1 This user and maintenance manual applies to the following models of SURGICAL ELECTROASPIRATORS:

model	code
6110-A1 MAX	66191
6110-A1 MAX	66190-5L
6110-A1 CURET-MAX	66192
6110-A1 CURET-MAX	66192-5L
6110-A1 LIPO-MAX	66193
6110-A1 LIPO-MAX	66193-5L

model	code
6110-A2 SPEEDY	66194.1
6110-A2 SPEEDY	66194-5L
6110-A2 CURET-SPEEDY	66196
6110-A2 CURET-SPEEDY	66196-5L
6110-A2 LIPO-SPEEDY	66198
6110-A2 LIPO-SPEEDY	66197-5L

1.2 ASSISTANCE

Read the instruction manual before using the device.
This manual must be kept with the device for later reference.

1.3 SIGNS AND SYMBOLS - ISO 15223-1:2021(E)

CE 0051 In compliance with the 2017/745 MDR regulation concerning medical devices. Reference IMQ Spa - Milan	This symbol indicates an insulation class I device IEC 60601-1	This symbol indicates an insulation class II device IEC 60601-1
Symbol for "MANUFACTURING DATE" (4 digits for the year, 2 for the month and 2 for the day)	This Symbol indicates a **type B** applied part in compliance with IEC 60601-1	This Symbol indicates a **type Bf** applied part in compliance with IEC 60601-1
Indicates the medical device manufacturer, Regulation (UE) 2017/745	This symbol indicates alternating current	This symbol indicates direct current
This symbol indicates the pressure limitation for operation, transport and storage	This symbol indicates the moisture limitation for operation, transport and storage	This symbol indicates the temperature limitation for operation, transport and storage
MD This symbol indicates that the device is a medical device	UDI unique device identifier	# This symbol indicates the model of the medical device
REF This symbol indicates the reference number of the medical device	SN This symbol indicates the serial number of the medical device	This symbol indicates the footswitch
This symbol indicates that the manual must be read. ISO 7010	Please refer to the instructions for use or the electronic ISO 15223-1 instructions for use	Connection to the Equipotential Node of Medical Premises (Standard IEC64-8/7 Section 710)
This symbol indicates "warning or caution" with the use of the device	Do not reuse / for disposable use only ISO 15223-1	IP21 Degree of protection of the casing of the DM CEI EN 60529/1997
This symbol indicates that at the end-of-life, the device must be disposed of according to local disposal regulations	This symbol indicates to avoid wetting the device	This symbol indicates to avoid direct exposure of the device to sunlight

PRESSURE MEASURE UNIT CONVERSION TABLE
bar, KPa, cm Hg, cm H2O are all measure unit of pressure (vacuum)

	bar	KPa	cm Hg	cm H2O
1 bar	1	100	75.006	1019.72
1 KPa	0.01	1	0.75006	10.1972
1 cm Hg	0.133	1.333	1	13.595
1 cm H2O	0.098	0.00098	0.07355	1

1.4 APPLICATION

The SURGICAL ELECTROASPIRATORS listed under point 1 are approved exclusively for the use as described in this user and maintenance manual. SIEM – NOVA SRL can only guarantee the safe functioning of the devices when they are used with the SIEM – NOVA SRL accessories and components.

PLEASE READ AND OBSERVE THESE WARNINGS AND SAFETY INSTRUCTIONS BEFORE USING THE DEVICE.

Please note that these instructions for use are a general guide for the use of the device. Medical information must be addressed to a doctor.

WARNING: The product has been designed with particular attention to patient and user safety. Nevertheless, the following warnings must be observed.

IMPORTANT: Users must be able to read, understand and follow the directions in this manual and the instructions provided by your doctor. If you are dependent on the device for airway aspiration and stopping operation of the device may lead to a critical situation, you must have another device available that can operate in an emergency.

1. Use the surgical electroaspirators listed under point 1 only on the person for whom it was ordered and only for the intended use. No other use is authorized.
2. The surgical electroaspirators listed under point 1 must be used by instructed and qualified operators.
3. If you note changing in performances of the device, please contact immediately authorized service centre.
4. Do not perform the therapy without your doctor supervision.
5. The connecting tubing delivered with the surgical electroaspirators listed under point 1 must always be connected to a sterile catheter or suitable accessories as prescribed by your doctor.
6. Do not modify the surgical electroaspirators listed under point 1 without manufacturer authorization.
7. The operator must always take every precaution to avoid dangers from accidental contact with blood or body fluids.
8. If the filter and the overflow valve do not operate and the liquids go inside the device, remove immediately the power supply connection.
9. Do not use the device in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxide.
10. Use of cellular phones, cordless phones and any other communication device may interfere with the surgical electroaspirators listed under point 1. A minimum safety distance of 1 meter from the device is recommended.
11. Keep the power supply cord of the surgical electroaspirators listed under point 1 away from hot surfaces.
12. Keep the power cords of the surgical electroaspirators listed under point 1 away from moisture.
13. Never remove the mains plug out of the fixed mains socket by pulling on the device power supply cord.
14. Never leave the device unattended when in use.
15. The device must stand upright during use.
16. Never use the device while bathing or showering
17. Do not use extension cords with the surgical electroaspirators listed under point 1.
18. Keep the power supply cord where it can not fall or trip over it.
19. The power cord and connecting pipes, due to their length, could be a risk of strangulation.
20. Never place the power supply cord or tubing around your neck.
21. Some device components for their small size could be ingested causing suffocation.
22. Keep the surgical electroaspirators listed under point 1 clean and dry.
23. Never place the surgical electroaspirators listed under point 1 in water or liquids.
24. Do not touch live electrical parts such as the electrical cable, socket and switch with wet or damp hands.
25. If the device gets wet, rub with dry towel. Do not dry in a microwave.
26. In the event of an accidental fall into water, the devices may only be extracted after the power supply has been cut off. After such an event, the surgical electroaspirators listed in point 1 of this manual may not be used and require a complete revision.
27. Keep the surgical electroaspirators listed in point 1 away from children and pets.
28. Keep the surgical electroaspirators listed in point 1 protected from direct sunlight.
29. During use, the surgical electroaspirators listed in point 1 must be kept away from heat sources.
30. Prevent the surgical electroaspirators listed in point 1 from falling to the floor.
31. Don’t forget to take a spare jar, tubing and filters with you.
32. Check the general condition of the delivery packaging of the material and the presence of all supplied accessories.
33. In the case of allergic reaction due to contact with the materials of this device, contact your doctor.

