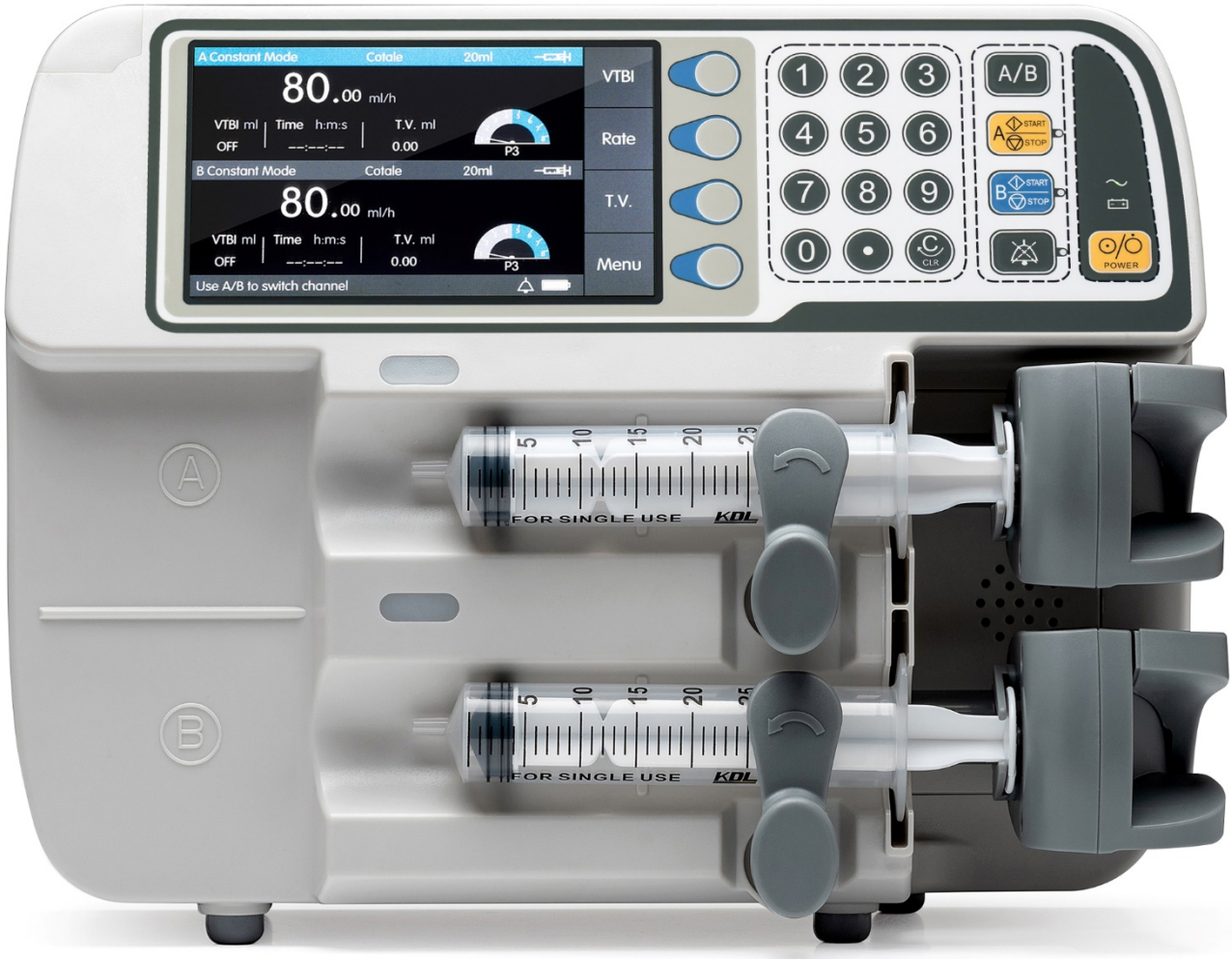
Medical Syringe Pump
Operation Manual



Manufacturing License：

Registration No.：

Standard：

Version：V1.0

Intellectual property

This Operation Manual and its relative product intellectual property belongs to our company.

Any person or organization will not allow to copy, amend or translate any content of this operation manual without the permission of our company.

Statement:

We reserves the right to interpret the operation manual.

We can revise the content of this operation manual without prior notice.

We will be not responsible for any software and equipment which is not provided by us.

We confirm the information in this Operation Manual is correct and reliable but not guarantee the content of this Manual.

We will only be responsible for the safety, reliability and performance in all the following case:

■ Installation, test, upgrade, maintenance are all done by our personnel or authorized person by us.

■ All the maintenance spare parts should be from us or accepted by us.

■ Please follow the electrical appliance national standard and the instruction of the operation manual.

■ Strictly follow the instruction of the operation manual.

Warranty and Maintenance Service

The warranty is 12 month for the device and accessories warranty is 6months, accessories is Power Cord, Battery

If the warranty period is not the same as above mentioned, please contact us. If it is not confirmed with us, please contact to your supplier.

The warranty period starts from the date of the Invoice and it is the only proof to calculate the warranty period. For your sake, please inform us the qualified installation within 30days, or the warranty date will starts from the date on the package over till 30days.

It will be free for after-sales service under warranty. It will be charged in the following case:

- Artificial damage
- Improperly operation
- Grid voltage is out of the ruled range.
- Force majeure
- Maintained by personnel not authorized by AUTOINFU.
- Use the spare parts which is not provided or confirmed by AUTOINFU
- Fault which is not caused by the device itself.

After warranty, the service will be charged. If service charge is rejected to pay or not paid on time, then we will have the right to stop servicing until the charge is paid.

Table Content

Precautions

Note:

This Operation Manual make a detailed introduction for the use, function and operation instructions. Please read the manual completely prior to using this device. Please carry out inspection and maintenance to the pump periodically according to the manual in order to avoid patient/user injury

The manual have the most complete function and features. Please pay attention to the relative model and the relative function and features. Any question, please contact us.

Please put the operation manual beside the device for easy reference.

Operator

The operation manual is only used by well-trained clinical nurse or doctors.

Others

The figures in the operation manual is only for reference. The settings or data in the figures may be not 100% same as the real ones.

Safety Precautions

(1) The device is not portable device and not used on the bed of the patient.
(2) This device is used for Intravenous infusions, not used for eternal and intragastric infusion. It can only be used by well-trained clinical nurses or doctors.
(3) Steady the syringe pump on the IV stand. Make sure the device installed steady before use.
(4) Please use three-plug socket and make sure the connection well and don't touch the socket by wet hands.
(5) It is not allowed to use voltage other than that specified on the product label, or else it might cause damage or even fire.
(6) Please check the device and the accessories completely before use to make sure the normal safe working.
(7) Please don't reply on the device alarm totally and pay attention to the remaining volume or any occlusion alarm during injection.
(8) Set the alarm value based on the patient's condition and keep a close eye on the patient rather than reply on the alarm only.
(9) Stop using the device when alarming.
(10) When there is any abnormal case, please stop using the device as priority measures.
(11) It may lead to work improperly under hyperbaric environment like hyperbaric oxygen ation.
(12) It may be dangerous if installing other infusion control device in the same injection line.
(13) Don't connect other brand infusion system or other brand accessories, or it may be dangerous.
(14) Keep the IV line smooth, folded IV line will lead to occlusion and malfunction or other potential accident, such as under flow.
(15) Use the device within 120cm around the patient's heart.
(16) Do not operate this device in environments where there are gas mixtures of flammable anesthetic, oxygen and oxidize ammonia, etc.
(17) Do not operate this device in environments where there is strong sun light, cold and hot wind and dusty.
(18) Microwave will influence the function of the device, the device near the syringe pump must meet the standard of EMC. Mobile phone, X-ray or MRI device will be the cause of malfunction due to its high frequency radiation.
(19) The device must be operated by medical professional staff, such as doctors, nurses, etc. Avoid operating by the patient himself.
(20) It is not allowed to dismantle or modify the device. Opening the shell may be electrocuted. Maintenance or upgrade the device must be done by the well-trained or authorized staff from AUTOINFU.
(21) Don't throw the battery into the fire or heat the battery,or there will be leakage and may be fire or explosion.
(22) Don't rip off the battery cover, or there may be explosion or chemical burn.
(23) To avoid patients being injured by over-flow or under-flow, please set parameters correctly and use the standard well calibrated syringe, or the accuracy will be not guaranteed and may reach more than ±40%.
(24) Check the device daily and check all the function in good condition if it is not used for long period.
(25) Clean the surface of the device with the soft cloth with warm water.
(26) Obey the local regulation or hospital rule when disposing the packing material and keep the packing material away from the children.
(27) Please stop to use the device when there is abnormal or function missing during the operation and contact the supplier on time, or the manufacturer and supplier won't be responsible for the loss, harm or injury caused by it.
(28) The possible maximum injection volume is 0.7ml in the single failure.

