Cylinder Pump

Anyfusion® H-100

User Manual

Doc No. MTH1-UM-E00
Revision 0.0 (2018.12.24)
Software Version : 1.00

Contents

Contents

Anyfusion H-100 User manual

01. This manual provides the method to use Cylinder Infusion pump and Anyfusion Cylinder cartridge set (Model name : Anyfusion H-100) and its technical specification.

02. Please read the manual of medical device and accessory before use.

03. Please ensure that only clinical doctors and nurses who are familiar with the operation of this pump use this pump.

04. The pump is the patient care equipment that is necessary for emergency room, newborn baby room and, etc.. This device can set the flow rate from 0.1ml to 9,999ml and infuse drugs into patient with accuracy deviation of ± 2%.

05. The pump can be set the range of flow rate from 0.1ml/h to 999.9ml/h by an User.

06. The pump allows you to set Standard infusion mode, Dosage mode and PCA mode.

07. Repair or circuit alteration of this equipment can be only carried out by the personnel who are authorized by Meinntech. Meinntech will not be responsible for any defects or damage caused from repairs or disassembly done by anyone other than personnel authorized by Meinntech.
(Safety shall not be assured).

PART 1.

Notes For Safety

1. Notes For Safety

Safety precautions are classified as below in accordance with the expected, Warning and Caution.

Warning	Caution
A precaution which could result in critical personnel injury or loss of life if instructions are not followed.	A precaution which could result in minor personnel injury or damage to the product if instructions are not followed.

When installing the pump

(1) Ensure that the pump is always clean prior to use.
(2) The correct electric power has to be provided.
(3) Ensure that the power cable is connected safely.
(4) The location of installation must not be affected by temperature, humidity and pressure.
(5) Avoid strong direct sunlight when placing or using.

When operating the pump with external power

(1) Do not use an extension cord without being grounded.
(2) Check the power plug prior to use.
(3) The power plug has to be plugged into grounded outlet in the hospital, and check the rated voltage and the frequency beforehand.

When operating the pump with battery

(1) General AC power is required for operating this device. Battery is used for as an auxiliary power when carrying the device or AC power failure etc.
(2) Please consider of the usage time when operating the pump with battery. (Runs 8hrs at 100ml/h with full charge.)
(3) Connect the power cord to the pump to charge the battery if the “Low Battery” warning alarm is on the LCD display.
(4) Charge the battery at least once in a month to prevent reduction of its life-span when unused in long term.
(5) The battery capacity is indicated on the LCD display while the battery charges. Charge the battery fully(100%).
(6) Replace the battery if the battery usage time drastically decreases after being fully charged.

>> Contact the supplier you purchased the product to replace the battery.

1-1. Warning

Be sure to follow mentioned warning below.

- This pump is prohibited for the purpose of infusing the blood products and/or blood cytoplasm.
- Do not open or disassemble the pump without permission of manufacturer.
- Please use designated Pole clamp when you are trying to fix the pump to IV Pole. (The usage of undesignated Pole clamp shall not assure the safety and functionality of the device. It might cause of malfunction of the pump or any accident.)
- Please connect enclosed AC power cable to AC power. Do not use enclosed AC power cable to any other equipment. (There is a possibility of malfunction to the pump when using undesignated AC power cable. Also, we don’t assure the electrical safety without ground connection.)
- Please check power supply status of the pump before use. (If power supply doesn’t work properly, internal battery should be used. Otherwise, emergency situation may be occurred.)
- Since during solution may cause a short-circuit, ensure that the connecting sections of the AC inlet and AC power cable are not wet when connecting. If you find moisture on the pump, please turn off the power and disconnect AC power cable. Then clean up the pump with a dry cloth. (This device is not waterproof. So the moisture may effect to inner electrical parts to get malfunction of the pump.)
- Cylinder cartridge is a single-use product. Therefore, it must be discarded. after it is used.
- Check the infusion volume, VTBI, flow rate, time and setting values carefully prior to infuse.
- Do not operate the pump in an area where strong sources of high frequency waves and electromagnetic field are presented.
- Do not leave the pump in a damp environment or disinfection gas area. (These environments may affect internal electrical parts and cause of malfunction or damage to the equipment.)
- The pump cannot be used for the purpose of infusion of blood or blood product of cytoplasm.
- In order to avoid the hazard of infections, the STERILIZATION for the part to be operated should be done thoroughly before the operation.
- Do not operate the pump in the presence of flammable anesthetics, flammable liquids, or explosive gases. (Danger of fire or explosion)
- Be careful of shocks as it may cause breakage or error due to physical shock.

1-2. Caution

Be sure to follow mentioned caution below.

- Check the sterilized packing condition when using before unpacking Cylinder cartridge, IV set at first.
- Please follow IV Pole instruction when you use IV Pole.
- Ensure that Cylinder Cartridge is installed correctly before operating the pump.
- Do not touch any buttons by mistake when the pump is operating. Use the key lock function if necessary.
- Please check any set-up errors before you start delivering fluid. (Errors in number, flow rate etc.)
- Please check Cylinder cartridge and tube installation, if the pump door doesn't close properly.
- Please be careful when infusing high viscosity liquid drug. It may cause occlusion alarm.
- When you start medicine fluid delivery, check the setting values before use if necessary.
- Please solve the problem when restarting the pump after the occlusion alarm.
- Be sure to remove the air inside the tube before connecting to the patient line.
- If the pump is used in the vicinity of the electrical scalpel (Medical electrical scalpel is surgical equipment for incision and coagulation by the high frequency current.), the following must be ensured before use.
  ① The electrical scalpel device shall be operated from a separate power systems.
  ② It shall maintain a minimum distance of 25cm between the device and the electrical scalpel cord (scalpel holders, scalpels cord and a return electrode) and the electrical scalpel body.
- Do not keep or use the infusion pump in the presence of electrostatic discharge. (It can cause malfunction.)
- Please avoid a heat source, dust, fluff and strong direct sunlight.
- Do not use the pump where can cause sudden changes in temperature, humidity and pressure.
- Connect the pump to a grounded AC Power source and charge for 5 hours or more with power off condition when using the pump for the first time or if you have not used for a long time. (If you do not charge properly, the internal battery may not work as power failure.)
- Please check the device regularly. If a malfunction is suspected, stop using the product and request for the inspection and repair.
- Use the micro filter to fill the fluid full with the arrow upper wise.
- Please carefully use the micro filter without any external impact.

PART 2.

General Details

2. General Details

Device	Cylinder Pump
Model Name	Anyfusion H-100
Manufacturer's Name	MEINNTECH CO., LTD
Address	301, 401, 501, 502, Digital Empire B/D, A-dong, 387 Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Korea.
Contact	TEL. +82-31-381-7076~7 FAX. +82-31-381-7053

PART 3.

Description of the Device

3. Description of the Device

3-1. Description of the Device

Anyfusion H-100 is a Cylinder pump that delivers medicine fluids into a patient's body in controlled amounts and speed. (Any types of drug which they need to be controlled accurately can be infused with this device not only existing infusion pump of peristaltic finger mechanism method but also the drug used at Syringe pump.) It is also equipped with safety features such as alarms or other operator alerts that are intended to activate in the event of a program. (Ex: air bubble, occlusion.)

3-2. Intended use

This pump is a cylinder type medicine infusion pump which is used to infuse a certain amount of medicine into the patient.

3-3. How to use

Refer to Instruction for use.

3-4. Device life-cycle

5 years

Caution
After 5 years, Please contact to Meinntech to checkup the device.

3-5. Cylinder cartridge life-cycle

3 years after sterilization has been done.

PART 4.

