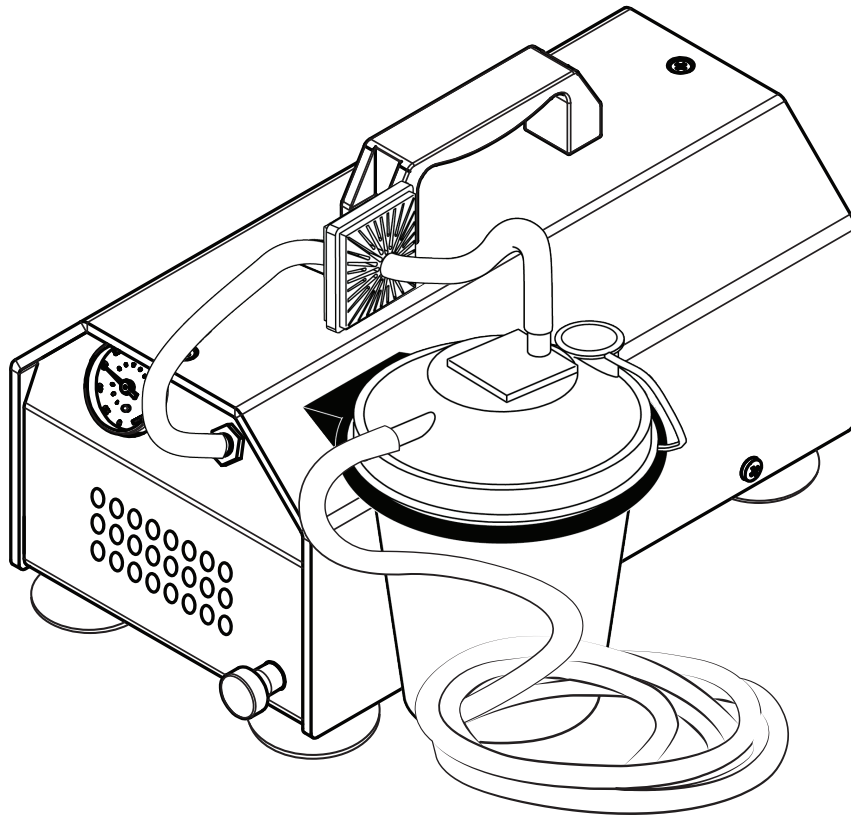


Cliq™

AS-1001D Suction Pump Instructions for Use



Please read this manual carefully before using this device. Keep this manual for future reference.

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Symbol Definitions



Manufacturer



Disposal of Electrical & Electronic Equipment (WEEE): This device contains electrical and/or electronic equipment that must be recycled and should be handed over to a suitable collection point for proper disposal.

SN

Serial number.



Class II equipment



Protection against electrical shock; type of applied part, body floating.

IP21

Solid particle protection > 12.5 mm.
Dripping water (vertically falling drops) shall have no harmful effect.



Caution: Consult instructions for warnings and safety precautions.



Refer to instruction manual.



One time use gloves required.



Temperature limits.



Humidity limits.



Off



On



MR Unsafe. This device must not be used in an MRI environment.

Please read this manual carefully before using this device. Keep this manual for future reference.

Important Safety Information

Important information is highlighted by these terms:

WARNING: Danger for patient or operating staff.

CAUTION: Information for preventing damage to the product.

ATTENTION: Important operating instructions.

