



AKITA® JET Inhalation System Instructions for Use

WARNING: Before using your AKITA JET Inhalation System, read and understand the entire Instructions for Use. Save these Instructions for Use for future reference.

Patents:

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Additional Patents Pending



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1 Introduction

These Instructions for Use contain information and safety precautions for the AKITA JET Inhalation System. Before using your AKITA JET Inhalation System, read and understand the entire Instructions for Use. Save these Instructions for Use for future reference. Please call the telephone number in section 14 if for any reason you do not understand any part of these Instructions for Use.

1.1 Intended Use

The combination of an AKITA JET control unit and a nebulizer set from the AKITA JET Year Pack are intended for aerosol therapy of lower respiratory airways with inhalation solutions and suspensions.

The system is suitable for use at home, hospital and general practice for temporary oral inhalation of inhalation solutions and suspensions prescribed or recommended by a physician.

The AKITA JET Inhalation System must be used only on conscious, cooperative patients from the age of 3 years onwards.

The system is not suitable for use in a healthcare environment with active HF Surgical Equipment and the RF shielded room of a system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

The AKITA JET Inhalation System guarantees a highly effective and rapid inhalation therapy for patients ranging from infants to adults. The AKITA JET Inhalation System can be used for medication therapy of lung diseases, such as bronchial asthma, chronic obstructive pulmonary disease (COPD) and cystic fibrosis (CF).

- Children
 - Treatment under supervision: 3 to 8 years
 - Treatment after instruction: from 8 years
- Adults
 - Treatment after physiotherapeutic instruction and in compliance with these Instructions for Use.

The AKITA JET Inhalation System should be used with inhalation solutions and suspensions approved for inhalation.

1.2 Liability

The AKITA JET Inhalation System is an electrically operated unit.

Unplug the power plug from the socket outlet to achieve full disconnection from the power supply.

It must neither be operated unattended nor in explosion hazarded or moist areas.

Accurate knowledge of and compliance with this Instructions for Use is required before the AKITA JET Inhalation System is used.

The operator of the AKITA JET Inhalation System is liable to its safe functioning in all cases when it is handled incorrectly.

It must be repaired only by Vectura or by a service depot expressly authorized by Vectura.

Only original AKITA JET accessories must be used for operation of the AKITA JET Inhalation System.

Vectura is not liable for any damage or malfunction resulting from incorrect use or from use for which the device is not intended.

2 Important Information for Your Safety

All safety precautions marked **WARNING** and/or **CAUTION** should be given special attention.

WARNING:

- Use the AKITA JET Inhalation System only for its intended use as described in these instructions for use.
- If medications are being inhaled for the first time or for the first time at a higher dose, this should be done under medical supervision only.
- Use the AKITA JET Inhalation System only when prescribed by a physician and only with the medication prescribed for the AKITA JET Inhalation System. Follow the dosage of your prescription. The use of other solutions and medications can lead to serious risks to health or can damage the device.
- The Package Leaflet of the drug must also be read as it provides important safety information and instructions about the medicinal product.
- When used in a home environment, the nebulizer may only be used by one single patient. Nebulizers shall not be shared with other patients.
- When used in a hospital environment: Patients who are known to have an infection or are carriers of pathogens, e.g. multi-resistant *Staphylococci* (MRSA), *Burkholderia cepacia*, etc., should always use only their own device and should inhale in a separate area from other patients.
- Only use nebulizers which were cleaned and disinfected according to section 5. At multi patient use the nebulizer must be sterilised according to section 7. Clean and disinfect the nebulizer before first use.
- The AKITA JET Inhalation System is not designed for emergency and life supporting usage.
- The AKITA JET Inhalation System must not be used for patients who are breathing or being ventilated via an endotracheal tube or a tracheal cannula.
- Do not leave children or infirm individuals unattended during treatment. Always use close adult supervision when administering a treatment to a child or infirm individual.
- The dosage of your medication is set by a Smart Card (see section 6.5 and 8). Inhale your medication with the corresponding Smart Card only.
- Do not use the device if it is damaged. Do not modify the device.
- Only use accessories described in these Instructions for Use. Only use the power supply delivered with the control unit.

- When using multiple medications and Smart Cards, always ensure that the correct Smart Card for the medication is inserted (see also section 8). Do not mix medication solutions.
- After each treatment session discard all excess medication (risk of contamination, potential loss of potency of medication).
- The basic Smart Card supplied with the AKITA JET control unit is not designed for inhalation of medications, and must be used for device testing and training only.
- To reduce the risk of contamination and strangulation, keep the AKITA JET Inhalation System and all medications away from small children.
- The applied part is the nebulizer or the face mask and the first 10 cm of the tube.
- The AKITA JET Inhalation System should not be used around flammable substances, or in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.
- Do not use AKITA JET Inhalation System in a ventilator circuit
- Use the AKITA JET Inhalation System in a clean environment free from dirt, dust, pet hair, etc.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Do not use the Akita Jet in the bathroom.
- Do not use without the filter
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AKITA JET nebulizer, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
-

CAUTION:

- Only use the AKITA JET Inhalation System according to the EMC (electromagnetic compatibility) information provided in the section 11.6.
- The AKITA JET Inhalation System may be affected by portable or mobile radio frequency communication equipment. In case of malfunction or error messages, increase distance to your cellular phone. Detailed information is provided in the section 11.6.

- Only use the AKITA JET Inhalation System with the approved accessories (see section 0). Non-approved accessories may have a negative effect on the EMC (electromagnetic compatibility).
- The AKITA JET Inhalation System is not intended for continuous operation. The normal use is up to 40 minutes.

Note:

- Please report any serious incidents that have occurred in relation to the device to Vectura as manufacturer of the device (section 14) and the competent authority of your home country).

3 Getting Started

Check your AKITA JET Inhalation System packages to make sure that you have the following items.

AKITA JET Control Unit:

- AKITA JET Control Unit
- AKITA JET Power Supply
- Power Cord (suitable for the power supply in your country)
- Nebulizer Holder
- Carrying Handle
- Basic Smart Card
- AKITA JET Carrying Bag
- Instructions for Use

AKITA JET Year Pack:

- Two AKITA JET nebulizer sets, each set consisting of:
 - Nebulizer (nozzle attachment: orange)
 - Nebulizer tube
 - Help flow tube
 - Help flow adapter
 - Tubing clips
- Year Pack Instructions for Use
- Filter

A complete AKITA JET Inhalation System ready for use consists of the AKITA JET control unit and an AKITA JET Year Pack.

