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# Copyright

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Shenzhen Comen Medical Instruments Co., Ltd.

## Product Information

Product Name: Infusion Pump

Models: ME600

Address: No.2 of FIYTA Timepiece Building, Nanhuan Avenue,  
Gongming sub-district, Guangming New District, Shenzhen,  
518106, Guangdong, China.

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Edition number of the User's Manual is subject to upgrade without further notice due to any changes in software, technical specification or other causes.

The User's Manual is only applicable to the ME600 manufactured by the Comen Company.

## **Warranty**

Comen Company will be responsible for the safety, reliability and performance of its products on the conditions that the following conditions are complied:

- The products are operated as per the User's Manual;
- The products are installed, maintained and upgraded by personnel approved or authorized by Comen company.
- Storage environment, working environment and electrical environment of the products conform to the product specifications;
- The product serial number label or indication of manufacture is clear and legible such that Comen may identify that the products are authentically manufactured by Comen Company;
- The damages are not caused by human factors (such as dropout by accident, deliberately sabotage etc.);

Comen Company will provide free warrenty services for all products failures satisfying the Comen's warrenty conditions. Comen may charge a service fees for any services not within the product's

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warranty. User has to bear all transportation costs (including custom's duties) for sending the products to Comen.

 **Caution**

**This instrument must not be operated at home.**

 **Warning**

**It is not a medical treatment device.**

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## **Return Purchase**

If return purchase is really necessary, please follow the steps given below:

Acquiring the right of return: Contact the After-sale Service Department of Comen company and inform it of the serial number of Comen instrument. The serial number can be found on the data plate. If serial number of an instrument is not clear and legible, return purchase may not be accepted. Furthermore, please indicate the serial number and date of production of the instrument, and describe briefly the causes of return purchase

## **After-sales Service Provider**

Provider: After-sales Service Department, Shenzhen Comen Medical Instruments Co., Ltd.

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## **Preface**

This Instruction Manual describes the performance, operation methods and other safety information of ME600 infusion pump manufactured by Comen. It is a start guide for new users of this infusion pump.

## **Scope of Application**

This infusion pump is used for intravenous fluids (Liquids, nutrient solution and so on) at a constant speed into patient's body in hospital.

## **Illustrations**

All illustrations provided in this Manual are for reference only. The menus, settings and parameters shown in the illustrations may be not exactly identical to those shown on the infusion pump.

## **Conventions**

- —>: Represents operation steps.
- [Character]: Represents character strings in the software.

## **Product life**

The expected service life of this product is 5 years.

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# Chapter 1 Overview

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This Manual provides you with safe and proper methods for operation of ME600 infusion pump. Please read this Manual carefully before use of this pump and keep it handy for reference by operators at any time.

## 1.1 Appearance

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### 1.1.1 Front

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## 1.2 Composition

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ME600 infusion pump consists of a shell, a motor drive system, an input system, a storage system, a control system, a display system, a sensor detection system and an alarm system.

## 1.3 Features

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- High intelligence: the double CPU chips enable real-time monitoring of the whole infusion process, ensuring a safer and more reliable infusion process.
- Wide range of infusion speed: 0.1ml/h~1500ml/h.
- Extensive scope of application: applying to 20 drops/ml and 60 drops/ml infusion sets.
- High-brightness LED light is used to indicate the alarm status, enabling medical personnel to clearly observe the infusion status from far away.
- The lamp set in the pump will automatically light up once the pump door is opened, facilitating medical personnel's operation in the nighttime.
- The tube heating function ensures the infusion precision and

## Chapter 1 Overview

reduces the influence of low temperature on the infusion precision.

- The history function allows saving more than 800pcs of historical infusion records.

# Chapter 2 Safety Information

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## 2.1 Overview of safety information

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This Manual provides several symbols to represent important matters or instructions. In order to properly operate this pump, please pay attention to the following symbols:

### **Warning**

- **Improper operations that may endanger life or cause severe injury.**

### **Caution**

- **Improper operations that may cause personal injury or damage of the infusion pump.**

### **Note**

- **Reference and supplementary information provided for operation.**

## 2.1.1 Warning

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### warning

- **Users must check the device, connectors and accessories before use.**
- **Use the device within the scope of 100cm beyond or below patient's heart, closer the distance between patient's heart and pump is, more accurate the pressure in transfusion tube will be.**
- **The device shall be used with recommended infusion apparatus, or Comen Company will not be responsible with the accuracy and alarm functions.**
- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.**
- **User shall pay a close attention to patient's clinical situation and pump working condition, and set the alarm limit and alarm volume according to the actual conditions. Do not just**

**rely on the auditory alarm. The minimum volume may lead to patient's life-threatening.**

### 2.1.2 Caution

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#### **caution**

- **After installing the infusion tube, check the weeping before use it.**
- **After transfusion, user shall adjust the tube position or replace the transfusion components to ensure the accuracy. recommend to adjust the pipe-gripping every 6 hours to ensure the accuracy.**

### 2.1.3 Attention

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#### **Attention**

- **During the transfusion process, infusion pump controls the velocity, transfusion volume and the time accurately, and monitors the stepper motor's speed and direction to protect the overflowing, undercurrent and back suction**

## 2.2 Installation and Storage

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### **Warning**

- **Do not install or store the pump in a place where liquid can easily splash because short circuit may be caused if any liquid splashes onto the power cord of the pump.**
- **Do not install or store the pump in a place where chemicals are stored or gases are exhausted.**
- **Please properly install or move this instrument and prevent the instrument from being damaged due to fall, collision, strong vibration or other external mechanical forces.**
- **The pump shall be installed and clamped as required or fixed reliably; do not place it on a panel without guardrail near the sickbed in order to protect the patient from being endangered by the possible drop of the pump when the tube is pulled.**
- **This pump applies the principle of full extrusion peristalsis, therefore shall NOT be used in blood transfusion.**
- **The performance of this product has nothing to do with gravity.**





## Caution

- Please use this device under the following environmental conditions:

**Ambient temperature: 5°C~40°C**

**Relative humidity: 20%~90%**

**Atmospheric pressure: 700hPa~1060hPa**

**AC supply voltage: 100V-240V~, 50/60Hz**

**Power: ≤ 35VA**

- This device is not applicable in an environment mixing oxygen and flammable anesthetics containing oxynitride; use of the device in such an environment may result in explosion.
- Make sure the environment in which this device is installed and used is free of strong electromagnetic interference, such as interference from radio transmitter and mobile phone.



## Note

- Please install the device in a place convenient for observation, operation and maintenance.
- Please keep the Instruction Manual near the device so that it

can be fetched conveniently and timely when needed.

## 2.3 Power supply



### Warning

- Before the instrument is switched on, please confirm whether the power supply used meets the requirements for power supply voltage and frequency designated in the nameplate label or in the instruction manual of this instrument.
- This pump shall use the specified power supply; otherwise, fire or electric shock may take place.
- The accompanying power cord shall be used and plugged into the wall socket with ground terminal. Abrasion of the power cord is not allowed because fire or electric shock may take place when the power cord is damaged.
- Do not plug in or out the power cord with a wet hand; otherwise, electric shock may be caused.
- In case the external protective wire is being installed, or there is any doubt about the cabling of the infusion pump, it should use

**the built-in battery to supply power for the work station.**

- **If the built-in battery doesn't supply power normally when it is being used, please maintain it or replace it.**
- **For the sake of the patient and medical personnel's safety, please**

**make sure the device is well grounded and the protective grounding of the power socket is in good condition; never connect the 3-core cable of this device to a two-pin plug.**

- **Do not open the shell of the device during operation or when connecting to power supply; only authorized maintenance engineers are allowed to open it.**

 **Caution**

- **Please connect the power cord to a socket of sufficient capacity.**
- **A separate AC socket shall be used for high-frequency instrument or high power consumption equipment (e.g., electric surgical instruments).**
- **If battery is to be used for operation, please check the charging condition and the battery state (e.g., whether the voltage is too**

low) before operation. If the device is used for the first time or reused after a long period of time, please connect the battery to AC power supply to charge it fully.

