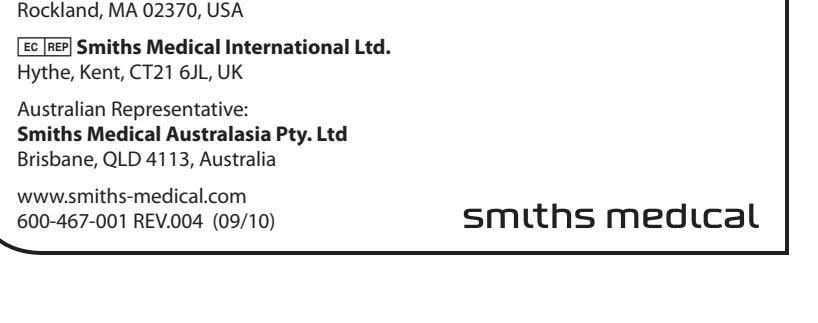


en acapella® choice Vibratory PEP Device.
de acapella® choice PEP Vibrationstherapie-System.
es Equipo vibratorio PEP acapella® choice.
fr Appareil de PEP vibratoire acapella® choice.
el Συσκευή δοντικής θεραπείας PEP acapella® choice.
it Dispositivo PEP a vibrazioni acapella® choice.
nl acapella® choice Vibratie-PEP-apparaat.
pt Dispositivo vibratório de PEP acapella® choice.



smiths medical

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 user to ensure that the instructions for use and handling information are understood by and provided to the care giver.

1. DESCRIPTION:

The Smiths Medical acapella® choice 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 respiratory problems, and patients with asthma and chronic bronchitis. The acapella® choice is designed to provide Positive Expiratory Pressure therapy, review the patient and the product to become familiar with all the product features.

The acapella® choice vibratory PEP device with one-way respiratory valve and 22 mm male fittings consists of: (See Abb. 1)

A: Detachable mouthpiece (device and adaptors)

B: Exhalation valve (frequency adjustment dial)

C: Detachable mouthpiece assembly – DO NOT disassemble the rocker arm from its platform base

2. INDICATIONS:

The Smiths Medical acapella® choice is intended for use as a Positive Expiratory Pressure (PEP) device. It may also be used as a non-invasive ventilator.

3. CONTRAINDICATIONS:

Although no absolute contraindications to the use of PEP therapy have been reported, the following should be carefully evaluated prior to use:

- Inability to tolerate increased work of breathing
- Hemodynamic instability
- Epistaxis
- Recent facial, oral or skull surgery
- Esophageal surgery
- Hypotension
- Known or suspected myocardial membrane rupture or other middle ear pathology

4. WARNINGS:

This device at excessive pressures may have adverse effects. Expiratory pressures above 20 cm H₂O in patients with respiratory diseases can cause adverse effects. Expiratory pressure above 20 cm H₂O in patients with normal lungs can cause adverse effects. Exhalation valve must be set to 20 cm H₂O. If the device is used without the exhalation valve set to 20 cm H₂O, the device will not function correctly. Failure to match the appropriate resistance setting on the +/- dial indicator with the patient's expiratory flow may result in failure to match the appropriate resistance setting on the +/- dial indicator with the patient's expiratory flow.

Adverse reactions may include:

- Increased respiratory rate and/or difficulty breathing
- Increased airway pressure
- Cardiovascular compromise
- Myocardial membrane rupture
- Decreased venous return
- Increased intrathoracic pressure and likelihood of vomiting and aspiration
- Claustrophobia
- Skin rash and discomfort from mask
- Pulmonary barotraumas

The rocker assembly is not designed to be disassembled - do not attempt to separate the rocker arm from its platform base.

5. PRECAUTIONS:

Blows to the device are not recommended for use on the acapella® choice, it may deteriorate the nickel plated mechanism located in the mouthpiece.

DON'T BLOW ON THE DEVICE. The metal and magnet might ignite.

It is the responsibility of the user to ensure sterility verification.

Verify all connections are secure.

6.1 Initial Settings:

If this is the first use of the acapella® choice device, turn the frequency adjustment dial to the lowest setting (0).

1.1 Instruct the patient to perform deep inspiratory and expiratory breathing and inspiring a volume of air larger than normal tidal volume.

