INFUSOVET IP II
INFUSION PUMP

USER MANUAL

Item no. 402087

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For this Operator’s Manual, the issued date is 2024-09

Important!

The product is for veterinary use only.

Preface

Manual Purpose

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

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

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

Intended Audience

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

Illustrations

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

Conventions

- **Bold text** is used to indicate the screen texts.
- → is used to indicate operational procedures.

Contents

1 Safety

1.1 Safety Information

⚠ WARNING

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

⚠ CAUTION

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

NOTE:

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

1.1.1 Warnings

⚠ WARNING

- **To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.**
- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **Do not use the multiple portable socket outlets (MPSO) or AC main power 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 animal.**
- **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 animals or personnel.**
- **Clearing the occlusion result from line kinks, filter coagulation, etc. may cause extra bolus to animals. Appropriate measures should be taken.**

- **Do not touch the animal and device connectors simultaneously. Otherwise leakage current may result in animal injury.**
- **To avoid electric shock, do not touch animal and other non-defibrillation proof equipments during defibrillation. Defibrillation will not affect the performance of the equipment.**

1.1.2 Cautions

⚠ CAUTION

- **When several infusion lines are connected to the same vascular access, there may be back flow or prolonged response time of occlusion alarm. Therefore, use check valve at the line end or follow local hospitals' instructions while in connection with other infusion system.**
- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss.**
- **Electromagnetic fields may affect equipment performance. This makes it necessary for other equipment used in the vicinity of this equipment to meet EMC standards. Mobile phones, X ray and MRI equipment are all potential interference sources because of their high-intensity electromagnetic radiation.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force. The equipment should be observed to verify normal operation after fall, otherwise it cannot be used.**
- **Dry the equipment immediately in case of rain or water spray.**
- **Some settings are password protected and can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.**

1.1.3 Notes

NOTE:

- The software was developed in compliance with IEC 62304.
- 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.
- The pump 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 pump 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 pump is degraded due to aging or environmental conditions, contact the Customer Service Department or your local distributor.

1.2 Equipment Symbols

Some symbols may not appear on your equipment.

	Refer to instruction manual/booklet		Alternating current
	Serial number		Input/output
	USB connector		Battery
	Protected against solid foreign objects of 1,0 mm Φ and greater. Protected against splashing water.		Defibrillation-proof type CF applied part
	Date of manufacture		Manufacturer
	Non-ionizing electromagnetic radiation		General warning sign
	Atmospheric pressure limitation		Humidity limitation
	This way up		Keep dry
	Stacking limit by number		Fragile, handle with care
	CE marking		UKCA marking
	Temperature limit		“ON” for part of equipment
	“OFF” for part of the equipment		
	The following definition of the WEEE label applies to EU member states only: the use of this symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, consult the distributor from whom you purchased the product.		

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2 Equipment Introduction

2.1 Intended Use

It is intended for use on animals for the delivery of medications for infusion therapy.

It is intended to be used by qualified and trained personnel in animal medical institutions.

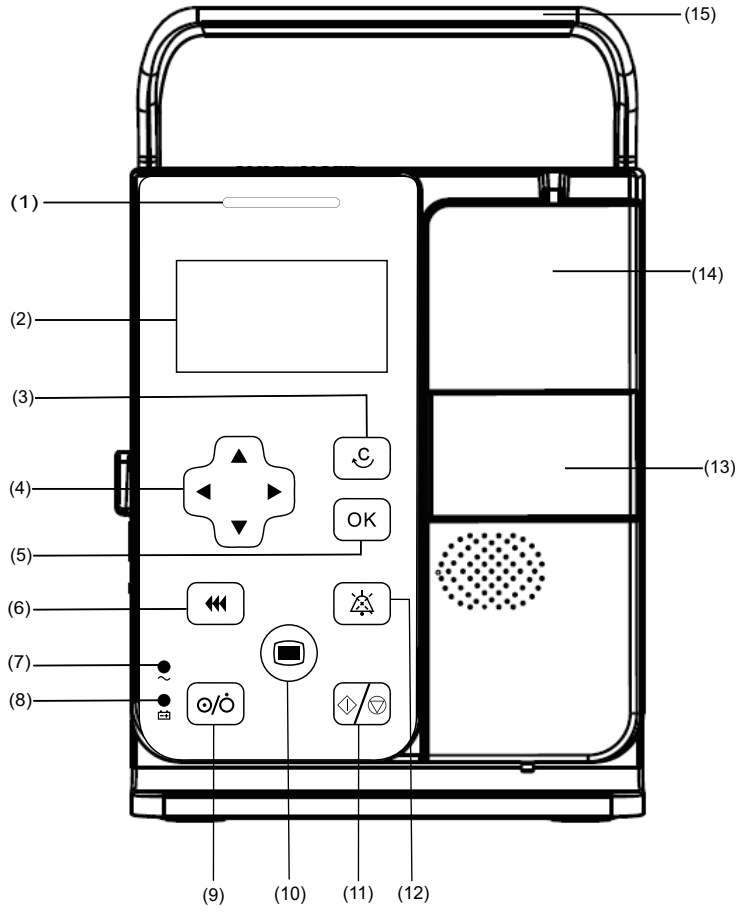
⚠ WARNING

Only properly trained or fully qualified personnel are authorized to operate this product.

2.1.1 Contraindications

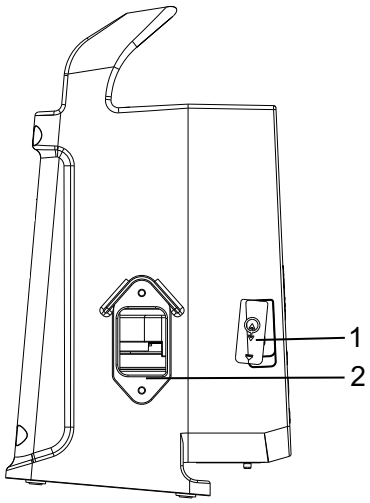
None.

