SINCE 1966
MADE IN ITALY

Aspira go

by FLAEM®

BATTERY-OPERATED PORTABLE SURGICAL ASPIRATOR

INSTRUCTION FOR USE MANUAL

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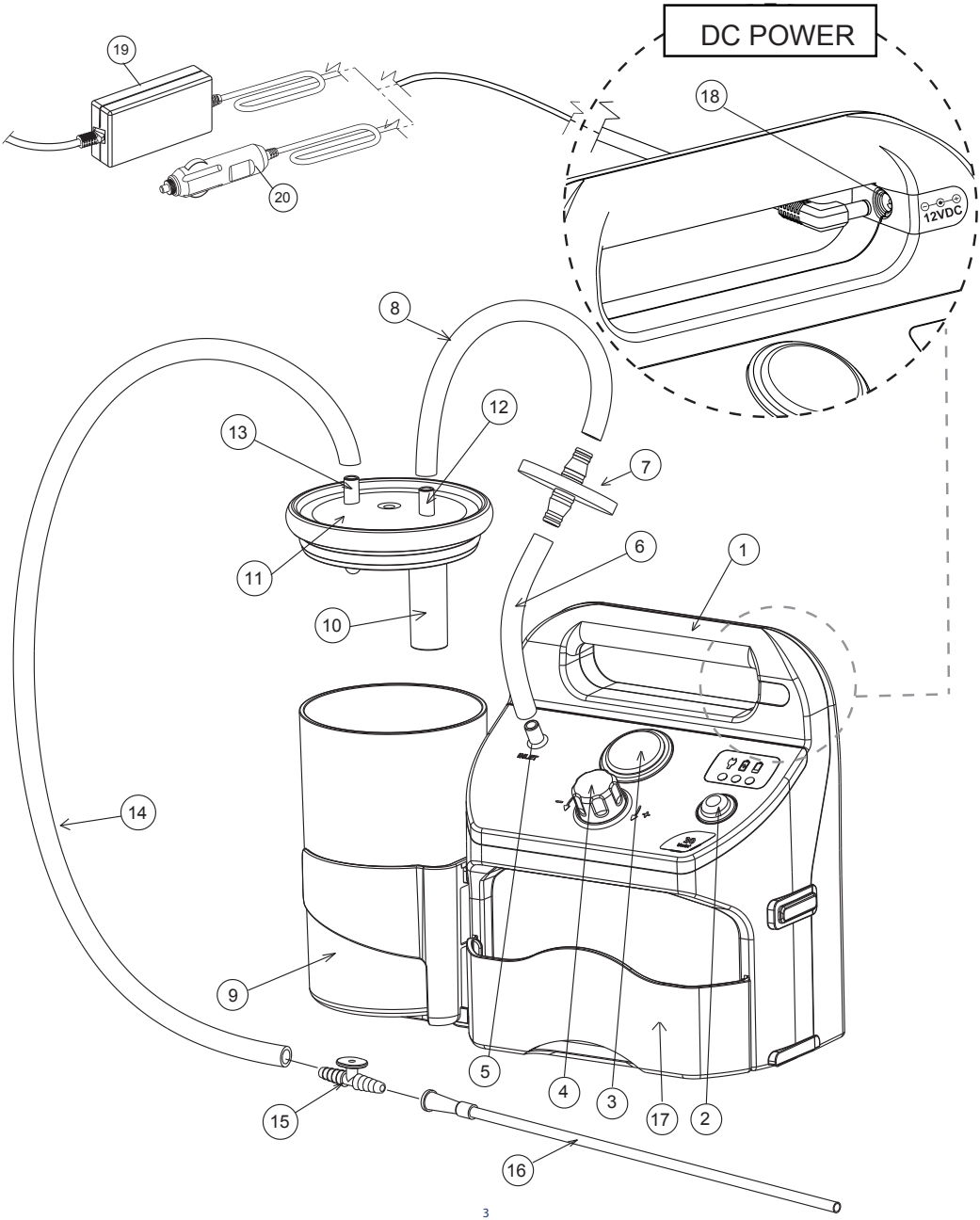
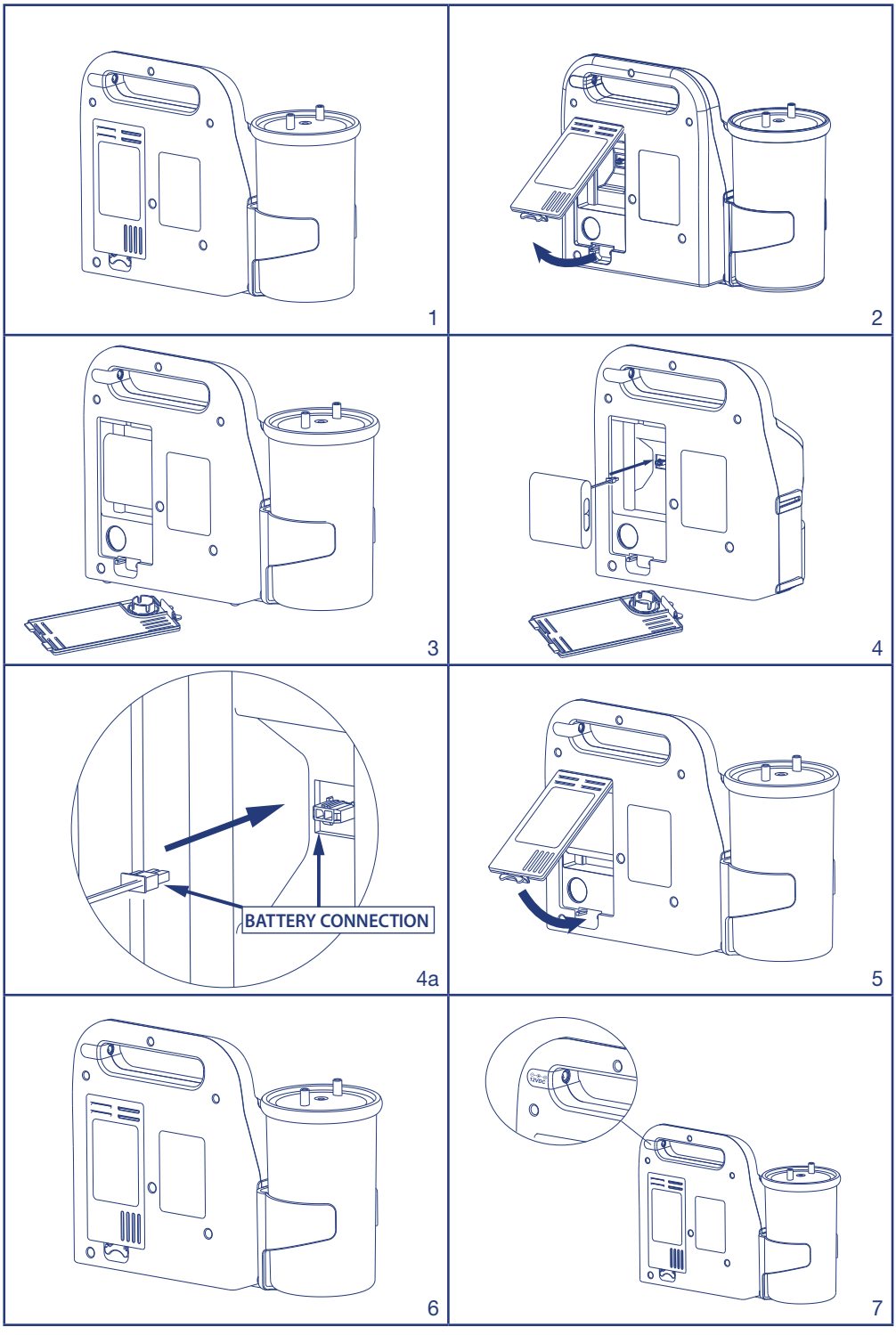
quality for life®