Appearance & Functions

4. Appearance & Functions

Main Device

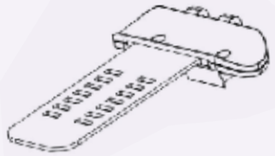

Left Side


Front


Right Side

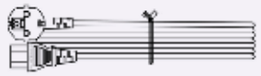

Back

Accessory Component


Syringe Holder


Rack(Option)


PCA Hardset(Option)


Power Cord(AC Cable)

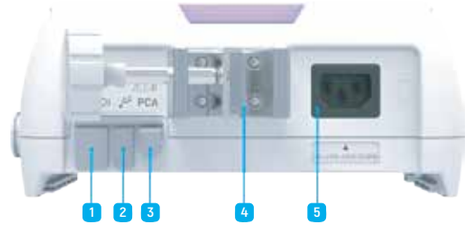
User Manual

4-1. Appearance

Description of Anyfusion H-100 appearance

[Front]

[Back]



Front Side

No	Item	Function
1	Handle	Use for holding or carrying the pump
2	Status Region	Display of operating status using symbol
3	Silence Key	Stop the buzzer in case of alarm
4	Alarm LED	Display of Green, Amber, Red as per the alarm status
5	Power Key	Switch to turn on the power
6	Window LCD	Screen displaying all infusion information (Infusion speed, infusion volume, alarm information, etc.)
7	Menu Key	Key for move the Main menu
8	Up Key	Move the cursor upwards
9	Down Key	Move the cursor downwards
10	BOLUS Key/ PURGE Key	Bolus key: Infusion of set amount under the set value of speed, activated only on the infusion mode. PURGE Key : Rapid infusion key for air bubble removal

4-1. Appearance

Description of Anyfusion H-100 appearance

Front Side

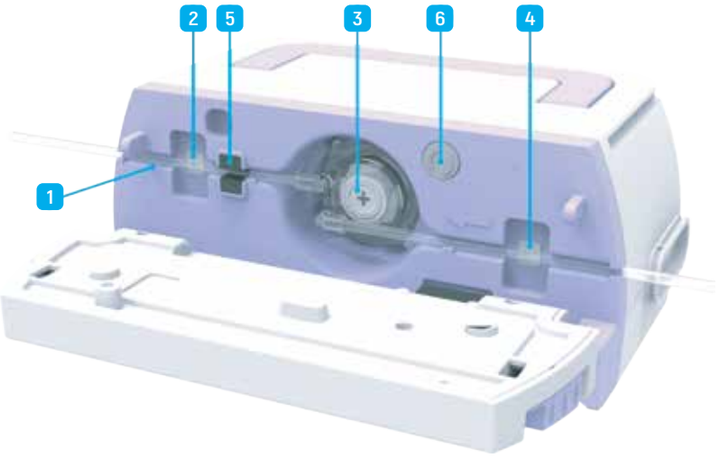
No	Item	Function
11	START Key	Start infusion
12	STOP Key	Stop infusion
13	Door Lock	Door lock button
14	Syringe holder mounting part	Use for fixing the Syringe holder
15	Numeric Key	Keys for set-up control
16	Key Lock	Locking function of button/Key
17	CLR Key	Key for delete input / Key for move the previous step
18	OK Key	Key for set-up completion

Back Side

No	Item	Function
1	RS232	Use to connect a RS232 cable
2	USB	Use to connect a USB cable for History Log Download
3	PCA Port	Use to connect a PCA Handset
4	Pole clamp	Use pole clamp to fix the pump to the IV Stand
5	AC Power Inlet	Inlet for main AC 220V power

4-2. Inner part

Description of inner part.

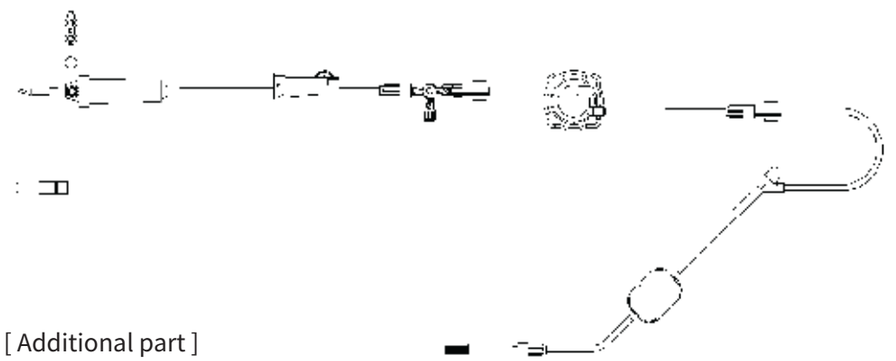


Inner Part

No	Item	Function
1	TUBE GUIDE	Guide for tube installation
2	Occlusion Detector (Downstream)	Detection of blockage for ringer solution set (Lower part)
3	Cylinder cartridge	A dedicated set used to delivers medicine fluids into patient from the pump
4	Occlusion Detector (Downstream)	Detection of blockage for ringer solution set (Upper part)
5	Air-in-line Detector	Detection of bubble inside the tube
6	Cylinder release Key	Cylinder release function

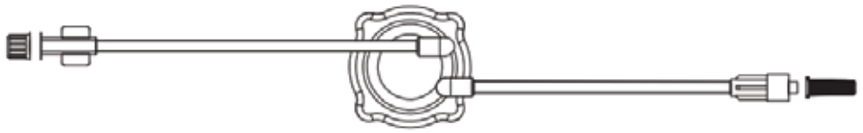
4-3. Anyfusion Cylinder Catridge Set

Description of Anyfusion H-100 components.



[Additional part]

Name	Model	Component	Description
Extension Type	AC11_5.0	Spike cover + Spike + Chamber + Roller calmp + Luer Lock + 3way stopcock + Female connector + Cylinder cartridge + Y site + Micro filter + Luer lock + Luer lock cover	5.0μm used
	AC11_1.2		1.2 μm used
	AC12_0.2		0.2 μm used
	AC12_1.2		1.2 μm used

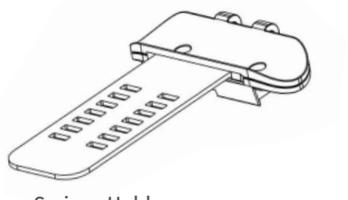


Name	Model	Component
Standard Type	AC00003	Female cover + Female connector + Cylinder cartridge + Luer lock + Luer lock cover

※ Please contact Meinntech Co,. Ltd to get more infumation.

4-4. Accessory

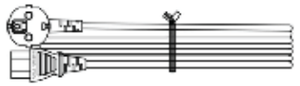
Description of anyfusion H-100 components.



Syringe Holder

Rack(Option)

PCA Hardset(Option)



Power Cord(AC Cable)

User Manual

Accessory Part

No	Item	Function	Q'ty
1	Syringe holder	Device for securing syringe to the pump	1EA
2	PCA Handset (Optional)	Device for using PCA function	1EA
3	Rack (Optional)	Apparatus for stacking pumps	1EA
4	AC Cable	AC power cable for supplying power to the pump	1EA
5	User Manual	Manual describing method of use the pump and functions	1EA

PART 5.

The Method of Installing Pump

5. The Method of Installing Pump

The preparation before use

Information of Anyfusion H-100 before use.

1. Check prior to use.

(1) Read this manual carefully before using Anyfusion H-100, understand its functions and please be aware of precautions.

(2) Please set-up the time and date in set-up window for recording accurate date before using the pump for the first time.

2. Essential requirement of using the pump at first.

Charge the battery more than 5 hours connecting to AC power with off state before use the pump for the first time.

01.

Installing pump

(1) In case of using the rack, secure both pole clamps on the rack to the IV stand and install the pump(s) to the rack.

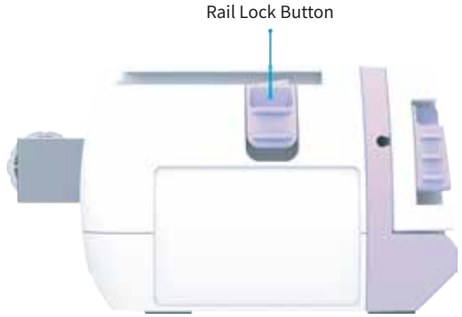
(2) When securing the pump(s) to the rack, push device(s) all the way along with the slide rail until the click sound that the rack meets the AC inlet on the device(s).

(3) When using the pump alone, fix the pole clamp on the back of the pump to the IV stand.

(4) When stacking the pumps (pump-to-pump); locate the device on the bottom first, and mount the upper pump with direction towards the front from the back side as shown on below image.

(5) When detaching the pump from the rack, press and hold the Rail Lock Button and pull the pump towards the front.

(6) When disconnecting the pump from the pump-to-pump connection, press and hold the Rail Lock Button on the bottom pump and push the upper device towards backward to remove it.



Caution

After mounting the pump securely, please ensure that the pump is fixed properly to the IV stand and no at risk falling.

5. The Method of Installing Pump

02.

Connecting AC power

(1) Plug the supplied AC power cord into AC inlet at the back of the pump.

