




## **Ultrasonic Nebulizer Model SalinaVita K5**

Instructions for use

## Table of Content

Notes on these instructions and system of symbols .....	3
Safety instructions .....	3
Warnings.....	4
Responsibility of the manufacturer .....	4
Intended purpose .....	4
Proper use .....	5
Areas of application.....	5
General description .....	6
Diagram Ultrasonic Nebulizer SALINAVITA K5 .....	7
Preparation for operation .....	8
ISAPAK system assembly instructions .....	9
Information on preparation for operation .....	10
Malfunction indicators .....	11
Fault causes .....	12
Exchange/replacement of disposable materials .....	13
Checking the device functions.....	14
Technical data.....	14
Technical description – Electromagnetic compatibility .....	16
Meaning of the symbols on the nameplates, accessories and consumables .....	21
Warranty.....	22
Distributor .....	22
Manufacturer .....	22

## Notes on these instructions and system of symbols

 <b>WARNING</b>	Warnings which can result in a hazard if ignored.
<b>HINT</b>	Special notes, tips
<b>=&gt;</b>	<i>Refer to...</i>
<b>UPPER CASE</b>	Indicates a button on the device
<b>Bold</b>	Particular highlighting in the text



## Safety instructions

- The instructions for use forms part of the device. All handling of the device requires precise knowledge and observance of this instructions for use . The device is only intended for the use described (=> Intended purpose / Application areas).
- Do not operate the device in rooms subject to a risk of explosion.
- The ultrasonic nebulizer is used in professional facilities in the healthcare system. Among others, these can be:
  - hospital rooms in hospitals or clinics
  - operating rooms or intensive care units in clinics
  - hospital rooms in nursing homes
  - medical practices
- The ultrasonic nebulizer may only be used by competent and trained personnel.
- Prolonged continuous operation with the nebulizer chamber empty and a high power setting causes temperatures to increase on the transducer head. Touching the transducer glass or contact water in the transducer head can cause burns.  
Never reach into the transducer head with the device switched on.  
This can cause burns



## Warnings

- Do not use the ultrasonic nebulizer with patients needing artificial respiration and do not integrate the ultrasonic nebulizer into respiratory systems!
- Do not operate the ultrasonic nebulizer without a bacteria filter.
- Do not use flammable or other explosive liquids (alcohol!) either as contact liquid or as an aerosol.
- Do not put the ultrasonic nebulizer into operation if the housing or the accessory material is damaged.
- Ensure that no mist containing brine can be absorbed by the nebulizer itself or other electrical devices.
- Do not operate the ultrasonic nebulizer with a face mask or mouth piece.

## Responsibility of the manufacturer

The manufacturer and importer shall be responsible only for the effects on safety, reliability and performance when:

1. assembly, installation, additions, readjustments, modifications or repairs are carried out only by personnel who have written authorization from Schumacher & Partner GmbH.
2. the ultrasonic nebulizer is used in compliance with the instructions for use.

We do not accept liability for any repairs, modifications, adjustments etc. carried out by the user's technical personnel. The same applies to devices which the manufacturer has designated as "reparable by the customer" and for which appropriate documents are available.

## Intended purpose

The Ultrasonic Nebulizer SALINAVITA K5 is used to deliver an aerosol solution (sterile water, isotonic saline solution or a brine solution) to the human respiratory system.

## Proper use

Isotonic saline solution, brine solution or sterile water may be used as the aerosol medium. Use of medications as an aerosol medium is permissible only if the medium in question has been designated by the manufacturer of the medication as suitable for such use and is prescribed as part of a therapy stipulated by the attending physician. The type of aerosol medium and the duration of use are to be selected according to medical considerations and the decision must be determined by a medical professional (physician).

Medical applications other than those named above are not permitted.

Side effects and contraindications:

There are no known side effects or contraindications.

## Areas of application

The ultrasonic nebulizer is for use in healthcare facilities such as clinics, medical practices and other medical facilities. The devices may be used within the facilities in patient rooms, examination rooms and treatment rooms or in rooms especially outfitted for their use.

The devices are not intended for home use.

The devices are to be operated by medical professionals.

Special breathing techniques are not required their use.

The ultrasonic nebulizer may be used with patients aged three (3) years and older. Thanks to continuous misting during use, no particular breathing techniques are required which results in an autonomous, passive application. The aerosol should be inhaled at a distance of 5 cm from the end of the tube over the mouth or nose.

The patient should be lying down or sitting during use.

Use of the ultrasonic nebulizer is indicated for use in the following applications:

- dryness of the mucous membranes
- mucous membrane rehabilitation therapy

## General description

The Ultrasonic Nebulizer SALINAVITA K5 uses an ultrasonic transducer to nebulize the liquid in the sterile nebulizing chamber using a contact liquid in the transducer head to produce tiny aerosol particles.

As a result, a dense aerosol mist is produced which is propelled to the patient in a filtered airflow through the aerosol tubes. Please note the application instructions specified below.

