Ultrasonic Nebulizer

Operation manual

No. 31978
Congratulations on your purchase of a NOUVAG AG product. Thank you for the confidence shown in our products.
Please consult the instruction manual for the use and maintenance of the device in order to ensure that it will function properly and efficiently for many years.
You will find the conformity statement and list of authorized service representatives attached.

- Before operating, please read instructions carefully!
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Instructions for use and safety precautions</td>
<td>3</td>
</tr>
<tr>
<td>1.1</td>
<td>Notes for the user</td>
<td>3</td>
</tr>
<tr>
<td>1.2</td>
<td>Warranty notes</td>
<td>3</td>
</tr>
<tr>
<td>1.3</td>
<td>Scope of delivery</td>
<td>3</td>
</tr>
<tr>
<td>1.4</td>
<td>Pictographs on the appliance</td>
<td>3</td>
</tr>
<tr>
<td>1.5</td>
<td>Pictographs in this manual</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Important Safeguards</td>
<td>4</td>
</tr>
<tr>
<td>2.1</td>
<td>Application and operational conditions</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>Device description</td>
<td>6</td>
</tr>
<tr>
<td>3.1</td>
<td>Device operation</td>
<td>6</td>
</tr>
<tr>
<td>3.2</td>
<td>Intended use</td>
<td>6</td>
</tr>
<tr>
<td>3.3</td>
<td>Improper use</td>
<td>7</td>
</tr>
<tr>
<td>3.4</td>
<td>Ultrasonic nebulizer for continuous operation</td>
<td>7</td>
</tr>
<tr>
<td>3.5</td>
<td>Ultrasonic nebulizer with medication cup</td>
<td>8</td>
</tr>
<tr>
<td>3.6</td>
<td>Function description</td>
<td>8</td>
</tr>
<tr>
<td>4</td>
<td>Starting up</td>
<td>9</td>
</tr>
<tr>
<td>4.1</td>
<td>Preparation</td>
<td>9</td>
</tr>
<tr>
<td>4.2</td>
<td>Voltage selection</td>
<td>9</td>
</tr>
<tr>
<td>4.3</td>
<td>Device check</td>
<td>10</td>
</tr>
<tr>
<td>4.4</td>
<td>Mounting the Nebulizing chamber</td>
<td>11</td>
</tr>
<tr>
<td>4.5</td>
<td>Installing the sterile water system</td>
<td>11</td>
</tr>
<tr>
<td>4.6</td>
<td>Nebulizing using the medication cup</td>
<td>11</td>
</tr>
<tr>
<td>4.7</td>
<td>Installing the bacteria filter and tubings</td>
<td>12</td>
</tr>
<tr>
<td>4.8</td>
<td>Operation with table model accessories</td>
<td>12</td>
</tr>
<tr>
<td>4.9</td>
<td>Operation with moveable rolling stand</td>
<td>13</td>
</tr>
<tr>
<td>5</td>
<td>Operation</td>
<td>14</td>
</tr>
<tr>
<td>5.1</td>
<td>Function test</td>
<td>14</td>
</tr>
<tr>
<td>5.2</td>
<td>Mist amount adjustment</td>
<td>14</td>
</tr>
<tr>
<td>5.3</td>
<td>Air amount adjustment</td>
<td>14</td>
</tr>
<tr>
<td>5.4</td>
<td>Timer setting</td>
<td>14</td>
</tr>
<tr>
<td>5.5</td>
<td>Shut down</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>Errors, fault detection</td>
<td>15</td>
</tr>
<tr>
<td>6.1</td>
<td>General</td>
<td>15</td>
</tr>
<tr>
<td>6.2</td>
<td>Replacing fuses</td>
<td>16</td>
</tr>
<tr>
<td>7</td>
<td>Cleaning and Disinfection</td>
<td>17</td>
</tr>
<tr>
<td>7.1</td>
<td>Preparation</td>
<td>17</td>
</tr>
<tr>
<td>7.2</td>
<td>Dismantling and assembling the nebulizer chamber lid after cleaning,</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>before sterilization</td>
<td></td>
</tr>
<tr>
<td>7.3</td>
<td>Execution notes</td>
<td>18</td>
</tr>
<tr>
<td>7.4</td>
<td>Cleaning procedures</td>
<td>19</td>
</tr>
<tr>
<td>8</td>
<td>Maintenance / Repairs</td>
<td>20</td>
</tr>
<tr>
<td>8.1</td>
<td>General</td>
<td>20</td>
</tr>
<tr>
<td>8.2</td>
<td>Maintenance</td>
<td>20</td>
</tr>
<tr>
<td>8.3</td>
<td>Repairs</td>
<td>21</td>
</tr>
<tr>
<td>8.4</td>
<td>Service-Address:</td>
<td>21</td>
</tr>
<tr>
<td>9</td>
<td>Product range</td>
<td>21</td>
</tr>
<tr>
<td>9.1</td>
<td>Standard scope of delivery: Art. Nr. 3274</td>
<td>21</td>
</tr>
<tr>
<td>9.2</td>
<td>Accessories</td>
<td>21</td>
</tr>
<tr>
<td>9.3</td>
<td>Spare parts and consumable materials</td>
<td>22</td>
</tr>
<tr>
<td>9.4</td>
<td>Interface description</td>
<td>22</td>
</tr>
</tbody>
</table>
Ultrasonic Nebulizer

10 Disposal 23

11 Technical data 23
11.1 Environmental conditions 23
11.2 Performance data 23

12 Electromagnetic compatibility (EMC) 24
12.1 Electromagnetic emission 24
12.2 Electromagnetic influence to other equipment 24
12.3 Electromagnetic immunity 25
12.4 Electromagnetic interference immunity, non critical equipment 26
12.5 Recommended separation distances 27

13 Particle distribution 28

14 Applied standards 29
1 Instructions for use and safety precautions

For your own safety and that of your patients please observe this manual and take note of following:

1.1 Notes for the user

This operation manual is directed at medical personnel and users at home. It is not a substitute for a required instruction by qualified personnel. Only personnel who have been instructed by authorized personnel may use the device. You must also read this operation manual and understand fully how to use the device. This operation manual is a part of the device and must always be kept near the device. Qualified personnel are: who have either the medical experience and or training, have been instructed and authorized by such personnel or who have been instructed by a technician who has been authorized by the manufacturer to operate the device.

1.2 Warranty notes

The manufacturer declares that he will only take responsibility for the reliability and usability of the device, when non original, accessories and spare parts are used and when repairs of the device are carried out by authorized and qualified personnel. Statutory rights apply for the warranty period. For warranty claims please contact your retailer/dealer.

1.3 Scope of delivery

Please check the contents of all packaging to ensure that you have all parts which are required for safe use of the device. Should anything be missing please contact your retailer/dealer.

