



VETERINARY SYRINGE PUMP

IPR220

USER MANUAL





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1. The Overview of the User Manual

This manual is for the sole use of the InfuPET[™] (IPR120) veterinary syringe pump, affiliated with Infusion Pump Repair Corp.

This User Manual describes the product's extensive configurations, accessories, and functions that may not occur in the User's device. For more detailed information, please contact Infusion Pump Repair Corp.

2. The Operator of the User Manual

This manual is intended for professionally trained veterinary nurses/doctors, veterinary anesthesiologists, and certified veterinary equipment technicians.

3. Instructions for the User Manual

This User Manual covers the basic information on the safety and effectiveness of the product for guiding the operator to install correctly, test, operate, use, and maintain the product. Please read this manual thoroughly before using and utilizing the product perfectly. We encourage users to keep the User Manual for future use.

IPR will take responsibility for the reliability and performance of the equipment if all the following conditions are met:

• The equipment is used according to this User Manual.

•The equipment has only been disassembled, assembled, replaced, tested, improved, and repaired by the professional technicians of our company.

• IPR provides all components and accessories as well as consumables for repairing.

• All relevant electric devices meet the international standard IEC/EN 60601-1 and this Manual.

4. Terminology

- () means mechanical button
- [] means touch button
- () further information
- means inapplicable
- ✓ means accordant
- ightarrow means operation steps

Bolus: Infuse large volumes of liquid in a short time.

KVO: Keep Vein Open, provides a constant flow to prevent blood/needle blockage.

Anti-bolus: Motor automatically reverts when the extension line has high pressure.

Warning /Attention/Caution: There is a possibility of physical injury, death, or property loss if the concerns/cautions in the Warning section occur.

Note: By failing to follow the supplementary or prompt information on the operation instructions, the User may cause damage to the equipment, which may lead to error or property loss.

Accessories: There are optional components necessary and (or) suitable for use with this syringe pump. Accessories help achieve the expected purpose, provide convenience for attaining the desired purpose, improve the expected purpose, and (or) increase the additional functions of the equipment.

5. Copyright

The copyright of this User Manual belongs to IPR. Without permission, any institute or individuals are prohibited from copying, modifying, or translating the contents speculated in this User Manual.

This User Manual will be revised and subject to product improvement, law updating, or instructions improving based on the preconditions of meeting-related laws and regulations. All modified records will be stated in the new version.

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Chapter 1 - Safety Instructions

1.1 Warnings

- Before using, please check the equipment, connecting wire, and accessories to ensure that it can work essentially and safely. If anything is abnormal, immediately stop working and contact our customer service department. Additionally, the adhesion or intrusion of fluid/drug may cause the equipment to fault and malfunction. Therefore, we suggest cleaning the equipment after use and storing it correctly.
- This equipment must be operated by trained professional or medical-care personnel.
- This equipment is <u>not applicable</u> for blood transfusion.
- To avoid any fire or explosion, do not put and use the equipment in the environment with both anesthetic and other flammable/explosive articles.
- Do not store or use the equipment in the environment with any active chemical gas (including gas for disinfecting) and moist environments. Unideal environments may influence the syringe pumps' inside components and cause a performance drop or damage to the inside parts.
- The operator shall guarantee that the set infusion parameters of this equipment are the same as the medical advice before starting the infusion.
- Please correctly install the syringe according to the infusion indication direction of this equipment. Ensure that the syringe and the extension line are smoothly and straightly cross the mechanism of the device. Otherwise, it may harm the patient or fail to reach the expected performance.
- Please do not only depend on the information prompt during use. Please periodically check the device to avoid accidents.
- We suggest that devices be fixed on an infusion stand to ensure the stability of the infusion device. We also advise users to be careful when moving the infusion stand to avoid the equipment from dropping or falling and damaging the surrounding objects.
- If the extension line is twisted, the filter or needle is obstructed, or blood in the needle obstructs the infusion, the line's pressure will rise. During occlusion adjustments, the pressure may cause a "bolus injection" (temporary excess of infusion) to the patient. The correct method to resolve an occlusion is to tightly hold or clamp the line near the puncturing position and remove the syringe to drop the pressure in the infusion line. If the infusion is restarted and the occlusion error exists, it may increase line pressure, breaking or cutting off the extension line and (or) hurting the animal.
- This equipment injects fluids/drugs by pushing the syringe and cannot detect any leakage if the extension line is cut off or broken. Therefore, please periodically check the device and the syringe to avoid any fault during the working period.
- During infusion, please periodically check to ensure the infusion is working. This
 equipment doesn't precisely measure the quantity of infusion fluid; therefore, it
 can't detect any missing intake under extreme conditions.

- This equipment has the occlusion detection function for detecting and alarming when the infusion needle deviates from the position in the vein or if the needle is not correctly inserted in the vein. However, the pump will only alarms when the occlusion pressure has reached a particular numerical value. The cannula site may become reddish, swell, or bleed. Additionally, in the chance, the device doesn't alarm for an extended period if the actual occlusion pressure is lower than the alarm threshold value, 6*. Therefore, please periodically check the cannula position. If there's any abnormal phenomenon, please take suitable measures to resolve the abnormality.
- Only use syringes, extension lines, infusion needles, and other medical components that meet the local laws and regulations and the requirements covered in this User Manual. We highly suggest utilizing the syringe programmed with the equipment. We can't ensure infusion accuracy if an unsuitable syringe is used.
- Do not disassemble or refit this equipment or use it for other purposes except standard infusion.
- No one is allowed to repair this equipment except our company or an authorized repair technician of our company.
- Maintenance or replacement of spare parts is prohibited during the clinical use of the equipment.
- This equipment must only be connected to A.C. with ground protection to avoid the risk of electric shock.

1.2 Cautions

- Before its first use after purchase, or if this equipment is not used for an extended period, please charge the pump with the A.C. power supply. The equipment can't fully function with just the built-in battery power supply.
- This equipment cannot be used in rooms with radiological installation, magnetic resonance equipment, and high-pressure oxygen therapy.
- Do not position this Medical Electrical Equipment to make it inaccessible for disconnection of the device.
- The DC power supply is only suitable for applications requiring a backup power supply. Only use the D.C. power supply line provided.
- Other devices near this equipment must meet corresponding EMC requirements. Otherwise, it may influence the performance of this equipment.
- Under general conditions, please use A.C.'s power supply as much as possible since it can prolong the battery's service life to a certain degree. When using an A.C. power supply, ensure that the grounding wire is relatively close to the ground, and only the A.C. power wire attached with this equipment is used. The built-in battery can only be used as the assistant of the power supply.
- Please keep the power socket and plug dry before connecting this equipment with the power supply. We also recommend that the power voltage and frequency meet the requirements listed in the equipment label and this User Manual.
- This device is equipped with an audible and visual alarm system. When the device turns on, the red and yellow alarm indicators will light up to show that the alarm system is usually working, and the speaker makes the "beep" sounds.
- Please keep the device away from the A.C. power socket. We recommend a certain distance to avoid fluid/drug splashing or dropping in the outlet as it may short circuit and (or) cause electrical damage.
- Please use the fluid/drug at or near room temperature; when the fluid/drug is used at low temperature, the air dissolved in the fluid/drug may cause more air bubbles and more frequent air bubble alarms.
- Do not press or operate the device's buttons with a sharp object (pencil tip and nail. Sharp objects may cause early damages to the switch and (or) the surface film of the device.
- Please close the extension line before taking it out. This action will help users to avoid liquid leakage.
- Under the condition of a low flow rate infusion, please pay special attention to occlusion. The lower the infusion flow rate, the longer the time of detecting occlusion, which may cause a longer infusion process.
- If the equipment is damaged from a drop or impact, please immediately stop using it, and contact our customer service department. The damage may cause the inside components to be damaged even when the appearance is not damaged.
- We recommend using the accessories specified in this manual to ensure patient safety.

