BeneHeart D6/BeneHeart D5

Defibrillator/Monitor

White Paper

CE 2797

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Intellectual Property Statement

Responsibility on the Manufacturer Party

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WARNING

This equipment must be operated by skilled/trained clinical professionals.

It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

Warranty

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Exemptions

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Notification of Adverse Events

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1 Safety

1.1 Safety Information

DANGER

Indicates an imminent hazard that, if not avoided, will result in death or serious injury.

WARNING

Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

Provides application tips or other useful information to ensure that you get the most from your product.

1.1.1 Dangers

DANGER

The equipment delivers up to 360 J of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this defibrillator unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

Defibrillation current can cause operator or bystander severe injury or even death. Keep distance from the patient or metal devices connected to the patient during defibrillation.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Keep the equipment and the operating environment dry and clean.

1.1.2 Warnings

WARNING

Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.

Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on smart lithium-ion batteries.

Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure leads to the loss of patient data.

Use and store the equipment in specified environmental condition. The equipment and accessories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.

This equipment is used for single patient at a time.

The equipment is not intended to be used within the Magnetic Resonance (MR) environment.

Before each use, the operator must check the equipment condition to ensure that the equipment is ready for operation.

Medical electrical equipment which does not incorporate defibrille

devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

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 or in this white paper.

Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.

Dry the equipment immediately in case of rain.

Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.

1.1.4 Notes

NOTE

Put the equipment in a location where you can easily view and operate the equipment.

The equipment uses a mains plug ma [he 3 main

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2 The Basics

2.1 Intended Use

2.1.1 Intended Purpose Statement

2.1.2 Indication for Use

2.1.6 Contra-indications

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2.1.7 Side-effects

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2.1.8 Clinical Benefit

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2.2 Applied Parts

WARNING

When the equipment is placed at a an ambient temperate above 45°C, the surface temperature of applied parts should be limit to below 47°C.

3 Basic Operations and Settings

3.1 Equipment Installation

WARNING

The equipment shall be installed by personnel authorized by the manufacturer.

The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

Devices connected to the equipment 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 equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact the manufacturer.

If it is not evident from the equipment specifications whether a particular combination is hazardous, for example, due to summation of leakage currents, consult the manufacturers or else an expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.

CAUTION

The docking station is part of the equipment. Use only the specified docking station.

3.1.1 Unpacking and Checking

WARNING

When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.

The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.

NOTE

Save the packing case and packaging material as they can be used if the equipment must be reshipped.

3.1.2 Environmental Requirements

NOTE

Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.

The equipment use a mains plug as isolation means to the mains power supply. Do not locate the equipment in a place difficult to operate the mains plug.

3.2 Basic Operation

3.2.1 Connecting the AC Mains

WARNING

Always use the accompanying power cord delivered with the equipment.

Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated besides the AC power input.

Use the cable retainer to secure the power cord to prevent it from falling off.

Use the battery if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.

3.2.2 Turning On the Equipment

4 Alarms

WARNING

A potential hazard exists if different alarm presets are used for the same or similar device in any single area, e.g. an intensive care unit or cardiac operating room.

If the equipment is connected to a CMS, remote suspension, inhibition, silence and reset of monitoring alarms via the CMS may cause a potential hazard. For details, refer to the operator's manual of the CMS.

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. Always make sure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.

4.1 Alarm Indicators

NOTE

When multiple alarms of different levels occur simultaneously, the equipment will select the alarm of the highest level and give visual and audible alarm indications accordingly. Alarm messages will be displayed circularly.

Some physiological alarms, such as Asystole, are exclusive. They have identical alarm tones and alarm lights with normal high level physiological alarms, but their alarm messages are displayed exclusively. That is to say, when an exclusive physiological alarm and a normal high level physiological alarms are triggered simultaneously, only alarm message of the exclusive physiological alarm is displayed.

4.2 Alarm Tone Configuration

4.2.1 Changing the Alarm Volume

NOTE

You cannot adjust the alarm volume when an alarm is switched off.

4.2.2 Setting the Interval between Alarm Sounds

WARNING

Do not rely exclusively on audible alarm system. Setting alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.

4.3 Understanding the Alarm Setup Menu

4.3.1 Setting Alarm Properties for All Parameters

WARNING

Make sure that the alarm limits settings are appropriate for your patient before patient monitoring.

Setting the alarm limit to an extreme value may cause the alarm system to be ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration, do not set the SpO_2 high alarm limit to 100%, which is equivalent to switching the alarm off.

When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.

NOTE

You cannot simultaneously switch on HR and PR alarms. In the case that PR alarm is on, switching on HR alarm will automatically turn off PR alarm, and vice versa.

4.3.2 Adjusting Alarm Limits Automatically

NOTE

You can enable auto alarm limits only when the current parameter measurement is within the auto alarm limits range.

5 Monitoring ECG

5.1 ECG Safety Information

WARNING

ECG monitoring is not suitable for direct cardiac application.

Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.

Use defibrillation-proof ECG cables during defibrillation.

When monitoring a patient implanted with a pacemaker, be sure to select correct paced status. Otherwise, the pace pulses may be counted in the case of cardiac arrest or some arrhythmias. Do not completely rely on the heart rate reading or the heart rate alarms. Always keep paced patients under close surveillance.

PACEMAKER PATIENTS – On ventricular paced patients, episodes of Ventricular Tachycardia may not

5.2.2 Checking Paced Status

5.4.2 Initiating Arrhythmia Relearning Manually

NOTE

Arrhythmia relearning in the case of ventricular tachycardia may affect correct arrhythmia alarm.

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6 Resting 12-Lead ECG Analysis

6.1 Placing 10-leadwire Electrodes

WARNING

When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.

When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.

6.2 Entering the 12-lead ECG Screen

NOTE

If the equipment is powered by AC mains, you should set [Notch Filter] [On] to avoid interference on the 12-Lead ECG acquisition and display.