1.4 Pictographs on the appliance

Following pictographs are used on and within this device:

- : Observe operation manual

>ABS< : Material description for polymer

O : Off

I : On

: Device with application parts, Type B

~ : AC voltage / Alternating current

IP 22 : Water-resistant

: Device fuse
1.5 Pictographs in this manual

Following pictographs are used in this manual:

- **DANGER, CAUTION**: Failure to observe can lead to light to medium injury or material damage. In the worst case serious or fatal injuries are possible.

- **Note**: Offers additional information

- **Observe manual**

## 2 Important Safeguards

For your own safety and that of your patients please take note of following:

**CAUTION, risk of injury!**

The device may only be used under the supervision of a qualified personnel. When not in use the device must be stored out of the reach of children.

### 2.1 Application and operational conditions

The device may only be used for the declared and intended use (see section 3). As the nebulizer particles can penetrate the alveolar ducts, special care must be taken with regards to hygiene when preparing and using the device. Medicines should only be nebulized with the manufactures medication cups. The necessity of inhaling medicines must always be established by a doctor.

**CAUTION!**

Do not use the device with flammable or explosive liquids! Explosion hazard! Use of the device within an explosive or volatile environment is prohibited.

**CAUTION!**

The airflow is only adequately filtered if a suitable bacteria filter is used. The bacteria filter must be replaced at the latest after 1 week or in accordance with the filter manufacturer's instructions. If a self contained sterile water system is used, the filter must be replaced after 48 hours of use or every two weeks. Reusable tubes should be cleaned daily or at every patient change. Disposable tubes should be changed daily or at every change of patient.
WARNING!
Under no circumstances may you use medicines which have not been released by the manufacturer with the device, in particular suspensions and medicines of high viscosity. If you are unsure as to whether the medicine you wish to or may be used, then please contact the manufacturer of the medicine.
Currently released (tested) medicines are:
- Atrovent-LS®
- Sultanol®
- Cromo-CT®

CAUTION, avoiding infections!
The relevant hygiene regulations must be observed in order to avoid infections or bacterial contamination. Please observe the indicated purpose of the bacterial filter. Be sure to always wear gloves during application.

CAUTION, Risk of injury!
The connector for the heated tube on the rear side of the device and the patient may not be touched simultaneously.

CAUTION, Federal law
Federal law restricts this device to sale by or on order of a physician.

CAUTION, Defective device!
Use of non original spare parts can lead to injury to persons and or cause to damages of the device. Failure to adhere to the notes in this operation manual is carried out at your own risk and the manufacturer will take no responsibility nor be liable for damages caused by not doing so.

Non original parts
Use of non original parts which does not meet the requirements of original parts or interface described in section 9.4 can lead to a malfunction of the device. The use non original parts leads to the loss of warranty coverage for the device.

Damage
Visually check unit for any external damage, before use. Any work/repairs which require the use of tools may only be carried out by either the manufacturer or authorized personnel.

Electrical supply
The power supply voltage must correspond with the specified voltage on the type label. Before cleaning the device the power cord must be detached from the power supply socket.

Liability for proper function or damage
The liability for the proper function of the device is irrevocably transferred to the owner or operator to the extent that the device is serviced or repaired by not authorized personnel or the device is used in a manner not conforming to its intended use. Nouvag AG cannot be held responsible for damage caused by non compliance with the recommendations given.
3 Device description

3.1 Device operation

The main switch is located on the rear side of the housing. Other functions are controlled by buttons which are placed on the front top side of the housing. Voltage is selectable to: 110 V/ 127 V/ 230 V/ at 50-60 Hz

See also section 4.2 Voltage selection.

3.2 Intended use

To humidify breathing air for patients who are breathing spontaneously and for aerosol therapy.

Two different models are available for different installation options.

Tabletop model with adjustable multi-position supporting arm.

Model with moveable rolling stand and adjustable multi-position supporting arm for bedside patient treatments.

Contraindications:

Patients should be advised that Ultrasonic generated inhalation aerosols are not indicated for the initial treatment of acute episodes of bronchi spasm where rescue therapy is required for rapid response.

Nebulizing medical treatment only makes sense in long term applications (more than several weeks). Medical staff should have professional experience with inhalative drugs delivery especially with aerosols forms and provide best advantages to patients.

The ultrasonic nebulizer is a support device for treatment of different diseases but not exclusive and universal device for all. It should not be used as supplementary to any common therapy rather than for support treatment. The greatest advantage of aerosol therapy is the good local effect. Besides inhalative administration relieves the gastrointestinal tract and prevents interactions with food and other orally used drugs. The possibility of a treatment at home by the patients themselves or their parents is another advantage of an inhalation therapy.

The device has been tested to confirm the particle size of the aerosol generated when tested with normal (0.9%) saline solution for inhalation and also with common medication as:

- Atrovent-LS®
- Sultanol®
- Cromo-CT®

The use of these drugs should be permitted by the prescribing person.

Drug volume:

Respire pattern and pulmonary disorders block up the tube output and lead to a decreasing amount of inspired volume. This case occurs mostly with patients which have a respiratory disease. The residual volume is therefore no evidence that something is going wrong during the inhalation or treatment. However, the patient should discuss this issue with the prescribing person during the regular visit. The minimum remaining or residual volume in the nebulizer will amount about 4ml of fluid solution. The remaining volume could be compensated with higher NaCl solution volume. However, the total volume (drug and NaCl solution) in the medication chamber should not be below 8 ml before the start of treatment.

Caution: Do not use the remaining or residual volume which remains in the medication cup after treatment again. The disposable medication may be used only ones and has to be replaced after each use.
3.3 Improper use

CAUTION, observe application area and operational conditions!

Observe following points;
• The device may never be thrown, bumped into anything or dropped.
• The device may not be used during artificial respiration.
• The device may not be used without a bacterial filter.
• The device may not be operated without sufficient liquid medium.
• The device may not be operated by children without adult supervision.
• The device may not be operated together with flammable or explosive liquids.
• The device may never be in operation within an explosive or flammable environment.
• Never stick any objects into the housing in particular through ventilation holes and slits.
• The device may not be used together with oxygen or any other gases which are of flammable or oxidizing nature.

3.4 Ultrasonic nebulizer for continuous operation

1. Ultrasonic nebulizer
2. Nebulizing chamber
3. Tube, 300 mm
4. Tube, 1200 mm
5. Disposable Tubing set, sterile
6. Bacteria filter
7. Power cord, USA, 3 m
8. Connector for bacteria filter
9. Button for nebulizing ON/OFF
10. Button: Fog (- slow, + fast)
11. Button: Fan (- slow, + fast)
12. Timer (- less, + more) 15, 30, 45, 60 minutes
13. Socket for Nebulizing chamber
3.5 Ultrasonic nebulizer with medication cup

The Ultrasonic nebulizer with medication cup contains medication cups with lids instead of a disposable tubing set and a lid for nebulizing chamber. The remain scope of delivery is the same as the ultrasonic nebulizer for continuous operation (chapter 3.4).

