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 direct current
 This symbol indicates manufacturer's catalogue number.	 This symbol indicates manufacturer's production lot number.	 This symbol indicates manufacturer's product serial number.
 This symbol indicates a CAUTION or WARNING associated with the device.	 This symbol indicates a single use device. Do not reuse the device.	 This symbol indicates the temperature limitation for operation, transport and storage.
 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 that interferences may occur in the vicinity of equipment marked with this symbol
 This symbol indicates do not dispose the device together with unsorted municipal waste (for EU only).	 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 to keep the device away from sunlight	 This symbol indicates do not short circuit the battery	 This symbol indicates the components material could be recycled
 This symbol indicates do not dismount or deform	 This symbol indicates do not expose to fire or flame	 This symbol indicates compliance with EEC Directive
 This symbol indicates do not immerse in water or other liquid	 This symbol indicates do not cut or open	 This symbol indicates the optimal storage and employ condition for the battery

1 WARNINGS AND SAFETY INSTRUCTIONS

1.1 APPLICATION

The 1001 NEB ultrasound nebulizer 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 1001 NEB is used with the Siem nova accessories.

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

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 1001 NEB 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. Do not use the equipment in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxid.
7.  The use of mobile telephones, cordless telephones and other communication equipments can affect the 1001 NEB suction pump. A safety distance of min. 1 m to the 1001 NEB pump is recommended.
8. Keep the power supply cord away from hot surfaces.
9. Keep the mains plug away from moisture.
10. Never remove the mains plug out of the fixed mains socket by pulling on the power cord!
11. Never leave the device unattended when it is operating.
12. The equipment must stand upright during use.
13.  Never use the device while bathing or showering
14. Do not use extension cords with 1001 NEB nebulizer.
15. Keep the power supply cord where you will not fall or trip over it.
16. The power cords or the tubes (for their length) may involve a risk of strangulation.
17. Never place the power supply cord or the tubes around your neck.
18. Some components for their small size could be swallowed causing suffocation
19. Keep the 1001 NEB clean and dry.
20.  Never place the pump in water or liquids.
21. Never touch with wet hands electrical parts.
22. If the pump gets wet, rub with dry towel. Do not dry in a microwave.
23. Do not touch the suction pump when it has fallen into water. Unplug device immediately from main power supply.
24. Keep the equipment away from children and pets.
25.  Keep the equipment protected from direct sunlight.
26. Keep the equipment away from heat source
27. Prevent the nebulizer from falling to the floor.
28. Check the general conditions of delivery package of the 1001 NEB for completeness and the presence of all accessories supplied.
29. 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
This 1001 NEB Nebulizer from Siem nova is a professional quality ultrasound nebulizer that combines easy handling and cleaning with safety features to ensure optimal operation. 1001 NEB Nebulizer has been manufactured to nebulize medical drugs or demineralized water. The range of the particles size nebulized is from 1 to 6 microns, so they can reach high and low airways.

2.2 Intended use
Nebulizer 1001 NEB has to be temporary used by patients to nebulize drug or water for respiratory system treatment. This device has to be used in hospital or ambulatory for home assistance. If required a heater for heating the flow of the nebulized product.

2.3 Contraindications
The device is not suitable for use for thoracic or gastro-intestinal aspiration

2.4 Intended user
The 1001 NEB should only be operated by properly instructed users.

2.5 Service life
The service life of the device is two years (drug nebulization chamber, tube and piezoelectric crystal not included)

2.6 Package contents

(Please ask your supplier in case of missing parts or for additional accessories)

The package contains:

quantity	*description*	*code*	*Rif.*
1	Equipment 1001 NEB (basic unit)	14010	1
1	Cylinder Humidification Chamber	14125	2
1	Arm for tube and humidification and physiological solution or drug solutions	14029	3
1	Flexible arm with connection to the tube	14030	4
0.50 m	Polyethylene corrugated tube 0.50 m (from flow regulator to chamber)	14033.1	5
1.50 m	Polyethylene corrugated tube 1.50 m (from chamber to patient mask)	14033	6
1	Humidification chamber cap	14034.1	7
5	Drug Chamber	14034	8
1	Disposable atomising chamber cap	14091	19
5	Disposable atomising chamber	14091.1	18
2	Adult soft mask	14514	9
2	Children soft mask	14516.A	10

