

acapella® choice Vibratory PEP System

Reference Guide

These instructions contain important information for safe use of the product. Read the entire contents of the Instructions for Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions and instructions could

result in death or serious injury to the patient. It is the responsibility of the healthcare practitioner to assure that the instructions for use and maintenance are understood by and provided to the caregiver.

1. DESCRIPTION:

The **acapella®** choice vibratory PEP system is a **single patient** use device that provides Positive Expiratory Pressure (PEP) therapy for patients who have Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis. All patients must be capable of following instructions for PEP therapy. Review the diagram and the product to become familiar with all of the product features.

The **acapella®** choice Vibratory PEP system with one-way inspiratory valve and 22 mm male fittings consists of: (See Figure 1)

- A. Detachable mouthpiece (device end adapts to mask)
- B. Expiratory resistance/frequency adjustment dial
- C. Detachable cover
- D. Detachable rocker assembly – DO NOT disassemble the rocker arm from its platform base

2. INDICATIONS:

The Smiths Medical **acapella®** choice system is intended for use as a PEP device. It may also be used simultaneously with nebulized aerosol drug delivery.

3. CONTRAINDICATIONS:

Although no absolute contraindications to the use of PEP therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Hemodynamic instability
- Intracranial pressure (ICP) > 20 mm Hg
- Acute sinusitis
- Recent facial, oral or skull surgery or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Untreated pneumothorax
- Nausea
- Known or suspected tympanic membrane rupture or other middle ear pathology

4. WARNINGS:

- 4.1 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.
- 4.2 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 +/- dial indicator with the patient's expiratory flow may result in failure to achieve therapeutic objectives of vibratory PEP therapy or one or more adverse side effects 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
 - Skin break down and discomfort from mask
 - Pulmonary barotraumas
- 4.3 The rocker assembly is not designed to be disassembled - do not attempt to separate the rocker arm from its platform base. Separating these components may cause the **acapella®** choice system to function improperly, which may deprive the patient of therapy and cause injury to the patient.

5. PRECAUTIONS:

- 5.1 Bleach is not recommended for use on the **acapella®** choice system. It may deteriorate the nickel plated mechanism located in the interior of the device.
- 5.2 DO NOT MICROWAVE. The metal and magnet might ignite.
- 5.3 It is the responsibility of the user to ensure all sterility verification(s).
- 5.4 Visually inspect the device to ensure that the unit is free of contamination and foreign objects.
- 5.5 Verify all connections are secure.

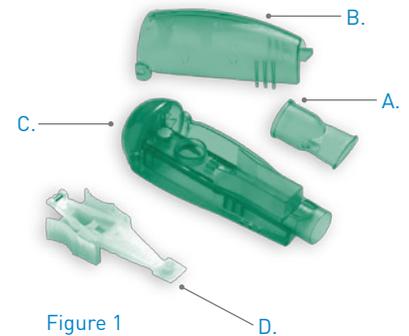


Figure 1



Figure 2



Figure 3



Figure 4

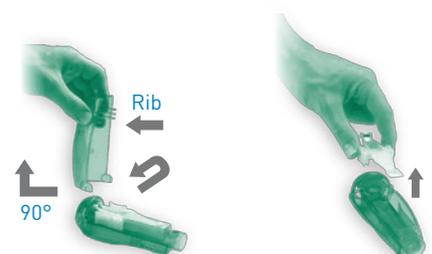


Figure 5

Figure 6

6. SUGGESTED INSTRUCTIONS FOR USE:

6.1 Initial Settings:

6.1.1 If this is the first use of the **acapella**[®] choice system, ensure that the frequency adjustment dial is turned counterclockwise to its lowest frequency-resistance setting, indicated at "1". [See Figure 2]

6.1.2 Instruct the patient to relax while performing diaphragmatic breathing and inspiring a volume of air larger than normal tidal volume (but not to total lung capacity).

6.1.3 Direct the patient to exhale to Functional Residual Capacity (FRC) actively, but not forcefully, through the device.

6.1.4 Adjust the dial to increase the resistance.

6.1.5 The patient should be able to exhale for 3-4 seconds while the device vibrates. Clockwise adjustment increases the resistance of the vibrating orifice; which will allow the patient to exhale at a lower flowrate. Counter-clockwise adjustment decreases the resistance.

6.1.6 Once the proper range has been identified, the patient may be instructed to exhale harder or softer, or dial adjustments may be made to optimize the response the user "feels" from the vibratory pressure.

6.2 Procedure for the User:

6.2.1 Ensure the adjustment dial is set to the correct range as identified by your clinician.

6.2.2 Sit with your elbows resting comfortably on the table.

6.2.3 Place the mouthpiece lightly in your mouth.

- Be sure to maintain a tight seal on the mouthpiece during exhalation.
- Your clinician may recommend the use of a nose clip, if necessary.
- If using a mask, apply the mask tightly but comfortably over your nose and mouth.

