Shenzhen Hawk Medical Instrument Co., Ltd.

Safety and Performance Information Relevant to The User or Other

(Enteral Feeding Pump)

Model: N300-H

Please read the manual before installing and using the product;

Please keep it for future reference!

CE 0197

057-00647-01

Contents

Revision notes of this Manual

This Manual may be subject to revision based on product improvement or update of laws and regulations on the premise of conformity to relevant laws and regulations.

This manual is applicable to N300-H enteral feeding pump.

Document No.	Revision	Revision date
057-00647-00	V1.0.0	10-06-2025
057-00647-01	V1.0.1	10-11-2025

Manual version upgrade notes:

V X.Y.Z

V: means version, stating the version number of the information.

X: indicates the major function update that corresponds to change or upgrade of the Manual in case of a major change of software, hardware or structure.

Y: indicates a slight enhancement update that corresponds to an update of the specification in case of a minor change in hardware, software, or structure to better use the enteral feeding pump (no need to re-register the test after evaluation).

Z: indicates the corrective update to correct text errors or better describe the change or upgrade in the Manual without any changes to software and hardware. For example, text, illustrations correction, new illustrations, text descriptions.

1. Warnings and cautions

Warnings

Warnings of operations that, if not followed correctly, may result in risk of personal injury or death.

a) The enteral feeding pump uses peristaltic rotor mechanism for nutrition feeding, but the leakage caused by the disconnection or rupture of the feeding set cannot be detected. Therefore, regular checks are necessary to ensure that the above-mentioned faults do not occur during the operation.

b) The enteral feeding pump must neither be used for arterial or intravenous infusion nor for an infusion of air

c) The user should ensure that the feeding set is embedded into the tube tank when installing the feeding set. Otherwise, the expected performance may not be achieved.

d) Please confirm that the feeding set is placed directly into the tube slot blocking the detector. In the case of not properly placed, the above alarm cannot be correctly issued.

e) It is recommended to install the flow clip of the feeding set in the downstream of the enteral feeding pump for use.

f) The enteral feeding pump should be firmly fixed to the infusion stand, and the stability of the infusion stand should be ensured. When moving the infusion stand and the enteral feeding pump, please be careful to prevent the enteral feeding pump slipping, the infusion stand falling or colliding with nearby objects.

g) The enteral feeding pump should not be used in parallel with the gravity infusion device, because the enteral feeding pump cannot detect the obstruction downstream of the joint or the liquid emptying in the gravity infusion line.

h) The enteral feeding pump should not be used in tube lines with excessive negative or positive pressure, such as in extracorporeal circulation circuit. Because in this case, enteral feeding pump cannot ensure the flow accuracy and alarm function of the normal.

i) This enteral feeding pump should not be used for blood transfusion.

j) Please install the feeding set correctly according to the direction indicated by the enteral feeding pump, otherwise it will be inhaled back.

k) The enteral feeding pump should not be used near flammable liquids or gases.

l) The enteral feeding pump should not be stored or used in an environment with chemically active gases (including the gases used for disinfection) or in a humid environment. This kind of environment will affect the internal device of enteral feeding pump and may cause the performance degradation or damage of internal device.

m) The enteral feeding pump cannot be directly powered by on-board power supply. If the on-board power supply is needed, a voltage regulator or inverter conforming to the safety requirements must be installed to turn the on-board output into a stable voltage meeting the input requirements of enteral feeding pump before it can be used. Otherwise, the enteral feeding pump may be damaged.

n) Do not rely solely on the alarm system. Medical personnel should make rounds and check on the process regularly.

o) Please use the feeding set that meets the requirements of this manual, otherwise feeding accuracy and normal detection alarm cannot be guaranteed.

p) This device is designed to minimize the effects of uncontrolled electromagnetic interference and other types of interference from external sources. Avoid use of other equipment that may cause erratic operation or degradation in the performance of this device.

q) Pay close attention to the patient's status. If vomiting, abdominal distension, diarrhea, abdominal pain, coughing, and changes in breathing patterns occur, they should be dealt with in time.

r) This enteral feeding pump was designed to meet IEC 60601-1 safety standards. For clarification, purposes, the feeding set is considered an Applied Part and has been tested and evaluated accordingly.

s) Restrict the access of other devices network/data couplings or non-specified forming parts other than the Infusion Monitoring System HK-M1000 through specific software protocols.

t) The pump is susceptible to interference with magnetic field generated by the MRI, CT, with HF Surgical Equipment. Use the device within a MRI environment is unexpected and unavoidable. Keep a safe distance from the magnetice field outside the area marked with “Controlled access area” or MDR symbol. The safe distance should be established in accordance with the Appendix 2 Information of Electromagnetic Compatibility (EMC).

u) The battery should be changed by Service personnel using a tool. If non-special accessories are used or unauthorized modified, it will cause malfunctions such as equipment unrecognition, accuracy, and alarm

v) 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.

w) Lay users should be instructed to contact manufacturer or the distributor if there is a change in the performance of the pump. Additionally, Lay Operators should be instructed on proper cleaning procedures to avoid hazards such as electric shock. Lay users should also be trained on inappropriate environments for use (e.g., bathtub) of the pump. For guidance on training, please contact manufacturer or the distributor.

x) Use only commercially available pre-packed or commercially prepared feeding solutions prescribed by a licensed health care provider, dietitian or nutritionist. Do not use homemade blenderized or liquidised foods or other non-prescribed, non-commercially available feeding solutions.

y) It is recommended not to use it under strong direct sunlight for a long time.

z) Avoid using accessories, detachable parts and materials with the pump that are not recommended in this manual.