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

1.3 The device should take approximately 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 of the vibrating orifice, which will allow the patient to exhale harder or softer, or dial adjustments may be made to optimize the user's feel from the vibratory pressure.

2.2 Frequency of the device is set to the correct range as identified by your clinician.

2.3 Sit with elbows resting comfortably on a table.

2.4 The device is the diagrams contained with the device.

2.5 A possible rebuilder and acapella® choice user is reflected. If you are a rebuilder, please contact your acapella® choice conservator.

2.6 Follow cleaning instructions contained with each device.

2.7 If damaged, do not use.

7. CLEANING AND DISINFECTION INSTRUCTIONS:

Precleaning is not recommended for use on the acapella® choice. It may deteriorate the nickel plated mechanism located in the mouthpiece.

1.1 The mouthpiece and acapella® choice device can be cleaned in a regular basis, or right after each use, especially if used in conjunction with a nebulizer. Medical cleaning recommends cleaning on a regular basis, or right after each use, especially if used in conjunction with a nebulizer. Always clean hands first.

2.1 Cleaning: This covers cleaning of the device and mouthpiece.

2.2 Cleaning: Mouthpiece Damp/Detergent.

2.3 Cleaning: Mouthpiece Damp/Detergent.

2.4 Cleaning: Mouthpiece Damp/Detergent.

2.5 Cleaning: Mouthpiece Damp/Detergent.

2.6 Cleaning: Mouthpiece Damp/Detergent.

2.7 Cleaning: Mouthpiece Damp/Detergent.

2.8 Cleaning: Mouthpiece Damp/Detergent.

2.9 Cleaning: Mouthpiece Damp/Detergent.

2.10 Cleaning: Mouthpiece Damp/Detergent.

2.11 Cleaning: Mouthpiece Damp/Detergent.

2.12 Cleaning: Mouthpiece Damp/Detergent.

2.13 Cleaning: Mouthpiece Damp/Detergent.

2.14 Cleaning: Mouthpiece Damp/Detergent.

2.15 Cleaning: Mouthpiece Damp/Detergent.

2.16 Cleaning: Mouthpiece Damp/Detergent.

2.17 Cleaning: Mouthpiece Damp/Detergent.

2.18 Cleaning: Mouthpiece Damp/Detergent.

2.19 Cleaning: Mouthpiece Damp/Detergent.

2.20 Cleaning: Mouthpiece Damp/Detergent.

2.21 Cleaning: Mouthpiece Damp/Detergent.

2.22 Cleaning: Mouthpiece Damp/Detergent.

2.23 Cleaning: Mouthpiece Damp/Detergent.

2.24 Cleaning: Mouthpiece Damp/Detergent.

2.25 Cleaning: Mouthpiece Damp/Detergent.

2.26 Cleaning: Mouthpiece Damp/Detergent.

2.27 Cleaning: Mouthpiece Damp/Detergent.

2.28 Cleaning: Mouthpiece Damp/Detergent.

2.29 Cleaning: Mouthpiece Damp/Detergent.

2.30 Cleaning: Mouthpiece Damp/Detergent.

2.31 Cleaning: Mouthpiece Damp/Detergent.

2.32 Cleaning: Mouthpiece Damp/Detergent.

2.33 Cleaning: Mouthpiece Damp/Detergent.

2.34 Cleaning: Mouthpiece Damp/Detergent.

2.35 Cleaning: Mouthpiece Damp/Detergent.

2.36 Cleaning: Mouthpiece Damp/Detergent.

2.37 Cleaning: Mouthpiece Damp/Detergent.

2.38 Cleaning: Mouthpiece Damp/Detergent.

2.39 Cleaning: Mouthpiece Damp/Detergent.

2.40 Cleaning: Mouthpiece Damp/Detergent.

2.41 Cleaning: Mouthpiece Damp/Detergent.

2.42 Cleaning: Mouthpiece Damp/Detergent.

2.43 Cleaning: Mouthpiece Damp/Detergent.

2.44 Cleaning: Mouthpiece Damp/Detergent.

2.45 Cleaning: Mouthpiece Damp/Detergent.

