SK-600 I
(This Operator’s Manual is also applicable for SK-600 I B infusion Pump)

Infusion Pump

Operator’s Manual
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- Installation, expansion, readjustment, improvement and maintenance must be operated by professionals authorized by SK Medical.
- All maintenance involving replacement of spare parts and its accessories, consumables should use the original sets or sets authorized by SK Medical.
- Relevant electrical equipment meets national standards and requirements of this Operator’s Manual.
- Please operate the product as per the Operator’s Manual.

⚠️ WARNING

- The device must be operated by professional clinicians or under the guidance of professional clinicians. The users must receive adequate product training. No unauthorized or untrained personnel should carry out any operation.
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Company Contact

Manufacturer: Shenzhen Shenke Medical Instrument Technical Development Co., Ltd
E-mail Address: http://www.skmedica.com
Service Hotline: +86 400 628 8806
Tel: +86 755 82402696
Fax: +86 755 82438567

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eifelstrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726
Preface

Manual Purpose

This Operator’s Manual describes the product’s application, function and operation in
details. Please read this Operator’s Manual carefully and understand the content
before use to ensure the proper usage and guarantee the safety of the patient and
the user.
This Operator’s Manual describes the product as per the most complete configuration.
Some content of this manual may not be applicable for the product on your hand.
Please contact us for any questions.
Please keep this Operator’s Manual beside the infusion pump in order to consult it
conveniently.

Intended Audience

This Operator’s Manual is only applicable for well-trained clinical people.

Illustrations

All illustrations in this Operator’s Manual are used for reference only. Its settings or
data may be not entirely consistent with the actual displayed info on the product.

Conventions

- *Italic* text is used in this manual to quote the referenced chapters or sections.
- The terms danger, warning, and caution are used throughout this manual to point
out hazards and to designate a degree or level of severity.
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1 Safety

1.1 Safety Information

The safety statements presented in this chapter refer to the basic safety information that the operator shall pay attention to and abide by. There are additional safety statements in other chapters or sections, which may be the same as or similar to the followings, or specific to the operations.

⚠️ DANGER

- Indicates an imminent hazard that, if not avoided, will result in death or serious injury.

⚠️ WARNING

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

⚠️ CAUTION

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

NOTE

- Provides application tips or other useful information to ensure that you get the most from your product.

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific “Danger” statements may be given in the respective sections of this manual.
1.1.2 Warnings

⚠️ WARNING

- This infusion pump is used for clinic infusion, do not for intestinal or gastric nutritional feeding solution. It can only be used by professional clinicians, medical electrical experts, or well-trained nurses on specific occasions.
- Infusion pump and its accessories must be inspected before use to guarantee its normal and safe operation.
- Avoid using this infusion pump in the flammable or explosive atmosphere in case of fire outbreak or explosion.
- Infusion alarms must be set based on the actual situation of the patients. Do not rely too much on the audible alarm system in the infusion supervision. Pay close attention to the actual clinical situation of the patient.
- Keep observing the remained liquid volume in infusion bags (or infusion bottles) and check if there is any air bubble in infusion tubes during the infusion. Do not rely on the alarm function of the infusion pump only.
- The pressure detector may not work normally in high-pressure environment, especially in hyperbaric oxygen therapy.
- Making sure the blood vessel is well protected before infusion.
- In the infusion tube, the occlusion caused by tube knot and filter coagulation or intubations may lead to the rise of the inner pressure of the infusion tube. At this moment, the effort to eliminate the occlusion may cause too much liquid to be infused into the patient's body with a large dose. Proper measures should be taken to prevent this phenomenon. For example, to clamp the infusion tube before occlusion elimination.
- This infusion pump should be used 120 CM above or below the patient’s heart.
- Avoid using the infusion pump when there is any alarm.
- When another set of infusion system or accessories is connected to the infusion tube used in this infusion pump, the operation of this pump may not meet its specifications.
- Only standard components, connectors and disposable products can be used with this pump. Subsidiary items are not allowed to be attached to the pump and its accessories. Reconstruction of the pumps is not allowed.
- The accuracy will not be maintained when the pump is used with the non-standard infusion tube or the parameters of the infusion tube are not set accurately. The maximum deviation may reach 40% or above.
● Disposable accessories must be disposed after use in accordance with the relevant regulations of the hospital.

● This infusion pump belongs to Class II (type of electric shock protection), the supplied Type I power cord PE earth terminal should not be used as ground protection and functional earthing.

● Do not open the case of the infusion pump, otherwise there might be electric shock. The infusion pump must be maintained or updated by maintenance staff trained and authorized by our company.

● Packing materials must be disposed in accordance with the relevant local statutes or the waste disposal regulations of the hospital. They must be kept out of the reach of children.

● The double thickness of the infusion tube should be between 0.8mm-1.2mm. Outer diameter should be between 3.5mm-4.5mm. Otherwise, its accuracy can not be guaranteed, which may cause severe injury to patients.
1.1.3 Cautions

⚠️ CAUTION

- Please use the accessories specified in this Operator’s Manual to guarantee the safety of the patient.
- Cables must be connected carefully to reduce the possibility of the patient getting intertwined or choked.
- Disposable accessories can only be used once. Repeated use may lead to declined performance or cross-infection.
- When installation of the infusion tube is Over, please observe whether there is leakage before the infusion. If any leakage the machine should be examined and processed immediately.
- Adjust the fixing place of the infusion tube every 4 hours after infusion begins to guarantee the accuracy. Replace the infusion tube after the infusion lasts for 24 hours.
- This infusion pump or its accessories must be disposed in accordance with local statutes or hospital regulations after its operating life. Please contact the distributor that sells the product to you or the manufacturer if there is any inquiry.
- Electromagnetic field may influence the performance of the infusion pump. Therefore, equipments or devices used near the infusion pump must meet the EMC standard. Mobile phones, X ray or MRI equipments are all potential interference sources because of their high-intensive electromagnetic radiation.
- Avoid the direct sunshine, high temperature or humidity.
- Avoid exposing this infusion pump to high-pressure sterilization or chemical materials.
- Check the built-in battery before use to make sure the power is enough. Recharge the battery if necessary.
- Before the infusion pump is connected to the power supply, make sure the voltage and frequency of the power supply meet the label of the pump or the specific requirements in this Operator’s Manual.
- Please install and carry the infusion pump appropriately to protect the pump from drop, impact, strong oscillation or other damage caused by machinery external force.
- Use a piece of wet soft cloth with warm water to wipe the surface of the infusion pump when there is any liquid on.
● If the surface tension, proportion and viscosity of the infusion solution is different from saline (for example, a kind of solusion mixed with surface activating agent), the infusion accuracy may be different from the accuracy listed in the specifications table.

● When the infusion rate is high (≥ 1000ml/h), high-quality silicone tubes with 0.9mm transfusion needles must be used with the pump to keep the infusion accuracy.

● If the infusion pump fails to work as specified in the Operator’s Manual due to any uncertainty, please stop infusion, and report the situation (including infusion accessories used with the pump, infusion volume, infusion rate, SN No., liquid type, etc.) to your supplier or our company.

● The drop sensor is not applicable for light-proof medicine infusion. Adopting light-proof IV sets on the pumps might cause failure operating of drop sensor and sever damage to the patients.

1.1.4 Notes

NOTES

● Please keep this Operator’s Manual along with the infusion pump for the convinent and timely reference.

● Please install the infusion pump to the place convinent for observation, operation and maintenance.

● This Operator’s Manual describes all the configuration and functions of the infusion pump. The infusion pump you buy may not have some of the configuration or functions.

● Please do not insert devices which are not specified by our company to the data interface.