WARNING

- This device is intended for use by trained and certified healthcare professionals such as doctors, nurses, and therapists, or by those under their guidance. Use only after consulting with your doctor and receiving proper training from a trained healthcare professional.
- Intended Use: The AS-1001D Suction Pump's intended use is to remove bodily fluids from a patient's airway or respiratory system. Using this device for any purpose other than the stated intended use may result in injury to the patient or operator.
- To ensure proper hygiene, collection container, inline filter, suction tubing, and intermediate tubing must only be used by the same patient. Do not use these accessories across multiple patients. Do not attempt to sterilize these accessories for use across multiple patients. Failure to abide by these warnings may result in infection or cross contamination between patients.
- Fluid collected in the collection container must be disposed of according to local regulations, institution policy (as applicable), and the instructions of a certified healthcare professional.
- Do not use this device with accessories which have not been approved by the distributor or manufacturer of the product. Use of unapproved accessories may cause harm to the patient and will void the warranty coverage for this device.
- Suction catheters are not included with this device and must be purchased separately, in accordance with the instructions of a trained and certified physician or healthcare professional. Only use disposable, single-use, sterile suction catheters compliant with local and/or national laws, regulations, and directives. In the EU, only use suction catheters that are labeled with the CE mark, are MDD-compliant, and have received market authorization from a certified notified body. Failure to do so could cause harm to the patient.
- To avoid the risk of infection, always use sterile single-use suction catheters. After use, immediately dispose of the suction catheter in accordance with local regulations, institution policy (as applicable), and the instructions of a certified healthcare professional. Do not attempt to re-use or re-sterilize suction catheters.
- During suction, do not exceed the maximum vacuum pressure recommended by your healthcare professional or physician.
- Never open, disassemble, or modify the device, or any accessories included with the device.
- Device is MR Unsafe. This device must not be used in an MRI environment. Further the device shall not be placed or operated in the following environments or near the following devices: CT, diathermy machine, RFID transmitters, electromagnetic security systems (such as metal detectors).

To reduce the risk of burns, electrocution, fire or injury to persons:

- Do not store the device where it can fall or be pulled into a tub, sink, or other water source.
- Never place the device in water or other liquids. If it falls in water, do not reach for it. Unplug immediately.
- Never leave the device unattended when switched on.
- The device must stand upright during use.
- Do not use this device to suction explosive, flammable, or corrosive liquids.
- Keep the power cord away from hot surfaces.
- Keep the plug and ON/OFF switch away from moisture.
- Never use the device (1) while bathing, showering, or close to a water source (2) when tired or not fully alert (3) outdoors (4) at high room temperatures (5) in an environment where there is a risk of explosion.
- Close supervision is required when this device is used for, with, or near children or infants. This device should not be operated by children.
- Do not operate where aerosol (spray) products are being used or where oxygen is being administered in a closed environment such as an oxygen reservoir.
- Never operate this product if: (1) It has a damaged power cord or plug. (2) It is not working properly. (3) It has been dropped or damaged. (4) It has been dropped into water. Send the product to an authorized service center for examination and repair. Never open or disassemble the unit yourself.

CAUTION

- Before plugging in the device, please check that the local power supply is the same as the specified voltage mentioned on the device. The voltage sticker can be found at the bottom of the device.
- Always unplug the device after use. Never pull the plug out of the mains socket by pulling on the power cable.
- This machine is an oil-less suction pump and does not require any lubrication. Do not add any lubricants to this machine.
- This aspirator is not suitable for prolonged continuous use.
- Do not disassemble the unit; there are no user serviceable components within the device.

ATTENTION

- Prior to first use, carefully unpack the unit and check for transportation damage. In case of damage, do not use.
- The device creates a negative pressure (vacuum) that draws fluids through a disposable suction catheter that is connected by suction tubing to a collection container. The suctioned fluids are then trapped in the collection container for proper disposal.
- This aspirator is suitable for use at home, in hospitals or clinics, and in nursing homes.
- Before using any approved third party accessories with this device, check to make sure they are compatible - that all fittings are tight. Loose fittings may degrade the performance of this device and may prevent the device from operating at its optimal level.

Product Introduction

Intended Use

The AS-1001D Suction Pump's intended use is to remove bodily fluids from a patient's airway or respiratory system.

