BeneFusion uVP
BeneFusion uVP ex

Infusion Pump

Instruction for Use

CE 2797

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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.

Contents

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.**

NOTE

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

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.**
- **Clearing the occlusion result from line kinks, filter coagulation, etc. may cause extra bolus to patients. Appropriate measures should be taken.**
- **Do not touch the patient and device connectors simultaneously. Otherwise leakage current may result in patient injury.**
- **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

- **When several infusion lines are connected to the same vascular access, there may be back flow or prolonged response time of occlusion alarm. Therefore, use check valve at the line end or follow local hospitals' instructions while in connection with other infusion system.**
- **When using this equipment for enteral nutrition, do not use enteral fluids for intravenous infusion to avoid patient injury, and use only dedicated disposable enteral feeding sets for enteral nutrition.**
- **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 Purpose

The infusion pump is intended for use for the delivery of medications, solutions, nutrition, lipids, blood and blood components indicated for infusion therapy.

WARNING

- **This pump 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. Thus, no residual risk associated with using the medical device should be disclosed.**

2.1.1 Indication for Use

Infusion pumps are for patients who need receive various types of medications, solutions, nutrition, lipids, blood and blood components in controlled amounts through an intravenous (IV) route or enteral route.

2.1.2 Intended Users

The infusion pump is intended to be used by trained healthcare professionals.

2.1.3 Intended Patient Population

The Infusion pump is intended for use on adult, pediatric and neonate.

2.1.4 Intended Medical Conditions

The infusion pump is intended to be used in professional healthcare facilities.

2.1.5 Contra-indications

None.

2.1.6 Side-effects

None.

2.2 Indirect Benefit

Through SOTA analysis, since the infusion pump is not directly used to treat diseases, it will not produce the direct clinical benefits, and its clinical benefits are mainly indirect clinical benefits (a positive impact on patient management): precise infusion.

2.3 Applied Part

The applied part of the equipment is the infusion set.

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 may lead to changes to the delivery accuracy.**

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.**
- **This equipment is in accordance with the EN1789:2020 standard, and can be used to transport patient through road ambulance.**

3.2 Installation

CAUTION

- **To ensure that the pump operates properly, the drop sensor should be properly installed when d/min is switched on.**
- **To avoid mistakenly triggering the Empty alarm, adjust the rate to lower than 400ml/h when using the infusion set of 60 drops/ml.**
- **After long time infusion, small drops may hang inside the drip chamber. These small drops should be eliminated, Otherwise, they may affect the drop detection accuracy and cause the Empty alarm.**

NOTE

- **The liquid surface in the drip chamber should be lower than the lower edge of the drop sensor, and lies between the one third and a half of the drip chamber.**
- **The positioning block of the drip chamber must be vertically inserted through the positioning groove of the drop sensor.**
- **Do not excessively tilt the drop sensor, or expose it to direct sunlight during infusion. Otherwise, accuracy of the drop sensor may be influenced.**
- **It is suggested that the signal line of drop sensor should be replaced every six months.**

3.3 Setting Up the Equipment

WARNING

- **Always use the accompanying power cord delivered with the pump.**
- **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.**

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

CAUTION

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

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4 Getting Started

4.1 Turning on the Pump

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

NOTE

- **Stay within 1 meter (39 inches) of the pump while setting it up and operating it, making sure that you have a clear view of the pump interface.**
- **The equipment uses a mains plug as isolation means to the mains power. Do not locate the equipment in a place difficult to operate the mains plug.**

4.2 Loading the Infusion Set

WARNING

- **To ensure the accuracy of air bubble detection, check and remove the remained fluid in the infusion set slot before loading the infusion set.**
- **While loading the infusion set, do not touch the free-flow clamp to avoid being hurt.**
- **This pump uses standard, single use infusion set with Luer lock connections.**
- **The pump must be mounted to the same level as the patient's heart. The most accurate pressure monitoring in the infusion set is achieved when the pump is positioned close to the patients heart level.**
- **We recommend you to use an infusion set stated in this manual. If a non-recommended infusion set must be used or a different set needs to be changed, perform the calibration and performance test before use.**

Otherwise, the accuracy of the infusion and the performance of the pump may be adversely affected.

