Amoul®

Safety And Performance Information Syringe Pump

CE 0051

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Product Information

Thank you for purchasing the syringe pump.

Please carefully review the Manual to ensure appropriate use of the device. After reviewing the Manual, please properly keep it in a convenient, easily accessible location.

This Manual provides an introduction to the products based on the most comprehensive configuration. Some information may not apply to the specific products you have purchased. If you have any questions, please contact our company.

Product Name:	Syringe Pump
Model and Specification:	SP10p, SP10n
Name of Registrant：	Ambulanc (Shenzhen) Tech. Co., Ltd.
Address of Registrant:	Evergrande Fashion Huigu Building 1#101, Fulong Road, Shanghenglang Community, Dalang Street, Longhua District, Shenzhen, Guangdong 518109, China
Manufacturer:	Ambulanc (Shenzhen) Tech. Co., Ltd.
Production Address:	3rd and 8th Floor, Block C, Building #5, and 1st to 10th Floor, Building #8, Skyworth Innovation Industry Park, Tangtou 1st Road, Shiyan, Baoan District, Shenzhen, Guangdong 518108, China
EU REP EU-Representative	Shanghai International Holding Corp. GmbH(Europe) Eiffestrasse 80, 20537 Hamburg, Germany Contact pers：Qiming Cheng Telephone: +49-40-2513175 Fax: +49-40-255726
Date of Manufacture	See the label on the main unit
Life time:	10 years
Software Version:	V1
Manual Version:	1.0
Revision Date:	2026.01

Note: This device is not designed for household use.

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Ambulanc (Shenzhen) Tech. Co., Ltd. assumes responsibility for the product’s safety, reliability, and performance only under the following conditions:

- Assembly, expansion, readjustment, improvement, and maintenance are carried out by the personnel approved by Ambulanc (Shenzhen) Tech. Co., Ltd.;
- All relevant electrical devices meet the applicable national and local requirements;
- The Syringe pump is used in accordance with the Manual.

Ambulanc (Shenzhen) Tech. Co., Ltd. assumes no responsibility for the product’s safety, reliability, and performance in any of the following situations:

- Any component is disassembled, stretched, or readjusted;

●The Syringe pump is repaired or modified by personnel who are non-authorized by Ambulanc (Shenzhen) Tech. Co., Ltd.;
●The Syringe pump is not properly used according to the Manual.

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Scope of Free Services:

Free service is available for any Ambulanc (Shenzhen) Tech. Co., Ltd. products covered under its warranty terms.

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Products, even if they remain under warranty, require service under the following circumstances:

●Artificial damage;
●Violent or Improper use;
●Grid voltage beyond the limits;
●Irresistible natural disaster;
●Use of any spare parts/consumables not approved, or any product service performed by personnel not authorized by Ambulanc (Shenzhen) Tech. Co., Ltd.

Warning

Failure by Syringe pump users, including hospitals or other institutions, to establish and follow an adequate repair and maintenance plan can lead to abnormal product malfunctions and even potentially jeopardize human health.

Warranty

Manufacturing Process and Materials:

Ambulanc (Shenzhen) Tech. Co., Ltd. guarantees that, under normal use and proper maintenance, its products will be free from defects in manufacturing and materials throughout the warranty period.

After-Sales Service Unit

After-Sales Service Dept., Ambulanc (Shenzhen) Tech. Co., Ltd.
Address: 6th Floor Building #8, Skyworth Innovation Industry Park, Tangtou 1st Road, Shiyan, Baoan District, Shenzhen, Guangdong 518108, China
Service Hotline: 400-9969-120
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Website: http: // www.amoulmed.com

Returns and Exchanges

Procedure for Returns and Exchanges

In case of returning any product to Ambulanc (Shenzhen) Tech. Co., Ltd., follow the procedures below:

Obtain the right for returns and exchanges: In accordance with the Law of the People's Republic of China on the Protection of Consumer Rights and Interests, users may contact the after-sales service department of Ambulanc (Shenzhen) Tech. Co., Ltd. to exercise the legal rights for returns and exchanges. Please provide the Ambulanc product serial number, which can be found on the main unit enclosure or the outer packaging box. Returns and exchanges will not be accepted if the serial number is not clearly identifiable. Please specify the product model, and briefly explain the reason for the return.

