Shenzhen Hawk Medical Instrument Co., Ltd

ENTERAL FEEDING PUMP

Model: HK-300

USER MANUAL

V1.0

Please read the manual before using the product;

Please keep the manual for reference !

CE 0120

Table of Contents

1. Warnings & Cautions

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

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

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

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

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

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

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

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

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

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

j) The enteral feeding pump can not use for blood transfusion.

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

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

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

n) It can not be used for ambulance.

Cautions: Failure to follow cautions below may lead to injury of operator/patient or loss of property.

a) Inspect the enteral feeding pump before use, making sure it can work normally. If any malfunction

is found, stop operation immediately and contact the distributor or the manufacturer. Besides, adhesion or leakage of nutrition may lead to malfunction of the enteral feeding pump. Therefore please clean the enteral feeding pump and store it properly after each use.

b) When use the enteral feeding pump the first time after purchasing or after long-time of storage, please connect it to AC power source and charge it for at least 10 hours with power on, or 3 hours with power-off. If not fully recharged, the internal battery can't support the enteral feeding pump with enough power in case of AC power failure.

c) If using near electric cautery equipment, the enteral feeding pump may result in wrong operation due to the high frequency wave of electric cautery equipment. If the enteral feeding pump has to be used with electric cautery equipment, please take proper measures as follows:

(1) Avoid using the enteral feeding pump along with old-fashioned electric cautery apparatus (open vacuum tube).

(2) The distance between enteral feeding pump and the body of electric cautery apparatus or its power source should be more than 25cm.

(3) The enteral feeding pump shall not use the same electric cabinet as that of electric cautery apparatus, and having reliable ground connection.

d) Do not use mobile phone, wireless device or cardiac defibrillator within 1 meter near the enteral feeding pump. Otherwise the high frequency noise/signal may cause wrong performance of the enteral feeding pump. Make sure the enteral feeding pump has ground connection and do not use the same power socket with that for the above-mentioned devices.

e) The enteral feeding pump can not use in area with radiotherapy equipment or magnetic resonance (MR) equipment or hyperbaric oxygen therapy.

f) Do not use pointed object like pen-tip or finger nail etc) to press on keys of the enteral feeding pump. Otherwise, the keys or the mask may suffer premature damage.

g) Keep the infusion bag, the enteral feeding pump a certain distance from the AC power source and DC socket to prevent the nutrition from splashing or dropping onto the socket to incur shortage of circuit. In addition, make sure the power plug and socket are dry before connecting to power source.

h) In normal conditions, try to use AC or DC power source to extend battery service life. When use AC power source, making sure it is well connected to ground and please use the power cord that is standard configuration with the enteral feeding pump. Just use battery when there is difficulty in ground connection or without AC power (such as AC power failure or mobile infusion).

i) Do not use the same segment of enteral feeding set for over 6 hours. The tube may be out of shape due to long-hour squeeze by the peristaltic fingers and thus cause accuracy error. It is suggested to move to a new section (15 cm upward or downward) after every 6 hours of usage, and then start operation again. Or replace the feeding bag with a new one.

j) To prevent free flow after door open please make sure to close the flow clip of feeding bag before taking it out of the enteral feeding pump.

k) Pay more attention to occlusion when infusion at low rate. The lower the rate, the more time needed for detecting occlusion, thus there may be a long interval of infusion interruption.

l) When using computer port, it may suffer interference from devices such as electric cautery apparatus, mobile phone, wireless device or cardiac defibrillator etc. Please try to keep away from the above-mentioned devices.

m) If enteral feeding pump falling off or suffering collision, stop using it immediately and contact the distributor or the manufacturer. Even there is no damage on appearance or no malfunction alarm, the internal parts may have damaged.

n) The enteral feeding pump must be operated by well-trained professionals such as doctor, nurse and medical device expert.

o)) Do not disassembly or modify the enteral feeding pump or use it for other purposes other than normal infusion. Otherwise, the manufacturer takes no responsibility.

2. Introduction

2.1 Features

Compact and light weight

User-friendly interface, easy parameters setting

2.8 inch colorful LCD with detailed menu

Internal multiple reliable design and alarm functions, more stable and safer infusion

Apply to vertical pole or horizontal bar

Removable pump body for easy cleaning

2.2 Application scope

a) Applicable for patient who without swallowing ability and have to use nasogastric feeding to supply the nutrition.

b) Intended use : An electromechanical peristaltic pump that administers nutrition directly to a patient

at a programmed flow rate through a trans-nasal feeding tube

2.3 Type and specifications

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

2.4 Operating conditions

a) Temperature: 5℃-40℃

b) Relative humidity: 10-95% (no frosting)

2.5 Affection on environment and energy

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

3. Components

The enteral feeding pump is mainly composed of 5 parts: microcomputer system, pump body, detection device, alarm system and Input & display part.

Microcomputer system: the brain of the whole system, giving an intelligent control and management to the whole system and processing signals detected, adopting double CPU.

