Medcaptain

ELFensor P2/ELFensor P5/ELFensor P8

Ambulatory Infusion Pump

User Manual

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

Manufacturer: MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
Manufacturer Address: 12th Floor, Baiwang Research Building,
No.5158 Shahe West Road, Xili, Nanshan, 518055
Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Production Address: Building C, Jiale Science and Technology
Industrial Park, Matian Street, Guangming, 518106
Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-755-26953369
Website: http://www.medcaptain.com
E-mail: mc.service@medcaptain.com

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About This Manual

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To ensure high accuracy and efficiency of its products and services, MEDCAPTAIN shall have the right to change the contents of this manual without prior notice under the premise of complying with medical device regulations. The latest version contains all changes made to earlier versions.

This manual describes all configurations supported by all models of the product, and therefore some descriptions may not apply to your model. Illustrations in this user manual are provided for your reference only and may differ from what is actually displayed on the screen or device.

MEDCAPTAIN is responsible for the safety, reliability, and performance of this product only if:

- The product is used in accordance with this manual.
- All installations, replacements, tests, modifications, and repairs are conducted by technicians authorized by MEDCAPTAIN.
- All spare parts for repair and replacement, accessories, and consumables used with this product are provided by MEDCAPTAIN.
- All maintenance and servicing records are kept.

Documentation

Understand the meanings of the following items clearly before reading this manual.

Item	Meaning
	Indicates a potentially hazardous situation that, if not avoided, may result in death or serious injury.
	Indicates a potentially hazardous situation that, if not avoided, may result in device malfunction or damage.
NOTE	Indicates precautions or recommendations that should be used in operating the device.

Item	Meaning
Boldfaced Word	Indicates controls on the control panel, or on-screen objects such as menu items or keys.
>	Select a menu item or a key following the path.

Customer Service

Thanks for purchasing the MEDCAPTAIN product.

- MEDCAPTAIN provides a limited warranty on the product. Within the warranty period, after-sales services for the product are provided free of charge. The length of the warranty period is stipulated in the sales contract. For details, contact your local distributor. However, a product damage or failure is not covered by the warranty if it is caused by:
  - Operation error;
  - Improper use;
  - Out-of-range grid voltage;
  - Force majeure such as natural disasters;
  - Replacement with or use of any component, accessory, or consumable other than authorized by MEDCAPTAIN; or
  - Other causes not related to the product itself.
- After the warranty expires, MEDCAPTAIN shall continue to provide paid maintenance service within the service life of the product.
- Feel free to contact us or your local distributor if you have any problem in using the product.

Contact our after-sales service department:

After-sales service provider: MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

After-sales service address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Tel: +86-755-26953369

Website: http://www.medcaptain.com

E-mail: mc.service@medcaptain.com

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1 Overview

1.1 Intended Purpose

This product is intended to deliver medications to patients through intravenous, intra-arterial, subcutaneous, intraoperative site (soft tissue, body cavity/surgical wound site), epidural space, or subarachnoid space. Total parenteral nutrition (TPN) is limited to intravenous infusion.

1.2 Intended Users

The pump can be used in medical settings, like hospitals, clinics, nursing homes, and homecare settings.

The pump can be used only by trained professional medical care personnel and patients who voluntarily accept patient-controlled analgesia (PCA) therapies.

If a patient needs to use the pump without the supervision of medical care personnel, the patient should receive a training and use the pump in accordance with the prescription. In case of any questions during use of the pump, the patient should contact medical care personnel immediately.

Use of the pump on pediatric patients shall be under the supervision of medical care personnel or adults. PCA operations shall be performed by the medical care personnel or adults.

1.3 Intended Patient Population

Adult and pediatric patients (not applicable for neonatal patients).

1.4 Contraindications

This product cannot be used for blood transfusion.

1.5 Indications

There are no indications in the classical sense since the pump can be used in a very wide variety of settings and patients.

1.6 Undesirable Side-effects

The device has no undesirable side-effects associated with its use when used in accordance with this user manual.

1.7 Clinical Benefits

The ambulatory infusion pump provides accurate and reliable infusion of drugs or total parenteral nutrition (TPN) to patients at precisely programmed rates. The pump, equipped with multiple infusion modes like PCA, PCS, PCEA, PIEB, chronological, rate, weight, and etc,

can deliver via clinical administration routes to support a variety of medical conditions, such as pain management, chemotherapy, nutrition therapy, anti-infection, and so on. (Note: its clinical benefits are just indirect.)

1.8 Product Features

The ELFensor P2/P5/P8 ambulatory infusion pump is applicable for patient-controlled infusion of analgesics, chemotherapeutic drugs, and nutrient solution.

The pump must be used in combination with single-use medication cassette reservoirs with registration certificates.

The infusion pump has the following features:

- Support for medication cassette reservoirs with various specifications.
- Touchscreen that supports convenient man-machine interactions.
- Power supply by AA batteries.
- Multiple infusion modes.
- Maximum infusion rate of 300 ml/h.
- Minimum infusion rate increment of 0.1 ml/h.
- Squeeze mechanism that squeezes the infusion tubing to realize liquid flow during infusion. After the medication cassette reservoir is attached, the squeeze mechanism immediately clamps the infusion tubing to prevent over-infusion.
- Occlusion alarms to prevent under-infusion.
- Wi-Fi networking function.
- Bluetooth connection function.
- Screen lock function, preventing accidental taps on the touchscreen from causing unexpected parameter modifications.
- Password-based protection, preventing irrelevant personnel from modifying parameters on the pump without permission.
- Various alarms, ensuring infusion safety.
- Connection to the PCA controller, allowing patient-controlled analgesia within a distance from the pump.
- Configuration of frequently used therapies. After configuration, you can select a therapy and the pump will automatically load the preset infusion parameters.
- Drug library function.
- Event logs, allowing medical care personnel to track event logs.

NOTE:

For information about device models and specifications, refer to *3 Specifications*.

2 Safety

This chapter describes important precautions for operating the ELFensor P2/P5/P8 ambulatory infusion pump. To ensure the safety of both the operator and the patient, read this chapter carefully before using the pump. You should be fully aware of the precautions provided in this manual. Otherwise, the manufacturer is not responsible for the safety, reliability, and performance of the pump.

2.1 Warnings and Cautions



- The pump can be used only by trained professional medical care personnel and patients who voluntarily accept patient-controlled analgesia (PCA) therapies.
- In case of any serious incident during use of the pump, report the incident to the manufacturer, your local distributor, or the competent authority immediately.
- The pump shall be installed and set up by personnel authorized or trained by the manufacturer. Unauthorized personnel cannot install, disassemble, or modify the pump.
- To avoid the risk of electric shock, do not allow liquid to splash onto or flow into the pump. If liquid accidentally flows into the pump, stop using the pump immediately and contact the after-sales service department of the manufacturer.
- Do not service or maintain the pump during use.
- During use, the pump shall be regularly monitored by professional medical care personnel.
- This pump is a reusable medical device.
- It is recommended that medication cassette reservoirs of designated brands should be used. Otherwise, infusion accuracy is not guaranteed and the alarm function may fail.
- Medication cassette reservoirs are single-use consumables and cannot be reused. Dispose of used medication cassette reservoirs in accordance with local laws and regulations.
- A medication cassette reservoir must be discarded after being used for 168 hours nonstop even if there is still drug left.
- Before detaching a medication cassette reservoir from the pump, ensure that the anti-free-flow clamp is closed to prevent liquid reflux. After injecting a liquid drug into the infusion bag, ensure that the anti-free-flow clamp is immediately closed to prevent unregulated gravity infusion.
- Do not fill an infusion bag with an undesignated liquid drug or other liquid.
- If the package of a medication cassette reservoir is damaged or the cassette reservoir has a leakage, do not use the cassette reservoir and dispose of it in accordance with local laws and regulations.

- If a battery stinks, has a high temperature, deforms, changes color, or encounters other exceptions during use or storage, stop using the battery immediately and take it out of the battery compartment. If necessary, contact the after-sales service department of the manufacturer.
- Do not use leaking batteries. If battery leakage gets onto your hand or clothes,wash it off with soapy water immediately. If battery leakage gets into your eye, rinse your eye with water immediately and go see an eye doctor.
- When a battery reaches the end of its useful life or the battery leaks, stinks, deforms, or changes color, stop using the battery immediately and dispose of it in accordance with local laws and regulations.
- During use, keep the pump away from devices that may cause interference, such as high-frequency surgical equipment, mobile phones, wireless devices, and defibrillators.
- Before starting an infusion, be sure to confirm whether the drug information, infusion parameters, and patient information are consistent with those in the prescription.
- After the pump and its recyclable components reach the end of their useful life, contact the manufacturer for recycling or disposal in accordance with local laws and regulations.
- To prevent cross infection, the PCA controller must be cleaned and disinfected before being used by each patient.
- If the infusion tubing and PCA controller cable are long, wind them to avoid the danger of choking and strangulation.
- Do not squeeze the infusion tubing. Ensure that there is no kink in the infusion tubing. Occlusions in the infusion tubing may cause under infusions.
- The pump cannot be used in certain scenarios such as in a swimming pool.
- Use the same alarm preset for identical or similar devices in the same area. Failure to do so may cause potential danger.
- If the operator shows any signs of allergic reaction after contact with the pump or its accessories, the operator should stop using the pump immediately and go see a doctor.
- Ensure that the infusion tubing connected to the pump is not connected to any other infusion system or accessory. Otherwise, the infusion rate may be unexpectedly changed and air may be infused into the patient's body.
- Additional equipment connected to medical electrical equipment through the network/data coupling must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Further more all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, 60601-1-2, respectively).
- Anybody connecting additional equipment to medical electrical equipment configurations a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.



- Do not use the pump in a strong electric or magnetic field or near mobile radio-frequency communication equipment as this may compromise the performance of the pump or cause a fault.

- Do not stack the pump with other equipment as this may compromise the performance of the pump or cause a fault.
- Use only the accessories provided by the manufacturer. Otherwise, the performance and safety of the pump may be compromised and the pump may be damaged.
- Before long-term storage, remove batteries from the pump and store the batteries at a temperature of -20℃ to 45℃ to prevent battery leakage.
- After long-term storage, the system date and time on the pump may be inaccurate and you need to reset it before use.
- Do not touch the touchscreen with a sharp object in case the screen is damaged.
- If an accessory is marked as sterilized on its package, open the package only before you use the accessory. Premature unpacking may cause contamination.
- If the operator is not the patient, the operator cannot touch the pump and the patient simultaneously.
- All other equipment connected to this pump must be certified based on standards such as IEC 60950 and IEC 60601-1. All configurations shall comply with the valid version of IEC 60601-1.
- Do not use the pump in a nuclear magnetic resonance (NMR) environment.
- Do not expose the pump to treatment-level ultrasound or ionizing radiation.
- The applied part of the pump is the infusion set.
- Do not leave the pump unattended near children and pets. Otherwise, the pump and accessories may be damaged.
- After the pump loses its power supply, the alarm logs and settings on the pump before the power loss are automatically saved and are not affected by the power-off time. When the power supply recovers, the alarm logs and settings are automatically loaded.
- The maintenance of this infusion pump must be conducted by authorized personnel. The authorized personnel can ask the manufacturer for materials such as the circuit diagram and component list.
- When operating the pump or checking its alarm system, stand in front of the pump and keep a distance of 0.5 m. The pump should be 1 m from the ground.
- The delay from the onset of an alarm condition to the generation of its alarm signal is no longer than 4.5s.
- The delay from the occurrence of a triggering event to when the alarm system determines that an alarm condition exists is no longer than 0.5s.
- After the infusion pump is exposed to defibrillation voltage, the recovery time of the pump is 1s. The pump functions properly when exposed to defibrillation voltage.

2.2 Symbol Description

The following table describes the symbols in this manual and on the labels of the ambulatory infusion pump.

