

Owner's Manual | Manuel de l'utilisateur | Manual de instrucciones  
Bedienungsanleitung | Gebruiksaanwijzing | Manuale d'uso | Användarmanual  
Brugermanual | Εγχειρίδιο Οδηγιών για τον Χρήστη | Kullanıcı El Kitabı  
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# AeroEclipse<sup>\*</sup> XL

Reusable Breath Actuated Nebulizer



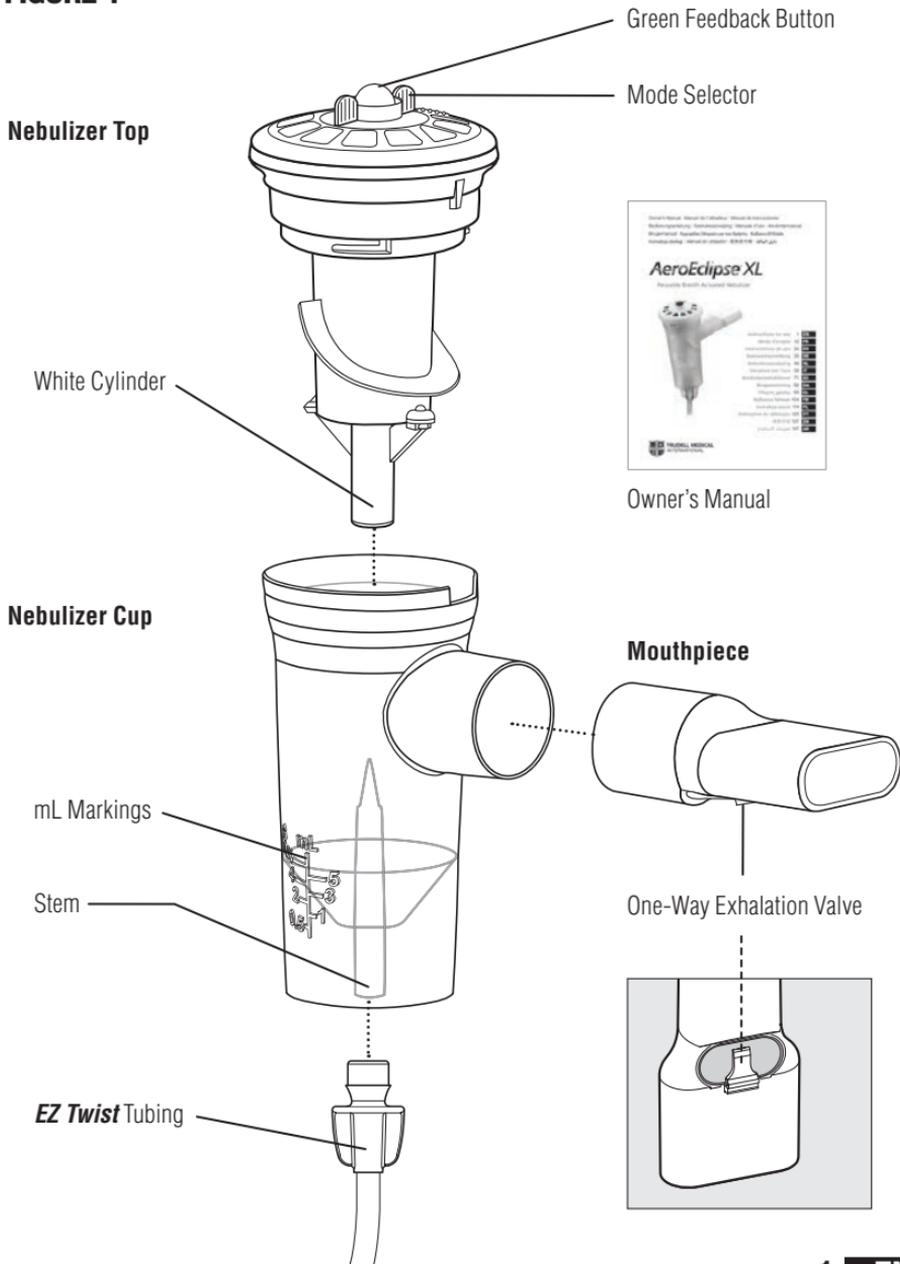
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**TRUDEL MEDICAL**  
INTERNATIONAL



