Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to The User or Other

Infusion Pump Management Unit

Model: 500 D

Please read the Manual before using the product.
Please keep it for future reference.

CE 0197

057-00663-01

Contents

Revision Notes

Under the premise of complying with relevant laws and regulations, this manual will be revised in due course according to the improvement of products or the update of laws and regulations.

This manual is applicable to 500 D Infusion Pump Management Unit.

Document No.	Version	Revision date
057-00663-00	V1.0.0	20-08-2025
057-00663-01	V1.0.1	10-11-2025

User manual version upgrade instructions:

V X.Y.Z

V means version No. of user manual.

X means device has big upgraded: When software, hardware and construction of device have big modified, the user manual should be upgraded accordingly.

Y means the device has small improvement: In order to better using the device, the software, hardware and construction of device have been tiny improved (it is not necessary for re-registration after evaluation), the user manual should be upgraded accordingly.

Z means correcting information of user manual while the device has no changed. It only correct the wrong word/ diagram/explanation and so on.

Operation Manual

The Infusion Pump Management Unit has an expected service life of 10 years from the date of product installation when operated according to the instructions provided with this device.These 10 years include suggested or mandatory actions of preventative maintenance and repair activities, as well as required calibration(s) that are needed. Required reading includes the instructions for use and other materials provided with the device. This also includes any hardware and software updates that may be required.

Expected service life: 10 years. The date of manufacture is shown on the label.

Please report any serious incidents involving this equipment to Shenzhen Hawk Medical Instrument Co., Ltd and your local authority (or, if applicable, to the appropriate regulatory authority in the country where the incident occurred).

Please refer to section VI of this Manual for a glossary of symbols used for infusion pump management unit of Shenzhen Hawk Medical Instrument Co., Ltd.

I Safety

1.1 Security Information

Warning:

- Prompting potential hazards or unsafe operations that, if not followed, may result in death or serious personal harm or property loss.

Caution:

- Prompting potential hazards or unsafe operations that, if not followed, may result in minor personal harm, product failure, damage or property loss.

Note:

- Emphasizing important precautions and providing instructions or explanations to better use this product.

1.2 Warning

No.	Content
1	Only professionals who have been trained how to use it and are familiar with device can use the infusion pump management unit. Any unauthorized personnel or untrained personnel are not allowed to carry out any operation.
2	Please use original equipment and compatible equipment combinations,accessories, working parts and consumables. Only consumables recommended by manufacturer can ensure functional safety.
3	To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth.
4	Do not use the infusion pump management unit near flammable liquids or gases.
5	The infusion pump management unit shall not be stored or used in an environment with chemically active gas (including gas for disinfection) and a humid environment. This kind of environment will affect the internal components of the Infusion Pump Management Unit, and may cause degradation or damage to the performance of the internal components.
6	This Infusion Pump Management Unit can not be directly powered by the vehicle power.
7	The user must ensure that the pump and other components of the infusion pump management unit are correctly inserted, locked and dismantled.

8	When disassembling and assembling parts of the plug-in box, make sure not to operate with electricity and not to introduce power into any part. Only after the whole infusion pump management unit is assembled, the power cord be inserted into the socket. The power cord must be properly placed to avoid tripping passers or pulling down or damaging the system.
9	The infusion pump management unit can stack up to 24 pumps, and too many pumps may result in unpredictable communication errors.
10	Do not only rely on the alarm system when using, and medical staff should inspect regularly to prevent accidents.
11	The operator should ensure that the infusion parameters in the syringe pump are the same as the doctor's advice before starting the infusion. Any parameter setting that exceeds the parameter range will result in invalid operations.
12	When the equipment is placed on a horizontal plane, only 2 channels are allowed at most to avoid the whole equipment rollover and harm accidents.
13	This device supports cascade extension of up to 6 plug-in box units, and ensures that each level of plug-in box units is reliably fixed during use.
14	This equipment can only be connected to the products designated by our company. In order to ensure patient safety, please do not connect products not designated by our company to the equipment and interface.
15	The equipment is not intended to be used within the Magnetic Resonance (MR) environment.
16	Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel. Moreover, the servicing must be done only after the AC power supply is disconnected.
17	Do not place the equipment or accessories in any position that might cause it to fall on the patient.
18	Do not touch the patient and device connectors simultaneously. Otherwise leakage current may result in patient injury.
19	To avoid electric shock, do not touch patient and other non-defibrillation proof equipments during defibrillation. Defibrillation will not affect the performance of the equipment.
20	Do not service or perform maintenance while the patient is using the device.

21	Unauthorized modifications to this equipment are not permitted,that may result in serious injury o patients.
22	Loss of power may result in unacceptable risks. The equipment must be connected to a suitable power supply.
23	Do not service or perform maintenance on the device while in use with a patient.

1.3 Caution

No.	Content
1	Before the first use,or after a long period of inactivity, the infusion pump management unit should be connected to the AC power supply, and the devices should be charged for at least 12 hours in the power on state (at least 5 hours in the shut down state). Under the condition of insufficient charging and power outage, the infusion pump management unit cannot continue to work with the power supply of the built-in battery.
2	Check before use. Users must check whether the infusion pump management unit function is safe and complete, and carry out independent function tests and technical safety checks for all other connected devices. And check whether the current software and hardware versions of the device components are the same as those indicated in the instructions. If any abnormality is found, stop using immediately and contact the manufacturer or local distributor. In addition, the adhesion or intrusion of liquid medicine may cause the failure of the infusion pump management Unit. Therefore, clean it after use and keep it properly.
3	When using it near the electrocautery equipment, the infusion pump management unit may occur malfunction due to the high-frequency clutter of the electrocautery equipment. When using medical electrocautery equipment simultaneously, please take the following steps and measures before use. a Avoid using it with old-fashioned (vacuum tube and open type) electrocautery equipment. b The distance between the power cord or body of the electrocautery equipment and the Infusion Pump Management Unit should be kept at least 25 cm. c The power cord of the electrocautery equipment and infusion information Infusion Pump Management Unit should be led from different power distribution cabinets, and to carry out reliable grounding.

