BeneHeart DX/BeneHeart DM

Defibrillator/Monitor

Instructions for Use

CE 2797

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WARNING

- **This equipment must be operated by persons who have been trained in its operation. The operator should be trained in basic life support, advanced cardiac life support or other emergency medical response.**
- **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.**

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- Others not caused by instrument or part itself.

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Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on the equipment.

Conventions

- *Italic text* is used in this manual to quote the referenced manuals, chapters, sections and formulas.
- **Bold text** is used to indicate the screen texts and names of hard keys.
- → is used to indicate operational procedures.

Contents

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 by following the prompts provided by the equipment, this electrical energy may cause serious injury or death. Do not attempt to operate this equipment unless thoroughly familiar with the operations and functions of all controls, indicators, connectors, and accessories.**
- **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.**
- **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.**

1.1.2 Warnings

WARNING

- **Only use parts and accessories specified in this manual. Follow the instructions for use and adhere to all warnings and cautions.**
- **This equipment is used for single patient at a time.**
- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **Do not disassemble the equipment. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.**
- **Before connecting the equipment to the external power supply, check that the voltage and frequency ratings are the same as those indicated on the equipment's label or in this manual.**
- **Before each use, the operator must check the equipment condition to ensure that the equipment is ready for operation.**

- **To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.**
- **Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.**
- **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.**
- **Do not exclusively rely on audible alarms for patient monitoring. Adjusting alarm volume to a low level or turning off alarm sound may result in patient hazards. Customize alarm settings according to patient situations and keep patients under close surveillance.**
- **Physiological data and alarm messages provided by the equipment should not be used as the sole basis for diagnosis or therapy decisions. They must be used in conjunction with clinical signs and symptoms. Misinterpreting measured values or other parameters may result in patient hazards.**
- **Do not place the equipment or accessories in any position that might cause it to fall on the patient.**
- **Do not start or operate the equipment unless the setup was verified to be correct.**
- **Place and secure cables and tubings carefully to prevent from stumbling, entanglement and patient strangulation.**
- **The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Disconnect the non defibrillation-proof devices from the patient during defibrillation.**
- **Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.**
- **Do not defibrillate a patient who lies on the wet or metal ground.**
- **Do not perform any functional check if the equipment is connected with a patient. Otherwise the patient might be shocked.**
- **Always keep the patients under close surveillance when delivering the therapy. If there is a delay in delivering a shock, the rhythm that has been analyzed as shockable may be converted to a non-shockable rhythm, which may result in an incorrect shock delivery.**
- **For the treatment of patients with implantable pacemakers, place electrode pads or paddles away from internal pacemaker generator if possible to help prevent damage to the pacemaker.**
- **Do not touch device connectors, recorder print head, battery connector or other live equipment if in contact with the patient. Otherwise patient injury may result.**
- **Do not touch the patient and live parts simultaneously.**
- **If the accuracy of any value displayed on the equipment, CMS, or printed on a graph strip or report is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.**

1.1.3 Cautions

CAUTION

- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **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 or water spray.**
- **Some settings are password protected and can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.**

- **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. If you have any questions concerning disposal of the equipment, please contact us.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**
- **Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.**

1.1.4 Notes

NOTE

- **The equipment use a mains plug as isolation means to the mains power. Do not locate the equipment in a place difficult to operate the mains plug.**
- **In normal use, the operator is expected to be in front of the equipment.**
- **The software was developed in compliance with IEC62304.**
- **This manual includes information related to all features of the equipment. Some features may not be available on your equipment.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**

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2 Equipment Overview

2.1 Intended Use

2.1.1 Intended Purpose Statement

The equipment is intended for external defibrillation, internal defibrillation, synchronized cardioversion and semi-automated defibrillation (AED). It can also be used for non-invasive external pacing, CPR feedback, CPR filter, ECG resting analysis as well as ECG, Resp, SpO_2, PR, NIBP, IBP, Temp and CO_2 monitoring.

2.1.2 Indication for Use

- External defibrillation/AED/internal defibrillation:

  External defibrillation, AED and internal defibrillation modes are intended for patients with ventricular fibrillation, pulseless ventricular tachycardia and ventricular flutter.

- Synchronized cardioversion:

  Synchronized cardioversion is intended for the treatment of Atrial Fibrillation and Atrial Flutter.

- Non-invasive external pacing:

  Non-invasive external pacing is intended for the treatment of bradycardia and asystole.

- CPR Feedback, CPR filter:

  CPR Feedback, CPR filter is intended for patients with cardiac arrest.

- Monitoring:

  Monitoring is intended for ECG Resting analysis, as well as the monitoring of ECG, Resp, SpO_2, PR, NIBP, IBP, Temp and CO_2 parameter.

2.1.3 Intended Users

The equipment must be operated by qualified medical personnel trained in the operation of the equipment and qualified by training in basic life support, advanced cardiac life support or defibrillation.

2.1.4 Intended Patient Population

- AED

  The AED mode is contraindicated in the treatment when the patient is showing any of the following:

  - Consciousness
  - Breathing
  - Detectable pulse or other signs of circulation

- Manual Defibrillation Mode

  Manual defibrillation is intended for the initial treatment of ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unconscious. Synchronized cardioversion is intended for termination of atrial fibrillation.

- Noninvasive Pacing Mode

  Noninvasive pacing therapy is intended for patients with symptomatic bradycardia.

- Monitoring Mode

  All the parameters can be monitored on single adult, pediatric and neonatal patients.

2.1.5 Intended Medical Conditions

The equipment is for use in hospital and pre-hospital institutions.

2.1.6 Contra-indications

- AED

  The AED mode is contraindicated in the treatment when the patient is showing any of the following:

  - Consciousness
  - Breathing
  - Detectable pulse or other signs of circulation

- Manual Defibrillation

  Manual defibrillation is contraindicated in the treatment when the patient is showing any of the following:

  - Consciousness
  - Breathing
  - Detectable pulse or other signs of circulation

2.1.7 Side-effects

None.

WARNING

- **According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.**

2.2 Applied Parts

The applied parts of the equipment are:

- ECG electrodes and leadwires
- SpO_2 sensor
- NIBP cuff
- Temp probes
- IBP/ICP transducer
- CO_2 sampling line/nasal sampling cannula and airway adapter
- Multifunction electrode pads
- External defibrillation paddles
- Internal defibrillation paddles
- CPR sensor

WARNING

- **When the equipment is placed at a an ambient temperate above 55°C, the surface temperature of applied parts should be limit to below 58°C.**

3 Equipment Preparation

3.1 Equipment Preparation Safety Information

WARNING

- **Use only installation accessories specified by Mindray.**
- **Connect only approved devices to this equipment. 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 are 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 Mindray.**
- **The equipment and accessories connected to the equipment are suitable for use within the patient environment. For other devices and accessories connected to the equipment, consult corresponding manufacturers for the suitability within the patient environment.**
- **If it is not evident from the equipment 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 will not negatively affect the devices themselves or the patient's safety.**

CAUTION

- **The equipment should be installed by authorized Mindray personnel.**
- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **Before use, verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**
- **Make sure that the equipment operating environment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**

NOTE

- **Put the equipment in a location where you can easily view and operate the equipment.**
- **Save the packing case and packaging material as they can be used if the equipment must be reshipped.**

3.2 Connecting the Power Supply

WARNING

- **Always use the accompanying power cord delivered with the equipment.**
- **Before connecting the equipment to the power supply, check that the voltage and frequency ratings are the same as those indicated beside the power input of the equipment.**
- **Use the battery if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.**

WARNING

- **Do not touch the exposed pins of the transport dock and equipment. Damaged pins affect the product performance.**
- **Ensure that the external power system has secure protective earth when the equipment is used together with the transport dock.**
- **To avoid a pinch hazard, be careful to connect the transport dock.**
- **Use the equipment and transport dock on a stable surface.**
- **Do not stack the equipment connected with a transport dock with other equipments.**
- **Keep the transport dock away from liquids. Use the transport dock in dry circumstances.**
- **Do not disassemble, puncture, or incinerate the transport dock.**

CAUTION

- **When connected with the transport dock, it is specified as a part of the equipment. Use only the specified transport dock.**

3.3 Turning on the Equipment

CAUTION

- **Do not use the equipment on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact the service personnel or Mindray.**
- **Check that visual and auditory alarm signals are presented correctly when the equipment is turned on.**

3.4 General Operations

CAUTION

- **Check that the touchscreen is not damaged or broken. If there is any sign of damage, stop using the equipment and contact the service personnel.**
- **If the touchscreen is loose, stop using the equipment and contact the service personnel.**

3.5 Setting Up the Equipment

CAUTION

- **Changing the date and time affects the storage of trends and events and may result in loss of data.**

NOTE

- **If Brightness is set to Auto, the screen brightness automatically changes according to the ambient light level.**

3.6 Taking Rescue Records

NOTE

- **In the Pacer mode, the equipment automatically takes records for the pacing related operation. These operations cannot be manually recorded.**

3.7 Turning Off the Equipment

CAUTION

- **Press and hold the power switch for 10s to forcibly shut down the equipment if it could not be shut down normally. This may cause loss of patient data.**

NOTE

- **To prevent the changes from losing in case of sudden power failure, the equipment saves the settings in real time. In case of a temporary power failure, if the power is restored within 60s, the equipment will resume with all active settings unchanged; if the power is interrupted for more than 120s, the equipment behaves the same as it is normally turned off; if the power is restored within 60s to 120s, the equipment will resume with all active settings unchanged, or behaves the same as it is normally turned off.**

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4 Therapy Preparation

4.1 Checking the Patient Contact Indicator

NOTE

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

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5 AED

5.1 AED Safety Information

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Do not touch the patient or any metal objects (including bed or gurney) connected to the patient 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.**
- **During defibrillation, do not allow electrode pads to contact each other or to contact with ECG electrodes, lead wires, dressings, etc. Contact with metal objects may divert current away from the heart, which result in electrical arcing and patient skin burns.**

WARNING

- **Motion artifact may delay analysis or affect the ECG signal resulting in an inappropriate shock or no shock advised message. Do not touch the patient during ECG rhythm analysis or charging in the AED mode.**
- **Air pockets between the patient skin and electrode pads can cause electrical arcing and patient skin burns during defibrillation. To avoid poor adherence and air pockets, make sure electrode pads are completely adhered to the patient skin.**
- **Do not use dried-out electrode pads.**

CAUTION

- **Improper handling of electrode pads during storage or before 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.**

5.2 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 Patient Category to Ped.**
- **The Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.**
- **Impedance is the resistance found between electrode pads or external paddles. To deliver an effective discharge of energy, the impedance must be overcome. The degree of impedance varies with the patient. It is affected by other factors, such as the presence of chest hair, moisture, and lotions or powders on the patient 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, replace the electrode pads or the pads cable with a new one.**

6 Manual Defibrillation

6.1 Manual Defibrillation Safety Information

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Do not touch the patient or any metal objects (including bed or gurney) connected to the patient 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.**
- **During defibrillation, do not allow electrode pads and paddles to contact each other or to contact with ECG electrodes, lead wires, dressings, etc. Contact with metal objects may divert current away from the heart, which result in electrical arcing and patient skin burns.**
- **During manual defibrillation, make sure your hands are dry and free from conductive gel to avoid shock 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.**
- **Clinicians must select an appropriate energy level for defibrillation of pediatric patients.**

CAUTION

- **Accessing the Manual Defib mode can be configured as password protected. Make sure you know and remember the password. Otherwise the manual defibrillation therapy cannot be delivered.**
- **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 defibrillation-protected.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

NOTE

- **Impedance is the resistance found between electrode pads orexternal paddles. To deliver an effective discharge of energy, the impedance must be overcome. The degree of impedance varies with the patient. It is also affected by other factors, such as the presence of chest hair, moisture, and lotions or powders on the patient 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, replace the electrode pads or the pads cable with a new one.**
- **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.**
- **Defibrillation is always performed through paddles or electrode pads. However, you can also use ECG electrode as an alternate ECG source to monitor ECG during defibrillation. If the ECG electrodes are connected, any available lead may be displayed.**

