

Preface

Important prompts

Please read this User Manual carefully before using Central Infusion System (hereinafter referred to as the System).

Please keep this User Manual well for future reference. Information in this User Manual is subject to change without prior notice.

Due to product updates, the product you get may not be the same as that described in this User Manual. We sincerely apologize for that.

Warning	Indicate an imminent hazard or an unsafe practice that could result in death, serious personal injury, or property damage.
Notes	Emphasize important precautions and provide instructions or explanations for better use of the product.

About this User Manual

This User Manual introduces the following contents:

- Overview, function introduction, and technical specifications;
- Installation and test methods;
- Operation methods of the System and the menu.

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Chapter 1 Technical Features - Performance Parameters

1.1 Features

- 1) With a powerful computing system, it can meet the needs for simultaneous infusion of multiple drugs.
- 2) With an audio alarm system, ensures safety.
- 3) With a 7-inch large color touch screen, it can centrally monitor the work of all pumps.
- 4) Network mode: wired and wireless, it enables multiple pumps to run online, and can be used in a variety of complex places.
- 5) It supports the hot-swapping function for the infusion / syringe pumps, convenient for clinical transport.
- 6) It monitors and manages the infusion / syringe pumps in real time to realize integrated and unified management.
- 7) Drug library function, and the commonly used drugs can be set, convenient to use.
- 8) With a data storage function, it can backtrack historical key information such as infusions and alarms, providing a basis for later treatment review.
- 9) The power is managed uniformly to avoid complex circuits due to multiple pumps.
- 10) Treatment data is made in association with patients by receiving and releasing patients to achieve rapid treatment.
- 11) Communication interfaces such as USB ports and network interfaces are available to facilitate further development and upgrading in the future.
- 12) The infusion / syringe pumps can be freely combined according to clinical needs.
- 13) Smooth relay workflow ensures stable and seamless drug-giving process, reduces the risks arisen from dressing changes.
- 14) Unified audio alarm is provided at the System.

1.2 Technical specifications

Display information	① Flow rate ② Drug name ③ Remaining time ④ Total volume ⑤ Working status ⑥ Device type
High-priority alarm	High-priority alarm list of Infusion Pump: ① Door open ② Occlusion ③ Air bubbles ④ Motor failure ⑤ Enter KVO ⑥ Battery depletion ⑦ Pressure failure High-priority alarm list of Syringe Pump: ① Syringe out ② Occlusion ③ Motor failure ④ Pressure failure ⑤ Enter KVO ⑥ Battery depletion
Low-priority alarm	Low-priority alarm list of Infusion Pump: ① Standby prompt ② Near end ③ Low battery Low-priority alarm list of Syringe Pump: ① Standby prompt ② Near end ③ Low battery
Safety Class	Class I, type BF
Degrees of protection provided by enclosure	IPX2

Mode of operation	Continuous operation
Power Requirements	100-240 V~ 50 / 60 Hz
Maximum weight	About 8 kg
Dimension	307 mm (L) × 116 mm (W) × 884 mm (H)
Working environment	① Temperature: +5 °C ~ +40 °C ② Relative humidity: 20 % ~ 90 % ③ Atmospheric pressure: 800 hPa ~ 1060 hPa
Storage environment	① Temperature: -30 °C ~ +55 °C ② Relative humidity: 5 % ~ 96 % ③ Atmospheric pressure: 500 hPa ~ 1060 hPa ④ No corrosive gas ⑤ Good ventilation
Input Power	≤165 VA

Chapter 2 Product Introduction

2.1 Overview

The Central Infusion System provides an intelligent infusion/injection solution for medical institutions. It is used with Infusion / Syringe Pumps, featuring with serial communication, LCD display and uploading infusion/injection parameters to the Center Infusion Station via wireless or wired network, which effectively improves clinical treatment efficiency and medical information management. The System can be widely used in the operating room, ICU, and various intensive care units of the hospital.

2.2 Scope of application

Used with the infusion / syringe pumps, the System is used for centralized monitoring and management of the infusion / injection status of the infusion / syringe pumps.