Chapter 1. Introduction

1.1 Application

Syringe Pump is intended to provide continuous injection with accurate flow rate and monitor the injection process with constant rate to the patient for clinical treatment for a period.

1.2 Main component and function

Syringe Pump is consisted by LCD, front shell module, back shell module, main control board, driving module, plunger head module, barrel clasp module, battery, etc., including the circuit control system, alarm detection system, input and output system and mechanical driving system.

The device main component and function：

- Main Control System: It is core of the whole system. It can intelligently control, manage and processing the signal of the system. The double CPU is monitoring and backing up for each other. When one CPU has problem, the other will make alarm and stop the power supply and stop working to make sure the safety of the patient.
- Mechanical driving system: It is the driving force of injection fluid. The step motor pull the plunger head, and the plunger head to push the drug injection.
- Detection system: mainly all kinds of sensor, such as size detection sensor, pressure sensor (detect the pressure in the syringe), etc.
- Alarm system: Consisted by audio, visual alarm, remind the operator the abnormal information to deal with and avoid the harm to the patient.
- Input and display: Input the parameter, such as VTBI, flow rate, etc. Display the injection parameter and alarm message.

1.3 Technical Specification

1.3.1. Compliance

Classification：Class Ⅱ

Protection against electric shocks: Class II, include the internal power supply

Protection against leakage current: Type CF, the part without defibrillation discharge effect

Protection against splashing fluid: IPX4

Working Mode：Constant injection

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1.3.2. Working and Transportation and storage conditions

Temperature ：+5℃～+40℃
Relative Humidity ：20～80%，not condensation
Atmospheric Pressure：70KPa～106Kpa
Transportation and Storage Temperature：-20℃～+50℃
Transportation and Storage Humidity ：10～95%， not condensation
Transportation and Storage Atmospheric Pressure：50KPa～106Kpa
Transportation and Storage Condition ： No corroded air and good ventilated environment

1.3.3. Power Supply

Volt：100～240V
Current：0.6～0.3A
Frequency：50Hz/60Hz

1.3.4. Battery

Quantity ： 1
Type： Rechargeable Lithium battery
Capacity：3000mAh
Rated Voltage：DC11.1V
Max. Power：50VA
Operation time： ≦7hr at 5ml/h after fully charged
Recharging time ： 14-16hrs

1.3.5. Physical Specification

Dimension：290mm×155 mm×225mm

Weight：≈3.5Kg

Display：LCD with high brightness

Screen Size：5.0 inch

1.3.6. Basic Parameter

Syringe Size：5ml、10ml、20ml、30ml、50(60)ml, auto-detection

Injection Mode： Constant Rate, Volume/ Time, Drug Weight, Micro-Mode, Sequential Mode and Drug Library Mode

Flow Rate：5ml:0.10～60.00ml/h； 10ml:0.10～300.00ml/h；
20ml:0.10～400.00ml/h； 30ml:0.10～600.00ml/h；
50(60)ml:0.10～1200.00ml/h

Increment：0.01ml/h

VTBI ： 0.10-9999.99ml or empty

Total Volume: 0-9999.99ml or＞9999.99ml

Time：1s～99h59m59s or >99h59m59s

Deviation：≤±2%（including mechanical deviation±1%）；

KVO：0.10～5.00ml/h adjustable （keep vein open）

Purge Rate： 5ml:30～60ml/h； 10ml:150～300ml/h；
20ml: 200～400ml/h； 30ml:300～600ml/h；
50(60)ml:600～1200ml/h

Occlusion Pressure ： Detection Range：20KPa～150KPa， 8 level sensitivity adjustable, with dynamic pressure value display.

Volume ： Standard Medical Alarm Voice with Mute function, 8 levels adjustable.

Screen Brightness ： 10 levels adjustable.

Keypad：Numeric Keypad, User friendly

BOLUS Rate：5ml:0.10～60.00ml/h； 10ml:0.10～300.00ml/h；
20ml:0.10～400.00ml/h； 30ml:0.10～600.00ml/h；
50(60)ml:0.10～1200.00ml/h

Syringe management：Preset 20 syringe brands, can add or edit the brand, accept all brands after calibration

Anti-motor verse： Monitor the motor to avoid verse injection.

Self-Testing：Self-Testing during loading and injection

Audio and Visual Alarm: Finished, near finished, near empty, empty, occlusion, syringe disconnected, no operation, parameter error, syringe size error, low battery, battery lost, battery ran out, AC power lost, abnormal injection, communication error

Syringe Management ： Can add or edit the brand, accept all brands after calibration

Communication Port ：USB, RJ45 for future use, Ethernet Port

Even History：10000 event log, can be transmitted to PC with USB

Language：Chinese or English

Note：

- ***The specification change not related to safety and law will not be noticed without prior notice.***
- ***The device with model：Constant rate、volume/time, drug weight mode, micro-mode and sequential mode drug library model.***

1.4 Function Description

1.4.1. Syringe pump is device with full function of acoustic and visual alarm and accurate injection-controlled system with high safety and reliability. It can make alarm, such as finished, occlusion, low battery, abnormal injection, etc.

1.4.2. Syringe is available for the intravenous injection of normal brine and dextrose, is also for the injection of high surface tension.

1.4.3. It can accept dedicated and standard single used syringe.

1.4.4. The battery supply system can guarantee the continuous injection when the patient needs to be moved or the AC power is disconnected. (The life can be more than 7hrs at the speed of 5ml/h after it is fully charged.

1.5 Components and Function

Syringe pump is consisted by LCD, front shell, back shell, main control board, driving module, plunger head module, barrel clasp module, battery, etc. including the circuit control system, alarm detection system, input and output system and mechanical driving module.

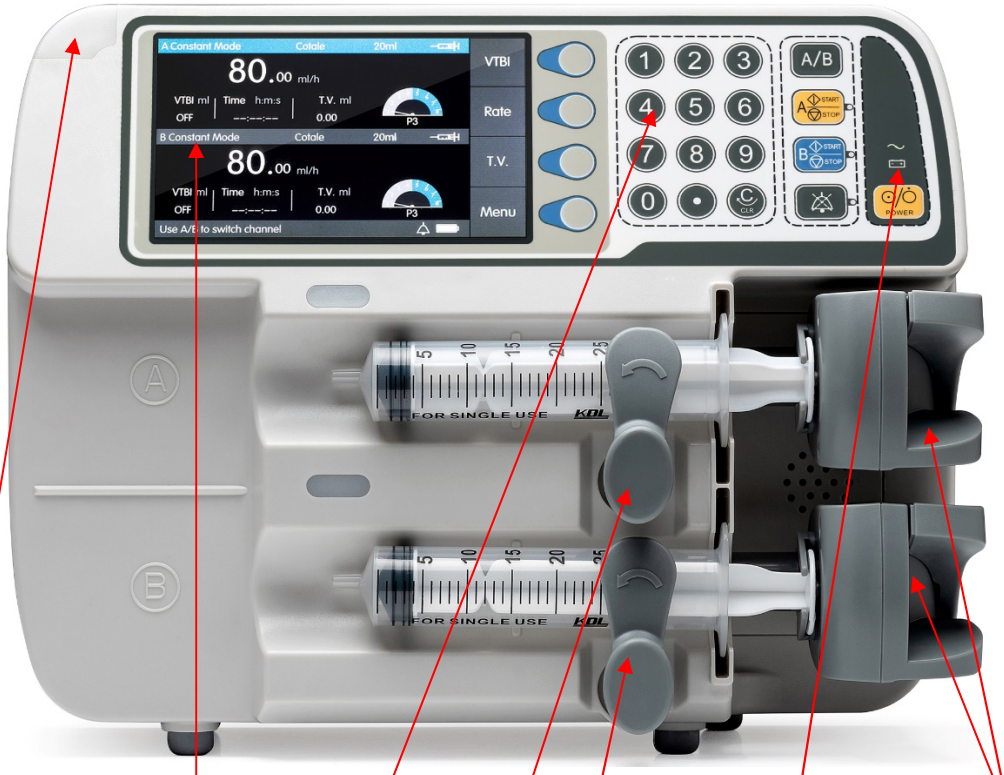
Circuit system is consisted by mother board, display control board, power board and all kinds of transfer board;

Input & Output system is consisted by LCD and keypad, etc.

Alarm detection system is consisted by speaker, alarm light, all kinds of sensor, etc.

Motor driving system is consisted by motor driving system, front and back shell, plunger head, barrel clasp, etc.