- **To ensure the accuracy of rate and alarm detection, the infusion set should be calibrated in this pump before first use.**
- **When using the pump for blood transfusion, only use disposables dedicated and labelled for transfusion.**
- **Single use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**

NOTE

- **Take care that your hands are not squeezed when you close the pump door.**
- **Make sure that the infusion set is located in both sides of the tubing channel notches after loading the infusion set.**

4.3 Purge

NOTE

- **If required, set the purge rate after the purge is started. The initial purge rate is 1200 ml/h.**
- **The Air in Line or Accumulated Air alarm will not given during purging.**
- **The volume used for purging is not added to the infused volume.**

4.4 Starting Infusion

WARNING

- **Do not connect patient until disposables have been purged and loaded into the pump. Connecting to patient before disposables are loaded and purged can cause serious injury or death.**
- **Check that no drops are falling in the drip chamber before infusion starts or stops. If drips are falling, close the roller clamp or the Robert clamp, do not use the equipment, and contact your service personnel.**

NOTE

- **Always discharge the previous patient before starting a new infusion for new patient. Failure to do so can lead to data being attributed to the wrong patient.**

- **If the infusion set type is Nutrition or the selected drug type is Enteral Nutrition, "Air detection will be closed" is always displayed in the system information area, "[Enteral feeding] Air detection will be closed" is displayed before starting the infusion or bolus infusion.**
- **The infusion could not be started when the door is open.**
- **Monitor the connection of infusion set, tubing, pump and patient, and the drug information on a regular basis. Start infusion according to the instructions in this manual.**

4.5 Bolus Infusion

NOTE

- **The delivered bolus volume will be added to the total infusion volume and subtracted from the volume to be infused (VTBI).**
- **The pump gives a beep every time a 0.5 ml bolus volume is infused.**

4.6 Setting Keep Vein Open (KVO) Rate

NOTE

- **If the KVO rate is greater than the infusion rate, the pump will continue to infuse at the set infusion rate.**
- **The pump runs for 30 minutes at a KVO rate. At the completion of the KVO infusion, the pump stops infusion, and gives a KVO Finish alarm.**
- **The volume used during KVO infusion will be added to the total infusion volume.**

4.7 Replacing the IV Container

NOTE

- **Check the infusion status after replacing the IV container. If the pump is running a KVO infusion, reconfigure the infusion parameters before restarting the infusion.**

4.8 Unloading the Infusion Set

WARNING

- **To prevent free flow, ensure that the roller clamp or Robert clamp is closed before removing the infusion set from the pump.**
- **It is recommended that the infusion sets be changed every 24 hours (or as per national hygiene regulations or manufacturer's instructions). If infusion sets not recommended by this manual are used, adjust the fixing site every four hours.**
- **It is recommended that the disposable enteral nutrition sets be changed every 24 hours.**
- **If the infusion sets are not changed within the recommended time, the accuracy of the infusion may be affected.**

4.9 Turning Off the Pump

CAUTION

- **Press and hold the power switch for no less than 10 seconds to forcibly shut down the pump if it could not be shut down normally. This may cause loss of patient data.**

NOTE

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

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.**
- **When the alarm sound is paused, the equipment gives no alarm tones even if a new alarm occurs. Be careful about whether to pause the alarm sound or not. When the alarm sound is paused, observe the patient frequently.**
- **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 make sure 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.**

5.2 Understanding the Alarms

NOTE

- **The tones of the alarm sound and the reminder sound are different.**
- **The frequency of the reminder sound and the bolus sound is 600Hz, which is different from the frequency of alarm sound.**
- **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 Alarm Solutions

WARNING

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

NOTE

- **The pump stops infusion when a high priority alarm is triggered.**
- **The pump continues infusion when a low priority alarm is triggered.**
- **The pump stops infusion after the first Battery Depleted alarm occurs, and the shutdown delay is at least three minutes.**

5.4 Occlusion Alarm

NOTE

- **If this pump is running at 0.1ml/h, and respectively configure the occlusion pressure alarm limit to the lowest level and highest level, the occlusion alarm delay time may reach up to one hour and 20.5 hours. Adjust the pressure limit to a lower level, or use the syringe pump for a low rate infusion.**

6 Menu Options

CAUTION

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

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7 Infusion Modes

NOTE

- **The BeneFusion uVP ex does not provide the Loading Dose Mode.**

7.1 Rate Mode/Time Mode/Drip Mode/Micro-infusion Mode

NOTE

- **When infusing in the rate mode, time mode, drip mode, and micro-infusion mode, you must set rate, but time and VTBI settings are optional.**