4	Do not use the infusion pump management unit near mobile phones, wireless devices and MRI equipment within one meter. Otherwise, the high-frequency noise signal in communication may cause the incorrect operation of the infusion pump in the system.
5	This infusion pump management unit cannot be used in the area of radiation equipment or magnetic resonance equipment and in places where hyperbaric oxygen therapy is performed.
6	The infusion pump management unit should keep a certain distance from AC and DC power sockets to avoid splashing or dripping liquid medicine into the sockets, resulting in a short circuit fault. In addition, please ensure that the power plug and socket are kept dry before connecting the power supply to the device.
7	If the infusion pump management unit is fixed on a removable infusion stand, a standard infusion stand must be used, because the center of gravity of the Infusion Pump Management Unit may change, and the infusion stand should be used with a locking device to prevent the infusion stand from rolling on a horizontal plane, especially on an inclined plane exceeding 5 degrees. Please check its stability and safety before moving the infusion stand.
8	Do not place other items on or against the infusion pump management unit
9	Usually, please use an AC power supply as much as possible, which can prolong the service life of the battery to a certain extent. When using an AC power supply, it is necessary to make sure that the grounding line of the power supply is well grounded, and only use the AC power cord attached to the infusion pump management unit. The built-in battery is only used as an auxiliary power supply when the AC power supply cannot be reliably grounded and the AC power supply cannot be used normally (during power outages or during the process of moving the infusion pump management unit).
10	After the infusion pump management unit has experienced the falling or collision, it is necessary to stop using and contact the manufacturer or distributor for assistance. Because even if the appearance is not damaged and no exception is reported at runtime, the interior of the equipment may still be damaged.
11	Operating buttons and other parts shall not be pressed with the front end of sharp objects (such as nibs, nails, etc.), otherwise, the buttons or layers may be damaged prematurely.
12	The infusion pump management unit shall not be disassembled or modified, or used for any purpose other than normal syringe, otherwise, our company

	will not be responsible.
13	In case of doubt about protective grounding, the internal power supply should be used.
14	The infusion pump management unit should not be placed in an area where it is difficult to operate the disconnect device.
15	When the power loss time does not exceed 30 seconds, the alarm setting before the power loss can be automatically restored.
16	The equipment must be used under the specified environmental specifications, otherwise it will not meet the technical specifications claimed in the manual, and may lead to unpredictable consequences such as equipment damage. If the performance of the equipment changes due to aging or bad environmental conditions, please contact the maintenance personnel.
17	Electromagnetic fields may affect equipment performance. This makes it necessary for other equipment used in the vicinity of this equipment to meet EMC standards. Mobile phones, X ray and MRI equipment are all potential interference sources because of their high-intensity electromagnetic radiation.

1.4 Note

No.	Content
1	This equipment has the function of power-down storage. After the abnormal interruption of the power supply, the alarm limit setting and historic records before the power outage can be saved for a duration equivalent to the equipment's life. After the power is on, the alarm settings before power interruption can be automatically loaded.
2	This manual describes all features and options. Your equipment may not have all of them.
3	This equipment only supports the use in conjunction with InnoFusion series infusion or syringe pumps of Hawk Medical.

II Overview

2.1 Features

- The Infusion Pump Management Unit can be flexibly superimposed and communicated in the medical environment, especially in the intensive care unit, which is very helpful to the safety of patients;
- It integrates the functions of data storage, display, alarm and control of the infusion pump/syringe pump;
- It supports the mixed use of any combination of Hawk InnoFusion series infusion/syringe pumps with up to 24 channels;
- The hot swap connection is supported between the syringe pump, the infusion pump and the Infusion Pump Management Unit, which can quickly assemble and disassemble the pump in the Infusion Pump Management Unit for plug and play;
- Some parameters can be set and changed synchronously through the infusion pump or the syringe pump or the Infusion Pump Management Unit;
- It has functions such as inputting historic records and patient information;
- Alarm functions: infusion control alarm, technical fault alarm, etc.;
- It is convenient and quick, and can export historic records and upgrade software online through USB flash disk;
- Physical integration and centralized power supply function: it supports the physical integration of up to 24 infusion pumps (insert the plug-in box unit to fix, saving stacking installation space), and provides a centralized power supply for these infusion pumps.
- Backup batteries and high-grade electrical safety standards.

2.2 Intended Use

The Infusion Pump Management Unit is in conjunction with the infusion pump and syringe pump, providing space management, power management, alarm management,information display, and communicate with pump to transmit data.

The Infusion Pump Management Unit is intended for use in those patients who requiring medication infusion in institutes or units with healthcare capabilities, such as operating rooms, emergency departments, wards, ICU.

This system is intended for use only by clinical professionals or under their guidance.It must only be used by persons who have received adequate training in its use.

The Infusion Pump Management Unit is intended for adults, pediatric and neonate.

Contra-indications : None known.