Cautions

Operations that, if not followed correctly, may result in personal injury or property damage.

a) Please check before use to ensure the normal operation of the enteral feeding pump. In case of something abnormal, stop the operation immediately and contact our customer service. In addition, the adhesion or invasion of nutrient fluid may cause the breakdown of enteral feeding pump and misoperation. Therefore, clean the device and store properly after use.

b) Before the first use of the product, or after a long period of not using it, the enteral feeding pump should be connected to the external power supply and charged for at least 12 hours when it is turned on (at least 7 hours when it is turned off). In the case of insufficient charging, the enteral feeding pump cannot continue to operate with the power provided by the internal battery when the power is cut off.

c) When used near electric cauterization equipment, the enteral feeding pump may misoperate due to the influence of high frequency clutter of electric cauterization equipment. The following steps and measures should be adopted if it is used together with the medical electric burning device:

(1) Do not use together with old type (vacuum opening type) electric burning device.

(2) The distance between the power adapter of the electric cauterization equipment or its main body and the enteral feeding pump should be kept at least 25 centimeters.

(3) The power adapters of electric cauterization equipment and enteral feeding pump should be introduced from different distribution cabinets and should be reliably grounded.

d) Mobile phones, wireless devices and defibrillators should not be used in the vicinity (within one meter) of the enteral feeding pump. Otherwise, the high frequency noise signal in the communication may cause the enteral feeding pump to misoperate. Please make sure the enteral feeding pump is grounded, and do not use the above equipment to power the enteral feeding pump using a power outlet.

e) Do not place the product in areas having radiological apparatus or resonance devices or use it in places with high-pressure oxygen therapy.

f) Do not press the operation keys with sharp objects (such as pen point and nail) to protect the keys or film.

g) The power supply adaptor is means of electrically isolating its circuits from main supply. Please keep the feeding bag, feeding set and enteral feeding pump at a certain distance from the AC and DC power socket to avoid the short circuit fault caused by spatter or dripping of nutrient fluid into the socket. Also, make sure the power plug or socket remains dry before the enteral feeding pump is connected to the power supply.

h) In general, please try to use external power supply, which may extend the service life of the battery to a certain extent. When using a external power supply, please make sure that the grounding wire of the power supply is well grounded and use only the power adapter attached to the enteral feeding pump. The built-in battery is used as auxiliary power only in the case that the external power supply cannot be reliably grounded and the external power supply cannot be used normally (during power failure or mobile feeding).

i) Do not keep using the feeding set for more than 24 hours. When used for a long time, the feeding set will be deformed and lead to flow error. It is recommended to recalibrate after replacing a new feeding set.

j) The clamping device of the feeding set must be closed and tightened before the feeding set is taken out, to avoid free flow of nutrient fluid.

k) In the case of low flow feeding, special attention should be paid to the occurrence of obstruction. The lower the feeding rate is, the longer the occlusion is detected, and the longer the feeding interruption is likely to occur.

l) Keep computer interfaces away from electric burning device, mobile phone, wireless device and cardiac defibrillator to prevent interruption.

m) If the enteral feeding pump has suffered a drop or collision, please stop using it immediately and contact our customer service. The device may be internally damaged even if its appearance is intact and no alarm goes off during operation.

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) The product should not be dismantled or modified or used for any purpose other than normal feeding; otherwise, the Company will not be liable for it.

r) During the complete loss of power supply (power supply network and internal power supply) of the alarm system, the log stored in the system will not be affected, but this complete loss of power will not be recorded in the log as an alarm.

s) If the same or similar equipment used in any independent area uses different alarm presets, there will be potential dangers, such as: intensive care units, cardiac operating rooms, etc.

t) In order to prevent the loss of patient data and alarm settings when the enteral nutrition pump is suddenly powered off, the enteral nutrition pump provides data and alarm settings for power-down storage. If the enteral nutrition pump suddenly loses power, after the enteral feeding pump is restarted, the patient's last feeding parameters, alarm information, etc., remain the same as before the power loss, and can be reloaded.U) When the power loss duration does not exceed 30s, the alarm setting before the power loss can be automatically restored;

u) When the power loss time does not exceed 30s, the alarm setting before the power loss can be automatically restored;

v) Before using the enteral nutrition pump, check whether the current alarm preset is applicable to each patient;

w) Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

x) Adapter shall be installed near the device and shall be easily accessible. The unplug is considered as a disconnect of adapter. And adapter must be used with a waterproof cover.

y) The product shall be connected to a USB interface of version USB2.0 or higher.

z) Avoid leaving power adapter cord, feeding set tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped around a child's neck, strangulation and death can occur.

