Patient Monitor Series

Brio X30 / Brio X50 / Brio X70

Operation Manual

Brio X30

Brio X50

Brio X70

Ver. 1.08

2024. 03. 28

bionet

www.ebionet.com

Revision

No.	Version	Date	Page	Description
1	1.00		-	New
2	1.01	2022.09.22		- New Form - 2 PART. Setup add menu description to manufacturer service - 19 PART. EWS & 20 PART GCS. Add score tables - 1 PART. Basic > 6) Device Markings > Add MD, packing box symbols
3	1.02	2022.09.29		- Introduction > 1) Added Intended use term - Introduction > 1) Intended Use Add patient group table by parameter - 5 PART. Alarm Settings > 6) Alarm Events > Add alarm details screen picture - 7 PART. ECG > 15) Full disclosure > Add screen picture - 7 PART. ECG > 17) Diagnosis method > Add preview screen picture
4	1.03	2022.11.10		- Consolidate/modify overall terms and replace images - PART 1-4) Add a table of product function information - PART 7 Modification of the name ECG > ECG - PART 20 GCS Image Replacement - PART 22 Infrared Thermometer Image Replacement

5	1.04	2022.12.27		- Delete Manufacturer's Address in Company Contact Method - Introduction-6) Delete CE Mark/Delete Content - Introduction-6) Add Manufacturing Date/Picture - Delete European representative - Change the company contact on the last page - Update document number - Fixed typos in BA address
6	1.05	2023.01.27		- PART 2-1) Addition of notes on blocking user account access - PART 2-2) Patient setting menu (F-1-9-1 ~ F-1-9-3) added - PART 2-2) Network addition menu (F-4-2-4) added - PART 2-6), Write License menu deleted, SD Card Format menu added - PART 6-4) Trend Settings description change (4. Add All ~ 11. Move Bottom) - PART 13-8) Added notes when setting EtCO2 - PART 21-1) Added precautions when connecting a printer - PART 25-7), SpO2 alarm message text change and Sensor Fault alarm added - PART 25-6) Update △Temp ˚F range - PART 25-3),4) Update 4.1 edition EMC information
7	1.06	2023.05.02		- PART 14-3) Added IBP transducer (Manufacturer: Ace medical) - PART 17-8) Added maximum

				required time to display CO value after connecting cable to note - PART 11-8) NIBP Gain setting change - PART 2-2) D-2. Add Time parameter menu - PART 2-2) F-1-9-2 menu description supplement - PART 2-2) F-1-9-4 ~ F-1-9-5 menu added - PART 3-2) Updated note description of supported USB Wi-Fi Dongle (Supportable chipset -> Supportable VID:PID) - BM Central notation changed to BM Central Pro - PART 4-6) Updating operation description when scanning barcode - PART 6-2) Parameter Table menu description update - PART 6-3) Parameter List menu description update - PART 7-9) Updated arrhythmia monitoring description - PART 11-4) Changing the measurement time in safety considerations - PART 11-4) Review description added - PART 14-8) Added description of Zero, Last zeroing time Chapter 1-8) Add caution using fixed key - Apply new logo
8	1.07	2023.06.15		Chapter 7-4) ECG measuring cable list update Chapter 14-3) Add Smith

				Medical Accessories Introduction – 2) Indicated for use added Chapter 16-4) Add accessories Chapter 25-5) Add comment to IBP accuracy section
8	1.08	2024.03.28		How to Contact Us) Changed E mail Website of European Representative Introduction) Added 2) Intended Use Environment, 3) Indications, 4) Intended Patient Target Groups, 5) Limitation, 7) Clinical benefit, 13) Side effect / Revised 1) Intended Purpose, 6) Contraindications Chapter 2-2) Add timer function description Chapter 5-2) Update alarm signal sound pressure level Chapter 14-3) Add IBP Cable, Accessories

Warranty

- This product is manufactured through our strict quality control and inspection process. Compensation standards for product repair and exchange follow the "Regulations of Compensation for Consumer's Damage" announced by the Fair-Trade Commission.

- Any questions regarding the warranty should be directed to the local sales or service representative.

- If a malfunction occurs under normal use, our service representative will repair it free of charge during the warranty period.

- If a problem occurs with the equipment during the warranty period, please notify us of the model name, serial number, date of purchase, and malfunction details.

How to Contact Us

To receive a variety of services and supplies, please contact our sales personnel at the following numbers or e-mails. Bionet's services are always open. Please contact us at the numbers below.

Contact information	**Bionet** ● H.Q. address: 5F, DreamMark1 61 Digital-ro 31 gil, Guro-gu, Seoul, Republic of Korea 08375 ● URL: http://www.ebionet.com
U.S.A sales & service representative	**Bionet America, Inc.** ● 2691 Dow Ave. Suite B Tustin, CA 92780 ● Toll Free: 1-877-924-6638 / Fax : 1-714-734-1761 ● E-mail: support@bionetus.com ● URL: www.bionetus.com
European sales & service representative	**Bionet Europe GmbH** ● 2Li Bessemerstr. 51, D-12103 Berlin, Germany ● Tel: +49-30-240-374-52 ● E-mail: be@ebionet.com ● Website: http://bionet-europe.com

Paid Service

A fee will be charged for all services except for breakdowns, so be sure to read this Operation manual below before putting in a request.

- Usage description and simple inspection without disassembly - In case of reinstallation due to poor installation by a distributor	Free the 1st time Charged starting the 2nd time
- Inadequate installation or loosening due to physical product movement, relocation, etc. - When re-installing after the first installation requested by the customer at the time of purchase - When reinstallation is required due to inexperienced installation by the customer - When a service is requested due to the input of foreign substances or improper cleaning	Charged starting the 1st time

1. Equipment cleaning, adjustment, and usage description are not product breakdowns.
(If repair is not possible, separate standards will apply)

2. Breakdowns caused by consumer negligence

Breakdowns and damage due to careless handling by the customer or incorrect repair are caused by:

- Using incompatible electric capacity.
- Mishaps such as dropping the product.
- Using the third party replacements or options not specified by our company.
- Non-Bionet technicians or agency technicians in the process of repair.

3. Other cases

- Breakdowns by natural disasters (fire, salt damage, flood damage, earthquake, etc.)
- When a consumable part has reached the end of its life (accessory)

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Introduction

* The terms of patient monitoring device or patient monitor used in this manual refer to Brio X30 / Brio X50 / Brio X70.

1) Intended Purpose

The patient monitors are intended for monitoring, displaying, reviewing, storing, notifying, and transferring of multiple physiological signs of a patient, such as (ECG / 3-Lead, 5-Lead, 10-Lead selectable), arrhythmia detection, ST-segment analysis, Heart Rate (HR), Respiration rate (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), End-tidal Carbon Dioxide Concentration (EtCO2), Invasive Blood Pressure (IBP), Anesthetic Gas (AG), Non-Invasive Cardiac Output (ICG), Depth of Anesthesia (qCON), and Neuromuscular Transmission Monitoring (NMT).

2) Intended Use Environment

These patient monitors are to be used in healthcare facilities by clinical professionals or under their guidance

3) Indications

The patient monitors are indicated for monitoring of normal or anomalous patient health conditions.

4) Intended Patient Target Groups

All the parameters measured by the patent monitors can be monitored on single adult, pediatric, and neonatal patients except for the following;

- The arrhythmia detection, SpO2, MIBP, qCON and NMT monitoring are intended for adult and pediatric patients only.
- The ICG monitoring is intended for adults only.

- ST segment analysis should be used for adult patients only.

Parameters	Patient Group
Heart Rate (HR)	Adult, Pediatric, Neonate
ST-segment Analysis	Adult
Arrhythmia Detection	Adult, Pediatric
Respiration (Resp)	Adult, Pediatric, Neonate
Pulse Oxygen Saturation (SpO2)	Bionet: Adult, Pediatric(15kg More than) Nellcor : Adult
Invasive Blood Pressure (IBP)	Adult, Pediatric, Neonate
Non-invasive Blood Pressure (NIBP)	Adult, Pediatric
Temperature (Temp)	Adult, Pediatric, Neonate
Infrared Temperature (IR Temp)	Adult, Pediatric, Neonate
Non-Invasive Cardiac Output (ICG)	Adult
End-tidal Carbon Dioxide Concentration (EtCO2)	Adult, Pediatric, Neonate
Anesthetic Gas (AG)	Adult, Pediatric, Neonate
Neuromuscular Transmission Monitoring (NMT)	Adult, Pediatric
Depth of Anesthesia (qCON)	Adult, Pediatric

5) Limitation

There are no sex limitations applicable to the Patient monitors. Furthermore, '4 Intended Patient Target Groups' includes information regarding device limitations for the measurement of physiological parameters in the intended patient target groups.

6) Contraindications

The Patient monitors are contraindicated for the following;

- Therapeutic use
- Home use
- Use during patient transportation within and between hospital environments (e.g. inter-ward patient transport, patient transport via helicopter or ambulance)

- Use during MRI
- Sleep apnea monitoring or diagnosis
- ECG measurements are contraindicated for the diagnosis of cardiac complex rhythm and
- morphology
- Monitoring of the following parameters in neonate patients: ST segment analysis, arrhythmia detection, NIBP, ICG, NMT, qCON
- Monitoring of the following parameters in pediatric populations: ST--segment analysis, ICG

Note	**Each model may have different parameter configurations.** **Please refer to PART 24. Technical Specifications for details.**

7) Clinical benefit

- Accurate monitoring of patient physiological signs within clinically relevant parameter ranges
- Appropriate display of patient physiological signs data
- Accurate/Correct alarming for deviant physiological sign data
- Correct storage, retrieval and transfer of patient physiological signs data

8) Functional Safety

The essential function of the patient monitors is to provide the healthcare practitioner with meaningful parameter values.

An alarm occurs if the parameter values are out of the specified range or when they are not provided properly.

Bionet has assessed the risks associated with the use of the patient monitors in consideration of the main functions and has mitigated the risks threatening their product life, provided that they are used in compliance with service recommendations and regular maintenance.

9) Warnings, Cautions and Notes

Read the "Warnings, Cautions and Notes" thoroughly to ensure safety and to prevent product damage before using the patient monitors. Be sure to follow the "Warnings, Cautions and Note" indicated below, as these are important messages related to safety.

Specifications or functions described in this manual are subject to change without notice for product improvement.

Warning	**[Warning] Failure to follow this message may cause severe injuries, casualty or physical damage to patients.**
Caution	**[Caution] Failure to follow this message may cause in non-life-threatening injury or damage to the equipment.**
Note	**[Note] indicates some important information and tips, which are not dangerous, about installation, operations and maintenance.**

10) Definition of Groups

E

Bionet defines user groups of the patient monitors as Users, Service representative, and Experts.

All defined groups should read this operation manual very carefully before starting to use the patient monitors and should be trained in their use, installation, reprocessing, maintenance, and repair.

The patient monitors can be used, installed, reprocessed, maintained, and repaired by the defined groups only.

User

Users shall use the patient monitors for their intended use.

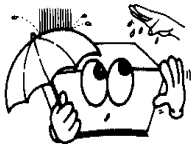
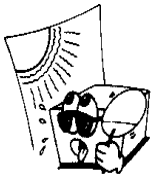
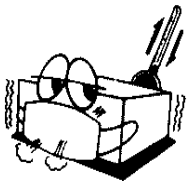
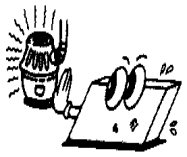
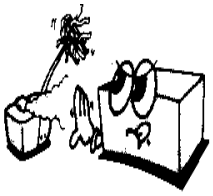
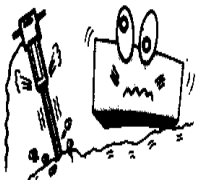
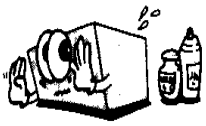
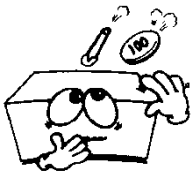
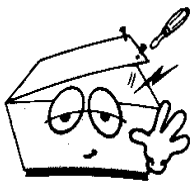
Service representative

Service representative are responsible for the maintenance of the patient monitors.

They shall be trained in the installation, reprocessing, and maintenance of them.

General Precautions on Environment

DO NOT store or operate the equipment in the places listed below.

	A place exposed to moisture (DO NOT touch the equipment with wet hands.)		A place under direct sunlight
	A place in areas with highly fluctuating temperatures.		A place in the vicinity of Electric heater
	A place with excessive humidity rise or poor ventilation		A place with sources that cause excessive shock or vibration
	A place exposed to chemicals or at risk of gas leakage		Avoid the invasion of small objects/ particles such as dust, and especially avoid metallic material.
	Do not disjoint or disassemble the equipment. (Bionet is not liable for broken products caused by attempted disassembly).		DO NOT connect power until the product is completely installed. It may cause damage to the product.

11) Electromagnetic Compatibility

The patient monitors have been designed and tested for compliance with current regulatory standards as to their capacity to limit electromagnetic emission (EMI), and as to their ability to block the effects of EMI from external sources.
They comply with the following standards pertaining to EMI emissions and susceptibility: EN60601-1-2.

To reduce possible hazardous situations caused by electromagnetic interference, we recommend the following:

- Use only accessories provided by Bionet.
- Ensure that other products used in areas where patient monitors and life support are used comply to accepted emissions standards (CISPR 11, Class A).
- Try to maximize the distance between electro-medical devices. High-power equipment related to electrical simulators, electrosurgical instruments, and radiators (X-ray machines), as well as evoked potential devices may cause monitor interference.
- Strictly limit exposure and access to portable radio frequency sources (e.g., cellular phones and radio transmitters). Be aware that portable phones may periodically transmit even when in standby mode.
- Maintain good cable management. Do not route cables over electrical equipment. Do not intertwine cables.
- Ensure all electrical maintenance is performed by qualified personnel.

Caution	**Infectious devices and parts must be sanitized and cleaned before disposal.**

12) Electronic Device Connection Precautions

SHOCK HAZARD — Improper use of this equipment may cause electric shock. Strictly observe the following guidelines. Failure to do so may endanger the lives of the patient, user, and bystanders.

To disconnect the equipment from the power line, first remove the power plug from the wall outlet before disconnecting the cables from the equipment; Otherwise, there is a risk that metal parts inadvertently inserted into the power cord socket comes into contact with line voltage.

Additional devices connected to medical electrical equipment shall comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment).

Additionally, all configurations must comply with the requirements for medical electrical system. (See IEC 60601-2 or Clause 16 of IEC 60601-1 edition 3.2.)
Anyone who connects additional devices to medical electrical equipment is in the position of configuring medical system, and is responsible for complying with the requirements of medical electrical system.
Keep in mind that local legislation takes precedence over the above-mentioned requirements.
If in doubt, consult your local representative or the technical service department.

POWER REQUIREMENTS— Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label. If this is not the case, do not connect the equipment to the power line until you adjust it to match the power source.

In the USA, if the installation of this equipment uses 240V instead of 120V, the source must be center tapped, 240V single-phase circuit.

This equipment is suitable for connection to public mains as defined in CISPR 11.

Equipment connected to the ECG system and in the patient, environment must be powered from a medically isolated power source or must be a medically isolated device. The equipment powered from a non-isolated source can result in chassis leakage currents exceeding safe levels. Chassis leakage current created by an accessory or device connected to a non-isolated outlet may add to the chassis leakage current of the ECG system.

13) Side effect

There is no known side effect.

PART 1. Basic

1) Electric Safety Precautions

Warning	**The patient monitor must be connected to an appropriate power source before use.** **Before using the patient monitor, check whether its power supply line is appropriate (AC100 - 240V).**
Caution	**Please check the following before using the patient monitor:** ● **Ensure that the power source is supplied from Bionet.** ● **Ensure that the entire connection of the patient monitor cables is properly and firmly fixed.** ● **Each monitor requires an independent circuit and a stable ground. When using the same power supply with other electrical devices, inaccurate measurements may occur.** ● **The patient monitor should be distanced from generators, X-ray equipment, broadcasting equipment, or transmitting wires to prevent electrical noises from being generated during the operation, producing inaccurate measurements. For Brio patient monitor series, both independent circuit and stable grounding are required. Sharing the same power source with other electronics can also produce inaccurate outputs.**

Warning	**Avoid physical contact with the patient during defibrillation, as it may cause serious injury or death. When using the defibrillator, follow standard safety precautions and only use the supplied cable.**

Warning	**In case the medical equipment does not operate normally, or if it has been damaged, do not use it on any patient; Contact the medical equipment**

	technician in your hospital or the equipment supplier.

Warning	• **To reduce the hazard of burns during high-frequency surgical procedures, ensure that the cables and transducers of the patient monitor never come into contact with the high-frequency surgical units.** • **The neutral electrode of the electro-surgery unit (ESU) must properly contact the patient, to prevent accidental burning of the patient.**

Note	**The patient monitor is classified as follows:** • **It is classified as Class I, BF & CF concerning electric shock.** • **It is classified as IPX2 for waterproofing, and according to KS C IEC 60529, it does not have a harmful effect on vertically falling water drops when inclined within 15 degrees.** • **Noise level is A class regarding IEC/EN 60601-1 and the subject of Noise is A level concerning IEC/EN60601-1-2.**

Note	**Waterproof Precautions** • **It is not proper to operate the patient monitor around combustible anesthetics or dissolvents.** • **If you spill liquid on the patient monitor, battery, or accessories, or if they are accidentally soaked in liquid, contact your service representative or the equipment supply division. Do not operate them before they have been tested and approved for further use.**

2) Equipment Connection

Caution	● **Doctors and patients in hospitals are exposed to the risk of uncontrollable currents. These currents are caused by a potential difference between the patient monitor and conductive objects, which may come into the monitor. To solve this problem, make sure that the auxiliary equipment connected to the patient monitor satisfies EN60601-1..** ● **Unsecured equipment may fall on the patient. Fix the equipment securely during installation.**

Note	**For measurements in or near the heart, it is recommended to connect the patient monitor to a potential equalization system. Use a potential equalization cable to connect to the pin marked with the equipotential symbol.**

Note	**The patient monitor uses a main plug as isolation means to the mains power. Do not place it in a place difficult to access the mains plug.**

3) Biocompatibility

When used as intended, the parts of the patient monitor 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.

4) Product Configuration

Basic components

1. Main body of Brio X30/50/70 monitor----------1 EA
2. 3-Lead or 5-Lead ECG patient cable ----------1 EA
3. Disposable electrodes----------10 EA
4. NIBP extension tube ----------1 EA
5. Reusable adult NIBP cuff ----------1 EA
6. SpO2 extension cable----------1 EA
7. Reusable adult SpO2 probe ----------1 EA
8. Operation manual----------1 EA
9. Power Cord----------1 EA

Optional modules

1. Paramount module for monitoring NMT, ICG, qCON, AG
2. Printer module
3. IR-temperature

Optional components

1. Reusable temperature probe (Skin type)
2. Sidestream EtCO2 module (Respironics)
3. Mainstream EtCO2 module (Respironics)
4. Sidestream EtCO2 sample lines
5. Mainstream EtCO2 airway adapters
6. 5-Lead ECG patient cable
7. 3-Lead ECG patient cable
8. 10-Lead ECG patient Cable
9. IBP extension cable

10. IBP transducer set (Disposable/Reusable)
11. qCON patient cable
12. qCON sensor
13. ICG patient cable
14. ICG electrode
15. NMT patient cable & sensor
16. Anesthetic Gas watertrap

Warning	**To avoid electrical shock, do not open the cover. Disassembling the patient monitor should be done only by service representative authorized by Bionet.**

Warning	**• Use only installation accessories specified by Bionet.** **• Connect only approved devices to the patient monitor.** **Devices connected to the patient monitor must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard.** **Any personnel who connect devices to the signal input/output port of the patient monitor are responsible for providing evidence that the safety certification of the connected devices has been approved in accordance to the IEC 60601-1. If you have any questions, please contact Bionet.** **• If it is not evident from the device specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturer or an expert in the field. A determination must be made that the proposed combination does not negatively affect the devices themselves or the patient's safety.**

Note	**All Bionet hardware drawings and screen shots in this operation manual are for illustrative purposes only. The actual product may differ slightly from drawings and screenshots used herein.**

Product Feature Information

*basics: ●

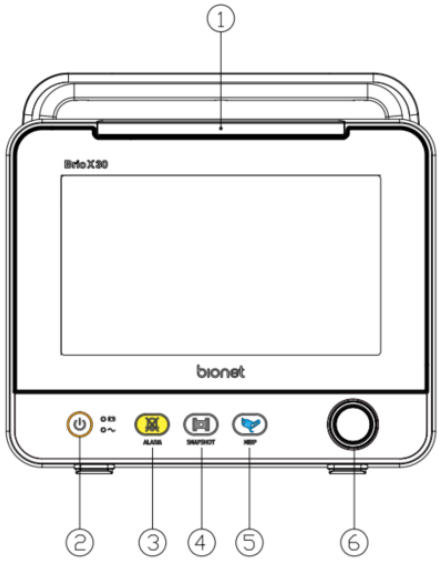
*option: O

Function	Brio X30	Brio X50	Brio X70
Display	8″	12.1″	15.6″
ECG 3-Lead	●	O	O
ECG 5-Lead	O	●	●
ECG 10-Lead		O	O
Respiration	●	●	●
EWS	●	●	●
GCS	●	●	●
Bionet SpO2	●	●	●
Nellcor SpO2	O	O	O
Bionet NIBP	●	●	●
Suntech NIBP	O	O	O
2CH IBP	●		
4CH IBP		●	●
EtCO2	●	●	●
2 Temp	●	●	●
IR-temperature			
Paramount		O	O
AG		O	O
ICG		O	O
NMT			O
qCON(EEG)			O
Battery(3250mAh)	●	●	●
Battery(6500mAh)	O	O	O
OxyCRG	●	●	●
B2B	●	●	●
HL7	●	●	●
Full disclosure	●	●	●
Wi-Fi	●	●	●
Printer	O	O	O

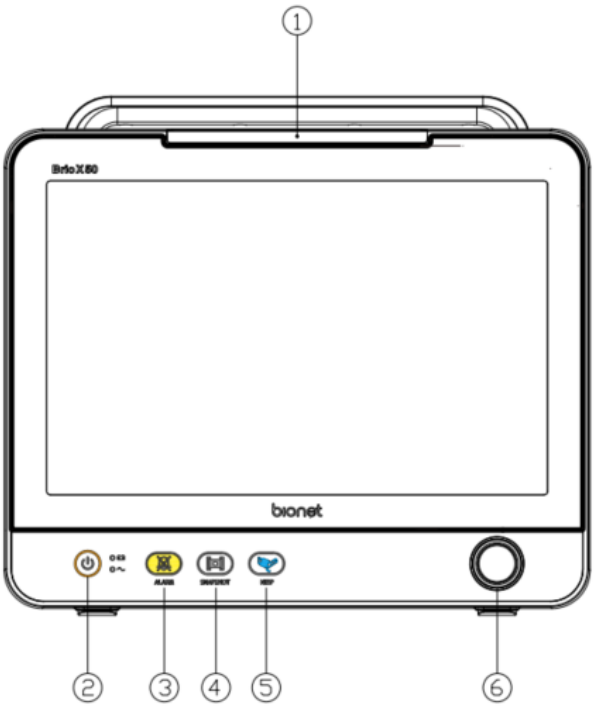
5) Basic Unit

Front view

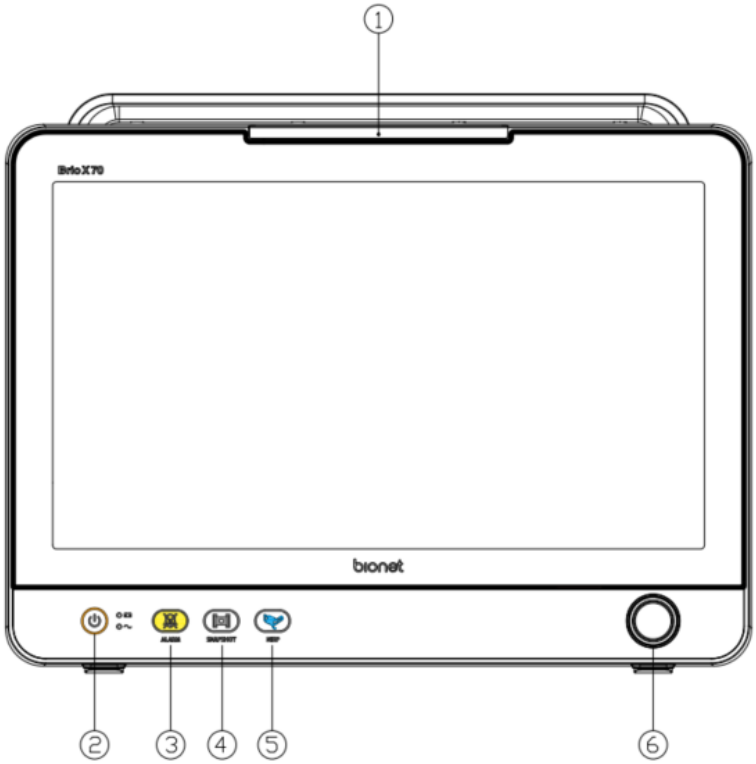
Brio X30



Brio X50



Brio X70



① Alarm lamp

② Power ON/OFF Key

③ Alarm control key

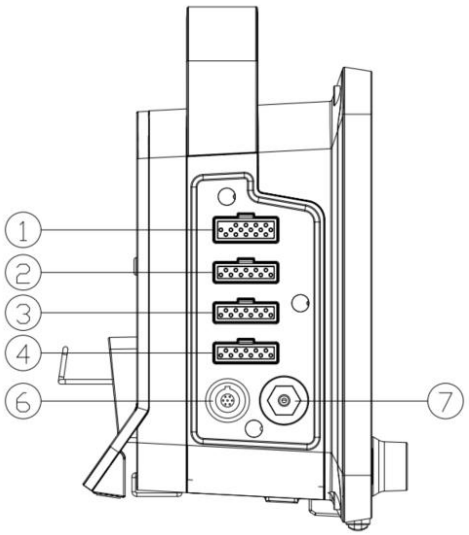
④ Screen shot key

⑤ Blood pressure measurement key

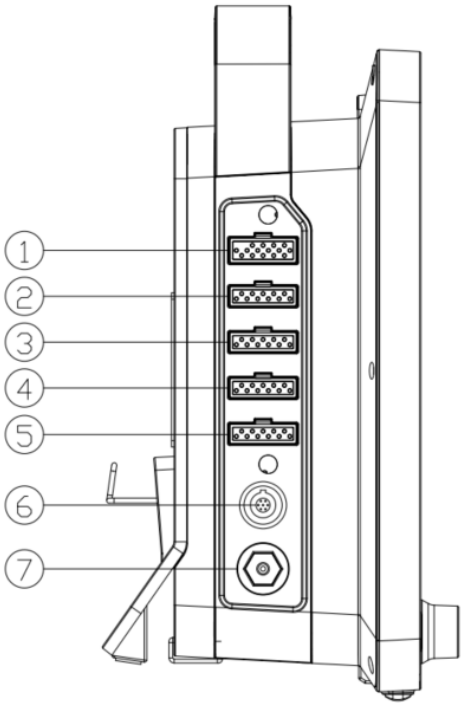
⑥ Rotary knob

Left side view

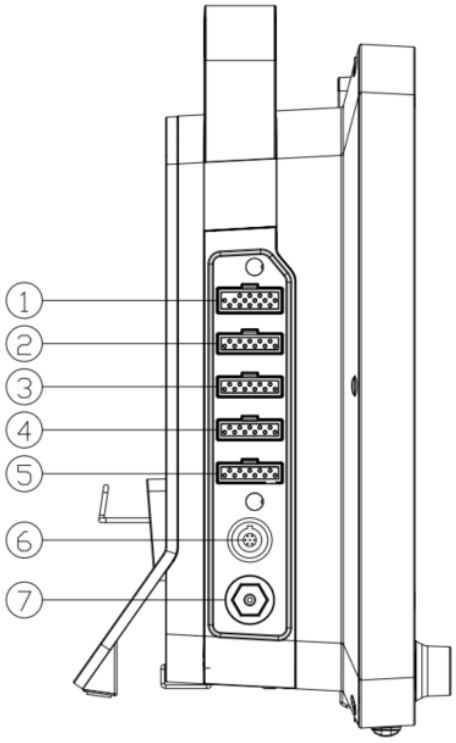
Brio X30



Brio X50



Brio X70



① ECG connector

② SpO2 connector

③ Temperature connector

④ IBP connector

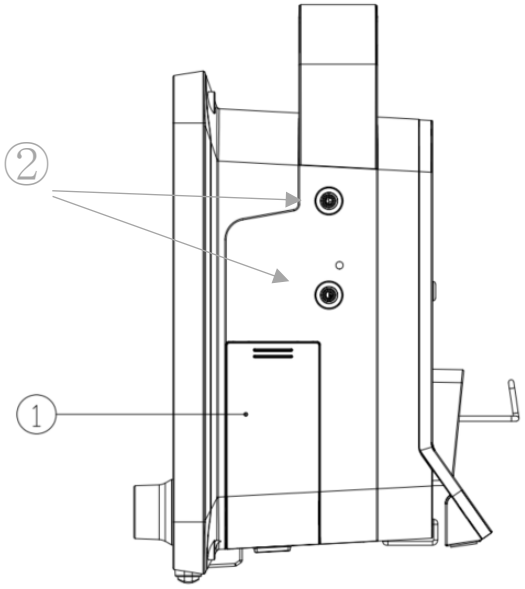
⑤ IBP connector2

⑥ EtCO2 connector

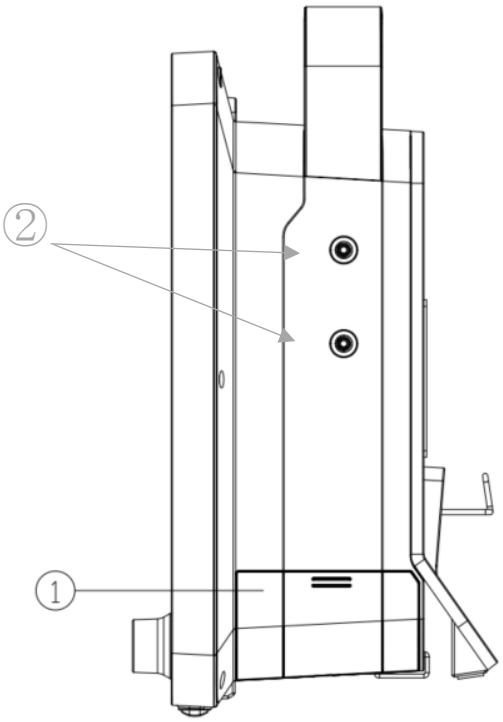
⑦ Blood pressure tube connector

Right side view

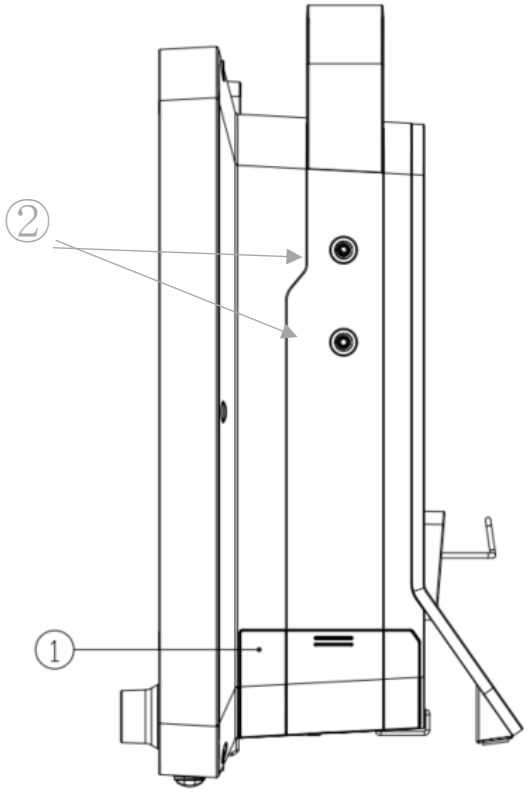
Brio X30



Brio X50



Brio X70

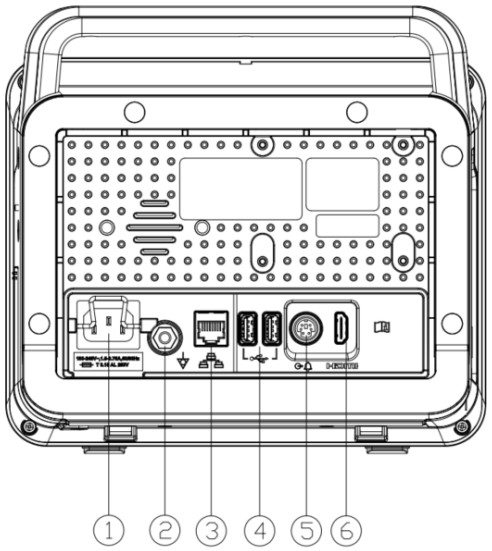


① Battery cover

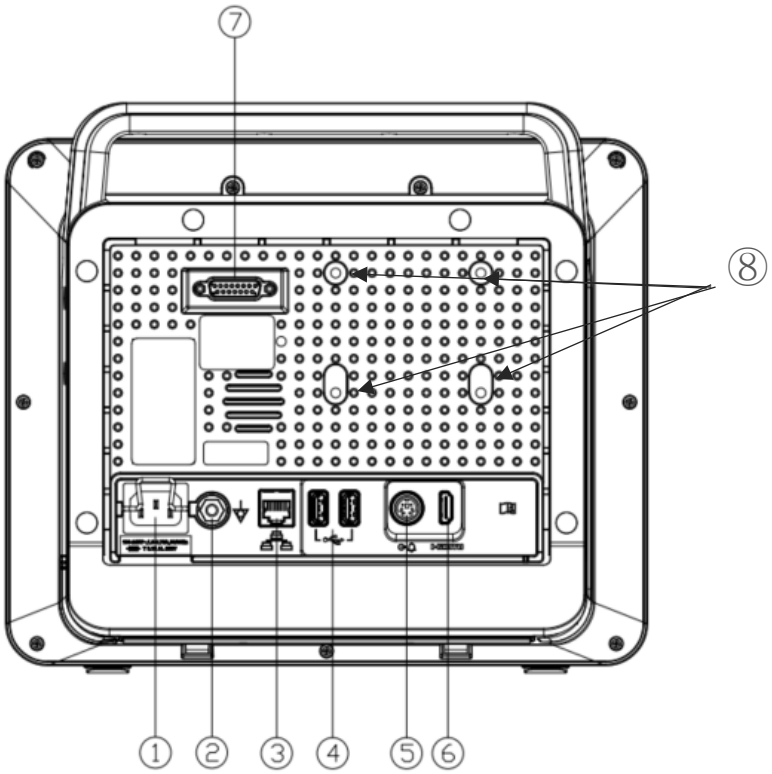
② Printer bracket

Back side view

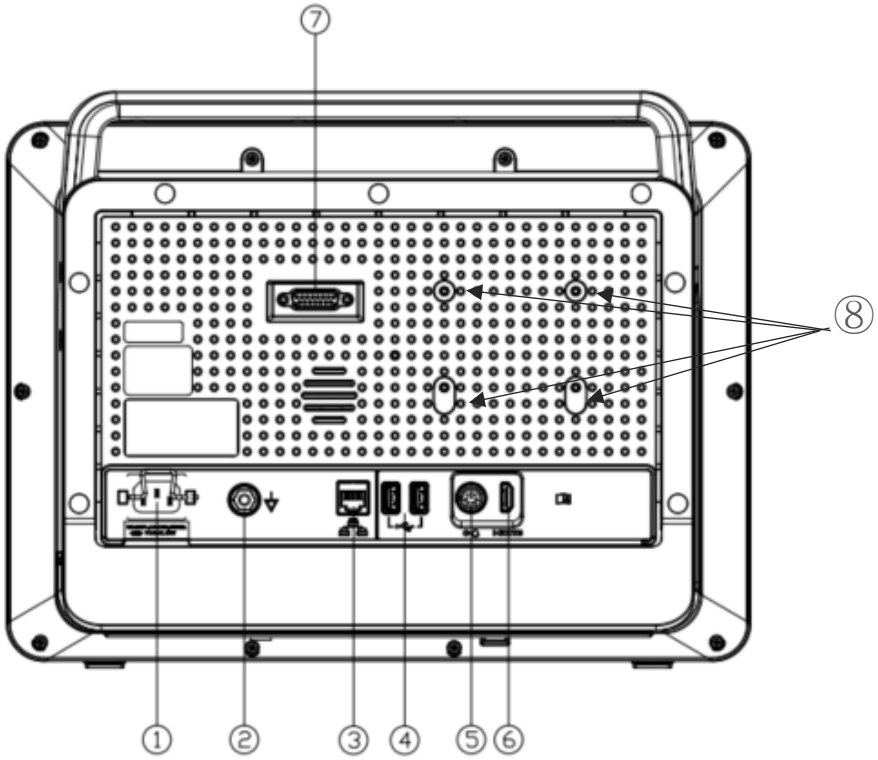
Brio X30



Brio X50



Brio X70



① AC input connector

② Equipotential Grounding Terminal

③ LAN port

④ USB port (USB 2.0 5Vdc / Max. 500mA)

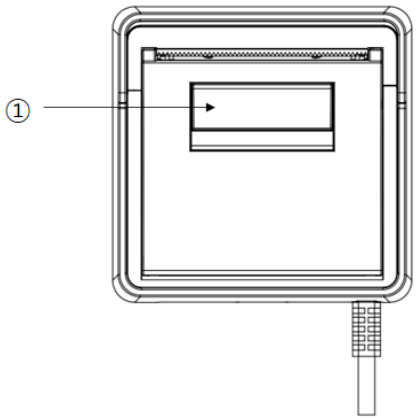
⑤ Printer connector

⑥ HDMI output port

⑦ Paramount module connector

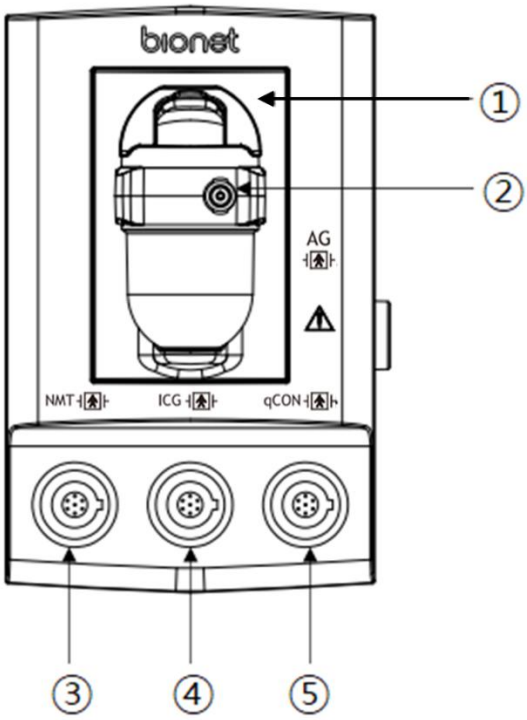
⑧ Paramount module bracket

Printer module (option)



① Printer door lever

Paramount module (option)



① AG (Anesthetic Gas) watertrap

② Gas sample line connector

③ NMT connector

④ ICG connector

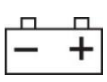
⑤ qCON connector

Warning	**USB compatible** ● **The patient monitor is compatible with external USB memory drives up to 64GB.** ● **We recommend the products of the brands listed in the manual (Sandisk, PNY, Transcend, Samsung).** ● **When using a product with high power consumption, such as an external hard drive, be sure to use the adapter dedicated to it for suitable power supply. (You can't use it with the patient monitor's power supply alone.)** ● **It is recommended to save the data of the connected devices before connecting any additional devices. Bionet recommends backing up data on an existing storage device before connecting a new storage device.** ● **Some high power USB devices may not be supported.** **Paramount Connection** ● **Connect the patient monitor to a Paramount module with the power turned off.**

Note	**The HDMI output of Brio X30, Brio X50, and Brio X70 is 1024x600 @60Hz, 1280x800 @60Hz. and 1366x768 @60Hz, respectively.** **Depending on the specifications of the patient monitor, the screen may not display the output, so please check beforehand.**

Note	**When using the patient monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential difference between them.**

6) Device Markings

	Caution: Consult accompanying documents		Type BF applied part
	Type CF applied part		ECG
	IP (Ingress Protection)		NIBP
T	Temperature	SpO2	SpO2
	EtCO2		Grounding terminal
IBP	IBP		LAN port
AG 	Anesthetic Gas(AG)	qCON	Depth of anesthesia
ICG	Impedance Cardiography		Snapshot
NMT	Neuromuscular Transmission		Auxiliary Port
	Printer connector		USB port
HDMI	HDMI external port		Date of manufacture
	Alarm Key		WEEE (Waste Electrical and Electronic Equipment)
	NIBP Key		Battery charge indicator
	Power ON /OFF Key		Safety Sign: It indicates that you should read

			the user manual. Read the user manual before starting work or operating the equipment.
	AC Power		Medical device
	Consult instructions for use. This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.		Fragile
	This way up		Keep dry
	Use no hooks		Manufactory
	Recycle		

7) Power

The patient monitor uses AC power (100 -240VAC, 1.5~0.75A, 50/60Hz). In the event of a power outage or cable shortage, the monitor automatically switches to battery power to continue patient monitoring without data loss. The built-in battery is intended for back-up use only during a power-outage.

When the power cable is connected to the back of the monitor, the AC input LED on the front lights up in green. When you press the power key, the monitor is powered on and ready to use.

Warning	**The patient monitor must be connected to a protective earth grounded power supply.**

Caution	**Do not position the patient monitor in a space that creates difficulty in unplugging its power supply cord.** **The patient monitor can only be used with AC power (100 ~ 240VAC, 1.5 ~ 0.75A, 50/60Hz), and no other power source should be used.** **Do not connect AC power with wet hands.**

Battery Power

The patient monitor uses battery power when there is a power-outage, or during portable use scenarios.

When the AC power supply is cut off, the monitor immediately switches to battery power and continues to operate.

The battery is attached to the side of the monitor.

Caution	**For a monitor without batteries, sudden interruption of AC power, such as a power outage, may result in loss of stored data or data corruption.**

Operation

1. The battery is automatically charged when connected to AC power. The battery charge indicator LED on the front lights up in orange while the battery is being charged and turns green when charging is complete. While being charged, the battery icon is shown as charging in the upper right corner of the screen.
2. AC input LED and charging LED do not light up while the monitor is working on battery.
3. The charging status of the battery is displayed with a 5 step-diagram.

Battery Status Display		
Display	**Charging Status**	**Remarks**
	Charging	
	Fully charged.	

	80% of battery remaining	
	60% of battery remaining	If possible, connect the monitor to the AC adapter.
	40% of battery remaining	Immediately connect the monitor to the AC adapter.
	Battery is very low. (Power will turn off soon.)	Immediately connect the monitor to the AC adapter.
	No battery	Connect the battery.