Symbol	Meaning
	Model number

Symbol	Meaning
	General warning sign (Background: yellow; Symbol & outline: black)
	Caution, read the accompanying documents
	Defibrillation-proof type CF applied part
IP34	Protected against solid foreign objects of 2,5 mm Ø and greater; protected against splashing water
	“OFF” for a part of equipment
	“ON” for a part of equipment
	PCAdose button
	Manufacturer
	Date of manufacturer
SN	Serial number
MD	Medical device
UDI	Unique device identifier
LOT	Batch code
	Refer to instruction manual/booklet (Background: blue; symbol: white)
	Comply with the requirements of Directive 2012/19/EU Waste Electrical & Electronic Equipment
	Non-ionizing electromagnetic radiation
	This way up

Symbol	Meaning
	Fragile, handle with care
	Keep dry
	Keep away from sunlight
	Atmospheric pressure limitation
	Temperature limit
	Humidity limitation
	Stacking limit by number

3 Product Specifications

Name	Ambulatory infusion pump
Model / Specifications	ELFensor P2, ELFensor P5, ELFensor P8
Dimensions	103 mm (W) × 87 mm (H) × 33 mm (D)
Weight	About 0.27 kg (battery included)
Operating Conditions	Ambient temperature: 5°C ~ 40°C Relative humidity: 15% ~ 95%, with the partial pressure of water vapor no greater than 5 kPa Atmospheric pressure: 70.0 ~ 106.0 kPa Altitude: ≤3000 m
Storage and Shipping Conditions	Ambient temperature: -20℃ ~ 55℃ Relative humidity: 10% ~ 95%, with the partial pressure of water vapor no greater than 5 kPa Atmospheric pressure: 22.0 ~ 106.0 kPa
Service Life	5 years
Classification	● Internally powered equipment ● Defibrillation-proof type CF applied part ● IP34 (Protected against solid foreign objects of 2,5 mm Ø and greater; protected against splashing water) ● Not sterilized ● Not category AP/APG equipment; not suitable for use in oxygen-enriched environments ● Mode of operation: continuous operation
Display Screen	2.4-inch resistive color touchscreen Resolution: 240 × 320 pixels
Power Supply	Powered by two AA batteries ● Battery brand: NANFU (model: LR6) ● Battery life (continuous operation at room temperature with default settings): ≥120h at the infusion rate of 5 ml/h; ≥24h at the infusion rate of 125 ml/h
Ports	PCA port: used for connection to the PCA controller

Wi-Fi Networking	When equipped with the Wi-Fi communication module (optional), the pump can be connected to an infusion central monitoring system over a wireless network.
Bluetooth	When equipped with the Bluetooth module (optional), the pump can be connected to a pulse oximeter or a carbon dioxide monitor.
Infusion Rate	0.1 - 300 ml/h
Increment of Infusion Rate	0.1 ml/h if the infusion rate is from 0.10 to 99.9 ml/h 1 ml/h if the infusion rate is from 100 to 300 ml/h
VTBI (Volume to be infused)	0.1 - 999.9 ml (increment: 0.1 ml)
Total Volume Display	0.0 - 9999.9 ml
Time	00:00:01 - 99:59:59 (h:m:s)
Prime Rate	0.1 - 300 ml/h
Drug Amount	0.1 - 99999 ● Between 0.1 and 99.9, the increment is 0.1. ● Between 100 and 99999, the increment is 1.
Concentration	0.1 - 9999 ● Between 0.1 and 99.9, the increment is 0.1. ● Between 100 and 9999, the increment is 1.
Dose Rate	0.1 - 9999 ● Between 0.1 and 99.9, the increment is 0.1. ● Between 100 and 9999, the increment is 1.
Bolus VTBI	0.1 - 50.0 ml (Accuracy: ±5%)
Unintended Bolus Volume	≤0.3ml
KVO Rate	0.1 - 20.0 ml/h (increment: 0.1 ml/h) The KVO function can be disabled if needed.
Infusion Accuracy*	≤±5% (the infusion volume caused by each single squeeze is about 0.05 ml)
Lockout Time	≤±10s (applicable to the PCA, PCS, PCEA, and PIEB modes)
Occlusion Level	● Patient-side occlusion: Three occlusion levels are available: 750 mmHg, 1125 mmHg, and 1500 mmHg. ● Accuracy: ≤±20%
Single Bubble	Bubble level: 100, 400, and 800 (μl). Default level: 400 μl.
Total Bubbles	Bubble level: 100, 400, and 800 (μl/15min). Default level: 800 μl/15min.

Air Bubble Alarm Accuracy	±20% or ±50μl (whichever is greater)
Medication Cassette Reservoir Specifications	Manufacturer: MEDCAPTAIN LIFE SCIENCE CO., LTD Specifications: 50 ml, 100 ml, 150 ml, 300 ml, and 500 ml
Infusion Modes	ELFensor P2/P5: PCA Mode, PCS Mode, PCEA Mode, PIEB Mode, and Rate Mode ELFensor P8: PCA Mode, PCS Mode, PCEA Mode, PIEB Mode, Chronological Mode, Rate Mode, Time Mode, Weight Mode, Sequence Mode, LoadingDose Mode, Intermittent Mode, and Trapezia Mode
Drug Library	The pump allows you to customize the drug library and therapies.
Alarm Message	Infusion End, Infusion End KVO Start, Battery Empty, Patient-side OCCL, Air Bubble In Line, Cassette Detached, Infusion Near End, Cass. Unlocked, Reminder Alarm, Standby End, Dose Limit Exceeded, Communication Error, Battery Low, PCA Controller Removed, and mechanical fault (ERR211)
Date of Manufacture	See the product label
Main Safety Standards	IEC 60601-1:2020: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2020: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 60601-2-24:2012: Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers IEC 60601-1-8:2020: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-11:2020: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

*Note: The manufacture defined the number of samples of infusion pump with regard to accuracy in the technical documentation

4 Product Description

Before using this ambulatory infusion pump, be familiar with the components, features, buttons, and interface operations related to the pump.

4.1 Structural Composition

The ambulatory infusion pump is mainly composed of the main unit, battery, and PCA controller.

The product does not include the pump infusion tubing and medication cassette reservoirs.

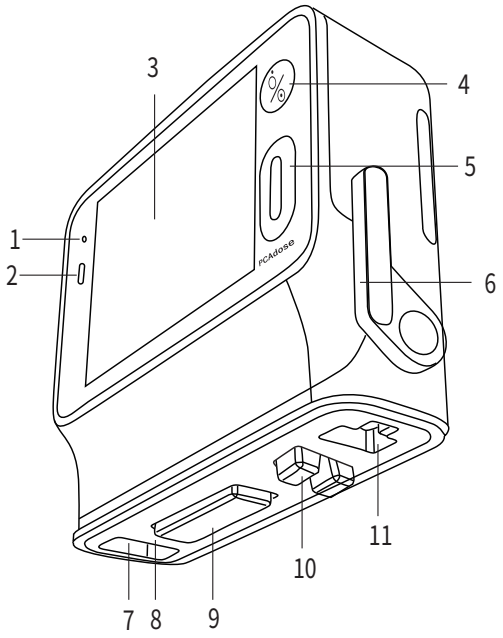
4.2 Operating Principle

This ambulatory infusion pump is intended to infuse, through positive pressure, a preset volume of drug liquid into the patient's body. The pump can be carried by a patient via a pouch.

This ambulatory infusion pump is intended to be used with a medication cassette reservoir and infusion tubing. The operator must set infusion parameters according to the prescription. The control system of this pump converts the infusion parameters into operating parameters to drive the motor, which further drives the squeezing mechanism to implement continuous liquid flow.

During an infusion, the patient-side occlusion sensor, the bubble sensor, and the motor speed sensor operate continuously to monitor the operating status of the pump so that the corresponding alarm is triggered immediately after an exception occurs.

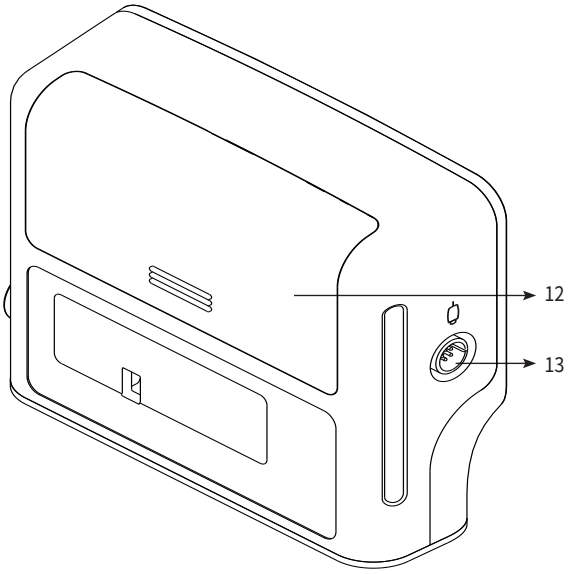
4.3 Schematic Description



No.	Item	Description
1	Operating indicator	When drug is infused at the continuous rate, this indicator flashes in green.
2	Alarm indicator	Red: high-priority alarm Yellow: low- or medium-priority alarm
3	Touchscreen	2.4-inch touchscreen
4	ON/OFF button	Used to power on or off the pump. ● When the pump is powered off, press this button to power on the pump. ● When the pump is powered on, you can press this button to power off the pump or put the pump into the standby state.
5	PCAdose button	After this button is pressed, a preset demand dose of liquid is infused into the patient's body for patient-controlled analgesia.
6	Cassette latch	Used to secure the cassette onto the pump and prevent unexpected detachment.
7	Hinge pin	Used to secure the medication cassette reservoir.
8	Patient-side occlusion sensor	Used to detect occlusions on the patient side.
9	Squeeze mechanism	Used to squeeze the infusion tubing to realize liquid flow during infusion.
10	Bubble sensor	Used to detect air bubbles in the infusion tubing.
11	Lock	Used to lock the medication cassette reservoir into place.

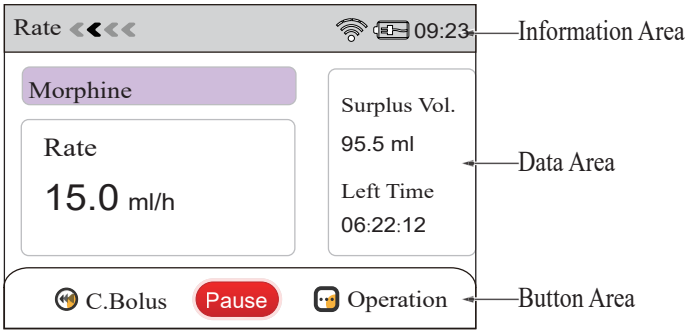
NOTE:

The infusion pump supports a built-in Type-C port that is used for software upgrade by professional service personnel only.



No.	Item	Description
12	Battery compartment	Used to contain AA batteries.
13	PCA port	Used to connect to the PCA controller.

4.4 Display



Area	Description
Information area	Displays information such as the interface name, time, Wi-Fi signal, battery level, and alarm message. Table 4-1 lists the icons that may appear in this area.
Data area	Displays information about the current infusion, such as the infusion mode, infusion rate, and remaining time.
Button area	Displays touch buttons such as **C. Bolus**, **Start/Pause**, and **Operation**.

Table 4-1 Icons in the Information Area

Icon	Description	Icon	Description
Start	Start button: start the infusion.	Pause	Pause button: pause the infusion.
	Home button: return to the home interface.		Powered by AA batteries (battery level: 100%)
	Powered by AA batteries (battery level: 75%)		Powered by AA batteries (battery level: 50%)
	Powered by AA batteries (battery level: 25%)		Powered by AA batteries (battery level: low)
	Powered by AA batteries (batteries depleted)		Keypad lock
	Rate Mode		Time Mode
	Trapezia Mode		Intermittent Mode
	Chronological Mode		LoadingDose Mode
	Weight Mode		Sequence Mode
	Wi-Fi not connected		Wi-Fi connected
	Connected to infusion central monitoring system		Bluetooth connected

4.5 Accessories

AA battery	2	User manual	1
Pump key	1	Packing list	1
PCA controller	/		

NOTE:

Two types of PCA controller are available: one with a 0.3m cable and one with a 2m cable. Users can purchase a desired type.

4.6 Optional Accessories

Quick operation guide	Pouch

WARNING Keep the pump key and AA batteries out of the reach of children to prevent accidental inhaling and swallowing.

5 Installation Instructions

5.1 Environmental Requirements

For proper operation of the ambulatory infusion pump, ensure that its installation environment meets the following requirements:

- No large noise source or power supply interference exists.
- The environment should be dust-free if possible.
- No corrosive or flammable gas exists.
- No flammable or explosive materials exist.
- The pump must be away from sources of heat and sources of moisture, such as a fireplace, radiant heater, nebuliser, or steam kettle.
- The pump must be away from devices that may cause interference, such as high-frequency surgical equipment, mobile phones, and wireless devices.
- The temperature and humidity must meet the requirements in Chapter 3.
- The pump must be installed and used in accordance with the EMC requirements.

5.2 Open Package Inspection

Inspect the package carefully before opening it. If you find any damage, contact your local distributor immediately.

1. Take the infusion pump and accessories out of the package carefully.
2. Check all the items against the packing list to see whether there is any item missing and check for mechanical damage. If you have any questions, contact your local distributor.

