CE 0197

Syringe Pump

BYZ-810 Series

Operator's Manual

Please read this manual carefully before using the devices

Table of Contents

Warnings and Precautions

Warnings:

- Before use, must check the pump, cables, and accessories to ensure that the pump works normally and safely.
- The user is obligated to perform calibration to ensure the accuracy of pump.
- Must connect the pump to grounded AC mains power source. Use the internal battery module to supply power instead of using the AC mains power without protective grounding in order to avoid hazards.
- Persons who do not receive training should not operate the pump.
- Operators must be appropriately trained to have a good command of necessary knowledge and operation competence on performing check, maintenance and repair.
- To avoid electric shock hazards, never open the enclosure or battery compartment for any reasons.
- The devices maintenance should be conducted by service personals who have received professional training.
- Always disconnect pump from mains power before performing maintenance and repair.
- To avoid fire and explosion hazards, keep the pump away from the environment full with vibrations, dust, excessive temperature or humidity, as well as large electrical equipment etc.
- Do not operate the pump in the presence of flammable anaesthetics to prevent explosion.
- Do not alter the devices without authorization of the manufacture (including software, hardware and construction).
- Always manually discharge air bubbles in the administration sets before start infusion.
- Never install other improper infusion controller on administration sets, which may cause safety hazards.
- The battery lifetime may be shortened due to long time use, excessive ambient temperature, etc.
- To ensure accuracy and essential performances of pump, must calibrate the syringe according to the instructions for use. Otherwise, the accuracy cannot be guaranteed
- The pump may be interfered by a large electromagnetic field, abnormal current and electrostatic discharge (ESD) which exceeds the EN/IEC60601-2-24 and EN/IEC60601-1-2 Provision. Please consult the authorized manufacturer if the pump is expected to be used under special conditions.
- When the pump is used together with electrosurgical equipment, patients' safety should be ensured.
- The battery of pump only can be supplied by our company. If replacement is needed, please contact us to help you install properly in order to avoid undesirable risks caused by incorrect replacement.
- When the fuse is damaged or broken, please contact the qualified service personals to replace it with suitable fuse.

- Once fault appears, immediately remove the pump from service and consult manufacturer or authorized distributors to perform maintenance.
- Please implement charge-discharge inspection before using to avoid working halt resulting from the accident power interruption. If the battery cannot be charged, please contact an authorized distributor or manufacture for help.
- If there is aged deformation or damages on the syringe plunger release levers, please timely change it with a new one to avoid hazards.
- The syringe's flange shall be firmly installed into its position to avoid unreliable infusion, like over-infusion or under-infusion.
- Environmental protection: When pump and accessories (battery, syringe etc.) are about to exceed their service life, please properly deal with them according to relevant environmental protection law.
- The package materials must be disposed in accordance with local regulations or the hospital's waste disposal regulations.
- Place the package materials at a place out of children's reach.

Precautions:

- Please read throughout the operator's manual before using the pump.
- Use the accessories specified in this manual.
- After properly installation, start the pump after correctly setting each parameter in accordance with clinical treatment requirements.
- Before infusion, check the whole pump to make sure there is no liquid leakage.
- Frequently inspect the pump at least once every six months.
- Keep the pump surface dry. If cleaning is needed, please use wet rag and proper detergent but never use organic solvent, such as benzene and butanone etc.
- Conduct inspection of battery charge-discharge status at least once every 3 months to prevent hazards or damages caused by low-power or sudden power interruption.
- Qualified and proper syringes should be selected to ensure safety because rate and pressure accuracy of device is affected by syringe's specifications.
- Timely charge the battery with grounded AC mains power if battery low alarm occurs.
- Firmly and properly install the pump to avoid falling or sliding hazards caused by pulling pipelines by accidence.
- Do not put pump at the edge of bed without fence.
- Do not expose the pump into a direct sunlight, excessive temperature or humidity.
- Should timely replace broken or damaged accessories so as to prevent hazardous situations.
- Please install the pump in a position where is easy to observe, operate, and maintain the pump.
- The disposable syringe consumables for pump can only be used once.
- Install the pump at a place where the power cable can be easily plugged out from the sockets.
- Contact us for more necessary information and technical supports specified in the EN/IEC 60601-1.

Symbols

Not all symbols are useful

∽	AC		Type CF applied part		Please read operator's manual before using
⎓	DC		Caution		STOP/SHIFT
	SILENCE		START		BOLUS
	Power indicator		Alarm indicator		Battery indicator
	External power supply	CE 0197	CE certificate marking	IPX2	Protected against splashing water
SN	Serial number	EC REP	European authorized representative		Recycle after sorting
	Manufacturer		Date of manufacture		

1. Introduction

1.1 Overview

1.1.1 Intended Use

BYZ-810 series Syringe pump is indicated for the following usages:

- In the administration of drug fluids that require precisely controlled infusion rates.
- Through clinically accepted IV routes of administration.
- By three delivery modes: Simple mode, Vol/T mode, Vol/W mode.
- In settings such as neonatal and pediatric intensive care, adult critical care, operation rooms, emergency rooms, and general wards or any other areas where the pump use can be monitored or supervised by a trained healthcare professional.

Warnings:

- This equipment/system is intended for use by healthcare professionals only.
- Before using any BYZ-810 pump, users must be thoroughly familiar with the contents of the operator's manual, including all warnings, cautions, and instructions for use.
- The user should ensure that the performance offered by the pump is fit for the intended use and that the pump is not used in any way or for any purpose other than its intended purpose.

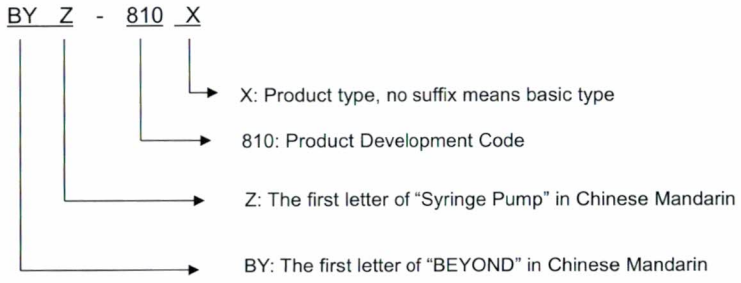
1.1.2 Working principle

The BYZ-810 series Syringe Pump is a kind of micro syringe pump with volume accuracy and rate consistency. It implements its infusion function through a microprocessor which accurately controls the stepper motor to produce the horizontal movement force through a mechanical transmission device to drive syringe plunger down its barrel. Various sensors are equipped in the pump to accurately control the infusion rate and monitor the infusion process. Therefore, it is a kind of high-precision intelligent syringe pump. Various alarm functions are inserted, prompt information is synchronously displayed with a LCD screen.

1.1.3 Contraindication

This equipment cannot be used for blood transfusion.

