

**BeneFusion iSP**

**BeneFusion iSP ex**

**Syringe Pump**

**Safety and Performance**

**Information**



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# 1 Safety

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## 1.1 Safety Information

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### WARNING

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

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- 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

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- 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

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#### WARNING

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- 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.
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- **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.**
  - **Check that the syringe and the extension set are securely connected and there is no leakage.**
  - **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.**
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## 1.1.2 Cautions

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### CAUTION

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- **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.**
- **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.**
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### **1.1.3 Notes**

#### **NOTE**

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- **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 file describes all features and options. Your equipment may not have all of them.**
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# 2 Equipment Introduction

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## 2.1 Intended Purpose

The syringe pump is intended for use on adults, paediatrics, and neonates for the intermittent or continuous delivery of medications, solutions, parenteral nutrition, lipids indicated for infusion therapy through an intravenous or intra-arterial routes.

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### WARNING

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- **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.**
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### NOTE

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- **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.**
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### 2.1.1 Indication for Use

Syringe pumps are for patients who need receive various types of medications, solutions, parenteral nutrition, lipids in controlled amounts through an intravenous or intra-arterial routes.

### 2.1.2 Intended Users

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

### 2.1.3 Intended Patient Population

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

### 2.1.4 Intended Medical Conditions

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

### **2.1.5 Contra-indications**

None.

### **2.1.6 Side-effects**

None.

## **2.2 Clinical Benefit**

The syringe pump allows administration of medications, solutions, parenteral nutrition, lipids accurately, evenly and continuously through an intravenous or intra-arterial routes.

## **2.3 Applied Part**

The applied part of the equipment is the syringe.

# 3 Equipment Preparation

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## 3.1 Equipment Preparation Safety Information

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### WARNING

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- 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.
- 
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### CAUTION

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- 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.
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## **NOTE**

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- **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.**
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## **3.2 Setting Up the Equipment**

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### **WARNING**

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- **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.**
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### **CAUTION**

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- **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

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## 4.1 Turning on the Pump

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### WARNING

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- 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
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### NOTE

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- 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.
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## 4.2 Loading the Syringe

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### WARNING

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- Check that the syringe and the extension set are securely connected and there is no leakage.
  - It is recommended that standard, single-use extension sets and syringes with Luer lock connections are used.
  - We recommend you to use syringes and extension sets of the types and brands stated in this file. If a non-recommended syringe must be used, 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 syringe size and brand should be calibrated using this pump before first use.
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- The pump must be mounted within  $51 \pm 5$  cm above the patient's heart. The most accurate pressure monitoring in the extension set is achieved when the pump is positioned close to the patient's heart level.
  - As the volume of fluid contained in the extension set and retained in the syringe at the end of infusion will not be infused, allow for this "dead space" volume when initially loading the syringe.
  - Secure the extension set using the extension set holder. This provides protection against accidental dislodging of the syringe from the pump.
  - Single use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.
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## CAUTION

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- Ensure that the syringe is properly loaded. The barrel flange is in the space between the pump and the flange retainer. The plunger grippers squeeze the plunger flange. Failure to properly load the syringe could result in uncontrolled fluid flow.
  - To avoid possible uncontrolled fluid flow, disconnect the pump from the patient before loading or changing the syringe. And always keep the pump under close surveillance.
  - To avoid unexpected fluid flow due to height difference, place the syringe as close to the patient as possible.
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## NOTE

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- The extension set and the pump should be placed in the same horizontal level before connected to the patient.
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## 4.3 Purge

### NOTE

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- If required, set the purge rate after the purge starts. The initial purge rate is 1200 ml/h or the maximum rate that the pump can currently support according to the syringe size, whichever is smaller.
  - The volume used for purging is not added to the infused volume.
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## 4.4 Starting Infusion

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### WARNING

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- 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 the syringe status before infusion starts or after infusion stops, and confirm the infusion is started or stopped.
  - Do not put your hand around the syringe flange clamp while the driver head is moving.
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### NOTE

