BOMBA DE INFUSIÓN AXAVET EN-V5 VET
AXAVET EN-V5 VET INFUSION PUMP
POMPE À PERFUSION AXAVET EN-V5 VET

REF. - CODE - RÉF. - ZMZ015

Este manual es parte inseparable del aparato por lo que debe estar disponible a todos los usuarios del equipo. Le recomendamos leer atentamente el presente manual y seguir rigurosamente los procedimientos de uso para obtener las máximas prestaciones y una mayor duración del mismo.

This manual should be available for all users of these equipments. To get the best results and a higher duration of this equipment it is advisable to read carefully this manual and follow the processes of use.

Ce manuel est une partie indissociable de l'appareil et doit être mis à la disposition de tous les utilisateurs de l'équipement. Nous vous recommandons de lire attentivement ce manuel et de suivre scrupuleusement les procédures d'utilisation afin d'obtenir des performances maximales et une plus longue durée de vie de l'appareil.

LANGUAGE INDEX

PREFACE

1 Application scope of the User Manual

Applicable to infusion pump model EN-V5 Vet.
This manual describes the most complete configuration of the product. For more detailed information contact your dealer.

2 Target personnel

Veterinary care services professionals and technicians who repair and maintain veterinary equipment.

3 Use instructions

This manual covers basic information on product safety and effectiveness, to guide the operator to properly install, test, use and maintain the equipment. Please read this manual carefully before using the pump and retain it for future reference.
The manufacturer guarantees the reliability and performance of the equipment only if all of the following conditions are met:

- Use the equipment according to this User Manual.
- The equipment can only be disassembled, repaired, tested and assembled by authorized Technical Service specialists.
- Accessories, as well as spare parts for repair are supplied by the manufacturer.

4 Phraseology

【】Means mechanical button
‘ ‘ Means touch button
( ) Further information
- Means inapplicable
√ Means compliant
→ Means operation steps

Bolo: Infusion of large volume of liquid in a short time.
KVO: Keep vein open, prevent blood back to the IV tube and needle blocked.
Anti-bolo: Motor automatically reverse while the IV tube with high pressure.
DPS: Used to indicate real-time detection and dynamic display of blocking pressure.
Warning /Attention: May cause physical injury or death if the precautions stated in the warning are not followed.
Caution: May cause physical damage or property loss if precautions are not followed.
Note: Failure to follow the supplemental information in the operating instructions may result in physical injury, equipment failure, or property loss.
Accessories: The optional components which are necessary and/or suitable for using with the equipment in order to achieve the expected purpose, or provide convenience for achieving the expected purpose, or improve the expected purpose, or increase the additional functions of the equipment.

TABLE OF CONTENTS

1 SAFETY INSTRUCTIONS

1.1 Warnings

■Before using, please check the equipment, connecting wire and accessories to ensure that it can work normally and safely. If there's anything abnormal, immediately stop working and contact our after-sale service department. Additionally, the adhesion or intrusion of fluid/drug may possibly cause the equipment fault and malfunction. Therefore, please clean the equipment after use, and store it correctly.
■This equipment must be operated by trained professional veterinary care personnel.
■This device is not applicable to blood transfusions.
■It is not allowed to put and use the equipment in the environment with anesthetic and other inflammable or explosive articles to avoid fire or explosion.
■It is not allowed to store or use the equipment in the environment with active chemical gas (including gas for disinfecting) and moist environment since it may influence the inside components of the infusion pump and may possibly cause performance drop or damage of the inside components.
■The operator must ensure that the established infusion parameters are those indicated by the veterinarian before starting the infusion.
■Please correctly install the infusion apparatus according to the infusion indication direction of this equipment, ensure that infusion tube smoothly and straightly cross the creep device. Otherwise, it may possibly suck blood from the animal or fails to reach the expected performance.
■Please do not only depend on shown information during use, periodically check it to avoid accident.
■Tightly fix this equipment on the infusion stand and ensure its stability. Be careful when moving the infusion stand and this equipment to avoid falling or knocking the surrounding objects.
■If the infusion tube is twisted, or the filter or needle is obstructed, or blood in the needle which may obstruct the infusion, the pressure in the infusion tube will rise. When removing such occlusion, it may possibly cause "bolus injection" (temporary excess infusion) to the animal. The correct method is to tightly hold or clamp the infusion tube near the puncturing position, then open the door to drop the pressure in the infusion tube. Then loosen the infusion tube, solve the reason of occlusion, and restart infusion. If infusion is restarted when the occlusion reason exists, then it may cause occlusion alarm persistently, and the pressure in the infusion tube may keep rising, and may break or cut off the infusion tube, or hurt the animal.
■This equipment injects fluid/drug through extruding the infusion tube, but it can't detect the leakage if the infusion line is cut off or broken. Therefore, please periodically check it to avoid above fault during the working period.
■During the infusion, periodically check the drip status of the fluid and the fluid/drug in the IV infusion bag/container, so as to ensure proper functioning during the infusion. This equipment does not directly measure the amount of infusion liquid, therefore, this equipment may not be able to detect the free flow of infusion under the extremely special condition. Even with the drip sensor connected, this equipment may not be able to detect the free flow of infusion that is less than the specific value for tolerance demands.
■This equipment has the occlusion detection function for detecting and alarming when the infusion needle deviates the position in the vein or the needle is not correctly punctured in the vein. However, it only alarms when the occlusion pressure has reached certain numerical value, and the puncturing part may possibly have become reddish, swelling or bleeding, additionally, it is possible that the device doesn't alarm for a long period if the actual occlusion pressure is lower than the alarm threshold value, therefore, please periodically check the puncturing part. If there's any abnormal phenomenon for the puncturing part, please timely take suitable measures, such as puncturing again.
■Only those infusion apparatus, line, infusion needle and other medical components that meet the local laws and regulations and the requirements covered in and this User Manual can be adopted, it is suggested to adopt the infusion apparatus with same brand as this equipment. It can't ensure the infusion

accuracy if the unsuitable infusion line is adopted.

- It is not allowed to disassemble or refit this equipment or use it for other purposes except normal infusion.
- Repair of this equipment can only be carried out by authorized Technical Service.
- Maintenance or replacement of spare parts is prohibited during clinical use of the equipment.
- To avoid risk of electric shock, this equipment must only be connected to AC with ground protection.

1.2 Cautions ⚠

- Before first use, or if the pump has not been used for a long period, charge the battery with AC power. If it is not fully charged, the device will not be able to continue operating with the built-in battery.
- This equipment cannot be used in places with radiological installation or magnetic resonance equipment, as well as places with high-pressure oxygen therapy.
- The DC power supply is only suitable for applications where a backup power supply is required. Only use the DC power supply line provided by the manufacturer.
- Other devices near this equipment must meet corresponding EMC requirements, otherwise, it may influence the performance of this equipment.
- Under general conditions, please use AC power supply as much as possible since it can prolong the service life of the battery at a certain degree. When using AC power supply, ensure that the grounding wire is reliably connected with the ground, and only the AC power wire attached with this equipment shall be adopted. The built-in battery can only be used as the assistant power supply when the AC power supply can't reliably connect with the ground and is not under normal conditions (power failure or moving infusion).
- Before connecting this equipment with power supply, please keep the power socket and plug dry, and the power voltage and frequency meet the requirements listed in the equipment label or this User Manual.
- The equipment is equipped with the audible and visual alarm system, and the red and yellow alarm indicators will light on by turn to check if the alarm system can work normally, and the speaker makes the "beep" sound.
- Please keep the equipment away from the AC power socket for a certain distance to avoid fluid/drug splashing or dropping in the socket, otherwise, it may possibly cause short circuit.
- Please use the fluid/drug after it has reached or nearly reached room temperature. When the fluid/drug is used at low temperature, the air which is dissolved in the fluid/drug may cause more air bubbles and result in frequent air bubble alarm.
- It is not allowed to press and operate the button with sharp object (such as pencil tip and nail), otherwise, it may possibly cause early damage to button or surface film.
- Please do not use the infusion tube for 8h at the same pumping position. Infusion tube may distort after using for a long time and cause flow rate error. It is suggested to replace the pumping position or directly replace the infusion tube every 8h.
- Please tightly close the flow rate adjuster of the infusion apparatus before taking out the infusion apparatus to avoid liquid leakage.
- Under the condition of low flow rate infusion, please pay special attention on occlusion. The lower the infusion flow rate, the longer the time of detecting occlusion, and it in turn may possibly cause a long-time infusion stop during this period.
- If the equipment suffered from dropping or impacting, please immediately stop using it, and contact our Technical Service, because the inside components of the equipment may be possibly damaged even the appearance is not damaged and abnormality is not occurred when working.
- It is recommended to use the accessories specified in this manual to ensure animal safety.

1.3 Dialog window

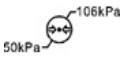
The dialog window includes content to select or confirm an operation and display useful information. For example:

(Figure 1.3-1 Information to select operation)

(Figure1.3-2 Parameter error reminder)

1.4 Symbols

Not all of the below symbols exist in the equipment you have purchased.

