DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

Instilar 1428 Syringe Pump

User's Manual

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Contents

INSTILAR 1428 syringe pump
User's Manual

1. Product introduction

INSTILAR 1428 syringe pump is a kind of intelligent automatic infusion device, and it is also an automatic drug delivery device for anesthesia infusion developed via application of advanced computer-based control technology and precise mechanical processing technology. This infusion pump has four infusion models (ml/h infusion mode, Continuous flow rate infusion mode, volume & Time infusion mode and Bolus & Infusion mode) for selection, and it is applicable for clinical intravenous infusion. Furthermore, it has such advantages as accurate drug infusion rate, complete function and easy operation.

2. Function

2.1 ml/h infusion mode

Take the easiest and common ml/h as speed unit in clinical, and display the infusion rate and infusion accumulation amount during infusion.

2.2 Continuous flow rate Infusion mode

Conduct infusion at a constant drug infusion rate, with 8 available infusion rate units (mg/h, μg/h, mg/min, μg/min, mg/kg/h, mg/kg/min, μg /kg/h and μg/kg/min).

2.3 Volume & Time Infusion mode

Control the infusion via setting of drug insertion amount and infusion time. The infusion pump automatically calculates the drug infusion rate and then infuses the drug at this speed.

2.4 Bolus & Infusion mode

Control the infusion via setting of weight, drug concentration, induction amount, induction time and maintenance speed, with easy and convenient clinical operation.

2.5 Alarming function

a) AC power failure: After the external power is off, the buzzer in the device will give a sound alarm and the LCD will give a character alarm.

b) Battery Low: When the infusion pump battery power is more than 1% but lower than 15%, the infusion pump gives out the alarm of 'Battery Low!'

c) Battery empty: when the infusion pump battery power is lower than 1%, the infusion pump gives out the alarm of 'Battery Empty!'

d) Drug Almost Empty: When the chemicals are going to be run out in the infusion pump, the infusion pump gives out the alarm of 'Almost Empty!' Besides, under volume and time infusion mode, during infusion when the residual dosage equals the 10% of set volume will give out this alarm too.

e) Occlusion: when the measured value of pressure exceeds the set value of alarm valve, the infusion pump gives out the alarm of 'Occlusion'

f) Drug Empty: when the liquid medicines in the syringe are used completely, the infusion pump gives out the alarm of 'Drug Empty'

g) No Syringe: when the syringe falls off, the infusion pump will send the alarm of 'No Syringe!'

h) Check Syringe: when the specification of the syringe cannot be automatically identified, the infusion pump gives out the alarm of 'Check Syringe!'

i) Syringe Changed: when the inspection of the syringe is changed, the infusion pump gives out the alarm of 'Syringe Changed'

j) Abnormal Motor: When the motor speed stops abnormally, the infusion pump gives out the alarm of 'abnormal Motor'

k) Speed too fast: When the motor speed is too fast, the infusion pump gives out the alarm of 'Speed too fast'

l) Speed too slow: When the motor speed is too slow, the infusion pump gives out the alarm of 'Speed too fast'

m) Plunger Stop: When the pushing pedestal is abnormal, the infusion pump gives out the alarm of 'Plunger Stop'

n) Stand By: If the infusion system long stays in non-infusion state above 5 minutes (paused state is 20 minutes) without any infusion pump operation, the infusion pump gives out the alarm of 'Stand By'

o） Motor Error: when self-testing during turn on the device, if there is something wrong to the motor, the device will automatically give out alarm and display 'Motor Error'.

p) Service Needed: when the device used time get to the service time, the device will automatically give out the alarm and display 'Service Needed!'

q） Pressure Rise: When sudden Rise in pressure during infusion, the device will automatically give out alarm and display 'Pressure Rise'.

r） Pressure Drop: When sudden drop in pressure during infusion, the device will automatically give out alarm and display 'Pressure Drop'.

2.6 AC/DC dual-purpose

There is Li-ion environmental battery which can be repeatedly charged built in this device, thus the infusion pump can be still under normal operation upon power-off. After 10 hours charging, the battery can continue to work for more than 10 hours. After AC is powered off, the system will automatically switch to built-in battery for power supply. When AC is plugged, under the condition of insufficient battery power, the battery will be automatically charged. The battery power is displayed on state column. When the power is to be exhausted, the under-voltage alarm will happen to remind the medical care personnel of plugging AC timely.

3. Technical indicators

3.1 Flow rate range

5ml syringe: 0.1～150.0ml/h;

10ml syringe: 0.1～300.0ml/h;

20ml syringe: 0.1～600.0ml/h;

30ml syringe: 0.1～900.0ml/h;

50(60)ml syringe: 0.1～1200.0ml/h.

3.2 Error of infusion volume

Error of infusion volume: ±2.0%, including ±1％ of mechanical error.

Remarks: Before inspection on infusion accuracy, take an empty breaker, and then weigh it, and record the value A; pump the water into empty breaker, and then weight it after 30min, and record the value B; the error of infusion volume = (B-A-Value shown on machine)/value shown on machine * 100%.

3.3 Pill dosage and pressure alarm level

pressure alarm level	Low (300±100) mmHg	Middle(500±150) mmHg	High (900±200) mmHg
Touch time	≤10min	≤20min	≤35min

Pill dosage (ml)	≤1	≤1.5	≤2.5

The above data is obtained based on B-D 20ml syringe and standard 1.2m extension pipe.

- Test method

1. Touch time

Use B-D 20ml syringe and 1.2m standard extension pipe, set the blocking point at 1.2m position, and running the syringe pump at 5ml/h; record the time from operation start to 'blocking alarm'.

2. Pill dosage

Use B-D 20ml syringe and 1.2m standard extension pipe, set the blocking point at 1.2m position, and running the syringe pump at 5ml/h. When the 'blocking alarm' start, remove the blocking point and calculate the drug amount accumulated in extension pipe due to blocking.

- Affecting factors

The response time of infusion pump on blocking incurred is affected by following factors:

a) Pressure level set – the lower the level is, the earlier the blocking alarm is;

b) Flow rate – the faster the flow rate is, the earlier the blocking alarm occurs;

c) Elasticity of extension pipe – the thicker the extension pipe is, the later the blocking alarm occurs

d) Length of extension pipe – the longer the extension pipe is, the later the blocking alarm occurs.

When the blocking alarm happens in infusion pump, the extension pipe will be expanded due to level and more and more drug liquid accumulated in extension pipe. The higher the pressure grade is set and the thinner and longer the extension pipe is, the more drug liquid will be accumulated in extension pipe.

3.4 Operating condition

a) Ambient environment: +5℃～+40℃;

b) Relative humidity: ≤90%;

c) Power supply : AC100V-245V～50/60Hz; Built-in rechargeable battery: DC 11.1V;

d) Atmospheric pressure: 700hPa～1060hPa;

e) Input power: ≤20VA.

3.5 Overall dimension

Length × Width × Height: 214mm×134mm×94mm

3.6 Weight

2.2kg

3.6 Safety classification

Class IIb, CF type, IP23

3.7 Transportation and storage environment

a) Range of ambient temperature: –20℃～+55℃;

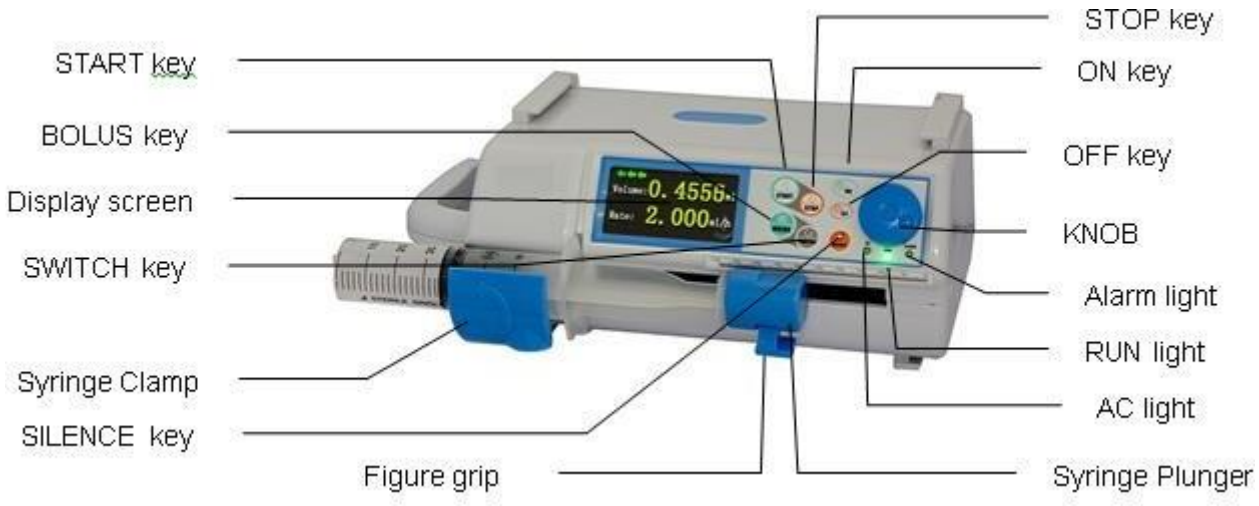
b) Range of relative humidity: 10%–93%;

c) Range of atmosphere pressure: 500 hPa～1060hPa.