2.3 Main composition

The name of each part:

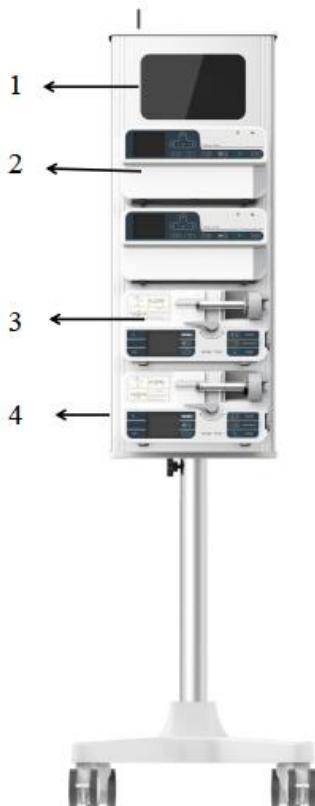


Figure 2-1 Overall view

No.	Name	Function
1	Console	Display various parameters by the touch screen.
2	Infusion Pump	An infusion unit of the System
3	Syringe Pump	An injection unit of the System
4	System host	Used for connecting and fixing the control units and infusion / injection units

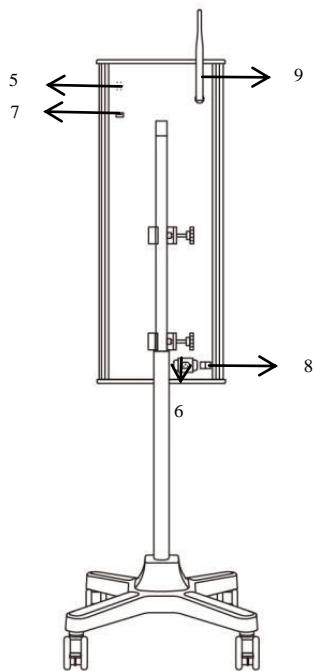


Figure 2-2 Rear view

No.	Name	Function
5	Speaker	Used to give an audio alarm
6	Power socket	Used for connecting the AC power cord
7	Network port	Used for communication and device networking
	USB interface	Used for subsequent system software upgrades
8	ON / OFF	Used to control system power
9	Antenna	Used for communication and device networking

Chapter 3 Safety Precautions

⚠ Warning ⚠

- This System is used for real-time monitoring and centralized management of the running status of the infusion/syringe pumps in clinical practice. Only professional clinicians, medical electrical experts, or professionally trained clinical medical staff are allowed to use it on designated occasions.
- Before using this System, the user must check the System and its accessories to ensure that they can work normally and safely.
- This System should only be connected to an power socket with protective earthing.
- This System should not be used in an environment where flammable or explosive materials are placed to prevent fire or explosion.
- When using this System, the alarm limit should be set according to the actual situation of the patient and the actual clinical condition of the patient should be closely monitored. The patient should not be monitored for injection or infusion only by the audible alarm system.
- Avoid using this System when there is an alarm. If there is an alarm, please clear it before continuing to use it.
- Do not touch the patient when connecting peripheral equipment through the signal input and output ports, to prevent the patient leakage current from being beyond standard.
- Please install or carry this System and its supporting equipment properly to prevent the System host, Syringe Pump, and Infusion Pump from falling, colliding, or being damaged by strong vibration or other mechanical external forces.
- When the System is transferred in the hospital, please ensure that there are at least two people to push and operate it to avoid damage or rollover, resulting in injury accidents.
- Please ensure that the System host is turned on first and turned off last for data integrity.
- For details about the safety warnings of Syringe Pump and Infusion Pump, please see the User Manuals of related products.
- Electromagnetic fields will affect the performance of the System and its supporting equipment, so equipment used near the System and its supporting products must meet the corresponding EMC requirements. Otherwise, system failure or system crashes may occur due to electromagnetic interference. Mobile phones and X-ray or MRI equipment are possible sources of interference that emit high-intensity electromagnetic radiation, so the System and its supporting products should be kept away from sources of interference as far as possible.
- Ensure that the use environment should not be subject to strong electromagnetic interference sources.
- Do not open the enclosures of the System, otherwise electric shock may occur. The maintenance or upgrade must be carried out by maintenance personnel trained and authorized by our company.
- Packaging materials must be disposed of in compliance with relevant local regulations or the hospital's waste disposal system, and shall be kept out of the reach of children.

- This System is not intended to be used as a portable device.
- Modifications to this System are not permitted. The parts that make up the main body of the System are not replaceable.
- This System can only access products specified by our company. To ensure patient safety, please do not connect products other than those specified by our company to the System.

