

Introduction

We thank you for purchasing our Aspirator V3 which is adaptable to your needs. It is very important that the health care worker and/or the patient read and understand the information for use and maintenance.

Intended Use

Suction unit (Aspirator) V3 can be used to remove unwanted fluids or infectious materials from the airway or respiratory support system in health care structures like hospitals and home care. The device generates suction (aspiration) which allows fluids to be extracted through connecting PVC tubing connected to a collection canister which retains the fluids until they can be properly disposed of. Use of the device must be prescribed by a doctor. Carefully follow the recommended operations and procedures outlined in this instruction guide to ensure proper functioning and maximize the life of the device.

Preliminary Remarks

This Suction unit (Aspirator) complies with the European regulations and bears the CE mark “CE 1639”. The quality of the device has been verified and conforms to the provisions of the EC council directive 93/42/EEC amended by 2007/47/EC (Medical Device Directive), Annex I essential requirements and applied harmonized standards.

EN ISO 10079-1: 2015 Medical suction equipment - Part 1: Electrically powered suction equipment.

Warnings and Safety Instructions

Suction unit (Aspirator) V3 is EMC-tested in conformity with the requirements of IEC 60601-1-2 and can be used in the vicinity of other EMC-tested devices that fulfill the requirements as outlined in the IEC 60601-1-2 standard. Untested HF sources, radio networks or the like can impair the function of the device and should not be operated in combination with the Aspirator V3. The suction equipment is not suitable for use in an MRI environment. Please read and observe these warning and safety instructions before operation. These instructions for use must be kept with the device for later reference. Please note that these instructions for use are a general guide for the use of the product. Medical matters must be addressed by a physician. Rossmax considers himself only responsible for the effect on BASIC SAFETY, reliability and performance of the Aspirator V3 if it is used in accordance with the instructions for use.

⚠ Important Safeguards
This is a medical device and must be used by qualified users. It must be operated as indicated in this user instruction manual.
📖 Read All Instructions Before Using This Device.
💾 Save These Instructions.

The manufacturer makes every effort to ensure that every product is of the highest quality and safety; however, as for any electrical appliances, basic safety regulations must always be observed in order to avoid harming persons and things.

DANGER, WARNING, CAUTION, NOTE/ATTENTION STATEMENT

⚠ DANGER: Urgent safety information for hazards that will cause serious injury or death.

⚠ WARNING: Important safety information for hazards that draws attention to a potential danger.

⚠ CAUTION: Indicates correct operating or maintenance procedures to prevent damage to the product or other property.

⚠ Note/Attention: Indicates information to which users should pay special attention.

- ⚠ DANGER:**
- The device is intended exclusively for the collection of NON-flammable or NON-corrosive fluid materials in medical applications only. This unit should not be used in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.
 - Do not use outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered in a closed environment such as an oxygen reservoir.
 -  Do not handle the AC/DC switching adaptor plug with wet hands or use the unit when taking a bath or shower. Never submerge the device in any liquids.
 - Do not use the unit if the plug or AC adaptor are worn or wet and remove or touch the immersed device. If by chance it falls into water, do not attempt to remove the device from the water while the plug is still connected; disconnect the mains switch, pull the plug out of the socket. Bring the device to your local distributor or authorized Rossmax service center immediately. Do not attempt to make the device work before it has been thoroughly checked by qualified personnel and/ or authorized Rossmax service center.
 - Do not place or store the device where it can fall or be pulled into a tub or sink.

⚠ Warning:
1. The medical device must NOT be used in the operating theater, for drainage or thoracic drainage and nasogastric suction.

- Never operate this product if a) it has a damaged cord or plug, b) it is not working properly, c) it has been dropped or damaged, d) it has been dropped into water.