Optional (on request):

quantity	*description*	*code*	*Rif.*
	Heater	14011	
	Air filter	14040	
	TROLLEY	14001	

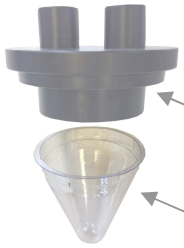
3.8 Description

1. Equipment 1001 neb (basic unit)
2. Cilinder Humidification Chamber
3. Arm for tube and liquids
4. Flexible arm with tubing support
5. Polyethylene corrugated tube
6. Polyethylene corrugated tube patient
7. Humidification chamber cap
8. Drug chamber
9. Adult Mask
10. Child mask
11. Main switch and timer
12. Nebulization power regulator
13. Air flow regulator
14. Floater (for liquid level)
15. Low level light (yellow)
16. Heater switch with light indicator
17. Heater
18. Disposable atomising chamber
19. Disposable atomising chamber cap

Cilinder humidification chamber (2)

Humidification chamber cap (7)

Drug chamber (8)



Disposable atomising chamber cap (19)

Disposable atomising chamber (18)

Arm for tube and liquids (3)

Polyethylene corrugated tube patient (6)

Flexible arm with tubing support (4)

Polyethylene corrugated tube (5)

Floater (14)

Air flow regulator (13)

Nebulisation power regulator (12)

Heater switch with light indicator (16)

Yellow light for low level (15)

Main switch knob and timer regulator (11) with green light

Adult and child masks (9) (10)

3 PREPARATION FOR USE

3.1 CHECKS BEFORE USE

Check 1001 NEB before use:

1. Damage of the power cord or of the main socket,
2. The device must be connected to room equipotential knot (earth knot). User is responsible for this.
3. Obvious equipment damage safety defects (1)
4. Proper functioning of the device.
5. Liquid presence in the humidification chamber (7) and in the drug chamber (if used)

Check all accessories before use:

1. Tubing (5) (6) for cracks, brittle areas and that connections are firmly attached. Replace if necessary
2. Sterile accessories must be checked on the integrity of the packaging before use. Replace if necessary
3. Not sterile and reusable accessories must be cleaned and disinfected before use.

CAUTION: **Do not use sterile accessories if the sterile packaging is damaged. Do not reuse disposable items or sterile accessories**

For continuous operation, turn left the timer knob and the machine will switch on till you turn right again the knob (the green light will be on), while for a timed operation of 0 to 2 hours, turn the timer knob to the right and place the arrow on the time required.

CAUTIONS The 1001 NEB device is to be set up in such a way, that a separation from the mains supply can be easy.

3.2 USE WITH DRUGS

For drug nebulization, the maximum quantity of drug you can nebulize is 10 ml.

1. Put only demineralized water into the humidification chamber (2) until reach to the lowest mark (if present otherwise 170/180 ml).
2. Put the nebulization chamber (8) into the cylinder.
3. Put the drug inside the drug chamber (8) max 10 ml (cc)
4. Connect the air tubing and turn on the equipment (continuously or by timer)

In order to add liquid, operate with the following instructions:

5. Turn off the device
6. Remove the tubing and then the nebulization chamber
7. Remove nebulization chamber taking it on its top side by doing a small torsion action.
8. Add drug
9. Repeat the operation as previous indications (point 1 to 4)

Liquid has never to be under the lowest level in the humidification chamber. If this happens the magnetic float in the cylinder will immediately stop the nebulization and a yellow light will blink (in this situation the air fan will continue to operate)

The use of drug has to be prescribed by authorized medical operators only.

3.3 USE WITH DEMINERALIZED WATER (HUMIDIFICATION)

For Humidification, the maximum quantity of demineralized water is 300 ml (higher mark on humidification chamber

1. Put demineralized water into the humidification chamber until reach to the higher mark (if present otherwise 300 ml).
2. Put the nebulization chamber cap (7) on the humidification chamber (2).
3. Connect the air tubing and turn on the equipment (continuously or by timer)

In order to add liquid, operate with the following instructions:

1. Turn off the device
2. Remove the tubing and then the nebulization chamber cap
3. Add demineralized water
4. Repeat the operation as previous indications. (point 1 to 3)

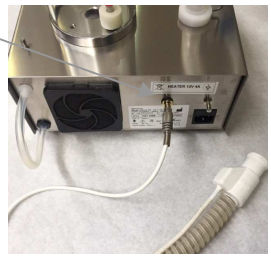
Use only demineralized water.

