CE 0123

MS 31 Series Syringe Pump User’s Manual

Version：1.0

2018.10

CONTENTS

1 Symbols, graphics and warnings

1.1 Symbol and Graphic Definition

Caution! Read included files.

Type CF Device

RoHS

Compliant to ROHS standards.

Date of Manufacturing

Serial Number

Manufacturer

Power On/Power Of

Start/Stop

Bolus

Mute alarm sound

IPX2

Ingress Protection Grade 2

AC Power

Classified collection, uncontrolled discard not allowed

Class II device

Be cautious with your hands when injection comes to the end

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.

- The MS 31 syringe pump is intended for intravenous therapy.
- Only trained and qualified healthcare givers are allowed to operate this pump. This user manual must be read carefully before using the pump.
- To avoid fire or explosion, this infusion pump should not be operated in an environment where flammable materials are stored.
- To ensure safe operation of this pump, do not stack the pump with other equipment that has electromagnetic emission.
- This pump is an IPX2 type device. Do not immerse pump into liquid.
- Operator must follow Section 10 Parameters Setting for Syringe Set to select the correct type for syringe and use the recommended syringes that have been calibrated.
- Using other syringe that are not among the list of recommended syringes will result in greater error in infusion accuracy and eventually lead to operation failures.
- While being used, the height of the infusion set can neither be placed lower or higher than 1 meter from the patient's heart.
- Do not use the same syringe on more than one machine.
- Do not press the buttons with finger nails or other sharp objects.
- 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.
- The parts and accessories for this device must be MDK recommended or approved.
- If sustained a severe impact or drop, the device should not be used until it has been checked by trained technical staff.
- According to 14 PRODUCT SERVICE AND MAINTENANCE, user can wipe the shell of pump. And battery replacement is allowed. Other parts shouldn't be maintain or repaired.
- 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.

- 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.

1.3 Warning

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

- Fix the pump in a level and secured position before and during operation.
- Operator must ensure there is no free-flow once the syringe is loaded. If free-flow is observed, the operator must stop the therapy and contact customer service.
- Pump operator must strictly follow doctor's prescriptions to set the infusion parameters, otherwise patient's health may be harmed.
- After setting injection parameters, operator must make sure that the infusion set is correctly installed on the pump before the pump is started.
- The device will automatically stop operation if an alarm is triggered. After the alarm condition is cleared, press 

to continue the therapy.
- 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 Attention

- Pump or accessories may not be usable if their lifetime for use has expired (the lifetime for use is 5 years). Contact MDK to upgrade to new products.

- Please check the voltage of the internal battery before using it for pump operation.
- Please do not connect any other device to the USB port other than the included DC adapter shipped with the pump.
- 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.
- Infusion sets are the applied part of the device.
- A statement that mobile RF communications equipment can effect medical electrical equipment.

2 Terminology and Definition

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 5ml/h.

Minimum Rate: A flow of 1ml/h.

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 syringe pump to meet its designed high accuracy, calibration and proper parametric compensation have to be done on the syringes. Calibration has to be performed only by trained professionals.

VTBI: Volume to be infused.

3 Introductions and Scopes

3.1 Introduction

MS31 syringe pump is a smart high-accuracy infusion device. It is consisted of a control system based on an ARM Cortex microcontroller, a pumping actuation system, a monitoring system, an alarm system, an input interface and a display.

The operation of manual injection of drug solution is lacking of consistency in flow rate, nor it has functions like occlusion alarm or injection 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 drug injection.

Users will gain the following 4 benefits in using the MS 31 pump:

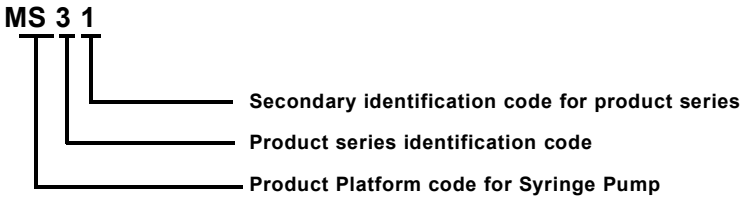
1. Ensured accuracy: The drug concentration in patient's blood has to be within a certain range when medication treatment is given. If the upper limit of drug concentration is exceeded, the patient's organs, such as liver, will be harmed. But if the concentration is too low, the medication treatment will not be effective. Infusion accuracy will be ensured when using MS 31 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 2100ml/h. Unless a syringe pump is to be used, otherwise the flow rate requirements cannot be met by using the gravity or manual injection methods.
3. Providing enough pressure: The necessary pressure for infusion cannot be reached by manual injection, while the injection pressure is controllable by using a syringe pump. Syringe pump works well in both vein and arterial intervention treatments.
4. Automatic monitoring: Light and sound alarms are available when injection 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: By controlling the flow rate, MS 31 syringe pump is intended to be used for Intravenous therapy at clinical service facilities on adults and pediatrics. Light and sound alarms help the users use the pumps properly.

Contraindication: NO.

3.3 Model Naming Convention



4 Main Features

- **A wide range of syringes are supported:** Automatic syringe size identification and 6 different models of syringes are supported: 2ml, 5ml, 10ml, 20ml, 30ml, and 50/60ml.
- **High accurate:** When the recommended syringes are used the accuracies for both flow rate and volume are within 2%.
- **High flow rate:** Injection flow rate can be adjusted from 0.1ml/h to 2100ml/h in a continuous manner, which makes MS 31 capable of meeting various flow rate requirements in different injection therapy cases.
- **Portable:** As thin as 8 cm, and as light as 1.5 kg.
- **Stackable:** MS 31 pump is stackable. It can also be stacked with MI20 infusion pump for operation. The miniature design of MS 31 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 injection unit.
- **Easy to operate:** Operator can use the touch screen on MS 31 to set parameters, which will still function with gloves on. A key pad is also available to ensure usability in different usage scenarios.
- **Fast installation:** Patented QuikMount system, which requires only one click to complete the pump installation.
- **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.