The pump, or WIFI module, and disposable feeding set all contain small parts which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler, or infant, which could result in suffocation and death. Keep all small components out of reach of small children.

Keep the pets and children away from the device.

aa) Please use the following recommended feeding set brand, and the actual feeding set must be consistent with the feeding set by the system, otherwise there will be problems such as low accuracy and abnormal alarm function.

ab) The heating function of external Heating Strips can only be used by inserting external power supply.

ac) This device needs to be managed by trained professionals to avoid leakage of machine information.

ad) Because the Wifi ports and the USB ports are potentially sensitive medical component, activity logging is strongly recommended for accountability and forensic reasons.The unauthorized user may repudiate the access to the system.

ae) This device and its accessories contain silicone, which may cause skin irritation in a small percentage of users.

af) Prevent pinched fingers during use.

ag) The degraded sensors and electrodes, or loosened electrodes can degrade performance or cause other problems.

ah) It is necessary to clean and disinfect the enteral feeding pump and accessories before used on the next patients. The methods for clean and disinfect please refer to Chapter 11.

2. Overview

2.1 Features

This enteral feeding pump is compact and portable. The adaptation of peristaltic rotor structure brings higher feeding pressure sensitivity and feeding accuracy. Easy to use, both suspended operation and operation on desktop platform are available.

Friendly human-machine interface is easy to operate and set up. 3.5-inch color LCD touch screen, detailed menu display. Internal multiple reliability design and rich alarm function, more stable operation, safer feeding.

Arc shape is beautiful without cutting hands, easy to be cleaned. It can be rinsed under tap water at home (water pressure not exceeding 0.35mpa) for the convenience of users.

2.2 Intended use

Used in combination with enteral feeding set without contact with the infusion fluid, for adjustable infusion of nutrient solution into the intestines or stomach of the patient with any condition requiring enteral feeding and/or enteral hydration, for enteral feeding infusion only.

The Enteral Feeding Pump is intended for use in those patients who required intermittent or continuous tube feedings. The target population is adults and children.

The pump is intended to be used in medical institutions and home care settings, such as hospitals, clinics and nursing homes.

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. The intended users range from layperson to clinicians.

Contraindications: none.

2.3 Clinical benefits

The clinical benefits are be identified as follows:

- Improve patient nutritional indicators;

- Reducing the number of complication, such as stomach bloating and diarrhea.

2.4 Types and models

This product is Class II Internally-powered Equipment and CF type, continuously operated device with internal batteries. It should not be carried continuously by the patient and should not be used in the presence of flammable anesthetic gas mixed with air, oxygen or nitrous oxide.

Classification of electromagnetic compatibility: Group 1, Class B.

2.5 Product model

Model/Description	N300-H	
Feeding mode	Continuous feeding and intermittent feeding	
Basic Function	Bolus	Rinse/flush
	Back pumping	Calibrate
Alarm		
Auxiliary functions	Start-up self-check	Selection of feeding set
	Automatic lock screen	Night mode
	Volume adjustment	Log
	Backlight adjustment	Maintenance reminding
	Key sound adjustment	Automatic shutdown
	Patient data	Time and date
Other functions	WIFI	Dedicated tube
	Nurse call	Heating Strip

2.6 Operating environment conditions

(1) Temperature: 5°C-40°C

(2) Relative humidity: 10-95%

(3) Atmospheric pressure: 70.0kPa-106.0kPa

2.7 Influence on environment and energy

The enteral feeding pump may have a certain amount of electromagnetic radiation, which may interfere with other equipment. In this case, appropriate measures should be taken to reduce interference, such as relocating the enteral feeding pump or introducing electricity from different places. For more information, please see Appendix II “Electromagnetic Compatibility (EMC) Information” of this Manual.

2.8 Production date and service life

The normal service life of the complete enteral feeding pump (without batteries) and the power adapter is 8 years. Please refer to the product tag for the production date.

2.9 Statement

The enteral feeding pump is compliant with Medical Devices Regulation 2017/745. According to this regulation, it is a class IIa device.

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3. Components and principles of operation

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4. Technical characteristics and parameters

Feeding accuracy	±5% *
feeding set specification	See 8.5 for details
Feeding rate	(1-400) ml/h Increment: 1ml/h
Feeding presets	(0,1.0-9999.9) ml Increment: 0.1ml
Total volume	(0.0-36000.0) ml

* Pump Sampling amount: 3 samples
Feeding set Brand and Model : Jiangxi Hawk enteral feeding set

Bolus rate	Bolus rate range (1 - 400) ml/h, 400ml/h by default, Increment: 1ml/h Bolus volume range (0,1.0-100.0) ml, 0 by default, Increment: 0.1ml Bolus feeding accuracy: ±10%
Purge rate	Purge rate range (700 - 1200) ml/h, 800ml/h by default, Increment: 1ml/h Purge volume range (0,1.0-9999.9) ml, default is 0, Increment: 1ml
KTO rate:	0-30 ml/h, increment 1 ml/h

