INSTRUCTIONS FOR USE
Symbol description

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>Medical Device</td>
</tr>
<tr>
<td>UDI</td>
<td>Unique Device Identifier</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>Caution</td>
<td>Protection against leakage current: type CF applied part</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>Protective earth (ground)</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Date of manufacture</td>
<td>Refer to the Instructions for Use</td>
</tr>
<tr>
<td>Part included in a recycling process</td>
<td>CE Marking</td>
</tr>
<tr>
<td>Index of protection against splashing liquids</td>
<td>Equipotentiality terminal</td>
</tr>
<tr>
<td>CLASS I</td>
<td>Protection class</td>
</tr>
<tr>
<td>Name and address of the manufacturing facility</td>
<td></td>
</tr>
<tr>
<td>Fragile, handle with care</td>
<td>Temperature limit</td>
</tr>
<tr>
<td>This way up</td>
<td>Humidity limitation</td>
</tr>
<tr>
<td>Keep dry</td>
<td>Atmospheric pressure limitation</td>
</tr>
</tbody>
</table>

**Danger symbol:**
Warning of an **imminent hazard** that could result in **serious personal injury** and/or **product damage** if the written instructions are not followed.

**Warning symbol:**
Warning of a **potential hazard** that could result in **serious personal injury** and/or **product damage** if the written instructions are not followed.

**Information symbol:**
Important information or recommendations to be followed.

For more information on temperature, pressure and humidity limitations, please refer to Section 1.4.5 Use environment in Chapter 1 “Introduction”.
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1 Introduction

INfusia SP7s is a stackable, single-syringe pump with drug library and more user options.

1.1 Scope
These Instructions for Use (IFU) are applicable to the INfusia SP7s pump (hereafter referred to as “pump” or “device”) with embedded software version 1.0.

Warning:
- Check that this IFU is applicable to the current pump software version. To find the software version, see the “Software version check” in Section 4.5.1.
- The user must adhere to the instructions specified in this IFU. Failure to adhere to these instructions may result in damage to the equipment, injury to patients or injury to users.

1.2 Principle of operation
The device is a syringe pump dedicated to IV routes of administration. The pump is used to administer to human patient a volume of specific fluid (see “Indication” in section 1.4.1) at a programmed flow rate. The infusion can be administered continuously.

1.3 Intended purpose
Syringe pump and accessories for administrate specific fluid (see “Indication” in section 1.4.1) through a syringe.

1.4 Intended use

1.4.1 Purpose
INfusia SP7s is intended for use in healthcare organizations by trained professionals on human patients for continuous delivery of medications, nutrients, or other parenteral fluids through clinically accepted IV routes of administration.

INfusia SP7s applied part: Syringe.

1.4.2 Contraindications
- Do not use the pump in the following situations:
  - Transfusion of blood and blood derivatives
  - Explosive or flammable environment, due to risk of ignition
  - Environments in which the pump is difficult to position securely
  - Environments with strong electromagnetic radiation
- The pump is not designed for the following:
  - Use in homecare
  - Enteral feeding
1.4.3 Intended users
The pump must only be operated by trained healthcare professionals.

**Warning:**
- The pump must only be used and cleaned by trained healthcare professionals.
- Keep the pump, syringe, extension set and power cord away from unsupervised children (and animals).

1.4.4 Intended patients
The pump can be used on patients that require an accurately controlled infusion flow rate.

**Danger:**
The pump can be used on one patient at a time, and on multiple patients throughout its lifetime.

1.4.5 Use environment
The pump is intended for use in hospital environment.

**Warning:**
The pump should be used in the following operational conditions to ensure proper performance:
- Operating temperature range:
  - 5°C to 40°C
- Operating pressure range:
  - 860 hPa to 1060 hPa
- Operating humidity range:
  - 20% to 90% with no condensation

The pump cannot be used in a mixture of flammable narcotic gas and air, or with a mixture of oxygen or nitrous oxide conditions.

1.5 Clinical benefits
Clinical benefits are achieved through the functions provided to the intend users, which has a positive impact on patient management.

Clinical benefits of INfusia SP7s are the following:
- Provide a controlled and reliable system for the intravenous infusion of medications, nutrients, or other parenteral fluids (flow rate accuracy with calibrated syringe: ± 3%. Applicable syringe: 5 mL, 10 mL, 20 mL, 30 mL, 50mL)
- Provide an easy-to-use interface and design to facilitate programming, monitoring and handling.
- Provide infusion functions adapted to the needs of patients and healthcare professionals. (several infusion modes: rate mode, time mode, dose mode and drug mode)
- Provide users with safety features and relevant alarms that improve infusion safety and prevent unexpected infusion discontinuation. (adjustable occlusion pressure threshold, alarm system compliant with EN/IEC 60601-1-8)
1.6 Side-effects
There is no side-effect directly associated to the use of INfusia SP7s.

1.7 Risks for patients
Failure to follow all instructions described in this document or loss or degradation of performance (see the “Performance” in Section 8.1) may result in: underdose, overdose, delay of therapy, air embolism, incorrect therapy, electric shock, infection, exsanguination, toxicity.

1.8 Infusion modes
The following infusion modes are available.

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate mode</td>
<td>The infusion delivers specified volume with specified flow rate.</td>
</tr>
<tr>
<td>Time mode</td>
<td>The infusion delivers specified volume within specified time, and the flow rate is determined by the infusion time and volume.</td>
</tr>
<tr>
<td>Dose mode</td>
<td>The infusion delivers specified volume, and the flow rate is determined by specified dose, drug mass, solution volume and patient weight.</td>
</tr>
<tr>
<td>Drug mode</td>
<td>The drug name is selected from the drug library. The infusion delivers specified volume, and the flow rate is determined by specified dose, drug mass, solution volume and patient weight for the selected drug.</td>
</tr>
</tbody>
</table>

1.9 Precautions to be taken
- Take the time to read and understand this “Instructions for Use” manual before operating the device.
- Do not service or modify the device without authorization from the manufacturer.
- Do not use the device in conjunction with other flow control devices.
- Device performance is independent of gravity under specified operational conditions.
- This device is a Class I equipment. To avoid the risk of electric shock, the equipment must only be connected to the mains supply with a protective earth connection.
- Connecting additional devices to the pump may increase leakage currents. To ensure user and patient safety, responsible organisations must consider the requirements of IEC 60601-1-1 and other related standards listed in the table given in Section 8.2.5.
- The device is designed to be installed on a pole.
- Syringes used with the device should comply with the ISO 7886-2 standard. We recommend the use of Luer lock connection.
- Extension sets used with the device should comply with the standard ISO 8536. We recommend the use of Luer lock connection.
- Do not connect the extension set to the patient when purging.
- If any ingress of fluids is suspected, switch off and unplug the device immediately. Contact Fresenius Kabi before cleaning and using the device again.
If any malfunctions occur and the device must be repaired, or for product descriptions, circuit diagrams, parts, or any other information, please contact Fresenius Kabi (Nanchang) CO., Ltd. (hereafter referred to as “Fresenius Kabi”).
2 Description

2.1 System definition
The INfusia SP7s infusion system comprises the pump, power cord, syringe and extension set.

2.2 Packaging contents
The INfusia SP7s packaging contains the following elements:

- 1 INfusia SP7s pump
- 1 “Instructions for use” manual
- 1 Power cord
- 1 Quality control certificate
- 1 Warranty card
- 1 Packing list

**Information:**
If packaging contents are incomplete or show sign of damage, please contact Fresenius Kabi.

2.3 Pump

2.3.1 Front view

**Legend**
1 Stacking Lock Cover
2 Front Panel
3 Pusher
4 Plunger Lock Arm 1
5 Plunger Lock Arm 2
6 Plunger Detector
7 Flange Detector
8 Syringe Holder
9 Extension Set Holder
10 Flange Slot
11 Plunger Notch
2.3.2 Back view

Legend:
1 Lower Case
2 AC Power Inlet
3 Reset Hole
4 Potential Equalization Terminal
5 RS232 Port
6 12Vdc Socket
7 Pole Clamp
8 Carrying Handle
9 Upper Case
10 Nameplate
11 Stacking Lock Knob

Information:
The potential equalization terminal connected to the external equipotential line to prevent danger caused by the difference in the potentials between the other devices.

Warning:
- The DC power supply is provided as a customer option. It has the following specification: Output voltage: from 12V ±1V; Output current > 2A.
- For the power connector plugged into the socket, the internal core of the interface must be the positive electrode, and the outer core the negative electrode, as indicated by: DC 12V
- The DC power adapter used must meet the requirement of the IEC60601-1.
2.4 User interface

2.4.1 Front panel
The front panel contains all keys and indicators.

**Information:**
The indicators provide information about the AC power source connection, alarm priorities and infusion modes, and whether the keyboard is locked or unlocked.

Legend:

- **1** Screen
- **2** Fast Increment
- **3** Fast Decrement
- **4** Decrement
- **5** Increment
- **6** Alarm indicator
- **7** BOLUS Indicator
- **8** BOLUS Indicator/Infusion indicators
- **9** Keyboard Unlock Indicator
- **10** KVO Indicator
- **11** BOLUS/Purge
- **12** Menu/Return
- **13** Start/Pause
- **14** Silences Alarm
- **15** Clear Alarm and Infused Volume
- **16** Moves to Next Option; Locks or Unlocks Keyboard
- **17** On/Off
- **18** AC power indicator
- **19** Battery indicator

2.4.2 Display
The **INfusia SP7s** displays the following elements on screen to indicate pump state or infusion status.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Syringe Icon" /></td>
<td>Syringe</td>
<td>Appears at the bottom right-hand corner of the screen. The description above the symbol indicates the nominal size of the installed syringe and selected brand.</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td>Battery</td>
<td>Appears at the top right-hand corner of the screen in</td>
</tr>
</tbody>
</table>
forms, representing 3 battery operation modes as described in Section 4.2.2.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Real_time_occlusion" /></td>
<td>Real time occlusion level</td>
<td>Appears close to the right center of the screen, and indicates the pressure level inside the syringe during infusion. A larger white area inside the symbol means a higher pressure level. The letter at the right (H/M/L) indicates the current setting of pressure level.</td>
</tr>
<tr>
<td><img src="image" alt="AudioPaused" /></td>
<td>AUDIO PAUSED</td>
<td>When audio paused, the icon is displayed on the screen.</td>
</tr>
<tr>
<td><img src="image" alt="Infusing" /></td>
<td>Infusing</td>
<td>When blinks on the screen, indicates that an infusion or BOLUS is in progress.</td>
</tr>
<tr>
<td><img src="image" alt="Pause" /></td>
<td>Pause</td>
<td>Indicates that an infusion is paused or the pump is idle.</td>
</tr>
<tr>
<td><img src="image" alt="BOLUSInfusing" /></td>
<td>BOLUS infusing</td>
<td>Indicates the BOLUS function is activated.</td>
</tr>
<tr>
<td><img src="image" alt="Purge" /></td>
<td>Purge</td>
<td>When blinks on the screen, indicates that the purge function is activated.</td>
</tr>
</tbody>
</table>
3 Installation

3.1 Global installation

**Danger:**
*Make sure to maintain the appropriate positions between patient, pump and extension set.*

![Diagram](image)

**Warning:**
*Place the patient on the opposite side from the pusher to protect the extension set from excessive bending or stretching.*

3.2 Installing the pump

The **INfusia SP7s** has a pole clamp on the back for attaching it to a pole.

