CE
2195

Infusion Pump

BYS-820/BYS-820D

Operating Manual

Please read it carefully before using this product.

Contents

I. Introduction

1.1 Working Principle and Intended Use

Infusion Pump is a kind of volumetric Infusion Pump. Through micro-processor's accurate control over precision stepper motor, it drives mechanical transmission mechanism to spur the peristaltic sheet, to accurately control the infusion rate with the squeezing board and monitor the transfusion process by sensors. Therefore, it is a kind of high-precision intelligent infusion pump.

This instrument is applied in internal medicine, surgical, pediatrics, obstetrics and gynecology, ICU, CCU, operation room and other clinical infusion treatment (but not suitable for blood transfusion). It is especially suitable for clinical treatment that needs long-time accurate control of infusion rate and supervision of infusion process.

1.2 Features

- Audible and visual alarm for occlusion, low battery, infusion finish, door open, wrong setting etc.;
- HD LCD Display, high capacity words, friendly user interface, dynamically display working status;
- Compatible with any brand of infusion sets after correct calibration;
- Preset solution volume to greatly reduce the workload of nurses;
- Work mode: ml/h and drop/min, and these two modes can switch freely;
- Three levels of occlusion: high, medium and low;
- Purge function;
- KVO (keep-vein-open) automatically opens as infusion is completed;
- Power Source: 100~240Vac, 50/60Hz; Internal Battery;
- Automatically record the settings of last infusion (BYS-820D can store 2000pcs infusion records).

1.3 Specifications

Infusion Rate: 1ml/h~1,200ml/h

Flow Rate Accuracy: Within ±5% (after correct calibration)

Mechanical Precision: Within ±2%

Purge Rate: 100ml/h~1,200ml/h (100ml/h step)

KVO Rate: 1ml/h~5 ml/h (1ml/h step)

Infusion Volume: 1ml~9999ml

Total Infusion Volume: 0.1ml~9999.9ml

Occlusion: High: 800mmHg ±200mmHg (106.7kPa±26.7kPa)

Medium: 500mmHg ±100mmHg (66.7kPa±13.3kPa)

Low: 300mmHg ±100mmHg (40.7kPa±13.3kPa)

Alarms: Tube is blocked; There are bubbles; Close the door; Infusion finish; Wrong setting, Low battery, AC power has pulled out; Purge; Data recovering; Data processing; BOLUS running; Forget to operate, etc.

Power Source: 100~240Vac, 50/60Hz; Internal rechargeable Li battery, capacity≥1,600mAh, voltage=11.1V, 4 hours backup time at the rate of 25ml/h (appointed medium rate in GB 9706.27-2005) for the new battery charged for 12hours.

Bubble Detector: Ultrasonic wave detector; detection sensitivity ≥25μL

Fuse: F2AL/250V, 2pcs installed

Power Consumption: 30VA

IP Classification: IPX4

Equipment Classification: Class II, internal power supply, Type CF

Operating Condition: Ambient temperature: +5℃~+40℃;

Relative humidity: 20%~90%

Atmospheric pressure: 86.0kPa~106.0kPa

Transport & Storage Condition: Ambient temperature: -30℃~+55℃

Relative Humidity: ≤95%

Dimension: 140mm (L) × 157mm (W) × 220mm (H)

Net Weight: 1.8kg

Infusion Set: Compatible with any brand of infusion sets after correct calibration

