

Infusion Pump IP41x Series

Operator's Manual



**Please read this Operation Manual carefully and follow Precautions for Use
before using the IP41X Series Infusion Pump.**

Version 1.1

DIGICARE ANIMAL HEALTH

DIGICARE ANIMAL HEALTH

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- All disassembly, replacement, test, modification and repair are executed by qualified persons approved by DIGICARE.
- All replacement parts, supporting accessories and consumables during the maintenance are provided by DIGICARE.
- Maintenance records for product are reserved.

DIGICARE ANIMAL HEALTH

Thank you for using the IP41x infusion pump from Digicare.

All products manufactured by Digicare Biomedical Technology Inc. are warranted to be free from defects in material and workmanship and to operate within published specifications, under normal use, for a period of one year from date of original shipment. The warranty on the Digipump series is 1 year parts and labor.

The warranty will be void if the pump is altered or repaired or has been misused in any way that would affect the reliability or detract from the performance.

If you have any questions regarding the IP41x please contact your local distributor or directly contact DIGICARE.

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Overview

1 Overview

1.1 Intended use

This product is intended for the administration of fluids to patients requiring continuous delivery at controlled infusion rates and should only be used by trained professionals.

1.2 Contraindication

This product is not intended for blood transfusions.

1.3 Product Features

DIGICARE IP41x Series is a micro-continuous infusion pump. It ensures constant infusion speed and accurate dosing volume during long time infusion.

This infusion pump is used for continuous and micro-volume infusion of liquid or liquid medicine of small volume and high concentration, including, but are not limited to the infusion of chemotherapeutic agents, cardiovascular drugs, antineoplastic, oxytocic, anticoagulant, anesthetic agents.

- Standard disposable IV sets are supportable.
- User can include new standard IV set.
- Eleven occlusion levels and displays the pressure status of the IV line.
- Maximum infusion rate can be set to 1200mL/h.
- Calibration function for infusion accuracy is available.
- Safety design by monitoring infusion states.
- Multiple modes of infusion.
- Multi-channel infusion workstation relay infusion function.
- WI-FI function, can be connected to the infusion central monitoring system by intravenous infusion.
- Touchscreen, providing quick and convenient user interface.
- Night mode display, reducing light interference to patients and environment
- Three types of power supply: AC mains supply, DC external supply, and internal lithium battery. The internal lithium battery can power the infusion pump for no less than 5 hours (at 25ml/h rate).
- Dual CPU and redundancy design for increased safety.
- Two-way alarm for monitoring the main control circuit and motor drive circuit.
- Independent motor driving CPU and motor subdivided drive chip design.

Overview

- Setting for automatic prompt of maintenance interval.
- Modular installation design enables multi-channel pumps among pumps.

Note:

Drip sensor, Barcode scanner, WI-FI communication module, voice communication, nurse call and relay infusion function are optional.

Precautions For Use

2 Precautions for Use

In this manual, precautions are classified into warning and caution as follows:



WARNING:

A **Warning** alerts you to a potential serious outcome, adverse event or safety hazard.

Failure to observe a warning may result in serious injury.

CAUTION:

A **Caution** alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may affect normal use of the product.



WARNING

- The infusion pump must be operated by qualified clinical professionals.
- The infusion pump cannot be used for blood transfusion.
- The pump does not have an upstream occlusion alarm, clamps must be below the pump at all times.
- Prior to use, please check the status of the pump, power cord and other related accessories to ensure the device can be used normally and safely.
- Pay extra attention to kinks of the infusion line when it is used for low-infusion. The smaller the set infusion rate becomes, the longer it takes from the occurrence of occlusion to its detection, which may suspend the infusion for a long time.
- To avoid the risk of fire or explosion, do not use the infusion pump in a flammable or oxygen rich environment.
- The altitude difference between the pump and heart position of the patient should not be larger than 100cm (3.3ft). Smaller difference of the altitude will increase the accuracy of the pressure sensor's result.
- In the event of tube twisting, filter condensation or intubation occlusion during infusion, the internal pressure of the infusion tube will increase. Once the causes for occlusion are removed, too much infusion liquid may be infused into the patient. Therefore, proper actions should be taken. For example, clamp the infusion tube before removing the occlusion causes.
- To guarantee the infusion safety and alarming function, it is recommended to use the IV sets specified by the manufacturer only.
- Only the IV set, tube, infusion needle and other medical parts complying with the

Precautions For Use

local regulations can be used on the infusion pump. Contact Digicare or your local distributor for more information.

- Operations against the requirements, procedures, warnings and cautions provided in this manual may cause infusion failure, inadequate, overdosing, or other potential risks.
- It is recommended to install the drop sensor and open the drop monitoring function. A long time extrusion without moving or replacing the tube may cause an inadequate infusion.
- There should be regular monitoring by clinical professionals to observe the clinical situation and infusion pump working condition when using the device.
- The power cord or other affiliated lines should be kept properly to avoid any risk of twining on patient or electrical disturbance.
- High-frequency surgical equipment, mobile phone, wireless device and defibrillator may have interference on the infusion pump. Keep away from such devices while operating.
- To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.
- If the pump and its related accessories are reaching over the lifetime, they must be scrapped and disposed in accordance with the local laws or hospital ordinances. Please contact your local representative for further details.
- Do not modify this equipment without authorization of the manufacturer.
- When operating the pump or checking the pump's alarm system, the operator shall be in front of the device, no farther than 1 meter.
- There is no patient circuit in this device. The output of the equipment is not allowed to be accessible to patient.
- The operator shall not touch IP41x and the patient simultaneously.

CAUTION:

- The infusion set is treated as an applied part of the pump.
- Check the setting values on the prescription and infusion pump. Infusion should start only when the values are equal.
- In order to prevent extra infusion, close the rolling clamp of the IV sets before removing the IV set from pump.
- Follow the tube replacement alarm on the display interface, replace the IV sets or move the IV sets tubing more than 10cm, to keep the infusion accuracy continuously.

Precautions For Use

- Ensure that the infusion pump has been fixed tightly on the stand and the stand is stable. Prevent the pump from collision, dropping mechanical vibration or other impact of external forces to avoid damage on the pump.
- Before pressing the [START] key, check if the infusion speed is correct, especially the position of the decimal point.
- Do not operate on the display with sharp objects. Otherwise, the display may be damaged.
- Occlusion alarm may occur when high-viscosity liquid is infused at high speed through a thin intravenous needle. Increase the occlusion level or decrease the infusion speed.
- The drop sensor detects drops, but not the flow rate. If the liquid in the drop chamber keeps dripping into continuous liquid flow, the drop signal cannot be detected.
- Infusion pump should be placed without the reach of patients and other irrelevant personnel.
- Avoid direct sunlight, high temperature and high humidity.
- Do not disinfect the infusion pump by using high-pressure steam sterilization method.
- Before using the internal battery, check the battery to ensure that sufficient power is available. Recharge, if required.
- Ensure that the infusion pump always has a battery installed during operation. Otherwise, the system may stop without issuing an alarm when external power is interrupted due to power failure or a short circuit, causing an unsafe condition.
- If the infusion pump cannot work as described in this manual for unknown reasons, stop it and report the details (including IV set, infusion flow, serial number of infusion pump, and type of infusion liquid) to your local distributor or our customer service department.
- Do not disassemble or reconstruct the infusion pump without authorization.
- Liquid intrusion into the AC power socket, USB or nurse call socket may cause short-circuiting. While connecting the power cable, check if the connecting parts are dry. If liquid spills on the infusion pump, clean the pump with a dry wiper. Use after the service engineer checking.
- The maximum temperature at the applied part of the pump may reach 41.1°C, when running continuously under the highest environment temperature at the highest infusion rate.
- Before use, carefully check if the occlusion pressure test function of the infusion

Precautions For Use

pump is normal. The Maximum infusion pressure at the end of the infusion tube generated by the pump may be up to 3500mmHg under the condition of occlusion when sensor failed.

- The delay time between the onset of the alarm condition and the representation of the alarm is no longer than 150ms.

Precautions For Use

Symbols

	Authorized Representative in the European Community
	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Manufacturer
	Specifies serial number
	TYPE CF APPLIED PART
	Alternating current
	Direct current
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	CAUTION! Read the accompanying document.
	General warning sign
	Refer to instruction manual / booklet
IPX2	Level of protection from liquid intrusion
	Interference may occur near the devices with below sign.
	Nurse call
	ON/OFF
	HOME

Product Specifications

3 Product Specifications

Product name	Infusion pump
Model	IP41x Series
Power supply	AC power supply: AC 100-240V,50/60 Hz, power consumption 45 VA External DC power supply: DC 12 V 1A Internal battery: lithium battery 11.1 V 1500 mAh Battery model: 154457 Time of battery continuous use: no less than 5 hours (for infusion at 25 mL/h rate with a new battery)
Fuse	T1.6AL 250VAC
Compatible IV sets	IV sets with external diameter from 3.5 to 5.5mm, shore A max 75.
Infusion mode	Rate, Time, Weight, Loading Dose, Trapezia, Sequence, Micro, Relay, Drip Mode
Infusion setting range	0.1-1200.0mL/h or(0.03-400d/min) See the least increment in chart 6-3
VTBI setting range	0.1 - 99.99(Least increment 0.01) 100 - 999.9(Least increment 0.1) 1000 - 9999(Least increment 1)
Total volume display	0-99999.99ml
Accuracy	±5%
Purge operation	1200.0ml/h
Bolus operation	0.1~1200.0ml/h Automatically calculate the bolus rate by bolus amount, cannot lower than the current rate.
KVO rate	0.1-5.0mL/h
Air-bubble sensor	Sensitivity: detect air-bubble $\geq 0.025^{+0.025}_{-0}$ mL
Occlusion level	225mmHg~975mmHg, 11 levels are available
Alarm	Near Finished, Finished, OCCL, Low Battery, Battery Empty, No Battery, No Power Supply, The Pump Door Open, Air Bubble , No Drip Sensor, No Drips, Drips Abnormal, Reminder Alarm , Relay Index Duplicate, Infusion Start Fail , Standby Time Expired
Special function	Repeat alarming:

Product Specifications

	If there is still alarm after mute alarm sound, it will alarm again in 2 minutes Event recording: can store and playback 2000 events maximum Sound volume: 11 levels are available Power supply switching: When AC/DC power supply is cut off, the infusion automatically switch to internal battery supply Barcode scanning: Input the patient information by barcode canning
Wi-Fi function	Connect infusion workstation, nurse pager, voice communication and infusion pump information network
Operating conditions	Temperature: 5°C to 40°C Humidity:15% to 95% RH Pressure altitude: 70.0kPa-106.0kPa
Storage conditions	Temperature: -20°C to +55°C Humidity: 10% to 93% RH Pressure altitude:22.0kPa-107.4kPa
Operation Mode	Continuous operation
Classification	1. Class I / Internally powered equipment; 2. Type CF applied part; 3. IPX2; 4. No sterilization requirement for pump 5. Not category AP / APG equipment; 6. Mode of operation: continuous
Dimensions	202(W) ×74(H) ×133(D)mm
Weight	< 1.22 kg (including battery)
Service Life	10 years
Main safety standards	IEC60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC60601-2-24 Medical electrical equipment –Part 2-24: Particular requirements for the safety of infusion pumps and controllers IEC60601-1-8 Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm

Product Specifications

	systems in medical electrical equipment and medical electrical systems IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility requirements and tests
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Product Description

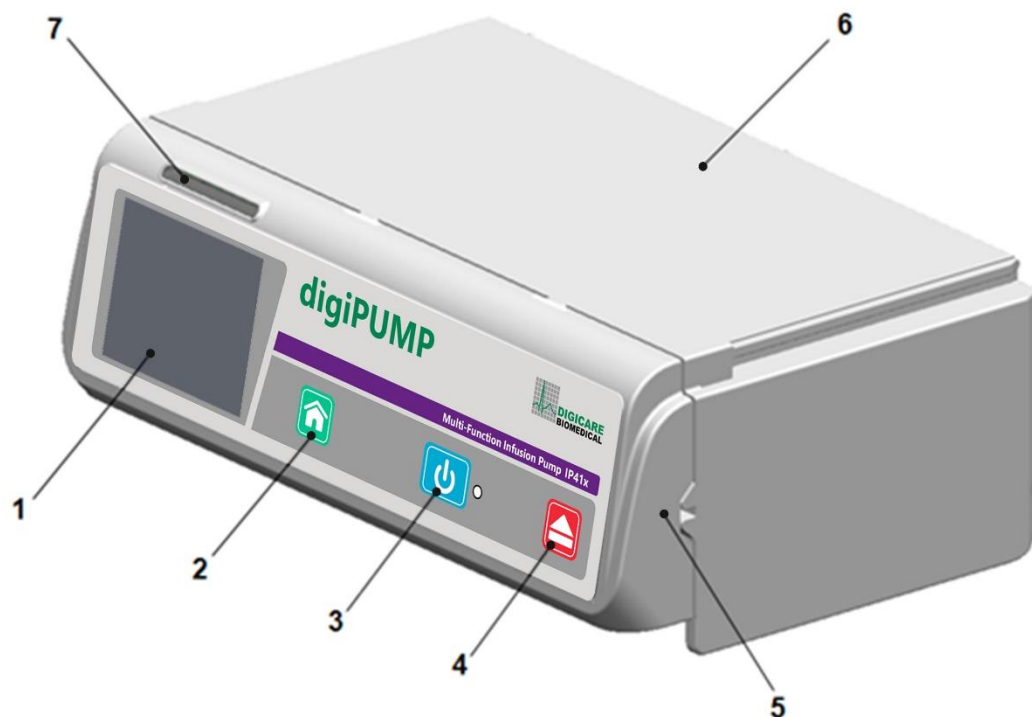
4 Product Description

4.1 Principle of Operation

The IP41x Series infusion pump mainly consists of pump shell, display screen and operating system, monitoring system, alarm system, motor drive system, tubing peristaltic module, power supply system, drop sensor (optional), WI-FI communication module (optional), handle and pole clamp.