1.5.1. Component of Front Shell



Alarm Light: Show the alarm from long distance

LCD: Display the working status and parameter

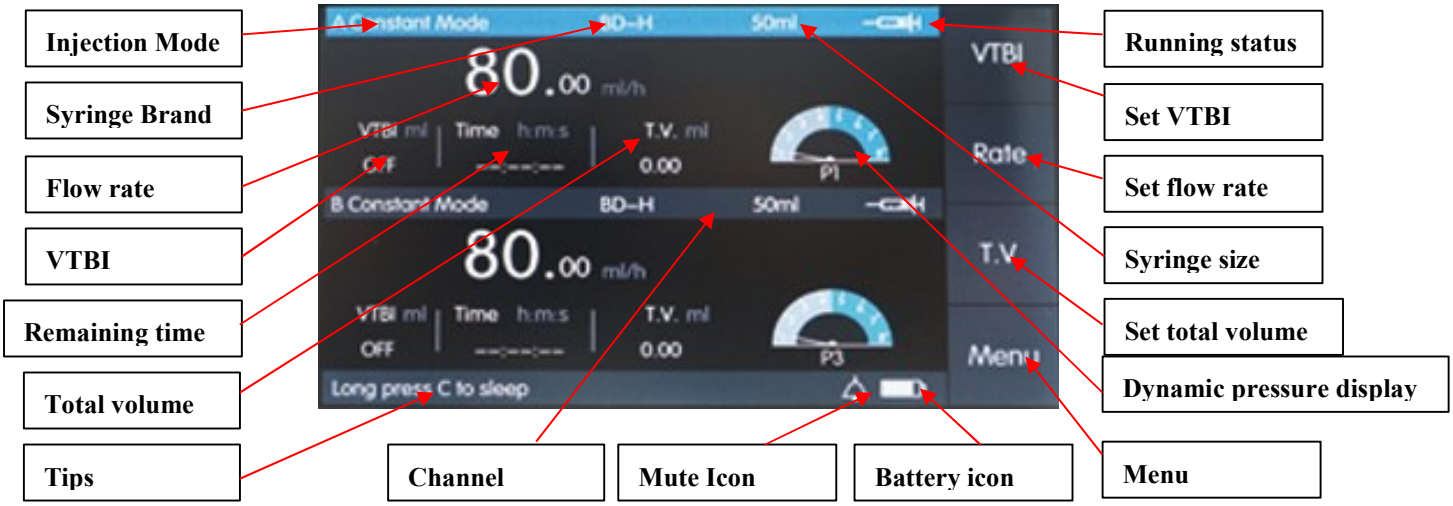
Keypad: Set the parameter

Plunger Head: Fix the syringes

Power Indicator: Power Supply indicator and battery indicator

Barrel Clasp: Push the syringe forward after the device starting

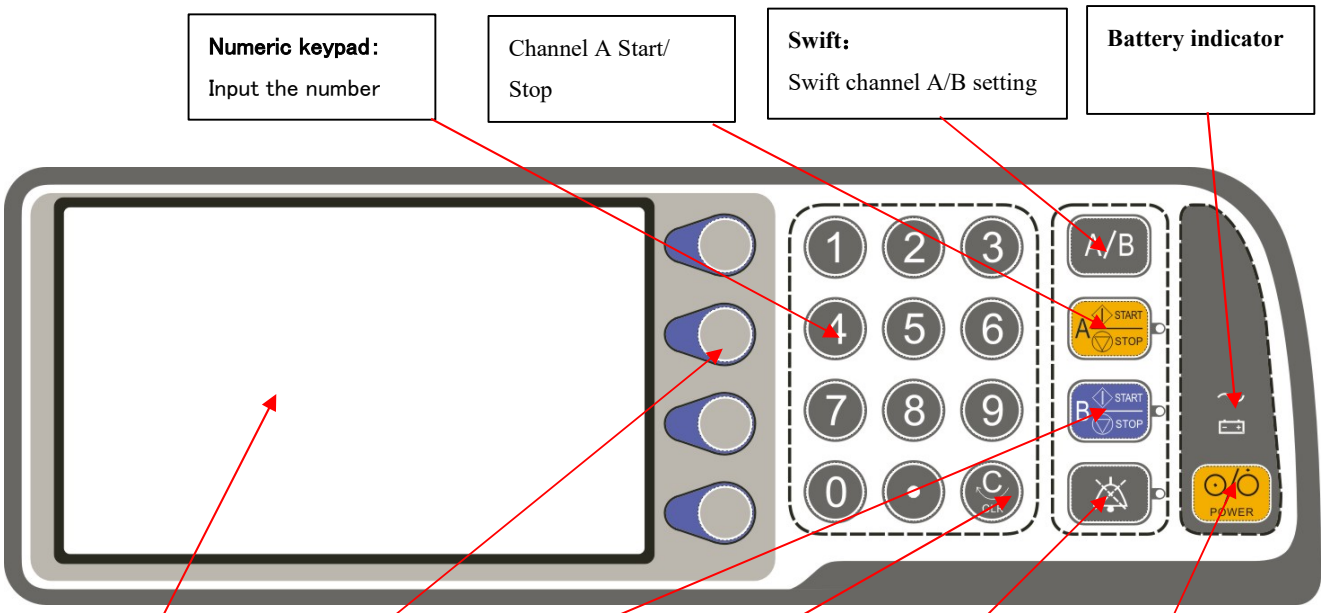
1.5.2. LCD Display



Note:

The above part in the screen is for Channel A, below part is the data for Channel B.