6.3 Changing 12-Lead ECG Analysis Settings

6.3.1 Enabling Patient Information Input Prompt

NOTE

It is recommended to turn on the patient information input prompt for your convenience to check the patient information before you start 12-lead ECG analysis.

6.3.2 Setting the Baseline Drift Removal

NOTE

The baseline drift removal introduces around 1-second delay. We recommend using BDR except when the delay is unacceptable.

The baseline correction function is only for 12-lead ECG monitoring. In 3-lead or 5-lead ECG monitoring, this function is disabled.

6.3.3 Setting Tachy and Brady Threshold

NOTE

The [Tachy (Adu)] setup is only effective for patients at the age of 18 or above.

The [Brady (Adu)] setup is only effective for patients at the age of 13 or above.

6.4 Initiating Resting 12-lead ECG Analysis

CAUTION

Keep the patient still while acquiring or analyzing 12-lead ECG. Motion of patient can lead to potential misdiagnosis.

NOTE

Always input the correct patient information before you start 12-Lead ECG analysis because the patient information, especially age, gender, and race, greatly affect the interpretation of the acquired ECG.

If no patient information is inputted, the system will interpret the acquired ECG on the basis of a default of a 50 years old Caucasian male, which may result in misdiagnosis.

The Lead Select hard key is disabled in the 12-lead ECG screen.

During 12-lead ECG acquisition or analysis, you cannot select a parameter area to enter the parameter setup menu. The Main Menu button and the Event button on the front panel are also disabled.

The filter mode is set to [ST] automatically for 12-lead ECG acquisition and analysis.

If the defibrillator is on a moving vehicle, stop the vehicle when acquiring 12-lead ECG.

7 AED

7.1 AED Safety Information

DANGER

Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any metal objects connected to the patient (including the bed or gurney) during defibrillation.

Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.

Do not allow electrode pads to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.

WARNING

During defibrillation, air pockets between the skin and electrode pads can cause patient skin burns. To help prevent air pockets, make sure electrode pads are completely adhered to the skin.

Do not use dried-out electrode pads.

CAUTION

Aggressive handling of electrode pads in storage or prior to use can damage the electrode pads. Discard the electrode pads if they become damaged.

For patients with implantable pacemaker, the sensitivity and specificity of AED algorithm may be impaired.

NOTE

Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of equipment performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or equipment performance.

7.2 AED Procedure

NOTE

Anterior - lateral placement for adult patients, and anterior-posterior placement for pediatric patients are recommended placements for defibrillation with electrode pads.

For defibrillation of pediatric patients under 8 years, pediatric electrode pads should be used.

If pediatric electrode pads are not available, the adult electrode pads may be used instead, and set the patient category to [Ped].

Motion artifact may delay analysis or affect the ECG signal resulting in an inappropriate shock or no shock advised message. Keep the patient still during ECG rhythm analysis.

The Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.

Impedance is the resistance between the electrode pads/external paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient

to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. If the "Impedance too high. Shock not delivered" message appears, make sure that the patient's skin has been dried and that any chest hair has been clipped. If the message persists, change the electrode pads and/or the pads cable.

7.3 CPR

NOTE

You can start analyzing patient's heart rhythm again at any time by pressing the [Resume Analyzing] soft key in the CPR status.

8 Manual Defibrillation

8.1 Manual Defibrillation Safety Information

DANGER

Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any metal objects connected to the patient (including the bed or gurney) during defibrillation.

Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.

Do not allow electrode pads and paddles to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.

During manual defibrillation, make sure your hands are dry and free from conductive gel to avoid shock hazard.

Use care when operating this equipment close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation. This can cause an explosion hazard.

WARNING

During synchronized cardioversion, if monitoring patient's ECG through external paddles, artifact introduced by paddle movement may resemble an R-wave and trigger a defibrillation shock.

Do not use conductive liquid. Use only conductive gel specified by the equipment manufacturer.

If external paddles are used for defibrillation, apply the external paddles tightly and evenly to the patient's chest to ensure good skin contact.

Never apply the paddles to human body to verify paddle connection.

Clinicians must select an appropriate energy level for defibrillation of pediatric patients.

Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.

CAUTION

Use of Manual Defib mode may be password protected. Make sure the operator knows and remembers the password as defined in Configuration. Failure to enter correct password will prevent the delivery of manual defibrillation therapy.

Clear the conductive gel from the external paddles at the completion of the therapy to prevent the paddles from being corroded.

Prior to using the equipment, disconnect the patient from all equipment that is not defibrillator-protected.

Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.

NOTE

Impedance is the resistance between the electrode pads/external paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. If the "Impedance Too High, Shock Not Delivered" message appears, make sure that the patient's skin has been dried and that any chest hair has been clipped. If the message persists, change the electrode pads and/or the pads cable.

Alarms are switched off automatically and the "Alarm Off" message is displayed when the equipment enters the asynchronous defibrillation mode. Alarms remain off until toggled on by pressing the Alarm Pause button, the Sync mode, the Monitor mode or Pacer mode is entered.

Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of equipment performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or equipment performance.

8.2 Manual Defibrillation Procedure

WARNING

Hold only the insulating parts of the paddle handles to avoid shock hazard during charging or shock delivery.

NOTE

Anterior - lateral placement for adult patients, and anterior-posterior placement for pediatric patients are recommended placements for defibrillation with electrode pads.

Anterior - lateral placement is the only placement for defibrillation with external paddles

8.3 Synchronized Cardioversion

CAUTION

Using internal paddles for synchronized cardioversion requires that the patient's ECG be acquired through a standard ECG cable. The patient's ECG acquired through the internal paddles may be unreliable for synchronized cardioversion due to excessive noise or artifact causing inappropriate R-wave detection.

NOTE

When you access synchronized cardioversion, monitoring alarms is reactivated autonomously.

8.3.1 Performing Synchronized Cardioversion

NOTE

During synchronized cardioversion, it is important to continue to hold the shock button (or the paddle's Shock buttons) until the shock is delivered. The equipment shocks with the next detected R-wave.

