Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to The User or Other

(ENTERAL FEEDING PUMP)

Model: HK-300

USER MANUAL

Please read the manual before using the product;
Please keep the manual for reference!

CE 0197

057-00687-00

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Revision Notes:

On the premise of comply with relevant laws and regulations, we'll revise the manual timely according to the improvement of products or update of laws and regulations.

This Manual applies to HK-300 ENTERAL FEEDING PUMP.

Version No.	Date of Preparation
V1.0.0	2025-12-22

Manual version upgrade instructions:

V X.Y.Z

V: Version for the declaration of this information for the version number information.

X: indicates a major function update, in the hardware and software, the structure of a major change, the corresponding changes in the instructions to upgrade.

Y: indicates a slight increase in class update, in order to make better use of Enteral feedingpump, and the resulting hardware and software, the structure of a small change (the assessment does not require re-registration detection), the corresponding changes in the instructions to upgrade.

Z: indicates that the corrective class is updated, the hardware and software have not changed, only in the manual to correct the text class error, or better explain the resulting changes to the upgrade. For example, text, illustrations are wrong, new illustrations, text descriptions.

1. Warnings & Cautions

Warning: Failure to follow precautions below may result in the risk of death or injury to patients.

a) The enteral feeding pump uses peristaltic mechanism for nutrition infusion, but cannot detect leakage caused by disconnection or crack of enteral feeding set. It is required to inspect the infusion status regularly to prevent above problems.

b) During infusion process, please regularly check the status of dripping as well as the residual nutrition inside the feeding bag to ensure correct performance of the infusion. The enteral feeding pump does not directly measure quantity of fluid so it may not detect certain free flow in extremely special case.

c) The enteral feeding pump is forbidden for intravenous, arterial infusion.

d) The user must install the enteral feeding set straight and properly along the peristaltic fingers from left to right. Otherwise, infusion may not reach expected performance.

e) Make sure the feeding pipe is properly installed to the peristaltic system; otherwise it may not achieve the desired performance.

f) Make sure install the feeding pipe to reach occlusion sensor, otherwise it may not give occlusion alarm correctly.

g) Fix the enteral feeding pump well to infusion stand/bar and also ensure the stability of the stand/bar. Be cautious when moving the stand/bar and the enteral feeding pump to prevent the enteral feeding pump falling off or the stand collision with surrounding objects.

h) The enteral feeding pump cannot parallel use with gravity infusion device, as the machine can't detect downstream occlusion or empty of gravity infusion set.

i) The enteral feeding pump cannot use with possible large negative or positive pressure piping such as extracorporeal circuit. As in such case, the enteral feeding pump cannot ensure infusion accuracy and correct alarm functions.

j) The enteral feeding pump cannot use for blood transfusion.

k) Please install the feeding pipe in correct direction (from left to right). If installing in a wrong direction, it will cause suck back.

l) Do not use the enteral feeding pump near inflammable liquid or gas.

m) Do not store or use the enteral feeding pump in humid environment or environment with chemically active gases (including gas for sterilization). Such environments may have impact on internal electronic parts and thus bring degradation or damage to their functions.

n) It cannot be used for ambulance.

o) Please use to meet the relevant laws and regulations, with a valid medical device registration certificate of the feeding set, or cannot guarantee the accuracy of infusion and normal detection alarm.

p)Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
q) Do not position me equipment to make it difficult to operate the disconnection device.
r) Unauthorized modifications to this equipment are not permitted,that may result in serious injury o patients.
s) Loss of power may result in unacceptable risks. The equipment must be connected to a suitable power supply.
t） The device must be connected to a certified DC power supply that conforming to IEC 60950-1/IEC 62368-1 or other relevant safety standards
when powered by DC power source.
u) To avoid the risk of electric shock, this equipment must only be connected
to a supply mains with protective earth.
w) When the power loss duration does not exceed 30s, the alarm setting before the power loss can be automatically restored.
x) The enteral feeding bag which can withstand a pressure of not less than 160kPa must be used.

Cautions: Failure to follow cautions below may lead to injury of operator/patient or loss of property.
a) Inspect the enteral feeding pump before use, making sure it can work normally. If any malfunction is found, stop operation immediately and contact the distributor or the manufacturer. Besides, adhesion or leakage of nutrition may lead to malfunction of the enteral feeding pump. Therefore please clean the enteral feeding pump and store it properly after each use.
b) When use the enteral feeding pump the first time after purchasing or after long-time of storage, please connect it to AC power source and charge it for at least 10 hours with power on, or 3 hours with power-off. If not fully recharged, the internal battery can’t support the enteral feeding pump with enough power in case of AC power failure.
c) If using near electric cautery equipment, the enteral feeding pump may result in wrong operation due to the high frequency wave of electric cautery equipment. If the enteral feeding pump has to be used with electric cautery equipment, please take proper measures as follows:
(1) Avoid using the enteral feeding pump along with old-fashioned electric cautery apparatus (open vacuum tube).
(2) The distance between enteral feeding pump and the body of electric cautery apparatus or its power source should be more than 25cm.
(3) The enteral feeding pump shall not use the same electric cabinet as that of electric cautery apparatus, and having reliable ground connection.

