Syringe Pump MP-30

Operation Manual

Please read this “Operation Manual” carefully and follow “Precautions for Use” before using the MP-30 Syringe Pump.

MEDCAPTAIN MEDICAL TECHNOLOGYCO., LTD.

Intellectual Property and Statement

Statements

MEDCAPTAIN reserves the right for final interpretation of this Service Manual.

MEDCAPTAIN reserves the right to modify the contents of this service manual for a more accurate and effective service quality. The modified contents should be reflected in the newly published service manual version.

MEDCAPTAIN is responsible for safety, reliability and performance of this equipment only in the condition that:

- Use in accordance with the Operation manual.
- All disassembly, replacement, test, modification and repair are conducted by qualified personnel approved by MEDCAPTAIN.
- All replacement parts, supporting accessories and consumables during the maintenance are provided by MEDCAPTAIN.
- Maintenance records for product are reserved.

Version Information

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Intellectual Property and Statement

- V2.2
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After Service

Thank you for using the syringe pump of MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

- During the warranty period, we provide free after-sale services except the following causes:
  - Artificially damaged.
  - Inappropriate use.
  - The voltage of supply network exceeds the range.
  - Irresistible natural disasters.
  - Replace or use parts, accessories and consumables without approval of MEDCAPTAIN.
  - Other troubles not caused by product itself.

  After the warranty period, we continue to provide charged maintaining service. If you have any question when using the syringe pump, please contact local distributor or directly contact us at any time.

  The after-sales service contact details of Medcaptain Medical Technology Co., Ltd. are as follows:

  Address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan District, Shenzhen, P.R.China

  Telephone: +86-755-26953369

  Fax:+86-755-26001651

  Postal: 518055

  Website: http://www.medcaptain.com

  E-mail:info@medcaptain.com
- MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD. and all local dealers established after-sales service agencies, can effectively, timely solutions to your problems.

WARNING:

- The device should be operated by clinic medical staffs or under the instruction of special clinic medical staffs. The operator should have been trained on how to use this product.

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1 OverView

1.1 Purpose

This product is intended for hospitals to infuse at constant speed liquid or liquid medicine through the veins of patients.

1.2 Contraindication

None.

1.3 Product Features

MEDCAPTAIN MP-30 is a micro-continuous syringe pump. It ensures constant infusion speed and accurate dosing volume during longtime infusion.

This syringe pump is used for continuous and micro-volume infusion of liquid or liquid medicine of little volume and high concentration, for example, infusion of chemotherapeutic agents, cardiovascular drugs, antineoplastic, oxytocic, anticoagulant, anesthetic agents, etc.

- All current disposable syringes conform to the standard are supportable.
- Automatically recognize disposable syringes of 10mL, 20mL, 30mL, and 50/60ml.
- Providing three occlusion levels and displaying pressure status of the tube.
- Having large speed range (up to 2000mL/h for 50/60ml syringe).
- Calibration functions for infusion accuracy.
- Safety design by monitoring infusion status of syringe.
- Multiple infusion modes.
- Configure with multi-channel infusion workstation, realizing relay infusion function.
- WIFI function, can be connected to the central station by intravenous infusion.
- Nurse call function.
- Voice Communication function.
- Touchscreen, providing quick and convenient man-machine interface.
- Display night mode, reducing light interference to patients and environment.
- Connection to barcode scanner function.
- Three types of power supply: AC power supply, DC power supply, and internal lithium battery are available. The lithium battery can power the syringe pump for no less than 6 hours (at5ml/h rate).
- Double CPU, and redundancy design for key units.

Overview

- Two-way alarm for monitoring the main control circuit and motor drive circuit
- Independent motor driving CPU and motor subdivided drive chip design.
- Setting and automatic prompt of maintenance interval.
- Modular installation design enables multi-channel pumps among pumps.

Note:

Handle, pole clamp, barcode scanner, WIFI communication module, voice communication, nurse call and relay infusion function are optional, depending on the user's need.

2 Precautions for Use

In this manual, precautions are classified into warning and caution according to their importance. The meanings are as follows:

WARNING:

The information is about safety and efficiency. Operation against the precautions may cause injuries.

CAUTION:

The information is about guiding suggestions. Operation against the precautions may affect normal use of the product. Read carefully the warnings and cautions in this manual.

WARNING:

- The syringe pump must be operated by clinical professionals.
- Prior to use, please check the status of the pump, power cord and other related accessories to ensure the device could be used normally and safely.
- The syringe pump does not support air-in-line detection. Always purge air from the system before each use.
- 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 syringe pump in a flammable or oxygenated environment.
- The altitude difference between the pump and heart position of the patient should not be larger than 100cm. 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, because the sliding syringe tube is loose.
- It is recommended that you use the syringes specified by the manufacturer only.
- If a syringe of other brands is used or the syringe parameters are not defined correctly, the infusion accuracy may be affected.
- Only the syringe, tube, syringe needle and other medical parts complying with the

local regulations can be used on the syringe pump. Contact your local distributor for more information.

- Operating the syringe pump against the requirements, procedures, warnings and cautions provided in this manual may cause infusion failure, inadequate or over dosing, or other potential risks.
- There should be a regular monitoring by clinical professionals when using the device.
- The power cord or other affiliated lines should be kept properly to avoid any risk of twining on patient or electronical disturbance.
- Electric equipment like high-frequency electric scalpel and mobile phone may have electromagnetic interference on the syringe pump.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- If the pump and its related accessories are reaching over the life time, they must be crapped 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 MP-30 and the patient simultaneously.

CAUTION:

- The infusion set is treated as the applied part of the pump.
- Check the setting values on the prescription and the syringe. Infusion can start only when the values are equal.
- Ensure that the syringe 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/STOP] 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.

- Syringe 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 syringe pump by using the high-pressure steam sterilization method.
- Before internal battery operation, check the battery to ensure that sufficient power is available. Recharge, if required.
- Ensure that the syringe pump always has a battery installed during operation. Otherwise, the system may stop without issuing an alarm when external power is interruption due to power failure or a short circuit, causing an unsafe condition.
- If the syringe pump cannot work as described in this manual for unknown reasons, stop it and report the details (including syringe, infusion flow, serial number of syringe pump, and type of infusion liquid) to your local distributor or our customer service department.
- Do not disassemble or reconstruct the syringe pump.
- 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 syringe pump, clean the pump with a dry cloth. Use after the service engineer checking.
- The maximum temperature at the applied part of the pump may reach 42.2℃, when running continuously under the highest environment temperate at the highest infusion rate.
- The highest pressure at the end of the infusion tube will be no higher than 3000mmHg under the condition of occlusion.
- 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 pager
	ON/OFF
	HOME

3 Product Specifications

Product name	Syringe pump
Model	MP-30
Power supply	AC power supply: AC 100-240V,50/60 Hz, power consumption less than 45 VA External DC power supply: DC 12 V 1A Internal battery: lithium battery 11.1 V 1500 mAh Battery model: 154457 Time of continuous use: no less than 6 hours (for infusion at 5 mL/h with a new battery)
Fuse	T1.6AL 250VAC
Compatible syringes	All syringes of 10ml,20ml,30ml,50/60ml conform to the standard
Infusion mode	Rate,Time,Weight, Sequence, Relay mode
Infusion setting range	0.1-300.0ml/h(10ml syringe) 0.1-600.0ml/h(20ml syringe) 0.1-900.0ml/h(30ml syringe) 0.1-2000.0ml/h(50/60ml syringe) See the least increment in chart 6-3
VTBI setting range	0.1 - 99.99ml(Least increment 0.01) 100 - 999.9ml(Least increment 0.1) 1000 – 9999ml(Least increment 1)
Total volume display	0-99999.99ml
Accuracy	Mechanical accuracy: ±1% Accuracy including syringe: ±2%
KVO rate	0.1~5ml/h
Occlusion level	300mmHg~900mmHg，3levels are available
Purge operation	300.0ml/h(10ml syringe) 600.0ml/h(20ml syringe) 900.0ml/h(30ml syringe) 2000.0ml/h(50/60ml syringe)

Product Specifications

Bolus operation	0.1-300.0ml/h(10ml syringe) 0.1-600.0ml/h(20ml syringe) 0.1-900.0ml/h(30ml syringe) 0.1-2000.0ml/h(50/60ml syringe) Automatically calculate the bolus rate by bolus amount, cannot lower than the current rate.
Alarm	Near Finished, Finished, Syringe Empty, Near empty, OCCL, Low Battery, Battery Empty, No Battery, No Power Supply, Unknow Syringe, Syringe Install Error, Standby Time Expired, Relay Index Duplicate, Syringe Start Fail, Reminder Alarm
Special function	Repeat alarming: 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
WIFI function	Connect infusion workstation, nurse pager, voice communication and syringe information network
Operating conditions	Temperature: 5℃ to 40℃ Humidity:15% to 95% RH Pressure altitude: 70.0kPa-106.0kPa
Storage and Shipping conditions	Temperature: -20℃ to +55℃ 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	244(W) ×74(H) ×164(D)mm
Weight	About 1.2 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 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