Fire risk:

34. Do not expose the surgical electroaspirators listed in point 1 to temperatures other than those indicated in the chapter ''technical characteristics''.
35. The surgical electroaspirators listed in point 1 are intended only for collection of NON-flammable fluids; they are not suitable for use in the presence of flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.

Risk of electrocution:

36. Prior to first use, and periodically during the life of the product, check the integrity of the structure of the device, the supplied power supply and the power cord for damage; if damaged, do not plug it in and immediately take the product to an authorized service centre or your dealer.
37. Do not perform any maintenance operation when the device is in use on a patient.
38. In presence of children and dependent persons, the device should be used under the close supervision of medical personnel who has read this manual.
39. Do not immerse the device into water; if this happens, unplug it immediately. Do not take out or touch the device immersed into water; unplug it first. Take it immediately to an authorized SIEM - NOVA SRL service centre or to your dealer.
40. Do not wash the device under running water or by immersion and keep it away from splashes of water or other liquids.

Risk of ineffectiveness of the therapy:

41. Only use original accessories and spare parts supplied by SIEM - NOVA SRL, no responsibility is taken if non-original parts or accessories are used.
42. The medical device is not suitable for use in MRI (Magnetic Resonance Imaging) environments.
43. Make sure the connections and closure of the jar are done carefully to avoid suction leakage.
44. With the tripping of the protective device the suction stops, turn off the device, empty the jar and perform cleaning operations.

Risk of infection:

45. Personal use of accessories, collection jars, connecting tubes, and filters is mandatory to avoid risk of infection from contagion.
46. The hydrophobic/antiviral and antibacterial filter, supplied with SIEM - NOVA SRL device is a disposable device and must be replaced each time it is used or if the filter becomes saturated. Check the expiration date on the original filter package or on the label on the device package.
47. Follow cleaning, sanitization, disinfection and sterilization procedures before each use.
48. Do not tip the jar while it is connected to the running device, as liquid may be sucked into the device and thus damage the pump. If this happens, turn off the device immediately and arrange for emptying and cleaning of the jar (send it to an authorized SIEM - NOVA SRL service centre).

Injury risk:

49. Do not place the medical device on an unstable supporting surface.
50. Always operate the medical device on a hard, stable and obstacle-free surface.

2 DESCRIPTION OF THE DEVICE

2.1 Introduction

The surgical electroaspirators listed in point 1 are quality surgical aspirators that combine easy handling and cleaning with safety features to ensure optimal operation.

2.2 Intended use

The surgical electroaspirators listed in point 1 are designed for continuous operation. Significant amounts of secretion, blood and serous fluids, including particles in them from natural body cavities and artificial openings, can be quickly suctioned.

The surgical electroaspirators listed in point 1 are intended for use in the following areas:

- Mod. 6110-A1 MAX code 66191 suitable for surgical suction.
- Mod. 6110-A1 MAX code 66190-5L suitable for surgical suction.
- Mod. 6110-A1 CURET-MAX code 66192 suitable in gynecology for endo-uterine aspiration as a hysterosuctor.
- Mod. 6110-A1 CURET-MAX code 66192-5L suitable in gynecology for endo-uterine aspiration as a hysterosuctor.
- Mod. 6110-A1 LIPO-MAX code 66193 suitable in plastic surgery as a liposuctioner for lipoaspiration.
- Mod. 6110-A1 LIPO-MAX code 66193-5L suitable in plastic surgery as a liposuctioner for lipoaspiration.
- Mod. 6110-A2 SPEEDY code 66194.1 suitable for surgical aspiration.
- Mod. 6110-A2 SPEEDY code 66194-5L suitable for surgical aspiration.
- Mod. 6110-A2 CURET-SPEEDY code 66196 suitable in gynecology for endo-uterine aspiration as a hysterosuctor.
- Mod. 6110-A2 CURET-SPEEDY code 66196-5L suitable in gynecology for endo-uterine aspiration as a hysterosuctor.
- Mod. 6110-A2 LIPO-SPEEDY code 66198 suitable in plastic surgery as a liposuctioner for lipoaspiration.
- Mod. 6110-A2 LIPO-SPEEDY 66197-5L suitable in plastic surgery as a liposuctioner for lipoaspiration.

2.3 Contraindications

The surgical electroaspirators listed in point 1 are not suitable for use for thoracic or gastro-intestinal suctioning.

2.4 Intended use

All devices listed in point 1 of this manual are for use in health care facilities, such as hospitals, outpatient clinics. The devices are intended for use by legally authorized medical personnel/health workers (doctors, nurses, anesthetists) and appropriately trained by SIEM - NOVA SRL or companies authorized by it. The device cannot be used directly by the patient.

2.5 Shelf life

The shelf life of the surgical electroaspirators listed in point 1 is ten years (for accessories, please refer to their user manual or contact the accessory manufacturer).

2.6 Package contents

(Please ask your supplier in case of missing parts or for additional accessories).
The disposable cannulas are not included and should be purchased separately.
The Cannulas must be in compliance with medical device directive 2017/745 MDR.