The infusion pump adopts the dual processor structure, controls the motor precisely, drives the peristaltic sheet to infuse through the mechanical drive device, monitors the sensors and infusion process, and provides audio and visual alarms.

4.2 Composition of Infusion Pump



1 –Touchscreen

2 – [HOME] key

3 – [ON/OFF] key

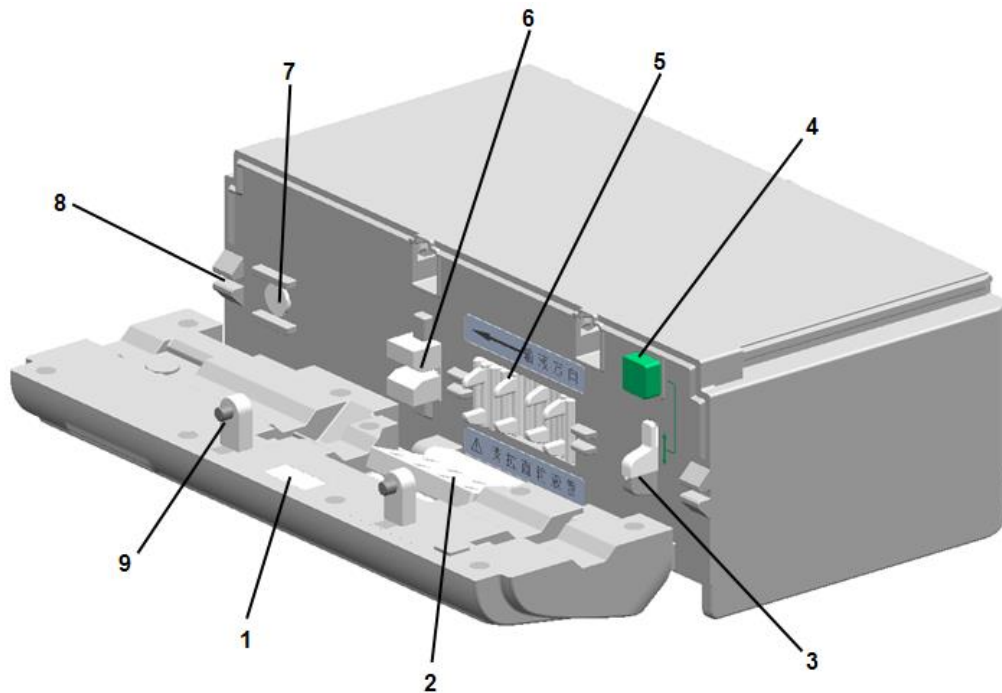
4 –[OPEN] key

5 –pump door

6 –Shell

7 –Alarm indicator

Product Description



1 –Lighting lamp

2 – Depressor

3 – Anti-free-flow clamp

4–Anti-free-flow clamp button

5 – Peristaltic pump plate

6 – Air bubble sensor

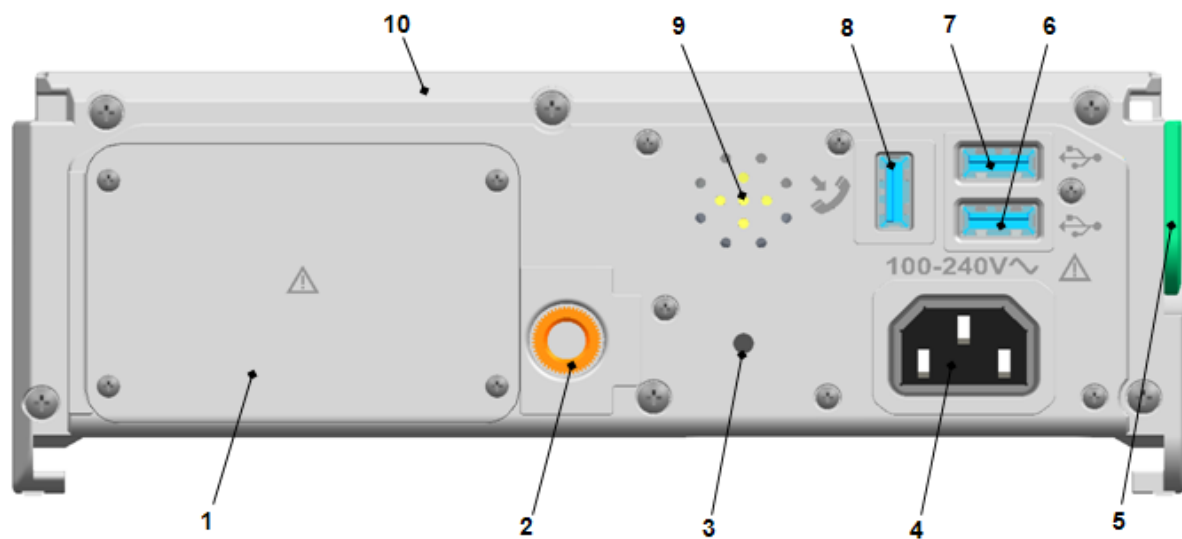
7 –Pressure sensor

8 –Infusion tube slit

9 – Catch

- Lighting lamp. To provide lighting in a dim environment, so as to install and check the infusion tube
- Depressor and peristaltic plate. Driven by the step motor, press and move the tube to realize liquid flow
- Anti-free-flow clamp. Stop liquid flow and infusion backwards after the pump door opens
- Anti-free-flow clamp button. Press the button and the clamp will automatically open or close.
- Pressure sensor and bubble sensor. Sensors monitor occlusion pressure and air bubble inside the infusion tube.
- Infusion tube slit. At sides of pump to guide the infusion tube in a line behind the pump door.
- Catch. The two catches are used to close the pump door.

Product Description



- | | | |
|---------------------|----------------------|---------------------|
| 1 –Battery cover | 2 –Threaded hole | 3 –Auxiliary alarm |
| 4 – AC power inlet | 5 –Combination clamp | 6 –External inlet 1 |
| 7 –External inlet 2 | 8 –External inlet 3 | 9 –Buzzer |
| 10 – Shell | | |

- Battery chamber. Replaceable battery inside the chamber.
- Threaded hole. To fix the pole clamp, then fix the pump to the IV pole via the pole clamp.
- Auxiliary alarm. Audible alarm sounds when product functions abnormally.
- Buzzer. To alarm in high, medium or low level during infusion and enable voice conversation.
- AC power inlet. To connect the external AC power source.
- External inlets 1, 2 and 3. The three inlets share the same signal and can be connected to 3 external devices at the same time. The external devices include drop sensor, barcode scanner, external DC power cord. The external inlet 1 and 2 could be used as the interface for the local WLAN.

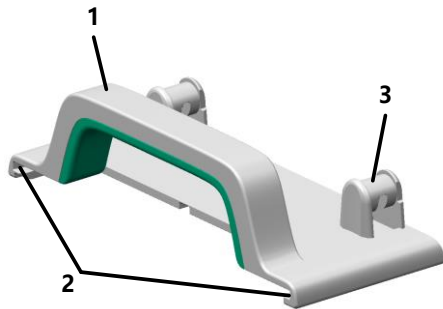
CAUTION:

- Only the accessories or devices specified by the manufacturer allowed to be connected to the Pump. Otherwise may cause electrical shock. See Table 4-1.
- The person who connects the devices and accessories to each other or who uses the devices and accessories is responsible and liable for installation and operation that complies with IEC/EN 60601-1-1 or clause 16 of IEC 60601-1.
- The plug is used as disconnect to the mains supply, do not position the pump so

Product Description

that it is difficult to operate the disconnection device.

4.3 Handle

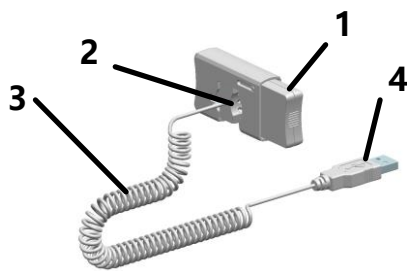


1 –Handle

2 –Slide rail

3 –Tubing management bracket

4.4 Drop sensor



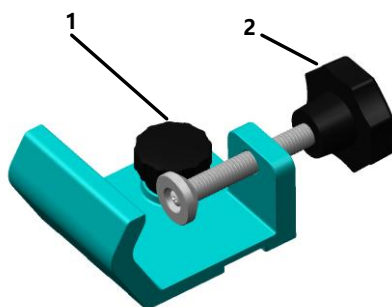
1 –Button

2 –Drop hole

3 –Cable

4 –Socket

4.5 Pole Clamp

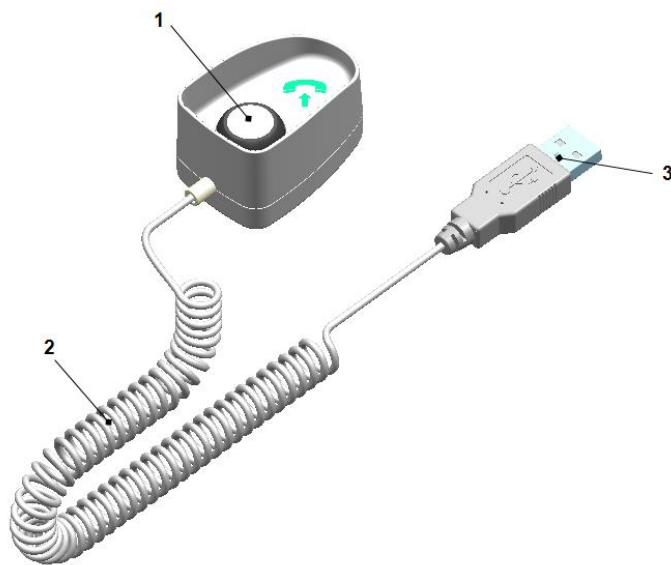


1 – Mounting screw

2 – Mounting knob of infusion stand

Product Description

4.6 Nurse Call



1 – Button

2 – Cable

3 – Socket

4.7 Accessories accompanied

1 – AC power cord	1	2 – Pole clamp	1
3 – Handle	1	4 – Operation manual	1
5 – Packing list	1	6 – Quick-operation instructions	1

4.8 Optional Accessories

Table 4-1 List of Optional Accessories

Options	Description	Parts code
Power cable	Standard configuration by factory	7000000005
Lithium battery pack	11.1V@1500mAh	7404000006
Handle	MP-1	9113000002
Nurse pager	MP-2	9113001002
Drop sensor	MP-3	9114002521
Barcode scanner	MP-4	9005000008
Pole clamp	—	9114002501