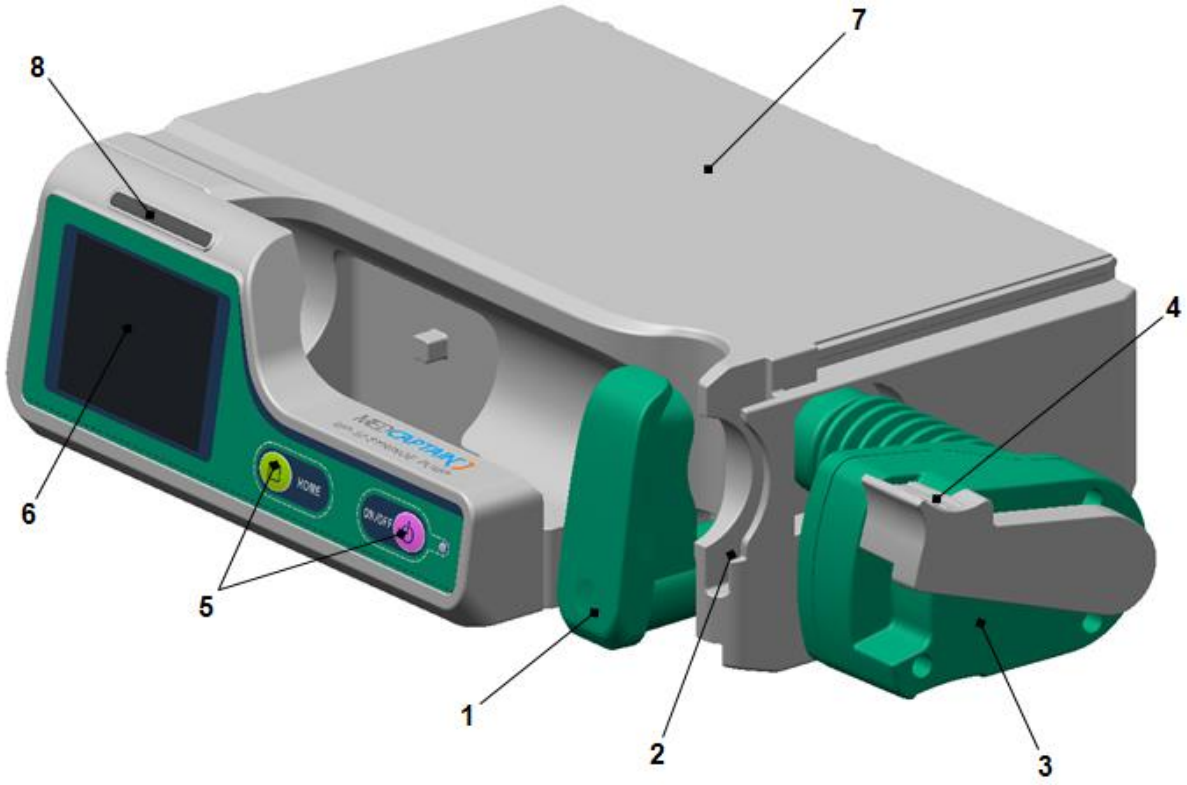
4 Product Description

4.1 Principle of Operation

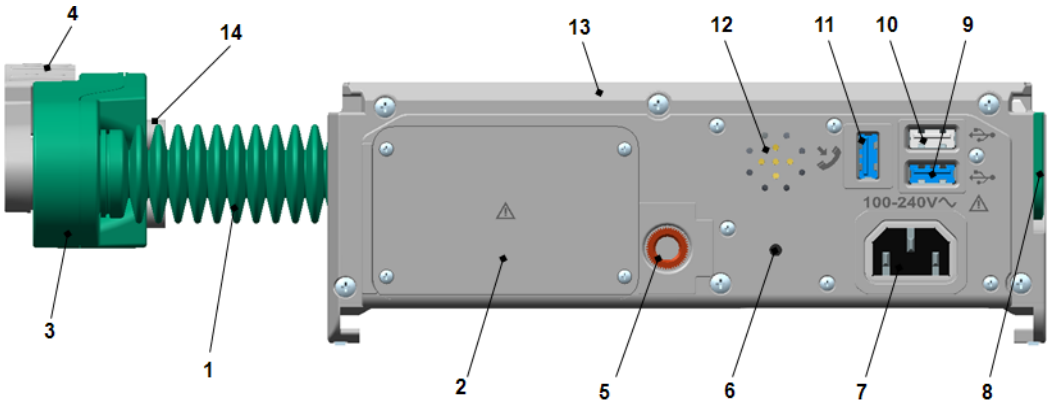
The MP-30 syringe pump mainly consists of the pump shell, display and operating system, monitoring system, alarm system, motor drive system, drive module, power supply system, WIFI communication module (optional), handle (optional) and pole clamp (optional).

The syringe 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 sound and light alarms.

4.2 Composition of Syringe Pump



1 - Clamp	2 - Slit	3 –Slider
4 - Clutch	5 –Operation button	6 –Touchscreen
7 –Shell	8 –Alarm indicator	



1 –Protective cover | 2 –Battery cover | 3 – Slider

4 -Clutch | 5 –Threaded hole | 6 –Auxiliary alarm

7 –AC power inlet | 8 -Multi-function connector | 9 –External inlet 1

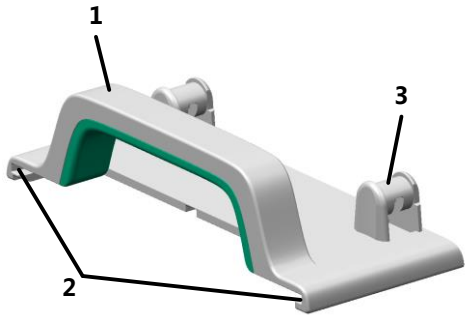
10 –External inlet 2 | 11 –External inlet 3 | 12 –Buzzer

13 –Shell | 14 –Syringe clamp

CAUTION:

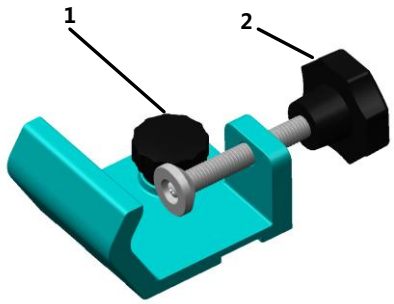
- The external inlet 1, 2 and 3 could be used to connect three external accessories at the same time: Drop sensor, scanner and DC power cord. The external inlet 1 and 2 could be used as the interface for the local WLAN.
- Do not insert the accessories which are not specified by the manufacturer into the external inlets.
- 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.
- Do not install the pump to the position which is not able to connect or disconnect the AC power cord.

4.3 Handle



1 –Handle | 2 –Slide rail | 3 –Tubing management bracket

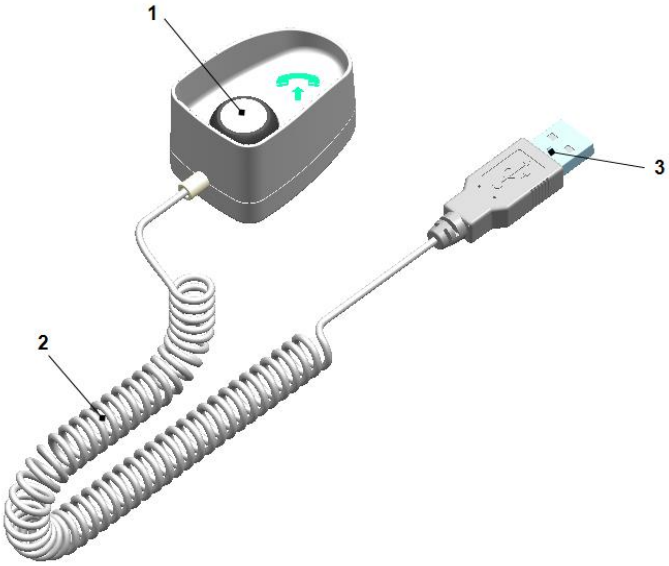
4.4 Pole Clamp



1 - Mounting screw

2 - Mounting knob of infusion stand

4.5 Nurse Pager



1 –Button

2 –Cable

3 –Socket

4.6 Accessories accompanied

1 –AC power cord 1

2 - Pole clamp 1

3 - Handle 1

4 - Operation manual 1

5 - Quick operation instruction 1

6 -Packing list1

4.7 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
Barcode scanner	MP-4	9005000008
Pole clamp	——	9114002501

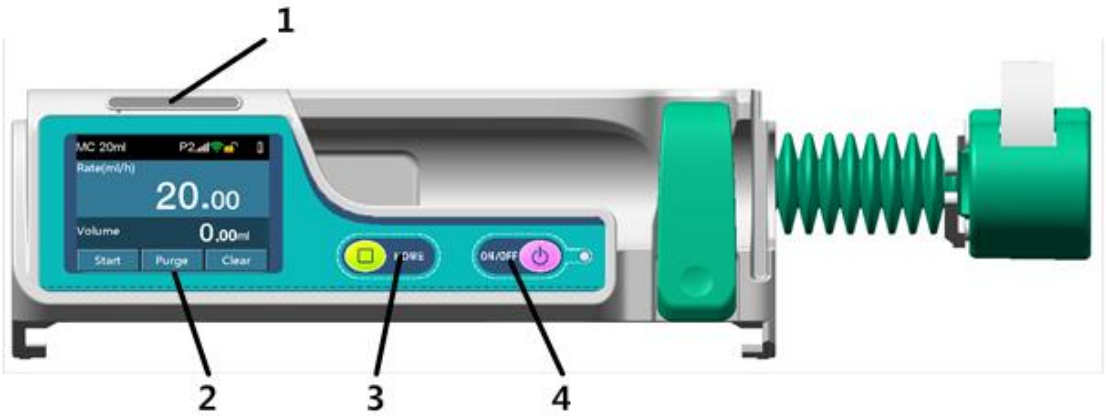
5 Preparations for Use

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

6 Operating Instructions

6.1 Display and keys

- Display



1 –Alarm indicator 2 –TFT touchscreen 3 –Home key

4 –ON/OFF key

The alarm indicator indicates alarms in three colors: red, yellow and green in three levels of high, medium and low.