1.1.4 Code Meaning



Function	Model		
	810S	810	810D
Human Voice Alarm	×	√	√
With Drug Library	×	×	√
Data Record	×	×	√
Time set	×	×	√
Please note: "√" means " with such function"; "×" means "No such function"			

1.1.5 Specifications

Infusion Rate	50/60ml Syringe: 0.1ml/h~1500ml/h (0.1ml/h step) 30ml Syringe: 0.1ml/h~900.0ml/h (0.1ml/h step) 20ml Syringe: 0.1ml/h~600.0ml/h (0.1ml/h step) 10ml Syringe: 0.1ml/h~300.0ml/h (0.1ml/h step)
Rate Accuracy	Within ±3% (after correct calibration)
Mechanical Precision	Within ±2%
Bolus Volume	50/60ml Syringe: 0.1ml~10ml (0.1ml step) 30 ml Syringe: 0.1ml~10ml (0.1ml step) 20 ml Syringe: 0.1ml~10ml (0.1ml step) 10 ml Syringe: 0.1ml~5ml (0.1ml step)
Bolus Rate	50/60ml Syringe: 0.1ml/h~1200ml/h (0.1ml/h step)

	30 ml Syringe: 0.1ml/h~720ml/h (0.1ml/h step) 20 ml Syringe: 0.1ml/h~480ml/h (0.1ml/h step) 10 ml Syringe: 0.1ml/h~240ml/h (0.1ml/h step)
Purge Rate	50/60ml Syringe: 1500ml/h 30ml Syringe: 900ml/h 20ml Syringe: 600ml/h 10ml Syringe: 300ml/h
Total Infusion Volume	0.1ml~9999.9ml (0.1ml step)
Volume Limit	0.1ml~9999.9ml
Maximum Infusion Pressure	150kPa
KVO Rate	0.1ml/h~5ml/h (0.1ml/h step)
Alarms	injection finish, limited finished, injection is blocked, battery empty, syringe falls off, equipment failure, syringe is improperly installed, abnormal operation, supply mains and internally powered both fail, low battery, forget the operate, injection soon finish.
Maximum Infusion Volume (under single fault condition)	1ml
Power Consumption	35VA
Power Source	100~240VAC, 50/60Hz; Internal rechargeable Li battery, capacity≥1,800mAh; voltage 11.1V, 4 hours backup time at the rate of 5ml/h for the battery charged for 12hours. To facilitate the use in some special occasions, the machine's DC outlet can be an external DC 12V 2A standby power supply.
Fuse	T2AL/250VAC, 2pcs installed
Equipment Classification	Class I, internal power supply, Type CF
IP Classification	IPX2
Ambient Environment	Temperature: +5℃~+40℃, Relative humidity: 20~90%, Atmospheric pressure:86.0kPa~106.0kPa
Transport & Storage Conditions	Temperature: -20℃~+55℃, Relative humidity: ≤93%, Atmospheric pressure:50.0kPa~106.0kPa
Occlusion	High: 800mmHg±200mmHg(106.7kPa±26.7kPa) Medium: 500mmHg ±100mmHg (66.7kPa±13.3kPa)

	Low: 300mmHg ±100mmHg (40.0kPa±13.3kPa)
Dimensions	270mm (L) ×210mm (W) × 121mm (H)
Net Weight	Approx. 2.2 kg
Recommended Syringes	BD, SHINVA, BBRAUN
Syringe	Compatible with any syringe brand (10ml, 20ml, 30ml, 50/60ml) after correct calibration
Applied part	Syringe, extension tubing

Attention :

- It is recommended to use SHINVA model 10ml, 20ml, 30ml, 50ml, 60ml syringes. The other brands syringes can also be used after correct calibration.
- Disposable syringes and extension tubes applied shall be sterilized by ethylene oxide and comply with the standards of ISO7886-1 Sterile Hypodermic Syringes for single use. The syringes or extension tubes which do not comply with the standards may lead to incorrect infusion rate, drug residues and other possible hazards.
- The accuracy of flow rate is affected by syringe brand, working environment, temperature, time, medicine concentration etc.
- Please regularly check and calibrate the accuracy of devices.

1.1.6 Service Life

7 years.

1.2 Appearance

1.2.1 Front view

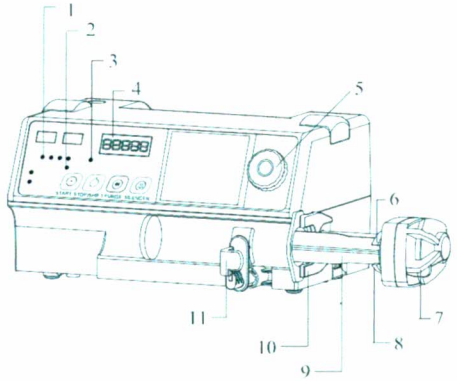


Figure 1-1

1. Working indicator
2. Syringe falling off indicator
3. Syringe installation indicator
4. Total infusion volume
5. Rotary knob
6. Syringe Plunger Holders
7. Syringe Plunger Release Lever
8. Syringe Plunger Holders
9. Syringe plunger
10. Flange clip
11. Syringe Barrel Clamp

1.2.2 Rear view

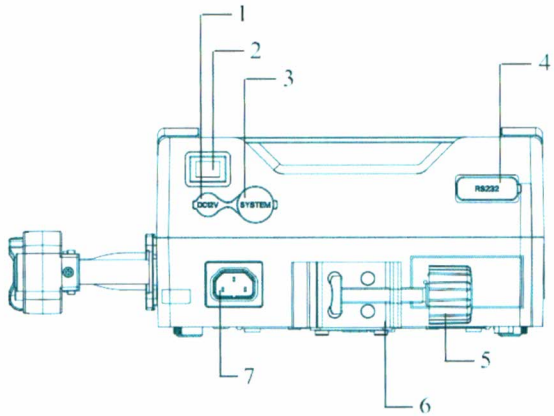


Figure 1-2

1. DC 12V interface
2. Power rocker switch
3. Program input interface
4. Reserved interface
5. Pole clamp knob
6. Mounting bracket
7. AC power interface

2. Installation

2.1 Install Pump

- Use the pole clamp to fix the pump on a supporting system;
- Unscrew the clamp knob by rotating anticlockwise until it can be fixed to the pole;
- Clockwise screw the clamp knob to securely fix the pump to the pole.

⚠Caution:

- Ensure that the pump is securely fixed;
- Changes of mounting position and severe vibration may affect the accuracy of device.
- This product can neither be used as portable device, nor be placed on the sick bed during use. Users should place the syringe pump on the table or fix it with the syringe support by tightening the screw handle.

Attention:

- Before installing, carefully check the stability of the support system.

- Make sure the syringe pump is firmly installed and the support system is stable.

2.2 Connect to AC Mains Power

The three-pin socket must be protectively grounded with grounding wire. If grounding of AC mains power is doubt, please use the internal battery module and contact the hospital's electrical technician or our company. The AC power indicator will be ON when the AC power is used and it will turn off when the internal battery is used.

3. Parameter Setting

3.1 Description of Each Option

Table 3-1

Button items	Symbols	Description
START		Press this button to start infusion;
STOP/SHIFT		Press this button to stop infusion;
SILENCE		Press this button to silence alarm;
BOLUS		Used to enter the Bolus or Purge mode.

3.2 System Setting

Press "STOP/SHIFT" button and hold on, whilst press the rotary knob to enters the menu interface as Figure 3-1.

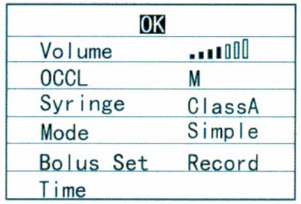


Figure 3-1 Menu interface

3.2.1 Sound Level

1) On the menu interface, rotate knob to move cursor on "Volume" option as Figure 3-2;

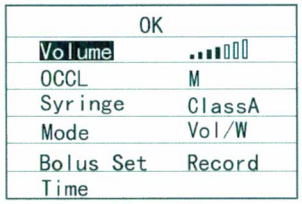


Figure 3-2

2) Press rotary knob and then rotate it to adjust the voice volume;

3) Press rotary knob again to confirm selection.