## 2.4 Operation

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### Warning

- This monitor is used for clinical infusion, so only the doctors medical electrical specialist and nurses who are qualified through training can use this equipment.
- Only qualified doctors and nurses after training are allowed to use this infusion pump.
- Always monitor the working condition of the infusion pump and check the infusion set and infusion tube; do not rely only on the alarm function of this system.
- Use of a non-conforming or non-calibrated infusion set may result in inaccurate infusion speed, which will cause injury to the patient.
- Disposable infusion sets shall be used in order to avoid

**cross-infection.**

- **During use of this device, attention should be paid to preventing the air from entering the patient's body to avoid injury to the patient.**

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- **The air bubbles between the pump and the patient cannot be detected, which shall be eliminated manually.**
- **During use, the infusion tube should be installed in the pump in proper sequence and direction and should be straightened out; operation without following proper sequence may result in no fluid output or excessive administration, which will cause injury to the patient.**
- **Before startup, please check if all parameters are set properly.**
- **When any other system or accessory is connected to the infusion set on the pump, please make sure there is no air bubble input and that the infusion set on the pump is equipped with a check valve.**
- **Before pressing the "Start" button, please confirm whether the type of the infusion tube selected is appropriate. Inappropriate type may result in inaccurate infusion speed, pressure alarm**

**error, etc.**

- **During using, the patients or their family members mustn't operation this instrument. To protect patient safety form the incorrect operation.**
- **Before using, user must check the device if there is any damage which may affect patient's safety, recommend the review cycle to be once a month or even shorter. If there is obvious damage, please replace the defective parts.**

## Chapter 3 Operating Principle

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ME600 infusion pump is a type of volumetric infusion pump; through accurate control of the precision stepper motor by the microprocessor, the mechanical transmission structure is driven, causing regular movement of the peristaltic piece; working with the sensors and the extrusion board, the speed of the disposable infusion set is accurately controlled; it is a high-precision infusion pump that detects the infusion process reliably. Branded disposable sterile infusion sets that meet the infusion set standard (hereinafter referred to as “infusion sets”) can be used for ME600 infusion pump; besides, its software debugging function allows the use of ordinary infusion sets of any brand.

The infusion pump is designed with the multi-sound and light alarm function, which makes it convenient for the user to operate the pump and meanwhile ensures safe and reliable infusion. This infusion pump is applicable for clinical treatment requiring long-time, uniform and accurate control of the infusion speed and monitoring of the infusion process. It applies to infusion treatment in internal medicine department, surgical department, pediatric department, gynaecology and obstetrics department, ICUs, CCUs and operating rooms in hospitals and other clinical applications (but not suitable for blood transfusion).

# Chapter 4 Configuration

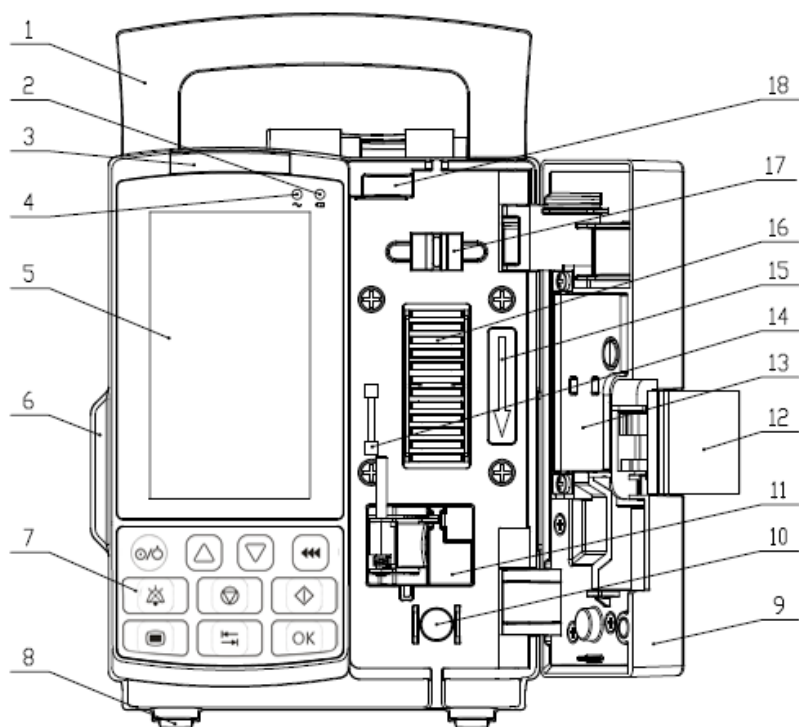
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## 4.1 Configuration

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### 4.1.1 Front

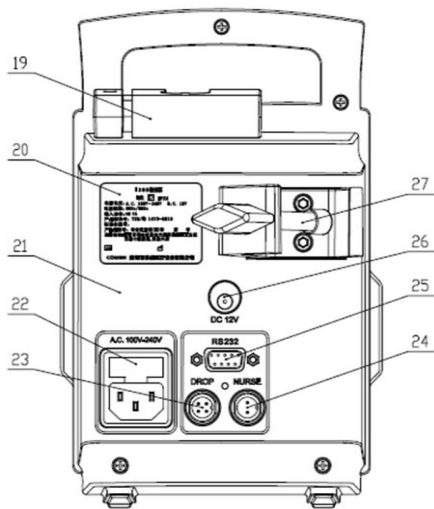
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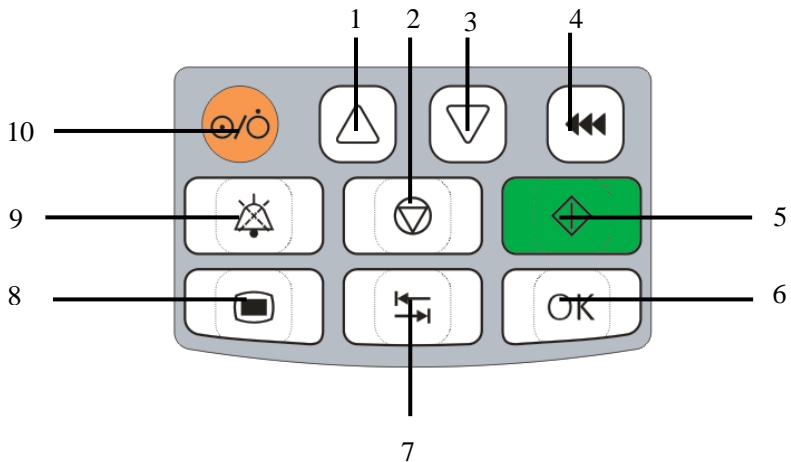
1	Handle	10	Pressure sensor
2	Charging indicator	11	Empty-bottle clamp
3	Alarm light	12	Pump door switch
4	AC indicator	13	Peristaltic pressing plate
5	Display screen	14	Door holder
6	Front shell	15	Infusion direction label
7	Button panel	16	Peristaltic system
8	Anti-slip foot pad	17	Bubble sensor
9	Pump door	18	Lamp

## 4.1.2 Back



19	Drop clamp	24	Nurse call connector
20	Nameplate	25	RS232 connector
21	Real shell	26	DC12V connector
22	AC socket	27	Clamping frame
23	Drop clamp connector		

## 4.2 Front Panel



1	Increase	6	OK
2	Stop	7	Tab
3	Decrease	8	Menu
4	Fast Forward	9	Mute
5	Start	10	Power

Descriptions of buttons:

No.	Name of Button	Description
1.	Menu	Select the key to enter the standby mode (multiple selection of Menu, the first-level menu cursor does not blink when entering standby mode), and can exit the standby mode to enter the first-level menu selection. When this button is used to select and set the first-level menus on the LCD screen; there are two first-level menus on the LCD screen; you can switch among these two menus by pressing this button.
2.	Increase	When the cursor hovers over a parameter option to be set, this button can be pressed to adjust the

		parameter; the parameter value will increase rapidly if you long press this button.
3.	Decrease	When the cursor hovers over a parameter option to be set, this button can be pressed to adjust the parameter; the parameter value will decrease rapidly if you long press this button.
4.	Fast Forward	<ul style="list-style-type: none"> <li>● Click this button in the Stop state. If you click this button again within 2s and keep pressing it, the system will enter the fast forward state; after loosening, the fast forward action will be stopped, and the system will return to the parameter setting state. If you do not click this button again within 2s, the system will exit the fast forward state, and the fast forward prompt will disappear automatically; at this point, the operation of the “Fast Forward” button will not be included in the total volume.</li> <li>● Click this button in the infusion state. If you click this button again within 2s and keep</li> </ul>