TFT 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: to display the syringe brand and specifications, occlusion pressure level, pressure real-time, external power supply, battery volume, WIFI signal. Touch the brand and specifications zone to enter a page of syringe brand adjustment. Touch the occlusion pressure level to enter a page of occlusion level selection.

See below for further description.

Occlusion pressure level: 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.

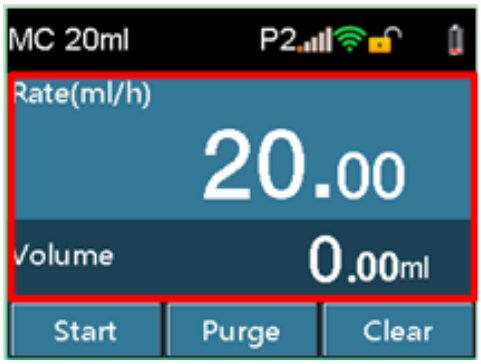
Screen lock symbol, consists of lock and unlock.

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

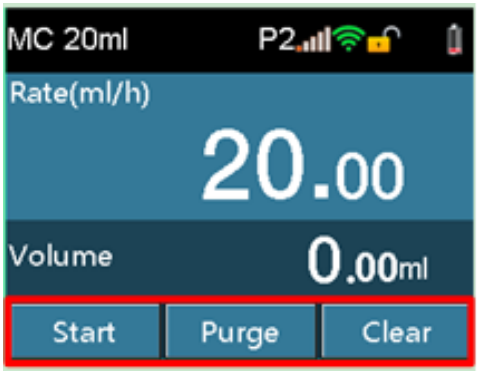
WIFI signal

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 difference working mode.



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



- Keys

Except touchscreen keys, there are also 2 keys on the key panel: [HOME]/[ON/OFF]

- [HOME] :Main menu key. Before infusion, press [HOME] once to enter a setting menu, such as patient information, IV set setting, event recall, device setting, etc. To return to the infusion preparing interface, press [HOME] once again in any setting interface.
- [ON/OFF] : Switch on/off key. When the pump is off, press and hold [ON/OFF] for 1 second to switch it on. When the pump is on, press [ON/OFF], and a prompt pops up: Are you sure to shut down? Press the key on the display to shut down or press and hold for 3 seconds to force shutdown.

6.2 Turning the power on

CAUTION:

- Power on and then install the syringe.
  - Press [ON/OFF] to switch it on.
  - The self-test starts.
  - After self-test finishes, enterinfusion preparing screen.
  - 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:

WARNING

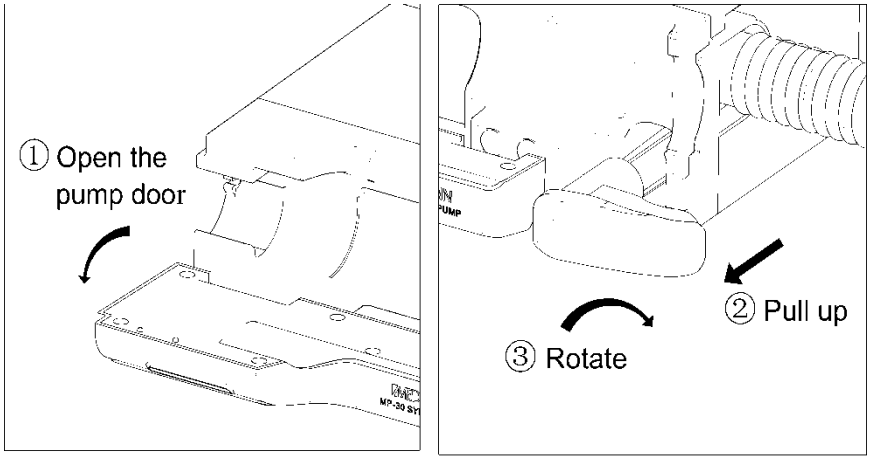
- After the power switch is turned on, confirm the loudspeaker, warning indicator is working all right, and check if the self-test is finished and no error messages appear.

(Refer to Chapter 8 Troubleshooting.)

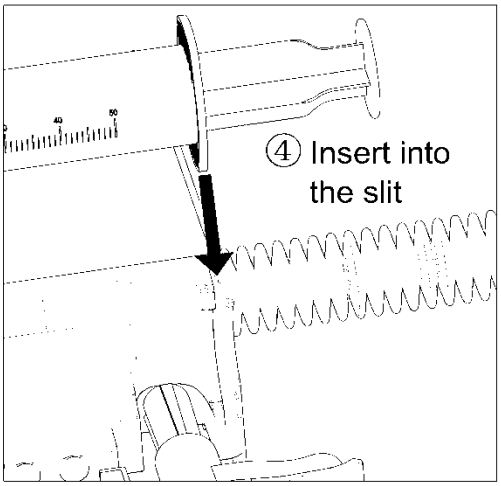
- Ensure the displayed syringe brand corresponds with the using syringe brand.
- If the syringe brand set is different from the using syringe brand, the infusion accuracy and alarm function cannot be guaranteed.

6.3 Syringe installation

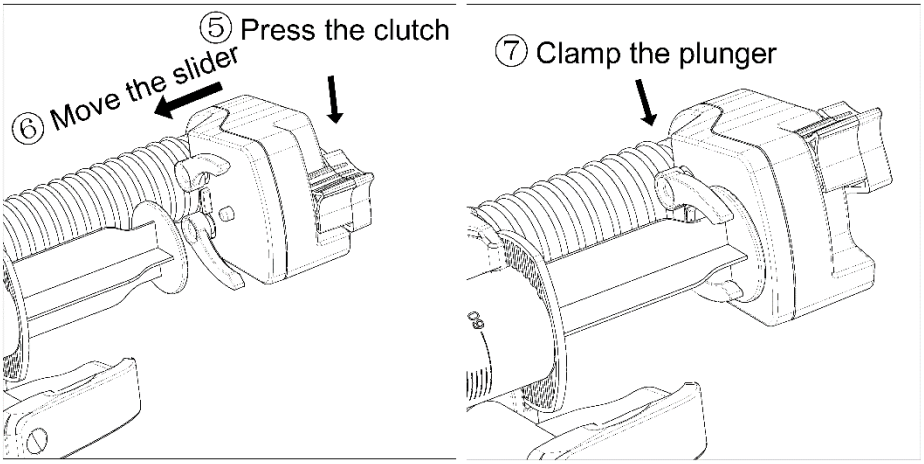
- Open the pump door, pull the clamp and turn rightwards (①/②/③)



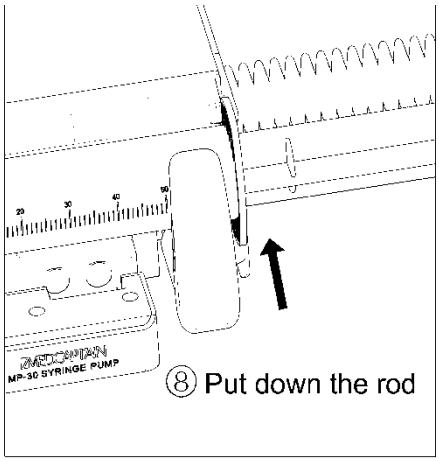
- Press the clutch and move the slider fully to the right.
- Attach the syringe. Insert the flange of the syringe into the slit (④)



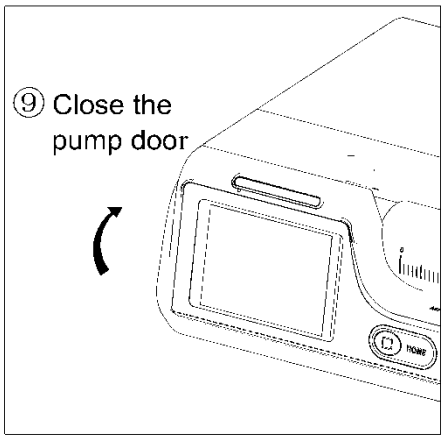
- Press the clutch, and move the slider until the contact pin of the slider hits the syringe plunger. (⑤/⑥ /⑦)



- Turn back the clamp and lower it slowly to hold the syringe securely (⑧).



