



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® System. Their meanings are as follows:

 Attention: Consult Accompanying Documents	 Warning: Risk of Electric Shock	 Upper and Lower Temperature Limits		
 Manufacturer	 Date of Manufacture	 Serial Number	 TUV Mark	
 Type BF Applied Part	 Lot Number	 Reference Number	RX Only Federal law restricts this device to sale by or on the order of a physician	 Protective Earth Terminal

RespirTech Business Hours: Monday – Friday 8 a.m. – 5 p.m. CT
Toll Free: 800.793.1261
www.respirtech.com

2896 Centre Pointe Drive, St. Paul, MN 55113
TF 800.793.1261 | Fax 800.962.1611

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900197-000 Rev B

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INTRODUCTION

Thank you for selecting inCourage Airway Clearance Therapy from RespirTech. RespirTech's vision is to improve lives by helping people breathe better.

▶ How does inCourage Airway Clearance Therapy work?

The inCourage System consists of an inflatable vest, interconnecting hoses and a pulsating therapy unit (PTU) that creates compressions to the chest to help loosen, thin and move mucus throughout the lungs.

▶ Indications for Use

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 High Frequency Chest Wall Oscillation (HFCWO).

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.

The device operating instructions contained herein apply to devices with V4.0 software.

Warranty provided separately with shipment of device.



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

COMPONENTS and CONTROLS

▶ Pulsating Therapy Unit (PTU)

The PTU is the main control unit, which creates the pulsating air compressions that are transferred to the vest. It is the source of control for the system. PTU Model number: ICS-1M-US-A



▶ inCourage Comfort Vest

The vest is made of multi-layered nylon. It is secured utilizing QuickFit straps that allow you to quickly set the vest to the recommended size to optimize the benefits of the pulsating air.



▶ Interconnecting Hoses

The two hoses are made of high-strength PVC. The hoses deliver the pulses of air from the PTU to the vest.



▶ Locking Hose Connectors

The connectors are made of high-strength plastic with 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 = I Off = 0



COMPONENTS and CONTROLS (cont'd)

▶ Control Panel

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



▶ Control Buttons

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

▶ Power Indicator

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

▶ Stop/Reset Button

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

▶ QuickFit Adjustable Straps

These straps allow you to size your vest 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 vest. The interconnecting hoses attach to the ports to complete the connection from the vest to the PTU.



SAFETY INSTRUCTIONS



WARNING: To reduce the risk of electrocution, ALWAYS unplug this product immediately after using. Failure to do so could result in personal injury, property damage, 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, property 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 RespiTech Customer Support Representative 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. Do NOT place objects on or over the top of the inCourage 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. **NEVER include the inCourage System in checked baggage, always include it in carry-on baggage.**
14. It is recommended that the owner or renter of the inCourage System insure the device under their renters or homeowner insurance policy to cover non-warranty damage expenses.

SYSTEM SETUP

► STEP 1: Fitting the inCourage Comfort Vest

Inspect the inCourage Comfort Vest:

Note: Prior to use, the vest should be inspected for any sign of defects. If any of the following defects are found, please contact a RespirTech Customer Support Representative at **1.800.793.1261** for immediate vest replacement:

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

Adjust the Comfort Vest Straps:

We have taken careful consideration in supplying you with the appropriate size vest 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 vest for best comfort.

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. Before putting on the vest, preset the QuickFit tabs to the pre-therapy position by placing the blue tabs over the yellow tabs.



SYSTEM SETUP (cont'd)

3. Put the vest on and connect the buckles located on the front.



4. Adjust the shoulder straps so the bottom edge of the vest 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 off the yellow tabs, then place the blue tabs over the white tabs.



SYSTEM SETUP (cont'd)

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



▶ STEP 2 : Plug in the PTU

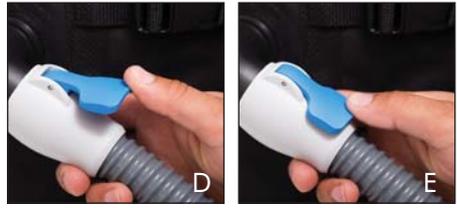
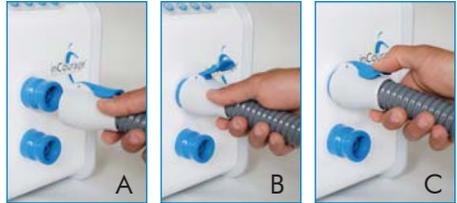
1. Place the PTU on a level, sturdy, dry surface, clear of any flammable materials or obstructions.
2. Plug the power cord to the back of the PTU.
3. Plug the power cord into a properly grounded, three-pronged outlet. Grounding reliability can only be achieved when the equipment is connected to a properly grounded, three-pronged outlet. See product specifications for power requirements.



▶ STEP 3 : Connecting the vest to the PTU

NOTE: The interconnecting hoses are interchangeable and can be flipped. You do not need to worry about which end of the hose is attached to the PTU or the vest.