	6110-A1 MAX	
	MEDICAL DEVICE SET-UP	
60750.1	Electrical cable and connector	n. 1
60973	Liner jar 3000 ml	n. 2
60815	Polycarbonate lid with overflow valve	n. 2
90020	Clamp holder for jar	n. 2
90312	Clamp bracket for jar	n. 2
66974	Antibacterial/viral filter 11x11 mm	n. 2
66609	Hydrophobic "LIQUID STOP" Filter	n. 2
66233	Silicon tube 7x13mm	4 m
81016	Pneumatic footswitch	n. 1
60786	Change over suction switch	n. 1
	OPTIONAL ACCESSORIES and COMPONENTS	
60972	Liner jar 2000 ml	
14103	Polycarbonate jar 5000 ml with lid	

	6110-A1 CURET-MAX	
	MEDICAL DEVICE SET-UP	
60750.1	Electrical cable and connector	n. 1
60973	Polycarbonate jar 3000 ml	n. 2
60815	Polycarbonate lid with overflow valve	n. 2
90020	Clamp holder for jar	n. 2
90312	Clamp bracket for jar	n. 2
66974	Antibacterial/viral filter 11x11 mm	n. 2
66609	Hydrophobic "LIQUID STOP" Filter	n. 2
66235	Silicon tube 9x15mm	4 m
81016	Pneumatic footswitch	n. 1
60786	Change over suction switch	n. 1
	OPTIONAL ACCESSORIES and COMPONENTS	
60972	Liner jar 2000 ml	
14103	Polycarbonate jar 5000 ml with lid	
20221	Over-flow jars with floating over-flow valve	
92000	Set of inox cannulas (Ø 5,6,7,8,9,10,11 mm and 1 handle)	

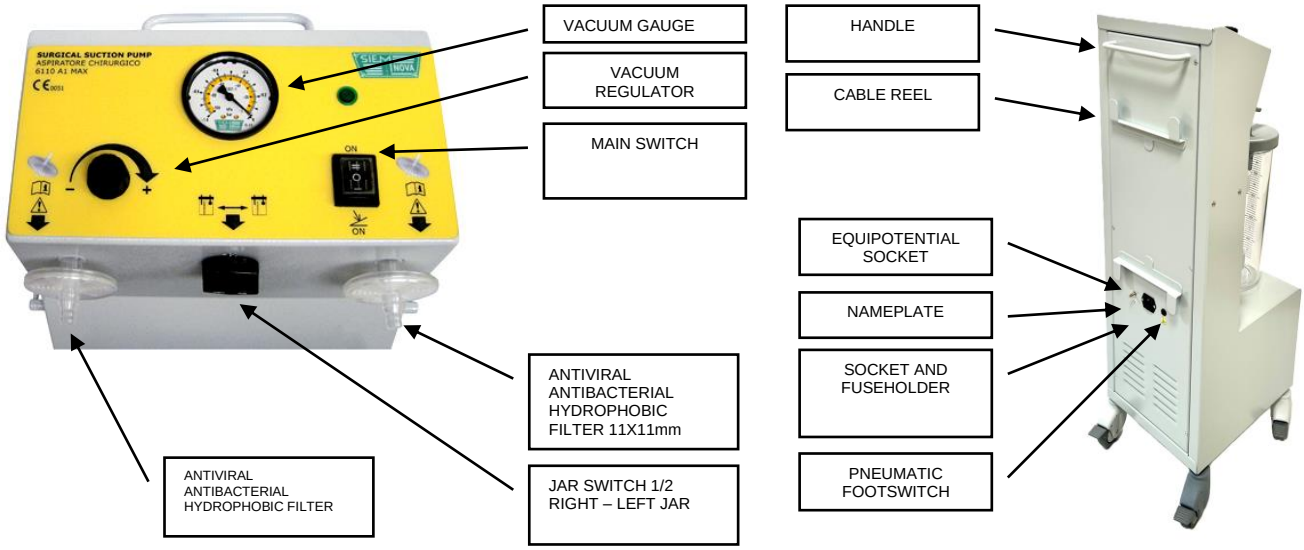
	6110-A1 LIPO-MAX	
	MEDICAL DEVICE SET-UP	
60750.1	Electrical cable and connector	n. 1
60973	Liner jar 3000 ml	n. 2
60815	Polycarbonate lid with overflow valve	n. 2
90020	Clamp holder for jar	n. 2
90312	Clamp bracket for jar	n. 2
66974	Antibacterial/viral filter 11x11 mm	n. 2
66609	Hydrophobic "LIQUID STOP" Filter	n. 2
66235	Silicon tube 9x15mm	4 m
81016	Pneumatic footswitch	n. 1
60786	Change over suction switch	n. 1
	OPTIONAL ACCESSORIES and COMPONENTS	
60972	Liner jar 2000 ml	
14103	Polycarbonate jar 5000 ml with lid	