Pump body: the heart of the whole system and the driving force of transfusing nutrition, squeezing nutrition forward along peristaltic fingers driven by step motor.

Detection device: mainly containing sensors, such as pressure sensor (for detecting occlusion) etc. They can detect corresponding signals, which after being amplified and transferred to microcomputer system for signal processing and thus incur control instruction for corresponding operation.

Alarm system: The signals detected by the sensor, after being processed by the microcomputer, shall incur alarm control signal and then at the response of alarm system, which alert the user for immediate correct operation. It contains mainly photoelectric alarm (light emitting diode) and audible alarm (loudspeaker and buzzer) etc.

Input & display part: Press keypad to set all parameters such as infusion volume and flow rate. LCD displays all parameters and present operation status.

4. Technical and specifications

Infusion accuracy	±10%
Applicable enteral feeding set	Any brands of enteral feeding set with diameter: 3.4~4.5mm
Flow rate range	1-400ml/h increment selectable: 1ml/h, 10ml/h or 100ml/h
Volume to be infused (VTBI)	1-9999ml,or 0 (no limit on VTBI) increment selectable: 1ml/h, 10ml/h, 100ml/h or 1000ml/h
Volume infused	0.0-36000ml
Alarm functions	Visual and audible alarms: Door open, Occlusion, Infusion completion, Empty, No operate, Low Battery, Battery exhausted, malfunction etc.
Bolus rate	400ml/h
Purge rate	400ml/h
Occlusion pressure	40-160kpa; 3 levels (adjustable): low, middle, high; default: middle
RS-232 port (optional)	RS-232 port enables user to check infusion/alarm record in computer terminal.
Water Proof Level	IPX3
AC power	100-240V 50/60Hz
Battery	Lithium Polymer 7.4V 1900mAh. Recharge time: 10h with power on, 3h with power off. Running time: more than 3h at rate of 25ml/h, environment temperature 25℃ after being fully charged.
Fuse	Slow Fuse, specifications: 250V 2A
Power consumption	25VA
DC	DC 12V ±1.2V

	Note： It can not be used for ambulance.
Operating conditions	Environment temperature 5℃～40℃ Relative humidity: 10-95% (no frosting) Air pressure: 86kPa～106kPa
Dimensions	145(L)x 120(H)x 100(W, not including pole clamp)mm
Net weight	≤1.4kg

5. Installation

5.1 Installation conditions and technical requirements

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

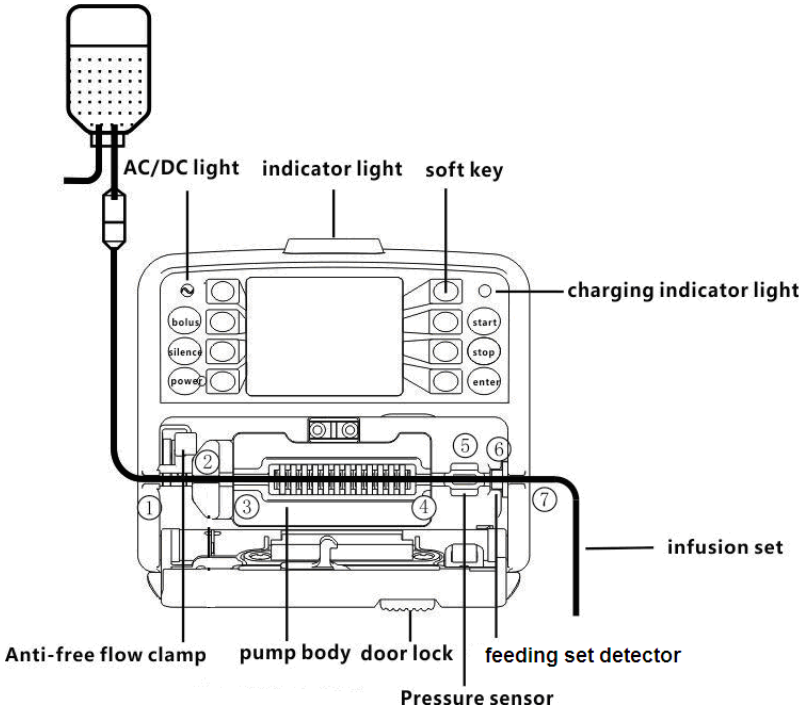
5.2 Installation method and cautions

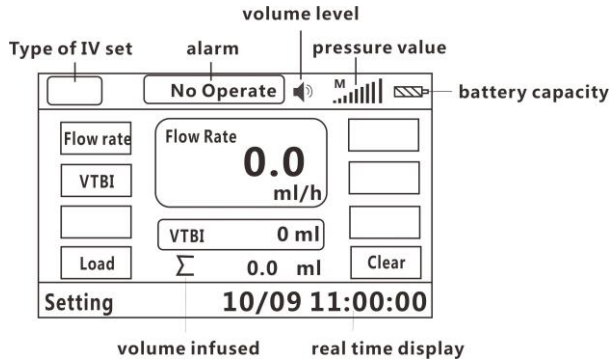
If the pole clamp is not in the same direction with that of IV stand or bar, adjust it to suit the direction of the IV stand or bar.

