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Infusion Monitor

User Manual

Zhejiang Zhier Information Technology Co., Ltd.

Version, Manual Vision 1.0

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Dear customer:

Hello!

Thanks for choosing Enjoyor technology products and services. To ensure your satisfied use, please read the user manual carefully before using this product, And please keep the manual properly for future reference.

Whenever you need our service and support, Please be freely to let us know.

Before using

- **This product Must be used by medical personnel who had received training by the manufacturer.**
- **If there are any problems when you using the product, please contact with our technician.**
- **Our company could provide the material for the devices which could be repaired.**

Basic Information

Registrant / Manufacturer/ After-sales service unit,

Zhejiang Zhier Informatin Technology Co., Ltd.

Address,

2F, Building 4, No. 2 West Park Road 8, West Lake Science and Technology Park, Sandun Town, Xihu District, Hangzhou

Medical Device Manufacturing License Number, _____

Medical Device Registration Certificate Number, _____

Medical Device Product Technical Requirements Number,_____

Contact address, 2F, Building 4, No. 2 West Park Road 8, West Lake Science Park, Sandun Town, Xihu District, Hangzhou, Zhejiang Province

Contact person of registrant / manufacturing enterprise, (86) 0571-8993 0386

The expiration date of this product is three years, please use it before expired.

Check production date on the Label.

The company has all the right to interpret this manual

1. Application and contraindications

Application, This product is used to monitor the infusion status of patients during infusion, which is convenient for emergency treatment in abnormal situations.

Contraindications, Can not be used for infusion monitoring of insulin, analgesics, chemotherapy drugs, etc.

2. Product Composition

The infusion monitor is mainly composed of the circuit board, battery, sensor, LCD screen, motor, shell and software (version V1.1.0).

The infusion monitor is powered by a rechargeable lithium battery, monitors the drip rate and status of the infusion through a built-in sensor, and automatically turn off the infusion tube after the infusion is completed.

The infusion monitor is shown in Figure 1.

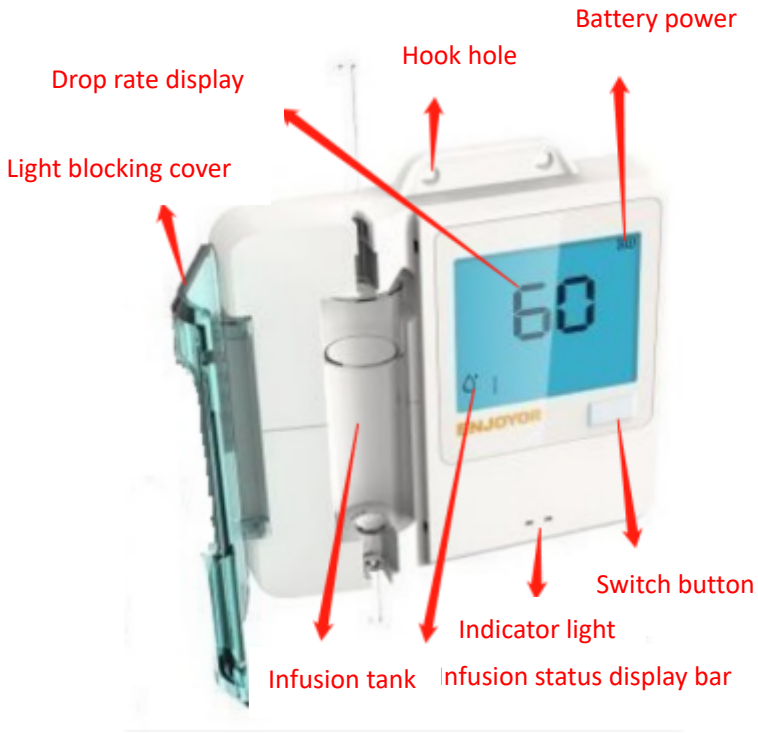


Figure1, Appearance structure of infusion monitor

The infusion monitor includes infrared sensors arranged on both sides of the infusion tube, a lock switch for turn off the infusion, a LCD screen for displaying the drip speed, and a microcontroller. The infusion monitoring controller adopts infrared induction

technology to sense the droplet passing in the infusion tube per unit time in real time to obtain the liquid dripping speed during the infusion process. When the infusion is completed and the empty bottle status is displayed, the infusion monitor will automatically block the infusion tube , To effectively prevent the patient's blood from flowing back.