Preparations For Use

5 Preparations for Use

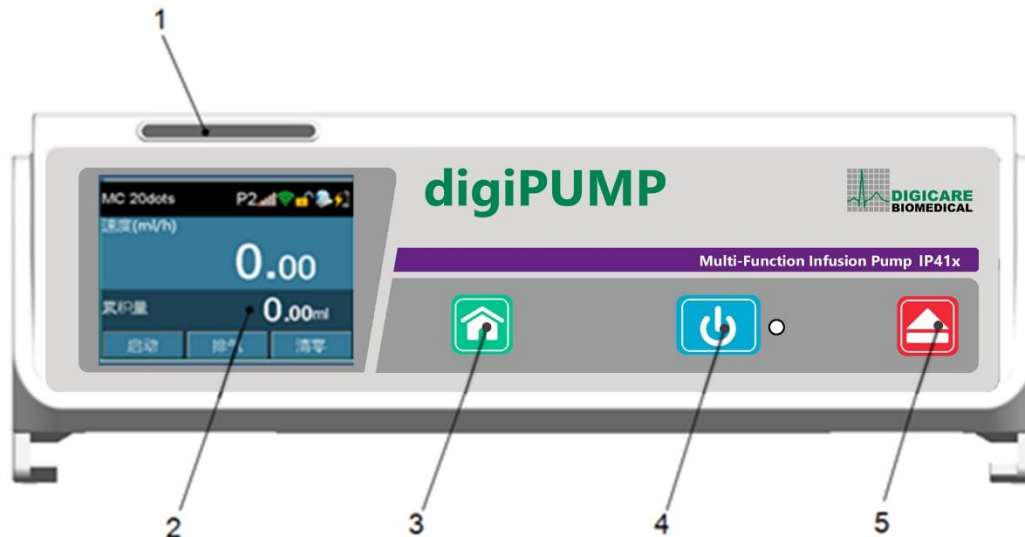
- Before using the infusion pump, read carefully the Operation Manual and precautions in this manual.
- When using the infusion pump for the first time, set up the date and time to ensure that history can be recorded correctly.
- Before using the infusion pump for the first time, set the brand of infusion set.
- Before using the infusion pump for the first time, recharge the internal battery fully. If the infusion pump is off, the battery will be fully charged in 10 hours after being connected to the mains supply.
- Place the infusion pump on a stable platform.
- Or use the provided pole clamp to mount the infusion pump on an infusion stand.
 - Put the infusion pump on the pole clamp while aligning the retaining knob with the threaded hole and rotate the handle to fix the infusion pump on the pole clamp.
 - Clamp the pole clamp on the infusion stand, adjust the infusion pump to an appropriate position, and tighten the retaining knob for infusion stand on the pole clamp.
- Connect to external mains supply.
 - Insert the supplied AC power cord into the AC inlet on the right side of the infusion pump. Plug the cord into an AC power outlet with grounding terminal.
 - To power the infusion pump with external DC power supply, contact Digicare or your local distributor.

Operating Instructions

6 Operating Instructions

6.1 Display and keys

- Display



1 – Alarm indicator

2 – TFT Touchscreen

3 – Home key

4 – ON/OFF key

5 – OPEN key

1. The alarm indicator indicates alarms with three colors: red, yellow and green, respectively to the alarm high, medium and low priority alarms.

2. TFT LCD with Touchscreen, resolution: 320X240.

The display is divided into three areas: information area, work data area and function key area. See below for further description.

Information area: Display the IV set brand and specification, occlusion level, real- time pressure, external power source, battery capacity and WI-FI signal. Touch the IV set brand and specifications zone to enter a page of IV set brand adjustment. Touch the occlusion pressure level to enter the page for occlusion level selection. See below for further description.



Operating Instructions

 Occlusion pressure alarm level set: 2

 Occlusion pressure real-time: a full set of 5 bars. The more bars displayed, the larger pressure it is.

 External power source. Displays when external AC/DC power source is connected.

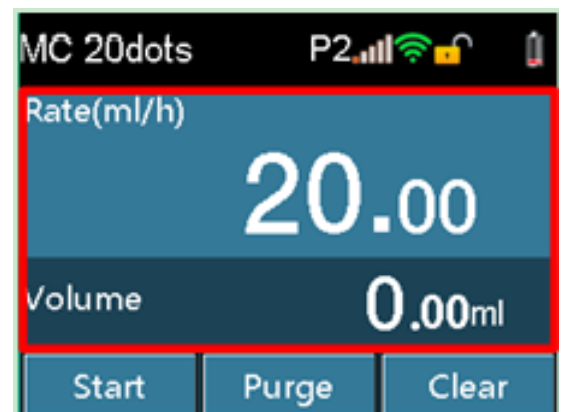
 Screen lock symbol, consists of lock and unlock.

 Battery volume and charging states: a full set of 4 bars, the more bars displayed, the larger battery volume.

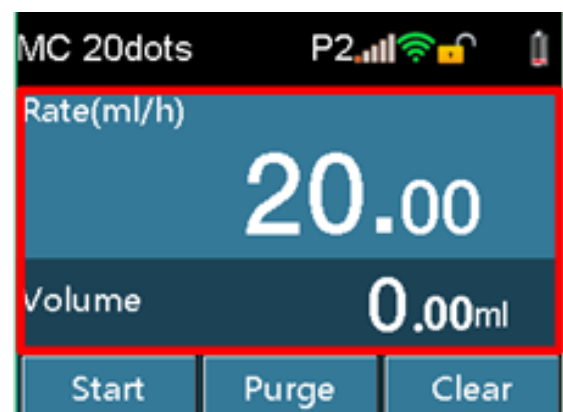
 WI-FI signal

 Display when connecting to workstation

Work data area: Displays infusion rate, infusion volume or different infusion work data according to different infusion mode. The work data could be adjusted by touching the specific zone in different working mode.



Function key area: Touchscreen includes keys of [Start], [Purge], [Clear], [Stop]. Setting keys such as numbers and letters appear on corresponding interfaces.



Operating Instructions

● Direct Keys

There are also 3 direct keys on the key panel: [HOME], [ON/OFF] and [OPEN]

- [HOME]: Main menu key. Before infusion, press [HOME] once to enter a setting menu, such as Infusion set, Local set, History and Interconnect set. To return to the infusion preparing interface, press [HOME] once again in any setting interface. During infusion, press [HOME] to switch to infusion interface, enlarge and display the infusion rate.
- [ON/OFF]: Switch on/off key. When the pump is off, press [ON/OFF] to turn on the pump. When the pump is on, press [ON/OFF], and shutdown interface pops up, select [Power Off]] or long press [ON/OFF] for 3 seconds to shut down.
- [OPEN]: Door open key. Press [OPEN] and the pump door open automatically, no matter the power is on or off. Push the door forward slightly till you feel the resistance, the door closes automatically.

6.2 Start up

CAUTION:

- Start up and then install the IV set.
 - Press [ON/OFF] to start up.
 - The self-test starts and start up interface appears.
 - After self-test finishes, it enters infusion preparing interface.
 - The screen displays patient information, infusion brand and occlusion level stored last time the device powered off.
 - If the self-test is abnormal, corresponding information will appear on information area.

Infusion preparation interface:



Operating Instructions

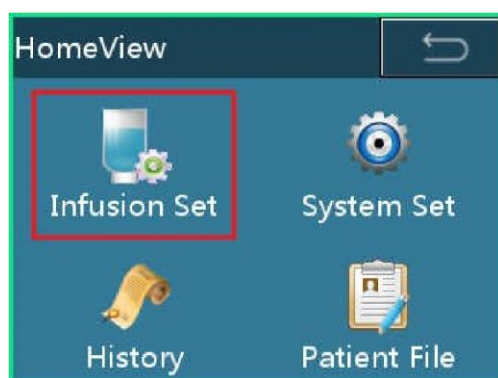
WARNING:

- After the power switch is turned on, confirm the loudspeaker, warning indicator is working all right, and check if the self-test is finished and no error messages appear. (Refer to Chapter 8 Troubleshooting.)
- Ensure the displayed IV set brand corresponds with the using IV set brand.
- If the IV set brand set is different from the using IV set brand, the infusion accuracy and alarm function cannot be guaranteed.
- Previous patient information will be cleared if [Yes] is selected on the New Patient screen.

6.3 Calibration of New IV Sets

1. Enable and Select IV set brand.

- 1.1. The IP41x has several IV line brands stored in the library. To add a new IV line, you need to edit and calibrate one of the brands that are not being used.
- 1.2. Press “Home” key to enter the Home screen.
- 1.3. Press “System Set” and press “Collection Set”.
- 1.4. Press “Brand Collection”. Check the box to enable any unused brand in the library.
- 1.5. Press “Home” key twice to enter the Home screen.
- 1.6. Press “Infusion Set”, press “Brand” and select the Brand you want to edit or calibrate.

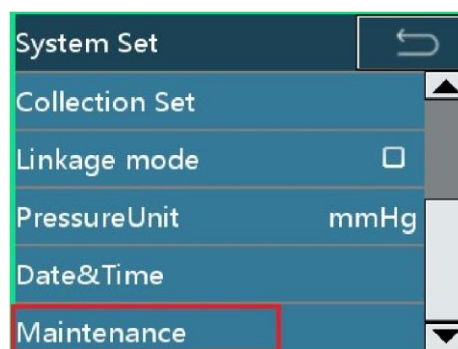
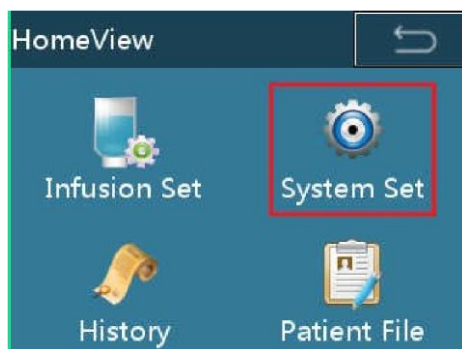


Operating Instructions

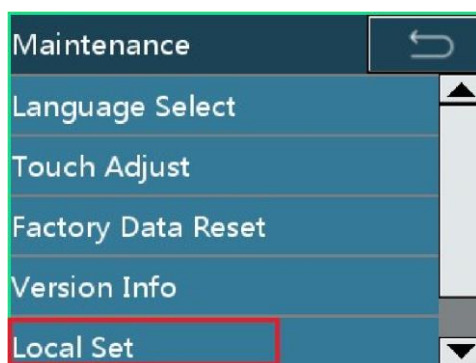
2. Edit and Calibrate IV Set brand

2.1. Press “Home” key twice to enter the Home screen.

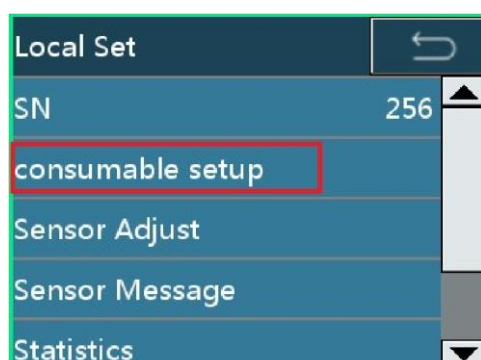
2.2. Then press “System Set” and press “Maintenance”.



2.3. Press “Local Set”, enter password “1666”, click “Confirm”

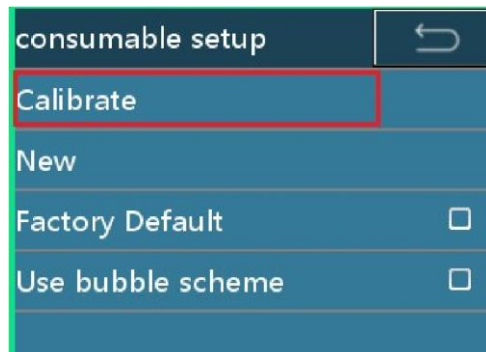


2.4. Press “Consumable setup”.



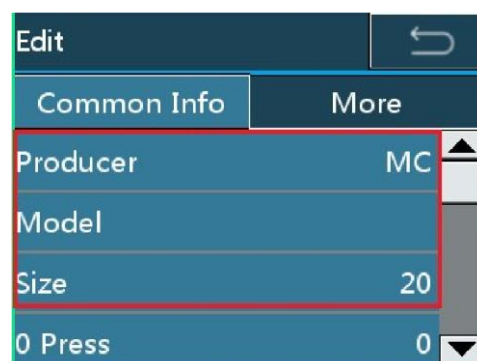
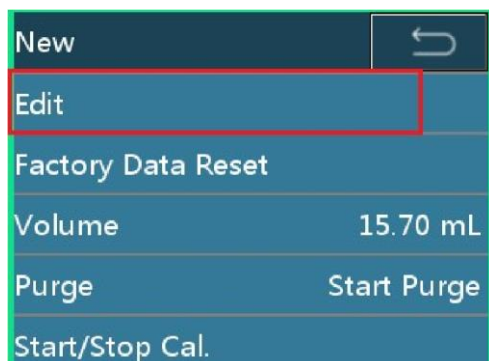
Operating Instructions

- 2.5. Press “Calibrate”.