- **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.**

6.2 External Defibrillation Procedure

6.2.1 Using the Electrode Pads for External Defibrillation

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, you can use the default energy level, or adjust the energy level to 2-4 J/kg for the first shock and 4 J/kg for additional shocks followed the first shock.**
- **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 Patient Category to Ped.**
- **For defibrillation of neonatal patients, set the energy level according to the patient's clinical condition. The energy level for neonatal patient should be lower than the default setting.**

6.2.2 Using the External Paddles for External Defibrillation

WARNING

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

NOTE

- **Anterior - lateral placement is the only placement for defibrillation with external paddles.**
- **When external paddles are used, the Shock button on the front panel is disabled.**
- **For defibrillation of pediatric patients, you can use the default energy level, or adjust the energy level to 2-4 J/kg for the first shock and 4 J/kg for additional shocks followed the first shock.**
- **For defibrillation of neonatal patients, set the energy level according to the patient's clinical condition. The energy level for neonatal patient should be lower than the default setting.**

6.3 Internal Defibrillation Procedure

NOTE

- **To avoid possible cardiac damage from higher energies, the energy selection for internal defibrillation is limited to 50J.**
- **Clean and sterilize the internal paddles after each use. Otherwise, severe infection may result.**

6.4 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.**

6.4.1 Synchronized Cardioversion Procedure

NOTE

- **During synchronized cardioversion, the shock will be delivered when the equipment detects the next R-wave. If electrode electrodes or internal paddles without button are used, you should press and hold the Shock button on the equipment until the shock is delivered. If external paddles are used, you should press and hold the Shock buttons on both the external paddles until the shock is delivered. If internal paddles with a button are used, you should press and hold the Shock button on the right paddle handle until the shock is delivered.**

6.4.2 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.**

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7 CPR Assistance

7.1 CPR Assistance Safety Information

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.**

7.2 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 settings of CPR metronome are affected by the settings of Voice Prompts and Voice Volume in the AED Setup menu.**

7.2.1 Viewing Filtered ECG Waveform

CAUTION

- **The CPR filter works only when you perform CPR using electrode pads or the CPR sensor.**
- **CPR compressions introduce CPR artifact into the ECG signal. The CPR filter relies on the correlation between CPR compressions and CPR artifacts from the ECG signal. The filtered ECG waveform should be used as a reference for the real waveform. Because the CPR filter will not remove all CPR artifact in some conditions. For example, in the case of asystole or low amplitude pulseless electrical activity (PEA), the residual artifact after filtered looks like fine ventricular fibrillation. You should always follow the standard procedure of stopping CPR to verify the patient's ECG rhythm before making treatment decisions.**

NOTE

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

7.3 CPR Feedbacks

NOTE

- **When the interruption time exceeds five minutes, a CPR event is automatically generated.**

7.4 CPR Quality (CQI) Monitoring

WARNING

- **CQI monitoring is not intended for pediatric and neonatal patients.**
- **CQI results should not be used as the sole basis for diagnosis or therapy decisions. It is not intended to replace the competent judgment of a clinician. CQI monitoring must be used in conjunction with the patient's medical history, the cause of heart attack, as well as the clinical judgment.**

NOTE

- **A license is required for CQI monitoring.**

CAUTION

- **Use recommended SpO_2 sensor and apply it to a proper site.**
- **Avoid moving the measurement site.**
- **Apply the SpO_2 sensor properly. If the SpO_2 sensor is improperly applied or a wrong SpO2 sensor is used, erroneous CQI could result. For more information, see *14.3 SpO_2 Display*.**

8 Noninvasive Pacing

8.1 Pacing Safety Information

WARNING

- **Heart rate and related alarms may be unreliable during pacing, you should always keep the patient under close survillance. The indicated heart rate or related alarms cannot be used as the sole basis for the patient's perfusion status.**
- **Monitoring ECG alone is sometimes not enough to verify that the patient's heart is providing cardiac output. The 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, or improved skin color.**
- **To avoid a possible shock hazard, be careful to apply the electrode pads on the patient during pacing.**
- **If you are using the pacing function with battery power and the alarm "Low Battery" is presented, connect the equipment to external power supply or install a fully charged battery.**

CAUTION

- **Accessing the Pacer mode can be configured as password protected. Make sure you know and remember the password. Otherwise the pacing therapy cannot be delivered.**
- **For treatment of the patient with an implanted devices, such as permanent pacemaker or cardioverter-defibrillator, consult a physician and the instructions for use delivered with the device.**
- **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, you must select Start Pacing 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.**
- **In the Pacer mode, arrhythmia analysis is supported and available arrhythmia alarms are asystole, ventricular vibrillation and ventricular tachycardia.**
- **The monitoring or pacing function may be unstable in the presence of ESU or other electronic devices.**

8.2 Choosing the Pacer Mode Setting

NOTE

- **Use the demand mode pacing whenever possible. Only use the fixed mode pacing when there are interferes causing R-wave unreliable or no available ECG electrodes.**

8.2.1 Demand Mode Pacing Procedure

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.**

8.2.2 Fixed Mode Pacing Procedure

NOTE

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

9 Monitoring Preparation

9.1 Networked Monitoring with BeneVision N1 Monitor

WARNING

- **Do not discharge a patient on the N1 monitor before data is completely transferred.**
- **Removing the N1 monitor when transferring data will cause patient data incomplete.**

9.2 Defining the Monitoring Display

9.2.1 Setting the Switch for a Parameter

NOTE

- **When a parameter is manually switched off, you cannot monitor this parameter even if related accessories are connected.**

9.2.2 Defining the Normal Screen Display

NOTE

- **ECG waveform and numerics are always displayed on the first line of the parameter waveform area and numeric area.**

9.3 Freezing Waveforms

NOTE

- **You can view the frozen waveforms of up to 120 seconds.**

9.4 Camera Shooting

WARNING

- **Do not look straight at the camera backlight.**
- **The camera is used for taking photos for the patient rescue, pay attention for the patient privacy.**

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10 Alarms

10.1 Alarm Introduction

NOTE

- **When multiple alarms of different priority levels occur simultaneously, the equipment selects the alarm of the highest priority to light the alarm lamp and issue the alarm tone.**
- **When multiple alarms of different priority levels occur simultaneously and should be displayed in the same area, the equipment only displays the messages of the highest priority alarm.**
- **When multiple physiological alarms of different priority levels occur simultaneously and should be displayed in the same area, the equipment displays the high priority alarm, while the medium and low priority alarms are displayed circularly.**
- **When multiple alarms of the same priority levels occur simultaneously, alarm messages are displayed circularly.**
- **Lethal arrhythmia alarms, apnea, and SpO_2 Desat are exclusive high priority alarms. When these alarms occur, the equipment only displays messages of exclusive alarms. Other high priority alarms will not be displayed. When multiple exclusive alarms occur simultaneously, alarm messages are displayed circularly.**

10.2 Alarm Safety Information

WARNING

- **A potential hazard can exist if different alarm presets and default configuration settings are used for the same or similar equipment in the same care area, for example an intensive care unit or cardiac operating room.**
- **The equipments in the care area may each have different alarm settings to suit different patients. Before starting monitoring, check that the alarm settings are appropriate for the patient. Always make sure that necessary alarm limits are active and set according to the patient's clinical condition.**
- **Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. Setting the SpO_2 high alarm limit to 100% is equivalent to switching the alarm off the SpO_2 alarm.**
- **When the alarm sound is switched off, the equipment gives no alarm tones even if a new alarm occurs. Be careful about whether to switch off the alarm sound or not. When the alarms are off or while alarm audio is paused either temporarily or indefinitely, observe the patient frequently.**
- **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.**
- **Do not exclusively rely on audible alarms for patient monitoring. Adjusting alarm volume to a low level or turning off alarm sound may result in patient hazards. Always make sure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.**

NOTE

- **In case of a temporary power failure, the equipment will save the alarms triggered before the power failure. The information of saved alarms is unchanged saved after the power failure.**

10.2.1 Setting Alarm Tone Properties

NOTE

- **When the alarm volume is set to 0, the alarm sound is turned off and the audio off symbol is displayed in the alarm status area.**
- **You cannot set the volume of high priority alarms if Alarm Volume is set to 0.**

10.2.2 Setting the Switch of SpO_2 Desat Alarm Off

WARNING

- **If you switch off the SpO2 Desat alarm, the equipment will not alarm when the patient's SpO_2 is extremely low. This may result in a hazard to the patient. Always keep the patient under close surveillance.**

10.2.3 Setting the Switch of Apnea Alarm Off

WARNING

- **If you switch off the apnea alarm, the equipment will not issue the apnea alarm in case that apnea happens. This may result in a hazard to the patient. Keep the patient under close surveillance.**

10.3 Pausing Alarms

10.3.1 Defining the Alarm Pause Function

WARNING

- **Pausing alarms may result in a hazard to the patient.**

10.3.2 Password Protected Alarm Pause Settings

NOTE

- **Prolonging alarm pause time does not affect the setting of alarm pause time.**

10.4 Switching Off All Alarms

WARNING

- **Switching off alarms may result in a hazard to the patient.**

10.5 Pausing Alarm Sounds

WARNING

- **Pausing alarm sounds may result in a hazard to the patient.**

10.6 Switching Off Alarm Sounds

WARNING

- **Switching off alarm sounds may result in a hazard to the patient.**

10.7 Resetting Alarms

NOTE

- **If a new alarm is triggered after the alarm system is reset, the alarm reset symbol will disappear, indications of the alarm lamp, alarm tone and alarm messages will be reactivated.**

10.8 Latching Alarms

NOTE

- **Changing alarm priority may affect the latching status of corresponding alarm. Determine if you need to reset the alarm latching status if you changed the alarm priority.**
- **When the alarm system is reset, latched physiological alarms are cleared.**

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11 Monitoring ECG

11.1 ECG Safety Information

WARNING

- **ECG monitoring provided by this equipment is not intended for direct cardiac application.**
- **Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact any other conductive parts including earth.**
- **Use defibrillation-proof ECG cables during defibrillation.**
- **Do not touch the patient or metal devices connected to the patient during defibrillation.**
- **To reduce the hazard of burns during high-frequency surgical procedure, ensure that cables and transducers connected to the equipment never come into contact with the electrosurgery unit (ESU).**
- **To reduce 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.**

CAUTION

- **Periodically inspect the electrode application site to ensure skin integrity. If the skin quality changes, replace the electrodes or change the application site.**
- **Interference from ungrounded instrument near the patient and electrosurgery interference can induce noise and artifact into the waveforms.**
- **If selected lead cannot provide valid ECG signals, a dash line is shown in the ECG waveform area.**

11.2 ECG Display

NOTE

- **The ECG numeric area and waveform area are configured to be different for different lead type and ECG settings.**

11.3 Preparing for ECG Monitoring

NOTE

- **The external paddles are not recommended for ECG monitoring.**

11.3.1 Preparing the Patient for Electrode Application

CAUTION

- **Proper skin preparation is necessary for good signal quality at the electrode site, as the skin is a poor conductor of electricity.**

11.3.2 Applying ECG Electrodes

NOTE

- **Store the electrodes at room temperature.**
- **Only open the electrode package immediately prior to use.**
- **Never mix patient electrode types or brands. This may lead to problem due to impedance mismatch.**
- **When applying the electrodes, avoid bony area, obvious layers of fat, and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of the thorax, may lead to erroneous arrhythmia alarms due to excessive muscle movement.**

11.3.3 Electrode Color Coding

NOTE

- **For the 5-lead electrode placement, place the precordial electrode according to the physician's preference.**

WARNING

- **To reduce the hazard of burns during use of electrosurgical units (ESU), the ECG electrodes should not be located between the surgical site and the ESU return electrode.**
- **Never entangle the ESU cable and the ECG cable together.**
- **If the ESU is used, do not place ECG electrodes near the grounding plate of the ESU. Otherwise interference on ECG signals may occur.**

11.3.4 Checking Paced Status

WARNING

- **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.**
- **For paced patients, set Paced to Yes. Otherwise the monitor could mistake a pace pulse for a QRS complex and fail to generate 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 heart rate meter alarms when monitoring patients with pacemakers. Always keep these patients under close surveillance.**
- **For non-paced patients, you must set Paced to No.**

