Shenzhen Hawk Medical Instrument Co., Ltd.

ENTERAL FEEDING PUMP

Model: Nutricare-300H

Please read the Manual before installing and using the product;

Please keep it for future reference!

CE 0197

057-00358-00

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 Nutricare-300H enteral feeding pumps.

Revision	Date of revision
V0.0.3	07-04-2023

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 nutrition tube. 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 nutrition tube 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) When in doubt about the protective grounding, the internal power supply should be used.

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 devices. Use the device within a MRI environment is 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) WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

w)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.

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 cord of the electric cauterization equipment or its main body and the enteral feeding pump should be kept at least 25 centimeters.

(3) The power cords 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 cord 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 nutrition tube 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 every 24-hour use. Or replace with a new nutrition tube.

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.

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 purpose

Use in combination with enteral feeding catheter 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 in medical institutions, for enteral feeding infusion only.

The Enteral Feeding Pump is intended for use in those patients who required intermittent or continuous tube feedings via the nasogastric or nasoenteric route. The target population is adults

and children.

The pump is intended to be used in medical institutions, such as hospitals and clinics.

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.

2.3 Clinical benefits

The clinical benefits include but not limited to:

(1) The use of enteral feed pumps is now considered the most accurate means of enteral feeding provision across all care settings and patient groups;

(2) Allowing functionality across a wide range of environments;

(3) Maintaining gut integrity and where tolerance and maximizing the feeding volume are finely balanced;

(4) Improving quality of life.

(5) Reducing incorrect administration and microbial risk.

(6) Use of continuous pump feeding is theoretically a safer means of formula delivery, through its potential to reduce high residual volumes and the risk of gastric aspiration.

(7) The jejunum secretes fluid in response to hyperosmolar solutions, and too rapid delivery of a hyperosmolar nutrition formula results in abdominal distention, hyperperistalsis, and diarrhea. The continuous pump infusions can help to prevent these symptoms through a more controlled delivery to the intestine.

2.4 Types and models

This product is Category I 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	Nutricare-300H	
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 cord 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. This model carries the marking:

CE XXXX

Date of first CE marking: xx/xx/xxxx

In accordance with the requirements of the Medical Device Regulation 2017/745, the enteral feeding pump 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/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3	EN 60601-1-8:2007+A1:2013+A1 1:2017+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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/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+A1:2021	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

3. Components and principles of operation

3.1Components

The enteral feeding pump is mainly composed of 5 parts: microcomputer system, pump body device, detection device, alarm system and man-machine interface.

Microcomputer system: the "brain" of the whole system, the whole system for intelligent control and management, and the detection signal processing, using dual CPU;

Pump body device: the "heart" of the whole system and the power source of conveying liquid. The brushless DC motor is used to drive the peristaltic wheel to promote the liquid flow.

Detection device: mainly a variety of sensors, such as pressure sensors (responsible for the detection of congestion), which can sense the corresponding signals. After amplification, these signals are sent to microcomputer system for signal processing, and then followed by corresponding control operations;

Alarm system: After the signal of sensor is processed by microcomputer, the alarm control signal is obtained, and then it is responded by the alarm system to attract people's attention and be processed correctly at the same time. It mainly includes photoelectric alarm (light-emitting diode), sound alarm (loudspeaker and buzzer) and screen display alarm.

Man-machine interface: Press the button to set feeding parameters, such as feeding amount and feeding speed. Display various parameters and current working status through color LCD.

3.2 Software information

1) **Software name:** Nutricare-300H enteral feeding pump software

2) **Software release version:** V01

3) **Minimum software environment:**

CPU：ARM 32-bit Cortex™-M4 CPU Coreor higher.

Highest frequency ：168MHz

Memory：512kbytes

This software is an embedded system based on single-chip microcomputer which does not require support from other softwares during operation.

It needs to connect to wireless LAN network when connect to the infusion monitoring system.

The computer should be equipped with an operating system of Windows XP or above when uploading datas.

4) **Functionality:**

This software controls the Enteral Feeding Pump to feed patients who required intermittent or continuous tube feedings via the nasogastric or nasoenteric route and has features such as feeding mode selection, history record, automatic lockout and alarms.

5) Composition:

This software is composed of a bootstrap program, a master level program and a slave level program.

Bootstrap program can realize the function of software upgrade using U disk.

Master level program can master CPU software main program, responsible for interface display, feeding mode selection, key press, alarm functions.

Slave level program: Slave CPU software program, responsible for functions such as motor drive.

3.3 Principles of operation

This enteral feeding pump is driven by the motor to squeeze the silicone tube of the feeding tube by the disc 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 touching the display, 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 characteristics and parameters

Feeding accuracy	±5% *
Nutrition tube 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

<table>
<tr><td></td><td>Bolus feeding accuracy: ±10%</td></tr>
<tr><td>Purge rate</td><td>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</td></tr>
<tr><td>KTO rate:</td><td>0-30 ml/h, increment 1 ml/h</td></tr>
<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>23h</td><td>21h</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 I</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	LXCP52-012 (manufactured by Shenzhen Longxc Power Supply Co., LTD) Or PH50-12 (manufactured by Zhuhai Xinhe Electronic Co., Ltd.)
Power cable	KC-015+KC-003

5. Installation

5.1 Installation conditions and technical requirement

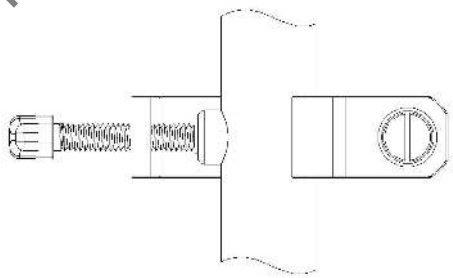
The enteral feeding pump can be fixed to a vertical IV pole or horizontal bar with diameter of 12-35mm, or on platform with slope angle not exceeding 5°.

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. As shown in Fig. 5.2.1.



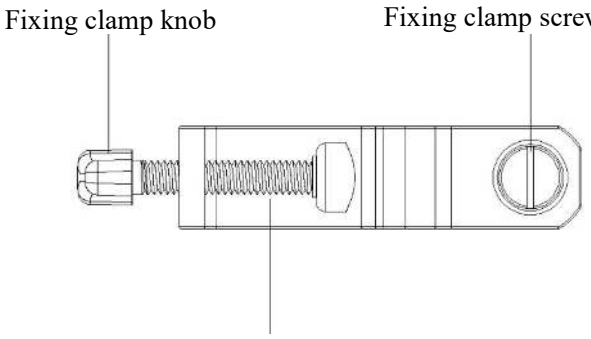
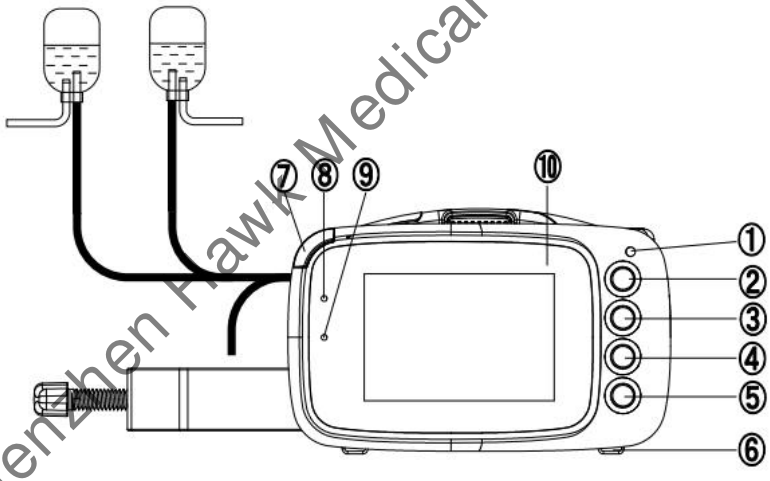


Fig. 5.2.1 Fixing clamp

6 Appearance

6.1 Structures



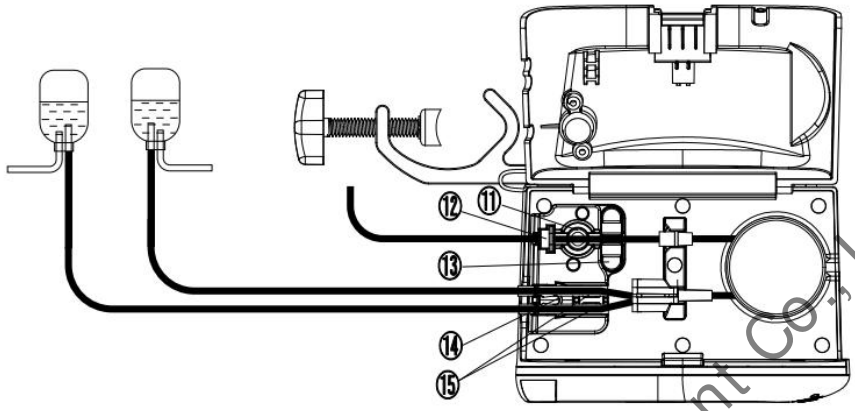


Fig. 6.1.1 Nutricare-300H Front View and Top View

①—Power on indicator light ②—Power key ③— Home key

④—Back pumping ⑤—Stop/Alarm Reset key ⑥— Base foot pad

⑦—Alarm indicator light ⑧—Charging indicator light ⑨—Power indicator light

⑩—Display screen ⑪—Pressure sensor ⑫—Dedicated tube identification

⑬—Air bubble sensor ⑭—Free flow clamp ⑮— Tube installation recognition

Description	Function
② Power key	To switch on / off the enteral feeding pump. 1. To switch on: when the pump is in 'power off' status, press and hold this key until the LCD screen display comes on. 2. To switch off: when the pump is in 'power on' status, press power key to access power menu interface for shutdown, lock screen and standby. Or press this key for 3s to switch off directly.
③ Home key	When the pump is under non-operation status, press Home key to return to main interface, press Home key again to return to the original interface.
④ Back Pumping	When the pump is under non-operation status, press Back Pumping key to enter back pumping parameter setting interface. Set the parameters according to requirements, press START key to start back pumping. Press Back Pumping key again to return to original interface.

