

BeneFusion mNP

Enteral Feeding Pump

**Safety and Performance
Information**

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1 Safety

1.1 Safety Information

WARNING

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

CAUTION

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

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.
 - Keep a distance of at least 20 cm away from the patient when operating the pump.
 - Ensure that the pumps are being operated correctly according to the warnings in the manual. If not, the devices should be observed that they are working normally.
-

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. If it is not sure whether the power supply is stable, it is recommended to prepare another equipment in case of power failure.
- 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.
-

2 Equipment Introduction

2.1 Intended Purpose

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.
-

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.
-

3.2 Installation

3.2.1 IV Pole Installation

NOTE

- After two pumps are mounted to a MIP-300 IV Pole, ensure that the maximum load of IV container does not exceed 4 kg. Failure to do so can result in system becoming unbalanced.
 - Remove the IV containers from the IV Poles before transporting the equipment. Carry each component separately. Failure to do so can result in system becoming unbalanced.
-

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.
-

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.
 - 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 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 Tube Open (KTO) Rate

NOTE

- If the KTO 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 KTO rate. At the completion of the KTO infusion, the pump stops infusion, and gives a KTO Finish alarm.
 - The volume used during KTO 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 KTO 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.
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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 hours. Adjust the pressure limit to a lower level 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.
-

7 Infusion Modes

7.1 Continuous Feeding/Time Feeding/Nourishing Feeding

NOTE

- When infusing in the continuous feeding, time feeding, and nourishing feeding, you must set rate, but time and VTBI settings are optional.
-

7.2 Intermittent Feeding

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.
-

8 Feeding Library

CAUTION

- The feeding 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 feeding library is loaded.
-

NOTE

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

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.**
-

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.
 - The maintenance personnel should confirm the accuracy of the pump every three years. If the accuracy not meet the claimed accuracy, perform the accuracy calibration and verify whether the accuracy meets the claimed specification.
-

- After the maintenance personnel complete the pressure calibration, the pressure accuracy must be tested to confirm whether the calibration is valid.
-

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

11.1 Care and Cleaning Safety Information

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.
-

11.2 Disinfecting the Pole Clamp and DC Adapter

CAUTION

- To avoid long term damage, the accessories should be disinfected only when necessary as determined by your hospital's policy.
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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.
-

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 |
| 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 and at least 11 hours for smart battery (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 (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 and ≤ 6 hours for smart battery (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 | ≤ 1.5 kg (with normal battery, without pole clamp) |

| | |
|----------------------------------|--|
| Main unit (W × D × H) | 100mm x 95mm x 200mm (without pole clamp, the error is ±3mm) |
| Display | 4.3 inches Color TFT LCD, resolution ≥ 272x480 pixels |
| Speaker | Gives alarm tones (sound pressure 50 to 75 dB). Supports multi-level tone modulation. Alarm tones comply with IEC 60601-1-8. |
| USB connector | 1, USB 2.0 protocol. Fixed time synchronization pulse specified by the USB protocol. |
| Multifunctional connector | 1, Uart protocol |

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 $\leq 8s$ |
| 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

| | |
|--|--|
| Accuracy | Infusion accuracy: $\leq \pm 5\%$ (use SHINVA ANDE Disposable Enteral Feeding Set EIS-22-A) Bolus accuracy: $\leq \pm 5\%$ or $\pm 0.02\text{ml}$, whichever is greater Note: Test in accordance with IEC60601-2-24:2012 |
| 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 nourishing feeding: 0.1ml/h to 100ml/h |
| Occlusion pressure | 75mmHg to 825mmHg Resolution: 1mmHg The maximum occlusion pressure is 990mmHg. |
| Occlusion pressure tolerance | $\leq \pm 20\%$ or $\leq \pm 125\text{mmHg}$, whichever is greater |
| Maximum volume (under single fault conditions) | $\leq 0.5\text{ml}$ |
| KTO rate | 0.1 to 50ml/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 Nourishing feeding: 0.1 to 1000ml |
| Conc. set range | 0.001 to 9999.99 |
| Conc. unit set range | ng/ml, ug/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 |
| 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 |
|--------------------------------|-----------|---|
| Disposable Enteral Feeding Set | Nutrition | SHINVA ANDE HEALTHCARE APPARATUS CO., LTD |

