RespiPEP Theravance™

Please read these instructions before using this device.

Introduction

RespiPEP Theravance™ is a portable, pocket-size, re-usable, hand-held medical device that improves lung volume, alleviates hyperinflation, and removes secretions (phlegm) from the lungs and upper airways using positive expiratory pressure (PEP) therapy. It is indicated for individuals with acute or chronic lung conditions, pre-operative lung rehabilitation, and post-operative lung complications.

Intended use

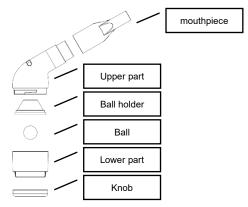
RespiPEP Theravance™ device efficiently creates pressure and oscillation (vibration), causing the mucus and phlegm in the airways to loosen and move progressively up the airways to the throat until it can be coughed out.

The device may also assist in improving lung function and increasing lung capacity and open-blocked and semi-closed airways.

PEP therapy has proven to be an effective means of clearing the airway for individuals with any of the following respiratory conditions:

- Asthma
- Atelectasis
- Bronchiectasis
- Chronic Obstructive Pulmonary Diseases (COPDs), such as Chronic Bronchitis and Emphysema
- Cystic Fibrosis or Bronchiectasis
- Other conditions producing retained secretions
- Pneumonia

Structure and Device Description



The Device Consists of:

- A mouthpiece
- An upper part
- A ball holder
- A steel ball
- A lower part
- A knob or resistance dial
- A securing rope

Technical specifications

Pressure Applied for Bubbles to Appear- Valve A as Restrictor

Volume	Applied Air Flow	Lower Limit	Applied Pressure	Upper Limit
(ml ³)	(lpm)	(cmH ² O)	(cmH ² O)	(cmH ² O)
0	0.0	4	0.0	4
200	0.10	4	3.5	4
400	0.10	4	6.5	4
600	0.10	4	9.7	4
800	0.10	4	12.8	4
1000	0.10	4	16.4	4

How to Use the RespiPEP Theravance™ device

1. Preparation

- Check the integrity of all components to ensure there is no damage or signs of wear.
- Do not use any of the components if damaged or worn.
- Properly connect the mouthpiece to the device.
- Turn the knob (resistance dial) clockwise or anti-clockwise to increase or decrease resistance.



2. How to Use RespiPEP Theravance™

You can use the device when lying down, sitting, or standing in an upright position.

- Take a deep breath through your nose and fill your lungs.
- Hold your breath for 2 to 3 seconds.
- Place the RespiPEP Theravance™ device in your mouth and hold the device upright. Exhale at a consistent pace for 3-5 seconds through your mouth into the mouthpiece until you empty your lungs. During exhalation, you should hear the ball fluttering in the ball holder. If the device is not in the upright position, you won't hear any fluttering of the ball during exhalation. Change the position of the device to the upright position until you hear the ball fluttering in the ball holder.
- Repeat approximately two times per minute for up to five minutes. To reduce the chance of feeling lightheaded, rest between each session.
- Frequent, ongoing, and regular use of the RespiPEP Theravance™ device will enhance the benefits of its therapeutic effects. Use as often as instructed by your healthcare professional.
- Always use this device under the guidance of a qualified healthcare professional.

Note

- The aim is to make the steel ball oscillate (vibrate or flutter) so it lifts off the ball holder. These flutters /vibrations /oscillations get transferred to the airways and assist in mobilising phlegm.
- Adjust the device pressure until you achieve maximum vibrations in your chest.
- After exhaling through the device, you may feel mucus gathering at the back of your throat or near the top of your lungs. If so, cough to expel the mucus.
- If you have asthma, make sure to use your inhaler before attempting to use this respiratory device.

Tip:

You can use your RespiPEP Theravance™ device with your nebuliser (adding an in-line T-piece) to enhance your respiratory rehabilitation during both the inspiration and expiration phases.

Warning:

As this device will be in contact with saliva and other body fluids during use, please **do not** share it to prevent potential transmission of infections.

Precautions

- Do not make changes to any prescribed medication or prescribed treatment program without consulting your healthcare professional.
- Do not use if any of the components are damaged or worn.