(2) When the AC power is connected, battery charge indicator appears in the LCD display.

(3) The charge complete display appears on the LCD screen if the internal battery is fully charged.

[Battery charging screen]

[Battery charging complete screen]

Caution

- Make sure that there is no water on the AC terminal before connecting the power cord to the Cylinder pump.
- Use designated power cord supplied with the product.

03.

How to install Cylinder cartridge

(1) Press the power button for 2~3 seconds to turn on the power, check if the self test is proceeding, and the screen changes to install the cylinder cartridge.

(2) When the self-test is completed, open the pump door and attach the cylinder cartridge onto the unit. Pay attention to the mounting directions of the cylinder cartridge.

(3) When the installation of Cylinder cartridge is completed, the motor axis will rotate to lock the Cylinder cartridge automatically.

(4) Insert the IV line into the tube guide and press it by hand to make sure it is properly mounted. Pay attention to install the IV line into the air bubble sensor.

(5) After completing the Cylinder cartridge installation, open the Roller clamp and close the door. The pump will show priming selection screen.

04.

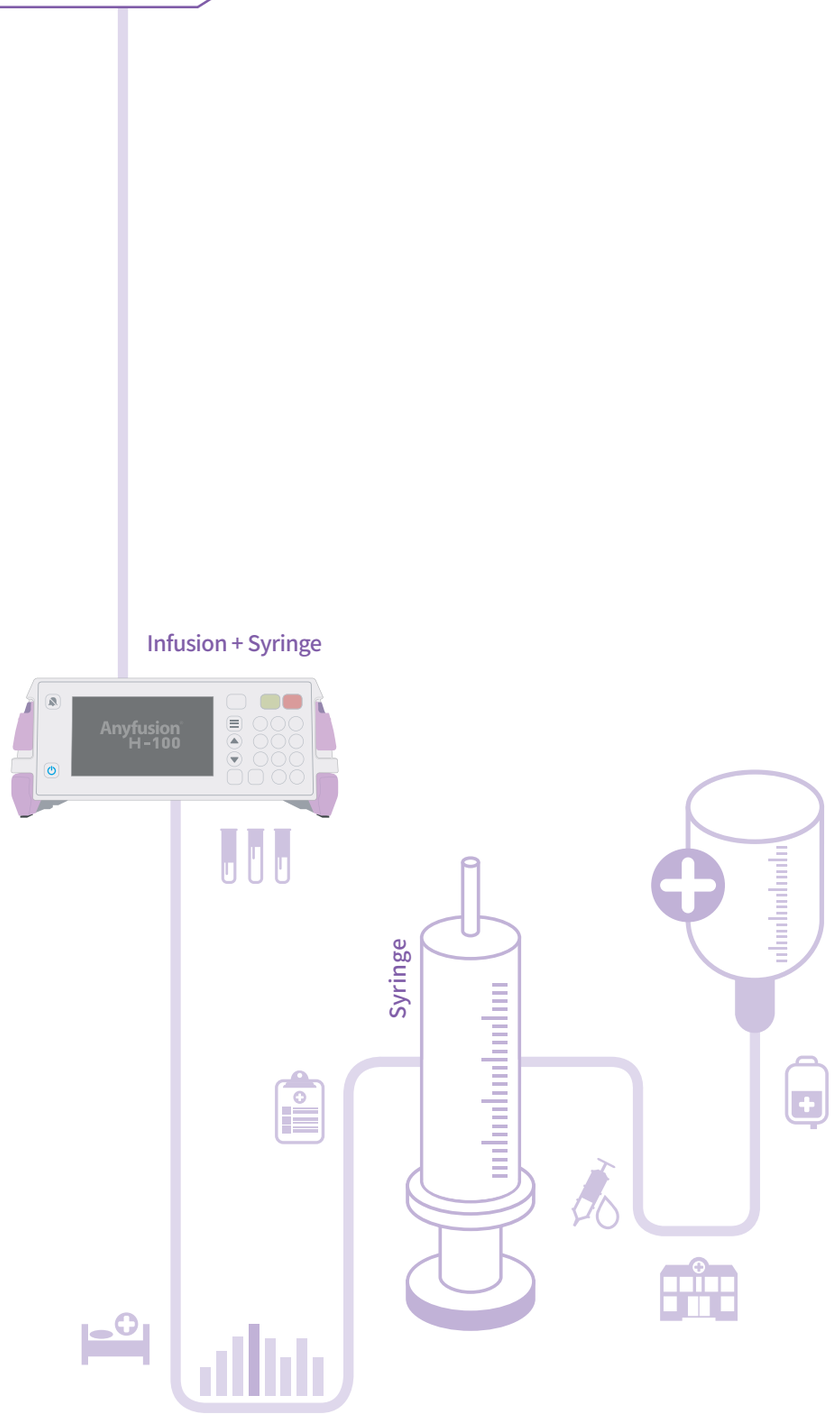
How to install Syringe

(1) Equip the syringe holder to the syringe holder mounting part on the right side of the pump.

(2) Connect syringe to the syringe holder.

(3) Connect IV set to the syringe.

(4) Installation of the cylinder cartridge complies with the above installation method of the cylinder cartridge.



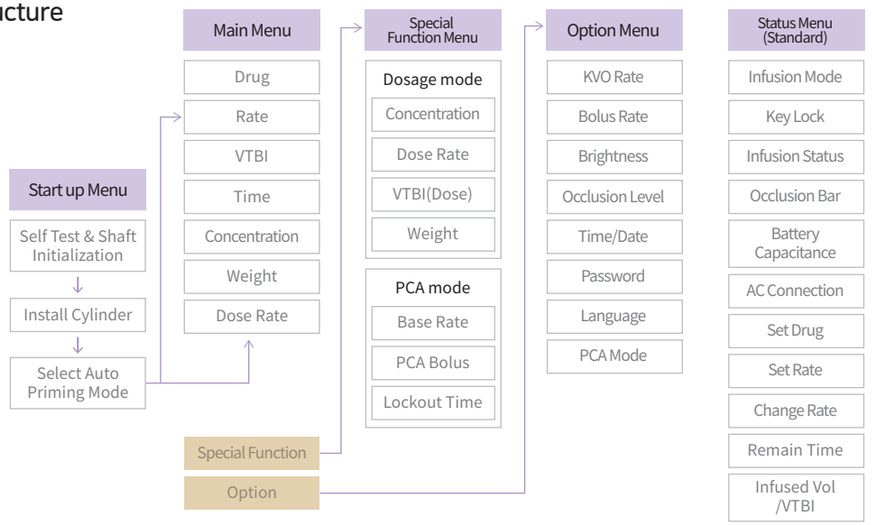
PART 6.

Pump Operation Sequence

6. Pump Operation Sequence

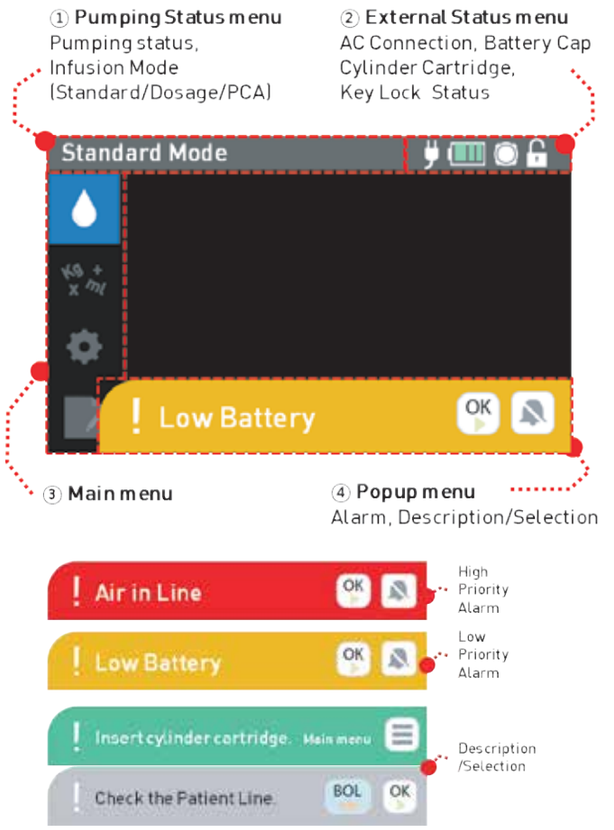
6-1. LCD Display

Menu Structure



Beginning Screen

Main Display



Menu Caption

No	Item	Description
1	Infusion status menu	Display showing infusion status, infusion mode
2	External status menu	Display showing AC, Battery status, Cylinder attached/detached, Key lock
3	Main menu	Menu showing Infusion mode, Set-up, Log
4	Popup menu	Popup showing Alarm, Choice instruction, Explanation phrase

6-1. LCD Display

External Status Menu Display Symbols

	Key Lock		Below 7%, Battery Empty
	Key Unlock		7%~20%, Battery Low
	Cylinder Cartridge Attached		Battery Status 20~50%
	Cylinder cartridge Detached		Battery Status 50~75%
	AC100~240V		Battery Status 75~100%

Standard Mode

No	Name	Description
1	Drug	Select the drug type to use.
2	Rate	Input Rate value to use. >> Set-up range : 0.1~999.9ml/h
3	VTBI	Input VTBI value to use. >> Set-up range : 0.1 ~ 9,999ml >> When you input Rate & VTBI value, Time is automatically calculated.
4	Time	Input Time value to use. >> Set-up range : 00:01 ~ 99:59 (hh:mm) >> When VTBI and Time are set, Rate is automatically calculated.

