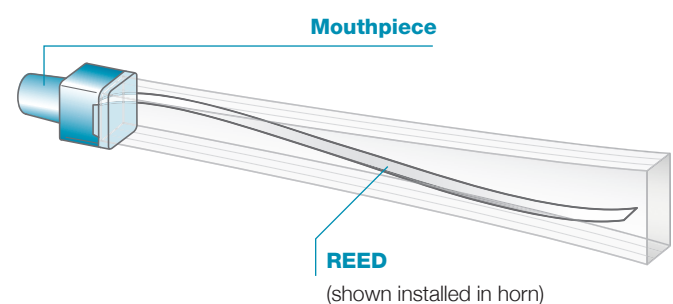




## Secretion Mobilization and Induction Device Dual-Indication for Diagnostic & Therapeutic Use



### INDICATIONS FOR USE

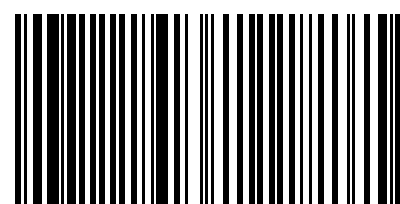
- The LUNG FLUTE® (Therapeutic) is indicated for Positive Expiratory Pressure (PEP) therapy.
- The LUNG FLUTE® is indicated for the collection of sputum samples for laboratory analysis and pathologic examination.

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

The LUNG FLUTE® is a disposable device.  
Single patient use device  
NON-STERILE

REF 1004-01 Quantity: 1

EC REP Horizon Phoenix Europe Limited  
Walderstown, Athlone,  
Westmeath, Ireland  
Tel: +353 9064 85966



(01) 00816133010003

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

Manufactured in the USA for:  
Medical Acoustics, LLC  
640 Ellicott St., Buffalo, NY 14203 USA  
(716) 759-6339 (888) 820-0970  
www.lungflute.com



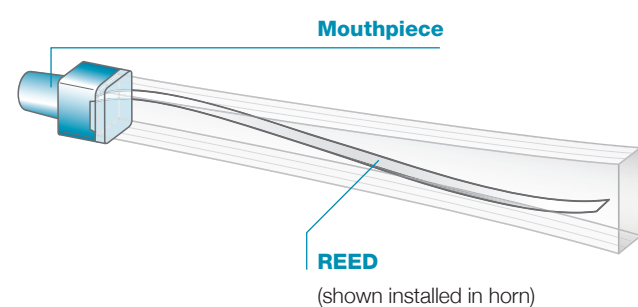
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U806 Rev. A (06/2011)



## Secretion Induction Device for Diagnostic Use



### INSTRUCTION FOR USE

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

The LUNG FLUTE® 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".<sup>1</sup> 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<sup>2</sup>
- Tuberculosis<sup>3</sup>
- Chronic bronchitis<sup>4, 5, 12</sup>
- Eosinophilic bronchitis<sup>5, 6</sup>
- Emphysema<sup>5</sup>
- Asthma<sup>1, 4, 7, 8</sup>
- Childhood asthma<sup>9</sup>
- Occupational asthma<sup>10</sup>
- Lung cancer<sup>11</sup>
- Cystic fibrosis<sup>12, 13</sup>
- Bronchiectasis<sup>12</sup>
- Pulmonary sarcoidosis<sup>14, 15</sup>
- Pneumoconiosis<sup>15</sup>
- Nongranulomatous ILD<sup>15</sup>

### To Healthcare Professionals:

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

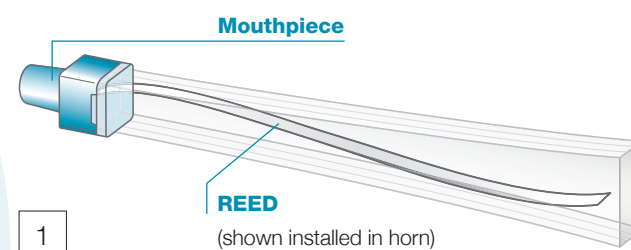
### WARNINGS

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

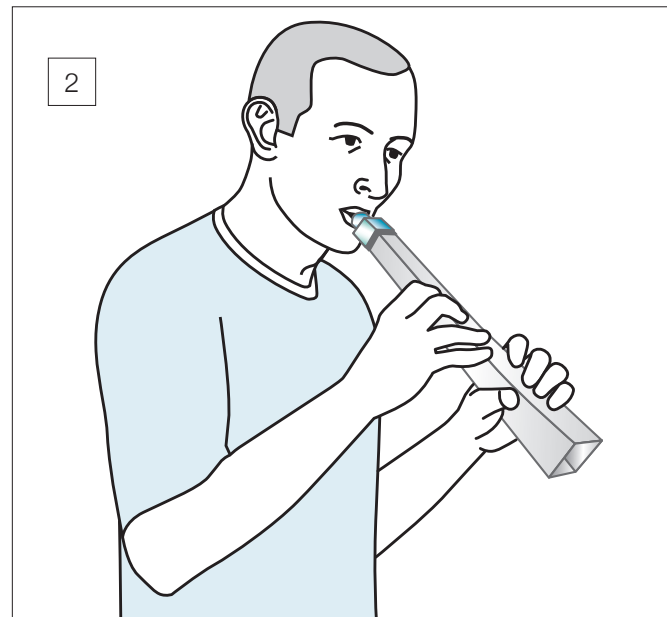
The LUNG FLUTE® is a disposable device used to help loosen, mobilize, and obtain a sputum sample from the airways. The LUNG FLUTE® consists of the following components: a mouthpiece and a reed inside a horn (see Figure 1 below).