2.3 Product Classification

The following specify the protection classification according to

EN60601-1:2006+A1:2013+A12:2014+A2:2021

Type of electric shock protection	Class I, internal power supply
Electric shock protection grade	Defibrillation-proof type CF, the CF applied parts are infusion pumps or syringe pumps that are not included in the system
Liquid entry prevention grade	IP33
Moving level	Portable type for four channels, Fixed type for more than four channels
Operation mode	Continuous operation

Note:

- This equipment cannot be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide gas.

2.4 Impact on the Environment and Energy

The Infusion Pump Management Unit may have a certain amount of electromagnetic radiation, which may interfere with other equipment. If this happens, corresponding measures need to be taken to reduce interference during use, such as relocate the infusion pump management unit or introducing grid power from different places. For more information, please refer to Appendix I of this manual, “Electromagnetic Compatibility (EMC) Information”.

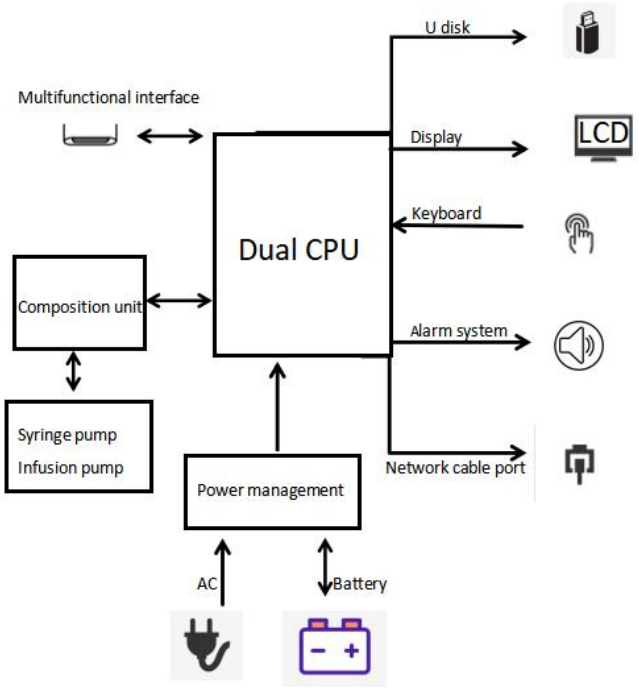
III Components

3.1 Working Principle

The Infusion Pump Management Unit monitors and collects the infusion status, alarm information and infusion volume of the stackable infusion pumps and syringe pumps through the wired connection inside the plug-in box, and provides centralised power supply of these pumps.Also,the control unit of Infusion Pump adopt the uses the centralised management management and control of the pumps' infusion parameter information .

In addition, the Infusion Pump Management Unit applies wireless networking to transmit the collected infusion data and alarm information to the monitoring software at the hospital side in real time for medical personnel to lookup.

The schematic is as follows:



3.2 Components

The Infusion Pump Management Unit main consists of control unit and Plug-in box.

Control unit: used to synchronize the system settings and amount the total medication volume of infusion or syringe pumps.Also,control unit cloud monitor the infusion/syringe pumps running status and synchronize an alarm signal from infusion or syringe pumps. The plug-in box is used to stack and combine multiple infusion/syringe pumps together.

Plug-in box: the main shell part of the Infusion Pump Management Unit for installing the infusion pump and syringe pump. The upper part of the device can be installed with an alarm after sliding, and the inner part contains a communication part and an AC network electric-to-DC module. The plug-in box unit can be superimposed and combined into more channels for use.

IV Technical Characteristics, Parameters and Explanation of Terms

Items	Technical parameters
Maximum number of connections	24 pumps
Overlay mode	Support combined expansion function, support up to 24 channels, divided into the host and the slave. The host supports up to 12 channels, the slave supports up to 12 channels, and the host and the slave are connected by data cable
Plug-in method	Support hot plug
Connect setup time	Less than 3 seconds (insert an infusion pump arbitrarily to establish connect operation)
Disconnection time	Less than 15 seconds (an infusion pump determines disconnection time)
Log	Store at least 10,000 records
Small screen display function	It can display the connection status of the infusion pump, the amount of infusion and the patient information
Duration of audio pause	105s
Alarm connection function	The alarm information of the pump connected to the Infusion Pump Management Unit can be processed centrally, and give audible and visual alarm according to priority
Alarm sound volume	1%-100% adjustable
Brightness level of the alarm light	1%-100% adjustable
Sound pressure level of the alarm signal	When it is set to a lowest level, the sound pressure level of the alarm signal shall not be less than 50dB. When it is set to a highest level, the sound pressure level shall not be less than 65dB.
Type of alarm	1. synchronize infusion pump and syringe pump alarm; 2. Self-alarm of the Infusion Pump Management Unit.

Support WIFI communication	WIFI (built-in WIFI module, optional)
Internal battery	Li_Polymer 11.1V 4400mAh； Charging time: Power on for about 11 hours of charging, and shut down for about 5 hours of charging. Running time: Running for no less than 12 hours (when the factory default settings are restored).
Waterproof grade	IP33
Electrical classification	Class I, internal power supply
Input power	12-channel 400VA, 24-channel 800VA (including pumps)
Shape parameter	Dual channel: 286*190*277mm (L*W*H, excluding fixing clips) Four channels: 286*190*451mm (L*W*H, excluding fixing clips) Six channels: 286*190*625mm (L*W*H, excluding fixing clips) Eight channels: 286*190*799mm (L*W*H, excluding fixing clips) Ten channels: 286*190*973mm (L*W*H, excluding fixing clips) Twelve channels: 286*190*1147mm (L*W*H, excluding fixing clips)
Safety standard	EN 60601-1:2006/A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-8:2007+A1:2013+A11:2017+A2:2021 Medical electrical equipment - Part 1:General requirements for basic safety and essential performance EN 60601-1-2:2015+A1:2021 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests EN 60601-2-24:2015 Medical electrical equipment - Part2-24: Particular requirements for the safety of infusion pumps and controllers