**Information:**
*The pump is designed for installation on a pole with a diameter between 15 and 35 mm.*

**Warning:**
*It is not recommended to place the pump on a flat table for infusion.*

1. Unscrew the clamp (item 2), place it around the pole (item 1), and screw the clamp until pump is fully secured to the pole.

2. Check that the pump is securely attached.
Warning:

- Make sure the load bearing capacity of the infusion stand is more than 2.5 times the weight of the device.
- Make sure the infusion stand is positioned securely, stably and will not topple over when tilted by up to 20 degrees.

3.3 Stacking the pump
Up to 8 INfusia SP7s pumps can be stacked on one pole. (Note: the pole needs the ability of loading 28Kg)

1. Use the pole clamp to securely mount the first pump on the pole.
2. Open the stacking lock covers on the first pump.
3. Place the second pump on the first one.
4. Use the stacking lock knobs of the second pump to secure it tightly onto the first pump.
5. Screw the knob of the pole clamp to securely mount the second pump on the pole.
6. Repeat steps 2 to 5 to stack more pumps as required.

The drawing on the right shows three pumps stacked on a pole.

3.4 Loading the syringe

3.4.1 Syringe recommendation

Warning:

- The syringes loaded on the device should comply with the ISO 7886-2 standard. We recommend the use of Luer lock connection.
- Use of a syringe that does not meet the above requirements may cause incorrect flow rate and damage to the device or injury to the patient.

3.4.2 Syringe loading procedure

Warning:

- Check the syringe. The syringe to be loaded must be calibrated before use (see Section 4.3 Syringe calibration) if either of the following is true:
- The brand is new and has never been used before.
- The brand or size is different from that of the previous syringe.
- A significant amount of liquid residue is left in the syringe when the infusion is complete.
- The rate abnormal alarm occurs.

- Before loading the syringe, check the integrity of the extension set and syringe, and make sure the extension set is not connected to the patient.
- Prepare the solution for the syringe according to your hospital’s protocol.
- Syringe and extension set are single use and must be replaced after 24 hours of use to avoid Vessel Catheter Associated Infection.

1. Fill the syringe with the solution prepared for infusion.

2. Connect the extension set to the syringe.

3. Install the syringe in the device and make sure that the extension set rests in the extension set holder, the flange of the syringe is securely inside the flange slot and one of the syringe plunger edge is aligned with the plunger notch (see Section 2.3.1 Front view).

Information:
You can perform a manual purge at this time to drive out the air in the extension set.
4. Secure the syringe in place by turning the syringe holder to point upwards.

5. Make sure that the syringe plunger head is securely held in place by the plunger locking arms and is in close contact with the pusher. When securing the syringe plunger head with the plunger locking arms, hold the syringe plunger firmly to keep its relative position to prevent any accidental BOLUS.

6. Check that patient is connected to the extension set and verify that potential stopcocks are open before starting the IV administration.

**Warning:**
- If the syringe is not loaded properly, the message [Syringe Loose] is displayed. Re-check the positioning of the syringe.
- Before starting the infusion, make sure no leak of solution.

### 3.4.3 Changing a syringe

1. Remove the syringe,
   - Make sure the infusion is stopped, follow the steps described in section 4.4.2 if necessary.
   - Disconnect the patient.
   - Loosen the pusher and syringe holder.
   - Remove the syringe from the pump.
   - Disconnect the syringe from its extension set in accordance with healthcare facility protocol.

2. Install another syringe, and follow the steps described in the flowchart. See section 3.4.2.
4 Operations

4.1 Electrical connection / disconnection

4.1.1 Electrical connection

**Warning:**
- Connect the pump to the AC power source with the power cord supplied by Fresenius Kabi.
- Position the device in a way that the AC power source remains readily accessible.
- The pump must be connected to an appropriate power source when loss of power would result in an unacceptable risk.

1. Securely install the pump on a pole at patient bedside.
2. Firmly plug the power cord’s appliance connector into the power inlet on the back of the pump.
3. Plug the other end of the power cord into the AC power source’s electrical outlet.

**Information:**
- The pump does not switch on automatically when connected to the AC power source.
- To switch on the pump, press and hold the key until the display lights up.
- Once the AC power is connected, the following occur:
  - The AC power indicator on the front panel lights up.
  - The internal battery begins to charge.

4.1.2 Electrical disconnection

Unplug the power cord to disconnect the AC power source.

**Information:**
- The AC power indicator switches off when the pump is disconnected from the AC power source.
- If the pump is on when it is disconnected from the AC power source, it does not switch off automatically. Instead, the pump switches to internal battery power.
- The battery indicator switches on when the pump switches to internal battery power.
- To switch off the pump, press and hold the key until the display goes black.

4.2 Operating on battery

The pump is equipped with an internal rechargeable Li-ion polymer battery in case of disconnection from mains power. When running at a rate of 5 mL/h, the pump’s battery operating time is typically 8 hours when fully charged.
Information:
Before using the pump for the first time, fully charge the battery by connecting the device to the AC power source for approximately 10 hours without switching it on.

Warning:
The internal battery must be present and connected properly in the pump. If this is not the case, when connecting to the AC power source and switching on the pump, the pump activates the no battery alarm (see Section 6.2 in Chapter 6 “Alarms” for details).

4.2.1 Battery precautions

Danger:
Li-Ion polymer batteries are more sensitive to physical stress. Improper handling of the pump or battery may cause overheating of the battery, smoke, explosions or fire. These could result in degraded performance, failure of or damage to the equipment, or injury to the user.

Warning:
- The battery operating time depends on several factors, one of which is infusion flow rate. When the battery low alarm is activated, recharge the battery by connecting the pump to an AC power source.
- The battery lifespan is 2 years. Contact Fresenius Kabi for replacement.
- Do not recharge the battery outside the device, or for more than 24 hours.
- Do not let the battery come into contact with metal objects such as coins, keys or jewellery, to avoid shorting the battery terminals and causing an accident.
- Do not let the battery get wet. The battery contacts or circuitry could slowly corrode and pose a safety hazard.
- Do not let the battery get close to areas that may get very hot, such as heaters, cooking appliances, soldering irons or radiators.
- Do not drop, crush, puncture or put a high degree of pressure on the battery, as this can cause an internal short-circuit and result in overheating.
- Do not use the battery if it is suspected to have been damaged.
- Do not replace with a battery other than that delivered by Fresenius Kabi.

4.2.2 Battery operating mode
When the pump is switched on and operates on battery, the battery symbol is displayed in one of the following 3 forms, each of which represents one of the 3 battery modes.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Battery mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌇 bile 🌇 bile 🌇 bile</td>
<td>Contains three white rectangles.</td>
<td>Battery is fully charged.</td>
</tr>
</tbody>
</table>
When the AC power source is connected, either the charging or the fully charged battery symbol is displayed.

### 4.2.3 Battery charging system

The battery charging system is part of the device’s internal circuitry. When the AC/DC power source is connected, the system charges the battery at a constant voltage, whether the device is switched on or not. Any problems related to the battery charging system must be serviced by authorised personnel.

### 4.3 Syringe calibration

**Warning:**
- System default syringe is BD USA, if not match with actual syringe, reselect in the “Syringe selection” in the menu.
- The syringe to be loaded on the device must be calibrated before use in the following cases:
  - New brand or model or size or reference.
  - An unexpected significant amount of liquid residue is left in the syringe when the infusion is completed.
  - The rate abnormal alarm occurs.
  - The syringe is not calibrated “Undefined Syringe Type!” note information occurs.
- Make sure the extension set is not connected to the patient before calibration.
- By default, the machines use the built-in pressure data, when necessary, the client may have new calibration pressure.

**Information:**
The device can calibrate syringes of 5 nominal sizes: 5mL, 10mL, 20mL, 30mL and 50/60mL.

Syringe calibration determines parameters such as the infusion ending point and the cross-sectional area of the syringe, and stores flow accuracy.

1. Prepare an empty syringe.
2. Securely position the syringe on the device.
3. Press and hold the key to switch on the pump.
4. Press the key when the display prompt currently selected syringe.
5. Press the menu key to enter the menu.

6. Select Advanced Config, press the ok key to enter the password interface.

7. Prompt for password, password (0804) to enter the Advanced Config menu.

8. Use the , , , or keys to select “Syringe Calibration”, press the ok key to enter the syringe calibration menu.

9. Use the , , , or keys to select the custom syringe to be calibrate, press the ok key to enter.

10. Use the , , , or keys to select the syringe sizes, press the ok key to enter the calibration interface.

11. Complete the calibration by the operational guide step.

Information:
- In the syringe calibration interface:
  - Operation instructions are displayed.
  - If the syringe is not installed properly, the “Calibration error! ” message appears when taking the operation.
- If needed, press the menu key to exit calibration.