● The SN No. of this infusion pump has been set. Users are not allowed to change it.
1.2 Equipment Symbols

Note! Please refer to the Operator’s Manual

Class II Equipment

Type BF applied parts

Splash-proof

Alternating Current Power Supply (AC)

Direct Current Power Supply (DC)

Batch No.

Serial No.

Date of Production

Manufacturer

Pollution-Free Treatment

Wireless transceiver

Upward or Add Value

Downward or Reduce Value

Confirm

Setting

Stop

Alarm silence

Start

Bolus

Clear

Select

Turn on

Turn off

Decimal point

Transport package fear of rain

Fragile items, handle with care

Transport should be straight up

The same packing stacked up to 5-layers

Authorised Representative in the European Community.

This product meets the EU Medical Device Directive 93/42/EEC and the basic requirements in Directive Appendix I, hence the CE mark.
2 The Basics

2.1 Product Introduction

2.1.1 Application Scope

This infusion pump is used in wards, operation rooms, and observation rooms for accurate and continuous infusion to patients. Do not for intestinal or gastric nutritional feeding solution.

Any institutes or units, such as hospital outpatient, emergency rooms, wards, operation rooms, observation rooms, clinics, nursing home, etc., capable enough to provide health care, is expected to use this infusion pump.

⚠️ WARNING

- Check the infusion pump and its accessories before use to ensure its normal and safe operation.

⚠️ CAUTION

- The operation environment and power supply of this infusion pump must meet the requirements in A. Product Specification.

2.1.2 Contraindications

None

2.1.3 Product Structure, Composition and Performance

SK-600 I / 600 I B Infusion Pump consists of the case, pump device, the board card and battery, etc.

SK-600 I / 600 I B Infusion Pump contains the following parts:

- **Microcomputer System**: the core of the whole system, which gives intellectualized control and management over the whole system and processes detection signals. In this system, two single-chip Micyoco (SCM) systems are adopted for mutual backup copy and supervision. When one SCM goes wrong, the other one will give a timely warning signal and cut the power of the host computer to stop the pump with the purpose to ensure the patient’s safety.
- **Pump Device:** the power source of infusion, employs step motor to drive the pump tablets continuously extruding upon infusion tube to materialize infusion.
- **Detection Device:** the device mainly includes all kinds of sensors, like air bubble sensor (detect air bubble inside the infusion tubes), pressure sensor (detect the pressure inside the infusion tube), etc.
- **Alarm Device:** the device mainly includes audible alarms and information alarms, drawing the user’s attention to the correct operation.
- **Input and Display Device:** the input device is in charge of setting infusion parameters, such as flow rate, etc. While the display device is in charge of displaying all the parameters and the current working status on the screen.
- **Built-in Battery:** the battery sustains the operation of the infusion pump when there is no AC power supply.

The performance of SK-600 I / 600 I B Infusion Pump:
- Accurate control of flow rate.
- Accurate control of infusion volume.
- Timely alarms for air bubble, over, occlusion, low battery, infusion tube installation error, and control abnormal, etc.
2.2 Appearance

2.2.1 Front Panel

1. Running indicator light

   The light is on and flashes during infusion when the infusion tube was properly installed.
2. SET key
   To set flow rate, volume limit, and Bed No.

3. STOP / SILENCE key
   - In running status, press this key to stop infusion. When the alarm is on, press this key to silence the alarm (except low battery alarm).
   - In value inputting status, press this key to stop saving the value newly set and quit.

4. CLEAR key
   In Stop status, press this key to clear accumulated volume.

5. SELECT key
   Select the needed parameter at setting interface.

6. Infusion tube
   Please use infusion tube in accordance with standards.

7. Display screen
   It displays working status and all parameters information.

8. Value-increase keys
   Press the keys to increase values respectively by 100, 10, and 1.

9. HANDLE
   - Pull up the handle: to install or take off the infusion tube
   - Push down Handle: to tightly clamp the tube. The running indicator light is on if infusion tube is well installed when the handle was pushed down.

10. Value-decrease keys
    Press the keys to decrease values respectively by 100, 10, and 1.

11. START/ BOLUS
    In stop status, if the infusion tube is correctly installed, press this key to start infusion. During infusion, by keeping your finger on the key as long as you need for bolus function, the pump shall start the bolus function after a few seconds (when flow rate is ≤600ml/h). After removing your finger from the key, it will return to its original infusion rate.

12. POWER key
    - Turn on the machine: Press the key and then release.
    - Turn off the machine: Press this key and then release.
    - Backlight: press it once to open or close display screen backlight
2.2.2 Back Panel

1. Vents
2. Power tab
3. Power socket
4. Fixing Clamp
5. Drop sensor socket (drop sensor is a selective purchasing accessory)
6. Product label
2.3 Screen Displaying

This infusion pump is built with LCD screen. The displayed information contains four major parts:

1. AC Power Information
   Displaying AC Power and battery icons
2. Functional Modes
   Displaying Current functional modes
3. Alarm information
   Displaying alarm information, e.g. air bubble, occlusion, empty, over.
4. Parameter setting
   Displaying Parameter under setting or working parameters

2.4 Battery

2.4.1 Overview

The infusion pump uses build-in rechargeable battery to guarantee the normal use of the pump during patients transfer or electricity fails in hospital. The battery will charge itself automatically once the pump is connected to the AC power and in Power on situation. The pump shall work with its battery in case of sudden electricity break down.

The battery shall provide the power for normal operation of the pump for a certain while, once the battery capacity reaches the lowest voltage, the pump will trigger a low voltage alarm every few seconds to notice the users; after a certain while, the pump shall trigger a serious low battery alarm with the battery indicator light flashes and a rapid and short alarming sound. If the pump is working at this time, it will stop infusion automatically and will not work until it is connected to the AC power. The low battery alarm will be eliminated only after the pump is connected to the AC power.
WARNING

- Keep the battery out of the reach of children.
- Use only the battery specified by the manufacturer.

NOTE

- When the battery capacity is 0 and in low battery condition, an alarm will be triggered within a few seconds to remind the users of low battery. Shortly after low battery alarm, the pump shall trigger a serious low battery alarm, the indicator light shall flash and the pump will give a rapid and short alarming sound. If the pump is in working status, it will stop infusion automatically and it can not be used for infusion until it is connected to the AC power. The serious low battery alarm will be eliminated when the pump is connected to the AC power.
- 8-14 hours will be needed to fully charge the battery.
- Please discharge the battery every three months to prevent damage of the battery if the product is not used very often.
- Battery is a consumable part. Please replace it when it is exhausted.
- In case the battery needs to be changed, please contact the local distributor or manufacturer.

2.4.2 Battery Guidelines

The life span of the battery depends on its usage frequency and environment. If proper usage and maintenance are adopted, its life span is 3 years. Otherwise, its life span will be deducted. The battery shall be replaced every 3 years. For safety usage and capably extend a longer battery life, please follow the battery instruction:

- Yearly battery check is needed. Before the pump is sent for maintenance purpose or you doubt the battery is the causing reason, the battery checked is needed.
- Optimize the battery every three months of use (or storage), or once the running hours of battery is significantly shortened.
- Using 1C current (1C current shall be larger than the working current of the working plate, the max charging current of the protection plate is the working current of protection plate) 8.4v voltage limiting to charge the battery for 0.5hour in order to guarantee the battery is stored with electricity.
2-8

WARNING

- Using the battery provided by the manufacturer.
- Please replace the battery once the battery is damaged or leaks
- Damaged battery shall not be used
- The used battery shall be returned to the distributor or manufacturer, or be disposed according to applicable laws.

2.4.3 Battery Maintenance

2.4.3.1 Conditioning a Battery

Optimize the battery when it is used for the first time. A complete optimizing cycle includes: continuously charging until the battery is fully charged, then discharge the battery until the pump powered off automatically. Then charge the battery continuously again. During the usage, a regular optimize battery performance will extend its life span.