Icons	Description	Icons	Description
	Batch code		Protective earth (ground)
	Serial number	**IP44**	Dustproof and waterproof. Prevent the pouring of solid objects larger than 1.0 mm in diameter and the intrusion of splashing water in all directions
	Caution		Both direct and alternating current
	Defibrillation-proof type CF applied part		Battery
	Manufacturing date		Do not throw garbage
	Environment-friendly use period (20 a)		Manufacturer
	Authorized representative in the European Community		Non-ionizing electromagnetic radiation
	Input / output		Direct current
	Unlock		Lock
	This side up		Fragile items
	Keep dry		Stacking level limit
	CE mark / Notified organism		Please refer to the instruction manual
	Transportation package temperature limit range is -20~60 ℃		The limited humidity range of transportation package is 10%~95 %
	The environmental pressure for transportation of package is limited to 50~106kPa		

2 OVERVIEW

2.1 Application scope

» 2.1.1 Expected purpose

The infusion pump is used together with infusion set to control the dose of liquid infused into animal's body, for example intravenous infusion.

» 2.1.2 Expected working environment

Animal hospital; pet clinic.

» 2.1.3 Suitable patients

Animals

2.2 Contraindications

This equipment is not applicable to blood transfusions.

2.3 Working principle

This equipment is a kind of instrument which can drive the pump to extrude the infusion tube for accurately control of the infusion drops or infusion flow rate with the motor and is capable of guaranteeing to convey drug fluid safely in the vein of animal with even rate and accurate dosage.

2.4 Structure and operation

» 2.4.1 Structure and operation

The infusion pump is mainly composed of a control system, a motor driving unit, a peristaltic pressing mechanism, a detecting device, an alarm device, an input and display device, a housing, a supporting structure thereof and a software component. Optional drop number sensor, DC power cable, DB15 serial communication cable. Double CPU has been adopted to our pump to ensure infusion safety. This equipment provides several infusion modes, such as ml/h mode, body weight mode, drip mode, sequence mode. Additionally, it also has functions such as history records, drug library, anti-bolus, alarm, etc.

» 2.4.2 Functional specifications

Function /Model		EN-V5 Vet
Infusion mode	Mode ml/h	●
	Body-weight mode	●
	Drip mode	●
	Drug library mode	O
	Micro mode	●
	Sequence mode	●
Occlusion alarm level		5 adjustable levels: Level 1:50mmHg Level 2:150mmHg Level 3:300mmHg Level 4:600mmHg Level 5:900mmHg
Drug library		≥2000
History entries		≥5000
Brand library		≥200
WIFI		O

Note: ● standar; O optional.

This manual describes most of the settings and functions; due to the difference in model or optional components, not all functions are equipped in the purchased product.

2.5 Product specifications

Safety classification	Electric protection type	Class I
	Electric protection level	Defibrillation-proof CF type applied part
	Protection against fluid ingress	IP44
	Working mode	Continuous operation
	Classification	Portable equipment, non-portable infusion pump
Specification parameters	Infusion set specification	10-60 gotas/ml
	Infusion rate	10-20 drips/ml infusion set specifications: 0.1-2000ml/h 21-40 drips/ml infusion set specifications: 0.1-800ml/h 41-60 drips/ml infusion set specifications: 0.1-400ml/h Minimum step is 0.01 ml/h <100ml/h step is 0.01 ml/h, <1000ml/h step is 0.1 ml/h, ≥1000ml/h step is 1ml/h
	Infusion accuracy	≤±5%

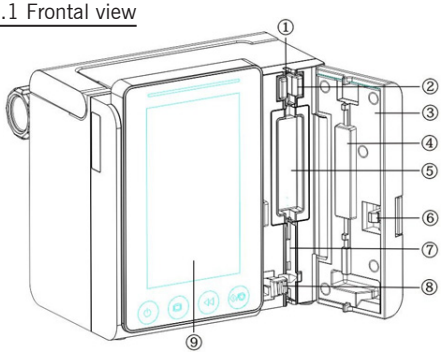
Specification parameters	Drop rate	Dripper adjustment range 10-60 drips/ml, drop rate 1-2000 drips/min, step is 1 drop/min
	Drop rate accuracy	≤±5%
	Bolus rate (Bolus)	10-20 drips/ml infusion set specifications: 1- 2000ml/h 21-40 drips/ml infusion set specifications: 1-800ml/h 41-60 drips/ml infusion set specifications: 1-400ml/h Minimum step is 0.01 ml/h <100ml/h step is 0.01 ml/h, <1000ml/h step is 0.1 ml/h, ≥1000ml/h step is 1ml/h
	Bolus rate accuracy	≤±10%
	Purge rate	10-20 drips/ml infusion set specifications: 100-2000ml/h 21-40 drips/ml infusion set specifications: 100-800ml/h 41-60 drips/ml infusion set specifications: 100-400ml/h Minimum step is 0.1 ml/h <1000ml/h step is 0.1 ml/h, ≥1000ml/h step is 1ml/h
	Bolus flow accuracy	≤±10%
	Purge rate	10-20 gotas/ml especificaciones del set de infusión: 100-2000ml/h 21-40 gotas/ml especificaciones del set de infusión:100-800ml/h 41-60 gotas/ml especificaciones del set de infusión: 100-400ml/h Paso mínimo es 0,1 ml/h <1000ml/h paso es 0,1 ml/h, ≥1000ml/h paso es 1ml/h
	Purge rate accuracy	≤±5%
	VAI	0-9999,99ml, minimum step is 0.01 ml
	Infusion accuracy	≤±5%
	Total volume infused	0-9999,99ml
	KVO rate	0~5ml/h, minimum step is 0.01 ml/h
	KVO rate accuracy	≤±10%
	Micro mode setting range	0.1~200ml/h
	Time range	1s - 99h59min59s
	Acti agentia	0.01-99999
	Volume	0.01-9999ml
	Conc.	0.01-99999
	Dose rate	0.01-9999
	Cumulative bubble	50~1000μl /15 min

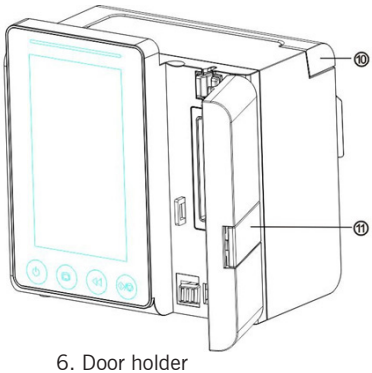
Specification parameters	Single fault bolus volume	≤2ml
	Anti-bolus volume	≤0.2ml
	Fuse type	T2AL 250V
	Dimensions	131.5*90*138mm (No fastening clamp, no drop sensor hook)
	Weight	≤1.55 kg
Power supply	AC power supply	100-240VCA, 50/60Hz, 0.25A-0.1A
	Input power	50VA
	DC power supply	DC 10-16V, 1.5-0.94A
Battery	Battery quantity	2 pieces
	Battery type	Lithium battery
	Rated battery voltage	7.4 V
	Battery capacity	5200mAh
	Charging time	≤8h
	Running time	Use a new, fully charged battery: Operating at 25 ml/h, the operating time from start-up to the low battery alarm is not less than 10 hours. Operating at 2000 ml/h, the operating time from start-up to the low battery alarm is not less than 5 hours.
Alarm	Sound of pressure level alarm signal	When the sound is set to the lowest level, the pressure level alarm signal is ≥50dB(A) When the sound is set to the highest level, the pressure level alarm signal is ≤80dB(A)
	Information alarms	VTBI near end, VTBI infused, high pressure, battery nearly empty, battery empty, system error, no power supply, reminder alarm, standby time expired, KVO finished, drop sensor connection, drop error, empty bottle, single bubble, cumulative bubble, door open, occlusion pre-alarm, drop in pressure, drug dose limits exceeded, backup battery power exhaustion
Environment	Non AP/APG type equipment	Do not use it in the environment with inflammable anesthetic gas mixed with air, and inflammable anesthetic gas mixed with oxygen or nitrous oxide.
	Operation	(1) Temperature: 5-40 ºC (2) Humidity: 15-95%, non-condensable (3) Atmospheric pressure: 57-106kPa
	Transport and storage	(1) Temperature: -20-60 ºC (2) Humedity: 10-95%, non-condensable (3) Atmospheric pressure: 50-106kPa

Safety standards	Principal safety	**IEC 60601-1:2005+A1:2012** Medical electrical equipment - Part 1: General requirements for basic safety and essential functioning. **IEC 60601-1-2:2014** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential functioning - Collateral standard: Electromagnetic disturbances - Requirements and tests. **IEC 60601-1-6:2010 (BS EN 60601-1 6:2010+A1:2015)** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential functioning - Collateral standard: Usability. **IEC 60601-1-8:2006+A1:2012** Medical electrical equipment - Part 1-8: General requirements for basic safety and essential functioning - Collateral standard: General requirements, testing and guidance for alarm systems in medical electrical equipment and electromedical systems. **IEC 60601-2-24: 2012** Medical electrical equipment - Part 2-24: Particular requirements for basic safety and essential functioning of infusion pumps and controllers.

3 APPEARANCE

3.1 Frontal view

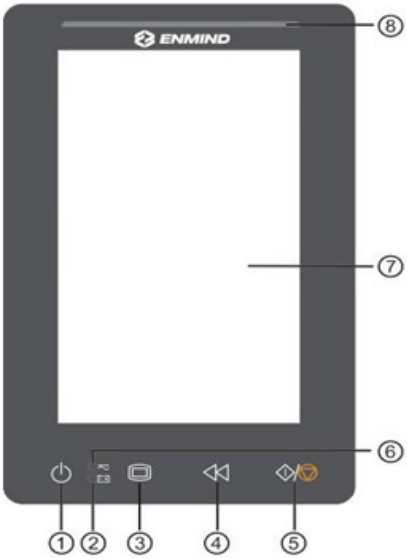




1. Tubing guide
2. Sensor de aire en línea (detección de burbujas en línea)
3. Pump door
4. Pressure plate
5. Waterproof film
6. Door holder
7. Lower pressure sensor
8. Anti-free flow clamp
9. Display screen
10. Handle
11. Door switch

Note: It is recommended to replace the waterproof film once every two years.

