SUCTION UNIT NEW ASKIR30 12V

USER MANUAL

CE 0123

www.medicalsuction.co.uk

NEW ASKIR 30 12V Surgical aspirator is a portable unit, working with 12V dc (autotration battery), designed for the aspiration of bodily fluids in adult and children. It's particularly suitable for nasal, oral or tracheal aspiration of mucus, catarrh or blood after minor surgical procedures and can be used in post-operative therapy at home or conveniently transported from one hospital ward to another.
The device is intended to be powered by a 12V DC car battery with non continuous operation (Ton: 20 min / Toff: 40 min)
Made of highly heat resistant, electrically insulated plastic material in conformity with the latest European safety standard, the product is supplied with a complete polycarbonate autoclavable jar with overflow valve and it is equipped with aspiration regulator and vacuum indicator located on the front panel.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE.

THE DEVICE IS FOR USE BY QUALIFIED PERSONNEL (SURGEON / PROFESSIONAL NURSE / ASSISTANT)

THE INSTRUMENT MUST NOT DISASSEMBLED. FOR TECHNICAL SERVICE ALWAYS CONTACT CA-MI SRL

IMPORTANT SAFETY RULES

1. Check the condition of the unit before each use. The surface of the unit should carefully inspected for visual damage. Check the mains cable and do not connect to power if damage is apparent;
2. Before connecting the appliance always check that the electric data indicated on the data label and the type of plug used, correspond to those of the mains electricity to witch it's to be connected;
3. Respect the safety regulations indicated for electrical appliances and particularly:

- Use original components and accessories provided by the manufacturer to guarantee the highest efficiency and safety of the device;
- The device can be used only with the bacteriological filter;
- Never immerge the appliance into water;
- Position the device on stable and flat surfaces in a way that the air inlets on the back aren't obstructed;
- To avoid incidents, do not place the aspirator on unstable surfaces, 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 energised 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 the CA-MI technical service department.
- Don't use in the presence of inflammable substances such as anaesthetic, oxygen or nitrous oxide;
- Don't touch the device with wet hands and always prevent the appliance coming into contact with liquids;
- Don't leave the appliance connected to the power supply socket when not in use;
- Don't pull the power supply cable to disconnect the plug remove the plug from the mains socket correctly;
- Store and use the device in places protected against the weather and far from any sources of heat. After each use, it is recommended to store the device in its own box away from dust and sunlight.
- Don't use the device thoracic drainage.

4. For repairs, exclusively contact technical service and request the use of original spare parts. Failure to comply with the above can jeopardise the safety of the device;
5. 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 regulation.
6. The medical device requires special precautions regarding electromagnetic compatibility and must be installed and used in accordance with the information provided with the accompanying documents: the NEW ASKIR 30 12V device must be installed and used away from mobile and portable RF communication devices (mobile phones, transceivers, etc.) that may interference with the said device.
7. Instrument and accessory discharging must be done according to current regulations in the country of use.
8. **WARNING**: Do not change this equipment without the permission of the manufacturer CA-MI Srl. None of electric or mechanical parts have been designed to be repaired by customers or end-users. Don't open the device, do not mishandle the electric / mechanical parts. Always contact technical assistance
9. Using the device in environmental conditions different than those indicated in this manual may harm seriously the safety and the technical characteristics of the same.
10. The medical device is in contact with the patient by means of a disposable probe (supplied with the device) furnished with the relative CE compliance certification according to the requirements of regulation ISO 10993-1: thus, no allergic reactions and skin irritations may occur.
11. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1.
12. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.

The manufacturer cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse.
Any minimal modification / repair on the device voids the warranty and does not guarantee the compliance with the technical requirements provided by the MDD 93/42/EEC (and subsequent changes) and its normatives.

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2002/96/EC:
In respect of art. 13 Decreto Legislativo 25 Luglio 2005, n.151 "Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal"
The symbol as over applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste. At the end of device useful, the user will must deliver it to the able collecting centres for electric and electronic garbage, or give back to the retailer in the moment of equivalent new device purchasing, one against one. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of witch it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the ambient and health. In case of abusive disposal of device by user, will be applied administrative endorsements in compliance with current standard.

