RESPIN 11 BRONCHIAL CLEARANCE SYSTEM INFORMATION PACK
About The RespIn 11 Bronchial Clearance System

This information packet will acquaint you with basic facts about the RespIn 11 Bronchial Clearance System. It is intended to help you select the most appropriate and effective method for your patients who need Airway Clearance Therapy. Please take a few moments to look over the information. We understand that your time is limited, and invite you contact us for any further information or for a demonstration:

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Introduction to the RespIn 11 Bronchial Clearance System

RespInnovation SAS has conceptualized, designed and realized its RespIn 11 Bronchial Airway Clearance System as a 2nd generation ‘focused pulse’ High Frequency Chest Wall Oscillation (HFCWO) device that maximizes the use of modern technologies and materials to produce a more comfortable, flexible and effective therapy delivery system. The RespIn 11 uses an innovative patented system of ‘focused pulse’ technology incorporating a system of proprietary valves, pressure pistons and electronic controls which deliver therapeutic pulsations directly to targeted areas of the patient’s thorax - exactly where most required and most beneficial in the treating clinician’s view.

RespIn 11 benefits from a totally new innovative approach to the 30-year-old concept of High Frequency Chest Wall Oscillation/Chest Compression therapy and makes maximum use of modern technologies and materials to:

- Delivers therapeutic ‘focused pulse’ therapy direct to selected parts of the patient thorax creating a more profound and efficient resonance in the bronchial airways which is delivered in a comfortable ‘massage like’ therapy.
- Flexibility of RespIn 11’s ‘focused pulse’ technology also gives treating clinicians greatly increased control and flexibility of therapy to best meet the needs of each individual patient and clinical condition.
- Very low background pressure - The RespIn 11 patented system of focused pulsations cycle from empty to full up to 20 times per second yet operates at a very low background pressure which is very beneficial to patients on both a comfort level during treatment and also therapeutic level with greatly increased efficiency in dislodging mucus and assisting its movement for expectoration.
- No negative physiological side effects - as a beneficial side effect of its low operating pressure of RespIn 11’s ‘focused pulse’ technology, it has no negative side effects to the patient’s physiological parameters, e.g. blood pressure and heart rate, and the RespIn 11 can therefore be safely used with a much wider range of patients and clinical conditions than existing Chest Compression devices.
What makes the RespIn 11 Bronchial Clearance System different?

The RespIn 11 uses the most modern and efficient method for Bronchial Clearance available today, RespInnovation’s ‘focused pulse’ technology.

Up until 30 years ago, traditional Chest Physiotherapy (CPT) with postural drainage was the only method available to treat Chronic Obstructions of Bronchial Airways caused by diseases such as Cystic Fibrosis (CF), chronic bronchitis and asthma, emphysema, bronchiectasis, and many others (now classed together as Chronic Obstructive Pulmonary Disorders (COPD)). Without this treatment the bronchial obstructions would become infected, pass to pneumonia and if left untreated can cause eventual loss of Pulmonary Vital Capacity - which translates into the body’s ability to transfer oxygen taken into the lungs into the blood to supply the brain and the body.

CPT usually takes on average 40-60 minutes to deliver therapy to all 12 classic treatment areas of the lungs they want to mobilize secretions in. This is very tiring for both the patients and the caregivers - who many times are family members.

30 years ago, High Frequency Chest Compression devices were developed and usually have treatment sessions which last 30 minutes 2 or 3 times per day. This is a very physically demanding form of therapy for the patients as it transfers a great deal of energy to the patient’s entire thorax using a high content background pressure then repeatedly squeezing the thorax up to 20 times per second to create the air movement in the airways to dislodge secretions. It can be effective, but it has a limited range of patients who are capable of tolerating the high level of energy transfer which therefore limits the number and type of clinical applications. In effect, weak or fragile patients cannot tolerate this type of therapy and must rely on CPT or drug therapy.