- Immediately Return the product to your local distributor or authorized Rossmax service center for examination and repair.
- For use only by medically trained persons who have been adequately trained in suction procedures and in the use of aspirators.
 - Incorrect use can cause pain and injury to the patient.
 - Do not start the machine if you suspect the presence of explosive or inflammable liquids or gases, water inside the machine or environmental conditions that are not within the specified limits.
 - Do not perform any maintenance operations while the device is being used on a patient.
 - Replacement device must always be available if a breakdown of the device for patients can lead to a critical situation (e.g. patients with acute dyspnoea or severe catarrhal congestion),
 - The patient should be monitored regularly according to the physicians instructions and facility guidelines. Objective indications or signs of a possible infection or complication must be met immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent discharge). Non-observance can lead to considerable danger for the patient. Monitoring the Aspirator V3 for operating status is a must.
 - Consult the indications for use and consider risk factors and contraindications before using the Aspirator V3. Failure to read and follow all instructions in this manual prior to use may result in serious or fatal injury of the patient.
 - In the presence of children and non self-sufficient individuals, the device must be used under the close supervision of an adult who has been adequately trained in suction procedures and in the use of aspirators.
 - Some parts of the device are small enough to be swallowed by children; keep the device out of the reach of children.
 - Do not use the provided tubing and AC adaptor for any other purpose than those specified, as they can cause risk of strangulation. Be particularly attentive with children and individuals with disabilities because they are often unable to correctly assess risk.
 - Repairs must be done only by your local distributor or authorized Rossmax service center. Unauthorized repairs void the warranty and may be hazardous for the user.
Attention: Do not modify this device without authorization from Rossmax.
 - The filter used by the same patient is recommended to be replaced after every application.
Attention: The antibacterial filter must be replaced for each new patient.
 - The suction catheter and the manual regulator are sterile, disposable products for single use and must be replaced after every application. Check the expiry date on the original packaging of the suction catheter and check the integrity of the sterile packaging. If expired and/or deteriorated, replace it at once.
Attention: The suction catheter and manual regulator are not supplied by Rossmax.
Rossmax declines any responsibility for harm to the patient correlated to the deterioration of the aforementioned sterile packaging due to THIRD PARTY handling during the original packaging of the entire device
 - Do not use sterile accessories when the sterile packaging is damaged.
 - Do not connect this device to a passive drainage tube.
 - Do not operate the device on an obstructed, unstable surface to avoid incidents, which may cause it to accidentally fall and lead to a malfunction and/or breakage. Should there be signs of damage to the plastic parts, which may expose inner parts of the device, do not connect the plug to the electrical socket. Do not attempt to make the device work before it has been thoroughly checked by qualified personnel and/or authorized Rossmax service center
 - Never obstruct the air inlet positioned on the device.
 - Use of the device in ambient conditions other than those specified in the manual may seriously impair its safety and technical characteristics.
 - Before cleaning the device, pull the plug out of the fixed mains socket.
 - The connecting tubing supplied with the canister must never come into direct contact with the suction area.
 - Never use while drowsy or asleep.
 - Always unplug the product immediately after use.
 - Use the device only in dust-free conditions, otherwise treatment could be compromised.

⚠ Caution:

- Use only for the purpose intended.** Don't use for anything other than the use defined by the manufacturer. The manufacturer will not be responsible for damage due to improper use or connection to an electrical system not complying with current regulations.
- Do not tip the canister over while the device is working as the liquid may be aspirated into the device causing pump damage. Should this occur, immediately switch off the suction machine, then empty and clean the canister. Immediately bring the device to your local distributor or authorized Rossmax service center.
- Ensure that the connecting tubing and the canister lid have been carefully sealed in order to avoid leakage of suction.
- When the overflow valve intervenes, suction is halted. Switch off the device, empty the canister and carry out the cleaning procedures.