NOTE:

Keep the package and packaging materials for future storage and transport.

5.3 Power Supply

The ELFensor P2/P5/P8 ambulatory infusion pump is powered by two AA batteries.



- Before AA battery replacement, be sure to stop the running infusion or power off the pump.
- Do not use new and used AA batteries, or batteries of different brands, to power the pump at the same time.
- AA batteries are for single use only. Dispose of used AA batteries in accordance with local laws and regulations.
- NANFU AA batteries (model: LR6) are recommended. Use of other models or brands of batteries may affect the continuous operation duration of the pump and the delays of battery-related alarms. Therefore, before using other models or brands of batteries, evaluate such effect on the pump.

- Do not charge AA batteries.
- Keep AA batteries dry. If liquid splashes onto or flows into AA batteries, stop using the pump and take the batteries out immediately.
- Do not store the pump for prolonged periods with the batteries installed. Battery leakage could damage the pump.

■ **Installing AA batteries**

1. Remove the battery compartment cover.
2. Install two AA batteries into the battery compartment one by one. Match the positive and negative terminals of the batteries with the + and - markings in the battery compartment.
3. Install the battery compartment cover back by aligning it with the clip and pushing it back in place until you hear a clicking sound.

■ **Removing AA batteries**

1. Remove the battery compartment cover.
2. Take the AA batteries out one by one.
3. Install the battery compartment cover back by aligning it with the clip and pushing it back in place until you hear a clicking sound.

5.4 Attaching and Detaching a Medication Cassette Reservoir

WARNING Before you attach a medication cassette reservoir to the pump, ensure that no air bubble exists in the cassette reservoir and the cassette reservoir has no crack or leakage.

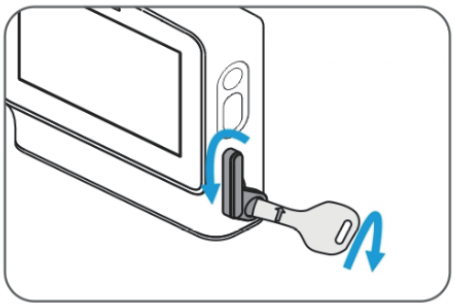
5.4.1 Attaching a Medication Cassette Reservoir

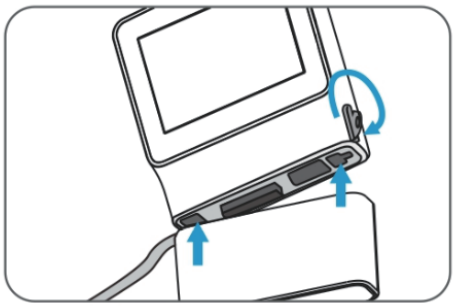
NOTE:

- Only medical care personnel are allowed to attach a medication cassette reservoir.
- When using a medication cassette reservoir, refer to its instructions for use.

This ambulatory infusion pump supports medication cassette reservoirs with various specifications. The following attachment method applies to all specifications of medication cassette reservoirs.

1. Insert the pump key into the cassette latch and turn the key clockwise for 90°.
2. Turn the latch counterclockwise for 90° to the horizontal position.
3. Clamp the tubing. Insert the cassette reservoir hook into the hinge pin on the bottom of the pump.





4. Push the right side of the cassette reservoir up until it firmly clicks into place.
5. Turn the cassette latch clockwise back to the vertical position.

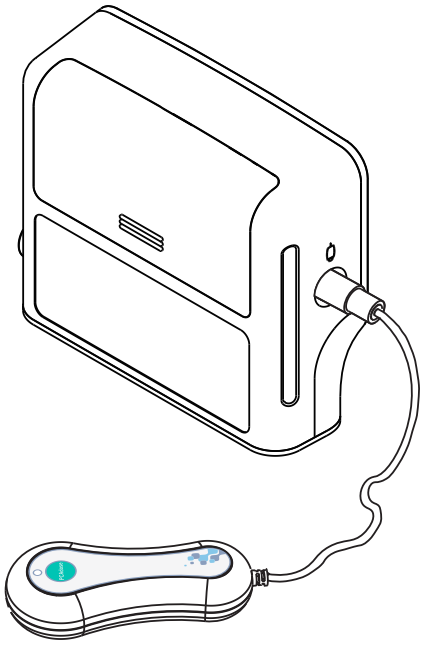
5.4.2 Detaching the Medication Cassette Reservoir

1. Insert the pump key into the cassette latch and turn the latch counterclockwise into the unlocked position.
2. Separate the cassette reservoir hook from the hinge pin on the bottom of the pump.

5.5 Connecting to the PCA Controller

The pump can be connected to the PCA controller, allowing patient-controlled analgesia within a distance from the pump.

1. Insert the connector of the PCA controller into the PCA port of the pump.
2. Rotate the connector counterclockwise to tighten it.



The indicator on the PCA controller has the following states:

- Solid green: indicates that the press is valid and a demand dose has started.
- Flashing in green: indicates that the patient now can press the PCA controller or the PCAdose button on the pump to start a demand dose.
- Dimmed: indicates that the PCA controller is not available now.

In case of a valid press, the PCA controller gives a prompt tone of "di-di". If a press is invalid, the PCA controller does not give the prompt tone.

NOTE:

Do not pull the PCA control cable by force.

5.6 Putting the Pump into the Pouch (Optional)

This ambulatory infusion pump can be put into the pouch provided by the manufacturer and then carried by the patient.

1. Put the pump, with the medication cassette reservoir attached, into the pouch.
2. Pull the infusion tubing out of the pouch through the opening.
3. Stick the hook and loop fasteners together, or fit the snap fastener socket onto an appropriate stud.

6 Operating Instructions

6.1 Preparations Before Use

- Before you use this ambulatory infusion pump, read the procedures and precautions in this user manual carefully.
- Before you use the pump for the first time, set the system date and time to ensure the accuracy of historical records.
- During use, the pump should be placed on a stable desk with the screen facing upwards or put in the pouch provided by the manufacturer.

6.2 Powering on the Pump

Press the ON/OFF button. The screen lights up and displays the self-check interface with sound and light signals. The pump can automatically detect whether a medication cassette reservoir is attached and locked. If you have not properly attached a medication cassette reservoir, attach one as instructed in *5.4.1 Attaching a Medication Cassette Reservoir*.

After the self-check, select whether to admit a patient.

- If you select **Yes**, a new patient is admitted. The last patient is automatically discharged and relevant patient data is cleared. Then, select an infusion profile.
- If you do not want to admit a new patient, select **No**.

6.3 Selecting an Infusion Mode

By default, the following infusion modes are supported: PCA mode, PIEB mode, PCEA mode, PCS mode, Chronological mode, Rate mode, Weight mode, Time mode, Sequence mode, LoadingDose mode, Intermittent mode, and Trapezia mode. The default infusion mode is PCA mode.

NOTE:

For ELFensor P2/P5, only five infusion modes are supported: PCA mode, PIEB mode, PCEA mode, PCS mode, and Rate mode.

To select an infusion mode, perform the following steps:

1. On the home interface, choose **Enter Infusion** > **Infusion Mode**.
2. On the **Infusion Mode** interface, select an infusion mode.
3. Complete the mode settings and tap **OK**. The mode settings of each infusion mode are listed in Table 6-1.

Table 6-1 Mode Settings of Each Infusion Mode

Infusion Mode	Setting	Description
PCA Mode PCS Mode Chronological Mode Intermittent Mode	Dose Method	Set the dose method to **ml** or **Dose Calculation**.
	Dose Calculation	When the dose method is set to **Dose Calculation**, select a dose calculation method.
PCA Mode PCS Mode PIEB Mode PCEA Mode	LoadingDose	Enable or disable the setting of a loading dose.
	Cont. Rate	Enable or disable the setting of a continuous rate.
	DemandBolus	Enable or disable the setting of a demand bolus.
	Infusion Rate	0.1 - 300 ml/h
	Dose Lmt.	Enable or disable the setting of an upper limit on the infusion volume within a certain number of hours.
	Dose Lmt. Hrs	Set the number of hours within which the total infusion volume cannot exceed the upper limit. You can set the number to 1 to 24. If the **Dose Lmt.** setting is turned off, you can ignore this setting.
PIEB Mode	Interval Type	Set the interval type to **Lockout Time** or **PIEB Interval** as needed. **Lockout Time** refers to the minimum interval between two valid presses on the PCA controller. **PIEB Interval** refers to the fixed-length interval from the end of a PIEB dose to the start of the next PIEB dose.
Chronological Mode	Cycle	Enable or disable the cycle mode for the infusion phases that are set for this mode. If this setting is turned on, the infusion phases will be completed as scheduled every day.
Weight Mode	Dose Calculation	Select a dose calculation method.
Intermittent Mode	Continuous Rate	Enable or disable the setting of a continuous rate.
Trapezia Mode	Calculation	Set the calculation method to **Maintain Rate** or **Total Time**.

NOTE:

In PCEA mode, the default occlusion level is 1500 mmHg.

6.4 Selecting a Drug

This pump supports the drug selection function. To enable this function, choose **Local Settings** > **Infusion Settings** > **Common Settings** and then turn on **Drug Selection**.

After you select an infusion mode, you can select **New Infusion** to start configuring a new infusion.

1. Select **New Infusion**.
2. Select **DoseControl** or **Regular Infusion**.
3. On the **Drug Classification** interface, select a drug category.
4. Select a drug.

NOTE:

On the interface that appears after you select an infusion mode, you can also perform the following operations:

- To repeat the last infusion, select **Last Infusion** and confirm the infusion parameters.
- To start an infusion based on a saved program, select **PreSet Program**. Select a program and confirm the infusion parameters.

6.5 Setting Infusion Parameters

After you select a drug, the parameter setting interfaces of the selected infusion mode appear in sequence. Set the infusion parameters properly.

Common operations on setting interfaces are as follows:

- Tap **OK** to save the setting.
- Tap ← to clear the entered content.
- Tap **Back** to cancel the current setting and return to the previous interface.
- Tap **Next** to go to the next interface for more options.

NOTE:

- If you set a parameter to a value out of the valid range and tap **OK**, a prompt appears and you need to set another value.
- Certain parameters can be enabled or disabled when you complete the mode settings after selecting the infusion mode. For details, refer to *6.3 Selecting an Infusion Mode*.

■ **PCA Mode/PCEA Mode/PCS Mode/PIEB Mode**

PCA stands for Patient Controlled Analgesia. When the patient feels pain during an infusion, the patient can press the PCAdose button on the pump or the connected PCA controller to intravenously administer a preset demand dose of medication to relieve the pain.

PIEB stands for Programmed Intermittent Epidural Bolus. In this mode, medication is administered based on intermittent pulses. When the patient feels pain during an infusion, the patient can press the PCAdose button on the pump or the connected PCA controller to administer a preset demand dose of medication to relieve the pain.

PCEA stands for Patient Controlled Epidural Analgesia. When the patient feels pain during an infusion, the patient can press the PCAdose button on the pump or the connected PCA controller to administer a preset demand dose of medication to the epidural space to relieve the pain.

PCS stands for Patient Controlled Sedation. When the patient suffers pain or anxiety caused by clinical intervention or treatment, the patient can press the PCAdose button on the pump or the connected PCA controller to intravenously administer a preset demand dose of medication for sedation.

The following table describes the common parameters of the PCA mode, PCEA mode, PCS mode, and PIEB mode.

Parameter	Description
VTBI	0.1 - 999.9 ml
LoadingDose	0.0 - 30.0 ml (Dose Method is set to ml)
Cont. Rate	0.0 - 50.0 ml/h (Dose Method is set to ml)
DemandBolus	0.0 - 30.0 ml (Dose Method is set to ml)
Lockout Time	PCA/PCEA/PIEB mode: 1 - 1440 min. Default value: 10 min. PCS mode: 00:00:00 - 24:00:00 (h:m:s). Default value: 2 min.
xh Dose Lmt.	0.1 - 9999.9 ml (x indicates the number of hours)

The following table describes the parameters particular to the PIEB mode.

Parameter	Description
Next Bolus	1 - 1440 min.
PIEB Interval	1 - 1440 min. Default value: 40 min.
PIEB Dose	0.1 - 30.0 ml.

NOTE:

- Apart from the listed parameters, the PCA and PCS modes also support the **Drug Amount**, **Volume**, **Drug Conc.**, and **Weight** parameters.
- The **Next Bolus** parameter indicates the interval from the end of the loading dose to the start of the first PIEB dose.
- If there is a loading dose, after the loading dose is completed, presses on the PCAdose button or the connected PCA controller within the lockout time are invalid. Only presses after the lockout time are valid.
- If there is no loading dose, a demand dose can be started at any time.
- After a valid press on the PCAdose button or the connected PCA controller, wait after the lockout time for another valid press.
- Presses on the PCAdose button or the connected PCA controller during a loading dose, bolus, or PIEB dose are invalid.
- Bolus operations do not affect the calculation of lockout time.