V Appearance View

5.1 Front View

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5.2 Extended Interface

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5.3 Rear View

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5.4 Operation Panel

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5.5 Screen Display

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VI Symbols and explanations

The following symbols appear on the labels and IFU:

Warning	The occurrence of this condition or action may result in personnel injury or life threatening risks.
Caution	It indicates that this information is a caution. Caution reminds you of a situation that may cause minor or moderate injury to the patient or operator. Please read and understand the contents of the caution carefully before operating this injection system.
Attention	It indicates that this information is an attention. Attention reminds you of a situation that may cause damage to the equipment. Please read and understand the contents of the attention carefully before operating this injection system.
Note	It indicates that the following information is additional important information, or a reminder to help you recover from an error, or to point you to relevant information in this Manual.

	Defibrillation-proof type CF applied part
	Follow the operation manual
IP33	Prevent solid foreign objects larger than 2.5 mm in diameter and Spray water in a direction with an angle of less than 60°from the top to the vertical
	Sound pause
	Battery
	Battery power
	Battery charging
	Battery abnormality
	AC
	Power on or shutdown
	Sound volume
	Wired network interface opened
	Input/output
	WIFI (representing WIFI disconnection, one signal, two signals and full signal respectively)
	Sequential cascade

	Button lock
	Cyclic cascade
	Arbitrary cascade
	prohibition sign
	USB flash disk access
	Manufacturer
	European Authorized Representative
	Production date
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Serial number
	Reference number
	This side up

	Keep dry
	The device is an electrical and electronic device and must be disposed according to WEEE Directives
	Contain RF transmitters or equipment that uses RF electromagnetic energy for diagnosis or treatment or external markings of the equipment
	Importer
UDI	Indicates a carrier that contains Unique Device Identifier information
MD	Indicates the item is a medical device
CE XXXX	This device is provided with a CE marking in accordance with the Medical Device Regulation 2017/745. XXXX is the Notified Body number.

VII Preparation and Precautions for Operation Before Use

7.1 Preparation and Inspection Before Use

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7.2 Precautions for Operation

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VIII Operation Method

8.1 Installation

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8.2 System Settings

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8.3 Dock Settings

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8.4 Alarm and Treatment

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8.5 Software Information

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IX Fault Analysis and Solutions

Fault phenomenon	Cause analysis	Elimination method
Key failure	● Damaged touch button ● Damaged key circuit	Please contact the manufacturer for replacement
The infusion pump/syringe pump failed to connect with the Infusion Pump Management Unit.	Infusion pump/syringe pump is not installed and inserted in place.	Pull out infusion pump/syringe pump and reinsert it.
	Damaged data interface of infusion pump/syringe pump	Please send it back to the dealer or manufacturer for inspection and repair
	The cable inside the insertion box is loose or not plugged in properly.	Please send it back to the dealer or manufacturer for inspection and repair
Unlock knob does not reset automatically after unlocking	Damaged reset spring in unlock knob	Manual reset
		Contact the manufacturer to replace the spring
Color deviation or patterns on display screen	● Damaged display ● FPC is not plugged in properly.	Please contact the manufacturer to replace the display screen

Please contact the supplier or manufacturer to eliminate other faults in addition to the common alarms in 8.4 and the above faults, and ensure the normal power supply state before making validation of the faults.

X Safety Invention and Troubleshooting

10.1 Safety Invention and precautions

1) External power supply: A double backup fuse is installed inside. When short circuit or any other malfunction occurs, the fuse will cut off the circuit in advance.

2) Battery protection: The battery contains protective features which protect it against excessive pressure, overheating or short circuit, etc. to avoid overheating or burns from occurring

3) Isolation transformer is the means of electrically isolating its circuits from supply mains simultaneously on all poles.

10.2 Troubleshooting

1) If the infusion pump management unit gives system error alarm, stop the operation and contact the distributor for repair. It can be used again only after it has been well repaired and tested. Infusion pump management unit working with malfunctions may incur unpredictable damage.

2) If the infusion pump management unit caught fire or displays any other malfunction, please disconnect the power immediately and contact the distributor/manufacturer.

XI Maintenance, Inspection, Repair and Recycling

11.1 Clean and disinfection

It is strongly recommended that the device is cleaned or disinfected using the materials and methods listed in this section. If other materials or methods are used,it may damage the device or reduce the lifespan of the device.

Note:

- Any questions about the use of cleaning and disinfectant, please consult the local distributor or manufacturer.
- Please dispose of the cleaned and disinfected waste according to the relevant regulations of the local hospital.

11.1.1 Preparations

1) Before cleaning or disinfecting the equipment, it must be disconnected from the patient.

2) The device must be powered off, and the AC power cord must be disconnected from the device.

3) Remove the connected consumables.

4) Wear rubber gloves, masks and other protective measures to prevent pollutants from splashing during cleaning and disinfection.

5. Prepare soft and lint-free gauze, and containers for cleaning agents and disinfectants.

11.1.2 Cleaning

This device should be cleaned regularly. In areas with serious environmental pollution or heavy sandstorms, the frequency of cleaning should be increased. Please check the hospital's regulations on cleaning in advance. The cleaning steps are as follows:

1) When cleaning the surface of the equipment, use a soft and lint-free gauze to soak in a neutral or weakly alkaline detergent. After the gauze is fully wet, wring it out until there is no liquid dripping, and then wipe the surface of the equipment with the gauze.