CONNECTION DIAGRAM




1
2
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BATTERY CONNECTION
4a
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GB

Mod. P1611EM-20 / Mod. P1611EM-30

We are pleased you have purchased our product and we thank you for your trust in us. It is very important that the health care worker and/or the patient read and understand the information for use and maintenance.

ENGLISH

INTENDED USE

ASPIRA Go is an aspirator designed for medical and surgical use in healthcare centres such as hospitals and for home care for pharyngeal suction and during transportation. The device generates suction (aspiration) which allows fluids to be extracted through single use tubing connected to a collection canister which retains the fluids until they can be properly disposed of. Use of the device must be prescribed by a doctor.

Carefully follow the user and maintenance instructions to ensure proper functioning and to extend the life of the device.

ASPIRA Go (1) is equipped with a vacuum flow adjustment knob (4), vacuum gauge (3) and 1000 ml canister (9) with inflow safety device (10) to prevent fluids from entering the suction pump. This device interrupts the vacuum flow via a float-controlled valve found in the canister lid. It does not require lubrication, is manageable, simple to use, reliable, resistant and quiet. This model comes with a rechargeable battery. ASPIRA Go is equipped with the following FLAEM accessories: 1000 ml canister (9) with inflow safety device (10), Power cable for vehicle power outlets (20), multi-voltage power supply (19), Connection tubes (6/8/14), Disposable cannula for aspirator (16), Disposable manual aspirated flow control (15) and Hydrophobic antiviral/antibacterial filter for single patient use (7).
Note: Use only original FLAEM accessories

DEVICE NOMENCLATURE

1) SUCTION MACHINE
2) ON/OFF SWITCH
3) VACUUM GAUGE
4) VACUUM FLOW ADJUSTMENT KNOB
5) AIR INLET
6) CONNECTING TUBING
7) HYDROPHOBIC ANTIVIRAL/ ANTIBACTERIAL FILTER (FOR SINGLE PATIENT USE)
8) CONNECTING TUBING
9) COLLECTION CANISTER
10) SAFETY DEVICE
11) CANISTER LID
12) CANISTER "VACUUM" INLET
13) CANISTER "PATIENT" INLET
14) CONNECTING TUBING
15) MANUAL VACUUM FLOW CONTROL
16) ASPIRATOR TIP
17) ACCESSORY COMPARTMENT
18) EXTERNAL POWER OUTLET
19) MULTI-VOLTAGE POWER SUPPLY
20) VEHICLE POWER OUTLET CABLE

⚠ IMPORTANT WARNINGS

The manufacturer makes every effort to ensure that every product is of the highest quality and safety; however, as for any electrical device, basic safety regulations must always be followed in order to avoid harming persons and things.

- **The medical device must NOT be used in the operating theatre, for drainage or for thoracic drainage.**
- Before using the product for the first time, and periodically during its lifetime, check the integrity of the device structure and of the power cable to make sure there is no damage. In the event of damage, do not plug in the cable and immediately take the product to an authorised FLAEM service centre or to your local dealer.
- Do not perform any maintenance operations while the device is being used on a patient.
- In the presence of children and non self-sufficient individuals, the device must be used under the close supervision of an adult who has read this manual.
- Some parts of the device are small enough to be swallowed by children; keep the device out of the reach of children.
- Do not use the provided tubing and cables for any other purpose than those specified, as they can cause risk of strangulation. Be particularly attentive with children and individuals with disabilities because they are often unable to correctly assess risk.

- The suction machine is intended exclusively for the collection of NON-flammable fluids. It is not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.
- Always keep the power supply and the power cable away from hot surfaces.
- Keep the power supply cable away from animals (for example, rodents) which could damage the insulation.
- Do not immerse the device in water; in the event of immersion disconnect the plug immediately. Do not remove or touch the immersed device; unplug the power cable first. Immediately bring the device to an authorised FLAEM service centre or to your trusted dealer.
- The device, power supply and battery casing are not waterproof. Do not wash the device under running water or by immersion and keep it safe from being sprayed by water or other liquids.
- Do not expose the device to particularly extreme temperatures.
- Keep the device and power supply away from sources of heat, direct sunlight or excessively hot places.
- Repairs must be done only by authorised FLAEM personnel. Unauthorised repairs void the warranty and may be hazardous for the user.

ATTENTION: Do not modify this device without authorisation from the manufacturer.