Caution	**The battery status display is accurate only when the battery is functioning normally.** **Do not disassemble, modify, or heat the battery.** **Do not subject the battery to shock.** **Do not use if the battery shows signs of leakage, deformation, discoloration, or other abnormalities.** **The patient monitor should only use batteries provided by Bionet**

Note	**When external power is not supplied, it takes about 2 minutes for the battery status display to reflect the actual remaining battery capacity.**

Battery information

- Battery specification: Li-ion , 10.8V

  3BL3CABIO (3250mAh) (Option)
  6BL6CABIO (6500mAh) (Option)

- Battery charging time:

  3BL3CABIO: More than 3 hours
  6BL6CABIO: More than 5 hours

- Continuous battery usage time when fully charged:

  Brio X30

- 3BL3CABIO: about 3 hours
- 6BL6CABIO: about 5 hours

Brio X50

- 3BL3CABIO: about 2 hours
- 6BL6CABIO: about 4 hours

Brio X70

- 3BL3CABIO: about 2 hours
- 6BL6CABIO: about 4 hours

* (NIBP measured every 15 minutes with SpO2 and ECG, LCD brightness 80%)

Warning	● **Capacity or operating time of old or defective batteries is significantly compromised.** ● **Bionet recommends replacing the lithium-Ion battery after 24 months of use.** ● **Remove the battery if the patient monitor is not likely to be used for an extended period of time.**

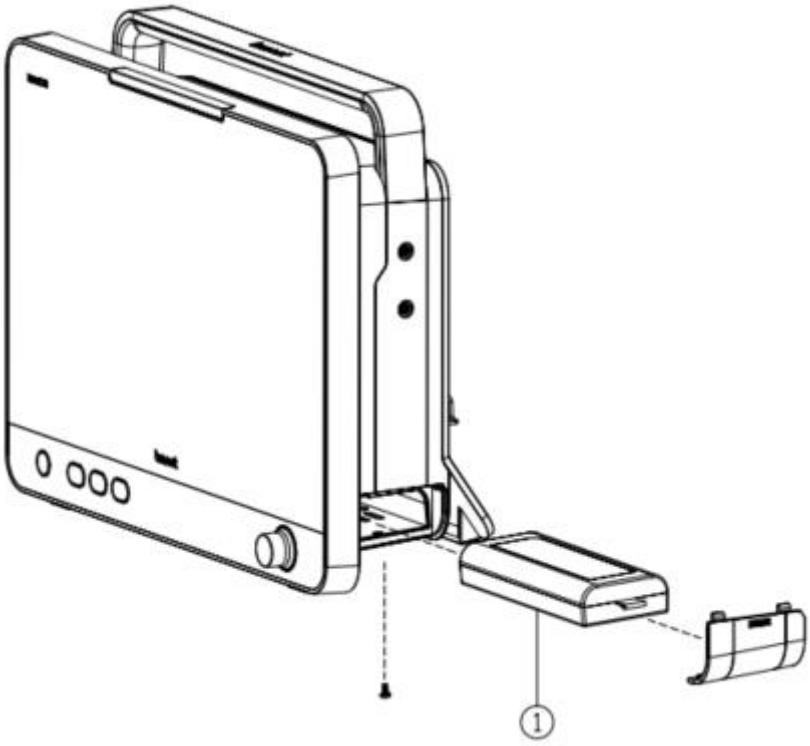
Note	**The Lithium-Ion battery is a rechargeable battery containing Lithium-Ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.**

Note	**To keep the patient monitor fully charged for patient transport, keep the patient monitor plugged in until you are ready to transport the patient. Reconnect it to AC power immediately after transfer.** **Battery life depends on the frequency of use. Continued use by the battery power reduces the battery life and shortens the time of replacement.** **Be sure to recharge the battery before it is completely discharged.**

How to replace the battery

Replace the battery as shown below.

If the battery of Brio X30 does fit in entirely, lay down the monitor with facing up and try again.



① Standard battery

Warning	**Pay attention to the polarity when replacing the battery.** **We strongly recommend the use of battery officially supplied by Bionet.** **Ensure that the battery is properly secured to the bracket.** **Do not inflict extreme levels of impact on the battery.** **Ignoring the above warnings may cause battery explosion or other critical damages to the patient monitor.**

Conditioning Guideline

Check battery performance by fully charging and completely discharging it every 6 months.

How to Recycle the Battery

When the battery no longer holds a charge, it should be replaced. The battery is recyclable. 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 as it may explode, which may cause you serious injury.**

Warning	**Do not use the battery that has been impacted, disfigured, or submerged; dispose of it.**

8) Getting Started

Starting the monitor

Press the power key at the bottom right of the monitor's front panel. The power light on the monitor and the alarm bar lights up, signifying that the power has turned on. Then, the screen lights up, displaying the main screen after a self-diagnosis test.

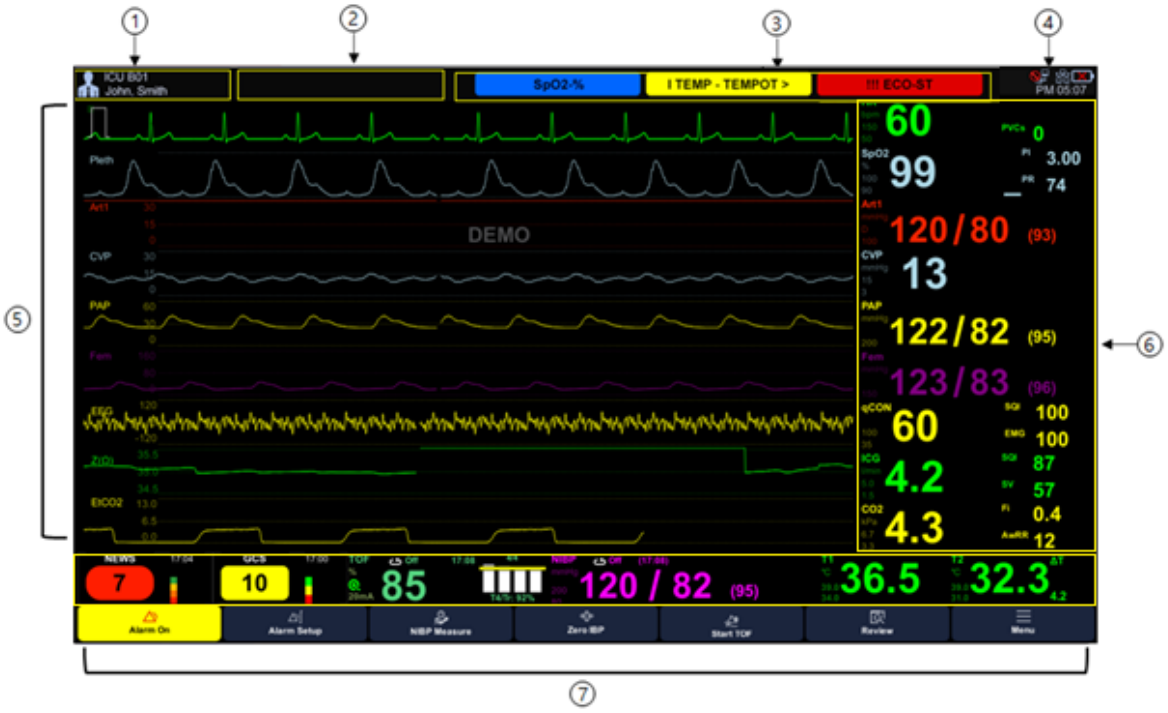
Caution	● **Check that the visual and audible alarm signals are displayed correctly when the patient monitor is powered on.** ● **Do not use the patient monitor on a patient if you suspect it is not working properly or has been mechanically damaged. Contact your service representative or Bionet.**

Stopping the monitor

Press and hold the power key for 3 seconds, and the screen goes off.

Main screen setup

After the monitor is turned on, the main screen is displayed.



Patient monitor Screen Layout

① Patient information: Displays patient information (patient type, gender, and name), unit name, and bed number. If you tap this area, the patient management dialog appears.

② Alarm mode information: Mode information is displayed in this area when changing the alarm mode. In Paused mode, the remaining time is also displayed.

③ Bio-signal alarm message: Displays high-priority alarms from the right.

④ System Status Information: Displays time, power status, network, and server connection status.

⑤ Parameter waveform: Displays the parameter waveform. When you select a waveform, the corresponding setting window appears.

⑥ Parameter Numerical: Displays the parameter value, alarm range and alarm status. If you select a numerical area, the corresponding setting window appears.

⑦ Menu: Displays the menu.

Rotary knob switch

The Rotary knob switch allows you to navigate menus, select settings, and perform menu functions. Rotate the Rotary knob to navigate the menu item. To confirm the selection, press the Rotary knob switch.

Fixed keys

The fixed keys on the front panel of the monitor allow you to perform the frequently used functions.

Fixed key	Description
	The alarm control key switches between Normal / Audio Paused/ Alarm Paused mode. Each time you press the key, alarm switches to Audio Paused -> Alarm Paused -> Alarm On. Press more than 3 seconds to switch to Audio Off or Alarm Off mode.
	It is the snapshot key. The data for 16 seconds right before the key is pressed is saved as a snapshot. You can view the saved snapshots in the Events menu of Review.
	It is the start or stop NIBP measurement. When the measurement is stopped, the automatic measurement cycle is also canceled.

Caution	**If the power key or fixed key is pressed hard with a fingernail, it may be torn or deformed.**

Function keys

On the right side of the monitor's front panel, you can find the touch screen icons that allows you to select frequently used functions.

Function key	Description	Function key	Description
	Alarm mode key: Switch between Normal/ Audio		Set alarm conditions for each parameter.

	Paused/ Alarm Paused mode.		
	Automatic blood pressure measurement interval setting menu.		Zero the IBP. (Displayed only when the IBP parameter is on.)
	Start or stop printing when the printing is in progress. (Displayed only when a printer is connected.)		Start or stop the stimulation of the muscle relaxation monitor. (Displayed only when the NMT parameter is on.)
	Check other patient monitors on the current monitor. (Only displayed if B2B Settings are turned on.)		Review the stored data in the monitor, including trends, alarm events, snapshots, and full disclosure.
	It displays the setup menu.		

PART 2. Setup

1) Overview

This part describes how to configure the monitor.

Some menus require user password authentication.

Note	**If you enter the wrong password 5 times in a row, access to the account is blocked.** **If access to the account is blocked due to entering the wrong password or expiration of the account, you must change the status of the account in the 5) Admin Service.**

2) Main Menu

Menu	Description	Available settings
A. Change Layout	Change the monitoring screen layout.	Waveform, Large Parameter, Popup Trend, OxyCRG (Neonate only), 12ch ECG (option)
B. Demo	Activate the demo mode. (Login or password required)	On, Off
C. Screen Lock	Enable user input lock. When input is locked, a lock icon is displayed in the center of the screen and the touch and keystrokes are disabled. You can unlock the input by touching the lock icon. User password authentication is required for locking and unlocking.	On
D. Display Setup	Parameter view settings	

D-1. Waveform Parameters	Waveform Layout parameter setting Decide whether to display and select parameter colors.	* Parameter : ECG, SpO2, Resp, EtCO2, IBP1&2, Temp, NIBP, EWS, GCS, * option Parameters : IBP 3&4, ICG, Gas(AG), qCON, NMT * Large Parameters only : Time * Color: Refer to the parameter color table below
D-2. Large Parameters	Set parameters of Large Parameter Layout. You can select a parameter to be placed on the split screen. The time parameter displays the current time and patient information in large format. When you select a time, the parameter next to it is automatically turned off. When you click on the time parameter screen, the timer starts working. It is reset when clicked again or upon patient discharge and linked to CMS depending on settings.	
E. System Information	System information If the information cannot be read, "Not Ready" is displayed.	
E-1. License	License information	
E-2. MAC address	MAC address	
E-3. SW, ECG, ITS, NIBP	S/W or F/W version information	
E-4. EtCO2	EtCO2 Module Details	
E-5. Gas	View Anesthetic Gas (AG) Module Details	
E-6. ICG	View ICG Module Details	
E-7. qCON	View qCON Module Details	
E-8. NMT	View NMT Module Details	
F. System Setup	System settings User password authentication required.	
F-1. General	General settings menu	

F-1-1. Unit Name	Monitoring group settings The unit name is displayed in the patient information area. The same group monitors can be connected thru B2B monitoring mode. When USER DEFINE is selected, you can directly input the unit name.	GENERAL ICU NICU OR CCU USER DEFINE
F-1-2. Bed Number	Bed number setting The bed number is displayed in the patient information area.	1~300
F-1-3. Language	Language settings	English, Korean French, Bulgarian Polish, German Chinese, Portuguese Hungarian, Czech Romanian, Italian Turkish, Spanish Russian, Greek Japanese, Dutch
F-1-4. Touch Volume	Touch sound settings	Off ~ 100%
F-1-5. Screen Brightness	screen brightness setting	10~100%
F-1-6. Hospital Name	Hospital name	
F-1-7. Doctor Name	Doctor name	
F-1-8. Date Format	Set date format	YYYY-MM-DD, MM/DD/YYYY, DD/MM/YYYY
F-1-9-1. Patient Setup > Patient Display	Set patient information to be displayed in the patient information area.	Unit + Bed ID
F-1-9-2. Patient Setup > Barcode ID Length	Limit the number of characters when entering an ID with barcode. The set number is entered as ID. If the length of the characters entered into the barcode is longer than the set	Blank (no input restrictions) 1-20 characters

	number, the excess characters are entered as the patient's name. When set to blank or 0, all entered characters are entered as ID.	
F-1-9-3. Patient Setup > When Entering Barcode ID	Set Admit action when entering ID with barcode. Auto Admit: Admit immediately Manual Admit: The patient management window appears and you can directly admit after confirmation.	Manual Admit, Auto Admit
F-1-9-4. Patient Setup > Default setting at Admit	Set default settings when admitting patients When On, alarm and parameter settings are applied as manufacturer settings for the current patient type. When off, the last setting of the current patient type is applied.	On, Off
F-1-9-5. Patient Setup > Default setting at Discharge	Set default setting when patient is discharged When On, the alarm and parameter settings are applied as the manufacturer's settings for adults. When off, the last setting for adults is applied.	On, Off
F-2. Units	Unit setting menu	
F-2-1. Weight	Weight measurement unit	kg lbs
F-2-2. Height	Height measurement unit	cm inch
F-2-3. Blood pressure	Blood pressure measurement unit	mmHg kPa
F-2-4. ST	ST measurement unit	mm mV

F-2-5. Temperature	Temperature measurement unit	°C °F
F-2-6. Gas > CO2	CO2 unit selection	mmHg kPa %
F-2-7. Gas > N2O	N2O unit selection	
F-2-8. Gas > O2	O2 unit selection	
F-2-9. Gas > Anesthetic gas unit	Anesthetic Gas (AG) unit selection	
F-3. Date Time	Date Time settings	
F-3-1. Date & Time	Date Time setting	Year, Month, Day, Hour (24H), Minute
F-3-2. Apply	Apply entered date and time	
F-4. Network	Network settings	
F-4-1. Wireless	Whether to use wireless	On, Off
F-4-2. AP Search	Execute the AP setting menu window. The SSID of the currently connected AP is displayed.	
F-4-2-1. AP List	Scanned AP list The SSID, signal strength, security information and connection status are displayed.	
F-4-2-2. Connect	Selected AP connection	
F-4-2-3. Refresh	AP list update	
F-4-2-4. Add AP (+)	Add network. Use if you manually add and connect hidden networks.	
F-4-3. DHCP	Auto IP allocation setting menu	On, Off
F-4-4. IP	IP manual Settings The set IP is displayed. It can be entered when DHCP is Off.	XXX.XXX.XXX.XXX
F-4-5. Subnet Mask	Subnet mask manual setting The set subnet mask is displayed It can be entered when DHCP is Off.	XXX.XXX.XXX.XXX
F-4-6. Gateway	Gateway manual setting The set Gateway is displayed. It can be entered when DHCP is Off.	XXX.XXX.XXX.XXX
F-5. Communication	Server Settings	

F-5-1. Central > Protocol version	The Central protocol version information is displayed.	1.4.0
F-5-2. Central > Central	Central link activation	On, Off
F-5-3. Central > Server IP	Central server IP address setting	XXX.XXX.XXX.XXX
F-5-4. B2B > B2B	B2B activation	On, Off
F-5-5. HL7 > HL7	Enable HL7 integration.	On, Off
F-5-6. HL7 > Server IP	HL7 Server IP Address Settings	XXX.XXX.XXX.XXX
F-5-7. HL7 > Port	Remote PC Port Address	XXXX
F-5-8. HL7 > Period	Message transmission cycle setting menu	10sec, 30sec, 1,3,5,10,15,30min, 1hour, 6 hour
F-5-9. HL7 > Check Response	Setting up server response verification for sent HL7 messages An exclamation mark is displayed on the HL7 icon if the HL7 message transmission fails only when set to On.	On, Off
F-5-10. HL7 > Labels Edit	Execute parameter LABEL edit menu window.	
F-5-10-1. Parameter 1	Enter default parameter label.	ECG, SpO2, Resp, NIBP (EtCO2, FiCO2, AwRR label is used with Gas/EtCO2)
F-5-10-2. Parameter 2	IBP parameter label input	
F-5-10-3. Parameter 3	Anesthetic Gas (AG) , ICG, qCON, NMT label input	IBP3, IBP4, AG, ICG qCON, NMT
F-5-10-4. Parameter 4	EWS, GCS, Temp label input	EWS, GCS, Temp
F-5-10-5. Unit	Unit label input	Percent, mmHg, kPa, bpm, rpm, 'C, 'F, mm, mV
F-5-10-6. Alarm Priority	Alarm label input	High, Medium, Low
F-6. Alarm	Alarm setting	
F-6-1. Alarm sound	Alarm sound type	IEC60601 BIONET
F-6-2. Alarm Paused Time	Alarm paused time setting	1, 2, 3, 5, 10, 15 min

Parameter colors

Selectable Colors			
green, light blue, magenta, yellow, blue, sky blue, white, coral, scarlet, purple, orange, pale green, pink, pale yellow			
Parameter	**Color**	**Parameter**	**Color**
ECG (ST)	Green	SpO2	Light Blue
RESP	Yellow	NIBP	Magenta
TEMP	Green	ETCO2	Yellow
IBP1	Scarlet	IBP2	Light Blue
IBP3	Yellow	IBP4	purple
Gas(AG)	Yellow	ICG	Green
NMT	White	qCON[2)]	Yellow

3) Drug Calculation

Warning	● **Decisions about the choice and dosage of drugs to be given to the patient should always be made by the attending physician. The drug calculation is based on the entered values; It does not validate the calculations performed.** ● **Check that the entered values are correct, and the calculated values are appropriate. Bionet is not responsible for any consequences resulting from incorrect input or improper operation.**

Execute the Drug Calculation menu in the main menu.

Menu	Description	Available settings
A. Titration Table	When the drug information is entered, the dose and infusion rate are calculated and displayed on the Titration Table.	
A-1. Drug type	Choose drug type.	Aminophylline Tpa Bretylium

		Lidocaine Procainamide Epinephrine Levophed Isoproterenol Dopamine Dobutamine Nitroglycerine Nitroprusside Inocor Heparin Insulin Streptokinase User Drug-1~5
A-2. Drug quantity	Set drug quantity.	
A-3. Solution volume	Set Solution volume.	
A-4. Dose quantity	Set dose quantity.	
A-5. Inflation rate	Inflation rate	
A-6. Weight	Patient weight	Some drugs may not be supported.
A-7. Dose step	Dose step	0.01, 0.05, 0.1, 1.0, 10.0
A-8. Calculate	Update the titration table by calculating the capacity and injection rate with input values.	
B. Setup	Drug settings (Five user medications can be set).	
B-1. Drug name	Set drug name.	
B-2. Drug unit	Unit setting	mg/hr, mg/min, mg/kg/hr mg/kg/min, mcg/hr, IU/hr, mcg/min, mcg/kg/hr, mcg/kg/min, units/hr

Formula for drug dose calculation

Unit	Name	Equation
mg/hr	Aminophylline Tpa	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mg/hr)} \times \text{SolutionVolume(ml)}}{\text{Drug QTY(mg)}}$
mg/min	Bretylium Lidocaine Procainamide	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mg/min)} \times \text{SolutionVolume(ml)} \times 60}{\text{Drug QTY (mg)}}$
mcg/min	Epinephrine Levophed Isoproterenol	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mcg/min)} \times \text{SolutionVolume(ml)} \times 60}{\text{Drug QTY (mg)} \times 1000}$
Mcg/kg/min	Dopamine Dobutamine Nitroglycerine Nitroprusside Inocor	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(mcg/kg/min)} \times \text{Weight(kg)} \times \text{SolutionVolume(ml)} \times 60}{\text{Drug QTY (mg)} \times 1000}$
units/hr	Heparin Insulin	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(units/hr)} \times \text{SolutionVolume(ml)}}{\text{Drug QTY(units)}}$
IU/hr	Streptokinase	$\text{Flow rate(ml/hr)} = \frac{\text{Dose(IU/hr)} \times \text{SolutionVolume(ml)}}{\text{Drug QTY (IU)}}$

Setting range for drug dose calculation

Dose		Drug QTY	
Unit	**Setting range**	**Unit**	**Setting range**
mg/hr	0.01 to 500	mg	0.01 to 2000
mg/min			
mg/kg/hr			
mg/kg/min			
mcg/hr			
mcg/min			
mcg/kg/hr			
mcg/kg/min			
IU/hr	1000 to 1500000	IU	1000 to 1500000

Items	Unit	Drug QTY unit
Volume of Liquid	mL	1 to 1000
WEIGHT	Kg	0 to 300
Velocity of Flow	ml/hr	0.1 to 600

4) Parameter Calibration

Select Parameter Calibration from the Calibration menu. Manufacturer certification is required.

Menu	Description	Available settings
A. ECG	ECG Parameter Calibration Menu	
A-1. ECG Calibration	ECG calibration and last calibration time is shown.	10mm/mV Input calibration indication
A-2. Resp Calibration	Resp calibration and last calibration time is shown.	1ohm 1mm
B. IBP	IBP parameter correction menu	
B-1. IBP1~4 Zero	IBP# Zeroing and last zeroing time is shown.	
B-2. IBP1~4 Calibration	IBP# calibration and last calibration time is shown.	
C. NIBP	NIBP parameter correction menu	
C-1. Zero Calibration	NIBP Zero Calibration Menu	Air Pressure Zero Calibration
C-2. Gain Calibration	NIBP gain Calibration menu	
C-3. Pneumatic pump	NIBP Pump Adjustment Menu	On, Off
C-4. Pneumatic valve	NIBP Valve Adjustment Menu	Close, Open

5) Admin Service

Only the administrator's account has access privilege to the Admin Service in order to properly manage access to the main menu by account and ensure security of the monitor. Execute the Admin Service menu in the main menu. Administrator authentication is required.

Menu	Description	Available settings
A. Account	Add and delete accounts, renew expiration dates, etc.	
A-1. Account List	It shows account list and status.	

	ID, role, final access date, expiration date, and status are shown.	
A-1. Prev/next	Move the page before/after the list	
A-2. Add	Add account. The Add Account menu screen appears.	
A-2-1. ID	register ID.	Same ID cannot be entered
A-2-2. Validity	Set the validity period of a new account or renew the validity period of an account that is about to expire. When saved, the expiration date is set to today's date + account expiration date.	
A-2-3. Role	Role	Admin, Physician
A-2-4. Activation	Decide whether to activate the account.	On, Off
A-2-5. Password	Set the password (Combine letters, symbols, and numbers. At least 8 letters)	
A-3. Remove	Delete an account.	
A-4. Edit	Edit account information. (Can only be deleted upon expiration)	
B. Security	Access control settings and log export	
B-1. Password protected	Set the use of password when accessing the menu.	On, Off
B-2. Remote control permission	Remote control permission setting via Central or B2B	On, Off
B-3. Log > Export	Export the log as an encrypted file to USB memory.	

6) Maker Service

Here provided the functions used by manufacturers. Execute the Maker Service menu in the main menu. Manufacturer certification is required.

Menu	Description	Available settings
1. Write MAC	Save the MAC address. Enabled only if there is no stored MAC.	
2. MAC address	MAC address display	
3. SD Card Format	SD Card Format Clear and initialize all data and settings except for parameter calibration values, account information, and network settings.	
4. Factory Reset	Factory Reset Erase and initialize all data and setting values.	
5. Erase Data	Erase data. Clear trends, alarm events, and full disclosure data.	
6. Reset Settings	Reset setting values.	
7. Reset Admin	Initialize the Admin password, which is the default account.	
8. eMMC Info	View eMMC status information.	
9. Export Settings	Export system and alarm setting files to USB memory.	
10. Import Settings	Import system and alarm setting files in USB memory to the device.	
11. F/W Download	Upgrade the firmware.	

Note	**When using the export settings, import settings, and F/W download menus, be sure to connect only one USB memory.**

PART 3. Network

1) Overview

When the patient monitor is connected to the network, it can be accessed remotely through other patient monitors or the central station.

BM Central Pro connects multiple patient monitors to the central station and allows the remote control of the connected patient monitors for various settings as well as patient data management.

The functions that can be remotely controlled from BM Central Pro are as follows.

- Patient admit and discharge
- Alarm condition setting
- Alarm status
- Display settings
- Start or stop NIBP measurement

The monitor's B2B View (Bed to Bed View) feature allows you to view other monitor screens connected to the network and to silence remote control and alarms [Audio Paused].

Only one device can be monitored and controlled at a time. The functions that can be remotely controlled from B2B View are as follows.

- Display settings
- Start or stop NIBP measurement

To set monitor's network and activate BM Central Pro and B2B function, please refer to **F-4. Network and F-5 at the PART 2.**
For remote control of the monitor through BM Central Pro or B2B View, please refer to **PART 2, B-2. Remote Control Permission of Administrator Service.**

Warning	**BM Central Pro cannot act as a primary alarm device and cannot rely on alarm notifications. There may be no audible or visible indications other than what is displayed on the screen, and the data displayed may be delayed.**

2) Network Connection

In a network, data can be transferred over wired or wireless connection.

All data interfaces (e.g., LAN, USB interface) follow the standard network procedure. Brio series can exchange patient data with other Brio monitors through the network during operation and supports the following functions.

- Display waveform and parameter data
- Alarm signals
- Remote control (e.g., alarm management)
- Device setup and patient data transmission

When Brio series are connected to the network with other devices, if there are any changes in the network, it could impose risks to patients, users, and third parties. These risks must be identified, analyzed, and evaluated before the monitor is connected to the network or before the network is changed, and appropriate measurement must be carried out.

Subsequent changes to the network examples are:

- Network configuration change
- Removing a device from the network
- Adding new devices to the network
- Upgrading or updating devices connected to the network

Warning	**Recommendations for wireless connections** • **The patient monitor connected to the network could vary depending on wireless AP (Access Point) performance.**

- When using a general AP, it is recommended to connect no more than 8 units to the same network.
- Due to the characteristics of wireless connection, the connectivity might not be stable depending on the environmental interferences.

Note

Supported USB Wi-Fi Dongle

The patient monitor supports the following USB VID and PID dongles.

USB VID:PID
2357:0120
2357:011e, 2357:0122
2357:011f
0bda:0811, 0bda:0821, 0bda:8822, 0bda:a811
2357:010d
148f:761a
0e8d:7650
148f:7601
0bda:8176

The patient monitor has completed the testing of the USB Wi-Fi dongle as follows.

TP-Link

Model	USB VID:PID	chipset
TP-LINK T2U plus	2357:0120	Realtek 8821a
TP-LINK T2U nano	2357:011e, 2357:0122	Realtek 8821a
TP-LINK T2U v3	2357:011f	Realtek 8821a
Etc 8821A MODEL	0bda:0811, 0bda:0821, 0bda:8822, 0bda:a811	Realtek 8821a
TP-LINK T2UHP	2357:010d	MediaTek 7650u

TP-LINK T2U	**148f:761a**	**Ralink 7610u**
TP-LINK T2UH	**148f:761a**	**Ralink 7610u**
TP-LINK T2U v2	**0e8d:7650**	**MediaTek 7650u**
TP-LINK AC600 archer T2U	**2357:011f**	**Realtek 88XXau**
TP-Link TL-WN727N v4	**148f:7601**	**Ralink 7601U**

ip Time

Model	USB VID:PID	chipset
ipTime N150UA	**148f:7601**	**Ralink 7601U**
ipTime N100mini (N300U / Ncubic)	**0bda:8176**	**Realtek 8188CU/8192CU**

Even if the USB VID and PID dongles are listed above, dongles that have not been tested by the company may not be supported.

Note	**The patient monitor is compatible with BM Central Pro v4.00 or later.**

3) IT Network Connection

As only the authorized personnel can connect the patient monitor to the network, consult with the IT staff in the hospital at the time of installation.
Please refer to the following documents to proceed with the installation.

- Documents attached to this unit
- Network Interface Manual
- BM Central Pro user documentation

We recommend following IEC 80001-1 (Hazard Management of IT Networks Connected with Medical Devices).

4) LAN Network

LAN networks are usually configured through a star topology. Individual devices can be combined into groups via a layer-n-switch. Other data traffic is separated by individual VLAN networks. Configure the device's network settings according to this manual and your network specifications. LAN connection specifications are described in the following standard standards.

LAN connection specifications are described in the following standard specifications.

- Wired Network: IEEE 802.3
- Wireless network: IEEE 802.11 (a, b, g, n)

If the monitor is to be used as a layer-2-switch or layer-3-switch, the port setting must be configured on the network switch. Configure the network of Bionet devices to be compatible with the specifications of your operating organization.

The patient monitor exchanges data with other medical devices over a LAN network. The network must support the following transports and protocols:

- TCP / IP
- Broadcast

5) VLAN Network

If data is exchanged within a single network, you must establish an independent VLAN network for clinical information systems. At least one of the following independent VLAN networks must be established.

- Network for medical devices in hospital
- Network for portable patient monitors

Also, you should build a network system that detects and defends against denial-of-service attacks by establishing a system dedicated to DDoS protection.

6) Inappropriate Network

If your network does not meet the requirements, the following risk factors can occur.

If the distributed alarm system is not safe:

- The alarm is not delivered.
- The alarm or data is delayed.
- An error alarm appears.

If the network connection is interrupted:

- The alarm is not delivered.

If you do not have firewall and antivirus software:

- Your data is not protected.
- The device settings may be changed.
- The device raises an error alarm or does not generate an alarm.
- Data is being sent incomplete, to the wrong device, or not at all.
- Patient data is blocked, falsified, or corrupted.
- The time stamp of the data is inaccurate.

Excessive over-loading due to very high network loading (e.g., denial of service attacks) can cause interface deactivation. The interface can only be used again after the device is restarted. Rarely, booting may be slow and repeated rebooting may occur.

7) B2B View

If a monitor is connected to the network, you can access other monitors in the same network by using the B2B menu at the bottom to see the real time data and silence alarms when needed.

Press B2B menu to activate B2B screen.

At the top of the B2B screen, a list of BEDs using the same Unit Name is shown.

The BED in which an alarm has occurred displays the highest alarm level in the background color. B2B can be operated with up to 16 monitors including the main one.

Use the settings menu to view the information about the beds in detail.

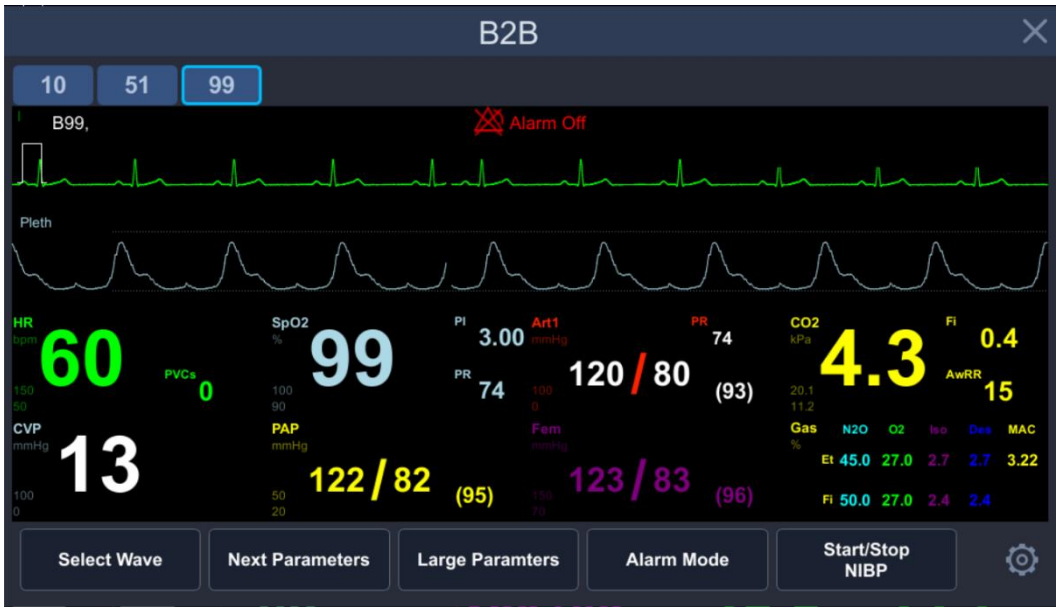
Note	• **Even if in the same network, if the Unit Name of a bed is different, the bed does not appear in the B2B list. If it does not appear in the B2B list, check the network settings and Unit Name of the patient monitor.** • **The patient monitor's unit name and Bed information is displayed in the patient information area.**

Waveform Layout

Two waveforms and numerical values are displayed together.

You can use the Select Wave menu to change to a waveform with different parameters.

Use the Next Parameters menu to view the values of other parameters.



Large Parameter Layout

Parameter values are displayed in large size.

Use the Next Parameters menu to view the values of other parameters.

Bed Control

You can control the bed being monitored by using Alarm Status and Start/Stop NIBP menus.

In order to use this function, however, you must obtain remote control permission from the other monitors.

For more information about remote control, please refer to **B-2 Remote Control Permission in PART 2, Administrator Service.**

8) B2B Settings

Menu	Description	Available settings
1. Select wave	Waveform selection menu to view	
1-1. Trace1, Trace2	The waveform selection menu for Trace I or II in the B2B view window	ECG, SpO2, RESP, EtCO2, IBP1, IBP2, IBP3, IBP4 Gas (AG), ICG, qCON
1-2. ECG channel	ECG Channel Selection Selectable when Trace1 or Trace2 is ECG.	I / II/ III/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6
2. Next Parameters	View next parameter. (If you read the last page, you will be	

	back to the first page.)	
3. Large Parameter / Waveform	Change the layout.	Large Parameter, Waveform
4. Alarm Status	Change the alarm state of the selected Bed. User authentication is required.	Alarm On, Audio Paused, Alarm Paused, Audio Off, Alarm Off
5. NIBP Start/Stop	NIBP measurement start and stop menu	Start Stop
6. Setup	View bed List Details.	

PART 4. Admission and Discharge

1) Overview

When a patient is connected to the monitor, it displays the patient's physiological data so that the patient can be monitored without hospitalization. However, since the monitor's alarm generation and trend data storage require the patient to be hospitalized, managing the patient's admission and discharge is important. The patient management menu enables you to manage the patient's admission, discharge, and patient information. The monitor displays the set unit and Bed information along with the information of a hospitalized patient and ID information.

Patient admission and discharge can be managed also from the central monitoring unit (BM Central Pro).

2) Admitting a Patient

Admit a patient to the hospital at the beginning of patient monitoring.
Upon admission, set an alarm condition with the current patient type and activate the alarm.
Bio signal data is saved as trend data for the current patient.

How to admit a patient:

1.  **Press the [Patient] icon button**.
2. Enter patient information (Patient Type, ID, name, birth) on the Patient Management dialog.

   If the same patient information as the entered ID already exists, the patient information is displayed on the screen.
3. Press the [OK] button to confirm the admission.

When the patient is admitted, the icon in the Patient Management menu changes as the following chart. The patient's name is displayed next to the icon that matches his or her gender and age group.

Type	Admit: Male	Admit: Female	Discharge
Adult			
Pediatric			
Neonate			

Warning	• **By default, the patient type is Adult and the Pacemaker is set to Off. Please Set Pacemaker On/Off and check if the Patient Type setting is correct.** • **For paced patients, set Pacemaker to On. If it is incorrectly set to Off, the patient monitor can mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak.** • **For non-paced patients, set Pacemaker to Off.**

Note	• **To change the patient's type (adult, pediatric or neonate), access the patient settings menu.** • **If you change the patient type, previous setting is loaded for the selected type. To return the settings to the manufacturer default settings, press the "Default Setting" menu on the Patient Management dialog.** • **Additional settings such as Gestational Age and Birth Weight are available for neonate mode.**

3) Editing Patient Information

1. Correct or add additional information about hospitalized patients.  Press the Patient Management Menu.
2. Enter patient information such as patient type, ID, name, and date of birth on the Patient Management screen.
3. Press the [OK] button to update patient information

Note	**If you change an ID of a patient, the patient is discharged and readmitted with the changed ID.**

4) Discharging a Patient

To terminate the monitoring of hospitalized patients, or admit new patients, discharge the current. Once a patient is discharged, trend data is not be saved any more.

How to discharge a patient:

1.  **Press the [Patient] icon button**
2. **Press the Discharge menu**. You can show Discharge confirm message
3. Press the **[Yes]** button. The discharge procedure is in progress.

When the patient is discharged successfully, Patient icon () changes to Discharge status.

Warning	**You must discharge the current patient before admitting a new patient. Otherwise, the data may be associated with the wrong patient.**

Note	**Upon discharge, the patient monitor resets to the previous adult settings.**

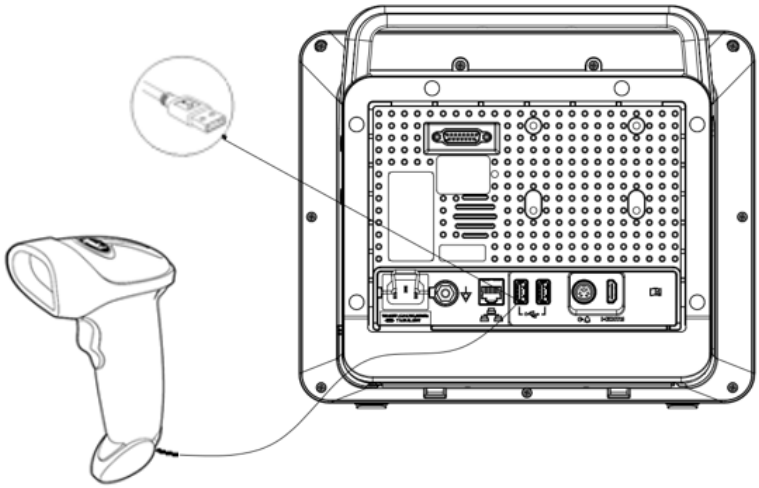
5) Patient Management Menu

Menu	Description	Available settings
1. Patient type	Select patient type.	Adult, Pediatric, Neonate
2. ID	Enter patient ID.	
3. First Name	Enter first name.	
4. Last Name	Enter last name.	
5. Gender	Select gender.	Male, Female
6. Pacemaker	Decide whether the patient to be a pacemaker.	On, Off
7. Birthday	Enter date of birth.	
8-1. Age	Enter age.	
8-2. Age Unit	Set age input unit.	Year, Week, Day
9-1. Gestation Age	Enter Gestational Age.	
9-2. Gestation Age Unit	Set gestational age input unit.	Week, Day
10. Weight	Enter weight.	XXX.XX kg (lbs.)
11. Height	Enter height.	XXX.XX cm (inch)
12. blood type	Select blood type.	A Rh+/ Rh-/ -D-/ Rh Null B Rh+/ Rh-/ -D-/ Rh Null O Rh+/ Rh-/ -D-/ Rh Null AB Rh+/ Rh-/ -D-/ Rh Null Unknown
13. Admit/Discharge	Patient admit/discharge	
14. Default Setting	Reset alarm and parameter settings to the manufacturer settings of the current Patient Type.	
15. Ok	Update entered patient information. The patient type, gender, and name	

	are displayed in the patient information area.	
16. Cancel	Cancel patient information update and close dialog.	

6) Registering Patient ID Using Barcode

The monitor can register the PATIENT ID in barcode format using a USB barcode scanner. First, connect the barcode scanner to the USB port on the back of the monitor as shown below. When you hear a beep, the barcode can be used.



When you press the button on the barcode reader to scan the patient ID, the patient management dialog appears and displays the scanned ID and corresponding patient information.

PART 5. Alarm

1) Overview

The monitor displays the alarm limit (parameter threshold) and can be configured to occur an alarm if exceeded limits are detected both in the alarm limits table and in the parameter box. If this limit is exceeded, a visual or audible alarm occurs.

Once the monitor's alarm and other parameter setting values are set, unless a separate operation is performed, they remain same even if the monitor power is turned off. After connecting the power to the monitor and turning it back on, it starts to operate normally, and the alarm and other parameter values keep the set values.

Warning	**A potential hazard can exist if different alarm presets and default configuration settings are used for the same or similar devices in the same care area: for example, an intensive care unit or cardiac operating room.**
Note	**When the patient monitor is connected to BM central Pro, an alarm signal is expected be delayed around 2 seconds from the patient monitor to the BM Central Pro.**

2) Alarm Priority

According to the severity of the alarm, it is divided into high priority, medium priority, and low priority.

If multiple alarms occur at the same time, the monitor displays the highest priority alarm sound with a light.

- High Priority (High)

  When the patient has a life-threatening clinical condition where the risk must be managed immediately, or the monitor is in a critical failure condition and the patient's life may be at risk because the patient's fatal condition cannot be detected.

- Mid Priority (Medium)

When the patient's physiological signs are abnormal and appropriate action or treatment is needed immediately, but not endangering to the patient's life. Or when the monitor is severely malfunctioning and may affect the normal monitoring of key physiological parameters.

- Low Priority (Low)

  The patient's physiological symptoms are abnormal and may require appropriate action or treatment or when a specific function of the monitor is malfunctioning, but the patient's life is not in jeopardy.

- Message (Message)

  Circumstances that require notification regarding the condition of the patient or monitor

The audible alarm tones according to the alarm priority are as follows.

Audible Alarm		
Alarm priority	**BIONET**	**IEC**
High	1 high tone every 10 seconds	10 consecutive beeps every 10 seconds
Medium	1 high tone every 15 seconds	3 consecutive beeps every 15 seconds
Low	1 low tone every 30 seconds	2 consecutive beeps every 30 seconds

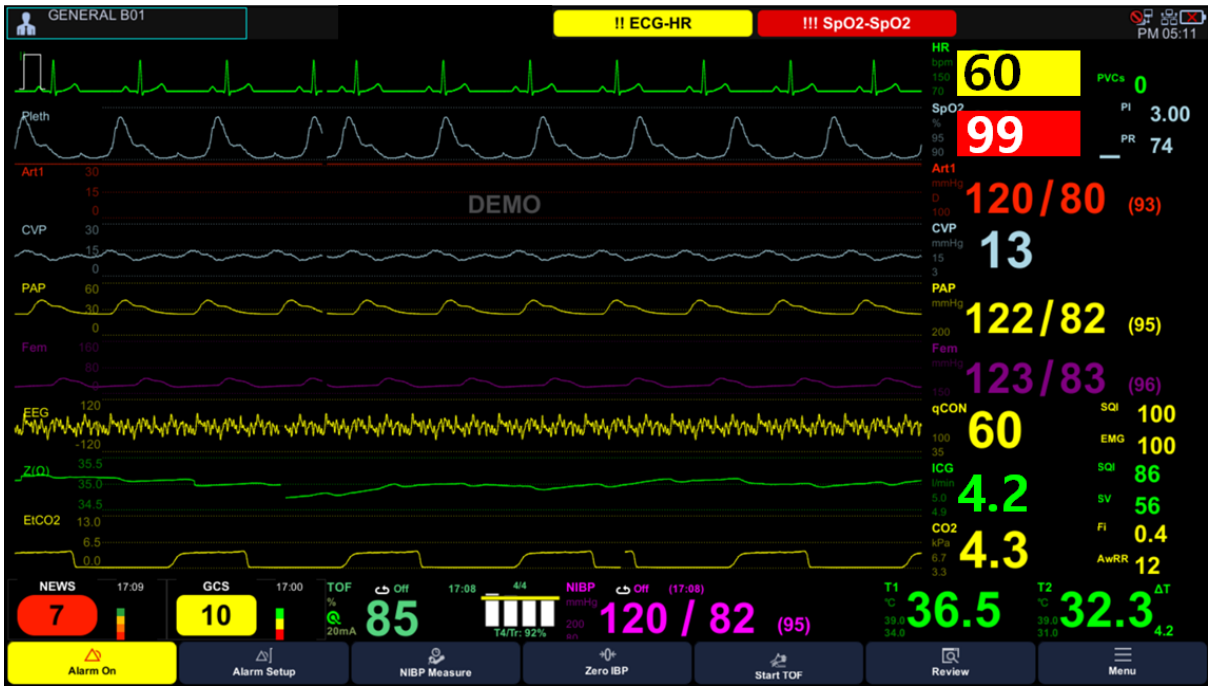
Note	
	- **The alarm signal sound pressure level is 55 dB (A) to 85 dB (A) within a range of 1 meter.** - **Refer to the F-6 Alarm, PART 2 about setting the audible alarm sound.**

3) Alarm Type

The alarm priority is divided into a patient status (physiological alarm) and monitor status (technical alarm).