These parts are needed for correct functioning of the AKITA JET Inhalation System.

If any of the equipment or accessories above is missing or damaged, please contact Vectura or your service representative.

4 Assembling AKITA JET Inhalation System

On each occasion before starting the equipment, as well as after periods of non-use, please comply with the cleaning instructions in section 5. Ensure that the nebulizer set was cleaned, disinfected and, if necessary, sterilised after the last treatment.

CAUTION:

- Make sure that the AKITA JET control unit is placed upright on a flat surface and that the air ventilation slots on the backside are not blocked.

4.1 Connection of Power Supply and Power Cord

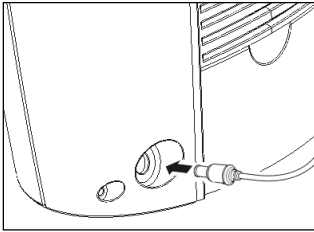


Fig. 1: Connect the power supply cable with the jack at the back of the control unit.

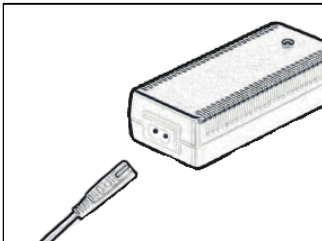


Fig. 2: Connect the power supply with the power cord.

Plug the power cord into a suitable socket outlet.

4.2 Inserting Smart Card

Insert the Smart Card, which complies with the intended therapy into the Smart Card slot of the AKITA JET. Make sure that the chip on the Smart Card is pointed down and that the arrow points in the direction of the Smart Card slot. The Smart Card is correctly inserted when it is flush with the front of the control unit. Do not switch on the device now.

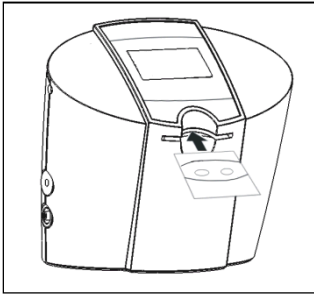


Fig. 3: Inserting the Smart Card.

CAUTION:

- Make sure that you only inhale with Smart Cards that have been prescribed by your physician.
- Please leave your Smart Cards inserted throughout your treatment with the AKITA JET and do not remove the Smart Card until the therapy is finished, otherwise the data on the Smart Card may be damaged. If you are inhaling only one medication with the AKITA JET, you can leave your Smart Card inserted in the Smart Card slot of the AKITA JET control unit.
- The Smart Card must only be changed when the AKITA JET control unit is switched off.

For additional information regarding the AKITA JET Smart Cards see Section 8.

4.3 Nebulizer Assembly

Assemble the AKITA JET nebulizer set as shown in the following illustrations. Take care to prevent damaging the individual parts.

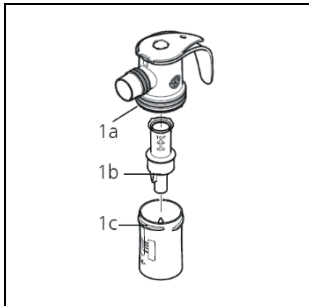


Fig. 4: Nebulizer assembly

Gently push the nozzle attachment (orange, 1b) as far as it will go onto the nozzle in the nebulizer lower section (1c) of the AKITA JET nebulizer.

The arrow on the nozzle attachment must point upwards.

Now place the nebulizer upper section on the nebulizer lower section and turn it clockwise to lock the two parts together.

4.4 Installing Nebulizer Holder

In order to simplify handling, the AKITA JET control unit is equipped with a holder for the nebulizer. The nebulizer may be placed in the holder at any time.

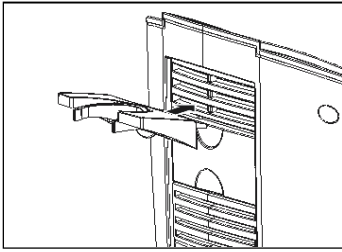


Fig. 5: Insert the nebulizer holder into the relevant slot at the back casing of the AKITA JET control unit.

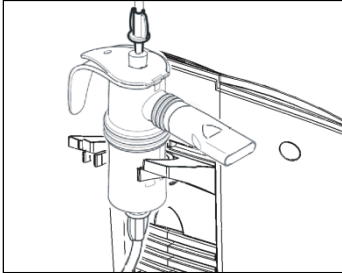


Fig. 6: Place the nebulizer in the nebulizer holder.

5 Cleaning and Disinfecting AKITA JET Inhalation System

The AKITA JET nebulizer is intended for repeated use. When used in a home environment the nebulizer shall only be used by one single patient. To avoid any risk to health, e.g. infection from a contaminated nebulizer, it is essential to comply with the following hygiene rules:

- The AKITA JET nebulizer must be cleaned after each treatment.
- The AKITA JET nebulizer must be disinfected once a day.
- Additional requirements concerning the necessary hygienic preparations (hand care, handling of medications or inhalation solutions) in high-risk groups (e.g., patients with cystic fibrosis) can be obtained from the respective self-help groups or your attending physician.
- Please check the parts of your AKITA JET nebulizer regularly and replace any defective (broken, deformed or discoloured) parts.

5.1 Immediately after Use

Immediately after each treatment, all parts of the AKITA JET nebulizer must be cleaned of medication residue and contamination. To do this:

- Disconnect nebulizer from tubing (tubing will not be cleaned).
- Discard excess medication.
- Disassemble the nebulizer into its individual parts as described in the following figure and rinse under running tap water.

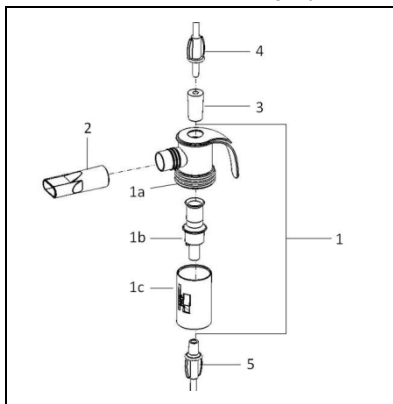


Fig. 7: Disassembling the nebulizer:

If the tubes (4 and 5) haven't been removed already for drying, remove tubes from the nebulizer.

Detach the mouth piece (2) from the nebulizer (1).

Unscrew the nebulizer (1).

Remove the nozzle attachment (1b) from the nebulizer lower section (1c).

Remove the help flow adapter (3) from the nebulizer upper section (1a).

5.2 Cleaning

The AKITA JET nebulizer must be cleaned after each treatment.