3. Product Performance and Basic Parameters

Product main performance index,

1. Infusion monitoring range, 10 drops / min-100 drops / min.
2. Measurement accuracy of infusion monitoring controller, ± 2 drops / min.
3. Infusion tube shut-off function,

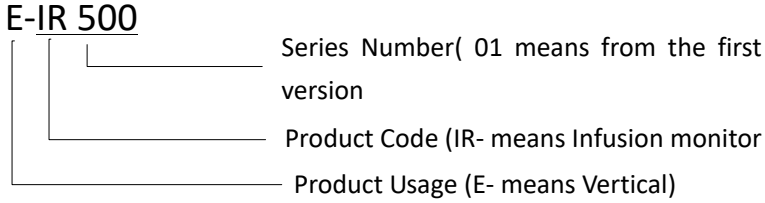
After the infusion is completed, the infusion monitor completes the interception within 6 seconds to prevent blood from flowing back.

Basic Parameters,

Infusion monitor weight, (260 ± 20) g
Infusion monitor size, (width x height x depth) 121mmx125mmx33mm
Atmospheric pressure, 860hPa-1060hPa
Operating environment temperature range, 5 ℃ -40 ℃
Relative humidity range, ≤80%
Storage temperature range, -10 ℃ -55 ℃
Storage relative humidity range, ≤95%
Equipment power supply, 3.7VDC, 6000mAh
Charging power supply, input 100-240VAC, 50 / 60Hz, 0.15A; output 5VDC, 1A

4. Product Model and specifications

1. Product Model, E-IR500
2. Division description,



3.Software Release Version

The infusion monitor contains embedded software officially released version, V1.1.0.

4. Version naming rules

The first field identifies the major version number of the software; there are major changes to the functional modules, such as the addition of multiple modules or

changes to the overall architecture.

The second field identifies the minor version number of the software, relative to the major version, the minor version number upgrade corresponds to a partial change. However, this local change caused the program to be incompatible with the previous version, or caused damage to the previous collaborative relationship of the program, or a major improvement or enhancement in functionality.

The third field identifies the revision number of the software, local changes, mainly functional improvements of local functions, or bug fixes, or expansion of functions.