<table>
<tr><td>Occlusion pressure</td><td>20-80 kPa (7 levels)
Units available: kPa, bar, mmHg, psi</td></tr>
<tr><td>Maximum infusion pressure:</td><td>240kPa</td></tr>
<tr><td>Maximum volume (Under single fault error output condition)</td><td>≤3 ml</td></tr>
<tr><td>Waterproof</td><td>IP24</td></tr>
<tr><td>Built-in battery</td><td>Optional: Li-ion_Polymer JW-Y2S-3 7.2V 3000mAh or INR18650MJ1(2INR19/66-2) 7.2V 7000mAh
The charging time and exhausting time of batteries are as follows:
<table>
<tr><th>Test Condition</th><th>Battery capacity</th><th>25 ml/h</th><th>125 ml/h</th><th>400 ml/h</th><th>Charge with power on</th><th>Charge with power off</th></tr>
<tr><td rowspan="2">Standard operating condition(fully charged new battery, 50% backlight, default volume level, without WIFI)</td><td>7000mAh</td><td>25h</td><td>24h</td><td>20h</td><td>12h</td><td>7h</td></tr>
<tr><td>3000mAh</td><td>14h</td><td>13h</td><td>11h</td><td>6h</td><td>4h</td></tr>
</table></td></tr>
<tr><td>Input power</td><td>120VA</td></tr>
<tr><td>External power supply</td><td>100-240VAC, tolerance±10%, 50Hz/60Hz ;</td></tr>
<tr><td>Electrical Classification</td><td>Class II Internally-powered Equipment</td></tr>
<tr><td>Electric protection level</td><td>Type CF</td></tr>
<tr><td>Pollution degree</td><td>2</td></tr>
<tr><td>Overvoltage category</td><td>II</td></tr>
<tr><td>Working conditions</td><td>Ambient temperature +5°C - +40°C
Relative humidity 10-95%
Atmospheric pressure 70.0kPa - 106.0kPa</td></tr>
<tr><td>Electronic memory</td><td>8 years</td></tr>
</table>

Dimension	145(L)×100(W)×94(H) mm (including bottom base, without fixing clamp)
Weight	≤0.95kg
Supply voltage	100-240VAC, 50Hz/60Hz
Silence time	1min 45s
Heating power	25W
Power Adapter	LXCP36-120B

5. Installation

5.1 Installation conditions and technical requirement

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

Use a screwdriver to install the pole clamp screws to the nuts of the rear casing of the enteral feeding pump and keep the pole clamp in horizontal or vertical status.

Put the enteral feeding pump on a stable platform, rotate the fixing clamp knob and screw out the rod, leave some space for the IV pole, firmly fix the device onto the IV pole by tightening the clamp knob (the IV pole should meet the balance and mechanical strength requirements). The user should hold the pump throughout the installation and only release it once the pump has been screwed in tightly.

If the fixing clamp knob is not in the same direction with IV pole or bar, adjust the direction by loosening the clamp screw on back of pump.

6. Appearance

6.1 Structures

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6.2 Rear shell

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6.3 Screen display

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6.4 Label

6.4.1 Product label (attached to the rear shell of enteral feeding pump)

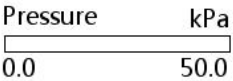
The symbols should be labeled according to ISO15223-1, including manufacturer information, Lot number, serial number, water proof lever, etc.

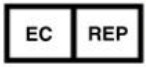
6.4.2 Identification and its meaning

(Table 1)

Identification	Description
	Production lot number
	Machine serial No.
	Prohibition
	Please refer to manual
	Type CF applied parts
	CLASS II equipment
IP24	Shell protection level
	Alternating current
	Direct current
	The device is an electrical and electronic device and must be disposed according to WEEE Directives

	Manufacturer
	Keep dry (on box)
	Fragile goods are packed in the transport package, and should be handled with care
	It should be straight up when being transported
	The same package can be stacked up to 5 layers.
	Humidity limitation
	Temperature limit
	Stop/Alarm Reset button
	Back pumping button
	Home button
	Power button
	Night mode on

	Current heating temperature
	Not heating
	Real-time pressure value
	WIFI (respectively represent WIFI dropped, one-segment signal, two-segment signal, full-segment signal)
	Volume level
	Battery charging
	Battery failure
	Key Lock
	Don’t press the door when the pump is running
	Audio Paused
	Alarm reset(alarm elimination)
	Acknowledged
	Bell cancel(to indicate that an Alarm Condition is in the Acknowledged state for an indefinite period)
	Unique device identifier

	Medical device
	Date of manufacture and Country of manufacture, CN: China
	Model number
	Importer
	EU Authorised representative
	This device is provided with a CE marking in accordance with the Medical Device Regulation 2017/745. 0197 is the Notified Body number.
	UK Responsible Person
	Atmospheric pressure limitation
	Non-ionising electromagnetic radiation (refer to IEC60417-5140)

7. Preparation before Use, Precautions and Start-up Self-inspection Instructions

7.1 Preparation and inspection before use

Note：Choose the appropriate positions among patient, pump, feeding set and container. Check the stability of the whole system. Don't position the pump in a place that it's difficult to disconnect it.

7.2 Cautions for operation

Note： It should be free from direct sunlight, high temperature or high humidity.

