RESPIN 11 INFORMATION PACK

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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 material. We understand that your time is limited, and invite you contact us:

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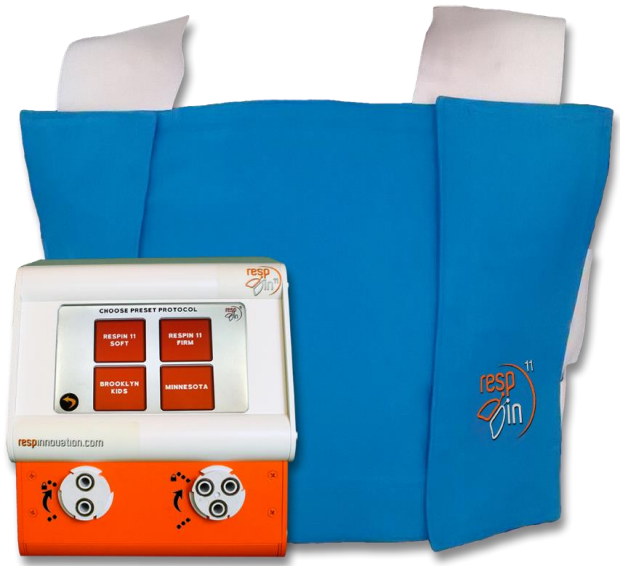

Introduction to the RespIn 11 Bronchial Clearance System

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 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 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, without the painful aspect, where we use up to 25 individual pressure pistons, each one several centimeters 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:

- Recurrent respiratory infections
- Mucus plugging and atelectasis
- Hyperproduction of secretions
- Abnormally thick, sticky secretions
- Respiratory muscle weakness
- Increased difficulty in breathing
- More frequent tightness in the chest
- Ineffective cough

What are some of the diseases and conditions for which 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:

- Cystic fibrosis (CF)
- Asthma
- Bronchiectasis
- Chronic obstructive pulmonary disease (COPD)
- Cerebral palsy (CP)
- Muscular dystrophy (MD)
- Amyotrophic lateral sclerosis (ALS)
- Spinal muscular atrophy (SMA)
- Primary ciliary dyskinesia (PCD)
- Spinal cord injury

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).

What are the Medicare requirements for these conditions?

Medicare Requirements for Bronchiectasis

Bronchiectasis (ICD-9 011.50-011.56, 494.0, 494.1, 748.61)

1. **Required:** CT scan confirming diagnosis of Bronchiectasis.
   AND
2. **Required:** Daily productive cough documented on two (2) physician notes at least six (6) months apart within the year prior to the date of the order.
   OR
   Physician notes documenting exacerbations treated by antibiotics at least three (3) times within the year prior to the date of the order.
   AND
3. **Required:** Documentation (chart notes) of another treatment (flutter valve, percussion, postural drainage, breathing techniques, suctioning) tried to mobilize secretions and clearly indicating that the other device has failed.

Medicare requirements for CF and Neuromuscular Conditions

Cystic Fibrosis (ICD-9 277.00, 277.02)

Post-polio (138)

Acid maltase deficiency (277.6)

Anterior horn cell diseases (335.0-335.9)

Multiple sclerosis (340)

Quadriplegia (344.00-344.09)

Hereditary muscular dystrophy (359.0, 359.1)

Myotonic disorders (359.21-359.29)

Other myopathies (359.4, 359.5, 359.6, 359.89)

Paralysis of the diaphragm (519.4)

1. **Required:** Documentation (chart notes) of another treatment (flutter valve, percussion, postural drainage, breathing techniques, suctioning) tried to mobilize secretions and clearly indicating why the other device has failed.

Medicare requirements for Documentation

Medicare requires that all orders and physician progress notes be signed by the physician. The method used must be a legible handwritten, full signature with credentials, handwritten initials or electronic signature. Stamped signatures are not acceptable.

What HCPCS codes are the RespIn 11 Bronchial Clearance System accepted under?

