




# Instruction Manual

RespirTech®



This manual contains words and symbols that bring attention to specific statements.

 **WARNING** Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

 **CAUTION** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

The following symbols are used in this manual and on the inCourage® Airway Clearance Therapy. Their meanings are as follows:



General Warning Sign  
indicating the risk of  
personal injury



Caution: Hot Surface



Warning: Risk of  
Electric Shock

## *RespirTech Business Hours:*

*Monday-Friday*

*8am – 5pm CST*

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900000-000 Rev P 05/11

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Thank you for selecting the inCourage® Airway Clearance Therapy from RespirTech. RespirTech's mission and vision is to provide superior products and services to a wide variety of individuals that will benefit from airway clearance management. In doing so, we will achieve strong business results, demonstrate the ability to provide for the needs of clinical care teams, patients and families by implementing innovative solutions, while creating and maintaining a positive workplace for our associates.

## *How does the inCourage® Airway Clearance Therapy work?*

The inCourage System consists of an inflatable jacket, interconnecting hoses, and a Pulsating Therapy Unit (PTU). The PTU delivers pulsating air to the jacket through the interconnecting hoses. The result is a rhythmic inflation and deflation of the jacket against the user's chest, creating High Frequency Chest Compression (HFCC) and mobilization of bronchial secretions.

## *Indications for Use*

The inCourage Airway Clearance Therapy is indicated when external manipulation of the chest is the physician's treatment of choice for increasing the clearance of mucus in patients with pulmonary disorders. The system promotes airway clearance and improves bronchial drainage utilizing HFCC.

This manual includes instructions for setup, use, and maintenance of the inCourage System. It is to be used as a reference guide. Please review all sections carefully prior to using the inCourage System.

Warranty provided separately with shipment of device.

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

## ***Pulsating Therapy Unit (PTU)***

The PTU is the main control unit, which creates the pulsating air that is transferred to the jacket. It is the source for all control of the system.



## ***Jacket***

The jacket is made of multi-layered nylon. It is secured utilizing QuickFit straps that allow you to quickly size the jacket to the recommended spacing that allows for the pulsating air.



## ***Interconnecting Hoses***

The two hoses are made of high-strength, fiber-reinforced PVC. The hoses deliver the pulses of air from the PTU to the jacket.



## ***Locking Connectors***

The connectors are made of nylon with stainless steel locking levers.

## ***Power Cord***

The power cord plugs into the PTU and to a grounded three-pronged outlet. Grounding reliability can only be achieved when the equipment is connected to a properly grounded, three-pronged outlet.



## ***On/Off Switch***

The power to the unit is controlled by the On/Off switch located on the back of the unit.

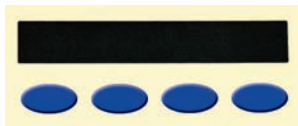
On = 1   Off = 0





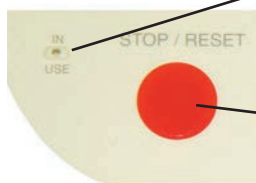
## **Control Panel**

The control panel is located on the top/front of the PTU and provides all interactive menus and performance readouts.



## **Control Switches**

The control switches are located just below the display. As the readout above each key changes, the function of the key changes.



## **Power Indicator**

The power indicator glows green when the unit is plugged in and the On/Off switch is in the On position.

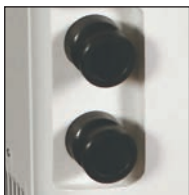
## **Stop/Reset Switch**

This switch ends all current functions, resets the control board, and returns to the main menu.



## **QuickFit Adjustable Straps**

These straps allow you to size your jacket to the exact, repeatable, recommended therapy spacing.



## **Air Ports**

The air ports are located at the front of the PTU and on the front of the jacket. The interconnecting hoses attach to the ports to complete the connection from the jacket to the PTU.

**⚠ WARNING: To reduce the risk of electrocution, ALWAYS unplug this product immediately after using. Failure to do so could result in personal injury or damage to equipment!**

