ASSISTANCE

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

SIGNS AND SYMBOLS

CE 0051 This symbol indicates the compliance with the essential requirements of the Directive 93/42/ EEC of 14 June 1993 concerning medical devices. Reference IMQ Spa - Milan	 This symbol indicates an insulation class I device.	 This symbol indicates to follow instructions for use.
 This symbol indicates the date of production (four digits for the year and two digits for the month).	 This Symbol indicates a type B applied part.	 This symbol indicates to consult instructions for use.
 This symbol indicates the manufacturer.	 This symbol indicates alternate current	 This symbol indicates the foot switch.
 This symbol indicates that interferences may occur in the vicinity of equipment marked with this symbol	 This symbol indicates a single use device. Do not reuse the device.	 This symbol indicates a CAUTION or WARNING associated with the device.
 This symbol indicates the humidity limitation for operation, transport and storage	 This symbol indicates the atmospheric pressure limitation for operation, transport and storage.	 This symbol indicates the temperature limitation for operation, transport and storage.
 This symbol indicates to keep the device away from sunlight	 This symbol indicates to keep the device dry.	**IP33** This symbol indicates the protection against harmful effects due to ingress of solid foreign objects and against harmful effects due to the ingress of water.
 This symbol indicates do not dispose the device together with unsorted municipal waste (for EU only).		 This symbol indicates do not immerse in water or other liquid

1 WARNINGS AND SAFETY INSTRUCTIONS

1.1 APPLICATION

The Smoke filtration system Model "FILTRUM®" is approved exclusively for the use as described in these user and maintenance manual. Siem Nova can only warranty the safe functioning of the equipment when the Smoke filtration system Model "FILTRUM®" is used with the Siem Nova accessories.

Please read and observe these warning and safety instructions before use the device.

WARNINGS: Please note that these instructions for use are a general guide for the use of the product.
Medical matters must be addressed by a physician.

WARNINGS: The product is designed for the safety care of patient and operator but some warnings must be followed.

REMARKS: The users must be able to read, understand and follow directions provided in this manual and provided by the physician. If you are dependent on the device for airway suctioning and a breakdown can lead to a critical situation, you must have another suitable device available.

1. Only use the Smoke Filtration System Model "FILTRUM®" on the person for whom it was ordered and only for its intended use.
2. The equipment must be used by instructed and qualified operators.
3. If you note changing in performances of the equipment, please contact immediately authorized service center.
4. Do not perform the therapy without your physician supervision.
5. Do not modify the equipment without manufacturer authorization.
6. The operator must always take all precautions to avoid dangers arising from accidental contact with blood or body fluids
7. If the internal filter and / or external filter are damaged, immediately shut off the power supply.
8. Do not use the equipment in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxid.
9.  The use of mobile telephones, cordless telephones and other communication equipments can affect the Smoke Filtration System Model "FILTRUM®" suction pump. A safety distance of min. 1 m to the Smoke Filtration System Model "FILTRUM®" pump is recommended.
10. Keep the power supply cord away from hot surfaces.
11. Keep the mains plug away from moisture.
12. Never remove the mains plug out of the fixed mains socket by pulling on the power cord!
13. Never leave the device unattended when it is operating.
14. The equipment must stand upright during use.
15.  Never use the device while bathing or showering
16. Do not use extension cords with Smoke filtration system Model "FILTRUM®".
17. Keep the power supply cord where you will not fall or trip over it.
18. The power cords or the tubes (for their length) may involve a risk of strangulation.
19. Never place the power supply cord or the tubes around your neck.
20. Some components for their small size could be swallowed causing suffocation
21. Keep the Smoke filtration system Model "FILTRUM®" clean and dry.
22.  Never place the device in water or liquids.
23. Never touch with wet hands electrical parts.
24. If the device gets wet, rub with dry towel. Do not dry in a microwave.
25. Do not touch the device when it has fallen into water. Unplug device immediately from main power supply.
26. Keep the equipment away from children and pets.
27.  Keep the equipment protected from direct sunlight.
28. Keep the equipment away from heat source.
29. Prevent the device from falling to the floor.
30. Never forget to have the replacement of the tubes and the antibacterial / viral hydrophobic filter available.
31. Check the general conditions of delivery package of the Smoke filtration system Model "FILTRUM®" for completeness and the presence of all accessories supplied.
32. In case of an allergic reaction due to the contact with the materials of this device, contact your doctor.

2 DESCRIPTION OF THE DEVICE

2.1 Introduction

Smoke filtration system model "FILTRUM®" combines quality and manageability with safety and cleaning features, to guarantee optimal operation.