8.4 Remote Synchronized Cardioversion

NOTE

During remote synchronized cardioversion, the local equipment does not display the ECG waveform. To view the patient's ECG, check the remote monitor.

When you use a remote monitor as the ECG source, a biomedical technician must verify that the remote monitor and the equipment combination will deliver a synchronized shock within 60 ms after the peak of the next R-wave is generated.

8.5 Patient Contact Indicator

NOTE

It is recommended to perform the defibrillation on a patient when the patient contact indicator is illuminated in green. If the patient contact indicator is illuminated in yellow, it also can be used for the defibrillation. However, the expected effects may not be achieved in this condition.

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9 CPR Assistance

9.1 CPR Assistance Introduction

WARNING

Perform CPR on a patient on firm ground if possible. When you perform CPR on a patient lying on a mattress, a backboard must be used to limit the amount of compressed depth which is absorbed by the mattress. Depending on characteristics of the mattress, backboard and patient, the compensation depth does not guarantee that the patient chest is compressed by 50 mm.

When the patient is breathing with high frequency or in the treatment of high-frequency ventilation, the CPR assistance disturbed by the thoracic movements may provide inaccurate feedback. You should count compressions by yourself and not rely on the compression rate provided by the CPR assistance in such conditions.

The CPR assistance is not intended for use in a moving environment, such as an ambulance. If used during patient transport, the CPR assistance may provide inaccurate feedback. If CPR is indicated in a moving environment, do not rely on feedback provided by the CPR assistance in such conditions.

NOTE

The CPR sensor is not available in the markets of UK, Germany and France.

9.2 Using CPR Metronome

WARNING

The CPR metronome sounds do not indicate information regarding the patient's condition. Because patient status can change in a short time, the patient should be assessed at all times. Do not perform CPR on a patient who is responsive or is breathing normally.

NOTE

The CPR metronome is disabled when [Voice Prompts] in the AED Setup menu is configured off through the Configuration Main menu.

The volume of CPR metronome is affected by [Voice Volume] in the AED Setup menu configured through the Configuration Main menu.

9.3 Using CPR Filter

CAUTION

The CPR filter works only when you perform CPR using electrode pads or the CPR sensor in the AED or Manual Defib mode.

The CPR filter will not remove all CPR artifact. You should always follow the standard procedure of stopping CPR to verify the patient's ECG rhythm before making treatment decisions.

The filtered ECG waveform must be used in conjunction with clinical signs and symptoms. It should not be used as the sole basis for diagnosis or therapy decisions.

NOTE

There is a slight delay between the original and filtered ECG waveforms.

9.4 Reviewing CPR Events

NOTE

A CPR event is automatically saved in the equipment when the interruption time exceeds five minutes.

You should select [Refresh] to save a CPR event before disconnecting the CPR sensor from the equipment.

10 Noninvasive Pacing

10.1 Pacing Introduction

NOTE

In the Pacer mode, arrhythmia analysis is supported and available arrhythmia alarms are asystole, ventricular vibrillation and ventricular tachycardia.

10.2 Pacing Safety Information

WARNING

Heart rate displays and alarms function during pacing, but they can be unreliable. Observe the patient closely while pacing. Do not rely on the indicated heart rate or heart rate alarms as a measure of the patient's perfusion status.

To avoid explosion hazard when pacing a patient who is receiving oxygen delivery, properly route the oxygen delivery tube. Do not keep it close to the electrode pads.

Monitoring ECG alone is sometimes not enough to verify that the patient's heart is providing cardiac output.a patient's response to pacing shall be verified by signs of improved cardiac output, such as: a palpable pulse rate the same as the rate which pace pulses are being delivered, a rise in blood pressure, and/or improved skin color.

CAUTION

Use of Pacer mode may be password protected. Make sure the operator knows and remembers the password as defined in Configuration. Failure to enter correct password will prevent the delivery of pacing therapy.

For treatment of patients with implanted devices such as permanent pacemakers or cardioverter-defibrillators, consult a physician and the instructions for use provided by the device's manufacturer

Prolonged noninvasive pacing may cause patient skin irritation and burns. Periodically inspect the underlying skin and change ECG electrodes and electrode pads.

NOTE

If pacing is interrupted for any reason, the [Start Pacing] soft key must be pressed to resume pacing.

In the Pacer mode, you cannot change the patient's internal paced status from the [ECG Setup] menu.

In the case that electrode pads poorly contact the patient, the alarm "Pacer Stopped Abnormally" and "Pads Off" may be presented.

Electrode pads are not an available choice for the source of ECG waveform in the Pacer mode.

10.3 Pacer Mode

CAUTION

Use demand mode pacing whenever possible. Use fixed mode pacing if noise or artifact interferes with proper sensing of R-wave or when monitoring electrodes are not available.

During fixed mode pacing, R-wave markers do not appear on the paced beats.

During demand mode pacing, spontaneous beats may be presented which are not associated with the delivery of pace pulse. If the patient's heart rate is above the pacer rate, pace pulses are not delivered and, therefore, pace markers do not appear.

10.4 Preparing for Pacing

10.4.1 Demand Mode Pacing

CAUTION

Routinely assess the patient's cardiac output.

NOTE

Pacing will not start if there is a problem with the pads cable connection, pad patient connection, or ECG monitoring electrodes connection. If any situation occurs, a message will appear in the pacer information area to alert you that a lead is disconnected or that the electrode pads have a poor connection.

10.4.2 Fixed Mode Pacing

WARNING

Use care when handling the electrode pads on the patient to avoid shock hazard during pacing.

If you are using the pacing function with battery power and the Low Battery alarm is presented, connect the equipment to external power or install a fully charged battery.

CAUTION

The monitoring or pacing function may be unstable in the presence of ESU or other electronic devices.

11 Monitoring Resp

11.1 Resp Safety Information

WARNING

When monitoring the patient's respiration, do not use ESU-proof ECG cables.

The respiration measurement does not recognize obstructive and mixed apneas: it only indicates an alarm when a pre-adjusted time had elapsed since the last detected breath. The safety and effectiveness of the respiration measurement method in the detection of apnea, especially the apnea of prematurity and apnea of infancy, has not been established.

