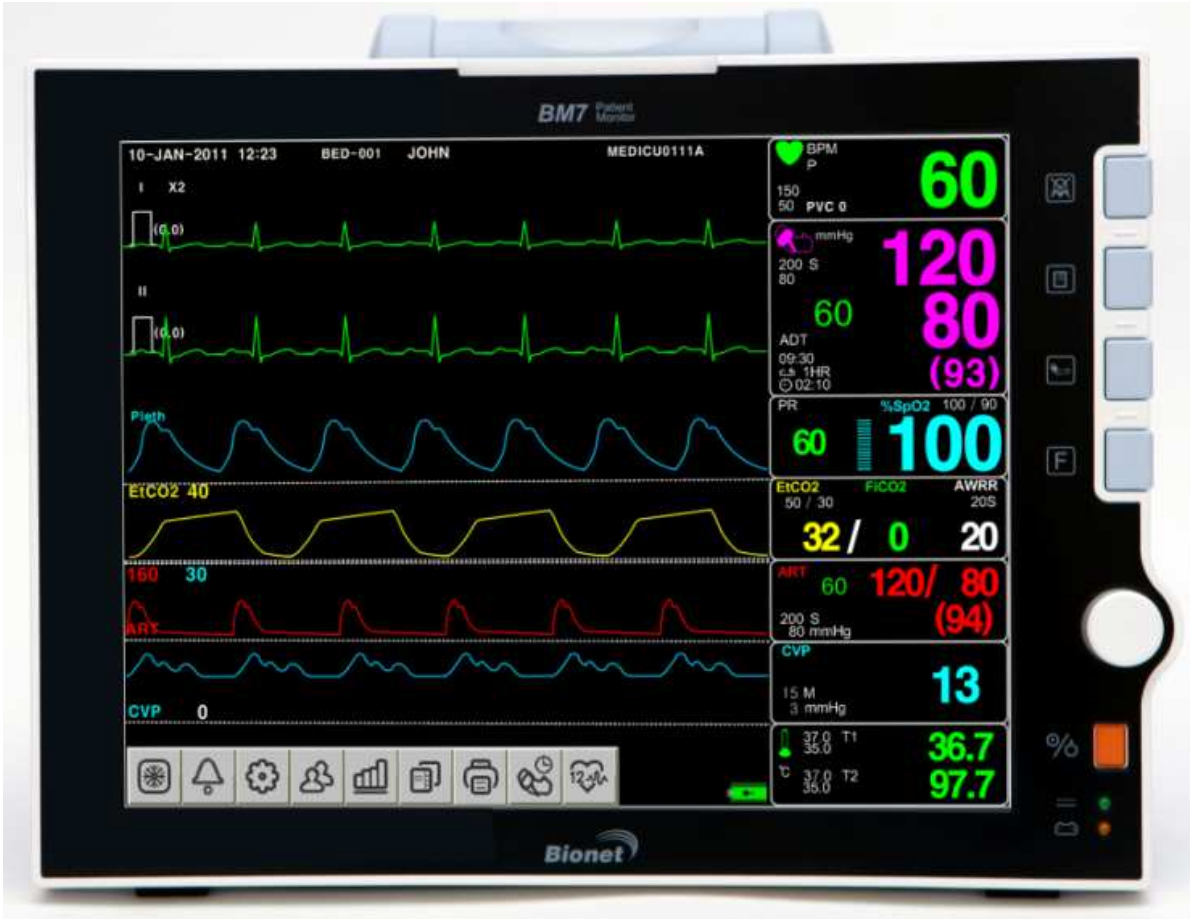
BM7 User's Manual

Patient Monitor

Rev. 1.1



Bionet

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1. BASIC

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1.2 Read before Use

Warranty Period

Warning, Caution, Note

General Precaution on Environment

General Precaution on Electric Safety

Equipment Connection, Maintenance & Washing Equipment Connection

1.3 Product Components

Product Outline

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Product Configuration and Option Product

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1.4 Function and Key

External Function

Operation Key

1.5 Standard Power Supply Application

1.6 Battery Power Supply Application

1.7 General Menu Operation

Screen Composition

Menu Selection

Menu Composition

1.1 CE Standard Information

Electromechanical safety standards met:

Information supplied by the manufacturer of medical devices

1. **EN 60601-1:1990+A1:1993+A2:1995+A13:1996 (IEC 60601-1:1988+A1:1991+A2:1995)**

   Medical electrical equipment Part1: General requirements for safety

2. **EN 60601-1-2:2001 + A1:2006 (IEC 60601-1-2:2001+A1:2004)**

   Electromagnetic Compatibility Requirement and tests

3. **EN 55011:2007+A2:2007 Group 1 Class B(CISPR11)**

   Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment

4. **IEC 60601-1-4:1996+A1:1999**

   Part 1-4 General requirements for safety Collateral standard: Programmable electrical medical system

5. **IEC 60601-1-6:2006**

   Part 1-6 General requirements for safety Collateral standard: Usability

6. **IEC 60601-1-8:2006**

   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

7. **EN 60601-2-30:2000 (IEC 60601-2-30:1999)**

   Part 2: Particular requirements for the safety, including essential performance of automatic cycling non-invasive blood pressure monitoring equipment

8. **EN 60601-2-49:2001 (IEC 60601-2-49:2001)**

   Part 2: Particular requirements for the safety of multifunction patient monitoring equipment.

9. **EN 12470-4:2000+A1:2009** : Performance test for Temperature

   Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement

10. **EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009**: Performance test for NIBP

Non-invasive sphygmomanometers- Part 1: General requirements, Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

11. **EN ISO 14971:2009**

    Medical devices - Application of risk management to medical devices

12. **EN ISO 9919:2009**

    Particular requirements for the basic safety and essential performance of pulse oximeter equipments for medical use.

13. **EN ISO 21647:2009** : EtCO2 test

    Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors

14. **EN 980:2008**

    Symbols for use in the labeling of medical devices

15. **EN 1041:2008**

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 152-050) 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 Economic Planning Dept.

- Warranty period is 1 year.(Two year 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.

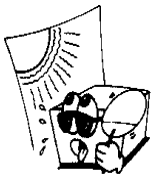
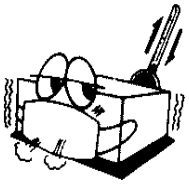
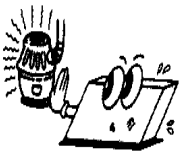
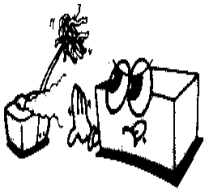
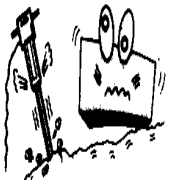
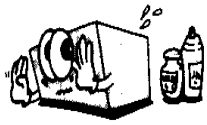
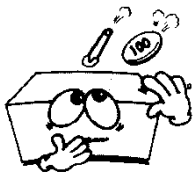
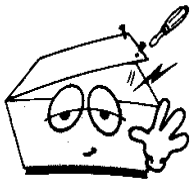
Warning
To inform that it may cause serious injury or death to the patient, property damage, material losses against the "warning" sign

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

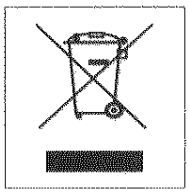
Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and lead wires.

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,2.5A,MW160 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.

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 BM7 system is intended for use in the electromagnetic environment specified below. The customer or the user of BM7 system should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BM7 system uses RF energy only for its internal function. Therefore. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The BM7 system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supplies buildings used for domestic purposes.
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	

Manufacturer's declaration - electromagnetic immunity

The **BM7** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **BM7** system 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	2kV for power supply lines 1kV for input/output lines	2kV for power supply lines 1kV 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 **BM7** system requires continued operation during power mains interruptions, it is recommended that the BM7 system 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 **BM7** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **BM7** system 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 BM7 system, 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** $d = [\frac{3,5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E1}]\sqrt{P}$ 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) telephone s 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 tra nsmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT sho uld be observed to verifynormal operation. If abnormal performance is observed, additional measure s 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 BM7 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 di stance (d) in meters (m) can be estimated using the equation applicable to the frequency of the tra nsmitter, where P is the maximum output power rating of the transmitter in watts (W) according to t he transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Immunity and Compliance Level

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

Guidance and manufacturer's declaration - electromagnetic immunity

The **BM7** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **BM7** system 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	**BM7** system 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 lo cation be verified to assure that they meet the minimum specification.
a- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephon es and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot b e 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 out side 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 th e EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

Note
For Type A Professional ME Equipment intended for use in domestic establishment instructions for use includes a warning: This ME equipment is intended for use by professional healthcare personnel only.

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;1996.

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 Leadwires

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

Cables and leadwires 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 leadwire.

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 leadwire.

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, EtCO2 and temperature on its LCD screen and monitoring parameter, and alarming. It also prints out waves and parameters via a printer.

Principal Characters of Product

BM7 is a small-size multifunctional monitoring equipment for a patient designed to an easy usage

during movement. It features devices for auto power supply (DC 12V-16V) and DC power supply (Bridgepower,MW160,DC 18V,2.5A) 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, EtCO2, 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.

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 ECG Cable	1EA
3. Disposable electrodes	10 EA
4. NIBP extension tube	1EA
5. Reusable Adult NIBP Cuff	1EA
6. SpO2 sensor extension cable	1EA
7. Reusable Adult SpO_2 Probe	1 EA
8. DC Adaptor (MW160 made in Bridgepower Co., Ltd.)	1 EA
9. Chart Paper	2ROLL

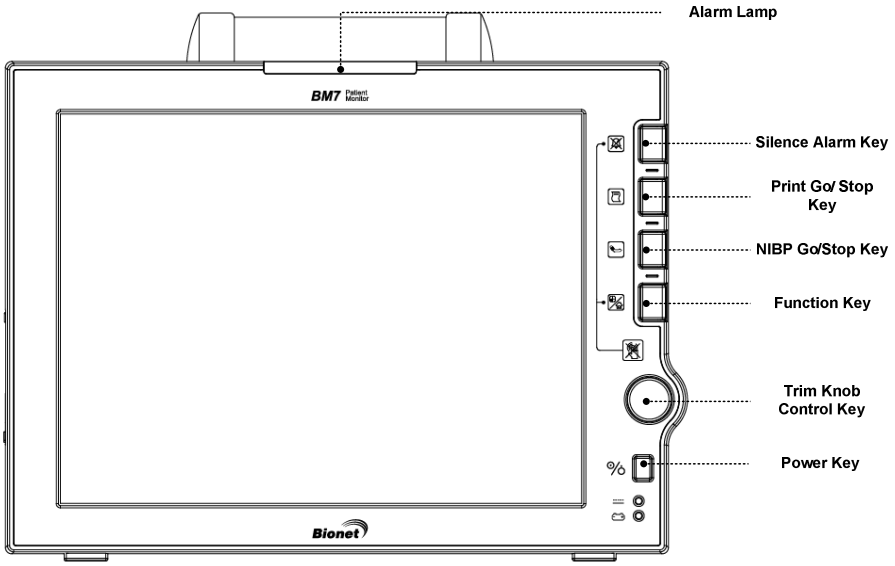
Option Product

1. Temperature probe
2. 3-Lead ECG Cable (MECA3(AHA),MECE3(IEC))
3. 10-Lead ECG Cable (MECA10(AHA),MECE10(IEC))
4. IBP kit
5. EtCO2 Module
6. Extended Li-ion 배터리 (4400mAh, 10.8V / Prime 3x2)
7. SpO2 disposable sensor DS01 (30Kg over, adult finger)
8. SpO2 disposable sensor DS02 (30Kg less, pediatric finger)
9. SpO2 disposable sensor DS03 (neonate / adult finger)
10. Adult NIBP large cuff (31~40Cm)
11. child NIBP cuff (18~26Cm)
12. pediatric NIBP cuff (12~19Cm)
13. neonatal NIBP cuff (8~13Cm)
14. neonatal disposable NIBP cuff1 (3.3~5.6Cm)
15. neonatal disposable NIBP cuff2 (4.2~7.1Cm)
16. neonatal disposable NIBP cuff3 (5.0~10.5Cm)
17. neonatal disposable NIBP cuff4 (6.9~11.7Cm)

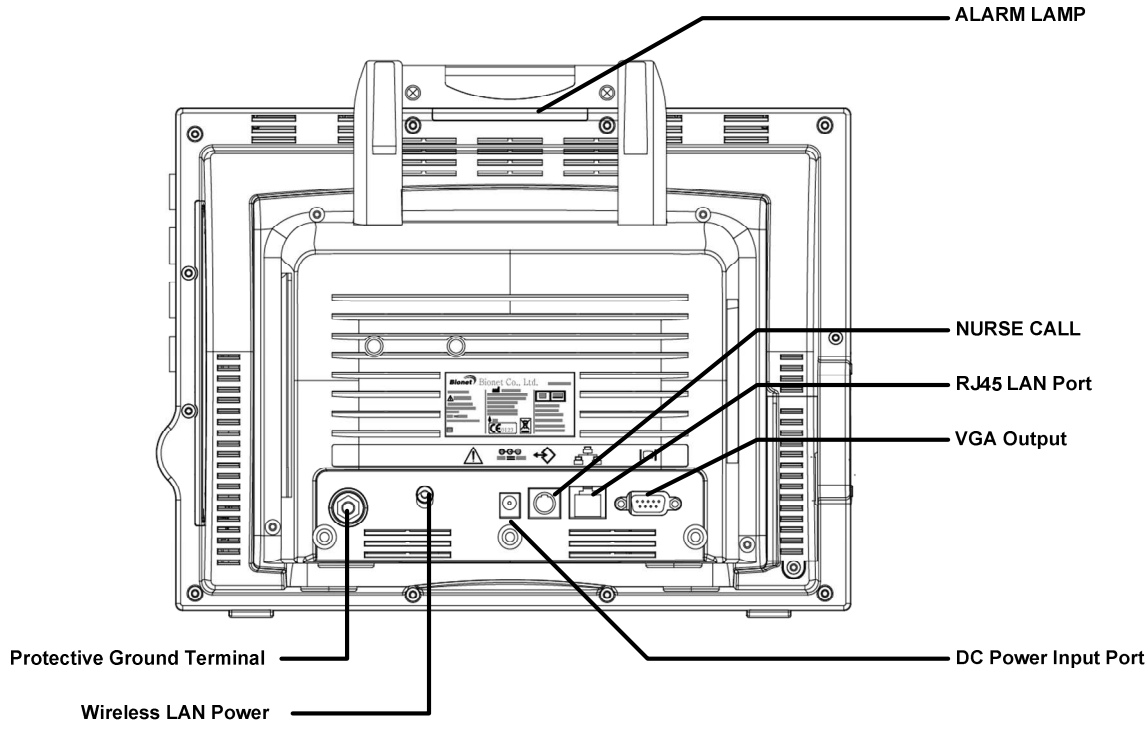
Warning
In order to avoid electrical shock, do not open the cover. Disassembling of the equipment should be done only by the service personnel authorized by BIONET

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.

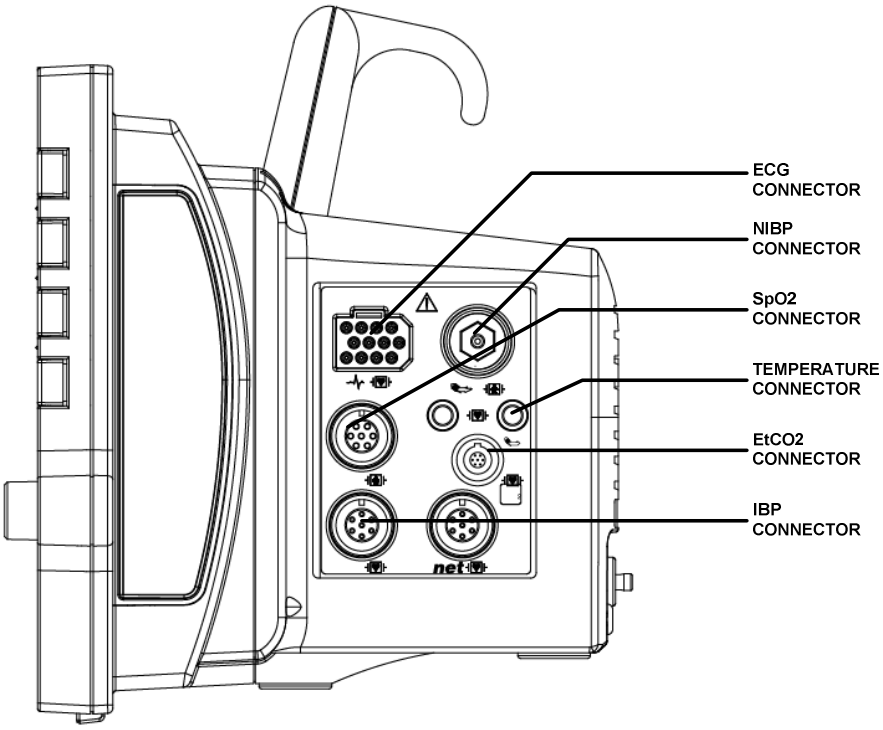
Features of Main Body



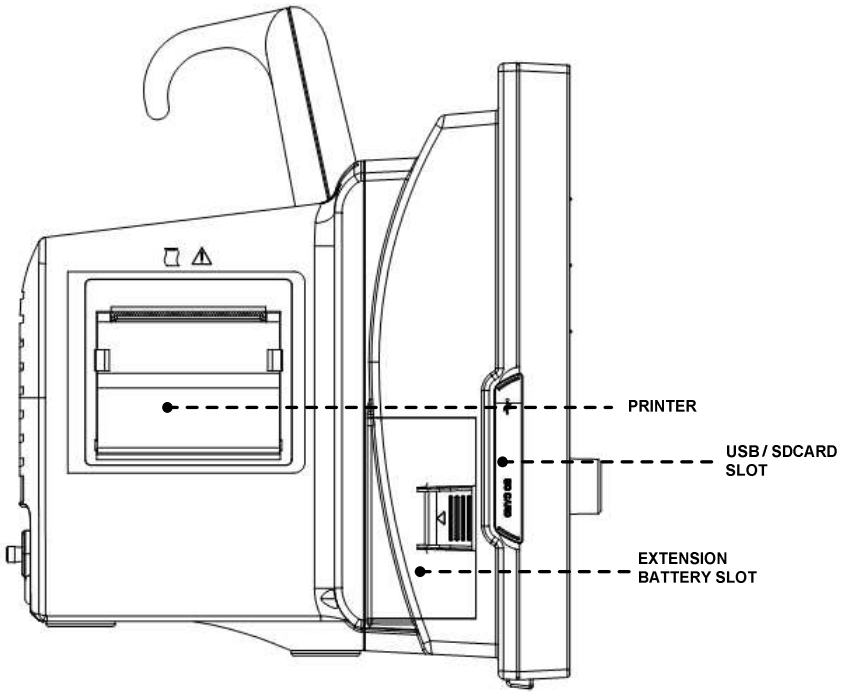
BACK



Right Side

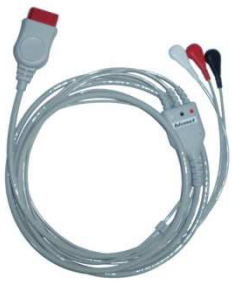

ECG
CONNECTOR
NIBP
CONNECTOR
SpO2
CONNECTOR
TEMPERATURE
CONNECTOR
EtCO2
CONNECTOR
IBP
CONNECTOR
net

Left Side

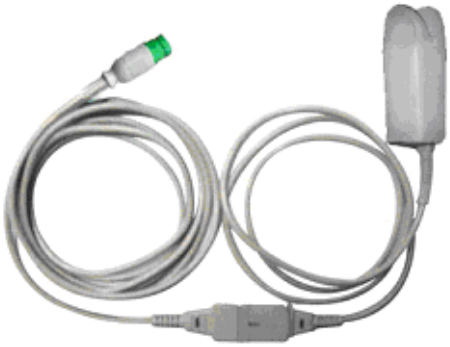

PRINTER
USB / SDCARD
SLOT
EXTENSION
BATTERY SLOT

Accessories

ECG Cable



SpO_2 Cable +
Extension Cable

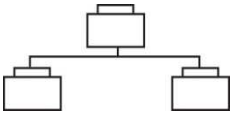
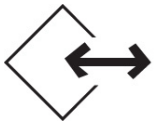
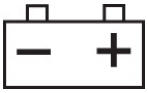
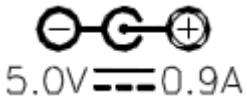
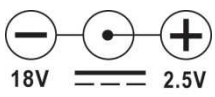


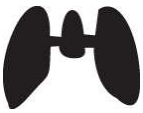
NIBP Cuff+
Extension cable

Temperature
sensor (Option)

Equipment Sign

	ATTENTION : Consult accompanying documents
	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.

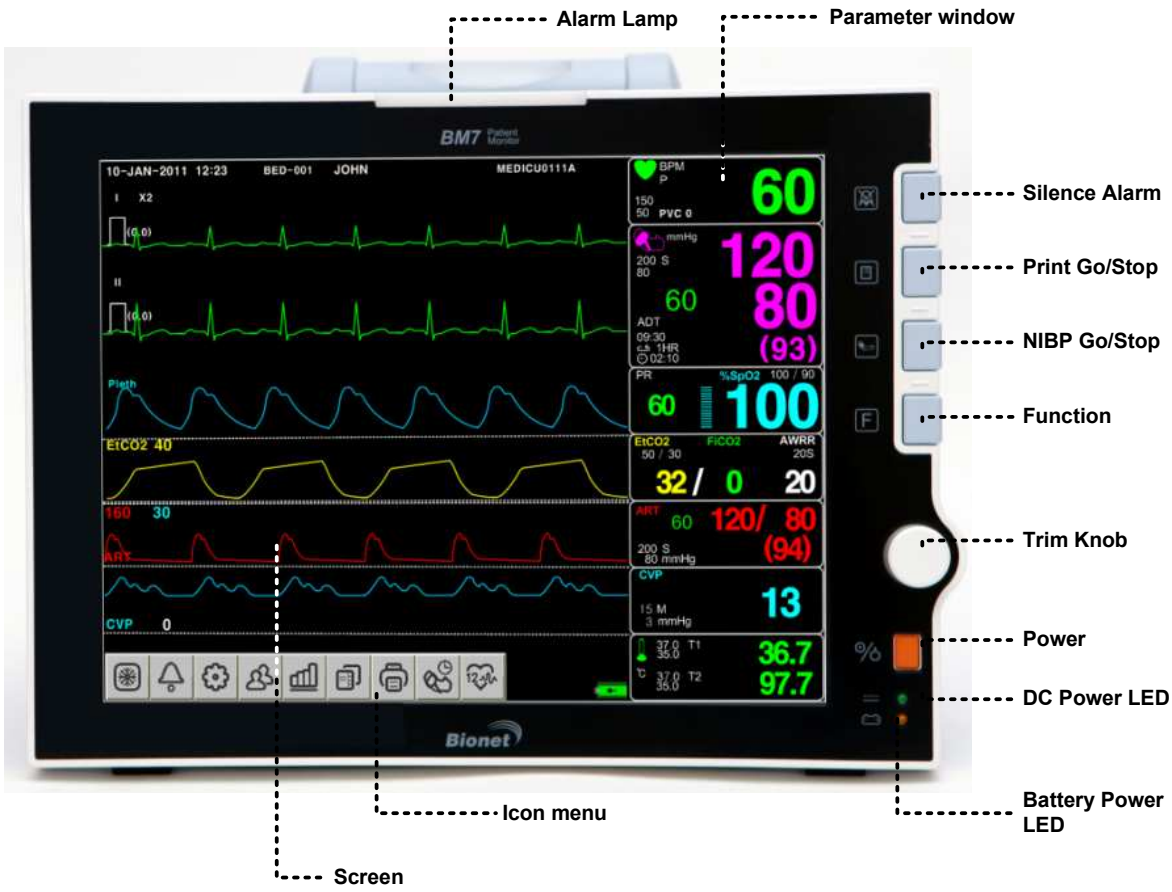
	**Ground**
	**Printer**
	**Serial Port**
	**LAN Port**
	**AUX Connector Port**
	**DC Input Indicator**
	**DSUB 15pin external VGA port**
	**Battery Operation Indicator**
	**WIRELESS LAN power output Port**
	**DC Input Connector**

	**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**

1.4 Function and Key

External Function

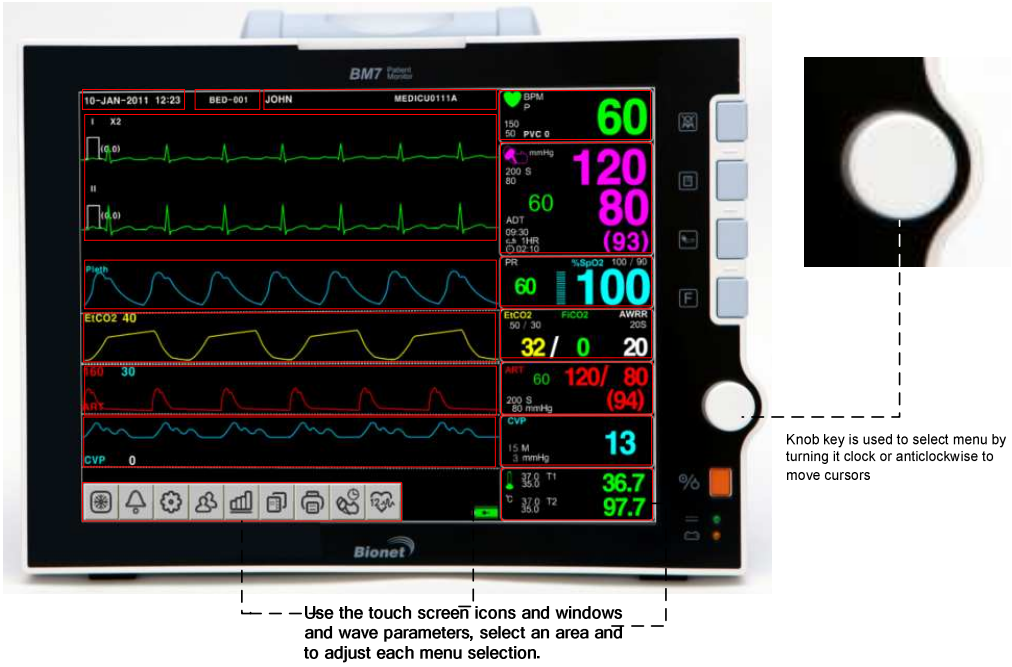
The front panel of this product consists of an LCD screen and five function keys and one trim knob.

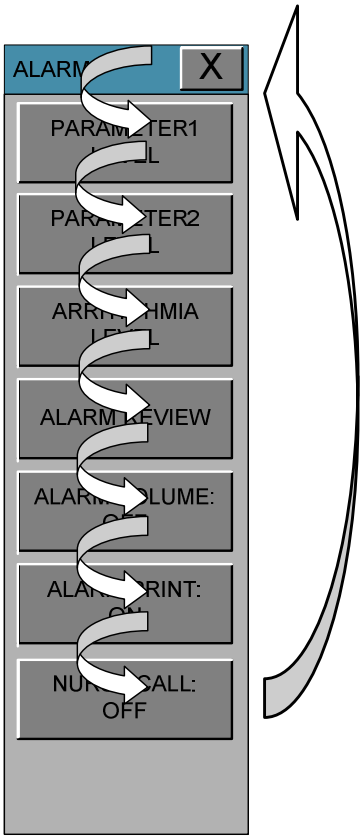


Operation Key

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.
   First press stops the current alarm for one minute
   Second press stops the all alarm for five 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.





1.5 Standard Power Supply Application

DC Power

- Product information

Manufacture: Bridgpower corp.

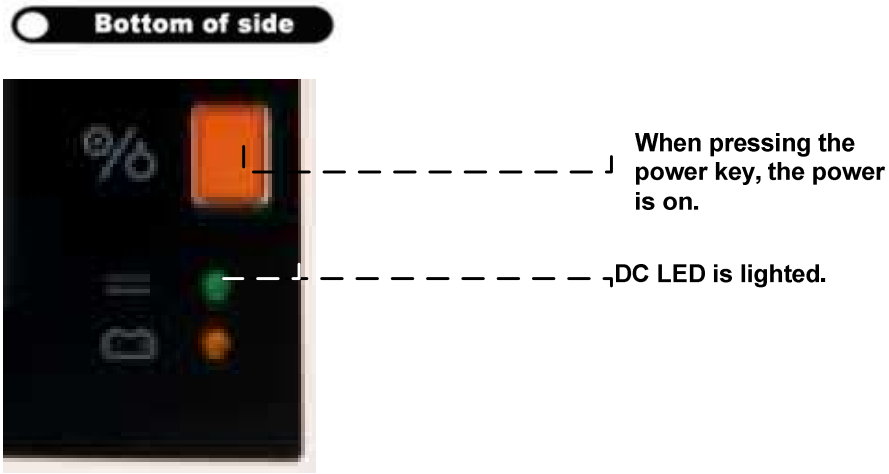
Model name: MW160

Input power: 100~240V 1.2A

Output power: 18V, 2.5A

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 a 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.

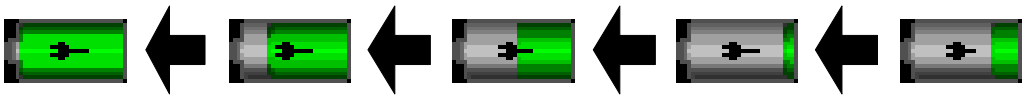
2. The DC/battery power is only sustainable for 1 hour and half.

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: LS1865L2203S1PMXZ(10.8V - 4400mA, Li-ion)

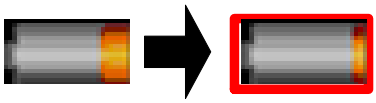
The Lithium-Ion battery is a rechargeable battery containing Lithium-Ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.



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.

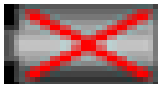
The device will be turned off automatically after 5 minutes from that warning sign. In case of that warning sign with red and blink at icon box, charge the device immediately with DC power adaptor which is provided from BIONET.



- Battery charging time: More than 6 hours
- 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. Automobile power supply: When an automobile power uses 12V~15V, the battery indication disappears and the "LOW" indication is active.

Display of automobile power

Note
Battery is not charged when the automobile power is used.

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.

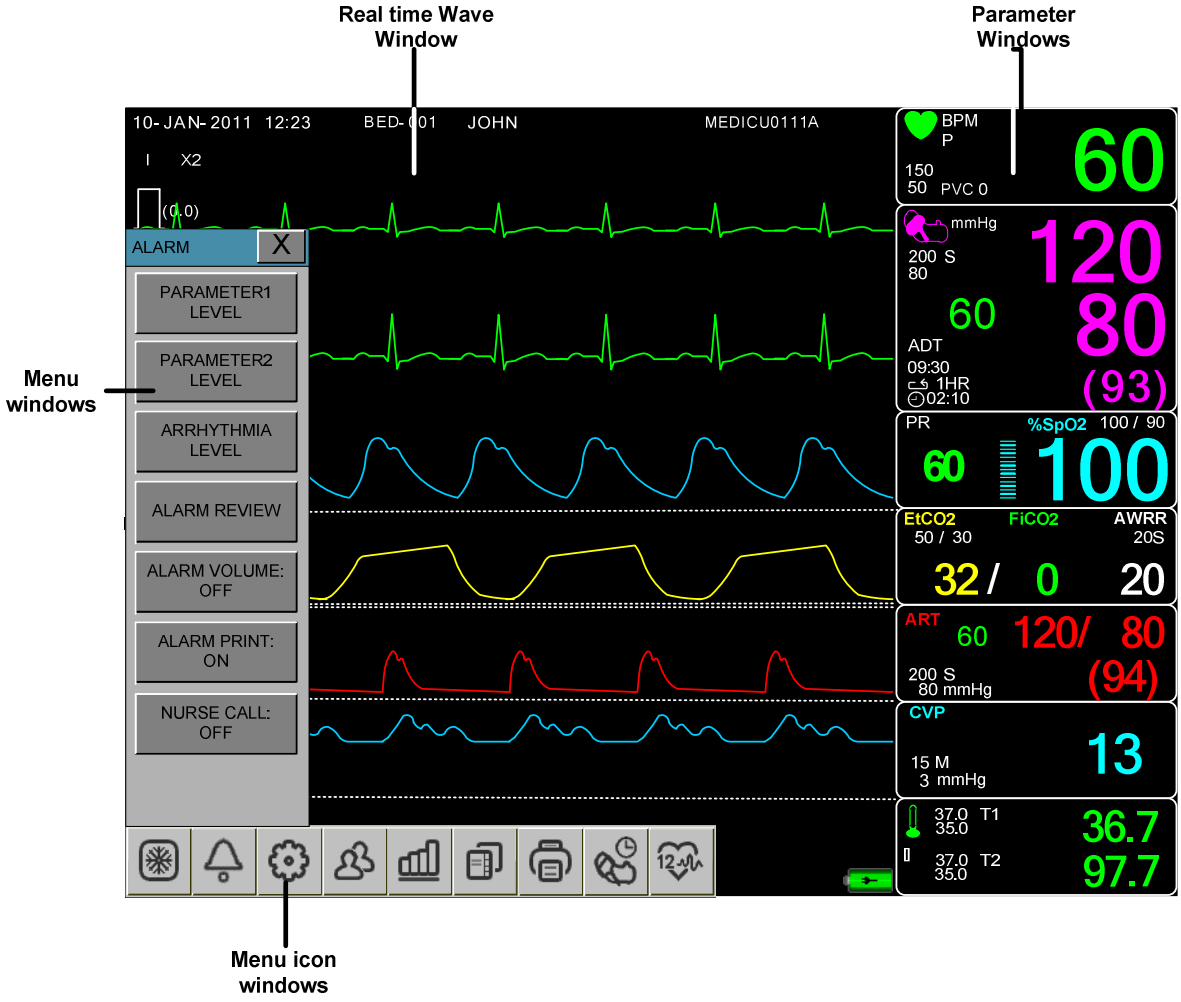
How to Recycle the Battery

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.

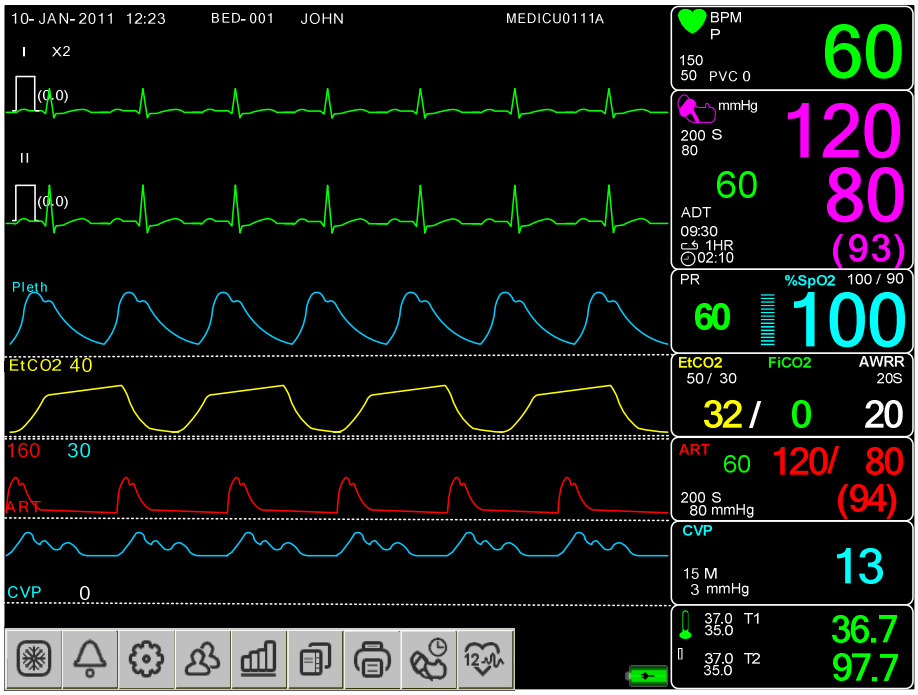
12CH diagnostic menu icon is supported on 12ch ECG select models only.

The screen consists of a total of two modes

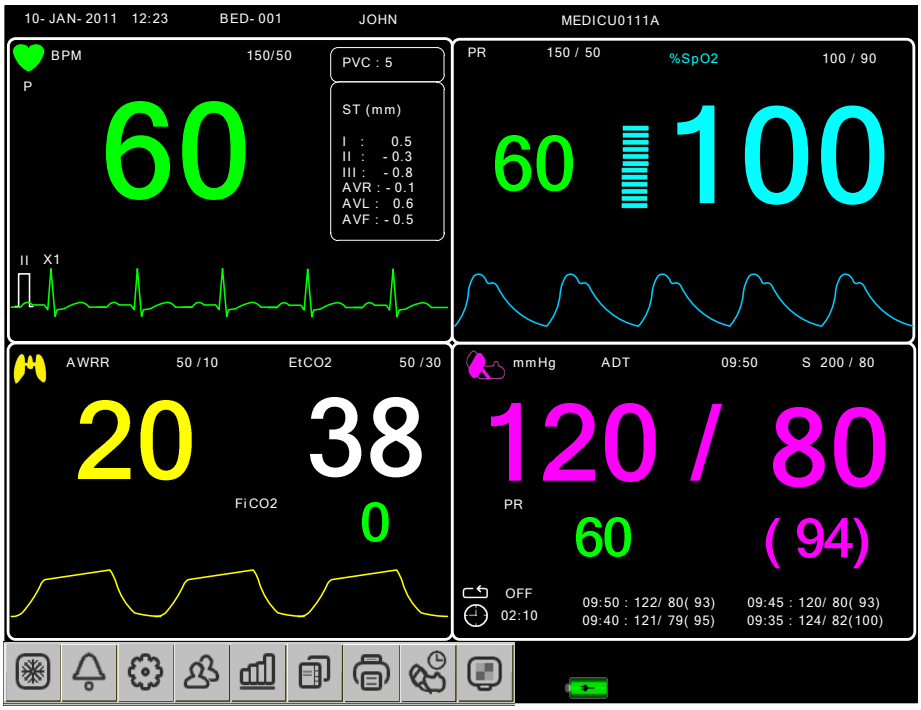
NORMAL MODE: As the figure shows the waveform parameters of the screen

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

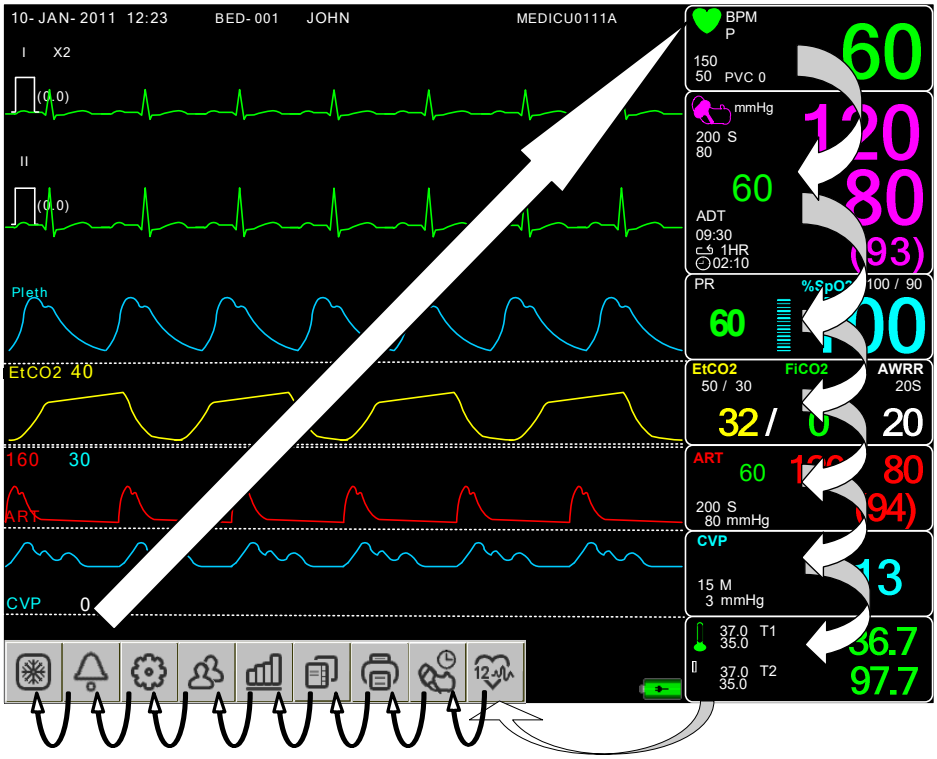
NORMAL MODE



PARAMETER MODE



Menu Selection



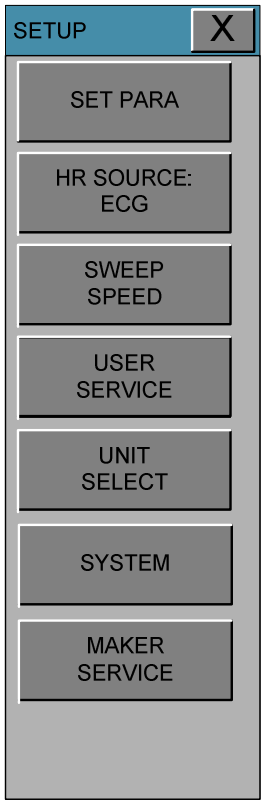
Turn or press the knob .

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

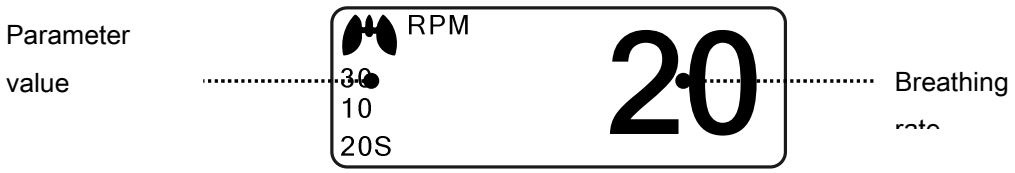
More Menu Window

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



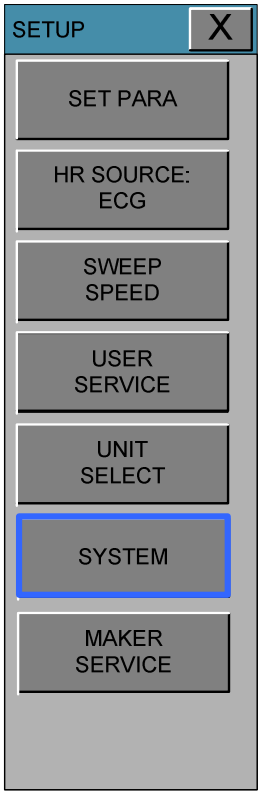
Numerical value sign widow

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



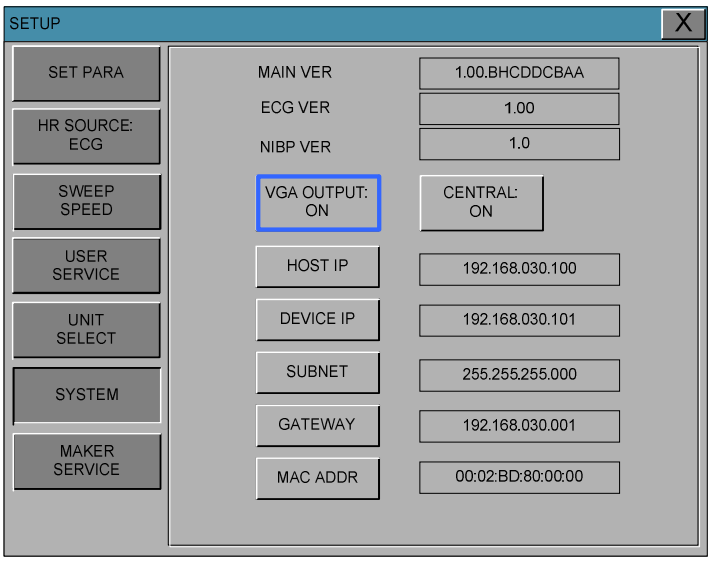
Menu selection by using Trim Knob key

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

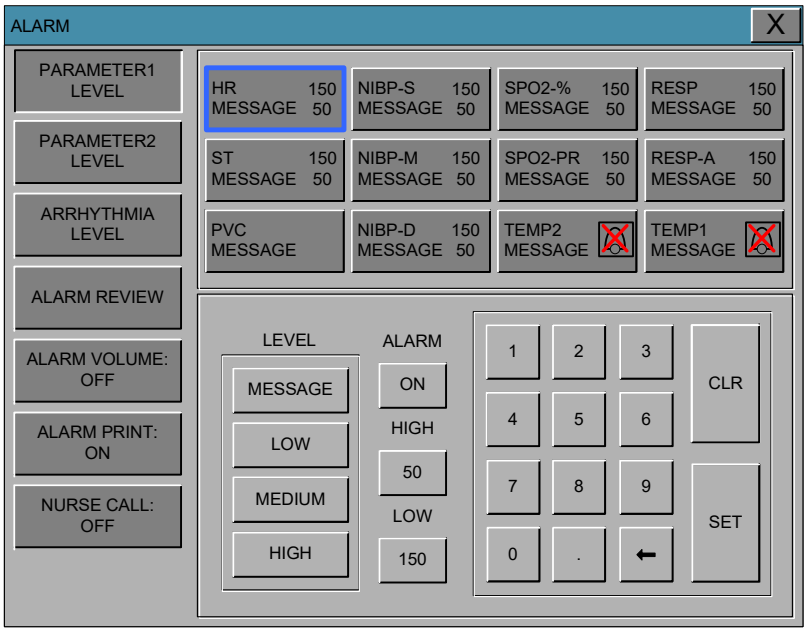
Touch the desired menu, the menu can be selected.