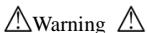
Notes:

- ☞ Confirm that the System has been firmly fixed to avoid the danger to the patient caused by the movement of the System due to the pulling of the pipe.
- ☞ Cables should be connected carefully to reduce the likelihood of the patient being entangled or asphyxiated.
- ☞ The System and its supporting equipment beyond their service life shall be processed by the relevant local laws and regulations or hospital regulations. If you have any questions, please contact the dealer or manufacturer who sold this product to you.
- ☞ The System and the infusion/syringe pumps and their accessories should be protected from direct sunlight, high temperature, and humidity.
- ☞ Try not to autoclave or expose this System and its associated equipment to chemicals.
- ☞ Before powering on the System, please ensure that the voltage and frequency of the power supply comply with the requirements as specified on the System label or in this Manual.
- ☞ If the System does not work normally as described in the User Manual and for unknown reasons, please stop using it and report the failure (including the SN number of the system components used) to the dealer or manufacturer who sold the product to you.
- ☞ Please keep this Manual near the System so that it can be consulted conveniently and in time when needed.
- ☞ Please install the System where it is easy to observe, operate and maintain.
- ☞ This Manual introduces the most complete configuration and functions of this System, and the System you have purchased may not have certain configurations or functions.
- ☞ Please do not insert devices other than those specified by our company into the USB port or network interface.
- ☞ Our company can provide, upon request, circuit diagrams, component lists, descriptions, calibration instructions, or other information that help the user's qualified technicians to repair the System.
- ☞ Do not insert the power plug into where it is difficult to disconnect.
- ☞ Maintenance cannot be performed while the System is in use.
- ☞ The application part of the system is the administration set.
- ☞ Date of manufacture: see the label.

Chapter 4 Installation

4.1 Requirements for installation sites

The power cord of the System shall be connected to a three-core (one core is the earth wire) power socket with 100-240 V, 50/60 Hz. Do not place the System with flammable liquids and gases. The operating ambient temperature should be kept within the range of 5 °C ~ 40 °C. When working, the System should be kept away from equipment that may generate high-frequency electromagnetic radiation (such as high-frequency scalpel, and electric cautery), otherwise false alarm signals may be generated.



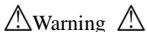
Do not open the enclosures for any adjustment, maintenance, and other operations on the System when it is powered on. If maintenance is required, it must be carried out by professional technical maintenance personnel authorized by the manufacturer.

The bracket of the rear enclosure can be used to install the System on the dedicated infusion stand that is located on the rear side of the System.

Before installing the System on the infusion stand, the stability of the infusion stand needs to be checked.

4.2 Preparation before use

- 1) Unpack the packaging.
- 2) Fix the System to the removable infusion stand.
- 3) Connect the power cord of the System to an earthed AC power socket.
- 4) Insert the infusion / syringe pumps into the System and fix them.



Users should keep packaging materials out of the reach of children. Packaging materials shall be disposed of in accordance with local laws and regulations or the hospital's waste disposal system.

Notes:

- ⚠ Please properly keep the packaging box and packaging materials for future transport or storage.

4.2.1 Installing the infusion pump

Steps to install the infusion pump to the System:

- 1) Align the power interface and Input/output on the back of the infusion pump to and insert them into the System.
- 2) Fix the infusion pump firmly on the System, and tighten the long handle screws on the back.

Notes:

- ⚠ When fixing the infusion pump, please be sure to tighten the long handle screws in case the infusion pump slips from the stand or vibrates during use.

4.2.2 Dismantling the infusion pump

Steps to dismantle the infusion pump:

- 1) Turn off the infusion pump.
- 2) Loosen the long handle screws on the back of the infusion pump, and then gently dismantle it from the System.

Notes:

- ⚠ Before dismantling the infusion pump, please make sure that the infusion set is removed from it (The method of removing the infusion set: close the flow regulator on the infusion set, open the pump door, open the infusion set clamp and take the infusion set out, and close the pump door.).

4.2.3 Installing the syringe pump

1) Align the power interface and Input/output on the back of the syringe pump to and insert them into the System.

2) Fix the syringe pump firmly on the System and tighten the long handle screws on the back.

Notes:

- ⚠ When fixing the syringe pump, please be sure to tighten the long handle screws in case the syringe pump slips from the stand or vibrates during use.

