ASU-I Safety and Performance Information

Product information

Thank you for purchasing the ASU-I suction unit.

To use this device correctly, please read and understand the contents of the device manual carefully before use. After reading, keep this manual in a proper place where it is easy to access.

Product name: Suction Unit
Model: ASU-I
Manufacturer name: Ambulanc (Shenzhen) Tech. Co., Ltd.
Manufacturer 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
Version: 1.0
Release date: 2024.7.15

Attention

This instrument can be used in emergency medical services environment.

CE **0051**

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Ambulanc will, at its own discretion, take responsibility for the safety, reliability, and performance of the instrument in one of the following cases:

- Any assembly, expansion, readjustment, improvement, and repair operations are performed by any professional approved by Ambulanc;
- Related electrical equipment is in compliance with national standards;
- The instrument is used in accordance with the operation instructions.
- Ambulanc will be responsible for the safety, reliability, and operation condition of the product in one of the following cases:
- Any component is dismantled, expanded, or re-adjusted;
- The instrument is repaired or changed not by any personnel approved by Ambulanc;
- The product is not used correctly in compliance with this User's Manual.

Safety Information

The following safety marks are used in this manual:

 **Warning!**

Indicating any risk of harm to the patient and/or user.

 **Attention!**

Indicating potential equipment damage and undesired treatment effects.

 **Tip:**

Giving usefully indicative information.

 **Warning!**

Failure to implement a satisfactory service or maintenance plan by any hospital or institute responsible for using this instrument may cause its malfunction or even endanger body health.

Important Information

1. After the purchase of the product, the customer shall take full responsibility for its maintenance and management.
2. Quality assurance will not cover the following, even during the warranty period:
   - any damage or loss resulting from improper use or misuse of the product;
   - any damage or loss caused by force majeure such as fire, earthquake, flood, or lightning;
   - any damage or loss attributed to failure to meet any operating condition required for the system, such as insufficient power supply, improper installation, or unfavorable environmental conditions;
   - any damage or loss incurred due to use of the system in the region not initially intended for it; and
   - any damage or loss caused by a purchase from any unauthorized dealer or agent.
3. This equipment can be used only by certified medical staff.
4. In any case, Ambulanc will take no responsibility for problems, damage, or loss resulting from the re-installation, change, or repair of the system performed by personnel not authorized by

Ambulanc.

5. This system is intended to provide the data required for clinical diagnosis for physicians.

   The physician takes responsibility for the diagnosis process. Ambulanc takes no responsibility for any diagnostic process.

6. Be sure to back any key data to an external storage medium, such as clinography and notes.

7. Ambulanc takes no liability for loss of data stored in the system due to the operator's fault or any exceptional condition.

8. This manual contains warnings for foreseeable potential hazards. The user shall keep watch at any time for any hazards not stated in the manual. Ambulanc takes no responsibility for damage or loss resulting from negligence or failure to observe the preventive measures stated in this manual.

9. This manual must be handed over to the successor when the system administrator is replaced.

Contents

1. Equipment Description

1.1. Intended Purpose

The suction unit is used to aspirate any secreta from the patient's respiratory tract, with negative pressure adjustable for flow velocity control with the regulating knob.

1.2. Intended Operating Environment

This equipment is intended for use in emergency rooms, operating rooms and wards.

1.3. Intended user

Personnel using the Suction Unit must meet the following conditions:

- This product should be operated by trained and authorized medical personnel.

⚠ Notice:

- Improper use may cause harm to personnel (operators and patients).

2. Safety Instructions

2.1. Safety Regulations

⚠ **Warning**

- It can be used only for the intended purpose (see 1.1 Intended Purpose).
- Before use, the user must inspect the equipment, connecting cables and accessories to ensure that they operate normally and safely.
- During operation, the user must not dismantle the equipment.
- This equipment can be connected only to a power socket with protective grounding.
- Use AC mains supply to power the equipment before the battery runs out.
- This equipment shall not be used in an environment exposed to inflammable or explosive material, which may cause fire or explosion.
- Suction Unit is not applicable for high-pressure applications (e.g., hyperbaric cabin).
- Suction Unit is not intended for use in MRI settings.
- Liquid in the collection container must be prevented from entering the equipment, which may cause short circuiting and thereby malfunction.
- Observe the instructions in 5. Sanitary Treatment to prevent infection or

bacillosis.