d) Do not use mobile phone, wireless device or cardiac defibrillator within 1 meter near the enteral feeding pump. Otherwise the high frequency noise/signal may cause wrong performance of the enteral feeding pump. Make sure the enteral feeding pump has ground connection and do not use the same power socket with that for the above-mentioned devices.
e) The enteral feeding pump cannot use in area with radiotherapy equipment or magnetic resonance (MR) equipment or hyperbaric oxygen therapy.
f) Do not use pointed object like pen-tip or finger nail etc. to press on keys of the enteral feeding pump. Otherwise, the keys or the mask may suffer premature damage.
g) Keep the feeding set, the enteral feeding pump a certain distance from the AC power source and DC socket to prevent the nutrition from splashing or dropping onto the socket to incur shortage of circuit. In addition, make sure the power plug and socket are dry before connecting to power source.
h) In normal conditions, try to use AC or DC power source to extend battery service life. When use AC power source, making sure it is well connected to ground and please use the power cord that is standard configuration with the enteral feeding pump. Just use battery when there is difficulty in ground connection or without AC power (such as AC power failure or mobile infusion).
i) Recommend to change the segment of enteral feeding set after using 6 hours. The tube may be out of shape due to long-hour squeeze by the peristaltic fingers and thus cause accuracy error. It is suggested to move to a new section (15 cm upward or downward) after every 6 hours of usage, and then start operation again. Or replace the feeding bag with a new one.
j) To prevent free flow after door open please make sure to close the flow clip of feeding bag before taking it out of the enteral feeding pump.
k) Pay more attention to occlusion when feeding at low rate. The lower the rate, the more time needed for detecting occlusion, thus there may be a long interval of infusion interruption.
l) When using computer port, it may suffer interference from devices such as electric cautery apparatus, mobile phone, wireless device or cardiac defibrillator etc. Please try to keep away from the above-mentioned devices.
m) If enteral feeding pump falling off or suffering collision, stop using it immediately and contact the distributor or the manufacturer. Even there is no damage on appearance or no malfunction alarm, the internal parts may have damaged.
n) The enteral feeding pump must be operated by or under the guidance of clinically trained and qualified technicians who have received a training related to the use of this device.
o) Do not disassembly or modify the enteral feeding pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.

p) The liquid level of the liquid supply container should be higher than that of the feeding pump by 0.5m±5cm, and infusion outside this distance will affect the infusion accuracy of the feeding pump.

2. Introduction

2.1 Features

Compact and light weight
User-friendly interface, easy parameters setting
2.8 inch colorful LCD with detailed menu
Internal multiple reliable design and alarm functions, more stable and safer infusion
Apply to vertical pole or horizontal bar
Removable pump body for easy cleaning

2.2 Intended use

Clinical operators: This user group refers to the authorized and well-trained medical personnel allowed to operate this Infusion Pump in clinical situations.
Reprocessing personnel: This user group refers to those who clean, disinfect and sterilize the Infusion Pump and its accessories.

Service personnel: This user group refers to the authorized customer service engineers who are responsible for calibrating its components, and for service or modifications to the Infusion Pump as permitted.

2.3 Type and specifications

This product belongs to class I, type CF applied part. It is a continuous operation and internal battery equipment. It cannot be carried by patient for mobile use. It can't be used in mixed gases of flammable anesthetic gas with air, or of oxygen or nitrous oxide with flammable anesthetic.

the CF applied parts are disposable feeding bag that are not included in the system.

The maximum temperature of applied part is 41.4 ℃ according to IEC60601-1 standard,and the duration of PATIENT with skin is a time ≥1min and ＜10min.

2.4 Affection on environment and energy

This product may have certain electromagnetic radiation which may influence other devices. In such case, please take proper measures to reduce the interference such as re-locating the enteral feeding pump, or using AC power from a different source.

2.5 Date of manufacture & lifespan

The lifespan of the enteral feeding pump (battery is not included) and its cable is 8 years. Please refer to label for date of manufacture.

2.6 Version of software

The version of the user manual for enteral feeding pump's software is V01.

2.7 Statement

This device is compliant with the Medical Devices Regulation 2017/745. According to this regulation, it is a class IIa device. This model carries the marking:

CE 0197

In accordance with the requirements of the Medical Device Regulation 2017/745, this device is compliant with the following standards:

No.	Standard No.	Standard Description
1	EN ISO 13485:2016+A1:2021	Medical devices – Quality management systems – Requirements for regulatory purposes
2	EN 60601-1:2006+A1:2013 +A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3	EN 60601-1-8:2007+A1:2013 +A2:2021	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical
4	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
5	EN 60601-1-6:2010+A1:2015 +A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability
6	EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices

7	EN 60601-2-24:2015	Medical electrical equipment - Part2-24: Particular requirements for the safety of infusion pumps and controllers
8	EN 62304:2006+A1:2015	Medical device software-Software life cycle processes
9	EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
10	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
11	EN ISO 20417:2021	Information supplied by the manufacturer with medical devices
12	EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
13	EN IEC 81001-5-1:2022	Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
14	ISTA 2A:2011	Packaged-Products 150 lb (68 kg) or Less
15	EN IEC 62506:2023	Methods for Product Accelerated Testing

3. Components and principles of operation

3.1 Components

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3.2 Software information

Software name: HK-300 enteral feeding pump software

Software release version: V01

3.3 Principles of operation

This enteral feeding pump is driven by the motor to squeeze the feeding tube by the Pump Piece Type peristaltic squeezing structure, which generates positive pressure to make the nutrition liquid in the feeding tube flow in a directional manner; various feeding parameters can be set by the soft key, and the purpose of fixed speed and quantitative feeding can be achieved under the precise control of the software. During the operation, various sensors monitor the feeding process in real time and provide corresponding sound and light alarm signals.