E0483 CODE INFORMATION	
Field Name	**Field Value**
Healthcare Common Procedure Coding System Code	E0483
HCPCS Long Description	High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each
HCPCS Short Description	Chest compression gen system
Pricing Indicator Code #1	36
Description	Capped rental DME (price subject to floors and ceilings). Durable Medical Equipment, Prosthetics, Orthotics, Supplies And Surgical Dressings
HCPCS Multiple Pricing Indicator Code	A
Description	Not applicable as HCPCS priced under one methodology
HCPCS Coverage Code	C
Description	Carrier judgment
HCPCS Berenson-Eggers Type Of Service Code	D1E
Description	Other DME
HCPCS Type Of Service Code #1	R
Description	Rental of DME
HCPCS Anesthesia Base Unit Quantity	0
HCPCS Code Added Date	20030101
HCPCS Action Effective Date	20030101
HCPCS Action Code	N
Description	No maintenance for this code

E7025 CODE INFORMATION	
Field Name	**Field Value**
Healthcare Common Procedure Coding System Code	E7025
HCPCS Long Description	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each
HCPCS Short Description	Replace chest compress vest

E7026 CODE INFORMATION	
Field Name	**Field Value**
Healthcare Common Procedure Coding System Code	E7026
HCPCS Long Description	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each
HCPCS Short Description	Replace chst cmprss sys hose

Medicare payment for Durable Medical Equipment (DME) is equal to 80% of the lower of either the actual charge for the item or the fee schedule amount calculated for the item, less any unmet deductible. The beneficiary is responsible for 20% of the lower of either the actual charge for the item of the fee schedule amount calculated for the item, plus any unmet deductible.

Capped Rental Items (Section 1834(a)(7))

These are items of DME that do not fall under any of the other DME payment categories. They are generally expensive items that have historically been routinely rented. In general, Medicare pays for the rental of these items, when covered, for a period of continuous use not to exceed 13 months, at which point the beneficiary takes over ownership of the equipement.

For capped rental items other than power wheelchairs, the fee schedule amount is calculated based on 10% of the base year purchase price increased by the covered item update. This is the fee schedule amount for months 1 thru 3. Beginning with the fourth month, the fee schedule is equal to 75% of the fee schedule amount paid in the first three months.

What is the current Medicare fee schedule for the RespIn 11 Bronchial Clearance System?

DMEPOS MEDICARE FEE SCHEDULES 2015 (STATES)

AL AR AZ CA CO CT DC DE FL GA IA ID IL IN KS KY LA MA MD ME MI MN MO MS MT NC ND NE NH NJ NM NV NY OH OK OR PA RI SC SD TN TX UT VA VT WA WI WV WY AK HI VI

$1,180.02

PR

$1,416.03

Cost Savings

Several articles have been written highlighting the use of airway clearance therapies such as High Frequency Chest Wall Oscillation (HFCWO) / High Frequency Chest Compression (HFCC) could potentially significantly reduce healthcare costs annually.

Currently in the United States, more than 23 million people have asthma. Approximately 13.6 million adults have been diagnosed with COPD, and an approximately equal number have not yet been diagnosed. The burden of respiratory diseases affects individuals and their families, schools, workplaces, neighborhoods, cities, and states. Because of the cost to the health care system, the burden of respiratory diseases also falls on society; it is paid for with higher health insurance rates, lost productivity, and tax dollars. Annual health care expenditures for asthma alone are estimated at $20.7 billion.

The following articles attempt to show the significant cost savings that can be made using HFCWO devices such as the RespIn 11 Bronchial Clearance System in home/clinical/hospital situations:

Chiappetta A, Mendendez A, Gozal D, Kiernan M. High-frequency chest wall oscillation in hospitalized non-cystic fibrosis patients. Am J Respir Crit Care Med 1996; 153:A566.

A retrospective medical chart review of 300 hospitalized non-cystic fibrosis patients (diagnoses unspecified) receiving professionally administered percussion and postural drainage (P&PD) treatments for secretion clearance found that a significant proportion of those costly treatments could have been effectively replaced with high frequency chest wall oscillation (HFCWO), thus providing a substantial savings in professional time, effort, and costs.

