GRASEBY™

CE
2862

MI20 Infusion Pump

User Manual

Version: 1.1

MDKMed Medical Technology Co., Ltd.
2024.7.5

GRASEBY™

Content

1 Symbols, Graphics and Warnings

1.1 Descriptions of Graphics and Symbols

Caution! Read included files

Type CF device

Compliant to ROHS standards

Date of manufacturing

Serial Number

Manufacturer

Power On/Power Off

Start/Stop

Purge/Bolus

Mute alarm sound.

AC (Alternating Current)

Classified collection, uncontrolled discard not allowed.

IP24

Ingress Protection Grade

Class II device

European Representative

1.2 Warning

Please read the following warnings carefully. Any operation that does not strictly follow the guidance will possibly damage the device or do harm to patients' health.

1) The infusion pumps are intended for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. The devices can be used together with liquid storage devices /IV infusion sets /Blood transfusion sets /Enteral feeding sets.
2) Only trained and qualified healthcare givers are allowed to operate this pump. This user manual must be read carefully before using the pump.
3) To avoid fire or explosion, this infusion pump should not be operated in an environment where flammable materials are stored.
4) To ensure safe operation of this pump, do not stack the pump with other equipment that has electromagnetic emission.
5) This pump is an IP24 type device. Do not immerse pump into liquid.
6) Operator must follow Section 10 Parameters Setting for Infusion Set to select the correct type for infusion set and use the recommended infusion sets that have been calibrated.
7) Using other infusion sets that are not among the list of recommended infusion sets will result in greater error in infusion accuracy and eventually lead to operation failures.
8) While being used, the height of the infusion set can neither be placed lower or higher than 1 meter from the patient's heart.
9) Do not use the same infusion set on more than one machine.

10) Do not press the buttons with finger nails or other sharp objects.
11) Only fully trained maintenance staffs are allowed to repair and calibrate this pump. The power cable must be unplugged before repair. Untrained personnel are not allowed to remove the cover, otherwise the warranty coverage for this pump will be lost.
12) The parts and accessories for this device must not be MDKMed recommended or approved.
13) If sustained a severe impact or dropped, the pump should not be used until it has been checked by trained technical staff.
14) According to 14 PRODUCT SERVICE AND MAINTENANCE, user can wipe the shell of pump. And battery replacement is allowed. Other parts shouldn't be maintained or repaired.
15) The battery must be replaced and maintained by a trained professional technician in accordance with the procedure defined in "Section 13: Use and Maintenance of Internal Battery". Replacement of the battery by unauthorized personnel without adequate training will lead to overheating, fire, explosion or other risks.
16) The alarm sound may fail to alert the operator if the acoustic pressure level is lower than that of the ambient noise. The operator should always adjust the volume of the alarm sound to an audible level that is greater than that of the ambient noise.
17) Do not use unapproved cleaners, materials or chemicals as they may damage device surfaces, labels, or cause equipment failures.
18) Do not route LVP supply bag or administration set right above the pump.
19) Do not route the administration set in a way that presents tripping hazard and administration set break off.
20) Do not change the height of pump during infusion, otherwise the infusion accuracy may be affected.

1.3 Caution

Please read the following information carefully, otherwise the usability of this device may be affected.

1) Fix the pump in a level and secured position before and during operation.
2) Fix the pump in a level and secured position before and during operation.
3) Pump operator must strictly follow doctor's prescriptions to set the infusion parameters, otherwise patient's health may be harmed.
4) After setting infusion parameters, operator must make sure that the infusion set is correctly installed on the pump before the pump is started.
5) In order to maintain a high infusion accuracy, the contacting spot of compression on an infusion set should be changed every 8 hours, if the same set is used continuously for a long period of time. The roller clamp on the pump should be turned off before this changing operation, and it should be turned back on after the changing is done.
6) To maintain high infusion accuracy, the pump needs to be re-calibrated when there is a significant change in ambient temperature.
7) The pump will stop operation automatically when there is an alarm. Please press " 

" to resume operation after alarm is cleared.
8) To avoid failure or false alarms caused by a dirty occlusion sensor or the air in line sensor, operator should wipe clean the pump on a regular basis to keep it clean.

1.4 Note

1) Pump or accessories may not be usable if their lifetime for use has expired (the lifetime for use is 8 years). Contact MDKMed to upgrade to new products.
2) The device has a internal rechargeable lithium batter and its lifetime is

2 years.

3) Please check the voltage of the internal battery before using it for pump operation.
4) Please do not connect any other device to the USB port other than the included DC adapter shipped with the pump.
5) When using the power plug or other separable plug as the isolation means from the main power, please do not position the device so that it is difficult to operate the disconnection device.
6) Infusion sets are the applied part of the device.
7) The Door Open Alarm will be activated if the pump door is open during normal operation. Please contact the MDKMed service engineer for support if the condition for Door Open Alarm is met but the alarm fails to be activated.
8) A statement that mobile RF communications equipment can effect medical electrical equipment.
9) After the lithium battery exceeds the service life (1 year), check whether the low battery alarm time is longer than 30 minutes every month. If it is less than 30 minutes, replace the battery immediately.

2 Terms and definitions

Operator: A professionally trained and qualified member of medical staff.

KVO: After infusion is completed based on the preset parameters, the pump will automatically switch to a mode with extremely low flow rate and continue to run (this mode virtually does not have any treatment effect), which is to keep the infusion set and vein unobstructed and to avoid the blood flowing backwards.

Intermediate Rate: A flow rate of 25 mL/h.

Minimum Rate: A flow of 1ml/h.

Free-flow: Drug solution is flowing in an uncontrolled manner under

the effect of gravity.

Operation State: After all needed parameters are set, the pump enters operation state when " 

"button is pressed.

Alarm State: A state that the pump will enter when a potential or an already existing danger is confirmed.

Calibration: To ensure the infusion pump to meet its designed high accuracy, calibration and proper parametric compensation have to be done on the infusion sets. Calibration has to be performed only by trained professionals.

VTBI: Volume to be infused.

3 Introduction and Scope of Application

3.1 Introduction

MI20 infusion pump is a smart infusion device. It is consisted of a control system based on an ARM Cortex micro controller, a peristaltic pump actuation system, a monitoring system, an alarm system, an input interface and a display.

The operation of traditional IV infusion is depending on the pressure gradient cause by gravity to infuse drug solutions into patient's body. The operation is all manual, the infusion flow rate is controlled by a roller clamp and it has to be monitored by human eyes of the care givers. The gravity infusion does not have occlusion alarm, air in line alarm, or infusion near end alarm, which places a big burden on care givers and fails to meet the demand for high-accuracy, small amount and fast speed in infusion.

Users will gain the following 4 benefits in using the MI20 pump:

1. Ensured accuracy: The drug concentration in patient's blood has to be within a certain range when medication treatment is given. If the upper limit of drug concentration is exceeded, the patient's organs, such as liver, will be harmed. But if the concentration is too low, the medication treatment will not be effective. Infusion accuracy will be ensured when using MI20 pump.

2. Meeting flow rate requirements: A certain flow rate has to be met for a given medication treatment, which can range from 1ml/h to 1800ml/h. Unless infusion pump is to be used, otherwise the flow rate requirements cannot be met by using the gravity or manual infusion methods.

3. Providing enough pressure: The necessary pressure for infusion cannot be reached by adjusting the height of drug solution bag or bottle, while the infusion pressure is controllable by using infusion pump. Infusion pump works well in both vein and arterial intervention treatments.

4. Automatic monitoring: Light and sound alarms are available when infusion pump is in use. They inform the care givers with these alarms by automatically monitoring the infusion pressure and the air bubbles in line during operation, which not only improves the quality of care but also serves as a basic source of patient data for the hospital.

3.2 Intended Use

Intended use of product: The infusion pumps are intended for the intermittent or continuous delivery of parenteral fluids, enteral fluids, medications, blood and blood products through clinically accepted routes of administration. The devices can be used together with liquid storage devices /IV infusion sets /Blood transfusion sets /Enteral

feeding sets.

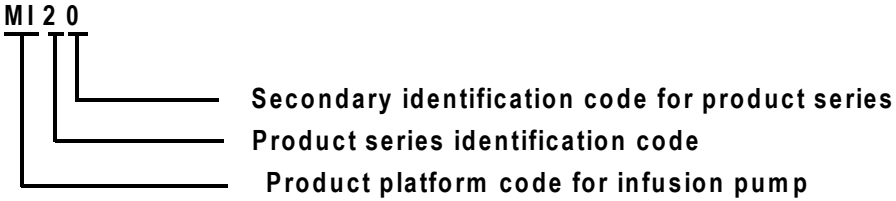
Indication for use: N/A.

Contraindications: not known.

Intended patient population: The target population is adults, pediatrics (including newborns) who need intravenous therapy, blood transfusion and enteral nutrition, no other specific requirements.

Intended users of the device: The device is intended to be used by trained healthcare professionals in medical institution environments.

3.3 Model Naming



3.4 Benefits

Since the infusion pumps do not come into contact with patient directly, they don't have direct clinical benefit to patients. So the clinical benefit of the infusion pump is that the device enables the precisely administration of intravenous fluid /blood /blood product /enteral fluid procedure to be undertaken, and realizes the monitoring of the infusion processing (the device is able to send alarms during infusion process when occlusion or other circumstances), which can greatly increase the infusion safety.

4 Important Features

1) High accuracy: The accuracy for both infusion flow rate and volume are kept within 5% when the MDKMed recommended infusion set is

used.

2) High flow rate: Infusion flow rate can be adjusted from 0.1ml/h to 1800ml/h in a continuous manner, which makes MI20 capable of meeting various flow rate requirements in different infusion cases.
3) Small size: Just 8cm tall and 1.5kg in weight, MI20 is not only very small in dimension but also very light.
4) Stackable: MI20 pump is stackable. The miniature design of MI20 is a room saver for the wards where space is very limited. It can also be inserted onto an MX infusion work station as an infusion unit.
5) Easy operation: Operator can use the touch screen on MI20 to set parameters, which will still function with gloves on. A key pad is also available to ensure usability in different usage scenarios.
6) Electric free-flow clamp: MI20 has a electric free-flow clamp that saves several steps in the infusion set installation process. To complete the installation process, the operator only needs to straighten the infusion set with both hands, clamp it at two ends, and close the pump door.
7) Upstream occlusion alarm: MI20 has upstream occlusion alarm in addition to downstream occlusion alarm. When infusion bag is running out or the free-flow clamp is not turned on by mistake, the embedded internal pressure sensor will detect these problems automatically and an alarm will be initiated accordingly.
8) Fast installation: Patented Quick Mount system, which requires only one click to complete the pump installation.
9) External power source: An external power adapter is used, which not only removes the safety concerns of using an internal power source but also makes the device lighter, safer, and more portable.
10) High battery capacity: The rechargeable internal high-capacity Lithium

battery can support normal operation for 7 hours, which is conveniently helpful during patient transport or power outage.