4. Technical and specifications

Infusion accuracy	±10%
Applicable enteral feeding set	Any brands of enteral feeding set with diameter: 3.4~4.5mm
Flow rate range	1-400ml/h increment selectable: 1ml/h, 10ml/h or 100ml/h
Volume to be infused (VTBI)	1-9999ml,or 0 (no limit on VTBI) increment selectable: 1ml, 10ml, 100ml or 1000ml
Volume infused	0.0-36000ml
Alarm functions	Visual and audible alarms: Door open, Occlusion, Infusion completion, Empty, No operate, Low Battery, Battery exhausted, malfunction etc.
Bolus rate	Bolus rate range (1 - 400) ml/h increment selectable: 1ml/h, 10ml/h or 100ml/h Bolus volume range (1-100) ml increment selectable: 1ml, 10ml or 100ml Bolus feeding accuracy: ±10%
Purge rate	Purge rate: 1-400ml/h Default: 400ml/h Purge VTBI: 0-9999ml
Occlusion pressure	40-160kpa; 3 levels (adjustable): low, middle, high; default: middle
Single fault infusion volume	≤0.5ml
RS-232 port (optional)	RS-232 port enables user to check infusion/alarm record in computer terminal.
Protection level	IP24
AC power	100V-240V ~ 50Hz/60Hz
Maximum feeding pressure	160kPa
Battery	Lithium Polymer 7.4V 1900mAh. Recharge time: 10h with power on, 3h with power off. Running time: more than 3h at rate of 25ml/h, environment temperature 25℃ after being fully charged.

Fuse	Slow Fuse, specifications: 250V 2A
Power consumption	35VA
DC	DC 12V ±1.2V 1.5A Note: It cannot be used for ambulance directly. Should work with voltage stabilizer
Operating conditions	Environment temperature 5℃～40℃ Relative humidity: 10%-95%RH Air pressure: 86kPa～106kPa
Dimensions	145(L)x 120(H)x 100(W, not including pole clamp)mm
Net weight	≤1.4kg

5. Installation

5.1 Installation conditions and technical requirements

The enteral feeding pump can be fixed to a vertical IV pole or horizontal bar with diameter of 12-35mm, or on platform with slope angle not exceeding 5°.

5.2 Installation method and cautions

If the pole clamp is in the same direction with that of IV stand or bar, rotate 90°to suit the direction of the IV stand or bar.

When fixing the pole clamp to IV stand or bar, use the other hand to hold the enteral feeding pump until the clamp is well fixed.

6. External Features

6.1 Front panel (Diagram 1)

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6.2 Rear panel (Diagram 2)

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6.3 Label

6.3.1 Product label (on the back shell)

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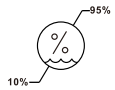
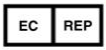
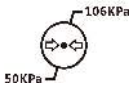
6.3.2 Symbols and significance

(Table 1)

Symbols	Descriptions
	Batch code
	Serial number
	Prohibition
	Please refer to manual
	Type CF applied part
	Protective earth; protective ground
IP24	The device against ingress of solid foreign objects ≥12.5mm diameter and splashing water
	Alternating current
	Direct current
	Battery and waste electrical and electronic device must be disposed of in accordance with the locally applicable regulations, not
	Date of manufacture and Country of manufacture, CN: China
	Manufacturer
	Wireless transceiver

	Keep away from rain
	Fragile; handle with care
	This way up
	Stacking limit by number
	Humidity limitation
	Temperature limit
	EU Authorised representative
	This device is provided with a CE marking in accordance with the regulation 2017/745. 0197 is the Notified Body
	Medical device
	Model number
	Audio paused
	Atmospheric pressure limitation

	Unique device identifier
	EU Importer
	EU distributor

7. Preparation and inspection

Whether the enteral feeding pump is a new one, or it has been stored for a period of time, or it just has been repaired, please check the following terms before use:

(1) The outlook remains good, clean, no crack and no leakage.

(2) All keys are responsive. No invalid key or stuck key.

(3) The door opens agilely and can be closed tight.

(4) The power cord can be plugged in tight, not easy to loose.

(5) If enteral feeding pump worked on internal battery only, charge it fully before use and also make sure the battery is still valid for use.

(6) In addition to the enteral feeding pump built-in brand feeding sets, the user before using other feeding sets, must be calibrated before use.

(7)The enteral feeding pump has occlusion detection function. It gives occlusion alarm when the infusion set is blocked that produce under-infusion.

(8) The enteral feeding pump has malfunction detection function. It gives high priority alarm when the pump is fault that produce over-infusion.

(9) When the door of the feeding pump opens and closes normally, the liquid-stop clamp can be raised and dropped to prevent free flow; after the infusion set is installed and the door is closed, the clamp can prevent free flow; and when the door is opened, the clamp can be dropped to prevent free flow.

(10)The feeding pump should be placed within 0.5 meters above or below the patient's heart level.

8. Operation Method

8.1 Operation

The whole infusion operation contains the following processes:

1) Fix the enteral feeding pump and connect it to AC power.
2) Switch on / off
3) Fill the feeding bag with nutrition and install it in the enteral feeding pump
4) Set infusion parameters
5) Purge the air in line
6) Clear Σ (volume infused)
7) Start infusion
8) Bolus infusion
9) Stop infusion
10) Infusion completion
11) Replace feeding bag

8.1.1 Adjust the pole clamp to fix the enteral feeding pump properly to a stand/bar/cage and connect it to AC/DC power. The AC/DC indicator light (on upper left corner) shall be on.

8.1.2 Switch on/off.

Press POWER key until LCD displaying to turn on the machine.