- Disposal of packing material must be subject to local laws and regulations or the hospital's waste disposal rules, and any packing material must be collected at a place out of children's reach.

Attention

- Only the pipeline supplied or recommended by the manufacturer can be used.
- The collection container shall be cleaned when the liquid level in it is higher than the overflow protector.
- Suction Unit shall not be used continuously for more than 60 minutes.
- The equipment shall be mounted and transferred properly to prevent it from falling, colliding, receiving strong shock, or any other mechanical force and thereby causing damage.
- It is recommended that maintenance work, such as inspection or service operations, be performed by Ambulanc (Shenzhen) Tech. Co., Ltd. or its authorized professional.
- Use of any spare part supplied by another manufacturer may result in malfunction and failure of biocompatibility in the equipment. Notes: In the event that any breakdown results from the use of any spare part or accessory neither recommended in the manual nor supplied by the manufacturer, the product warranty becomes invalid.
- Proper measures should be taken to prevent any silica gel or rubber parts from being exposed to UV light or sunlight for a long time, which may result in cracks.

2.2. Symbol Description

	General warning sign

3. Installation

Attention

During installation and connection, the intermediate tubing supplied by Ambulanc (Shenzhen) Tech. Co., Ltd. must be used, and any other hose not intended for the equipment shall not be used.

3.1. Connecting intermediate tubing to the collection container

Warning

1. Connect the pipes strictly according to the port identifier. Otherwise, sputum may overflow into the main unit after filling the collection tank, causing contamination or even damage to the main unit.

2. The inner diameter of the hose must be greater than or equal to the inner diameter of the OUT or IN interface. It is recommended that the hose provided by the manufacturer be used

4. Operations

Attention

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 are established. And serious incidents mean any incident that directly or indirectly led, might have led, or might lead to any of the following:

- The death of a patient, user, or other person.
- The temporary or permanent serious deterioration of a patient's, user's, or other person's state of health.
- A serious public health threat.

4.1. Install the suction tubing assembly

Warning

1. The intermediate tubing circuit components supplied by Ambulanc must be used to ensure product performance. Ambulanc will take no responsibility for any problems resulting from the use of any component other than those supplied by Ambulanc.

2. Any disposable Yankauer Suction Sets and Suction Catheters must be rejected after being used.

4.2. Startup

Attention

1. Insufficient battery levels may cause the equipment to be unable to start up.

2. If there is leakage in the suction catheter, the negative pressure value may not

reach the limits.

4.3. Suction

Attention

1. During suction, much care shall be taken to avoid any injury to the patient's oral cavity and cavum pharyngis, especially to the patient's mucous membrane.
2. You may interrupt or proceed with suction by blocking the air vent with your thumb and then releasing it.

Tip:

1. During operation, the collection container must always be kept erect, or otherwise the overflow protector may not start up, and thereby the secreta is sucked into and damages the pump.
2. During suction regularly examine the battery level and connect an external power adapter to recharge the battery when the battery level indicator starts flashing red, or otherwise the equipment will shut down automatically due to a low battery level. Over-discharging the battery may cause damage to it and thereby shorten its service life.
3. When the temperature is too high, the pump is guarded. The pump is about to start up after the temperature is lower.

4.4. Adjusting Negative Pressure

Warning

To avoid injury to the patient, remove the suction catheter from the patient's respiratory tract before adjusting the negative pressure.

4.5. Operation of the collection container

Attention

1. The liquid storage capacity of the collection container is 1000 mL, please do not exceed the amount. Otherwise, it will affect the normal use of the Suction Unit.
2. When the overflow protector in the collection container is activated, empty the collection container on time or shut down the equipment.
3. In case any liquid or solid substance is sucked into the pump, stop operating the suction unit and contact Ambulanc (Shenzhen) Tech. Co., Ltd. to assign its authorized professional for equipment service.