⑤Stop/Alarm Reset key	Stop feeding key and alarm reset key (silence/stop the alarm). 1. In the normal feeding status, press this key to stop feeding. 2. In the alarm status, after eliminating the alarm preconditions, press this key to reset (silence/stop) the alarm status (alarm sound, alarm indicator light, alarm prompt box).
⑦Alarm indicator light	It is used to display the running or alarm status. Properly install the feeding set and close the door, the green light will be on. Steady green indicates it is ready to operate. When start feeding, green light will flash to indicate the machine is running. In case of high priority alarm, red light will flash; In case of medium priority alarm, yellow light will flash; In case of low priority alarm, the light will be steady yellow; * See **Appendix I Table I** for details of alarm priority.
⑧Charging indicator light	ON: The battery is charging OFF: The battery is not charging
⑨Power indicator light	ON: The pump is connected to external power supply. OFF: The pump is not connected to external power supply.
Door Latch	Press door latch to open the door automatically. Press pump door and hear a 'click' sound, it means the door is closed

6.2 Rear shell

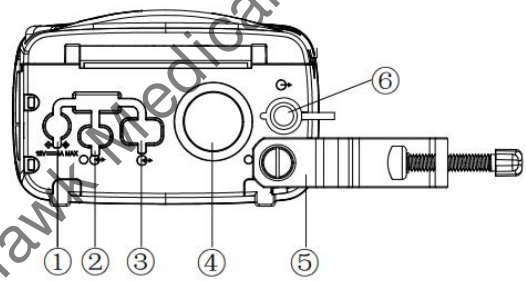


Fig. 6.2.1 Nutricare-300H Rear case

Description	Function
① Input DC 12V	Machine power supply
②Type_C interface	Used to connect U disk to upgrade software or connect to computer(comply with IEC 60950-1) to review history records.
③ USB - A interface	Used to connect to computer(comply with IEC 60950-1) to upgrade software
④ Speaker	For alarm reminder

⑤ Fix clamp and knob	Used for fixing the enteral feeding pump. The direction of fixing clamp can be adjusted by loosening the clamp screw. (Horizontal and vertical options available)
⑥ PJ Nurse call/ heating strip interface	Nurse call interface needs to be connected to a special signal cable to achieve the function. Connect the Heating Strip.

6.3 Screen display

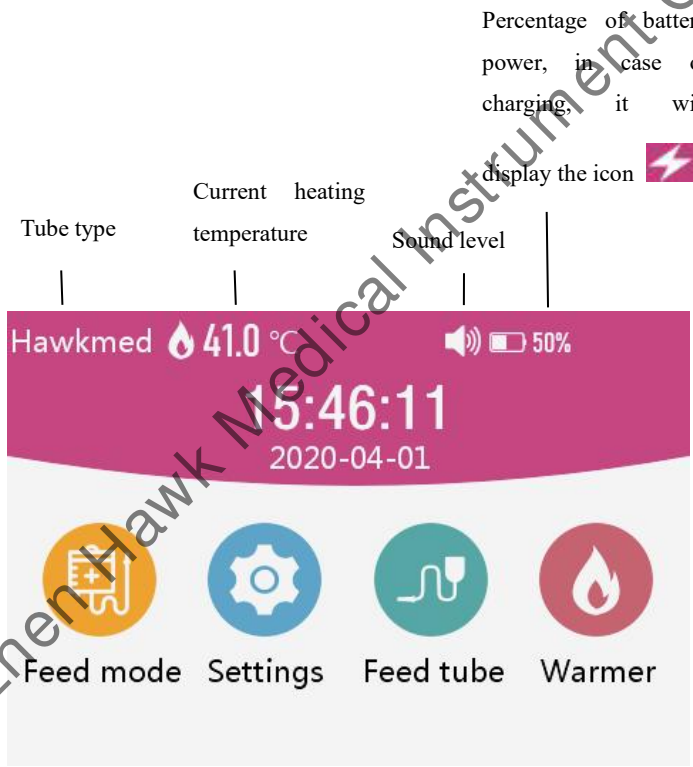


Fig. 6.3.2 Nutricare-300H Screen Display

6.4 Label

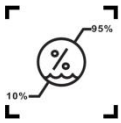
6.4.1 Product label (attached to the rear shell of enteral feeding pump)

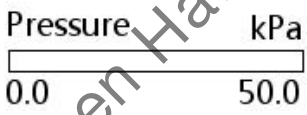
The symbols should be labeled according to ISO15223-1, including manufacturer information, Lot number, serial number, water proof lever, etc.

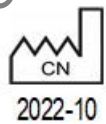
6.4.2 Identification and its meaning

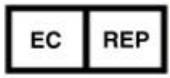
(Table 1)

Identification	Description
	Production lot number
	Machine serial No.
	Attention! Check documents attached with the device
	Please refer to manual
	Type CF applied parts
	Protective grounding
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.
	Ambient humidity of transportation package should be within 10 - 95%
	Ambient temperature of transportation package should be within -20°C - 55°C
	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. XXXX is the Notified Body number.

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

7.1 Preparation and inspection before use

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.

For new machines and those that are stored for a long period of time and then put back into use, or for machines that are ready to be used after maintenance, please do the following inspection and test before use to ensure that the enteral feeding pump works normally:

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

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

(3) Flexible opening and tight closing.

(4) The power cord can be plugged in tightly, not easy to pull off.

(5) If run it on built-in battery only, charge it fully before use and make sure the battery is still valid for use.

(6) Set and check system time to make sure the history events are recorded correctly.

(7) Please read the precautions and operation steps of this user manual carefully.

(8) Detect the occlusion alarm function according to the method described in 11.3.1 below.

(9) Make sure the feeding tubing set has been installed correctly. The orientation of the pump in compliance with drip chamber.

7.2 Cautions for operation

(1) It should be free from direct sunlight, high temperature or high humidity.

(2) Avoid feeding pump failure operation, to avoid medical accidents, harm to patients' health and even life.

(3) Setting or changing the parameters of the feeding pump should be carried out by trained professionals.

(4) If the panel is damaged, please replace the panel in time to avoid liquid leakage into the enteral feeding pump and damage it.

(5) If the ambient temperature exceeds the predetermined range, the feeding precision will decrease or even the operation will be abnormal.

(6) The viscosity and specific gravity of the feeding liquid will affect the accuracy of the feeding pump.

(7) In addition to the brand nutrition tube built in this feeding pump, the user must calibrate before using other nutrition tube.

(8) During feeding, the feeding pump can precisely control the feeding speed, feeding amount and feeding time, and monitor the speed and direction of the motor in real time to effectively prevent overcurrent, undercurrent and back pumping.

(9) The enteral feeding pump should be placed within 0.5 meters above the patient and not lower than the patient's heart, otherwise it will affect the feeding accuracy.

(10) The height of the nutrition bottle or nutrition bag should not exceed 100cm, otherwise feeding accuracy cannot be guaranteed.

8. Operation Method

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

8.1 Feeding

The entire feeding operation consists of the following procedures or actions:

1> Fix the machine and plug in the power cord

2> Press the button ON/OFF to start

3> Prefill and install the feeding tube

4> set feeding parameters

5> set water feeding parameters

6> remove air bubbles

7> clear total volume

8> start feeding

9> fast feeding/bolus

10> stop feeding

11> feeding completed

12> replace nutrition tube group

8.1.1 Fix the machine and connect the power cord

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.

System self-checking identification:

(1) Internal communication: Communication fails, system fault is reported after startup; communication succeeds, no alarm

(2) Pressure sensor: Abnormal pressure detection, system failure after startup; normally, no alarm.

(3) Dedicated tube: Dedicated tube switch is on. If no dedicated tube signal is detected, the dedicated tube error will be reported after starting up.

(4) External power supply: External power is not detected, and AC power failure will be prompted after starting up.

(5) Main battery: If no main battery is detected, battery failure will be reported after starting up.

(6) Spare battery: If no spare battery is detected, system failure will be reported after starting up.

(7) Liquid stop clip motor: If no liquid stop clip motor is detected, system failure will be reported after starting up.