Press POWER key for about 2 seconds to turn off the machine.

8.1.3 Fill the feeding bag and install the feeding bag properly.

(1) Put the flow clip downstream of the enteral feeding pump and close the flow clip tight. Put nutrition into feeding bag, and then squeeze the drip chamber to fill with 1/2 of nutrition. Open the flow clip and let the nutrition flow to the tip of the needle. Then close the flow clip again.

(2) Install the feeding bag

Press door lock and the door shall pop open. Upward the anti-free flow clamp and place it at top of right side plastic block. Then pull the feeding bag straight and install it in correct direction as shown in Diagram 1 (from left to right), making sure the feeding bag is properly inserted in all positions from ① to ⑦. Press the door to close it (A 'click' sound indicates the door is well closed).

When use new brand of feeding set, it should make calibration on the device. For details, please refer to 8.3.7 Calibration.

8.1.4 Set infusion parameters

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8.1.5 Purge

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8.1.6 Clear the volume infused

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8.1.7 Start infusion

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8.1.8 Bolus infusion

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8.1.9 Stop infusion

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8.1.10 Infusion completion

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8.1.11 Replace the feeding bag

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8.2 Alarms and solutions

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8.3 Parameters Setting and Accuracy Calibration

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9. Malfunction Analysis and Solutions

Problems	Causes	Solutions
Accuracy discrepancy	The feeding bag is not calibrated.	Calibrate the accuracy of feeding bag
	The feeding bag currently used does not match the default brand.	Select the correct brand of feeding bag.
	Due to variation in weather and temperature, the internal parameters of the pump incompatible with that of the feeding bag actually used.	Re-calibrate the accuracy of feeding bag.
	Certain parts of the machine may be defective.	Contact distributor or manufacturer for repair

Beside the problems mentioned in 8.2, please contact the sales agent / manufacturer for repair.

10. Safety Invention and Troubleshooting

10.1 Safety Invention and precautions

(1) AC power: built-in double fuses. When short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.

(2) DC input: built-in fuse. When short circuit or any other malfunction occurs, the fuse shall cut off circuit in advance.

(3) Battery protection. The battery contains protective devices against excessive pressure, over heat or short circuit, etc. to avoid overheating or burnt.

10.2 Troubleshooting

(1) If the enteral feeding pump gives system error alarm, stop the operation and contact the sales agent for repair. It can be used again only after it is well repaired and tested. enteral feeding pump working with malfunctions may incur unpredictable damage.

(2) If the enteral feeding pump caught fire or displays any other malfunction, please disconnect the power immediately and contact the sales agent /manufacturer.

11. Maintenance, Inspection, repair and recycling

11.1 Routine maintenance

Daily maintenance includes the cleaning of outer shell and pump body. Clean it with wet soft cloth and natural drying. Do not use solvents like xylene or acetone or other similar solvents which may corrode the infusion pump.

Disinfect the infusion pump according to your hospital's disinfection protocols. Should cleaning pump before disinfection. Follow the manufacturer's instructions for diluting and using the disinfectant. The recommended disinfectant is: Ethanol 75%.

Disinfection steps：

1. Using a soft cloth, dip it in an appropriate amount of water or 75% ethanol and squeeze it dry

2. Wipe the display screen.

3. Wipe the surface of the pump or accessories, taking care to avoid interfaces and metal parts.

4. Using dry cloth to wipe off the cleaning agent on the pump or accessory surface, and air it dry in a cool, ventilated environment.

Note: To avoid damage to the pump or accessories by improper disinfection, please disinfect them only when necessary according to your hospital's system

11.2 Maintenance during operation

Please do not service or maintain the enteral feeding pump while in use with a patient.

11.3 Periodic Inspection

11.3.1 Inspect anti-free flow clamp (once every 2 months)

Check if the anti-free flow clamp can stop the free flow effectively.

(1) Install feeding bag on the enteral feeding pump. Close the door and open the flow clip of feeding bag.

(2) Keep pressing BOLUS key until liquid drops from the tip of needle.

(3) Open the pump door.

(4) Observe and confirm no liquid drips from the needle and no liquid drops into drip chamber.

11.3.2 Check the alarm function of occlusion sensor (once every 2 months)

Check if the Occlusion alarm is given within 2-10 seconds.

(1) The testing conditions: The enteral feeding pump should be 20cm away from the flow clip of feeding bag and 30cm away from the filter, flow rate at 150 ml/h, volume to be infused as 200ml, and occlusion level as middle.

(2) Install feeding bag in the enteral feeding pump. Close the door and open the flow clip of feeding bag.

(3) Upon pressing START key, use a stopwatch to measure the time taken for occlusion alarm.

11.3.3 Inspect delivery accuracy (once every 2 months)

The enteral feeding pump built in mechanism driving system which may suffer abrasion during usage. Frequently use of the machine and variation on temperature may cause accuracy error. It requires check infusion accuracy periodically.

(1) Install feeding bag in the enteral feeding pump. Close the door and open the flow clip of feeding bag.

(2) Calibrate the accuracy as per instructions of 8.3.6.

(3) After calibration, setting flow rate at 150ml/h and volume to be infused as 10ml to test delivery accuracy. The delivery accuracy should be about ±10%.

11.3.4 Inspect internal battery

The battery shall reduce the performance due to prolonged usage, please check the battery capacity every other month.

(1) First recharge the battery fully (10 hours with power on, or 3 hours with power off).

(2) Let enteral feeding pump work on battery only and set flow rate at 25ml/h. Record the whole working time when the battery is exhausted.