4.2.4 Dismantling the syringe pump

Steps to dismantle the syringe pump:

1) Turn off the syringe pump.

2) Loosen the long handle screws on the back of the syringe pump, and then gently remove it from the System.

Notes:

- ⚠ Before dismantling the syringe pump, make sure the syringe is removed from it.

Chapter 5 Function Introduction

5.1 Main interface display



Figure 5-1 Main display interface

As shown in Figure 5-1:

1) Display of a patient's basic information:

Display of a patient's basic information, including case ID, bed number, and name, the default is 0001, Bed 1, and cis respectively.

2) Display of time, date and network status:

Display of the current system time: MM/DD h:m; display of the connection status to the System:



connected status , disconnected status ; display of the network connection status:



wireless network (connected status , disconnected status), wired network



(connected status , disconnected status).

3) Display of alarm sound:



Status: indicates the audio is paused; indicates the audio is not paused.

Rules:

- When the audio is paused, the current high-priority and low-priority audios are paused.
- When a high-priority alarm occurs or is removed for any pump, the audio paused state is removed if the audio is current paused.
- The audio paused state is automatically removed after about 120 seconds.

4) Display of pump types

Infusion Pump: ; Syringe Pump: 

5) Display of high-priority alarm

6) Display of low-priority alarm

7) Display of working status

Working status: work, pause, stop

8) Entry of the menu

Enter the monitoring page on the homepage, and click "Menu" button in the upper left corner to enter the menu interface.

5.2 Functions of the menu

Click "Menu" on the main display interface to enter the interface shown in Figure 5-2, which mainly includes the functions of Case Manage, Advice, History, System Setup and Maintenance.

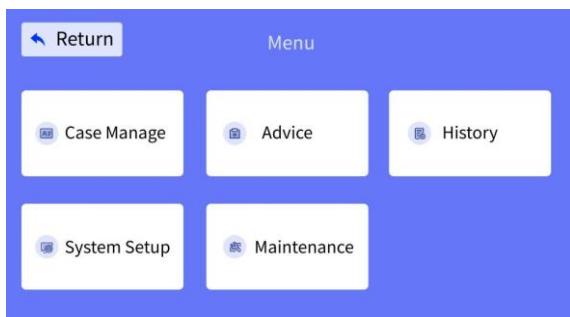


Figure 5-2 Menu interface

5.2.1 Case management

Click "Case Manage" in the menu interface to set the relevant information of the case, as shown in Figure 5-3.



Figure 5-3 Case management interface

1) Case No.: The default value is 0001, and four Chinese characters or eight English letters or symbols can be entered;

2) Name: The default value is cis, and eight Chinese characters or sixteen English letters or symbols can be entered;

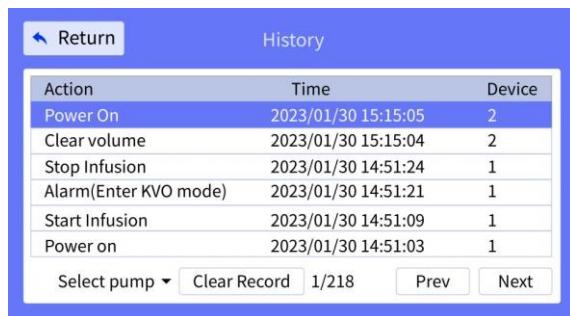
- 3) Bed No.: The default value is 1, and an integer from 1 to 60 can be entered;
- 4) Gender: The default value is male. Male or female can be selected in the drop-down list;
- 5) Age: The default value is 30, and the maximum input value is 200;
- 6) Patient type: The default value is adult. Adult, Neonate, or Pediatric can be selected in the drop-down list;
- 7) Height (cm): The default value is 160, and an integer from 50 to 200 can be entered;
- 8) Weight (kg): The default value is 50, and an integer from 1 to 400 can be entered.

5.2.2 Advice

This function is currently unavailable.

5.2.3 History

Click “History” in the menu interface to view the relevant history information, as shown in Figure 5-4.



Action	Time	Device
Power On	2023/01/30 15:15:05	2
Clear volume	2023/01/30 15:15:04	2
Stop Infusion	2023/01/30 14:51:24	1
Alarm(Enter KVO mode)	2023/01/30 14:51:21	1
Start Infusion	2023/01/30 14:51:09	1
Power on	2023/01/30 14:51:03	1

Buttons at the bottom: Select pump ▾, Clear Record, 1/218, Prev, Next.