Freight: The user is responsible for all freight costs associated with returning or exchanging the product to the after-sales service department of Ambulanc (Shenzhen) Tech. Co., Ltd., including any applicable customs fees.

Important Information

1.Once the product is purchased, the customer assumes full responsibility for its maintenance and management.

2.Even if the product is still under warranty, the following situations are not covered by the warranty:

●Damage or loss resulting from improper or rough handling.

●Damage or loss resulting from force majeure events, such as fire, earthquake, flood, or lightning.

●Failure to comply with the service conditions specified for the product, including any damage or loss resulting from inadequate power supply, improper installation, or unfavorable environmental conditions, may lead to system failure.

●Damage caused by improper packaging during return shipping.

●Damage or loss arising from the use of the product outside the territory of the original purchase.

●Damage or loss resulting from products not purchased through Ambulanc or its authorized distributors or agents.

3.Only qualified healthcare providers with appropriate certificates can use this product.

4.Unauthorized modification of the product’s software, hardware, or any other components is strictly prohibited.

5.Under no circumstances will Ambulanc be liable for any problems, damage, or loss resulting from the reinstallation, alteration, or repair of the product by personnel not authorized by Ambulanc.

6.Doctors are responsible for the clinical treatment. Ambulanc is not responsible for the clinical treatment.

7.Back up important data to external storage media, such as clinical records and notebooks.

8.Ambulanc (Shenzhen) Tech. Co., Ltd. assumes no responsibility for any loss of data stored in the product resulting from operator errors or other abnormalities.

9.Ambulanc (Shenzhen) Tech. Co., Ltd. assumes no responsibility for any damages not arising from product defects or caused by improper operation during use.

10.Ambulanc (Shenzhen) Tech. Co., Ltd. assumes no responsibility for any damage resulting from continued use of the product beyond its shelf life.

11.If the warranty claim is rejected, Ambulanc (Shenzhen) Tech. Co., Ltd. will assume no responsibility for the cost of round-trip shipping.

12.The Manual includes warnings about potential, foreseeable risks. Remain highly vigilant all the time to guard against any unspecified risks. Ambulanc (Shenzhen) Tech. Co., Ltd. assumes no responsibility for any damage or loss caused by negligence or disregard of the preventive measures specified in the Manual.

13.Once the administrator of this system changes, the Manual must be handed over.

14. A notice to the user and/or patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.Overview

1.1.Safety Instructions

Review these safety instructions carefully. These safety instructions are an integral part of the device and must always be accessible. For safety concerns, note the following:
In the Manual, the safety instructions are indicated as follows:

Prompt	Description
Warning:	•Indicates potentially hazardous or unsafe operations which, if not avoided, could result in death, serious personal injury, or property damage.
Caution:	•Indicates potentially hazardous or unsafe operations which, if not avoided, could result in minor personal injury, product malfunction, damage, or property loss.
Note:	•Emphasizes important precautions and provides instructions or explanations for better use of this product.
Ignoring the safety information should be considered beyond any further reasonable risk control measures.	

Warning:

●To avoid the risk of electric shock, ensure that the syringe pump is connected to a power supply network with proper protective grounding. It should only be plugged into a power outlet with protective grounding. The use of portable multi-socket power strips is not allowed. If the power socket is not grounded, please avoid using it and power the device with batteries instead.

●When using an external power supply for the syringe pump, ensure it is connected via a plug interface, allowing for quick disconnection in the event of a failure.

●Avoid using the device in an oxygen-rich environment or any area where flammable or explosive materials, such as anesthetics, are present, to prevent the risk of fire or explosion.

● The device is not suitable for use in a nuclear magnetic resonance (NMR) environment.

● Avoid using mobile multi-position sockets (MSOs) or AC power extension cords. Ensure that the total individual ground leakage currents do not exceed the allowable limit.

● Do not open the enclosure of the device, as doing so may result in electric shock. Maintenance or upgrades to the device must be performed by maintenance personnel who have been trained and authorized by Ambulanc.

● All settings should be verified and confirmed to be correct before starting the infusion.