---If infusion time more than 90 minutes, the battery is in good condition.

---If Infusion time more than 45 minutes but less than 90 minutes, the battery starts low quality but still can be used.

---If infusion time less than 45 minutes, the battery reaches the end of its life and needs to be replaced.

Replace internal battery
(1) Unscrew the screws at the bottom of machine; remove the battery cover.
(2) Unplug the battery cable and take out the battery.
(3) Install the new battery. Please make sure the battery cable won't be squeezed by the battery
Cover. Then install battery cover. After replacing new battery, please check its working condition.

11.4 Normal repair procedures

The repair job should be performed by supplier or distributor. It needs to make a complete inspection on machine after maintenance. If necessary, contact the manufacturer for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.

11.5 Maintenance for long-time storage

If the enteral feeding pump will not be used for long time, it should be placed in packing carton and avoid direct sunlight and keep it in cool and dry place. Refer to 13.2 for detailed storage conditions.
When using an enteral feeding pump of long time storage, please refer to following steps before use:
(1) Calibrate the enteral feeding pump to ensure infusion accuracy and avoid possible medical accident.
(2) Test occlusion alarm.
(3) Test the working time and recharging time of battery to ensure the battery can still be used.

11.6 Recycling

The machines and its cable which have been used over its lifespan should be scrapped. For more information, please contact manufacturer or our distributors. (Whether it is used frequently or not and whether it is repaired properly or not will impact enteral feeding pump's lifespan.)
(1) The scrapped enteral feeding pump can be sent back to manufacturer or distributor.
(2) The used battery can be sent back to manufacturer or distributor, or can be scrapped according to legally proper way.

12. Electromagnetic Compatibility declaration

Warning:

- Enteral feeding pump should not be used in proximity or in stack with other devices, and if it must be used in proximity or in stack, it should be observed and verified to operate normally in the configuration used;
- Except for cables sold by the manufacturer of enteral feeding pump as spare parts for internal components, the use of accessories and cables other than specified may result in increased emission or reduced disturbance immunity of enteral feeding pump.

Caution:

- Enteral feeding pump meets the electromagnetic compatibility requirements of IEC60601-1-2 Clause 201.17.202. The Essential Performance of devices are defined as:

1) Feeding accuracy: ±5%
2) Bolus feeding accuracy: ±10%
3) Protection against unintended bolus volumes and occlusion
4) Correct Alarm signal of high-priority

- User should install and use according to the Electromagnetic Compatibility information provided by random file.
- Portable and mobile RF communication equipment may affect the performance of enteral feeding pump, please avoid strong electromagnetic interference during usage, such as near mobile phone, microwave oven, etc.

Please see enclosed Guideline and manufacturer’s statement

Guidance and manufacture’s declaration – electromagnetic emission		
The enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer of the user of the Enteral feeding pump should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Enteral feeding pump use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Enteral feeding pump is suitable for

Harmonic emissions IEC 61000-3-2	Class A	use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
Guidance & Declaration — electromagnetic immunity			
The Enteral Feeding Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Enteral Feeding Pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2kV, ±4kV, ±6kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2kV, ±4kV, ±6kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5kV,±1kV,±2kV Line to ground	±0.5 kV, ±1 kV line to line ±0.5kV,±1kV,±2kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT	Mains power quality should be that of a typical commercial or

power supply input lines IEC 61000-4-11.	(>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	(>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	hospital environment. If the user of the Enteral Feeding Pump require continued operation during power mains interruptions, it is recommended that the Enteral Feeding Pump be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m Power	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			
Guidance and manufacture's declaration – electromagnetic immunity			
The Enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of Enteral feeding pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	385MHz-5785MHz Test specifications for ENCLOSURE PORT

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)	IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1:2020)

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Enteral feeding pump is used exceeds the applicable RE compliance level above the Enteral feeding pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Enteral feeding pump.

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

13. Transport and storage

13.1 Precautions during transport

(1) Place the product as per No. of layers indicated on packing carton.

(2) Temperature: -20℃～55℃;

(3) Relative humidity: 10%～95%RH

(4) Atmosphere pressure: 50.0kPa～106.0kPa

13.2 Storage conditions

Storage temperature: -20℃～+55℃(With battery);

-20℃～+60℃(Without battery)

Relative humidity: 10～95% (no frosting)

Atmosphere pressure: 50.0kPa～106.0kPa

14. Package list

14.1Standard configuration in a package:

① Enteral feeding pump 1 unit

② AC power cord 1 set

③ User Manual 1 pcs

④ Warranty card 1 pcs

⑤ Product qualification certificate 1 pcs

14.2 Replaceable Parts

Name	Model	Specification
Power cable	KC-015	AC250V, 16A
Lithium battery (power)	AEC903466	7.4Vdc,1900mAh

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.

15. Open-package Inspection

Cautions for Open-package inspection:

(1) Opening the packing carton carefully to avoid damaging the machine or its accessories.

(2) Handle with care all items inside the package.

(3) Keep all accessories, warranty card and User Manual well for future use and reference.

(4) Keep some packing cartons in case of using them to deliver defective machines.

(5) If there is any accessory lacking or damaged, please contact the supplier at the earliest.

16. After sales service

The warranty for the enteral feeding pump is one (1) year.

Note: The following situation is not within the range of free maintenance and repair

(1) Malfunctions resulting from improper operation, or modification / repair of the enteral feeding pump without supplier's knowledge and permission

(2) Bruise or damage caused by improper handling during transport.