1.5.3. Button Function



LCD: Show the working status and parameter

Button: Related the menu to the function

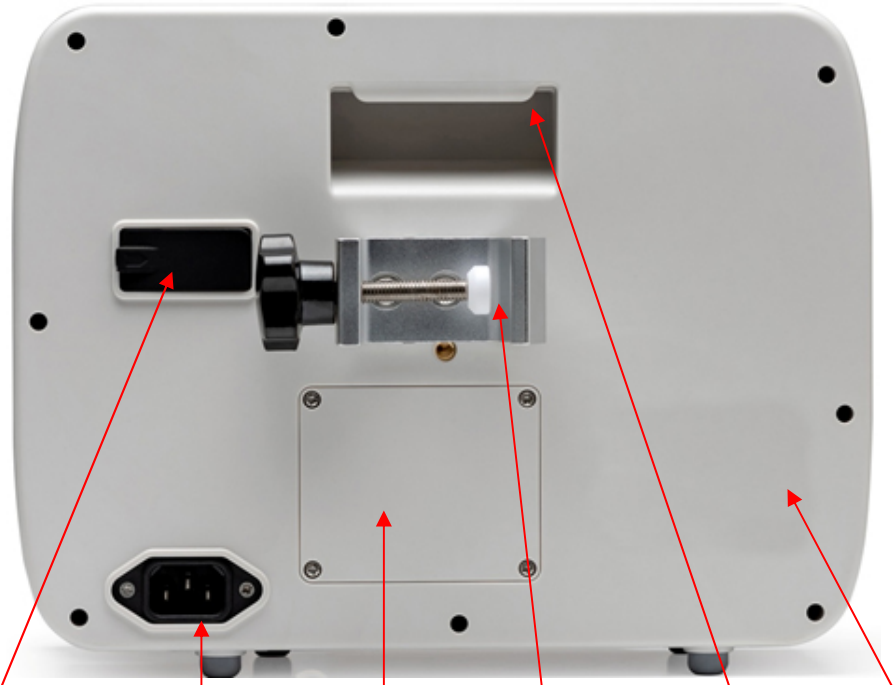
Channel B Start/ Stop

Clear Button: clear the data or alarm

Mute Button: Press Mute, Light on, Press second time, Light off

Power: Long press around 2 sec to power on or off

1.5.4. Back Shell Module



Date Port

AC Power Socket

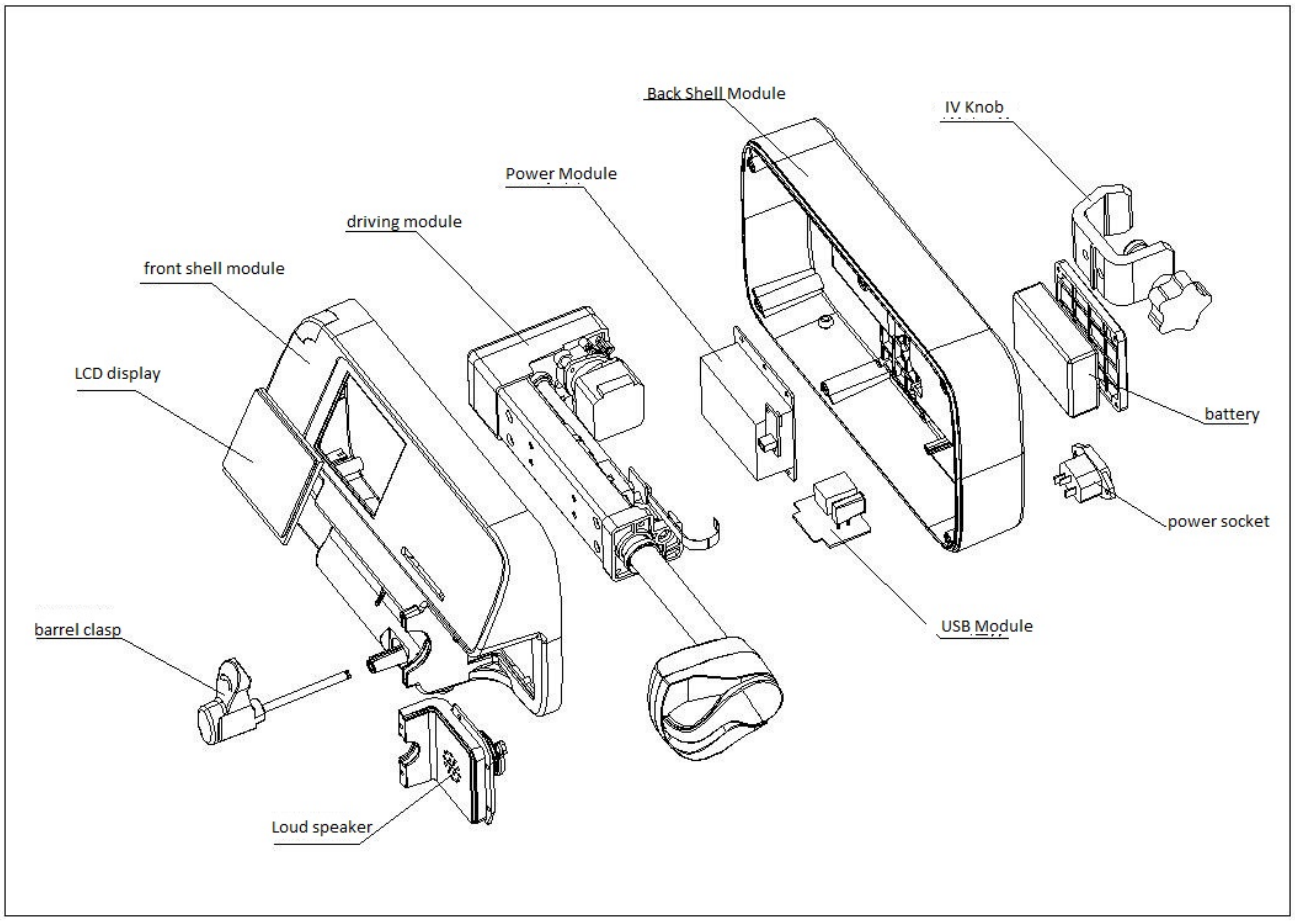
Battery cover

IV Knob

Handle

Label: display the address, SN, etc

1.5.5. Main Unit Component



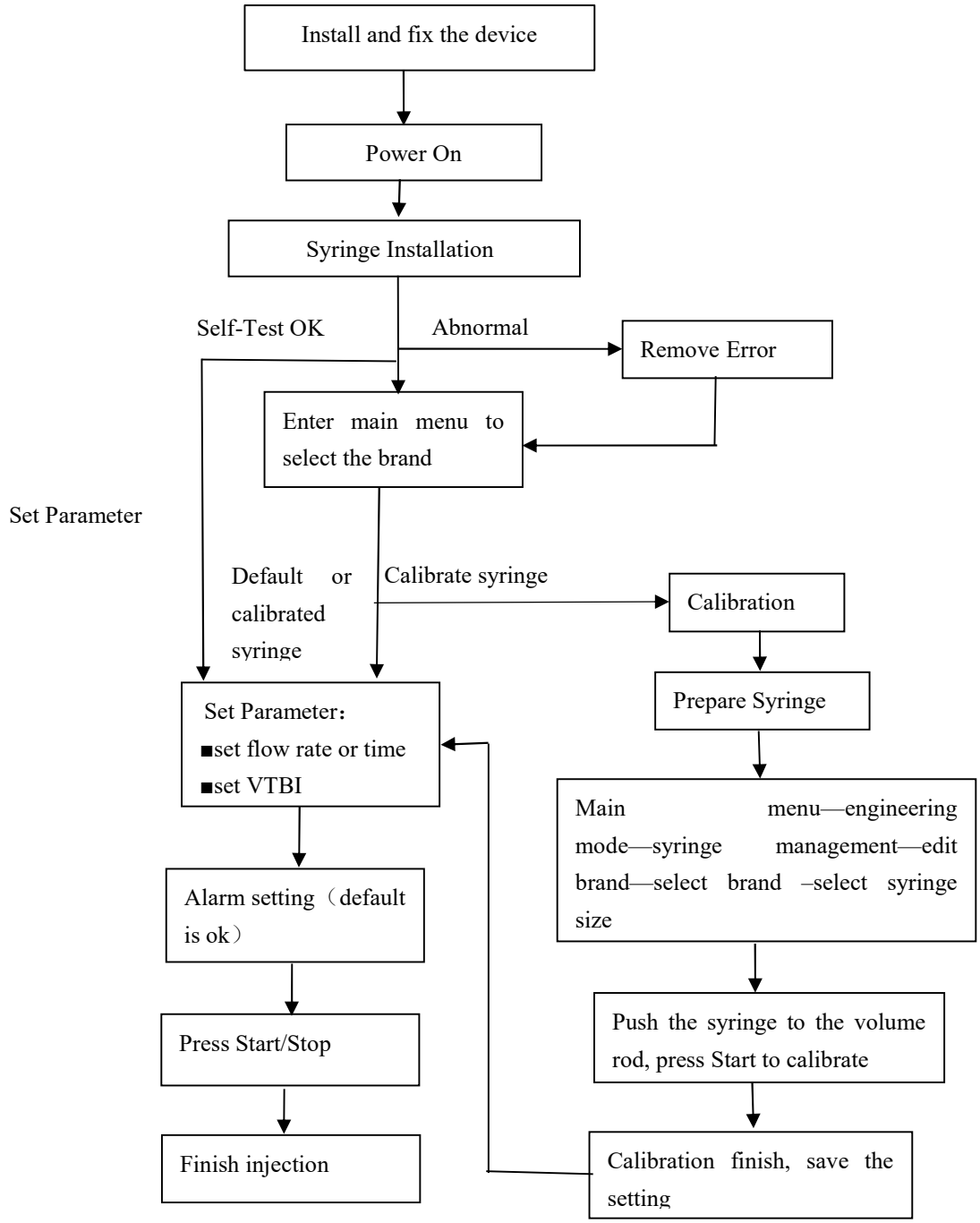
Chapter 2. Packing List and Operation Process

2.1 Packing List

The following parts is included:

- Syringe Pump …… 1PC
- Power Cord…… 1PC
- Operation Manual……1PC
- Quick Operation Guide……1PC
- Quality Inspection Certificate……1PC

2.2 Operation Process



Note !

- ***If the injection unit is the same as last injection, the flow rate, time, VTBI and other parameter can be set directly, the step of injection mode, syringe brand selection, and alarm setting can be skipped.***
- ***The last parameter will be kept in memory except the total volume to be clear after the device power off.***

Chapter 3. Operation Guidance

3.1 Preparation

3.1.1. Package Open Inspection

Before package open, please check the package carefully and confirm whether any parts is broken. If any, please contact the forwarder or supplier immediately.

If all is ok, then please open it properly and take out the device and other spare parts. Check the parts list and make sure all is well. If any question, please contact us.

Note!

- ***Please put packing material where the child can't reach. Follow the local regulation or hospital rule when dealing with the packing material.***
- ***Keep the packing material in stock for future use.***

3.1.2. Environment Standard

Please keep the device away from the noisy, shaking, dusty, corrosive, flammable, explosive environment. Please keep at least 5cm distance around the device to make good loss of heat and good air recycle.

When the device is moved to other environment, it may have condensation due to the temperature difference, in which case, please don't start the device until the condensation finish.

Keep the device away from mobile phone, X ray or MRI equipment, or it will lead to device problem or breakdown from the electromagnetic interference.

3.1.3. AC Power Supply Standard

Please run the device under the AC Power range on the label only.

Note !

- ***Use the proper AC Power supply based on the power voltage setting. Or it will make damage to the device or cause fire.***
- ***Power Feeding Spec：5*20mm, Ceramic tube high breaking fuse, model: 5H, 2A, 250V.***

3.1.4. Power Cord Installation

Connect the Power Cord into the socket in the back shell of the device and connect to the AC Power. The will be flashing on the keypad, the battery will start charging at the same time. Flashing indicate battery charging.

Note !

Please make sure the power cord connecting well.

- ***AC Power voltage range is 100～240V,50/60Hz.***
- ***Please make sure the power cord connecting well.***
- ***Put the AC Power in order to avoid people tied up by it.***

3.2 Installation and Setting

3.2.1. Installation and Power On

3.2.1.1. Install the device straightly and tightly on the IV stand. Connect to AC Power and will be flashing on the keypad.

3.2.1.2. Press Power Button around 2s and the device will start self-testing to check whether all function is working normally. If any wrong, it will show the alarm on the screen (eg. AC Power Lost)

3.2.1.3. The device will manage the battery automatically.

Note !

