SUCTION UNIT NEW ASKIR36 BR

USER MANUAL

CE 0123

ASKIR 36BR is a surgical aspirator with the following electrical features : 14V 4A with AC/DC adapter mod. UE60-140429SPA3 of FUHUA (input: 100-240V**~ -** 50/60Hz - 100VA) or Internally powered equipment (Pb Battery 12V 4A) or with cigarette lighter adapter (12V 4A). ASKIR 36BR is a desk-type electric suction unit for the aspiration of body liquids, oral, nasal and tracheal aspiration in adults or children. The appliance is designed for easy transport and almost continuous use.
The unit is operated by means of an electronic power management system, also monitoring the internal battery operation and status. Provided with acoustic alarm and LED system indicating low battery level and battery charge status. The unit is equipped with suction regulator on the front panel and polycarbonate autoclavable jar complete with overflow valve. Thanks to these characteristics and to its functions, this device is particularly suitable for different applications: utilization in hospital wards, for tracheotomy, for suction of body liquids and for minor surgery.

GENERAL WARNING

READ INSTRUCTION MANUAL CAREFULLY BEFORE USE

ONLY HIGHLY QUALIFIED STAFF USE RESERVED

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

IMPORTANT SAFETY RULES

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;
Do not place or store the aspirator in places where it may fall or be pulled into the bathtub or washbasin. In the event it is accidentally dropped, do not attempt to remove the device from the water whilst the plug is still connected: disconnect the mains switch, remove the plug from the power supply and contact the CA-MI technical service department. 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.
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.
In general, it is inadvisable to use single or multiple adapters and/or extensions. Should their use be necessary, you must use ones that are in compliance with safety regulations, however, taking care not to exceed the maximum power supply tolerated, which is indicated on the adapters and extensions.
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 ASKIR 36BR 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 (not 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.
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.
13. The lead battery integrated in the device is not to be considered as an ordinary domestic waste. Such a component must disposed of in a specific collection centre in order to be recycled.

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.

IMPORTANT INFORMATION FOR CORRECT DISPOSAL OF THE PRODUCT IN ACCORDANCE WITH EC DIRECTIVE 2002/96/EC:

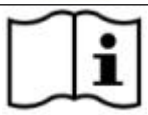
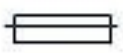
In respect of art. 13 Decreto Legislativo 25 Luglio 2005, n.151 "Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal"
The symbol as over applied on the device or its packaging 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.

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.

TECHNICAL CHARACTERISTICS

Model	**ASKIR 36BR**
Typology (MDD 93/42/EEC)	Class IIa Medical device
UNI EN ISO 10079-1 Classification	HIGH VACUUM / HIGH FLOW
Power Feeding	14V 4A with AC/DC adapter mod. UE60-140429SPA3 of FUHUA (input: 100-240V~ - 50/60Hz - 100VA) or Internally powered equipment (Pb Battery 12V 4A) or with cigarette lighter adapter (12V 4A)
Current Consumption	4.0A
Maximum Suction Pressure (without jar)	-80kPa (- 0.80 bar)
Minimum Suction Pressure (without jar)	Less -40kPa (-0.40 bar)
Maximum Suction Flow (without jar)	36 l /min
Weight	4.39 Kg
Insulation Class (when used with the AC/DC adapter mod. UE60-140429SPA3)	Class I
Insulation Class (when used with an Internal battery)	Internally Powered Equipment
Insulation Class (when used with a car cigarette lighter cable)	Class II
Size	350 x 210 x 180 mm
Battery Holding Time	60 minutes
Battery Time Charge	240 minutes
Accuracy of Vacuum Indicator	± 5%
Working Condition	Room temperature: 5 ÷ 35 °C Room humidity percentage: 10 ÷ 93 % RH Atmospheric pressure: 800 ÷ 1060 hPa
Conservation condition and Transport	Room temperature: - 25 ÷70 °C Room humidity percentage: 0 ÷ 93% RH Atmospheric pressure: 500 ÷ 1060 hPa