2.2 Main Unit

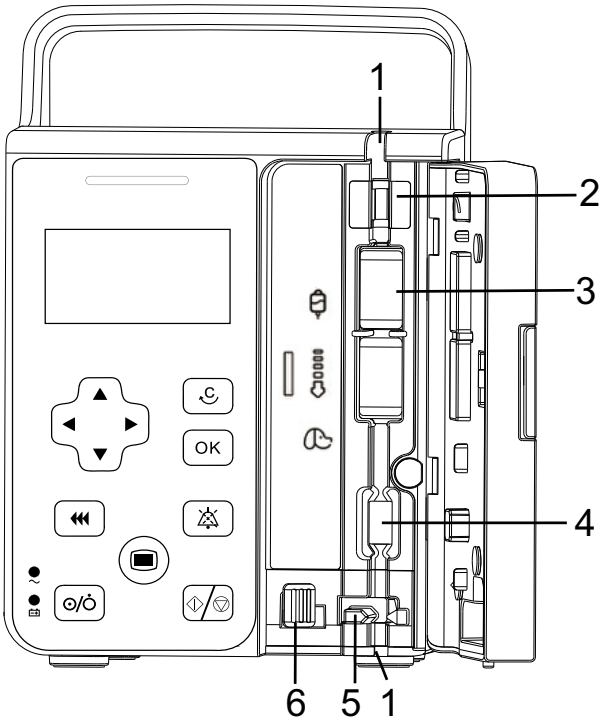


No.	Name	Description
1.	Alarm light	When an alarm occurs, this lamp lights and flashes corresponding with the alarm priority • High priority alarms: the lamp quickly flashes red. • Low priority alarms: the lamp lights in yellow without flashing
2.	Display	Used for displaying infusion parameters and relevant content
3.	 (Clear key)	• Under non-setting status, indicate to return to the previous menu or operation • Under the setting status, indicate to clear the current set or cancel the edit
4.	 (Direction keys)	Used for adjusting value, change lines and pages
5.	 (OK key)	Used for confirming input operation and saving values
6.	 (Bolus key)	• During infusion, press this key to enter the Bolus settings screen • When the pump is stopped, press this key to enter the Purge prompt screen
7.	External power indicator	• On: when external power supply is connected • Off: when external power supply is not connected
8.	Battery indicator	• Green: the battery is being charged • Flashing green: the pump runs on battery power • Off: no battery is installed, or no external power is connected when the equipment is off
9.	 (Power key)	• Under powering off status, press this key to power on the pump • Under powering on status, press this key to enter standby mode, or hold this key to power off the pump
10.	 (Menu key)	• Under non-operation status, used for switching **Main Menu** interface and other interfaces. • Under operation status, press and hold this key to lock; in locked state, press and hold to unlock
11.	 (Start/Stop key)	After loading the infusion set correctly and completing setting infusion parameters, press this key to start the infusion. During infusion, press this key to stop the infusion
12.	 (Audio paused key)	• For low priority alarms, press this key to confirm the alarm • For high priority alarms, press this key to pause alarm
13.	Door holder	Pull it to open the door

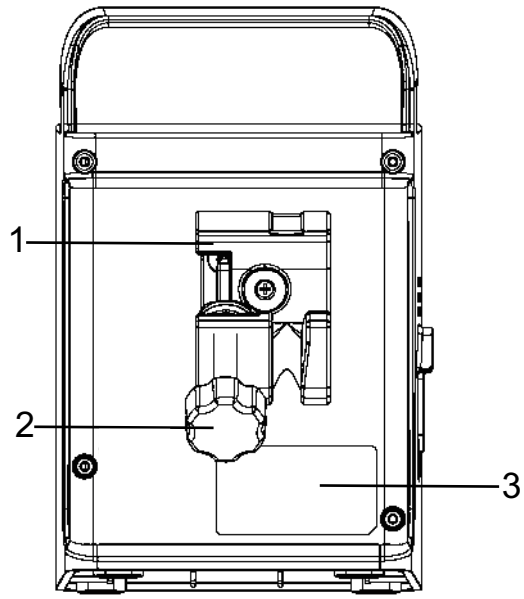
No.	Name	Description
14.	Door	Open the door to load or unload the infusion set
15.	Handle	/

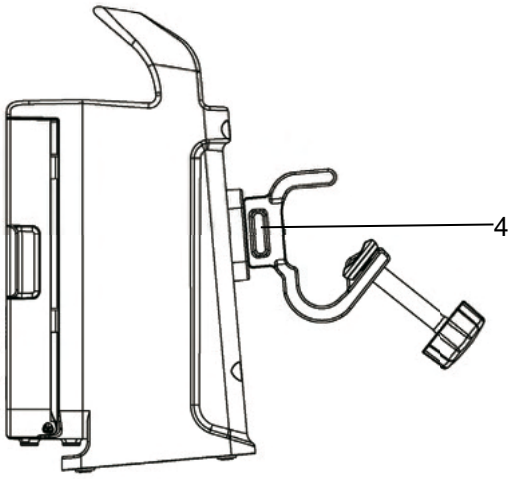


No.	Name	Description
1.	Multifunctional connector	Connects to the drop sensor
2.	AC power input connector	Connects the AC power cord



No.	Name	Description
1.	Tubing channel notches	Secures the infusion set
2.	Ultrasonic sensor	Detects air in the infusion set
3.	Pumping mechanism (with waterproof membrane)	Includes the pumping fingers and a waterproof membrane covering them to keep fluid from entering the mechanism
4.	Pressure sensor	Detects the pressure in the infusion set
5.	Anti free-flow clamp	Occludes the tubing
6.	Release lever	Used for release or close the anti free-flow clamp

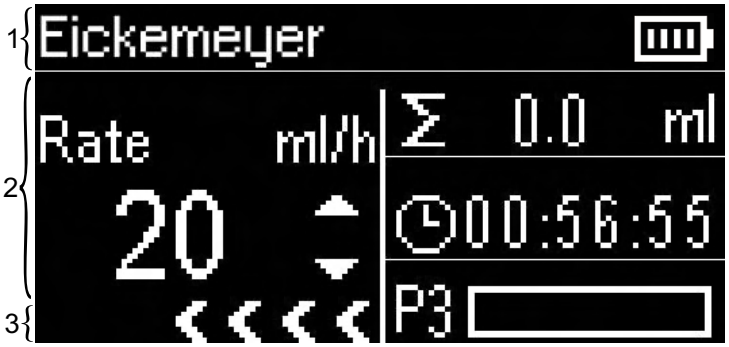




No.	Name	Description
1.	Pole clamp	/
2.	Pole clamp handle	/
3.	Product label	/
4.	Lock block	• Press the lock block to rotate the pole clamp • Loosen the lock block to lock the pole clamp

2.3 Screen Display

The screen may look slightly different in different infusion modes. The following figure shows the infusion screen of the rate mode:



No.	Name	Description
1.	Title bar	Displays current infusion set mode, alarm information, battery information, and etc.
2.	Parameter area	Displays every parameter and the parameter value of the current screen. Press ◀/▶ to adjust the display items for parameters
3.	Prompt bar	Displays run icon and so on. The icon indicates normal running. Arrows move from right to left, and the running speed increases as the rate increases

2.3.1 On-screen Symbols

Symbol	Description	Symbol	Description
	Keys are locked		The battery has critically low charge and needs to be charged immediately. Otherwise, the equipment will automatically shut down
	Pauses alarm sound		0% < Battery ≤ 20%
	Alarms are confirmed		20% < Battery ≤ 50%
	Accumulated infusion volume		50% < Battery ≤ 90%
	Remaining infusion time		90% < Battery < 100%
	Volume to be infused		

2.3.2 Occlusion Pressure Symbol

Symbol	Description
	• The number beside P indicates the current occlusion pressure level. For example, P1 indicates that the current occlusion pressure is level 1. • The rectangular area displays the ratio between the real-time pressure of the infusion line to the preset occlusion pressure threshold.

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3 Equipment Preparation

3.1 Equipment Preparation Safety Information

⚠ WARNING

- **Use only installation accessories specified by the manufacturer.**
- **The equipment software copyright is solely owned by the manufacturer. 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 62368-1 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 the manufacturer.**
- **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 animal'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 animal.**

NOTE:

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

3.2 Installation

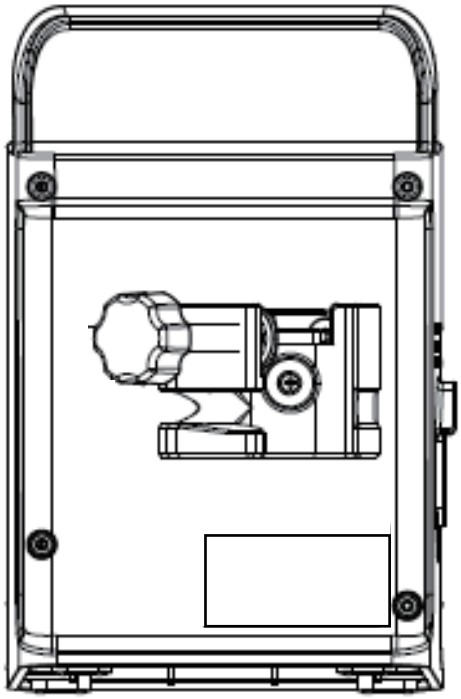
3.2.1 Pole Clamp Installation

The pole clamp secures the pump to either a horizontal or vertical bar of the medical supply unit or IV pole, or secure the pump to pet cages.