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- 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.
  - Monitor the connection of syringe, extension set, pump and patient, and the drug information on a regular basis. Start infusion according to the instructions in this file.
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## 4.5 Bolus Infusion

### NOTE

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- 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 Changing the Infusion Parameters

### NOTE

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- In the TCI mode, the drug name cannot be changed after the infusion is started.
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## 4.7 Setting Keep Vein Open (KVO) Rate

### NOTE

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- 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.
- 

## 4.8 Unloading a Syringe

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### WARNING

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- Change the extension set as per the manufacturer's instructions or the hospital regulation.
  - To prevent free flow, make sure that the clamp has fully occluded the extension set before unloading a syringe.
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## 4.9 Turning Off the Pump

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### CAUTION

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- 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.
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### NOTE

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

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## 5.1 Alarm Safety Information

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### WARNING

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- 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.
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## 5.2 Understanding the Alarms

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### NOTE

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- 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.
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## 5.3 Alarm Solutions

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### WARNING

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- 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.
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### NOTE

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- 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.
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## 5.4 Occlusion Alarm

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### NOTE

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- If this pump is running at 0.1 ml/h using 50ml syringe, and respectively configure the occlusion pressure alarm limit to the lowest level and highest level, the occlusion alarm delay time may reach up to three hours and 27 hours. Adjust the pressure limit to a lower level, or use a small size syringe for the low rate infusion.
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# 6 Menu Options

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## CAUTION

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- **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

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## NOTE

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- The BeneFusion iSP ex does not provide the Loading Dose Mode.
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## 7.1 Rate Mode/Time Mode/Micro-infusion Mode

### NOTE

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

## 7.2 Dose Mode

### NOTE

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- 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

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- 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

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- 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 syringe is empty.
-

## 7.5 Ramp Mode

### NOTE

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- 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

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- 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 TCI Mode

### CAUTION

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- TCI mode is intended for adult and pediatric patients.
- Avoid using the extension set that is too long or too curl, or whose line diameter is too small, as such extension sets are unfavorable for liquid flowing. Unexpected occlusion alarm may be triggered when the pump is running at the initial rate of the TCI mode using such extension sets. It is recommended that extension sets with the inner diameter of at least 1.5 mm should be used.
- The estimated  $C_e$  and  $C_p$  are for reference only.
- When the pump is restarted after an accidental power down or crash, the TCI of the same drug is not allowed.
- The default TCI parameters are not suitable for all patients and should be adjusted according to patient characteristics.
- As for patients with old age, heart failure, hepatorenal function failure, plasma esterase abnormality, ASA classification III-IV, recombination application of other drugs or other PK-PD process, we recommend using plasma target mode at lower  $C_{pt}$ , and slowly increase  $C_{pt}$  according to actual situation of the patients. Please refer to the prescription data of drugs for the influencing factors of PK-PD process.
- TCI should only be performed by experienced anaesthetists who is fully aware of the available literature for any parameter set used in association

with a drug and needs to refer to the prescribed information for rate and dosing limits.

- Pharmacokinetic and pharmacodynamic interactions among anaesthetic drugs are known, but are not taken into account into the calculation of the plasma and effect site concentrations. They have to be taken into account by the user.
  - The user should be fully aware of the drug to be infused, and check the patient information and the set target concentration conform with the prescription.
- 

## **NOTE**

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- If the infused drugs are diluted, ensure that the right concentration is entered.
  - Ensure that the parameter settings conform with the prescription. The patient information and drug name cannot be changed after the TCI is initiated.
  - When the TCI is completed, the same drug cannot be infused again to the same patient.
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# 8 Drug Library/Drug Info Library

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## CAUTION

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- **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.**
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## NOTE

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

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## CAUTION

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- **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

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## 10.1 Maintenance Safety Information

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### **WARNING**

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- 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.
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### **CAUTION**

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- 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.
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### **NOTE**

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

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## **WARNING**

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- 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.
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## **NOTE**