Word feature menu

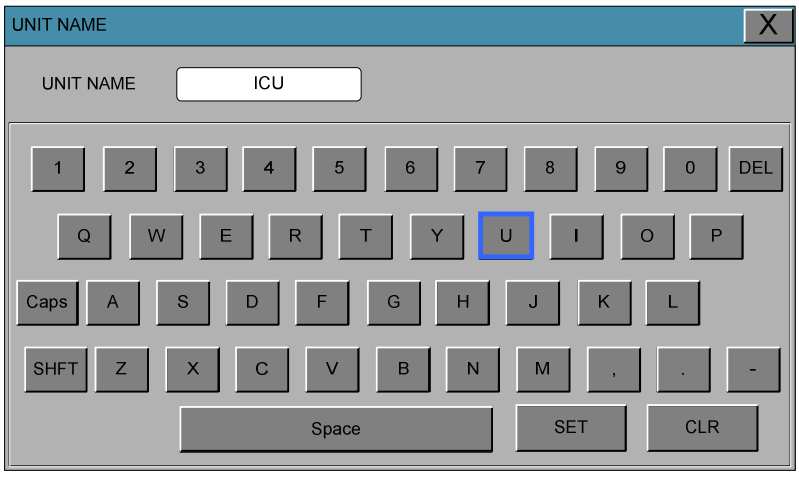
The following figure shows the screen where the word sequence menu is activated within the word sequence correction menu. Here, the cursor moves over the words when the Trim Knob key is turned in the clockwise direction.

Touch the desired menu box, select the menu is available



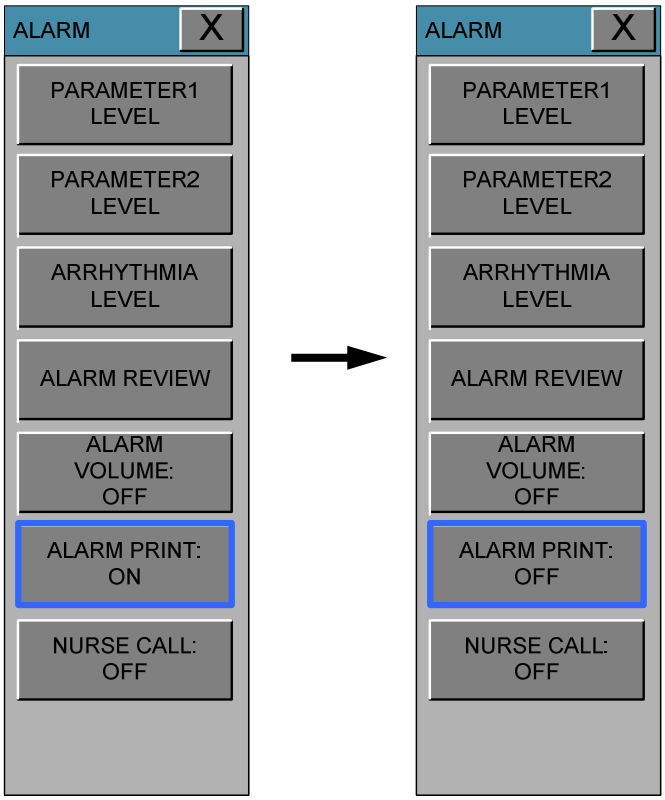
Word feature menu

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.



2. PATIENT/DATA MANAGEMENT

2.1 ADMIT

CHANGE ADMIT INFO

DISCHARGE

HEIGHT

WEIGHT

2.2 ALARM

ALL LIMITS

ALARM PRINT

ALARM VOLUME

ALARM LEVEL

ARRHYTH LEVEL

ALARM REVIEW

ALARM LIST

SAVE ALARM LEVEL

NURSE CALL

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

2.1 ADMIT

CHANGE ADMIT INFO

DISCHARGE

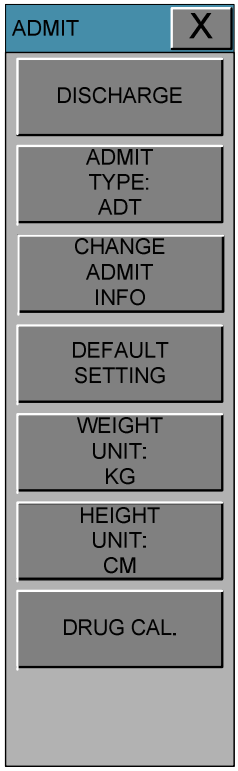
ADMIT TYPE

DEFAULT SETTING

HEIGHT UNIT

WEIGHT UNIT

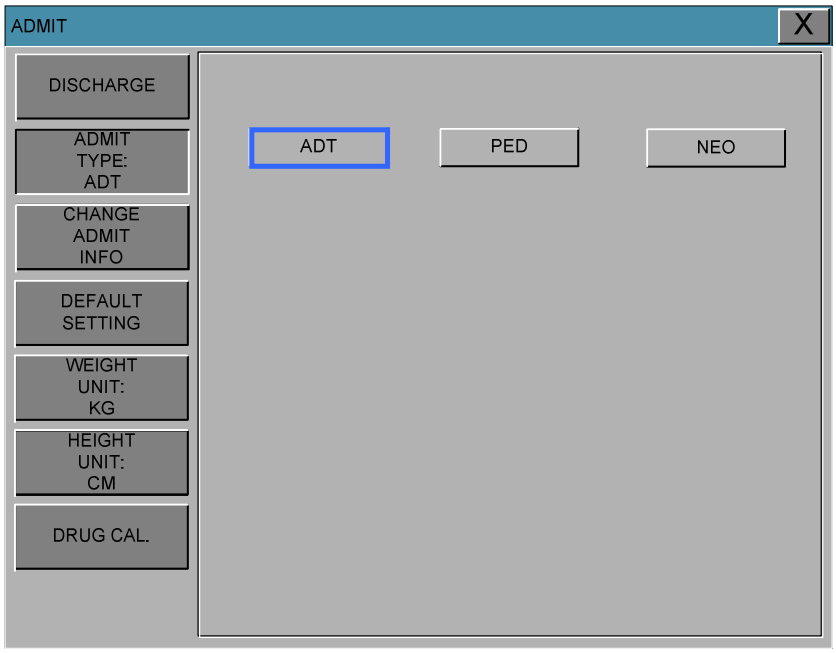
DRUG CAL.



ADMIT TYPE

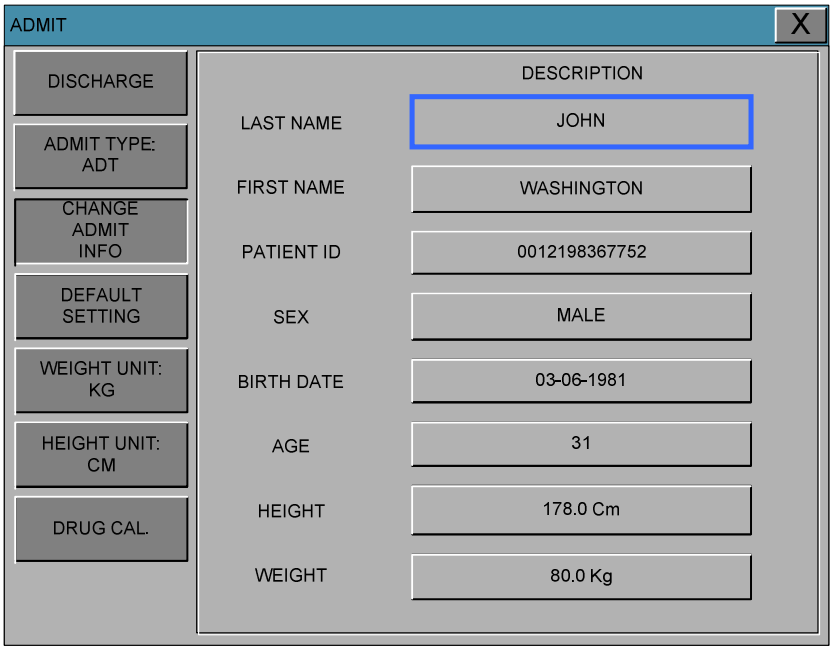
Set the exercise environment of equipment in discharge status.

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



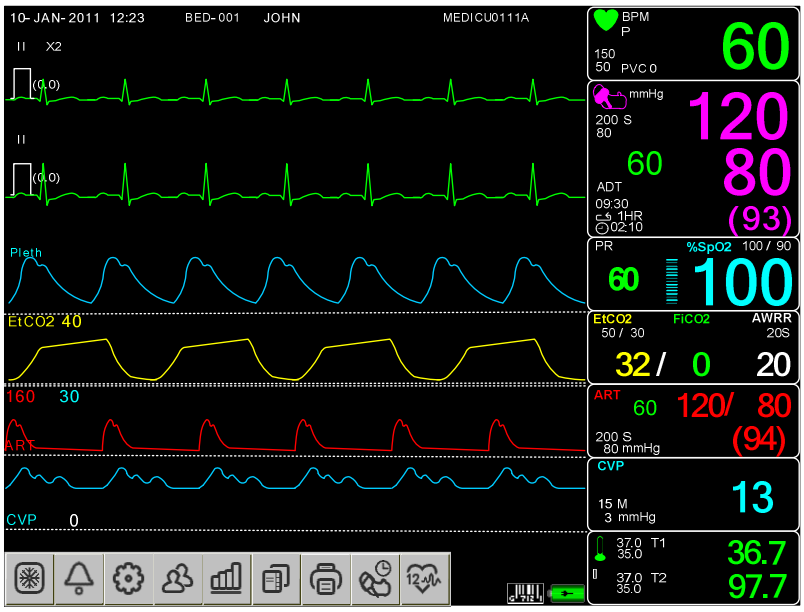
CHANGE ADMIT INFO

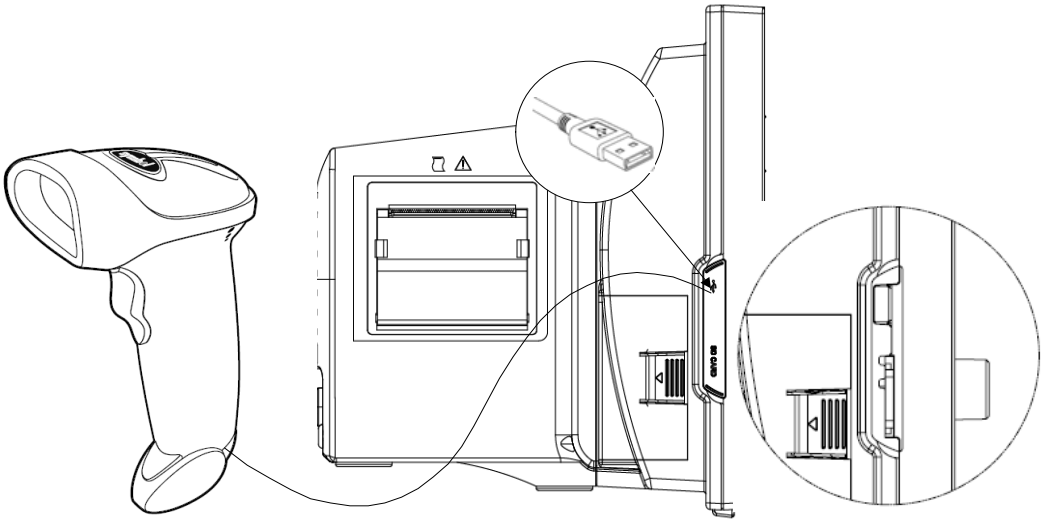
Last and first name (11 letters for each), sex (male or female), date of birth, weight, height, and patient ID (11 characters)



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.

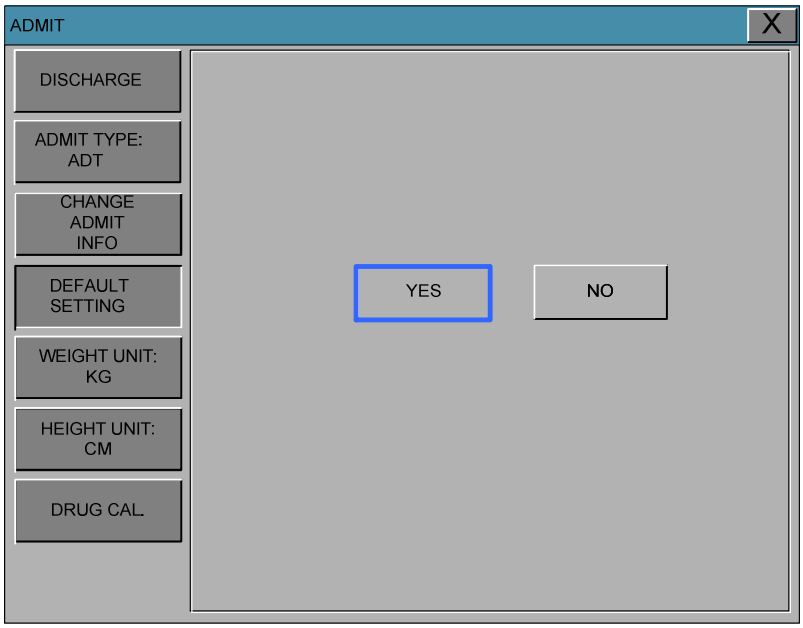




You want to input from a barcode scanner to index LED well focused, the corresponding button is pressed, the input ID and sends it to the monitor. Sender ID is displayed in the upper portion of the center of the screen.

DEFAULT SETTING (알 람 및 데 이 터 초 기 화 설 정)

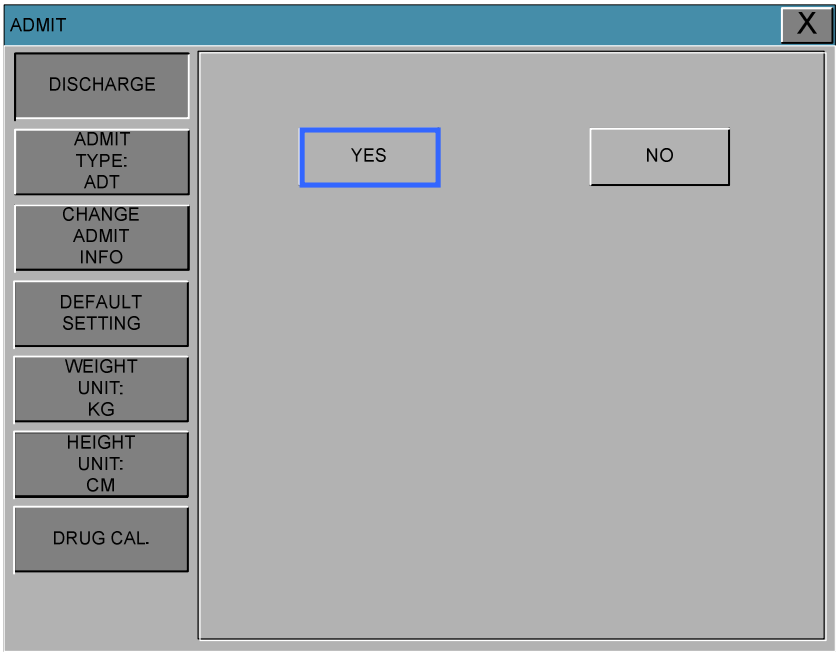
Parameter range settings, alarm settings, and patient-specific initialization settings.



DISCHARGE

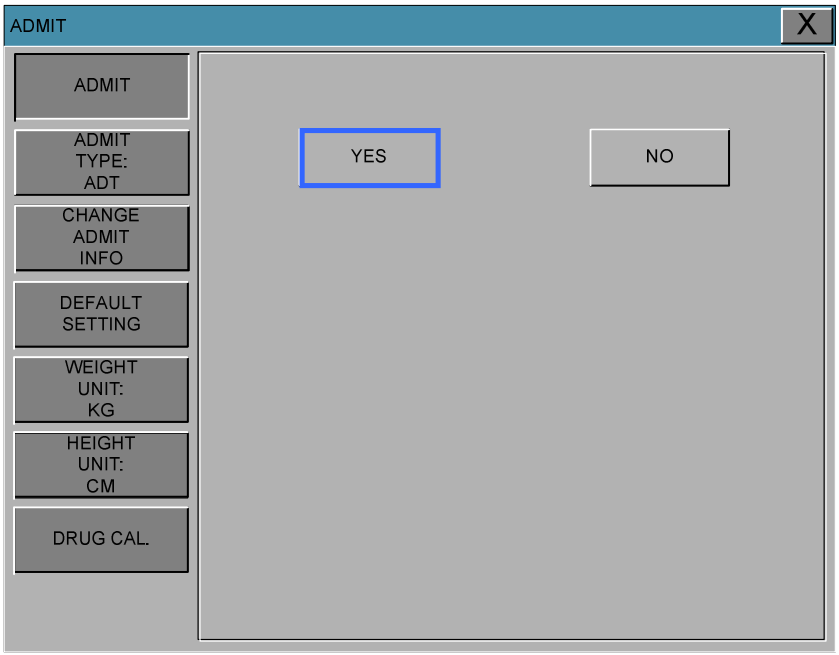
Patient information and all numbers change to standard, and the screen displays, "ALL ALARMS

OFF ADMIT PATIENT TO ACTIVE ALARMS."



ADMIT

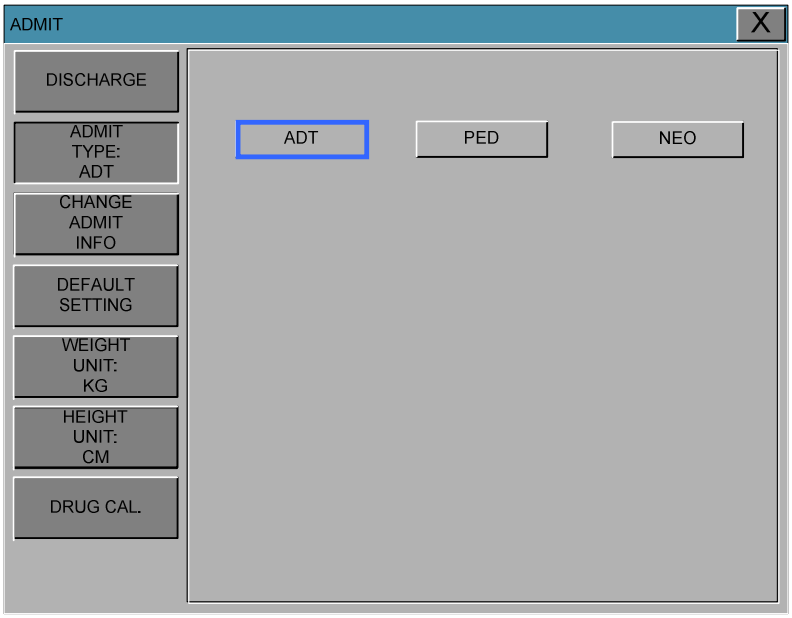
Data set of patients who Trent to start saving, and apply the appropriate settings.



ADMIT TYPE

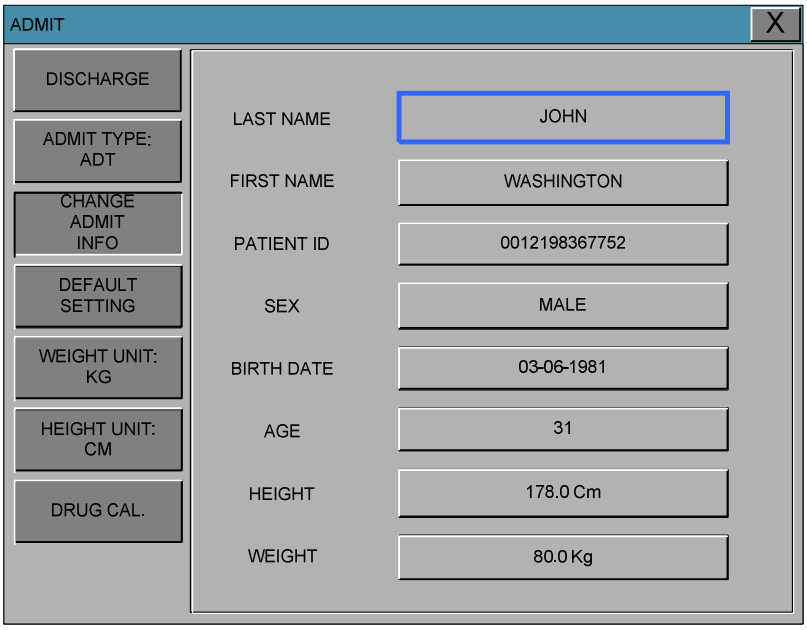
DISCHARGE set up the environment to use of the equipment in the state.

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



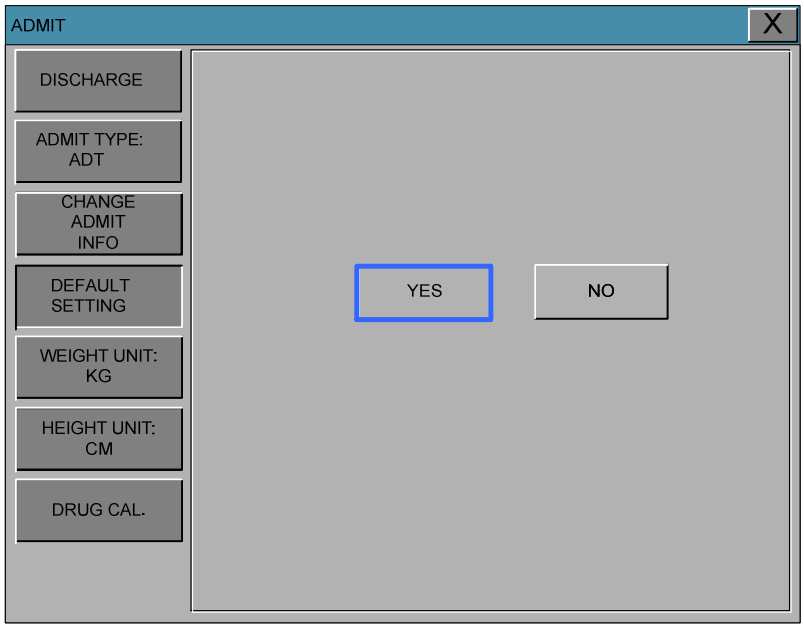
CHANGE ADMIT INFO

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



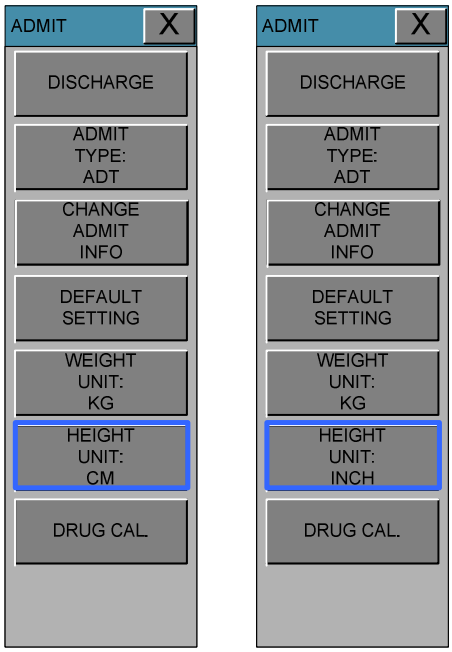
DEFAULT SETTING

Range of parameters, alarm set, feature set is selected by group initialization values.



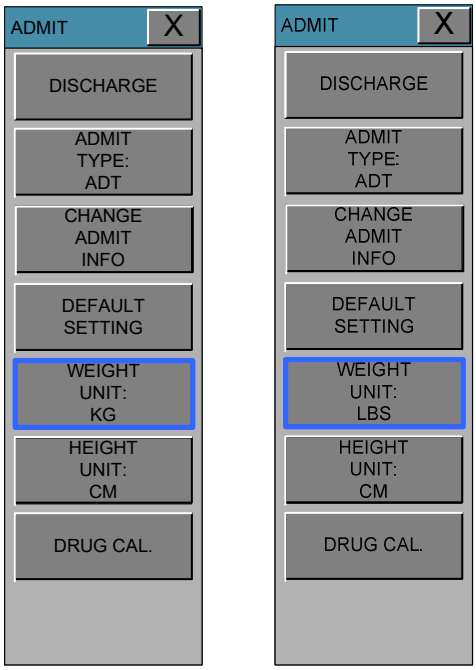
HEIGHT

Unit of height is set as Cm / Inch.



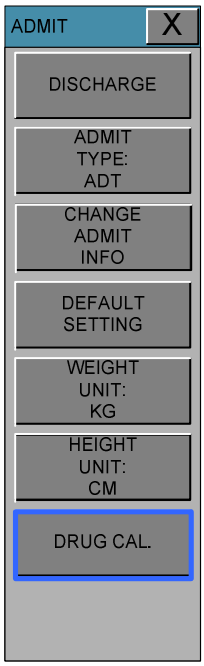
WEIGHT

Unit of weight is set as Kg / LBS.



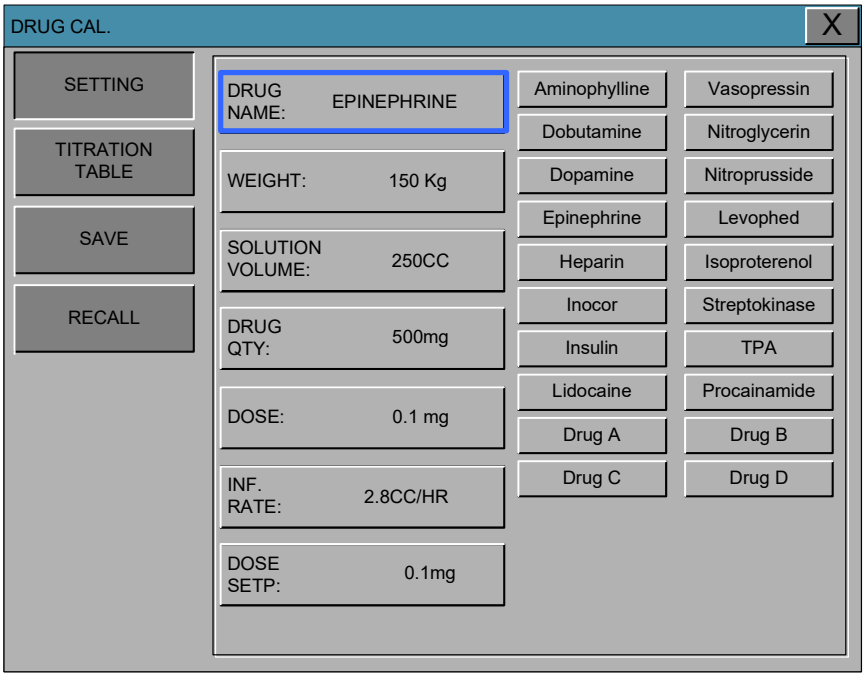
DRUG CAL.

Patients with a commitment to be a medicine that automatically calculates the menu.



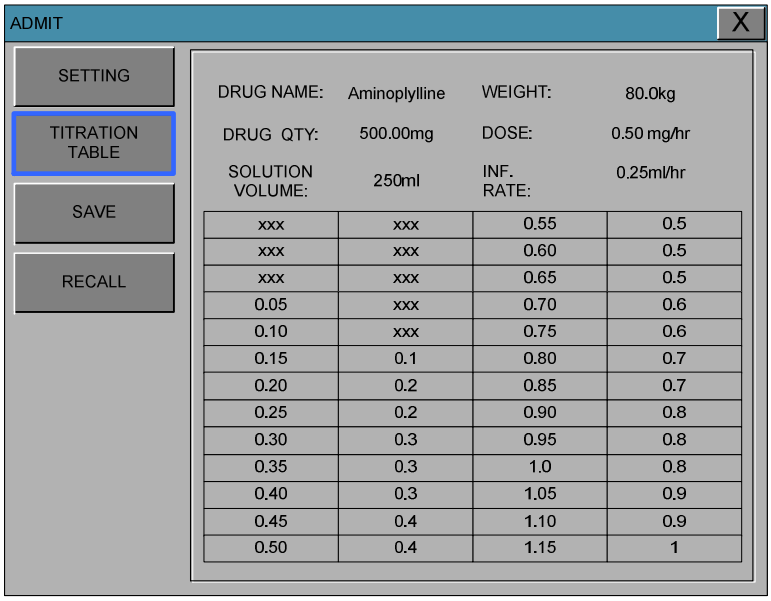
SETTING

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, INF TIME), etc.



TITRATION TABLE

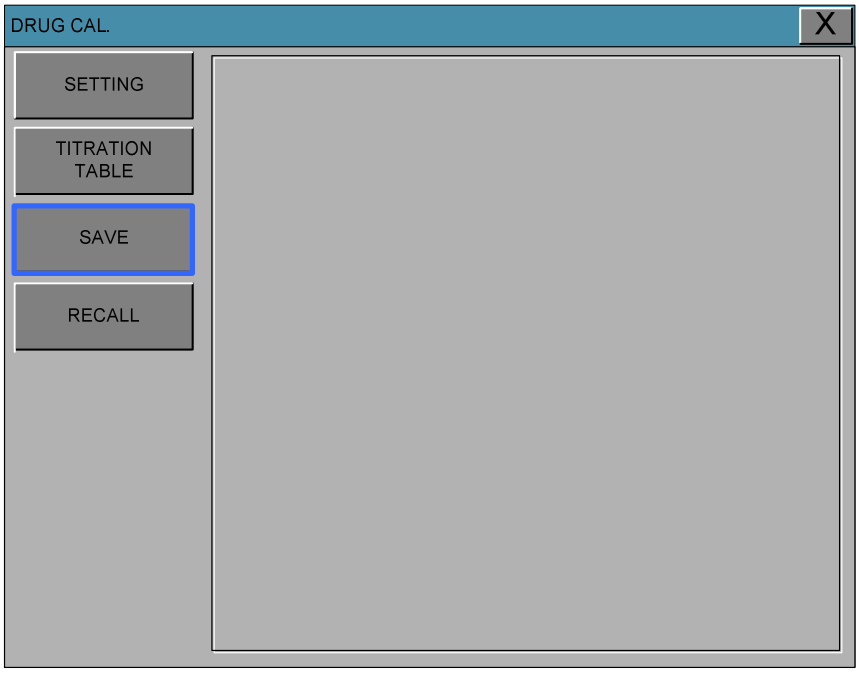
Display calculated drug dosage in a titration table using parameters such as drug name, weight, solution volume,drug QTY, INF. rate(DOSE/MIN, DOSE/HR, DOSE/KG/MIN, INF RATE, DIRP RATE, DROP SIZE, INF TIME), etc.



xxx	xxx	0.55	0.5
xxx	xxx	0.60	0.5
xxx	xxx	0.65	0.5
0.05	xxx	0.70	0.6
0.10	xxx	0.75	0.6
0.15	0.1	0.80	0.7
0.20	0.2	0.85	0.7
0.25	0.2	0.90	0.8
0.30	0.3	0.95	0.8
0.35	0.3	1.0	0.8
0.40	0.3	1.05	0.9
0.45	0.4	1.10	0.9
0.50	0.4	1.15	1

SAVE

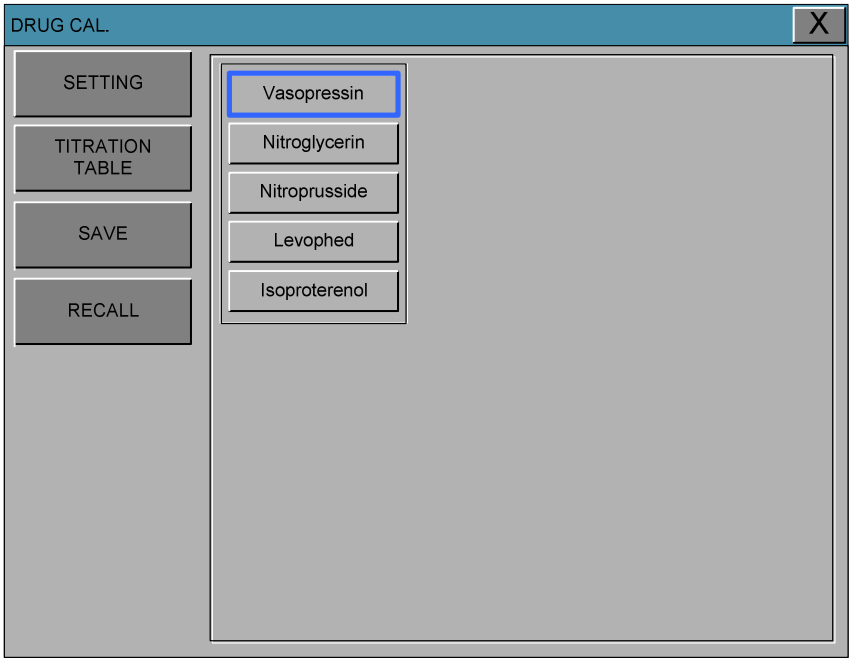
Medicinal dose is calculated to save the menu.



RECALL

Loading dose of medicine is stored in the menu.

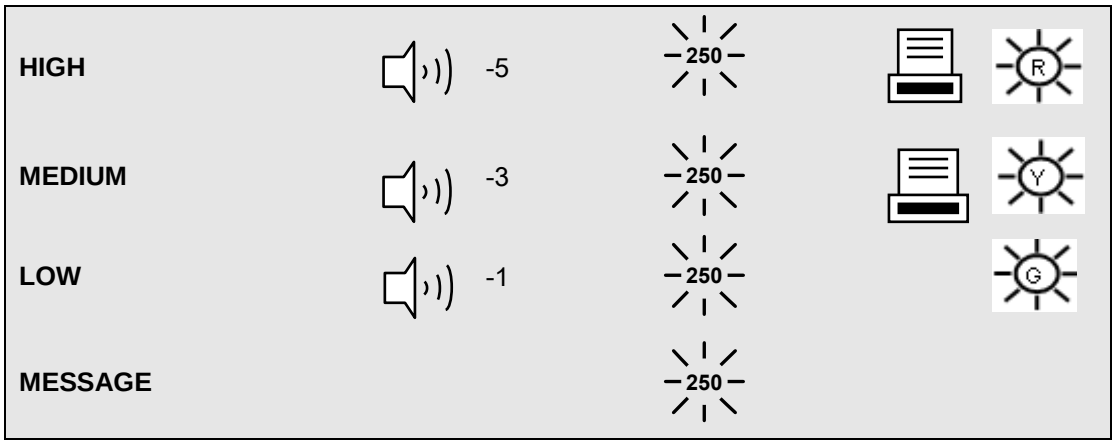
You can delete the saved settings.



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 for the Product

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

LOW  -1 

ALARM LIMITS：The machine enables one to see and change the limits of alarm for all parameter functions.

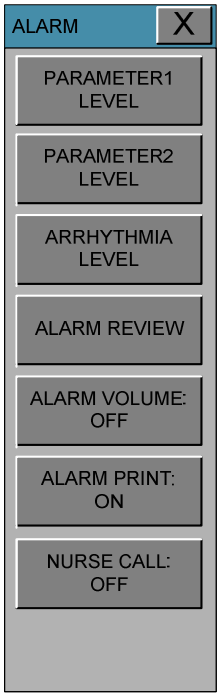
ALARM PRINT：with an ON/OFF setup, the related information is printed out whenever an alarm is given.

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

ALARM LEVEL：Priority of each parameter alarm can be set up.

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

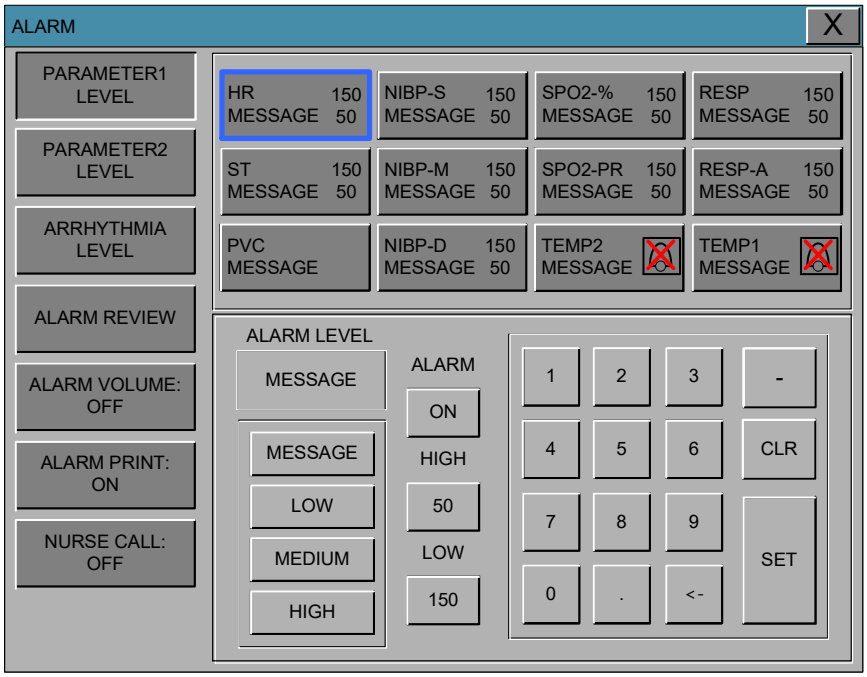
NURSE CALL： Set the ON/OFF feature of the NURSE CALL.



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

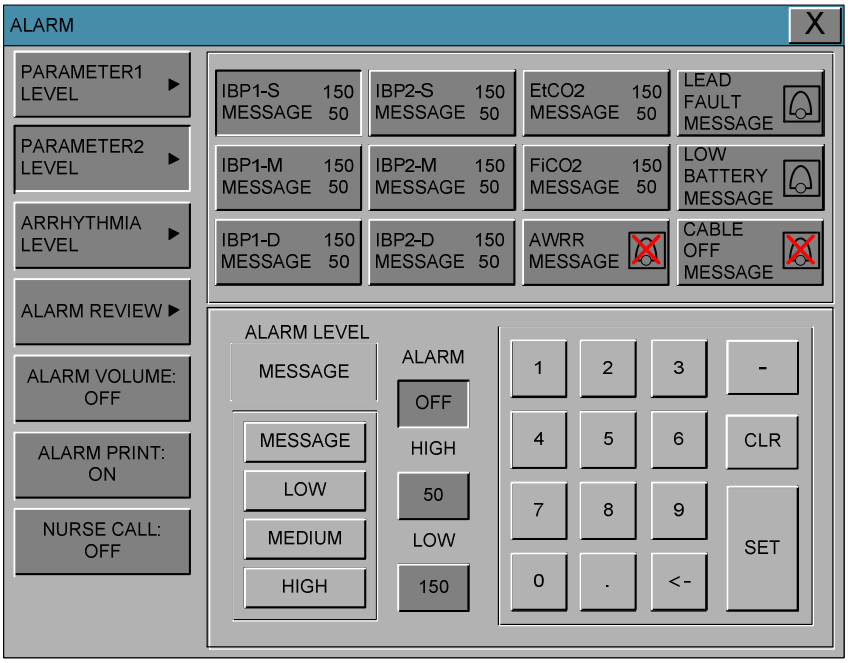
PARAMETER1 LEVEL

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



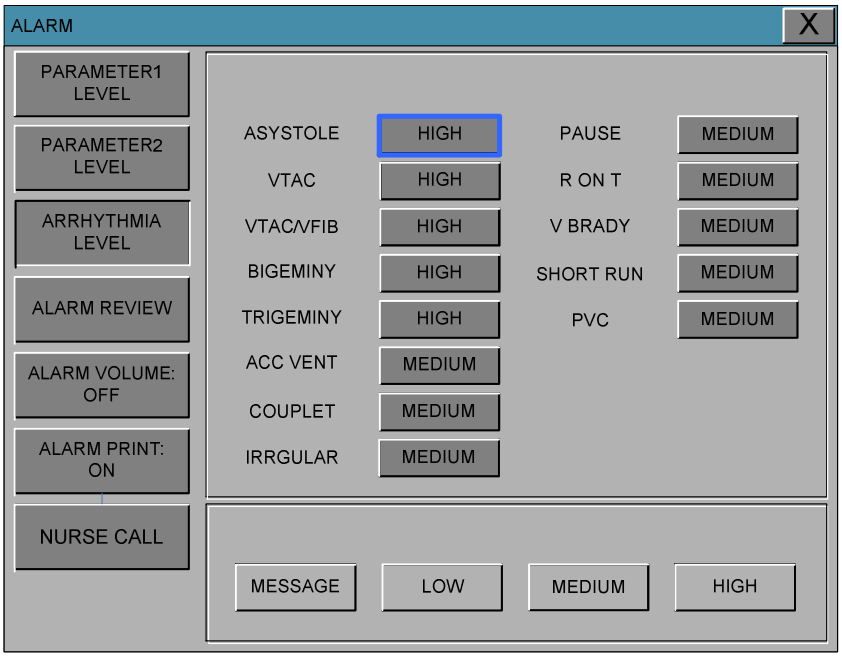
PARAMETER2 LEVEL

IBP, EtCO2 information about all of the alarm is set.



ARRHYTHMIA LEVEL

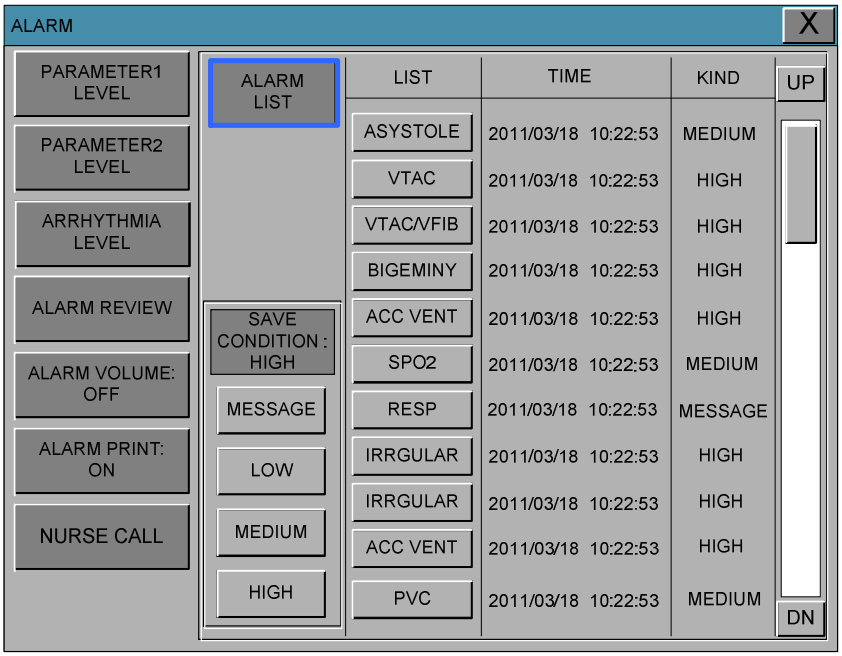
Diagnostics when the alarm is set to the priority of the alarm is set.