- ***The device will be under battery supply automatically if AC Power disconnected or lost. will be flashing and alarming AC Power Lost with acoustic and visualize alarm to remind the operator. It can be removed by press CLR on the keypad.***
- ***It is advisable to switch the device first and then install the syringe and set the parameter.***

3.2.2. Syringe Installation

3.2.2.1. Install the syringe correctly and prime the bubble in it.

3.2.2.2. Pull the barrel clasp and install it on the device.

3.2.2.3. Pull the syringe handle to the end and put it on the device.

3.2.2.4. Place syringe in its cradle, the flanges correctly in the provided slot.

3.2.2.5. Press down and release the button of the plunger head on the right side and move it forward to the end of syringe by engaging the small button on the left side of the plunger head, then the button on the right side will be bounced back automatically.

3.2.2.6. Check whether the syringe install correctly or not.

Note !

- ***Make sure to move the plunger head handle to the end of the device during moving the plunger***
- ***head, or there may be mechanical damage to the device.***

3.2.3. Parameter Setting

3.2.3.1. In the standby mode, VTBI, flow rate, total volume and mode will on the right side of the LCD.

3.2.3.2. Press the function button to enter into the setting.

3.2.3.3. Press swift button A/B to swift Channel A/B parameter setting.

3.2.3.4. Select VTBI, Flow rate and input the value, press Enter to proceed.

3.2.3.5. Press Total Volume can clear the value.

3.2.3.6. Press “Menu” to the main menu interface.

Note !

- ***Total volume is only for the current injection and will be cleared after device power off***
- ***If VTBI is set Empty, the injection will keep pushing until all the fluid finish inside the syringe.***
- ***Confirm the current syringe brand is the same as the selected one before setting the parameter.***
- ***The function button is different for different mode.***
- ***The default mode is constant rate mode.***

- ***There will be alarm" Parameter error "if the VTBI, flow rate, etc. is out of the range.***
- ***Channel A, Channel B parameters are single and no influence to each other.***

3.2.4. Start Injection

3.2.4.1. Check if the syringe is installed correctly and firmly.

3.2.4.2. Check if the parameter is set correctly.

3.2.4.3. Check no air bubble inside the syringe.

3.2.4.4. Make the venous puncture for the patient.

3.2.4.5. Press Start/Stop to proceed in the standby mode and the syringe icon in the LCD will keep moving.

⚠ ***Note !***

- ***Remaining volume will decrease during the injection.***
- ***The time in the LCD is the remaining injection time if the VTBI is set correctly during injection.***
- ***It is advisable not to use one syringe for more than 24hrs.***
- ***Prime the air inside the syringe or the extended tube by long pressing the Prime button until all the air removed.***
- ***It is advisable to prime the air before the venous puncture especially in the low rate injection, which can make the plunger head and the syringe handle connecting totally.***
- ***The hospital staff should watch the injection time to time and not totally reply on the device alarm only during injection.***

3.2.5. Near Empty

If VTBI is set "Empty", it will make acoustic and visual alarm and show "Near Empty "in LCD when the drug in the syringe is going to be empty; press Mute button to clear "Near Empty "alarm and get back to the injection interface.

⚠ ***Note !***

- ***When there is "Near Empty" alarm, the injection will not stop and keep going until all fluid finish.***

3.2.6. Injection Finish

3.2.6.1. When the total volume reach the set volume, VTBI will show 0ml and alarming "Finish! KVO". The injection will stop and enter into KVO mode to keep vein open.

3.2.6.2. When VTBI is more than the fluid volume inside the syringe, it will show "Empty "alarm when the fluid is finish and it will stop injection.

3.2.6.3. Press "Start/Stop" button and stop injection.

3.2.6.4. Remove the needle.

3.2.6.5. Press Power button around 2second to power off.

3.2.6.6. Press the plunger head handle and pull out the syringe by rotating the barrel clasp 90 degree counterclockwise and take out the syringe.

3.2.6.7. Remove the AC Power socket and take away the device.

⚠ ***Note !***

- ***Set the parameter correctly and press Start/Stop to continue the new injection.***
- ***The last injection parameter except total volume will keep in memory after device power off.***

3.3 System Setting

3.3.1. Select Mode

3.3.1.1. Press Menu to enter into main menu.

3.3.1.2. Press ∧or∨ to select"1. Select Mode" and press Enter to proceed.

3.3.1.3.Press ∧or ∨ to select the injection mode and press Enter to proceed.

3.3.1.4. There is Constant Rate, Volume/Time, drug weight, micro and drug library mode in the menu. Press∧ or∨ to select the mode and press Enter to proceed.

3.3.1.5. Constant Rate Mode: injection with the unit ml/h.

3.3.1.6. Volume/Time: Injection with VTBI and Time and flow rate calculate automatically.

3.3.1.7. Drug Weight Mode: Input Dose, solution, drug, weight and calculation, etc. flow rate calculate automatically.

3.3.1.8. Micro Mode: The maximum rate is less than 99.9ml/h.

3.3.1.9. Drug Library: select the drug for injection

3.3.1.10. Sequential Mode: Select flow rate or time for injection, 5 step at most for injection.

3.3.1.11. Press Enter to proceed.

⚠ ***Note !***

- ***The device with mode: Constant rate mode, time/volume mode, drug weight mode, micro mode, sequential mode, drug library mode.***
- ***Sequential Mode: flow rate or time can be programmable.***

3.3.2. Parameter Setting

3.3.2.1. Press Menu to enter into main menu。

3.3.2.2. Press∧or∨ to select" 2. Parameter Setting "and press Enter to proceed.

3.3.2.3. Parameter setting include: select brand, KVO, occlusion pressure level, prime setting, near empty setting. Press ∧or ∨ to select and press Enter to proceed.

3.3.2.4. Select Brand: there are default syringe brand well calibrated in the menu and press the number to select.

3.3.2.5. KVO Setting: Set KVO VTBI with range: 0.1-5.00ml; KVO flow rate with range:0.01-5.00ml/h; Press Save after setting and press Enter to proceed.

3.3.2.6. Occlusion Pressure Setting: Press ∧or ∨ to select the level, Level 1 –Level 8, the lower the level, the more sensitive(sensitivity: Level 1> Level 8), press Enter to proceed.

3.3.2.7. Prime Setting: Auto Prime and Manual Prime. Select to calculate the prime volume into Total volume or not and set the flow rate, press Enter to proceed.

3.3.2.8. Near Empty Setting: Select near empty alarm with time or volume. Set time as near empty alarm, time

range: 30-900 second, set remaining volume as near empty alarm: around 10% volume remaining, press Enter to proceed.

Note：

- ***Maximum auto Prime Volume is 5ml, range: 0.10-5.00ml.***
- ***Select remaining volume as near empty alarm, either time or remaining volume will trigger the alarm when reach the alarm value.***

3.3.3. System Setting

3.3.3.1. Press Menu to enter into main menu.

3.3.3.2.Press ∧or∨ to select"3. System Setting "and press Enter to proceed.

3.3.3.3. System Setting includes: date/time, LCD brightness, system information. Press ∧or∨ to select and press Enter to proceed.

3.3.3.4. Set Date/Time: Press ∧or ∨ to set date and time and press Enter to proceed.

3.3.3.5. Set LCD brightness: press ∧or ∨ to select 1-10 level, brightness : Level 10> Level 1 and press Enter to proceed.

3.3.3.6. System Information: Check device Model, version, etc and press Exit to proceed.

Note !

- ***If the system time is not correct, the history time will be not correct also.***
- ***Select remaining volume as near empty alarm, either time or remaining volume will trigger the alarm when reach the alarm value.***

3.3.4. Event Log

3.3.4.1. Press Menu to enter into main menu.

3.3.4.2. Press ∧or∨ to select"4.Event Log" and press Enter to proceed.

3.3.4.3. The menu includes Check Event Log, search event log. Press ∧or∨ to select and press Enter to proceed.

3.3.4.4.Check event log: Press ∧or∨ to check the log and press Enter to read it and press Exit to proceed.

3.3.4.5. Search event log: Press ∧or∨ to select the date and press Enter to read and press Exit to proceed.

3.3.5. Engineering Mode

3.3.5.1. Press Menu to enter into main menu.

3.3.5.2. Press ∧or∨ to select"5.Engineering Mode "and press Enter to input the password to proceed.

3.3.5.3. Engineering mode includes the function check event log, drug library, syringe brand management, alarm volume setting, language setting, reverse volume setting, pressure sensitivity Setting, calibration setting, factory setting, and software upgrade. Press ∧or∨ to select and press Enter to proceed.

3.3.5.4. Event Log: Clear event log, export event log. Press ∧or∨ to select and press Enter to check or clear the log. Connect USB to export the event log and press Enter to proceed.

3.3.5.5. Drug Library: Select drug, add drug, delete drug, import drug , export drug. Press ∧or∨ to select and press Enter to proceed.