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- 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.
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## 10.3 Checking the History Record

### NOTE

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- 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.
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## 10.4 Disposing of the Equipment

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### WARNING

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- 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

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## WARNING

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- 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.
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## CAUTION

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- 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

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## WARNING

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

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- 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

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

<b>Power Supply</b>	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
<b>Battery run time</b>	At least 6.5 hours for normal battery, at least 12.5 hours for smart battery, and at least 21 hours for dual smart batteries (operating at a rate of 5ml/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.
<b>Battery charge time</b>	≤ 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).
<b>Shutdown delay</b>	Operating at a rate of 5ml/h, at least 30 minutes after first low battery alarm
<b>Main unit weight</b>	≤ 1.7 kg (with normal battery, without pole clamp) Pole clamp ≤ 0.15 kg
<b>Main unit (W × H × D)</b>	252mm x 118mm x 134mm (without pole clamp, the error is ±3mm)
<b>Display</b>	4.3 inches Color TFT LCD, resolution ≥ 272x480 pixels
<b>Speaker</b>	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 pump 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
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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: $\leq 16$
Data transmission delay between the pump and the CMS	Total data transmission delay time between the pump and the CMS is $\leq 8s$
Interruption number and time between the pump and the CMS	Total interruption duration $\leq 0.01*$ 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	$\leq 14 s$

## A.3 Infusion Specifications

Compatible syringe sizes	2ml/3ml, 5ml/6ml, 10ml/12ml, 20ml, 30ml/35ml, 50ml/60ml
Accuracy	Mechanical accuracy: $\leq \pm 0.5\%$ Infusion accuracy* ( $0.01\text{ml/h} \leq \text{rate} < 0.1\text{ml/h}$ ): $\leq \pm 5\%$ Infusion accuracy* ( $0.1\text{ml/h} \leq \text{rate} \leq 2300\text{ml/h}$ ): $\leq \pm 1.8\%$ or $\pm 0.005\text{ml/h}$ , whichever is greater Bolus accuracy: $\leq \pm 2\%$ or $0.05\text{ml}$ , whichever is greater (under standard operating conditions, test in accordance with IEC60601-2-24:2012) *Infusion accuracy use Double-Dove and B.Braun Original Perfusor Syringe, under standard operating conditions, test in accordance with IEC60601-2-24:2012)

Remaining infusion time error	±10%
Set range of the infusion rate/ purge rate/bolus rate	0.01 to 150ml/h (2/3ml syringe) 0.01 to 300ml/h (5/6ml syringe) 0.1 to 800ml/h (10/12ml syringe) 0.1 to 1200ml/h (20ml syringe) 0.1 to 1500ml/h (30/35ml syringe) 0.1 to 2300ml/h (50ml/60ml syringe and 60ml syringe) Resolution: 0.01ml/h (0.01 to 99.99ml/h) 0.1ml/h (100.0 to 999.9ml/h) 1ml/h(1000 to 2300ml/h)  Range of the infusion rate for micro-infusion mode: 0.01 to 100ml/h
Occlusion pressure	50mmHg to 1125mmHg Resolution: 1mmHg 1000mmHg to 1125mmHg: not applicable for 50ml/ 60ml syringe 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 (operating at a rate ≥ 0.1ml/h)
Maximum volume (under single fault conditions)	≤ 0.2ml
KVO rate	0.01 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	0.01 to 9999.99 ml Minimum resolution: 0.01ml  Micro-infusion mode: 0.01 to 1000ml
Weight set range	0.1 to 499.0 kg/0.2 to 1100.1 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/TIVA 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

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## WARNING

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

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- **The infusion accuracy tests and occlusion pressure tests are performed in accordance with IEC60601-2-24:2012 (test temperature: 20°C ± 2°C).**
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## A.4 Recommended Syringes

Product Name	Size	Manufacturer
Sterile Hypodermic Syringes for Single Use	5ml, 10ml, 20 ml, 30 ml, 50ml	Double-Dove
B. Braun Original Perfusor Syringe	20ml, 50ml	B. Braun Melsungen AG
B. Braun Omnifix Luer Lok Solo	2ml, 3ml	B. Braun Melsungen AG

