BeneHeart D6/BeneHeart D5

Defibrillator/Monitor

White Paper

CE 2797

■ Release time: 2022-05

■ Revision: 1.0

Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this Mindray product and this white paper. This white paper may refer to information protected by copyrights or patents and does not convey any license under the patent rights of Mindray, nor the rights of others.

Mindray intends to maintain the contents of this white paper as confidential information. Disclosure of the information in this white paper in any manner whatsoever without the written permission of Mindray is strictly forbidden.

Release, amendment, reproduction, distribution, rental, adaption and translation of this white paper in any manner whatsoever without the written permission of Mindray is strictly forbidden.

mindray and BeneHeart are the registered trademarks or trademarks owned by Mindray in China and other countries. All other trademarks that appear in this white paper are used only for editorial purposes without the intention of improperly using them. They are the property of their respective owners.

Responsibility on the Manufacturer Party

Contents of this white paper are subject to changes without prior notice.

All information contained in this white paper is believed to be correct. Mindray shall not be liable for errors contained herein nor for incidental or consequential damages in connection with the furnishing, performance, or use of this white paper.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements;
- the product is used in accordance with the instructions for use.

WARNING

- **This equipment must be operated by skilled/trained clinical professionals.**
- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Company Contact

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680

EC-Representative:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

Summary of Safety and Clinical Performance (SSCP):	https://www.mindray.com/etc.clientlibs/xpace/clientlibs/clientlib-site/resources/plugins/web/viewer.html?file=/content/dam/xpace/en/site/mdr-sscp/KF-0651-4-202-%20%20Summary-of%20safety-and%20-clinical-performance.pdf

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

Purpose

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

This white paper 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 white paper 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 white paper 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 white paper serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

- ***Italic*** text is used in this white paper to quote the referenced chapters or sections.
- [ ] is used to enclose screen texts.
- → is used to indicate operational procedures.

Contents

This page intentionally left blank.

1 Safety

1.1 Safety Information

DANGER

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

WARNING

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

CAUTION

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

NOTE

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

1.1.1 Dangers

DANGER

- **The equipment delivers up to 360 J of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this defibrillator unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.**
- **Defibrillation current can cause operator or bystander severe injury or even death. Keep distance from the patient or metal devices connected to the patient during defibrillation.**
- **Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Keep the equipment and the operating environment dry and clean.**

1.1.2 Warnings

WARNING

- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on smart lithium-ion batteries.**

- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure leads to the loss of patient data.**
- **Use and store the equipment in specified environmental condition. The equipment and accessories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.**
- **This equipment is used for single patient at a time.**
- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **Before each use, the operator must check the equipment condition to ensure that the equipment is ready for operation.**
- **Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.**
- **Do not defibrillate a patient who lies on the wet ground.**
- **Do not touch the patient and live parts simultaneously.**
- **Do not touch the patient when connecting the peripheral equipment via the I/O signal ports to prevent patient leakage current from exceeding the requirements specified by the standard.**
- **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**
- **Do not perform any functional check if the equipment is connected with a patient; otherwise the patient might be shocked.**
- **Remain attentive to the patient during applying therapy. Delay in delivering a shock may result in a rhythm that was analyzed as shockable converting spontaneously to non-shockable and could result in inappropriate delivery of a shock.**
- **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 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.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.**
- **If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the equipment for proper functioning.**
- **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. Misinterpretation of the measured values or other parameters can endanger the patient.**
- **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.**
- **To ensure patient safety, use only parts and accessories specified in this white paper.**
- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**

1.1.3 Cautions

CAUTION

- **Use of Manual Therapy security password requires the clinician to know and remember the password. Failure to enter correct password will prevent the delivery of manual defibrillation, synchronized cardioversion and pacing therapy.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.**
- **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 phones, X-ray equipment or MRI**

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

- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this white paper.**
- **Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- **Dry the equipment immediately in case of rain.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

1.1.4 Notes

NOTE

- **Put the equipment in a location where you can easily view and operate the equipment.**
- **The equipment uses a mains plug as isolation means to the mains power supply. Do not locate the equipment in a place difficult to operate the mains plug.**
- **During normal use, the operator shall stand in front of the equipment.**
- **Keep this white paper in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **If the equipment operates on a DC power supply, a DC/AC adapter we supply should be used.**
- **This white paper describes all features and options. Your equipment may not have all of them.**

This page intentionally left blank.

2 The Basics

2.1 Intended Use

2.1.1 Intended Purpose Statement

The equipment is intended for external defibrillation, internal defibrillation, synchronized cardioversion and semi-automated external defibrillation (AED). It can also be used for non-invasive external pacing 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

  The 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.

- Monitoring

  Monitoring is intended for the monitoring of ECG, Resp, SpO_2, PR, NIBP, IBP, Temp and CO_2 parameters.

2.1.3 Intended Users

The Defibrillator/Monitor is for 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 Mode

  The AED mode is to be used only on patients in cardiac arrest. The patients must be:

  - Unconsciousness
  - Absence of normal breathing
  - Absence of a pulse or 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 unresponsive. 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 Defibrillator/Monitor is for use in hospital and pre-hospital areas.

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

Through clinical data from literature and clinical data from post-market surveillance activity of device in question, there is no side-effects identified.

After search the literature of similar device, the results of SOTA evaluation shown that undesirable effects may include myocardial damage.

2.1.8 Clinical Benefit

Through the parameter monitoring, medical staff have established sufficient conditions to provide patients with a better medical monitoring environment, and the benefits are obvious.

Although there is also the possibility of false positives and false negatives in parameter monitoring, the impact of false positives and false negatives is limited and will not cause substantial harm to patients.

In addition, the parameter monitoring of the Defibrillator/Monitor has the advantages of simplicity of equipment, convenient operation, timeliness, economy, etc. compared with other known ones.

Therefore, from the perspective of benefit and risk, the parameter monitoring of the Defibrillator/Monitor has obvious benefits, controllable risks, and has strong clinical application popularization characteristics.

The Defibrillator/Monitors are life-saving device used in emergency situations. They have been shown to have a high benefit for patients with underlying diseases that remain undetected until sudden cardiac arrest occurs. The time from collapse to defibrillation is critical in-patient survival. For every minute that passes between collapse and defibrillation, survival rates from VF SCA decrease 7% to 10%.

2.2 Applied Parts

WARNING

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

3 Basic Operations and Settings

3.1 Equipment Installation

WARNING

- **The equipment shall be installed by personnel authorized by the manufacturer.**
- **The software copyright of the equipment is solely owned by the manufacturer. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact the manufacturer.**
- **If it is not evident from the equipment specifications whether a particular combination is hazardous, for example, due to summation of leakage currents, consult the manufacturers or else an expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.**

CAUTION

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

3.1.1 Unpacking and Checking

WARNING

- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**

NOTE

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

3.1.2 Environmental Requirements

NOTE

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **The equipment use a mains plug as isolation means to the mains power supply. Do not locate the equipment in a place difficult to operate the mains plug.**

3.2 Basic Operation

3.2.1 Connecting the AC Mains

WARNING

- **Always use the accompanying power cord delivered with the equipment.**
- **Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated besides the AC power input.**
- **Use the cable retainer to secure the power cord to prevent it from falling off.**
- **Use the battery if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.**

3.2.2 Turning On the Equipment

WARNING

- **Do not use the equipment for any monitoring or therapy procedure on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact your service personnel or Mindray.**

NOTE

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

, department, height, weight, admit date or doctor information can also be changed on the CMS.