(3) Malfunction or damage caused by fire, salt, poisonous gas, earthquake, hurricane, flood, abnormal electric voltage or any other natural disaster.

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

After-sales service provider:

Shenzhen Hawk Medical Instrument Co. ,Ltd.

1st-5th Floor, Building C, Jianyetai Industrial Zone, No.11 Minhuan Road, Fukang Community, Longhua Street, Longhua District, Shenzhen,518109 Guangdong, P.R.China

Tel.: 0086 755-83151901

Fax: 0086 755-83151906

Email: szhk@hawkmedical.cn

Website: http://www.hawkmed.com.cn

Annex 1

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light
System error alarm	High priority	Red/ 2Hz
Door Open alarm	High priority	Red/ 2Hz
Occlusion alarm	High priority	Red/ 2Hz
Low Battery alarm	High priority	Red/ 2Hz
B. Exhaust alarm	High priority	Red/ 2Hz
Finished alarm	High priority	Red/ 2Hz
Empty	High priority	Red/ 2Hz
Almost Done alarm	Low priority	Yellow,steady
AC Fail alarm	Low priority	Yellow,steady
Use Battery alarm	Low priority	Yellow,steady
No Operate alarm	Low priority	Yellow,steady

Table 2 Alarm conditions and alarm signal delay

Names of alarms	Alarm condition delay	Alarm signal delay
System error alarm	10ms	100ms
Door Open alarm	10ms	100ms
Occlusion alarm	840s@1ml/h, 27s@25ml/h	100ms
Low Battery alarm	10ms	100ms
B. Exhaust alarm	500ms	100ms
Almost Done alarm	10ms	200ms
Finished alarm	10ms	100ms
empty	72s@25 ml/h	100ms
AC Fail alarm	10ms	200ms
Use Battery alarm	10ms	200ms
No Operate alarm	120 ms	200ms

Table 3 Characteristic parameters of alarm signals

Alarm level	Intervals	Alarm information
High	8s±2s	Black on red
Low	25s±2s or no repeating	Black on yellow

Note: Only the three alarms "No Operate", "Almost Done" and "Low Battery" sound three tones at intervals of 25s±2s, all other Low Priority alarms sound one tone and are not repeated.

Table 4 Occlusion response characteristic

Flow Rate (ml/h)	OCCL alarm level	Occlusion pressure(Kpa)	OCCLUSION alarm time	Dosage (ml)
1	Low	70	0h52min11sec	0.26
	Middle	93	1h9min16sec	0.39
	High	137	1h32min1sec	0.45
25	Low	61	0h1min45sec	0.26
	Middle	97	0h2min29sec	0.42
	High	147	0h3min34sec	0.50

★ The above test uses ‘Greatcare’ brand of feeding set. All the data are obtained by following conditions:
The flow clip of feeding bag is 20cm away from the enteral feeding pump; the filter 30cm away from the enteral feeding pump; two operations at rate of 1ml/h and 25ml/h respectively.

Annex 2- Accuracy curve

Considering the operation principle and clinical use of enteral feeding pump, 100ml/h is used to replace the minimum infusion rate and intermediate rate during the test.

★Note:

Feeding accuracy may be affected by the environment in which the device is used (pressure, temperature, humidity, brand of feeding tube used, concentration of nutrient solution, etc.)

Feeding accuracy does not reflect clinical criteria such as patient age, weight or medications used.

The following experimental data only represent laboratory data.

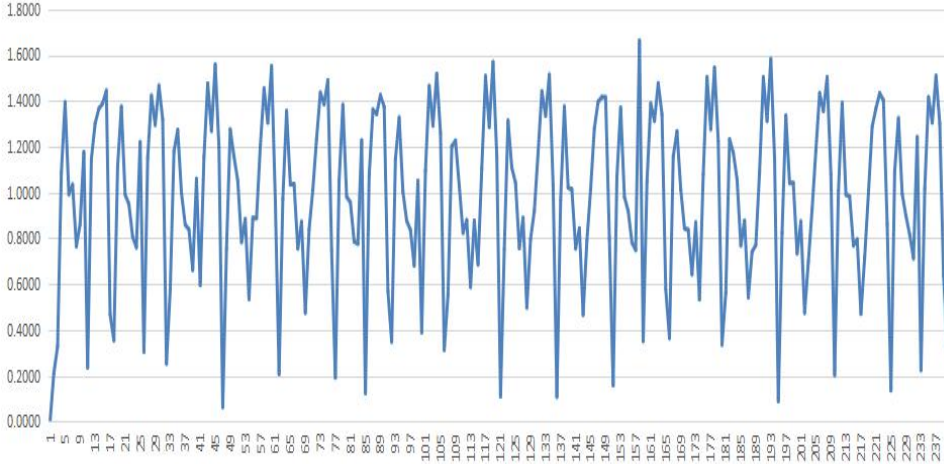
The following data test conditions:

Pump Sampling qty: 3 samples.