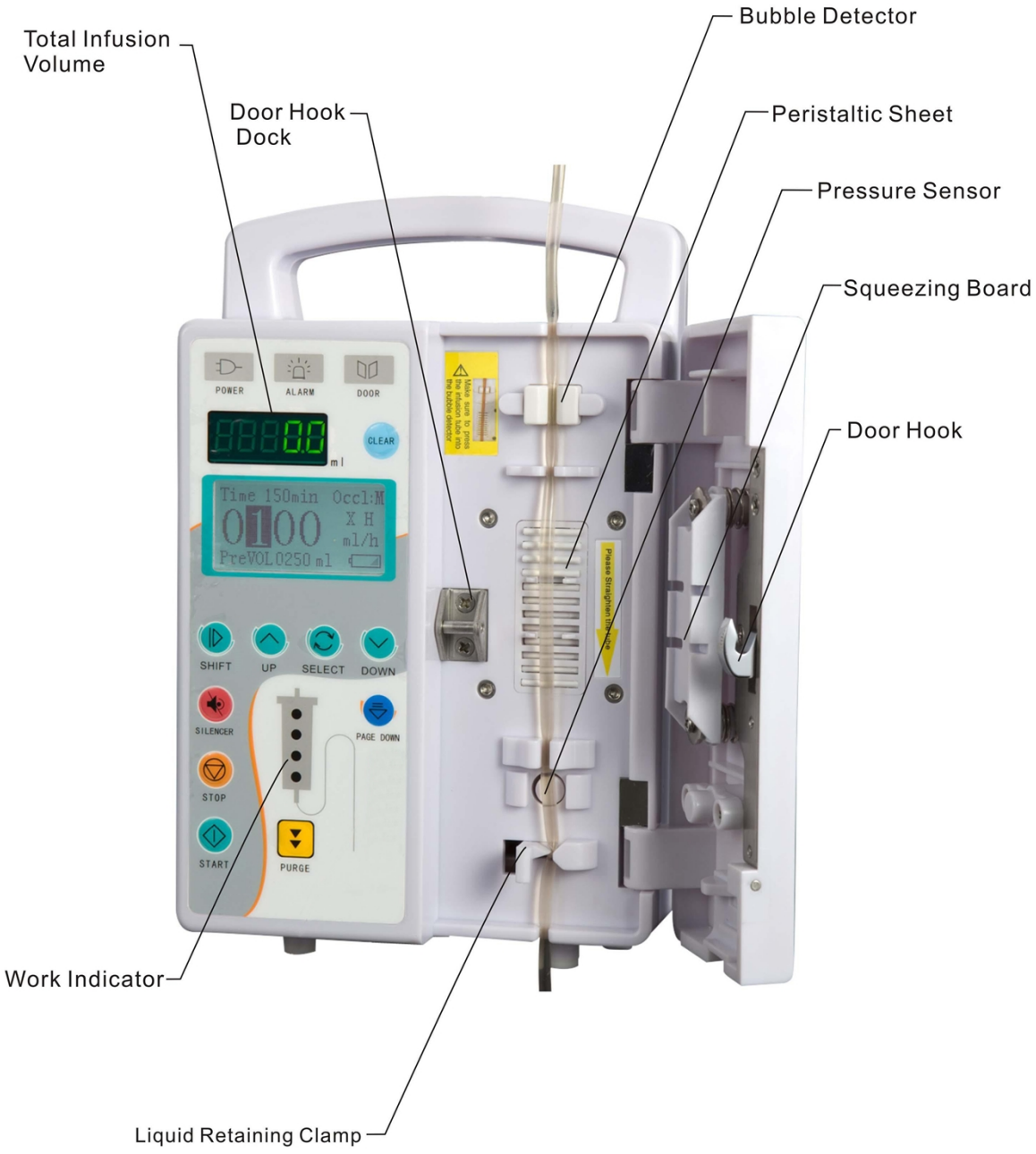
Notes:

- Disposable infusion sets used with this product shall comply with the standards of *GB 8368－2005 Infusion Sets for Single Use, Gravity Feed*. The infusion sets which do not comply with the standards may lead to incorrect infusion rate, incontrollable transfusion, tube breakage etc.
- The accuracy of flow rate is affected by brand of infusion set, working environment, temperature, time, medicine concentration etc. Please calibrate it once its accuracy does not meet requirements.
- The max. default infusion rate is 1ml/h~800ml/h; If the rate 800ml/h~1200ml/h is required, please enter the password "16" at the the interface as Figure 5 to make adjustment (password "001.6" for BYS-820D).

1.4 Symbol Description

Symbol	Description
	Type CF Applied Part
	Class II Double Insulated
IPX4	Drip Proof
	Symbol for the electrical devices according to Directive 2002/96/EC. The device, accessories and the packaging have to be disposed correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.
	93/42/EEC

1.5 Appearance



II. Installation

1. **Pump installation:** This product can neither be used as portable device, nor be placed on the sick bed or table during use. Users should fix the pump to the infusion support at a proper altitude by tightening the screw handle. Before use, please make sure the infusion pump is firmly installed and the infusion support is stable.

2. Connect AC power with the three-pin plug power cord supplied with the product. And use the internal battery only in case of AC power failure. The AC power indicator will be ON when the AC power is used and it will black out when the internal battery is used.

3. **Infusion set installation:** Hang the infusion bottle (bag) filled with medicine liquid on the infusion support. The infusion bottle (bag) should be 20cm~80cm above the cardiac position of the patient. Connect the infusion set to the infusion bottle (bag).

4. Extrude the Murphy's drip bulb of the infusion set with hand to get the liquid in it to be 1/2 of the whole chamber. Exhaust the air in the tube according to normal steps.

5. Pull the door handle upward to open the door, press the infusion tube into the bubble detector, the upper clamping tube trough, peristaltic squeezing sheet, and the lower clamping tube trough from top to bottom. Turn the liquid retaining clamp left, then press the infusion tube into the trough of liquid retaining clamp. Make sure the infusion tube is straight and clamped by the liquid retaining clamp, the Murphy's drip bulb must be placed vertically to prevent air from flowing into the tube so as to avoid liquid leakage or other dangers.

6. Pull the door handle upward and make sure hang it to the door hook dock. Then press the door handle downward to close the door. Please stop working if there is liquid leakage.

7. **Infusion reinstallation:** Please press "Stop" before reinstallation the infusion set. Then follow above instruction to install it. Make sure not install the extruded tube at the position of bubble detector. Otherwise, there may be false alarm for bubbles.