NOTE

- The actual battery capacity will reduce after the battery is used for some time. If the battery capacity is shortened obviously during optimizing, please replace the battery.

Please follow the steps below during optimizing:
1. Disconnect the infusion pump the patients, stop the infusion.
2. Connect the infusion pump to the AC power, charging continuously for 12 hours.
3. Disconnect the infusion pump and the AC power, using the battery as the power supply until the infusion pump powered off automatically.
4. Connect the infusion pump to the AC power, charging continuously for 12 hours
5. Optimizing battery performance is Over.
2.4.3.2 Checking a Battery

Regular check for the battery is needed due to the reason that the battery function will decrease during usage. Please follow the steps below when checking battery function.

1. Connect the pump to the AC power, charging continuously for 8 to 14 hours.
2. Disconnect the AC power supply and let the machine work on battery until it is turned off due to battery exhausting.
   - If the battery works for over 200 minutes, the battery is in fine condition.
   - If the battery works for 60 to 200 minutes, the battery is close to the end of its life.
   - If the battery works less than 60 minutes, the battery needs to be replaced.
3. Please charge the battery for future usage after checking.

**NOTE**

- If the using time of the battery is too short after full-charge, there might be a damage of the battery. The power supply time of the battery depends on the using frequency of the pump and its setting parameters. E.g. the display is in backlight mode.
- If the battery has obvious damage (deformation, bumps, leakage) or can not reach the capacity, it should be replaced and recycled.

2.4.4 Battery Recycling

If the battery has obvious damage (deformation, bumps, leakage) or can not reach the capacity, it should be replaced and recycled. Please follow the applicable laws during recycle.

⚠️ **WARNING**

- The battery must not be disassembled, thrown into fire or short circuited. The burning, explosion and leakage of the battery may cause personal injury.
3 Installation and Maintenance

3.1 Installation

⚠️ WARNING

- The software copyright of this infusion pump belongs to our company. Any infringement act such as falsification, reproduction or exchanging by any means or in any form by any organization or individual is not allowed without permission.

3.1.1 Out of Box Audit (OOBA)

Before opening the box, please check the package carefully to find if there is any damage to the products during transportation. If there is any damage, please contact the forwarder or our company immediately.

If the package is intact, please open the package in right way, take out the infusion pump and its accessories with care, and check them out in accordance with the packing list. Please examine if there is any mechanical damage to the pump and whether the package includes all things on the packing list. Please contact our customer service department immediately if there is any inquiry.

⚠️ WARNING

- Please keep the packing materials out of the reach of children. The packing materials must be disposed in compliance with the local laws and regulations or the hospital policy on waste treatment.

NOTE

- Please keep the packing case and packing materials for the future use.
- Please contact the sales agent or our company if any of the spare parts is missing when you open the package.
- When the infusion pump is not connected to the AC power supply, after several seconds, it will give a sound of ‘di...alarm for ' no AC power supply’.
3.1.2 Environmental Requirements

The service environment of this infusion pump must meet the requirements in *A.2 Product Specifications*.

The service environment of this infusion pump should also be appropriately protected from noise, vibration, dust, or corrosive, flammable or explosive, Substances. There should be 2 inch (5cm) interspace around the infusion pump to make sure the air moves freely.

When the infusion pump is transferred from one place to another, the difference in temperature and humidity may cause condensation to the infusion pump. In this case, please do not turn on the pump until there is no condensation.

3.1.3 Power Supply Requirements

The power supply of this infusion pump must meet the requirements in *A.3 Product Specifications*.

⚠️ WARNING

- Make sure the working environment and power supply meet the environmental requirement and the power supply requirement listed above. Otherwise, the infusion pump will not meet the technical specifications claimed in *A Product Specifications*, and it may also cause the unexpected consequence such as device damage.

- The power supply must be selected in accordance with the settings of the system power voltage. Otherwise, it may cause sever damage to the system.
3.1.4 Fix Infusion Pump

[Figure 3-1]
Direction for fixing infusion pump as shown in Figure 3-1:
1. Steel tube of infusion pump stand
2. Screw of clamp
Steps to install infusion pump to infusion pump stand:

1. As shown in Figure 3-2, for convenience, counter-clockwise twist the clamp knob and make enough room for the installation of the pump on the stand.
2. As shown in Figure 3-3, place the stand at a position corresponding to the clamp, and then twist the clamp knob clockwise till the infusion pump installed well on the stand.

**NOTE**

- The infusion pump must be put horizontally.
- Please make sure the stability of stand before installation.

### 3.1.5 Install Power Cord

Plug the power cord into the outlet of the machine.

**NOTE**

- Applicable power supply scope is: 100-240V~, 50/60HZ.
- A.C power cord should be inserted properly and tightly.

### 3.1.6 Installation of Drop Sensor (Optional)

**NOTE**

- This section has to be used with the optional Drop Sensor. The user may skim over the instruction in the section, if Drop Sensor is not equipped with the infusion pump.
- The Drop Rate function can be started only when the rate ≤ 400ml/h.
1. Firmly insert the power cord of Drop Sensor to the connecting port on the rear panel, and make sure the volume of the liquid to be filtered less than 1/3 that of the liquid filter at meantime.

2. As shown in Figure 3-5, the Drop Sensor to be clipped to the liquid filter (the direction of pressure by hand as shown in Figure 3-4) must be over the liquid interface.

**NOTE**

- The liquid interface in the filter must be lower than the Drop Sensor.
- The positioning block of the filter must be vertically inserted through the positioning groove of the Drop Sensor.
- The infusion tube/pipe must be changed by a new one after continuously working over 24 hours.
- Do not incline the drop rate sensor, or expose it to sunshine during infusion.
- Make sure that the medicine liquid filter is not clamped too tightly by the drop rate sensor.
3.2 Maintenance

⚠️ WARNING

- The hospital or medical establishment using this infusion pump must set up a complete maintenance plan. Otherwise, it may cause device failure or some unexpected consequence, and even threaten the personal safety.
- All the safety inspection or the maintenance work which involves the disassembling the device must be proceeded by the professional maintenance personnel. The operation of any unqualified people may cause device failure and even threaten the personal safety.
- Please contact the distributor or our company immediately if you find any problem of the pump.

3.2.1 Inspection

The pump must be given an overall inspection before use, after 6~12 months’ continuous use, or after maintenance or updating to ensure the normal operation and work.

The inspection standards are:
- The environment and power supply meet the requirements
- The battery performance
- The power cord has no abrasion and is well performed in electric insulation.
- Pass the leakage current test.
- The devices and accessories have no mechanical damage
- The accessories used with the pump are specified.
- The alarm system is well functioned.
- No leakage after installation of the infusion tube
- The pump works well under all infusion modes.

If there is any pump damage or abnormal phenomena, please do not use the infusion pump, and immediately contact the distributor or our company.

3.2.2 Cleaning

The pump must be cleaned or disinfected with the materials and methods listed in this chapter. Otherwise, our company will not take the responsibility for any damage or accident caused by the cleaning and disinfection with other materials and methods.
Our company will not take any responsibility for the effectiveness of the infection control with the following chemicals or methods. Please contact the infection prevention department of the hospital or epidemic experts for the method of infection control.

Please keep your devices and accessories away from the dust, and comply with the following provisions to prevent the device damage:

- Please dilute the cleanser and disinfectant in accordance with the manufacturer’s indication, or with their concentration as low as possible.
- Do not submerge the pump in the liquid.
- Do not dump the liquid on the device or its accessories
- Prevent liquid from the pump body.
- Do not use the abrasive material (such as steel wool or silver polishing agent) and any strong dissolvent similar to acetone and acetone to prevent outer shell damaged.