3.2 Operation panel

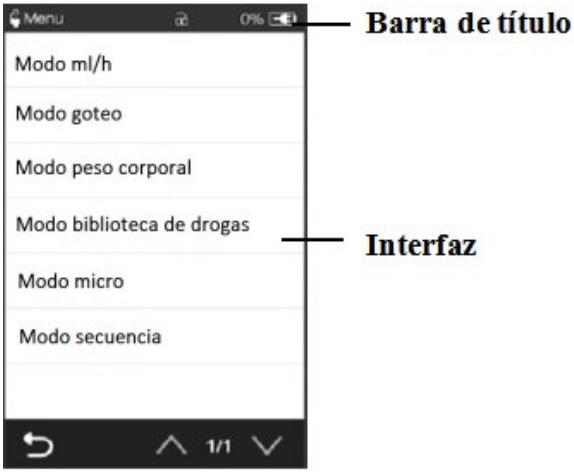


1.Power
Pump power switch, press and hold , pump power off. Stand-by selection button. Long press the power button until the screen closes and the pump shuts down.
2.Battery indicator (green)
Indicator flashing: device on, battery charging/power supply.
Indicator light on: the battery is full of electricity.
Indicator light off: equipment shut down, no batteries.
3.Menu: Enter system home page.
4.Bolus/Purge
5.Start/Stop
6.AC/DC indicator (green)
Turn on:Connect AC/DC power supply
Turn off:Disconnect AC/DC power supply
7.4.3 inches TFT (LCD) touch screen
8.Alarm indicator (red/yellow)

While pump alarms, indicator light glitters, with different frequency and color; for more information please refer to Section 8.1.

3.3 Display screen

The display screen interface layout composes of title bar and typical interface.



» 3.3.1 Title bar

Title bar displays real-time state information and is not touchable, the left upper corner displays the name of current editing parameter.

Table 3.3.1-1

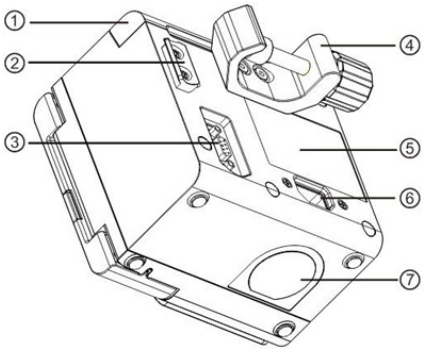
Icon	Meaning	Description
	Infusion apparatus indication icon	Infusion apparatus indication icon
	Lock screen indication icon	Unlock state icon is 
	Battery charging indication icon	Displays the current battery charging state
	WIFI indication icon	Indicates the WIFI connection state
	Battery status indication icon	The percentage numerical or remaining time value at the left side of the icon displays the remained battery. Since the remained battery may change, it can show the following states: 

» 3.3.2 Interface icons description

Table 3.3.2-1

Icon	Meaning	Description
X/Y	Page indication	Arabic numerals mean, X is the current page, Y is the total number of pages
	Up	Click this icon, return to the back page
	Down	Click this icon to enter into the next page
	Return/Cancel	Click this icon, return to the back menu
	Radio button-1	The current parameter is selected
	Radio button -2	The current level is selected
	Confirm	Click to save the input parameters or the selected parameters and exit
	ON	Means this function is ON
	OFF	Means this function is OFF
	Clear button	Click it to clear input
	Backspace button	Click it to backspace delete
	Toggle key	Click it to toggle between the options

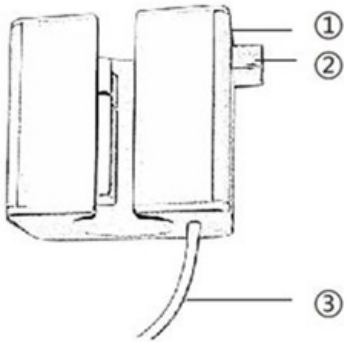
3.4 Rear view



1. Handle
2. Drop sensor bracket
3. DB15 multi-functional interface, with following functions:
- DC power input interface
- Software uploading interface
- Nurse call interface
- Drop sensor interface

Note: The above functions cannot be used at the same time.
4. Clamp
5. Product label
6. AC/DC adapter port
7. Loudspeaker

3.5 Drop sensor (optional)



1. Housing
2. Slider

Push the slider to left direction to adjust the spacing, loosen the slider to automatically release.
3. Cable

4 INSTALLATION

4.1 Unpacking and checking

1.Please check the appearance before unpacking, if broken, please contact the transportation company or your distributor quickly.
2.Please carefully open the package to avoid damaging the equipment and accessories.
3.After unpacking, please check the objects according to the packing list, if there're insufficient or damaged accessories, please contact your distributor as soon as possible.
4.Please keep the relevant accessories and the User Manual.
5. Please keep the packing case and packing materials for future transportation or storage.

⚠

Warning: please put the packing materials out of reach of children. Please obey local laws and regulations or the hospital waste treatment system to handle the packing materials.

4.2 Installation

Warning: ⚠

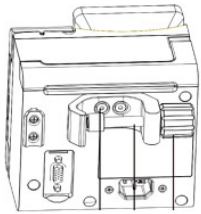
■This equipment shall be installed by the trained technicians.

■All devices connected to this equipment must pass the designated IEC certification standards (e.g. IEC 60601-1 safety of medical electrical equipment) and all devices must be connected according to the valid version of IEC 60601-1. The technician who is responsible for connecting other devices to the equipment interface is responsible for compliance with IEC 60601-1. Please contact your distributor if you have any questions.

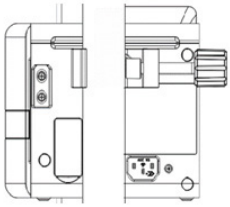
■When connecting this equipment with other electric devices to form the combination with special function, if the combination can't be confirmed dangerous or not, please contact our company or the electric expert of hospital to ensure that the necessary safety of all devices in the combination won't be destroyed.

■This equipment must be used and stored in environment regulated by the manufacturer.

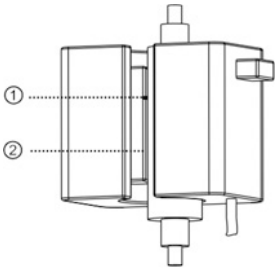
» 4.2.1 Installing the infusion pump



1.Turn the stand clamp screw (knob) and unscrew it to release.
2.Lock the infusion stand clamp, adjust the position of the infusion pump, tighten the clamp screw to fix the infusion pump in the infusion stand (shown in the figure below). Hold the infusion pump when tightening the fixing clamp; leave it after tightening to avoid dropping.
3.The stand clamp holds the stand vertically by default. To adjust the direction of the clamp, please remove the clamp screw by unscrewing it, pull the stand out of the clamp and adjust the direction, then tighten the screw.



» 4.2.2 Installing the drop sensor



1. Insert the drop sensor plug into the drop sensor port of this equipment and ensure tight connection.
2.Drop start should be above the line 1.
3.Liquid level should be below the line 2.

Warning:
- The fluid/drug volume in the Murphy's dropper must be less than 1/3 of its volume.
- The drop sensor shall be vertical.

5 PREPARATION AND PRECAUTIONS BEFORE USE

5.1 Use preparation

In the new equipment, or reused after storing for a period, or after repair, please check the following to ensure before use:

■The equipment appearance is clean and under good condition without crack and leakage.

■The moving components are smooth and effective, for example: the pump door can be opened and

closed smoothly, the button is effective.
- The touch screen can be operated smoothly and effectively.
- The power cable is installed tightly and won't be easily damaged when pulling.
- Set and check the system time to ensure that the history records will be correctly recorded.
- In case only built-in battery is adopted for supplying power, please charge it to full before using, and ensure that the battery keeps at the effective working conditions.
- Carefully read the warnings, cautions and operation steps listed in this User Manual.

5.2 Operation cautions

Cautions: ⚠
- Avoid direct sunlight, high temperature or high humidity.
- The equipment shall be put at a position less than 1.2m, in relation to the height of the animal.
- The parameters can only be set or changed by the trained and authorized personnel.
- Avoid the equipment working with fault so as to avoid medical negligence, which may hurt the health and even life of the animal.
- It may possibly drop the infusion accuracy or abnormal work of the equipment if the working environment temperature exceeds the designated range.
- The viscosity and specific gravity of infusion fluid will influence the infusion accuracy.

6 BASIC OPERATION

6.1 Operation flow

- Power on
- Install IV set
- Select infusion tube brand or add new brand
- Select infusion mode
- Set infusion parameters
- Remove air bubble from the line
- Connect the infusion line with the animal
- Start infusion
- Finish infusion
- Remove the IV set
- Power off or standby

6.2 Infusion operation

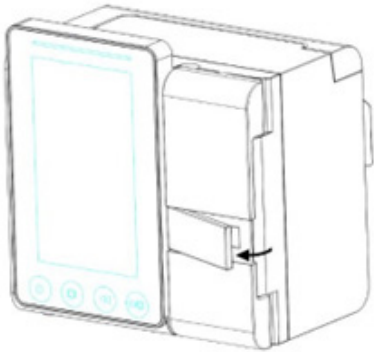
» 6.2.1 Starting and self-test

1.Press  , power on the equipment.
2.After power on, the system will automatically check the motor, sensor, battery, memorizer, CPU communication, alarm indicator.
3.After the self-test is successful, the prompt interface: "New treatment" and "Last treatment".
Select "New Treatment" to go directly to the ml/h mode setting interface.
Select "Last treatment" to enter the parameter setting interface of the last used mode.