3.2.3 Turning Off the Equipment

NOTE

- **To completely disconnect the power supply, unplug the power cord.**

4 Alarms

WARNING

- **A potential hazard exists if different alarm presets are used for the same or similar device in any single area, e.g. an intensive care unit or cardiac operating room.**
- **If the equipment is connected to a CMS, remote suspension, inhibition, silence and reset of monitoring alarms via the CMS may cause a potential hazard. For details, refer to the operator's manual of the CMS.**
- **Do not rely exclusively on the audible alarm system for monitoring. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always make sure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.**

4.1 Alarm Indicators

NOTE

- **When multiple alarms of different levels occur simultaneously, the equipment will select the alarm of the highest level and give visual and audible alarm indications accordingly. Alarm messages will be displayed circularly.**
- **Some physiological alarms, such as Asystole, are exclusive. They have identical alarm tones and alarm lights with normal high level physiological alarms, but their alarm messages are displayed exclusively. That is to say, when an exclusive physiological alarm and a normal high level physiological alarms are triggered simultaneously, only alarm message of the exclusive physiological alarm is displayed.**

4.2 Alarm Tone Configuration

4.2.1 Changing the Alarm Volume

NOTE

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

4.2.2 Setting the Interval between Alarm Sounds

WARNING

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

4.3 Understanding the Alarm Setup Menu

4.3.1 Setting Alarm Properties for All Parameters

WARNING

- **Make sure that the alarm limits settings are appropriate for your patient before patient monitoring.**
- **Setting the alarm limit to an extreme value may cause the alarm system to be ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration, do not set the SpO_2 high alarm limit to 100%, which is equivalent to switching the alarm off.**
- **When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.**

NOTE

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

4.3.2 Adjusting Alarm Limits Automatically

NOTE

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

5 Monitoring ECG

5.1 ECG Safety Information

WARNING

- **ECG monitoring is not suitable for direct cardiac application.**
- **Periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.**
- **Use defibrillation-proof ECG cables during defibrillation.**
- **When monitoring a patient implanted with a pacemaker, be sure to select correct paced status. Otherwise, the pace pulses may be counted in the case of cardiac arrest or some arrhythmias. Do not completely rely on the heart rate reading or the heart rate alarms. Always keep paced patients under close surveillance.**
- **PACEMAKER PATIENTS – On ventricular paced patients, episodes of Ventricular Tachycardia may not always be detected. Do not rely entirely upon the system's automated arrhythmia detection algorithm.**

CAUTION

- **Interference from a non-grounded instrument near the patient and electrosurgery interference can cause problems with the waveform.**

NOTE

- **When connecting electrodes and/or patient cables, make sure that the connectors never come into contact with other conductive parts, or with earth. Particularly make sure that all of the ECG electrodes are attached to the patient.**
- **If selected lead cannot provide valid ECG signals, a dash line is shown in the ECG waveform area.**
- **Avoid using external paddles for ECG monitoring if possible.**
- **Use the same type of ECG electrodes when monitoring ECG through ECG lead set.**

5.2 Preparing for ECG Monitoring and Measurement

5.2.1 Using ECG Electrodes

WARNING

- **When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.**
- **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.**

5.2.2 Checking Paced Status

WARNING

- **For paced patients, you must set [Paced] to [Yes]. If it is incorrectly set to [No], the equipment could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak. Do not rely entirely on 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]. If it is incorrectly set to [Yes], the equipment may be unable to detect premature ventricular beats (including PVCs).**
- **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. Keep pacemaker patients under close surveillance.**

5.3 Changing ECG Settings

5.3.1 Setting the ECG Filter

NOTE

- **For paced patients, you must set [Paced] to [Yes]. If it is incorrectly set to [No], the system may mistake an internal pace pulse for a QRS or fail to alarm when the pacer is broken.**

5.3.2 Switching On or Off the Notch Filter

NOTE

- **The setting of [Notch Filter] will not be changed by restoring to factory default settings nor shutting down the system.**

5.4 Arrhythmia Analysis

WARNING

- **Arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect supraventricular arrhythmias. It may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.**
- **Atrial fibrillation (Afib) detection function is not intended for pediatric and neonatal patients.**
- **Arrhythmia analysis is not intended for neonatal patients.**

5.4.1 Changing Arrhythmia Alarm Settings

NOTE

- **The alarm level for asystole, ventricular fibrillation, ventricular tachycardia, ventricular bradycardia, extreme bradycardia, and extreme tachycardia alarms is always high and unchangeable. These alarms are always on. As long as the alarm condition occurs, corresponding alarm will be triggered whether arrhythmia analysis is switched on or off.**

5.4.2 Initiating Arrhythmia Relearning Manually

NOTE

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

This page intentionally left blank.

6 Resting 12-Lead ECG Analysis

6.1 Placing 10-leadwire Electrodes

WARNING

- **When using electrosurgical units (ESU), place ECG electrodes between the ESU and its grounding plate to prevent unwanted burns. Never entangle ESU cable and ECG cable together.**
- **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.**

6.2 Entering the 12-lead ECG Screen

NOTE

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

6.3 Changing 12-Lead ECG Analysis Settings

6.3.1 Enabling Patient Information Input Prompt

NOTE

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

6.3.2 Setting the Baseline Drift Removal

NOTE

- **The baseline drift removal introduces around 1-second delay. We recommend using BDR except when the delay is unacceptable.**
- **The baseline correction function is only for 12-lead ECG monitoring. In 3-lead or 5-lead ECG monitoring, this function is disabled.**

6.3.3 Setting Tachy and Brady Threshold

NOTE

- **The [Tachy (Adu)] setup is only effective for patients at the age of 18 or above.**
- **The [Brady (Adu)] setup is only effective for patients at the age of 13 or above.**

6.4 Initiating Resting 12-lead ECG Analysis

CAUTION

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

NOTE

- **Always input the correct patient information before you start 12-Lead ECG analysis because the patient information, especially age, gender, and race, greatly affect the interpretation of the acquired ECG.**
- **If no patient information is inputted, the system will interpret the acquired ECG on the basis of a default of a 50 years old Caucasian male, which may result in misdiagnosis.**
- **The Lead Select hard key is disabled in the 12-lead ECG screen.**
- **During 12-lead ECG acquisition or analysis, you cannot select a parameter area to enter the parameter setup menu. The Main Menu button and the Event button on the front panel are also disabled.**
- **The filter mode is set to [ST] automatically for 12-lead ECG acquisition and analysis.**
- **If the defibrillator is on a moving vehicle, stop the vehicle when acquiring 12-lead ECG.**

7 AED

7.1 AED Safety Information

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any metal objects connected to the patient (including the bed or gurney) during defibrillation.**
- **Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.**
- **Do not allow electrode pads to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.**

WARNING

- **During defibrillation, air pockets between the skin and electrode pads can cause patient skin burns. To help prevent air pockets, make sure electrode pads are completely adhered to the skin.**
- **Do not use dried-out electrode pads.**

CAUTION

- **Aggressive handling of electrode pads in storage or prior to use can damage the electrode pads. Discard the electrode pads if they become damaged.**
- **For patients with implantable pacemaker, the sensitivity and specificity of AED algorithm may be impaired.**

NOTE

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

7.2 AED Procedure

NOTE

- **Anterior - lateral placement for adult patients, and anterior-posterior placement for pediatric patients are recommended placements for defibrillation with electrode pads.**
- **For defibrillation of pediatric patients under 8 years, pediatric electrode pads should be used.**
- **If pediatric electrode pads are not available, the adult electrode pads may be used instead, and set the patient category to [Ped].**
- **Motion artifact may delay analysis or affect the ECG signal resulting in an inappropriate shock or no shock advised message. Keep the patient still during ECG rhythm analysis.**
- **The Shock button must be pressed to deliver a shock. The equipment will not automatically deliver a shock.**
- **Impedance is the resistance between the electrode pads/external paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient**