Device Description

The AS-1001D suction pump is a portable AC-powered suction pump. The AS-1001D suction pump creates a negative pressure (vacuum) that draws fluids through a disposable suction catheter that is connected by suction tubing to a collection container. The suctioned fluids are then trapped in the collection container for proper disposal. The device must only be used on the order of a physician. If practiced outside of the hospital setting, the care giver must be trained by a certified healthcare professional and the training must be recorded and documented. The AS-1001D suction pump consists of an on/off switch, a pump unit, a power cord, a collection container, relief valve, pressure adjustment knob, pressure gauge, inline filter, long intermediate tubing, short intermediate tubing, and suction tubing. Disposable suction catheters are not packaged with this device and must be purchased separately. Use only sterile single-use suction catheters that are compliant with local and/or national laws, regulations, and directives. In the EU, only use suction catheters that are labeled with the CE mark, are MDD-compliant, and have received market authorization from a certified notified body.

Service Life

The expected service life of the device is four years.

Product Specification

Power requirement: AC 220-240V 50Hz

Max airflow: 48 l/min

Vacuum: 0 - 620 mmHg

Dimensions: L33 x W16.5 x H20 cm

Weight: 8 kg / 17.6 lbs

Collection canister capacity: 800 ml

Power cord length: 185 cm

Operating temp: 5 - 40 °C

Operating relative humidity: 0 - 93%

Operating atmospheric pressure: 10.2 - 15.4 psi (70 - 106 kPa)

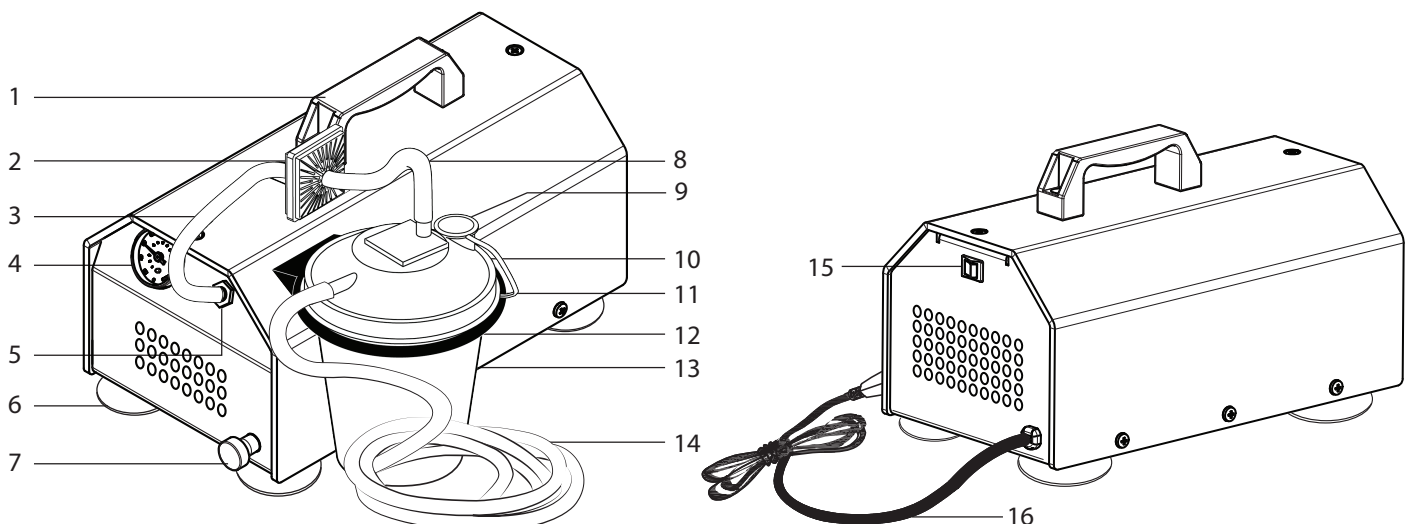
Storage and transport temp: -25 - 70 °C

Storage and transport humidity: 0 - 93%

Storage atmospheric pressure: 7.3 - 15.4 psi (50 - 106 kPa)

Part List

- | | | |
|-----------------------------|------------------------------|--------------------------------------|
| 1. Handle | 6. Rubber foot | 11. Patient port |
| 2. Inline filter | 7. Vacuum regulator knob | 12. Collection container holder |
| 3. Long intermediate tubing | 8. Short intermediate tubing | 13. Collection container |
| 4. Vacuum gauge | 9. Vacuum port | 14. Suction tubing |
| 5. Inlet | 10. Collection container lid | 15. Power switch |
| | | 16. Suction pump power cord and plug |



Accessories / Replacement Parts

The following items can be purchased as a replacement for your machine. Please contact our distributors or authorized service centers for inquiries.