1. Grasp the sides of the locking hose connector and push hose connector on the device as shown (Image A). Blue lever on hose connector will move upward during this process (Image B).
2. Continue to push the hose connector firmly against the device until the hose connector has been properly fitted against the device. The lever will move downward.
3. Gently press down on the lever to verify a secure connection (Image C). If you experience any unusual resistance, push the hose connector more firmly against the device. Repeat steps 1-3 for connecting the second hose to the device.
4. Grasp the sides of the locking hose connector and push hose connector on the vest port as shown (Image D). Blue lever on hose connector will move upward during this process.
5. Continue to push the hose connector firmly against the vest port until the host connector has been properly fitted against the hose port. The lever will move downward.
6. Gently press down the lever to verify a secure connection (Image E). Repeat steps 1-3 for connecting the second hose to the vest.



NOTE: To disconnect the vest, lift the lever and pull hose off the vest port.

TREATMENT DEFINITIONS

▶ Treatment Definitions:

1. **FREQUENCY (F)** – 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 (P)** – 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 session every five minutes. Press RUN to resume.
7. **HOUR METER READING (HMR)** – Represents the total use time over the life of the device. This timer cannot be reset.
8. **USE INFO** – Represents the average session length in minutes and average pressure setting for the previous number of sessions displayed. Only sessions over five minutes will be counted. The user can reset this information.
9. **PAUSE TIME** – Allows for automatic continuation of therapy after a pre-programmed pause during an Auto Pause or Multi Step session.
10. **PRESSURE LIMIT** – The maximum allowable pressure setting for all therapy sessions and programming.
11. **PRESSURE INCREMENT** – The amount of pressure percent (%) changed when increasing or decreasing pressure.
12. **FAST SET PROGRAMMING (FS)** – A method for creating a customized Multi Step session of up to 12 steps with alternating frequency with an input of six settings: Number of Steps, Low Frequency, High Frequency, Pressure Setting, Total Program Time and Auto Pausing On or Off.



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

STARTING A TREATMENT SESSION

The inCourage System 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 session that starts immediately. The Auto Pause session is the Quick Start program with an automatic feature to pause the session every five minutes¹. The Multi Step sessions are for custom programs that can be saved for future use.

	QUICK START	AUTO PAUSE	MULTI STEP
Key Feature	Instant 30-minute ¹ ramping session	Pauses session every five minutes ¹	Customized therapy with multiple steps and ramping
Program	Pre-programmed	Pre-programmed	Programmable up to 12 steps
Session Length	30-minute session divided into 12 steps of 2.5 minutes each ¹	Same as Quick Start with automatic pause every five minutes ¹	12 User-programmable steps up to 99 minutes each
Pressure	Default set at 60% and adjustable during session	Default set at 60% and adjustable during session	Set at desired pressure per step and adjustable during session
Frequency	Ramps from 6Hz to 15Hz over a 2.5 minute period – then ramps from 15Hz to 6Hz over the next 2.5 minutes and repeats for a total of 30 minutes ¹	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 ¹	User defined per step between 5Hz and 30Hz Ramping
Memory	Last pressure setting used is retained for the start of the next session	Last pressure setting used is retained for the start of the next session	Three programmable memory buttons

NOTE: The PTU will generate an audible tone as feedback when pressing any of the front panel buttons.²

1. Quick Start and Auto Pause default duration of 30 minutes can be adjusted by five minute intervals from a minimum of five minutes to a maximum of 90 minutes per session, the number of minutes per step will vary.
2. By default, the audible tone is only generated when pressing one of the front panel buttons. Setting Beep Control to 'On' will also generate audible feedback at the end of a step.

STARTING A TREATMENT SESSION (cont'd)

▶ STEP 1: Turn on the inCourage System

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.)



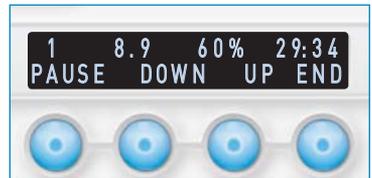
NOTE: The power indicator light on the control panel will light green to show that the unit is in use.



▶ STEP 2: Choose a Session Mode (Quick Start, Auto Pause, Multi Step)

To run Quick Start mode:

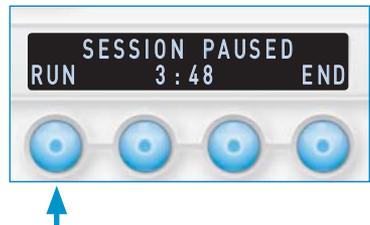
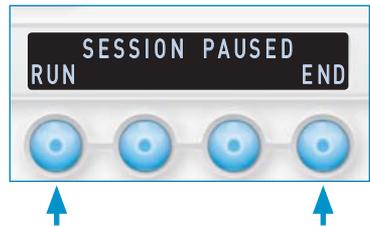
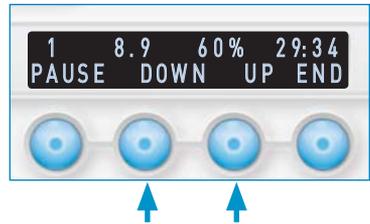
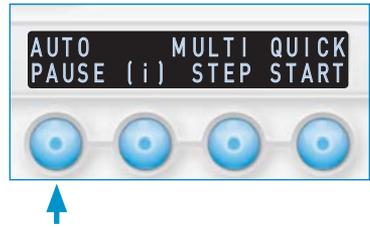
1. From the startup screen, select **QUICK START**. Your **QUICK START** session will begin.
2. Adjust pressure by pressing either **DOWN** or **UP**. Press **PAUSE** to temporarily stop the session. Press **RUN** to resume the session or **END** to return to the startup screen.
3. When the session pauses,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



STARTING A TREATMENT SESSION (cont'd)

To run Auto Pause mode:

1. From the startup screen, press AUTO PAUSE. Your AUTO PAUSE session will begin.
2. 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.
4. When a Pause Time is set, a countdown to resume will be displayed and therapy will automatically resume when the counter reaches 0:00. The RUN button will also continue therapy at any time.



STARTING A TREATMENT SESSION (cont'd)

To run Multi Step mode:

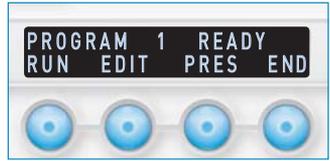
1. From the startup screen, press MULTI STEP.



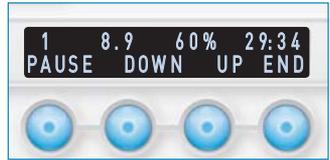
2. Select the program number you would like to run. (Program 1 will be used as an example.)



3. To run the previously saved program, press RUN. To edit the previously saved program, see the Modify a Multi Step Session section on page 17.



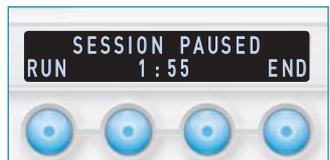
4. The Program 1 session will begin. Adjust pressure by pressing either DOWN or UP. Press PAUSE to temporarily stop the session or END to return to the startup screen.



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



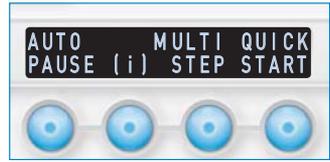
6. When a Pause Time is set, a countdown to resume will be displayed and therapy will automatically resume when the counter reaches 0:00. The RUN button will also continue therapy at any time.



MODIFY A MULTI STEP SESSION

Multi Step Editing Options:

1. From the Startup Screen, Press MULTI STEP
2. Select the program number you would like to edit. (Program 1 will be used as an example.)
3. The Program Ready screen has two options for editing the selected program. Selecting EDIT will continue to the Program Edit Menu. Selecting PRES will allow a single pressure to be set for all steps.
4. The Program Edit Menu screen has three options for editing the selected program: STEPS, FS, and DFLT. These options are described in the following instructions.



Fast Set Programming (FS) for Multi Step Sessions:



Fast Set Programming creates a customized Multi Step session of up to 12 steps of alternating frequencies with an input of six settings: Even Number of Steps, Low Frequency (odd steps), High Frequency (even steps), Pressure Setting, Total Program Time and Auto Pausing On or Off. Total time is divided equally over the number of steps.

The FS menu is accessed as described in the previous Multi Step Editing Options section above. FS menu screens prompt for setting of STEP QTY, LOW FREQ, HIGH FREQ, PRESSURE, TOTAL PRG TIME and PAUSE STEPS, YES or NO. Selecting the SAVE option in the PAUSE STEPS menu will store the new selections into the selected program.

MODIFY A MULTI STEP SESSION (cont'd)

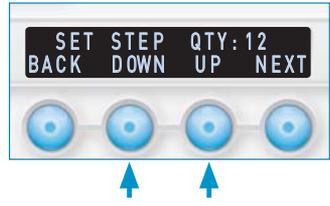
Review and Adjust Multi Step Session Settings:

PRESS: **MULTI STEP** ➤ **PROGRAM #** ➤ **EDIT** ➤ **STEPS**

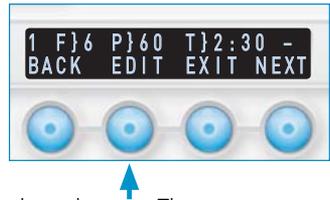
The STEPS edit option is used to review or manually change the individual set points for each parameter of each step within a Multi Step Session.

1. Select STEPS edit option from the Multi Step Editing Options described on page 17.

2. After the STEPS option is selected, session step quantity is requested for the selected program. Press DOWN or UP to adjust desired number of steps, then press NEXT.