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

6. External Features

6.1 Front panel (diagram 1)



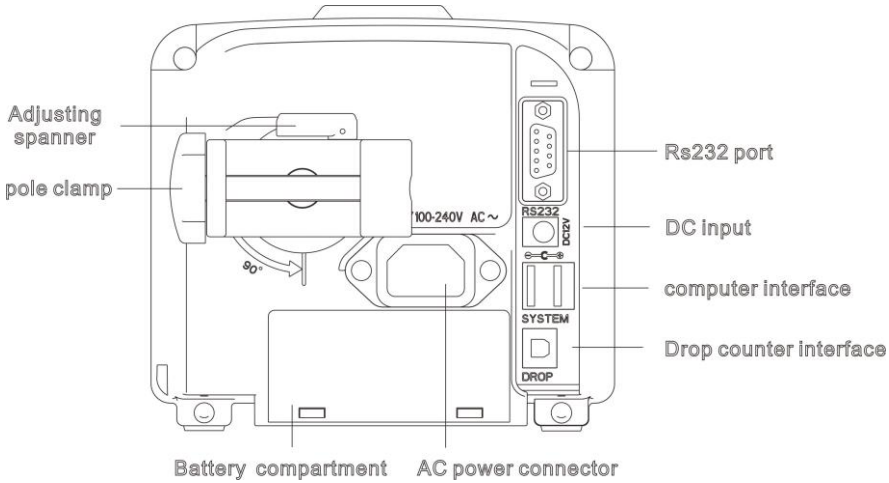


(LCD display)

Description	Functions
BOLUS key	In 'stop' status, press & keep finger on 'bolus' key, the pump starts purging (default purge rate: 400ml/h). After releasing the finger, purging stops. During operation, press & keep finger on 'bolus' key, the pump starts bolus infusion (400ml/h). Release the finger, bolus infusion stops and the pump continues infusion at original rate.
SILENCE key	Press this key to silence the alarm signal
START key	In 'stop' status, press this key to start infusion.
POWER key	Switch on / off the enteral feeding pump. In 'power off' status, press this key until LCD screen displays, which means the pump is switched on. In 'power on' & 'stop' status, or in 'alarm' case, press this key for about 2 seconds, the pump shall be switched off.
STOP key	Press this key to stop infusion.
ENTER key	Press this key to confirm / save the parameter newly setting
Soft key	The soft keys have various functions. Pressing the key next to the text displayed in the LCD, the text will be highlighted for further parameters setting by pressing soft keys again.
AC / DC indicator light	If on, it indicates there's AC/DC input; if off, it indicates there's no AC/DC input.
Charging indicator light	This indicator light on means the battery is recharging.
Door lock	Pressing the door lock, the door shall pop open automatically. Press the door with a bit force to close the door. A 'click' sound indicates the door is well closed.
feeding set detector	It can identify the dedicated feeding bag, or prevent the feeding bag from being installed in wrong direction. This function is optional. (This function is not available yet for this version)

Description	Functions
Indicator light	Indicator light on top of the pump indicates operating status/alarms cases. If the feeding bag is correct installation, the indicator light shall be green after the door is closed, which also indicating the pump is ready for operation. The green indicator light flashes when the infusion is in normal progress. If high-priority alarm occurs during operation, the indicator light shall turn red and flash. If middle-priority alarm occurs during operation, the indicator light shall turn yellow and flash. If low-priority alarm occurs during operation, the indicator light shall turn yellow but not flash. ★ Please refer to Annex Table I for priority of alarm classification

6.2 Rear panel (Diagram 2)



Description	Functions
Pole clamp & adjusting spanner	It is used to fix the enteral feeding Pump on IV stand. Draw the adjusting spanner outward or upward; then rotate clamp for 90°for horizontal bar or vertical stand; then draw the spanner back in place to fix the clamp.
Adjusting spanner	Rotate 180° , used to adjust the clamp direction.
Battery compartment	Battery location. Open it from the bottom of machine.
AC power connector	The socket for connecting to AC power source.
RS-232 port	It is used to connect enteral feeding pump to standard PC to transfer infusion history records. **Note: This process must be carried out when machine in non-infusion state.**
DC input	It can be connected to exterior DC power supply (12V±1.2V). Must use the adapter that in accordance with IEC 60601-1.
computer interface	This socket is for connecting to infusion monitoring system. (This function is not available yet for this version)
Drop counter interface	This interface is for connecting to exterior drop sensor. (This function is not available yet for this version)

6.3 Label

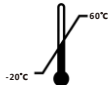
6.3.1 Product label (on the back shell)

The label contains information such as manufacturer, date of production, product serial No., classification, waterproof level, etc.