### Advantages of the system:

- Alveolar accessible particle sizes of 1 to 5  $\mu\text{m}$  (45%) and 1 to 7  $\mu\text{m}$  (65%)  
(Data refers to nebulizer level 3 / air flow level 3)
- There are no parts requiring sterilization in an autoclave
- No contact with the patient
- Sterile nebulization with reduced amount of disposable material

### Application Instructions:

Due to the particle size giving good alveolar access, special attention must be given to hygiene when preparing and performing the inhalation procedure.

HINT

**Important:** To ensure that the airflow is properly filtered, use a suitable bacteria filter (11) (see figure layout diagram on page 7).

## Diagram Ultrasonic Nebulizer SALINAVITA K5

Example: ISAPAK system

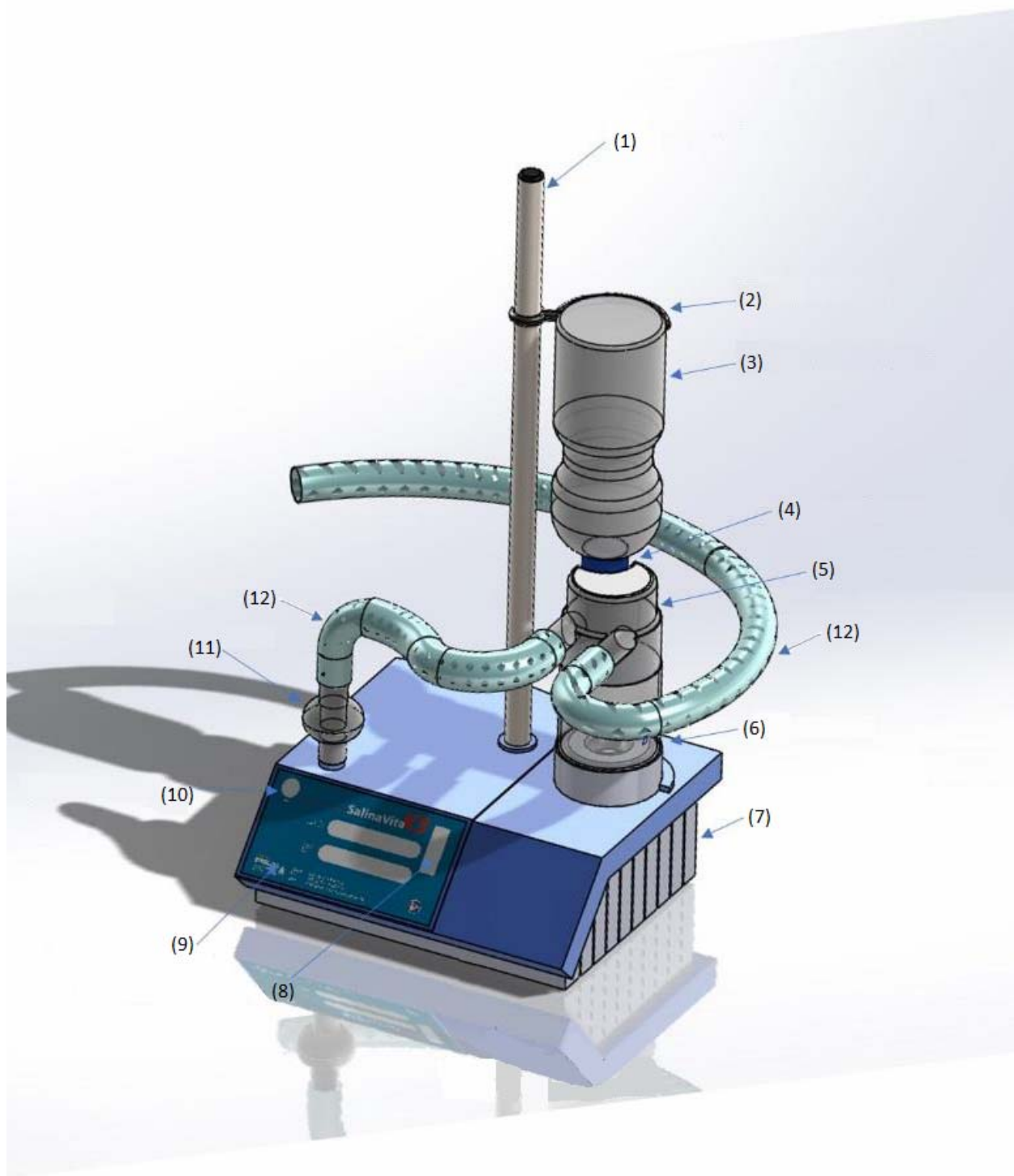




Figure 1: Layout diagram

(1) support rod	(2) bottle holder	(3) sterile water bottle
(4) chicken feeder	(5) nebulizing chamber	(6) transducer head
(7) main switch	(8) error display	(9) control panel
(10) ON / OFF button	(11) bacteria filter	(12) aerosol tube