		<p>pressing it, the system will enter the “fast forward infusion” state (Bolus state) ; after loosening, it will return to the normal infusion state. At this point, the operation of the “Fast Forward” button will be included in the total volume.</p> <ul style="list-style-type: none"><li>● Fast forward speed (Bolus rate) and infusion limit (Bolus volume) function setting.</li></ul> <p>Press the fast forward button during infusion to display the fast forward speed and infusion limit settings page. The page can be set fast forward speed and infusion limit, press the start button, you can start the automatic fast forward, the device will automatically stop after the preset infusion limit complete, then the device will return to normal speed; During infusion, press the fast forward button on the fast-forward page, then you can do it manually, as long as the user does not let go, the preset</p>
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		<p>fast forward speed will be fast forward, unlimited limit.</p> <ul style="list-style-type: none"> <li>● The purge rate setting function.</li> </ul> <p>In the stop state, press the fast forward button, display the purge rate setting page, then you can set the purge rate, Press and hold the fast forward key on this page to drain the tubing air.</p>
5.	Tab	<p>This button is used to select and set the second-level menus on the LCD screen; when the “Menu” button is used to switch to the corresponding menu, the system will enter the corresponding menu setting interface after the “Tab” button is pressed.</p> <p>When cursor is flashing in a number, press the “Tab” can move cursor left or right in the number.</p>
6.	OK	<p>This button is used to set the third-level menus on the LCD screen.</p>
7.	Start	<p>After all parameters are properly set, you can press the “Start” button to start infusion; the infusion pump will enter the infusion state at the same time.</p>

8.	Stop	<p>You can press the “Stop” button to stop the on-going infusion operation; parameters can be set in the stop state. After an alarm is sent, you can press the “Stop” button to stop both the infusion and the alarm signal sent by the device. In the stop state, no other changes will be caused if this button is pressed repeatedly.</p>
9.	Mute	<p>When a sound alarm is sent, you can press the “Mute” button once to eliminate the alarm sound. For “Battery Depleted” and “System Error” alarms, the alarm sound cannot be stopped by pressing the “Mute” button. For reminder alarm, if the alarm is not processed within 2min, the alarm sound will come again 2min after such alarm is sent.</p> <p>When AC Off Alarm, press the mute for the first time, only cancel AC Off Alarm, other alarms are not quiet, but the second time you press mute, you can quiet other alarms.</p> <p>If the infusion is close to completion alarm, the first time to press the mute button, only the close to</p>










		<p>completion alarm will be cancelled, the other alarm will not be silent, the second time the other alarm will be mute.</p> <p>If at the same time, the AC Off Alarm and the close to completion alarm rang, the first time press the mute button, only cancel the AC Off Alarm.</p> <p>If there is no alarm, the mute button is invalid.</p> <p>Press the mute button to restore alarm sound during the alarm.</p>
10.	Mute + OK	When these two buttons are pressed simultaneously, the total volume will be cleared to zero.
11.	Mute + Stop	When these two buttons are pressed simultaneously, Timeout alarm function can be turned off.
12.	Mute + Menu	When these two buttons are pressed simultaneously, you can enter the maintenance menu.(ACCU and dEFt)
13.	Mute + Tab	When these two buttons are pressed simultaneously, select dAtE, you can set date and time.
14.	Menu+ Increase	When these two buttons are pressed simultaneously, you can adjust the volume level, 1 for the minimum







	or Decrease	volume, 5 for the maximum volume, the current volume value will be in the long press the set button or press the Menu + Increase or Decrease , immediately displayed in the original infusion tube brand code area.
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## 4.3 Marks and Their Meanings

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	Date of manufacture		This way up
	Type CF applied part		Fragile Handle with care
	Address of manufacturer		Stacking Limit
	Serial Number		Keep dry
	Separate collection for electric and electronic equipment		Caution
IPX4	Protected against splashing water		Refer to instruction manual/ booklet

## Chapter 4 Configuration

	Battery full		Battery not full
	Battery low		Battery runs out

# Chapter 5 Operation Guide


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## 5.1 Power-on

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After connection to the external power supply, the external power supply indicator will turn on; long press  for about 2s to power on the system.

### Notice

- **When mains supply (alternating current) is not connected to, the built-in battery of the infusion pump will supply power to the pump after the pump is turned on.**

## 5.2 Preoperational check

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### 5.2.1 Power-on Self-test

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The system begins self-test upon power-on; the infusion pump will automatically test each function. And when the screen is turned on, it

displays all the contents of the interface for the user to check whether the corresponding area display is normal.

After self-test is completed, the LCD screen will display the infusion tube function settings interface; at this point, Start to enter the infusion tube function settings interface: each boot, the bottom of the interface shows the infusion tube function settings, the initial cursor positioning in the model selection, the specific settings see chapters 5.6 and chapters 5.7 and chapters 5.8 and chapters 5.9, after the parameters are set, press the Menu button to jump directly to the main interface.

## **5.2.2 Drop Clamp Test**

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Move your finger downwards over the infrared light receiver once, the injection drops downwards and the indicator of drop clamp should flash once. Otherwise, the drop clamp malfunctions. Please contact the manufacturer for maintenance.



Under normal operation, when the infusion drops once, the indicator of drop clamp should flash once. If the indicator doesn't flash or flashes more than once, it indicates that the drop clamp may be installed improperly or may malfunction. Please check and reinstall the drop




clamp following the requirements.

### 5.2.3 System maintain

1. Press “+”key to enter the calibration menu.


There are two options available in this menu: [ACCU] (Accuracy calibration) and [DEFT] (Restore factory settings).

2. Press  to select one option and press  to enter its catalog.

3. Enter [DEFT] (Restore factory settings) option, you can press Confirmation key “” and press Add key“” or Minus key“” to select U01–U04, the meaning of U01–U04 see the table below, [ACCU] (Accuracy calibration) see details in [5.2.4 Speed Accuracy Calibration](#).

Code	Code meaning
U01	Clear the Log

U02	Restore the injection parameter as the default value
U03	Restore [ACCU] (Accuracy calibration) as the default value
U04	Clear the Log,and restore [ACCU] (Accuracy calibration) and the injection parameter as the default value.

4. Press  to exit this menu and return to operating mode interface.

## 5.2.4 Speed Accuracy Calibration

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Recalibration is needed when you want to use an infusion set that is not defined in the system or when infusion is not so accurate.




### 5.2.4.1 Measurement Calibration

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Calibration conditions: 1 50ml-range standard measuring cylinder (or 1 precision balance), 500ml distilled water, and at least 1 new

infusion set to be calibrated.

Enter the speed calibration (ACCU) interface, see the method for entry in **5.2.3 system maintain**, and the system default is calibration step 1[STEP -01-] with infusion limit of 10ml. The “ACCU”(means ” accuracy”) shown on the bottom of the display screen is the percentage deviation of current infusion set. This percentage means the deviation between current calibration value and default calibration value rather than actual infusion accuracy.

1. In this interface, you can press Confirmation key “” and Add key “” or Minus key “” to select the brand (b01-b09 and U01-U03) and model (20d/ml and 60d/ml) of the infusion set to be calibrated.
2. After selecting the brand and model of infusion set to be calibrated, use distilled water to vacuum the infusion set based on actual infusion requirements. Then load the infusion set onto the infusion pump with the output end being inserted into dry 50ml-range measuring cylinder;
3. Press “Start” key to calibrate it at low speed. Then

[ACCU](Accuracy) on the lower right of the device is changed into [CALIB](calibration) and infusion volume internally measured will be shown. When the infusion volume internally measured reaches 10ml, the device will send a completion alarm. At this moment, press Stop key to stop the alarm and the cursor will point to 10ml infusion volume on the right of [CALIB](calibration). Read the liquid volume actually measured now and press Add or Minus key to change the liquid volume on the right of [CALIB](calibration) to actually measured volume. Press “OK” key to go to next step for calibration;

4. The system enters Step 2 [STEP -02-] for calibration with the infusion limit of 40ml. Insert the output end into dry 50ml-range measuring cylinder and directly press “Start” key to start calibration at higher speed. When the internally measured volume reaches 40ml, the device will send a completion alarm. At this moment, press “Stop” key to stop the alarm and the move cursor to the infusion volume of 40ml on the right of [CALIB](calibration). Read the liquid volume



actually measured now and press Add or Minus key to change the liquid volume on the right of [CALIB](calibration) to actually measured volume. Press “OK” key to go to next step for calibration;

In step 3 or 4, if the deviation between the calibrating infusion set and default infusion set(current calibration value and default calibration value), we show as “ACCU”, is exceeds 80%, this is not supported by the system, the system will return to Step 1 to start recalibration again.