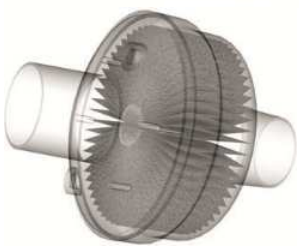
2.2 Intended use

Smoke filtration system model FILTRUM® is a device for the removal and filtration of fumes caused by electrosurgical procedures or minor lasers. The integration of the high-quality two-component filter allows the filtration of surgical fumes and effective removal of particles and odours from the surgical site. Its compact shape allows it to be placed even in small spaces, such as the outpatient clinic, offering excellent results during the services offered in public and private facilities, used for medical health care. The fumes can be evacuated by inserting the flexible corrugated tube, the external filter and devices such as vaginal speculum, etc. The extension having a smaller diameter can be removed to allow a higher suction of fumes in non- circumscribed environments.

2.3 SMOKE FILTRATION SYSTEM MODEL FILTRUM® IS COMPOSED OF:

a) **HEPA-CARBON INTERNAL FILTER**, excellent efficiency in the removal of BACTERIA and VIRUS with a bacterial / viral efficiency of 99.999% and the DOP test is 99.97%. The particularity is given by activated carbon, a special component that removes smoke, odours and all the other harmful components present in the air. Composed of a Hepa part, which removes all pollutants with a size of less than 0.027 microns, and a section of activated carbon that at 150 l / p / m, absorbs any gaseous pollutants. (NB: at a flow higher than 150 l / p / m, coal does not have time to completely absorb the gas). If you always use the ULPA FILTER in front of the HEPA-CARBON filter you can have a minimum of 6 months of filter life. The combined efficiency of both filters will be higher up to 99.999999% bacterial viral efficiency, and the test PDO is 99.999%. (The DOP test evaluates the penetration resistance of the particles and the filtration air flow).

b) **ULPA EXTERNAL FILTER**, single-use product, in a high-strength STYROLUX transparent case. Tested according to BS 3928 (flame with sodium). Each filter is tested with this method has a bacterial efficiency of 99.99999% and viral efficiency of 99.99989%. It holds the particles of 0.3 MICRON to 99.999% up to 0.027 MICRON.



c) **ELECTRIC ASPIRATION MOTOR** with variable power HIGH-FLOW with soundproof hood.

d) **ON-OFF-ON** switch for continuous operation and connection to the foot control with pneumatic functioning

e) Manual regulator of the suction power.

All assembled in a silent, compact and transportable machine body. The electric motor of the Smoke filtration system, model FILTRUM®, is high speed for high flow applications. The motor speed is continuously adjustable with a knob on the front panel of the instrument. The activation of the system is obtained by acting on the ON-OFF-ON switch, choosing continuous operation, or the pneumatic pedal operation that is connected behind the unit.

2.4 OPERATING PRINCIPLE

The fumes produced during operations performed with electro-surgical or laser instruments have an unpleasant, strong and persistent odour. These odours consist of organic gases, water vapor, visible and non-solid particles and viral particles. It is good practice to suck the fumes from the operating field and filter them. In the last decade, the increase in the number of excision or ablation operations with lasers or electrosurgical units, together with the aspects on the potential infectious nature of the HIV virus, HPV, HBV, has led to the adoption of suction and filtration systems of fumes. A high level of suction and filtration of the fumes is obtained with two types of filters: particle and organic absorption. Generally an activated carbon chamber is used for organic absorption filters. Activated charcoal is very effective for the absorption of gases and aerosols, which are the main sources of the smell of fumes. Particle filters are effective for capturing particles with a very varied size. The suction motor used in the device Smoke Filtration System, model FILTRUM®, produces a vacuum up to about 300 (l / min) liters per minute, through a two meters long tube and with an internal diameter of 22 mm. This value is effective in removing fumes from the operative field as required in many surgical procedures. It should be noted that a smaller inner tube diameter would significantly reduce the flow.

2.5 CAPTURE OF THE PARTICLES CONTAINED IN SURGICAL FUMES

The filtration system uses two mechanisms for capturing particles contained in surgical fumes:

a) The direct interception, which is effective in the filtration of the fattest particles. The direct interception of a particle with a filter takes place due to the size of the particle itself, larger than the filter pores. The inertial impact acts on the smaller particles that would otherwise be able to pass through the filter that has the largest pores of the particle itself. These particles due to their speed are captured by the depth of the filter.

b) The spread interception, the second and last mechanism for particle filtration, acts on the smallest particles (less than about 0.5 microns). Modern HEPA and ULPA filters, filters that have pore size larger than 0.5 µm, can still effectively filter these particles by spread interception. These filters are effective on smaller particles due to the thermally induced movement, commonly called Brown motion. Because of their small mass, these particles are forced by their own surrounding environment to vibrate continuously, which involves a real dimension of the particle, largest than it really is, and this allows interception with filters. An example for all: the human papillomavirus virus (HPV) measures about 0.055 pm in diameter and the one of immunodeficiency (HIV) is about 0.11 µm in diameter.