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

7.3 CPR

NOTE

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

8 Manual Defibrillation

8.1 Manual Defibrillation Safety Information

DANGER

- **Defibrillation current can cause operator or bystander severe injury or even death. Never touch the patient or any metal objects connected to the patient (including the bed or gurney) during defibrillation.**
- **Avoid contact between parts of the patient's body such as exposed skin of head or limbs, conductive fluids such as gel, blood, or saline, and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.**
- **Do not allow electrode pads and paddles to touch each other or to touch other ECG monitoring electrodes, lead wires, dressings, etc. Contact with metal objects may cause electrical arcing and patient skin burns during defibrillation and may divert current away from the heart.**
- **During manual defibrillation, make sure your hands are dry and free from conductive gel to avoid shock hazard.**
- **Use care when operating this equipment close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation. This can cause an explosion hazard.**

WARNING

- **During synchronized cardioversion, if monitoring patient's ECG through external paddles, artifact introduced by paddle movement may resemble an R-wave and trigger a defibrillation shock.**
- **Do not use conductive liquid. Use only conductive gel specified by the equipment manufacturer.**
- **If external paddles are used for defibrillation, apply the external paddles tightly and evenly to the patient's chest to ensure good skin contact.**
- **Never apply the paddles to human body to verify paddle connection.**
- **Clinicians must select an appropriate energy level for defibrillation of pediatric patients.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

CAUTION

- **Use of Manual Defib mode may be password protected. Make sure the operator knows and remembers the password as defined in Configuration. Failure to enter correct password will prevent the delivery of manual defibrillation therapy.**
- **Clear the conductive gel from the external paddles at the completion of the therapy to prevent the paddles from being corroded.**
- **Prior to using the equipment, disconnect the patient from all equipment that is not defibrillator-protected.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

NOTE

- **Impedance is the resistance between the electrode pads/external paddles that the defibrillator must overcome to deliver an effective discharge of energy. The degree of impedance differs from patient to patient and is affected by several factors including the presence of chest hair, moisture, and lotions or powders on the skin. If the "Impedance Too High, Shock Not Delivered" message appears, make sure that the patient's skin has been dried and that any chest hair has been clipped. If the message persists, change the electrode pads and/or the pads cable.**
- **Alarms are switched off automatically and the "Alarm Off" message is displayed when the equipment enters the asynchronous defibrillation mode. Alarms remain off until toggled on by pressing the Alarm Pause button, the Sync mode, the Monitor mode or Pacer mode is entered.**
- **Successful resuscitation is dependent on many variables specific to the patient's physiological state and the circumstances surrounding the patient event. Failure to have a successful patient outcome is not a reliable indicator of equipment performance. The presence or absence of a muscular response to the transfer of energy during electrical therapy is not a reliable indicator of energy delivery or equipment performance.**

8.2 Manual Defibrillation Procedure

WARNING

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

NOTE

- **Anterior - lateral placement for adult patients, and anterior-posterior placement for pediatric patients are recommended placements for defibrillation with electrode pads.**
- **Anterior - lateral placement is the only placement for defibrillation with external paddles.**
- **Defibrillation is always performed through external paddles or electrode pads. However, during defibrillation you may choose to monitor the ECG using an alternate ECG source (3- or 5-lead monitoring electrodes). If an alternate ECG source is connected, any available lead may be displayed.**
- **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 pediatric patients under 8 years, pediatric electrode pads should be used.**
- **If pediatric electrode pads are not available, the adult electrode pads may be used instead, and set the patient category to [Ped].**
- **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.**

8.2.1 Using Internal Paddles

NOTE

- **When internal paddles are used for defibrillation, the energy selection is automatically limited to 50 joules because of possible cardiac damage from higher energies.**
- **Sterilize the internal paddles before each use. Otherwise, severe infection may result.**
- **Clean the internal paddles after each use.**

8.3 Synchronized Cardioversion

CAUTION

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

NOTE

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

8.3.1 Performing Synchronized Cardioversion

NOTE

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

8.4 Remote Synchronized Cardioversion

NOTE

- **During remote synchronized cardioversion, the local equipment does not display the ECG waveform. To view the patient's ECG, check the remote monitor.**
- **When you use a remote monitor as the ECG source, a biomedical technician must verify that the remote monitor and the equipment combination will deliver a synchronized shock within 60 ms after the peak of the next R-wave is generated.**

8.5 Patient Contact Indicator

NOTE

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

This page intentionally left blank.

9 CPR Assistance

9.1 CPR Assistance Introduction

WARNING

- **Perform CPR on a patient on firm ground if possible. When you perform CPR on a patient lying on a mattress, a backboard must be used to limit the amount of compressed depth which is absorbed by the mattress. Depending on characteristics of the mattress, backboard and patient, the compensation depth does not guarantee that the patient chest is compressed by 50 mm.**
- **When the patient is breathing with high frequency or in the treatment of high-frequency ventilation, the CPR assistance disturbed by the thoracic movements may provide inaccurate feedback. You should count compressions by yourself and not rely on the compression rate provided by the CPR assistance in such conditions.**
- **The CPR assistance is not intended for use in a moving environment, such as an ambulance. If used during patient transport, the CPR assistance may provide inaccurate feedback. If CPR is indicated in a moving environment, do not rely on feedback provided by the CPR assistance in such conditions.**

NOTE

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

9.2 Using CPR Metronome

WARNING

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

NOTE

- **The CPR metronome is disabled when [Voice Prompts] in the [AED Setup] menu is configured off through the Configuration Main menu.**
- **The volume of CPR metronome is affected by [Voice Volume] in the [AED Setup] menu configured through the Configuration Main menu.**

9.3 Using CPR Filter

CAUTION

- **The CPR filter works only when you perform CPR using electrode pads or the CPR sensor in the AED or Manual Defib mode.**
- **The CPR filter will not remove all CPR artifact. You should always follow the standard procedure of stopping CPR to verify the patient's ECG rhythm before making treatment decisions.**
- **The filtered ECG waveform must be used in conjunction with clinical signs and symptoms. It should not be used as the sole basis for diagnosis or therapy decisions.**

NOTE

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

9.4 Reviewing CPR Events

NOTE

- **A CPR event is automatically saved in the equipment when the interruption time exceeds five minutes.**
- **You should select [Refresh] to save a CPR event before disconnecting the CPR sensor from the equipment.**

10 Noninvasive Pacing

10.1 Pacing Introduction

NOTE

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

10.2 Pacing Safety Information

WARNING

- **Heart rate displays and alarms function during pacing, but they can be unreliable. Observe the patient closely while pacing. Do not rely on the indicated heart rate or heart rate alarms as a measure of the patient's perfusion status.**
- **To avoid explosion hazard when pacing a patient who is receiving oxygen delivery, properly route the oxygen delivery tube. Do not keep it close to the electrode pads.**
- **Monitoring ECG alone is sometimes not enough to verify that the patient's heart is providing cardiac output.a patient's response to pacing shall be verified by signs of improved cardiac output, such as: a palpable pulse rate the same as the rate which pace pulses are being delivered, a rise in blood pressure, and/or improved skin color.**

CAUTION

- **Use of Pacer mode may be password protected. Make sure the operator knows and remembers the password as defined in Configuration. Failure to enter correct password will prevent the delivery of pacing therapy.**
- **For treatment of patients with implanted devices such as permanent pacemakers or cardioverter-defibrillators, consult a physician and the instructions for use provided by the device's manufacturer**
- **Prolonged noninvasive pacing may cause patient skin irritation and burns. Periodically inspect the underlying skin and change ECG electrodes and electrode pads.**