3.2.2 Occlusion Pressure

1) On the menu interface, rotate knob to move cursor on "OCCL" option;
2) Press rotary knob and then rotate it to choose H (high), M (medium) or L (low);
3) Press rotary knob again to confirm selection.

3.2.3 Syringe Brand

1) On the menu interface, rotate knob to move cursor on "Syringe" option;
2) Press rotary knob and then rotate it to choose a syringe brand;
3) Press rotary knob again to confirm selection.

3.2.4 Infusion Mode

1) On the menu interface, rotate rotary knob to move the cursor on "Mode" option;
2) Press rotary knob and then rotate it to choose among Simple, Vol/T or Vol/W;
3) Press rotary knob again to confirm selection.

Simple Mode:

1) If Simple Mode is selected, return to the main interface as Figure 3-3;

Figure 3-3

Figure 3-4

2) On the main interface, rotate knob to move curse on "RATE" option and press knob to begin adjusting rate as Figure 3-4.
3) Rotate knob right or left to increase or decrease rate value. The "STOP/SHIFT" also can also be used to shift cursor;
4) After setting, press rotary knob again to confirm;
5) (If necessary) On the main interface, rotate rotary knob to move the cursor to "Limit" and press it to adjust limit volume through rotating rotary knob and "STOP/SHIFT" button.
6) To ensure infusion safety, user is obligated to check each parameter's accuracy before starting infusion.

Vol/T (Volume/Time) Mode:

1) If Vol/T Mode is selected, return to the main interface;
2) On the main interface, rotate knob to move curse on "RATE" option and press knob to begin adjusting time and volume as Figure 3-6;

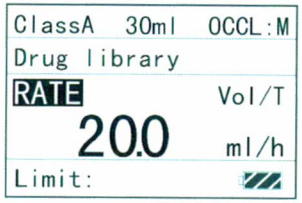


Figure 3-5

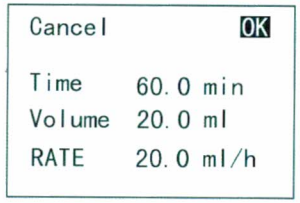


Figure 3-6

3) The infusion rate will be automatically calculated according to the format (Rate=volume/time).
4) After all parameters are set completely, move curse on "OK" option and press knob to save current parameters and back to main interface. If there are setting errors or do not want to save current settings, move cursor on "Cancel" option and press the knob to cancel current selection.
5) To ensure infusion safety, user is obligated to check each parameter's accuracy before starting infusion.

Vol/W (Dosage/Weight) Mode:

1) If Vol/W Mode is selected, return to the main interface;
2) On the main interface, rotate knob to move cursor on "RATE" option and press knob to begin adjusting parameters as Figure 3-8;

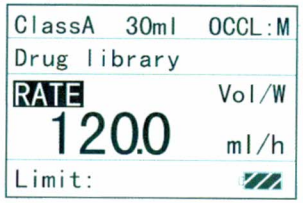


Figure 3-7

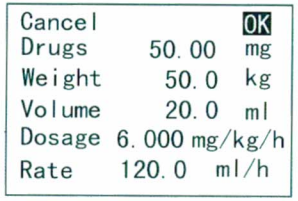


Figure 3-8

3) Drug amount: move cursor on "Drugs" option and then press knob to adjust value in accordance with clinical treatment needs.
4) Patient's weight: move cursor on "Weight" option and then press knob to adjust value. The weight unit is default as "Kg". After adjustment, press knob to save selections.
5) Drug volume: move cursor on "volume" option and then press to adjust volume value. After adjustment, press knob to save selections.
6) Dosage: move cursor on "Dosage" or "Unit" option and then press to adjust value. Total 7 units are available: ng/kg/min, ug/kg/min, mg/kg/min, g/kg/min, ug/kg/h, mg/kg/h, g/kg/h. (Note: If the dose unit is changed, the unit of drug amount will change accordantly.) After adjustment, press knob to save selections.
7) The infusion rate will be calculated automatically after all relative parameters are set (rate=volume×weight×dosage/drugs);
8) After all parameters are set completely, rotate rotary knob to move the cursor to "OK" and press it to save the setting.
9) Follow the same instructions in Simple Mode to set the limit volume.
10) To ensure infusion safety, user is obligated to check each parameter's accuracy before starting infusion.

Attention:

- To ensure safety during the infusion process, please check all the parameters one by one after setting, to make sure the parameters in line with clinical treatment needs. If the parameters exceed specified range, the syringe pump will give prompt "Wrong setting" to remind users to reset.
- The syringe pump records the settings of last infusion therapy automatically. There is no need to set again for the same infusion parameters next time.

3.2.5 BOLUS setting

1) On the menu interface, rotate knob to move cursor on "Bolus Set" option;
2) Press knob to enter sub-interface as Figure 3-10 and then rotate knob to move cursor on the syringe size that intended to change;

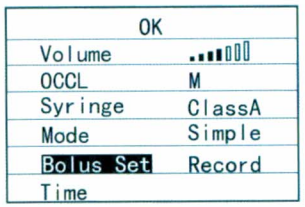


Figure 3-9

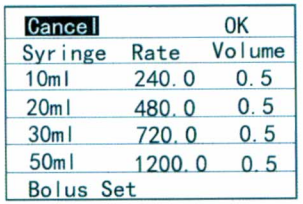


Figure 3-10

3) After select the syringe size, press knob to confirm changing its Bolus rate first and then press knob again to confirm change its Bolus volume;
4) After all parameters are set, move curse on "OK" option and press knob to save current parameters. If there are setting errors or do not want to save current settings, move cursor on "Cancel" option and press the knob to cancel current selection.

3.2.6 Record

1) On the menu interface, rotate knob to move cursor on "Record" option;
2) Press knob to enter the records checking interface;
3) Rotate knob to check every infusion event records, including start time, end time, drug name, infusion rate, volume, etc.
4) The machine can store at least 2000 records.

3.2.7 Time Setting

1) On the menu interface, rotate knob to move cursor on "Time" option;
2) Press knob to enter the interface as Figure 3-12;
3) Move the cursor to time unit (Hour, Minute, Day, Month, Year) which needs resetting.
4) Press rotary knob and then rotate it to set the time;
5) Press rotary knob to save the setting;
6) Rotate knob to move cursor to "OK" and press it to return to menu interface.

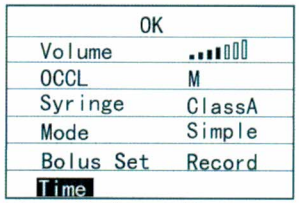


Figure 3-11

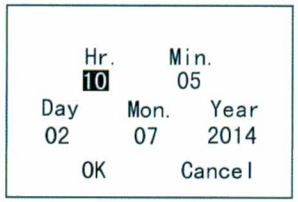


Figure 3-12

3.3 Drug Library

1) Select drug:

- On the main interface as figure 3-13, move cursor on "Drug library" option and then press knob to enter the drug catalog interface as figure 3-14;
- Under catalog interface, rotate knob select a catalog and then press knob to enter sub-interface as figure 3-15 to choose a specified drug.