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

8.1.3 Prefill and install nutrition tubes.

1.Prefill nutrition tube

Arrange the flow clip in the rear side of the enteral feeding pump and tighten it. Connect the nutrition tube group with the nutrient fluid container, then squeeze the drip chamber and inject about half of the nutrient fluid. Open the flow clamp to let the nutrient fluid fill to the end of the nutrition tube, and then close the flow clamp.

2.Install nutrition tubes

Nutricare-300H nutrition tube installation，as shown in Fig. 8.1.3.1

a. Press the door buckle, open the door cover, and put the nutrient tube three-way shunt interface into the positioning slot 1 with the left hand. For a double bag, the water feeding tube and the feeding tube can be put into the tube identification slot in sequence as shown in Fig.8.1.3. For a single bag, it can be put into either side of the tube identification slot.

b. Hang the silicone tube section of the nutrition tube from bottom to top around the pump rotor in the positioning slot 2 with your right hand.

c. Press the tube into the air bubble sensor slot. If it is a dedicated tube, put the dedicated buckle into the dedicated tube identification slot.

★Note 1: For better accuracy, the initial fluid level shall be at least 15 cm higher than the pump and the pump shall be placed higher than the feeding site.

★Note 2: Please note the direction of installation of the water feeding tube and the feeding tube if it is a double bag, the correct direction as shown in Fig. 8.1.3.1

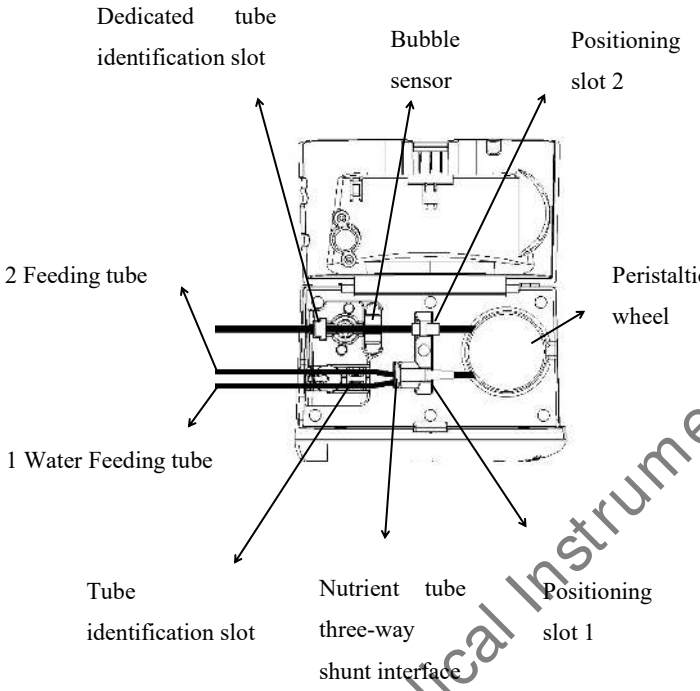


Fig. 8.1.3.1 Nutricare-300H Installation diagram

8.1.4 Set Feeding Parameters

(1)Continuous feeding parameter interface，as shown in Fig. 8.1.4.1

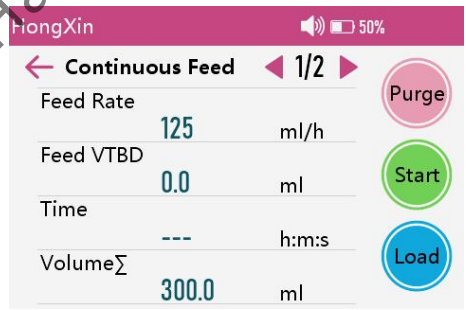


Fig. 8.1.4.1 Continuous feeding parameter interface

(2)Intermittent feeding parameter interface

Compared with continuous feeding, intermittent feeding has two more parameters: feeding times and feeding interval . shown in Fig. 8.1.4.2

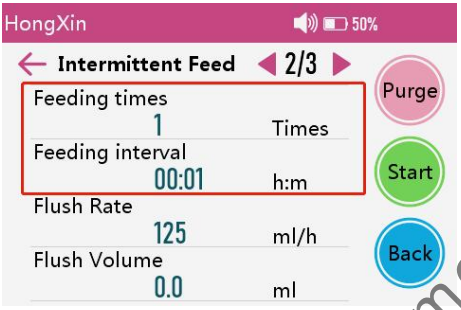


Fig. 8.1.4.2 Intermittent feeding parameter interface

Feeding tube: Enter “Feed Tube” - “Select feeding tube”, choose required feeding tube brand.

Feeding mode: Enter “Feed Mode” , Choose “continuous feed” or “intermittent feed”.

Feed rate: Click the area where the flow rate value is, a small keyboard will pop up, enter the flow rate, and press OK to save the parameters.

Feed VTBD: Click the area where the preset value is, a small keyboard pops up, input the preset value. If want to finish feeding the nutrient fluid in the bottle, omit the input preset value (i.e., the preset value is 0 ml). Press OK to save the parameters.

Feeding times： It is under intermittent feeding mode. It indicates the total number of feedings. Click the area where the feeding times is located, a small keyboard will pop up, enter the number of feeding needed, press OK to save the parameters.

Feeding interval： It is under intermittent feeding mode. It indicates the pause time for each feeding. Click the area where the feeding interval is located, a small keyboard will pop up, enter the required feeding interval time, press OK to save the parameters.

Load: Press load soft key to load the preset volume (Feed VTBD) and feed rate of last time directly.

★ Note: After selecting loading, the flow rate and preset value must be checked to make it consistent with the current feeding requirements and preset value; otherwise, it should be changed.

8.1.5 Set Flush parameters

When nutricare-300H recognizes there are two tubes, click the upper right corner 1/2 to switch to the second page to set flush parameters: Flush volume, Flush rate, Flush interval time.

When flush volume is 0, the flush function doesn't work (same as the single tube).

When flush volume is more than 0, flush function works. It will switch to another tube (water feeding bag) to run at flush rate by flush interval time. When water feeding reaches the preset volume, it will automatically switch back to the original nutrition tube (nutrient feeding bag). The parameters setting of intermittent mode is the same with continuous mode. As shown in Fig. 8.1.5.1.

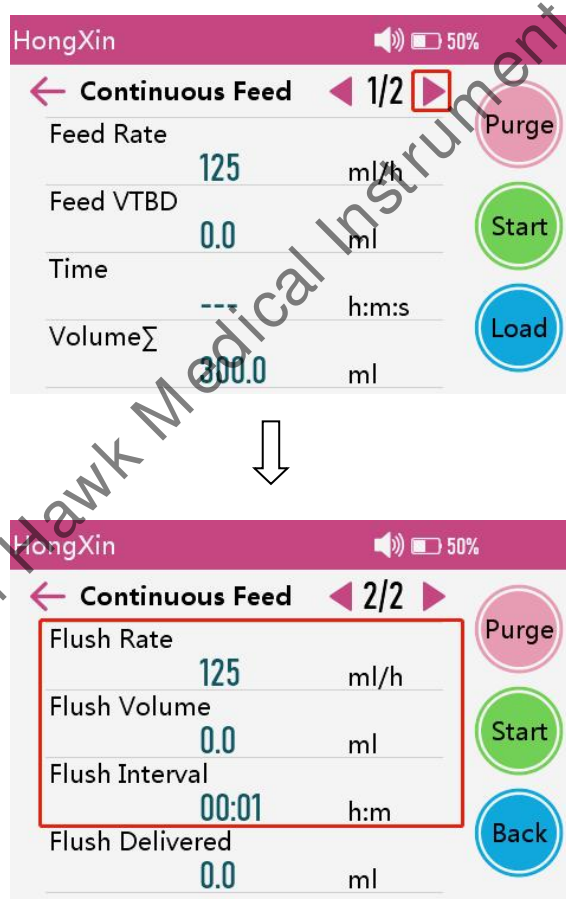


Fig. 8.1.5.1 Set Flush parameters

8.1.6 Purge

Enter “Settings”--“User settings”--next page-- “Purge”

It could set purge VTBI and purge rate.

1) When purge VTBI is 0, it is manual purging. Keep pressing Purge soft key to start purge function. Release Purge soft key to stop.

2) When purge VTBI is more than 0, it is auto purge function. After setting purge VTBI and purge rate, press purge soft key to start purge function automatically.

3) Tube switching: The purge tubes of Nutricare-300H can be Off or On when double bag is installed. The tube switching function is Off by default. Press Start, the liquid control valve will stop water feeding tube and purge feeding tube. When the tube switching is On, press Start, liquid control valve will stop feeding tube and purge the water feeding tube.

8.1.7 Clear Accumulated Volume

Press the area of volume, “Clear fed volume” interface will pop up. Press to clear accumulated volume, as shown in Fig. 8.1.7.1.