11.3.5 Setting the Switch of Pacer Rejection

NOTE

- **When pace pulses are detected, the pace pulse marks "|" are shown on the ECG waveforms. Pacer Rejection setting has no impact on the display of pace pulse marks "|".**
- **You can switch on pacer rejection only when Paced is set to Yes. If Paced is set to no, the setting of Pacer Reject is disabled.**

11.4 Changing ECG Settings

11.4.1 Setting the Analysis Mode

NOTE

- **It is difficult for the equipment to differentiate an aberrantly conducted beat from a ventricular beat. An aberrantly conducted beat may be misclassified as a ventricular beat. In this case, choose the lead with a narrow R-wave for ECG1 and select Single Lead.**
- **When a 3-lead ECG cable is used, the equipment always uses single lead as calculation lead and the Analysis Mode option is not available.**

11.4.2 Changing ECG Waveform Settings

11.4.2.1 Selecting the Displayed ECG Leads

CAUTION

- **Ensure that you have selected the optimal leads with the best waveform amplitude and the highest signal-to-noise ratio. Selecting the optimal leads is important for detecting beats, classifying beats, and detecting ventricular fibrillation.**

11.4.2.2 Setting the Switch of Notch Filter

NOTE

- **The notch filter can only be switched on or off when ECG Filter is set to Diagnostic. In other filter modes, the notch filter is always on.**

11.4.3 Adjusting the Minimum QRS Detection Threshold

CAUTION

- **The setting of the QRS detection threshold can affect the sensitivity for arrhythmia, ST, QT/QTc detection, and heart rate calculation.**
- **If QRS amplitude is low, the equipment might not be able to calculate heart rate and false asystole calls may occur.**

NOTE

- **The minimum QRS detection threshold can only be adjusted when the ECG filter is set to Monitor.**

11.5 Monitoring Arrhythmia

11.5.1 Arrhythmia Safety Information

WARNING

- **Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.**
- **The arrhythmia analysis program may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.**
- **Atrial fibrillation (A-Fib) detection function is not intended for pediatric and neonatal patients.**

CAUTION

- **Since the arrhythmia detection algorithm sensitivity and specificity are less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.**
- **The ECG size and minimum QRS detection threshold settings affect arrhythmia detection and heart rate calculation sensitivity.**
- **If QRS amplitude is low, the equipment might not be able to calculate heart rate and false asystole calls may occur.**
- **During the learning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitor patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.**

11.5.2 Changing Arrhythmia Settings

11.5.2.1 Changing Arrhythmia Alarm Settings

NOTE

- **You can switch off lethal arrhythmia alarms only when you Lethal Arrhys Alarm Off is switched on. For more information, see *11.5.2.2 Setting the Switch of Lethal Arrhythmia Alarms*.**
- **The priority of lethal arrhythmia alarms is always high. It cannot be changed.**

11.5.2.2 Setting the Switch of Lethal Arrhythmia Alarms

WARNING

- **If you switch off all arrhythmia alarms, the equipment will not alarm for any arrhythmia event. This may result in a hazard to the patient. Always keep the patient under close surveillance.**

NOTE

- **If any of the lethal arrhythmia alarms is switched off, the message "Lethal Arrhys Off" is displayed in the ECG waveform area.**

11.5.2.3 Changing Arrhythmia Alarm Threshold Settings

NOTE

- **The asystole delay time relates to ECG relearning. When heart rate is less than 30 bpm, it is recommended to set Asystole Delay to 10 sec.**

11.5.2.4 Arrhythmia Shielding Period

NOTE

- **The arrhythmia shielding period has no impact on HR High, HR Low, Tachy, Brady, A-Fib End, Irr Rhythm End.**
- **The arrhythmia shielding period is only applicable to the alarms in the medium priority chains and atrial fibrillation chain. For the alarms in the high priority chain, alarm tone and alarm lamp are presented as soon as the alarm condition is detected.**

11.5.2.5 Setting Arrhythmia Refractory Periods

NOTE

- **Refractory periods are only applicable to arrhythmias in the medium priority chains.**
- **Refractory periods have no impact on Tachy, Brady, HR High, HR Low, A-Fib/A-Fib End, Irr Rhythm/Irr Rhythm End.**

11.6 ST Segment Monitoring

11.6.1 ST Safety Information

WARNING

- **ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.**
- **ST deviation is often calculated at a fixed offset from the J point. Changes in heart rate may affect ST.**
- **The ST deviation measurement algorithm has been tested for accuracy. The significance of ST segment changes needs to be determined by a physician.**
- **The equipment provides ST deviation level change information. The clinical significance of the ST level change information should be determined by a physician.**

11.6.2 Saving the Current ST as Baseline

CAUTION

- **Updating ST baseline affects ST alarms.**

11.7 QT/QTc Interval Monitoring

11.7.1 Displaying QT/QTc Numerics

NOTE

- **QTc values are calculated based on the QT-HR, not the ECG HR. For more information, see *11.7.2 Saving the Current QTc as Baseline*.**
- **The display of the QT numeric area differs as related settings change.**

11.7.2 Saving the Current QTc as Baseline

CAUTION

- **Updating QTc baseline affects ΔQTc value and alarm.**

11.8 ECG Relearning

CAUTION

- **Take care to initiate ECG relearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If ECG learning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.**

11.9 ECG Troubleshooting

NOTE

- **For the physiological and technical alarm messages, see *D Alarm Messages*.**

12 Resting 12-Lead ECG Analysis

12.1 Resting 12-Lead ECG Analysis Introduction

WARNING

- **Resting 12-lead ECG analysis provided by this equipment is not intended for direct cardiac application.**

12.2 Changing 12-Lead ECG Settings

NOTE

- **For patients under 16 years old, it is recommended to V3 Placement to V4R and place chest electrodes at V4R, V1, V2, V4, V5, V6. This is a normal practice for a patient of this age.**

12.3 Initiating 12-Lead ECG Measurement

NOTE

- **Check that patient information is correct before initiating 12-lead ECG auto measurement.**

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13 Monitoring Respiration (Resp)

13.1 Resp Safety Information

WARNING

- **When monitoring the patient's respiration, do not use ESU-proof ECG cables.**
- **If you do not set the detection level for the respiration correctly in manual detection mode, it may not be possible for the equipment to detect apnea. If you set the detection level too low, the equipment is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.**
- **The respiration measurement does not recognize the cause of apneas. It only indicates an alarm if no breath is detected when a pre-adjusted time has elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.**
- **If operating under conditions according to the EMC Standard IEC 60601-1-2 (Radiated Immunity 3V/m), field strengths above 3V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.**
- **The impedance respiration measurement may cause rate changes in Minute Ventilation Rate Responsive Pacemakers. Set the pacemaker rate responsive mode off or disable the impedance respiration measurement on the equipment.**
- **When using the electrosurgery unit, ensure proper contact of the ESU return electrode to the patient to avoid burns at measurement sites. Also ensure that the ESU return electrode is near the operating area.**

CAUTION

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

13.2 Resp Display

NOTE

- **If ESU-proof ECG cables are used, the Resp waveform area will display the message "Check Leads". Replace the ECG cable if necessary.**

13.3 Preparing for Resp Monitoring

13.3.1 Placing the Electrodes

CAUTION

- **To reduce cardiovascular artifact, apply the respiration electrodes so that the liver area and the ventricles of the heart are not in the line between the respiratory electrodes. This is especially important for neonatal patients.**
- **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.**
- **To optimize respiratory waveforms for patients breathing mainly abdominally, apply the LL electrode on the left abdomen at the point of maximum abdominal expansion.**

- **For patients expand chests laterally (normally neonatal patients), to avoid negative intrathoracic pressure and optimize respiratory waveforms, respectively apply the electrodes in the right midaxillary and the left lateral chest areas at the maximum point of the breathing movement.**
- **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**

NOTE

- **Store the electrodes at room temperature. Open the electrode package immediately prior to use.**
- **Check that the electrode packages are intact and not expired. Make sure the electrode gel is moist.**

13.4 Changing Resp Settings

NOTE

- **You can switch off the apnea alarm only when Apnea Alarm Off is enabled. For more information, see *10.2.3 Setting the Switch of Apnea Alarm Off*.**

14 Monitoring Pulse Oxygen Saturation (SpO_2)

14.1 SpO_2 Introduction

NOTE

- **The SpO_2 extension cable should be compatible with the SpO_2 connectors. For example, you can only the Mindray SpO_2 extension cable to the Mindray SpO_2 connectors.**
- **Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.**
- **A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.**
- **A functional tester or SpO_2 simulator cannot be used to assess the SpO_2 accuracy.**

14.2 SpO_2 Safety Information

WARNING

- **If the patient has a trend of deoxygenation, analyze the blood samples with a laboratory CO-oximeter to completely understand the patient's condition.**
- **Do not use the equipment or SpO_2 sensors during MRI scanning or in an MRI environment. Induced current could potentially causes burns. The equipment may affect the MRI image, and the MRI device may affect the accuracy of the SpO_2 measurements.**
- **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.**
- **Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. Setting the SpO_2 high alarm limit to 100% is equivalent to switching off the SpO_2 alarm.**
- **Do not place the equipment or accessories in any position that might cause it to fall on the patient.**
- **Do not start or operate the equipment unless the setup was verified to be correct.**
- **Do not loop the patient cabling into a tight coil or wrap around the equipment, as this can damage the patient cabling.**
- **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 interference with photodynamic therapy.**
- **SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.**
- **The pulse oximeter function of the equipment should not be used for apnea monitoring.**
- **The pulse oximeter function of the equipment should not be used for arrhythmia analysis.**

CAUTION

- **Change the application site or replace the sensor and/or patient cable when a persistent "SpO2 Low Signal Quality" message is displayed on the equipment. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.**
- **Replace the cable or sensor when a "SpO2 Sensor Off", "SpO2 No Sensor", or "SpO2 Low Signal Quality" message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.**
- **Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.**
- **Do not place the pulse oximeter where the controls can be changed by the patient.**
- **If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.**

NOTE

- **Additional information specific to the Masimo sensors compatible with the equipment, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).**
- **Masimo cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.**

14.3 SpO_2 Display

NOTE

- **PI is only available for Mindray SpO_2 and Masimo SpO_2.**

14.4 Preparing for SpO_2 Monitoring

CAUTION

- **Select proper SpO2 sensor according to application site. Applying sensor too tight may severely obstruct circulation and lead inaccurate measurements. Loose application may result in measurement site exposing to ambient light.**
- **Avoid placing the SpO_2 sensor on the same extremity with an NIBP cuff, arterial catheter, or intravascular line.**
- **When monitoring SpO_2 at high ambient temperature, to avoid burns at the application site that is not well perfused, pay attention to prolonged SpO_2 sensor application.**

14.5 Changing SpO_2 Settings

14.5.1 Changing the SpO_2 Alarm Properties

NOTE

- **You can switch off the SpO2 Desat alarm only when SpO2 Desat Alarm Off is enabled. For more information, see section *10.2.2 Setting the Switch of SpO_2 Desat Alarm Off*.**

14.5.2 Nellcor Sat-Seconds Alarm Management

NOTE

- **The SpO_2 Too Low or SpO_2 Too High alarm is presented in the case that SpO_2 value violates the alarm limits for 3 times within one minute even if the setting of Sat-Seconds is not reached.**

14.5.3 Setting SpO_2 Sensitivity (for Masimo SpO_2)

CAUTION

- **When using the Maximum Sensitivity setting, performance of "Sensor Off" detection may be compromised. If the equipment and the sensor becomes detached from the patient, the potential for false readings may occur due to environmental noise such as light, and vibration.**

14.6 SpO_2 Troubleshooting

NOTE

- **For the physiological and technical alarm messages, see *D Alarm Messages*.**

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15 Monitoring Noninvasive Blood Pressure (NIBP)

15.1 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.**
- **NIBP measurement can be performed during electro-surgery and discharge of defibrillator.**