● Please arrange the power cord and other cables carefully to prevent entanglement, patient suffocation, cable interference, or electrical disruptions.

● During the infusion process, blockage resulting from knotting of the infusion pipeline will lead to an increase in internal pressure within the extension pipeline. Removing the blockage at this time could lead to an excessive injection of liquid medication into the patient's body; therefore, appropriate preventive measures should be implemented.

● Please refrain from touching the patient and device interfaces (Type C interface and DC power input interface) simultaneously, as this may result in harm caused by leakage current.

● The device is intended for use by healthcare professionals, medical electrical specialists, or professionally trained clinical medical personnel in designated settings. Personnel operating the

device should be properly trained. Unauthorized or untrained personnel are strictly prohibited from performing any operations.

- During the defibrillation process, do not touch the patient or their non-defibrillation devices to avoid the risk of electric shock injuries. The defibrillation process will not affect the basic performance of the device, such as infusion, alarms, signal transmission, and other related functions.
- Regular daily cleaning and maintenance of devices is necessary.
- If repairs are needed, original accessories should be used.
- Utilizing different alarm settings and default configurations for the same or similar devices within the same area (such as an intensive care unit or operating room) can pose significant safety risks.
- The alarm settings for different syringe pump within the same area may vary to accommodate the patient's condition. Before starting the infusion, verify that the alarm settings are appropriate for the patient receiving the infusion.
- When setting the alarm sound, an alarm volume lower than the ambient noise level may prevent the operator from recognizing the alarm status. The alarm sound should be loud enough to ensure the operator can promptly detect the occurrence of the alarm.
- The device is portable but not explosion-proof. It is not designed to be carried by patients for use during work.
- The device must be operated exclusively by medical professionals, who should be kept at an appropriate distance from the device, such as doctors or nurses, to prevent patients from operating the device on their own.
- The user should confirm that the performance provided by the pump is suitable for the intended use and is not used in any way or for any purpose other than the intended use. Failure to do so will lead to reduction of pump function, resulting in patient or user casualties.
- Any defective pump should not be used. If the syringe pump detects a fault, it will emit an alarm sound, and the indicator light will turn red. If the issue cannot be resolved using the methods outlined in Section9. Faults & Alarms and Troubleshooting Methods, please turn off the syringe pump, disconnect it from the power source, and contact a qualified engineer for assistance. Errors in the performance of syringe pump can result in complications and, in some cases, patient casualties.
- The device cannot be used in situations where there are mixed gases such as flammable anesthetic gas, oxygen and ammonia oxide gas.
- Protect patients from injuries caused by overcurrent or undercurrent by setting parameters correctly and using calibrated syringes.
- Once an abnormality is found, pause should be the preferred safety measure.
- To avoid possible fault of the syringe pump, do not expose the pump to X-rays, γ-rays or ionizing radiation, or subject it to RF interference or strong electric (magnetic) field generated by diathermy apparatus or mobile phone. If the pump is to be used in or with a magnetic resonance imaging (MRI) device, it must be protected from interference by the magnetic field generated by such device. Fault of the syringe pump may lead to incorrect injection or insufficient injection, which may result in patient casualties.
- When using the syringe pump, keep it away from objects that generate strong electromagnetic

waves or noise. Additionally, avoid proximity to high-frequency surgical instruments to prevent interference and ensure the syringe pump functions properly.

●It is prohibited to use voltages other than those specified on the device's nameplate; otherwise, it may cause damage or even fire.

●The battery should not be thrown into fire or exposed to heat; otherwise, it may cause the battery to leak, catch fire or even explode.

●Do not tear off the battery sheath; otherwise, it may cause explosion or hazardous chemical burns.

●When the low battery alarm activates or the device is used continuously for an extended period, please connect it to an external power source to prevent power loss, which may lead to treatment interruptions or even potential patient harm or casualties.

●When plugging in or unplugging AC wires, ensure not to touch the metal component of the AC plug with wet or damp hands to avoid the risk of electric shock.

● It is recommended not to share a socket with other electrical devices.

● Do not disassemble or modify the device without proper authorization.

● The device should be checked daily. If it is not used for a long time, all functions should be confirmed to be intact before reuse.