- **High battery capacity:** The rechargeable built-in high-capacity Lithium battery can support normal operation for 7 hours, which is conveniently helpful during patient transport or power outage.
- **Highly secure STM32 microcontroller:** a mutual monitoring dual-CPU architecture design. Ensure the control to the motor and sensor.
- **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.
- **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 Specification, Essential Performance and Main Features

5.1 Specification

Dimension	270mm×140mm×80mm(W x D x H)
Weight	1.5 Kg
Power Adaptor rate voltage and frequency	A.C. input 100V-240V~ 50/60Hz 0.7-0.35A, D.C. output 15V-1.66A max
Syringe Pump Power Supply	DC 15V
Power Consumption	<55VA
Syringe Requirement	Refer to “Section 11 Notes on Disposable Syringes”
Maximum Flow Rate	2100 (ml/h)

5.2**Main Performance**

Rate Range	0.01-2100ml/h, step size 0.01ml/h. 2ml syringe: 0.01-100ml/h 5ml syringe: 0.01-150ml/h 10ml syringe: 0.01-400ml/h 20ml syringe: 0.01-600ml/h 30ml syringe: 0.01-1000ml/h； 50/60ml syringe: 0.01-2100ml/h；
Rate Accuracy (Essential Performance)	±2% Note: One pump and twenty syringes for the accuracy test.
Volume Range	0.01~9999.99ml，step size 0.01ml
Volume Accuracy (Essential Performance)	±2% Note: One pump and twenty syringes for the accuracy test.
High Rate	1ml/h～2100ml/h continuously adjustable Maximum Flow Rate Limitation: 2ml syringe: 100ml/h； 5ml syringe:150ml/h； 10ml syringe: 400ml/h； 20ml syringe: 600ml/h； 30ml syringe: 1000ml/h； 50/60ml syringe: 2100ml/h；
Supported Syringe Size	2ml, 5ml, 10ml, 20ml, 30ml and 50/60ml
Maximum infusion pressure	140kPa
Occlusion alarm threshold (Pressure) (Essential Performance)	Maximum 130 kPa, Minimum 26 Kpa. 9 adjustable setting. Accuracy ±20kPa

Time to activate the occlusion alarm; max bolus (Essential Performance)	Under Minimum rate and maximum occlusion alarm threshold, the alarm trigger time: 3h30 m Under Minimum rate and minimum occlusion alarm threshold, the alarm trigger time: 1h Under intermediate rate and maximum occlusion alarm threshold, the alarm trigger time and bolus volume: 45m, 2mL Under intermediate rate and minimum occlusion alarm threshold, the alarm trigger time: 15m The minimum selectable rate is the minimum flow rate. It equals to 1 mL/h. The time to activate the occlusion alarm is the same as minimum flow rate. (Tested with KANGJIN(KJ) syringes. The occlusion is introduced at the end of the syringe. Measure environment is 20 ℃ ,and patient line is 1 meter.)
KVO Rate	3mL for Rate ⩾ 10ml/h 1mL for 1ml/h ≤ Rate < 10ml/h KVO Rate = Rate for Rate < 1ml/h
Alarm sound recover time for recoverable alarm	1min50s～2min
Overtime alarm suspension time	1min50s～2min
High priority alarm (Essential Performance)	Syringe size error, Plunger Error, Occlusion Alarm, VTBI complete alarm, out of battery alarm, battery/mains power double disconnect alarm, malfunction alarm
Classification	Class II, CF continuously volume syringe pump with internal power supply

	IPX2
Environmental Requirement	Storage Temperature: -30℃~＋55℃ Operation Temperature: 5℃~＋40℃ Storage relative humidity: ≤75%； Operating relative humidity: 20%～90%； Barometric pressure range: 80.0kPa～106.0kPa;
Software Version	V1.0.0
Product lifetime	5 years

5.2 Main and Frequently used Features

- Automatic identification of syringe size;
- Set injection flow rate, set VTBI and display real-time data;
- Display the completed volume;
- Purge/Bolus;
- Alarms;
- Automatically change the flow rate to KVO rate after the VTBI complete alarm is activated;
- Temporary mute for alarm sound and timer for recovering alarm sound;
- Display the TVI;
- Clear the TVI data;
- Various brands of syringes are supported;
- Internal battery
- External DC adapter;
- Wi-Fi connectivity.

6 Product Structure and Operation Interface

6.1 Main Components

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

The font view and back view are illustrated in Figure 6-1-1 and

Figure 6-1-2.

Descriptions for components

1	Charging Indicator	2	External Power Indicator	3	Working Indicator
4	Touch Screen	5	Keypad	6	Plunger
7	Syringe Clamp	8	Syringe Push Handle	9	Foot
10	Battery Compartment Cover	11	Power Supply Port	12	Fixation Pole
13	Positioning Pin	14	Clamping Port for Stacking		

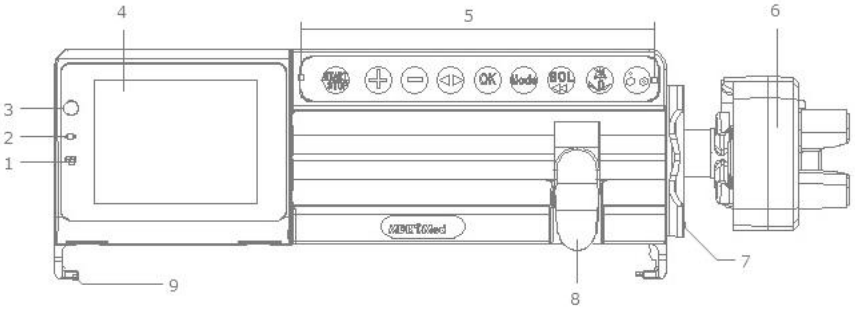


Figure 6-1-1 Front View

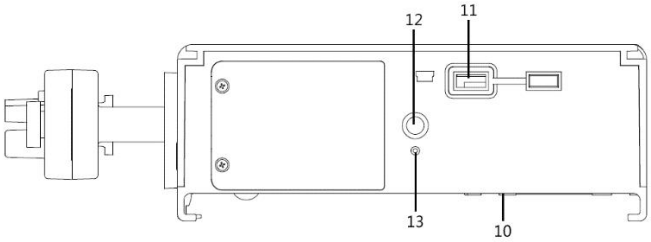


Figure 6-1-2 Back View

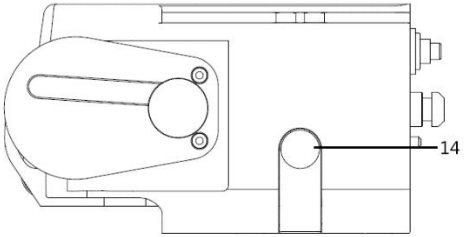


Figure 6-1-3 Side View

6.2 Operation Interface

The display interface is shown in Figure 6-2. The keypad interface is shown in Figure 6-4.