TECHNICAL CHARACTERISTICS

TYPOLOGY (MDD 93/42/EEC)	Medical Device Class IIa
MODEL	**NEW ASKIR 30 12V**
CLASSIFICATION UNI EN ISO 10079-1	HIGH VACUUM / HIGH FLOW
MAIN VOLTAGE	12V dc
POWER CONSUMPTION	40W
MAXIMUM SUCTION PRESSURE (without jar)	-80kPa (- 0.80 bar)
MAXIMUM SUCTION FLOW (without jar)	25 l/min
WEIGHT	2.5 Kg
SIZE	350 x 210 x 180 mm
DUTY CYCLE (to 35°C and 110% operating voltage)	Ton: 20 min / Toff: 40 min
SICILICONE TUBE SIZE	Ø 6 x 10 mm
ACCURANCY OF VACUUM INDICATOR	± 5%
WORKING CONDITION	Room temperature: 5 ÷ 35°C Room humidity percentage: 30 ÷ 75% RH Altitude: 0 ÷ 2000m s.l.m.
CONSERVATION CONDITION AND TRASPORT	Room temperature: -40÷ 70°C Room humidity percentage: 10 ÷ 100% RH

SYMBOLS

	Class II isolation equipment
CE 0123	CE marking in conformity with EC directive 93/42/EEC and subsequent changes
	Warning, consult the instruction manual
	Keep in a cool, dry place
	Conservation temperature: -40 ÷ 70°C
	Type B equipment
	Fuse
PHT DEHP	DEHP Phthalates (Suction catheter)
12V ~	Alternate Current
Hz	Mains Frequency
I	ON
O	OFF

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The surgical aspirator NEW ASKIR 30 12V is intended for use in the electromagnetic environment specified below.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The surgical aspirator NEW ASKIR 30 12V only used RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not cause interference in proximity of any Electronic appliances.
Irradiated / Conducted emissions CISPR11	Class [B]	The surgical aspirator NEW ASKIR 30 12V can be used in all environments, including domestic and those connected directly to the public mains distribution that supplies power to environments used for domestic scopes
Harmonic emissions IEC/EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic Immunity		
The surgical aspirator **NEW ASPIRET** is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator **NEW ASPIRET** should assure that it's used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic environments - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6kV on contact ± 8kV in 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/EN 61000-4-4	± 2kV power supply	Mains power quality should be that of a typical commercial environment or hospital
Surge IEC/EN 61000-4-5	± 1kV differential mode	Mains power quality should be that of a typical commercial environment or hospital
Loss of voltage, brief voltage interruptions and variations IEC/EN 61000-4-11	5%U_T for 0.5 cycle 40%U_T for 05 cycle 70%U_T for 25 cycle <5%U_T for 5 sec	Mains power quality should be that of a typical commercial environment or hospital If the user of the surgical aspirator NEW ASPIRET. request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field IEC/EN 61000-4-8	3A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Conducted Immunity IEC/EN 61000-4-6	3Vrms 150kHz to 80MHz (for appliances that aren't life - supporting)	-
Irradiated Conducted IEC/EN 61000-4-3	3V/m 80MHz to 2.5 GHz (for appliances that aren't life - equipment)	-
Note U_T is the value of the power supply voltage		

ACCESSORIES SUPPLIED

DESCRIPTION
COMPLETE ASPIRATION JAR 1000cc
CONICAL FITTING
TUBES SET 6 mm x 10 mm
ASPIRATION PROBE CH20
ANTIBACTERIAL FILTER

Antibacterial Filter: The filter is produced with (PTFE) hydrophobic material witch prevents fluids entering the pneumatic circuit.
The filter is for a single patient use which will protect patients and machines from cross contamination.
When the filter is wet, it's not possible to use the unit therefore the filter should be changed immediately.
In case of possible contamination or discolouration, change the filter immediately.
Don't use the suction unit without the protection filter fitted.
Suction catheter: Single-use device to be used on a single patient. Do not wash or re-sterilize after use. Reuse may cause cross-infections.
Don't use after lapse of the sell-by date

WARNING: Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.

Aspiration jar: The mechanical resistance of the component is guaranteed up to 30 cycles of cleaning and sterilization. Beyond this limit, the physical-chemical characteristics of the plastic material may show signs of decay. Therefore, we recommend that you to change it.
Silicone tubes: the number of cycles of sterilization and/or cleaning is strictly linked to the employment of the said tube. Therefore, after each cleaning cycle, it is up to the final user to verify whether the tube is suitable for reuse. The component must be replaced if there are visible signs of decay of the material constituting the said component.
Conical fitting: the number of cycles of sterilization and the number of cleaning cycles is strictly linked to the employment of the said component. Therefore, after each cleaning cycle, it is up to the final user to verify whether the fitting is suitable for reuse.
The component must be replaced if there are visible signs of decay in the material constituting the said component.
Service life of the device: More than 850 hours of operation (or 3 years) in accordance with the standard conditions of testing and operation. Shelf life: maximum 5 years from the date of manufacture.