12. Follow the instructions on the display:
- Install the syringe on the device.
- Select the syringe brand, such as Custom1, Custom2, etc.
- Select the syringe type, such as 5mL, 10mL, 20mL, 30mL, 50mL.
- Step 1: Push the syringe to zero press OK key.
- Step 2: Press OK key to confirm step 1.
- Step 3: Push the syringe to xx mL press OK key.
  Note: Pull the plunger until the tip reaches the syringe’s full scale (for example, for a 50 mL syringe, the tip should be at 50 mL).
- Step 4: Press OK key to confirm step 3.

Information:
- After the ok key is pressed, the instructions change.

Warning:
- For a 60 mL syringe, pull the plunger until the tip reaches the scale of 50 mL.

Information:
- If the calibration is successfully, “Calibration completed!” is displayed briefly,
and press the menu key, it will return to the previous interface.

- If the calibration fails, “Calibration error!” is displayed briefly, and press the menu key, it will return to the previous interface.
- After calibration, only the most recent syringe information is stored in the device. The information stored for the previous brand and size of syringe is erased.

4.4 Basic operations

4.4.1 Switch on and off

1. Switch on

- Press and hold the menu key until the display lights up.
- All indicators light up momentarily.
- The device performs a self-test.
- The alarm indicator flashes twice in sequence: first in yellow, and next in red.
- Two audio tone sounds.
- Display the logo of Fresenius Kabi. Switch to the syringe brand confirm interface automatically. Please confirm the current syringe brand, if yes, please press key to confirm, if not, please reselect the syringe brand used in menu.

If the self-test is successful, the device will be in pause state to wait for user’s choice of infusion mode and input.

Information:

- When the device is paused, the pause message is displayed, signaling the user to take an action such as starting the infusion or adjusting infusion parameters. If no action is taken within 3 minutes, the no action alarm is activated.

If the self-test fails, an error message will be displayed. Contact Fresenius Kabi immediately.

2. Switch off

- Press and hold the menu key until the display goes black.

Warning:

- The device cannot be switched off when an infusion is in progress.
- Unplug the power cord to avoid overcharging the battery.

Information:

- The pump can memory the key parameters when it is switched off. Such as the infusion mode, syringe brand/type and so on.
When holding the key to switch off the device, Number 3, 2, 1 is shown on the screen in turn. Until Number 1 disappears, the device will be switched off.

4.4.2 Start or stop infusion
Infusion can be performed in the following modes:
- Rate mode
- Time mode
- Dose mode
- Drug mode

**Information:**
The infusion mode can be changed in the interface of Mode Selection.

1. Start infusion
- Select the Mode Selection and press key, and select desired infusion mode.
- Set the parameters for the selected mode.
- Press the key to start infusion.

**Information:**
When infusion is in progress:
- is displayed and blinking.
- The arrows in the infusion indicator turn green in succession repeatedly.
- The keyboard is locked except for the , , and keys.

2. Stop infusion
- Press the key to stop infusion when infusion is in progress.

**Information:**
- is displayed when infusion is stopped.
- After the infusion is stopped:
  - You may adjust parameters and resume the infusion.
  - The infused volume is not cleared automatically. When it blinks, press the key to clear it.

4.4.3 Rate mode

**Information:**
In rate mode, the user can set the parameters flow rate and volume to be infused (VTBI).
In the ⚫ Mode Selection interface, select the “Rate Mode”.

The “Rate” parameter blinks.

Use the , , , or key to set the flow rate.

Press the key. “VTBI” blinks.

Use the , , , or key to set the volume to be infused (VTBI).

Press the key. “VI” blinks.

Press the key, clear the “VI” value.

Information:

- Some factors that may affect the decision to set “Pressure Level” to H, M or L include infusion flow rate, syringe size, infusion safety level, psychological stress on the part of the patient.
- For example, “Pressure Level” H or M may be set for adult patients when infusion is delivered with a small sized syringe at high flow rate. Similarly, L or M may be set for young children or elderly patients with a large sized syringe at low flow rate.

Press the key to start infusion.

Information:
To adjust flow rate during infusion, please refer to Section 4.4.10 “Change flow rate setting during infusion” section in this chapter.

4.4.4 Time mode

Information:
In time mode, the following are true:
- The infusion duration (TIME) and solution volume (VIBI) parameters are set by the user.
- The flow rate is determined by TIME and VTBI settings.

In the ⚫ Mode Selection interface, select the “Time Mode”.

The “Time” parameter blinks.

Use the , , , or key to set infusion time.

Information:
The infusion time can range from 00h01min to 99h59min.
• Press the key. “VTBI” blinks.

• Use the , , or key to set solution volume as desired.

**Information:**
- “VTBI” is the total volume of the drug solution in the syringe.
- The flow rate value changes according to the TIME and VTBI settings.

• Press the key. “VI” blinks.

• Press the key, clear the “VI” value.

**Information:**
- “VTBI” is the current volume to be infused.
- “VI” is the infused solution.

**Information:**
For example, “Pressure Level” H or M may be set for adult patients when infusion is delivered with a small sized syringe at high flow rate. Similarly, L or M may be set for young children or elderly patients with a large sized syringe at low flow rate.

• Press the key to start infusion.

4.4.5 Dose mode

**Information:**
In dose mode, the following are true:
- The DRUG MASS, SOL VOL, WEIGHT, DOSE UNIT, DOSE, and VTBI parameters are set by the user.
- The flow rate is determined by the settings of the parameter listed above (excluding VTBI). The conversion formula is: \( \text{RATE} = \text{SOL VOL} \times \text{DOSE} \times \text{WEIGHT} / \text{DRUG MASS} \).

• In the Mode Selection interface, select the “Dose Mode”.
• The drug mass unit blinks.
• Use the , , or key to set the drug mass unit.
• Press the key. “Drug Mass” blinks.
• Use the , , or key to set the drug mass.
• Press the key. “SOL VOL” blinks.
Use the ↺, ↻, or → key to set the solution volume.

**Information:**
- “SOL VOL” is the total volume of the drug solution in the syringe.
- The solution volume can range from 0.1 to 199.9mL.
- The flow rate value changes with the above parameter settings.

Press the → key. “Weight” blinks.

Use the ↺, ↻, or → key to set the patient’s weight.

**Information:**
- “Weight” may not be available for the setting of some dose units.
- Weight can range from 0.1 to 300.0 kg or none.

Press the → key. “Dose Unit” blinks.

Use the ↺, ↻, or → key to set the dose unit.

**Information:**
- Available dose units include: ug/kg/min, mg/kg/min, g/kg/min, U/kg/min, IU/kg/min, ug/kg/h, mg/kg/h, g/kg/h, U/kg/h, IU/kg/h, mg/min, g/min, U/min, IU/min, ug/h, mg/h, g/h, U/h, IU/h.
- Improper parameter settings may cause the set flow rate to be out of limit and the “Below minimum rate!” or “Exceed maximum rate!” message is displayed.

Press the → key, the display changes into the infusion interface in dose mode.

**Information:**
To return to the parameter setting interface in dose mode, press the → key once when the “Rate” blinks.

“Rate” blinks.

Press the → key. “Dose” blinks.

Use the ↺, ↻, or → key to change the dose value.

Press the → key.

“VTBI” blinks.

Use the ↺, ↻, or → key to set the volume to be infused (VTBI).

Press the → key. “VI” blinks.
• Press the button, clear the “VI” value.

**Information:**
VTBI is the current volume to be infused.

**Information:**
For example, “Pressure Level” H or M may be set for adult patients when infusion is delivered with a small sized syringe at high flow rate. Similarly, L or M may be set for young children or elderly patients with a large sized syringe at low flow rate.

• Press the button to start infusion.

### 4.4.6 Drug mode

**Information:**
*In drug mode, the following are true:*
- The drug name can be selected from the drug library.
- If you require the list of drugs available in the drug library, please contact your Fresenius Kabi representative.
- The dose rate should be set according to the physician’s prescription.
- The setting of the parameters for the selected drug is performed in a similar process as in dose mode.

• In the Mode Selection interface, select the “Drug Mode” mode.

• Use the or key to move the cursor to the desired drug category.

• Press the button to select the drug category.

• The names of drug are displayed.

• Use the or key to move the cursor to the desired drug name.

• Press the button to select the drug.

• The “Set the parameters according to prescription” message is displayed.

• Press the button Key to enter parameter setting interface.

• Dose unit blinks.

• Use the or key to set the dose unit.
4.4.7 BOLUS setup and function

1. **BOLUS setup**
   - In the interface of System Config., select the “BOLUS” item.
   - Press and key to enter the BOLUS setting interface.
   - The “BOLUS Rate” parameter blinks.
   - Use , , or key to set the BOLUS rate.

   **Information:**
   
The BOLUS rate range is specified in Chapter 8.

   - Press the key. “BOLUS VOL” blinks.
   - Use the , , or key to set the BOLUS volume.

   **Information:**
   
The BOLUS volume can range from 1.0 to 50.0 mL.

   - Press the key to save the settings and press key to exit the BOLUS setup interface.

2. **Start/Stop BOLUS function**
Information:

- The BOLUS function is performed manually.
- A BOLUS is delivered at preset BOLUS rate till it is stopped or the target BOLUS volume is reached.

- Start infusion in one of the modes.
- Press and release the key.

- Immediately press and hold the key again to start the BOLUS.
- Keep the key pressed for as long as you want the BOLUS to last.

Information:

After BOLUS function has started, the following are true:

- is displayed and blinking. is also displayed.
- The BOLUS indicator lights up and blinks.
- The arrows in the infusion indicator turn green in succession repeatedly. A preset BOLUS flow rate is displayed instead of the normal flow rate.

- Release key to stop the BOLUS function and resume the prior infusion.

Information:

- The BOLUS continues as long as the key is pressed and held, as long as no alarms are triggered and the target BOLUS volume limit has not been reached.
- If the BOLUS reaches the target BOLUS volume, the device stops the BOLUS and resumes the prior infusion.
- The total infused volume includes the BOLUS volume.
- If the pump is in Bolus function, the alarm system can work properly.
- The BOLUS rate resumes its default value of 1000mL/h when the device is restarted.
  - When the maximum infusion rate is ≥1000mL/h, it defaults to run at 1000mL/h.
  - On the contrary it defaults to run at maximum rate.