Figure 3-13

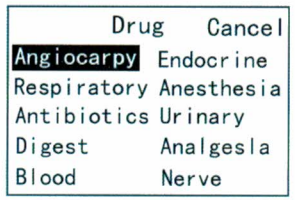


Figure 3-14

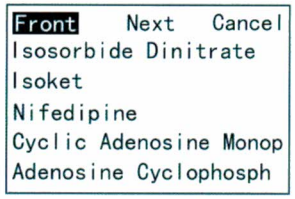


Figure 3-15

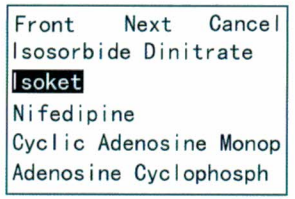


Figure 3-16

- Rotate knob to choose and press knob to confirm. After confirmation, the pump will automatically back to main interface.

- If it is under Vol/T or Vol/W mode, a rate setting interface will display after select a specific drug. Set the infusion rate according to instructions in 3.2.4.
- The drug name will be saved with infusion mode when this infusion event is finished.

2) Cancel drug:

- On the main interface, move cursor on "Drug" option and then press knob to enter the drug catalog interface;
- Directly move cursor on "Cancel" option and then press knob to confirm cancelling current drug selection.

3.4 KVO

1) After normal infusion is completed, the pump will enter KVO mode automatically at default rate 1ml/h. the KVO indicator will light on.
2) If KVO rate need to change, at shutdown state, press "START" and hold on whilst turn on the power switch at the back of pump, the pump will enter the password interface.
3) Enter the password "010.0" by rotating knob and pressing "STOP/SHIFT" button.
4) Rotate the knob to adjust KVO rate. After adjustment, press knob to confirm and back to main interface.

3.5 Clear

Press "STOP/SHIFT" and "SILENCE" at the same time, the total infusion volume shown on the digital display screen will be zeroed.

3.6 Bolus Function

1) This function is used to temperately change the infusion rate while the pump is working.
2) Press and hold on STOP/SHIFT button and press the knob at the same time, the setting interface will jump out, refer to scetion 3.2.5 for more setting details;
3) While the pump is normal working, double-click the "BOLUS" button to enter the Bolus mode. On this condition, the pump will run according to preset Bolus rate and volume, the main interface will show words "Bolus injection".
4) While bolus running, the buzzer will sound a beep every 0.5ml until the preset bolus volume is finished.
5) The pump will automatically stop Bolus mode and return to normal working after preset Bolus volume is finished. The Bolus volume will be counted into the total infusion volume.

3.7 Purge

- When the pump is under non-operation state, double-click "BOLUS" button and hold on to enter fast forward mode. This function is used to remove airs in the syringe and extension tubing.
- During the purging operation, the liquid volume discharged will not be added up into the total infusion volume.
- Refer to the 1.1.5 for more Purge specifications.

Attention:

- Make sure airs in the syringe and extension tubing are removed completely before starting infusion. Otherwise, there may be dangers

4. Operation

Working Procedures:

Power on	Press "ON/OFF" rocker switch on the back of pump to turn the pump on;
Install syringe	Install syringe;
Choose the syringe	Choose syringe brand according to the current usage;
Select injection mode	Refer to 3.2.4 to select the infusion mode;
Set the parameters	Set the parameters refer to chapter 3;
Exhaust air	Manually discharge air in the syringe and tubing;
Connect to patient & start injection	Press the "START" button to start infusion after connecting extension tube to the patient;
Injection finishes	Press the "STOP/SHIFT" button to finish infusion;
Remove syringe	Disconnect pump from the patient, and then remove the syringe;
Power off	Press the "ON/OFF" rocker switch to switch pump off.

4.1 Power On

1) After connecting to AC mains power, the power indicator will light on in green. As switching the pump on by pressing the rocker switch on the backside, the pump

will enter self-testing mode:

- First, the system loudspeaker emits a "Di-Di-Di Di-Di" sound, when the loudspeaker self-testing is completed;
- Then the red and yellow alarm lights light up and then off, when the alarm light self-testing is completed;
- Last, the buzzer will sound a beep when the buzzer self-testing is completed;

2) After successful self-testing, the pump will display the main interface shown as figure 4-1. However, do not use the pump if any abnormality occurs in self-testing mode.

Figure 4-1

3) If turn on the pump without connecting to AC mains power, a prompt of "AC power has been pulled out" will be generated. And the pump will work with inserted battery. The power indicter is in blue at this condition.

⚠Caution:

- Please carefully observe the self-testing condition to make sure the loudspeaker, alarm light and buzzer are successful self-tested. Otherwise, do not use the pump.
- Only all faults are removed, it can be used normally and safely.

4.2 Install Syringe

1) Fill the syringe with drug liquid and then connect the syringe to extension tube.;
2) Pull out the Barrel Clamp and rotate it clockwise or anti-clockwise 90° to fix it;
3) Squeeze the Plunger Release Levers to move the pushing block outside;
4) Properly place the syringe into its position with its flange inserting into flange clip;
5) Rotate the Barrel Clamp backward 90° to clamp the syringe barrel firmly;
6) And then squeeze the Plunger Release Levers to move the pushing block inside until the Plunger Holders can hold the syringe plunger;
7) Make sure the syringe is installed properly and firmly and then adjust relevant infusion parameters.
8) After all parameters are set (refer to section 3 for more adjustment details), double-click the "BOLUS" button and hold it to discharge the air in the tubing until liquid flows out the needle.
9) After discharging air in tubing, connect the needle into patient and press "START" button to infuse.
10) Replacement or reinstallation of syringe: if the administration sets need to be replaced or reinstalled, please press "STOP/SHIFT" button to stop infusion and then remove the old syringe and install a new one according to the above steps 1~9.

Attention:

- After the syringe connected with extension tubing is installed on the pump, please raise the needle vertically to prevent liquid free-flow.
- Make sure the air in tubing is discharged completely.
- Under single fault condition, need manually discharge the air in tubing if machine's purge function is unavailable.
- All parameter settings are locked and cannot be adjusted during infusion. Users can reset the parameters only while pump stops working.

4.3 Choose Syringe Brand

- Please refer to the contents in 3.2.3 to select right syringe brand which is calibrated.
- If the syringe brand intended to use is not calibrated, calibration should be performed before using. Detailed steps refer to 5.1.
- Always verify that the syringe brand selected is what is actual in use.

Attention:

- When using other syringes not recommended by our company, must confirm the relevant essential performances (such as accuracy and pressure) on the pump. Otherwise, our company will not be responsible for the performances and corresponding alarm functions.

4.4 Select Infusion Mode

Select the infusion mode according to section 3.2.4.

4.5 Discharge Air

- While the pump is non-operation, double-click the "BOLUS" button and hold on until all the air bubbles have been removed from the syringe and extension tubing.
- Purge volume is not counted into total infusion volume.
- About the Purge rate, please refer to the contents in 1.1.5.

Attention:

- To avoid hazards caused by air infusion, always discharge all air in syringe and tubing before connecting to patients.
- When exhaust air, must disconnect the pump from patients to avoid safety hazards.

4.6 Set Parameters

After exhausting air, set the infusion parameters in accordance with actual clinical needs. Different infusion modes have different specific parameters.
For details, please refer to Chapter 3 and 1.1.5.

4.7 Start Infusion

Connect pump to patient after air is completely discharged and infusion parameters are set strictly in line with clinical treatment needs.

- Press "START" button to start infusion.
- Always verify that all parameters shown are in consistency of actual needs.

Attention:

- Should frequently check the connection between the syringe, extension tube, pump and patient, before start infusion.
- Comply with the instructions for use to execute infusion.