1.3 Dialogue Window

Dialogue window displays options, including operation selections, operation confirmations, and further information. For instance :

Figure 1.3-1 Operations Selection window





Figure 1.3-2 Parameter error reminder

1.4 Symbols

Not all the below symbols may exist in the product.

Table 1.4-1

Marks	Description	Marks	Description
LOT	Batch code		Protective earth (ground)
SN	Serial number	IP24	Water-Resistant Degree
	Caution	8	Both direct and alternating current
┦♥₽	Defibrillation-proof type C.F. applied part		Handle with care
~~~	Date of Manufacture		Manufacturer
20	Environment-friendly use period (20 a)	$((\mathbf{e}))$	Non-ionizing electro- magnetic radiation
$\bigcirc$	Input / output	(	Input
1	Unlock	T	Lock
	Fragile items		This side up
8	Please refer to the instruction manual/manual	$\bigcirc$	Stand-by
	Keep dry		Stacking level limit
<b>CE</b> 0197	CE-mark/Notified Body		

# Chapter 2 – Overview

### 2.1 Application Scope

The syringe pump is used together with a syringe to control the dose of liquid infused into the patient's body, i.e., syringe infusion.

### 2.2 Operating Conditions

Animal Hospital, Pet clinics.

## 2.3 Intended Patients

Animals.

# 2.4 Specifications

This equipment is not applicable to blood transfusion.

### 2.5 Purpose

This equipment is an instrument that moves in a linear motion with a microcontroller-based system that drives a step motor. This system allows the pump to have a wide range of pumping rates configured to the volume inside a loaded syringe. A lead screw and drive-nut mechanism will push the syringe plunger to infuse the drugs into the patient. This device can guarantee the delivery of fluid/drugs safely into the patient at an even pace and dosage.

# 2.6 Design and Performance

#### 2.06.1 Design and Performance

The syringe pump consists of a central unit and a built-in battery. This syringe pump provides several infusion modes, such as ml/h mode, bodyweight mode, and loading dose mode. In addition, it also has functions such as history records, drug library, antibolus, alarm, and so on.

Function /Model		PRSP-S300(V)
	ml/h mode	V
infusion mode	Bodyweight mode	٧
	Loading dose mode	V
Drug Library	Drug name display	V
	Drug names	20
Occlusion alarm level		3 levels

#### 2.06.2 Functional Specifications

This User Manual defines the most configurations and most complete functions. Due to model differences or optional components, not all parts are equipped in the purchased product.

# 2.7 Product Specification

Safety Classification			
Electric Class Type	Class I		
Electric Level	Type CF Defibrillation Proof Applied		
Water-Resistant Class	IP24		
Working Mode	Continuous Operation		
Classification	Portable equipment, non-portable during infusion*		
Specification Parameters			
Compatible Syringes	5ml, 10ml, 20ml, 30ml , 50/60ml		
System Accuracy	$\geq$ 1ml/h, ±2% (Mechanical Accuracy ±1%)		
Bolus Accuracy	≥ 1ml/h, ±2%		
	Syringe size 5ml: (0.01-100) ml/h		
	Syringe size 10ml: (0.01-200) ml/h		
Infusion Rates	Syringe size 20ml: (0.01-400) ml/h		
	Syringe size 30ml: (0.01-600) ml/h		
	Syringe size 50ml: (0.01-1500)ml/h		
	Syringe size 5ml: (0.2-100) ml/h		
Bolus Rate	Syringe size 10ml: (0.2-200) ml/h		
(Bolus)	Syringe size 20ml: (0.2-400) ml/h		
	Syringe size 30ml: (0.2-600) ml/h		
	Syringe size 50ml: (0.2-1500)ml/h		
	Syringe size 5ml: 100 ml/h		
	Syringe size 10ml: 200 ml/h		
Purge Rate	Syringe size 20ml: 400 ml/h		
	Syringe size 30ml: 600 ml/h		
	Syringe size 50ml: 1500 ml/h		

KVO Rate	0 $\sim$ 5.00ml/h, minimum step is 0.01ml/h	
KVO Rate Accuracy	≤±10%	
Micro Mode Setting Range	100ml/h-max rate	
Minimum Flow Rate Increment	0.01 ml/h	
	Syringe size 5ml: Minimum 0.1ml, max 5ml	
	Syringe size 10ml: Minimum 0.1ml, max 10ml	
Bolus Volume	Syringe size 20ml: Minimum 0.1ml, max 20ml	
	Syringe size 30ml: Minimum 0.1ml, max 30ml	
	Syringe size 50ml: Minimum 0.1ml, max 50ml	
VTBI	0.01 – 99999,	
Total Volume	0.01 – 9999.99ml	
Time Range	1 min – 99 hrs. 59 min	
Fuse Type	T2AL 250V	
Dimensions	11 x 3.5 x 4.8 inches	
Weight	Approx. 4.41 lbs.	
Power Supply		
A.C. power supply	100V-240V A.C., 50Hz/60Hz	
Input power	50VA	
D.C. power supply	DC 12V-16V, 1.5A-0.94A	
Battery		
Battery Model	DC 203	
Rated battery voltage	11.1V	
Battery capacity	2600mAh	
Charging time	Off status ≤ 5 hrs.	

	Use the new battery after it's been fully charged.		
Running time	≥ 12 hrs. (Temperature is 25°C and flow rate is 5ml/h, this is a constant working time)		
Alarm			
Alarm signal's sound pressure level	When the sound is set at the lowest level, the alarm signal's sound pressure level ≥ 50 dB(A) When the sound is set at the highest level, the alarm signal's sound pressure level ≤ 80 dB(A)		
Alarm information	VTBI near end, Syringe Near Empty, VTBI Completed, Syringe Empty, Pressure High, Battery Nearly Empty, Battery Empty, No Power Supply, Check Syringe, Reminder Alarm, Standby Time Expired, KVO Finished, System Error.		
Environment			
Non-AP/APG type equipment	Please do not use it in the environment with a flammable anesthetic gas mixed with air or a combustible anesthetic gas mixed with oxygen or nitrous oxide		
Operating	<ul> <li>(1) Temperature: 41 - 104 °F</li> <li>(2) Humidity: 15-95%, non-Condensable</li> <li>(3) Atmospheric Pressure: 57-106kPa</li> </ul>		
Transport & Storage Safety Standard	(1) Temperature: -4 - 140 °F (2) Humidity: 10-95%, non-Condensable (3) Atmospheric Pressure: 50-106kPa		
Main Safety Standards	IEC 60601-1:2005+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2 :2014		

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances- Requirements and Tests.
IEC 60601-1-6 :2010+A1:2015
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
IEC 60601-1-8 : 2006+A1 : 2012
Medical electrical equipment –Part 1-8: General requirements for basic safety and essential performance –Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.
IEC 60601-2-24: 2012
Medical electrical equipment –Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.

# Chapter 3 – Appearance

### 3.1 Front View



- 2. Slider Box
- 3. Syringe Clip
- 4. Lead Screw Mechanism
- 5. Syringe Fixture Lever

Pull forward, then turn right, install the syringe into the slot.

- 6. Tube Guide
- 7. Extension line Hook

Keep the extension line straight and in position.

8. Syringe Protected Cover

# A Note: The Water-resistant film is recommended to be replaced once every two years.

# 3.2 Operation Panel



- 1. 【Menu】
- 2. 【Stop】

Stop infusion and operation.

3. 【Start】

After setting all parameters, press [Start] to begin infusion.

- 4. 【ОК】
- 5. Directional Arrow Keys
- 6. Gliding Alarm indicator
- 7. A.C. indicator
- 8. Return/Clear
- 9. [Bolus/Purge]
- 10. 【Mute】
- 11. 【 Power 】

Press and hold the power button to switch ON/OFF.

# 3.3 Display Screen

The display screen layout consists of a title bar and typical interface options.



#### 3.03.1 Title Bar

The title bar displays real-time information and is not touchable. The left upper corner indicates the name of the current editing parameter.

lcon	Paraphrase	Description
E.	Syringe Set	Brand Name of Syringe
₽	Lock Screen Icon	Unlock state icon is 🗃
	Battery status	A numerical percentage or time value is displayed on the left side of the screen. The remained battery life may change. It may show the following states:

#### 3.03.2 Typical Options

Before and during infusion, the standard menu options will display the following: main Menu, working opportunities, alarm options, prompt options, control panel, parameters setting, input method, standby options, etc.

3.03.2.1 Input Method Options