3.4 USE WITH HEATHER

- ✓ Follow previous instruction for liquid to be nebulized
- ✓ Replace the tube (6) with the heater (17)
- ✓ Connect the heather plug in the socket (on the back of the equipment)
- ✓ press the heater switch (16), a light will be turned on

Heater (17)

Heater plug and equipment socket



The heater works only when main switch is on

3.5 POWER REGULATION

Regulation rotating knob is on the front side.
The oscillating circuit board can generate a frequency of 1,635 + 1,750 MHz, which change the effectiveness of nebulization.
Usually better nebulization (crystal life) is obtained keeping the frequency at an intermediate value.

3.6 HEATER (Available on request)

The Heater should be used for heating the nebulized product's flow at a max temperature of 37°C. It has to be inserted into a corrugated tube and supplied accordingly to instructions at point 4.

The use of heater must be prescribed by authorized medical operators only

3.7 AIR FAN

The air flow produced by the inner fan push the nebulization from the nebulization chamber (or humidification chamber) to the patient through the corrugated tube. The inlet of the air is filtered by a replaceable foam filter

3.8 FLOW REGULATOR (13)

It is inside the joint connected with the tubing to the nebulization cap (or chamber). By positioning it in suitable position is possible have the required air flow regulation.

No air flow

Max air flow

3.9 HUMIDIFICATION CHAMBER (2)

It is an acrylic transparent tube with 2 circular marks showing the lowest and the highest level of demineralized water level.

3.10 DRUG NEBULIZATION CHAMBER (8)

It is a Polyethilene chamber and it has to be fitted on the humidification Chamber (2) cylindrical container by pressing it.

WARNING: insert and remove nebulization chamber only when device is off and removed from the corrugated tube.

4 OPERATING INSTRUCTIONS

CAUTIONS:
The 1001 NEB device is to be set up in such a way, that a separation from the mains supply can be easy.

4.1 Connect 1001 NEB to mains power

1. Check the 1001 NEB before use following the instruction in chapter 4 "Preparation for use". Check always if the power supply voltage is suitable equipment voltage.

4.2 Functional check

1. Follow the instruction in chapter 3 **preparation for use**
2. Turn the On / off knob (2) to switch on the equipment. Turn on left or right the main switch knob (11) (for continuous or timed operation)

3. Turn the power regulator knob to the desired position (for required nebulization)
4. Turn the air flow regulator to the desired position (for required air flow rate)

4.3 Placing out of operation after use

1. Turn the On / off knob (2) to switch off the equipment.
2. Remove the power cord from the main socket and then from the equipment.
3. Disconnect all the tubing.
4. Remove drug nebulization chamber (8)
5. Remove the liquid inside the humidification chamber (2) pulling out the silicone tubing on the back of the equipment (see pictures).
6. Clean and disinfect the humidification chamber. (2) See chapter 6 "Cleaning guidelines"
7. Clean and disinfect all the tubing and drug nebulization chamber (8) or humidification chamber cap (7). See chapter 6 "Cleaning guidelines"
8. For disposable material follow local after-use guidelines (if used)

Warning:
the equipment must be stored absolutely dry (above all the humidification chamber) to avoid corrosion and/or crystal damage

Pull this side for discharge humidification chamber liquid

5 TROUBLESHOOTING

In case device doesn't work properly, please check if the problem can be solved with one of the interventions below mentioned:

DEFECT	REASON	SOLUTION
Device doesn't start	No power supply	Check net voltage and supplying cable
Device doesn't start	No power supply	Check the fuses and if they are burnt, please call technical Assistance
Device doesn't atomise Level pilot light is on	Liquid level in the cylinder is low	Fill up with other demineralized water
Nebulization flow is low	Power regulation	Turn and set it for increasing the nebulization rate
Nebulization flow is low	Flow valve is closed	Open It in suitable position
Device doesn't produce the required nebulization	Nebulization chamber is broken	Replace it
Device doesn't produce the required nebulization	Nebulization chamber and or the humidification chamber are empty	Please put the liquids in the chamber/chambers
Device doesn't produce the required nebulization	Piezoelectric crystal broken	Call technical Assistance
Device doesn't produce the required nebulization	Electric board problems	Call technical Assistance
Device is noisy	Fan troubles	Call technical Assistance
Outside or inside Liquid leakage	Broken humidification chamber and /or tubing	Call technical Assistance

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.