CLEANING OF ACCESSORIES

To clean the plastic housing of the device wear disposable latex gloves and clean with denaturated alcohol or hypoclorite solutions.
Washing and / or cleaning the autoclavable jar as to be carried out as follows:

- Wear protection gloves and apron (glasses and face mask if necessary) to avoid contact with contaminating substances;
- Disconnect the jar from the device
- Disconnect all tubes from the jar and the protection filter
- Empty and dispose of the content and of the suction catheter according to the laws in force in your country;
- Separate all parts of the cover (overflow valve, o-ring);

After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thoroughly.
Then soak in warm water (temperature shall not exceed 60°C).
Wash thoroughly and if necessary use a non-abrasive brush to remove incrustations.
Rinse in running warm water and dry all parts with a soft cloth (non-abrasive).
The jar and the cover can be autoclaved by placing the parts into the autoclave and running one sterilization stem cycle at 121°C (1 bar relative pressure) making sure that the jar is positioned upside down.
Mechanical resistance of the jar is guaranteed up to 30 cycles of sterilization and cleaning at the indicated conditions (EN ISO 10079-1). Beyond this limit the physical-mechanical characteristics of the plastic may decrease and replacement of the part is therefore recommended.

After sterilization and cooling at environment temperature of the parts make sure that these are not damaged.
Assemble the jar as follows:

- Place the overflow valve into its seat in the cover (under VACUUM connector)
- Insert floating valve keeping the o-ring towards the opening of the cage
- Place the o-ring into its seat around the cover
- After completing assembling operations always make sue that cover seals perfectly to avoid vacuum leakages or liquid exit

The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 120°C.
The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C.
The device is ready for a new employment now.

DO NOT WASH, STERILIZE OR PUT IN AUTOCLAVE THE ANTIBACTERIAL FILTER

MAINTENANCE

The NEW ASKIR 30 12V suction equipment does not need maintenance or lubrication.
It is, however, necessary to inspect the unit before each use. With regard to training, given the information contained in the user manual and since it is easy to understand the said device, it doesn't appear to be necessary.
Unpack the instrument and always check integrity of plastic parts and feeding cable, they might have been damaged during previous use. Connect the cable to electrical network and turn the switch on.
Close the aspirator outlet with your finger and with suction regulator at maximum check that the vacuum indicators reaches at least -75kPa (-0.75 bar). Rotate the knob from right to left. The vacuum indicator should go down -25kPa (-0.25 bar).
Check that no loud noises are present. The device is protected by a safety fuse (F 10A L 250V) situated in the cigarette lighter adapter. For fuses replacing, always the type and the range.
Before changing the fuse, disconnect the plug from the power supply socket.

Fault type	Cause	Solution
1. The suction unit doesn't work	Cable is damaged External power source failure	Replace the cable Check the external power source
2. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
3. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
4. The Vacuum power on the patient side is either very low or absent	a) Vacuum regulator set to minimum b) Protection filter blocked or damaged c) Connection tubes blocked, kinked or disconnected d) Shut-off valve blocked or damaged e) Pump motor damaged	a) Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge b) Replace the filter c) Replace or reconnect the tubes, check the jar connections d) Empty the jar, or disconnect the tube from the jar and unblock the shut-off valve. The unit twill only work in the upright position e) Refer to authorised service personnel
5. The float doesn't close	If the cap has been washed, ensure that the float is not partially detached	Insert the float into it's place
6. The float doesn't close	The float it's covered by dirty material	Unscrewed the cap, leave the and put in on autoclave
7. Low suction	Foam inside the jar	Fill the jar to 1/3 full of ordinary water
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7	**None of the remedies has achieved the desired results**	**Contact the seller or CA-MI After-sales Assistance Service**

If the overfill security system it's activated, don't proceede with the liquid aspiration.
If the overfill security system doesn't work there are two cases:
1° case – If the overfill security system doesn't work the aspiration will be stopped by the bacteriological filter who avoid the liquid penetration inside the device.
2° case – If both the security system doesn't work, there is the possibility that liquid comes inside the device, in this case return the device to CA-MI technical service.