7.2 Dose Mode

NOTE

- **Time can only be obtained by calculation. It is not available for manual input.**
- **Some departments, for example the Neonatology, may use fixed drug amounts, diluent volumes, or concentrations. Using the drug info library to predefine these infusion parameters can simplify the setting process.**

7.3 Loading Dose Mode

NOTE

- **If you do not configure the loading dose parameters, the pump infuses at the Primary Rate until the set VTBI is finished.**

7.4 Intermittent Mode

NOTE

- **Total VTBI and Maintain Rate are optional parameters. If the Maintain Rate is not set, infusion stops at the maintenance stage. If the Total VTBI is not set, the infusion stops when the IV container is empty.**

7.5 Ramp Mode

NOTE

- **The Steady Rate can only be obtained by calculation. It is not available for manual input.**
- **Up Time and Down Time are optional parameters. The pump runs an infusion at the steady rate if they are not set.**

7.6 Dose Time Mode

NOTE

- **In the dose time mode, the supported dose rate units are X/min, X/h, and X/24h, in which X represents ng, ug, mg, g, mU, U, kU, EU, mmol, mol, mcal, cal, kcal, and mEq.**
- **Time can only be obtained by calculation. It is not available for manual input.**

7.7 Rhythm Dose

NOTE

- **In the rhythm dose, the supported dose units are mg/kg and mg/m^2.**
- **The infusion parameters cannot be changed after the infusion is started.**

8 Drug Library/Drug Info Library

CAUTION

- **The drug library and the drug info library should be created by professionals. Checked that the drug and parameter settings are suitable for the care area before use.**
- **The facility is responsible for performing initial checks to ensure that the proper drug library / drug info library is loaded.**

NOTE

- **The predefined parameters can be changed during a therapy. This does not affect the embedded library.**

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9 Networked Communication

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.**

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10 Maintenance

10.1 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 or illegible, 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.**

10.2 Maintaining the Battery

WARNING

- **Use only specified battery. Use of a different battery may present a risk of fire or explosion.**
- **The battery must only be installed and replaced by service personnel trained and authorized by Mindray Scientific.**
- **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.**

NOTE

- **Remove the battery if it will not be used for an extended period of time.**
- **The battery should be charged only in this equipment.**
- **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.**
- **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 use the pump for infusion during battery conditioning.**
- **Do not interrupt battery conditioning.**

10.3 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 pump stores up to 5000 events. When the capacity is reached, earlier events will be overwritten by later ones.**

10.4 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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11 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.**
- **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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12 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 Specifications

Classifications	Connect to AC power source, type of protection against electrical shock: CLASS I EQUIPMENT, equipment energized from an internal electrical power source Connect to DC power source, type of protection against electrical shock: CLASS II EQUIPMENT, equipment energized from an internal electrical power source Degree of protection against electrical shock: Defibrillation-proof type CF applied part (direct cardiac application) Mode of operation: Continuous Degree of protection against harmful ingress of water: IP44 Degree of mobility: Portable
Operating conditions	Temperature: 5°C to 40°C Relative humidity (noncondensing): 15% to 95% Barometric: 57.0 kPa to 107.4 kPa
Storage conditions	Temperature: –20°C to 60°C Relative humidity (noncondensing): 10% to 95% Barometric: 16.0 kPa to 107.4 kPa Corrosive-free and ventilated
Shock	Complies with requirements for medical devices of 6.3.4, EN1789 (10.1.3 a, IEC60601-1-12): Peak acceleration: 300m/s^2 (30g) Duration: 11ms Pulse shape: half-sine Number of shocks: 3 shocks per direction per axis (18 shocks in total)
Vibration	Complies with requirements for medical devices of 6.3.4.2, EN1789 (10.1.3 b, IEC60601-1-12): 10 Hz to100 Hz: 5.0 (m/s^2)^2/Hz 100 Hz to 200 Hz: -7 dB/Octave 200 Hz to 2000 Hz: 1.0 (m/s^2)^2/Hz Duration: 30 minutes per direction per vertical axis (3 axises in total)
Free fall	Complies with requirements for medical devices of 6.3.4, EN1789 (10.1.3 c, IEC60601-1-12): Height of fall: 0.75 m Number of falls: 1 on each of the six surfaces