4.4.8 Purge

Information:

The purge function drives air out of the extension set quickly.
Warning:

- Ensure the infusion is stopped before starting the purge function.
- Make sure that the extension set is not connected to the patient during purging.
- When occlusion occurs in the extension set, do NOT start purge function on the device. Instead, perform purge manually.

- Pause the infusion, **PAUSE** is displayed.
- Press and release the **BOLUS** key.
- Immediately press and hold the **BOLUS** key to start purge. **PURGE** is displayed.

Information:

After purge is started:
- **PURGE** is displayed and is blinking.
- The arrows in the infusion indicator turn green in succession repeatedly.
- The purge continues at the factory default flow rate, as specified in Chapter 8.
- If the pump is in purge function, the alarm system can work properly, except the alarm of infusion complete.

- Release the **BOLUS** key to stop the purge function and return the device to the paused state.

4.4.9 KVO (Keep Vein Open)

When the infused volume reaches the target volume during infusion, the normal flow rate automatically switches to KVO rate.

Information:

- KVO rates can range from 0.1 to 1.0mL/h or the last delivery rate, whichever is smaller.
- After KVO is started, the following are true:
  - The audio alarm sounds.
  - The KVO indicator blinks.

The KVO continues until the **OK** key is pressed, or until it is interrupted by a high priority alarm.

4.4.10 Change flow rate setting during infusion

Information:

This function is only available when infusion is in rate mode.

- Start the infusion in rate mode.
• Press the key once to unlock other keys. The keyboard unlocked indicator lights up.

• Use the , , or key to adjust the flow rate according to clinical requirements.

• Press the key within 2 seconds, and the adjustment takes effect.

• Press the key to lock the keys.

**Information:**

• The keyboard is locked again, and the keyboard unlocked indicator switches off.

• Before the flow rate adjustment takes effect:
  - If any alarm occurs (except for battery low alarm), the flow rate returns to the previous setting.
  - If the BOLUS function is running, the new flow rate will not take effect when BOLUS ends.
  - If the key is pressed, the flow rate returns to the previous setting.

• If the flow rate is adjusted, new setting will take effect after press the key even if key is not pressed.

• To lock the other keys, press the key again. If no action is taken for over 30 seconds, the keyboard is locked automatically, and the keyboard unlocked indicator switches off.

4.5 Client menu

Press key to enter the client menu. To finish Mode Selection, Syringe Selection, System Config., Advanced Config., Information Inquiry.

Common functions have been introduced in other chapters. The following will be introduced:
Software version check
System time
Pressure calibration
History records
Reset factory setting
Syringe Selection
Near Empty/Volume
Pressure Level/Brightness/Contrast/Night Mode Setting.

Note: after setting the parameter, please press the key to confirm.

4.5.1 Software version check

• Press to select the “Information Inquiry” and enter the interface.
● Select the “Version Inquiry” and press the OK key to get the software version information.

● Press the MENU key to exit.

4.5.2 System time

Information:
The time and date are only used in log reports.

● Press the MENU key to select the “System Config” and enter the interface.

● Use the , , or key to select the “System Time” item.

● Press the OK key, so that system time appears. The year is selected.

● Use the , , or key to set the year.

● Press the OK key to confirm it.

● Press the key, so that the month number is selected.

● Use the , , or key to set the month.

● Press the OK key to confirm it.

● Set the day, hour, minute, second as the above method.

● Press the MENU key to exit the setting.

4.5.3 Pressure calibration

Warning:
● By default, the machines use the built-in pressure data, when necessary, the client may have new calibration pressure.

● Make sure the extension set is not connected to the patient before calibration.

● Calibration needs to use professional pressure detection device and calibration equipment.

Information:
● The device can calibrate syringes of 5 nominal sizes: 5 mL, 10 mL, 20 mL, 30 mL and 50/60 mL.

● If the calibration failed, press the MENU key to exit the calibration.

● Press the MENU key and select the “Advance Config”.

• Press the OK key to enter the interface.

• Enter the code: 0804 to enter the sub menu.
• Select the “Pressure Calibration”.
• Press the OK key, enter pressure calibration.
• Select the syringe brand and type.
• Operation instructions are displayed on the screen.
• Action as the operation instructions.
• When pressure calibration is finished successfully, “Calibration completed!” display, otherwise “Calibration error!”.
• Press the MENU key to exit the calibration.

4.5.4 History records
For records inquiry:
• Press MENU key then select the “Information Inquiry” and press OK to enter the interface.

• Select the “Records” and press the OK key to enter the records interface.

• Select “Records Inquiry” item then press OK key to enter the records list interface.

• Use the , , , or key to select one specific record under list then press the OK key to access detail.

• Press MENU to exit the interface after inquiring finish.

For records export:
• Press MENU key then select the “Information Inquiry” and press OK to enter the interface.

• Select the “Records” and press the OK key to enter the records interface.

• Select the “Records Export” item then press OK to enter the export interface and wait for exporting.
• Press MENU key could exit the interface.

Information:
• The device stores up to 5000 most recent infusion and alarm history events.

• When the alarm system is power down or it has experienced a total loss of power for a finite duration, the history records can be saved automatically, but can’t record the time of powering down.

• If it is necessary to export logs, please contact Fresenius Kabi for the required data communication software.
4.5.5 Reset factory setting

- Press **Menu** key and select the “Advance Config”.
- Press the **OK** key to enter the interface.
- Enter the code: 0804 to enter the sub menu.
- Select the “Reset Factory Setting” item and press the **OK** key to enter the interface.
- Press the **OK** key, the device will reset factory setting and restart at once.

**Information:**
Recover occlusion alarm pressure level (H, M or L) and sound level (H, M or L) to M.

4.5.6 Syringe Selection

- Press **Menu** key and select the “Syringe Selection”.
- Press the **OK** key to enter the interface.
- Select the syringe brand used, such as BD USA, Custom1, Custom2, etc.
- Press the **OK** key to confirm and exit the setting.

4.5.7 Near Empty/Volume

Near Empty Setting:

- Press **Menu** key and select the “Advance Config”.
- Press the **OK** key to enter the interface.
- Enter the code: 0804 to enter the sub menu.
- Select the “Near Empty” item.
- Press **OK** key to enter the near empty setting interface.
- “Near mode” item blinks.
- Use ✷, ◆, ◈ or ◊ key to set “Time” or “Percent”.
- Press the **OK** key to select “Near Percent” item.
- Use ✷, ◆, ◈ or ◊ key to set percent parameter.
- Press the **OK** key to select “Near Time” item.
- Use ✷, ◆, ◈ or ◊ key to set time parameter.
- Press **OK** key to confirm.
Press key to exit the setting.

**Volume Setting:**
- Press key and select the “Advance Config”.
- Press the key to enter the interface.
- Enter the code: 0804 to enter the sub menu.
- Select the “Volume” item.
- Press key and setting parameter is selected.
- Use , , or key to set parameter(L/M/H).
- Press key to confirm and exit the setting.

**4.5.8 Pressure Level/Brightness/Contrast/Night Mode Setting**

**Pressure Level Setting:**
- In the interface of system config, select the “Pressure Level” item.
- Press key and setting parameter is selected.
- Use , , or key to set parameter(L/M/H).
- Press key to confirm and exit the setting.

For Brightness/Contrast/Night Mode Setting, please refer to “pressure level” Setting.

**4.6 Device reset**
- Insert the end of a needle, a straightened paper clip or a toothpick into the reset hole near the AC power inlet.
- Push it in as far as it goes until the display goes black.

**Information:**
*The device needs to be reset when the control of the device cannot be restored by any other means, for example, the device cannot be switched off.*

**Warning:**
*Contact Fresenius Kabi if the reset does not work and the device continues to malfunction.*
5 Cleaning and disinfecting

The device must be cleaned after each use, and before maintenance. Only disinfect the device after it has been cleaned, and only when appropriate.

Recommended agent for cleaning: locally available multi-enzymatic cleanser or detergent (for example, Endozime by Ruhof Corporation).

Recommended agent for disinfecting: 10% household bleach in water (produces 0.55% Sodium Hypochlorite).

5.1 Prohibited cleaning and disinfecting agents

The following agents are prohibited for use in cleaning or disinfecting:
- Full strength bleach
- Trichloroethylene
- Abrasive detergents
- Undiluted alcohol

Use of these aggressive agents may damage the plastic parts of the device and cause it to malfunction.

5.2 Precautions for cleaning

Warning:
- The device must only be cleaned and disinfected by trained staff.
- Switch off the device, and disconnect the power cord from the AC power source before cleaning. Disconnect all other cables.
- Verify that the RS232 and other connectors are properly covered.
- Do not autoclave or use steam sterilisation.
- Do not clean in a dishwasher or shower.
- Carefully read and follow the instructions on the container of each cleaning and disinfecting agent.

5.3 Cleaning and disinfecting guidelines

1. Prepare both cleaning and disinfecting solutions.
2. Wet a piece of disposable cloth with the cleaning solution and carefully wring it out.
3. Wipe the least exposed case and panel surfaces, then the most exposed surfaces, the most critical zones and the mains power cord.
4. Repeat the steps 2 - 3 with a fresh piece of cloth wetted with water.
5. Wet a piece of disposable cloth with the disinfectant solution and carefully wring it out.
6 Alarms

INfusia SP7s Syringe Pump immediately activates audible and visual alarm signals when an alarm condition occurs.

**Information:**
- Key sound: if any key is pressed, the buzzer will make a brief beep.
- When the parameter adjusted is invalid and the key for adjustment pressed still, the buzzer will make a continuous beep.

**Warning:**
- When an alarm is activated, check and respond to the cause of the alarm, clear the alarm.
- Restart the device only after the corrective action has been taken.
- The effect that auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions and the alarm system, please adjust the alarm sound level and pay attention to the visual alarm signal.
- When the user operates within one meter of the device, the high, medium and low priority alarm sounds and indicator should be clearly identifiable. Otherwise, contact the device manufacturer immediately.