3.8 Insurance

Fuse protector: φ5×20, F,1A

4. Introduction on control panel

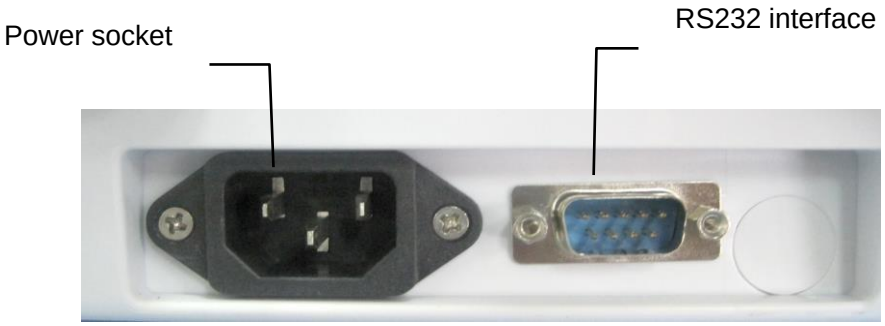


【Figure 1-1】

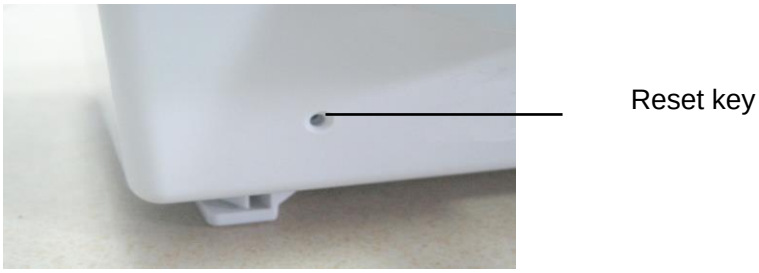
(Table 1) Function table of operation panel of infusion pump

Device name	Function and application
KNOB	There are three operation ways: clockwise rotation, counterclockwise rotation and KNOB pressing, which is applicable for page turning of content displayed, selection of infusion parameter and adjustment of infusion parameter value. During infusion, the infusion rate can be real-time modified under ml/h mode and constant-speed mode, and the typeface page can be switched under other mode. ☆ Clockwise rotation: display backward page turning of content or expand the adjustment value; ☆ Counterclockwise rotation: display forward page turning of content or reduce the adjustment value; ☆KNOB pressing: finish the current parameter setting (confirm the setting); ☆ When the KNOB quickly rotates, adjust the first-bit significant digit during value adjustment; when the KNOB slowly rotates, adjust the last-bit significant digit during value adjustment.
START key	Start the infusion.
STOP key	Press this key to stop or suspend infusion during infusion.
BOLUS key	☆If the system is under a condition that the setting of infusion parameter is completed, press this key (Don't let go), start pre-charging (The pushing device presses the syringe and removes the air in tube), and then loosen this key to complete the pre-charging. ☆If the system is under infusion, press this key (Don't let go), start BOLUS infusion, and then loosen this key to complete BOLUS infusion.
SWITCH key	This key can preset the total infusion amount before infusion under Continuous-flow infusion mode; during infusion, this key can be used to switch typeface page.
SILENCE key	Press SILENCE key to close the alarm sound when the alarm happens. **Long press SILENCE key to lock or unlock the keyboard.**
ON key	Press this key to start the infusion pump when the infusion pump is closed.
OFF key	Press this key to close the infusion pump when the infusion pump is under no-infusion.
Display page	Display the infusion setting parameter, infusion operation parameter, information about infusion state and alarm information etc.

AC light	Light after the device is connected to AC
Alarm light	Light after the alarm happens.
RUN light	Light during pre-fill tube, BOLUS and infusion.



【Figure 1-2】



【Figure 1-3】

Power socket: connected to AC power.

RS232 page: None.

Reset key: In case that the machine can't be operated due to abnormality, it is able to press this key to conduct reset.

Note: The device will shut down after the reset key is pressed, and then the device is powered on via ON key.

5. Operating instructions

5.1 Infusion pump placement

The infusion pump shall be placed on a flat surface, leveled, or fixed on an upright tube, vertical. While in use or in the intervals, it can be carried from one place to another.

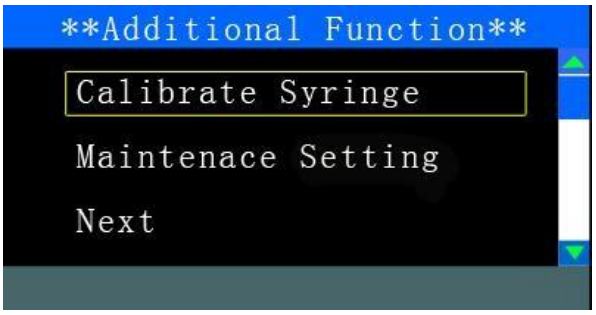
5.2 Switching on and off

When the battery of infusion pump is sufficient or connected to AC, press down the 'ON' button on the panel to start up, after starting up, it will show welcome page(as shown in Figure 2).When the infusion pump kept switch on and under the status of non-infusion, press down the 'OFF' button to switch off.

【Figure 2】

5.3 Additional function

When the infusion pump is under the status of switch off, press on 'KNOB', then 'ON', it will show the expansion function page (as shown in Figure 3). There are 3 options of expansion function, one is 'Calibrate Syringe', the other is 'Maintenance Setting' and' Next'. When select 'Calibrate Syringe', press down the KNOB, it will enter function of auto calibrate infusion (detailed function instructions, see Appendix 2). Select 'Maintenance Setting' will enter the Maintenance signal settings (as shown in Figure 9). Select 'Next' to enter the parameter setting page.

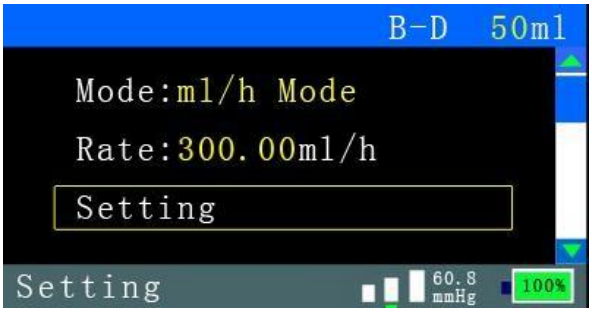


【Figure 3】

5.3.1 Selecting syringe brands

When we use infusion pump for the first time, or use brand of syringe different from prior brand, setting of syringe is needed.

After enter the parameter setting page, turn the 'KNOB', move the cursor to 'Setting' (as shown in Figure 4) , press down 'KNOB' to enter the page as shown in Figure 5, move the cursor to 'Syringe', press down 'KNOB' to enter editing status, turn 'KNOB' to select the needed syringe brand, then press down 'KNOB' to finish selection.



【Figure 4】

【Figure 5】

Built-in syringe brands and specifications of infusion pump please see (Table 2).

(Table 2) List of built-in syringe brands and specifications of infusion pump

Brand	Nominal Capacities	Manufacture
B-D	5ml,10ml, 20ml, 50ml	America
KDL	5ml,10ml, 20ml, 30ml,50ml	China
INTM	5ml,10ml, 20ml,30ml, 50ml	China
Diprifusor	50ml	Germany
B.Br	50ml	Germany
HAYAT	5ml, 10ml, 20ml, 50ml	
MEDSET	10ml, 20ml	
AYSET	20ml	
TYUMEN	5ml, 10ml	Russia
User	5ml,10ml, 20ml, 30ml,50ml	Customize

5.3.2 Auto/Manual definition of syringe

If the user needed syringe is not in the built-in syringe list of infusion pump, user can keep using such kind of syringe by auto-calibrate syringe function or manual define relevant syringe specifications. Detailed introduction, please see Appendix 1.

5.3.3 Set the occlusion alarm level

The operating the same to select syringe brand (See 5.3.1). There are three pressure level: Low, Medium and High, when the pressure change, the color of corresponding column will change too, and at the same time the right side of column will display the current pressure(unit: mmHg).Occlusion sensitivity is adjustable according to customer's request between 100 mmHg to 900 mmHg. The lower occlusion alarm setting, the more sensitive detecting on occlusion condition (Dose and occlusion alarm See 3.3). When the flow rate is equal or faster larger than 300ml/h, the pressure level will automatically change to be high level.