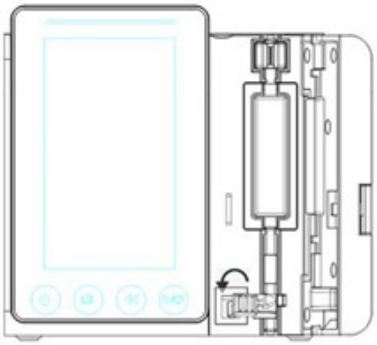
⚠

Warning: If the pump does not pass the self-test, contact Technical Service and do not continue to use the equipment.

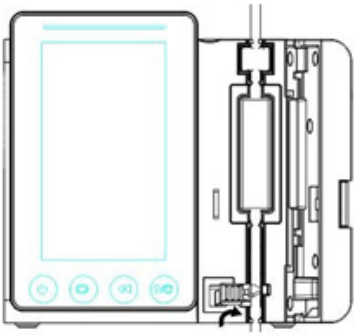
» 6.2.2 Installation of infusion set



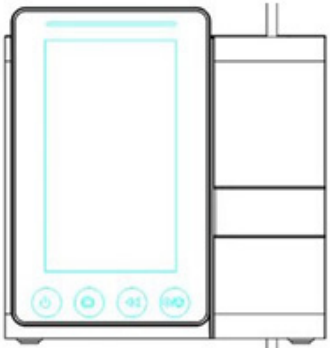
1. Unlock and open pump door to the left.



2. Push down the anti-free-flow clip.



3. Gently pull the infusion tube, straighten it, and fix the infusion tubing the tube groove at both ends from top to bottom, and close the antifree flow clip to clamp the infusion tube.



4. Close the pump door, then pop up the infusion tube selection interface, indicating that the infusion tube is installed correctly. Otherwise you need to reinstall.

Warnings: ⚠

- It is recommended to use the infusion set built into the system.
- Please confirm the infusion set brand specifications displayed on the touch screen, which is consistent with the actual use.
- Although the device supports the calibration of the customized infusion set, in order to ensure the accuracy of the infusion, it is strongly recommended that the user contact the company for IV set calibrated and tested by the manufacturer's professionals.

5.Install the drop sensor

Install it according to Section 4.2.2. After installation press 'Settings' - 'Drop sensor' to activate this function.

⚠ Caution: The default state of the drop sensor function is deactivated, this function can be activated manually by the user when using the drop sensor.

» 6.2.3 Replace infusion line/infusion container

■ Please replace the infusion tube assembly according to the following steps:
- Close the flow rate adjuster of the infusion tube assembly, open the infusion pump door, and then remove the infusion tube assembly.
- According to Section 6.2.2, prefill and install the new infusion tube assembly.
- Operate to restart infusion according to the above infusion steps if needed.

■ Please replace the fluid/drug container according to the following steps:
- Close the flow rate adjuster of the infusion tube assembly.
- Remove the fluid/drug container from the infusion tube assembly.
- Connect the infusion tube with the new fluid/drug container.
- Restart infusion according to the above steps of replacing infusion tube assembly.

⚠

Warning: The infusion tube will distort if it worked for a long period and may result in flow rate error, it is suggested to replace the pump pressing position or infusion tube assembly after working for 8h.

» 6.2.4 Select the infusion set brand

In the infusion tube selection interface, click on the currently used infusion set brand. See 7.1.13 brand for specific brands.

⚠

Warning: ENMIND-CA is the brand of infusion set built in the device. If using a non-built-in infusion set, please confirm the relevant infusion performance (accuracy, air bubble, pressure) on the infusion pump before confirming the use, otherwise the infusion will not be guaranteed.

» 6.2.5 Set the infusion mode

Enter the 'Modes' interface, select the infusion mode and then set the infusion parameters.

■ ml/h mode

This mode allows to set three parameters: rate, VTBI (volume to be infused) and time; set any two of the three parameters, and the system will automatically calculate the third parameter; if the VTBI is 0, then the equipment works at the set rate till stop with alarm.

■ Body-weight mode

In this mode, set the Weight (body weight), Acti agentia (drug mass), Conc.unit (concentration unit), Volume (fluid volume), Dose rate, Dose unit, VTBI.
The system will automatically calculate the flow rate from the specified dose rate (ug/kg/min, mg/kg/min, ug/kg/h, mg/kg/h,…etc) according to related formula {dose rate × weight}/{Acti agentia(drug mass)/Volume(fluid volume)}, and automatically calculate the time according to (VTBI) /(flow rate).

■Drip mode

In this mode, set the VTBI and drop rate, and the system will automatically calculate the infusion flow rate and time.

⚠

Note: The flow rate under drip mode is calculated according to the specification of the current infusion apparatus, before adopting the drip mode, please confirm that the specification of the current infusion apparatus is accordant with the specification displayed in the interface title bar display, if it is not accordant, please contact the equipment maintenance technician to modify, otherwise, it may cause serious deviation of flow rate.

■Drug library mode

“None” means that the drug library mode is turned off. Click on the drug name and follow the instructions to enter the infusion parameters.
DERS is suitable for this mode and the drug dose rate will be limited. If the cumulative dose exceeds the preset dose limit for a certain period of time, the “drug dose overrun” alarm will be triggered.

⚠

Note: This device supports customized drug information editing functions. Please contact the licensor if necessary.

■Sequence mode

Sequence mode means to infusion according to the set sequence after setting the rate and time of different sequence groups. At most 5 sequences can be set in this mode.

» 6.2.6 Purge air

To prevent air from entering the body, the air bubbles in the infusion set must be removed before infusion.Under the parameters setting interface, short press Bolus button to enter the exhaust interface, and exhaust according to the interface instructions to clear the bubbles in the infusion line.
The purge total volume is not calculated in the Total Volume Infused.

⚠

Before purging the air, please confirm that the infusion line is not connected to the animal.

» 6.2.7 Set the infusion parameters

In each infusion mode, the user sets the infusion parameters through the touch screen. For the setting range of the infusion parameters, see 2.5 Product Specification.

» 6.2.8 Start infusion

Connect IV tube with animal, confirm infusion parameters, press Start button, start infusion.

» 6.2.9 Changing infusing parameters during infusion

During the infusion process, click the flow rate value on the running interface to reset the flow rate. After confirmation, click ✓ to continue the infusion.

⚠ Note: Sequence mode does not support changing the flow rate during infusion.

» 6.2.10 Bolus

In operation, bolus functions have two operation modes: manual bolus and automatic bolus; bolus volume is included in the total amount of infusion.

■ **Manual Bolus:** Short press the Bolus button to enter the fast forward infusion setting interface, set the fast infusion speed, Long press the Bolus button to fast forward the infusion, and release the button to the original rate infusion.

■ **Automatic Bolus:** Short press the Bolus button to set any two parameters of the preset amount, speed and time of the fast-forward infusion. Click the bottom line Start. After the Bolus set volume is completed, the device reuse the original infusion rate. If you want to end the fast-forward infusion early, press the Bolus button.

⚠ Note: The “VTBI near end” alarm is not triggered during Bolus.

» 6.2.11 Completion of the infusion

When infusion near completion, pump will alarm. If ignore it, the system will keep alarming until finishing infusion.

After VTBI completed, it activates VTBI infused alarm, if KVO function is ON, the equipment automatically starts KVO function, click ✓ in the alarm interface to stop KVO and eliminate alarm.

The default working time of the KVO system is 30min, after reaching the time, it will activate KVO completion alarm and stop infusion.

Please refer to Section 7.1.2 to set KVO rate.

» 6.2.12 Stop infusion

During infusion or after infusion, click Stop, infusion stops. The interface display Total Volume Infused and adjustable parameters.

» 6.2.13 Remove IV set

Disconnect the infusion set from the animal. After opening the pump door, push the button to the lower left to remove the infusion set.

» 6.2.14 Power off or standby

Method 1: Hold the ⏻ button till the screen is OFF, the equipment is OFF.

Method 2: Press the ⏻ button to enter into OFF interface.

1.Turn off the device: Click “Power off” icon, the equipment is turned OFF.

2.Standby: Click “Standby” icon to enter into standby time setting interface, set the standby time.

Standby time range: 1min - 99h59min

Under standby state, the screen brightness will be lowest, after standby, the screen brightness will be recovered.

3.Cancel: Click “Cancel”, return to the interface before OFF setting.

4.If no operation, the device will enter standby interface automatically.

Note: The equipment has standby function only under the non-working state.

7 SYSTEM SETTING

7.1 Setting

Click on the 'Settings' icon in the main interface to enter the parameter configuration interface.

» 7.1.1 Drug library

Click the 'Settings' icon on the main interface to enter the submenu, find the 'Drug Library' menu, click to enter, then set the ON/OFF status of the drug library and view the drug library information.

■ Introduction to the drug library

It supports more than 2000 drug names, which can be imported with an external tool, and has functions such as upper and lower limit, concentration and so on.
Select the drug and then import the drug parameters, the user can change parameters such as concentration and dose, but the parameters are not saved.