Power Supply	AC Power Supply: 100 VAC to 240 VAC, 50/60 Hz, 0.30A to 0.13A DC Power Supply: 10 VDC to 16 VDC, 2.0A to 1.3A
Battery run time	At least 5.5 hours for normal battery, at least 11 hours for smart battery, and at least 21 hours for dual smart batteries (operating at a rate of 5ml/h or 25ml/h, under standard operating conditions*) At least 1 hour for normal battery, and at least 2.5 hours for smart battery and dual smart batteries (operating at a rate of 2000ml/h, under standard operating conditions*) *Operating with a fully charged new battery at 20°C ± 2°C, default screen brightness and volume, Wi-Fi disabled, without accessories.
Battery charge time	⩽ 5 hours for normal battery, ⩽ 6 hours for smart battery, and ⩽ 12 hours for dual smart batteries (the pump is off, and charged by the AC power supply).
Shutdown delay	Operating at a rate of 25ml/h, at least 30 minutes after first low battery alarm
Main unit weight	⩽ 1.3 kg (with normal battery, without pole clamp) Pole clamp ⩽ 0.15 kg
Main unit (W × H × D)	125mm x 95mm x 186mm (without pole clamp, the error is ±3mm)
Display	3.5 inches Color TFT LCD, resolution ⩾ 320x480 pixels
Speaker	Gives alarm tones (sound pressure 50 to 75 dB). Supports multi-level tone modulation. Alarm tones comply with IEC 60601-1-8

NOTE

- **The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.**
- **When stored under temperature conditions beyond the defined operating conditions, the equipment needs to be placed under room temperature at least one hour before use.**
- **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.2 Wireless Network

Standards	IEEE 802.11a/b/g/n
Modulation mode	BPSK, QPSK, 16-QAM, 64-QAM
Operating frequency	2412MHz to 2472MHz 5180MHz to 5320MHz 5500MHz to 5700MHz 5745MHz to 5825MHz
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
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	Standard: OPEN and WPA/WPA2-PSK Encryption: TKIP and AES
System capacity	Number of the pumps supported by a single AP: ⩽ 16
Data transmission delay between the pump and the CMS	Total data transmission delay time between the pump and the CMS is ⩽ 8s
Interruption number and time between the pump and the CMS	Total interruption duration ⩽ 0.01* total communication time (Test within 24 hours, with 16 pumps, in which three pumps are roaming for 30 times)
Delay time of network disconnection alarm	⩽ 14 s

A.3 Infusion Specifications

Accuracy	Infusion accuracy: ⩽ ±5%(use SHINVA ANDE single use infusion set for pump) Infusion accuracy: ⩽ ±4.5% (use B. Braun Intrafix Primeline) Bolus accuracy: ⩽ ±5% or ±0.02ml, whichever is greater Drip accuracy: ⩽ ±10% **Note:**Test in accordance with IEC60601-2-24:2012
Infusion accuracy sensor error	⩽ ±3% (operating at a rate of 100 ml/h)

Set range of the infusion rate/ purge rate/bolus rate	0.1ml/h to 2000ml/h Minimum resolution: 0.01ml/h (0.1 to 99.99ml/h) 0.1ml/h (100.0 to 999.9ml/h) 1ml/h (1000 to 2000ml/h) Range of the infusion rate for micro-infusion mode: 0.1ml/h to 100ml/h
Set rang of drop rate	(1 to 400) d/min
Occlusion pressure	50mmHg to 1125mmHg Resolution: 1mmHg The maximum occlusion pressure is 1350mmHg.
Occlusion pressure tolerance	50mmHg to 149mmHg: ⩽ ±75mmHg (operating at a rate ⩽ 100 ml/h) 150mmHg to 1125mmHg: ⩽ ±20% or ⩽ ±125mmHg, whichever is greater
Maximum volume (under single fault conditions)	⩽ 0.5ml
KVO rate	0.1 to 5.0ml/h Minimum resolution: 0.01ml/h
Time set range	00:00:01 to 99:59:59 (h:min:sec)
VTBI set range	0.1 to 9999.99 ml Minimum resolution: 0.01ml Micro-infusion mode: 0.1 to 1000ml
Weight set range	0.1 to 499.0 kg/0.2 to1100.1 lb
Drug Amt. set range	0.001 to 99999
Drug Amt. unit set range	ng, μg, mg, g, mU, U, kU, EU, mmol, mol, mcal, cal, kcal, mEq
Volume set range in Dose Time Mode/Dose Mode	0.1 to 9999.99ml
Conc. set range	0.001 to 9999.99
Conc. unit set range	ng/ml, μg/ml, mg/ml, g/ml, mU/ml, U/ml, kU/ml, EU/ml, mmol/ml, mol/ml, mcal/ml, cal/ml, kcal/ml, mEq/ml
Dose Rate set range	0.001 to 99999
Patient management	Discharging/admitting a patient, Editing/exporting/importing patient information