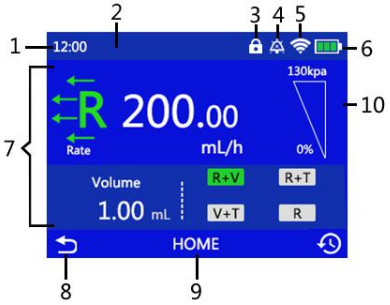


Figure 6-2 Display Screen

Display Component：

1	Time	2	Status Indication	3	Mute Icon
4	Screen Lock Icon	5	WIFI Icon	6	Internal Power Status
7	Parameters Setting Area	8	Return to Previous Menu	9	Return to Home Menu

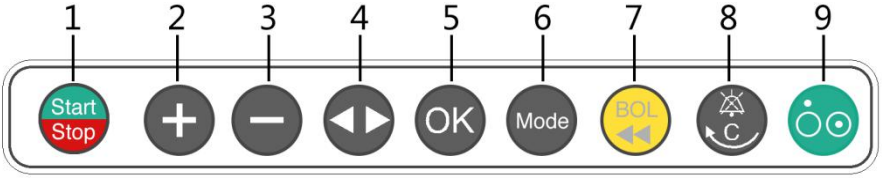


Figure 6-4 Keypad Interface

Key Definition

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

7 Operation Instruction

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Attention

All syringes must follow Section 10 Syringe Pump Parameter Set Up before they can be used on this device for the first time.

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Operation Instructions

Install syringe pump -> Power up -> Safety self-test -> Install syringe -> Set up parameter -> Clear air bubble by purge -> Start therapy -> Complete therapy -> Uninstall accessory -> Power off.

Make sure the installed syringe is consistent with the syringe setting on the device.

7.1 Set up Syringe Pump

7.1.1 Mount the 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 Install the Syringe Pump

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

upright position.

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

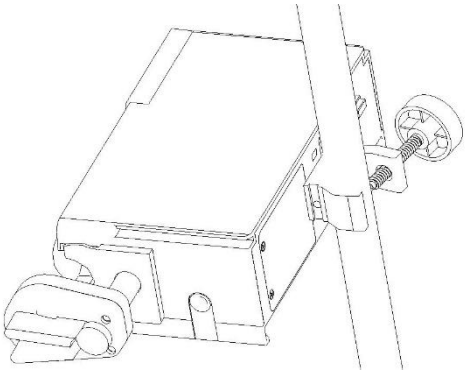

Figure 7-1-1 Install the syringe pump

7.1.3 Stack the pump

Multiple MS 31 pumps can be used when stacked together. Press down the release button to unstack a pump from a stack.

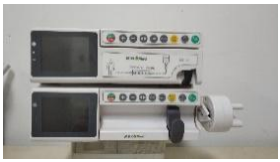

Figure 7-1-2 Stack the Syringe Pump

7.2 Power on and Self Safety 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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Caution

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 Device Self Safety 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 “Deeh, deeh” 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 MDK customer service immediately.

7.3 Install Syringe

Open the pump door; squeeze and hold the finger grips on the plunger holder to open the claws, pull the plunger out to an appropriate position and release the finger grips.

Pull the syringe holder out and turn it in either direction for 90° to horizontal position, place the syringe barrel flange in the slot between the plunger holder and the claws, pull the syringe holder out again, turn it back for 90° to upright position and release it to clamp the syringe tight; straighten the syringe extension line, place it inside the hook behind the pump door to prevent the extension line from being pressed, then close the pump door.

Squeeze and hold the finger grips on the plunger holder, slide it to the left until it reaches the plunger end. Release the finger grips. Make sure that the plunger claws are securing the plunger in place and the finger grip returns to its original position.

If there is bubble in the syringe pump set, press the button “ 

”

twice within 1 second. The device will enter the purge mode and clear the air bubble. Press “ 

” to exit the purge mode.

7.4 Set Parameters

7.4.1 Select Syringe

Power on the device and install the syringe, the brand and model of syringe will be displayed in the setup screen.

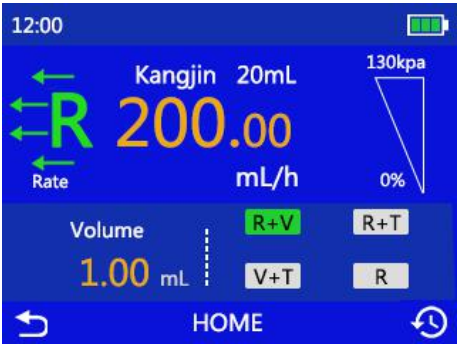

Figure 7-4-1 Identify syringe model

Please check to make sure the brand displayed is correct. If the brand needs to be changed, select the correct brand in the Home – Settings – Brand, then go back to the HOME page. No selection or modification is needed if the syringe set used in current use is the same as the last time.

Figure 7-4-2 Select Syringe

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Caution

When syringes from the same brand but different lots are used, calibration of the syringe is recommended, which is described in Section 10.2 Syringe Calibration. It is possible that the syringes from the same brand but different lots have different characteristics, which will affect their injection accuracy if they are not calibrated before use.

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7.4.2 Select Infusion Mode

MS 31 supports 6 injection modes in total, including R+V, R+T, V+T, R, Drug Library and Body Weight.