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 | < 01:50:00 | < 00:04:00 |
| 25 | < 00:03:00 | < 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:

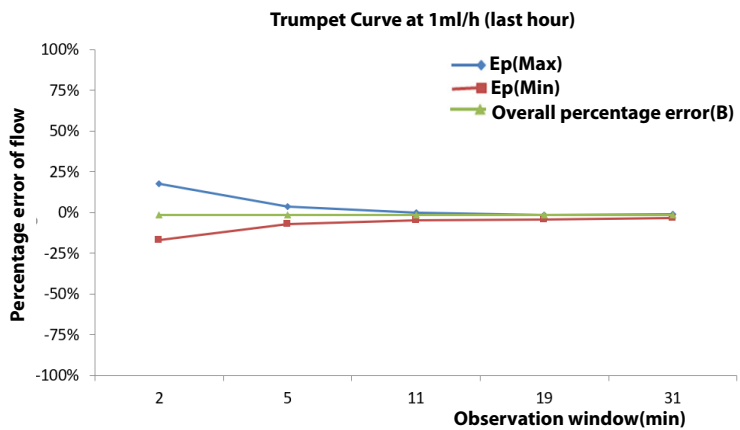
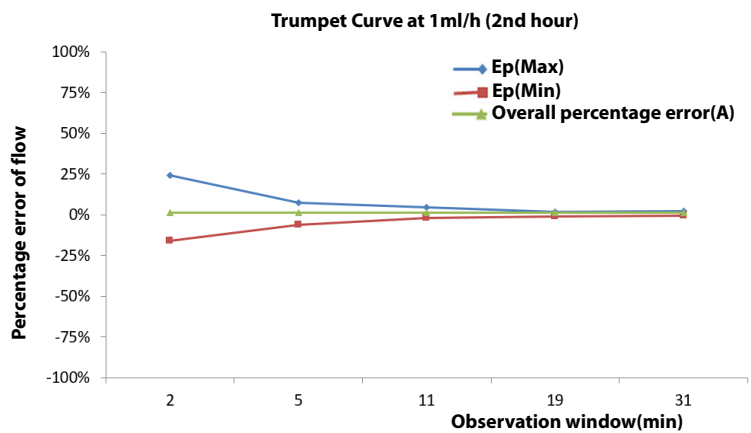
- Infusion set brand: SHINVA ANDE EIS-22-A
- Anti-bolus: On
- Test temperature: 20°C ±2°C
- Infusion line length: 1 meter