2) Wipe each surface of the equipment until the pollutants are detached from the surface of the equipment.

3) During the wiping process, ensure that the edges and corners of the equipment are cleaned.

4) After wiping, use a dry lint-free gauze to remove the residual detergent solution, and place it in a ventilated and cool environment to air dry.

Note：

- Do not immerse the device in liquid.
- Do not let liquid seep into the device casing.
- Do not use halogenated or petroleum-based solvents, glass cleaners, acetone, or other harsh cleaners.

Recommended detergents:

Cleaner	Cleaning Method
Clean water	Wipe

11.1.3 Disinfection

Disinfect the device according to the disinfection procedures of your hospital.

The disinfection steps are as follows:

1) Before disinfection, please clean the equipment according to the method described in Section 12.1.1.

2) When disinfecting the surface of the equipment, use soft and lint-free gauze to immerse in medium and high-efficiency disinfectants.After the cloth is fully wet, wring it dry until no liquid drips, and wipe the surface of the device with gauze.

3) All surfaces of the equipment should be wiped , and the action time should refer to the instructions of the disinfectant.

4) During the wiping process, ensure that the edges and corners of the equipment are disinfected.

5) After disinfection, wipe the surface of the equipment with gauze wetted with water and remove residual disinfectant solution, and place it in a ventilated and cool place to air dry.

Note：

- Do not immerse the device in liquid.
- Do not let liquid seep into the device casing.
- When using disinfectant, please follow its instructions.
- This equipment cannot be sterilized by high pressure steam

The following table lists the disinfectants recommended for the device and the required contact time for the disinfection.

Recommended disinfectant solution:

Disinfectant solution	Contact time	Disinfection method
75% alcohol	3min	Wipe

11.2 Maintenance Plan

The inspection items and recommended frequencies are as follows:

Items of inspection	Recommended frequency
Safety test	
Selection of test items based on IEC60601-1 requirements	■ After the power module is repaired or replaced. ■ At least once every two years, or as needed. ■ After the main control board is replaced or the equipment falls.
Other inspection	
Visual inspection	Before the time of first use for every day.
Power on check	At every time of power on.
Battery Check	■ At the time of first installation. ■ After the replacement of battery. ■ Every three months or when the running time of the battery is significantly shortened. ■ It is recommended to charge the battery at least once a month.

Warning:

- To prevent electric shock caused by leakage current, please stop using the equipment when the shell of equipment is damaged. Please contact the distributor or manufacturer for handling.
- No modification of this equipment is allowed.
- Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.
- This equipment does not contain components that can be repaired by users.
- All full inspection or maintenance work requiring disassembly of equipment should be carried out by professional maintenance personnel. The operation of non-professional may cause equipment failure and endanger personal safety.
- Maintenance personnel authorized by the manufacturer should have qualified

qualifications and be familiar with product operation.

11.3 Regular Inspection

11.3.1 Check of appearance

1) The appearance of equipment is free of stains, and the panel and display screen are free of injury or damage.

2) Each button is flexible and effective, without invalidity or adhesion.

3) All interfaces, plugs and cables are free of damage and winding.

4) The power cord is free of wear in appearance, with good insulation, tight connection that is not easy to fall off.

11.3.2 Power on check

Self-test will be performed after the equipment power on, and the items of self-test for power on are as follows:

- Equipment (including pumps) can undertake normal shutdown and power on.
- The function of alarm system is normal.
- Equipment is displayed normal.
- Equipment (including pump) charging is normal.

11.3.3 Battery Maintenance

This equipment is equipped with a rechargeable lithium battery to ensure that the equipment can work normally without external power supply. When connected to an external power supply, the equipment is preferentially powered by an external power supply.

a) Battery charging

To maintain the good performance of the battery, the fully discharged or nearly fully discharged battery must be charged as soon as possible. The equipment can be charged automatically after being connected with AC power supply.

Note:

- Only this device can be used to charge the battery.

- When this equipment is used together with the pump, this pump can also be charged if the equipment is connected with AC power supply.
- Before use of the built-in battery, please check the battery to make sure it has enough power. The battery should be recharged when necessary.

b) Battery optimization

The service life of the battery depends on the frequency and time of battery use. The proper use and storage of the battery could contribute to about two-year service life of lithium battery. The improper use and storage of the battery could result in the shortened service life. We recommend replacing the battery every two years. The steps for battery optimization are as follows:

1）Disconnect this equipment from the patient.

2）Turn off this equipment and connect the external power supply.

3）Continuously charge the battery until it is fully charged.

4）Disconnect the external power supply and turn on the equipment. Use the battery to supply power to the equipment until the battery is exhausted, and the equipment will automatically shut down.

5）Recharge the battery for its use, and recharge the battery to 40-60% power for its storage.

6）After the battery is used for a period of time, the battery will have loss, and the percentage display of battery power may have deviation. Please charge the battery regularly. The battery power percentage can be automatically calibrated after full charge. It is recommended to charge the battery at least once a month.

Note:

- Failure of battery maintenance for a long time may cause incorrect power display, resulting in wrong judgment of battery working time. In addition, if the battery is fully charged for a long time and is free of regular maintenance, the aging of the battery will accelerate, leading to the early failure of the battery.
- Please do not interrupt charging or discharging in the process of battery optimization.

c) Replacement internal batteries

It is recommended to replace the battery once every two years. The battery must be replaced by trained professional. It is recommended to contact the distributor or manufacturer to replace the battery.

Steps of battery replacement are as follows:

1) Remove the alarm of Infusion Pump Management Unit,

2) Loosen the screws on the battery cover of the alarm bottom case and remove the battery cover.