- If the continuous rate is not set to 0, apart from demand doses initiated by the patient, there is a continuous infusion at this rate in the background.
- A bolus cannot be started during a loading dose, a demand dose, or a PIEB dose.
- If a bolus is going on when a PIEB dose is supposed to start, the PIEB dose starts after the bolus ends.

■ **Chronological Mode**

Based on the characteristics of human cell cycles and optimal effects of a chemotherapeutic drug in human body, the chronological mode allows the drug to be administered through multiple phases at different infusion rates.

On the parameter setting interfaces, set the following parameters.

Parameter	Description
VTBI	0.1 - 999.9 ml
Phase Settings	Time: 00:00 - 24:00 (h:m) Tap +/- to adjust the time. The increment for hours is 1 hour and the increment for minutes is 30 minutes.
	Rate: 0.1 - 300 ml/h Dose rate: 0.1 - 9999
	Number of phases: 1 - 24

On the **Phase Settings** interface, perform the following operations as needed:

- When setting time and rate values, tap + to increase the value and − to decrease the value. The increment for hours is 1 h and the increment for minutes is 30 minutes.
- After setting time and rate values for a phase, tap ⊕ to add another phase.
- Tap 🗑 to delete a phase.

NOTE:

- If the cycle mode is enabled on the mode setting interface of the chronological mode, the pump automatically completes the infusion phases every day. To enable the cycle mode, on the **Enter Infusion** interface, choose **Infusion Mode** > **Chronological** and then turn on **Cycle**.
- Apart from the listed parameters, the Chronological mode also supports the **Drug Amount**, **Volume**, **Drug Conc.**, and **Weight** parameters.

■ **Rate Mode**

In rate mode, the pump infuses liquid at a constant infusion rate until the infusion volume or infusion duration reaches the preset value.

On the parameter setting interfaces, set the **VTBI** and **Infusion Rate** parameters and the **Infusion Time** parameter is automatically calculated.

Parameter	Description
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.

Parameter	Description
Infusion Rate	0.1 - 300 ml/h ● Between 0.1 and 99.9 ml/h, the increment is 0.1 ml/h. ● Between 100 and 300 ml/h, the increment is 1 ml/h.
Infusion Time	00:00:01 - 99:59:59 (h:m:s).

■ **Time Mode**

In time mode, the pump infuses liquid at a constant infusion rate for a specified period of time.

On the parameter setting interfaces, set the **VTBI** and **Infusion Time** parameters and the **Infusion Rate** parameter is automatically calculated.

Parameter	Description
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.
Infusion Time	00:00:01 - 99:59:59 (h:m:s).

■ **Weight Mode**

In weight mode, the pump infuses liquid at a constant infusion rate calculated based on the patient's weight or BSA (body surface area) until the infusion volume reaches the preset value.

If you have set the **Dose Calculation** parameter to **Conc. & BSA** when selecting the weight mode, enter a height and weight and the pump will automatically calculate the BSA.

If you have chosen **Local Settings** > **Infusion Settings** > **Common Settings** and set **Conc. Config.** to **Amount & Vol.**, enter a drug amount and liquid volume and the pump will automatically calculate the drug concentration.

Parameter	Description
Concentration Unit	ng/ml, μg/ml, mg/ml, g/ml, unit/ml, kunit/ml, munit/ml, mIU/ml, IU/ml, kIU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml, and mEq/ml
Drug Conc.	0.1 - 9999 ● Between 0.1 and 99.9, the increment is 0.1. ● Between 100 and 9999, the increment is 1.
Drug Amount	0.1 - 99999 ● Between 0.1 and 99.9, the increment is 0.1. ● Between 100 and 99999, the increment is 1.
Volume	0.1 - 999.9 ml. The increment is 0.1 ml.
Height	1.0 - 300.0 cm. This parameter is available only for BSA calculation.
Weight	1.0 - 300.0 kg. The increment is 0.1 kg.
BSA	0.01 - 5.60 m^2. The increment is 0.01.

Parameter	Description
Dose Rate Unit	If you set the calculation method to weight, available dose rate units are X/kg/h, X/kg/min, X/kg/24h, X/h, X/min, and X/24h. If you set the calculation method to BSA, available dose rate units are X/m²/h, X/m²/min, X/ m²/24h, X/h, X/min, and X/24h. Where X is the unit of drug amount, which may be ng, µg, mg, g, unit, kunit, munit, mIU, IU, kIU, EU, mmol, mol, kcal, and mEq.
Dose Rate	0.1 - 9999 ● Between 0.1 and 99.9, the increment is 0.1. ● Between 100 and 9999, the increment is 1.
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.

■ **Sequence Mode**

In sequence mode, the pump infuses liquid based on infusion sequences. Each sequence contains an infusion rate and an infusion duration. After finishing the infusion of a sequence, the pump continues to perform the infusion of the next sequence until the infusions of all sequences are finished.

For each sequence, set any two of the **VTBI**, **Infusion Time**, and **Infusion Rate** parameters and the other parameter is automatically calculated. The total VTBI and infusion time are dynamically calculated when you setting infusion sequences.

Parameter	Description
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.
Infusion Rate	0.1 - 300 ml/h ● Between 0.1 and 99.9 ml/h, the increment is 0.1 ml/h. ● Between 100 and 300 ml/h, the increment is 1 ml/h.
Infusion Time	00:00:01 - 99:59:59 (h:m:s)
Sequence No.	1 - 10

On the **Sequence Settings** interface, perform the following operations as needed:

- After setting time and rate values for a sequence, tap ⊕ to add another sequence.
- Tap 🗑 to delete a sequence.

■ **LoadingDose Mode**

In LoadingDose mode, to rapidly increase the drug concentration in blood, a loading dose is first infused into the patient's body at the preset loading rate. Then, in the maintain phase, the remaining amount is infused at the preset maintain rate until the total infusion volume reaches the preset VTBI.

On the parameter setting interfaces, set the **VTBI**, **LoadingDose**, **Loading Rate**, and **Maintain Rate** parameters. The values of the **Loading Time** and **Maintain Time** parameters are automatically calculated.

Parameter	Description
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.
LoadingDose	0.1 - 999.9 ml. The increment is 0.1 ml.
Loading Rate/ Maintain Rate	0.1 - 300 ml/h ● Between 0.1 and 99.9 ml/h, the increment is 0.1 ml/h. ● Between 100 and 300 ml/h, the increment is 1 ml/h.

NOTE:

- Loading Time = LoadingDose/Loading Rate.
- Maintain Time = (VTBI - LoadingDose)/Maintain Rate.

■ **Intermittent Mode**

In intermittent mode, drug is infused into the patient's body through multiple cycles. Each cycle consists of a single infusion and an infusion interval.

During each single infusion, the pump infuses liquid at the preset bolus rate until the infusion volume reaches the preset value. During each infusion interval, the pump infuses liquid at the preset continuous rate for the specified period of time.

On the parameter setting interfaces, set the following parameters.

Parameter	Description
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.
Single Dose	0.1 - 999.9 ml
SingleDoseRate	0.1 - 300 ml/h
Inf. Interval	00:00:01 - 99:59:59 (h:m:s)
Cont. Rate	0.1 - 9999

NOTE:

Apart from the listed parameters, the Intermittent mode also supports the **Drug Amount**, **Volume**, **Drug Conc.**, and **Weight** parameters.

■ **Trapezia Mode**

In trapezia mode, an infusion goes through three phases: rise phase, maintain phase, and fall phase. This mode is suitable when the patient is sensitive to changes in drug amount and prone to side-effects.

On the parameter setting interfaces, set the following parameters.

Parameter	Description
VTBI	0.1 - 999.9 ml. The increment is 0.1 ml.
Steady Rate	0.1 - 300 ml/h ● Between 0.1 and 99.9 ml/h, the increment is 0.1 ml/h. ● Between 100 and 300 ml/h, the increment is 1 ml/h.
Total Time	00:00:01 - 99:59:59 (h:m:s)
Rise Time/ Fall Time	00:01:00 - 99:59:59 (h:m:s)

NOTE:

- The sum of rise time and fall time must not be greater than the total time or twice the quotient of total drug amount and the maintain rate.
- If the maintain rate is less than 1 ml/h or the total time is less than 1 minute, the **Rise Time** and **Fall Time** parameters are unavailable.
- The valid range of the **Total Time** parameter is affected by the VTBI and maximum infusion rate. When the **Total Time** parameter is set to the minimum allowed value, the valid range of the **Rise Time** and **Fall Time** parameter is 00:00:00 to 00:00:00.

6.6 Priming

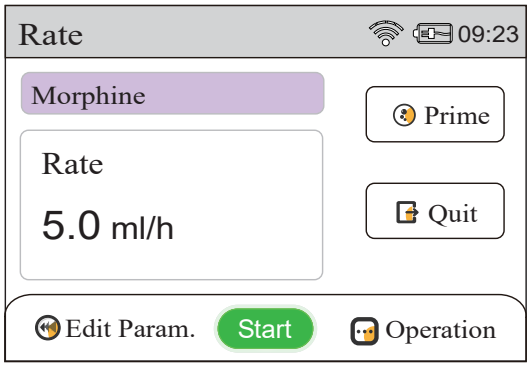
WARNING

- Before you attach a medication cassette reservoir to the pump, expel air bubbles from the cassette reservoir and the infusion tubing.
- Before priming, disconnect the infusion tubing from the patient.

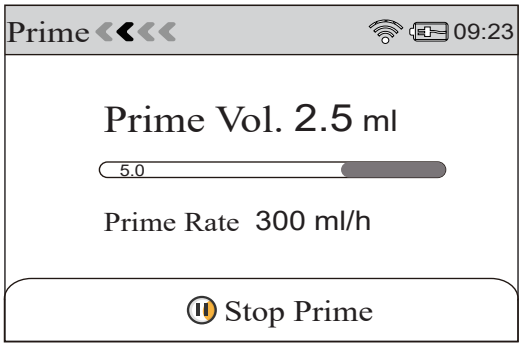
1. After you set the infusion parameters, tap **OK**.
2. On the confirmation interface, tap **Yes** to enter the infusion preparation interface. You can also tap **No** to return to the previous interface.

   NOTE:

   On the confirmation interface, you can check **Save as preset program** so that you can directly start the same infusion next time without having to set the parameters again.
3. On the infusion preparation interface, tap **Prime**. A prompt interface appears.



4. After ensuring that the administration set is disconnected from the patient, tap **Yes**. The pump starts priming at the default prime rate and stops when the prime volume reaches the preset value or when you tap **Stop Prime**.



NOTE:

- The default prime rate is the maximum infusion rate supported by the pump. When a high-viscosity solution is infused through a small intravenous needle during the prime, an occlusion alarm may be triggered. In this case, you can reduce the prime rate in prime settings and then continue priming.
- The prime volume is not calculated into the total infusion volume.
- During priming, the air bubble alarm is disabled.

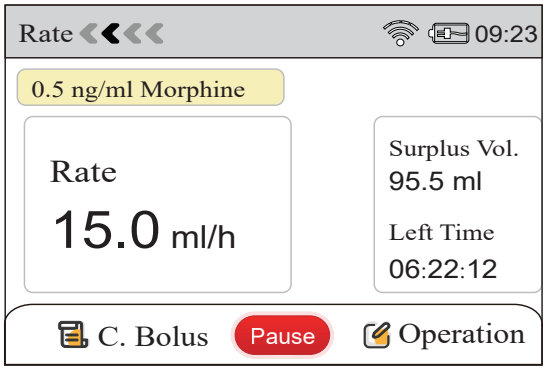
6.7 Starting the Infusion

NOTE:

- Before you start an infusion, ensure that the patient information and parameter values on the pump are consistent with those in the prescription.
- If no operation is performed within the preset reminder time (1 to 10 minutes) after a medication cassette reservoir is attached, the **Reminder Alarm** is triggered.
- If no VTBI is set or an inappropriate VTBI is set, the **Infusion Near End** and **Infusion End** alarms may fail.

To start the infusion, perform the following steps:

1. Connect the infusion tubing to the patient.
2. Tap Start. The pump starts to infuse liquid based on the infusion parameters that you set.