To secure the pump to a vertical bar of IV pole

Follow this procedure:

1. Press the lock block of the pole clamp, and then rotate the pole clamp to the horizontal position.

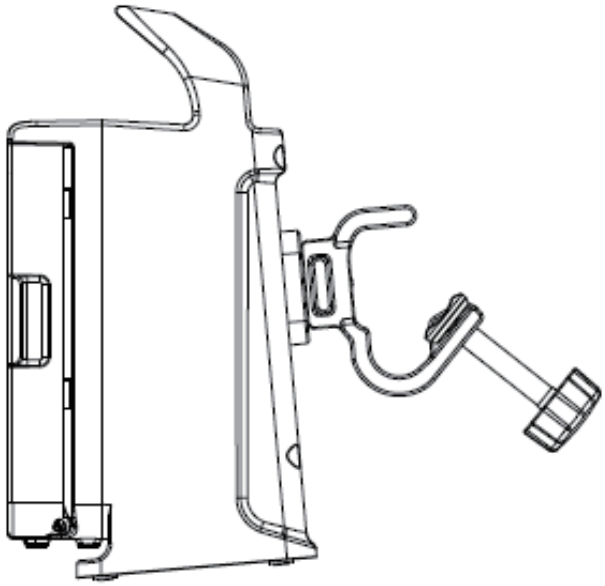


2. Rotate the pole clamp handle counterclockwise, and then loosen the pole clamp handle until the vertical bar of IV pole can be inserted.
3. Rotate the pole clamp handle clockwise to secure the pump to the vertical bar of IV pole.

To secure the pump to the horizontal bar of IV pole

Follow this procedure:

1. Press the lock block of the pole clamp, and then rotate the pole clamp to the vertical position.

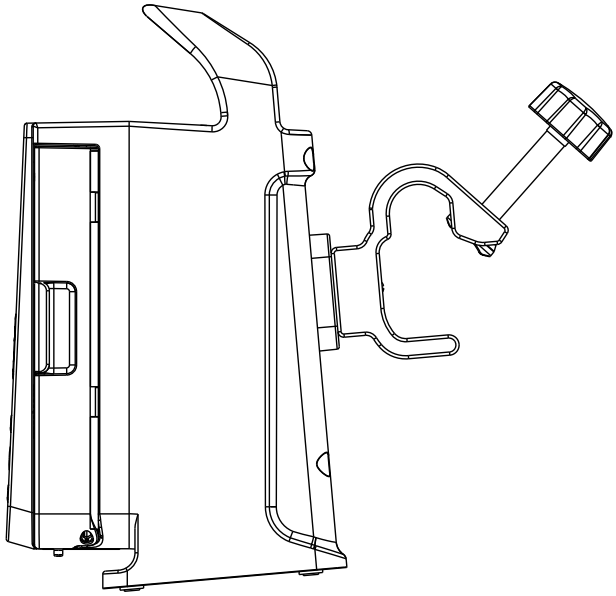


2. Rotate the pole clamp handle counterclockwise, and then loosen the pole clamp handle until the horizontal bar of IV pole can be inserted.
3. Rotate the pole clamp handle clockwise to secure the pump to the horizontal bar of IV pole.

To secure the pump to the pet cage

Follow this procedure:

1. Press the lock block of the pole clamp, and then rotate the pole clamp to the vertical position, with the pole clamp handle turning upwards.



2. Rotate the pole clamp handle counterclockwise, and then loosen the pole clamp handle to secure the pump to the pet page.

3.2.2 Drop Sensor Installation

⚠ CAUTION

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

NOTE:

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

To install the drop sensor, follow this procedure:

1. Connect the signal line of the drop sensor to the multifunctional connector.
2. Install the drop sensor to the drip chamber, ensuring that the lower edge of the drop sensor is above the surface of the liquid.

   The indicator of drop sensor flashes green when drops are detected during the infusion.

3.3 Setting Up the Equipment

NOTE:

- Always use the accompanying power cord delivered with the pump.
- Before connecting the equipment to the AC mains power, 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.

Before getting started, ensure that the pump is properly set up:

- The pump is placed on a stable surface, or properly mounted to an IV pole or to a pet cage using the pole clamp.
- The pump is plugged into a properly-grounded AC power outlet. When AC mains power is connected, the external power indicator is illuminated in green.
- If the pump is run on battery power, ensure that the battery is adequately charged.

- To ensure the history records are stored correctly, the system date and time should be checked before first use.

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4 Getting Started

4.1 Turning on the Pump

⚠ WARNING

- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **Check that visual and auditory alarm signals are presented correctly when the equipment is powered on.**
- **Do not use the equipment if you suspect it is not working properly, or if it is mechanically damaged. Contact the Customer Service Department or your local distributor.**

Press ⊙/Ó, the system initiates the self-test and the screen displays the **System Self-test** interface:

- System gives out a sound “di”, indicating the self-test of the loudspeaker is successful.
- The color of the alarm indicator light changes from red to yellow, turn on and off orderly, indicating the self-test of the alarm light is successful.
- System gives out a sound “didi”, indicating the self-test of the buzzer is successful (If applicable, the buzzer is optional).
- Enter the operation interface after successfully completing the system self-test, and you can operate the system through the key board.

4.2 Preparing the IV Container

The height between the IV container and the pump is critical to the flow accuracy. To prepare the IV container, follow this procedure:

1. Hang the IV container.
2. Adjust the height of the pump so that there is 51 ± 5 cm (20 ± 2 in.) between the fluid line and the middle of the pump. Distances outside of this tolerance can adversely affect flow accuracy.

4.3 Loading the Infusion Set

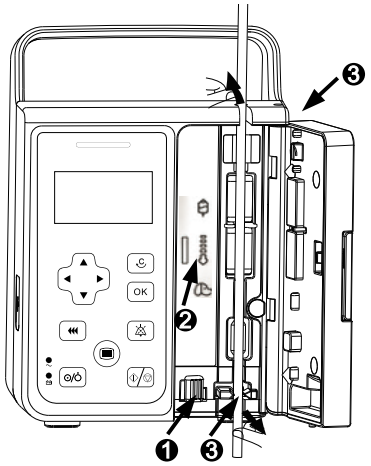
⚠ WARNING

- **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 anti free-flow clamp to avoid injury.**
- **The pump must be mounted to the same level as the animal’s heart. The most accurate pressure monitoring in the infusion set is achieved when the pump is positioned close to the animals 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:

- Make sure the roller clamp is closed before opening the pump door.
- 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.



To load the infusion set, follow this procedure:

1. Pull the door holder to open the pump door.
2. Pull the release lever ① upward left to release the anti free-flow clamp.
3. Avoiding any slack, insert the infusion line into the slot, following the flow direction indicator ② . Ensure that the infusion set is straightly and firmly clipped into the tubing channel notches ③ on both sides of the casing.
4. Close the pump door.