3.6 Function description

The ultrasonic nebulizer produces high frequency by a transducer module which causes liquids in the nebulizing chamber.

Plug the power cord (7) into the power cord socket (16). Check the correct voltage selection according to the label on the appliance.

Switch the device on with the power switch (14) on the rear side of the device.

Press button start:
Pressing the switch (9) will start the device and the nebulization will automatically begin.

Push button fog volume:
Push the switch (10) the desired fog volume can be set. Push (+) increase the fog volume. Pressing (-) decrease the fog volume.

Push button switch flow:
Push the switch (11) the desired airflow can be set. Push (+) increase the air volume. Push (-) decrease the air volume.

Push the time button:
Push the button (12) activates the timer. Push (+) to increase the time period. Pressing (-) to decrease the time period.
The timer can be set in 15 min increments. The maximum time is 60 minutes.
If the timer is active the yellow LED will light. Once the set time has been exceeded the Ultrasonic Nebulizer will switch off automatically.
If you wish to interrupt the timer then press the button (9) and the nebulizing procedure stops. Red and audio warning will come on for 2 minutes.
To restart the device, push the on/off switch O/I.

The nebulizing chamber (19) is filled with liquid up to the max. fill mark. Then insert chamber (13) in the Ultrasonic Nebulizer. (be careful to position properly)
Push lid onto the chamber. Fit bacteria filter (6) to fan connection. Fit one end of the short tube to the nozzle on the bacteria filter and the other end to the nozzle on the lid.
Fit one end of the patient tube (4) to the nozzle on the lid and push the tube into the clips on the pint join arm. Route the tube upwards so the condensation can flow back into the nebulizer chamber.

NOTE: The assembly for use with the medication cup and the normal lid are the same.

4 Starting up

4.1 Preparation

Remove the device from the packing and check the content first according to the scope of delivery. The scope of delivery is to be found in the order confirmation.
Put the device upright on a horizontal, solid surface in order to guarantee proper function.
Cushions, mattresses, blankets and the like provoke a danger of blocking the ventilation air ducts which could cause the device to overheat.
Prior to the first use, please make sure the proper voltage is set.

4.2 Voltage selection

CAUTION, choosing the correct voltage!
DANGER
The device may only be connected to an electrical circuit which has a protective conductor connection. Failure to observe this can cause to damage of the device or personal injury.

1) Remove the fuse cartridge (1) carefully with a small screw driver used on both sides. Disengage and pull out straight.

2) Remove the voltage selector (2) from the cartridge and turn in the desired direction which shows the voltage required. Replace into cartridge, replace fuse. Install fuse cartridge back into the housing. Push until a click can be heard.

3) The voltage (110 V / 127 V / 230 V) can be seen in the window of the fuse cartridge.

   1. Fuse cartridge
   2. Voltage selector
   3. Voltage indicator

DANGER, choose the correct fuse!

Ensure that you use the correct fuse for the voltage you have selected:

110 VAC = T800 mA H 250 V
127 VAC = T800 mA H 250 V
230 VAC = T500 mA H 250 V

If you are in doubt then please consult a technician, your supplier or the manufacturer.

CAUTION, observe hygiene regulations!
Contaminated device parts may be harmful to the health of the patient. Prior to the first use, the device has to be prepared in accordance with applicable hygiene regulations.

4.3 Device check

CAUTION, Device check!

Only device parts that are in perfect condition guarantee correct function of the device. Device parts must therefore be checked thoroughly prior to any assembly work:

A product safety check (PSC) is required at the latest after two years or in accordance with national regulations.
Check the power cord for damage. Check all device parts made of plastic or rubber (tubes, nebulizing chamber etc.) to insure that these are faultless and show no age decay (porous tubing, cracks in housing).
• Check to make sure that the device has been cleaned correctly and that there are no residues or soiled areas.
• Damaged parts are not to be used
4.4 Mounting the Nebulizing chamber
The nebulizing chamber (19) is already mounted. Put the nebulizing to the connector (13) on the housing.

For to clean remove the lid (18) from the nebulizing chamber (19). Unscrew the transducer module (20) from the base of the nebulizing chamber (19). Reassemble after it is done in reverse manor.

**CAUTION!**
Do not use flammable or explosive liquids in the device

4.5 Installing the sterile water system
Install the lid for the nebulizer chamber (18) and connect the tubing set on the lid. Connect the tubing set (5) with the bag and the connector to nebulizing chamber lid.

- fluid should run into the nebulizer chamber,
- as soon as the max. level has been reached the flow stops automatically due to the overfill protection system (range between min. and max. mark).

In the event of a fault clean the float valve and check operation again.

Then put the ultrasonic nebulizer into operation. In case you have to change the tubing set, close the roller valve and remove the tubing set and connect the new one as described.

The tubing set (5) is a single-use product so dispose of it when it has been used once.

**CAUTION!**
The height difference between the nebulizer chamber and the liquid container (bag/flexible bottle, not in the scope of delivery) must not exceed 1000 mm.

Do not break the tube, handle with care. Make sure, that the container is ventilated sterile!

After the connection of the container check-up function of the flow:
The flow ensures, that the nebulizer chamber cannot be filled beyond the maximum mark. Only after impeccable working start up the nebulizer. If there is any malfunction, check-up the flow once again.

For a longer stopover period close the continuous filling set (with the roller valve at the tubing set).

4.6 Nebulizing using the medication cup
Only medication cups supplied by the manufacturer may be used. The medication cup consists of a cup and a lid. For nebulizing medicines only the medication cup may be used.

The necessity of inhaling medicines must always be established by a doctor.

Fill the nebulizing chamber (19) with sterile water up to approximately 2 mm above the mark for contact water (approximately 100 ml). Take care of enough liquid inside nebulizing chamber and sterile water system.

Contact water must be changed after use, or at least once a day.

Place the medication cup onto the nebulizing chamber and fill with the required medicine. Close the lid of the medication cup using sufficient pressure. Secure lid on the medication cup with clamp.
4.7 Installing the bacteria filter and tubings

Plug on the bacteria filter (6) to the connector (8) on the housing. Connect one side of the 300 mm tube (3) to the bacteria filter (6) and the other side to one of the connectors on the nebulizing chamber lid (18). If used with medication cup (see Medication cup picture above) connect the tubing in the same way to the medication cup.

Connect the 1200 mm tube (4) to the other connector on the nebulizing chamber lid (18) or to the lid of the medication cup (if used with medication cup)

Connect plug on the heated tube to the socket (17) at the rear side of the control box. The tube heating switches on automatically when switch (9) is on. Depending on environment the operating temperature of max. 37°C is reached after about 2 minutes.

NOTE: Take care to insure that the tube leading to the patient does not hang down in order to prevent condensation within the tube..