NOTE

- **If pacing is interrupted for any reason, the [Start Pacing] soft key must be pressed to resume pacing.**
- **In the Pacer mode, you cannot change the patient's internal paced status from the [ECG Setup] menu.**
- **In the case that electrode pads poorly contact the patient, the alarm "Pacer Stopped Abnormally" and "Pads Off" may be presented.**
- **Electrode pads are not an available choice for the source of ECG waveform in the Pacer mode.**

10.3 Pacer Mode

CAUTION

- **Use demand mode pacing whenever possible. Use fixed mode pacing if noise or artifact interferes with proper sensing of R-wave or when monitoring electrodes are not available.**
- **During fixed mode pacing, R-wave markers do not appear on the paced beats.**
- **During demand mode pacing, spontaneous beats may be presented which are not associated with the delivery of pace pulse. If the patient's heart rate is above the pacer rate, pace pulses are not delivered and, therefore, pace markers do not appear.**

10.4 Preparing for Pacing

10.4.1 Demand Mode Pacing

CAUTION

- **Routinely assess the patient's cardiac output.**

NOTE

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

10.4.2 Fixed Mode Pacing

WARNING

- **Use care when handling the electrode pads on the patient to avoid shock hazard during pacing.**
- **If you are using the pacing function with battery power and the Low Battery alarm is presented, connect the equipment to external power or install a fully charged battery.**

CAUTION

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

11 Monitoring Resp

11.1 Resp Safety Information

WARNING

- **When monitoring the patient's respiration, do not use ESU-proof ECG cables.**
- **The respiration measurement does not recognize obstructive and mixed apneas: it only indicates an alarm when a pre-adjusted time had elapsed since the last detected breath. The safety and effectiveness of the respiration measurement method in the detection of apnea, especially the apnea of prematurity and apnea of infancy, has not been established.**

11.2 Placing Resp Electrodes

NOTE

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

11.2.1 Optimizing Lead Placement for Resp

NOTE

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

This page intentionally left blank.

12 Monitoring PR

12.1 PR Introduction

NOTE

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

This page intentionally left blank.

13 Monitoring SpO_2

13.1 SpO_2 Safety Information

WARNING

- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.**
- **Do not use SpO_2 sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns.**
- **Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For neonates or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.**
- **If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.**
- **When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.**
- **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. If this is a consideration, do not set the high alarm limit to 100%, which is equivalent to switching off the alarm.**
- **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 is not an apnea monitor.**
- **The pulse oximeter 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 white paper.**
- **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.**
- **Use only SpO_2 sensors specified in this white paper. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.**
- **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.**
- **The SpO_2 extension cable should be compatible with the SpO_2 connectors. For example, you can only connect the Mindray SpO_2 extension cable to the Mindray SpO_2 connectors.**
- **The SpO_2 simulator can be used to verify the accuracy of the SpO_2 sensor.**

13.2 SpO_2 Display

NOTE

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

13.2.1 Setting SpO_2 Sensitivity (for Masimo SpO_2)

CAUTION

- **When using the Maximum Sensitivity setting, performance of "SpO2 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.**

13.3 SpO_2 Desat Alarm

NOTE

- **In the case that the SpO_2 low limit alarm value is set below the Desat limit, the SpO_2 low limit is automatically adjusted to the Desat value.**

14 Monitoring NIBP

14.1 NIBP Introduction

NOTE

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

14.2 NIBP Safety Information

WARNING

- **Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise it may present a safety hazard.**
- **Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.**
- **Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.**
- **NIBP reading can be affected by the measurement site, the position of the PATIENT, exercise, or the patient's physiologic condition. If you doubt the NIBP readings, determines the patient's vital signs by alternative means and then verify that the equipment is working correctly.**
- **Do not use the NIBP cuff on the arm on the side of a mastectomy or lymph node clearance.**
- **Continuous CUFF pressure due to connection tubing kinking may cause blood flow interference and resulting harmful injury to the patient.**
- **NIBP diagnostic significance must be decided by the physician.**

14.3 NIBP Measurement Procedure

14.3.1 Preparing the Patient

NOTE

- **It is recommended that the patient relaxes as much as possible before performing measurement and that the patient does not talk during NIBP measurement.**
- **It is recommended that 5 min should elapse before the first reading is taken.**
- **A wrong cuff size and a folded or twisted bladder can cause inaccurate measurements.**
- **Do not touch or apply external pressure against the cuff and air tubing during NIBP measurement. This may cause inaccurate blood pressure values.**

14.3.2 Starting Auto NIBP Measurements

WARNING

- **Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately.**

14.4 Setting Initial Cuff Inflation Pressure

NOTE

- **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**
- **Setting initial cuff inflation pressure is disabled during NIBP measurement.**
- **The initial cuff inflation pressure is restored to the default setting if NIBP module has been reset or patient category has been changed.**

15 Monitoring Temp

15.1 Temp Measurement Procedure

NOTE

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

This page intentionally left blank.

16 Monitoring IBP

16.1 IBP Safety Information

WARNING

- **Use only pressure transducers specified in this white paper. Never reuse disposable pressure transducers.**
- **Make sure that the applied parts never contact other conductive parts.**
- **To reduce the hazard of burns during high-frequency surgical procedure, ensure that the equipment's cables and transducers never come into contact with the high-frequency surgical units.**
- **When accessories are used, make sure the operation environment meets the requirements for accessory's operation temperature specified by the instructions for use.**

16.2 IBP Measurement Procedure

NOTE

- **If air bubbles appear in the tubing system, flush the system with the infusion solution again. Air bubble may lead to wrong pressure reading.**
- **If measuring intracranial pressure (ICP) for a sitting patient, level the transducer with the top of the patient's ear. Incorrect leveling may give incorrect reading.**

16.3 IBP Troubleshooting

NOTE

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

This page intentionally left blank.

17 Monitoring CO_2

17.1 CO_2 Safety Information

WARNING

- **Remove the airway sampling line from the patient's airway while nebulized medications are being delivered.**
- **Leakage in the breathing or sampling system may cause the displayed $EtCO_2$ values to be significantly low. Always make sure that all components are securely connected.**
- **$EtCO_2$ values measured from the CO_2 module may differ from those of from the blood gas analysis.**
- **Route all tubing away from the patient's throat to avoid strangulation.**
- **Inspect the airway adapter for a tight connection and proper operation before attaching it to the patient.**
- **Squeezing or bending the sampling line during the CO_2 measurement may cause inaccurate CO_2 reading or no reading.**

17.2 Preparing for Measuring CO_2

CAUTION

- **Connect the gas outlet to the scavenging system when measuring CO_2 using the sidestream CO_2 module.**
- **To avoid blocking the airway, empty the DRYLINE II watertrap container whenever half full. Replacing the DRYLINE II watertrap once a month is recommended.**
- **The watertrap has a filter preventing bacterium, water and secretions from entering the module. Extended use could destroy the filter in watertrap and fail to stop the bacterium, water and secretions entering the module, result in damaging the gas module and having infection risk.**

NOTE

- **Do not apply adult watertrap to the neonate patient. Otherwise, patient injury could result.**
- **To extend the lifetime of the watertrap and module, disconnect the watertrap from the module and set the operating mode to Standby mode when CO_2 monitoring is not required.**
- **The emptying interval of the DRYLINE II adult/pediatric watertrap is 31 hours @ 100 ml/min, sample gas of 37 °C, room temperature of 23 °C, 100% RH.**
- **The emptying interval of the DRYLINE II neonatal watertrap is 45 hours @ 70 ml/min, sample gas of 37 °C, room temperature of 23 °C, 100% RH.**