ALARM REVIEW

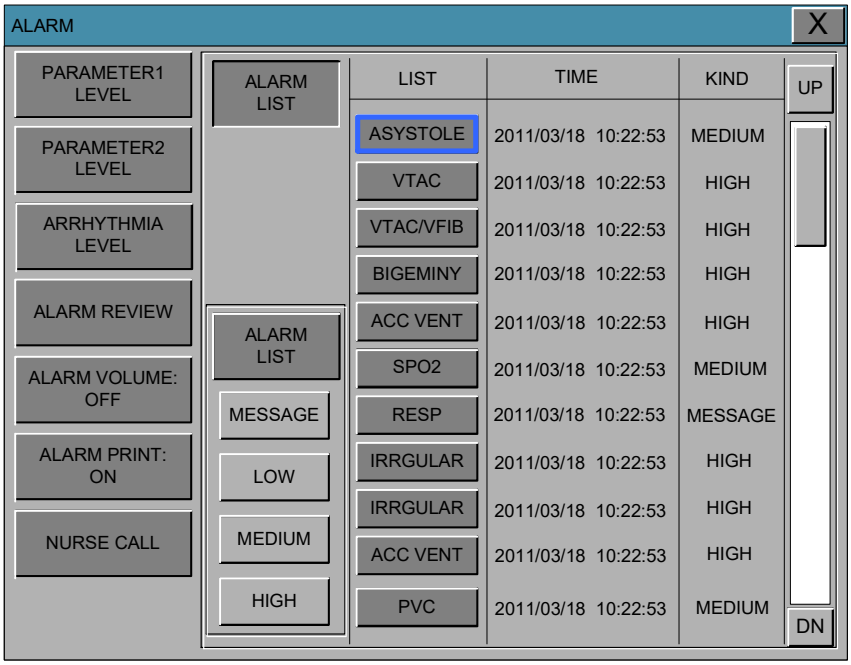
After an alarm is triggered the alarms and data wave pattern can be reviewed. Set up for priority of

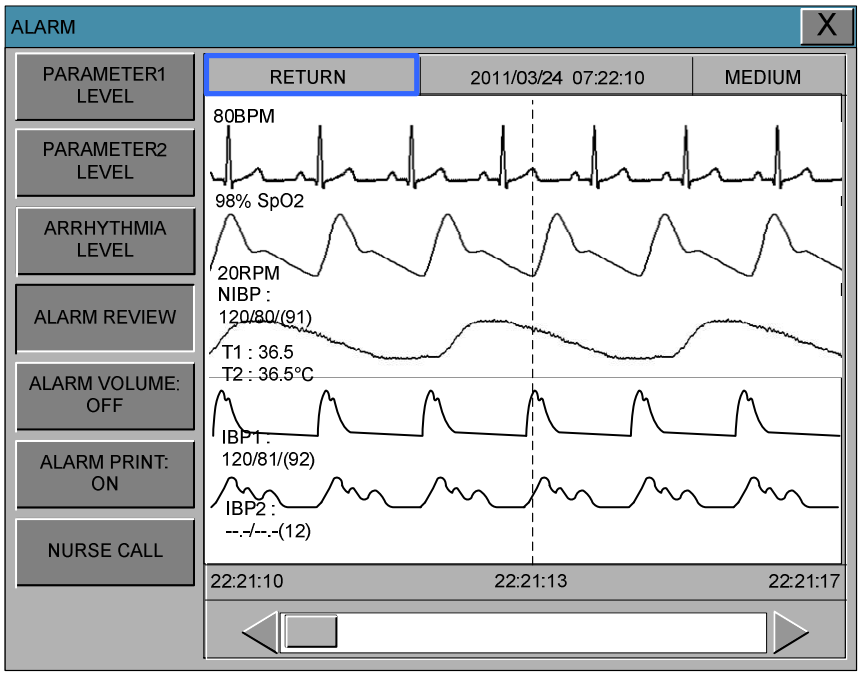
each parameter alarm.



ALARM LIST

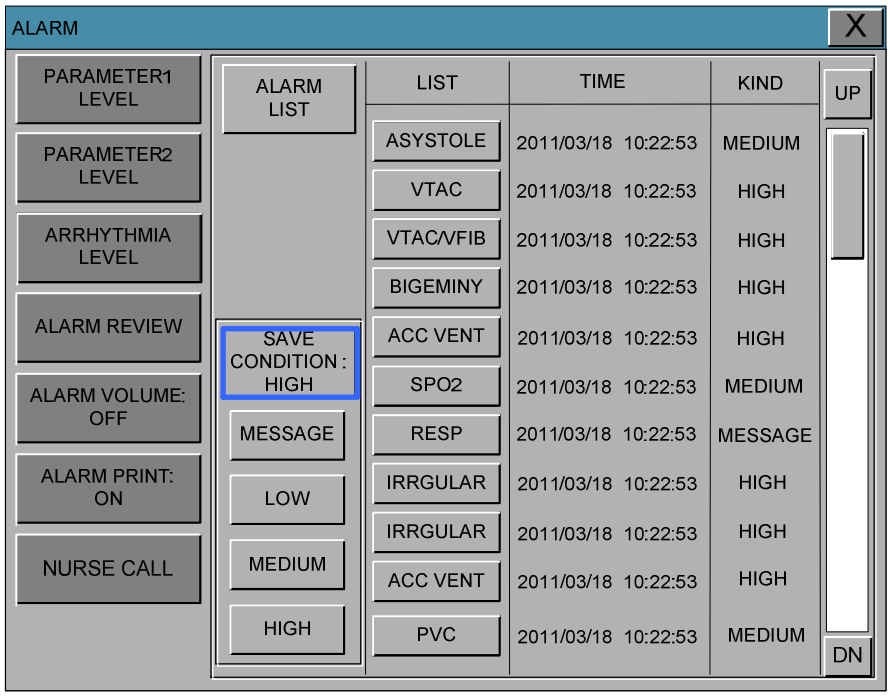
When an alarm activates, this shows the order of the alarms. The alarm can be stored up to 20 case.





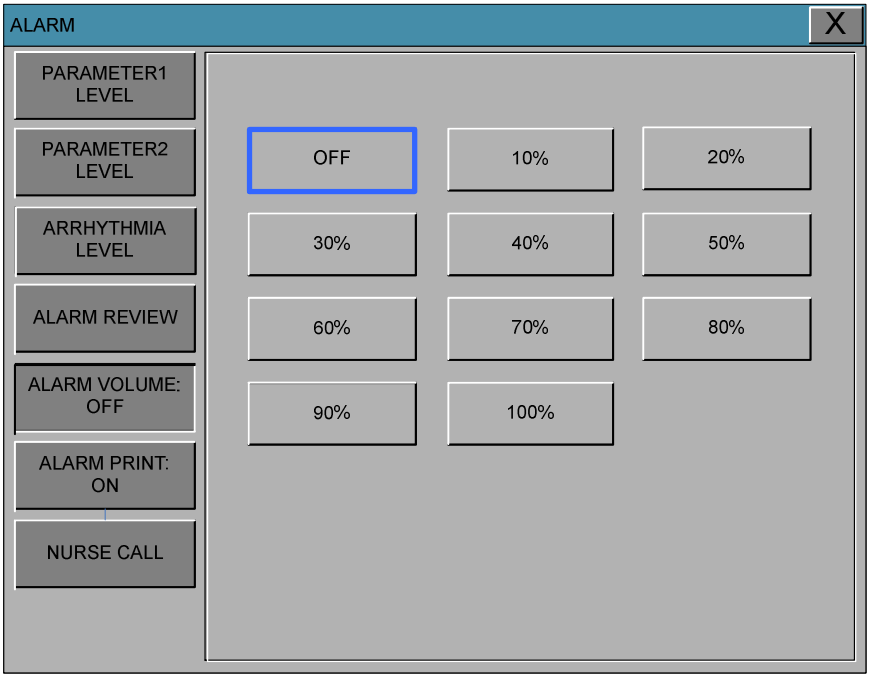
SAVE CONDITION

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

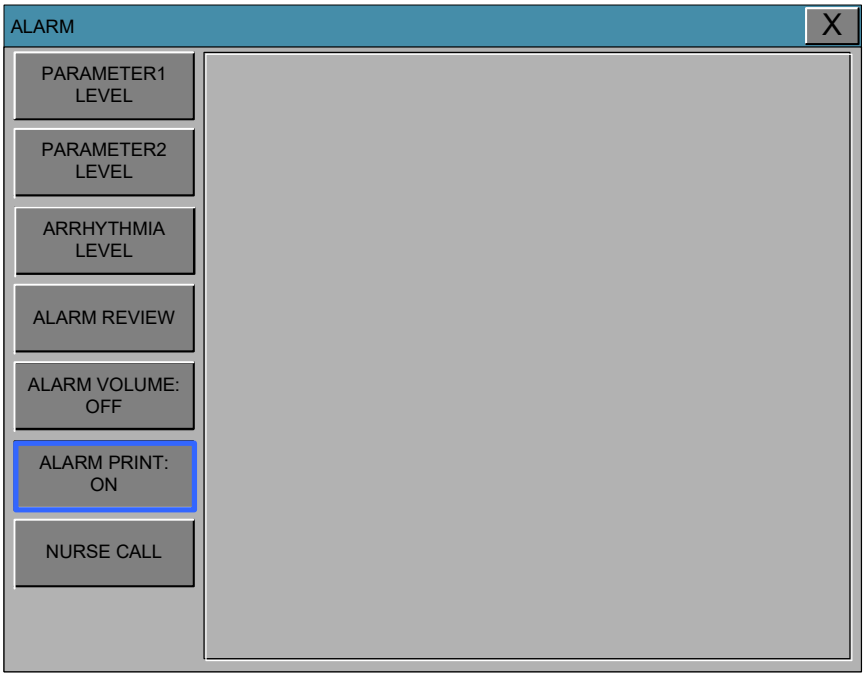
Set the alarm volume to be set at 10 grades.



ALARM PRINT

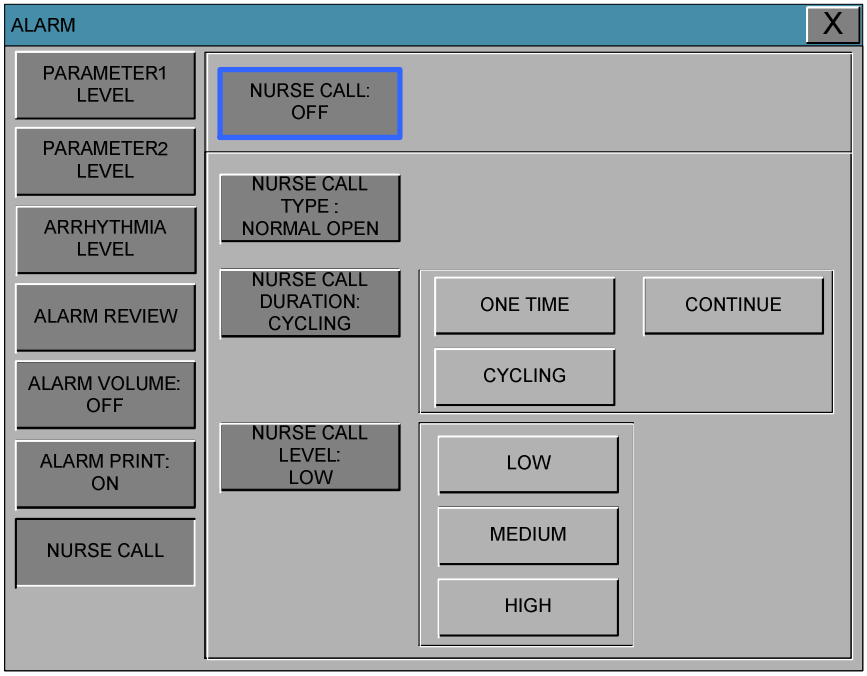
ON / OFF settings for when the alarm sounds are printed on thermal paper.

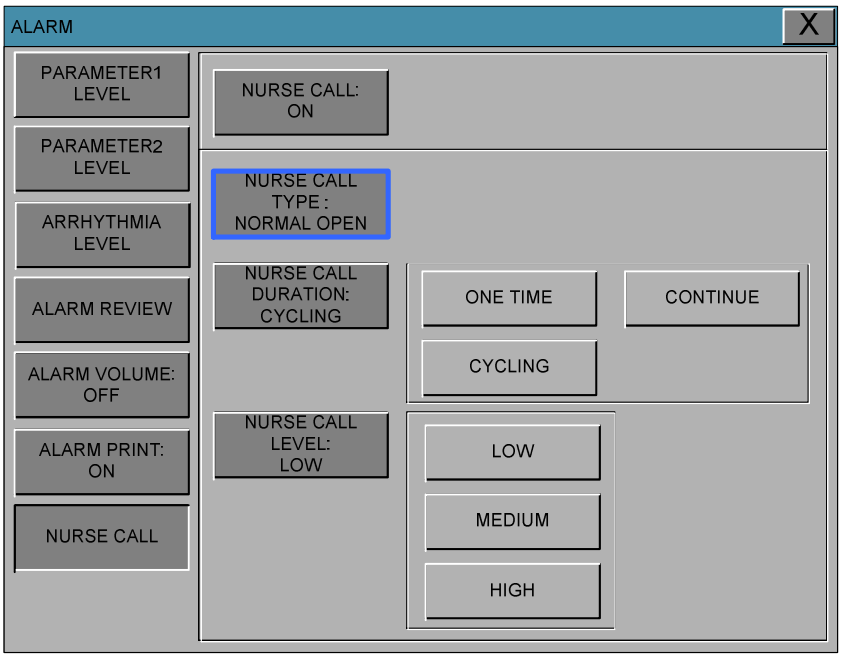
MEDIUM alarm level is greater than if only the printer output.



NURSE CALL

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



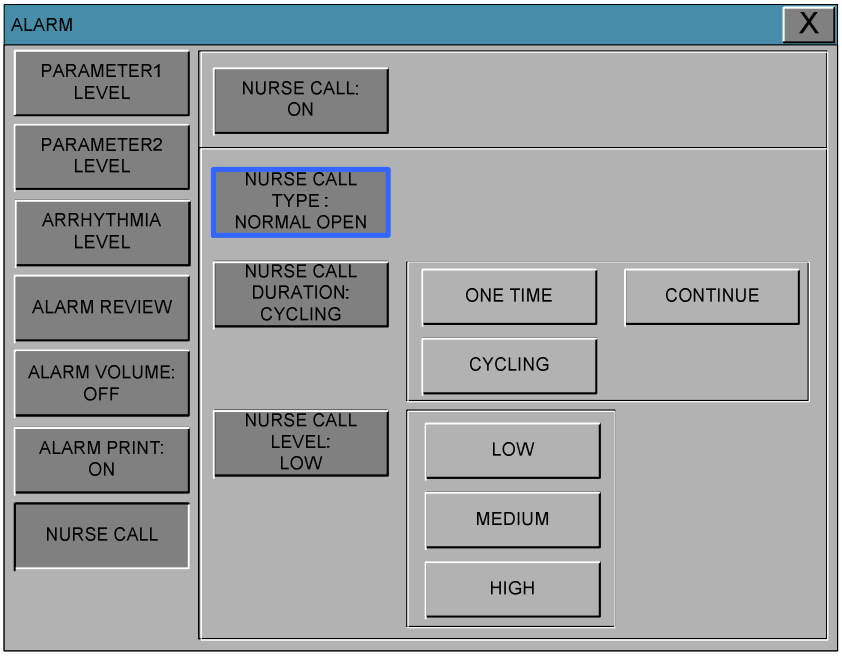


NURSE CALL TYPE

NURSE CALL function call 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.



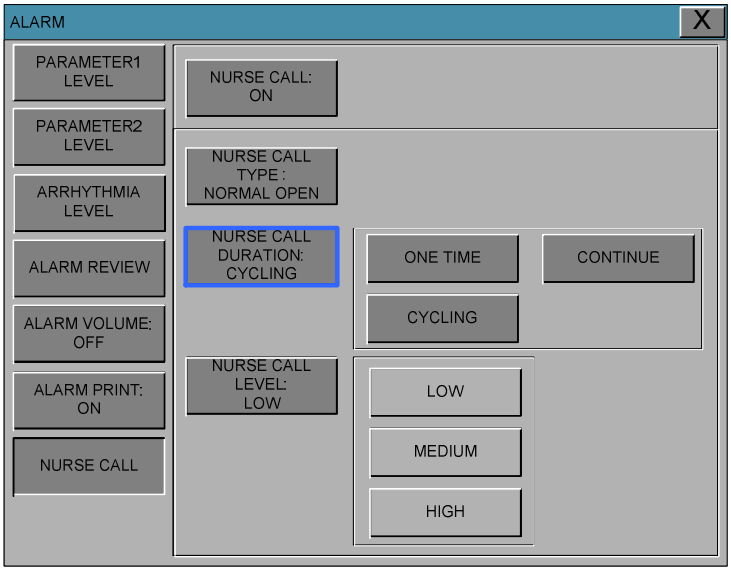
NURSE CALL DURATION

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.



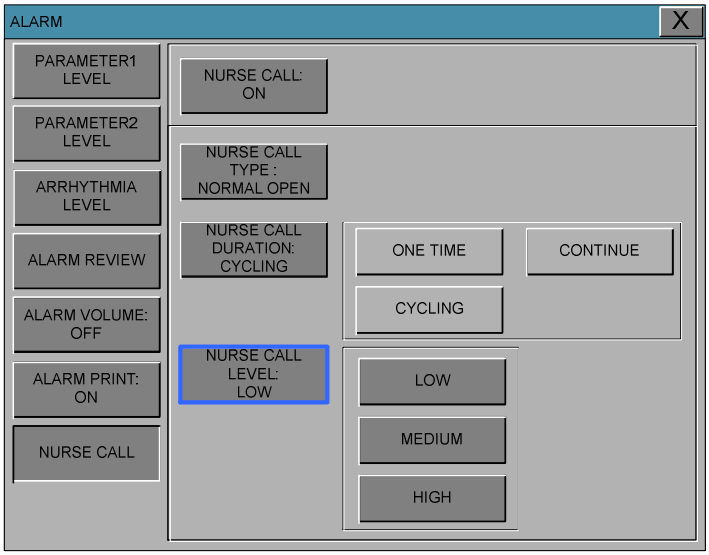
NURSE CALL LEVEL

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

DISPLAY

DEMO

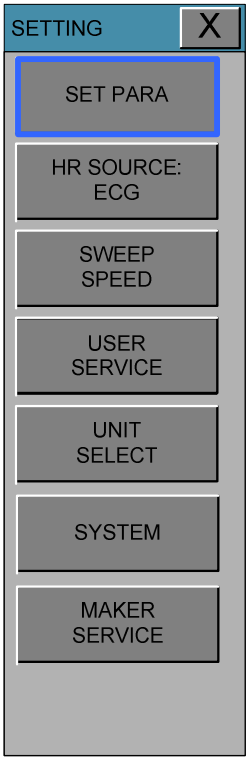
USER SERVICE

MAKER SERVICE

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.



DISPLAY : screen set menu

KEY SOUND : This is the menu to set the key sound generation.

USER SERVICE : This is the menu to set the connection used to interface with an external computer.

DEMO: This is the menu to set the demonstration.

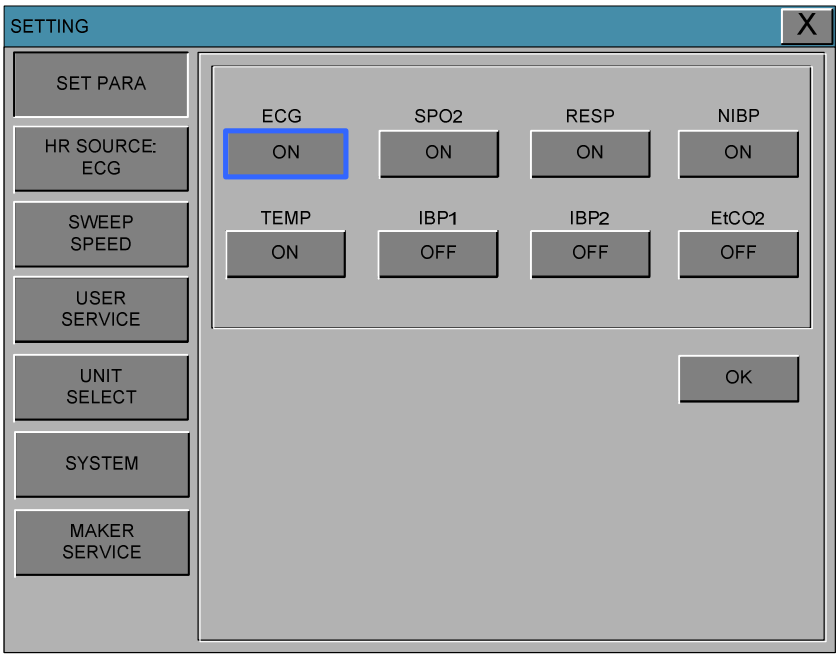
MAKER SERVICE : This is the basic adjustment menu used to adjust the features of this product.

COLOR SELECT: Set screen display color.

SET SWEEP: Set speed of ECG, RESP WAVE DISPLAY

SET PARA

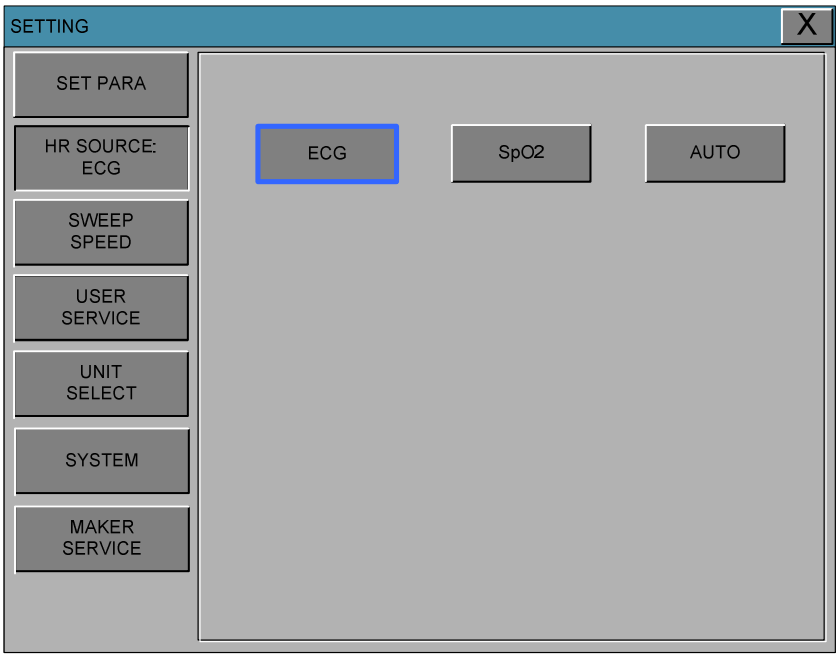
Select measurement function to use.



HR/PR SOURCE

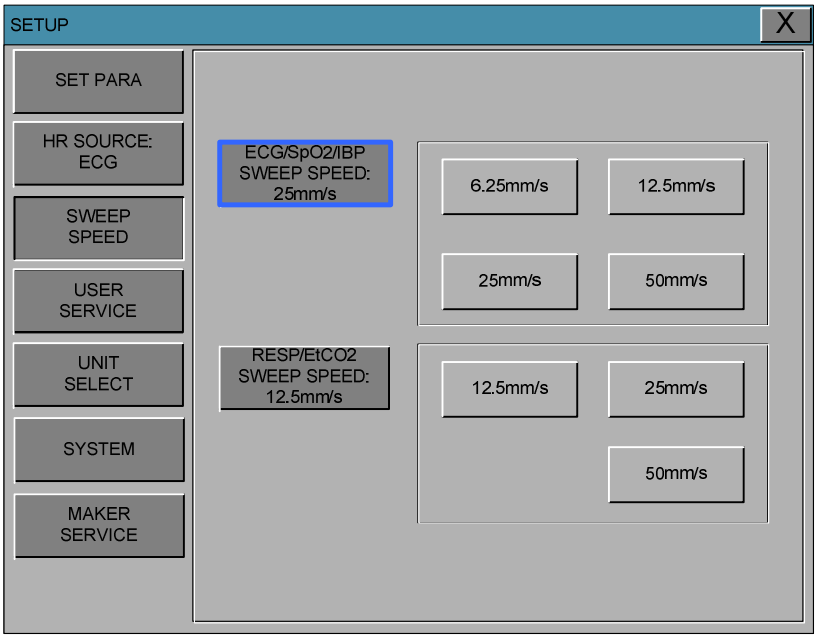
This menu is used to set the source that detects heart and pulse rate.

The source can select among ECG and SPO2. Select AUTO ECG/SPO2 parameter turned on after checking both when on ECG as a priority to display.



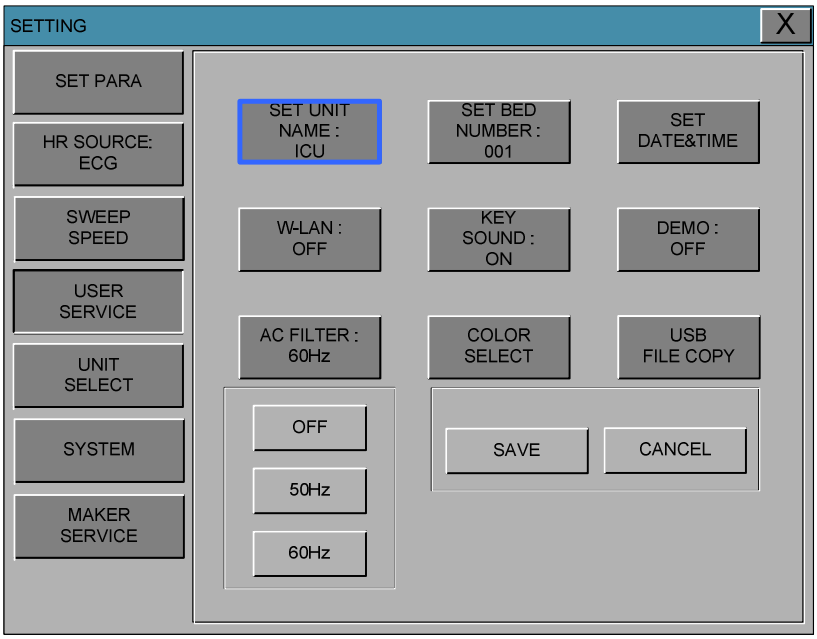
SET SWEEP

Set speed of drawing wave signal pattern in this widow.



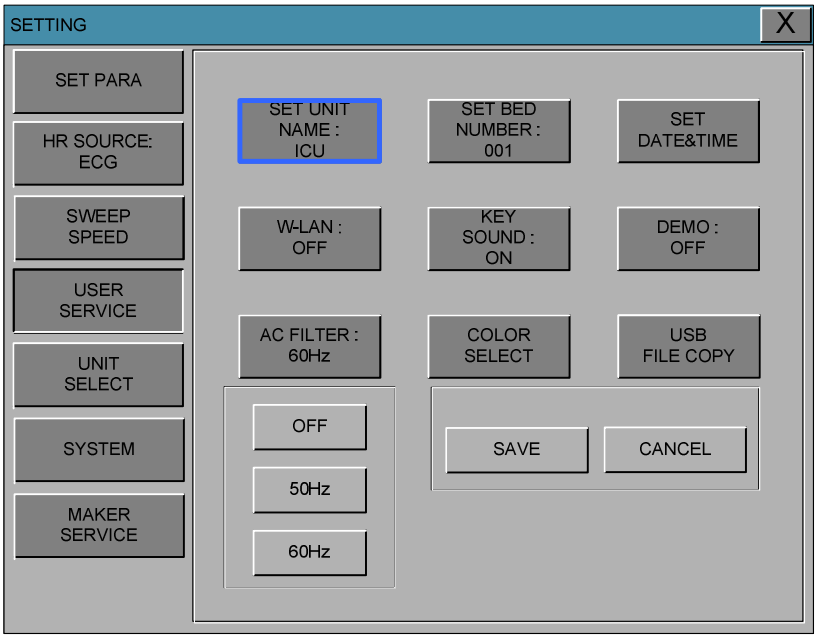
USER SERVICE

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



SET UNIT NAME

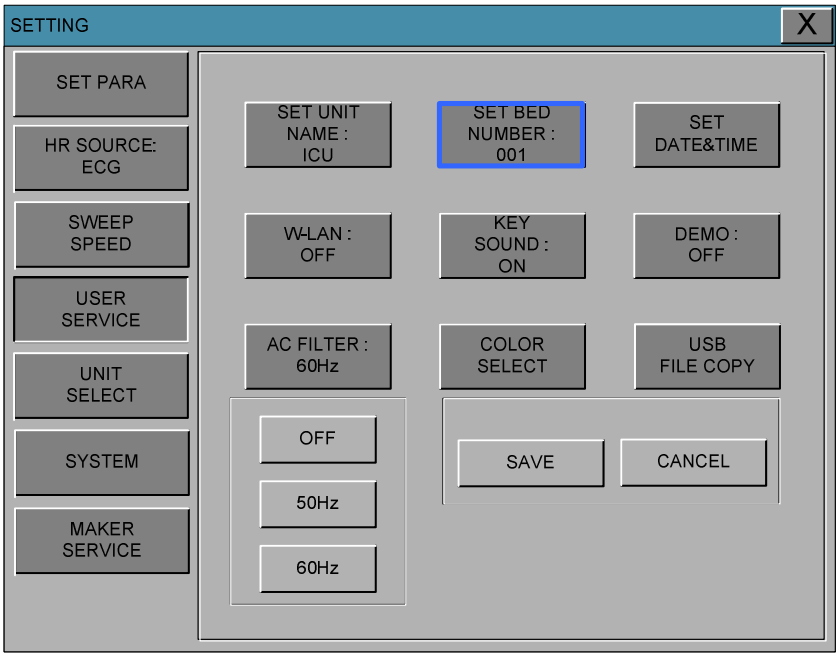
Set up for Equipment name

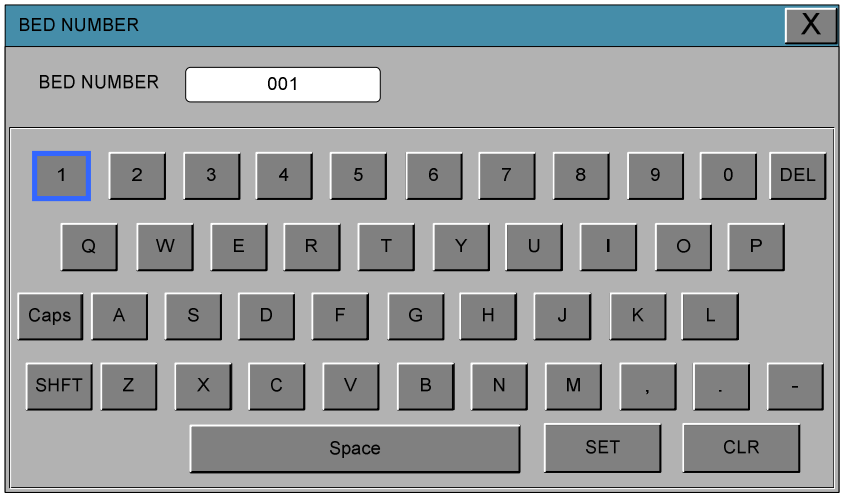


SET BED NUMBER

Set up for patient bed number.

Allowable setters are from 1 to 255.

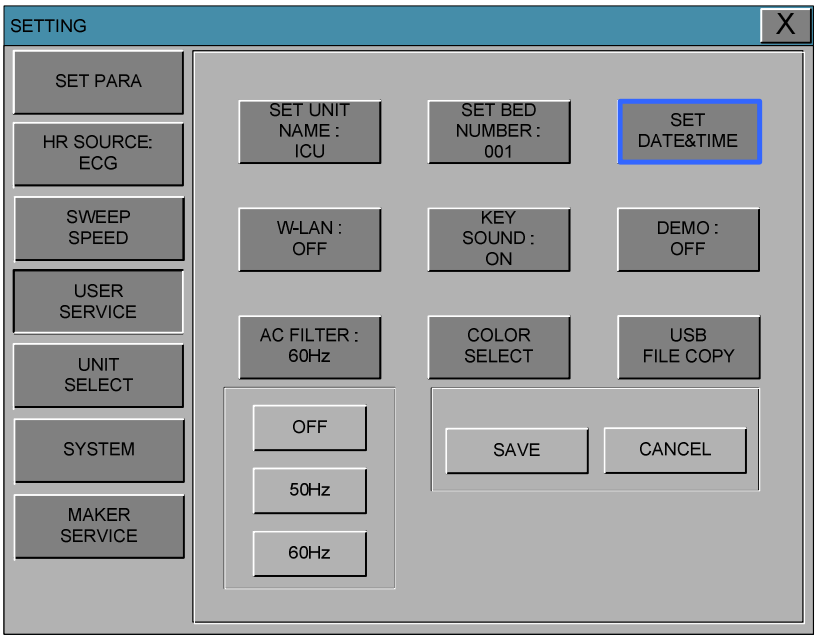


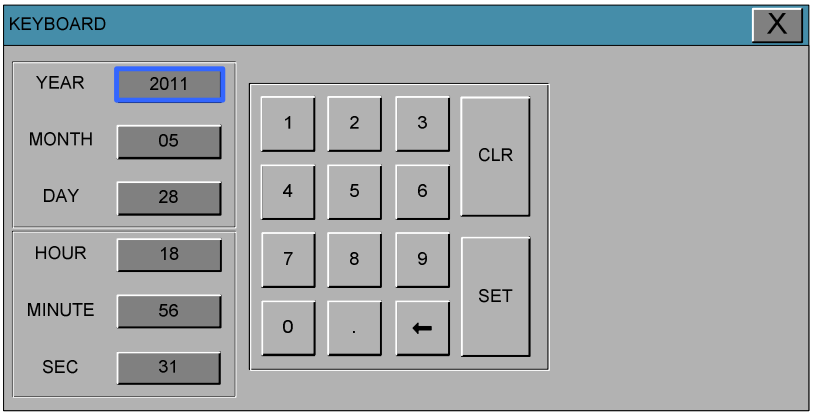


SET DATE & TIME

Set date and time of equipment.

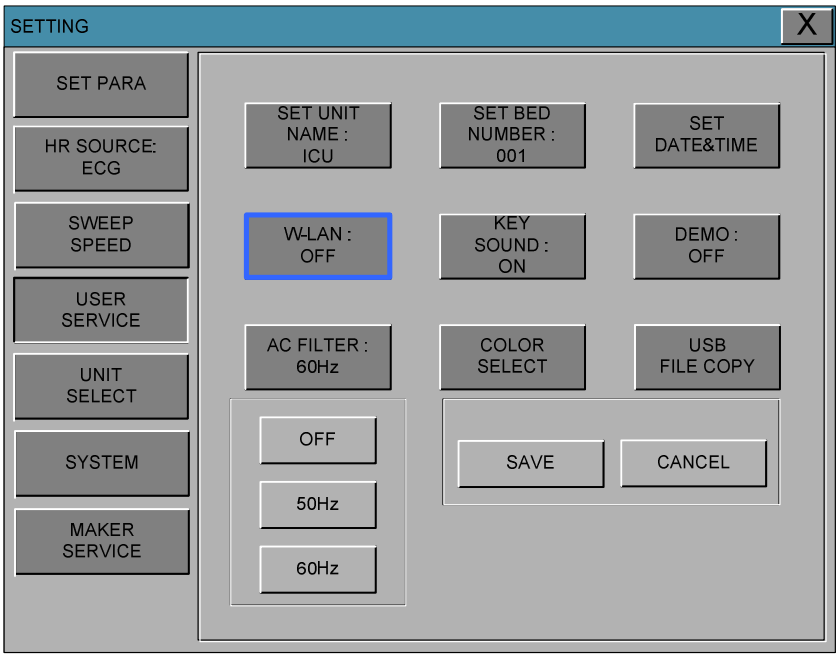
Press the SET button after each input change you want to change the year, month, day, hour, minute, and second item during the setting will be entered.





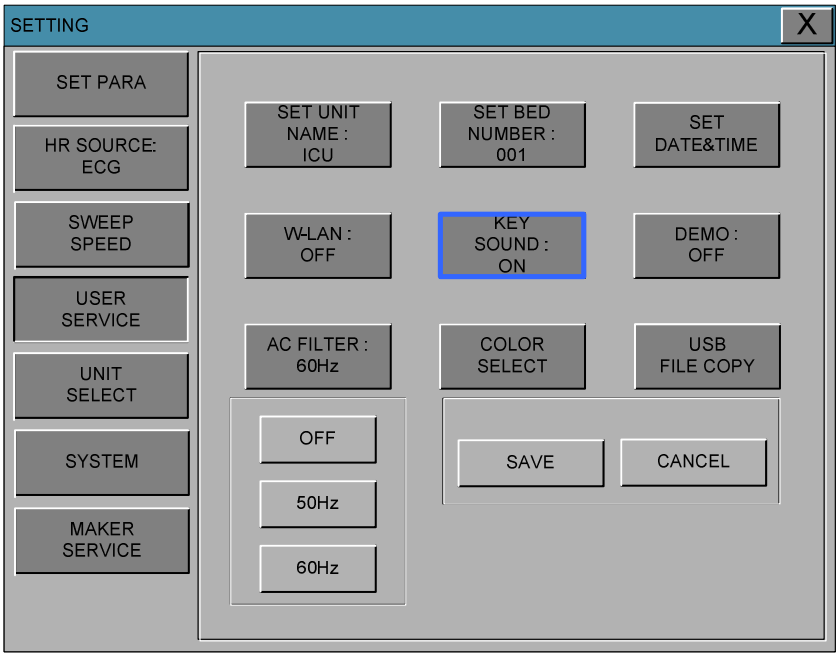
W-LAN

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



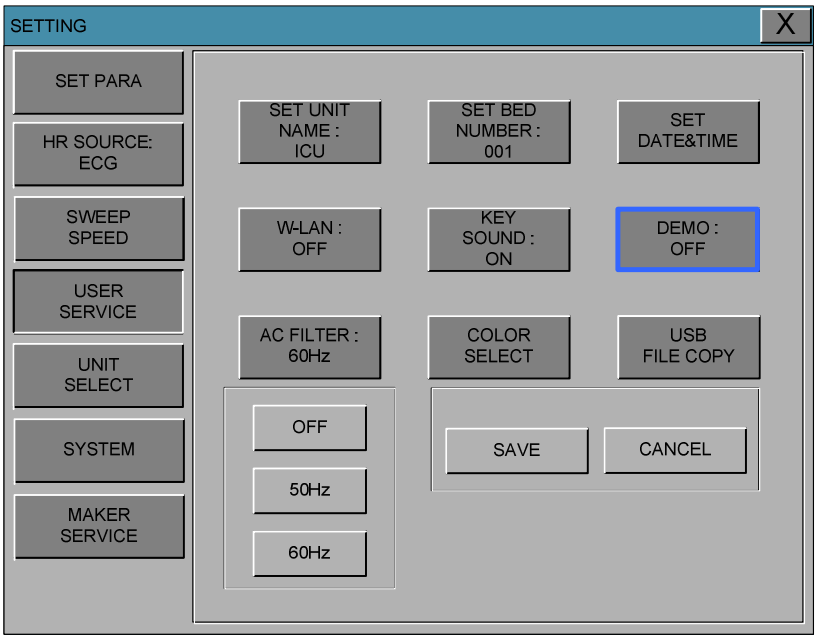
KEY SOUND

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



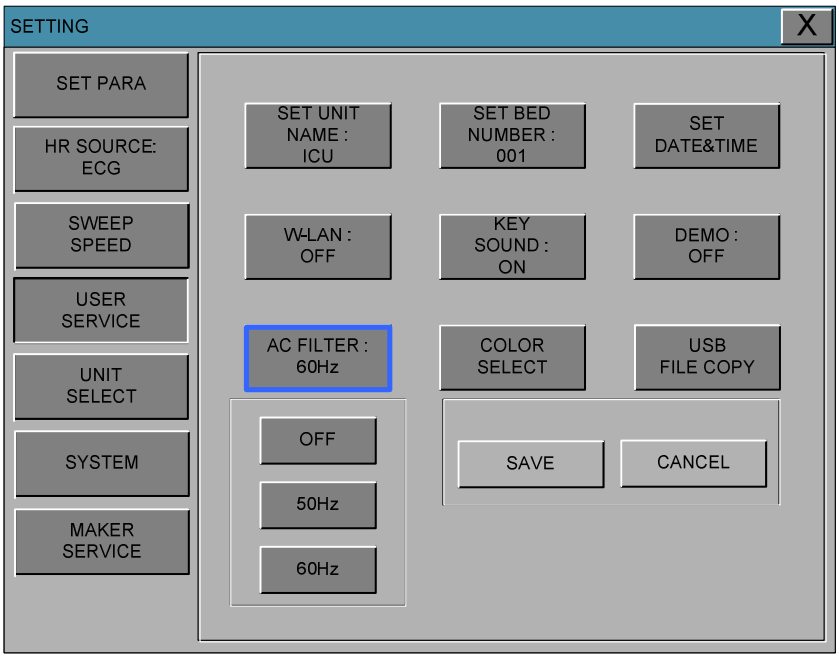
DEMO

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.)

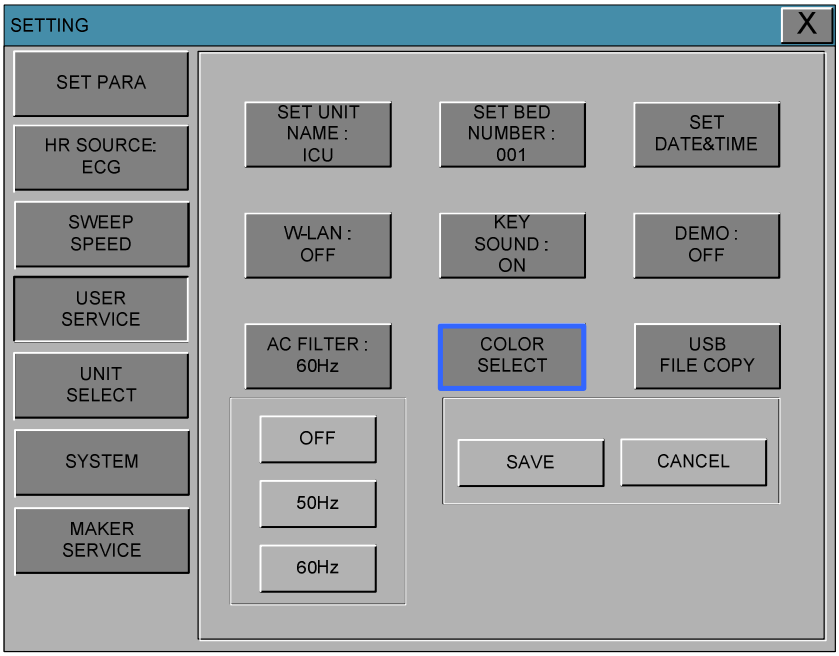


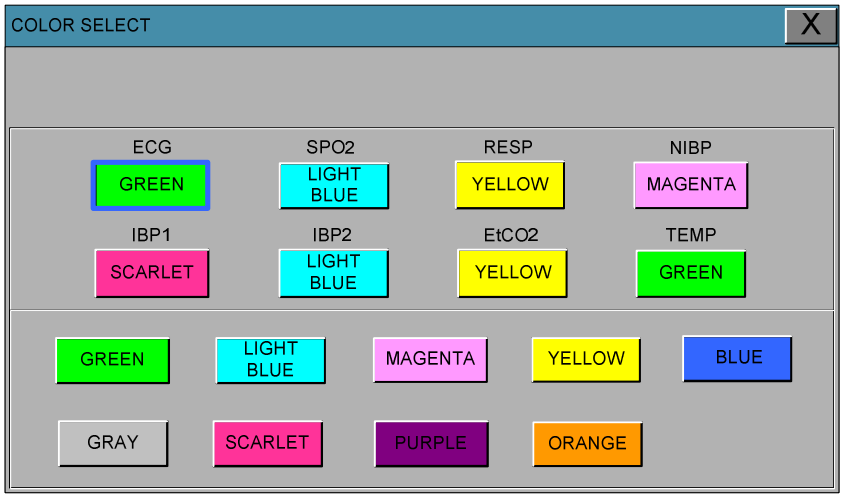
COLOR SELECT

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

It has ten color below table.