■ Drug library configuration

After the drug library function is activated, the infusion tubing is successfully installed in the infusion pump and the infusion set brand is selected. In the drug information selection interface pop-up window, click on the preset drug name. The selected drug will be displayed in the infusion mode parameter.

» 7.1.2 KVO rate

Click on 'KVO rate', enter the numerical value, after confirmation, click on ✓
Please refer to chapter 2.5 for the adjustable KVO range.

⚠ Note: KVO will be closed if the KVO rate is 0 ml/h.

» 7.1.3 Bolus rate

Click on "bolus rate", enter the numerical value, after confirmation, click on ✓
Please refer to section 2.5 for the adjustable bolus rate range.

» 7.1.4 Occlusion pressure

Click 'Occlusion Pressure' to enter the occlusion pressure level setting interface, move the long box to the preset level, after confirmation, click ✓
The higher the level chosen, the higher the level of occlusion, it is advisable to select the appropriate occlusion pressure according to the actual requirement.
DPS is enabled by default, and the line pressure is graphically and dynamically visible during the infusion state.

Warnings ⚠

■When high viscosity liquid/drug is used and the occlusion pressure is set at a low level, it is possible that the system will inform you of occlusion alarm even when the line is not clogged, under this condition, please carefully observe the pressure indication icon on the display and infusion line and increase the occlusion pressure if necessary.

■When the occlusion pressure is set at a high level, it may cause the patient to become uncomfortable, after raising the occlusion pressure, please carefully observe the patient's condition, and take action immediately if there is any abnormality.

■Under the equipment failure condition, the maximum pressure generated by the perfusion line is 1500mm Hg. Under a single failure condition, the maximum infusion volume is 2 ml.

■If not used for intravenous infusion, e.g. intra-arterial infusion, Total Parenteral Nutrition (TPN) or enteral nutrition (EN) therapy, the occlusion level should be adjusted to the higher levels.

⚠ Note: The lowest pressure (50mmHg) limits the flow rate to ≤100 ml/h, and the remaining levels 2-5 have no flow rate limit.

When the line occlusion triggers the occlusion alarm, the system shall automatically activate the anti-bolus function to drop the line pressure and prevent further bolus impact to the patient after the occlusion is resolved. Fluid leakage shall be less than 0.2, line pressure shall be less than 300mmHg.

» 7.1.5 Bubble detection level

Click 'Bubble Size' to enter the air bubble size adjustment interface, move the selector to the preset level, confirm and then click ✔

The sensitivity of the bubble is 20 μl.

Single bubble detection: An individual bubble alarm is triggered when the volume of the individual bubble in the infusion tubing reaches the preset bubble detection alarm threshold. The different levels of bubble detection are listed in the table below:

Standard software		Optional software	
Bubble detector level air	**Alarm threshold value**	**Air bubble detector level**	**Alarm threshold value**
Level 1	50 μl	Level 1	20 μl
Level 2	100 μl	Level 2	50 μl
Level 3	200 μl	Level 3	100 μl
Level 4	400 μl	Level 4	200 μl
Level 5	800 μl	Level 5	400 μl
		Level 6	800 μl

» 7.1.6 Accumulated bubble

Click ‘Cumulative Bubble’ to enter the cumulative bubble configuration interface, enter the cumulative alarm threshold value, and then click ✓ to confirm.
The accumulated bubble detection range is 50 ~ 1000 μl /15min. When the accumulated bubble volume within 15 minutes reaches the preset alarm threshold, the accumulated bubble alarm is activated. It is recommended to set the accumulated bubble detection range according to actual needs.

» 7.1.7 Pre-termination alarm

Pre-alarm time refers to the alarm activation time due to end when the infused liquid/drug volume almost reaches the preset value.
Click ‘Pre-Alarm Completion’ to enter the pre-alarm time setting interface, select ON or OFF, click the preset time option, and then the corresponding icon of this option changes to ◉
The adjustable time interval for the pre-alarm is: 2min 5min, 10min, 15min, 20min, 30min.

» 7.1.8 Reminder alarm

Click ‘reminder alarm’ to enter the reminder alarm time setting interface, select ON or OFF, click the preset time option, and then the corresponding icon of this option changes to ◉ . The adjustable time interval for reminder alarm is: 2min 5min, 10min, 15min, 20min, 30min.
Reminder alarm means that the system will activate “reminder alarm” if no button has been pressed within the time set for “reminder alarm”. When the equipment is not under any infusion no alarm status will be activated.

» 7.1.9 Unit of weight

Click on ‘weight unit’ to enter the body weight unit configuration interface, click on the preset body weight unit option, and then the corresponding icon of this option changes to ◉

⚠ Note: The current version of the software only supports the kg unit

» 7.1.10 Pressure unit

Click ‘pressure unit’ to enter the configuration interface of choosing the pressure unit, four units are available: mmHg, kPa, bar, psi, click the preset unit option.

⚠ Note: Please confirm with care when changing the current pressure unit.

Unit	Conversion of units
kPa	1 kPa=7.5mmHg=0.145psi=0.01 bars
PSI	1psi=51.724mm Hg=6.897kpa=0.069bar
Bar	1bar=750mmHg=14,5 psi=100kPa

» 7.1.11 Micro Mode

Click 'Micro Mode' to select micro mode on and off. In activated mode, the infusion rate under any infusion mode cannot exceed this limit.
Setting the speed limit in Micro Mode: Click on 'system'.
- 'Maintenance' - enter password 2341 - 'Micro mode setting' to enter the micro mode speed limit setting interface.

⚠ Warning: Speed adjustment requires authorisation from the head of nursing department.

» 7.1.12 Drip sensor

Click on 'drip sensor' to set ON or OFF.
The "drip error" alarm function is only available when the drip sensor is installed.

⚠ Note: The default state for the drip sensor function is off, the system can be manually activated by the user when the drip sensor is to be used. If the function is activated when the drip sensor is not installed, the system will report "drip sensor connection" alarm.

» 7.1.13 Tube brand

For the infusion set brands built into the system, after installing the infusion set, click on 'commonly used set brand' to enter the infusion set brand selection interface and click on the preloaded brand option.
The brand of infusion set incorporated in the system: ENMIND CA.

⚠ Note: Infusion sets of different brands may possibly cause flow rate deviation, when using them, please confirm if the information displayed on the interface is consistent with the infusion set actually being used.

7.2 General

In the main interface, click on 'General' to enter the equipment configuration interface.

» 7.2.1 Network

This equipment is compatible with wireless or wired interconnection, when this equipment is equipped with a wireless module and connects to the internet via WIFI, the equipment display shows the icon 
Click on "Network' in the main interface to set the response.

Notes: ⚠
- This function shall be set by the professional technical maintenance team.
- After activating the networking function, the device can periodically transmit data from the device to the outside, and the data is for display only and does not provide any therapy suggestions.

■ Connection mode

The connection mode is compatible with WLAN modes.

■ WLAN

When the WIFI function is in use, turn on the WLAN switch of the equipment, set the name and password of the access point, and configure the TCP/IP parameters.

Notes: ⚠
- The wireless access must be set up by the professional technician recognised by our company.
- The data transmitted from this equipment does not provide any suggestions on therapy, and these data will not be used to calculate the therapeutic programme.
- When data is used by third party equipment or software, it is for display only, and will not be used for calculations or to generate alarms.

» 7.2.2 Sound

Click 'Sound' to enter the sound parameter setting interface, the volume has 10 levels. The lowest volume is ≥50dB, and the highest volume is ≤80dB. Move the selector to the preset level, after confirmation, click ✓

» 7.2.3 Date & time

Click on 'Date & Time' to enter the date and time setting interface. It allows you to set the date, time and format in this interface.
When setting date and time, directly enter the numerical value in the input method interface. For example, to preset a date "2015- 08-31", enter "20150831"; at the same time to preset the time "13: 34", enter "1334".
Time is displayed in 24h format or 12h format, date is displayed in British type, American type or Chinese type, please set according to requirement.

» 7.2.4 Screen lock

Click 'Screen Lock' to enter the automatic screen lock setting interface, select On or Off.
The automatic screen lock time can be set to 15s, 30s, 1 min, 2 min, 5 min, 10min 30min and so on, which means that the device will automatically lock the screen if the button is not touched or pressed within the corresponding time after start-up. If the display or the keypad is locked, no operation can be carried out.
After turning on the "Screen Lock' function during infusion, press the Power key to lock or unlock the device manually.
Unlock: press any key or click on the screen, a reminder to unlock will be displayed, click ✓

⚠ Note: The equipment shall be automatically unlocked if there is a high-level alarm.

» 7.2.5 Brightness

Click on 'Brightness' to enter the screen brightness configuration interface. The brightness has 10 levels.

» 7.2.6 Night mode

Click ‘Night Mode’ to enter the night mode configuration interface to set the start and end time of night mode and the brightness at night. At night, the system automatically adjusts the brightness to the user-defined value.

» 7.2.7 Nurse call

Click on ‘call nurse’ to select the function on and off.

Notes: ⚠
- The nurse call function must be used with the special cable.
- The user will not only rely on the relaying of the nurse call function as the primary alarm notification mode but will identify according to the equipment alarm and patient status.

» 7.2.8 Nurse call alarm level

Click on ‘Nurse Call Alarm Level’ to select different alarm levels.

» 7.2.9 Battery capacity indicator

The battery capacity display under H:M or percentage status can be changed and the display in the title bar changes accordingly.

7.3 Patient

Click on ‘Patient’ in the main interface to enter the configuration interface.