**⚠ WARNING: To reduce the risk of electrocution, fire, or personal injury, follow these instructions!**

1. Be sure to read all information and instructions prior to setting up and using the inCourage System. Failure to do so could result in equipment damage, personal injury, or death.
2. Close supervision is necessary when this product is used by or near children or individuals incapacitated by a chronic illness or injury.
3. Product is to be used only as described in this manual and only as prescribed by a physician. Failure to do so could result in serious injury or death.
4. All attachments must be recommended by the manufacturer. Use only components specified in the manual.
5. Do not use device near flammable substances.
6. Inspect power cord and unit prior to use. Do not use this product if any damage has occurred to power cord or any part of the system. Call a RespirTech Customer Care Specialist at 1-800-793-1261 if any damage is suspected.
7. Keep all components of the inCourage System away from heated surfaces to avoid damage and possible injury.
8. Do NOT insert any object into any opening on the system.
9. Always observe ALL warnings, cautions, and notes listed in this manual and posted on the inCourage System.
10. Be sure to plug the inCourage System DIRECTLY into a properly grounded three-pronged electrical outlet. Grounding reliability can only be achieved when the equipment is connected to a properly grounded, three-pronged outlet.
11. Do not use the inCourage System near water or ANY wet surface. Allow the inCourage System to dry completely before plugging it into an electrical outlet if the system becomes wet.
12. Place the inCourage System only on a flat and stable surface away from any materials that could block unit air intake or exhaust.
13. When traveling by air, the inCourage System should always be considered carry-on baggage and NEVER checked baggage.
14. It is recommended that the owner or renter of the inCourage Airway Clearance Therapy insure the device under their apartment or homeowner's insurance policy to cover non-warranty damage expenses.

## STEP 1 – Plug in the PTU

1. Place the PTU on a level, sturdy, dry surface, clear of any flammable materials or obstructions.
2. Plug the power cord to the back of the PTU.



3. Plug the power cord into a properly grounded, three-pronged outlet. Grounding reliability can only be achieved when the equipment is connected to a properly grounded, three-pronged outlet. See product specifications for power requirements.



## STEP 2 – Fitting the Jacket

**Note:** Prior to use, the jacket should be inspected for any sign of defects. If any of the following defects are found, please contact a RespirTech Customer Care Representative at **1-800-793-1261** for immediate jacket replacement:

1. Any size hole found in the jacket (inner layer, outer layer, seams, or jacket ports).
2. Any stitching that has become loose or frayed on the jacket.
3. Any damage to the buckles or straps that restricts the function of the strap system.



We have taken careful consideration in supplying you with the appropriate size jacket based on your information. Please take a moment and review the fitting instructions carefully and consult your physician if any discomfort develops.

**Note:** We recommend a thin layer of cotton clothing to be worn under the jacket for best comfort.

**Note:** To loosen straps, lift the back of the buckle. To tighten straps, hold the buckle and pull the end of the strap to the patient's right.

1. These instructions refer to the three colored QuickFit tabs: blue, white, and yellow.



2. Preset the QuickFit tabs to the pre-therapy position by placing the blue tabs over the yellow tabs.



3. Put the jacket on and connect the buckles located on the front of the jacket.



## SYSTEM SETUP (cont'd)

4. Adjust the shoulder straps so the bottom edge of the jacket sits at the top of the hipbone.



5. Gently tighten the front straps until each is snug to the chest.



6. Pull each of the QuickFit blue tabs to the user's right, placing them over the white tabs.



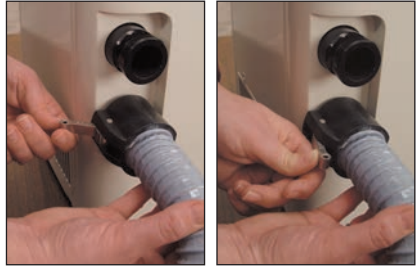
7. You are now ready to connect jacket to the PTU.



**STEP 3 – Connecting the Jacket to the PTU**

**Note:** The interconnecting hoses are interchangeable and can be flipped. You do not need to worry about which direction the hoses are attached to the PTU or the jacket.

1. Lift the metal lever and place connector on the PTU as shown.
2. Push the metal lever firmly against the locking connector to secure to PTU. (Repeat steps 1 and 2 for the second hose.)



3. Lift the metal lever and place connector on the jacket port as shown.
4. Push the metal lever firmly against the locking connector to secure to jacket. (Repeat steps 3 and 4 of these instructions for the second hose.)

**Note:**

To disconnect the jacket, lift the metal lever and pull hose off the jacket port.

# STARTING A TREATMENT SESSION

The inCourage® Airway Clearance Therapy is programmed to provide easy-to-follow instructions with an easy-to-understand menu. It has three types of sessions, each with unique advantages. The QUICK START session is a pre-programmed 30-minute session that starts immediately. The AUTO PAUSE session is the QUICK START program with an automatic feature to pause the session every 5 minutes. The MULTI STEP session is for custom programs that can be saved for future use.