Figure 5-4 History

The contents in the History interface:

- 1) Action: Power On, Power Off, Start Infusion, Stop Infusion, Alarm, Cancel Alarm, Clear Volume.
- 2) Time: MM/DD/YYYY h:m:s
- 3) Equipment: Pump No. 1-4
- 4) Click “Start Infusion”, “Stop Infusion”, and “Alarm” to pop up a window showing the current detailed infusion information as shown in Figure 5-5,Figure 5-6.



Action	Mode:	Rate Mode	Device
Power on	Drug Name:	Amoxicillin	2
Power off	Total:	20.0 ml	4
Power off	Speed:	40.0 ml/h	3
Stop infusion	Already:	14.222 ml	1
Stop infusion			3
Start infusion			1

Buttons at the bottom: Close, Clear record, 1/218, Prev, Next.

Figure 5-5 History

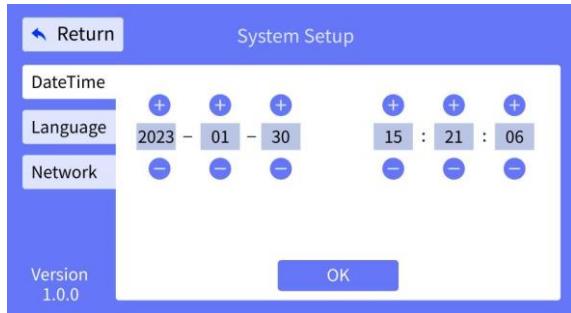


Action	Mode	Drug Name	Total	Speed	Already	Device
Power on	Rate Mode					2
Power off						4
Power off						3
Stop infusion		Amoxicillin	20.0 ml	40.0 ml/h	14.222 ml	1
Stop infusion						3
Start infusion						1
Select pump	Close					
	Clear record 1/210					
	Prev					
	Next					

Figure 5-6 History

5.2.4 System setup

Click “System Setup” in the menu interface to set the date and time, Language and Network of the system, as shown in Figure 5-7.



System Setup

DateTime

Language

Network

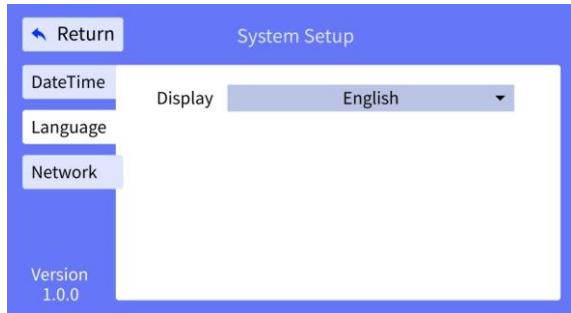
Version 1.0.0

OK

2023 - 01 - 30 15 : 21 : 06

Figure 5-7 Date and time settings

As shown in Figure 5-7, the default date and time is the current system time, which can be adjusted from 2000-1-1 ~ 2037-1-1 (excluded).



System Setup

DateTime

Display English

Language

Network

Version 1.0.0

Figure 5-8 System language settings

As shown in Figure 5-8, the default system language is English, and Chinese or English can be selected from the drop-down list.



Figure 5-9 Wired network settings

The default network type is wired, and wired or wireless can be selected from the drop-down list. The default server IP is 202.114.5.119 (this is the IP of the computer where the PC software is located), as shown in Figure 5-9.

In the wired network mode, click “Next step” to set the local IP, subnet mask, default gateway, DNS, and whether to automatically obtain IP, as shown in Figure 5-10.

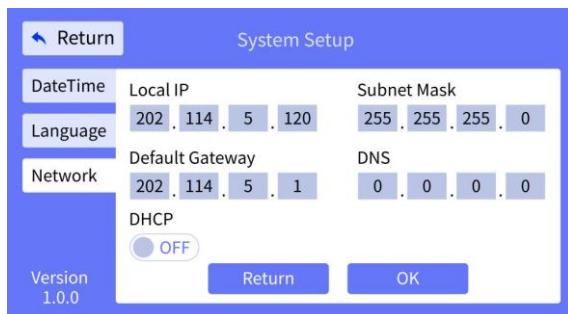


Figure 5-10 Wired network settings



Figure 5-11 Wireless network settings

When the network type is wireless, click the “Choose wireless” to display all wireless networks within the current valid range. Select the name of the network where the PC software resides for connection.