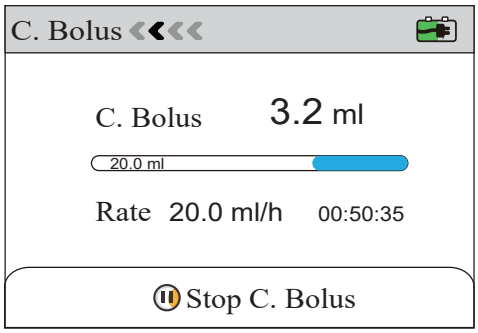
6.7.1 Starting a Bolus

During the infusion, you can start a bolus as needed.

1. Tap **C. Bolus** to enter the **C. Bolus Set** interface.
2. Set the **C. Bolus Rate** and **C. Bolus VTBI** parameters. The value of the **C. Bolus Time** parameter is automatically calculated.

Parameter	Description
C. Bolus Rate	0.1 - 300 ml/h
C. Bolus VTBI	0.1 - 50.0 ml

3. Tap **OK**. The pump starts a bolus.



4. During the bolus, you can tap **Stop C. Bolus** to stop the bolus and continue the infusion.

NOTE:

- The bolus volume is calculated into the total infusion volume.
- During a bolus, the air bubble alarm is available.

6.7.2 Editing Parameters

On the infusion preparation interface or infusion pause interface, you can choose **Operation** > **Edit Param.** to view or modify the infusion parameters. After modification, tap **OK**.

NOTE:

- In PCA, PCEA, PIEB, PCS, or Intermittent Mode, you can also edit parameters during infusion.
- This parameter editing function is available only for clinicians.
- The VTBI parameter can be edited only before an infusion is started or when the infusion is paused. The **LoadingDose** parameter can be edited only before an infusion is started.

6.7.3 Viewing Report

During the infusion, you can choose **Operation** > **View Report** to view historical infusions and event logs.

NOTE:

When there is no infusion going on, you can view the report by selecting **View Report** on the home interface.

■ **Delivery History**

On the infusion running or pause interface, choose **Operation** > **View Report** > **Delivery History**. Information about historical infusions of the current patient is displayed.

■ **Patient Bolus Graph**

On the infusion running or pause interface, choose **Operation** > **View Report** > **Patient Bolus Graph**. The interface that appears displays the statistical information about patient demand boluses within a specified period of time.

You can tap **Last** to select a period of time. The default period of time is the last 8 hours.

■ **Event Log**

On the infusion running or pause interface, choose **Operation** > **View Report** > **Event Log**. The **Event Log** interface displays the operation and alarm records related to the current patient.

- A maximum of 5000 records can be stored. When the number of events stored on the pump exceeds 5000, the earliest records are deleted.
- Operation and alarm records are sorted by generation time in descending order.
- After the pump is powered off, the historical records can be stored for up to 5 years.

6.7.4 Clearing the Volume Infused

To clear the volume infused, on the infusion running or pause interface, choose **Operation** > **Clear VI**.

6.7.5 Setting Pain Scores

Pain scoring is supported during an infusion. Ten levels are available. A higher level indicates more severe pain.

■ **Pain Score At Rest**

On the infusion running or pause interface, choose **Operation** > **Pain Score At Rest**. Select a pain level and tap **OK**.

■ **Pain Score Under Activity**

On the infusion running or pause interface, choose **Operation** > **Pain Score Under Activity**. Select a pain level and tap **OK**.

6.7.6 Selecting Adverse Reactions

On the infusion running or pause interface, choose **Operation** > **Adverse Reactions**. Select one or more adverse reactions and tap **OK**.

6.7.7 Performing Quick Settings

On the infusion running or pause interface, choose **Operation** > **Quick Settings**. On the Quick Settings interface, you can change patient information, the brightness and volume levels, alarm settings, and infusion settings.

6.7.8 Viewing Vital Signs

You can view the vital signs of the patient during the infusion.

On the infusion running or pause interface, choose **Operation** > **Vital Signs**. The **Vital Signs** interface displays the patient's oxygen saturation (SpO^2), amount of carbon dioxide in exhaled air ($ETCO^2$), pulse rate (PR), and respiratory rate (RR).

6.7.9 Starting a Demand Dose

During an infusion in PCA, PIEB, PCEA, or PCS mode, the patient can start a demand dose (outside the lockout time) for analgesia in two ways:

- Press the PCAdose button on the right side of the pump.
- If the pump is connected to the PCA controller, press the button.

6.8 Suspending or Quitting the Infusion

To suspend the infusion on the infusion running interface, tap Pause. The infusion is paused.

To resume the infusion, tap Start.

On the infusion pause interface or after the infusion is finished, tap **Quit**. The infusion stops and the operating indicator dims.

6.9 Setting up DoseControl (Optional)

The pump provides the optional DoseControl function to simplify the operation procedure and prevent the risk caused by misoperations.

The DoseControl function supports at least:

- 10000 types of drug;
- 30 drug categories;
- 30 colors for differentiating the drug categories.

Procedure for using the DoseControl function:

1. On the **New Infusion** interface, select **DoseControl**.
2. Select **Drug Search** to search for a drug or select a drug category and then a drug.
3. Select a concentration or set a custom concentration.
4. Set the infusion parameters of the selected infusion mode and select **OK**.
5. On the confirm interface, select **YES**.
6. On the infusion preparation interface, select **Start**.

6.10 Putting the Pump into the Standby State

Press the ON/OFF button. On the interface that appears, tap **Standby**.

The screen displays the remaining standby time. You can tap **Settings** to modify the remaining standby time or tap **Quit** to exit the standby state.

6.11 Powering off the Pump

Press and hold the ON/OFF button and tap **Power Off** on the interface that appears.

NOTE:

- After the pump is powered off, the infusion parameters are automatically stored and the storage duration is not affected by the power-off time.
- If the infusion pump is shut down forcibly, some parameters may fail to be saved.
- The alarm system of the pump is powered off only when the pump is powered off. The power-off time is recorded in the logs.

7 Menu Settings

Local settings of this ambulatory infusion pump include system settings and infusion settings. These settings are stored in the internal memory of the pump and are not lost in case of power failures. During each startup, the pump automatically loads these settings.

When you power on the pump, the pump starts a self-check and then displays the home interface. Tap **Local Settings**. On the **Local Settings** interface, you can configure system settings and infusion settings, and view device information.

When configuring local settings, you may perform the following operations as needed:

- Tap a setting to go to the corresponding setting interface.
- Tap **Next** to go to the next interface for more settings.
- Tap **Previous** to go to the previous interface.
- Tap **Back** to cancel the current setting and return to the previous interface.
- Tap **OK** to save the settings.

7.1 Local Settings

7.1.1 System Settings

System settings include alarm settings, general settings, time and language, user maintenance, and manufacturer maintenance.

■ **Alarm Settings**

Parameter	Description
Alarm Volume	Set the volume level of alarms. You can set the level to **Low**, **Medium**, or **High**.
Cass. Unlocked	Specify whether the pump continues or stops the infusion when the cassette reservoir is unlocked.
Reminder T.	Set a period of time. If no operation is performed within this period of time after a medication cassette reservoir is attached, the pump triggers the **Reminder Alarm.**
Standby End	Enable or disable the **Standby End** alarm.
Alarm Advance	Set an alarm advance time for the **Infusion Near End** alarm to go off before the end of an infusion. Valid values: 1 to 240 minutes.

NOTE:

- Set an appropriate alarm volume based on clinical conditions. If the alarm volume level is set to lower than the ambient noise, the alarm audio may not be heard, which may cause patient hazards.
- Alarm settings must be completed by professional technicians authorized by the manufacturer to ensure appropriate priorities for the alarm system.
- Do not set alarm limits to extreme values that can render the alarm system useless.

■ **General Settings**

Parameter	Description
Brightness	Adjust the brightness of the display. Ten levels are available.
Alarm Volume	Set the volume level of alarms. You can set the level to **Low**, **Medium**, or **High**.

■ **Time & Language**

To ensure the accuracy of historical records, set the date and time for the system when you use the pump for the first time.

Parameter	Description
Date Format	Select a date format. Three formats are available: Y-M-D, M-D-Y, and D-M-Y.
Date Settings	Set the date.
24h system	Enable or disable the 24-hour clock system.
Time Settings	Set the time.
Clock SYNC	Enable or disable time synchronization between the pump and the connected NTP server. If you enable this function, the following parameters are required: ● Time Zone: the time zone where the pump is located. ● NTP Server: the IP address of the NTP server. If the pump is connected to the Infusion Central Monitoring System, this parameter is automatically set. ● NTP Status: indicates whether the pump is connected to the NTP server.
Language	Select a display language.

NOTE:

If time synchronization is enabled, the system date and time cannot be manually set.

7.1.2 Infusion Settings

Infusion settings include KVO settings, occlusion settings, bubble settings, common settings, prime settings, and auto sleep.

■ **KVO Settings**

KVO stands for Keep Vein Open. If the KVO function is enabled, after finishing an infusion task that features a preset VTBI, the infusion pump continues to infuse liquid at the preset KVO rate.

Parameter	Description
KVO	Enable or disable the KVO function.
KVO Rate	Set a KVO rate. Valid values: 0.1 - 20.0 ml/h.

■ **OCCL Settings**

Parameter	Description
Pressure Unit	Select a pressure unit.
OCCL Level	Select an occlusion level.
Auto-Restart	Enable or disable the Auto-Restart function. When this function is enabled, if the detected occlusion pressure does not exceed the alarm threshold within 3 seconds after an occlusion alarm condition disappears, the infusion automatically continues.

Table 7-1 Occlusion Levels in Different Units

Pressure (mmHg)	Pressure (kPa)	Pressure (bar)	Pressure (psi)
750	100	1.00	14.50
1125	150	1.50	21.75
1500	200	2.00	29.01

The occlusion alarm accuracy of this infusion pump is ≤±20%.

NOTE:

- When an occlusion alarm is triggered, disconnect the infusion tubing from the patient immediately. This prevents extra liquid from being infused into the patient's body after the occlusion is eliminated.
- If a low occlusion level is set and the drug being infused is a high-viscosity solution, an occlusion alarm may be triggered even if no occlusion exists. In this case, check the infusion pressure in the data area on the display and adjust the occlusion level to a higher level as needed.
- If a high occlusion level is set, the occlusion alarm is triggered only when a relatively high pressure is accumulated in the infusion tubing. Ensure that the infusion tubing is firmly connected to the medication cassette reservoir.
- An occlusion alarm may be triggered when a high-viscosity solution is infused through a small intravenous needle at a high infusion rate. In this case, set the occlusion level to a high level or reduce the infusion rate.

- Under normal circumstances, the maximum infusion pressure generated by the infusion pump does not exceed 1800 mmHg.
- The occlusion alarm response time is affected by the factors such as temperature and the length of the infusion tubing.

■ **Bubble Settings**

Parameter	Description
Single Bubble	Set an alarm level for single bubbles. Available levels are 100, 400, and 800 (μl).
Total Bubbles	Set an alarm level for total bubbles. Available levels are 100, 400, and 800 (μl/15min).

NOTE:

If you set the bubble level to 100 μl/15min for total bubbles, the infusion pump triggers an alarm when the total volume bubbles accumulated within 15 minutes reaches 100 μl.

■ **Common Settings**

Parameter	Description
Drug Selection	Enable or disable the drug selection function.
Conc. Config.	Select a concentration configuration method. Available methods are **Amount & Volume** and **Drug Conc**.
BSA Formula	Select a BSA formula. Available formulas are **DuBois** and **Stevenson**.
BSA Config.	Select a BSA configuration method. Available methods are **Height & Weight** and **BSA**.
Bolus Count	Select a PCA press mode. Available modes are **Intermittent** and **Continuous**.
Underdose Ct.	Set a number for determining underdose. Valid values: 1 - 20. If the number of invalid presses between two valid presses reaches this number, the pump generates a prompt.

NOTE:

- Stevenson formula: BSA (m^2) = 0.0061 × height (cm) + 0.0128 × weight (kg) - 0.1529
- DuBois formula: BSA (m^2) = 0.007184 × height (cm) $^{0.725}$ × weight (kg)$^{0.425}$

■ **Prime Settings**

Parameter	Description
Prime Rate	Set a prime rate. Valid values: 0.1 - 300 ml/h.
Prime Vol.	Set a prime volume. Valid values: 1.0 - 30.0 ml.

■ **Auto Sleep**

Parameter	Description
In-Infusion	Select a time interval for auto sleep during an infusion. If you select OFF, this function is disabled.
Non-Infusion	Set a time interval for auto sleep when the pump is not infusing. If you select OFF, this function is disabled.