11.2 Placing Resp Electrodes

NOTE

To optimize the respiration waveform, place the RA and LA electrodes horizontally when monitoring respiration with ECG Lead I; place the RA and LL electrodes diagonally when monitoring respiration with ECG Lead II.

11.2.1 Optimizing Lead Placement for Resp

NOTE

Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.

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12 Monitoring PR

12.1 PR Introduction

NOTE

A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.

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13 Monitoring SpO_2

13.1 SpO_2 Safety Information

WARNING

When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

Do not use SpO_2 sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns.

Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For neonates or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.

If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.

When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize inteq a mic a ra y xhd %

NOTE

Additional information specific to the Masimo sensors compatible with the equipment, including information about parameto

14 Monitoring NIBP

14.1 NIBP Introduction

NOTE

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.

14.2 NIBP Safety Information

WARNING

Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise it may present a safety hazard.

Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.

Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.

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

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 readings, determines the patient's vital signs by alternative means and then verify that the equipment is working correctly.

Do not use the NIBP cuff on the arm on the side of a mastectomy or lymph node clearance.

Continuous CUFF pressure due to connection tubing kinking may cause blood flow interference and resulting harmful injury to the patient.

NIBP diagnostic significance must be decided by the physician.

14.3 NIBP Measurement Procedure

14.3.1 Preparing the Patient

NOTE

It is recommended that the patient relaxes as much as possible before performing measurement and that the patient does not talk during NIBP measurement.

It is recommended that 5 min should elapse before the first reading is taken.

A wrong cuff size and a folded or twisted bladder can cause inaccurate measurements.

Do not touch or apply external pressure against the cuff and air tubing during NIBP measurement. This may cause inaccurate blood pressure values.

14.3.2 Starting Auto NIBP Measurements

WARNING

Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormity occurs, move the cuff to anop y □ □ q m arem eo

15 Monitoring Temp

15.1 Temp Measurement Procedure

NOTE

Verify that the probe detection program works correctly before Temp monitoring. If plug out the probe cable from the T1 or T2 connector, the equipment shall give an alarm and display corresponding message correctly.

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16 Monitoring IBP

16.1 IBP Safety Information

WARNING

Use only pressure transducers specified in this white paper. Never reuse disposable pressure transducers.

Make sure that the applied parts never contact other conductive parts.

To reduce the hazard of burns during high-frequency surgical procedure, ensure that the equipment's cables and transducers never come into contact with the high-frequency surgical units.

When accessories are used, make sure the operation environment meets the requirements for accessory's operation temperature specified by the instructions for use.

16.2 IBP Measurement Procedure

NOTE

If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubble may lead to wrong pressure reading.

If measuring intracranial pressure (ICP) for a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect reading.

16.3 IBP Troubleshooting

NOTE

For the physiological and technical alarm messages, refer to *E Alarm Messages*.

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17 Monitoring CO_2

17.1 CO_2 Safety Information

WARNING

Remove the airway sampling line from the patient's airway while nebulized medications are being delivered.

Leakage in the breathing or sampling system may cause the displayed $EtCO_2$ values to be significantly low. Always make sure that all components are securely connected.

$EtCO_2$ values measured from the CO_2 module may differ from those of from the blood gas analysis.

Route all tubing away from the patient's throat to avoid strangulation.

Inspect the airway adapter for a tight connection and proper operation before attaching it to the patient.

Squeezing or bending the sampling line during the CO_2 measurement may cause inaccurate CO_2 reading or no reading.

17.2 Preparing for Measuring CO_2

CAUTION

Connect the gas outlet to the scavenging system when measuring CO_2 using the sidestream CO_2 module.

To avoid blocking the airway, empty the DRYLINE II watertrap container whenever half full. Replacing the DRYLINE II watertrap once a month is recommended.

The watertrap has a filter preventing bacterium, water and secretions from entering the module. Extended use could destroy the filter in watertrap and fail to stop the bacterium, water and secretions entering the module, result in damaging the gas module and having infection risk.

NOTE

Do not apply adult watertrap to the neonate patient. Otherwise, patient injury could result.

To extend the lifetime of the watertrap and module, disconnect the watertrap from the module and set the operating mode to Standby mode when CO_2 monitoring is not required.

The emptying interval of the DRYLINE II adult/pediatric watertrap is 31 hours @ 100 ml/min, sample gas of 37 °C, room temperature of 23 °C, 100% RH.

The emptying interval of the DRYLINE II neonatal watertrap is 45 hours @ 70 ml/min, sample gas of 37 °C, room temperature of 23 °C, 100% RH.

17.2.1 Measuring CO_2 Using the Microstream CO_2 Module

CAUTION

Do not apply adult watertrap to the neonate patient. Otherwise, patient injury could result.

Connect the gas outlet to the scavenging system when measuring CO2 using the microstream CO2 module.

NOTE

Disconnect the sampling line from the module when CO_2 monitoring is not required.

When sample gas of 37 °C, sample flowrate of 50 ml/min, room temperature of 23 °C, 100% RH, the sampling line with a general type should be replaced once at most every 8 hours, and the sampling line with a humidified type should be replaced once at most every 72 hours.

17.2.2 Zeroing the CO_2 Sensor

NOTE

The CO_2 module temporally stops measuring during zeroing.

17.2.3 Selecting Gas Compensations

WARNING

Make sure that the appropriate compensations are used. Inappropriate compensations may cause inaccurate measurement values and result in misdiagnosis.

17.3 Removing the Exhaust Gases from the System

WARNING

When taking the CO_2 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.

17.4 CO_2 Calibration

CAUTION

Connect the gas outlet to the scavenging system when calibrating CO_2.

18 Review

18.1 Reviewing Events

NOTE

Pausing or switching off alarms will not be recorded as events.

A total loss of power has no impact on the saved events.

Earlier-recorded events might be overwritten by later ones if it reaches capacity.