- 2.6. Press “Edit”.

- 2.7. Press “Producer”. Use the back “arrow” to erase the current Brand and type the new IV set Brand and press “confirm”. Repeat same procedure to edit the new IV Model and Size. Size is the milliliters (ml) per drop specification.



- 2.8. Press “” to return to the “Calibrate” page. Install the IV Set in the pump.

Use “Start Purge” to get the disposable prepared for the calibration, remove all the bubbles and prepare a calibrated cylinder at the end of the IV set to measure the infused volume during the calibration infusion. Press “Stop Purge” to stop the purge.

Make sure there is enough liquid in the IV bag for the calibrating volume of 15.70 ml or other automatically set volume for the calibration test.

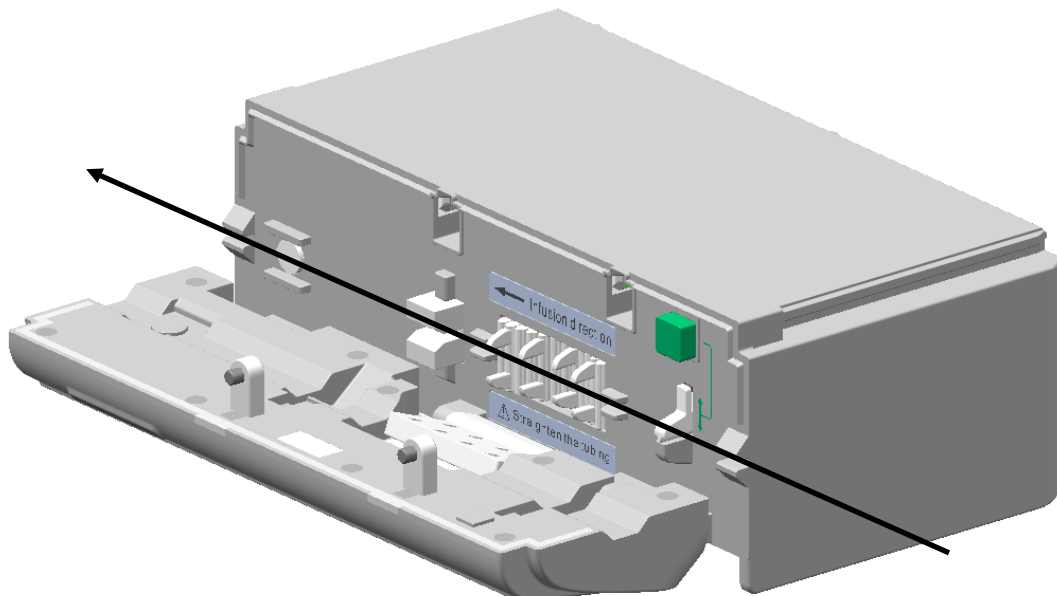
Operating Instructions

6.4 IV set installation

- Insert the needle into IV bottle vertically, and the liquid infuses into the drop chamber.
- When the liquid level is at 1/3 of the drop chamber, open the roller clamp.
- Infuse liquid into the tube to purge the air, and then close the roller clamp.
- Press [OPEN] to open the pump door.
- Press [Anti-Free-Flow Clamp] to open the anti-free-flow clamp, place the tube inside the clamp, and press the key again to clamp the tube.
- Place the tube inside the air bubble sensor and pressure sensor in sequence, then stretch the tube. Make sure the tube is inside both ends of the tube slit, and then push the pump door to close it.

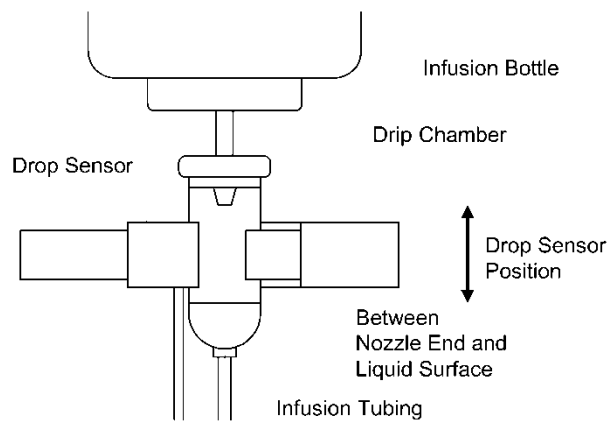
CAUTION:

- The height range of the liquid container above the PATIENT and/or pump should be 20-80cm.
- The roller clamp must be installed between the patient and the pump, downstream of the pump to avoid undetected upstream occlusions.
- Too loose or too tight tube may cause inaccurate infusion.
- The tube must be fixed into the air bubble sensor completely.



- Install the drop sensor

Operating Instructions



CAUTION:

3. To ensure the accuracy of drop detection, the drop sensor should be installed as far as possible close to the down liquid level. The liquid level is appropriate to be in the 1/3 of the drop chamber.
4. The liquid level must be lower than the drop sensor.
5. Prevent the drop sensor from being tilt and always stay out of the sun during infusion.
6. Avoid the drip bottle is clipped too tight by drop sensor.
7. Drop sensor detects the drop but not Measures fluids flow. Drop signal are undetectable if the continuous fluids flow is formed in the drip bottle.

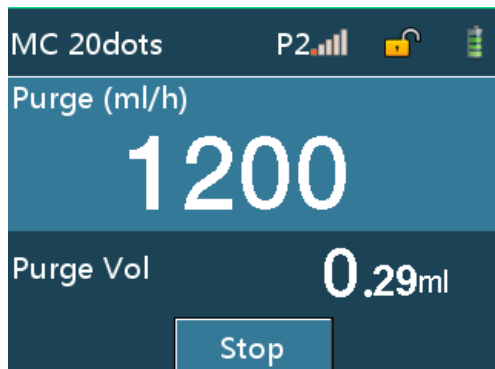
6.5 Purge

WARNING:

- Before purging the IV line, ensure that the IV line is not connected to patient.
- Priming can be done only in non-infusion process.
- Ensure liquid has run out from the needle before stopping purging.
- Air bubble detection alarm function is closed during purge.

Operating Instructions

- Click [PURGE], then click [yes] on the pop-up interface, the infusion pump would purge quickly. Click [stop], the purge stops.



- The green indicator flashes when purging.
- Relationship between IV set specifications and purge rate, refer to the Table 6-1.

Table 6-1 Relationship between IV set specifications and purge rate

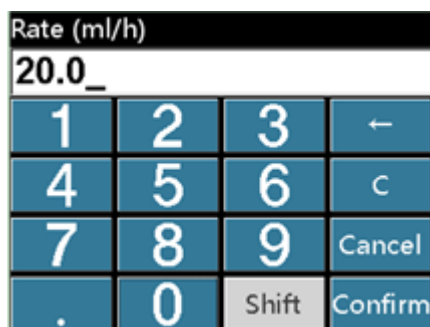
IV set specification(d/mL)	Purge rate(mL/h)
20	1200.0

CAUTION:

- When high viscosity IV fluids are infused through thin vein needle by bolus operation, occlusion alarm may occur. In such conditions, reduce the infusion speed to purge.
- Total volume cannot be cleared after infusion starts.
- The volume under the purge function will not be calculated into the total volume.

6.6 Setting the infusion rate

- Click the rate area on the Touchscreen to enter the setting interface.



- Click [CLEAR] to clear the total volume.
- Relationship between IV set specifications and range, see Table 6-2. The minimum increment is 0.01ml/h, see Table 6-3.

Operating Instructions

Table 6-2 Relationship between IV set specifications and range

IV set specification (d/mL)	Setting range (mL/h)
20	0.1-1200.0

Table 6-3 Relationship between rate range and the minimum increment

Rate range(ml/h)	Minimum increment(ml/h)
0.10 - 99.99	0.01
100 - 999.9	0.1
1000 - 1200	1

CAUTION:

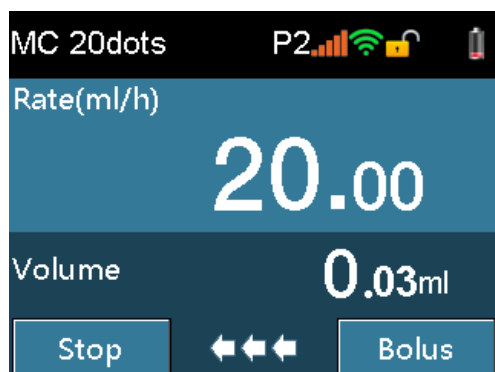
- If the flow rate is changed in the infusion process, the infusion will be done at the new flow rate.

6.7 Puncture

Place IV catheter into the patient's vein.

6.8 Starting Infusion

Click [START], start infusion at the setting rate and green indicator flashes.



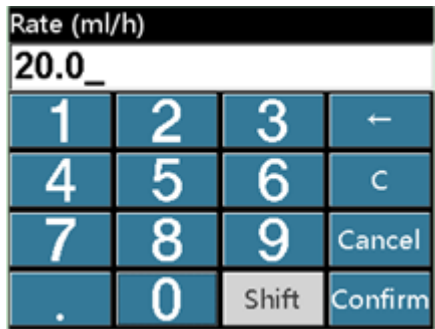
CAUTION:

- Infusion can only start when the recipe value equals to the set value.
- If no operation is performed after IV set installation for more than 2 minutes, START-REMINDER alarm sounds.

6.9 Change rate during infusion

- Click the rate display area on the screen, enter and change the rate on the pop-up interface.

Operating Instructions



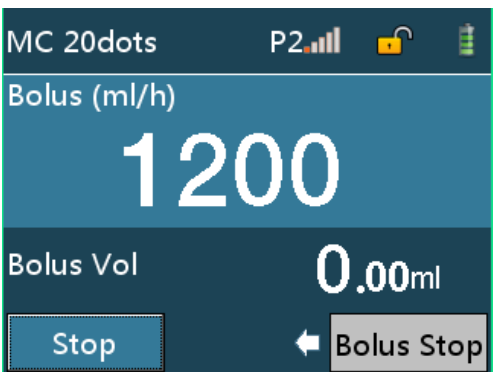
- After entering the rate, if click [Cancel], it will return to original infusion interface without change; Click [Confirm], it will return to original infusion interface and operates at the new rate.

CAUTION:

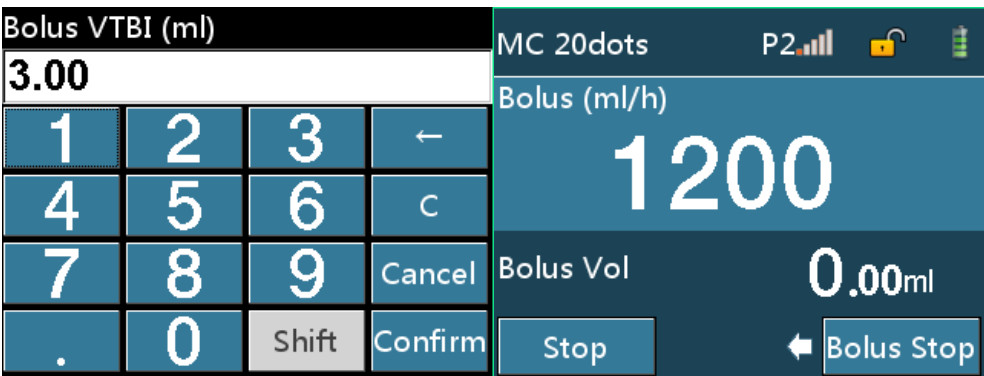
- If no operation is performed in reference and setting rate interfaces for more than 10 seconds, it will return to infusion interface automatically.

6.10 Bolus

- Choose “Manual bolus”, during the infusion, press [Bolus] for 1s to enter the bolus interface loosen, the bolus stop.