## Preparation for operation

1. Assemble nebulizer as described (page 9).
2. Check whether the mains voltage and power information on the nameplate (rear of the device) correspond to your mains power supply.  
Plug the mains cable into the mains socket on the rear of the device and connect with the mains power supply.
3. Check whether there is enough distilled water in the transducer head (6) (blue marker).
4. Switch the device ON at the main switch (7) on the rear. Press the ON/OFF button (10) on the control panel and start nebulization. The green "operation" indicator lights up.
5. You can adjust the following values on the control panel (9):

Parameter	Symbol	Settings
Aerosol quantity		Level 1 to 5
Air flow		Level 1 to 5

6. After use: Switch off the device with the ON/OFF button on the control panel (10).

The device is now in standby mode. This will be displayed by the green operation indicator, which lights up at regular intervals.

If not used for a longer period, the nebulizer needs to be switched OFF with the main switch (7) at the rear of the device.

### Aerosol quantity

Select level 1 or a low aerosol quantity and level 5 or a high aerosol quantity.

### Air flow

Select level 1 or a low air flow and level 5 or a high air flow.

### Resetting

When the device is turned on, the setting values of the previous operating phase are selected again.



### WARNING

To avoid the risk of electric shock, this device may only be connected to a supply network with protective conductor.

## ISAPAK system assembly instructions

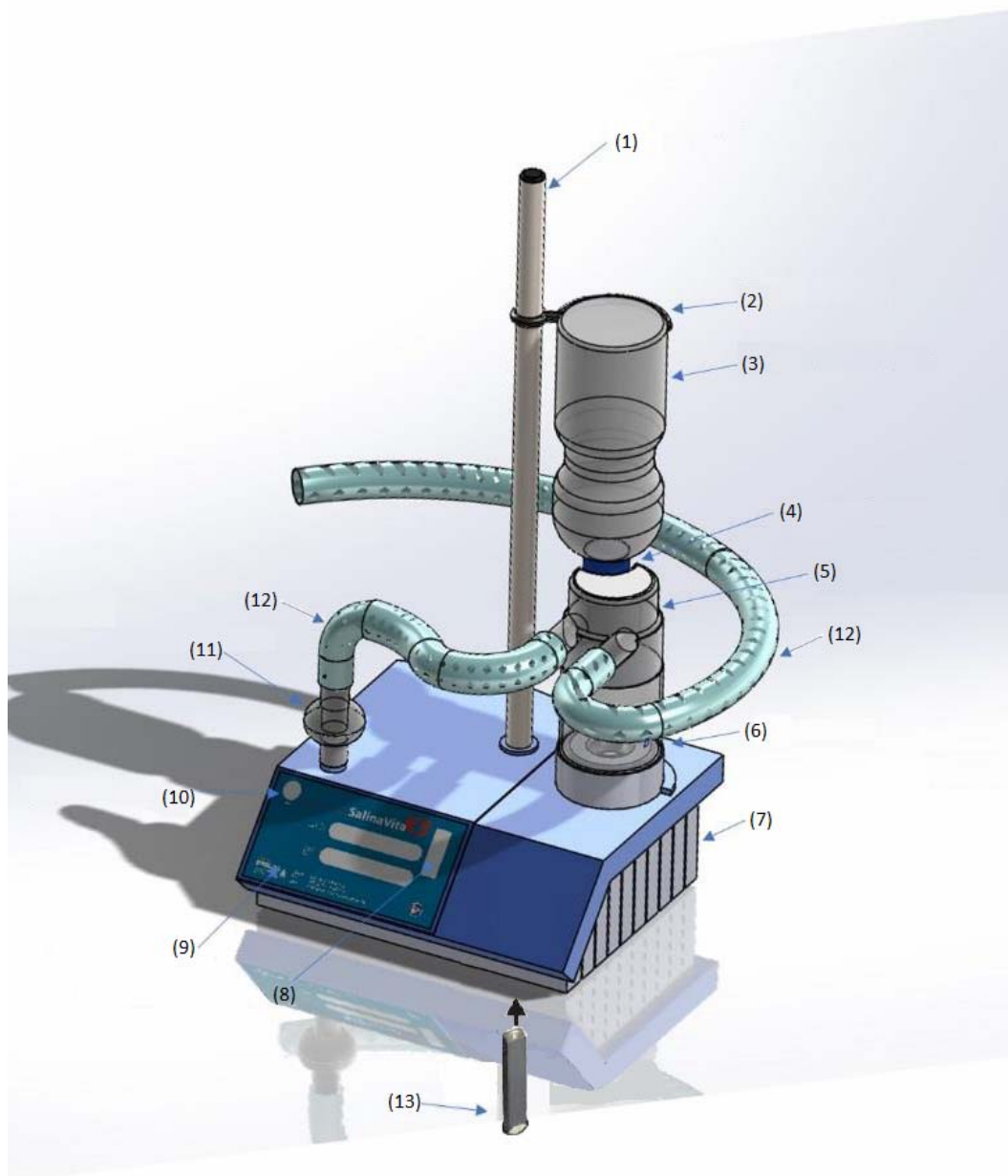


Figure 2

### Sequence of assembly:

- a) Insert the aluminum square peg (13) through the nebulizer base.
- b) Screw on the support rod (1).
- c) Fill the transducer head (6) up to the mark with sterile water. Do not turn it when inserting.
- d) Insert the nebulizing chamber (5) into the transducer head (6).
- e) Fit the bacteria filter (9).
- f) Fit the aerosol tubes (12).
- g) Nebulization with sterile water bottle: (3):  
Screw the adapter (4) onto the sterile water bottle (3), insert into the nebulizing chamber (5) and secure with the bottle holder (2).
- h) Nebulization without sterile water bottle:  
Fill liquid into the nebulizing chamber and close the opening with the plug (not shown).

## Information on preparation for operation

### Cleaning the transducer head

The transducer head containing the sterile disposable nebulizing chamber can be easily removed for cleaning and emptying by pulling it upwards. Take care not to turn it.

The transducer head should be flushed out with clean water after every use. Never immerse the transducer head completely in water!

For preventive disinfection of the transducer head, use commercially available liquids such as antiseptic agents, Dodacarna S, Septolit or Gigasept. The transducer head can also be flushed out with a 70% alcohol solution.

