CE 0473

PORTEX™

en acapella® Vibratory PEP Therapy System

fr acapella® Système de thérapie par PEP vibratoire

de acapella® PEP-Vibrationstherapiesystem

it Dispositivo PEP a vibrazioni acapella®

es Sistema acapella® de PEP vibratoria

pt Sistema de Terapia de Pressão Expiratória Positiva (PEP) Vibratório acapella®

nl acapella® Vibratie-PEP-therapiesysteem

sv acapella® vibrerande system för PEP-behandling

da acapella® PEP-system med vibration.

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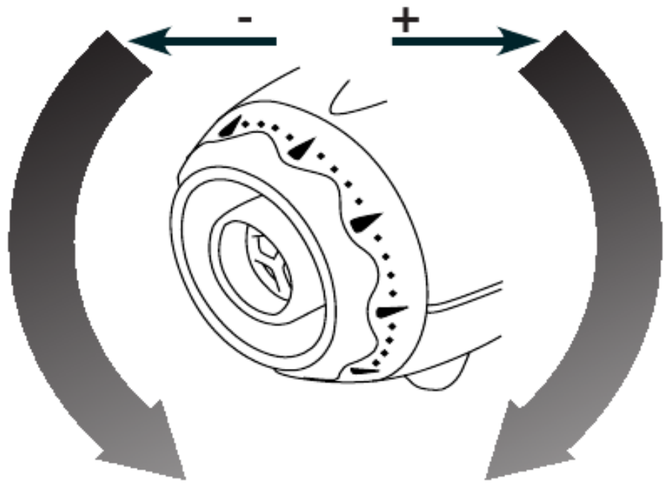
smiths medical

Figure 1.
Figure 1.
Abb. 1.
Figura 1.
Figura 1.

Figura 1.
Figuur 1.
Figur 1.
Figur 1.



Counterclockwise Decreases frequency-resistance.

Dans le sens inverse des aiguilles d'une montre - Diminue la fréquence-résistance.

Drehung entgegen dem Uhrzeigersinn verringert den Frequenzwiderstand.

In senso antiorario per ridurre resistenza-frequenza.

De dcha. a izda. reduce la resistencia-frecuencia.

A rotação no sentido contrário ao dos ponteiros do relógio diminui a frequência-resistência.

Naar links draaien verlaagt de frequentieweerstand.

Moturs minskar frekvensen/motståndet.

Mod uret: mindsker frekvensmodstand.

Clockwise Increases frequency-resistance.

Dans le sens des aiguilles d'une montre - Augmente la fréquence-résistance.

Drehung im Uhrzeigersinn erhöht den Frequenzwiderstand.

In senso orario per aumentare resistenza-frequenza.

De izda. a dcha. aumenta la resistencia-frecuencia.

A rotação no sentido dos ponteiros do relógio aumenta a frequência-resistência.

Naar rechts draaien verhoogt de frequentieweerstand.

Medurs ökar frekvensen/motståndet.

Med uret: øger frekvensmodstand.

Figure 2.
Figure 2.
Abb. 2.
Figura 2.
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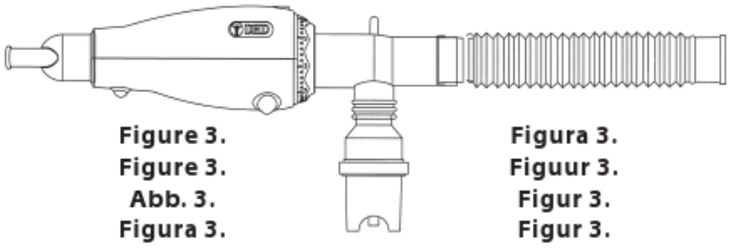

Figure 3.
Figure 3.
Abb. 3.
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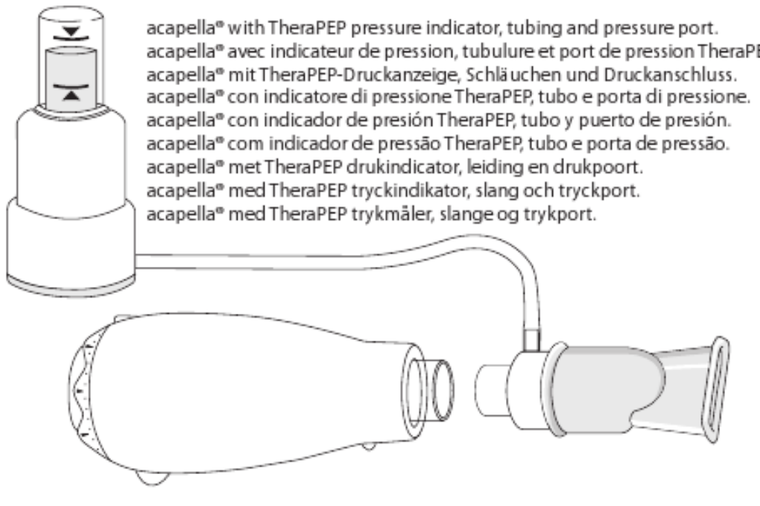

acapella® with TheraPEP pressure indicator, tubing and pressure port.
acapella® avec indicateur de pression, tubulure et port de pression TheraPEP.
acapella® mit TheraPEP-Druckanzeige, Schläuchen und Druckanschluss.
acapella® con indicatore di pressione TheraPEP, tubo e porta di pressione.
acapella® con indicador de presión TheraPEP, tubo y puerto de presión.
acapella® com indicador de pressão TheraPEP, tubo e porta de pressão.
acapella® met TheraPEP drukindicator, leiding en drukpoort.
acapella® med TheraPEP tryckindikator, slang och tryckport.
acapella® med TheraPEP trykmåler, slange og trykport.

