

BeneFusion nDS

BeneFusion nDS ex

**Infusion Supervision
System**

Instruction for Use



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- 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 Scientific Co., Ltd.
Address: 6/F, Bldg 2, 1203 Nanhuan Avenue, Yutang Block,
Guangming District, 518106 Shenzhen, 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: Eiffestraße 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Summary of Safety
and Clinical
Performance
(SSIP):

Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY SCIENTIFIC 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 SCIENTIFIC CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY SCIENTIFIC CO., LTD. provides only the highest quality products.

Preface

Manual Purpose

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

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

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

Intended Audience

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

Illustrations

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

Conventions

- ***Italic text*** is used in this manual to quote the referenced chapters or sections.
- **Bold text** is used to indicate the screen texts.
- → is used to indicate operational procedures.

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1 Safety

1.1 Safety Information

WARNING

- Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or damage to product/property.
-
-

CAUTION

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

- Provides application tips or other useful information to ensure that you get the most out of the product.
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-

1.1.1 Warnings

WARNING

- To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.
- To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.
- The equipment is not intended to be used within the Magnetic Resonance (MR) environment.
- Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Ensure that the sum of the individual ground leakage currents does not exceed the allowable limits.

- **Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel. Moreover, the servicing must be done only after the AC power supply is disconnected.**
 - **Do not place the equipment or accessories in any position that might cause it to fall on the patient.**
 - **Do not start an infusion 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 by patients or personnel.**
 - **Do not touch the patient and device connectors simultaneously. Otherwise leakage current may result in patient injury.**
 - **Ensure that more than two people are present to support and operate the equipment when it is transferred within the hospital, so as to prevent damage to the equipment and avoid tipping which can cause injury.**
 - **The communication distance between the Dock and BeneFusion nCS Infusion Supervision System, the Dock and BeneVision Central Monitoring System should be less than 50 m.**
 - **Support cascade for up to six shelf modules, and ensure that each shelf module is reliably fixed.**
 - **Equipments connected to the Dock must meet the requirements of IEC 60950. Only equipments designated by the manufacturer can be connected to the Dock. Based on patient safety, do not insert products that are not specified by the manufacturer into the Dock and its connectors.**
 - **To avoid electric shock, do not touch patient and other non-defibrillation proof equipments during defibrillation. Defibrillation will not affect the performance of the equipment.**
-
-

1.1.2 Cautions

CAUTION

- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss.**
- **Electromagnetic fields may affect equipment performance. This makes it necessary for other equipment used in the vicinity of this equipment to meet EMC standards. Mobile phones, X ray and MRI equipment are all potential interference sources because of their high-intensity electromagnetic radiation.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force. The equipment should be observed to verify normal operation after fall, otherwise it cannot be used.**

- **Dry the equipment immediately in case of rain or water spray.**
 - **Some settings are password protected and can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.**
-

1.1.3 Notes

NOTE

- **The software was developed in compliance with IEC62304.**
 - **The equipment provides power-down storage. Alarms limit setting and history record are saved and will be maintained if the equipment is powered down suddenly. The storage time is equals to the equipment's service life. The alarm limit settings before power-down are reloaded when the equipment is restarted.**
 - **This manual describes all features and options. Your equipment may not have all of them.**
-

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2 Equipment Introduction

2.1 Intended Use

The Infusion Supervision System is in conjunction with the infusion pump and syringe pump, providing space management, power management, alarm management, information display, and communicate with pump to transmit data.

The Infusion Supervision System is intended for adults, pediatric and neonate.

The Infusion Supervision System is expected to be used in institutes or units with healthcare capabilities, such as operating rooms, emergency departments, wards, ICU. Nurses can easily centrally manage and operate pumps.

WARNING

- **This system is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.**
-
-

NOTE

- **According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Besides, the residual risks are disclosed in the corresponding chapter of this IFU as precautions or warnings.**
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3 Equipment Preparation

3.1 Equipment Preparation Safety Information

WARNING

- Use only installation accessories specified by Mindray Scientific.
 - The equipment software copyright is solely owned by Mindray Scientific. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
 - Connect only approved devices to this equipment. Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Mindray Scientific.
 - If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturer or an expert in the field. A determination must be made that the proposed combination will not negatively affect the devices themselves or the patient's safety.
 - Ensure that the equipment is properly secured and positioned. Position change and severe shock can lead to changes to the delivery accuracy.
-
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CAUTION

- The equipment should be installed by the authorized personnel.
 - Before use, verify whether the packages are intact. In case of any damage, do not apply it to patient.
-
-

NOTE

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

3.2 Environmental Requirements

CAUTION

- Ensure that the equipment operating environment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.
-

