NEW ASKIR 118 BASIC

Italian Medical Touch

IT Manuale d'uso

EN Instruction Manual

FR Mode d'emploi

ES Manual de istrucciones

DE Handbuch

PT Manuale de instruções

30751/112 - Rev.1 del 30/09/2019

CE 0123

MADE IN ITALY

NEW ASKIR 118 BASIC is a surgical aspirator with the following electricaL features : 14V ⎓ 4A with AC/DC adapter mod. UE60-140429SPA1 of FUHUA (input: 100-240V~ - 50/60Hz - 100VA) or Internally powered equipment (Li-Ion Battery 14.8V ⎓ 5.2A) or with cigarette lighter adapter (12V ⎓ 4A). **NEW ASKIR 118 BASIC** is a desk-type electric suction unit for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. Its shape, elegantly narrow, is motly designed for fitting into ambulance car and emergency use. This device has been designed to offer ease of transport and continuous use, thanks to an electronic system that manages the power supply. The lithium battery (14.8V ⎓ 5.2A model RYLI186504S2P14.8V) with which the device is equipped and the pressure switch (installed directly on the internal circuit board of the device) ensure intelligent use automatically adjusting the suction power, consequently increasing the battery life and decreasing the noise produced. The "PROXIMITY" function allows the device to be activated/deactivated via an infra-red proximity sensor (detecting the presence of the hand from a distance of tenths of centimetres without touching the suction unit) and it prevents and avoids possible cross-contamination between patients as they are treated in turns.
The unit is equipped with suction regulator on the front panel and polycarbonate autoclavable jar complete with overflow valve.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE.

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

THE USE OF THE DEVICE AT HOME IS RESTRICTED TO AN ADULT IN FULL POSSESSION OF MENTAL FACULTIES AND / OR HOME CARERS

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;
   - Store and use the device in places protected against the weather and far from any sources of heat
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 118 BASIC 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. Do not perform repairs or maintenance operations on the device when it is being used on a patient
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 medical device is in contact with the patient by means of a disposable probe (supplied with the device). Suction tubes for insertion in the human body purchased separately from the machine should comply with ISO 10993-1 standards on material biocompatibility.
12. The product and its parts are biocompatible in accordance with the requirements of regulation EN 60601-1.
13. Operation of the device is very simple and therefore no further explanations are required other than those indicated in the following user manual.
14. The battery integrated in the device is not to be considered as an ordinary domestic waste. Such a component must be disposed of in a specific collection centre in order to be recycled.

EN

CONTRAINDICATIONS

- Before using the NEW ASKIR 118 BASIC, consult the instructions for use: failure to read all the instructions in this manual can be harmful for the patient.
- The device cannot be used to drain chest fluids;
- The device must not be used for suction of explosive, corrosive or easily flammable liquids.
- NEW ASKIR 118 BASIC is not suitable for MRI. Do not introduce the device in MRI environments.

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2012/19/UE-RAEE: The symbol on the device indicates the separated collection of electric and electronic equipment. At the end of life of the device, don't dispose it as mixed solid municipal waste, but dispose it referring to a specific collection centre located in your area or returning it to the distributor, when buying a new device of the sample type to be used with the same functions. This procedure of separated collection of electric and electronic devices is carried out forecasting a European environmental policy aiming at safeguarding protecting and improving environment quality, as well as avoiding potential effects on human health due to the presence of hazardous substances in such equipment or to an improper use of the same or of parts of the same. Caution: The wrong disposal of electric and electronic equipment may involve sanctions.