6.3.2 Symbols and significance

(Table 1)

Symbols	Descriptions
LOT	Production batch No.
SN	Product serial No.
	Caution， consult accompanying documents
	Consult instruction for use
	Type CF
	Protective Earthing
IPX3	Waterproof level: dripping water by slope angel 60°
	AC power
	DC power

Symbols	Descriptions
	Dispose in environmental-friendly way
	Date of production
	manufacturer
	Caution Against Wet
	Fragile. Handle with care!
	Keep upright during transport
	5 layers at most of the same package
	Transport package humidity 10～95%
	Transport package temperature -20°C～60°C
	Authorized Representative in the European Community

7. Preparation and inspection

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

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

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

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

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

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

8. Operation Method

8.1 Operation

The whole infusion operation contains the following processes:

1) Fix the enteral feeding pump and connect it to AC power.

2) Switch on / off

3) Fill the feeding bag with nutrition and install it in the enteral feeding pump

4) Set infusion parameters

5) Purge the air in line

6) Clear Σ (volume infused)

7) Start infusion

8) Bolus infusion

9) Stop infusion

10) Infusion completion

11) Replace feeding bag

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

8.1.2 Switch on/off.

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

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

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

(1) Put the flow clip down stream of the enteral feeding pump and close the flow clip tight. Put nutrition into feeding bag, and then squeeze the drip chamber to fill with 1/2 of nutrition. Open

the flow clip and let the nutrition flow to the tip of the needle. Then close the flow clip again.

(2) Install the feeding bag

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

8.1.4 Set infusion parameters

Rate: Press for 'rate' and input rate value. Press ENTER key to save the value and exit to the main menu.

VTBI: Press for 'VTBI' and input volume to be infused. If you are to infuse all the liquid inside the bottle, do not input VTBI value (just leave it as '0ml'). Press ENTER key to save the value and quit to the main menu.

Load: Press for 'Load'. It can directly load the rate and VTBI of last infusion.

★ After pressing 'Load', please check and verify if the rate and VTBI are the ones you need for this infusion, otherwise you need to reset the rate and VTBI.

8.1.5 Purge

In 'stop' status, press & hold on BOLUS key until all air inside the tube is purged. After exhaust the air, connect feeding pipe output connector and nose intestine connected catheter together.

8.1.6 Clear the volume infused

Press for 'clear' to clear Σ (volume infused) as '0.0ml'.

★ If Σ (volume infused) is not cleared after VTBI completion, when the next VTBI less than the previous Σ (volume infused), the pump shall give FINISH alarm and this FINISH alarm can only be eliminated by clearing the previous Σ (volume infused).

8.1.7 Start infusion

Confirm the top indicator light turning green and the feeding bag clipper is open, press START key to start infusion. Flow rate and VTBI shall display in the middle and Σ (volume infused) shall display in the lower right corner.

During infusion, only BOLUS key and STOP key shall function.

8.1.8 Bolus infusion

During infusion, press & keep finger on BOLUS key, the pump shall start bolus infusion at

default rate. Releasing the finger, the pump shall continue infusion at original rate.

8.1.9 Stop infusion

During infusion, press STOP key to stop infusion. Press START key to re-start infusion.

8.1.10 Infusion completion

After VTBI completion or Σ (volume infused) reaching 36000ml, the pump will stop function give alarm. Press STOP key to stop infusion.

8.1.11 Replace the feeding bag.

★ If you need to replace feeding bag, please follow steps below:

Close the flow clip of feeding bag. Open the pump door and take out the feeding bag.

As per instructions of 8.1.3, fill the new feeding bag with nutrition and install it properly. Restart infusion as required.

★ The feeding bag may be out of shape due to long-hours squeeze by the peristaltic system and which can cause accuracy error. It is suggested that change the section of the enteral feeding set that is against peristaltic chips or replace a new enteral feeding set after continuously working for 6 hours.

8.2 Alarms and solutions

During infusion preparation and infusion process, alarms may occur as follows. Please treat them as per instructions below. Table 2（Refer to Annex Table1,2&3 for corresponding alarm parameters）

Name of alarms	Cause for alarms	Solutions
No Operate alarm	If there is no operation on machine for 2 minutes after switch on , it shall give 'no operate' alarm.	Press any key to clear the alarm. ★ This alarm function can be closed (See 8.3.9)
Door Open alarm	The pump door is opened during infusion.	Press SILENCE key to clear the alarm signal. Close the pump door to eliminate the alarm.

AlmostDone alarm (infusion near over)	Three (3) minutes before VTBI completion.	Press SILENCE key to clear the alarm signal. ★ This alarm function can be set as 'OFF' if there is no need. (See 8.3.10)
Finished alarm	1. The VTBI is completed. 2. Volume infused reaches 36000ml.	Press SILENCE key to silence the alarm sound. Press STOP key to clear the alarm. Press for 'clear' to clear Σ (volume infused) as '0'.
Occlusion alarm	1. The enteral feeding set is blocked.	Press SILENCE key to clear the alarm signal. Open the door to clear the occlusion properly and press START key to start infusion again.
	2. The occlusion sensitivity is too high.	Adjust occlusion level of the enteral feeding pump as per instructions of 8.3.12.
	3. The pressure sensor is defective.	Contact distributor / manufacturer for repair.
Name of alarms	Cause for alarms	Solutions
AC Fail alarm	Power failure or AC power plug off.	Press SILENCE key to clear the alarm signal and re-plug in the power cord properly.
Use Battery alarm	1. AC power is not plugged in.	Press SILENCE key to clear alarm signal. Check whether the AC power cord is plugged in or not well inserted.
	2. The enteral feeding pump's electric circuit has problem.	Contact distributor / manufacturer for repair.