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



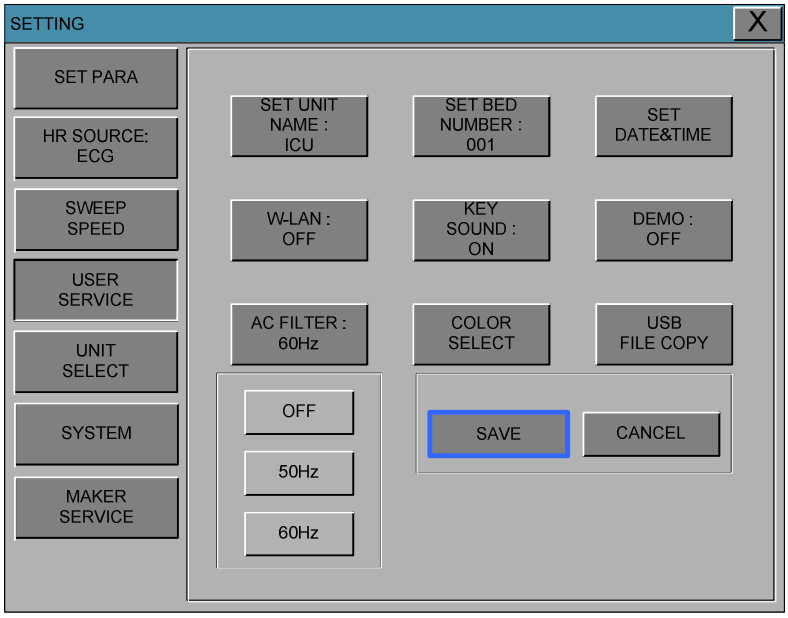


USB FILE COPY

Menu to save the file on the USB.

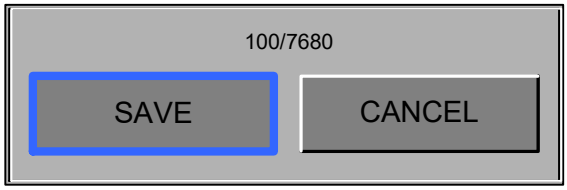
SAVE: command to save TREND DATA in the USB memory.

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

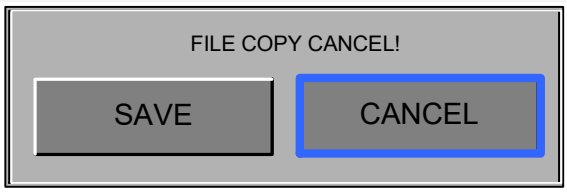


Display the progress of the file data stored.

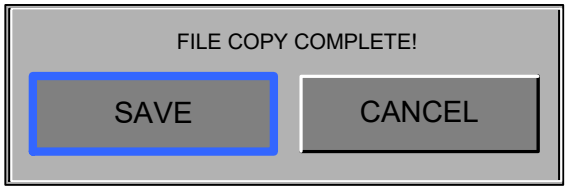
The number on the left is a number of stores, and The number on the right displays the number of the total number.



Data is stored cancel the message display.



Data is stored upon completion message displays.



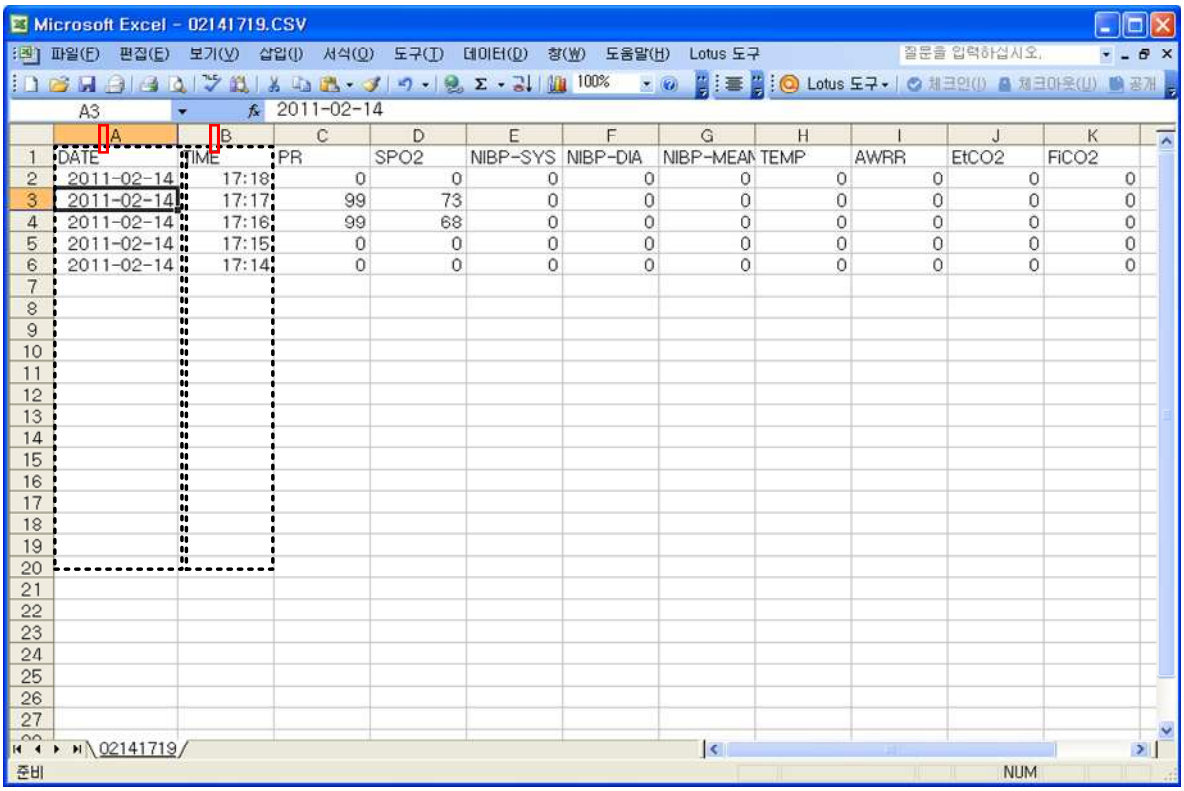
Save the date-hour-minute format. CSV file is stored.

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

is.

① date data items and to properly view the data in this column, the cell format is set to "day-month-year".

② 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 can not work if you remove the USB while stored in USB.

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

UNIT SELECT

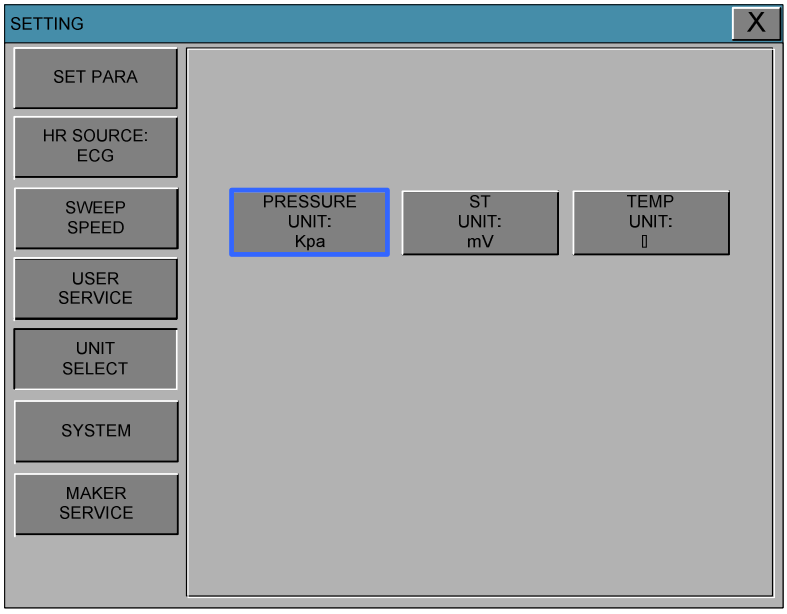
This is the menu for converting the units of BM7.

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

Pressure: kPa ← → mmHg

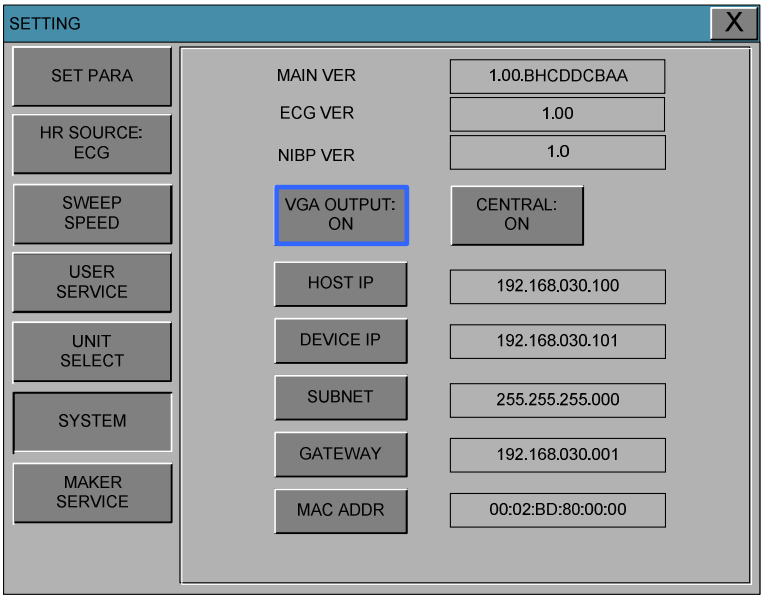
ST mm ← → mV

Temperature: ℃ ← → ℉



SYSTEM

System 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.

HOST IP, DEVICE IP, SUBNET, 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.

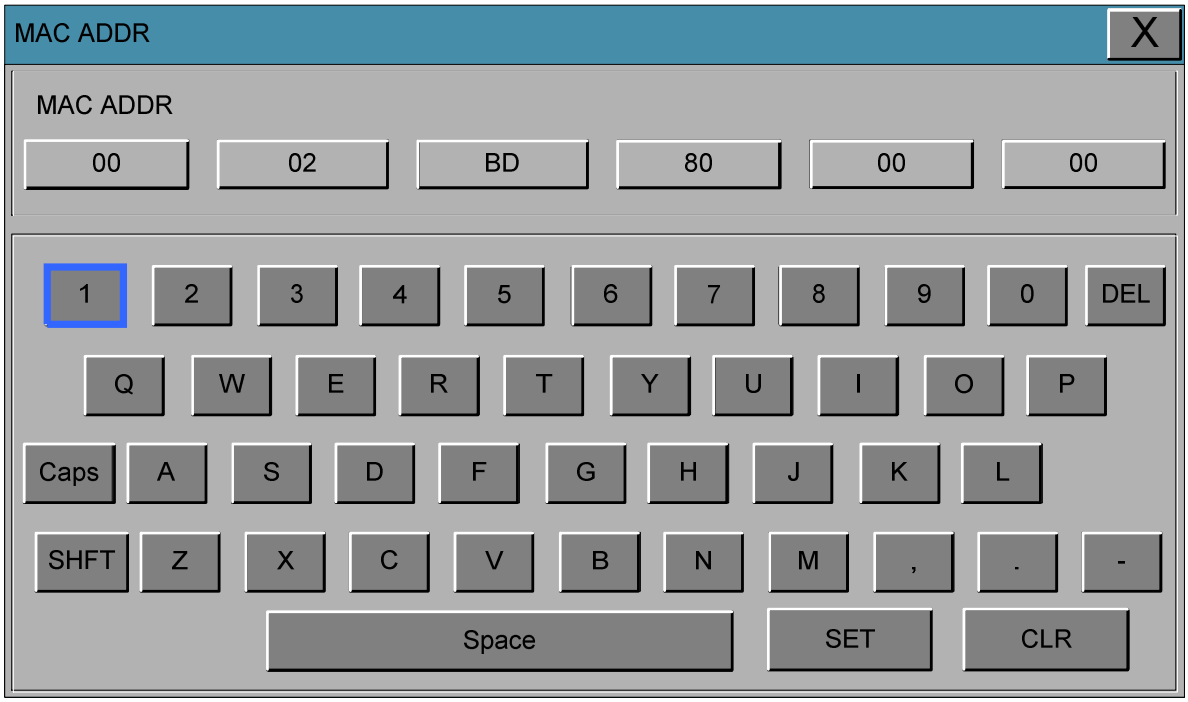
DEVICE IP: Press the SET button to set the address of the sending and receiving equipment.

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

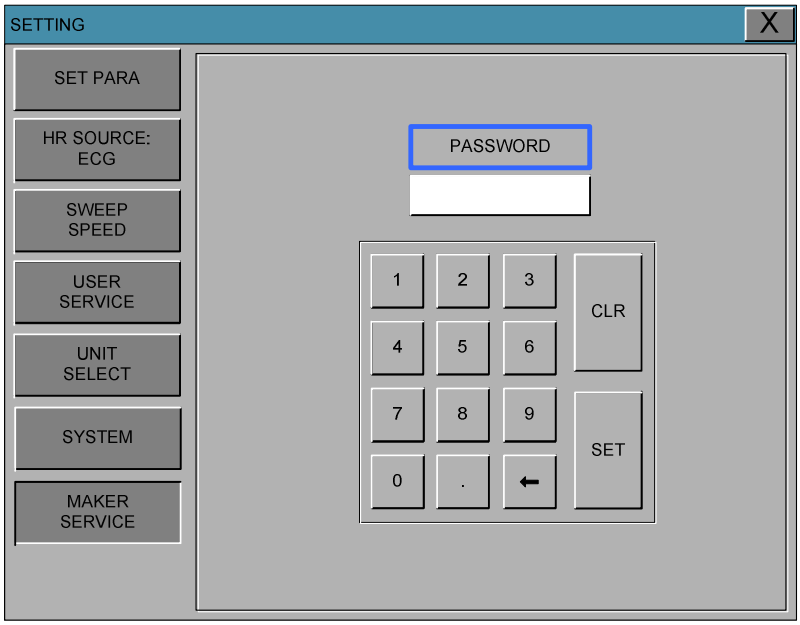
.

MAC ADDR : Press the SET button to set the hardware address for the network settings. (MAC ADDR는 Impossible to modify the user.)



MAKER SERVICE

Maker service is a menu is used by manufacturers.



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

GRAPHIC TREND

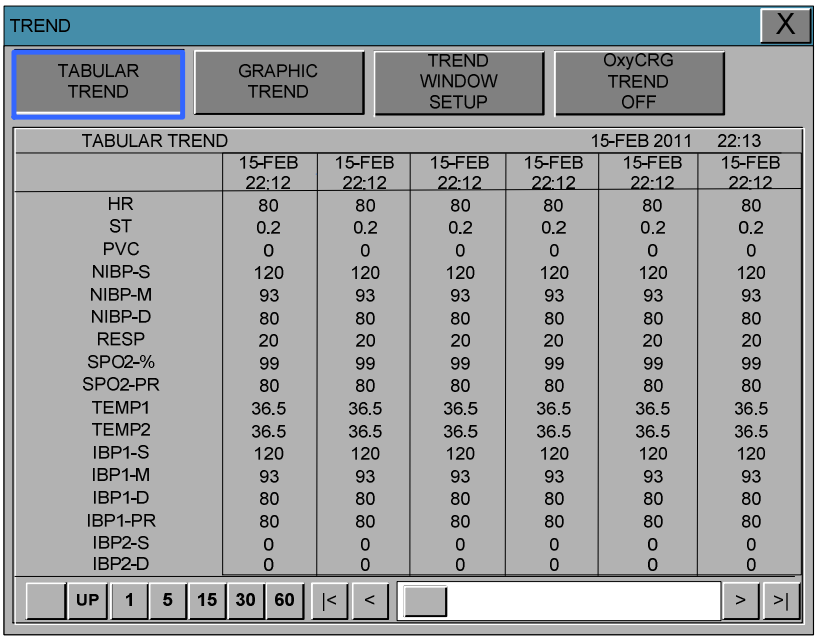
TABLE TREND

TREND WINDOW SETUP

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.



X : Move to main screen.

1 : Move within the tables.

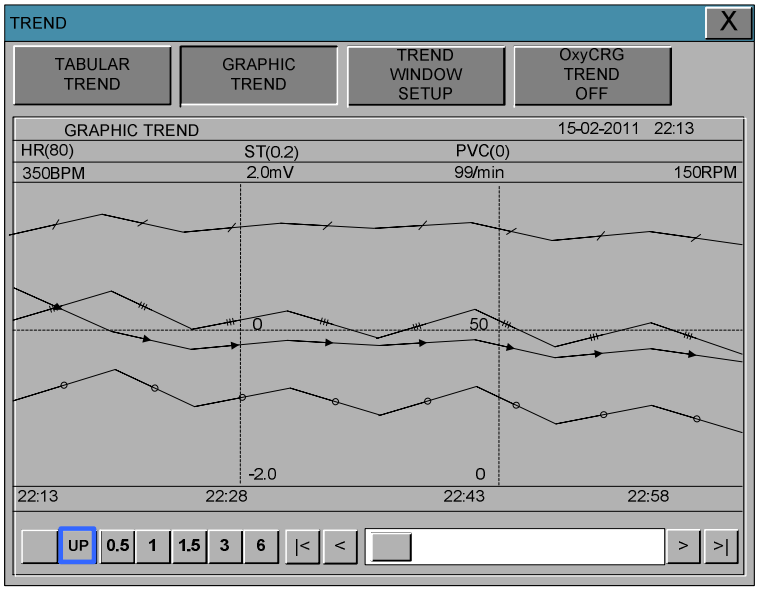
UP : Move to other analysis function.

0.5 1 1.5 3 6

1 5 15 30 60 : Time period set menu

GRAPHIC TREND

Wave Data can be stored and seen according to section.

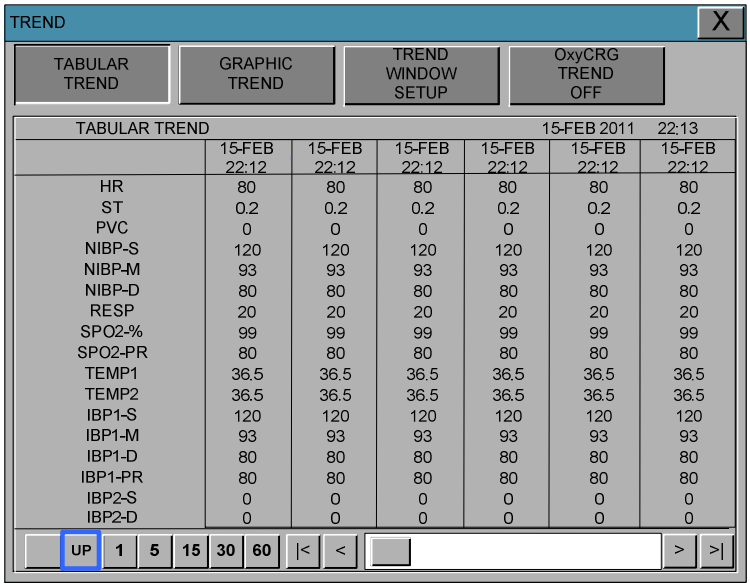


TIME PERIOD

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

TABULAR TREND

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

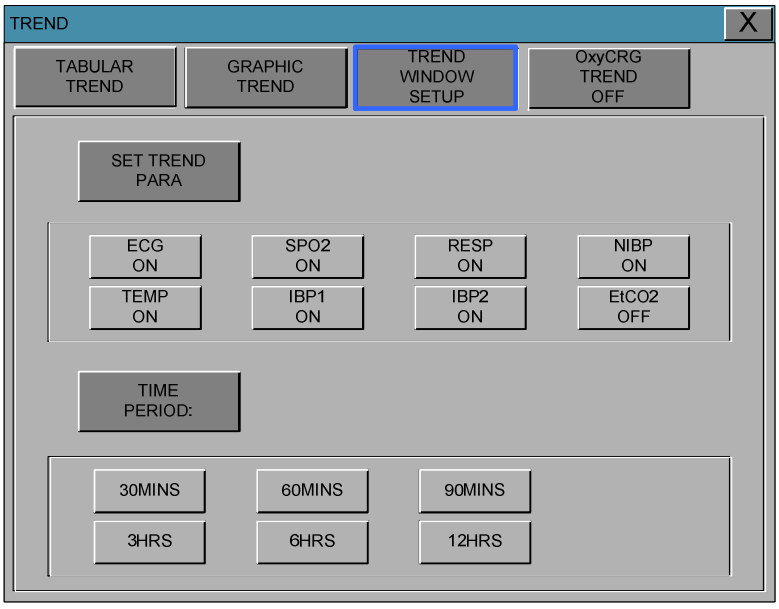


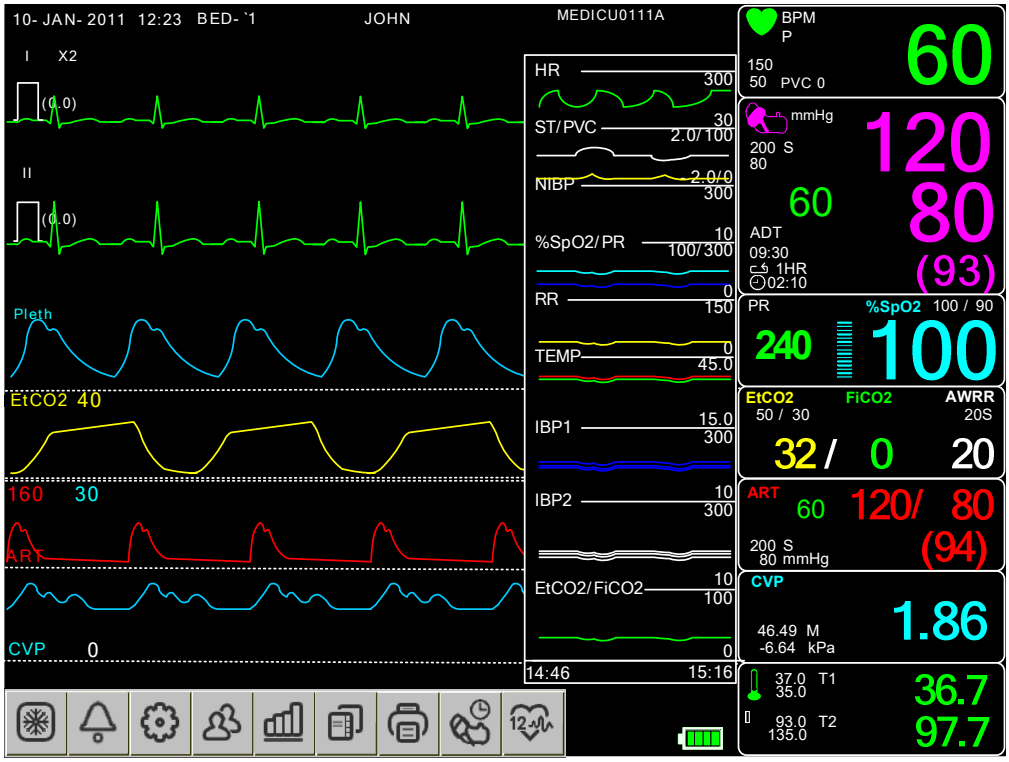
TIME INTERVAL

One can store data and set up time.

TREND WINDOW SETUP

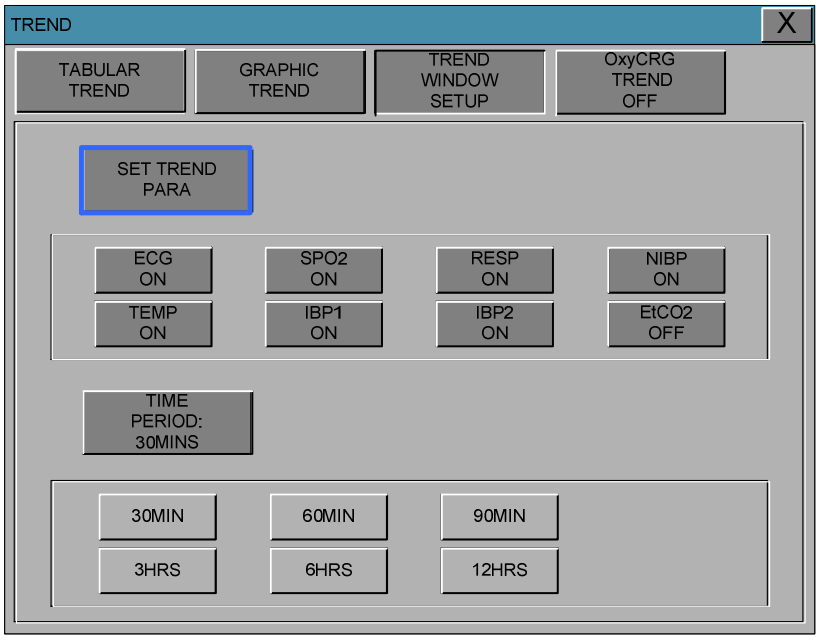
Set the trend display window that will show the real time wave window.





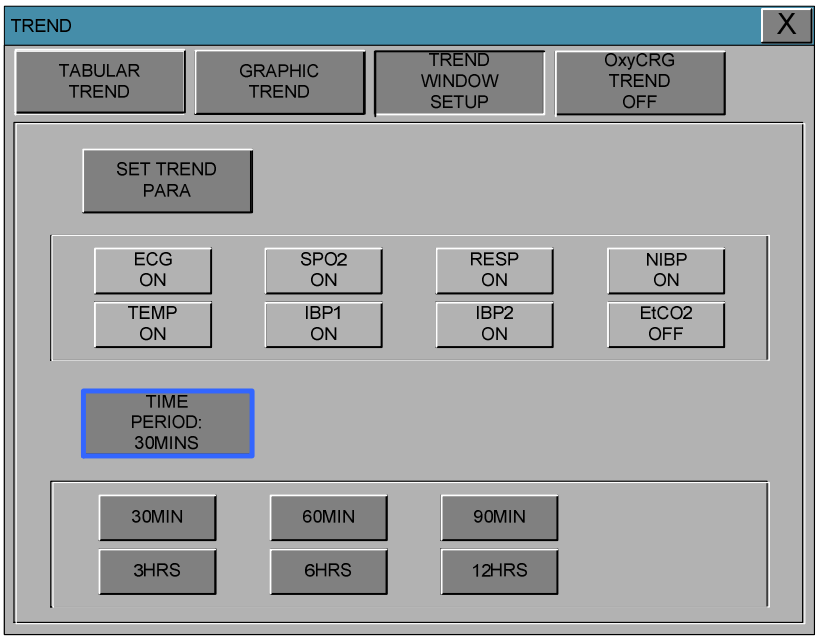
SET TREND PARA

Set visible parameter in a screen.



TIME PERIOD PARA

Set visible time period in a screen.



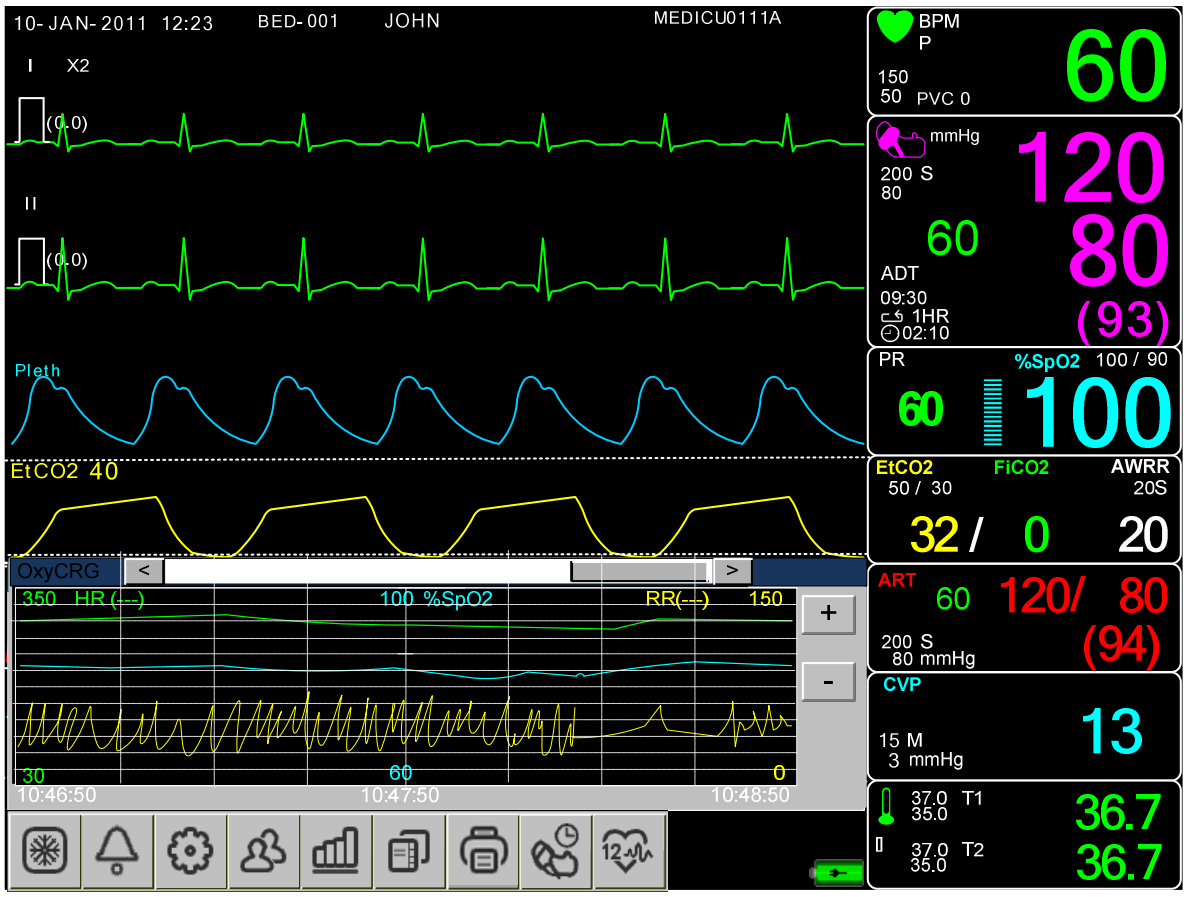
TREND PRINT

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

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

TRACE 1 LEAD SELECT

ALARM LIMIT

ALARM

QRS VOLUME

ECG SIZE

HEART RATE SOURCE

ECG SPEED

ANALYSIS SETTING

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

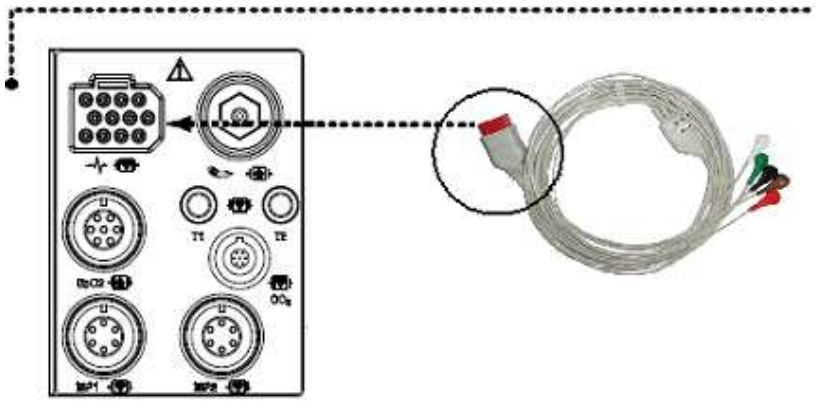
Leadwire	AHA Color code	AHA Label	IEC Color code	IEC Label
Right arm	White	RA	Red	R
Left arm	Black	LA	Yellow	L
Right leg	Green	RL	Black	N
Left leg	Red	LL	Green	F
V1(precordial)	Brown	V1	White	C1

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:

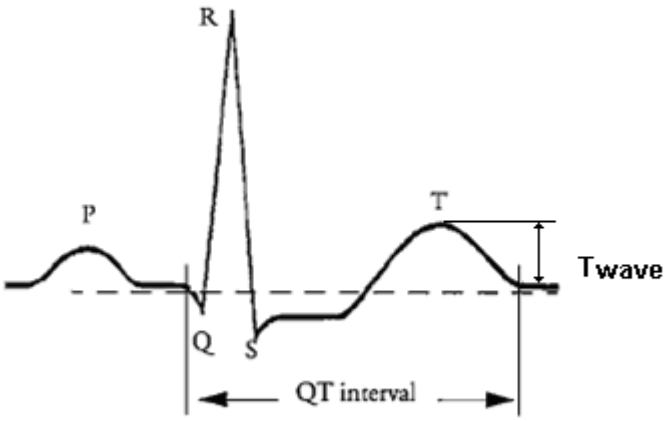
- ✓ QRS should be tall and narrow(recommended amplitude > 0.5mV)
- ✓ R wave should be above or below the baseline (but not bi-phasic)
- ✓ T wave should be smaller than 1/3 R-wave height.
- ✓ The P-wave should be smaller than 1/5 R-wave height.

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.

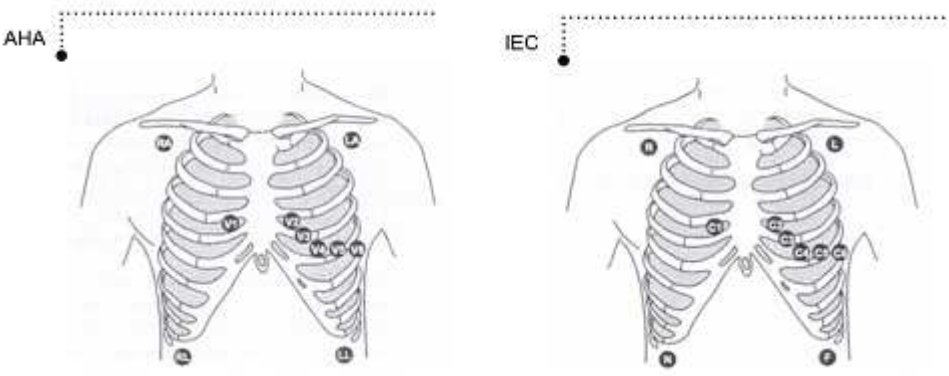
To prevent detection of P-waves or baseline noises as QRS complexes, the minimum detection level for QRS complexes is set at 0.15mV. Adjusting the ECG wave size on the monitor display(gain adjustment)does not affect the ECG signal which is used for arrhythmia analysis. If the ECG signal is too small,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

Information on the ECG waveform

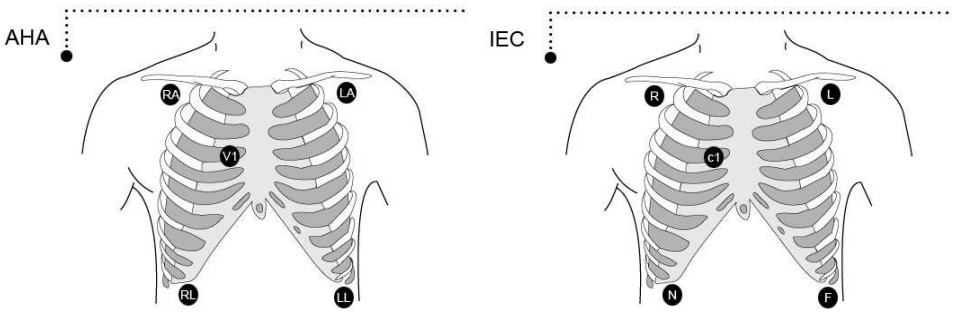


When ECG signal is 80bpm T-wave duration is 180ms, and the QT interval is 350ms.

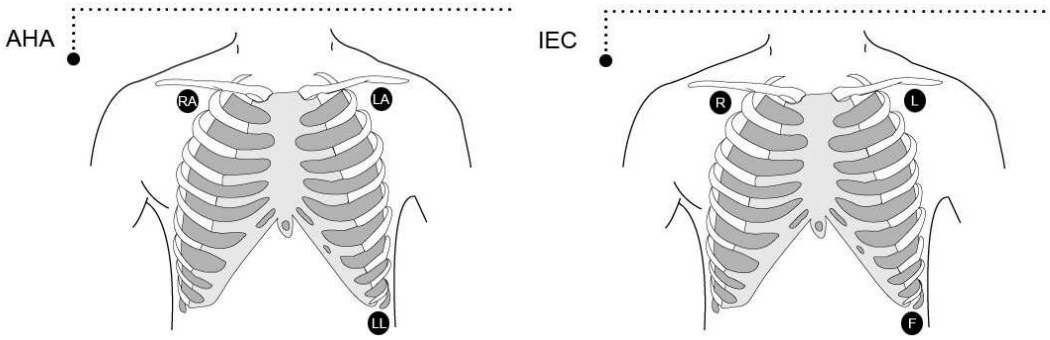
10 Position of 10-Lead



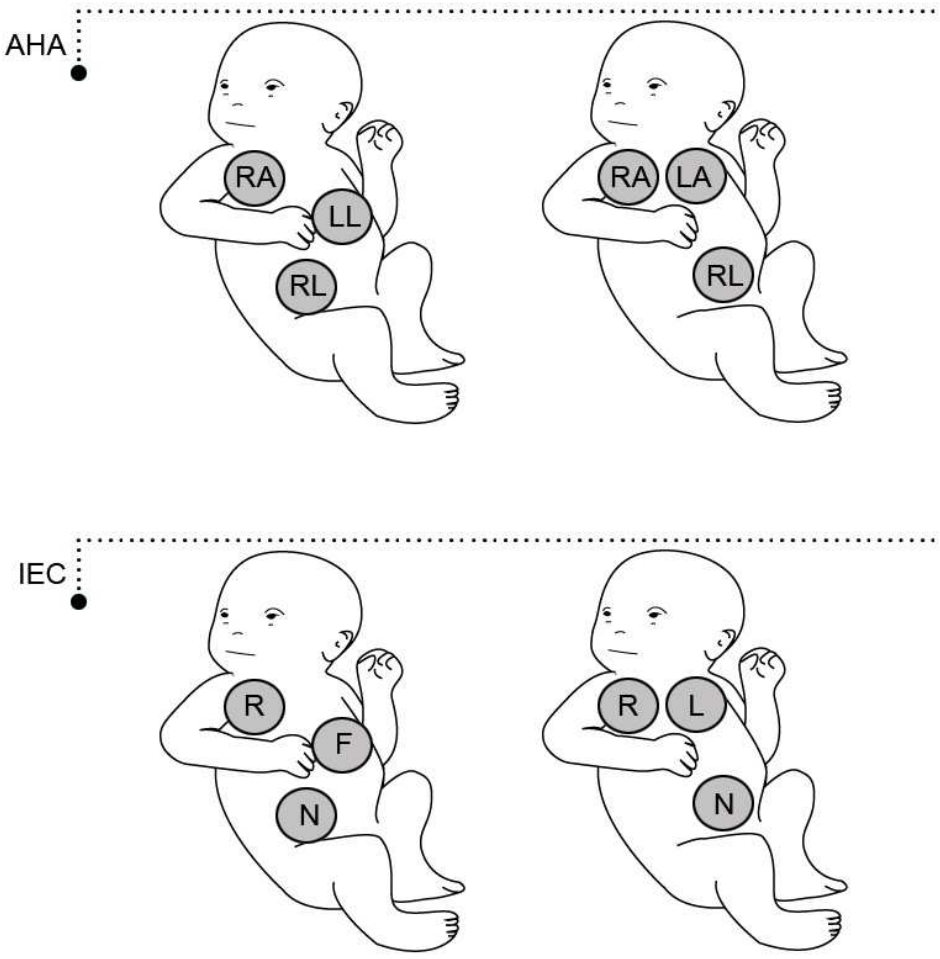
5 Position of 5-Lead



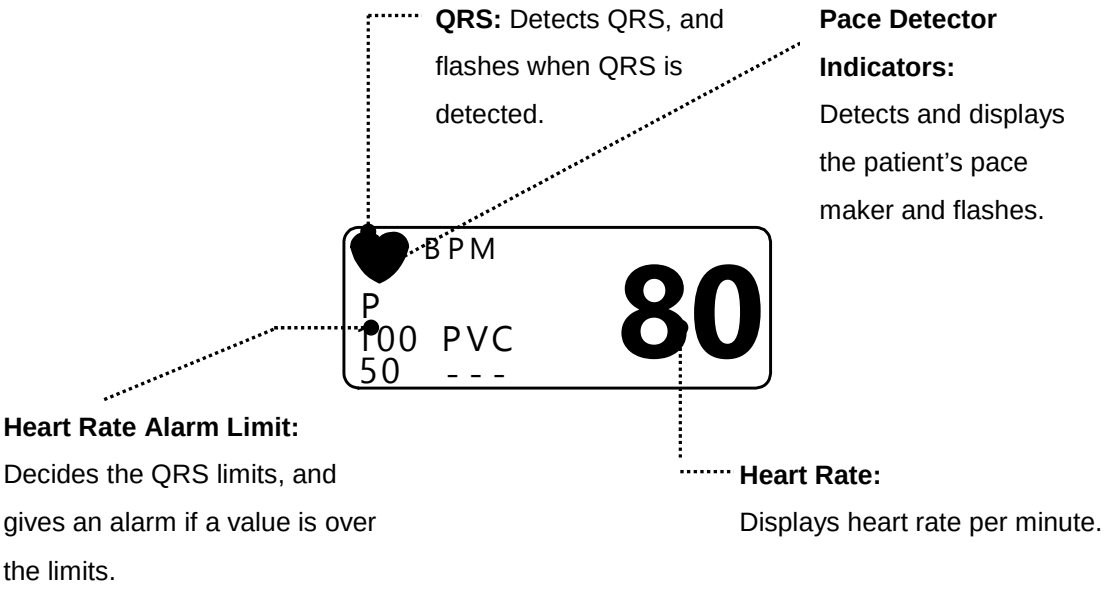
Position of 3-Lead Wrier Electrode



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. ECG 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

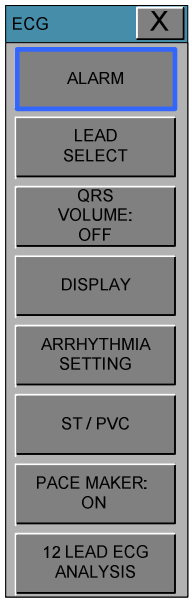
personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, 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.

Electrosurgery Unit

- ✓ Electrosurgical units(ESU) emit 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 opssite 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.

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.

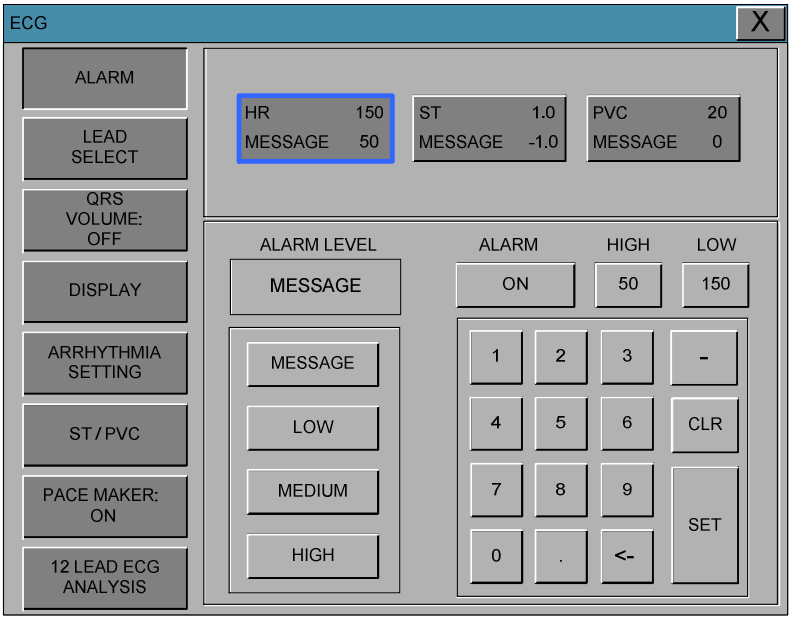


*12LEAD ECG ANALYSIS menu option.