11) Highly secure STM32 micro controller: a mutual monitoring dual-CPU architecture design. Ensure the control to the motor and sensor.

12) No false alarm in air-in-line detection: Based on ultrasonic technology and with the help from a unique algorithm, the air-in-line detection is accurate and reliable, which eliminates false alarms.

13) LCD screen: A 2.8-inch TFT LCD display offers high contrast and visibility, which is sharp and clear even from a distance of 5 meters away.

14) Smart occlusion removal: When the infusion line is occluded, the stepper motor will rotate reversely to release the pressure accumulated in the infusion line after it has been occluded.

5 Specifications

5.1 Basic Specifications

Dimensions	215mm×129mm×80mm(width x depth x height)
Weight	1.5 kg
Power supply	Network power supply: ~ 100 V-240 V, 50/60 Hz Internal battery: ⎓ 11.1 V rechargeable Lithium battery
Rate of work	55VA
Requirements for infusion sets	See Section 11: CAUTIONS FOR USING DISPOSIBLE INFUSION SET
Maximum flow rate	1800(ml/h)

5.2 Main Performance

Range of flow rate	0.01-1800ml/h,

setting	with resolution 0.01ml/h;
Flow rate accuracy (Essential Performance)	±5% Note: One pump and ten IV sets for the accuracy test.
VTBI range	0.01~9999.99ml, with resolution 0.01ml
Infusion volume accuracy (Essential Performance)	±5% Note: One pump and ten IV sets for the accuracy test.
Purge speed	1ml/h~1800ml/h, with resolution of 1 mL/h
Occlusion alarm(pressure) (Essential Performance)	High: 120 kPa±20 kPa Middle: 80 kPa±20 kPa Low: 40 kPa±20 kPa
Maximum infusion pressure	160 kPa
Time to activate the occlusion alarm; max bolus (Essential Performance)	Minimum flow rate(0.01mL/h): occlusion alarm is activated when pressure is within 40 kPa ± 20 kPa for 16h. And when pressure is within 120 kPa ± 20 kPa for 48h. When operated at minimum Infusion rate: < 1h when the occlusion alarm pressure threshold is set to the lowest pressure; or < 3h30min when the occlusion alarm pressure threshold is set to the highest pressure. When operated at intermediate speed: < 1min30s when occlusion alarm pressure threshold is set to the lowest pressure, and the Bolus produced during occlusion is < 0.20 mL; < 2min30s, when the occlusion alarm pressure threshold is set to the

	highest pressure, the Bolus during occlusion is not more than 0.40 mL. (Tested with the Hanaco IV infusion set when an occlusion was created 1 meter away from the pump outlet for testing purpose at 20 ℃)
KVO flow rate	KVO=3ml/h when flow rate≥10ml/h; KVO=1ml/h when flow rate ≥ 1ml/h and <10ml/h; KVO=the set infusion flow rate when flow rate <1ml/h.
Recover time after the recoverable alarm sound is cleared.	1min50s~2min
Time for pause over time alarm.	1min50s~2min
High priority alarm (Essential Performance)	Door open alarm, occlusion alarm, VTBI complete alarm, air in line alarm, out of battery alarm, battery/mains power double disconnect alarm, malfunction alarm.
Classification	Class II Type CF, capacity infusion pump with internal power source for continuous operation Grade IP24.
Environmental Requirement	Storage Temperature: -20℃~＋55℃; Operation Temperature: 10℃~＋40℃; Ambient humidity for transportation, storage and operation: 20%~90%; Barometric pressure range: 70.0 kPa~106.0 kPa.
Software Version	MI20-V1
Product lifetime	8 years.

5.3 Main Functions and Common Functions

1) Set infusion flow rate, set VTBI, and display real-time data;

2) Display the already infused volume;

3) Purge/bolus;

4) Alarms;

5) Automatically change the flow rate to KVO rate after the VTBI complete alarm is activated;

6) Temporary mute for alarm sound and timer for recovering alarm sound;

7) Automatic free-flow stopping function;

8) Display the TVI;

9) Clear the TVI data;

10) Support various brands of infusion sets;

11) Internal battery;

12) External DC adapter;

6 Structure and Operation Interface

6.1 Structural Composition

MI20 pump is mainly consisted of a user interface panel, a pump housing, a mechanical actuation system, and an electrical control system.

The front and back of the pump are shown in Figure 6-1-1 and Figure 6-1-2.

Descriptions for parts and components:

1	Charging indicator	2	External power indicator	3	Working indicator
4	Touch screen	5	Keypad	6	Pump door button
7	Pump door	8	Foot	9	Battery compartment cover

10	DC power port	11	Fixation pole	12	Positioning pin
13	Clamping port for stacking	14	On/off button for infusion set test	15	Powered free-flow clamp
16	Downstream occlusion sensor	17	Pumping operation device	18	Air in line sensor
19	Upstream occlusion				

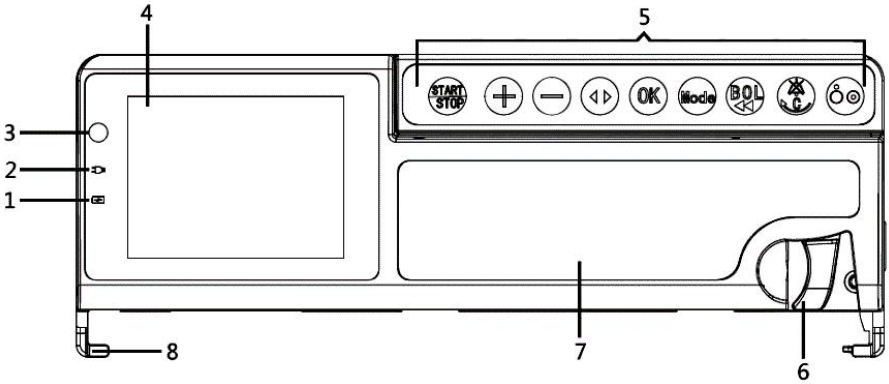


Figure 6-1-1 Front view.

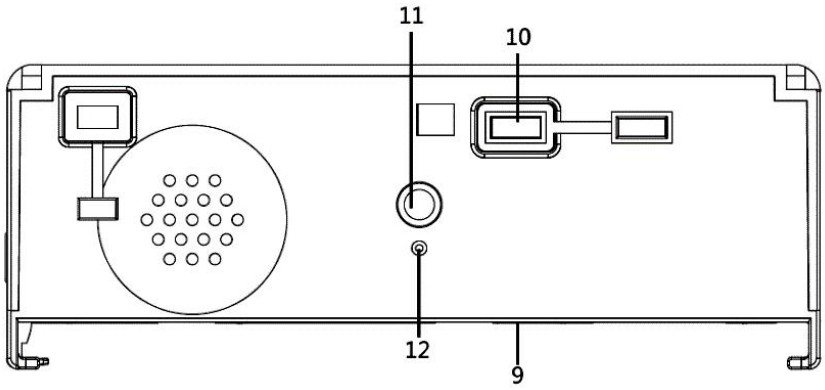


Figure 6-1-2 Back view.

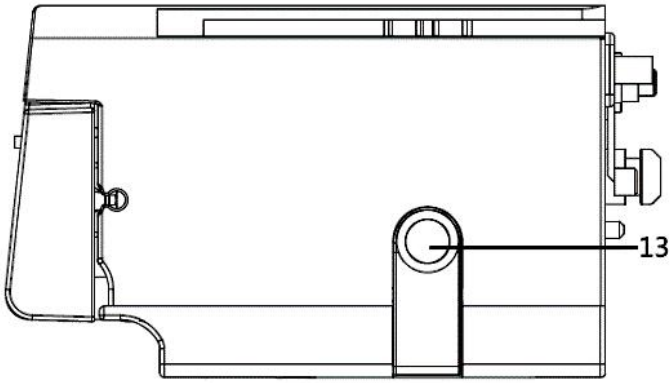


Figure 6-1-3 Side view.

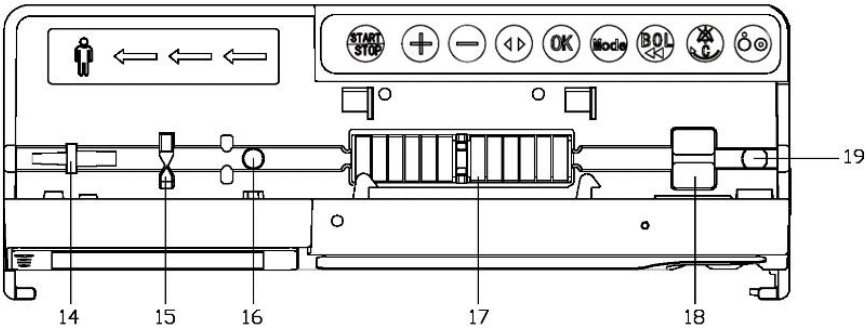


Figure 6-1-4 Pump door open view.

6.2 Display and Operation Interface

The display interface is shown in Figure 6-2-1. The keypad operation interface is shown in Figure 6-2-2.

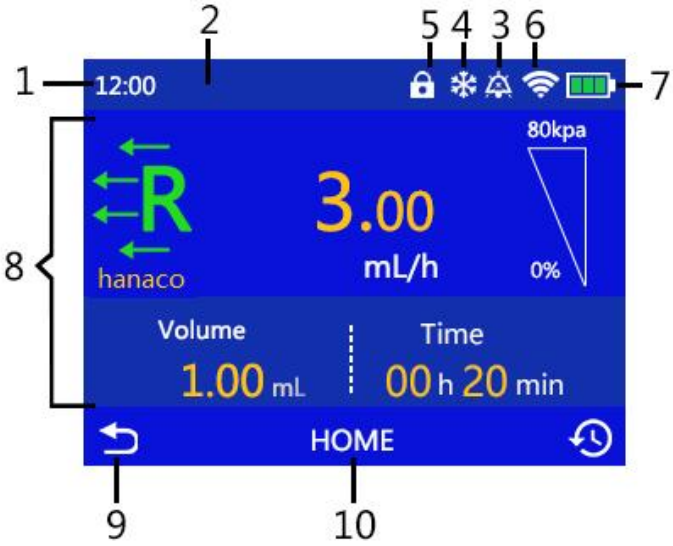


Figure 6-2-1 Display screen.