The Menu will display the title bar, sub-title bar, an input box, hint box, and a bottom title bar when the input method is chosen.



- 1. Title Bar: displays the name of the syringe brand and the size of the syringe.
- 2. Sub-title Bar: displays the name of the current editing parameter.
- 3. Input Box: the real-time display of the input content.
- 4. Hint box: displays a hint of how to edit the data/input.

### 3.4 Rear View



- 1. Label
- 2. Battery Cover
- 3. Loudspeaker
- Multi-functional Interface A
   For D.C. power supply options.
- 5. Multi-functional Interface B

For the software upgrade options.

- 6. Handle
- 7. Mounting Handle Hole
- 8. Pole Clamp

Used to mount the pump on the infusion stand.

- 9. A Hole for the Pole Clamp mount
- 10. The Knob for the Pole Clamp
- 11. A/C Adapter Port

# Chapter 4 – Installation

# 4.1 Unpacking and Checking

- 1. Please check the appearance before unpacking. Please get in touch with the transportation company or our customer service department quickly if broken.
- 2. Please carefully open the package to avoid damaging the equipment and relevant accessories.
- 3. After unpacking, please check according to the packing list. If there're insufficient or damaged accessories, contact our company.
- 4. Please keep all relevant accessories. (ex. User Manual)
- 5. Please keep the packing case and materials for future transportation or storage.

Warning: Please put the packing materials out of reach of children. Please obey local laws and regulations or hospital waste treatment systems to handle the packing materials.

# 4.2 Installation

Warning :

- The designated technicians of our company should install this equipment.
- All devices that connect to this pump must pass the designated IEC standards (for example, the IEC60950 Information Technology Equipment Safety and IEC60601-1 Medical Electric Device Safety) certification. All devices must be connected according to the correct version of the IEC60601-1-1 system. The technician who performs and connects the additional devices with this equipment is responsible for complying with the IEC60601-1-1 standard. Please contact our company if you have any general inquiry.
- Please check with a technician when connecting this equipment with other electric devices to perform functions. Verification is recommended. Please contact our company or a hospital technician to ensure that all necessary safety precautions are taken so that all devices in combination won't be destroyed.
- This equipment must be used and stored in an environment regulated by our company.

#### 4.02.1 Installing the Syringe Pump

- 1. Rotate the pole clamp screw(knob) and unscrew to leave the space.
- 2. Lock the Pole Clamp on the infusion stand, adjust the position of the syringe pump, tighten the pole clamp to fix the syringe pump on the infusion stand (shown in the drawing). Hold the syringe pump when tightening the fixing clamp; only let go after tightening to avoid falling.



3. The pole clamp supports the vertical pole at default state. To adjust the pole clamp direction, please remove the bolt from the pole clamp with a screwdriver, take out the pole clamp, change the direction, and then tighten the bolt.



# Chapter 5 – Preparation and Precautions Before Use

### 5.1 Use Preparation

When using new equipment, or reusing after storing for a period, or reusing after repair, please confirm that:

- The equipment's appearance is clean and in good condition without cracks and leakage.
- The moving components are smooth and functional. For example, the pump door can be opened and closed smoothly, and the buttons work.
- The touch screen can be operated smoothly and effectively.
- The power cable is installed tightly and can't be easily damaged when pulling.
- Set and check the system time to ensure that the history records will be correctly recorded.
- *In exceptional cases only* The built-in battery will supply Power. Before using it, please charge it to complete and ensure that the battery keeps working adequately.
- Carefully read the Warnings, Cautions, and Operation Steps listed in this User Manual.

# 5.2 Operation Cautions

Cautions:

- Avoid direct sunlight, high temperature, or high humidity.
- The equipment shall be put at less than 0.65 m to the animal's height.
- The parameters can only be set or changed by trained and professional personnel.
- Avoid the equipment working with fault to avoid medical negligence, which may hurt the animal's health and even life.
- If the working environment temperature exceeds the designated range, it may drop the equipment's infusion accuracy or cause abnormal work.
- The viscosity and specific gravity of infusion fluid will influence the infusion accuracy.

# Chapter 6 – Basic Operation

# 6.1 Operation Flow

× Mount the syringe pump on the IV stand

- ¤ Power on
- ¤ Install syringe
- ¤ Select syringe brand or add a new brand
- ¤ Select infusion mode
- × Set infusion Parameters
- x Remove air bubble(s) in the line
- × Connect infusion line with patient
- x Start infusion
- ¤ Infusion finish
- ¤ Remove syringe
- ¤ Power off or Standby

# 6.2 Infusion Operation

#### 6.02.1 Mounting Installation

Mount the device on the infusion stand according to Chapter 4.02.1, connect with the A.C. power supply and check the A.C. indicator lights.

#### 6.02.2 Starting and Self-Test

- 1. Press we to Power on the equipment.
- 2. After the Power is on, the system will automatically check the motor, sensor, battery, memorizer, CPU communication, and alarm indicator.
- 3. After the self-test is successful, the pump will enter ml/h mode and display.

Warning: If the self-test item does not pass, please contact the company. Do not continue using the equipment.

#### 6.02.3 Installing the Syringe

- 1. Hold the clutch and pull the slider to the right side.
- 2. Pull the syringe fixture lever and turn it to the right.
- 3. Insert the syringe flange into the slot and clip the plunger firmly.
- 4. Align the extension line of the syringe and put the extension line through the tube guide, leaving excess on the extension hook.



- The flange of the syringe should be firmly inserted and not jutting on the outside of the flange plate.
- Before using the syringe pump, please confirm the brand specifications of the syringe. This information must be established. The brand of syringe pump should be calibrated to the equipment, so if there are no settings for the syringe used, the rate and the alarms may not be accurate.

#### 6.02.4 Set Infusion Parameter

Enter the **[**Home**]** interface, select infusion mode, and set infusion parameters.

The flow rate range will depend on the current syringe specification for both the manually entered infusion rate and the rate calculated by the pump system.

If a VTBI is not given, the pump will complete the fluid/drugs left in the syringe.

Infusion Mode	Infusion Parameter	Parameter Range
	VTBI	0.1 – 9999 ml
ml/h mode	Rate	(0.01-100)ml/h for 5 ml syringes (0.01-200)ml/h for 10 ml syringes (0.01-400)ml/h for 20 ml syringes (0.01-600)ml/h for 30 ml syringes (0.01-1500)ml/h for 50 ml syringes
	Time	1 min – 99 hrs. 59 min
	Weight(Bodyweight)	0.1 - 661 lbs.
	Acti agentia(Drug mass)	0.01-99999
	Conc.unit (Concentration unit)	ug/ml, mg/ml, g/ml, U/ml, kU/ml, IU/ml, EU/ml, mmol/ml, mol/ml, kcal/ml
	Volume(Fluid amount)	0.01-9999ml
	Dose rate	0.01-9999
Body weight mode	Dose rate unit	ug/min, mg/min, g/min, U/min, KU/min, IU/min, EU/min, mmol/min, mol/min, kcal/min, ug/h, mg/h, g/h, U/h, KU/h, IU/h, EU/h, mmol/h, mol/h, kcal/h, ug/kg/min, mg/kg/min, g/kg/min, U/kg/min, KU/kg/min, IU/kg/min, EU/kg/min, mmol/kg/min, mol/kg/min, kcal/kg/min, ug/kg/h, mg/kg/h, g/kg/h, U/kg/h, KU/kg/h, IU/kg/h, EU/kg/h, mmol/kg/h, mol/kg/h, kcal/kg/h