5. Sanitary Treatment

Attention

1. Any disposable accessory in the Suction Unit is only for a single use and shall not be recycled. Reusing any disposable accessory in the Suction Unit may pose a hazard to equipment performance and safety.
2. Do not soak the front panel of the Suction Unit in any disinfectant or other liquid. Clean and disinfect it by wiping instead. Soaking the panel in liquid may damage the equipment, cause malfunction, and endanger the patient.

5.1. Cleaning and Disinfection

Attention

1. The cleaning and disinfection of accessories such as the collection container, No. 1 intermediate tubing, and No. 2 intermediate tubing can be repeated ≥30 times. In order to ensure the normal use of the Suction Unit, it is recommended that you replace the corresponding accessories after cleaning and disinfecting 30 times.

2. After disinfection, the parts are carefully rinsed with distilled water and then dried.

3. The disinfection solution can be a solution containing ethanol, isopropyl alcohol, or n-propyl alcohol.

4. Disinfectant configuration should be carried out according to the manufacturer's instructions.

5. Disinfectants generally damage material surfaces and shorten the service life of objects. You should pay attention to the instructions for use of disinfectants, choose recommended disinfectants as much as possible, and follow the recommendations of the disinfectant manufacturer.

6. If any damage to the accessories (such as cracks and breaks) is found after cleaning or disinfection, they need to be replaced in time.

5.2. Disposal of products

Attention

Use only the accessories recommended by the manufacturer. The use of other accessories may cause abnormal use or equipment failure.

6. Function Inspection

Attention

If a significant deviation from the set value is found in the function inspection, the equipment shall not be used until the fault is removed.

The user must perform a function inspection before each startup and after disassembly, as well as at least once every six months.

Tip:

In the event that any malfunction is identified during function inspection, the suction unit shall not be used. First, remove the trouble by following the instructions. If the trouble cannot be eliminated, contact Ambulanc or assign its authorized professional to repair the equipment.

7. Maintenance

7.1. Maintenance Cycle

Attention

Observe the safety inspection and function inspection cycles for the suction unit.

After each operation:

Clean and disinfect the recycled collection container by following the instructions as stated in Section 6.

Once every year:

Clean and disinfect the equipment, and perform a safety inspection by following the instructions in Section 6. In addition, request the manufacturer or its authorized professional to perform a maintenance examination.

7.2. Performing Safety Inspection and Maintenance

Attention

This product does not contain any sensors or electrodes; there is no deterioration in performance due to aging, but if the suction capacity of the product is reduced, please contact the manufacturer for repair and testing.

7.3. Battery

Attention

1）When a low battery alarm occurs, connect the external power supply in time.

2）If the voltage fluctuation of the network power supply is large, please do not charge.

3）If you do not use this product for a long time, please charge and discharge the battery every 3 months to avoid battery damage.

4）If the power supply time is too short after the battery is fully charged, the battery may be damaged or faulty, and it should be replaced and properly recycled.

5）The battery is a consumable component and must be replaced when it is exhausted.

6）The battery equipped with this product cannot be removed at will. Improper replacement of the battery may cause damage to the device. If you need to replace the battery, please contact the distributor or manufacturer who sold you this product.

7）Only the technical service engineers authorized by the security company can replace the batteries.

Warning

1） Only batteries recommended and provided by the manufacturer can be used, otherwise abnormal operation may occur.

2） If the battery is damaged or leaked, replace it immediately; otherwise, the device may be damaged.

3） Do not use the faulty battery on the device.

4） Do not open or remove the battery protective shell.

5） Keep the battery away from open flames and other hot objects. Do not throw it into the fire.

6） Do not short-circuit the battery terminals.

7） Do not cause a serious physical impact on the battery. Do not hammer the battery.

8） Check the battery periodically for leakage and replace the leaked battery in time.

9） In case of leakage or strange odor, keep it away from the fire source to prevent the leaking electrolyte from catching fire.

10） If the battery leaks or leaks liquid into the eyes, rinse immediately with water and consult a doctor.

11） Do not place the battery in direct sunlight or at a high temperature.