NOTE:

- You can also put the pump into sleep state manually by pressing the ON/OFF button. After the pump is put into sleep state, the screen is locked. Press the ON/OFF button again to exit the sleep state.
- In sleep state, if the operating indicator flashes in green, it indicates that the pump is operating properly.

7.1.3 Device Information

The **Device Information** interface displays the pump number, software release version, and complete software version of the pump.

7.1.4 User Maintenance

■ **Communication (Optional)**

Parameter	Description
WLAN	Enable or disable the WLAN function.
Available WLAN	Display available wireless networks. You can tap **Add Network** to enter a network name and password to connect to the network.
CMS IP	Enter the IP address of the server of the infusion central monitoring system.
CMS Port	Enter the port number of the server of the infusion central monitoring system.
WLAN Settings	Enable or disable DHCP (Dynamic Host Configuration Protocol). ● If you enable DHCP, network information is obtained automatically. ● If you disable DHCP, you need to configure network information manually.
Login Tip	Enable or disable the prompt that reminds you to log in to the infusion central monitoring system.
Login System	Select a theme of the infusion central monitoring system. Available system themes are Postoperative Analgesia Management, Labor Analgesia Management, and Carcinomatous Analgesia Management.

■ **Bluetooth (Optional)**

Parameter	Description
Bluetooth	Enable or disable Bluetooth connection.
Available BT	Display a list of available bluetooth devices.

NOTE:

- The device to be connected to this pump through Bluetooth must have a medical registration certificate and must be used in accordance with its user manual.
- The Bluetooth parameter requirements must be met during Bluetooth settings, connection, and usage. For more information, contact the after-sales service department of the manufacturer.

■ **Mode Configuration**

Mode configuration allows you to disable certain infusion modes. By default, all infusion modes are enabled.

■ **Patient Data**

Parameter	Description
Admit Pat. Tip	If you enable this function, after you power on the pump, the pump displays a prompt reminding whether to admit a new patient.
Patient Display	You can choose to display patient name or PID.

■ **PWD Change**

Parameter	Description
Keypad PWD	Set a password for unlocking the screen. Default password: 1234.
Clinician PWD	Set a password for clinician roles. Default password: 2121.
Admin. PWD	Set a password for administrator roles. Default password: 1018.



We recommend that when you use the pump for the first time, you change the password to ensure security.

7.1.5 Manufacturer Maintenance

To ensure the stability and precision of the pump, manufacturer maintenance shall be performed by professional technicians of the manufacturer.

7.2 Patient Management

On the home interface, tap **Patient Mgmt**. On the **Patient Mgmt** interface, you can perform the following operations:

- Change the infusion profile when multiple infusion profiles are available.
- Edit patient information including name, PID, department, ward, and bed No.

Tap **Admit Patient** in the upper-right corner. The **New Patient** interface appears. Tap **Yes** to admit the new patient and the original patient information will be cleared, or tap **No** to return to the **Patient Mgmt** interface.

8 Alarms and Faults

8.1 Alarm Priorities

The infusion pump provides status information about itself and infusion processes. In case of an exception such as a fault, the pump triggers an alarm with text, sound, and light signals.

Based on fault severity and threat to safety, alarms are classified into three priorities: low-priority alarms, medium-priority alarms, and high-priority alarms. Table 8-1 describes the tones and indicator colors of different alarm priorities. The alarm volume ranges from 45 to 70 dB(A). When checking the pump's alarm system, stand 1 m away from the pump. All the alarms generated on this pump are technical alarms.

Table 8-1 Tones and Indicator Colors of Different Alarm Priorities

Alarm Priority	Alarm Tone	Indicator Color
Low	"Di-Di-Di", repeating every 18s	Solid yellow
Medium	"Di-Di-Di", repeating every 12s	Flashing yellow
High	"Di-Di-Di—Di-Di—Di-Di-Di—Di-Di", repeating every 3s	Flashing red
Prompt	"Di-Di"	/

When an alarm is triggered, you can perform the following operations:

- Tap **Audio Pause** to silence the alarm. If the alarm cause is not eliminated within 2 minutes, the alarm goes off again.
- Tap **Acknowledge** to stop the alarm. The alarm message is displayed.

8.2 Alarms and Elimination Methods

Table 8-2 Alarm Message, Alarm Priority, Fault Cause, and Troubleshooting

Alarm Message	Alarm Priority	Fault Cause	Troubleshooting
! Battery Low	Low	The batteries are running low.	Replace the batteries.
!!! Battery Empty	High	The batteries are depleted.	Replace the batteries.
!!! Infusion End	High	The infusion volume or duration has reached the preset value.	Tap **Acknowledge** to eliminate the alarm.

Alarm Message	Alarm Priority	Fault Cause	Troubleshooting
! Infusion Near End	Low	The infusion will be completed within the time period indicated by the alarm.	Wait until the infusion is finished.
!!! Infusion End KVO Start	High	The infusion volume or duration has reached the preset value and the infusion has entered the KVO mode.	Tap **Acknowledge** to eliminate the alarm.
!!! Patient-side OCCL	High	1. An occlusion exists in the cassette reservoir tubing. 2. The drug being infused is a high-viscosity solution and the occlusion level is set to a low level.	Disconnect the pump from the patient and tap **Acknowledge** to eliminate the alarm. Identify and remove the alarm cause. Then, restart the pump and continue the infusion.
! Standby End	Low	The standby time is out.	Tap **Acknowledge** to exit the standby state.
!!! Air Bubble In Line	High	1. Air bubbles exist in the infusion tubing. 2. The infusion tubing is deformed due to extrusion.	Disconnect the pump from the patient and tap **Acknowledge** to eliminate the alarm. Check whether the infusion tubing is deformed due to extrusion and expel air bubbles.
!!! Cassette Detached	High	1. The cassette reservoir is detached. 2. A sensor error occurred.	1. Reattach the cassette reservoir. 2. Contact your local distributor.
!! Cass. Unlocked	Medium	The cassette reservoir is unlocked.	Lock the cassette reservoir.
!! Communication Error	Medium	The network connection failed.	Reconnect the pump to the network.
! PCA Controller Removed	Low	The infusion has started but the pump is not connected to the PCA controller.	Connect the PCA controller to the pump.

Alarm Message	Alarm Priority	Fault Cause	Troubleshooting
! Reminder Alarm	Low	When there is no infusion going on, no operation is performed within the preset period of time for triggering the reminder alarm (2 minutes by default).	1. Tap any button on the screen. 2. Press the PCAdose button on the pump or the connected PCA controller. 3. Open or close the cassette latch.
! Dose Limit Exceeded	Low	The infusion volume has reached the limit within a period of time.	Wait until the alarm automatically stops.
!!! ERR211	High	A mechanical fault has occurred. The driving mechanism is stuck.	Remove the obstruction and restart the pump.

8.3 System Faults and Troubleshooting

Fault Code	Alarm Priority	Fault Cause	Troubleshooting
ERR XXX	High	System fault	Record the fault information, power off the pump, and then contact your local distributor.

NOTE:

In ERR XXX, "XXX" refers to a numeric string. For example, ERR XXX can be ERR 100 or ERR 101.

9 Cleaning and Disinfection

Use the materials and methods described in this chapter to clean and disinfect the ambulatory infusion pump. Use of other materials or methods may damage the pump or shorten its service life.

CAUTION

- If you have any questions about the use of cleaning agents or disinfectants, consult your local distributor.
- Dispose of the waste generated after cleaning and disinfection according to the regulations of the relevant hospital.
- It is recommended that the pump should be cleaned and disinfected every week. If the pump has dirt or stains on the surface or the pump is stored in a home environment, clean and disinfect the pump before use.
- If the pump is used on multiple patients, the pump should be cleaned and disinfected before being used on each patient.

9.1 Preparations

Before you clean and disinfect the infusion pump:

- Disconnect the pump from the patient.
- Power off the pump.
- Remove the medication cassette reservoir and accessories connected to the pump, such as the PCA controller.
- Wear protective equipment such as a pair of medical gloves and a gauze mask in case that contaminants splash onto your skin during cleaning and disinfection.
- Prepare several lint free cloths, a cleaning agent container, and a disinfectant container.

NOTE:

Do not disassemble this pump for cleaning and disinfection. If you need to disassemble the pump, contact your local distributor.

9.2 Cleaning

WARNING

- Do not immerse the pump in a cleaning agent.
- Do not let a cleaning agent seep into the pump.
- Do not use halogenated solvents, petroleum-based solvents, glass cleaner, acetone, or other irritant cleaning agents.
- Only manual cleaning is allowed for the pump. Automatic cleaning is not allowed.

Cleaning procedure:

1. Immerse a lint free cloth in a neutral or weakly alkaline cleaning agent and then wring out the cloth.
2. Use the lint free cloth to wipe the surfaces of the pump until all contaminants are removed. Be sure to wipe every side and corner of the pump.
3. Use a dry lint free cloth to wipe off the residual cleaning agent.

Table 9-1 lists the cleaning agents recommended for the infusion pump.

Table 9-1 Recommended Cleaning Agents

Cleaning Agent	Cleaning Method
Clean water	Wipe
Soapy water (pH value: 7.0 - 10.5)	Wipe

9.3 Disinfection



- Do not immerse the pump in a disinfectant.
- Do not let a disinfectant seep into the pump.
- Use a disinfectant according to its instructions for use.
- Do not autoclave the pump.
- Only manual disinfection is allowed for the pump. Automatic disinfection is not allowed.

Disinfection procedure:

1. Before disinfection, clean the pump as instructed in *9.2 Cleaning*.
2. Immerse a lint free cloth in an intermediate-acting or high-acting disinfectant and then wring out the cloth.
3. Use the lint free cloth to wipe the surfaces of the pump. Be sure to wipe every side and corner of the pump. For information about the required contact time, see the instructions for use of the disinfectant.
4. After disinfection, immerse another lint free cloth in clean water, wring out the cloth, and then use the cloth to wipe off the residual disinfectant on the surfaces of the pump.

Table 9-2 lists the disinfectants recommended for the infusion pump and the required contact time.

Table 9-2 Recommended Disinfectants

Disinfectant	Contact Time	Disinfection Method
75% alcohol	3 minutes	Wipe
70% isopropanol	3 minutes	Wipe
0.2% quaternary ammonium salt	20 minutes	Wipe
3% hydrogen peroxide	30 minutes	Wipe

9.4 Air Drying and Transport



Do not dry the pump by using a drying machine or similar product.

After cleaning and disinfection, place the pump in a shady, cool, and ventilated environment for air drying.

If you are not going to use the pump soon after air drying, place the pump in its original package for future storage and transport.

10 Maintenance

WARNING All preventative and corrective maintenance and all such activities should be performed by Qualified Service Personnel only, with reference to the Service Manual.

10.1 Regular Maintenance

To ensure safe use and lengthen the service life of the infusion pump, perform regular maintenance on the infusion pump as described in the following table or perform maintenance when needed.

Maintenance Item	Frequency	Operator
Appearance check	Before each use	User
Infusion accuracy check	Every six months	Distributor/Hospital engineer
Alarm check	Every two years	Distributor/Hospital engineer
Electrical safety test	Every two years	Distributor/Hospital engineer

10.1.1 Appearance Check

- Check for signs of cracks or damage.
- Check whether buttons can be pressed smoothly and function properly.

10.1.2 Infusion Accuracy Check

Use a graduated cylinder and a stopwatch to check the infusion accuracy of the pump. Perform a test with the following conditions:

Medication Cassette Reservoir	Infusion Rate	Infusion Time	Liquid Volume in the Graduated Cylinder
150 ml	60 ml/h	10 minutes	9.5 - 10.5 ml

10.1.3 Alarm Check

- During startup, the infusion pump automatically checks the alarm system. You can check whether the alarm system works properly based on the following description. If an exception is found, stop using the pump and contact your local distributor or the manufacturer for repair.
  - Loudspeaker: alarm tone (di_di_di).
  - Alarm indicator: flashes in red and yellow alternately.
- Cass. Unlocked

During an infusion, open the cassette latch. Check the alarm message displayed on the screen and the alarm tone.

- Cassette Detached

During an infusion, detach the cassette reservoir from the pump. Check the alarm message displayed on the screen and the alarm tone.

- Air Bubble In Line

Add air into the infusion tubing to form a bubble of about 20 mm, set the single bubble level to 100 μl, and then start an infusion. When the bubble reaches the bubble sensor, check the alarm message displayed on the screen and the alarm tone.

- Patient-side OCCL

Perform a test with the following conditions to check the occlusion alarm:

Medication Cassette Reservoir	Infusion Rate	Occlusion Level	Alarm Time
150 ml	60 ml/h	1500 mmHg	<3 min

WARNING Check the alarm system of the infusion pump on a regular basis to ensure proper function.