Select drug: Press √ to select the drug and the drug will be showed in the menu of Drug Library.

Add Drug: Input the drug name by press the soft keypad.

Delete Drug: Delete the drug in the system.

Import Drug: Import the drug from USB data.

Export Drug: Export the drug to USB.

3.3.5.6. Syringe Brand Management: Select Brand, Edit brand, add brand, delete brand, import brand, export brand. Press∧ or∨ to select and proceed.

Select brand: Press √ to select and it will be shown " Paramter Setting"in the menu "Select brand".

Edit Brand: change the syringe length, diameter, empty length and other parameter to make the accuracy better.

Add brand: add the brand by press the soft keypad.

Delete brand: delete the brand in the system.

Import brand: Import the brand from USB data.

Export brand: Export the brand data to USB.

3.3.5.7. Alarm volume setting: press ∧or∨ to select the level, level 1-level8, alarm volume : Level1<Level8

3.3.5.8. Language Setting: press ∧or∨ to select Chinese or English and press Enter to proceed.

3.3.5.9.Reverse Volume setting: Input volume 0.1-0.5ml by press the numeric keypad and press Enter to proceed.

3.3.5.10.Pressure Sensitivity Setting: Press ∧or∨ to select the level: Level 1- Level8.Lower level it is, more sensitivity it will be.

3.3.5.11.Calibration Setting: Press ∧or∨ to select the parameter to be calibrated and press Enter to proceed.

3.3.5.12. Factory Setting: Set the brand data, drug library data, and event log into factory setting and press Enter to proceed.

⚠ ***Note !***

- ***Reverse Volume is the motor reverse pressure release volume in the syringe.***
- ***The event log is 10000 log. The log cleared can't be checked any more, please pay attention to this step.***
- ***Please get the password from the manufacturer or supplier.***

3.4 Other Operation

3.4.1. Pause

3.4.1.1. During injection, press Start/Stop to pause (the injection icon will stop in the LCD and injection indicator will also stop flashing).

3.4.1.2. Press Start/Stop to start the injection again.

3.4.2. Mute

Press Mute button to clear the alarm when there is alarm and the mute button will be on around 2mins.

Note !

- ***Mute is only to stop the alarm and the alarm error is not clear.***

3.4.3. Prime

In the standby mode, press Prime button to prime with the set flow rate and display the prime total volume.

Note !

Please watch the channel when priming. The blue icon is the current priming channel.

3.4.4. Change Parameter without stop injection

During the injection, change the flow rate and VTBI without stop the injection.

Press “Change Parameter” in the injection mode and press” VTBI to change and press “Flow rate” to change and press Enter to proceed. The blue line is the current setting channel.

3.4.5. Bolus Setting

Press Prime button to set the Bolus parameter .Press ”VTBI” to set and press “Flow rate ”to set and press Enter and Press Start/Stop to start bolus.(Bolus volume: 0.10ml-5.00ml).

Note !

- ***It will sound “ Di”after bolus finish and the previous injection will continue.***

3.4.6. Battery Supply

3.4.6.1. The device will work under battery supply in the following case:

- ■ The device work under battery supply without connecting AC power.
- ■ The device work under battery supply when AC Power disengaged.

3.4.6.2. Under Battery supply.

a. When AC Power disengaged, the device will work normally under battery (AC power indicator will be off, battery indicator will be on, and alarm light will keep flashing, low level alarm will be on)

b. The device work under battery supply. The battery capacity will be decreasing from full to be 1 until 0 capacity.

c. When the battery is low, it will alarm “Battery Low” and  keep flashing with acoustic and visualalarm. The device will keep working around 30mins to remind the operator to connect the AC Power on time.

d. When the battery is ran out, it will stop the injection until it is total ran off and power off automatically in 3mins after the alarm “Battery ran out”.

Note：

- ***When the battery is fully charged and injection with the rate 5ml/h, the battery supply time is not less than 10hrs.***

3.4.7. Sleeping Function

In the standby status, long press C button can enter into sleeping status and the device is in the standby mode and will not trigger "No operation" alarm. Long press C button or Start/Stop button can cancel sleeping status.

Note:

- ***When one channel in the sleeping mode, the other channel's function is not influence. Two channel can also in sleeping model at the same time.***

Chapter 4. Alarm and solution

4.1 Alarm

Alarm will happen when there is abnormal in the injection circuit or device error, which will lead to injection in failure. The device will alarm to remind the hospital staff with acoustic and visual and message to take action. The standard is following:

a. The volume can be heard the lowest volume 45db within 1m distance.

b. The default mute time is around 2mins.

c. The device should keep working in the 2mins' mute time.

d. Stop working when there is error.

4.2 Alarm Level and alarm way

4.2.1. Alarm Level

There are two alarm level: High level and low level, the details is below:

Level	High	finished、near finish、near empty, empty、occlusion、syringe disengaged、parameter error 、 syringe error 、 battery lost, battery ran out 、 injection abnormal、communication error
	Low	No operation, battery low, AC power disengaged.

4.2.2 Alarm Way

The device will have light alarm, voice alarm, message alarm when there is alarm with acoustic and visual alarm to remind the operator. Distinguish the alarm in different way as following standard:

Chart 1:

Level	Alarm light	Alarm light flashing	percentage	Period	Volume db

		frequency			
High	Red	2.0±0.6Hz	20%-60% on	2-15seconds	Not less than 45db in 1meter distance
Low	Yellow	on all the time	100% on	>15seconds	Not less than 45db in 1meter distance

Chart 2:

Level	Volume	Light Color			Nurse call	Operator Confirm
		Red light	Yellow light	message		
High	yes	flashing	Off	Air, etc	yes	Press Mute button, and Enter to confirm
Low	yes	off	flashing	No operation, etc.	yes	Press Mute button, and Enter to confirm

4.2.3. Action for the Alarm

When there is alarm, please check the patient in priority.

When there is alarm, please take the following action:

1. Check the patient
2. Confirm the alarm type
3. Find the alarm reason
4. Find the way to remove the alarm
5. Confirm the alarm is removed.

4.2.4 Alarm and Solution

Alarm message	Cause	Solution
Finish	Infused volume equals to VTBI	Take away the device once finish;Reset VTBI to continue the injection

Near empty	remaining volume is less than 10% of the VTBI	Press any button to clear the alarm
Near finish	Less than 30-900s to finish	Press any button to clear the alarm
Empty	VTBI more than real volume, all fluid is finish inside the syringe.	Take away the device once finish;Reset VTBI to continue the injection
Occlusion	The occlusion reaches to the maximum occlusion value	Remove the occlusion and press Clear to remove the alarm and press Start to proceed.
Syringe Disengaged	a、Syringe not installed well, plunger head can't detect the syringe b、Syringe not installed or in the right position c、Fixed button is disengaged in the syringe during injection.	a、Syringe Handel not fixed on the plunger head b、The distance between the syringe handle and plunger head is too big. c、The button on the plunger head is not pressed well by the syringe handle d、Check the fixed button is in good condition or not
No operation	no operation more than 2mins	a、Press Clear button to remove the alarm b、Press Start/Stop to proceed after parameter set c、Power off if no injection
Parameter error	parameter is out of range or syringe not installed	Set the parameter correctly or install the syringe correctly
Syringe error	The syringe size is not correct	Install the correct size syringe
Battery low	battery capacity is not enough	Connect the AC Power
Battery Lost	Battery disengaged or battery damaged	Connect the battery or change the battery
Battery ran out	battery is going to be run out	Connect AC power or power off.
AC power disengaged	AC Power is disconnected	1、Connect to AC Power again 2、Press Clear to remove the alarm and work with battery supply
Abnormal injection	Motor error	Contact manufacturer or distributor for maintenance
Communication error	Mother board error	Contact manufacturer or distributor for maintenance

Note !

- ***The maximum injection volume is not more than 0.7ml in the single error.***
- ***The maximum hydraulic pressure cannot be more than 140Kpa in the single error.***
- ***The injection will stop working when there is alarm except battery low or AC power disengaged to remind the operator to take action to avoid the harm from over current to the patient.***
- ***Check the patient in priority after the alarm to avoid any harm to the patient.***

4.3 Other Error

Check the device as following before contact the supplier.