● If any abnormality is found or if any functions are lost, please discontinue use and contact the supplier promptly. Otherwise, the manufacturer/seller assumes no responsiblity for any loss, damage or injury caused.

● Avoid vibration, falling and bumping, direct sunlight or strong light.

● Avoid hot and humid air blowing directly from heaters, electric stoves or humidifiers.

● Avoid using in areas with chemical storage, excessive dust, vibration or high humidity.

● Avoid reusing or re-sterilizing disposable syringes. After use, dispose of these syringes according to appropriate instructions.

● Please work or store and transport in accordance with the working environment and the transportation and storage conditions specified in this manual.

● The characteristics of syringe pump, syringes and consumables may affect the physiological effects of drugs. Please confirm that these characteristics are consistent with the drug prescription, trumpet curve and blockage alarm time set according to the injection flow rate.

● Please monitor the device during injection and check the remaining liquid volume in the syringe. Do not rely solely on the device's alarm function.

● The volume in the connecting pipeline is a residual volume and will not be injected. Such extra fluid must be replenished when the syringe is first filled and the system is emptied.

● If an internal fault is detected, the device will automatically cease operation and trigger an alarm.

● The syringes and infusion lines used in conjunction with the device should have a valid medical device product registration certificate and should be properly calibrated before use. The use of inappropriate syringes and infusion lines will result in inaccurate infusion rate or dosage, compromising the therapeutic effect or causing harm to patients.

●Avoid connecting other infusion systems or accessories to the device's infusion set.

●Please regularly inspect the power adapter and battery to ensure they remain in proper working

condition. If the adapter is damaged or the battery is unable to charge, replace them promptly with new accessories.

- When the device is connected to the same infusion port as other infusion systems, backflow may occur due to interactions between extension pipes, or the response time of the blockage alarm may be extended. Therefore, when it is necessary to connect with other infusion systems, a one-way valve should be used at the end of the extension pipeline or under the guidance of local hospital.

Caution:

- Ensure a continuous power supply while using the device. In the event of a sudden power outage, certain settings may not be saved.
- Given that electromagnetic fields can affect the device's performance, any device used near the device must meet EMC requirements. X-ray, or MRI equipment can be sources of interference, as all emit high-intensity electromagnetic radiation.
- Install or move the device properly to avoid falls, collisions, strong vibrations, or other mechanical damage.
- The device should be dried immediately after exposure to rain or splashing water.
- Some settings are secured with a password. Password changes should only be made by authorized personnel. If a password is required to access the relevant functions, please reach out to the appropriate personnel.

Note:

- The Manual introduces the product based on the most comprehensive configurations, therefore, some of the information provided may not apply to the specific model you have purchased.
- The device is equipped with a power-off storage function. After an unexpected power outage, the alarm limit settings prior to the outage can be preserved for the entire lifespan of the device. After startup, the alarm limit settings prior to power interruption can be automatically restored.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;

1.2.Cybersecurity

Note:

To ensure cybersecurity, unauthorized devices and personnel are strictly prohibited from connecting to the device to access information. Non-medical devices are also prohibited from being connected. If connecting to the IT-network containing other devices may pose previously unidentified risks to patients, operators, or third parties, the responsible party should identify, analyze, assess, and mitigate these risks.

2.Device Description

2.1.Intended Use

The Syringe Pump is intended for use by medical staff for the purposes of controlling infusion rate and volume.

2.2.Intended Use Environment

The Syringe Pump is intended to be used in healthcare institutions and emergency transport.

2.3.Intended Clinical Benefits

The Syringe pump provides controlled and accurate infusion of medications or solutions through an intravenous routes.

2.4.Residual Risks and Side Effects

One or more risks arising from all identified hazardous conditions have been brought under control and within acceptable limits. After all risk control measures have been implemented, no new risks have been created.

The residual risks are within the acceptable range after risk control.

2.5.Indications

The Syringe Pump is for patients who need receiving various types of medications, solutions through an intravenous routes.

2.6.Contraindications

The infusion of analgesics, chemotherapy, insulin, parenteral nutrition, enteral nutrition, blood and blood products.

2.7.User Qualification

The Syringe Pump is intended to be used by trained and authorized healthcare professionals.