## NOTE

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- **The recommended extension set is B.Braun Original Perfusor Line (using IV-Standard-PE, and with Luer lock).**
  - **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

Syringe size (ml)	Rate (ml/h)	Occlusion alarm delay time (hh: mm: ss)	
		High occlusion alarm pressure level	Low occlusion alarm pressure level
20	1	< 00:52:00	< 00:03:55
	5	< 00:09:05	< 00:00:45
50	1	< 02:43:48	< 00:09:28
	5	< 00:32:07	< 00:03:53

Syringe size (ml)	Rate (ml/h)	Bolus volume after occlusion (ml)	
		High occlusion alarm pressure level	Low occlusion alarm pressure level
20	5	< 0.2	< 0.1
50	5	< 0.3	< 0.15

Test conditions:

- Syringe brand: B.Braun Original Perfusor Syringe, B. Braun extension line
- Test temperature: 20°C ±2°C

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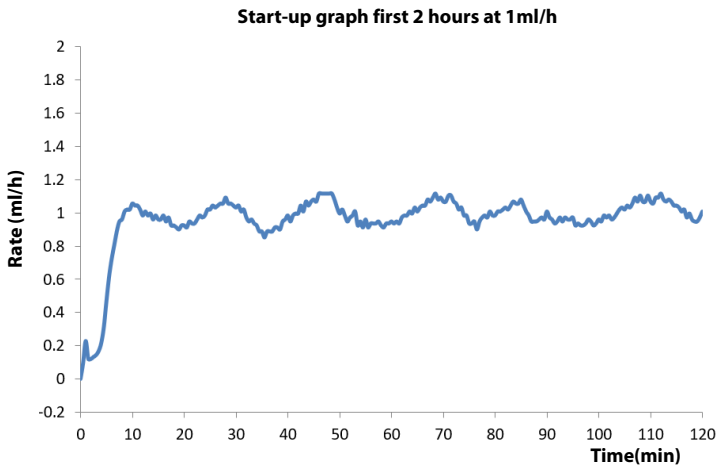
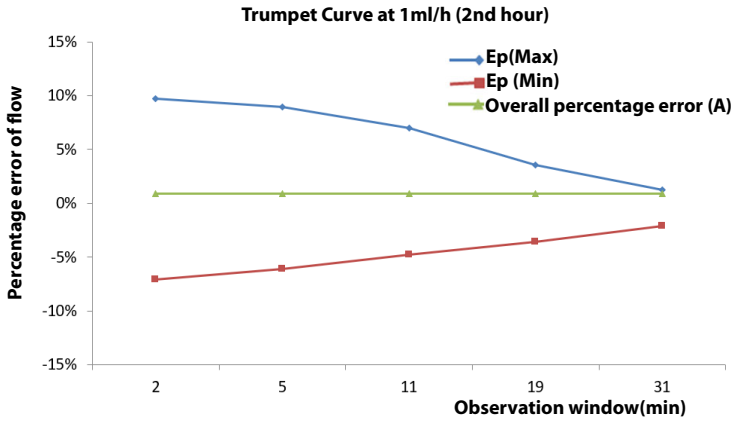
### WARNING