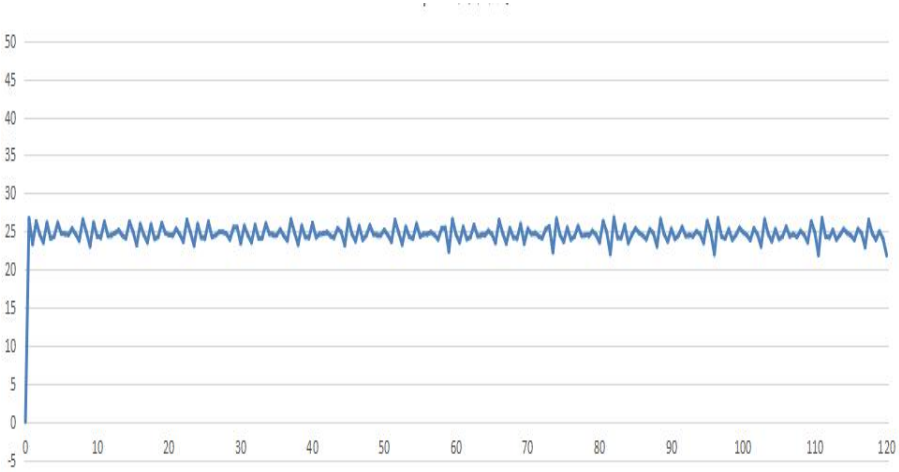
Feeding set Brand and Model: Jiangxi Hawk enteral feeding set.

Use continuous feeding mode.

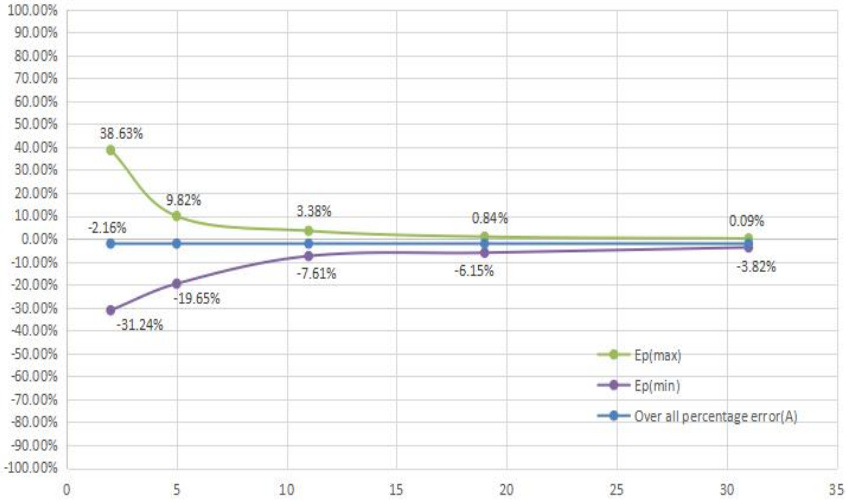
The experimental sampling time is 0.5min, the test period is 8h, and the test temperature is 25±2°C.