TECHNICAL CHARACTERISTICS

Model	**NEW ASKIR 118 BASIC (REF RE 410170)**	
Typology (MDD 93/42/EEC)	Class IIa Medical device	
UNI EN ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW	
Power Feeding	5,2 A - 14,8 V ⎓ by internal Li-Ion battery 12V ⎓ 4A by ambulance adapter model ASKIR 118 SUPPORT (REF ASU 118)	
Maximum Suction Pressure (adjustable)	-75kPa (- 0.75 bar)	
Minimum Suction Pressure (adjustable)	-15kPa (-0.15 bar)	
Maximum Suction Flow	36 l /min	
Weight	2.50 Kg	
Insulation Class (when used with the ASKIR 118 SUPPORT BRACKET mod. ASU 118)	Class II	
Insulation Class (when used with an Internal battery)	Internally Powered Equipment	
Size	350 x 150 x 190 mm	
Battery Holding Time	70 minutes	
Battery Time Charge	360 minutes	
Noise Level	**Without Suction**	**During Maximum Suction**
	54,7 dB	68,2 dB
Working Condition	Room temperature: Room humidity percentage: Atmospheric pressure:	5 ÷ 40°C 0 ÷ 85% RH 800 ÷ 1060 hPa
Conservation condition and Transport	Room temperature (≤ 1 mounth): : Room Temperature (≤ 3 mounth): Room Temperature (≤ 1 year): Room humidity percentage: Atmospheric pressure:	- 20°C ÷ 45°C - 20°C ÷ 35°C 0°C ÷ 25°C 0 ÷ 85% RH 500 ÷ 1060 hPa

Please note that the maximum suction value can vary according to reduced atmospheric pressure if the device is used at high altitude. The operator must take use at high altitude into account. In such conditions, the vacuum produced by the internal pump can considerably drop due to the reduction of atmospheric pressure.

CLEANING DEVICE

Use a soft dry cloth with not – abrasive and not – solvent detergents. To clean the device external parts always use a cotton cloth dampened with detergent. Don't use abrasive or solvent detergents.

PARTICULAR CARE SHOULD BE TAKEN TO ENSURE THAT THE INTERNAL PARTS OF THE EQUIPMENT DO NOT GET IN TOUCH WITH LIQUIDS. NEVER CLEAN THE EQUIPMENT WITH WATER.

During all clearing operations use protection gloves and apron (if need be, also wear a face mask and glasses) to avoid getting in contact with contaminating substances (after each utilization cycle of the machine).

SYMBOLS

	Insulation Class II (when used with AC/DC power adaptor or with cigarettes lighter adaptor)
CE 0123	CE marking in conformity with EC directive 93/42/CEE and subsequent changes
 10R-052527	Device approved according to international standards ECE-R10
	General warnings and/or specifications
 	Consult the instruction manual before every use
	Manufacturer: **CA-MI S.r.l.** Via Ugo La Malfa nr.13 – Frazione Pilastro 43013 Langhirano (PR) Italia
	Applied Part type BF (suction probe)
	Room Humidity Percentage
	Conservation temperature
	Atmospheric Pressure
	Battery (Li-Ion Battery 14.8V ⎓ 5.2A)
	Direct Current
	ON / OFF
	Batch production
	Serial number
	Model / Ref number
IP22	Degree of protection an electrical device provides in the case of accidental or intentional contact with the human body or with objects, and protection in the case of contact with water.
	1st DIGIT **PENETRATION OF SOLIDS**: Protected against solids having a dimension greater than Ø 12mm
	2nd DIGIT **PENETRATION OF LIQUIDS**: Protected against drops of water diverted up to 15° inclination

CARE AND MAINTENANCE

If the device was stored at a temperature below the minimum value specified by the manufacturer, keep it in a place with a room temperature of 20°C for at least 1 hour before using the device.

If the device was stored at a temperature above the maximum value specified by manufacturer, keep it in a place with a room temperature of 20°C for at least 30 minuted before using the device.

DISPOSAL OF WASTE BATTERIES - (Directive 2006/66/EC)

This symbol on the battery or on the packaging indicates that the battery provided with this product shall not be treated as household waste. By ensuring these batteries are disposed of correctly, you will help prevent potentially negative consequences for the environment and human health which could otherwise be caused by inappropriate waste handling of the battery. The recycling of the materials will help to conserve natural resources.

At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, your household waste disposal service or the shop where you purchased the product.