Notes:

- Pump should stop working once the infusion tube continuous used for more than 6hours. Replace it with another section of the infusion tube that not extruded or a new infusion tube. Make sure replace a new one once it

is continuous used for about 12hours. Otherwise, it may cause wrong flow rate and tube breakage, which will cause medicine liquid leakage and bubble entry.

- Manual handling is needed if cleaning the tube can't be finished by purging when the infusion tube is blocked.
- Make sure the Murphy's drip bulb is between the infusion bottle (bag) and infusion pump, the flow regulator is between the infusion pump and the patient.

III. Operation

3.1 Parameter Setting

Turn on the power switch, the infusion pump will give alarm "AC power has been pulled out" to remind users if it is not connected to AC power, the interface is show as Figure 1. Press "Page Down" key and hold on without release for about 3 seconds, it comes into the interface as Figure 2.

Figure 1

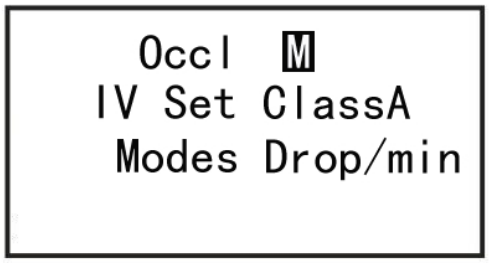


Figure 2

Occlusion: Press "Up" or "Down" key at Figure 2 to select occlusion level: H (high), M (medium) or L (low). Press "Select" key to come to IV line selection as Figure 3, or press "Page Down" key to come into another interface as Figure 4.

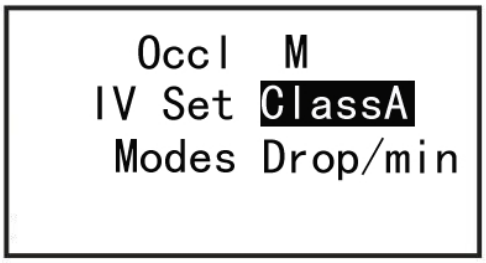


Figure 3

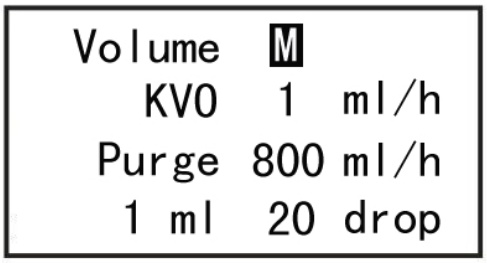


Figure 4

IV Set: Press "Up" or "Down" key at Figure 3 to select IV set. There are 3

recommended brands in total, while IV set of other brands can also be used after calibration. Press “Select” key to come to work modes selection, or press “Page Down” key to come into another interface as Figure 4.

Work Mode: Follow the same instructions as above to select work mode: ml/h or drop/min. Press “Page Down” key to come into another interface as Figure 4.

Voice Volume: Press “Up” or “Down” key at Figure 4 to adjust the voice volume: H (high), M (medium), L (low) or C (clear). Press “Select” key to come to next parameter setting, or press “Page Down” key to come into the interface as Figure 5.

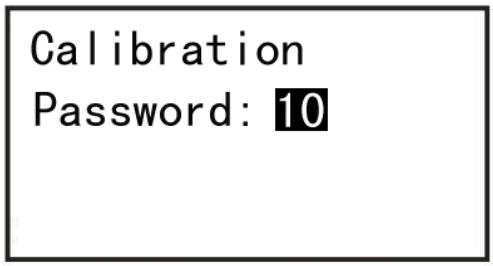


Figure 5

KVO (Keep-vein-open) Rate: Follow the same instructions as above to select KVO Rate from 1ml/h to 5ml/h, 1ml/h step.

Purge Rate: Follow the same instructions as above to select purge rate from 100ml/h to 1200ml/h, 100ml/h step.

Infusion Tube Type Selection: Follow the same instructions as above to select the infusion tube type: 15, 19, 20 or 60drops. Press “Page Down” key to come into the interface as Figure 5, press again to come into main interface.

Note: The selected infusion tube type should be the same as the installed infusion set.

Infusion Rate and Preset Volume: At the interface as Figure 1, press “Select” key to move the cursor to Infusion Rate, Time or Preset Volume, press “Up” and “Down” keys to adjust them.

Drug Library (only for BYS-820D): Press “Page Down” key and hold on without release for about 3 seconds at main interface, it comes into an interface as Figure 6. Press “Select” key to move the cursor to Drug as Figure 7, press “Shift” key to come into the interface as Figure 8. Press “Select” key to move the cursor to the related drug category, like Angiocarpy, press “Shift” key to come into the drug selection interface as Figure 9. Press “Select” key to move the cursor to the related drug, like Isoket as Figure 10, press “Shift” key

to start the transfusion of Isoket and come into the interface as Figure 11.