### 2

#### How the LUNG FLUTE® works

When the patient blows out through the LUNG FLUTE®, 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

#### Proper use of the LUNG FLUTE®

Proper use of the LUNG FLUTE® is important to successfully obtain a sputum sample. Although the method presented here works well for most users, "individualizing" the technique for the patient's specific condition may be necessary in order to obtain the best results.

### 4

#### Preparing to use the LUNG FLUTE®

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 back is not touching the back of the chair, and should tilt 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 FLUTE®.
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.

### 5

#### Stage One: Secretion Loosening and Mobilization

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

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

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.

### 6

#### Stage Two: Secretion Elimination

The patient should let the LUNG FLUTE® do the work. The LUNG FLUTE® will thin 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 FLUTE® from his/her 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®, 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 H <sub>2</sub> O
Sound output	68 dBA*
Pressure resistance	1.0 cm H <sub>2</sub> O

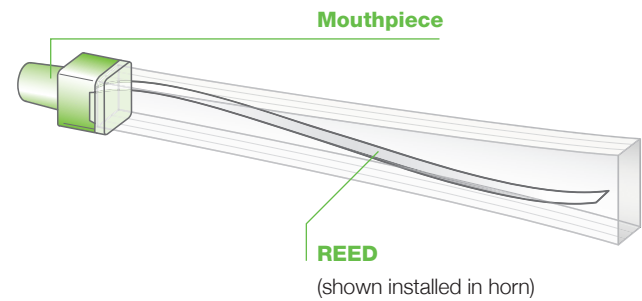
\* Measured with a standard General Radio 1933 Precision Sound Level Meter. OSHA limit over a 15 min. interval is 115dBA CFR 29.1910.95 (b)(2)

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## Secretion Mobilization Device for PEP/Bronchial Hygiene Therapy



**NOTE: We encourage you to tell us about your experience with the LUNG FLUTE®. Please contact us at the address or phone number on the cover panel of these Instructions for Use.**

### INSTRUCTIONS FOR USE

The LUNG FLUTE® (Therapeutic) is indicated for Positive Expiratory Pressure (PEP) therapy.

PEP therapy, when combined with “huff” coughing, will help remove secretions from airways, reduce the amount of air that may be trapped in airways, keep airways open and clear secretions, and improve delivery of bronchodilator medication. As with all therapies, you will need to begin slowly and build up the length and repetitions of your therapy sessions. Please read these Instructions for Use carefully before starting your new therapy. Consult with your healthcare professional to develop a personalized therapy regimen that best fits your needs.

### WARNINGS

- Do not attempt to inhale through the LUNG FLUTE®.
- If you experience shortness of breath and/or dizziness, discontinue use of the LUNG FLUTE® and consult your healthcare professional.
- A transient throat irritation, lasting less than 24 hours, was noted in some participants in clinical trials.
- Individuals who cannot follow a healthcare professional's verbal instructions should not use the LUNG FLUTE®. 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

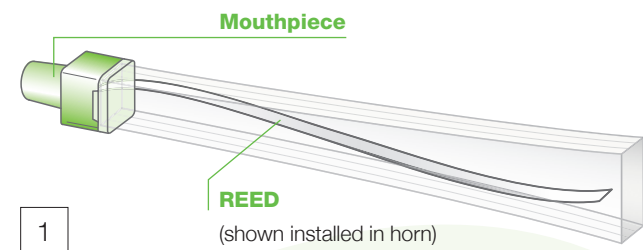
### Getting the most benefit from the LUNG FLUTE®

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 secretion 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

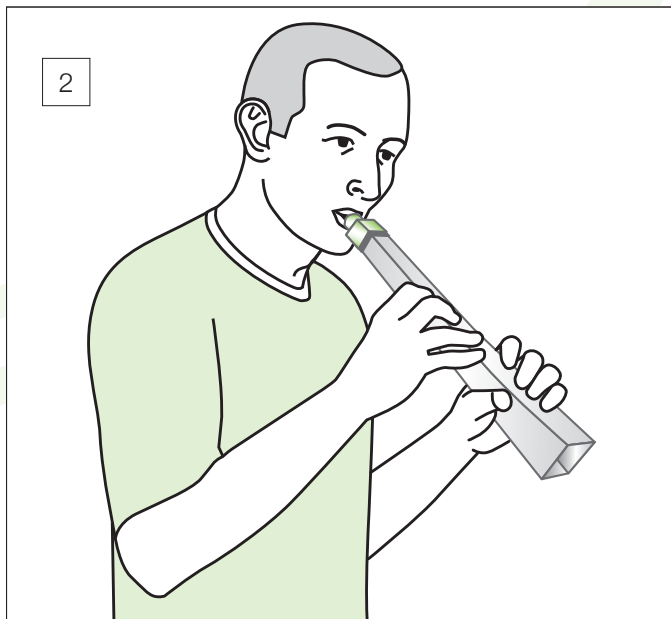
### What is the LUNG FLUTE®?

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.



### 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.

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.

6

### 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.

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® is normal

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

Frequency	16–25Hz
Minimal flow rate	128.4 L/min
Minimal pressure	1.0 cm H <sub>2</sub> O
Sound output	68 dBA <sup>1</sup>
Pressure resistance	1.0 cm H <sub>2</sub> O

<sup>1</sup> Measured with a standard General Radio 1933 Precision Sound Level Meter. OSHA limit over a 15 min. interval is 115dBA CFR 29.1910.95 (b)(2)