2.8.Intended patient population

The Syringe Pump is intended for adult, adolescents, children and infants.

3.Device Installation

3.1.Installation and Removal of Clamp

Note

- Before securing the device, ensure that the stability of the fixed bracket is checked.
- To prevent the pump from falling off the infusion stand or bed rail, ensure that the pump is securely installed, and always check the safety and stability of the installed pump. Failure to comply with this warning may result in damage to the pump and injury to the user or patient.

3.2.Installation and Removal of Hanger

Note

•Before and after securing this device, ensure the safety and stability of the installed hangers and pumps are thoroughly checked. Failure to do so may damage the pump and pose risks to users or patients.

3.3.Syringe Installation

Warning

•Users should use the disposable syringe recommended by our company. If not, please contact our staff to calibrate the device again and confirm the infusion performance of the device. It can be used after confirmation; otherwise, it may affect the infusion accuracy, pressure detection and other functions of the device.

•Do not reuse disposable accessories, as doing so may lead to performance degradation or cross-contamination of the syringe pump.

•It is recommended to use the device within 51±5 cm above and below the patient's heart height. The smaller the height difference between the device and the patient's heart, the more accurate the pressure test in the infusion pipeline.

Note

•After syringe installation, it is necessary to confirm whether it is installed in place. After successful installation, the device can automatically identify the syringe specifications. If the installation is not successful, a corresponding prompt will pop up on the screen.

•For safe operation of the syringe pump, the syringe and extension pipe must be properly installed according to the syringe installation instructions. Ensure that the syringe bezel (flange) is properly seated in the slot and the extension pipe is correctly placed on the fixing hook and infusion stand; otherwise, it may cause infusion error, and may lead to patient injury or even death.

•To avoid siphoning (free flow) of fluid in the syringe, be sure that you have clamped the extension pipe before installing or removing the syringe; ensure that the syringe is properly installed on the pump; and ensure that the syringe piston is correctly seated in the pump jaws.

3.4.Power Supply Connection

3.4.1.AC Power Supply Connection

Warning

•If there is any doubt about the integrity of the external protective wire during installation or wiring, battery power should be used to prevent the patient or use from possible electric shock injury.

3.4.2.DC Power Supply Connection

Warning

•Check both ends of the power connector for residual liquid medication to prevent safety hazards.

•Only power cords and batteries approved by our company can be used. Using power cords or batteries not approved by our company may cause device fault and even affect the personal safety of users.

4.Interface Function Description

4.1.Main Interface

4.1.1.Param Set Interface

Note

•Users can utilize the drug lib function based on their specific needs, with the capability to store a minimum of 2,000 different drugs.

•This device supports updating the drug lib. If you need to update the drug lib, please contact our after-sales service personnel.

•When the drug lib is closed, the drug selection function is not supported.

4.1.2.System Settings Page

Note

•When the "Time Near End", "No Operation Time", and "Lock Time" are set to off, the device will no longer trigger this function.

4.1.3.Advice Sys Interface

Tips

•Before exporting the patient information, insert the USB flash drive into the USB interface located on the back of the syringe pump. If the flash drive is not connected, the syringe pump will display the message: "Connect USB!"

4.1.4.History Record Interface

Note

•This device can store a minimum of 5,000 history records, 20 recent treat records, and cumulative data within 24 hours. When the storage capacity is reached, new records will overwrite the oldest ones.

•Power failure will not affect stored history record. The stored alarm information will remain unaffected by the power-off time.

•Cumulative volume cannot be cleared during infusion.

5.Introduction to Infusion Mode

5.1.Loading Dose Mode

Notes

•After the device is started, it will enter the first dose phase preferably. When the device does not set the parameters of the first dose phase, the device will directly enter the main phase.

•The parameter of Vtbi must be greater than the Initial parameter; otherwise, a relevant prompt will be generated.

5.2.Sequential Mode

Note

•This device supports only continuous sequential infusions. If the parameter settings are not entered in a continuous sequence, the device will terminate the process after completing the last sequence within the initial continuous set.

5.3.Intermittent Mode

Note

•VTBI and maintain rate are optional settings. When the volume to be infused is not set, stop infusion after syringe emptying. When the maintain rate is not set, no infusion will be performed during the hold phase, and it will automatically switch to the infusion phase after reaching the set interval time.