15.2 NIBP Safety Information

WARNING

- **Be sure to select the correct patient category setting for your patient before NIBP measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may present a safety hazard.**
- **Do not perform NIBP measurements on patients with sickle-cell disease.**
- **To avoid further injury, do not apply the NIBP cuff on the limb with a wound.**
- **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.**
- **To avoid the risk of patient injury, do not apply the NIBP cuff on a limb that has an intravenous infusion or catheter in place. Apply the cuff on another limb if possible.**
- **Do not apply 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 in harmful injury to the patient.**
- **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 monitor is working correctly.**
- **Taking NIBP measurements exert pressure on the patient's tissue. This can cause skin purpura, ischemia, and neuropathy. Periodically check the cuff site and the limb distal to the cuff for normal color, warmth and sensitivity. If there is a sign of skin change or poor distal circulation, move the cuff to another limb or stop NIBP measurements. Check more frequently when using the STAT mode or using the auto mode at short intervals. Auto NIBP measurements with one and two minute intervals are not recommended for extended periods of time.**
- **NIBP diagnostic significance must be decided by the physician.**

CAUTION

- **Using IABP may cause NIBP, including PR, measurements inaccurate or failed.**
- **Accuracy of NIBP measurement depends on using a cuff of proper size. It is essential to measure limb circumference and choose a cuff with proper size.**

15.3 NIBP Measurement Limitations

NOTE

- **The effectiveness of the sphygmomanometer has not been established in pregnant, including pre-eclamptic patients.**

15.4 NIBP Display

NOTE

- **If NIBP measurement fails, "XX" is displayed; if NIBP measurement is not taken, "--" is displayed.**
- **Outlined NIBP numerics indicate that the measurement exceeds the NIBP timeout. So these NIBP values are not recommended for reference. The setting of NIBP timeout can be changed in the Configuration mode only. For more information, see *24.7.4.8 NIBP Setup Tab*.**

15.5 Preparing for NIBP Measurements

15.5.1 Preparing the Patient for NIBP Measurements

NOTE

- **It is recommended that the patient calms down and relaxes as much as possible before performing the measurement and that the patient do not talk during the measurement.**
- **It is recommended to have the patient sit quietly for several minutes before taking the measurement.**
- **Other factors that have been shown to result in an overestimation of blood pressure are labored breathing, full bladder, pain etc.**

15.5.2 Placing the NIBP Cuff

CAUTION

- **Using a cuff of wrong size, or a cuff with twisted bladder and kinked air tubing, 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.**
- **Use care when placing the cuff on an extremity used for monitoring other patient parameters.**

15.6 Changing NIBP Settings

NOTE

- **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**

16 Monitoring Temperature (Temp)

16.1 Temperature Troubleshooting

NOTE

- **For the physiological and technical alarm messages, see *D Alarm Messages*.**

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17 Monitoring Invasive Blood Pressure (IBP)

17.1 IBP Safety Information

WARNING

- **Use only pressure transducers specified in this manual. 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 using accessories, their operating temperature should be taken into consideration. For more information, see instructions for use of accessories.**
- **All invasive procedures involve risks to the patient. Use aseptic technique. Follow catheter manufacturer's instructions.**
- **Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero balance and calibration, and cause erroneous readings.**

CAUTION

- **Using IABP may cause IBP, including PR, measurements inaccurate or failed.**

17.1.1 Measuring an IBP

CAUTION

- **Make sure that all the transducers are zeroed correctly before the IBP measurement.**
- **Make sure that no air bubble exists in the IBP transducer system before the IBP measurement.**
- **If measuring intracranial pressure (ICP) with a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect values (not applicable if measuring ICP with the Codman ICP transducer).**

17.2 Measuring ICP Using the Codman ICP Transducer

CAUTION

- **If equipment of different brands are used to zero the Codman ICP transducer, the zero reference values can be different. Use a Mindray equipment to Zero the Codman ICP transducer if you will take ICP measurement using a Mindray equipment. Otherwise the ICP measurement can be inaccurate.**

17.3 IBP Display

NOTE

- **For some pressures, only the mean pressure is displayed in numeric area. Measurement units for different pressures may be different. If the Art and ICP pressures are measured simultaneously, CPP value is displayed in the ICP numeric area, which is obtained by subtracting ICP from the Art mean.**

17.4 Changing IBP Settings

NOTE

- **It is not allowed to select the same label for different pressures.**

17.5 IBP Troubleshooting

NOTE

- **For the physiological and technical alarm messages, see *D Alarm Messages*.**

18 Monitoring Carbon Dioxide (CO_2)

18.1 CO_2 Safety Information

WARNING

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

CAUTION

- **Remove the airway sample line from the patient's airway while nebulized medications are being delivered.**
- **EtCO_2 values measured from the CO_2 module may differ from those of from the blood gas analysis.**

NOTE

- **The CO_2 module automatically suppresses physiological alarms until breathing waves have been detected. Make sure that a patient is properly connected when monitoring with the CO_2 module.**

18.2 Measuring Sidestream CO_2

18.2.1 Preparing to Sidestream CO_2 Measurement

CAUTION

- **Do not apply adult or pediatric sampling line to the neonate patient. Otherwise, patient injury could result.**
- **Connect the gas outlet to the scavenging system when measuring CO_2 using the sidestream CO_2 module.**

NOTE

- **To extend the lifetime of the sampling line and CO_2 module, set the operating mode to Standby mode when CO_2 monitoring is not required.**
- **If not necessary, do not disconnect the CO_2 adapter from the equipment after the first installation. This reduces the risk of the CO_2 adapter becoming lost or damaged.**
- **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.**

18.2.2 Zeroing the Sidestream CO_2 Module

NOTE

- **The CO_2 module temporally stops measuring during zeroing.**

18.3 Changing CO_2 Settings

18.3.1 Setting the Gas Compensation

WARNING

- **Make sure to use the appropriate compensations. Inappropriate compensations may cause inaccurate measurement values and result in misdiagnosis.**

18.3.2 Changing Barometric Pressure

18.4 CO_2 Calibration

CAUTION

- **Connect the gas outlet to the scavenging system when calibrating the CO_2 module.**

18.5 CO_2 Troubleshooting

NOTE

- **For the physiological and technical alarm messages, see *D Alarm Messages*.**

19 Clinical Assistive Applications

19.1 Glasgow Coma Scale (GCS)

CAUTION

- **GCS is intended as an adjunct in patient assessment and must be used in conjunction with observation of clinical signs and symptoms.**
- **GCS is not applied to patients that are sedated, muscularly relaxed, with artificial airway, drunk, or in status epilepsies.**
- **GCS is not applied to deaf people and patients having language barrier or with mental disorder.**
- **When applied to children under five years old or elder people who are slow, the GCS score might be low.**

NOTE

- **A license is required for GCS.**

19.1.1 Setting the GCS Scoring Type

NOTE

- **Manually setting Score Type has no impact on settings of Patient Category and Age in the Patient Management menu.**

19.2 Early Warning Score (EWS)

WARNING

- **EWS should not be used as the sole basis for diagnosis or therapy decisions. It is not intended to replace the competent judgment of a clinician.The EWS scores and recommended actions must be used in conjunction with observation of clinical signs and symptoms.**
- **MEWS and NEWS are not applicable to pregnant woman, COPD (Chronic Obstructive Pulmonary Disease) patients and patients under 16 years old. NEWS2 is not applicable to pregnant woman and patients under 16 years old.**

NOTE

- **A license is required for EWS.**

19.2.1 Performing EWS Scoring

NOTE

- **The decision to use the SpO2 Scale 2 should be made by a competent clinical decision maker and should be recorded in the patient's clinical notes.**
- **EWS total score can be calculated only when all required measured items have been measured or entered.**

19.3 HEART Score

NOTE

- **A license is required for HEART score.**

19.4 Traumatic Brain Injury (TBI) Assessment

NOTE

- **A license is required for TBI assessment.**

20 Review

20.1 Reviewing Events

NOTE

- **A total loss of power has no impact on the events stored.**
- **Alarms are saved as events and will be maintained if the equipment is powered down. The time of equipment power down is not recorded as an event and cannot be reviewed.**
- **Earlier events will be overwritten by later ones if the capacity is reached.**

20.1.1 Viewing Event Details

CAUTION

- **Ensure that you have selected the optimal leads with the best waveform amplitude and the highest signal-to-noise ratio. Selecting the optimal leads is important for detecting beats, classifying beats, and detecting ventricular fibrillation.**

NOTE

- **The switch setting for Beat Anno. on the Events review page is relevant to that on the Full Disclosure review page.**

20.2 Reviewing Full Disclosure

NOTE

- **The more waveforms you select to be stored, the shorter waveform storage time becomes. The waveforms may not be stored for 48 hours. Please exert caution when selecting waveforms.**

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21 Printing

21.1 Loading Paper

CAUTION

- **Use only specified thermal paper. Otherwise, it may cause damage to the recorder's printhead, 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 reload paper or remove troubles.**

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22 Discharged Patient Management

22.1 Generating Patient Data

NOTE

- **Earlier stored data will be overwritten by later ones if the equipment capacity is reached.**

22.2 Accessing the Discharged Patient Mode

WARNING

- **Patient therapy and monitoring automatically end when you access the Discharged Patient mode. The equipment automatically restarts and takes effects changes after the Discharged Patient mode.**

22.3 Exporting Patient Data

NOTE

- **Do not remove the USB drive from the equipment before data is completely exported.**

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23 Data Communication

23.1 Data Communication Safety Information

CAUTION

- **Wireless network design, deployment, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.**
- **Always deploy the wireless network according to local wireless regulations.**
- **Using 5 GHz frequency band is recommended whenever possible. There are more interference sources in 2.4 GHz frequency band.**
- **Private APs and wireless routers are not allowed. These devices may cause radio interference and result in monitor and CMS data loss.**
- **To ensure network security and stability, data communication must be performed within a closed network or within a virtually isolated hospital network. The hospital is responsible for ensuring the security of the virtually isolated network.**
- **WPA2-PSK and WPA2-Enterprise verification and encryption should be used if possible. Otherwise, the equipment may not be able to work or patient information may be leaked. WPA2-Enterprise and a long password are recommended.**
- **Keep network authentication information, for example password, from being accessed by unauthorized users.**
- **Do not connect non-medical devices to the monitor network.**
- **If wireless network signal is poor, there may be a risk of CMS data loss.**
- **Maximum number of monitors connected to a single AP is 3. Too many monitors connected to the same AP may result in network disconnection.**
- **RF interference may result in wireless network disconnection.**
- **Disconnecting from the network may result in CMS data loss and function failure. Check the patient in case of network disconnection and reconnect the network as soon as possible.**
- **Ensure that the monitor IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.**

23.2 Connecting the CMS

NOTE

- **You can select CMS only when Select CMS is switched on. For more information, see *24.7.6.4 Central Station Setup Tab*.**

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24 Configuration Management

24.1 Configuration Management Introduction

WARNING

- **Accessing the Configuration mode is password protected. Patient therapy and monitoring automatically end when you access the Configuration mode.**
- **The configurations must be changed by authorized personnel only.**
- **Never connect the equipment with the patient when accessing the configuration management.**

24.2 Changing Configurations

NOTE

- **Restoring factory defaults have no impact on the item marked with "*" in the following tables.**
- **The alarm limits are effective for all patient categories if not specified.**
- **The alarm volume escalation function is not applied to the latched alarms.**

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25 Battery

25.1 Battery Safety Information

WARNING

- **Keep batteries out of children's reach.**
- **Use only specified battery. Use of a different battery may present a risk of fire or explosion.**
- **Keep the batteries in their original package until you are ready to use them.**
- **Do not expose batteries to liquid.**
- **Do not crush, drop or puncture the battery. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is externally visible or not, remove the battery from use and dispose of it properly.**
- **If the battery shows signs of damage or signs of leakage, replace it immediately.**
- **The battery should be charged in this equipment or the specified charger station.**
- **Extremely high ambient temperature may cause battery overheat protection, resulting in equipment shutdown.**
- **Do not open batteries, heat batteries above 60 °C, incinerate batteries, or short battery terminals. They may ignite, explode, leak or heat up, causing personal injury.**

NOTE

- **Always connect the equipment to external power supply whenever it is possible.**
- **Always install a fully charged battery in the equipment.**

25.2 Battery Indications

NOTE

- **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.**
- **The alarm "Low Battery" means that the battery is beginning to weaken, you should immediately replace with a fully charged battery or connect the equipment to the external power supply. After this alarm is triggered, at least 20 minutes of monitoring and 6 shocks at 360J can be performed.**

25.3 Conditioning the Battery

NOTE

- **Do not use the equipment during battery conditioning.**
- **Do not interrupt battery conditioning.**