17.2.1 Measuring CO_2 Using the Microstream CO_2 Module

CAUTION

- **Do not apply adult watertrap to the neonate patient. Otherwise, patient injury could result.**
- **Connect the gas outlet to the scavenging system when measuring CO2 using the microstream CO2 module.**

NOTE

- **Disconnect the sampling line from the module when CO_2 monitoring is not required.**
- **When sample gas of 37 °C, sample flowrate of 50 ml/min, room temperature of 23 °C, 100% RH, the sampling line with a general type should be replaced once at most every 8 hours, and the sampling line with a humidified type should be replaced once at most every 72 hours.**

17.2.2 Zeroing the CO_2 Sensor

NOTE

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

17.2.3 Selecting Gas Compensations

WARNING

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

17.3 Removing the Exhaust Gases from the System

WARNING

- **When taking the CO_2 measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.**

17.4 CO_2 Calibration

CAUTION

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

18 Review

18.1 Reviewing Events

NOTE

- **Pausing or switching off alarms will not be recorded as events.**
- **A total loss of power has no impact on the saved events.**
- **Earlier-recorded events might be overwritten by later ones if it reaches capacity.**

This page intentionally left blank.

19 Data Management

19.1 Generating Patient Data

NOTE

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

19.2 Exporting Patient Data

NOTE

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

This page intentionally left blank.

20 Recording

20.1 Setting the Recorder

NOTE

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

20.2 Loading Paper

CAUTION

- **Use only specified thermal paper. Otherwise, it may cause damage to the recorder's print head, the recorder may be unable to print, or poor print quality may result.**
- **Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.**
- **Do not leave the recorder door open unless you have to reload paper or remove troubles.**

20.3 Cleaning the Recorder Print Head

CAUTION

- **Do not use anything that may destroy the thermal element.**
- **Do not add unnecessary force to the thermal head.**

This page intentionally left blank.

21 Network Connection

21.1 Network 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.**
- **To ensure network security and stability, data communication should be performed within a closed network or within a virtually isolated network provided by a hospital for all network functions. The hospital is responsible for ensuring the security of the virtually isolated network.**
- **Keep network authentication information, for example password, from being accessed by unauthorized users.**
- **Do not connect non-medical devices to the hospital network.**
- **If wireless network signal is poor, there may be a risk of CMS data loss.**
- **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 problem as soon as possible.**
- **Ensure that the equipment network settings are correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on the network settings.**

This page intentionally left blank.

23 Battery

23.1 Battery Safety Information

WARNING

- **The batteries should be charged in this equipment or in a device approved by the equipment manufacturer.**
- **Keep the batteries out of children's reach.**
- **Use only specified batteries.**

NOTE

- **Always connect the equipment to AC mains whenever it is possible.**
- **Always install a fully charged battery in the equipment.**
- **After long term use, the power capacity indicated by the battery symbol may be different from the actual capacity. Always observe the alarm information displayed on the screen.**
- **Remove the battery before transporting the equipment or if the equipment will not be used for a long time.**

23.1.1 Low Battery Alarm

NOTE

- **The alarm "Low Battery" means that the battery is beginning to weaken, you should replace the battery or connect the equipment to the external power supply immediately. At least 20 minutes of monitoring and six 360J shocks can be performed when "Low Battery" is triggered.**

23.2 Conditioning the Battery

NOTE

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

23.3 Checking Battery Performance

NOTE

- **Battery operating time depends on the device configuration and operation. For example, measuring NIBP repeatedly will shorten the battery operating time.**

23.4 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.**

23.5 Recycling the Batteries

WARNING

- **Do not disassemble, puncture or incinerate batteries. Do not short the battery terminals. They may ignite, explode, or leak, causing personal injury.**

24 Care and Cleaning

WARNING

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

24.1 General Points

WARNING

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

CAUTION

- **Contact your service personnel in case of spilling liquid on the equipment or accessories.**

NOTE

- **To clean or disinfect reusable accessories, refer to the instructions for use delivered with the accessories.**

This page intentionally left blank.

25 Maintenance

25.1 Maintenance Safety Information

WARNING

- **Failure for the responsible individual, hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **If you find a problem with any of the equipment, contact your service personnel or the manufacturer.**
- **No modification of this equipment is allowed.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**
- **Do not touch any connected electrode pads or external paddles with hands during user test and auto test. Otherwise, electric shock could result.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.**

25.2 Routine Maintenance

25.2.1 Auto Test

NOTE

- **If turned off, the auto test is performed only when AC mains is connected.**
- **The auto test simulates the discharge test through impedances in the paddle tray. The auto test passes only when external paddles properly contact the metal parts of the paddle tray.**
- **Thoroughly clean the external paddles and properly place them in the paddle tray after each use. Otherwise, the auto test may fail or damaged external paddles may result.**
- **The auto test reduces the battery power. If the equipment is not connected to the AC mains immediately, low battery may result.**
- **Before the auto test, check that the equipment is connected to the AC mains with a battery installed, and external paddles are properly placed in the paddle tray or the equipment is connected with the pads cable and 50 Ω test load. If the pads cable is not connected with the 50 Ω test load, the message "Test load not connected with cable" appears when the auto test passes. This means that the equipment only passes the internal discharge test, but not pass the external discharge test connected with the test load.**

25.2.2 User Test

WARNING

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

NOTE

- **Before the user test or after each use, thoroughly clean the external paddles and properly place them in the paddle tray. The user test passes only when external paddles properly contact the metal parts of the paddle tray.**
- **If the impedance value indicated by impedance indicator changes greatly, check that external paddles and metal parts of the paddle tray are clean.**
- **Install at least one battery and properly place the external paddles in the paddle tray or connect the pads cable and 50 Ω test load. Otherwise the user test will fail.**

25.2.2.1 Starting the User Test

You can start the user test mode while operating in the Monitor, Manual Defib or Pacer mode. Patient

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

25.2.2.2 Viewing the User Test Summaries

NOTE

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

26 Accessories

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.**
- **Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.**
- **When using the accessories, consider the accessories' operating temperature. Refer to corresponding accessory's instruction for use for details.**

This page intentionally left blank.

A Specifications

A.1 General Specifications

A.1.1 Safety Specifications

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

Type of protection against electrical shock	Class I, equipment energized from an external and internal electrical power source. If you suspect the integrity of the external protective earthing or the protective earthing wire, you should run the equipment on internal electrical power supply (battery).
Degree of protection against electric shock	Type BF defibrillation proof for CO_2 monitoring and external defibrillation. Type CF defibrillation proof for ECG,TEMP, SpO_2, IBP, NIBP, internal defibrillation and CPR sensor.
Mode of operation	Continuous
Degree of protection against harmful ingress of solid	IP4X
Degree of protection against harmful ingress of water	IPX4 (when running on battery) IPX1 (when running on AC power supply)
Degree of mobility	Portable

A.1.2 Physical Specifications

Size (Width × depth × height)	295 mm×218 mm×279 mm, without external paddles
Maximum weight	7.0 kg, including a battery, external paddles and 3-leadwire.

A.1.3 Display Specifications

Type	TFT Color LCD
Size	8.4 inch
Resolution	800×600 pixels
Viewed waveforms	4 at maximum
Wave viewing time	16s at maximum (ECG)

A.1.4 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.
Audio signal	Alarm tone: ISO mode with frequency of 600 Hz QRS tone: short beep with frequency of 650 Hz Charge tone: long beep with frequency of 400 Hz Charge done tone: double beeps with frequency of 870 Hz Key tone: short beep with frequency of 1000 Hz

A.1.5 Interface Specifications

USB connector	Connects USB flash memory
VGA connector	Connects TFT display of medical grade.
RJ45 connector	Connects standard network cable.
Multifunctional connector	Connects a cable for analog output or a cable for synchronized cardioversion.