5.2.5 Maintenance

Click “Maintenance” in the menu interface to pop up a window as shown in Figure 5-12, then enter the password “8888” to enter the maintenance interface.

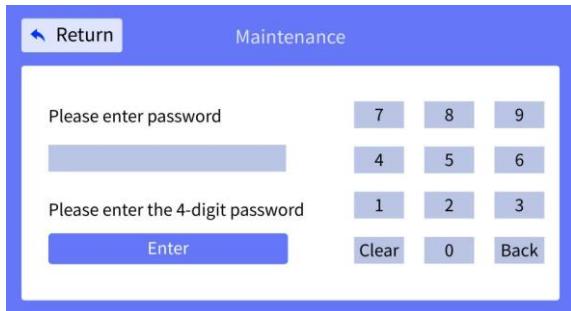


Figure 5-12 Entry of maintenance

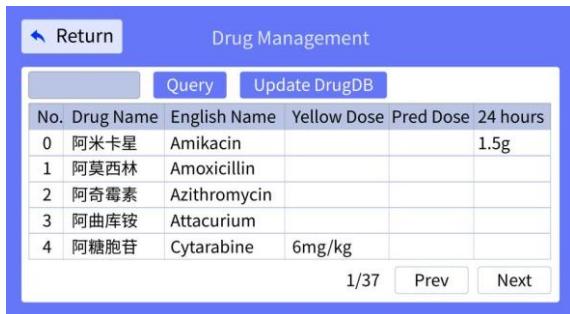


Figure 5-13 Maintenance interface

In the maintenance interface, there are four options: Drug Management, Pipe Management, Upgrade Program, and Restore Settings.

1) Drug management:

- In Drug Management, there is more than 180 pieces of drug information in the drug list by default, as shown in Figure 5-14.
- This is a query function in this option. You can enter the drug number or drug name you want to query in the edit box for fuzzy query, and the query results will be displayed in the drop-down list. When the drug name is not displayed completely, click the corresponding list box to pop up the drug name detail window as shown in Figure 5-15.
- To upgrade the drug database, you can put the drug information table to be updated in the “cis/drugupdateinfo.db” file in the USB flash disk, and click “Update DrugDB” to upgrade.



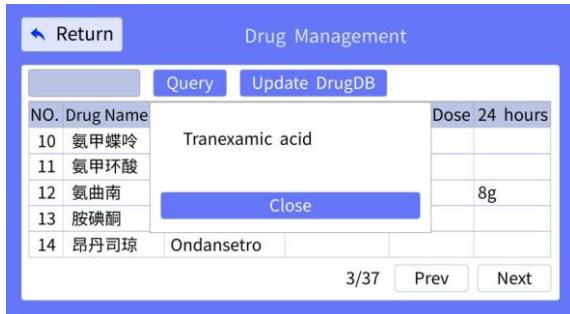
Drug Management

Query Update DrugDB

No.	Drug Name	English Name	Yellow Dose	Pred Dose	24 hours
0	阿米卡星	Amikacin			1.5g
1	阿莫西林	Amoxicillin			
2	阿奇霉素	Azithromycin			
3	阿曲库铵	Atacurium			
4	阿糖胞苷	Cytarabine	6mg/kg		

1/37 Prev Next

Figure 5-14 Drug management interface



Drug Management

Query Update DrugDB

NO.	Drug Name	English Name	Dose	24 hours
10	氨甲蝶呤	Tranexamic acid		
11	氨甲环酸			
12	氨曲南			
13	胺碘酮		8g	
14	昂丹司琼	Ondansetron		

3/37 Prev Next

Figure 5-15 Drug management interface

- 2) Pipe management: 1. List of infusion pump pipes: Ander, Tube A; 2. List of syringe pump pipes: WEIGO, ANDE, Type1, Type 2, Type3.
- 3) Upgrade program: Put the upgrade program “cis_upgrade_boot.tar.gz” in a USB flash disk, click the Upgrade Program, and upgrade according to the prompts.
- 4) Restore settings: Click “Restore Settings” to pop up the second confirmation screen. Click “OK” if you decide to restore the factory settings, or click “Cancel” if you accidentally touch the button or do not restore the factory settings.