**FIGURE 1**



## INDICATIONS FOR USE

The reusable **AEROECLIPSE\*** XL Breath Actuated Nebulizer (BAN) is a single patient, reusable device when used in a home environment and multi-patient when cleaned according to Hospital instructions. The nebulizer is intended to administer prescribed aerosolized medication to spontaneously breathing patients under the care or treatment of a licensed healthcare professional. The device may be used with an **Ombra\*** Compressor or an air source capable of delivering a flow of 3.5 to 5.0 litres per minute (Lpm) under a nominal operating pressure of 0.92 to 1.79 bar (13.3 to 26 pounds per square inch (psi)). The intended environments for use include the home, hospitals and clinics.

## IMPORTANT SAFETY INFORMATION

The following statements will be used to draw attention to potential use errors that could cause harm.

ⓘ **NOTE** - Indicates information to which the user should pay special attention.

⚠ **CAUTION** - Information for preventing damage to the product or causing personal injury.

⚠ **WARNING** - Important safety information for hazards that could cause serious injury or death.

## BEFORE YOU BEGIN

1. This package should contain one reusable **AEROECLIPSE\*** XL BAN with mouthpiece, one **EZ Twist** TUBE and one Owner's Manual (See Figure 1). If any parts are missing, please contact the authorized distributor from whom you purchased this unit. To download an electronic copy of this **OWNER'S MANUAL**, visit [www.aeroeclipse.com](http://www.aeroeclipse.com).
2. Prior to use, carefully examine the product for foreign objects, damaged or missing parts. Inspect the tubing for fray, wear or loose particulate, and ensure nothing is blocking the air supply pathway of the nebulizer cup. If any parts are missing or a defect is noticed, contact the authorized distributor where you originally purchased your reusable **AEROECLIPSE\*** XL BAN. Ensure you clean your nebulizer before first use and between each treatment.
3. Read your **OWNER'S MANUAL** to be sure you understand all instructions for use, cautions and warnings before starting a nebulizer treatment. If you have questions about the performance or usability of this product, please contact your healthcare professional prior to use.
4. The nebulizer should be replaced after 6 months of use. Be sure to follow the use and cleaning instructions as outlined in this **OWNER'S MANUAL**, and replace your nebulizer within the timeframe indicated to ensure it functions correctly. Failure to follow the appropriate cleaning instructions may have an adverse affect on device performance.
5. It is recommended that you have an extra nebulizer on hand in the event your nebulizer becomes damaged, lost or otherwise unusable.

## SETTING UP YOUR NEBULIZER

For nebulizer part descriptions see Figure 1.

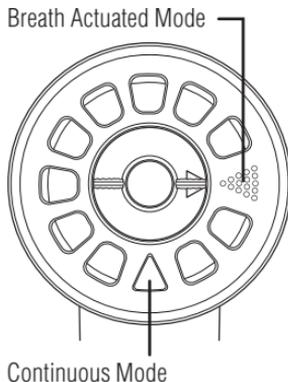
⚠ **CAUTION:** The reusable **AEROECLIPSE\*** XL BAN can deliver aerosolized medication in either **BREATH ACTUATED** or **CONTINUOUS** Mode. In **BREATH ACTUATED** Mode, medication is delivered on inspiration only and may result in an increase of the dosage to the lungs. Clinicians should take this information into consideration when determining dosage.

1. Prior to use, inhale and exhale through the Mouthpiece to verify the movement of the **GREEN FEEDBACK BUTTON** located on the top of the device (Fig. 1). The button should move up and down freely. If not, move the **MODE SELECTOR** to the **BREATH ACTUATED** position (  – Fig. 2).

If the **GREEN FEEDBACK BUTTON** still does not move freely contact your authorized distributor for a new unit.