### 6.1 Technical alarm information

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Priority</th>
<th>Visual Signal</th>
<th>Audio signal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Indicator</td>
<td>Message displayed</td>
</tr>
<tr>
<td>Syringe Holder Loose</td>
<td>H</td>
<td>Red</td>
<td><strong>SYRINGE LOOSE</strong></td>
</tr>
<tr>
<td>Syringe Plunger Disengagement</td>
<td>H</td>
<td>Red</td>
<td><strong>SYRINGE LOOSE</strong></td>
</tr>
<tr>
<td>Syringe Flange Insertion Error</td>
<td>H</td>
<td>Red</td>
<td><strong>SYRINGE LOOSE</strong></td>
</tr>
<tr>
<td>Occlusion</td>
<td>H</td>
<td>Red</td>
<td><strong>OCCLUSION</strong></td>
</tr>
<tr>
<td>Syringe Empty</td>
<td>H</td>
<td>Red</td>
<td><strong>EMPTY</strong></td>
</tr>
<tr>
<td>Rate Abnormal</td>
<td>H</td>
<td>Red</td>
<td><strong>RATE ABNORMAL</strong></td>
</tr>
<tr>
<td>Battery Empty</td>
<td>H</td>
<td>Red</td>
<td>(Display alternately)</td>
</tr>
<tr>
<td>No Battery</td>
<td>H</td>
<td>Red</td>
<td><strong>No Battery Error!</strong></td>
</tr>
<tr>
<td>Key Stuck During Infusion</td>
<td>H</td>
<td>Red</td>
<td><strong>KEY ERR</strong></td>
</tr>
<tr>
<td>Alarm Condition</td>
<td>Alarm Condition Description</td>
<td>Suggested action</td>
<td></td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>Infusion Complete</td>
<td>H Red</td>
<td>COMPLETE</td>
<td></td>
</tr>
<tr>
<td>Key Stuck During Pause</td>
<td>M Yellow</td>
<td>KEY ERR</td>
<td></td>
</tr>
<tr>
<td>Syringe Near Empty</td>
<td>L Yellow</td>
<td>NEAR EMPTY</td>
<td></td>
</tr>
<tr>
<td>No Action</td>
<td>L Yellow</td>
<td>NO ACTION</td>
<td></td>
</tr>
<tr>
<td>Battery Low</td>
<td>L Yellow</td>
<td>VOL ERR (Display alternately)</td>
<td></td>
</tr>
<tr>
<td>Volume error.</td>
<td>L Yellow</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Information:**
- The device stops infusion and triggers audio and visual alarm signals when a high or medium priority alarm occurs (except infusion complete state).
- The device automatically goes to KVO mode when the infusion complete alarm is activated.

### 6.2 Alarm conditions and corrective actions

<table>
<thead>
<tr>
<th>Alarm Condition</th>
<th>Alarm Condition Description</th>
<th>Suggested action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe loose (Syringe Holder Loose)</td>
<td>Syringe holder has turned, and is no longer holding the syringe in place during operation.</td>
<td>Check the syringe installation, and make sure the syringe holder is in the right position and is holding the syringe.</td>
</tr>
<tr>
<td>Syringe loose (Syringe Plunger Disengagement)</td>
<td>The pusher releaser is pressed during operation.</td>
<td>Check the syringe installation, and make sure the syringe is in close contact with pusher and that the pusher release is not pressed during infusion.</td>
</tr>
<tr>
<td>Syringe loose (Syringe Flange Insertion Error)</td>
<td>Syringe flange is not detected during operation.</td>
<td>Check the syringe installation, and make sure the flange is placed in the flange slot and the syringe holder is in right position.</td>
</tr>
<tr>
<td>Occlusion</td>
<td>Pressure inside the syringe and extension set reaches a certain level (H, M or L) during infusion.</td>
<td>Check the syringe and extension set for signs of occlusion, and take any necessary actions.</td>
</tr>
<tr>
<td>Syringe Empty</td>
<td>The solution in the syringe has been infused completely, and the syringe is empty.</td>
<td>Replace syringe or end the therapy.</td>
</tr>
<tr>
<td>Rate Abnormal</td>
<td>The device detects an abnormal infusion rate.</td>
<td>Recalibrate the syringe.</td>
</tr>
<tr>
<td>Battery Empty</td>
<td>The remaining battery operating time is less than 3 minutes.</td>
<td>Connect the device to the AC power source.</td>
</tr>
</tbody>
</table>
### Intelligent Alarm System

If multiple alarm conditions occur at the same time, the intelligent alarm system prevents a lower priority alarm condition from generating alarm signals when a higher priority alarm condition occurs. In other words, the device only generates signals for the alarm with the highest priority.

When alarms with the same priority occur at the same time, the device responds according to the following alarm logic.

<table>
<thead>
<tr>
<th>Alarm Priority</th>
<th>Logic</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Battery Empty comes before Syringe Holder Loose.</td>
</tr>
<tr>
<td></td>
<td>Battery Empty comes before Syringe Plunger Disengagement.</td>
</tr>
</tbody>
</table>

---

**Information:**

- In addition to the actions suggested above, see Chapter 7 “Troubleshooting” for more troubleshooting solutions.
- For the “Battery Empty” alarm, if the power loss is less than or equal to 30 seconds, the alarm settings prior to the power loss are restored automatically.
- When the “Infusion Complete” alarm is triggered, the device automatically switches to KVO.
- The maximum delivery volume caused by a single fault conditions (for example, stepper motor anomaly) is 6mL.
Battery Empty comes before Syringe Flange Insertion Error.
Battery Empty comes before Occlusion.
Battery Empty comes before Syringe Empty.
Battery Empty comes before Rate Abnormal.
Battery Empty comes before Key stuck During Infusion.
Battery Empty, Syringe Holder Loose, Syringe Plunger Disengagement, Syringe Flange Insertion Error, Occlusion, Syringe Empty, Rate Abnormal and Key stuck During Infusion comes before Infusion Complete.

### 6.4 Features of alarm signals

<table>
<thead>
<tr>
<th>Alarm Priority</th>
<th>Visual Signal</th>
<th>Audible Signal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>- Alarm indicator lights up in red.</td>
<td>- 10 tones, repeat.</td>
</tr>
<tr>
<td></td>
<td>- Frequency: 2.0±0.5Hz.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- The alarm message is displayed.</td>
<td></td>
</tr>
<tr>
<td><strong>Middle</strong></td>
<td>- Alarm indicator lights up in yellow.</td>
<td>- 3 tones, repeat.</td>
</tr>
<tr>
<td></td>
<td>- Frequency: 0.5±0.1Hz.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- The alarm message is displayed.</td>
<td></td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td>- Alarm indicator lights up in yellow.</td>
<td>- 3 tones, repeat.</td>
</tr>
<tr>
<td></td>
<td>- The indicator remains steadily lit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- The alarm message is displayed.</td>
<td></td>
</tr>
</tbody>
</table>

**Information:**
If the battery empty alarm is activated, the battery symbol also flashes on the display.

### 6.5 Alarm silence

- Press the key to silence an audible alarm.

**Information:**
- The following alarms cannot be silenced: Key stuck during pause, battery empty and fault alarm.
- All visual signals, including the indicator and the displayed message, remain visible when an audible alarm is silenced.
- A silenced audible alarm resumes in 110 seconds.

### 6.6 Alarm dismissal

- Press the key to dismiss an active alarm.

**Warning:**
After an alarm is dismissed, the infusion remains stopped, and the audible and visual signals disappear. However, the alarm’s cause must still be found and corrected.
Information:
The following alarms cannot be dismissed: Key stuck during pause, battery empty, battery low, syringe near empty and fault alarm.

6.7 Volume of audible alarm signals
- High priority alarm signals are louder than or equal to medium priority alarm signals, which are in turn louder than or equal to low priority alarm signals.
- In a particular set of audible alarm signals, high priority signals convey a higher level of urgency than low priority and informational signals.
- Similarly, medium priority signals convey a higher level of urgency than low priority and informational signals.

6.8 Alarm signal sound pressure level
The alarm sound level is adjustable, and the alarm signal sound pressure level range is 45-85dB.

6.9 Maximum alarm delay
For all alarms, the time between the alarm condition and the alarm signals is less than 5 seconds.
7 Troubleshooting

**Information:**
Some entries in the Troubleshooting Guide and Error Messages may involve technical details for service personnel.