Physiological Alarm Screen

It occurs when a patient's physiological parameters exceed the alarm limits, or the patient is physiologically abnormal. When a bio signal alarm occurs, the corresponding parameter blinks, and information is displayed in the bio signal alarm message area at the top of the screen.



The alarm indications according to its alarm priority are shown as follows

Alarm priority	Alarm sound	Numeric window	Alarm lamp	Alarm Message
High	10	**RED** Blinking 1 time every 2 sec	Blinking 2 times every 1 sec	**RED** Prefix: !!!
Medium	3	**YELLOW** Blinking 1 time every 2 sec	Blinking 1 time every 2 sec	**YELLOW** Prefix: !!

Low	2	YELLOW Blinking 1 time every 2 sec	No blinking.	YELLOW Prefix: !

numbers : Alarm sound indication and number of beeps

RED : Alarm indicator in red on the screen

YELLOW : Alarm indicator in yellow on the screen

: Alarm lamp in red

: Alarm lamp in yellow

Technical Alarm Screen

Technical alarms are caused by improper operation or conditions that result in monitor failure or distortion of monitoring results. When a technical alarm occurs, the information is displayed in the corresponding parameter area.

Technical alarm table

Alarm priority	Alarm sound	Numeric window	Alarm lamp
Low	1	**BLUE** Blinking 1 time every 2 sec	No blinking.
Message		**BLUE** Blinking 1 time every 2 sec	

numbers : Alarm sound indication and number of beeps

BLUE : Alarm indicator in blue on the screen

: Alarm lamp in cyan

4) Alarm Status

The monitor provides five different alarm conditions. Different icons indicate the current alarm status. You can adjust the alarm status by using the alarm status key or the alarm status menu.

Alarm management

- Alarm Status Key

  Press the pausing key to adjust the alarm status.

  A short press of the alarm control key circulates through the Audio Paused -> the Alarm Paused -> the Alarm On modes.

  Press and hold the key for more than 3 seconds to switch to Alarm Off / Audio Off mode using the mode selection dialog regardless of which alarm mode the monitor is currently in. User password authentication is required to set Alarm Off / Audio Off mode.

- Alarm Status Menu

  Press  the yellow menu at the bottom left of the screen.

  Each time you press it, the status switches between Audio Paused -> Alarm Paused -> Alarm On.

Alarm Status Display

Alarm status is displayed in the alarm status information area at the top of the screen and in the alarm status menu.

 **Audio Paused**

The audible alarm stops for 1 minute while the visual alarm is still activated. A window notifying that the audio has paused appears on the screen, along with the remaining time of the Audio Paused. When you press the alarm button or after the timeout period has elapsed, visual and audible alarms are activated again.

 **Alarm Paused**

The visual and audible alarms stop during user defined time. Alarm Paused message and countdown timer are shown in the alarm status area on the top of the screen. When you press the alarm button for another alarm mode or after the timeout period has elapsed, visual and audible alarms are activated again.

You can set the pause time in **F-6 Alarm** in the main menu.

 **Audio Off**

The audible alarm stops. Audio Off. Alarm window with audible sound is Off and shown on the screen. The monitor maintains Audio Off mode until you switches to another alarm mode.

 **Alarm Off**

The visual and audible alarms stop. Alarm Off. Alarm window with audible sound is Off and shown on the screen. The monitor maintains Alarm Off mode until user switches to another alarm mode.

Warning	● **When the alarm sound is switched off, the patient monitor gives no alarm tones even if a new alarm occurs. Be careful when considering switching off the alarm sound.** ● **When the alarms are off or while alarm audio is paused either temporarily or indefinitely, observe the patient frequently.**

Note	● **Alarm Paused and Off modes only stop the audible alarm sound. Touch and key sounds are still heard. To adjust the Touch or Key Sounds, use the Key Sound menu in Setup.** ● **When the connection with the central monitoring device (BM Central Pro) is cut when the alarm sound is off (Audio Off), it switches to the alarm on (Alarm On).**

5) Setting an Alarm

Press the  icon to pop up the alarm setting menu.

User password authentication is required to change the alarm settings.

Changed alarm settings are maintained even if the monitor is suddenly turned off due to a power shortage, etc.

To return the alarm settings to the manufacturer's default settings, run the "Default Setting" menu on the Patient Management dialog (See **PART 4, Patient Management Menu**).

Menu	Description	Available settings
A. Alarm	Alarm, level, action setting menu for each parameter	
A-1. Parameter List	List of Parameters Only the currently displayed parameters are displayed. Select a parameter to display the	Parameters : ECG, SpO2, Resp, EtCO2, Temp, NIBP, IBP1&2 Optional parameters : IBP 3&4, ICG, Gas

	alarm. setting menu.	(AG), qCON
A-2. Alarm	Set whether to detect an alarm.	On, Off
A-3. Priority	Set alarm priority.	High, Medium, Low
A-4. Low	Set alarm lower limit.	
A-5. High	Set alarm upper limit.	
A-6. Print	Set print when an alarm occurs.	On, Off
B. Arrhythmia	Arrhythmia alarm level, action setting menu	
B-1. Arrhythmia List	List of arrhythmias	Asystole, V-Tach, V-Tach/V-Fib, Bigeminy, Trigeminy, Acc Vent, Couplet, Irregular, Pause, R on T, V-Brady, Short Run, PVC
B-2. Alarm	Set whether to detect an alarm.	On, Off
B-3. Priority	Set alarm priority.	High, Medium, Low
B-4. Print	Set print when an alarm occurs.	On, Off
B-5. Off	Turn off all arrhythmia alarms.	
B-6. Lethal	Turn on Asystole, V-Tach, V-Tach/V-Fib alarms only	
B-7. Full	Turn on all arrhythmia alarms.	
C. Setup	Alarm setting menu	
C-1. Alarm volume	Alarm volume setting	10~ 100%

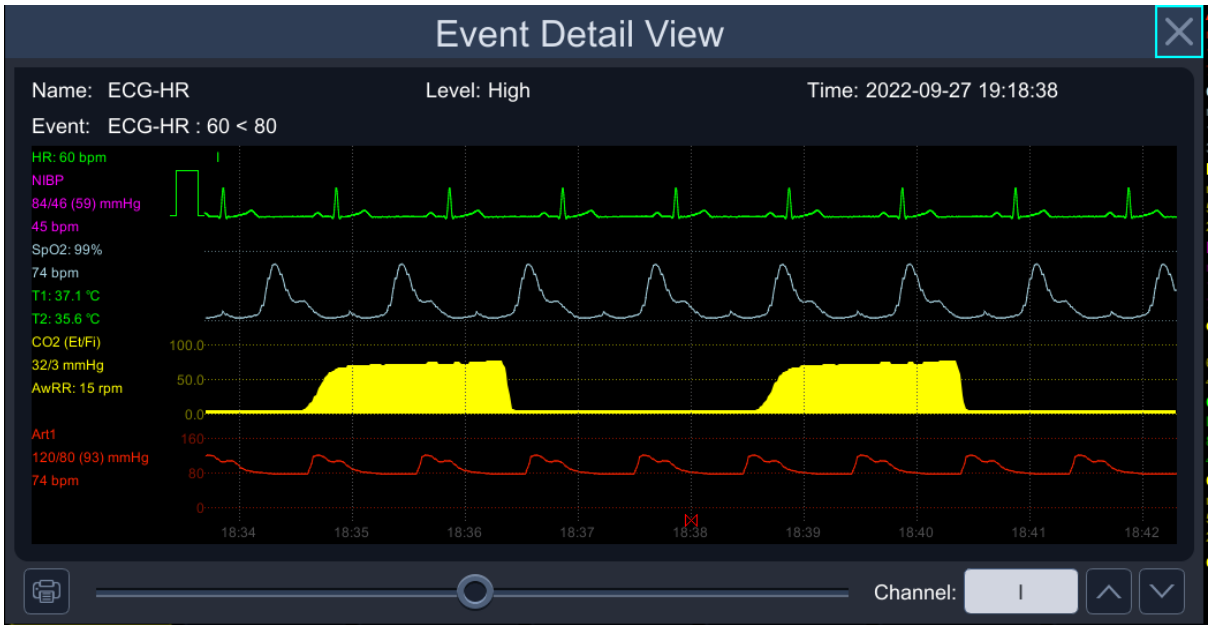
Warning	• **Check the saved alarm setting of the patient monitor in advance to ensure that the current setting is appropriate for the patient.** • **Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient.**

6) Alarm Events

When a bio signal alarm occurs, data for a total of 16 seconds is saved for 8 seconds before and 8 seconds after the alarm occurrence. You can check the alarm events in the Events screen of the "Review" menu ( ).

The Events screen shows up to 1000 alarms in chronological order with the most recent occurrence. The list shows the alarm occurrence time, priority, and description.

You can select an item to view in detail, print, or delete.



Note	• **Alarms are saved per events and is maintained even if the patient monitor is powered down. The time of powering down the patient monitor is not recorded as an event and cannot be reviewed.** • **Earlier events are overwritten by recent events if the maximum storage of 1000 list is reached.** • **A total loss of power does not affect the events already stored.**

Manual Event

If necessary, you can manually save the event by pressing the [Snapshot] key (

) on the front of the monitor. In this case, data is saved for the 16 seconds immediately before the Snapshot key is pressed. You can check the saved manual events on the Events screen of the Review menu, which are marked as Manual Event with Message priority.

Testing Alarms

On the demo mode, you can test the alarm tone and the alarm lamp by changing the alarm range and the alarm level. We recommend you to test the alarms every day.

Note	**When using the patient monitor, we recommend you to operate it from the front.**

PART 6. Trend

1) Overview

The monitor stores trend data for all connected signals. Trend data can be retrieved in the form of a table or graph and printed out or exported in the form of a csv file to a USB memory.

Trends can be stored for up to 168 hours, and old data is deleted when the storage capacity is exceeded.

Two trend modes (Graphic / tabular) are available at the Review menu ( ).

2) Tabular Trend

The tabular trend tables display the trend data in an easy-to-read table format. Up to six lists are shown and updated every minute. The time stamp above each column indicates the interval at which the data in that column was saved. The displayed value is the recently acquired data during the interval, and the most recent data is shown in the right column. Alarm events that occurred within the time interval displayed on the screen are displayed as a red inverted triangle above the Timeline.

① Tabular Trend tab

② Graphic Trend tab

③ Event tab

④ Full Disclosure tab

⑤ Event List menu

⑥ Patient ID

⑦ Event list navigation button

⑧ Tabular Trend Setting button

⑨ Tabular Trend Printer button

⑩ Export trend data

⑪ Selection navigation window

⑫ Trend interval setting menu

⑬ Parameter select button

When you select the  Review menu in the menu screen area, the Review screen appears. Select the Tabular Trend tab.

Menu	Description	Available settings
1. Patient information	The information of a patient admitted during the time zone where the cursor is positioned. Patient type, ID, Gender and Name	
2. Event list	Alarm event list up When you select an event, the cursor moves to that event time.	
3. Move prev/next event	The cursor moves to the previous/post event.	
4. Time header	The trend table is divided into 6 columns and the time zone is displayed. In case of an alarm, an alarm marker is shown at the corresponding position.	1 column = Interval
5. Parameter List	Parameter name and unit display	
6. Parameter Table	The parameter name, unit, and numeric value of cursor position is displayed.	
7. Move first page/prev page, Move last page/next page, Navigation slider	Move section and update tabular trend.	
8. Page up/down	Page up/down	
9. Interval	Trend data interval	1 min, 5 min, 10 min, 15 min, 30 min, 1 hr, 2 hrs
10. Setup	Select parameters to display.	Note on Trend settings
11. Print	Print tabular trend data from the current time zone to the patient change (activated when printer is connected).	
12. Trend Export	Export the trend data.	Note on Trend file export

3) Graphic Trend

Graphic trend shows the saved trend data with individual graph type for each parameter. These graphs show that the displayed parameters are active over a significant period, five channels at a time. Confirmed color and scale meter labels and numbers are shown on the left side of the trend channel. Vertical lines show each graph, which displays the time of distribution. Alarm events that occurred within the time interval are displayed as a red inverted triangle above the Timeline.

① Tabular Trend tab

② Graphic Trend tab

③ Event tab

④ Full Disclosure tab

⑤ Event List menu

⑥ Patient ID

⑦ Event List navigation button

⑧ Graphic Trend Setting button

⑨ Graphic Trend Printer button

⑩ Export trend data

⑪ Selection navigation window

⑫ Graphic trends zoom menu

⑬ Parameter select button

When you select the  Review menu in the menu screen area, the Review screen appears. Select the Graphic Trend tab.

Menu	Description	Available settings
1. Patient information	The information of a patient admitted during the time zone where the cursor is positioned. Patient type, ID, Gender, and Name	
2. Event list	When you select an event, the cursor moves to the point of alarm event	
3. Move prev/next event	The cursor moves to the previous/post event.	
4. Time header	The graphic trend table is divided into 6 columns and the time zone is displayed. In case of an alarm, an alarm marker is shown at the corresponding position. In the corner, the cursor position time is shown.	
5. Parameter List	The parameter name, unit, and numeric value of cursor position is displayed.	
6. Parameter Graph	The parameter data is displayed according to the number of graphs in setting.	
7. Move first page/prev	Move section and update graph.	

page, Move last page/next page, navigation slider		
8. Page up/down	View before/after page.	
9. Zoom	Change the resolution of the graphic trend table.	30 min, 1hr, 1.5 hrs, 2 hrs, 3 hrs, 5 hrs, 6 hrs, 8 hrs, 12 hrs
10. Setup	Select parameters to display.	Note on Trend settings
11. Print	Print the graphic trend data of the current time zone (activated when printer is mounted).	
12. Trend Export	Export the trend data.	Note on Trend file export

4) Setting Trend

Set the parameters to be displayed.

Menu	Description	Available settings
1. Zoom	Trend resolution settings (trend time range settings)	30min, 1hr, 1.5hrs, 3hrs, 6hrs
2. Original Parameter List	Available parameter list	
3. Selected Parameter List	List of parameters to display at the trend table	
4. Add	List of parameters to add at the trend table	
4. Add All	Move all Original Param List to Selected Param List.	
5. Remove	Move selected Param item to Original Param List.	
6. Remove All	Move all Selected Param Lists to Original Param List.	
7. Move Top	Move the selected Param item to the	

	top.	
8. Move Up	Move the selected Param items up one.	
9. Move Down	Move the selected Param items down one.	
10. Move Bottom	Move the selected Param item to the bottom.	
11. Close	Save Settings + Close Window.	

5) Exporting a Trend file

You can use the file extract function to transfer trends to a file using a USB memory device.

1. Connect a USB memory device.
2. Set a start time, end time, export time, and export order.
3. Press [Export] button.
4. A completion message is displayed when the transmission is completed.

Menu	Description	Available Settings
1. Start/ End Time	Start/end time of trend data	
2. Interval	Trend data interval	1 min, 5 min, 10 min, 15 min, 30 min, 1 hr

3. Order	Sort order	Ascending, Descending
4. Export	Export	

Note	**The file format of USB memory supported by Brio series is FAT32.**

6) Popup Trend

When selecting Popup Trend Layout from the Change Layout menu of the main menu, you can view and monitor the latest trends at the same time.

You can continue to monitor the main screen waveform and parameter box while watching the trend data for up to 7 parameters for up to 6 hours. The pop-up trend graph follows the display order indicated by each parameter in the trend setup and is updated with new trend data every 60 seconds.

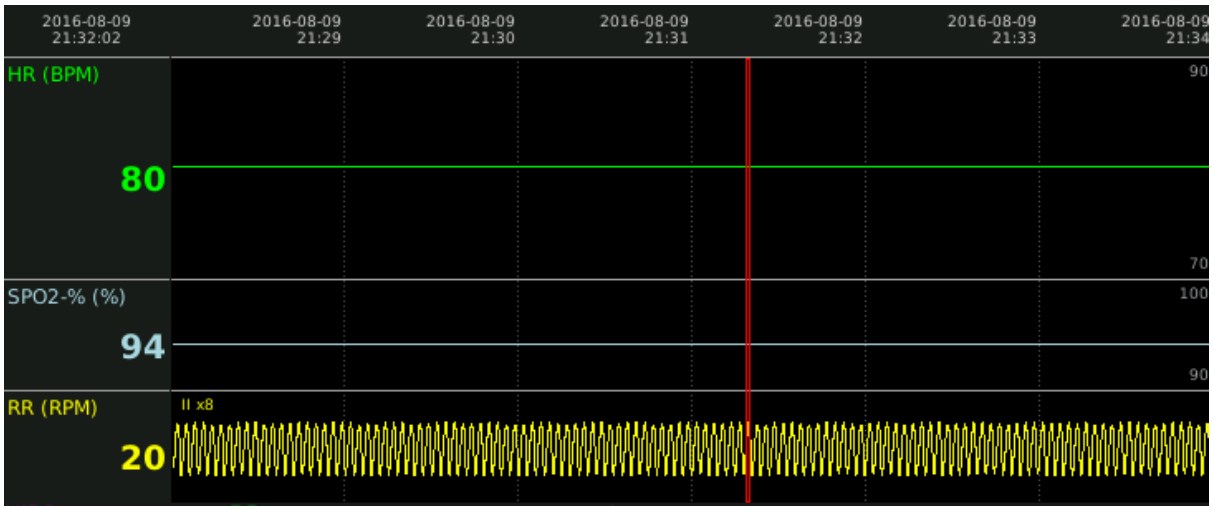
To change the popup menu window, touch the top and bottom of the popup menu with the touch key, or select it with the rotary switch. You can change the size of the popup menu by pressing and

releasing the center of the popup menu for at least 0.5 second.

7) OxyCRG Monitoring

The monitor can display Oxycardiorespirogram (OxyCRG or OCRG) in neonatal mode.

OxyCRG displays trends in heart rate, oxygen saturation, respiration, or EtCO2 waveforms for the last 6 minutes; with data updated every minute. The parameters area of the OxyCRG screen displays the maximum and minimum heart rate, minimum oxygen saturation and respiration rate (or EtCO2 value) for the last 6 minutes. The graph area shows the trend of HR and SpO2, and the waveform of respiration (or EtCO2). When you tap the graph area on the OxyCRG screen with your finger, a cursor appears at that location, and the value of the time zone where the cursor is located is displayed in the parameter area. After a certain period, the cursor disappears, and the numerical value is displayed as it was.



Note	**OxyCRG's breathing parameters are set to the parameters currently being monitored. To change the breathing parameters of OxyCRG, select one of Resp, EtCO2, and Anesthetic Gas (AG) from the Display Setup menu from the main menu.**

8) OxyCRG Setup

When you press the numerical area of OxyCRG, the HR Scale setting window appears.

Menu	Description	Available settings
1. HR Scale	Set the HR Scale method. In case of Auto, the scale of the trend graph is automatically adjusted based on the maximum and minimum heart rates for the last 6 minutes.	Auto, Manual
2. HR Upper, HR Lower	Set the HR range manually. It can be set when HR Scale is Manual. Use it when you want to see the trend graph by fixing the HR range.	0~350

9) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before requesting service. If the problem persists, contact your service representative.

Problem	Solution
When the data is unable to be saved	The trend data may not have been saved. No trend data is saved when the patient is *discharged*. Make sure the patient is admitted.

PART 7. ECG

1) Overview

The monitor can calculate heart rate, detect arrhythmias (adult and pediatric patients), and display ECG data.

The electrocardiogram screen provides 1 channel, 2 channel, 7 channel, and 12 channel displays.

The monitor's Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations.

Basic systems deliver 12-Lead ECG's and interpretive analysis and can be upgraded to provide software analysis options such as high-resolution signal averaging of QRS and P wave portions of the electrocardiogram.

The 12 channel ECG interpretive algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which require physicians' confirmation with other relevant clinical information.

The Brio series is intended to be used by personnel trained in hospitals or medical professional facilities under the direct supervision of a licensed healthcare practitioner.

2) ECG Precautions

Warning	• **For defibrillator protection, use only accessories specified by the manufacturer, such as electrodes, leads, and patient cables.** **Follow the instructions for use and adhere to all warnings and cautions.** • **CABLES — Keep 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. There must be no contact of the neutral electrode and ground.

- DEFIBRILLATION — Do not make contact with patient during defibrillation. Otherwise, severe 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 devices connected to the patient.

  After defibrillation, the screen display recovers within 5 seconds if the correct electrodes are used and applied in accordance with the manufacturer's instructions. Patient cables can be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again.

  The peak of the synchronized defibrillator discharge should be delivered within 60ms of the peak of the R wave. The signal at the ECG output on the veterinary patient monitor is delayed by a maximum of 30ms.

- If the ECG waveform on the screen is too unstable to synchronize with the patient's heartbeat 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 DEVICES — Devices may only be interconnected with each other or to parts of the system when a qualified biomedical engineering personnel determined that there are no dangers to the patient, the operator, or the environment as a result. In the instances when there are any element of doubt concerning the safety of connected

devices, you must contact the manufacturers regarding the concerned matters (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use and system standards. IEC 60601-1-1/EN 60601-1-1 must be complied with.

- Electro Surgery Unit

✓ Electrosurgical unit (ESU) emits a lot of RF interference. If the patient monitor is used with an ESU, RF interference may affect the monitor operation.

✓ Locate the patient monitor as far as possible from the ESU. Locate them on opposite sides of the operating table, if possible.

✓ Connect the patient monitor and ESU to different AC outlets located as far as possible from each other.

✓ When using the patient monitor with an electrosurgical unit, its return plate and the electrodes for monitoring must be firmly attached to the patient. If the return plate is not attached correctly, it may burn the patient's skin where the electrodes are attached.

- During Surgery:

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

- Vibrations during intrahospital transport may disturb ECG measurement.

Caution	• **The patient monitor is not intended for direct cardiac application.** • **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. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.** • **Ensure that the conductive parts of ECG electrodes and associated connectors, including the neutral electrode, do not come into contact with any other conductive parts including earth.** • **To minimize the hazard of burns during high-frequency surgical procedures, ensure that the patient monitor's cables and transducers never come into contact with the electrosurgery unit (ESU).** • **To minimize the hazard of burns during use of high-frequency surgical unit (ESU), the ECG electrodes should not be located between the surgical site and the ESU return electrode.**

3) Preparing the Patient

Proper skin preparation is necessary to ensure good signal quality at the electrode sites, as the skin is a poor conductor of electricity. To properly prepare the skin, choose flat areas and then follow this procedure:

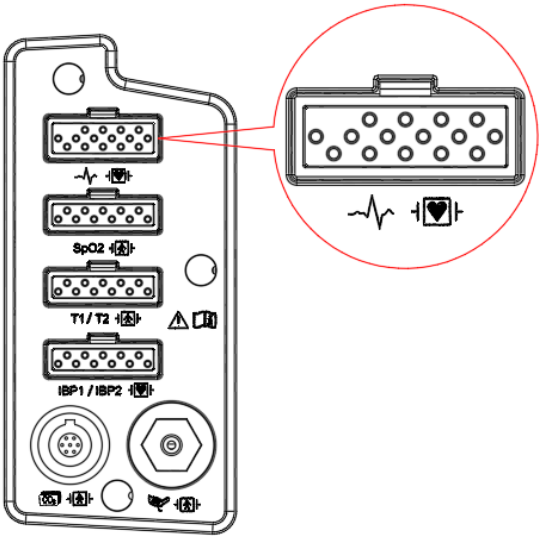
- Shave hair from skin at chosen electrode sites.
- Gently rub skin surface at sites to remove dead skin cells.
- Thoroughly cleanse the site with a mild soap and water solution. (We do not recommend using ether or pure alcohol because this dries the skin and increases the resistance.)
- Dry the skin completely before applying electrodes.

In the event of a technical alarm such as a broken lead, re-prepare the patient according to the recommendations above.

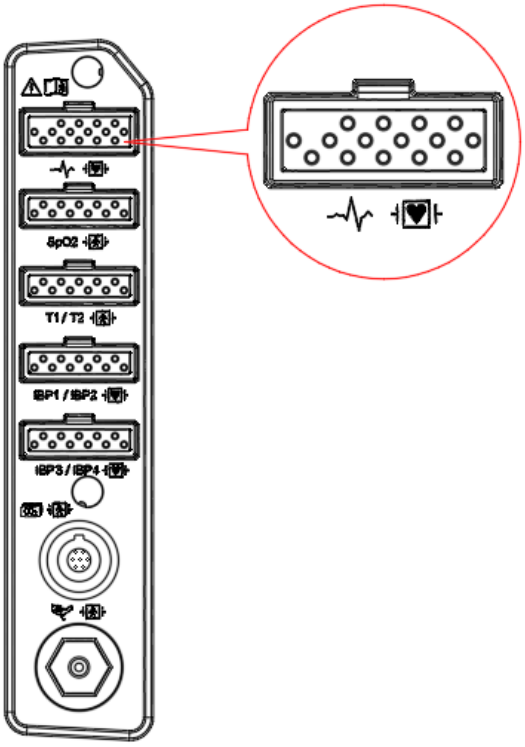
4) Connector and Measuring Cable

ECG connector

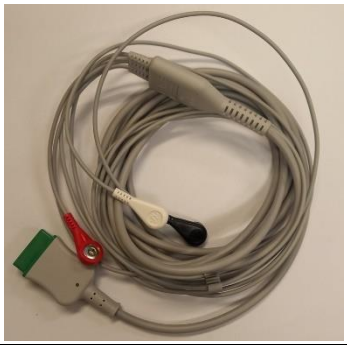
Brio X30

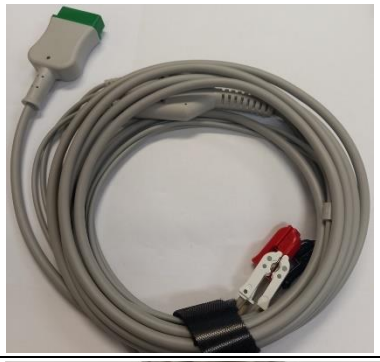
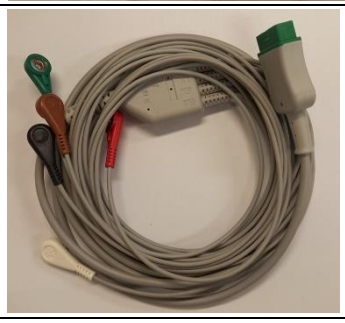


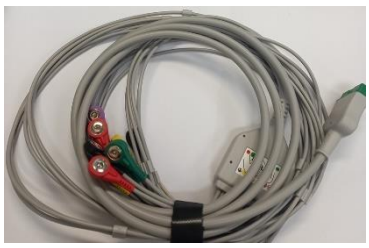
Brio X50, Brio X70



ECG Measuring Cable

Number	Part	Picture	Dimensions and Weight	Remarks
1	152600-041200		MECA 3 LEAD CABLE Main: 2500±30mm Lead: 1000±20mm W = 169g	
2	152600-041400		MECA 3 LEAD CABLE Main: 2500±30mm Lead: 1000±20mm W = 169g	

3	152600-041300		MECA 3 LEAD CABLE Main: 2500±30mm Lead: 1000±20mm W = 180g	
4	152600-041500		MECA 3 LEAD CABLE Main: 2500±30mm Lead: 1000±20mm W = 180g	
5	152600-043200		L= 2500±30mm W = 105g	
6	152600-041600		MECA 5 LEAD CABLE Main:2500±30mm Lead:1000±20mm W = 203g	
7	152600-041800		MECA 5 LEAD CABLE Main:2500±30mm Lead:1000±20mm W = 203g	
8	152600-041700		MECA 5 LEAD CABLE Main:2500±30mm Lead:1000±20mm W = 220g	

9	152600-041900		MECA 5 LEAD CABLE Main:2500±30mm Lead:1000±20mm W = 203g	
10	152600-042000		MECA 10 LEAD CABLE Main: 1950±50mm Lead1: 750±20mm Lead2: 1100±30mm W = 358g	
11	152600-042200		MECA 10 LEAD CABLE Main: 1950±50mm Lead1: 750±20mm Lead2: 1100±30mm W = 358g	
12	152600-042100		MECA 10 LEAD CABLE Main: 1950±50mm Lead1: 750±20mm Lead2: 1100±30mm W = 377g	
13	152600-042300		MECA 10 LEAD CABLE Main: 1950±50mm Lead1: 750±20mm Lead2: 1100±30mm W = 377g	
14	152600-047100		3-Lead ECG Extension Cable, AHA 2500 ± 30 mm w = 163g	Connecting with No. 18 and No. 20

15	152600-047200		5-Lead ECG Extension Cable, AHA 2500 ± 30 mm w = 155g	Connecting with No. 22
16	152600-047300		3-Lead ECG Extension Cable, IEC 2500 ± 30 mm w = 163g	Connecting with No. 19 and No. 21
17	152600-047400		5-Lead ECG Extension Cable, IEC 2500 ± 30 mm w = 155g	Connecting with No. 23
18	152600-001900		3-Lead ECG Lead Wires, Snab type, AHA 1000 ± 30 mm w = 55g	
19	152600-002000		3-Lead ECG Lead Wires, Snab type, IEC 1000 ± 30 mm w = 55g	

20	152600-028700		3-Lead ECG Lead Wires, Grab type, AHA 1000 ± 30 mm w = 57g	
21	152600-028710		3-Lead ECG Lead Wires, Grab type, IEC 1000 ± 30 mm w = 57g	
22	152600-002600		5-Lead ECG Lead Wires, Snab type, AHA 1000 ± 30 mm w = 87g	
23	152600-002500		5-Lead ECG Lead Wires, Snab type, IEC 1000 ± 30 mm w = 87g	

5) Attaching Electrodes

1. Unpack the electrode package and take out the electrodes.
2. Remove the protecting film on surface of the electrode. Be careful not to touch the adhesive side.
3. Attach the disposable electrodes to the sterilized skin, which has been prepared as mentioned earlier.
4. Connect the lead of the electrodes to the monitor cable.

5. Fix the electrodes to the skin and secure the cable with the remaining length between the monitor and the electrode by using surgical tape. This fixation prevents the electrode from moving.

Change the electrodes every 24 to 48 hours to improve signal quality. You may need to replace them more often in the following situations:

- ECG signal degradation
- Excessive sweating of the patient
- Patient's skin irritation

There are a variety of reusable and disposable electrodes available. Choose the electrodes that best fits for monitoring situation. Bionet recommends Ag / AgCl disposable electrodes.

If you are using a gel before attaching the electrodes, make sure that the gel is applied sufficiently on the electrodes. Never use disposable electrodes that have passed their expiration date or if the gel has dried.

Determine the electrode locations that provide the best ECG in the configuration (P-wave and T-wave amplitudes should not exceed 1/3 of the QRS amplitude).

Choose a flat, less muscular location to maximize contact with the electrodes and minimize muscle fatigue. Avoid joints or bony protrusions.

When choosing a location for electrode placement, consider the following special conditions:

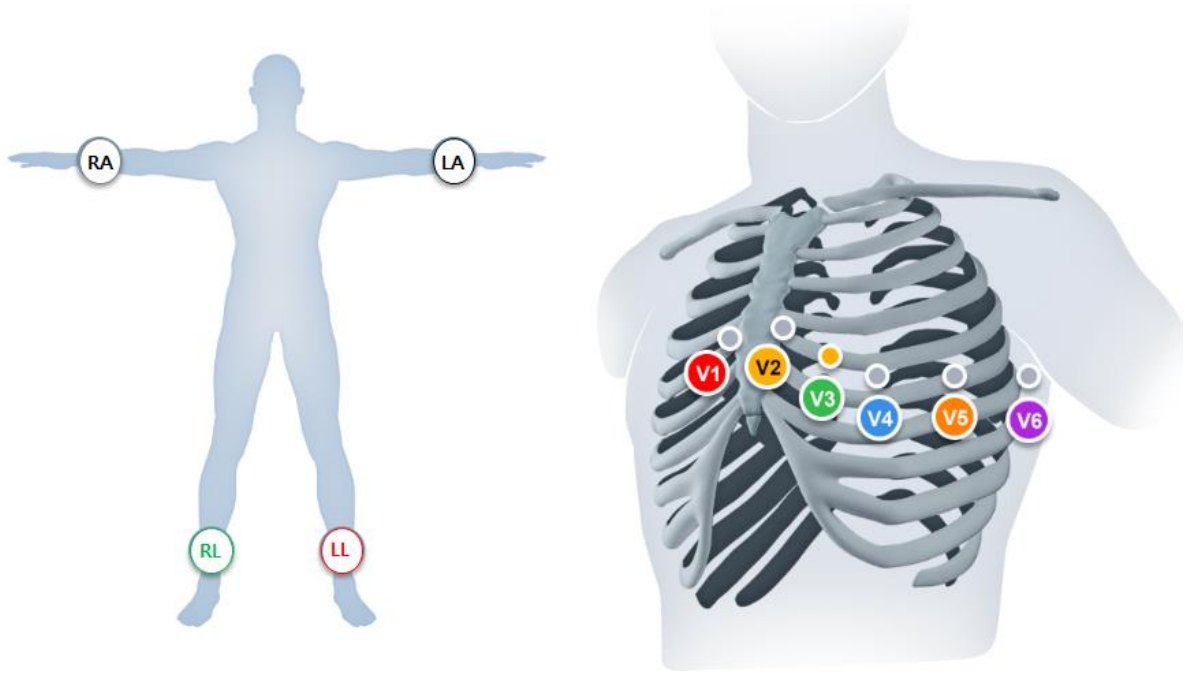
- Surgery patient - Place electrodes as far away as possible from the surgical area.
- Burn patient - Use sterile electrodes. Clean the monitor thoroughly. Follow the procedures of infection control from the hospital.

Note	• Make sure that the contact area of the disposable electrode are not dry to maintain good connection between the electrode and the skin. • If you suspect that the disposable electrode is in poor contact, replace it immediately with a new one. Otherwise, the contacting impedance of the skin and electrode is increased, and the ECG signal is not obtained correctly. • If the packing condition is not proper even if the expiration date on the packaging is not reached yet, it should be replaced with a new one. • To get a stable ECG waveform, rub the skin with gel or benzoin tincture.

Caution	• When using a generating electric potential equipment, it may interfere with ECG monitoring. • Do not rely solely on ECG for patients with epileptic tendencies. Electrical disturbances of non-cardiac circles such as seizures may interfere with the detection of specific arrhythmias.

6) ECG Lead

10-Lead Electrode Placement



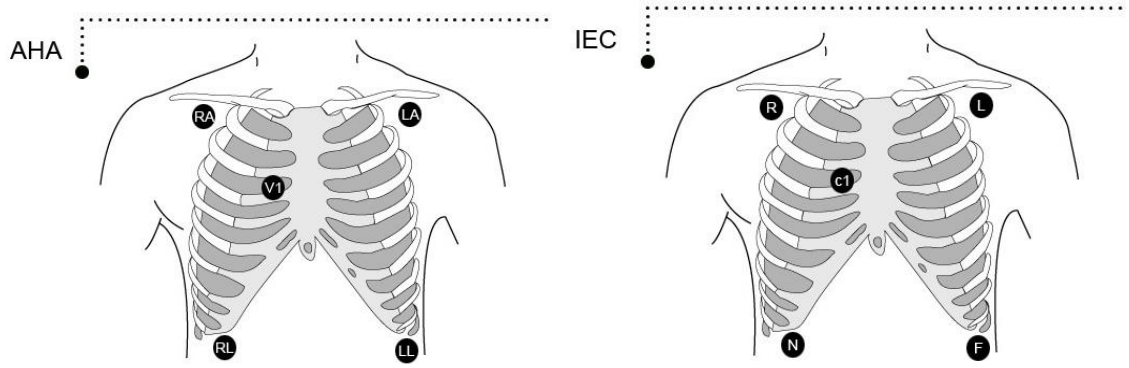
Locations of limb electrodes are as follows.

- RL (N): Right leg
- LL (F): Left leg
- RA (R): Right arm
- LA (L): Left arm

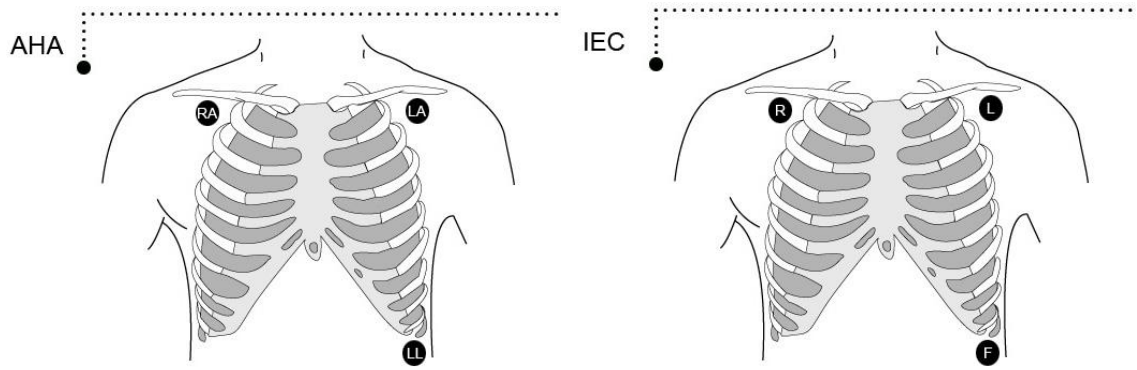
Locations of chest electrodes are as follows.

- V1 (C1): Boundary of fourth intercostal on right side of chest
- V2 (C2): Boundary of fourth intercostal on the left side of chest
- V3 (C3): Mid-location between V2(C2) and V4 (C4)
- V4 (C4): Mid-location of the front side of fifth intercostal collarbone
- V5 (C5): Front armpit on the horizontal line with V4(C4)
- V6 (C6): Mid-armpit on the horizontal line with V4(C4), V5(C5)

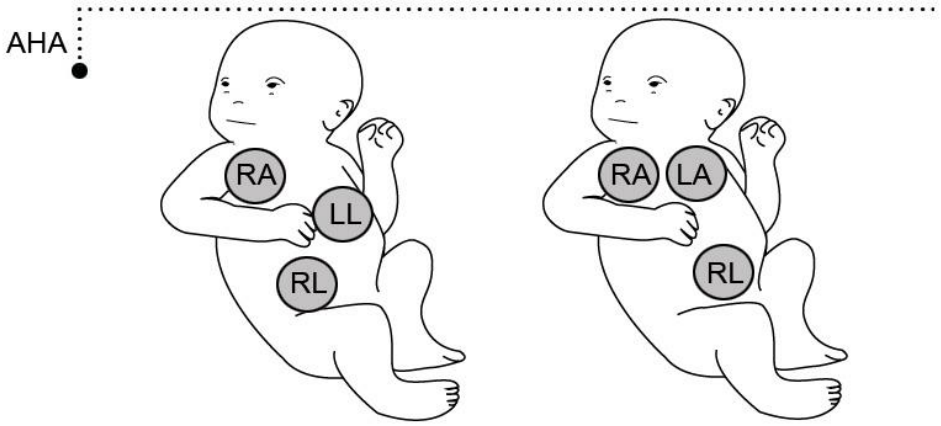
5-Lead Electrode Placement

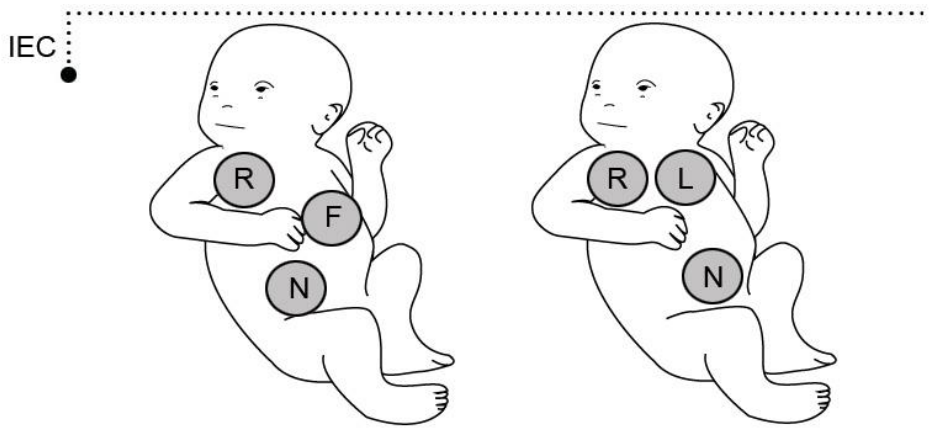


3-Lead Electrode Placement



How to Attach Electrodes for Neonate





Cable Color and Size

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

IEC: International Electro technical Commission (Europe standard)

3-Lead / 5-Lead / 10-Lead

Lead wire	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	V	White	C

7) Setting Pacemaker

For patients using a Pacemaker, you must set the Pacemaker On in the patient management screen.

1. Press the [Patient] icon in the upper left corner of the monitor.
2. When the Patient Management screen appears, set Pacemaker to On.
3. Press the [OK] button to apply the settings.

Warning	● **Patients using a pacemaker must set Pacemaker to On. If it is incorrectly set to Off, the patient monitor can mistake a pace pulse for a QRS complex and fail to alarm when the ECG signal is too weak. On ventricular paced patients, episodes of ventricular tachycardia may not always be detected. Do not rely entirely upon the system's automated arrhythmia detection algorithm.** ● **False low heart rate or false asystole alarms may result with certain pacemakers because of pacemaker artifacts, such as electrical overshoot of the pacemaker overlapping the true QRS complexes.** ● **Do not rely entirely on rate meter alarms when monitoring patients with pacemakers. Always keep these patients under surveillance closely.**

8) Enabling Pace Rejection

To eliminate the pacing pulse from the ECG waveform of paced patients, it is recommended to enable the pace pulse rejection function. The pace pulse rejection function is disabled by default.

To enable this function, follow this procedure:

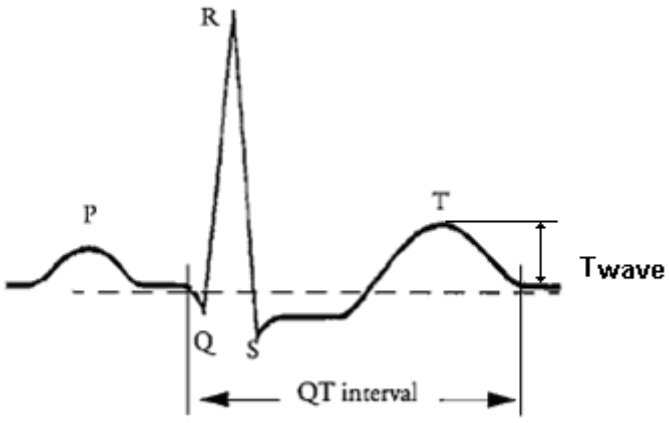
1. Select the ECG numeric area or waveform area to enter the ECG parameter.
2. Select the Setup tab.
3. Switch on Pace Rejection.

Note	• **When pace pulses are detected, the pace pulse markers "|" are shown on the ECG waveforms. Pacer Rejection setting has no impact on the display of pace pulse markers of "|".** • **You can switch on Pacer Rejection only when Pacemaker is set to On. If Pacemaker is set to Off, the Pacer Reject function is disabled.**

9) ECG Signal Processing and Display

The monitor distinguishes the QRS amplitude of 0.4 to 5.0 mV (0.2-5.0 mV with a scale setting of 0.5 mV / cm or less) and an adult with a QRS width of 70-120ms (or neonates with a QRS / ARR Select chapter). The heart rate is calculated from 15 to 300 times per minute using the last 10 seconds of the R-R interval and the two longest intervals and the two shortest intervals at the R-R interval. The remaining interval is averaged, and the current heart rate is displayed in the HR parameter area of the main screen as a result.