	QUICK START	AUTO PAUSE	MULTI STEP
<b>Key Feature</b>	Instant 30-minute ramping session	Pauses session every five minutes. Press RUN to resume	Customized therapy with multiple steps and ramping
<b>Program</b>	Pre-programmed	Pre-programmed	Programmable up to 12 steps
<b>Session Length</b>	30-minute session divided into 12 steps of 2.5 minutes each	Same as QUICK START with automatic pause every five minutes	12 User-programmable steps up to 99 minutes each
<b>Pressure</b>	Set at 60% and adjustable during session	Set at 60% and adjustable during session	Set at desired pressure per step and adjustable during session
<b>Frequency</b>	Ramps from 6Hz to 15Hz over a 2.5 minute period – then ramps from 15Hz to 6Hz for the next 2.5 minutes and repeats for a total of 30 minutes	Ramps from 6Hz to 15Hz over a 2.5-minute period – then ramps from 15Hz to 6Hz for the next 2.5 minutes followed by a pause. Repeats for a total of 30 minutes	User defined per step between 5Hz and 30Hz Ramping
<b>Memory</b>	Factory programmed – does not change	Factory programmed – does not change	3 programmable memory keys

**Note:** The PTU will generate an audible tone as feedback when pressing any of the front panel buttons, or at the end of a step.

## Definitions:

1. **FREQUENCY** – Represents the number of air pulses that are delivered over a period of time. (The inCourage System represents frequency in Hertz (Hz), or the number of pulses per second.)
2. **PRESSURE** – Represents the force that the system places against your body. (The inCourage System represents pressure as a percentage of the maximum pressure created.)
3. **SESSION** – A full treatment of individual or combined steps.
4. **STEP** – A segment of frequency, pressure, and time that together with other steps make up a complete session.
5. **RAMPING** – During a step, the inCourage System gradually increases or decreases the frequency to the next step's frequency.
6. **AUTO PAUSE** – Automatically pauses at the end of each 5 minute step. Press RUN to resume.

**⚠ CAUTION:** Use of the system other than as prescribed could result in ineffective treatment. Prescribed settings must be utilized!

## STEP 1 – Powering up the inCourage Airway Clearance Therapy

1. Turn the power switch on the back of the PTU to the On position. (Ensure unit is plugged in to a properly grounded three-pronged outlet.)



**Note:** The power indicator light on the control panel will light green to show that the unit is in use.

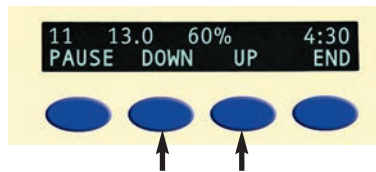
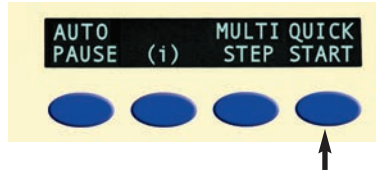


# STARTING A TREATMENT SESSION (cont'd)

## STEP 2 – Choose a Session Mode (QUICK START, AUTO PAUSE, MULTI STEP)

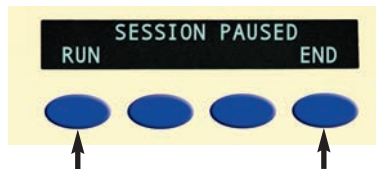
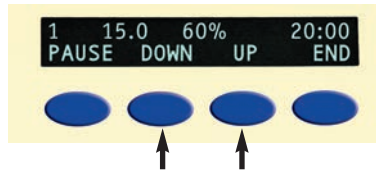
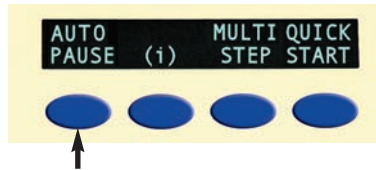
### To run QUICK START mode:

1. From the startup screen, select QUICK START.
2. Your QUICK START session will begin. Adjust pressure by pressing either DOWN or UP. Press PAUSE to temporarily stop the session. Press RUN to resume the session or END to return to the startup screen.



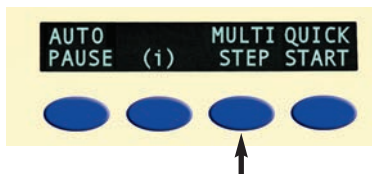
### To run AUTO PAUSE mode:

1. From the startup screen, press AUTO PAUSE.
2. Your AUTO PAUSE session will begin. Adjust pressure by pressing either DOWN or UP. Press PAUSE to temporarily stop the session or END to return to the startup screen.
3. When the session pauses, press RUN to resume the session or END to return to the startup screen.