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19 Data Management

19.1 Generating Patient Data

NOTE

A total lost of power has no impact on the saved patient data.

19.2 Exporting Patient Data

NOTE

Do not remove the USB flash memory from the equipment before data is completely exported.

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20 Recording

20.1 Setting the Recorder

NOTE

Switching on or off gridlines is not available for 80 mm recorder paper.

20.2 Loading Paper

CAUTION

Use only specified thermal paper. Otherwise, it may cause damage to the recorder's print head, the recorder may be unable to print, or poor print quality may result.

Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.

Do not leave the recorder door open unless you have to reload paper or remove troubles.

20.3 Cleaning the Recorder Print Head

CAUTION

Do not use anything that may destroy the thermal element.

Do not add unnecessary force to the thermal head.

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21 Network Connection

21.1 Network Safety Information

CAUTION

Wireless network design, deployment, debugging, and maintenance should be executed by Mindray

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23 Battery

23.1 Battery Safety Information

WARNING

The batteries should be charged in this equipment or in a device approved by the equipment manufacturer.

Keep the batteries out of children's reach.

Use only specified batteries.

NOTE

Always connect the equipment to AC mains whenever it is possible.

Always install a fully charged battery in the equipment.

After long term use, the power capacity indicated by the battery symbol may be different from the actual capacity. Always observe the alarm information displayed on the screen.

Remove the battery before transporting the equipment or if the equipment will not be used for a

23.4 Storing Batteries

NOTE

Remove the battery from the equipment if the equipment is not used for a prolonged time (for

24 Care and Cleaning

WARNING

The responsible hospital or institution shall carry out all cleaning and disinfection procedure specified in this chapter.

24.1 General Points

WARNING

Be sure to shut down the system, disconnect the power cord and other cables, and remove the batteries before cleaning the equipment.

CAUTION

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25 Maintenance

25.1 Maintenance Safety Information

WARNING

Failure for the responsible individual, hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.

If you find a problem with any of the equipment, contact your service personnel or the manufacturer.

No modification of this equipment is allowed.

The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.

Do not touch any connected electrode pads or external paddles with hands during user test and auto test. Otherwise, electric shock could result.

Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.

25.2 Routine Maintenance

25.2.1 Auto Test

NOTE

If turned off, the auto test is performed only when AC mains is connected.

The auto test simulates the discharge test through impedances in the paddle tray. The auto test passes only when external paddles properly contact the metal parts of the paddle tray.

Thoroughly clean the external paddles and properly place them in the paddle tray after each use. Otherwise, the auto test may fail or damaged external paddles may result.

The auto test reduces the battery power. If the equipment is not connected to the AC mains immediately, low battery may result.

Before the auto test, check that the equipment is connected to the AC mains with a battery installed, and external paddles are properly placed in the paddle tray or the equipment is connected with the pads cable and 50 Ω test load. If the pads cable is not connected with the 50 Ω test load, the message "Test load not connected with cable" appears when the auto test passes. This means that the equipment only passes the internal discharge test, but not pass the external discharge test connected with the test load.

25.2.2 User Test

WARNING

Do not perform the user test when a patient is connected to the equipment.

NOTE

Before the user test or after each use, thoroughly clean the external paddles and properly place them in the paddle tray. The user test passes only when external paddles properly contact the metal parts of the paddle tray.

If the impedance value indicated by impedance indicator changes greatly, check that external paddles and metal parts of the paddle tray are clean.

Install at least one battery and properly place the external paddles in the paddle tray or connect the pads cable and 50 Ω test load. Otherwise the user test will fail.

25.2.2.1 Starting the User Test

The "Off" position of the Mode Select knob is not tested during the controls test. If you turn the knob to "Off" for more than 10 seconds, the equipment will be turned off.

The tested controls are indicated in green during the controls test.

25.2.2.2 Viewing the User Test Summaries

NOTE

If the routine test item (external discharge) of the auto test, or the energy delivery test item (external discharge) of the user test is passed, the delivered energy and accuracy are displayed, but results are for your reference only.

26 Accessories

WARNING

Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.

Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.

When using the accessories, consider the accessories' operating temperature. Refer to corresponding accessory's instruction for use for details.

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A Specifications

A.1 General Specifications

A.1.1 Safety Specifications

IEC 60601-1:

A.1.2 Physical Specifications

A.1.3 Display Specifications

A.1.4 Audio Indicators

A.1.5 Interface Specifications

→ B	C → B m m
GA	C E m
J45	C
	C

A.1.6 Signal Outputs Specifications

Multifunctional connector	
	m E 60601-1
ECG Analog Output (only ECG lead set)	
B (-3 B; : 10 H)	D : 0.05 150 H m : 0.5 40 H m : 1 20 H
m m	25 m(m ,)
	1 / m 5%
m	2.5 : 10 m 5% m 100
Synchronous input	
	0 5 (L)
m	10
	>5 m
Alarm output	
m m m m m m m m 4 m m m	m m m m m m m
m	45 (A) 85 (A) m

A.2 Defibrillator Specifications

	IEC 60601-2-4
D m	, AED
D m	B (B E) m
D	E m
C E	C E
< 8	
Range of selected energy	
E	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 150, 170, 200, 300, 360 J
I	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50 J
Patient impedance range	

E	25 300
L	15 300
Synchronized discharge delay	
L	< 60 m(m)
m	< 25 m)
AED	
	E : 100 360J, ; 10 100J, ; : 1, 2, 3, ; AHA/E C 2015