Our ‘focused pulsation’ therapy is completely different, it starts from the premise of treating specific zones of the thorax by transferring a focused pulsation of energy to the ribcage which then propagates this energy in a wave evenly through the lungs and bronchial tree soliciting vibrations in the bronchial tree breaking up and dislodging mucus from the bronchiole walls and helping to transport this to the larger airways for expectoration.

‘focused pulse’ transfers only 10% of the energy to the patient that High Frequency Chest Compression devices or HFCWO therapy devices do. This means for the patient that they only need to be able to tolerate 1/10th of the energy that existing devices on the market today deliver. This alone makes for a much more comfortable therapy for the patients very much like a gentle massage.

In addition, our clinical and scientific studies have shown that ‘focused pulse’ technology in the RespIn 11 creates amplitudes of reaction movement 4-6 times greater in the most important area of the lungs (from the 5th to 15th generation of the bronchial tree) where most mucus accumulates, therefore more effectively dislodging secretions and soliciting coughing.
To put how this works and is different into an everyday context, think of a dance partner with flat shoes who steps on your foot - okay it will hurt a bit, but you won’t scream. However, if you are unlucky enough to have the same partner step on your foot wearing a stiletto heeled shoe, you will feel like someone is trying to drill a hole through your foot. A much higher concentration of the partner’s weight over a much smaller surface area making the effect many times greater - and your pain level up to scream level.

‘focused pulse’ uses the same principal, thankfully without the pain aspect, where we use up to 23 individual pressure pistons, each one several centimetres in diameter which are distributed to selected areas of the thorax. Overall, they represent a very small fraction of the surface area which the tradition HFCC/HFCWO therapy devices compress by covering the entire thorax for each pulsation, but they deliver a therapeutic pulsation much more effective at helping clear your bronchial airways and move your secretions, helping you to breathe easier, live better.

In effect, we get much more ‘bang for our buck’ which for the patient means much greater effectiveness and results for much less overall energy and a much more comfortable ‘massage-like’ therapy that they are happy to use regularly.

What are common indications for required Airway Clearance Therapy?
The need for airway clearance is not disease specific, but may arise from a variety of risk factors that impair normal secretion clearance, including:

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<thead>
<tr>
<th>Recurrent respiratory infections</th>
<th>Respiratory muscle weakness</th>
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<tbody>
<tr>
<td>Mucus plugging and atelectasis</td>
<td>Increased difficulty in breathing</td>
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<tr>
<td>Hyper production of secretions</td>
<td>More frequent tightness in the chest</td>
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<tr>
<td>Abnormally thick, sticky secretions</td>
<td>Ineffective cough</td>
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What are some of the conditions that the RespIn 11 Bronchial Clearance System is prescribed?
In cystic fibrosis, primary ciliary dyskinesia, or bronchiectasis, secretion clearance therapy is an established standard of care. However, in conditions other than primary disorders of the mucociliary system, airway clearance therapy is generally prescribed when an individual patient’s pulmonary health is compromised by adverse events arising from one or more risk factors. Others include:

<table>
<thead>
<tr>
<th>Cystic fibrosis (CF)</th>
<th>Muscular Dystrophy (MD)</th>
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<tr>
<td>Asthma</td>
<td>Amyotrophic Lateral Sclerosis (ALS)</td>
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<tr>
<td>Bronchiectasis</td>
<td>Motor Neurone Disease (MND)</td>
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<tr>
<td>Chronic Obstructive Pulmonary Disease (COPD)</td>
<td>Primary Ciliary Dyskinesia (PCD)</td>
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<tr>
<td>Cerebral Palsy (CP)</td>
<td>Spinal Cord Injury</td>
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<td>Spinal Muscular Atrophy (SMA)</td>
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HFCWO has been studied extensively. Safety and efficacy are established by more than 80 clinical trials conducted at over 60 research institutions. Peer-reviewed studies demonstrate that HFCWO clears mucus and helps improve or maintain pulmonary functions more effectively than conventional chest physiotherapy (CPT).