ALARM LIMIT

Alarm Limit is 0 ~ 350BPM.

ECG alarm feature ON / OFF and the menu is set to LEVEL.



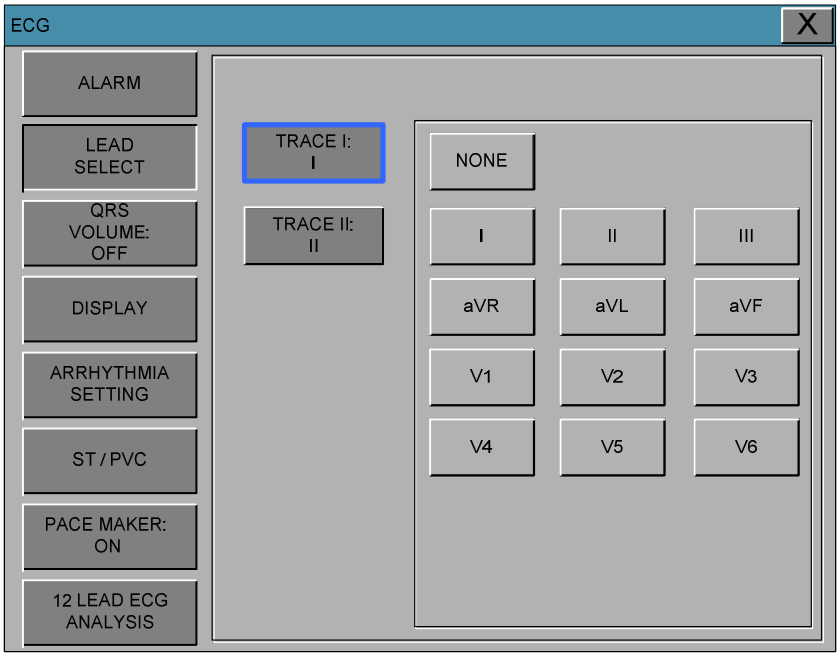
*12LEAD ECG ANALYSIS menu option.

LEAD SELECT

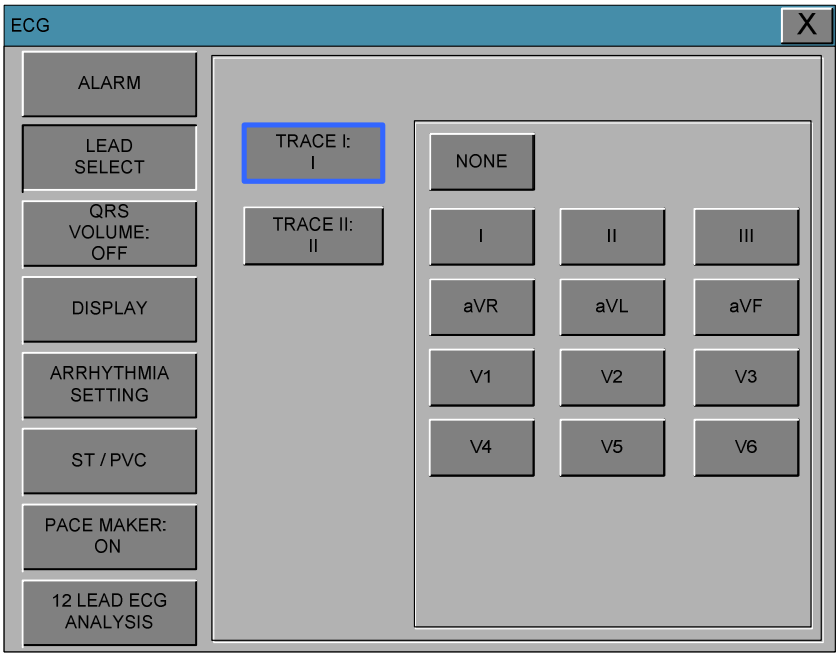
Select channels from I to V in ECG

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

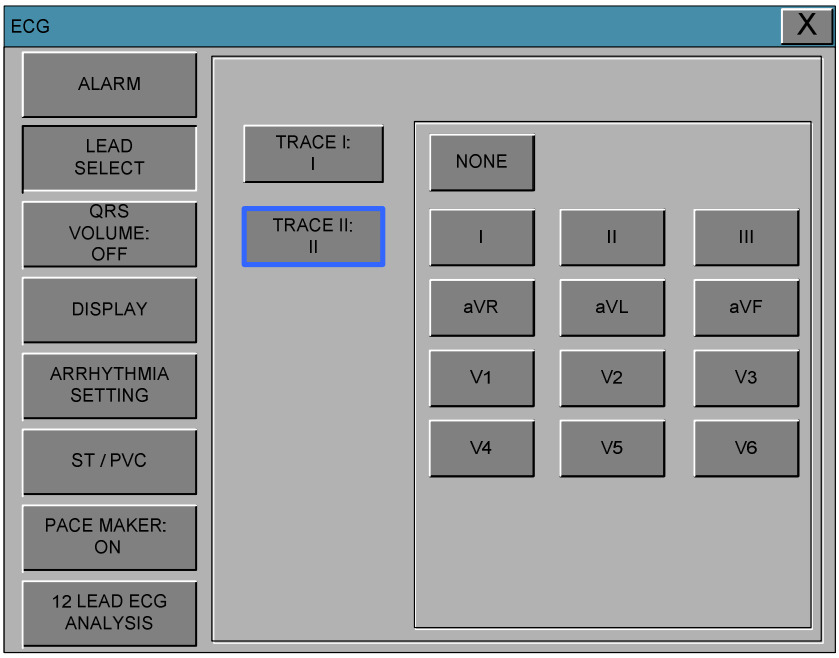
Lead I, II, III, aVR, aVL, aVF, V show up in case of connecting 5-Leads ECG Cable.
(*12LEAD ECG ANALYSIS menu option.)



TRACE I SELECT MENU



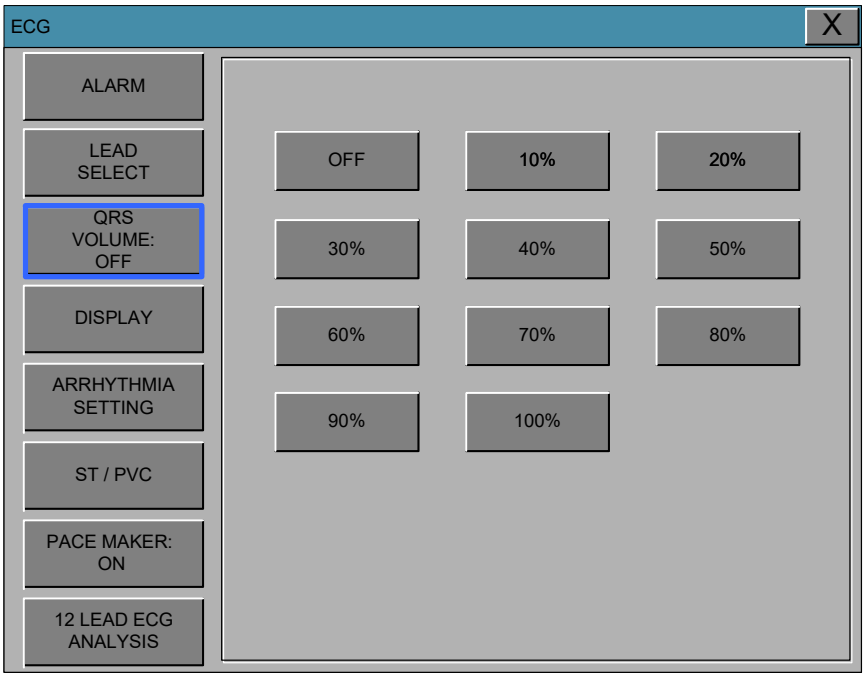
TRACE II SELECT MENU



QRS VOLUME

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

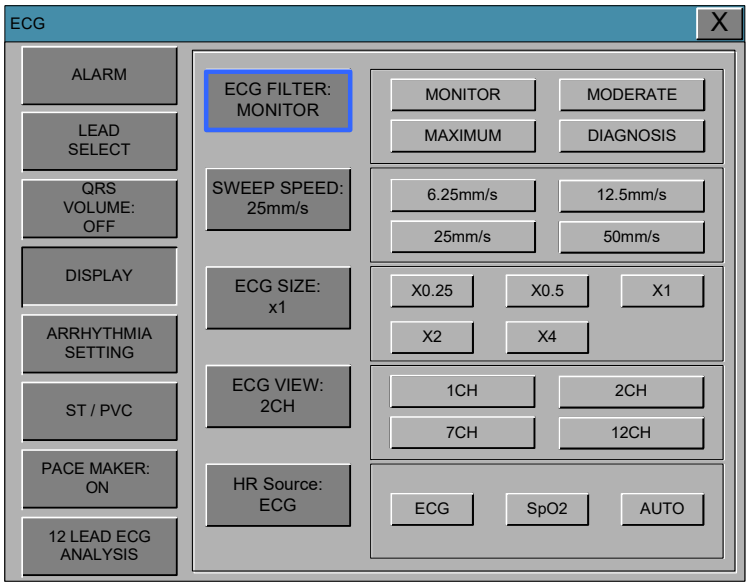
SpO2 volume setting is set OFF automatically.



*12LEAD ECG ANALYSIS menu option.

DISPLAY

Set the sweep speed and waveform size.



*12LEAD ECG ANALYSIS menu option.

ECG FILTER

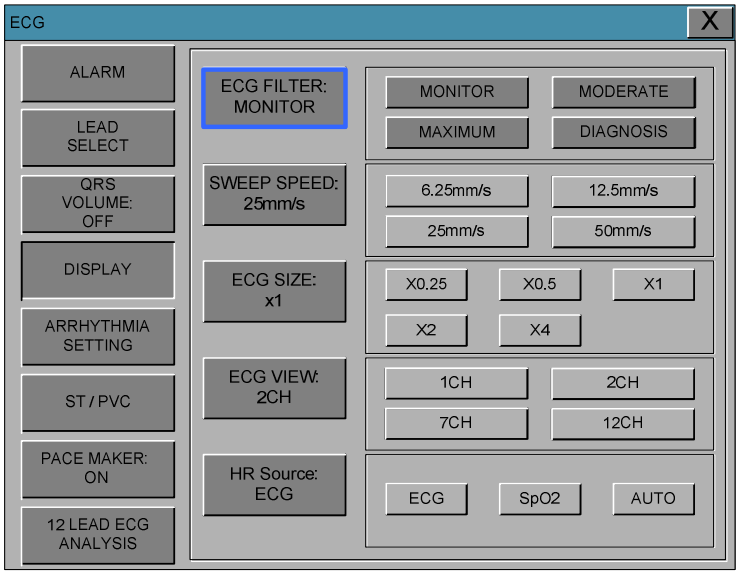
One may select from three frequency types for WAVE FILTER.

MONITOR 0.5Hz ~ 40Hz

MODERATE 0.5Hz ~ 25Hz

MAXIMUM 5Hz ~ 25Hz

DIAGONOSIS 0.05Hz ~ 150Hz

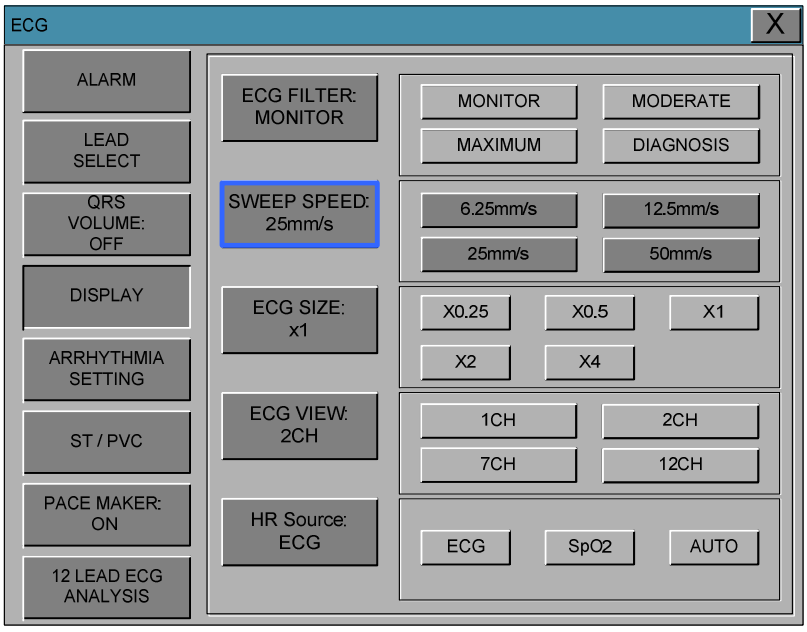


*12LEAD ECG ANALYSIS menu option.

ECG **SWEEP** SPEED

ECG speed on the LCD is 25 mm/s.

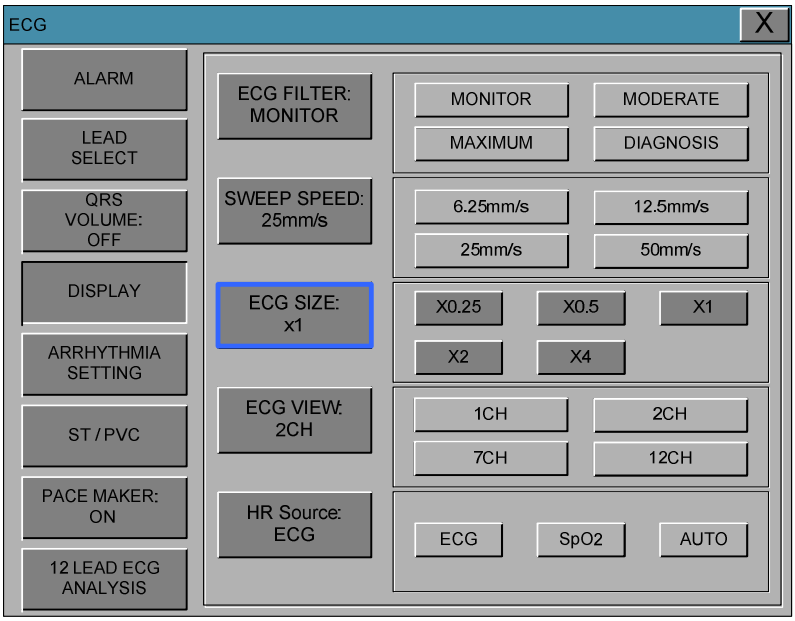
Speed is changeable to 6.25, 12.5, 25, 50mm/s.



*12LEAD ECG ANALYSIS menu option.

ECG SIZE

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



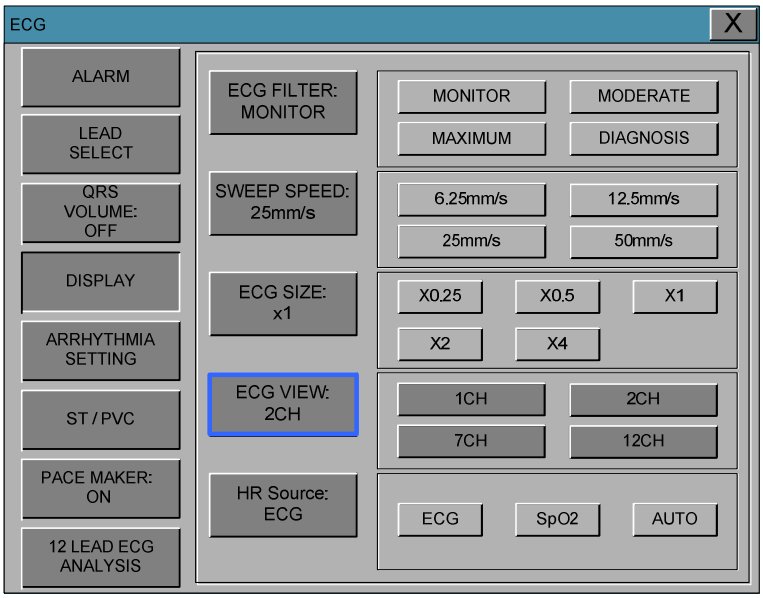
*12LEAD ECG ANALYSIS menu option.

ECG VIEW

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

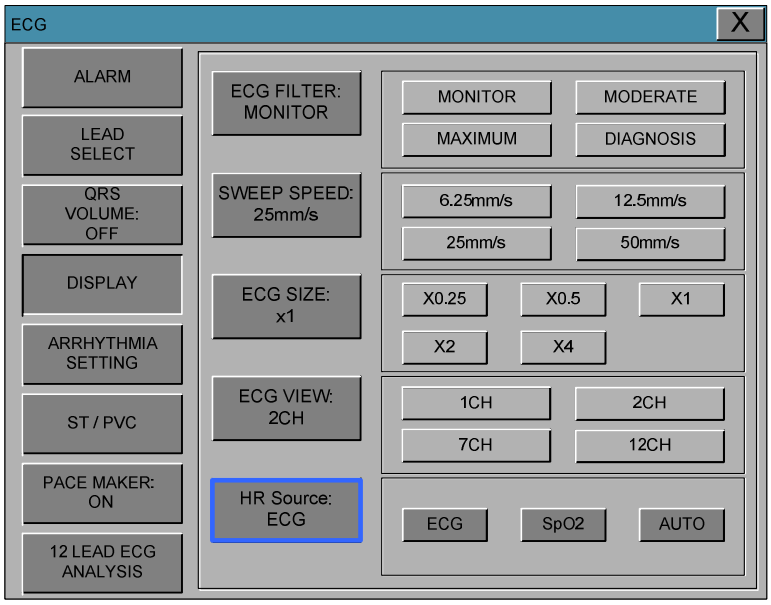
In case of 1 CH, there are 2 traces of 1 CH data at the ECG wave.

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



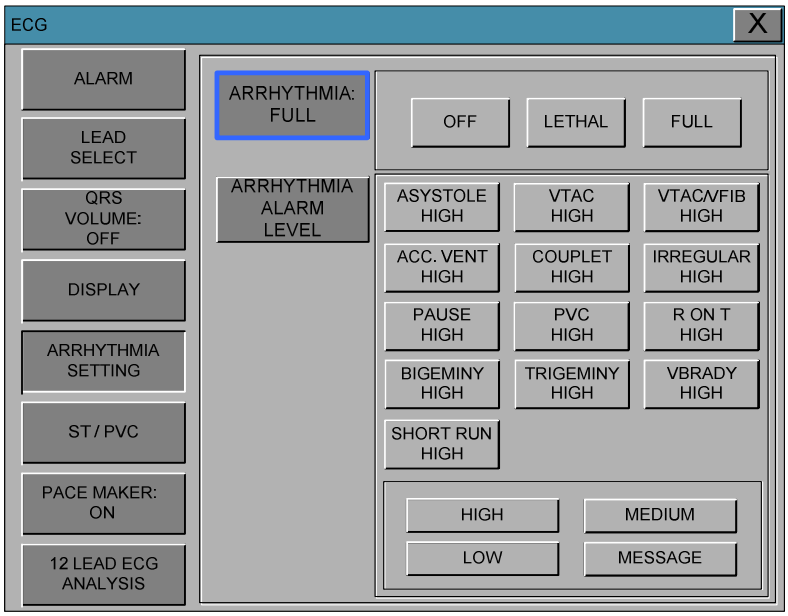
HR Source

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).

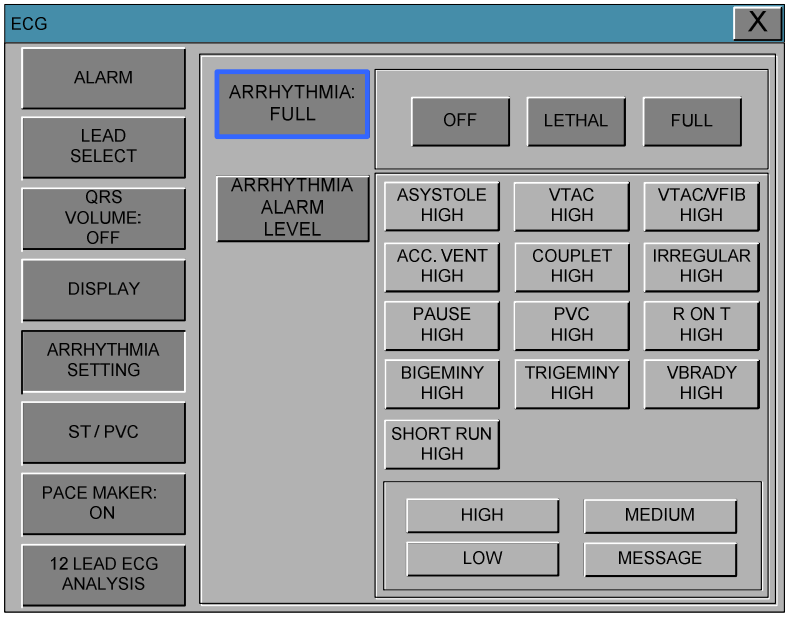
OFF: Do not perform arrhythmia diagnosis.

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.

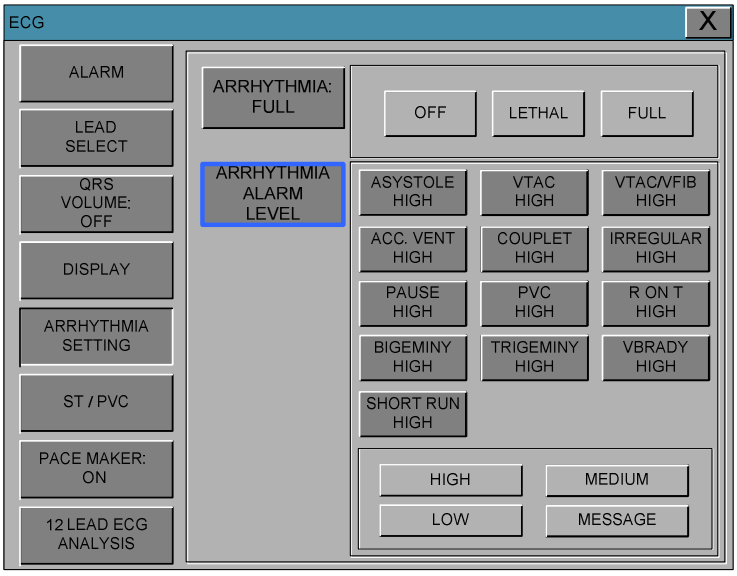
0-2, 3-10, and 11-13 years—Occurs when a run of three or more ventricular beats is detected with an average heart rate that is less than or equal to 60 beats per minute.

VFIB/VTAC

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

ARRHYTHMIA ALARM LEVEL

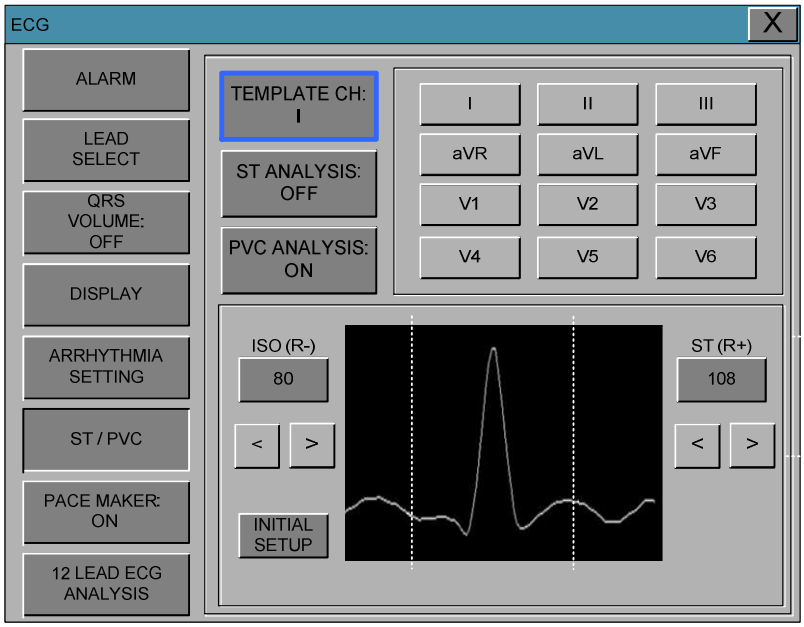
Diagnostic alarm level is set.



*12LEAD ECG ANALYSIS menu option.

ST/PVC

ST signal and setting related ST menu and PVC menu.



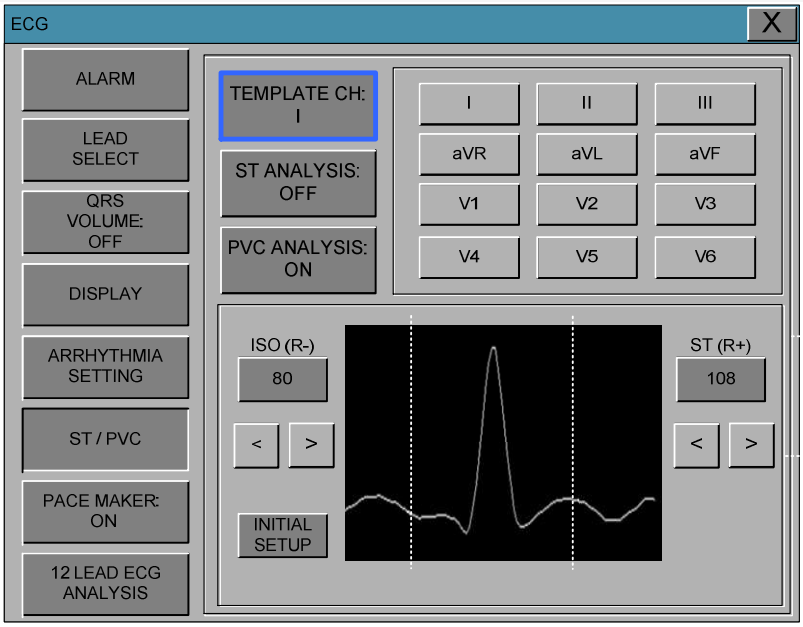
*12LEAD ECG ANALYSIS menu option.

TEMPLETE CH:

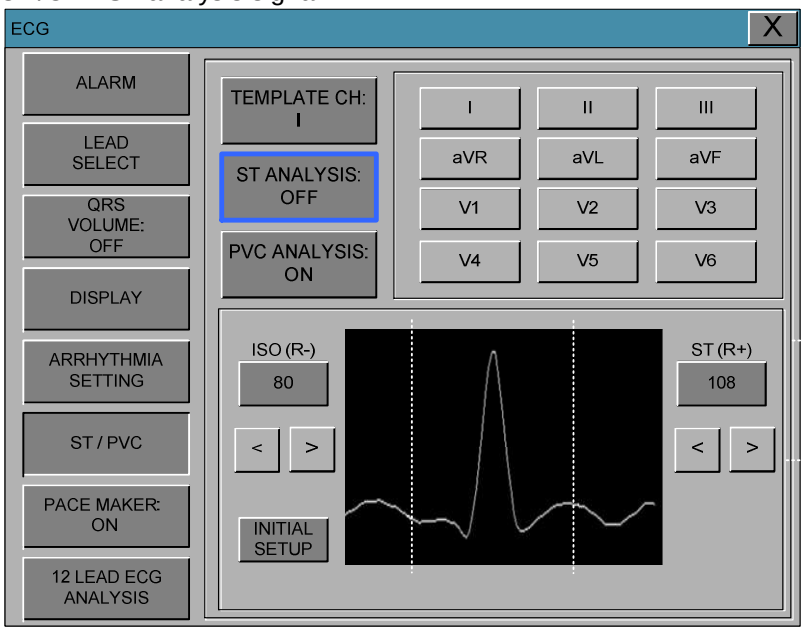
TEMPLETE SELECT: Select a Representative Lead of ST LEVEL.

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

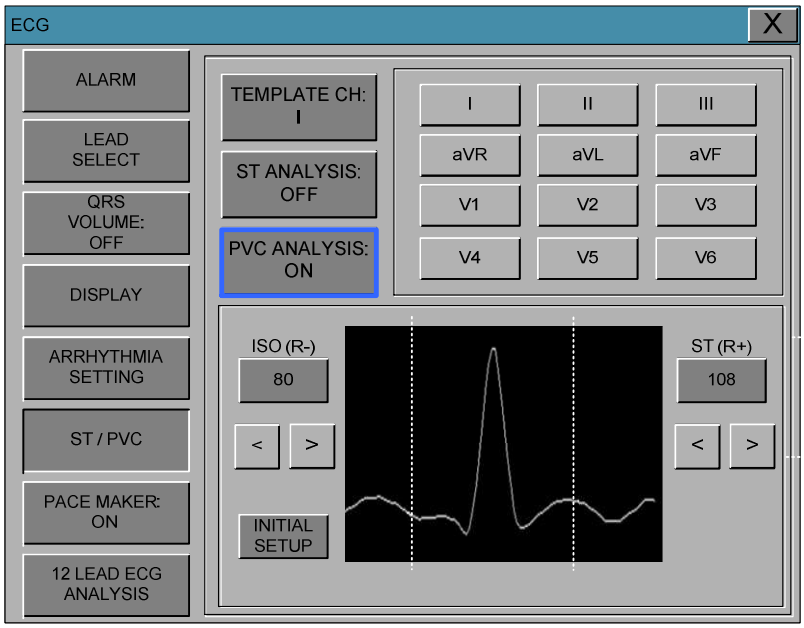
* 3lead is fixed in lead II



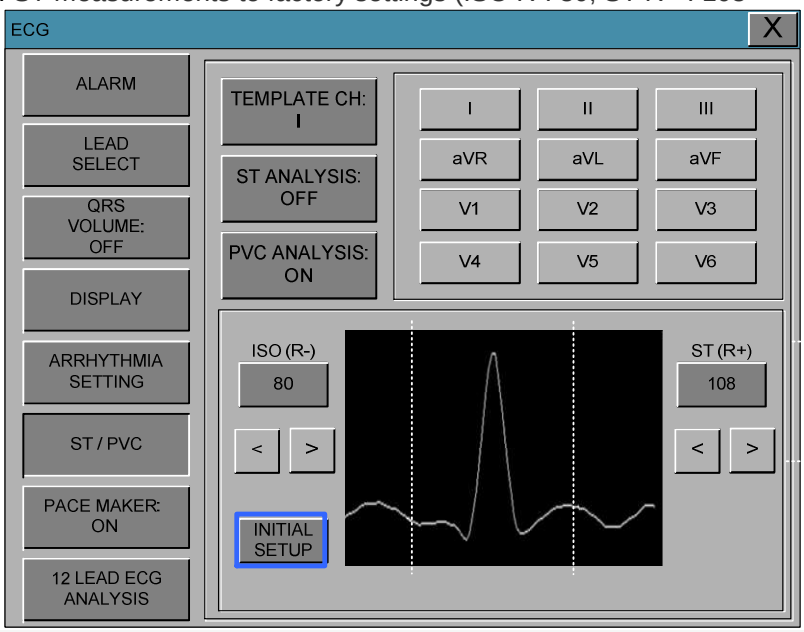
ST ANALYSIS: ON/OFF ST analysis signal.



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

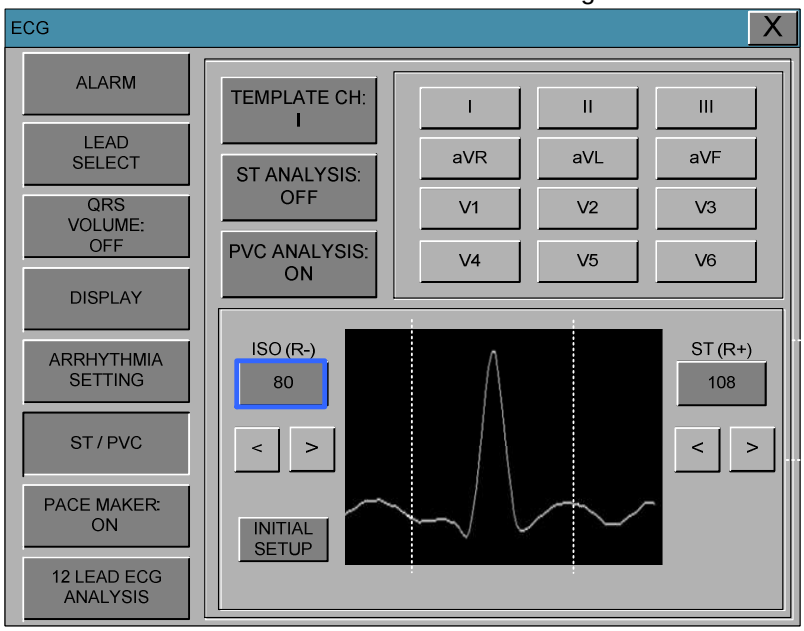


INITIAL SETUP: ST measurements to factory settings (ISO R-: 80, ST R +: 108



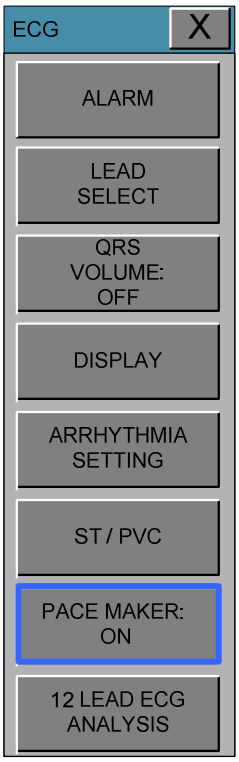
ST MEASUREMENT CONDITION fine-tune the ISO and ST in order to position the cursor keys to select the rotary and then to be adjusted and controlled at ISO and ST TOUCH TOUCH button arrow and then fine-tuning is possible when TOUCH.

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.



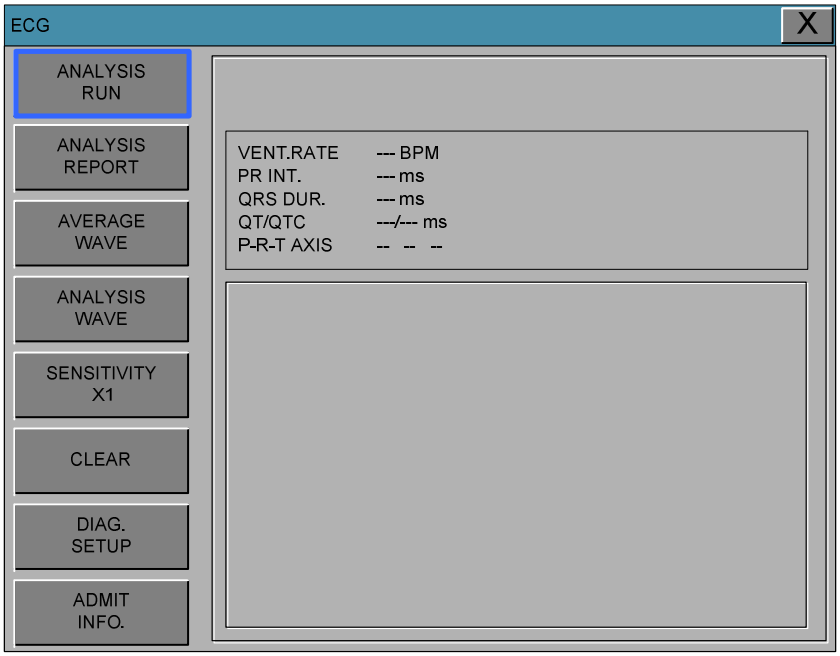
Be aware of the following when monitoring a patient with a pacemaker.

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 rate meter ALARMS. Keep pacemaker patients under close surveillance.

12 CH ECG ANALYSIS

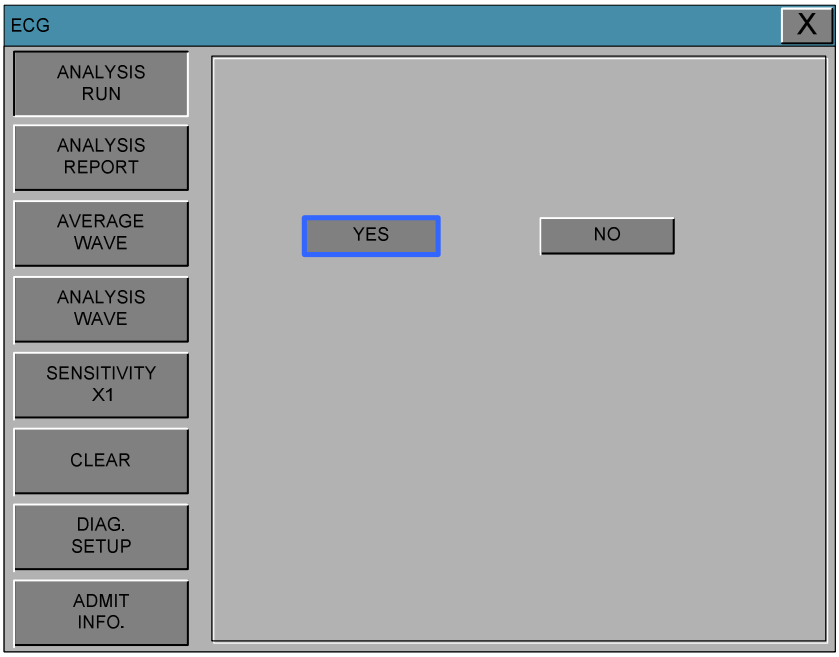
There are 8 sub-menus for 12 CH ECG ANALYSIS menu as following.

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



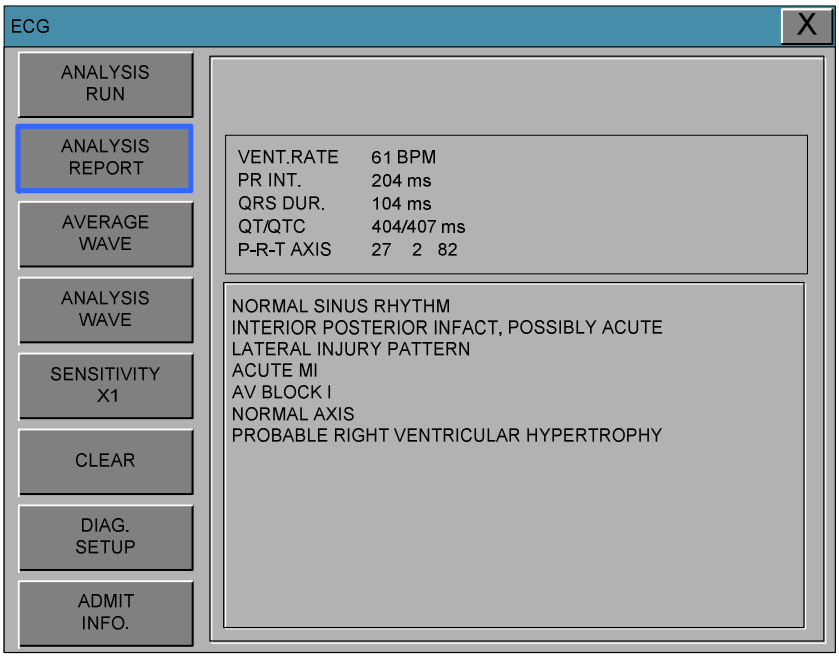
12LEAD ANALYSIS RUN

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)

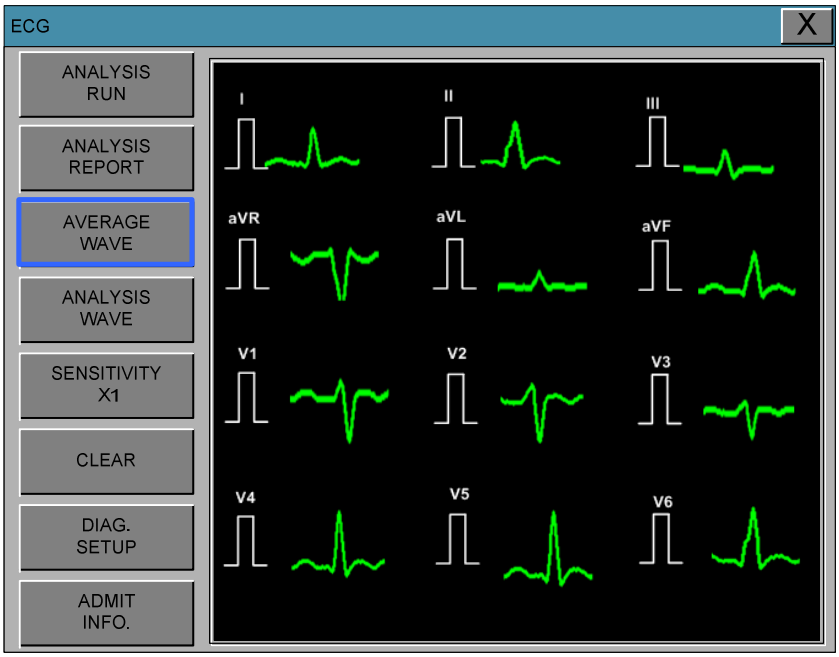
AV and Intraventricular Conduction		
47	411	AV Block I
48	412	AV Block II-1
49	413	AV Block II-2
50	414	2:1 AV Block
51	415	AV Block III
52	421	ICRBBB (Incomplete Right Bundle Branch Block)
53	422	CRBBB (Complete Right Bundle Branch Block)
54	423	Bifascicular Block (RBBB + LPFB)
55	424	Bifascicular Block (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 vectorcardiograms from surface ECG electrodes, not for positioning (floating) temporary pacemaker leadwires, performing pericardiocentesis, or other internal applications

AVERAGE WAVE

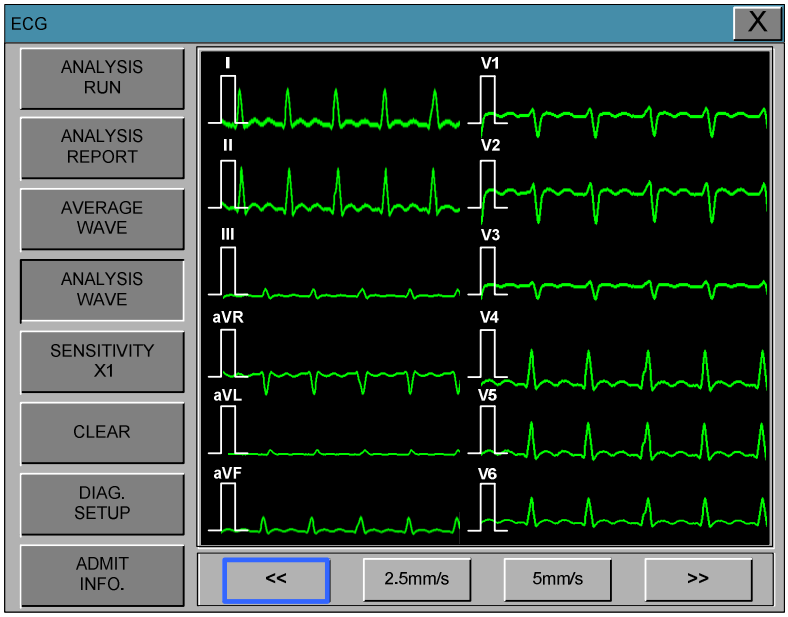
Showing AVERAGE WAVE of each ECG channel when the module interprets them.



