SUCTION UNIT NEW ASKIR20

USER MANUAL

CE 0123

medical suction

www.medicalsuction.co.uk

NEW ASKIR 20 Surgical aspirator is a portable unit, working with 230V ~ / 50 Hz network electricity, 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. Easily portable equipment designed for continuous use.
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 WARNINGS

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE

ONLY HIGHLY QUALIFIED STAFF USE RESERVED

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. If the plug supplied with the appliance is incompatible with the mains electricity socket, contact qualified staff for replacement of the plug with a suitable type. The use of simple or multiple and / or extension adapters is not generally recommended. Whenever their use is indispensable, use those in compliance with safety regulations, however paying attention not to exceed the maximum power supply limits, which are indicated on the adapters and extensions;
4. 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;
   - Place instrument on stable and flat surfaces;
   - Position the device in a way that the air inlets on the back aren't obstructed;
   - 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;
   - Keep off the reach of children or not capable people without supervision;
   - 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;
   - Preserve and use the medical device in environments protected from atmospheric factors and at a distance from heat sources;
   - Don't use the device thoracic drainage.
5. 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;
6. **This medical device must be destined exclusively for the use for witch it has been designed ad described in this manual.**
   Any different use must be considered incorrect and therefore dangerous; the manufacturer will not be responsible for damage due to improper use or connection to an electrical system not complying with current regulations;
7. Particular precautions must be made concerning electromagnetic compatibility. The medical device must be installed and used according to information supplied with the accompanying documents;
8. Instrument and accessories discharging must be done following current law regulations in every country of use.
9. 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
10. 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.
11.

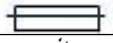
The manufactured cannot be held liable for accidental or indirect damages should the device be modified, repaired without authorization or should any of its component be damaged due to accident or misuse.

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.

TECHNICAL CHARACTERISTICS

Model	NEW ASKIR 20
Typology (MDD 93/42/EEC)	**Medical Device Class II a**
Classification UNI EN ISO 10079-1	HIGH VACUUM / LOW FLOW
Main Voltage	230 V ~ / 50 Hz
Power consuption	184 VA
Fuse	F 1 x 1.6A 250 V
Maximum suction aspiration (without jar)	-75kPa (- 0.75 bar) Regolable from -75kPa (-0.75 Bar) to -10kPa (-0.10 Bar)
Maximum flow (without jar)	16 l/min
Weight	2.5 Kg
Dimension	350 x 210 x 180 mm
Functioning (to 35°C and 110 % operating voltage)	NON-STOP OPERATED
Working condition	Room temperature: 5 ÷ 35 °C Room humidity percentage: 30 ÷ 75 % RH Altitude: 0 ÷ 2000m s.l.m
Conservation condition	Room temperature: - 40 ÷70 °C Room humidity percentage: 10 ÷ 100% RH

SYMBOLS

	Class 2 isolation equipment
CE 0123	CE marking in conformity with EC directive 93/42/CEE and subsequent changes Manufacturer: CA-MI Srl - Via Ugo La Malfa n°31, 43010 Pilastro (PR) Italy
	Warning, consult the instruction manual
	Type B equipment
	Fuse
	To preserve in place coolness and dry land
	Conservation temperature: - 40 ÷ 70° C
~	Alternate current
Hz	Mains frequency
I	ON
0	OFF
	DEHP Phthalates (Suction catheter)

Please note tecnica specifications may vary upon the manufactures's discretion!

Guidance and manufacturer's declaration – electromagnetic Emissions		
The surgical aspirator NEW ASKIR 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the surgical aspirator NEW ASKIR 20 should assure that it's used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
Irradiated / Conducted emissions CISPR11	Group 1	The surgical aspirator NEW ASKIR 20 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 20 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 ASKIR 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the surgical aspirator NEW ASKIR 20 should assure that it's used in such an environment.		
Immunity Test	**Compliance**	**Electromagnetic environment - 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 ASKIR 20 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)	-
Nota U_T is the value of the power supply voltage		

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 thouroughly.
Then soak in warm water (temperature shall not exceed 60°C). Wash thouroughly 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 upsidedown.
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 leackages 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**

ACCESSORIES SUPPLIES

DESCRIPTION
COMPLETE ASPIRATION JAR 1000cc
CONICAL FITTING
TUBES SET 6mm x 10mm (TRASPARENT SILICON)
ASPIRATION PROBE CH 20
ANTIBACTERIAL FILTER

The filter is produced with (PTFE) hydrophobic material witch prevents fluids entering the pneumatic circuit.
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. If the suction unit is used in an emergency or in a patient where the risk of contamination is not know the filter must be changed after each use. Available under request with different versions with complete jar 2000cc.

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.

PERIODICAL MAINTENANCE CHECKS

The **NEW ASKIR 20** suction equipment does not need maintenance or lubrication.
It is necessary to check functioning and instrument before every use. Unpack the instrument and **always check** integrity of plastic parts and feeding cable, they might have been damaged during previous use. Connect cable to electrical network and turn switch on. Close the aspirator outlet with your finger and with suction regulator in maximum vacuum position check that the vacuum indicators reaches -75kPa (-0.75 bar) minimum.
Rotate the knob from right to left and check the aspiration regulating control. The vacuum indicator should go down -25kPa (-0.25 bar). Verify that loud noises are not present, these can indicate wrong functioning. A protection fuses **(F 1 x 1.6 A 250V)** reachable from exterior and situated in the plug protects the instrument. For fuses replacing, always the type and the range.

Type of fault	Cause	Remedy
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	• Vacuum regulator set to minimum • Protection filter blocked or damaged • Connection tubes blocked, kinked or disconnected • Shut-off valve blocked or damaged • Pump motor damaged	• Turn the vacuum regulator clockwise and check the value of the vacuum on the gauge • Replace the filter • Replace or reconnect the tubes, check the jar connections • 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 • 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.

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

INSTRUCTION FOR USE

- Place the unit on a flat, horizontal surface
- Connect the end of the short silicon tube, with antibacterial filter, to the suction connector.
- 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.

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

COMPLYING WITH THE NEW EUROPEAN RULES, CA-MI Srl INDICATES THE IMPORTANT POINTS TO PROTECT INSTRUMENT AND OPERATORS HYGIENE. THESE RULES MUST BE RESPECTED IN ORDER TO GUARANTEE HYGIENE AND SAFETY TO ALL THE PEOPLE OPERATING WITH THE INSTRUMENT TO OBTAIN QUALITY AND WELL BEING.
CA-MI warrants it’s product for **24 months** after purchasing date.
Every returned instrument will be hygienically checked before repairing. If CA-MI finds instrument not suitable for repairing due to clear signs of internal or external contamination, the same will be returned to customer with specification of NOT REPAIRED INSTRUMENT, accompanied by an explanation letter. CA-MI will decide if contamination is due to bad functioning or misuse. If contamination is due to bad functioning, CA-MI will substitute the instrument, only if a SALE RECEIPT and STAMPED GUARANTEE accompany the same.
CA-MI is not responsable for contaminated accessories, they will be substitute at customer's expenses.
For this reson it is **COMPULSORY** to carefully disinfect the external part of the instrument and accessories with a cloth soaked in methylated spirits or hypochlorite-based solutions. Put the instrument and accessories in a bag with indication of disinfecting. We also request to specify the kind of fault, in order to speed up repairing procedures. To this end, please read the instructions carefully in order

to avoid damaging the equipment through improper use. Always specify the fault encountered so that CA-MI Srl can establish whether it falls into the category of the faults covered by the guarantee.