CA-MI Srl will provide upon request electric diagrams, components list, descriptions, setting instructions and any other information that can help the technical assistance staff for product repair

BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT CA-MI TECHNICAL SERVICE. THE MANUFACTURER DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

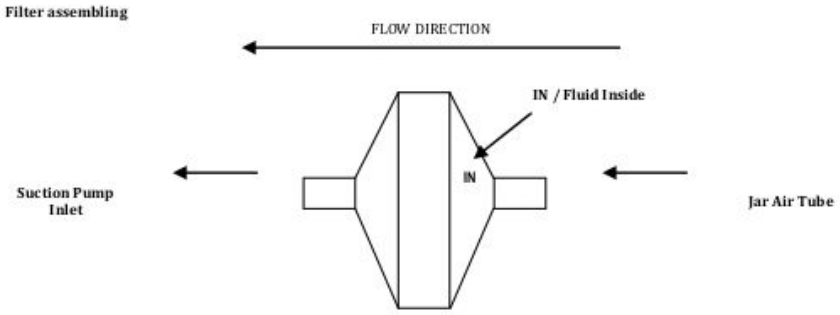
INSTRUCTIONS

- The device must be checked before each use in order to detect malfunctions and / or damage caused by transport and / or storage.
- The working position must be such as to allow one to reach the control panel and to have a good view of the empty indicator, the jar and the antibacterial filter.
- It is recommended not to keep the device in your hands and / or to avoid prolonged contact with the body of apparatus.

WARNING: For proper use, place the aspirator on a flat, stable surface in order to have the full volume of use of the jar and better efficiency of the overflow device.

- Place the unit on a flat, horizontal surface
- Connect one end of the short silicon tube, with antibacterial filter, to the suction connector on the lid of the jar.
- The other tube already connected to the filter has to be connected to the "VACUUM" jar outlet, where has been fixed the red float (security float). When the 90% of the volume of the jar is reached there is the activation of the security float (the float close the aspiration connector on the jar) to avoid liquid penetration inside the device.

WARNING: Ensure that the FLUID SIDE or IN marker on the filter is on the side facing the collection jar lid and fitted into the "VACUUM".A wrong connection causes immediate destruction in case of contact with sucked liquids.



- Connect the long silicone tube to the "PATIENT" jar outlet
- Connect the other end of the long silicon tube to the probe plastic connector then connect the suction probe to it.
- Connect the power cord to the device then connect the plug to the electrical mains supply.
- Push switch on position **I** to start suction.
- Unscrew the jar's lid and fill the jar 1/3 full or ordinary water (this for an easy cleaning operations and an rapid reaching of the functionality vacuum) then rescrew the lid on the jar correctly.
- During operation the jar has to be in vertical position to avoid overflow valve to cut off aspiration. Should this happen, switch off the device and disconnect the tube from the jar cover (from "VACUUM" outlet).
- Once finished push switch on **O** position and unplug.
- Remove the accessories and clean.

WARNING: The on/off button (used as a network switch) is the element that separates the mains; in any case, even if the device is equipped with a specific on/off button, the 12V
power plug must remain accessible once the device is in use, to allow for an additional method to simultaneously disconnect all the poles from the mains.

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER

MAKE SURE THAT CHILDREN AND/OR MENTALLY ILL PEOPLE DO NOT USE THE DEVICE WITHOUT ADULT SURVEILLANCE

ALWAYS PLACE THE DEVICE IN POSITIONS FOR EASY DISCONNECTION.

RULES FOR RETURNING AND REPAIRING

UNDER NEW EUROPEAN RULES, CA-MI REQUIRES THE FOLLOWING PROCEDURES TO BE CARRIED OUT TO PROTECT THE INSTRUMENT AND THE SAFETY OF ALL WHO COME IN CONTACT WITH IT.

CA-MI warrants it's product for **24 months** after purchasing date.

Before returning an instrument for repair, the external surfaces and all accessories **MUST** be carefully disinfected with a cloth soaked in methylated spirits or hypochlorite-based solution. The instrument and accessories should then be placed in a bag with a note outlining the disinfection undertaken.

Failure to follow this procedure will result in the instrument being returned to the purchaser unrepaired.

Instruments returned for repair **MUST** be accompanied by a description of the problem. CA-MI will not be responsible for damage caused through improper use. To avoid such damage, please read the instruction carefully.

Where CA-MI determines that an instrument is faulty, a replacement will be provided only if a SALES RECEIPT and STAMPED GUARANTEE are provided. CA-MI will not be responsible for damage accessories. These may be replaced at the customer's expense.