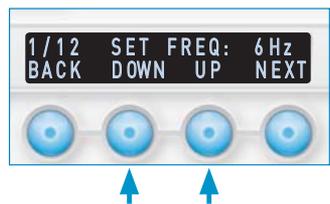
3. The step summary information will then display for the first step as displayed in the example to the right. The line includes the step number (1), frequency (6), pressure (60), step time (2:30), and pause step ("-"). If no selections are made, the top line will begin to scroll providing expanded parameter information about the step. The user can quickly check the settings of each step by pressing NEXT after reviewing a step. The EXIT button will return to the Program Ready screen.



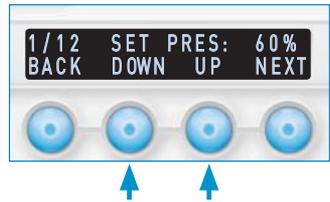
4. Select EDIT to begin adjusting the parameters of the selected step that is currently displayed.

5. Once in step EDIT mode, pressing the BACK button at any time will return to the step summary for the previous parameter viewed.

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

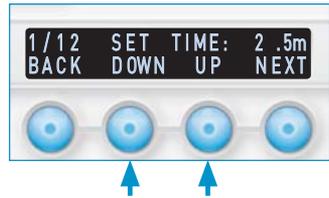


7. Press DOWN or UP to adjust pressure (PRES) to desired level, then press NEXT.

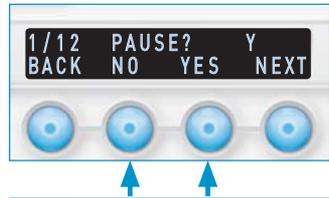


MODIFY A MULTI STEP SESSION (cont'd)

8. Press DOWN or UP to adjust the desired length of time, then press NEXT.



9. 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 that settings were saved.



10. After a full step is programmed, the display will proceed to the next step.



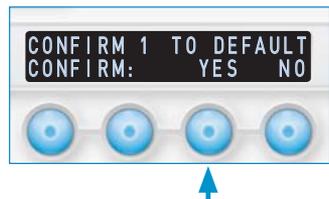
11. Repeat six through nine above to program each of the remaining steps. The screen will automatically bring you to the Program Ready screen after the final step.

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

Set a Multi Step Session to Factory Default Settings:



Selecting DFLT as described in the Multi Step Editing Options section on page 17 will bring up the default confirmation screen. To confirm program reset to default, select YES.



Screen Saver:

If the device is not actively running a program and a button is not pressed for ten minutes, the display will start a scrolling text. After an additional 20 minutes, the screen will blackout. At any time, press any button to reactivate the display and return to the main menu.

The screen saver cannot be modified.

Information Menu (i):

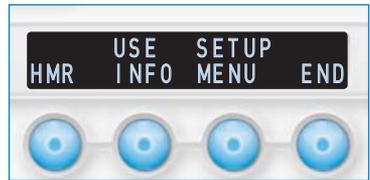
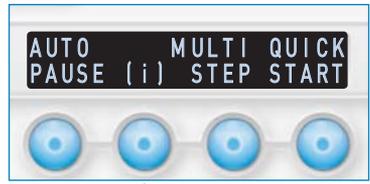
The Information Menu contains options to view the device Hour Meter Reading (HMR), Average Use Information, and Setup Menu. The Information Menu is accessed by pressing the (i) option from the startup screen.

Selecting END will return to the startup screen.

To Retrieve Hour Meter Reading (HMR) and Device Software Version:

PRESS: (i) ➔ HMR

1. Press the Information (i) button to display the Information Menu.
2. Press the HMR button.
3. The HMR will be displayed on the right side of the screen, Hours : Minutes : Seconds. The software version will be displayed on the left side of the screen.
4. Press the END button to return to the Information Menu. The HMR and Software Version screen display will remain up until the END button is pressed or the screen saver timeout is reached.



Information Menu (i)



SYSTEM UTILITIES (cont'd)

To Retrieve Device Average Use Information:

PRESS: (i) > USE INFO

1. Press the Information (i) button to display the Information Menu.
2. Press the USE INFO button.
3. The display will show average session time in minutes and average pressure used over the number of therapy sessions displayed.

Note: Only sessions over five minutes will be averaged.



4. Press any button to return to the Information Menu. If a button is not pressed within 30 seconds, the display will return to the Information Menu automatically. See the Reset Defaults section to clear the session count and average use information.

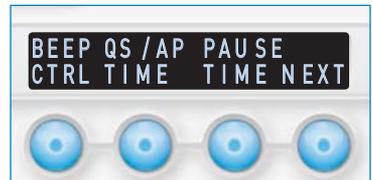
Setup Menu:

PRESS: (i) > SETUP MENU

Select SETUP MENU from the Information (i) menu shown on page 20. The Setup Menu contains device operational parameters that can be adjusted. These parameters are: the Beep Control, QS/AP Time, Pause Time, Pressure Limit, Pressure Increment, Default Settings, and Clear Use Information. The Setup Menu is displayed over two menu screens as shown to the right. Selecting NEXT from Setup Menu 1 will display Setup Menu 2.