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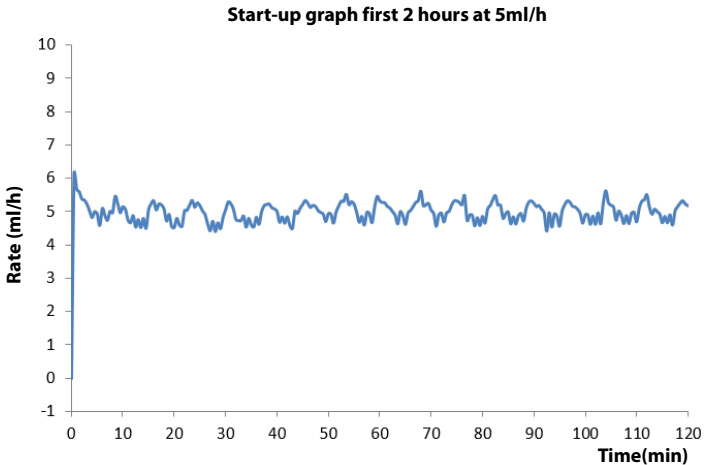
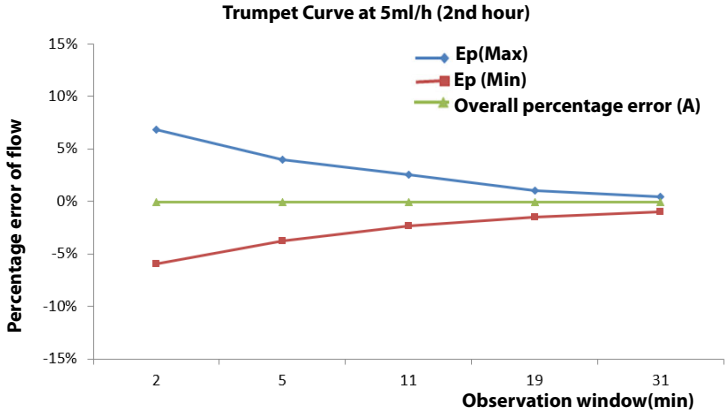
- **Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length. Using syringe of a larger size and infusing at a lower rate may cause longer occlusion alarm delay.**
-

## A.6 Infusion Accuracy Graphs

### A.6.1 Infusion Accuracy at 1 ml/h



## A.6.2 Infusion Accuracy at 5ml/h



Test conditions:

- Syringe brand: B.Braun Original Perfusor Syringe, B.Braun extension set
- Syringe size: 50ml
- Test interval:  $\Delta t = 0.5$  minute

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### WARNING

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- Infusion accuracy may be influenced by the pump's environment (such as pressure, temperature, humidity, and any infusion consumables used).
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## A.7 Operating Environment

Operating system	FreeRTOS
Classification	OS Core
Version Information	9.0.0

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# B EMC and Radio Regulatory Compliance

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## B.1 EMC

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

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### WARNING

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- **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.

<b>Emission test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
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

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- **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

<b>Guidance and Declaration - Electromagnetic Immunity</b>			
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.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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 % U <sub>T</sub> ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % U <sub>T</sub> for 1 cycle and 70 % U <sub>T</sub> for 25/30 cycles  0 % U <sub>T</sub> for 250/300 cycle	0 % U <sub>T</sub> ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % U <sub>T</sub> for 1 cycle and 70 % U <sub>T</sub> for 25/30 cycles  0 % U <sub>T</sub> 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 <sub>T</sub> 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
	6 Vrms in ISM bands between 0,15 MHz and 80 MHz <sup>a</sup>	6 Vrms	
Radiated RF EM fields IEC61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	$d = 1.2\sqrt{P}$ 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 <sup>b</sup> , should be less than the compliance level in each frequency range <sup>c</sup> . Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

<sup>a</sup> 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.

<sup>b</sup> 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.

<sup>c</sup> 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.

<b>IMMUNITY TEST</b>	<b>IEC 60601 TEST LEVEL</b>	<b>COMPLIANCE LEVEL</b>	<b>ELECTROMAGNETIC ENVIROMENT - GUIDANCE</b>
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

<b>Recommended separation distances between portable and mobile RF communications equipment and the device</b>						
<p>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:</p>						
<b>Test frequency (MHz)</b>	<b>Band (MHz)</b>	<b>Service</b>	<b>Modulation</b>	<b>Maximum power (W)</b>	<b>Distance (m)</b>	<b>Immunity test level (V/m)</b>
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	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth , WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN, 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

**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
<p>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.</p> <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>				

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	/

## B.2 Radio Regulatory Compliance

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



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

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### WARNING

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