» 7.3.1 Patient information

Click on ‘Patient’ to enter the configuration interface for patient information and bed number, NHC, name, gender, age, weight, height.

7.4 Records

Click on ‘Records’ in the main interface to enter the configuration interface.

» 7.4.1 History entries

Click ‘Records’ in the main interface to enter the submenu, click on menu item ‘history entries’ in the history log query interface. The equipment supports saving more than 5000 history records, and can display the event name, event date and event time. When full, new records will cover the old records in turn. The history log contains alarm information, processing and escape logs, accumulation of delete, change, wait operation information.

» 7.4.2 Latest therapies

Click on “Records” in the main interface to enter the submenu, click on the menu item “latest therapies” in the medical records query interface.
1.This interface displays the last 20 medical records, the user can directly select as the current infusion plan, after confirming the parameters, and then start the infusion.
2.The system can store a maximum of 20 medical records, when full, the new records will cover the old records per shift.

» 7.4.3 Exporting history records

Log in to the PC Tool to connect this equipment to the PC.
After the device has achieved communication with the PC, the PC can automatically read the data in this device.
Create the history folder on the PC to export the data from the folder.

⚠ Note: Please do not export data when the equipment is running.

7.5 System

Click 'system' under the menu interface, enter the system information configuration interface.

» 7.5.1 Language

This equipment supports simplified Chinese, English, etc. Click on 'Language' to change the language of the device.

» 7.5.2 SN (serial number)

It checks the serial number of the equipment and the user cannot change the serial number.

» 7.5.3 Version

Check the software version in this interface.

7.6 Reset total volume

In ml/h Mode setting interface, click 'Reset total volume', the interface displays the operation confirmation dialog box, click ✓ to confirm the reset, otherwise click ↩
Click on the "volume" in the run interface during infusion. The interface displays the operation confirmation dialog box, click ✓ to confirm the reset, otherwise click ↩

7.7 Electronic memory function

After the device is switched off or loses all power, the history and alarm settings of the storage device are not affected, and the electronic memory function is stored for not less than 10 years.
When the power failure time is ≤30s, the alarm setting before power failure shall be recovered automatically.

8 ALARM INDICATOR AND TROUBLESHOOTING

8.1 Introduction to the level of alarm

During infusion and infusion preparation, this equipment will provide alarm when the fixed alarm threshold value is reached or exceeded and report it with light, sound and text. According to the importance of alarm information, as well as safety and emergency, the alarm is divided into three levels: high, medium and low. Refer to the following table for details:

Table 8.1-1

Alarm level	Sound signal interval	Sound signal interval	Light colour / flash frequency	Duty cycle
High alarm	10s	Di di di di di, Di di di di di	Red indicator flashes / 2.0±0.6Hz	20%-60%
Medium Alarm	15s	Di di di	Yellow indicator flashes / 0.6±0.2 Hz	20%-60%
Low alarm	25s	Di di di	The yellow indicator lights on	100%

In case of alarm, the system shall display the alarm interface. Click ✓ to exit the alarm interface. Click  to silence, if the alarm is not removed, the alarm sound will be sent 2min later.
Alarm signal sound pressure level range:
50dB(A)≤ low priority audible warning signals ≤ medium priority audible warning signals ≤ high priority audible warning signals ≤80dB(A)

⚠

Warning: Some alarm thresholds of this device can be set by the user without password protection restrictions: Occlusion pressure, alarm reminder, VTBI pre-alarm infused, alarm sound volume and timeout, the user shall confirm the parameters when setting the alarm threshold value, otherwise it could influence the alarm function or infusion safety.

8.2 Multilevel alarm rules

When there are multiple alarms, the system will send an alarm according to the following rules:

Table 8.2-1

Multilevel alarm	Rules
Several alarms of different levels are generated simultaneously	Display the highest-level alarms, with light, sound and text, average alarm report after deleting all highest-level alarms
Several alarms of the same level are generated simultaneously	Alarm in shifts circularly, time interval is 3s

8.3 Alarm management

⚠

Warning: When there is an alarm, check the patient's condition, remove the reason for the alarm, and then continue working.
Refer to Appendix C for alarm resolution.

8.4 Fault analysis and solution

When there is failure, the infusion pump display will show the failure alarm information, this item is the high-level alarm. Please clear the fault alarm according to the indicator. If it cannot be eliminated, please stop the equipment, contact our company to repair and test the equipment, do not put it into operation before the equipment has passed the inspection, otherwise, it may cause unforeseeable damage if it works with the fault.
If the equipment is on fire/burning for an unknown reason, or has other abnormal conditions, the user should shut off the power supply immediately and contact our customer service department.
- Under a single failure condition, the maximum infusion volume is 2 ml.

Notes: ⚠
- The distance between the pump operator and the infusion pump should not exceed 0.5 m, so as not to affect the operator's ability to correctly identify the alarm.
- The visual alarm signal is visible at 4 meters, the alarm indicator or analogue alarm indication area is visible to the naked eye; the visual alarm information is 1 meter away, and the alarm text or alarm icon is visible to the naked eye.

9 MAINTENANCE

9.1 Cleaning, disinfection and sterilisation

Warning ⚠
- Please turn off the power supply and unplug the AC/DC power cord before cleaning the equipment.
- During cleaning and disinfection, please keep the equipment in a horizontal and upward position to protect equipment and accessories from fluid spillage.

» 9.1.1 Cleaning

- Daily maintenance is mainly to clean the pump casing and pump body. It is inevitable that liquid/drug may flow into the equipment during infusion. Some liquids may corrode the pump and cause working problems. After infusion, please wipe the equipment, wipe with a clean damp soft cloth and then let it dry naturally.
- During cleaning of the equipment interface, please wipe with soft dry cloth, confirm that the interface is dry before use.
- Please do not immerse the equipment in water. Although this equipment has some waterproof function, when you see liquid splashes on the equipment, check if it works normally, perform electrical leakage test and insulation test if necessary.

» 9.1.2 Disinfection

1. Disinfection may possibly cause damage to the equipment, if necessary, it is suggested:
Please disinfect the equipment with common disinfectant such as 70% ethanol, 70% isopropyl alcohol and so on. Please follow the instructions of the disinfecting agent.
2. After disinfection, moisten the soft cloth with lukewarm water, dry the cloth and then wipe the equipment with it.
3. Do not sterilise the equipment with a high-pressure steam steriliser, do not dry with a hair dryer or similar product.

⚠
Warning: Please do not adopt Cidex OPA orthophthalaldehyde, methyl ethyl ketone or similar solvent, otherwise it may corrode the equipment.

9.2 Periodic maintenance

Notes: ⚠
- The professional will establish the complete maintenance plan, otherwise it could cause equipment malfunction or failure, and possibly harm physical safety.
- In order to ensure the safe use and prolong the service life of the equipment, it is suggested to maintain periodically and check once every 6 months. Some items will be maintained by the user, and some items will be maintained by the distributor of the equipment.
- Please contact our company in a timely manner if the equipment is found to be defective.

» 9.2.1 Visual verification:

1.The appearance of the equipment shall be clean and in good condition, free of cracks and water leaks.
2.The buttons are flexible and effective without invalid phenomenon; the sensitivity of the touch screen is normal.
3.The infusion pump should open and close the door smoothly, the safety clamp switch is in good condition.
4.The power cable is in good condition and securely installed.
5.After connecting the external power supply, check whether the AC and DC indicators of the device and the battery indicator light up normally.
6.Use the accessories designated by the manufacturer.
7.The environment meets the requirements.

» 9.2.2 Performance check

Self-diagnosis and normal perfusion function.
Normal alarm function.
Normal battery performance.

» 9.2.3 Maintenance plan

The following check/maintenance elements must be carried out by a professional technician recognised by our company. Please contact our company if the following maintenances are necessary. Clean and disinfect the equipment before testing or maintenance.

Maintenance elements	Cycle
Safety testing according to IEC 60601-1	Once every 2 years, check after replacing the printed circuit board assembly or if the equipment has been dropped or knocked.
Maintenance elements of the preventive system (pressure calibration, sensor calibration, pump)	Once every 2 years, or when the occlusion alarm, air bubble, alarm or precision infusion appears to be abnormal.
User-defined brand of the infusion set, calibration of the infusion set	When using the device for the first time, first use of the infusion set brand, reuse of the device after stop for a very long period of time.

9.3 Add new set brand and calibration

In the 'System' submenu, click on 'Maintenance' to enter the marking configuration interface, create the consumable marking, delete and calibrate the marking.

⚠

Warning: It is suggested to contact our company or local distributor, and customize and calibrate by a professional technician, otherwise, it cannot guarantee the accuracy of the infusion.

⚠ Note: The manufacturer's built-in mark may not be removed.

1. Add new brand

⚠

Note: If the current infusion set is not in the list of sets in the system, add the infusion set brand in this interface.
Click 'Add new brand' to enter the new brand. Edit brand infusion set, specifications and other information.

2. Delete
Enter the 'Delete' interface, click on it to delete user-defined infusion sets.

3. Calibration

⚠

The pump needs calibration:
- When it is the first time it is used.
- When new brand is added.
- When accuracy is not good.

Please calibrate the infusion set when using the built-in markings on the device for the first time, or the first user-defined infusion set, or after periodic maintenance.
Please prepare the following materials before calibrating:
A new, unused infusion set, balance, measuring cylinder.