#### **Note**












- **Multiple calibrations can be conducted to ensure accurate calibration. When the infusion volume actually measured is very close to the infusion limit, it means the infusion set is accurately calibrated.**

#### **5.2.4.2 Setting the Calibration Value**


---

Calibration value can reflect the deviation value of calibration. After calibration, the calibration value will change correspondingly. Calibration value can be used for

batch calibration. After calibrating one machine, enter the same calibration (CALIB) value to the other machines with infusion set of the same brand and model and finish the calibration without repeating the above calibration operation.

1. In the [ACCU] setup interface, press  and  or  to select brand and model, and select  twice, the “CALIB” flashes.
2. Press  or  to adjust the calibration value and the calibration value flashes.
3. After setting the calibration value, press  to save low speed calibration value, then higher speed calibration value flashing, Press  or  to adjust higher speed calibration value, Press  to save it; If not to save the set calibration value, press  to exit the calibration value setup status. After exiting the calibration value setup, the infusion accuracy percentage



deviation will change.

Under calibration value setup status (Calibration value flashing), the “Menu” key is not available. Only after exiting calibration value setup (“Calibrate” is not flashing) can the users press “Menu” key to exit this menu and return to operating mode interface. Press  to return to accuracy calibration menu.



## 5.3 Start of Infusion Pump

---


When all parameters have been set, press  for two consecutive times and keep pressing it at the second time until there is fluid coming from the tip of the infusion tube; insert the needle into the patient’s vein (artery), and then press ; at this point, the infusion pump starts infusion.

### **Caution**

- **If the speed is zero, or the total amount is greater than the limit, the infusion pump will not start infusion, the cursor will be moved to the wrong parameter.**

## **5.4 Stop of infusion pump**

---

Press  to stop the infusion pump after confirmation.

## **5.5 Mode Selection and Setting**

---

ME600 infusion pump provides three infusion modes: Speed Mode, Drop Mode, and Time Mode.

### **Note**








- **In the parameter setting interface of each mode, switch to the parameter setting interface of other mode, the parameters set in the current mode will not return to zero; When the pump is power-off, it can save setting speed, drop, time, limit and other**

**parameters. When power on, the default mode is on the user's last shutdown.**

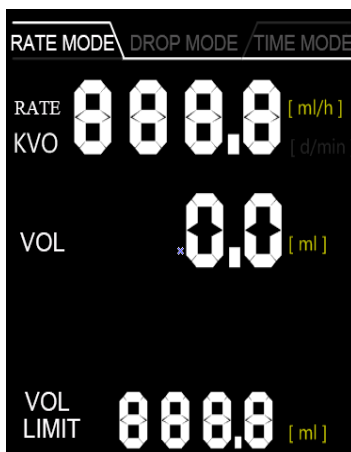
### 5.5.1 Rate Mode

---

Four parameters are shown in the Rate Mode: Rate, KVO, Total Volume , and Volume Limit.








1. Press  to enter the mode setting interface.
2. Press  to select [Rate Mode]; then press  to enter parameter setting.
3. Press  to switch among [Rate], [KVO] and [Volume Limit]; when the selected parameter flashing, you can press  or  or  to set the corresponding parameter value.

The setting interface of Rate Mode is shown below:



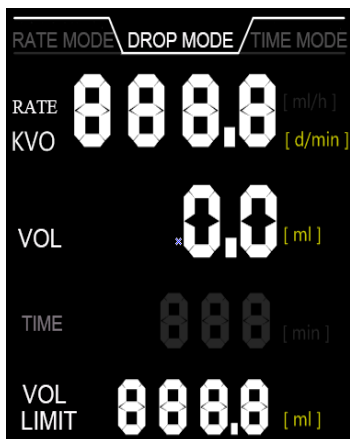
## 5.5.2 Drop Mode

Four parameters are shown in the Drop Mode: Rate, KVO, Total Volume ,and Volume Limit.

1. Press  to enter the mode setting interface.
2. Press  to select [Drop Mode]; then press  to enter parameter setting.
3. Press  to switch among [Rate], [KVO] and [Volume Limit]; when the selected parameter flashing, you can press  or  or  to set the corresponding parameter

value.





The setting interface of Drop Mode is shown below:






### 5.5.3 Time Mode

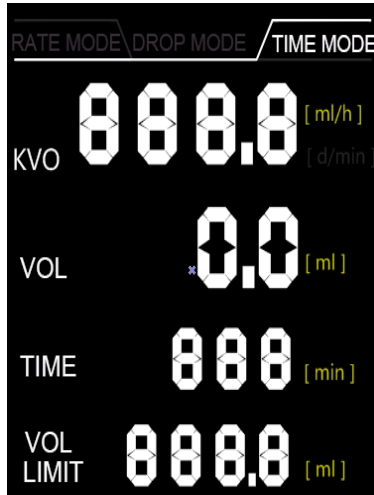
---

Five parameters are shown in the Time Mode: Rate ,KVO, Total Volume, Time and Volume Limit.

1. Press  to enter the mode setting interface.
2. Press  to select [Time Mode]; then press  to enter parameter setting.
3. Press  to switch among [Time], [Volume Limit] and [KVO]; when the selected parameter flickers, you can press

 or  or  to set the corresponding parameter value.

The setting interface of Time Mode is shown below:









 **Note**

- After setting “Time” and “Volume Limit”, the characters “KVO” displayed will be switched to “Rate”.
- KVO indicating keep vein open, when infusion pump finishes instructions, it will keep infusion at a low flow to avoid haemal circumfluence or blood blockages.








## 5.6 Infusion Set Type Setting

1. Press  to switch to the parameter setting interface; when the white horizontal stripe on the screen flashing, press  to enter the parameter setting interface.
2. Press  until select [TUBE] (Infusion Set); the two figures [20] and [60] will be displayed under cycle selection after  is pressed; when the corresponding figure flickers, it indicates the corresponding type of infusion set is selected.
3. After selecting the proper parameters, press  or  to complete the setting.

### Notice

- **The infusion set parameters are determined by the infusion set used; the type of infusion set shall be selected after checking and confirmation and shall not be changed at random.**

## 5.7 Infusion Set Brand Selection



1. Press  to switch to the parameter setting interface; when the white horizontal stripe on the screen flashing, press  to enter the parameter setting interface.
2. Press  until select[ bxx] or[ Uxx] brand code, the brand code will flashing.
3. Figures such as “-b01-” will be displayed on the digital display screen; you can press  and  to select any of the infusion sets provided by the following infusion set manufacturers.

No.	Manufacturer	Type specification
b01	Double-Dove	IS-VA-2D 0.7×2.5 RWLB
b02	LONGXIN	IS-G-V4、IS-G-V4-60
b03	HANACO	H-06APD
b04	WEIGAO	/
	TERUMO® (for	TERUFUSION® SOLUTION

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


b05	TERUFUSION PUMPS)	ADMINISTRATION SET FOR INFUSION PUMP REF:TI*PU200L(20 drops/ml)
b06	M.E. MEDITEK	20 Drops/ml: INFUSION SET,WITH I.V. NEEDLE 21G*1 1/2''(0.8*38mm) AND AIR INLET DEVICE
		60 Drops/ml: MICRODRIP SET ,WITH I.V. NEEDLE 25G*1''(0.5*25mm) AND AIR INLET DEVICE
b07	B.M.I.(BEVER MEDICAL INDUSTRY)	Intra Venous Solution Administration setIV NEEDLE 21G*1 1/2''(20 drops/ml)
b08	TERUMO®	TERUFUSION® Solution Administration Set ,REF:TI*U200L07(20

		drops/ml)
b09	Tianjin Hanaco Medical	INFUSION SET WITH NEEDLE,Model:H-09A-6(20 drops/ml)
U01	User-defined	
U02	User-defined	
U03	User-defined	

4. Press  to confirm and exit the infusion set selection.
5. Then, press  to go back to the standby mode.

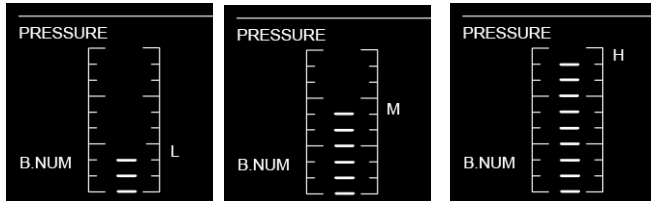
## 5.8 Pressure Setting



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1. Press  to switch to the parameter setting interface; when the white horizontal stripe on the screen flashing, press  to enter the parameter setting interface.
2. Press  until select [Pressure]; when the characters [L] or [M] or [H] flashing, press  to select among the three

pressure stages: [Low], [Medium], and [High].