Prescription	Accepting and performing the prescription

WARNING

- **The infusion accuracy and pressure detection is affected by viscosity of liquids and disposables used (for example diameter, material, elasticity and needle).**

NOTE

- **The infusion accuracy tests and occlusion pressure tests are performed in accordance with IEC60601-2-24:2012 (test temperature: 20°C ± 2°C).**

A.4 Recommended Infusion Sets

Product Name	Type	Manufacturer
Transfusion Sets for Single Use	Transfusion	SHANDONG WEIGAO GROUP MEDICAL POLYMER CO., LTD
Single Use Infusion Set for Pump	Regular	SHINVA ANDE HEALTHCARE APPARATUS CO., LTD
Disposable Enteral Feeding Set	Nutrition	SHINVA ANDE HEALTHCARE APPARATUS CO., LTD
B.Braun Intrafix Primeline	Precision	B. Braun Melsungen AG

NOTE

- **The pump will not affect the quality of disposables from other suppliers. Changes in quality may affect the technical data of the pump. Mindray Scientific is not responsible for such changes.**

A.5 Occlusion Alarm Delay and Bolus Volume

Rate (ml/h)	Occlusion alarm delay time (hh: mm: ss)	
	High occlusion alarm pressure level	Low occlusion alarm pressure level
1	< 02:01:00	< 00:04:37
25	< 00:03:25	< 00:00:30

Rate	Bolus volume after occlusion (ml)	
	High occlusion alarm pressure level	Low occlusion alarm pressure level
25ml/h	< 0.18	< 0.18

Test conditions:

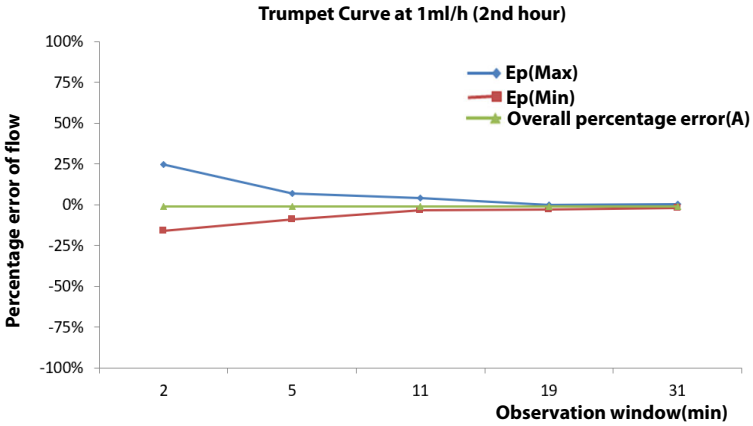
- Infusion set brand: B.Braun Intrafix Primeline)
- Anti-bolus: On
- Test temperature: 20**℃** ±2**℃**
- Infusion line length: 1 meter