⚠️ WARNING

- Please turn off the power and disconnect the AC power supply before cleaning the device.

⚠️ CAUTION

- Please turn off the power and disconnect the AC power supply before cleaning the device. If the liquid is dumped on the infusion pump or its accessories by accident and make the infusion pump not work; please contact with the agent or manufacturer.

The device should be cleaned regularly. The cleaning frequentness should be improved in areas with serious environmental pollution or heavy wind and sand. Please consult or refer to the specific regulations about device cleaning in the hospital.

The recommended cleansers are:

- Warm water
- Diluted soap water
- Diluted aqua ammonia
- Sodium hypochlorite (bleaching power for washing)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)
When cleaning the device:
1. Turn off the power, and disconnect the power cord.
2. Wipe the case with soft cotton balls adsorbing the cleanser.
3. Wipe the surface of the device with soft cloth adsorbing 75% of alcohol.
4. Keep the device in the cool and ventilated environment to dry up.
The above steps are for reference only. Disinfection effects should be checked with the correct method.

⚠ CAUTION

- Do not use gas (EtO) or formaldehyde for sterilization.

3.2.3 Preventive Maintenance

1. Check the Infusion Rate
   Using measuring cylinder and stopwatch to check the infusion volume for every 6 month.
2. Maintain the Battery Performance
   Please refer to 2.4.3 Battery Maintenance
3. Regular Maintenance

<table>
<thead>
<tr>
<th>Interval</th>
<th>Routine Maintenance Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>According to the</td>
<td>Thoroughly clean the feeding pump shell before or after</td>
</tr>
<tr>
<td>hospital policy</td>
<td>long period of storage.</td>
</tr>
<tr>
<td>Check to the pump at</td>
<td>1. Check the AC power plug and power cord.</td>
</tr>
<tr>
<td>least once a year.</td>
<td>2. Run the machine until it gives a low battery alarm.</td>
</tr>
<tr>
<td></td>
<td>Then charge the battery to ensure it works and recharge well.</td>
</tr>
<tr>
<td></td>
<td>3. Check if the machine leakage after correct installation of feeding set</td>
</tr>
</tbody>
</table>

3.2.4 Pollution-Free Treatment and Recycling

The service life of this product is 3 years. The pump exceeding its service life should be discarded. Please contact the manufacturer or distributor for more relevant information.
You can make the following treatments:
1. SK-600 I / SK-600 I B infusion pump that has been scrapped could be sent back to its distributors or manufacturer for proper recycling.
2. Used-up lithium polymer batteries could be delivered to its distributor or manufacturer for disposition, or treated according to corresponding regulations.
4 Operation Guide

4.1 Operation Flow Chart

1. Fix the infusion pump
2. Start the infusion pump
3. Install infusion tube
4. Set infusion parameter
5. Eliminate air bubble from Infusion
6. Clear accumulated volume
7. Insert infusion accessories into patient
8. Start infusion
9. Infusion completed
10. Shut down the infusion pump

Fix the infusion pump on the stable infusion tube stand;
Press the key .
Fix the infusion tube to the groove bottom of the pump straightly, and check if there is any leakage after well installation of the infusion tube;
Press the key to set parameter;
Press the key to infusion firstly and then the key after air bubble eliminated from infusion tube;
Press the key ;
Connect infusion accessories to the patient;
Press the key .
Press the key .
Press the key .
4.2 Operation Steps

NOTE

- Part of this section covers the function of Drop Sensor. If the user needs to use this function, it is necessary to choose Drop Sensor as accessory to the infusion pump. For more details, please consult the distributor that sells the product to you or the manufacturer.

4.2.1 Start Infusion Pump

After fixing the pump, please take the following steps to turn on the machine:

1. Please refer to 3.2.1 Inspection to make safety inspection before turn on the pump;

2. Press the key $\%$. The pump will start self-checking. LCD will display the software version and the machine will play the start-up music;

3. After a few seconds, the pump will finish the self-checking and enter the main interface;

4. Now user can operate the pump by keypad and panel.

NOTE

- Symbol of power plug displayed on LCD means that the pump is supplied by A.C power.

- Press the key $\%$ to open or close backlight of LCD when the pump is turned on.

- The battery can be recharged only when the machine is connected to AC power and the machine is turned on.
4.2.2 Install the Infusion Tube

(1) Pull out the door lock as the arrowhead’s.

(2) Pull straight the infusion tube.

Install the two ports of infusion tube to the bottoms of the infusion groove.

(3) Place the infusion tube to the bottom of the pump’s groove straightly and horizontally.

(4) Pull down the handle after installation.
**WARNING**

- Pull down the handle after installation of infusion tube properly when the pump is on. When green indicator light is on, it means the infusion tube is proper installation. Otherwise, infusion tube need reinstallation.
- When use the same infusion tube, change the part of pipe installed in groove of machine every 4 hours. The enteral feeding pipe should be discarded after 24 hours of continuous using.
- Infusion tube is loose or pulled too tightly, which may cause abnormal infused volume.
- The double thickness of the infusion tube should be between 0.8mm-1.2mm. Outer diameter should be between 3.5mm-4.5mm. Otherwise, its accuracy can not be guaranteed, which may cause severe injury to patients.

**CAUTION**

- After installation of infusion tube and before infusion, please check if there is any leakage. If so, please check the machine and installation of pipe.

### 4.2.3 Setting Infusion Parameters

1. Press the key 🌐 to make the pump in stop condition.
2. Press the key 🌘 to enter setting interface of infusion parameters. Press the key 🔁 to select rate, volume limit and bed No.. The parameter is flashing when it is selected. Press the key ⬅️ or ➤️ to adjust the value, press the key ✍️ to save the parameter newly setting.

### 4.2.4 Clearing Accumulated Volume

Press the key 🗑️ to clear the accumulated volume when the machine is in stop condition.
NOTE

- The accumulated volume can be cleared only when the infusion pump is in stop status.

4.2.5 Starting Infusion

After setting all the parameters and proper installation of the infusion tube, press the key, the motor begins to run, and the pump starts infusing. The indicator light is flashing when the machine is working.

NOTE

- The pump will stop working automatically once the serious low battery alarm sounds during the infusion.

⚠️ WARNING

- The pressure calibration interface has no occlusion alarm. Do not carry out the infusion operation in order to prevent any severe harm to patients.

4.2.6 Infusion Over

When the accumulated volume reaches the volume limit, the LCD will display “Over” and sends an audio-visual alarm to alert the user that the infusion is finished. Press the key to stop the infusion.

4.2.7 Shutdown

Please take the following steps to turn off the infusion pump:

1. Disconnect infusion tube between patient and the pump.
2. Press key. After the backlight flicker seconds release the key, the power is turned off.
NOTE

- The battery cannot be recharged when the machine is turned off
- Rate and the other parameters shall return to default values after machine is turned off
5  Function and Interface

5.1 System Function Setting

5.1.1 Setting Flow Rate

As shown in Figure 5-1, turn on the infusion pump to enter the infusion mode interface. Press key in “Stop” status to enter the mode of parameters settings. Press key to select the flow rate, volume limit and bed No. in turns. Flow rate parameter will keep flashing when it is selected. Please select the corresponding value from “100”, “10”, or “1” first, and then press key or key to increase or reduce 100, 10, or 1 from the initial value. Press to save the value newly setting.

NOTE

- The rate setting range for SK-600 I: 1~600 ml/h
- The rate setting range for SK-600 IB: 1~2000 ml/h

5.1.2 Setting Volume Limit

As shown in [Figure 5-2], turn on the infusion pump and press key in “Stop” status to enter the parameters setting status. Press key to select the volume limit, and the parameter will keep flashing. Please select the value from “100”, “10”, or
“1” first, and then press $\left\uparrow\right\downarrow$ key or $\left\downarrow\right\uparrow$ key to a increase or reduce 100, 10, or 1 from the initial value. Press $\text{SET}$ to save the value newly setting.