See the figures below:





3. Select the proper pressure stage, and press  or  to finish the setting.


## 5.9 Heater Setting

---

1. Press  to switch to the parameter setting interface; when the white horizontal stripe on the screen flashing, press  to enter the parameter setting interface.
2. Press  until select [HEAT]; when the characters [Heat] related flashing, , the characters [On] and [Off] will be displayed under cycle selection after  is pressed; when the corresponding characters flashing, it indicates that the corresponding “On” or “Off” is selected.

- When [On] is selected, the digits and unit will be displayed on the right side; you can press  or  to adjust the heating temperature within the range of 25°C-40°C.
- When [Off] is selected, the digits and unit will not be displayed on the right side.

3. After selecting the proper parameters, you can press 

or  to finish the setting.

### **Warning**

- **Do not turn on the heat function for Temperature sensitive drugs.**

### **Notice**











- **The upper and lower limits of the temperature to be set are 40°C and 25°C, respectively; however, the actual temperature may not reach the set temperature under the influence of such factors as environment and infusion Rate.**

## 5.10 System Time Setting

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### 5.10.1 Time Setting









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1. The infusion in the stop state, press  and , enter the date settings menu.
2. Press  to select the **【dAtE】**, when the characters [dAtE] flicker, press  to enter the date selection interface.
3. Press  until enter “Hour” setting; then, press  or  to adjust “Hour”.
4. Press  again to enter “Minute” setting; then, press  or  to adjust “Minute”.

### 5.10.2 Date Setting

---

1. When the infusion pump is in off position, press  and

-  simultaneously to enter the date setting menu.
2. Then, press  to select [dAtE]; when the characters [dAtE] flicker, press  to enter the date selection interface.
  3. Press  again to select the desired digits for “Year”, “Month” and “Day” from the top down; when the digits flicker, press  or  to select the proper digits.
  4. After finishing the setting, press  to go back to the date setting menu.
  5. Then, press  to go back to the current infusion interface.

## 5.11 Use of Built-in Battery for Power Supply

---

- If AC/DC power supply is not connected, the system will be powered by the built-in battery.






- In case of power failure when the system is being powered by AC or DC power supply, the built-in battery will start automatically. In this case, a power cord off alarm will be generated.
- When the system is powered by the battery, the battery indicator will turn on.
- When the built-in battery is fully charged, the system can work for 8h with the battery.
- The approximate remaining capacity of the built-in battery is indicated by the three-bar battery indicator.



## 5.12 Battery Status

---

After connection to mains supply (alternating current), the charging indicator turns on and the pump is in the charging state.

The battery icon displayed on the front panel indicates the current battery status:





-  Battery full.
-  Battery not full.
-  The yellowish-green light is constantly on.

-  The yellowish-green light flickers, indicating a low battery alarm and that it is needed to charge the battery; after the alarm is sent, the device can work for about 30min at the Rate of 25ml/h.
-  Battery depleted alarm; the battery frame icon flickers.

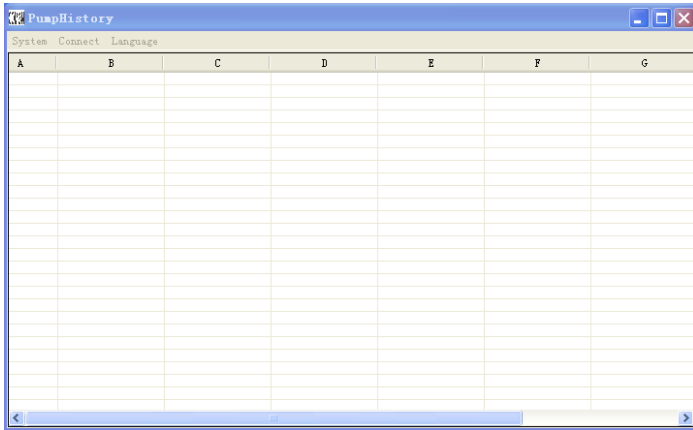
### 5.13 Log Information

---

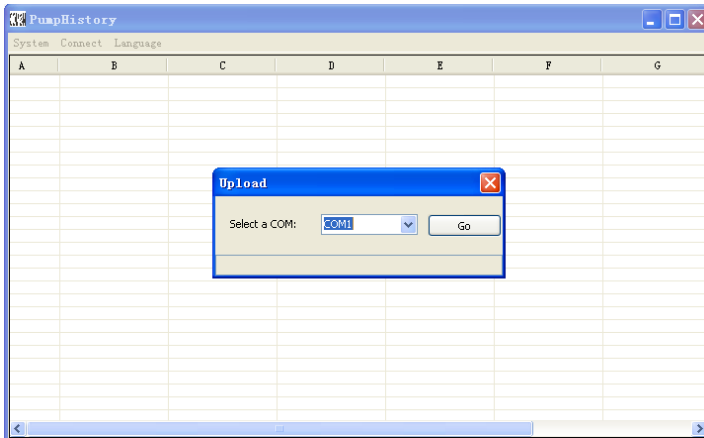
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1. Connect one end of the data cable to the RS232 serial port at the back of the device, and the other end to the PC.
2. When the infusion pump is in off position, press  and  simultaneously to enter the log info reading menu.
3. Press  to select [SENd]; when the characters [SENd] flicker, press  to confirm the selection.
4. At this moment, the characters [SENd] will stop flickering for several seconds, indicating that the log info is being sent to the PC.
5. Open the computer's export log of the serial port software, the software is called PumpHistory.exe.

## Chapter 5 Operation Guide

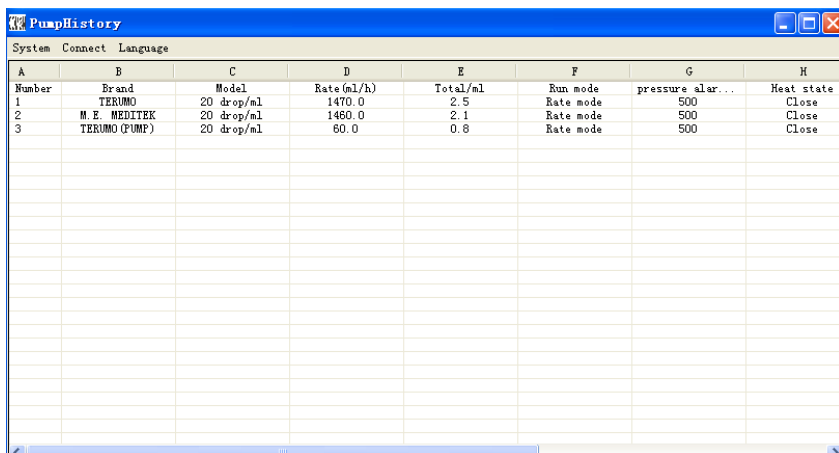


6. Click **【Connect】**, select a COM, then click **【GO】**.



7. At this point, press , the infusion pump will display **【----】**, the prompt is sending the log. If the log is sent successfully, the message will be prompted **【End】**, the send failure displays **【FAIL】**. Log messages are successful, and information is

displayed on serial software.



The screenshot shows a window titled "PumpHistory" with a menu bar containing "System", "Connect", and "Language". Below the menu bar is a table with columns labeled A through H. The table contains three rows of data:

A	B	C	D	E	F	G	H
Number	Brand	Model	Rate(ml/h)	Total/ml	Run mode	pressure alar...	Heat state
1	TERUMO	20 drop/ml	1470.0	2.5	Rate mode	500	Close
2	M.E. MEDITEK	20 drop/ml	1460.0	2.1	Rate mode	500	Close
3	TERUMO (PUMP)	20 drop/ml	80.0	0.8	Rate mode	500	Close

8. Then, press  to go back to the current infusion interface.

## 5.14 Nurse call connector

The pump is designed with the nurse call connector, and support to access hospital nurse call system. A call will be made when a senior alarm is generated, call will stop when the senior alarm is cancelled.

## 5.15 Standard RS232 Connector


The pump is designed with the standard RS232 connector for two-way communication. A shielded cable should be used for the RS232

communication cable, and any device connected to the RS232 connector shall comply with the requirements of GB4943.1-2011 *Information technology equipment – Safety*. For more details, you may ask the sales personnel of our company for the RS232 interface protocol. Any device connected to the pump shall be one of those devices designated by our company.