4.4 Purge

NOTE:

- The volume used for purging is not added to the infused volume.
- The **Air in Line** or **Accum. Bubble** alarm will not pop up during purging.

The infusion set should be purged prior to being connected to the animal. If the infusion set is not purged before being loaded into the pump, proceed as follows to purge the line:

1. Ensure that the pump is disconnected from the animal.
2. Under non-running status of any infusion mode, press ⏮ to enter **Purge** prompt screen. Hold ⏮ to start purge according.
3. Release ⏮ after the air bubbles are purged.

4.5 Starting Infusion

⚠ WARNING

- **Do not connect an animal until disposables have been purged and loaded into the pump. Connecting to animal before disposables are loaded and purged can cause serious injury or death.**
- **Before infusion starts or after infusion stops, check that no drops are falling in the drip. If drips are falling, do not use the equipment, and contact the Customer Service Department or your local distributor.**

⚠ CAUTION

Please confirm that the current selected infusion set brand is the same as the brand actually used, or its accuracy cannot be guaranteed.

NOTE:

- Monitor the connection of infusion set, tubing, pump and animal, and the drug information on a regular basis. Start infusion according to the instructions in this manual.
- When the pump is in running status, if there is no operation in other interface over 2 minutes, it will return to the running screen automatically.

4.5.1 Selecting Infusion Set Brand

Press ■ to enter the main screen, select **General Options** → select **Infusion Set Selection** to select the infusion set brand.

4.5.2 Selecting Infusion Mode

Press ■ to enter the main screen, select **Select Mode**. Press ▲/▼ to select infusion mode, and press OK for confirmation.

4.5.3 Setting Infusion Parameters

After selecting infusion mode, the pump enters the infusion parameter setting screen. Under each infusion mode, users can set infusion parameters by pressing direction keys, ⟲, and OK.

4.5.4 Starting Infusion

To start infusion, follow this procedure:

1. After setting infusion parameters, connect the infusion set to the animal.
2. Press ⏯ to start the infusion.

NOTE:

- The pump gives a prompt sound when starting or stopping infusion.
- The screen displays the running icon. An arrow moves from right to left and the speed of the arrow increases as the rate increases.

4.6 Bolus Infusion

Bolus infusion is a controlled volume of fluid or drug being delivered at an increased rate for diagnostic or therapeutic purposes. The pump supports manual bolus and automatic bolus.

NOTE:

- The delivered bolus volume will be added to the total infusion volume.
- The pump gives a beep every time a 0.5 ml bolus volume is infused.
- If no operation is performed within 2 minutes, the pump will automatically exit the bolus setting screen and the procedure must be repeated.
- Animal's clinical condition and working condition of the pump must be monitored carefully.

4.6.1 Setting Bolus Mode

To set up bolus mode, follow this procedure:

1. Press ■ to enter the main screen, select **General Options** → select **Bolus Mode**
2. Press OK to change the setting, press ◀/▶ to select **Manual** or **Auto**.
3. Press OK for confirmation.

4.6.2 Manual Bolus Infusion

To start manual bolus infusion, follow this procedure:

1. In any running screen of the infusion mode, press ⏮ to enter the **Manual Bolus** screen.
2. Set **Bolus Rate**.
3. Hold ⏮ to start manual bolus infusion.
4. Release ⏮ to finish manual bolus infusion and return to the original rate.

NOTE:

When the **BolusVTBI** reaches the bolus limit, the device automatically stops the manual bolus. For details, see “6.3 General Options”.

4.6.3 Automatic Bolus Infusion

To start automatic bolus infusion, follow this procedure:

1. In any running screen of the infusion mode, press ⏮ to enter the **Auto** screen.
2. Set **Bolus Rate** and **BolusVTBI**.

NOTE:

When the **BolusVTBI** reaches the bolus limit, the device gives a prompt sound, and you need to reset **BolusVTBI**. For details, see "6.3 General Options".

3. Press [⏮] to start automatic bolus infusion.
4. The pump automatically exit automatic bolus infusion and continues the original infusion when the configured **BolusVTBI** has been infused. Or you can press [↺] to exit automatic bolus infusion and continues the original infusion.

4.7 Changing the Rate during Infusion

To change the rate during infusion, follow this procedure

1. In any running screen of the infusion mode, press [OK] or press ▲/▼ to change the value of **Rate** into the adjustable state.
2. Set the expected rate.
3. Press [OK] for confirmation.

   The pump starts infusion under the new set rate.

4.8 Completing Infusion

During the infusion, if the remaining infusion time is close to the **Near End** set by the users, the **Near End** alarm will be triggered. If no action has been taken, the alarm will not be cancelled automatically until the infusion is completed, and then switch to **VTBI Done** alarm.

4.9 Setting Keep Vein Open Rate

At the end of infusion, the pump continues to infuse at a very low rate. Keep Vein Open (KVO) is used to keep the animal's vein open, to prevent back flow or vascular occlusion.

NOTE:

- If the Keep Vein Open (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.

To set the KVO rate, follow this procedure:

1. Press [■] to enter the main screen, select **General Options** → select **KVO Rate**.
2. Set **KVO Rate**.

   If **KVO Rate** is zero, the pump will not initiate a KVO infusion when the preset volume is complete.

NOTE:

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

4.10 Replacing the IV Container

NOTE:

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

To replace the IV container, follow this procedure:

1. To prevent animal injury due to free flow, before replacing the IV container, please shut down the Robert clip (or flow rate regulator). During infusion, press ⏎/▽ to stop the infusion.
2. Remove the IV container from the IV pole, and replace a new container.

4.11 Unloading the Infusion Set

⚠ WARNING

- **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 4 hours.**
- **If the infusion sets are not changed within the recommended time, the accuracy of the infusion may be affected.**

To unload the infusion set, follow this procedure:

1. Press ⏎/▽ to stop the infusion.
2. Disconnect the animal from the infusion set.
3. Pull the door holder to open the pump door.
4. On the outside of the pump, grasp the tubing on both sides of the pump and pull the tubing straight out of the pumping channel.

4.12 Entering the Standby Mode

To enter or exit the standby mode, follow this procedure:

1. Under non-running status, press ⊙/Ò to enter the **Standby** prompt screen.
2. Press OK to enter the standby mode, and the screen displays **Standby**.

3. On the **Standby** screen, press any key to exit the standby mode.

4.13 Turning Off the Pump

To turn off the pump, hold ⊙/Ò until the **Turn Off** progress bar complete, and the pump turns off.

⚠ 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 data.

NOTE:

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

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5 Alarms

5.1 Alarm Safety Information

⚠ WARNING

- **A potential hazard can exist if different alarm presets and default settings are used for the same or similar equipment in the same care area, for example an intensive care unit or cardiac operating room.**
- **The equipment in your care area may each have different alarm settings to suit different animals. Always check that the alarm settings are appropriate for your animal before starting infusion.**
- **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 animal 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 animal. Always make sure that the audio alarm volume level is adequate in your care environment. Always keep the animal 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

By severity, the alarms are classified into the high priority alarms and low priority alarms. When an alarm occurs, the equipment indicates it visually and audibly. For more information, see the following table:

Alarm priority	Alarm lamp color	Alarm lamp flashing frequency	Alarm sound interval	Alarm priority indicator
High priority alarm	Red	1.5 Hz	10s	!!!
Low priority alarm	Yellow	Not flashing	20s	!

