
%	percent
±	plus or minus

PRODUCT WARRANTY

Product Name	**Patient Monitor**
Model Name	**BM7**
Approval Number	
Approval Date	
Serial Number	
Warranty Period	**1 year from date of purchase (2 years in Europe)**
Date of Purchase	
Customer Section	**Hospital Name :** **Address :** **Name :** **Phone :**
Sales Agency	
Manufacturer	

* Thank you for purchasing BM7
* The product is manufactured and passed through strict quality control and through inspection.
* Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's Protection Law" noticed by Korea Fair Trade Commission.

International Sales & service

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