To exit the Setup Menu, select NEXT and/or END to return to the Information Menu and then END again to return to the startup screen.

After adjusting a parameter within the Setup Menu, the display is returned to the Setup Menu of which that parameter was selected from.



Setup Menu 1



Setup Menu 2

SYSTEM UTILITIES (cont'd)

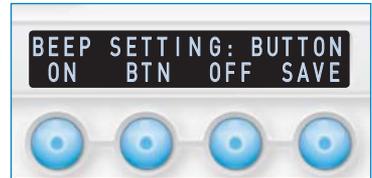
Beep Control:

PRESS: (i) ► SETUP MENU ► BEEP CTRL

This allows the user to control when the audible beep will sound. To set the audible beep, select BEEP CTRL from the Setup Menu 1 screen as shown on page 21.

The audible beep has three settings:

- **ON** – Audible beep for button pushes and alternating tones at the end of every session step completed
- **BUTTON (BTN)** – Audible beep for button pushes only (default)
- **OFF** – No audible tones will sound



The current selection for the beep setting is displayed on the top line of the display. Press SAVE to exit the menu and to save the selected beep setting.

Quick Start and Auto Pause Session Time

PRESS: (i) ► SETUP MENU ► QS/AP TIME

This allows the user to adjust the therapy session length for the one-touch start Quick Start and Auto Pause programs. The default 12 step, 30 minute session can be set between five and 90 minutes in five minute increments. If the session time is less than 30 minutes, the number of 2.5 minute steps is reduced. If session time is greater than 30 minutes, the time is equally divided over 12 steps.

To adjust the Quick Start and Auto Pause session time, select QS/AP TIME from the Setup Menu 1 screen described on page 21.

Select BACK to return to Setup Menu 1 without saving changes.



Pause Time:

PRESS: (i) ► SETUP MENU ► PAUSE TIME

When a Pause Time is set, a session will automatically restart after a programmed pause during an Auto Pause or Multi Step session. By default, the Pause Time is set to OFF. A session can still be started manually at anytime by pressing RUN. When active, a Pause Time countdown will be shown on the display.

SYSTEM UTILITIES (cont'd)

To adjust the Pause Time, select PAUSE TIME from the Setup Menu 1 screen described on page 21. Use the DOWN and UP buttons to set the Pause Time from OFF to 10 minutes in half minute increments. When the desired setting is shown, select SAVE.



Select BACK to return to Setup Menu 1 without saving changes.

Pressure Limit:



This sets the maximum pressure allowed for all programs and programming. To adjust the Pressure Limit, select PRESS LIMIT from the Setup Menu 2 screen described on page 21. Use the DOWN and UP buttons to set the system pressure limit. When the desired setting is shown, select SAVE.

Select BACK to return to Setup Menu 2 without saving changes.

Pressure Increment:



This sets the pressure increment used when adjusting pressure for all running sessions and session programming.

To adjust the Pressure Increment, select PRESS INC from the Setup Menu 2 screen described on page 21. Use the DOWN and UP buttons to set the pressure increment to 5% or 10%. When the desired setting is shown, select SAVE.

Select BACK to return to Setup Menu 2 without saving changes.

Reset Defaults and Clear Average Use:



This allows the user to reset settings to original factory parameters. There are three reset options. All defaults (ALL DFLTS) resets all programs and setup menu variables. Setup defaults (SETUP DFLTS) resets only setup menu variables. CLEAR USE resets the session count and average use information to zero.

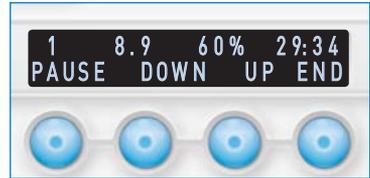
To reset settings to original factory defaults, select NEXT then RESET DFLTS from the Setup Menu 2 screen described on page 21. The RESET DFLTS menu will display the three reset options to select: ALL DFLTS, SETUP DFLTS, and CLEAR USE. Selecting a reset option will display a confirmation screen to continue. Select YES to confirm or select NO to cancel.

USING THE BUTTON LOCK

The Button Lock feature will prevent certain functions of the inCourage System from operating during a treatment session. When enabled, the pressure UP, DOWN, and END buttons will not function. The PAUSE and RESET buttons will still function.

▶ To Enable or Disable the Button Lock

1. During any treatment session, press and hold the PAUSE button.
2. Within one second, press and hold the END button.
3. To disable the Button Lock, repeat steps 1 and 2.



NOTE: The Button Lock will be disabled when the Reset button is pressed or when turning the power off.

CLEANING THE SYSTEM

The inCourage System requires very little maintenance. Cleaning and filter replacement are all that is 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 System, please call a RespiTech Customer Support Representative 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 inCourage Comfort Vest

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

1. Insert the two red plugs (supplied) into both vest ports.
Note: Make sure the rim of the plug fits tightly into the port.
2. Machine wash vest on gentle or normal cycle with a mild detergent in warm water.
3. Remove both plugs from the vest ports and tumble-dry vest on low heat setting until dry.
4. To ensure all moisture is removed from the vest, attach one hose onto the top port of the Pulsating Therapy Unit (PTU). Attach the other end of the hose onto one vest port.