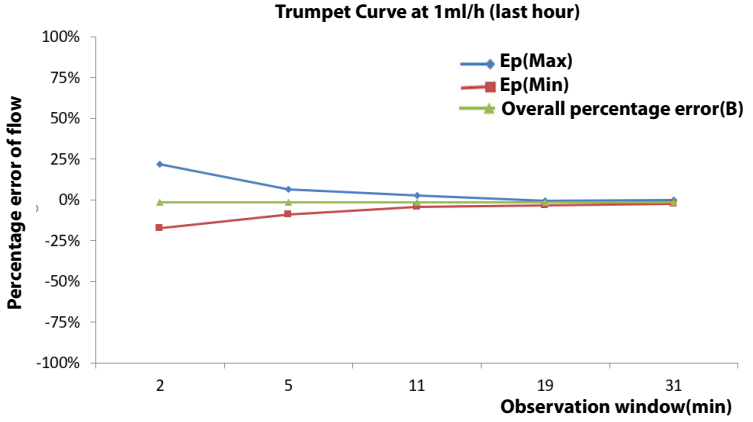
WARNING

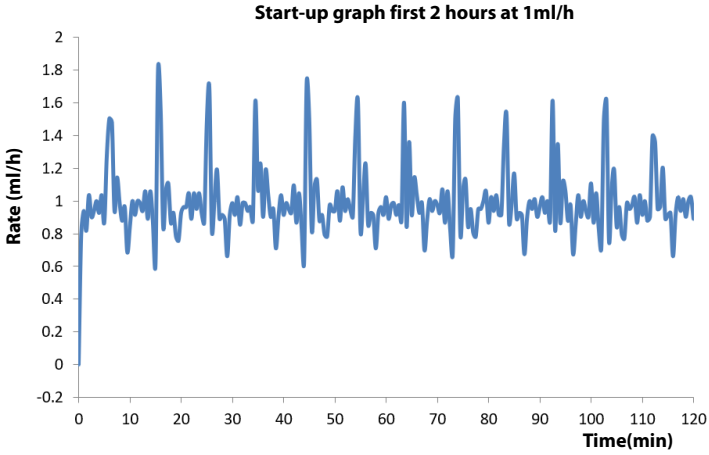
- **Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length.**

A.6 Infusion Accuracy Graphs

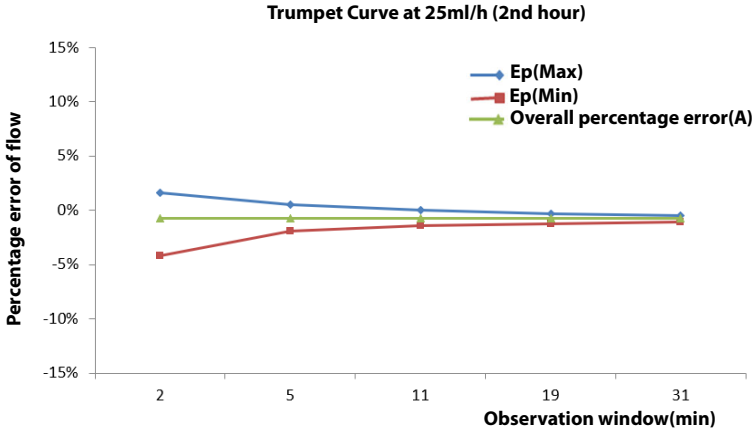
A.6.1 Infusion Accuracy at 1 ml/h

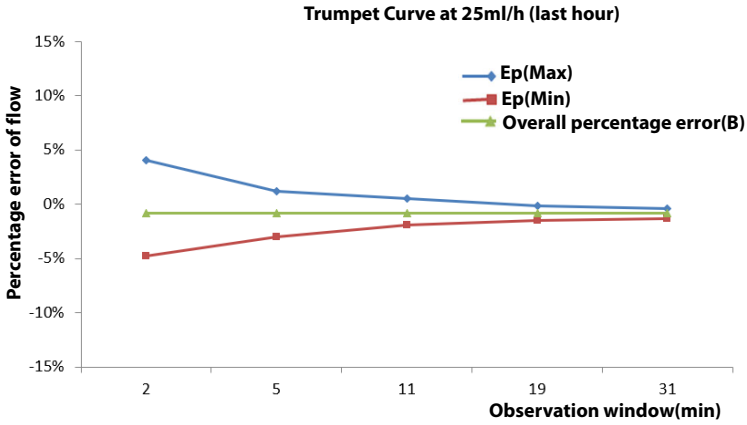

Trumpet Curve at 1ml/h (2nd hour)
Percentage error of flow
100%
75%
50%
25%
0%
-25%
-50%
-75%
-100%
2
5
11
19
31
Observation window(min)
Ep(Max)
Ep(Min)
Overall percentage error(A)