Press Home-Select Infusion Mode

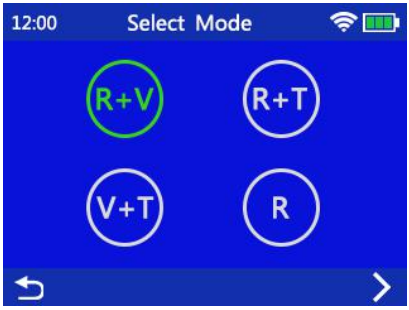

Figure 7-4-2-1 Select Infusion Mode

Once the selected infusion mode is entered, transitions between modes can be done by clicking on the R+V、R+T、V+T、R buttons listed in the parameters setting area.

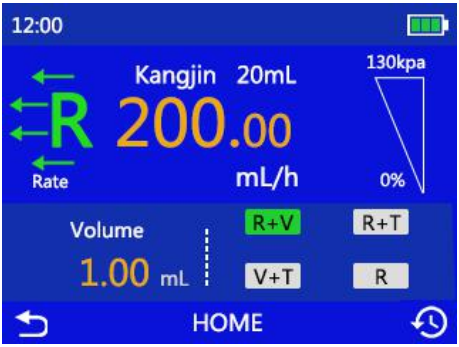

Figure 7-4-2-2 Switch Injection Mode

7.4.3 Set 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.

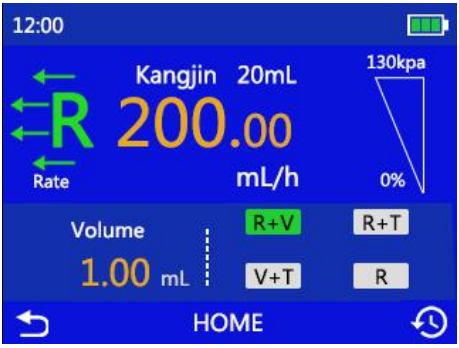

Figure 7-4-3-1 Set the Volume

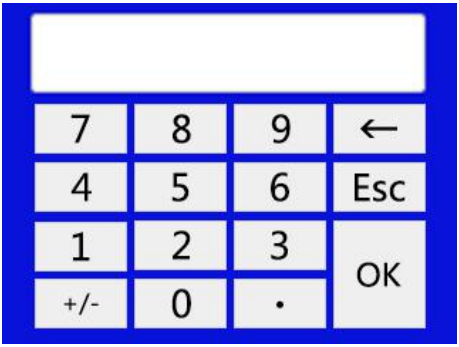

Figure 7-4-3-2 Input the number with on-screen key board

7.4.4 Set up Rate

Same as 7.3.3.

7.4.5 Set up Time

Same as 7.3.3.

Figure 7-4-5 Set up injection time.

7.4.6 Set Purge Parameters

Click on HOME-Settings-Purge Setting to set speed and volume for purge.

Figure 7-4-6 Purge setting.

7.4.7 Set up Occlusion Alarm Threshold

Enter the occlusion pressure setting screen by pressing the upside-down triangle shape icon on touch screen. The occlusion pressure has 9 levels, with the maximum pressure being 130kPa±30kPa and minimum pressure being 26 kPa±20kPa. 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.

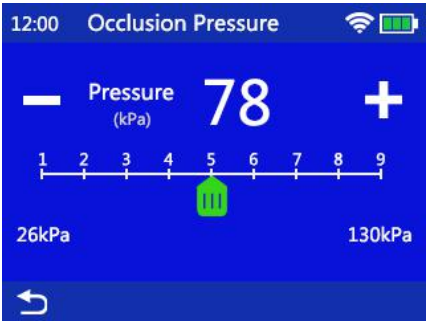

Figure 7-4-7 Set occlusion pressure level.

7.5 Start Injection

7.5.1 Automatic Purge and Start Infusion

After the correct installation of infusion set is confirmed, press

the 

button, MS 31 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 syringe 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.

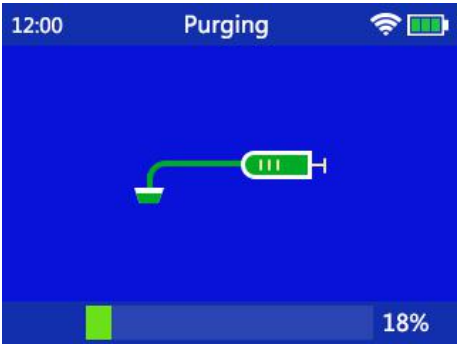

Figure 7-5-2 Purging in progress

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 bubble in line after the syringe set is installed, or use the roller clamp on the syringe set to purge the air in line before installing the syringe set onto pump.

After the syringe 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 Injection 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 Injection in progress.

7.6 Stop Therapy and Clear Alarm

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

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Caution

If the Start Stop is pressed to stop injection, but the C is not pressed to reset the accumulated volume back to zero, then if the Start Stop is pressed again the injection task will resume from where it left last time.

==========

Injection will be stopped if the Start Stop button is pressed when injection operation is in progress. If no injection parameters are changed during the stop, the injection will pick up from where it left last time and continue to run when the Start Stop is pressed again. If any injection parameter is modified, such as rate, volume or time, then a

new injection task is established. When the 

is pressed down again, injection 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

Based on the different working mode of the device, there will be three different responses When the key 

is pressed.

- Automatic purge mode: in the injection mode parameter setting page, double click on 

will make the injection 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 alarm function enable in automatic purge mode as injection in progress.

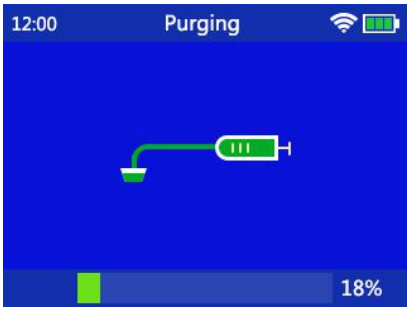


Figure 7-8-1 Purge in progress

- Automatic bolus mode: when injection 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 injection operation, and the bolus volume will be included in the accumulated injection volume. Under the injection 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 injection operation is in progress, bolus speed and bolus volume setting page will be entered by clicking on 

button once. Set the bolus parameters and continuously press down the 

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 

button is released. Pump will return to where it left before manual bolus was entered and continue to run injection. The manual bolus volume is included in the accumulated injection volume.