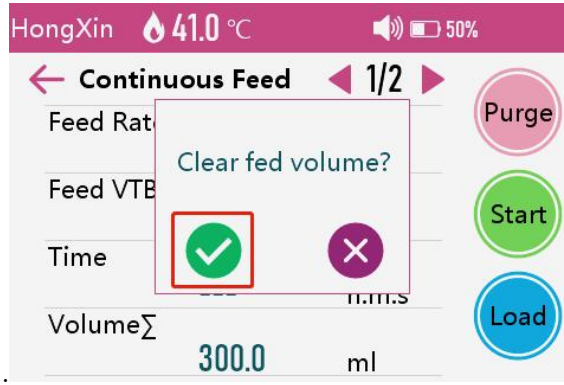


Fig. 8.1.7.1 Clear accumulated volume

8.1.8 Start Feeding

After confirming indicator light is on and in green, the flow clip of feeding tube is opened, press "Start" soft key to start feeding. During feeding, only Bolus key, pause key, stop key, unlock and alarm functions are effective.

Note: Please check whether the current feeding volume is suitable before use.

8.1.9 Bolus

There are manual Bolus and automatic Bolus for fast feeding.

1）Manual Bolus. In the feeding process, keep pressing Bolus soft key to start fast feeding at preset Bolus rate. When release the finger, the device will return to original feeding rate.

2）Automatic Bolus. When Bolus volume is not 0, after setting Bolus rate, press Bolus soft key to start Bolus function automatically.

3）When the feeding operation pauses, click Bolus to enter the Bolus setting interface.

Note: Bolus rate can be set on the system settings or during pause of nutrition feeding.

8.1.10 Stop Feeding

During feeding, press Stop/Pause soft key to pause feeding. Press Start soft key to start feeding again.

8.1.11 Feeding Completed

After completing the preset feeding volume or the accumulated volume reaches 36,000 ml, the pump will issue finish alarm and automatically stop feeding and start KTO function.

8.1.12 Replacement of feeding tube group and nutrient fluid container

★ If it needs to replace the feeding tube, please follow these steps:

- Clamp the free flow clip on the feeding tube, open the pump door, the interface of "remove the feeding tube?" will pop up, click OK, the free flow clamp on the pump will automatically open, then remove the used feeding tube.
- Prefill and install the new feeding tube as required in **8.1.3** above.
- Follow the above feeding procedures and start feeding again as required.

★ Note: The feeding tube will be deformed for using a long time then cause flow error. It is suggested to replace the feeding tube with a new one after continuous use of 24 hours.

★ If it needs to replace the nutrient fluid container, please follow these steps:

- Clamp the free flow clip on the feeding tube, open the pump door, remove the feeding tube
- Remove the nutrient fluid container.
- Connect the feeding tube to the new nutrient fluid container.
- Install the new feeding tube as per above steps and start feeding again.

8.2 Alarms and solutions

Warnings:

A) Do not adjust the volume of alarm sound less than the levels of ambient sound. Ensure you can hear the alarm sound. Missing the alarms could pose a serious risk to the patient, since the operator may not hear a critical alarm.

B) There can be inherent alarm delay(refer to Appendix I).

C) Please make sure the appropriate reaction to alarm is undertaken. A wrong or delayed reaction leads to a delay of therapy.

D) Do not set ALARM parameters such as occlusion pressure or air bubble size to a limit value. Set a too low threshold may cause a false alarm that may lead to a patient hazard. The threshold of occlusion pressure is impacted by the tube characteristic or formula viscosity. It should be set depending on cases

During feeding preparation and feeding, the following alarms may occur. They are grouped as technical alarm conditions . Please refer to the instructions for handling.

(Table 1) Description of alarm symbols

Symbol	Description
	In an alarm state, after clearing the alarm preconditions, press this key to reset the alarm state (alarm sound, alarm indicator light, and alarm prompt box will all be cleared).
	In the state of alarm, press this key, the alarm sound will pause for 1min45s, after this time or press this key again, the alarm sound will be reset
	In an alarm state, press the key to mute the sound alarm

(**Table 2**) (Alarm parameters are shown in Table 1 and Table 2 in Appendix 1)

Name	Priority	Alarm reasons	Fault resolutions
No operation	Low	When the pump is turned on, it will not run feeding state. After 3 min (the time corresponds to the time set by the system, the default is 3 min), there will be no keystroke operation.	Press any key to eliminate this alarm. ★ Note: It can choose to close this alarm. See **8.3.13** herein.
Door Open	High	The enteral feeding pump door opens during flushing/back pumping/feeding	Press the symbol "  " to pause audio. Closing the pump door can eliminate this alarm.
Almost Done	Low	Preset feeding volume Finish the first 3 min (the time can be set in system Settings)	Press the symbol "  " to pause audio. ★ Note: It can choose to close this alarm. See **8.3.12** herein.
Finished	High	1. Complete the preset feeding amount 2. The accumulated volume reached 36,000 ml	Press the symbol "  " to pause audio. Press the stop button to eliminate the alarm.
Occlusion	High	1. Feeding circuit occlusion	Press the symbol "  " to pause audio.

		2. occlusion sensitivity is too high	Refer to **8.3.10** in this manual to adjust the pressure alarm coefficient of enteral feeding pump obstruction.
		3. Enteral feeding pump sensor is faulty	Inform the distributor or the manufacturer for repair.
AC Fail	Low	Power failure/external power cord falling off after startup	Press the symbol “ ” to pause audio or press the icon to cancel the alarm sound. Turn on AC power again/ reconnect the AC power cord.
Low Battery (if only battery can be used in case of power failure or during moving)	Low	1. At least 30 min before stopping feeding due to battery depletion.	Press the symbol “ ” to pause audio. The alarm sounds again 1 min45s later if AC power is not supplied. Stop using and charge the battery fully.
		2. Battery aging or enteral feeding pump charging circuit fault	Inform the distributor or the manufacturer for repair.
Battery exhaust (if only battery can be used in case of power failure or during moving)	High	1. At least 3 min before automatic stop of the pump due to battery running out.	Stop using and charge the battery fully
		2. Battery aging or enteral feeding pump charging circuit failure	Inform the distributor or the manufacturer for repair.
Heating over temperature (In the case of a hot strip inserted)	High	1. Failure of external Heating Strip, heating out of control temperature exceeding 45°C	Inform the distributor or the manufacturer for repair.
		2. Circuit fault of heating	

System error	High	The enteral feeding pump system is malfunctioning	1.The enteral feeding pump is restarted once. If it alarms again, you can choose to restart the enteral feeding pump after resuming the factory setting. 2.If the alarm is still there, please contact the manufacturer for inspection and maintenance
Dedicated tube error	High	When the dedicated tube switch is turned on, the dedicated tube signal is not detected when starting the self-check	1. Install the dedicated tube to start the machine 2. Check whether the dedicated tube magnetic ring is normal 3. Please contact the manufacturer for inspection and maintenance
Battery fail	Low	No installed batteries are detected during start-up self-check	Check whether the battery is inserted normally and restart it. If the battery is detected normally, the alarm will be eliminated. If the battery is still not detected and continues to alarm, please contact the manufacturer for repair
No nutrition tube (with tube switch on)	High	No nutrition tube installation is detected when starting feeding	Press the symbol “  ” to pause audio. Press the stop button to eliminate the alarm. Reinstall the nutrition tube.
Air Bubble	High	The presence of bubbles in the tube is detected during feeding initiation or operation	After opening the door, press the symbol “  ” to eliminate the alarm .

Timed shutdown	Information signal	The automatic shutdown function is on, the machine is not in operation and the chronometer is less than 3 min	When the set time is greater than 3 minutes, press any key to cancel the information signal. When the set time is less than 3 minutes, the information signal cannot be cleared. The information signal can only be cleared when the timer shutdown function is turned off or the set time is greater than 3 minutes.
Without heating strip	Low	1. Turn on the Heating Strip function and the Heating Strip is not detected. 2. The Heating Strip is suddenly removed during heating	Press the stop button to eliminate the alarm. Re-insert the Heating Strip.
Standby end	Low	Standby function is turned on	Press the symbol “  ” to pause audio. press the symbol “  ” to eliminate the alarm .

★Note:

1. The sound pressure generated by the alarm volume is shown in the table below.

Priority	Sound pressure	Distance
High	52-75dB	1m
Low	50-72dB	1m

2. The operator position of enteral feeding pump is the position where the enteral feeding pump can be operated normally (0.5m), and the non-operator position may affect the operator's correct identification and alarm.

3. Delay time of triggering alarm signal is no more than 2S.

8.3 System settings

This section explains the setting of feeding parameters

Press system settings on the main interface to enter the system settings menu. System settings

are divided into user settings and admin setting.

User setting password: 11.

Administrator setting password: Please contact the manufacturer.

User password and administrator password can be modified in administrator settings

8.3.1 Volume setting

（1）Enter "Settings" - "User Settings" - "Volume level" - "Key sound" to turn key tone on or off.

（2）Enter "Settings" - "User Settings" - "Volume level" - “Volume Level", enter password to adjust the alarm volume.

★ Note: Please avoid to set the alarm volume too low. Please set it according to surrounding environment.

8.3.2 Display setting

Enter "Settings" - "User Settings" - "Display", drag the slider to adjust the backlight of the screen and the backlight of the keys.

★ Note: keypad backlight will automatically turn off without any operation.