Item	Part No.	Specification	
Collection container	3304025C	ø 150 x 185 (H) mm / 800ml	Must be replaced if damaged. One month expected service life. ▲
Intermediate tubing (Long)	3406073A	7 (ID) x 13 (OD) x 250 (L) mm	Must be replaced if damaged. One month expected service life. ▲
Intermediate tubing (Short)	3406072A	7 (ID) x 13 (OD) x 150 (L) mm	Must be replaced if damaged. One month expected service life. ▲
Inline filter	3406074A	1/4" hose barb x 1/4" hose barb	Must be replaced if damaged or has been in contact with fluid. One month expected service life. ▲
Suction tubing	3318007A	7 (ID) x 10.4 (OD) x 1800 (L) mm	Must be replaced if damaged. One month expected service life. ▲

▲ Use only with the same patient. Do not use for multiple patients

For suctioning of an adult airway, experts recommend sterile, single-use suction catheters with diameters of 10 - 16 Fr/Fg 3.35 - 5.35 mm.

WARNING: Suction catheters are not provided with this device and must be purchased separately, in accordance with the instructions of a trained healthcare professional or physician:

- Only use disposable, single-use, sterile suction catheters.
- Only use the type and size of suction catheters that are recommended by your healthcare professional.
- Only use suction catheters that are compliant with local and/or national laws, regulations, and directives. In the EU, only use suction catheters that are labeled with the CE mark, are MDD-compliant, and have received market authorization from a certified notified body. Failure to do so, may cause harm to the patient.
- Disposable suction catheters are single-use only; do not attempt to re-use or re-sterilize.

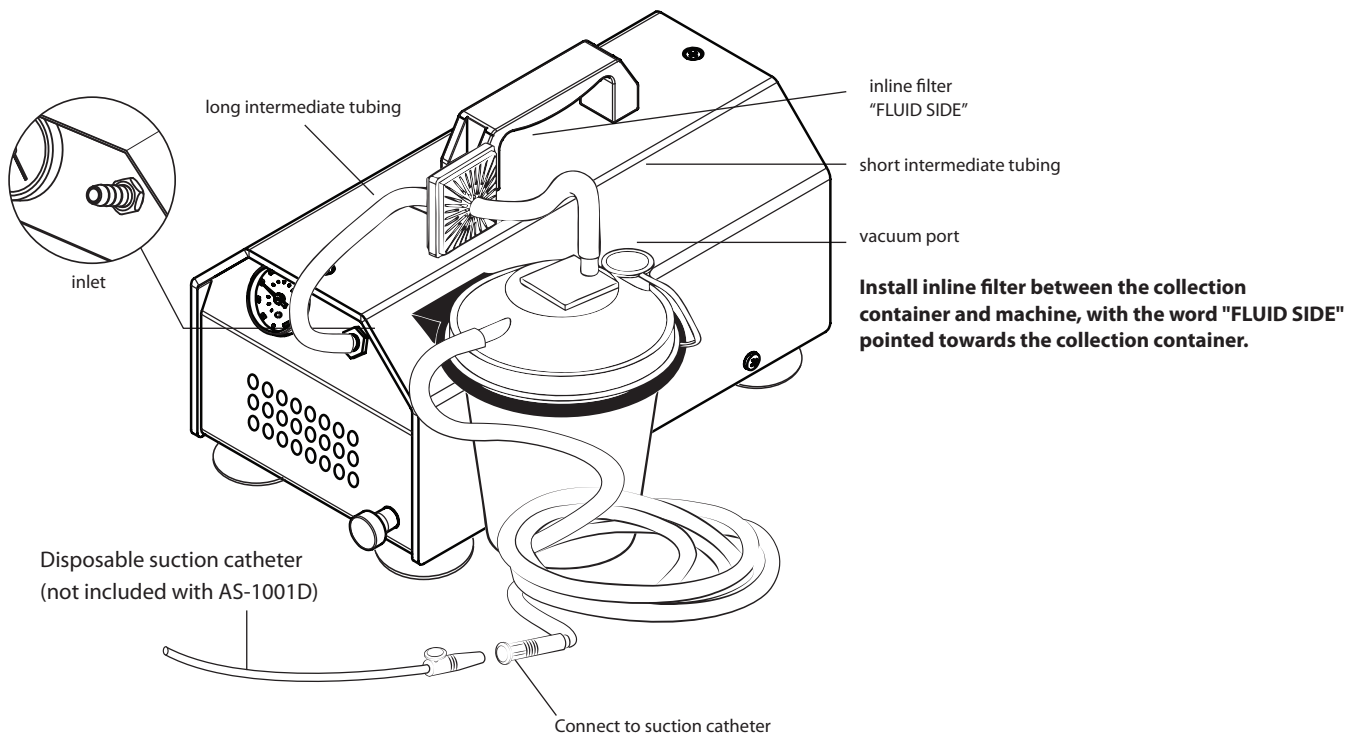
WARNING: If third party suction tubing is used, the third party suction tubing must also be compliant with local and national laws, regulations and directives. In the EU, only use suction tubing that is labeled with the CE mark, is MDD-compliant, and has received market authorization from a certified notified body. Failure to do so may cause harm to the patient.