Loading Dose mode	Maintain Rate	
	Loading Rate	
	Loading Time	
	VTBI	The same as ml/h mode
	Dose Rate	
	VTBI	

6.02.4.1 Infusion Parameters Setting Range

#### 6.02.4.2 Infusion Mode Settings

Before and after the automated self-test, the pump will automatically enter ml/h mode and the ml/h parameter display. If you would like to select other modes, press the <code>[Menu]</code> button to enter the Main Menu and choose the desired preset mode option and the set parameters.

#### 6.02.4.3 ml/h Mode

This mode allows you to set three parameters: Rate, VTBI (Volume to be Infused), and Time. The system will automatically calculate the third when you put two of the three parameters. If VTBI is set to 0, the equipment will work at the set rate until an alarm stops the infusions.

#### 6.02.4.4 Body Weight Mode

The Weight (bodyweight) mode will require you to set the patient's weight, the concentration unit (Conc. unit), the drug mass (Acti Agentia), the Fluid Volume (Volume), the Dose rate, the Dose unit, and the VTBI.

The system will automatically calculate the flow rate from the specified dose rate (ug/kg/min, mg/kg/min, mg/kg/h...etc.) The related formula is referred as {dose rate × weight}/{Acti agentia(drug mass)/Volume(fluid volume)}. The time is automatically calculated by (VTBI) /(flow rate).

Example: the dose rate unit(ug/kg/min)  $flow rate (ml/h) = \frac{Dose \ rate(ug / kg / min) \times Weight(kg) \times Volume(ml)}{Acti \ agentia(mg) \times 1000} \times 60$ 



#### 6.02.4.5 Loading-dose Mode

The loading-dose mode means infusion with a Loading flow rate according to a Loading time. After reaching the Loading time, it works at the set maintain rate until the VTBI (Volume to be infused).

Loading dose VTBI = Loading rate × Loading time

Maintain time = (VTBI -Loading VTBI) /Maintain rate

Under this mode, set the VTBI, maintain rate, loading rate, loading time, and the system will automatically calculate loading dose VTBI and the maintaining time.

Note: VTBI must be greater than the loading dose VTBI; otherwise, the excess part can't be set when the setting exceeds the limit.

#### 6.02.5 Purge Air

To prevent the pump from infusing air into the patient's body, the User must purge the air bubbles from the syringe before infusion.

Under the Menu, press the [Bolus] button down to clear the bubbles in the infusion line.

The total purge volume is not calculated in the Total Volume Infused.

Cautions: Before purging air, please confirm the infusion line is **not connected** to a patient.

Purge Rate is the max rate of the syringe size; when purge volume  $\geq$  5ml, purge will automatically stop.

#### 6.02.6 Start Infusion

Connect extension line with the patient and confirm infusion parameters. Press the [Start] button to start the infusion.

#### 6.02.7 Changing Infusing Parameters During Infusion

The flow rate value can be changed during the infusion process. Press **[OK]** while the infusion is running, a pop-up input box will appear. This prompt will allow the User to modify the flow rate input accordingly.

Note: Only the ml/h Mode and Bodyweight Mode supports rate modification during infusion.

#### 6.02.8 Bolus

Bolus functions have two operation modes: Manual Bolus and Automatic Bolus.

- 1. Manual Bolus: Press and hold the [Bolus] button to enter the fast infusion mode. Upon release of the button, the pump will run back to its previous set infusion rate.
- Automatic Bolus: During infusion, short press the 【Bolus】 button to set any two parameters- volume, speed, and time, this will fast-forward an infusion. When ready, press 【Start】. After the Bolus set volume is completed, the device returns to the initial infusion rate. To stop Bolus in

advance, press

Note: The "VTBI near end" alarms are not triggered during Bolus.

#### 6.02.9 Anti-Bolus

The system will automatically drop the line pressure when the extension line signals an occlusion alarm. This action will ensure no additional impact on the patient after occlusion was signaled.

#### 6.02.10 Infusion Completion

When the infusion is near completion, the pump will alarm. If a user ignores it, the system will keep alarming until the infusion is finished.

After VTBI is completed, it activates VTBI infused alarm; if the KVO function is ON, the equipment automatically starts the KVO function, press [OK] in the alarm interface to stop KVO and end the alarm.

The default working time of the KVO system is 30min. After reaching the time, it will activate the KVO completion alarm and stop the infusion.

Please refer to Chapter 7.01.2 for KVO settings.

#### 6.02.11 Stop Infusion

During Infusion or after Infusion, press [Stop], the infusion will stop. The display screen will identify the Total Volume Infused and adjustable parameters.

#### 6.02.12 Removing the Syringe

First, disconnect the extension line from the patient, then remove the syringe set from the equipment. To replace the syringe, please refer to Chapter 6.02.3.

#### 6.02.13 Power off or Standby

- 1. To turn off the equipment: Hold the Power button until the screen is OFF and the equipment is OFF.
- 2. For Standby mode: press to enter the standby settings and modify the set time for Standby.

Note: The equipment has a standby function only under the non-working state.

# Chapter 7 - System Setting

### 7.1 Settings

Select the **[**Settings] icon displayed on the Main Menu to enter any parameters setting options.

#### 7.01.1 Drug library

Select [Settings] in the main Menu to find the [Drug Library], press [OK] to enter and then set the ON/OFF state of drug library and select the drug option.

#### 7.01.1.1 Introduction to Drug library

This device supports over 20 drug names, which our company can import with an external tool. Our company also can change some functions such as upper and lower limit, concentration and more.

Select the fluid/drugs and then import the parameters, the User may change the parameters, including the concentration and dosage rate, but the parameters won't be saved.

#### 7.01.1.2 Setting Drug library

This function can be selected as ON or OFF.

Once this function is turned on, select the fluid/drug name with its preset value. The chosen medicine will be displayed in the running infusion menu after the drug library function is turned on and fluid/drug is selected.

#### 7.01.2 KVO rate

Select **[**KVO rate**]**, input the numerical value, confirm value, and press **[**OK**]**.

Please refer to Chapter 2.7 for the adjustable KVO range.

Note: KVO will be closed if the KVO rate is 0ml/h.

#### 7.01.3 Occlusion Pressure

Select Occlusion pressure  ${\tt J}$  to enter the occlusion pressure level setting. There are three different drop sensor levels available. After selection and confirmation, press [OK].

The higher the chosen selection level, the higher the occlusion level. We suggest selecting suitable occlusion pressure according to actual requirements.



- When infusing fluid/drug of high viscosity and the occlusion pressure is set at a low level, the system may sound the occlusion alarm even when the line is not blocked. Under this condition, please carefully observe the pressure indication icon in the display screen and the infusion line. Raise the occlusion pressure if needed.
- When the blocking pressure is set to a high degree, the immense pressure inside may pull the extension line away from the connection of the syringe. Please confirm that the extension line is securely attached to the syringe.