3) Pull off the battery connector and take out the battery.

4) Connect the new battery and install the battery cover under the condition that the battery cable is not squeezed by the battery cover. And put the alarm back into the Infusion Pump Management Unit. After replacement of the battery, it is necessary to check the battery.

Please replace the battery for recycle under the following conditions:

- The battery is damaged or malfunctioning.
- The battery is aging, or the battery life is obviously lower than the time claimed in the specification.
- The use time of battery exceeds its service life.

Warning:

- Only the specified battery is used for power supply. Using non-specified batteries may cause fire or explosion.
- Do not squeeze, drop or puncture the battery. Mechanical abuse may cause internal damage or short circuit of the battery. If the battery has been dropped or hit a hard physical surface, it should go out of service regardless of whether the damage can be seen from the outside.
- If the battery is damaged or leaked, please replace it immediately.
- Extremely high ambient temperature may cause thermal shutdown of battery, resulting in power interruption of equipment.

- Lithium battery has a service life. Please replace the battery after the service life expires, otherwise serious harm may made to the equipment due to overheating of the battery during use.
- Do not disassemble the battery, place it in an environment higher than 60 ℃, burn it or make short circuit of the battery, all of which may cause the burning, explosion, leaking or heating of battery, resulting in personal harm.

Caution:

- Installation and replacement of batteries by inadequately trained professional may cause hazard (over temperature, fire or explosion).
- Disposing of used batteries should abide by the corresponding laws and regulations.

Note:

- Storage of the battery in high temperature environment for a long time will greatly shorten the expected service life of the battery.
- Storage of the battery in a cool environment can continue the aging of the battery. Ideally, the battery should be stored in an environment of 15 ℃.

11.4 Normal Repair Procedure

In case of any abnormality, please contact the distributor or manufacturer, and should not disassemble and repair the equipment by users themselves. The Infusion Pump Management Unit should be fully tested after maintenance. If needed, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.

11.5 Maintenance during Long-Term Parking

If the Infusion Pump Management Unit is not used for a long time, it should be put in the package box, placed in a cool and dry place and avoid direct sunlight. Please refer to 12.2 for specific environmental conditions.

If the Infusion Pump Management Unit is not used for a long time, the following operations should be carried out before reuse:

1. Test whether the communication between the Infusion Pump Management

Unit and the infusion pump is normal. Please refer to 8.2.1 for the test method.

2. Conduct various alarm tests.

3. Conduct battery discharge and charging time test to validate the usability of the battery.

4. Charging and discharging the battery must be carried out every three months to ensure the service life of the battery.

11.6 Recycling

The service life of this product is 8 years. equipment and power cord having exceeded their service life must be scrapped. Please contact the manufacturer or distributor for more relevant information (Frequency of use and maintenance will affect the service life of the Infusion Pump Management Unit and power cord.)

Warning:

- For disposal of parts, batteries, packaging materials and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

XII Operation,Transportation and Storage Conditions

12.1 Operation Condition

Temperature: +5℃～+40℃;

Relative humidity: 15%～95%RH

Atmospheric pressure: 57.0kPa～106.0kPa

12.2 Transport and Storage Conditions

Temperature: -30℃～+70℃;

Relative humidity: 10%～95%RH

Atmospheric pressure: 57.0kPa～106.0kPa

XIII Packing List

13.1 Standard Configuration inside Package Box

Name	Units
Infusion Pump Management Unit	1
Cascade cable	1
AC Power cord	2
User manual	1
Product qualification certificate	1
Product warranty card	1

13.2 Optional Parts

Name	Description
Nurse call cable	Output a signal to the nurse call system to call the nurse when an alarm occurs
WIFI communication module	connected to HK-M1000 infusion monitoring software to look the running situation in real time

13.3 Replaceable Parts

Name	Model	Specification
Power cord	KC-015	AC250V, 16A
Lithium battery (power)	AEC124572-3S1P	11.1 V,4400mAh,48.84Wh
Lithium battery (alarm)	GSP422025	3.7V/DC,180mAh

The replacement should comply with the product standards or contact after-sales service personnel for replacement.

For all the components replaced by dismantling the shell with a tool, should be operated by authorized maintenance personnel.

XIV Open-package Inspection

Cautions for open-package inspection:

Open the box carefully to avoid artificial damage to the Infusion Pump Management unit and related parts.

Handle all items inside the package. carefully.

Please keep relevant internal , warranty card and instructions after unpacking.

Try to keep part of package box for transporting the Infusion Pump Management Unit.

In case of spare parts missing or damaged after unpacking, please contact the seller as soon as possible.

XV After-Sales Service

This device has free warranty within 1 year after purchase.

However,the following situation is not within the range of free maintenance and repair:

1) Faults caused by improper usage, unauthorized modification or maintenance.

2) Equipment injury or damage caused by improper operation in the process of handling after purchase.

3) Faults and injuries caused by fire, salt damage, poisonous gas, earthquake, wind disaster, flood disaster, abnormal voltage and other natural reasons.

For all the malfunctions and damage due to above reasons, the manufacturer can offer repair but charge for the cost.

Appendix I Information of Electromagnetic Compatibility

Note:

- 500 D Infusion Pump Management Unit meets the electromagnetic compatibility requirements of EN60601-1-2:2015+A1:2021, EN60601-2-24:2015 Clause 201.17.202. The Essential Performance of Infusion Pump Management Unit are defined as:
  1) Normal power supply to infusion/syringe pumps
  2) Accuracy of communication information with infusion/syringe pumps
  3) Consistency of alarm information gathered from the infusion/syringe pumps
- Users should install and use according to electromagnetic compatibility information provided by attached documents.
- Portable and mobile RF communication equipment may affect the performance of 500 D Infusion Pump Management Unit. When the using the device, it should avoid strong electromagnetic interference from other devices, such as mobile phones and microwave ovens.
- Refer to the annex for details of the manual and manufacturer's statement.

