

THE EMPATHY LUNGS™

Chronic Obstructive Pulmonary Disease Simulator

Instructor Training Manual

How to Use and Demonstrate
The Empathy Lungs™ COPD Simulator

PLEASE NOTE:

To realize the maximum benefits from The Empathy Lungs, it is ESSENTIAL that you read this manual in it's entirety and learn to use the product correctly. You should also view the demonstration video tape that was shipped with this product.

The effective presentation of this teaching resource depends on YOU!

****** KEEP FOR FUTURE REFERENCE ******

Introduction

What is “The Empathy Lungs”™ and what are its benefits?

“The Empathy Lungs”™ C.O.P.D. Simulator is a unique and powerful tool for smoking prevention and cessation. It is comprised of a custom designed Torso Constrictor (a truss-like garment) that is strategically weighted -- and worn around the wearer’s torso – along with a customized Airway Mask which, when worn together will temporarily simulate the pronounced “shortness of breath” or “breathlessness” that characterizes **Chronic Obstructive Pulmonary Disease** (which is comprised primarily of Emphysema and/or Chronic Bronchitis), as well as that of Asthma, and Lung Cancer. Used only on a voluntary basis and only while under the supervision of a trained professional, this unique, hands-on simulator has been engineered for one-time, short term use of just fifteen to thirty minutes, during which time it will safely enable the wearer to physically experience COPD’s typically strenuous, labored, shallow, “upper-chest breathing only”, as well as the subsequent fatigue, irritability and emotional distress that inevitably results from the feeling of “not getting enough air”.

Wearing The Empathy Lungs™ also measurably reduces the wearer’s total lung volume capacity, as evidenced by the “before and after” measurements of their **Peak Expiratory Flow** rates; these **PEF** rates are quickly measured by an easy-to-use Peak Flow Meter (included). Such an experience invariably impacts the wearer with a realistic “sneak preview” of the eventual, debilitating effects of smoking, which is the primary cause of COPD -- currently affecting over 45 million patients as of 2005. COPD is the 4th largest cause of death in the U.S., and is projected to become the 3rd leading cause of death by 2020. Since The Empathy Lungs™ simulator can be worn by both males and females, ranging in age from 12 to 82, it finally gives teachers and medical professionals a hands-on, uniquely effective approach to motivate adolescents to never begin smoking, and to help current smokers gain an emotional “gut-level” determination to quit smoking for good. Furthermore, in many instances, wearing this simulator will motivate a smoker to finally go to their family physician for simple Spirometry testing of their current lung function, and learn what practical changes they can make to preserve their remaining lung health.

Symptoms And Effects Simulated By “The Empathy Lungs”™ Are:

1. Shortness of Breath (Dyspnea) while at rest, and increased upon mild exertion (e.g. standing, pacing, climbing stairs, etc.)
2. Reduction in Peak Expiratory Flow rate
3. Breathlessness or feeling of “not being able to get enough air”
4. Shallow, “upper chest breathing” only (vs. deep or abdominal breathing)
5. Strenuous, labored or difficult breathing
6. Fatigue and reduction of normal activity level
7. Feelings of irritability, anxiety and/or emotional distress
8. Possible wheezing



Methods Utilized By “The Empathy Lungs”™ To Simulate These Eight Effects:

1. If properly tightened on the wearer, the Torso Constrictor greatly reduces the normal upward and outward expansion of the rib cage, thereby reducing lung volume capacity. Likewise, the Torso Constrictor prevents the normal contraction of the intercostals muscles of the wearer’s chest, thereby preventing the normal decrease in air pressure which is required for air to be drawn into the lungs. The reduction in the wearer’s total lung volume capacity is evidenced by a 50 to 200 L/Min decline in their “before and after” measurements of their Peak Expiratory Flow rate (PEF); this rate is quickly measured by an easy to use, hand-held Peak Flow Meter that accompanies the COPD Simulator.
2. By also tightly constricting the lower abdominal area, the Torso Constrictor significantly prevents the normal downward, contracting movement of the wearer’s diaphragm, and thereby prevents deep or abdominal level breathing. The resulting shallow, “upper chest breathing only” is further exacerbated by the inhibition of normal diaphragmatic movement due to the direct, inward compression and displacement of the abdominal organs (e.g. stomach, colon, small intestines) by the Simulator’s Weighted Pouches (10 lbs. in the Medium to Large size, and 5 lbs. in the Small to Medium size).