5.4.Ramp Mode

Note

•Stab. time and stab. rate can only be obtained by calculation and cannot be entered.

•Up time and down time are optional settings. When none of them are set, the syringe pump performs infusion at a stab. rate.

5.5.Dose Time Mode

Note

•Time can only be obtained by calculation and cannot be entered.

•Unit of dose rate in the dose time mode: X/min, X/h and X/24h are optional, where X represents ng, ug, mg, g, mU, U, kU, EU, mmol, mol, mcal, cal, kcal and mEq

5.6.Trace Mode

Notes

•In the trace mode, the rate must be set before starting the infusion. The vtbi and time can be selected

as needed.

6.Operation and Use

6.1.Purge

Notes

•When the default purge rate is greater than the rate max of syringe, the purge rate is equal to the rate max of syringe.

Warning

•Before purging, please make sure that the syringe pump and extension pipe are disconnected from the patient end. If disconnected, click [Yes].

•To avoid embolism, be sure that all bubbles in the syringe and extension pipe are emptied before any drug delivery. The syringe pump has an emptying function to assist in completing this process. The presence of air in the drugs may lead to complications and even patient casualties.

6.2.Start Infusion

Warning

•When setting the infusion parameters, be sure to check the medical advice to ensure that the infusion parameters are consistent with the medical advice.

•Ensure that the brand of syringe consumables currently used in the device is consistent with the selected brand of syringe consumables.

•Ensure the extension pipe is purged in place and properly connected to the device before attaching it to the patient.

•When the ambient temperature is 40°C, the surface temperature of the extension pipeline may reach 42°C when it comes into contact with patient. If it gets too hot, do not contact it for a long time to avoid harming the patient.

6.3.Bolus

Warning

•When using the bolus function, make sure that the syringe pump is properly connected to the patient.

Tips

•The [Bolus] function cannot be used in the ramp mode.

•There is a corresponding prompt tone during bolus, that is, "beep" once every 0.5 mL of bolus.

•If the set rapid injection limit exceeds the maximum capacity of the currently used syringe, the pump will prompt you to reset the rapid injection volume on the rapid injection parameter setting interface. The range is from 0.10ml to the maximum capacity of the currently used syringe.

6.4.KOR Function

Note

•When the KOR rate of syringe pump is set to 0 mL/h, the KOR function is turned off, that is, after the syringe pump completes the set volume to be infused, the KOR function will not be started. When the set KOR rate is greater than the current infusion rate of syringe pump, the syringe pump will continue to run at the current infusion flow rate.

•After the KOR infusion run is complete, the syringe pump stops operating and triggers a [KOR Completed!!!] alarm.

•The infusion volume of KOR will be included in the cumulative infusion volume. If the bolus function is activated during the operation of the KOR function, the device will restart the KOR function at the end of bolus.

6.5.Pause Infusion

Warning

•Avoid reusing or re-sterilizing disposable syringes. Please dispose of the used syringes and extension pipes in accordance with the relevant laws and regulations or the disposal procedures of the local hospital, and do not reuse them.

•Please replace the syringe extension pipe according to the recommended time specified by the manufacturer and the requirements set by hospital management.

6.6.Shutdown

Note

•In some special cases, if the device cannot be shut down normally, press and hold the ON/OFF button for no less than 10 seconds to force the shutdown. However, a forced shutdown can lead to data loss or potential damage to the device. It is not recommended unless necessary or under special circumstances.

•If the device has been connected to an external AC power supply, the AC power supply of the device will not be cut off after shutdown. To completely disconnect the power supply, please pull the power plug.

7.Cleaning and Disinfection

7.1.Daily Cleaning and Disinfection

Notes

•Only the detergents, disinfectants and treatment methods recommended by the manufacturer can be used to clean or disinfect the device or its accessories. The company does not provide any guarantee for damage or accident caused by the use of other materials or methods.

•Do not mix different disinfectants before use; otherwise, it may cause certain hazards.