Dosage Mode

No	Name	Description
1	Drug	Select the drug type to use.
2	Conc.	Input Conc value to use. >> Set-up range : 0.1~999.9mg/ml
3	Dose	Input Dose value to use. >> Set-up range : 0.1~999.9mg/h
4	VTBI	Input VTBI value to use. >> Set-up range : 0.1~9,999ml
5	Time	Input Time value to use. >> Set-up range : 00:01 ~ 99:59 (hh:mm)
6	Weight	Input weight of patient. >> Set-up range : 0.1 ~ 300.0 kg

PCA Mode

No	Name	Description
1	Drug	Select the drug type to use.
2	Rate	Input Conc value to use. >> Set-up range : 0.1~999.9ml/h
3	PCA Bolus	Selection when adjusting infusion volume with PCA handset >> 1~99.9 ml
4	Lock	Input Time value to use. >> Set-up range : 00:01 ~ 59:59 (mm:ss)

6-1. LCD Display

Set-up

No	Name	Description
1	KVO Rate	Control KVO dosage rate >> Level 0.1~5ml/h
2	Bolus Rate	Control rapid infusion rate >> 50~999.9ml/h
3	Brightness	Control brightness of screen. >> Level 1~5
4	Alarm Vol.	Control Volume >> Level 1~5
5	Occ. Sens.	Control occlusion sensitivity >> Level 1~5 (Level 1 : 150mmHg, Level 5 : 750mmHg)
6	Time/Date	Control Time/Date
7	Password	Set/change password
8	Language	Select the language

History

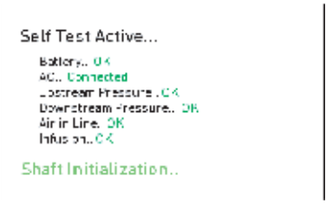
No	Name	Description
1	History Log	For checking device history, select Log icon on Main screen. >> The log can be stored up to 2,000 events, and the oldest in saving will be automatically deleted when exceeded.

6-2. The usage and operation sequence

Power On

(1) Press the power button for 2~3 seconds to turn on the power, check if the self test is proceeding, and the screen changes to install the cylinder cartridge.

[Booting screen]



[Self Test screen]

[Cylinder cartridge installation Noticing screen]

[Priming select screen]

[Priming Screen]

(2) Infusion set : Operating infusion mode with drug bag

(3) Syringe : Operating syringe mode with drug bag or Syringe

Installation of Cylinder Cartridge

(1) Open the pump door and install the Cylinder cartridge.

(2) When the installation of Cylinder cartridge is completed, the motor axis will rotate to lock the Cylinder cartridge automatically.

6-2. The usage and operation sequence

Tube Guide Correctly

Place the tube onto the tube guide correctly.

Caution

If the tube is not properly inserted into Air-in-line detector properly, alarm function and priming may not be performed normally.

Process Priming Aautomatically

After completing the Cylinder cartridge installation, open the Roller clamp and close the door. The pump will show priming selection screen.
The priming mode is divided into Infusion set and Syringe depending on the type of container used (drug bag, syringe). When you select the mode, pump will process priming automatically.

Caution

Please ensure that the Roller clamp is opened before priming operation.
If the IV line connected to the patient during priming, then an air embolism or drug overdose may occur and cause serious injury or death.
Please ensure IV line is disconnected before priming.

Priming

(1) When priming is completed, it will automatically shift to infusion settings screen

(2) If the medicine fluid is not completely filled into the tube, press the [BOL] button to fill the IV line.

(3) If you press [STOP] button during priming operation, the operation is stopped automatically.

[Priming Screen]

Caution

If you open the door or turn off the power before the priming is completed, normal infusion may not be possible.
Do not open the door or power off during the priming phase.

Connect IV Needle

Connect IV needle to the patient. Make sure that the pump is stopped before connecting to the patient. The pump cannot detect whether IV needle falls apart from the vein of the patient. Please check the connecting of IV needle to the patient regularly.
(IV needle is not provided. Only licensed IV needle must be used.)

Mode Settings

(1) Standard mode

① Please ensure that the pump is not infusing.

② Select “Standard mode” in Main screen to enter into Standard mode setting screen

③ Use Numeric Keys to set up the infusion rate. (Set-up range: 0.1~999.9ml/h)

④ If you want to change the rate value, Press [CLR] button and input the new value of infusion rate..

⑤ In the settings screen, when rate is entered infusion is performed at the set rate. When VTBI and Time are set, Rate is automatically calculated.

⑥ Select “Drug” in infusion setting screen to enter into Drug List select screen. Select the drug from Drug List and select ‘Others’ if the type of drug you are going to infuse is not listed.

[Standard mode setting screen]

< Note >
The Drug List only displays drug names, no other information.

6-2. The usage and operation sequence

Mode Settings

(2) Dosage Mode

① Please ensure that the pump is not infusing.

< Calculation Formula of Flow Rate >

$$\text{Flow rate(ml/h)} = \frac{\text{Dose rate(mg/kg/h)} \times \text{Body weight(kg)}}{\text{Concentration(mg/ml)}}$$

>> After setting of Concentration, Dose rate and Body weight, the flow rate(ml/h) will be automatically calculated and displayed.

Caution

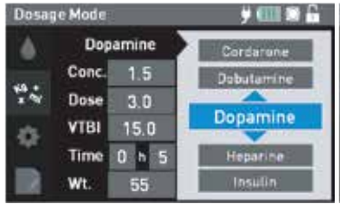
If calculated flow rate is less than 0.1ml/h or more than 999.9ml/h, The operation will not be possible.

② Select “Dosage” in main screen and enter into settings screen for Dosage.

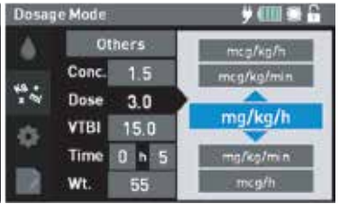
[Dosage settings screen]

③ Select “Drug” in infusion settings screen to enter into Drug List selection screen. Select drug from the Drug List and select ‘Others’ if the type of drug you are going to infuse is not listed. If you select Drug, you can use automatic search function.

④ Once the drug is selected, the screen will switch to the Dosage unit selection. Please select the proper unit for the drug.



[Drug list selection screen]

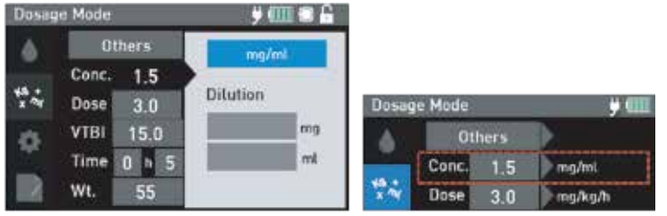


[Dose unit selection screen]

Mode Settings

⑤ Select the Dosage Unit by the Numeric Keys and then set up the Concentration and dose of the drug that you are going to infuse and weight of a patient. (VTBI mode is activated if VTBI is inputted).

⑥ When setting the drug concentration (Conc.), the following settings screen will be displayed differently depending on whether dilution function is enabled or not.