3. The breathlessness or feeling of “not being able to get enough air” results from the Simulator’s stringent torso binding which simulates the effect of damaged air sacs (alveoli) as occurs in emphysema; the damage leads to reduced surface area of the alveoli sacs, which causes a progressive and debilitating decline in the normal exchange of blood gases that is supposed to occur in the lungs (i.e. intake of oxygen upon sufficient inhale, followed by exhale of carbon monoxide that has been absorbed from the blood returning to the lungs). Consequently, this results in a buildup of excess carbon monoxide trapped in the lungs, which leads to all of the eight COPD symptoms named above.
4. The Simulator’s Restricted Airway Mask has two special, circular, soft vinyl flaps that, in this device’s unique design, intentionally cover the two, circular, five-hole air vents located on each side of the Mask. These flaps permit the wearer’s air to be exhaled, but they prevent any air from being inhaled through these vents. Rather, air must be laboriously inhaled through the slight openings in the perimeter of the Mask as it makes contact with the nose, cheeks and chin of the wearer, or through the three, very small openings in the hard plastic, cylindrical protrusion under the mask’s nosepiece. This reduction in the ability to inhale normally simulates the narrowed airways (bronchi and bronchioles) – especially as occurs in chronic bronchitis and asthma – due to the inflammation, thickened muscle layers, and excess mucous buildup typical in damaged airways. In turn, this shortness of breath causes much of the wheezing, fatigue, irritability and emotional distress characteristic of moderate to severe C.O.P.D.
5. The Simulator’s instructions specify that the wearer not sit down, but rather that they stand or pace throughout their fifteen to thirty minutes of wearing the whole device. This mild exertion, in addition to carrying the 5 or 10 pounds of the Weighted Pouches, increases the body’s workload and subsequent demand for more oxygen at a time when there is a significant decrease in the amount of oxygen available to the wearer because of the above-described methods.

Who benefits from using The Empathy Lungs™ ?

All educational, counseling, and medical professionals involved in achieving the objectives of smoking prevention and smoking cessation for their students or patients. These professionals would include:

- Health and Family Life teachers in all Junior and Senior High Schools, colleges, universities, and vocational technical schools.
- Family practice physicians and nurses (who usually are the first to encounter and diagnose symptoms of C.O.P.D. in a patient).
- Respiratory therapists, cardiologists, and pulmonary specialists.
- Instructors of private or hospital based classes for smoking cessation.
- The rapidly increasing number of employers who (as per recent changes in the laws of many states in the U.S.) are instituting totally smoke-free work environments, and who wish to assist employees in successfully adapting to this often difficult change.
- Instructors in medical and nursing education.

PREPARATION

If this is your first opportunity to use The Empathy Lungs™, take some time to first examine it in the steps described below:

1. Lay the “truss like” **Torso Constrictor** garment on a table vinyl side facing up. The zipper* pull should be at the top of the simulator; if not, rotate the simulator so that the zipper pull is at the top. Notice the 2 “V” like straps that flank the zipper; these are called the **V-Wings** and add a measurable degree of “tightness” on the chest later on (Figure 1).

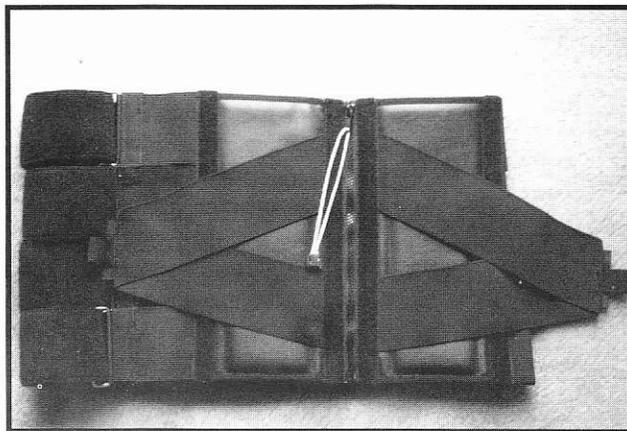


Figure 1 Closed Torso Constrictor With Zipper & V-Wings

Note: The zipper is only to be used by the wearer as a **Quick Release Zipper in the rare event that he/she experiences an adverse physical or emotional reaction to the simulator experience (e.g. dizziness, sudden dull or sharp pain, excessive panic, etc.). It is reassuring to the wearer that in such an event, he/she has complete control, and may easily and immediately remove the simulator by slowly pulling down the Quick Release Zipper, which will immediately restore the wearer's normal breathing (Figure 2).*