ACCESSORIES SUPPLIES

DESCRIPTION	CODE
COMPLETE ASPIRATION JAR 1000ml	RE 210001/02
CONICAL FITTING	RE 210420
TUBES SET 8 mm x 14 mm	51100/01
HYDROPHOBIC AND ANTIBACTERIAL FILTER	SP 0121
SUCTION PROBE CH20	25723
ASKIR 118 SUPPORT BRACKET	ASU 118
AC/DC ADAPTER (UE60-140429SPA1)	SP 0208/01
POWER SUPPLY CORD FOR AC/DC ADAPTER	SP 0020/03

The filter is produced with (PTFE) hydrophobic material to prevent fluids entering the pneumatic circuit. It should be changed immediately if it becomes wet or if there is any sign of contamination or discolouration. If should also be changed if the unit is used with a patient whose risk of contamination is unknown. **Don't use the suction unit without the protection filter**. 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 2000ml.
On request, it's available version with disposable collection system (FLOVAC® 1000ml) composed by a reusable polycarbonate vessel and polyethylene disposable bag (collection liner for fluids suction canisters).

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
If there are breakages and/or damage to the suction probe (see blister) don't use the device and contact the CA-MI technical service.

Check the expiry date on the original packaging of the suction catheter and check the integrity of the sterile packaging. CA-MI declines any liability for injury to the patient correlated to the deterioration of the above-mentioned sterile packaging due to handling of the original packaging by third parties.

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 10000 hours of operation in accordance with the standard conditions of testing and operation. Shelf life: maximum 5 years from the date of manufactured.

CLEANING OF ACCESSORIES

Before using the device, the manufacturer advises you to clean and/or sterilize the accessories.
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 tank from the device and remove the said container from the support of the device.
- Separate all the parts of the cover (overflow device, washer).
- Disconnect all tubes from the jar and the protection filter
- Wash each part of the container from secretions under cold running water and then clean every single part in hot water (temperature not exceeding 60°C)
- Once again, carefully wash each single part using, if necessary, a non-abrasive brush to remove any deposits. Rinse with hot running water and dry all parts with a soft cloth (non-abrasive). It is possible to wash with commercial disinfectants by carefully following the instructions and dilution values supplied by the manufacturer. After cleaning, leave the parts to dry in an open, clean environment.
- Dispose of the aspiration catheter according to that provided by local laws and regulations.

The silicone aspiration tubes and the conical fitting may be carefully washed in hot water (temperature must not exceed 60°C). After cleaning, leave the parts to dry in an open, clean environment.

When cleaning is complete, reassemble the container for liquid aspirations according to the following procedure:

- 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

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 – 15 min) 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.
The aspiration tubes can be sterilized on autoclave using a sterilization cycle at 121°C (1 bar relative pressure – 15 min).
The conical connector can be sterilized on autoclave using a sterilization cycle at 121°C (1 bar relative pressure – 15 min).

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

Instruction for disposal Liner Flovac®:
If the device is equipped with disposable collection systems FLOVAC ® carry out the disposal of the bag as follows:
Turn off the Vacuum and remove all the tubes connected to the Liner, giving particular attention to avoid accidental contamination.
Fit the appropriate plugs to the "PATIENT" and "TANDEM" ports, pressing the home firmly, taking care to avoid accidental contamination. Remove the liner bag from the rigid container and transfer it to the waste disposal area, ensuring that all the openings are sealed, keeping in mind the product is potentially infectious. This product must be disposed of in accordance with the current hospital regulations.

PERIODICAL MAINTENANCE CHECKS

The **NEW ASKIR 118 BASIC** suction equipment does not need maintenance or lubrication.
It is, however 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, they might have been damaged during previous use. Turns sitch on and verify that lous noises are not present, these can indicate wrong functioning.
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). Rotate the knob from right to left and check the aspiration regulating control.
The device is protected by a safety fuse (**F 10A L 250V**) situated in the cigarette lighter cable. When replacing, always check the type and value as indicated. Internally, the device is protected (see electrical specifications) by two fuses (**T 15A L 125V**) that cannot be reached from the outside. Therefore, contact the manufacturer to request the assistance of an authorized and qualified technician when they need to be replaced. If it's replaced make sure that its replacement is always the same type and value, as indicated. The device is equipped with a Lithium-Ion Battery, which cannot be reached from the outside.
Only refer to CA-MI technical service personnel to replace it.
The device should be checked at least once every 12 months by technical service.
Every 24 months it is compulsory to have a safety inspection and technical maintenance performed on the device.