5. Product Working Principle

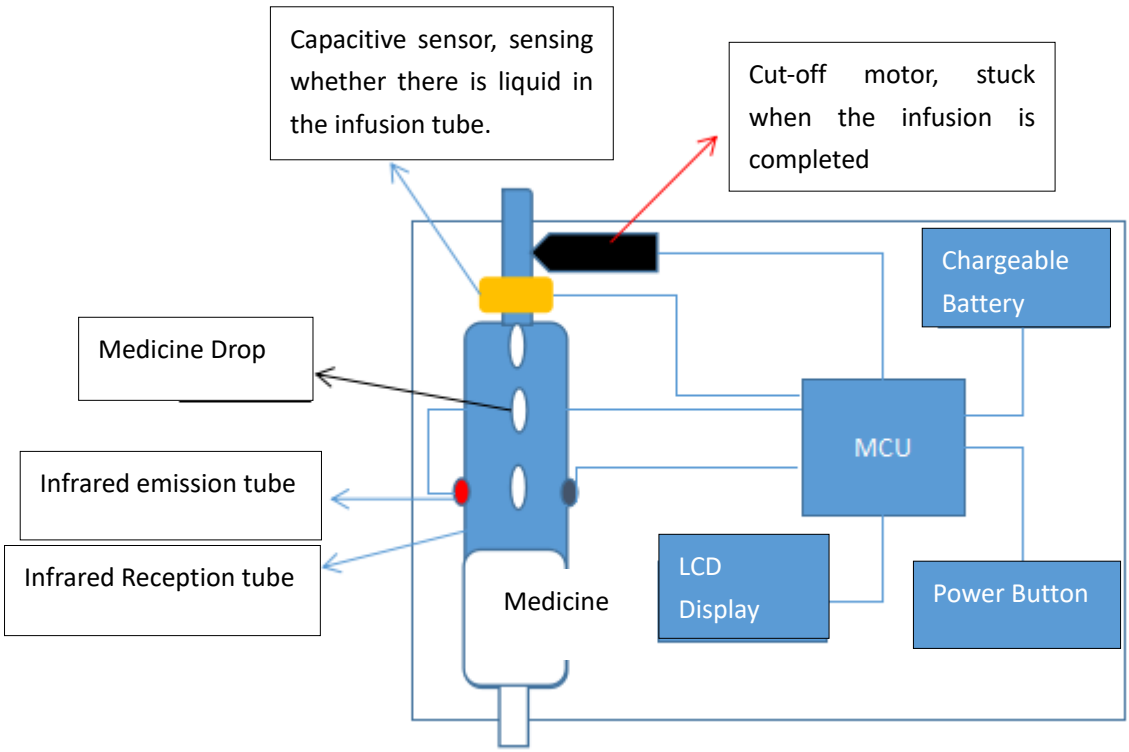


Figure2, Product working principle diagram

The principle of drip speed measurement: the infrared emission tube is controlled by the MCU, and the infrared is continuously transmitted to send infrared. Normally, the infrared reception tube can receive the signal of the infrared emission tube. When the medicine drops, the water drops will block the infrared reception. At this time, it is judged that there is a drop, and the MCU will calculate the drop speed according to the blocking time between the two drops.

The principle of infusion completion: the principle of capacitive induction is used to complete the infusion, and the induction capacitor is placed on the upper end of the

infusion tube. When the tube is empty, it is a capacitance value. The capacitance value will change when there is a liquid medicine. .

Infusion interception function: When the infusion completion status is detected, the motor is controlled by the MCU to rotate the gear to block the upper end of the infusion tube to achieve the interception function.

6. Installation

Use the hook to hook the hanging hole of the infusion monitor, and then hang it on the hook of the infusion rod. Hang the medicine bag or medicine bottle on the hook above the hanging rod, then adjust the position of the infusion tube, and snap the Murphy dropper into the card slot of the infusion monitor. As shown in Figure 3.

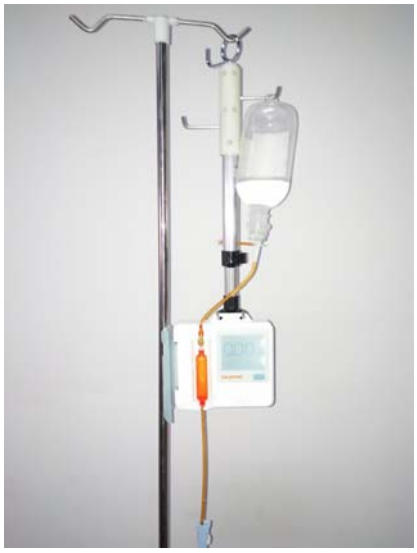


Figure3, The installation of vertical monitor

7. Instructions

1.Check whether the outer packaging is intact before opening the box.

2.Check the appearance of the infusion monitor after opening the package.

3.Then hang the product on the infusion rod. Before starting to use, the entire device is in standby mode, the device will only start when the power button is pressed, and long press the button when shutting down. When the power button is pressed, the two LED lights and the display will light up, and check whether the work light (LED2 green) on the infusion monitor flashes normally. After the infusion monitor is working normally, the infusion drip hopper will be stuck into the infusion tank of the infusion

monitor. The infusion monitor will automatically detect the drip rate.

4.When the battery level on the device is low, you need to connect the charger to charge. During charging, LED1 (yellow) will blink continuously until the LED1 light is always on which means charge completed. LED2 is the work indicator light.

5.When the infusion is completed and the bottle is empty, the clamp of the infusion monitor will automatically catch the infusion tube, effectively preventing the back flow of blood from the patient. When you need to remove the infusion tube, you only need to press a button on the panel, the clip is to release the stuck infusion tube. When you do not need to use it, you have to press and hold the button to make the infusion monitor in the sleep state.

The LED indicator is shown in Figure 3.

Figure3, The indicator of Infusion monitor

5. Hang the barb of the infusion tube upside down in the hook hole of the infusion monitor

2. Turn off the left infusion cover, adjust the infusion rate. The left infusion controller will monitor the drop rate and send to the right side display through infrared, infusion start.

The display status-- it will display the drop rate when

4. Press the power button to start the infusion monitor.

The display will show the status

3. Turn on the left infusion cover, Lightly press the dropper into the corresponding groove. (The drip irrigation controller detects the liquid through the sensor-------LED indicator always being Green.)

Display status--Liquid deficit showing "----"

1. When the left drop controller didn't detect liquid (LED indicator light off). The alarm will be triggered after finish the infusion. The shrapnel on the upper right side of the groove ejects the stuck dropper to prevent blood from flowing back

Figure4, Infusion Monitor usage flowchart

8. Precautions

1. Waterproof, anti-fall, lightly handle.
2. When the infusion monitor is not in use, press and hold the button to shut down to enter the low power consumption mode.
3. If the equipment battery is not replaceable and the battery cannot be charged or used, please do not disassemble it privately, contact our after-sales service for disposal.
4. It is recommended not to discard the equipment that cannot be used and put it together, please contact our company for disposal.
5. The use period of this product and its accessories is 3 years. After expiration, it will be recycled by the corresponding professional scrap electronic product recycling agency (enterprise).
6. It is not suitable for the input of liquid medicine with high viscosity.