8. Operation Method

In order to ensure feeding accuracy, it is recommended to use the built-in feeding set brand of this pump (pump-type disposable feeding bag/nutrition bag).

8.1 Feeding

8.1.1 Fix the machine and connect the power adapter

Adjust the fixing clamp knob so that the enteral feeding pump is firmly fixed on the infusion stand, and then plug in the external power supply. At this point, the power indicator on the enteral feeding pump will light up.

8.1.2 ON/OFF

Power-on: Long press the power button, the system starts up and carries out self-checking. A progress bar interface will be displayed on the screen, indicating the progress of self-checking. At the same time, the alarm lamp alternately flashes of red, green and yellow colors.

After self-checking, the alarm lamp turns green, the loudspeaker sounds a beep, and the system enters the parameter setting interface. If there is no such audio or light alarm, it's indicated some faults. In this case, please contact the supplier or manufacturer.

The main checking items are: Internal communication, pressure sensor,, external power supply, main battery, spare battery, heating circuit and liquid stop clip motor.

Note: To shut down, press the power button for about 2 seconds.

8.1.3 Prefill and install feeding sets.

1).Prefill feeding set

2).Install feeding sets

8.1.4 Set Feeding Parameters

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8.1.5 Set Flush parameters

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8.2 Alarms and solutions

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8.3 System settings

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8.4 Admin Setting

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9. Malfunction Analysis and Solutions

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

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

10. 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 enteral feeding pump 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. 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 distributor/manufacturer.

11. Maintenance, inspection, repair and recycling

11.1 Clean and disinfect

★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 and DC power adapters must be disconnected from the device.

3. Remove the consumables and the connected accessories (such as heating strip, etc.).

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

★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:

Detergent Name	Cleaning Method
Clean water	Wipe

11.1.3 Disinfection

★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 Name	Contact Time	Disinfection Method
75% alcohol	3min	Wipe

11.2 Sterilization

Sterilization of this device or accessories is not permitted unless specifically stated in the manual.

11.3 Periodic Inspection

11.3.1 Check the alarm function of the occlusion sensor (once every 2 years)

Note： The testing conditions: The enteral feeding pump should be 20cm away from the flow clip of feeding tube and 30cm away from the filter, feed rate at 150 ml/h, feed VTBD as 200ml, and occlusion level as Level 4.

11.3.2 Inspect delivery accuracy (once every 2 years)

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 delivery accuracy periodically.

11.3.3 Inspect internal battery

The battery shall reduce the performance due to prolonged usage, please check the battery every 2 years or when the runtime of the battery is significantly reduced.

11.3.4 Replace internal battery

WARNING: Replacing the battery needs to be operated by after-sales team of the manufacturer or maintenance personnel authorized by the manufacturer. Installation and replacement of batteries by inadequately trained personnel may result in hazards (such as overheating, fire, or explosion), as well as machine failure.

Disposal of used batteries should follow the regulations accordingly.

11.3.5 Replaceable parts

Replaceable part: Power adapter, Heating Strip

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.

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, our company can offer circuit diagram and components list to authorized maintenance personnel.

11.5 Maintenance for long-time storage

If the enteral feeding pump is not used for more than 1 month, it should be placed in package to avoid direct sunlight, and keep it in cool and dry place. See 12.2 for detailed storage conditions.

If the enteral feeding pump is not used for long time, to ensure that this pump remains in good operating condition after a long-time storage period, please carry out the following maintenance procedures:

1. Calibrate the enteral feeding pump to ensure feeding accuracy and avoid possible medical accident.

2. Test the pressure alarm.

3. Test the working time and recharging time of battery to ensure the battery can still be used.

11.6 Recycling

The service life of this product is 8 years. After the equipment reaches the service life, it should be disposed according to local laws and regulations.(For more information, please contact manufacturer or our distributors.)

WARNING: Disposal of parts, batteries, packaging materials and accessories must comply with local laws, regulations or the hospital's waste disposal system.

12. Transport and storage

12.1 Precautions during transport

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

2. Temperature range:-20°C- +55°C;

3. Relative humidity: 10-95%

4. Atmospheric pressure: 50.0 kPa - 106.0 kPa

12.2 Storage conditions

Storage temperature: -20°C - +55°C

Relative humidity: 10-95%

Atmospheric pressure: 50.0kPa～106.0kPa

13. Packing list

14. 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 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.

15. After-sales services

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

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

Appendix 1

Time between alarm condition and alarm generation is less than 1 seconds

Table 1 Classification of alarms and color of alarm indicator light

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Table 2 Alarm sound interval time

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

Appendix 2 Information of Electromagnetic Compatibility (EMC)

1. Notes

- N300-H Enteral feeding pump meets the electromagnetic compatibility requirements of IEC 60601-1-2, IEC 60601-2-24 Clause 201.17.202.
- Users should install and use according to the EMC information mentioned in the attached documents.
- Portable and mobile RF communication equipment may affect the performance of N300-H enteral feeding pump and avoid strong electromagnetic interference when used, such as near mobile phones, microwave ovens, etc.;
- See attachments for the manual and manufacturer’s statement.

2. Warning

- N300-H 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 N300-H 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 N300-H enteral feeding pump.