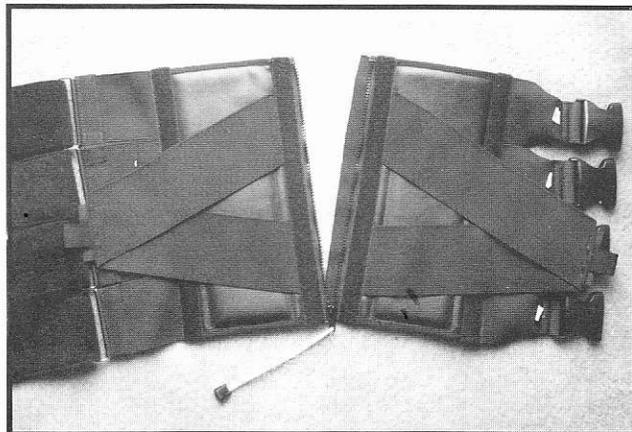


Figure 2 Quick Release Zipper in Open Position

2. Now turn the simulator over so that the four **Plastic Buckles** are on the left. Notice that they are each labeled with a small, white tab that says A, B, C or D, which corresponds with the white tabs on the four adjacent straps (Figure 3).

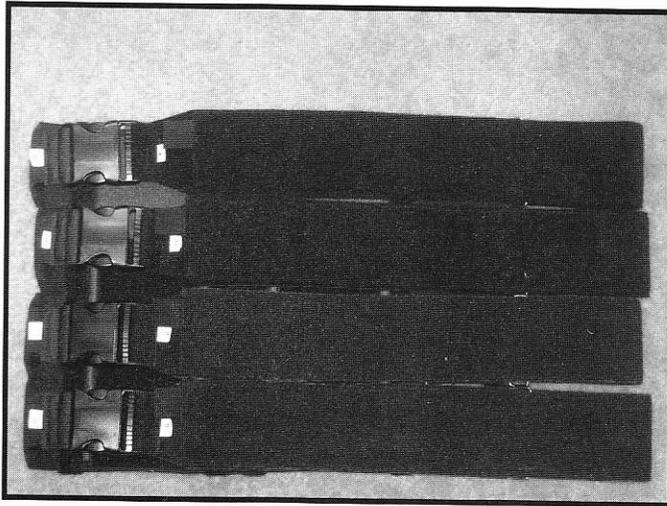


Figure 3 Four Buckles and Tightening Straps Labeled A, B, C and D

3. By pinching the buckles' sides, unclasp all four buckles. Extend outward (to the right) the four **Tightening Straps**; these are the three inch wide, soft pile Velcro® straps. Notice the two soft pile Velcro® sections sewn on both sides of the zipper. These will later on attach to the corresponding, "hook" Velcro® of the **Weighted Pouches** (Figure 4). In figure 4 you will also see a 2-3/4" by 4" hook Velcro® patch that is called a **Floaters**; each Torso Constrictor uses 4 Floaters.