***Note* (Cancel the drug):** Follow the same instructions as above to come into the interface as Figure 8, press “Page Down” key to exist drug category selection. Thus, the selected drug is canceled.

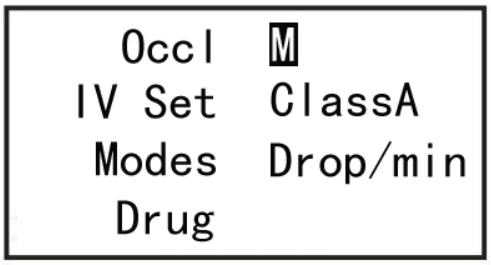


Figure 6

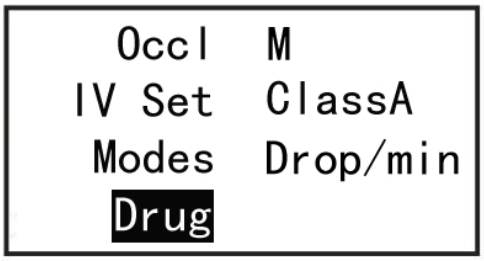


Figure 7

Figure 8

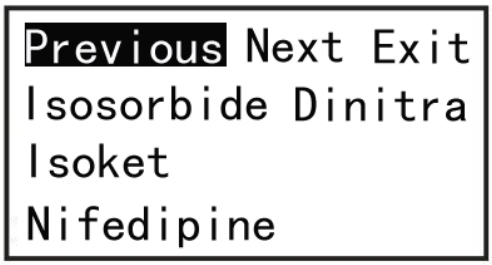


Figure 9

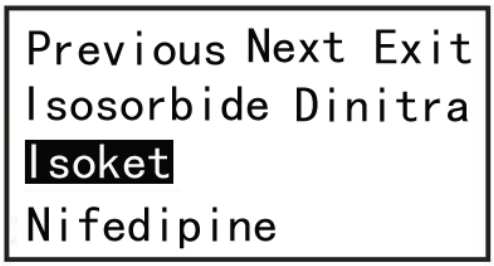


Figure 10

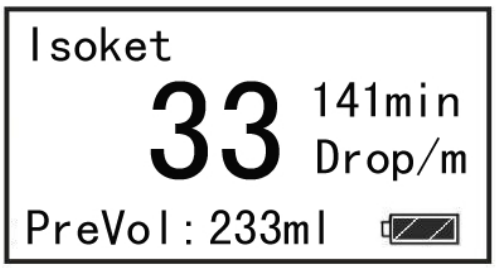


Figure 11

Time (only for BYS-820D): Press the “Page Down” key at Figure 4 to come into another interface as Figure 12, press “Shift” key to come into the interface as Figure 13 to set the time. Press “Shift” key to move the cursor and press “Up or “Down” key to select numbers based on the local time. Press “Shift” key to move the cursor to OK as Figure 14 and press “Select” or “Page Down” key to return to the interface as Figure 12.

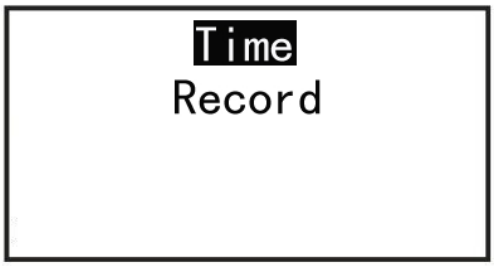


Figure 12

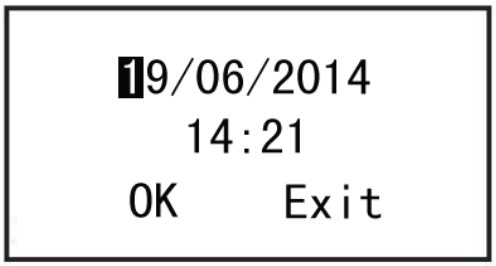


Figure 13

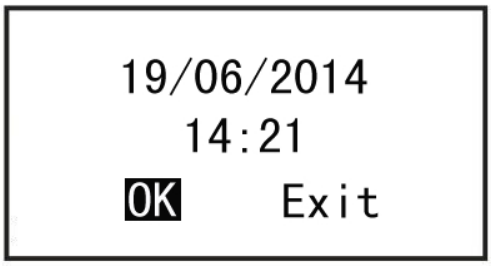


Figure 14

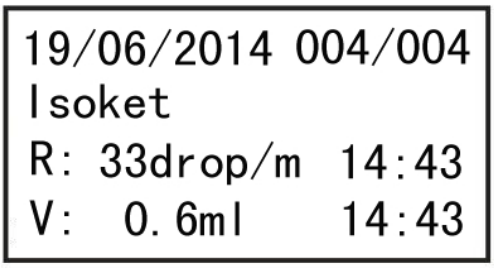


Figure 15

Record (only for BYS-820D): Press the “Select” key at Figure 12 to come to record and press the “Shift” key to come into the interface as Figure 15. Press “Up” or “Down” key to check the different records. Press “Select” or “Page Down” key to return to the interface as Figure 12.