7.1 Troubleshooting guide

<table>
<thead>
<tr>
<th>Trouble</th>
<th>Possible causes</th>
<th>Corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device cannot be switched on when the AC power source is not connected.</td>
<td>1. Battery is empty.</td>
<td>1. Connect device to AC power source.</td>
</tr>
<tr>
<td></td>
<td>2. Battery connection wires are disconnected.</td>
<td>2. Check battery connection wires.</td>
</tr>
<tr>
<td></td>
<td>3. Battery is defective.</td>
<td>3. Replace battery.</td>
</tr>
<tr>
<td></td>
<td>4. On/Off key is broken.</td>
<td>4. Replace display board.</td>
</tr>
<tr>
<td></td>
<td>5. The Ribbon Flat Cable connecting J16 on main board to J1 on display board is badly connected.</td>
<td>5. Reconnect or replace Ribbon Flat Cable.</td>
</tr>
<tr>
<td></td>
<td>6. Main board is defective.</td>
<td>6. Replace main board.</td>
</tr>
<tr>
<td></td>
<td>7. Reset switch is defective.</td>
<td>7. Replace reset switch.</td>
</tr>
<tr>
<td>The device cannot be switched on when the AC power source is connected.</td>
<td>Possible causes include 4, 5, 6 and 7 above.</td>
<td>Corrective actions include 4, 5, 6 and 7 above.</td>
</tr>
<tr>
<td></td>
<td>AC power source is badly connected, and battery is empty.</td>
<td>Reconnect AC power source, or replace appliance inlet.</td>
</tr>
<tr>
<td></td>
<td>AC power source is badly connected, and battery is defective.</td>
<td>Reconnect AC power source, or replace appliance inlet and battery.</td>
</tr>
<tr>
<td>AC power indicator does not light up.</td>
<td>AC power source is badly connected.</td>
<td>Reconnect AC power source.</td>
</tr>
<tr>
<td></td>
<td>AC power indicator is defective.</td>
<td>Replace display board.</td>
</tr>
<tr>
<td></td>
<td>The Ribbon Flat Cable connecting J16 on main board to J1 on display board is badly connected.</td>
<td>Reconnect or replace Ribbon Flat Cable.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td></td>
<td>Fuses are burnt out.</td>
<td>Replace fuses.</td>
</tr>
<tr>
<td></td>
<td>Display board is defective.</td>
<td>Replace display board.</td>
</tr>
<tr>
<td>Alarm indicator does not light up.</td>
<td>Alarm indicator is defective.</td>
<td>Replace display board.</td>
</tr>
<tr>
<td></td>
<td>The ribbon flat cable connecting J16 on main board to J1 on display board is badly connected.</td>
<td>Reconnect or replace Ribbon Flat Cable.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>Battery cannot be fully</td>
<td>Battery is defective.</td>
<td>Replace battery.</td>
</tr>
<tr>
<td>Issue Description</td>
<td>Possible Cause</td>
<td>Solution</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>charged after the device is connected to the AC power source for more than 24 hours</td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>Display does not show battery is being recharged when AC power source is connected</td>
<td>AC power source is badly connected.</td>
<td>Reconnect AC power source.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td></td>
<td>Fuses are burnt out.</td>
<td>Replace fuses.</td>
</tr>
<tr>
<td>Display does not light up, or only shows backlight, or shows partial contents, or backlight brightness cannot be adjusted</td>
<td>Display screen connection wires are badly connected</td>
<td>Reconnect display screen connection wires.</td>
</tr>
<tr>
<td></td>
<td>The ribbon flat cable connecting J16 on main board to J1 on display board is badly connected</td>
<td>Reconnect or replace Ribbon Flat Cable.</td>
</tr>
<tr>
<td></td>
<td>Display screen is defective.</td>
<td>Replace display screen.</td>
</tr>
<tr>
<td></td>
<td>Display board is defective.</td>
<td>Replace display board.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>No sound or abnormal sound for alarms or key presses.</td>
<td>Speaker is defective.</td>
<td>Replace speaker.</td>
</tr>
<tr>
<td></td>
<td>Speaker connection wires are badly connected or disconnected</td>
<td>Reconnect speaker.</td>
</tr>
<tr>
<td></td>
<td>Audio driver part is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>Motor does not spin, or spins abnormally.</td>
<td>Motor is defective.</td>
<td>Replace motor.</td>
</tr>
<tr>
<td></td>
<td>Motor connection wires are badly connected.</td>
<td>Reconnect motor.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>Some keys do not work.</td>
<td>The ribbon flat cable connecting J16 on main board to J1 on display board is badly connected</td>
<td>Reconnect or replace Ribbon Flat Cable.</td>
</tr>
<tr>
<td></td>
<td>Display board is defective.</td>
<td>Replace display board.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>KVO, BOLUS, Unlocked or Infusion indicators do not light up.</td>
<td>Indicator is defective.</td>
<td>Replace display board.</td>
</tr>
<tr>
<td></td>
<td>The ribbon flat cable connecting J16 on main board to J1 on display board is badly connected</td>
<td>Reconnect or replace Ribbon Flat Cable.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>Invalid time is displayed, and the time cannot be adjusted.</td>
<td>Button cell battery is empty.</td>
<td>Replace button cell battery.</td>
</tr>
<tr>
<td></td>
<td>Main board is defective.</td>
<td>Replace main board.</td>
</tr>
<tr>
<td>Log reports cannot be exported.</td>
<td>RS232 circuit on main board is defective.</td>
<td>Replace main board.</td>
</tr>
</tbody>
</table>
RS232 connection wires are disconnected. | Reconnect RS232 port to main board.

The displayed syringe size is incorrect.
- Syringe size detection board is badly connected. | Reconnect or replace the related wires or connectors.
- Syringe size detection board is not installed properly or is defective. | Reinstall or replace syringe size detection board.
- Main board is defective. | Replace main board.

Syringe cannot be calibrated.
- Potentiometer connected to J11 on main board is disconnected or defective. | Reconnect or replace potentiometer.
- Main board is defective. | Replace main board.

Displayed pressure level clearly disagrees with reality.
- Force sensor connection wires are disconnected. | Reconnect force sensor.
- Force sensor is defective. | Replace force sensor.
- Main board is defective. | Replace main board.

**7.2 Error messages**

*Information:*

Error messages include switch on self-test messages, operational failure messages and alarm messages. All messages are displayed as text or symbols. For alarm messages, also refer to Section 6.2 *Alarm conditions and corrective actions* for corrective actions.

<table>
<thead>
<tr>
<th>Message displayed</th>
<th>Description</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>EEPROM Error!</td>
<td>EEPROM error. 1. EEPROM chip or main board is defective.</td>
<td>1. Replace main board.</td>
</tr>
</tbody>
</table>

| Speaker Error!    | Audio driver part error. 1. The audio driver part is disconnected. 2. Speaker is defective. 3. Main board is defective. | 1. Check the connection of speaker. 2. Replace speaker. 3. Replace main board. |

| Pressure sensor error! | Pressure sensor error. 1. Pressure sensor disconnected. 2. Pressure sensor is defective. | 1. Reconnect pressure sensor. 2. Replace pressure sensor. |

<p>| No Battery Error!   | No battery error or alarm. 1. Battery is disconnected. 2. Battery is defective. | 1. Reconnect good battery to main board. 2. Replace battery. |</p>
<table>
<thead>
<tr>
<th><strong>Syringe Flange Insertion Error Alarm</strong></th>
<th><strong>Syringe Plunger Disengagement Alarm</strong></th>
<th><strong>Syringe Holder Loose Alarm</strong></th>
<th><strong>Undefined Syringe Type!</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Syringe flange detection board is defective.</td>
<td>1. Syringe plunger detection board is defective.</td>
<td>1. Loose syringe detection board is defective.</td>
<td>1. Syringe is not calibrated.</td>
</tr>
<tr>
<td>2. Syringe flange detection board is disconnected from main board.</td>
<td>2. Pusher releaser detection board is defective.</td>
<td>2. Loose syringe detection board is disconnected from main board.</td>
<td>2. Pressure sensor is defective.</td>
</tr>
<tr>
<td>3. Main board is defective.</td>
<td>3. Pusher releaser detection board is disconnected from main board.</td>
<td>3. Main board is defective.</td>
<td>3. Main board is defective.</td>
</tr>
<tr>
<td>2. Re-solder the wire connecting syringe flange detection board and main board.</td>
<td>2. Replace pusher releaser detection board.</td>
<td>2. Re-solder the wire connecting pusher releaser detection board and main board.</td>
<td>2. Replace pressure sensor.</td>
</tr>
<tr>
<td>3. Replace main board.</td>
<td>3. Replace main board.</td>
<td>3. Replace main board.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Occlusion Alarm</strong></th>
<th><strong>Empty</strong></th>
<th><strong>Rate Abnormal</strong></th>
<th><strong>Battery Empty</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Syringe or extension set is occluded.</td>
<td>1. Syringe is empty.</td>
<td>1. Actual flow rate differs from expected flow rate.</td>
<td>1. Battery is exhausted.</td>
</tr>
<tr>
<td>2. Pressure sensor is defective.</td>
<td></td>
<td>1. Replace motor or related transmission components.</td>
<td>2. Battery is defective.</td>
</tr>
<tr>
<td>1. Check syringe or extension set for sign of occlusion, and take necessary connective action.</td>
<td>1. Change syringe or end the infusion.</td>
<td>1. Connect to AC power source.</td>
<td>1. Connect to AC power source.</td>
</tr>
<tr>
<td>2. Replace pressure sensor.</td>
<td></td>
<td>2. Replace battery.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Key Stuck During Infusion / Pause Alarm</strong></th>
<th><strong>Undefined Syringe Type!</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Key stuck during infusion / pause alarm.</td>
<td>Syringe not calibrated note.</td>
</tr>
<tr>
<td>1. A key is stuck or was pressed for more than 5</td>
<td>1. Syringe is not calibrated.</td>
</tr>
<tr>
<td>1. Check keyboard and release the stuck key.</td>
<td>1. Calibrate syringe.</td>
</tr>
<tr>
<td>Alarm Type</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>COMPLETE</strong></td>
<td>Infusion complete alarm. 1. Infused volume reaches the target volume.</td>
</tr>
<tr>
<td><strong>NEAR EMPTY</strong></td>
<td>Syringe near empty alarm. 1. Syringe is nearly empty.</td>
</tr>
<tr>
<td><strong>NO ACTION</strong></td>
<td>No action alarm. 1. Device is switched on but no action is taken by the user for over 3 minutes.</td>
</tr>
<tr>
<td><strong>Battery low alarm.</strong> (Display alternately)</td>
<td>Battery low alarm. 1. Refer to Section 6.2 and Section 7.1 for cause descriptions.</td>
</tr>
<tr>
<td><strong>Distance Error!</strong></td>
<td>Distance error alarm. 1. Travel potentiometer is disconnected or defective.</td>
</tr>
<tr>
<td><strong>Diameter Error!</strong></td>
<td>Syringe diameter error. 1. Diameter potentiometer is disconnected or defective.</td>
</tr>
<tr>
<td><strong>Param Error!</strong></td>
<td>Parameter error. 1. The mistake of parameter check appears when turning on the device.</td>
</tr>
<tr>
<td><strong>Uncalibrated Reference Value!</strong></td>
<td>Uncalibrated reference. 1. The mistake of reference value appears when turning on the device.</td>
</tr>
<tr>
<td><strong>VOL ERR</strong></td>
<td>The volume detected exceed the 35% of actual volume.</td>
</tr>
<tr>
<td><strong>Subordinate MCU Error! / Blank screen</strong></td>
<td>Main CPU or Slave CPU cannot get the signal correctly.</td>
</tr>
<tr>
<td><strong>Red alarm light blinks and buzzer sounds (No power)</strong></td>
<td>AC power and battery fail simultaneously.</td>
</tr>
</tbody>
</table>

**Warning:**

If the above troubleshooting measures do not guide you to solve the problem, please contact Fresenius Kabi immediately.
8 Technical Information

8.1 Performance

8.1.1 Infusion flow rate
Range:  
- 50 mL syringe:  From 0.1 to 1800.0 mL/h
- 30 mL syringe:  From 0.1 to 1200.0 mL/h
- 20mL syringe:  From 0.1 to 800.0 mL/h
- 10mL syringe:  From 0.1 to 400.0 mL/h
- 5 mL syringe:  From 0.1 to 200.0 mL/h
Increments: 0.1mL/h
Accuracy: ±3% for flow rate ≥1mL/h and ±0.03mL/h for flow rate <1mL/h total accuracy in accordance with EN/IEC 60601-2-24.