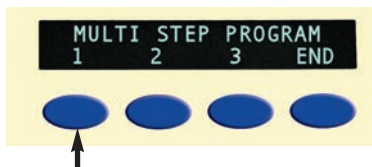


## To run MULTI STEP mode:

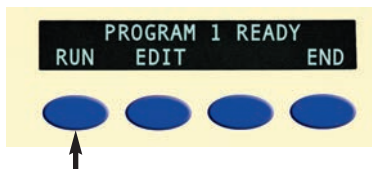
1. From the startup screen, press MULTI STEP.



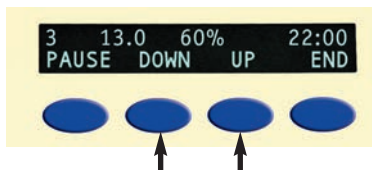
2. Select the program number you would like to run or edit. (PROGRAM 1 will be used as an example.)



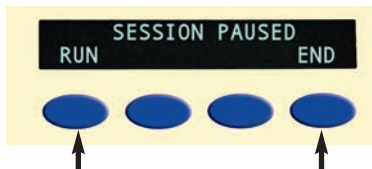
3. To run the previously saved program, press RUN. To edit the previously saved program, see step 6 below.



4. The PROGRAM 1 session will begin. Adjust pressure by pressing either DOWN or UP. Press PAUSE to temporarily stop the session or END to return to the startup screen.

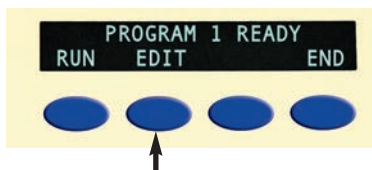


5. If the session is paused, press RUN to resume the session or END to return to the startup screen.



## STARTING A TREATMENT SESSION (cont'd)

6. To edit PROGRAM 1, press EDIT.



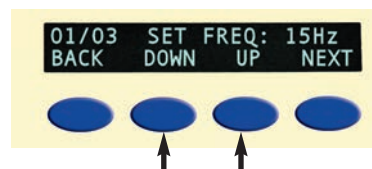
7. Press DOWN or UP to adjust desired number of steps, then press NEXT.

**Note:** You will need to set frequency, pressure, time, and auto pause for each of the steps.

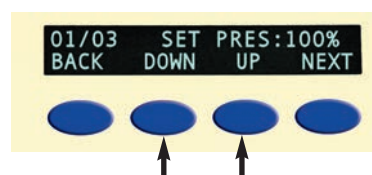
**Note:** Three steps will be displayed in this example.



8. Press DOWN or UP to adjust frequency (FREQ) to desired level, then press NEXT.

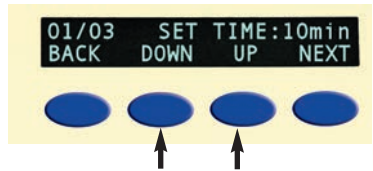


9. Press DOWN or UP to adjust pressure (PRES) to desired level, then press NEXT.





10. Press DOWN or UP to adjust the desired length of TIME, then press NEXT.



11. Press YES or NO to enable or disable the Auto Pause, then press NEXT.



**Note:** As you complete programming for each step, the display will briefly show your progress.



12. When you have completed programming this step, the display will proceed to the next step for programming and update the display to "02/03" showing that you are now programming the second of three steps.



13. Repeat steps 8 through 11 of the MULTI STEP mode instructions until all steps are programmed. The screen will automatically bring you to the PROGRAM 1 READY screen.

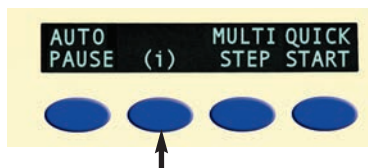


**Note:** After programming is completed, it is recommended to verify program for accuracy.

Press RUN and return to step 4 within the MULTI STEP mode instructions on page 15.

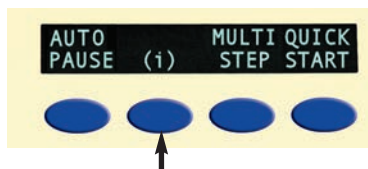
## To Retrieve Hour Meter Reading (HMR)

Press the information ( i ) key once, and it will show from top-left, clockwise: software version, total HMR, QUICK START HMR and AUTO PAUSE HMR for about 10 seconds. All HMR will show as "Hours : Minutes : Seconds"



The System Utilities Section also allows the setting of the year, month, day and local time.