10.1.4 Electrical Safety Test

To ensure safety, conduct a leakage current test according to the method stipulated in IEC 60601-1.

10.2 Repair

If you encounter any problem when using the infusion pump, report the problem to your local distributor and request for repair.

Do not disassemble or try to repair the infusion pump. The manufacturer and distributor shall not be responsible for any infusion pump that has been disassembled, modified or used for any purpose other than its intended purpose.

If the infusion pump falls to the ground or it is affected by an external force, stop using the pump even if it appears normal. Contact your local distributor or the manufacturer and have an inspection performed to check whether the pump can still operate properly.

10.3 Storage and Transport

■ **Storage**

- Avoid water spills on the pump.
- Do not store the pump in an environment with a high temperature and humidity.
- Protect the pump against vibration, dust, and corrosive gases.
- Keep the pump away from direct sunlight and ultraviolet ray.
- If the pump has been stored at the lowest or highest allowed temperature, place the pump at room temperature for at least half an hour before use.

■ **Transport**

The pump can be transported in a common vehicle and must be protected against drastic impact, vibration, and rain and snow splash during transport. In addition, the pump must be transported in accordance with the requirements stipulated in the order contract.

10.4 Disposal

- Information on disposal of Waste Electrical and Electronic Equipment

This  symbol on the product and/or accompanying documents means that used electrical and electronic products should not be mixed with household waste.

If you wish to discard electrical and electronic equipment, perform the following steps:

1. Power off the pump (refer to *6.11 Powering off the Pump*).
2. Take the pump out of the pouch.
3. Remove the medication cassette reservoir from the pump.
4. Remove the PCA controller. Plug the connector of the PCA controller out of the PCA port of the pump.
5. Remove the AA batteries from the pump.
6. Pack the pump, batteries, and accessories with dedicated medical waste bags and mark them properly.
7. Contact the importer for further disposal.

Disposing of this product correctly will help to save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

- Information on disposal in countries outside the European Union

This  symbol is only valid in the European Union. The product should be disposed of taking environmental factors into consideration. To prevent risks and hazards, remove the battery of the control board and dispose of as outlined by the local country regulations. All other components can be safely disposed of as per local regulations.

11 Infusion Characteristics

The following tests are performed in accordance with IEC 60601-2-24:2012 to monitor the infusion accuracy and occlusion alarm response time of the infusion pump. For detailed test conditions, see IEC 60601-2-24:2012.

In the following tests, the specification of medication cassette reservoirs is 150 ml.

NOTE:

- It is recommended that medication cassette reservoirs of designated brands should be used. Otherwise, infusion accuracy is not guaranteed and the alarm function may fail.
- The infusion accuracy and occlusion alarm response time of the infusion pump may be affected by the factors such as pressure, temperature, humidity, the medication cassette reservoir used, and the length of the infusion tubing.
- The monitored infusion accuracy does not reflect clinical standards such as the patient's age, weight, or prescribed drug.
- Under single-fault circumstances, the maximum infusion volume of the pump is ±10% or 0.4 ml.
- The following test results are only laboratory data.

11.1 Infusion Accuracy Characteristics

Start-up graphs and trumpet curves are provided to show the performance of the infusion pump after an infusion starts and the changes in the infusion status after the infusion rate reaches the preset value.

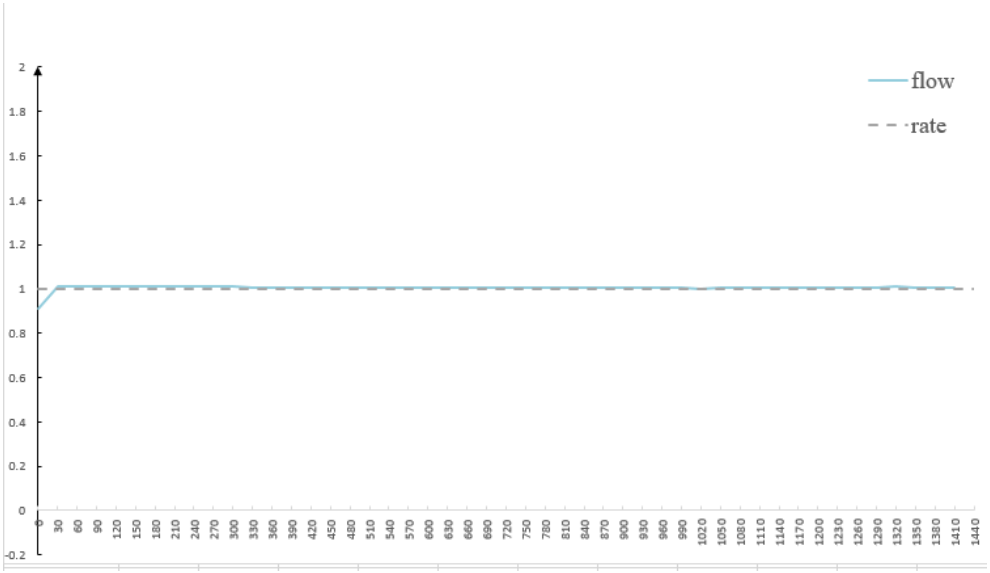
The following test is performed by using the method described in chapters 201.12.1.103 and 201.12.1.104 of IEC 60601-2-24:2012. For details, see the previous chapter.

■ **Accuracy test conditions (chapter 201.12.1.103)**

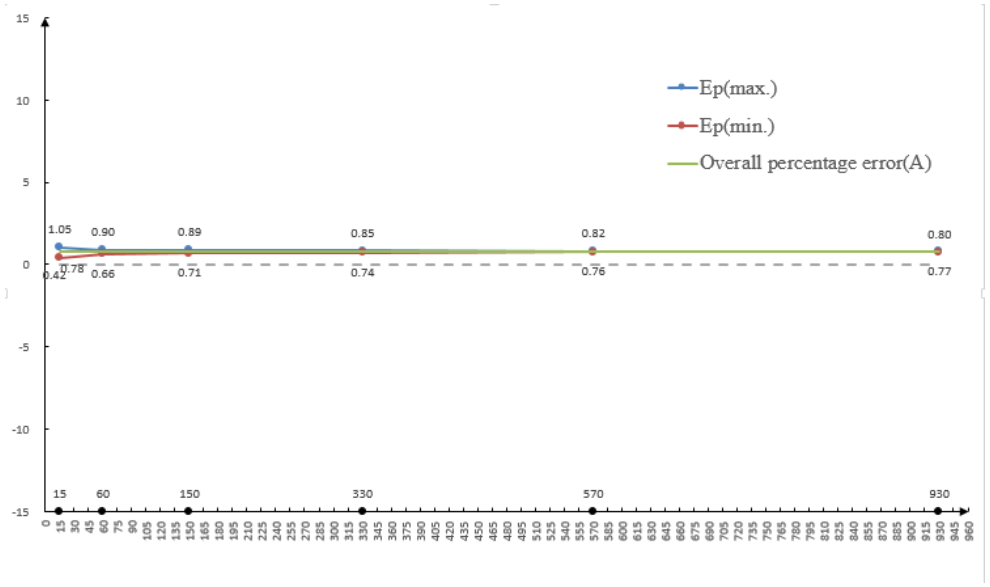
- Temperature: 20.5~21.7℃
- Relative humidity: 59.1~62.7%
- Medication cassette reservoir: MEDCAPTAIN LIFE SCIENCE CO., LTD (500ml); 1 pc
- Infusion pump: 1 pc
- Sampling interval: 15 min
- Test period: 2940 min
- Test liquid: ISO 3696:1987 Class III water