2.6 THE SMOKE FILTRATION IS OBTAINED THROUGH TWO STAGES AND MORE COMPONENTS.

The effectiveness of filtration, as a percentage of the captured particles, is typically given on the basis of two different control parameters: particle size or particle size range and flow ratio. The effectiveness of filtration will vary with both parameters. Generally the HEPA and ULPA filters will have their minimum efficiency in the range 0.1 - 0.3 µm. All filters will lose filtration efficiency as the flow ratio increases.

The "INTERNAL" HEPA-CARBON filter code 81001, contains an activated carbon chamber, for the absorption of odourous gases and a HEPA filter for particle filtration. This filter located inside the front panel of the device must be replaced at least twice a year.

The "EXTERNAL" ULPA VIRAL AND BACTERIAL FILTER code 81002 consists of a ULPA filter cartridge. This filter must be replaced at the end of each operation.
Instructions for changing it can be found in the Maitenance section of this manual.

2.7 CONTRAINDICATIONS

Smoke filtration system "FILTRUM®" model is not suitable for use OTHER THAN THE INTENDED USE.

2.8 INTENDED USER

The Smoke filtration system Model "FILTRUM®" should only be operated by properly instructed users.

2.9 SERVICE LIFE

The service life of the device is ten years (except for accessories).

2.10 HOUR COUNT

The hour counter is located at the back of the machine and is a time measuring instrument. Particularly indicated to determine the operating time of the machine, program filter replacement and preventive maintenance.

2.11 PACKAGE CONTENTS

(Please ask your supplier in case of missing parts or for additional accessories).
All accessories must comply with the 93/42 EEC directive on medical devices

The package contains:

Quantity	Description	code
1	FILTRUM	81000
1	ELECTRIC CABLE WITH PLUG	60750.1
1	INTERNAL HEPA-CARBON FILTER	81001
1	EXTERNAL ULPA ANTIBACTERIAL / VIRAL FILTER	81002
2,5 m	CORRUGATED TUBE diam. 22 mm.	14032
1	FLEXIBLE ARM WITH SUPPORTS FOR CORRUGATED TUBES	14030
1	PNEUMATIC SWITCH	81016
1	MAINTENANCE MANUAL	