Descriptions for Figure 6-2-1:

1	Time indicator	2	Alarm indication zone	3	Mute indicator
4	Low temperature indicator	5	Screen locked indicator	6	Wi-Fi indicator
7	Internal power source status indicator	8	Parameter setting zone	9	Return to the previous menu
10	Return to home menu				

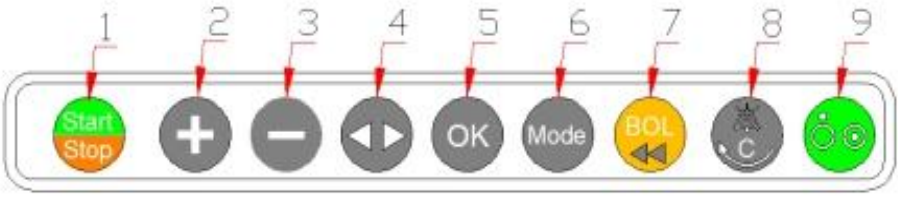


Figure 6-2-2 Keypad operation interface

Descriptions for Figure 6-2-2:

1	Start/Stop button	2	Increase	3	Decrease
4	Left/Right	5	OK to confirm	6	Mode
7	Purge/Bolus	8	Mute/Cancel	9	Power On/Off button

7 Operation Instructions

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Attention

All infusion sets must follow Section 10 PARAMETERS SETTING FOR INFUSION SET before they can be used on this device for the first time.

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Operation steps

Install infusion pump → power on → device safety self-test → install infusion set→ parameters setting → purge to squeeze out air bubble → start infusion → infusion completed → remove accessories → power off.

Before infusion starts, confirm the infusion set in use matches the current infusion set selected in menu.

7.1 Installation of Infusion Pump

7.1.1 Installation of fixation clamp

The fixation clamp is a separate accessory. First loosen the locking screw, fix the clamp to the pole, adjust the height of clamp, and then tighten the locking screw. Stainless steel poles with coating or other protective layers should not be used as the material for the infusion stand (The installation of the clamping device might damage the protective layer on the pole surface).

7.1.2 Installation of infusion pump

As shown in Figure 7-1, fix the fixation clamp onto the fixation pole, make sure the positioning pin is inside the correct hole accordingly, and make sure the infusion pump is installed in an upright position.

The operator must make sure that the infusion pump is positioned and fixed in a secure, stable and reliable manner.

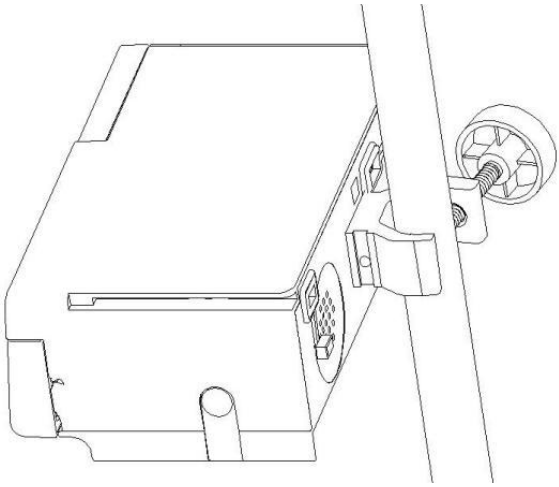

Figure 7-1-1 Pump fixation.

7.1.3 Stacking of infusion pumps

Multiple MI20 pumps can be used when stacked together. Press down the release button to unstuck a pump from a stack.

7.2 Power on and Device Safety Self-test

7.2.1 Power on

Connect to mains power, check the power indicator on the pump front panel. If the indicator is not lit up, check the connection of power cable and the pump, or check if there is a power outage. Then press

the "  " button on the front panel to turn the power on.

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Attention

Before connecting the mains power, check if there is foreign matter inside the power outlets (such as drug solution residue).

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7.2.2 System self-test

Device self-test: the pump will perform an automatic safety self-test after power on, if the test is passed then it will be followed by two short beeps "Beep, beep" as an acoustic reminder. If a continuous alarming sound is initiated or there is no any sound at all, then the device cannot be used, contact MDKMed customer service immediately.

7.3 Setting parameters

7.3.1 Infusion set selection

After power on, select the brand for infusion set in the Home – Settings – Brand, then go back to the HOME page. No selection or modification is needed if the infusion set used in current use is the same as the last time.

Figure 7-3-1 Select infusion set brand.

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Attention

When infusion sets from the same brand but different lots are used, calibration of the infusion set is recommended, which is described in Section 10.2 CALIBRATION FOR INFUSION SET ACCURACY. It is possible that the infusion sets from the same brand but different lots have different characteristics, which will affect their infusion accuracy if they are not calibrated before use.

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7.3.2 Infusion mode selection

MI20 has 5 different infusion modes, including Normal Mode(intravenous therapy, blood transfusion and enteral nutrition),

Dose Mode, Weight Mode, Relay Mode, Gradient Mode.

Click on HOME-Select Infusion Mode page.

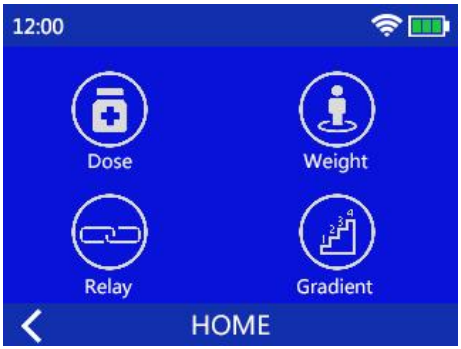

Figure 7-3-2-1 Select infusion mode.

Press Previous Page Button to enter Normal mode.

Figure 7-3-2-2 Infusion mode transition

7.3.3 Setting Volume to Be Infused (VTBI)

When pump is in standby, a keypad will show up when the volume parameter on touch screen is pressed. Input VTBI and confirm to complete the setting.

Figure 7-3-3-1 Set VTBI.

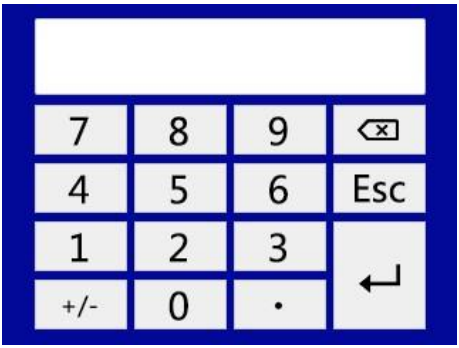

Figure 7-3-3-2 Data input with keypad.

7.3.4 Setting infusion flow rate

Same as described in Section 7.3.3.

7.3.5 Setting infusion time

Same as the operation described in Section 7.3.3.

Figure 7-3-5-1 Set infusion time.

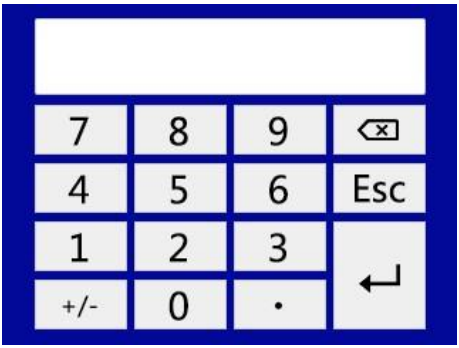

Figure 7-3-5-2 Data input with keypad.

7.3.6 Purge setting

Click on HOME-Settings-Purge Setting to set speed and volume for purge. The factory default purge speed is 800ml/h with resolution of 1ml/h. The default volume for purge is 25ml, which is to ensure an initial volume to be filled into the infusion set.

Figure 7-3-6 Purge Setting.

7.3.7 Setting occlusion pressure levels

Enter the occlusion pressure setting screen by pressing the upside-down triangle shape icon on touch screen. The occlusion pressure has 3 levels, with the maximum pressure being 100kPa and minimum pressure being 40 kPa. Drag the slider along the horizontal axis to adjust the pressure levels of occlusion pressure alarm. This is can also be done by clicking on the + or – sign on the two upper corners. Click on "Back" to go back to the parameter setting page for infusion mode.

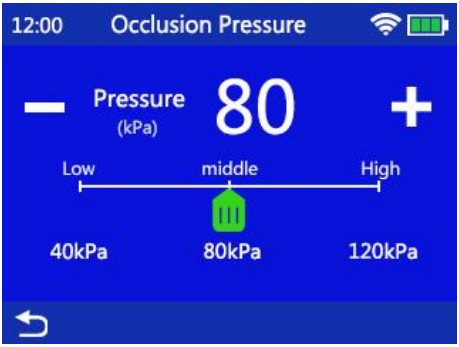

Figure 7-3-7 Set occlusion pressure level.

7.4 Installation and uninstallation of infusion set

7.4.1 Installation of infusion set

First, open the pump door by unlocking the door lock on the right hand side of the infusion pump. Straighten the infusion line below the drip chamber, clamp the line into the two notches on both sides of the pump. When the contact sensor on the left hand side detects the infusion line has been placed in the right place, the powered free-flow clamp will start to operate automatically to clamp the infusion line tightly to prevent free flowing, as shown in Figure 7-4-1. Then close the pump door, adjust the roller clamp on the infusion set to open position. The installation of infusion set is completed.

When the pump door is closed, the powered free-flow clamp will be opened. If the pump door is opened again, then the powered free-flow clamp will start to clamp the infusion set tightly again; if the infusion line is pulled outward at this time, the contact sensor will detect the infusion line is detached, and the powered free-flow clamp will be opened.

If there is air in the infusion line, press the bolus button " 

" twice within one second, the pump will go into the purge mode after the second press. The purge mode will stop when " 

" button is pressed down.

Figure 7-4-1 Powered free-flow clamp.

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Attention

After the infusion set is installed and the pump door is closed, make sure the roller clamp on infusion set is opened before infusion is started.

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7.4.2 Infusion set replacement

Before changing infusion set or changing drug solution, the roller clamp on infusion set has to be turned to the close position to prevent free flowing of the medication solution. To change or re-install the infusion set, first open the pump door, take the infusion set out, install the infusion set again, adjust the roller clamp on infusion set to open position when infusion set installation is done.