When multiple alarms exist:

- If there is unconfirmed high priority alarm, the high priority alarm occupies the screen and all alarm information are displayed in the title bar in turn.
- If there is no unconfirmed high priority alarm, the title bar displays all alarm information in turn.
- If there is unconfirmed **Battery Empty** alarm, **Battery Empty** alarm displays in the front.

5.3 Alarm Handling Rules

Using the audio paused key:

- For high priority alarms (except **Battery Empty**), press [🔕] to pause alarm sound for 2 minutes. When the alarm pause time expires or press again within 2 minutes if the alarm condition still exists, the alarm tone will sound.
- For low priority alarms (**Reminder**, **Near End**, and **Battery Low**), the alarms are acknowledged after [🔕] is pressed, system will give out a sound for every 5 minutes, and a "" appears in the title bar, indicating that the alarm is acknowledged.
- For other low priority alarms, press [🔕] to turn off the alarm sound, the alarm message and alarm light still exist, and a "" appears in the title bar, indicating that the alarm is acknowledged.

5.4 Alarm Countermeasures

⚠ WARNING

When an alarm is triggered, the animal's condition should be checked firstly and operation should only be allowed to proceed after the reason for the triggering of the alarm is ruled out.

When an alarm is triggered, please follow these steps and take appropriate action:

1. Check the animal.
2. Check the alarm type and the parameter which triggered the alarm.
3. Determine the reason for the alarm.
4. Eliminate the reason for the alarm.
5. Check whether the alarm has cleared.

Alarm	Priority	Causes	Solutions
Battery in Use	Low	The external power source has been disconnected and the pump runs on battery power.	Connect the pump to AC power
Para. Unconfirmed	Low	On the infusion parameter setting screen, online titration screen, bolus setting screen, and purge setting screen, **Para. Unconfirmed** is triggered when parameters are in editable status and no operation is performed for 10 seconds.	Press any key (except [🔕]).

Alarm	Priority	Causes	Solutions
Battery Low	Low	During startup, only the internal battery is used for power supply. The **Battery Low** alarm is triggered when the battery is lower than the threshold (at least 30 minutes before the **Battery Empty** alarm is triggered).	Connect the pump to AC power.
Reminder	Low	No operation is detected after the preset reminder time is reached.	• Press any key (except). • Open the door.
Near End	Low	During infusion, when the remaining VTBI is less than or equal to the **Near End** alarm time set by the user, the **Near End** alarm is triggered.	The alarm will be automatically cleared when infusion is completed.
Battery Error	Low	**Battery Error** alarm is triggered when battery error occurs.	The alarm cannot be cleared. Contact the Customer Service Department for troubleshooting.
Occlusion	High	During infusion, **Occlusion** alarm is triggered when the occlusion pressure of the pipeline (between the pimp and the animal) reaches the set threshold.	• The alarm is automatically cleared when the occlusion restarts successfully. • Manually remove the tube occlusion, make the pressure within the threshold range, and press to clear the alarm.
Air in Line	High	During infusion, **Air in Line** alarm is triggered when the bubble sensor detects that the size of a single bubble is larger than the threshold of a single bubble.	Press to clear the alarm and return to the parameter setting screen.
Accum. Bubble	High	During infusion, **Accum. Bubble** alarm is triggered when the bubble sensor detects that the accumulated bubbles reaches the threshold of the accumulated bubble within one hour.	Press to clear the alarm and return to the parameter setting screen.
Door Opened	High	**Door Opened** alarm is triggered when door opens during infusion.	The alarm is cleared automatically after the door is closed.
VTBI Done	High	**VTBI Done** alarm is triggered when the preset VTBI is completed.	Press to clear the alarm and return to the parameter setting screen.
KVO Finish	High	**KVO Finish** alarm is triggered when the KVO infusion is running for thirty minutes.	Press to clear the alarm and return to the parameter setting screen.

Alarm	Priority	Causes	Solutions
Battery Empty	High	When the pump is powered on, only the internal battery is used for power supply, and **Battery Empty** alarm is triggered when the battery is under the alarm limit.	Connect the pump to AC power.
No Infusion Tube	High	Start infusion when the infusion set is not loaded or the pump door is open.	After the infusion set is loaded and the pump door is closed, the alarm is automatically cleared.
Drop Error	High	When the drop sensor switch is on and the drop error alarm is on, if the infusion is running and the drop sensor is configured, **Drop Error** alarm is triggered when the drip rate is detected to be too fast or too slow.	Press ⏎ to clear the alarm and return to the parameter setting screen.
Empty Bottle	High	When the drop sensor switch is on and the empty bottle sensitivity is not off, if the drop sensor is configured, **Empty Bottle** alarm is triggered when no drip is detected.	Press ⏎ to clear the alarm and return to the parameter setting screen.
System Error	High	When the system detects a motor error or an internal error of the system, **System Error** alarm is triggered and the system error code is displayed.	Press ⏎ to confirm the alarm and return to the previous screen.

6 Menu Options

6.1 Volume Clearing

- Check the total infusion volume.

  Total infusion volume refers to the amount of liquid infused into the animal within a certain time. Press ■ to enter the main screen, select **Volume Clearing** to view the total infusion volume.
- Clearing volume

  If you wants to clear the volume after connecting to a new animal, press ■ to enter the main menu, select **Volume Clearing**, and press OK to manually clear volume.

NOTE:

- When the volume exceeds 9999 ml, it is automatically cleared.
- After the pump is shut down, the total volume is automatically cleared.

6.2 Select Mode

Press ■ to enter the main screen, select **Select Mode**.The pump provide the following infusion modes: Rate Mode, Drip Mode, Micro Mode, Time Mode.

- Rate Mode/Drip Mode/Time Mode

  In rate mode, drip mode and time mode, the IV drug therapy continues to infuse at a set rate. Rate mode, drip mode and time mode offers three parameters: rate, time and VTBI. When two of these parameters are entered, the third is calculated.
- Micro mode

  Micro mode is typically use for low rate infusions for animals. Micro-infusion mode offers three parameters: rate, time and VTBI. When two of these parameters are entered, the third is calculated by the pump.The setting range for rate in micro mode is 0.1 to 100 ml/h, and the set range for VTBI is 0.1 to 1000 ml.

6.3 General Options

Press ■ to enter the main screen, and select **General Options**.

Menu Item	Function
Occl. Pressure	Set the occlusion alarm limit. The pump gives the **Occlusion** alarm when the occlusion pressure exceeds the alarm limit.
Pressure Unit	Sets the pressure unit.

Menu Item	Function
Infusion Set Selection	Set the infusion set brand. and. This device provides 2 built-in infusion set brands and 3 customized infusion set brands.
Bubble Size	Set the alarm limit for the size of single air bubble. The pump gives the **Air in Line** alarm when the size of single air bubble exceeds the alarm limit.
Accum. Bubble	Set the alarm limit for the volume of accumulated air bubble. The pump gives the **Accum. Bubble** alarm when the accumulation air bubble volume exceeds the alarm limit.
KVO Rate	Set the KVO rate. If KVO rate is set to zero, the pump stops infusion when VTBI is completed.
Bolus Mode	Sets the fast bolus mode. When **Auto Bolus** is selected, when the set bolus volume is reached, the pump exits auto bolus. When **Manual Bolus** is set, manual exit is required.
Bolus Limit	Sets the upper limit for automatic bolus or manual bolus.
VTBI Near Done	Set for how long the **Near End** alarm is triggered since the infusion is completed. The switch is turned off: the pump does not give the **Near End** alarm.
Auto-lock	Sets the auto-lock time. After the specific time is set, if no operation or high priority alarm is performed during the auto-lock period, the key is automatically locked. If it is set to **Off**, the auto lock function is disabled.
Reminder	Set for how long the **Reminder** alarm is triggered since the pump is last operated. The switch is turned off: the pump does not give the **Reminder** alarm.
Drip	Set the number of drops per milliliter liquid dripping into the drip chamber.