Klous DR, Boyle M, Hazelwood A, McComb RC. Chest vest & CF: Better care for patients. Adv Mgrs Respir Care 1993; 2(3):45-50.

This early report (1993) by respiratory care managers includes a six month cost/benefit of high frequency chest compression (HFCC)/high frequency chest wall oscillation (HFCWO) therapy in the in-patient setting. Using departmental quality assurance data, the mean number and session times of standard chest physiotherapy (CPT) were compared with the HFCC/HFCWO then being used for 55% of cystic fibrosis (CF) in-patients. Data analysis showed that by replacing 600 CPT treatments per month with HFCC/HFCWO, staff time savings of 236 hours would translate into a labor displacement of 2.85 full time equivalencies. (FTE). Advantages of HFCC/HFCWO included perceived effectiveness, patient satisfaction and increased ability of users to self-manage their CF.

Ohnsorg F. A cost analysis of high-frequency chest-wall oscillation in cystic fibrosis. Am J Respir Crit Care Med 1994; 149(4 pt.):A669.

BlueCross and BlueShield of Minnesota (BCBS/MN) conducted this retrospective record review of 23 cystic fibrosis (CF) clients to assess the impact of high frequency chest wall oscillation (HFCWO) therapy on total healthcare expenditures. Respiratory-illness related costs incurred during one year of HFCWO treatment, including the cost of the device itself, were compared with costs for the previous year. Data showed an aggregate reduction of 49% in total direct respiratory care costs during the year of HFCWO use.

How does the RespIn 11 Bronchial Clearance System compare to other devices?

Features	RespIn® 11 	The Vest® 	InCourage® 	SmartVest® 	Advantage
Therapy Delivery System	**Patented 'focused pulse' Pressure Pistons**	Inflatable Bladder	Inflatable Bladder	Inflatable Bladder	In an extreme example 5 different pads of air pressure pistons could be applied to each of the 5 lung lobes to directly imitate Chest Physical Therapy.
Independent Treatment Zones	**2**	1	1	1	Individual pressure pistons allow specific zones of the thorax to be treated separately.
Touch Screen Controls	**Yes**	No	No	No	Easy to read and easy to select touch screen control panel.
Background Pressure Level	**Between 4 – 6 mbar**	Between 42 – 50 mbar	Between 42 – 50 mbar	Between 42 – 50 mbar	RespIn 11 ensures that patients only need to tolerate 10% of the energy transfer compared to existing devices.
Hose Attachment	**Secure Twist Lock Connectors**	Push Fit	Locking Connectors	Push Fit	Our secure twist lock hose connection system ensures an effortless fit.
Noise Level at 20Hz	**63db**	66db	75db	66db	The RespIn 11 can be used whilst talking, watching TV, etc. with its low operating volume.
Jacket/Vest Fit	**Setup Once, Proper Fit every time**	Must be adjusted before each use	Setup Once, Proper Fit every time	Must be adjusted before each use	Snap lock buckles ensure the same fit each and every time.
RT Programmable Therapies	**Yes**	No	No	No	Respiratory Therapists can enter, program and memorize up to 3 therapies per patient.

WRAP SIZE CHART

WEIGHT

		14	18	25	27	32	36	41	45	50	54	59	64	68	73	77	82	86	91	96	100	*100+*	*(kg)*
(cm)	*(in)*	30	40	50	60	70	80	90	100	110	120	130	140	150	160	170	180	190	200	210	220	*220+*	*(lbs)*
97	38																						
102	40																						
107	42																						
112	44																						
117	46																						
122	48																						
127	50																						
132	52																						
137	54																						
142	56																						
147	58																						
152	60																						
157	62																						
163	64																						
168	66																						
173	68																						
178	70																						
183	72																						
188	74																						
193	76																						
198	78																						
203	80																						

HEIGHT

LEGEND

RI110310WK	5-8 year old	
RI110310WA	XS/M	
RI110310WC	L/XXL	

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