4.8 Infusion Finished

- Infusion had been finished or infusion of limited amount finished.
- Or press the "STOP/SHIFT" button to stop infusion and then disconnect pump from patient

4.9 Remove Syringe

Pull out the syringe barrel clamp and rotate it clockwise or anticlockwise 90° and then clench the release levers to pull the pushing block outside. Lastly, remove the syringe from pump carefully.

4.10 Power off

- Turn off the pump by pressing rocker switch on the back of machine.
- Operation data and parameters are automatically saved.

5. Accessibility

5.1 Calibration

Please perform calibration prior to use of any new syringe brand (10ml, 20ml, 30ml and 50/60ml). There is no need to calibrate again when the same brand of syringe is used next time.

- Pull the syringe plunger to its largest scale (e.g. pull the 50ml syringe to the scale of 50ml) and install the syringe properly.
- Under shutdown state, press "START" button and hold on, whilst turn on the power switch at the back of pump, the pump will enter the password interface as Figure 5-1. Enter the password "012.0" by rotating knob and pressing "STOP/SHIFT" button.
- After password entry, enter the setting interface as Figure 5-2.
- Press knob and rotate it to select Class A, B or C and press knob again to confirm the selection. And then move the cursor to "OK" and press knob to start the calibration.
- After the calibration is completed, the pump will automatically return to main interface.

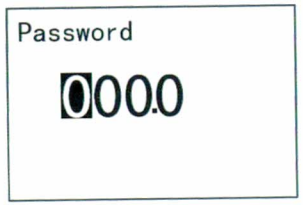


Figure 5-1

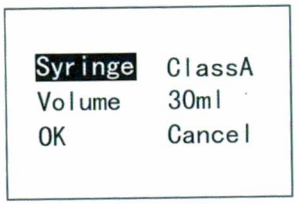


Figure 5-2

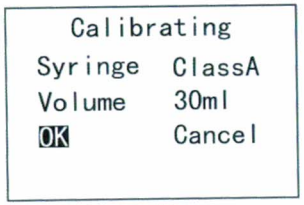


Figure 5-3

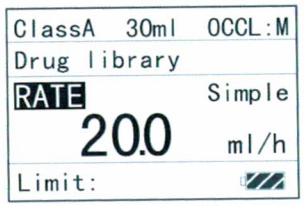


Figure 5-4

Attention:

- Always check the consistence of syringe size recognized by system and size displayed on the calibrating interface.
- Always ensure the syringe brand in actual use is the same as selection.

5.2 Restore Factory Setting

At shutdown state, press the "START" button and rocker switch at the same time to enter the password interface, and then enter the password "120.0" by rotating knob and pressing "STOP/SHIFT" button.

After password entry, press knob to confirm and a prompt "whether to restore factory settings" will be given on the interface. Press knob again to reset machine and back to main interface.

6. Maintenance

To avoid device damages, the following rules are intended to be complied with.

Hereby acknowledge that the responsibilities of damages or accidents which are caused by violating following rules should not be taken by our company. This chapter is only for provision of proper materials and methods of maintenance and cleaning of devices.

Please make sure no dust on the devices and any other accessories.

6.1 Regular Cleaning

- Before cleaning, must shut down the device and disconnect the AC power.
- Regularly conduct cleaning every 3 months; the cleaning frequency should be increased if the devices are used in a place with serious environmental pollution or large wind and sand or there is obvious dirt on the pump surface.
- Clean the devices with 95% alcohol solution and disposable wet wipes. Never use the corrosive chemical cleaners in that they can damage the plastic parts of devices;
- Use a dry soft cloth to clean the AC interface and other connectors, and make sure the socket and interface are dry before cleaning. Never use abrasive materials such as steel balls or silver polish to clean devices.
- It is forbidden to sterilize by means of using equipment such as autoclave. Do not use dryer or similar product to dry devices.
- If liquid spills on the pump, please check if the device is working normally; if necessary, should conduct tests of insulation and leakage current.
- Must prevent liquid entering the device enclosure; dry treatment must be conducted before reusing the devices to ensure safe and normal work.

6.2 Routine Maintenance

6.2.1 Battery Maintenance

The rechargeable Li-battery is equipped to enable the devices can work normally in the case of transferring patients in hospital or sudden interruption of power. Once connected to AC power, the battery can be charged no matter the device is power on or off.

If battery is charging while the device is on, the battery icon is displayed on the right corner. When the icon is still with full levels, it indicates that the battery is fully charged. Only charge the battery inside the device.

The battery will be activated to supply power for the pump automatically if there is power failure or interruption of mains supply.

1. If it is the first time to use battery, a complete optimization cycle should be implemented as following steps:
   - under the condition that mains will not be interrupted, continuously charge the battery until it is fully charged;
   - and then start the device at any running speed to exhaust the power of battery;
   - Charge the battery again until it is fully charged.
2. When the duration of battery running is obviously shorter than before, battery optimization should be conducted as well.

Optimize the battery as following steps:

- Press the STOP/SHIFT button to stop infusion. When the pump stops working, disconnect the connection between patients and pump;
- Shut down the pump and connect it to AC power to charge the battery continuously until battery is fully charged;
- Disconnect the power and turn the pump on, then operate the pump at any running speed to discharge the battery until the pump shut down;
- Connect the pump to AC power again to charge the battery continuously until battery is fully charged.

3. If do not use the pump for a long time, please charge the battery every 3 months to avoid battery damages.
4. The essential performances of battery are to decline as time goes by. Therefore, please conduct inspection to battery essential performances once every 3 months (inspection procedures are the same as second optimization steps 1)- 3)). Notices: The running speed is fixed at 5ml/h; record the actual running time and compare it with the time specified in manual; if the actual running time of battery and alarm time of battery low/empty (after being fully charged) are shorter than the specified time, please contact service personals to replace the battery.
5. If the battery cannot be charged or discharged normally, please conduct service personals for help.

⚠Caution:

- Do not expose battery to excessive temperature, which may cause explosion.
- Put the battery out of children's reach.
- Only use the battery specified by manufacture.
- The support time of battery is affected by using time, running speed, working

environment and not fully charged.

6.2.2 Device Maintenance

- Keep the device dry before reuse. It is highly recommended that the device should be maintained once every 3 months.
- Make sure that the keyboard panel is always clean and dry.
- When replacing the fuse, please make sure the specification of the replaced fuse is the same as the specification (T2AL/250VAC) that specified in this manual. If using fuse with different specification, it may burn out immediately, and even cause damages to device.

⚠Caution:

- Should not perform maintenance when the pump is running and is connected to the patients.

7. Alarms & Alarm Removal

7.1 Alarm List

The pump will give audible and visual alarms when the alarms occur. Please deal with alarms immediately.