6.4 System Options

Press ▣ to enter the main screen, and select **System Options**.

Menu Item	Function
Volume	Sets the volume of alarm sound.
Date	Sets the current date.
Time	Sets the current time.
Version Information	Views the software version information.

6.5 User Maintenance

⚠ 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.

Press ▬ enter the main screen, select **User Maintenance** → enter the password "8868" → press **OK**.

Menu Item	Function
Accuracy Calibration	Contact your service personnel to perform the calibration as per the recommended frequency in “7.2 Maintenance and Testing Schedule”.
Pressure Calibration	Contact your service personnel to perform the calibration as per the recommended frequency in “7.2 Maintenance and Testing Schedule”.
Commonly Used Tube	Select at least one infusion set as needed.
Language	Sets the language.This setting is effective after the pump has been restarted.
Purge Limit	Sets the maximum volume of the purge. The purge stops when the set volume is reached.
Battery in Use	Sets whether to enable **Battery in Use** alarm. When **On** is selected, this equipment is running due to external power interruption. Power the machine with batteries, and trigger the **Battery in Use** alarm. When **Off** is selected, the **Battery in Use** alarm is disabled.
Para. Memory	Sets the parameter memory switch. If this switch is turned on, the pump can automatically reload the infusion mode and other infusion parameters when restarted if the same drug has been selected.
Auto-restart	Sets whether to restart the infusion or not when the occlusion pressure is reduced.
Brand Selection	Sets whether the brand list will be displayed after the infusion set is loaded or replaced.
Drip Sensor	Sets the drop sensor switch.
Alarm Sound	Sets the alarm sound mode.
Modify Password	Modifies the password for accessing the **User Maintenance** menu.

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7 Maintenance

Regular maintenance is essential to ensure that the pump functions properly. This chapter contains information on periodic testing and maintenance.

7.1 Maintenance Safety Information

⚠ WARNING

- **To avoid electric shock, stop using the pump if you find the housing of the pump 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 pump to implement a recommended maintenance schedule may cause undue pump failure and possible health hazards.**
- **No modification of this pump is allowed.**
- **This pump contains no user serviceable parts.**
- **The safety checks or maintenance involving any disassembly of the pump should be performed by professional service personnel. Otherwise, undue pump failure and possible health hazards could result.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the pump.**

⚠ CAUTION

- The pump and accessories shall not be served or maintained while in use with an animal.
- If you discover a problem with the pump, 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 pump.

7.2 Maintenance and Testing Schedule

Follow the maintenance and testing schedule or local regulations to perform testing and maintenance. Make sure to clean and disinfect the pump before taking any tests and maintenance. The following table lists the maintenance and testing schedule:

Test/Maintenance Item		Recommended Frequency
Performance Tests		
Tests required by IEC 60601-2-24		• Once every three years. • When you suspect that the occlusion alarm is abnormal. • When you suspect that the rate is abnormal.
Safety Tests		
Electrical safety tests required by IEC 60601-1		• Once every three years, or if required. • When the power board is repaired or replaced. • When the main board is replaced. • When the pump drops to the ground.
Other Tests		
Visual inspection		Every day, before first use.
Power-on test		Each time the pump is powered on.
Battery check	Functionality test	• When the battery is first installed. • When the battery is replaced.
	Performance test	Every four months or if the battery runtime reduces significantly.
Pressure calibration, and accuracy calibration.		If the performance test fails. For more information, see the service manual.

Except the regular check and battery check, all other test and maintenance tasks should be performed by the qualified service personnel only. If your pump needs a safety test and performance test, contact the service personnel.

7.3 Maintaining the Battery

7.3.1 Battery Safety Information

⚠ 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 the manufacturer.**
- **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 pump 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 pump 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 pump.
- 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.
- A total loss of power has no impact on the history records stored.

7.3.2 Installing the Battery

The battery must only be installed by service personnel trained and authorized by the manufacturer. To install the battery, contact your service personnel. The battery is installed when the pump leaves the factory.

Replace a battery in the following situations:

- The battery has visual signs of damage or the battery fails.
- The battery is aged and its runtime significantly shorter than the specification.
- The battery service life expires.

7.3.3 Charging the Battery

To optimize performance, a fully or nearly fully discharged battery should be charged as soon as possible. The battery is recharged automatically when the pump is connected to AC mains power.

7.3.4 Conditioning the Battery

The service life of a battery depends on how frequent it is used. When properly used, the lithium-ion battery has a service life of approximately three years. If improperly used, its service life can be shorten. We recommend replacing the battery every three years. The performance of the battery deteriorates over time. You should condition the battery every four months.

To condition a battery, follow this procedure:

1. Disconnect the pump from the animal.
2. Turn off the pump, and connect the pump to the external power.
3. Allow the battery to be charged uninterruptedly till it is fully charged.
4. Disconnect the pump from the external power source, and turn on the pump.

5. Allow the pump to run on the battery until the battery is completely depleted and the pump automatically shuts down. Fully charge the battery again for use or charge it to 40 – 60% for storage.

7.4 Disposing of the Pump

The service life of this pump is ten years. Dispose of the pump when its service life is reached. Follow local regulations regarding the disposal of such product.

⚠ WARNING

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

8 Care and Cleaning

In this chapter we only describe cleaning and disinfection of the pump. For the cleaning and disinfection of other accessories, refer to their instructions for use.

8.1 Care and Cleaning Safety Information

⚠ WARNING

- **Use only the approved cleaners, disinfectants and methods listed in this chapter to clean and disinfect your pump. 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 pump and remove the power cord from the pump before cleaning and disinfecting.**
- **Never immerse any part of the pump or accessories in liquids or allow liquid to enter the interior of the pump 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 pump or accessories or permit fluid to seep into connections or openings.**
- **If you spill liquid on the pump or accessories, disconnect the power supply, dry the pump, and contact the Customer Service Department or your local distributor.**
- **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 pump after cleaning and disinfecting. If there is any sign of damage, remove it from use.**

8.2 Cleaning the Pump

- Recommended cleanser includes: water and ethanol (70%).
- Cleaning tool includes: absorbent cotton ball, soft gauze, soft brush, and soft cloth.

Clean the pump on a regular basis. Before cleaning and disinfection, consult your hospital's regulations.

To clean the pump, follow this procedure:

1. Dampen a soft lint-free cloth with the water and ethanol (70%), wring excess liquid from the cloth.
2. Wipe the display screen of the pump, wipe the external surface of the pump with the damp cloth, avoiding the connectors and metal parts.
3. Dry the surface with a clean cloth. Allow the pump air dry in a ventilated and cool place.

8.3 Disinfecting the Pump

Recommended disinfectant includes: ethanol (70%).