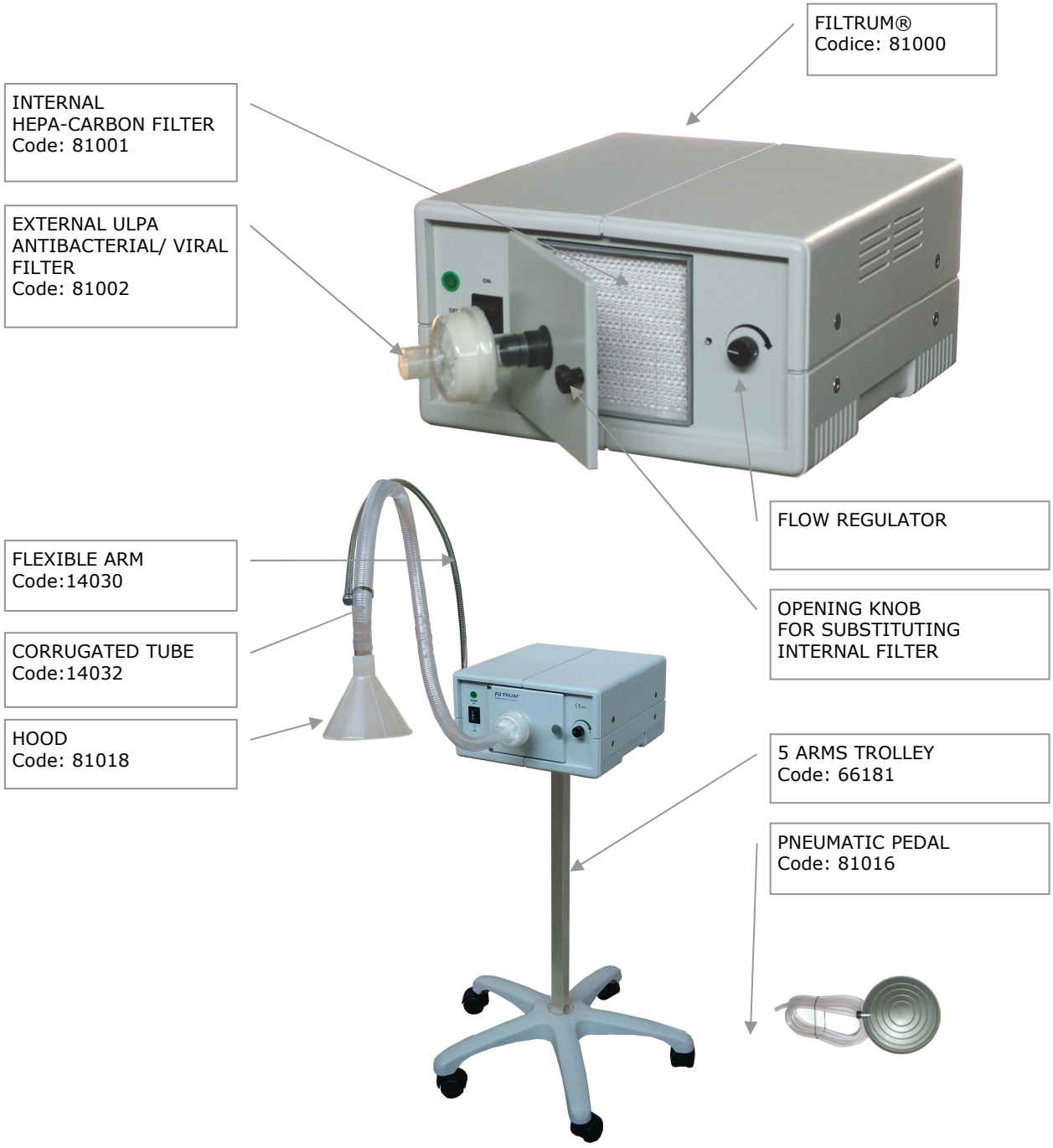
Optional:

Quantity	description	code
1	5 ARMS TROLLEY	66181
1	HOOD diam. 120 mm WITH CONNECTOR diam. 22 mm FOR CORRUGATED TUBE	81018
1	STERILE VAGINAL SPECULUM	81025
1	STERILE CONNECTOR FOR VAGINAL SPECULUM	81014

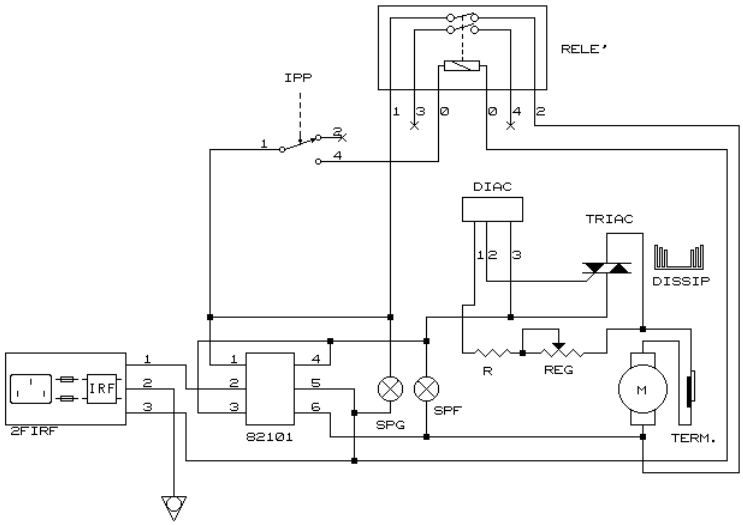
⚠ **CAUTIONS: The Smoke filtration system Model "FILTRUM®" device is to be set up in such a way, that a separation from the mains supply can be easy.**

WARNING:This equipment should only be used by personnel with medical training who have received appropriate training and are therefore familiar with suction procedures and the use of vacuum cleaners. Always wear gloves for all operations and use only accessories and vacuum adjustments as prescribed by your doctor.