When using arrhythmia monitoring (excluding neonatal patients), when an arrhythmia alarm occurs, the name of the arrhythmia is displayed in the upper right corner of the ECG waveform area and in the vital signal alarm message area of the screen. . (Refer to 8. Monitoring Arrhythmia for details on arrhythmia monitoring.)



for details on arrhythmia monitoring.)

When the ECG signal is 80 BPM, the interval of the T wave is 180ms, and the QT period is 350ms.

10) ST Signal Processing and Display

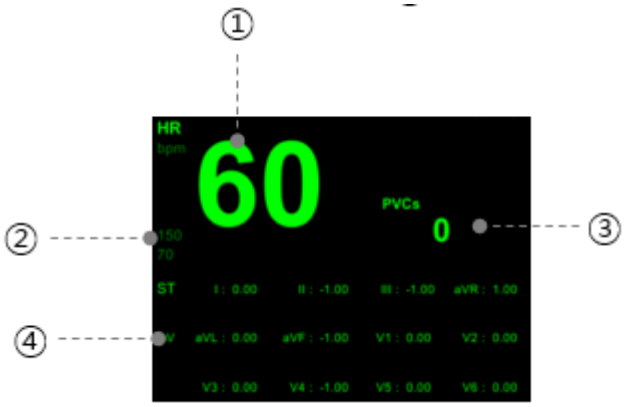
ST segment deviation is defined as the movement above or below the equipotential level (mm). The different measurement compares the isoelectric point with the ST measurement point. The isoelectric point defines a zero-volt point (no electrical activity, 0 mm) on the horizontal axis. A zero-volt point with a base position is occurred on F-Point before 40msec. The default position is 80ms after the QRS offset.

The ST analysis feature examines the QRS complex that are classified as "normal" beats, from the selected ECG leads. The monitor learns each ST-lead and combines measurements and characteristics of a normal beat into a composite (or average) QRS Complex. Take the ST segment deviation from this mean. If ST monitoring is enabled, the current ST value is stored in the trend and can be reviewed in the trend display. The significance of the ST segment changes needs to be determined by a clinician.

11) Alarm and Its Status

High P-wave and T-wave - Long P-wave or T-wave with high amplitude duration can be detected by QRS Complex. Place the leads on the ECG1 channel with the highest R-wave (compare to T-wave and / or P-wave) to allow the monitor to detect properly low heart rate conditions in this situation. If the monitor continues to misinterpret the P-wave or T-wave, use a pulse oximeter to reposition the electrodes or monitor the patient's pulse rate.

12) Display



① Heart rate: Displays the heart rate per minute.

② HR Alarm limits: Displays heart rate threshold.

③ PVC count number per 1 minute

④ ST value per channel

13) Setting ECG

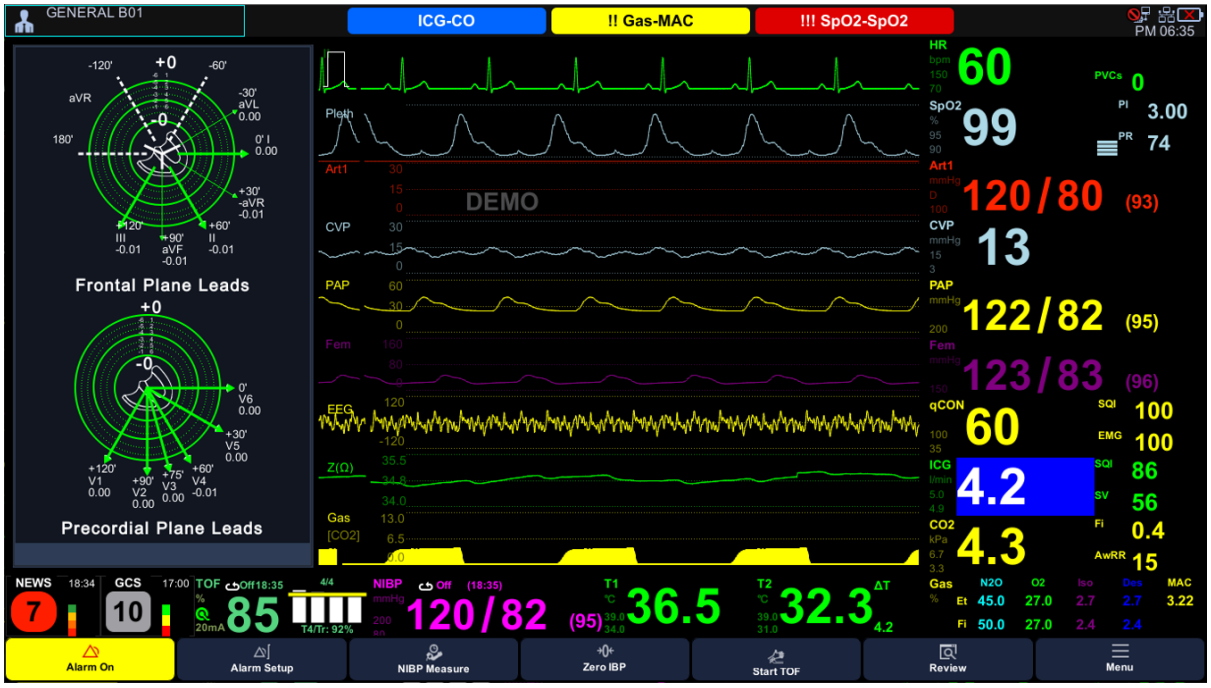
When you select an ECG value or waveform area, the setup menu appears.

Menu	Description	Available settings
A. Alarm	ECG alarm setting menu	HR, ST, PVCs
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority.	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B. Setup	ECG settings	
B-1. Speed	Set wave sweep speed.	6.25mm/s, 12.5mm/s, 25mm/s, 50mm/s
B-2. Size	Set wave size.	x0.25, x0.5, x1, x2, x4
B-3. Filter	Set waveform filter.	Diagnostic, Monitor, Surgery, ST

B-4. View channel	The number of channels of the ECG waveform to be displayed on the screen Menu is displayed according to the currently connected cable. The ECG waveform of 1CH is displayed in two lines.	Common: 1CH, 5, 10-Lead : 2CH, 7CH
B-5. View channel Trace 1, Trace 2	Select ECG Channel. Menu is displayed according to the currently connected cable. Trace2 is displayed when View Channel is 2CH.	*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
B-6. Pacemaker	Set Pacemaker Patient.	On, Off
B-7. Pace Rejection	Set the pacing pulse removal from the ECG waveform. Enabled only when Pacemaker in the Patient Management menu is On.	On, Off
B-8. QRS Volume	Set QRS volume. When SpO2 pulse rate volume is turned on, QRS volume is automatically turned off.	Off ~100% (10% unit)
B-9. HR source	Select heart rate source. When it is set to Auto, if ECG cable is not connected, SpO2 pulse is displayed.	ECG, SpO2, Auto
C. ST/PVC	PVC and ST analysis setup	
C-1. PVC analysis	Set PVC analysis result display. When it is set to On, PVCs are displayed.	On, Off
C-2. ST analysis	Set ST analysis result display. When it is set to On, ST value for each channel is displayed.	On, Off
C-3. ST map	Set ST map display. When it is set to On, ST value is displayed as map on the left side of	On, Off

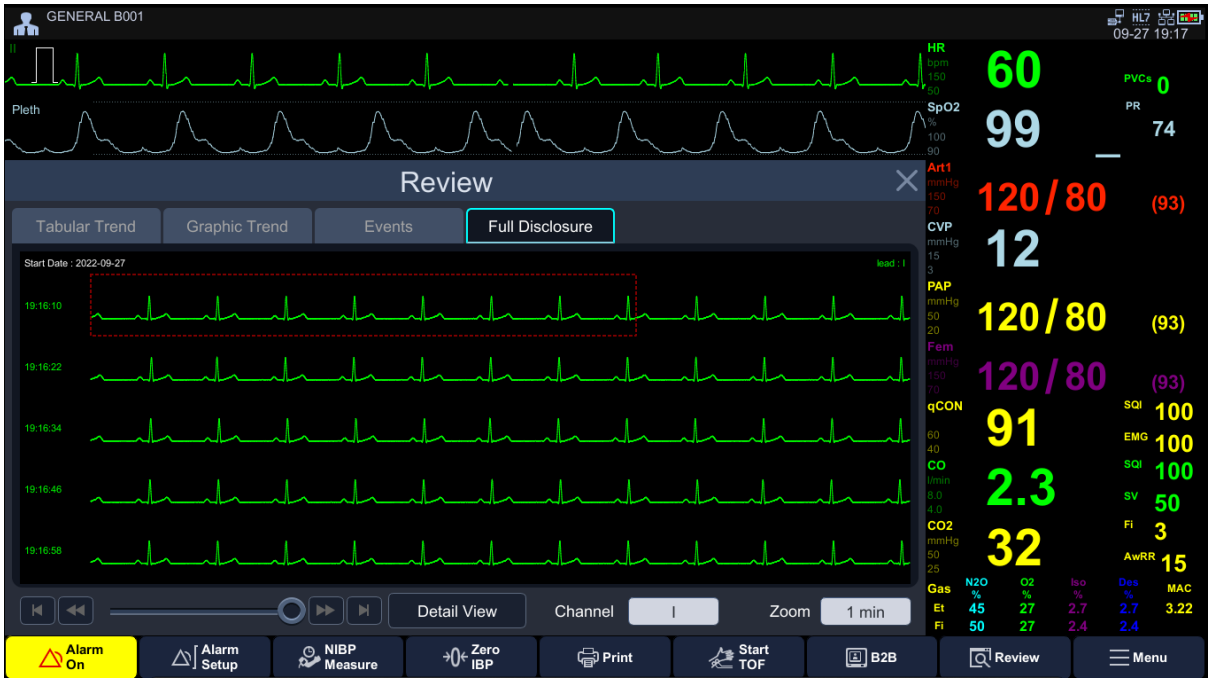
	the screen.	
C-4. ST template Channel	Set ST analysis ECG channel. Menu is displayed according to the currently connected cable.	*3-Lead: I / II / III *5-Lead: I / II/ III/ AVR/ AVL/ AVF/ V *10-Lead: I / II/ III/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6
C-5. ISO(R-)	Set ISO point position. It can be increased or decreased in 2ms increments.	20~160 ms
C-6. ST(R+)	Set ST point position. It can be increased or decreased in 2ms increments.	20~160 ms
C-7. Initial setup	Set ISO, ST point position initial value.	ISO: 90 ms ST: 60 ms

14) ST Map



15) Full Disclosure Review

Enable to check the ECG waveform on the Full disclosure screen in the Review menu. Full disclosure data can be stored for up to 48 hours, and the old data is deleted when the storage exceeds its capacity.



Menu	Description	Available settings
A. Full disclosure	View ECG Waveforms.	
A-1. Disclosure View	Display the ECG waveform in 5 rows according to the zoom setting. Tab the view area to move the cursor to that position.	
A-2. Page move and navigation slider	Move Section and update data.	
A-3. Channel	Select ECG channel. When it is changed, the waveform is updated with the selected channel.	I / II/ III/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6
A-4. Zoom	View resolution settings.	1 min, 2 min, 3 min, 4 min, 5 min
B. Detail	Cursor Area Details	

B-1. View	12 channels displayed in the set waveform layout.	
B-2. Waveform	Set Waveform layout.	12 ch, 6ch + 1, 3ch + 1, 3ch + 3
B-3. Rhythm Channel 1,2,3	Set 1,2,3 Rhythm Channel.	I / II/ III/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6

16) Resting 12-Lead ECG Analysis

The Patient monitor offers 12-Lead Resting ECG analysis algorithms.

Diagnostic algorithms are intended for adult, pediatric and neonatal patients.

When the diagnosis is completed, the result report is displayed on the screen. On the window, you can export the report in pdf file format to USB memory.

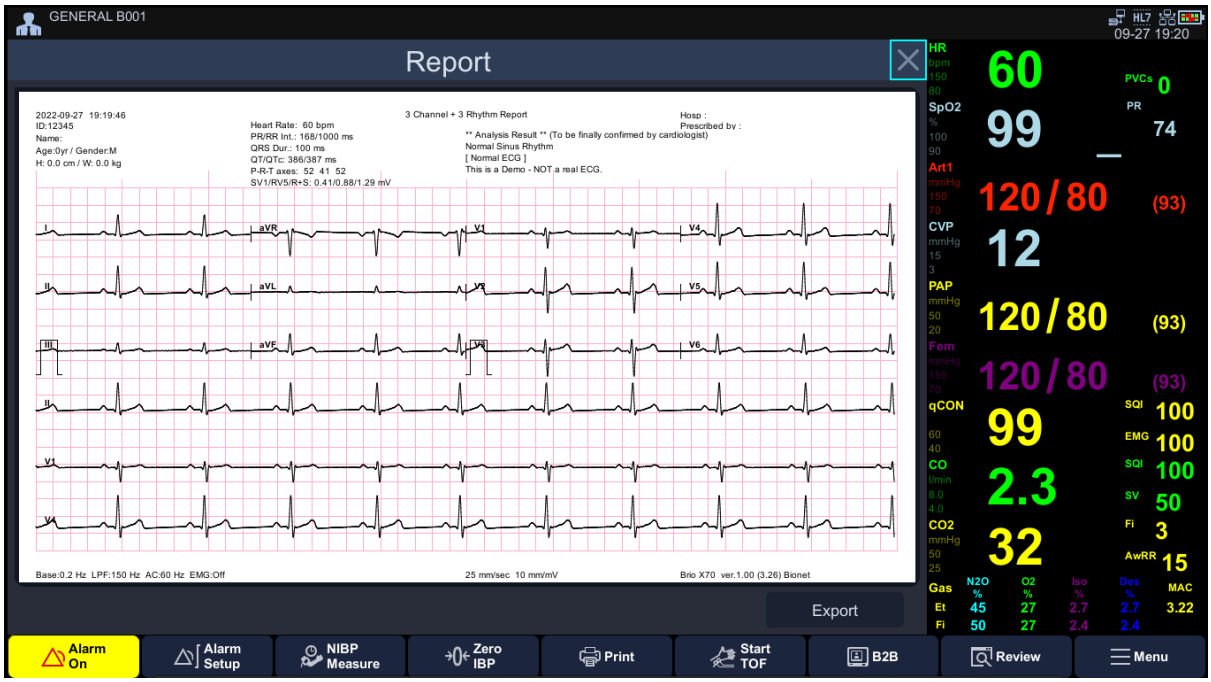
If you select 12ch on Change Layout of the main menu, it is converted to the 12ch ECG screen.

Note	12-Lead ECG analysis function is only supported by some models only.

17) Starting Analysis

Before starting the 12-lead ECG analysis, ensure that all electrodes are properly connected to the lead wires and the ECG cables are properly connected. Make sure that the patient's information is correct and leave the patient in a stable way.

Press the Analysis menu to acquire data for 10 seconds, perform diagnosis. You can see the results in a preview screen. If you press the Export menu, you can export the report to a USB memory.



18) Setting Analysis

When you press the ECG value area, the ECG setting menu appears. Select the Analysis tab of the Settings menu.

Menu	Description	Available settings
1. Analysis Level	Set the analysis level.	Basic, Professional
2. ST Analysis	Set the ST analysis.	Auto, 60 msec, 80 msec
3. Export Target	Analysis report export target	USB
4. Export File Format	Analysis report export file format	PDF
5. Report Waveform	Set Analysis report waveform layout.	3ch+3, 3ch+1, 6ch+1, 12ch
6. Report Rhythm Channel 1	Set Analysis report waveform rhythm channel.	Ⅰ / Ⅱ/ Ⅲ/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6
7. Report Rhythm Channel 2	Set Analysis report waveform rhythm channel setting. Applied only in 3ch+3 waveform.	Ⅰ / Ⅱ/ Ⅲ/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6
8. Report Rhythm Channel 3	Same as above	Ⅰ / Ⅱ/ Ⅲ/ AVR/ AVL/ AVF/ V1/ V2/ V3/ V4/ V5 / V6
9. Show Information > Patient Name	Decide whether to show patient information in analysis reports.	Show, Hide
10. Show Information > Hospital Info	Decide whether to show hospital information in analysis reports.	Show, Hide

Note	**For accurate diagnosis, it is recommended to set the ECG filter to Diagnostic. In this case, an unfiltered ECG waveform is displayed to show changes such as R-wave notching or discontinuous rise or fall in the ST segment. Refer to the Setting ECG for ECG filter settings.**

19) Troubleshooting

This section lists the problems that might occur. If you encounter some problems when using the monitor or accessories, check the table below before requesting service representative. If the problem persists, please contact your service representative.

Problem	Solution
Noisy ECG traces	1. Check that the electrodes are not detached or dry. Replace with new ones if necessary. 2. Check that lead wires are not defective. Replace lead wires if necessary. Check that the patient cable or lead wires are not too close to other electrical devices. Move the patient cable or lead wires away from electrical devices if necessary.
Muscle Noise	Inadequate skin preparation, tremors, tense subject, and/or poor electrode placement. 1. Perform skin preparation again and re-place the electrodes. For more information, refer to **Preparing the Patient and Attaching the Electrodes.** 2. Apply new with moist electrodes. Avoid muscular areas.
Intermittent Signal	1. Check that cables are properly connected. 2. Check that electrodes are not detached or dry. Perform skin preparation again on patient and apply new with moist electrodes. 3. Check that the patient cable or lead wires are not damaged. Change them if necessary.
Excessive alarms: heart rate, lead fault	1. Check that electrodes are not dry. Perform skin preparation again and re-place the electrodes. For more information, see Preparing the Patient and Attaching Electrodes. 2. Check for excessive movement of patient or muscle tremor. Reposition the electrodes. Replace new with moist electrodes if necessary.
Low Amplitude ECG Signal	1. Check if the ECG gain is set too low. Adjust the gain control as required. For more information, see ECG setup menu. 2. Perform skin preparation again and re-place the electrodes. For more information, see Preparing the Patient and Attaching Electrodes.

	3. Check electrode application. Avoid bone or muscular area. 4. Check that electrodes are not dry or have been used for a prolonged time. Replace with new ones if necessary.
No ECG Waveform	1. Check if the ECG gain is set too low. Adjust the gain control as required. For more information, see ECG Setup menu. 2. Check if the lead wires and patient cables are properly connected. 3. Change cable and lead wires if necessary. 4. Check that the patient cable or lead wires are not damaged. Change them if necessary.
Base Line Wander	1. Check for excessive movement of patient or muscle tremor. Secure lead wires and cable. 2. Check that electrodes are not detached or dry and replace with new ones if necessary. For more information, see Preparing the Patient and Attaching Electrodes. 3. Check ECG filter setting.

PART 8. Monitoring Arrhythmia

1) Overview

Arrhythmia monitoring is available for adult and pediatric patients only; it is not available for neonates. The monitor compares the received beats to the reference beats that have been recorded and stored in the reference template. Through this process, it can identify the occurrence of an arrhythmia event, classify it, and draw clinical conclusions based on the frequency and type of the signal. It observes all doubtful beats if the baseline moves beyond a defined limit. It uses QRS processing results for arrhythmia analysis. During multiple lead arrhythmia treatment, it measures the QRS Complex of each lead and compare it to the main learned beats. It classifies the beats based on information obtained from all available leads.

When an arrhythmia alarm occurs, the message below is displayed in the upper right corner of the ECG waveform area and in the bio signal alarm message area on the screen.

2) Arrhythmia Template

Template	Description	
Asystole	Ventricular asystole occurs whenever the displayed heart rate drops to zero.	
V-Fib / V-Tach	Ventricular fibrillation occurs when the ECG waveform indicates a chaotic ventricular arrhythmia.	
V-Tach	Adult	Occurs when three or more ventricular beats greater than 100 beats per minute are detected.
	Pediatric	Occurs when three or more ventricular beats greater than 130 beats per minute are detected.
	Neonate	Occurs when three or more ventricular beats greater than 150 beats per minute are detected.
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.
	Pediatric	Occurs when an average heart rate of between 60 and 130 beats per minute is detected as 6 or more.

	Neonate	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.
Bigeminy	Occurs when two or more bigeminal cycles (a ventricular beat followed by a non-ventricular beat) are detected.	
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 ventricular COMPLEX is detected within the repolarization period of the normal beat (when the RR interval is less than or equal to 360 msec)..	
Trigeminy	Occurs when two or more trigeminal cycles (a ventricular beat followed by two non-Ventricular beats) are detected.	
Short Run	Occurs when three or more consecutive ventricular beats are detected and have a normal beat before/after.	
V-Brady	Adult	Occurs when three or more ventricular beats less than 50 beats per minute are detected.
	Pediatric, Neonate	Occurs when three or more ventricular beats less than 60 beats per minute are detected.

Note	• **The Brady limit matches the low heart rate limit. if the low heart rate limit is changed, the Brady limit changes.** • **The Tachy limit matches the high heart rate limit. If the high heart rate limit is changed, the Tachy limit changes.**

3) Setting Arrhythmia

When you select an ECG value or waveform area, the setup menu appears. Select the Arrhythmia tab.

Menu	Description	Available settings
1. Arrhythmia List	List of arrhythmias	Asystole, V-Tach, V-Tach/V-Fib, Bigeminy, Trigeminy, Acc Vent, Couplet, Irregular, Pause, R on T, V-Brady, Short Run, PVC
2. Alarm	Set whether to detect an alarm.	On, Off
3. Priority	Set alarm priority.	High, Medium, Low
4. Print	Set print when an alarm occurs.	On, Off
5. Off	Turn off all arrhythmia alarms.	
6. Lethal	Turn on Asystole, V-Tach, V-Tach/V-Fib alarms only.	
7. Full	Turn on all arrhythmia alarms.	

Warning	● **Display Heartbeat Equipment Signal** **Pacemaker signal is shown when the PACE mode is ON; it is shown in a consistent form. The signal size or form are clinically meaningless.** ● **Number Of Heartbeat** **Patient with pacemaker needs close attention. The pacemaker can continue to show heartbeat even during arrhythmia. Therefore, do not depend on heartbeat alarm excessively.**

Warning	● **VENTRICULAR ARRHYTHMISAS** **The arrhythmia analysis program is intended to detect ventricular arrhythmia. This program is not designed to detect trial or supra ventricular arrhythmias. In some cases, it may not be possible to distinguish the presence or absence of arrhythmias. Therefore, doctors should analyze the arrhythmia information**

	like other medical information. ● **SUSPENDED ANALYSIS** **Certain conditions can delay the arrhythmia analysis. Detection and alarms associated with arrhythmias do not occur when arrhythmia conditions are delayed. This message is generated when the arrhythmia analysis is delayed:.** ➢ **Lead Fault, Alarm Paused, Alarm Off, Patient Discharge**

PART 9. RESPIRATION

1) Overview

Respiration via ECG Lead I or Lead II electrode is measured by using the changes in the resistance of skin, caused by the chest skin enlargement. In this process, the respiration value per minutes is calculated and the alarm is triggered according to limit value.

The monitor can use ECG leads I or II for breath detection, regardless of the leads selected for QRS processing.

2) RESP Precautions

Safety and efficacy of respiration measurement methods for apnea detection, especially apnea of premature babies and apnea of infants, have not yet been established.

- The patient monitor does not monitor obstructive apnea**.** Patients in a breathing crisis should be closely monitored.
- Impedance breath monitoring should not be considered as the only way to detect breathing stops. Bionet recommends monitoring of additional parameters, such as EtCO2 and SpO2, that indicate the patient's oxygen supply status.
- If you use an ESU block or cable, the impedance breath monitor may not work, and the pacemaker detection performance may be degraded. If pacemaker detection is enabled, ESU interference may be detected as a pacemaker.
- Large amplitude pacemaker pulses (>100mV) may interfere with the monitor's breath measurement or detection function.

3) Preparing the Patient

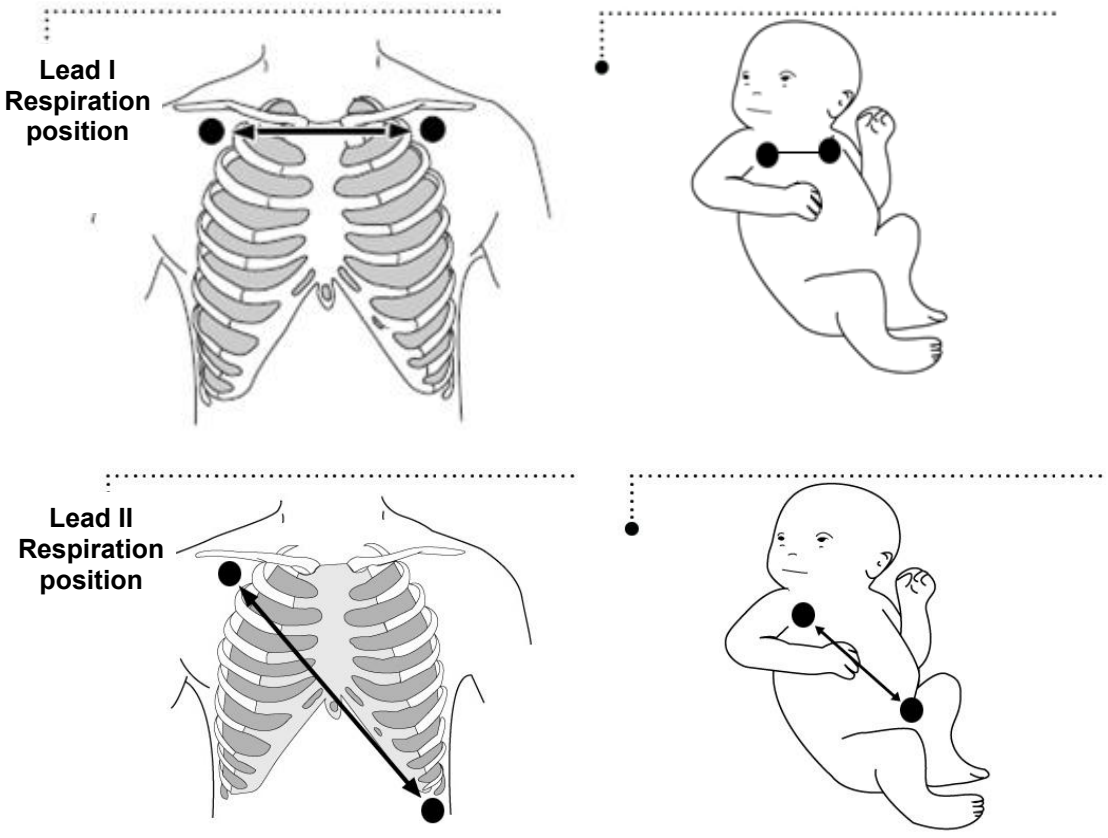
Skin preparation and electrode placement must be properly and carefully monitored in impedance

breath monitoring. Refer to the **Preparing the Patient in PART 7.**

In general, the electrodes should be placed as clean as possible with the 60Hz noise minimized to make it possible to generate a signal. The best results can be obtained when the electrodes are firmly bonded, and the electrode area is wide.

To improve the RESP signal, use a 5-lead cable set (RL as a neutral electrode). It is recommended that the electrodes be placed in the maximum expansion and contraction range of the lung, especially if deep breathing is involved.

For neonates, place the RA and LA electrodes on the mid-armpit line with the nipple. Place the LL electrodes under the diaphragm and navel. Avoid the liver and the ventricles of the heart to prevent 60Hz noise from pulsatile blood circulation. The following figure shows where we recommend placing ECG leads for impedance breathing in adults and neonates.



Note	**Cables and connectors to measure respiration rate (RR) are commonly used with ECG.**

4) Display

① The number of respirations per minute

② Respiration alarm limit indicates respiration limits

5) Respiration Setting Menu

When you select the numerical or waveform area of Resp, the setting menu appears.

Menu	Description	Available settings
A. Alarm	Set RESP alarm.	RR, Zero RR
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority.	High, Medium, Low
A-3. Low / High	Set Alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B. Setup	Setup menu	
B-1. Speed	Set Waveform range speed.	6.25 mm/sec 12.5 mm/sec 25.0 mm/sec
B-2. Size	A menu to setup wave display	x2, x4, x6, x8, x10
B-3. Lead selection	This is for changing the reference lead for respiration.	Lead I Lead II

PART 10. SpO2

1) Overview

SpO2 monitoring is a non-invasive technique that measures the total amount of oxygen in hemoglobin. The pulse rate is measured by measuring the absorption of the wavelength of the selected light. The light emitted by the sensor in the probe passes through the tissue and is converted into an electrical signal by the light-detecting sensor in the probe. The monitor processes the electrical signal and displays the waveform, %SpO2, and pulse rate on the screen as quantified values. Red and infrared rays are passed through the capillaries of the fingertip to detect the pulsating component, calculate HR and oxygen saturation, and alarm according to the set alarm value. You can calibrate the patient monitor to display functional oxygen saturation.

2) Precautions

SpO2 measurements are particularly sensitive to arterial and arteriolar pulse rates. Patients experiencing shock, hypothermia, anemia, or patients taking medications that reduce arterial blood flow may have incorrect measurements.

Warning	● **The pulse oximeter cannot be used as an apnea monitor.** ● **High oxygen levels can make premature babies vulnerable to retrolental fibroplasia. When this is the case, do not set the maximum alarm limit to 100%, such as the effect of turning off the alarm. Percutaneous SpO2 monitoring is recommended for premature infants receiving supplemental oxygen.** ● **Ambient lighting, physical behavior, diagnostic tests, electromagnetic interference, and improper positioning of the probe may affect SpO2 accuracy.** ● **Inspect the applied area every 2-3 hours to check the skin condition and check if the sensor is well attached with the naked eye. If skin conditions**

	change, move the sensor to another location. Change the application every 4 hours at least. ● **Check compatibility before using the patient monitor, probe, and cable specified by the Bionet.** ● **Use only Bionet-designated sensors. Other sensors may not provide adequate protection against defibrillation or may put the patient at risk.** ● **Disposable accessories (disposable electrodes, transducers, etc.) should be used only once. Do not reuse disposable accessories.** ● **Pulse oximeters have been validated for low perfusion accuracy in bench-top tests on simulators with signal strength of 0.02% or more, and transmissions of 5% or more to standard deviations include 68% of the population.**

3) Preparing the Patient

The accuracy of SpO2 monitoring is largely dependent on the strength and quality of the SpO2 signal.

The age, sex and race of the clinical study report used to assess SpO2 accuracy are as follows:

- Age: 20-36 years
- Race: White, African, American, Hispanic
- Sex: Male, Female

If you use your fingers as a monitoring site, remove the nail polish. Cut the patient's fingernail if needed to improve placement of the sensor. Only use sensors provided by Bionet and apply them according to manufacturer's recommendations on a per-sensor basis.

If the sensor is not attached correctly, the ambient light may interfere with the pulse oximetry, making the measurement irregular or causing the value to disappear. If you suspect interference from ambient light, make sure that the sensor is properly positioned and that the sensor cover with the opaque body is covered.

1. Select the sensor type and size that best suits your patient.

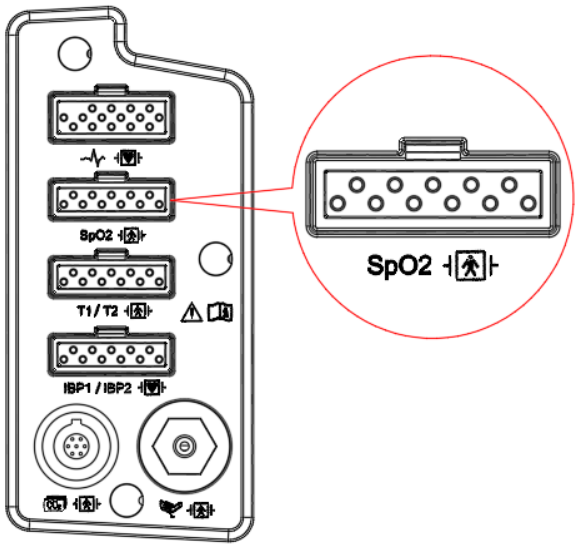
2. If the sensor can be reused, please wash it before use for each patient.
3. Position the sensor correctly and attach it to the patient.
4. Connect the sensor to the patient cable.
5. Check the application area of the sensor from time to time If the sensor is too tight, it may delay blood flow or overheat the skin and damage the tissue. Do not use a damaged sensor.

Note	• **Read the documentation that came with your sensor for the best application technology and safety information. Never use a damaged sensor.** • **If the sensor does not turn on after connecting the sensor, observe that a message appears on the patient monitor. If the sensor-LED does not turn on, replace the sensor.**

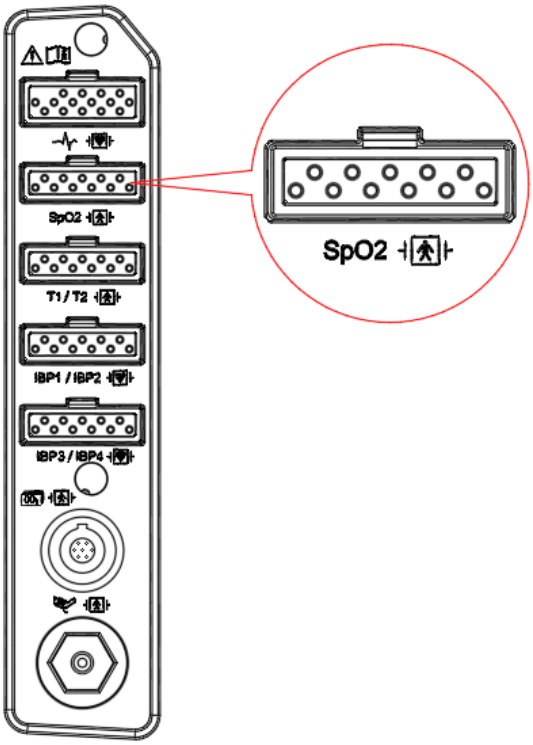
4) Connector and Measurement Cable

SpO2 connector

Brio X30



Brio X50, Brio X70



SpO2 measurement extension cable

	SpO2 measurement extension cable

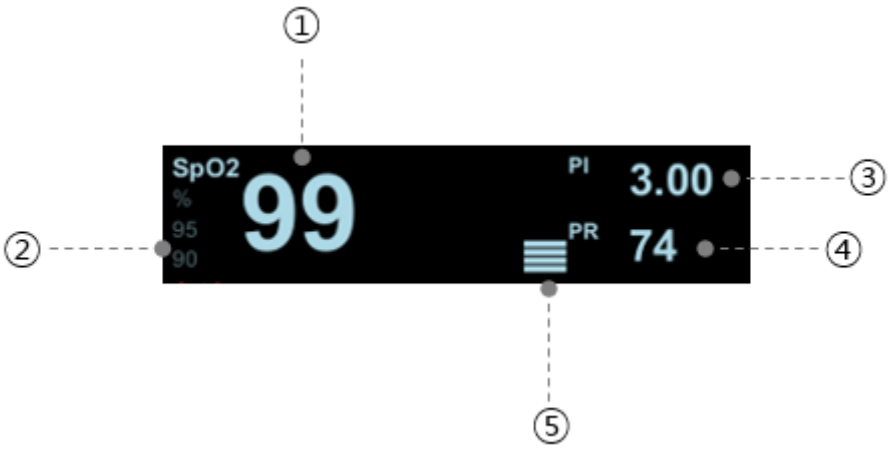
SpO2 sensors

	Adult SpO2 Sensor (Reusable type)

	Disposable SpO2 Sensor
	Nellcor Adult SpO2 Sensor (Reusable type)

Note	**The signal input is a high-insulation port protected from defibrillator. ( )** **The insulated input ensures patient safety and protects the patient monitor during defibrillation and electro surgery.**

5) Display



① %SpO2 Value display

② %SpO2 alarm limits display

③ SpO2 PI (Perfusion Index) measurement display (Bionet SpO2 Only)

④ SpO2 pulse rate display

⑤ SpO2 strength indicator

The SPO2 measurements are averaged over a 6-second period of time and the monitor display is updated every second.

Note	• **SpO2 wave size is changed automatically.** • **A functional tester or SpO2 simulator (Fluke, Index 2 simulator) can be used to verify operation of pulse oximetry function.** • **A functional tester or SpO2 simulator cannot be used to assess the SpO2 accuracy.**

6) Signal and Data Validity

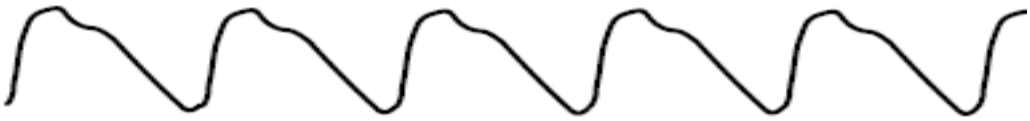
It is extremely important to determine that the probe is attached to the patient correctly and the data is verifiable. To make this determination, three indications from the monitor are assisted: the signal strength bar, the quality of the SPO2 waveform, and the stability of the SPO2 values. It is critical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

Signal Strength Bar

Pulse histogram and perfusion index (PI) are useful features that can be used to determine the reliability of readings. If the pulse bar's height is less than 30%, this indicates an inadequate signal and the displayed SpO2 or pulse rate values may be potentially inaccurate.

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 you find a probe placement with the least noise spikes present. The figure below represents an SPO2 waveform of good quality.



SpO2 Waveform in Good Quality

If noise (artifact) is seen on the waveform because of poor probe placement, the photo detector may not go through 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). In order to reduce motion noise, you should carefully look at the SpO2 waveform and check the probe position on the patient.

SpO2 Waveform with Artifact

SpO2 Wavelength and Optical Output Power

BSpO2 and Nellcor Oximax pulse oximetry display functional saturation.
This information can be useful to medical staff performing photodynamic therapy.

- The Nellcor Oximax pulsed oximetry sensor emits red light at a wavelength of approximately 660 nm and a wavelength of approximately 900 nm. It contains an LED that emits infrared at a wavelength. The total optical output power of the sensor LEDs is less than 15mW.
- The BSpO2 pulse oximetry sensor contains an LED that emits red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905.920 nm.

Stability of SpO2 Values

The stability of the displayed SpO2 values can also be used as an indication of signal validity. You can improve the stability of SpO2 values with a little practice. SpO2 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 may simulate a plausible parameter reading, so that the patient 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.**

7) SpO2 Setting Menu

When you select the numerical or waveform area of SpO2, the setup menu appears.

Menu	Description	Available settings
A. Alarm	Set SpO2 alarm.	SpO2, PR
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority.	High, Medium, Low
A-3. Low / High	Set Alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B. Setup	Setup menu	
B-1. Speed	Set waveform range speed.	6.25 mm/sec, 12.5 mm/sec, 25.0 mm/sec, 50.0 mm/sec
B-2. Rate Volume	Set pulse volume. When ECG volume is set, it is automatically set to Off.	Off ~100% (10% unit)

8) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before requesting service representative. If the problem persists, contact your service representative.

Problem	Solution
"---" is displayed in place of numeric.	1. Make sure the SpO2 cable is securely connected. If necessary, replace the SpO2 cable. 2. Connect the SpO_2 sensor if the alarm Probe Off appears. 3. Check the PI value If the PI value is too low, adjust the SpO_2 sensor, or apply the sensor with better perfusion. 4. Move the sensor to a place with weaker ambient light, or cover the sensor to minimize the ambient light if the alarm Too Much Light appears.
Low amplitude SpO2 signal	1. The SpO2 sensor and NIBP cuff are placed on the same limb. Change the monitoring site if necessary. 2. Check the PI value. If the PI value is too low Adjust the SpO2 sensor or apply the sensor to a site with better perfusion.
SpO2 value is inaccurate.	1. Check the patient's vital signs. 2. Check for conditions that may cause inaccurate SpO2 readings. 3. Check the monitor, the SpO2 module for proper functioning.

PART 11. NIBP

1) Overview

The monitor uses the oscillometric method for measuring Non-Invasive Blood Pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. The oscillometric device uses a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure, and measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

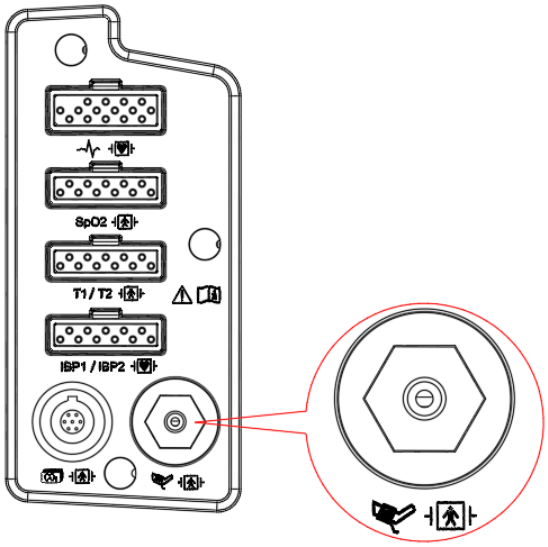
If the pulse signal is weak due to patient movement, improper cuff positioning, or noise in the signal, deflate the cuff and try a second measurement. Refer to the status alarm message table for causes and solutions for weak pulse signals. Connect the cuff and monitor with a hose to measure contraction, dilatation, and mean blood pressure in adult, pediatric, or neonatal patients.

The monitor's NIBP system expands and contracts the Pneumatic Cuff wrapped around the patient's arm or leg to initiate blood pressure measurement alone based on a set interval or persistence lasting more than 5 minutes.

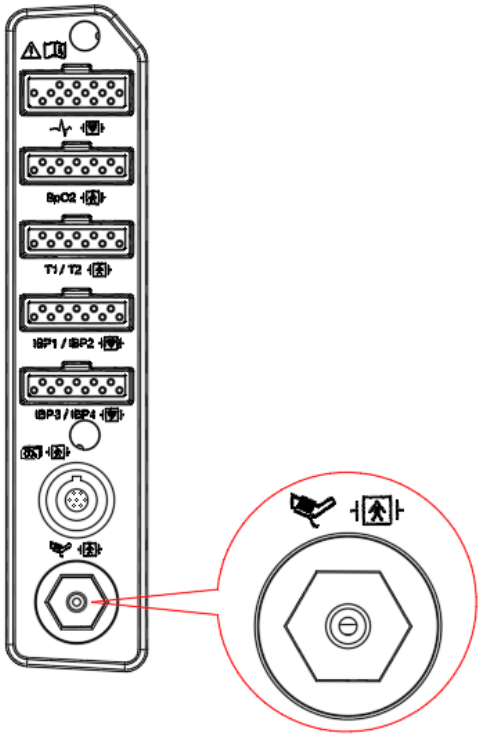
Note	• **The patient monitor has been clinically investigated in accordance with the requirements of ISO 81060-2: 2013, and the blood pressure measurements taken with the patient monitor are identical to those obtained by the intra-arterial method within the limits prescribed by the Association for Advancement of Medical Instrumentation, Electronic Automated Sphygmomanometers (AAMI/ANSI SP-10).** • **You can perform NIBP measurement during electro-surgery and discharge of a defibrillator.** • **NIBP performance may be affected by extreme temperature, humidity, and altitude. For environmental conditions, refer to PART 25. System Specifications.**

2) Connector and Cuff

Brio X30



Brio X50, Brio X70



Cuff extension tube

Adult cuff

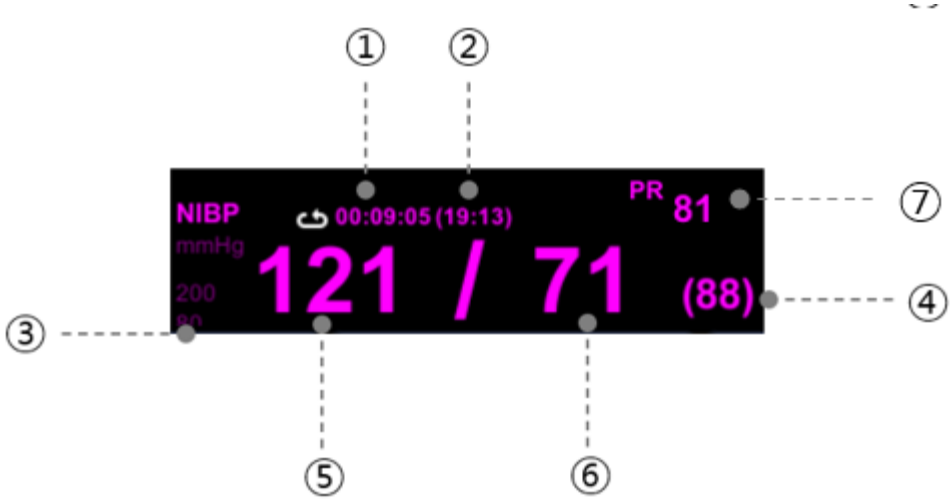
Optional accessory list

Adult		**Adult NIBP Cuff** Cuff Size: 520 * 140 Thigh circumference: 27.5 to 36.5 Cm Option
Small Adult		**Small Adult NIBP Cuff** Cuff Size: 405 * 112 Thigh circumference: 20.5 to 28.5 Cm Option
Pediatric		**Pediatric NIBP Cuff** Cuff Size: 308 * 88 Thigh circumference: 13.8 to 21.5 Cm Option

Thigh Adult		**Big Adult NIBP Cuff** Cuff Size: 745 * 210 Thigh circumference: 38 to 50 Cm Option
Large Adult		**Big Adult NIBP Cuff** Cuff Size: 635 * 173 Arm circumference: 31 to 40 Cm Option
Adult		**Adult NIBP Cuff** Cuff Size: 495 * 140 mm Arm circumference: 23 ~ 33 Cm, basic
Small Adult		**Small Adult NIBP Cuff** Cuff Size: 430 * 108 mm Arm circumference: 17 ~ 25 Cm, option
Pediatric		**Pediatric NIBP Cuff** Cuff Size: 304 * 83 Arm circumference: 12 to 19 Cm Option

Note	**The ESU does not cause a burn hazard through the NIBP cuff, because there is no electrical connection between the cuff and the NIBP measuring electronics.**

3) Display



① Measurement period or remaining measurement time: Before measurement starts, the set measurement period is displayed. When the measurement is complete, the remaining time until the next measurement is displayed.