3.3 Installation

NOTE

- One pole clamp per shelf module must be used to ensure stability of the Dock.
 - Remove the infusion bags and tubings from the IV poles or pumps, and pumps from shelf module before transporting the Dock. Carry each component separately. Failure to do so can result in system becoming unbalanced. Two or more people are required to carry the Dock configured with multiple shelf modules.
 - According to IEC 60601-1, ensure that the carrying capacity of infusion support shall be four times more than the total weight of the Dock (including the controller, shelf module, and pumps). For example, if you are mounting a four-pump system with a total weight of 17.6 lbs (8 kg), the carrying capacity of the infusion support needs to be more than 70.5 lbs (32 kg).
-

3.3.1 Securing a Pump in the Dock

NOTE

- Cascade Docks support maximum 24 pumps.
 - Only the BeneFusion n series and e series pumps can be secured in the Dock.
-

3.3.2 Securing a Dock in the Medical Supply Unit

NOTE

- Use one pole clamp for each shelf module to ensure that the Dock is properly secured on the IV pole of the medical supply unit.
-

3.4 Setting Up the Equipment

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 on the equipment.
 - Use the battery if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.
 - Do not touch the power connector with wet hand. Eliminate the liquid or any residue inside of or at the surroundings of the AC power input connector and power cord connectors.
-
-

NOTE

- The battery can only be charged by the equipment.
 - If the equipment is run by battery power, ensure that the battery is adequately charged.
-

3.5 Setting Up the Dock

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.
 - Only a shelf module containing maximum four pumps can be used on a flat surface. Larger shelf module configurations are more top heavy and have an increased risk of tipping, which could lead to patient or user injury.
-
-

NOTE

- Stay within 1 m of the Dock while setting it up and operating it, ensuring that you have a clear view of the interface.
 - The Dock use a mains plug as isolation means to the mains power. Do not locate the Dock in a place difficult to operate the mains plug.
-

3.6 Turning on the Dock

CAUTION

- Check that visual and auditory alarm signals are presented correctly when the Dock is powered on. Do not use the Dock if you suspect it is not working properly, or if it is mechanically damaged. Contact your service personnel or us.
-

NOTE

- The Dock is automatically turned on when the external AC power supply is connected.
-

3.7 Turning off the Dock

NOTE

- Turning off the Dock does not disconnect the Dock from the AC mains. To completely disconnect the power supply, unplug the power cord.
-

4 Dock Setup

CAUTION

- The Dock Setup can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.
-

NOTE

- Dock Setup menu and Batch Config menu are available when the pump and Dock are in proper connection.
-

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5 Alarms

5.1 Alarm Safety Information

WARNING

- A potential hazard can exist if different alarm presets and default settings are used for the same or similar equipment in the same care area, for example an intensive care unit or cardiac operating room.
 - The equipment in your care area may each have different alarm settings to suit different patients. Always check that the alarm settings are appropriate for your patient before start infusing.
 - Do not rely exclusively on the audible alarm system during an infusion. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always ensure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.
 - Fully evaluate the risk before changing the alarm mode setting. New alarms may be failed to be detected if the operator is not familiar with the new sound.
 - The maximum alarm delay from the alarm status of the pump or shelf module to the alarm signal (sound and text displays) generated by the equipment should not exceed 5 sec.
 - The CMS/eGW Disconnected alarm delay time from the equipment to the CMS is less than 14 sec, and other alarms delay time is less than 8 sec.
-
-

5.2 Understanding the Alarms

NOTE

- When multiple alarms occur simultaneously, the alarm messages are displayed circularly, and the sound and light of the higher priority alarm are given.
-
-

5.3 Nurse Call

NOTE

- **Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.**
-

5.4 Alarm Solutions

WARNING

- **When an alarm occurs, check the Dock's status and handle the alarm as soon as possible. If the alarms do not conform with the actual situation, contact your service personnel.**
-
-

6 Networked Communication

6.1 Network Safety Information

CAUTION

- **Wireless network designing, deploying, debugging, and maintenance should be executed by the service personnel or authorized technicians.**
 - **Always set the wireless network according to local wireless regulations.**
 - **Data communication for all network functions must be performed within a closed network or within a virtually isolated network provided by a hospital. The hospital is responsible for ensuring the security of the virtually isolated network.**
 - **Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.**
 - **Do not connect non-medical devices to the 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 solve the network problem as soon as possible.**
 - **Ensure that the IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.**
-

6.2 Connecting the Equipment to the CMS

NOTE

- **The equipment can communicate with the CMS only when it is properly connected the CMS. If the network is interrupted, you are not able to view the infusion information through the CMS.**
-

