

Aerobika*

Oscillating Positive
Expiratory Pressure Therapy System



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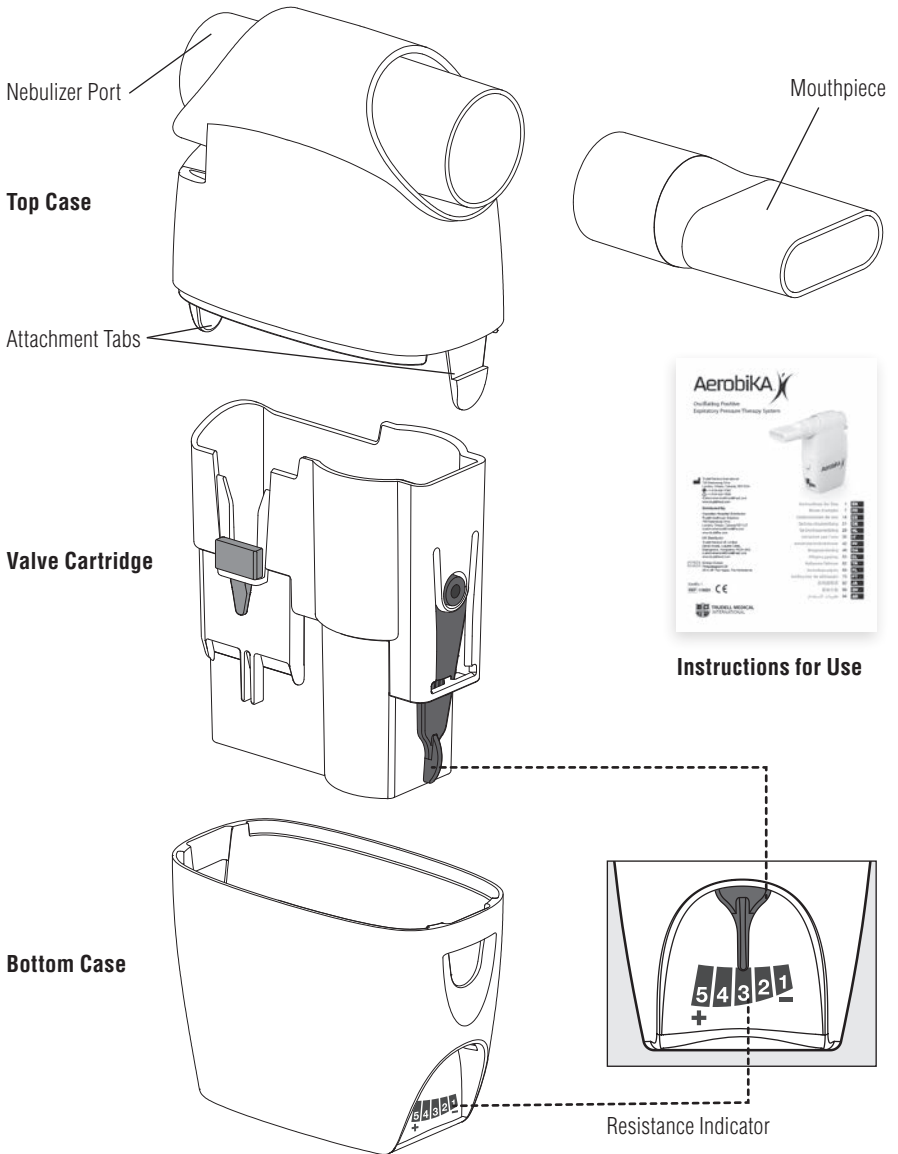
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TRUDELL MEDICAL
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FIGURE 1



INTENDED USE

The **Aerobika*** Oscillating Positive Expiratory Pressure Therapy System is intended for use as a Positive Expiratory Pressure (PEP) device. The **Aerobika*** Oscillating PEP device may also be used simultaneously with nebulized aerosol drug delivery. The device is intended to be used by patients capable of generating exhalation flow of 10 lpm for 3–4 seconds.

CAUTIONS

- Do not leave the device unattended with children. It is not a toy.
- Do not press attachment tabs when the case is disassembled. Doing so could break the tabs and prevent proper assembly of the device.
- Ensure contraindications are observed.

