

RespiPEP Therafizz™

Please read these instructions before using this device.

Introduction

RespiPEP Therafizz™ is a portable, 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

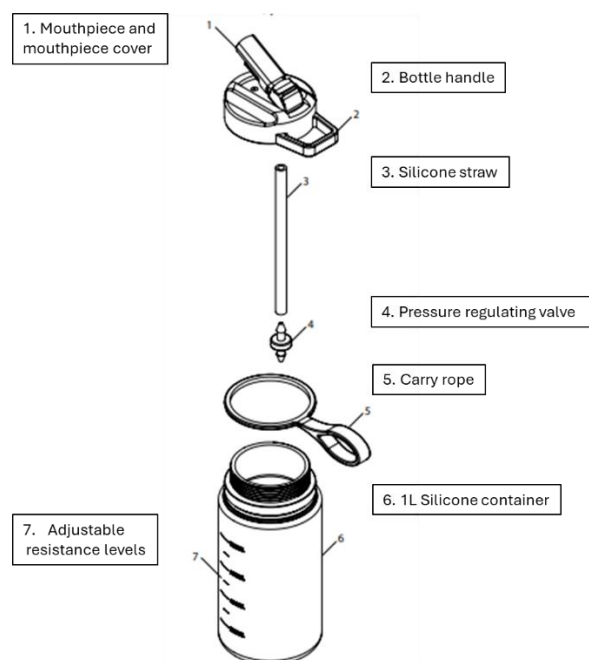
RespiPEP Therafizz™ device efficiently creates pressure and oscillation (vibration), causing the mucus and phlegm in the airways to loosen and move progressively up the airways to the throat until it can be coughed out.

The device may also assist in improving lung function and lung capacity and opening 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)
- Cystic Fibrosis or Bronchiectasis
- Other conditions producing retained secretions
- Pneumonia

Structure and Device Description



The Device Consists of:

- A mouthpiece cover
- A mouthpiece
- A detachable lid
- A handle
- An air vent
- A silicone straw
- A securing rope
- A pressure-regulating valve
- A 1L silicone container

Technical specifications

Pressure Applied for Bubbles to Appear– No Valve as Restrictor ($\pm 2\text{cm H}_2\text{O}$)

Volume (ml^3)	Applied Air Flow (lpm)	Applied Pressure (cmH_2O)
0	0.0	0.0
200	0.06	3
400	0.10	6
600	0.10	9
800	0.10	12

Pressure Applied for Bubbles to Appear– Valve as Restrictor ($\pm 2\text{cm H}_2\text{O}$)

Volume (ml^3)	Applied Air Flow (lpm)	Applied Pressure (cmH_2O)
0	0.0	0.0
200	0.10	4
400	0.10	7
600	0.10	10
800	0.10	13

How to Use the RespiPEP Therafizz™ Device

1. Preparation

- Check the integrity of all components to ensure no damage or signs of wear.
- Do not use if any of the components are damaged or worn.
- Ensure the pressure regulating valve is properly connected to the silicone straw (if the valve restrictor is used).
- Fill the container with water to the prescribed resistance level.

2. How to Use RespiPEP Therafizz™

You can use the device only in the upright position.



- Take a deep breath through your nose and fill your lungs.
- Hold your breath for 2 to 3 seconds.
- Place the RespiPEP Therafizz™ device mouthpiece in your mouth and **hold the device upright**. Exhale consistently for 3-5 seconds through your mouth into the mouthpiece until your lungs are emptied. During exhalation, you should hear the bubbles in the water. If the device is not positioned correctly, you might not hear any bubbles during exhalation. Adjust the device to the upright position until you hear the bubbles.
- To reduce the chance of feeling lightheaded, rest between each session.
- Frequent, ongoing, and regular use of the RespiPEP Therafizz™ 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

- To keep the mouthpiece clean and hygienic, avoid touching it with your hands. Instead, lift and pull back the mouthpiece cover slowly and gently; the mouthpiece will lift automatically.
- The aim is to ensure there are plenty of bubbles forming in the water. These bubbles create flutters, vibrations, or oscillations that are transferred to the airways, assisting in mobilising phlegm.
- Adjust the device pressure by increasing or decreasing the water level 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.

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.
- If you feel pain whilst using the RespiPEP Therafizz™ 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
- Patients with marked elevated left ventricular end-diastolic volume and pressure
- Patients with worsening heart failure signs and symptoms
- **If in doubt, always consult your healthcare professional.**

Side Effects

- **Coughing or throat irritation:** Some people may experience a cough or throat irritation when using RespiPEP Therafizz™. 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 Therafizz™ 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 Therafizz™, particularly if they have low blood pressure or when used consecutively without rest. When this occurs, stop using the device and rest until symptoms resolve.
- **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 doctor.

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

RespiPEP Therafizz™ Features

- Made from durable and flexible silicone, 100% BPA-free.
- A mouthpiece cover protects against external contaminants, such as airborne particles, and is an effective measure for infection control.
- An ergonomic mouthpiece design directs airflow for effective therapy.
- Handle with a secure grip, enhancing stability and control.
- A portable rope to enhance mobility and independence.
- Its foldable design makes it an ideal travel companion.
- Easy to clean due to smooth silicone surface and wide opening
- Lightweight and portable.
- Environmentally friendly, reusable, eco and ocean-friendly as it will not break down into harmful micro-particles.

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 straw from the detachable lid.
- Wash the parts with a mild soap solution, rinse with clean and clear water, and allow them to air dry. Re-assemble.
- The RespiPEP Therafizz™ 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 Therafizz™ can be cleaned with a soft, dust-free cloth.
- This cleaning procedure should be followed before initial use and thereafter as required.
- The product is not dishwasher safe.

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 three years, assuming normal usage and correct storage conditions.

Warranty

The RespiPEP Therafizz™ 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 or courier 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 healthcare professional.

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

Caution: Choking Hazard

Keep the RespiPEP Therafizz™ device out of the reach of children and ensure it is not used by unsupervised children.

Content

1 x RespiPEP Therafizz™ device containing:

- 1 x 1L silicone container
- 2 x pressure-regulating valves
- 3 x silicone straws

Applicant

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