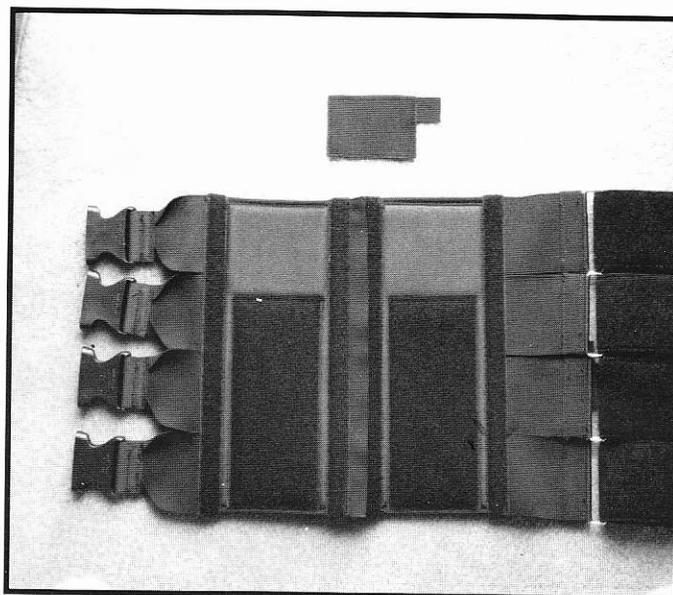


Figure 4 Open, Interior View of the Torso Constrictor, and Floater

4. To understand the way the Tightening Straps work, detach Strap “A” from its Floater. You will notice that it’s actually an independent strap that is threaded through a 3” **Metal Loop**. Pull the strap back and forth through the metal loop. This free-moving mechanism enables the four Tightening Straps to be adjusted to fit around a wide variety of body sizes. For instance, if you move the floater **away** from the plastic, buckle end, this will give you a longer strap to fit around a large physique. Conversely, if you move the Floater **towards** the buckle, this will result in an overall shorter strap that will fit smaller physiques. Now reattach Strap A and its floater to their original positions. The two, 3” by 3” **Elastic Sections** attached to each buckle and each metal loop also allows the constrictor to fit a wide variety of body shapes (See Figure 5).

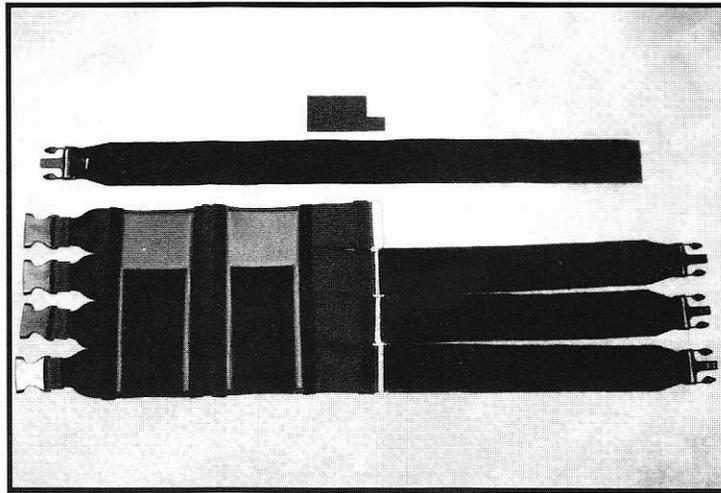


Figure 5 Tightening Strap A, and it’s Floater, detached from Constrictor

NOTE: The only time the floaters should be exposed is when adjusting or tightening the straps! Velcro® is **very** “sticky”! Maintaining the Tightening Straps in a connected position to their Floaters will prevent the straps from becoming a tangled mess!

Two Sizes of The Empathy Lungs™ Constrictors and “Cover-up” Shirts

The Torso Constrictors come in two sizes, which are quickly recognized by the color of the **6” Cord** on the Quick Release Zipper: **Yellow** is the Large size, and **Blue** is the Small size. Be sure to choose the appropriate size for the volunteer who will be wearing it; generally, they will fit individuals as follows:

- The **Large size** is designed to fit males and females who have a medium to very large build; use the **Navy Blue** color shirt (Sized as “2XL” on tag)
- The **Small size** fits males and females who have a very small or slender build, on up to those with a medium build; use the lighter, **Royal Blue** color shirt (Sized as “Large” on tag)

IMPORTANT!!! View the ½ hour, Demonstration Video Tape to see examples of questions to ask, and how to do effective role playing with The Empathy Lungs™