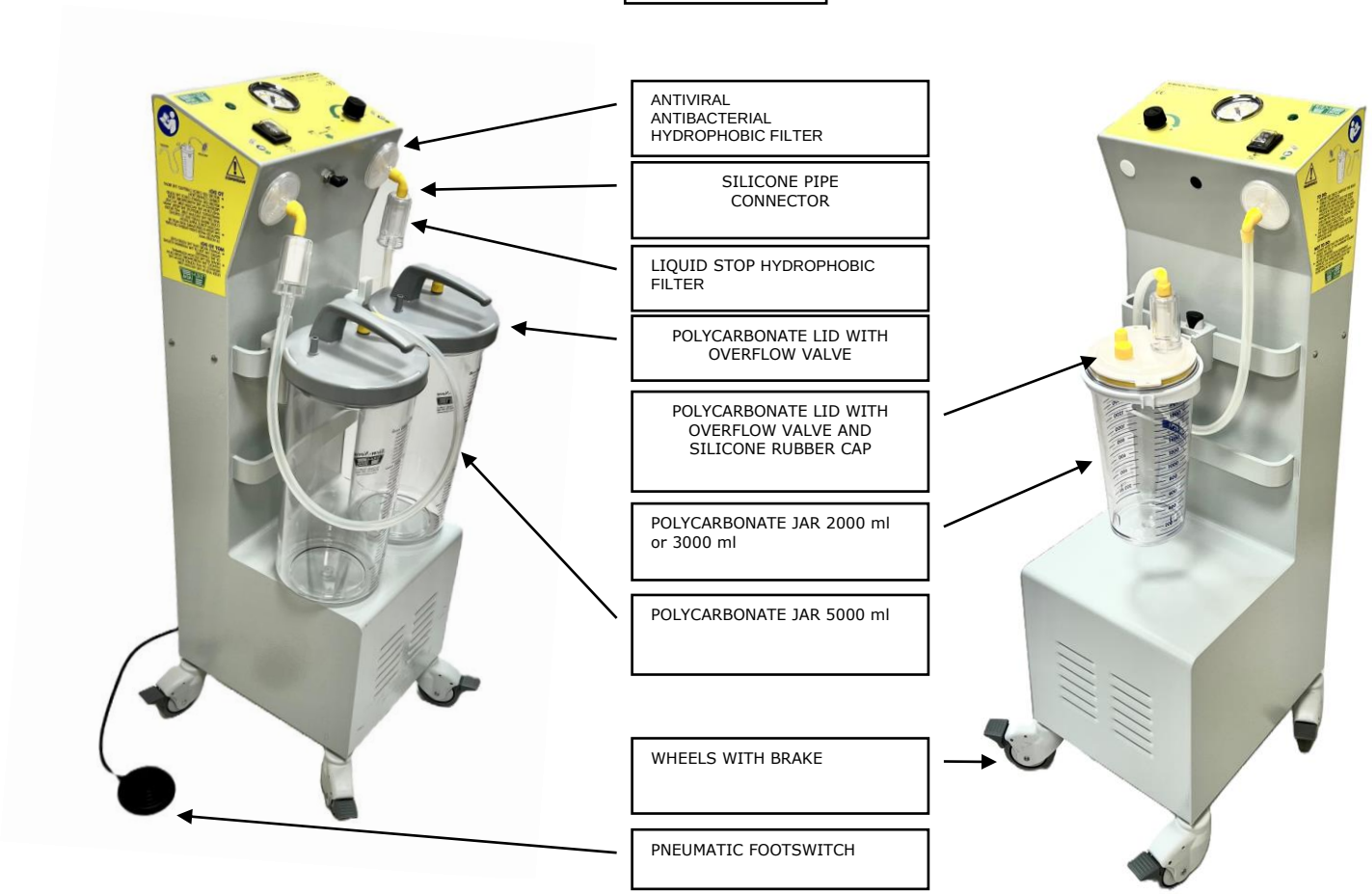
	6110-A2 CURET-SPEEDY	
	MEDICAL DEVICE SET-UP	
60750.1	Electrical cable and connector	n. 1
60973	Liner jar 3000 ml	n. 1
60815	Polycarbonate lid with overflow valve	n. 1
90020	Clamp holder for jar	n. 1
90312	Clamp bracket for jar	n. 1
66974	Antibacterial/viral filter 11x11 mm	n. 1
66609	Hydrophobic "LIQUID STOP" Filter	n. 1
66235	Silicon tube 9x15mm	2 m
81016	Pneumatic footswitch	n. 1
	OPTIONAL ACCESSORIES and COMPONENTS	
60972	Liner jar 2000 ml	
14103	Polycarbonate jar 5000 ml with lid	
20221	Over-flow jars with floating over-flow valve	
92000	Set inox cannulas (Ø 5, 6, 7, 8, 9, 10, 11 mm and 1 handle)	

	6110-A2 LIPO-SPEEDY	
	MEDICAL DEVICE SET-UP	
60750.1	Electrical cable and connector	n. 1
60973	Liner jar 3000 ml	n. 1
60815	Polycarbonate lid with overflow valve	n. 1
90020	Clamp holder for jar	n. 1
90312	Clamp bracket for jar	n. 1
66974	Antibacterial/viral filter 11x11 mm	n. 1
66609	Hydrophobic "LIQUID STOP" Filter	n. 1
66235	Silicon tube 9x15mm	2 m
81016	Pneumatic footswitch	n. 1
	OPTIONAL ACCESSORIES and COMPONENTS	
60972	Liner jar 2000 ml	
14103	Polycarbonate jar 5000 ml with lid Reusable liposuction cannulas and handle	

	6110-A2 SPEEDY	
	MEDICAL DEVICE SET-UP	
60750.1	Electrical cable and connector	n. 1
60973	Liner jar 3000 ml	n. 1
60815	Polycarbonate lid with overflow valve	n. 1
90020	Clamp holder for jar	n. 1
90312	Clamp bracket for jar	n. 1
66974	Antibacterial/viral filter 11x11 mm	n. 1
66609	Hydrophobic "LIQUID STOP" Filter	n. 1
66233	Silicon tube 7x13mm	2 m
	OPTIONAL ACCESSORIES and COMPONENTS	
81016	Pneumatic footswitch	
60972	Liner jar 2000 ml	
14103	Polycarbonate jar 5000 ml with lid	
20221	Over-flow jar with floating over-flow valve	

2.7 DESCRIPTION





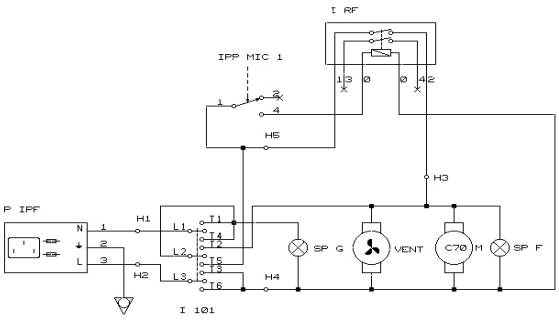
CAUTIONS: The surgical electroaspirators listed in point 1 must be positioned so that disconnection from the power grid can be done easily.