Low Battery alarm (when battery has to be used during power failure or mobile infusion)	1. Thirty (30) minutes before the battery capacity is exhausted.	Press SILENCE key to clear the alarm signal. If AC power cord is not plugged in, the alarm shall sound again 2 minutes later. Stop infusion and connect to AC power to charge the battery fully.
	2. The battery is aging or the enteral feeding pump's charging circuit is defective.	Contact distributor / manufacturer for repair.
empty	There is no nutrient solution in the feeding bag.	Press STOP key to clear alarm signal.
B. Exhaust alarm (battery depleted alarm. when battery has to be used during power failure or mobile infusion)	1. Three (3) minutes before the battery capacity is exhausted.	Stop infusion and connect to AC power to charge the battery fully.
	2. The battery is aging or the charging circuit of the enteral feeding pump is defective.	Contact distributor / manufacturer for repair.
Name of alarms	Cause for alarms	Solutions
0xE0,0xE1 0xE2,0xE3	1. 0xE0: data communication error.	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor / manufacturer for repair.
	2. 0xE1: The enteral feeding pump's driving system has problem.	Reboot the machine and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor / manufacturer for repair.

	3. 0xE2: The enteral feeding pump's motor has problem.	Reboot the pump and load the parameters of last infusion to try operation again. If problem still occurs, contact distributor / manufacturer for repair.
	4. 0xE3: The enteral feeding pump's data storage system has problem.	Reboot the pump to try operation again. If problem occurs again, try to restore default setting to try again. If problem still occurs, contact distributor / manufacturer for repair. ★ After restoring factory default setting, you need to calibrate the feeding bag parameters again.

8.3 Parameters Setting and Accuracy Calibration

This chapter illustrates how to set infusion parameters.

Press and hold on STOP key first, then press (1st soft key on top left) to enter 'parameter setting interface'. If the first page has no parameters for setting, press (4th soft key on the right) to skip to 'next' page for setting. For any parameter setting, press ENTER key to save the value. After all parameters are well setting, press and hold on STOP key first, then press (1st soft key on top left) to quit to main menu.

8.3.1 "KLock" on and off setting

After entering 'parameter setting interface', press for 'KLock' and press "+1" key for 1min, 2min, 3min, 4min or 5min, or press "-1" key to select OFF. Then press ENTER key to save the value and exit.

Setting as 1min means all keys shall be locked (except POWER key) after 1minute if no operation on keys. This icon  shall display on LCD.

To unlock the panel, press ENTER key + (2nd soft key on top left) together.

8.3.2 Set occlusion sensitivity level.

After entering 'parameter setting interface', press for 'Occl.' and select required occlusion level (low, middle, high). Then press ENTER key to save the value and exit. Recommended setting for low occlusion alarm level for elderly or pediatric patients.

8.3.3 Set alarm sound level

After entering 'parameter setting interface', press for 'Next' to turn to next page. Press for 'Sound' and select desired sound level (low, high). Then press ENTER key to save the value and exit..

8.3.4 Set LCD backlight level

After entering 'parameter setting interface', press for 'Back L' and press "+1" to select 1min, 2min, 3min, 4min, 5min (i.e. dark after 1min etc), DARK or press "-1" to select BRIGHTNESS. Then press ENTER key to save the value and exit.

★ Selecting '1min' means the LCD shall automatically darken in 1 minute if no operation on keys.

8.3.5 Select feeding bag brand

After entering 'parameter setting interface', press for 'Tube' and select a brand/type of feeding bag (A, B, C ~ J). Then press ENTER key to save the value and exit.

★ After selecting a brand of feeding bag, its corresponding accuracy which has been calibrated shall be automatically effective.

★ The enteral feeding pump uses feeding bag under brand of Greatcare for factory setting (default setting). Using the other brand of feeding bag needs calibrating the accuracy of that feeding bag, otherwise accuracy can't be ensured.

8.3.6 Accuracy calibration of feeding bag

Install the feeding bag as per instructions in 8.1.3, and prepare a measuring cup for flown-out

liquid. After entering 'parameter setting interface', press for 'Accu.' to enter feeding bag calibration mode.

Press START key, the enteral feeding pump shall start operation at 150ml/h. After it finishes VTBI (10ml), measuring the flown-out liquid in measuring cup, input this actual flown-out volume on "real" text of calibration interface. Then press ENTER key to save the value and exit. The calibration of this brand/type of feeding bag is completed.