CONTRAINDICATIONS

Use of the **Aerobika*** Oscillating PEP device is not recommended for the following conditions

- Patients unable to tolerate the increased work of breathing
- Intracranial pressure (ICP) > 20 mm Hg
- Hemodynamic instability (blood pressure instability)
- Recent facial, oral, or skull surgery or trauma
- Acute sinusitis
- Epistaxis (bleeding nose)
- Esophageal surgery
- Nausea
- Active hemoptysis (bleeding from lungs)
- Untreated pneumothorax (untreated collapsed lung)
- Known or suspected tympanic membrane rupture or other middle ear pathology

WARNING

Use of this device at excessive pressures may have adverse effects. Expiratory pressures above 20 cm H₂O in patients sensitive to increased transpulmonary pressure may develop one or more of the adverse side effects listed below. Expert clinical judgment should be exercised in the selection of the appropriate setting for each individual patient. Failure to match the appropriate resistance setting on the Adjustment Indicator with the patient's expiratory flow may result in failure to achieve therapeutic objectives of oscillatory PEP therapy or one or more adverse side effects listed below.

Adverse reactions may include

- Increased work of breathing that may lead to hypoventilation and hypercarbia
- Increased cranial pressure
- Cardiovascular compromise
 - Myocardial ischemia
 - Decreased venous return
- Air swallowing with increased likelihood of vomiting and aspiration
- Claustrophobia
- Pulmonary barotraumas

SETTING UP YOUR AEROBIKA* OSCILLATING PEP

For device descriptions see Figure 1.

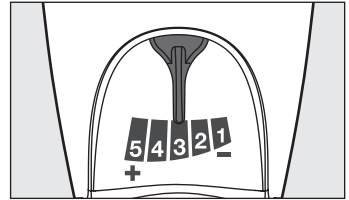
Before use, ensure these instructions have been read and are kept available at all times. If you have questions about the performance or usability of this product, please contact your healthcare professional prior to use.

DETERMINING PROPER RESISTANCE SETTING

The **Aerobika*** Oscillating PEP device should be set up by a healthcare professional using the following steps:

1. Start with the Resistance Indicator at the middle setting. (Fig. 2)
2. With the patient in a comfortable seated position, have them inhale through the device taking a deeper breath than normal, but not to total lung capacity, then exhale briskly but not forcefully through the device.
3. Resistance should be set so exhalation lasts for 3–4 times longer than inhalation. Resistance can be increased by moving the indicator to the left. To reduce resistance, move the indicator to the right.

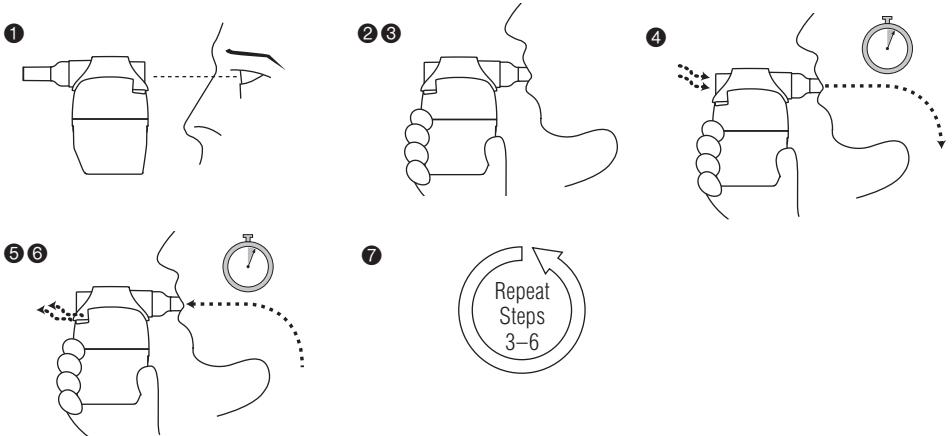
FIGURE 2



- ① **NOTE:** Selection of the proper resistance setting will produce the desired inspiratory:expiratory flow ratio of 1:3 or 1:4 for 10–20 minutes without excess fatigue.
4. Patients should be reevaluated periodically or with any change in status. As airways become less congested, more resistance will be needed to maintain inspiratory:expiratory ratios.

PROPER TECHNIQUE FOR USING YOUR AEROBIKA* OSCILLATING PEP

Treatments should be conducted twice daily or as directed by your healthcare professional.