![Figure 5-2](image)

**NOTE**

- **Volume Limit**: 1~9999 ml/h

### 5.1.3 Setting Bed No.

As shown in [Figure 5-3], turn on the enteral feeding pump and press $\text{Bed}$ key in “Stop” status to enter the parameters setting status. Press $\text{Bed}$ key to select the Bed No., and the parameter will keep flashing. Please select the value from “100”, “10”, or “1” first, and then press $\left\uparrow\right\downarrow$ key or $\left\downarrow\right\uparrow$ key to increase or reduce 100, 10, or 1 from the initial value. Press $\text{SET}$ to save the value newly setting.

![Figure 5-3](image)

**NOTE**

- **Bed No. Setting Range**: 1~100
5.2 Starting Bolus Function

During the infusion, if you need to accelerate the infusion when the current flow rate is under the bolus rate (600ml/h), please keep pressing \( \text{key to increase the flow rate to 600ml/h, and release the key to return to the original flow rate.} \)

**NOTE**

- The bolus function should be used under normal infusion.
- The bolus function will not affect any alarm functions.
- The flow rate for the bolus function is 600ml/h, and is not adjustable.

5.3 Pressure calibration

Under the infusion pump starting state, simultaneously press the 100-increment key \( \text{and the 10-increment key } \) to enter into the interface of pressure sensor calibration as shown in Figure 5-4.

![Figure 5-4]

1. Connect infusion tube and pressure gauge to the infusion pump;
2. Set rate (100ml/h is to be recommended when setting rate. Simultaneously press the 100-increment key \( \text{and the 10-increment key } \) to enter into the interface of pressure sensor calibration);
3. Start infusion by pressing the key \( \text{;}
4. Press the 100-decrement key \( \text{ to stop motor when the pointer of pressure gauge reads 100kpa and then the 10-decrement key to save the result of calibration and exit the interface.} \)
NOTE

- The pressure factor ranges from 40 to 150. Please save the factor if it is within the normal limits, and exit from the interface; if not, there will be voice prompts and the calibrated parameter is just the value saved last time.
- It is necessary to calibrate the pressure when the material of infusion tube is too hard or soft.
- To turn off the infusion pump on the interface of pressure calibration is not allowed.

5.4 Changing Brand of Infusion Tube

We test and set this infusion pump with “Dragon Heart” brand of enteral feeding pipe with the model of “IS-G-V3(1)”. If you use the other brand of feeding pipes with the pump, please reset the parameters of this enteral feeding pipes in the following steps:

Step 1: Prepare a new enteral feeding pipe.

Step 2: Turn on the enteral feeding pump to enter the main menu interface.

Step 3: Install the enteral feeding pipe as per normal procedures.

Step 4: In the main menu interface, press key and key at the same time to set the parameters of the new enteral feeding pipe.

5.4.1 Selection of infusion tube

This infusion pump can save the parameters of 3 different brands of infusion tubes. “A”, “B”, or “C” displayed on the top right corner of LCD stand for infusion tubes of Brand A, Brand B and Brand C respectively. Press key and key at the same time, the parameters of the enteral feeding pipe in use will be displayed on the screen as shown in [Figure 5-5]. You can select different enteral feeding pipe at the moment.

[Figure 5-5]
If you need to change the brand of the infusion tube or set its corresponding parameters, please take the following steps:

Press \( \text{C} \) key and \( \text{\leftarrow} \) key (which stands for the increment of 100) at the same time as is shown in [Figure 5-6]. The LCD will display A on the top right corner.

Press \( \text{C} \) key and \( \text{\leftarrow} \) key (which stands for the increment of 10) at the same time as is shown in [Figure 5-7]. The LCD will display B on the top right.

Press \( \text{C} \) key and \( \text{\leftarrow} \) key (which stands for the increment of 1) at the same time as shown in [Figure 5-8]. The LCD will display C on the top right.

According to the above steps, press the key \( \text{C} \) to cyclically select parameter of infusion tube on the infusion tube parameter setting interface. When the parameter flashes, increase or decrease the parameter value by pressing the key \( \text{\leftarrow} \) or \( \text{\rightarrow} \) and finally save it by pressing the key \( \text{C} \).

### 5.4.2 Calibrate the Accuracy

![Figure 5-9]
When there is error during infusion or change to a new infusion tube, please recalibrate the accuracy of the pump as follows:

**Step 1:** Turn on the infusion pump, set the flow rate at 150ml/h and preset volume at 20ml. Start infusion after installation of new brand of feeding pipe properly. Use the measuring cup to measure the liquid volume flowed from the infusion tube.

**Step 2:** If the liquid flowed into the measuring cup is more than the volume limit (20ml), please add 3 to the original accuracy value for each 1ml more than the volume limit; If the liquid flowed into the measuring cup is less than the volume limit (20ml), please reduce 3 from the original accuracy value for each 1ml less than the volume limit. If the liquid flowed into the measuring cup is the same with the volume limit (20ml), no need to adjust the accuracy value. Press 🔄 key and 🔄 key at the same time, 3 lines of values will display on LCD as shown in [Figure 5-9]. The second line is the accuracy value. Select the accuracy value and it shall keep flashing.

Press 🔄 key or 🔄 key to increase or reduce this value.

Example 1: If the actual liquid flowed into the measuring cup is 21ml, and the original accuracy value is 50, we should set the current accuracy value to 53.

Example 2: If the actual liquid flowed into the measuring cup is 19ml, and the original accuracy value is 50, we should set the current accuracy value to 47.

**Step 3:** Repeat Step 1 and Step 2 until the accuracy value is accurate (the actual liquid volume flowed into the measuring cup is the same with the volume limit).

**NOTE**

- Infusion accuracy of the infusion pump is ±5%
- In order to reduce the infusion test error, the enteral feeding pipe should be filled with liquid, without any air bubble.
- When change to a new enteral feeding pipe, we need to recalibrate the accuracy value.
5.4.3 Setting Occlusion Level

As shown in Figure 5-10, there are 3 lines of value displayed on the LCD after pressing the key and the key simultaneously. The first-line value, standing for occlusion level, flashes and is adjustable on the default status. Increase or decrease the parameter value by pressing the key or the key.

**NOTE**

- The pressure value needs to be set again when changing the brand of infusion tube.
- The lower the occlusion level, the higher the occlusion sensitivity.

5.4.4 Setting Air Bubble Filter Level

By pressing the key and the key simultaneously, the air bubble filter level value displays on the top line of the screen as shown in Figure 5-11. The filter level ranges from 1 to 4, among which 1 stands for closing air bubble filter. To press the key or the key is to increase or decrease the parameter value. The higher the filter level, the larger capacity the air bubble filtered.
5.5 Drop Rate Function (Optional)

NOTE

- The higher the filter level, the larger capacity the air bubble filtered.

5.5.1 Open and Close Drop Rate Function

In the stop status after the infusion pump starts, press the 100-decrement key and the 1-increment key simultaneously to enter into the interface of the drop rate. When the rate value is 1 and the rate unit ml/min, as shown in Figure 5-12, it means the infusion pump has drop rate; when the value is 0 and the rate unit ml/h, as shown in Figure 5-13, it means the pump has no drop rate function. Finally, press the key to save the setting.
5.5.2 Setting Drop Rate for Infusion Tube

When different kinds of infusion tubes are used, it is necessary to refer to the parameters on the package of infusion tube, because of different drop rate parameters for different infusion tubes.