12） Do not let the battery come into contact with water.

13） Place the battery away from direct sunlight, heat, and water vapor.

14） When disposing of batteries, follow local regulations.

7.4. Storage

Important

Even during storage, the aforesaid maintenance cycle shall be observed before the equipment is put back into operation.

8. Technical Parameters

8.1. Detailed Parameters

Type of suction	High vacuum/ High flow
CE classification	Class IIa
EMC classification	Group 1 Class B

8.2. EMC Statement

Attention

- ASU-I Suction Unit is IEC 60601-1-2 EMC compliant.
- The user should install and operate the equipment in accordance with the EMC information provided in the document attached.
- ASU-I Suction Unit performance may be impaired by any portable or mobile RF communication equipment, so it should be kept away from any strong EMI source, such as a cell phone or microwave oven, during operation. Don’t use it in an MRI environment.
- A guide and manufacturer statement are attached as appendices.

Caution

- ASU-I Suction Unit shall not be operated adjacent to or overlaid on any other equipment. If it is unavoidable, observe and check that the aspirator is able to operate normally in the given configuration.
- Use of any accessory or cable other than those supplied as spare parts for the ASU-I Suction Unit by the manufacturer may increase emissions or degrade the electromagnetic immunity of the aspirator.

Guide and Manufacturer Statement - EM Emission		
The purchaser or user shall ensure to operate the ASU-I Suction Unit in the following EM environment, which it is intended for.		
Emission Test	Compliance	EM Environment - Guide
RF Emission (CISPR 11)	Group 1	ASU-I Suction Unit emits RF energy only for its internal function, so it generates very low RF emissions and rarely interferes with electronic equipment nearby.
RF Emission (CISPR 11)	Class B	ASU-I Suction Unit is intended for use in any facilities, including household facility and public low-voltage supply grids connected to resident buildings. Warning: The ASU-I Suction Unit is for use by healthcare professionals only. This equipment may cause radio interference or disrupt the operation of nearby equipment. Necessary measures may need to be taken, such as re-adjustment of the ASU-I Suction Unit's direction, location, or lighting response platform.
Harmonic Emission (IEC6100-3-2)	Class A	
Voltage Fluctuation/Glint Emission (IEC6100-3-3)	Compliant	

Guide and Manufacturer Statement - Electromagnetic Immunity			
Purchaser or user shall ensure to operate ASU-I Suction Unit in the following EM environment which it is intended for.			
Electromagnetic Immunity Test	IEC 60601 Test Level	Compliant	EM Environment - Guide
ESD (IEC 61000-4-2)	±6kV Contact Discharge ±8kV Air Discharge	±6kV Contact Discharge ±8kV Air Discharge	The floor should be built of wood, concrete, or tiles. If the floor is covered with any composite material, the relative humidity will be at least 30%.
Fast Transient Train of Impulses (IEC 61000-4-4)	±2kV for power cable ±1kV for input/output cable	±2kV for power cable ±1kV for input/output cable	Overhead contact power should be of the quality intended for a typical commercial or hospital environment.
Surging (IEC 61000-4-5)	±1kV cable to ground ±2kV cable to cable	±1kV cable to ground ±2kV cable to cable	Overhead contact power should be of the quality intended for any typical commercial or

			hospital environment.
Voltage dip, short interruption and voltage variation in power input cable (IEC6100-4-11)	<5% UT, lasting for0.5 cycle (with voltage dip >95% on UT) 40% UT, lasting for5 cycles (with voltage dip of 60% on UT) 70% UT, lasting for25 cycles (with voltage dip of 30% on UT) <5% UT, lasting for 5s (with voltage dip >95% on UT)	<5% UT, lasting for0.5 cycle (with voltage dip >95% on UT) 40% UT, lasting for5 cycles (with voltage dip of 60% on UT) 70% UT, lasting for25 cycles (with voltage dip of 30% on UT) <5% UT, lasting for 5s (with voltage dip >95% on UT)	Overhead contact power should be of the quality intended for a typical commercial or hospital environment. It is recommended to use an UPS to power ASU-I Suction Unit if the user is to operate it even during a power interruption.
Power Frequency Magnetic Field (50/60Hz) (IEC6100-4-8)	3A/m	3A/m	The power frequency magnetic field shall have the characteristics of typical locations in a typical commercial or hospital environment.
Notes: UT means AC grid voltage before the test voltage is applied.			