ONLY USE BATTERIES RECOMMENDED BY CA-MI. USE OF BATTERIES OTHER THAN THOSE RECOMMENDED WILL MAKE THE WARRANTY VOID AND NULL.
ONLY QUALIFIED PERSONNEL ARE AUTHORISED TO REPLACE THE INTERNAL BATTERY. ANY OPERATION PERFORMED BY NON-TRAINED PERSONNEL MAY CAUSE DANGER (E.G. EXCESSIVE TEMPERATURE)

Fault type	Cause	Solution
1. Fixed Red Led	Battery run down	Hook up the power cord to the electricity mains, positioning the equipment power switch on 0. If it is intended to be used in ambulances, position the device on the support bracket and leave the battery charge until the Fixed Green Ledgives the signal (TAB. I).
2. No light	Locking device	Internal technical problem. Contact the technical service
3. No aspiration	Jar Cap badly screwed down	Unscrewed the cap, then rescrew it correctly
4. No aspiration	Lid seal not in its seat	Unscrew the cap and insert the seal properly in its seat
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
8. No aspiration due to flow leakage of mucus	Filter blocked	Replace filter
9. The Vacuum power on the patient side is either very	• Protection filter blocked or damaged	• Replace the filter • Replace or reconnect the tubes, check the jar

low or absent	• Connection tubes blocked, kinked or disconnected • Shut-off valve blocked or damaged • Pump motor damaged	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 • Contact the technical service
10.Noisy	Technical internal problem	Contcat the technical service
Faults 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 – 9 - 10	**None of the remedies has achieved the desired results**	**Contact the seller or CA-MI After-sales Assistance Service**

Lithium-Ion Battery Charging Cycles: The Lithium-Ion battery contained inside the device is guaranteed for a number greater than 300 charging cycles. In the vicinity of 300 charging cycles you can ask for verification of operating status to the manufacturer or to require replacement of the battery pack in such a way that you always have the component in perfect condition.

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.
The medical device contains firmware (revision 4 dated 10.04.2015). This information is made available in order to assist the technical assistance personnel in the eventual repair of the appliance.

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.

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.

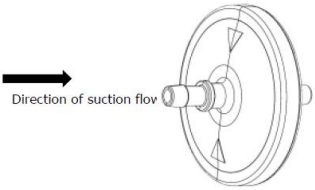
INSTRUCTION FOR USE

- 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 Vacuum Gauge screen, the suction jar and the antibacterial filter.

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.
The PATIENT and the OPERATOR cannot be considered as the same person when the device is being used.

Operation with Internal Battery
- Place the unit on a flat, horizontal surface.
- Connect the short silicon tube, with antibacterial filter, to the suction connector. The other tube, with one end connected to the antibacterial filter with the other end to jar's lid connector where has been fixed the red 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 the avoid liquid penetration inside the device.
- Connect the long silicon tube to the other jar's lid connector
- Connect the other end of the long silicon tube to the probe plastic connector then connect the suction probe to it.
- Connect the switching adapter to the device with the appropriate connector. To start the treatment press the **I** switch to turn it on
- Set the desired vaccum value (kPa / mmHg) with the appropriate vacuum regulator. Turning the handle clockwise increase the vacuum value: these values can be read on the "vacuum indicator" instrument.
- To suspend and / o r terminate the treatment, press the switch againg and pull the plug out from the power socket.
- 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 functionally vacuum) then rescrew the lid on the jar correctly.
- To extract the accessories and start with cleaning.
- The battery is fully charged in about 70 minutes with continuous operation.