25.4 Checking Battery Performance

NOTE

- **Life expectancy of a battery depends on how frequent and how long it is used. When properly used, the lithium-ion battery has a useful life of approximately two years. If improperly used, its life expectancy can be shorten. It is recommended to replace the battery every two years.**
- **To optimize the battery performance, a fully discharged (or near fully discharged) battery should be charged as soon as possible.**
- **Battery operating time depends on the equipment configuration and operation. For example, measuring NIBP repeatedly will shorten the battery operating time.**

25.5 Storing Batteries

NOTE

- **Remove the battery from the equipment if the equipment is not used for a prolonged time (for example, several weeks). Otherwise the battery may overdischarge.**
- **Storing batteries at high temperature for an extended period of time will significantly shorten their life expectancy.**
- **The battery storage temperature is between -20°C (-4°F) and 60°C (140°F). Storing batteries in a cool place can slow the aging process. Ideally the batteries should be stored at 15 °C.**

26 Care and Cleaning

26.1 Care and Cleaning Safety Information

WARNING

- **Use only cleaners, disinfectants and methods specified in this chapter. Using unapproved substances or methods may damage the equipment and void the warranty.**
- **Do not mix disinfecting solutions, as hazardous gases may result.**
- **Mindray is not liable for the efficacy of the specified cleaners, disinfectants, or methods as a means for controlling infection. Refer to your hospital for infection controlling.**
- **Be sure to power off the equipment and disconnect all power cables from the outlets before cleaning the equipment.**
- **The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.**

CAUTION

- **Never immerse any part of the equipment or accessories in liquids or allow liquid to enter the interior.**
- **Any contact of cleaners or disinfectants with connectors or metal parts may cause corrosion.**
- **Do not pour or spray any liquid directly on the equipment or accessories or permit fluid to seep into connections or openings.**
- **If you spill liquid on the equipment or accessories, disconnect the power supply, dry the equipment, and contact your service personnel.**
- **Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).**
- **Dilute and use the cleaners or disinfectants according to the manufacturer's instructions.**
- **Check the equipment after cleaning and disinfecting. If there is any sign of damage, remove it from use.**

26.2 Cleaning and Disinfecting the Equipment

26.2.1 Cleaning the Main Unit

CAUTION

- **During the cleaning procedure, disable the touch function by turning off the equipment or locking the touchscreen.**

26.2.2 Cleaning the Thermal Print Head

CAUTION

- **Do not use anything that may destroy the thermal element.**
- **Do not add unnecessary force to the thermal head.**
- **The thermal print head gets hot when printing. Do not clean the print head immediately after printing.**

26.3 Cleaning and Disinfecting the Accessories

CAUTION

- **Fluids entering the NIBP air hose can damage the equipment. When cleaning or disinfecting the NIBP air hose, prevent liquid from entering the hose.**
- **Periodically inspect the NIBP air hose and connector for signs of wear or deterioration after cleaning or disinfecting the NIBP air hose. Replace the NIBP air hose if you detect a leak. Dispose of damaged NIBP air hose according to local laws for disposal of hospital waste.**
- **Never immerse or soak the accessories in any liquid.**
- **Never clean or disinfect the connectors and metal parts.**
- **Use only Mindray approved cleaners and disinfectants and methods listed in this section to clean or disinfect the accessories. Warranty does not cover damage caused by unapproved substances or methods.**
- **To avoid long term damage, the accessories should be disinfected only when necessary as determined by your hospital's policy.**

27 Maintenance

27.1 Maintenance Safety Information

WARNING

- **Stop using the equipment for any signs of visible damages. If damaged, contact your service personnel.**
- **Follow the maintenance and testing schedule or local regulations to perform testing and maintenance.Not implementing the maintenance schedule may cause equipment failure and possible health hazards.**
- **No modification of this equipment is allowed.**
- **This equipment contains no user serviceable parts.**
- **Do not open the equipment housings. 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.**
- **Do not touch any connected electrode pads or external paddles with hands during auto test and user test. Otherwise, electric shock could result.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**

CAUTION

- **The equipment and accessories shall not be served or maintained while in use with a patient.**
- **If a problem occurs to the equipment, contact the service personnel.**
- **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. If you have any questions concerning disposal of the equipment, please contact Mindray.**

NOTE

- **If needed, contact the manufacture for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.**

27.2 Routine Maintenance

27.2.1 Auto Test

NOTE

- **If the equipment is turned off, it can carry out the auto test only when it is either connected with the external power supply or installed with a battery (at least 60% of battery capacity).**
- **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 external power supply immediately, low battery may result.**
- **Before the auto test, check that the equipment is connected to the external power supply 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 prompt "Test load not connected with cable" is displayed 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.

27.2.2 User Test

WARNING

- **If the equipment has been dropped or strongly impacted, you should immediately perform a user test to check the equipment performance.**
- **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 patient contact 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.**
- **The power switch is not tested during the buttons test. If you press and hold the power switch for more than 3 seconds, the equipment will be turned off.**
- **The tested buttons illuminate in green during the buttons test.**
- **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.**

27.3 User Maintenance Settings

WARNING

- **Accessing the User Maintenance mode is password protected. Patient therapy and monitoring automatically end when you access the User Maintenance mode.**
- **The user maintenance settings must be changed by authorized personnel only. If needed, contact your department manager or biomedical engineering department for the passwords used at your facility.**

A Specifications

A.1 Safety Specifications

A.1.1 Safety Classifications

The equipment is classified, according to IEC 60601-1:

Type of protection against electrical shock	• Used together with AC transport dock or AC power adapter: Class I • Used together with a DC transport dock: Class II
Degree of protection against electrical shock	Type BF defibrillation proof for CO_2 monitoring and external defibrillation. Type CF defibrillation proof for ECG, Resp, SpO_2, NIBP, Temp, IBP and internal defibrillation.
Degree of protection against harmful ingress of solid Degree of protection against harmful ingress of water	Main unit: IP55, IP52 (with an external power supply)
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous
Degree of mobility	Portable

A.1.2 Environmental Specifications

WARNING

- **The equipment may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.**
- **When the equipment and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.**

NOTE

- **The environmental specification of unspecified modules are the same as those of the main unit.**

Main unit				
Item		**Temperature**	**Relative humidity**	**Barometric**
Operating condition	When configured with ECG and manual defibrillation, without batteries	-20ºC to 55ºC	5% to 95%, non-condensing	-382m to 4575m (57.0 kPa to 106.2kPa)
	When configured with all functions	0ºC to 50ºC		
Storage condition		-40ºC to 75ºC		
Shock				

Complies with requirements for medical devices of 6.3.4.2, EN1789 (10.1.3, IEC60601-1-12): Peak acceleration: 1000m/s^2 (102g) Duration: 6ms Pulse shape: half-sine Number of shocks: 3 shocks per direction per axis (18 shocks in total)
Bump
Complies with the requirements for road ambulances of 6.3.4.2, EN1789. Peak acceleration: 15g Pulse duration: 6ms Number of bumps: 1000 Direction: vertical, with the equipment in its normal operating position.
Vibration
Complies with requirements for medical devices of 6.3.4.2, EN1789 (10.1.3, IEC60601-1-12). 10 Hz to100 Hz: 5.0 $(m/s^2)^2$/Hz 100 Hz to 200 Hz: -7 dB/Octave 200 Hz to 2 000 Hz: 1.0 $(m/s^2)^2$/Hz Duration: 30 minutes per direction per vertical axis (3 axises in total) • **Vibration (for fixed wing aircrafts): complies with requirements of 10.1.4, IEC60601-1-12** Test category: S Curve: C Frequency: 10 to 2000Hz Grms: 4.12 Direction: 1 hour per direction per axis (3 axises in total) • **Vibration (for helicopters): complies with requirements of 10.1.4, IEC60601-1-12** Test category: U2 Curve: F (performance level test) Frequency: 5Hz to 300Hz; APSD 5Hz to 40Hz: 0.0063 g^2/Hz,+3 dB/Octave; APSD 40Hz to 200Hz: 0.05 g^2/Hz; APSD 200Hz to 300Hz: 0.05 g^2/Hz, -12 dB/Octave Grms: 3.37 Curve: F1 (endurance level test) Frequency: 5Hz to 300Hz; APSD 5Hz to 40Hz: 0.0126 g^2/Hz,+3 dB/Octave; APSD 40Hz to 200Hz: 0.1 g^2/Hz; APSD 200Hz to 300Hz: 0.1 g^2/Hz, -12 dB/Octave Grms: 4.76 Duration: performance level test for minimum of 10 minutes at the beginning and end of the test, endurance level test for 3 hours (repeated per axis)
Free fall
1 fall on each surface (6 surfaces in total), at the height of 1.5 m

CO_2 module			
Item	**Temperature**	**Relative humidity**	**Barometric**
Operating condition	5°C to 40°C	5% to 95%, non-condensing	430mmHg to 790mmHg (57.3kPa to 105.3kPa)
Storage condition	-20°C to 60°C		

A.2 Power Supply Specifications

A.2.1 External Power Supply Specifications

DC power input	
Input voltage	18 VDC (±5%)
Input current	7.2Amax
AC power adapter and transport dock (with AC input)	
Input voltage	100 to 240 VAC (-15%, +10%)
Input current	1.8 to 0.8A
Frequency	50/60Hz (±3Hz)
Transport dock (with DC input)	
Input voltage	12/24VDC (-15%, +25%)
Input current	15.5 to 6.5A

A.2.2 Battery Specifications

Battery type	Rechargeable lithium-ion battery	
Battery voltage	14.4V	
Battery capacity	4500 mAh	
Maximum number of batteries configured	Two batteries can be connected at the same time.	
Battery charge time	Charged by the equipment connected to the external power supply	• Less than 3 hours to 90% and less than 4 hours to 100% with equipment turned off. • Less than 5 hours to 90% and less than 6 hours to 100% with equipment turned on.
	Charged by the charger station	Less than 3 hours to 90% and less than 4 hours to 100%.

Battery run time	Operating condition	One battery	Two batteries	Testing condition
	Monitor	≥6.5 h	≥13 h	• New fully charged battery. • Ambient temperature of 20ºC±5 °C. • The equipment is configured with 3-/5-lead ECG, manual defibrillation, screen brightness set to the lowest level without printing.
		≥5.5 h	≥11 h	• New fully charged battery. • Ambient temperature of 20ºC±5 °C. • The equipment is configured with 3-/5-lead ECG, manual defibrillation, screen brightness set to the factory default without printing. • The N1 monitor is configured with 3-/5-lead ECG, Resp, SpO_2, NIBP measurements set at an interval of 15 minutes.
	Defibrillation	≥220 discharges of 360J	≥440 discharges of 360J	• New fully charged battery. • Ambient temperature of 20ºC±5 °C. • The equipment is configured with 3-/5-lead ECG, manual defibrillation, screen brightness set to the factory default without printing. • 3 discharges every minute.
		≥300 discharges of 200J	≥600 discharges of 200J	
	Pacing	≥4.5 h	≥9 h	• New fully charged battery. • Ambient temperature of 20ºC±5 °C. • The equipment is configured with 3-/5-lead ECG, manual defibrillation, external pacing, screen brightness set to the factory default without printing. • 50 Ω load impedance, pacer rate at 80bpm, pacer output at 60mA, pacer pulse at 40ms.
	Low alarm presented	At least 20 minutes of monitoring and 6 discharges of 360J	At least 40 minutes of monitoring and 12 discharges of 360J	• Ambient temperature of 20ºC±5 °C. • The equipment is configured with 3-/5-lead ECG, manual defibrillation, screen brightness set to the factory default without printing.
Battery fuel gauge	5 LEDs indicating the current battery charge level			
Shutdown delay	At least 20 minutes of monitoring and 6 discharges of 360J			

A.2.3 Charger Station Specifications

Maximum number of batteries charged	Two batteries can be charged at the same time.
AC power input	
Input voltage	100 to 240 VAC (±10%)
Input current	1.8 to 0.8A

Frequency	50/60Hz (±3Hz)
DC power input	
Input voltage	12.4 to 30.3 VDC
Input current	15.5 to 6.5A

A.3 Physical Specifications

Dimensions (W × D × H)	275 mm×155 mm×280 mm (including the handle, configured without the paddle tray)
Maximum weight	4.1 kg (the equipment is configured with DC power input, 3-/5-lead ECG, manual defibrillation and one battery)

A.4 Hardware Specifications

A.4.1 Display Screen

Screen type	Capacitive, multi-point color touchscreen
Screen size	9 inch
Resolution	1200×1020 pixels
Viewed waveforms	7 at maximum
Wave viewing time	36s at maximum (ECG)

A.4.2 Recorder

Method	High-resolution thermal dot array
Horizontal resolution	16 dots/mm (25 mm/s paper speed)
Vertical resolution	8 dots/mm
Paper width	110 mm
Paper speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Number of waveforms	6 at maximum
Grid lines	Printing can be configured with or without grid lines

A.4.3 LEDs

Alarm lamp	1 (two color-coded: red and yellow)
Power-on LED	1 (green)
Battery LED	1 (two color-coded: yellow and green)
Status indicator	1 (two color-coded: red and green)

A.4.4 Audio Indicators

Speaker	Gives alarm tones (45 to 85 dB), key tones, QRS tones Supports PITCH TONE and multi-level tone modulation Alarm tones comply with IEC60601-1-8.
Beep	Gives reminder tones

Audio signal	Alarm tone: ISO mode with frequency of 600 Hz QRS tone: short beep with frequency of 495 Hz Charge tone: long beep with frequency of 400 Hz to 533 Hz Charge done tone: double beeps with frequency of 440 Hz Key tone: short beep with frequency of 1000 Hz

A.4.5 External Connectors

Power input	1, connects the external power supply.
Multifunctional connector	1, connects a CPR sensor or synchronized cardioversion.
USB connector	• 1 USB 2.0, connects USB devices. • 1 USB 3.0,
Network connector	1 RJ45 connector, 100 Base-TX, IEEE 802.3, connects a standard network cable.