Warning:

- 500 D Infusion Pump Management Unit should not be closed to or stacked with other equipment when using,as it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Use of cables other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- 500 D Infusion Pump Management Unit is intended for use in professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.

List below the cables information:

No.	Cable name	Length(m)	Shield or not
1	Power cord	2.5m	No
2	Signal cable	1m	No

Guidelines and manufacturer's statements:

Guide and Manufacturer's Statement-Electromagnetic Emission		
The 500 D Infusion Pump Management Unit is expected to be used in the following specified electromagnetic environments, and the customer or user shall ensure that it is used in such electromagnetic environments:		
Emission test	Conformance	Electromagnetic Environment-Guide
RF radiation CISPR 11	Group 1	The 500 D uses RF energy only for its internal functions. Therefore, its radio frequency emission is very low, making low possibility of interference to nearby electronic equipment.
RF radiation CISPR 11	Class A	The 500 D 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 domestic purposes.
Harmonic radiation EN6100-3-2	Class A	
Voltage fluctuation /flickering emission EN 61000-3-3	Complies	

Guide and Manufacturer's Statement-Electromagnetic Immunity			
The 500 D is expected to be used in the following specified electromagnetic environments, and the customer or user shall ensure that it is used in such electromagnetic environments:			
Immunity test	EN60601 Test level	Coincidence level	Electromagnetic Environment-Guide
Electrostatic discharge EN 61000-4-2	± 8kV contact discharge ± 15kV air discharge	± 8kV contact discharge ± 15kV air discharge	The floor should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, its relative humidity should be at least 30%
Electrical fast transient pulse group EN 61000-4-4	± 2kV pair power cord ± 1kV pair of input/output lines	± 2kV pair power cord ± 1kV pair of input/output lines	The grid power supply should be of typical quality used in commercial or hospital environment
Surge EN 61000-4-5	± 1kV line to line ± 2kV line to ground	± 1kV line to line ± 2kV line to ground	The grid power supply should be of typical quality used in commercial or hospital environment
Voltage dips, short interrupt and voltage variations in power input lines EN 61000-4-11	< 5% U_T for 0.5cycles (> 95% sag on U_T) 40% U_T for 5 cycles (60% sag on U_T) 70% U_T for 25 cycles (30% sag on U_T) < 5% U_T for 5s (> 95% sag on U_T)	< 5% U_T for 0.5 cycles (> 95% sag on U_T) 40% U_T for 5 cycles (60% sag on U_T) 70% U_T for 25 cycles (30% sag on U_T) < 5% U_T for 5s (> 95% sag on U_T)	The grid power supply should be of typical quality used in commercial or hospital environment. If users of the 500 D need to operate the system continuously during the interruption of power, it is recommended that the system be powered by an uninterruptible power supply or battery.

Power frequency magnetic field (50/60 Hz) EN 61000-4-8	3A/m	3A/m, 50Hz/60Hz	The power frequency magnetic field should be of typical quality used in typical places in the commercial or hospital environment.
Note: UT refers to the AC network voltage before the test voltage is applied.			

Guide and Manufacturer's Statement-Electromagnetic Immunity

The 500 D Infusion Pump Management Unit is expected to be used in the following specified electromagnetic environments, and the customer or user shall ensure that it is used in such electromagnetic environments:

Immunity test	IEC 60601 Test level	Coincidence level	Electromagnetic Environment-Guide
Radio frequency conduction EN 61000-4-6	3 Vrms 150 kHz to 80MHz 6 Vrms in ISM and amateur radio bands	3Vrms 6Vrms	Portable and mobile RF communication equipment should not be used closer to any part of [ME equipment or ME system] (including cables) than the recommended separation distance. The distance is calculated with the formula corresponding to the transmitter frequency. Recommended isolation distance
Radio frequency radiation EN 61000-4-3	3 V/m, 10 V/m 80 MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment	3 V/m 10V/m	$d = [3.5/V_1]\sqrt{P}$ $d = [3.5/E_1]\sqrt{P}$ 80 MHz～800 MHz $d = [7/E_1]\sqrt{P}$ 800 MHz～2.5 GHz In the formula: P-Maximum rated output power of transmitter provided by the manufacturer, with the unit of watts (W);

			d-Recommended separation distance that is measured in meters (m). The field strength of the fixed RF transmitter is determined by the survey of electromagnetic field, and should be lower than the compliant level in each frequency range. Interference may occur near devices marked with the following symbols. 

Note 1: At 80MHz and 800MHz frequency points, the formula of higher frequency band is adopted.
Note 2: These guides may not be appropriate for all cases, where electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

a The field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and television broadcasts, cannot be accurately predicted in theory. To assess the electromagnetic environment of fixed RF transmitter, it is necessary to consider the survey of electromagnetic field. If the measured field strength of [ME equipment or ME system] is higher than the applicable RF compliant level mentioned above, it is advisable to observe [ME equipment or ME system] to verify its normal operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or repositioning [the ME equipment or the ME system].
b In the whole frequency range from 150kHz to 80MHz, the field strength should be lower than 3V/m.