A.1.6 Signal Outputs Specifications

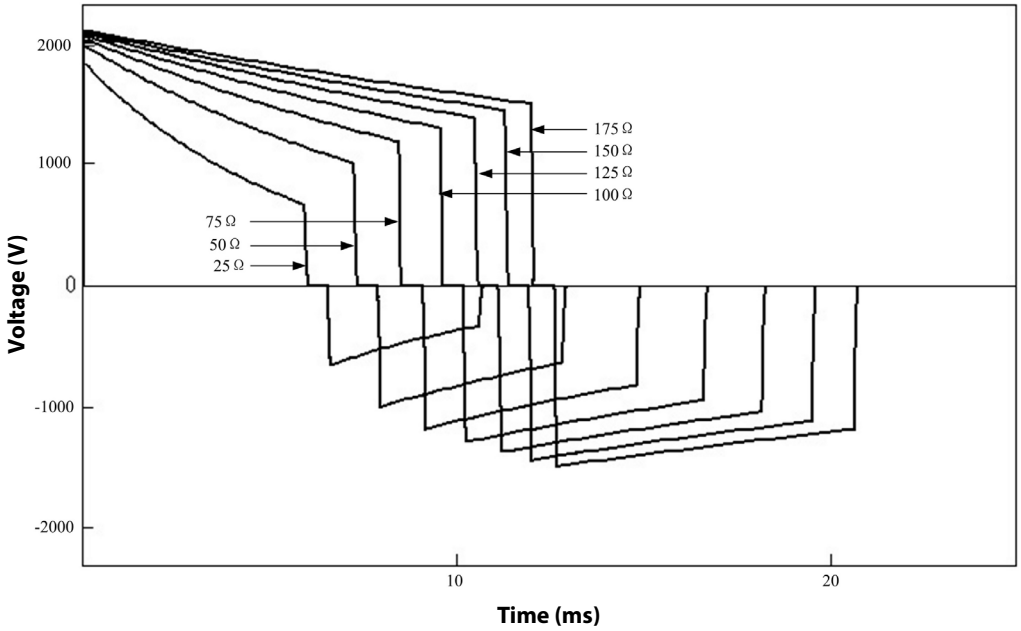
Multifunctional connector	
Standard	Meets the requirements of EN60601-1 for short-circuit protection and leakage current
ECG Analog Output (only ECG lead set)	
Bandwidth (-3 dB; reference frequency: 10 Hz)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Therapy mode: 1 to 20 Hz
Maximum QRS 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
Synchronous input	
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	The alarm delay time from the equipment to other remote equipment is ≤4 seconds, measured at the equipment signal output connector.
Alarm signal sound pressure level range	45 db(A) to 85 db(A) within a range of one meter

A.2 Defibrillator 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
Shockable rhythm analysis time	< 8s
Range of selected energy	
External defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 70, 100, 150, 170, 200, 300, 360 J
Internal defibrillation	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 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 *B Mindray Shockable Rhythm Analysis Algorithm*.

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



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

Charge time (Note: at 20 ±5 °C of ambient temperature)												
	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 15 360 J discharges	<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 90% to 100% rated mains voltage	<4 s	<7 s	<11 s	<14 s	<7 s	<10 s	<11 s	<12 s	<22 s	<24 s	<14 s	<15 s

NOTE

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

A.3 CPR Compression Specifications

CPR Compressions from Defibrillation Electrodes

Compression rate	Measurement range: 60 to 200 cpm (compressions per minute) Accuracy: ±3 cpm (compression per minute)

CPR Compressions from CPR Sensor

Compression depth	Measurement range: 0.0 to 8.0 cm Effective range: 1.5 to 8.0 cm Accuracy (for effective range): ±0.5 cm or ±10%, whichever is greater Resolution: 0.1 cm Refreshing rate: ≥0.5Hz
Compression rate	Measurement range: 40 to 160 cpm (compressions per minute) Effective range: 40 to 160 cpm (compressions per minute) Accuracy: ±2 cpm (compression per minute) Resolution: 1 cpm Refreshing rate: ≥0.5Hz
Interruption time	Measurement range: 0 to 300 s Effective range: 0 to 300 s Resolution: 1 s Refreshing rate: ≥0.5Hz

A.4 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.
Output protection	The equipment has no sign of damage after defibrillation-proof test.

NOTE

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

A.5 Monitor Specifications

A.5.1 ECG Specifications (from ECG Lead Set)

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 set: I, II, III 5-lead ECG set: I, II, III, aVR, aVL, aVF, V 12-lead ECG set: I, II, III, aVR, aVL, aVF, V1 to V6
Gain	2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto. Error less than ± 5%
Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
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
Common mode rejection	Diagnostic mode: >90 dB Monitor mode: >105 dB Therapy mode: >105 dB ST mode: >105 dB
Notch filter	50/60Hz, In Monitor, Therapy and ST modes: notch filter turns on automatically In Diagnostic mode: notch filter is turned on manually
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Differential input impedance	≥5 MΩ
Electrode offset potential tolerance	±500mV
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
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
HR	

Measurement range	Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 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, PVCs/min, PVC, Couplet, VT>2,Bigeminy, Trigeminy, R ON T, Brady, Tachy, Missed Beat, PNP, PNC, Vent Rhythm, Multif. PVCs, Nonsus. Vtac, Pause, Irr. Rhythm, A-Fib
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.
Lead-off detection current	Measuring electrode: ≤0.1 μA Drive electrode: ≤1 μA
Baseline recovery time	<2.5 s (after defibrillation)
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
12-lead ECG Interpretation	
Sampling rate	500 samples/second/channel
Ampitude quantisation	1 μV/LSB

A.5.2 ECG Specifications (from Defibrillation Electrodes)

Patient connection	paddles or multifunction electrode pads
ECG inputs	pads/paddles
Gain	2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40mm/mV (×4), Auto. Error less than ± 5%
Sweep speed	6.25mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Bandwidth (-3dB)	Therapy mode: 1 to 20 Hz
Common mode rejection	Therapy mode: >105 dB
Notch filter	50/60Hz In Therapy mode: notch filter turns on automatically
ECG signal range	±8mV (peak-to-peak value)
Calibration signal	1mV (peak-to-peak value) ±5%
Differential input impedance	≥5 MΩ
Electrode offset potential tolerance	±1V
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
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
HR	
Measurement range	Pediatric: 15 to 350 bpm Adult: 15 to 300 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.
Lead-off detection current	≤0.1 μA
Baseline recovery time	<2.5 s (after defibrillation, in therapy mode)
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.5.3 Resp Specifications

Technique	Trans-thoracic impedance
Measurement range	0 to 200 rpm
Resolution	1 rpm
Accuracy	121 to 200 rpm: ±2 rpm 0 to 120 rpm: ±1 rpm
Respiration excitation waveform	<300 μA, sinusoid, 62.8 kHz (±10%)
Minimum respiration impedance threshold	0.3Ω with× 5 gain
Bandwidth	0.2 to 2.5 Hz (-3 dB)
Reference impedance range	2200 to 4500Ω, using an ECG cable with 1 kΩ resistor
Apnea alarm time	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s

A.5.4 SpO_2 Specifications

Mindray SpO_2 Module

Standard	Meet standards of ISO 80601-2-61
Measurement range	0 to 100%
Resolution	1%
Response time	<20 s (SpO_2 value sudden changes from 70% to 100%)

Accuracy*	70 to 100%: 70 to 100%: 0% to 69%:	±2% (in adult/pediatric mode) ±3% (in neonate mode) Not specified
Refreshing rate	≤2 s	
*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.		