The max. operating temperature of ceramic resonators (oscillating quartz components) for the ultrasonic nebulizer is 85°C. Autoclaving damages the transducer head.

### Cleaning the nebulizer

The housing may be cleaned with a wipe disinfection.

Liquid agents such as Incidin Foam or Sekusept Aktiv may be used for this. Make sure that no moisture enters the device.

HINT

### NOTE

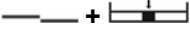
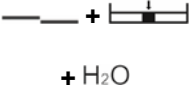
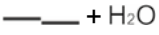
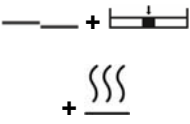
Do not clean the device while it is in use. To clean, turn the device off and unplug it from the power line.

## Malfunction indicators

The display panel (8) for any error messages is on the right side of the control panel (9).

In the event of a malfunction, the device switches off power and emits an audible warning.  
The nature of the malfunction is indicated.

If a malfunction is indicated, first switch off the device (push ON/OFF button for approx. 1 s)  
If possible, remedy the cause of malfunction and switch on the nebulizer again.

Display	Possible cause	Remedy
	Transducer head incorrectly inserted	Mount transducer head correctly. Note the anti-rotation device
	Contact liquid in transducer has not been refilled	Fill contact water up to blue mark or replace nebulizing chamber
	Aerosol empty	Replace nebulizer chamber
	Internal temperature too high	Turn device off and allow it to cool down

## Fault causes

Possible cause	Remedy
No contact water	Fill transducer head (6) up to the mark with distilled water
Transducer head incorrectly inserted	<b>Fit transducer head (6) up to the</b> limit stop. Watch out for the ant rotation device at the back
In the event of poor aerosol flow due to	
Air bubbles forming on the quartz or in the nebulizing chamber (5)	Switch off the nebulizer, remove bubbles
Moist bacteria filter (11)	Exchange filter. Discontinue use of wet filter!
Accumulation of water in the aerosol tube (12)	Reposition the tube with a continuous slope
Water level in chamber (5) too high	Reduce the water level

If malfunctions cannot be remedied, contact the service department of Schumacher & Partner GmbH.

Upon request the Schumacher & Partner GmbH will provide accessory and spare parts lists for the Ultrasonic Nebulizer SALINAVITA K5.

## Exchange/replacement of disposable materials

Replace the bacteria filter after one week at the latest or at intervals specified in the manufacturer's special directions.

Replace the aerosol tubes according to the manufacturer's instructions. In case of damage or visible pollution an immediate replacement must be made.

When changing patients, all the disposables must be changed.

Do not use an opened sterile water container for longer than a maximum of one week, or as specified by the hygienist responsible.

The coarse filter (3) (back of the nebulizer) should be changed at regular intervals, at least once a month.