NOTE: Make sure hose is attached to the top port of the unit and leave the other vest port open.

5. Unbuckle all straps of the vest and lay on flat surface. Run the Pulsating Therapy Unit (PTU) for 20 minutes at a frequency of five Hz and at 100% pressure.



WARNING: CHOKING HAZARD — Keep small red plugs away from children under three years!

FILTER and FUSE REPLACEMENT

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.

If a nebulizer is used along with the inCourage System, it is recommended that the filters be replaced monthly. Failure to change filter could impede device performance.

NOTE: If service is required, please call a RespiTech Customer Support Representative at 1.800.793.1261.

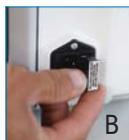
Filter panel is located on the right side of the device when looking at the front of the device.

1. Unplug the PTU.
2. Grasp bottom of side panel. Gently pull away from unit until you hear a click. (Image A)
3. Pull panel down until it is completely disconnected from the unit. (Image B)
4. Pull out existing filter and replace with new filter. The filter must go behind the four small tabs and in front of the support grate. (Image C).
5. To reconnect the panel, align the tabs and gently push up and in at the bottom until you hear a click for a secure fit.



Fuse Replacement

1. Remove the black fuse holder located on the back of the device using a small flat head screwdriver. (Image A & B)
2. Replace both fuses with 5 A, 125 VAC, 5 mm x 20 mm, slow blow, 10000 A interruption rated fuses. (Image C)
3. Insert replacement fuses into holder and place back into unit until you hear a click. (Image D)



TROUBLESHOOTING GUIDE

CONDITION	POSSIBLE CAUSE	SOLUTION
The pulsating therapy unit (PTU) will not turn on	<p>Power cord is not securely inserted into the electrical inlet on the rear panel</p> <p>Power cord is not securely inserted into the wall outlet</p> <p>Fuse is damaged</p> <p>Other cause</p>	<p>Remove power cord from the rear panel and re-insert</p> <p>Ensure power cord is fully plugged into the wall outlet</p> <p>Replace fuse with proper fuse (see below)</p> <p>Contact a RespirTech Customer Support Representative at 1.800.793.1261</p>
The vest no longer fits	Normal growth	Re-adjust the vest closures to accommodate change in chest size – if the vest still does not fit properly, contact a RespirTech Customer Support Representative at 1.800.793.1261
No air is pulsing into the vest	<p>Hoses are not connected to the vest</p> <p>Hoses are clogged</p> <p>Air filter is clogged</p> <p>Other cause</p>	<p>Connect hoses to the vest and PTU</p> <p>Clean inside and outside of the hoses, vest ports, and PTU ports according to maintenance guidelines</p> <p>Replace air filter</p> <p>Contact a RespirTech Customer Support Representative at 1.800.793.1261</p>
Displayed is unreadable or non-responsive	Internal problem	<ol style="list-style-type: none"> 1. Press Reset 2. Switch power off for 30 seconds 3. Contact a RespirTech Customer Support Representative at 1.800.793.1261
Display shows error or warning message	PTU error detected	<ol style="list-style-type: none"> 1. Write down error or warning message. 2. Switch power off for 30 seconds 3. If the error reoccurs, contact a RespirTech Customer Support Representative at 1.800.793.1261

SPECIFICATIONS

▶ Principles of Operation

inCourage Airway Clearance Therapy utilizes three main components:

1. Pulsating therapy unit (PTU)
2. Inflatable vest
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 Wall Oscillation (HFCWO). The rhythmic inflation and deflation of the vest 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-A
Manufactured By:	Respiratory Technologies, Inc. 2896 Centre Pointe Drive, St. Paul, MN 55113
Mode of Operation:	Continuous Use
Operating Temperature:	10° C to 33° C (50° F to 92° F) Ambient Temperature
Storage/Transport:	-25° C to 85° C (-13° F to 185° F)
Operating Humidity:	20% to 80% RH (non-condensing)
PTU Length:	13.5"
PTU Width:	9"
PTU Height:	13"
PTU Weight:	17.5 lbs.
Input Source:	120 VAC RMS, 50/60Hz, Single Phase
Wattage:	500 Watts
Fuses:	5 A, 125 VAC, 5 mm x 20 mm, slow blow , 10000 A interruption rating

▶ Vest 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

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

ELECTROMAGNETIC EMISSIONS

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.

► Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The inCourage System, Model ICS-1M-US-A, 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.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The inCourage System, Model ICS-1M-US-A, 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 B	The inCourage System, Model ICS-1M-US-A, 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	

ELECTROMAGNETIC IMMUNITY

► Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

inCourage Airway Clearance Therapy, Model ICS-1M-US-A, 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	A	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	A	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	A	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/output lines	N/A	
Surge IEC 61000-4-11	±1 kV differential mode	A	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV common mode	C	
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	A	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.
	40% U_T (60% dip in U_T) for 5 cycles	A	
	70% U_T (30% dip in U_T) for 25 cycles	A	
	<5% U_T (>95% dip in U_T) for 5 sec	A	
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.			

PATIENT BILL OF RIGHTS AND RESPONSIBILITIES

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 information both verbally and in writing, including estimates of expected billed charges, third party payments and patient's financial obligations to RespirTech, if any, prior to shipment/delivery for all care/services provided. 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 the development and revision of all decisions/care plans related to their health care, including the right to be fully informed in advanced about the care/services and frequency of care/services being provided by RespirTech and its employees and representatives. 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 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 receive considerate, respectful care from all employees and representatives of RespirTech, free from mistreatment, neglect and verbal, mental, sexual and physical abuse, 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 be advised of RespirTech's policies regarding the disclosure of patient's records. 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: compliance@respirtech.com, or 1.844.649.7730.
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 1.844.649.7730; e-mail compliance@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.

You may also submit a complaint to the U.S. Department of Health and Human Services by contacting ocrmail@hhs.gov or your state's regional office at:

**New England Region —
(Connecticut, Maine,
Massachusetts, New Hampshire,
Rhode Island, Vermont)**

Office for Civil Rights
U.S. Department of Health and
Human Services
J.F. Kennedy Federal Building
Room 1875
Boston, MA 02203
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

**Eastern and Caribbean Region
— (New Jersey, New York, Puerto
Rico, Virgin Islands)**

Office for Civil Rights
U.S. Department of Health and
Human Services
Jacob Javits Federal Building
26 Federal Plaza - Suite 3312
New York, NY 10278
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

**Mid-Atlantic Region —
(Delaware, District of Columbia,
Maryland, Pennsylvania,
Virginia, West Virginia)**

Office for Civil Rights
U.S. Department of Health and
Human Services
150 S. Independence Mall West
Suite 372, Public Ledger Building
Philadelphia, PA 19106
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

**Midwest Region — (Illinois,
Indiana, Iowa, Kansas, Michigan,
Minnesota, Missouri, Nebraska,
Ohio, Wisconsin)**

Office for Civil Rights
U.S. Department of Health and
Human Services
233 N. Michigan Ave., Suite 240
Chicago, IL 60601
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

Kansas City —

Office for Civil Rights
U.S. Department of Health and
Human Services
601 East 12th Street, Room 353
Kansas City, MO 64106
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

**Southeast Region — Atlanta
(Alabama, Florida, Georgia,
Kentucky, Mississippi, North
Carolina, South Carolina,
Tennessee)**

Office for Civil Rights
U.S. Department of Health and
Human Services
Sam Nunn Atlanta Federal Center,
Suite 16T70
61 Forsyth Street, S.W.
Atlanta, GA 30303
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

**Southwest Region — (Arkansas,
Louisiana, New Mexico,
Oklahoma, Texas)**

Office for Civil Rights
U.S. Department of Health and
Human Services
1301 Young Street, Suite 1169
Dallas, TX 75202
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

**Rocky Mountain Region —
(Colorado, Montana, North
Dakota, South Dakota, Utah,
Wyoming)**

Office for Civil Rights
U.S. Department of Health and
Human Services
1961 Stout Street, Room 08-148
Denver, CO 80294
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

Pacific Region — (Alaska, American Samoa, Arizona, California, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Hawaii, Idaho, Marshall Islands, Nevada, Oregon, Republic of Palau, Washington)

Office for Civil Rights
U.S. Department of Health and
Human Services
90 7th Street, Suite 4-100
San Francisco, CA 94103
Voice Phone 800.368.1019
FAX 202.619.3818
TDD 800.537.7697

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 139 Weston Oaks Ct., Cary, North Carolina 27513. Telephone: 919.785.1214. Website: 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.

910014-000 Rev I

NOTICE OF PRIVACY PRACTICES

Effective Date: 5/21/18

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 Providing You with This Notice

RespirTech is committed to protecting the privacy of your medical information and protected health information (PHI). Federal and state laws require us to protect the privacy of such information and to tell you how we do so. We must give you notice of our legal duties and our privacy practices with respect to your medical information. We are required to do the following:

- Maintain the privacy of your medical information.
- Notify you if we are made aware that your medical information has been acquired, accessed, used, or disclosed inappropriately.
- Explain how, when, and why we may use or disclose your medical information.
- Use or disclose your medical information only in the ways we have described in this Notice.

How We Protect Your Health Information

- We restrict access to your medical information 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 medical information. 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 information.

