Secretion Mobilization and Induction Device Dual-Indication for Diagnostic & Therapeutic Use

U.S. Patent Numbers: 6,702,769 & 6,984,214

©2010 Medical Acoustics, LLC

INDICATIONS FOR USE

- The LUNG FLUÒTE® (Therapeutic) is indicated for Positive Expiratory Pressure (PEP) therapy.
- The LUNG FLUÒTE® is indicated for the collection of sputum samples for laboratory analysis and pathologic examination.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

The LUNG FLUÒTE® is a disposable device.

Single patient use device
NON-Sterile

U.S. Pat. No. 6,702,769 & 6,984,214

Quantity: 1

What is the LUNG FLUÒTE®?
The LUNG FLUÒTE® is a disposable device used to help loosen, mobilize, and obtain a sputum sample from the airways.

The LUNG FLUÒTE® consists of the following components: a mouthpiece and a reed inside a horn (see Figure 1 below).

INSTRUCTION FOR USE

The LUNG FLUÒTE® is intended for the collection of sputum samples for laboratory analysis and pathologic examination.

The LUNG FLUÒTE® has been designed to induce sputum for diagnostic purposes. Over the past 45 years, sputum induction has been used for multiple diagnostic applications. In 1997, the Canadian Thoracic Society published a training manual entitled "Sputum Examination for Indices of Airway Inflammation: Laboratory Procedures". A significant portion of the manual focused on sputum induction and asthma. The following conditions have been diagnosed with the assistance of induced sputum:

- Pneumonia
- Tuberculosis
- Chronic bronchitis
- Cystic fibrosis
- Emphysema
- Asthma
- Childhood asthma
- Occupational asthma
- Lung cancer
- Bronchiectasis
- Pulmonary sarcoidosis
- Pneumonococcosis
- Noninflammatoty ILD

To Healthcare Professionals:
If there are any questions about the LUNG FLUÒTE® or these instructions, contact Medical Acoustics at the address on the cover panel of these Instructions for Use.

WARNINGS

- The patient should not attempt to inhale through the LUNG FLUÒTE®.
- For single patient use only – do not sterilize.
- If the patient experiences shortness of breath and/or dizziness, discontinue use of the LUNG FLUÒTE®.
- A transient throat irritation, lasting less than 24 hours, was noted in some participants in clinical trials.
- Bronchodilation may occur (approx. 5% frequency based on clinical trials).
- Individuals who cannot follow a healthcare professional’s verbal instructions should not use the LUNG FLUÒTE®.

Specifically, young individuals who cannot follow verbal instructions and adults who, due to physical or mental challenges, cannot follow verbal instructions from a healthcare professional.

1. What is the LUNG FLUÒTE®?
The LUNG FLUÒTE® is a disposable device used to help loosen, mobilize, and obtain a sputum sample from the airways. The LUNG FLUÒTE® consists of the following components: a mouthpiece and a reed inside a horn (see Figure 1 below).

2. How does the LUNG FLUÒTE® work?
When the patient blows out through the LUNG FLUÒTE®, as if blowing out a candle, his/her breath moves the reed inside. This causes acoustic vibrations that thin and loosen secretions deep in the lungs and results in the secretions moving progressively up the patient’s airway until they collect at the back of the throat (see Figure 2 below).

3. Preparing to use the LUNG FLUÒTE®
1. The patient may want to have a glass of water available to drink after use of the device.
2. The patient should get into a relaxed position. He/she should sit up straight so his/her breath is not touching the back of the chair, and should lift the head slightly downward so the throat and windpipe are wide open (See Figure 2, left). This allows acoustic waves to flow into the lungs from the LUNG FLUÒTE®.
3. If the patient is bedridden, have him/her sit as upright as possible in a position that will not restrict the smooth breathing effort.

4. Stage One: Secretion Loosening and Mobilization
The patient should hold the LUNG FLUÒTE® pointing down, as shown in Figure 2, in a little deeper than normal, place his/her lips completely around the mouthpiece, and gently blow out through the LUNG FLUÒTE®, as if trying to blow out a candle. As the breath blows out, he/she will hear the reed inside the LUNG FLUÒTE® make a fluttying noise as it moves. The patient should concentrate on making this sound.

Next, the patient should remove the mouthpiece from his/hers mouth, quickly inhale again, put the mouthpiece back in his/hers mouth, and blow gently through the LUNG FLUÒTE®.