2. Examine the **MOUTHPIECE** to ensure the **EXHALATION VALVE** is on the bottom, facing down to ensure exhaled breath is directed away from the face.
3. For patients unable to use the **MOUTHPIECE**, the reusable **AEROECLIPSE® XL BAN** can be used with an optional Mask by removing the **MOUTHPIECE** and inserting the Mask into the **MOUTHPIECE** opening.
4. Unscrew and remove the **NEBULIZER TOP**. Carefully place prescribed medication into **NEBULIZER CUP** (Fig. 3). The reusable **AEROECLIPSE® XL BAN** has a minimum fill of 1 mL and a maximum fill of 6 mL. Reattach the **NEBULIZER TOP**, making sure to line up the **WHITE CYLINDER** with the **STEM** of the **NEBULIZER CUP** and gently hand tighten until a stop is detected, as shown in Figure 4. Ensure nebulizer is kept in an upright position so medication does not spill. (e.g. Use your compressor's nebulizer cup holder).

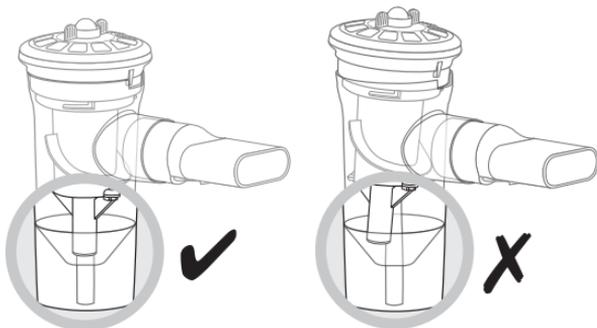
**FIGURE 2**



**FIGURE 3**



**FIGURE 4**



5. Attach one end of the supplied **EZ Twist TUBING** to the fitting on the bottom of the nebulizer and the other end to your compressed air source. Ensure both ends are securely engaged.

## NEBULIZER TREATMENT

The reusable **AEROECLIPSE® XL BAN** can be operated in **CONTINUOUS MODE** (constantly producing aerosol) by rotating the **MODE SELECTOR** to the **CONTINUOUS MODE** position ( $\Delta$  – Fig. 2). The nebulizer can be returned to **BREATH ACTUATED Mode** by rotating the **MODE SELECTOR** to the **BREATH ACTUATED** position (••• – Fig. 2).

Always follow your healthcare professional's treatment instructions.

**⚠ WARNING** - Close supervision is necessary when this product is used by or near infants, children or anyone requiring assistance to use the device. It contains parts that may present a choking or strangulation hazard. **DO NOT LEAVE CHILDREN UNATTENDED DURING TREATMENTS.**

## BREATH ACTUATED MODE

Ensure the **MODE SELECTOR** is in **BREATH ACTUATED** position (▲ – Fig. 2).

1. While sitting in a comfortable, upright position, switch on your compressor.
2. Place the **MOUTHPIECE** in your mouth, ensuring your lips are sealed around the edge. Be careful not to cover the **EXHALATION VALVE** on the bottom of the **MOUTHPIECE**, as doing so will prevent the valve from functioning properly.
3. Inhale slowly and deeply. As you inhale, the **GREEN FEEDBACK BUTTON** on the top of the nebulizer (Fig. 1) will move down, indicating that the reusable **AEROECLIPSE® XL BAN** is producing aerosol in response to your inhalation.
4. Exhale normally through the device. The valve on the mouthpiece only opens during exhalation to allow air to exit the device. This helps prevent re-breathing of exhaled air. During exhalation, the **GREEN FEEDBACK BUTTON** returns to the up position indicating no aerosol is being produced (Fig. 5).
5. Continue to breathe normally through the device until it begins to make a 'sputter' noise or as instructed by your healthcare professional.
6. Switch off the compressor when finished with your treatment.

ⓘ **NOTE:** If you are unable to trigger the device during inhalation (unable to get the **GREEN FEEDBACK BUTTON** to go down when you breathe in) it can be manually operated with your index finger by depressing/releasing the **GREEN FEEDBACK BUTTON** in coordination with your breathing. Alternately, you may switch the device to **CONTINUOUS MODE** (△ – Fig. 2).

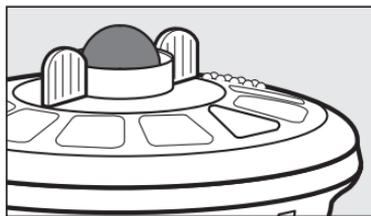
## CONTINUOUS MODE

Ensure the **MODE SELECTOR** is in **CONTINUOUS** position (△ – Fig. 2).