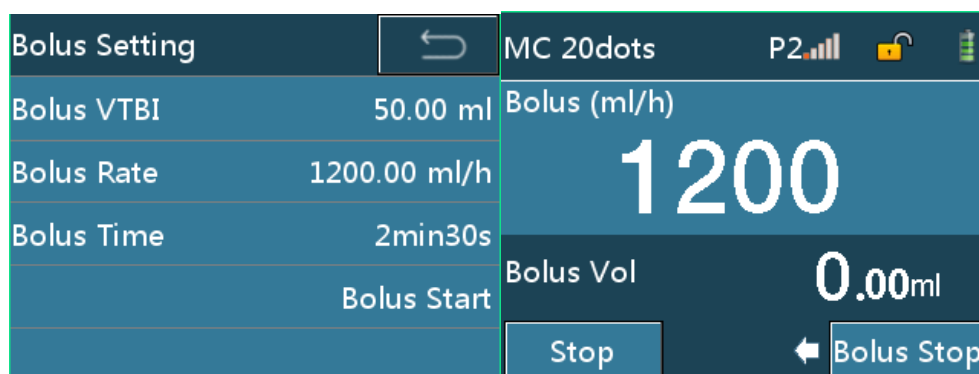


- Choose “Rapid quantitative Bolus”, during the infusion, click [Bolus] to enter the bolus VTBI interface, set the bolus volume, click [Confirm] to start and click [Bolus Stop] to stop the bolus and return to infusion interface.



Operating Instructions

- Choose “Automatic Bolus”, during infusion; click [Bolus] to enter the bolus setting interface. Set any two of Bolus VTBI, Bolus rate and Bolus Time, click [Bolus Start] to enter the bolus interface, click [Bolus Stop] to stop the bolus.



Bolus rates are different depending on the IV set specification as follows.

Table 6-4 Relationship between IV set specification and flow rate

IV set specification (d/ml)	Bolus rate(ml/h)	The minimum bolus volume(ml)	The maximum bolus volume(ml)
20	0.1-1200.0	0.1	50.0

CAUTION:

- Current bolus volume is displayed when bolus is running.
- Bolus volume will be accumulated into the total volume.

6.11 Stopping Infusion

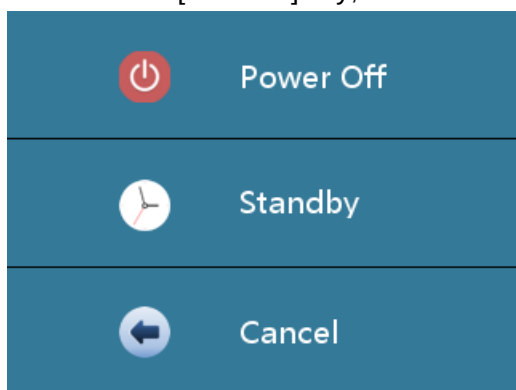
In the infusion process or after infusion, press the [STOP] key to stop the operation and green indicator will be off.

6.12 Replacing or adjusting IV set

An extrusion damage of tube in continuous infusion of the IV set would affect the infusion precision. After about 8-hour or regulated hour continuous infusion of the IV set, the infusion should be stopped, open the pump door, and move the IV tube about 10 cm from the original position, so that the IV tube functions better. Changing the whole IV set is better solution.

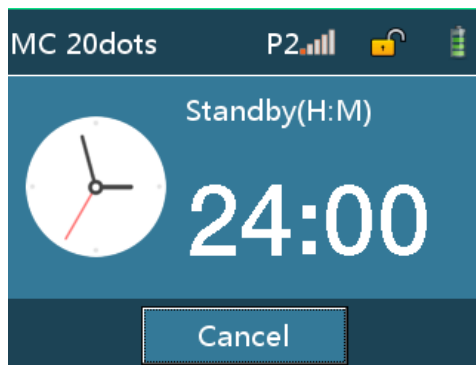
6.13 Turning the Power Off

- Press the [ON/OFF] key, choose Power Off, Standby or Cancel.



- Click [Power Off] to shut down.
- Click [Standby] to enter standby interface, the standby time can be modified

Operating Instructions



- Click [Cancel] to return to previous interface.

Setting the Infusion Pump

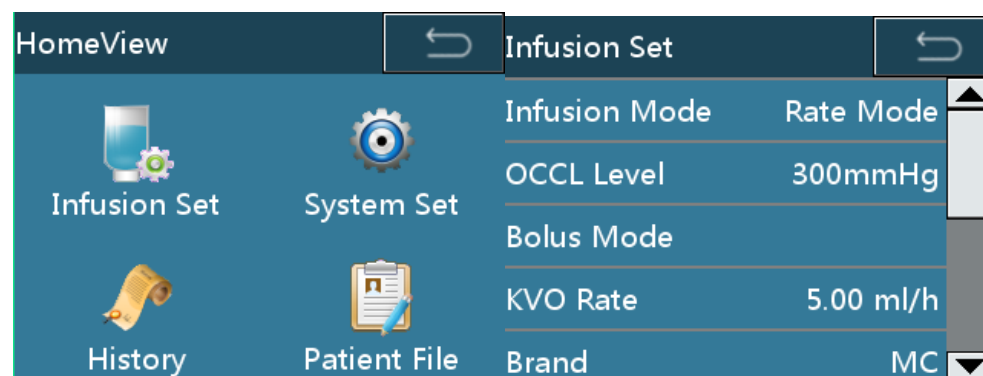
7 Setting the Infusion Pump

CAUTION:

- After the pump is shutdown, all parameter settings will be automatically saved.
- Parts of parameters will not be saved in force shutdown.

7.1 Infusion set

Press [HOME] key to enter the setting interface, click [Infusion Set] to enter the detailed infusion setting interface. Infusion set, occlusion level, bolus mode, KVO rate, brand, relay set, micro mode, bubble level, near finished and recent therapy could be set and adjusted here.



7.1.1 Infusion mode

- 7 Infusion modes: Rate, Time, Weight, Trapezia, Loading Dose, Sequence, Drip.

■ Rate mode

Under the Rate Mode, set the drug name, rate and VTBI, click [Confirm] to operate.

Rate Mode		↩
Drug Name	None	
Rate	---- ml/h	
VTBI	---- ml	
Volume	---- ml	
Confirm		

■ Time mode

Under the Time Mode, set the drug name, VTBI and Time, click [Confirm] to operate.

Setting the Infusion Pump

Time Mode	
Drug Name	None
VTBI	---- ml
Time	--h--min
Rate	---- ml/h
Confirm	

■ Weight mode

Under the Weight Mode, set the drug Info, Dose Rate, Weight and VTBI, the device will calculate the rate automatically, click [Confirm] to operate.

Weight Mode	
Drug Info	---- mg/ml
DoseRate	---- ug/kg/min
Weight	---- kg
VTBI	---- ml
Confirm	---- ml/h

■ Trapezia mode

Under the Trapezia Mode, set the drug name, VTBI, rate, rise time and fall time, automatically calculate the rate, and then click [Confirm] to operate.

Trapezia Mode	
Drug Name	None 
VTBI	---- ml
Rate	---- ml/h
RiseTime	--h--min
FallTime	--h--min 

■ Loading Dose mode

Under the Loading Dose mode, set the drug name, VTBI, maintain rate, loading rate and loading time, automatically calculate the rate, and then click [Confirm] to operate.

Setting the Infusion Pump

LoadingDose Mode	
Drug Name	None
VTBI	---- ml
MaintainRate	---- ml/h
LoadingRate	---- ml/h
LoadingTime	-- h-- min

■ Sequence mode

Under the Sequence mode, set the drug name, 10 sequence rate and time, click [Confirm] to operate in sequence.

Sequence Mode	
Drug Name	None
Rate1	---- ml/h
Time1	--h--min
Rate2	---- ml/h
Time2	--h--min

■ Drip mode

Under the Drip mode, set the drug info, loading dose, loading time dose rate and weight, automatically calculate the rate, and then click [Confirm] to operate.

Drip Mode	
Drug Name	None
Rate	-- dots/min
VTBI	---- ml
Volume	---- ml
Confirm	

CAUTION:

- The pump will calculate the corresponding rate according to the current drip rate (dots/min) and current IV set's spec.
- The pump will control the flow by using corresponding flow rate (ml/h) but not by detecting the drip rate (dots/ml).

Setting the Infusion Pump

- The drug library function could be applied to all working modes. The therapy data of the drug library is not edited by the manufacturer.

7.1.2 Occlusion Level

- 11 levels of occlusion are available (Factory setting is level 6).

Table 7-1 Relations between occlusion level and pressure

Occlusion level	Display	Pressure (mmHg)	Pressure (kPa)	Pressure (bar)	Pressure (psi)
1	P 1	225	30	0.3	4.35
2	P 2	300	40	0.4	5.8
3	P 3	375	50	0.5	7.25
4	P 4	450	60	0.6	8.7
5	P 5	525	70	0.7	10.15
6	P 6	600	80	0.8	11.6
7	P 7	675	90	0.9	13.05
8	P 8	750	100	1	14.5
9	P 9	825	110	1.1	15.95
10	P 10	900	120	1.2	17.4
11	P 11	975	130	1.3	18.85

CAUTION:

- To prevent the unblocked alarm to cause patients with extra amount of fluid after input, Anti - Bolus alarm, electric opportunity back automatically release line pressure.
- When you infuse viscous solution with the Occlusion Level setting under 4 and the tubing is clear, occlusion alarm tends to be issued. Carefully watch the  on the upper information area and change the occlusion level if above 2 bars appear.
- When you operate the pump with the Occlusion Level setting over 8, the in-line pressure builds up substantially until Occlusion alarm is issued. Always make sure that the IV line is securely connected to the pump.
- Occlusion alarm may occur when high-viscosity liquid is infused at high speed through a thin intravenous needle. Increase the occlusion level or decrease the infusion speed.

7.1.3 Bolus Mode

Setting the Infusion Pump

- There are three modes: Manual Bolus, Rapid quantitative Bolus and Automatic Bolus. Please refer to the chapter 6.9 for further instructions.

7.1.4 KVO Rate

- KVO-rate could be adjusted from 0.1ml/h to 5ml/h (Step by 0.01ml/h), Default rate: 1ml/h.

7.1.5 Brand

- You can choose the consumable brand by: [Home] -> [Infusion Set] -> [Brand].
- Several brands of 20d/mL IV set have been preset and customized. Select the infusion accordingly for clinical uses.

CAUTION:

- Users must use the consumable brand which is specified by the manufacturer or calibrate accordingly.
- To add in infusion of other brand, users are strongly recommended to contact the supplier of the infusion pump to set and test, so as to ensure the infusion accuracy.

7.1.6 Relay set

- Open relay mode, set the relay number under the mode.

Relay Set	
Relay On-Off	☒
Relay Index	1
Enable Relay Cycle	☐

CAUTION:

- The relay number must be set in sequence from number 1 when there are several infusion pumps or infusion pumps.
- When “Enable Relay Cycle” is activated, infusion will cycle from the first pump after the last pump finishes the infusion.

7.1.7 Drip Mode Set

- Open the drip mode, detect the drop sensor and count the drops during infusion.

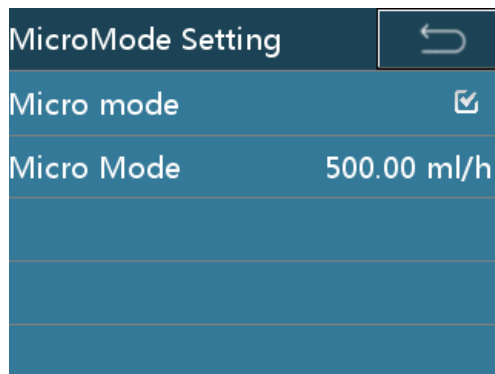
Setting the Infusion Pump

CAUTION:

8. If disconnected the drop sensor but the drip mode is open, the pump produces no drop sensor alarm.

7.1.8 Micro Mode Set

9. Open the Micro Mode, the maximum rate can be set under the mode.



7.1.9 Air bubble testing level

- Air bubble testing level of 25, 50, 100, 200, 300, 500, 800 (ul) 7 is configurable, a single air bubble volume accumulated within 15 min will alarm, the default air bubble testing level is 25 ul.

CAUTION:

10. Choose L gear level to detect bubbles may cause discomfort or danger to the patient, according to the actual clinical choose the right gear, and closely observe if there is any abnormal immediate measures should be taken.

7.1.10 Near Finished

11. Near Finished Alarm: Alarm-time can be adjusted from 1min to 30min before Finished (Step by 1min), Default time: 3min before Finished.

7.1.11 Recent Therapy

12. The therapy of the recent 20 times usage will be recorded. The recorded therapy can be started quickly by simply selection.