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7 Maintenance

7.1 Maintenance Safety Information

WARNING

- To avoid electric shock, stop using the equipment if you find the housing of the equipment has signs of broken. Contact the service personnel for help in that case.
 - Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.
 - No modification of this equipment is allowed.
 - This equipment contains no user serviceable parts.
 - The safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.
 - The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.
-
-

CAUTION

- The equipment and accessories shall not be served or maintained while in use with a patient.
 - If you discover a problem with the equipment, such as the product label falls off, contact your service personnel.
-
-

NOTE

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

7.2 Maintaining the Battery

WARNING

- **Use only specified battery. Use of a different battery may present a risk of fire or explosion.**
 - **Do not crush, drop or puncture the battery. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is externally visible or not, remove the battery from use and dispose of it properly.**
 - **If the battery shows signs of damage or signs of leakage, replace it immediately. Use caution in removing the battery. Avoid contacting the leakage.**
 - **Extremely high ambient temperature may cause battery overheat protection, resulting in equipment shutdown.**
 - **The lithium-ion battery has a service life. Replace your battery when it reaches the end of its service life. Failure to replace the battery may cause serious damage to your equipment from battery overheating.**
 - **Do not open the battery, heat the battery above 60 °C, incinerate battery, or short battery terminals. They may ignite, explode, leak or heat up, causing personal injury.**
-
-

CAUTION

- **Remove the battery if it will not be used for an extended period of time.**
 - **Lithium batteries replaced by inadequately trained personnel could result in a hazard, such as excessive temperatures, fire or explosion.**
 - **Properly dispose of the battery according to local regulations.**
-

NOTE

- **Storing the battery at high temperature for an extended period of time will significantly shorten their life expectancy.**
- **Storing the battery in a cool place can slow the aging process. Ideally the battery should be stored at 15 °C.**
- **The battery should be charged only in this equipment.**
- **When this equipment is used with a pump, and the equipment is connected to the AC power source, the pump battery is charged automatically.**
- **Check the battery for adequate power when the equipment runs on battery power. Charging the battery if required.**

- If the battery is not conditioned for a prolonged time, its charge indication may not be accurate and you may wrongly evaluate the remaining battery runtime.
 - Do not interrupt battery conditioning.
-

7.3 Checking the History Record

NOTE

- A total loss of power has no impact on the history records stored.
 - Alarms are saved as events and will remain if the equipment is powered down. The time of equipment power down is also recorded as an event.
 - The Dock stores up to 2500 events. When the capacity is reached, earlier events will be overwritten by later ones.
-

7.4 Disposing of the Equipment

WARNING

- For disposal of parts, batteries, packaging materials, and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.
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8 Care and Cleaning

WARNING

- Use only the approved cleaners, disinfectants and methods listed in this chapter to clean and disinfect your equipment and accessories. Warranty does not cover damage caused by unapproved substances or methods.
 - Do not mix disinfecting solutions, as hazardous gases may result.
 - We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's infection control officer or epidemiologist.
 - Be sure to turn off the system and disconnect all power cables before cleaning the equipment.
 - The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.
-
-

CAUTION

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

WARNING

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

CAUTION

- **The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.**
 - **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
 - **Use the accessories before the expiry date if their expiry date is indicated.**
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A Product Specifications

A.1 Classifications

The equipment is classified, according to IEC60601-1:

Type of protection against electrical shock	CLASS I EQUIPMENT, equipment energized from an internal electrical power source.
Degree of protection against electrical shock	The pump: Defibrillation-proof type CF applied part (direct cardiac application)
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IP33
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Degree of mobility	Portable

A.2 Environmental Specifications

Item	Temperature (°C)	Relative humidity (noncondensing)	Barometric (kPa)
Operating conditions	5 to 40	15% to 95%	57.0 to 107.4
Storage conditions	-30 to 70	10% to 95%	16.0 to 107.4

Storage Conditions: Corrosive-free and ventilated

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.**
-
-

A.3 Power Supply Specifications

A.3.1 External Power Supply Specifications

Item	External AC Power Supply
Voltage	100 VAC to 240 VAC
Current	8A to 3.4A
Frequency	50/60 Hz
Fuse	T2AL/AC 250V (1 controller)

A.3.2 Battery

Battery Type	Lithium-ion
Rated battery voltage	7.2 VDC
Battery capacity	2500mAh
Power supply time	Discharge for at least 2 hours (1 controller and 4 shelf modules, Wi-Fi disabled, not provide power to the pump)
Charging time	Charging time is not longer than 6 hours.
Shutdown delay	At least 30 minutes after first low battery alarm (new battery, Wi-Fi disabled, not provide power to the pump)