1. Press the Information ( i ) key to display the System Usage screen.



2. Within one second, press and hold the ( i ) key again to access the Utilities menu.



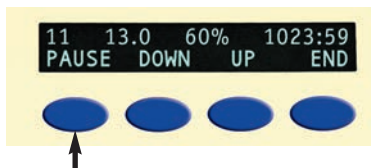
3. Use the BACK, DOWN, UP, and NEXT keys to adjust the settings for the current date and time. Press the NEXT key to advance through the screens.



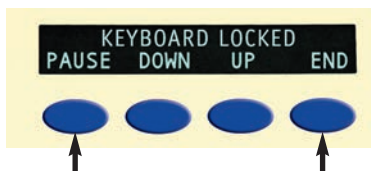
The Key Lock feature will prevent certain functions of the inCourage® Airway Clearance Therapy from operating during a treatment session. When enabled, the PRESSURE UP, DOWN, and END keys will not function. The PAUSE and RESET keys will still function.

## To Enable or Disable The Key Lock

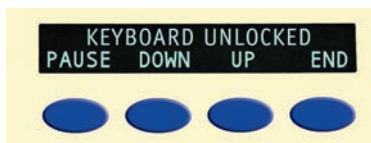
1. During any treatment session, press and hold the PAUSE key.



2. Within one second, press and hold the END key.



3. To disable the Key Lock, repeat steps 1 and 2.



**Note:** The Key Lock will be disabled when the Reset key is pressed or when turning the power off.

# CLEANING AND FILTER REPLACEMENT

The inCourage® Airway Clearance Therapy requires very little maintenance. Cleaning and filter replacement are all that are required. **DO NOT MAKE ANY ATTEMPTS TO REPAIR THE SYSTEM.** Tampering or altering any of the components of the system will void the warranty. If any problems are experienced with the inCourage® Airway Clearance Therapy, please call a RespirTech Customer Care Specialist at 1-800-793-1261.

**⚠ WARNING: Do not immerse the Pulsating Therapy Unit (PTU) in water. This could result in electrocution!**

## Cleaning the PTU and Hoses

All components of the inCourage System may be cleaned with a damp, soft cloth and mild detergent, or any commercial household/hospital disinfectant. This includes the exterior of the PTU and the interconnecting hoses. Always make sure the power cord is removed while cleaning the PTU or replacing the filter. Wipe away any residue with a damp cloth and let the components dry thoroughly before use.

## Cleaning the Jacket

The inCourage System jacket may be machine-washed in any commercial or household washing machine by following these steps:

1. Insert the two red plugs (supplied) into both jacket ports.  
**Note:** Make sure the rim of the plug fits tightly into the port.
2. Machine wash jacket on gentle or normal cycle with a mild detergent in warm water.
3. Remove both plugs from the jacket ports and tumble-dry jacket on low heat setting until dry.
4. To ensure all moisture is removed from the jacket, attach one hose onto the top port of the Pulsating Therapy Unit (PTU). Attach the other end of the hose onto one jacket port.  
**Note:** Make sure hose is attached to the top port of the unit and leave the other jacket port open.
5. Unbuckle all straps of the jacket and lay on flat surface. Run the Pulsating Therapy Unit (PTU) for 20 minutes at a frequency of 30 hertz and at 100% pressure.

**⚠ WARNING: CHOKING HAZARD - Keep Small Red Plugs Away From Children Under 3 yrs.**

### Filter Replacement

Inspect the air filter regularly. Replace the filter when it appears dirty, shows signs of wear, after 90 hours of use, or after 90 days of use, whichever comes first.

To replace the filter, remove the two screws as shown below. Remove and discard the old filter and slide the new filter into the filter holder. Close filter door and replace screws.

**⚠ WARNING: Do not overtighten the screws.**

**Note:** If service is required, please call a RespirTech Customer Care Specialist at 1-800-793-1261.



Condition	Possible Cause	Solution
The pulsating therapy unit (PTU) will not turn on	Power cord is not securely inserted into the electrical inlet on the rear panel	Remove power cord from the rear panel and re-insert
	Power cord is not securely inserted into the wall outlet Fuse is damaged	Ensure power cord is fully plugged into the wall outlet Replace fuse with proper fuse (See below)
	Other cause	Contact the RespiTech Customer Care Center at 1-800-793-1261
The jacket no longer fits	Normal growth	Re-adjust the jacket closures to accommodate change in chest size – if the jacket still does not fit properly, contact the RespiTech Customer Care Center at 1-800-793-1261
No air is pulsing into the jacket	Hoses are not connected to the jacket	Connect hoses to the jacket and PTU
	Hoses are clogged	Clean inside and outside of the hoses, jacket ports, and PTU ports according to maintenance guidelines
	Air filter is clogged	Replace air filter
	Other cause	Contact the RespiTech Customer Care Center at 1-800-793-1261
“Error” is displayed on screen	Internal problem	1. Press Reset 2. Contact the RespiTech Customer Care Center at 1-800-793-1261

## Fuse Replacement

1. Open fuse cover, located next to the On/Off switch.
2. Remove red fuse holder.
3. Replace fuse with 5 A, 250 VAC, 1 ¼" x ¼", slow blow.
4. Insert replacement fuse into fuse holder and place into system with the fuse down (see photo).
5. Snap fuse cover closed.