USES AND DISCLOSURES OF YOUR HEALTH INFORMATION

There are a number of ways in which we use or disclose your medical information in providing health services 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

NOTICE OF PRIVACY PRACTICES (cont'd)

Without further notice to you, RespirTech may use your medical information for the following purposes:

- **Treatment.** We may use or disclose medical information about you to provide you with medical treatment or services and/or to assist medical providers in coordinating and managing your care.
- **Payment.** We may use or disclose your health information so that the treatment and services you receive may be billed to and payment may be collected from you, an insurance company, or a third party. We may also disclose your medical information to contractors who provide claims processing services to RespirTech.
- **Health Care Operations.** We may use or disclose your health information 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. We may combine medical information about many patients to decide what additional services to offer and whether certain treatments are effective.

2. Uses and Disclosures Authorized by Law.

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

- To family members, a personal representative, or others involved in your health care or payment for your health care, unless you tell us not to disclose such information to those individuals.
- To business associates, such as to facilitate treatment, payment, and/or health care operations.
- For facility directories (such as a hospital), unless you object.
- For public health activities, such as when reporting to public health authorities the exposure to certain diseases or reporting data about immunizations.
- For health oversight activities, such as when disclosing health data to a state or federal health oversight agency so it can monitor the safety of medical devices.
- About victims of abuse, neglect, or domestic violence where required by law.
- For judicial or administrative proceedings, such as when responding to a court order.
- For law enforcement purposes, such as in response to a subpoena, warrant, or summons.
- To a coroner, medical examiner, or funeral director.
- To the extent allowed by state workers compensation laws.
- To avert a serious and imminent threat of harm to you, another person or to the public.
- For certain, specialized government functions, such as regarding military personnel, national security, or prison inmates.

NOTICE OF PRIVACY PRACTICES (cont'd)

- For research purposes, such as for a research project as approved by an Institutional Review Board or Privacy Board, in compliance with governing law.

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 use or disclose your health information to contact you for our fundraising activities. If you do not want to be contacted for this purpose, you have the right to opt out of receiving such communications.

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 information. If you provide an authorization to us, you may revoke it, in writing, at any time.

- We will not use or disclose your psychotherapy notes, if applicable, without your prior written authorization, except pursuant to state or federal law.
- We will not use or disclose your health information for marketing purposes or accept any payment for marketing communications using such health information without your prior written authorization. The authorization will disclose whether we receive any compensation for any marketing activity you authorize, and we will stop any future marketing activity when you revoke your authorization, in writing, which you may do at any time.
- We will not sell your health information without your prior written authorization. The authorization will disclose that we will receive compensation for your health information if you authorize us to sell it. We will stop any future sales of such information when you revoke your authorization, in writing, which you can do at any time.

YOUR INDIVIDUAL RIGHTS

1. Right to Inspect and Copy Your Health Information.

You may access, inspect, and receive a copy of your health information contained in our records. You need to make your request in writing. Write or call RespirTech to 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 Information.

You may request that we amend your medical information. You need to make your request in writing and explain your reason for the amendment. Write or call RespirTech to 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 information include your requested amendment and our denial of your request.

3. Right to Request Restrictions on Uses and Disclosures of Your Health Information.

You may request that we restrict our use or disclosure of your health information 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. If you tell us not to disclose medical information to your health plan concerning health care items or services for which you paid for in full out-of-pocket, we will abide by your request, unless we must disclose the information for treatment or legal reasons.

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 a particular email account or 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 information. 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 with one accounting in any 12-month period free of charge. For additional accountings, we may charge you for the costs of providing the listing.

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 Officer at the telephone number or address listed below.

CHANGES TO THIS NOTICE OF PRIVACY PRACTICES

RespirTech reserves the right to amend this Notice at any time in the future. Until such amendment is made, we are required by law to comply with the terms of this Notice currently in effect. After an amendment is made, we will make available to you a revised Notice of Privacy Practices which will apply to all PHI that we maintain, regardless of when it was created or received.

QUESTIONS OR COMPLAINTS

If you are concerned that your privacy rights have been violated, you may file a complaint with RespirTech or with the Secretary of the U.S. Department of Health and Human Services. You will not be retaliated against for filing a complaint. To file a complaint with us, contact our Privacy Officer at: RespirTech, 2896 Centre Pointe Drive, St. Paul, MN 55113-1134 or call 1.844.649.7730 (Toll Free) or email compliance@respirtech.com. You may also contact our Privacy Officer at these numbers for any further information or questions you may have.

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MEDICARE DMEPOS SUPPLIER STANDARDS

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.
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. A supplier must have an authorized individual (whose signature is binding) sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory, or contract with other companies for the purchase of items necessary to fill orders. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or 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 and must maintain a visible sign with posted hours of operation. The location must be 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.
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 is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57 (c) (11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.

MEDICARE DMEPOS SUPPLIER STANDARDS (cont'd)

14. A supplier must maintain and replace at no charge or repair cost either directly, or through a service contract with another company, any 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 standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose 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 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 for those specific products and services (except for certain exempt pharmaceuticals).
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. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57 (d).
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 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act) or physical and occupational therapists or a DMEPOS supplier working with custom made orthotics and prosthetics.

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