CAUTION!
The airflow is only adequately filtered if a suitable bacteria filter is used. The bacteria filter must be replaced at the latest after one week of use or in accordance with the instructions of the manufacturer of the filter.

If a self-contained sterile water system is used, the filter must be replaced after 48 hours of operation or every two weeks.
The reusable tubes are to be cleaned according to section 7 daily or on change of patients.
Disposable tubes are to be replaced daily or on change of patients.

4.8 Operation with table model accessories

Insert the stainless steel support pipe (25) into the mounting on the back of the housing of the device and tighten the screw knob.
Place the adjusting ring of the clamp (28) onto the stainless steel support pipe and slide it onto the lid of the nebulizing chamber, the continuous filling set or the sterile water capsule. Tighten the screw knob of the retainer.
Place the adjusting ring of the pin joint arm onto the stainless steel support pipe and fix in the desired position.
Attach the 1200mm tube or the heatable silicone tube to the tube clamps of the Multi position supporting arm and move the arm to the desired position. The fixing levers are used to arrest the joints. Make sure that the tube used does not hang through so that condensation cannot accumulate.
25. Stainless steel support pipe 25 x 600 mm
26. Multi position supporting arm with adjusting ring
27. Stainless steel infusion hook with adjusting ring
28. Stainless steel nebulizing chamber clamp

NOTE: Now place the adjusting ring of the infusion hook on the stainless steel support pipe and fix it in the desired position by tightening the screw knob. Hang up the bottle with the fluid to be nebulized on the infusion hook.

NOTE: Make sure that the tube used does not hang through so that condensation cannot accumulate.

4.9 Operation with moveable rolling stand

Assemble the moveable rolling stand (30) according to following instructions:

Place the bore of the clamp of the rear of the appliance over the support pipe and push it onto the pipe (25). Tighten the screw knob when the required position is reached. Put the retainer (28) onto the support pipe and position it to retain the lid of the nebulizing chamber (18), the continuous filling system (21), or the sterile water system. Tighten the screw knob when positioned. Push the bore of the multi position supporting arm adjusting ring over the support pipe and adjust to the position required. Tighten the screw knob. To adjust the joints, turn the levers to loosen the joint. Position the arm as required and tighten the lever to lock in position. Push the adjusting ring of the infusion hook onto the support pipe and position as required. Tighten the screw knob. Hand the vessel containing the nebulizing liquid on the infusion hook.

25. Support pipe
26. Multi position supporting arm with adjusting ring
27. Infusion hook with adjusting ring
28. Nebulizing chamber clamp
30. Moveable rolling stand

NOTE: Make sure that the tube used does not hang through so that condensation cannot accumulate.
5 Operation

5.1 Function test

CAUTION, function check!
The ultrasonic nebulizer is used for patient treatment. A performance reduction may lead to complications in patient treatment.

The ultrasonic nebulizer must thus receive a complete function check prior to any kind of application. Make sure that,
• the bacteria filter is installed correctly,
• the tubes and the nebulizing chamber are installed and correctly and that there are no residues within them.
• the tubes and the nebulizing chamber lid are sealed tight and that there are no mechanical forces acting upon the tubes; the tubes must not be bended,
• device parts made of plastic or rubber are in perfect condition and do not show any aging damages,
• the power cord is not damaged,
• the nebulizing chamber is filled sufficiently and the roller valve of the tubing-set is open,
• the clamp is fitted correctly on the nebulizing chamber lid, the sterile water capsule or the lid of the medication cup.

CAUTION!
Make sure that the nebulizing chamber is filled sufficiently. If the contact water level is too low, the transducer module can radiate back and damage the chamber by overheating.

5.2 Mist amount adjustment

Switch the device on using the press button switch (9) on the left. Use the button (10) to regulate the mist amount.

5.3 Air amount adjustment

Use the button (11) to regulate the airflow to the desired amount.

5.4 Timer setting

Push the time button (12) to increase the timer in 15 increments. The maximum time is 60 minutes. After the set time has elapsed the device switches off automatically. The red indicator above the on/off button (9) lights up and audio warning will come for 2 minutes. The device can only be reactivated after being switched off using left press left of the button (9).

CAUTION!
If self-contained sterile water systems are used, the following points must be observed:

1) If sterile water capsules are used without a continuous filling system, the maximum setting time for the timer is 15 minutes. Do no operate with an empty sterile water capsule or empty medicine cup.

2) In the case of prolonged nebulization with sterile water systems, make sure that the capsule in the nebulizing chamber is not operated without liquid. Do no operate with an empty sterile water capsule or medicine cup.

Failure to observe these points over a prolonged period will cause damage to the quartz module or the nebulizing chamber.
5.5 Shut down

Push the O/I button to set the device to stand-by mode. This switches off transducer, fan and tube heating. Green light diode is lit. Close the roller valve at the tubing set. For long term shut down set the device from standby to power switch the power switch to off.

6 Errors, fault detection

6.1 General

A thorough quality check has been performed on the ultrasonic nebulizer in the factory. Should any malfunction nevertheless arise, you may be able to solve the problem yourself using the following guide.

**CAUTION, defective device!**
Using incorrect spare parts may lead to personal injury or to malfunction. Only use original spare parts authorized by the manufacturer.

On the left-hand operation panel there is a fault indicator above the press button switch (9). This light up red in the event of a fault or when the timer has come to an end.

In the event of a fault immediately switch off the device.

To turn off, use the press button switch (9) and the device is turned off and the lamps are no longer illuminated.

Eliminate the fault if possible and then switch the device on again.

Possible fault cases may be:

<table>
<thead>
<tr>
<th>Fault</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red LED comes on</td>
<td>Nebulizing chamber not fitted correctly</td>
<td>Insert the nebulizing chamber correctly. Be careful it is correctly positioned.</td>
</tr>
<tr>
<td></td>
<td>Nebulizing chamber is empty</td>
<td>Refill with nebulizing fluid.</td>
</tr>
<tr>
<td></td>
<td>Leak in nebulizing chamber</td>
<td>Screw transducer module firmly into nebulizing chamber</td>
</tr>
<tr>
<td></td>
<td>Faulty transducer module</td>
<td>Replace transducer module</td>
</tr>
<tr>
<td></td>
<td>Electronics failure</td>
<td>Call retailer for assistance</td>
</tr>
<tr>
<td>Insufficient nebulization when set to maximum output</td>
<td>Nebulizer fluid does not match scale</td>
<td>Refill with nebulizing fluid or remove some fluid</td>
</tr>
<tr>
<td></td>
<td>Resistance of filter too high</td>
<td>Replace filter</td>
</tr>
<tr>
<td></td>
<td>Condensation in patient tube</td>
<td>Empty condensation. Reroute patient tube so that condensation can flow back into the nebulizing chamber</td>
</tr>
<tr>
<td></td>
<td>Leak in tubes or lid of nebulizing chamber</td>
<td>Fit lid tightly and secure with clamp</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Connect tubes firmly to nozzles</td>
</tr>
<tr>
<td>No nebulization</td>
<td>Main switch at “0” (off)</td>
<td>Turns mains switch to “I” (on)</td>
</tr>
<tr>
<td></td>
<td>Not connected to power supply</td>
<td>Connect to power supply</td>
</tr>
<tr>
<td></td>
<td>Fuse blown</td>
<td>Replace fuse</td>
</tr>
<tr>
<td></td>
<td>No liquid in the nebulizing chamber</td>
<td>Fill liquid</td>
</tr>
<tr>
<td></td>
<td>Electronic fault</td>
<td>Call retailer for assistance</td>
</tr>
</tbody>
</table>
6.2 Replacing fuses