8.3.3 Night mode setting

Enter "Settings" - "User Settings" - "Night Mode", turn on the night mode switch (it is off by default), set the start time, end time and brightness (screen brightness when entering night mode). When the current time reaches the start time, it will automatically enter the night mode. The icon will be displayed at the top of the screen. The brightness of the screen will automatically switch to the set night brightness. When the current time reaches the end time, the night mode will be automatically off. The night mode icon on the screen will disappear. The screen brightness will return to the brightness before the night mode.

8.3.4 Time and date setting

Enter "Settings" - "User Settings" - "Time & Date", it can set the time, date, date format. It supports three date formats:

Year - month - day(yyyy-MM-dd),

Day - month - year(dd-MM-yyyy),

Month - day - year(MM-dd-yyyy)), after setting, press OK to save and exit.

8.3.5 Automatic screen lock setting

Enter "Settings" - "User Settings" - "Auto lock screen". It can set it “Off” (password: 11), 15 seconds, 30 seconds, 1 minute, 2 minutes, 5 minutes, 10 minutes, 20 minutes, and 30 minutes. The factory default setting is 1 minute. After selecting the time, if the machine is not operated within the set time, the keypad and the screen will be locked. The  key lock icon will be displayed above the screen. Clicking the screen or pressing the keypad will pop up an interface “Unlock screen?”, press "OK" to confirm unlock the screen.

8.3.6 KTO speed setting

Enter "Settings" - "User Settings", click KTO rate to modify it, press OK to save and exit. When the feeding is completed, it will start KTO automatically .

8.3.7 Purge setting

Enter “Settings” - “User Settings” - “Purge”, set purge VTBI and purge rate as required, press OK to save and exit.

Mode	Default value	Adjusting range
Purge	Purge Rate: 800ml/h	(700-1200) ml/h
	Purge VTBI: 0ml	(0,1.0-9999.9) ml, 0 represents manual purge.

Note: Please use purge function before feeding, and please make sure the feeding tube is not connected to the patient.

8.3.8 Bolus setting

Enter “Settings” –“User Settings”- “Bolus”, set Bolus flow rate and Bolus volume as required, press OK to save it.

Mode	Default value	Adjusting range
Bolus	Bolus Rate: 400ml/h	(1-400) ml/h
	Bolus Volume: 0ml	(0,1.0-100.0) ml, 0 represents manual Bolus.

8.3.9 Back pumping setting

Enter “Settings” - “User Settings” - “Backpumping”, set back pumping rate and volume as required, press OK to save it.

Mode	Default value	Adjusting range
Back pumping	Back pumping rate: 125 ml/h	(1-400) ml/h
	Back pumping volume: 0 ml	(0,1.0-9999.9)ml, 0 represents manual back pumping.

8.3.10 Occlusion pressure level setting

Enter "Settings" - "User Settings" - "Occlusion" (if the patient is elderly or children, it is recommended to set the low occlusion level.)

The occlusion pressure has 7 levels adjustable (20kPa-80kPa). Four pressure units are available: Kpa, mmHg bar, psi.

The higher the occlusion level, the higher pressure value. Please select the occlusion level according to the demand. The occlusion levels and its corresponding pressure ranges are as below:

Occlusion level	Occlusion pressure range
Level--1	20±15kPa
Level--2	30±15kPa
Level--3	40±15kPa
Level--4	50±15kPa
Level--5	60±15kPa
Level--6	70±15kPa
Level--7	80±15kPa

Attention: 1. When using a high viscosity liquid and the occlusion pressure level is setting to a low level, there is possible occlusion alarm even there is no block in feeding tube. Please carefully check the feeding tube and the pressure level indicated on top of LCD screen. If necessary, please increase the occlusion pressure level.

2. When the occlusion pressure is setting to a high level, the pressure accumulated in the feeding tube is large. Please confirm the feeding tube connected firmly.

3. Before closing the door, please make sure the pressure in the feeding tube was released, otherwise the occlusion alarm will be inaccurate.

8.3.11 Air Bubble level setting

Enter "Settings" - "User Settings" - "Air Bubble Size", select the bubble size.

Air bubble size	Corresponding limit value
50μl (Level 1)	50μl±20%
100μl (Level 2)	100μl±20%
250μl (Level 3)	250μl±20%
500μl (Level 4)	500μl±20%
800μl (Level 5)	800μl±20%

8.3.12 Almost Done

Enter "Settings" - "User Settings" - "Almost Done", it can set 1 minute, 2 minutes, 3 minutes, 4 minutes, 5 minutes, 6 minutes, 7 minutes, 8 minutes, 9 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, and 60 minutes. The factory default setting is 3 minutes. After set the time, when the remaining feeding time is less than the set time, the "Almost Done" alarm will be triggered.

8.3.13 No operation

Enter "Settings" - "User Settings" - "No operation", it can set as “Off” (password: 11), 1 minute, 2 minutes, 3 minutes, 5 minutes, 10 minutes, 20 minutes, 30 minutes and 60 minutes. The factory default setting is 3 minutes. After setting the time, no operation on the machine within the set time will trigger "No operation" alarm.

8.3.14 Timed shutdown

Enter "Settings" - "User Settings" - "Timed Shutdown", it can set as “Off”, 1 minute, 2 minutes, 3 minutes, 5 minutes, 10 minutes, 10 minutes, 15 minutes, 20 minutes, 25 minutes, 30 minutes, 45 minutes, 1 hour, 2 hours, 5 hours, 10 hours, 20 hours. The factory default setting is off. The machine will shut down automatically if no operation within the set time. Shutdown countdown 3mins starts to display the timing shutdown prompt.

Note:

1.When the timer of shutdown time is less than that of forget operation time, it cannot be set.

2.The timer of shutdown function will only take effect in the non-running and non-alarm status.

8.3.15 Language setting

Enter “Settings” - “User Settings”- “Language”, select the required language.

8.3.16 View the event logs

The maximum history record is 50,000. When the historical records exceed 50,000, the new historical records will overwrite the old historical records. To enter the history record, you need to enter the user password: 11.

Enter “Settings” - “User Settings”- “infusion log”, , select “View Log” to directly view the feeding records on the pump. Choose "Upload Log" to view all specific records/alarm info on the computer. Only authorised after-sales service personnel are allowed to upload log.

(1) View history:

Select the date to view, press OK to confirm (the default date is the current date), click  to view the previous record, click  to view the next records. Click “Latest” will automatically jump to the latest record of the current date.Click the upper part of the history record area to view the previous line of records, and click the lower part of the history record area to view the next line of records.

The history records at least the following events: time, date and Id of the current history event, power on, power off, start feeding, stop feeding, start flushing, stop flushing, start back pumping, stop back pumping, start Bolus, stop Bolus, important parameters when starting feeding (feeding mode, feeding speed, feeding preset amount, total amount, calibration value, nutrient tube used), when stopping feeding Total amount, online change of feeding speed, KTO speed change, heating temperature switch, heating temperature change, alarm message.

(2)Upload Log:

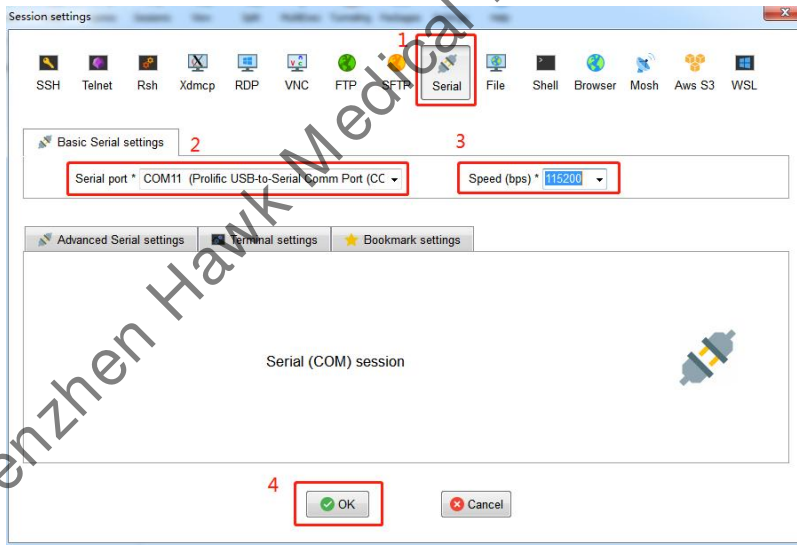
It can be connected to the computer by the communication interface for viewing. The specific operation process is as follows:

a.Open the HyperTerminal " 

"

b. Click "Sessions" to enter the Session setting interface.

c. Click "Serial", set the COM port (the specific COM port can be viewed in the computer device manager), set the baud rate: 115200, and then click " OK".



d. Enter the date you want to upload the history record in the upload history interface of the enteral nutrition pump, click upload, and wait for the prompt "Upload completed".

★Note:

1. If you need upload log, please contact manufacturer or our distributors.

2. History record is read-only mode and does not support user modification.

8.3.17 Patient information

Enter “Settings” - “User Settings” – “Patient information” to view and edit the patient info. It can select current patient at the bottom of screen. Click the corresponding patient to set the name, bed number, Id and age information.

The current patient bed number can be used to connect to the monitoring system.

★Note:To enter the patient information interface, you need to enter the user password: 11.