[Dilution function disabled setting screen]

[Dilution function enabled setting screen]

Set-up range	
Dose rate	0.1 ~ 999.9 mg/h
Body weight	0.1 ~ 300.0 kg
Drug Concentration	0.1 ~ 999.9 mg/ml
Infusion time	00:00 ~ 99:59 hh:mm

< Note >

The dose units are as follows :

mg/kg/h, mg/kg/min, mcg/kg/h, mcg/kg/min, mg/h, mg/min, mcg/h, mcg/min

6-2. The usage and operation sequence

Mode Settings

(3) PCA Mode

[Pumping screen]

① Please ensure that the pump is not infusing.

② After connecting the PCA Handset to the pump, make ensure PCA Mode is enabled.

③ Select “Drug” in infusion setting screen to enter into the Drug List select screen. Select drug from the Drug List and select ‘Others’ if the type of drug you are going to infuse is not listed.

④ Press numeric key to set PCA Bolus and Rate.

⑤ If designated time is set on the infusion settings screen, an overlapped infusion within the set time will not be possible even if the PCA Handset button is pressed.

Start Infusion

When the setting is completed, check the IV line and Press [START] button to start infusion. If the pump is in Stand-by(mode) over 2 minute with ready status, alarm will beep.(Press [OK] button to stop the alarm.)

>> Press [Menu] button to check the set value while pumping.

[Infusion setting values confirm screen while pumping]

Infusion Settings Change/Stop

Infusion Settings Change/Infusion Stop

(1) If you press [OK] button during the infusion, you can change the infusion rate. If you press [OK] button after inputting infusion rate, the infusion rate change screen disappears.

(2) Press [STOP] button during the infusion to pause the infusion, and the drug infusion pause screen will appear.

(3) Press [START] button on drug infusion pause screen to resume infusion.

(4) Press [STOP] button on drug infusion pause screen to switch to infusion setting screen.

[Infusion settings change screen]

[Pumping Resume or Stop check screen]

Infusion Complete

When infusion is completed, the pump stops automatically with alarm sound. After the completion of infusion; KVO function is automatically activated, and infusion with pre-set speed is continued.

[Infusion complete screen]

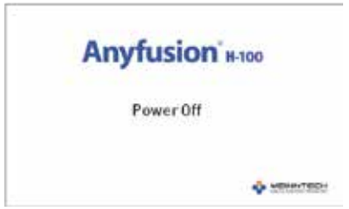
Remove Cylinder Cartridge

When the pump is stopped, close the Roller clamp and remove Cylinder Cartridge. (Open the door and press [UNLOCK] button to rotate the motor before removing Cylinder Cartridge. You can easily remove Cylinder Cartridge.)

6-2. The usage and operation sequence

Power Off

After use and removal, press [Power] button for 3 seconds to power off.



[Power OFF screen]

Other Functions

(1) Purge

① If the air bubble alarm occurs, remove the patient line and press the [BOL] button once until the air is completely removed from the IV line.

② Purge operating speed is set to 999.9ml/h and accumulated amount is not added during the purge operation.

③ When the air bubble is completely removed, press the [STOP] button in order to the stop the Purge operation. Then the screen will be switched to the Pumping pause screen. At this time, if you want to continue the infusion, press [START] button to operate the pump.

[Purge screen]

[Pumping pause screen]

Caution

Please ensure that the IV line to the patient is disconnected prior to pressing the [BOL] button.
If an end-user presses [BOL] button while the IV line is connected to the patient. An air embolism or drug overdose may occur and cause serious injury or death.

Other Functions

(2) Bolus

① Press the [BOL] button when performing the quick infusion separately during the infusion.

② In the Bolus settings window, set the bolus volume to be injected and press [OK] button to infuse automatically at the current set speed of bolus and press [STOP] button to stop bolus operation.

③ Bolus speed can be changed in the settings screen. Bolus amount is indicated separately.

Caution

When Bolus is completed, very first setting values are still be remained.
So please check the Bolus Rate setting.

(3) Set-up

① To change set-up, select Set-up in Main screen and enter into Set-up change screen.

[Set-up change screen]

② Available settings : KVO Rate, Bolus Rate, Brightness, Alarm Vol., Occ Level, Time/Date, Password, Language

- KVO(Keep Vein Open) rate : Control KVO dosage rate
- Bolus rate : Control rapid infusion rate
- Brightness : Control brightness of screen
- Alarm Vol : Control Volume
- Occ Level : Control occlusion sensitivity
- Time/Date : Control Time/Date
- Password : Password setting
- Language : Language setting

Level	1	2	3	4	5
Pressure [mmHg]	150	300	450	600	750

6-2. The usage and operation sequence

Other Functions

(4) History Log

For checking device history, select Log from the Main screen. (the log can be stored up to 2,000 events, and the oldest in saving will be automatically deleted when exceeded)

[History screen]

(5) Key Lock

① Set-up password to select Set-up icon in Main screen.

② If New Password is set, password should be input for unlocking Key Lock. If Password is not in a reset, initial Password is '0000'.

[Password change screen]

< Note >
When the Key Lock function is activated, all buttons except the [START] [STOP] button are disabled during infusion.

How to Reattach Cylinder Cartridge

If the Cylinder cartridge has been removed from the pump, reattach if as follows.

[Cylinder cartridge reattach selection screen]

(1) When the Pump power is off

① Turn on the power and proceed axis initialization.

② Press [CLR] button on the cylinder cartridge re-installation screen to move the axis to the previous position.

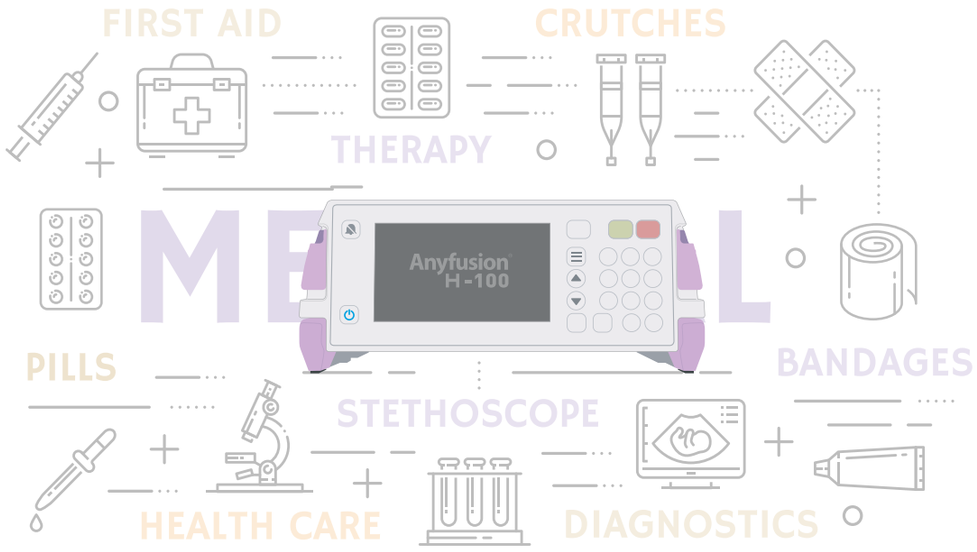
③ Open the door and replace the cylinder cartridge.

(2) When the Pump power is on

① When removing the cylinder cartridge from the pump and closing the door, axis initialization will proceed.

② After axis initialization is completed, press [CLR] button on the cylinder cartridge re-installation screen to move the axis to the previous position.

③ Open the door and replace the cylinder cartridge.



PART 7.

Feature of Product & Declaration

7. Feature of Product & Declaration

7-1. Feature of Product

01 Occlusion Detection Characteristic

(1) Flow rate is measured as 5ml/h and 25ml/h for detecting occlusion.

• Infusion Mode

Flow Rate	Occlusion level (Setting)	Occlusion pressure (mmHg)	Time required before an Occlusion alarm(sec)	Bolus volume (ml)
25ml/h	1	143	28	0.16
	5	741	105	0.58

• Syringe Mode

Flow Rate	Occlusion level (Setting)	Occlusion pressure (mmHg)	Time required before an Occlusion alarm(sec)	Bolus volume (ml)
5ml/h	1	141	124	0.15
	5	740	524	0.65

02 Memory Function

(1) Recent infusion rate, infusion time, infusion volume are stored in the internal memory.
(2) The data entered through the setting window, KVO rate, Bolus rate, Brightness level, volume level, occlusion sensitivity, date, time, Password, PCA mode through setting are stored in the internal memory and display through the LCD window.