- When the occlusion pressure is set at a high level, it may cause the animal to feel uncomfortable; after raising the occlusion pressure, please carefully observe its condition. Immediately take measures if there's any abnormality.

- Under the equipment fault state, the max pressure generated by the infusion line is 3000 kPa. Under a single fault state, the max infusion volume is 2ml.
- If not used for syringe infusion, for example, Intra-arterial Infusion, TPN (Total Parenteral Nutrition), or EN (Enteral Nutrition) treatment, the occlusion level should be adjusted to higher levels.

Applicable Model: PRSP-S300(V) Occlusion Pressure Level: 3 levels						
Level	Pressure Intensity (mmHg)	Pressure Intensity (Kpa)	Pressure Intensity (bar)	Pressure Intensity (psi)		
1	150	20	0.2	2.9		
2	525	70	0.7	10.15		
3	900	120	1.2	17.4		

Table 7.01.3: Relation of Occlusion Level and Pressure

#### 7.01.4 Finish Pre-Alarm

Pre-alarm refers to the time of infusion nearing completion. The alarm signifies when the fluid/drug-infused volume nearly reaches the preset value.

Select [Finish pre-alarm] to enter the pre-alarm setting, select ON or OFF, and select the preset time option.

The time range for pre-alarm is 2 min, 5 min, 10 min, 15 min, 20 min, 30 min.

#### 7.01.5 Reminder alarm

Select [Reminder alarm] to enter a time for reminder alarm setting, select ON or OFF. Select the desired preset time option, and press [OK].

The range of time for the Reminder alarm is 2min, 5min, 10min, 15min, 20min, 30min.

There is no reminder alarm state when the equipment is under no infusion or a syringe is not installed.

#### 7.01.6 Weight unit

Select  $\llbracket$  Weight unitfloor to enter the bodyweight menu, then select the preset body weight unit option, and press **[**OK**]**.

Note: The current software version only supports unit kg.

Unit Mark	Unit Conversion
kg	1 lbs. = 0.4535 kg

#### 7.01.9 Commonly Used Syringe Brand

To change the Syringe brand for the infusion pump.

1. Install the Syringe. Select [Commonly used Syringe Brand] to enter the Syringe option menu and select the desired preset brand option.

Syringe brand 5ml 10ml 20ml 30ml 50ml v ٧ ٧ Double-Dove ٧ v **B.Braun Perfusor** v v BD ٧ ٧ ٧ ٧ ٧ TERUMO ٧ v v v v

The built-in syringe brands are Double-Dove, B.Braun Perfusor, B.D., Terumo.

Note: The syringes of different brands may cause flow rate deviations. When used, please confirm if the displayed information on the screen is congruent with the actual syringe brand.

### 7.2 General

#### 7.02.1 Sound

Select [Sound] to enter the sound setting menu. The volume has three-level settings. The lowest volume is  $\geq$ 50 dB, and the highest volume is  $\leq$ 80 dB.

#### 7.02.2 Date & Time

Select [Date &Time] in the settings menu to enter the correct date and time into the device. This setting allows users to set the device's date, time, and format.

When setting date and time, directly input the numerical value into the input. For example, to preset one date "2022-02-13", input "20220213"; to preset the time "12: 34", input "1234".

The time can be displayed in 24 hr. format or 12 hr. format, the date can be shown in Euro-American style or Eastern-Asian style, please set accordingly.

#### 7.02.3 Screen Lock

Select  $\llbracket$  Screen lock $\rrbracket$  to enter the automatic lock screen setting menu, select ON or OFF.

Automatic lock screen time can be set at 15 secs, 30 secs, 1 min, 2 min, 5 min, 10 min or 30 min and so on, which means that the equipment will automatically lock the screen if it is not touched, or the button is pressed within corresponding time after starting. If the screen or keypad is locked, no operation can be conducted.

After turning on 『Screen lock』 function during infusing, press 【Power】 key to lock or unlock the device manually.

To unlock: Press any keypad. A reminder of unlocking will pop up; press [OK].

Note: The equipment will automatically unlock if there is a High-Level alarm.

#### 7.02.4 Brightness

Select **[**Brightness] to enter the display brightness setting menu. The brightness setting has three levels.

#### 7.02.5 Nurse call

Select [Nurse call] to select functions ON and OFF.



The nurse call function must be used with a special cable.

The User should depend not only on the nurse call function as the primary alarm notice but also on identifying the alarm according to the equipment and the animal state.

#### 7.3 Records

Press [Records] in the Main Menu to enter records settings.

#### 7.03.1 History entries

In the system's settings, select the [History entries] to see the records list. The equipment can save over 5000 historical records and display event names, dates, and times. When entries are full, the new records will cover the old records by turn.

The historical records contain alarm information, treatment and purges records, cumulative bubbles, changes, and standby operations.

#### 7.03.2 Export history records

With the P.C. tool, connect this equipment to a P.C.

After the equipment has achieved connection with P.C., the P.C. can automatically read the data in the device.

We encourage users to create a history record folder in the P.C. to export the data into that folder.

Note: Please do not export data when the equipment is working.

#### 7.4 System

Select  $\llbracket$ Systemlambda under the Main Menu and enter the system setting interface

#### 7.04.1 Language

This equipment supports English, simplified Chinese, and more. Select [Language] to change device language.

#### 7.04.2 Factory Default

Select  $\llbracket$ Factory defaultl to clear all User-defined options, and this function is open to the User.

#### 7.04.3 S.N. (Serial Number)

Check the serial number of the equipment. A user cannot modify the serial number.

#### 7.04.4 Version

Check the software version in this interface.

#### 7.04.5 Maintenance

Call IPR for any preventive maintenance or issues. For more details, please refer to Chapter 11.

### 7.5 Electronic Memory Function

When the power failure time is  $\leq$  the 30s, the alarm setting will automatically recover before power failure.

# Chapter 8 - Alarm Prompt and Troubleshooting

# 8.1 Introduction to Alarm Level

This equipment will alarm when reaching or exceeding the set alarm threshold values. During infusion preparation and infusion, alarms will prompt with sound, light, and text. According to the importance of alarm information, emergency and safety, the alarm will be divided into high, medium, and low. Please refer to the table below for details:

Alarm	Sound Signal	Sound Signal	Light color /flash
Level	Interval	Interval	frequency
High	10s	Di di di-di di, Di	Red indicator
alarm	103	di di-di di	flashes /2.0±0.6Hz
Medium	15c	Di di di	Yellow indicator
alarm	153	Dididi	flashes / 0.6±0.2Hz
Low alarm	25s	Di di di	Yellow indicator lights on

Table8.1-1

If there is an alarm, the system will display an alarm prompt. Press **[OK]** to exit the alarm prompt.

Press 💱 to mute. If the alarm is not muted, an alarm sound will be sent out 2 minutes later.

ALARM SIGNAL sound pressure level range:

 $50dB(A) \le the LOW PRIORITY auditory ALARM SIGNALS \le the MEDIUM PRIORITY auditory ALARM SIGNALS \le the HIGH PRIORITY auditory ALARM SIGNALS \le 80dB(A)$ 

Warning: Some alarm thresholds of this device can be set by the User without password protection restrictions: occlusion pressure, reminder alarm, VTBI infused pre-alarm, alarm sound volume, and Standby time. The User shall confirm the parameters when setting the alarm threshold value; otherwise, it may influence the alarm function or infusion safety.3

# 8.2 Multi-level Alarm Rules

When there are several alarms, the system will alarm according to the following rules:

Table 8.2-1

Multi-level Alarm	Rules
Several alarms of different	Display the alarms of the highest level
levels generate simultaneously	with sound, light, and text, report medium alarm after eliminating all alarms of the highest level
Several alarms of the same level	Alarm circularly by turns; the time interval
generate simultaneously	is 3s for each.

# 8.3 Alarm Treatment

Warning: When there's an alarm, please check the conditions of the animal, remove the reason for the alarm, and then continue working.

Please refer to Appendix C for the alarm solution.

# 8.4 Malfunction Analysis and Solution

When there is a malfunction, the syringe pump screen will display the malfunction alarm information; this item is a high-level alarm. Please eliminate the malfunction alarm according to the prompt. If it can't be eliminated, please stop the equipment, contact our company to repair and test it, and do not put it into operation before the equipment has passed the inspection. Otherwise, it may cause unpredictable harm if it works with a malfunction.

Suppose the equipment is on fire/burns for an unknown reason or has any other abnormal conditions. In that case, the User shall immediately cut off the power supply and contact our customer service department.

Notes: The distance between the operator of the syringe pump and the pump should not exceed 0.5 m so as not to affect the operator to identify the alarm correctly.

The visual alarm signal should be visible from 4 meters away. The alarm indicator or analog alarm indication area should be visible to the naked eye; the visual alarm information should be visible 1 meter away. The alarm text or alarm icon is visible to the naked eye.

# Chapter 9 - Maintenance

# 9.1 Cleaning, disinfecting, and sterilizing

# A Warning

- Please cut off the power supply and unplug the AC/DC power wire before cleaning the equipment.
- Please keep the equipment horizontal and upwards during cleaning and disinfecting to protect the equipment and accessories from a fluid.

#### 9.01.1 Cleaning

- 1. The daily maintenance is mainly to clean the housing and pump body as fluids/drugs may inevitably flow in the equipment during infusion. But some fluids/drugs may corrode the pump and cause a fault. After the infusion, please clean the equipment. Wipe it with moist, clean, soft fabric, and please dry naturally.
- 2. When cleaning the equipment interface, please wipe it with dry and soft fabric and confirm the interface is dry before using it.
- 3. Please do not soak the equipment in water. Although this equipment has certain water-resistant functions, please check beforehand and ensure it still works when fluid splashes on the equipment. Perform a test infusion and electric leakage test, if needed.

#### 9.01.2 Disinfecting

- 1. Disinfecting may cause harm of a certain degree to the equipment. We suggest disinfecting the equipment only if it is needed.
- 2. Please disinfect the equipment with common disinfecting agents such as 70% ethanol, 70% isopropyl alcohol, etc. Please follow the instructions of the disinfecting agent.
- 3. After disinfecting, wet wipe with a soft fabric and warm water. With another dry cloth and wipe the equipment thoroughly.
- 4. Do not sterilize the equipment with a high-pressure steam sterilizer, do not dry the equipment with a dryer or similar product.

Warning: Please do not adopt Cidex OPA orthophthalaldehyde, methyl ethyl ketone, or a similar solvent. Otherwise, it may corrode the equipment.

# 9.2 Periodical maintenance

# A Notes:

- With this device, please set up a complete maintenance plan. Otherwise, it may cause the equipment malfunction or fault and may hurt the physical safety of others.
- To ensure the safe use and prolong the equipment's service life, we suggest periodically maintaining and checking it once every six months. The User shall hold some items, and some parts shall be maintained by the dealer of the equipment, IPR.
- Please timely contact our company if the equipment is found defective.

#### 9.02.1 Check the Appearance

- 1. The appearance of the equipment should be clean and under excellent condition without crack and water leakage.
- 2. The buttons are flexible and effective without invalid use; the touch screen's sensitivity is normal.
- 3. The slider of the syringe pump is flexible in movement, and the clamp is functioning.
- 4. The power wire is in good condition and installed tightly.
- 5. After connecting with the external power supply, check whether the A.C. and D.C. indicators of the device and the battery indicator are lit.
- 6. Adopt the accessories designated by our company.
- 7. The environment meets the requirements.

#### 9.02.2 Performance Check

- Self-test and normal infusion function.
- The alarm function is normal
- Battery performance.

#### 9.02.3 Maintenance Plan

The following check/maintenance items must be performed by the professional technician recognized by our company. If the following maintenances are necessary, please contact our company. Please clean and disinfect the equipment before testing or maintaining it.

Maintenance Items	Cycle
Safety check according to IEC 60601-1	Once every two years, check and replace the printed circuit board assembly or if the equipment has been dropped or knocked.
Preventive system maintenance items (pressure calibrate, sensor calibrate, pump)	Once every two years, when the occlusion alarm or infusion accuracy is doubted to be abnormal
Brand of user-defined infusion apparatus, infusion accuracy calibration	Using the equipment for the first time, using a syringe brand for the first time, reusing the equipment after stopping for a very long period.

### 9.3 Add New Brand and Calibration

In the **[**System] submenu, select **[**maintenance] to enter the brand setting menu, this allows you to create a brand, delete, and calibrate any syringe brand.

Warning: We suggest contacting our company to customize and calibrate sets with our professional technicians. Otherwise, there is no guarantee of infusion accuracy.

1. Add new brand

Note: If the existing syringe brand is not listed in the system, please select the syringe brand from User 1 to User 4 in the settings.

2. Calibrate

# <u>∧</u> Note

- With the first-time use of the pump, it will need calibration.
- When adding a new syringe brand, the pump will need calibration.
- When accuracy is not correct, the pump needs calibration.

#### 9.03.1 Calibrating Steps:

Automatic:

- 1. Select the brand name. (User 1 User 4)
- 2. Select Syringe size.
- 3. Install syringe, pull the syringe plunger beyond size scale line slightly. Press and hold [Bolus] until the correct syringe volume is chosen.
- 4. Press [Start] to start Calibration.
- 5. Calibration completed.

#### Manual:

- 1. Select the brand name.
- 2. Select Syringe size.
- 3. Select and enter parameters for "Outer Diameter," "Full Range Length," "Empty Space," and more if needed.
- 4. Calibration Completed.

### 9.4 Repair

Warning: The maintenance of equipment and the replacement of components shall be carried out by professionals of the company. When the power module is replaced, particular attention shall be paid to detecting the power supply. Observe whether there is a false alarm, connect the A.C. power supply, and charge the battery normally.

#### 9.4.1 Normal Repair Process

Please contact our company to repair if there's any fault, do not disassemble and repair the equipment. After repair, please perform a comprehensive test for the equipment. Please contact our company if an authorized repair technician if needed.