■ **Accuracy test results**

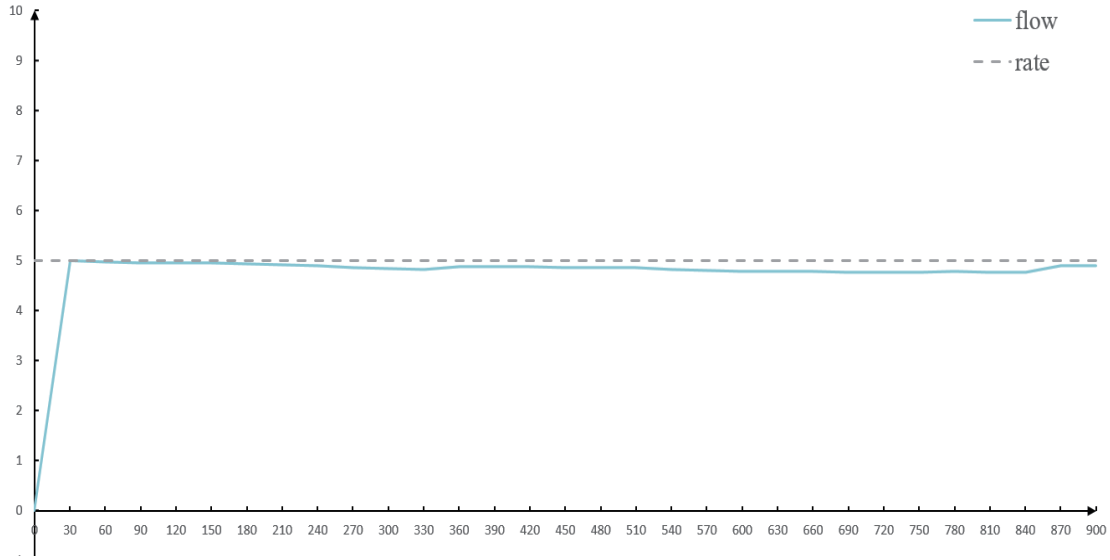
Start-up graph @ 1 ml/h



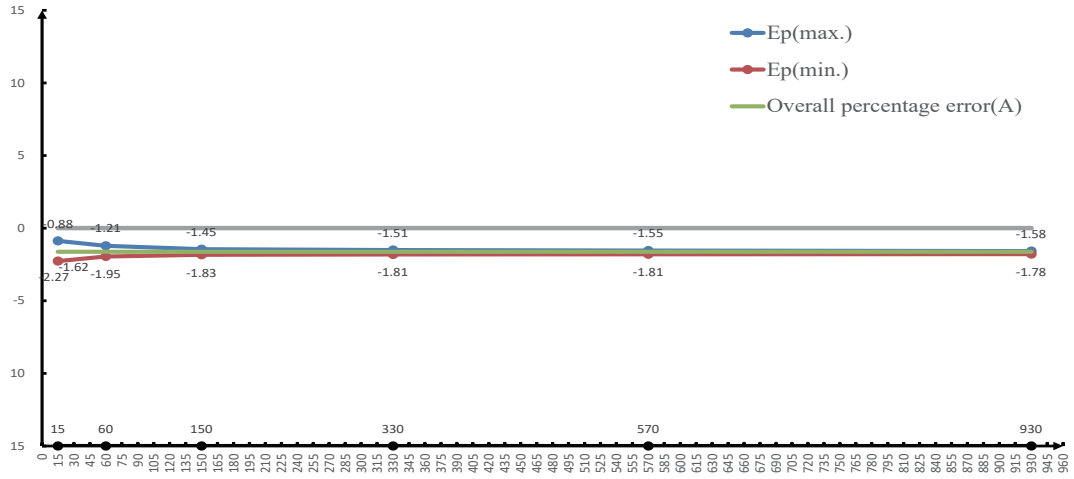
Trumpet curve @ 1 ml/h



Start-up graph @ 5 ml/h



Trumpet curve @ 5 ml/h

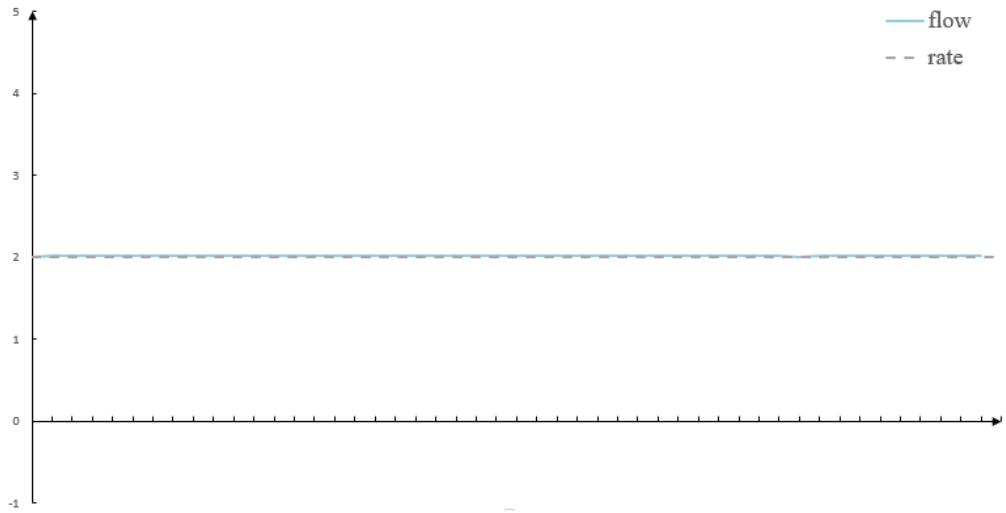


■ **Accuracy test conditions (chapter 201.12.1.104)**

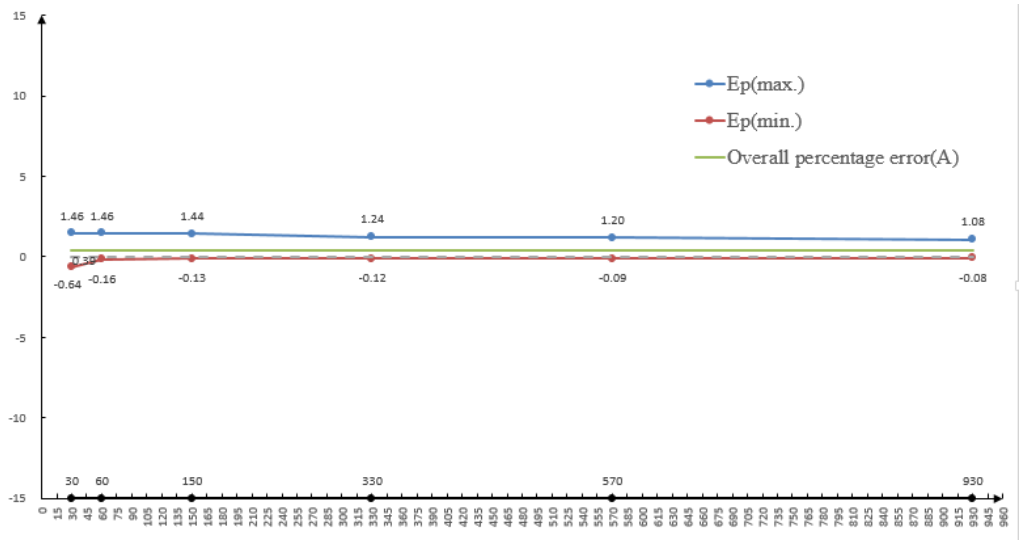
- Temperature: 22.5~24.1℃
- Relative humidity: 57.5~70.0%
- Medication cassette reservoir: MEDCAPTAIN LIFE SCIENCE CO., LTD (500ml); 1 pc
- Infusion pump: 1 pc
- Infusion mode: intermittent mode
- Preset infusion rate: 5ml/h (Actual infusion rate during sampling intervals: 2 ml/h)
- Preset single dose: 1 ml
- Sampling interval: 30 min
- Test period: 4440 min
- Test liquid: ISO 3696:1987 Class III water

■ **Accuracy test results**

Start-up graph @ 2 ml/h



Trumpet curve @ 2 ml/h



11.2 Occlusion Response Characteristics

The occlusion response characteristics of the infusion pump are reflected by the longest delay to start an alarm and the unintended bolus volume.

The following test is performed by using the method described in chapter 201.12.4.4.104 of IEC 60601-2-24:2012. For details, see the previous chapter.

■ **Occlusion test conditions**

- Temperature: 21.3~22.0℃
- Relative humidity: 61.5~62.2%
- Medication cassette reservoir: MEDCAPTAIN LIFE SCIENCE CO., LTD (150ml); 1 pc

- Infusion pump: 1 pc
- Length of the infusion tubing: 1m

■ **Occlusion test results**

Table 11-1 Occlusion Level, Alarm Delay, and Unintended Bolus Volume

Infusion Rate	Occlusion Pressure (mmHg)	Occlusion Alarm Time (h:m:s)
0.1 ml/h	750	03:00:00
	1500	06:00:00
1 ml/h	750	00:18:00
	1500	00:36:00

Infusion Rate	Occlusion Pressure (mmHg)	Occlusion Alarm Time (h:m:s)	Unintended Bolus Volume (ml)
5 ml/h	750	00:04:00	0.3
	1500	00:08:00	0.3

Table 11-2 Unit Conversions

Physical Variable	Unit	Unit Conversion
Pressure	kPa	1 kPa = 7.5 mmHg
	psi	1 psi = 51.715 mmHg
	bar	1 bar = 750 mmHg

Appendix A Electromagnetic Compatibility (EMC)

CAUTION

- The ELFensor P2/P5/P8 ambulatory infusion pump complies with the EMC standards IEC 60601-1-2:2020 and IEC 60601-2-24:2012.
- Users must install and use the ELFensor P2/P5/P8 ambulatory infusion pump based on the EMC information provided in the accompanying document.
- Portable and mobile RF (Radio-Frequency) communication devices may affect the performance of the ELFensor P2/P5/P8 ambulatory infusion pump. During use, keep the infusion pump away from such devices that may cause strong electromagnetic interference, such as mobile phones and microwave ovens.
- The declaration of emissions CLASS and group and Immunity level, please see the Appendix.
- The ELFensor P2/P5/P8 ambulatory infusion pump is suitable for home healthcare environments.
- The key performance of ELFensor P2/P5/P8 ambulatory infusion pump includes accuracy, unintended bolus volumes and occlusion, and high-priority alarm signals. If the key performance is lost or degraded due to EM DISTURBANCES, the ELFensor P2/P5/P8 ambulatory infusion pump may cause patient hazard.
- To assure that the ELFensor P2/P5/P8 ambulatory infusion pump remains safe with regard to electromagnetic disturbances throughout the expected service life:
  - Conduct periodic maintenance based on the recommended maintenance/service interval and method provided in the user manual.
  - After each maintenance, ensure that the internal structure, shielding system, and grounding system of the device remain complete and effective.

WARNING

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Only the following cables provided by the manufacturer are allowed to be used to meet the electromagnetic emission and anti-interference requirements:

Table 11-3 Cable Information

No.	Cable Name	Length (m)	Shielded
1	PCA controller cable	2	No
2	PCA controller cable	0.3	No

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment 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 ELFensor P2/P5/P8 Ambulatory Infusion Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration – electromagnetic emissions

The ELFensor P2/P5/P8 ambulatory infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of the ELFensor P2/P5/P8 ambulatory infusion pump should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment and Guidance
RF emissions CISPR 11	Group 1	The ELFensor P2/P5/P8 ambulatory infusion pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ELFensor P2/P5/P8 ambulatory infusion pump 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 for domestic purposes.
Harmonic emission IEC 61000-3-2	N/A	
Voltage fluctuation Flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity

The ELFensor P2/P5/P8 ambulatory infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of the ELFensor P2/P5/P8 ambulatory infusion pump should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment and 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 100KHz AC power cable ±2 kV 100KHz DC power cable (>3m) ±1 kV 100KHz SIP/ SOP cable (>3m)	N/A	N/A
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line ±0.5 kV, ±1 kV, ±2 kV Line-to-ground AC power cable DC power cable (>3m) ±2 kV Line-to-ground SIP/SOP outdoor cable	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º,225 º, 270 º and 315 º ; 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 º 0% 300 cycle	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	30kHz 8A/m 134.2kHz 65A/m 13.56MHz 7.5A/m	30kHz 8A/m 134.2kHz 65A/m 13.56MHz 7.5A/m	Induction Cooker and RFID reading device should be used no closer to any part of the ELFensor P2/P5/ P8 ambulatory infusion pump, including cables.

Guidance and manufacturer's declaration – electromagnetic immunity

The ELFensor P2/P5/P8 ambulatory infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of the ELFensor P2/P5/P8 ambulatory infusion pump should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment and Guidance
Conducted RF IEC 61000-4-6	3 V r.m.s. 150 kHz to 80 MHz; 6 V r.m.s. in ISM and amateur bands[a] between 0.15 MHz and 80 MHz; 80% AM at 1 kHz	3 V r.m.s. 150 kHz to 80 MHz; 6 V r.m.s. in ISM and amateur bands Between 0.15 MHz and 80 MHz; 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the ELFensor P2/P5/P8 ambulatory infusion pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz - 800 MHz $d = 2.3\sqrt{p}$ 800 MHz - 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)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz; 80% AM at 1 kHz 27V/m:380-390MHz; 28V/m:430-470MHz; 9V/m:704-787MHz; 28V/m:800-960MHz; 28V/m:1700-1990MHz; 28V/m:2400-2570MHz; 9V/m:5100-5800MHz;	10 V/m 80 MHz – 2.7 GHz; 80% AM at 1 kHz 27V/m:380-390MHz; 28V/m:430-470MHz; 9V/m:704-787MHz; 28V/m:800-960MHz; 28V/m:1700-1990MHz; 28V/m:2400-2570MHz; 9V/m:5100-5800MHz;	

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 0,15MHz 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 10,15MHz, 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] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/ portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] 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 ELFensor P2/P5/ P8 ambulatory infusion pump is used exceeds the applicable RF compliance level above, the ELFensor P2/P5/P8 ambulatory infusion pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ELFensor P2/P5/P8 ambulatory infusion pump.

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

Recommended separation distances between portable and mobile RF communications equipment and the ELFensor P2/P5/P8 ambulatory infusion pump

The ELFensor P2/P5/P8 ambulatory infusion pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ELFensor P2/P5/P8 ambulatory infusion pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ELFensor P2/P5/P8 ambulatory infusion pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz - 80 MHz (Outside ISM and amateur bands) $d = 1.2\sqrt{p}$	**150 kHz to 80 MHz in ISM and amateur bands)** $d = 1.2\sqrt{p}$	**80 MHz - 800 MHz** $d = 1.2\sqrt{p}$	**800 MHz - 2.7 GHz** $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* 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 separation distance for the higher frequency range applies.

NOTE 2 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 0,15MHz 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 10,15MHz, 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.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RF parameters - Wi-Fi

Item	**Description**
Working band	2412MHz~2484MHz, 4.9GHz~5.975GHz
Transmitting power	＜ 18dBm
Protocol	IEEE 802.11 a/b/g/n

RF parameters - Bluetooth

Item	**Description**
Working band	2.402GHz~2.480GHz
Transmitting power	-9dBm ~ +8dBm
Protocol	IEEE 802.15.1

Appendix B Default Factory Settings

This appendix lists some default factory settings of the ELFensor P2/P5/P8 ambulatory infusion pump. You can restore the infusion pump to default factory settings if necessary.

Parameter	Default Factory Setting
Infusion Mode	PCA mode
Prime Vol.	5 ml
C. Bolus VTBI	10 ml
KVO rate	1.0 ml/h
OCCL Level	750 mmHg
Pressure Unit	mmHg
Single Bubbles	400 μl
Total Bubbles	800 μl/15min
Alarm Volume	Medium
No AC Power	ON
Standby End	ON
Cass. Unlocked	Stop infusion
Reminder T.	2 min
Alarm Advance	3 min
Brightness	Level 5
Standby Time	24:00
Auto sleep	In-Infusion: 1 min Non-Infusion: 3 min
Date Format	Y-M-D
24h system	ON
Language	English

Appendix C Minimum IT Requirements

■ **Hardware**

2.4GHz or 5GHz wireless network

■ **IT networks characteristics**

- Support the TCP/IP communication protocol.
- Support the IPv4 protocol.

■ **IT security measures**

- Always deploy the wireless network according to local wireless regulations.
- Data communication for all network functions must be performed within the closed network or within the virtually isolated network provided by the hospital. The hospital is responsible for the security of the virtually isolated network.
- Ensure the security of encrypted information such as passwords. Do not expose encrypted information to unauthorized persons.
- Do not connect devices for non-medical use to the network.

Appendix D Parameter Units

Parameter	Unit
Drug amount	ng, ug, mg, g, unit, kunit, munit, mIU, IU, kIU, EU, mmol, mol, kcal, and mEq
Concentration	ng/ml, μg/ml, mg/ml, g/ml, unit/ml, kunit/ml, munit/ml, mIU/ml, IU/ml, kIU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml, and mEq/ml
Dose rate	X/min, X/h, X/kg/min, X/kg/h, X/24h, X/kg/24h, X/m^2/min, X/m^2/h, and X/m^2/24h Where X is the unit of drug amount, which may be ng, ug, mg, g, unit, kunit, munit, mIU, IU, kIU, EU, mmol, mol, kcal, or mEq.