2.11 DESCRIPTION



2.12 ELECTRICAL DIAGRAM AND COMPONENTS DESCRIPTION



3 PREPARATION FOR USE

3.1 Check before use

Check Smoke filtration system Model "FILTRUM®" before use:

a) Damage of the power cord or of the main socket
b) Obvious equipment damage safety defects
c) Proper functioning of the device
d) Presence of liquids inside filters

Check all accessories before use:

a) Presence of cracks or alterations on the filter. Replace if necessary
b) Presence of cracks or alterations on tubing and connectors. Replace if necessary
c) The integrity of the packages of the sterile accessories. Replace if necessary
d) Cleaning and disinfection of non-sterile and reusable accessories

CAUTION:
Do not use tubes or other sterile accessories if the sterile package is damaged. Do not re-use disposable accessories and / or sterile accessories. Always check the presence of materials in the EXTERNAL ULPA filter, if there are visible contaminations, the FILTER must be replaced immediately

3.2 OPERATING INSTRUCTIONS

CAUTION:
Smoke filtration system model FILTRUM® must be positioned so that it is easy to disconnect from the mains.

CAUTION:
The EXTERNAL ULPA VIRAL AND BACTERIAL FILTER if used for a number of interventions above the maximum indicated by the manufacturer, compromises the effectiveness in the removal of particles and odours, for an optimal result it must be replaced at the end of each intervention. The filter is disposable and can be a source of odours and possible viral and bacterial contaminants, the replacement of the filter must follow what is indicated in the maintenance program.

CAUTION:
The internal HEPA-CARBON FILTER can withstand a much higher number of procedures. It is recommended to replace it at least twice a year. See Annual Maintenance.

CAUTION:
The CORRUGATED TUBE if used for a number of interventions above the maximum indicated by the manufacturer can be source of odours and possible viral and bacterial contaminants, the replacement of the tube must follow what is indicated in the maintenance program.

CAUTION:
Filters are used to filter and retain fumes produced during electro-surgical or laser procedures. Being possible receptacles of many toxic organic substances and viral particles, the filters can be potential sources of irritation, infection, especially of the respiratory tract. So the used filters and tubes must be treated as special hospital waste. In any case, use gloves when handling used filters and tubes, and handle them the least possible. Store these parts in appropriate marked and closed containers. Throw together with other special medical waste.

CAUTION:
The device is equipped with a thermal protection sensor for excessive temperature which causes the motor stop. Keep the airflow sufficiently free to avoid such situations.

CAUTION:
This device must be used by personnel who has been adequately trained, also from the medical point of view, for the use of the Smoke filtration system, model FILTRUM®. Always wear gloves during use.

4 USE OF THE DEVICE

4.1 Disassembly

Check that the packaging is not damaged, in case of damage, send a written complaint to the carrier, also indicating the delivery note number and the date. Then communicate the inconvenience to the seller. Open the box and remove the packing material.

4.2 Electrical connection

Check that the mains voltage corresponds to the one indicated on the nameplate. Make sure that the electrical system of the premises used to operate the machine complies with the CEI regulations. Connect the power cord to the mains socket.

4.3 Initial installation

a) Open the device box and store it for future packaging.
b) Inspect the unit for visible damage or lack of accessories. If damage is found, contact the SIEM-NOVA Area Representative immediately.
c) The unit must be placed on a straight surface with respect to the earth.
d) The unit must be placed in a room with adequate ventilation.
e) Connect the pneumatic pedal to the coupling on the back of the unit, near the corresponding icon.
f) Attach the label provided with the HEPA-CARBON filter to the device and note the installation date of the filter on both the outdoor unit and the label applied to the filter.
g) Open the front panel door by operating on the locking knob until the indicator is positioned on the open icon.
h) Insert the HEPA-CARBON filter into the internal niche of the door and close it again.
i) Insert the external filter on the fitting located at the center of the front door.
j) Insert the external corrugated tube and the accessories required for the application.
k) Connect the power cord to the back of the device
l) Insert the plug into the socket

4.4 Activation

a) Insert the internal HEPA-CARBON filter code 81001, into the INTERNAL housing on the front panel.
b) Insert the external ULPA VIRAL / BACTERIAL filter code 81002 by pressure on the front panel connection
c) Attach the corrugated tube to the end of the filter and to the outlet on the speculum or other instrument to be used.
d) Alternatively, the tube can be left without a reducer for maximum suction. Place the end of the suction tube as close as possible to the surgical area. As a general indication the end of the tube should be placed no more than 2-3 cm from the surgical area in order to be able to suck easily. This distance may need to be adjusted, depending on the diameter of the tube used, on the aspiration speed selected, etc.
e) Set the main switch to the ON position. The light will light on.
f) To activate the pedal, set the main switch to the ON position on the corresponding icon. Press the pedal to turn off or turn on the device.
g) Check that the engine has started and that the suction works. If necessary adjust the suction speed by turning the knob on the front panel.
h) Prepare the patient for the procedure.
i) Activate the device.
j) Perform the intervention.