#### 9.4.2 Maintenance for Long Term Store

Suppose the device won't be used for an extended period. In that case, we encourage removing the battery, packing it with its original packaging, and storing it in a shady, cool, dry place without direct sunlight.

Please note the following operations are necessary for using it again:

- 1. Verify flow rate accuracy to avoid unconformity between the syringe parameters set in the equipment and the actual parameters after. There may be an infusion error if it hasn't been used for an extended period or other reasons. This error may influence the therapeutic effects and even cause medical negligence.
- 2. We highly encourage performing an occlusion alarm test.
- 3. Experiment with the battery discharging and charging duration to confirm that the battery is also usable.

# 9.5 Equipment Components/Accessories

Warning: Only the components and accessories designated by our company shall be adopted. Otherwise, it may damage the equipment or drop the equipment performance.

During the average service life of the equipment, the battery and water-resistant membranes are consumables. As a suggestion, it is best to replace them once every two years. Please contact our company to replace them.

Variety	Name
	Pole clamp
Equipment Components	Power Cord
- 4	Handle

# 9.6 Production Date

Please refer to the label of the product.

### 9.7 Recycling

The average service life of this equipment is ten years and depends on the use frequency and maintenance. The equipment must be rejected after reaching its service life. Please contact our company to get more detailed information.

- 1. We suggest the obsolete equipment be returned to our company.
- 2. According to the applicable laws and regulations, the used lithium-ion polymer battery needs to be thrown at a hazardous waste facility.
- 3. Regarding consumables, please handle them according to the waste system of your facility.

# Chapter 10 - Battery

This equipment is equipped with a rechargeable lithium-ion polymer battery to ensure a standard infusion if the equipment is moved, or the external power supply is cut off.

When connecting an external power supply, whether the equipment is powered on or not, the battery will charge. In extraordinary instances, only a built-in battery is implemented to supply Power. When the remaining battery is less than 20%, please connect the equipment with an external power supply to charge the battery.

Warning: Only the battery designated by our company shall be adopted.

# 10.1 Check the Battery Performance

The performance of the built-in battery may drop according to the using duration. It is a suggestion to check the battery at least once a month.

- 1. Disconnect the equipment from the animal and stop all infusions.
- 2. Supply public Power to the equipment to charge the battery for at least 5 hours.
- 3. Supply power to the syringe pump only with the battery, infusion at the rate of 5ml/h, test the time till the battery runs down and the equipment is off.
  - When testing if the infusion time exceeds ten hours and completes infusion, the battery is in good condition.
  - When testing if the infusion time exceeds seven hours but less than ten hours, the battery has deteriorated but can be used temporarily.
  - If the infusion time is less than seven hours and the battery cannot complete an infusion, please replace the battery.
- 4. If the battery power supply time is significantly lower than the time stated in the specification, consider replacing the battery by contacting us.

# 10.2 Replacing the Battery

It is recommended to replace the battery every two years; it is suggested to replace the battery by our company.

Warning: Untrained personnel is forbidden to replace the battery; otherwise, it may cause the battery to burn, explode, leak, and cause personal injury.

# Chapter 11 - Customer Service

This product includes a 1-year warranty after purchase. The warranty period is from the date it is in the User's possession. The equipment damages caused by the following are not covered under the warranty service.

- 1. Fault caused by incorrect operation, unauthorized refitting, or repair.
- 2. Damages caused by incorrect operation during the transportation process, after purchase.
- 3. The fault and damages caused by fire, salt injury, toxic gas, earthquake, windstorm, flood, abnormal voltage, and other natural disasters.

Our company provides repair services for the damages or faults mentioned above but with repair costs.

# Chapter 12 - Appendix Appendix A Start-Up Graphs and Trumpet Curves

Appendix A.1 Start-up Graphs

Brand and specification of syringe: Double-Dove

Size: 50 ml

Number of Sampling equipment: 3 sets

Number of sampling syringes: 3

Flow Rate: 1ml/h

Measurement Interval:  $\Delta t = 0.5 min$ 

Measurement duration: T = 2h



Graph 1 Start-up graph: Flow rate 1 (ml/h) against time (min) plotted from data gathered during the first two hours of the test period.

Brand and specification of syringe: Double-Dove

Size: 50 ml

Number of Sampling equipment: 3 sets

Number of sampling syringes: 3

Flow Rate: ml/h

Measurement Interval:  $\Delta t = 0.5 min$ 

Measurement duration: T = 2h



Graph 2 Start-up graph: Flow rate 5 (ml/h) against time (min) plotted from data gathered during the first two hours of the test period.

#### Appendix A.2 Trumpet Curves

Brand and specification of syringe: Double-Dove

Size: 50ml

Number of Sampling equipment: 3 sets

Number of sampling syringes: 3

Flow Rate: 1ml/h

Measurement Interval:  $\Delta t = 0.5 min$ 

Measurement duration: T = 2h



Graph 3 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period

Brand and specification of syringe: Double-Dove

Size: 50ml

Number of Sampling equipment: 3 sets

Number of sampling syringes: 3

Flow Rate: 5ml/h

Measurement Interval:  $\Delta t = 0.5 min$ 

Measurement duration: T = 2h



Graph 4 Trumpet curve: Percentage variation Ep against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period

Note: Infusion accuracy may be affected by the syringe pump environment, such as pressure, temperature, humidity, infusion consumables, and so on.

# Appendix B Occlusion Response Property

Delay and Possible Dose

Flow Rate (ml/h)	Occlusion Pressure (mmHg)		Time to occlusion alarm(min)	Max bolus (ml)
0.1	Low	150	3h32min30sec	0.047
0.1	High	900	38h17min09sec	0.102
1	Low	150	0h38min40sec	0.046
-	High	900	2h11min0sec	0.085
5	Low	150	0h13min55sec	0.053
	High	900	0h29min46sec	0.077



This device's alarm pressure intensity error is  $\pm 15\%$  or  $\pm 100$  mmHg; the higher value shall be taken.

A Notes:

Conditions for above testing data: Syringe Brand: Double-Dove; Size: 50 ml.

The test conditions, temperature, and line length influence the occlusion alarm pressure, alarm delay time, and Bolus.

The above data is the typical value under the test conditions. Please see the test data of the product for the actual data. The data may be different when the test conditions are different

# Appendix C Alarm and Solution

Alarm Type	Alarm Level	Alarm Delay	Reason	Solution
VTBI infused	High	<1s	The preset value infusion completion.	Press 【Stop】 button to stop the alarm.
Syringe Empty	High	<1s	The fluid/drugs in the syringe are empty.	Press 【Stop】 button to stop the alarm.
			1. Line occlusion during infusion.	Press 🐑 to silence. Manually solve the problem of occlusion. Press 【Start】 button to continue the infusion.
Pressure high	High	<1s	2. Fluid/drug in the actual infusion line of high viscosity, while the system occlusion level is set too low.	Rise the alarm Level, Press 【Start】 button to restart infusion.