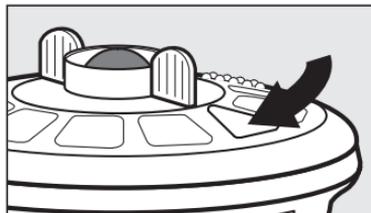
In **CONTINUOUS** Mode, the nebulizer may be used with the reusable **ComfortSeal®** Mask.

1. While sitting in a comfortable, upright position, switch on your compressor.
2. **Mouthpiece:** Place the **MOUTHPIECE** in your mouth, ensuring your lips are sealed around the edge. Be careful not to cover the **EXHALATION VALVE** on the bottom of the **MOUTHPIECE**, as doing so will prevent the valve from functioning properly.  
**Mask:** Place the mask securely over your nose and mouth, ensuring you have a good seal with the edge of the mask and face. Even tiny gaps may affect medication delivery.
3. Inhale slowly and deeply. The **GREEN FEEDBACK BUTTON** will stay down for the duration of the treatment, indicating the device is constantly producing aerosol. (Fig. 5)
4. Exhale normally through the device. The **EXHALATION VALVE** on the **MOUTHPIECE** or Mask will open allowing air to exit the device.

**FIGURE 5**



Breath Actuated Mode 'up' position



Continuous Mode 'down' position

5. Continue to breathe normally through the device until it begins to make a 'sputter' noise or as instructed by your healthcare professional.
6. Switch off the compressor when finished with your treatment.

## CLEANING YOUR NEBULIZER

Ensure you clean your nebulizer before first use and between each treatment.

- For optimum performance you should replace your nebulizer every 6 months.

### 1. PREPARATION

Immediately after each treatment, all parts of the reusable **AEROECLIPSE\*** XL BAN (excluding tubing) must be cleaned of medication residue and contamination.

To do this, disassemble nebulizer as follows:

- 1.1 Rotate the **MODE SELECTOR** to the **BREATH ACTUATED** position before cleaning to ensure free movement of the parts.
- 1.2 Remove the **EZ Twist TUBING** from the bottom of the nebulizer.
- 1.3 Unscrew and remove the **NEBULIZER TOP** and remove **MOUTHPIECE** from the **NEBULIZER CUP**.

For re-use at home, continue to read starting with Section 2.

For re-use in hospital or medical practice, please read Section 5.

**⚠ CAUTION:** Failure to follow manufacturer's cleaning or disinfection instructions may have an adverse effect on device performance. Do not disassemble the product beyond what is recommended in the cleaning instructions or damage may result.

### 2. AT HOME

#### 2.1 RECOMMENDED METHOD

- Wash the three nebulizer parts (excluding tubing) in a solution of warm water and liquid dish detergent for about 5 minutes.
- Rinse in clean, warm water.
- Dry according to instructions in Section 2.3.

#### 2.2 ALTERNATIVE METHOD

- The reusable **AEROECLIPSE\*** XL BAN disassembled into its three parts (excluding tubing) may be washed in a dishwasher by securing the nebulizer parts in a basket on the top rack. Wash in a normal wash cycle, being sure to remove the basket prior to the drying cycle.
- Dishwashing with overly dirty dishes is not recommended.
- Dry according to instructions in Section 2.3.

#### 2.3 DRYING

- To dry, shake the nebulizer parts to remove any excess water.
- We recommend you briefly reconnect the **EZ Twist TUBING** to the bottom of the nebulizer cup and the compressed air supply to clear the air pathway.
- Allow parts to air dry thoroughly before reassembling.
- The nebulizer components may also be dried with a clean lint-free cloth prior to reassembly.

## **EZ TWIST TUBING**

Occasionally you may notice condensation on the inside of your tubing. This is normal. To remove the condensation, simply connect one end of the **EZ Twist** TUBING to a pressurized air source, such as an **Ombra**<sup>®</sup> Compressor, and allow the air to run without the nebulizer attached. This will force air through the tubing, drying the inside. To clean the exterior, wipe with a damp cloth. Ensure the tubing is dry prior to storage.