Disinfect the equipment as required in your hospital’s servicing schedule. Cleaning the equipment before disinfecting is recommended. Always dilute and use disinfectants according to the manufacturer's instructions.

9 Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1 when in use with the pump. For details about the accessories, refer to the instructions for use provided with the accessory.

⚠ WARNING

Use accessories specified in this chapter. Using other accessories may cause damage to the pump 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 the Customer Service Department or your local distributor.**
- **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.**

- Power cord
- Pole clamp
- Drop sensor

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A Product Specifications

A.1 Specifications

Classifications	• Type of protection against electrical shock: CLASS I EQUIPMENT, equipment energized from an internal electrical power source • Degree of protection against electrical shock: Defibrillation-proof type CF applied part (direct cardiac application) • Degree of protection against harmful ingress of water: IP44 • Mode of operation: Continuous
Operating conditions	• Temperature: 5ºC to 40ºC • Relative humidity: 15% to 95%, noncondensing • Barometric: 57.0 kPa to 107.4 kPa
Storage conditions	• Temperature: –20ºC to 60ºC • Relative humidity: 10% to 95%, noncondensing • Barometric: 16.0 kPa to 107.4 kPa
Power supply	AC power supply: 100 V to 240 V±10%, 50/60 Hz, 0.30A to 0.13A
Battery run time	At least 4.5 hours for normal battery (operating at a rate of 25ml/h, operating temperature: 20°C ± 2°C, default screen brightness and volume)
Battery charge time	≤ 6 hours for normal battery
Shutdown delay	At least 3 minutes after first low battery alarm
Main unit weight	≤ 1.4 kg (with normal battery, without pole clamp and other accessories)
Main unit (W × D × H)	130 mm x 120 mm x 180 mm (without handle and pole clamp, the error is ±3 mm)
Display	⩾ 2.2 inches

A.2 Infusion Specifications

Accuracy	• Infusion accuracy: ≤ ±5% (use SHINVA ANDE single use infusion set for pump) • Infusion accuracy: ≤ ±4.5% (use B. Braun Intrafix Primeline) • Bolus accuracy: ≤ ±5% or ±0.02 ml, whichever is greater • Long-time infusion accuracy: At the 25 ml/h rate, the accuracy error within 24 hours does not exceed ±10% (use B. Braun Intrafix Primeline) • Drip accuracy: ≤ ±10% Test in accordance with IEC 60601-2-24:2012 Temperature: 20 ± 2ºC

Set range of the infusion rate	• 0.1ml/h to 2000 ml/h
	• Minimum resolution:
	  • 0.01ml/h (0.1 ml/h to 99.99 ml/h)
	  • 1ml/h (1000 ml/h to 2000 ml/h)

Set rang of bolus rate	• 0.1ml/h to 2000ml/h
	• Minimum resolution:
	  • 0.01ml/h (0.1 ml/h to 99.99 ml/h)
	  • 0.1ml/h (100.0 ml/h to 999.9ml/h)
	  • 1ml/h (1000 ml/h to 2000ml/h)

Time set range	00:00:01 to 99:59:59 (h:min:sec), minimum resolution:1 second
VTBI set range	• 0.1ml to 9999.99 ml • Minimum resolution: 0.01 ml • Micro-infusion mode: 0.1ml to 1000 ml
Occlusion pressure	Default setting: P3 600mmHg
Bubble size	Default setting: 100μl.
Accumulated bubble	Default setting: 5ml/h
KVO rate	Default setting: 0.5 ml/h
Bolus limit	• Automatic bolus: the default setting is 50 ml • Manual bolus: the default setting is 3 ml
Drip	Default setting: 20 drip/ml

⚠ WARNING

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

A.3 Recommended Infusion Sets

Product Name	Type	Manufacturer
Single Use Infusion Set for Pump	Regular	SHINVA ANDE HEALTHCARE APPARATUS CO., LTD
B.Braun Intrafix Primeline	Precision	B. Braun Melsungen AG

NOTE:

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

A.4 Occlusion Alarm Delay and Bolus Volume

The maximum time required for the occlusion alarm to be triggered when the pump operates under the following conditions:

Rate (ml/h)	Occlusion pressure (mmHg)	Alarm time (hh: mm: ss)
1	150	< 00:18:00
	1125	< 02:01:00
25	150	< 00:01:50
	1125	< 00:03:25

Test conditions:

- Infusion set brand: B.Braun Intrafix Primeline
- Test temperature: 20°C±2°C
- Infusion line length: 1 meter

When the pump operates under the following conditions, the bolus volume are:

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

Test conditions:

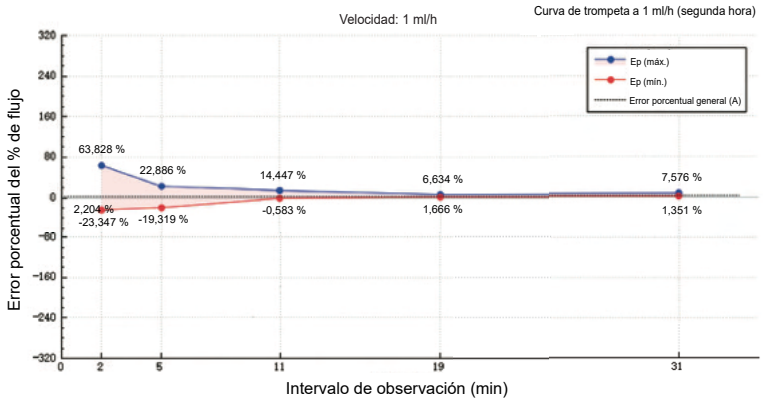
- Infusion set brand: B.Braun Intrafix Primeline
- Anti-bolus: On
- Test temperature: 20°C ±2°C
- Infusion line length: 1 meter

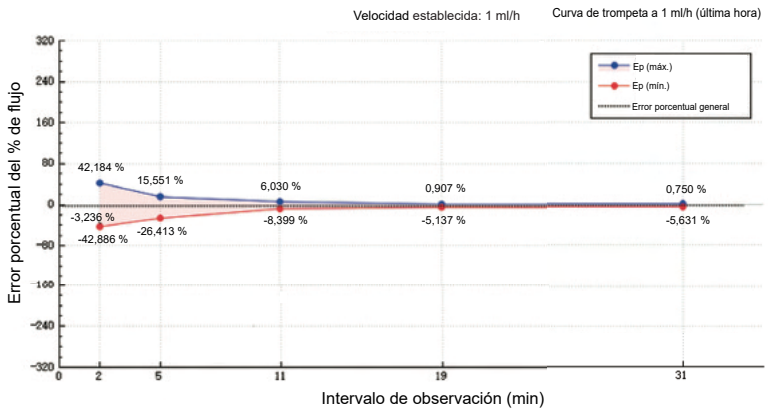
⚠ WARNING

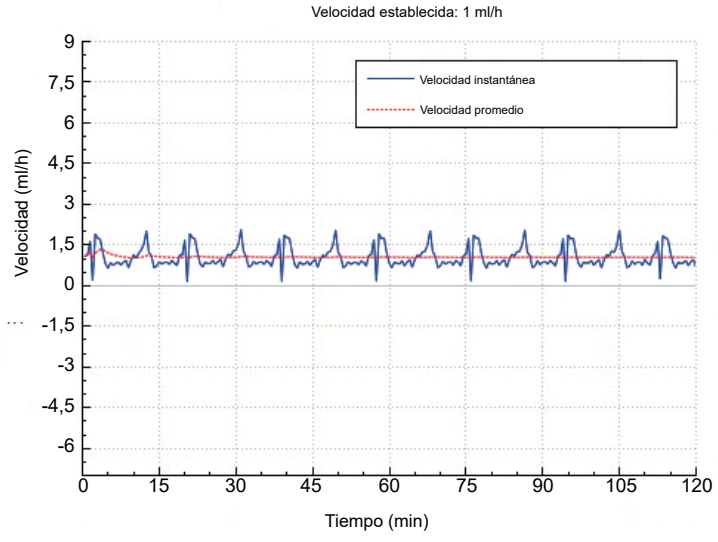
Occlusion alarm pressure, alarm delays and bolus volume may vary depending on test conditions, temperature and tube length.