To replace the fuse in the device proceed as follows:

**CAUTION! Electric shock!**
Disconnect the device from the power supply before carrying on.

1) Pull out the device plug (1).
2) Release centre lock (3) at the device socket (1) carefully using a small flat screwdriver and then pull out the fuse cartridge (4).
3) Remove the defect fuse (2) and replace with a new fuse.
4) Install the fuse cartridge (4) into the socket and push until a „Click“ can be heard.
5) Check that the fuse cartridge is installed correctly.

1. Power socket
2. Fuses
3. Centre lock
4. Fuse cartridge

**DANGER, observe correct fuse type!**

Only the following fuse types may be used with this appliance non observance can lead to personal injury or malfunction of the device:

- 110 VAC = T800 mA H 250 V
- 127 VAC = T800 mA H 250 V
- 230 VAC = T500 mA H 250 V

If you are in doubt then please consult a technician, your supplier or the manufacturer.
Particular care in matter of hygiene is required in preparation and during inhalation because of the mist particle size that can enter the alveoli. Nebulizing of medicines should be done only with medication cups.

The airflow is only adequately filtered if a suitable bacteria filter is used. The bacteria filter must be replaced at the latest after 1 week or in accordance with the filter manufacturer's instructions. If a self contained sterile water system is used, then the filter must be replaced after 48 hours of operation or every two weeks. The bacteria filter has to be changed immediately after contact with water or other noticeable problems (color change, breakage, bacteria, etc.)

Multiple-use tubes must be suitable cleaned or with change of patient. Single-use tubes must be replaced daily or with change of patient.

### 7.1 Preparation

Remove the tubes from the nebulizing chamber and the bacteria filter.
Remove the tubing set from the bag and the nebulizing chamber lid.
Remove the nebulizing chamber lid from the nebulizing chamber and unscrew the transducer module out of the bottom of the nebulizing chamber.

Remove the rubber ring (2) out of the groove through the mounting hole using a blunt object. Remove the float body (3) and the valve body (4) from the float chamber.

**The tubing set (5) is a single-use product so dispose them when it has been used once.**

### 7.2 Dismantling and assembling the nebulizer chamber lid after cleaning, before sterilization

Dismantling: Remove the continuous chamber lid from the chamber. Remove the O-ring from the groove with a blunt object through the assembly hole (e.g. small hex key). Remove the float. Remove the valve body from the float chamber.

Assembly: Insert the valve body (4) with the conical tip into the valve seat. Insert the float (3), insert the O-ring (2) and make sure it is fitted in the groove properly.

Note: Even reusable accessories (e.g. after they have been reprocessed) have a limited service life. Because of many factors in handling and reprocessing, the material may be subjected to considerable attack, for example, from disinfectant residues when autoclaving. Wear may increase and the service life may be reduced significantly. If there are any external signs of wear such as cracks, deformations, discolorations, peeling materials or the like, these parts have to be replaced.
7.3 Execution notes

The components of the device can be cleaned and disinfected according to the data to be found in the table in section 7.3

**DANGER! Electric shock!**
Prior to any cleaning or disinfection work, the device has to be separated from the external power supply. Failure to do so can lead to electric shock.

Please observe the following notes:

1) Prior to disinfection, the parts have to be cleaned and then dried. Dirt particles may encapsulate and thus cause device parts to remain unsterile even after disinfection. Therefore all device parts have to be cleaned thoroughly prior to disinfection and heavily soiled surfaces be wiped with a cloth and cleaning agent.

2) Always pay attention to the manufacturers and hygiene specialists notes when applying disinfectants.

**CAUTION, hazard of injury!**
Disinfectants may contain agents that are harmful to one’s health, causing injuries in contact with skin and eyes. Protect your skin and eyes and always observe the hygiene regulations when working with disinfectants.

**CAUTION! Material modifications!**
Almost all the device components are made of plastic materials. Solvents as well as some disinfectants and cleaning agents may damage the plastic parts or cause tension cracks. You should therefore never use agents containing hydrocarbon or alcohol for cleaning the surfaces.

3) After disinfection in a solution, the device parts must be rinsed with sufficient water and dried immediately.

4) Autoclaving with heated steam accelerates the natural ageing of plastic parts. Providing autoclaving is carried out correctly then the parts will endure a minimum of 50 cycles. Under normal circumstances (with correct use of autoclaving) this value will be well exceeded.

**DANGER! Material alteration**
Autoclaving with heated steam accelerates the natural ageing on plastic materials, thus changing the sensitivity of the material which could impair the function of the device parts.

5) Always check that the device functions after cleaning.

**DANGER! Function check!**
Check for correct operation of device parts after any kind of cleaning or disinfection according to section 5.1.

**NOTES:**
If non-color –fast protective wrap is used the plastic parts can become discolored.

The nebulizing chamber, the nebulizing chamber lid, and the tubes are made of consumable materials. Depending on the applied cleaning process, they are subject to a more or less extensive material wear. All parts have to be checked for proper condition prior to operation. They have to be replaced in cases of discernible damage. If damage is seen they should be replaced.
7.4 Cleaning procedures