CAUTION:

- Use standard dishwashing detergent (for manual dish washing, neutral pH between 6 and 8) without disinfection properties and without skincare additives (no balsam).
- Do not use of other cleaning detergents that may cause severe damage to the device or impose health hazards such as detergents that have disinfectants, detergents with skin care additives, detergents for dish washing machines, acids (such as vinegar), organic solvents (such as isopropyl alcohol), or oxidizing agents (such as bleach).

Recommended Procedure:

- Fill a clean bowl with warm tap water (minimum temperature 35°C). Add standard dish washing detergent (dosage according to the manufacturer's recommendations).
- Place the nebulizer components into the bowl. Clean all parts of the nebulizer thoroughly for 5 minutes using a soft brush or soft clean cloth.
- Then rinse all parts thoroughly under warm running water.
- To remove excess water you may shake the parts.
- Drain and place all parts on a new paper towel and let dry completely, or
- Continue with disinfection (see section 5.3).

5.3 Disinfection

The AKITA JET nebulizer must be disinfected once a day.

Recommended Procedure: Steam disinfectant (Baby bottle disinfectant)

- After cleaning the device according to the instructions above, place all components into the steam disinfectant. Make sure that the nebulizer remains disassembled.
- Operate the bottle disinfectant according to the instructions of the manufacturer. Select a minimum disinfection duration time of 6 minutes.
- After the disinfection cycle, open the lid of the steam disinfectant to allow drying and cooling.
- Once the components are cool, place them onto a flat dry paper towel.
- Let the components dry completely (overnight).

Effective cleaning and disinfection were demonstrated by an independent accredited test laboratory using the dishwashing detergent "Palmolive Original" (Colgate Palmolive GmbH, Hamburg, Germany) and a steam disinfectant (iQ24 Electronic Steam Steriliser, Philips AVENT, Suffolk, England, operated in mode 1) used according to the recommended procedure described in these Instructions for Use. Use of alternate disinfectant devices or methods is in the responsibility of the user.

Possible Alternative: In boiling water

- After cleaning the device, fill a saucepan with distilled water.

- Place all components into the saucepan. Make sure that all components are submerged in water.
- Boil the water for 5 minutes.
- Carefully remove the components from the saucepan.
- Shake the nebulizer components to remove excess water.
- Place the components onto a flat dry paper towel.
- Let the components dry completely (overnight).

CAUTION:

- Only the recommended disinfection method is validated. Boiling water cannot disinfect the device as reproducible as the steam disinfecter.

5.4 Storage, Transporting

- Make sure that the components have completely dried.
- Between uses and breaks in treatment, wrap the nebulizer in a clean, lint-free cloth (e.g. a tea-towel) and keep it in a dry, dust-free environment.
- To carry the device around, you can clamp the carrying handle on the metal buttons on each side on the control unit.
- For transporting, you may pack the AKITA JET Inhalation System in the carrying case provided for this purpose.
- Keep the nebulizer in a dry, dust-free place protected from contamination.

5.5 Cleaning AKITA JET Control Unit

CAUTION:

- Switch off the AKITA JET control unit and unplug the power cord from socket outlet each time before cleaning.
- To clean the AKITA JET control unit wipe the exterior of the housing with a damp cloth, and if it is used by several patients also use a disinfecting cloth.
- To prevent damage to the electrical circuitry, NEVER spray liquids into the ventilation slots.
- If liquid has entered the case, contact Vectura or your service representative. Use your AKITA JET Inhalation System only after advice from Vectura or your service representative (or after an examination and possible repairs have been carried out).

5.6 Replacing Filter

- NEVER attempt to clean the control unit filter.
- The filter for the AKITA JET control unit must be changed at least once a year.

- Change the filter more frequently if the air quality where the device is used is poor (such as from heavy cigarette smoking).
- Replace the filter if it becomes wet or damp.

To replace the filter:

- Remove the filter cover from the back of the device and remove the used filter from the air inlet of the device (see figure below). Then insert the new filter into the recess and refit the filter cover.

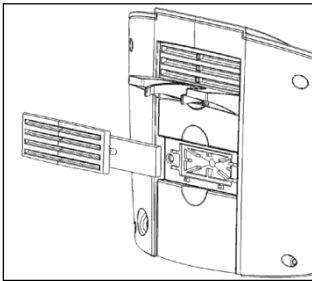


Fig. 8: Exchanging the filter.

6 Taking Treatment

6.1 Filling the Nebulizer

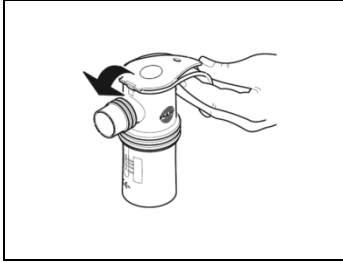


Fig. 9: Open the AKITA JET nebulizer cap by pressing your thumb against the underside of the cap.

Now prepare the inhalation solution. Follow the package leaflet that you received with your medication and the dosage prescribed by your physician.

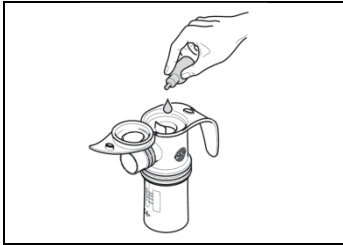


Fig. 10: Pour the quantity of medication prescribed by your doctor into the nebulizer funnel (max. filling volume 8 ml).

Close the cap on the nebulizer upper section by clicking it into place.

WARNING:

Ensure that the medication level is not higher than the topmost mark on the scale. If it has been overfilled, pour it all away and clean the nebulizer set (see section 5). Afterwards start again with filling in the medication.

To prevent under dosage always fill in the complete medication as provided within the ampoule.

6.2 Connecting Tubes to the Nebulizer

The AKITA JET Inhalation System operates with two tubes, which have different connectors so that they cannot be confused.

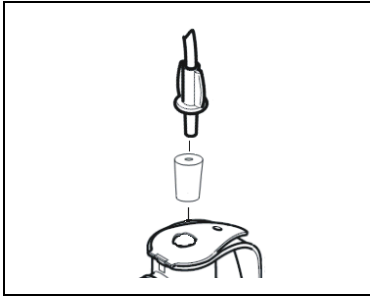


Fig. 11: Attach the help flow adapter to the upper opening of the nebulizer and connect the help flow tube.