2.46 Cleaning: Mouthpiece Damp/Detergent.

2.47 Cleaning: Mouthpiece Damp/Detergent.

2.48 Cleaning: Mouthpiece Damp/Detergent.

2.49 Cleaning: Mouthpiece Damp/Detergent.

2.50 Cleaning: Mouthpiece Damp/Detergent.

2.51 Cleaning: Mouthpiece Damp/Detergent.

2.52 Cleaning: Mouthpiece Damp/Detergent.

2.53 Cleaning: Mouthpiece Damp/Detergent.

2.54 Cleaning: Mouthpiece Damp/Detergent.

2.55 Cleaning: Mouthpiece Damp/Detergent.

2.56 Cleaning: Mouthpiece Damp/Detergent.

2.57 Cleaning: Mouthpiece Damp/Detergent.

2.58 Cleaning: Mouthpiece Damp/Detergent.

2.59 Cleaning: Mouthpiece Damp/Detergent.

2.60 Cleaning: Mouthpiece Damp/Detergent.

2.61 Cleaning: Mouthpiece Damp/Detergent.

2.62 Cleaning: Mouthpiece Damp/Detergent.

2.63 Cleaning: Mouthpiece Damp/Detergent.

2.64 Cleaning: Mouthpiece Damp/Detergent.

2.65 Cleaning: Mouthpiece Damp/Detergent.

2.66 Cleaning: Mouthpiece Damp/Detergent.

2.67 Cleaning: Mouthpiece Damp/Detergent.

2.68 Cleaning: Mouthpiece Damp/Detergent.

2.69 Cleaning: Mouthpiece Damp/Detergent.

2.70 Cleaning: Mouthpiece Damp/Detergent.

2.71 Cleaning: Mouthpiece Damp/Detergent.

2.72 Cleaning: Mouthpiece Damp/Detergent.

2.73 Cleaning: Mouthpiece Damp/Detergent.

2.74 Cleaning: Mouthpiece Damp/Detergent.

2.75 Cleaning: Mouthpiece Damp/Detergent.

2.76 Cleaning: Mouthpiece Damp/Detergent.

2.77 Cleaning: Mouthpiece Damp/Detergent.

2.78 Cleaning: Mouthpiece Damp/Detergent.

2.79 Cleaning: Mouthpiece Damp/Detergent.

2.80 Cleaning: Mouthpiece Damp/Detergent.

2.81 Cleaning: Mouthpiece Damp/Detergent.

2.82 Cleaning: Mouthpiece Damp/Detergent.

2.83 Cleaning: Mouthpiece Damp/Detergent.

2.84 Cleaning: Mouthpiece Damp/Detergent.

2.85 Cleaning: Mouthpiece Damp/Detergent.

2.86 Cleaning: Mouthpiece Damp/Detergent.

2.87 Cleaning: Mouthpiece Damp/Detergent.

2.88 Cleaning: Mouthpiece Damp/Detergent.

2.89 Cleaning: Mouthpiece Damp/Detergent.

2.90 Cleaning: Mouthpiece Damp/Detergent.

2.91 Cleaning: Mouthpiece Damp/Detergent.

2.92 Cleaning: Mouthpiece Damp/Detergent.

2.93 Cleaning: Mouthpiece Damp/Detergent.

2.94 Cleaning: Mouthpiece Damp/Detergent.

2.95 Cleaning: Mouthpiece Damp/Detergent.

2.96 Cleaning: Mouthpiece Damp/Detergent.

2.97 Cleaning: Mouthpiece Damp/Detergent.

2.98 Cleaning: Mouthpiece Damp/Detergent.

2.99 Cleaning: Mouthpiece Damp/Detergent.

2.100 Cleaning: Mouthpiece Damp/Detergent.

2.101 Cleaning: Mouthpiece Damp/Detergent.

2.102 Cleaning: Mouthpiece Damp/Detergent.

2.103 Cleaning: Mouthpiece Damp/Detergent.

2.104 Cleaning: Mouthpiece Damp/Detergent.

2.105 Cleaning: Mouthpiece Damp/Detergent.

2.106 Cleaning: Mouthpiece Damp/Detergent.

2.107 Cleaning: Mouthpiece Damp/Detergent.

2.108 Cleaning: Mouthpiece Damp/Detergent.

2.109 Cleaning: Mouthpiece

sv acapella® choice Vibrerande PEP-enhet.**pl Urządzenie acapella® choice PEP z masażem vibracyjnym.****tr acapella® choice Vibrasyonlu PEP Cihazı.****ru acapella® choice Вибрационное ПВД-устройство.****zh acapella® choice 振动PEP设备。****ar مهارات الاصوات الاصطناعية acapella® choice - مهارات الاصوات الاصطناعية acapella® choice****ko acapella® choice Vibratory PEP 기기.****ja acapella® choice 振動PEP療用器具****Smiths Medical ASD, Inc.****Rockland, MA 02370, USA****IEC Smiths Medical International Ltd.****Huntingdon, UK SG4 9AB****Australian Representative:****Smiths Medical Australia Pty. Ltd.****Brisbane, QLD 4113, Australia****www.smiths-medical.com****600-467-001 REV094 (09/10)****smiths medical****sv Svenska**