- Close the pump door (⑨).



WARNING

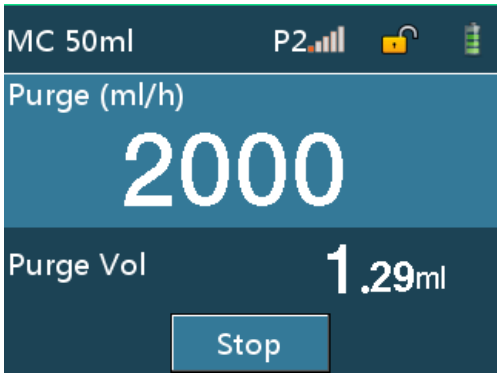
- Ensure that there is not air bubbles in the syringe.

- If the syringe flange is not properly engaged in the slit , flow rate accuracy and alarmfunction cannot be guaranteed.

6.4 Purging

WARNING:

- After loading a syringe on the syringe pump, remove the air bubbles from the syringe and the IV line.
- Before purging the IV line, ensure that the IV line is not connected to patients.
- Priming can be done only in non-infusion process.
- Ensure liquid has run out from the needle before stopping purging.
  - Press [PURGE], the purge interface pops up. Click[Stop], the purge stops.



  - The green indicator flashes when purging.
  - The purging rate varies depends on the syringe size. Refer to the Table 6-1.

Table 6-1 Relationship between syringe size and purge rate

Syringe size	Purge rate (mL/h)
10	300.0
20	600.0
30	900.0
50/60	2000.0

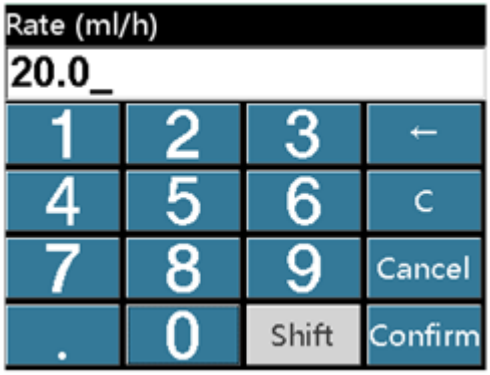
CAUTION:

- 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.
- The volume used for priming will be added to the total volume delivered
- The fast forward function can be used to remove any mechanical gap. Otherwise, may cause considerable delay in the start of the infusion.
- Total volume cannot be cleared after infusion starts.

- The volume under the fast forward function will not be calculated into the total volume.

6.5 Setting the infusion rate

- Press the rate area on the touchscreen to enter the setting interface.



- Press [CLEAR] key f to clear total volume.
- The flow rate varies with different syringe sizes. See Table 6-2.The minimum increments see Table 6-3.

Table 6-2 Relationship between syringe size and rate

Syringe size (mL)	Setting range (mL/h)
10	0.1-300.0
20	0.1-600.0
30	0.1-900.0
50/60	0.1-2000.0

Table 6-3Relationship 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 - 2000	1

CAUTION:

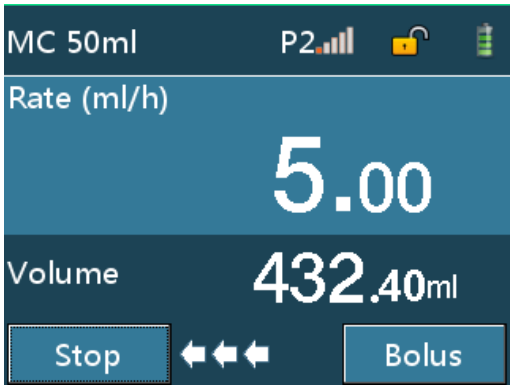
- When a syringe of different size is installed, if the flow rate is out of range, please reset the rate to maximum valid rate.
- To change the flow rate in the infusion process, the flow rate can be set while the pump is infusing.

6.6 Puncture

Insert the vein infusion needle into the patient's vein.

6.7 Starting Infusion

Click [START] key to start infusion at the setting rate, the green indicator lights.

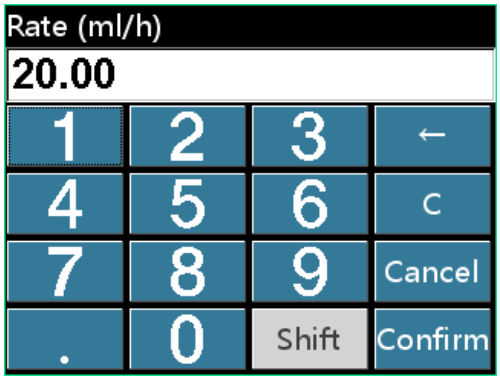


CAUTION:

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

6.8 Change rate during infusion

- Click the rate display area on the screen, click [OK] in the pop-up interface, then click [NO] to return to original infusion interface.



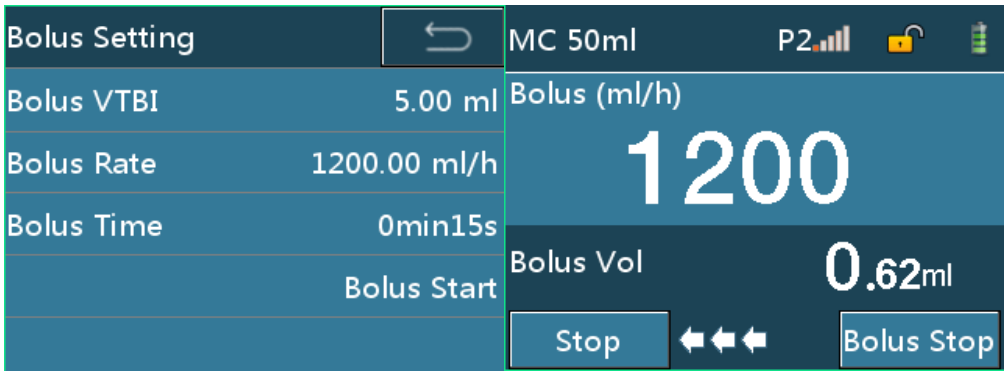
- After entering the rate, if click [Cancel], it will return to original infusion interface without change; Click [Confirm], it will return to original infusion interface and operates at the new rate.

CAUTION:

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

6.9 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 syringe specification as follows.

Table 6-4Relationship between syringes specification and flow rate

Syringe size (mL)	Bolus rate (ml/h)	The minimum bolus volume(ml)	The maximum bolus volume(ml)
10	300.0	0.1	10.0
20	600.0	0.1	20.0
30	900.0	0.1	30.0
50/60	2000.0	0.1	50.0

CAUTION:

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

6.10 Stopping Infusion

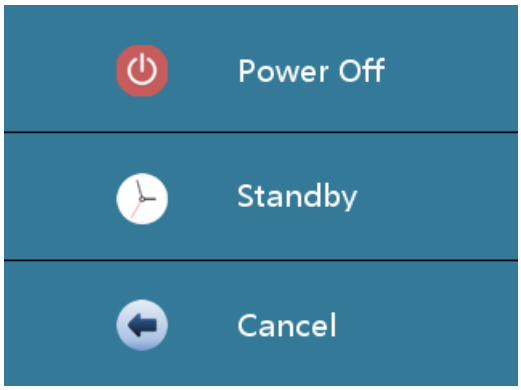
In the infusion process or after infusion, click [STOP] to stop the operation.

6.11 Replacing Syringe

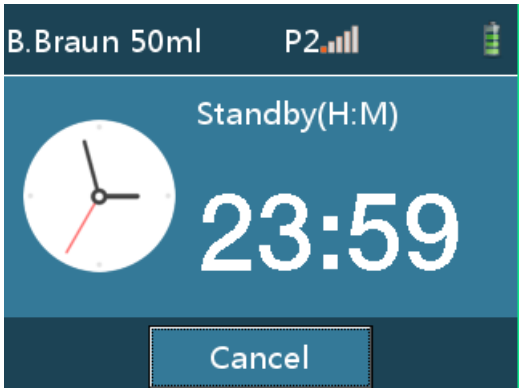
If the amount of solution in the syringe is getting low, repeat the steps in sections 6.3 and 6.6 to replace the syringe.

6.12 Turning the Power Off

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



- Click [Power Off] to shutdown.
- Click [Standby] to enter standby interface, the standby time can be modify.



- Click [Cancel] to return to previous interface.