7.5 Start infusion

7.5.1 Automatic purge and start infusion

After the correct installation of infusion set is confirmed, press the " Start Stop " button, MI20 pump will show the following message "Purge or Not?" on screen. If YES is selected, the pump will run based on the fast infusion rate and volume values that are set in the HOME-System Settings-Purge Setting, pushing the air inside the infusion set out. See HOME-Settings-Purge Operation Indication page to learn how to turn off the purge operation indication page.

Figure 7-5-1 Purge operation indication page.

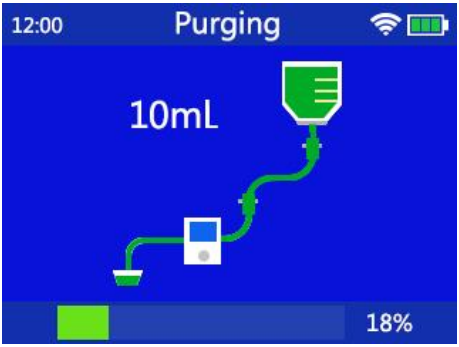

Figure 7-5-2 Purge in progress.

When purge is completed, the screen returns to the previous

parameter setting page. Confirm that the drug solution is flowing normally from the needle tip, insert the needle into patient's vein and fix the needle. Press the " 

" button to start infusion. From right to left, the operation indicator arrow on the bottom of the screen will start to flash continuously in a cyclic manner.

7.5.2 Manual purge and start infusion

When the purge indication page is turned off, press the " 

" button to manually purge the air in line after the infusion set is installed (the system has to be in infusion mode setting page to start this operation). Or use the roller clamp on the infusion set to purge the air in line before installing the infusion set onto pump.

After the infusion set is installed correctly onto the pump and the air in line is purged out, confirm that the drug solution is flowing normally from the needle tip, insert the needle into patient's vein and fix the needle. Press the " 

" button to start infusion. From right to left, the operation indicator arrow on the bottom of the screen will start to flash continuously in a cyclic manner.

7.5.3 Infusion in progress

The status of normal infusion operation is shown in Figure 7-5-3. The two display windows on the bottom show remaining volume and time. When the pump is currently in drug library mode, the display window on top shows the type of infusion set and the drug name. When occlusion pressure exceeds 80% of the preset value for alarming pressure, the alarm will be activated by showing a yellow triangle on

screen. When occlusion pressure exceeds the preset alarm pressure value, a red triangle will be displayed on the screen, and an occlusion alarm message will be shown at the same time.

Figure 7-5-3 Infusion in progress.

7.6 Stop and clear alarms

The " Start Stop " button can be pressed to stop an alarm, or to stop infusion, while the operation indicator will stop flashing as well.

==========

Attention

If the " Start Stop " is pressed to stop infusion, but the " C " is not pressed to reset the accumulated volume back to zero, then if the

" 

" is pressed again the infusion task will resume from where it left last time.

==========

Infusion will be stopped if the " 

" button is pressed when infusion operation is in progress. If no infusion parameters are changed during the stop, the infusion will pick up from where it left last time and continue to run when the " 

" is pressed again. If any infusion parameter is modified, such as rate, volume or time, then a new infusion task is established. When the " 

" is pressed down again, infusion will run based on the newly set parameters.

7.7 Mute alarm sound

When an alarm is triggered, the device will annunciate an alarm sound. The alarm sound can be muted temporarily when " 

" button is pressed. But if the alarm source has not been removed after two minutes, the system will automatically turn the alarm on again.

7.8 Purge and bolus mode

Based on the different states the device is in, pressing down the " 

" button will give three different results:

➢ Automatic purge mode: in the infusion mode parameter setting page, double click on " 

" will make the infusion pump go into the

automatic purge mode based on the rate and volume values set in the HOME-Settings-Purge Setting page. The pump will stop automatically after the operation is completed, and the screen will return to the parameter setting page. The total volume for purge is not included in the accumulated volume. The AIR IN LINE alarm will be disabled in automatic purge mode.

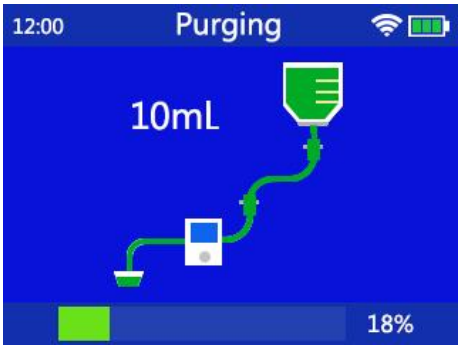

Figure 7-8 Purging operation.

- Automatic bolus mode: when infusion operation is in progress, bolus speed and bolus volume setting page will be entered by a single click on " " button. Set the parameters on this page and press the "OK" button on the lower right corner on screen, the pump will go into an automatic bolus mode. The bolus operation will stop when the preset bolus volume has been completed, the pump will return to normal infusion operation, and the bolus volume will be included in the accumulated infusion volume. Under the infusion operation state, double click on " " will make the pump go into an automatic bolus operation state and run based on the bolus rate and volume that were set last time.

- Manual bolus mode: when infusion operation is in progress, bolus speed and bolus volume setting page will be entered by clicking on "BOL" button once. Set the bolus parameters and continuously press down the "BOL" button, the pump will enter manual bolus mode. Bolus operation will run based on the set bolus speed (total bolus volume is not effective during manual bolus mode) until the "BOL" button is released. Pump will return to where it left before manual bolus was entered and continue to run infusion. The manual bolus volume is included in the accumulated infusion volume.

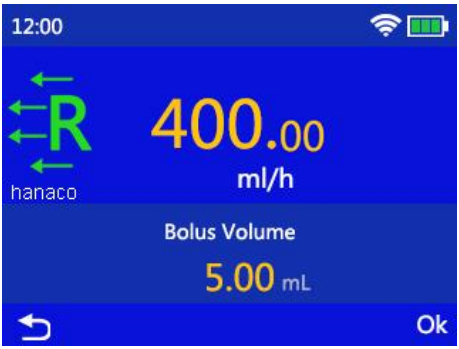

Figure 7-8-1 Set parameters for bolus.

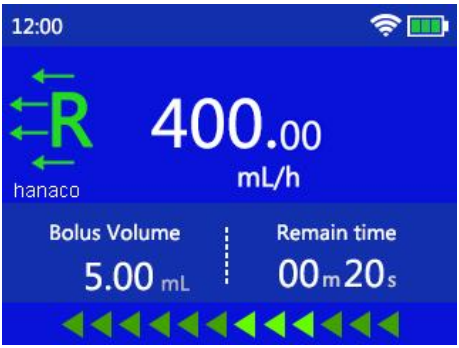

Figure 7-8-2 Bolus operation in progress.

7.9 Infusion complete

When the infused volume (the incremental of accumulated infusion volume) has reached the set value, the infusion preset volume complete alarm will be triggered. The pump will annunciate an alarm sound and display a "VTBI Infused" alarm message in the alarm indication area. Then the device will automatically switch to KVO speed to continue to operate.

Press the " Start Stop " button to clear the infusion complete alarm and to exit the KVO infusion state.

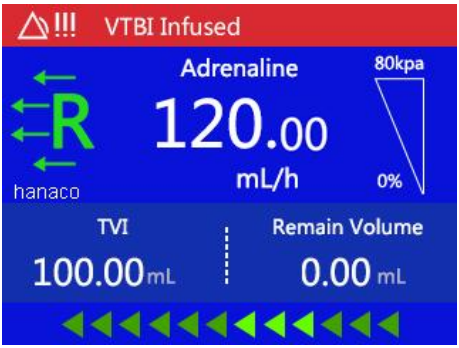

Figure 7-9 Infusion complete.

Press the "Start Stop" button to clear the VTBI infused alarm and to exit the KVO infusion state. The screen will show information such as the accumulated infusion volume and speed. Press and hold the "C" button for 3 seconds will clear the accumulated infusion volume. Click on the "Back" button on the lower left corner to go back to the infusion parameters setting page, then a new round of infusion operation can be initiated.

==========

Attention

When KVO is entered, a KVO indication message will be shown on top of the infusion speed numbers, indicating the device has entered the KVO state. However, the KVO speed will not be shown on the screen.

==========

7.10 Automatic infusion accumulation and accumulation zeroing

When pump is at stop, press and hold the "C" button for 3 seconds to clear the accumulated infusion volume. The accumulated infusion volume shows the total infused drug solution volume received by a patient. For example: Drug A is given to patient during the first

infusion with a preset volume of 1ml. When the accumulated volume reaches 1ml, the pump will annunciate preset volume complete alarm, which means 1ml of Drug A has been infused into patient. And when Drug B of 2ml is given to patient without clearing the accumulated infusion volume. Then the pump will annunciate preset volume complete alarm when the accumulated infusion volume reaches 3ml, meaning 2ml of Drug B has been infused into patient. In total, the patient has been given 3ml of drug solutions, including 1ml of Drug A and 2ml of Drug B.

7.11 Lock and unlock

The device will be locked automatically after running for a certain period of time. When under operation mode, press and hold the "Mode" button for 3 seconds to unlock.

See the automatic locking time setting in HOME - Settings - Auto-Lock Time.

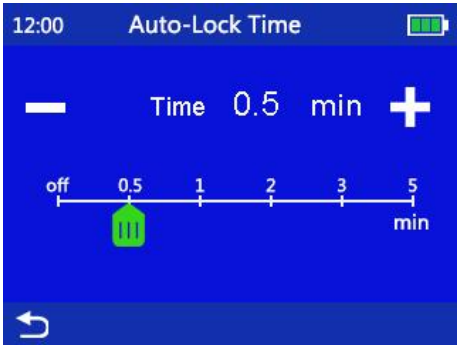

Figure 7-11 Screen auto-lock time setting.

When not in operation mode, click the "Mode" button once the

device will switch to R+V mode parameter setting page.

7.12 Power off

Press and hold the "  " button for 3 seconds will turn the device off.

Figure 7-12 Power off count down.

==========

Attention

Do not turn the pump off when infusion operation is in progress, otherwise the device will stop infusion.

==========

7.13 Uninstallation of infusion pump

To uninstall the pump, pull the ring on the fixation base up and pull the pump outward while holding it.