The patient should then remove the mouthpiece again and wait five seconds, taking several normal breaths. To achieve adequate results, it is suggested that the patient complete 20 sets of 2 blows each. Individual results may vary (see Section 3).

Reminder: The patient only needs to blow through the mouthpiece with as much force as they would to blow out a candle. They should not force a cough or use their diaphragm or stomach muscles to try to force out more air.

5. Stage Two: Secretion Elimination
The patient should let the LUNG FLUÒTE® do the work. The LUNG FLUÒTE® will then and loosen secretions.

The patient should wait five minutes after the session for secretions to collect at the back of the throat and then start to cough vigorously. The patient should then spit sputum produced by coughing into a sample collection cup.

The patient may notice thinned secretions collecting at the back of his/her throat for several hours after the session. This is normal. A drink of water can prevent minor throat irritation.

7. Recommended length of a session
A session should range between 5 to 10 minutes, depending on the patient’s pulmonary condition.

8. Important Tips
- When inhaling, the patient should remove the LUNG FLUÒTE® from his/her mouth.
- Pointing the LUNG FLUÒTE® slightly toward the floor may make it work more efficiently.
- To avoid dizziness or shortness of breath while using the LUNG FLUÒTE®, he/she should take more time between each set of two blows.

9. Product Performance Data

Frequency 16-25Hz

Minimal flow rate 128.4 L/min

Minimal pressure 1.0 cm H2O

Sound output 68 dBA

Pressure resistance 1.0 cm H2O

- Measured with a standard General Radio 1933 Precision Sound Level Meter. OSCIA limit over a 15 min. interval is 1165BA CTR 25.10.153 (7dB).

Bibliography


When inhaling, remove the Lung FLUTe® from your mouth and blow gently through the Lung FLUTe® as if you were trying to blow out a candle. As you blow, you will hear the reed inside the Lung FLUTe® make a fluttering noise as it moves. Concentrate on making this sound, if the reed does not move right away, practice with the Lung FLUTe® for several sessions. If you are still unable to move the reed, consult your healthcare professional. Remove the mouthpiece from your mouth and quickly inhale again. Put the mouthpiece back in your mouth and blow gently through the Lung FLUTe®. Remove the mouthpiece and wait five seconds. You may notice thinned secretions collecting at the back of your throat. Several minutes of coughing should bring up most of the secretions. You may notice thinned secretions collecting at the back of your throat for several hours after your therapy session. Before you begin, drink after your therapy session. Before you begin, please read these Instructions for use. Using the Lung FLUTe® will assist you in using this device. Using the Lung FLUTe® on a regular basis in a manner that is comfortable for you will provide benefits that will help you breathe easier. If you have any questions about the LUNG FLUTe® or these instructions, contact your healthcare professional for assistance.

1 Getting the most benefit from the LUNG FLUTe®

Although your healthcare professional may have trained you in the use of the LUNG FLUTe®, these instructions for use will assist you in using this device. Using the LUNG FLUTe® on a regular basis in a manner that is comfortable for you will provide benefits that will help you breathe easier. If you have any questions about the LUNG FLUTe® or these instructions, contact your healthcare professional for assistance.

2 The LUNG FLUTe® clears secretions build up

In many chronic cardiopulmonary conditions there is a build up of secretions in the airways. Bronchial hygiene therapy with the LUNG FLUTe® can help clear these secretions so they can be swallowed or coughed up.

3 What is the LUNG FLUTe®?

The LUNG FLUTe® is a device used to help loosen, mobilize, and eliminate secretions from your airways. It consists of a mouthpiece and a reed inside a horn (see Figure 1 above).

4 How the LUNG FLUTe® works

When you blow gently into the LUNG FLUTe® in a series of repetitions, your breath moves the reed inside (see Figure 2 below). This causes acoustic vibrations, which thin and loosen secretions deep in your lungs and results in the secretions moving progressively up your airways until they collect at the back of your throat.

5 Proper use of the LUNG FLUTe®

Proper use of the LUNG FLUTe® is important for successful therapy. Although the technique presented here works well for most users, “individualizing” the technique for your specific condition may be necessary in order to obtain the best results. Please meet with your healthcare professional for complete personal training before beginning your LUNG FLUTe® therapy. Continue to review your technique on a regular basis, especially if you are not getting the expected results or if you notice a change in how your therapy is progressing.