A.4 Physical Specifications

Item	Maximum Weight (kg)	L x W x H (mm)
Dock (1 controller and 2 pump bays)	≤ 2.9	≤ 270 x 173 x 245
Dock (1 controller and 4 pump bays)	≤ 3.9	≤ 270 x 173 x 395
Dock (1 controller and 6 pump bays)	≤ 5.4	≤ 270 x 173 x 550
Extension 4 pump bays	≤ 3.0	≤ 270 x 173 x 335

A.5 Hardware Specifications

A.5.1 Displays

Type	Size (diagonal)	Resolution
OLED	≥ 3 inches	≥ 256x64 pixels

A.5.2 LEDs

Alarm lamp	2 (two color coded: yellow and red)
External power LED	1 (green)
Battery LED	1 (green)

A.5.3 Audio Indicator

Speaker	Gives alarm tones (sound pressure 50 to 68 dB). Supports multi-level tone modulation. Alarm tones comply with IEC 60601-1-8.
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A.5.4 Interface Specifications

Multifunctional connector	1
Secondary Dock connector	1
USB connector	2
Network connector	1
Power input connector	1
Shelf module extension connector	1

A.5.5 Signal Output Specifications

Multifunctional connector	
Standard	Meets the requirements of IEC 60601-1 for short-circuit protection and leakage current
Nurse Call Signal	
Driving mode	Relay drive

Electric specification	≤ 60W, ≤ 2A, ≤ 36VDC, ≤ 25VAC
Isolation voltage	>1500VAC
Action mode	Normally open or normally closed (optional)

A.6 Wireless Network

Standards	IEEE 802.11a/b/g/n/ac
Modulation mode	BPSK,QPSK, QAM
Operating frequency	2412 MHz to 2472 MHz 5180 MHz to 5825 MHz
Data rate	IEEE 802.11a: 6 to 54 Mbps IEEE 802.11b: 1 to 11 Mbps IEEE 802.11g: 6 to 54 Mbps IEEE 802.11n: MCS0 to MCS7 IEEE 802.11ac: MCS0 to MCS8
Transfer power	< 20 dBm (CE requirement: detection mode – RMS) < 30 dBm (FCC requirement: detection mode – PEAK)
Operating mode	Transmitting data through the wireless access point (AP)
Data security	Standards: WPA/WPA2 PSK, WPA/WPA2 EAP, WPA/WPA2 CCKM EAP methods: LEAP, EAP-TTLS, EAP-TLS, EAP-FAST, PEAP-MSChapV2, PEAP-GTC, PEAP-TLS Encryption modes: TKIP and AES
System capacity	Number of the Docks supported by a single AP: ≤ 16
Data transmission delay between the Dock and the CMS	Total data transmission delay time between the Dock and the CMS is ≤ 8s
Interruption number and time between the Dock and the CMS	Total interruption duration ≤ 0.01* total communication time (Test within 24 hours, 16 Docks are roaming for 30 times)

A.7 Operating Environment

Host CPU	AM3358ZCZ
Primary programming language	C&C++
Operating system	Linux 3.2.0

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B EMC and Radio Regulatory Compliance

B.1 EMC

The device 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.**
 - **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.**
 - **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.**
 - **This device is intended for use in professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.**
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-

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1	The device 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 device.
Conducted and radiated RF EMISSIONS CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC 61000-3-2	Class A	The device 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.
Voltage fluctuations and flicker IEC 61000-3-3	Complies	

NOTE

- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may affect this device even though they meet the requirements of CISPR.**
- **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**
- **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the infusion pump system and contact the service personnel.**

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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: $d = \left[\frac{3.5}{V} \right] \sqrt{P} \quad 150\text{k to } 80 \text{ MHz}$
	6 Vrms in ISM bands between 0,15 MHz and 80 MHz	6 Vrms	
Radiated RF EM fields IEC61000-4-3	10V/m 80 MHz to 2.7 GHz	3V/m	$d = \left[\frac{3.5}{E} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$
Proximity fields from RF wireless communications equipment IEC61000-4-3	27 V/m 380–390 MHz	27 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^b , should be less than the compliance level in each frequency range ^c . Interference may occur in the vicinity of equipment marked with the following symbol: 
	28 V/m 430–470 MHz, 800– 960 MHz, 1700–1990 MHz, 2400– 2570 MHz	28 V/m	
	9 V/m 704–787 MHz, 5100– 5800 MHz	9 V/m	
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

^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 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 re-orienting or relocating the device.

^c 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 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 $d = \left[\frac{3.5}{f} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E} \right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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



The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

WARNING

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