7.14 Body weight mode setting

Select to enter the body weight mode setting screen, as shown in Figure 7-14-1. Based on the prescriptions given by doctor, input information such as Dose, D. Volume, Solvent, and Weight and etc.. The device will then automatically calculate concentration and flow rate. Click the "OK" button to enter R+V mode parameter setting page, where the flow rate and the total volume are displayed are the ones that are calculated under the body weight mode setting page. Press the "Start Stop" button to start infusion under the body weight mode.

Figure 7-14 Body weight mode setting

On the body weight mode setting page, click the "Units" button on the upper right corner to change between different units, which will in turn change the units of parameters such as dosage and concentration accordingly.

Concentration and Rate Calculation:

Concentration is calculated by the following equation as:

dosage (mg)/solution volume (ml)

Flow rate is calculated by the following equation as:

dosage(mg/kg/h)*body weight(kg)*solution volume(ml)/dosage(mg)

7.15 Drug library mode

On the drug library mode setting page, click on the first column of letters on the left, the pump will display drug names that begin with the same initial letter and their corresponding flow rates in their last infusion. Click on the "Pg Dn" (Page Down) button on the lower right corner, the pump will show more drug names that begin with the same initial letters.

Confirm the drug name, click once to select, the device goes into R+V mode parameter setting page, where speed shows the flow rate value of this drug during last infusion, and total volume shows the solution volume during last infusion. Click on the " Start Stop " button, the pump will run infusion under the drug library mode, while the drug name is shown on top of the infusion speed number during operation.

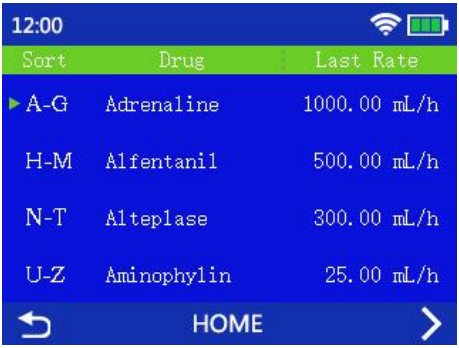

Figure 7-15 Drug library mode setting

7.16 Drug library

Both MI20 and MS31 pumps can be installed and operated on the MX infusion work station made by the MDKMed, which will enable them to work in corporation with the work station to realize advanced features such as relayed infusion and drug library management and etc.

Inside HOME-Drug Library, the operator can perform operations like adding new drugs or setting infusion speed for each drug. Tasks like importing drug information in volume, or setting upper/lower thresholds for dosage can be done by using the MX infusion work station.

7.17 Viewing log

In HOME-Log page, 200 log messages are shown, including information such as time, speed, and volume for each infusion event.

Using the MX infusion work station, infusion and alarm log information can be saved and inquired without capacity limitations. All logs can also be transferred via network and be printed out, helping care providers in managing their work.

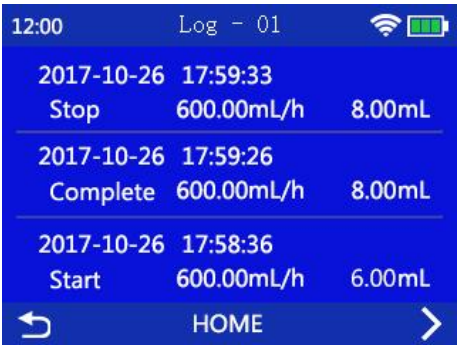

Figure 7-17 Log

8 Alarms

MI20 infusion pump will initiate alarms in the forms of sound, lights, or displaying signs and messages on screen to remind care providers when the following conditions take place: the infusion to patient cannot be performed correctly and smoothly either because of an infusion change caused by an abnormal condition happens in the infusion set, or some malfunctions within the pump itself. All alarms of infusion pump are technical alarms.

The alarm sound and the acoustic reminder have the same acoustic pressure level and their minimum acoustic pressure level is greater than 60 dB.

MI20 alarm priority levels:

Priority Level	Type of Alarm Conditions
High Priority	Door open alarm, occlusion alarm, VTBI complete alarm, air in line alarm, out of battery alarm, battery/mains power double disconnect alarm, malfunction alarm.

Low Priority	Pause over time alarm, internal battery low voltage alarm, infusion near to end alarm.

High priority and low priority alarms are distinguished by different sound and light indications according to the standards requirements. High priority alarm is indicated by red light and low priority alarm is indicated by yellow light.

The following alarms are defined as latching and unlatching alarms:

Latching alarms: Door open alarm, occlusion alarm, preset infusion volume complete alarm, air in line alarm, out of battery alarm, battery failure alarm, and malfunction alarm.

Unlatching alarms: Pause over time alarm, internal battery low voltage alarm, near to end alarm, and battery/mains power double disconnect alarm.

All the alarm settings will remain the same if the power is turned back on within 30 seconds after it was turned off.

==========

Attention

Latching alarm: alarm remains even though the event that triggered the alarm does not exist anymore, until the operator intentionally ends the alarm (press the " 

" button); unlatching alarm: alarm stops automatically when the alarm causing event is not there anymore.

==========

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8.1 Door open alarm

Reason: while in operation, if the pump door is not closed, or the pump door is opened by accident, the pump will initiate an alarm sound, stop infusion, and display "Door Open" alarm message in the alarm indication area.

Solution: during the door open alarm, press the " Start Stop " button to clear the alarm sound, and the "Door Open" alarm message will disappear. Check the pump, close pump door and continue to operate.

Alarm test: Start the pump, and then open the pump door. The pump will initiate an alarm sound, stop infusion, and display "Door Open" alarm message in the alarm indication area. This indicates that the Door Open alarm is correct.

Figure 8-1 Door open alarm.

8.2 Downstream occlusion alarm

Reason: when the infusion line is occluded, the occlusion sensor will detect this condition and activate an alarm. A message "Occlusion"

will be displayed in the alarm indication area and the pump will stop infusion. As a safety measure at the same time, the motor will rotate in the opposite direction to retrieve a small amount of drug solution to reduce the bolus volume before occlusion is removed.

Solution:

1) When occlusion alarm is activated, press the " Start Stop " button to clear the alarm sound, the "Occlusion" alarm message will disappear.
2) Check if the infusion line is kinked, or if the patient is pressing on the infusion line by accident.
3) If occlusion alarm remains, shut off the roller clamp on the infusion set, open the pump door, pull out the infusion set, check if the filter or the needle on infusion set is occluded, change a new infusion set if necessary and restart infusion.

Alarm test: Install the infusion pump and IV set. Set the infusion parameter and start infusion. Clamp the end of IV set and an occlusion will be detected after a while. A message "Occlusion" will be displayed in the alarm indication area and the pump will stop infusion. This indicates that the Downstream Occlusion alarm is correct.

Figure 8-2 Occlusion alarm.

8.3 Upstream occlusion alarm

Reason: when there is no drug solution left in the infusion bag, or the clamp between the bag and pump has been forgotten to be opened, the infusion line will become flat when infusion gets started. The pump will then initiate an upstream occlusion alarm and display an "Upstrm Occl" alarm message in the alarm indication area on screen, while giving out high-priority alarm sound and red light alarm signal, and the pump will stop infusion.

Solution:

1) During upstream occlusion alarm, press the 

button to clear alarm sound, and the "Upstrm Occl" alarm message will disappear.
2) Check if the infusion set is kinked, or if the roller clamp is opened, or if the infusion bag has any drug solution remaining. Restart infusion when everything is back to normal.

Alarm test: Install the infusion pump and IV set. Set the infusion parameter and start infusion. Close the clamp in the supply line and an occlusion will be detected after a while. A message "Upstrm Occl" will be displayed in the alarm indication area and the pump will stop infusion. This indicates that the Upstream Occlusion alarm is correct.

Figure 8-3 Upstream occlusion alarm.

8.4 VTBI Complete alarm

Reason: when the accumulated infusion volume shown in the current display window reaches the preset value, the pump will annunciate an alarm sound, stop infusion based on the preset speed, and display a "VTBI Infused" alarm message in the alarm indication area on screen. As a safety and protection measure, the pump will automatically switch to KVO mode to continue infusion.

Solution: during VTBI infused alarm, press the 

button to clear alarm sound, and the "VTBI Infused" alarm message will disappear. Then follow the operation steps to reset the pump and start to use.

Alarm test: Install the infusion pump and IV set. Set the infusion parameter and start infusion. A message "VTBI Infused" will be displayed in the alarm indication area and the pump will stop infusion. This indicates that the VTBI Complete alarm is correct.

Figure 8-4 VTBI complete alarm.

8.5 Air in line alarm

Reason: During pump operation, when the air-in-line sensor detects that the size of air bubble is larger than that of the preset limit, infusion will be stopped. The pump will initiate an air in line alarm sound and display "Air in Line" alarm message in the alarm indication area.

Solution:

1) During air in line alarm, press the Start Stop button to clear alarm sound, and the "Air in Line" alarm message will disappear.
2) To remove air bubbles from the infusion line, close the roller clamp, open pump door, pull out infusion set, check whether there is air bubbles in line, shake and move the air bubbles to the drip chamber by hands if there is, reinstall the infusion set, close the pump door, open the roller clamp, and press the Start Stop to restart infusion.
3) Check if the air in line sensor is clean. If sensor probe is dirty,

uninstall the infusion set, wipe clean the sensor probe with alcohol, reinstall the infusion set, and restart infusion.

4) If the alarm remains, change to a new infusion set, install the infusion set and restart.
5) Air in line alarm will be activated too, when the infusion line between the infusion bag and the pump is occluded. Remove the occlusion in infusion line and restart infusion.

Alarm test: Install the infusion pump and IV set. IV set is empty. Set the infusion parameter and start feeding. An air in line alarm will be detected after a while. A message "Air in Line" will be displayed in the alarm indication area and the pump will stop infusion. This indicates that the Air in Line alarm is correct.

Figure 8-5 Air in line alarm.

8.6 Out of battery alarm

Reason: when the battery is used up, the device will initiate a high-priority alarm sound and red light alarm signal, while displaying an "Out of Battery" alarm message in the alarm indication area on screen. The infusion will stop, and the pump operation will remain in stop and it

will completely shut down in 3 minutes.

Solution: Connect to mains power for power supply. When connected to mains power, the battery charging indicator will be lit up while the battery is being charged. The battery charging indicator will go off when battery is fully charged.

Alarm test: Install a used up battery in the infusion pump. A message "Out of Battery" will be displayed in the alarm indication area. This indicates that the Out of Battery Alarm is correct.

Figure 8-6 Out of battery alarm.