Masimo SpO_2 Module

Standard	Meet standards of ISO 80601-2-61	
Measurement range	1 to 100%	
Resolution	1%	
Response time	≤20 s (SpO_2 value sudden changes from 70% to 100%)	
Accuracy[1]	70 to 100%: 70 to 100%: 70 to 100%: 1% to 69%:	±2% (measured without motion in adult/ pediatric mode) ±3% (measured without motion in neonate mode) ±3% (measured with motion) Not specified
Refreshing rate	≤2 s	
SpO_2 averaging time	2-4 s, 4-6 s, 8 s, 10 s, 12 s, 14 s, 16 s	

[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%	
Accuracy	70 to 100%: 70 to 100%: 0% to 69%:	±2% (in adult/pediatric mode) ±3% (in neonate mode) Not specified
Refreshing rate	≤2 s	

A.5.5 PR Specifications

PR from Mindray SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Accuracy	±3 bpm
Response time	<20 s (PR value sudden changes from 25 to 240 bpm)

PR from Masimo SpO_2 Module

Measurement range	25 to 240 bpm
Accuracy	±3 bpm (measured without motion) ±5 bpm (measured with motion)
Response time	≤20 s (PR value sudden changes from 25 to 220 bpm)

PR from Nellcor SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Accuracy	±3 bpm (20 to 250 bpm) Not specified (251 to 300 bpm)

PR from IBP Module

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

A.5.6 Temp Specifications

Standard	Meet the standard of ISO 80601-2-56
Operating mode	Direct mode
Parameters	Max. 2 channels. T1, T2, TD
Measurement range	0 to 50 °C (32 to 122 °F)
Accuracy	±0.1 °C or ±0.2 °F (without considering probe error)
Resolution	0.1 °C
Minimum time for accurate measurement	Body surface: <100 s Body cavity: <80 s

A.5.7 NIBP Specifications

Standards	Meet standard of IEC 80601-2-30
Technique	Oscillometry
Mode of operation	Manual, Auto and STAT
Auto mode repetition intervals	1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min
STAT mode cycle time	5 min
Static pressure measurement range	0mmHg to 300mmHg

Static pressure measurement accuracy	±3mmHg				
Maximum measurement time	Adult, Pediatric: 180s Neonate: 90s				
Initial cuff inflation pressure range	Adult: 80 to 280 mmHg Pediatric: 80 to 210 mmHg Neonate: 60 to 140 mmHg				
Default Initial cuff inflation pressure	Adult: 160 mmHg Pediatric: 140 mmHg Neonate: 90 mmHg				
Measurement range			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
Software overpressure protection	Adult: 297±3 mmHg Pediatric: 297±3 mmHg Neonate: 147±3 mmHg				
Measurement accuracy*	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg				
Resolution	1 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 stardard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.

A.5.8 IBP Specifications

Standard	Meet the standard of IEC 60601-2-34
Channels	2
Zero adjustment range	±200 mmHg
Resolution	1 mmHg
Sensitivity	5 μV/V/mmHg
Measurement range	-50 mmHg to 360mmHg
Accuracy	±2% or ±1mmHg, whichever is greater (without considering transducer error)
IBP sensor temperature range	Operation temperature: 15 to 40ºC Storage temperature: -25 to 70ºC
Waveform label	Art, Ao, FAP, BAP, UAP, PA, CVP, UVP, LAP, RAP, ICP, P1, P2, etc

A.5.9 CO_2 Specifications

Sidestream CO_2 Module

Measurement range	0 to 150 mmHg	
Accuracy*	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) ISO accuracy mode: Add ±2mmHg to the full accuracy mode	
Sart-up time	20 s (typical), 90 s (maximum)	
Accuracy drift	Meets the requirement for measurement accuracy within 6 hours.	
Resolution	1mmHg	
Sample flowrate	Connecting the DRYLINE II watertrap for adult and pediatric patient: 70 ml/min or 100 ml/min Connecting the DRYLINE II watertrap for neonatal patient: 70 ml/min or 100 ml/min	
Sample flowrate tolerance	±15% or ±15 ml/min, whichever is greater.	
Rise time	Measured with a DRYLINE II neonatal watertrap and a 2.5-meter neonatal sampling line: ≤250 ms @ 70 ml/min or ≤250 ms @ 100 ml/min Measured with a DRYLINE II adult watertrap and a 2.5-meter adult sampling line: ≤400 ms @ 70 ml/min or ≤330 ms @ 100 ml/min	
Response time	Measured with a DRYLINE II neonatal watertrap and a 2.5-meter neonatal sampling line: <4 s@70ml/min or <3.5 s@100ml/min Measured with a DRYLINE II adult watertrap and a 2.5-meter adult sampling line: <7 s@70ml/min or <5.5 s@100ml/min	
awRR measurement range	0 to 150 rpm	
awRR accuracy	<60 rpm: ±1 rpm 60 to 150 rpm: ±2 rpm	
awRR resolution	1 rpm	
Effect of interference gases on CO_2 measurements (for sidestream CO_2 module)		
Gas	**Concentration (%)**	**Quantitive effect***
N_2O	≤60	±1 mmHg
Hal	≤4	
Sev	≤5	
Iso	≤5	
Enf	≤5	
Des	≤15	±2 mmHg
*: means an extra error should be added in case of gas interference when CO_2 measurements are performed between 0-40mmHg. 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.		

Microstream CO_2 Module

Measurement range	0 to 99 mmHg
Accuracy*	0 to 38 mmHg: ±2 mmHg 39 to 99 mmHg: ±5% of reading (0.08% increased in error for every 1 mmHg if the reading is more than 38)
* Accuracy applies for respiration rate up to 80 rpm. For respiration rate above 80 rpm, the accuracy is 4 mmHg or ±12% of the reading, whichever is greater, for EtCO2 exceeding 18 mmHg. For respiration rate above 60 rpm, the above accuracy can be achieved by using the humidified sample line for Infant/Neonatal. In the presence of interfering gases, the above accuracy is maintained to within 4%.	
Accuracy drift	Meets the requirement for measurement accuracy within 6 hours.
Resolution	1mmHg
Flow rate	$50\ ^{+15}_{-7.5}$ ml/min
Initialization time	30 s (typical)
Response time	2.9 s (typical) (The response time is the sum of the rise time and the delay time when using a sampling line of standard length) Rise time: <190 ms (10% to 90%) Delay time: 2.7 s (typical)
awRR measurement range	0 to 150 rpm
awRR accuracy	0 to 70 rpm: ±1 rpm 71 to 120 rpm: ±2 rpm 121 to 150 rpm: ±3 rpm
Apnea alarm time	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s

A.6 Power Supply Specifications

A.6.1 External Power Supply Specifications

AC power	
Line voltage	100 to 240 VAC (±10%)
Current	1.8 to 0.8A
Frequency	50/60Hz (±3Hz)
DC Power (with an external DC/AC adapter)	
Input voltage	12VDC
Power consumption	150W

A.6.2 Battery Specifications

Battery type	Smart lithium ion battery, rechargeable and free of maintenance, two batteries can be installed, two types of batteries can be configured Battery LI24I004A: 14.4V, 5600mAh Battery LI34I001A: 14.8V, 4500mAh	
Battery LI24I004A charge time	Charged by the equipment connected to the AC power	Less than 3 hours to 90% and less than 4 hours to 100% with equipment power off;
		Less than 5 hours to 90% and less than 6 hours to 100% with equipment power on.
	Charged by the charger station	Less than 5 hours to 90% and less than 6 hours to 100%.