Calibration steps:
1) Select the brand name
2) Install the IV tube
3) Press bolus to remove an air bubble in the line, place the needle in the graduated cylinder to collect the liquid.
4) Click on “Start / Calibrate” to start calibrating
5) After 3 minutes, the equipment will stop automatically and then record the net weight of liquid per ml.
6) Click on ‘Volume’, enter net weight (ml)
7) Calibration completed

Note ⚠
When the ‘Volume’ is less than 10ml, the infusion rate is ≤1500 ml/h.
When the ‘Volume’ is less than 7.5ml, the infusion rate is ≤1200 ml/h.

9.4 Repair

⚠
Warning: Maintenance of the equipment and replacement of components shall be carried out by professionals recognised by the company. Special attention shall be paid to the detection of the power supply when replacing the power module. Note if there is a false alarm, switch on the AC power supply and the battery will charge normally.

» 9.4.1 Normal repair process

Contact our company or authorised service personnel to repair if there is any fault, do not disassemble and repair the equipment. After repair, perform the overall test for the equipment. The manufacturer company can provide the circuit diagram and component list for authorized service personnel if necessary.

» 9.4.2 Maintenance for long-term storage

If the equipment is not used for a long period of time, store the equipment in the carton and keep it in a shaded, cool, dry place out of direct sunlight.
The following operations are necessary to use it again:
1. Check the flow rate accuracy to avoid discordance between the infusion set and the actual parameters after it has not been used for a long period or for other reasons, otherwise, it may cause infusion error, may influence the therapeutic effects and even cause medical negligence.
2. Perform verification of air bubble alarm and occlusion alarm.
3. Test charging and discharging the battery to confirm that the battery life is also usable.

9.5 Equipment components and accessories

⚠
Warning: Only components and accessories designated by our company should be used, otherwise the equipment may be damaged or the performance of the equipment may be impaired.
During the normal lifetime of the equipment, the battery and waterproof membranes are consumables, it is suggested that they are replaced once every 2 years, please contact your distributor.

Standard accessories	Two batteries
	Waterproof membrane
	Locking mechanism
	Power cable
Optional accessories	Wifi module
	Drop sensor
	DC power cable
	DB15 cable

9.6 Date of production

Refer to the product label.

9.7 Recycling

The normal service life of this equipment is 10 years and depends on the frequency of use and maintenance. The equipment should be discarded after reaching the useful life, please contact the manufacturer or the distributor for more detailed information.
1. Obsolete equipment can be returned to the original distributor or manufacturer.
2. The lithium-ion polymer battery has the same treatment method, or in accordance with applicable laws and regulations.
3. Please proceed in accordance with your institution's medical equipment disposal plan.

10 BATTERY

This equipment is equipped with rechargeable lithium-ion polymer battery to ensure normal operation when the equipment is transported or not connected to external power supply.
When the external power supply is connected, no matter the equipment is on or off, the battery will be charging. When charging, the equipment display shows the battery charging indication icon  .
In case only the built-in battery is being used for power supply, when the battery reaches 20%, please connect the equipment to an external power supply to charge the battery.

⚠ Warning: Only the battery designated by the manufacturer shall be used.

10.1 Check the performance of the battery

The performance of the built-in battery may decrease depending on the duration of use, it is recommended to check the battery once a month.
1.Disconnect the equipment from the patient and stop all infusions.
2.Provide power supply to the equipment to charge the battery, at least 10h.
3.Run the infusion pump on battery only, infuse at a rate of 25 ml/h, test the time until the battery is depleted and the equipment is switched off.
4.If the battery power time is significantly less than the time indicated in the specification, consider replacing the battery or contacting us.

10.2 Replacement of the battery

It is recommended to replace the battery every 2 years; please contact your dealer.

Warning: ⚠
Inexperienced personnel are prohibited from replacing the battery, otherwise it may cause the battery to explode, or leak and cause personal injury.

11 AFTER-SALES SERVICE

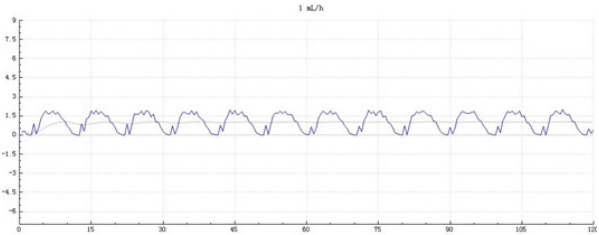
The warranty for this product is 2 years from the date of purchase, with respect to materials and workmanship.
The following circumstances will invalidate the warranty.
1. Failure caused by misuse or unauthorised repair.
2. Damage caused during transport after purchase.
3. Failure and damage caused by fire, corrosive gas and salt spray environment, earthquake, hurricane, flood, abnormal voltage and other natural disasters.
Our company has a Technical Service for repairs after the expiration of the warranty period.

12 APPENDIX

Appendix A Charts and trumpet curves

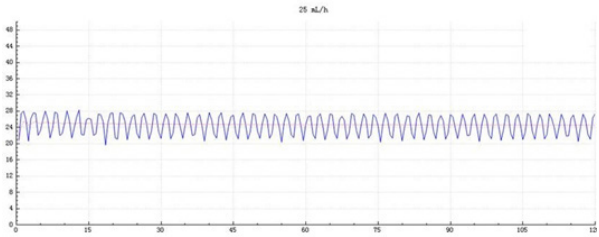
■ Appendix A.1 Start-up charts

Brand and specification of infusion set:
ENMIND-CA (20 drops)
Sample Quantity: 3 units
Qty. sample IV set: 3 sets
Flow rate: 1 ml/h
Measuring interval: Δ t = 0.5min
Measuring duration: T = 2h



Graph 1: Flow rate (ml/h) versus time (min) plotted from data collected during the first 2 hours of the test period.

Brand and specification of infusion set:
ENMIND-CA (20 drops)
Sample Quantity: 3 units
Qty. sample IV set: 3 sets
Flow rate: 25 ml/h
Measuring interval: Δ t = 0.5min
Measurement duration: T = 2h



Graph 2: Flow rate (ml/h) versus time (min) plotted from data collected during the first 2 hours of the test period.

■Appendix A.2 Trumpet curves

Brand and specification of infusion set: ENMIND-CA (20 drops)
Sample quantity: 3 units
Qty. sample IV set: 3 sets
Flow rate: 1 ml/h
Measuring interval: Δ t = 0.5min
Measuring duration: T = 2h

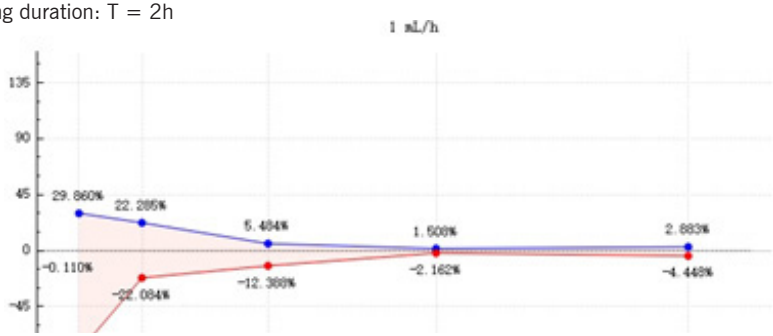


Figure 3: Percentage variation of the Ep trumpet curve against the observation window duration P (min) and the total mean percentage error once plotted from the data collected during the second hour of the test period.

Brand and specification of infusion set:
ENMIND-CA (20 drops)
Sample Quantity: 3 units
Qty. sample IV set: 3 sets
Flow rate: 25 ml/h
Measuring interval: Δ t = 0.5min
Measurement duration: T = 2h

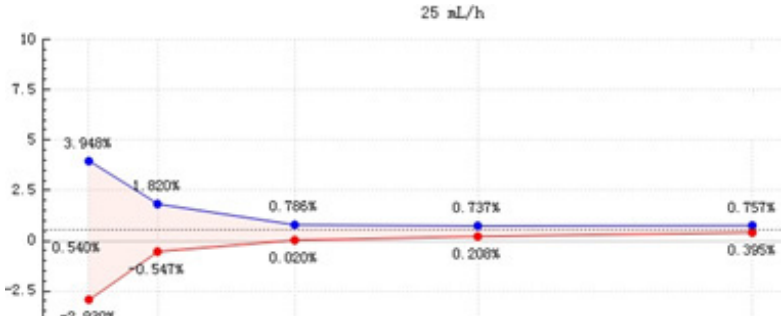


Figure 4: Percentage variation of the Ep trumpet curve against the observation window duration P (min) and the total mean percentage error once plotted from the data collected during the second hour of the test period.

⚠

Note: Infusion accuracy may be affected by the environment of the infusion pump, such as pressure, temperature, humidity, infusion ingredients and so on.

Appendix B Occlusion, speed of response

Occlusion pressure (mmHg)		Flow rate (ml/h)	Occlusion alarm activation time (h:m:s)	Max. bolus (ml)
1	50	0.1	01:44:10	0,137
		1	00:10:58	0,178
		25	00:00:15	0,134
5	900	0.1	35:07:19	0,102
		1	01:50:32	0,172
		25	00:04:22	0,132

⚠

Notes:
The pressure alarm intensity error is ± 40 mmHg when the occlusion alarm level is 1.
The pressure alarm intensity error is ± 125 mmHg when the occlusion alarm level is 2-4.
The pressure alarm intensity error is ± 180 mmHg when the occlusion alarm level is 5.