8.3.18 Device information

Enter “Settings” - “User Settings” – “Device info” to view the software version information.

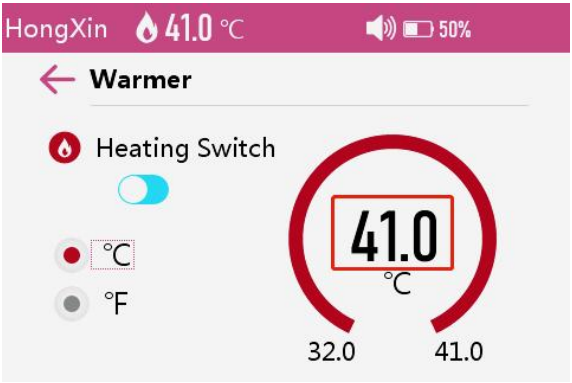
8.3.19 Heating Strip setting

Nutricare-300H can be equipped with external Heating Strips (the heating function can only be used by inserting external power supply). The heating temperature is from 32°C to 41°C, and the temperature difference is ±2°C. The ramp-up time to 41°C is less than 5min at an ambient temperature of 25±3°C.

(1) Method of setting: Click the “Warmer” in the main interface, click the temperature value area, enter the required temperature, click OK to save and exit. Press heating switch button to switch on heating function, the current temperature will display at top of screen. It can set heating function as on or off, choosing temperature unit as °C or °F.

(2) After heating, the actual temperature of the nutrient fluid is affected by the feeding rate and the ambient temperature. The lower the flow rate and the higher the ambient temperature, the higher actual temperature of the nutrient fluid. The highest temperature is 41°C.

(3) With the heating on, click the temperature value area in the top status bar in the main interface to enter the “Warmer” settings screen.



8.4 Admin Settings

Enter “Settings” -“Admin Setting”, Enter the administrator password. Ordinary users are not allowed to use this setting.

8.4.1 Nurse call

Enter "Settings" - "Admin Settings" - "Nurse Call", click On or Off to turn on or turn off the function.

Nurse call function means that this device can output a signal to the nurse call system to call the nurse when an alarm occurs. The device provides a nurse call interface to output nurse call signal when a alarm occurs. To obtain nurse call signal, use the nurse call cable to connect the hospital`s nurse call system with the device`s nurse call interface.

Alarms are indicated on the nurse call device only when the following conditions are met:

■ The nurse call system is enabled.

■ A alarm occurs.

★Note: Do not rely exclusively on the nurse call system for alarm notification. Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient`s clinical condition.

8.4.2 Dedicated tube

Enter "Settings" - "Admin Settings" - "Dedicated tube", click “On” or “Off” to turn on or turn off the function. If the setting is on, please install the dedicated set before switching on the pump. If the enteral feeding set is installed without the dedicated key, the alarm of wrong dedicated set will be triggered during system self-checking when switch on the pump, and the machine will not work.

★Note:

1. If you need to enter the special tube setting interface, please contact the manufacturer to provide a password, which can be modified, please keep it properly after modification. If you forget your password, please contact the manufacturer.

2. Dedicated tube function ensures the accuracy and safety in feeding process.

3. You are highly recommended to use the dedicated tube stated in this manual. Otherwise, the accuracy of the feeding and the performance of the pump cannot be guaranteed.

Brand	Specification and model	Manufacturer
Hawkmed	Disposable Infusion Enteral Giving Sets	Jiangxi Hawk Medical Supplies Co. Ltd.
HongXin	Enteral feeding bag(Pump type)	Jiangsu HongXin Medical Device Co., Ltd.

4. To add other brands of dedicated tube, you must contact the manufacturer for help.

8.4.3 Tube switch

Enter "Settings" - "Admin Settings" - "Tube switch". If the tube switch is off, the enteral feeding pump will not give “No nutrition tube” alarm if the tube is not installed properly.

8.4.4 WIFI

The enteral feeding pump supports wireless WIFI network connection. It can be connected to HK-M1000 infusion monitoring software to check the feeding situation in real time. Please refer to the following steps:

WIFI Setting: Select WIFI under the admin settings, set the WIFI switch as "On" to enable WIFI function. It will connect to the last successfully linked network by default.If the network environment has changed, you need to reconfigure the WIFI module, the configuration method is as follows:

1. WIFI name and WIFI password configuration: click WIFI list, wait for the search to finish, click the WIFI name you need to connect, enter the WIFI password, and click 'OK' to save it, it will be automatically connected after successful saving. If you can't find the WIFI name in the WIFI list, you can also configure it manually by going to "Admin Setting" - "WIFI" - "WIFI Configuration" to manually configure WIFI name and WIFI password.

2. WLAN IP configuration:

Enter "Extended Settings", and the configuration items are shown in the following table.:

Menu items	**Default Setting**	**Description**
Protocol Type	Default: UDP Unicast	There are four types available: TCP Server, TCP Client, UDP Boardcast, UDP

		Unicast. Connect to HK-M1000 infusion monitoring software and select the default one.
Remote IP	192.168.1.90	To be consistent with the IP address of the PC
Remote port	6111	Consistent with HK-M1000 infusion monitoring software settings
Local port	6373	Consistent with HK-M1000 infusion monitoring software settings
DHCP	On	Set whether to obtain IP address automatically

Enter "WIFI Configuration", the configuration items are shown in the table below, if the DHCP switch is on, the following configuration is not needed..

Menu items	Default Setting	Description
Local IP	192.168.1.100	Valid when DHCP is off
Subnet Mask	255.255.255.0	Valid when DHCP is off
Default Gateway	192.168.1.1	Valid when DHCP is off

After the above configuration is successful, WIFI will be reconnected and the corresponding WIFI signal icon will be displayed on the top status bar after successful connection.

After connected to HK-M1000 infusion monitoring software wirelessly, the enteral nutrition pump will send feeding information, alarm information and system setting parameters to HK-M1000 infusion monitoring software in real time. Please refer to the manual of HK-M1000 infusion monitoring software for detailed description.

If WIFI is disconnected , the icon “  ” will be displayed on the screen.

Note: The installation of the wireless network must be carried out by the technical personnel or service engineer approved by the manufacturer.

8.4.5 Regular Maintenance

Enter “Settings” - “Admin Settings” - “Regular maintenance”, select maintenance time (3 months by default), after setting, press OK key to save parameters and exit.

This function is mainly to remind the user to carry out regular maintenance of the machine and set the interval time of maintenance. When switch on the pump, a reminder box will pop up to remind the user to carry out maintenance.

8.4.6 Factory Reset

Enter "Settings" - "Admin Settings" - "Restore Default", a prompt will pop up and the factory settings will be restored after confirmation.

8.4.7 Change Password

Enter "System Settings" - "Admin Settings" - "Change Password", enter the password modification interface, you can choose to modify the user password and administrator password, click the password area to be modified, the numeric keyboard interface will pop up, and then enter the new password, Press OK to save and return.

★Note: Please keep it properly after changing the password. If you forget your password, please contact the manufacturer.

8.5 Feeding tube

You can select the desired brand of enteral giving set. Users are recommended to use the following built-in brands. Only the enteral giving sets conforming to applicable standards and having a valid CE certificate can be used on the enteral feeding pump.

★Note：

1. You are highly recommended to use the enteral giving set brands specified for the enteral feeding pump. Otherwise, the feeding accuracy cannot be guaranteed.

2. To add other brands of enteral giving set, you must contact the distributor for help. The specialized persons of the distributor will conduct a setting and perform a test after adding a brand to ensure the feeding accuracy.

3. If the user requests to add a new brand of nutrition tube by himself, please contact the local dealer or the after-sales service department of the manufacturer for the setting method.

4. If you insist on adding a new brand by yourself, please contact the local distributor or the after-sales service department of the manufacturer to ask for the setting method.

5. To access the feeding tube screen you need to enter the user password: 11.

Nutricare-300H nutrition tube:

Brand	Specification and model	Manufacturer
Hawkmed	Disposable Infusion Enteral Giving Sets	Jiangxi Hawk Medical Supplies Co. Ltd.
HongXin	Enteral feeding bag(Pump type)	Jiangsu HongXin Medical Device Co., Ltd.

8.5.1 Regular feeding tube

Enter "Feed tube" - "Regular feeding tube", select a commonly used brand , when the quantity of brands selected is more than 1, and the door detects a tube, the "Select Feeding Tubes" interface will pop up, please select the correct brand of feeding tube (the brand selected should be the same as the brand of feeding tube used).

★Note 1: If the brand chosen is not the same as the brand of feeding tube used, feeding accuracy may be affected.

8.5.2 Self-defined feeding tube

Enter "Feed tube" - "Self-define Tube", enter password 11, choose the tube number, enter tube brand name. Make precision calibration, pressure calibration and so on.

8.5.3 Accuracy calibration

1. Select the feeding tube to be calibrated, enter the accuracy calibration interface, press the purge key until there is liquid flowing out (exhaust the air bubble). Install feeding tube as per above instructions, press start key to start the calibration. During calibration, the running indicator will flash and the sector will be dynamically filled. When the filling is completed, the calibration is done.