Notes:

- To ensure safety during the infusion, please check all the parameters one by one after setting, which is to make sure the parameters conform to clinical treatment.
- The door cannot be opened during the infusion; otherwise, the transfusion will be out of control and there may be dangers.

3.2 Purge

After parameter settings are completed, please open up the flow regulator of the infusion set before inserting the needle into patient. Press “Purge” key twice without release at the second time to remove the bubbles in the tube until liquid medicine appears at the tip of the needle. During the purging operation, the liquid medicine will not be included into the total infusion volume.

Note: Make sure all the bubbles in the infusion tube are removed before transfusion. Otherwise, there may be dangers.

3.3 KVO (keep-vein-open)

When the preset volume is finished under the normal transfusion, the infusion pump will alarm and turn into KVO automatically, keeping the infusion tube open in case of haemal circumfluence.

3.4 Calibration

Please do Calibration when any new brand infusion set is being used for the first time. The calibration will allow the infusion pump to measure the parameters of that infusion set and store them automatically. There is no need to calibrate again when the same brand infusion set is used later.

Steps:

1. Install the infusion set properly and purge the bubbles.

2. Press “Page Down” key without release for about 3 seconds, press it twice again to come into the interface as Figure 5.

3. Input the Password “12” by pressing “Up” key, then press “Page Down” key to come into the interface as Figure 16.

4. Press “Up” or “Down” key to select IV Line from Class A, Class B and Class C, press “Select” key and “Up” or “Down” key to preset volume (default is 20.0ml) and Rate (default is 600ml/h), then press “Select” key, see the interface as Figure 17.

5. Put the needle into a calibrated measuring cylinder or container, press “Page Down” key to start the first calibration, see the interface as Figure 18.

6. When the infusion volume reaches the preset volume, the first calibration is finished and the interface is as Figure 19. Modify the “Vol Enter” based on the volume in the cylinder or container by pressing “Up” and “Down” keys.

7. Press “Select” key to start the second calibration. After the second calibration is finished, modify the “Vol Enter” based on the volume in the cylinder or container again by pressing “Up” and “Down” keys.

8. Press “Select” key. The system will save the parameters automatically and it comes into the main interface.

Note: BYS-820D will need six times of Calibration.

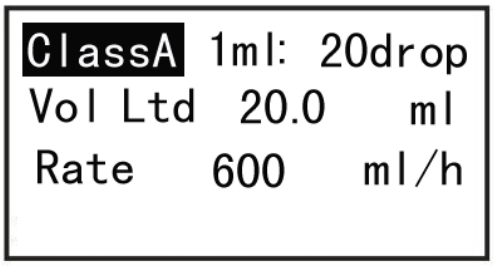


Figure 16

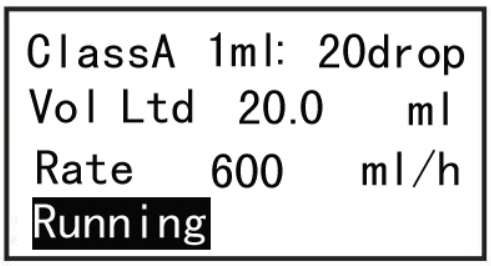


Figure 17

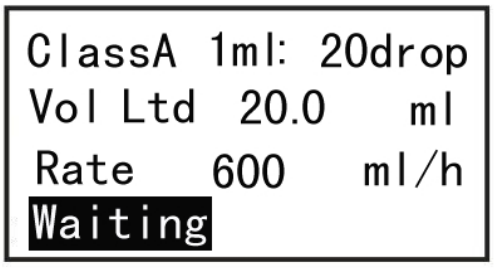


Figure 18

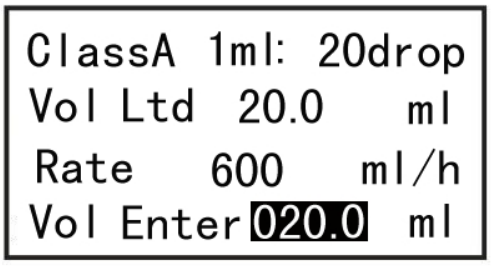


Figure 19

3.5 Clear

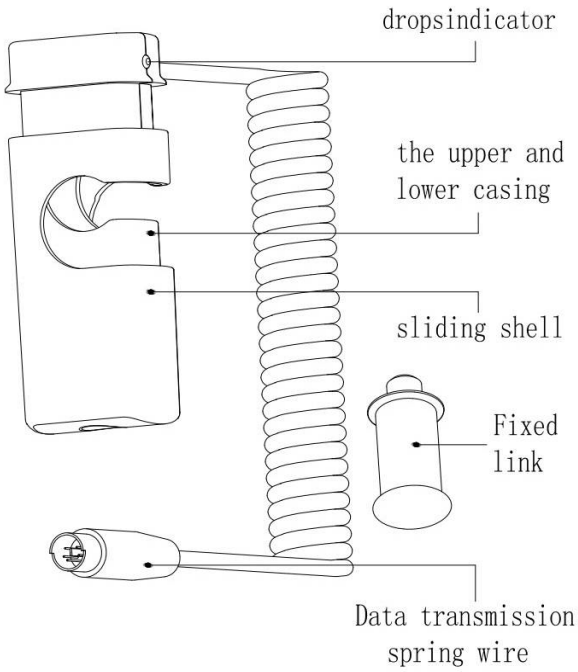
Press “Clear” key and the total infusion volume will be cleared to zero.