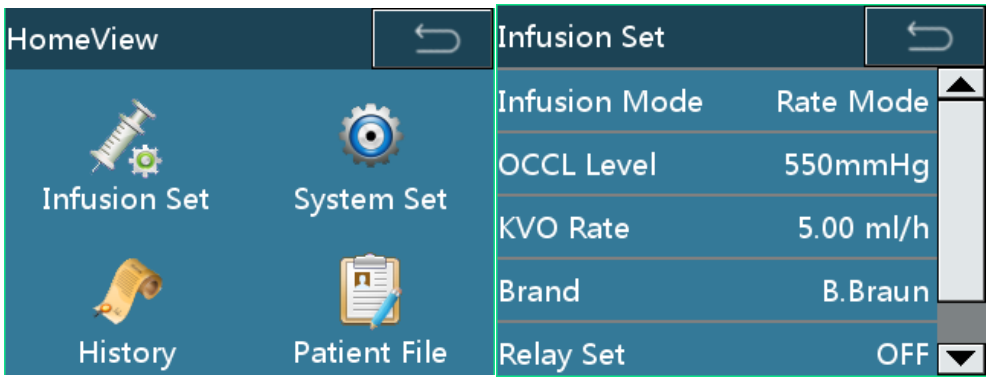
7 Setting the Syringe Pump

CAUTION:

- After the pump is powered off, all parameter settings will be automatically saved.
- Parts of parameters will not be saved if the device is forced to shutdown.

7.1 Infusion setting

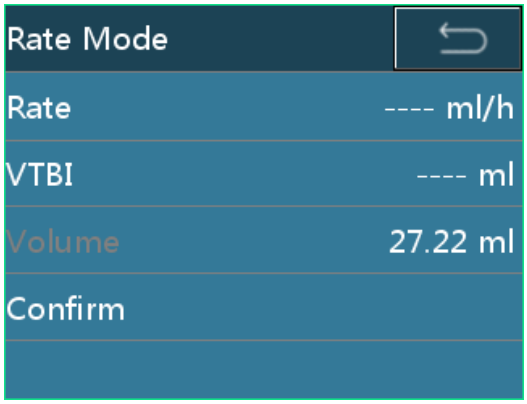
Press [HOME] key to enter the setting interface, click [Infusion Set] to enter the detailed infusion setting interface. Infusion set, occlusion level, bolus mode, KVO rate, brand, relay set, near finished could be set and adjusted here.



7.1.1 Infusion Mode

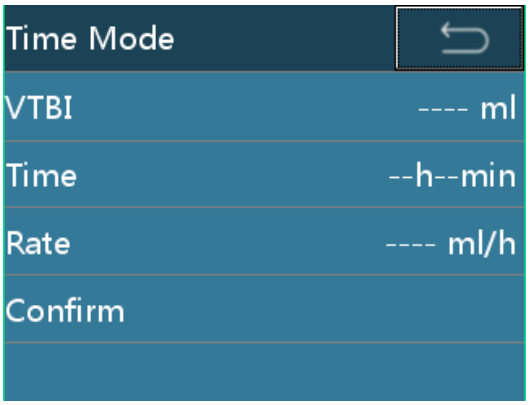
- 4infusion modes: Rate, Time, Weight, Sequence are available.
  - Rate mode

  Under the Rate Mode, set therate and VTBI, click [Confirm] to operate.



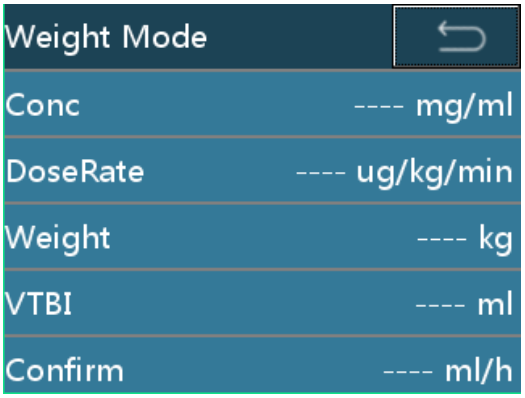
- Time mode

Under the Time Mode, set theVTBI and time, click [Confirm] to operate.



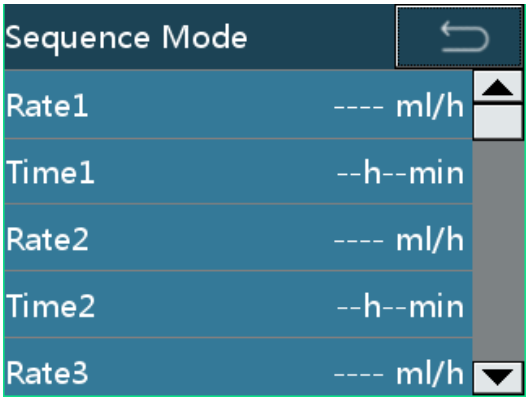
- Weight mode

Under the Weight mode, set the concentration, VTBI, doserate and body weight, automatically calculate the rate, and then click [Confirm] to operate.



- Sequence Mode

Under the Sequence Mode, set the 5 sequence rate and time, click [Confirm] to operate in sequence.



7.1.2Occlusion Level

- 3 levels of occlusion are available (Factory setting is level 2).

Table 7-1 Relations between occlusion level and pressure

Occlusion level	Display	Pressure (mmHg)	Pressure (Kpa)	Pressure (bar)	Pressure (psi)
1	P 1	300	40	0.4	5.8
2	P 2	550	73	0.7	10.6
3	P 3	900	120	1.2	17.4

CAUTION:

- When the occlusion alarm occurred, motor will reverse automatically to release the pressure in the tube (Anti-Bolus), so that no extra bolus will be infused during the operation of cancelling the occlusion alarm.
- When you infuse viscous solution with the Occlusion Level setting under 1 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 3, the in-line pressure builds up substantially until Occlusion alarm is issued. Always make sure that the IV line is securely connected to the syringe.
- 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.

7.1.3KVO

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

7.1.4Brand

- You can choose the consumable brand by: [Home] -> [Infusion Set] -> [Brand]
- Several brands syringe of 5ml, 10mL, 20mL, 30mL, 50/60ml have been preset and customized. Select the syringe accordingly for clinical uses.

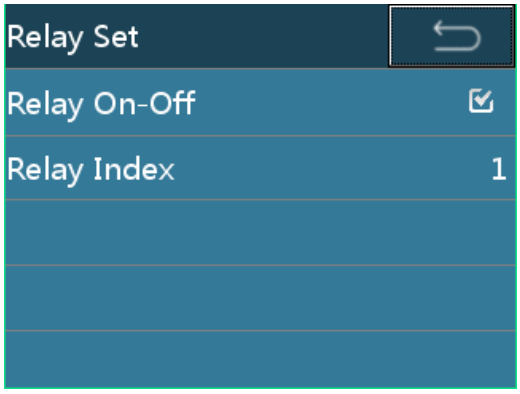
CAUTION:

- Users must use the consumable brand which is specified by the manufacturer.

- To add in syringes of other brand, users are strongly recommended to contact the manufacturer or manufacturer's representative to set and test, so as to ensure the infusion accuracy.

7.1.5Relay Set

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



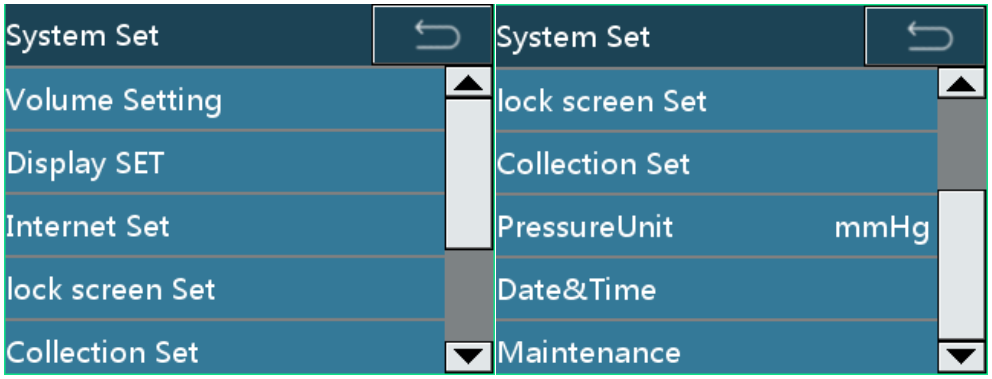
CAUTION:

- The relay number must be set in sequence from number 1 when there are severalsyringe pumps or infusion pumps.

7.1.6NearFinished

- Near Finished Alarm: Alarm-time could be adjusted from 1min to 30min before Finished (Step by1min), Default time: 3min before Finished

7.2 System Set



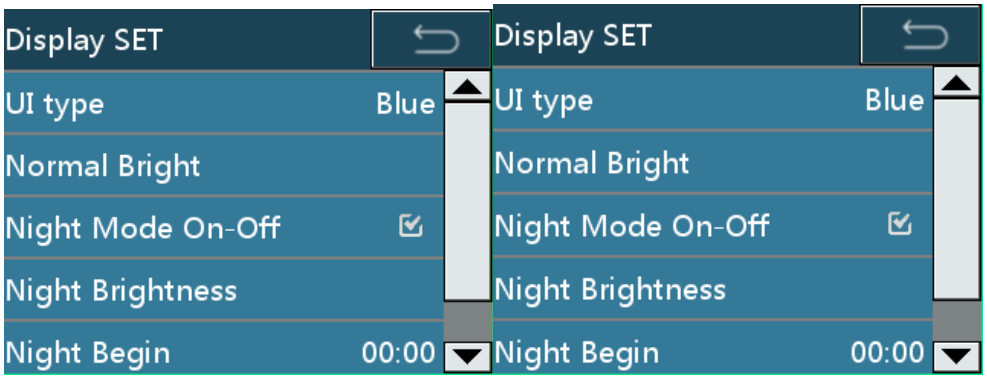
7.2.1Volume Set

- 11 volume levels are available (The factory setting is level 5)

CAUTION:

- Do not set the alarm volume lower than the ambient noise to ensure the alarm could be recognized correctly.
- If 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 working station, once the volume setting on the pump is changed, the setting on the station will be synchronized at the same time.