The accuracy calibration is directly related to the measurement of the actual flown-out fluid/quality. Please use high-precision electronic scale or other measuring instrument.

8.3.7 Set real date and time

After entering 'parameter setting interface', press for 'Time' and input value for year/month/day/hour/minute/second. Press ENTER key to save the value and exit.

8.3.8 Set key tone

After entering 'parameter setting interface', press for 'Key S' and select ON or OFF. Then press ENTER key to save the value and exit.

8.3.9 "No Operate" alarm on and off setting

After entering 'parameter setting interface', press for 'Next' to turn to next page. Press for 'No Op' and select ON or OFF. Then press ENTER key to save the value and exit.

"No Operate" alarm setting as on: in 'stop' status, "No Operate" alarm shall sound when no operation on keys in 2 minutes.

8.3.10 "Almost Done" alarm on and off setting

After entering 'parameter setting interface', press for "Almost Done" and select ON or OFF. Then press ENTER key to save the value and exit.

If setting as ON, "Almost Done" alarm shall sound 3 minutes before VTBI is complete.

8.3.11 NIGHT mode on and off setting

After entering 'parameter setting interface', press for 'NIGHT' and select ON or OFF. Then press ENTER key to save the value and exit.

If setting as ON,  shall display on LCD. Key sound shall be off; the screen shall turn dark after 1 minute if no operation on keys; the top indicator light shall be off during infusion. (if there is any alarm, the indicator light shall be on.)

8.3.12 Adjust occlusion alarm pressure value.

This parameter needs to be calibrated with a pressure scale. User should adjust the parameter according to the selected IV set.

The occlusion alarm pressure has three levels that are respectively 40-80Kpa (low), 80-120Kpa (middle) and 120-160Kpa (high). If the actual pressure is out of this range, the occlusion alarm pressure value needs adjusting.

After entering 'parameter setting interface', press for 'Press.' and adjust the value accordingly. Then press ENTER key to save the value and exit.

If the actual pressure value measured upon Occlusion alarm is higher, adjust occlusion alarm pressure value to a smaller one. Otherwise, adjust occlusion pressure value to a larger one.

After setting, re-measure the actual pressure value to ensure actual pressure value is within occlusion alarm pressure range.

8.3.13 View the event logs/alarm records

After entering 'parameter setting interface', press for 'Log'. Select '1 Upload log', all infusion records can be viewed on computer (only available when connect the pump to computer by RS232 interface). Select '2 View log', the pump can directly display the latest 2000 infusion / alarm information. Select '3 Back'', the pump shall return to 'parameter setting interface'.

(1) Upload log: upload infusion records to computer. Please refer to steps as follows:

a. Connect the Enteral feeding pump to a computer with RS-232 cable.

Computer (in power-on status)—click "start" (left bottom corner)—click "programs"—click "accessories'—click "communication"—click "hyper terminal"—click disconnect icon  .

Then in “file” menu, select “properties” and set COM interface (according to actual 232 port).

b. In “115200 properties” interface, click “configure” and set “baud rate” as 115200 and data flow control as Xon/Xoff.

c. After setting is complete, click call icon  to connect to terminal.

d. In Hyper Terminal interface to select "Transfer - Capture Text", recommending set up a txt named after an enteral feeding pump serial number on the computer, and then click "Start."

e. Press 1 soft key, upload infusion records to computer terminal. Press “transfer-capture text” after finishing uploading. And all infusion/alarms records can be reviewed on the txt that setting previously. After finishing uploading, the enteral feeding pump returns to superior menu interface automatically.

(2) 2 View Log: Select “2 View log” to view latest 2000 pieces of infusion / alarm information. Press ‘Prev.’ to check the previous records or ‘Next’ for next records. Press ‘Back’ to return to ‘Log’ interface. Select “3.Back” to return to parameter setting interface.

8.3.14 Select language and restore default

Press and hold on STOP key first, then press (2nd soft key on top left) to enter language setting interface. select ‘1.Chinese’ or ‘2. English’. If selecting ‘3. Restore Default’, all factory settings shall be restored.

★ After selecting ‘Restore Default’, the IV parameters need re-calibration.

Press and hold on STOP key first, then press (2nd soft key on top left) to exit.

8.4 Operation Precautions

- After the feeding bag is continuously used for 6 hours, please change the section of feeding bag that is against the peristaltic chips, or replace a new one. Meanwhile pay attention to the length of the feeding bag. Use extension lines if necessary in case the feeding bag is stretched out of position when patient turns his body.
- Avoid direct sunlight, high temperature and 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 infusion parameters.
- The enteral feeding pump should be placed within 1.2 meters above or below patient's heart.
- 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 infusion accuracy or even cause malfunction.
- The degree of viscosity and ratio of medical liquid may influence infusion accuracy.
- The feeding bag used on this enteral feeding pump should get valid Medical Device Registration Certificate.
- The enteral feeding pump uses 'Greatcare' brand feeding bag for factory settings. If users use the other brands of feeding bag, please calibrate its accuracy on machine before use.