- In the event of aspiration without the canister and/or antibacterial filter, or if it is suspected that substances have entered the aspiration circuit, contact your local distributor or authorized Rossmax service center at once.
- Portable and mobile RF communications equipment can affect medical devices.
- The AC adaptor provided has been specifically designed for use with Rossmax series aspirators. Never use the AC adaptor with other devices or for uses other than that specified in this manual and never use Rossmax series aspirators with other AC adaptor.
- Before connecting the device always check that the electric data indicated on the data label and the type of plug used.
- The device casing is not waterproof. Do not wash the device under running water or by immersion and keep it safe from being sprayed by water or other liquid.
- Keep the AC/DC switching adaptor away from animals (for example, rodents) which could damage the insulation.
- Keep the device and AC/DC switching adaptor away from sources of heat, direct sunlight or extreme hot locations.
- When the liquid level reaches 50% of the total volume of the collection canister, it is recommended to empty or change it before the overflow valve acts, in this way the risk of the entrance of humidity in the antibacterial filter is minimized.

Instructions for Use

The device must be checked before each use in order to detect malfunctions and / or damage caused by transport and / or storage and do not connect to power if damage is apparent. Before each use, the accessories must be carefully inspected to ensure the absence of dust, incrustation, clots or liquid substances both inside the connecting tubing and the collection canister. Furthermore, they must be cleaned following the instructions rigorously as stated in the “cleaning, sanitization, disinfection “. We recommend personal use of the accessories, the collection canister, the connecting tubing and antibacterial filter to prevent risk of contagious infection.

- 1. Assembling procedures**
- 1-1. Connect one end of connecting silicone tubing (Ø8mm,14cm), with the antibacterial filter marked “**IN**” side, to the VACUUM inlet of the collection canister marked in yellow
 - 1-2. Connect the other end, with the antibacterial filter marked “**OUT**” side, to the “AIR INLET” connector of the suction unit marked in yellow.
 - 1-3. Connect the connecting PVC tubing (Ø1/4”,180 cm) to the “PATIENT” inlet of the collection canister.
 - 1-4. Connect the AC adaptor with the AC adaptor jack on the right side of the unit.
- Note:**
1. Use only the authorized Rossmax AC adaptor with this aspirator.
 2. Ensure that the FLUID SIDE or **IN** marker on the filter is on the side facing the collection canister and fit into the “**VACUUM**” inlet. A wrong connection may cause immediate destruction in case of contact with sucked liquids.

- 2. Setup Before Use**
- 2-1. Before each use, inspect the unit and accessories. If damaged, expired and/ or deteriorated, replace it at once.
 - 2-2. Place the unit on a flat, horizontal surface.
 - 2-3. Plug the AC adaptor into the socket.
 - 2-4. Place the switch to the “I” (ON) position.
 - 2-5. Collapse the tubing with the antibacterial filter and check the vacuum gauge to test that the unit makes vacuum without any leakage and this level varies when the vacuum regulator is acted on.
 - 2-6. Obstruct the connecting tubing and adjust the level of vacuum prescribed by the doctor in the vacuum gauge turning the vacuum flow adjustment knob/ vacuum regulator.
- Note:** The vacuum regulator can be used to set the level of vacuum required (mmHg/kPa). Turn the regulator clockwise, in the “**+**” direction, to obtain a higher vacuum; or anticlockwise for a lower vacuum; these values can be read on the vacuum gauge.

Important: The vacuum values on the control decal are purely for guidance; always refer to the reading shown on the vacuum gauge.

Note: Gauge is for reference only. If the unit sustains a severe drop, accuracy of the gauge must be checked.

- 2-7. Place the switch to the “O” (OFF) position.

Note:

- The device is intended to be used on a flat, horizontal surface in order for the overflow valve to function correctly and prevent liquids from entering the suction pump. The device must be kept away from walls to allow for adequate engine cooling.
- In case unit is dropped, always transport unit with vacuum regulator rotated fully clockwise.

3. Starting the Suction

- 3-1. Connect the suction catheter to the connecting PVC tubing (Ø1/4”, 180 cm)

Note: suction catheter and manual regulator are not supplied by Rossmax.