② Measurement completion time

③ Alarm upper/lower limits for systolic or diastolic blood pressure: When the systolic blood pressure alarm is off, the alarm upper/lower limits for diastolic blood pressure are displayed.

④ Mean blood pressure: Indicates the average blood pressure

⑤ Systolic blood pressure: Indicates the maximum blood pressure

⑥ Diastolic blood pressure: Indicates the minimum blood pressure

⑦ Pulse rates: Indicates pulse rate

4) NIBP Setting Menu

When you select the NIBP numerical are, the setting menu appears.

Menu	Description	Available settings
A. Alarm	Set NIBP alarm.	Sys, Dia, Mean, PR
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority.	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs	
B. Setup	Setup menu	
B-1. Initial Pressure	Set initial pressure. Default settings: *Adult: 160 mmHg *Pediatric: 140 mmHg *Neonate: 90 mmHg	* Adult: 120 - 250mmHg * Pediatric: 80 - 170mmHg * Neonate: 60 - 140mmHg
B-2. Interval	Set the blood pressure measurement cycle. *Manual: Manual measurement *Others: Periodic measurement. After setting, press NIBP menu to start periodic measurement.	Manual, 1min, 2, 2.5, 3, 4, 5, 10, 15, 20, 30, 1hour, 1.5, 2, 4, 8
B-3. Start Mode	Set repeat measurement method. *Clock: On-time measurement *Interval: Measure at the set interval	Interval, Clock
B-4. PR Display	Whether to display Pulse Rate	On, Off
C. Review	reiew recent blood pressure measurements (up to 1000)	
C-1. Latest / Prev /Next	Go to lastest/previous/after page	

Warning	● **Check periodically to see if the circulation from the cuff to the distal part of the patient's arm is good.** ● **Check the patient's condition frequently when using the automatic measurement of 1 minute and 2-minute interval. It is not recommended for measuring blood pressure for a long time after the measurement time is set to 10 minutes or less.**

Note	**Safety Considerations** **Software and Hardware for Cuff pressure Blocking** **The cuff is automatically reduced when the measurement time is longer than two minutes in Adult / Pediatric mode and more than 75 seconds in Neonatal mode. Extension limits are set for all patient categories to prevent overpressure on the patient.** **The maintenance is performed every 2 years.** **Check the following list to ensure the patient monitor always operates properly and safely.** **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.**

It is recommended that patient position in normal measurement, as below.

1. Comfortably seated

2. Legs uncrossed
3. Feet flat on the floor
4. Back and arm supported
5. Place the cuff about in the middle level of the right atrium of the heart. We recommend waiting 5 min before taking the first reading.

Note	
	● **It is recommended that the patient remains calm and relaxed as much as possible before being measured and does not talk during the measurement.** ● **Other factors that have been shown to result in an overestimation of blood pressure are labored breathing, full bladder, pain etc.** ● **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**

5) Measurement Restrictions

The measurement may be inaccurate or impossible:

- Measurements are impossible with heart rate extremes of less than 40 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine
- With excessive and continuous patient movement such as shivering or convulsions
- If a regular arterial pressure pulse is hard to detect
- With cardiac arrhythmias
- With rapid blood pressure changes
- With severe shock or hypothermia that reduces blood flow to the peripheries
- With obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- On an edematous extremity

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

6) Selecting and Placing the Cuff

The quality of NIBP monitoring depends largely on the quality of the signals received by the monitor. For this reason, it is important to select the correct cuff size for your patient. Cuff sizes are clearly marked on the cuff. Measure the circumference of your patient's limb. Use only Bionet cuffs with your monitor.

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.** • **Do not apply the cuff over a wound, as this can cause further injury.** • **Do not cuff the mastectomy on one arm.** • **Since the value of NIBP may vary depending on the age of the patient, the correct patient type must be set in the Patient Management menu before measurement.** • **Tubes between the cuff and the patient monitor are not kinked or blocked. Air must pass unrestricted through the tubing.** • **Pay attention not to block the connecting hose when you put cuff on patient.** • **Check for leaks on the cuff or hose connection. Measurements can be inaccurate if air leaks.** • **The air pad should be exactly over the branchial artery. Tubing is immediately to the right or left of the branchial artery to prevent kinking when elbow is bent.** • **Try to measure infants when they are calm. A kicking or crying baby**

	may disturb or jiggle the cuff, causing noise within the system and resulting in unstable blood pressure readings. If necessary, hold the cuffed limb steady, without impeding circulation. Do not hold onto the cuff and do not pat the cuffed limb to comfort the child. • **Even manual methods using a sphygmomanometer and stethoscope are ineffective in unstable or active patients.** • **Pressurization of the cuff may result in loss of function of monitoring medical electrical devices used simultaneously on the same extremity.** • **It is necessary to check that the operation of the NIBP does not cause organ damage to the patient's blood circulation.** • **Devices that exert pressure on tissue have been associated with purpura, ischemia, and neuropathy. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or STAT measurements. Auto NIBP measurements with one- and two-minute intervals are not recommended for extended periods of time.** • **When measuring in neonate, the correct patient classification must be selected (See Ch4 Admission and Discharge). Do not subject neonates to the high pressure, overpressure limits, and measurement times that apply to adults. Otherwise, it may pose a safety hazard.** • **NIBP reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. If you doubt the NIBP measurements, determine the patient's vital signs by alternative means, and then verify that the patient monitor is working correctly.**

7) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before contacting service representative. If the problem persists, contact your service representative.

Problem	Solution
Weak or no oscillometric signal	Check that the cuff is in the correct position. Check the patient. Check that the cuff is properly tightened. Check that there is no excessive clothing between arm and cuff. Check that the correct size cuff is being applied.
Artifact / erratic oscillometric signal	The patient may have been moving too much. Check that the cuff is in the correct position. Check that the correct size cuff is being applied.
Out of Range BP Value /Exceeded measurement time limit	The patient may have been moving too much. Check the patient. Patient may have serious BP-related issue. Check that the cuff is in the correct position. Check that the correct size cuff is being applied. Check that there is no excessive clothing between arm and cuff.
Pneumatic Blockage	Check that the hose has no sharp bends or is pinched. Check that the patient is not lying on the cuff. Check that the cuff is in the correct position.
Inflate Timeout, Air Leak or Loose Cuff	Check that the hose is connected to the system and the cuff. Check that the cuff is properly tightened. Check that the cuff is in the correct position. Check that the correct size cuff is being applied. Check that the cuff is not leaking air. Check that the hose connections are not damaged or loose.
Safety Timeout	Check the patient. Check that the cuff is in the correct position. The patient may have been moving too much. Take another BP reading.

Cuff Overpressure	Check that the correct size cuff is being applied. Check that the hose has no sharp bends or is pinched. Check that the cuff is in the correct position. Check that the patient is not lying on the cuff.

8) Calibration

1. Menu -> Calibration -> Parameter Calibration
2. Enter Password.
3. Select NIBP Tab.
4. NIBP ZERO: Press the [Zero] button with no pressure on the cuff.
5. NIBP Gain : Press the Calibration button while applying a pressure of 250mmHg for the Suntech NIBP module and 200mmHg for the Bionet NIBP module using the JIG.

   Note) NIBP module information can be checked in Main Menu -> System Information.

Warning	● **Calibration procedures may only be performed by service representative or designated trained personnel.** ● **To reduce the risk of injury, do not perform any in-use calibration procedures on the patient.** ● **Incorrect calibration values may result in patient harm.**

PART 12. Temperature

1) Overview

The Brio Series monitor can continuously monitor the patient's skin temperature via the Temp module. It uses a heat-sensitive resistor (thermistor) and is based on the principle that the electrical resistance of the thermistor changes with temperature change. The change in resistance of the resistor is used to calculate the temperature.

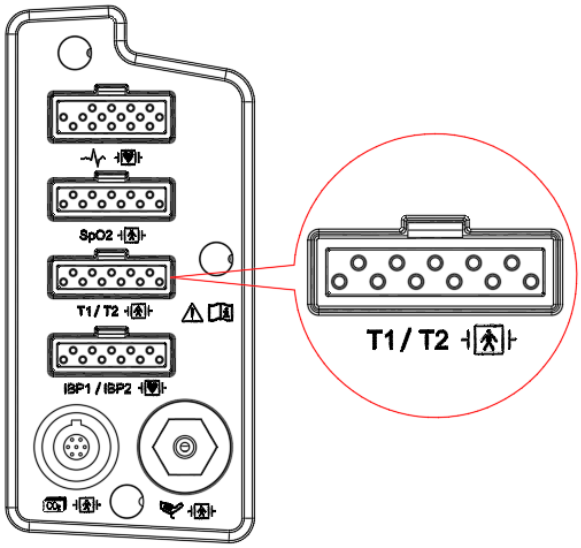
2) Preparing the Patient

Select an appropriate probe for your patient according to patient type and measured site.
The measurement areas are as follows:

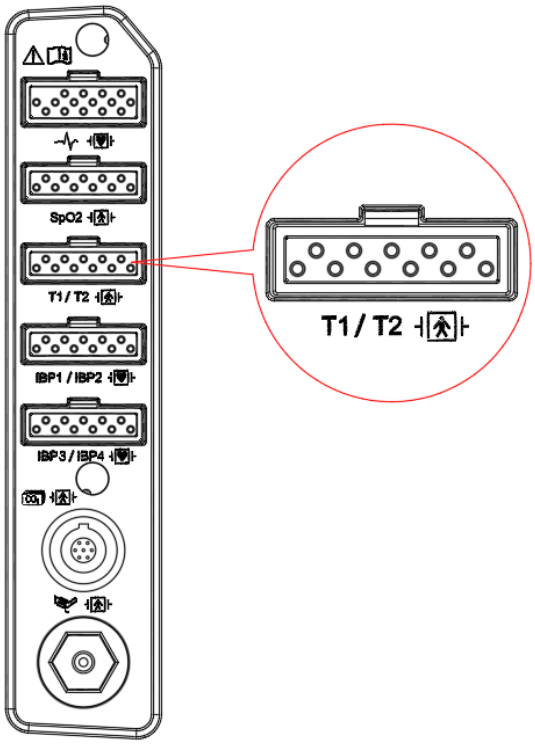
- Skin temperature
- Axillary temperature

3) Connector and measurement cable

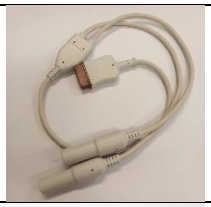
Brio X30



Brio X50, Brio X70

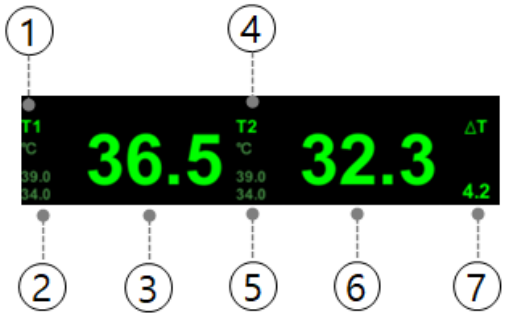


Temperature measurement sensor and cable

	**Temperature measurement cable**
	**Temperature measurement sensor**

Note	**Correctly position the temperature probe and fix it not to be disconnected from the patient.**

4) Display



① T1 temperature label

② T1 temperature unit and alarm limit

③ T1 temperature value

④ T2 temperature value

⑤ T2 temperature unit and alarm limit

⑥ T2 temperature value

⑦ Temperature difference

Note	• **The minimum measuring time required to obtain accurate readings at the specific body site is at least three minutes.** • **If the measurement site like the patient's skin is directly exposed to air, the temperature may be lower than normal.** • **It takes about 20 ~ 30 minutes to reach temperature equilibrium by attaching this sensor.**

5) Temp Setting Menu

When you select the Temp numerical area, the setting menu appears.

Menu	Description	Available settings
A. Alarm	Set Temp alarm.	Temp1, Temp2, DT
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority.	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B. Setup	Setup menu	
B-1. Temp Type	Set the thermometer type. * Continuous: Sensor thermometer * IR-USB: Infrared thermometer	Continuous, IR-USB
B-2. View Channels	View Channel. Fixed to 'T1' when Temp Type is 'IR-USB'	T1 T2 T1, T2
B-3. Delta Display	Decide whether to display Delta Temp. Shown when View Channels is T1, T2.	On, Off

6) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor accessories, check the table below before requesting service. If the problem persists, contact your service representative.

Problem	Solution
"---" is displayed in place of numeric.	Try using a known good probe in case the sensor is damaged.

PART 13. EtCO2

1) Overview

The Brio Series monitor measures concentrations of end-tidal CO2 (EtCO2) when this option is enabled and the EtCO2 module is connected to your monitor. Both mainstream and sidestream measurements use infrared light. The intensity of infrared light passing through the breathing gas is measured with a photodetector. Because some of the infrared radiation is absorbed by the CO2 molecules, the amount of light passing through the gas probe depends on the measured CO2 concentration. When using a ventilator, monitor CO2 as a mainstream measurement rather than a side stream. Measurements are taken at the patient's airway at a sampling frequency of 100 Hz, so response is faster and there is less chance of erroneous, artifact data.

The EtCO2 module can perform mainstream measurements in all monitoring modes and sidestream measurements in the adult and pediatric monitoring modes. For side stream measurements, the capnostat fits on the nasal sampling cannula tubing.

2) EtCO2 Caution

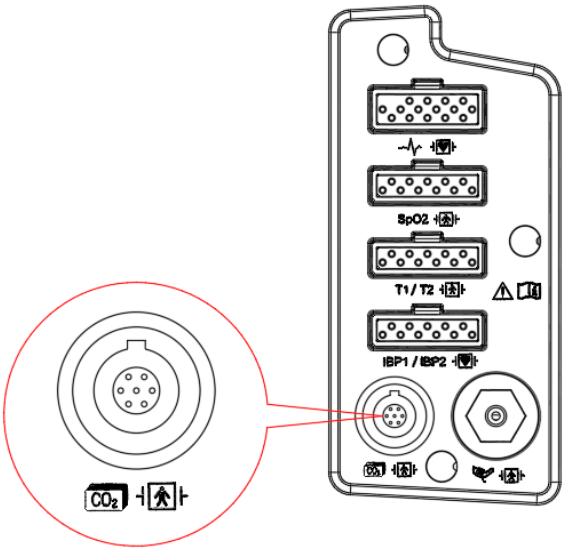
Warning	● **The safety and efficiency of breath measurement methods for apnea detection, especially apnea of premature babies and apnea of infants, have not yet been established.** ● **Patient monitors that measure CO2, anesthetics, and/or respiratory mechanics cannot be used as apnea monitoring and/or recording equipment. While these monitors provide an apnea alarm, the alarm condition begins with the elapsed time from when the last breath was detected. However, there are several physiological indications for the clinical diagnosis of real apnea events.** ● **The CO2 alarm is not activated until the first breath is detected after the patient monitor is turned on or the patient is discharged.**

	• **Accuracy of the CO2 and breathing rate measurements may be impaired due to improper attachment of the sensor or due to certain patient conditions and certain environmental conditions.** • **If the tube connection is faulty, lose or damaged, gas may leak and the accuracy of the measurement may be lowered, resulting in poor breathing. To prevent this, connect all component securely and check the connection according to standard clinical procedures to ensure that there are no leaks.**

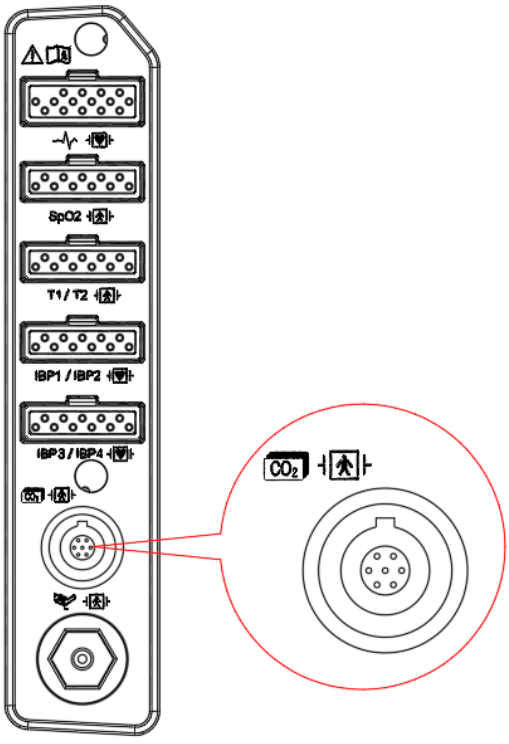
Warning	• **Industrial safety: Carefully dispose used sampling tubes and T-connectors as they may cause infection. There is a risk of infection. Dispose of all equipment in accordance with local regulations.** • **Optimize reaction time by minimizing dead space and keeping sample collection tubes as short as possible. Long sampling tubes can lead to poor accuracy and slow response times for side stream measurement techniques.** • **Do not place the airway adapter between the suction catheter and the endotracheal tube when using the sample collection line as a closed suction device for tuberous patients. This is to ensure that the airway adapter does not interfere with the function of the suction catheter.**

3) Connector and Measurement Accessory

Brio X30



Brio X50, Brio X70

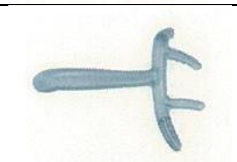


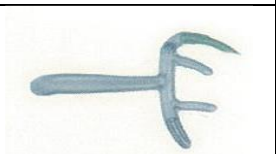
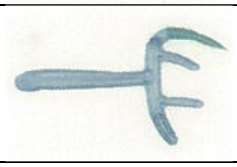
LoFlo Sidestrem CO2 sensor and connector

Sidestream sensor

Sidestream sensor connector

Sidestream EtCO2 Accessories

Non-Intubation Sidestream Accessories			
Part	**Picture**	**Description**	**type**
3468ADU-00		Nasal CO2 sampling cannula	Adult
3468PED-00		Nasal CO2 sampling cannula	Child
3468INF-00		Nasal CO2 sampling cannula	Neonate
3470ADU-00		Oral/Nasal CO2 sampling cannula	Adult
3470PED-00		Oral/Nasal CO2 sampling cannula	Child
3469ADU-00		Nasal CO2 sampling cannula w/O2 delivery	Adult

3469PED-00		Nasal CO2 sampling cannula w/O2 delivery	Child
3469INF-00		Nasal CO2 sampling cannula w/O2 delivery	Neonate
3471ADU-00		Oral/Nasal CO2 sampling cannula w/O2 delivery	Adult
3471PED-00		Oral/Nasal CO2 sampling cannula w/O2 delivery	Child

Intubation accessories			
3473ADU-00		Airway adapter kit w/ dehumidification tubing	Adult /Child (ET tube Size > 4.0 mm)
3473INF-00		Airway adapter kit w/ dehumidification tubing	Child/Neonate (ET tube Size <= 4.0 mm)

CAPNOSTAT 5 Mainstream CO2 sensor and connector

Mainstream Sensor

Mainstream Sensor Connector

Mainstream EtCO2 Accessories

Intubation patient airway adaptor		
Model	**Picture**	**Description**
6063-00		Adult (disposable)
6312-00		Neonate/Pediatric (Disposable)
7007-00		Adult (Reusable)
7053-00		Neonate/Pediatric (Reusable)

Warning	**The disposable airway adapters are designed for single use only and cannot be reused. Reuse may cause inaccurate readings, erratic readings, or no readings at all. Also, reuse may cause an increased risk of cross contamination among patients.** **The reusable airway adapters can be reused but to avoid infection, it shall be reused only after sterilized.**

4) CO2 Measurement Restrictions

The following factors may affect measurement accuracy:

- Sample gas leakage or internal emission
- Mechanical impact
- Periodic pressure of up to 10 kPa (100 cmH2O)
- High concentration of nitrous oxide gas
- Rapid temperature change
- High humidity
- Oher interference factors

Warning	**Measurement accuracy of the sidestream CO2 module may be affected by the breath rate and inspiration/expiration (I/E) ratio.**

Caution	• **The measured values may be inaccurate when using the patient monitor 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 an anesthesia machine that uses a volatile anesthetic, CO2 values may be inaccurate.**

5) Display

① End tidal CO2 value (EtCO2)

② Fraction of inspired CO2 (FiCO2)

③ EtCO2 alarm high/low limit value

④ Airway respiration rate

6) How to Sample

Connecting the CAPNOSTAT® 5 CO2 sensor to the host system

1. Insert the CAPNOSTAT 5 CO2 sensor connector into the receptacle of the host monitor as shown in Figure 1.

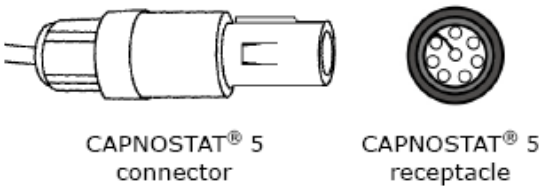


Figure 1

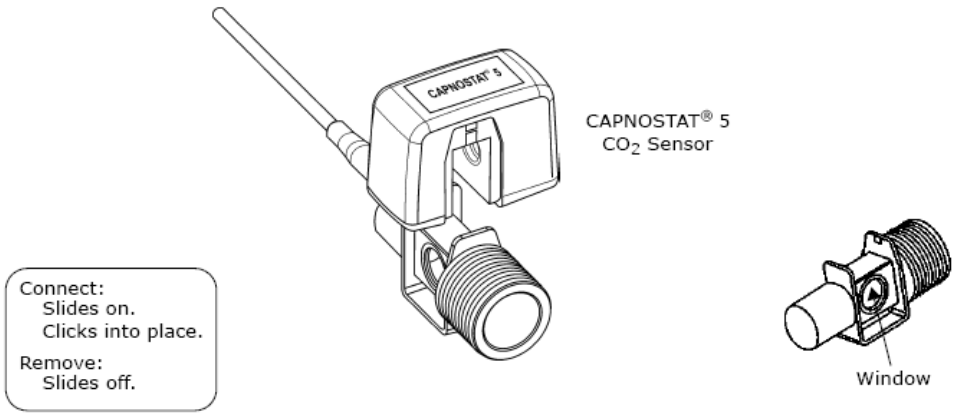
2. Make sure the arrows on the connector are at the top of the connector, and line up the two keys of the connector with the receptacle and insert.

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

Caution	**Do not remove by pulling cable.**

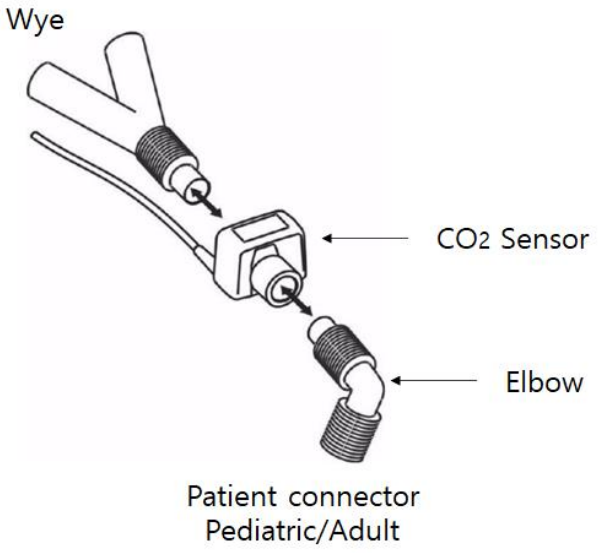
Connecting the mainstream CO2

1. Connect the CAPNOSTAT 5 CO2 sensor to the Respironics Novametrix CO2 adapter as shown below. The airway adapter clicks into place when seated correctly.



Note	**If zeroing is required, do this step. For details, see Zero Calibration.**

2. Shown below is the CAPNOSTAT 5 CO2 Sensor with a patient circuit



Warning	• **To prevent stress on the endotracheal tube, support the sensor and airway adapter.** • **Position sensor cables and tubing carefully to avoid entanglement or potential strangulation. Do not apply excessive tension to any cable.** • **Replace the airway adapter, if excessive moisture or secretions are observed in the tubing or if the CO2 waveform changes unexpectedly without a change in patient status.** • **To avoid infection, use only sterilized, disinfected, or disposable airway adapters.** • **Inspect the airway adapters prior to use. Do not use if airway adapter appears to have been damaged or broken. Observe airway adapter color coding for patient population.**

Connecting the sidestream CO2 (LoFlo Sample Kit)

1. The sample cell of the sampling kit must be inserted into the sample cell receptacle of the LoFlo CO2 Module as shown in Figure 1. A "click" is heard when the sample cell is properly inserted.

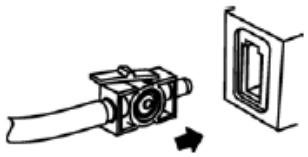


Figure 1

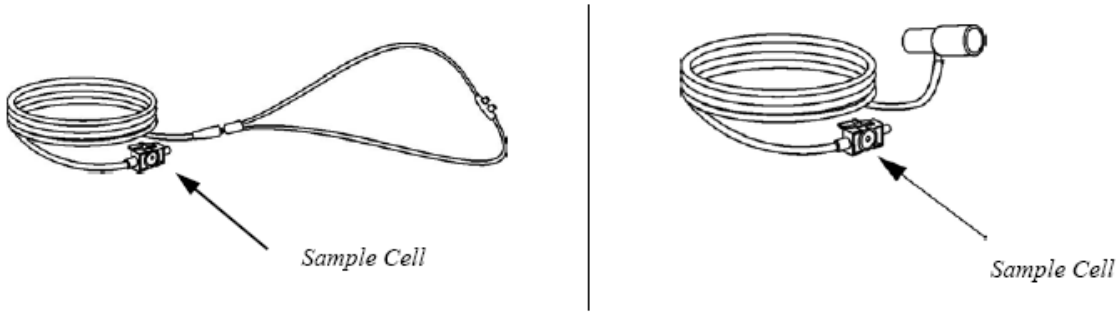


Figure 2

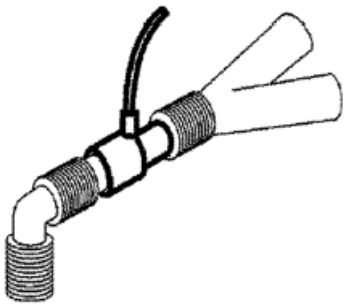
Inserting the sample cell into the receptacle automatically starts the sampling pump.

Removal of the sample cell turns the sample pump off.

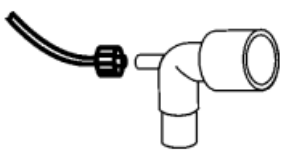
To remove the sampling kit sample cell from the sample cell receptacle, press down on the locking tab and pull the sample cell from the sample cell receptacle.

Note	**If zeroing is required, do this step for details, see Zero Calibration.**

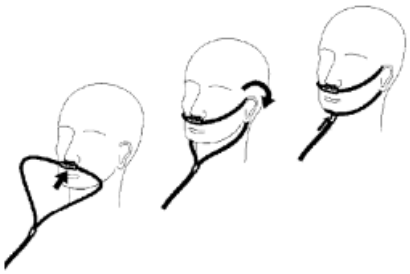
2. For intubated patients requiring an airway adapter: Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.



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



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



For patients prone to mouth breathing use an oral-nasal cannula. For nasal or oral-nasal cannulas with oxygen delivery, place the cannula on the patient as shown. Then attach the oxygen supply tubing to the oxygen delivery system and set the prescribed oxygen flow.

Warning	● **Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.** ● **Make sure that you do not accidentally connect the luer connector of the gas sample line to an infusion link or any other links in the patient vicinity.**

Caution	**Always disconnect the cannula, airway adapter or sample line from the sensor when not in use.**

Removing Exhaust Gases from the System

Warning	● **Connect the gas outlet to the scavenging system when measuring CO2 using the side stream CO2 module.** ● **Anesthetics: When using the side streamCO2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.**

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

7) Zero Calibration

Perform zero calibration when you connect the CAPNOSTAT 5 CO2 sensor to the monitor for the first time or when replacing the airway adapter.

1. Expose the sensor to room air and keep it away from all sources of CO2 including the ventilator, the patient's breath and your own.

2. From the CO2 setup menu, launch the Zero menu and the CO2 waveform displays a "Zeroing" message.

3. When the "Zeroing" message disappears, zero calibration is complete, and monitoring can begin.

Caution	• **For mainstream CO2, connect the sensor to the adapter and wait 2 minutes before zeroing the adapter.** • **For sidestream CO2, connect the gas outlet to the scavenging system when calibrating the CO2 module.** • **A zero calibration is performed the first time a monitor is connected. Then do zeroing each time you install an adapter of a different style, such as changing from reusable to single use, or the system prompts you to perform zeroing. Zero calibration is not necessary when you change the type within the same adapter style.** • **The figures shown are invalidated within 30 seconds of the start of calibration/zero Calibration.**

8) EtCO2 Setting Menu

When you select the EtCO2 numerical or waveform area, the setup menu appears.

Menu	Description	Available Settings
A. Alarm	EtCO2 alarm setup menu	EtCO2, FiCO2, AwRR, ZeroRR
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B. Setup	Setup menu	
B-1. Speed	Set waveform range speed.	6.25 mm/sec 12.5 mm/sec 25.0 mm/sec
B-2. Size	Set waveform size The values that can be selected are the maximum pressure range values shown as waveforms. The size value set in the waveform area is displayed.	40mmHg (5.0 %, kpa) 50mmHg (6.5 %, kpa) 60mmHg (8.0 %, kpa) 80mmHg (10.0 %, kpa) 100mmHg(13.0 %, kpa) 150mmHg(20.0 %, kpa)
B-3. Fill	Choose whether to fill the waveform inside.	On, Off
C. Module setup	EtCO2 module setup menu	
C-1. Current period	This setting is used to set the calculation period of the ETCO2 value. The end-tidal CO2 value is the highest peak CO2 value of all ends of expirations (end of breaths) over the selected time period. If less than two breaths exist in the selected time period, the value is the maximum ETCO2 value for the last two breaths.	1 breath, 10 sec, 20 sec

C-2. Balance gas	This setup mode to setup the gas in the measurement. the type of gas that is mixed with the breathing gas measuring.	Room air N2O Helium
C-3. Operating mode	Sleep and Standby are used to conserve power when the main unit goes to standby. * Sleep stays warmed up to use Capnostat immediately upon exiting Sleep mode * Standby requires a warm-up process and there may be a delay until the system is stably ready.	Measure Sleep Standby
C-4. Barometric Pressure	Set ambient barometric pressure. *Default: 760 mmHg	
C-5. 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. *Default: 35.0 ℃	
C-6. O2 compensation	Use this setting to correct for the compensation of the gas mixture administered to the patient. * Default: 16%	
C-7. Anesthetic agent	Anesthetic agent is ignored when the balance gas is set to helium.	
C-8. Zero	Zero calibration	

Note	**Set the menu only when the EtCO2 module is in monitoring status.** **If it is set when the EtCO2 module is not in a monitoring state such as Startup, Sleep, Standby, or Zeroing, it may not be applied.**

Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before requesting service. If the problem persists, contact your service.

Problem	Solution
$EtCO_2$ measurements too low	1. Check the patient status. 2. Check the sample line and connectors for leakage. 3. Ventilate the room if the environmental CO_2 concentration is too high.
CO2 value is not output, or numerical error.	1. Check the connection between the main unit and the module. 2. Check the module line connection with the filter line or airway. 3. Replace filter line or airway.

PART 14. Invasive Blood Pressure (IBP)

1) Overview

It converts the changes in resistance components, which are caused by the changes in the blood flow in the blood vessels, into electrical signals, and measures the minimum, maximum, and average blood pressures through signal processing.

2) Precautions

The following precautions apply to IBP procedures. See the hospital's clinical guidelines for details.

Warning	● **All parts, except Transducer, should not be conductive. Otherwise discharge energy may induce a shock to operators during cardioversion.** ● **Single-use accessories are not to be reused.** ● **Use of non-approved transducers may compromise this protection.**

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 the 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.**

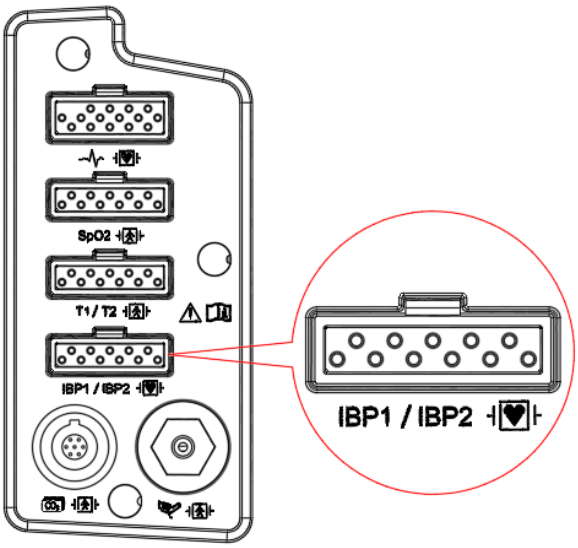
Defibrillator on a Patient

IBP transducers must comply with the requirements of IEC 60601-2-34, must be provided with defibrillator protection, have a frequency response exceeding 15Hz and contribute not more than 2mmHg to the overall measurement error.

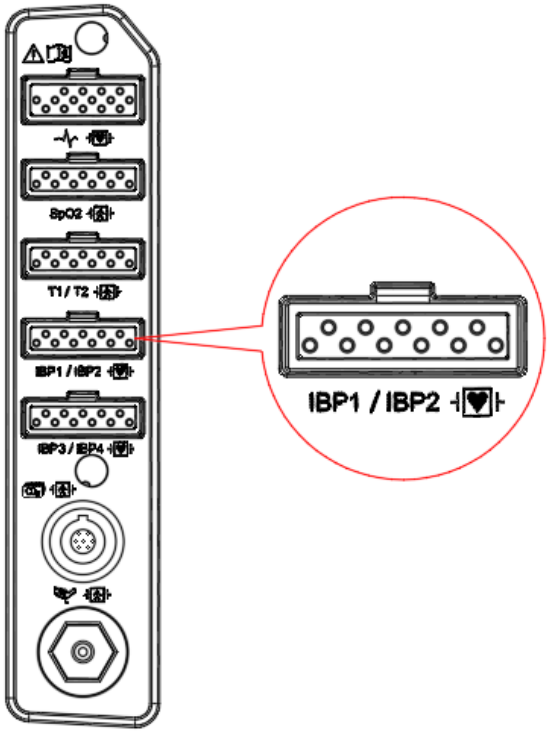
Warning	● **Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cables and lead wires. Do not reuse the single-use entropy electrodes.** ● **Proper placement of defibrillator pads in relation to the electrodes is required to ensure successful defibrillation.**

3) Connector and Measurement Kit

Brio X30



Brio X50, Brio X70



IBP Cable

Model No	Description
152600-042800	Medex/Abbott/Ace medical IBP Cable
152600-042900	Edwards/Baxter IBP Cable
152600-042400	BD/Datex Ohmeda IBP Cab
152600-043400	Medex/ Logical IBP Cable
152600-048300	Ace medical IBP Cable USB Type

IBP Accessory

For IBP accessories other than Ace Medical and Smiths Medical manufacturer, contact the accessory manufacturer.

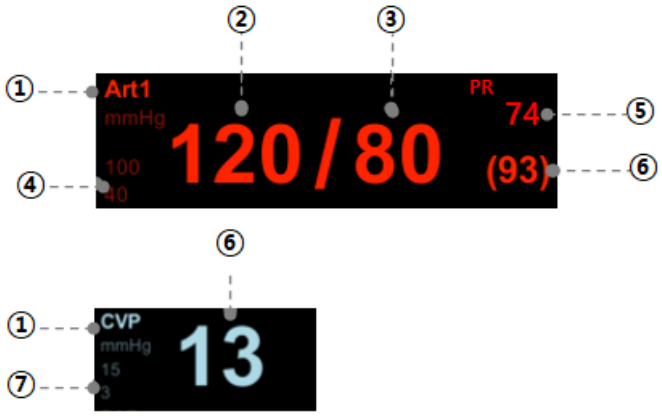
Manufacturer: Ace Medical

Model No	Description
AMK 150	IBP Single Kit
AMK 250	IBP Double Kit
VATG7ADH1	IBP Single Kit (USB Type)
VATG8ADH1	IBP Double Kit (USB Type)
VATG7EDJ1	IBP Single Kit (USB Type)
VATG8EDJ1	IBP Double Kit (USB Type)

Manufacturer: Smiths Medical	
Model No	**Description**
MX9504T	Single Line Monitoring Kit
MX800	Modular transducer mounting plate
MX240	Pole clamp for mounting a transducer plate
MX4810	C-Fusor 1000ml Pressure Infusor complete unit with squeeze bulb and pressure gauge

4) Display

IBP is displayed in two forms as shown in the selected label below. For label description, refer to the IBP measurement parameter label list and description.



① IBP label: Measuring Position

② Systolic blood pressure: Indicates the maximum blood pressure

③ Diastolic blood pressure: Indicates the minimum blood pressure

④ Alarm upper/lower limits for systolic or diastolic blood pressure: When the systolic blood pressure alarm is off, the alarm upper/lower limits for diastolic blood pressure are displayed.

⑤ Pulse rate

⑥ Mean blood pressure: Indicates the average blood pressure

⑦ Alarm upper/lower limit of mean blood pressure

5) Procedures

Zeroing

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. Align the wave line with the data.

5. Zeroing is performed by executing the Zero menu of IBP Setting or the "Zero IBP" menu at the bottom of the screen. When zeroing is complete, a notification window appears.
6. 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.

6) List & Description of IBP Measurement Parameter Label

Parameter window, Scales menu window or Alarm limits pop-up menu appears according to the Labels.

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

Select ''User Defined' for a measuring position not in the listed positions.

Label	Description	Display Value
Art1, Art2	Arterial blood pressure(alternative)	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 atrial pressure	mean
RAP	Right atrial pressure	mean
ICP	Intracranial pressure	mean
User Defined	Other	systolic, diastolic, and mean
UAP	Umbilical arterial pressure	systolic, diastolic, and mean
UVP	Umbilical venous pressure	mean

The table below shows the default waveform size settings by label.

Label	Adult/Pediatric (mmHg)	Neonate (mmHg)
Art1, Art2	160	100

Fem	160	100
UAP	160	100
PAP	60	60
CVP	30	30
RAP	30	30
LAP	30	30
UVP	30	30
ICP	30	30
User Defined	160	100

7) IBP Setting Menu

When you select an IBP numerical or waveform area, the setup menu appears.

Menu	Description	Available settings
A. Alarm	Set IBP alarm.	Sys, Dia, Mean, PR
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B. Setup	Setup menu	
B-1. Label	Set measuring position.	Art1, Art2, Fem, PAP, RAP, LAP, UAP, UVP, CVP, ICP, User Defined
B-2. Speed	Set waveform range speed.	6.25 mm/sec, 12.5 mm/sec, 25.0 mm/sec, 50.0 mm/sec
B-3. Size	Set size of measurement waveform on screen.	30, 60, 80, 100, 160, 200, 300 mmHg (4.0, 8.0, 10.0, 13.0, 21.0, 27.0, 40.0 kpa)
B-4. Auto Size	Set automatic waveform size. Set to the size that best shows the	

	current systolic or mean blood pressure	
B-5. BP Filter	Menu to set filter *Off: 0Hz ~ 40Hz *12Hz: 0Hz ~ 12Hz *20Hz: 0Hz ~ 20Hz (default)	Off / 12Hz / 25Hz
B-6. PR Display	PR Display Setup	Off / On
B-7. Zero	IBP zeroing	
B-8. Latest zeroing time	Last zeroing time information (date, time) display	

8) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before requesting service. If the problem persists, contact your service representative.

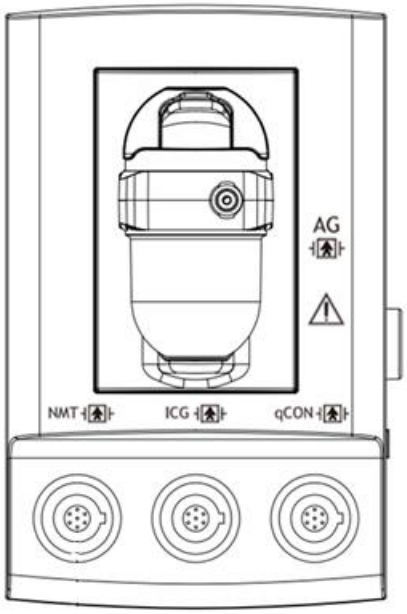
Problem	Solution
"---" is displayed in place of numeric.	1. Check the connection of IBP cable, IBP transducer. 2. Check that the three-way valve is turned to the correct position. 3. Check that the IBP transducer has been zero calibrated. 4. It may be outside the measurement range. Check the measurement conditions. 5. If the blood pressure transducer is damaged, replace it with a new one.
IBP readings seem unstable	1. Make sure there are no air bubbles in the transducer systems. 2. Check that the transducer is properly fixed. 3. Zero the transducer again. 4. Replace the transducer.
Zeroing of IBP channel(s) fails.	1. Ensure that the channels are open to air. 2. Perform zeroing again. Do not sway the IBP transducer and tubing during the calibration. 3. If zeroing still fails, replace the transducer.

PART 15. NMT

1) Overview

The Neuromuscular Transmission (NMT) module measures the intensity of muscle response after electrical stimulation of specialized motor nerves and evaluates the patient's muscle relaxation in the state of nerve root interruption. Place two electrodes on the patient's skin through special nerves. The controllable current source transmits stimulation pulses to two electrodes, and the acceleration of muscle contraction is measured by a triaxial accelerometer.

NMT monitoring is for adults and pediatric patients only.