8.5 Contraindications: No findings so far

9. Malfunction Analysis and Solutions

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

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

10. Safety Invention and Troubleshooting

10.1 Safety Invention and precautions

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

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

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

10.2 Troubleshooting

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

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

11. Maintenance, Inspection, repair and recycling

11.1 Routine maintenance

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

11.2 Maintenance during operation

The maintenance during operation mainly concerns the cleaning of the pump body and surrounding areas. Nutrition may drip into the enteral feeding pump during infusion process. Certain nutrition may corrode the pump body and certain may stick on the peristaltic chips, therefore clean the enteral feeding pump every time after infusion completion.

11.3 Periodic Inspection

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

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

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

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

(3) Open the pump door.

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

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

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

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

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

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

11.3.3 Inspect delivery accuracy (once every 2 months)

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

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

(2) Calibrate the accuracy as per instructions of 8.3.3.

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

11.3.4 Inspect internal battery

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

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

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

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

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

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

replaced.

Replace internal battery

(1) Unscrew the screws at the bottom of machine; remove the battery cover.

(2) Unplug the battery cable and take out the battery.

(3) Install the new battery. Please make sure the battery cable won't be squeezed by the battery Cover. Then install battery cover. After replacing new battery, please check its working condition.

11.4 Normal repair procedures

The repair job should be performed by supplier or distributor. It needs to make a complete inspection on machine after maintenance. If necessary，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 will not be used for long time, it should be placed in packing carton and avoid direct sunlight and keep it in cool and dry place. Refer to 12.2 for detailed storage conditions.

When using an enteral feeding pump of long time storage, please refer to following steps before use:

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

(2) Test occlusion alarm.

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

11.6 Recycling

The normal working life of the enteral feeding pump is five (5) years. The usage frequency and maintenance property level shall affect working life of machine. When exceeding the normal working life, the enteral feeding pump needs to be well scrapping. Please contact the manufacturer or distributor for more info.

(1) The scrapped enteral feeding pump can be sent back to manufacturer or distributor.

(2) The used battery can be sent back to manufacturer or distributor, or can be scrapped according to legally proper way.

12. Electro Magnetic Compatibility declaration

(1)This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and

mobile RF communications equipment.

(2)Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

(3) Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

(4) Warning:

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the enteral feeding pump as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the enteral feeding pump.

<table>
<tr><td colspan="3">Guidance and manufacture's declaration – electromagnetic emission</td></tr>
<tr><td colspan="3">The enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer of the user of the Enteral feeding pump should assure that it is used in such an environment..</td></tr>
<tr><td>Emission test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Enteral feeding pump use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class B</td><td rowspan="3">The Enteral feeding pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions</td><td>Complies</td></tr>
</table>

IEC 61000-3-3			
Guidance and manufacture's declaration – electromagnetic immunity			
The Enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of Enteral feeding pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±15 kV air	±6 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1 kV differential mode	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% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Enteral feeding pump requires continued operation during power mains interruptions, it is recommended that the

	(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Enteral feeding pump be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	400A/m	400A/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 and manufacture's declaration – electromagnetic immunity			
The Enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of Enteral feeding pump should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.5 GHz	3 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Enteral feeding pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

			Recommended separation distance $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d=2.333\sqrt{P}$ 800 MHz to 2.5 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 metres (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 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 Enteral feeding pump is used exceeds the applicable RE compliance level above the Enteral feeding pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Enteral feeding pump. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			
Recommended separation distances between portable and mobile RF communications equipment and the Enteral feeding pump .			
The Enteral feeding pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Enteral feeding pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Enteral feeding pump as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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) according 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.

13. Transport and storage

13.1 Precautions during transport

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

(2) Temperature: -20℃～60℃;

(3) Relative humidity: 10～95% (no frosting)

(4) Atmosphere pressure: 50.0kPa～106.0kPa

13.2 Storage conditions

Storage temperature: -20℃～45℃;

Relative humidity: 10～95% (no frosting)

Atmosphere pressure: 50.0kPa～106.0kPa

14. Package list

Standard configuration in a package:

① enteral feeding pump	1 unit
②AC power cord	1 set
③ User Manual	1 pc
④Warranty card	1 pc
⑤Product qualification certificate	1 pc

15. Open-package Inspection

Cautions for Open-package inspection:

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

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

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

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

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

16. After sales service

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

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

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

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

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

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

Annex

Table 1 Classification of alarms and color of alarm indicator light

Classification of alarms	Alarm priority	Color and frequency of alarm indicator light
Door Open alarm	High priority	Red/ 2Hz
Occlusion alarm	High priority	Red/ 2Hz
LowBattery alarm	High priority	Red/ 2Hz
B. Exhaust alarm	High priority	Red/ 2Hz
AlmostDone alarm	Middle priority	Yellow/0.5Hz
Finished alarm	Middle priority	Yellow/0.5Hz
empty	Middle priority	Yellow/0.5Hz
AC Fail alarm	Low priority	Yellow,steady
UseBattery alarm	Low priority	Yellow,steady
No Operate alarm	Low priority	Yellow,steady