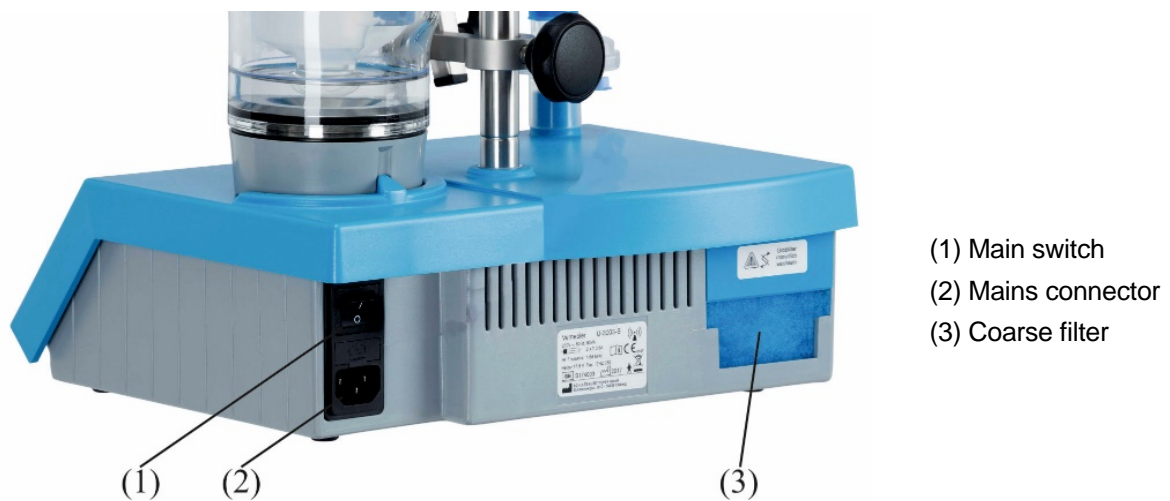


Figure 4: Rear view of the device

Only use approved accessories from Schumacher & Partner GmbH.  
Other systems or accessories are not allowed.

HINT

### NOTE

The replacement of components, the cleaning of the device and the performance of maintenance must not be carried out during use. To do this, switch off the device and disconnect the mains plug.

## Checking the device functions

The device function must be checked before each use and after each re-use / preparation. Also note the summary of information on start-up on page 8.

Switch the device ON at the main switch (1) on the rear for this purpose. Press the ON/OFF button (10) on the control panel and start nebulization.

Check the mist quantity output using the keys for the mist quantity. The highest quantity of mist should be released on setting 5.

Change the air flow using the keys for the air quantity. The highest air flow should be released on setting 5.

Detach the transducer head from the device. The device goes into a malfunction state, the red LED flashes and a warning signal sounds. Switch off the device, replace the transducer head and switch the device on. The nebulizer should resume its operation.

We recommend that the ultrasonic nebulizer undergoes a technical safety inspection (STK) once a year by the service department of Schumacher & Partner GmbH within the annual maintenance.

## Technical data

### Electrical Data

Rated voltage, rated frequency:	230 V AC, 50 Hz
Power consumption:	71 VA
Ultrasonic frequency:	1.68 MHz, +/- 5%
Classification:	Protective Class I
Operating mode:	Continuous operation
Sound pressure level:	Approx. 45 dB(A)
Operating conditions:	10° C to 40° C (short period operating) 10° C to 25° C (continuous operation) Humidity 15 – 90% non-condensing Air pressure 1060 – 700 mbar
Storage temperature :	-10° C to + 50° C Humidity: 15 – 90% non-condensing Air pressure 1060 – 700 mbar
Dimensions :	290 x 210 x 280 mm (B x H x D)
Weight:	3.9 kg
Degree of protection according to IEC 60519:	IP 21

### Regulatory data

Classification to MPG :	Ila, 93 / 42 / EEG
CE mark	CE 0197

We reserve the right to make any alterations!

## Performance data

Aerosol flow : 0.5 - 3 ml / min.  
Airflow: 1.5 - 8 l / min. with bacteria filter  
Droplet size: 1 to 7  $\mu\text{m}$  (63%), 1 to 5  $\mu\text{m}$  (45%)  
(Data refers to nebulizer level 3 / air flow level 3.  
Deviations are possible at different settings)

MMAD 5.3  $\mu\text{m}$   
(Mass Median Aerodynamic Diameter)

GSD 2.1  
(Geometric Standard Deviation)

FPF 44.8%  
(Fine Particle Fraction FPF)