7.2.2Display Set



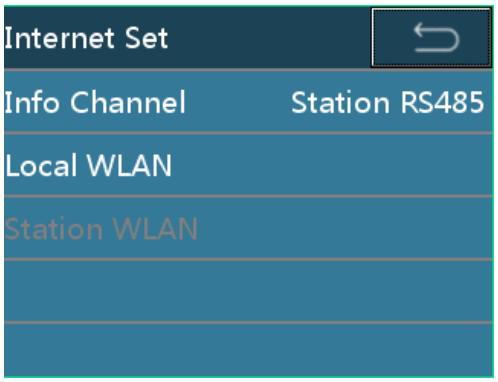
- There are seven different color options for UI type
- The brightness could be adjusted in [Normal Bright]
- All the parameters of the night mode could be adjusted here

CAUTION:

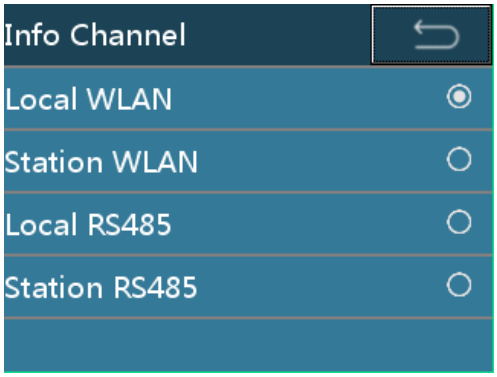
- Under the night mode, setting range of start time is 17:00-09:00, finish time range is the same as start time range. By default, the start is 00:00; finish time is 00:00.
- If the pump is inserted to a working station, once the display setting on the pump is changed, the setting on the station will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

7.2.3Internet Set

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



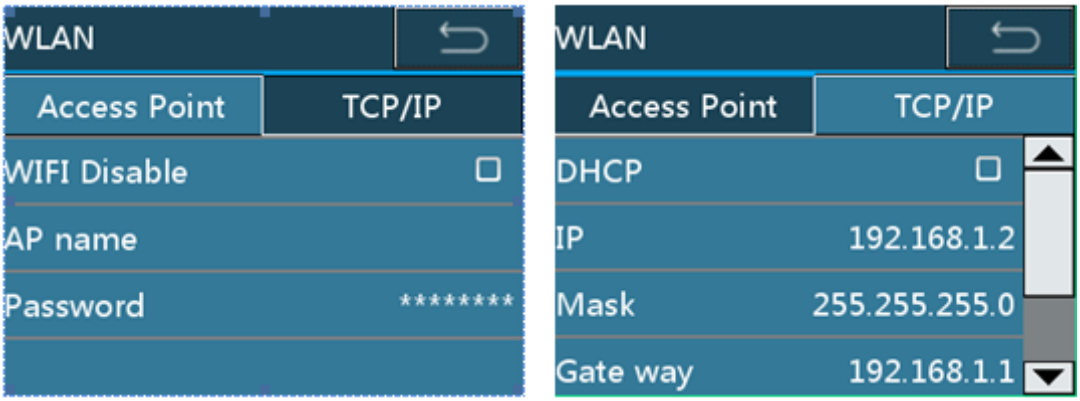
- Click [Info Channel] to choose the channel type
  - Choose [Local WLAN] to use local WLAN channel to connect to the network, and the local WLAN parameters could be set
  - Choose [Station WLAN] to use station WLAN channel to connect to the network, and the station WLAN parameters could be set
  - Choose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



CAUTION:

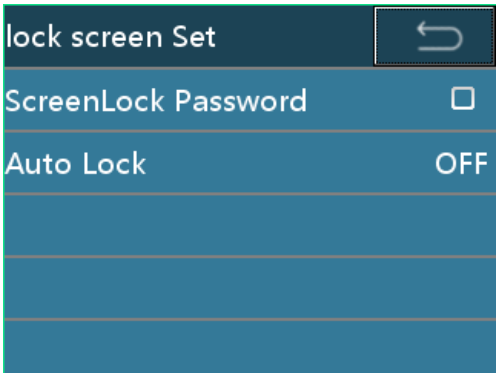
- The pump could communicate with working station, and the working station could manage the alarm and implement relay function between pumps.
- The setting of [Local RS485] and [Station RS485] must be done by the manufacturer's representatives. Please contact manufacturer or local dealer for further 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.
- [WIFI Disable] option should be cancelled, the AP name, Password of the network should be inputted, and the TCP/IP's information should be set.



7.2.4Lock screen Set

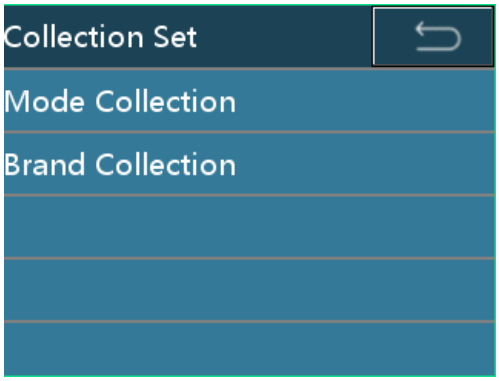
- Click [ScreenLock Password] to enable/disable the screen lock password function. When the function is enable, a password is required to unlock the screen. When the function is disable, there will be no require on password to unlock the screen
- Click [Auto Lock] to set up the screen auto lock function. This function could 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



7.2.5Collection Set

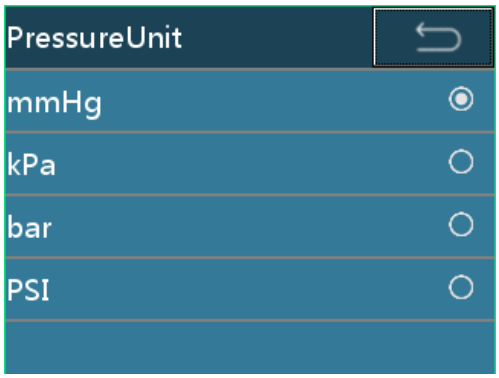
- [Mode Collection]: Choose the frequently used infusion mode from the [Infusion mode] option. Once the frequently used infusion modes are chosen, the unnecessary modes will not appear in the list of 7.1.1 [Infusion mode] option. The default setting is "all the four infusion modes are chosen".
- [Brand 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”



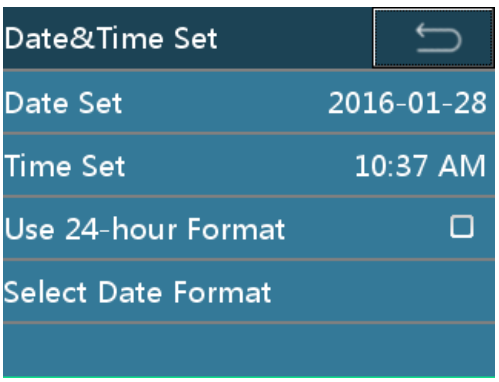
7.2.6PressureUnit

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



7.2.7Date&Time set

- Set the date, time, and their format.

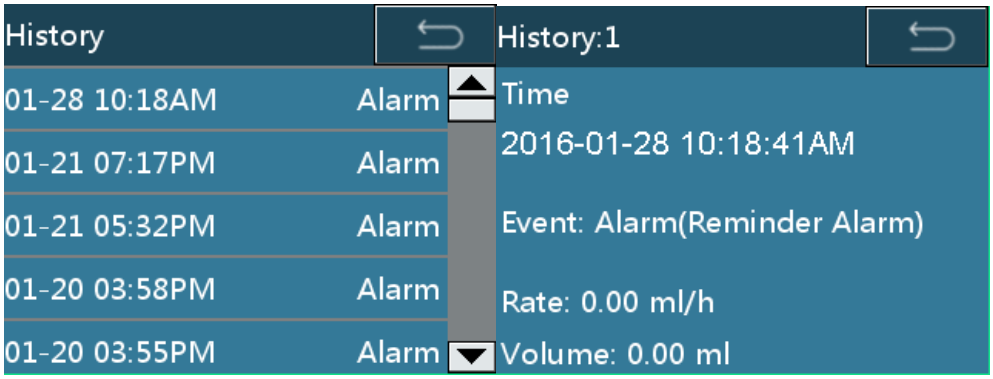


7.2.8Maintenance

- Click [Maintenance] option to do the [Language Select], [Touch Adjust], [Factory Data Reset], and check the version information

- To check the version information, follow the route of: [Home] -> [System Set] -> [Maintenance] -> [Version Info]

7.3 History



The history records are as Table 7-2.