< Initialization values >

Item	The initialization value
KVO Rate	0.5 ml/h
Bolus Rate	999.9 ml/h
Brightness Level	3/5
Alarm Volume	3/5
Occlusion Level	3/5
Time/Date	N/A
Password	0000
Language	English

03 EMS Issue

This equipment has been tested and found to comply with the limits for medical devices in EN 60101-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

(1) Reorient or relocate the receiving device.

(2) Increase the distance between the equipment.

(3) Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

(4) Consult the manufacturer or field service technician for help.

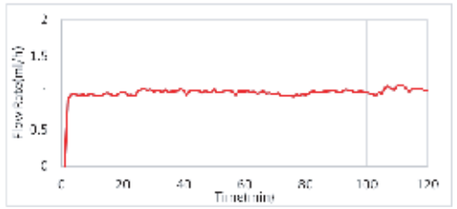
04 Characteristics Curves

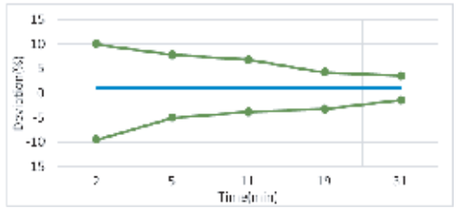
>> The following characteristics curves were achieved in the same conditions as those of IEC 60601-2-24.

(1) Start-up curve: This curve is measured every 30 seconds within 2 hours after the start of infusion. The starting curve represents the characteristic when the stable after the infusion. The horizontal axis represents the measured time and the vertical axis represents the measured flow rate (ml/h). The dashed horizontal line indicates the set flow rate. The start-up curve shows the time till the actual flow rate reaches the set flow rate.

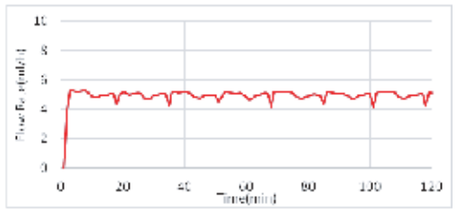
(2) Trumpet curve: Horizontal axis of Trumpet curve represents the observation window. The vertical axis represents the percentage error of the actual flow rate to the specified flow rate.
The dashed horizontal line indicates the set flow rate. The solid horizontal line indicates the overall mean percentage error.

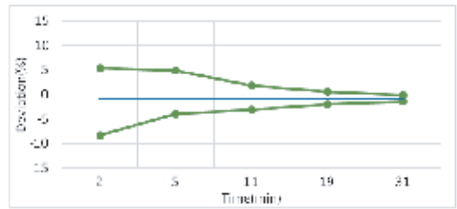
Flow Rate : 1ml/h



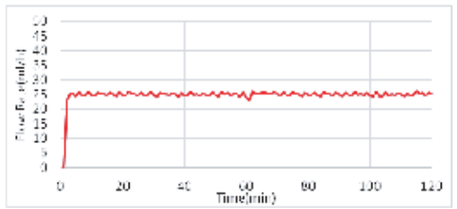


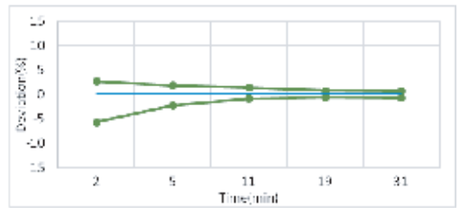
Flow Rate : 5ml/h





Flow Rate : 25ml/h





7-2. Declaration of manufacturer

01 Electromagnetic Emissions

The Anyfusion H-100 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Anyfusion H-100 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment-guidance
RF emissions CISPR 11	Group 1	The Anyfusion H-100 uses RF energy only for its internal function. Therefore, its RF emissions are very low amd are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Anyfusion H-100 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. Warining: The Anyfusion H-100 is intended for use by healthcare professionals only. It may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Anyfusion H-100 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

02 Immunity and Compliance Levels

Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	6V in the ISM bands	6V in the ISM bands	6V in the ISM bands
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz to 2.7GHz	3 V/m, 80 MHz to 2.7GHz	3 V/m, 80 MHz to 2.7GHz

7-2. Declaration of manufacturer

03 Electromagnetic Immunity

The Anyfusion H-100 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Anyfusion H-100 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	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at lea st 30 %
Electrical fast Transient / burst IEC 61000-4-4	±2kV for power supply lines / 100kHz	±2kV for power supply lines / 100kHz	Mains power quality shoul d be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line to line 2 kV line to earth	1 kV line to line 2 kV line to earth	Mains power quality shoul d 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 0.5cycle 0% UT (60% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycle <5% UT (<95% dip in UT) for 250/300 cycles	<5% UT (>95% dip in UT) for 0.5cycle 0% UT (60% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycle <5% UT (<95% dip in UT) for 250/300 cycles	Mains power quality shoul d be that of a typical com mercial or hospital environ ment. If the user of the Anyfusion H-100 requires continued operation during power mains interruptions, it is recommended that the Anyfusion H-100 be powered from an uninterruptible power supply or a battery Power frequency magnetic fields should be at levels charac teristic of a typical location in a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Mains power quality shoul d be that of a typical commercial or hospital environment.

< Note >
UT is the a.c. mains voltage prior to application of the test level.

04 Electromagnetic Emissions

The Anyfusion H-100 is intended for use in the electromagnetic environment specified below.
The customer or the user of the Anyfusion H-100 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	6V in the ISM bands	6V in the ISM bands	Portable and mobile RF com munications equipment should be used no closer to any part of the Anyfusion H-100, including ca bles, than the recommended s eparation distance calculated f rom the equation applicable to the frequency of the transmitter. [Recommended separation distance] $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.7GHz	3 V/m 80 MHz to 2.7GHz	[Recommended separation distance] $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum out put power rating of the transm itter in watts (W) according to the transmitter manufacturer and d is the recommended separation dista nce in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromag netic site survey, (a) Should be less than the co mpliance level in each frequen cy range (b). Interference may occur in the vicinity of equipment marked with the fol lowing 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 Anyfusion H-100 is used exceeds the applicable RF compliance level above, the Anyfusion H-100 should be observed to verify normal operation. If abnormal performance is observed, additional measuresmay be necessary, such as re-orienting or relocating the Anyfusion H-100.

b. 6V in ISM bands

7-2. Declaration of manufacturer

05 Recommended Separation Distances

The Anyfusion H-100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Anyfusion H-100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Anyfusion H-100 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 $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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

PART 8.

Notes For Safekeeping

8. Notes For Safekeeping

8-1. Cleaning & storage

01) Before cleaning the pump, make sure of turning off the power and disconnecting the AC power cord.

02) Please be careful about floating particles of dust. They might pass through the pump when cleaning up.

03) If any solution spills on the pump or the pump gets heavily soiled, wipe it immediately with gauze or similar cloth dampened with cold or lukewarm water.

04) Clean AC inlet and Cylinder cartridge install area regularly.

05) Do not use organic solvent such as alcohol or thinner.

06) After using a disinfectant for cleaning, wipe it out using gauze or similar cloth dampened with cold or lukewarm water.

07) The following table lists examples of disinfectants that may be used to clean the pump

Ingredients	Chlorhexidine gluconate	Benzalkonium chloride

(1) Please follow the instruction of disinfectant.
(2) The Cylinder pump cannot be autoclaved.
(3) Never use a dryer or similar device to dry the Cylinder pump.

08) Do not leave the pump in wet conditions.

09) Do not store the pump in a place where atmospherically pressure, temperature, humidity, ventilation, air containing salinity or sulfur may have adverse effects on it.

10) Do not store the pump in a place where vibrations frequently present.

11) Please remove the Cylinder cartridge before storing the pump.

12) Cylinder cartridge, needle and injection needle cannot be reused and have to be discarded as an infectious waste.

13) Clean the cartridge install part with disinfection cotton after use.

14) If you don't use the pump for a long time, remove the power cord from the pump and store it separately.