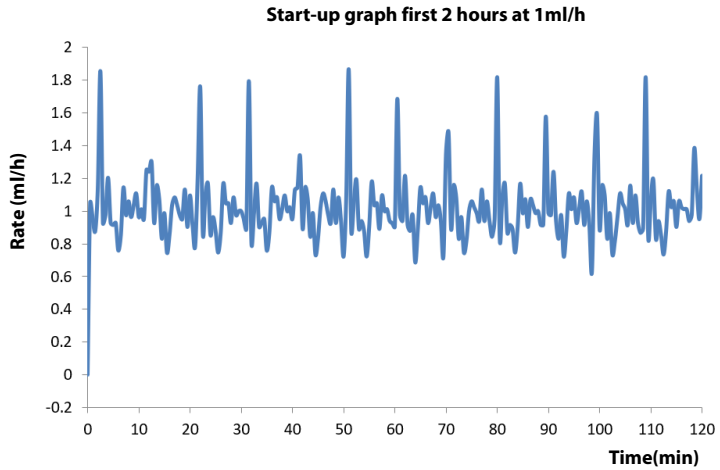
WARNING

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

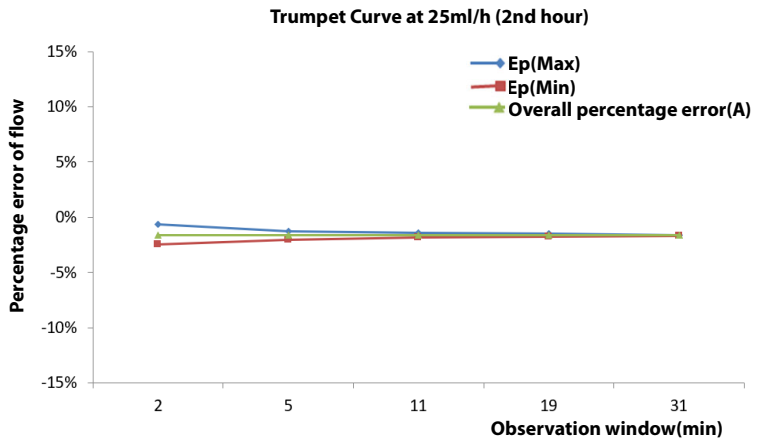
A.6 Infusion Accuracy Graphs

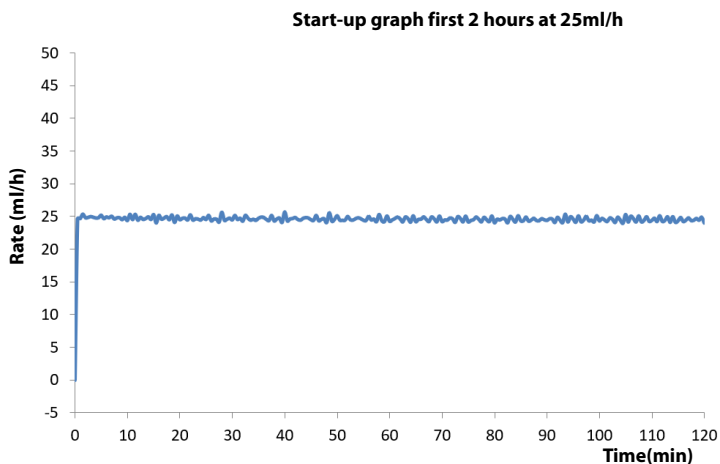
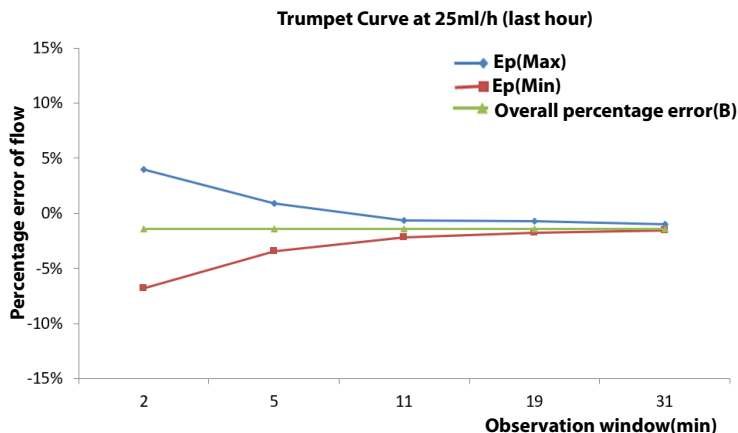
A.6.1 Infusion Accuracy at 1 ml/h





A.6.2 Infusion Accuracy at 25ml/h





Test conditions:

- Infusion set brand: SHINVA ANDE EIS-22-A
- Test interval: $\Delta t = 0.5$ 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 system complies with the EMC standard IEC60601-1-2:2020.