3. Guidelines and manufacturer's statements:

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The model N300-H are intended for use in the electromagnetic environment specified below. The customer or the user of the model N300-H should assure that they are used in such an environment</td></tr>
<tr><th>Emissions test</th><th>Conformity</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The model N300-H use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR11</td><td>Class B</td><td rowspan="3">The model N300-H are suitable for 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations
/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance & Declaration — electromagnetic immunity			
The model N300-H are intended for use in the electromagnetic environment specified below. The customer or the user of the model N300-H should assure that they are used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±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 ±1kV for Input/output 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, ±1kV line to line ±0.5 kV, ±1kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1kV , ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T(>95% dip in U_T.) for 0.5cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	<5 % U_T(>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T)for 25/30 cycles <5% U_T(>95 % dip in U_T) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model N300-H require continued operation during power mains interruptions, it is recommended that the model N300-H be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m	3 A/m, 30 A/m	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 & Declaration - Electromagnetic immunity			
The model N300-H are intended for use in the electromagnetic environment specified below. The customer or the user of the model N300-H should assure that they are used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to80MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7GHz 385MHz-5785MHz Test specification s for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 Vrms 150 kHz to80MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7GHz 385MHz-5785MHz Test specification s for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	Portable RF communications equipment including antennascan be used no closer than 30 cm (12 inches) to any part of the N300-H Enteral Feeding Pump, including cables specified by the manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field 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 model N300-H are used exceeds the applicable RF compliance level above, The model N300-H should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model N300-H.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the model N300-H

The model N300-H are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model N300-H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model N300-H are recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz～80 MHz $d=1.2\times P^{1/2}$	80 MHz～800 MHz $d=1.2\times P^{1/2}$	800 MHz～2.7 GHz $d=2.3\times P1^{/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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

Appendix 3 Cyber security

1. Serial communication

Note：use password for user identity identification Electronic interface:Type-C interface

2. WIFI communication

a) User access control mechanism: use password for user identification

b) Electronic interface:WIFI (IEEE 802.11)

c) Data type: device operation information (alarm signal, feeding mode, feeding flow rate, time, totalization)

d) Technical features: Local area network composed by wireless WIFI, one-way data communication via electric port with WIFI (IEEE 802.11b/g/n) standard protocol. Modulation mode is BPSK, QPSK, QAM. operating frequency range is 2.412GHz ~ 2.484GHz. wireless rate is IEEE 802.11b: 1 ~ 11 Mbps, IEEE 802.11g: 6 ~ 54 Mbps, IEEE 802.11n: 6.5 ~ 65 Mbps. transmit power is < 20 dBm (CE Requirement: detection mode - RMS). Hawk Medical private encryption method, communication with the computer is a one-way data type transmission, the enteral feeding pump to send data to the computer, will not accept any feeding control instructions sent by the computer, and will not send any operation instructions to the computer.

e) Network security features configuration: data transmission type is one-way transmission; relevant records at the device end cannot be deleted.

f) Security mechanism: Standard: WPA-PSK, WPA2-PSK; Encryption: TKIP, AES.

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

h) Operating environment.

Software environment: WIN7 and compatible versions; Hawk infusion monitoring software (HK-M1000), software version: V01 and compatible versions.

Hardware environment.

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

Network Environment：Network Architecture：C/S；Network Type：Local Area Network；Network Bandwidth：not less than 100Mbps

Appendix 4 Pressure alarm delay and bolus dose reference table

Flow rate(mL/h)	Alarm grade	Occlusion alarm response time(min)	BOLUS(mL)
1	Gear-1（MIN）	<31	<0.6
	Gear-7（MAX）	<148	<2.0
25	Gear-1（MIN）	<3	<0.5
	Gear-7（MAX）	<4	<1.0

★Note: Occlusion alarm pressure, delay time and Occlusion bolus are all affected by test conditions, temperature and tube length.