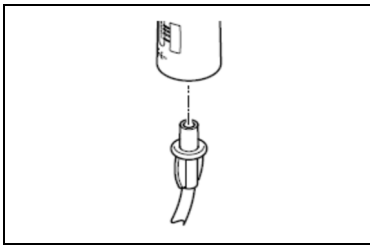


Fig. 12: Hold the nebulizer upright and attach the nebulizer tube to the nebulizer bottom.

6.3 Connecting Tubes to the Control Unit

The AKITA JET nebulizer is connected to the control unit via help flow tube and nebulizer tube. The help flow tube supplies you with a constant flow of air during inhalation.

The nebulizer tube supplies the compressed air for atomizing the medication through the nebulizing nozzle.

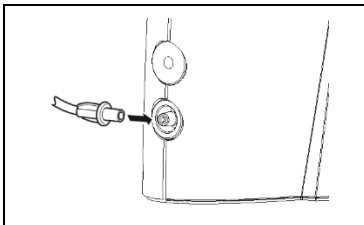


Fig. 13: Attach the nebulizer tube to the lower connection of the AKITA JET control unit.

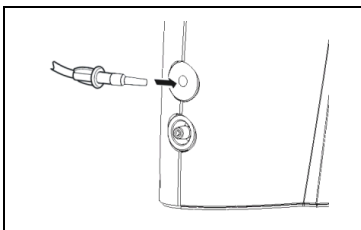


Fig. 14: Attach the black end of the help flow tube to the upper connection of the AKITA JET control unit.

Finally attach the mouth piece to the nebulizer upper section. Your AKITA JET Inhalation System is now prepared for the treatment.

CAUTION:

- Check before every inhalation and during treatment, that the tubes are connected as shown in the following figure.

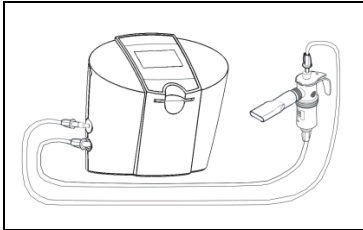


Fig. 15: AKITA JET with connected nebulizer.

6.4 Switching on AKITA JET Inhalation System

Before every inhalation, check that the nebulizer is correctly assembled.

Ensure that the device is connected as described in the previous section, that a filter is inserted (see section 5.6) and the Smart Card is correctly inserted (see section 4.2).

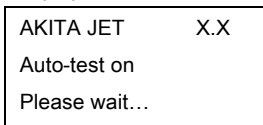
CAUTION:

- Always ensure when operating the AKITA JET Inhalation System that the ventilation slots at the back of the control unit remains unobstructed. Never cover the control unit during use.
- Switch on the AKITA JET Inhalation System with the on/off button.
- The treatment time for normal use is up to 40 minutes.



Fig. 16: Button for switching on the AKITA JET.

- Wait until the AKITA JET Inhalation System has completed the self-test.
- During the self-test, the compressor functionality and the connection of the help flow tube is tested. During this time, the display shows the following message:



- After the self-test the display will show you the following message:

Only use a clean and disinfected nebulizer!

6.5 Setting Inhalation Time (per breath)

The inhalation time defines the time for one inhalation (without expiration).

Your health care provider will usually determine the optimal inhalation time for you by a lung function test. The best way to test this is by a test inhalation with the AKITA JET Inhalation System with your health care provider.

Your health care provider can individually adjust the inhalation time with the "vol." key.

You may change the inhalation time setting any time that your lung function has changed (such as during illness or infection).



Fig. 17: Key for setting the inspiration time.

- You can select 10 different inhalation times between 1.5 s and 8.0 s with the "vol." key.
- The inhalation time is increased one step every time the key is pressed.
- To decrease the inhalation time, press the key until the first setting is shown.
- The display shows the selected inhalation time with the corresponding volume.

Substance/Dosage
 X.X s – X.X l
 XXXX breaths
 START>INHALE

or

Substance/Dosage
 X.X s – X.X l
 number breaths
 free START > INHALE

The last selected inhalation time is saved on the Smart Card. This means that the setting is only required at the first inhalation.

If you switch on the AKITA JET Inhalation System with the Smart Card again, your last selected inhalation time will be automatically displayed.

6.6 Medication Selection

If a Smart Card intended for different medications is used, after the self-test the following display is shown for 5 seconds or until a key is pressed:

Press KEY to
 select operation mode

To select a medication, press the “med.” key until the display shows the desired medication.



Fig. 18: Key to select a medication. This key is only required if special Smart Cards intended for different medication inhalations are used.

6.7 Inhalation

If several or different medications are inhaled in turn within the scope of inhalation treatment, remove the remaining medication solution from the nebulizer after every use and rinse it briefly with water.

Before you start your inhalation treatment, please comply with the following instructions:

- Sit in a relaxed and upright position. Sit in a position from which you can see the display and keep the nebulizer upright.
- Exhale and then take the mouthpiece between your teeth and enclose it completely with your lips.
- Watch the AKITA JET control unit display carefully particularly during your first few inhalations. If you breathe in too fast, the display will show "inhale slowly". This message shows that you are inhaling faster than the optimum flow pre-set by the AKITA JET Inhalation System. Try to inhale more slowly until the message "inhale slowly" no longer appears.
- Do not block the mouthpiece with your tongue during inhalation.
- Note how the AKITA JET Inhalation System exerts a light pressure for optimum delivery of the medication to your lungs.
- Make sure that medication aerosol does not escape through your nose during inhalation.
- Take the mouthpiece out of your mouth and breathe out into the room air. Do NOT breathe out through the mouthpiece. Alternatively you can keep the mouthpiece in your mouth and breathe out through your nose.

Inhalation will not start until the device confirms that you are inhaling through the mouthpiece.

1. Breathe in slowly through the mouthpiece. Breathe in for a short time only, and then the inhalation flow of the AKITA JET Inhalation System will start.
2. While inhaling, let yourself be guided by the constant air flow of the AKITA JET. Avoid allowing the aerosol to escape through your nose during inhalation. Please note the information on the display.

With correct inhalation, the following display appears:

Inhale for
xxx more seconds

3. Leave the mouthpiece in your mouth until the inhalation flow has switched off. The display shows you when you should exhale. Please release the mouthpiece an exhale into the room air. Do NOT exhale into the nebulizer.

Exhale

4. Breathe out and then breathe in through the mouthpiece before the start the next inhalation.
5. You can pause as you wish between inhalations. If applicable, the pauses can be used for physiotherapy treatments. You can also park the nebulizer in its holder to drink or to rest. If you do not use the device for 30 minutes, it switches itself off automatically and saves the status of your treatment. Clamp the nebulizer to the nebulizer holder provided. If you want to continue inhalation, press the "on/off"-key. After the self-test, the device shows the following message:

Inhale to
continue last inhalation
or cancel > KEY

You can now resume the last inhalation therapy simply by inhaling through the mouthpiece. If you don't want to resume this inhalation, just press any of the keys.