Warning: Flow rate accuracy can be influenced by extension set configuration, fluid viscosity, and fluid temperature.

8.1.2 Volume to be infused
Range: 0 to 9999.9 mL
---.mL: default when volume infused reaches to 9999.9 mL, the “COMPLETE” information appears.
Increment: 0.1mL

8.1.3 Infusion time
Range: 00h01min to 99h59min
Increment: 1min

8.1.4 BOLUS or Purge rate

<table>
<thead>
<tr>
<th>Syringe size</th>
<th>BOLUS range</th>
<th>Purge rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mL</td>
<td>0.1 to 1800.0 mL/h</td>
<td>1800.0 mL/h</td>
</tr>
<tr>
<td>30 mL</td>
<td>0.1 to 1200.0 mL/h</td>
<td>1200.0 mL/h</td>
</tr>
<tr>
<td>20mL</td>
<td>0.1 to 800.0 mL/h</td>
<td>800.0 mL/h</td>
</tr>
<tr>
<td>10mL</td>
<td>0.1 to 400.0 mL/h</td>
<td>400.0 mL/h</td>
</tr>
<tr>
<td>5 mL</td>
<td>0.1 to 200.0 mL/h</td>
<td>200.0 mL/h</td>
</tr>
</tbody>
</table>

BOLUS increment: 0.1mL/h for all syringe types

8.1.5 BOLUS volume
Range: 1.0 to 50.0 mL
Increment: 0.1 mL
8.1.6 BOLUS volume precision
- If test bolus volume is no more than 10mL, the mean deviation of the bolus volume shall be within 0.3 mL;
- If test bolus volume is more than 10mL, the mean deviation of the bolus volume shall be within ± 3%.

8.1.7 KVO rate
0.1 to 1.0 mL/h or the most recent delivery rate, whichever is lower.

8.1.8 Occlusion alarm pressure level
High (H): 120-150 kPa
Medium (M): 80-120 kPa
Low (L): 50-80 kPa

8.1.9 Occlusion alarm response time

<table>
<thead>
<tr>
<th>Flow Rate</th>
<th>Occlusion alarm level</th>
<th>Alarm response time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 mL/h</td>
<td>High</td>
<td>≤30 h</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>≤20 h</td>
</tr>
<tr>
<td>1 mL/h</td>
<td>High</td>
<td>≤3 h</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>≤2 h</td>
</tr>
<tr>
<td>5 mL/h</td>
<td>High</td>
<td>≤50 min</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>≤30 min</td>
</tr>
</tbody>
</table>

Information:
- Occlusion alarm response time and occlusion pressure varies according to the device, flow rate, temperature, the syringe and the extension set.
- The maximum occlusion pressure in the syringe and extension set generated by the device is 200 kPa.
- When an occlusion alarm occurs, the anti-BOLUS function is automatically started to reduce the amount of BOLUS generated by the occlusion.

8.1.10 BOLUS volume at occlusion release

<table>
<thead>
<tr>
<th>Flow Rate</th>
<th>Occlusion alarm level</th>
<th>BOLUS volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mL/h</td>
<td>High</td>
<td>≤0.5 mL</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>≤0.3 mL</td>
</tr>
<tr>
<td>5 mL/h</td>
<td>High</td>
<td>≤0.5 mL</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>≤0.3 mL</td>
</tr>
</tbody>
</table>

8.1.11 Parameters in Dose mode

<table>
<thead>
<tr>
<th>Setting Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Mass</td>
</tr>
<tr>
<td>Drug Mass Units</td>
</tr>
</tbody>
</table>
Dose

<table>
<thead>
<tr>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.001 to 9.999, in 0.001 increment;</td>
</tr>
<tr>
<td>10.00 to 99.99, in 0.01 increment;</td>
</tr>
<tr>
<td>100.0 to 999.9, in 0.1 increment;</td>
</tr>
<tr>
<td>1000 to 9999, in 1 increment.</td>
</tr>
</tbody>
</table>

Dose Units

<table>
<thead>
<tr>
<th>Dose Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>ug/kg/min, mg/kg/min, g/kg/min, U/kg/min, IU/kg/min, ug/kg/h, mg/kg/h, g/kg/h, U/kg/h, IU/kg/h, ug/min, mg/ min, g/min, U/min, IU/min, ug/h, mg/ h, g/h, U/h, IU/h.</td>
</tr>
</tbody>
</table>

Patient Weight

<table>
<thead>
<tr>
<th>Patient Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 to 300.0 kg, in 0.1 kg increment</td>
</tr>
</tbody>
</table>

Solution Volume

<table>
<thead>
<tr>
<th>Solution Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 to 199.9 mL, in 0.1 mL increment</td>
</tr>
</tbody>
</table>

8.2 Technical characteristics

8.2.1 Operation mode
The pump is designed for continuously delivery of intravenous infusion.

8.2.2 Power supply specifications
The wall plug must be connected directly to the mains power socket.

<table>
<thead>
<tr>
<th>AC Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power source</td>
</tr>
<tr>
<td>Fuses</td>
</tr>
<tr>
<td>Maximum consumption</td>
</tr>
<tr>
<td>Power cord length</td>
</tr>
<tr>
<td>External DC power supply (user option)</td>
</tr>
</tbody>
</table>

⚠️ **Warning:**
An external DC power source can be only used in an ambulance.

8.2.3 Battery specifications

<table>
<thead>
<tr>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1Vdc, 2000mAh - Li-ion polymer battery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>120±20 g</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Battery operating time</th>
</tr>
</thead>
<tbody>
<tr>
<td>At an infusion rate of 5 mL/h, the battery operating time is typically 8 hours when fully charged.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Battery recharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump OFF: &lt; 10 h, Pump ON: &lt; 14 h</td>
</tr>
</tbody>
</table>

8.2.4 Dimensions and weight

<table>
<thead>
<tr>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump</td>
</tr>
<tr>
<td>Packaging</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dimensions (W x D x H)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump</td>
</tr>
<tr>
<td>Packaging</td>
</tr>
</tbody>
</table>

8.2.5 Compliance with standards

<table>
<thead>
<tr>
<th>Safety of Electro</th>
<th>Compliant with standards:</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPX4</td>
<td>Protection against splashing</td>
</tr>
</tbody>
</table>
8.3 Start-up and Trumpet Curves

The start-up curve represents the change in flow rate over a certain period of time, and the trumpet curve shows the variations of the mean flow accuracy over specific observation periods.

The following graphs are obtained from the tests performed with the system consisting of an INfusia SP7s syringe pump and a BD 50mL syringe. The fluid used is 0.9% saline. For other syringe sizes, the start-up and trumpet curves please contact Fresenius Kabi.

These tests were conducted in accordance with IEC60601-2-24 requirements.

The results may not be very close to those obtained in clinic because of the variations in extension sets, syringes, physical properties of infused fluid, the environment, and so on. The error in flow accuracy caused by such variations may be larger than 3% as specified in Section 8.1.1 Infusion flow rate.

8.3.1 Start-up curves

The following graphs are obtained from tests performed with a system consisting of an INfusia SP7s syringe pump and a BD 50mL syringe. The fluid used in the test is 0.9% saline.
- Flow rate: 5mL/h

![Graph showing flow rate of 5mL/h over time]

- Flow rate: 1mL/h

![Graph showing flow rate of 1mL/h over time]
8.3.2 Trumpet curves

- Flow rate: 5mL/h, the second hour

![Trumpet curve on 2nd hour (5mL/h)](image)

- Flow rate: 1mL/h, the second hour

![Trumpet curve on 2nd hour (1mL/h)](image)
9 EMC Declaration

**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.
- 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 INfusia SP7s, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**Guidance and manufacturer's declaration – electromagnetic emission**

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The INfusia SP7s Syringe Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions</td>
<td>Class A</td>
<td>The INfusia SP7s Syringe Pump System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations /</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>flicker emissions IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Guidance and manufacturer's declaration – electromagnetic immunity

<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>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air</td>
<td>±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrostatic fast transient / burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV line to line ±2 kV line to earth</td>
<td>±1 kV line to line ±2 kV line to earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% ( U_T ) (&gt;95% dip in ( U_T )) for 0.5 cycle &lt;5% ( U_T ) (&gt;95% dip in ( U_T )) for 1 cycle 70 % ( U_T ) (30% dip in ( U_T )) for 25/30 cycles &lt;5% ( U_T ) (&gt;95% dip in ( U_T )) for 5/6 sec</td>
<td>&lt;5%( U_T ) (&gt;95% dip in ( U_T )) for 0.5 cycle &lt;5% ( U_T ) (&gt;95% dip in ( U_T )) for 1 cycle 70 % ( U_T ) (30% dip in ( U_T )) for 25/30 cycles &lt;5% ( U_T ) (&gt;95% dip in ( U_T )) for 5/6 sec</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the <strong>INfusia SP7s</strong> Syringe Pump requires continued operation during power mains interruptions, it is recommended that the <strong>INfusia SP7s</strong> Syringe Pump be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td>
<td>30A/m</td>
<td>30A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

NOTE: \( U_T \) is the AC mains voltage prior to application of the test level.
Guidance and manufacturer's declaration – electromagnetic immunity

The INfusia SP7s Syringe Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the INfusia SP7s Syringe Pump should assure that it is used in such an 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>Conducted RF</td>
<td>IEC 61000-4-6</td>
<td></td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the INfusia SP7s Syringe Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td></td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>3 Vrms 150 kHz to 80 MHz</td>
<td>Recommened separation distance</td>
</tr>
<tr>
<td></td>
<td>6 Vrms in ISM and amateur radio bands</td>
<td>6 Vrms in ISM and amateur radio bands</td>
<td>d = [3.5 / V_1 ] \times P^{1/2}</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3</td>
<td></td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>10 V/m 80 MHz to 2.7 GHz</td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol:</td>
</tr>
<tr>
<td></td>
<td>385MHz-5785MHz</td>
<td>385MHz-5785MHz</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2)</td>
<td>Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2)</td>
<td></td>
</tr>
</tbody>
</table>

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** 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 INfusia SP7s Syringe Pump is used exceeds the applicable RF compliance level above, the INfusia SP7s Syringe Pump should be observed in order to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the INfusia SP7s Syringe Pump.