Operation



1. Operator must wear disposable single-use gloves when operating and handling unit.
2. Place the machine on a flat and stable surface. **WARNING:** Inspect power cord. If power cord is frayed or damaged, do not use device.
3. Prior to use, inspect collection container and tubing for cracks or leaks, and replace all damaged accessories immediately. Do not use device if accessories are damaged.
4. Place the collection container securely into the collection container holder.
5. Connect the inline filter into the inlet, ensuring that the "FLUID SIDE" is facing upwards. Connect one end of the intermediate tubing to the inline filter on the "FLUID SIDE". Connect the other end of the intermediate tubing to the "vacuum port" on collection container lid.

WARNING: Never operate the unit without the inline filter.



6. Connect one end of suction tubing to the "patient port" on the collection container lid.
7. Check all connections and make sure they are secure and tight. A poor connection could result in an air leak that diminishes pump performance.
8. Insert the plug into a wall (mains) outlet with a voltage matching the device's requirements. (See device label located on the underbelly of the device for device's voltage requirements.) Turn the power switch on.
9. Adjust the unit to its desired suction level before beginning patient suction.
 - a. Create a vacuum by completely blocking the open end of the suction tubing.
 - b. Adjust the vacuum regulator knob until you reach the desired vacuum level displayed on the vacuum gauge.
 - c. As long as the open end of the suction tubing remains completely blocked, the vacuum level should remain steady.

For suctioning of an adult airway, experts recommend a vacuum level between 100-150 mmHg.

WARNING: Set vacuum pressure in accordance with instructions provided by your healthcare professional. Never exceed your healthcare professional's maximum pressure guidelines. Failure to follow the instructions and guidance of your healthcare professional could cause bodily injury.

10. Once unit is set to the desired vacuum pressure, attach disposable suction catheter to the open end of the suction tubing.

WARNING: Disposable medical suction catheters are not provided with this unit and must be purchased separately in accordance with the instructions of a trained healthcare professional or physician. Only use suction catheters that are compliant with local and/or national laws, regulations, and directives. In the EU, only use suction catheters that are labeled with the CE mark, are MDD-compliant, and have received market authorization from a certified notified body.
11. Proceed with suctioning as instructed by your healthcare professional. Remove suction catheter from patient immediately after suctioning.
12. After each use, turn off the power switch and unplug the unit.

CAUTION

- Make sure the power switch is turned off before inserting or removing the plug.
- The unit should not be left running for over 1 hour continuously. If the machine has been operating continuously for 1 hour, please turn off the power for at least 30 minutes before turning back on.
- Keep the machine and relevant accessories dry. Avoid direct sun exposure during storage.