360 J defibrillation waveform into impedance of 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ω

Impedance / Selected energy	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy
1 J	1	1	1	0.9	0.9	0.9	0.8	¸2J
2 J	2	2	2	1.9	1.8	1.7	1.6	¸2J
3 J	2.9	3	2.9	2.8	2.7	2.6	2.4	¸2J
4 J	3.9	4	3.9	3.7	3.6	3.4	3.2	¸2J
5 J	4.9	5	4.9	4.7	4.5	4.3	4.1	¸2J
6 J	5.8	6	5.8	5.6	5.3	5.1	4.9	¸2J
7 J	6.8	7	6.8	6.6	6.3	6	5.7	¸2J
8 J	7.8	8	7.8	7.4	7.1	6.8	6.5	¸2J
9 J	8.8	9	8.8	8.4	8	7.7	7.3	¸2J
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1	¸2J
15 J	15	15	15	14	13	13	12	¸15%
20 J	20	20	20	19	18	17	16	¸15%
30 J	29	30	29	28	27	25	24	¸15%
50 J	49	50	49	47	45	43	41	¸15%
70 J	68	70	68	65	62	60	57	¸15%
100 J	97	100	97	93	89	85	81	¸15%
150 J	146	150	146	140	134	128	122	¸15%
170 J	166	170	166	159	151	145	138	¸15%
200 J	195	200	195	187	178	170	163	¸15%
300 J	292	300	292	280	267	255	244	¸15%
360 J	351	360	350	336	321	306	293	¸15%

Charge time (Note: at 20 ±5 ℃ of ambient temperature)

Manual Defib	AED
C m F. m J (. m	

NOTE

The equipment startup time in the fast startup mode is less than 2s.

A.3 CPR Compression Specifications

CPR Compressions from Defibrillation Electrodes

C	: 60 200 (n m)
A	: 3 (n m)

CPR Compressions from CPR Sensor

C	: 0.0 8.0 m E : 1.5 8.0 m A ( ): 0.5 m 10%, : 0.1 m : 0.5H
C	: 40 160 (n m) E : 40 160 (n m) A : 2 (n m) : 1 m : 0.5H
l m	: 0 300. E : 0 300. : 1. : 0.5H

A.4 Pacer Specifications

	IEC 60601-2-4
m	D m ,
m	20 m 40 m A : 5%
	30 m 210 m A : 1.5% : 5 m
	0 A) 200 A) A : 5% 5 A) : 1 A) 2 A) 5 A)
	200 300 m( )
4:1	4
	m m

NOTE

When pacing rate is changed from 30ppm to 210ppm, the response time to pacing (HR rising from 30bpm to 210bpm) is less than 20s.

A.5 Monitor Specifications

A.5.1 ECG Specifications (from ECG Lead Set)

	IEC 60601-2-27 IEC 60601-2-25
	3- ECG , 5- ECG 12- ECG
ECG	3- ECG: I, II, III 5- ECG: I, II, III, L, F, 12- ECG: I, II, III, L, F, 1 6
G	2.5 m/m m(0.25), 5 m/m m(0.5), 10 m/m m(1), 20 m/m m(2), 40 m/m m(4), A E ±5%
	6.25 m/m, 12.5 m/m, 25 m/m, 50 m/m, E m ±5%
B (-3 B)	D m: 0.05 150 H m: 0.5 40 H m: 1 20 H m: 0.05 40 H
C m m m	D m: >90 B m: >105 B m: >105 B m: >105 B
	50/60H , l m : l D m : m
ECG	8 m( )
C	1 m( ) 5%
D m	5
E	500 m
D	E 5000 (360 J) B m<2.5. ( ) m<10. D : 10% (100)
E	C- m :300 C m :100 m 10. l m 202.6.2.101. IEC 60601-2-27
Pace Pulse	
m	m ACE m : A m- : 2 700 m : 0.1 2 m m 10 100
	IEC 60601-2-27: 201.12.1.101.13, m A m- : 2 700 m : 0.1 2 m m 10 100 : 2.2 / 15% l
HR	

	: 15 350 m : 15 350 m A : 15 300 m
A	1%. 1 m
	1 m
	200 (II)
H	I m C 201.7.9.2.9.101) 3). IEC 60601-2-27, m I 3 1200 m 4 m m H m m m m m m m m 12 m H
m	m IEC 60601-2-27: C 201.7.9.2.9.101) 5). F. 80 120 m 11. F. 80 40 m 11.
m m	m C 201.7.9.2.9.101) 6). IEC 60601-2-27. m 4 : <11. 4 : <11. 4 : <11. 4 : <11. 4 : <11. 4 : <11.
mA C	A -F / B E m E mB C / m, C, C >2,B m m, B B, C, m C, I. mA-F.
	m C 201.12.1.101.17. IEC 60601-2-27, m 100 m m 1.2 m m 180 m 350 m
L	: 0.1 A D : 1 A
B m	<2.5. ( )
m	I m C 201.7.9.2.9.101) 4). IEC 60601-2-27, 20. : m (3): 80 1 m m (3): 60 1 m m (3): 120 1 m B (3): 90 2 m
12-lead ECG Interpretation	
m	500 m / /
A m	1 /L, B

A.5.2 ECG Specifications (from Defibrillation Electrodes)

ECG	
G	2.5 mm/mV (0.25), 5 mm/mV (0.5), 10 mm/mV (1), 20 mm/mV (2), 40 mm/mV (4), A	±5%
	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s E	±5%
B (-3 B)	: 1 20 H
C mm	: >105 B
	50/60H
ECG	8 m( )
C	1 m( ) 5%
D 5	
E 1	
D	E 5000 (360 J) B <2.5. ( ) <10. D : 10% (100)
E	C : 300 C : 100 10. 202.6.2.101. IEC 60601-2-27
Pace Pulse	
	ACE A : 2 700 m : 0.1 2 m 10 100
	IEC 60601-2-27: 201.12.1.101.13, A : 2 700 m : 0.1 2 m 10 100
HR	
	: 15 350 m A : 15 300 m
A	1% 1 m
	1 m
	200
H	201.7.9.2.9.101.) 3). IEC 60601-2-27, 3 1200 m 4 m H 12 H

	IEC 60601-2-27: C 201.7.9.2.9.101) 5).
	F. 80 120 11. F. 80 40 11.
	C 201.7.9.2.9.101) 6). IEC 60601-2-27. 4 : <11. 4 : <11. 4 : <11. 4 : <11. 4 : <11. 4 : <11.
A mA C	A -F. / C
	C 201.12.1.101.17. IEC 60601-2-27, 100 1.2 180 350
L	_0.1 _A
B	<2.5. ( )
	I C 201.7.9.2.9.101) 4). IEC 60601-2-27, 20 : (3): 80 1 (3): 60 1 (3): 120 1 B (3): 90 2

A.5.3 Resp Specifications

	0 200
	1
A	121 200 2 0 120 1
	<300 A, , 62.8 H (- 10%)
	0.3 5
B	0.2 2.5 H (-3 B)
	2200 4500 , ECG 1
A	10. , 15. , 20. , 25. , 30. , 35. , 40.