8.7 Battery/mains power double disconnection alarm

Reason: When pump is in operation, and when the mains power is disconnected and the battery is completely out or disconnected, the device will initiate high-priority sound and light alarms.

Solution: Connect to mains power or use battery to supply power.

Alarm test: First, disconnected the mains power. Then start the infusion pump and disconnect the battery. The infusion pump will initiate high-priority sound and light alarms. This indicates that the Battery/Mains Power Double Disconnection Alarm is correct.

8.8 System error alarm

Reason: Infusion will stop when there is a system error in the device hardware. A high priority alarm will be activated and the error name will be displayed accordingly. The following errors are defined as system errors: motor error, communication error, and the internal battery communication error.

Solution: Press the 

button to clear alarm sound. Check if infusion set is installed correctly. Restart infusion after corrections are made. Contact the MDKMed customer service if alarm remains.

Alarm test: Error Alarm can't be simulated. If there is an error alarm, please call for our service engineer.

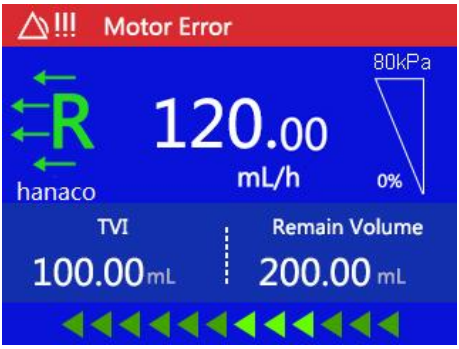


Figure 8-8 Motor error alarm.

8.9 Pause overtime alarm

Reason: When system is in a pause state for more than 2 minutes after device is powered on and parameter settings are done, a pause overtime alarm will be initiated. The pump will give out an alarm sound and display a "Pause Overtime" alarm message in the alarm indication area.

Solution: Press any key or rotate the dial will clear the alarm sound, and the "Pause Overtime" message will disappear.

Alarm test: Don't touch the infusion pump for 2 minutes. A message "Pause Overtime" will be displayed in the alarm indication area. This indicates that the Pause Overtime Alarm is correct.

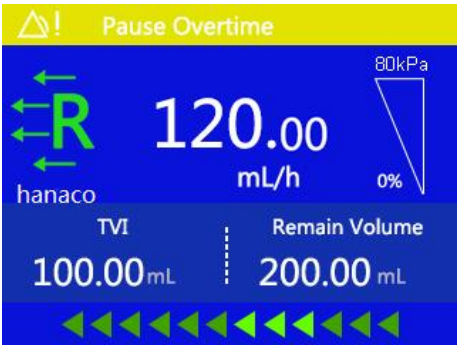


Figure 8-9 Pause overtime alarm.

8.10 Internal battery low voltage alarm

Reason: When internal battery is low, the device will annunciate a low-priority alarm sound, and display a "Low Battery" alarm message in the alarm indication area. If infusion is in progress, the pump will not stop operation.

Solution: Connect to mains power immediately. When connected to mains power, the battery charging indicator will be lit up, the battery will start to be charged, and the "Low Battery" message will disappear. The battery charging indicator will go off when battery is fully charged.

Alarm test: Install a battery with less than 20% charge in the infusion pump. A message "Low Battery" will be displayed in the alarm indication area. This indicates that the Internal Battery Low Voltage Alarm is correct.

Figure 8-10: Low battery alarm.

8.11 Infusion near end alarm

Reason: When the remaining time is less than the preset alarm time, the device will initiate a low-priority alarm sound, and display a "Near End" alarm message in the alarm indication area on screen. Infusion will not stop.

Solution: Press the "  " button to clear alarm sound. Check remaining drug solution and the remaining time, wait for infusion to complete.

Alarm test: Install the infusion pump and IV set. Set the infusion parameter and start infusion. A message "Near End" will be displayed in the alarm indication area. This indicates that the Infusion Near End Alarm is correct.

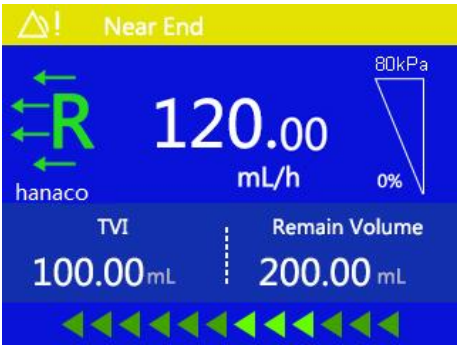


Figure 8-11: Infusion near end alarm.

9 System Parameter setting

System parameters can be set in the HOME-Settings page.

9.1 Brightness

Brightness of the screen can be set in HOME-Settings-Light. Brightness can be adjusted by dragging the slider along the horizontal axis, or it can be done by clicking on the + or – signs on the upper left and right corners. After brightness setting is completed, click on the "Back" button on the lower left corner to return to the previous menu.

Figure 9-1 Brightness setting.

9.2 Alarm Sound Volume

Alarm sound level can be set in the HOME-Settings-Alarm Volume page. Drag the slider along the horizontal axis to adjust the volume of alarm sound, which can also be done by clicking on the + or – signs. After sound level setting is completed, click on the "Back" button on the lower left corner to return to the previous menu.

The default setting for alarm sound volume level is low level. The alarm sound volume level will be reset to the default setting when the device is restored to the default factory settings. The alarm sound volume level will remain the same as the most recent set value if the device is restarted.

Figure 9-2 Alarm sound volume setting.

9.3 Air in line detection sensitivity level

Air in line detection sensitivity level can be set in the HOME-Settings-Air Bubble Sensitivity setting page. Drag the slider along the horizontal axis to adjust the sensitivity level for air in line detection, which can also be done by clicking on the + or – signs. After setting is completed, click on the "Back" button on the lower left corner

to return to the previous menu.

Level 5 is for detecting air bubble sizes that are less than 0.05ml. The higher the level, the larger the air bubble sizes.

Figure 9-3 Air bubble detection sensitivity level setting.

9.4 Purge setting

The speed and volume for purge can be set in the HOME-Settings-Purge Setting page. Click on the speed or volume to set their value respectively. The parameter set in the Purge Setting will not affect the speed and volume in bolus mode.

Figure 9-4 Purge setting.

9.5 Purge indication

Whether or not to turn on the purge indication page can be set in the HOME-Settings-Purge Indication Page. The icon means the purge indication page is turned on. With purge indication page turned on, the pump will ask operator if the infusion set needs to be purged when Start Stop is pressed after all infusion related parameters have been set. The icon means the purge indication page is turned off.

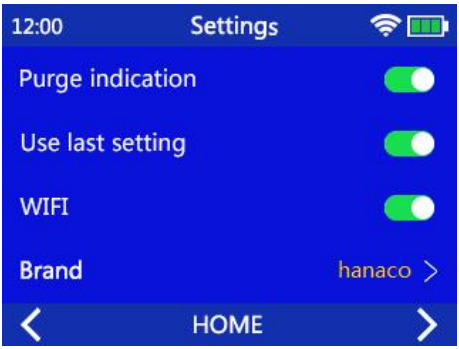


Figure 9-5 Purge indication page setting.

9.6 Load settings from last use

In the HOME-Settings-Load Settings from Last Use page, operator can decide whether to load the parameters from last use. The icon means that the feature to load parameters from last use is turned on. When power is turned on, the pump will show an indication page reminding the operator that parameters from last use are being loaded. Information such as infusion mode, speed, volume and time will be displayed on pump screen. When YES is pressed, the pump will go into the corresponding infusion mode, load and use the parameters from last use accordingly, which will help the operator quickly start the infusion task.

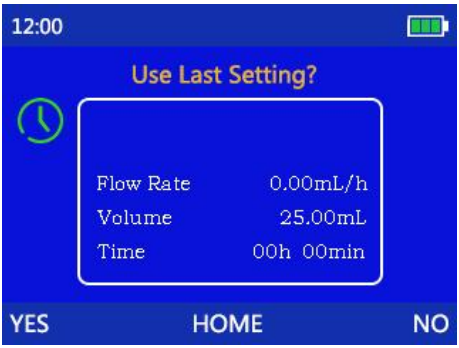


Figure 9-6 The reminding page for loading the parameters from last use.

9.7 Type of infusion sets

The type of the infusion set for the current use can be set in the HOME-Settings-Brand page. Click on the check box on the right to choose infusion set brand. When completed, click on the "Back" button on the lower left corner to return to the previous menu.

The selected infusion set type will be shown on the page for infusion mode setting, which can remind the operator to use the right infusion set to maintain infusion accuracy.

Read Section 10.2 CALIBRATION FOR INFUSION SET ACCURACY on how to characterize an infusion set.

Figure 9-8 Selection for infusion set type.

9.8 Screen auto-lock time

The time for locking the screen or the keypad can be set in the HOME-Settings-Auto-Lock Time page. Drag the slider along the horizontal axis to adjust the time that is allowed to elapse before the screen or keypad is locked, which can also be done by clicking on the + or – signs. After setting is completed, click on the "Back" button on the lower left corner to return to the previous menu.

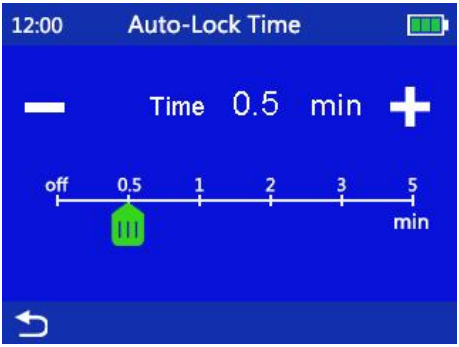


Figure 9-9 Screen auto-lock time setting.

9.9 Daytime/nighttime setting

In HOME-Settings-Daytime/Nighttime Setting, set different values for brightness and sound volume for daytime and nighttime. Drag the slider along the horizontal axis to adjust the numbers for alarm sound volume and screen brightness. When completed, click on the "Back" button on the lower left corner to return to the previous menu.

The brightness and alarm sound volume settings in HOME-Settings-Light and HOME-Settings-Alarm Volume have a higher priority than the ones in Daytime/Nighttime setting. When it is

the time for the Daytime Start Time or Nighttime Start Time, the device will automatically adjust brightness and alarm sound volume to the level where it has been defined in the HOME-Settings-Daytime/Nighttime setting. The brightness and sound volume can be adjusted either in HOME-Settings-Light and HOME-Settings-Alarm Volume, or in HOME-Settings-Daytime/Nighttime page.