Phenomenon	Possible Cause	Solution
Can't switch on the device.	Battery installed well?	Install the battery well
	AC Power connect correctly?	Connect the AC Power correctly
Deviation too big	The selected syringe is the same as the current one? The syringe is installed correctly?	a、Select the same syringe as set one. b、Calibrate the syringe correctly

4.4 Occlusion Pressure

a. Occlusion Pressure threshold, occlusion alarm real value and postponed alarm time reference chart:

Level	Occlusion pressure threshold	Real detection pressure value（kPa）					Postponed alarm time（s）				
		5ml	10ml	20ml	30ml	50ml	5ml	10ml	20ml	30ml	50ml
L1	20kPa	25kpa	28kpa	30kpa	31kpa	34kpa	70S	151s	246s	300s	456s
L2	30kPa	35kpa	34kpa	40kpa	45kpa	47kpa	140s	300s	401s	452s	600s
L3	40kPa	55kpa	48kpa	58kpa	60kpa	57kpa	260S	464s	555s	603s	750s
L4	60kPa	66kpa	78kpa	69kpa	72kpa	80kpa	411S	620s	704s	760s	902s
L5	80kPa	70kpa	75kpa	81kpa	84kpa	90kpa	588S	777s	859s	937s	1050s
L6	100kPa	90kpa	88kpa	100kpa	92kpa	101kpa	690S	920s	911s	1088s	1230s
L7	120kPa	100kpa	110kpa	112kpa	115kpa	109kpa	800S	1070s	1066s	1233s	1435s
L8	140kPa	120kpa	123kpa	119kpa	134kpa	131kpa	910S	1190s	1203s	1367s	1655s

b. The longest time between the alarm pressure value from occlusion threshold at the minimum and maximum rate and trigger alarm time during the working of the device at the speed 1ml/h(for reference):

Syringe	Alarm threshold	Alarm pressure value（kpa）	Trigger alarm time（min）
5ml	L1（20kpa）	35kpa	30m21s
	L8（140kpa）	135kpa	50m12s
10ml	L1（20kpa）	37kpa	38m23s
	L8（140kpa）	125kpa	68m12s
20ml	L1（20kpa）	40kpa	45m40s
	L8（140kpa）	133kpa	85m12s
30ml	L1（20kpa）	35kpa	48m31s
	L8（140kpa）	129kpa	97m12s
50ml	L1（20kpa）	41kpa	55m28s

	L8（140kpa）	131kpa	115m12s

c. The bolus volume from the alarm threshold at the middle rate and minimum rate during device working reference chart:

Syringe Size	Alarm threshold（kpa）	Bolus（g）
5ml	L1（20kpa）	0.08g
	L8（140kpa）	0.20g
10ml	L1（20kpa）	0.10g
	L8（140kpa）	0.22g
20ml	L1（120kpa）	0.13g
	L8（140kpa）	0.26g
30ml	L1（20kpa）	0.14g
	L8（140kpa）	0.30g
50ml	L1（20kpa）	0.15g
	L8（140kpa）	0.40g

Note：

1. ***The test syringe brand is "Kangdelai".***
2. ***The occlusion alarm pressure value and the longest postpone time depends on the test condition.***
3. ***Occlusion pressure value deviation: ±25kpa***

Chapter 5. Product daily check, storage and transportation condition

For product maintenance requirement, we can provide the board circuit, components, reference chart, calibration instructions or other technical instructions. Please use the mention below material and method to clean or sterilize the device. We will be not responsible for the damage or accident caused by other material and method clean or sterilization. The listed chemical and method is only for control the infection. We will not bear any responsibility for its validity.

Please enquiry the hospital Infection Prevention Department or local epidemiological expert for the infection

control method.

5.1 Daily Check

Ethylene oxide sterilization or ultrasonic sterilization can be used. Clean the device with

⚠ ***Note !***

- ***Don't clean the device with diluent, alcohol, etc***

5.1.1. Shell Clean

Clean the shell the shell with soft cloth wet by warm water or diluted neutral detergent and wipe the shell and make the device dry after clean.

5.1.2. Daily check for the syringe fixed clip, plunger head and barrel clasp.

Clean the syringe fixed clip, plunger head and the barrel clasp with soft wet cloth and make it dry.

5.1.3. LCD and keypad daily check

Clean the LCD and keypad with soft wet cloth and make it dry.

⚠ ***Note !***

- ***Don't let the fluid coming into the keypad.***

5.1.4. Daily check for syringe guides and guides port

Clean the syringe guides and guides port with soft wet cloth and make it dry.

⚠ ***Note !***

- ***Power off and disconnect the AC socket and power cord before cleaning.***
- ***Use the recommended dilute detergent and disinfectant or use the low concentration as possible.***
- ***Don't soak the device into fluid and don't pour fluid on the device or components and don't make the fluid into the device.***
- ***Do not use abrasive materials (such as steel balls or silver polish) and solvents similar to xylene or acetone to avoid damage to the shell.***
- ***Optional detergents and disinfectants: warm water, diluted soapy water, diluted ammonia, sodium hypochlorite (bleaching powder for washing), hydrogen peroxide (3%), ethanol (70%), isopropanol (70%), etc.***
- ***No gas (Eto) or formaldehyde should be used for disinfection.***
- ***Stop to use the device and contact the manufacturer or distributor if pouring the water into the device or its components by accident, which lead to device abnormal working.***

5.2 Battery

The internal rechargeable battery (hereinafter referred to battery) make sure the device continue the normal working during transport or no power supply. It will charge automatically when connecting to the AC Power. It will work under battery supply when there is no AC Power. Please take out the battery if it is not used for long period; the battery can discharge automatically, the life of the battery will decrease if not charge it every three month especially in high temperature.

5.2.1. Charge Battery

1、Connect to AC Power to charge when there is battery low alarm.

2、Please charge the battery if it is the first time use or it is put in stock for long period.

a、Before power off the device, the indicator will be on and LCD will show the charging icon and the indicator on the keypad will be flashing after connecting to AC power.

b、Press Power button around 2s to switch the device, will be on on the keypad , flashing, moving on the LCD.

c、Press Power button around 2s to switch off the device. It keeps charging and will be off after fully charged. (Around 16hours).

Note !

- ***Please charge the battery every 3months to avoid battery damage if the device is kept in stock for long period.***
- ***It takes 16hours for fully charged the battery after it is ran out.***
- ***Battery is only for backup use and please connect to AC power during injection.***

5.2.2. Battery performance inspection

Disconnect AC power, the battery can use around 10hours at the speed 5ml/h. The performance of the battery will degrade over time and please check the performance regularly. Check the battery as following step:

a、 Connect the device with AC power and charge it for 16hours.

b、Disconnect the AC Power, make the injection at the speed of 5ml/h until the battery ran out and device power off automatically.

If it can work more than 120mins, it means battery is in good condition.

If it can work 60-120mins, it means battery is near the end life period.

If it work less than 60mins, it means battery is the end life.

b、 Please recharge the battery after checking the battery for next time use.

Note !

- ***If the battery has obvious damage (bulk bag, deformation, leakage) or the battery cannot store power, it should be replaced in time and properly recycled.***

5.2.3. Replace battery

The life of the battery depends on the use frequency and operation environment. The life is around 2years if it is used properly or the life may be shortened. It is advisable to replace the battery around 2years. If the battery has obvious damage (bulk bag, deformation, leakage) or the battery cannot store power, it should be replaced in time and properly recycled. Please follow the local regulation when dealing with the battery.

Step to replace the battery：

a、Loosen the battery cover screw at the back shell of the device and take out the port to get the battery.

b、Put new battery inside and connect to the power and put the battery cover well. Fix the screw well.

Note！

- Please don't disassemble or throw into fire or short-circuit the battery. Battery burning, explosion, or leakage will be harmful to human.
- The battery should not be disposed of as domestic waste.
- Battery is consumable and please replace it when the life is exhausted.
- Please get the original battery from manufacturer or distributor when replacing it.
- The device can only accept the specified battery from the manufacturer and the device may be damaged or cause fire from not specified battery.
- Please replace the battery when the battery is damaged or leakage.
- Don't use the faulted battery in the device.

5.3 Regular Maintenance

5.3.1. Check the deviation of the device

Please calibrate the syringe every 3months or calibrate the syringe when changing the brand.

5.3.2. Routine maintenance

Interval period	Step
As hospital cleaning rules	Clean the surface completely after or before long time storage
Check at least one time per year	1. Test the AC power socket and cable 2. Run the device until battery low alarm and charge the battery to confirm it is normal working 3. Check if the device can recognize the syringe size or not

5.4 Replace the components at routine.

The device has exclusive components: battery can be replaced regularly depends on the real use condition.

Battery is consumable and it is advisable to replace every two years.

5.5 Transportation and storage

Store the device in the following condition after cleaning:

Temperature：-20℃-50℃；Relative Humidity:：10%～95%；Atmospheric Pressure：50KPa～106KPa。

Please don't store the device in the following condition:

a、Environment with direct sunlight or strong light.

b、Environment with hot or wet air coming from heating installation, furnace and humidifier.

c、Environment with chemical materials, dust, and humidity.

d、Environment with water, dust, and humidity or shaking or unflat floor

f、Don't overlap the device more than 5laps

5.6 Pollution-free disposal and recycle

The life of the device is 5years. Please scrap disposal for the device used more than 5year and contact the manufacturer and distributor for more details

Dispose the device as following:

1. Deliver the disposed device back to the manufacturer or distributor for recycle.
2. Deliver the waste battery to the manufacturer or distributor or dispose it following the local recycle regulation

5.7 Compliance

 ：Please read the operator manual prior to using this device!