2) Precautions

Warning	• **Explosion hazard: Do not use NMT modules in areas where fire breaks out or where flammable anesthetics are concentrated.** • **NMT modules are not designed to operate in environments with MRI or other magnetic field generating device. In addition, it cannot be used in environments with shortwave therapy instruments or microwave therapy instruments.** • **Electrode cables, electrodes and connectors shall not be in contact with other conductors or insulators.** • **Do not place the NMT module pacing electrodes between the surgical site and the electrodes of the ESU to reduce the risk of burns during high frequency surgery.** • **Connecting the patient to the NMT module and the high frequency surgical machine (e.g. electrical scalpel) at the same time may cause burns to the electrode attachment position of the NMT module and damage to the patient monitor.** • **The NMT module, like other muscle relaxation measuring instruments, must be connected to an electrical stimulation electrode that can accommodate a maximum voltage of 300V and a current of 60mA. The minimum contact area of the electrode is 1.8cm^2.** • **Electrical stimulation induces painless stimulation, so adjust the intensity of the stimulation according to the patient's pain relief level.** • **Patients wearing implanted electronic devices (e.g. pacemakers) should not be subjected to electrical stimulation unless they have a professional medical opinion.** • **When using the patient monitor, be sure to check the results before using it for patients with cardiac pacemakers. In the case of your patient's surgery, you need to prepare as much as possible.** • **Do not use NMT module near short wave therapy device.** • **Make sure that other devices or tools are connected to the electrodes before use.** • **Sensors and electrodes should only be used on clean, intact skin.**

- **Make sure that the screen and cable (electrodes and sensors) are not damaged before using the patient monitor. NEVER USE THE PATIENT MONITOR IF DEFECTS OR DAMAGES ARE FOUND.**
- **Please handle carefully so that the parts of the patient monitor and monitor itself do not fall off.**
- **Only one patient should use the NMT module at a time for a specified period. Be sure to clean it before using it on other patients.**
- **NMT modules can be used temporarily or continuously during surgery. The number of hours per patient should not exceed 24 hours.**
- **After installing the sensor in the patient, check the installation area at least every 2-3 hours to prevent pressure or excessive damage to the patient's skin contact surface. If skin condition changes, change the attached sensor.**
- **To prevent electromagnetic wave interference, install the NMT module at a distance of at least 30cm from the radio frequency emission device.**
- **To prevent interference or malfunction of NMT modules, do not place them very close to other devices or overlap them. Be sure to use the NMT module after confirming that other devices are functioning properly if necessary.**
- **When using products other than manufacturer's genuine accessories, cables and converters, the electromagnetic wave resistance of emitted electromagnetic waves and NMT modules may change and cause problems with the use of the patient monitor.**
- **Cybersecurity risks may increase when using products other than the manufacturer's genuine cables.**
- **NMT monitoring is intended as an adjunct in patient assessment and must be used in conjunction with observation of clinical signs and symptoms.**
- **NMT stimulation can be painful to a non-sedated patient. It is recommended not to stimulate before the patient is adequately sedated.**
- **Use only electrodes suitable for nerve stimulation deemed appropriate by the attending physician.**

	• **Pay special attention to current densities exceeding 2mA r.m.s/cm2 for any electrodes.**

Caution	• **The NMT stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, especially the carotid sinus, or from electrodes placed on the chest and the upper back or cross over the heart.** • **Do not allow NMT modules, monitor components and accessories to enter the steam sterilizer.** • **Do not allow the patient monitor or its parts to come into contact with or be soaked in liquid. Do not wash it with liquid.** • **NMT modules and components are not suitable for gas sterilization, laser sterilization (e.g., gamma sterilization), boiling water sterilization, steam sterilization or heat sterilization.** • **NMT module users should be careful not to contact other electronic products when using the patient monitor.** • **After measuring the suitability and intensity of stimuli applicable to the patient, the doctor performs NMT electrical stimulation.** • **Never touch electrodes during electrical stimulation. Electrodes are compatible with electrical stimulators only (CE Marked Products)** • **Do not use products other than cables or accessories provided by the manufacturer.** • **Noise may occur when using unipolar cutter or other cutter and NMT module at the same time, resulting in incorrect results or failure to measure.** • **To prevent static electricity, use NMT modules in an environment where static electricity can be controlled.** • **NMT modules are designed to transmit electrical stimuli to patients. Therefore, electrical stimulation of NMT can be detected in electrophysiological measuring devices (EEG, ECG). This is a temporary**

	interference and may vary depending on the peripheral configuration.

3) Stimulation Mode

The NMT module provides the following stimulation modes. Some stimulus modes require minimum neurophysiological recovery time and cannot initiate the same stimulus during this recovery stage.

Train-Of-Four (TOF)

In most cases, TOF mode is recommended.

In TOF mode, four stimulus pulses are generated at 0.5 second intervals. Each stimulus contracts the muscles. The fade-in of individual responses to each single stimulus provides the basis for evaluation. The reaction is measured after each stimulus and the deviation between the first and fourth measurements is calculated as a percentage (T4/T1, %). As relaxation deepens, TOF% decreases until the fourth reaction disappears and the TOF% is not calculated. If the response to the first stimulus (T1) is low, TOF% is not available. If so, the degree of nerve root block can be deduced from the number of responses or TOFs. The fewer responses detected, the deeper the relaxation.

When you measure a reference value, a yellow horizontal line is displayed with a bar chart to show the T4/Tcal ratio.

The minimum neurophysiological recovery time in TOF mode is 12 seconds. TOF cannot be measured during this time.

Single Twitch (ST)

The single switch mode (ST) is the simplest stimulus to induce single muscle contraction. Since the patient's motor response is not measured, you must evaluate it directly.

Post-Tetanic Count (PTC)

When neuromuscular block deepens, different parameters are needed to measure the response. At first, when the response to the fourth TOF stimulation pulse disappears or the first twitch is very weak, the TOF% is not available and only the number of detected counts can be observed. When stimulation pulses no longer give any stimulation response, you do not get the TOF count either. PTC is used to confirm deep nerve root blocking when TOF stimulation is unresponsive. PTC

stimulation consists of 50 Hz tonic stimulation (Tetanus), 3 seconds stop, and 10 single twitch stimulation. At the end of the stimulus (18 seconds), the number of muscle reactions detected are displayed on the screen. The less the response, the more relaxed it becomes.

PTC mode must have a pause time of 3 minutes after use. In general, remember that PTC stimulation can only be used when there is no response to ST stimulation and TOF.

Double Burst Stimulation (DBS)

Double Burst Stimulation (DBS) allows better visual observation of response fading.

DBS stimulation consists of two sets of stimulation at 50 Hz at 750 mm intervals. DBS supports two types of stimuli. Depending on the selected DBS, two or three sets of stimuli (stimulation time: 200 μs).

When DBS stimulation is performed, the number of responses measured, and the relative amplitude of each response are displayed in a bar chart. The percentage of the second response amplitude relative to the first amplitude is displayed on the screen.

This module supports DBS 3.2 and DBS 3.3.

■ In DBS 3.2 mode, the first pulse consists of three consecutive pulses and the second pulse consists of two consecutive pulses.

■ In DBS 3.3 mode, both busts consist of three continuous pulses.

The minimum neurophysiological recovery time in DBS mode is 20 seconds. DBS cannot be measured during this time.

Note	**DBS stimulation is not recommended for monitoring eyebrow muscle.**

Tetanus (TET)

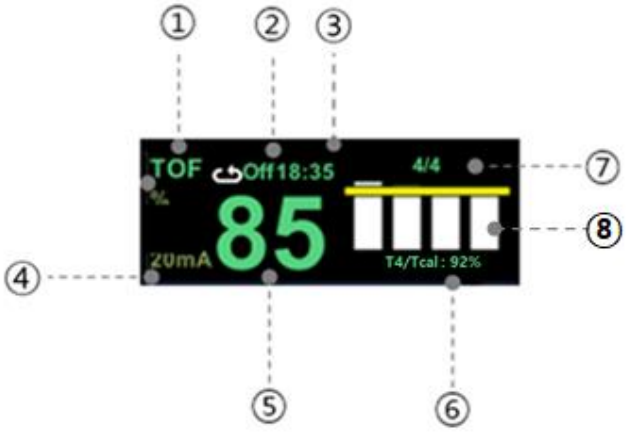
TETANUS stimulates the patient at 50 Hz for 5 seconds. Since the patient's motor response is not measured, it is necessary for you to evaluate it for yourself.

Minimum neurophysiological recovery time in DBS mode is 3 minutes. TET cannot be measured

during this time.

Note	**TET stimulation is not recommended for eyebrow muscle.**

4) NMT Parameters



① Stimulation mode and unit

② Measurement period or remaining measurement time: Before measurement starts, the set measurement period is displayed. When the measurement is complete, the remaining time until the next measurement is displayed.

③ Measurement completion time

④ Stimulation current selected

⑤ Tx/T1 ratio: Deviation of 1st and 4th measurements in TOF mode (T4/T1)

Deviation of first measurement and second measurement in DBS mode (T2/T1)

⑥ T4/Tcal ratio: Deviation of the calibration value and the fourth measured value. It is displayed only in case of TOF.

⑦ Number of muscle responses: number of measured muscle responses / number of stimulation

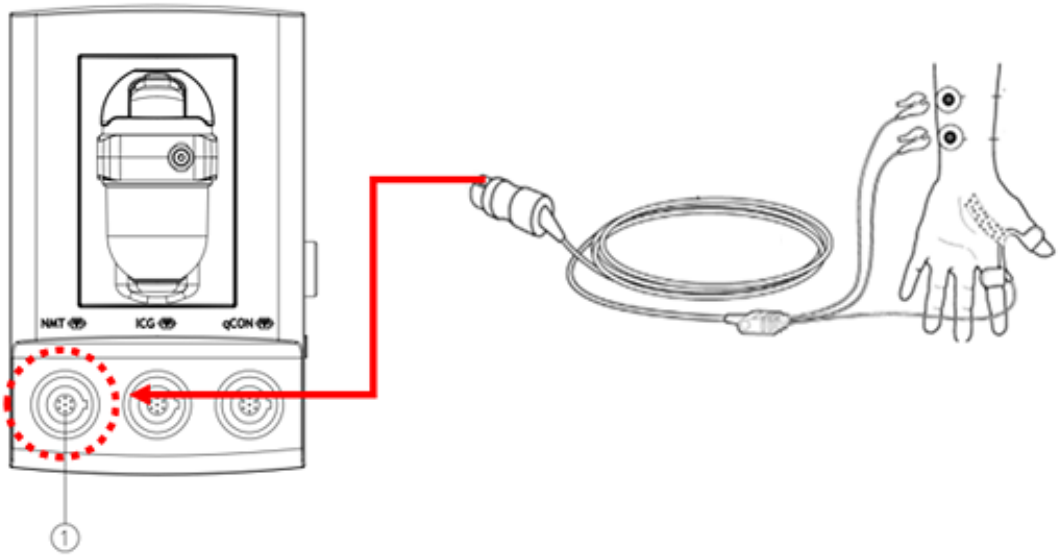
⑧ Bar Graph: A graph of the amplitude of response to a stimulus. In case of TOF, the calibration value is displayed as a horizontal yellow line (100%).

The following table lists the NMT parameters in different stimulation modes.

Stimulation Mode	Parameter Label	Unit	Number of Bars
TOF	TOF	%	4
	TOF-count	/	4
ST	ST		
PTC	PTC		
DBS	DBS	%	2
	DBS count	/	2

5) Preparing NMT Monitoring

Connect the patient to the NMT device.



6) Preparing the Skin

Good electrode-skin contact is important for good signal quality. Before attaching electrodes, clean oil or dust and do not place electrodes on excessive body hair or lesions. Inadequate skin cleaning may increase skin impedance and interrupt irritation.

To properly follow skin preparation, follow the steps below.

1) Select a complete skin area without any kind of lesion.

2) Shave your hair from the skin of the selected area.

3) Rub the skin surface gently and remove keratin.

4) Wash the area thoroughly with a soap and water solution that are gentle to the skin.

5) Dry the skin completely before applying electrodes.

7) Configuring Electrodes and Sensors

Accelerated measurements of ulnar nerve stimulation and adductor muscles in the wrist are preferred for routine monitoring. When monitoring nerve root transmission, round surface electrodes with snap connections are required. Electrodes are compatible with the stimulation values of the common muscle relaxation measuring instrument, which can withstand up to 300V and up to 60mA current. Electrode adhesion area shall be at least 1.8cm². To ensure stable signal quality, only use electrodes marked with CE.

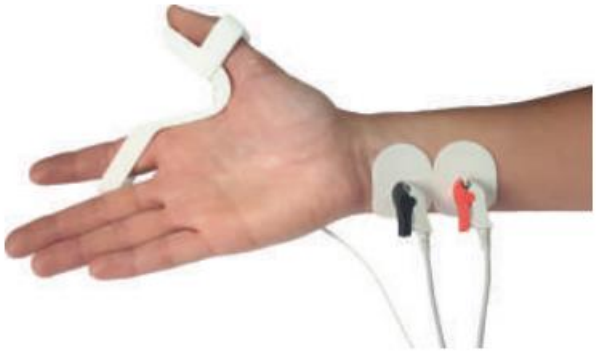
When installing a sensor, do not pin the sensor or sensor tongs to the sensor cable. The cable must be free to move the sensor according to muscle contraction. Be careful not to cause pressure or excessive irritation by the sensor installed on the patient and damage the patient.

Before applying NMT electrodes and sensors, make sure your thumb can move freely. Follow the steps below to configure electrodes and sensors.

1) Attach electrodes to the ulnar nerve near the wrist inside the arm.

2) For a single electrode, connect the electrode at intervals of 2~5cm.

3) Attach the sensor tongs to the patient's hand shape as much as possible and touch the bones at the tip of the thumb.



Position of the sensor attached to the patient's hand

Fixed with band-aid

Pediatric thumb sensor attachment locations

Thumb sensor attachment location for pediatric patients with small hand

Warning	● **Do not let the electrodes touch one another during configuration.** ● **Attach the electrodes to the appropriate positions to stimulate nerves, not muscles.** ● **Incorrect configuration of electrodes stimulates the wrong nerves and causes the wrong muscle reaction.** ● **If various nerves are stimulated, the measured response may be affected by other muscle activities.** ● **When the stimulating electrode is placed very close to the palm of the hand, the stimulating pulse stimulates the muscles directly.** ● **An electric current that is too strong can over irritate the muscles.**

	• If the patient is moved or touched during the measurement, incorrect results may occur. • Do not allow NMT cables to touch external heart rate adjusters or catheter wires. • To prevent unintended electric shock, always make sure that NMT stimulation is stopped before touching the electrode. • Handle the NMT sensor with care and do impose impact on the sensor. • After changing the patient's position, check the NMT sensor application area to make sure that the sensor is still applied correctly and that the thumb can move freely. • Do not apply electrodes to the patient in areas of obvious inflammation or injury. • Never touch the electrodes unless the stimulation has been stopped • Patients with nerve damage or other neuromuscular problems may not respond properly to stimulation. The NMT measurement may show unusual patterns when monitoring muscle paralysis in these patients.

Warning	• The correct position of the electrodes is important. Small displacements can cause significant changes in the requirements of stimulating current. Electrodes must also be positioned in a way that prevents direct muscle irritation. • Electrodes must be properly attached to the patient's skin. It has been shown that applying a little pressure to the electrodes can significantly improve the stimulation. Therefore, it is advisable to tape the electrodes.

Note	• Ensure that the sensor remains in the initial installation position while the NMT module is running. Also, do not allow the patient to move his or her arms, legs, or head during muscle relaxation monitoring. • If the thumb sensor is difficult to fix in your hand, use a medical bandage to fix it in the correct position. When monitoring the thumb, improve the

	movement of the thumb and fix the index finger, middle finger and ring finger with a medical bandage to obtain more accurate measurements. ● **When using thumb sensors, make sure that the sensor clip or the hook between the index finger does not compress the finger or cause excessive irritation. You can secure scissors and rings with adhesive plaster (refer to the location image of adhesive plaster).** ● **If the sensor is used for a certain period, light marks may appear on the skin attached to the sensor, or the skin may turn red. This is caused by the direct contact between the skin and the sensor, and the light marks disappear over time, without leaving a scar.**

8) TOF Calibration

The size of the sensor signal varies from patient to patient. If the patient is anesthetized but does not reach muscle relaxation, the patient's motor response to TOF electrical stimulation can be saved in calibration mode. This calibration value more accurately determines the degree of muscle recovery after muscle relaxation in patients and enables the actual measurement of polarizing muscle relaxant effect. The NMT module performs TOF stimulation to calculate the mean deviation of four near reactions, which is displayed in Tcal. The mean deviation value is used as T4/Tcal and is displayed during the next TOF stimulation.
The pause time between reference stimuli is 12 seconds.

Warning	**• To prevent spontaneous muscle contraction and tension from interfering with the reference search, correct the muscle relaxant before administration (but after general anesthesia-induced sleep).**

9) TOF Calibration

To save the NMT measurement calibration, perform the following

1) Select the NMT numeric area and enter the NMT menu.

2) Select the Settings tab.

3) Confirm stimulation current setting.

3) Select TOF mode in Measure tab and press Calibration menu.
4) Check the TOF measurement value. If it is measured incorrectly, re-calibrate.

Note	● **Nerve irritation may be painful, so anesthetize the patient before measuring.** ● **If you change the stimulation current after saving the calibration, the saved calibration data is invalid, so you need to save the calibration again.**

10) Clearing TOF Calibration

To clear the NMT measurement calibration, perform the following

1) Select the NMT numeric area and enter the NMT menu.

2) Run the Clear Calibration menu on the NMT menu screen.

Note	**The calibration value is automatically deleted when the patient is discharged, or you power off and turn on the patient monitor.**

11) Terminating NMT Measurement

To stop NMT measurements in progress, select one of the following methods.

■ Press the Stop menu on the monitoring screen. (ex. PTC case 

)

■ Press the Stop menu button at the bottom of the NMT menu.

12) Making Changes in NMT Measurement

To select NMT measurement mode, perform the following:

1) Select the NMT numeric area and enter the NMT menu.

2) Select the Measurement tab.

3) Select the desired stimulation mode.

4) When selecting TOF mode, ST mode, and DBS mode, select the measurement period and set the time interval between the two measurements.

13) Making Changes in Stimulation Current

Verify that the desired stimulation current is selected before calibration and NMT measurements. To set the stimulation current, perform the following:

1) Select the NMT numeric area and enter the NMT menu.

2) Select the Settings tab.

3) Set the stimulation current.

◆ The initial value is set to 50 mA. The maximum current required for maximum stimulation is 50 mA in adults and 30 mA in pediatric patients. The tolerable stimulation value for eyebrow muscle monitoring is 30 mA. The stimulus value can be adjusted in special cases. You should also consider the possibility of inappropriate stimulation and potential risks to the patient.

Note	**The stimulation current is adjusted in units of 10 mA.**

14) NMT Setting Menu

When you select the NMT numerical area, the setting menu appears.

Menu	Description	Available settings
A Measure	Set NMT stimulation mode.	

	Select one of TOF, DBS, ST, TET, PTC.	
A-1 TOF	Set TOF mode.	On, Off
A-2 TOF Interval	Set the repeated measurement cycle.	Manual, 15sec, 30sec, 1min, 2min, 5min, 15min
A-3 DBS	Select DBS mode. Displays the selected DBS mode.	On, Off
A-4 DBS Interval	Set the repeated measurement cycle.	Manual, 15sec, 30sec, 1min, 2min, 5min, 15min
A-5 ST	Set ST mode.	On, Off
A-6 ST Interval	Set the repeated measurement cycle.	Manual, 1 sec, 10 sec
A-7 TET	Set TET mode.	On, Off
A-8 PTC	Set PTC mode.	On, Off
A-9 Start/Stop All (stimulation mode)	Start and stop the selected stimulus mode measurement. When Stop All is set, NMT measurement is stopped and repeated measurement is canceled.	
A-10 Calibration	Perform TOF calibration. After the TOF measurement, the measured value is saved as a correction value.	
A-11 Clear Calibration	Delete calibration value.	
B Setup	Setup menu	
B-1 Stimulation Current	Set stimulus intensity.	20,30,40,50,60 mA
B-2 Stimulation Beep Volume	Set stimulus volume size.	Off, 10~100% (in 10% units)
B-3 TOF Ratio T4/T2	Set the TOF Ratio calculation method.	On, Off

	If it is On, if T2 is greater than T1, the TOF Ratio is calculated using T2 instead of T1.	
B-4 DBS Mode	Set DBS mode. *DBS 3.3: Consists of two occurrences of 0.2 msec impulse x 3 at 750 ms intervals *DBS 3.2: Consists of two occurrences of 0.2 msec impulse x 2 at 750 ms intervals	DBS 3.3, DBS 3.2
B-5 TET Frequency	Set TET, PTC Frequency.	50Hz, 100Hz

15) Troubleshooting

This section lists possible problems. If you encounter any problems using the monitor or accessory, check the following table before requesting service. Contact your service representative if the problem persists.

Problem	Solution
Module is connected but a Module Off message is displayed.	Please check the module connection status. Please reconnect the module cable.
Sensor is connected but Cable Off message is displayed.	Please check the status of the cable and sensor clip. Please reconnect the cable.

PART 16. Anesthetic Gas (AG)

1) Overview

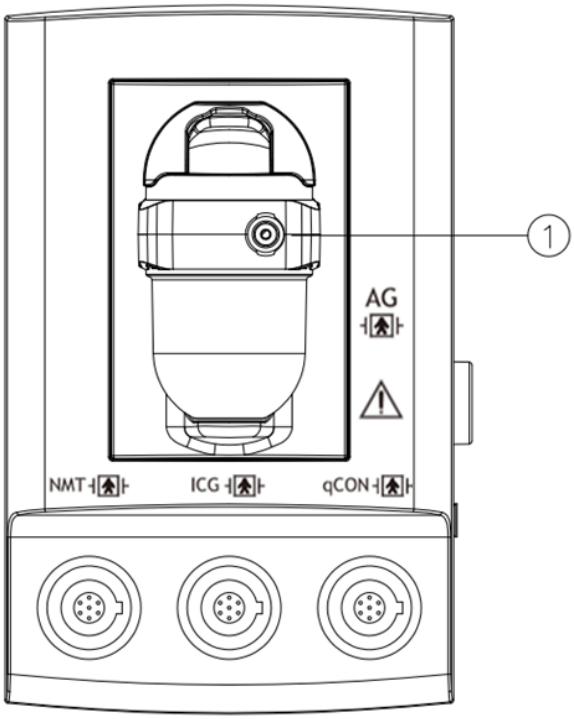
The anesthetic gas (AG) module is connected to the intubated patient's airway or collects gas from designated accessories to measure the patient's anesthesia and respiratory gas. It also integrates the functions of the O2 module.

The AG module uses infrared (IR) absorption measurements to determine the concentration of a particular gas. Each gas has its own absorption characteristics. The gas is transported through the sample unit, and the optical IR filter selects IR light in a specific band through the gas. Multiple IR filters exist for multiple gas measurements. At a given volume, the higher the gas concentration, the more IR light it absorbs. This means that if the IR absorption gas concentration is high, the IR light transmittance decreases. The concentration of gas present can be calculated by measuring the amount of IR light transmitted through the gas.

Oxygen does not absorb infrared rays like other respiratory gases, so it is measured by irregular distribution characteristics. Inside the O2 sensor, there are two nitrogen-filled glass balls mounted on a strong, rare metal band suspension. This component is suspended from a symmetric non-uniform magnetic field. In the presence of paramagnetic oxygen, the glass sphere is pushed farther away from the strongest part of the magnetic field.

The torque intensity acting on the suspension is proportional to the oxygen concentration. The oxygen concentration is calculated from the torque strength.

AG monitoring is for adults, pediatric patients, and neonates.



Note	**The AG module is configured with automatic barometric pressure compensation.**

Warning	● **Please measure in a well-ventilated environment.** ● **EtCO2 values measured by AG modules may differ from those measured by blood gas.** ● **The emptying interval of the adult/pediatric watertrap is 26 hours @ 120 ml/min, sample gas of 37 °C, room temperature of 23 °C, and relative humidity is 100%.** ● **The emptying interval of the neonatal watertrap is 35 hours @ 90 ml/min, sample gas of 37 °C, room temperature of 23 °C, and 100% RH.**

Caution	● **To prevent explosion, do not use flammable anesthetics such as ether or cyclopropane in the patient monitor.** ● **High frequency electrosurgical devices may increase the risk of skin burns. Do not use antistatic or inverted respiratory tubes.**

	● **Remove all tubes from the patient's neck to avoid strangulation.**

Note	**The AG module automatically suppresses physiological alarms until a breathing wave is detected.** **Make sure the patient is properly connected when monitoring with the AG module.**

2) AG Measurement Restriction

The following factors may affect measurement accuracy:

- Sample gas leakage or internal emission
- Mechanical impact
- Periodic pressure of up to 10 kPa (100 cmH2O)
- Other interference factors

Note	**Accuracy is affected by the breath rate and I: E. The EtCO2 accuracy is within specification for breath rate ≤ 60 rpm and I/E ratio ≤ 1:1, or breath rate ≤ 30 rpm and I/E ratio ≤ 2:1.**

3) AG Display

The AG module can send waveforms and numbers for all measured anesthetic gases to be displayed on the monitor, including:

① EtCO2 unit and alarm high/low limit value

② End-tidal carbon dioxide concentration value

③ Intake carbon dioxide concentration value

④ Airway respiration rate

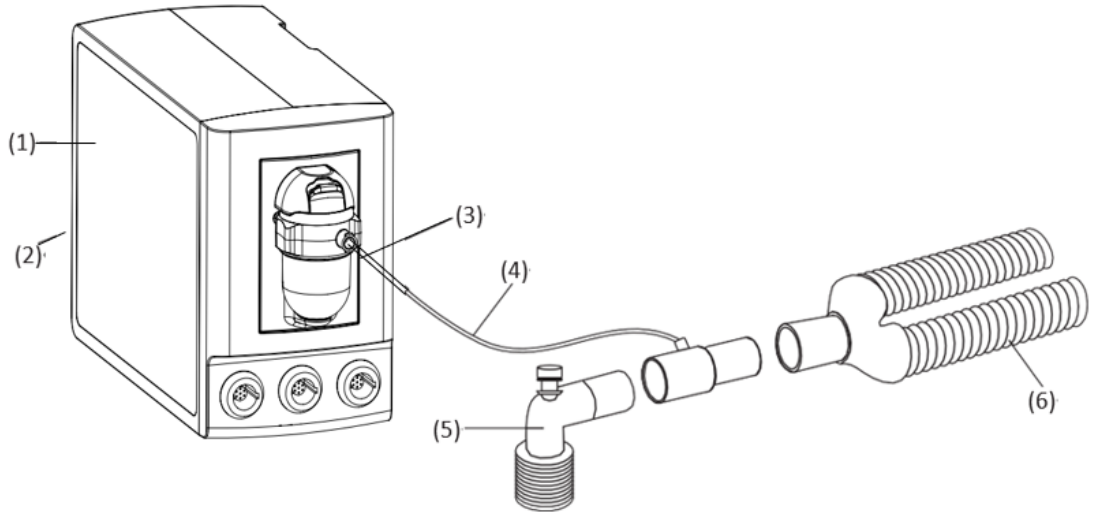
⑤ Unit of AA1

⑥ End tidal (Et) and fraction of inspired (Fi) numerics for N2O, O2, AA1, AA2 and MAC value

⑦ Gas waveform

AA (Anesthetic Agent) indicates Des (desflurane), Iso (isoflurane), Enf (enflurane), Sev (sevflurane), or Hal (halothane).

4) Connecting a Patient to AG Device



(1) AG module

(2) Gas outlet

(3) Watertrap

(4) Gas sample line

(5) Airway adapter (connected to patient)

(6) Y-piece (connected to the anesthesia machine)

Accessory

Water trap

Number	Part	Picture	Dimensions	Weight
1	100-000080-00 / 115-058733-00		33mm(W) X 47mm(H) X 37mm(D)	10g
2	100-000081-00 / 115-058734-00		33mm(W) X 47mm(H) X 37mm(D)	10g

Sampling line

Number	Part	Picture	Dimensions	Weight
1	60-15300-00 / 115-043018-00		Neonate, 2.5m	13g
2	60-15200-00 / 115-043017-00		Adult, Pediatric, 2.5m	17g

Dryline Airway adapter

Number	Part	Picture	Description	Weight

1	60-14100-00 / 115-043020-00		Dryline airway adapter, straight	12g
2	60-14200-00 / 115-043021-00		Dryline airway adapter, elbow	15g

5) Preparing AG Monitoring

To prepare AG monitoring, perform the following:

1) Select the appropriate gas sample line and watertrap according to the patient's range.

2) Connect the watertrap to the AG module and connect the gas sample line to the watertrap.

3) Connect both ends of the gas sample line to the patient with an airway adapter.

4) Use an exhaust pipe to connect the gas outlet to the cleaning system or the patient's respiratory circuit.

5) Make sure they are all firmly connected.

Warning	● **When using the AG module, connect the gas outlet to the scavenging system or the patient respiration circuit when in use with the anesthesia machine.** ● **Please make sure that all connections are firm. Leakage of the system may cause ambient air to mix with the patient's gas and deteriorate the reading.** ● **Always check that the airway adapter is connected and operating properly before installing it in the patient.** ● **If you squeeze or bend the gas sample line during AG measurement, the reading may be incorrect or missing.**

	• **The disposable airway adapters are designed for single use only and cannot be reused. Reuse may cause inaccurate readings, erratic readings, or no readings at all. Also, reuse may cause an increased risk of cross contamination among patients.** • **The reusable airway adapters can be reused but to avoid infection, they shall be reused only after it is sterilized.**

Caution	• **Position the airway adapter so that the connection to the gas sample line is facing up. This prevents the condensed droplets from entering the gas sample line and causing obstruction.** • **The watertrap prevents the condensed droplets from collecting in the sample line and flowing into the module. Empty it when it is halfway full to prevent airway obstruction.** • **The watertrap has filters that prevent bacteria, water, and secretions from entering the module. If used for a prolonged time, dust or other substances can degrade the filter and block the airway. In this case, replace the watertrap. It is recommended changing the water bottle once a month.**

Note	• **Do not apply adult watertrap to neonates. Otherwise, the baby may be injured.** • **To extend the life of the watertrap and module, if AG monitoring is not required, separate the watertrap from the module and set the action mode to standby mode.**

6) MAC value

Minimum alveolar concentration (MAC) is the minimum concentration of drugs in the alveoli. A basic indicator of the depth of anesthesia. Standard ISO 80601-2-55 defines MAC as follows: The alveolar concentration of inhaled anesthetics is no other anesthetic, and 50% of patients in

equilibrium respond to standard surgical stimuli and become unable to move.

The MAC values are as follows.

Agent	Des	Iso	Enf	Sev	Hal	N_2O
1 MAC	6%	1.15%	1.7%	2.1%	0.77%	105%*

* 1 MAC nitrous oxide can only be reached in high-pressure chambers.

Note	• **The MAC values shown in the table above are published by the US Food and Drug Administration for healthy 40-year-old adult male patients.** • **In practical application, MAC values may be affected by age, weight, and other factors.**

The formula for calculating MAC values is as follows.

$$MAC = \sum_{i=0}^{N-1} \frac{EtAgent}{AgentVol_{age}i}$$

Where N is the number of all agents (including N2O) that the AG module can measure. EtAgenti is the concentration of each agent, and AgentVolagei is the concentration of each agent at 1 MAC with age correction. The formula for calculating age correction of 1 MAC is:.

$$MAC_{age} = MAC_{40} \times 10^{(-0.00269 \times (age-40))}$$

For example, the Des concentration at 1 MAC of a 60-year old patient is.

$$6\% \times 10^{(-0.00269 \times (60-40))} = 6\% \times 0.88$$

The AG module measures 4% of Des, 05% of Hal and 50% of N2O in the patient's end-tidal gas.

$$MAC = \frac{4.0\%}{6\% \times 0.88} + \frac{0.5\%}{0.77\% \times 0.88} + \frac{50\%}{105\% \times 0.88} = 2.04$$

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

7) AG Setting Menu

When you select the AG numerical or waveform area, the setting menu appears.

Menu	Description	Available settings
A. Alarm	Anesthetic Gas (AG) alarm settings menu	EtCO2, FiCO2, AwRR, ZeroRR, EtN2O, FiN2O, EtO2, FiO2, EtAA1, EtAA1, ETAA2, EtAA2
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	
B Setup	Setup menu	
B-1. Speed	Set waveform range speed.	6.25mm/s, 12.5mm/s, 25mm/s
B-2. Size	Set waveform size. The values that can be selected are the maximum pressure range values shown as waveforms. The size value set in the waveform area is displayed.	40, 50, 60, 80, 100, 150, 300, 500, 800, 1000 mmHg (5.0, 6.5, 8.0, 10.0, 13.0, 20.0 40.0, 65.0, 100.0, 130.0 % , kpa)
B-3 Wave Fill	Select whether to fill in the waveform and draw it.	On / Off
B-4 Waveform Type	Set gas waveform to display.	CO2 / O2 / N2O / AG1 / AG2
B-5 O2 Display	Set whether to mark O2.	On / Off
B-6 Operating mode	Set AG Module Mode. When it is not used, set Standby mode. If used, set Measurement mode.	Measure/ Standby
B-7 Current Flow Rate	Current flow rate display (ml/sec)	

	Used for Anesthetic Gas (AG) leak testing.	

8) Making Changes in Anesthetic

If the anesthetic used in the patient changes, the AG module detects mixed anesthetic gas during the switching between the two anesthetics. The time required to complete the replacement depends on the anesthetic type (low or high flow) and the anesthetic characteristics (dynamic). The monitor does not display a prompt message between the two anesthetics, and the displayed MAC value may be incorrect.

The AG module can automatically identify two anesthetics. If the proportion of primary and secondary anesthetics in the mixture changes, the AG module can distinguish them according to their contribution to MAC values. Then the primary and secondary anesthetics is replaced for exhibition.

9) Performing AG Leakage Test

AG leakage test is required every time before AG measurement. To perform AG leakage test, follow the steps below.

1. Insert AG module into module rack.

2. Wait about 1 minute for AG module to be preheated. Please completely block the gas injection inlet of the AG module. Then, an alarm message saying, "**Airway Occluded**" appears on the screen.

3. Close the gas inlet for 1 minute.

4. Check the current flow rate by pressing the AG numerical area and select the Setup tab of the AG setting menu.

6. Check that the current flow rate is less than 10 ml/min and ensure that the "**Airway Occluded**" alarm message does not go away.

This indicates that the module is not leaking. If the alarm message disappears or the flow rate is

more than 10ml/min, the module may leak. Please run the leak test again. If you encounter any problems, contact your service representative for help.

10) AG Module Calibration

Calibrate the AG module every year or automatically if the measurement is out of specification. Contact your service representative when modifying the AG module.

Caution	● **Connect the gas outlet to the scavenging system when calibrating the AG module.** ● **The figures shown are invalidated within 30 seconds of the start of calibration/zero calibration.**

11) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before requesting service. If the problem persists, contact your service.

Problem	Solution
Airway blocked	**The Airway Occluded message appears. In this case, check the following until the message disappears**. 1) Check the airway adapter for obstruction and replace it if necessary. 2) Check the sample line for blockages or kinks and replace it if necessary. 3) Check the watertrap for water or blockages. Empty the watertrap or replace it if necessary. 4) Check the gas outlet and exhaust tube for blockages.

PART 17. ICG

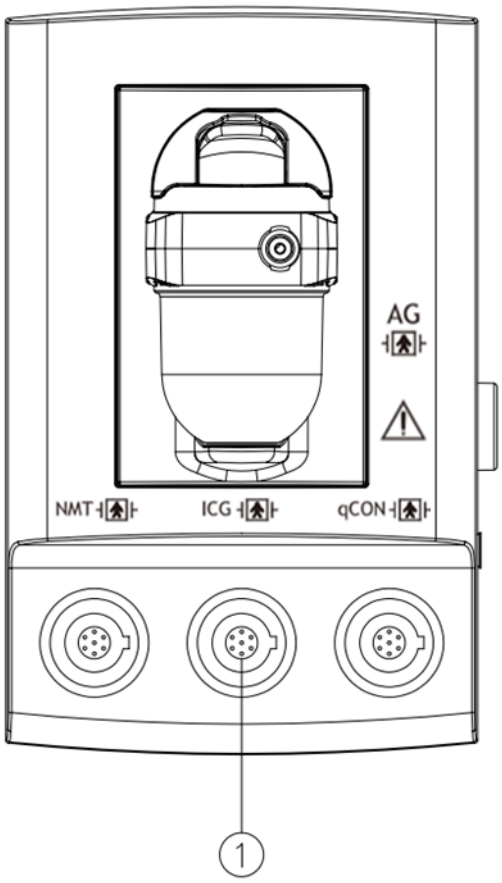
1) Overview

Non-invasive cardiac output (Impedance Cardiograph/Cardiac Output) measurement uses the chest impedance signal to calculate key parameters related to cardiac output non-invasively. The technique is used to guide medical experts to determine a patient's cardiac output through chest blood flow monitoring.

Cardiac output monitoring provides valuable information for setting up treatment plans and applying targeted therapy as soon as possible.

ICG monitoring aims for adults, pediatric patients, and neonates.

- Cardiac output (CO): The amount of blood pumped from the heart through the circulatory system per minute
- Stroke volume (SV): the amount of blood released from the left ventricle of the heart by a single contraction
- Waveform: Graphic curve of impedance. The scale is automatically updated every second.
- Signal Quality Index (SQI): The quality of the collected signal



2) Precautions

Caution	● **Joint Measurement results may be incorrect during electrical surgery.** ● **Please use only the accessories specified in this manual. Do not allow accessories to touch the conductive parts.** ● **ICG monitoring is not intended for pediatric patients and neonates.** ● **The patient monitor requires special EMC-related precautions, such as mobile phones and other nearby devices.**

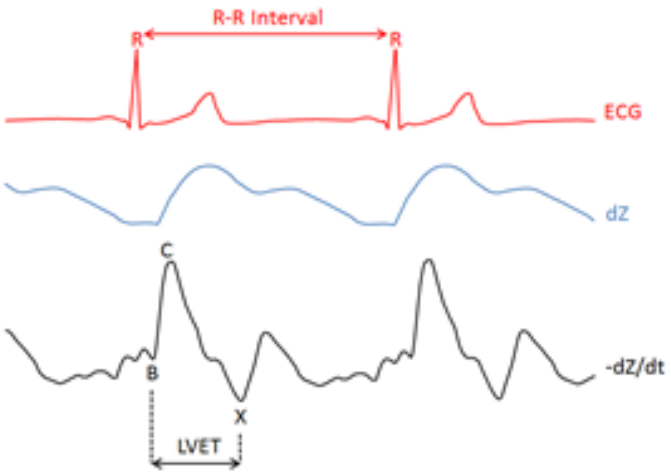
Warning	● **Only medical professionals can use this module.** ● **The patient monitor may cause radio interference or interfere with the operation of nearby devices. It may be necessary to take mitigation measures, such as redirecting, relocating, or shielding the patient monitor.**

	• **Do not use this module adjacent to or overlapping with other devices. If you need to use adjacent or overlapping modules, observe the modules to ensure proper operation in the configuration you are using.** • **Do not place the patient monitor near metal objects that may cause interference or devices that can produce radio frequency interference.** • **To insulate the patient monitor from the network, the power supply must be separated.**

3) Calculating CO

The electrical impedance signal in the thoracic cavity indicates a change in space. The first derivative of this impedance signal is differentiated by displaying the inflection point. The most important characteristic points of impedance differential waveforms are B, C, and X. All of this is related to a clear physiological event in the systolic part of the heart cycle.

For all heartbeats, the CO algorithm detects these characteristic points and uses amplitude to calculate the CO index that represents the blood flow through this space.



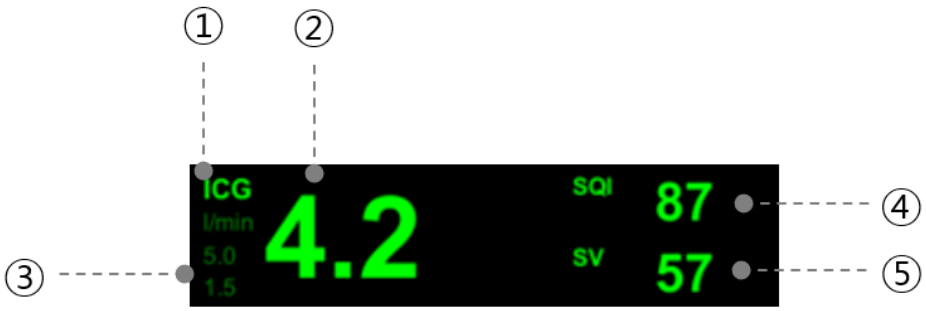
B: Open aortic plate (minimum point before point C)

C: left ventricular maximal blood flow

X: Obstruction of aortic plate. the lowest value since point C

Left ventricular ejection time: aortic plate opening and closing time interval (interval between B and X)

4) ICG Display



① ICG label / CO unit

② CO measurement

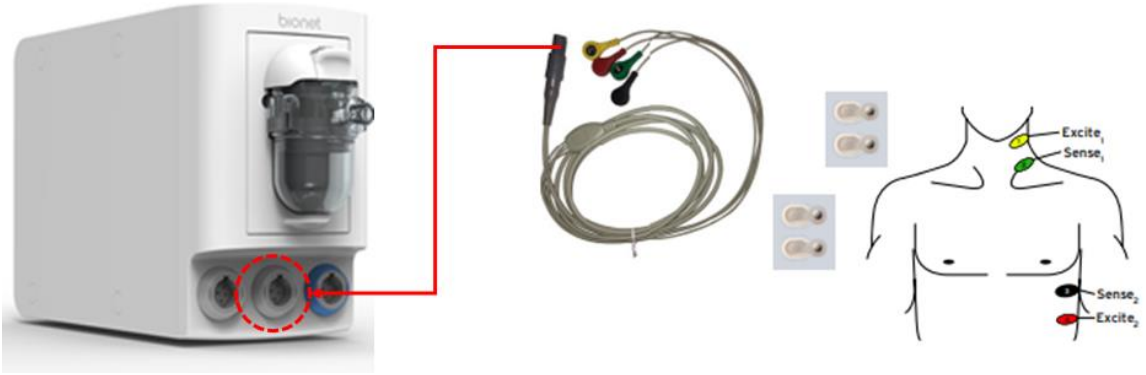
③ CO Alarm limits

④ SQI

⑤ SV value and unit

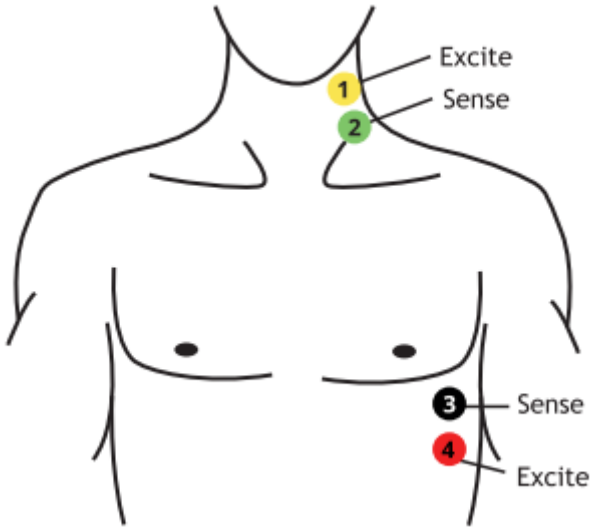
5) Connecting a Patient to ICG Device

The following figure shows the ICG patient cable and patient connection.



6) Electrode Configuration

To begin use, attach electrodes to the patient's skin. In order to measure cardiac output on the patient's back, the electrodes should be placed on the left side as shown in the picture below.



Electrode	Color	Position
1	Yellow	Carotid region near the patient's jaw
2	Green	Carotid region below or near the red electrode
3	Black	The left side of the chest, above the lowest rib.
4	Red	Below or near the black electrode (No. 3) near the lowest rib on the left side of the chest.