8-2. Waste & Recycle

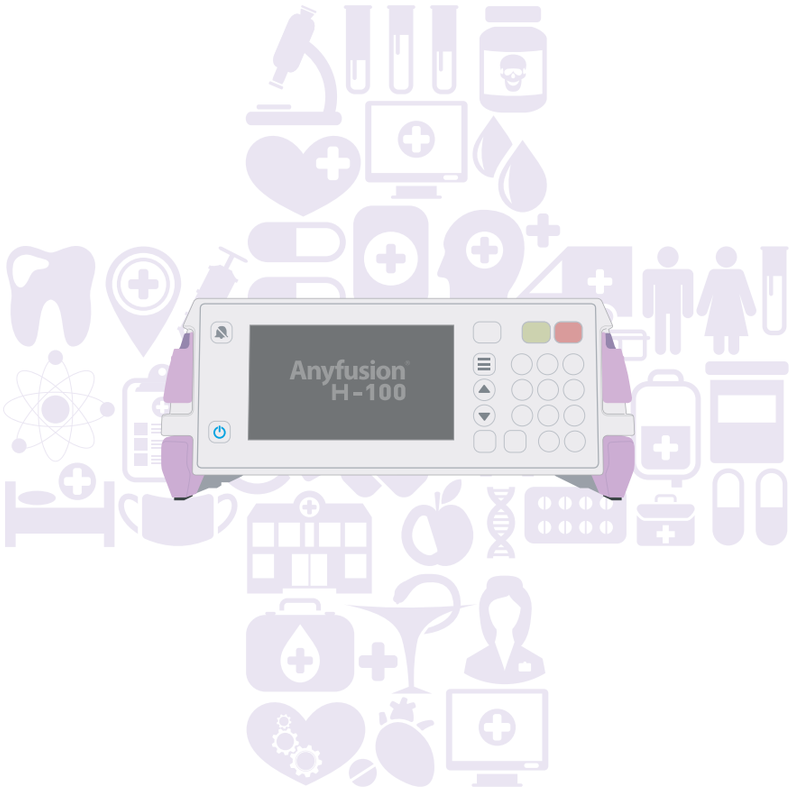
1) If you want to discard or recycle the pump, Li-ion battery should be removed from the equipment
2) Disposal of this Cylinder pump / batteries according to your local regulations or contact your local distributor

8-3. Operating condition

Operating condition	
TEMPERATURE	10 °C~ 40 °C
HUMIDITY	30 % ~ 75 %
PRESSURE	700hPa ~ 1,060 hPa

8-4. Transport & Storage condition

Transport & Storage condition	
TEMPERATURE	-20 °C~ 60 °C
HUMIDITY	10 % ~ 95 %
PRESSURE	650 hPa~ 1,060 hPa



PART 9.

Service & Trouble Shooting

9. Service & Trouble Shooting

- If occurs any trouble during use, follow the instruction below.
- If following these trouble shooting suggestions does not solve the problem call sales distributor or it's A/S center

9-1. Power & Battery

No	symptoms	Causes	Corrective Actions
1	AC indicator doesn't' appear when connecting AC power.	1. AC Power cable may be not connected properly to the pump. 2. AC Power cable may be malfunctioning. 3. Fuse, SMPS or AC Power may be malfunctioning.	1. Please re-check the connection status of AC power cable. 2. Replace AC Power cable. 3. Call A/S center.
2	Power switch on when using AC power, malfunction occurs from the battery capacity indicator.	1. Battery recharging or battery may be malfunctioning	1. Call A/S center.
3	When the power switch is on, battery capacity indicator is on but the motor doesn't operate.	1. Transient error may be occurred in the pump. 2. Motor, Motor controller circuit is defective.	1. Call A/S center.
4	The pump doesn't shut down after Power switch off operated.	1. Power doesn't go off during infusion process. 2. Power button may be malfunctioning.	1. Please stop the pump by pressing STOP KEY then turn off. 2. Call A/S center.
5	When using battery power, malfunction of battery capacity indicator appeared.	1. Transient error may be occurred in the pump. 2. Battery or Power may be malfunctioning.	1. Call A/S center.
6	Full charge mark doesn't appear at the indicator after the battery is fully charged.	1. Battery recharging time may not enough. 2. Battery recharging or battery may be malfunctioning.	1. Connect AC Power cable to recharge battery over 5 hrs. 2. Call A/S center.
7	Using time is short after the battery is fully charged.	1 Battery exceeds is life-span.	1. Call A/S center.
8	Battery is not charging.	1. Battery recharging or battery may be malfunctioning.	1. Call A/S center.

- Battery life-span may differ depending on the environment and the frequency of use.
- Please operate the pump at least once a month with the battery for checking battery performance.

9-2. Alarm/Message Section

< Characteristics of alarm indicator >

Alarm category	Indicator color	L E D	Sound
HIGH PRIORITY	Red	Blink	HIGH ALARM
LOW PRIORITY	Yellow	Constant (on)	LOW ALARM

No	ALARM	DESCRIPTION	CAUSE OF OCCURRENCE	ACTION
1	POWER ON	1) Alarm LED : Green, Yellow, Red Light ON 2) Sound : POWER ON MELODY	-	-
2	POWER OFF	1) Alarm LED : Green, Yellow, Red Blinks 2) Sound : POWER OFF MELODY 3) Message : POWER OFF	-	-
3	BATTERY CHARGING	1) Message : CHARGING	-	
4	BATTERY CHARGE COMPLETE	1) Message : 100% CHARGED	-	-
5	DOOR OPENED WHILE WAITING FOR INFUSION	1) Alarm LED : Green Blinks 2) Sound : DOOR OPEN ALARM 3) Message : DOOR OPEN	Door opened while waiting for the infusion.	Close the pump door
6	INFUSING	1) Alarm LED : Green Light Blink	-	-
7	PAUSE WHILE INFUSING	1) Alarm LED : Yellow Light ON	-	-
8	NEAR INFUSION COMPLETE	1) Alarm LED : Yellow Blinks 2) Sound : LOW PRIORITY ALARM	-	-

9-2. Alarm/Message Section

No	ALARM	DESCRIPTION	CAUSE OF OCCURRENCE	ACTION
9	START REMINDER	1) Alarm LED : Yellow Blinks 2) Sound : LOW PRIORITY ALARM	Alarm occurs when 2 minutes over after power on and Stand-by status.	-
10	INPUT TIME EXPIRED	1) Alarm LED : Yellow Blinks 2) Sound : LOW PRIORITY ALARM	Alarm occurs when input time is expired (over 1 min)	-
11	LOW BATTERY	1) Alarm LED : Yellow Blinks 2) Sound : LOW PRIORITY ALARM 3) Message : BATTERY NEARLY EMPTY	Alarm beeps when the remaining capacity of batter is below 30 mins.	Connect AC power cable to recharge the battery.
12	EMPTY BATTERY	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message : BATTERY EMPTY	Alarm beeps when the remaining capacity of batter is below 5 mins.	Connect AC power cable to recharge the battery.
13	INFUSION COMPLETE	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message : INFUSION COMPLETED	-	Press [OK] KEY to complete infusion.
14	NO BATTERY	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message : NO BATTERY	Alarm occurs if the internal battery is not connected properly.	Call A/S center.
15	DEPLETED BATTERY	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message : DEPLETED BATTERY	Alarm occurs if the battery replacement is required when the battery is expired.	Call A/S center.
16	OCCLUSION DETECTION	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message : UPSTREAM/DOWN STREAM OCCLUSION	Alarm occurs if occlusion is detected during the infusion.	After clearing the cause of occlusion and press [OK] KEY to release the alarm.
17	AIR IN LINE DETECTION	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message: AIR IN LINE	Alarm occurs if air bubble is detected during the infusion.	Press [BOL] KEY to remove air bubble in line.
18	SYSTEM MALFUNCTION	1) Alarm LED : Red Blinks 2) Sound : HIGH PRIORITY ALARM 3) Message : SYSTEM ERROR[-error code]	Alarm occurs if there is a malfunction of internal system of the pump.	Call A/S center.

PART 10.