A.5 Infusion Accuracy Graphs

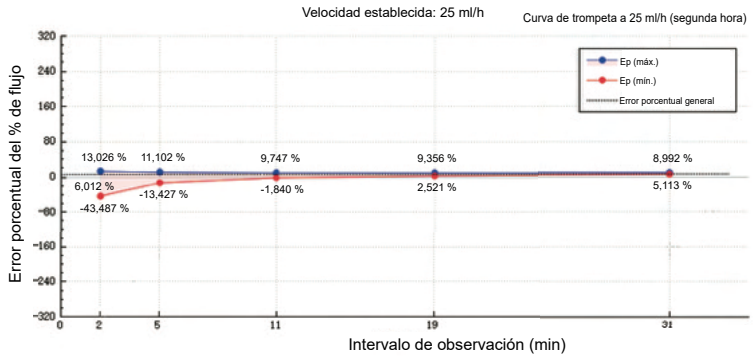
- Infusion accuracy at 1 ml/h

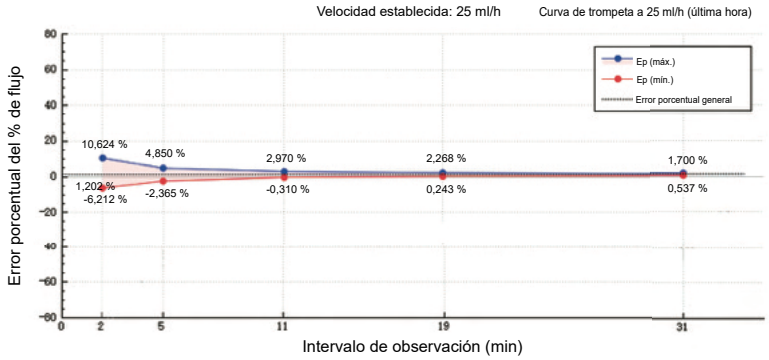


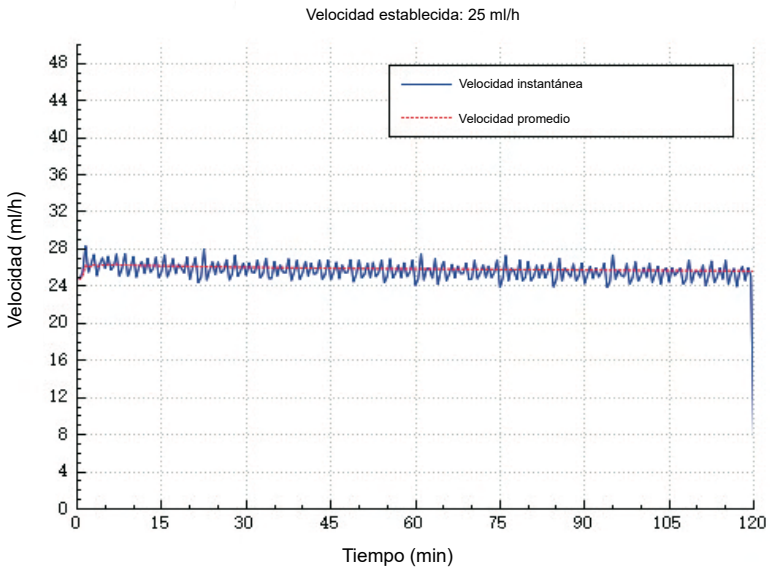




- Infusion accuracy at 25ml/h







Test conditions:

- Infusion set brand: B.Braun Intrafix Primeline
- Test interval: △ t =0.5 minutes

⚠ WARNING

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

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B EMC

The device meets the requirements of IEC 60601-1-2:2014+A1:2020.

⚠ WARNING

- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**
- **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**
- **Portable RF communications device (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.**

NOTE:

- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Use of portable or mobile communications devices will degrade the performance of the device.
- Other devices may affect this device even though they meet the requirements of CISPR.
- If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the pump system and contact the service personnel.

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

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

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
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 RF EMISSIONS CISPR 11	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable	

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15 kV air	±8 kV contact ±2kV, ±4kV, ±8kV, ±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 ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV (Line to line) ±0.5kV, ±1kV, ±2kV (Line to ground)	±0.5kV, ±1kV (Line to line) ±0.5kV, ±1kV, ±2kV (Line to ground)	

Voltage dips and Voltage interruptions IEC 61000-4-11	0% U_T for 0.5 cycle Duration: 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25/30 cycles Duration: 0° 0% U_T for 250/300 cycle	0% U_T for 0.5 cycle Duration: 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25/30 cycles Duration: 0° 0% U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted disturbances induced by RF fields 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 the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \times \sqrt{p}$
	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	$d = 1.2 \times \sqrt{p}$

Radiated RF EM fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m 80 MHz to 2.7 GHz	$d = 1.2 \times \sqrt{p}$ 800 MHz to 2.7 GHz $d = 2.3 \times \sqrt{p}$ 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: 
	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[c] Over the frequency ranges 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Guidance and 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

Pulse Magnetic Field (PMF) IEC 61000-4-39	65 A/m 134.2 kHz Pulse modulation 2.1 kHz	65 A/m 134.2 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	

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.

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
350	430 -470	GMRS 460 FRS 460	FM ±5 kHz deviation1 kHz sine	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

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

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

The device is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Rated Maximum Output power of Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**			
	150 kHz to 80 MHz $d = 1.2 \times \sqrt{p}$	150 kHz to 80 MHz (ISM bands) $d = 1.2 \times \sqrt{p}$	80 MHz to 800 MHz $d = 1.2 \times \sqrt{p}$	800 MHz to 2.7 GHz $d = 2.3 \times \sqrt{p}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.64	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.4	3.8	7.3
100	12	20	12	23

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

C Abbreviations

Abbreviation	Full Name
AC	Alternating Current
Anti-Bolus	Anti-Bolus
BOLUS	Bolus
CCU(CICU)	Cardiac Intensive Care Unit
CE	Conformité Européenne
CISPR	International Special Committee on Radio Interference
CPU	Central Processing Unit
DC	Direct Current
DERS	Dose Error Reduction Systems
DPS	Dynamic Pressure System
EEC	European Economic Community
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
EtO	Ethylene oxide
ICU	Intensive Care Unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
ISO	International Organization for Standardization
IV	Intravenous
KVO	Keep Vein Open
LED	Light Emitting Diode
Max	Maximum
Min	Minimum
MRI	Magnetic Resonance Imaging

Abbreviation	Full Name
N/A	Not Applied
OR	Operating Room
SN	Series Number
USB	Universal Serial Bus
VTBI	Volume To Be Infused

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