Warning	● **If rash or other abnormal symptoms appear on the skin, remove the electrodes from the patient.** ● **Pay special attention to the patients with skin problems.** ● **Do not place electrodes on any wounds.**

Note	● **Always cleanse patient's skin and avoid hairy areas before applying electrodes.** ● **Recommended to use Ambu Neuroline 720 reference 72000-S25.** ● **Excessive sweating or dropping liquid on the electrodes may affect the adhesion of the sensor.**

7) Connecting Patient Cable and Electrodes

The next step is to connect each cable by means of a color pattern.

Patient cables can be easily plugged in. Place the end of the cable on the corresponding electrode and gently press the end of the cable until you hear a click.

8) Connecting Patient Cable and Monitor

The next step is to connect the patient's cable to the monitor when all the ends of the cable are connected correctly to the electrodes. Simply insert the cable connector into the monitor connector.

Note	● **Make sure that the patient cable connector is fully inserted into the patient monitor.** ● **To unplug the patient's cable, pull it from the arrow symbol drawn on the connector.**

	● **After connecting the patient cable, it may take up to 2 minutes before the cardiac output per minute (C.O.) is displayed.**

9) Measuring ICG

Warning	**The patient must be in a resting state during the measurement. The patient's movements may interfere with the collected signals.**

10) ICG Setting Menu

When you select an ICG figure or waveform area, the setting menu appears.

Menu	Description	Available Setting
A. Alarm	ICG alarm setup menu	CO, SV, SQI
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	On, Off
B. Setup	Setup menu	
B-1. Speed	Set waveform range speed.	6.25 mm/sec, 12.5mm/sec, 25.0 mm/sec, 50.0 mm/sec
B-2. Size	Set waveform size.	x2, x4, x6, x8, x10

PART 18. qCON

1) Overview

qCON is a non-invasive function for monitoring anesthesia depth. EEG calculates the index, which is used to evaluate the consciousness of anesthetized patients. qCON is displayed as an index without data parsing data.

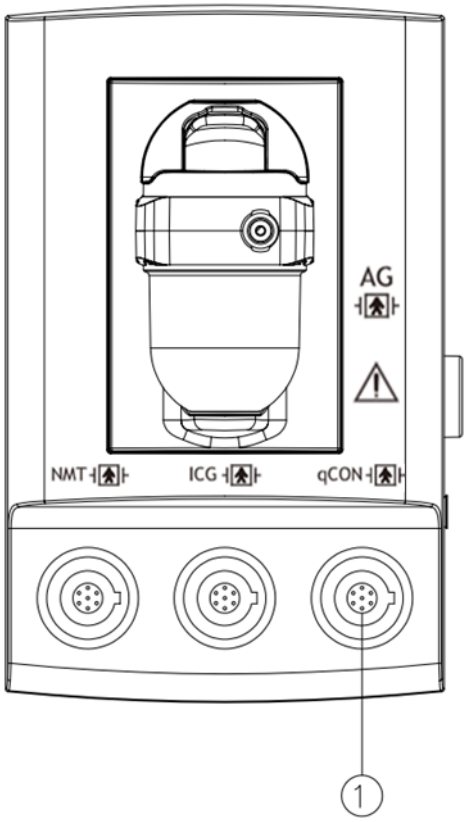
The qCON index is obtained by recording three surface electrodes on the patient's forehead and analyzing brain waves digitally. The qCON index guides experts to determine the effectiveness of anesthetics on anesthetized patients.

QCON monitoring is for adults, pediatric patients, and neonates.

2) qCON Restrictions.

Use of qCon is restricted in psychiatric or neurological diseases, drug abuse, or good substance abuse that affect the central nervous system.

Do not use on patients with skin damage, since the sensor may cause skin irritation.



3) qCON Precautions

Warning	● **It is important that the conductive parts of the electrodes and connectors do not meet the other conductive parts, including the electrically grounded parts.** ● **To reduce the risk of burns in high frequency surgical neutral electrode connections, the qCON sensor should not be located between the surgical site and the electrosurgical device return electrode.** ● **When using defibrillator in monitoring patients, the qCON electrode should not be located between defibrillator pads.** ● **Use only recommended cables and leads for proper defibrillator protection.** ● **qCON is a complex monitoring technology intended for use only as an**

	adjunct to clinical judgment and training. ● qCON anesthesia depth should not be used as the only parameter for adjusting the anesthetic capacity.

Caution	● Use only the parts and accessories specified in this manual. Observe all warnings and precautions in accordance with the instructions for use. ● Transplanting devices (e.g., heartbeat regulators), other patient connections, and other devices (e.g., high frequency surgical devices) may interfere with waveforms, numbers, and CSA presentation equipment. ● External radiation devices may interfere with measurements. It is recommended not to use an electrical radiation device near the patient monitor. ● The time of use of gel electrodes is limited by the gel electrode. AMBU electrode manufacturers limit sensor usage to 24 hours.

Note	● In the event of electrode connection problems, the patient monitor provides error indication only when automatic sensor Inspection is performed according to the set time interval. ● If abnormal waveforms or high noise are observed, it is recommended to start checking the manual sensor. ● For low electrode impedance, the skin must always be prepared with sandpaper. It is recommended not to use alcohol because it may leave a fine membrane on the skin that increases electrode impedance.

4) qCON Parameters

qCON Index (Range 0-99): The qCON index is a continuous processing of electroencephalogram parameters related to the patient's level of consciousness. Decreasing qCON index is equivalent to gradually losing consciousness and increasing anesthesia for most individuals, qCON is more than 80 when it's happening. However, when some individuals remain calm, they are seen to decrease to about 60 during waking hours.

qCON Index	Clinical State
99	Awakening
80	Sedation
60-40	General anesthesia
0	Deep anesthesia

5) qCON Display

① qCON alarm limit

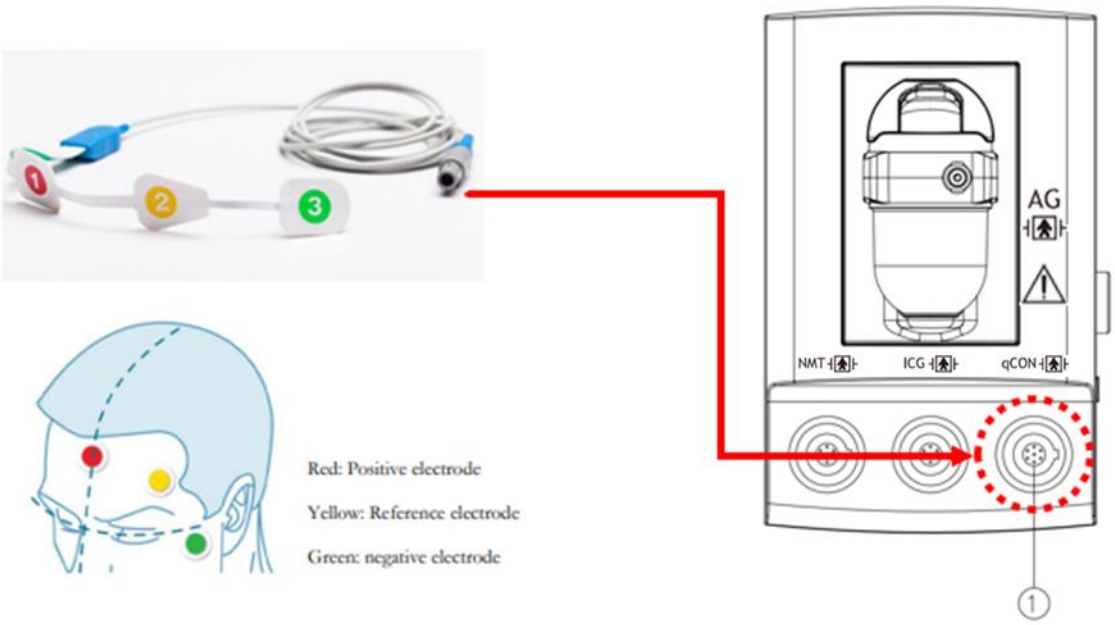
② qCON Index

③ SQI

④ EMG

Note	**The electrode status can be checked in the Setup tab of the qCON setup menu. The status of Electrode off, High Impedance, and Pass are displayed in red, yellow, and green, respectively.**

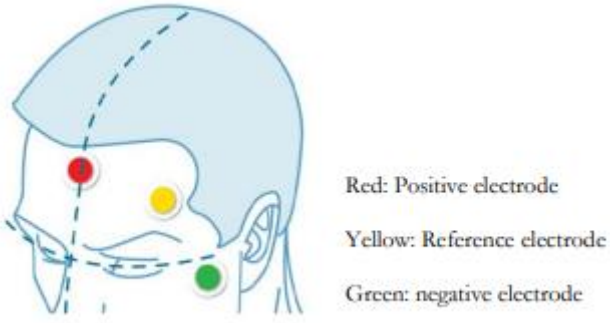
6) Connecting the patient to qCON Device



To monitor qCON, perform the following:

1) Wipe the patient's skin with fine sandpaper.

2) Install three captures in the following positions



3) Connect one end of the patient cable to the monitor and the other end to the electrodes attached to the patient's skin.

4) Perform the Inspection and observe the results.

Caution	● **If rash or other abnormal symptoms appear on the skin, remove the electrodes from the patient.** ● **Pay special attention to the patients with skin problems.** ● **Do not place electrodes on any wounds.**

Caution	**To receive low electrode impedance, the skin must always be prepared with sandpaper. Alcohol can leave a fine membrane on the skin, so it is better not to use it because it can increase electrode impedance**

Note	● **Electrodes can be located on the left or right side of the patient's head.** ● **After pressing around the sensor, use tape to attach the electrode to the skin when the electrode is not sufficiently bonded or in contact. This increases the impedance value.** ● **Make sure that the gel of the electrode is not leaked and press the end of the electrodes to improve adhesion.**

7) qCON Setting Menu

When you select the qCON numerical or waveform area, the setting menu appears.

Menu	Description	Available Settings
A. Alarm	Alarm settings menu	qCON, SQI, EMG
A-1. Alarm	Set whether to detect an alarm.	On, Off
A-2. Priority	Set alarm priority.	High, Medium, Low
A-3. Low / High	Set alarm low/high limit value.	
A-4. Print	Set print when an alarm occurs.	On, Off
B. Setup	Setup menu	
B-1. Speed	Set waveform range speed.	6.25 mm/sec, 12.5mm/sec, 25.0 mm/sec, 50.0 mm/sec
B-2. Size	Set the size of the measurement waveform to be displayed on the screen	25uV, 50uV, 120uV, 475 uV
B-3. EEG Filter	EEG filter settings	87.8 Hz, 33.8 Hz, 23.6 Hz
B-4. Electrodes Status	Display the status of the electrode by color. Off: Red Impedance High: Yellow Pass: Green	Off, High, Pass

8) qCON Troubleshooting

This section lists problems you may encounter. If you experience problems using the monitor or accessories, the table below may help you resolve the problem before calling for a service representative visit. If the problem persists, contact your service representative.

Problem	Solution
"---" is displayed in place of numeric.	The patient's high muscle activity in the head area, or noise from interfering devices is coupling to electrode cables. Relax the patient and remove the source of noise.
When the impedance value is too high	The ground electrodes are poorly connected to the patient. Check the electrodes and cables. If the impedance of the electrode is too high, the measurement fails even if the electrodes are properly attached. Use better electrodes or prepare the skin better.
EEG signal is noisy	1. Check that the electrodes are properly connected and not dried out. 2. Check that the electrodes properly contact with skin. 3. Check electrode impedance. 4. Calm the patient since frontal muscle activity can cause artifact. 5. Remove sources of external electrical noise (for example, the lamps) from the vicinity of the patient's head. 6. ECG monitoring may cause artifact; change electrode positioning.
EEG waveform baseline fluctuates	1. Sweating may cause variations in the electrode impedance. Check the patient. 2. If the fluctuation is disturbing, prepare the skin and replace the electrodes.

PART 19. EWS

1) Overview

Early Warning Points (EWS) can help patients recognize early signs of deterioration based on vital signs and clinical observations. The calculated score displays the appropriate recommendations.

The monitor supports the following protocols.

- MEWS (Modified Early Warning Score)
- NEWS (National Early Warning Score)
- PEWS (Pediatric Early Warning Score)
- MEOWS (Modified Early Obstetric Warning Score)
- TEWS (Triage Early Warning Score)

Provide a lower score for each parameter based on the measured or entered value. When all required parameters are entered or measured, the lower scores are added up to calculate the total early warning score. Each sub-point has a color coding that represents the degree of risk involved. Action is recommended if the total score falls short of the threshold.

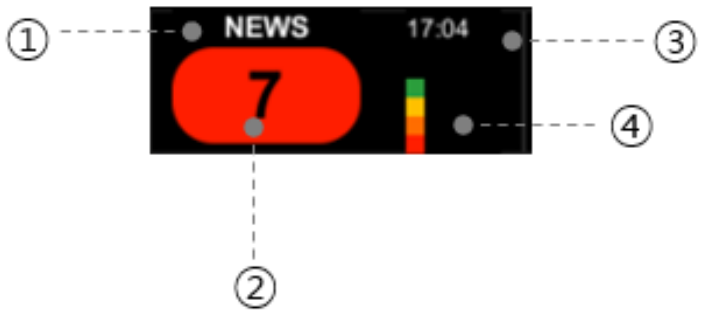
Warning	• **EWS scores and recommended measures are for reference only and cannot be used directly for diagnostic interpretation.** • **EWS cannot be used as a prognostic indicator. It's not a clinical judgment tool. Clinicians should always make clinical decisions in conjunction with EWS tools.** • **MEWS and NEWS are for adult patients only. NEWS is not applicable to pregnant women or COPD patients.**
Note	**The EWS score does not trigger an alarm and cannot be used for continuous**

	monitoring.

2) EWS Numeric Area Display

To view the EWS numeric area, select Menu > Display Settings > EWS Items.

3) EWS Parameters



① EWS Protocol name

② Total point the color of the circle indicates the degree of danger.

③ Last measurement time

④ Hazard level marking bar: The risk increases up and down

4) EWS Screen Access

Press the EWS numeric area to display the EWS screen.

Taking NEWS as an example, the EWS screen is shown below. Depending on the configuration, the screen may vary slightly.

① Parameter area: Displays the lower score and parameter values of each parameter. Tab the value area to display a keypad that can be entered manually.

② Total point calculation: Summarizes the points of the parameters.

③ Reset: Erases the previous score and update the values of the currently monitored parameters and related lower scores.

④ Last Calculation Time

⑤ Total point: The color of the circle indicates the degree of danger.

⑥ Hazard level indicator: The risk increases up and down. The current level is surrounded by black frames.

⑦ Automatic Calculation Cycle Settings

⑧ Time remaining until the next calculation

⑨ EWS Protocol Label

5) EWS Grading

To complete the grading, perform the following:

1) Select Reset to delete the previous score and update the currently monitored parameters and related lower score values.

2) Confirm parameter value or enter manually.

3) Press [Calculate] button to calculate the total point.

Note	• **Select Reset to delete the previous score before calculating the score.** • **If the parameter values are entered manually, the value is no longer updated.** • **Points can only be scored if all necessary parameters are measured or entered.**

The score table by protocol is as follows.

- NEWS

Physiological Parameters	Name	Unit	3	2	1	0	1	2	3
Respiratory rate	RR	rpm	<9		9-11	12-20		21-24	24<
Oxygen Saturations	SpO2	%	<92	92-93	94-95	95<			
Any Supplemental Oxygen	ASO			Yes		No			
Temperature	Temp	°C	<35.1		35.1-36	36.1-38	38.1-39	39.0<	
Systolic blood pressure	NIBP-S	mmHg	<91	91-100	101-110	111-219			219<
Heart Rate	HR	bpm		<41	41~50	51~90	91~110	111~130	130<
Level of Consiousness	LOC					A			V,P,U

Total Score	Clinical risk
0	Non Acute
1~4	Acute
5~6	Urgent
7 ~	DOA

- MEWS

Physiological Parameters	Name	Unit	3	2	1	0	1	2	3
Systolic blood pressure	NIBP-S	mmHg	<71	71–80	81–100	101–199		199<	
Heart Rate	HR	bpm		<41	41–50	51–100	101–11	111–129	129<
Respiratory rate	RR	rpm		<9		9–14	15–20	21–29	29<
Temperature	Temp	°C		<35		35–38.4		38.4<	
Level of Consiousness	LOC					A	V	P	U

Total Score	Clinical risk
2 이하	Non Acute
3~4	Acute
5~6	Urgent
7 ~	DOA

- MEOWS

Physiological Parameters	Name	Unit	3	2	1	0	1	2	3
Respiratory rate	RR	rpm	<12			12-20		21-25	25<
Oxygen Saturations	SpO2	%	< 92	92-95		95<			
Any Supplemental Oxygen	ASO			Yes		No			
Temperature	Temp	°C	< 36.1			36.1-37.2		37.3-37.7	37.7 <
Systolic blood pressure	NIBP-S	mmHg	< 90			90-140	141-150	151-160	160 <
Systolic blood pressure	NIBP-D	mmHg				<91	91-100	101-110	110 <
Heart Rate	HR	bpm	< 50	50-60		61-100	101-110	111-120	120 <
Level of Consiousness	LOC					Alert			V,P, U
Pain	Pain					Normal			Abnormal
Discharge, Lochia	Discharge Lochia					Normal			Abnormal
Proteinurea	Proteinurea					Normal		+	++ >

Total Score	Clinical risk
0	Non Acute
1~4	Acute
5~6	Urgent
7 ~	DOA

- PWES

Physiological Parameters	Name	Unit	3	2	1	0	1	2	3
Behavior	Behavior					Appropriate	Sleeing	Irritable	Lethargic
Capillary refill	Capillary refill	seconds				<3	3	4	4 <
Respiratory	Respiratory					normal	10 < RPM or 30% FiO2 or 3L/min	20 < RPM or 40% FiO2 or 6L/min	RPM < 5 or 50% FiO2 or 8L/min
Quarter hourly nebulizers	Nebulizers					No	Yes		
Persistent vomiting	Vomiting					No	Yes		

Total Score	Clinical risk
0	Non Acute
1~2	Acute
3~4	Urgent
5 ~	DOA

- TEWS

Physiological Parameters	Name	Unit	3	2	1	0	1	2	3
Respiratory rate	RR	rpm		<9		9~14	15~20	21~29	29 <
Heart Rate	HR	bpm		<41	41~50	51~100	101~110	111~129	129 <
Systolic blood pressure	NIBP-S	mmHg	<71	71~80	81~100	101~199		> 199	
Temperature	Temp	°C		<35		35~38.4		> 38.4	
Level of Consiousness	LOC					A	V	P	U
Mobility	Mobility					Walking	With help	Immobile	
Trauma	Trauma					Absent	Present		

Total Score	Clinical risk
0~2	Non Acute
3~4	Acute
5~6	Urgent
7 ~	DOA

6) EWS Setting Menu

When you select the EWS numerical area, the setting menu appears.

Menu	Description	Available Setting
A. Calculate	Calculate score	

A-1. Parameter Score	Value input for each parameter and score calculation. Value can be entered manually or automatically, and the score is automatically calculated when a value is entered. Parameter items are changed according to the set protocol.	
A-2. Interval	Automatic calculation cycle setting. Automatically calculate with the currently monitored parameter value at the end of the period. User-required input parameters use the last input value.	Off, 5 min, 10 min, 15 min, 30 min, 1hr, 2hrs, 3 hrs, 4 hrs, 6 hrs, 8 hrs, 12 hrs, 24 hrs
A-3. Reset	Score Reset Parameter and total score are initialized, parameter values are automatically updated, and the Calculation menu is activated.	
A-4. Calculate	Calculate the total score. Calculate the total score and display the last count time. Parameter values are no longer updated and the Calculation menu is disabled.	
B. Setup	Setup menu	
B-1. Protocol	Protocol settings	MEWS, NEWS, PEWS, MEOWS, TEWS

PART 20. GCS

1) Overview

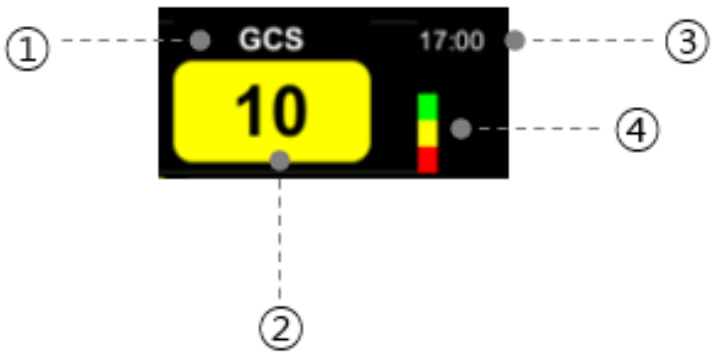
The Glasgow Coma Scale (GCS) function is based on Teasdale's Coma Scale (Lancet, 1974). Three aspects of behavior are measured independently: awakening, verbal, and motor responses. The scores are added up to indicate the patient's level of consciousness.

GCS targets adult and pediatric patients.

Caution	• **GCS is for reference only. Refer to other clinical observations for diagnosis.** • **Refer to the hospital policy for permissible GCS use.**

2) GCS Parameter Area Display

To display the GCS numeric area, press Menu → Display Settings → Select GCS items → select the GCS item.



① GCS label

② Total point. The color of the circle indicates the degree of danger.

③ Last measurement time

④ Hazard level marking bar. The risk increases up and down.

3) GCS Screen Access

Press the GCS numeric area to display the GCS screen.

① Parameter area: Displays the lower score and parameter values of each parameter. Tab the value area to display a keypad for entering values manually.

② Total point calculation: Summarizes the points of the parameters.

③ Last Calculation Time

④ Total point: The color of the circle indicates the degree of danger.

⑤ Hazard level indicator: The risk level shifts up and down. The current level is surrounded by black frames.

⑥ Calculation cycle setting

⑦ Time remaining until the next calculation

4) GCS Grading

To complete the grading, perform the following.

1) Select the items that indicate the patient's condition in the wake-up area, language response area, and motor response area respectively.

2) Select Confirm to score the total score.

The parameter and total score table is as follows.

Glasgow Coma Scale		
Response	Scale	Score
Eye Opening Response	Eyes open spontaneously	4 Points
	Eyes open to verbal command, speech, or shout	3 Points
	Eyes open to pain (not applied to face)	2 Points
	No eye opening	1 Point
Verbal Response	Oriented	5 Points
	Confused conversation, but able to answer questions	4 Points
	Inappropriate responses, words discernible	3 Points
	Incomprehensible sounds or speech	2 Points
	No verbal response	1 Point
Motor Response	Obeys commands for movement	6 Points
	Purposeful movement to painful stimulus	5 Points
	Withdraws from pain	4 Points
	Abnormal (spastic) flexion, decorticate posture	3 Points
	Extensor (rigid) response, decerebrate posture	2 Points
	No motor response	1 Point

Level	**Total Score**	**Color**
Mild damage	13-15	Green
Moderate damage	9 - 12	Yellow
Severe damage	3 - 8	Red

5) GCS Setting Menu

When you select the GCS numerical area, the setting menu appears.

Menu	Description	Available settings
1. Parameter Score	Calculate the reaction points of Eye, Verbal, and Motor. The score of values being entered are calculated automatically.	
2. Interval	Set computational cycle. if the calculation cycle is reached and no other scores are performed, the score is disabled and displayed as a gray background.	Off, 15 min, 30 min, 1hr, 2hrs, 4 hrs, 8 hrs, 12 hrs
3. Calculate	Calculate the total score.	

PART 21. Printer

1) Overview

The printer mounted outside the monitor prints the observed results including trend and alarm data. Recording can be on-time or continuous and it is printed at the speed of 50 mm/s. Recordings are identified by the patient's name, ID as well as the date and time of the recording request. The monitor can automatically trigger alarm recordings for life-threatening alarms and limit violations if the Record function is enabled on the alarm limits table.

The thermal paper is used for printing. The size of the thermal paper roll is 58mm wide and 38mm in diameter. Any thermal paper of same dimension can be used with the printer.

Caution	● **Connect the printer cable with the patient monitor turned off.** ● **Due to the nature of thermal paper, heat is generated under continuous operation. It is recommended to let the printer cool down for 10 minutes after every five minutes of printing.**

2) Printer Setting Menu

When you select the Print Setup from the main menu, the setup menu appears.

1. Speed	Set print speed.	25 mm/s 50 mm/s
2. Waveform1	Set the first waveform.	Off, I / II/ III/ AVR/ AVL/ AVF/ V1, SpO2, Resp, EtCO2, IBP1, IBP2 V2/ V3/ V4/ V5 / V6, Gas(AG), IBP3, IBP4, ICG qCON, NMT

3. Waveform2	Set the second waveform.	Same as above
4. Waveform3	Set the third waveform.	Same as above
5. Print from Time	Set the starting point of the data to be printed. *Real Time: Data is printed from the time you press the Print menu. *Delay (5sec): Data from 5 seconds before you press the Print menu is printed.	Real time Delay (5sec)
6. Period	Set print time. If you do not stop manually after pressing the Print menu, printing continues for the set time.	Continue, 10sec, 20sec, 30sec

Note	**The waveforms of IBP1, IBP2, and ETCO2 on paper look different from the waveforms on screen. This is because the waveforms on paper can be scaled while the waveforms on screen cannot.**

3) Storing the Thermal Paper

To avoid print quality degradation or attenuation of printouts, follow these precautions.

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

- Store the paper 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 does not degrade thermal traces in themselves. However, these materials do not protect 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.

4) Changing the Paper

1. Open the printer window.
2. Insert the paper roll offered with the monitor 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. Improper closure may cause failure in printing.

5) Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the monitor or accessories, check the table below before requesting service. If the problem persists, contact your service.

Problem	Solution
No printing	1 Check the printer module connection status. 2 Check that the tray cover is closed properly. 3 If there is no paper, put in new paper. 4 If the print side is reversed, turn the paper over.

PART 22. IR-Temperature

1) Overview

The patient monitor can measure body temperature intermittently by scanning the forehead skin over the temporal artery using an infrared thermometer. The thermometer provides a peak temperature reading from plural readings during the step of scanning. Electronic circuitry processes the measured peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature, the electronic circuitry computing an internal temperature of the body as a function of ambient temperature (Ta) and sensed surface temperature.

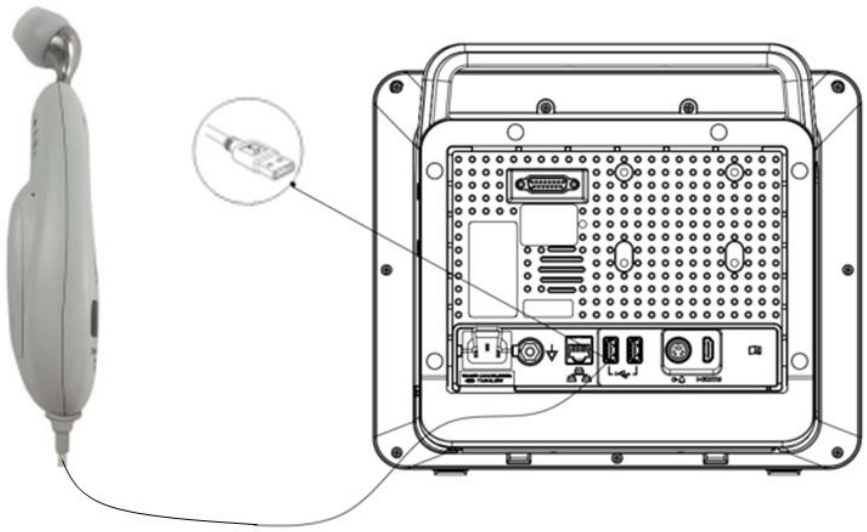
When using the monitor, basic safety precautions should always be followed, including the following.

Caution	• **Use the patient monitor only for its intended use as described in this manual.** • **Do not take temperature over scar tissue, open sores, or abrasions.** • **The operating environmental temperature range for the patient monitor is 60° to 104°F (15.5° to 40°C).** • **Always store and transport the thermometer in a clean, dry place where it does not become excessively cold (-4°F/-20°C), or hot (122°F/50°C). Relative humidity 93% Maximum non-condensing, atmospheric pressure 50 kPa to 106 kPa.** • **The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.** • **Do not autoclave. Please note cleaning and sterilizing procedures in this manual.** • **Do not use the thermometer if it is not working properly, has been exposed to temperature extremes, damaged, subject to electrical shocks, or soaked in water.** • **There are no parts that you can service yourself except for the battery, which you should replace when low by following the instructions in this manual. For service, repair, or adjustments, return your thermometer to**

	Exergen. **Warning: No modification of the patient monitor is allowed.** ● **Never drop or insert any object into any opening, unless stated in this manual.** ● **If your thermometer is not used regularly, remove the battery to prevent possible damage from chemical leakage.** ● **Follow the battery manufacturer's recommendations or your hospital policy for the disposal of used batteries.** ● **The thermometer is not suitable for use in the presence of flammable anesthetic mixtures.**

2) Connecting the Thermometer

Connect the infrared thermometer to the USB connector on the back as shown below.



3) Introduction to Temporal Artery Thermometry

Temporal artery thermometry (TAT) is a unique method of temperature assessment, using infrared technology to detect the heat naturally emitting from the skin surface. In addition, and of key importance, this method incorporates a patented arterial heat balance system to automatically account for the effects of ambient temperature on the skin.

This method of temperature assessment has been shown to improve results and reduce costs by non-invasively measuring body temperature with a degree of clinical accuracy unachievable with any other thermometry method.

Before Using, Familiarize yourself with the thermometer.

• To scan: Press the red button. The thermometer continuously scans for the highest temperature when the button is held down.

• To detect: The increasing frequency of the clicking sound signifies a rise of temperature, similar to a radar detector. The slower clicking frequency indicates that the thermometer has not yet detected any higher temperature.

• To preserve or lock-in the reading: The reading remains on the display for 30 seconds after the button has been released. When measuring room temperature, the temperature remains on the display for only 5 seconds.

• To restart: Press the restart button. The thermometer conducts a new scan every time the button is pressed, and you do not need to wait for the screen to clear.

4) Basics of Using the Temporal Scanner

Temporal Scanner instructions

1. Only scan the exposed surface.

Clear the hair that covers the superficial temporal artery.

Place the probe at the center of the forehead and press and hold down the red button.

2. Slow and steady, navigate the probe across the forehead all the way until it reaches the hairline.

3. Brush the hair away if it covers the ear.

While still holding down the red button, lift the probe from the forehead and bring it to the mastoid process behind the ear. Then, pull it down to the depressed area behind the earlobe.

4. Release the button and record the temperature.

5) 2 Steps to measure Infant Temperature

1. Place the probe at the center of the forehead and press and hold down the red button. Slow and steady, navigate the probe across the forehead all the way until it reaches the hairline.

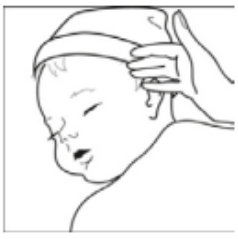
2. Release the button and record the temperature.

• How to improve the accuracy of measurements of infants

The preferred site is the temporal artery area. Unless visibly diaphoretic, one measurement here is typically all that is required

If the temporal artery is covered, then the area behind the ear, if exposed, can be an alternate site.

Measure straight across the forehead and not down side of face.
At mid-line, the temporal artery is about 2 mm below the surface, but can go deeply below the surface on the side of the face.



Brush the hair aside if covering the area to be measured. Measurement site must be exposed.

6) 3 Steps to Measure Adult Temperature

1. Clear the hair that covers the superficial temporal artery.

Place the probe at the center of the forehead and press and hold down the red button.

2. While still holding down the red button, lift the probe from the forehead and bring it to the mastoid process behind the ear. Then, pull it down to the depressed area behind the earlobe.

3. Release the button and record the temperature.

• How to improve the accuracy of your measurements of adults

Measure only the up-side on a patient in a lateral position. The down-side will be insulated preventing the heat from dissipating, resulting in falsely high readings.

Think of a sweatband.
Measure straight across the forehead and not down the side of the face. At mid-line, the temporal artery is about 2 mm below the surface, but can go deeply below the surface on the side of the face.

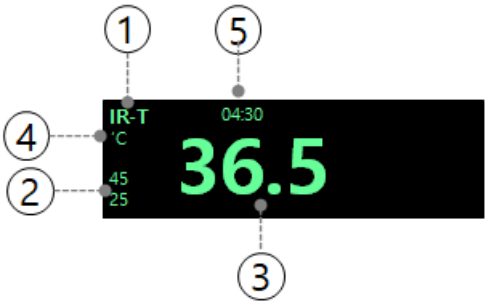
Measure exposed skin.

Brush the hair and bangs aside if covering the area to be measured.

Note	**Minimum measuring time: 2 seconds** **Minimum time between successive measurements: 30 seconds**

7) Display

To use the infrared thermometer, set Temp Type in the body temperature setting menu to IR-USB.



① IR-Temperature label

② Temperature alarm limit

③ Temperature value

④ Temperature unit

⑤ Measurement time

Note	**Continuous and instantaneous body temperature measurement cannot be used at the same time.**

8) Setting Temperature

Please refer to the **Temperature setting Menu in PART 12.**

9) Care and Maintenance

• Battery: A standard alkaline 9V battery provides approximately 15,000 readings. ** To replace the battery, insert the tip of a paper clip into the pinhole on the side of the unit to release the battery

compartment door. Disconnect the old battery and replace it with a new one in the same location. Then replace the cover. Refer to the pictures below. Only use high-quality alkaline batteries.

• Handling: The Temporal Scanner is designed and built to industrial durability standards in order to provide long and trouble-free service. However, it is also a high precision optical instrument, and should be accorded the same degree of care as you would provide for most precision optical instruments.

• Cleaning the case: The Temporal Scanner case can be wiped down using a cloth dampened with 70% isopropyl alcohol.

• Cleaning the sensor lens: With normal use, the only maintenance required is to keep the lens on the end of the probe clean. It is made of a specialized mirror-like, silicon infrared-transmitting material. However, dirt, greasy films, or moisture on the lens interferes with the passage of infrared heat and affect the accuracy of the instrument. Regularly clean the lens with a cotton swab dampened with an alcohol wipe. Only use light force for cleaning to avoid damaging the lens. Water can be used to remove any residual film left by the alcohol. Do not use bleach or other cleaning solutions on the sensor lens. Use 70% isopropyl alcohol.

• Disinfection: The industrial grade housing and design of the electronic components allow for completely safe disinfecting with 70% isopropyl alcohol. Do not soak. Do not autoclave.

• Calibration: Factory calibration data is installed via a computer which communicates with the Temporal Scanner's microprocessor. The instrument automatically self-calibrates each time it is turned on using this data and never requires recalibration.

• Unit: Insert the end of a bent paper clip into the pinhole on the side to release and remove the cover. Remove the battery from the compartment. Locate the switch, and with the tip of a screwdriver, slide left or right to the opposite position. Remove the screwdriver and replace the cover.

Disposable cover: As being cost effective, the disposable covers provide protection against all levels of cross-contamination. The disposable options include caps and full instrument sheaths, mainly used for isolation patients.

Using the Disposable Probe Caps:

1. Push the cap onto the probe head.

2. Remove the cap by pushing the edge forward with a thumb.

3. You can reuse the cap on the same patient.

Using the disposable full sheath:

1. Insert the Temporal Scanner into the bottom end of the sheath. If the Temporal Scanner is connected to a cable, insert the probe end first. Then twist the sheath at its neck with fingers to assure film is smooth over probe lens.

2. Wrap additional film around the probe neck. Film should be smooth over probe lens.

3. Slide additional film under fingers while using.

Probe Cap
Covers Entire
Probe

Full Sheath
Covers Entire
Instrument

PART 23. Maintenance and Troubleshooting

1) Maintenance Safety Information

Warning	**Modifications to the patient monitor are not permitted.**
Caution	• **To avoid electric shock, if the housing is damaged, stop using the patient monitor and contact your service representative.** • **If the responsible individual hospital or institution neglects to follow the recommended maintenance schedule in the use of the patient monitor, excessive equipment failure and health risks.** • **The patient monitor contains no user serviceable parts.** • **Safety checks or maintenance related to disassembling the patient monitor must be performed by qualified service representative. Failure to do so may result in excessive monitor failure or hazards to operators.** • **Service representative should possess a working knowledge of the test tools and make sure that test equipment and cables are applicable.** • **The battery and AC cords must be removed for repair.**

2) Equipment Inspection

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

- Examine unit exteriors for cleanliness and general physical condition. Make sure the housings are not cracked or broken, everything is present, there are no spilled liquids, and there are no sign of abuse.
- If the EtCO2 and Multi-gas module are mounted on the monitor, make sure that they are locked into place and do not slide out without releasing the locking mechanism.
- Inspect all accessories (cables, transducers, sensors and etc.). If any show signs of damage,

do not use.

- Switch the monitor on and make sure the backlight is bright enough. Check that screen is at its full brightness. If the brightness is not adequate, contact your service representative or your supplier.

Warning	**Using the patient monitor adjacent to or stacked with other devices should be avoided because it could result in improper operation. If such use is necessary, the patient monitor and the other devices should be observed to verify that they are operating normally.**

3) Cable Inspection

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

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

4) Maintenance Tasks and Test Schedule

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

Maintenance and test schedule	Frequency
Monitor tests	
Safety checks Selected tests on the basis of IEC 60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped
Monitor maintenance	
Check ECG synchronization of the monitor and defibrillator (only if hospital protocol requires use of monitor during defibrillation).	At least once every two years, or as needed
Backlight replacement (integrated displays only).	35,000 - 40,000 hours (about four years) of continuous usage, or as needed
Parameter module tests	
Performance assurance for all measurements not listed below	At least once every two years, or if you suspect the measurement values are incorrect
Parameter module maintenance	
NIBP calibration	At least once every two years, or as specified by local laws
Mainstream and Sidestream CO2 calibration check	At least once a year, or if you suspect the measurement values are incorrect
Battery maintenance	
Battery	See the section on Maintaining Batteries in PART 1.

5) Troubleshooting

In case of touchscreen malfunctions

Recalibrate the screen with the following steps.

1. Access the [Calibration] menu from the main menu, then select [Touch Screen Calibration].

2. Press the cross markers on the Touch Calibration Screen in chronological order.

3. Once the calibration is complete, the screen disappears.

In case of the admin account's access becoming restricted

If access of the admin account becomes restricted due to forgotten/incorrect password, please contact the hospital's support personnel or the manufacturer.

※ For manufacturer contact information, please refer to the table of contents of How to contact us.

Cyber security issues

1. If equipment is stolen or lost, immediately report it to the hospital staff or manufacturer. When reported of a loss, the hospital network administrator must take measures to prevent the device from accessing hospital network.
2. If a cyber security threat is detected while using the equipment, immediately disconnect it from the network and contact the hospital staff or manufacturer.

※ For manufacturer contact information, please refer to the table of contents of How to contact us.

Storage lifetime issues

If the storage is nearing the end of its life, the following warning message appears when booting the monitor or admitting the patient.

If the warning message appears, contact the customer center or the purchasing agent to check the monitor.

The storage has expired. Contact the customer center or the store where you purchased the product and inspect the equipment

Interruption of the supply mains exceeding 30 seconds

1. Check that the visual and auditory alarm signals are presented correctly when the monitor is powered on.

2. Operate the monitor on battery power if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.

3. If the power supply is cut off for more than 30 seconds, it returns to the default setting of the manufacturer, restores the default setting of the responsible authority, and returns to the last setting used.

PART 24. Cleaning and Care

1) Overview

Clean the monitor and accessories daily or after each patient use according to your hospital's standard protocol or procedures below.

Bionet does not claim the right to the following chemical efficacy, disinfectant method, the ability of the drug to inhibit bacterial infection, environmental impact, safe handling or precautions related to use. For more information on these topics, see the information provided by the detergent manufacturer.

2) Monitor and Accessories

Moisture can damage the monitor and accessories. (For example, around connectors or EtCO2 modules).

Please read the following instructions carefully before cleaning the monitor or accessories.

- Do not sterilize by autoclaving, pressure sterilization or gas sterilization.
- Do not spray any cleaning solution on the monitor or accessories. Excessive use of cleaning liquid may flow into the monitor and cause damage to internal components.
- Wipe off the cleaning solution with a damp cloth.
- Disinfect the surface with diluted alcohol gauze.
- Do not use petroleum/acetone cleaning solutions or other strong solvents to clean the monitor or accessories. These substances may damage the device and cause the device to malfunction.
- Wipe clean with a lint-free cloth.
- Do not touch, press, or rub the display panel with abrasive tools, brushes, or rough surfaces. Also, don't come close to anything that could scratch the panel.
- Do not spray detergent on the monitor or peripheral devices. Wipe it off with a damp cloth.

Caution	• **Do not wet or rinse the patient monitor and accessories. Disconnect the monitor from the power source if you accidentally spilled liquid on it. Contact your technician for stability before operating the patient monitor.** • **To prevent damage to the patient monitor, do not use sharp tools or abrasives. Never leave the electrical connector soaked in water or other liquids. When cleaning, be careful not to let the liquid stick to the edge of the screen.**

All Patient Cables

- Clean the patient cables with a gauze pad moistened with a soap solution.
- To disinfect patient cables, wipe the cables with a gauze moistened with diluted alcohol or a glutaraldehyde-based disinfectant.
- Ethylene oxide is suitable for intensive disinfection (almost sterilization), but it shows that the service life of cables and lead wires is reduced.
- Dry thoroughly with a lint-free cloth.

All patient cables can be wiped or cleaned with a warm, damp towel, mild soap, or isopropyl alcohol. Disinfect all patient cables with gauze moistened with diluted alcohol.

Caution	• **Do not use disinfectants that contain phenol as they can spot plastics. Do not autoclave or clean the accessories with strong aromatic, chlorinated, ketone, ether, or ester solvents. Never have the electrical connectors soaked.** • **When cleaning, do not apply excessive pressure or bend the cable unnecessarily. Excessive pressure can damage the cables.**

Reusable ECG Electrodes

Clean the electrode cup regularly with a toothbrush. When removing gel-like residues, use a soft brush with flowing water. Wipe the electrode with a soapy cloth moistened with soapy water.

- Sterilize the electrodes by soaking the diluted alcohol in cloth.
- Dry thoroughly with a lint-free cloth.

Reusable SpO2 sensor

Use clean SpO2 sensor by wiping it with soapy water gauze. Disinfect the sensor by wiping with 70% alcohol solution. Allow the sensor to dry completely with a lint-free cloth before applying to the patient.

Reusable Temperature Probe and Cables

Do not use excessive pressure or flex the cables as this can stretch the covering and break the internal wires.

- Clean the Probe with a 3% hydrogen peroxide or 70% alcohol.
- Quickly soak the cables in a detergent solution.
- Make sure the tip of the probe is firmly connected.

Capnostat Sensor

Wipe the sensor surface and sensor window with a damp cloth. Do not attempt to wet the sensor or disinfect it with hot water Allow to dry completely with a lint-free cloth. Make sure the sensor window is clean and dry before use.

IBP Transducer

Handle transducers and other pressure accessories with care. Do not apply excessive pressure to the conversion board. Do not expose the transducer to water, steam, dry heat sterilization, ether, chloroform, or other similar chemicals. Always protect the connector from water.

Warning	• **For more information on cleaning, disinfecting, and sanitizing reusable accessories, refer to the accessory manufacturer's instructions for use.** • **Do not reuse disposable accessories.**

Warning	**Never boil or autoclave the cables. Vinyl withstands temperatures up to 100°C but begins to soften at around 90°C. Handle gently when hot and wipe away from the tip toward the cables.**

Caution	**Decisions on disinfection should be made by your organization in accordance with the integrity of the wires or lead wires.**

Note	**The patient monitor should be inspected regularly once a year. For Inspection items, refer to this operation manual or service manual.**

Carefully inspect the monitor and sensor after cleaning the monitor. Do not use damaged or old monitor.

Clean the exterior of the monitor at least once a month using a soft cloth moistened with lukewarm water or alcohol. Do not use lacquer, thinners, ethylene, or oxidizers that could damage the monitor.

Make sure that the cables and accessories are free from dust and dirt. Then wipe them with a soft cloth moistened with 40 ° C water. Please wipe it with clinical alcohol at least once a week.