⚠

Notes:
- Previous test conditions: ENMIND-CA brand infusion set.
- The occlusion pressure alarm, alarm delay time and bolus are influenced by temperature conditions and test line length. (Increased line length will lead to increased alarm delay. Low temperature will produce poor tube elasticity, exceeding the stated error range, resulting in inaccurate alarm pressure. Shortening the line length and increasing the temperature has no effect).
- The above data are typical values under test conditions, refer to product test data for actual data, data may be different if test conditions are different.

Appendix C Alarm and solution

Type of alarm	Alarm level	Alarm delay	Reason	Solution
VTBI infused	High	<1s	The infusion is complete	Press the Stop button to stop the alarm.
High pressure	High	The device operates at 1ml/h, and the file lock level is set to 4. The delay of the lock alarm activation must be ≤ 2h.	1. Line occlusion during infusion.	Manually solve the occlusion problem, press the Start button to continue the infusion.
			2. Liquid/drugs in the current infusion line of high viscosity, while the occlusion level of the system is too low.	Increasing the alarm level, press the Start button to restart the infusion.
			3. The pressure sensor is damaged.	Please contact the distributor for repair.
Empty battery	High	<1s	1.When the power is supplied by the battery incorporated, in low battery, the alarm duration is >30min.	Immediately connect to an external power supply.
			2. Ageing of the battery or the circuit equipment The load is damaged.	Please contact the distributor or manufacturer for repair.
Backup battery depletion	High	<1s	1.Backup battery is almost depleted.	Immediately connect to an external power supply.
			2. Backup battery is disconnected or damaged.	Please contact the distributor for repair.
KVO complete	High	<1s	KVO working time reached 30min, infusion pump stops running.	Press the Stop button to stop the alarm.
Unique bubble	High	<1s	Air bubble in the infusion line.	Press the Stop button. to stop the alarm, disconnect the patient line, remove air with purge function, or open the infusion pump door to manually remove air bubbles.
Cumulative bubble	High	<1s	When bubbles in the infusion line within 15 minutes reach the cumulative bubble alarm threshold	Press the Stop button to clear the alarm, separate the tubing from the patient, using the Purge function to remove bubbles, or open the door manually to remove bubbles.

Type of alarm	Alarm level	Alarm delay	Reason	Solution
Open door	High	<1s	When the infusion pump door opens during infusion.	Close the infusion pump door to stop this alarm.
Drug dosage limits exceeded	High	<1s	While using drugs in a drug library for infusion, the alarm will be activated if the maximum dose in a certain period of time has exceeded the preset limits.	Press the Stop button to stop the alarm.
System error	High	<3s (100ml/h operation, open-circuit analogue sensor)	If the auto check failed or internal fault system was activated, the system will give the error alarm with the code number.	Reset the device to verify if the alarm disappears, if it persists, contact maintenance personnel.
Drip error	High	<1s	The angle of inclination of the dripper is too large or a drip sensor is installed that is smaller than the liquid level of the dripper.	Verify drop sensor installation or drip cup liquid level, press Stop button to stop the alarm.
			The specifications of the infusion set are not consistent with the specifications displayed on the drip rate interface, which causes the error.	Check if the characteristics of the infusion set match the displayed parameter specification, if it is not constant, it will be modified by the technical maintenance professionals.
Empty bag	High	<1s	The dropper was detected with no drops falling within the specified time.	Check for fluid in the infusion bag, press Stop to cancel the alarm.
Occlusion pre-alarm	Medium	<1s	The line pressure is close to the preset occlusion pressure level.	Check for online occlusion and click OK to remove the alarm.
The waiting time is over	Medium	<1s	The timeout has been reached.	Press the Stop button to stop the alarm.
VTBI near the end	Low	<1s	During infusion, the remaining time is less than or equal to the set time.	This alarm cannot be cleared and wait until the end of the infusion.
Battery almost empty	Low	<1s	1. When the power is supplied only by the built-in battery, with low battery, the alarm duration is >30min.	The alarm is automatically cleared after the external power supply is connected.
			2. Aging of the battery or the charging circuit is damaged.	Please contact the distributor or manufacturer for repair.

Type of alarm	Alarm level	Alarm delay	Reason	Solution
Alarm reminder	Low	<1s	After installing the infusion set, under non-working or alarm status, it is not operated within the system time.	Click on any button to stop.
There is no power supply	Low	<1s	In this state, the AC power supply is approved, but the AC power cord may be disconnected.	The alarm is automatically cleared after the external power supply is connected.
Drip sensor connection	Low	<1s	When activating the drip sensor, the device is not connected to the drip sensor.	Switch on the drip sensor or deactivate the drip sensor in the menu.

⚠ Note: When the alarm sounds, click the 'Mute' icon on the display to temporarily stop the audible alarm for 2 min.

Appendix D Electromagnetic Compatibility Declaration EMC

This product needs to take special precautions regarding EMC and needs to be installed and commissioned in accordance with the EMC information provided, and this unit may be affected by portable and mobile RF communication equipment.

Precautions: ⚠
- This unit has been fully tested and inspected to ensure proper performance and operation.
- This equipment should not be used near or on top of other equipment and, if it is necessary to do so, the normal operation of the pump in the configuration to be used should be verified.

Warnings: ⚠
The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the infusion pump manufacturer, as replacement parts for internal components may result in increased emissions or decreased immunity of the infusion pump.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the infusion pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The infusion pump only uses RF energy for its internal functioning. Therefore, their RF emissions are very low and are not likely to cause interference at equipment electronic devices nearby.
RF emissions CISPR 11	Class A	The infusion pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Fluctuations from voltage / emissions of flicker IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - electromagnetic immunity

The infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the infusion pump should assure that it is used in such an environment.

Immunity test	Test level IEC 60601	Level of compliance	Electromagnetic environment - guide
The electrostatic discharge (ESD) IEC 61000-4-2	Contact ±6 kV ±8 kV air	±8 kV contact ±15 kV air	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity shall be of at least 30%.
Fast electrical burst/transients IEC 61000-4-4	±2 kV for power supply lines +1 KV for input/ output lines	±2kV for lines of power supply	The quality of the power grid should be that of a typical commercial or hospital environment.
Increase IEC 61000-4-5	± 1 kV on line(s) to line(s) +2 KV on line(s) to earth	± 1 kV on line(s) to line(s) +2 KV on line(s) to earth	The quality of the power grid should be that of a typical commercial or hospital environment.
Voltage drops , short interrup-tions and voltage variations on the input lines of power supply IEC 61000-4-11	<5% UT (>95% decrease in UT) for 0.5 cycle 40% UT (60% decrease in UT) for 5 cycles 70% UT (30% decrease in UT) for 25 cycles <5% UT (>95% decrease in UT) for 5 sec.	<5% UT (>95% of decrease in UT) for 0.5 cycles 40% UT (60% of decrease in UT) for 5 cycles 70% UT (30% of decrease in UT) during 25 cycles <5% UT (>95%of decrease in UT) for 5 sec.	The quality of the mains power supply should be that of a typical commercial or hospital environment. If the user of the infusion pump requires continuous operation during power interruptions, it is recommended that the infusion pump be powered from a battery or uninterruptible power supply.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a normal lo-cation in a typical commercial or hospital environment.

Note: UT is the AC voltage prior to the application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The infusion pump is intended for use in the electromagnetic environment specified below. The customer or the user of the infusion pump should ensure that it is used in such an environment.

Immunity test	Level IEC 60601 test level	Level of compliance	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the infusion pump, including cables, than the recommended distance calculated using the equation for the frequency of the transmitter. Recommended separation distance $D = 1{,}167 \sqrt{P}$ 80 MHz to 800 MHz $D = 2.333 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths of fixed RF transmitters, as determined by an electromagnetic site survey, should be below the compliance level for each frequency range (B). Interference may occur in the in the vicinity of equipment marked with the following symbol: 
RF radiated IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

Note 1: At 80 MHz and 800 MHz, the upper frequency range applies.
Note 2: These guidelines may not be applicable 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 of radiotelephones (mobile/wireless) and land mobile radios, amateur radio, AM and FM radio and TV broadcasting, 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 at the location where the infusion pump is used exceeds the applicable ER compliance level above the infusion pump, they should be observed to verify normal operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the infusion pump.
B: Above the frequency range 150 kHz to 80 MHz, field strengths must be less than 10 V/m.

Recommended separation distances between
Portable and mobile RF communications equipment and the infusion pump.

The infusion pump is designed for use in an electromagnetic environment where radiated disturbances are controlled. The customer or the user of the infusion pump can help to avoid electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the infusion pump, as recommended below, depending on the maximum output power of the equipment communications.

Maximum rated output power of the 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 with a maximum output power not listed above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance applies for the upper frequency range.
Note 2: These guidelines may not be applicable in all situations. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix E Wireless module information

Parameter name	Parameter value
Frequency range	2.412GHz-2.482GHz
Type of modulation	CCK, DSSS, OFDM
Effective radiation power	<20dBm

Appendix F Factory default dataset

Parameters	Default settings	Parameters	Default settings
Drug library	OFF	KVO	1ml/h
WIFI	OFF	Bolus dose	1000ml/h
Drip sensor	OFF	Purge rate	1000ml/h
Micro Mode	OFF	Sound	10%
Nurse call	OFF	Brightness	50%
Anti-bolus	ON	The size of the bubble	100 μl
DPS	ON	Cumulative bubble	300 μl/15min
Screen lock	1min	Occlusion pressure	600mmHg
Finish pre-alarm	2min	Alarm reminder	2min