1. Before use carefully examine the device. Replace immediately if any defect is noticed. Always ensure the Resistance Indicator is positioned as prescribed by your healthcare professional. Gently press the two halves together to make sure the Attachment Tabs are engaged.
2. Although the **Aerobika*** Oscillating PEP is orientation independent, it is recommended that treatments be done in a comfortably seated position.
3. Put the mouthpiece in mouth and close lips around it to ensure an effective seal. Make sure your hand does not block the exhalation path on the back of the device.
4. Inhale through the device taking a deeper breath than normal, but do not totally fill your lungs. Hold your breath for 2–3 seconds before exhaling.
5. Exhale actively, but not forcefully, through the device. Ideally, exhalation should last 3–4 times longer than inhalation. Keep your cheeks flat and firm to maximize treatment effectiveness. Ensure you maintain a good seal on the mouthpiece for the duration of your treatment.
6. Continue taking deep breaths and long exhalations for 10–20 breaths, or as instructed by your healthcare professional. After at least 10 breaths, perform 2–3 'huff' coughs to clear your airways. Your healthcare professional

will instruct you on the proper technique. For maximum efficacy, try to suppress coughing until the end of your treatment.

7. Repeat steps 3–6 for 10–20 minutes or as prescribed by your healthcare professional. The entire procedure should be performed at least twice a day on a regular basis, and increased to 3–4 times per day if you are producing a lot of mucus.
8. The goal is to keep your lungs clear and ventilatory capacity up. Continue to use your treatments on a regular basis even if you are bringing up just a little mucus.

⚠ CAUTION: If you feel dizzy or lightheaded, or have any other discomfort during treatment, discontinue therapy and contact your physician or healthcare provider.

HOW TO USE YOUR **AEROBIKA*** OSCILLATING PEP WITH YOUR NEBULIZER

The **Aerobika*** Oscillating PEP device may also be used with a small volume nebulizer with a 22 mm adapter. Your healthcare professional will advise which medication to use for combined treatments.

Medications which open your airways (eg. albuterol) or help to thin mucus (eg. hypertonic saline) would be good choices to use with your **Aerobika*** Oscillating PEP because they would help remove or thin the mucus in your lungs. Medications you want to stay in your lungs, like antibiotics, should be taken after you have completed your treatment.

1. Ensure you have read and understood the instructions provided with your nebulizer prior to starting your treatment.
2. Ensure your nebulizer is set-up correctly and medication has been added to the nebulizer cup. Remove the mouthpiece (or mask) from the nebulizer.
3. Attach the nebulizer to the Nebulizer Port of the **Aerobika*** Oscillating PEP, as shown in Figure 3.
4. Switch on the compressed air source, and complete your combined treatment using the breathing technique outlined above.

ⓘ NOTE:

- No adapter is required if used with the **AEROECLIPSE*** brand of Breath Actuated Nebulizer.
- Always ensure the **Aerobika*** Oscillating PEP mouthpiece is used otherwise the device will not work properly. (See Figure 3)
- If used in combination with a nebulizer, the device should be cleaned before next use to remove any residue that may have deposited on exhalation.

FIGURE 3

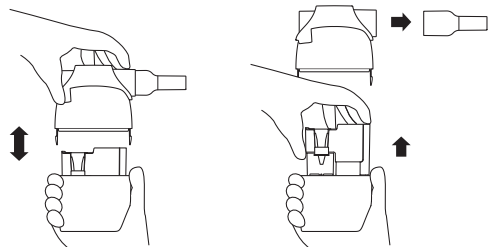


CLEANING AND DISINFECTING YOUR **AEROBIKA*** OSCILLATING PEP DEVICE

1. CLEANING INSTRUCTIONS

The **Aerobika*** Oscillating PEP device will disassemble into four parts for cleaning: the mouthpiece, top case, bottom case and valve cartridge. If necessary, the **Aerobika*** Oscillating PEP may be cleaned after each treatment.

Healthcare providers should always use clinical judgment to select the appropriate Cleaning (1) and Disinfection (2) method and frequency, based on the severity of the patients' disease state.



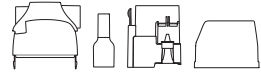
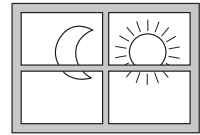
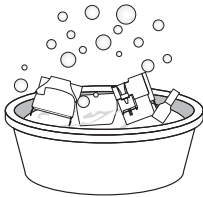
A. TAKING THE DEVICE APART

- Press the Attachment Tabs on either side of the device. Holding the tabs in, gently pull up on the top case until the two parts separate.
- Remove the valve cartridge. **Do not disassemble any part of the cartridge.**
- To remove the mouthpiece, grip firmly and rotate while pulling away from the device.