- The Manufacturer, the Vendor and the Importer shall be held responsible for safety, reliability and performance only if: a) the device is used in compliance with the instructions for use b) the wiring where the device is being used is in compliance with safety regulations and current laws.
- The Manufacturer must be contacted to communicate unexpected problems/events related to functioning.
- Ensure that the connection tubing and the canister lid have been carefully sealed in order to avoid loss of suction.
- Do not upset the canister while the device is working as the liquid may be aspirated into the device, damaging the pump. Should this occur, immediately switch off the suction machine, then empty and clean the canister (send it to an authorised FLAEM service centre).
- When the safety device (10) intervenes, suction is halted. Switch off the device, empty the canister (9) and carry out the cleaning procedure.
- We recommend personal use of accessories, collection canisters and connection tubing to prevent the risk of contagious infection.
- The aspirator tip and the manual vacuum flow control are single use sterilised products and must be replaced after each use.
- Check the expiration date on the original aspirator tip packaging and make sure the sterile packaging is intact. FLAEM NUOVA declines any responsibility for harm to the patient correlated to the deterioration of the aforementioned sterile packaging due to third party handling during the original packaging of the entire device.
- The 12V DC power cable for vehicle power outlets is equipped with a safety fuse, which can be inspected in the event of a fault.
- The power supply provided has been specifically designed for use with the Aspira Go series aspirators. Never use the power supply with other devices or for uses other than that specified in this manual and never use the Aspira Go series aspirators with other power supplies.

INSTRUCTIONS FOR USE

Before each use, the accessories must be carefully inspected to ensure the absence of dust, incrustation, clots or liquid substances both inside the connecting tubing and in the canister and its respective lid. Furthermore, they must be cleaned following the instructions rigorously as stated in the "CLEANING, SANITISATION, DISINFECTION, STERILISATION" paragraph. We recommend personal use of the accessories, the collection canisters and the connecting tubing to prevent risk of contagious infection.

1. Operation with internal battery:

1.1. The device is supplied with the battery partially charged and it is recommended to charge it before use. Insert the battery as shown on page 1. Release, lift and remove the lid of the battery compartment located at the back of the device (dwg.1,2,3); insert the battery, fitting the connector properly (dwg.4,4a); put the battery compartment lid back in place and close it (dwg.5,6). Recharge the battery by following the instructions in section 2.3.1.

1.2. Switch the device on by pressing the switch (2).

1.3. At the end of each suction procedure, always turn the switch (2) to 0 (even if the battery is flat) to save the battery life. If during use the red LED (1c) flashes and the buzzer sounds, it means that the device's battery charge is about to run out, in this case recharge the device as soon as possible.

ATTENTION: periodically check the battery status so that you are never in a situation requiring the device urgently without being able to rely on the internal power source

2. <u>Operation and charging with the vehicle power outlet (12V DC), or with the multi-voltage power supply</u>:

2.1. Vehicle power outlet cable (12V DC) (20):

2.1.1. Using the vehicle power outlet cable (20), connect the external device socket (18) to the vehicle power outlet. Check the battery charge status of the vehicle or boat before connecting the power outlet cable.

2.1.2. Switch the device on by acting on the switch (2); the operation is displayed by the activation of the green LED (1a). The device is designed for an intermittent use of 30 min ON/30 min OFF.

2.2. Multi-voltage power supply (switching) (19).

2.2.1. Connect the connector to the external device socket (18). Plug the power cable into the mains socket that is compatible with the device voltage. The position of the socket must be such that the device can be easily unplugged from the mains network. In the event that the power cable plug is unsuitable for the mains socket, contact the dealer or an authorised service centre.

2.2.2. Repeat the instructions in section 2.1.2

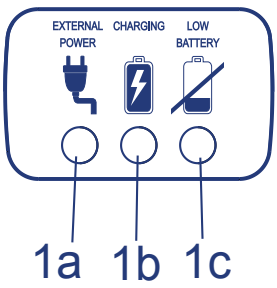
2.3. <u>Charging the internal battery using the vehicle power outlet cable or multi-voltage power supply:</u>

Check the battery charge status of the vehicle or boat before connecting the power outlet cable.