## 5.16 Power-off

---

---

1. Confirm that the infusion pump can be stopped.
2. Long press  for about 2s to power off the system.

# Chapter 6 Installation and Connection

## Warning

- This device shall be installed by an engineer designated by the manufacturer.

## 6.1 Installation of Infusion Tube

1. Lift up the door switch of the infusion pump with one hand, as shown in the figure:



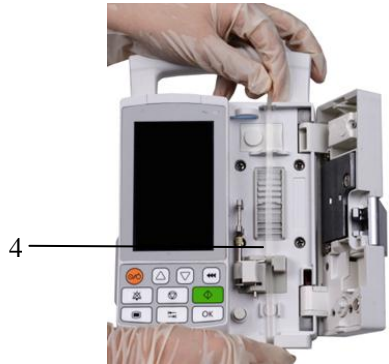
2. Open the door of the infusion pump, as shown in the figure:



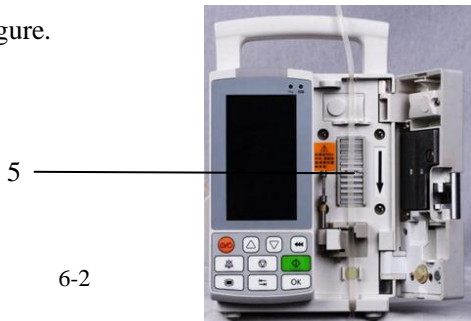
3. Open the empty-bottle clamp, as shown in the figure:



4. Install the infusion tube in the infusion tube track, as shown in the figure:



5. Arrange the infusion tube to make it cling to the infusion tube panel, as shown in the figure.



6. Close the door of the infusion pump.



7. The infusion tube is installed.



### **Warning**

- **Infusion tube shall be stuck in the tube track**
- **Try to use the designated tube, otherwise, please calibration as required.**

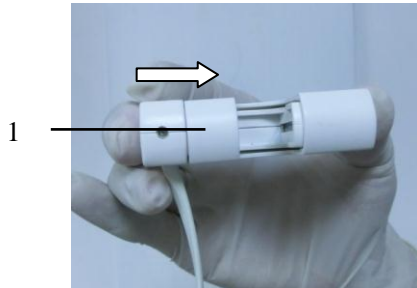


## 6.2 Installation of Drop Clamp

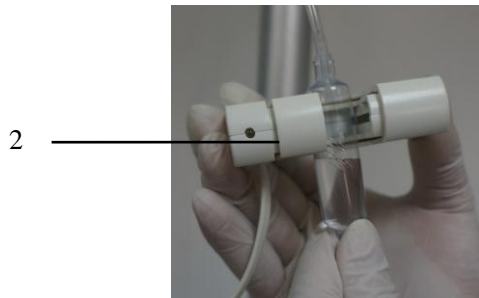
### **Warning**

- **The drop clamp shall not be used in an environment with direct sunshine.**
- **The fluid level in the drop chamber shall be at about 1/3 of the drop chamber, and the drop clamp shall be installed above the fluid level.**

1. Hold the drop clamp with the fingers, and press it inwards to open the drop clamp:



2. Place the drop chamber of the infusion tube in the drop clamp:



3. Loosen the drop clamp to make it tightly clamp the drop chamber of the infusion tube, as shown in the figure:



### **Note**

- After installation of the infusion tube, please adjust the infusion tube well to ensure no bending or buckling.
- Make sure the drop clip is straight down, otherwise the drop signals cannot be detected or equipment may regard it as abnormal situation with sound-light alarm.

## **6.3 Removal of Infusion Tube**

---

Please follow the inverse process of the operation steps stated in **6.2** *Installation of Infusion Tube*.

### **Note**

- Please dispose or recycle used infusion tubes in accordance with relevant regulations.

- **Infusion tubes are disposable, which shall not be used repeatedly.**

# Chapter 7 Alarm Prompts

Some essential physiologic and technical alarm messages are listed in this chapter, however, some alarm messages are not necessarily listed.

Caution: In this chapter, L indicates default alarm level, H indicates high level, M indicates medium level, and L indicates low level.

Corresponding countermeasures are listed for each alarm message. In case the problem still exists after operation is performed as per the countermeasure, contact the maintainers.

## 1 Physiologic Alarms:

Alarm messages	Alarm level	Causes and countermeasures	Auditory	Visual
Air Bubbles	H	If the ultrasonic bubble sensor in the pump detects air bubbles during running of the pump, or the “Start” button is pressed when the	71.0dB	Yes

Chapter 7 Alarm Prompts

		<p>infusion set is improperly installed.</p> <p>After pressing the ‘Stop’ button, the alarm status will be eliminated, and then manually discharged bubbles.</p>		
<p><b>Tube Occlusion Alarm</b></p>	H	<p>Unsmooth infusion caused by needle occlusion or buckling of the infusion tube.</p> <p>Replace needle , adjust the infusion tubing to ensure smooth management.</p>	71.0dB	Yes
<p><b>Door Open Alarm</b></p>	H	<p>The pump door is opened during running of the</p>	71.0dB	Yes

Chapter 7 Alarm Prompts

		infusion pump, the pump will send intermittent light alarms and stop running		
<b>Infusion Finished Alarm</b>	H	When the fluid of the set infusion volume is completely infused, accompanied by sound-light alarms.  After the infusion is finished, the system will automatically start infusion at the KVO Rate. If the device is not stopped to replace the infusion tube within half an hour, the	71.0dB	Yes

Chapter 7 Alarm Prompts

		device will shut down automatically.		
<b>Empty Alarm</b>	H	In the “Drop Mode”, the drop clamp cannot detect the signal when fluid in the infusion tube is completely infused. Stop infusion.	71.0dB	Yes
<b>Close to Completion Alarm</b>	L	In case of infusion with a set Volume Limit, an alarm prompt will be given when the remaining time for the set infusion volume is about 2min.  When the “Stop” button is pressed, the alarm status will be	65.9dB	Yes

		eliminated.		
--	--	-------------	--	--

**Technical Alarms:**

<b>Alarm messages</b>	<b>Alarm level</b>	<b>Causes and countermeasures</b>	<b>Auditory</b>	<b>Visual</b>
<b>Drop Signal Error Alarm</b>	H	When any abnormality of drop signal is detected in the “Drop Mode”, the device will stop running.  When the “Stop” button is pressed, the alarm status will be completely eliminated. Detection drop folder and, if abnormal, please replace.	71.0dB	Yes
<b>Timeout</b>	L	After parameters are	65.9dB	Yes



Chapter 7 Alarm Prompts

<b>Alarm</b>		<p>set, if infusion is not started or no other button operation is performed within 2min, the device will send a timeout alarm. You can press any button to eliminate this alarm.</p>		
<b>AC Off Alarm</b>	L	<p>In case that the device is turned on without connection to AC power supply or the power cord is loosened during use, the pump will make intermittent alarm sound</p> <p>Check and plug in the power cord.</p>	68.5dB	Yes

<b>Low Battery Alarm</b>	L	low battery voltage Connect AC power.	65.9dB	Yes
<b>Battery Depleted Alarm</b>	H	When a Battery Depleted Alarm is sent, the device will shut down automatically in 3min. Connect AC power.	71.0dB	Yes
<b>System Error Alarm</b>	H	Driver error caused by improper operations, internal communication error, or other errors of the system. Correct operation of the machine. If the alarm still occurs, please contact the	71.0dB	Yes

Chapter 7 Alarm Prompts

		factory maintenance personnel related.		
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## Chapter 8 Troubleshooting

Products within the warranty scope of Comen may enjoy our free service; for products beyond the warranty scope, Comen will provide paid services. Transportation expenses (including customs charges) for any product sent to Comen for repair shall be borne by the user.