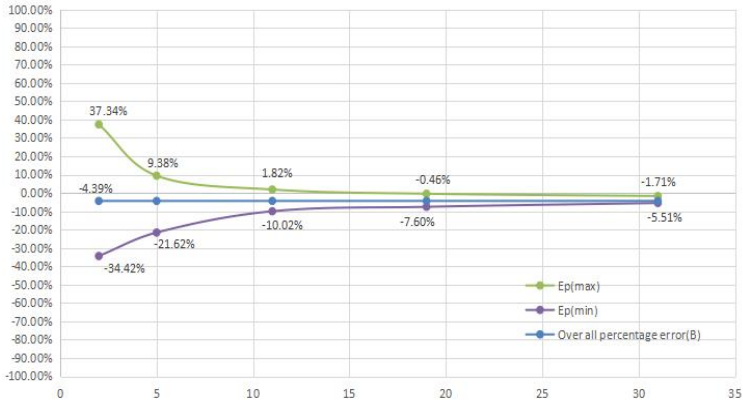
1ml/h Start-up Curve



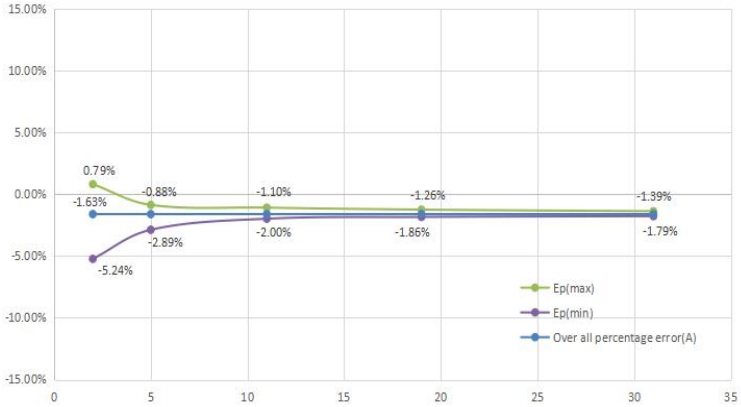
25ml/h Starting Curves



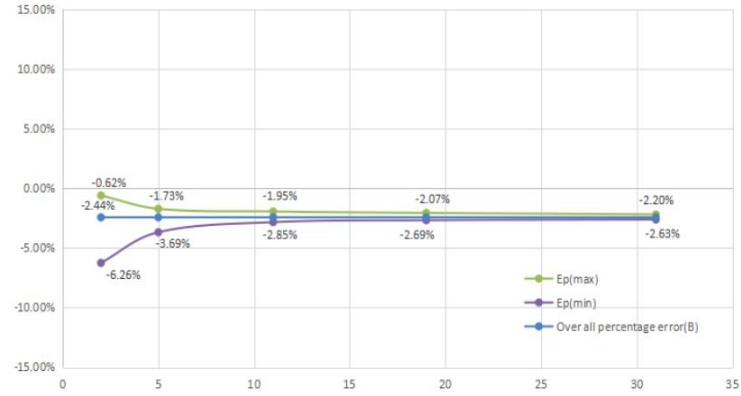
The 2nd hour Trumpet Curve at 1ml/h



The last hour Trumpet Curve at 1ml/h



The 2nd hour Trumpet Curve at 25ml/h



The last hour Trumpet Curve at 25ml/h

Appendix II Cybersecurity

Table 1 Serial communication

Data type	Equipment operation information
User access control mechanism	Press the key combination to enter system settings.
Electronic interface	serial port
Technical features	A personal area network is formed by connecting with a wired serial port line, and the RS232 standard protocol is used for one-way data communication through the electrical port. Communication interface configuration: 115200, the sending character is ASCII code.
Network security feature configuration	Data transmission type is one-way transmission; Device-side related records cannot be deleted.
Data backup and disaster recovery	The related records of the device cannot be deleted.
Operating environment	WIN7 and compatible versions; MobaXterm, software version: V21.2 and compatible versions; USB to serial driver CH340, software version: 3.5.2019.1 and compatible versions; Computers must comply with IEC 62368-1.
Security software	None
External software environment	Not applicable
Security software update	Not applicable
Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	Universal serial port protocol

Table 2 Wi-Fi communication

Data type	Equipment operation information
User access control mechanism	Press the key combination to enter system settings.
Electronic interface	Wi-Fi (IEEE 802.11)
Technical features	A local area network (LAN) is formed through wireless Wi-Fi, and Wi-Fi (IEEE 802.11b/g/n) standard protocol is used for one-way data communication. The modulation modes are BPSK, QPSK, QAM. The operating frequency range is 2.412GHz to 2.484GHz. The wireless rate is IEEE 802.11b: 1 to 11 Mbps, IEEE 802.11g: 6 to 54 Mbps, IEEE 802.11n: 6.5 to 65 Mbps. The transmit power is < 20 dBm (CE requirement: detection mode – RMS). Hawk Medical's private encryption method, the communication with the computer is a one-way data transmission, the infusion pump sends data to the computer, it will not accept any infusion control instructions sent by the computer, and will not send any operation instructions to the computer.
Network security feature configuration	The data transmission type is one-way transmission; related records on the device side cannot be deleted.
Data backup and disaster recovery	The relevant records on the device side cannot be deleted
Operating environment	Software environment: WIN7 and compatible versions; Hawkmed infusion monitoring software (HK-M1000), software version: V01 and compatible versions; Hardware environment: CPU: Intel i3, memory: ≧4GB, hard disk: ≧200GB free space, screen resolution≧: 1920*1080 Network environment: Network architecture: C/S; Network type: LAN; Network bandwidth: not less than 100Mbps
Security software	None
External software environment	Not applicable
Security software update	Not applicable
Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	WIFI 802.11b/g/n

Table 3 Software upgrade

Data type	Device data
User access control mechanism	After shutdown, enter upgrade mode via the adapter board.
Electronic Interface	Universal Serial Interface
Technical features	Software upgrade
Network security feature configuration	The data transmission type is one-way transmission; related records on the device side cannot be deleted.
Data backup and disaster recovery	Device-side related records cannot be deleted
Operating environment	None
Security software	None
External software environment	Not applicable
Security software update	Not applicable
Off-the-shelf software	None
Off-the-shelf software list	Not applicable
Communication protocol	Serial Port Protocol

IT Network Instructions

1. IT Network-Related Risks

During data transmission between the infusion pump and a computer, the following risks may arise:

(1) Malfunction of PC-side software: The downloaded software on the PC may fail to operate correctly.

(2) Unauthorized physical access to embedded software: Risk of data leakage due to illegal tampering with embedded software.

(3) Data interception or tampering during transmission: Third parties may intercept or alter transmitted data.

Corresponding control measures for the above risks are as follows:

(1) Install firewalls and antivirus software on the PC.

(2) Restrict data access: Data retrieval must be performed exclusively by internal professional technicians. Software maintenance must be conducted only by authorized personnel to prevent unauthorized access or data loss.

(3) Implement data validation: Add checksum fields to verify data integrity. If checksum validation fails, discard corrupted data and request retransmission.

When performing data export or software updates , the above risks must be identified, analyzed, evaluated, and mitigated with appropriate control measures.

2. IT Network Update Instructions

The infusion pump software does not support remote network updates. If software-related security risks emerge during use, system security measures may be upgraded upon request by users or maintenance personnel.

The following table describes potential IT network changes, root causes, and mitigation measures:

Change Item	Root Cause Analysis	Mitigation Measures
IT network configuration changes	Security software is uninstalled or real-time protection is disabled; data transmitted to the pump may be tampered with; incompatibility between new drivers/firmware and existing hardware/software in test environments.	Verify security software configuration and activation before connecting the pump to the PC. Validate compatibility between devices and the Central Infusion Management System.
Addition of new IT network connections	Connecting the PC to external networks may expose infusion pump data or control commands to broader network environments.	Ensure the PC is not connected to external networks. Use dedicated or validated PCs for data transmission.
Disconnection of IT network items	Incomplete cables, loose interfaces, failed software upgrades, or incomplete data exports; unstable Wi-Fi due to distance from the router or router malfunctions.	Inspect cable integrity and interface connections. Verify connectivity between the pump and the Central Infusion Management System or router functionality.
Updates to IT network-connected devices	Software upgrade tools or data export tools may fail to operate on updated devices.	Ensure compatibility of upgrade and data export tools with updated devices.
Upgrades to IT network-connected devices	Incorrect PC OS installation or missing security software may lead to tool malfunctions or data tampering.	Install a validated Windows OS and the latest security software on the PC.

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