Table 2 Alarm conditions and alarm signal delay

Names of alarms	Alarm condition delay	Alarm signal delay
Door Open alarm	10ms	100ms
Occlusion alarm	840s@1ml/h, 27s@25ml/h	100ms
LowBattery alarm	10ms	100ms
B. Exhaust alarm	500ms	100ms
AlmostDone alarm	10ms	200ms
Finished alarm	10ms	200ms
empty	72s@25 ml/h	100ms
AC Fail alarm	10ms	200ms
UseBattery alarm	10ms	200ms
No Operate alarm	120 ms	200ms

Table 3 Characteristic parameters of alarm signals

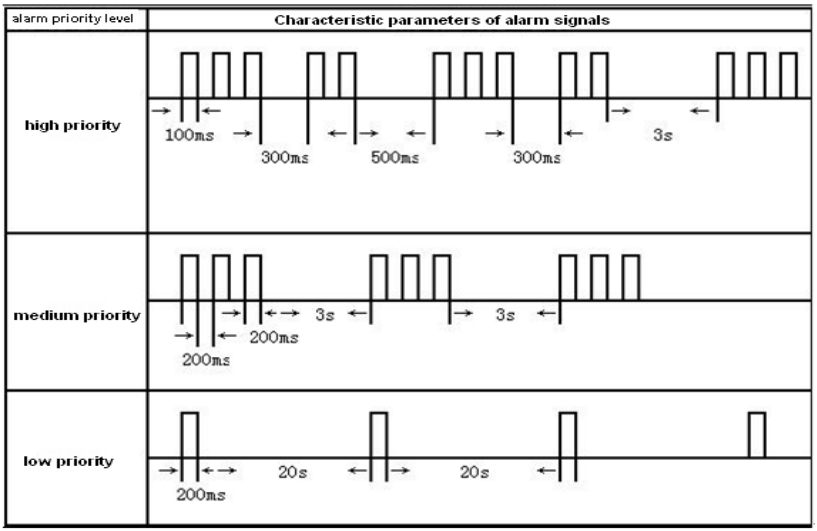


Table 4 Occlusion response characteristic

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

★ The above test uses 'Greatcare' brand of feeding bag. All the data are obtained by following conditions:

The flow clip of feeding bag is 20cm away from the enteral feeding pump; the filter 30cm away from the enteral feeding pump; two operations at rate of 1ml/h and 25ml/h respectively.

Table 5 circuit diagram

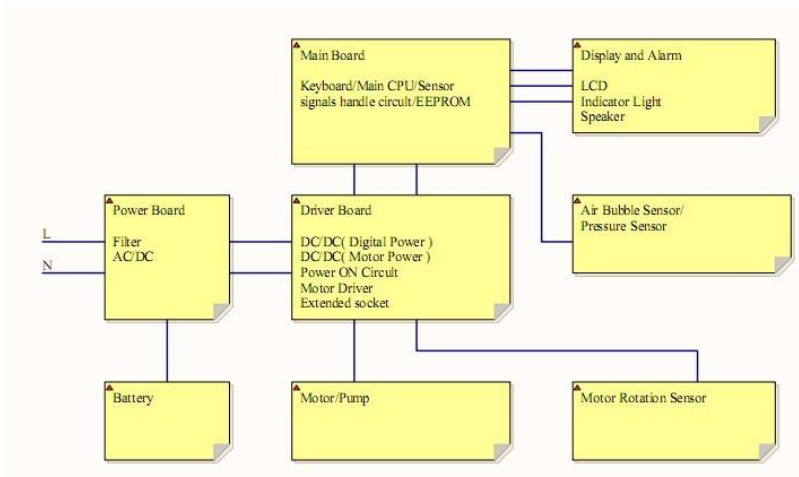


Table 6 component part list

Comment	Designator	Quantity	Supplier
7.4V 1900mAH	BT1	1	GuoGuang elec
AC powercord	CB_AC2	1	BoMingKe
2 phase1.8°42 motor	M1	1	XinNong
HK-100_Main	PCBA1	1	JiaLiChuang
HK100_Driver	PCBA2	1	JiaLiChuang
HK-100_Power	PCBA3	1	JiaLiChuang
HK-100_YLDB	PCBA4	1	JiaLiChuang
LCD_2.8	LCD1	1	TianMa
Pres_Sensor	SNR4	1	Measurement
16ohm 1w	SPK1	1	XinFeng elec

Manufacturer : Shenzhen Hawk Medical Instrument Co.,Ltd.
Address: 2B, Building No.2, Aerospace Science & Industry factory areas,
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Fax: 0086-755-8315 1906
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Fax: +353(1)6864856
Web: www.CE-marking.com www.CE-marking.eu www.well-kang.com
Email: AuthRep@CE-marking.eu