## Principles of Operation

The inCourage® Airway Clearance Therapy utilizes three main components:

1. Pulsating Therapy Unit (PTU)
2. Inflatable Jacket
3. Interconnecting Hoses

These components work in conjunction with each other to deliver pulsating positive pressure air pulses to the patient known as High Frequency Chest Compression (HFCC). The rhythmic inflation and deflation of the jacket against the patient's chest aids in the mobilization and clearance of bronchial secretions.

## Product Specifications

System:	inCourage Airway Clearance Therapy, Model ICS-1M-US
Manufactured By:	Respiratory Technologies, Inc. 2896 Centre Pointe Drive, St. Paul, MN 55113
Mode of Operation:	Continuous Use
Operating Temperature:	0° C to 50° C (32° F to 122° F)
Storage/Transport:	-25° C to 85° C (-13° F to 185° F)
Operating Humidity:	20% to 80% RH @ 25° C (77° F) (non-condensing)
Length:	13"
Width:	8"
Height:	13"
Weight:	17 lbs.
(Measurements are approximate.)	

Input Source:	120 VAC RMS, 50/60 Hz, Single Phase
Wattage:	500 Watts
Fuses:	5 A, 250 VAC, 1¼" x ¼", slow blow

## Jacket Specifications

- 1050 Denier Nylon outer shell, PVC-coated
- 200 Denier Nylon inner shell, PVC-coated
- Nylon auto-adjusting securement straps with quick-release connectors

# CONTRAINDICATIONS

The inCourage® Airway Clearance Therapy is contraindicated (not appropriate for use) if the following conditions are present:

- Head and/or neck injury that has not yet been stabilized
- Active hemorrhage with hemodynamic instability

## **Relative Contraindications\***

The decision to use the inCourage System for airway secretion clearance in the presence of the conditions listed below requires careful consideration and assessment of the individual patient's case.

- Intracranial pressure (ICP) > 20 mmHg
- Recent spinal surgery, acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Rib fractures, with or without flail chest
- Surgical wound or healing tissue, recent skin grafts or flaps on the thorax
- Uncontrolled hypertension
- Distended abdomen
- Recent esophageal surgery
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration (tube feeding or recent meal)
- Subcutaneous emphysema
- Recent epidural spinal infusion or spinal anesthesia
- Burns, open wounds, and skin infections on the thorax
- Recent placement of transvenous pacemaker or subcutaneous pacemaker
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Osteoporosis, osteomyelitis of the ribs
- Coagulopathy
- Complaint of chest wall pain

\*According to the AARC Guidelines for Postural Drainage Therapy



The inCourage System needs special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service according to the EMC information provided in the tables below.

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>		
The inCourage System, Model ICS-1M-US, is intended for use in the electromagnetic environment specified below. The user of the inCourage System should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic Environment - Guidance</b>
RF emissions CISPR 11	Group 1	The inCourage System, Model ICS-1M-US, uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The inCourage System, Model ICS-1M-US, is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Not applicable	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The inCourage® Airway Clearance Therapy, Model ICS-1M-US, is intended for use in the electromagnetic environment specified below. The user of the inCourage System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-4	±6 kV contact ±8 kV air	A A	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	A N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-11	±1 kV differential mode ±2 kV common mode	A A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 sec	A A A C	Mains power quality should be that of a typical commercial or hospital environment. If the user of the inCourage System requires continued operation during power mains interruptions, it is recommended that the inCourage System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**NOTE:**  $U_T$  is the AC mains voltage prior to application of the test level.