Figure 4.
Figure 4.
Abb. 4.
Figura 4.
Figura 4.

Figura 4.
Figuur 4.
Figur 4.
Figur 4.

en English

These Instructions contain important information for safe use of the product. Read the entire contents of these 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 care giver.

1. **DESCRIPTION:**
The **acapella**® 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 a telectasis. All patients must be capable of following instructions for Positive Expiratory Pressure Therapy. Review the diagram and the product to become familiar with all of the product features.

The **acapella**® system consists of:
1. Removable mouthpiece (mask options are also available)
2. **acapella**® vibratory PEP device with 22 mm male fittings (See Figure 1) including:
   A. Expiratory resistance/frequency adjustment dial
   B. One-way inspiratory valve
   C. Patient end which adapts to a mouthpiece, or mask. (If pressure monitoring feedback is desired, the Smiths Medical TheraPEP™ pressure port may be inserted (See Figure 4).
   D. Mouthpiece (detachable)

acapella® is available in:
GREEN: acapella® DH is recommended for patients able to maintain an expiratory flow of 15 liters per minute or greater for 3 seconds.
BLUE: acapella® DM is recommended for patients capable of less than 15 liters per minute for 3 seconds.

2. **INDICATIONS:**
The Smiths Medical **acapella**® is intended for use as a Positive Expiratory Pressure (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
- 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. **WARNINGS:**
4.1 Use of this device at excessive pressures may have adverse effects. Expiratory pressures above 20 cm H_2O 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 patients 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:

5. **PRECAUTIONS:**
5.1 Bleach is not recommended for use on the **acapella**®. 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.

6. **SUGGESTED INSTRUCTIONS FOR USE:**
6.1 **Initial Settings:**
6.1.1 If this is the first use of the **acapella**® device, ensure that the frequency adjustment dial is turned counterclockwise to its lowest frequency-resistance setting. (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 The patient should be able to exhale for 3-4 seconds while the device vibrates. If the patient cannot maintain an exhalation for this length of time, adjust the dial clockwise (See Figure 2). Clockwise adjustment increases the resistance of the vibrating orifice, which will allow the patient to exhale at a lower flow-rate.
6.1.5 Selection of the proper resistance range produces the desired inspiratory to expiratory (I:E) ratio of 1:3 to 1:4.
Note:
If the desired resistance and I:E ratio cannot be achieved, consider using an **acapella**® device designed for alternate flow ranges.
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. Several uses may be needed to ensure that individual patient needs are being met.
6.1.7
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 elbows resting comfortably on table.
6.2.3 Place mouthpiece lightly in 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 mask tightly but comfortably over 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 clinician.
6.2.8 Remove 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**® 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.
6.4 **Set up pressure gauge/indicator: (See Figure 4)**
6.4.1 Place the pressure gauge/indicator (Smiths 20-0010) between the mouthpiece and the device.
6.4.2 Verify all connections are secure.

7. **CLEANING AND DISINFECTING INSTRUCTIONS:**
Precaution: Bleach is not recommended for use on the acapella®. It may deteriorate the nickel plated mechanism located in the interior of the device.
7.1 ***Cleaning: This should be done prior to Disinfecting (7.2)***
As per the Cystic Fibrosis Foundation's cleaning and disinfecting guidelines entitled, *"Respiratory, Stopping the Spread of Germs"* 2008, below are the guidelines for **acapella**®.
Cleaning with Liquid Dish Detergent:
As needed, detach 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 1)
7.2 ***Disinfecting:***
- **Alcohol** – Soak five (5) minutes, twice daily. **acapella**® is compatible with 70% Isopropyl alcohol. Rinse with sterile water. You can make water sterile by boiling for five (5) minutes.
- **Hydrogen Peroxide** – Soak in 3% hydrogen peroxide for 30 minutes. Rinse with sterile water. You can make water sterile by boiling for five (5) minutes.
- **Glutaraldehydes** (Cidex® or equivalent) – **acapella**® will maintain its integrity using cold sterilizing solutions such as glutaraldehydes.

8. **DISPOSAL:**
Dispose of **acapella**® 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**® 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® DM (Blue) Catalog Number	acapella® DH (Green) Catalog Number	Quantity Per Case
Mouthpiece	21-1015	21-1530	10
Pediatric Mask	21-3015	21-3530	1
Medium Mask	21-5015	21-5530	1
Large Mask	21-7015	21-7530	1

Accessory Products	Catalog Number	Catalog Number	Quantity Per Case
Pressure Port	20-0010	20-0010	10
TheraPEP pressure indicator, tubing, and pressure port	20-0022	20-0022	10