Technical Specification

10. Technical Specification

10-1. H-100 Specification

Product name	Cylinder pump
Model name	Anyfusion H-100
Cylinder cartridge	Single-use Cylinder cartridge (with Luer connector)
Flow rate	0.1~999.9 ml/hr
Flow rate accuracy	± 2%
VTBI selector, ml	0.1 ~ 9,999ml
Total volume infused display, ml	0.01 ~ 9,999ml
KVO rate, ml/hr	0.1 ~ 5 ml/hr
IV set	Compatible with any brand of IV sets (Compatible with installed Micro filter 0.2um~5.0um)
Purge rate, ml/hr	999.9 ml/hr
Bolus rate, ml/hr	999.9 ml/hr(default), 50~999.9ml/hr
Bolus Volume	0.1 ~ 99.9ml
Occlusion Pressure	150 ~ 750 mmHg
Display	4.3'' TFT-LCD (Resolution : 480 x272)
Alarm	- Infusion completed alarm - Start reminder alarm (after 2mintues from Standby state.) - Repeat alarm - Low battery alarm. - No battery alarm. - Depleted battery alarm. - Upstream Occlusion alarm. - Downstream Occlusion alarm - Air-in-line alarm. - Door open alarm. - System error alarm. - Input time expired alarm.
Safety Features	- Door open: Infusion is unavailable when the door is open. - Key Lock: Locking function of button/Key - Cylinder removal function (Door open status) - Occlusion Sensor: Detects clogging of the extension tube. - Air sensor: Detects air bubbles. - Cylinder Sensor: Detects detached Cylinder.
Other Functions	- Standard Mode: Set the flow rate, time, VTBI - DOSAGE Mode : Calculates the flow rate by setting the dosage. - PCA Mode : Use when rapid infusion using PCA Handset. - Date and Time : The date and time can be checked without a power supply, since a designated clock in installed. - Log : saves up to 2,000 in the pump and it can viewed in the pump at log
Power	AC 100 ~ 240 V, 50/60 Hz / Fuse: 250V, 1.6A
Battery type	Rechargeable Li-ion
Battery life	8 hours at 100 ml/h
Recharge time	Approx. 5hrs
Power Consumption	Max. 75 VA
Protection Type	- Protection from electric shock : Class I - Protection capacity for electric shock : Type CF - Protection from liquid infiltration : IPX2
Dimension	225(W) x 145(D) x 96(H)mm
Weight	Approx. 1.9 kg
Operating condition	- Temperature : 10 ~ 40 °C - Humidity : 30 ~ 75 % - Atmospheric : 700 ~ 1,060 hpa
Storage condition	- Temperature : -20 ~ 60 °C - Humidity : 10 ~ 95 % - Atmospheric : 650 ~ 1,060 hpa
Accessories	Syringe holder PCA Handset(Optional), AC power cord, Operator manual, RACK(Optional)

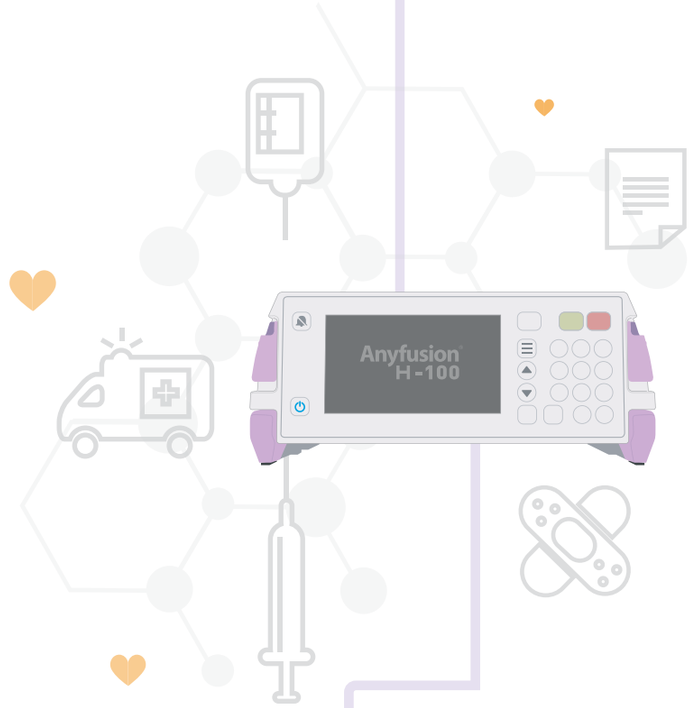
10-2. AC/DC Power Supply

No	Name	Specification
1	Input voltage	100 VAC to 240 VAC
2	Input Frequency	50Hzto60Hz
3	Inrush current	< 60A at 230VAC, < 30A at 115VAC
4	Efficiency	84%
5	Output Voltage	18.0V
6	Ripple and noise	100mVpp
7	Load regulation	<±1%
8	Hold up time	18 ms typical at rated load and 115VAC
9	Overload protection	Auto-recovery
10	Short circuit protection	Auto-recovery
11	Overvoltage protection	Latch-off (Over voltage protection mode is defined at 60% rated load)
12	Cooling	Free air convection
13	Storage temperature	-40°C to +85°C
14	EMI	EN55022, level B conducted & radiated
15	Safety	EN60950-1, cUL60950, IEC60950-1, EN60601-1, cUL60601-1, IEC60601-1

10-3. Rechargeable Battery

- Component of cell: Lithium Ion Battery 4 Cell.
- Rated voltage: +14.4V
- Capacity : 2,600mAh
- PCM : Overcharge, Over discharge, short, protect from overheat temperature.

Inspection Item		Unit	Allowable Value
Overcharge protection voltage		V	17.20±0.100
Overcharge protection release voltage		V	16.23±0.200
Overcharge protection delay time		ms	1000.0±500
Overdischarge protection voltage		V	10.00±0.400
Overdischarge protection release voltage		V	12.00±0.400
Overdischarge protection delay time		ms	100±50
Overcurrent protection current		A	10±2.5
Overcurrent protection delay time		ms	10.0±5
Operating temperature range		°C	-10~50
Storage temperature range		°C	-20~60
Current Consumption	Normal	μA	Max. 30
	Power saving	μA	Max. 0.1



PART 11.

Warranty

11. Warranty

WARRANTY

Product Name	Cylinder Pump	Agency	
Model	Anyfusion H-100	Tel no.	
Seller		Person in Charge	
Product No.		Applicant name	
Rated Voltage		Applicant Tel no.	
Date of Purchase		Applicant address	
Warranty period	1 year from the date of purchase	Gender / Age	

- Please fill out above when you purchase the product.
- We are not responsible for the after service or any disadvantage when you do not have a warranty sheet.

Regulation of Warranty

<Warranty Period>

Warranty period is 1 year after the date of purchase with no repair charge in case the damage happened in normal condition of the device.

<The exception of warranty>

We are not responsible for :

1) Damage due to careless handling or mistake by user.
2) Damage due to renovation of production or repair by others than our A/S representative.
3) Damage due to using other accessories or expendables than our appointed equipment.
4) The warranty sheet is not filled out, Fake signature is filled out.
5) Damage cause from the power problem
6) Damage due to using the device for other purpose.
7) Damage due to natural disaster like fire, earthquake, flood and etc.

<Repair after warranty period>

For the repair after warranty period, Consumer will pay for the repair. The exceptional matters which are not mentioned in this sheet will be treated according to regulation of compensation for consumers based on law of consumer protection. Please contact to the agency for the other damage or request. Please read the manual carefully before using.

Thanks for purchasing our product. You will need this warranty sheet when you ask for A/S, so please keep this safely. For any dissatisfying service or request, please contact the agency.

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PART 12.

Symbols & Labels

12. Symbols & Labels

12-1. Symbols

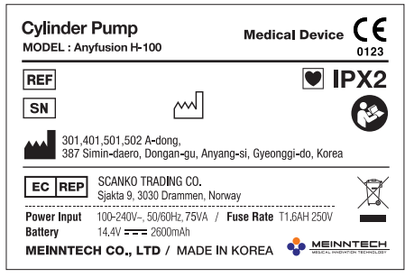
The symbols of the device as below.

SN Serial number	REF Catalogue number	Caution	-20℃ 60℃ Temperature limitation	Follow instructions for use.
Use by date (expiration date)	CE 0123 CE Marking	WEEE Marking	Manufacture date	Manufacturer
IPX2 Ingress protection rating	Type cF Applied part	Do not use if package is damaged	Keep away from sunlight	Do not re-use
LATEX Latex Free	RHT DEHP FREE DEHP Free	LOT Batch code	EC REP Authorized representative in the European Community	STERILE EO Sterilized using ethylene oxide

12-2. Labels

Main Device

This regulation label is attached at the side of the pump.



Cylinder Cartridge

This sterilization label is printed at the back of the Cylinder cartridge packing.