As shown in Figure 5-14, on the display of starting infusion pump, select the infusion tube (i.e.: A brand infusion tube) that the system needs. Meanwhile, press the key and the 1-decrement key together to enter into the parameter setting interface for “drop/ml”, and then set the system parameter the same as the drop rate parameter, and finally press the key to save the parameter.
NOTE

- The setting range for infusion tube: 1~100.

5.5.3 Convert the Drop Rate Unit

As shown in Figure 5-15, under the infusion stop status, press the key \[\text{\textbullet}\] to enter into the interface of infusion parameters setting. Then press the key \[\text{C}\] and the 1-increment key \[\rightarrow\] simultaneously, the flow rate will convert between unit ml/min and unit ml/h.

![Figure 5-15]
6 Alarms

6.1 Overview

Alarm is a warning indication given by infusion pump to alert medical care personnel through sound, light, information etc. Alarm occurs in case of completed infusion, accidental circumstance (machine abnormal, installation error of infusion tube) or machine malfunction that result in abnormal infusion.

⚠️ WARNING

- There is a potential hazard for the same or similar devices to use different preset alarm in any single area.

6.2 Alarm Type

The infusion pump will give light and audible alarm to remind the users as follows:
- Visual alarm
- Audible alarm

Among them, the visual alarm and audible alarm will give in different ways to identify the alarm types.

6.2.1 Audible Alarm

Audible alarm means when alarm sounds, the infusion pump will send audible alarm.

6.2.2 Alarm Information

Alarm information means when alarm sounds, the corresponding alarm information will be displayed in the status bar.
- If a new alarm occurs, audio, visual and the alarming text shall indicate in a loop.
- The alarm shall be triggered when the pressure value exceeds the higher or lower value of the set occlusion value.

The status bar of the infusion pump would display the corresponding alarm information when it alarms. The alarm categories are as follows:
- Air Bubble
- Over
- Occlusion
- NO AC power supply
- Low battery
6.3 Alarm Countermeasures

WARNING

• Please check the condition of the patients when an alarm occurs.

When the infusion pump gives alarms, please take the following steps and measures:
1. Check the condition of the patient.
2. Confirm the alarm parameters and alarm type.
3. Identify the cause of alarms.
4. Solve the cause of alarms.
5. Confirm if the alarm has been eliminated.

NOTE

• Regarding detailed counter measures to each alarm, please refer to Appendix C Alarm Information.
A

Product Specification

A.1 Safety Specification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFDA Classification</td>
<td>Class II</td>
</tr>
<tr>
<td>Type of Shock Protection</td>
<td>Class II, including inner power supply device</td>
</tr>
<tr>
<td>Degree of Shock Protection</td>
<td>Type BF, except quiver discharge effect application part.</td>
</tr>
<tr>
<td>Classification of Waterproof</td>
<td>IP21</td>
</tr>
<tr>
<td>Operating Mode</td>
<td>Continuous operation</td>
</tr>
<tr>
<td>Degree of Mobility</td>
<td>Portable device</td>
</tr>
</tbody>
</table>

A.2 Environmental Specification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature</td>
<td>5~40ºC</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>20~80%, non-condensing</td>
</tr>
<tr>
<td>Operating Atmospheric Pressure</td>
<td>86~106kPa</td>
</tr>
<tr>
<td>Storage and Transportation Temperature</td>
<td>-20~50ºC</td>
</tr>
<tr>
<td>Storage and Transportation Humidity</td>
<td>10~95%, non-condensing</td>
</tr>
<tr>
<td>Storage and Transportation Atmospheric Pressure</td>
<td>50~106kPa</td>
</tr>
<tr>
<td>Storage Condition Statement</td>
<td>Non-corrosive gases and well-ventilated room</td>
</tr>
</tbody>
</table>

A.3 Power Supply Specification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>AC Power Supply</td>
<td></td>
</tr>
<tr>
<td>Input Voltage</td>
<td>100~240V</td>
</tr>
<tr>
<td>Input Current</td>
<td>0.25~0.11A</td>
</tr>
<tr>
<td>Frequency</td>
<td>50/60Hz</td>
</tr>
<tr>
<td>Battery</td>
<td></td>
</tr>
<tr>
<td>Quantity</td>
<td>1 piece</td>
</tr>
<tr>
<td>Type</td>
<td>Rechargeable Lithium Polymer Battery</td>
</tr>
<tr>
<td>Voltage</td>
<td>DC 7.4V</td>
</tr>
<tr>
<td>Capacity</td>
<td>1600mAh</td>
</tr>
<tr>
<td>Max. Power Consumption and operating Time</td>
<td>25VA, running no less than 4 hours at the rate of 25ml/h after being fully recharged.</td>
</tr>
</tbody>
</table>
The battery shall charge automatically when the pump is connected to the AC power and in power on situation. It takes 8-14 hours for the battery to get fully charged.

### A.4 Hardware Specification

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Appliance</td>
<td></td>
</tr>
<tr>
<td>Size</td>
<td>120 mm×140 mm×195mm (Length×Width×Height)</td>
</tr>
<tr>
<td>Weight</td>
<td>≈1.7kg</td>
</tr>
<tr>
<td>LCD (Liquid Crystal Display)</td>
<td></td>
</tr>
<tr>
<td>Type</td>
<td>LCD</td>
</tr>
<tr>
<td>Size</td>
<td>2.7 inches</td>
</tr>
<tr>
<td>Indicator Light</td>
<td></td>
</tr>
<tr>
<td>Quantity</td>
<td>2 pieces</td>
</tr>
<tr>
<td>Fuse Wire</td>
<td></td>
</tr>
<tr>
<td>Withstand Voltage and Flow Resistance</td>
<td>T 2A 250V~</td>
</tr>
<tr>
<td>AC Power Port</td>
<td></td>
</tr>
<tr>
<td>Quantity</td>
<td>1</td>
</tr>
</tbody>
</table>

### A.5 Basic Parameters of Infusion Pump

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Requirement for infusion tube</td>
<td>Comply with “GB 8368-2005 Standard for Disposable Infusion Set with Gravity Infusion-style”</td>
</tr>
<tr>
<td>Infusion pump mechanism</td>
<td>Peristaltic Mechanism</td>
</tr>
</tbody>
</table>
| Flow rate range                        | SK-600 I : 1~600 ml/h  
SK-600 I B: 1~2000 ml/h                    |
<p>| Bolus rate                             | 600 ml/h                                                            |
| Drop rate (settable)                  | Drop rate: 1 <del>666 drop/min                                         |
| Increment                             | 1, 10, 100                                                         |
| KVO rate                              | 1ml/h (After occlusion alarm, it will start KVO)                    |
| Volume limit range (VTBI)             | 1</del>9999 ml                                                          |
| Accumulated Infusion Volume Display   | 0.1~9999 ml                                                        |
| Infusion accuracy                     | ±5%                                                                |
| Displayed and indicated information   | Battery indicator, AC power indicator, infusion application indicator, infusion rate, infusion rate |</p>
<table>
<thead>
<tr>
<th>Status indication</th>
<th>Stop, infusion, bolus, KVO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm function</td>
<td>Air bubble, Over, occlusion, no AC power, low battery, batter exhausted, communication error (Err1 displayed), operation error (Err2 displayed), drop rate error (Err3 displayed), handle opened (Err4 displayed)</td>
</tr>
<tr>
<td>Air bubbles measurement</td>
<td>The minimum air bubbles is 0.005ml at 600ml/h</td>
</tr>
<tr>
<td>Infusion pressure</td>
<td>The maximum pressure that can be generated is 160kPa. The pressure threshold scope for occlusion alarm is (40~160) kPa. The maximum time of occlusion alarm is 2 mints at 25ml/h; the maximum time of occlusion alarm is 5 mints at 5ml/h;</td>
</tr>
</tbody>
</table>
A.6 Pressures that trigger a occlusion alarm, maximum alarm delays, and permissible maximum volumes per infusion