Cleaning

WARNING

- Prior to cleaning, make sure machine is turned off and unplugged.
- To ensure proper hygiene, collection container, inline filter, suction tubing, and intermediate tubing must only be used by the same patient. Do not use these accessories across multiple patients. Do not attempt to sterilize these accessories for use across multiple patients. Failure to abide by these warnings may result in infection or cross contamination between patients.
- Any parts or the device or accessories that come into contact with bodily secretions must be cleaned after each suction operation. All single-use accessories, such as the suction catheter, must be disposed of according to local regulations, institution policy (as applicable) and the instructions of a certified healthcare professional.
- Wear disposable gloves during cleaning procedures.



Cleaning the surface of the unit

- Clean the surface of the unit after each use. Wipe machine clean with a damp cloth.
- Do not clean machine with powder-type cleaning agents or soap.
- Do not clean machine in water.

WARNING: If the inside of the unit comes into direct contact with liquids, the aspirator must be sent to an authorized service center for examination and repair.

ATTENTION: Slight discoloration of plastic housing or the stickers on the housing may occur over time. This will not impact the performance or function of the device.

Cleaning reusable accessories

- Clean the collection container after each use. Empty contents and wash all components using a mixture of 3 parts white vinegar 1 part warm tap water.
- Clean intermediate and suction tubing after each use. Disconnect tubing from machine and clean by rinsing inside and outside of tubing with hot tap water. Air dry.
- Clean the collection container coaster after each use. Rinse with hot tap water and air dry.

WARNING

- To ensure proper hygiene, collection container, inline filter, suction tubing, and intermediate tubing must only be used by the same patient. Do not use these accessories across multiple patients. Do not attempt to sterilize these accessories for use across multiple patients. Failure to abide by these warnings may result in infection or cross contamination between patients.
- Fluid collected in the collection container must be disposed of according to local regulations, institution policy (as applicable), and the instructions of a certified healthcare professional.

CAUTION: Do not immerse inline filter in liquid. Doing so will damage the filter. If the fibrous material inside the inline filter is wet, replace immediately.

Maintenance & Repair

- Replace the inline filter if the fibrous material in the filter is wet or in the case of a collection container overflow. With the vacuum regulator fully closed and the tubing disconnected from the "Fluid Side" of the filter (filter open to atmosphere), a vacuum reading in excess of 50 mmHg on the gauge indicates the filter should be replaced. The filter must be replaced in the event fluids have been in contact with the filter, such as in a collection container overflow.
- Do not disassemble the unit; there are no user-serviceable components inside the device. If repair or servicing is required, please send unit to an authorized service center. Disassembly or tampering of the device will damage the device and void the warranty.

Warranty Length

The AS-1001D suction pump is warranted to be free from defective workmanship and materials for one year from the date of purchase. Within the warranty period, any defective part(s) will be repaired or replaced at manufacturer's option. Manufacturer is not liable, and warranty is voided, for any damage or consequential damage resulting from incorrect operation of the unit, inappropriate usage of the unit, disassembly of the unit, or use by unauthorized or untrained persons.

Troubleshooting

If you run into problems with the product, refer to the possible causes below to perform simple troubleshooting. If the problem cannot be solved, send the product to an authorized service center for examination and repair.

Problem	Possible cause	Remedy
Unit does not start	Unit is not plugged into mains properly.	Check plug connection. Make sure plug is properly inserted into mains.
	Mains not supplying power.	Check that the mains is live by trying another device.
	The fibrous material inside the inline filter is wet or damaged.	Replace the inline filter.
	Wrong voltage and current levels.	Check that the mains provides the voltage and current levels required by this device.
	Unit over heated.	Please contact qualified service personnel for repair.
Reduced performance	The fibrous material inside the inline filter is wet, stained, or damaged.	Replace the inline filter.
	Tubing is blocked.	Check if any tubing is blocked. If so, replace tubing.
	Tubing is leaking air.	Make sure that all tubing is securely connected and that there are no leaks.
	Connection between inline filter and inlet is loose.	Check filter connection. Make sure filter is tightly connected to inlet.
	Collection container is damaged.	Replace collection container.
No suction	Collection container overflowed.	Empty the collection container.
	The fibrous material inside the inline filter is wet or damaged.	Replace the inline filter.
	Suction tubing is blocked.	Clean or replace suction tubing.