6. After every breath, the display shows the remaining breaths. This number of breaths is still necessary to administer the entire dose of medication. If you use a Smart Card for inhaling bronchodilating medications or saline solutions, the number of inhaled breaths will be displayed. When the specified number of breaths has been reached, press the "on/off" key briefly to stop the inhalation. The display shows:

Inhale. complete
Disconnect nebulizer
from
tubes > KEY

Disconnect the tubes from the nebulizer and leave the other side of the tubes connected to the AKITA JET control unit. Press any key to begin the drying cycle. At this point, the compressor will start running again to remove condensed water that may have collected in the tubes.

7. After the drying cycle, the nebulizer must be dismantled and cleaned. The display shows following message for 10 seconds:

Clean and
disinfect the nebulizer
now!

8. Wait 10 seconds, or press any key to show the residual drying time on the display:

Drying system
120 seconds left

9. After the tubes have been dried the display will show:

System dry
Auto-power off

10. At this point, the AKITA JET Inhalation System will auto-power off.
11. Immediately continue with section 5.

7 Additional Requirements for Multi Patient Use

CAUTION:

- When the AKITA JET is used by multiple patients (e.g. in a hospital) it is essential to reduce the risk of cross contamination between patients. Therefore it is required to follow hygienic rules set out in the following subsections of the instructions for use.
- If an AKITA JET control unit is used by several patients, every patient should only use their personal nebulizer set (nebulizer plus connecting tubes) and Smart Cards. After treatment these personal parts must be removed from the AKITA JET control unit.
- If nebulizers are centrally cleaned and hygienically prepared in the hospital, it is important to ensure that only sufficiently device-specific and product-specific validated processes are used for cleaning, disinfection and sterilisation and that the validated parameters are maintained for every cycle.
- The cleaning and disinfection procedure used must be recognized as effective (e.g. in the list of tested and recognized disinfectants and procedures issued by the Robert Koch Institute/DGHM) and already validated in all cases.
- If another procedure is used, its effectiveness must be confirmed during validation. CE-approved chemical disinfectants may also be used, provided they satisfy the requirements for material resistance.
- In addition, follow the hygiene regulations of the hospital or the medical practice.

7.1 Precautions When Inhaling

CAUTION:

- Instruct each patient before first use of the AKITA JET Inhalation System
- Request patients to disinfect hands before use
- Each patient shall be provided with her/his individual tubing
- Change tubes upon patient change
- The applied part is the nebulizer and the first 10 cm of the tube.

7.2 Immediately After Use

Immediately after each treatment, all parts of the AKITA JET nebulizer must be cleaned of medication residue and contamination.

To do this:

- Disconnect Nebulizer from tubing, tubing is not subject to hygienic preparation
- Remove excess medication.

- Disassemble the nebulizer into its individual parts as described in the following figure.
- Rinse each component under running tap water.

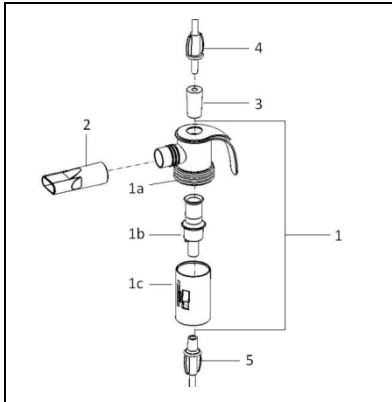


Fig. 19: Disassembling the nebulizer:

If the tubes (4 and 5) haven't been removed already for drying, remove tubes from the nebulizer.

Detach the mouth piece (2) from the nebulizer (1).

Unscrew the nebulizer (1).

Remove the nozzle attachment (1b) from the nebulizer lower section (1c).

Remove the help flow adapter (3) from the nebulizer upper section (1a).

7.3 Cleaning / Disinfect the Nebulizer

CAUTION:

- The nebulizer must be cleaned, disinfected and, in the event of a change of patient, also sterilised as described in this section within four hours of its last application. Only in this manner can undesirable bacterial growth be avoided.
- Nebulizers can be sterilised up to 300 times, but then they must be replaced. Even if the nebulizer has been sterilised fewer than 300 times, it must still be replaced after one year's use.
- Do not expose the nebulizer to temperatures above 137°C.
- When choosing appropriate chemicals for cleaning and disinfection make sure that they are suitable for cleaning the following Materials: Polypropylene (PP), Thermoplastic Elastomer (TPE), Polyoxymethylene (POM).
- In all cases, the aldehyde group of cleaning and disinfecting agents is suitable for cleaning and disinfecting the AKITA JET nebulizer.

Recommended Procedure: Automated Washer / Disinfector

- Place the nebulizer components in the instrument disinfector.
- Select the 93°C program (treatment time 10 minutes).

The effectiveness of this procedure has been proven using a G7836 CD disinfector produced by Miele with neodisher®medizym produced by Chemische Fabrik Dr. Weigert, Hamburg.

Recommended Procedure: Manual cleaning/disinfection

- The components must be placed in a 0.5% solution of Korsolex®-Endo-Cleaner and approx. 50°C warm water, and cleaned thoroughly for 5 minutes.
- The components are then placed in a 4% disinfectant solution of Korsolex®basic for 15 minutes.
- Then thoroughly rinse the nebulizer components under hygienically tested water and leave them to dry completely on a clean, dry and absorbent surface (for at least 4 hours).

The effectiveness of this procedure has been proven using the Korsolex®-Endo-Cleaner cleaning agent in combination with the Korsolex®basic disinfectant made by BODE CHEMIE HAMBURG.

Possible Alternative: Chemical-thermal Disinfection

- Place the nebulizer components in the instrument disinfectant.
- Add a suitable cleaner/ disinfectant and select the 60°C program.

7.4 Sterilisation of the Nebulizer

The AKITA JET control unit and the nebulizer are non-sterile products. Sterilisation process as described below is required in case of multi patient use. Sterilised parts do not need to be stored sterile or applied sterile to the patient.