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 the equipment unit, power cord and stripes

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

1. remove the power cord
2. use a soft sponge or tissue with cold disinfectant solution (i.e. solution containing up 2% sodium hypochlorite) avoiding liquid penetration inside the unit and the power cord.
3. avoid any operation causing liquid penetration inside the equipment.
4. Remove the liquid inside the humidification chamber (2) pulling out the silicone tubing on the back of the equipment (see pictures).
5. Clean and disinfect the humidification chamber.
6. Follow the cold disinfectant solution manufacturer instruction. Use soft clean cloth to dry

6.6 Cleaning the tubing
Separate all individual parts before cleaning and disinfecting.

1. Clean components in hot water (60–70 °C) containing a detergent with a pH range between 6.0 and 8.0 only, in order to avoid damage.
2. Soak all parts thoroughly with warm, soapy water (60–70 °C) or in enzymatic detergent for 1–5 minutes.
3. Remove visible dirt with a cleaning tool (i.e. general-purpose cleaning brush, such as pipe cleaners or non-abrasive lint cloths).
4. Rinse thoroughly in clear water.
5. Allow to dry.
6. Check the parts for visible dirt and repeat these steps if necessary.

Warning: the equipment must be stored absolutely dry (above all the humidification chamber) to avoid corrosion and/or crystal damage

6.7 Sterilization (if required) of tubing chamber and masks

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 ,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 solution of Phenol for 30 minutes (see handbook disinfectants).

All the material reusable after the decontamination and before the sterilization process must be thoroughly washed in all its parts.

1. Only cool sterilizing or dipping could be made. Follow instructions of the suitable chemical product manufacturer for using it.
2. After 30 sterilizing cycles it is recommended to check the wholeness of the items.

7 MAINTEINANCE

The 1001 NEB ultrasound nebulizer requires few maintenance operations if used following the indication of this manual.
If a 1001 NEB ultrasound nebulizer within the warranty period due to a manufacturing defect, it will be replaced.

7.1 DAILY CHECK UP

User has to do it each time after using the device:

1 Empty the cylinder of liquid using suitable tool.
2 Clean and dry the humidification chamber using a cotton cloth.
3 Substitute (if required by doctors) all fittings: corrugated tube, filter, nebulization chamber etc. otherwise clean and dry them.
4 Check, after every use, if magnetic float works good changing the liquid level

7.2 AFTER 100 WORKING HOURS CHECK UP

1 Replace the air filter

7.3 6-12 MONTHS CHECK UP (or after 1000 working hours)

1 Cleaning of the flow valve and general cleaning of electric board and the inner of the equipment.

These maintenance operations have to be done by Siem-Nova or only by Siem-Nova authorized people. All these operations are necessary for keeping the device fully operative.

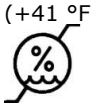
8 TECHNICAL SPECIFICATION

8.1 Transport/Storage conditions

The 1001 NEB nebulizer 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).

8.2 Operating temperature

The 1001 NEB nebulizer and accessories must be operated within a temperature range of +5 °C and +45 °C (+41 °F and +104 °F). Do not operate the products in extreme cold or heat.



8.3 Transport/Storage/operating conditions (humidity)

The 1001 NEB nebulizer and accessories must remain in the packaging for storage and used at a humidity range from 15% to 93 %

8.4 Transport/Storage/operating conditions (atmospheric pressure)

The 1001 NEB nebulizer and accessories must remain in the packaging for storage and used at an atmospheric pressure range from 0,7 bar to 1,06 bar

IP33

8.5 Protection class

The 1001 NEB nebulizer is protected against ingress of dripping water (**IP33**).

The 1001 NEB equipment is protected against the penetration of liquids and solids (IP33) It is always good though protect from heavvy rains. During operation and storage, the device should be kept dry. If the device is completely wet, move it to a dry, dry externally and wait at least 30 minutes before using it again.