## *RespirTech Patient Bill of Rights and Responsibilities*

- 1. Information Disclosure.** Patients have the right to receive accurate, easily understood information and some may require assistance in making informed decisions about their purchase. RespirTech will strive to provide clearly understood billing statements and the patient's financial obligations to RespirTech, if any, prior to shipment. Patients will also have a thorough understanding of the appeals process, if any. RespirTech does not receive any financial incentive from any source other than required payments made on the patient's behalf from their third party payer(s). RespirTech employees or representatives visiting patients will present proper identification.
- 2. Participation in Treatment Decisions.** Patients have the right and responsibility to fully participate in all decisions related to their health care. Patients who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators. Patients may refuse care or treatment after the consequences of refusing such care or treatment has been fully presented to the patient.
- 3. The Right to Choose.** Patients have the right to a choice of health care providers that is sufficient to assure access to appropriate high-quality health care including giving women access to qualified specialists such as obstetrician-gynecologists and giving patients with serious medical conditions and chronic illnesses access to specialists.
- 4. Access to Emergency Services.** Patients have the right to access emergency health services when and where the need arises. Health plans should provide payment when a patient presents himself/herself to any emergency department with acute symptoms of sufficient severity "including severe pain" that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that patient's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.
- 5. Respect and Non-Discrimination.** Patients have the right to considerate, respectful care from all employees and representatives of RespirTech at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality experience with RespirTech. RespirTech will not discriminate against or harass any customer for services because of race, color, creed, religion, national origin, sex, sexual orientation, disability, diagnosis or disease, age, marital status, or status with regard to ability to pay.

6. **Confidentiality of Health Information.** Patients have the right to communicate with RespirTech employees and representatives in confidence and to have the confidentiality of their individually identifiable health care information protected. Patients also have the right to review and copy their own medical records and to request amendments to their records. Please contact the HIPAA Privacy Official with any questions or concerns at: [privacyofficial@respirtech.com](mailto:privacyofficial@respirtech.com), or call 651-379-8960 for assistance.
7. **Alleged Grievances and Abuse.** All patients have the right to a fair and efficient process for resolving differences with RespirTech, including a rigorous system of internal review. Differences can be resolved through respectful discussion, written notification of the issues, and a thorough investigation process. An alleged grievance or abuse violation should be directed to the RespirTech Privacy/Compliance Officer via phone at 651-379-8960; e-mail ([privacyofficial@respirtech.com](mailto:privacyofficial@respirtech.com)); or to the company address:

Respiratory Technologies, Inc.  
Attn: Privacy Official  
2896 Centre Pointe Drive  
St. Paul, MN 55113

A Company representative will respond back to the patient within five (5) days to confirm receipt of the notification of concern and will initiate an investigation of the alleged grievance or abuse concern.

**FOR MEDICARE BENEFICIARIES:** Within fourteen (14) days of receipt of the beneficiary's alleged grievance or abuse concern, RespirTech will provide a written investigation response, to the beneficiary. Concerns regarding grievances or alleged abuse may also be submitted to the Accreditation Commission for Health Care, Inc. (ACHC) at 4700 Falls of the Neuse Road, Suite 280, Raleigh, North Carolina 27609. Telephone: (919) 785-1214. Website: [www.achc.org](http://www.achc.org)

8. **Patient Responsibilities.** In a health care system that protects patients' rights, it is reasonable to expect and encourage patients to assume reasonable responsibilities. Greater individual involvement by patients in their care increases the likelihood of achieving the best outcomes and helps support a quality improvement, cost-conscious environment.

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

## **Why We Are Sending This Notice**

RespirTech is committed to protecting the privacy of your health data. Federal and state laws require us to protect the privacy of your health data. We must give you notice of our legal duties and our privacy practices. We are required to do the following:

- We must protect your health data.
- We must notify you about how we protect your health data.
- We must explain how, when and why we use or disclose your health data.
- We may only use or disclose your health data as we have described in this Notice.

## **How We Protect Your Data**

- We restrict access to your health data to only RespirTech staff members who provide services to you. All RespirTech staff members have been trained to protect privacy. Staff members who violate these policies are subject to disciplinary action.
- We use safeguards to protect your health data. These safeguards comply with federal regulations regarding security.
- We periodically review our policies and practices. We monitor our computer networks. We monitor and test our security to ensure the privacy and security of your health data.

## **USES AND DISCLOSURES OF YOUR HEALTH DATA**

There are a number of ways in which we use or disclose your health data in providing health benefits to you.

### **1. Uses and Disclosures for Treatment, Payment or Health Care Operations.**

When you first became a patient or customer of RespirTech, you authorized the release of your medical records for the following purposes:

- Payment and insurance coverage
- Conducting quality of care and performance review
- Assuring coordination of medical services

Without further notice to you, RespirTech may use your health data for the following purposes:

- Treatment. We may use or disclose your health data to assist medical providers in coordinating and managing your care.

- **Payment.** We may use or disclose your health data to facilitate the payment to medical providers who have provided services to you. We may also disclose your health data with contractors that provide claims processing services to RespirTech.
- **Health Care Operations.** We may use or disclose your health data to perform necessary health plan functions. For example, we may use your data to help us train new staff and to conduct quality improvement activities.

