



ASU-I User's Manual Suction Unit

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

Authorized representative: Shanghai International Holding Corp. GmbH(Europe)

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Manufacturing Date: See the mainframe

Life time: 8 years Shelf life: 1 year

Manual Revision date: 2024-05

Manual Release Version: 2.0



Attention!

This instrument can be used in emergency medical services environment.

Intellectual Property Right

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Unless otherwise specified, "Ambulanc" and "the Company" in this Operation Manual refer to Ambulanc (Shenzhen) Tech. Co., Ltd.

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.

Warranty

Manufacturing Process and Raw Material

Ambulanc warrants to provide the free-charge of service within the warranty period for the failure because of the production process or the material failures when this instrument is used and serviced correctly.

Maintenance Service

Scope of Charge-Free Service:

Charge-free service is provided for any equipment in the range of Ambulancs' warranty terms.

Scope of Paid Service:

Paid service is provided for any equipment beyond the range of Ambulancs' warranty terms, as well as in one of the following cases even during the warranty period: damage caused by personal fault; improper use; grid voltage beyond the limits; irresistible natural disaster; or use of spare part or consumables not approved or machine service performed by personnel not authorized by Ambulanc.



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.

Return

Return Procedure

Any return, as necessary, shall comply with the following procedure:

Acquire a right of return: Contact Ambulancs' customer service, and provide the product ID labeled on the external packaging of the instrument, which must be legible for return approval. Indicate the product model and describe the reason for the return.

Freight: Any expenses (including customs fees) incurred in transporting the instrument to Ambulanc shall be paid by the user.

After-Sales Service Unit

After-Sales Service Dept., Ambulanc (Shenzhen) Tech. Co., Ltd.

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Web site: www.amoulmed.com

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Postal Code: 518108

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.

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- 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.

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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 patient

- weak cough;
- dyspnea due to sputum excretion, such as in an insensible patient;
- newborn, critical, or narcotized patient;
- first aid for suffocation, such as for near-drowning or amniotic fluid inhalation;

1.4. 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).

1.5. Side effects

- VAP.
- Airway injury.
- Hypoxemia.
- Cough.
- Respiratory tract infection.

1.6. Product Construction

The suction unit consists of the main unit (including a collection container), intermediate tubing, power adapter, power cable, and battery.

2. Safety Instructions

2.1. Safety Regulations

For the sake of safety, the following regulations must be observed.

Overview

Read this manual carefully. This manual is an integral part of the equipment and shall be kept at an accessible location nearby, ready for consultation at any time.

The Suction Unit is powered by an internal electrical power source and is a type of BF applied part of mobile equipment.

Operating Conditions:

Ambient temperature: +5°C to +40°C

Air humidity: 15%-95%, no condensation

Atmospheric pressure: 70 kPa ~ 110 kPa

Storage conditions:

Storage temperature: -40°C to +60°C

• Storage humidity: 15%-95%, no condensation

• Storage pressure: 50 kPa-110 kPa

Transient operating conditions:

Suction Unit can work normally for no less than 20 minutes in the following envir onment:

Ambient temperature: -20°C to +50°C

• Air humidity: 15%-90%, no condensation



Warning!

- It can be used only for the intended purpose (see 2.1 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 6. 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. The suction unit is capable of operating continuously for more than 40 minutes under the maximum negative pressure (-80 kPa). Be sure to shut down the aspirator in 60 minutes to avoid performance reductions due to overheating. Cool the equipment for at least 2 hours after the shutdown.
- 3. 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 \geq 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 in Section 8.. 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. Supply Configuration

8.1. Optional Configuration



Attention!

The specific configuration will be subject to the packing list.

9. Technical Parameters

9.1. Detailed Parameters

Type of suction	High vacuum/ High flow
CE classification	Class IIa
EMC classification	Group 1 Class B
IP code	IP33
Suction device classification	Used for pharyngeal suction and capable of sucking simulative vomitus of 200 mL within 10s
Sizes:	400 mm (L) ×240 mm (H) ×150 mm (W)
Weight	ASU-I: 3.35kg

Input power	Power Supply: 100-240V ~ 50/60Hz 12V == 5A Power Input: 30VA-60VA
Suction rate	≥20 L/min
Maximum vacuum level	≥80 kPa
Vacuum level accuracy	±5 kpa
Internal power source	Class II
collection container	Capacity: 1000mL
Noise level	≤70dB
Power supply	Internal battery for mobile sucking equipment
Built-in lithium battery	standard configuration: 11.1V, 2600mAh Cycle life: ≥300 times
Operating cycle	When fully charged, operate continuously for at least 20 minutes, during which time it shall maintain a free air flow of not less than 21 L/min and a vacuum level of not less than 40 kpa.

9.2. 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 -	FM	Emission
Oulde alla	Manuacturer	Otatomont -		

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
Harmonic Emission (IEC6100-3-2)	Class A	buildings. Warning: The ASU-I Suction Unit is for use by
Voltage Fluctuation/Glint Emission (IEC6100-3-3)	Compliant	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.

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 for 0.5 cycle (with voltage dip >95% on UT) 40% UT, lasting for 5 cycles (with voltage dip of 60% on UT) 70% UT, lasting for 25 cycles (with voltage dip of 30% on UT) <5% UT, lasting for 5s (with voltage dip of 5s)	<5% UT, lasting for 0.5 cycle (with voltage dip >95% on UT) 40% UT, lasting for 5 cycles (with voltage dip of 60% on UT) 70% UT, lasting for 25 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.

Electr omag	IEC 60601 Test Level	Complian t	EM Environment - Guide
			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.
RF	3 V	3 V	Recommended spacing distance

Cond uctio n IEC6 100-4	(effective value) 150 kHz ~ 80 MHz 3V/m	(effective value)	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ 80MHz ~ 800MHz
	80 MHz ~ 2.5 GHz	3V/m	$d = \left[\frac{7}{E_1}\right] \sqrt{P}$ 800MHz ~ 2.5MHz
RF Radia tion IEC6 100-4 -3			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	Spacing Distance (m) for Various Transmitter Frequencies
rotod	

	150 kHz ~ 80 MHz (excluding ISM frequency band) $d = 1.17\sqrt{P}$	80 MHz \sim 800 MHz d = $1.17\sqrt{P}$	800 MHz ~ 2.5 GHz d = $2.33\sqrt{P}$
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.

Basic EMC Performance of ASU-I Suction Unit		
ASU-I Suction Unit will operate normally based on a setting with a negative pressure regulating knob (see Section 5.3 in this manual for more details) and ensure accurate parameters in an EMC environment.		
Vacuum regulation range 20 kPa to the maximum vacuum level		
Vacuum level accuracy ±5 kPa		

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

10. 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.





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