Fault	Cause Analysis	Solution
Inaccurate speed	The infusion set is improperly installed	Reinstall it as required
	The drop detector is not installed or is improperly installed	Reinstall the drop detector as required
	The infusion set is not calibrated	Calibrate the infusion set as required before use
There is dropping fluid in the tube when the device is	The infusion set is improperly installed or the infusion set used does not meet the requirement	Readjust the infusions set

Chapter 8 Troubleshooting

off	The component is damaged or deformed, or the screw is loosened	Readjust or replace the component (adjustment shall be made by professionals)
Low battery alarm	The device is placed without operation for a too long period, or the battery level is low	Charge it timely
	The built-in battery is damaged or faulted because of improper use	Replace the battery
No display upon power-on	The battery voltage is too low	Charge the battery or replace it with a new one
	System error	Restart the device; if the problem still exists, contact the manufacturer for repair.
“Occlusion” alarm is often sent	The infusion tube is knotted	Recheck the infusion tube
	The set pressure stage is	Raise the set pressure

Chapter 8 Troubleshooting

<p>during infusion</p>	<p>too low</p>	<p>stage</p>
<p>Infusion process often occurs "bubble" alarm</p>	<p>After the infusion tube is used for a period of time, move the mounting position, where the rolling deformation is installed in the bubble sensor position</p>	<p>Move the position of the infusion tube, so that the filling of the pipeline is located in the pump, to avoid the deformation of the pipeline is located in the bubble sensor position.</p>
<p>Photoelectric sensor failure</p>	<p>System error</p>	<p>contact the manufacturer for repair.</p>
<p>Alarm E106</p>	<p>Error in storage data.</p>	<p>The user can be recalibrated and can be used.</p>

## Chapter 9 Care and Maintenance

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### **Warning**

- **During using this instrument, please do not maintain it in order to avoid dangers.**
- **Please contact Personnel Service of our company for maintenance. the person who is without maintenance experience of such equipment is not allow work for maintenance service.**

### **Caution**

- **The damaged parts shall be replaced with designated one of our company, and test to ensure the device meet the manufacture requirements.**
- **Please contact Personnel Service of our company if needed.**
- **Contact our Personnel Service if you want to know more information and relevant technical data about our products, we**

**will provide some documents for you in accordance with specific conditions.**

## **9.1 leaning and Disinfection**

### **Warning**

- **Uperization, electron beam and  $\gamma$  radiation are not allow for disinfection.**

1. Always keep the device and the drop clamp clean.
2. Periodically use a piece of soft cloth wetted with warm water and some detergent to wipe the external surface; then, use a piece of clean wet cloth to wipe the surface; last, use a piece of clean cloth to wipe the surface dry, and place it on a dry shelf.

\* The above operations are for guidance only; proper methods shall be adopted to check the disinfection effect.

### **Note**

- **Before disinfection of the system, please power it off and disconnect the AC and DC power cord.**
- **Please do not clean the infusion pump with xylene, acetone or**



**similar solvents in order to avoid damage of the shell.**

## 9.2 Battery Maintenance

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- When ME600 infusion pump sends intermittent sound-light alarms under the condition of low battery voltage, please timely charge the battery or connect the infusion pump to AC power supply. When ME600 infusion pump sends high-level sound-light alarms for battery depleted, please power off the pump immediately and connect it to AC power supply before reuse. Charging method: Connect ME600 infusion pump in off position to AC power supply; the infusion pump is in the charging state when the charging indicator turns on.

### **Note**

- **The device shall be charged for 5h uninterruptedly in off position.**
- If ME600 infusion pump is not used for a long period, it shall be charged every three months to avoid damage of the built-in battery

due to automatic discharge.

- If ME600 infusion pump is not used for a long period, it is necessary to check the charge and discharge condition of its built-in battery before reuse, so as to make sure the battery can be used in case of power failure. If it is found that the battery cannot be charged or discharged normally, please contact the After-service Department of our company to replace it with a new chargeable battery.



### **Warning**

- **Please take out the built-in battery when this instrument is no being used for a long time.**

## **9.3 Safety check**

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The safety check below should be carried only by the personnel who is with knowledge and practice through training once two year or according to the rule designated by public institution.

- ◆ Check if there is any mechanical damage and function damage.

- ◆ Check if the safety related tags can be recognized easily.
- ◆ Verified if the function is consistent with the instruction.

## **9.4 Unit replacement**

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### **9.4.1 Drop clamp replacement**

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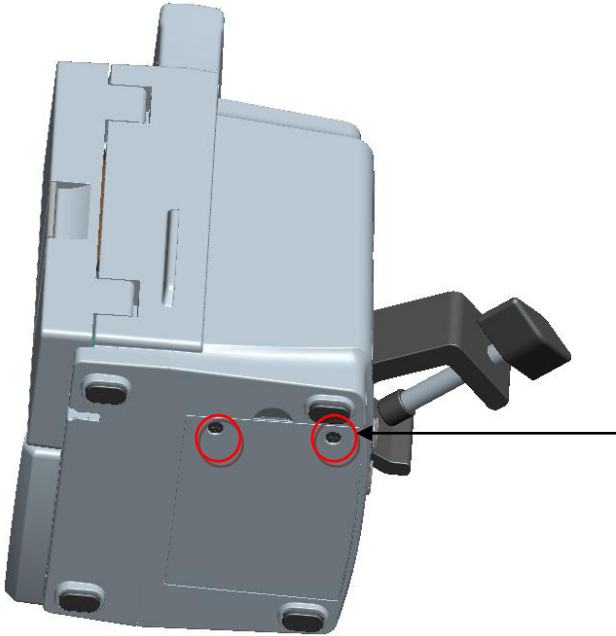
Refer to chapter *6.2 the installation of drop clamp* for the drop clamp disassemble and replacement.

### **9.4.2 The build-in battery replacement**

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Unscrew the two screws on the bottom of infusion pump and replace the battery, as show below:



## 9.5 Pollution-free Disposal and Recycling

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- This product has a service life of 5 years; any device out of its service life shall be reported as unserviceable.
- ME600 infusion pump out of use can be sent back to the distributor or manufacturer where you buy the product for proper recycling.
- Used batteries shall be disposed according to applicable laws and regulations.
- Used disposable infusion sets shall be disposed according the

regulations on treatment of medical wastes.

## 9.6 Toxic/Hazardous Substances/Elements

Component		Pb	Hg	Cd	Cr(VI)	PBB	PBD E
Housing	Front housing	O	O	O	O	O	O
	Back housing	O	O	O	O	O	O
	Keys	O	O	O	O	O	O
	Facing	O	O	O	O	O	O
	Labels	O	O	O	O	O	O
Monitor	Monitor	×	×	×	×	×	×
Main unit	Hardware	O	O	O	×	O	O
	Internal wires	O	O	O	O	O	O
	PCBA	×	O	O	O	O	O
Package	Packing	×	×	O	O	×	

Chapter 9 Care and Maintenance

	materials						
General components	Connectors	○	○	○	×	○	○
	Power cord	○	○	○	○	○	○
Battery	Lithium battery	×	×	×	×	×	×
Note	<p>○: Such hazardous/toxic substance contained in all homogeneous materials of such component falls within the content limit specified in SJ/T11363-2006.</p> <p>×: Such hazardous/toxic substance contained in one or more homogeneous materials of such component goes beyond the content limit specified in SJ/T11363-2006.</p>						

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# Chapter 10 Infusion Characteristics

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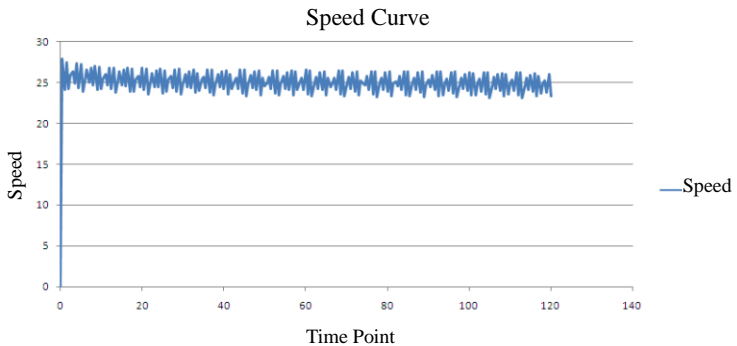
## 10.1 Speed Accuracy Characteristic

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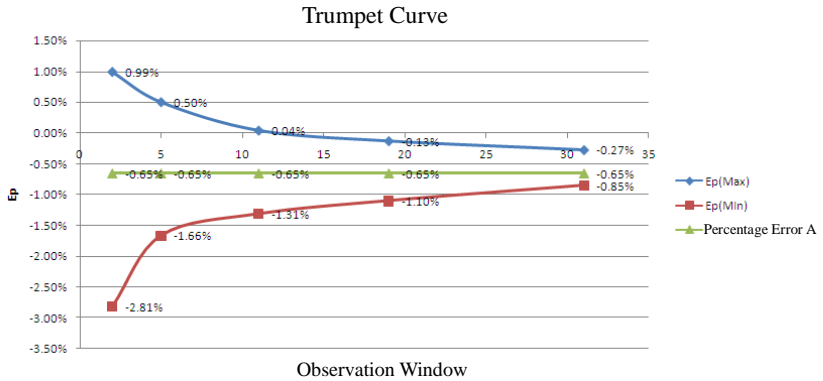
Infusion set used in the test: Double-Dove 20 drops/ml infusion set

Test method: According to the method as specified in IEC 60601-2-24.