Battery LI34I001A charge time	Charged by the equipment connected to the AC power		Less than 2 hours to 90% and less than 3 hours to 100% with equipment power off;	
			Less than 6 hours to 90% and less than 9 hours to 100% with equipment power on.	
	Charged by the charger station		Less than 3.5 hours to 90% and less than 4 hours to 100%.	
Battery LI24I004A run time	Operating mode	One new fully charged battery	Two new fully charged batteries	Testing condition
	Monitoring	≥6 h	≥12 h	The equipment is configured with a 5-lead ECG, Resp, SpO_2, 2-channel temp and CO_2, NIBP measurements set at an interval of 15 minutes. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Defibrillation	≥200 discharges	≥400 discharges	360J discharge, the equipment is configured with a 5-lead ECG, Resp, SpO_2, 2-channel temp, NIBP and CO_2. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
		≥300 discharges	≥600 discharges	200J discharge, the equipment is configured with a 5-lead ECG, Resp, SpO_2, 2-channel temp, NIBP and CO_2. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Pacing	≥4.5 h	≥9 h	50 Ω load impedance, pacing rate 80ppm, pacing output 60mA. The equipment is configured with a 5-lead ECG, Resp, SpO_2, 2-channel temp, NIBP and CO_2. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
Battery LI34I001A run time	Operating mode	One new fully charged battery	Two new fully charged batteries	Testing condition
	Monitoring	≥5 h	≥10 h	With a typical configuration, the equipment operates with ECG only. WI-Fi is disabled. The screen brightness is set to the factory default without recording.
	Defibrillation	≥100 discharges	≥200 discharges	360J discharge at intervals of one minute, without recording
	Pacing	≥3 h	≥6 h	50 Ω load impedance, pacing rate: 80ppm, pacing output 60mA, without recording
Battery fuel gauge	5 LEDs indicating the current battery charge level			
Shutdown delay	At least 20 minutes of monitoring and six 360J discharges (after the low battery alarm occurs)			

Note: The specifications above are based on a new battery, and at 20°C±5 °C of ambient temperature.

A.7 Recorder Specifications

Method	High-resolution thermal dot array
Number of waveforms	• 50 mm recorder paper: 3 at maximum. • 80 mm recorder paper: 4 at maximum.
Paper speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s. Error no more than ± 5%
Paper width	50 mm, 80 mm
Grid lines	The operator can choose to print grid lines or not
Reports	Real-time waveforms, frozen waveforms, tabular trends, 12-lead, user test, auto test, configuration
Auto record	Charge events, shock events, marked events, auto test report, parameter alarms, ARR alarms, if configured on

A.8 Alarm Specifications

Alarm Levels	High, medium, low level alarms, complying with IEC60601-1-8
Alarm Categories	Physiological alarms, technical alarms; Latched alarms and unlatched alarms.
Alarm lamp	Independent alarm LED
Parameter alarm setting	Alarm properties of all available parameters can be set simultaneously in the Para. Alarm menu
Auto alarm limits	Parameter alarm limits can be automatically adjusted according to currently measured vital signs

A.9 Data Storage

Internal storage	1G Bytes
Marking events	16 types of events, user customized
Events	At least 1000 events for each patient.
Waveforms	At least 24 hours of consecutive ECG waveforms and pace pulses
Voice recording (available in the AED mode)	At least 180 minutes in total, more than 60 minutes for each patient
Data export	Data can be export to a PC through a USB flash memory
Tabular trends	Up to 72 hours for all measured parameters with the resolution no less than 1 minute.
Patient archives	Up to 100
12-lead ECG	5 sets for each patient

A.10 Wi-Fi Specifications

Protocol	IEEE 802.11a/b/g/n
Modulation mode	DSSS and OFDM
Operating frequency	IEEE 802.11b/g/n (at 2.4G): 2.4 GHz to 2.495 GHz IEEE 802.11a/n (at 5G): 5.15 GHz to 5.825 GHz
Channel spacing	IEEE 802.11b/g/n (at 2.4G): 5 MHz IEEE802.11a/n (at 5G): 20 MHz
Wireless baud rate	IEEE 802.11b: 1 Mbps to 11 Mbps IEEE 802.11g: 6 Mbps to 54 Mbps IEEE 802.11n: 6.5 Mbps to 72.2 Mbps IEEE 802.11a: 6 Mbps to 54 Mbps
Output power	<20dBm (CE requirement: detection mode- RMS) <30dBm (FCC requirement: detection mode- peak power)
Operating mode	Infrastructure
Data security	Standards: WPA-PSK, WPA2-PSK Encryption: TKIP, AES
System capacity and resistance to wireless interference	When the following conditions exist simultaneously, ■ Number of the equipments supported by a single AP: ≤ 4 ■ Each equipment can communicate with the CMS. ■ The weakest AP signal strength detected at the equipment's position cannot be less than -65 dBm. ■ When the distance between interfering devices and the equipment is greater than 20 cm, and a co-channel interference Wi-Fi network (at least -85 dBm weaker than the monitor's network) and an adjacent-channel Wi-Fi network (at least -50 dBb weaker than the monitor's network) also synchronously exist. Note: The interfering devices do not include Wi-Fi devices. They include but are not limited to: ◆ 2.4 G wireless devices (excluding Wi-Fi devices) ◆ Cellular mobile communication networks ◆ Microwave ovens ◆ Interphones ◆ Cordless phones ◆ ESU equipment The total delay of data transmission from the monitors to the Central Station: ≤ 4 seconds.
Wi-Fi network stability	When the following conditions exist simultaneously, ■ Number of the equipments supported by a single AP: ≤ 4 ■ Each equipment can communicate with the CMS. ■ The weakest AP signal strength detected at the equipment's position cannot be less than -65 dBm. The time percentage of any equipment failing to transmit data to the CMS does not exceed 0.1% over a 24-hour period.
Distinct vision distance	The distinct vision distance between the equipment and the AP is greater than or equal to 50 meters.

A.11 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	0ºC to 45ºC (at least 60 minutes of working time when the temperature reduces from room temperature to -20ºC)	10% to 95%, non-condensing	-381m to 4575m (57kPa to 106.2kPa)
Storage condition	-30ºC to 70ºC		
Microstream CO_2 module			
Item	**Temperature**	**Relative humidity**	**Barometric**
Operating condition	0ºC to 40ºC	10% to 95%, non-condensing	430mmHg to 790mmHg (57.3kPa to 105.3kPa)
Storage condition	-20ºC to 60ºC		
Sidestream CO_2 module			
Item	**Temperature**	**Relative humidity**	**Barometric**
Operating condition	5ºC to 40ºC	10% to 95%, non-condensing	430mmHg to 790 mmHg (57.3kPa to 105.3kPa)
Storage condition	-20ºC to 60ºC		

Shock
Complies with requirements of 21.102, ISO9919: Peak acceleration: 1000m/s^2 (102g) Duration: 6ms Pulse shape: half-sine Number of shocks: 3 shocks per direction per axis (18 total)
Vibration
Complies with requirements of 21.102, ISO9919.
Bump
Complies with the requirements of 6.3.4.2, EN1789. Peak acceleration: 15g Duration: 6ms Number of impacts: 1000 Impact direction: vertical impacts are applied when the equipment under test is placed at normal operating position.
Free fall

Shock
Complies with the requirements of 6.3.4.3, EN1789. Drop height: 0.75 m Number of drops: once for each of the six surfaces

A.12 Operating Environment

Host CPU	Intel Atom
Primary programming language	C++
Operating system	Linux 3.2.0

This page intentionally left blank.

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, Temp accuracy, NIBP 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.**

P/N: KF-H-046-022578-00(1.0)