**b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.
Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

<table>
<thead>
<tr>
<th>Rated maximum output of transmitter [W]</th>
<th>Separation distance[m] according to frequency of transmitter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</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>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) as given by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.
10 Device Storage and Transport

If the device is not used for an extended period of time, it is recommended that the device be stored in an area that is clean, organized and compliant with the storage conditions below.

10.1 Storage and transport conditions

**Warning:**
Please store or transport the device according to the specified transport and storage conditions:
- Temperature range: -10°C to +55°C.
- Pressure range: 860 hPa to 1060 hPa.
- Humidity range: 20% to 90%, no condensation.

10.2 Preparing for storage

- Power off the device and remove the syringe.
- Connect to AC power source to recharge the battery.
- Disconnect the power cord and all other cables.
- Remove the pump from the mounting pole.
- Carefully handle the device and store it in an area specially prepared for storage.

**Warning:**
If the device will be stored for a very long time, connect it to an AC power source every one (1) month to recharge the battery.

10.3 Using after storage

**Warning:**
After storage or transport, do the following before using the device:
1. Connect the device to an AC power source to recharge the battery for about 10 hours without switching the device on.
2. Test the device’s functioning, and check it for traces of damage, especially after transport.
11 Services

11.1 Maintenance

**Warning:**
- Maintenance procedures are intended to be performed only by qualified personnel.
- It is recommended that preventive maintenance is carried out once per year according to the requirements of the technical manual.

**Information:**
If PCB diagrams, intervention procedures, test procedures, spare parts lists, and other technical information are needed for maintenance, please contact Fresenius Kabi.

11.1.1 Regular inspections
To ensure that the pump remains in good operating condition, regular inspections are required each time the pump is used.

**Warning:**
Failure to perform these inspections can result in improper device operation.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Upper &amp; lower cases</td>
<td>- No obvious damage, burrs, deformations or scratches are seen on external surfaces.</td>
</tr>
<tr>
<td></td>
<td>- The two cases are closed and fit together perfectly.</td>
</tr>
<tr>
<td></td>
<td>- The stacking lock cover can be opened easily, and the stacking lock knob rotates smoothly.</td>
</tr>
<tr>
<td></td>
<td>- The extension set holder is firmly installed, and the slot is smooth.</td>
</tr>
<tr>
<td>2. Screen</td>
<td>- No obvious damage, deformations, or scratches are seen on the external surface.</td>
</tr>
<tr>
<td></td>
<td>- Texts and symbols are displayed clearly and completely with no tilted, deformed or missing contents.</td>
</tr>
<tr>
<td>3. Keyboard</td>
<td>- No obvious damage is seen on the external surface.</td>
</tr>
<tr>
<td></td>
<td>- Keys are easily pressed and released without getting stuck.</td>
</tr>
<tr>
<td>4. Pole clamp</td>
<td>- No obvious damage is seen.</td>
</tr>
<tr>
<td></td>
<td>- It can be operated properly without resistance or the need to apply extra force.</td>
</tr>
<tr>
<td></td>
<td>- The pole clamp screw is still functioning well.</td>
</tr>
<tr>
<td>5. Pusher and syringe holder</td>
<td>- No obvious damage, burrs, deformations or scratches are seen on external surfaces.</td>
</tr>
<tr>
<td></td>
<td>- The pusher can be pulled out and pushed in smoothly when the pusher</td>
</tr>
<tr>
<td>Component</td>
<td>Condition</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>6. RS232 port</td>
<td>⚫ It is firmly installed on the rear case.</td>
</tr>
<tr>
<td></td>
<td>⚫ Screws and nuts are not loose, damaged or rusted.</td>
</tr>
<tr>
<td>7. Potential equalisation terminal</td>
<td>⚫ It is firmly installed on the rear case.</td>
</tr>
<tr>
<td></td>
<td>⚫ It is not damaged or rusted.</td>
</tr>
<tr>
<td>8. AC power inlet</td>
<td>⚫ It is firmly installed on the rear case.</td>
</tr>
<tr>
<td></td>
<td>⚫ The power cord can be plugged in easily and securely.</td>
</tr>
</tbody>
</table>

### 11.1.2 Battery

The device contains a rechargeable lithium-ion polymer battery which recharges automatically when the device is connected to the AC power source. The initial full battery charge (before switching on the pump for the first time) takes about 10 hours.

To avoid overcharging the battery, please switch off and disconnect the device from the AC power source when it is not being used.

It is necessary to recharge the battery if the device is stored for more than one month.

Please contact **Fresenius Kabi** for a replacement battery. The old battery should be handled according to local laws.

### 11.1.3 Fuses

When the fuses need to be replaced, please contact **Fresenius Kabi**.

### 11.1.4 Device service life

To ensure the safety of medical equipment, the service life for the device should NOT exceed 7 years after the production date.

The electronic memory storage time of the device after switching off is 20 years.

**Warning:**

*Use of expired products may cause damage to patients and healthcare staff.*

### 11.1.5 Disposal

- Expired devices, removed batteries, and used syringes, needles and extension sets must be disposed of according to your local laws on electronic and medical waste.
- Improper management of expired devices, removed batteries and used syringes, needles and extension sets can contaminate environments and pose a health risk to public and waste workers.
11.2 Warranty

11.2.1 General conditions of warrant
Fresenius Kabi guarantees that this product is free from defects in material and workmanship during the period defined by the accepted sales conditions, except for the batteries and the accessories.

11.2.2 Limited warranty
To benefit from the materials and workmanship guarantee from Fresenius Kabi, make sure to observe the following conditions:

● The device must have been used according to the instructions described in this IFU and other accompanying documents.
● The device must not have been damaged whilst being stored or repaired, and must not show sign of improper handling.
● The device must not have been altered or repaired by non-qualified personnel.
● The internal battery of the device must not have been replaced by a battery other than that specified by the manufacturer.
● The serial number (SN) must not have been altered, changed or erased.

Information:

● If one or more of these conditions have been violated, Fresenius Kabi will prepare a repair estimate covering all required parts and labour.
● To repair or return a device, please contact Fresenius Kabi.

11.2.3 Warranty conditions for battery and accessories
Batteries and accessories may have specific conditions of warranty. Please contact Fresenius Kabi for more information.

11.3 Notification of serious incident
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority.

Information and contact information:
Fresenius Kabi AG
Else-Kröner -Str. 1
61352 Bad Homburg
Germany
Tel.: +49 (0) 6172 / 686-0
http://www.fresenius-kabi.com
## 12 Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Ampere</td>
</tr>
<tr>
<td>AC</td>
<td>Alternating Current</td>
</tr>
<tr>
<td>BATT EMPTY</td>
<td>Battery Empty</td>
</tr>
<tr>
<td>BOLUS</td>
<td>A discrete quantity of liquid which is delivered in a short time as an infusion but not part of a priming routine</td>
</tr>
<tr>
<td>°C</td>
<td>Degree Celsius</td>
</tr>
<tr>
<td>CISPR</td>
<td>Special International Committee on Radio Interference</td>
</tr>
<tr>
<td>CPU</td>
<td>Central Processing Unit</td>
</tr>
<tr>
<td>DC</td>
<td>Direct Current</td>
</tr>
<tr>
<td>EEPROM</td>
<td>Electrically Erasable Programmable Read-Only Memory</td>
</tr>
<tr>
<td>ERR</td>
<td>Error</td>
</tr>
<tr>
<td>g</td>
<td>Gram</td>
</tr>
<tr>
<td>GHz</td>
<td>Giga-Hertz</td>
</tr>
<tr>
<td>h</td>
<td>Hour</td>
</tr>
<tr>
<td>hPa</td>
<td>Hectopascal</td>
</tr>
<tr>
<td>H</td>
<td>High</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>IFU</td>
<td>Instructions for Use</td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>KEY ERR</td>
<td>Key Error</td>
</tr>
<tr>
<td>kg</td>
<td>Kilogram</td>
</tr>
<tr>
<td>kHz</td>
<td>KiloHertz</td>
</tr>
<tr>
<td>kPa</td>
<td>Kilopascal</td>
</tr>
<tr>
<td>KVO</td>
<td>Keep Vein Open</td>
</tr>
<tr>
<td>L</td>
<td>Low</td>
</tr>
<tr>
<td>mA</td>
<td>Milliampere</td>
</tr>
<tr>
<td>mAh</td>
<td>Milliampere hour</td>
</tr>
<tr>
<td>mm</td>
<td>Millimeter</td>
</tr>
<tr>
<td>mL</td>
<td>Milliliter</td>
</tr>
<tr>
<td>mL/h</td>
<td>Milliliter per hour</td>
</tr>
<tr>
<td>MHz</td>
<td>Mega-Hertz</td>
</tr>
<tr>
<td>M</td>
<td>Middle</td>
</tr>
<tr>
<td>N</td>
<td>No</td>
</tr>
<tr>
<td>PCB</td>
<td>Printed Circuit Board</td>
</tr>
<tr>
<td>SOL VOL</td>
<td>Solution Volume</td>
</tr>
<tr>
<td>V</td>
<td>Volt</td>
</tr>
<tr>
<td>VA</td>
<td>Volt-ampere</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>Vdc</td>
<td>Volt direct current</td>
</tr>
<tr>
<td>VTBI</td>
<td>Volume to Be Infused</td>
</tr>
<tr>
<td>VI</td>
<td>Volume infused</td>
</tr>
<tr>
<td>VOL</td>
<td>Volume</td>
</tr>
<tr>
<td>W</td>
<td>Watt</td>
</tr>
<tr>
<td>Y</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Local contacts for servicing and use issues

Fill this box with your distributor seal:

Fresenius Kabi Syringe Pump INFUSIA SP7s

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Made in China

Revision date: July 2023

Reference: AD-FKN-ADOC-00203 V1 SP7s V5 Master IFU_ENG-RU

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Authorized representative of the Manufacturer in the territory of the Russian Federation Federations:

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125167, Moscow, Leningradsky Prospekt, 37, bldg.9, fl. 3, room XXIV, com. 15
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