2.3.1. The battery is charged by leaving the vehicle power outlet cable or the multi-voltage power supply (19) connected to the external device socket (18). The activation of the green LED (1a) and of the yellow LED (1b) indicate that the internal battery is charging.

Charge the device for 24 hours the first time it is used; subsequently 7 hours (minimum) are sufficient to charge model P1611EM-20 and 4 hours (minimum) for model P1611EM-30.

LED FUNCTIONS



GREEN LED (1a): when it is switched on it means that the external power supply is connected (12VDC), i.e. the switching power supply has been inserted in the device socket (18).

YELLOW LED (1b): when it is switched on it means that the battery is charging while when it is switched off it means that the battery is charged and ready for use*.

Only for model P1611EM-30: of the YELLOW LED (1b) flashes is means that the battery is not connected and/or is not connected to the circuit properly (see dwg. 4, 4a, 4b).

RED LED (1c): flashing and acoustic alarm active, both mean that the battery is about to run out and must be charged as soon as possible.

***IMPORTANT:** to charge the battery insert the power supply plug (12VDC) into the device socket (18).

REPLACING THE BATTERY

To replace the battery, follow the instructions on page 1. Release, lift and remove the lid of the battery compartment located at the back of the device (dwg.1,2,3); remove the battery to be replaced and insert the new one, fitting the connector properly (dwg.4,4a); put the battery compartment lid back in place and close it (dwg.5,6). Then charge the battery following the instructions in section 2.3.1.

Flat batteries must be disposed of in special waste collection containers, or by contacting a suitable waste disposal centre.

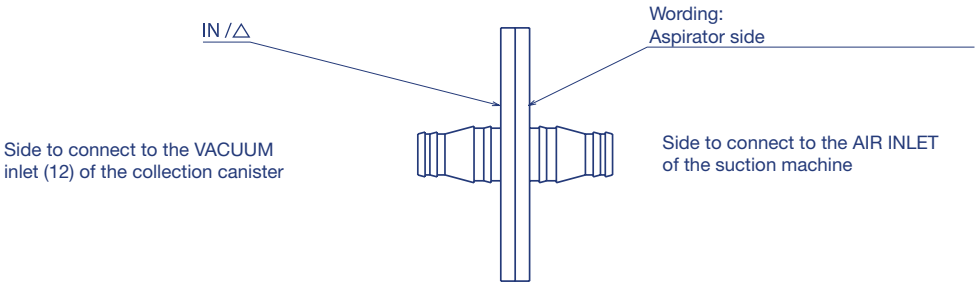
It is forbidden to use batteries other than those provided with the medical device. If necessary contact an authorised FLAEM service centre.

3. Instructions for suction on the patient:

3.1. Connect the accessories, referring to the "CONNECTION DIAGRAM" on the cover.

ATTENTION: in addition to being antibacterial/antiviral, the hydrophobic filter also acts as secondary protection device and stops any fluids that the primary safety device in the canister lid cannot manage to stop.

Follow the directions below for proper filter assembly:



3.2. Switch the device on by following the instructions for the required operation. Always use the device on a flat surface; this will ensure the proper operation of the inflow safety device to prevent the inflow of fluid in the suction device.

3.3. For more comfortable aspirations, set the desired vacuum value (bar) using the vacuum regulator (4). Turn the knob clockwise to increase vacuum and turn it anticlockwise to decrease vacuum; these values can be read on the "vacuum gauge" instrument (3).

3.4. Place your finger on the manual vacuum flow control (15) and, activating it in pulses, begin suction on the patient using the aspirator tip.