Do not soak the accessories in liquid or detergent. Also. prevent any fluid from seeping into the monitor or probe.

Caution	• **Do not dispose of the disposable probe in a potentially hazardous area.** • **Always be careful about environmental pollution.**

Caution	**There is a backup battery inside the system.** **When disposing of the battery, dispose of it in an appropriate place to protect the environment.**

Warning	When replacing the backup battery, check the battery electrode.

If you suspect the installation or disposition of the external ground wire, operate the monitor by means of the internal power supply.

If the monitor is not used for a certain period, remove the backup battery to avoid any safety hazard.

PART 25. Technical Specifications

1) Overview

The patient monitor is not user installable. Qualified service representative must install it.

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

The patient monitor is intended for use in health care facilities.

2) EMC Compatibility (EMC)

Much of the information below has been borrowed from the requirements set forth in the Electromagnetic Compatibility Standard IEC 60601-1-2 for medical electrical equipment issued by the International Electro technical Commission and is available from a variety of sources. Although primarily aimed at equipment manufacturers, most of the information contained here is useful for users interested in medical equipment.

The information contained in this section (such as separation distance) are general information about the Bionet's patient monitor. The numbers provided here are not guaranteed but are provided with reasonable assurance of error-free operation. This information may not apply to other medical and electrical systems, and older equipment may be particularly susceptible to interference.

Warning	**Low amplitude signals such as EEG and ECG are particularly sensitive to interference from electromagnetic energy. The patient monitor complies with the tests listed at the bottom but does not guarantee complete operation. The "quiet" electrical environment is better. In general, the greater the distance between electrical equipment, the lower the likelihood of interference.**
Note	**Medical electrical equipment requires special precautions for electromagnetic compatibility and must be installed and serviced in accordance with the EMC information in this section and in the operating instructions supplied with the**

patient monitor.

Portable and mobile RF communication equipment can affect medical electrical equipment.

Cables and accessories not specified in this manual are not certified. Using other cables and / or accessories may adversely affect safety, performance, and electromagnetic compatibility (increased electromagnetic emissions and reduced immunity).

- **Use of this patient monitor adjacent to or stacked with other devices should be avoided because it could result in improper operation. If such use is necessary, this monitor and the other equipment should be observed to verify that they are operating normally.**

- **The patient monitor communicates over a 2.4 GHz 80211b / g wireless network. Other equipment may interfere with data reception on this wireless network. This is also true if the equipment complies with the CISPR emission requirements. When using the patient monitor to communicate over a wireless network, be sure to check that it is compatible with existing or new wireless systems (e.g., cell phones, pager systems, cordless phones, etc.). For example, a Bluetooth-compliant device using the 2.4 GHz frequency band may interfere with the wireless communication of the patient monitor. For more information on wireless deployment, please contact your Bionet representative.**

3) Manufacturer's Declaration - Electromagnetic Emission

The patient monitor are intended for use in the electromagnetic environment specified below. The customer or the user of the patient monitor system must ensure that it is used in such as environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**

Mains terminal disturbance voltage CISPR 11	GROUP1, CLASS A	The EMISSIONS characteristics of the patient monitor make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) The patient monitor might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
RADIATED DISTURBANCE CISPR 11	GROUP1, CLASS A	
Harmonic Current Emission IEC 61000-3-2	CLASS A	The patient monitor are suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Patient monitor or shielding the location.
Voltage fluctuations/Flicker IEC 61000-3-3	Complies	

4) Manufacturer's Declaration - Electromagnetic Immunity

The patient monitor system are designed for use in the electromagnetic environment specified below. The customer or the user of the Patient monitor system must ensure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic Environment - guidance**

Electrostatic Discharge Immunity (ESD) IEC 61000-4-2	±8 kV/Contact ±2, ±4, ±8, ±15 kV/Air	±8 kV/Contact ±2, ±4, ±8, ±15 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%.
Radiated RF Electromagnetic Field Immunity IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	The patient monitor are suitable to use in professional healthcare environment. RF communication equipment is used no closer than 30 cm to any part of the patient monitor including cables specified by Bionet.
Immunity to Proximity Fields from RF wireless Communication s Equipment IEC 61000-4-3	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	28 V/m Max. 385-5785 MHz in according to table 9 in IEC 60601-1-2	
Electrical Fast Transient/Burst Immunity IEC 61000-4-4	±2 kV, 100 kHz repetition frequency	±2 kV, 100 kHz repetition frequency	The quality of supplied power should be suitable for general business site or hospital environment.
Surge Immunity IEC 61000-45	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV	Line to Line ±0.5 kV, ±1 kV Line to Ground ±0.5 kV, ±1 kV, ±2 kV	The quality of supplied power should be suitable for general business site or hospital environment.

Immunity to Conducted Disturbances Induced by RF fields IEC 61000-4-6	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	The strength of RF field in the frequency range higher than 150 kHz~80 MHz, the strength of the RF field is smaller than 3 V.
Power Frequency Magnetic Field Immunity IEC 61000-4-8	30 A/m 50 & 60 Hz	30 A/m 50 & 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 30 cycles Single phase: at 0°	0% U_T: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T: 1 cycle and 70 % U_T; 30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the patient monitor requires continued operation during power mains interruptions, it is recommended that the patient monitor be powered from an uninterruptible power supply, or a battery be used with the system power source.

Voltage interruptions IEC 61000-4-11:	0% U_T: 250/300 cycles	0% U_T: 250/300 cycles	The patient monitor are suitable to use in professional healthcare environment. Portable radio frequency (RF, RFID) communication devices can interfere with the medical electrical device. Therefore, do not use your mobile phone in a medical office or hospital environment.
Radiated fields in close proximity IEC 61000-4-39	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	65 A/m Max 30 kHz - 13.56 MHz in according to table 11 in IEC 60601-1-2	The patient monitor are suitable to use in professional healthcare environment. Portable radio frequency (RF, RFID) communication devices can interfere with the medical electrical device. Therefore, do not use your mobile phone in a medical office or hospital environment.
Note U_T is the AC mains voltage prior to application of the test level.			

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.

Warning	**Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer.**

Warning	**Using accessories and cables other than those specified or provided by the manufacturer of the patient monitor could result in increased electromagnetic emissions or decreased electromagnetic immunity of the patient monitor and result in improper operation.**

5) System Specifications

Physical				
Model		**Brio X30**	**Brio X50**	**Brio X70**
Dimension (HxWxD) (mm)		237 x 221 x 136.5	308 x 273 x 140	394 x 305 x 157
Weight (Kg)		Approx. 2.0	Approx. 3.1	Approx. 4.1
Cooling		Air flow		
Power		AC power (100-240VAC, 1.5~0.75A, 50/60Hz)		
Power consumption		< 25 Watts	< 35 Watts	
Operating Mode		Continuous		
Display	**Type**	TFT-LCD		
	Resolution	1024 x 600	1280 x 800	1366 x 768
	Size	8″	12.1″	15.6″
Measurement Parameter	**Common**	ECG, heart rate, respiration rate, EtCO2, FiCO2, airway respiration rate, temperature x2, IBP x2 SpO2, pulse rate, systolic BP, diastolic BP, mean BP		
	Option	IR Temp	IBP x 2, ICG, 12ch ECG, AG, qCON, NMT, IR Temp	
TRACE	**Waveforms**	5 waveforms: ECG, SpO2, RR or EtCO2, 2*IBP	9 Waves: ECG, SpO2, RR or EtCO2 or AG, IBP x 4, ICG, qCON	
	Sweep Speed	Sweep speed: 6.25, 12.5, 25, 50 mm/sec		
Indicator		(Based on alarm type and priority) 3-color visual alarm lamp, SpO2 pulse pitch tone, Battery status, External power LED		
Interface		AC input connector LAN port for transferring data HDMI output connector USB connector Printer module connector		

		Paramount module connector
Battery		Rechargeable Li-ion battery
Degree of protection against harmful ingress of water		IPX2
Thermal Printer (option)		Speed: 50mm/sec, Paper width: 58mm
Data Storage	**Common**	168 hours trends data
	Option	1000 alarm events (all numbers and waveforms for a total of 16 seconds, 8 seconds before and after the event)
Language		English, Korean, French, Polish, German, Chinese, Portuguese, Hungarian, Czech, Romanian, Italian, Turkish, Spanish, Russian, Japanese, Dutch
Environments		
Temperature		Operating: 5 ~ +40 °C (41 ~ 104 °F) Storage: –20 ~ +60 °C (–4 ~ +140 °F)
Humidity		Operating: 30% ~ 85%, Storage: 10% ~ 95% (Package)
Operating Altitude		Operating: 525 ~ 795 mmHg (70 ~ 106 kPa) Storage: 375 ~ 795 mmHg (50 ~ 106 kPa)

ECG Specification	
Method	meets the requirements of IEC 60601-2-27: 2011 and IEC 60601-2-25: 2011
Lead Type	3-Lead 5-Lead 10-Lead
Lead Selection	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V

	10-Lead: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4,V5,V6
ECG waveforms	3-Lead: 1 channel 5-Lead: 2/7 channel 10-Lead: 2/7/12 channels
Heart Rate Range	Adult: 15 ~ 300 bpm Pediatric / Neonate: 15 ~ 350 bpm
Heart Rate Accuracy	±1bpm or ±1%, whichever is greater
Sweep Speed	6.25, 12.5, 25, 50 mm/sec
Filter	Diagnostic, Monitor, Surgery, ST
ST Segment Detection Range	-2.0 to 2.0 mV
Arrhythmia Analysis	Asystole, V-Tach, V-Tach/V-Fib, Bigeminy, Trigeminy, Acc Vent Couplet, Irregular, Pause, R on T, V-Brady, Short Run, PVC
Pacemaker Detection Mode	Indicator on waveform display (user selectable)
Protection	Against electrosurgical interference and defibrillation
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Rise time: 10 µs to 100 µs (< 10% of pulse width) No overshoot
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 2011: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Rise time: 10 µs to 100 µs (< 10% of pulse width) No overshoot

<table>
<tr><td>Tall T-wave rejection capability</td><td>When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27: 2011, the heart rate calculation is not affected for QRS of 1 mV amplitude and 100 ms duration, T-wave duration of 180 ms and amplitude lower than 1.2 mV, and QT interval of 350 ms.</td></tr>
<tr><td>Response to irregular rhythm</td><td>In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27: 2011, the heart rates for the specified test signals after 20 seconds of stabilization are:
Ventricular bigeminy (waveform A1): 80±1 bpm
Slow alternating ventricular bigeminy (waveform A2): 60±1 bpm
Rapid alternating ventricular bigeminy (waveform A3): 120±1 bpm
Bidirectional systoles (waveform A4): 90±2 bpm</td></tr>
<tr><td>Time to alarm for tachycardia</td><td>1) waveform B1:
<table>
<tr><td>Amplitude</td><td>Time to alarm</td></tr>
<tr><td>0.5 mV (1/2)</td><td>Fail – 0 bpm</td></tr>
<tr><td>1 mV</td><td>7 sec</td></tr>
<tr><td>2 mV (2)</td><td>4 sec</td></tr>
</table>
2) waveform B2:
<table>
<tr><td>Amplitude</td><td>Time to alarm</td></tr>
<tr><td>1 mV (1/2)</td><td>Fail – under 60 bpm</td></tr>
<tr><td>2 mV</td><td>2 sec</td></tr>
<tr><td>4 mV (2)</td><td>2 sec</td></tr>
</table></td></tr>
<tr><td>Respiration</td><td>
<table>
<tr><td>Sensing leads</td><td>I, II (user-selectable)</td></tr>
<tr><td>Measuring method</td><td>Impedance pneumography</td></tr>
<tr><td>Auxiliary current</td><td>≤10uA for any active electrode</td></tr>
<tr><td>Detection threshold</td><td>1.0 Ω To 3.0 Ω</td></tr>
<tr><td>Measuring range</td><td>5 to 120 breaths per min</td></tr>
<tr><td>Accuracy</td><td>±1 breath/min or 2% of rate</td></tr>
<tr><td>Apnea detection</td><td>For all patients</td></tr>
<tr><td>Alarms</td><td>User-selectable upper/lower respiration rate</td></tr>
</table>
</td></tr>
</table>

Respiration Specifications

Method	Thoracic impedance
Channel Selection	RA-LL / RA-LA
Measurement Range	5 ~ 120 breaths per minute
Accuracy	±1 breath per minute
Apnea Alarm	Yes

SpO2 Specifications (ChipO2)	
SpO2 Range	0 ~ 100%
SpO2 Accuracy *The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values.	70 ~ 100%: ±2 digits 0 ~ 69%: unspecified
Pulse Rate Range	30 ~ 254 bpm
Pulse Rate Accuracy	±2 bpm

Test methods used in 2012.12.101.2 to establish SpO2 accuracy claims

1. Connect the SpO2 sensor to the SpO2 connector on the monitor. Set patient category as adult and PR source.
Go to SpO2.
2. Apply the SpO2 sensor to the ring finger of a healthy person.
3. Check the PLT waves and PR readings on the screen and ensure that the SpO2 shown is measured within the error range.
4. Remove the SpO2 sensor from the finger and verify that the SpO2 Sensor Off alarm is triggered.

Verification of measurement accuracy:
SpO2 accuracy was confirmed in human experiments compared to arteries.
Based on blood samples measured by CO-oximeter. Pulse oximeter measurements are made statistically.
Approximately two-thirds of the measurements must be within the specified accuracy range.
Compared to the CO-oximeter measurement.

SpO2 Specifications (Nellcor)	
SpO2 Range	0 ~ 100%
SpO2 Accuracy *The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values.	70 ~ 100%: ±3 digits 0 ~ 69%: unspecified
Pulse Rate Range	20 ~ 300 bpm
Pulse Rate Accuracy	20 ~ 250 bpm ±3 bpm 250 bpm: unspecified

NIBP Specifications	
Standard	Meets the requirements of ISO 80601-2-30: 2018
Method	Oscillometry with step deflation
Operation Mode	Manual/Automatic/Continuous
Measurement Range	**[Adult]** Systolic: 40 ~ 255 mmHg MAP: 26 ~ 220 mmHg Diastolic: 20 ~ 200 mmHg **[Pediatric]** Systolic: 40 ~ 230mmHg MAP: 26 ~ 183mmHg Diastolic: 20 ~ 160mmHg **[Neonate]** Systolic: 40 ~ 130mmHg MAP: 26 ~ 110mmHg Diastolic: 20 ~ 100mmHg

Accuracy	Mean error: less than ±5 mmHg Standard deviation: less than 8 mmHg

Temperature Specification	
Standard	meets the requirements of ISO 80601-2-56: 2018
Method	Thermal resistance
Operation mode	Direct mode
Measurement Range	0 ~ 50℃ (32 ~ 122℉)
Accuracy	25 ~ 45℃: ±0.1℃ Below 25℃, above 45℃: ±0.2℃
Compatibility	98ME04GA603 temperature probes

IR Temperature Specification	
Measurement Range	16 ~ 43℃ (61 ~ 110℉) Below 16℃ (61℉): not supported
Operation mode	Adjusted mode
Accuracy	±0.1℃ (±0.2℉)

Sidestream CO2	
Standard	meets the requirements of ISO 80601-2-55: 2018
Warm-up time	Full specifications within 2 minutes at an ambient temperature of 25º C. Capnogram in 15 seconds
Measurement Range	0 ~ 150 mmHg, 0 ~ 19%
Accuracy (at 760 mmHg, ambient temperature of 25℃)	0 ~ 40mmHg ±2 mmHg, 41 ~ 70mmHg ±5% of reading 71 ~ 100mmHg ±8% of reading, 101 ~ 150mmHg ±10% of reading (At respiration rates> 80 breaths per minute, all ranges are ±12% of

	actual.)
Respiration Rate	2 ~ 150 breaths per minute
Respiration Accuracy	±1 breath per minute
Rise Time	< 3 seconds (includes transport and rise time)
Sample Flow Rate	50 ml/min ±10 ml/min
Data sample rate	100 Hz

The test method used to determine the RATED respiration rate range and the corresponding effects of end-tidal GAS READING accuracy as a function of respiratory rate as required in 201.7.9.2.9 i) and j)

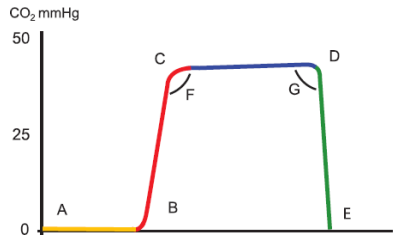
The method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources.

During the test, the valve is set to switch gas source at several frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the CAPNOSTAT is noted.

From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified.

The method used to calculate end-tidal GAS READINGS

Inspiratory and end tidal CO2 concentration readings are identified by CAPNOSTAT sensor using the lowest and highest values respectively of the temporal CO2-curve.



Phase I: A-B End of inspiratory phase and start of exhalation. Represents anatomical dead space

with no measurable CO2.

Phase II: B-C Early exhalation. Rapid rise in CO2 concentration as anatomical dead space is replaced with alveolar gas.

Phase III: C-D Alveolar Plateau. Corresponds to alveolar emptying. In the normal capnogram the alveolar plateau has a slight rise. The end of the alveolar plateau corresponds to the ETCO2 (D).

Phase IV: D-E Inspiration begins. Rapid downward stroke corresponds to the fresh gas which is essentially free of carbon dioxide. The capnograph falls to zero and then remains at zero baseline throughout inspiration.

Mainstream CO2	
Standard	Meets the requirements of ISO 80601-2-55: 2018
Warm-up time	Full specifications within 2 minutes at an ambient temperature of 25º C. Capnogram in 15 seconds
Measurement Range	0 ~ 150 mmHg, 0 to 19%
Accuracy (at 760 mmHg, ambient temperature of 25°C)	0 ~ 40mmHg ±2 mmHg, 41 ~ 70mmHg ±5% of reading 71 ~ 100mmHg ±8% of reading, 101 ~ 150mmHg ±10% of reading (At respiration rates> 80 breaths per minute, all ranges are ±12% of actual.)
Respiration Rate	2 ~ 150 breaths per minute
Respiration Accuracy	±1breath per minute
Rise Time	< 60 ms (Adult/pediatric adapters) < 60 ms (Infant/pediatric adapters)
Data sample rate	100 Hz

The test method used to determine the RATED respiration rate range and the corresponding effects of end-tidal GAS READING accuracy as a function of respiratory rate as required in 201.7.9.2.9 i) and j)

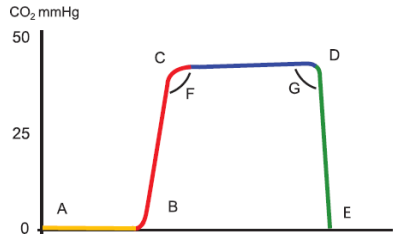
The method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources.

During the test, the valve is set to switch gas source at several frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the CAPNOSTAT is noted.

From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified.

The method used to calculate end-tidal GAS READINGS

Inspiratory and end tidal CO2 concentration readings are identified by CAPNOSTAT sensor using the lowest and highest values respectively of the temporal CO2-curve.



Phase I: A-B End of inspiratory phase and start of exhalation. Represents anatomical dead space with no measurable CO2.

Phase II: B-C Early exhalation. Rapid rise in CO2 concentration as anatomical dead space is replaced with alveolar gas.

Phase III: C-D Alveolar Plateau. Corresponds to alveolar emptying. In the normal capnogram the alveolar plateau has a slight rise. The end of the alveolar plateau corresponds to the ETCO2 (D).

Phase IV: D-E Inspiration begins. Rapid downward stroke corresponds to the fresh gas which is essentially free of carbon dioxide. The capnograph falls to zero and then remains at zero baseline throughout inspiration.

IBP Specifications	
Standard	Meets the requirements of IEC 60601-2-34: 2011
Channels	2 ch or 4 ch
Measurement Range	-50 ~ 300mmHg
Accuracy	±4 % of reading or ± 4 mmHg, whichever is greater (excluding sensor error)
Pulse Rate Measurement Range	20 ~ 300bpm
Zero Balancing	Range: ±200mmHg Accuracy: ±1mmHg Drift: ±1mmHg over 24hours
Transducer Sensitivity	5μV/V/mmHg

NMT Specifications	
Standard	Meets the requirements of IEC 60601-2-10:2016
stimulation mode	• TOF (Train Of Four), T4/T1, T4/Tcal calculate • ST (Single Twitch) 0.1 Hz and 1 Hz • TET (50 Hz Tetanus tonic stimulation) • DBS (Double Burst Stimulation) mode 3.3 or 3.2. • PTC (Post Tetanic Count)
near-acceleration sensor	3D near acceleration(10bits per ±8G, frequency: 200Hz, resolution 0.016G)
electrical stimulation	• Output current 20-60 mA (error: ±10%) (resistance value 4 Kohms) • Monophasic, stimulation time 200 μs, frequency 50 Hz • Stimulation electrodes or ECG electrodes: - Can withstand current of 60 mA to 300 V - Contact area: Minimum 1.8cm². Recommended Electrode Example: - 3M, RED DOT ref. 2560 - FIAB, F9047 Verify that the monitor is certified by an official customer or manufacturer in your country.

Anesthetic Gas (AG) Specifications		
Standard	Meets the requirements of ISO 80601-2-55: 2018	
Technique	Infrared absorption, paramagnetic properties for O_2 monitoring	
Warm-up time	≤10 min	
Sample flow rate	Adult, pediatric: Neonate: Accuracy:	200 ml/min 120 ml/min ±10 ml/min or ±10%, whichever is greater
Measurement range	CO_2: O_2: N_2O: Des: Sev: Enf: Iso: Hal: awRR:	0 to 30% 0 to 100% 0 to 100% 0 to 30% 0 to 30% 0 to 30% 0 to 30% 0 to 30% 2 to 100 rpm
Resolution	CO_2: O_2: N_2O: Des: Sev: Enf: Iso: Hal: awRR:	0.1% 1% 1% 0.1% 0.1% 0.1% 0.1% 0.1% 1 rpm

Full accuracy	**Gases**	**Range (%REL)[1]**	**Accuracy (%ABS)**
	CO_2	$0 \le CO_2 \le 1$ $1 < CO_2 \le 5$ $5 < CO_2 \le 7$ $7 < CO_2 \le 10$ $CO_2 > 10$	±0.1 ±0.2 ±0.3 ±0.5 Not specified
	N2O	$0 \le N2O \le 20$ $20 < CO_2 \le 100$	±2 ±3
	O_2	0 to 25 25 to 80 80 to 100	±1 ±2 ±3
	Des	0 to 1 1 to 5 5 to 10 10 to 15 15 to 18 >18	±0.15 ±0.2 ±0.4 ±0.6 ±1 Not specified
	Sev	0 to 1 1 to 5 5 to 8 >8	±0.15 ±0.2 ±0.4 Not specified
	Enf, Iso, Hal	0 to 1 1 to 5 >5	±0.15 ±0.2 Not specified
	awRR	2 to 60 rpm >60 rpm	±1 rpm Not specified
	Note1: The highest GAS LEVEL for a single halogenated anesthetic gas in a gas mixture that is concealed when the anesthetic concentration falls is 0.15/0.3% (Full/ISO accuracy)		
Accuracy drift	Meets the requirement for measurement accuracy within 6 hours		
Zero RR alarm delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s		
Refresh rate	1 s		
Rise time (10% ~ 90%)	Gas sample flow rate 120ml/min, using a DRYLINE II neonatal watertrap and sampling line (2.5m):		
	CO_2: ≤250 ms N_2O: ≤250 ms Hal, Iso, Sev, Des: ≤300 ms		

	Enf: ≤350 ms O_2: ≤600 ms
	Gas sample flow rate 200 ml/min, using the adult DRYLINE II watertrap and sampling line (2.5 m):
	CO_2: ≤250 ms N_2O: ≤250 ms Hal, Iso, Sev, Des: ≤300 ms Enf: ≤350 ms O_2: ≤500 ms
Delay time	<4 s
Response time	Measured with a DRYLINE II neonatal watertrap and a 2.5-meter neonatal sampling line: 120 ml/min: CO_2: ≤4s N_2O: ≤4.2s O_2: ≤4s Hal, Iso, Sev, Des, Enf: ≤4.4s
	Measured with a DRYLINE II adult watertrap and a 2.5-meter adult sampling line: 200 ml/min: CO_2: ≤4.2s N_2O: ≤4.3s Hal, Iso, Sev, Des, Enf: ≤4.5s O_2: ≤4s
Anesthetic agent limit	Primary anesthetic agent In full accuracy mode: 0.15%
	Secondary anesthetic agent: In full accuracy mode: 5% of primary agent if primary agent is greater than 10%, 0.3% if primary agent is less than or equal to 10%.
Data sample rate	25 Hz

Accuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15 rpm and I:E ratio smaller than 1:1 relative to the gas readings without breath; Add ±6%REL to inaccuracy for Hal and O_2 for breath rate larger than 15 rpm; Add ±6%REL to inaccuracy for all gases for breath rate larger than 30 rpm (inaccuracy for HAL and O_2 are unspecified in this case); inaccuracy is unspecified for breath rate larger than 60 rpm.

Effect of interference gases on AG measurements					
Gas	**Concentration (%)**	**Quantitative effect(%ABS)3)**			
		CO_2	**N_2O**	**Agent 1)**	**O_2**
CO_2	/	/	0.1	0	0.2
N_2O	/	0.1	/	0.1	0.2
Agent 1) 2)	/	0.1	0.1	0.1	1
Xenon	<100%	0.1	0	0	0.5
Helium	<50%	0.1	0	0	0.5
Ethanol	<0.1%	0	0	0	0.5
Acetone	<1%	0.1	0.1	0	0.5
Methane	<1%	0.1	0.1	0	0.5
Saturated Isopropanol vapour	/	0.1	0	0	0.5
Metered dose inhaler propellants	/	Unspecified	Unspecified	Unspecified	Unspecified
O_2	/	0.2	0.2	1.0	/

1) Agent represents one of Des, Iso, Enf, Sev, and Hal.

2) Multiple agent interference on CO_2, N_2O and O_2 is typically the same as single agent interference.

3) For CO_2, N_2O and Agents, maximum interference from each gas at concentrations within specified accuracy ranges for each gas. The total interference of all gases is never larger than 5%REL.

The test method used to determine the RATED respiration rate range and the corresponding effects of end-tidal GAS READING accuracy as a function of respiratory rate as required in 201.7.9.2.9 i) and j)

The effect of rise time distortion to the gas curve becomes apparent when the breathing rate increases so that the time for a full inspiratory or expiratory event gets shorter.

In those situations, due to the effect of the rise time, the gas curve does not reach the true end-tidal (or first inspired value) and the end-tidal gas value may then be underestimated.

Correspondingly, the first inspired value may be overestimated.

Below is an exaggerated illustration of the effect.

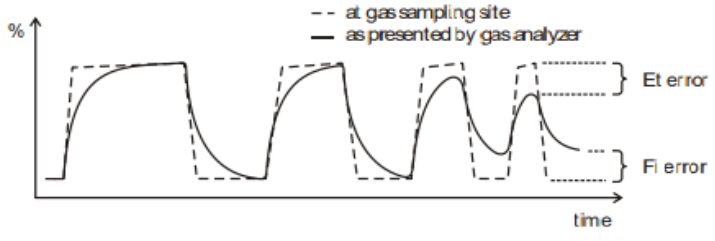


Figure - Gas curve distortion at high breath rates

The breath rate limit for accurately resolved end-tidal gas values (at an I:E ratio of 1:1) may be found in the respective technical specifications of Artema Technology® products.

The effect of other I:E ratios may be calculated by determining the length of the shortest inspiratory/expiratory event that can be resolved accurately:

$$t_{resolved} = 60 / (2 \times BR_{limit}(1:1)$$

$$BR_{limit}(I:E) = 60 / ((I + E) \times t_{resolved})$$

The difference in these results when compared to the rise time's specification is that rise time's only tests 10-90% performance.

This specification is for (0 + accuracy) to (100 -accuracy) % and is thus much tougher.

The ability to properly resolve end-tidal values can be measured by using the set-up described in ISO 80601-2-55:2011 figure 201.101. In short, the method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources. During the test, the valve is set to switch gas source at several frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the gas analyzer is noted. From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified.

The method used to calculate end-tidal GAS READINGS

Inspiratory and end tidal CO2 concentration readings are identified by AION™ Platinum Multigas Analyzers using the lowest and highest values respectively of the temporal CO2-curve. Corresponding readings of N2O and anesthetic agents are taken at the same point in time.

Inspiratory and end-tidal O2 concentration readings are identified by the O2 mean value during the respiratory phase as identified by the temporal CO2 curve.

Once correctly identified, the highest and lowest O2 concentration readings during each part of the phase is presented as inspiratory and end-tidal O2 respectively.

Operating Condition		
Temperature (°C)		10~40
Relative humidity (noncondensing) (%)		15~95
Barometric (mmHg)		430~790

ICG Specifications	
Method	Impedance

Input impedance	0-100 Ohm
Sample rate	250 samples/second, 32 bits/sample
Bandwidth	0.1-120 Hz
Display update	1s
Measurement range	CO : 0~20 l/min SV : 0~200 ml/beat SQI : 0~100 %
Artifact rejection	Yes

qCON Specifications	
Standard	Meets the requirements of IEC 60601-2-26: 2019
Method	EEG
EEG sensitivity	44.5 nV
Noise	<2μVp-p, (1–43 Hz)
CMRR (Common Mode Rejection Ratio)	>100dB
Input impedance	>1Mohm (10Hz)
Sample rate	1024 samples/s, 16 bits
Band width	2- 120 Hz
Max DC Input offset	±300 mV
Accuracy of Input Signal Reproduction	Compliance checked according to IEC 60601-2-26 Fig.201.104
Display update	1s
EEG range	±475 μV

Measurement range	qCON Index: 0 – 99, 1s. Index of depth of anesthesia. EMG: Curve, index 0-100 unitless, electromyogram SQI: Curve, index 0-100
Artifact rejection	Yes
Electrode impedance range	0-10 KOhm

6) Default Parameter Alarm Settings

Alarm		Level	Adult	Pediatric	Neonate
NIBP – S (mmHg)		Medium	80 – 200	60 – 160	40 – 100
NIBP – M (mmHg)		Medium	40 – 140	40 – 120	30 – 70
NIBP – D (mmHg)		Medium	20 – 120	30 – 100	20 – 60
NIBP- PR		Low	50 – 150	50 – 160	50 – 170
SpO_2		Low	90 – 100	90 – 100	88 – 100
SpO_2-Rate		Low	50 – 150	50 – 160	100 – 200
Temp1 (℃/℉)		Low	34.0/93.2 - 39.0/102.2	34.0/93.2 - 39.0/102.2	34.0/93.2 - 39.0/102.2
PVC Count		Low	0 – 20	0 – 20	0 – 20
ST(mV)		Low	-0.4 – 0.4	-0.4 – 0.4	-0.4 – 0.4
HR		Medium	50 – 150	50 – 160	100 – 200
Temp2 (℃/℉)		Low	34.0/93.2 - 39.0/102.2	34.0/93.2 - 39.0/102.2	34.0/93.2 - 39.0/102.2
△Temp(℃/℉)		Low	0.0/0.0 - 2.0/3.6	0.0/32.0 - 2.0/35.6	0.0/32.0 - 2.0/35.6
RR		Low	10 – 30	10 – 50	15 – 100
ZeroRR (seconds)		Low	20	20	15
IBP1,2 (mmHg)	Art-S	Low	70 – 150	70 – 150	40 – 100
	Art-M	Low	50 – 115	50 – 115	30 – 70
	Art-D	Low	40 – 100	40 – 100	20 – 50
	Art-PR	Low	50 – 150	50 – 150	50 – 170
	Fem-S	Low	70 – 150	70 – 150	40 – 100
	Fem-M	Low	50 – 115	50 – 115	30 – 70
	Fem-D	Low	40 – 100	40 – 100	20 – 50

	Fem-PR	Low	50 – 150	50 – 150	50 – 170
	PAP-S	Low	20 – 50	20 – 50	40 – 100
	PAP-M	Low	10 – 40	10 – 40	30 – 70
	PAP-D	Low	5 – 30	5 – 30	20 – 50
	PAP-PR	Low	50 – 150	50 – 150	50 – 170
	RAP-M	Low	3 – 15	3 – 15	3 – 15
	LAP-M	Low	3 – 15	3 – 15	3 – 15
	UAP-S	Low	70 – 150	70 – 150	40 – 100
	UAP-M	Low	50 – 115	50 – 115	30 – 70
	UAP-D	Low	40 – 100	40 – 100	20 – 50
	UAP-PR	Low	50 – 150	50 – 150	50 – 170
	UVP-M	Low	3 – 15	3 – 15	3 – 15
	CVP-M	Low	3 – 15	3 – 15	3 – 15
	ICP-M	Low	3 – 15	3 – 15	3 – 15
	User-S	Low	70 – 150	70 – 150	40 – 100
	User -M	Low	50 – 115	50 – 115	30 – 70
	User -D	Low	40 – 100	40 – 100	20 – 50
	User -PR	Low	50 – 150	50 – 150	50 – 170
EtCO2(mmHg)		Low	25 – 50	25 – 50	25 – 50
FiCO2(mmHg)		Low	0 – 5	0 – 5	0 – 5
AwRR		Low	10 – 30	10 – 50	15 – 100
EtCO2-ZeroRR (seconds)		Low	20	20	20
IBP3		Low	Same as IBP1,2		
IBP4					
Gas(AG)-EtCO2(mmHg)		Medium	25 – 50	25 – 50	30 – 45
Gas(AG)-FiCO2(mmHg)		Medium	0 – 4	0 – 4	0 – 4
Gas(AG)-AwRR		Medium	10 – 30	10 – 50	15 – 100
Gas(AG)-ZeroRR (seconds)		Medium	20	20	20
EtN2O (%)		Medium	0.0 – 55.0	0.0 – 55.0	0.0 – 55.0
FiN2O (%)		Medium	0.0 – 53.0	0.0 – 53.0	0.0 – 53.0
EtO2 (%)		Medium	18.0 – 88.0	18.0 – 88.0	18.0 – 88.0
FiO2 (%)		High	18.0 – 100.0	18.0 – 100.0	18.0 – 90.0
EtDes (%)		Medium	0.0.0 – 8.0	0.0 – 8.0	0.0 – 8.0
FiDes (%)		Medium	0.0 – 6.0	0.0 – 6.0	0.0 – 6.0
EtEnf (%)		Medium	0.0 – 3.0	0.0 – 3.0	0.0 – 3.0
FiEnf (%)		Medium	0.0 – 2.0	0.0 – 2.0	0.0 – 2.0
EtHal (%)		Medium	0.0 – 3.0	0.0 – 3.0	0.0 – 3.0

FiHal (%)	Medium	0.0 – 2.0	0.0 – 2.0	0.0 – 2.0
EtIso (%)	Medium	0.0 – 3.0	0.0 – 3.0	0.0 – 3.0
FiIso (%)	Medium	0.0 – 2.0	0.0 – 2.0	0.0 – 2.0
EtSev (%)	Medium	0.0 – 6.0	0.0 – 6.0	0.0 – 6.0
FiSev (%)	Medium	0.0 – 5.0	0.0 – 5.0	0.0 – 5.0
ICG (CO) (L/min)	Low	4.0 – 8.0	4.0 – 8.0	4.0 – 8.0
SV (mL)	Low	60 – 100	60 – 100	60 – 100
ICG - SQI	Low	50 – 100	50 – 100	50 – 100
qCON	Low	40 – 60	40 – 60	40 – 60
EMG	Low	50 – 100	50 – 100	50 – 100
qCON – SQI	Low	50 – 100	50 – 100	50 – 100

7) Default Technical Alarm Settings

Biosignal Class	Technical Alarm	Level	Status & Solution
ECG	Module Error	Low	Occurs when communication is not possible due to a module failure, etc. (If the problem persists, contact your service representative.)
	Cable Off	Low	Occurs when no cable is connected. Check the cable connections.
	Lead Fault	Low	Occurs when the lead has fallen. Check lead attachment.
	Saturation	Low	Check lead attachment.
SpO2	Module Error	Low	Occurs when communication is not possible due to a module failure, etc. (If the problem persists, contact your service.)
	Probe Disconnected	Low	Occurs if the cable or probe is not connected. Check the cable connection.
	Probe Off	Low	Occurs when the reusable finger probe is removed from the patient. Check out the probe.

	Poor Signal	Low	Occurs when an interruption in the pulse is detected repeatedly. Check patient and probe location.
	Lost Pulse	Low	SpO2 data is displayed continuously, but the quality of the signal is questionable. Check the patient and probe location.
	Artifact	Low	This indicates when you have trouble breathing. Check to see if these noises are abnormal or irregular.
	Pulse Search	Message	Occurs when an interruption in the pulse is detected repeatedly. Check the patient and probe location.
	Interference	Low	The SpO2 signal has interference. Check for any possible sources of signal noise and check the patient for excessive motion.
	Wrong sensor	Low	Occurs when the wrong sensor is connected. Make sure it is a Nellcor sensor.
	Sensor Fault	Low	If the alarm persists, contact your service representative.
Resp	Module Error	Low	Occurs when communication is not possible due to a module failure, etc. (If the problem persists, contact your service.)
	Cable Off	Low	Occurs when no cable is connected. Check the cable connections.
	Lead Fault	Low	Occurs when the lead has fallen. Check lead attachment.
	Saturation	Low	Check lead attachment.
NIBP	Module Error	Low	Occurs when communication is not possible due to a module failure, etc. (If the problem persists, contact your service.)
	Over Pressure	Low	When the cuff pressure is excessive
	Overtime Pressure	Low	Occurs when pressure is applied for more than a specified time.
	NIBP Overrange	Low	The measured NIBP value exceeds the module measurement range. Check the patient's condition.

	NIBP Airway Error	Low	The air tubing may be occluded. Check the air tubing for an occlusion or kinking. If the alarm persists, contact your service representative.
	Weak Signal	Low	The patient's pulse is weak or the cuff is loose. Check the patient's condition and replace the cuff application site.
	Air Leak or Loose Cuff	Low	There is a leak in the cuff or air tubing or pump. Use a cuff of correct type based on the patient size. Apply the cuff and connect the air tubing as instructed in the manual.
	Excessive Motion	Low	Check the patient's condition and reduce patient motion.
	System Fault	Low	If the alarm persists, contact your service representative.
Temp	Module Error	Low	Occurs when communication is not possible due to a module failure, etc. (If the problem persists, contact your service representative.)
	TEMP-1-PROBE OFF	Low	Occurs when no cable is connected. Check the cable connections.
	TEMP-2-PROBE OFF	Low	
IR-Temp	Module Off	Low	Check the module connections. Disconnect and reconnect the module cable
IBP	Module Error	Low	Occurs when communication is not possible due to a module failure, etc. (If the problem persists, contact your service representative.)
	Cable Off	Low	Occurs when no cable is connected. Check the cable connections.
	Pulse Search	Message	Finding pulses.
EtCO2	Module Off	Low	Check the module connections. Disconnect and reconnect the module cable
	Sensor Over Temp	Low	Ambient temperature is too high or there is a module failure. 1. Lower the operating temperature. 2. Reinsert the module. 3. If the alarm continues, the CO2 module may have failed, contact your service representative.

	Sensor Faulty	Low	Check that the sensor is properly plugged in. Reinsert or reset the sensor if necessary. If error persists, return sensor to factory for servicing.
	Check Sampling Line	Low	Check that the sampling line is not occluded or kinked.
	Zero Required	Low	Check airway adapter and clean if necessary. If this does not correct the error, perform an adapter zeroing. If you have to do adapter zeroing more than once, there can exist an error in the hardware.
	CO2 out of range	Low	If alarm persists, perform a zero calibration.
	Check Adapter	Low	It usually occurs when the airway adapter is removed from the module or when there is an optical blockage on the windows of the airway adapter. It may also be caused by failure to perform zeroing when the adapter type is changed. To clear, clean airway adapter if mucus or moisture is visible. If the adapter is clean, perform zeroing.
	Sample line disconnected	Low	Check that the sampling line is not occluded or kinked.
Anesthetic Gas (AG)	Module Off	Low	Check the module connections. Disconnect and reconnect the module cable
	No Watertrap	Low	Check the connections of the watertrap and re-connect it.
	Change Watertrap	Low	Replace the watertrap.
	Watertrap Type Mismatch	Low	Check the patient category and use a correct watertrap.
	Zero Failed	Low	There is external electromagnetic interference, airway occlusion or module failure. 1. Check for external inference sources. 2. Check for "Airway Occluded" alarm

			message. Remove the occlusion. 3. If the alarm persists, contact your service representative.
	Calibration Error	Low	When the alarm persists, contact your service representative.
	Airway Occluded	Low	1. Check if the sample line is occluded. 2. Replace the sample line. 3. Reinsert the module. If the alarm persists, contact your service representative.
	Unspecified accuracy	Low	When the alarm persists, contact your service representative.
	Data limit error	Low	When the alarm persists, contact your service representative.
	HW error	Low	When the alarm persists, contact your service representative.
	SW error	Low	When the alarm persists, contact your service representative.
	Pump error	Low	When the alarm persists, contact your service representative.
	Temp/Press Error	Low	When the alarm persists, contact your service representative.
	IR signal Error	Low	When the alarm persists, contact your service representative.
	Motor speed Error	Low	When the alarm persists, contact your service representative.
	O2 Error	Low	When the alarm persists, contact your service representative.
ICG	Module Off	Low	Check the module connections. Disconnect and reconnect the module cable
	No Signal	Low	Indicates that the recorded signal does not match the expected impedance signal. This condition primarily reflects the lead-off situation, but can also reflect persistent and high electrical interference, such as electrocautery.

qCON	Module Off	Low	Check the module connections. Disconnect and reconnect the module cable
	Lead Off	Low	Check the condition of cables and electrodes.
NMT	Module Off	Low	Check the module connections. Disconnect and reconnect the module cable
	Cable Off	Low	Occurs when no cable is connected. Check the cable connections.
	Lead Fault	Low	Occurs when the lead has fallen. Check lead attachment.
System	Low Battery	Low	The battery is very low. Immediately connect the monitor to the AC adapter.

8) Default Display Settings

Item	Default Setting
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	I
Alarm volume	50%
QRS volume	Off
Pulse volume	Off
Units for height	cm
Units for weight	kg
Temperature units	℃

Blood pressure units	mmHg
EtCO2 units	mmHg
AG units	%
NIBP limit type	Systolic
ECG filter	Monitor
PVCs	ON
ST	ON

PART 26. Abbreviations and Symbols

Abbreviations and symbols are alphabetized by reference, which can be read while reading the manual or using the patient monitor..

1) Abbreviations

A	amps
AC	alternating current
ADT	adult
AG	Anesthetic Gas
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,	minute
MM, mm	millimeters
MM/S	millimeters per second
MMHG, mmHg	millimeters of mercury
mV	millivolt

N

NIBP	non-invasive 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)

Y

Z

2) Symbols

&	and
°	degree(s)
>	greater than
<	less than
–	minus
#	number
%	percent
±	plus or minus

Caution	**Please read this operation manual before operating the patient monitor. Keep it well for future reference.**

Brio X30/Brio X50/Brio X70 User Manual

The entire manual should be carefully read.

This manual contains information on limitations, cautions, and warnings associated with the use of the Brio patient monitors.

Regardless of the complexity of the equipment, patient monitoring device should never be used to replace human care, attention, and judgement by trained health professionals.

PRODUCT WARRANTY

Product Name	**Patient Monitor**
Model Name	**Brio X30 / Brio X50 /Brio X70**
Approval Number	
Approval Date	
Serial Number	
Warranty Period	**1 year from date of purchase**
Date of Purchase	
Customer section	**Hospital Name:** **Address:** **Name:** **Phone:**
Sales Agency	
Manufacturer	

※ Thank you for purchasing Patient monitor Siri.

※ This monitor is a medical device.

※ The monitor is manufactured and passed through strict quality control and through inspection.

※ Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's Protection Law" noticed by Korea Fair Trade Commission.

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