Table 7-1

Alarm condition	Priority	Reasons	Measures
Injection finishes	H	The infusion has been completed	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm.
Injection of limited amount finished	H	The preset limit volume is finished.	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm.
Occlusion	H	There is an occlusion, line knot, or other conditions that cause excessive infusion force.	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm. Check for empty syringe, kinked tubing, etc. Press the "START" button to continue.
		High drug concentration, but with a low occlusion pressure level setting.	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm. Increase the blocking pressure level. Press the "START" button to continue.
Syringe falls off	H	1.Attempt to start an infusion but the plunger release lever is not restoration.	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm. And then ensure
		2.The plunger release lever does not clamp the syringe during operation, causing the syringe to fall off	syringe is installed firmly.
Syringe is improperly installed	H	1.Thesyringe plunger is not properly inserted in place. . 2. Attempt to start an infusion without a syringe in right place.	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm.And then ensure syringe is installed firmly.
Battery empty	H	The battery will run out in at least 3 minutes.	Connect the AC power, the alert self-cancels.
Equipment failure	H	Storage error, pressure sensor abnormality, communication abnormality, etc.	Unable to eliminate the alarm, remove the device from service immediately and contact the manufacture.
Abnormal Operation	H	The motor is running in reverse or the motor runs at an abnormal speed.	Unable to eliminate the alarm, remove the device from service immediately and contact manufacturer
Power failure	H	The external power and battery both fail at the same time.	Unable to eliminate the alarm, remove the device from service immediately and contact manufacturer
Low battery	L	The battery voltage is low	Connect the AC power, the alert self-cancels.
Please note injection soon finishes	L	Remind that infusion is going to finish.	Press the "SILENCE" button to clear the audible alarm or "STOP/SHIFT" button to cancel the alarm.
Forget the operations	L	After the syringe pump is turned on, the unoperated time is more than 2 minutes	Cancel the alarm by pressing any button

7.2 Prompts

1. **Injection begins:** "Injection begins" will be given when press "START" button to start injection.
2. **Setting error**: If the set parameters exceed the specified range, the Syringe pump will give signal "Set error" to remind users to reset.
3. **AC power has been pulled out:** An alarm signal "AC power has been pulled out" will be given when turning pump on without connecting to AC power or disconnecting the AC power during infusion.

7.3 Alarm Threshold and Triggering Time

The occlusion pressure limit of the alarm is: Low (40.0kPa ± 13.3kPa), medium (66.7kPa ± 13.3kPa) and high (106.7kPa ± 26.7kPa). When the syringe pump works at a medium rate (5ml/h) or a low rate (1ml/h), the triggering time of alarm is as below table. Select a proper level of blockage alarm pressure after the occlusion fault is cleared. The maximum infusion pressure during working is less than 150kPa.

Table 7-3 (Syringe: SHIVA 50ml)

Infusion Rate (ml/h)	Occlusion Level	Occlusion (mmHg)	Triggering Time
5	Low	300	<30min
5	High	800	<1h
1	Low	300	<1h30min
1	High	800	<2h30min

Attention:

- The triggering time is the main index of blockage response characteristics. The above data only stand for the test results of the used 50ml syringe of SHIVA brand and extension tube with length 1m during the test. Please kindly note: the triggering time will be affected by syringe manufacturing technique, syringe specification, infusion rate, absorbed volume, length of the extension tube, pressure, etc.
- This series of syringe pump is with pressure release function. To release the block pressure, the motor reverses a certain number of steps while the machine block alarm triggers. Therefore, the pill dosage caused by blockage can be ignored.
- Set the machine to the speed of 5ml / h according to Figure 201.112 IEC60601-2-24 icon connection and running, when it is set to low pressure alarm, the amount of bolus is: 2.5ml; when it is set to high-pressure alarm, resulting the amount of the bolus is 3 ml. (In the case of the anti-bolus function off)

8. Alarm System

8.1 Alarm Priority

1. When multiple alarms conditions occur at the same time, the signal of the light alarm and audible alarm is consistent with the highest alarm level.

2. When multiple alarms conditions occur at the same time, the highest priority alarm is displayed prior to the secondary alarms. In other words, the inferior alarm can be displayed only until higher priority alarms are all released.

3. When the same priority alarms are activated at the same time, the device will process according to the default alarm program.

8.2 Alarm Expression of Sound and Light

Table 8-2

Alarm priority	Sound	Light
Low priority	"Di-Di-Di" Loop alarm	Yellow light is always bright
High priority	"Di-Di-Di—Di-Di—Di-Di-Di—Di-Di" Loop alarm	Flashing red light at interval per 500ms
Information signal	Only human voice prompt	N/A

8.3 Characteristics of Audible Alarm Signals

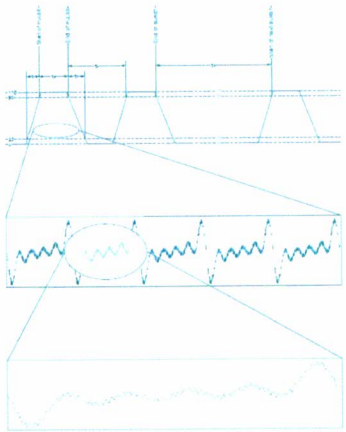
- The auditory alarm signal sound pressure ranges from 45db to 80db.
- The high priority alarm signal sound pressure level >= the low priority alarm signal sound pressure level.
- High priority auditory alarm signals of a particular set of alarm signals shall convey a higher level of urgency than the low priority alarm signals and information signals of that alarm signal set.
- The features of the pulse group of the auditory alarm signals are listed in the table 8-3 and figure 8-1 below:

Table 8-3

Features	High priority	Low priority
The number of pulses	10	3
tr(ms)	18.4	33.6
td(ms)	98.4	182
tf(ms)	18.4	40.8
the interval between the 1st and 2nd pulse(ms)	94.4	206
the interval between the 2nd and 3rd pulse(ms)	94.4	206
the interval between the 3rd and 4th pulse(ms)	287.2	-----
the interval between the 4th and 5th pulse(ms)	94.4	-----
the interval between the 5th and 6th pulse(ms)	974	-----
the interval between the 6th and 7th pulse(ms)	94.4	-----
the interval between the 7th and 8th pulse(ms)	94.4	-----

the interval between the 8th and 9th pulse(ms)	287.2	-----
the interval between the 9th and 10th pulse(ms)	94.4	-----
Pulse group interval(s)	7.42	20.1

Figure 8-1



8.4 Alarm Delay

Table 8-4

Alarms	Alarm Causes	Alarm State Delay	Alarm Signal Delay	Mean
Limited finished	The set Infusion Volume finished completely	10ms	10ms	Negligible
Battery empty	Alarm is activated when the remaining battery life is less than 3 minutes.	10ms	10ms	Negligible
Low Battery	Alarm is activated when the remaining battery life is less than 30 minutes.	10ms	10ms	Negligible
Injection finished	Alarm is activated when the infused volume is equal to the target volume	10ms	10ms	Negligible
Forget the operate	If the Syringe pump is ON and not in operation for more than 2 minutes	2min	10ms	1min
Syringe falls off	The machine draw rod is pulled out	10ms	10ms	Negligible
Equipment failure	One of the prerequisites for system operation does not function correctly	100ms	10ms	60ms
Syringe is improperly installed	The syringe spanner is disengaged from the syringe	10ms	10ms	Negligible
Abnormal operation	The motor rotates in reverse or the deviation between the actual speed and the set speed is outside the error range (by 5ml/h count)	1min	10ms	30s
Injection soon finish	Infusion will be completed within 2min	10ms	10ms	Negligible
Supply mains and internally powered both fail	The external power and battery both fail at the same time.	10ms	10ms	Negligible

Conclusion: The maximum alarm state delay plus the maximum alarm signal delay is less than 3 minutes.

8.5 Alarm Signal Inactivation Status

1. The audible and visual alarm will be terminated or silenced only when the alarms are resolved or paused.

2. Press "SILENCE" button while a high priority alarm occurs, "  " will be displayed on the LCD, the alarm sound will be paused and the red alarm light will still flash at the original frequency; after 1min, the device will restore previous alarm status.