2. After the sector area is filled, a prompt will be displayed. Press "Confirm" or "Cancel" to clear the prompt. Click the middle area of the sector to input the liquid volume actually flowed out, the calibration is completed. If actually flowed out liquid volume is out of the range displayed on the screen, please recalibrate.

8.5.4 Pressure calibration

1. Select the feeding tube needed calibration, enter the pressure calibration interface, press start button after operating according to the instructions.

2. Observe the reading of the pressure gauge. When the reading of the pressure gauge is between 60-100kpa, press stop button, input the reading of the pressure gauge in the middle of the sector. Press OK key to confirm. It will prompt that the calibration is completed. If the pressure exceeds 100kpa during calibration, re-calibrate after releasing the pressure in the tube.

Note: Please use the same brand and model of feeding tube with the one that under accuracy and pressure calibration, otherwise calibration value is invalid.

8.6 Operation Precautions

- After the feeding tube is continuously used for 24 hours, a new feeding tube should be replaced to ensure the accuracy. Meanwhile pay attention to the length of the feeding tube. Use extension lines if necessary in case the feeding tube is stretched out of position when patient turns his body.
- Avoid exposing the enteral feeding pump to direct sunlight, high temperature or high humidity.
- If the pump work on battery only, please check battery capacity before operation and make sure it has enough power. Otherwise, recharge the battery fully.
- Avoid using the enteral feeding pump with problems, which may cause medical accidents and bring harm to patient's health and even life.
- Only well-trained professionals are permitted to set or adjust feeding parameters.
- The damaged front panel (mask) needs to be replaced in time to prevent leakage.
- Enteral feeding pump works under conditions that exceed the prescribed range may influence feeding accuracy or even cause malfunction.
- The degree of viscosity and ratio of nutrient liquid may influence feeding accuracy.
- The feeding tube used on this enteral feeding pump should get valid Medical Device Registration Certificate.
- If using new brand of feeding tube, please calibrate its accuracy on machine before use.

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

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

★Note:

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

11.1.1 Preparations

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

2. The device must be powered off, and the AC and DC power cords 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

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

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

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

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

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

★Note：

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

Recommended detergents:

Detergent Name	Cleaning Method
Clean water	Wipe

11.1.3 Disinfection

Disinfect the machine according to the disinfection procedures of your hospital. The disinfection steps are as follows:

1. Before disinfection, please clean the equipment according to the method described in Section 11.1.2.

2. When disinfecting the surface of the equipment, use soft and lint-free gauze to immerse in medium and high-efficiency disinfectants.

After the cloth is fully wet, wring it dry until no liquid drips, and wipe the surface of the device with gauze.

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

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

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

★Note

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

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

Recommended disinfectant solution:

Disinfectant Solution 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 user manual.

11.3 Periodic Inspection

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

Check if the Occlusion alarm is given within 1-10 seconds.

(1)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.

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

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

11.3.2 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 delivery accuracy periodically.

(1) Install the feeding tube to the enteral feeding pump, close the door and open the flow clip.

(2) Calibrate the accuracy as per instructions of 8.5.3.

(3) After calibration, set feed rate at 150ml/h and feed VTBD as 10ml to test delivery accuracy. The delivery accuracy should be within ± 5%.

11.3.3 Inspect internal battery

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

(1) Firstly, charge the battery fully (for 7000mAh, 12 hours with power on, or 7 hours with power off; for 3000mAh, 6 hours with power on, or 4 hours with power off;).

(2) Let enteral feeding pump work on battery only, and set feed rate at 125ml/h. Record the whole working time when the battery is exhausted.

- If feeding time more than 90 minutes, the battery is in good condition.
- If feeding time more than 45 minutes but less than 90 minutes, the battery starts low quality but still can be used.
- If feeding time is less than 45 minutes, the battery reaches the end of its life and needs to be replaced.

11.3.4 Replace internal battery

(1) Loosen the 4 screws that fix the cover, open the cover, unplug the flexible cables on the cover, and take off the cover.

(2) Remove the plate screws and the plate pressing the battery.

(3) Unplug the battery connector and take out the battery.

(4) Tidy the output wire of the new battery and insert it into the battery compartment. Lock the plate with screws and connect the battery connector to the main board plug.

(5) Retrieve the previously removed cover assembly, connect the flexible cable ,cover it on the back cover and fasten the screws. Check the working status of the 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 more than 1 month, 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

13.1 Standard configuration in package

1. Enteral feeding pump	1
2. DC-12V adapter with waterproof cover	1
3. AC Power cord	1
4. User Manual	1
5. Product qualification certificate	1
6. Product warranty card	1
7. Fix clamp	1
8. Heating Strip	1

The above accessory is dedicated accessory for the equipment. To replace the above equipment, please contact Shenzhen Hawk Medical Instrument Co., Ltd. for replacement. If incorrect accessories are used or unauthorized modified, it will cause malfunctions such as equipment unrecognition, inaccuracy, and alarm.

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 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.

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

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-4th 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

Alarm classification	Alarm priority	Color/ frequency of alarm indicator light	Alarm signal delay
System error	High	Red light/ 2 Hz	<1s
Door Open	High	Red light/ 2 Hz	<1s
Occlusion	High	Red light/ 2 Hz	<1s
Low Battery	Low	Yellow light on	1s
Battery exhaust	High	Red light/ 2 Hz	1s
Dedicated tube error	High	Red light/ 2 Hz	<1s
No nutrition tube	High	Red light/ 2 Hz	<1s
Battery fail	Low	Yellow light on	<1s
Heating over temperature	High	Red light/ 2 Hz	1s
Without heating strip	Low	Yellow light on	<1s
Air Bubble	High	Red light/ 2 Hz	<1s
Almost Done	Low	Yellow light on	<1s
Finished	High	Red light/ 2 Hz	<1s
AC Fail	Low	Yellow light on	<1s
No operation	Low	Yellow light on	<1s
Standby end	Low	Yellow light on	<1s

Table 2 Alarm sound interval time

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

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

- Nutricare-300H 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 Nutricare-300H 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

- Nutricare-300H 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 Nutricare-300H 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 Nutricare-300H enteral feeding pump.

Cable Information:

S/N	Name	Cable length (m)	Shield or not	Remarks
1	AC Power cord	2.5 m	No	Magnetic loop
2	Control line, I/O line	/	/	/
3	Interconnection cord	/	/	/
4	Patient cable	/	/	/

3. Guidelines and manufacturer's statements:

Guidance and manufacturer's declaration - electromagnetic emissions		
The model Nutricare-300H are intended for use in the electromagnetic environment specified below. The customer or the user of the model Nutricare-300H should assure that they are used in such an environment		
Emissions test	**Conformity**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model Nutricare-300H 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.
RF emissions CISPR11	Class B	The model Nutricare-300H 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity			
The model Nutricare-300H are intended for use in the electromagnetic environment specified below. The customer or the user of the model Nutricare-300H 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 ±1 kV 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, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±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 0.5 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	<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 Nutricare-300H require continued operation during power mains interruptions, it is recommended that the model Nutricare-300H 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 Nutricare-300H are intended for use in the electromagnetic environment specified below. The customer or the user of the model Nutricare-300H 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 to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 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	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless	Portable and mobile RF communications equipment should be used not closely to any part of the model Nutricare-300H, including cables, and the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V_1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). 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

	60601-1-2:2014)	communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	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 Nutricare-300H are used exceeds the applicable RF compliance level above,

The model Nutricare-300H should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Nutricare-300H.

[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 Nutricare-300H

The model Nutricare-300H are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Nutricare-300H can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Nutricare-300H are recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W) 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 $d=2.3\times P^{1/2}$
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

a) User access control mechanism: use password for user identity identification Electronic interface:Type-C interface

b) Data type: equipment operation information (alarm signal, feeding preset amount, feeding speed)

c) Technical features: through the wired multifunctional serial line connection to form a domain network, through the electrical port for RS232 standard protocol for one-way data communication. Communication interface configuration: 115200, send characters for ASCII code.

d) Network security features configuration: data transmission type for one-way transmission; equipment end related records can not be deleted by.

e) Security mechanism: transmission data encryption

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

g) Running 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.

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

The above data test conditions:

1. Feeding tube brand: Hawkmed

2. Test temperature: 25±2℃

3.Tube length: 1m

★ 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:

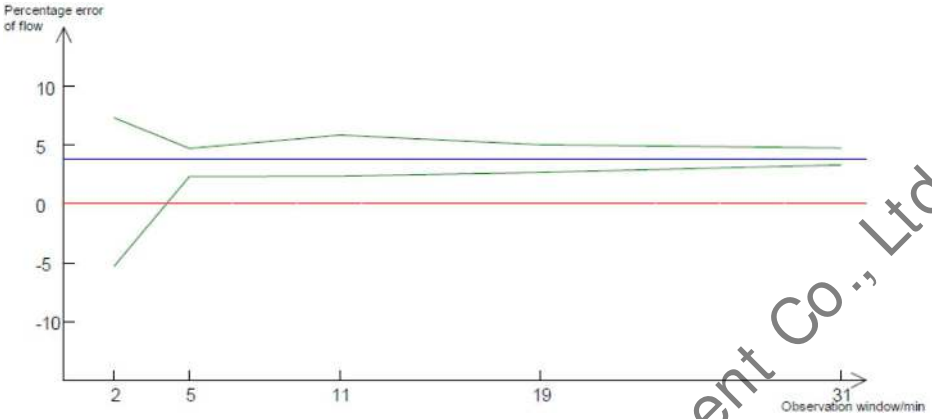
- Feeding accuracy may be affected by the environment in which the device is used (pressure, temperature, humidity, brand of nutrition tube used, concentration of nutrient solution, etc.)
- Feeding accuracy does not reflect clinical criteria such as patient age, weight or medications used.
- The following experimental data only represent laboratory data.