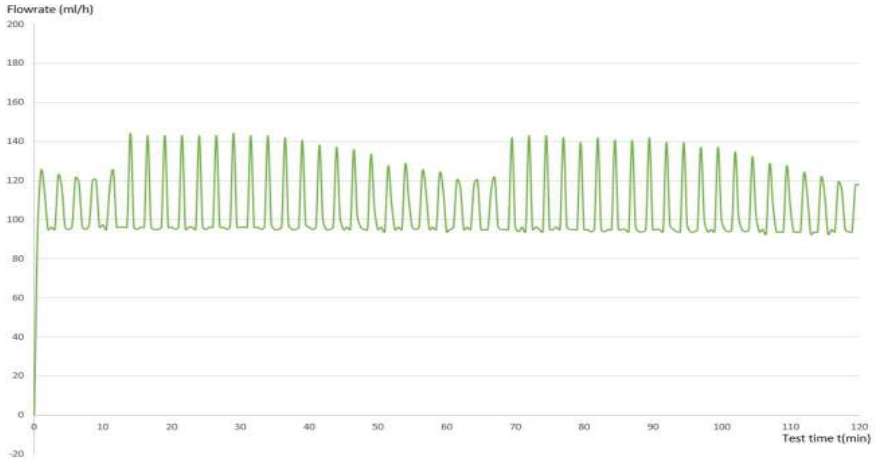
Appendix 5 Accuracy curve

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。

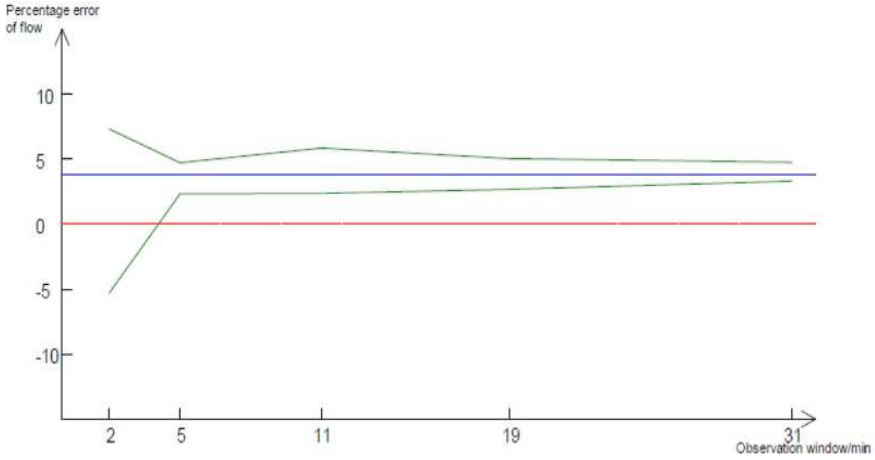
★Note:

- Feeding accuracy may be affected by the environment in which the device is used (pressure, temperature, humidity, brand of feeding set 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.

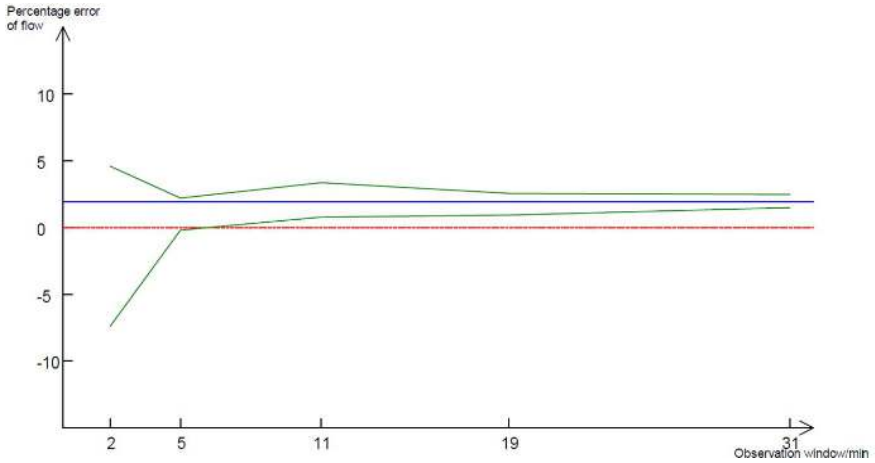
1. Starting curve in the first 2 hours, Condition：Normal condition, 100ml/h



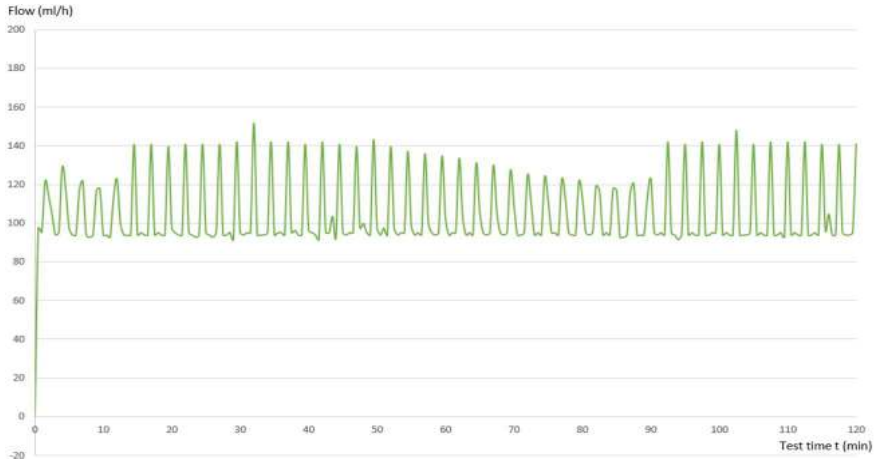
2. Trumpet curve in the second hour (T1), Condition：Normal condition, 100ml/h