SYMBOLS	
	Class II isolation equipment (only when connected to a car cigarette lighter cable)
CE 0123	CE marking in conformity with EC directive 93/42/EEC and subsequent changes
	Warning, consult the instruction manual
	Consult the instruction manual
	Manufacturer: **CA-MI S.r.l.** Via Ugo La Malfa nr.13 – 43010 Pilastro (PR) Italia
	Keep in a cool, dry place
	Conservation temperature: -40 ÷ 70°C
	Applied Part type BF (suction probe)
	Battery
	Fuse
	DEHP Phthalates (Suction catheter)
	On / Off
Hz	Mains Frequency
I	ON
O	OFF
	Batch Production
	Serial Number
	Model / Ref Number
IP 21	Degree of protection an electrical device provides in the case of accidental or i ntentional contact with the human body or with objects, an protection in the case of contact with water. **1st DIGIT PENETRATION OF SOLIDS** / **2nd DIGIT PENETRATION OF LIQUIDS** Protected against solids having a dimension greater than Ø 12mm / Protected against the vertical

CLEANING OF THE 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).

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 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 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.

WARNING: The medical device is provided without a specific suction probe. If this device must be used with a specific suction probe, the end user is responsible for making sure it complies with the EN 10079-1 regulation.

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 1000 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

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 leakages or liquid exit

After disposing of disposable parts and disassembling the jar wash in running cold water and rinse thoroughly.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 – 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

MAINTENANCE

The **ASKIR 36BR** 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 and AC/DC switching adapter , 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 – 80kPa (-0.80 bar) minimum (internal battery). 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. 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 made up of a lead battery which cannot be accessed by outside. In order to replace it, consult the technical staff authorised by the manufacturer.

Fault type	Cause	Solution
1. Red light on	Battery run down	Hook up the power cord to the electricity mains, positioning the equipment power switch on 0.
2. No light	Defective AC/DC adapter or technical internal 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 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 Contact the technical service
10. Noisy	Technical internal problem	Contact 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**

The device is made up of a lead battery which cannot be accessed by outside. In order to replace it, consult the technical staff authorised by the manufacturer.

USE ONLY THE RECOMMENDED BATTERIES FROM CA-MI. THE USE OF OTHER BATTERIES ARE NOT RECOMMENDED AND INVOLVING THE CANCELLATION OF WARRANTY

In the event that the service personnel has to replace the internal battery, pay special attention to the polarity of the same component. The + / - polarities are indicated directly on the battery.

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.

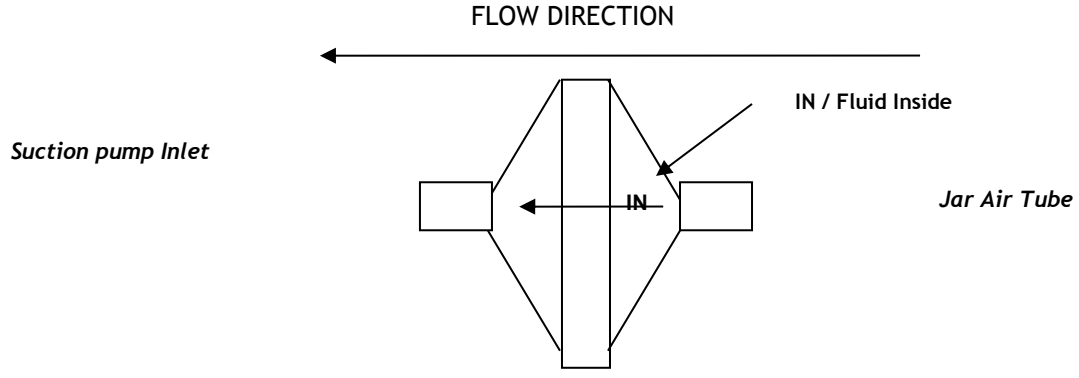
BEFORE EVERY CHECKING OPERATION, IN CASE OF ANOMALIES OR BAD FUNCTIONING, PLEASE CONTACT CA-MI TECHNICAL SERVICE. CA-MI DOES NOT GIVE GUARANTEE IF INSTRUMENT, AFTER THE TECHNICAL SERVICE CHECKING, APPEARS TO BE TAMPERED.