Denna handbok innehåller teknisk information angående saker avseende produkten. Läs hela handboken, inklusive alla varningar och försägelseshälsor, innan du använder den. Produkten. Underhållent och rengöringstips för utrustningen är också en del av handboken för utvärdering och underhåll för till och från världen.

BEKRÄFTNING:
Smiths Medical acapella® choice vibrerande PEP-system är ett avsett för **expativen** (Positive Expiratory Pressure) till patienter som har cystisk fibrosis, COPD, astma eller lungsjukdom med sekretionsproblem samt patienter med akut respiratorisk insufficiens. Det är inte avsett för utvärdering och underhåll för utvärdering och underhåll för till och från världen.

INSTRUKTIONER:
Av en annan kontrolleradhet på utvärderingen för PEP-behandling har rapporteras bör följande tillstånd noggrant för att kunna identifiera om det är tillåtet att använda det för utvärdering och underhåll för till och från världen.

CONTRAKTATIONER:
Av en annan kontrolleradhet på utvärderingen för PEP-behandling har rapporteras för följande beteckning:

• Oförmåga att tolka ordet adrenalinresistans
• Hemodynamisk instabilitet
• Bronchial inflammation
• Nyfiken utbrott i armarna eller i skallen, eller motsvarande trauma
• Nistolit
• Asthenoprys
• Bronchial kram
• Kind- och lårskram
• Konstaterat röntgen på thoraxen eller halsen

4.1 VÄRDE:
Användning av denna enhet vid alltför hög tryck kan ha negativ effekt. Utvärdering över 20 cm H₂O hos patienter med akut respiratorisk insufficiens kan leda till hyperventilation och hyperkapni.

2.2 INDIKATIONER:
Smiths Medical acapella® choice vibrerande PEP-system är avsett för användning som en PEP-enhet. Det kan också användas som en vibrerande PEP-enhet för utvärdering och underhåll för till och från världen.

KONTAKTANSTÄLLNING:
Av en annan kontrolleradhet på utvärderingen för PEP-behandling har rapporteras för följande tillstånd noggrant för att kunna identifiera om det är tillåtet att använda det för utvärdering och underhåll för till och från världen.

5. FÖRSIKTIGHETSGÅRDER:
Av en annan kontrolleradhet på utvärderingen för PEP-behandling har rapporteras för följande tillstånd noggrant för att kunna identifiera om det är tillåtet att använda det för utvärdering och underhåll för till och från världen.

5.1 BESVÄR:
Det är rekommenderat att använda en PEP-enhet för utvärdering och underhåll för till och från världen.

5.2 ANVÄND INTE MUNVÄGRAR:
Det är rekommenderat att använda en PEP-enhet för utvärdering och underhåll för till och från världen.

5.3 INSPEKTIONER:
Det är rekommenderat att använda en PEP-enhet för utvärdering och underhåll för till och från världen.

6. REKOMMENDERADE INSTRUKTIONER FOR ANVÄNDNING:
Initiativ i utvärdering:

• Okid andningsrestriktion som kan leda till hyperventilation och hyperkapni

• Kardiovaskular risk

• Kind- och lårskram

• Miniskt ventrat flertid

• Självbeträffande och framtid

• Ventilfysioterapeutiskt tillstånd

<b