5.3.4 Selecting Bolus Rate

Turn knob to Bolus rate option until the cursor points an exact volume (See Figure 6); and press the key to confirm. Then you can select the flow rate for Bolus infusion by turning the knob.

Bolus rate for 5ml syringe: 150ml/h,

For 10ml syringe: 150ml/h, 200ml/h, 250ml/h, and 300ml/h

For 20 ml syringe: 150ml/h, 200ml/h, 250ml/h, 300ml/h, 350ml/h, 400ml/h, 450ml/h, 500ml/h, 550ml/h,

and 600ml/h

For 30 ml syringe: 150ml/h, 200ml/h, 250ml/h, 300ml/h, 350ml/h, 400ml/h, 450ml/h, 500ml/h, 550ml/h, 600ml/h, 650ml/h, 700ml/h, 750ml/h, 800ml/h, 850ml/h, and 900ml/h

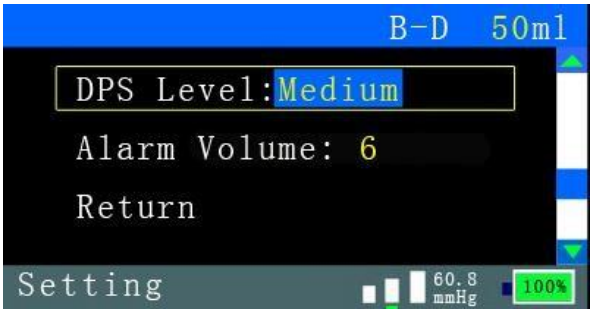
For 50ml syringe: 150ml/h, 200ml/h, 250ml/h, 300ml/h, 350ml/h, 400ml/h, 450ml/h, 500ml/h, 550ml/h, 600ml/h, 650ml/h, 700ml/h, 750ml/h, 800ml/h, 850ml/h, 900ml/h, 950ml/h, 1000ml/h, 1050ml/h, 1100ml/h , 1150ml/h ,and 1200ml/h.

【Figure 6】

In Infusion, start the Bolus function by pressing the 'FAST' button.

5.3.5 Setting DPS level

Move the cursor to 'DPS level' (see figure 7), press KNOB key to edit status, then select the level by turning the KNOW key, last press KNOB to confirm selection.



【Figure 7】

In addition, if want to adjust the DPS level during infusion, press STOP key then press SWITCH key to the DPS level adjustment page, after finish adjustment, press SWITCH key back to last page.

Note: (DPS Dynamical Pressure System) the DPS level means the ability to detect the minimum change. When the pressure sudden change and if the degree of change equal the set DPS level, device will automatically give out alarm and display 'Pressure Rise' or 'Pressure Drop'. The higher level can be detected by the smaller of change. Set the resolution level low / medium / high / off in order to meet the different clinical settings, such as customers do not need this function, you can choose 'OFF' to close.

This function will begin after start infusion 30 seconds, another, the smaller infusion rate the smaller amount of change and difficult to check the change.

5.3.6 Set the alarm volume

Turn the KNOB key move the cursor to 'Alarm Volume' (see figure 8), press KONB key to edit status, select the volume level by turning the KNOB key, then press down the KNOB key to confirm the selection. There are 7 levels can be selected.

If want to adjust the alarm volume during infusion, press STOP key then press SWITCH key to the setting page to adjust it and press SWITCH key to returning.

【Figure 8】

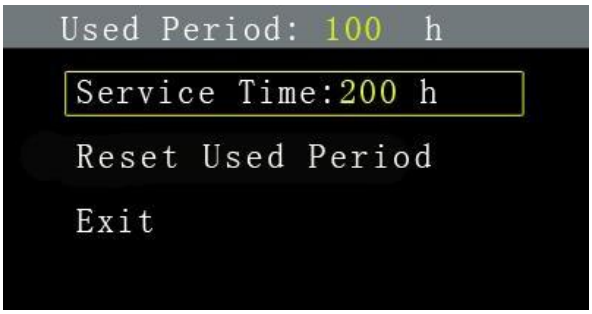
5.3.7 Maintenance signal settings

Under page as shown in figure 3, move the cursor to 'Maintenance Setting', the press down the KNOB key to set the maintenance signal, as shown in figure 9.

'Used Period' means the time from start use the device to now.

'Service time' means the time, set by user, for maintenance. If the accumulated time gets to the service time user set, the device will automatically give out alarm and display 'Service Needed' every time to turn on the device, press the SILENCE key to mute sound. If need to stop next alarm, please adjust the service time or select the 'OK' to item ' Reset Used Period', then the used time will be re-counted again.

Note: the service time is from 20h to 65500h, will increase by 10. If want to stop this function, please select the 'OFF'.



【Figure 9】

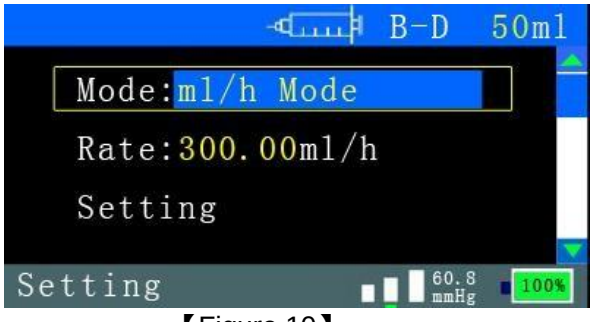
5.3.8 Lock the keyboard function

Press the SILENCE key for 3 seconds to lock the keyboard, then the keyboard will invalid, at the same time lower title bar will display the lock icon  Press the SILENCE key for 3 seconds to unlock the keyboard then the lock icon  will disappear.

5.4 Selecting infusion mode

5.4.1 ml/h infusion mode

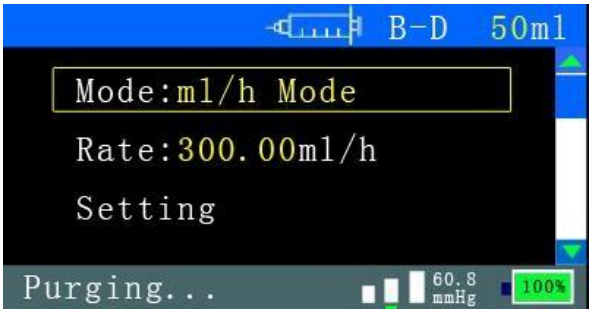
Turn on the pump, turn knob to 'Mode' to select ml/h infusion mode. (See figure 10)



【Figure 10】

5.4.1.2 Purge

In order to ensure the infusion accuracy, the user has to purge the extension tube and the syringe before start infusion. Press and hold the BOLUS key to start purging (The system acquiesce the maximum speed to inject), disentangle BOLUS key and the purging will stop. (See figure 11)

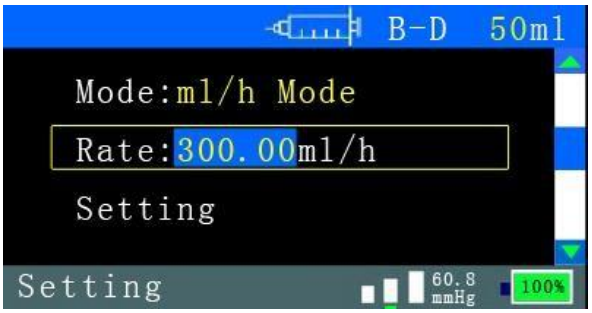


【Figure 11】

Note: When the pump is stop or under the setting page, press BOLUS key will enable purge function. When the pump is infusing, press BOLUS key will enable pill dosage infusion function (BOLUS function).