<table>
<thead>
<tr>
<th>Parts</th>
<th>Cleaning</th>
<th>Disinfection</th>
<th>Washing machine program</th>
<th>Sterilization with heated steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nebulizing chamber lid (without valve body, float body, rubber ring)</td>
<td>In warm water with mild household cleaning agent</td>
<td>Immerse in diluted solution</td>
<td>Wash cycle up to 95°C</td>
<td>Up to 135°C for at least 5 min.*</td>
</tr>
<tr>
<td>Nebulizing chamber without quartz module</td>
<td>Alternative: Solution of 1 part wine vinegar and two parts water. Soak for 30 minutes</td>
<td>Concentration and reaction time according to notes of the agents manufacturer</td>
<td>1 cycle</td>
<td>The bag must be large enough so that the seal is not under tension.</td>
</tr>
<tr>
<td>Tube 300 mm</td>
<td>Rinse thoroughly afterwards with clear water.</td>
<td>For example: Gigasept Instru AF 2 % solution 30 min. reaction time or Buraton 10F 1 % solution 30 min. reaction time</td>
<td></td>
<td>Autoclave in vacuum autoclaves at max. 135°C for at least 5 minutes*. Do not exceed the maximum load of the steriliser, if several instruments are sterilized during one sterilization cycle. Observe a drying phase for autoclaves without post-vacuum. Allow the run-on system to dry in the bag with the paper side upwards.</td>
</tr>
<tr>
<td>Tube 1200 mm</td>
<td></td>
<td>Rinse thoroughly afterwards with clear water.</td>
<td></td>
<td>*The temperature hold times must comply with the local guidelines and standards.</td>
</tr>
<tr>
<td>Components of Nebulizing chamber lid (Valve body, float body, rubber ring)</td>
<td>In warm water with mild household cleaning agent</td>
<td>Immerse in diluted solution</td>
<td>Prohibited</td>
<td>Up to 135°C for At least 5 min. * (after reassemble with nebulizer chamber lid)</td>
</tr>
<tr>
<td></td>
<td>Alternative: Solution of 1 part wine vinegar and two parts water. Soak for 30 minutes</td>
<td>Concentration and reaction time according to notes of the agents manufacturer</td>
<td></td>
<td>The bag must be large enough so that the seal is not under tension.</td>
</tr>
<tr>
<td></td>
<td>Rinse thoroughly afterwards with clear water.</td>
<td>For example: Gigasept Instru AF 2 % solution 30 min. reaction time or Buraton 10F 1 % solution 30 min. reaction time</td>
<td></td>
<td>Autoclave in vacuum autoclaves at max. 135°C for at least 5 minutes*. Do not exceed the maximum load of the steriliser, if several instruments are sterilized during one sterilization cycle. Observe a drying phase for autoclaves without post-vacuum. Allow the run-on system to dry in the bag with the paper side upwards.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rinse thoroughly afterwards with clear water.</td>
<td></td>
<td>*The temperature hold times must comply with the local guidelines and standards.</td>
</tr>
</tbody>
</table>
bacteria filter
Disposable: **Replace at the latest after 1 week** of in accordance to manufacturers specific instructions. If a closed sterile water system is used, filter change is recommended **after 48 hours of operation or every 14 days.**

Medicine cup
Disposable: Intended for only a single use.

Medicine cup lid

Housing
Wipe with a damp cloth
Wipe disinfection (DGHM-List or equivalent)
For example: Antifect Liquid Spray solution 30 min. reaction time
Not permitted

Power cord

Accessories set

Quartz module

The nebulizing chamber shall be rinsed with distilled water after each use.

The above mentioned are examples for disinfection/cleaning from the manufacturer of the appliance. Only products in accordance with the DGHM-List or equivalent may be used. For countries in which the DGHM-List is not known the agents described apply.

This does not exclude the need for the user to consult the hygiene specialist when need be nor the need to check the compatibility of the components to be disinfected when agents/solutions not listed here are to be used.

---

### 8 Maintenance / Repairs

#### 8.1 General

**CAUTION, Health hazard!**
The device is used for patient treatment.
The device or parts of the device could be contaminated.
Before the device is sent in for inspection or repairs, the nebulizing chamber, the continuous filling set, the bacteria filter and all tubes must be removed and the device cleaned and disinfected.

#### 8.2 Maintenance

The device is maintenance free. There is no necessity for maintenance above the level of normal cleaning and disinfection. Visual and functional checks are to be carried out before use to ensure correct functionality at all times.

To guarantee the device safety and the availability of all functions and to extend the lifespan, according to the manufacturer recommendation that the device is checked once a year by an authorized service technician. The scope of the maintenance is dependable upon the operational conditions under which the device is used.

The maintenance includes an inspection according to the regulation IEC 601-1.

The manufacturer stipulates that a yearly safety check according to. §6 MPBetreibV or equivalent is carried out.
8.3 Repairs

NOTE: Liability disclaimer

No liability can be accepted when unauthorized, unqualified personnel carry out any repairs to the device and accessories. Repairs may only be carried out by service technicians authorized by NOUVAG AG. Service technicians authorized by NOUVAG AG have access to spare parts lists, inspection plans, wiring diagrams and descriptions. These documents can be obtained from NOUVAG AG.

Should damage be noticed which requires a repair to the device then the device may no longer be used. In such cases please take note of the serial number to be found on the type label along with the service address.

8.4 Service-Address:

NOUVAG USA Inc.
18058 Albyn Court
Lake Hughes
CA 93532
USA

Phone: +1 (661) 724 0217
Fax: +1 (661) 724 1590
Toll Free: (800) 673 7427
E-Mail paul@nouvagusa.com

9 Product range

9.1 Standard scope of delivery: Art. Nr. 3274

- Ultrasonic nebulizer
- Power cord USA 3 m
- Nebulizing chamber (can be sterilized) including quartz module
- Nebulizing chamber lid
- Disposable tube 300 mm
- Disposable tube 1200 mm
- Bacteria filter
- Mouthpiece
- Tubing set

9.2 Accessories

The following are not part of the standard delivery and must be ordered extra:

Moveable rolling stand accessory set Art. Nr. 3302z comprising of:
5 legged rolling stand, chrome plated, 50 mm casters,
Stainless steel support pipe, multi position supporting arm adjusting ring

Table tope model set Art. Nr. 3301z comprising of:
Stainless steel support pipe 25 x 600 mm, multi position supporting arm with adjusting ring
9.3 Spare parts and consumable materials

Bacteria filter complete, disposable .............................................................................................................................. 3213
Medication cup and lid (6 pcs.) .................................................................................................................................. 3304
Tube 300 mm (autoclavable) ..................................................................................................................................... 3218
Tube 1200 mm (autoclavable) ................................................................................................................................... 3199
Nebulizing chamber lid .................................................................................................................................................. 3306
Nebulizing chamber incl. marking ................................................................................................................................. 3305
Transducer module ....................................................................................................................................................... 3307
Clamp, Stainless steel .................................................................................................................................................. 3308
Infusion hook, Stainless steel .................................................................................................................................. 3309
Mouthpiece ................................................................................................................................................................. 3277
Power Cord USA 3 m .................................................................................................................................................... 22266
Tubing set, disposable .................................................................................................................................................... 3303
Rubber ring for chamber lid ......................................................................................................................................... 3312
Float body for chamber lid ............................................................................................................................................ 3313
Valve body for chamber lid ........................................................................................................................................... 3314

CAUTION, defective device!
The use of incorrect parts may cause personal injury and or malfunction. Therefore, only original accessories and spare parts may be used.

9.4 Interface description

All units or accessory parts that are used in combination with the device must be listed in section 9.2 accessories or fulfill the requirements of the interface descriptions contained in section 11.

Only appropriate accessories and consumables specifically manufactured for the intended use which carry the CE sign may be used.
The configuration of the complete system and the inspection of the functionality lay in the hands and responsibility of the medical personnel.