### **3. DISINFECTION INSTRUCTIONS**

The reusable **AEROECLIPSE**<sup>®</sup> XL BAN (excluding tubing) should be disinfected at least every other treatment day using any of the methods listed below.

#### **A. BLEACH**

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- The three nebulizer parts (excluding tubing) may be soaked in 1:50 bleach to water solution (approximately 1 tablespoon bleach in 3¼ cups water) for 3 minutes. Rinse well with clean water. You may substitute a respiratory equipment disinfectant (such as Milton<sup>†</sup>, Dodie<sup>†</sup> or Control III<sup>†</sup>) for the bleach solution by following the manufacturer's instructions for use.
- Dry according to instructions in Section 3.1.

#### **B. BOILING**

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- The three nebulizer parts (excluding tubing) may be boiled in water for 15 minutes. Place the individual nebulizer parts in the water once it has reached the boiling point. Remove from water and allow to cool.
- Dry according to instructions in Section 3.1.

① **NOTE:** For Cystic Fibrosis patients, guidelines recommend boiling for a full 10 minutes to disinfect.

① **NOTE:** Ensure there is enough water in the pan to avoid contact of the plastic parts with the bottom of the hot pan.

#### **C. ISOPROPYL ALCOHOL (70%)**

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- Wipe the outside surfaces of the three nebulizer parts (excluding tubing) with a tissue dipped in 70% Isopropyl Alcohol then submerge the three parts in a soak of 70% Isopropyl Alcohol for 1 minute before shaking to remove any excess alcohol.
- Rinse well with clean water.
- Dry according to instructions in Section 3.1.

#### **D. MICROWAVE STEAM BAG**

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.

- The three nebulizer parts (excluding tubing) may be disinfected in the microwave in a steam cleaning bag (i.e. Quick-Clean<sup>†</sup> MicroSteam<sup>†</sup> bag) following the manufacturer's instructions for use. Remove from bag and allow to cool.
- Dry according to instructions in Section 3.1.

#### **E. ELECTRONIC STEAM STERILIZER**

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- The three nebulizer parts (excluding tubing) may be disinfected using an electronic steam sterilizer for baby bottles, following the manufacturer's instructions for use (e.g. AVENT<sup>†</sup> Electronic Sterilizer). The disinfection cycle should last approximately 15 minutes. Allow parts to cool.
- Dry according to instructions in Section 3.1.

#### **F. VINEGAR (Not recommended for high level disinfection)**

- Prior to disinfection, follow Section 1 and 2 'Cleaning Your Nebulizer'. Do not dry or reassemble the device.
- The three nebulizer parts (excluding tubing) may be soaked in 1:3 vinegar to water solution (approximately 1 cup vinegar to 3 cups water) for 1 hour. Rinse well with clean water.
- Dry according to instructions in Section 3.1.

#### **3.1 DRYING**

- To dry, shake the nebulizer parts to remove any excess water.
- We recommend you briefly reconnect the **EZ Twist** TUBING to the bottom of the nebulizer cup and the compressed air supply to clear the air pathway.
- Allow parts to air dry thoroughly before reassembling.
- The nebulizer components may also be dried with a clean lint-free cloth prior to reassembly.

### **4. STORAGE**

- Reattach the NEBULIZER TOP, making sure to line up the WHITE CYLINDER with the STEM of the NEBULIZER CUP and gently hand tighten until a stop is detected.
- Reattach the MOUTHPIECE to the device with the EXHALATION VALVE facing down.
- Nebulizer components should be stored together (with tubing) in a dry, dust-free place avoiding continuous exposure to direct sunlight.

### **5. HOSPITAL INSTRUCTIONS (For Multiple Patient Re-Use)**

If the nebulizer will be used for multiple patients, it must be cleaned, disinfected and sterilized between patients and before first use. The **EZ Twist** TUBING cannot be reprocessed and must be replaced between patients.

The following are the cleaning and disinfectant procedures exclusively for qualified medical specialists familiar with the hygiene requirements in hospitals and medical practices validated by Trudell Medical International according to DIN EN 17664. If different sterilization procedures are used, particular care should be taken to ensure they are suitable for cleaning or disinfecting medical products and that they satisfy the requirements for material resistance.