Setting the Infusion Pump

Recent Therapy		
Adalat1	Rate50.00ml/h	
Adalat1	Rate50.00ml/h	
Adalat1	Rate20.00ml/h	
Rate20.00ml/h	VTBI 0.00ml	
Rate20.00ml/h	VTBI 0.00ml	

7.2 Local Set

Local Set

Local Set		Local Set	
General	More	General	More
Local WLAN		Maintenance Period	
Volume Setting		Touch Adjust	
Display SET		Language Select	
Date&Time		Factory Data Reset	

7.2.1 Volume Setting

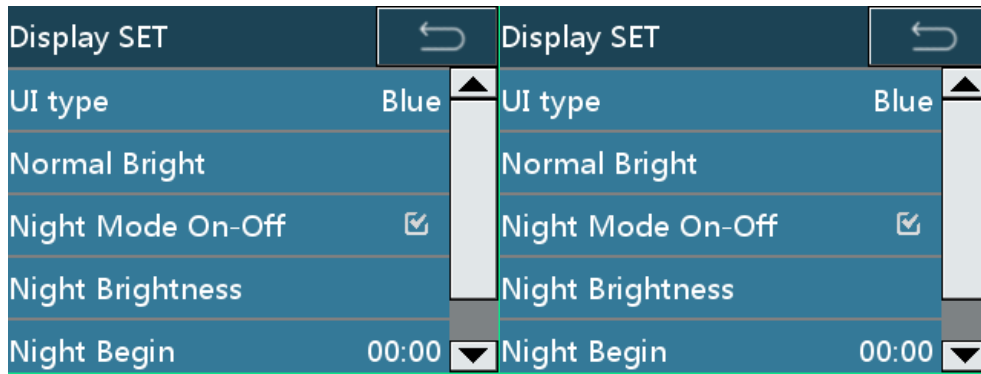
- 11 volume levels are available (The factory setting is level 5). Volume password is 1234.

CAUTION:

- Do not set the alarm volume lower than the ambient noise to ensure the alarm can be heard and recognized correctly.
- Setting alarm to extreme values that can render the alarm system useless. Check the alarm limited according to clinical condition.
- If the pump is inserted to a workstation and the volume setting on the pump is changed, the setting on the station will be synchronized at the same time.

7.2.2 Display SET

Setting the Infusion Pump



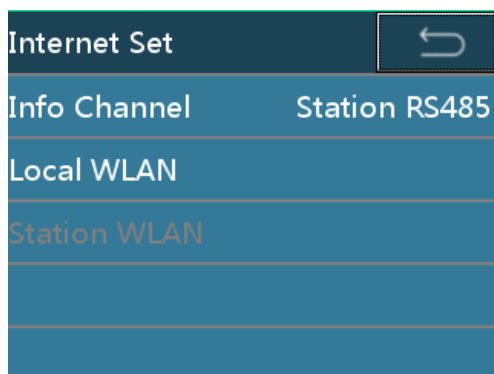
- There are seven different color options for UI type.
- The brightness can be adjusted in [Normal Bright].
- All the parameters of the night mode can be adjusted here.

CAUTION:

- Under the night mode, setting range of start time is 17:00-09:00, finish time range is the same as start time range. By default, the start is 00:00; finish time is 00:00.
- If the pump is placed in a workstation, the display setting on the pump is changed and the setting on the station will be synchronized at the same time.

7.2.3 Internet Set

- [Info Channel], [Local WLAN], and [Workstation WLAN] (not available if the pump is not connected to a workstation) can be chosen and set.



- Click [Info Channel] to choose the channel type.
 - Choose [Local WLAN] to use local WLAN channel to connect to the network, and the local WLAN parameters could be set.
 - Choose [Station WLAN] to use station WLAN channel to connect to the network, and the station WLAN parameters could be set.
 - Choose [Local RS485] to use local RS485 cable to connect to the network.
 - Choose [Station RS485] to use station RS485 cable to connect to the network.

Setting the Infusion Pump

Info Channel	
Local WLAN	☒
Station WLAN	☐
Local RS485	☐
Station RS485	☐

CAUTION:

- The pump can communicate with workstation, and the workstation can manage the alarm and implement relay function between pumps.
- The setting of [Local RS485] and [Station RS485] must be done by the manufacturer's representatives. Please contact manufacturer or local dealer for further information.
- Only the accessory or devices supplied or specified by manufacturer allowed to be connected with the pump. Otherwise it may cause the pump not work normally or other unpredictable hazards.
- Click [Local WLAN]/[Station WLAN] to set up WLAN parameters.
- [Wi-Fi Disable] option should be cancelled, the AP name, Password of the network should be inputted, and the TCP/IP's information should be set.

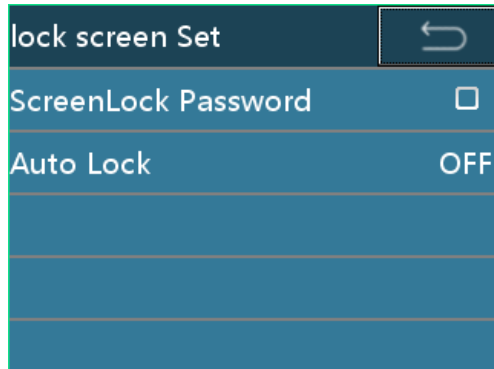
WLAN				WLAN			
Access Point		TCP/IP		Access Point		TCP/IP	
WIFI Disable		☐		WIFI Disable		☐	
AP name				AP name			
Password		*****		Password		*****	

7.2.4 Lock screen Set

- Click [Screen Lock Password] to enable/disable the screen lock password function. When the function is enabled, a password is required to unlock the screen. When the function is disabled, there will be no require on password to unlock the screen.

Setting the Infusion Pump

- Click [Auto Lock] to set up the screen auto lock function. This function can be set as: OFF, 15s, 30s, 1min, 2min, 5min, 10min, 30min. The default value is OFF, which means the screen auto lock function is disable.



Setting the Infusion Pump

7.2.5 Collection Set



- [Mode Collection]: Choose the frequently used infusion mode from the [Infusion mode] option. Once the frequently used infusion modes are chosen, the unnecessary modes will not appear in the list of 7.1.1 [Infusion mode] option. The default setting is “all the four infusion modes are chosen”.
- [Brand Collection]: Choose the frequently used infusion set’s brand from the [Brand] option. Once the frequently used brands are chosen, the unnecessary brands will not appear in the list of 7.1.5 [Brand] option. The default setting is “all the preloaded brands are chosen”.
- [Drug Collection]: Choose the frequently used drug from the drug library. Once the frequently used drugs are chosen, the chosen drugs will be shown on the top of the drug library list. The default setting is “none of the drug is chosen”. The data of the drug library is not edited by the manufacturer.

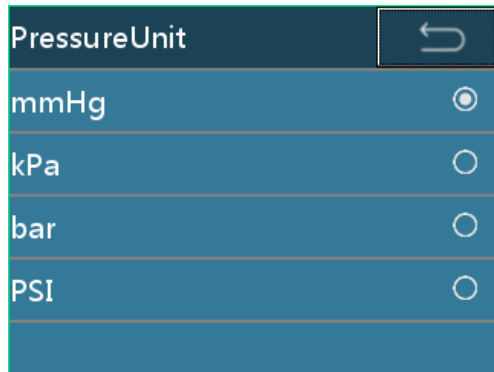
7.2.6 Linkage mode

- If the linkage mode is turned on, press the anti-free flow clamp button to open the clamp, and release the button to clamp the tube.

Setting the Infusion Pump

7.2.7 Pressure Unit

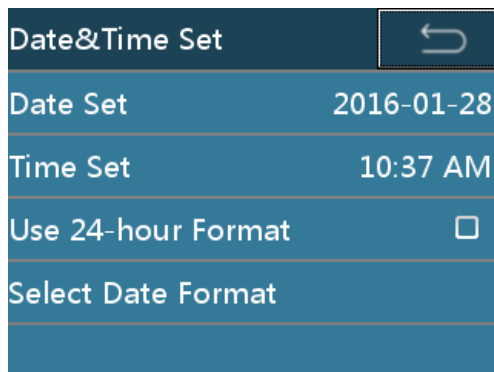
- Choose the measurement unit for the pressure. The optional units are: mmHg, kPa, bar and PSI. The default setting is mmHg.



PressureUnit	
mmHg	☒
kPa	☐
bar	☐
PSI	☐

7.2.8 Date & Time set

- Set the date, time, and their format.



Date&Time Set	
Date Set	2016-01-28
Time Set	10:37 AM
Use 24-hour Format	☐
Select Date Format	

7.2.9 Maintenance

- Click [Maintenance] option to do the [Language Select], [Touch Adjust], [Factory Data Reset], and check the version information. The password to change language is 1666.
- To check the version information, follow the route of: [Home] -> [System Set] -> [Maintenance] -> [Version Info].

Setting the Infusion Pump

7.3 History

History		History:1	
01-28 10:18AM	Alarm	Time	
01-21 07:17PM	Alarm	2016-01-28 10:18:41AM	
01-21 05:32PM	Alarm	Event: Alarm(Reminder Alarm)	
01-20 03:58PM	Alarm	Rate: 0.00 ml/h	
01-20 03:55PM	Alarm	Volume: 0.00 ml	

The history records are as Table 7-2.

Table 7-2 History records

Event	Record Parameters
Start up	Occurred time
Shutdown	Occurred time
Standby	Occurred time, standby set time
Start	Occurred time, rate, VTBI
Bolus	Occurred time, Bolus rate, Bolus way
Bolus stop	Occurred time, Bolus rate, Bolus accumulated volume
Stop	Occurred time, rate, accumulated volume
KVO	Occurred time, accumulated volume, KVO rate
KVO stop	Occurred time, KVO rate, KVO accumulated volume
Flow rate change	Occurred time, Flow rate before and after change
Alarm	Occurred time, alarm event, system trouble with trouble code
Purge	Occurred time, purge rate, accumulated volume
Purge stop	Occurred time, purge rate, purge accumulated volume

CAUTION:

- 2000 history records are available to be stored at maximum. If the amount reaches storage limit, the earliest record would be removed.
- Alarm system can't be powered off separately by operator unless the pump is powered off. The time of powering off is captured in the history records.

Setting the Infusion Pump

7.4 Patient File

- Click [Patient File] to enter the patient file page. The [Department], [Room No.], [Bed No.] and [Patient Data] can be set up.

Patient File	↩
Department	
Room No.	
BedNo.	
Patient Data	

- Click [Patient Data] option to enter patient data setting page. Choose [New] to build a new patient data and the previous patient data will be cleared automatically. Choose [Modify] to modify the current patient data.

Patient Data	↩	Patient Data	↩
New		Hospital No.	
Modify		Name	
		Sex	Male
		Age	0
		Weight	0.0 kg

CAUTION:

- If the pump is inserted to a workstation, once the patient file on the pump is changed, the data on the station will be synchronized at the same time.

7.5 Use Internal battery

- If there is not any AC/DC power supply, the internal battery operates. Battery time is 4-6 hours, depending on VTBI and rate.
- When external battery stops working, the internal battery starts and the yellow indicator lights with a short alarm sound.
- Before first use or reuse before a long time, please charge at least 10 hours.
- The approx. remaining power in the built-in battery is displayed by [battery] indicators. During battery operation, battery discharged is shown by a decreasing

Setting the Infusion Pump

number of active indicators. For details, see Table 7-3.

Table 7-3 when battery works, the [Battery capacity] diagram state

[Battery capacity] state	The remaining capacity*1)
Four bars light	Operation will be possible for 300 minutes.
Three bars light	Operation will be possible for 210 minutes.
Two bars light	Operation will be possible for 140 minutes.
One bars light(green)	Operation will be possible for 70 minutes.
One bars light(red)	Operation will be possible for 30 minutes.

*1) Working conditions:

- New battery (within one year of manufacture).
- Operating at 25mL/h using a 20d/ mL infusion. Close WI-FI function.
- Room temperature of 25°C.
- When the infusion pump is connected to any external AC or DC power supply, the charge of the built-in battery starts. When battery is charging, a lightning symbol will be displayed at the left side of the battery symbol on the screen.

CAUTION:

- If AC or DC power is connected, the battery will be recharged.
- Use AC power to charge the battery. If recharged by an external 12 VDC power supply, the battery cannot be fully charged (50% at most).
- During infusion and the pump powered by battery, if a low-battery alarm occurs, press [SILENCE] to silence the alarm will repeat in two minutes, connect the pump to AC/DC power supply immediately. If battery empty alarm occurs, the silence does not function and infusion pump will stop.
- 3 minutes before the battery is empty, the pump will auto power off.
- The actual battery duration may be different and affected by the ambient temperature, flow rate, external communication, etc.
- If the battery is aging, the actual battery duration may be shorter. Periodically check the battery.