5.4.1.3 Setting Infusion rate

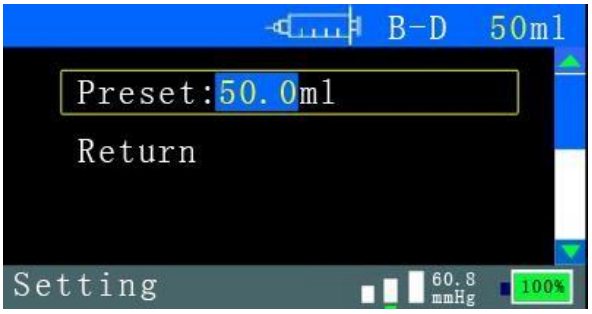
Turn Knob to set the rate, press it to confirm the selection. (See figure 12)



【Figure 12】

5.4.1.4 Preset a total volume

Press down the SWITCH key setting the preset volume, the range can be selected from 0.1ml to 1000ml. After finish setting, turn knob to 'Return' option and press it down to enter the previous menu or press Start key to start Infusion. (See figure 13)



【Figure 13】

If no need to setup a preset volume, please turn knob to the end of anticlockwise direction. Or, turn knob to the clockwise direction to select a preset volume. (See figure 14)

【Figure 14】

5.4.1.5 Start Infusion

Press Start key to start infusion. On the screen, 'Volume' means the total volume, 'Rate' means the current infusion speed; and 'Alarm Press' shows the current setting of occlusion alarm level.(See figure 15)

【Figure 15】

In case of the user needs a big font display on screen for a better looking, please press down 'SWITCH' key during the infusion process. In case of needed to return to the previous display just press down 'SWITCH' key again. (See figure 16)

【Figure 16】

5.4.1.6 Adjust Infusion rate or stop Infusion

In case of the user needs to regulate the current infusion rate, please make sure it is not under big font display page (See Figure 17)

【Figure 17】

Press down the knob to locked the value of infusion rate, rotate knob to select the infusion rate and press down the knob again to confirm operating. The pump will go on infuse to the patient automatically.

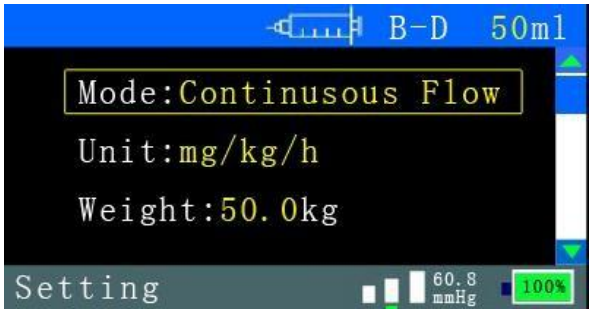
5.4.1.7 BOLUS

During the process of infusion, press down BOLUS key to enable pill dosage function. Release BOLUS key will stop BOLUS infusion. The default infusion rate of BOLUS is 300ml/h. (See figure 18)

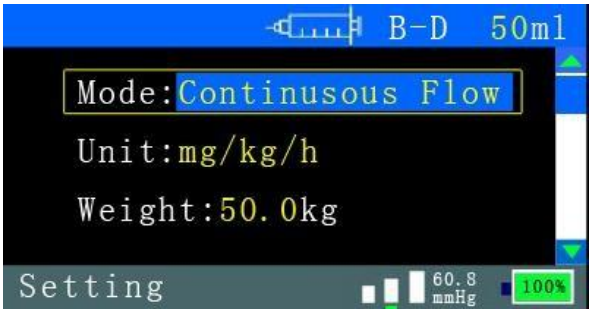
【Figure 18】

5.4.2 Continuous Flow Rate infusion mode

The system has memory function, after switching on, it will show last time infusion mode and setting parameters, if you want to change infusion mode, turn 'KNOB', move the cursor to 'mode' (as shown in Figure 19). Press down 'KNOB' to enter the editing status, turn 'KNOB' to select needed infusion mode, then press down 'KNOB 'to finish setting (as shown in Figure 20)



【Figure 19】



【Figure 20】

The continuous-flow infusion mode provides 9 infusion rate units, select the speed units except ml/h, please enter correctly the patient's weight and dose of needed drug and volume of the solution, the software will automatically calculating drug concentration and speed value of corresponding speed unit, removing the trifles and faults by human. 9 infusion rate units are as follows, the conversion relation of

speeds as shown in the following formulas.

Vmg/h = Vml/h × Cmg/ml

Vug/h = Vml/h × Cug/ml

Vmg/min = Vml/h × Cmg/ml/ 60

Vug/min = Vml/h × Cug/ml/ 60

Vmg/kg/h = Vml/h × Cmg/ml / Wkg

Vug/kg/h = Vml/h × Cug/ml / Wkg

Vmg/kg/min = Vml/h × Cmg/ml / Wkg / 60

Vug/kg/min = Vml/h × Cug/ml / Wkg / 60

V——Speed corresponding to each speed unit, its subscript represents speed unit.

C——Concentration of the drug used, its subscript represents unit of drug concentration, among which, C = M / V, M--- dosage of drug, V---volume of solution.

W——Weight of patient, the unit is kg

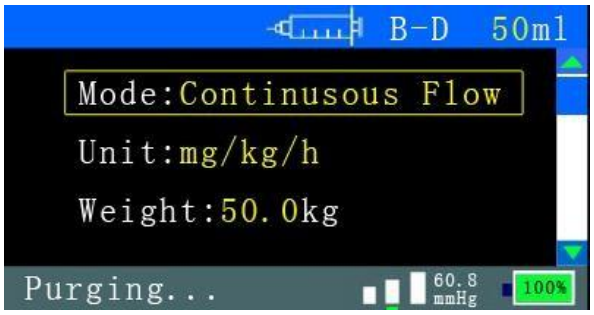
For instance, if the weight of patient is 60 kg, use propofol as anesthesia induction, dosage drug concentration is C= M / V = 10mg/ml, setting the drug dosage is 1.5mg/kg/min, auto calculation process is as follows:

Vmg/kg/min = 1.5； Cmg/ml ＝10； Wkg ＝60 。

Appling formula (5), we can get the infusion rate is Vml/h ＝ 1.5 × 60 × 60 / 10 ＝ 540ml/h.

5.4.2.1 Purging tube

To make the infusion more accurate, before infusion, we can press SWITCH key to purge the tube, to remove air out of syringe and extension tube. Press on 'BOLUS 'button, the infusion pump will begin to purge tube (the max speed as system defaulted), loosen 'BOLUS 'button, the infusion pump will stop purging. (As shown in Figure 21)

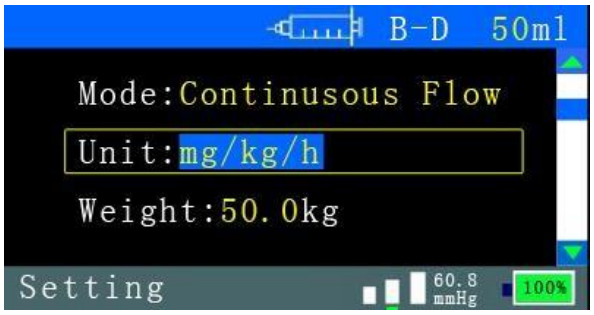


【Figure 21】

☆Attention: The purging function can be used both 'setting period' and 'stop period', but during the infusion, press SWITCH key to is to start Bolus function.

5.4.2.2 Selecting syringe unit

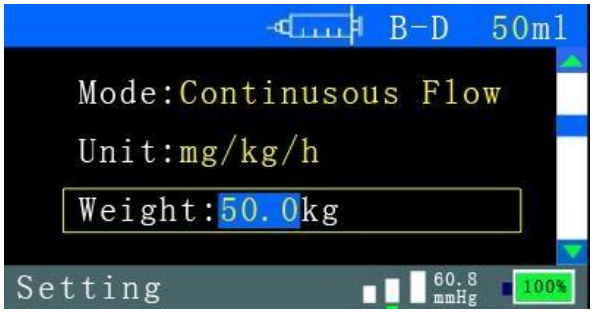
Under the parameter setting page, move the cursor to 'Unit', press down 'KNOB' to enter editing status, turn 'KNOB' to select speed unit, press down 'KNOB' to confirm current setting (As shown in Figure 22).



【Figure 22】

5.4.2.3 Setting weight of patient

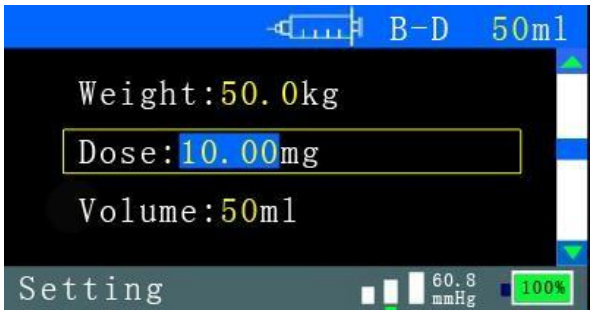
If the selected speed unit comprises factors of patient weight, we need to input patient weight. Turn 'KNOB' to set weight, select 3-150 kg, and press down 'KNOB' to confirm current setting (As shown in Figure 23).