After cleaning/disinfection, pack the dismantled nebulizer in sterilisation packaging (disposable sterilisation packaging, e.g. foil/paper sterilisation bags). The sterilisation packaging must conform to DIN EN 868/ ISO 11607 and be suitable for steam sterilisation. Then sterilise the nebulizer using the following sterilisation procedure:

Recommended Procedure: Steam Sterilization

- Sterilisation temperature:
 - 121°C (to be maintained for at least 20min.) or
 - 132°C/134°C (to be maintained for at least 3min.)
 - max. 137°C

This procedure has been validated according to EN ISO 17664-1 as well as DGKH guidelines for the validation and routine monitoring of sterilisation processes using damp heat for medical devices.

The provided process has to be validated according EN ISO 17665.

8 Smart Card

Every medication that is prescribed for inhalation with the AKITA JET Inhalation System must be inhaled in a specified dose for the best therapeutic effect. Inhalation with the correct Smart Card ensures that the AKITA JET Inhalation System releases exactly the required dosage of medication as an aerosol. The physician sets the medication dosage to be inhaled with the AKITA JET Inhalation System.

The medication-specific and dosage-specific Smart Card that controls the AKITA JET Inhalation System terminates the therapy automatically as soon as the required dosage of medication has been nebulised. This eliminates the possibility of overdose as a result of too much medication in the device, if the medication has been added in the correct concentration. Under dosage of a medication is only possible if the therapy was not completed. The display of the AKITA JET control unit keeps the patient informed of how many inhalations are still required to complete the therapy.

Unless otherwise specified by the physician, the medication-specific and dosage-specific Smart Cards of the AKITA JET Inhalations System control the medication for nebulisation in accordance with a specific inhalation pattern. This ensures that the medication is primarily deposited in the deep respiratory passages (alveolar-peripheral) for the best therapeutic effect. Medication aerosol is initially nebulised for every inspiration followed by a short air bolus. The concluding air inhalation supports peripheral-alveolar lung deposition.

8.1 Important Instructions for the Smart Card

- Use Smart Cards as prescribed and directed by the physician only. Never use a Smart Card with a different medication than prescribed on the Smart Card or as recommended by your physician.
- Smart Cards need to be replaced after the number of pre-set dosages on the Smart Card have been inhaled. Always consult your physician to ensure that all active substances and dosages are as specified.
- If you have misplaced your Smart Card or if it is not available for other reasons, you can operate the AKITA JET for 60 days without a Smart Card. When you switch on the device without a Smart Card the display shows "No card! Inhalation for further 60 days". Order immediately a replacement Smart Card by your health care provider.
- In case of an error message regarding the Smart Card check that your Smart Card is correctly inserted in the Smart Card slot. Ensure that the colour printout on the Smart Card faces upwards and avoid leaving fingerprints on the metal contacts on the back of the Smart Card.

- Remove the Smart Card from the device only when this is necessary. Switch the device off before removing the Smart Card.

8.2 Medication-Specific Smart Cards

Every medication Smart Card is specific to the active substance and dosage and provides the following information:

(01)	Global Trader Item Number (GTIN)
(02)	Serial Number
EN:	Language indicator (e.g. English)
Active Substance:	Name substance
Dosage:	Dosage in active substance concentration per unit of volume
Filling dose	Amount of drug
Deposition:	Inhalation pattern deposition
Inhalation time and –volume:	Selection of inhalation time/volume per breath
Number of breaths total:	Total number of breaths required for one complete therapy treatment
REF	Catalogue Number

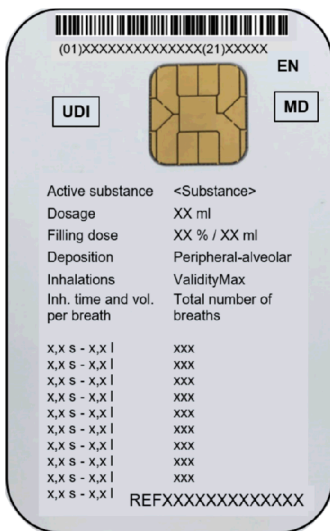


Fig. 20: Example of the label of a medication-specific Smart Card.

When using a medication-specific Smart Card, the active substance and dosage, the selected inhalation time and the remaining number of breaths required to reach the required dosage are displayed at the start of the therapy. During therapy the active substance, the dosage and the remaining number of breaths required to reach the required dosage are displayed continuously.

Substance/Dosage X.X s - X.X l XXXX breaths START>INHALE

or

Substance/Dosage X.X s - X.X l Ready XXXX more breaths

9 Troubleshooting

ERROR	POSSIBLE CAUSES AND REMEDY
<p>Nothing appears on display. The display is not illuminated and the internal compressor is not operating.</p>	<p>Ensure compliance with the following points:</p> <ul style="list-style-type: none"> • The power plug is plugged in • The power supply is connected to the power cord and the AKITA JET • The device has been switched on with the on/off button
<p>You have switched on the device but after the message: “Auto-test on...” the message “Error: Check connections” appears.</p>	<p>Ensure compliance with the following points:</p> <ul style="list-style-type: none"> • The original help flow tube is used • The tube is correctly connected • The tube is not kinked
<p>The AKITA JET performs the self-test, but does not start nebulisation even though you have briefly sucked on the mouthpiece.</p>	<p>Ensure compliance with the following points:</p> <ul style="list-style-type: none"> • The nebulizer is correctly assembled • The help flow tube is connected via help flow adapter to the nebulizer • The help flow tube is not kinked • The mouthpiece is correctly connected
<p>At every breath “Inhale slowly” appears.</p>	<p>Ensure compliance with the following points:</p> <ul style="list-style-type: none"> • You follow the given air flow during inhalation and do not inhale faster • The nebulizer tube is correctly connected
<p>During inhalation the display shows the message “Error: Overpressure > KEY”</p>	<p>Ensure compliance with the following points:</p> <ul style="list-style-type: none"> • You have not covered the mouthpiece with your tongue. • The tubes are correctly connected and not kinked.
<p>During exhalation the display shows the message: “Overpressure error: Do not exhale into device > KEY”</p>	<p>Do not exhale into the mouthpiece. Take the mouth piece out of your mouth for exhalation.</p>