A.4.6 Signal Outputs

Multifunctional connector	
Standard	Meets the requirements of EN60601-1 for short-circuit protection and leakage current
ECG Analog Output (only from ECG accessories)	
Bandwidth (-3 dB; reference frequency: 10 Hz)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz ST mode: 0.05 to 40 Hz
Maximum QRS delay	25 ms (in diagnostic mode, and with Notch off)
Sensitivity	1 V/mV ±5%
Pace enhancement	Signal amplitude: V_{oh}≥2.5V Pulse width: 10ms±5% Signal rising and falling time: ≤100μs
IBP analog output	
Bandwidth (-3dB; reference frequency:1Hz)	0 to 40 Hz
Maximum transmission delay	30 ms
Gain (reference frequency 1 Hz)	1 V/100 mmHg, ±5%
Video output	
Video signals	Visual graphics captured through a camera.
Synchronous input	
Input limit	Vih≥2.4v; Vil≤ 0.4v
Input signal range	0 to 5V (TTL level)
Input impedance	≥10 kΩ
Pulse width	>5 ms
Alarm output	
Alarm delay time from the equipment to other remote equipment	• For pre-hospital network: the alarm delay time measured at the equipment signal output connector: ≤10 s • For hospital network: the alarm delay time measured at the equipment signal output connector: ≤2s
Alarm signal sound pressure level range	45 db(A) to 85 db(A) within a range of one meter

A.5 Data Storage

Internal storage	4 GB
Events	At least 1000 events for each patient.
Waveforms	At least 120 hours for one ECG waveform and pace pulses with the resolution no less than 1 second, or 60 hours for two ECG waveforms and pace pulses
Voice recording	At least 8 hours for each patient
Tabular trends	At least 200 hours trend data with the resolution no less than 1 minute.
Auto test reports	At least 1000 records
Data export	Data can be export to a PC through a USB drive

A.6 Communication Specifications

A.6.1 Wi-Fi Specifications (SX-SDMAC-2832S+ as Station)

Protocol	IEEE 802.11a/b/g/n/ac
Modulation mode	BPSK, QPSK, 16QAM, 64QAM, 256QAM
Operating frequency	2412 MHz to 2472 MHz 5180 MHz to 5320 MHz, 5500 MHz to 5700 MHz, 5745 MHz to 5825 MHz
Wireless baud rate	IEEE 802.11a: 6 Mbps to 54 Mbps IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: MCS0-MCS7 IEEE 802.11n: MCS0-MCS8
Output power	<20 dBm (CE requirement: detection mode- RMS)
Operating mode	As station, access AP for data transmission
Data security	Standards: WPA-PSK, WPA2-PSK, WPA-Enterprise, WPA2-Enterprise EAP method: EAP-TLS, EAP-TTLS, PEAP-MSCHAPv2 Encryption: TKIP, AES
Distinct vision distance	The distinct vision distance between the equipment and the AP: ≥ 50 m.
Alarm delay time of network disconnection	The message and alarm delay of network disconnection between the equipment and the CMS: ≤ 14 s.
Pre-hospital network performance	
System capacity, interference immunity and network stability	Meets the following requirements: • The total delay of data transmission from the equipment to the CMS: ≤ 10 s. • The delay for the equipment related settings configured at the CMS to be effective: ≤ 10 s. • The data loss percentage of Wi-Fi communication over a 4-hour period: ≤ 0.5%.

Test conditions	Meets the following conditions simultaneously: • One equipment supported by a single AP • Each equipment can communicate with the CMS. • The weakest strength of the AP signal where the equipment is located is not less than -65 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, interphones, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices.
Hospital network performance	
System capacity, interference immunity and network stability	Meets the following requirements: • The total delay of data transmission from the equipment to the CMS ≤ 2s. • The delay for the equipment related settings configured at the CMS to be effective: ≤ 2 s. • The equipment connected to the network roam for 30times, the data loss percentage of Wi-Fi communication over a 24-hour period: ≤ 0.1%.
Test conditions	Meets the following conditions simultaneously: • Number of the equipments supported by a single AP: ≤ 3 • Each equipment can communicate with the CMS. • The weakest strength of the AP signal where the equipment is located is not less than -65 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, microwave ovens, interphones, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices.

A.6.2 Wi-Fi Specifications (Wlink as Station)

Protocol	IEEE 802.11a/b/g/n
Modulation mode	BPSK, QPSK, 16QAM, 64QAM
Operating frequency	2412 MHz to 2472 MHz 5180 MHz to 5320 MHz, 5500 MHz to 5700 MHz, 5745 MHz to 5825 MHz
Wireless baud rate	IEEE 802.11a: 6 Mbps to 54 Mbps IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: MCS0 to MCS7
Output power	<20 dBm (CE requirement: detection mode- RMS)
Operating mode	As station, access AP for data transmission
Data security	Standards: WPA-PSK, WPA2-PSK, WPA-Enterprise, WPA2-Enterprise EAP method: EAP-TLS, EAP-TTLS, PEAP-MSCHAPv2 Encryption: TKIP, AES
Distinct vision distance	The distinct vision distance between the equipment and the AP: ≥ 50 m.
Alarm delay time of network disconnection	The message and alarm delay of network disconnection between the equipment and the CMS: ≤ 14 s.
Pre-hospital network performance	

System capacity, interference immunity and network stability	Meets the following requirements: • The total delay of data transmission from the equipment to the CMS: ≤ 10 s. • The delay for the equipment related settings configured at the CMS to be effective: ≤ 10 s. • The data loss percentage of Wi-Fi communication over a 4-hour period: ≤ 0.5%.
Test conditions	Meets the following conditions simultaneously: • One equipment supported by a single AP • Each equipment can communicate with the CMS. • The weakest strength of the AP signal where the equipment is located is not less than -65 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, interphones, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices.
Hospital network performance	
System capacity, interference immunity and network stability	Meets the following requirements: • The total delay of data transmission from the equipment to the CMS ≤ 2s. • The delay for the equipment related settings configured at the CMS to be effective: ≤ 2 s. • The equipment connected to the network roam for 30 times, the data loss percentage of Wi-Fi communication over a 24-hour period: ≤ 0.1%.
Test conditions	Meets the following conditions simultaneously: • Number of the equipments supported by a single AP: ≤ 3 • Each equipment can communicate with the CMS. • The weakest strength of the AP signal where the equipment is located is not less than -65 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, microwave ovens, interphones, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices.

A.6.3 Wi-Fi Specifications (Wlink as AP)

Protocol	IEEE 802.11a/b/g/n
Modulation mode	BPSK, QPSK, 16QAM, 64QAM
Operating frequency	2412 MHz to 2472 MHz 5180 MHz to 5320 MHz, 5500 MHz to 5700 MHz, 5745 MHz to 5825 MHz
Wireless baud rate	IEEE 802.11a: 6 Mbps to 54 Mbps IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: MCS0 to MCS7
Output power	<20 dBm (CE requirement: detection mode- RMS)
Operating mode	As AP, accessed by Wi-Fi station for data transmission
Data security	Standards: WPA2-PSK Encryption: AES
Distinct vision distance	The distinct vision distance between the equipment and N1 monitor: ≥ 30 m.

Alarm delay time of network disconnection	The message and alarm delay of network disconnection (both Wi-Fi and bluetooth) between the equipment and the N1 monitor: ≤ 14 s.
Network performance	
System capacity, interference immunity and network stability	Meets the following requirements: • The total delay of data transmission from the N1 monitor to the equipment: ≤ 2s. • The data loss percentage of N1 monitor connected to the network over a 24-hour period: ≤ 0.1%.
Test conditions	Meets the following conditions simultaneously: • With a distance greater than 2m from each other, three equipments operate properly at the same time. • Each equipment can communicate with one N1 monitor. • The weakest signal strength where N1 monitor is located is not less than -80 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, interphones, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices. • The bluetooth devices operate properly.

WARNING

- **Do perform all network functions of data communication within an enclosed network.**

A.6.4 Cellular Specifications

Network type	4G, 5G
Operating frequency	■ 4G module (EU): ◆ LTE FDD: B1/B3/B7/B8/B20/B28A ◆ LTE TDD: B38/B40/B41 ◆ WCDMA: B1/B8 ◆ GSM: B3/B8 ■ 5G module: ◆ NR: n1/n2/n3/n5/n7/n8/n12/n20/n28/n38/n40/n41/n48/n66/n71/n77/n78/n79 ◆ LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B9/B12/B13/B14/B17/B18/B19/B20/B25/B26/B28/B29/B30/B32/B66/B71 ◆ LTE-TDD: B34/B38/39/B40/B41/B42/B48
Standard/Modulation mode	LTE, 5G Sub-6GHz
Alarm delay time of network disconnection	The message and alarm delay of network disconnection between the equipment and CMS: ≤ 14 s.
Pre-hospital network performance	
System capacity, interference immunity and network stability	Meets the following requirements: • The total delay of data transmission from the equipment to the CMS: ≤ 10 s. • The data loss percentage of cellular communication over a 4-hour period: ≤ 0.5%.

Test conditions	Meets the following conditions simultaneously: • With a distance greater than 2m from each other, three equipments operate properly at the same time. • Each equipment can communicate with the CMS. • The weakest signal strength where the equipment is located is greater than -95 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, interphones, cordless phones.

A.6.5 Bluetooth Specifications

Protocol	Bluetooth low energy 5.0
Modulation mode	GFSK
Operating frequency	2402 MHz to 2480 MHz
Channel spacing	2 MHz
Wireless baud rate	2 Mbps, 1 Mbps, 125kbps
Output power	≤20 dBm
Data security	AES128
Distinct vision distance	• The distinct vision distance between the equipment and the Pad: ≥ 10 m. • The distinct vision distance between the equipment and the N1 monitor: ≥ 30 m.
Alarm delay time of network disconnection	The message and alarm delay of network disconnection (both Wi-Fi and bluetooth) between the equipment and the N1 monitor: ≤ 14 s.
Network performance	
System capacity, interference immunity and network stability	Meets the following requirements: • The success rate of data transmission from the equipment to the Pad: >99%. • The total delay of data transmission from the N1 monitor to the equipment: ≤ 2s. • The data loss percentage of communication between the equipment and the N1 monitor over a 4-hour period: ≤ 0.1%.
Test conditions	Meets the following conditions simultaneously: • With a distance greater than 2m from each other, three equipments operate properly at the same time. • Bluetooth communication does not interrupt. • The weakest signal strength where the equipment is located is not less than -80 dBm. • The distance between the interfering devices and the equipment is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4 G wireless devices, cellular mobile networks, interphones, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices.