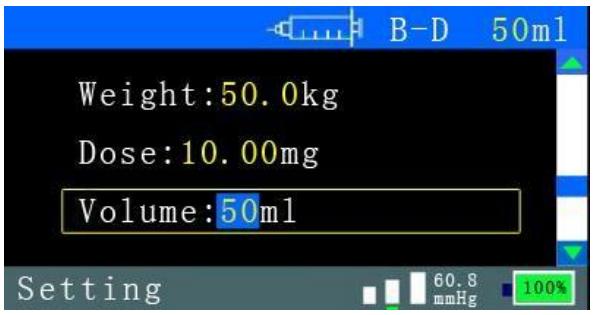
【Figure 23】

5.4.2.4 Setting doses of drug and volume of solution

If the selected speed unit comprises factors of doses of drug and volume of the solution, we need to set doses of drug and volume of the solution. Turn 'KNOB' to set dose, press down 'KNOB' to confirm current setting (As shown in Figure 24). Turn 'KNOB' to set volume of the solution; press down 'KNOB' to confirm current setting. (As shown in Figure 25)



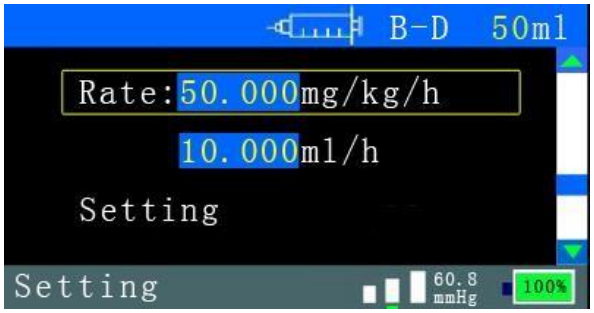
【Figure 24】



【Figure 25】

5.4.2.5 Setting infusion rate

Turn 'KNOB' to set rate; press down 'KNOB' to confirm current setting. (As shown in Figure 26)



【Figure 26】

5.4.2.6 Presetting volume

Press down 'MANU' button, to enter main menu of preset volume, through KNOB to select and confirm preset volume, the volume scope is 0.1-1000 milliliter. After setting, we can select 'Return', to enter the main parameter page, or we can directly press 'START' button to start infusion. (As shown in Figure 27)

【Figure 27】

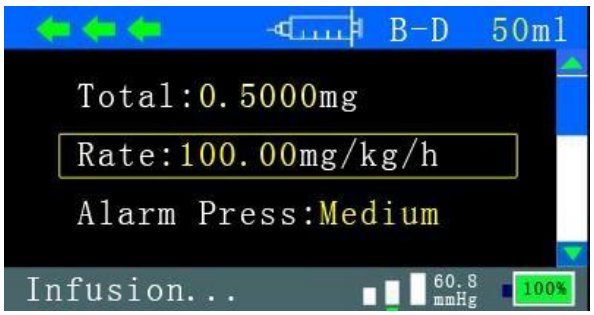
Preset volume setting is 'OFF', we can cancel preset. (As shown in Figure 28)

【Figure 28】

5.4.2.7 Starting infusion

Press down 'START' button to start infusion. After the infusion started, the page will display current infusion rate and current infusion volume amounted, the warning grid will display 'infusion' (As shown in Figure 29).

If it is under the continuous-flow infusion mode, after the infusion started, the page will display current infusion rate and current gross infusion amount (As shown in Figure 16), if it is under the continuous-flow infusion mode, it will display current infusion rate and current gross infusion volume (As shown in Figure 30).



【Figure 29】

【Figure 30】

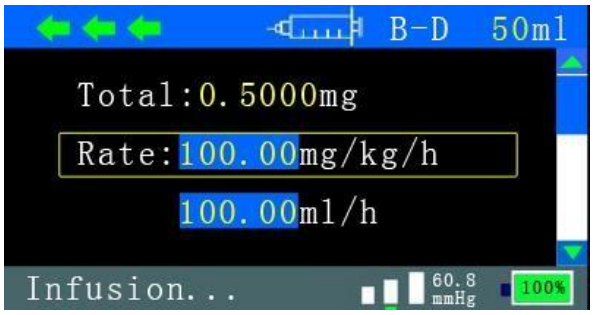
The infusion pump will provide another display method during infusion, with larger typeface big font to display infusion rate and volume amounted. The user can press down 'MENU' button to switch the two displays accordingly. (As shown in Figure 31)

【Figure 31】

5.4.2.8 Real-time adjustment of infusion rate or stopping infusion

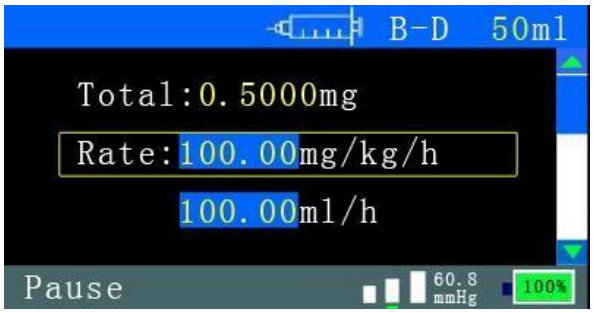
During the infusion, we can adjust operation rate real-time, press down 'KNOB' button, turn 'KNOB' to adjust infusion rate, press down 'KNOB' to confirm newly adjusted infusion rate, the machine will operating according to the confirmed infusion rate (As shown in Figure 32).

Press down 'STOP' button, press down 'KNOB', turn 'KNOB' to adjust 'Rate', press down 'KNOB' to confirm newly adjusted infusion rate, press 'START', the infusion pump will infuse according to the new infusion rate. (As shown in Figure 33)



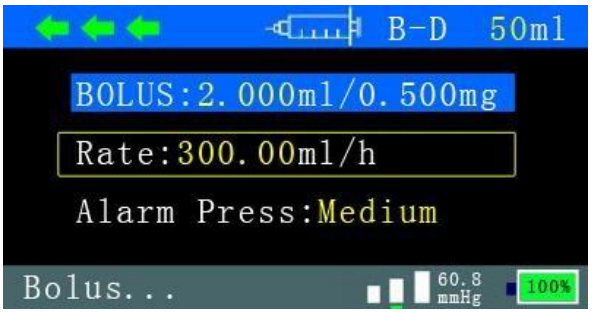
【Figure 32】

5.4.2.9 Starting Bolus



【Figure 33】

During the infusion, if we need 'Bolus' function, keep pressing on 'BOLUS' to start Bolus function, the system defaulted to infuse at the rate of 300ml/h (specification of 5 ml is 150ml/h), loosen 'BOLUS' button to stop Bolus function, the system will operating according to original speed. Bolus process will display speed and amount (volume and dose). (As shown in Figure 34)



【Figure 34】

5.4.3 Volume and Time infusion mode

5.4.3.1 Setting infusion volume

The infusion volume means the dose user wish to infuse. Turn 'KNOB' to set the gross drug dose needed, press down 'KNOB' to confirm current setting (As shown in Figure 35).

【Figure 35】

5.4.3.2 Setting infusion time

The 'Time' means the time needed for infusing setting volume, the form is hh:mm:ss （hour: minute: second）. Turn 'KNOB' to set time, we can adjust hour and minute individually (minimum set is 1 minute), press down 'KNOB' to confirm current setting. The time scope is related to syringe specification and setting volume. (As shown in Figure 36)

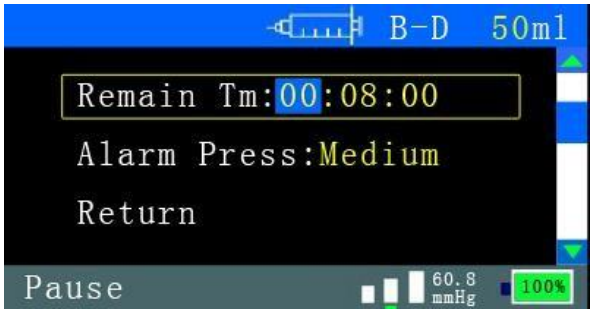
5.4.3.3 Purging tube

【Figure 36】

To make the infusion more accurate, before infusion, we can purge the tube, to remove air out of syringe and extension tube. Press on 'BOLUS' button, the infusion pump will begin to purge tube (the max speed as system defaulted), loosen 'BOLUS' button, the infusion pump will stop purging

5.4.3.4 Adjusting time during infusion

During infusion, it will display speed and volume, after pressing 'STOP' button, we can adjust time (the time means remaining time, adjust hour and minute individually only), remains volume is not adjustable. After adjusting time, press 'KNOB' to confirm current time, then press 'START' button to restart infusion.(As shown in Figure 37).