Filter assembling
Ensure that the filter is fitted with the Arrows at the patient side.



WARNING: The inside of the medical device must be regularly checked for the presence of liquids or other visible contamination (secretions). If liquids or other visible contamination are present, the medical device must be replaced immediately due to the risk of insufficient vacuum flow. These products have been designed, tested and manufactured exclusively for "single use" and for a period of use not exceeding 24 hours unless stated below.

WARNING: The seal hook placed on the ASKIR 118 SUPPORT (mod. ASU 118) is the dividing element from the 12V mains, even if the device is equipped with the specific ON/OFF button.

A pressure sensor fitted in the device allows decreasing the motor revolutions [in the absence of suction] safeguarding the internal battery life. The motor will resume full speed only when the operator carries out the body fluid aspiration process (with the adjustment knob set to +). If the operator does not carry out the suction process the device lowers the number of revs of the motor, thus protecting the duration of the internal battery.

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER

WARNING: Before using the device, check the battery power status. Before each use proceed with charging the battery. To maintain the device in good conditions, recharge the battery every 3 months (when not in use).

Recharging operations: to be able to charge the internal battery it is necessary to connect the universal switching adapter (mod. UE60-140429SPA1 of FUHUA) to the electric network for approx. 360 minutes with the main switch to position 0. The battery's autonomy when fully charged is approx. 70 minutes with continued operations.

Operation using with AC/DC switching adapter : The symbol positioned near the 12V jack on the device casing indicates that the instructions must be viewed before each user operation, identifying the model and type of power supply to be connected, in line with the information mentioned in the instructions for use.

PROXIMITY FUNCTIONS:

- Pressing the "Proximity" (Lights BLUE LED) is activated on / off the motor by an infrared proximity sensor that detects the presence of the operator's hand from a few inches away. This allows the operator to use the device without touching or focus on pressing the button.
- The on / off button is also active with the function of proximity inserted and can be used as an alternative.
- To remove the "Proximity" you have to re-press the button.

The "Proximity" is retained, or if it was active before power off, then on again to return to this, but if it was not active will remain disabled. The function set to power down the card after 20 minutes after turning off the engine if it is not then on again.

The unwanted approach of the hand to the Proximity sensors causes the device to switch off. To reactivate the function, place the hand close to the sensors.

NOTE: *It is up to the end user to activate or deactivate the Proximity sensor. With the Function off, the device is activated/deactivated by pressing the ON/OFF key*.

LIGHT INDICATORS:

The device is provided with a light indicator (directly on the front panel) which allows you to view the operation of the device, autonomy of the battery, and the charge phase in progress.
The light indications, which appear during operation, are indicated in table I.

TAB. I – INDICATOR LIGHTS DURING OPERATIONS

LED signals	Phase	Problem / Cause	Solution
Flashing Green Led	During rechanrge	Battery recharge running	Wait
Steady Greed Led	During recharge	Recharging cycle complete	Remove the device from the support plate (ASKIR SUPPORT 118 - mod. ASU 118) of the ambulance
Steady Red Led	During battery operation	Flat battery	Start recharging cycle **WARNING:** During this signal, you will hear a long, continuous beep (duration of sound 0.8 sec / sound frequency: every 8.5 sec, which notifies the user regarding the battery discharge.
Flashing Red Led	Device automatically turns off when the battery is flat	Battery completely flat	When the device is restarted the LED will flash red: begin the battery recharge cycle immediately
Steady Yellow Led	During battery operation	Intermediate status	Guaranteed battery function / Recharge when the red LED signal comes on.

TAB. II – WRITTEN SIGNALS / BUTTON LED SIGNAL

Button LED signal / written signal	Function	Colour	Position
ON/OFF button	Power on	Green / Yellow / Red	Near the front panel key
Proximity Button	Switch the ON/OFF key	Blue	LED located above the "Proximity" key

Using FLOVAC® disposable collection system: Before connecting the disposable collection system, remove the blu ring fitted on the tank holder for a more comfortable insertion of the same container.