3.5. Once the process is complete, switch off the device.

3.6. Empty and clean the canister and connecting tubes.

CLEANING, SANITISATION, DISINFECTION, STERILISATION

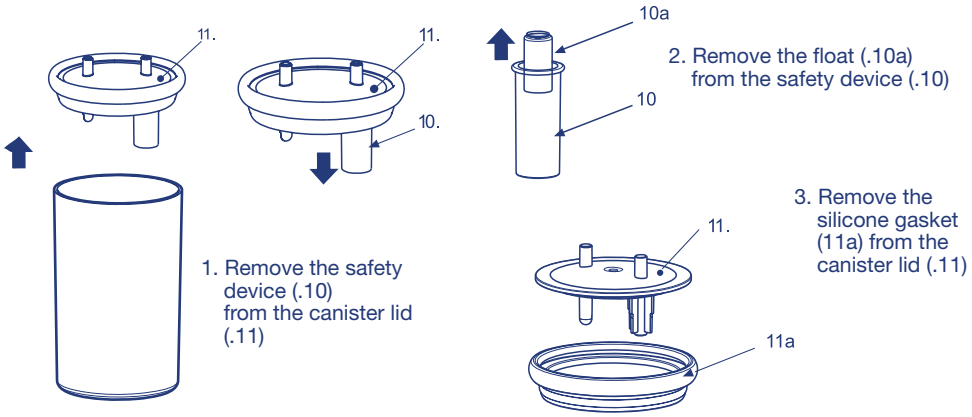
Switch off the device before any cleaning procedure and unplug the power cable from the socket.

DEVICE CLEANING

Use only a damp cloth with antibacterial soap (non-abrasive and with no solvents of any sort).

COLLECTION CANISTER AND CONNECTING TUBING

- Detach the aspirator tip (16), the manual vacuum flow control (15) and the tubing (14) from the canister (9). Disconnect the tubing (6/8) from both the canister and the filter (7). Remove the canister from its holder, keeping it upright, and empty it (in the WC at home, in the biological waste container in the hospital) and clean it, disassembling it as shown below:



SANITISATION

Before and after each use, sanitise the collection canister and the connecting tubing choosing one of the methods described below.

(method A): rinse each part (6,8,9,10,10a,11,11a,14) with hot potable water (approximately 40°C) with gentle washing up liquid (non-abrasive) or in the dishwasher on a hot cycle.

(method B): soak each part (6,8,9,10,10a,11,11a,14) in a solution of 50% water and 50% white vinegar. Finally, rinse with plenty of hot potable water (approximately 40°C).

(method C): boil each of the parts (6,8,9,10,10a,11,11a,14) in water for 20 minutes; it is preferable to use de-mineralised or distilled water to prevent calcium deposits.

After having sanitised the accessories, shake them vigorously and place them on a paper towel. Alternatively, dry them with a jet of hot air (for example, a hair dryer).

DISINFECTION

The accessories which can be disinfected are (6,8,9,10,10a,11,11a,14)

The disinfection procedure described in this paragraph is to be followed before using the accessories. It is effective on the parts that undergo this treatment only if each step is followed and only if the parts to be treated have previously been sanitised.

The disinfectant must be an electrolytic chloroxidizer (active principle: sodium hypochlorite) specific for disinfecting, which is available in any pharmacy.

Procedure:

- Fill a container big enough to hold all of the parts to disinfect with a solution of potable water and disinfectant, according to the proportions indicated on the packaging of the disinfectant.
- Completely immerse each part in the solution, taking care to avoid the formation of air bubbles on the parts. Leave the parts immersed for the amount of time indicated on the packaging of the disinfectant associated with the concentration chosen for the solution.
- Remove the disinfected parts and rinse abundantly with warm potable water.
- After having disinfected the accessories, shake them vigorously and place them on a paper towel. Alternatively, dry them with a jet of hot air (for example, a hair dryer).
- Dispose of the solution following the instructions provided by the disinfectant manufacturer.

STERILISATION

The accessories that can be sterilised are (6,8,9,10,10a,11,11a,14)

The sterilisation procedure described in this paragraph is effective on the parts that undergo this treatment only if every step is followed and only if the parts to be treated have previously been sanitised. The procedure is validated in its conformity to ISO 17665-1.

Device: Fractionated vacuum overpressure steam steriliser in accordance with standard EN 13060.

Procedure: Wrap every single part to be treated with a sterile barrier system or packaging in accordance with Norm EN 11607. Place the wrapped parts into the steam steriliser, ensuring that the canister (9) is in an upright position.