- 3-2. Switch on the unit (ON/OFF switch)
 - 3-3. Place your finger on the manual regulator to activate the suction, begin suction on the patient using the suction catheter. The unit is ready to put the suction catheter to the patient.
 - 3-4. After application, switch off the device and remove the AC adaptor from the mains socket. Perform the cleaning operations as described in the “cleaning, sanitization, disinfection ”paragraph.
- Note:** A 30-minute interval is recommended after each use. Do not operate the device continuously for more than 30 minutes for a single use without turning it off and following with a cooling period for at least 30 minutes

Cleaning, Sanitization, Disinfection operations

Before using the device, the manufacturer advises you to clean and/or disinfect the accessories. Switch off the device before any cleaning procedures and unplug the AC adaptor from the socket.

Cleaning of the device

Use only a damp cloth with antibacterial soap (non-abrasive and with dissolvents of any sort) to clean the external surfaces of the main unit.

Caution:

- Particular care should be taken to ensure that the internal parts of the device do not get in touch with liquids.
- Do not submerge in water as this will result in damage to the vacuum pump.
- Do not use any cleaners or disinfectants that contain ammonia, benzene and/or acetone to clean the unit.

Collection canister and connecting tubing

- Detach the suction catheter (18), the manual regulator (17) and the connecting PVC tubing (16) from the collection canister.
- Disconnect the silicone tubing (14) from both the canister and the unit.
- Remove the canister from its holder. keep it upright, and empty it (in the WC at home, in the biological waste container in the hospital) and clean it after each use. Disassemble it as below:

1. Open the collection canister
 2. Remove the overflow valve(12) from the canister lid (11)
 3. Remove the rubber valve and float (12a) from the overflow valve (12)
- Sanitization, Disinfection operations**
- ⚠ Warning:**
- To prevent possible risk of infection from contaminated cleaning/disinfection solutions, always prepare fresh solution for each cleaning cycle and discard solution after each use.
 - Contaminated devices must be thoroughly cleaned prior to disinfection.
 - Personal protective equipment must be worn when handling contaminated equipment, particularly tubing, filter and collection canister (protective clothing, disposable latex gloves, mask, eye protection)
 - If any liquid accidentally enters in the main unit or in the pump, the unit may be damaged. For this reason, we recommend not to use the aspirator. The failure should invalidate the guarantee under the manufacturer’s responsibility.
 - In the event that contaminated fluids have moved past the internal unit, remove the tubing and the filter, clean the casing, and decontaminate the collection canister. Return the device to your local distributor or authorized Rossmax service center following “**Rules for returning and repairing**” paragraph.

1. Sanitization

Before and after each use, sanitize the collection canister and the connecting tubing.

Rinse each part (7,11,12,12a,14,16) with clean, hot running water (<50°C) with gentle dishwashing liquid (non-abrasive).

After cleaning, leave the parts to dry in an open, clean environment.

2. Disinfection

The accessories which can be disinfected are (7,11,12,12a,14). You can choose one of the methods described below.

Method A: wash with a commercial disinfectant that must be an electrolytic chloroxidizer (active principle: sodium hypochlorite) specific and follow the instructions and dilution rates supplied by the disinfectant manufacturer carefully.

Method B: boil each of the parts in water for 15~20 minutes, it is preferable to use de-mineralized or distilled water to prevent calcium deposits.

It is effective on the parts that undergo this treatment only if the parts to be treated have previously been sanitized. After cleaning, leave the parts to dry in an open, clean environment.

Parts	Material	Sanitization	Disinfection	Steam Sterilization (Gravity autoclave)
Collection Canister (7)	PC (Polycarbonate)	O	O	X
Canister Lid (11)	PP	O	O	X
Overflow valve (12)	PP	O	O	X
Rubber valve (12a)	Silicone	O	O	X