Recommended Separation Distance between Portable and Mobile RF Communication Equipment and 500 D Infusion Pump Management Unit

The 500 D Infusion Pump Management Unit is expected to be used in electromagnetic environments where RF radiation disturbance is controlled. Depending on the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) and the 500 D Infusion Pump Management Unit recommended below.

Maximum rated output power of transmitter W	**Isolation distance corresponding to different frequencies of transmitter/m**		
	150 kHz ～ 80 MHz $d = [3.5 / V_1]\sqrt{P}$	**80 MHz ～ 800 MHz** **d** $= [3.5 / E_1]\sqrt{P}$	**800 MHz～ 2.5 GHz** **d** $= [7 / E_1]\sqrt{P}$
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 the maximum rated output power of transmitters not listed in the above table, the recommended separation distance d, which is measured in meters (m), can be determined by the formula in the frequency column of corresponding transmitter. Here P, with the unit of watts (W), is the maximum rated output power of the transmitter provided by the transmitter manufacturer.

Note 1: At 80MHz and 800MHz frequency points, the formula of higher frequency range is adopted.

Note 2: These guides may not be appropriate for all cases, where electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

Appendix II Alarm Information

Table 1 Alarm Classification and Alarm Light Color

Alarm classification	Alarm priority level	Color/frequency of warning light	Alarm signal delay
Malfunction	High	Red light/2Hz	<1s
Abnormal Battery Power	Low	The yellow light stays on	1s
AC Fail	Low	The yellow light stays on	1s
Low Battery	Low	The yellow light stays on	1s
Battery Exhaust	High	Red light/2Hz	<1s
Cascading failure	High	Red light/2Hz	<1s
Secondary controller abnormal	Low	The yellow light stays on	1s
Cascading near failure	Low	The yellow light stays on	1s

Table 2 Alarm Sound Characteristic Parameters

Alarm level	Time interval	Alarm message
High	8s±2s	White characters on a red background
Low	25s ± 2s or no repetition	White characters on a yellow-green background

Appendix III Cybersecurity

1. Wi-Fi Communication

a) User access control mechanism: use password for user identity authentication.

b) Electronic interface: Wi-Fi (IEEE 802.11)

c) Data type: Information of equipment operation (alarm signal, infusion mode, flow rate, time, amount to be infused, amount being infused)

d) Technical features: The LAN is formed by wireless Wi-Fi, and one-way data communication is carried out by Wi-Fi (IEEE 802.11 b/g/n) standard protocol through electrical port, with the modulation modes of BPSK, QPSK and QAM.

e) The operating frequency ranges from 2.412 GHz to 2.484 GHz.

f) The wireless rate is 1~11 Mbps for IEEE 802.11b, 6~54 Mbps for IEEE 802.11g, and 6.5~65 Mbps for IEEE 802.11n.

g) The transmit power is less than 20 dBm (CE requirement: detection mode-RMS).

h) For Hawk Medical's private encryption mode, the data communication with the computer is transmitted in one-way direction. The infusion pump sends data to the computer, and will not accept any instructions on infusion control sent by the computer, nor send any operation instructions to the computer.

i) Configuration of cybersecurity features: Data is unidirectionally transmitted. The related records on the device side cannot be deleted.

j) Security mechanism:

standards: WPA-PSK, WPA2-PSK; encryption: TKIP, AES.

k) Data backup and disaster recovery: The related records on the device side cannot be deleted.

l) Running environment:

Software environment: WIN7 and compatible version; Hawke Company’s Infusion Monitoring Software (HK-M1000), Software Version: V01 and compatible version;

m) Hardware environment:

CPU: Intel i3, Memory: ≧ 4 GB, Hard disk: ≧200 GB free space, Screen resolution≧: 1920*1080

n) Network environment: Network architecture: C/S; Network type: LAN; Network bandwidth: not less than 100Mbps

o) Cybersecurity feature configuration: The data transmission type is the bidirectional encrypted transmission.

p) Data backup and disaster recovery: related records on the device side cannot be deleted.

The type approval code of radio transmitting module is CMIIT ID: 2017DP1516.

2. USB Communication function

a) User access control mechanism: use password for user identity authentication

b) Electronic interface: Type-C interface

c) Data type: Information of equipment operation (alarm signal, status of equipment operation, master-slave procedure, UI picture)

d) Technical features: Data communication is conducted by USB 2.0 standard protocol through Type-C interface. Full speed: 12Mbps. Low speed: 1.2 Mbps.

e) Cybersecurity feature configuration: The data transmission type is the bidirectional encrypted transmission.

f) Data backup and disaster recovery: related records on the device side cannot be deleted.

3. Interface function of wired network

a) User access control mechanism: using password for user identity authentication

b) Electronic interface: RJ45 interface

c) Data type: Information of equipment operation (alarm signal, status of equipment operation)

d) Technical features: A LAN is formed by wired connection, and data communication is carried out by TCP protocol through RJ45 interface, with the operating speed of 10-Mbit/s and 100-Mbit/s.

e) Configuration of cybersecurity features: the type of data transmission is unidirectional encryption.

f) Data backup and disaster recovery: related records on the device side cannot be deleted.

4. Function of cascading extensions

a) User access control: The ability of the product to provide physical protection against access and use by unauthorized users.

b) Electronic interface: CAN bus interface

c) Data type: Information of equipment operation (alarm signal, status of equipment operation, pump online ID)

d) Technical features: Data communication is carried out by connecting custom protocol through CAN bus, with the data rates of up to 1Mbps.

e) Cybersecurity feature configuration: The data transmission type is the bidirectional encrypted transmission.

f) Data backup and disaster recovery: related records on the device side cannot be deleted.

Manufacturer:

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