### **2. Uses and Disclosures Authorized by Law.**

Under certain circumstances, we are authorized by law to use or disclose your health data without obtaining authorization from you and without notifying you of such uses or disclosures. These circumstances may include when the use or disclosure is:

- For public health activities. For example, when reporting to public health authorities the exposure to certain diseases or reporting data about immunizations.
- For health oversight activities. For example, when disclosing health data to a state or federal health oversight agency so it can monitor the safety or medical devices.
- About victims of abuse, neglect or domestic violence.
- For organ or tissue donation purposes.
- For judicial or administrative proceedings. For example, when responding to a court order.
- For law enforcement purposes.
- To a coroner or medical examiner.
- To avert a serious threat to health or safety to you, another person or to the public.
- Related to specialized government functions. For example, regarding military personnel.

We may also make disclosures without your consent or authorization when required to do so by state or federal law.

### **3. Other Uses and Disclosures.**

We may also contact you to tell you about treatment options or other health services that may be of interest to you.

### **4. Uses and Disclosures that Require Authorization.**

For all other purposes, we may be required to obtain a specific authorization to use or release your health data. If you provide an authorization to us, you may revoke it at any time.

## YOUR INDIVIDUAL RIGHTS

### **1. Right to Access and Copy Your Health Data.**

You may access, inspect and receive a copy of your health data contained in our records. You need to make your request in writing. Write or call RespirTech and ask for a "RespirTech Information Access Form". We may charge a reasonable fee for copies. There are limited situations in which we may deny your request for access. In these situations, we will let you know why we cannot grant your request and how you may ask for a review of our denial.

### **2. Right to Request an Amendment of Your Health Data.**

You may request that we amend your health data. You need to make your request in writing and explain your reason for the amendment. Write or call RespirTech and ask for a "RespirTech Information Amendment Request Form". Under limited circumstances, we may deny your request. If we do so, you may file a statement of disagreement with us. You may also ask that any future disclosures of your health data include your requested amendment and our denial of your request.

### **3. Right to Request Restrictions on Uses and Disclosures of Your Health Data.**

You may request that we restrict our use or disclosure of your health data for payment or health care operations. You need to make your request in writing. We are not required to agree to your request for a restriction. However, if we do agree, we will comply with our agreement, unless there is an emergency or we are otherwise required to use or disclose the data. If we decide to end our agreement to the restrictions, we will tell you.

### **4. Right to Request Confidential Communications.**

You may request that we communicate with you in a specific way or at a specific location. For example, you may request that we contact you at an address other than your home address. We will agree to your request if we determine that your request is reasonable. You need to make your request in writing.

### **5. Right to Request an Accounting of Disclosures of Health Data.**

You may request a listing of certain disclosures we have made of your health data. You need to make your request in writing. You may ask for disclosures made up to six (6) years before the date of your request. We will provide you one accounting in any 12 month period free of charge.

### **6. Right to Receive a Copy of this Notice.**

You have the right to receive a paper copy of this Notice at any time. To exercise any of these rights, contact our Privacy Office at the telephone number or address listed below.

## QUESTIONS OR COMPLAINTS

If you are concerned that your privacy rights have been violated, you may file a complaint with RespirTech. Contact:

Privacy Official @ RespirTech, 2896 Centre Pointe Drive, St. Paul, MN 55113  
1-800-793-1261 (Toll Free) or 651-379-8960 (Direct Dial)

You may also submit a written complaint to the U.S. Department of Health and Human Services at:

Region V Office for Civil Rights, U.S. Department of Health and Human Services  
233 N. Michigan Avenue, Suite 240 Chicago, IL 60601  
Hotline: (800) 368-1019

We support your right to the privacy of your health data. We will not retaliate in any way if you file a complaint with us or with the U.S. Department of Health and Human Services.

## CHANGES TO OUR PRIVACY PRACTICES

RespirTech reserves the right to change the terms of this Notice and make provisions effective for all Protected Health Information we maintain. We will send a new Notice to you when we make a significant change in our privacy practices.

## QUESTIONS?

If you want more information about our privacy practices, please call the RespirTech Privacy Official toll free at: 1-800-793-1261

Effective Date: 04/16/2009



**Note:** *This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).*

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.

11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date - October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.

- 24.** All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
- 25.** All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
- 26.** Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c).  
Implementation date- May 4, 2009
- 27.** A supplier must obtain oxygen from a state- licensed oxygen supplier.
- 28.** A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
- 29.** DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
- 30.** DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.