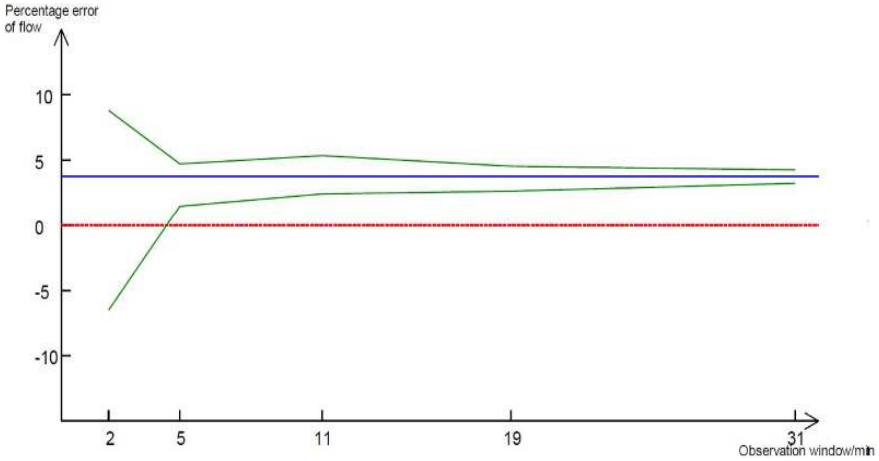
3. Trumpet curve in the last one hour (T2), Condition：Normal condition, 100ml/h



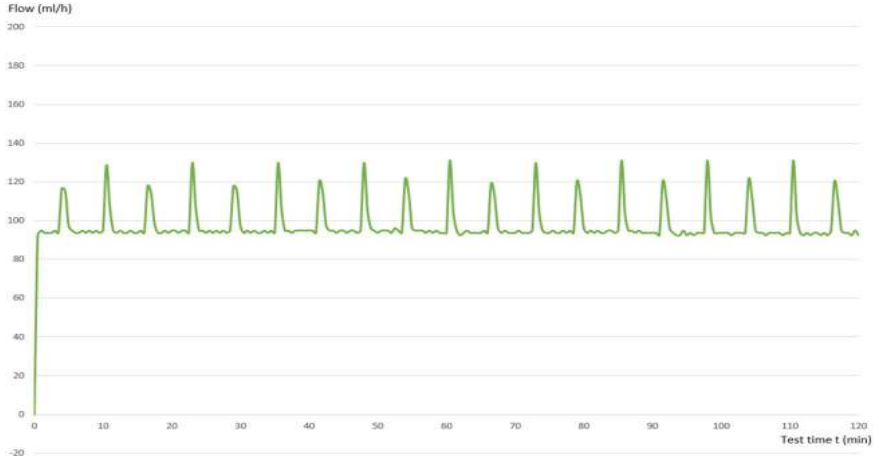
4. Starting curve in the first two hours, Condition：+13.33kPa background pressure, 100ml/h



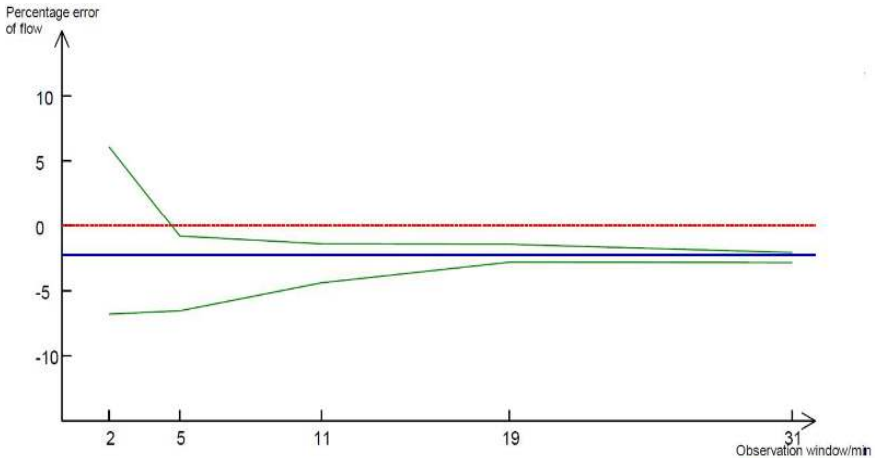
5. Trumpet curve in the second hour (T1), Condition：+13.33kPa background pressure, 100ml/h



6. Starting curve in the first two hours, Condition：-13.33kPa background pressure, 100ml/h



7. Trumpet curve in the second hour, Condition：-13.33kPa background pressure, 100ml/h



Appendix 6 Bolus accuracy reference table

Bolus Volume	Bolus Rate	Weight of 25 successive bolus Deliveries(g)	Average error
1ml	100ml/h	1.02,0.95,1.02,1.01,1.00, 0.99,1.03,0.99,1.01,0.97, 1.00,0.99,0.99,0.99,1.01, 0.99,0.99,0.97,1.01,1.00, 1.00,0.99,0.99,0.99,0.97 24.87g in total	-0.52%
100ml	400ml/h	100.06,99.1,98.19,98.53,98.40, 99.56,98.68,98.77,98.85,98.66, 98.75,97.95,97.61,99.59,99.60, 99.05,98.71,99.78,98.93,99.29, 98.30,98.80,98.76,99.15,98.65 2471.72g in total	-1.13%

The above data test conditions:

- Brand of Feeding tube: Hawkmed
- Test temperature: 25±2℃

Shenzhen Hawk Medical Instrument Co. ,Ltd.

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UK Responsible Person: Umedwings UK LTD

Add: 291 Brighton Road, South Croydon, United Kingdom, CR2 6EQ