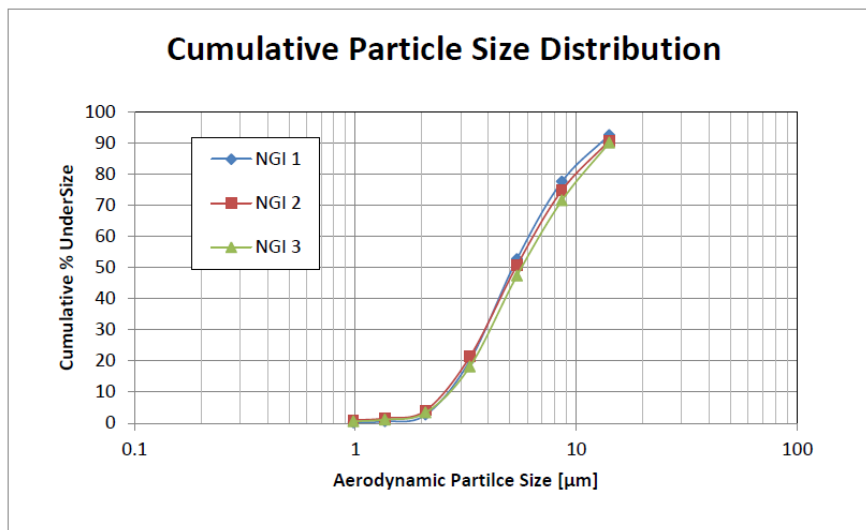


Figure 5: Particle Size Distribution

## Technical description – Electromagnetic compatibility

The Ultrasonic Nebulizer SALINAVITA K5 is suitable for use in professional health care facilities subject to IEC 60601-1-2: 2014. It is suitable for use in medical practices, clinics, hospitals and other professional healthcare facilities.

### Essential performance

The main feature of the device is the humidification of the respiratory system with aerosol according to the selected settings. An aerosol spectrum is generated according to the performance data of the SALINAVITA K5.

The SALINAVITA K5 has been tested for fault-free operation to comply with the listed requirements.

However, electromagnetic interference which exceeds the test levels can lead to a deterioration or loss of essential features. If excessive electromagnetic interferences occur, technical alarms may occur that affect the operation. In that case, measures are to be taken, for example:

- Turn off nearby appliances and then turn them back on to detect the device causing the interference.
- Place the device causing the interference in a different location or change its orientation.
- Increase the distance between the device causing the interference and the ultrasound system. - Use separate power supplies.
- Prevent or eliminate electromagnetic interference with technical solutions (for example, shielding).
- Acquire medical equipment that meets the requirements of EMC standards IEC 60601-1-2.

### Information on maintaining basic safety and the essential performance characteristics related to electromagnetic disturbance and for the service life of the medical device

Medical equipment is subject to specific precautionary measures with regard to EMC (electromagnetic compatibility) which must be observed in the installation and start-up of the equipment.

These include observing the recommended safety distances to neighboring electronic devices, which are given in the tables below. Carry out regular safety checks on the SALINAVITA K5 according to the manufacturer's instructions. The manufacturer's instructions list the specific internal EMC protection measures.

Accessories for SALINAVITA K5		
Accessories	Cable length	Manufacturer, description
Power cord	max. 2.0 m	Various manufacturers
<p><b>WARNING:</b> The use of accessories not listed here on the SALINAVITA K5 can lead to reduced interference immunity or to increased electromagnetic radiation.</p> <p><b>WARNING:</b> PORTABLE HF-communication devices (radios) (including their ACCESSORIES such as antenna cables and external antennas) should not be used within 30 cm (12 inches) of the parts and wires of the SALINAVITA K5, as specified by the MANUFACTURER. Failure to comply may lead to a reduction in the performance of the device.</p> <p><b>WARNING:</b> The characteristics of this device, determined by EMISSIONS, permit its use in industrial environments and hospitals (CISPR 11, Class A). When used in a residential environment (which typically requires Class B, according to CISPR 11), this device may not provide adequate protection from radio services. If necessary, the user must take corrective measures such as transposition or reorientation of the device.</p> <p><b>WARNING:</b> Use of the SALINAVITA K5 next to other devices or with other devices in stacked form should be avoided, as this could result in inaccurate operation. If use in the manner described above is nevertheless necessary, the SALINAVITA K5 and the other devices should be monitored to ensure that they are working properly.</p>		


Guideline and manufacturer's declaration- electromagnetic emissions		
The SALINAVITA K5 is intended for operation in the environment as specified below. The customer or user of the SALINAVITA K5 should ensure that it is operated in this type of environment.		
Interference emission	Conformity	Electromagnetic environment – guideline
RF emissions according to CISPR11	Group 2	The SALINAVITA K5 generates internal RF energy and conducts this to the transducer head to produce aerosol. The RF emission is very low. Electronic equipment in the immediate vicinity could, however, be subject to interference.
RF emissions according CISPR11	Class A	The SALINAVITA K5 is used in professional health care facilities. These can be, for example : - Hospital rooms in hospitals or clinics - Operation rooms or intensive care units in clinics - Hospital rooms in nursing homes - Medical practices
Emissions of harmonics according to IEC 61000-3-2	Class A	
Emissions of voltage fluctuations / flicker according to IEC 61000-3-3	In conformity	

Guidelines for the avoidance, detection and rectification of electromagnetic interference with other equipment		
Other electrical / electronic equipment should not be operated in the immediate vicinity of the SALINAVITA K5 or be included in an equipment stack with the latter. If such an arrangement is unavoidable, this equipment should be monitored for correct function. Because of the variety of equipment functions, the effects can vary considerably and can be difficult to detect. Examples:		
Equipment	Malfunction	Remedy
Radio and TV equipment	- Noise / crackling in the audio - Horizontal lines in the picture	- Increase distance
Monitoring systems e.g. baby monitors	- Noise / crackling in the audio	- Change arrangement
Cordless telephones		- Change alignment
Radio thermometer Radio weather stations	- Interference with data transmission, missing or erroneous display	- Change reception channel
General electronic equipment	- Malfunction e.g. stop or change from the intended mode	