⚠ **CAUTION** - Ensure nebulizer components are allowed to air dry thoroughly between cleaning steps. Condensation or residual wetness can present an increased risk through the growth of bacteria.

## 5.1 CLEANING/DISINFECTION

⚠ **CAUTION** - Clean and disinfect immediately after use with a single patient. Clean, disinfect and sterilize before every change in patient.

### 5.1.1 RECOMMENDED PROCEDURE: MECHANICAL CLEANING AND DISINFECTION

- Prepare the nebulizer as described in Section 1 'Preparation'.
- Place the nebulizer components (excluding tubing) in the washer disinfector in a manner that they can be cleaned most effectively.
- Select the Vario TD program.
- Following thermal disinfection, remove nebulizer components from washer disinfector and shake to remove excess water.
- Allow to air dry thoroughly prior to continuing to sterilization.
- The effectiveness of this procedure has been proven using a Miele mechanical washer disinfector with Neodisher<sup>†</sup> Mediclean forte 0.5% and Neodisher<sup>†</sup> Z for neutralization (Dr. Weigert, Hamburg). The equipment used for thermal disinfection should conform to DIN EN ISO 15883.

### 5.1.2 RECOMMENDED PROCEDURE: MANUAL CLEANING AND DISINFECTION

⚠ **CAUTION:** The **AEROCLIPSE\*** XL BAN (and its accessories) are not suitable for treatment with disinfectants based on quaternary ammonium compounds. Quaternary ammonium compounds tend to become concentrated in plastic materials, which can cause incompatibility reactions in patients.

- Prepare the nebulizer as described in Section 1 'Preparation'.
- Place the nebulizer components (excluding tubing) in a solution of Korsorex<sup>†</sup> EndoCleaner 0.5% and approximately 50°C warm water and clean thoroughly with a brush. This process should take approximately 5 minutes.
- Next, place the nebulizer components (excluding tubing) in a disinfectant solution of Korsorex<sup>†</sup> basic 4% for 15 minutes.
- Thoroughly rinse the nebulizer components under hygienically tested water, shake to remove excess water and leave to air dry thoroughly on a clean, dry and absorbent surface.
- The effectiveness of this procedure has been proven using Korsorex<sup>†</sup> EndoCleaner 0.5% cleaning agent in combination with the Korsorex<sup>†</sup> basic 4% disinfectant (Bode Chemie, Hamburg).

## 5.2 STERILIZATION

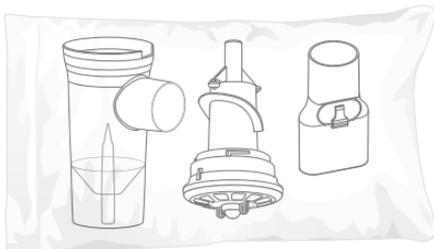
Your nebulizer (excluding tubing) may be sterilized using the following validated procedures. If another procedure is used, its effectiveness must be validated. Hospital hygiene standards should be followed.

- A validated sterilization process can only be carried out on products once they have been cleaned and disinfected following instructions in Section 5.1.

- After cleaning/disinfection, pack the nebulizer disassembled into its three parts in sterilization packaging (disposable sterilization packaging) conforming to DIN EN ISO 11607. Packaging size should be no smaller than 70 mm x 120 mm.

① **NOTE:** When placing the nebulizer components in the sterilization packaging, the **WHITE CYLINDER** portion of the **NEBULIZER TOP** should be positioned in the packaging so it is not bent or pressed into corners where it can become bent (as shown).

- The nebulizer components should then be sterilized using the following sterilization procedure.



### 5.2.1 RECOMMENDED PROCEDURE: STEAM STERILIZATION

Autoclave the reusable **AEROECLIPSE**\* XL BAN following the autoclave manufacturer's instructions preferably with fractionated pre-vacuum – in accordance with DIN EN 285 or DIN EN 13060 (type B).

#### Maximum sterilization and holding time:

**A.** 121°C (to be maintained for at least 20 minutes).

OR

**B.** 134°C (to be maintained for at least 3 minutes). Do not exceed a temperature of 137°C.

Ensure the nebulizer components do not come in contact with other materials, metal trays or shelving in the autoclave and that nothing is placed on top of the device during reprocessing.