Preparing for your LUNG FLUTe® therapy

1. You may want to have a glass of water available to drink after your therapy session. Before you begin, think about what you will be doing, how you are going to breathe, and the goals of the therapy. Visualize your airways being vibrated by acoustic waves, and secretions being loosened and mobilized along with your exhaled air to progressively larger airways, where they can be coughed up.

2. Get into a relaxed position. Sit up straight so that your back is not touching the back of the chair. Tilt your head slightly downward so your throat and windpipe are wide open (see Figure 2, left). This allows the acoustic waves produced by your breath to flow from the LUNG FLUTe® into your lungs.

3. If you must perform therapy in bed, sit as upright as possible, in a position that will not restrict your smooth breathing effort.

6 A NOTE ABOUT ACOUSTIC WAVE TECHNOLOGY

The acoustic waves produced by the LUNG FLUTe® cannot be heard by human ears. The only sound you will hear is the fluttering of the reed when you exhale through the LUNG FLUTe® mouthpiece. You will not feel any vibration of the LUNG FLUTe® during operation.

7 Stage One: Secretion Loosening and Mobilization

Hold the LUNG FLUTe® pointing down, as shown in Figure 2. Inhale a little deeper than normal, place your lips completely around the mouthpiece, and gently blow out through the LUNG FLUTe® as if you were trying to blow out a candle. As you blow, you will hear the reed inside the LUNG FLUTe® make a fluttering noise as it moves. Concentrate on making this sound, if the reed does not move right away, practice with the LUNG FLUTe® for several sessions. If you are still unable to move the reed, consult your healthcare professional. Remove the mouthpiece from your mouth and quickly inhale again. Put the mouthpiece back in your mouth and blow gently through the LUNG FLUTe®. Remove the mouthpiece and wait five seconds, taking several normal breaths. As you adapt to using the device, your goal should be to complete up to 20 sets of 2 blows each. Depending on your condition, you may wish to perform only a few repetitions of 2 blows, one or two times a day, until you are able to do more. After several sessions, you should be able to determine for yourself the appropriate number of 2-breath repetitions needed to adequately clear secretions.

Remember, you only need to blow through the mouthpiece with as much force as you would to blow out a candle. Do not force a cough or use your diaphragm or stomach muscles to try to force out more air.

8 Stage Two: Secretion Elimination

Once you have worked up to the required number of 2-blow repetitions, the LUNG FLUTe® has thinned and loosened your secretions. Wait five minutes after your session for secretions to collect at the back of your throat. Several minutes of coughing should bring up most of the secretions. You may notice thinned secretions collecting at the back of your throat for several hours after your session. This is normal. A drink of water can prevent minor throat irritation.

9 Recommended length and frequency of sessions

Your healthcare professional will advise you on how often you should use the LUNG FLUTe® and how long each session should last. Generally, morning and late afternoon/evening sessions are recommended. The average session lasts 5 to 10 minutes, depending on the severity of the pulmonary condition. To avoid becoming overly tired from therapy, it is better to add a session rather than extending a session to the point of discomfort.

10 Important Tips

• When inhaling, remove the LUNG FLUTe® from your mouth.

• Pointing the LUNG FLUTe® slightly toward the floor may make it work more efficiently.

• To avoid dizziness or shortness of breath while using the LUNG FLUTe®, take more time between each set of two blows.

• Beginning LUNG FLUTe® users or those with thick mucus may experience throat irritation caused by large quantities of secretions collecting at the back of the throat. Drinking water after a session can help reduce this irritation.

• Performing 3 “huff” coughs after each 5 sets of 2 blows may further assist you in clearing your secretions.

11 Condensation build up inside the LUNG FLUTe®

If condensation builds up inside the horn place it in a warm spot, such as a sunny window. The condensation should be gone before you start your next session.

12 Product Performance

<table>
<thead>
<tr>
<th>Frequency</th>
<th>16-25Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal flow rate</td>
<td>128.4 L/min</td>
</tr>
<tr>
<td>Minimal pressure</td>
<td>1.0 cm H2O</td>
</tr>
<tr>
<td>Sound output</td>
<td>68 dB(A)</td>
</tr>
<tr>
<td>Pressure resistance</td>
<td>1.0 cm H2O</td>
</tr>
</tbody>
</table>

1 Measured with a standard General Radio 1033 Precision Sound Level Meter. OSHA limit over a 15 min. interval is 115dB(A) CBR 291910.95(93)