Guide and Manufacturer Statement - Electromagnetic Immunity			
The purchaser or user shall ensure to operate ASU-I Suction Unit in the following EM environment, which it is intended for.			
Electromag	IEC 60601 Test Level	Compliant	EM Environment - Guide
RF Conduction IEC6	3 V (effective value) 150 kHz ~	3 V (effective value)	Any portable or mobile RF communication equipment shall be located minimally at the distance as recommended below to any operating part of the ASU-I Suction Unit, including cable. Such distance is determined based on a formula involving transmitter frequency. Recommended spacing distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$

100-4-6 RF Radiation IEC6100-4-3	80 MHz 3V/m 80 MHz ~ 2.5 GHz	3V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz ~ 800MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz ~ 2.5MHz Where, P —maximum transmitter rated output power in Watt provided by the transmitter manufacturer; d—recommended spacing distance in meter ; Field strength of fixed RF transmitter is determined based on measurement in EMI sitea, and each frequency rangeb should be lower than the acceptable level. EMI may be present near any equipment labeled with the following sign. 

Note 1: For the frequency range 80 MHz~800 MHz, a formula for the higher frequency band is used.

Note 2: These guides may not be applicable in all cases, as electromagnetic propagation is affected by the absorption and reflection of nearby buildings, objects and the human body.

a In theory, the field strength of any fixed transmitters, such as wireless (cell or cordless) phones, mobile radio base station, amateur radio, AM/FM radio broadcasting, and TV broadcasting equipment, cannot be foreseen accurately. The assessment of the electromagnetic environment of a fixed RF transmitter should take into consideration measurements of the EMI location. If the field strength measured in the location where the ASU-I Suction Unit is operated is higher than the aforesaid acceptable RF level, the user should observe the aspirator to verify its normal operation. If the aspirator is identified as operating improperly, additional measures may be necessary, such as re-adjustment of orientation or location ASU-I.

b Throughout the frequency range of 150 kHz~80 MHz, the field strength should be below 3 V/m.

Recommended Spacing Distance between Portable/Mobile RF Communication Equipment and ASU-I Suction Unit

ASU-I Suction Unit is intended for use in electromagnetic environment with controlled RF radiation interference. Based on maximum rate output power of communication equipment, purchaser or user may maintain the following recommended minimum distance between portable/mobile RF communication equipment (transmitter) and ASU-I Suction Unit to prevent EMI.

Maximum rated output power of transmitter (W)	Spacing Distance (m) for Various Transmitter Frequencies		
	150 kHz ~ 80 MHz (excluding ISM	80 MHz ~ 800 MHz d = $1.17\sqrt{P}$	800 MHz ~ 2.5 GHz d = $1.17\sqrt{P}$

	frequency band) d = $1.17\sqrt{P}$		
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	7.38
100	11.70	11.70	23.33
The recommended distance in meters for maximum rated output power values not listed above may be determined based on the corresponding formula given in the column of frequency range, where P is the maximum rated output power (in watts) provided by transmitter manufacture. Note 1: For the frequency range 80 MHz~800 MHz, a formula for the higher frequency band is used. Note 2: These guides may not be applicable in all cases, as electromagnetic propagation is affected by the absorption and reflection of nearby buildings, objects and the human body.			

EMC Cable Material Parameters	
Adapter Input Cable	1.0±0.1m
Adapter Output Cable	1.4±0.2m

9. Storage and Transport

Warning

The equipment shall be in a standard environment for 8 hours or longer before being operated in the event that the storage condition is beyond the operating condition limits.

Ambulanc(Shenzhen)Tech.Co.,Ltd.

Add: 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

Tel: +86-755 26072210 Fax: +86-755 23016012

Web site: www.amoulmed.com E-mail: info@amoulmed.com