9. Maintenance

1. The infusion monitor is powered by a rechargeable lithium battery. Try not to overcharge and over discharge. When the battery power shows a space, it needs to be charged in time. The charging voltage is DC5V and the current is less than 1A. When the charging indicator (LED1) light is on You can stop charging.

2. After using the infusion monitor once, the nurse or a special person can check the displayed power to see if it shows that the low power needs to be charged.

3. It is recommended that after each use of the product, wipe and disinfect with 75% alcohol without charging.

4. Disposal of scrapped equipment: Do not discard the batteries contained in the equipment at random, and recycle them by corresponding professional waste electronic product recycling institutions (enterprises).

10. Transportation

The packaged products can be transported by ordinary transportation ways. The ambient temperature during transportation should be within the range of -10 ℃ -55 ℃, the relative humidity need to be less than 95%, and strong shock, vibration, extrusion and moisture should be prevented during transportation.

11. Storage

1. Avoid water splash, rain and direct sunlight;

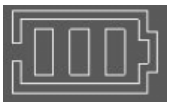
2. Dry, well-ventilated room without corrosive substances. The ambient temperature is -10 ℃ -55 ℃, and the relative humidity is ≤95%.

4. Avoid strong electric or magnetic fields;

5. There is no strong vibration and impact in the storage place.

6. The packing box need to longer than 10cm from the ground and 50cm from the wall;

12. Explanation of graphic symbols

 Number of drops	 Liquid deficit	 Infusion
 Complete infusion	 Battery	 Lock down after infusion finished

13. Basic Troubleshooting

Table1, Troubleshooting list

SN	Problem	Solution
1	The drip rate of the infusion monitor cannot be detected	Check if the infrared tube is blocked or if there is liquid medicine at the liquid sensing position.
2	The drop rate cannot be measured as "000" or "FFF"	First block the light to see if it is restored. If it is restored, it is light interference and needs to be returned to the factory for inspection.
3	Infusion tube stuck	Check the lock switch in manual mode

14. Packing List

Table2, Packing list

SN	Name	Quantity	Unit
1	Infusion Monitor	1	Set.
2	Hanging rod	1	Pcs.
3	Instructions	1	Pcs.
4	Packing list	1	Pcs.

15. Electromagnetic compatibility instructions

This product (infusion monitor) requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in accordance with the relevant information provided in this user manual.

Portable and mobile RF communications equipment may affect the operation of this product.

⚠ **WARNING** Except for transducers and cables sold by manufacturers of equipment or systems as spare parts for internal components, the use of unspecified accessories, transducers, and cables may result in increased emissions or reduced immunity of the equipment or system.

⚠ **WARNING** The equipment or system should not be used close to or stacked with other equipment. If it must be used close to or stacked, observe and veri-f y that it can work normally in the configuration in which it is used.

Guidance and manufacturer's statement-electromagnetic emissions		
This product (E-SY01) is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Emission Test	Compliance	Electromagnetic environment- Guidelines
Radio frequency emission GB4824	Group 1	This product (E-SY01) uses radio frequency energy only for its internal functions. Therefore, its RF emissions are very low and there is little possibility of interference to nearby electronic equipment.
Radio frequency emission GB4824	Class A	
Harmonic emission GB/T 17625.1	Not applicable	This product (E-SY01) is suitable for non-domestic use and all facilities that are not directly connected to the public low-voltage power supply network of residential buildings.
Voltage fluctuation / flicker emission GB/T 17625.2	Not applicable	