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.
Operation using with AC/DC switching adapter
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 and insert the power cable plug to the power socket. To start the treatment press the **I** switch to turn it on
Set the desired vaccum value (Bar / kPa) 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.

Filter assembling

Mod: NEW ASKIR 36BR



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.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the state of the protective conductor of the installation, to which the medical device in question is connected, appear to be dubious, the use of equipment with a internal battery is recommended.

The power supply cable plug is the element of separation from the electrical mains system: even if the units equipped with a special on / off switch button, the power supply plug must be kept accessible once the device is in use so as to allow a further method of disconnection from the mains supply system.

Operation using cigarette lighter DC 12V
Connect the device’s external plug 12V to the ligther plug with the cigarette lighter cable. Check the battery power status of the vehicle before the cigarette lighter cable. Press the switch to start suction
Press the switch to the **I** position to turn it on.

WARNING: **Only use the originally supplied or recommended replacement cigarette ligther cables (view the chapter “Important Safety Rules”)**

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. UE 60140429SPA3 of FUHUA) to the electric network for approx. 120 to 150 minutes with the main switch to position 0. The battery’s autonomy when fully charged is approx. 60 minutes with continued operations.

TAB. I – INDICATOR LIGHTS DURING OPERATIONS

When an external power supply (regardless of the state of the battery charger) and when the device is working (after having turned it on), the LED stays in a FIXED GREEN position.

LED Signal	Phase	Problem / Cause	Solution
Flashing Green Led	During rechanrge	Battery recharge running	Wait
Steady Greed Led	During recharge	Recharging cycle complete	Remove power supply
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 Orange Led	During battery operation	Intermediate status	Guaranteed battery function / Recharge when the red LED signal comes on.

NEVER USE THE DEVICE WITHOUT JAR AND / OR PROTECTION FILTER

RISK OF ELECTROMAGNETIC INTERFERENCE AND POSSIBLE REMEDIES

This section contains information regarding the conformity of the compliance with the EN 60601-1-2 Standard.
The ASKIR 36BR 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. The following tables supply information regarding the EMC (Electromagnetic Compatibility) characteristics of the electro-medical device.

Guidance and manufacturer's declaration – electromagnetic Emissions		
The surgical aspirator ASKIR 36BR is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator ASKIR 36BR 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 ASKIR 36BR 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 ASKIR 36BR is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator ASKIR 36BR 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) IEC/EN 61000-4-2	± 6kV on contact ± 8kV 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%UT (>95% dip UT) for 0.5 cycle 40%UT (>60% dip UT) for 5 cycle 70%UT (>30% dip UT) for 25 cycle <5%UT (>95% dip UT) for 5 sec	-	Mains power quality should be that of a typical commercial environment or hospital If the user of the surgical aspirator ASKIR 36BR request that the appliance operates continuously, the use of a continuity unit is recommended.
Magnetic field EN 61000-4-8	3A/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 UT is the value of the power supply voltage			

Guidance and manufacturer's declaration – Immunity Emissions			
The surgical aspirator ASKIR 36BR is intended for use in the electromagnetic environment specified below. The customers or the user of the surgical aspirator ASKIR 36BR 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 lifesupporting devices)	V1 = 3 V rms	The portable and mobile RF communication devices, including cables, must not be used closer to the ASKIR 36BR device, than the separation distance calculated by the equation applicable to the transmitter frequency. Recommended separation distance d = [3.5 / V1] *P* d = [12 / E1] *P* from 80 MHz to 800MHz d = [23 / E1] *P* from 800 MHz to 2.5 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), could be lower than the level of conformity of each frequency interval b).
Radiated Immunity EN 61000-4-3	3V/m 80MHz to 2.5GHz (for non lifesupporting devices)	E1 = 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 ASKIR 36BR surgical aspirator is intended to operate in an electro-magnetic environment where RF irradiated interferences are under control. The client or operator of the ASKIR 36BR device can help prevent electro-magnetic interference by keeping a minimum distance between the portable and mobile RF communication devices (transmitters) and the ASKIR 36BR 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 2.5 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 whether 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 excluded 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 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.

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.