WARNING: This device must be used only by medically trained persons who have been adequately trained in suction procedures and in the use of aspirators. Always wear gloves for all operations and use only accessories and vacuum adjustments as prescribed by your doctor.

3 ELECTRICAL DIAGRAM AND COMPONENTS DESCRIPTION

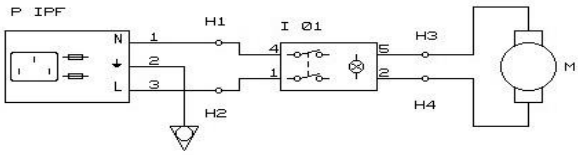
The surgical electroaspirators listed in point 1
Series 6110-A1 MAX and 6110-A1 CURET-MAX; 6110-A1 LIPO-MAX
with pneumatic footswitch

REFERENCE	DESCRIPTION
I 101	Three-pin switch
H1…	Connectors
M	Motor-driven compressor
P IPF	Socket with fuses door
IPP MIC1	Pneumatic footswitch
I RF	Footswitch relay
SPG	Main light
SPF	Functioning light
VENT	Impeller



The surgical electroaspirators listed in point 1
Series 6110-A2 SPEEDY; 6110-A2 CURET-SPEEDY; 6110-A2 LIPO-SPEEDY

REFERENCE	DESCRIPTION
I 01	Bipolar switch with light
H1…	Connectors
M	Motor-driven compressor
P IPF	Socket with fuses door
VENT	Impeller



4 PREPARATION FOR USE

4.1 CHECKS BEFORE USE

Always check device before use by verifying:

a) Possible damage of the power cord or main socket
b) Any obvious safety defect and/or damage to the MEDICAL DEVICE.
c) Proper functioning of the device
d) Presence of Liquid in the filter
e) Liquid stop filter occlusion

Check all accessories before use:

a) Presence of cracks or alterations on the jar and/or lid. Replace if necessary.
b) Presence of cracks or changes in stiffness on pipes and/or that connectors and/or plugs are firmly fixed. Replace if necessary.
c) The integrity of sterile accessory packs. Replace if necessary.
d) Cleaning and disinfection of non-sterile and reusable accessories.

CAUTION: Do not use tubing or other sterile accessories if the sterile packaging is damaged. Do not reuse disposable and/or sterile accessories.

4.2 Assembly of the jar

a) check if the overflow valve is fixed on the lid of the jar and if the float (with sealing) is inside the cage.
b) Mount the lid on the jar. Check the "V" gasket. Place fittings, vacuum tube, antibacterial/viral hydrophobic filter, and Liquid Stop filter (if mounted).

OVERFLOW SAFETY VALVE

It is placed under the lid of jars and in each jar. It is made by a float and a support cage.
Its function is to stop the aspiration when reached the maximum liquids level.

4.3 Positioning of the jar

a) Put the jar on the device on the suitable track.

4.4 Positioning the Hydrophobic and antibacterial filter.

1. Insert the Hydrophobic filter on rubber adapter, connect the vacuum tube on the filter and on the lid.
2. Connect the patient tube (patient) to the lid and to the available accessories (catheters or cannulas or others following to doctor indications) for better fixing you could use the yellow silicone hose adapter available on lid.
3. Close unused patient connections with yellow silicone rubber plugs.

WARNING:

Always check the presence of liquids or other materials into the hydrophobic filter and/ or into the vacuum tube, if liquids or other visible materials are inside, the filter should be replaced immediately because of the risk that the pressure exerted by the vacuum may break the inner membrane and allow liquids to enter the device and cause its damage (with a vacuum level of -0.69 bar, the dirty filter membrane will break after 10 minutes).

CAUTION: These filters have been designed, tested and manufactured exclusively for single patient use and for a period of use not exceeding 24 hours.

ATTENTION: NEVER WASH THE ANTIBACTERIAL AND LIQUID STOP FILTER, NEVER IMMERSE INTO WATER OR OTHER SOLUTIONS BECAUSE THE MEMBRANE IS HYDROPHOBIC.

4.5 Positioning the Hydrophobic filter LIQUID STOP

Place the LIQUID STOP filter on the jar lid and suction tube, taking care to position the VACUUM side correctly. Combined with the antibacterial filter, the hydrophobic "Liquid stop" filter effectively protects the surgical aspirator not only from excess sucked-in body liquid, but also from the small droplets in the air (aerosols) formed during suction operation; these small droplets cannot be stopped by the overflow valve located on the lid and are usually stopped by the antibacterial/viral filter, but often the operator does not promptly replace this filter, as indicated in the warnings, and sometimes this means breaking the filter membrane and contaminating and damaging the aspirator. The LIQUID STOP filter should be replaced when visibly dirty and/or blocked (by sucked-in liquid droplets).

WARNING: Always check the presence of liquids or other materials into the liquid stop hydrophobic filter, if liquids or other visible materials are inside, the FILTER must be replaced immediately

5 OPERATING INSTRUCTIONS

CAUTIONS:

The surgical electroaspirators listed in point 1 must be positioned so that disconnection from the power grid can be done easily.

WARNING: The surgical electroaspirators listed in point 1 must be used only by medically trained personnel who has been adequately trained in suction procedures and in the use of aspirators. Always wear gloves for all operations.

5.1 Connection to mains power

1. always check the SURGICAL aspirators before use by following the instructions in the "preparation for use" chapter.
2. connect the VDE plug to the socket located at the back of the medical device and the SCHUKO plug to the power supply outlet with earth-fault protection.