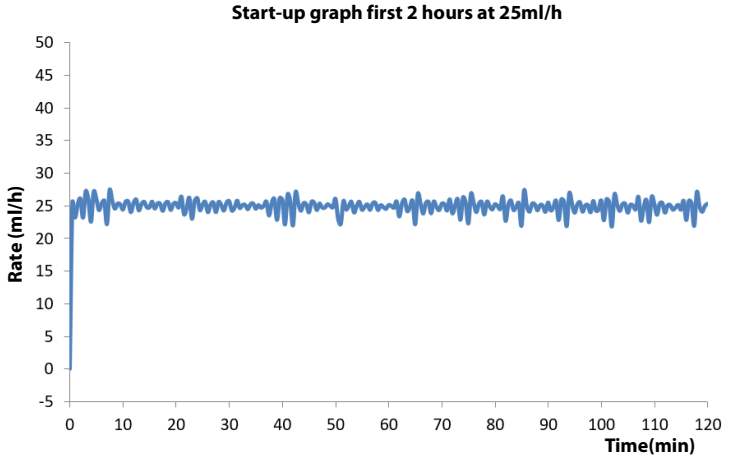

Trumpet Curve at 1ml/h (last hour)
Percentage error of flow
100%
75%
50%
25%
0%
-25%
-50%
-75%
-100%
2
5
11
19
31
Observation window(min)
Ep(Max)
Ep(Min)
Overall percentage error(B)



A.6.2 Infusion Accuracy at 25ml/h







Test conditions:

- Infusion set brand: B.Braun Intrafix Primelin)
- Test interval: △ t =0.5 minute

WARNING

- **Infusion accuracy may be influenced by the pump's environment (such as pressure, temperature, humidity, and any infusion consumables used).**

A.7 Operating Environment

Operating system	FreeRTOS
Classification	OS Core
Version Information	9.0.0

B EMC and Radio Regulatory Compliance

B.1 EMC

The device meets the requirements of IEC 60601-1-2: 2020.

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 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 device may be disrupted by the operation of nearby equipment.**

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 B	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.
Harmonic distortion IEC 61000-3-2	Class A	
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.**
- **Use of portable or mobile communications devices will degrade the performance of the device.**
- **Other devices may affect this device even though they meet the requirements of CISPR.**
- **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 pump system and contact the service personnel.**

If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration —Electromagnetic Immunity**, the system will remain safe and provide the following essential performance:

- Operating mode
- Accuracy
- Function
- Protection against UNINTENDED BOLUS volumes
- Occlusion
- ALARM CONDITIONS regarded
- Data stored

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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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	±0,5 kV, ±1 kV line(s) to line(s); ±0,5 kV, ±1 kV, ±2 kV line(s) to earth	±0,5 kV, ±1 kV line(s) to line(s); ±0,5 kV, ±1 kV, ±2 kV line(s) to earth	
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle and 70 % U_T for 25/ 30 cycles 0 % U_T for 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 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: $d = 1.2\sqrt{P}$ 150kHz to 80 MHz $d = 2\sqrt{P}$ 150kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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). 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: 
	6 Vrms in ISM bandsa between 0,15 MHz and 80 MHz[a]	6 Vrms	
Radiated RF EM fields IEC61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/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] 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.

GUIDANCE AND MINDRAY DECLARATION - ELECTROMAGNETIC IMMUNITY

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIROMENT - GUIDANCE
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz CW	8 A/m 30 kHz CW	/
	65 A/m 134,4 kHz Pulse modulation 2,1 kHz	65 A/m 134,4 kHz Pulse modulation 2,1 kHz	
	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	7,5 A/m 13,56 MHz Pulse modulation 50 kHz	

TABLE EMC-5- Test specifications and minimum distances

Recommended separation distances between portable and mobile RF communications equipment and the device						
The system is intended for use in an electromagnetic environment in which radiated RF disturbances 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 communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:						
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity test level (V/ m)**
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 -470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/ 900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and the device

The device 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 Out ISM and amateur radio bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d = 2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.2	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2	1.2	2.3

10	3.8	6.4	3.8	7.3
100	12	20	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.				

Cable information:

PORT No.	Name	Cable Length (m)	Cable Shielded (Y/N)	Remark
1	Power cord	2.5	N	/
2	Nurse call cable	2.8	N	with ferrite core
3	DC power cord	2.8	N	/
4	Drop sensor cable	1.2	N	/
5	Infusion accuracy sensor cable	1.2	Y	/

B.2 Radio Regulatory Compliance

Refer to ***A.2 Wireless Network*** for the details of RF parameters.

CE

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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