4.5 Out of service after use

a) Press the ON / OFF / ON switch to turn off the device
b) Remove the power cord from the mains socket and then from the socket
c) Remove the disposable material
d) The used filter must be handled as a special hospital waste
e) Reassemble the cleaned material
f) Disinfect as described in "Guidelines for cleaning and sterilization"
g) Disposal of disposable materials as required by local disposal procedures and / or guidelines

5 TROUBLESHOOTING

If the machine does not work correctly, it is advisable to check whether the problem can be solved by carrying out one of the operations described below.

<u>The engine of the device does not start when the pedal is pushed:</u>

a) Check the connections of the power cable.
b) Check that the fuses are intact. If broken replace them with others of the same type. Check that the main switch is in the ON position and the light is illuminated.
c) Press the pedal. Verify that the pedal tube is connected to the panel.
d) Adjust by rotating the speed control slider.

<u>The main switch is in the II ON-PEDAL position, the light is illuminated but the pedal does not work.</u>

Verify that the pedal tube is connected to the panel. Inspect the tube and check for damage. Cut the damaged part and reconnect it to the panel. If the device has worked without proper engine cooling, the unit may have intervened to protect against overheating. Verify that the airflow is free. When the engine has sufficiently cooled down, the unit will automatically reset itself. If the engine worked when the overheat protection intervened, it will restart.

<u>The device does not aspirate and does not filter effectively</u>

Place the distal part of the suction tube closer to the wound. Verify that the filter is not obstructed.
The external filter may be occluded due to excessive use, change it.
The internal filter may have moved.
Check that the filter is in the correct position and that the locking ring is in the closed position.

6 CLEANING AND STERILIZATION GUIDELINES

6.1 General notes

a) Follow the cleaning instructions given by your local regulations.
b) Wear protective gloves for cleaning / disinfection.
c) Dispose of all contaminated parts according to local regulations and / or guidelines.

6.2 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 in order to reduce this problem.

6.3 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.

6.4 Disassembly

Separate all individual parts before cleaning and disinfecting.

6.5 Cleaning of the device


WARNING: Before cleaning the device, pull power cord out of the main socket. Do not immerse it in water

a) remove the power cord
b) use a soft sponge or tissue with cold disinfectant solution (i.e. solution containing up 2% sodium hypochlorite)
c) avoid any operation causing liquid penetration inside the equipment

7 MAINTEINANCE

The Smoke filtration system Model "FILTRUM®" requires few maintenance operations if used following the indication of this manual.
If a Smoke filtration system Model "FILTRUM®" falls within the warranty period due to a manufacturing defect, it will be replaced.

NOTE: Defective devices must be returned to the supplier.

7.1 Daily check up

The power cable must be inspected upon activation of the device, it must not be used if there are breaks in the covering.
The external filter ULPA VIRAL AND BACTERIAL FILTER code 81002 must be replaced after every use.
The corrugated tube and any other device indicated for single use must be replaced every time it is used.
To change the external filter:

a) With hands protected by gloves, remove the external filter which is press-fitted on the connector diameter 22 mm and throw it into special waste.
b) Insert the new filter in the appropriate housing, making sure that the suction direction is correct as indicated by the arrow on the filter cartridge and that it is well inserted.
c) Insert the corrugated tube and any other device indicated for single use.

7.2 MONTHLY CHECK

The pedal connection tube can occasionally be damaged. The tube must be inspected to guarantee its good conditions. In case of damage, it must be replaced, or cut the damaged part and reconnected. The cable of the current must be inspected, it should not be used if there are breaks in the lining.

7.3 6-12 months check up

For an excellent odour control in the environment and in the ambulatory, the HEPA-CARBON internal filter code 81001, must be replaced at least twice a year.
To change the internal filter:


CAUTION:
first disconnect the instrument from the network
a) Unscrew the door retaining ring until it is open
b) With hands protected by gloves, remove the internal filter cartridge and throw it in special waste.
c) Insert the new cartridge into the appropriate housing, making sure the filter is inserted.
d) Screw the filter retaining door ring, turn it to the closed position.
e) Attach the installation date label, set the installation date and apply the label on the device.

7.4 Daily test

This test allows to quickly check whether the device is suitable for use in the field and provides functional checks that can be completed in a few minutes.
a) Connect the appliance to the mains.
b) Operate the device through the switch on the front panel (O = off, II = on I = on for pneumatic pedal). The device must operate smoothly and no changes in the internal pump speed should be noticed. No abnormal noises and / or accentuated vibrations should be perceived.
c) Check that the filters are clean, if they are not white they must be replaced. A dirty filter prevents the correct operation of the suction and reduces its performance.