B. CLEANING THE DEVICE

SOAP AND WATER

- Wash the four parts in a solution of lukewarm clean water and liquid dish detergent, allowing the parts to soak for 15 minutes. Agitate gently.
- Rinse only in warm water.
- To dry, shake the parts to remove any excess water. Allow parts to air dry thoroughly before you put the parts back together.



OR

DISHWASHER

- The four disassembled parts may be washed in a dishwasher by securing parts in a basket on the top rack. Wash in a normal wash cycle with dishwasher detergent **ensuring use of rinse aid. (eg. Jet Dry®).**
- If excess water remains, shake the parts and allow to air dry thoroughly before reassembly.
- Dishwashing with overly dirty dishes is not recommended.



C. REASSEMBLING THE DEVICE

- Insert the valve cartridge into the bottom case. If it does not slip easily into place, rotate 180° and try again.
- Connect the top and bottom cases until you hear both Attachment Tabs “click” (this may occur simultaneously). Ensure the tabs are engaged by firmly pressing the two halves together.
- Reattach the mouthpiece.

MONTHLY CLEANING

Tap water can be high in minerals which may result in scale build-up on the device. We recommend you soak the disassembled device in a solution of 1 cup vinegar and 1 cup water for 1 hour, then wash as normal, every month. If you wash your device daily in tap water, you may need to soak it more often.

2. DISINFECTION INSTRUCTIONS

If necessary, the **Aerobika*** Oscillating PEP device may be disinfected weekly using any of the methods listed below. Prior to disinfection, follow cleaning instructions. Do not dry or reassemble the device.

HIGH LEVEL DISINFECTION

If considered clinically necessary for the patients' disease state, the device may be cleaned **after each use** and disinfected **once each treatment day. STERILE water must be used for rinsing.**

RECOMMENDED METHOD - ELECTRONIC STEAM STERILIZER

The four disassembled parts may be disinfected using an electronic steam sterilizer, following the manufacturer's instructions for use. Allow the parts to cool and air dry thoroughly before reassembly.

ALTERNATIVE METHODS

A. BOILING

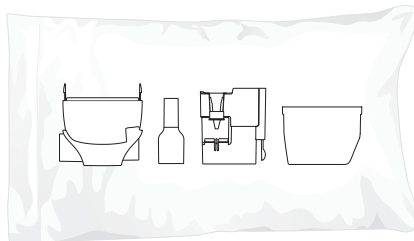
Place the four disassembled parts in a pot when boiling point has been reached and allow to boil for 5 minutes. Remove from water and allow parts to cool and air dry thoroughly before reassembly.

- ① **NOTE:** Place a small rack, on the bottom of the pot to prevent plastic parts from coming in contact with the hot bottom.

B. MICROWAVE STEAM BAG

The four disassembled parts may be disinfected in the microwave in a steam cleaning bag (i.e. Quick-Clean[†] MicroSteam[†] bag) following the manufacturer's instructions. Remove from bag and allow parts to cool and air dry thoroughly before reassembly. Position parts in bag as shown in Figure 4.

FIGURE 4



C. ISOPROPYL ALCOHOL (70%)

The four disassembled parts may be soaked in 70% isopropyl alcohol for 5 minutes. Rinse well and allow to air dry thoroughly before reassembly.

D. HYDROGEN PEROXIDE (3%)

The four disassembled parts may be soaked in 3% hydrogen peroxide for 30 minutes. Rinse well and allow to air dry thoroughly before reassembly.

E. BLEACH (Not recommended for high level disinfection)

The four disassembled parts may be soaked in 1:50 bleach to water solution (approximately 1 tablespoon bleach in 3¼ cups water) for 3 minutes. Rinse well and allow to air dry thoroughly before reassembly. You may substitute a respiratory equipment disinfectant (such as Milton[†], Dodie[†], Control III[†] or Cidex[†]) for the bleach solution by following the manufacturer's instructions for use.

- ⚠ **CAUTION:** Failure to diligently follow the cleaning or disinfection instructions may have an adverse effect on device performance.

DISPOSAL

The **Aerobika**^{*} Oscillating PEP device can be disposed of with domestic waste unless this is prohibited by the disposal regulations prevailing in the respective member countries.

NOTES

- SINGLE PATIENT USE.
- Product should be replaced after 12 months of use or immediately if damaged.
- This product has not been made (or manufactured) with latex.
- Do not share this medical device.
- If you are unable to exhale through the device, check the resistance setting or try cleaning the device thoroughly.
- Store the **Aerobika**^{*} Oscillating PEP device in a dry, dust-free place avoiding continuous exposure to sunlight.