Patient tube
The patient tube of the nebulizing chamber has a conical 22 mm ISO standard plug and socket connection so that, conventional patient respiration tube systems with these dimensions can also be connected.

CAUTION, environment temperature
Heatable tubes may only be used up to an environmental temperature of 37°C. 
Health hazard for patients.

CAUTION, operational check!
The user must check the function and the suitability of the parts for the respective purpose as well as for biocompatibility.
10 Disposal

At the end of the service life of the device, it must be disposed according to the applicable local waste disposal regulations. Make sure that the various materials are separated correctly.

The device Ultrasonic nebulizer contains no hazardous materials. The materials and device components can be recycled.

NOUVAG AG takes back old devices at low cost for disposal purposes.

DANGER, disposal!
The device has been used for patient treatment. The device or parts thereof may be contaminated after use. Therefore you must clean and sterilize the device prior to disposal.

Disposal
Disposal of this device may underlie national disposal regulations and laws. Please make sure to inform yourself adequately beforehand.

11 Technical data

11.1 Environmental conditions
In operation:
Temperature ......................................................................................................................... 10°C to 40°C
Humidity ............................................................................................................................. 0 up to 90% relative humidity without condensation

Storage:
Temperature ........................................................................................................................ -20°C to 70°C
Humidity ............................................................................................................................. 0 up to 90% relative humidity without condensation

Ambient operational air pressure ....................................... Normal air pressure conditions of 1013 mbar

11.2 Performance data
Voltage, rated frequency ......................................................................................... 110/127/230 VAC, 50 to 60 Hz
Fuses ......................................................................................................................................
110 VAC = T800 mA H 250 V
127 VAC = T800 mA H 250 V
230 VAC = T500 mA H 250 V

Power consumption ............................................................................................................ 50 VA
Ultrasound frequency ........................................................................................................ 1.68 MHz +/- 5%
Noise pressure level ....................................................................................................... 35 dB(A) approx.
Protection class .................................................................................................................. I, Type B
Humidity protection class ..................................................................................................... IP 22 (drip water)
Operation mode .............................................................................................................. Timer controlled or continuous operation
Nebulizing capacity ......................................................................................................... max. 3ml/min
Nebulizing capacity when using sterile water system .................................................. up to 2,5ml/min
Nebulizing-chamber volume .... 0 – „Min“ approx. 80 ml ; „Min“ – „Max“ approx. 85 ml ; total volume approx. 170 ml
Droplet size (MMAD) ......................................................................................................... average 4 μm, about 86% lower than 5 μm
Air flow ......................................................................................................................... up to 20 L/min. (when using AQUA + F or SecuRed Big)
Device dimensions H x W x D ..................................................................................... 190 x 205 x 315 mm
Weight ............................................................................................................................. approx. 3.500 g
Classification acc. to EG-Directive 93/42/EEC annex IX ...................................................... Class IIa
UMDNS-Code ................................................................................................................... 12-719
12 Electromagnetic compatibility (EMC)

12.1 Electromagnetic emission

Guideline and manufacturer declaration- Electromagnetic emission

The device is designed for use in the environments described below. It is the responsibility of the customer and or the user to insure that the appliance is not used under other conditions.

<table>
<thead>
<tr>
<th>Interference emission</th>
<th>In accordance with</th>
<th>Electromagnetic environmental - Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>HF-emission according to CISPR11</td>
<td>Group 2</td>
<td>The ultrasonic nebulizer generates HF energy internally and conducts it to the ultrasonic head for the purpose of creating the aerosol mist. The level of HF emission is very low. Electronic devices very near by may however experience interference.</td>
</tr>
<tr>
<td>HF-emission according to CISPR11</td>
<td>Class B</td>
<td>The ultrasonic nebulizer is suitable for use in all establishments including domestic establishments, and those directly connected to a public power supply network that also supplies buildings used for residential purposes.</td>
</tr>
<tr>
<td>Emission of harmonics according to IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Emission of Voltage fluctuation /flicker according to IEC 61000-3-3</td>
<td>Compliant</td>
<td></td>
</tr>
</tbody>
</table>

12.2 Electromagnetic influence to other equipment

Guideline to avoid, recognize and correct electromagnetic disturbance of other equipment

Other electrical / electronic equipment should not be used in the immediate vicinity of the device, neither should they be stacked upon or around the device. If it is not possible to avoid such a constellation then these other devices need to be observed to make sure their correct function. The effects of electromagnetic influence can be of wide variety and differ greatly depending on the device used. The functionality can be influenced and is not always easy to recognize as electromagnetic influence.

Examples:

<table>
<thead>
<tr>
<th>Device</th>
<th>Type of interference</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radio and TV receivers</td>
<td>Noise or crackling in the sound, Stripes across the picture</td>
<td>Increase distance</td>
</tr>
<tr>
<td>Monitoring systems e.g. Baby phone</td>
<td>Noise or crackling in the sound</td>
<td>Change physical arrangement</td>
</tr>
<tr>
<td>Wireless telephones</td>
<td></td>
<td>Change direction</td>
</tr>
<tr>
<td>Radio-Thermometer Radio-Weather station</td>
<td>Interference with data transmission, display blank or incorrect</td>
<td>Change reception channel</td>
</tr>
<tr>
<td>Electronic equipment in general</td>
<td>Incorrect function e.g. Intended operating mode stops or changes</td>
<td></td>
</tr>
</tbody>
</table>
### 12.3 Electromagnetic immunity

**Guideline and manufacturers declaration – electromagnetic interference immunity**

The ultrasonic nebulizers intended for operation in the following electromagnetic environment. The customer or user of the ultrasonic nebulizer should ensure that is used in such environment.

<table>
<thead>
<tr>
<th>Immunity check</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electro static discharge / (ESD) IEC 61000-4-2</td>
<td>+/- 6 kV contact</td>
<td>+/- 6 kV contact</td>
<td>Floors should be of wood or concrete or have ceramic tiles. If the floor has synthetic material, the relative humidity of the air must be at least 30%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>+/- 8 kV air</td>
<td>+/- 8 kV air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient / Bursts IEC 61000-4-5</td>
<td>+/- 2 kV for power supply lines</td>
<td>+/- 2 kV for power supply lines</td>
<td>Mains supply voltage quality should be that of a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td>Surges IEC 61000-4-11</td>
<td>+/- 1 kV Differential mode</td>
<td>+/- 1 kV Differential mode</td>
<td>Mains supply voltage quality should be that of a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>+/- 2 kV Common mode</td>
<td>+/- 2 kV Common mode</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and supply voltage variations IEC 61000-4-11</td>
<td>0,5 Cyc. UT - 100%</td>
<td>0,5 Cyc. UT - 100%</td>
<td>Mains supply voltage quality should be that of a typical commercial or hospital environment.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 Cyc. UT - 60%</td>
<td>5 Cyc. UT - 60%</td>
<td>If the user of the device requires continuous operation including during interruptions in the mains supply, powering the device from an uninterruptible power supply or a battery is recommended.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25 Cyc. UT - 30%</td>
<td>25 Cyc. UT - 30%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 sec. UT - 100%</td>
<td>5 sec. UT - 100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should have values typically found in commercial and hospital environments.</td>
<td></td>
</tr>
</tbody>
</table>