3.6 Restore Factory Settings

When the interface is as Figure 5, press “Up” key to input the password “22” (password “120.0” for BYS-820D), then press “Page Down” key to restore factory settings. It comes into main interface automatically.

3.7 Drop Sensor (only for BYS-820D)

- **Structure Chart**



- **Product Introduction**

Drop sensor is the device which test the liquid drops during infusion pump working. It could judge whether there are liquid drops fallen down through the influence of liquid drops to the light, then it could calculate the exact drops fallen down. This product has to be used together with our infusion pump.

- **Installation and Usage**

a. Screw the fixed link of drop sensor into the corresponding tapped hole as photo 01.

b. Plug the data transmission spring wire into the corresponding interface and hang the upper and lower casing of drop sensor onto the fixed link according to photo 02. Now the product is on standby as photo 03.

c. Remove the drop sensor from the fixed link and install it with the drip chamber of infusion set according to photo 04 while using. Please note that the liquid in drip chamber could not be higher than the red index line when installing drop sensor as photo 05.

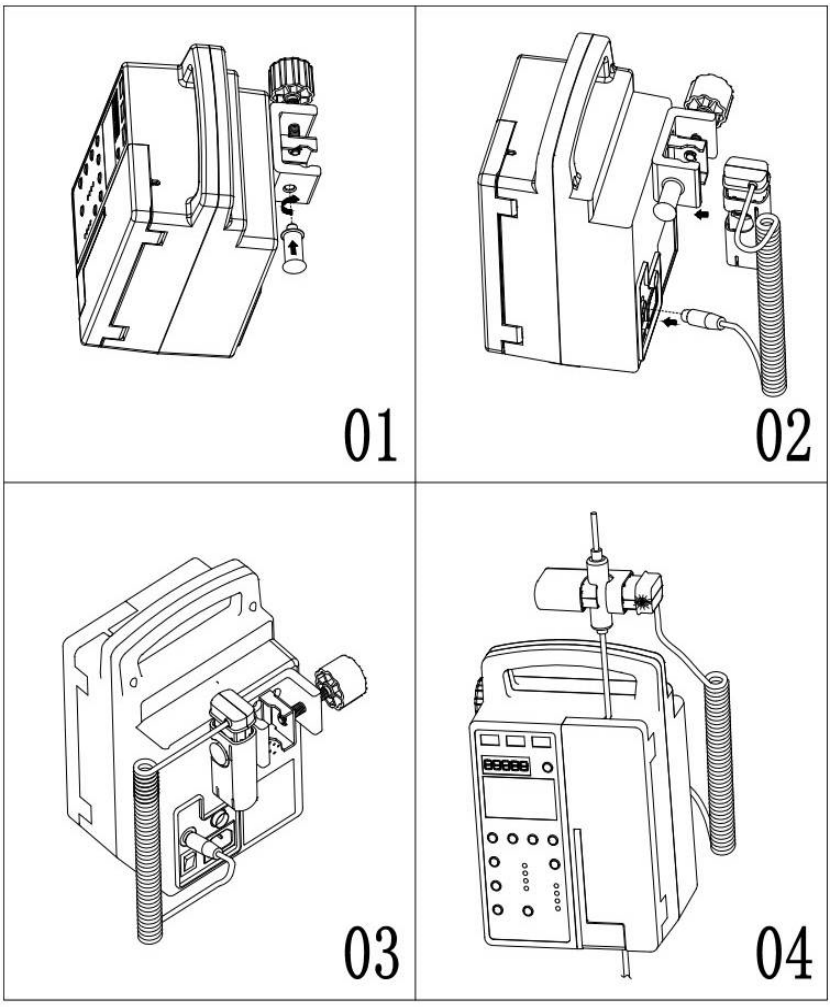
d. Press the start key of infusion pump, the drop sensor starts working at the same time. The drop sensor would blink once when one drop falls down.