This method has been validated according to DIN EN ISO 17665-1.

① **NOTE:** The reusable **AEROECLIPSE**\* XL BAN may be autoclaved up to 150 times or for 6 months (whichever is first), but then it must be replaced. Visually inspect the nebulizer after each cleaning cycle. Replace any damaged, misshapen or seriously discoloured parts.

⚠ **CAUTION:** Use of cleaning and disinfection procedures other than those listed above have not been validated and may cause damage to the device.

### 5.3 STORAGE

Keep the sterilized nebulizer in a dry, dust-free place protected from contamination.

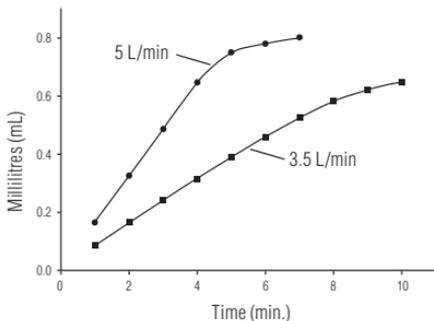
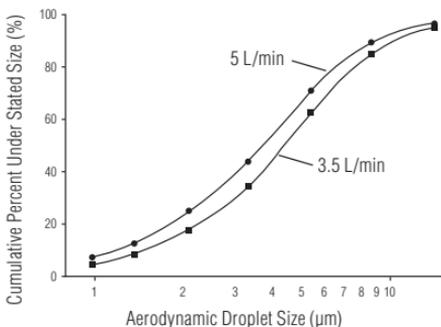
## SINGLE PATIENT USE

When not cleaned according to the Hospital Instructions for Multiple Patient Re-Use, this device is intended for single patient use (one patient only). The device should be replaced after 6 months or immediately if components are cracked or the nebulizer does not function properly.

## DISPOSAL

The nebulizer components used can be disposed of with domestic waste unless this is prohibited by the disposal regulations prevailing in the respective member countries.

## AEROSOL CHARACTERISTICS



## TECHNICAL SPECIFICATIONS

<b>Nebulizing Method</b>	Breath Actuated or Continuous Mode	
<b>Nebulizer gases</b>	Air, Oxygen	
<b>Actuation Flow Rate</b>	12 L/min	
<b>Fill Volumes</b>	Minimum Fill: 1 mL Maximum Fill: 6 mL	
<b>Operating Angle</b>	Up to 45 degrees	
<b>Recommended Flow Rates</b>	3.5 L/min to 5.0 L/min.	
<b>Corresponding Operating Pressures</b>	91.7 kPa (13.3 psi) to 179.3 KPa (26 psi)	
<b>Mass Median Aerodynamic Diameter (MMAD)</b>	4.3 µm @ 3.5 L/min	3.7 µm @ 5.0 L/min
<b>Respirable Fraction</b>	58% @ 3.5 L/min	67% @ 5.0 L/min
<b>Operating Temperature Limits</b>	+15°C (59°F) to +40°C (104°F)	
<b>Operating Relative Humidity Range</b>	15% to 95% RH (non-condensing)	
<b>Storage Temperature Range</b>	-40°C (-40°F) to +70°C (158°F)	
<b>Storage Relative Humidity Range</b>	Ambient to 95% RH (non-condensing)	
<b>Latex Free</b>	Yes	
<b>Nebulizer Materials</b>	Polypropylene, Acetal (Mode Selector only), Silicone, PVC ( <i>EZ Twist</i> Tubing only)	
<b>Information Last Updated</b>	March 2019	

## REORDER NUMBERS

Reusable <b>AEROECLIPSE*</b> XL BAN (Includes: Reusable <b>AEROECLIPSE*</b> XL BAN with mouthpiece, <b>EZ Twist</b> Tubing, owner's manual)	10551393010
Reusable <b>ComfortSeal*</b> Mask with Elbow Adapter – Small (0 – 18 months)	10550393010
Reusable <b>ComfortSeal*</b> Mask with Elbow Adapter – Medium (1 – 5 years)	10550293010
Reusable <b>ComfortSeal*</b> Mask with Elbow Adapter – Large (5+ years)	10550493010