A.5.4 SpO_2 Specifications

Mindray SpO_2 Module

	I 80601-2-61
	0 100%
	1%
	<20. (2 70% 100%)

A[illegible] *	70[illegible] 100%: [illegible] 2% ([illegible]) 70[illegible] 100%: [illegible] 3% ([illegible]) 0%[illegible] 69%: [illegible]
[illegible]	_2[illegible]

* [illegible] C [illegible] C [illegible]

Masimo SpO_2 Module

[illegible]	[illegible] 80601-2-61
[illegible]	1[illegible] 100%
[illegible]	1%
[illegible]	_20[illegible] 70%[illegible] 100%)
A[illegible] [1]	70[illegible] 100%: [illegible] 2% ([illegible]) 70[illegible] 100%: [illegible] 3% ([illegible]) 70[illegible] 100%: [illegible] 3% ([illegible]) 1%[illegible] 69%: [illegible]
[illegible]	_2[illegible]
[illegible]	2-4[illegible], 4-6[illegible], 8[illegible], 10[illegible], 12[illegible], 14[illegible], 16[illegible]

[1] [illegible] 70%[illegible] 100% [illegible] 2 [illegible] ECG [illegible] 68%[illegible]

[illegible] 2[illegible] 4 H[illegible] A [illegible] 1[illegible] 2 [illegible] 1[illegible] 5 H[illegible] A [illegible] 2[illegible] 3 [illegible] 70%[illegible] 100% [illegible] 2 [illegible] ECG [illegible] 68%[illegible]

[2] [illegible] B[illegible] 2 [illegible] 0.02% [illegible] % [illegible] 5% [illegible] 70[illegible] 100% [illegible] 68%[illegible]

Nellcor SpO_2 Module

[illegible]	[illegible] 80601-2-61
[illegible]	0[illegible] 100%
[illegible]	1%
A[illegible]	70[illegible] 100%: [illegible] 2% ([illegible]) 70[illegible] 100%: [illegible] 3% ([illegible]) 0%[illegible] 69%: [illegible]
[illegible]	_2[illegible]

A.5.5 PR Specifications

PR from Mindray SpO_2 Module

	3 mmHg				
	A : 180 : 90				
	A : 80 280 mmHg : 80 210 mmHg : 60 140 mmHg				
	A : 160 mmHg : 140 mmHg : 90 mmHg				
			A		
		mmHg	25 290	25 240	25 140
		mmHg	10 250	10 200	10 115
		mmHg	15 260	15 215	15 125
	A : 297 3 mmHg : 297 3 mmHg : 147 3 mmHg				
*	5 mmHg : 8 mmHg				
	1 mmHg				

*

A.5.8 IBP Specifications

	IEC 60601-2-34
C	2
	200 mmHg
	1 mmHg
	5 / / mmHg
	-50 mmHg 360 mmHg
A	2%. 1 mmHg,
IB	: 15 40 C : -25 70 C
	A , A , FA , BA , A , A, C , , LA , A , IC , 1, 2,

A.5.9 CO_2 Specifications

Sidestream CO_2 Module

	0 ~ 150 mmHg
A *	F: 0 ~ 40 mmHg: ±2 mmHg 41 ~ 76 mmHg: ±5% of reading 77 ~ 99 mmHg: ±10% of reading 100 ~ 150 mmHg: ±(3 mmHg +8% of reading) I: A ±2 mmHg
	20 ~ 40 °C, 90% RH (non-condensing)
A	6 hours
	1 mmHg
	C: D LL E II 70 mL/min 100 mL/min C: D LL E II 70 mL/min 100 mL/min
	±15% of reading ±15 mL/min,
	D LL E II. 2.5- : ±250 mL@70 mL/min ±250 mL@100 mL/min D LL E II 2.5- : ±400 mL@70 mL/min ±330 mL@100 mL/min
	D LL E II. 2.5- : <4 @70 mL/min <3.5 @100 mL/min D LL E II 2.5- : <7 @70 mL/min <5.5 @100 mL/min
	0 ~ 150
	<60 ±1 60 ~ 150 ±2
	1

Effect of interference gases on CO_2 measurements (for sidestream CO_2 module)		
Gas	**Concentration (%)**	**Quantitive effect***
2	60	±1 mmHg
H	4	
	5	
l	5	
E	5	
D	15	±2 mmHg

*: C 2 0~40 mmHg.

l E E C 2 60 l/E 1:1, 30 l/E 2:1.

Microstream CO_2 Module

	0 ... 99 mmHg
A *	0 ... 38 mmHg: 2 mmHg 39 ... 99 mmHg: 5%, (0.08% 1 mmHg 38)
* A 80 mL/min, 80 mL/min, 4 mmHg 12%, E C 2 18 mmHg. F 60 mL/min 4%.	
A	6
	1 mmHg
F	50 $^{-7.5}_{+15}$ /min
l m	30. ( )
m	2.9. ( ) (m, m, m, m) m<190 m(10% 90%) D m2.7. ( )
m m	0 ... 150 m
	0 ... 70 m 1 m 71 ... 120 m 2 m 121 ... 150 m 3 m
A m m	10., 15., 20., 25., 30., 35., 40.