To activate the device with the foot switch (if mounted or requested):

a) insert the foot switch tube into the foot switch socket located on the back of the device
b) set the ON/OFF/ON switch to the indicated symbol, then press the pneumatic foot pedal with your foot
c) pressing it a second time, the MEDICAL DEVICE will be turned off

5.2 Functional check

1. Press the ON/OFF switch to switch on the device (the light on control panel will turn ON).
2. If the foot switch is used, the medical device is activated by pressing the "ON/OFF/ON" switch, choosing either continuous operation or pneumatic foot operation (the light indicator on the panel lights up) .
3. If a jar switch is provided, the user can collect the sucked liquids to one or the other jar of his choice by positioning the jar selector to the right if he wants to collect the sucked liquids to the right jar, vice versa to the left to collect the sucked liquids to the left jar.
4. Set vacuum regulator to position «max.»
5. Close the PATIENT tube with a finger and check if there is suitable suction. If there is suction, proceed with next step, if not, see chapter "Troubleshooting".
6. Use accessories and vacuum levels as prescribed by a doctor.

5.3 Changing vacuum level

Act on the vacuum regulator while keeping the patient tube closed and turning the vacuum regulator knob clockwise to increase the vacuum level and counterclockwise to decrease it. Read the vacuum level on the vacuum gauge when the instrument pointer is stopped at the indicated value.

5.4 Jar selection (only for models 6110-A1 MAX, 6110-A1 CURET-MAX; 6110-A1 LIPO-MAX)
The operators can collect liquids aspirated into one or into the other jar simply by turning the switch for the selection.

5.5 Placing out of operation after use

1. Press the ON/OFF switch to switch off the device
2. Remove the power cord from the main socket and then from the socket
3. Remove collection jar from the device
4. When removing and/or transporting the used jar and in the presence of secretions, always seal the lid with plugs
5. Install a clean jar (if necessary).
6. Disinfect as described in the "Guidelines for Cleaning and Sterilization"
7. Dispose of disposable materials as per local disposal procedures and/or guidelines

WARNING: **Daily or when the fluid level reaches 70% of maximum jar capacity or the overflow valve stops suction into the jar, the jar should be emptied, cleaned and sterilized. Always check the presence of liquids inside the filter and the vacuum tube. Empty jar and dispose wasted material in accordance with local guidelines.**

6 TROUBLESHOOTING

6.1 If the device is not running

Check if:
1. the device is switched on
2. the mains voltage is correct
3. the plugs of the power cord are both correctly inserted in the mains socket and in the device.

6.2 the pump does not suck strongly enough

Check if:
1. the vacuum regulator is set to the correct and prescribed suction level.
2. the jar switch is mounted, check if you are using the right jar.
3. the tubing is not defective and/or broken and/or obstructed and/or bended. (if necessary, replace it).
4. all tubing connections are tight.
5. the jar and/or the lid has no cracks. (if necessary, replace it).
6. there is no liquids or other material inside the VACUUM tube or filters and the hydrophobic filters aren't occluded.

WARNING: **IF LIQUIDS REACH THE FILTERS, THE AIR FLOW WILL STOP**

NOTE: If the problem cannot be solved, please contact assistance.

7 CLEANING AND STERILIZATION GUIDELINES

7.1 General notes
1. Follow the cleaning instructions given by your local regulations.
2. Always wear gloves and personal protective devices.
3. Dispose of fluids such as blood and secretions and the contaminated parts according to local guidelines.

7.2 Washing water
Use only the purest quality of water for cleaning. Water hardness is a serious consideration since deposits left on medical products may not be properly removed. Use demineralized water to reduce this problem.

7.3 Disposable products
These are single use products not intended to be reused. Reuse could cause loss of mechanical, chemical and / or biological characteristics. Reuse could cause cross contamination (check on the user manual or contact the accessory manufacturer).

7.4 Disassembly
Separate all individual parts before cleaning and disinfecting.

7.5 Cleaning the suction unit and power cord.
WARNINGS: Before cleaning the device, pull the mains plug out of the wall socket. Do not immerse the device into water.

1. remove the power cord
2. remove the jars
3. use a soft sponge or tissue with cold disinfectant solution (i.e. solution containing up 2% sodium hypoclorite)
4. avoid any operation causing liquid penetration inside the device or inside the power cord plugs
5. follow the cold disinfectant solution manufacturer instruction and check the compatibility between the solution and the case material of unit (ABS), use a soft and clean cloth to dry

7.6 Cleaning jar, lid and tubing (for reusable jars only)
WARNING: The procedure must be done by the qualified personnel after every use: personnel should have individual protections such as coats, masks, gloves, screens, glasses, peaks, anti-sprinklings, etc.: the procedure is intended to reduce the microbial load provided for protecting the operator from HIV contamination and to limit the risk of infection. This procedure requires that all reusable material came into contact with potentially infectious materials, shall, after the use, be immediately immersed in a sanitizing solution.

1. Remove the lid of reusable jar
2. Disassembly the cage of the overflow valve and the overflow valve
3. Clean components in hot water (60–70 °C) containing a detergent with a pH range between 6.0 and 8.0 only, to avoid alterations to materials
4. Soak all parts thoroughly with warm, soapy water (60–70 °C) or in enzymatic detergent for 1–5 minutes.
5. Remove visible dirt with a cleaning tool such as a cleaning brush or a non-abrasive cloth
6. Rinse well
7. Dry
8. Check the parts for visible dirt and repeat these steps if necessary

7.7 Sterilization jar, lid and tubing
CAUTION: All reusable material after decontamination and before the sterilization process must be thoroughly washed in all its parts (see section 7.6)

1. sterilize the items into an autoclave (cycle 15'-121° C) or into an autoclave with ethylene oxide, cycle at 37°C (After ethylene oxide sterilization, material must be degassed for 48 hours), carefully follow the instructions of the manufacturer of the component and/or accessory supplied by SIEM - NOVA Srl.
2. As an alternative to point 1) cool sterilizing or dipping could be made. Follow the instructions of the manufacturer of the appropriate chemical product for its use and carefully follow the instructions of the manufacturer of the component and/or accessory supplied by SIEM - NOVA Srl.
3. After 30 sterilizing cycles it is recommended to check the wholeness of the container, lid, tube and vacuum connectors.