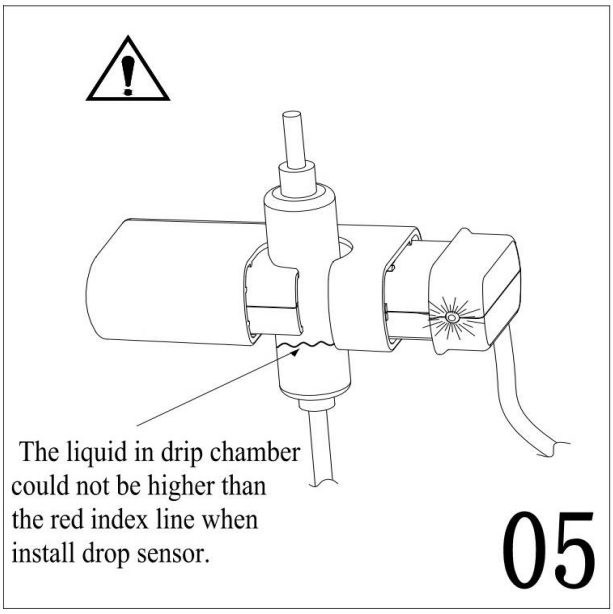
Notes:

- Please avoid direct sunlight so as to make the drop sensor test the drops

correctly.

- Please keep the drop sensor stable to make sure the test accuracy.





IV. Alarms and Disposition

The infusion pump will give audible and visual alarms when the alarms happen. Please deal with alarms immediately. The causes and solutions are given as below:

1. Infusion begins. — Infusion pump will give alarm *"Infusion begins"* when infusion begins.

2. Infusion finishes. — Infusion pump will give alarm *"Infusion finishes"* and switch to KVO automatically when the preset volume is finished. Clear the audible alarm by pressing "Silencer" key or pressing "Stop" key to return to the main interface.

3. Infusion of limited amount finished. — Infusion pump will give alarm *"Infusion of limited amount finished"* when the preset volume is finished. Clear the audible alarm by pressing "Silencer" key or pressing "Stop" key to return to the main interface.

4. Tube is blocked. / Infusion is blocked. — When *the alarm "Tube is blocked" / "Infusion is blocked"* occurs, the infusion pump will stop working automatically. Please check the tube and needle etc. to clear the alarms. Clear the audible alarm by pressing "Silencer" key or pressing "Stop" key to return to the main interface.

※ Alarm Threshold and Triggering Time: There are three levels for the occlusion pressure threshold: high, medium, and low. The occlusion is affected by infusion rate, material hardness of the infusion tube, ambient temperature and blocked part of the tube. The occlusion pressure limit of the alarm is: Low (40.7kPa ± 13.3kPa), medium (66.7kPa ± 13.3kPa) and high (106.7kPa ± 26.7kPa). When the infusion pump works at a medium rate (25ml/h) or the lowest rate (1ml/h), the triggering time of alarm is as below table (the data in the table only represent the results of the infusion set used in the test). Select a proper level of blockage alarm pressure after the occlusion fault is cleared. The maximum transfusion pressure during working is 150kPa.

Infusion Rate	1ml/h		25ml/h	
Selected Alarm Pressure Level	Low	High	Low	High
Alarm Triggering Time	＜1h	＜2h	＜2min	＜3min

Note: When the infusion pump works at a medium rate, the pill dosage does

not exceed 0.8ml when the selected alarm pressure level is low and it does not exceed 1.2ml when the selected alarm pressure level is high.

5. Please note there are bubbles in the tube. — When there are bubbles in the infusion tube and the bubbles are detected, the alarm *"Please note there are bubbles in the tube"* will be triggered, please deal with it immediately. Clear the audible alarm by pressing "Silencer" key.

Notes:

- Under the normal transfusion, when there are bubbles in the tube, the infusion pump will automatically stop working and the alarm will be triggered. Transfusion can be started only after the bubbles are cleared.
- If the infusion pump is started with bubbles in the tube, the alarm will be triggered. Transfusion can be started only after the bubbles are cleared.

6. This is the current volume. — When adjusting the voice volume, the alarm *"This is the current volume"* will be triggered in each volume.

7. Please note the door is open. — When the door is opened during transfusion, the pump will stop working and give alarm *"Please note the door is open".*

8. Please close the door. — If the infusion pump is started when the door is open, the transfusion can't be started and the alarm *"Please close the door*" will be triggered.

9. Infusion device is improperly installed. — If the infusion set is installed improperly, the transfusion can't be started and the alarm *"Infusion device is improper installed"* will be triggered.

10. Wrong setting. — If the setted parameters exceed the specified range, the infusion pump will stop working and give alarm *"Wrong setting"* to remind users to reset.

11. Please do not forget the operations. — If the infusion pump is not be started after proper installation for more than 2 minutes, the alarm *"Please do not forget the operations"* will be triggered to remind users to start the transfusion.

12. AC power has been pulled out. — Infusion pump will give alarm *"AC power has been pulled out"* when turning on it without connecting the AC power or disconnect the AC power during transfusion.