Table 7-2 History records

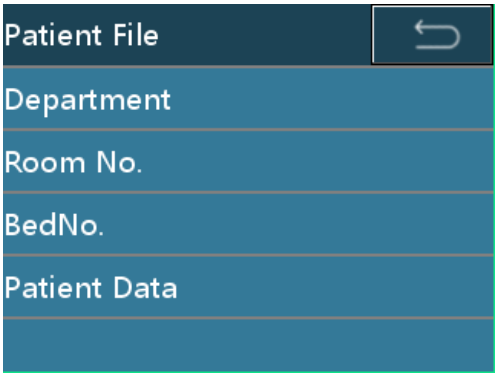
Event	Record Parameters
Start up	Occurred time
Shutdown	Occurred time
Standby	Occurred time, standby set time
Start	Occurred time, rate, VTBI
Bolus	Occurred time, Bolus rate, Bolus way
Bolus stop	Occurred time, Bolus rate, Bolus accumulated volume
Stop	Occurred time, rate, accumulated volume
KVO	Occurred 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:

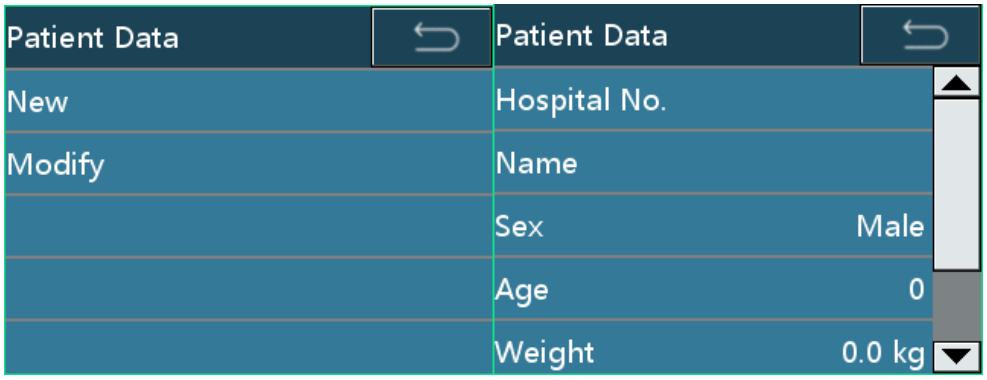
- The history records could be saved when power is cut.
- 2000 history records could be saved. When the record number reaches the storage limit, the oldest record will be replaced by the new one.
- Alarm system can’t be poweredoff separately by operator unless the pump is powered off.The time of powering off is captured in the history records.

7.4 Patient File

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



- 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.



CAUTION:

- If the pump is inserted to a working station, 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.
- When external power 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 number of active indicators. For details, see Table 7-3.

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

[Battery capacity]state	**The remaining capacity*1)**
Four bars light	Operation will be possible for 360 minutes.
Three bars light	Operation will be possible for 240 minutes.
Two bars light	Operation will be possible for 160 minutes.
One bars light(green)	Operation will be possible for 80 minutes.
One bars light(red)	Operation will be possible for 30 minutes.

***1)** Working conditions:

- New battery (within one year of manufacture).
- Operating at 5mL/h using a 50/60mL syringe. Close WIFI function.
- Room temperature of 25°C.

- When the syringe 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 syringe pump will stop.
- 3 minutes before the battery 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.

7.6 Connecting to the <Infusion Central Monitoring System>(optional)

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

CAUTION:

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

7.7 Nurse pager (optional)

After syringe pump is connected to the central station, patient can press nurse pager in bed, and then the central station in nurse station would gives 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 syringe pump is connected to the central station, patient can press nurse pager in bed, and then the central station in nurse station would gives 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 syringe pump. For any modification, contact your local distributor.

8 Troubleshooting

8.1 Alarm

The syringe pump provides users with a variety of status information about itself and its injection process. If any abnormality is detected, the syringe 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	Give out three beeps at intervals of 25 seconds.	The yellow indicator keeps on.
Mid-level alarm	Give out three beeps at intervals of 15 seconds.	The yellow indicator flashing.
High-level alarm	Give 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 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.

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 syringe 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 syringe IV line is occluded； 2.The OCCL level is too low for high viscosity drug’s infusion.	Press [STOP] to stop the injection. Check and remove the cause, continuous to inject.
Near Empty	Low-level	It takes less than three minutes to complete the infusion.	Wait till syringe is purged to be empty.
Syringe Empty	High-level	The syringe is empty.	Press [STOP] to clear the alarm.
Unknown Syringe	High-level	Syringe disengagement from slit during infusion.	Press [STOP] to clear the alarm. Check if the syringe pump clamp or syringe is installed correctly.

Alarm Symptoms	Alarm level	Causes	Troubleshooting
Syringe Install Error	High-level	The slider is loosen during the infusion or the slider is not installed in a right way.	Press [STOP] to clear the alarm. Check if the holder is installed correctly.
Finished	High-level	The limit amount or the infusion time is complete	Press [STOP] to clear the alarm.
Reminder Alarm	Low-level	Forget to operate the alarm (no key operation is made two minutes after the syringe is installed).	Press any key to clear the alarm.
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
Syringe Start Fail	High-level	Syringe pump cannot be started under the relay mode.	Check the syringe 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 8-3troubles and troubleshooting

Trouble code	Alarm level	Troubleshooting
Sensor Error	High-level	Record the troublecode andturn off, Contactmanufacturer or manufacturer's representatives.
Motor Error	High-level	
Circuitry Error	High-level	
Driver COM 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 any solution spills on the pump or the pump gets heavily soiled，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.
- If the clamp or clutch needs to be removed for cleaning，contact your local distributor.
- 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 syringe pump cannot be autoclaved.
- Never use a dryer or similar device to dry the syringe 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 the syringe pump into water.

WARNING:

- Do not clean or disinfect 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 syringe pump，and check the syringe pump once every 2 years. You can maintain some items by yourself and contact your local distributor to maintain some other items. Contact manufacturer or manufacturer’s representatives for any doubt.

9.2.1Check the Appearance

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

9.2.2Check 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 representativesfor replacement in time.
- If you connect the syringe pump to the AC/DC power and there is no indication of powering on, contact manufacturer or manufacturer's representatives for maintenance in time.

9.2.3Check the infusion rate

- Check the infusion flow once every 2 years by the graduate and timer.

Checking condition:

Syringe	Infusion rate	Infusion time	Volume in graduate
MC /B.Braun50/60ml	60mL/h	10min	9.8-10.2mL

9.2.4Alarms

- Syringe unknown

Pull of the syringe clamp during infusion, alarm information will be visible on the display and audible.

- Syringe Install Error

Press of the clutch during infusion, alarm information will be visible on the display and audible.

- Occlusion

Checking condition:

Syringe	Infusion rate	Occlusion level	Alarm time
MC /B.Braun50/60ml	25mL/h	P2	Within 1 min

9.2.5Electric and mechanical safety

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

9.2.6Checking 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 and attach the syringe (50/60mL syringe).
- Set the infusion rate to 5 mL/h and start the infusion. Record the start time.

- Operate the system until it stops infusing due to low battery alarm.
  - 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 2 hours， the battery condition is reaching its service life.
  - 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 lever check is complete, recharge the battery for next use.

9.2.7Replacing the Battery

- **Remove an 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, short circuit or throw the battery into fire in case of the danger caused by linkage or explosion.
- Please follow the local low to dispose the old battery.

9.3 Maintenance

- If any trouble，explain the situation to the manufacturer or manufacturer's representative and request for repair.
- Never disassemble or try to repair the syringe pump. Doing so may cause a serious failure. The manufacturer and the distributor shall not be responsible for any syringe pump that has been disassembled，modified or used for any purpose other than that for which it is intended.
- If the syringe 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.

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.
- Parts of the Pump are not serviced or maintained while in use with the patient.

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

The syringe pump can be transported by common vehicles and shall be protected from being clashed, shook, or wetted by rain and snow. Transportation method shall be in accordance with the order contract specifications.

9.6 Environmental Protection and Recovery

At the end of life，please dispose of this equipment to the distributor you purchased the product from or dispose of them by a suitable method according to the applicable environmental laws and regulations.

10 Flow Rate 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.
- The max accuracy difference is ±40% under the condition of single failure.