			3. The pressure sensor is damaged.	Please contact the dealer or manufacturer for repair
Battery empty	High	<1s	When Power is supplied by the built-in battery only, under low battery, the alarm duration is >30min.	Immediately connect with the external power supply.
			<ol> <li>Battery aging or the equipment charging circuit is faulty.</li> </ol>	Please get in touch with the dealer or manufacturer for repair.
Check Syringe	High	<15	Syringe drop-off during infusion.	Reinstall the syringe.
KVO finished	High	<1s	KVO working time reached 30min; infusion pump stopped working.	Press【Stop】button to stop the alarm
System error	High	<3s	The error alarm will give a code number if a system self-check fails or an internal fault.	Restart the device to check whether the alarm is eliminated. If it still exists, contact our company.
VTBI near end	Medium	<15	During infusion, the remaining time reached or is less than the set nearing completion time.	This alarm can't be eliminated; wait till infusion completes.

Alarm Type	Alarm Level	Alarm Delay	Reason	Solution
Syringe nearly empty	Medium	<1s	The syringe is near empty, calculated by the current flow rate's remaining medicine in the syringe.	This alarm can't be eliminated; wait till the syringe is empty.
Battery Nearly Empty	Medium	<1s	<ol> <li>When Power is supplied only with the built-in battery, under low battery, the alarm duration is &gt;30min.</li> <li>Battery aging or the equipment charging circuit is a fault.</li> </ol>	The alarm is automatically eliminated after connecting the external power supply.
Reminder alarm	Low	<1s	After installing the syringe, under a non-working or alarm state, it is not operated within the set time of the system.	Press any button to stop.
Standby time expired	Medium	<1s	During Standby or after reaching the standby time.	Press 【Stop】 button to stop the alarm.
No power supply	Low	<1s	Under ON state, A.C. power supply is adopted, but the A.C. power wire is dropped during the process.	The alarm is automatically eliminated after connecting the external power supply.

Notes: When the alarm rings, press the riccon on the screen to temporarily stop the sound alarm for 2min.

# Appendix D EMC Electro Magnetic Compatibility Declaration

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. This unit can be affected by portable and mobile R.F. communications equipment.



- This unit has been thoroughly tested and inspected to assure proper performance and operation!
- This machine should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this machine should be observed to verify regular operation in the configuration in which it will be used.



The use of ACCESSORIES, transducers, and cables other than those specified, except for accessories, transducers, and cables sold by the Infusion Pump Repair as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the syringe pump.

#### Guidance and manufacture's declaration – electromagnetic emission

The Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the Syringe pump user should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
R.F. emissions CISPR 11	Group 1	The Syringe pump uses R.F. energy only for its internal function. Therefore, its R.F. emissions are very low and are not likely to cause any interference in nearby electronic equipment.
R.F. emissions CISPR 11	Class A	The Syringe pump is suitable for use
Harmonic emissions IEC 61000-3-2	Not applicable	domestic establishments and those directly connected to the public low-
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	voltage power supply network that supplies buildings used for domestic purposes.

#### **Guidance and manufacture's declaration – electromagnetic immunity**

The Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the Syringe pump user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines <u>+</u> 1 K.V. for input/output lines	±2kV for power supply lines	The main power quality should be a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) <u>+</u> 2 KV line(s)to earth	± 1 kV line(s) to line(s) <u>+</u> 2 KV line(s)to earth	The main power quality should be a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT)for 5 sec	The main power quality should be a typical commercial or hospital environment. Suppose the Syringe pump user requires continued operation during power mains interruptions. In that case, it is recommended that the syringe pump be powered from an uninterruptible power supply or a battery.

Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a specific location in a typical commercial or hospital environment.
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NOTE: U.T. is the A.C. mains voltage before applying the test level.

**Guidance and manufacture's declaration – electromagnetic immunity** 

The Syringe pump is intended for use in the electromagnetic environment specified below. The customer or the Syringe pump user should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compli ance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile R.F. 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 transmitter's frequency.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	Recommended separation distance $d = 1.167 \sqrt{P}$ $d = 1.167 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.333 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). As determined by an electromagnetic site survey, field strengths from fixed R.F. transmitters should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and F.M. radio broadcast, and T.V. broadcast cannot be predicted theoretically with accuracy. An electromagnetic site survey should be considered to assess the electromagnetic environment due to fixed R.F. transmitters. Suppose the measured field strength in the location where the Syringe pump is used exceeds the appropriate RE compliance level above. In that case, the Syringe pump should be observed to verify regular operation. If abnormal performance is regarded, additional measures may be necessary, such as reorienting or relocating the Syringe pump.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

#### **Recommended separation distances between**

#### portable and mobile R.F. communications equipment and the Syringe pump.

The Syringe pump is intended for use in an electromagnetic environment in which radiated R.F. disturbances are controlled. The customer or the Syringe pump user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile R.F. communications equipment (transmitters) and the Syringe pump as recommended below, according to the maximum output power of the communications equipment.

The rated maximum output	Separation distance according to the frequency of the transmitter (m)			
power of the transmitter (W)	150 KHz to 80 MHz d = 1.167 $\sqrt{P}$	80 MHz to 800 MHz d = 1.167 $\sqrt{P}$	800 MHz to 2.5 GHz d = 2.333 $\sqrt{P}$	
0.01	0.117	0.117	0.233	
0.1	0.369	0.369	0.738	
1	1.167	1.167	2.333	
10	3.689	3.689	7.379	
100	11.667	11.667	23.333	

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

- NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

# Appendix E Wireless Module Information*

Parameter Name	Parameter Value	
Frequency Range	2.412GHz-2.482GHz	
Modulating Type	OFDM,CCK,DSSS	
Effective Radiating Power	<20dBm	

# Appendix F Factory Default Setting

Parameters	Default Setting	Parameters	Default Setting
KVO rate	1ml/h	Sound	Middle
Occlusion pressure	Middle	Screen lock	ON
Finish pre-alarm	2min	Nurse call	OFF
Reminder alarm	2min	Drug Library	OFF
Commonly used syringe brand	Double-Dove	Brightness	High



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