Figure 7-8-2 Bolus in progress

Figure 7-8-3 Bolus in progress

7.9 Infusion Complete

When the injected volume (the incremental of accumulated injection volume) has reached the set value, the injection 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 VTBI infused alarm and to exit the KVO injection state.

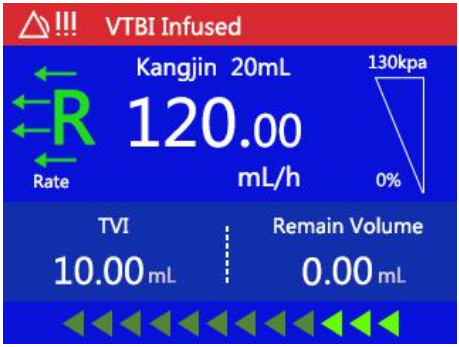


Figure 7-9 Infusion Complete

The screen will show information such as the accumulated injection volume and speed. Press and hold the button for 3 seconds will clear the accumulated injection volume. Click on the “Back” button on the lower left corner to go back to the injection parameters setting page, then a new round of injection operation can be initiated.

==========

Caution

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

==========

7.10 Automatic volume accumulation and Reset

When pump is at stop, press and hold the button for 3 seconds to clear the accumulated infusion volume.

The accumulated injection volume shows the total injected drug solution volume received by a patient. For example: Drug A is given to patient during the first injection 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 injected into patient. And when Drug B of 2ml is given to patient without clearing the accumulated injection volume. Then the pump will annunciate preset volume complete alarm when the accumulated injection volume reaches 3ml, meaning 2ml of Drug B has been injected 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, the device will

be powered off.

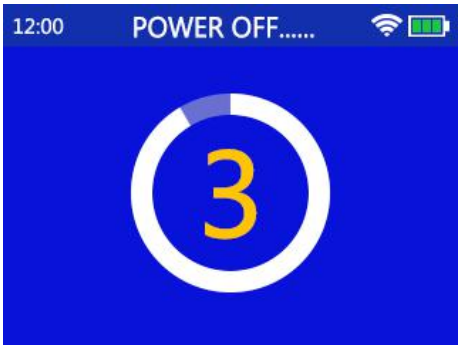


Figure 7-12 Power off count down.

==========

Caution

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

==========

7.13 Uninstall Syringe 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

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 injection under the body weight mode.

Figure 7-14 -1 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 = dosage (mg)/solution volume (ml)

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

7.15 Drug Library Set up

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 “>” (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 injection, and total volume shows the solution volume during last injection. Click on the 

button, the pump will run injection under the drug library mode, while the drug name is shown on top of the injection speed number during

operation.

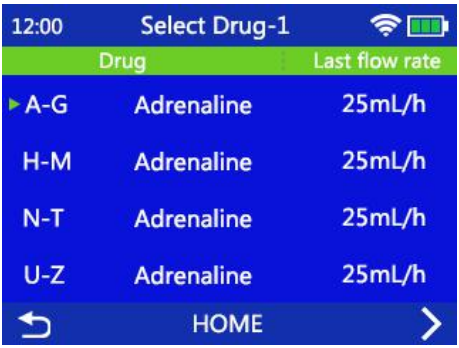


Figure 7-15 Drug Library Set up

7.16 Drug Library

Both MS 31 and MI20 pumps can be installed and operated on the MX infusion work station made by the MDK, which will enable them to work in corporation with the work station to realize advanced features such as relayed injection/infusion and drug library management and etc.

Inside HOME-Drug Library, the operator can perform operations like adding new drugs or setting injection 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 Log

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

Using the MX infusion work station, injection 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 Alarm Function

Alarm is activated when there is either abnormality in the injection liquid path or failure within the pump itself that will cause the device fails to carry out injection correctly. Sound and light alarms are used to draw attentions from the care givers. 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.

MS 31 alarm priority levels:

Alarm Priority	Type of Alarm Conditions
High Priority	Syringe size error, Plunger Error, Occlusion Alarm, VTBI complete alarm, out of battery alarm, battery/mains power double disconnect alarm, malfunction alarm
Low Priority	Pause over time alarm, internal battery low voltage alarm, injection 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: VTBI complete alarm, out of battery alarm, battery error alarm, occlusion alarm, syringe plunger 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.

==========

Caution:

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

==========

8.1 Syringe size mismatch alarm

Trigger conditions: When the device detects that the syringe size is not among the supported 6 sizes, an alarm will be activated and the injection will be terminated. An error message “Syringe Holder” will be displayed in the alarm indication area. The alarm can be triggered if the syringe push handle is accidently pulled out, or a nonstandard syringe is used.

Solution: When the “Syringe Holder” alarm is triggered, press Start Stop to clear the alarm. Check the syringe plunger and the size of syringe. Reinstall the syringe and continue the operation.

Alarm test: Install a 50ml syringe. Add an 2mm paper between the syringe and syringe holder. When start the syringe pump, an alarm will be activated and the injection will be terminated. An error message “Syringe Holder” will be displayed in the alarm indication area. The alarm can be triggered if the syringe push handle is accidently pulled out, or a nonstandard syringe is used.

Figure 8-1 Syringe holder error alarm.

8.2 Plunger Error Alarm

Trigger Condition: When the syringe plunger is detached from the pump plunger pressure sensor, the device will initiate an alarm and stop infusion. “Plunger Error” will be displayed in the alarm indication area.

Solution: When the plunger error alarm is triggered, press Start Stop to clear the alarm. Check the syringe plunger and the size of syringe. Reinstall the syringe and continue the operation.

Alarm test: Start the syringe pump. Squeeze and hold the finger grips on the plunger holder to open the claws, pull the plunger out. The device will

initiate an alarm and stop infusion. “Plunger Error” will be displayed in the alarm indication area. This indicates that the Plunger Error alarm is correct.

Figure 8-2 Plunger error alarm.

8.3 Occlusion Alarm

Trigger condition:

When the syringe set 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 injection. 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 syringe set line is kinked, or if the patient is pressing on the line by accident. Restart injection operation when occlusion is removed.

Alarm test: Install the syringe pump and syringe. Set the infusion

parameter and start injection. Clamp the end of patient line 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 injection. This indicates that the Occlusion alarm is correct.