ANALYSIS WAVE

Showing interpreted ECG wave for 2.5 seconds period of each 3 channels in total 10 seconds from

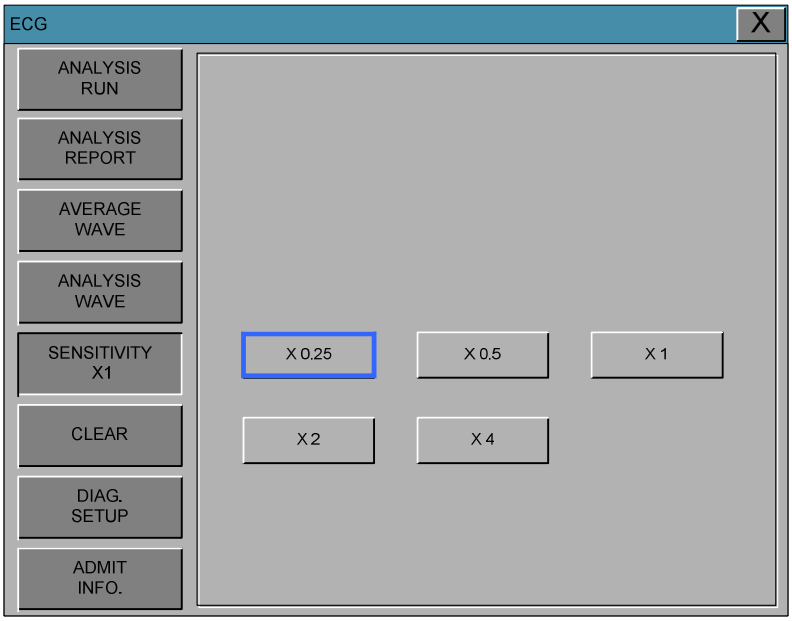
starting Interpretation. For example, each channel shows each time period as CH I, II, III show for 0~2.5 second section, CH aVR, aVL, aVF show in 2.5~5 second section, CH V1, V2, V3 show in 5~7.5 second section and CH V4, V5, V6 show in 7.5~ 10 second section. Under this window, all the ECG channels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



SENSITIVITIY

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

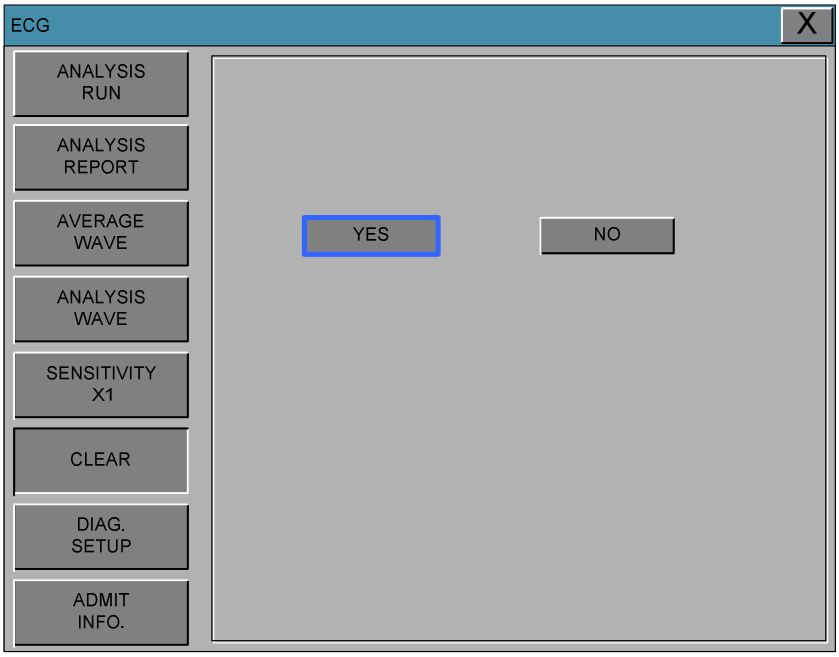
There are 5 kinds of gain from x0.25 to x4 as following.



CLEAR

This is the deleting function for result of interpretation.

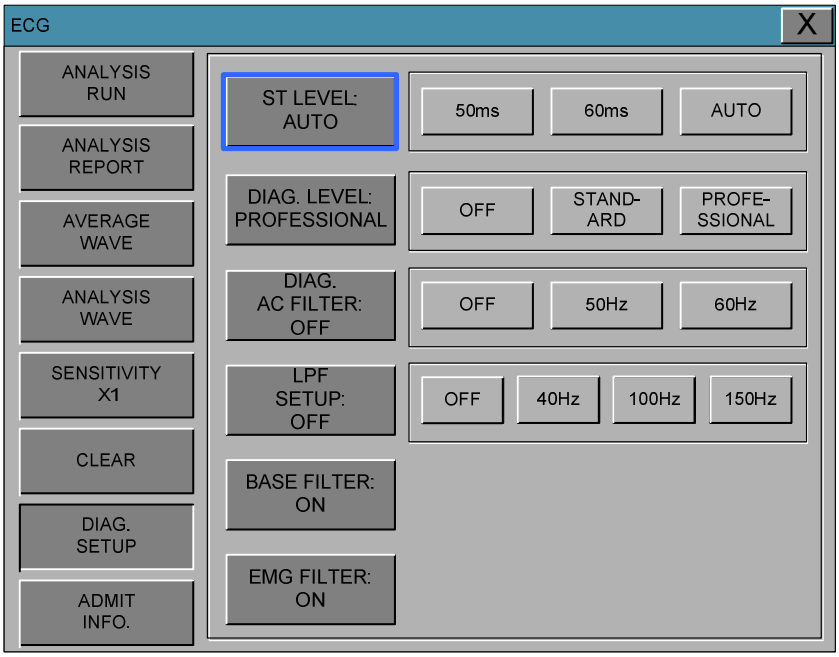
The results of analysis report, average wave and analysis wave are deleted if this menu is selected.



DIAG. SETUP

Diagnosis is related to the setup menu.

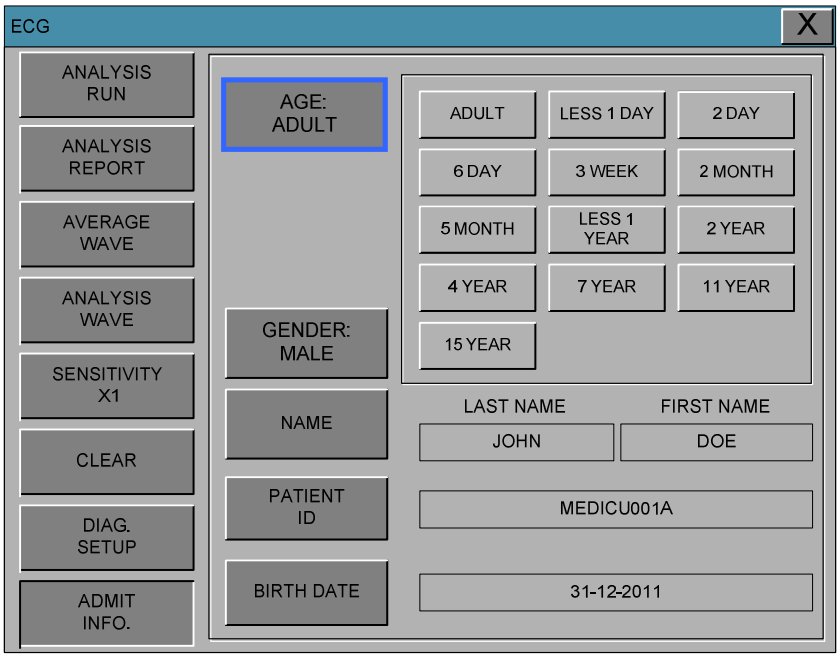
The filter used in the diagnosis and level can be set up to do.



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.

CAUTION

FDA POSTMARKET SAFETY ALERT

The United States FDA Center for Device and Radiological Health issued a safety bulletin October 14, 1998. this bulletin states "that minute ventilation rate-adaptive implantable pacemakers can occasionally interact with certain cardiac monitoring and diagnostic programmed rate."

The FDA further recommends precautions to take into consideration for patients with these types of pacemakers. These precaution for patients with these types of pacemakers. These precautions include disabling the rate responsive mode and enabling an alternate pace mode. For more information contact:

Office of Surveillance and Biometrics, CDRH, FDA
1350 Packard Drive, Mail Stop HFZ-510 Rockville, MD 20850 U.S.A

NOTE

ECG monitoring with patients in non-invasive trans coetaneous pacemakers may not be possible due to large amounts of energy produced by these devices. Monitoring ECG with an external device may be needed.

WARNINGS

VENTRICULAR ARRHYTHMISAS

The arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect a trial or supra ventricular arrhythmias. Occasionally it may incorrect identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information in conjunction with other clinical findings.

SUSPENDED ANALYSIS

Certain conditions suspend arrhythmia analysis. When suspended, arrhythmia conditions are not detected and alarms associated with arrhythmias do not occur. The messages which alert you to the conditions causing suspended arrhythmia analysis are : ARR OFF, ARRHYSUSPEND, LEADS FAIL, ALARM PAUSE, ALL ALARMS OFF, and DISCHARGED.

Trouble shooting

Problem :

Inaccurate heart rate and/or false a systole.

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

SWEEP SPEED

RATE VOLUME

ALARM

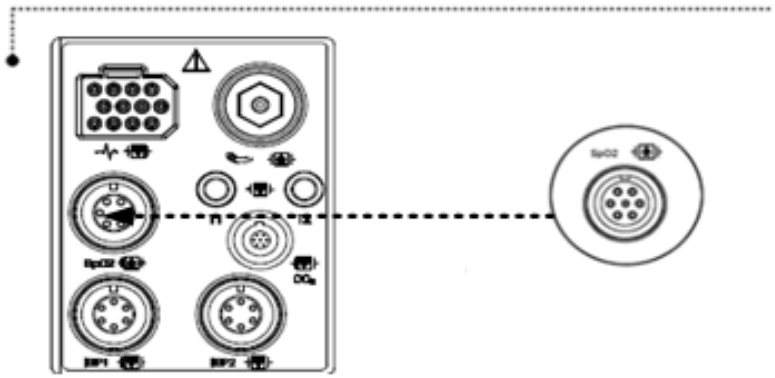
ALARM LIMIT

6.1 Outline

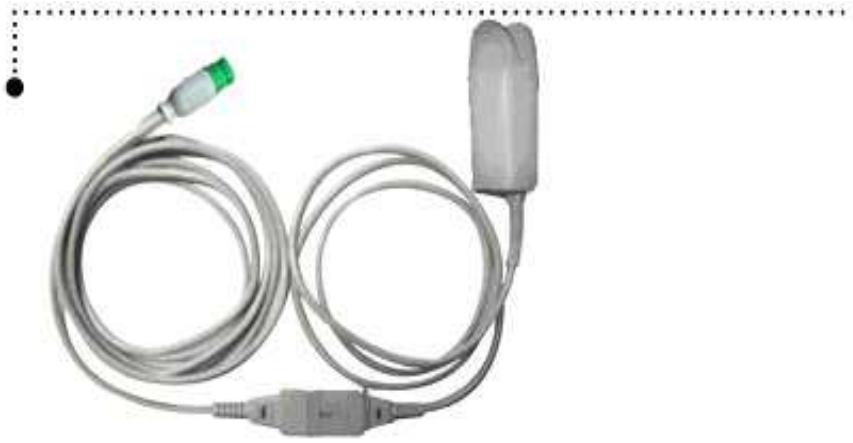
SPO2 monitoring is a noninvasive technique used to measure the amount of oxygenated hemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into an electrical signal by the photodetector in the 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

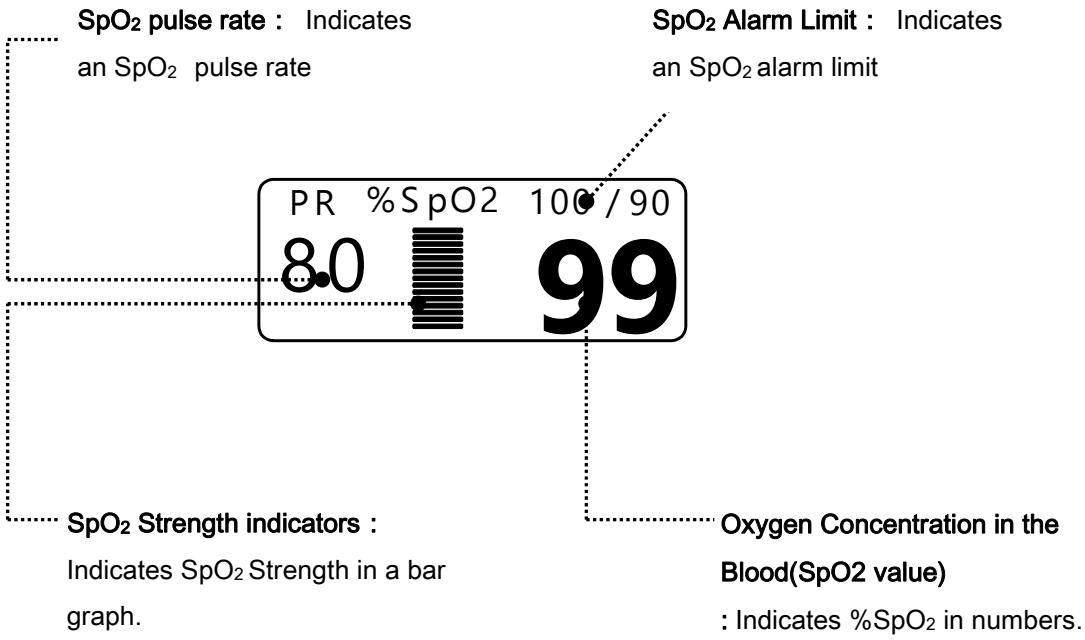


SpO_2 Measuring Cable



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 electrosurgery.

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

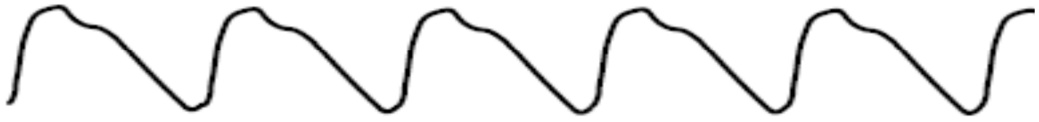
It is extremely important to determine that the probe is attached to the patient correctly and the data is verifiable. To make this determination, three indications from the monitor are of assistance—signal strength bar, quality of the SPO2 waveform, and the stability of the SPO2 values. It is critical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

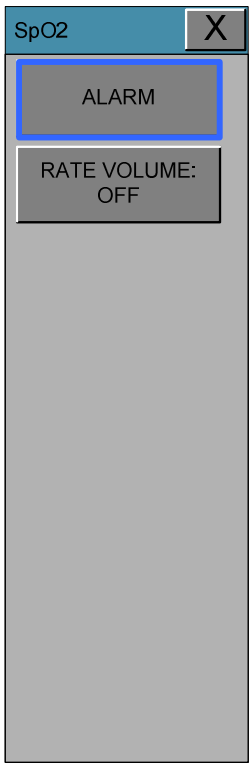
The stability of the displayed SPO2 values can also be used as an indication of signal validity. Although stability is a relative term, with a small amount of practice one can get a good feeling for changes that are artifactual or physiological and the speed of each. Messages are provided in the SPO2 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 %SpO2 is 0 ~ 100

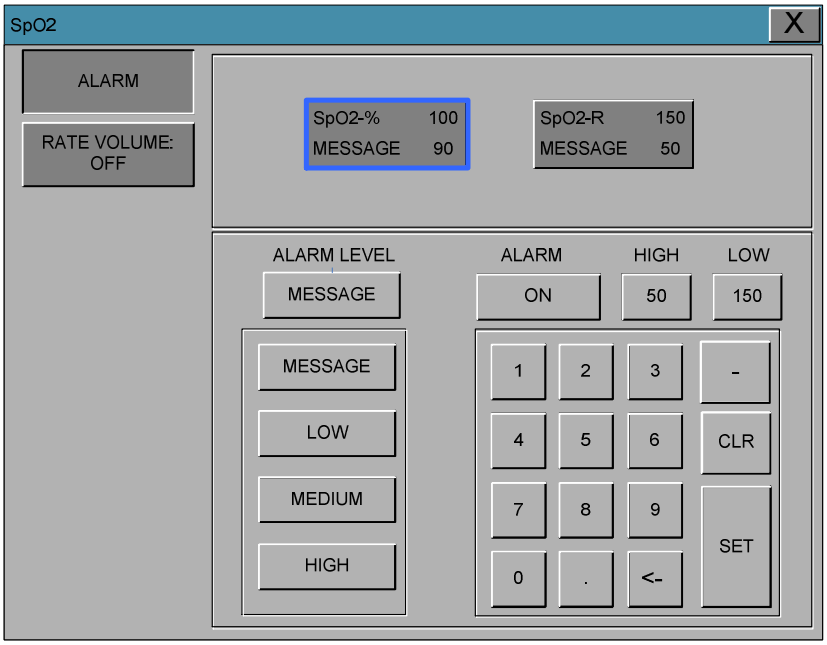
Warning sound or message displays configuration menu when an alarm is triggered.

1. Move the □ mark to select from RETURN, SpO2 or SpO2-R, and press.
2. After pressing at SpO2, 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 SpO2 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 SpO2-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.

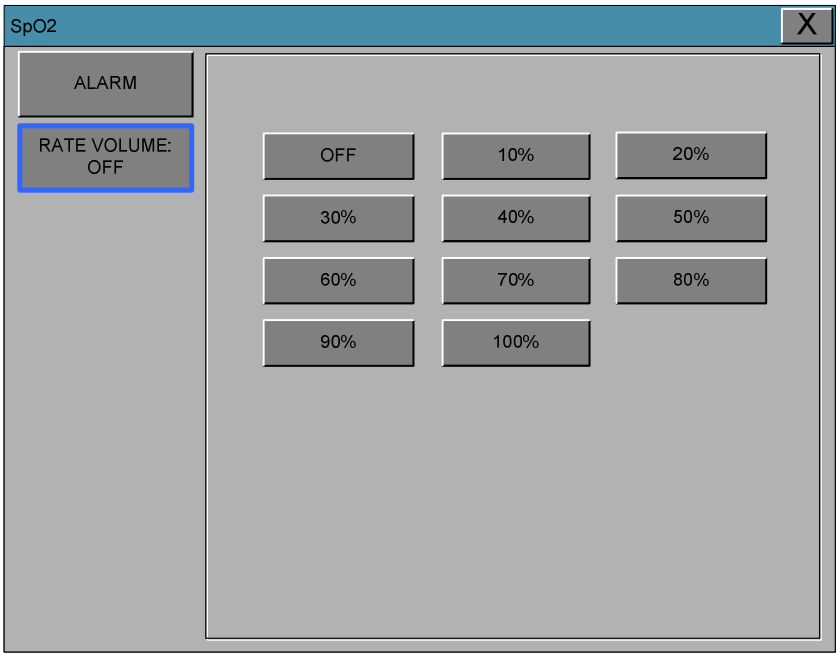
8. With the selection of RETURN the user gets out of the menu.



RATE VOLUME

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

When the ECG volume rate is set, it turns OFF automatically.



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.

7. RESPIRATION

7.1 Outline

Respiration Connector and Measuring Cable

7.2 RESPIRATION Data Window

7.3 RESPIRATION Data Setup

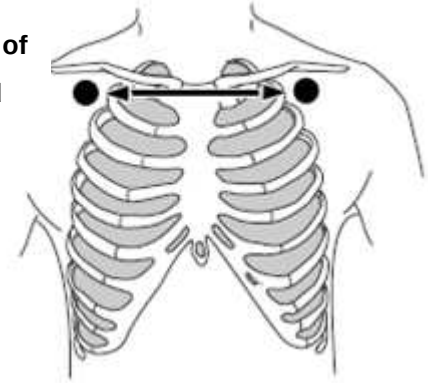
Respiration Size

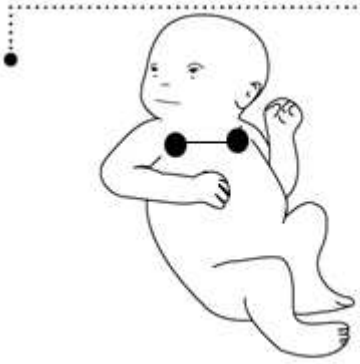
Alarm Limit

7.1 Outline

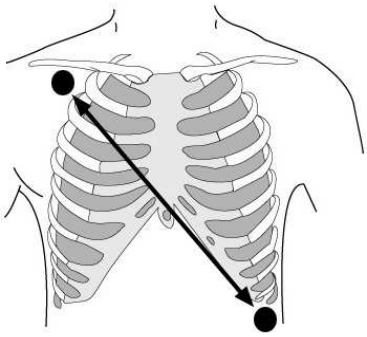
Respiration via ECG Lead II electrode makes the skin area of the chest enlarged, causing changes in the resistance of skin. Through this it calculates respiration value per minutes and performs the alarm function according to limit value.

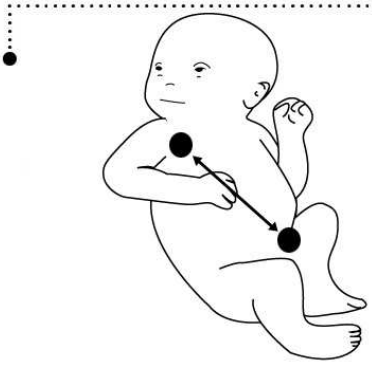
Position of Detected Lead Ⅰ





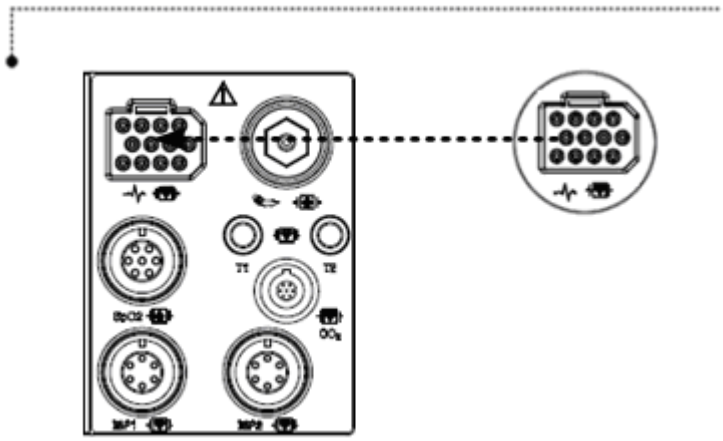
Position of Detected Lead Ⅱ





Respiration Connector and Measuring Cable

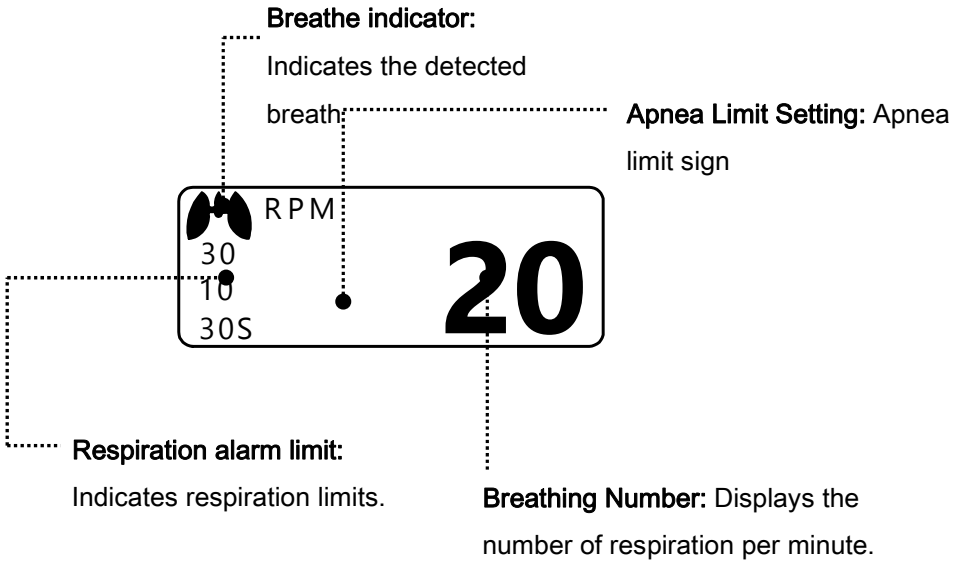
Respiration Connecter



Respiration Measuring Cable

Note
RR measure the cable and connector will be used as the ECG and common.

7.2 Respiration Data Window



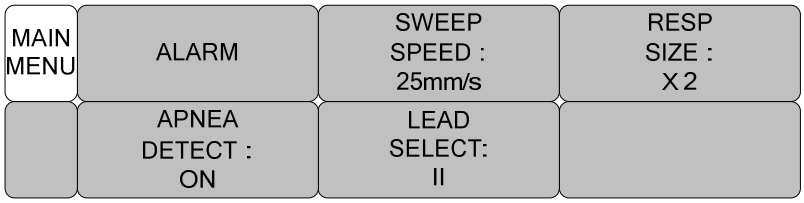
7.3 Respiration Data Setup

ALARM: Respiration alarm setting menu

RESP SIZE: A menu to setup Wave Display

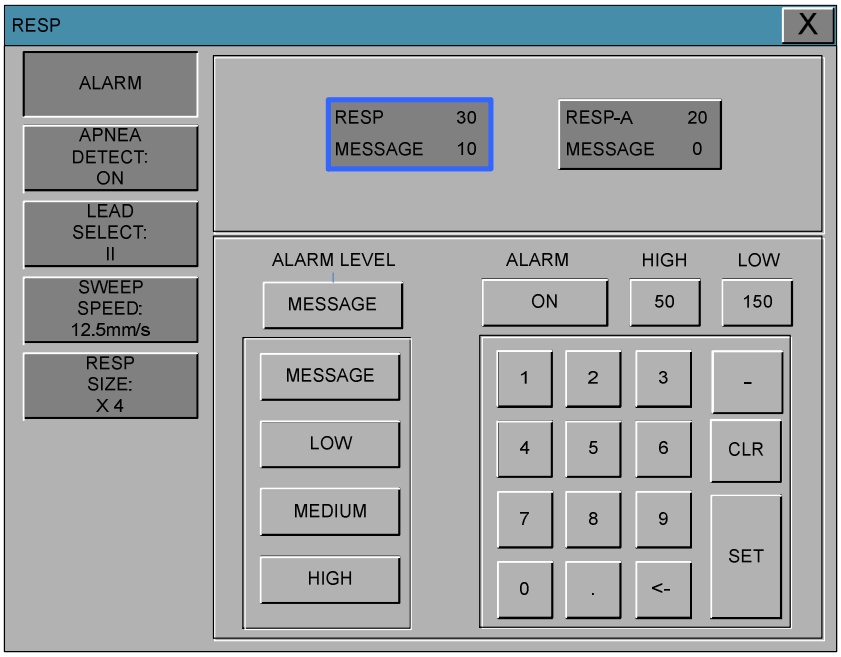
SWEEP SPEED: A menu to setup Wave Display of speed

APNEA DETECT: A menu to setup APNEA alarm display



ALARM

Alarm menu provide ALARM LIMIT and ALARM SOUND .



Alarm Limit of Respiration Numeric Value is 5 ~ 150bpm

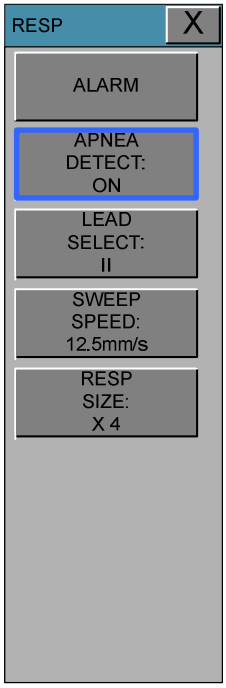
Alarm Limit of RESPIRATION APNEA Numeric Value is 3 ~ 30sec.

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

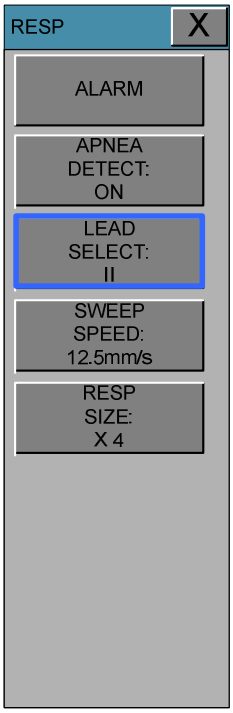
Deciding function of activating Apnea Alarm



LEAD SELECT

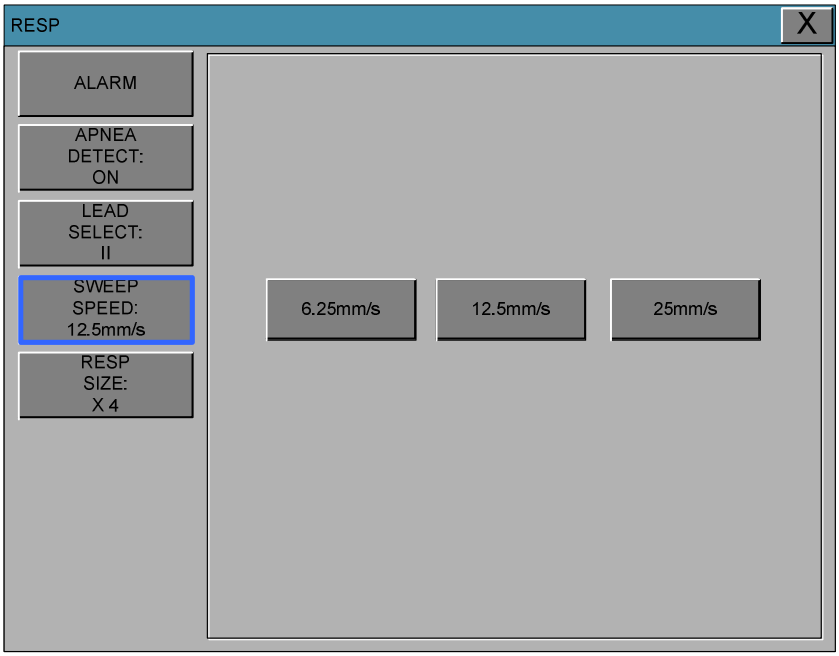
This is for changing the reference LEAD for respiration

LEAD I or LEAD II can be selected.



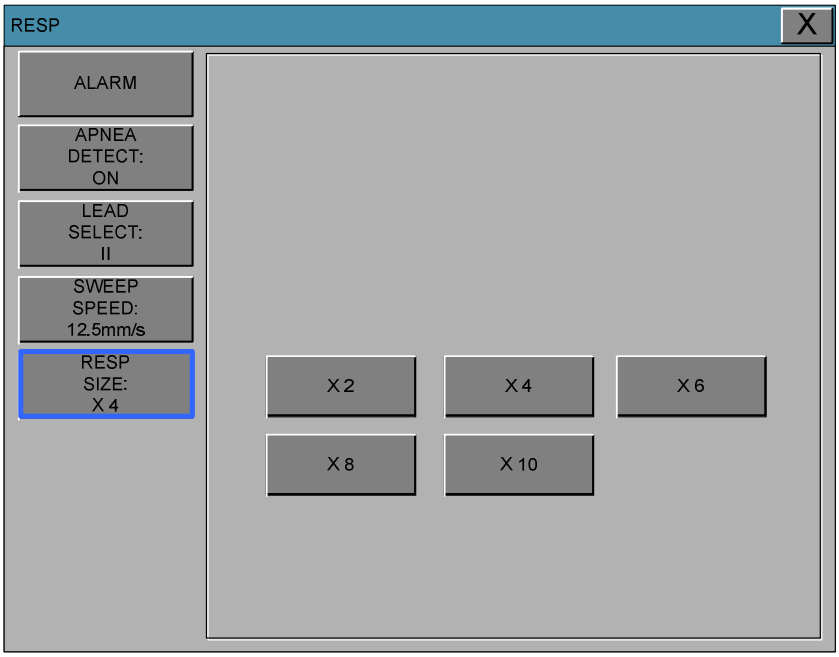
RESPIRATION SPEED

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 LIMIT

ALARM

CUFF SIZE

UNIT SELECT

INTERVAL

STAT

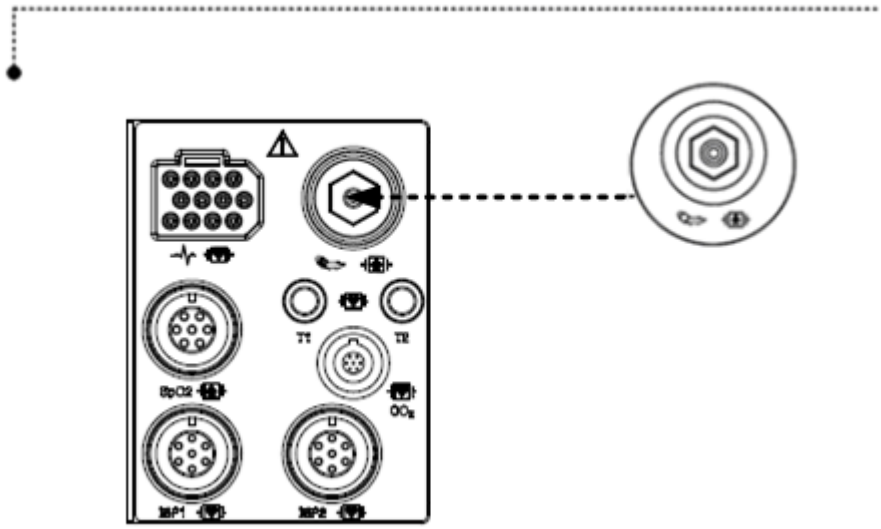
INFLATION

8.1 Outline

This function is to measure minimum, Maximum and average blood pressure by using Oscillometric method

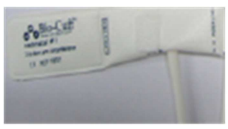
Position of NIBP Connecter and cuff

NIBP Connector



ADULT CUFF

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

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.

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.

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. 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.

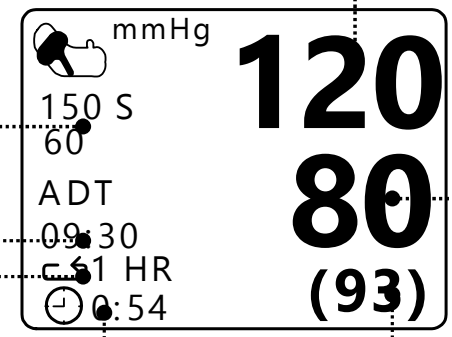
The maintenance is performed every 2 years.
Check the following list devise to operates properly and safety at all times.

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.

8.2 NIBP Data Window

Alarm Limit：Indicates alarm limit of blood pressure.

Systolic pressure：Indicates the maximum limit of blood pressure



Diastolic blood pressure：Indicates the minimum limit of blood pressure

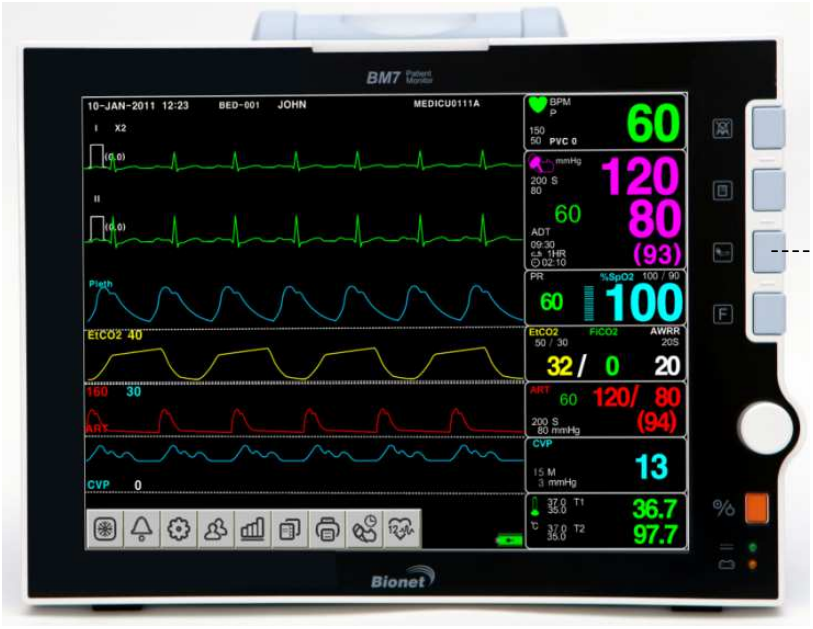
Measurement time Indicates the completion time of measuring

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

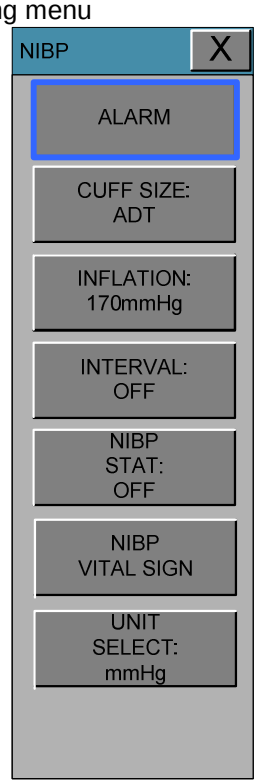
ALARM： A menu to set the Alarm

CUFF SIZE：A menu to select cuff size

UNIT SELECT: A menu to select the pressure unit

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

INFLATION: Initial Pressurization setting menu



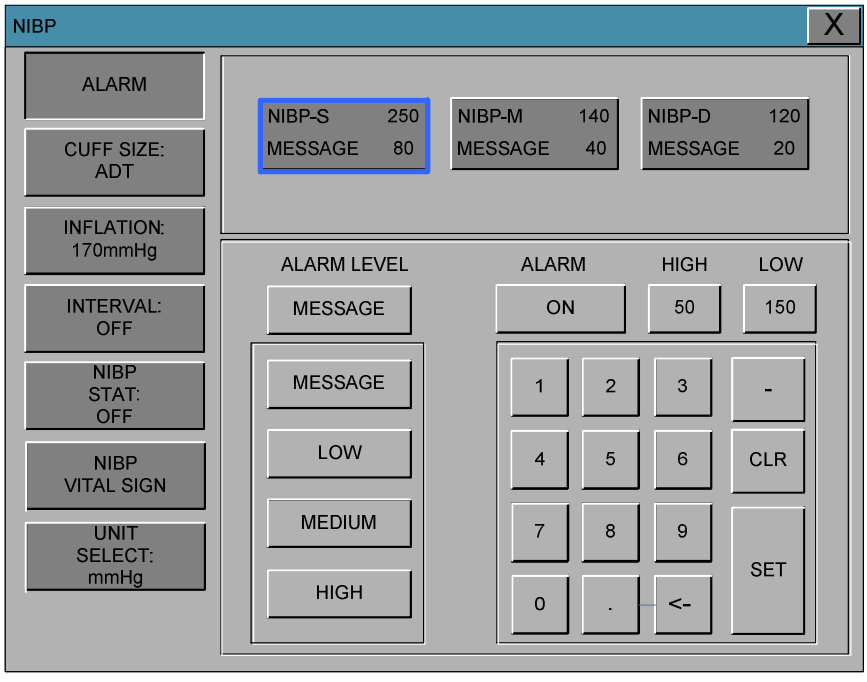
ALARM

The alarm provides ALARM LIMIT and ALARM SOUND.

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

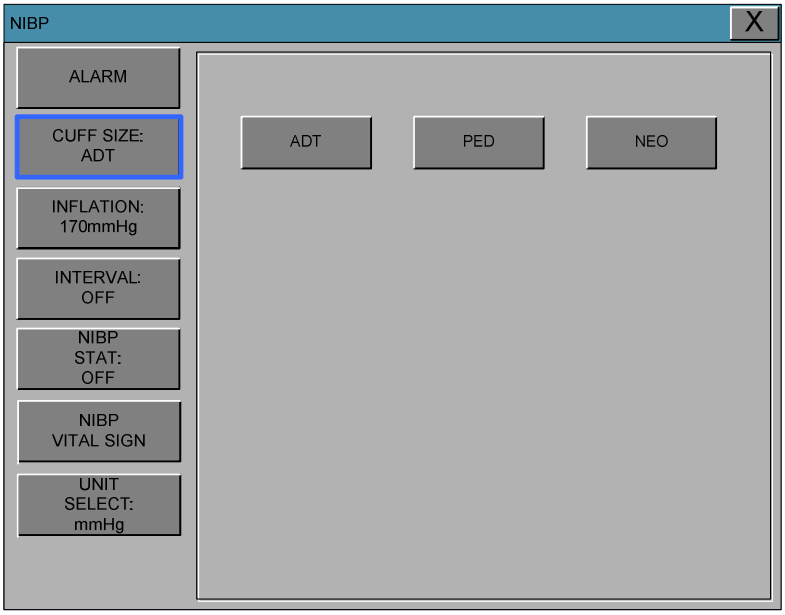
The menu which decide activate of warning sign and message display when the respiration alarm is on.

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 and NEONATAL.



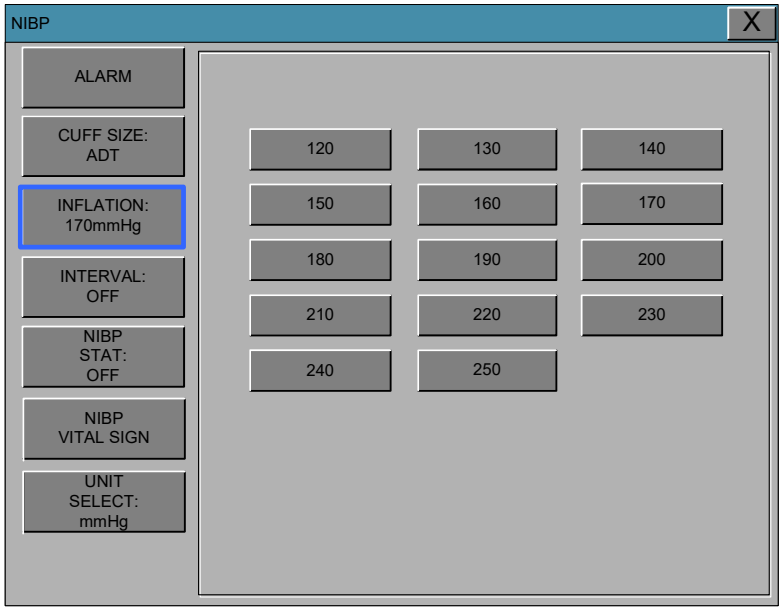
INFLATION

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 80, 90, 100, 110, ~ 230, and 240.

Numeric value is 60, 70, 80, 90, 100, 110, and 120.

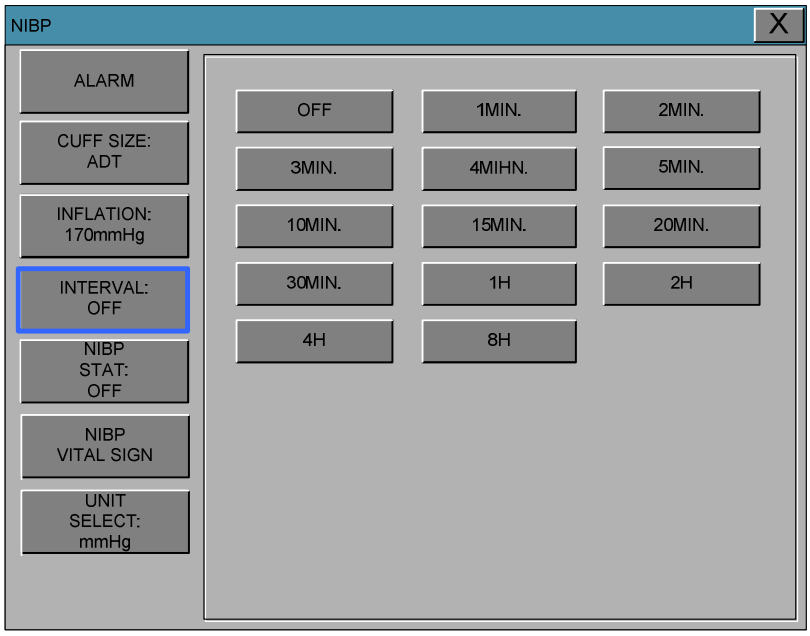


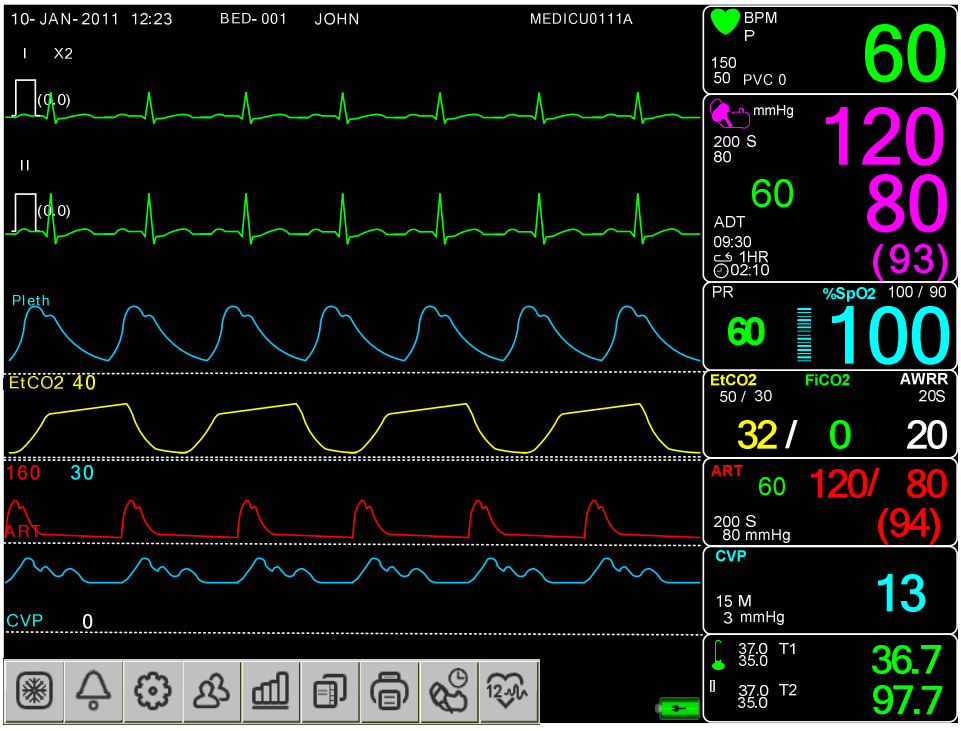
INTERVAL

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

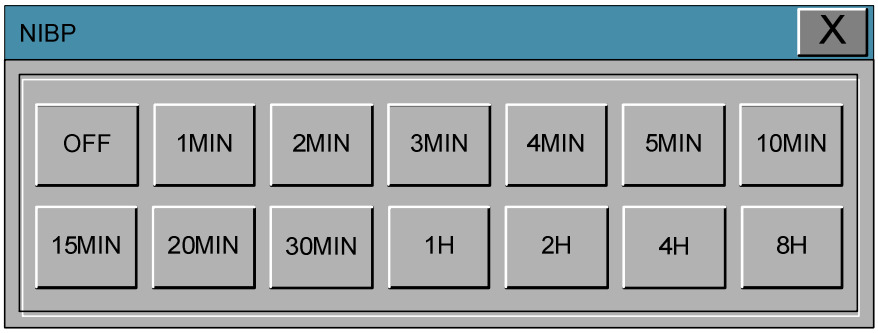
Select a target interval from 1min, 2, 3, 4, 5, 10, 15, 20, 30, 1hour, 2, 4, 8.