Technical informations:

Dimensions (h x w x l):	30 X 25 X 27 cm (no trolley)
Voltage:	230 V 50 Hz AC (other voltage available on request)
Operating cycle:	continuous
Power:	90VA
Isolation Class:	I
Weight:	6,4 Kg (trolley 4 Kg)
CEI EN60601-1 Classification:	- Class II device - Applied part type B - Device not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrogen protoxid.
Noise:	less than 50 dB
Air fan	230V 50Hz AC 12,5 W
Inner transformer	Input 230V 50Hz AC (100VA) output 1 12V 50Hz AC / output 2 48V 50Hz AC

ULTRASONIC CIRCUIT BOARD E70947 (S)

Input voltage	48 V 50 Hz AC
power	30 VA ± 5
Ultrasounds frequency from	1,635 MHz to 1.75 MHz
Nebulization effectiveness	1 ml/min ± 0,2
Liquid temperature	from 0 to 37°C
Piezoelectric life	2000 h (approx)

HEATER 12 V. 4 A. (Optional)

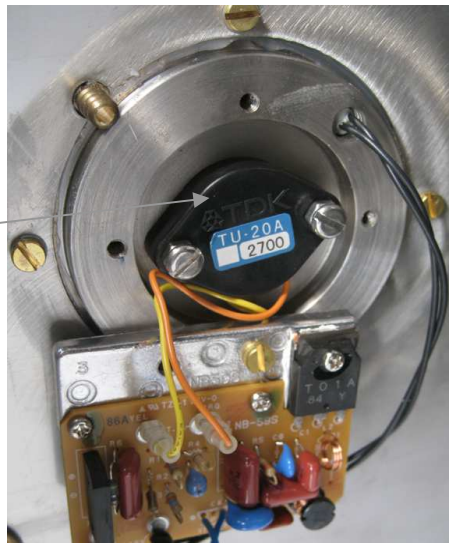
The heater can be activated by its own switch and it is a yellow light will be turned on. It works only when main switch is on.
The electrical connection socket is on the back side of the equipment.

8.6 OTHER SPARE PARTS LIST

CODE	DESCRIPTION	N°
14017	Regulating valve of air flow	1
14031	Potentiometer, power regulator	1
14035	Magnetic float for liquid level	1
14037	Electric outlet for anti-noise fuses	1
14038	Electric socket BNC for heater	1
14012	Main switch and timer	1
14040	Air Filter	1
14019	Piezoelectric transducer	1