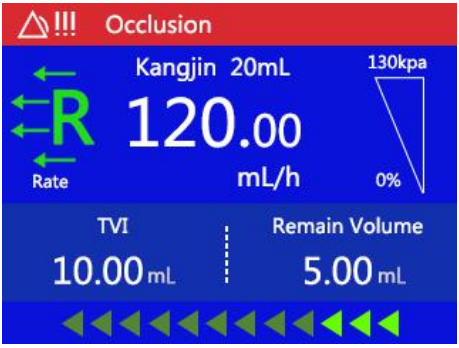


Figure 8-3 Occlusion alarm.

8.4 VTBI Complete Alarm

Trigger Condition:

When the accumulated injection volume shown in the current display window reaches the preset value, the pump will annunciate an alarm sound, stop injection 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 injection.

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 syringe pump and syringe. 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 Out of Battery Alarm

Trigger Condition:

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 injection 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 an used up battery in the syringe 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 8-5 Out of battery alarm.

8.6 Battery/Mains Power Double Disconnection Alarm

Trigger condition:

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 syringe pump and disconnect the battery. The syringe pump will initiate high-priority sound and light alarms. This indicates that the Battery/Mains Power Double Disconnection Alarm is correct.

8.7 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 Start Stop button to clear alarm sound. Check if syringe set is installed correctly. Restart injection after corrections are made. Contact the MDK 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 8-6 Motor error alarm.

8.8 Pause Overtime Alarm

Trigger Condition:

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.

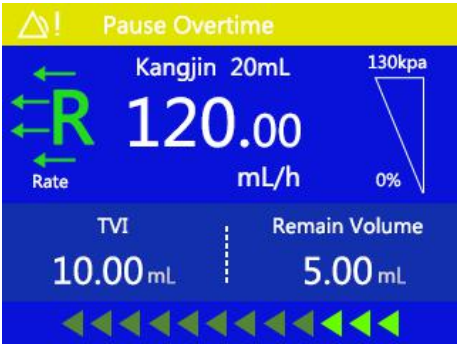


Figure 8-7 Pause overtime alarm.

8.9 Internal Battery Low Alarm

Trigger Condition:

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 injection 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 syringe 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 8-8: Low battery alarm.

8.10 Injection Near End Alarm

Trigger Condition:

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. Injection will not stop.

Solution:

Press the  button to clear alarm sound. Check remaining drug solution and the remaining time, wait for injection to complete.

Alarm test: Install the syringe pump and syringe. Set the infusion parameter and start injection. A message “Near End” will be displayed in the alarm indication area. This indicates that the Injection Near End Alarm is correct.

Figure 8-9 Injection near end alarm.

9 Setting System Parameters

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

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 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 9-3 Purge setting.

9.4 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 syringe set needs to be purged when Start Stop is pressed after all injection related parameters have been set. The icon means the purge indication page is turned off.

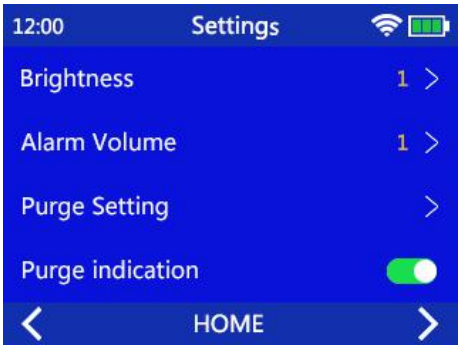


Figure 9-4 Purge indication page setting.

9.5 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 injection mode, speed, volume and time will be displayed on pump screen. When YES is pressed, the pump will go into the corresponding injection mode, load and use the parameters from last use accordingly, which will help the operator quickly start the injection task.

Figure 9-5 The reminding page for loading the parameters from last use.

9.6 WIFI

In the HOME-Settings-Wi-Fi page, operator can decide whether to turn on Wi-Fi connection. The icon means Wi-Fi connection is turned on. A symbol will appear on the upper right corner of the screen, which means Wi-Fi is on and other devices can be connected with the pump via Wi-Fi. The icon means Wi-Fi is turned off. When MI20 is used together with an MX injection work station, please read the MX's user's manual for directions on how to set up the connection between the two and how to perform relayed injection operations.

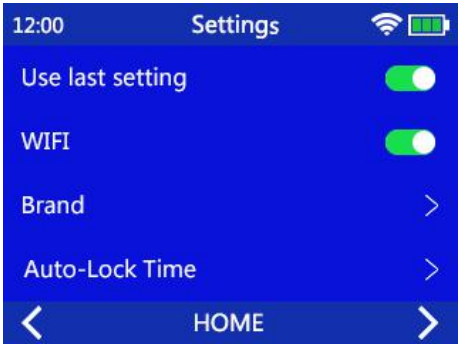


Figure 9-6 Wi-Fi on/off setting.

9.7 Syringe Type

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

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

The operation of syringe calibration can be found in Section 10.2 Syringe Calibration.

Figure 9-7 Syringe brand configuration.

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 9-8 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.

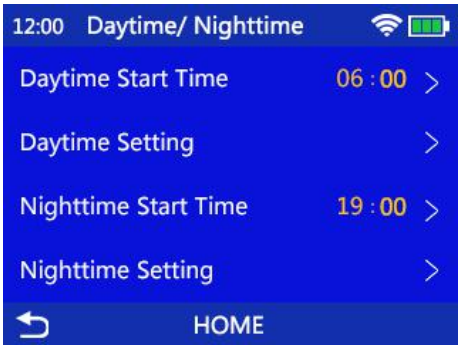


Figure 9-9 Daytime/Nighttime setting.

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 MDK for password assistance.

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

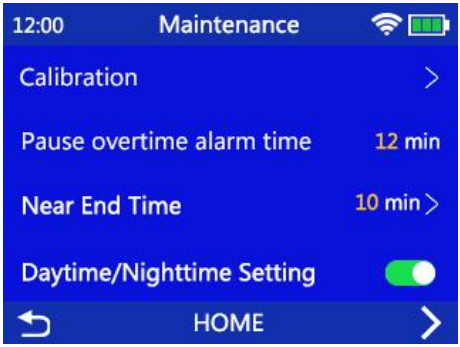


Figure 9-10 System maintenance setting.