The test results are shown as follows:



## Chapter 10 Infusion Characteristics



## 10.2 Occlusion Response Characteristic

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The occlusion alarm time is the main indicator of the block response characteristic; Double-Dove 20 drops/ml infusion set is used in this test; the following data only represent the conclusions obtained from the infusion set used in the test. Note: The occlusion alarm time is affected by many factors such as infusion speed, manufacturing process of infusion set, specification of infusion set, volume of fluid, and length and pressure of patient tube.



Chapter 10 Infusion Characteristics

	Speed (ml/h)	Occlusion Alarm Level	Occlusion Pressure (mmHg)	Alarm Response Time (t)
1	1	Low	300	t<13min50s
2	1	Medium	500	t<22min10s
3	1	High	900	t<52min05s
4	25	Low	300	t<28s
5	25	Medium	500	t<47s
6	25	High	900	t<1min28s
7	100	Low	300	t<6s
8	100	Medium	500	t<11s
9	100	High	900	t<20s

## Chapter 11 EMC Information

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### **Warning**

- **ME600 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ME600 should be observed to verify normal operation in the configuration in which it will be used.**

### **Warning**

- **ME600 meets the requirement of electromagnetic compatibility in IEC60601-1-2.**
- **The user needs to install and use according to electromagnetism compatibility information which is attached with it.**
- **Portable and mobile RF communication devices may influence ME600 performance, so ME600 should be kept away from them during using.**
- **Guidance and manufacturer's declaration stated in the appendix.**

<b>Guidance and manufacturer's declaration –electromagnetic emissions</b>		
The ME600 is intended for use in the electromagnetic environment specified below. The customer or the user of the SECP-II should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The ME600 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ME600 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for
Harmonic emissions IEC 61000-3-2	Class A	
Voltage	Complies	

fluctuations / flicker emissions IEC 61000-3-3		domestic purposes.
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**Guidance and manufacturer’s declaration –  
electromagnetic immunity**

The ME600 is intended for use in the electromagnetic environment specified below.

The customer or the user of the ME600 should assure that it is used in such an environment.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Electrostatic discharge (ESD)	$\pm 8$ kV contact	$\pm 8$ kV contact $\pm 15$ kV air	Floors should be wood, concrete or ceramic tile. If floors

IEC 61000-4-2	±15 kV air		are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>IEC 61000-4-11</p>	<p>&lt;5 % <math>U_T</math> (&gt;95 % dip in <math>U_T</math>) for 0.5 cycle</p> <p>40 % <math>U_T</math> (60 % dip in <math>U_T</math>) for 5 cycles</p> <p>70 % <math>U_T</math> (30 % dip in <math>U_T</math>) for 5 cycles</p> <p>70 % <math>U_T</math> (30 % dip in <math>U_T</math>)</p>	<p>&lt;5 % <math>U_T</math> (&gt;95 % dip in <math>U_T</math>) for 0.5 cycle</p> <p>40 % <math>U_T</math> (60 % dip in <math>U_T</math>) for 5 cycles</p> <p>70 % <math>U_T</math> (30 % dip in <math>U_T</math>) for 25 cycles</p> <p>&lt;5 % <math>U_T</math> (&gt;95 % dip in <math>U_T</math>) for 5 s</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME600 requires continued operation during power mains interruptions, it is recommended that the ME600 be powered from an uninterruptible power supply or a battery.</p>
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	for 25 cycles <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 s		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>NOTE</b> $U_T$ is the a.c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration – electromagnetic**

<b>immunity</b>			
<p>The ME600 is intended for use in the electromagnetic environment specified below.</p> <p>The customer or the user of the ME600 should assure that it is used in such an environment.</p>			
<b>Immuni ty test</b>	<b>IEC 60601 test level</b>	<b>Complia nce level</b>	<b>Electromagnetic environment – guidance</b>
Conduct ed RF IEC 61000-4	3Vrms  150kHz to  80MHz	3Vrms          3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ME600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  $d = 1.2\sqrt{P}$



<p>-6</p> <p>Radiate</p> <p>d RF</p> <p>IEC</p> <p>61000-4</p> <p>-3</p>	<p>3V/m</p> <p>80MHz to</p> <p>2.5GHz</p>		<p><math>d = 1.2 \sqrt{P}</math> 80MHz to 800MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800MHz to 2.5GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked</p>
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			<p>with the following symbol:</p> 
<p>NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME600 is used exceeds the applicable RF compliance level above, the ME600 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ME600.</p> <p><sup>b</sup> Over the frequency range 150kHz to 80MHz, field strengths should</p>			

be less than 3V/m.

**Recommended separation distances between  
portable and mobile RF communications equipment and the ME600**

The ME600 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME600 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME600 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80MHz and 800MHz, 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.

# Chapter 12 Product Specifications

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## 12.1 Product Specifications

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- Operating environment conditions:
  - a) Ambient temperature: 5°C~40°C
  - b) Relative humidity: 20%~90%
  - c) Atmospheric pressure: 700hPa~1060hPa
  - d) The infusion pump should work in an environment without strong impact and vibration, free of corrosive gases, and where water and other fluids cannot intrude into the device.
- Transportation and storage conditions:
  - a) Ambient temperature: - 40°C ~+60°C
  - b) Relative humidity: 0%~90%
  - c) Atmospheric pressure: 70kPa~106kPa
- Overall dimensions: 132mm×196mm×219mm
- Net weight: 1.8Kg

- Speed range

“ml/h” is selected as the unit:

20 drops/ml infusion set: 0.1-1500ml/h; step increment by 0.1ml/h within the range of 0.1-100ml/h, step increment by 1ml/h when above 100ml/h;

60 drops/ml infusion set: 0.1-300ml/h; step increment by 0.1ml/h within the range of 0.1-100ml/h, step increment by 1ml/h when above 100ml/h;

“d/min” is selected as the unit:

20 drops/ml infusion set: 1-400d/min; step increment by 1 d/min;

60 drops/ml infusion set: 1-300d/min; step increment by 1 d/min;

KVO Rate: 0.1-5ml/h; step increment by 0.1ml/h. Factory default: 5ml/h

Fast forward speed: The minimum step increment 0.1ml/h;

- Ranges of total volume and Volume Limit

Total volume: 0.1-9999ml; step increment by 0.1ml within the range of 0.1-1000ml, step increment by 1ml when above 1000ml.

Volume Limit: 0.1-9999ml; step increment by 0.1ml within the range of 0.1-100ml, step increment by 1ml when above 100ml.

Fast forward interface Volume limit: when each mode sets the limit, the maximum allowable fast forward (fast-forward interface Volume limit) = Volume limit - current total -0.1.

- The thresholds of pressure levels are as follows:  
High: 900mmHg $\pm$ 100mmHg (120 $\pm$ 13.3KPa);  
Medium: 500mmHg $\pm$ 100mmHg (66.7 $\pm$ 13.3KPa);  
Low: 300mmHg $\pm$ 50mmHg (39.9 $\pm$ 6.6KPa);
- Speed accuracy:  $\pm$ 5% (the infusion accuracy of a calibrated infusion tube can be within  $\pm$ 3%).
- Alarms: Tube Occlusion, Close to Completion, Infusion Finished, Air Bubbles, Door Open, Forgetting Operation, System Error, Over-speed, Power Cord Off, Low Battery, Battery Depleted.
- Power supply: 100-240V  $\sim$  50Hz/60Hz; built-in 11.1VDC, 2200mAh, chargeable lithium battery; the battery fully charged can support more than 8h of operation of the pump at the speed of 25ml/h (the speed specified in IEC 60601-2-24).
- Power: 35VA

## 12.2 Standard list

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MDD 2007/47/EC

ISO 13485

ISO14971

IEC 60601-1

IEC 60601-2-24

EN 1041

EN ISO 15223-1

IEC 60601-1-2

IEC 60601-1-8

IEC 62366-1

IEC 60601-1-6

IEC 62304



# Chapter 13 Product Packaging and Accessories

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No.	Name	Unit	Quantity
1.	Main unit	PCS	1
2.	Operation Instructions	Copy	1
3.	Qualification card.	PCS	1
4.	Warranty Card	PCS	1
5.	Power cord	PCS	1
6.	Drop clamp	PCS	1

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