6.2.4 Breathe from the diaphragm, as directed by your clinician, taking in a larger than normal breath, but not filling your lungs to capacity.

6.2.5 Hold your breath for 2-3 seconds.

6.2.6 Exhale actively, but not forcefully, through the device. Exhalation should last approximately 3 to 4 times longer than inhalation.

6.2.7 Perform 10-20 PEP breaths as recommended by your clinician.

6.2.8 Remove the mouthpiece (mask) and perform 2-3 "huff" coughs to raise secretions as needed. Your clinician may direct you on proper cough technique.

6.2.9 Repeat steps 6.2.2 to 6.2.7 as prescribed.

Note: See nebulizer set-up section.

6.3 Set-up Nebulizer

6.3.1 Review the diagrams contained with the devices.

6.3.2 A possible nebulizer and **acapella**[®] choice system set up is reflected below. [See Figure 3]

6.3.3 Follow set-up instructions for each device.

6.3.4 Follow cleaning instructions contained with each device.

6.3.5 Inspect device(s) on a routine basis to ensure proper use and function.

6.3.6 If damaged, do not use.

6.3.7 Verify all connections are secure.

7. CLEANING AND DISINFECTING INSTRUCTIONS:

Precaution: Bleach is not recommended for use on the acapella[®] choice system. It may deteriorate the nickel plated mechanism located in the interior of the device.

7.1 There are four parts to clean:

- A. The mouthpiece
- B. The base unit (with frequency adjustment dial)
- C. The cover
- D. The rocker assembly – DO NOT disassemble the rocker arm from its platform base

7.2 Disassembly

7.2.1 Detach the mouthpiece or mask. [See Figure 4]

7.2.2 Detach the cover by placing your forefinger and thumb on the (3) ribs located on the unit toward the mouthpiece.

7.2.3 Gently press on the ribbed surface and lift the cover up.

Note: The cover should only be lifted to a 90° angle. [See Figure 5]

Warning: The rocker assembly is not designed to be disassembled - do not attempt to separate the rocker arm from its platform base. Separating these components may cause the **acapella**[®] choice system to function improperly, which may deprive the patient of therapy and cause injury to the patient.

7.2.4 Detach the rocker assembly by placing your forefinger and thumb.

7.3 Cleaning/Disinfecting Instructions

As per the Cystic Fibrosis Foundation's cleaning and disinfecting guidelines entitled, "Respiratory, Stopping the Spread of Germs" 2003, below are the guidelines for the **acapella**[®] choice system.

Note: The **acapella**[®] choice system is for single patient use

7.3.1 Cleaning: This should be done prior to Disinfecting (7.3.2)

Cleaning with Liquid Dish Detergent:
As needed, detach the mouthpiece (mask) then soak the device and mouthpiece in warm, soapy water as required to remove visible contaminants. Use a liquid dish detergent (Dawn[®] or equivalent), mixing two (2) tablespoons of detergent per one (1) gallon water. Rinse thoroughly with sterile water, and allow parts to air dry.

Drain the device by placing it in a normal resting position. [See Figure 2]

7.3.2 Disinfecting:

- **Boiling** – Boil the device in water (100°C/212°F) up to twice daily for five (5) minutes. In addition, Smiths Medical suggests the use of distilled or sterile water to lessen the potential of local community, mineral-rich tap waters from calcifying the **acapella**[®] choice systems metallic components.
- **Autoclaving** – The **acapella**[®] choice system will functionally withstand autoclaving at temperatures not to exceed 136°C/277°F for a maximum of 30 cycles.
- **Automatic Dishwasher** – The **acapella**[®] choice system is dishwasher safe. It is recommended to place the parts on the top shelf.
- **Alcohol** – Soak five (5) minutes, twice daily. The **acapella**[®] choice system is compatible with 70% isopropyl alcohol. Rinse with sterile water. You can make water sterile by boiling for five (5) minutes.
- **Glutaraldehydes** (Cidex[®] or equivalent) – The **acapella**[®] choice system will maintain its integrity using cold sterilizing solutions such as glutaraldehydes.

8. DISPOSAL:

Dispose of the **acapella**[®] choice system in a safe manner according to Federal/State/Local regulations and guidelines for disposal of contaminated medical waste.

9. ESTIMATED DEVICE LIFETIME:

Assuming the manufacturer recommended cleaning protocol is followed, the **acapella**[®] choice system device should have a useful life of six (6) months under normal and customary usage.

The six (6) month usage duration is measured from the date of initial use.

Ref	acapella [®] choice system Catalog Number	Quantity Per Carton
Mouthpiece	27-7000	10



Caution • Latex Free • Do not use if package is damaged • Non-sterile • Contains or Presence of Phthalate: bis[2-ethylhexyl] phthalate (DEHP) [www.smiths-medical.com/phthalates] • Catalogue Number • Batch Code • Date of Manufacture

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. SINGLE PATIENT USE

For more information visit our website at www.smiths-medical.com

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