9.11 Restore Factory Default

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 syringe set. Please take caution when decide whether or not to perform a restoration to the factory default settings.

Figure 9-11 Restore to factory settings.

10 Parameters Setting for Syringe

10.1 Enter Syringe Calibration Setup Screen

Follow Section 9 Setting System Parameters to enter the syringe set calibration setting screen. Select the brand name of the syringe set accordingly, as it is shown in the following figure.

Figure 10-1 Calibration for syringe set accuracy.

10.2 Syringe Calibration (Method One)

1) Like performing a normal injection operation procedure, install the syringe set first, 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 that needs to be calibrated. Return to the Calibration page.
3) Click on Model and select the type that needs to be calibrated. Return to the Calibration page.
4) Press the “Size Confirm” button on the touch screen and press the “Start/Stop” key on the keypad to start injection. Wait until the injection is completed.
5) Read the injected volume in the measuring tube. Press the “Real Volume” button on the touch screen and input the volume data. Click on the “BACK” button to complete the syringe calibration.

10.3 Syringe Calibration (Method Two)

1) Like performing a normal injection operation procedure, install the syringe set first, 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 that needs to be calibrated. Return to the Calibration page.
3) Click on Model and select the type that needs to be calibrated. Return to the Calibration page.
4) Use a caliper to measure the length between the 0ml mark to the mark of full scale on the syringe. For example, on a 20ml syringe, the length between 0ml to 20ml is 68.0mm, as shown in the figure below.
5) Click on the data input area next to L1 to enter the measured length and press the Back button to complete the syringe calibration.

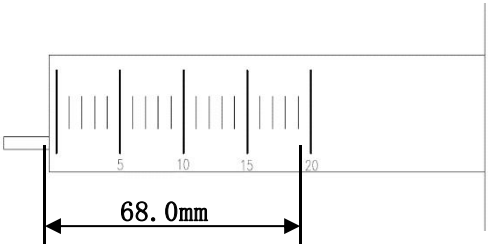


Figure 10-2 Syringe accuracy measurement

11 Notes on Disposable Syringe

The ambient temperature should be kept at least at 5℃ or above when a recommended syringe set is used. The injection accuracy will be compromised if ambient temperature is lower than 5℃.

When there is significant variation in ambient temperature, the device shall be recalibrated to ensure the accuracy. The syringe calibration procedure is described in Section 10 e Parameters Setting for Syringe.

Strictly follow the requirements described in Section 10 Parameters Setting FOR Syringe to calibrate the syringe set before use when change to a new syringe set from a different manufacturer.

The recommended syringe brand list is as follows:

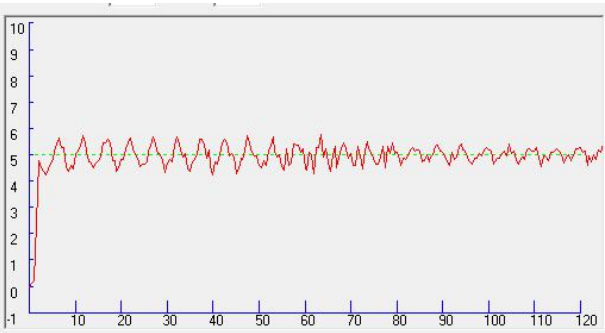
No.	Brand Name	Accuracy
1	KANGJIN	2%

12 Technical Specifications

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 syringe 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 (milliliter).

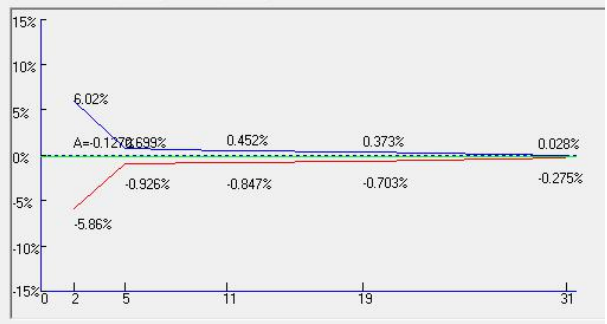
5) Medium flow rate performance curve（20mL syringe）

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 (5ml/h in this figure), and the solid line is the continuous connection line for the average flow rate during a sampling period.

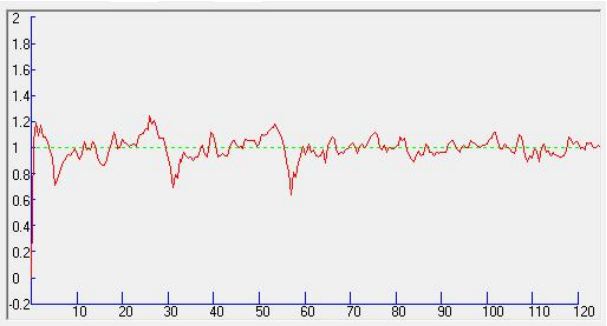
b.The trumpet curve for medium flow rate during the second hour of operation.



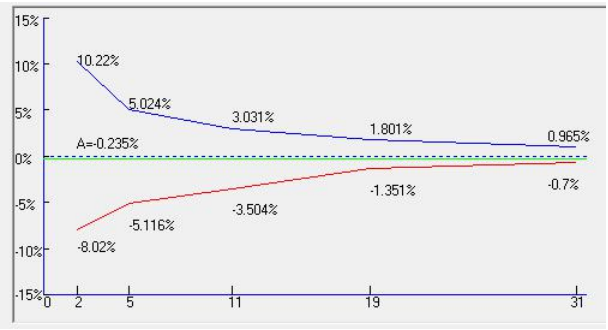
The dashed line is the final value that the error of the device is eventually converging to. The solid line above the dashed line is the maximum positive deviation during the second hour of operation. The solid line below the dashed line is the maximum negative deviation during the second hour of operation.