However, it is mandatory to check the maximum number of sterilization cycles allowed by the manufacturer of the component and/or accessory supplied by SIEM - NOVA Srl and indicated in its user manual.

8 PREVENTIVE MAINTEINANCE
The surgical electroaspirators listed in point 1 should not require preventive maintenance if used following the indication of this manual.

REMARK: The defective device will need to be returned to the supplier (see point 13 WARRANTY).

8.1 Daily checkup (by user)
This test quickly verifies whether the device is suitable for field use and includes functional checks that can be completed in few minutes.
1. Connect the device to a main power supply.
2. Operate the device through the switch on the front panel (**O** = off, **II** = on, **I** = on for pneumatic pedal).
   The device should operate smoothly and no change in the internal pump speed should be felt.
   No abnormal noises and/or pronounced vibrations should be perceived.
3. Close the VACUUM tube with a finger, turn clockwise the Vacuum regulator and check that the VACUUM level reaches at least the value stated in the "TECHNICAL DATA" table.
4. With the VACUUM tube open, turn counter clockwise the Vacuum regulator and check that the VACUMM level will decrease towards 0 (zero) (due to load loss could be accepted a residual vacuum level of 40-50 mbar).
5. Switch off the device.
6. Check if the filters are clean and no liquid or other material are inside. If the color of the filter is not white it must be replaced. A dirty filter prevents proper operation of the vacuum cleaner and decreases its performance.

7. If necessary, replace filters and disposable bag.

8.2 Test on an annual basis (to be carried out after the warranty period).

This test provides an accurate verification of whether the device is fully in compliance with the original manufacturing characteristics and is therefore suitable for use in the field. The checks and inspections should be carried out by people and/or companies specialized in this king of operation. Following the inspection, the designated company should perform an electrical safety test in accordance with IEC60601-1 and issue a document summarizing the test.

TEST LIST TO BE DONE ON THE DEVICE:

1. Do not open the device under any circumstances. For technical intervention only contact the authorized service centres.
2. Check the functioning of the internal pump by turning the switch. There should be no functional anomalies such as abnormal noises, excessive vibration of the entire device (place it on a horizontal plane in ON mode and check that it does not move due to vibration).
3. Check the vacuum regulator, which must operate from minimum to maximum by turning anti-clockwise. No obstructions must be present during rotation. A small vacuum value when the regulator is fully open is permissible (vacuum drop related to the anti-bacterial filter) and the maximum vacuum value must be no less than what stated in the "TECHNICAL DATA" table.
4. Check the mechanical integrity of the case. The penetration of external liquid or solid materials could damage the device or create danger to the operators.
5. Check if the labels are still sticked and readable.
6. Check the functional status of the vacuum gauge. With the device switched off, the pointer must be on "0".
7. Check that jars, pipes and fittings are intact and that there are no cracks that could impair the proper functioning of the suction.
8. If necessary, replace filters or disposable bag.
9. Before declaring the device in compliance with the manufacturer features, make a safety electrical test (IEC 60601-1). For making this test ask to the authorized service centre and/or to the manufacturer.

Use disposable or spare parts supplied by the manufacturer only. Do not use similar or seemingly identical components. The compliance of disposable or spare parts could be confirmed by the manufacturer only.

Keep a document stating that you have carried out all the checks described and if possible, a photographic report on the condition of the device at the time of the check. Always also keep a copy of the safety report carried out with the appropriate calibrated instrument.

The operator must consider the use of the device at high altitudes. Under such conditions, the vacuum of the internal pump may drop considerably due to the reduction in atmospheric pressure. Do not use the surgical electroaspirators listed in point 1 over 3000 m above sea level (9,842 ft above sea level).

9 TECHNICAL SPECIFICATIONS

9. 1 TEMPERATURE - Storage conditions

When storing the SURGICAL ELECTROASPIRATORS listed in section 1 of this manual, they must remain in their original packaging and stored in a temperature range of -25 °C to +70 °C (-13 °F to 158 °F).

9.2 TEMPERATURE - Working conditions

The SURGICAL ELECTROASPIRATORS listed in section 1 must be used in a temperature range of + 5 °C and + 40 °C (41 °F and +104 °F). Do not use the device in extremely cold or hot climatic conditions.

9.3 MOISTURE - Transport/Storage/working conditions

The SURGICAL ELECTROASPIRATORS listed in section 1 must remain in the original packaging for storage and used at a moisture range from 15% to 93 %.

9.4 ATMOSPHERIC PRESSURE - Transport/Storage/working conditions

For storage of the SURGICAL ELECTROASPIRATORS listed in section 1, they must remain in their original packaging, stored and used with an atmospheric pressure of 0.7 bar to 1.06 bar.

IP21

9.5 Protection class against penetration by liquids

The SURGICAL ELECTROASPIRATORS listed in section 1 are protected against penetration of liquids and solids (IP21)

The SURGICAL ELECTROASPIRATORS listed in section 1 are protected against the penetration of liquids and solids (IP21). However, it is always a good idea to protect the device against heavy water jets. During use and storage, the device should be kept dry. If the device is completely wet, move it to a dry environment, dry it externally and wait at least 30 minutes before using it again only if you are certain that no water has penetrated inside.