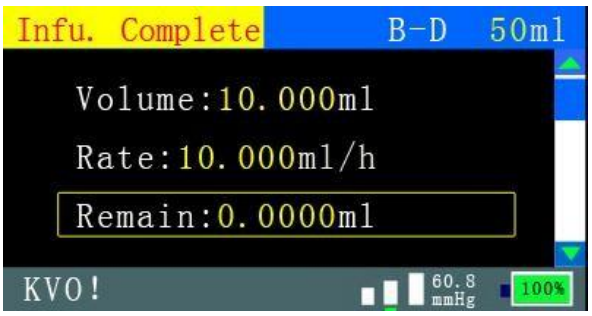
【Figure 37】

5.4.3.5 Infusion completion

After infusion completion, it will display infusion volume and time using, sound and light alarming simultaneously, it will also display alternately 'Infusion Complete!', 'Keep Vein Open'. Press 'START' or 'SILENCE' button to remove alarming sound, and then turn 'KNOB' to select 'Return', readjust volume

and time, and restart infusion again (As shown in Figure 38).

5.4.3.6 KVO function



【Figure 38】

After infusion complete each time, the system will automatically start KVO function (Keep Vein Open), it will operate at the rate of 0.1ml/h (As shown in Figure 38).

5.4.3.7 Almost Empty

When the drug in the syringe will empty the device will display 'Almost Empty', in addition, when the residual dosage equals the 10% of set volume will display 'Almost Empty' and give out audio alarm too.

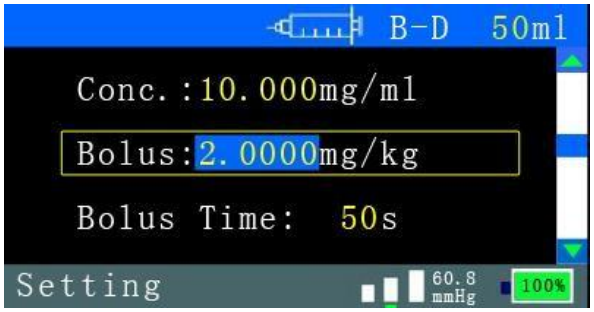
5.4.4 Bolus &Infusion mode（TIVAI mode）

Turn the' KNOB' and select Bolus & Infusion mode

The following parameters can be set in the Bolus & Infusion mode, such as weight, concentration, induction amount, induction time, sustainable rate, syringe and pressure. Among them, the settings of weight and concentration are same with the above. The alarm pressure is set under the selection of 'Syringe and Pressure' and the concentration unit only is mg/ml. After all the parameters are set, press 'START' to infusion. The infusion pump will automatically count the dosing rate of induction amount. When the induction amount is infused completely, the rate will be regulated automatically to maintain the rate and continue infusion.

5.4.4.1 Setting induction amount

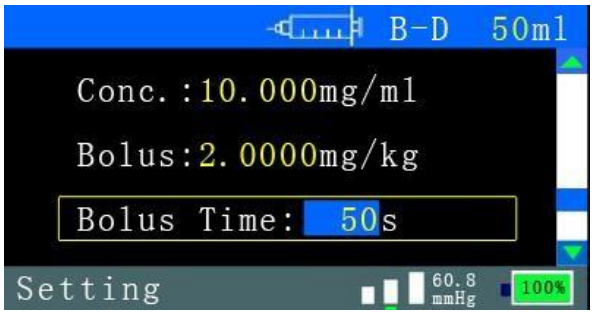
Turn the 'KNOB' to set the induction amount (Bolus) and press the 'KNOB' to confirm current settings. (as Figure 39 shown)



【Figure 39】

5.4.4.2 Setting induction time

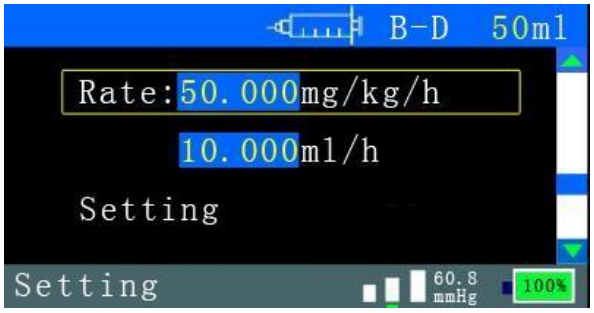
Turn the 'KNOB' to set the dosing time of induction amount (Bolus Time) and press the 'KNOB' to confirm the current settings. The dosing time range of induction amount (Bolus Time) is 1 to 3600 seconds (as Figure 40 shown).



【Figure 40】

5.4.4.3 Setting sustainable speed

Turn the 'KNOB' to set the sustainable time and press the 'KNOB' to confirm it. The sustainable time range is 0.1 to 100ml/h. (as Figure 41 shown)



【Figure 41】

5.5 Alarm solutions

5.5.1 AC power fail

When the AC power is disconnected, if the battery power is more than 15%, the infusion pump gives out the alarm of 'AC power fail!' (as shown in Figure 42). When this kind of circumstance appears, the user can eliminate the alarm through connecting AC power or pressing the key 'SILENCE'.

Note: It is not recommended that the infusion pump is used when the AC power supply is not connected. If it must be in this case, the user must pay attention to the battery power icon that indicates the battery power changes at right lower corner of the page.

【Figure 42】

5.5.2 Battery Low

Under the condition that the infusion pump is not connected with the AC power, if the infusion pump battery power is more than 1% but lower than 15%, the infusion pump gives out the alarm of ' Battery Low!' (as shown in Figure 43). The user can press the key 'SILENCE' to eliminate the alarm. At this time, the user should prepare the AC power connection.

【Figure 43】

5.5.3 Battery Empty

Under the condition that the infusion pump is not connected with the AC power, if the infusion pump battery power is lower than 1%, the infusion pump gives out the alarm of 'Battery Empty!' (as shown in Figure 44). The user cannot eliminate the alarm even though press the key 'SILENCE'. At this time, the user should immediately connect the pump to the AC power supply. If not, the infusion pump will shut down automatically.

Note: When infusion pump gives out the alarm of 'Battery Empty!' the user should immediately connect it to the AC power or the infusion pump will shut down in five minutes automatically.

【Figure 44】

5.5.4 Drug Almost Empty

When the chemicals are going to be run out in the infusion pump, the infusion pump gives out the alarm of 'Almost Empty!' (as shown in Figure 45). At this time, the user should be ready to replace the syringe and can press the key 'SILENCE' to eliminate the alarm.

【Figure 45】

5.5.5 No Syringe

In the infusion pump state of parameter setting or infusion, when the syringe falls off, the infusion pump will send the alarm of 'No Syringe!' (as shown in Figure 46). Then if the infusion pump is in the state of infusion parameter setting, the alarm signal can be eliminated automatically after the user replaces the syringe that can be identified by the infusion pump.

【Figure 46】

5.5.6 Check Syringe

In the infusion pump state of parameter setting or infusion, when the specification of the syringe cannot be automatically identified, the infusion pump gives out the alarm of 'Check Syringe!' (as shown in Figure 47). Then if the infusion pump is in the state of infusion parameter setting, the alarm signal can be eliminated automatically after the user replaces the syringe that can be identified by the infusion pump. But if the infusion pump is in the state of infusion, the user should press the key 'SILENCE' key to eliminate the alarm.

5.5.7 Occlusion

【Figure 47】

In the infusion pump state of infusion, when the measured value of pressure exceeds the set value of alarm valve, the infusion pump gives out the alarm of 'Occlusion' (as shown in Figure 48) after the pressure release. At this time, if the infuse has pushed to be empty, it can be changed to a new one. If not, check to ensure whether the infusion pipe is folded or blocked. After release the pressure in the pipe, the user can press the key 'SILENCE' to eliminate the alarm.

【Figure 48】

5.5.8 Drug Empty

In the infusion pump state of infusion, when the liquid medicines in the syringe are used completely, the infusion pump gives out the alarm of 'Drug Empty' (as shown in Figure 49). The user can press the key 'SILENCE' to eliminate the alarm.

【Figure 49】

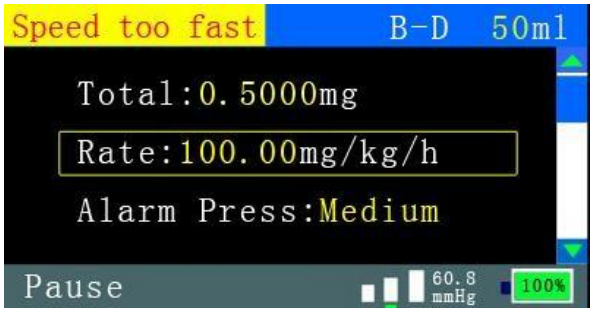
5.5.9 Abnormal Motor

When the motor speed stops abnormally, the infusion pump gives out the alarm of 'abnormal Motor' as shown in (Figure 50). At this time, check to ensure whether the pushing rod is operated to the end or it is jammed. Run it again to observe whether there is the alarm repeatedly. If the alarm still exists, contact the maintenance to repair. The user can press the key 'SILENCE' to eliminate the alarm.