Setting the Infusion Pump

7.6 Connecting to the Infusion Central Monitoring System(optional)

Infusion pumps can be connected to the Infusion Central Monitoring System, which can obtain working states of pumps remotely.

CAUTION:

- Infusion pump cannot be operated through the Infusion Central Monitoring System.

7.7 Nurse call (optional)

After infusion pump is connected to the central station, patient can press nurse pager in bed, and then the central station in nurse station would give out sound tip and display patient's information in screen, so that the nurse can take care of the patient in time.

7.8 Voice communication(optional)

After infusion pump is connected to the central station, patient can press nurse pager in bed, and then the central station in nurse station would give out sound tip. Nurse can press the talk-listen button and communicate with patient in real time to know the information.

7.9 Connecting a barcode scanner (optional)

After a barcode scanner is connected to the pump, the patient information, such as record No. and hospital No., can be scanned, and the patient information in the pump will update automatically by pump prompts.

The barcode scanner can scan maximum 18 figures.

7.10 User-specific Requirements (optional)

7.10.1 Maximum Flow rate

Parameters the maximum flow rate is already set with the infusion pump. For any modification, contact your local distributor.

Troubleshooting

8 Troubleshooting

8.1 Alarm

The infusion pump provides users with a variety of status information about itself and its injection process. If any abnormality is detected, the infusion pump sounds an alarm and notes users in the form of sound, light, and character.

All the alarms on this pump are the technical type alarm.

Considering the importance of abnormal information, alarm information is classified into three levels from the viewpoint of security: low-level, mid-level, and high-level alarms. For audio and visual expressions of alarms at three levels, see Table 8-1. The alarm volume ranges from 45 dB to 85 dB.

Table 8-1 Alarm severity and the audio and visual expressions of each level

Alarm	Sound	Light
Low-level alarm	Gives out three beeps at intervals of 25 seconds.	The yellow indicator stays on.
Mid-level alarm	Gives out three beeps at intervals of 15 seconds.	The yellow indicator flashing.
High-level alarm	Gives out a series of beeps at intervals of 15 seconds.	The red indicator flashing.

When an alarm occurs, press [SILENCE] to silence the alarm. But the buzzer beeps again if you do not eliminate the mid/high-level alarm within 2 minutes.

CAUTION:

- The setting of the alarm will be saved when the power is cut. When the pump restarts from a power failure situation, the alarm setting will be reloaded to the system and remains the same as it was before the power failure.



WARNING:

- There will be a potential risk if the same or similar devices are using different alarm setting in any specialized region.

Troubleshooting

8.2 Faults and Troubleshooting

Table 8-2 Alarm symptom, alarm level, fault cause, and troubleshooting

Alarm Symptoms	Alarm level	Causes	Troubleshooting
No Power Supply	Low-level	No external AC/DC power supply is connected.	Immediately connect the AC power supply or the external DC power supply.
No Battery	Mid-level	The infusion pump has no internal battery or the internal battery operates abnormally.	Replace the internal battery.
Low Battery	Low-level	The internal battery is running critically low.	Immediately connect an AC power supply or an external DC power supply.
Battery Empty	High-level	The battery is out.	Immediately connect an AC power supply or an external DC power supply.
Near End	Low-level	The infusion is end within the Near Finished Alarm setting period.	Wait until the infusion finishes.
Occlusion Alarm	High-level	1.The infusion IV line is occluded; 2. The OCCL level is too low for high viscosity drug's infusion.	Press [STOP], check to ensure clamps are open. If a high viscosity medication is being infused, increase pressure setting.
Air-bubble	High-level	1. Air bubble in the infusion line. 2. The flattened tube is fixed inside the air bubble detector.	Click [Stop] to remove the alarm, check that the line is not flattened. Disconnect line from patient and press [PURGE] to release air bubble.
Finished	High-level	The limit amount or the infusion time is complete	Press [STOP] to remove the alarm.
Reminder Alarm	Low-level	Forget to operate the alarm (no key operation is made two minutes after the IV set is installed).	Press any key to clear the alarm.

Troubleshooting

Alarm Symptoms	Alarm level	Causes	Troubleshooting
Drop Error	Low-level	The drip rate is detected to be incorrect at the drip kettle during the infusion.	Press [Cancel] to remove alarm and check the installation of the drop sensor.
No drop sensor	Mid-level	The drop sensor detection function is turned on, but drop sensor is not installed.	Install the drop sensor or turn the drop sensor detection function.
No drop	High-level	No drop is detected by the drop sensor.	Press [Stop] to remove alarm, check the installation of the drop sensor and the IV set.
Standby Time Expired	Mid-level	Standby mode is end	Press cancel to exit Standby mode.
Relay Index Duplicate	High-level	Relay Index Duplicate	Reset Relay Index
Infusion Start Fail	High-level	Infusion pump cannot be started under the relay mode.	Check the infusion pump, remove the problem that causes the failure of start.

8.3 Troubles and trouble shooting

When the device goes wrong, a corresponding trouble code appears in the interface and gives out high-level alarm.

Table 8-3 troubles and troubleshooting

Trouble code	Alarm level	Troubleshooting
Sensor Error	High-level	Record the trouble code and turn off, contact manufacturer or manufacturer's representatives.
Motor Error	High-level	
Circuitry Error	High-level	
Diver COM Error	High-level	
Pump finger error	High-level	
Pump door error	High-level	
Bubble sensor error	High-level	
System Error	High-level	

9 Maintenance

9.1 Cleaning, Disinfecting

- Before cleaning the pump, be sure to turn off the power and disconnect the AC or DC power cables.
- If there is dirt on the pump, wipe it with wet soft cloth dampened with cold or lukewarm water.
- Use a piece of dry soft cloth to clean the AC power supply socket, USB socket or the nurse call socket, ensure that the socket is dry before using it.
- Do not use organic solvent such as alcohol or thinner.
- If disinfection is necessary, using the common disinfectors such as Chlorhexidine gluconate and Benzalkonium chloride. After using the agent with a soft cloth, wipe off it with a soft cloth dampened with water or warm water. When using the disinfecting agent, follow the caution of each agent.
- The infusion pump cannot be autoclaved.
- Never use a dryer or similar device to dry the infusion pump.
- If liquid spills onto the pump, check whether the pump still functions normally. Test the insulation and leakage current when necessary.
- Do not soak or spray the infusion pump directly.

WARNING:

- Do not clean or sterilize the pump when it is running.

9.2 Periodic Maintenance

Perform a periodic maintenance inspection to ensure safe operation and the longest possible life of the infusion pump once a year. Contact manufacturer or manufacturer's representatives for any doubt.

9.2.1 Checking the Appearance

- Appearance checking: There are no cracks and damages.
- Key operations: If the keys are pressed smoothly, they are available.

9.2.2 Checking the Power Cable

- Check the appearance of the power cable. If the appearance is damaged and the plug and the socket are in poor contact, contact manufacturer or manufacturer's

Maintenance

representatives for replacement in time.

- If you connect the infusion pump to the AC/DC power and there is no indication of powering on, contact manufacturer or manufacturer's representative for maintenance in time.

9.2.3 Checking the infusion rate

- Check the infusion flow once a year by the graduate and timer.

Checking condition:

IV set	Infusion rate	Infusion time	Volume in graduate
MC/B.Braun20d/mL	120mL/h	6min	11.5-12.5mL

9.2.4 Alarm

- Occlusion alarm

Checking condition:

IV set	Infusion rate	Occlusion level	Alarm time
MC/B.Braun20d/mL	120mL/h	P5	Within 1 minute

- Air bubble alarm

Add in 3-5mm air in the upper infusion tube then start the infusion. When the air bubble reaches to air bubble sensor, check the displayed alarm information and sound.

9.2.5 Electric and mechanical safety

To ensure safety, test the insulation voltage, leakage current, and earthing resistance according to the IEC 60601-1.

9.2.6 Checking the Internal Battery

Perform the following inspections on the battery every 2 years:

- Connect to the AC power supply to recharge the battery for over 10 hours.
- Turn on the power.
- Set the infusion rate to 25 mL/h and start the infusion. Record the start time.
- Operate the system until it stops infusing due to low battery alarm. Record the finish time.
 - If the time from the start of the infusing to end of operation is 4 hours or more, the battery condition is good.
 - If the time from the start of the infusing to end of operation is 1 to 1.5 hours, the battery condition is reaching its service life.

Maintenance

- If the time from the start of the infusing to end of operation is less than 1 hour, the battery has reached its service life. Replace the battery. You are advised to contact manufacturer or manufacturer's representative to replace the battery.
- When the battery level check is complete, recharge the battery for next use.

9.2.7 Replacing the Battery

- Remove the internal battery.
 - Turn the power off and disconnect the power cord.
 - Use a screwdriver to loosen the battery cover fixing screws at the bottom of the pump.
 - Remove the battery cover.
 - Disconnect the battery cable connector.
 - Remove the battery.
- Install the internal battery.
 - Insert the connector of the battery cable into the battery.
 - Insert the new battery into the battery compartment.
 - Attach the battery cover.
 - Use a screwdriver to tighten the screws securing the battery cover.

CAUTION:

- Remove the battery if the infusion pump is not likely to be used for some time.



WARNING:

- The battery's replacement must be done by specialist who has been trained to finish such operation. Otherwise there will be a risk of danger.
- Please strictly follow the instruction to replace the battery, and the battery should be provided by the manufacturer. Otherwise there will be a risk of danger.
- Do not disassemble or short circuit the battery, do not throw the battery into the fire. Otherwise there will be a risk of danger caused by the battery linkage or explosion.
- Please follow the local law to dispose the old battery.

9.3 Maintenance

- If any trouble, explain the situation to your local the manufacturer or manufacturer's representative and request for a repair.
- Never disassemble or try to repair the infusion pump or it may cause a serious

Maintenance

failure. The manufacturer and the distributor shall not be responsible for any infusion pump that has been disassembled, modified or used for any purpose other than that for which it is intended.

- If the infusion pump is dropped or subjected to impact, remove it from service even if it doesn't appear damaged externally. Request the manufacturer or manufacturer's representative to inspect it for a possible internal problem.

CAUTION:

- Serviceman could request for the related service manual from the manufacturer if needed.
- Parts of the Pump are not serviced or maintained while in use with the patient



WARNING:

- The accessories' replacement must be done by specialist who has been trained to finish such operation. Otherwise there will be a risk of danger.

9.4 Storage

- Avoid water spills.
- Never store in a hot and humid place.
- Store the pump out of excessive vibration, dust, and corrosive gas.
- Store the pump out of direct sunlight and ultraviolet ray as discoloration may result.

9.5 Transportation

You can deliver the infusion pump by using a common vehicle, but you must protect the infusion pump from being clashed, shook, or wetted by the rain and snow during the transportation. You must deliver the infusion pump in accordance with the method specified in the order contract.

9.6 Environmental Protection and Recovery

At the end of life, please contact the manufacturer or manufacturer's representative for dispose advise, or dispose by a suitable method according to the applicable environmental laws and regulations.

Infusion Accuracy Characteristics

10 Infusion Accuracy Characteristics

The following test is performed in accordance with the IEC60601-2-24:2012 standard. It is used to observe the infusion accuracy and the occlusion response. (For detailed test conditions, see the IEC60601-2-24:2012 standard.)

CAUTION:

- The infusion accuracy and the occlusion response may be affected by the use conditions including the pressure, temperature, humidity, IV set, and infusion tube.
- The infusion accuracy does not reflect the clinical standards, for example, patients' age and weight and medicine taken.
- The experiment data only represents the measurement data in the lab.
- To ensure the infusion precision, it is recommended that the infusion tube be changed or moved every 8hours.
- Under the single fault condition, the maximum infusion precision error may be up to $\pm 40\%$

10.1 Flow Rate Characteristics

Start-up and Trumpet curves show the characteristics of the infusion pump after the injection begins and the injection changing status after the infusion pump reaches a normal flow rate.

The following test method is accordance with the method mentioned in chapter 201.12.1.102 of the standard IEC 60601-2-24:2012 (Please check above chapter for further details.).