13. Low battery! Please connect external power. — When the battery

voltage is low, the battery cursor on the panel will blink intermittently and the infusion pump will give alarm *"Low battery, please connect external power"*. Press "Silencer" key to clear the audible alarm. The infusion pump can still work for about 30min at the rate of 25ml/h and will stop working automatically at least 3 minutes before power off. The infusion pump will continue to work only after connecting the AC power. At the same time, the AC power indicator will light up and the internal battery will be charged.

14. Infusion speed is abnormal. (only for BYS-820D) — When the drop sensor detects the drip number abnormal, the infusion pump will stop working and the alarm *"Infusion speed is abnormal"* will be triggered.

15. Drop sensor has been pulled out. (only for BYS-820D) — When the drop sensor is not be installed or pulled out at drop/min mode, the infusion pump will stop working and the alarm *"Drop sensor has been pulled out"* will be triggered to remind users to install it properly.

V. Maintenance

- Please read the operating manual carefully before using the infusion pump.
- Please keep the infusion pump dry and clean it with wet rag with cleanser. Do not wash it with organic solvent, such as benzene and butanone etc.
- Please use the infusion set recommended by the manufacturer or after correct calibration to ensure precision.
- Please don't use the high frequency interference equipments near to the infusion pump, like mobile phone etc.
- The infusion pump should be away from vibrations, dust, corrosive or explosive atmosphere, extreme temperature or excessive humidity & all large electrical appliances etc.
- When there are other transfusion systems or accessories connected to the infusion sets, please ensure no air bubbles entry and the infusion sets must be equipped with one-way valve.
- The bubbles in the tube between the infusion pump and the patient can not be detected and they must be removed by manual operation.
- Occlusion alarm threshold is affected by environment and materials of infusion set very much. It may be inaccurate if the material is too bad.
- Fault alarms may occur because the tube wall becomes hard at lower

temperature. So please do not set the occlusion pressure to be “L” (low) when the temperature is lower than 15℃ or the rate is above 30ml/h.

- The charge-discharge times of the internal battery is about 500 times. The infusion pump can work for more than 4 hours at power failure if the battery has been charged for 6~8hours. However, the backup time will be affected by battery usage time, environment and incomplete charging, etc.
- Please conduct charge-discharge inspection for the battery once per month. Please timely connect the AC power when low battery alarm occurs. Please use the AC power as often as possible and the internal battery is only used at AC power failure. Battery replacement should be operated by qualified service engineer.
- Please do not press the pressure sensor hard. Otherwise, it may be damaged.
- The liquid retaining clamp will automatically clamp the infusion tube to prevent flowing when the door is open.
- The preset volume should be close to the volume in the infusion bottle/bag. Usually, it can be 15ml less. Otherwise, transfusion will not stop until bubble alarms occur when the bottle/bag is empty.
- The infusion pump can record the last setting of infusion tube type and brand, KVO rate, Purge rate and occlusion, which can reduce the workload of nurses for the same infusion.
- Overdoses and other accidents may be caused by wrong operation.
- Please replace the door handle if it is broken.
- Please contact qualified service engineer for fuse replacement when the fuse is broken.
- Only professionals and trained people can repair the product. Please contact manufacturer or distributors if the operation key cannot be up again.
- Please stop working and contact manufacturer or distributors if the infusion pump is fault. The maximum infusion volume is 1ml at the single fault condition.
- Please avoid direct sunlight to drop sensor so as to keep it testing drips properly.
- This product can not be used for blood transfusion.

- The infusion pump must be grounded as other equipments.
- The performance of the infusion pump has no relation to gravity.
- Environmental protection: When the life of the infusion pump (including spare parts, such as batteries) expires, please deal with them according to related environmental regulations.

VI. Troubleshooting

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 startup	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
Liquid drops from the tube when pump does not work	1. Adjustive screw of squeezing board loosened 2. Infusion set unqualified	1.Adjust the position of squeezing board (by qualified person) 2. Replace infusion set
Transfusion rate is inaccurate	1. Infusion tube inside of the pump is wrongly installed 2. Infusion set not conforming to the pump	Replace the infusion set recommended by manufacturer or do correct calibration
Other faults		Restore factory settings

VII. Warranty

- Warranty for the infusion pump is two years from the date of purchase. We only charge maintenance costs that's not caused by product quality.
- Warranty for the battery is six months from the date of purchase.
- Considering the life of components and safety, medical devices should not be used longer than 7 years. Expired products should be discarded according to corresponding regulations.

VIII. Packing List

Item	Quantity/unit
Infusion Pump	1
Operating Manual	1
Power Cord	1

IX. Manufacturer

Changsha Beyond Medical Devices Co., Ltd.

Address: Beyond Zone, Lijiacun Rd, Xueshi Street, Yuelu District, Changsha, China.

Hotline : 400-006-7111

After Service: 86 731 88862455

Fax: 86 731 88940857

Post Code:410208

Website: www.csbeyond.com

Email: pump-pub@csbeyond.com

X. EC Rep Information

Wellkang Ltd.

29 Harley St., London W1G 9QR, UK

Version No.: BYS-820/820D/20151202