*Note: UT is the a.c. mains voltage before application of the test level.*
12.4 Electromagnetic interference immunity, non critical equipment

Guideline and manufacturers declaration – Electromagnetic interference immunity, non critical equipment

The device is designed to be used in surroundings as described below. It is the responsibility of the customer and/or the user to ensure that the device is not used under other conditions.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 Test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted HF disturbance</td>
<td>3 V rms 150 kHz – 80 MHz</td>
<td>3 V rms 150 kHz – 80 MHz</td>
<td>Portable and mobile radio equipment should not be brought up too close to the appliance in accordance with the following equation.</td>
</tr>
<tr>
<td>Radiated HF disturbance</td>
<td>3 V/m 80 MHz – 2,5 GHz</td>
<td>3 V/m 80 MHz – 2,5 GHz</td>
<td><strong>Recommended separation distance:</strong></td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td></td>
<td></td>
<td>d = 1,2 √P (for 150 kHz – 80 MHz)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 1,2 √P (for 80 MHz – 800 MHz)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>d = 2,4 √P (for 800 MHz – 2,5 GHz)</td>
</tr>
<tr>
<td>Portable and mobile radio</td>
<td></td>
<td></td>
<td>where P is the transmitter rated power in Watts (W) as stated by the transmitter manufacturer and d is the recommended separation distance in meters (m)</td>
</tr>
<tr>
<td>equipment should not be brought up too close to the appliance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>according to the following equation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recommended separation distance:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement on-site (see a) should show the field strength of stationary radio transmitters to be less than the compliance level (see b) at all frequencies.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disturbances are possible in the neighborhood of devices that carry the following symbol.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note 1:**
At 80 MHz and 800 MHz the higher frequency range is applicable.

**Note 2:**
These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by absorption and reflection by buildings, objects and people.

a) The field strength of stationary transmitters, e.g. base stations of mobile telephones and mobile land radio, amateur radio stations, AM and FM radio and TV transmitters, can not accurately be determined theoretically in advance. To determine the electromagnetic environment due to stationary transmitters, an investigation of the site should be considered. If the field strength, measured at the location where the device is used, exceeds the above compliance levels, the device should be monitored to determine that it is operating correctly. If any abnormal behavior is observed, further measures may be required, e.g. resisting of the device.

b) Over the frequency range 150 kHz to 80 MHz the field strength should be below 3 V/m.
12.5 Recommended separation distances

...between portable and mobile HF telecommunications devices and the ultrasonic nebulizer.

The ultrasonic nebulizer is intended for operation in an electromagnetic environment in which the HF disturbance levels are controlled. The customer or user of the ultrasonic nebulizer can help to avoid electromagnetic interference by respecting the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the ultrasonic nebulizer – depending on the output power of the communications device as shown below. Separation distance in meters depending on the transmitted frequency:

<table>
<thead>
<tr>
<th>Transmitter rated power in Watts</th>
<th>150 KHz – 80 MHz (d = 1,2 \sqrt{P})</th>
<th>80 MHz – 800 MHz (d = 1,2 \sqrt{P})</th>
<th>800 MHz – 2,5 GHz (d = 2,4 \sqrt{P})</th>
</tr>
</thead>
<tbody>
<tr>
<td>0,01</td>
<td>0,12</td>
<td>0,12</td>
<td>0,24</td>
</tr>
<tr>
<td>0,10</td>
<td>0,38</td>
<td>0,38</td>
<td>0,76</td>
</tr>
<tr>
<td>1,00</td>
<td>1,20</td>
<td>1,20</td>
<td>2,40</td>
</tr>
<tr>
<td>10,00</td>
<td>3,80</td>
<td>3,80</td>
<td>7,60</td>
</tr>
<tr>
<td>100,00</td>
<td>12,00</td>
<td>12,00</td>
<td>24,00</td>
</tr>
</tbody>
</table>

For transmitters with a maximum rated power not given in the table, the recommended separation distance in meters \((m)\) can be determined by use of the equation in the appropriate column, where \(P\) is the maximum rated power of the transmitter in Watts \((W)\) as stated by the transmitter manufacturer.

**Note 1:**
At 80 MHz and 800 MHz the higher frequency range is applicable.

**Note 2:**
These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by absorption and reflection by buildings, objects and people

a) The field strength of stationary transmitters, e.g. base stations of mobile telephones and mobile land radio, amateur radio stations, AM and FM radio and TV transmitters, cannot accurately be determined theoretically in advance. To determine the electromagnetic environment due to stationary transmitters, an investigation of the site should be considered. If the field of strength measured at the location where the ultrasonic nebulizer is used, exceeds the above compliance levels, the ultrasonic nebulizer should be monitored to determine that it is operating correctly. If any abnormal behavior is observed, further measures may be required, e.g. resisting of the Ultrasonic nebulizer.

b) Over the frequency range of 150 KHz to 80 MHz the field strength should be bellow 3 V/m.
13 Particle distribution

![Particle distribution diagram](image1)

![Mass distribution diagram](image2)
14 Applied standards

**Directive 93/42/EWG**
14. of June 1993 for medical products

Electro- and Electronic – Old devices

Quality management medical products

Breath therapy devices - Part 1
Nebulizing systems and its components
German version EN 13544-1: 2001

Application of the risk management for medical products

Sterilization of medical products
According to the manufacturers information for re-sterilizable medical products processing

Medical electrical devices
Part 1 General determination for safety

**DIN EN 60601-1-2Edition: 2001-10**
Medical electrical devices
Switzerland

Nouvag AG • St.Gallerstr. 23–25 • CH-9403 Goldach
Phone +41 (0)71 846 66 00 • Fax +41 (0)71 845 35 36
info@nouvag.com • www.nouvag.com

Germany

Nouvag GmbH • Schulthaißstrasse 15 • D-78462 Konstranz
Phone +49 (0)7531 1290–0 • Fax +49 (0)7531 1290–12
info–de@nouvag.com • www.nouvag.com

USA

Nouvag USA, LLC • 6201 Airport Freeway, Suite 200 • Haltom City, Texas 76117 • USA
Phone +1 (817) 887 9814 • Fax +1 (817) 887 9817 • Toll free (800) 673 7427
www.nouvagusa.com

Alle Nouvag-Servicestellen weltweit siehe:
For all Nouvag servicecenters worldwide please check:
Tous nos centres de service mondial visitez:
Per tutti i servizi tecnici mondiale di Nouvag vedere sul:
Nouvag Centros de Servicio autorizados ver:

www.nouvag.com