WARNING

- The use of unapproved accessories may diminish system performance.
 - Use of components, accessories, probes, and cables other than those specified may result in increased emission or decreased immunity of system.
 - The system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
 - Use of the system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the system and the other equipment should be observed to verify that they are operating normally.
 - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the system could result in increased electromagnetic emissions or decreased electromagnetic immunity of the system and result in improper operation.
 - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of the system could result.
 - Other devices may interfere with the system even though they meet the requirements of CISPR.
 - Use of portable or mobile communications devices can degrade the performance of the equipment.
 - The system is not intended for use in residential environments and can possibly not provide adequate protection to radio reception in such environments.
-

If the system is operated within the electromagnetic environment listed in TABLE EMC-2, EMC-3, TABLE EMC-4 and TABLE EMC-5, the system will remain safe and will provide the following basic performances:

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


Table EMC-1

| Guidance and Mindray Declaration - Electromagnetic Emissions | | |
|---|-------------------|--|
| The system 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. | | |
| Emission test | Compliance | Electromagnetic environment - guidance |
| RF Emissions CISPR 11 | Group 1 | The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| RF Emissions CISPR 11 | Class B | |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 | Complies | |

Table EMC-2

| Guidance and Mindray Declaration - Electromagnetic Immunity | | | |
|---|---|---|---|
| The system 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 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 | ±2 kV for power supply lines; | 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, Short interruptions and voltage variation on power supply input voltage IEC 61000-4-11 | 0% U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70% U_T for 25/30 cycle at 0° 0% U_T ; 250/300 cycle | 0% U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T ; 1 cycle 70% U_T for 25/30 cycle at 0° 0% U_T ; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 HZ) magnetic field IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note: U_T is the A.C. mains voltage prior to application of the test level. | | | |

Table EMC-3

| Guidance and Mindray Declaration - Electromagnetic Immunity | | | |
|---|--|--|--|
| The system 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 environment - guidance |
| Conducted RF IEC 61000-4-6 | 3 Vrms 0,15 MHz to 80 MHz | 3 Vrms 0,15 MHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 2\sqrt{P}$ |
| | 6 Vrms in ISM bands ^a between 0,15 MHz and 80 MHz | 6 Vrms in ISM bands ^a between 0,15 MHz and 80 MHz | |
| Radiated RF IEC 61000-4-3 | 3V/m 80 MHz to 2.7 GHz | 3V/m 80 MHz to 2.7 GHz | $d = 1.2\sqrt{P}$ 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:  |
| 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.

^bField 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.

Table EMC-4

| Guidance and Mindray Declaration - Electromagnetic Immunity | | | |
|---|--|--|---|
| The system 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 environment - guidance |
| Proximity magnetic fields IEC 61000-4-39 | 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 Equipment and the System | | | | | | |
|--|-------------------|--|--|--------------------------|---------------------|----------------------------------|
| <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 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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> | | | | | | |
| 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 | 1700 - 1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS | Pulse modulati on 217 Hz | 2 | 0.3 | 28 |
| 1845 | | | | | | |
| 1970 | | | | | | |
| 2450 | 2400 - 2570 | Bluetooth , WLAN, 802.11 b/ g/n, RFID 2450, LTE Band 7 | Pulse modulati on 217 Hz | 2 | 0.3 | 28 |
| 5240 | 5100 - 5800 | WLAN, 802.11 a/ n | Pulse modulati on 217 Hz | 0.2 | 0.3 | 9 |
| 5500 | | | | | | |
| 5785 | | | | | | |

Table EMC-6

| Recommended Separation Distances between Portable and Mobile RF Communications Device and the System | | | | |
|--|---|--|--|---|
| The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and system 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 | | | |
| | 150 kHz to 80 MHz Out ISM bands $d = 1.2\sqrt{P}$ | 150 kHz to 80 MHz in ISM 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> | | | | |

Table EMC-7

| No. | Name | Cable Length (m) | Shield or not | Remark |
|-----|------------------|------------------|---------------|-------------------|
| 1 | Power cord | 2.5 | Not shield | / |
| 2 | Nurse call cable | 2.8 | Not shield | with ferrite core |
| 3 | DC power cord | 2.8 | Not shield | / |

B.2 Radio Regulatory Compliance

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

WARNING

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