

## 7 SAFETY REQUIREMENTS

### 7.1 Electrical safety



The commissioning of the medical device must be carried out by specialized personnel and approved by the manufacturer.

Before performing any kind of maintenance, disconnect the unit from the mains power supply.



In the presence of smoke, and/or burning smell, disconnect the appliance immediately and call the service personnel, authorized by the manufacturer.

### 7.2 Residual risks

The medical device has been designed in accordance with safety principles, but there are residual risks due both to the improper use of the device.

For risks due to the improper use of the equipment, please refer to the requirements and recommendations provided in this manual.



Drain Star Revolution system complies with IEC 60601-1-2:2014 electromagnetic compatibility requirements (EMC).

## 8 PRECAUTIONS FOR USE



This section contains general warnings, precautionary measures and attention; important for the use of the device.

**Warnings:** are intended to ensure the proper functioning of the device.

**Precautionary measures:** provide information about the correct use.

**The Attentions:** concern the safe use.

### 8.1 Warnings

- The use of the unit near devices with high electromagnetic emissions, may cause malfunctions and is therefore not recommended.
- The connection of accessories, or the use of disinfectant products other than those recommended by the manufacturer, can harm safety and compromise the proper functioning of the unit, and is therefore prohibited **[3.1]**.
- The unit must be moved slowly, avoiding shocks that could cause damage to the device and its internal and external devices.
  - The suction and drain pipes must be regularly cleaned with special detergents.
  - After the extraction of organic liquids, proceed, daily, to a washing cycle with disinfectant product, as required in the Section “**Instructions for use**” **[12.10]**. Before use, after a period of inactivity beyond 48 hours, perform a washing cycle with disinfectant **[12.10]**.
  - After a long period of inactivity, proceed to a full battery recharge **[3.5]**.
  - Do not use disinfectant products not authorized by the manufacturer.
  - Use the unit in environments between 10 °C and 45 °C, and with relative humidity between 10% and 90%.
  - Do not expose the unit to direct sun rays, heat from thermal radiation sources, humidity, vibration, or mechanical blows.
  - Have the device maintained and monitored every 12 months only by personnel authorized and instructed by the manufacturer.
  - Do not perform repairs, maintenance, or changes that are not reported in this manual.
  - There are no user-replaceable parts except for the consumer parts and ancillary products listed in this document **[3.1]**.

**Failure to comply with these warnings impairs good operation and may cause damage to the device as well as causing the warranty to lapse.**

## 8.2 Precautionary measures:

Pay special attention in the following situations:

- Always place the unit so that the power cord and pipes do not clutter the passage and cannot be accidentally detached or moved.
- For the handling of the device, hold the handle firmly (2), proceed slowly in the presence of floor differences or obstacles and avoid, sudden accelerations, sudden changes of direction, bumps against people and things.
- Do not tilt or overturn the unit for any reason. This may cause internal and external spillage of liquids.
- Do not leave the equipment unattended near ramps or stairs.
- Operate the brakes on the wheels when it is necessary to prevent unwanted movement or when leaving the device unattended.
- Prevent use to people who are not instructed about how the unit works.
- Keep equipment out of children's reach.
- The disposal of organic liquids and washing must be carried out in special rooms prepared for this purpose and under surveillance.
- Do not subject, and protect, equipment from direct water jets.
- The use of sharp objects (e.g., pencil tip, pen cap, nails) in order to manipulate the buttons of the push button can cause damage to the coating of the control panel, and it is therefore forbidden.
- The use of masks and gloves is imposed by guidelines on the protection of operators.



**During the AUTOMATIC washing and disinfection cycle, the unit performs some phases of washing and unloading automatically.**

**Make sure that all the intake and discharge pipes are properly positioned and fixed, that the water dispenser is open and that the drain zone is free from clinging and that the device has been preloaded with the disinfectant dose.**

**Monitor the proper operation of the unit.**

**At the end of the wash close the water interception tap.**

## 8.3 Attentions



- Operators should be aware of the operating procedures of each mode of operation, indications, warnings and precautionary measures, before starting any use of the unit.
- The unit is not suitable for use in environments where there is the possible presence of flammable mixtures.
- The unit has been designed and built exclusively to perform the extraction of organic liquids, in medical premises. Any other use is prohibited.
- Although it is equipped with protections and sound warnings on maneuvers that require attention, in medical rooms, it is not recommended to use the unit connected to the network: incorrect controls or maneuvers as well as the obstruction of the network cable could create risk situations.

- It is advisable to use the unit, connected to the mains, for suction in the operating room. It is necessary for unloading, washing and recharging the accumulator.
- Use, exclusively, the supplied power cable (27) as an integral part of the power circuit, to guarantee the safety of use.
- Connection to the 220 VAC - 240 VAC power grid must be via a wall outlet with grounding, in accordance with local national laws, relating to electrical installations, and applicable to medical environments.
- Before connecting or disconnecting the device from the network, make sure that the unit is turned off by means of the network switch (12) on the back of the unit.
- Do not use continuous currents (DC/DC) to power the unit.
- Read carefully the warnings, precautionary measures and instructions of use, always faithfully and constantly applying the indications provided. Refer to the limits and hazards associated with the use of vacuum cleaners, and observe the warnings and license plates applied to the equipment.
- In case of liquid leaks, press the Emergency button (8), remove the plug from the wall outlet, and have the equipment inspected by technicians.
- It is made explicit, to operators, to remove carters or shelters, this activity and allowed only to technicians authorized for extraordinary maintenance.
- The internal accumulator contains material harmful to the environment. Comply with local regulations on the disposal of products of this category.
- The use of accessories or disinfectant products other than those authorized by the manufacturer can harm the safety of the patient and operator and also compromise the proper functioning of the unit, and is therefore prohibited.

For additional information regarding disinfection and bacteriological contamination, refer to specific treatises on the subject and/or contact the distributor.

#### 8.4 Obligations

**Users and distributors are obliged to notify MAS of the occurrence of any event with the risk of compromise of the safety of operators and/or patients, and any malfunctions found.**