The following data test conditions:

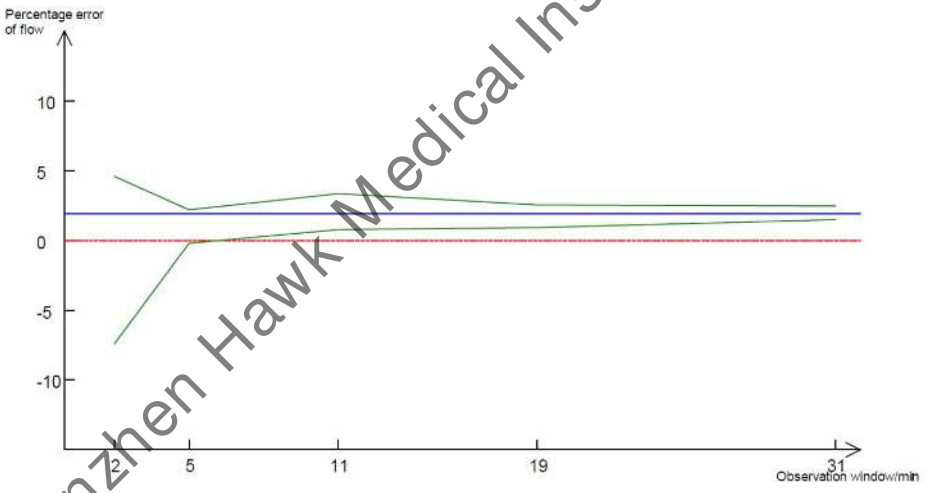
- Pump Sampling qty: 3 samples.
- Feeding set Brand and Model: Jiangxi Hawk enteral feeding set.
- Use continuous feeding mode.
- The experimental sampling time is 0.5min, the test period is 8h, and the test temperature is 25±2°C.

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

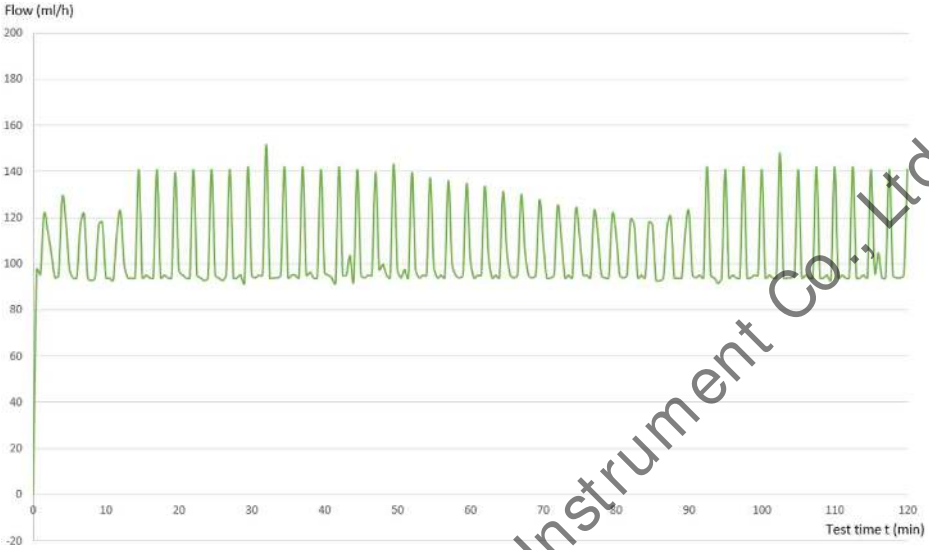
2. Trumpet curve in the second hour（T1）, Condition：Normal condition, 100ml/h



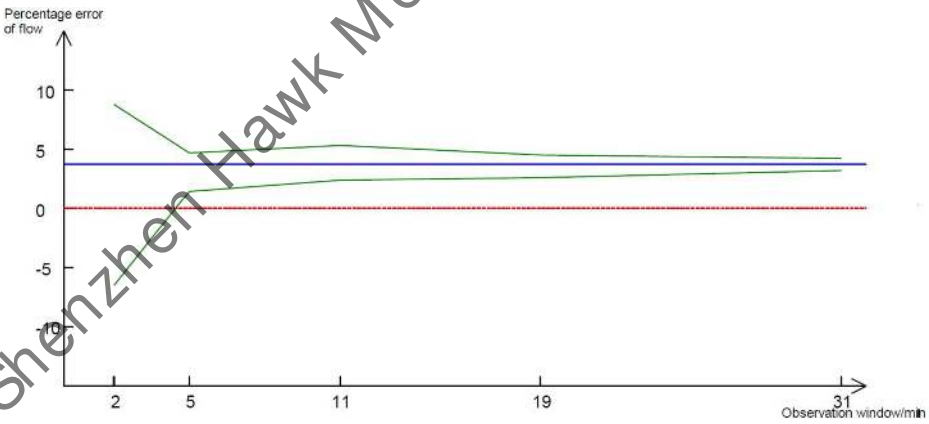
3. Trumpet curve in the last one hour（T2）, Condition：Normal condition, 100ml/h



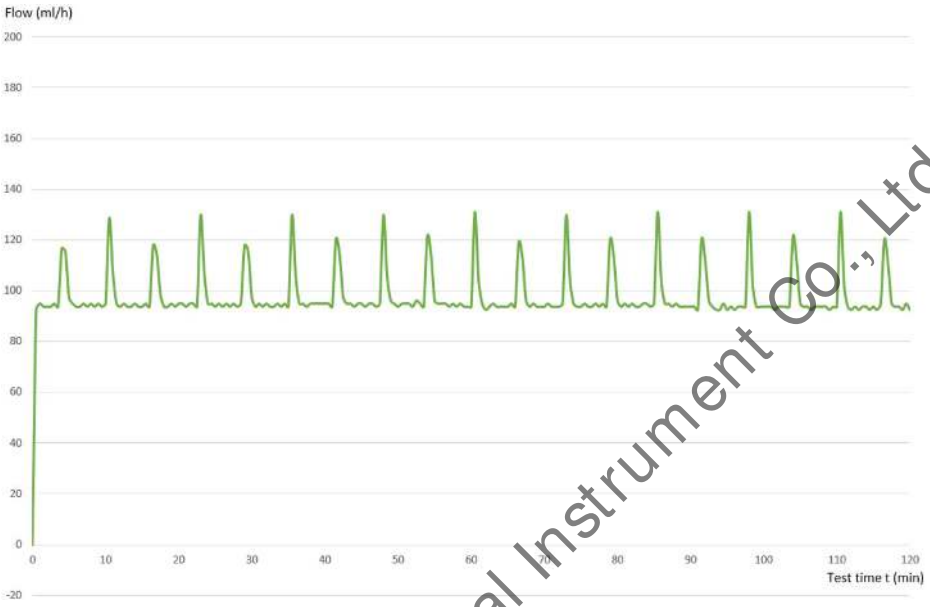
4. Starting curve in the first two hours, Condition：+13.33kPa background pressure, 100ml/h



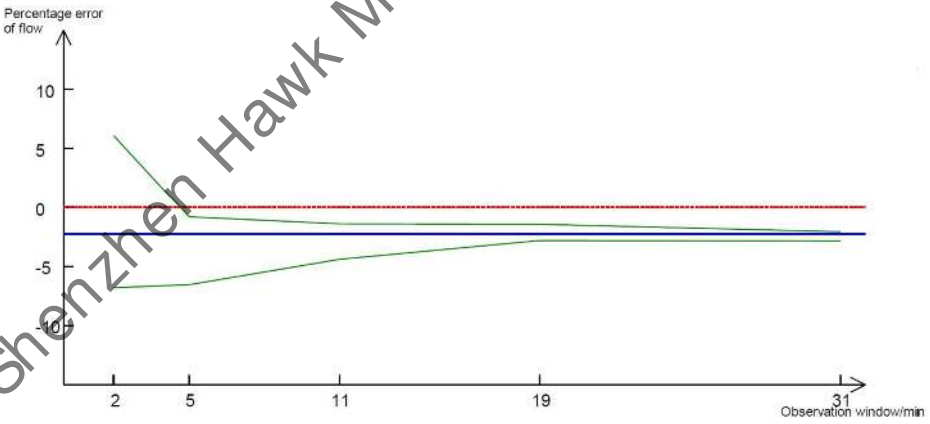
5. Trumpet curve in the second hour（T1）, Condition：+13.33kPa background pressure, 100ml/h



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℃

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