Guidance and manufacturer's declaration-Electromagnetic immunity			
This product (E-SY01) is expected to be used in the electromagnetic environment specified below, the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity Test	IEC60601 Test Level	Conforming level	Electromagnetic environment guide
Electrostatic discharge GB/T 17626.2	± 6kV Contact discharge ± 8kV Air discharge	± 6kV Contact discharge ± 8kV Air discharge	The floor should be wood,concrete or ceramical tiles. If the floor is covered with materials, the relative temperature should be at least 30%.
Electrical fast transient burst GB/T 17626.4	± 2kV to power line. ± 1kV on input/output line.	± 2kV to power line. Not applicable	The network power supply should have quality used in a typical commercial or hospital environment.
Surge GB/T 17626.5	± 1kV line to line. ± 2kV line to ground.	± 1kV line to line. ± 2kV line to ground.	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dips, short interrup-tions and vol-tage changes on the power input line. GB/T17626.11	<5% UT for 0.5 cycle (On UT,> 95% drop) 40% UT for 5 cycles (On UT, 60% drop) 70% UT for 25 cycles (On UT, a 30% drop) <5% UT for 5s (On UT,> 95% drop)	<5% UT for 0.5 cycle (On UT,> 95% drop) 40% UT for 5 cycles (On UT, 60% drop) 70% UT for 25 cycles (On UT, a 30% drop) <5% UT for 5s (On UT,> 95% drop)	The network power supply should have the quality used in a typical commercial hospital environment If the user of this product (E-SY01) needs to run continuously during the power interruption, it is recommended that this product (E-SY01) use uninterruptible Power supply or battery power Supply.

Power frequency magnetic field （50 Hz） GB/T 17626.8	3A/m	3A/m	The power frequency magnetic field should have the level characteristic of power frequency magnetic field in a typical place in a typical commercial or hospital Environment.
Note: UT refers to the AC grid voltage before the test voltage is applied.			

Guidance and manufacturer's declaration-electromagnetic immunity

This product (E-SY01) is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity Test	IEC60601 Test Level	Conforming Level	Electromagnetic environment-guide
Conducted RF GB/T17626.6 Radiated RF GB/T17626.3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communication equipment should not be used closer to any part of this product (E-SY01) than the recommended isolation distance, including cables. The distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distance d=1.2 √ P d=1.2 √ P80MHz~800MHz d=2.3 √ P800MHz~2.5GHz Among them, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W), d is the recommended isolation distance, in meters (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field, and it should be lower than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note 1: At 80 MHz and 800 MHz, the higher frequency band formula is used.
Note 2:These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

Guidance and manufacturer's declaration-electromagnetic immunity

This product (E-SY01) is expected to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in this electromagnetic environment:

Immunity Test	IEC60601 Test Level	Conforming Level	Electromagnetic environment-guide

A. The strength of a fixed transmitting airport, such as: base stations for wireless (cellular / cordless) phones and ground mobile radios, amateur radio, AM) and FM radio broadcasts and TV broadcasts, the field strength cannot be predicted theoretically accurately. To assess the electromagnetic environment of fixed RF transmitters, surveys of electromagnetic sites should be considered. If the measured field strength of the product (E-SY01) is higher than the RF compliance level of the above application, the product (E-SY01) should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of this product (E-SY01)

B. In the entire frequency range from 150KHz to 80MHz, the field strength should be less than 3 V / m.

Recommended separation distance between portable and mobile RF communication equipment with this product (E-SY01)

This product (E-SY01) is expected to be used in an electromagnetic environment where radio frequency radiation disturbance is controlled. Depending on the maximum output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) and this product (E-SY01) as recommended below.

Transmitter rating Maximum output power (W)	Isolation distance corresponding to different frequencies of transmitter (m)		
	150 kHz to 80 MHz d = 1.2 √ P	80 MHz to 800 MHz d = 1.2 √ P	800 MHz to 2.5 GHz d = 2.3 √ P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the rated maximum output power of the transmitter not listed in the table above, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the transmitter provided by the transmitter manufacturer Maximum output rated power in watts (W).

Note 1: At 80MHz and 800MHz frequencies, the formula for the higher frequency band should be used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic

CE Caution:

Use the Product in the environment with the temperature Between -10℃ and 40℃; Otherwise, it may damage your product. Products can only be used below 2000m altitude

For the following equipment:

Product Name: Infusion Monitor Device

Brand Name: --

Model No.: E-IR500

Zhejiang Zhier Information Technology Co., Ltd.

E-mail: qiliping@enjoyor.net

CAUTION
RISK OF EXPLOSION IF BATTERY IS REPLACED
BY AN INCORRECT TYPE.
DISPOSE OF USED BATTERIES ACCORDING
TO THE INSTRUCTIONS

This product is intended for sale and application in a business environment.

RED Article 10 2

-This product can be used across EU member states

RED Article 10 10

-The product is class 1 product, No restrictions

Frequency Range: 433.8MHz

RF Output Power: 7.620dBm(ERP)

FCC Warning

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE 1: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential 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 radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, 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:
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTE 2: Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.