3. Press "SILENCE" button while a low priority alarm occurs, "  " will be displayed on the LCD, the alarm sound will be paused, the yellow alarm light will still bright; after 1min, the device will restore previous alarm status.
4. Press the "STOP/SHIFT" button to terminate alarm signal inactivation states (prompt signal is terminated at the same time)
5. Alarm signal characteristics: duration: 70ms, level: 50dB, frequency: 2.5 kHz.

Attention:

- When the equipment failure and power failure,alarm occur, it's invalid to press the "SILENCE" button.
- The silence state disappears when another alarm is generated.

9. Recommended Inspection and Safe Operation

9.1 Appearance Inspection

- Appearance inspection: no cracks or damages
- Buttons inspection: The button can be pressed smoothly and effectively.
- Display screen inspection: Display normally .

9.2 Power Cable Inspection

- Check the appearance of the power cable. If there is damage to its skin and the connection between plug and socket is improper, please contact an authorized distributer to repair.
- If the power indicator does not light and pump cannot be turned on while connecting to the AC mains power. Please contact an authorized distributer to repair.

9.3 Infusion Accuracy Inspection

Use a graduated cylinder and a stopwatch to check infusion accuracy at least every 3 months. The inspection conditions are shown as table below:

Syringe	Rate	infusion time	Liquid in graduated cylinder
SHINVA 50ml	60ml/h	10min	9.7-10.3ml

When syringe SHINVA is unavailable, the syringes recommended in this manual can also be used for testing after calibration. When the test result exceeds the above cylinder volume range, please consult the service staffs or technicians for calibration.

10. Transport and Storage

When transporting or storing, use original package as possible and adhere to ambient temperature, humidity and pressure described in the Specification section 1.1.5.

11. Disposal

Considering the lifetime of components and safety performance of medical equipment, the service life of pump shall not exceed 7 years calculated from the production date. The expired products should be manipulated according to local laws. It is dangerous to use expired products.

12. Troubleshooting

Table 12-1

Faults	Possible Causes	Possible Remedies
No response after switch-on or black or words missing during setting	1. Low battery 2. Fuse melt 3. LCD display breakage 4. System halted	1. Check the connection of AC power 2. Reboot the pump after shutdown 3. Contact authorized service agent 4. Restore factory settings
Low battery alarm after start up	1. Battery is not timely charged after use 2. Pump is idle for too long	Charge the battery at shutdown
	1. Improperly use the battery 2. Out of battery life	Replace battery
The pole/rod can not be moved smoothly.	There is medicine that stick to the main shipper pole/rod of the syringe pump.	Wipe it with alcohol
Infusion rate is inaccurate.	The syringe brand is not the recommended or the syringe is not correctly calibrated.	Correctly calibrate the syringe
	The hemming of the syringe is not inserted into the hemming trough of the syringe pump.	Correctly reinstall the syringe
There is back blood when infusion begins.	1. The syringe pump is not started after needle head is inserted into patient. 2. The mechanical interval is not eliminated.	1. Start the syringe pump 2. Press “BOLUS” button to push the blood into the vein
Other faults		Reset machine

13. Infusion Features

13.1 Infusion Accuracy

Infusion accuracy is ±3%. If there are following requirements of the syringe under supervision inspection and inspection according to IEC60601-2-24: the tolerance of syringe cross section dimension should be within ±1%; the each connecting part shall not have tiny leakage under the ±13.33kPa system pressure (Liquid leaks under positive pressure, Air enters into the syringe system under negative pressure).

13.2 Infusion Accuracy Features

Trumpet curve indicates the variation range of average flow rate in observation window when the syringe pump combines with syringe.

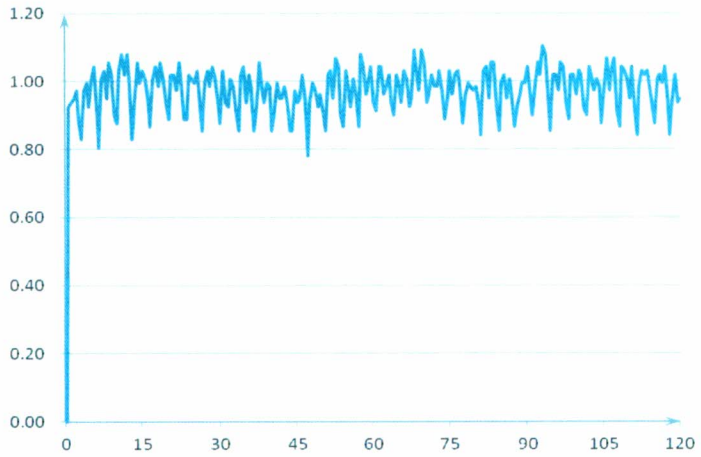
The following results are the testing data according to IEC60601-2-24 and our

company's product standard. Please check relevant National Standard if more information is needed.

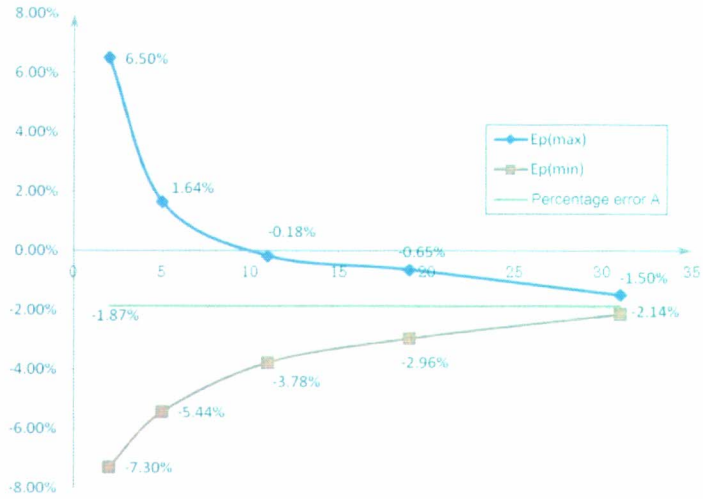
The following curve is the test result of the testing syringe pump and syringe and it can be regarded as an important symbol of comprehensive features of the pump. Please contact the manufacturer's after-sale service department for other relevant information. (The following accuracy is measured under the BYZ-810D(SN:BY-16810120753) model with the use syringe 50ml of SHIVA Brand, when the customer uses the other different syringe, please do the calibration first, and this SHIVA brand accuracy can be used as a reference.)

Attention:

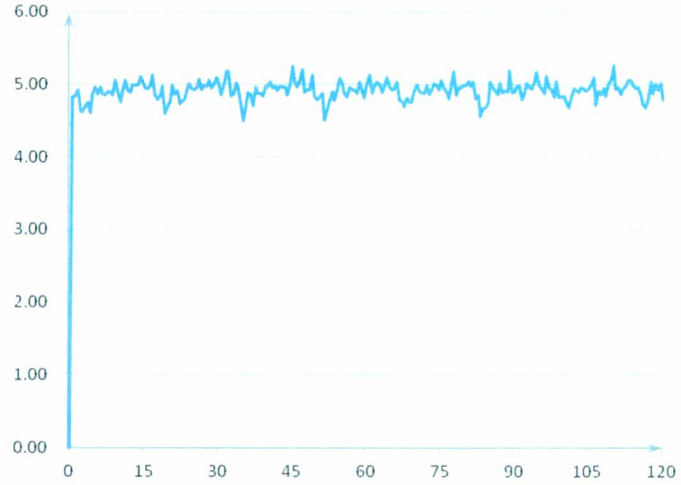
- The infusion accuracy may be affected by ambient temperature, fluid temperature, pressure.
- Examples of conditions under which the syringe pump may fail to maintain the specified accuracy, including short time periods, unusual infusion liquid characteristics, the use of excessively fine bore needles, inadequate protection against the extremes of environmental conditions, occlusion of the syringe set upstream of the syringe pump.