<table>
<thead>
<tr>
<th>Reference occlusion value (Kpa)</th>
<th>Flow rate (ml/h)</th>
<th>Actually measured value of pressure intensity (Kpa)</th>
<th>Alarm time (Min)</th>
<th>High dose volume (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>5ml</td>
<td>40.80±10</td>
<td>00:03:44</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>100ml</td>
<td>43.47±10</td>
<td>00:00:10</td>
<td>0.17</td>
</tr>
<tr>
<td></td>
<td>500ml</td>
<td>44.93±10</td>
<td>00:00:03</td>
<td>0.25</td>
</tr>
<tr>
<td>100</td>
<td>5ml</td>
<td>101.33±20</td>
<td>00:05:14</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>100ml</td>
<td>102.27±20</td>
<td>00:00:16</td>
<td>0.27</td>
</tr>
<tr>
<td></td>
<td>500ml</td>
<td>107.2±20</td>
<td>00:00:06</td>
<td>0.50</td>
</tr>
<tr>
<td>160</td>
<td>5ml</td>
<td>161.20±30</td>
<td>00:08:38</td>
<td>0.70</td>
</tr>
<tr>
<td></td>
<td>100ml</td>
<td>162.27±30</td>
<td>00:00:24</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>500ml</td>
<td>163.8±30</td>
<td>00:00:07</td>
<td>0.58</td>
</tr>
</tbody>
</table>

**NOTE**

- Test condition of the above data:
  - FLUKE IDA4 PLUS tester
  - Infusion tube brand: Dragon Heart
- The occlusion pressure value, maximum delayed time and maximum dosage volume will be affected by test conditions.
A.7 Infusion accuracy table

The accuracy chart is as follows, indicating the infusion change from the beginning of infusion to steady infusion.

A.7.1 Accuracy Curve

It is based on the data from a two hours' observation cycle.
- Sampling rate: 25ml/h
- Sampling intervals: $\Delta t = 0.5$ minutes
- Test period: $T = 120$ minutes
- Infusion rate: $Q$ (m/h)
A.7.2 Horn-shaped curve

The deviation of infusion rate in short term ($p\Delta t$)
Sampling rate: 25ml/h
Sampling intervals: $\Delta t = 0.5$ minutes
Observation window duration: $p\Delta t = 2, 5, 11, 19, 31$ minutes
Max. deviation in Provisions Duration: EPmax (%)
Min. deviation in Provisions Duration: EPmin (%)
Average percentage for flow rate deviation: A (%)

![Graph showing percentage error of flow over $p\Delta t$ minutes]

**NOTE**

- Infusion accuracy does not reflect the clinical criteria, such as patient’s age, weight and the usage of medication.
- Infusion accuracy may be affected by the machine working environment (such as pressure, temperature, humidity, and other components used for transfusion).
EMC GUIDANCE AND MANUFACTURER’S DECLARATION

This infusion pump meets the EMC standard EN 60601-1-2.

Note

- Using the accessories, sensors and cables beyond the specified range may increase the electromagnetic emission of infusion pump or reduce the electromagnetic immunity.
- The infusion pump must not be closed or stacked with other equipments. When infusion pumps have to be used with other equipment, closely observe them to ensure normal operation.
- It needs special protection for the EMC of the infusion pump. And the installation and maintenance of machine should be under the following EMC environment:
- Infusion pump should not be used with MRI (magnetic resonance imaging) or similar devices, otherwise electromagnetic interference may cause malfunction or breakdown.
- Even the other devices comply with the emission requirements of CISPR, they may also interfere with the infusion pump.
- When the input signal amplitude is lower than the minimum amplitude in technical specifications, it may lead to inaccurate measurements.
- Portable and mobile RF communications equipment can affect the performance of monitor.

Electromagnetic Emission Guidance and Statement

<table>
<thead>
<tr>
<th>Emission Testing</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio-frequency emission CISPR 11</td>
<td>Group 1</td>
<td>This infusion pump uses RF energy only when running its internal functions. Therefore, its RF emission is very low and will not produce any electromagnetic interference which affects the nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emission CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emission IEC61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuation and flashing</td>
<td>Applicable</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Guidance and Statement of Electromagnetic Immunity

The infusion pump should be used under stipulated electromagnetic environment. Customer or user shall ensure using infusion pump under the following stipulated electromagnetic environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>±6 kV contact discharge ±8 kV air discharge</td>
<td>±6 kV contact discharge ±8 kV air discharge</td>
<td>The ground must be woodiness, concrete or ceramic tile. If floor is covered with synthetic materials, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electricity rapid pulse group (EFT)</td>
<td>±2 kV power cord ±1 kV I/O cable</td>
<td>±2 kV power cord</td>
<td>Nets power quality must be a typical business or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV differential-mode ±2 kV common-mode</td>
<td>±1 kV differential-mode ±2 kV common-mode</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage drop, short supply interruption and voltage change</td>
<td>&lt;5% U_T (drop&gt;95% U_T) 0.5 cycle 40% U_T (drop 60% U_T) 5 cycle 70% U_T (drop 30% U_T) 25 cycle &lt;5% U_T (drop&gt;95% U_T) 5 seconds</td>
<td>&lt;5% U_T (drop&gt;95% U_T) 0.5 cycle 40% U_T (drop 60% U_T) 5 cycle 70% U_T (drop 30% U_T) 25 cycle &lt;5% U_T (drop&gt;95% U_T) 5 seconds</td>
<td>Nets power quality must be a typical business or hospital environment. If the infusion pump needs continuous working during a break in the nets power, we recommend uninterrupted UPS power supply.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industrial frequency magnetic field (50Hz /60Hz)</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Not applicable</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: U_T refers to the exchange net voltage before exerting test voltage
Guidance and Statement of Electromagnetic Immunity

The infusion pump should be used under stipulated electromagnetic environment. Customer or user shall ensure using infusion pump under the following stipulated electromagnetic environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduction immunity</td>
<td>IEC61000-4-6</td>
<td>3 Vrms 150k~80MHz</td>
<td>3 V Portable and mobile RF communications equipment must be used outside the equipment and/or systems (including cable) of any parts the prescribed distance. The separation distance is based on the transmitter frequency to choose the right formula calculated. The suggested calculation formula of isolation distance is:</td>
</tr>
<tr>
<td>Radiation immunity</td>
<td>IEC61000-4-3</td>
<td>3V/m 80M~2.5GHz</td>
<td>3V/m</td>
</tr>
</tbody>
</table>

\[ d = 1.2\sqrt{P} \]

\[ d = 1.2\sqrt{P} \quad 80M\sim800MHz \]

\[ d = 2.3\sqrt{P} \quad 800M\sim2.5GHz \]

Among them, \( P \) is the Nominal maximum output power of transmitters, its unit is watt; \( d \) is the recommended distance, its unit is meter.

The field strength of RF transmitter obtained in electromagnetic field measurements \( a \) in every frequency range \( b \) must be less than line level. It may appear interference by the equipment marked the following sign:

Note 1: Use higher frequency band formula between 80 MHz and 800 MHz

Note 2: The above guidance does not apply to all cases, because material structure, objects and persons can absorb and reflect the electromagnetic wave and then affect the electromagnetic transmission.

\( a \): The field strength of Radio (honeycomb and wireless) mobile phone’s base stations and ground mobile radio receivers, the antenna devices, FM and AM radio, television broadcast is unable to use pure theory for the accurate estimation.

In order to evaluate the electromagnetic environment produced by fixed RF transmitters, we should consider method of electromagnetic field measurement. If the measured field strength of working environment of infusion pump exceeded the stipulated RF level, we must observe whether infusion pump can work normally. Once abnormal situation was found, we must take corresponding measures, such as changing the direction of infusion pump or moving it to other places.