Guidelines and manufacturer's explanations- electromagnetic interference immunity			
The SALINAVITA K5 is intended for operation in the electromagnetic environment described below. The customer or user of the SALINAVITA K5 should ensure that it is used in this type of environment.			
Interference immunity	IEC 60601 Test level	Conformity level	Electromagnetic environment --
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge  ±15 kV air discharge	±8 kV contact discharge  ±15 kV air discharge	The floor should be wood or concrete or provided with ceramic tiles. If the floor is provided with synthetic material, the relative air humidity must be at least 30%.
Rapid transient electrical disturbance / bursts according to IEC 61000-4-4	±2kV for power cords	±2kV for power cords	The quality of the supply voltage should correspond to a typical business or hospital environment.
Impulse voltage (Surges acc. to IEC 61000-4-5	±1kV Normal modes voltages  ±2kV in-phase voltages	±1kV Normal modes voltages  ±2kV in-phase voltages	The quality of the supply voltage should correspond to a typical business or hospital environment.
Voltage drops, short power outages and fluctuations of the supply voltage according to IEC 61000-4-11	70% UT for 10 ms 40% UT for 100ms 0% UT for 100ms 0% UT for 5s	70% UT for 10 ms 40% UT for 100ms 0% UT for 100ms 0% UT for 5s	The quality of the supply voltage should correspond to a typical business or hospital environment. If the user of the SALINAVITA K5 requires it to continue in operation also during interruptions to the power supply, it is recommended that the SALINAVITA K5 be supplied from an uninterruptible power supply or a battery.
Magnetic fields with the supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields with the supply frequency should correspond to, typical values, as can be found in a business or hospital environment.
Note: UT is the a. c. supply voltage before application of the test level			

# **Guidelines and manufacturer's explanations– electromagnetic interference immunity**

The SALINAVITA K5 is intended for operation in the electromagnetic environment described below. The customer or user of the SALINAVITA K5 should ensure that it is used in this type of environment.

Interference immunity	IEC 60601-12:2014	Conformity level	Electromagnetic environment –
<p>Conducted RF- interference according to IEC 61000-4-6</p> <p>Radiated RF interference according to IEC 61000-4-3</p>	<p>3Veff 150kHz – 80 MHz 3Veff ISM Range</p> <p>3V/m 80MHz – 2,5GHz</p>	<p>3Veff</p> <p>3 V/m</p>	<p>Portable and mobile radio equipment should not be used at a closer distance to the SALINAVITA K5, including the cables, than the safe clearance calculated according to the equation appropriate to the transmission frequency.</p> <p><b>Recommended safe clearance</b></p> $d = 1,2 \cdot \sqrt{P}$ $d = 1,2 \cdot \sqrt{P} \quad \text{for 80-800 MHz}$ $d = 2,4 \cdot \sqrt{P} \quad \text{for 0.8-2.5 GHz}$ <p>where P is the rated power of the transmitter in Watt (W) according to the transmitter manufacturer's data and d is the recommended safe clearance in meters (m)</p> <p>The field strength of stationary radio transmitters at all frequencies tested on site should be (a) less than the conformity level (b)</p> <p>Interference is possible in the vicinity of equipment bearing the following mark.</p> 

Note 1: In the case of 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These instructions may not apply in all cases. The propagation of electromagnetic interference is influenced by absorptions and reflections of buildings, objects and persons.









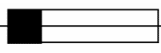


(a) The field strength of stationary transmitters, such as base stations of radio telephones and mobile surface radio equipment, amateur radio stations, AM and FM radio broadcast and television transmitters cannot in theory be accurately determined in advance. In order to assess the electromagnetic environment with regard to stationary transmitters, a study of the location should be undertaken. If the field strength measured at the location at which the SALINAVITA K5 is used exceeds the above conformity level, the SALINAVITA K5 should be monitored to confirm that it is operating correctly. If unusual performance characteristics are observed, additional measures may be needed, e.g. a different location for the SALINAVITA K5.

(b) With the frequency range of 150kHz to 80MHz, the field strength should be less than 3 V/m.