- After opening the package, fully stretch the bag and then flatten it concentrically to eliminate as much air as possible.
- Insert the bag and apply the cover to an appropriately sized reusable rigid container by pressing firmly around the entire perimeter. Make sure that the system is completely sealed.
- close the connector marked as "TANDEM" with the lid provided.
- Connect the power source of the vacuum to the VACUUM port equipped with specific reusable conical fitting with "male" connection.
- Connect the patient tube to the PATIENT port of the cover
- Before use, check all closures and make sure there are no leaks, starting the aspiration source. If the bag expands to fully adhere to the walls of the rigid container and the cover bends towards the inside of the glass, the system is not leaking.
- Start the aspiration and periodically check the filling level of the container. The overflow valve will cause the interruption of aspiration if the aspirated fluids have reached the maximum filling level of the device.
- When the float valve intervenes signalling the device is too full, the suction source must be disconnected within no more than 5 minutes.

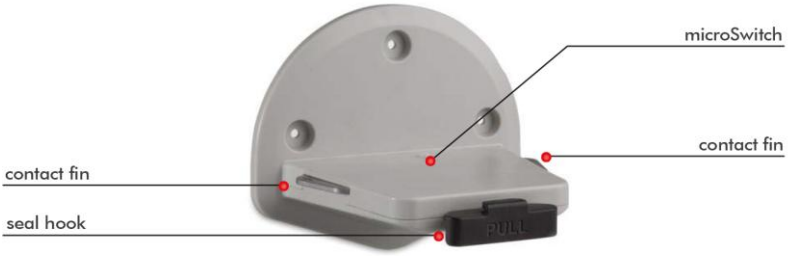
Warning: The accidental inversion of connections may cause contamination for the operator and/or for the vacuum generation equipment.

SUPPORT BRACKET AND CHARGE

The device is supplied with support bracket, therefore, the NEW ASKIR 118 BASIC suction unit can be fixed to the rescue means, in compliance with the standards of reference. This bracket is equipped with electrical cable connected to the 12V ⎓ power supply source of the ambulance and allows the internal battery of the suction unit to be charged.

- The bracket must be installed in compliance with the indications provided in this manual. Failure to comply with such warning may compromise the conformity to standard EN 1789 (design and construction of medical vehicles) and significantly reduce the safety of the medical device;
- Never alter mechanical, electrical, and structural parts of the bracket. These interventions make the device dangerous and, therefore, they preclude its use;

The support bracket of the NEW ASKIR 118 BASIC device consists of a plastic part (ABS) and a seal hook, which allows the suction unit to be fixed safely and easily. The figure below shows the bracket complete in all its parts.



The electrical cable of the bracket has double insulation and it must always be connected to an electrical source (12 V) of the ambulance. Connection to the power supply source must always comply with the polarity.
In case of incorrect connection, the internal battery cannot be charged.

NOTE: *The operations required to fix the bracket are described in the manual (30751/143 - rev.0 dated 15.05.2018), which is available to the installation service of the medical vehicle.*

The electrical connections must always be performed by qualified and authorised personnel. Connections must never be entrusted to unauthorised personnel.
Even if voltage is only 12V ⎓, short circuit may cause serious damage to persons and objects (risk of fire, etc.).

SECURING THE NEW ASKIR 118 BASIC SUCTION UNIT

The support bracket has been designed and manufactured only to fix and charge the NEW ASKIR 118 BASIC suction unit; no other device can be secured to this system.
The seal efficiency and charge of the device is guaranteed only for this surgical suction unit model.

Insertion and extraction operations of the suction unit:

- Take the NEW ASKIR 118 BASIC suction unit;
- Place the device on the support bracket pulling the seal hook. Try to fit it inside the section on the bottom of the device;
- Before removing your hands from the suction device, make sure that it is fixed correctly (pull the handle of the device upwards and check the correct position of the device on the bracket);
- To remove the suction unit from the bracket, pull the seal hook and remove the suction unit from the section on the bottom of the device. Firmly hold the device and remove it from the bracket placing it in a safe point.