 ：Protection against leakage current: Type CF equipment.

IPX4：Protection against splashing fluid.

Chapter 6. Appendix

6.1 Appendix I Electromagnetic Compatibility

 ***Note !***

- ***The device meet the Electromagnetic Compatibility standard of YY0505-2012.***
- ***Please install and operate the device based on the Electromagnetic Compatibility information with the device packing.***
- ***Portable and mobile RF communication equipment may affect the performance of the syringe pump,***

avoiding to use the device near strong electromagnetic interference, such as mobile phones, microwave ovens, etc.

- ***Please read the instructions and manufacturer statement in the attachment.***

Note !

- ***The device or system should not be used close to or stacked with other devices. If it must be used close to or stacked, please pay attention to the normal working under the configuration during use.***
- ***Class A equipment is intended for use in industrial environments. Due to conducted disturbances and radiated disturbances by the syringe pump, it may be potentially difficult to ensure electromagnetic compatibility in other environments.***
- ***In addition to the transducers and cables sold by the manufacturer of the device or system as spare parts for internal components, the use of additional accessories, transducers, and cables may result in increased emissions or immunity to the device or system.***
- ***Use of accessories, transducers, or cables outside of the regulations with equipment and systems may result in increased emissions or immunity to emissions from equipment or systems.***

Note !

- ***Use of accessories, transducers, or cables outside of the regulations with equipment and systems may result in increased emissions or immunity to emissions from equipment or systems.***
- ***The device or system should not be used close to or stacked with other devices. If it must be used close to or stacked, please pay attention to the normal working under the configuration during use.***
- ***Special EMC protection for syringe pumps is required and installation and maintenance are required in an environment that meets the following EMC information.***
- ***The syringe pump should be avoided to use with MRI or similar equipment. Otherwise, the device may get malfunction or collapse due to electromagnetic interference.***
- ***Even if other equipment meets the CISPR emission requirements, it may also interference to use of the syringe pump.***
- ***When the input information number is lower than the minimum specified in the technical specifications, the measurement may be inaccurate.***
- ***Portable and mobile RF communication equipment may affect the performance of the syringe pump.***

SN	ITEM	Length（m）	Hide or not	Note
1	Power cord	3.0	no	/

6.2 Guidance and manufacturer’s declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [A]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

6.3 Guidance and manufacturer's declaration - electromagnetic Immunity I

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines Not Applicable 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

6.4 Guidance and manufacturer's declaration - electromagnetic Immunity II

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1 700 –	GSM 1800;	Pulse	2	0.3	28

	1845 1970	1 990	CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	modulation 217 Hz			
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9

6.5 Appendix IIIV Trumpet Curve

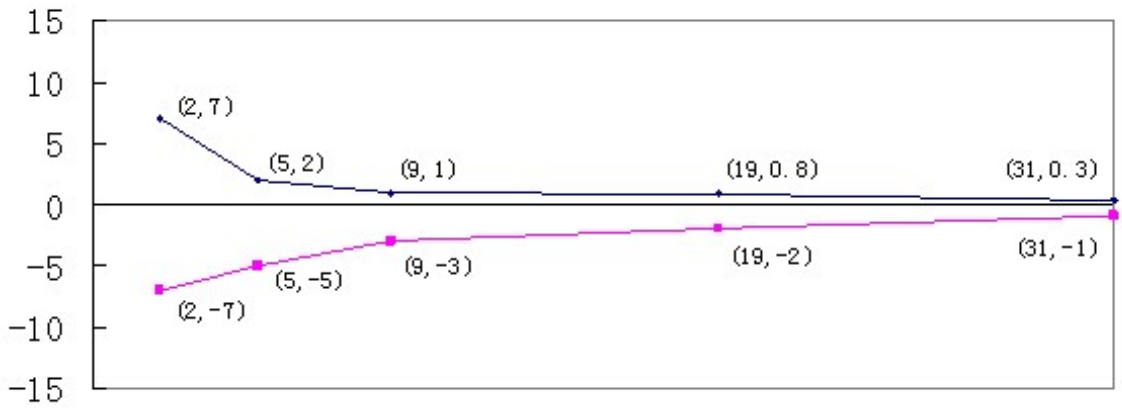
Trumpet curve

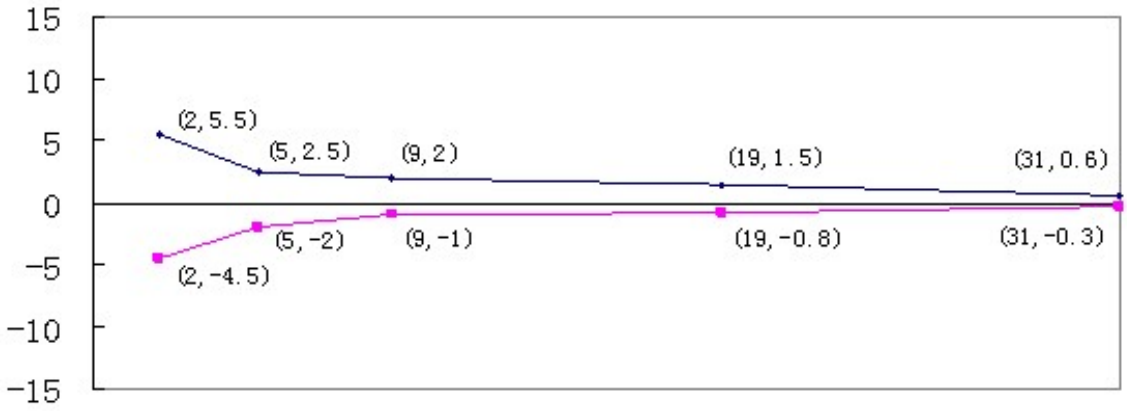
Trumpet curve indicates the trend of the max and min deviations of the syringe and pump. The detection proposals introduced for obtaining results in this aspect are based on EN60601-2-24. For more detailed information, please refer to this publication.

The following curve represents the results after using Yusheng syringe in the test; and it is considered as only one basis of the overall performance of the syringe pump. For more related information, contact the supplier.

(1) Trumpet Curve

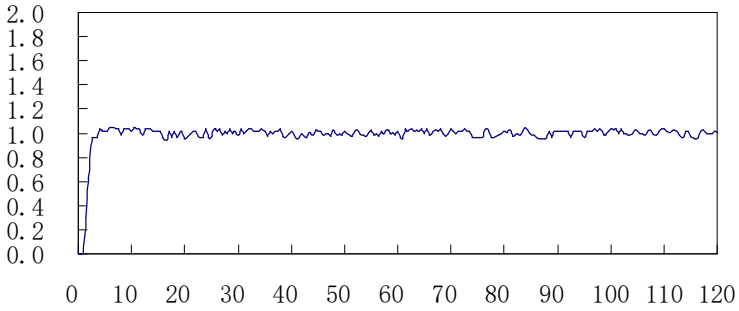
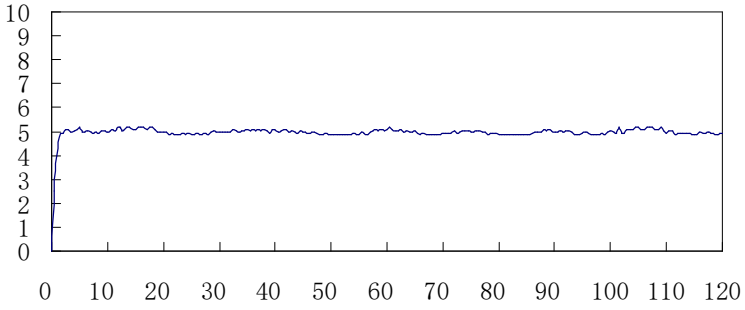
Varia	Flow Rate=1 mL/h

	
	Observation windows (min)

Variance (%)	Flow Rate=5 mL/h
	
	Observation windows (min)

（2）Start-up and Real-time Curve (Startup Curve)

Flow rate	Flow Rate=1 mL/h

	
	Time (min)
Flow rate (mL/h)	Flow Rate=5 mL/h
	
	Time (min)

6.6 Appendix 5 Symbol and terms

Unit reference sheet

Abbreviation	English
Min	Minute
H	Hour
Hz	Hertz
Mg	Milligrams
G	Gram
Kg	Kilogram
kPa	Kilopascal
Ml	Milliliter

Unit reference sheet

Abbreviation	English
MRI	Magnatic resonance imaging
AC	Altenating current
DC	Dirct current
EMC	Electromagnetic compatibility
KVO	Keep vein open
IEC	International Electrotechnical Commission
ISO	International organization for Standardization
LED	Light emitting diode
CPU	Central processing unit
RAM	Random access memory
ROM	Read-only memory
Eto	C2H4O
BOLUS	Bolus