Notes: Restore Settings cannot be performed when a pump is working on the System.

Chapter 6 Alarm

6.1 Overview

Alarm refers to a prompt signal (visual, audible or letters display, etc.) which indicates an abnormal patient condition due to the change of the delivery drugs or that the system fails to monitor the patient due to the system's failure.

⚠ Warning ⚠

- In any single area, there are potential risks if the same or similar devices use different alarm presets.
- The maximum delay alarm time does not exceed 5 s from generating alarm by Infusion / Syringe Pump to giving an alarm signal by the system.
- When alarm occurs on Infusion / Syringe Pump, it will transmit the alarm status to the System through serial communication without delay.

6.2 Alarm mode

When an alarm occurs in the system, it will remind user by the following visual and audible alarm.

Alarm level	Sound signal period	Alarm information
High-priority alarm	2.5 ~ 15 s	White letters on red background
Low-priority alarm	2.5 ~ 30 s	Yellow letters on white background

When an alarm occurs in a Infusion / Syringe Pump, it will remind user by the following visual and audible alarm.

When the communication between the Infusion / Syringe Pump and the system is normal, the alarm sound is given by the system, not the pump, and the sound is consistent with the highest level of alarm sound of the pump that generates alarms.

When the communication between the Infusion / Syringe Pump and the system is interrupted, the pump will give an alarm sound.

Notes:

- ⌚ When there is an alarm, the operator should observe the alarm information on the front of the device, refer to “Appendix II Illustration for System Alarm” for troubleshooting, shut down if necessary and ask the dealer.
- ⌚ The system will detect whether the alarm function is normal when starting up.
- ⌚ The audible alarm shall produce a sound pressure level of at least 45 dB(A) at a 1 m.

Chapter7 Maintenance

7.1 Maintenance

The System you have purchased is a well-designed product and should be used with care. Proper maintenance can extend its life.

It is recommended that the pump should be maintained once per month by the medical staff in accordance with the following steps:

- 1)Wipe it with a soft cloth soaked mild soapy water.
- 2)Wipe it with a dry cloth.

Notes:

- ⚠ The power cord must be disconnected from the supply mains during cleaning and maintenance.
- ⚠ Do not immerse in the liquid and do not splash the liquid directly on the system.

7.1.2 Pollution-free disposal and recycling

The service life of this product is 10 years, and the System beyond that service life must be scrapped.

The dealer from whom you purchased this product or our offices will accept the unused System for proper recycling.

Please contact the manufacturer or dealer for more information.

7.2 Transport and storage

1. Severe impact, vibration, as well as rain and snow splash should be avoided during transport.
2. The packed product should be stored in a room with no corrosive gases and good ventilation, temperature: -30 °C ~ +55 °C, relative humidity: 5 % ~ 96 %, atmospheric pressure: 500 hPa ~ 1060 hPa.

Chapter 8 Accessories

Standard configuration in the packaging box:

- 1) A Central Infusion System
- 2) A power cord
- 3) A User Manual

Notes:

If you find some accessories missing after opening the packaging, please contact the dealer who sold the product to you as soon as possible.

Chapter 9 Symbols and Meanings

Symbol	Illustration
	Type BF applied part
IPX2	Degrees of protection provided by enclosure
	Attention! Refer to the accompanying document.
	Manufacturer
	Serial number
	Atmospheric pressure limitation
	Temperature limitation
	Humidity limitation
	This way up
	Fragile, handle with care
	Keep dry
	Stacking limit by number

	Alternating current
	Input/output
	Refer to the instruction manual/booklet
	AUDIO PAUSED
	No pushing
	USB port
	Computer network
	WEEE (2012/19/EU).
	This item is compliant with Directive 93/42/EEC of 14 june 1993 concerning medical devices; Including, at 21 march 2010, the amendments by Council Directive 2007/47/EC.
	European Representative
	Date of manufacture

Appendix I EMC Guidance and Manufacturer Declaration

The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

The ME EQUIPMENT or ME System is suitable for professional healthcare facility environments(hospital).

Don't near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

Warning:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”

This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME System or shielding the location.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Cord	Cable length(m)
Power cord	1.8

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment , including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note:

Other devices may affect this device even though they meet the requirements of CISPR.