Once the suction unit has been fitted in the support bracket, make sure that the charge is in progress by checking the signal as indicated in TAB. I and TAB. II.

The charge time of the internal battery (fully discharged) with support bracket must last about 6 hours (360 minutes) with the device switched off (not running). Always charge the battery after each use. The continuous charge of the battery does not damage the internal battery but allows maximum autonomy.

SUPPORT BRACKET FUNCTIONAL TEST

All test described here allow the user to check the efficiency of support, proper charging of the vacuum cleaner and / or the need for intervention by the service technician. This check must be performed at least once a day, and always weekly.

- Check the operation of the bracket (without suction unit) by repeatedly acting on the seal hook. The movement must be free from obstructions.
- Always make sure that the fixing screws are tightened correctly;
- Fit the suction unit in the bracket as indicated in Chapter "Securing the NEW ASKIR 118 BASIC suction device;
- Visually check (as in TAB.II) that the LED lights up to indicate that the internal battery on the central panel is recharging.

In the event one or more phases fail, refer to the technical service.
Do not tamper with mechanical and/or electrical parts as this may affect the safety and efficiency of the device.
No electrical and/or mechanical part of the support bracket has been designed to be repaired by the manufacturer, customer, and/or user. Always refer to the authorised technical service.

MAINTENANCE AND REUSE

Once the device has been fitted in the bracket, always make sure that, upon activation, the LED confirms the charge in progress of the internal battery.
When using emergency vehicles, always check the housing of the suction unit in the support bracket at the end of the intervention.
In case of accidents or collisions of the emergency vehicle, always request the authorised technical service to check the support bracket and the suction unit.

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

This section contains information regarding the conformity of the compliance with the EN 60601-1-2 (2015) Standard.
The NEW ASKIR 118 BASIC surgical aspirator is an electro-medical device that requires particular precautions regarding electro-magnetic compatibility and which must be installed and commissioned according to the electro-magnetic compatibility information supplied. Portable and mobile radio communication devices (mobile phones, transceivers, etc.) may interfere with the medical device and should not be used in close proximity with, adjacent to or on top of the medical device. If such use is necessary and unavoidable, special precautions should be taken so that the electro-medical device functions properly in its intended operating configuration (for example, constantly and visually checking for the absence of anomalies or malfunctions). The use of accessories, transducers and cables different to those specified, with the exception of transducers and cables sold by the appliance and system manufacturer as spare parts, can lead to an increase in emissions or in a decrease of the immunity of the device or system..

Guidance and manufacturer's declaration – electromagnetic Emissions		
The surgical aspirator NEW ASKIR 118 BASIC is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator NEW ASKIR 118 BASIC 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 ASKIR 36BR 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 118 BASIC 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 EN 61000-3-2	Class [A]	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator NEW ASKIR 118 BASIC is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator NEW ASKIR 118 BASIC should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 8kV on contact ± 15kV in air	The device doesn't change its state	Floors should be wood, conceret or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4	± 2kV power supply lines ± 1kV for input / output lines	The device doesn't change its state	Mains power quality should be that of a typical commercial environment or hospital.
Surge EN 61000-4-5	± 1kV differential mode	The device doesn't change its state	Mains power quality should be that of a typical commercial environment or hospital.
Loss of voltage, brief voltage interruptions and variations EN 61000-4-11	5%U_T (>95% dip U_T) for 0.5 cycle 40%U_T (>60% dip U_T) for 5 cycle 70%U_T (>30% dip U_T) for 25 cycle <5%U_T (>95% dip 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 118 BASIC request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field EN 61000-4-8	30 A/m	The device doesn't change its state	The power frequency magnetic field should be measured in the intended installation location to assure that it's sufficiently low.
Nota U_T is the value of the power supply voltage			

Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator NEW ASKIR 118 BASIC is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator NEW ASKIR 118 BASIC should assure that it's used in such an environment.			
Immunity Test	**Level indicated by the EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted Immunity EN 61000-4-6	3Vrms 150kHz to 80Mhz (for non life-supporting devices)	V_1 = 3 V rms	The portable and mobile RF communication devices, including cables, must not be used closer to the NEW ASKIR 118 BASIC device, than the separation distance calculated by the equation applicable to the transmitter frequency. Recommended separation distance d = [3.5 / V_1] $\sqrt{P}$ d = [12 / E_1] $\sqrt{P}$ from 80 MHz to 800MHz d = [23 / E_1] $\sqrt{P}$ from 800 MHz to 2.7 GHz Where P is the maximum nominal output voltage of the transmitter in Watt (W) depending on the manufacturer of the transmitter and the recommended separation distance in metres (m). The intensity of the field from the fixed RF transmitters, as determined by an electro-magnetic study of the site[a], could be lower than the level of conformity of each frequency interval [b]. It is possible to check for interference in proximity to devices identified by the following symbol: 
Radiated Immunity EN 61000-4-3	3V/m 80MHz to 27GHz (for non life-supporting devices)	E_1 = 3 V / m	

Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied
Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by reflection from buildings, objects and people.

a) The field intensity for fixed transmitters such as the base stations for radiotelephones (mobile and cordless) and terrestrial mobile radio, amateur radio devices, radio AM and FM transmitters and TV transmitters can not be theoretically and accurately foreseen. To establish an electro-magnetic environment generated by fixed RF transmitters, an electro-magnetic study of the site should be considered. If the field intensity measured in the place where the device will be used surpasses the above mentioned applicable level of conformity, the normal functioning of the device should be monitored. If abnormal performance arises, additional measures such as changing the device's direction or positioning may be necessary.

b) The field intensity on an interval frequency of 150 kHz to 80 MHz should be less than 3 V/m.

Recommended separation distance between portable and mobile radio-communication devices and the monitor

The NEW ASKIR 118 BASIC surgical aspirator is intended to operate in an electro-magnetic environment where RF irradiated interferences are under control. The client or operator of the NEW ASKIR 118 BASIC device can help prevent electro-magnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and the NEW ASKIR 118 BASIC device, as recommended below, in relation to the radio-communication maximum output power.

Maximum nominal output power of the Transmitter W	**Separation distance from the frequency transmitter (m)**		
	150 kHz to 80 MHz d = [3.5 / V_1] $\sqrt{P}$	80 MHz to 800 MHz d = [12/E_1] $\sqrt{P}$	800 MHz to 2.7 GHz d = [23/E_1] $\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters with a maximum nominal output power not shown above, the recommended separation distance in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the maximum nominal output power of the transmitter in Watt (W) depending on the transmitter's manufacturer.

Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied

Note 2: These guide lines may not be applicable in all situations. The electro-magnetic propagation is influenced by the absorption and by the reflection from buildings, objects and people.

WARRANTY CONDITIONS

This product is guaranteed for a period of **24 months** from the date of purchase. The warranty includes the repair or replacement of defect spare parts free of charge, if the defect has been clearly described by the customer and determined by technical service. Inspections on the part of the seller, performed at the request of the customer and intended to determined wjether the device is fully functional, are not covered by the free-of-charge warranty service. This service will be charged to the customer depending on the effort required. The consumables components are not subject to warranty. Consumable components are silicon tubes, filters, seals, conical adaptor and suction catheter. Also exluded from warranty is all damage resulting from improper handling, wilful damage or improper care of the device.
The warranty shall expire if repairs and servicing are not carried out by technical service.

RULES FOR RETURNING AND RAPAIRING

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.

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 expence.

Italian
Medical
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Certificato di Garanzia / Warranty Certificate

Apparecchio tipo / Device model _____

Lotto di produzione / Lot _____ n° serie / serial number _____

Acquistato in data / Purchasing date _____

Rivenditore / Authorized Dealer _____

Via / Street _____ Località / Place _____

Venduto A / Purchased By _____

Via / Street _____ Località / Place _____

Descrizione del Difetto / Defect description _____

Timbro del Rivenditore / Retailer's stamp

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