5.5.10 Speed too fast

【Figure 50】

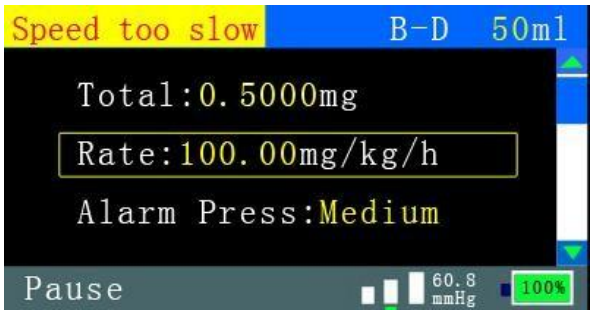
When the motor speed is too fast, the infusion pump gives out the alarm of 'Speed too fast' (as shown in Figure 51). At this time, check to ensure whether the pushing rod is operated to the end or it is jammed. Run it again to observe whether there is the alarm repeatedly. It the alarm still exists, contact the maintenance to repair. The user can press the key 'SILENCE' to eliminate the alarm.



【Figure 51】

5.5.11 Speed too slow

When the motor speed is too slow, the infusion pump gives out the alarm of 'Speed too fast' (as shown in Figure 52). At this time, check to ensure whether the pushing rod is operated to the end or it is jammed. Run it again to observe whether there is the alarm repeatedly. It the alarm still exists, contact the maintenance to repair. The user can press the key 'SILENCE' to eliminate the alarm.



【Figure 52】

5.5.12 Plunger Stop

When the pushing pedestal is abnormal, the infusion pump gives out the alarm of 'Plunger Stop' (as shown in Figure 53) once the chemicals are pushed. At this time, check to ensure whether the pushing rod is operated to the end or it is jammed. Run it again to observe whether there is the alarm repeatedly. If the alarm still exists, contact the maintenance to repair. The user can press the key 'SILENCE' to eliminate the alarm.

5.5.13 Syringe Changed

【Figure 53】

During the process of infusion, when the inspection of the syringe is changed, the infusion pump gives out the alarm of 'Syringe Changed' (as shown in Figure 54). At this time, remount the syringe and press the key 'SILENCE' to eliminate the alarm to restart the infusion.

【Figure 54】

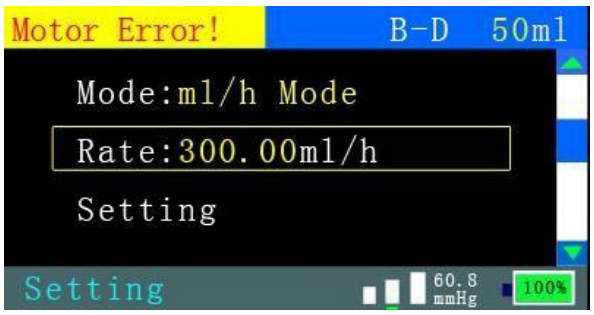
5.5.14 Stand By

If the infusion system long stays in non-infusion state above 5 minutes (paused state is 20 minutes) without any infusion pump operation, the infusion pump gives out the alarm of 'Stand By' (as shown in Figure 55). The user can press 'SILENCE' or start the chemical solution infusion to eliminate the alarm.

【Figure 55】

5.5.15 Motor Error

when self-testing during turn on the device, if there is something wrong to the motor, the device will automatically give out alarm and display 'Motor Error', as shown as figure 56, press SILENCE key to eliminate the audio. If can't eliminate the alarm by press SILENCE key and the alarm audio still appear when turn on the device again, please send the device to repair.

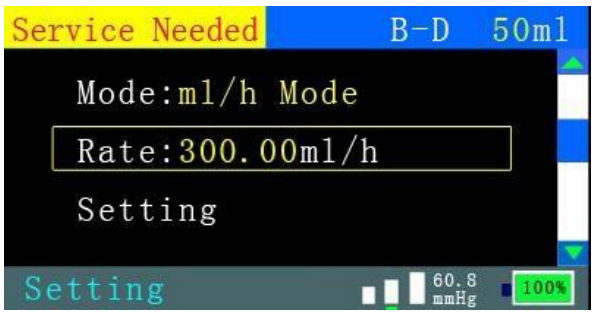


【Figure 56】

5.5.16 Service needed

When the device used time get to the service time, the device will automatically give out the alarm and display 'Service Needed!' as shown as figure 57. Press SILENCE key to eliminate the audio and maintain the device.

5.5.17 Pressure Rise



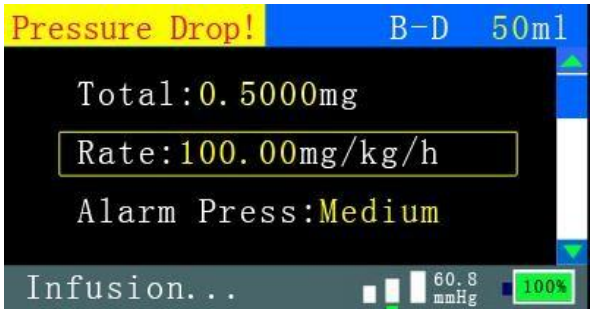
【Figure 57】

When sudden rise in pressure during infusion, the device will automatically gives out alarm and display 'Pressure Rise', as shown as figure 58, if like this, please check the extension tube whether appear liquid loading occlusion. Press SILENCE key to eliminate audio.

【Figure 58】

5.5.18 Pressure Drop

When sudden drop in pressure during infusion, the device will automatically give out alarm and display 'Pressure Drop', as shown as figure 59, if like this, please check the extension tube whether drop off.. Press SILENCE key to eliminate audio.



【Figure 59】

6. Notes

6.1 If the infusion pump is in failure or needs the precision accuracy calibration, do not dismount by yourself and please promptly contact the manufacturer.

6.2 Follow the instruction to perform operations.

6.3 Please use the built-in brand syringe of the infusion pump and what's more, the set syringe brand shall be same with the actual placed one, or the infusion precision accuracy will not be guaranteed. If the used syringe brand is not in the infusion pump, add the used syringe via automatically calibrating the syringe or manually setting the relevant sizes of user-defined syringe. Please see the detailed introduction in【Appendix 1】.

6.4 If the syringe specification cannot be identified in the process of using, stop the infusion.

6.5 When other extension system or accessories are connected to the patient pipe, there will be the error between the equipment settings and the actual value. Please use carefully.

6.6 In order to avoid the electromagnetism or other intervene, when this equipment is in operation, keep a certain distance of it from other high-frequency sources.

6.7 Before the infusion, the syringe and its extension pipe should be prefilled and exhausted. When replace the syringe, clamp the extension pipe with chips.

7. Maintenance

7.1 Periodical check

Carry out the checks by yourself following the instructions according to the hospital equipment use frequency.

7.2 Cleaning

Keep the equipment clean and use the soft cloth to clean the surface.

7.3 Battery charge

7.3.1 If it is first time used or isn't used more than one week, charge it 10 hours before using.

7.3.2 After the AC power supply connection, the built-in battery can be charged without the equipment startup.

7.3.3 Because the battery is specially provided by our company, if battery change is asked, please contact us.

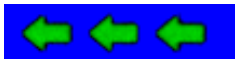
8. Symbol instruction

AC power

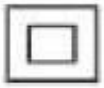
Battery

Occlusion alarm level and current pressure

Syringe



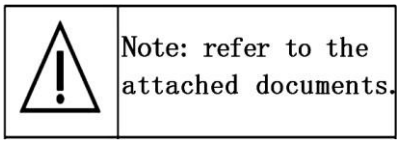
The infusion is infusing



II class

Lock keyboard

CF type



9. Environment protection

Please handle the deserted infusion pump and its accessories according to the local related laws and regulations. Do not desert them at will!

10. Others

10.1 Product packaging and accessories

1 instruction;

1 power line;

1 syringe;

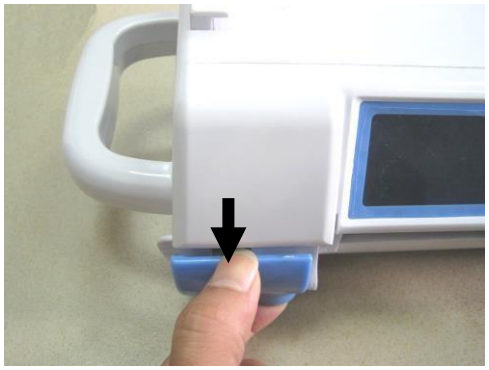
1 product certificate;

1 after-sale service instruction (including the service voucher);

1 packing list;

10.2 Operation instructions for syringe installation and assembly and disassembly of infusion pump

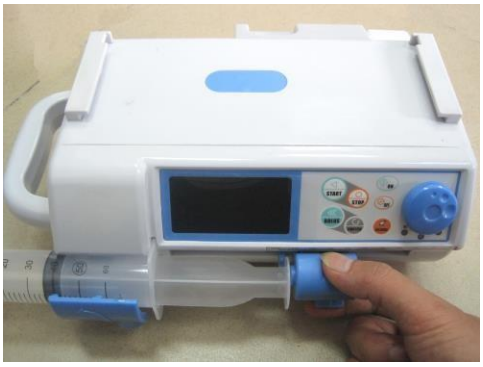
The operation instructions of syringe installation and infusion pump assembly and disassembly are as shown as (Figure 60, 61, 62, 63, 64 and 65).