A.6.6 NFC Specifications

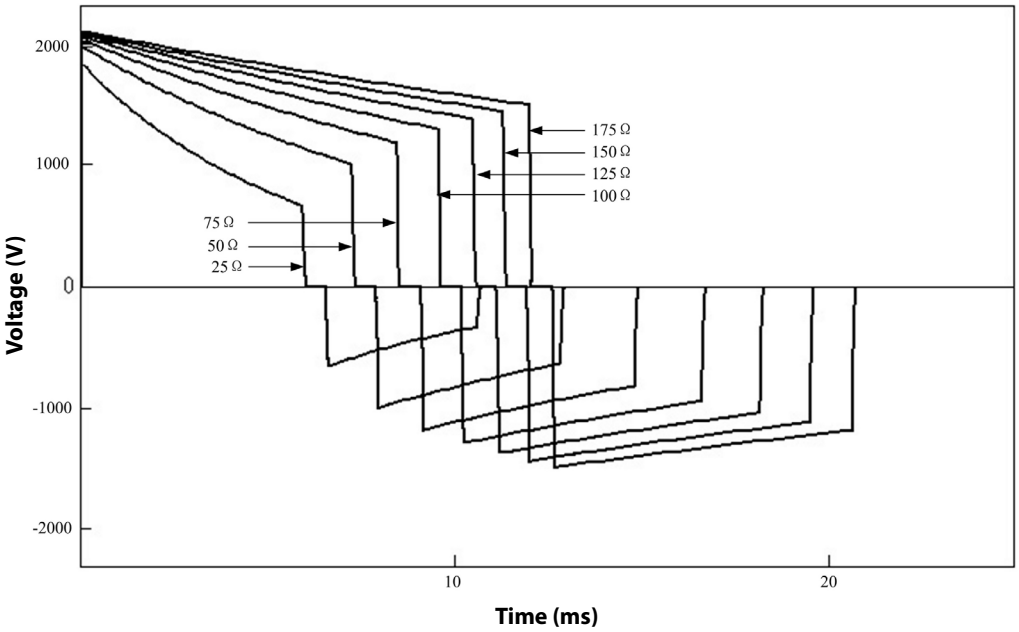
Protocol	ISO/IEC 14443 A, ISO/IEC 1443 B
Operating frequency	13.56 MHz

A.7 Therapy Specifications

A.7.1 Defibrillation Specifications

Standards	Meet standards of IEC 60601-2-4
Defibrillation mode	Manual defib, synchronized cardioversion, AED
Defibrillation waveform	Biphasic truncated exponential (BTE) waveform, auto-compensation according to patient impedance
Defibrillation electrodes	External paddles set coming with pediatric paddles included, multifunction electrode pads and internal paddles
Controls and indicators on external paddles	Charge button, Shock buttons, Energy Select buttons, charge done indicator and patient contact indicator
Controls and indicators on internal paddles	Shock button
Shockable rhythm analysis time	< 5 s
Range of selected energy	
External defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 50, 70, 100, 120, 150, 170, 200, 300, 360 J
Internal defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 50 J
Patient impedance range	
External defibrillation	25 to 300 Ω
Internal defibrillation	15 to 300 Ω
Synchronized discharge delay	
Local synchronized discharge delay	< 60ms (from the peak of R-wave)
Remote synchronized discharge delay	< 25ms (from the rise edge of synchronous signal)
AED	
Shock series	Energy level: 100 to 360J, configurable for adult; 10 to 100J, configurable for pediatric Shocks: 1, 2, 3, configurable; Meeting AHA/ERC guidelines 2015 by default
AED ECG analysis performance	Refer to *C Mindray Shockable Rhythm Analysis Algorithm*.

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



Selected energy	Impedance							Accuracy
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	
1 J	1	1	1	0.9	0.9	0.9	0.8	±10% or ±2J, whichever is greater
2 J	2	2	2	1.9	1.8	1.7	1.6	
3 J	2.9	3	2.9	2.8	2.7	2.6	2.4	
4 J	3.9	4	3.9	3.7	3.6	3.4	3.2	
5 J	4.9	5	4.9	4.7	4.5	4.3	4.1	
6 J	5.8	6	5.8	5.6	5.3	5.1	4.9	
7 J	6.8	7	6.8	6.6	6.3	6	5.7	
8 J	7.8	8	7.8	7.4	7.1	6.8	6.5	
9 J	8.8	9	8.8	8.4	8	7.7	7.3	
10 J	9.7	10	9.7	9.3	8.9	8.5	8.1	
15 J	15	15	15	14	13	13	12	
20 J	20	20	20	19	18	17	16	
25 J	24	25	24	23	22	21	20	
30 J	29	30	29	28	27	25	24	
50 J	49	50	49	47	45	43	41	
70 J	68	70	68	65	62	60	57	
100 J	97	100	97	93	89	85	81	
120 J	116	120	116	111	106	101	97	
150 J	146	150	146	140	134	128	122	
170 J	166	170	166	159	151	145	138	
200 J	195	200	195	187	178	170	163	
300 J	292	300	292	280	267	255	244	
360 J	351	360	350	336	321	306	293	

Power supply	Manual Defib						AED					
	Charge time*		From initial power on (from cold start) to charge done		From initial power on (from fast startup mode) to charge done		From initiation of rhythm analysis to charge done		From initial power on (from cold start) to charge done		From initial power on (from fast startup mode) to charge done	
	200J	**360J**	**200J**	**360J**	**200J**	**360J**	**200J**	**360J**	**200J**	**360J**	**200J**	**360J**
With a new fully charged battery	<3 s	<7 s	<11 s	<14 s	<6 s	<10 s	<10 s	<12 s	<21 s	<26 s	<13 s	<15 s
With a new fully charged battery, depleted by 15 discharges of 360 J	<4 s	<8 s	<12 s	<15 s	<7 s	<11 s	<11 s	<13 s	<23 s	<27 s	<14 s	<16 s
With an external power supply	<4 s	<7 s	<11 s	<14 s	<7 s	<10 s	<11 s	<12 s	<22 s	<24 s	<14 s	<15 s
* The battery is charged at ambient temperature of 20 ±5 °C.												

NOTE

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

A.7.2 CPR Compression Specifications

Compressions from CPR Sensor

Compression rate	Measurement range: 40 to 160 cpm Accuracy: ±2 cpm

Compressions from Electrode Pads

Compression rate	Measurement range: 60 to 200 cpm Accuracy: ±3 cpm

A.7.3 Pacer Specifications

Standards	Meet standards of IEC 60601-2-4
Pacer mode	Demand, fixed
Output waveform	Monophasic square wave pulse pulse width 20 ms or 40 ms Accuracy: ±5%
Pacing rate	30ppm to 210ppm Accuracy: ±1.5% Resolution: 5 ppm
Pacing output	0mA to 200mA, Accuracy: ±5% or ±5mA, whichever is greater Resolution: 1mA, 2mA or 5mA
Refractory period	200 to 300 ms (depending on pacing rate)
4:1 pacing	Pacing pulse frequency reduced by factor of 4 when this function is activated.

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.8 Monitor Specifications

A.8.1 ECG Specifications (from ECG Accessories)

Standards	Meet standards of IEC 60601-2-27 and IEC 60601-2-25
Patient connection	3-lead ECG cable, 5-lead ECG cable or 12-lead ECG cable
ECG inputs	3-lead ECG: I, II, III 5-lead ECG: I, II, III, aVR, aVL, aVF, V 12-lead ECG: I, II, III, aVR, aVL, aVF, V1 to V6
ECG standard	AHA, IEC
Display sensitivity	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto, less than ± 5% error
Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, less than ± 5% error
Bandwidth (-3dB)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz ST mode: 0.05 to 40 Hz High Freq Cut-off (for 12-lead ECG analysis): 350 Hz, 150Hz, 35Hz, 20Hz, selectable
Common mode rejection	Monitor, Therapy and ST modes: >105 dB (with notch filter on), >90 dB (with notch filter off) Diagnostic mode: >90 dB (with notch filter off) High Freq Cut-off (for 12-lead ECG analysis): >90 dB (with notch filter off)
Notch filter	50/60Hz, Monitor, Therapy and ST modes: notch filter turns on automatically. Diagnostic mode and High Freq Cut-off: notch filter is turned on manually. Rejection on power frequency interference: ≥20 dB
Differential input impedance	≥5 MΩ
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Electrode offset potential tolerance	±500mV
Lead-off detection current	Measuring electrode: ≤0.1 μA Drive electrode: ≤1 μA
Baseline recovery time	<2.5 s (after defibrillation)
Defibrillation protection	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <2.5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s Noise rejection: 2mV In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27
Pace Pulse	

Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs (no greater than 10% of pulse width) No overshoot
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs Input slew rate: 2.2 V/s ± 15% RTI No overshoot
HR	
Measurement range	Adult: 15 to 300 bpm Pediatric, neonate: 15 to 350 bpm
Accuracy	±1% or ±1bpm, which ever is greater
Resolution	1 bpm
Sensitivity	200 µV (lead II)
Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the screen is updated every second.
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s
Time to alarm for tachycardia	Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27. Waveform 4ah - range: <11 s 4a - range: <11 s 4ad - range: <11 s 4bh - range: <11 s 4b - range: <11 s 4bd - range: <11 s
Arrhythmia analysis classifications	Asystole, V-Fib/V-Tach, V-Tach, Vent. Brady, Extreme Tachy, Extreme Brady, Vent Rhythm, PVCs/min, Pauses/min, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVC, Brady, Tachy, Missed Beat, Pacer Not Pacing, Pacer Not Capture, Multiform PVC, Nonsus V-Tach, Pause, Irr Rhythm, A-Fib (only for adults), SVT, SVCs/min
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): 80±1 bpm Slow alternating ventricular bigeminy (3b): 60±1 bpm Rapid alternating ventricular bigeminy (3c): 120±1 bpm Bidirectional systoles (3d): 90±2 bpm

ST Segment Analysis	
Measurement range	-2.0 to 2.0 mV RTI
Accuracy	-0.8 to 0.8 mV: ±0.02 mV or ±10%, whichever is greater. Beyond this range: Not specified.
Resolution	0.01 mV
QT/QTc Analysis	
Measurement range	QT: 200 to 800 ms QTc: 200 to 800 ms QT-HR: 15 to 150 bpm for adult, 15 to 180 bpm for pediatric and neonate
Accuracy	QT: ±30 ms
Resolution	QT: 4 ms QTc: 1 ms
12-lead ECG Interpretation	
Sampling rate	1000 samples/s (A/D) 500 samples/s (ECG algorithm)
Amplitude quantization	24 bits
Measurements	Heart rate, PR interval, QRS duration, QT/QTc interval, P/QRS/T axis and diagnosis statement

A.8.2 ECG Specifications (from Therapy Accessories)

Patient connection	Paddles or multifunction electrode pads
ECG inputs	Paddles or Pads
Display sensitivity	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto, less than ± 5% error
Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, less than ± 5% error
Bandwidth (-3dB)	Therapy mode: 1 to 20 Hz $\binom{+0.4dB}{-3.0dB}$
Common mode rejection	Therapy mode: >105 dB (with notch filter on)
Notch filter	Therapy mode: 50/60Hz, notch filter turns on automatically.
Differential input impedance	≥5 MΩ
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Electrode offset potential tolerance	±1V
Lead-off detection current	≤0.1 μA
Baseline recovery time	<2.5 s (after defibrillation)
Defibrillation protection	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <2.5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
ESU protection	Cut mode: 300 W Coagulate mode: 100 W Recovery time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27
Pace Pulse	

Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs (no greater than 10% of pulse width) No overshoot
Pace pulse rejection	When tested in accordance with the IEC 60601-2-27: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ± 700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs No overshoot
HR	
Measurement range	Adult: 15 to 300 bpm Pediatric 15 to 350 bpm
Accuracy	±1% or ±1bpm, which ever is greater
Resolution	1 bpm
Sensitivity	200 µV
Heart rate averaging	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the screen is updated every second.
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s
Time to alarm for tachycardia	Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27. Waveform 4ah - range: <11 s 4a - range: <11 s 4ad - range: <11 s 4bh - range: <11 s 4b - range: <11 s 4bd - range: <11 s
Arrhythmia analysis classifications	Asystole, V-Fib/V-Tach, PNP, PNC
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (3a): 80±1 bpm Slow alternating ventricular bigeminy (3b): 60±1 bpm Rapid alternating ventricular bigeminy (3c): 120±1 bpm Bidirectional systoles (3d): 90±2 bpm