ERROR	POSSIBLE CAUSES AND REMEDY
<p>The message “Card error: Check card” appears.</p>	<ul style="list-style-type: none"> • Ensure that the Smart Card is fitting correctly in the Smart Card slot. • Switch off the device and ensure that the metal contacts on the back of the Smart Card are clean. If necessary, clean the metal contacts with a clean cloth. Reinsert the Smart Card in the Smart card slot and switch the device on again. • Read the additional information in section 8.
<p>The message “Card valid for another 30 days” appears.</p>	<ul style="list-style-type: none"> • The Smart Card becomes invalid after three years. You can operate the AKITA JET for further 30 days with this Smart Card. • Please order a new Smart Card.
<p>The message “No card! Inhalation another 60 days” appears.</p>	<ul style="list-style-type: none"> • You can operate the AKITA JET for further 60 days without a Smart Card. • If you have no valid Smart Card available, you should order a new Smart Card through your doctor/dealer. • If you have inserted a valid Smart Card, ensure that the Smart Card is fitting correctly in the Smart card slot. • Read the additional information in section 8.
<p>The AKITA JET switches off even though the treatment has not been finished.</p>	<p>The AKITA JET has an internal temperature switch, which shuts off the device in case of overheating. If your device switches off due to an extended treatment time (longer than 40 minutes), let the device cool down before you start a new treatment.</p>
<p>The message “System error ?? see instructions XX breaths taken” appears. In place of ?? a number is shown by which the error can be identified.</p>	<p>Ensure that the nebulizer set has been correctly assembled and connected.</p> <p>Switch off the device and wait 5 seconds. Then switch it on again. If the error persists, please contact your dealer. Please note down the error number.</p>

If after following these instructions the error persists, contact Vectura or your service representative immediately to have the AKITA JET Inhalation System serviced or replaced.

10 Warranty

During the warranty period, we or our customer service provider will repair manufacturing or material faults on the AKITA JET Inhalation System free of charge. Claims for conversion, reduction or cancellation are excluded.

Damage resulting from improper handling of the AKITA JET Inhalation System is not covered by this warranty.

The warranty becomes void in the event of interventions in the device by parties not authorized to do so.

Compensation for direct or indirect damage or injury is excluded from the warranty.

Please ensure that you always operate the device with a filter.

Should you have a complaint, please take the complete equipment to Vectura or your service representative or send it to us postage paid in its original packaging along with the warranty certificate stamped by Vectura or your service representative.

Consumables are excluded from the warranty.

The warranty period for the AKITA JET Inhalation System is 2 years starting from the date of purchase.

11 Technical Data

11.1 General

AKITA JET Control Unit

Inhalation Flow:	12 l/min
Nebulizer Pressure:	1.6 bar
Weight:	2.5 kg
Dimensions (WxHxD):	206 x 180 x 130 mm (with nebulizer holder, otherwise D=117mm)
Electrical Protective Class:	II
Applied Part:	Nebulizer and first 10 cm of the tube: Type BF
Sound pressure level (unweighted):	70 dB

Power Supply A

Manufacturer:	FUHUA ELECTRONIC CO., LTD.
Model:	UE60-240250SPA1
Power Input:	100 - 240 V ~ 50 /60 Hz 1.5 A
Power Output:	24 VDC 2.5 A

Power Supply B

Manufacturer:	XP Power GmbH
Model:	AFM60US24C2
Power Input:	100 - 240 V ~ 50 – 60 Hz 1.5 A
Power Output:	24 VDC 2.5 A

AKITA JET Nebulizer

Minimum Fill:	2 ml
Maximum Fill:	8 ml

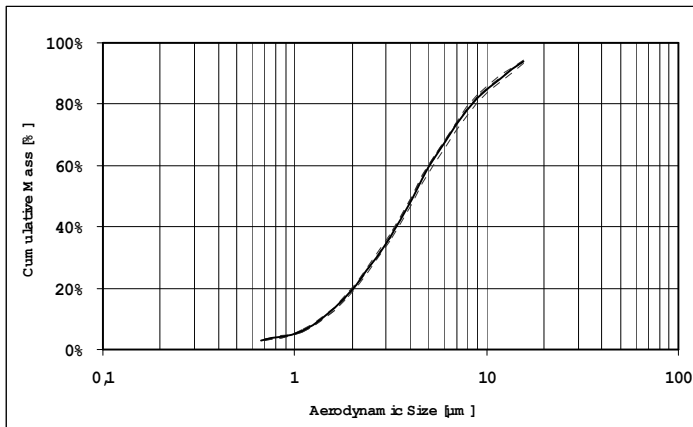
11.2 Aerosol Characteristics

The particle size and output rate of the AKITA JET nebulizer (based on PARI LC SPRINT) was measured according to EN 13544:2007 Respiratory therapy equipment – Part 1: Nebulising systems and their components. The stated values may not be valid for medications with high viscosity or suspensions. In these cases please gather information from the medication supplier.

Aerosol Output: 0.75 ml¹
 Aerosol Output Rate: 0.23 ml/min¹
 Mass Median Aerodynamic Diameter MMAD: 3.8 μm²

Particle size distribution according to EN 13544-1

Stage	Cut-off diameter [μm]	Cumulative Mass Distribution of a 2.5 % solution of sodium fluoride			
		Mean value	Measurement 1	Measurement 2	Measurement 3
MOC	0,00	3,0%	3,4%	2,7%	2,9%
7	0,98	5,9%	6,4%	5,6%	5,7%
6	1,36	16,8%	17,7%	16,3%	16,4%
5	2,08	36,4%	37,6%	35,0%	36,6%
4	3,30	62,0%	62,8%	60,3%	62,9%
3	5,39	82,1%	82,6%	80,5%	83,1%
2	8,61	93,8%	94,0%	93,2%	94,3%
1	14,1	100,0%	100,0%	100,0%	100,0%



11.3 Operating Conditions

Ambient conditions under which the stated aerosol characteristic is ensured:

- Ambient temperature: 5 to 40°C
- Relative humidity: 15 to 93% non-condensing atmospheric humidity
- Atmospheric pressure: 700 hPa to 1060 hPa

¹ Filling: 2 ml Sodium fluoride dilution 1.0 %, Flow rate: 12 l/min

² Filling: 3 ml Sodium fluoride dilution 2.5 %, Flow rate: 15 l/min

The instrument is radio and television interference suppressed according to DIN EN 60601-1-2. Nevertheless, electromagnetic interference can under certain conditions impair the device function. Interference can, for example, be caused by mobile telephones. If you detect such interference, switch off the AKITA JET and increase the distance from possible sources of interference (see also section 11.6).

11.4 Storage- and Transport Conditions

Ambient conditions for transport and storage of the AKITA JET Inhalation System.