•Do not pour liquid on the device or its accessories. In case of accidentally pouring liquid on the device or its accessories, disconnect the power supply immediately and clean it, and drain the liquid promptly. If the device is abnormal, please contact Ambulanc's after-sales service department or an authorized representative to provide maintenance services.
•After cleaning or disinfection, please check the device and its accessories. If any signs of aging or damage are found, stop using them or replace them immediately.
•Abrasive materials (such as steel wool or silver polish) or strong solvents (such as acetone or detergents containing acetone) should not be used for cleaning.
•To avoid damage to the accessories caused by improper disinfection, please disinfect the accessories only when necessary according to the local hospital's system.
•Under normal use, there is no limit to the number of times the main unit enclosure, clamp and bracket can be cleaned within the recommended life time.

7.1.1.Main Unit Enclosure

Notes
•Before cleaning, please disconnect the power cord of syringe pump.

8.Maintenance and Inspection

8.1.Device Inspection Method

8.1.1.Startup Inspection

Notes
•If the startup self-test of the device fails, a "System Error!!!" alarm will be triggered after the device is turned on. If this happens, please contact our after-sales service personnel.

8.1.2.Battery Performance Inspection

Note:
•Do not use the device for infusion during battery performance inspection, and do not interrupt charging or discharging.

8.2.Battery Maintenance

Warning:
•Do not open or remove the protective case of the battery when the device is working.
•Do not expose the battery to open flames or other heat sources. Do not dispose of it in fire.
•Do not short-circuit the battery terminals.
•Do not subject the battery to severe physical impact. Do not strike with an iron hammer.
•Please check the battery regularly for leakage and replace the leaking battery in a timely manner. In case of leakage or strange odor, please keep the battery away from the fire source to prevent the

leaked electrolyte from catching fire; if the battery leaks or the leaked liquid enters your eyes, please rinse with clean water immediately and consult a doctor.

•Do not place the battery in direct sunlight or high temperature area; do not let the battery come into contact with water.

•Please store the battery in an area away from direct sunlight, high temperatures, and moisture.

•When disposing of batteries, follow local regulations.

•Do not place the battery in an unsafe environment.

Note:

•Only the battery specified by the manufacturer may be used. After replacement, please dispose of the battery according to the relevant regulations.

8.3.Disposal of Obsolete Device

Warning

•The disposal of batteries, accessories, packaging materials and device components must comply with the relevant local regulations or the hospital's waste disposal system.

9.Faults & Alarms and Troubleshooting Methods

9.1.Alarm Information

Note:

•After the high-level alarm is triggered in the running state, the syringe pump stops running.

•After the low-level alarm is triggered, it will not affect the infusion of syringe pump, and the syringe pump continues to infuse.

•After the syringe pump emits a [Battery Depleted!!!] alarm, the pump stops infusing and the shutdown is delayed for at least 5 minutes.

•Under standard working conditions (Fully new battery, brightness set to Gear 2, manufacturer default sound set to Gear 6, Wi-Fi turned off, and a rate of 5 ml/h), the device can operate for at least 30 minutes after the first [Battery Low!] alarm is triggered.

•When a blockage occurs, the device will stop infusion and trigger the [Block!!!] alarm.

•If there is overcurrent or undercurrent caused by partial or complete blockage of the infusion pipeline, it can be handled according to 9.6 Block Alarm. If the abnormal situation has not been eliminated, please contact Ambulanc's after-sales service department for assistance.

9.2.Block Alarm

Notes

•The block pressure takes effect immediately after being set and saved, and does not change with the duration of power outage. Therefore, the blockage alarm level must be checked before injection to ensure that it meets the current injection requirements. Otherwise, the blockage alarm time may be

delayed, resulting in patient casualties.

•Before the blockage is relieved, the device pumps back the drug liquid to relieve the block pressure using the method of controlling the stepping motor reversal based on the injection speed and blockage level.

•If a pipeline block alarm occurs, immediately close the rate regulator and briefly press the syringe piston release handle to reduce the pipe pressure to eliminate the possibility of the agent being injected into the patient's body. Then check whether the extension pipeline is bent or blocked or whether the syringe cap has not been removed, and eliminate the blockage before re-injection. Accidental drug injection may lead to patient casualties.