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





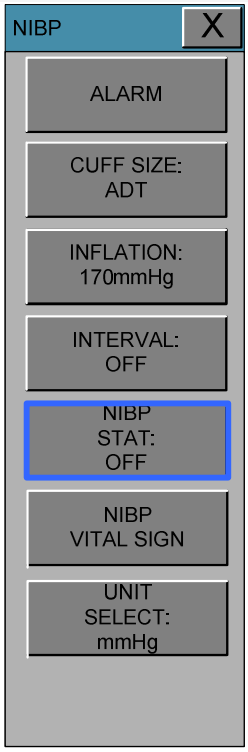
If you select the icon  from the main screen of the equipment to the fast cycle setting from the following menu window you can select the measurement cycle.



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.

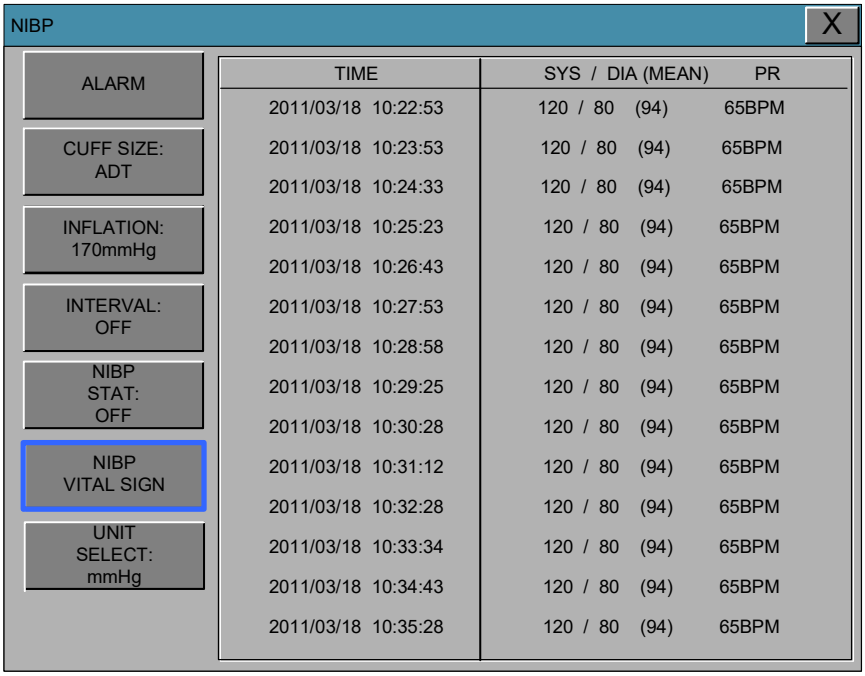
NIBP STAT

5 minutes to continuous measurement mode.



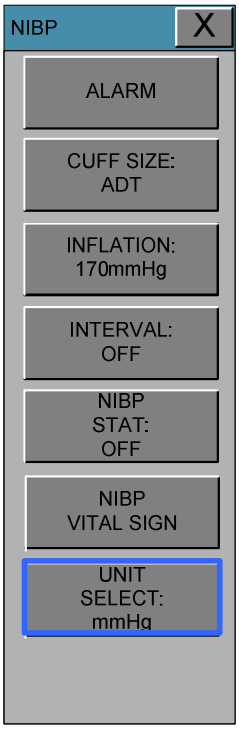
NIBP VITAL SIGN

15 recently measured blood pressure values are recorded.



UNIT SELECT

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



Warning
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.

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)

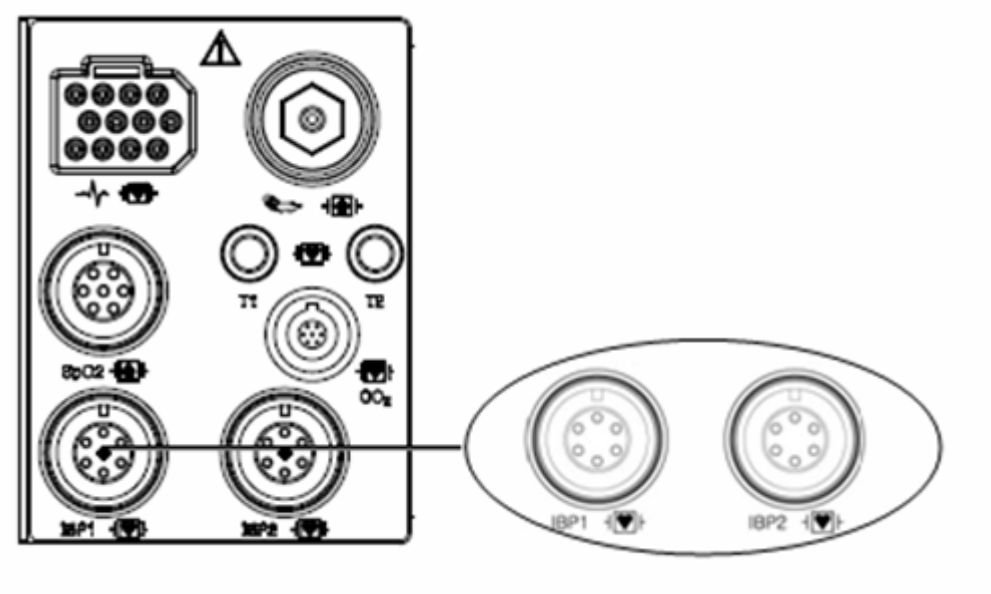
ZERO (Zero-Point Setting)

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

IBP connector

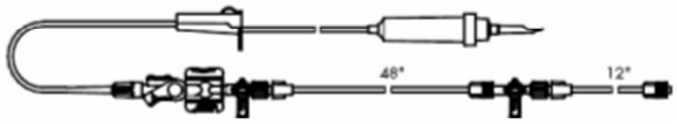


IBP ACCESSARY

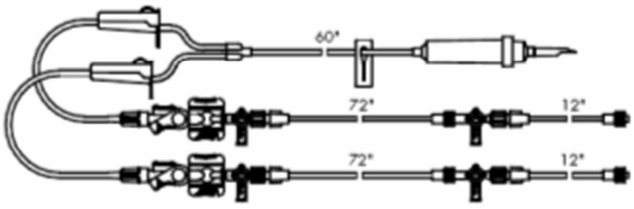
MEDEX Kit is used for IBP MONITORING KIT.

LogiCal Disposable Pressure Transducers Cartridges and Monitoring kit

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

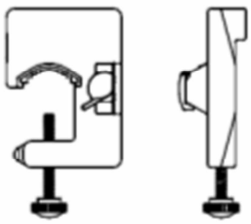


MX9602A LogiCal® double line monitoring kit.



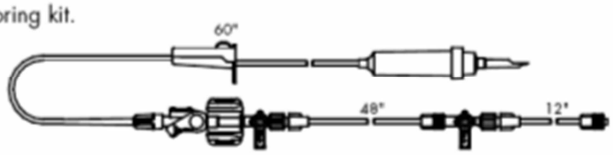
MX960 LogiCal® transducer mounting plate.

MX261 LogiCal® clamp for transducer bracket.

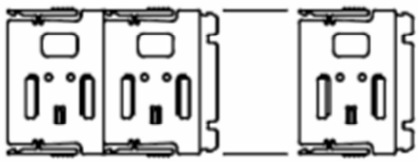


TranStar Disposable Pressure Transducers Cartridges and Monitoring kit

MX9504T TranStar® 60" single line monitoring kit.

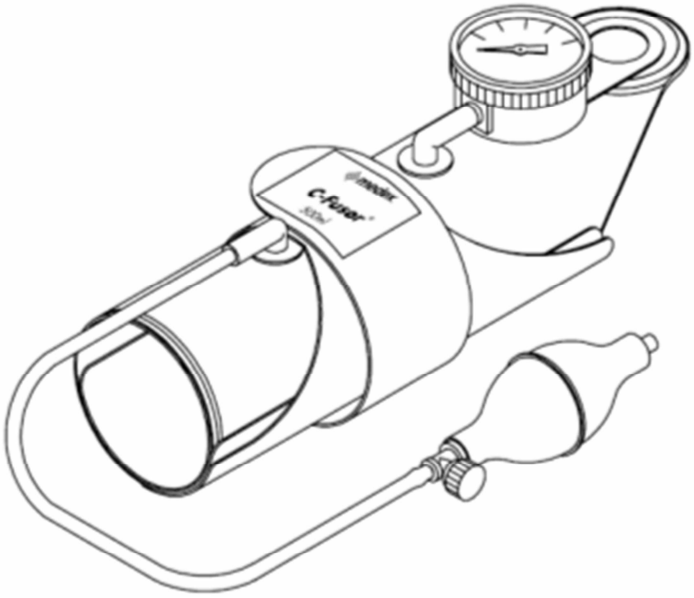


MX800 Modular transducer mounting plate.



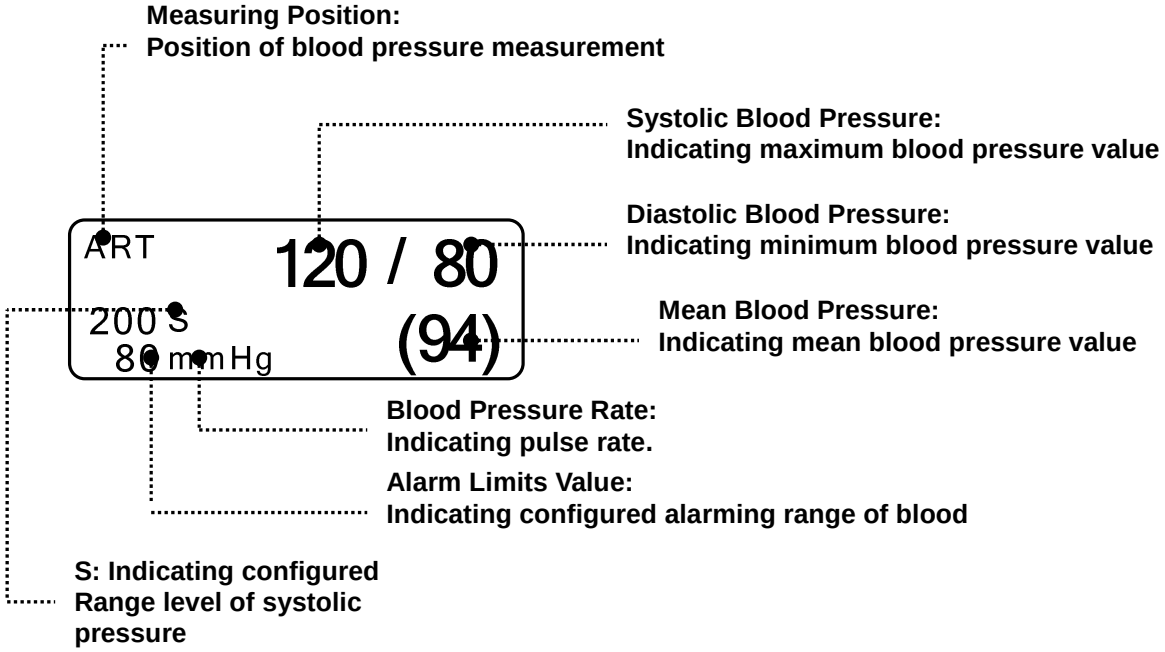
MX240 Pole clamp for mounting a transducer plate (fits 3/4" to 1-1/2" I.V. pole).

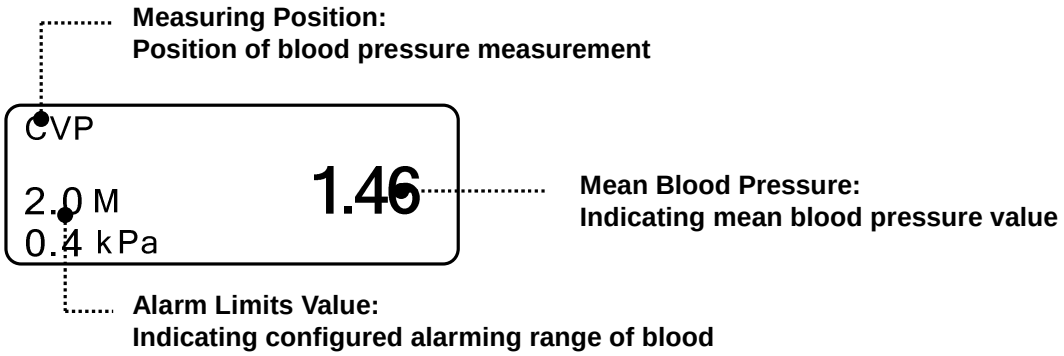
MX4810 C-Fusor® 1000ml Pressure Infusor complete unit with squeeze bulb and pressure gauge.



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.

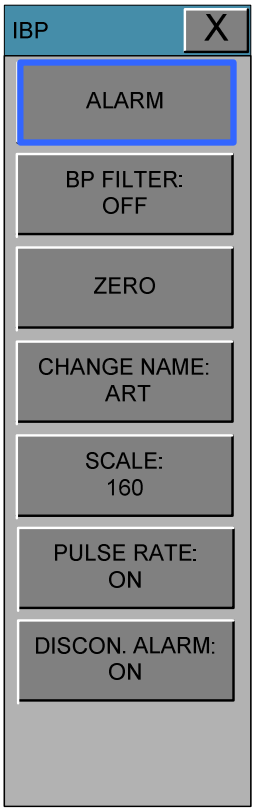
ZERO: Menu to set zero-point of Transducer.

CHANGE NAME: Menu to set measuring position

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

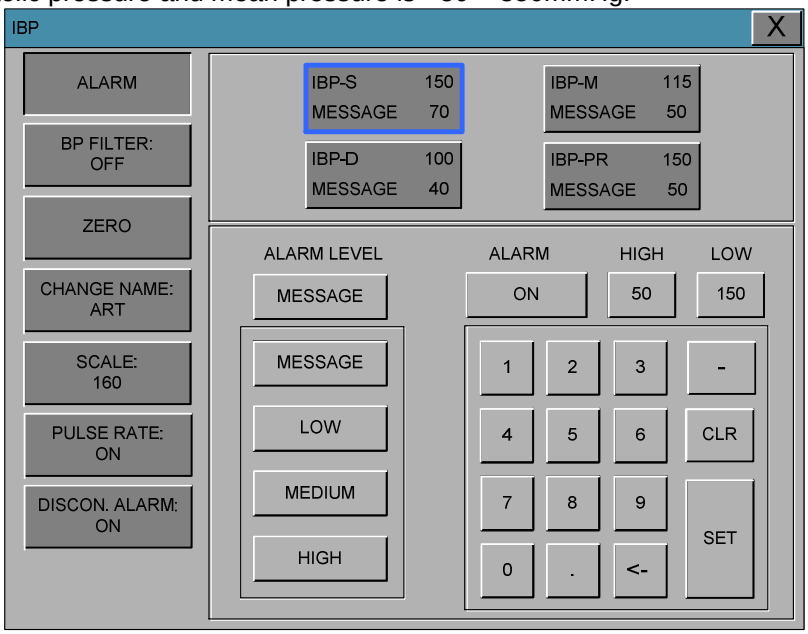
PULSE RATE: Menu to Set display of blood pressure pulse. (ART, FEM, UAP LABEL)

DISCON. ALARM: Menu for Alarming function 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.



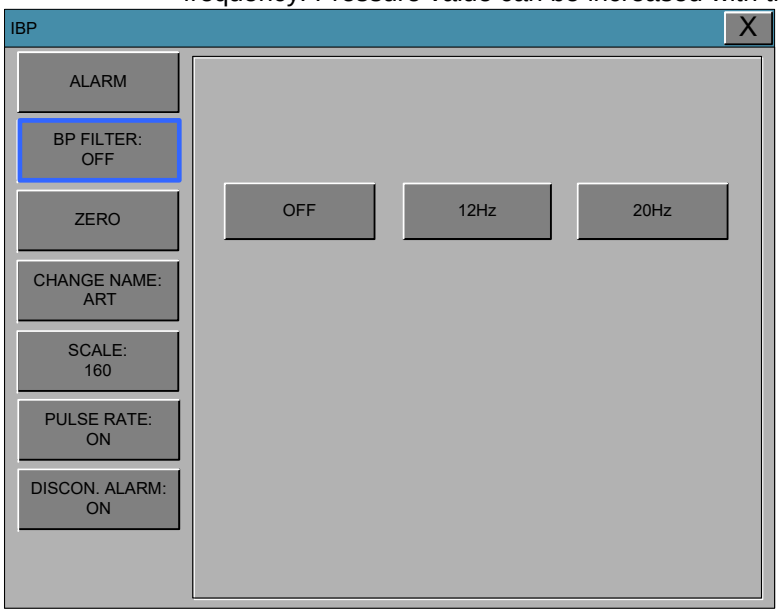
BP FILTER:

It filters waveforms by selecting three frequency bands.

OFF **0Hz ~ 40Hz**

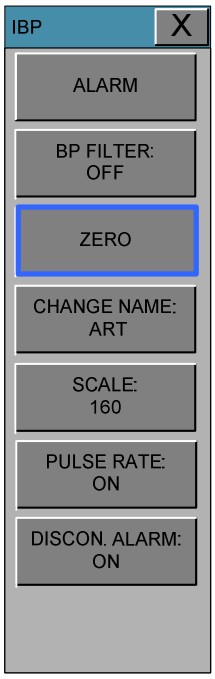
12Hz **0Hz ~ 12Hz** Generally recommended for monitoring

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.

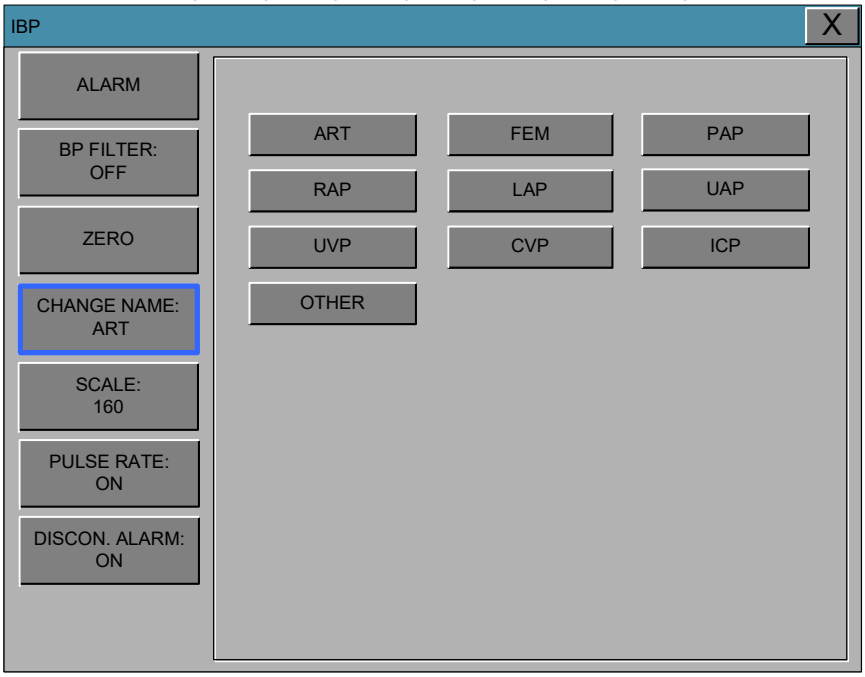
Troubleshootings for a case that blood pressure value is not displayed on screen

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.

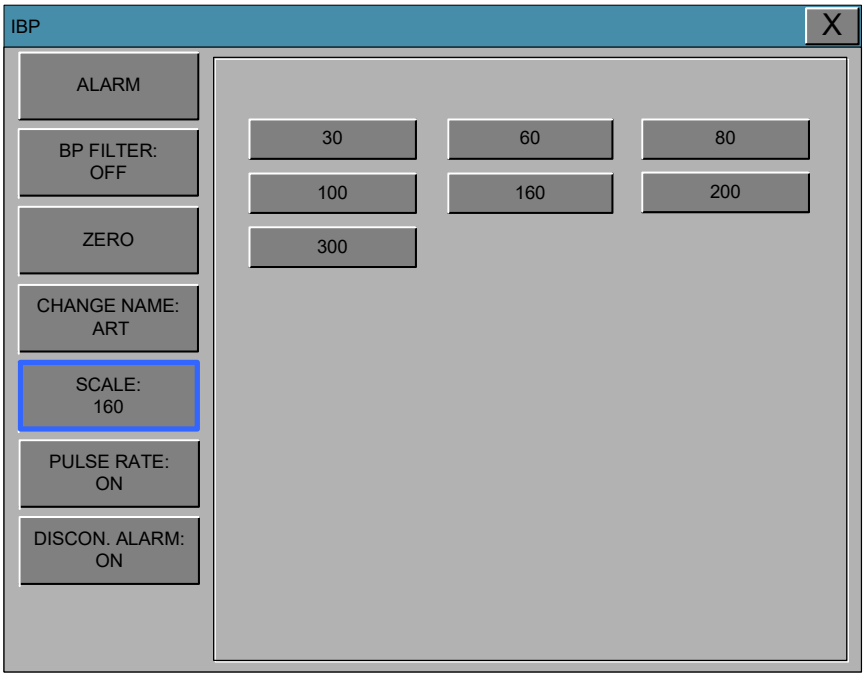
LABEL	DESCRIPTION	DISPLAY VALUE
ART	Arterial Pressure	- Systolic, Diastolic and Mean
FEM	Femoral Pressure	- Systolic, Diastolic and Mean
PAP	Pulmonary Artery Pressure	- Systolic, Diastolic and Mean
CVP	Central Venous Pressure	- Mean

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.



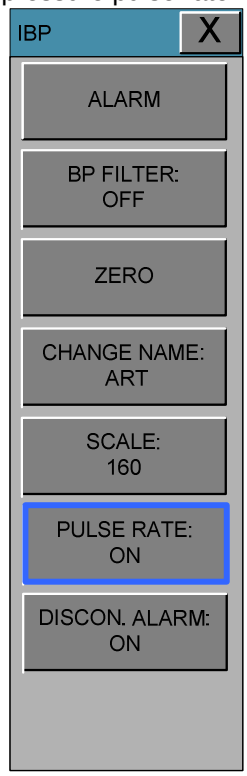
The below table shows the settable values of standard alarm limits and scales of parameters for label setting.

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

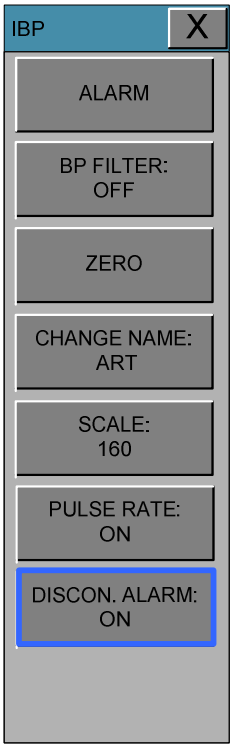
DISCONN ALARM: (Alarming function for disconnection)

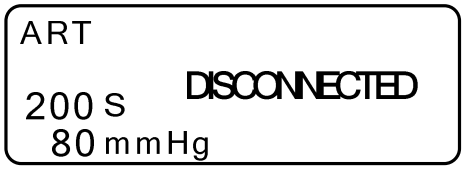
DISCONN ALARM MENU will be displayed when measurement label is set for ART, FEM and UAP.

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'.

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





Troubleshootings 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.

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. ● Do 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

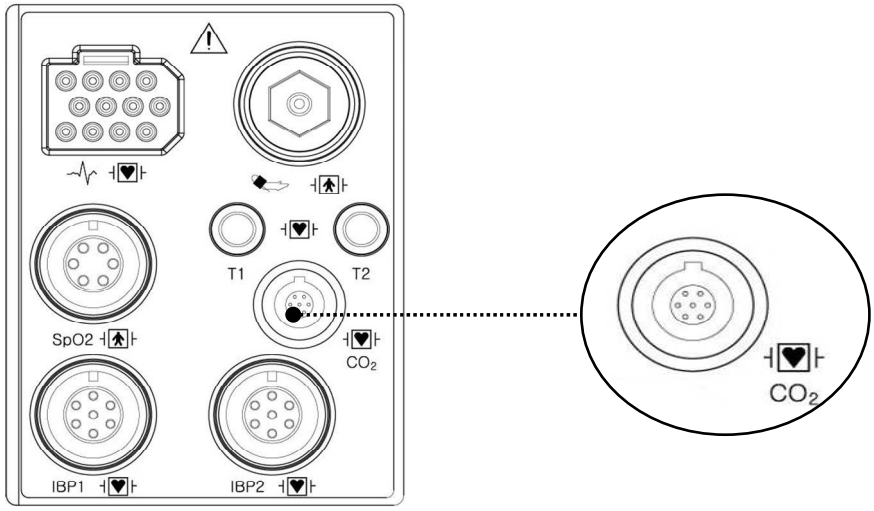
10.3 $EtCO_2$ Parameter Setting Menu

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)

EtCO2 Connector



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 Deadspace – adds approximately 7 cc of deadspace **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 Deadspace – adds approximately 1 cc of deadspace **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.

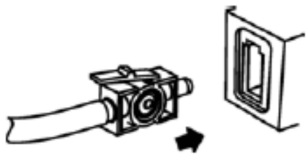


Figure 1

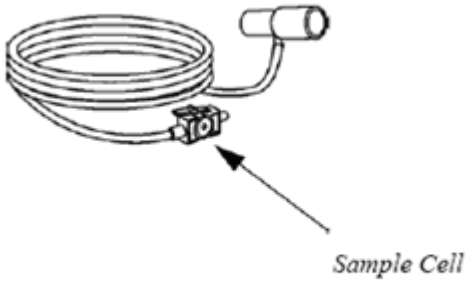


Figure 2

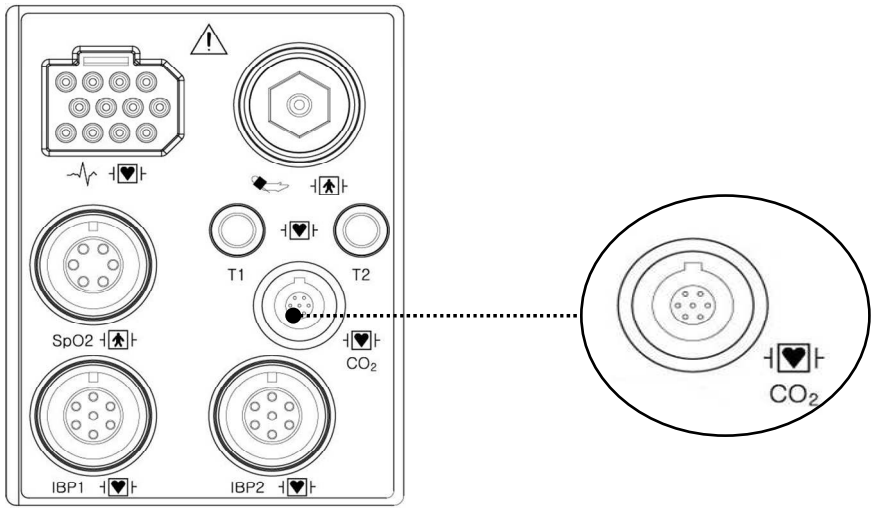
2. Inserting the sample cell into the receptacle automatically starts the sampling pump.

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)

EtCO2 Connector



CAPNOSTAT 5 mainstream CO2 sensor and connector

Mainstream sensor

Mainstream sensor connector

EtCO2 accessories for mainstream applications

EtCO2 monitoring accessory uses the accessories for CapnoStat 5 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.

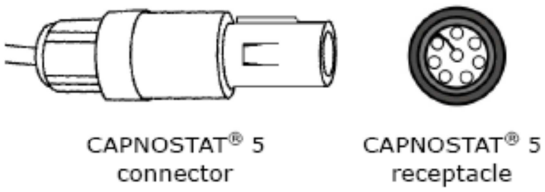


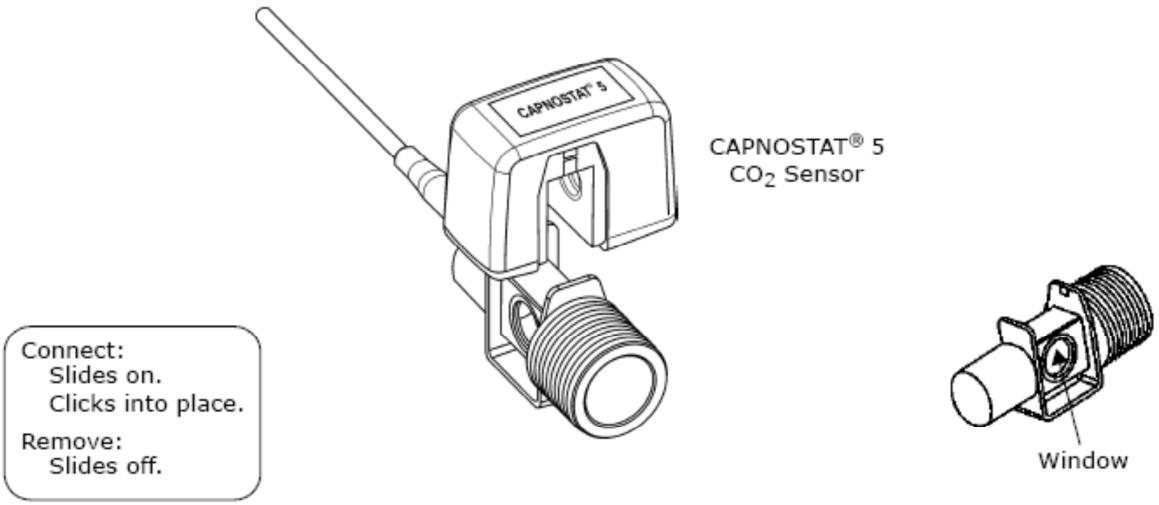
Figure 1

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.

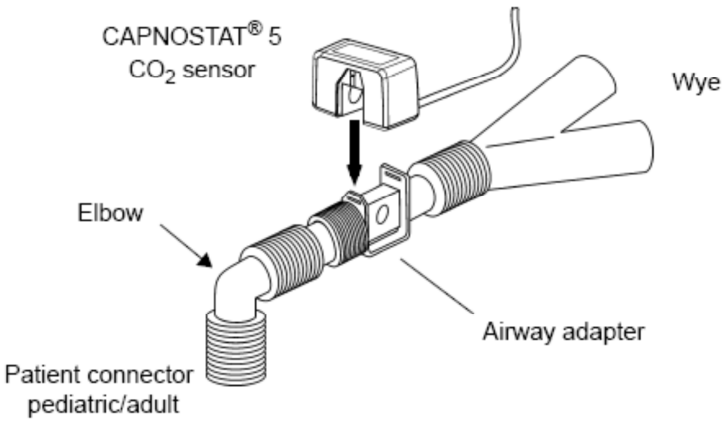
Note: Do not remove by pulling cable.

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

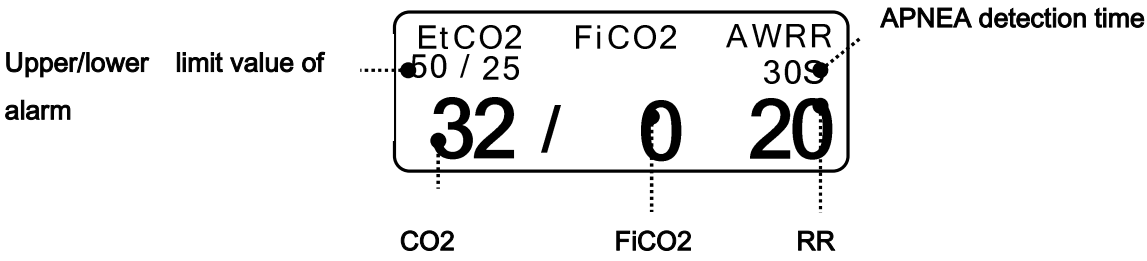
adapter



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

RR: Display of the number of respirations per miniute

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)

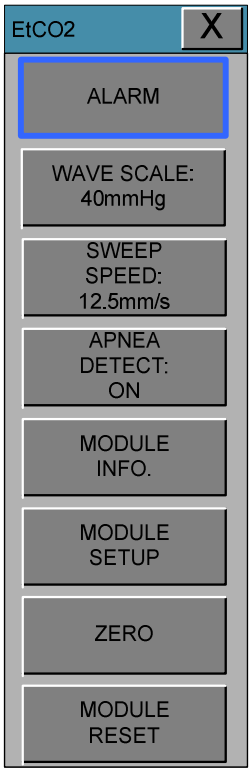
APNEA DETECT: Menu for the detection of apnea

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

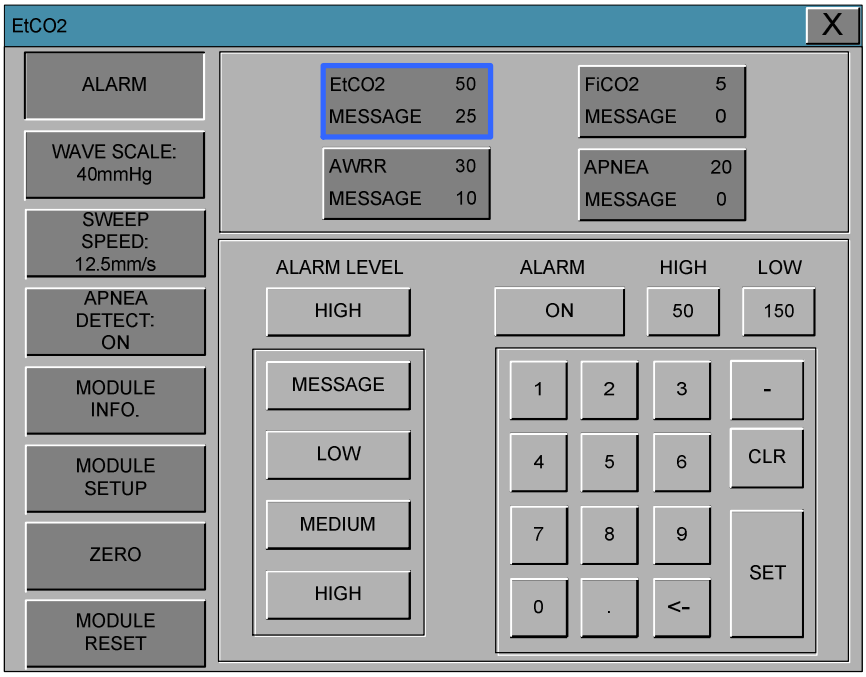
MODULE RESET: EtCO2 MODULE menu to initialize the run



ART LIMIT(Upper/lower limit value of 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, RR, APNEA.



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

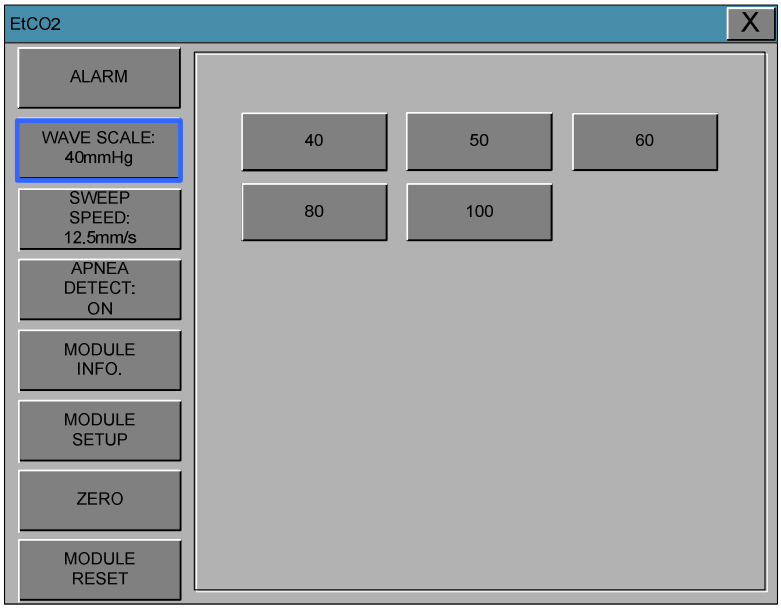
Parameter	Adult			Neonatal		
	Low	High	Scale	Low	High	Scale
EtCO2	0	98	40	0	98	40
FiCO2	0	20		0	20	
AWRR	0	100		0	100	
APNEA	0	40		0	40	

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.

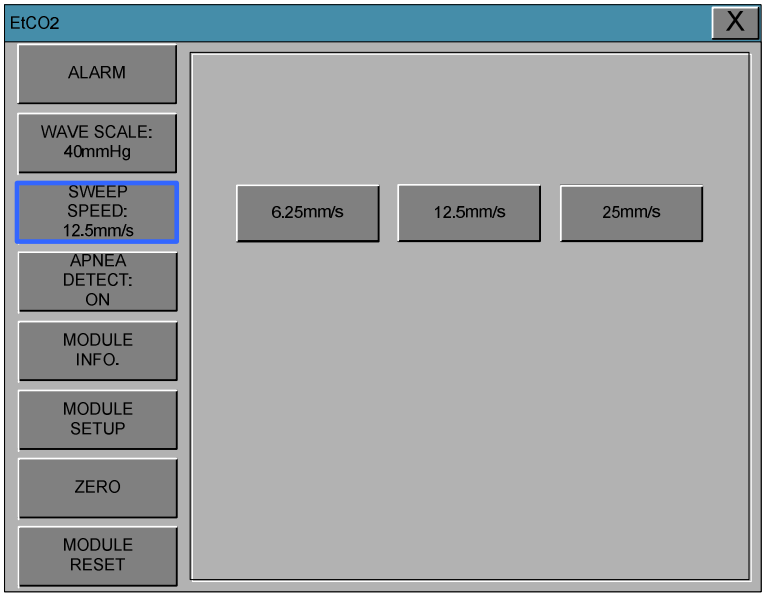
Pressing the knob switch key and then selecting the desired range value displays the selected pressure range value below the upper dotted line among two dotted lines in the left middle of wave window.



EtCO2 SWEEP SPEED

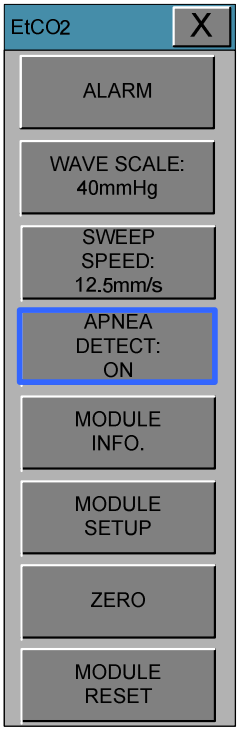
EtCO2 speed is 6.5mm/s.

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



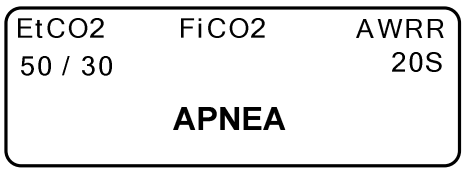
APNEA DETECT

Turn the APNEA detection alarm off and on

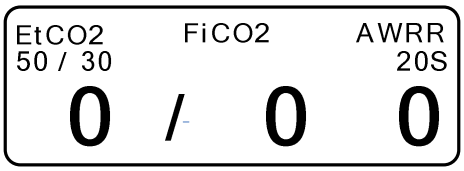


APNEA ALARM: This performs a function to set the display of apnea message alarm.

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.

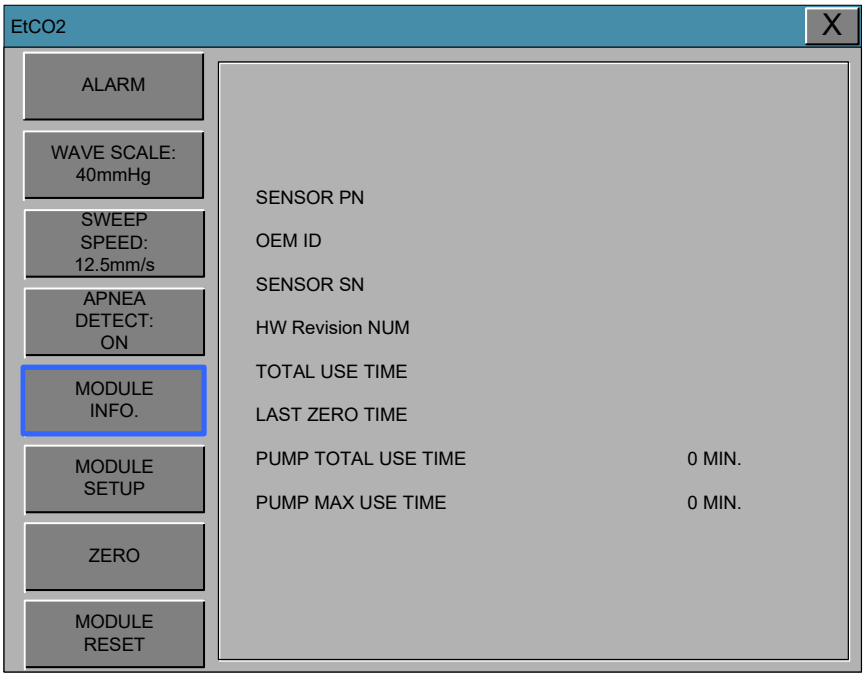


With apnea alarm off, measured values are displayed instead of message.