Following the device instruction manual, start the sterilisation cycle and select a temperature of:

- 134°C for 10 minutes for a maximum of 30 times for the SILICONE TUBES (6,8,14) and the GASKET (11a)
- 121°C for 15 minutes for a maximum of 50 times for the POLYCARBONATE CANISTER (9) and for components 10,10a, 11.

Storage: Store the sterilised parts as per the instructions for use of either the sterile barrier system or packaging.

After sanitising, disinfecting or sterilising, reassemble the canister and the connecting tubing following the directions provided in the "CONNECTION DIAGRAM".

- The aspirator tip and the manual vacuum flow control are single use sterilised products and must be replaced after each use.

FILTER

The hydrophobic/antiviral and antibacterial filter supplied with Flaem aspirators must be strictly replaced for each new patient, or if the said filter is saturated. Should the aspirator be used on the same patient, the filter for Single-patient use must be replaced within a maximum period of TWO MONTHS or if the filter is saturated. The filter cannot be sanitised, disinfected, or sterilised. It is in any case a good idea to sanitise and disinfect the device and the accessories, with the exception of the Filter, always after each use, whether it is for the same patient or for a new patient. The parts that can be sterilised, which are indicated in the user manual, must be sterilised every time the device is used for a new patient.

ACCESSORY COMPARTMENT

The accessory compartment (17) can easily be removed for thorough cleaning. See the disassembly sequence on page 2 in drawings 8-9-10-11.

CANISTER HOLDER

For convenience, the canister holder can be detached and reattached on the most suitable side (left or right). Using a tool (dwg.12) release the canister holder from the bottom of the device (dwg.13) and turn it so that is disengaged (dwg.14). Reattach it, repeating the procedure in the reverse order, on the chosen side.
Ensure that the canister holder is properly fastened to the bottom of the device. This system ensures the connection of up to two canister holders. (dwg.15)

ACCESSORY SPECIFICATIONS

- single-use hydrophobic antibacterial/antiviral filter
- PC collection canister w/ compl. lid
- Ø 13 x 7.5 mm L 1300 mm silicone tubing
- Ø 13 x 7.5 mm L 250 mm silicone tubing
- Ø 13 x 7.5 mm L 40 mm silicone tubing
- CH18 single use sterile aspirator tip
- manual vacuum flow control (single use)

MICROBIAL CONTAMINATION

In the presence of pathologies with the risk of infection and microbial contamination, we recommend personal use of the accessories, collection canister and connecting tubing (consult your doctor).

Interactions:

The materials used for contact with the secretions are highly stable and chemical resistant thermoplastic polymers (PP, PC, SI). We cannot, however, exclude interactions. Therefore, it is suggested: a) to always avoid prolonged contact of liquid with the canister or tubing and sanitise immediately after use. b) Should anomalous situations occur, i.e. softening or cracking of the accessories, quickly terminate the procedure and substitute the used materials. Contact the authorised service centre and specify how the product was used.

Note: Use only with original FLAEM accessories.

TECHNICAL SPECIFICATIONS

Mod. P1611EM-20 / P1611EM-30

Voltage	12V ⎓
Internal battery supplied:	2500 mAh; 14,8 V; lithium-ion 2500 mAh; 14,4 V; lithium-ion 2900 mAh; 14,4 V; lithium-ion
Battery autonomy:	approximately 45 minutes
Device size:	36 (W) x 14 (D) x 27 (H) cm
Weight: Use	2.5 Kg 30 minutes ON/ 30 minutes OFF

APPLIED PARTS

Type BF applied parts are:	patient accessories (16)
Operating conditions:	Temperature min. 0°C; max. 35°C Relative humidity min. 10%; max 95%
Storage conditions:	Temperature min. -5°C; max. 35°C Relative humidity min. 10%; max. 95%
Operating/storage atmospheric pressure:	min. 690 hPa; max. 1060 hPa

12 V VEHICLE POWER OUTLET POWER CABLE⎓
COD. 16667
In the event of a fuse failure, replace with a 5A - 250V approved fast fuse, size Ø 6.3 x 30 mm, by undoing the end of the plug to be inserted in the vehicle power outlet.