A.8.3 Resp Specifications

Lead	Options are lead I, II and Auto.
Respiration excitation waveform	<300 μA RMS, 62.8 kHz (±10%)
Minimum respiration impedance threshold	0.3Ω with× 5 gain
Baseline impedance range	200 to 2500Ω, using an ECG cable with 1 kΩ resistor
Bandwidth	0.2 to 2.5 Hz (-3 dB)
Sweep speed	6.25 mm/s, 12.5 mm/s or 25 mm/s, less than ± 5% error
Respiration Rate	
Measurement range	0 to 200 rpm
Resolution	1 rpm
Accuracy	121 to 200 rpm: ±2 rpm 0 to 120 rpm: ±1 rpm
Apnea alarm time	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s

A.8.4 SpO_2 Specifications

Mindray SpO_2 Module

Standard	Meet standards of ISO 80601-2-61
Measurement range	0 to 100%
Resolution	1%
Response time	< 30 s (normal perfusion, no disturbance, SpO_2 value sudden changes from 70% to 100%)
Accuracy*	70% to 100%: ±2%ABS (adult, pediatric) 70% to 100%: ±3%ABS (neonate) 0 to 69%: not specified
Refreshing rate	≤1 s

* One percent was added to the accuracies for neonatal sensors to account for accuracy variation due to properties of fetal hemoglobin. Studies were performed to validate the accuracy of Pulse Oximeter with neonatal SpO_2 sensors by contrast with a CO-Oximeter. Some neonates aged from 1 day to 30 days with a gestation age of 22 weeks to full term were involved in this study. The statistical analysis of data of this study shows the accuracy (Arms) is within the stated accuracy specification. Please see the following table.

Sensor type	Totally neonates	Data	Arms
518B	97 (51 male & 46 female)	200 pairs	2.38%
520N	122 (65 male & 57 female)	200 pairs	2.88%

The Pulse Oximeter with neonatal SpO_2 sensors was also validated on adult subjects.

PI	
Measurement range	0.05 to 20%
Resolution	0.05% to 9.99%: 0.01% 10.0% to 20.0%: 0.1%
CQI	
Display range	0 to 100
Resolution	1

Rate	
Display range	20 to 300 cpm
Accuracy range	40 to 160 cpm
Accuracy	±3 cpm
Resolution	1 cpm

Masimo SpO_2 Module

Standard	Meet standards of ISO 80601-2-61
Measurement range	1% to 100%
Resolution	1%
Response time	≤20 s (normal perfusion, no disturbance, SpO_2 value sudden changes from 70% to 100%)
Accuracy[1]	70% to 100%: ±2%ABS (measured without motion in adult/pediatric mode) 70% to 100%: ±3%ABS (measured without motion in neonate mode) 70% to 100%: ±3%ABS (measured with motion) 1% to 69%: not specified
Refreshing rate	≤1 s
SpO_2 averaging time	2-4 s, 4-6 s, 8 s, 10 s, 12 s, 14 s, 16 s
Low perfusion conditions	Pulse amplitude: >0.02% Light penetration: >5%
Low perfusion SpO_2 accuracy[2]	±2%
PI measurement range	0.02 to 20%

[1] The Masimo pulse oximeter with sensors have been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. One percent was added to the accuracies for neonatal sensors to account for accuracy variation due to properties of fetal hemoglobin.

The Masimo pulse oximeter with sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz. At an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz. At an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Nellcor SpO_2 Module

Standard	Meet standards of ISO 80601-2-61	
Measurement range	0 to 100%	
Resolution	1%	
Response time	≤30 s (normal perfusion, no disturbance, SpO_2 value sudden change from 70% to 100%)	
Accuracy	70% to 100%: 70% to 100%: 0 to 69%:	±2%ABS (adult, pediatric) ±3%ABS (neonate) not specified
Refreshing rate	≤1 s	

When the SpO_2 sensor is applied for neonatal patients as indicated, the specified accuracy range is increased by ±1%, to compensate for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.

A.8.5 PR Specifications

PR from Mindray SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Response time	<30 s (normal perfusion, no disturbance, PR value sudden changes from 25 to 220bpm)
Accuracy	±3 bpm
Refreshing rate	≤1 s

PR from Masimo SpO_2 Module

Measurement range	25 to 240 bpm
Resolution	1 bpm
Response time	≤20 s (with normal perfusion, no disturbance, and a PR value transition from 25 to 220 bpm)
Accuracy	±3 bpm (measured without motion) ±5 bpm (measured with motion)
Refreshing rate	≤1 s

PR from Nellcor SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Response time	≤30 s (normal perfusion, no disturbance, PR value sudden change from 25 to 250 bpm)
Accuracy	20 to 250 bpm: ±3 bpm 251 to 300 bpm: not specified
Refreshing rate	≤1 s

PR from IBP Module

Measurement range	25 to 350 bpm
Resolution	1 bpm
Accuracy	±1 bpm or ±1%, whichever is greater

A.8.6 NIBP Specifications

Standards	Meet standard of IEC 80601-2-30
Technique	Oscillometry
Mode of operation	Manual, Auto, STAT, Sequence
Auto mode repetition intervals	1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 1.5 h, 2 h, 3 h, 4 h, 8 h
STAT mode cycle time	5 min
Maximum measurement time	Adult, pediatric: 180s Neonate: 90s

Measurement range	Measurement Item	Adult	Pediatric	Neonate
	Systolic (mmHg)	25 to 290	25 to 240	25 to 140
	Diastolic (mmHg)	10 to 250	10 to 200	10 to 115
	Mean (mmHg)	15 to 260	15 to 215	15 to 125
Measurement accuracy*	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg			
Static pressure measurement range	0mmHg to 300mmHg			
Static pressure measurement accuracy	±3mmHg			
Resolution	1 mmHg			
Software overpressure protection	Adult: 297±3 mmHg Pediatric: 297±3 mmHg Neonate: 147±3 mmHg			
Initial cuff inflation pressure range	Adult: 80 to 280 mmHg Pediatric: 80 to 210 mmHg Neonate: 60 to 140 mmHg			
*Measurement accuracy verification: In adult and pediatric modes, the blood pressure measurements measured with this device are in compliance with the Standard for Non-invasive sphygmomanometers (ISO 81060-2)in terms of mean error and stardard deviation by comparing with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. For auscultatory reference, the 5th Korotkoff sound was used to determine the diastolic pressure. In neonatal mode, the blood pressure measurements measured with this device are in compliance with the American National Standard for Non-invasive sphygmomanometers (ISO 81060-2) in terms of mean error and standard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.				
PR				
Measurement range	30 to300 bpm			
Resolution	1 bpm			
Accuracy	±3bpm or ±3%, whichever is greater			

A.8.7 Temp Specifications

Standard	Meet the standard of ISO 80601-2-56
Technique	Thermal resistance
Operating mode	Direct mode
Measurement range	0 °C to 50 °C (32 °C to 122 °F)
Accuracy	±0.1 °C or ±0.2 °F (without considering probe error)
Resolution	0.1 °C
Refreshing rate	≤1 s
Minimum time for accurate measurement	Body surface: <100 s Body cavity: <80 s

A.8.8 IBP Specifications

Standard	Meet the standard of IEC 60601-2-34
IBP	
Measurement range	-50 mmHg to 360mmHg
Resolution	1 mmHg

Accuracy	±2% or ±1 mmHg, whichever is greater (excluding sensor error)
Refreshing rate	≤1 s
Pressure transducer	
Excitement voltage	5 VDC, ±2%
Sensitivity	5 μV/V/mmHg
Zero adjustment range	±200 mmHg
Impedance range	300 to 3000Ω
Volume displacement	<0.04 mm^3 /100 mmHg

A.8.9 CO_2 Specifications

Standard	Meet the standard of ISO 80601-2-55	
Measurement range	0 to 150 mmHg	
Accuracy[1]	Full accuracy mode: 0 to 40 mmHg: ±2 mmHg 41 to 76 mmHg: ±5% of reading 77 to 99 mmHg: ±10% of reading 100 to 150 mmHg: ±(3 mmHg+8% of reading)	
Accuracy drift	Meets the requirement for measurement accuracy within 6 hours.	
Resolution	1mmHg	
Sample flowrate tolerance	±15% or ±15 ml/min, whichever is greater.	
Sart-up time	20 s (typical), 90 s (maximum)	
Sample flowrate	50 ml/min	
Rise time	≤200 ms @ 50 ml/min (measured with a CO_2 adapter and sampling line) ≤250 ms @ 50 ml/min (measured with a standard sampling line) ≤280 ms @ 50 ml/min (measured with a long sampling line)	
Response time	≤5.0 s@50ml/min (measured with a CO_2 adapter and sampling line) ≤5.0 s@50ml/min (measured with a standard sampling line) ≤6.5 s@50ml/min (measured with a long sampling line)	
Apnea time	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s	
awRR		
awRR measurement range	0 to 150 rpm	
awRR accuracy	≤60 rpm: ±1 rpm 61 to 150 rpm: ±2 rpm	
awRR resolution	1 rpm	
Effect of interference gases on CO_2 measurements		
Gas	**Concentration**	**Quantitative effect[2]**
O_2	≤100%	±1 mmHg
N_2O	≤60%	
Hal	≤4%	
Sev	≤5%	
Iso	≤5%	
Enf	≤5%	

Des	≤15%	±2 mmHg

[1] Inaccuracy specifications are affected by the breath rate and I: E change. The $EtCO_2$ accuracy is within specification for breath rate ≤ 60rpm and I/E ratio ≤1:1, or breath rate ≤30rpm and I/E ratio ≤ 2:1.

[2] means an extra error should be added in case of gas interference when CO_2 measurements are performed between 0-40mmHg.

B EMC and Radio Regulatory Compliance

B.1 EMC

The equipment meets the requirements of 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		
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60601-1-2 EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 60601-1-2 EN 61000-3-3	Complies	

If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration — Electromagnetic Immunity**, the equipment will remain safe and provide the following essential performance: HR accuracy, Resp accuracy, SpO_2 accuracy, PR accuracy, NIBP accuracy, Temp accuracy, IBP accuracy, CO_2 accuracy, Pacing rate accuracy, Pacing output accuracy, energy accuracy, CPR function, alarm, data stored, user's interface function.

Guidance and Declaration - Electromagnetic Immunity			
The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips and Voltage interruptions IEC 61000-4-11	0% U_T for 0,5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/300 cycle	0% U_T for 0,5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity

The equipment is suitable for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conduced RF IEC 61000-4-6	3 Vrms 150k to 80 MHz	3 Vrms (V1)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$ 150k to 80 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range [d] Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM bands and amateur radio bands[a] between 0.15 MHz and 80 MHz	6 Vrms (V2)	
Radiated RF EM fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz (IEC60601-2-27, IEC60601-2-25, IEC60601-2-49, IEC60601-2-34)	3 V/m (E1)	
	10V/m 80 MHz to 2.7 GHz (IEC60601-2-4)	10 V/m	
	20V/m 80 MHz to 2.7GHz (IEC60601-2-4, IEC80601-2-30, ISO 80601-2-55, ISO 80601-2-56, ISO 80601-2-61)	20 V/m	
Proximity fields from RF wireless communications equipment IEC61000-4-3	27 V/m 380 to 390 MHz	27 V/m	
	28 V/m 430 to 470 MHz, 800 to 960 MHz, 1700 to 1990 MHz, 2400 to 2570 MHz	28 V/m	
	9 V/m 704 to 787 MHz, 5100 to 5800 MHz	9 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] Compliance level in the ISM frequency bands between 150 kHz to 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that portable/ mobile communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

[d] Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment			
The equipment is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00
For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

B.2 Radio Regulatory Compliance

CE

The device comply with the essential requirements and other relevant provisions of Directive 2014/53/EU.

WARNING

- **Keep a distance of at least 20 cm away from the equipment when wireless function is in use.**

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