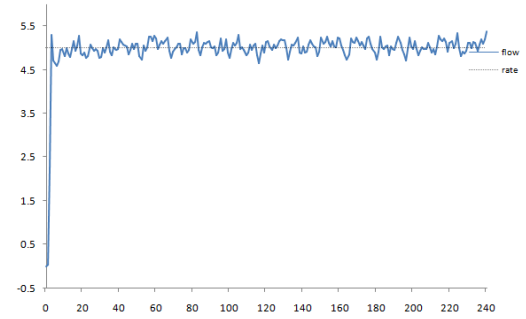
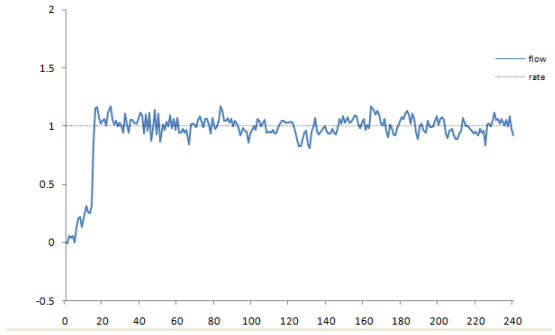
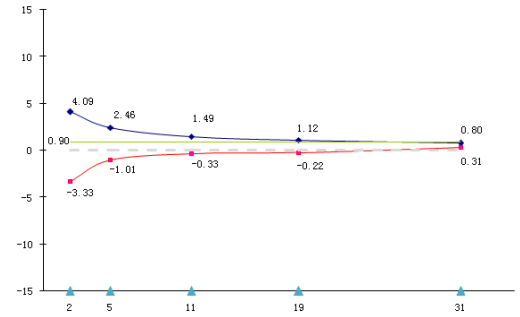
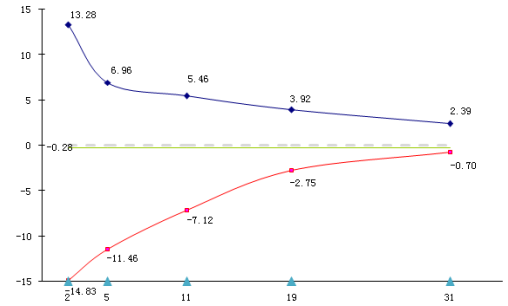
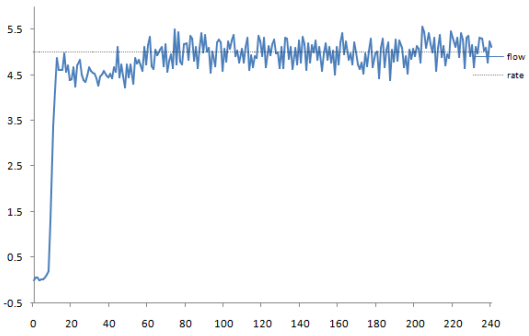
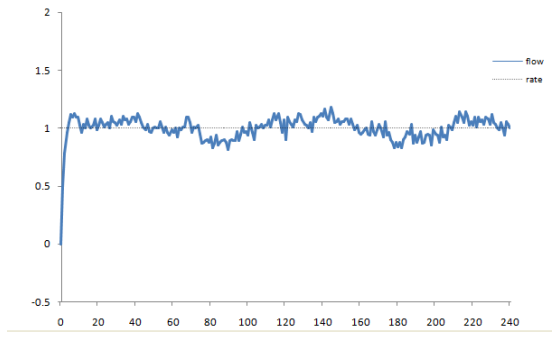
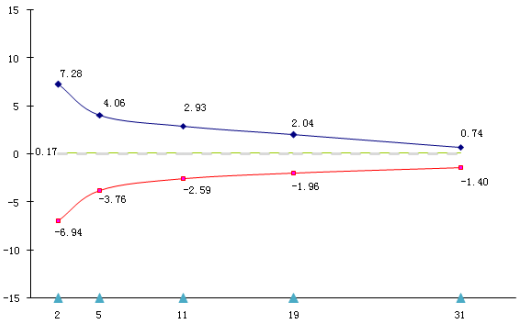
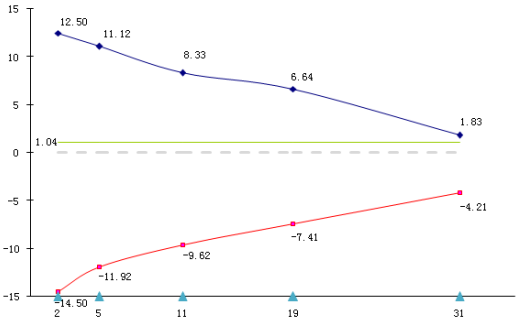
10.1 Flow Rate Characteristics

Start-up and Trumpet curves show the characteristics of the syringe pump after the injection begins and the injection changing status after the syringe 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℃;
  - Relative humidity:60%;
  - Syringe type:MC（10ml、20ml、30ml、50/60ml）,B.Braun （20ml、50/60ml）; 4 sets each.
  - Syringe pump: 1 set
  - Sampling interval: 0.5min
  - Test Period: 120min

Flow Rate Characteristics

Start-up curves of MC(50/60ml) 5ml/h	Start-up curves of MC(50/60ml) 1ml/h
	
Trumpet curve of MC(50/60ml) 5ml/h	**Trumpet curve of MC(50/60ml) 1ml/h**
	
Start-up curves of B.Braun(50/60ml) 5ml/h	**Start-up curves of B.Braun(50/60ml) 1ml/h**
	
Trumpet curve of B.Braun(50/60ml) 5ml/h	**Trumpet curve of B.Braun(50/60ml) 1ml/h**
	

10.2 Occlusion Characteristics

The occlusion characteristics are reflected by the longest delay time to start an alarm and performance of pill amount.

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℃;
  - Relative humidity: 65%;
  - Syringe type:MC（50/60ml）; 1 set
  - Length of the infusion tube: 1m

Table 10-1 The occlusion level, alarm delay time and pill amount under the rate of 5mL/h

Infusion rate	**Occlusion pressure level**	**Occlusion pressure （mmHg）**	**Occlusion alarm time （hh:mm:ss）**	**Bolus (ml)**
5mL/h	I	300±100	00:26:28	0.86
	III	900±200	00:40:06	1.97

Table 10-2 The occlusion level, alarm delay time and pill amount under the rate of 1mL/h

Infusion rate	**Occlusion pressure level**	**Occlusion pressure （mmHg）**	**Occlusion alarm time （hh:mm:ss）**
1mL/h	I	300±100	00:60:17
	III	900±200	02:05:17

Table 10-3The 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	I	300±100	06:05:00
	III	900±200	11:28:00

CAUTION:

Unit conversion list

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

Appendix A

Appendix A Electron Magnetic Compatibility (EMC)

The MP-30 syringe pump conforms to EMC standard EN 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic emissions		
The MP-30 syringe pump should be used under the regulation electromagnet environment. The user should operate the MP-30 syringe pump under following electromagnet environment.		
Emission measurement	conformance	Electromagnet environment-instructions
Radio-frequency emission CISPR 11	Group 1	MP-30 syringe pump only use radio-frequency while operating its internal functions, therefore, the radio-frequency is much low and has little interference to the electronic devices nearby.
Radio-frequency emission CISPR 11	Class A	The MP-30 syringe 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	conform	

Appendix A

Guidance and manufacturer's declaration – electromagnetic immunity			
The [MP-30] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MP-30] should assure that it is used in such an environment.			
IMMUNITYtest	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 [MP-30] requires continued operation during power mains interruptions, it is recommended that the [MP-30] be powered from an uninterruptible power supply or a battery..
Power	3 A/m	3 A/m	Power frequency magnetic

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

Appendix A

<table>
<tr><td colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The [MP-30] is intended for use in the electromagnetic environment specified below. The customer or the user of the [MP-30] should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment –guidance</td></tr>
<tr><td>Conducted RF IEC61000-4-6</td><td>3 Vrms 150k ~ 80MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the [MP-30], 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 Pis the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis the recommended separation distance in metres (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:  </td></tr>
<tr><td>Radiated RF IEC61000-4-3</td><td>3V/m 80M ~ 2.5GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

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 dueto fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [MP-30] is used exceeds the applicable RF compliance level above, the [MP-30] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [MP-30].

[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 [MP-30]			
The [MP-30] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [MP-30] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [MP-30] 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 din metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pis 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 inall situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix B The Default Factory Settings

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

Parameters

Parameters setting	The default factory setting
KVO flow rate	1ml/h
Pressure unit	mmHg
Occlusion pressure	P2（middle level）
Near end	3min
Built-in consumable brand	MC(10, 20, 30, 50/60ml), B.Braun(20,50/60ml)

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 CToxic and Hazardous Substances or Elements

Description	Plumbum Pb	Mercury Hg	Cadmium Cd	Chromium VI Cr(VI)	Polybrominated biphenyls PBB	polybrominated 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.

“×”shows that he content of this toxic and harmful substance in one homogeneous materials is over the regulated limitation requirement of SJ/T11363-2006.

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

Registration address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan District, Shenzhen, P.R.China

Production address: 1-4 Floor,11th Building,Nangang Industrial Park, Songbai Road, Xili, Nanshan District, Shenzhen, P.R.China

After-sales service address: 12th Floor, Baiwang Research Building, No.5158 Shahe West Road, Xili, Nanshan District, Shenzhen, P.R.China

EU- Representative name: WellKang Ltd

EU- Representative address: Suite B, 29 Harley Street LONDONW1G 9QR, England, United Kingdom

Telephone: +86-755-26953369

CE 0123

Fax: +86-755-26001651

Postal code: 518055

Website: http://www.medcaptain.com

E-mail: info@medcaptain.com