6) minimum flow rate performance curve（20mL syringe）

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

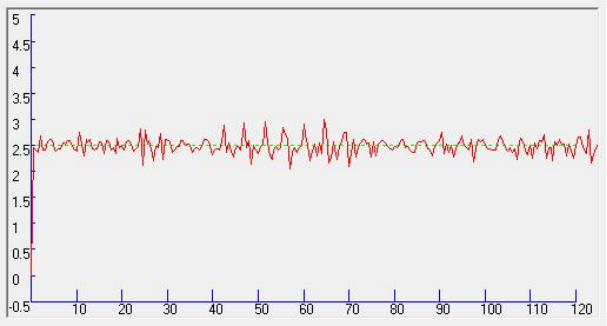


b.The trumpet curve for minimum flow rate during the second hour of operation.

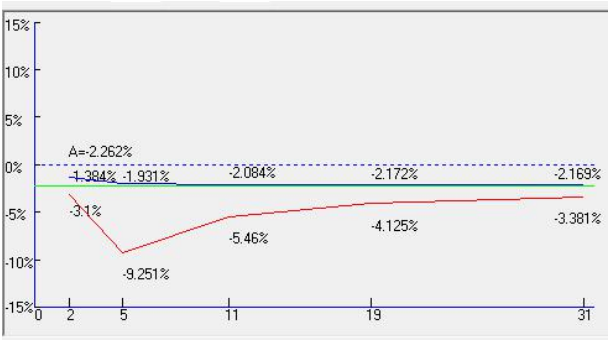


7) medium flow rate and back pressure +13.3kPa performance curve (5mL syringe)

a. The waveform for 2.5ml/h flow rate and at back pressure of +13.3kPa during the first two hours of operation.

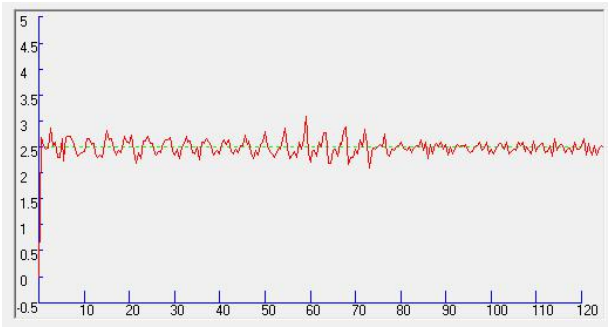


b.The trumpet curve for 2.5ml/h flow rate and at back pressure of +13.3kPa during the second hour of operation.

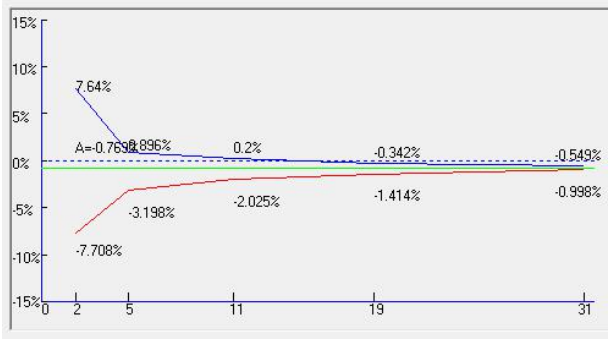


8) medium flow rate and back pressure performance curve（5mL syringe）

a. The waveform for 2.5ml/h flow rate and at back pressure of -13.3kPa during the first two hours of operation.



b.The trumpet curve for 2.5ml/h flow rate and at back pressure of -13.3kPa during the second hour of operation.



13 Use and Maintenance of Internal Battery

The MS 31 syringe pump has an internal rechargeable Lithium battery with the following specification: DF18650/2200mAh /1P3S/10.8V. 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 injection speed.

Battery Maintenance:

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 MDK 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, MDK 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.

MS 31 is installed with one internal single use button battery. The battery life is larger than 5 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 syringe set. Check the battery level.

Charge the battery if necessary.

During operation

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

4）Make sure the injection 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.

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

Storage and Cleaning

6）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.

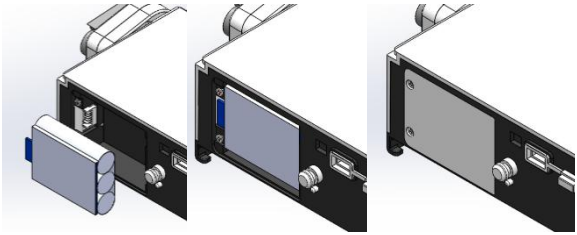
7）Use a clean and dampened cloth or an alcohol pad to wipe clean the device. Take caution to avoid any liquid from entering the device.

8）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.

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 Syringe

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

16.3 MS 31 Syringe Pump

The product lifetime of this device is 5 years. Dispose the device after its lifetime has expired. The disposed SYRINGE PUMP can be returned to MDK 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 SYRINGE PUMP MS 31 is intended for use in the electromagnetic environment specified below. The customer or the user of the SYRINGE PUMP MS 31 should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SYRINGE PUMP MS 31 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	Class A	The SYRINGE PUMP MS 31 is

CISPR 11		suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
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 SYRINGE PUMP MS 31 is intended for use in the electromagnetic environment specified below. The customer or the user of SYRINGE PUMP MS 31 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	±6 kV contact ±15 kV air	±6 kV contact ±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 SYRINGE PUMP MS 31 requires continued operation during power mains interruptions, it is recommended that the SYRINGE PUMP MS 31 be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	If image distortion occurs, it may be necessary to position the SYRINGE PUMP MS 31 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

Guidance and manufacture's declaration – electromagnetic immunity			
The SYRINGE PUMP MS 31 is intended for use in the electromagnetic environment specified below. The customer or the user of SYRINGE PUMP MS 31 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 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	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** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 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 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: 

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 SYRINGE PUMP MS 31 is used exceeds the applicable RF compliance level above, the SYRINGE PUMP MS 31 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SYRINGE PUMP MS 31.

[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 SYRINGE PUMP MS 31

The SYRINGE PUMP MS 31 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SYRINGE PUMP MS 31 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MS 31 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 Anti-static Precautions

The MS 31 syringe 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 Package and Accessories

Recommended Accessory List for MS 31 (One Unit)

Accessory Name	quantity	Unit
User’ s Manual	1	Book
DC Adapter	1	Set
fixation clamp	1	PCs
Refer to the packing slip for all other accessories.		