A.6 Power Supply Specifications

A.6.1 External Power Supply Specifications

AC power	
L	100 ... 240 AC (10%)
C	1.8 ... 0.8A
F	50/60Hz (3Hz)
DC Power (with an external DC/AC adapter)	
l	12 DC
m	150

A.6.2 Battery Specifications

B	m m, m B LI24I004A: 14.4 , 5600 Ah B LI34I001A: 14.8 , 4500 Ah	
B LI24I004A m	C AC	L 3 90% 4 100% m ;
		L 5 90% 6 100% m
	C	L 5 90% 6 100%.

B LI34I001A	C AC		L 2 90% 3 100% ;	
			L 6 90% 9 100%	
	C		L 3.5 90% 4 100%.	
B LI24I004A				
		6	12	5- ECG, 2- C 2, IB 15 I-F
	D	200	400	360J 5- ECG, 2- 2, IB C 2. 1-F
		300	600	200J 5- ECG, 2- 2, IB C 2. 1-F
		4.5	9	50 80 60 A 5- ECG, 2- 2, IB C 2. 1-F
B LI34I001A				
		5	10	ECG I-F
	D	100	200	360J
		3	6	50 : 80 60 A
B	5 LED			
	A 20 360J ( )			

20 C 5 C.

A.7 Recorder Specifications

	H
	50 mm 80 mm
	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s E ±5%
	50 mm/80 mm
G	
	12-
A	C mA

A.8 Alarm Specifications

A	H IEC60601-1-8
A	L
A	LED
	A A
A	

A.9 Data Storage

	1GB
	16
E	A 1000
	A 24 ECG
(AED)	A 180 60
D	D C B
	72 1
	100
12- ECG	5

A.10 Wi-Fi Specifications

	IEEE 802.11 /. / /.
	D FD
	IEEE 802.11. / /. (2.4G): 2.4 GH 2.495 GH IEEE 802.11 /. (5G): 5.15 GH 5.825 GH
C	IEEE 802.11. / /. (2.4G): 5 H IEEE802.11 /. (5G): 20 H
	IEEE 802.11. : 1 11 IEEE 802.11 : 6 54 IEEE 802.11. : 6.5 72.2 IEEE 802.11 : 6 54
	<20 B (CE : <30 B (FCC :)
	l
D	: A- K, A2- K E : KI , AE
	A : 4 E C A -65 B m 20 -F (-85 B m) -F (-50 B m : -F 2.4 G (-F) C m m l C E m C

A.11 Environmental Specifications

Shock
C m . m . 6.3.4.3, E 1789. D. : 0.75 m m . . . . .

A.12 Operating Environment

H . C	l A. m
m mm	C++
m	L. 3.2.0

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B EMC and Radio Regulatory Compliance

B.1 EMC

IEC 60601-1-2: 2014.

WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.

Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.

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 this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

Other devices may affect this equipment even though they meet the requirements of CISPR.

When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

NOTE

The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment may affect this equipment.

This equipment is intended for use in professional healthcare facility environment or in home healthcare environment such as restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres. If it is used in special environment, such as magnetic resonance imaging environment, the equipment may be disrupted by the operation of nearby equipment.

Guidance and Declaration - Electromagnetic Emissions		
Emission test	**Compliance**	**Electromagnetic environment - guidance**

I **Guidance and Declaration — Electromagnetic Immunity,** H 2 IB IB C 2 C

Guidance and Declaration - Electromagnetic Immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
E (E, D) IEC 61000-4-2	8 15	8 15	F 30%.
E IEC 61000-4-4	2 1 (3)	2 1 (3)	
IEC 61000-4-5	1 ( ) ( ) 2 ( )	1 ( ) ( ) 2 ( )	
IEC 61000-4-11	0% 0,5 0% 1 70% 25/30 0% 250/300	0% 0,5 0% 1 70% 25/30 0% 250/300	
A ED IEC 61000-4-8	30 A/ m	30 A/ m	
A.C.			

Guidance and Declaration - Electromagnetic Immunity			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
C F IEC 61000-4-6	3 Vrms 150 k 80 MHz	3 Vrms (1)	F
	6 Vrms ... 0.15 MHz ... 80 MHz	6 Vrms (2)	
F E IEC 61000-4-3	3 V/m 80 MHz 2.7 GHz (IEC60601-2-27, IEC60601-2-25, IEC60601-2-49, IEC60601-2-34)	3 V/m (E1)	$= \left[\frac{3.5}{1}\right]\sqrt{\ }$ 150 k 80 MHz
	10 V/m 80 MHz 2.7 GHz (IEC60601-2-4)	10 V/m	$= \left[\frac{3.5}{1}\right]\sqrt{\ }$ 80 MHz 800 MHz
	20 V/m 80 MHz 2.7GHz (IEC60601-2-4, IEC80601-2-30, I 80601-2-55, I 80601-2-56, I 80601-2-61)	20 V/m	$= \left[\frac{7}{1}\right]\sqrt{\ }$ 800 MHz 2.7 GHz
F IEC61000-4-3	27 V/m 380 390 MHz	27 V/m	F F 
	28 V/m 430 470 MHz, 800 960 MHz, 1700 1990 MHz, 2400 2570 MHz	28 V/m	
	9 V/m 704 787 MHz, 5100 5800 MHz	9 V/m	
1: A 80 MHz 800 MHz, ... 2: ... E ...			
I (...). 150 kHz 80 MHz 6.765 MHz 6.795 MHz; 13.553 MHz 13.567 MHz; 26.957 MHz 27.283 MHz; 40.66 MHz 40.70 MHz ... 0,15 MHz 80 MHz 1,8 MHz 2,0 MHz, 3,5 MHz 4,0 MHz, 5,3 MHz 5,4 MHz, 7 MHz 7,3 MHz, 10,1 MHz 10,15 MHz, 14 MHz 14,2 MHz, 18,07 MHz 18,17 MHz, 21,0 MHz 21,4 MHz, 24,89 MHz 24,99 MHz, 28,0 MHz 29,7 MHz 50,0 MHz 54,0 MHz. C I 150 kHz 80 MHz ... 80 MHz 2.7 GHz ... / ... F ... 10/3 ... F ... (/). ... A F ... F ... F ... 150 kHz 80 MHz, ... 3 V/m			