- Ambient temperature: -25 to 70°C
- Relative humidity: 15 to 93% non-condensing atmospheric humidity
- During storage and transportation, the equipment should not be exposed to constant direct solar radiation.
- Use the carrying handle provided when transporting the unit.
- Do not store the nebulizer set, control unit or power supply in damp areas (e.g. bathroom) or transport them together with damp objects.
- In the event of extreme fluctuations of the ambient temperature, the system can malfunction due to condensation.
- In general between treatments the nebulizer set should be stored as described in section 5.4.
- After transport or storage of the device: Wait one hour before treatment for temperature acclimatization.

11.5 Service Life

The AKITA JET Inhalation System is intended for repeated use. The average life of the components is given in the table below.

COMPONENT	SERVICE LIFE
AKITA JET control unit (the device can continue to be used after maintenance)	10 Years (at a daily inhalation treatment time of 20 minutes)
AKITA JET nebulizer set	12 Months from First Use (maximum 300 sterilisation cycles)
Filter	12 Months from First Use

At the end of the service life, replacement is recommended to ensure problem-free operation. In the event of visible damage or a noticeably longer nebulisation time with the same substance and same quantity of medication, the components must be replaced immediately.

11.6 Electromagnetic Compatibility (EMC)

CAUTION:

Guidance and Manufacturer's Declaration		
Electromagnetic Emission		
The AKITA JET nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the AKITA JET should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The AKITA JET nebulizer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AKITA JET nebulizer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	


Guidance and Manufacturer's Declaration			
Electromagnetic Immunity Enclosure Port			
The AKITA JET nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the AKITA JET nebulizer should assure that it is used in such an environment.			
Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact	± 8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	± 15 kV air	± 15 kV air	

Radio-frequency EM fields and Proximity fields from RF wireless communications equipment IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz	Mains power quality should be that of a typical home healthcare or hospital environment.
	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz	
	27 V/m 380 - 390 MHz 50% PM at 18 Hz	27 V/m 380 - 390 MHz	
	28 V/m 430 - 470 MHz 50% PM at 18 Hz	28 V/m 430 - 470 MHz	
	9 V/m 704 - 787 MHz 50% PM at 217 Hz	9 V/m 704 - 787 MHz	
	28 V/m 800 - 960 MHz 50% PM at 18 Hz	28 V/m 800 - 960 MHz	
	28 V/m 1700 - 1990 MHz 50% PM at 217 Hz	28 V/m 1700 - 1990 MHz	
	28 V/m 2400 - 2570 MHz 50% PM at 217 Hz	28 V/m 2400 - 2570 MHz	
	9 V/m 5100 - 5800 MHz 50% PM at 217 Hz	9 V/m 5100 - 5800 MHz	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration

Electromagnetic Immunity AC Power Port

The AKITA JET nebulizer is intended for use in the electromagnetic environment specified below. The customer or the user of the AKITA JET nebulizer should assure that it is used in such an environment

Immunity test	IEC 60601-1-2:2014 Test Condition	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radio-frequency field IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the AKITA JET nebulizer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E} \sqrt{P}$ where ρ is the maximum output power rating of the transmitter in watts (W)
	6 Vrms ISM/amateur Bands	6V	according to the transmitter manufacturer, E is the filed strength in V/m and d is the recommended separation distance in metres (m). ^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV line to line	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV line to ground	± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AKITA JET nebulizer requires continued operation during power mains interruptions, it is recommended that the AKITA JET nebulizer be powered from an uninterruptible power supply or a battery.
	0 % U_T for 1 cycle at 0° 70 % U_T	1 cycle	
	0 % U_T for 25/30 cycles at 0°	25/30 cycles	
	0 % U_T for 250/300 cycles	250/300 cycles	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3: U_T is the a. c. mains voltage prior to application of the test level.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AKITA JET nebulizer is used exceeds the applicable RF compliance level above, the AKITA JET nebulizer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AKITA JET nebulizer.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

12 Accessories and Spare Parts

Use only approved spare parts. In particular, do NOT substitute other nebulizers for the AKITA JET nebulizer set.

DESCRIPTION	ARTICLE-NO.	GTIN No.
AKITA JET Year Pack (comprising 2x AKITA JET nebulizer sets, 1x filter,)	01VB0111	5056143200352
Nebulizer Set (consisting of 1 nebulizer and 1 tube system)	01VB0100	5056143200093
Tube System	01VB0103	5056143200123
AKITA JET Control Unit	01RS0100	5056143200154
AKITA JET Power Supply Type A	99ZB0142	5056143201786
AKITA JET Power Supply Type B	99ZB0141	5056143201823
Power Cable EU (2m)	05ZB0026	5056143201588
Power Cable UK (2m)	05ZB0027	5056143201595
Power Cable US (2m)	05ZB0028	5056143201601
Filter Cover	01RS0126	5056143200338
Filter	05VB0002	5056143201564
AKITA JET carrying Bag	01ZB0157	5056143200369
Nebulizer Holder	01RS0127	5056143200345
Carrying Handle	05ZB0002	5056143201571

13 Recycling and Disposal

This product falls within the scope of the European Council Directive on Waste Electrical and Electronic Equipment WEEE (Directive 2002/96/EC of the EUROPEAN PARLIAMENT AND THE EUROPEAN COUNCIL of January 27, 2003 on waste electrical and electronic equipment) and is included in product category 8: Medical devices for the purposes thereof. Accordingly, this product must not be disposed of with domestic waste. The disposal regulations prevailing in the respective member countries must be observed (e.g., disposal by local authorities or service representative). Used and cleaned hygiene articles can be disposed of in the normal household refuse.

14 Service, Maintenance and Reporting

For repairs, claims under warranty or for disposal of equipment, please send the equipment to the following address:















Vectura Group plc.
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Wiltshire
SN14 6FH
United Kingdom

International telephone number: +44 (0) 20 7881 1208

Email: support@akita-jet.com

15 Explanation of Symbols used

The following symbols are used on the backside of the AKITA JET control unit, on the power supply or on the packaging:

SYMBOL	MEANING
	Manufacturer
GTIN	Global Trade Item Number
	Medical Device
	Unique Device Identifier
	This device complies with the requirements of the Medical Devices Regulation (2017/745/EU)
	Follow Instructions for Use
	Polarity: Centre positive, outer negative
	The AKITA JET is a Type BF equipment.
	The AKITA JET is a protection class II appliance.
IP21	The Akita Jet is protected against ingress of solid foreign objects or water. The AKITA JET is rated IP-class IP21.
	This product must not be disposed of with normal domestic waste. The symbol of the refuse bin with a line through it indicates that it must be collected separately.
	European Authorized Representative or Authorized Representative in European Community
	Serial Number
	Catalogue number
	Batch Code
	Non-ionizing electromagnetic radiation