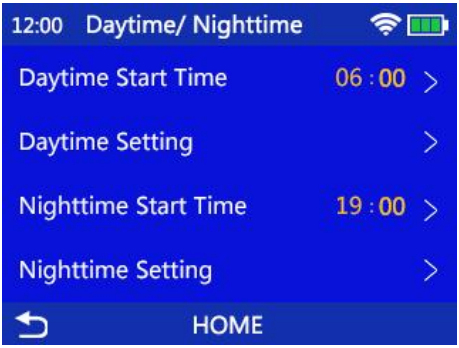


Figure 9-10 Daytime/Nighttime setting.

9.10 System maintenance

System maintenance can be performed in the HOME-Settings-Maintenance page, including the calibration of infusion set, system time setting, system language setting, and etc.. A password is required to enter the system maintenance page. Contact the customer service at MDKMed for password assistance.

Read Section 10 in this manual for the procedure of performing calibration for infusion sets.

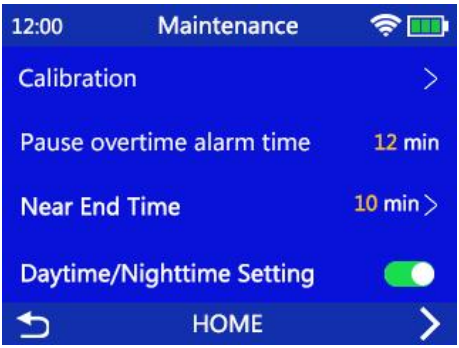


Figure 9-11 System Maintenance setting.

9.11 Restore to factory settings

Factory settings can be restored in the HOME-Settings-Restore to Factory Settings page. The settings that can be restored are all of the parameters described in Section 9 in this manual, including the accuracy value for the default infusion set. Please take caution when decide whether or not to perform a restoration to the factory default settings.

Figure 9-12 Restore to factory settings.

10 Parameters setting for infusion set

10.1 Enter infusion set calibration setting screen

Follow Section 9 SETTING SYSTEM PARAMETERS to enter the infusion set calibration setting screen. Select the brand name of the infusion set accordingly, as it is shown in the following figure.

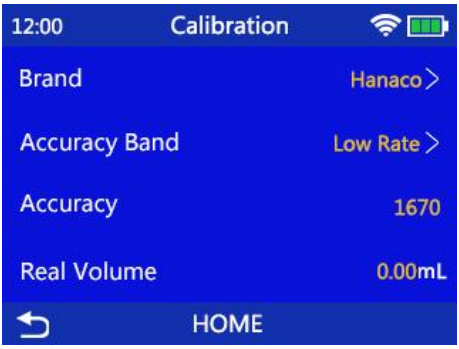


Figure 10-1 Calibration for infusion set accuracy.

10.2 Calibration for infusion set accuracy

1) First, install the infusion set just like performing a normal infusion operation. Then place the scalp needle into a measuring tube with scales. Enter the HOME-Settings-System Service-Calibration page.

2) Click on Brand and select the brand name and type of the infusion set that needs to be calibrated. Then return to the Calibration page.

3) Click on Accuracy Band and select between High Rate and Low Rate. Then return to the Calibration page. Note that the selected Accuracy Band should match the type of the scalp needle that is being used.

4) While in the Calibration page, press the " Start Stop "key and the infusion pump will output 8ml drug solution based on the current accuracy

setting. The pump will automatically stop infusion when the 8ml solution has been infused.

5) Check the remaining solution in the measuring tube (use the bottom point of the concave surface to measure liquid level), and enter the volume to the slot next to the Real Volume in the Calibration page. The pump will automatically calculate a new accuracy value based on this volume and display it on the screen.

6) Back to normal pump operation, and check if the infusion is running with the correct accuracy after the infusion set was calibrated.

11 Cautions for using disposable infusion set

The ambient temperature should be kept at least at 10℃ or above when a recommended infusion set is used. The infusion accuracy will be compromised if ambient temperature is lower than 10℃.

In order to maintain high infusion accuracy, pump needs to be re-calibrated when the ambient temperature has a dramatic change. Follow the steps in Section 10 PARAMETERS SETTING FOR INFUSION SET to calibrate infusion sets.

Strictly follow the requirements described in Section 10 PARAMETERS SETTING FOR INFUSION SET to calibrate the infusion set before use when change to a new infusion set from a different manufacturer.

The recommended brand list is as follows:

No.	Brand Name	Accuracy	Ambient Temperature
1	HANACO	±5%	10℃~40℃
2	MDK	±5%	10℃~40℃
3	Terumo	±5%	10℃~40℃

Consumables should be used in accordance with the IFU, and the following points should be noted:

— infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and

— physical hazards such as from sharps.

12 Technical specification

1) The methods of controlling bolus volume before occlusion is removed: control bolus volume by making the stepper motor to rotate in the opposite direction to reduce the pressure in infusion line after it has been occluded.

2) Storage time for the electronic memory after power off: 100 years.

3) The maximum volume that may be infused under single fault conditions is 30%. Note: Accuracy test under the motor error.

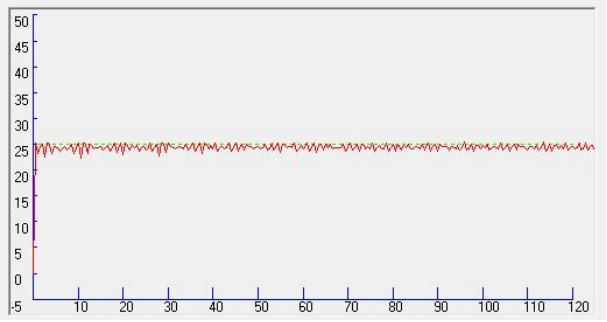
4) Unit used in device calibration: ml.

5) The methods to avoid overflow or underflow due to device failure: to prevent overflow or underflow by using drop counting sensor to measure flow rate.

6) The sensitivity of the air in line sensor: the minimum air bubble size that can be detected is 50uL.

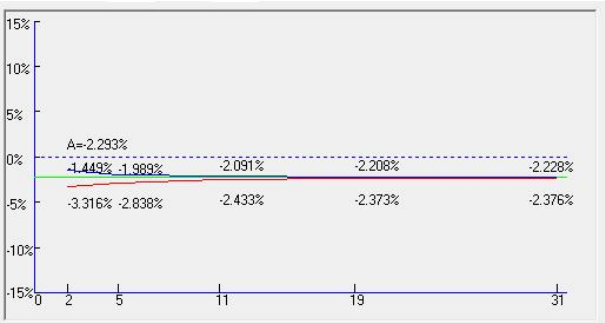
7) Medium flow rate performance curve

a.The waveform for medium flow rate during the first two hours of operation.



In the above figure, the dashed line shows the set flow rate (25ml/h in this figure), and the solid line is the continuous connection line for the average flow rate during a sampling period.

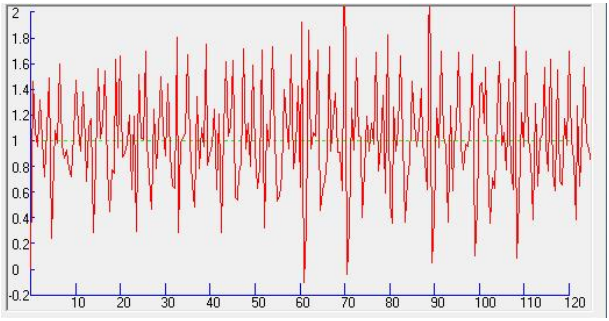
b.The trumpet curve for medium flow rate during the second hour of operation.



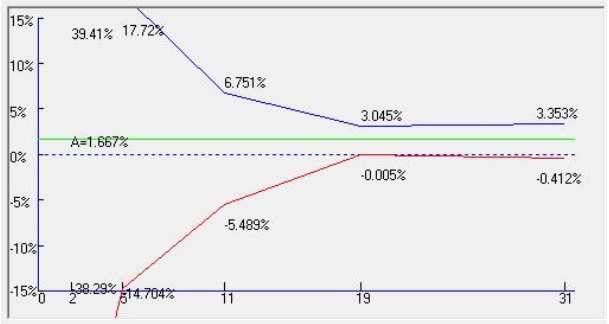
The dashed line is the final value that the error of the device is eventually converging to. The solid line above the dashed line is the maximum positive deviation during the second hour of operation. The solid line below the dashed line is the maximum negative deviation during the second hour of operation.

8) minimum flow rate performance curve

a. The waveform for minimum flow rate during the first two hours of operation.

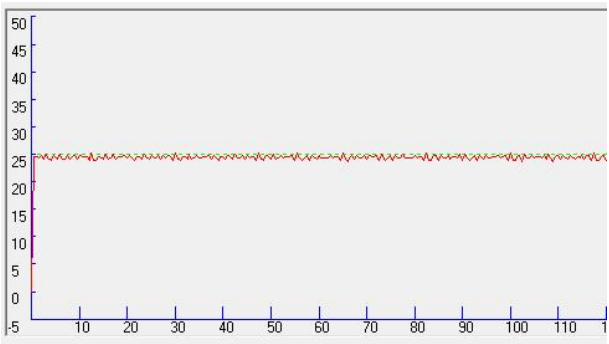


b.The trumpet curve for minimum flow rate during the second hour of operation.



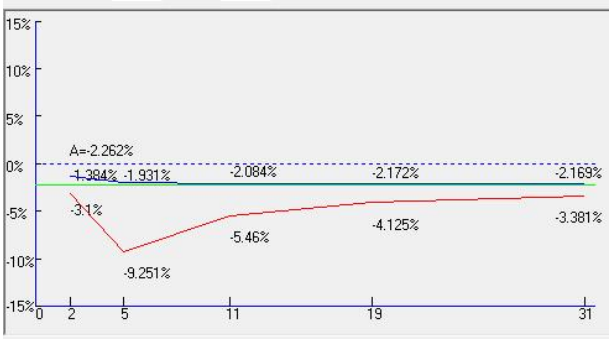
9) medium flow rate and back pressure +13.3kPa performance curve

a. The waveform for medium flow rate and at back pressure of +13.3kPa during the first two hours of operation.