7.5 Every six months / year test

This test allows you to verify accurately whether the device is completely compliant with the original production characteristics and so suitable for use in the field. The checks should be performed by persons and / or companies specialized in this type of operation. Following the check, the inspection company should perform an electrical safety test in accordance with IEC60601-1 and issue a test summary document.

7.6 Cleaning

The device can be cleaned with a cloth soaked in alcohol or a detergent for instruments.
Do not use acetone.
Do not wet the instrument directly with the cleaning liquid.

8 DISPOSAL

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

Remark: the components of the equipment or accessories don't contain pthalates or natural latex

Items	***Material or regulation***
Smoke filtration system Model "FILTRUM®"	Waste from Electric and Electronic Equipment (WEEE)
Unit case	Stainless steela nd polystyrene painted bogie /TSG)
External filter	stirolux
Internal filter	Stainless steel and coal
Rubber components	Silicone
Corrugated tube	Polypropylene
Box	Cardboard
Manual	Paper

9 TECHNICAL SPECIFICATION

9.1 Transport/Storage conditions
The Smoke filtration system Model "FILTRUM®" and accessories must remain in the packaging for storage and stored at a temperature range from –25 °C to +70 °C (–13 °F to +158 °F).

9.2 Operating temperature
The Smoke filtration system Model "FILTRUM®" and accessories must be operated within a temperature range of +5 °C and +40 °C (+41 °F and +104 °F). Do not operate the products in extreme cold or heat.

9.3 Transport/Storage/operating conditions (humidity)
The Smoke filtration system Model "FILTRUM®" must remain in the packaging for storage and used at a humidity range from 15% to 93 %

9.4 Transport/Storage/operating conditions (atmospheric pressure)
The Smoke filtration system Model "FILTRUM®" must remain in the packaging for storage and used at an atmospheric pressure range from 0,7 bar to 1,06 bar

Do not use the devices above the altitude of 3000 meters above sea level (9.842 feet).

IP33

8.5 Protection class
The Smoke filtration system Model "FILTRUM®" is protected against ingress of dripping water (**IP33**).

The Smoke filtration system Model "FILTRUM®" is protected against the penetration of liquids and solids (IP33). It is always good though to protect from heavy rains. During operation and storage, the device should be kept dry. If the device is completely wet, move it to a dry place, dry externally and wait at least 30 minutes before using it again.

Technical informations: Smoke filtration system Model "FILTRUM®"

Dimensions (h x w x l):	220 mm X 330 mm X 310 m ((8,66 x 13,00 x 12,20 inch)
DIMENSIONS with trolley	1030 x 640 x 640 mm (40,5 x 25 x 25 inch)
Voltage:	230 VAC; 50 Hz; 485 VA
Operating cycle:	continuous
FLOW	>600 Liters/minute (+/- 5 %)
weight	8 kg / 48,5 lbs approx
CEI EN60601-1 Classification:	- Class I device - Applied part type B - Device not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxid.
DDM 93/42 CEE Classification	Class II b

(*) Measured at 0- meter, atmospheric pressure (1,01325 bar)

NOTE: The vacuum level may vary depending on the place of use (altitude above sea level, atmospheric pressure and temperature).

13 ELECTROMAGNETIC COMPATIBILITY
The Smoke filtration system Model "FILTRUM®" is in compliance with the requirements of CEI EN 60601-1-2-2015 for the electromagnetic compatibility of medical devices, anyhow the use of mobile telephones, LAN / WLAN, walkie-talkies (two-way radios) and cordless telephones sets could affect the Smoke filtration system Model "FILTRUM®" pump. A safety distance of min. 3.3 ft (1 m) to the equipment is recommended.

ELECTROMAGNETIC EMISSIONS
The Smoke filtration system Model "FILTRUM®" is intended for use in the electromagnetic environment specified below. **The customer or the user of the Smoke filtration system Model "FILTRUM®" should ensure that it is used in such conditions:**

Emissions test	Compliance	Electromagnetic environment
RF emissions CISPR 11.	Group 1	The Smoke filtration system Model "FILTRUM®" uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment nearby.
RF emissions CISPR 11.	Class B	The Smoke filtration system Model "FILTRUM®" can be used in all buildings, including domestic establishments and those directly connected to a public power supply low voltage which supplies buildings intended for domestic use.
Harmonic emissions EN 61000-3-2	Class A compliant	
Fluctuations emissions voltage / flicker EN 61000-3-3	Complies	