Technical information REF: 66191 / 66192 / 66193 / 66194.1 / 66196 / 66198

Dimensions (h x w x l):	H 1010, W 400, L 320 mm (40.4x15.7x12.8 inches)
Voltage with motor HP 120:	230 VAC; 50 Hz; 325 VA
Operating cycle:	**continuous**
flow rate (before the filter):	> 120 liters/minute - 7,2 m³/h. (± 5 %)
Standard Jar volume:	3000 ml
weight (without jar):	20 kg / 44,1 lbs approx
max. vacuum level:	– 697,55 mmHg / – 93 kPa /- 0,93 bar (±5 %) (*)
Classification: CEI EN60601-1	Insulation Class I device - Applied part type B Device not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxide.
Classification: UNI EN ISO10079-1	Device with HIGH VACUUM level and HIGH FLOW
Classification: 2017/745 MDR	Class II a

(*) Value measured at 0 metres above sea level (1.01325 bar).

Technical information REF: 66190-5L /66192-5L / 66193-5L / 66194-5L / 66196-5L / 66197-5L

Dimensions (h x w x l):	H 1010, W 400, L 320 mm (40.4x15.7x12.8 inches)
Voltage with motor HP 120:	230 VAC; 50 Hz; 180 VA
Operating cycle:	**continuous**
flow rate (before the filter):	95 litres/minute – 5,7 m³/h. (± 5 %)
Standard Jar volume:	3000 ml
weight (without jar):	18 kg / 39,68 lbs approx
max. vacuum level:	– 697,55 mmHg / – 93 kPa /- 0,93 bar (±5 %) (*)
Classification: CEI EN60601-1	Insulation Class I device - Applied part type B Device not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxide.
Classification: UNI EN ISO10079-1	Device with HIGH VACUUM level and HIGH FLOW
Classification: 2017/745 MDR	Class II a

(*) Measured at 0-meter, atmospheric pressure: 1013.25 hPa.

WARNING: Do not use the devices over 3000 metres above sea level (9,842 feet).

PLEASE NOTE: vacuum levels may vary depending on location (height above sea level, atmospheric pressure and temperature).

10 DISPOSAL

At the end of their operative life the device and accessories must be disposed of in compliance with the local regulation and environmental laws, if no legal regulation exists the different material must be sorted and disposed of separately (see the below table)

Remark: all components of the device and accessories don't contain phthalates or latex

Accessory/component	**Material or regulation**
Suction pump unit and power cord	Waste from Electric and Electronic Device (Raee)
Unit case	ALUMINIUM
Jar	PC
Lid	PC
Rubber components	Silicone
Cage and float	Polypropilene
Box	Cardboard
Instruction manual	Paper

11 ELECTROMAGNETIC COMPATIBILITY

The SURGICAL ELECTROASPIRATORS listed in section 1 are equipped with an induction motor and has no electronic components and by its own nature neither generates nor is affected by electromagnetic interference, it therefore automatically complies with the requirements of the CEI EN 60601-1-2-2015 standard for electromagnetic compatibility of medical devices, however a minimum safety distance of 1 m (3,3 ft. from the device) is recommended when using mobile phones, LAN / WLAN, walkie-talkies (two-ways radios and cordless phones).

RECOMMENDED SEPARATION DISTANCES BETWEEN RADIOCOMMUNICATION DEVICES
The device does not, by its nature, generate or receive electromagnetic interference, however, it is recommended that the device is used in an electromagnetic environment where radiated RF interference is under control. The customer or the operator of the device can help to prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communications device (transmitters) and the medical device as recommended below, in relation to the maximum output power of the radio communications device.

Maximum nominal power of the transmitter output (W)	Separation distance to the frequency of the transmitter (m)		
	From 150 kHz to 80 MHz	from 80 kHz to 800 MHz	From 800 kHz to 2,5 GHz

	d=1,2 x √P	d=1,2 x √P	d=2,3 x √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 rated output power not listed above, the recommended separation distance "d", in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where "p" is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the exposure distance for the higher frequency range is applicable. Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

12 SPARE PARTS

Use only accessories or components supplied by SIEM - NOVA SRL. The use of spare parts not supplied by SIEM -NOVA SRL could invalidate the warranty and especially the CE0051 marking of the device according to the 2017/745 MDR.

13 WARRANTY

SIEM - NOVA SRL (or its authorized distributor) warrants that the device will be free from defects in materials and workmanship for a period of 2 years from the date of delivery.

The warranty includes defects in materials, components and/or manufacturing only if:

A. THE DEVICE IS USED IN RESPECT TO ALL INSTRUCTIONS OF OPERATOR'S MANUAL
B. ROUTINE MAINTENANCE HAS BEEN DONE
C. THE ACCESSORIES ARE SUPPLIED BY SIEM-NOVA SRL

The guarantee of The SURGICAL ELECTROASPIRATORS listed in section 1 applies when the lack of conformity occurs within 24 months from the date of purchase of the good and must be reported by the Customer within 2 months from the date of discovery of the defect. The following are strictly excluded from the warranty: batteries, glasses, power supply cable, discoloration (especially due to the use of detergents), consequences of wear and normal aging of the article. Warranty repairs must be carried out at authorized technical assistance centres. Any technical tampering carried out outside the Technical Assistance Centres will cause the termination of the Guarantee. The same thing is said for failed replacement of the filters, as described in the user manual. Finally, any damage or breakage caused by accidental impacts in the presence of which the Warranty will have no effect, is excluded from the Guarantee, especially if parts of the unit case are missing.

14 Technical features update

To continuously improve performance, safety and reliability, all medical devices listed in section 1 manufactured by SIEM - NOVA SRL are periodically reviewed and changed. The instruction manuals are therefore amended to ensure their continued compliance with the characteristics of the devices on the market. If the instruction manual accompanying this device is lost, you can obtain from the manufacturer a copy of the version corresponding to the device provided supplying serial number on the device label.

15 ACCIDENT NOTICE

Any serious accident occurring with the device must be reported to the manufacturer and to the competent authority of the Member State where is the user and/or patient.