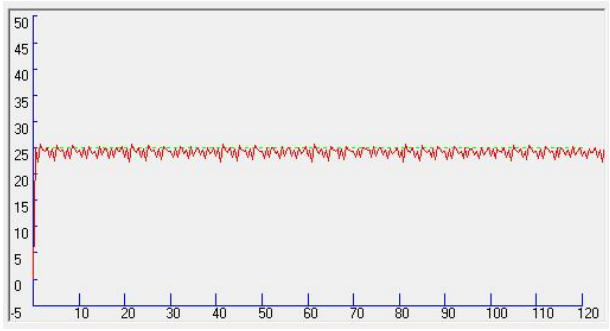
b.The trumpet curve for medium flow rate and at back pressure of

+13.3kPa during the second hour of operation.

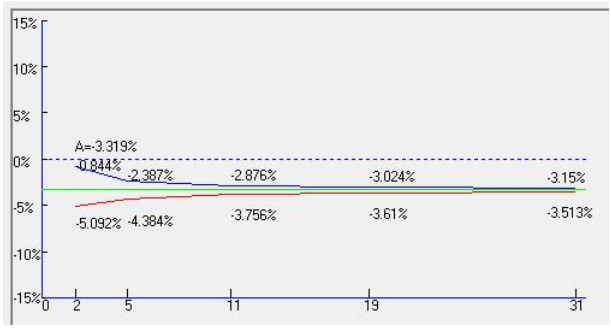


10) medium flow rate and back pressure performance curve

a. The waveform for medium flow rate and at back pressure of -13.3kPa during the first two hours of operation.

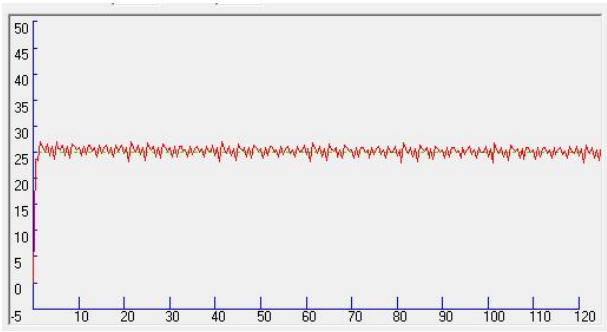


b.The trumpet curve for medium flow rate and at back pressure of -13.3kPa during the second hour of operation.

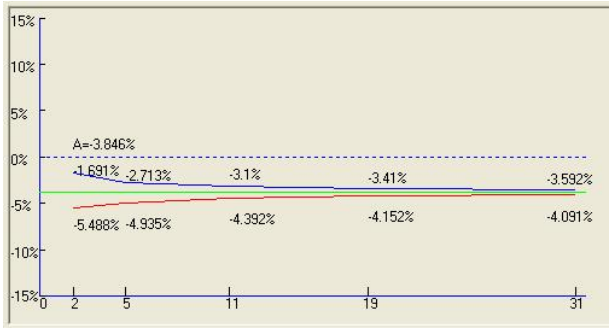


11) medium flow rate and below distance 0.5 meter performance curve

a. The waveform for medium flow rate and the supply container below the pump mechanism at a distance of 0.5m during the first two hours of operation.



b.The trumpet curve for medium flow rate and the supply container below the pump mechanism at a distance of 0.5m during the second hour of operation.



13 Use and maintenance of internal battery

MI20 has an internal rechargeable Lithium battery with the following specification: DF18650/11.1V-2200mAH. When connected to mains power, the internal battery charging management module inside the pump will control the charging process of the Lithium battery

automatically. When disconnected from the mains power, the system will automatically switch to the internal battery as its power source.

When fully charged, the internal battery can support the pump to operate continuously for at least 7 hours with an intermediate infusion speed. And for 6 hours with a maximum infusion speed.

The daily maintenance for battery:

1) When the pump is not used for a long period of time, it is recommended to charge the internal battery every 3 months or remove the battery, in order to save the battery life.

2) Contact MDKMed customer service immediately if the internal battery cannot be charged normally or cannot work normally. Do not tamper with the battery. For the medical agencies with the ability to repair a device, MDKMed will provide the necessary technical documents after giving the related personnel from these agencies the proper training. Then a device can be disassembled and the battery can be changed by these agencies on their own.

MI20 is installed with one internal single use button battery. The battery life is larger than 8 years. When the battery is expired, the device should be disposed according to the instruction in section 16, "Wast Disposal".

14 Product service and maintenance

Inspection before use:

1） Check if there are foreign objects inside the power outlet (such as drug solution residue). Confirm that the system has passed the self-test after the pump is powered on.

2） Select the correct type for infusion set. Check the battery level. Charge the battery if necessary.

During operation:

1） To prevent giving an incorrect dosage of drug solution to patient, disconnect the pump from patient before changing a device,

2） Make sure the infusion line is not kinked. Insert the needle to the vein on a patient’s body part that is not likely to be squeezed or pressed.

3） To prevent the spilled drug solution on pump surface from entering the device, wipe it dry immediately.

4） When the time of low battery alarm is short,stop using and contact the dealer or MDKMed for the battery replacement.

Storage and daily maintenance:

1） To keep the device clean, wipe clean it at least once a month, which can prevent the corrosion caused by the drug solution and avoid the mobility of the mechanical parts to be affected by the dried-up solution.

2）Use a clean and dampened cloth or an alcohol pad to wipe clean the device. Take caution to avoid any liquid from entering the device.

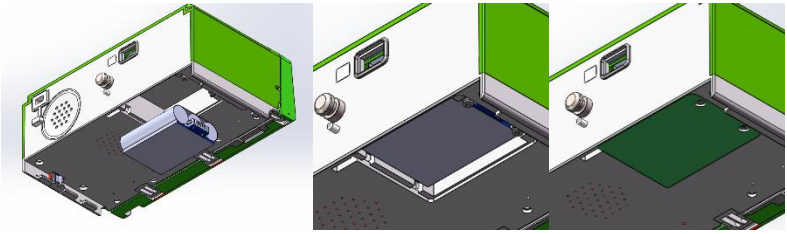
3) Keep the surface of the air bubble sensor probe clean. A dirty probe will reduce the sensor’s sensitivity in air bubble detection or cause false alarm. Take caution when cleaning the probe to avoid damaging it.

4） Check the time of low battery alarm at least once every month,when the device under the non-clinical use status, it should be more than 30mints since the "low battery" alarm.

The manufacture will provide the schematics, parts list and other documents to facilitate the maintenance.

15 Installation of the removable battery

Connect the battery to device before use, as shown in Figure 15-1.



(a) (b) (c)

Figure 15-1 Install the internal battery.

16 Waste disposal

16.1 Battery

Follow the local laws and regulations to dispose the expired old battery.

16.2 Infusion set

Follow the local laws and regulations to dispose the infusion set after use.

16.3 MI20 Infusion pump

The product lifetime of this device is 8 years. Dispose the device after its lifetime has expired. The disposed infusion pump can be returned to MDKMed or its distributors to be recycled properly.

17 Electromagnetic Compatibility

Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC

EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission

The INFUSION PUMP MI20 is intended for use in the electromagnetic environment specified below. The customer or the user of the INFUSION PUMP MI20 should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The INFUSION PUMP MI20 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The MI20 infusion pump is suitable for use in household and all facilities directly connected with the public low-voltage power supply network of household.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The INFUSION PUMP MI20 is intended for use in the electromagnetic environment specified below. The customer or the user of INFUSION PUMP MI20 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8kV ontact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic

			material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. Make sure there is not impulse interference >1kV in use environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the INFUSION PUMP MI20 requires continued operation during power mains interruptions, it is recommended that the INFUSION PUMP MI20 be powered from an uninterruptible power supply or a battery.
Power	3A/m	3A/m	If image distortion occurs, it

frequency (50Hz) magnetic field IEC 61000-4-8			may be necessary to position the INFUSION PUMP MI20 further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The INFUSION PUMP MI20 is intended for use in the electromagnetic environment specified below. The customer or the user of INFUSION PUMP MI20 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz 3 V/m	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the P15G including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$

Radiated RF IEC 61000-4-3	80 MHz to 2.5 GHz		$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance 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: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the INFUSION PUMP MI20 is used exceeds the applicable RF compliance level above, the INFUSION PUMP MI20 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the INFUSION PUMP MI20.

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

Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the INFUSION PUMP MI20

The INFUSION PUMP MI20 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the INFUSION PUMP MI20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MI20 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.117**	**0.117**	**0.234**
0.1	**0.370**	**0.370**	**0.740**
1	**1.170**	**1.170**	**2.340**
10	**3.700**	**3.700**	**7.400**
100	**11.7**	**11.7**	**23.4**

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.

18 Antistatic Precautions

The MI20 infusion pump has been tested and conforms to the medical equipment standard YY0505-2012.

When used by an operator, the pump should not be contacted with connector pins that have electrostatic discharge warning signs. Unless electrostatic discharge prevention measures are taken, the pump should not be contacted with these connectors.

The operator should be aware of the following things:

a)Unless appropriate preventive measures have already been taken, do not use hand or hand tool to touch connectors with electrostatic discharge warning signs. Preventive measures include: 1 Methods for preventing electrostatic charge accumulation (such as air conditioning, air humidification, floor conductive coating, synthetic clothing);2 Discharge electrostatic charge from human body to the framework of equipment , or to the ground, or to a large piece of metal; 3 Use a wrist band to connect human body to the equipment or to the ground.

b)All staffs who may be in contact with connectors with electrostatic discharge warning signs should receive training, including all clinical/biomedical engineering and healthcare personnel.

c)Electrostatic discharge training should include the introduction of static charges in the theory of physics, the voltage that may be produced in normal practice, and the damage to the electronic components caused by the electrostatic charge from an operator. Further, methods for how to prevent electrostatic charge accumulation should be provided, as well as how and why to discharge the electrostatic from human body to the framework of equipment or to the ground, and how to use wrist band to connect someone's body to the equipment or to the ground.

19 Packaging and Accessories

The recommended accessories to be used with the device (single unit):

Accessory Name	Quantity	Units
User's Manual	1	Book
DC Adapter	1	Set
Fixation Clamp	1	PCs
Refer to the packing slip for all other accessories.		

Legal manufacture: MDKMed Medical Technology Co., Ltd.

Address: 502A, Building 7, No. 22, Xinyan Road, Donghu Street, Linping District,Hangzhou City, Zhejiang Province, P. R China 311323

After sale service: MDKMed Medical Technology Co., Ltd.

Tel: 400-880-8392

Email: sales@graseby.com

Web: http://www.graseby.com

European Authorized Representative:

MedNet EC-REP C IIb GmbH

Borkstrasse 10

48163 Münster, Germany