POWER SUPPLY MULTI-VOLTAGE - SWITCHING
COD. 16545
Primary: 100-240V ~ 50/60Hz
Secondary: 12V ⎓ 5 A 60W

	Mod. P1611EM-20	**Mod. P1611EM-30**
Suction:	high vacuum / high flow	high vacuum / high flow
Adjustable vacuum level:	from -0.10 a -0.80 bar (approx) (accuracy class 2.5)	from -0.10 a -0.85 bar (approx) (accuracy class 2.5)
Max air flow:	20 l/min (approx)	30 l/min approx
Noise (at 1 m)	63 dB (A) (approx)	62 dB (approx)
Battery charging time	minimum 7 hours	minimum 4 hours
Ambient temperature for battery charging	From 10°C to 35°C	

SYMBOLS

Class II device

Type BF applied part

Attention: check the instructions for use

Single use

More vacuum

Less vacuum

Socket for low safety voltage

STERILE EO — Ethylene oxide sterilisation

SN — Device serial number

TÜV approval ref. ISO 10079-1

Keep away from sunlight

Risk: electrocution.
Consequence: Death.
Do not use the device
while taking a bath or a shower

Switch on

Switch off

Direct current

Alternating current

CE 0051 — CE Marking medical ref. Dir 93/42
EEC and subsequent updates

LATEX — Without latex

Production year

Manufacturer

DEVICE DISPOSAL

In compliance with the Directive 2012/19/EC, the symbol printed on the device shows that the device to be disposed of is considered waste and must therefore be a "separate collection" item. Consequently, the user must take it (or have it taken) to the differentiated collection sites provided by the local authorities, or turn it in to the dealer when purchasing an equivalent new device. Differentiated waste collection and the subsequent treatment, recycling and disposal procedures promote the production of devices made with recycled materials and limit the negative effects on the environment and on health caused by potential improper waste management. The unlawful disposal of the product by the user could result in administrative fines as provided by the laws transposing Directive 2012/19/EC of the European member state or of the country in which the product is disposed of.

ELECTROMAGNETIC COMPATIBILITY

This device was designed to satisfy the currently required requisites for electromagnetic compatibility (EN 60 601-1-2:2007). Electro-medical devices require particular care during installation and use relative to EMC requirements. Users are therefore requested to install and/or use these devices following the manufacturer's specifications. There is a risk of potential electromagnetic interference with other devices, in particular with other analysis and treatment devices. RF mobile or portable radio and telecommunications devices (mobile telephones or wireless connections) can interfere with the functioning of electro-medical devices. For further information visit our website www.flaemnuova.it.
Flaem reserves the right to make technical and functional modifications to the product with no prior warning.

TROUBLE-SHOOTING

Switch off the device before any procedure and unplug the power cable from the socket.

PROBLEM	CAUSE	SOLUTION
The device does not work	- Battery flat	- Charge the battery
	- Battery not inserted properly	- Check that the battery connector is inserted properly
	- The power cable has not been inserted properly into the device socket or into the mains power socket	- Correctly insert the power cable into the sockets
Lack of suction	The collection cannister lid has not been correctly positioned on the cannister	- Correctly position the collection cannister lid
	Lid gasket not in place	- Correctly position the gasket on the lid
Lack of suction caused by fluid leakage	Blocked filter	- Replace the filter
Blocked float	Incrustation on the float	- Remove the cannister lid and safety device and extract the float. Continue by carrying out the cleaning procedures as described in the paragraph, "CLEANING, SANITISATION, DISINFECTION, STERILISATION"
Vacuum power poor and/or non-existent	Vacuum adjustment knob completely open	- Fully close the adjustment knob and check the vacuum power
	Blocked protection filter	- Replace the filter
	Connecting tubing to the filter and device clogged, bent or disconnected	- Check the condition of the tubing, replace it if blocked and correctly connect it as per the "ASSEMBLY DIAGRAM" of this manual
	Cannister lid overflow valve closed or blocked	- Unblock the overflow valve, keeping the device upright
	Dirty, blocked or damaged pump	- Take the device to your trusted dealer or an authorised FLAEM service centre

If, after checking the aforementioned conditions, the device still does not work properly, we recommend that you contact your local dealer or an authorised FLAEM service centre.