- Accuracy test conditions:
 - Temperature: 21°C;
 - Relative humidity: 65%;
 - Infusion type: MC(20d/mL)、(B.Braun 20d/mL): 5 sets each.
 - Infusion pump: 1 set
 - Sampling interval: 0.5min
 - Test Period: 120min
 - Test Liquid: ISO 3696:1987 Class III water

Infusion Accuracy Characteristics

■ Table 10-1 Accuracy test result

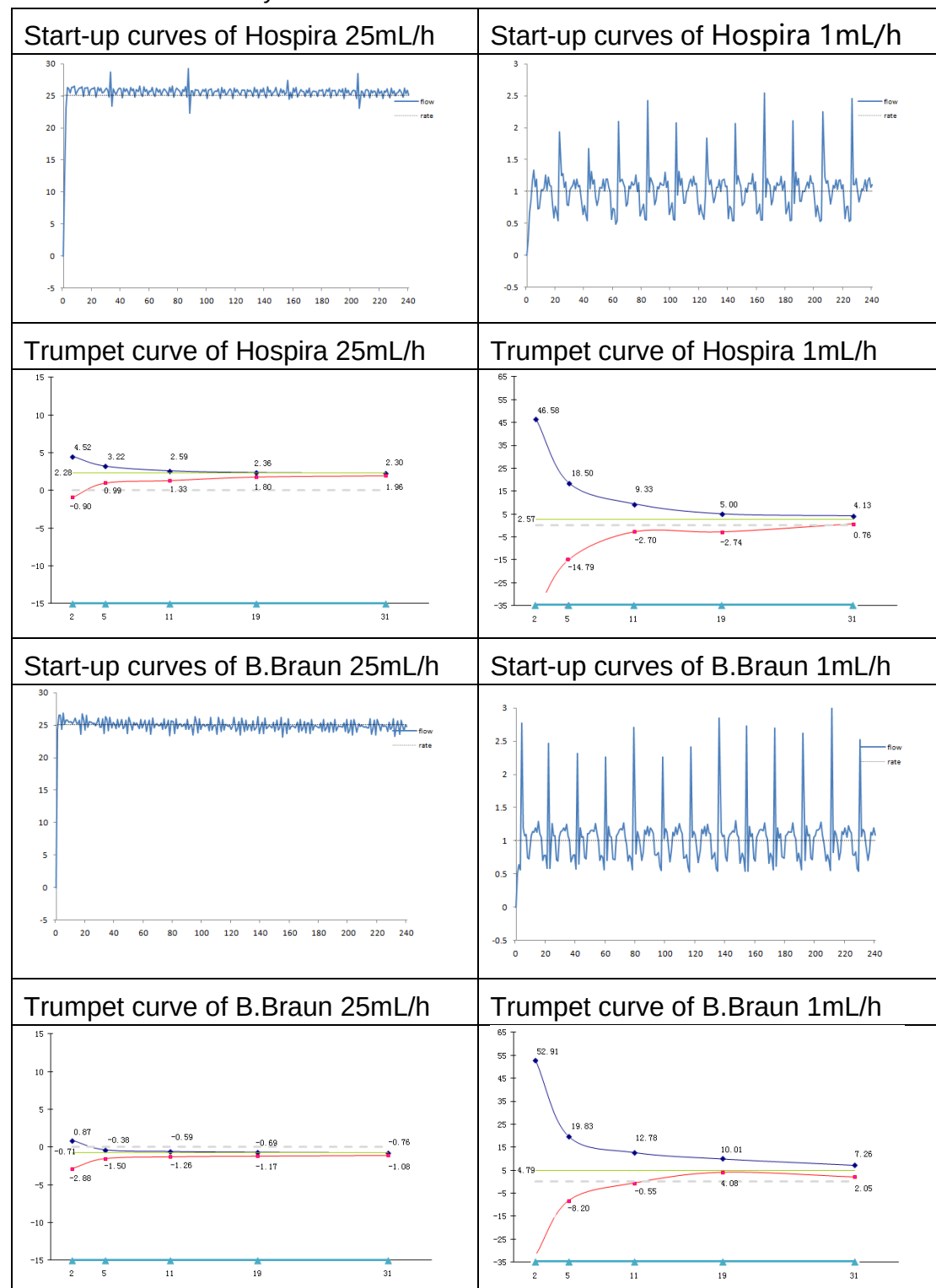
Administration set (IV set) Brand	Accuracy(%)	Remarks
B.Braun 20d/mL	+4.79	Minimum rate 1ml/h, normal condition
	-0.71	Intermediate rate 25ml/h, normal condition
	+0.91	Intermediate rate 25ml/h, with +13.3kpa backpressure
	+0.79	Intermediate rate 25ml/h, with -13.3kpa backpressure
	-6.61	Intermediate rate 25ml/h, when the supply container below the pump mechanism at a distance of 0.5m
HOSPIRA 15d/mL	+2.57	Minimum rate 1ml/h, normal condition
	+2.28	Intermediate rate 25ml/h, normal condition
	-1.10	Intermediate rate 25ml/h, with +13.3kpa backpressure
	+1.00	Intermediate rate 25ml/h, with -13.3kpa backpressure
	-11.62	Intermediate rate 25ml/h, when the supply container below the pump mechanism at a distance of 0.5m

CAUTION:

- The accuracy maybe up to -11.62% when the supply container below the pump mechanism at a distance of 0.5m.
- To ensure the infusion accuracy, the supply container must be higher than the pump mechanism.

Infusion Accuracy Characteristics

■ Table 10-2 Accuracy test result



Infusion Accuracy Characteristics

10.2 Occlusion Characteristics

The occlusion characteristics are reflected by the longest delay time to start an alarm.

The following test method is accordance with the method mentioned in chapter 201.12.4.4.104 of the standard IEC 60601-2-24:2012 (Please check above chapter for further details.).

Occlusion test conditions:

Temperature: 21°C;

Relative humidity: 65%;

Length of the infusion tube: 1m

Table 10-3 The occlusion level, alarm delay time and pill amount under the rate of 25mL/h

Infusion rate	Occlusion pressure level	Occlusion pressure (mmHg)	Occlusion alarm time (hh:mm:ss)	Bolus (ml)
25mL/h	P1	225±200	00:00:31	0.23
	P11	975±200	00:02:23	0.53

Table 10-4 The occlusion level and alarm delay time under the rate of 1mL/h

Infusion rate	Occlusion pressure level	Occlusion pressure (mmHg)	Occlusion alarm time (hh:mm:ss)
1mL/h	P1	225±200	00:07:20
	P11	975±200	00:33:42

Table 10-5 The occlusion level and alarm delay time under the rate of 0.1mL/h

Infusion rate	Occlusion pressure level	Occlusion pressure (mmHg)	Occlusion alarm time (hh:mm:ss)
0.1mL/h	P1	225±200	02:09:18
	P11	975±200	06:15:12

CAUTION:

Unit conversion list

Description	Unit	Unit conversion
Pressure	kPa	1kPa=7.5mmHg
	psi	1psi=51.724mmHg
	bar	1bar=750mmHg

Appendix A

Appendix A Electro Magnetic Compatibility (EMC)

The IP41x Series Infusion Pump conforms to EMC standard EN 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic emissions		
The IP41x Series Infusion Pump should be used under the regulation electromagnet environment. The user should operate the IP41x Series Infusion Pump under following electromagnet environment.		
Emission test	Emission test	Electromagnet environment-instructions
RF emission CISPR 11	Group 1	IP41x Series infusion pump only use radio-frequency power while operating its internal functions, therefore, the radio-frequency emission is much low and has little interference to the electronic devices nearby.
Radio-frequency emission CISPR 11	Class A	The IP41x Series infusion pump can be used in any building including civil residence.
Harmonic emission IEC61000-3-2	Class A	
Voltage fluctuation and flashing IEC 61000-3-3	Complies	

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The [IP41x Series] is intended for use in the electromagnetic environment specified below. The customer or the user of the [IP41x Series] should assure that it is used in such an environment.			
IMMUNITY test	IEC60601test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient (EFT) IEC61000-4-4	±2 kV power cable ±1 kV I/O cable	±2 kV power cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV difference mode ±2 kV common mode	±1 kV difference mode ±2 kV common mode	
The voltage dropping, short interruption and voltage change IEC 61000-4-11	< 5% U_T (dropping > 95% U_T)0.5 period 40% U_T (dropping 60% U_T)5 period 70% U_T (dropping 30% U_T)25 period < 5% U_T (dropping > 95% U_T)5seconds	< 5% U_T (dropping > 95% U_T)0.5 period 40% U_T (dropping 60% U_T)5 period 70% U_T (dropping 30% U_T)25 period < 5% U_T (dropping > 95% U_T)5seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [IP41X Series] requires continued operation during power mains interruptions, it is recommended that the [IP41X Series] be powered from an uninterruptible power supply or a battery.

Appendix A

Power frequency magnetic fields (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The [IP41x Series] is intended for use in the electromagnetic environment specified below. The customer or the user of the [IP41x Series] should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Conducted RF IEC61000-4-6	3 Vrms 150k ~ 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the [IP41x Series], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80M ~ 800MHz $d = 2.3\sqrt{P}$ 800M ~ 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis the recommended separation distance d in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3V/m 80M ~ 2.5GHz	3 V/m	
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.			

Appendix A

^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 [IP41x Series] is used exceeds the applicable RF compliance level above, the [IP41x Series] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [IP41x Series].

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

Appendix A

Recommended separation distances between portable and mobile RF communications equipment and the [IP41X Series]

The [IP41X Series] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [IP41X Series] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [IP41X Series] as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m).		
	150k ~ 80MHz $d = 1.2\sqrt{P}$	80M ~ 800MHz $d = 1.2\sqrt{P}$	800M ~ 2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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) according to 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.

Appendix B

Appendix B The Default Factory Settings

This chapter lists some default factory settings of infusion pump. Users can not modify the default factory settings, but if necessary, they can recover the infusion pump to the default factory settings state.

Parameters

Parameters setting	The default factory setting
KVO flow rate	1ml/h
Pressure unit	mmHg
Occlusion pressure	P6(middle level)
Near end	3min
Built-in consumable brand	MC(20d/ml)、 B.Braun(20d/ml)

System time

System time and date	The default factory setting
Time	00:00
Date	2014-1-1
Time form	24 hours
Date form	Year-month-day

Appendix C

Appendix C Toxic and Hazardous Substances or Elements

Description	Plumbum Pb	Mercury Hg	Cadmium Cd	Chromium VI Cr(VI)	Polybromi nated biphenyls PBB	polybrominat ed diphenyl ethers PBDE
pump shell	○	○	○	○	○	○
key and cover	○	○	○	○	○	○
label	○	○	○	○	○	○
display	×	×	×	×	×	×
hardware	○	○	○	×	○	○
connection wire	○	○	○	○	○	○
PCBA	×	○	○	○	○	○
packing material	○	○	○	○	×	×
battery	×	×	×	×	×	×
accessory	×	○	○	○	○	○
remark: “○” shows that the content of this toxic and harmful substance in all homogeneous materials are under the regulated limitation requirement of SJ/T11363-2006. “×						

Appendix D

Appendix D Difference Between IP41X Series

No.	Model Difference	IP41X	IP41XT	IP41XA	IP41XC
1	Infusion Mode	Rate Time Weight Sequence Drip Relay	Rate Time Weight Sequence Drip Relay	Rate Time Weight Sequence Drip Relay Trapezia Loading Dose Micro	Rate Time Weight Sequence Drip Relay Trapezia Loading Dose Micro
2	Sequence Mode	5 sequences	10 sequences	10 sequences	10 sequences
3	Relay Mode	Available, rate and time can be set under Relay Mode.	When activated, Relay available with pumps in workstation in any infusion mode	When activated, Relay available with pumps in workstation in any infusion mode	When activated, Relay available with pumps in workstation in any infusion mode
4	Bolus Mode	Automatic	3 kinds: Manual, Rapid quantitative, Automatic	3 kinds: Manual, Rapid quantitative, Automatic	3 kinds: Manual, Rapid quantitative, Automatic
5	Occlusion Level	3 levels adjustable (40Kpa-120Kpa)	3 levels adjustable (40Kpa-120Kpa)	11 levels adjustable (30Kpa-130Kpa)	11 levels adjustable (30Kpa-130Kpa)

Appendix D

6	Air Bubble Level	Not adjustable	Not adjustable	7 levels adjustable (25µl-800µl)	7 levels adjustable (25µl-800µl)
7	Drug Library	Not support	Not support	Support (Drug selection in any modes)	Support (Drug selection in any modes)
8	IV Set Brand Identity	Not support	Not support	Not support	Support
9	Recent Therapy	Not support	Not support	Support	Support