ELECTROMAGNETIC IMMUNITY

The Smoke filtration system Model "FILTRUM®" is intended for use in the electromagnetic environment specified below. The customer or the user of the Smoke filtration system Model "FILTRUM®" should ensure that it is used in such conditions:

IMMUNITY test	Test level EN 60601-1-2	Compliance level	Electromagnetic enviroment
electrostatic discharge (ESD) EN 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Transient / a sequence of rapid electrical impulses to EN 61000-4-4	± 2 kV for power supply	± 2 kV for power supply	The voltage quality should be compatible with a typical commercial or hospital environment
Surge EN 61000-4-5	± 1 kV between phases ± 2 kV between phases and earth	± 1 kV differential mode ± 2 kV common mode	The voltage quality should be compatible with a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% UT for 0.5 cycles (> 95% UT hole) 40% UT for 5 cycles (60% UT hole) 70% UT for 25 cycles (30% UT hole) <5% UT for 0.5 cycles (> 95% UT hole)	5% UT for 0.5 cycles (> 95% UT hole) 40% UT for 5 cycles (60% UT hole) 70% UT for 25 cycles (30% UT hole) <5% UT for 0.5 cycles (> 95% UT hole)	The voltage quality should be compatible with a typical commercial or hospital environment. If the Smoke filtration system Model "FILTRUM®" user requires continued operation also during power mains voltage black out, it is recommended to feed the Smoke filtration system Model "FILTRUM®" with an uninterruptible power supply or batteries.
Magnetic field to the mains frequency (50/60 Hz) EN61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should be at levels characteristic of a typical location in a commercial or hospital environment.

The Smoke filtration system Model "FILTRUM®" is intended for use in the electromagnetic environment specified below. The customer or the user of the Smoke filtration system Model "FILTRUM®" should ensure that it is used in such conditions:

Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should not be used close to any part of the Smoke filtration system Model "FILTRUM®", including cables than the recommended separation distance calculated from the equation applicable to the transmitter frequency. **Recommended separation distance** calculated from the equation applicable to the transmitter frequency. Recommended separation distance d = 1.2 x √P 80 MHz to 800 MHz d = 2.3 x √P 800 MHz to 2.5 GHz d = 1.2 x √P where "P" is the maximum rated power of the transformer output, in watts (W) according to the transmitter manufacturer and "d" is the recommended separation distance in meters (m). The field strength of fixed RF transmitters, determined by an electromagnetic site survey, may be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF EN 61000-4-6	3 V/m 150 MHz to 80 GHz	3 V	

Note 1: At 80 MHz and 800 MHz, the exposure distance for the higher frequency range.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RECOMMENDED SEPARATION DISTANCES BETWEEN RADIOCOMMUNICATION DEVICES

The Smoke filtration system Model "FILTRUM®" is intended for use in an electromagnetic environment in which radiated RF disturbances under control. The customer or the Smoke filtration system Model "FILTRUM®" operator of the device can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication equipment (transmitters) and the Smoke filtration system Model "FILTRUM®" device as recommended below, in relation to the maximum output power the communications equipment.

Maximum nominal power of the transmitter output (W)	Separation distance to the frequency of the transmitter (m)		
	From 150 kHz to 80 MHz $d=1,2 \times \sqrt{P}$	from 80 kHz to 800 MHz $d=1,2 \times \sqrt{P}$	From 800 kHz to 2,5 GHz $d=2,3 \times \sqrt{P}$
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 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 d '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.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11 SPARE PARTS

Use only accessories or spare parts supplied by Siem Nova srl. The use of spare parts not supplied from Siem Nova could invalidate the warranty.

12 WARRANTY

Siem Nova srl (or his 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.
Faulty material will be replaced free of charge (except transport cost) during this period if not resulting from abuse or misapplication. Warranty includes defects in materials, components and/or workmanship only if:

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

This will not apply to parts subject to wear and tear in use (i.e: tubing, drug nebulization chamber, piezoelectric transducer, filters)
To better ensure compliance with this warranty we recommend the exclusive use of spare parts supplied by Siem Nova srl.
The right to the replacement of faulty parts will not be recognized by Siem Nova srl if any work has been made on the equipment by unauthorized persons.

13 TECHNICAL FEATURES UPDATE

In order to continuously improve performance, safety and reliability, all products medical devices from Siem Nova Srl are periodically reviewed and changed. The instruction manuals are therefore amended to ensure their continued compliance with the characteristics of the input 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 of the device.