<b>Recommended safety distances between portable and mobile RF telecommunication equipment and the SALINAVITA K5</b>			
The SALINAVITA K5 is intended for operation in an electromagnetic environment, in which the RF interference variables are verified. The customer or user of the SALINAVITA K5 can help to prevent electromagnetic interference by complying with the minimum distance between portable and mobile RF telecommunication equipment (transmitters) and the SALINAVITA K5 – depending on the power output of the communication equipment as stated below.			
Safe clearance in meters depending on the transmission frequency			
<b>Rated power of the transmitter in watts</b>	<b>150 KHz – 80 MHz</b> $d = 1,2 \cdot \sqrt{P}$	<b>80 MHz – 800 MHz</b> $d = 1,2 \cdot \sqrt{P}$	<b>800 MHz – 2,5 GHz</b> $d = 2,4 \cdot \sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.76
1	1.2	1.2	2.4
10	3.8	3.8	7.6
100	12	12	24
For transmitters whose maximum power rating is not stated in the above table, the recommended safety distance d in meters can be determined using the equation belonging to the relevant column, in which P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer's data. Note 1: In the case of 80 MHz and 800 MHz, the higher frequency range applies Note 2: These instructions may not apply in all cases. The propagation of electromagnetic interference is influenced by absorptions and reflections of buildings, objects and persons.			

<b>Test distance for interference resistance of the SALINAVITA K5 to wireless RF communication devices</b>						
<b>Test frequency (MHz)</b>	<b>Frequency band a) (MHz)</b>	<b>Service a)</b>	<b>Modulation b)</b>	<b>Max. power (W)</b>	<b>Distance (m)</b>	<b>Immunity test level (V/m)</b>
385	380 - 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM c) $\pm 5$ kHz 1 kHz Sinus	2	0,3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
810 870 930	800 – 960	GSM 800 /900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
1720 1845 1970	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation b) 217 Hz	2	0,3	28
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
Note: If necessary, to achieve immunity test levels, the distance between the transmitting antenna and the ME device or the ME system can be reduced to 1 meter. The 1 m test distance is permitted according to IEC 61000-4-3. a) For some radio services, only the frequencies for the radio circuit from the mobile communication device to the base station (uplink) have been included in the table. b) The carrier must be modulated with a Square wave signal with 50% duty cycle c) Alternatively to the frequency modulation (FM), a pulse modulation with 50% duty cycle at 18 Hz can be used, as this, although not the actual modulation, would represent the worst case scenario.						

## Meaning of the symbols on the nameplates, accessories and consumables

Symbol	Meaning
	Manufacturer
	Year of manufacture
	Device serial number
	Do not use the device if you are not familiar with the instructions for use
	Instructions for use must be observed before use
CE 0197	CE conformity with details of notified body
IP21	Protection against foreign bodies > 12.5 mm and splashes
	Notes on disposal requirements
	Application part type B - protection against electric shock
	High frequency radio transmitter - The device operates at 1.68 MHz
	Device fuse
	Marked articles are for single use only. When patients change, they have to be switched
	Do not use if the packaging is damaged



### **Disposal instructions:**

Dispose of the packaging sorted according to type of material.

When you want to dispose of the product, ensure that this is done according to legal requirements.

Your local authority will provide you with information.

## Warranty

This device has been carefully manufactured and checked before leaving the factory. We accept a 24-month warranty from the date of purchase for this product, in accordance with the following conditions:

1. Within the warranty period, we remedy defects in the device, which are based on material and production failures, free of charge at our discretion by repair or by replacement of the defective parts or of the device.
2. From the warranty consumable and wear parts, e.g. O-rings, gaskets, filters and tubing as well as fragile parts, e.g. glass are excluded.
3. Replaced parts or devices become our property.
4. The warranty does not cover damage caused by improper use, handling/operating errors, mechanical damage or non-compliance with the instructions for use. Furthermore, damages resulting from force majeure or exceptional circumstances are excluded.
5. The warranty period is not affected by warranty cases.
6. The warranty claim expires if the annual maintenance and safety inspection (STK, Sicherheitstechnische Kontrolle acc. to §6 MPBetreibV) has not been carried out or if any modifications, repairs or maintenance have been made by companies or persons not authorized by the manufacturer or if the device is equipped with accessories and / or spare parts of foreign origin.
7. In case of a warranty claim send the device with all accessories carefully packed with your proof of purchase to the distributor address below.  
The delivery must take place free-of-charge. Unstamped or insufficiently stamped deliveries can not be accepted.
8. The warranty becomes effective only if the date of purchase is confirmed by the dealer's stamp and signature.  
When the device is purchased directly Schumacher & Partner, the invoice number is sufficient.
9. On-site repairs are carried out on the basis of the above warranty conditions. Incidental costs for travel time, travel expenses, accommodation costs and other expenses are not covered by the warranty.
10. Other claims of any kind, in particular compensation for damages or compensation for pain and suffering, are excluded. This also applies to cases which are clearly based on a technical failure of the device.

## Distributor

### Distribution and Service:

Schumacher & Partner GmbH  
Langgasse 70  
56132 Dausenau  
Germany

Tel.: +49 2603 / 96090

Fax.: +49 2603 / 960930

e-mail: [info@schumacher-medizintechnik.de](mailto:info@schumacher-medizintechnik.de)



## Manufacturer

SCHULTE-ELEKTRONIK GMBH  
Schörenbergstr. 20  
59939 Olsberg  
Germany