Transportation, Storage, and Disposal

Transportation

- General transportation of the unit should correspond to the conditions outlined in the 'Product Introduction' section of this manual.
- In the event that the AS-1001D suction pump needs to be sent to an authorized service center for inspection and repair, do not package the collection container, suction tubing, inline filter, intermediate tubing, collection container coaster, or any single-use accessories (such as a suction catheter) in the shipment.

Storage

Storage of the AS-1001D suction pump should correspond to the conditions outlined in the "Product Introduction" section of this manual.



Disposal

- When the product's life cycle is at an end, all components of the unit must be disposed of in accordance with local regulations.
- Take care that the unit is clean and that the various materials are carefully separated for disposal.
- The European Union (EU) directives 2012/19/EU, known as the WEEE (Waste Electrical and Electronic Equipment) Directive, and 2011/65/EU, referred to as the RoHS (Restrictions on Hazardous Substances) Directive prohibits the disposal of this device in the domestic waste.
- Outside the EU: Follow disposal regulations in the country of use.

GUIDANCE AND MANUFACTURER'S DECLARATION

- All Medical Electrical Equipment requires special precautions regarding Electromagnetic Compatibility (EMC) and should only be installed and put into service according to EMC information provided in the accompanying section.
- Portable and Mobile RF Communications Equipment could affect Medical Electrical Equipment.
- The Medical Electrical Equipment should not be stacked with, or close to other equipment. If this is necessary, ensure that the equipment is observed as having normal operation in the configuration of its intended use.
- EMC testing performed by Electronics Testing Center of Taiwan (Web: <http://www.etc.org.tw/>; Phone: +886-2-26023052).
Report No.: ETC 13-02-RBO-026

WARNING: Use of this device with electrical accessories such as extension cords or plug adapters may result in non-compliance and may negatively affect EMC performance.


Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The AS-1001D suction pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AS-1001D suction pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AS-1001D suction pump recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.67	11.67	23.33

Declaration – electromagnetic immunity

The AS-1001D suction pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AS-1001D suction pump should assure that it is used in such an environment.

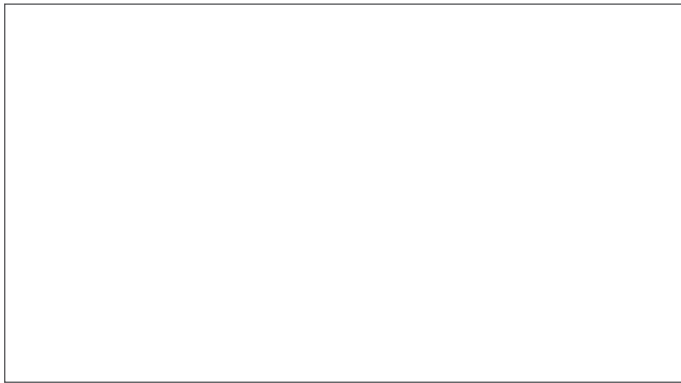
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V, 10V	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m, 10V/m	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	< 5 % UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Declaration – electromagnetic emissions

The AS-1001D suction pump is intended for use in the electromagnetic environment specified below. The customer or the user of the AS-1001D suction pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
CE emissions CISPR11	Group 1	The AS-1001D suction pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RE emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Authorized Service Center Contact Infomation:



ANEST IWATA SPARMAX Co., Ltd.
Rm 4B-02/03, Taipei World Trade Center
4th Fl. No. 5 Hsinyi Rd. Sec. 5
Taipei, Taiwan 11011



www.cliqmedical.com
info@cliqmedical.com
Tel: +886.2.2345.1868
4B-03 Taipei World Trade Center
4F No.5 Sec.5 HsinYi Rd. Taipei Taiwan 11011