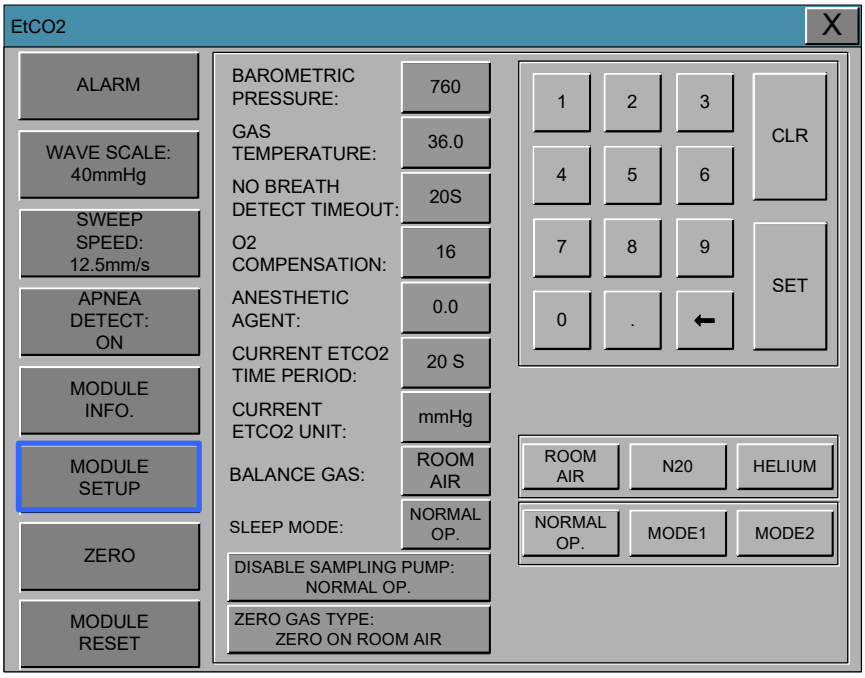
MODULE INFO

This is information for handling the EtCO2 module.



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.

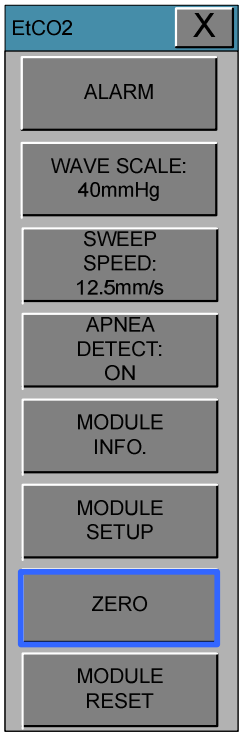
DISABLE SAMPLING PUMP: This setting allows the pump to be forced off. In Normal Operating Mode, the pump will be turned on when the sampling cell is connected and no pneumatic system errors are detected. In Pump Disabled Mode, the pump will remain off in all circumstances.

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.

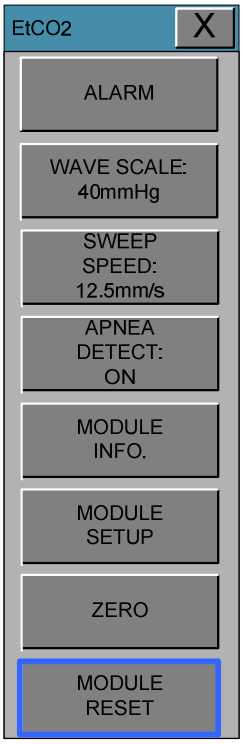


1. Set the Host to the zeroing function.
2. Connect the CAPNOSTAT 5 CO2 Sensor
3. Place the CAPNOSTAT 5 CO2 Sensor onto a clean and dry CO2 adapter that is exposed to room air and away from all sources of CO2, including the ventilator, the patient's breath and your own.
4. Start the adapter zero. The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

8.4 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 LIMIT

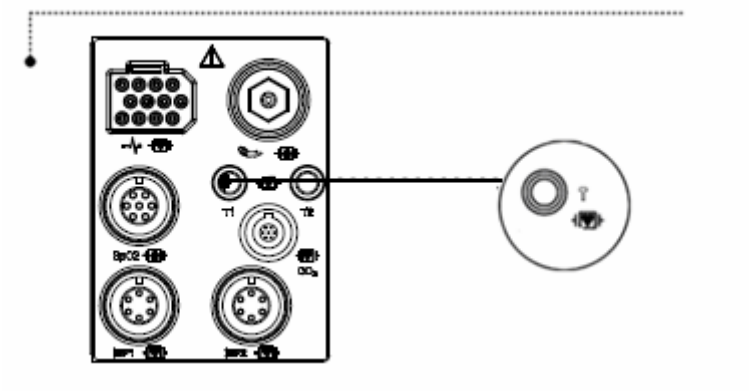
UNIT SELECT

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.

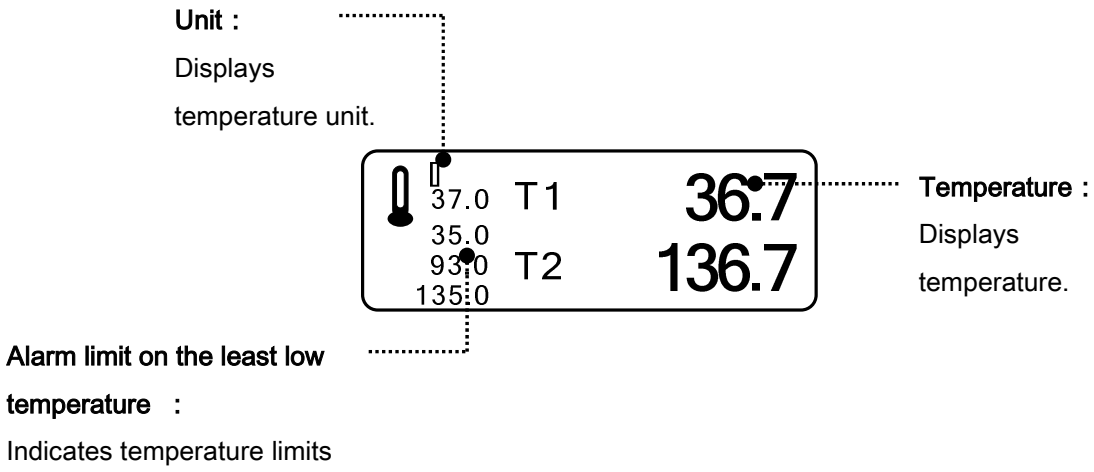
Temperature Connector and Measuring Cable

Temperature Connector



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

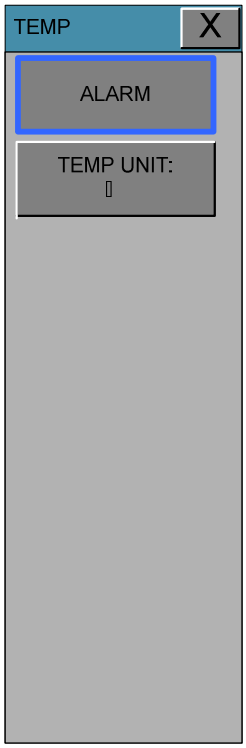


Note
The minimum measuring time required to obtain accurate readings at the specific body site is at least 3 minutes.

11.3 Temperature Data Setup

ALARM： Temperature measurement alarm set

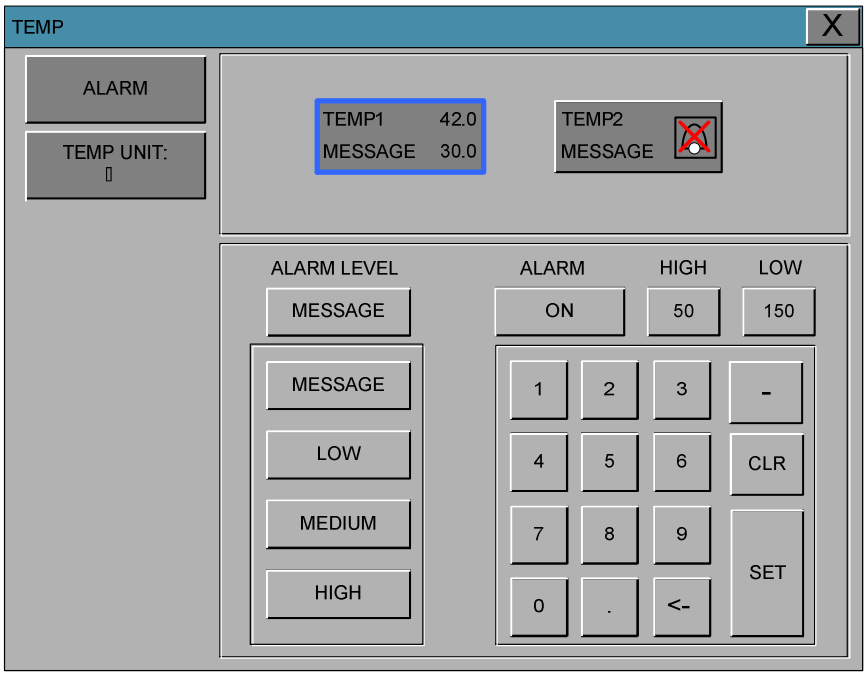
UNIT: Temperature measurement unit set



ALARM

Alarm menu provide ALARM LIMIT and ALARM.

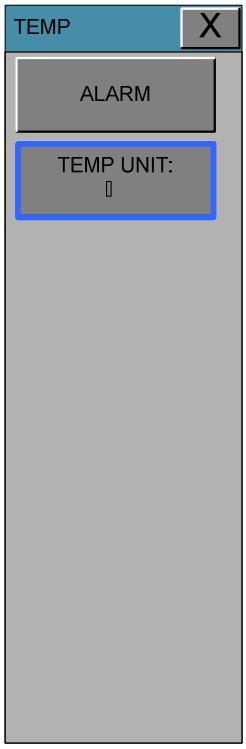
Setting numeric value is 15.0□ ~ 45.0□.



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.

UNIT SELECT

Able to select unit with °C, °F.



12. PRINT

12.1 Print

Printer and Heat Sensitivity Paper

Function and Setup Menu

12.2 Paper Change

12.1 Print

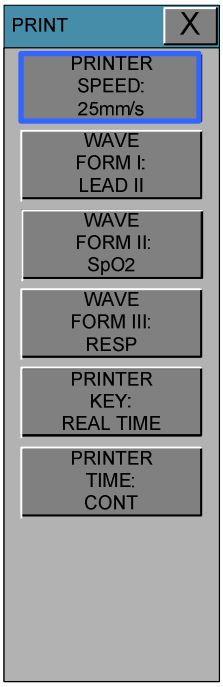
Printer and Heat Sensitivity Paper

A printer used to print data onto thermal paper.

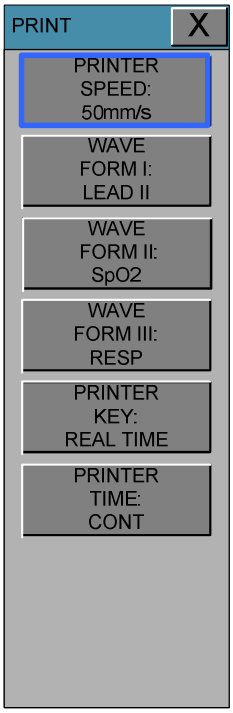
Size of the thermal paper roll: 580mm wide x 380mm in diameter any thermal paper of same size can be used for the printer.

Side View of Printer

Function and Setup Menu



1. Press the PRINT Key for continuous printing.
2. Select Printing Speed 25, 50 mm/s.



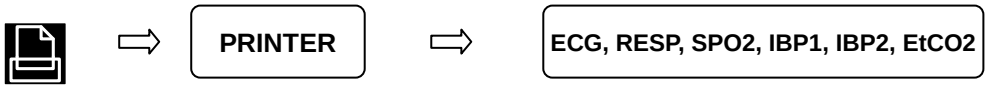
3. Set up ALARM PRINT in the MORE menu to activate ALARM during printing.

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

leadfault 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.




PRINT
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
V5
V5
EtCO2
V5
V5
V5
V5
LEAD III
aVR
aVL
V5
V5
V5
V5
V5
V5
V5


PRINT
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
V5
V5
EtCO2
V5
V5
V5
V5
LEAD III
aVR
aVL
V5
V5
V5
V5
V5
V5
V5

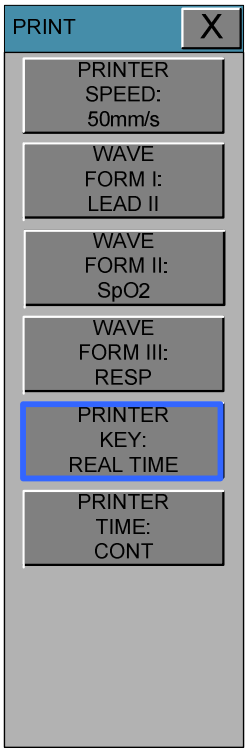
PRINTER KEY

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.

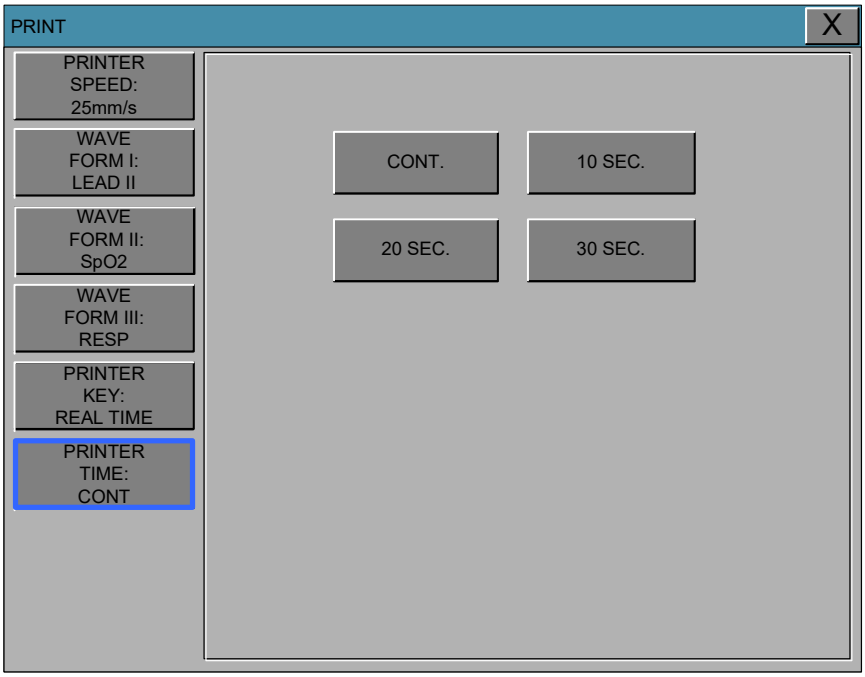
Delayed time: This configuration makes printing out the data after 5 seconds from the Printer Key is pushed.



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.**

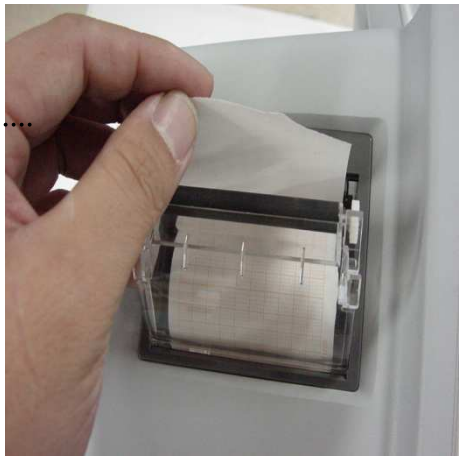
12.2 Paper Change

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.

13. MESSAGE LIST

Function	Message	Details
ECG	LEAD FAULT	Cable is not properly connected.
SpO_2	CHEK PROBE LEAD FAULT	Patient's finger is off the probe. Cable is not properly connected.
RESP	LEAD FAULT APNEA	Cable is not properly connected. APNEA gives an alarm.
NIBP	INFLATION FAILURE CHECK CUFF OVER PRESSURE DEFLATION FAILURE CHECK CUFF OVER TIME CUFF PRESSURE MEASUREMENT ERROR PULSE TOO WEAK	Cuff hose is not properly connected. Cuff pressure is putting on excessively. Cuff is bent, preventing deflation. Measure time exceeds the preset Level. Measure signal absent
IBP	CHECK SENSOR DISCONNECTED IMBALANCE	Cable is not properly connected. Cable is not properly connected. Zeroing procedure when necessary.
EtCO2	MODULE OFF SENSOR WARMUP CHECK ADAPTOR CHECK LINE APNEA ZERO IN PROGRESS SENSOR FAULTY	Module is not properly connected. Sensor is initializing Adaptor is not properly connected. Tube is not properly connected. APNEA gives an alarm. Zeroing procedure when necessary. Sensor is not properly measured
TEMP	LEAD FAULT	Cable is not properly connected.
ALARM	ALARM VOL.OFF SILENCED ALARM PAUSE 5MIN	Alarm volume is off. Alarm key is pressed once Alarm key is pressed twice
TREND	NO PATIENT DATA	No patient's data input.

14. DEFAULT SETTING VALUE

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(℃)				0
T2℃)				0
IBP1(S/M/D)			0	
IBP2(S/M/D)			0	
EtCO2			0	
FiCO2				0

AWRR			**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 ° C/° F	**30.0/86.0**	**42.0/107.6**
ST	**-1.0**	**1.0**
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**
IBP1/2-PR	**50**	**150**
AWRR	**0**	**20**

EtCO2	25	50
FiCO2	0	5

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	℃
NIBP Limit Type	Systolic
ECG Filter	Monitor
PVC	ON
ST	ON

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	
EtCO2			0	
FiCO2				0
AWRR			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	-10.0	10.0
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	50
IBP2-S (CVP)	0	300
IBP2-M (CVP)	3	15
IBP2-D (CVP)	0	300
IBP1/2-PR	50	170
EtCO2	25	50
FiCO2	0	5

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**

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	
EtCO2			0	
FiCO2				0
AWRR			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 ° C/° F	**30.0/86.0**	**42.0/107.6**
ST	**-1.0**	**1.0**
PVC	**0**	**20**
T2 ° C /° F	**30.0/86.0**	**42.0/107.6**
IBP1-S (ART)	**60**	**140**
IBP1-M (ART)	**40**	**105**
IBP1-D (ART)	**30**	**90**
IBP2-S (CVP)	**0**	**300**
IBP2-M (CVP)	**0**	**300**
IBP2-D (CVP)	**0**	**300**
IBP1/2-PR	**50**	**160**
AWRR	**0**	**20**
EtCO2	**25**	**50**
FiCO2	**0**	**5**

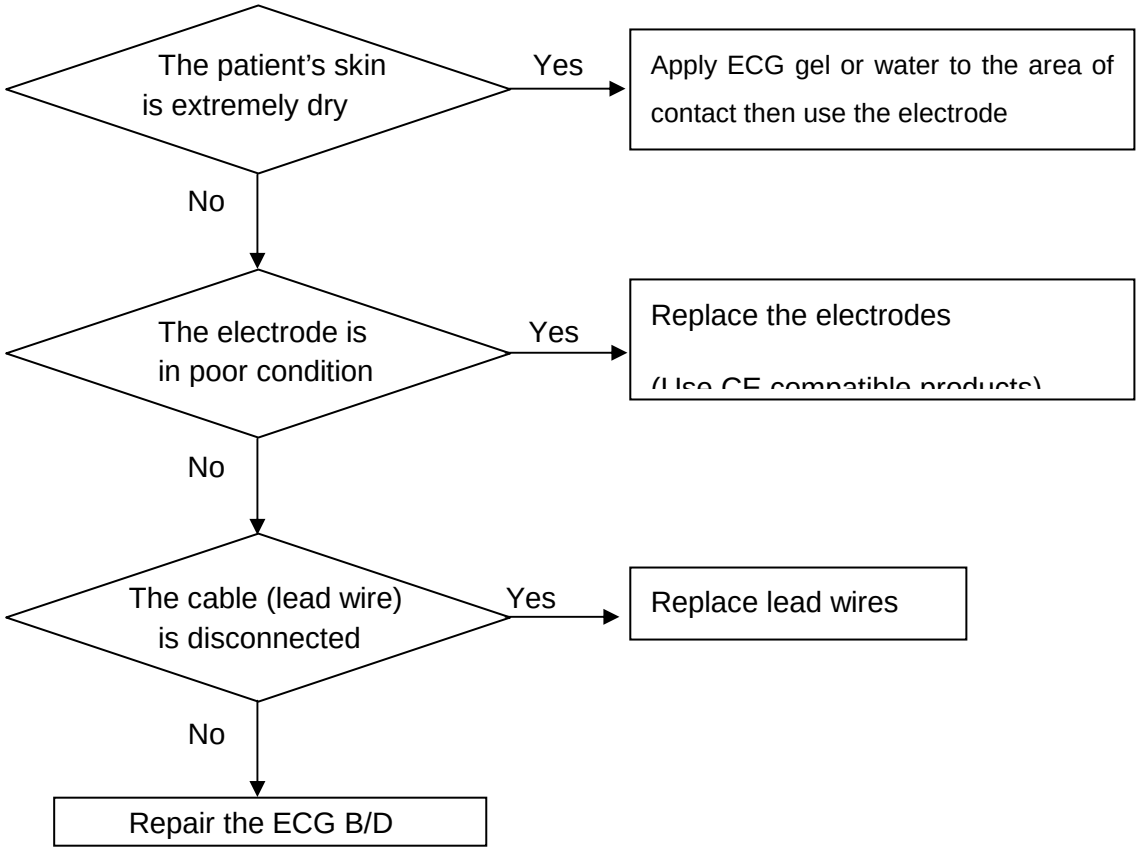
Display

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**

15. TROUBLE SHOOTING

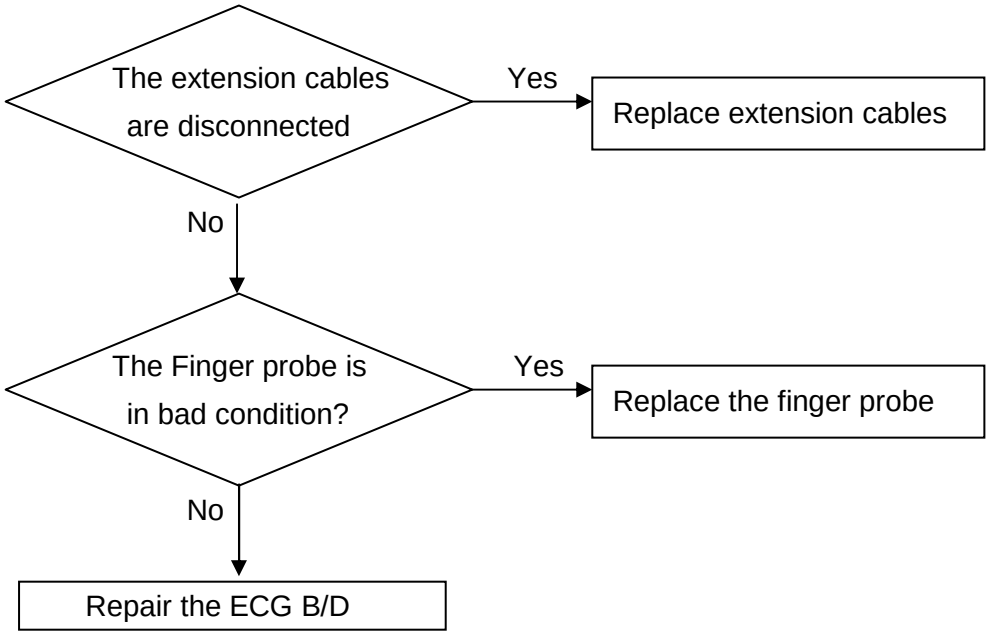
1. Noise in ECG

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

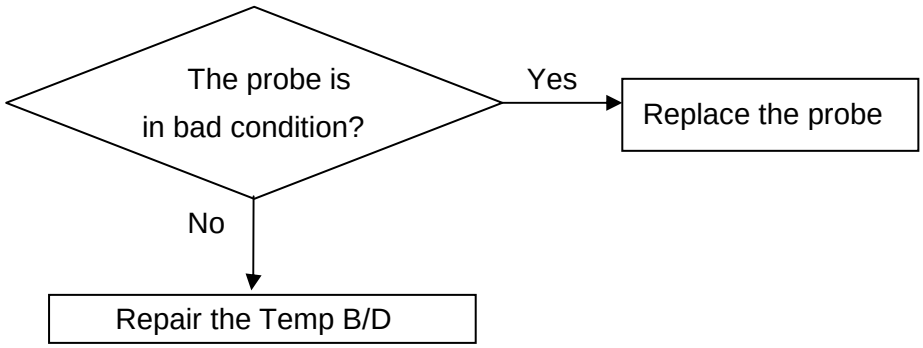


2. SpO_2 malfunction

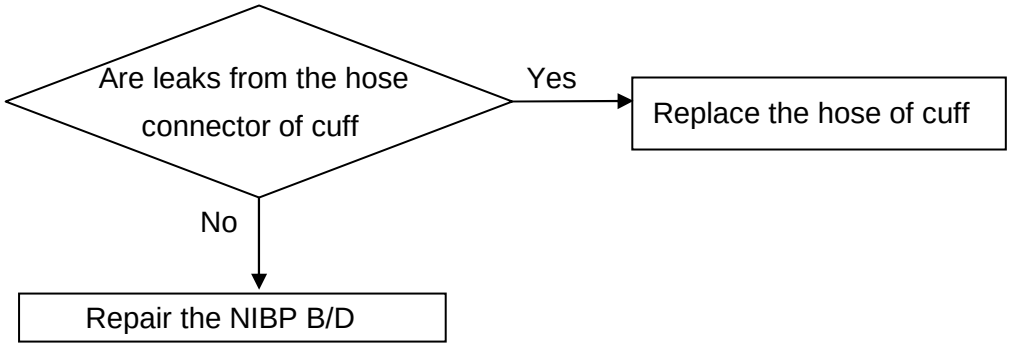
Connectors of the equipments are in bad condition?



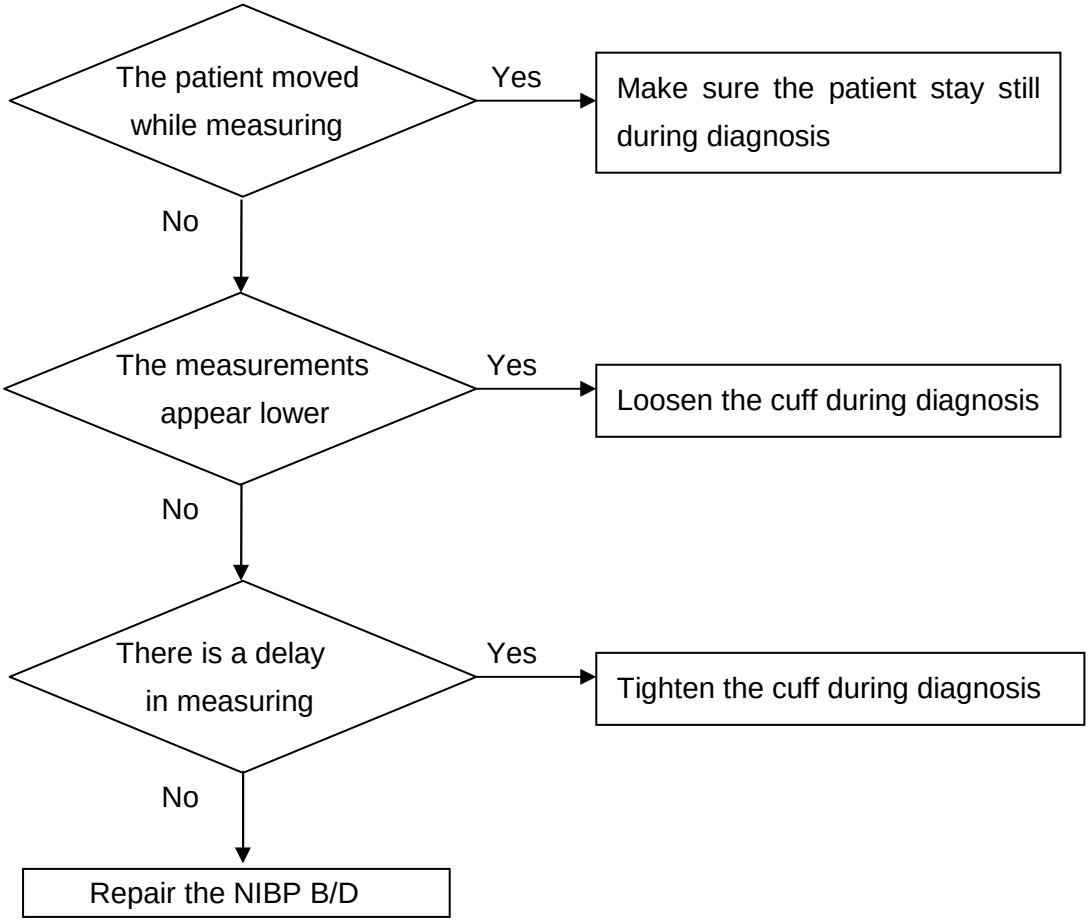
3. Temp malfunction



4. NIBP malfunction

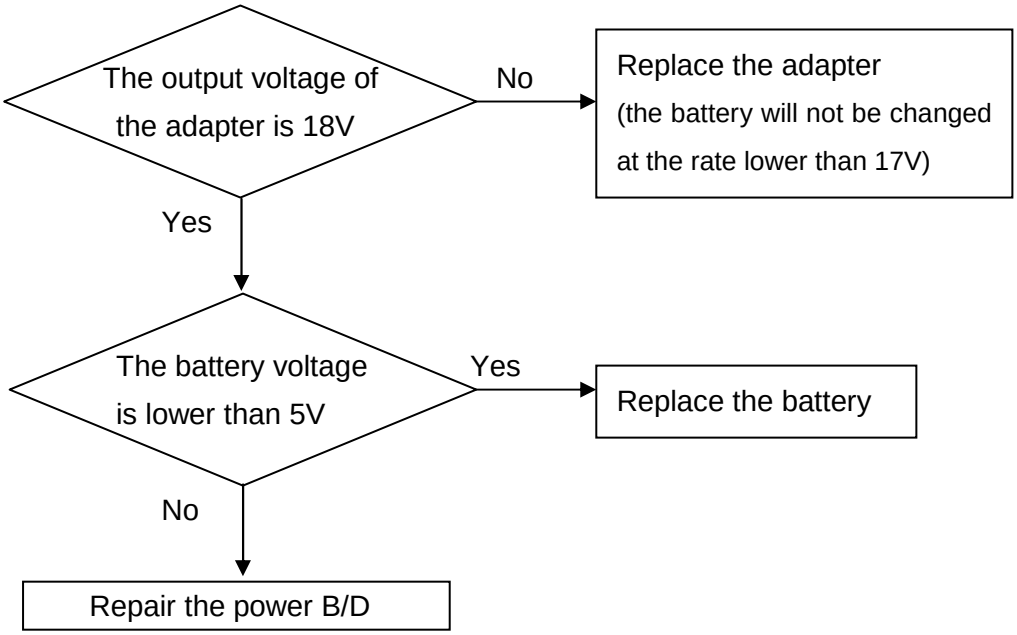


5. Abnormality in NIBP measurements

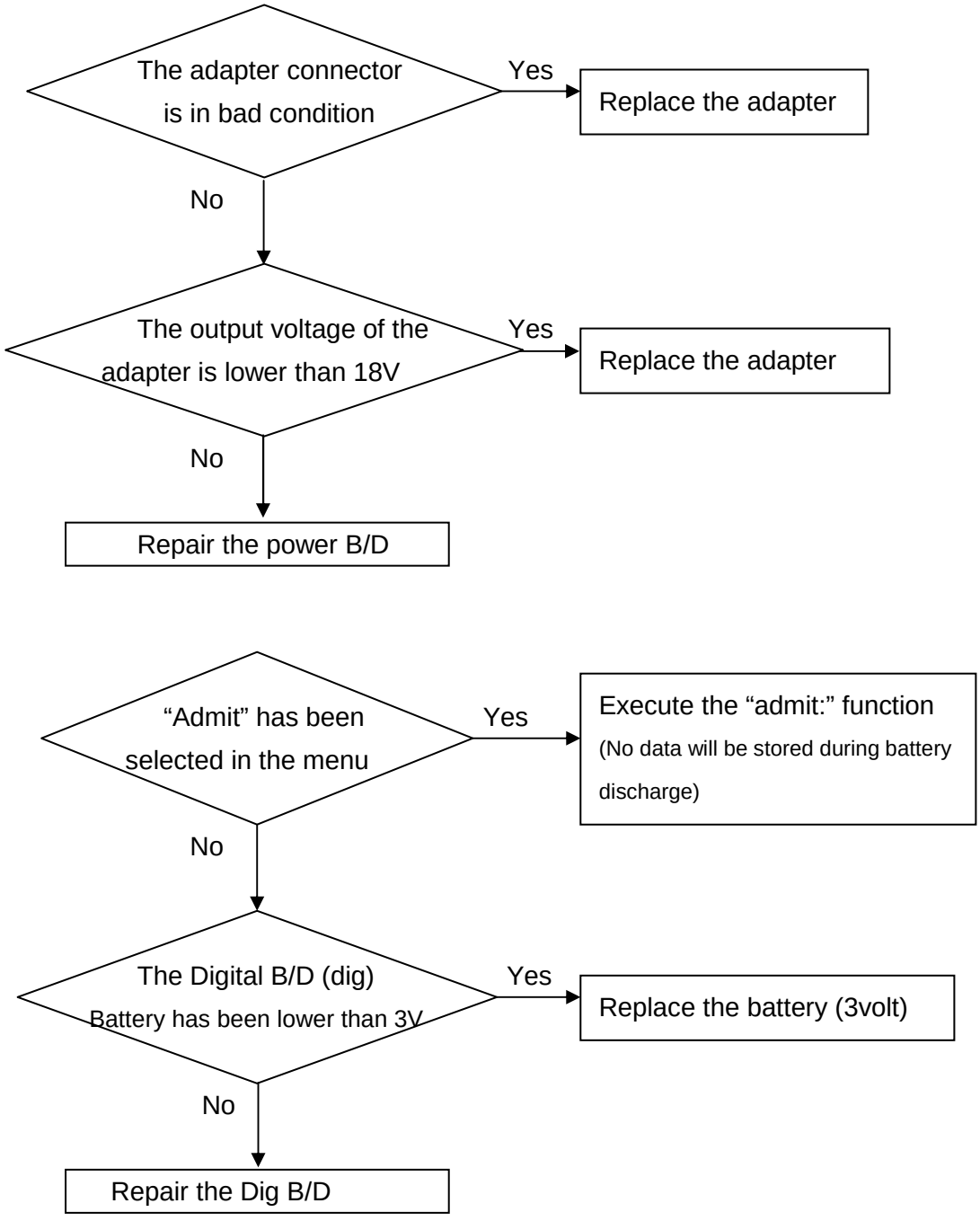


6. Failure in battery recharge

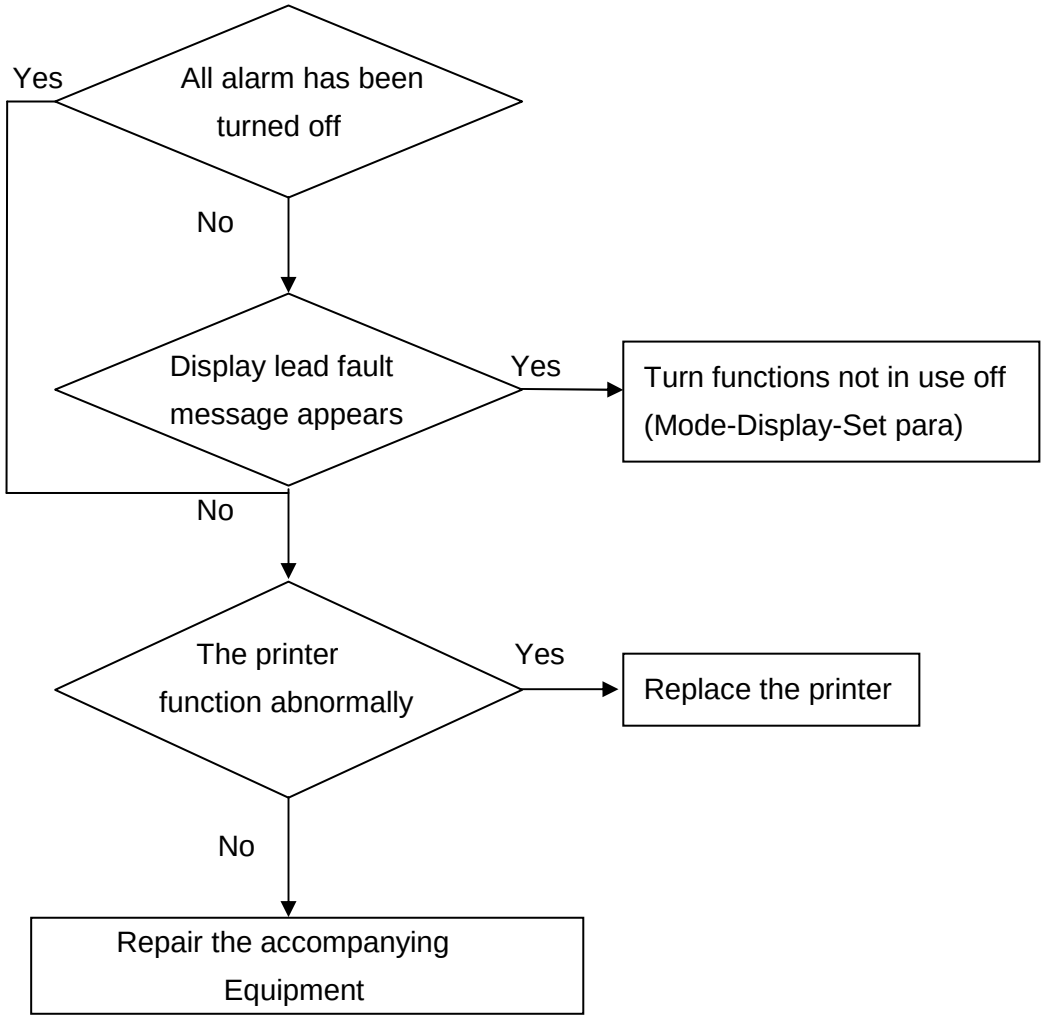
(the battery does not fully recharge in 6 hours or more)



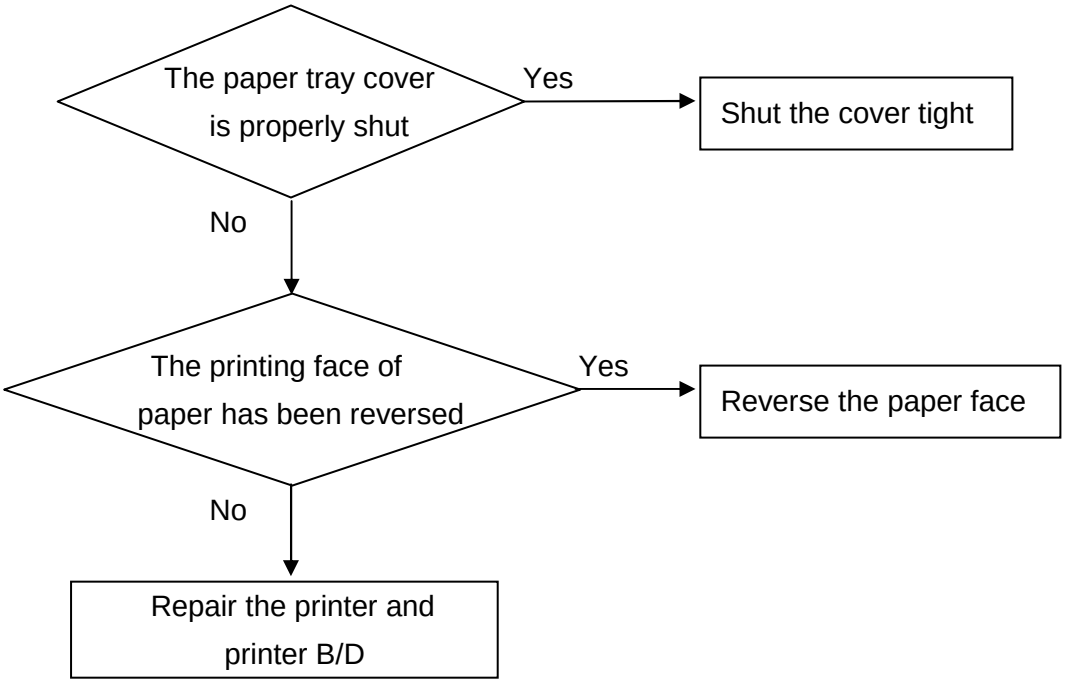
7. Power failure



8. Periodic noises



9. Print failure



16. 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

Ease of use

· Battery operation
· Attached printer
· Table and graphic trend

Additional Function

· Able to use auto mobile power supply
· 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, 2.5 A

Specification

Display, Resolution	**12.1" color TFT, 800 x 600 pixels**
Dimension, Weight	322(W) x 250(H) x 224.8(D) mm, Approx. 4.5kg
Parameter	ECG, Heart Rate, Respiration Rate, SpO2, Pulse Rate, Systolic BP, Diastolic BP, Mean BP, **2 x Temperature, 2 x IBP, EtCO2, FiCO2, Airway Respiration Rate**
Trace	**6 waveforms : 2*ECG, SpO2, RR or EtCO2, 2*IBP** Sweep speed : 6.25, 12.5, 25, 50 mm/sec
Indicators	Categorized alarms (3 priority levels), Visual alarm lamp handle Heart beat tone, SpO2 pulse pitch tone Battery status, External power LED
Interfaces	DC input connector : 12 to 18VDC, 2.5A Defibrillator Sync. Output : - Signal Level : 0 to 5V pulse - Pulse width : 100 ± 10 ms LAN digital output for transferring data, Nurse call system connection DC output : 5VDC, 1A Max
Battery	Rechargeable Li-ion battery, 1hours 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
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 : 3/7 channels 10-lead: 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	Diagnostic mode : 0.05Hz - 150Hz Monitoring mode : 0.5 – 40 Hz Surgical mode : 0.5 – 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
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	0 to 254 bpm
Pulse rate accuracy	±2 bpm
NIBP Performance	
Method	Oscillometry with linear deflation
Operation Mode	Manual/Automatic/Continuous
Measurement range	Adult Pressure : 20 to 260 mmHg Pediatric Pressure : 20 to 230 mmHg Neonate Pressure : 20 to 120 mmHg
Accuracy	mean error : less than ±5 mmHg standard deviation : less than 8 mmHg
Temperature Performance	
Measurement range	0 to 50℃ (0 to 122℉)

Accuracy	±1℃
Compatibility	YSI Series 400 temperature probes
IBP Performance (Option)	
Channels	2
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
Microstream CO2 (Option)	
Measurement range	0 to 99 mmHg
Accuracy	0-40 mmHg ±2 mmHg 41-76 mmHg ±5% of reading, 77-99 mmHg ±10% of reading
Respiration rate	0 to 150 breath per minute
Respiration accuracy	±1breath per minute
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

Accessories Included:

1. Main body of BM7 Monitor	1 EA
2. 5-Lead ECG Cable (MECA5(AHA), MECE5(IEC))	1 EA
3. NIBP extension tube (NBPCBL-400)	1 EA
4. Reusable Adult NIBP cuff (ACUFF-430)	1 EA
5. SpO_2 sensor extension cable (SPCBL-400)	1 EA
6. Reusable Adult SpO_2 sensor (SPASENS-400)	1 EA
7. DC Power Adaptor with Power Cord (18VDC/2.5A, KA1803F52)	1 EA
8. Operator`s Manual	1 EA
9. Chart Paper (PAPER-400)	2 Roll

Option

1. Reusable Temperature Probe (Surface/Skin, TEMPSENS-430)	1 EA
2. IBP Transducer Set (Disposable/Reusable)	1 SET
3. Capnography Station (Microstream $EtCO_2$, Oridion)	1 SET
4. Sidestream EtCO2 Module (Respironics)	1 SET
5. Mainstream EtCO2 Module (Respironics)	1 SET
6. Microstream $EtCO_2$ airway adapter aampling kit	1 EA
7. Sidestream EtCO2 airway adapter sampling kit	1 EA
8. Mainstream EtCO2 airway adapter	1 EA
9. 3-Lead ECG Cable (MECA3(AHA), MECE3(IEC))	1 EA
10. 10-Lead ECG Cable (MECA10(AHA), MECE10(IEC))	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
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
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 Economic Planning Dept.

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BIONET CO., LTD.

Product Name: BM7