\( b \): When the frequency range is between 150 k and 80 Mhz, the field strength shall be less than 3 V/m.
The infusion pump can be used in the electromagnetic environment where RF interference can be controlled. In order to avoid electromagnetic interference, the customer or user should ensure that the infusion pump and portable/mobile RF communications equipment maintain the minimum recommended distance. The following recommended distance is calculated according to the maximum output power of communication equipment.

<table>
<thead>
<tr>
<th>The transmitter’s maximum output power (W)</th>
<th>Calculate isolation distance according to the transmitter frequency (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150k~80MHz</td>
</tr>
<tr>
<td></td>
<td>$d = 1.2\sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

If the transmitter’s maximum output power is not within the above range, we can estimate isolation distance by corresponding equation in column. $P$ in the equation is the maximum output power given by transmitter manufacturer. The unit is watt.

**Note 1:** Use the higher frequency band formula between 80 M and 800 Mhz.

**Note 2:** The above guidance does not apply to all cases, because material structure, objects and persons can absorb and reflect the electromagnetic wave and then affect the electromagnetic transmission.
### C.1 Alarm information

Note: Column A means it can be totally eliminated; Column B means it can be eliminated to acousto-optic; Column L means the alarm level.

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Display</th>
<th>A</th>
<th>B</th>
<th>L</th>
<th>Causes</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air bubble</td>
<td><img src="image1.png" alt="Image" /></td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Air bubble in the infusion tube.</td>
<td>Press [] to stop alarm, remove the air bubble in the set, then press [] to restart infusion.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Infusion tube installation error.</td>
<td>Refer to “4.2.2 Install the infusion tube” to reinstall the infusion tube</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Malfunction with the sensor.</td>
<td>Contact manufacturer.</td>
</tr>
<tr>
<td>Over</td>
<td><img src="image2.png" alt="Image" /></td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Preset infusion volume have been finished.</td>
<td>Press [] key to stop infusion and stop alarm, then press [] key to eliminate the accumulated volume, press [] key to restart infusion.</td>
</tr>
<tr>
<td>Occlusion</td>
<td><img src="image3.png" alt="Image" /></td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Infusion loop occlusion.</td>
<td>Press [] key to stop infusion and silence alarm, then press [] key to restart infusion after moving the occlusion in the loop.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The occlusion value is much too sensitive.</td>
<td>Refer to “5.4.3 Set the occlusion alarm level” to increase the occlusion level.</td>
</tr>
<tr>
<td>Alarm</td>
<td>Display</td>
<td>A</td>
<td>B</td>
<td>L</td>
<td>Causes</td>
<td>Solutions</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>No AC power</td>
<td><img src="image1" alt="Image" /></td>
<td>No</td>
<td>No</td>
<td>Low</td>
<td>Malfunction with the sensor.</td>
<td>Contact manufacturer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The power cord does not connect to the ac power supply.</td>
<td>Check whether the power cord has been inserted or well inserted.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>There is a problem with the power circuit.</td>
<td>Contact manufacturer.</td>
</tr>
<tr>
<td>Low battery</td>
<td><img src="image2" alt="Image" /></td>
<td>No</td>
<td>No</td>
<td>Med</td>
<td>Low battery.</td>
<td>Connect to ac power to charge the battery.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Battery aging or infusion pump charge circuit fault.</td>
<td>Contact manufacturer.</td>
</tr>
<tr>
<td>Battery exhausted</td>
<td><img src="image3" alt="Image" /></td>
<td>No</td>
<td>No</td>
<td>High</td>
<td>Low battery and the battery sign is flashing and giving out rapid alarm sound. It will stop infusion automatically if it is under infusion and it can not continue infusion until it connects to the ac power.</td>
<td>Connect to ac power to charge the battery.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Battery aging or infusion pump charge circuit fault.</td>
<td>Contact the manufacturer</td>
</tr>
<tr>
<td>Alarm</td>
<td>Display</td>
<td>A</td>
<td>B</td>
<td>L</td>
<td>Causes</td>
<td>Solutions</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------</td>
<td>---</td>
<td>---</td>
<td>-----</td>
<td>------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Communication error (Err1)</td>
<td><img src="image1.png" alt="Display" /></td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Internal data communication error.</td>
<td>Press  to stop infusion and eliminate alarm. Press (\text{Again}) again to restart infusion. If this alarm appears again, please contact the manufacturer for repair.</td>
</tr>
<tr>
<td>Abnormal operation (Err2)</td>
<td><img src="image2.png" alt="Display" /></td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Abnormal operation of the motor of infusion pump.</td>
<td>Press  to stop infusion and eliminate the alarm. Press (\text{Again}) to restart infusion. If this alarm appears again, please contact the manufacturer for repair.</td>
</tr>
<tr>
<td>Handle opened (Err4)</td>
<td><img src="image3.png" alt="Display" /></td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Handle is opened during infusion.</td>
<td>Press  to stop infusion and eliminate the alarm. Put down the handle, press (\text{Again}) to restart infusion.</td>
</tr>
<tr>
<td>Alarm Description</td>
<td>Display</td>
<td>A</td>
<td>B</td>
<td>L</td>
<td>Causes</td>
<td>Solutions</td>
</tr>
<tr>
<td>-------------------</td>
<td>---------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>--------</td>
<td>-----------</td>
</tr>
<tr>
<td>Drop rate error (Err3) (drop rate sensor is required)</td>
<td>![Display Image]</td>
<td>Yes</td>
<td>Yes</td>
<td>High</td>
<td>Setting error of drop rate parameter.</td>
<td>Set the correct drop rate parameters.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Accuracy is not calibrated.</td>
<td>Calibrate the accuracy of the infusion tube again.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>There is droplet on the funnel tube wall after operation for a long time, which affects the detection of the drop rate sensor.</td>
<td>Shake off the droplet on the tube wall.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The infusion pipeline is not smooth.</td>
<td>Eliminate the occlusion in the infusion loop.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The drop rate sensor is faulty.</td>
<td>Contact the manufacturer.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The liquid level of medicine in the funnel is beyond the drop rate sensor.</td>
<td>Lower the liquid level of the funnel properly to keep it below the drop rate sensor. The liquid medicine in the medicine filter must be less than 1/3 of its volume.</td>
</tr>
</tbody>
</table>

**C.2 Prompt Message**

None
## D Symbols and Terminology

### D.1 Units

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>min</td>
<td>Minute</td>
</tr>
<tr>
<td>h</td>
<td>Hour</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>mg</td>
<td>Milligrams</td>
</tr>
<tr>
<td>g</td>
<td>Gram</td>
</tr>
<tr>
<td>kg</td>
<td>Kilogram</td>
</tr>
<tr>
<td>kPa</td>
<td>Kilopascal</td>
</tr>
<tr>
<td>ml</td>
<td>Milliliter</td>
</tr>
</tbody>
</table>
## D.2 Terminology

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>AC</td>
<td>Alternating current</td>
</tr>
<tr>
<td>DC</td>
<td>Direct current</td>
</tr>
<tr>
<td>EMC</td>
<td>Electromagnetic compatibility</td>
</tr>
<tr>
<td>KVO</td>
<td>Keep vein open</td>
</tr>
<tr>
<td>ERR</td>
<td>Error</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>ISO</td>
<td>International organization for Standardization</td>
</tr>
<tr>
<td>LED</td>
<td>light emitting diode</td>
</tr>
<tr>
<td>CPU</td>
<td>Central processing unit</td>
</tr>
<tr>
<td>RAM</td>
<td>Random access memory</td>
</tr>
<tr>
<td>ROM</td>
<td>Read-only memory</td>
</tr>
</tbody>
</table>