When an input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

The basic performance:maintain the normal operation.

Table 1

Guidance and Declaration - Electromagnetic Emissions	
Emissions test	Compliance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1
Conducted and radiated RF EMISSIONS CISPR 11	Class A
Harmonic distortion IEC 61000-3-2	Not applicable
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable

Table 2

Guidance and Declaration - Electromagnetic Immunity		
Immunity Test	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
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
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % UT; 0,5 .cycle. At0 °,45 °,90 °,135 °,180 °,225 °,270 ° and315 °. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0 °. 0 % UT; 250/300 cycle	0 % UT; 0,5 .cycle. At0 °,45 °,90 °,135 °,180 °,225 °,270 ° and315 °. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0 °. 0 % UT; 250/300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio

	bands between 0,15MHz to 80 MHz 80%AM at 2kHz	bands between 0,15MHz to 80 MHz 80%AM at 2kHz
Radiated RF IEC61000-4-3	3V/m 80 MHz-2,7GHz 80%AM at 2kHz	3V/m 80 MHz-2,7GHz 80%AM at 2kHz
NOTE UT is the a.c. mains voltage prior to application of the test level		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulati on	IEC6060 1-1-2 Test level (V/m)	Complia nce level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 -390	TETRA 400	Pulse modulatio n b) 18 Hz	27	27
	450	430-4 70	GMRS 460, FRS 460	FM c) \pm 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulatio n b) 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulatio n b) 18 Hz	28	28
	870					
	930					

	1720		GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulatio n b) 217 Hz	28	28
	1845	1 700 – 1 990				
	1970					
	2450	2 400 – 2 570	Bluetoot h, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulatio n b) 217 Hz	28	28
	5240					
	5500	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulatio n b) 217 Hz	9	9
	5785					

Appendix II Illustration for System Alarm

Name	Causes	Troubleshooting Methods
Bubble alarm	1. There are air bubbles in the infusion set; 2. The infusion set is installed incorrectly; 3. Sensor failure.	Find the corresponding alarm machine number and perform the following operations: 1. Long press the menu button to clear the alarm, manually remove the air bubbles in the infusion set, and then press the “Start/Stop” button to restart the infusion; 2. Reinstall the infusion set; 3. Contact customer service (manufacturer or supplier).
Occlusion alarm	1. Infusion occlusion; 2. The occlusion alarm value is too small, which makes the alarm system too sensitive; 3. Sensor failure.	Find the corresponding alarm machine number and perform the following operations: 1. Long press the menu button to clear the alarm, remove the occlusion, and then press the “Start/Stop” button to restart the infusion; 2. Check the “Pressure Threshold” section in the User Manual; 3. Contact customer service (manufacturer or supplier).
Low battery alarm	1. The battery power is too low; 2. The battery is aging or the battery charging circuit is damaged.	Find the corresponding alarm machine number and perform the following operations: 1. Check the connection between the infusion / syringe pumps and the System; 2. Connect the AC power of the infusion / syringe pumps to charge the battery; 3. Contact customer service (manufacturer or supplier).
Battery depletion alarm	1. The battery runs out; 2. The battery is aging or the battery charging circuit is damaged.	Find the corresponding alarm machine number and perform the following operations: 1. Check the connection between the the infusion / syringe pumps and the System; 2. Connect the AC power of the infusion / syringe pumps to charge the battery; 3. Contact customer service (manufacturer or supplier).
Motor failure alarm	1. The infusion set is installed incorrectly; 2. The motor itself	Find the corresponding alarm machine number and perform the following operations: 1. Long press the menu button to clear the alarm, reinstall the infusion set, and then press the

	is faulty.	Start/Stop button to restart the infusion; 2. Contact customer service (manufacturer or supplier).
Syringe out	1. The pressure rod is loose or falls off; 2. The push handle of the syringe is separated from the push-pull case.	Find the corresponding alarm machine number and perform the following operations: 1. Long press the menu button to clear the alarm, reinstall the syringe, and then press the “Start/Stop” button to restart the infusion 2. Contact customer service (manufacturer or supplier).

FCC Caution

§ 15.19 Labeling requirements.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

§ 15.21 Information to user.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

§ 15.105 Information to the user.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

The device has been evaluated to meet general RF exposure requirement. The device can be used in mobile exposure condition at least 20cm distance between the human body