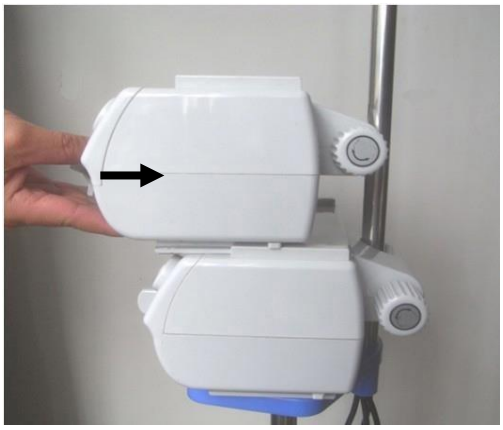
【Figure 60】Pull the syringe grip out (pinch it and pull)

【Figure 61】Turn the grip 90 degrees counterclockwise after pull out

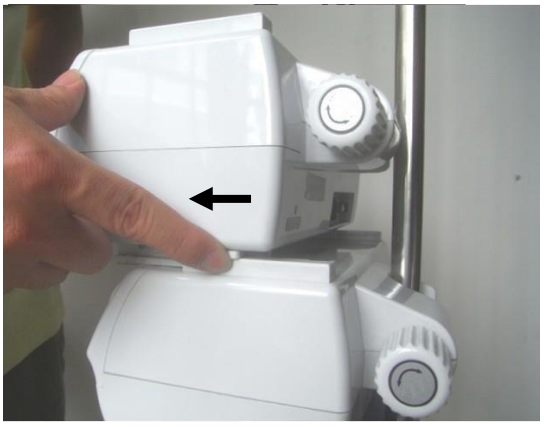
【Figure 62】Syringe installation



【Figure 63】Move the Syringe Plunger of syringe



【Figure 64】 Assembly of syringe pump



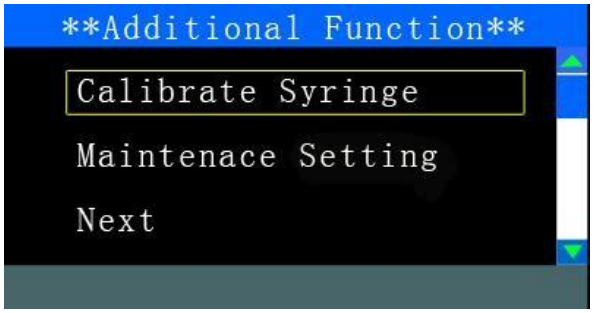
【Figure 65】 Disassembly of syringe pump

Appendix 1

Brief instructions to syringe auto-calibration function

Aiming to various problems in the syringe utilization process, it has been provided the auto-calibration function solution. After the user calibrate the used syringe by himself and save the data it in. After this, the user can select the specifications of the user-defined syringe that has calibrated to realize the function user-defined syringe utilization.

The syringe calibration function is on the Additional Function page, as shown below (Figure 66):



【Figure 66】

Click the option 'Calibrate syringe' and then achieve the user-defined syringe calibration in three steps:

1. Confirm the syringe specification (Figure 67)

【Figure 67】

2. After specification confirmation, press the 'KNOB' key to enter the next step (step 2) (Figure 68).

【Figure 68】

3. Use the key 'SWITCH' to pre-fill the syringe beyond the scale of this specification and press the 'KNOB' key to enter the next step (step 3) (Figure 69).

【Figure 69】

On this page, if other preparations are done (confirmation of pre-filling and syringe specifications), select the menu 'Start' and press the KNOB to start calibrating(Figure 70).

【Figure 70】

The calibration maintains about 1 minute and the syringe changes a little according to various specifications. After the calibration, the next page appears(Figure 71).

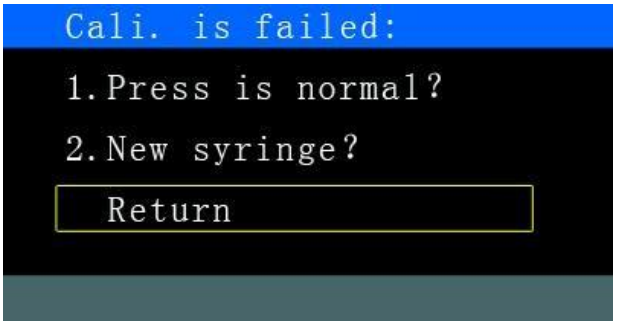
【Figure 71】

If select 'yes', the system will save this calibration data to corresponding user-defined data field and at the same time cover the previous calibration data. If select 'yes', the system will abandon this calibration data and go back to the page of first step to start calibrating again (start from the nominal scale).

In the calibration process if the user wants to terminate this calibration for any variety of reasons, hecan press the button 'STOP' to stop calibration and go back to the page of first step. Press the 'STOP' again to exit calibration page.

Caution: The syringe auto-calibration function must be based on understanding how to operate, and operated according to the regulation steps strictly. Only by this, the syringes can be added. If not, the potential negative consequences shall be borne by the user himself.

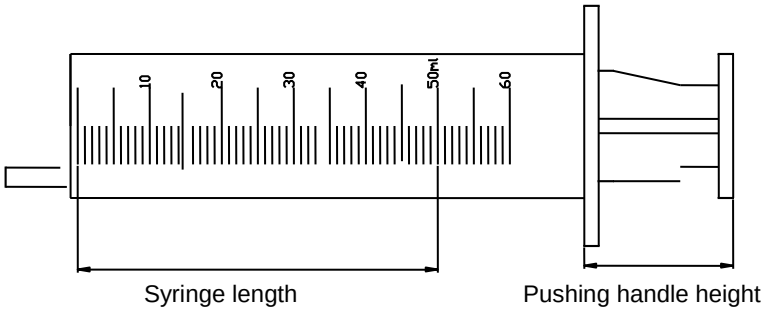
Note: During the calibration, if the below shown alarm appears(Figure 72), check to ensure whether the equipment pressure is normal and whether the used syringe is pressure up caused by over tight or whether the calibration starts from the nominal scale. Repeat the operation and if the alarm appears again, contact the maintenance to repair. The user can go back by pressing the 'KNOB' key.



【Figure 72】

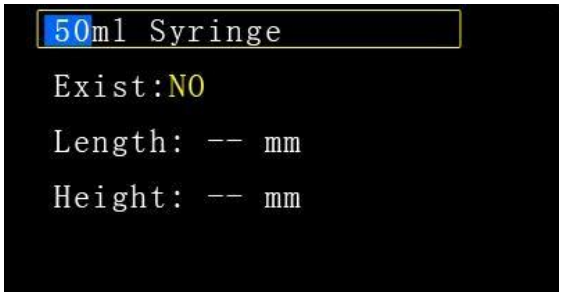
In addition, on the Additional Function page, directly press the button 'SWITCH' to enter manual input page of user-defined syringe parameters. The setting method is as follows:

The infusion pump can be user-defined to set parameters for three specifications of the syringe, i.e. 5ml, 10ml, 20ml and 30ml, 50(60)ml. Every specification of syringe shall be set the syringe specification, scale and pushing handle height in sequence. Among them, the syringe length is not the total length of the syringe, but the scale length of nominal volume. The syringe length and pushing handle height are shown as Figure 73.



【Figure 73】

Turn the 'KNOB' to select the specification of syringe that is going to be defined by self. Press 'KNOB' key to confirm it and select 'yes' at 'Exist' item. Separately input the scale length and pushing handle height and select the button 'KNOB' to finish parameter settings of the syringe with current specification. Turn the 'KNOB' to continue setting other syringes as shown in Figure 74 and 76. If you don't need continuing adding the syringes, turn the 'KNOB' and select 'exit' as shown in Figure 64 to finish the parameter settings of user-defined syringe and go back to Additional Function page.



【Figure 74】

【Figure 75】

【Figure 76】

Important Notice:

1. If the syringe is not identified correctly during the Infusion, please stop the Infusion.
2. The user must well-known 'Self-defined' function at the beginning, then setting the syringe parameters step by step. Otherwise, the user must bear all adverse consequences during any wrong operating.

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change or any other important changes of information. Contents of this manual are subject to change without prior notice.

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