9.3.Alarm Mute

 **caution**

•When setting the alarm sound, an alarm volume lower than the ambient noise level may prevent the operator from recognizing the alarm status. The alarm sound should be loud enough to ensure the operator can promptly detect the occurrence of the alarm.

•During the alarm sound pause period, the device will not emit an alarm sound, even if a new alarm is triggered. Therefore, it is essential to carefully decide whether to pause the alarm sound. Once the alarm sound is paused, users should regularly monitor the device's status.

9.4.Nurse Call

 **Warning**

•Clinical medical staff must ensure that they are within the visible and audible range of the syringe pump, so that important alarms can be responded to quickly. If the alarms cannot be responded to quickly, it may lead to patient injury or even death.

10. Accessories

 **Warning**

• Users should use the disposable syringe recommended by our company. If not, please contact our staff to calibrate the device again and confirm the infusion performance of the device. It can be used after confirmation; otherwise, it may affect the infusion accuracy, pressure detection and other functions of the device.

• Please be sure to use the accessories specified by our company. Using other accessories may be incompatible with the device, which may cause performance degradation or damage to the device.

• Before using the relevant accessories, please be sure to check the life time and intact packaging of the accessories. If the accessories have expired or the packaging is damaged, do not use them.

11.Product Technical Parameters

11.1.Anti-bolus and Blockage Alarm Delay and Possible Bolus Injection

Notes

•The blockage bolus volume, block alarm pressure and delay time will be affected by the test temperature, condition and pipeline length.

•When using a large-volume syringe to set a low flow rate for infusion, it may cause a greater delay in the blockage alarm. For example: When using a 50 mL syringe at the running speed of 0.1 mL/h, and setting the block pressure to the minimum and maximum, the delay in the blockage alarm may reach more than 9 hours and 25 hours respectively. If it is indeed necessary to infuse at a low rate, it is recommended to use a small-sized syringe to ensure the timeliness of blockage test.

11.2.Infusion Accuracy Curve

Warning

•Infusion accuracy may be affected by the environmental factors (e.g. humidity, pressure, temperature, brightness and infusion consumables used). In order to ensure the infusion accuracy of the device, the user shall set the parameters according to the parameter range specified in the manual. If beyond the range, the device cannot guarantee the infusion accuracy.

12.EMC

Notes

•SP10p and SP10n syringe pump meet the relevant requirements of electromagnetic compatibility in IEC 60601-1-2:2020, Chapter 11 of IEC 60601-1-12:2020 and Chapter 202 of IEC 60601-2-24:2012.

•The user should install and use the device according to the electromagnetic compatibility information provided in the accompanying documents.

•Since portable and mobile RF communication devices may affect the performance of SP10p and SP10n syringe pump, it is necessary to avoid strong electromagnetic interference when use.

•See the accessories for details of the guideline and the manufacturer's statement.

Warning

•SP10p and SP10n syringe pump should not be used close to or stacked on top of other devices. If it cannot be avoided, check and make sure that these syringe pump can function normally under the configuration used.

•Except for the cables sold as spare parts for internal components by the manufacturers of SP10p and SP10n syringe pump, the use of accessories and cables other than those specified may result in an increase in emission or a decrease in immunity of SP10p and SP10n syringe pump.

•This device is intended for use by healthcare professionals only. This device may lead to radio interference or disturb the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting, repositioning or shielding the corresponding sites of SP10p and SP10n

syringe pump.

•SP10p and SP10n syringe pump may still be interfered with by other devices even if they meet the emission requirements of the corresponding national standards. Table of emission frequency or bands, modulation types, frequency characteristics, and effective radiated power.

13.Storage and Transportation

Warning:

When the storage conditions exceed the requirements of the working environment and the device is transferred from the storage state to the use state, it should be placed in a working environment for more than 2 hours before use.

14.Software Description

14.1.1.Portability

Caution:

•The device should be disconnected from the patient before software upgrade. Please make sure that important data within the device is saved.

•Shutdown or outage should not be allowed during the upgrade of the bootstrap program, otherwise, this will lead to the breakdown of the device.

Note:

•Program upgrades can only be performed by the Ambulanc's after-sales service department.

•Before upgrading, please ensure that the version of the upgrade package is the one you need. To obtain the latest version of the upgrade package, please contact our after-sales service department.

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