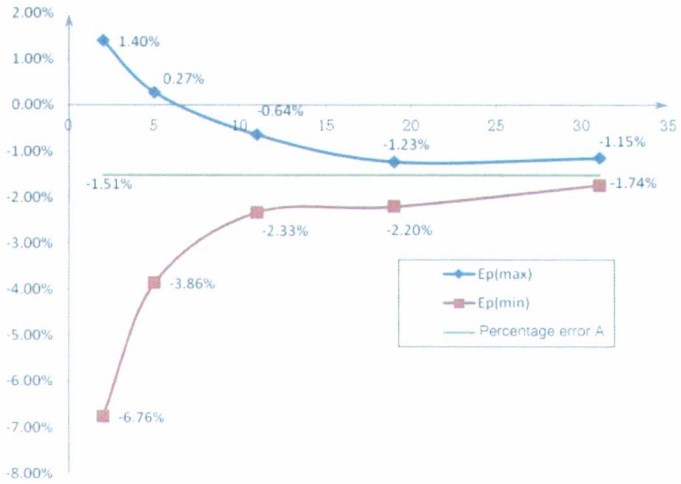
Graph 1: Up curve made from the connected data of 2hrs (50ml syringe min. rate)



Graph 2: Trumpet curve made from the connected data of the 2nd hr (50ml syringe min. rate)



Graph 3: Up curve made from the connected data of 2hrs (50ml syringe medium rate)



Graph 4: Trumpet curve made from the connected data of the 2nd hr (50ml syringe medium rate)

14.Recommended Syringe Brand

No.	Brand	No.	Brand
—01—	BBRAUN	—04—	Class A
—02—	BD	—05—	Class B
—03—	SHINVA	—06—	Class C

15.Packing List

Table 15-1

Item	Quantity (pc)	Item	Quantity (pc)
Syringe pump	1	Operator's Manual	1
Power cable	1		

16.Warranty

BEYOND Medical (the "Manufacturer") warrants to the Original Purchaser that the BYZ-810 series syringe pump module (the "Pump"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one (1) year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and specifically excludes, battery pack, administration sets, extension sets or any other accessory items or equipment used with the Pump.

Subject to the conditions of and upon compliance with this Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any Pump (not including accessories) which is defective if a claim is made during such one-year period. The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This warranty extends only to the Original Purchaser of the Pump. This warranty does not extend to subsequent purchasers. The Original Purchaser may be a patient, medical personnel, a hospital, or institution which purchases the Pump for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, 410208 Changsha, Hunan, China. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE PUMP. If authorized, the Pump must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty: The warranty is void if the Pump has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected (which includes use of service/replacement parts not supplied by BEYOND Medical or its authorized agents, including the battery pack); 3) misused; or, 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the Pump's serial number will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the Pump or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the manufacturer to any representation or warranty, expressed or implied.
2. There is no warranty of merchantability or fitness or use of the pump for any particular purpose.
3. The Pump can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Pump for any particular medical treatment.

The Manufacturer disclaims responsibility for the suitability of the Pump for any particular medical treatment or for any medical complications resulting from the use of the Pump. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Pump.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

17.EMC

The syringe pump complies with the EMC standard EN/IEC 60601-1-2

Note

- Using accessories, cables or sensors not included in standards, may increase the syringe pump's electromagnetic emission, or decreased the syringe pump's electromagnetic immunity.
- Never use the syringe pump close to or stacked with other equipment. When necessary, should observe the syringe pump closely, ensure the syringe pump could running properly under used configuration.
- Need special protection of syringe pump's EMC, also the installation and maintenance should under the environment that meets the following EMC information.
- Avoid using the syringe pump with MIR or similar devices, otherwise the syringe pump may failure and equipment breakdown because of electromagnetic interference.
- Portable or mobile RF communication devices may affect the performance of syringe pump.
- User should install and use the machine by following the EMC information in random file.
- Class A equipment is intended for use in hospital environment, due to conducted and radiated disturbances, in other environments may come with potential difficulty to ensure EMC.
- Using accessories, transducers or cables outside of regulation with equipment and system, may cause the equipment or system increase the electromagnetic emission, or decrease the electromagnetic immunity.

Cable information

Item	Cable length（m）	Whether Shield
Power Cable	1.8	NO

Guidance and manufacturer's declaration – electromagnetic emission		
The models BYZ 810S, BYZ 810, BYZ 810D are intended for use in the electromagnetic environment specified below. The customer or the user of the models BYZ-810D, BYZ-810, BYZ-810S should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models BYZ-810D, BYZ-810, BYZ-810S uses RF energy only for its internal function. Therefore, theirs RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The models BYZ-810D, BYZ-810, BYZ-810S are suitable for used in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is needed: **Warning**: The models BYZ-810D, BYZ-810, BYZ-810S are intended for use by healthcare professionals only. The models BYZ-810D, BYZ-810, BYZ-810S may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and declaration – electromagnetic immunity

The models BYZ-810D, BYZ-810, BYZ-810S are intended for use in the electromagnetic environment specified below. The customer or the user of the models BYZ-810D, BYZ-810, BYZ-810S should assure that they are used in such an environment.

Immunity test	EN 60601-1-2 EN 60601-2-24 test level	Compliance level	Electromagnetic environment - guidance
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	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	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 % U_T (>95 % dip in U_T) for 0,5 cycle 70 % U_T (30 % dip in U_T) for 25/30 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec <5% U_T (>95 % dip in U_T) for 5/6 sec	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 70 % U_T (30 % dip in U_T) for 25/30 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec <5% U_T (>95 % dip in U_T) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Syringe pump Equipment requires continued operation during power mains interruptions, it is recommended that the Syringe pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m,30 A/m	3 A/m,30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a. c. mains voltage prior to application of the test level.

Guidance and declaration – electromagnetic immunity

The models BYZ-810D, BYZ-810, BYZ-810S are intended for use in the electromagnetic environment specified below. The customer or the user of the model BYZ-810D, BYZ-810, BYZ-810S should assure that they are used in such an environment

Immunity test	EN 60601-1-2 EN 60601-2-24 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM banda 6 Vrms in ISM and amateur radio bands	3 V (V1) 6V (V2)	Portable and mobile RF communications equipment should be used no closer to any part of the Syringe pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ d = $[3.5/E1]\sqrt{P}$ 80 MHz~800 MHz d = $[7/E1]\sqrt{P}$ 800 MHz~2.7 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m (E1)	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 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 models BYZ-810D, BYZ-810, BYZ-810S are used exceeds the applicable RF compliance level above, the models BYZ-810D, BYZ-810, BYZ-810S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models BYZ-810D, BYZ-810, BYZ-810S.

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

Recommended separation distances between portable and mobile RF communications equipment and the models BYZ-810D, BYZ-810, BYZ-810S

The models BYZ-810D, BYZ-810, BYZ-810S are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models BYZ-810D, BYZ-810, BYZ-810S can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BYZ-810D, BYZ-810, BYZ-810S are recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)

Rated maximum output power of transmitter W	150 kHz to 80 MHz outside ISM bands $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $[3.5/E1]\sqrt{P}$	800 MHz to 2.7 GHz $[7/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable 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.Manufacturer

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19.EC Rep Information

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