- This device contains small parts and should never be given to a child unattended.
- Suitable only for the ages of 12 years and above.
- While training with this device, you should feel resistance when inhaling, but it should not be painful. If you feel pain whilst using the RespiPEP Theravance™ device, stop immediately and consult your doctor.

Contraindications

Consult your healthcare provider before using this device if you suffer from any of the following conditions:

- A history of spontaneous pneumothorax
- Undrained pneumothorax
- Pulmonary hypertension or large bullae on chest X-ray
- If you suffer from a ruptured eardrum or any other ear condition.
- Increased intracranial pressure
- After eye surgery
- Severe cardiovascular conditions
- If you suffer from a ruptured eardrum or any condition of the ear
- Patients with marked elevated left ventricular end-diastolic volume and pressure
- Patients with worsening heart failure signs and symptoms after RMT/IMT
- If in doubt, always consult your medical advisor.

Side Effects

- Coughing or throat irritation: Some people may experience a cough or throat irritation when using RespiPEP Theravance™. This may be due to the vibrations caused by the device, which should improve over time.
- Haemoptysis: If you cough up blood in your sputum, stop using the device and contact your doctor immediately.
- Shortness of breath and increased heart rate: RespiPEP Theravance™ may cause shortness of breath in rare cases, mainly if the device is used too aggressively or without rest or when the pressure setting is too high. If this occurs, stop using the device and consult your healthcare professional.
- Dizziness, light-headedness or fainting: Some people may experience dizziness or light-headedness when using RespiPEP Thervance™, particularly if they have low blood pressure or when used consecutively without rest. When this occurs, stop using the device and rest until symptoms
- Ear discomfort: Ear discomfort, especially after a cold, is caused by inadequate equalisation of pressure between the mouth and ears. If symptoms persist, please consult your

Note: If you feel faint, fatigued or tired during exercise, please take a rest.

RespiPEP Theravance™ Features

- Compact design
- Easy to clean
- Suitable for ages 12 and above
- Portable and easy to use
- Small and lightweight
- The rope can be positioned around your neck to minimise the risk of dropping the device.

Please Note:

This RespiPEP™ PEP therapy device complements physiotherapy, enhancing its effectiveness when combined.

Cleaning and Maintenance

Carefully follow the cleaning procedure to maintain the device's performance and maximise your therapy benefits.

- After Use, disconnect the mouthpiece, steel ball, upper and lower parts and the ball holder of the device.
- Wash the parts with a mild soap solution, rinse with clean and clear water, and allow them to air dry. Re-assemble.



- The **RespiPEP Theravance**™ is made of robust, high-quality material but should not be bleached or washed in other chlorine compounds as these may have a corrosive effect on the materials.
- RespiPEP Theravance™ can be cleaned with a soft, dustfree cloth.
- This cleaning procedure should be followed before initial use and thereafter as required.

Storage And Device Lifespan

- The device should be stored in a clean, well-ventilated room at room temperature or in its original packaging.
- The lifespan of this device is 3 years, assuming normal usage and correct storage conditions.

Warranty

The **RespiPEP Theravance**™ device is warranted against manufacturing defects for 12 months from the date of purchase. A receipt showing the date of purchase will be required to claim warranty replacements. The warranty excludes device replacements due to accidental user damage. All freight costs associated with the warranty claims will be borne by the user/consumer.

Disclaimer Please Note:

This product is not intended to compensate for diagnosis, treatment, cure, or mitigation of medical conditions. If you or a family member are experiencing any health-related problems, you should obtain medical advice from a certified health professional, as this device may be harmful to your health. You are, therefore, advised to use this product with caution and under the supervision of a health professional.

This RespiPEP Theravance™ device is not intended to diagnose, treat, cure, or prevent any disease.

Caution: Choking Hazard

Keep the RespiPEP Theravance™ device out of the reach of children and ensure it is not used by unsupervised children. The device is designed to be disassembled for cleaning for multiple uses. Because of this, some of the small parts, like the stainlesssteel ball and circular cone (ball holder), may pose a choking hazard to children.

What's in the box

1 x RespiPEP Theravance™ device

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