9 INFO LEAFLET

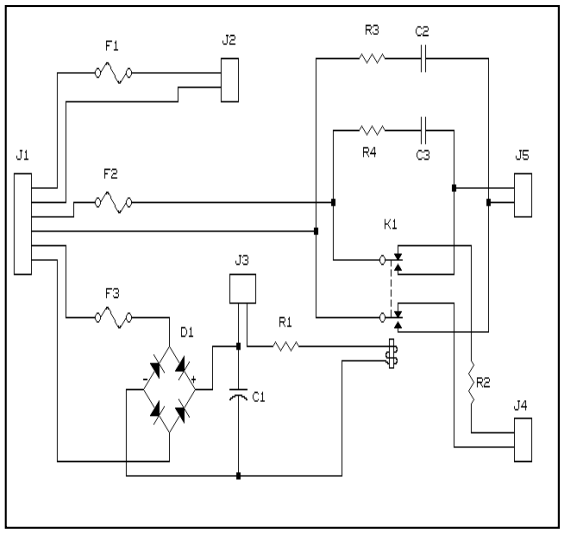
Fuses

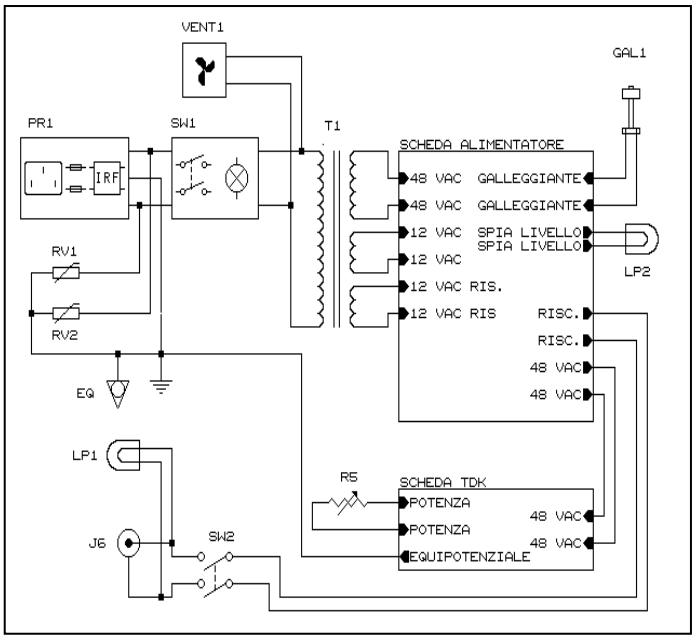


Piezoelectric transducer

Electric outlet for anti-noise fuses

10 ELECTRICAL DIAGRAM





11 ELECTRICAL COMPONENTS LIST

N	Ref.	Description
1	**PR1**	Electrical outlet with anti-noise filter, fn9260b-6- 06, two fuses first type t,f5x20,250 vac,50/60 Hz
1	**SW1**	two-pole switch with pilot light on/off
1	**VENT**	Ventilator type 8550 N, 230 VAC, 50 Hz, 12 w
1	**T**	transformer toroidal m. 2473-01; -major (dark) 230 vac, 50 Hz, 100 VAT -minor (red) 12 vac, 4 a; -minor (green) 48 vac, 1 a; -minor (yellow) 12 vac, 250 ma; - thermal security 112 °c.
1	**GAL1**	float reed fs2301
1	**SW2**	Two-pole heater's switch
1	**J6**	Electrical outlet bnc for heater
1	**R5**	Linear potentiometer 10 kΩ
1	**LP1**	Yellow pilot light for heater
1	**LP2**	Yellow pilot light 12 v for level
1	**TDK**	Atomiser card TDK e70947
1	**J1**	Six-pole connector for card power supply
1	**D1**	Rectifier 400 v, 1 a
1	**C1**	470 µf, 35 v
2	**C2,C3**	100 NF, 400 v
1	**EQ**	Equipowering knot
1	**R1**	82 Ω, 1/2 w
1	**R2**	470 Ω, 3 w
2	**R3,R4**	100Ω, 1/2 w
1	**K1**	relay rks-11dx-12
1	**F1**	fuse 5 a, type t, f5x20
1	**F2**	fuse 1 a, type t, f5x20
1	**F3**	fuse 100 ma, type t, f5x20
1	**J2**	Two-pole connector for heater
1	**J3**	Two-pole connector for float
1	**J4**	Two-pole connector for level pilot light
1	**J5**	Two-pole connector for TDK card
2	**RV1 - RV2**	SIO V S14K 275
1		Printed circuit of power supplier mod 1001 NEB, with solder resist.

12 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 of separately (see the below table)

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

Items	***Material or regulation***
1001 NEB ultrasound nebulizer	Waste from Electric and Electronic Equipment (WEEE)
Unit case	Stainless steel
Humidifier chamber	Metacrilate
Tubing, drug chamber	Polypropylene
Rubber components	Silicone
box	Cardboard
manual	Paper

13 ELECTROMAGNETIC COMPATIBILITY

The 1001 NEB ultrasound nebulizer 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, walkietalkies (two-way radios) and cordless telephones sets could affect the 1001 NEB pump. A safety distance of min. 3.3 ft (1 m) to the equipment is recommended.

ELECTROMAGNETIC EMISSIONS		
The 1001 NEB ultrasound nebulizer is intended for use in the electromagnetic environment specified below. **The customer or the user of the 1001 NEB should ensure that it is used in such conditions:**		
Emissions test	**Compliance**	**Electromagnetic environment**
RF emissions CISPR 11.	Group 1	The 1001 NEB 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 1001 NEB ultrasound nebulizer 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 1001 NEB ultrasound nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the 1001 NEB 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 ± 6 kV Air	± 6 kV Contact ± 6 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 1001 NEB user requires continued operation also during power mains voltage black out, it is recommended to feed the 1001 NEB 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 1001 NEB ultrasound nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the 1001 NEB 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 1001 NEB ultrasound nebulizer, 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 1001 NEB ultrasound nebulizer is intended for use in an electromagnetic environment in which radiated RF disturbances under control. The customer or the 1001 NEB operator of the device can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication equipment (transmitters) and the 1001 NEB 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 x √P	from 80 kHz to 800 MHz d=1,2 x √P	From 800 kHz to 2,5 GHz 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 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.

14 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.

15 WARRANTY

Siem Nova srl (or his authorized distributor) warrants 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.

16 Technical features update

In order to continuously improve performance, safety and reliability, all products medical devices from Siem Nova Srl are periodically reviewed and changes. 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 on the device label.