5-Minute Set-up in Advance of Demonstration

1. Lay out the 2 Torso Constrictors, interior sides face up and buckles detached, so that the 2 soft pile Velcro® sections are facing you.
2. Lay out the three, **5-lb. Weighted Pouches**: you will use two of these pouches for the LARGE size simulator, and one pouch for the SMALL size simulator.
3. Lay out the **Peak Flow Meter** included with the COPD Simulator; and position the meter's red arrow at the lowermost, zero mark. This meter, often used by Asthma patients, measures the Peak Expiratory Flow rate of the user. Also lay out at least two, unused disposable, **One-Way Valve Mouthpieces** ; each volunteer will use a new mouthpiece, and discard it after wearing the Simulator. These one-time use, disposable mouthpieces are designed to prevent any cross-contamination between multiple users of the Peak Flow Meter.
4. Lay out at least two of the custom-made, **Air Way Restriction Masks** included with the simulator. Just as with the disposable mouthpieces, each volunteer will use a new Air Way Mask, and discard it after wearing the simulator, thus preventing cross-contamination among users. IMPORTANT! Check to make sure that the two, circular, soft vinyl “flaps” are securely positioned on each side of the mask over the circular “5-holes” air vent.
5. Lay out the two, **“Cover-up” Shirts** (O.R. scrubs).

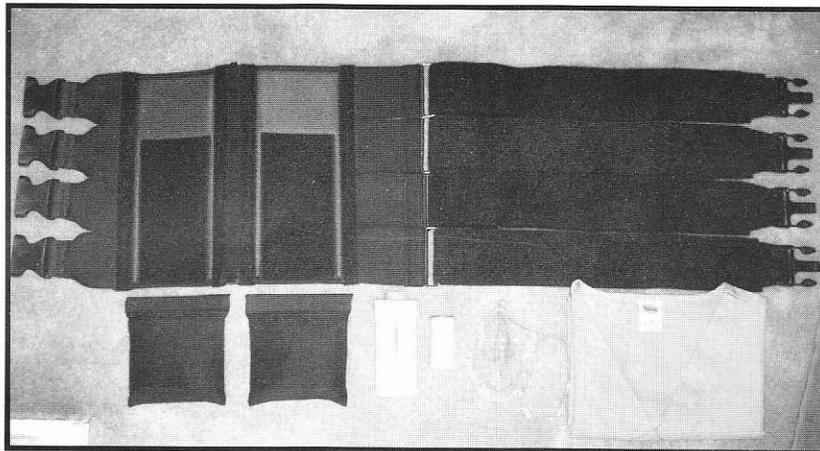


Figure 6 One Torso Constrictor and it's accessories laid out

NOTE: In addition to the above Simulator and it's accessories, you should lay out 1) at least two, Informed Consent Release Forms, 2) at least two Pamphlets, “The ABC’s of Smoking, and 3) at least two brochures from the National Lung Health Education Program. These will be given to each volunteer to read while they are wearing the Simulator.

Live Demonstration of The Empathy Lungs™

Time Required

In a medical office or a classroom setting, allow approximately 5 minutes to put on the various components of the Empathy Lungs™ on each patient or student.

1. Allow an additional 15 to 30 minutes for each volunteer to wear the simulator in order to achieve its full effects (unless the wearer elects to terminate the simulation by using the Quick Release Zipper).
2. Additional time should be allowed for follow up discussion, depending upon the facilitator's objectives and time available.
3. Future class meetings with the same group will require less time, since the full introduction and explanations won't be necessary. You will simply put the simulator(s) on another two students or patients.

Introduce The Empathy Lungs™

Briefly explain 1) how breathing works (see *flashcard* included) and 2) what The Empathy Lungs™ Simulator is, its purpose and benefits (see *Introduction*).

Select a Volunteer

1. When demonstrating the Empathy Lungs™, ask for a volunteer to wear it. Ask him/her to silently read and complete the **Informed Consent Release** form (see the *appendix*).
2. If the volunteer is a minor, the *Informed Consent Release* form must be completed by his/her parent or guardian prior to the demonstration. You should have already signed and dated the Supervising Instructor section on page 2 of the form.

Prepare the Volunteer

1. Examine and approve the volunteer's completed Informed Consent Release form to ensure that he/she has NOT checked "YES" to any of the medical conditions or health impairments itemized in the checklist on page one (1). ***IMPORTANT!*** If he/she has checked "yes" to any of the 13 items listed, then they should NOT wear the Empathy Lungs™!
2. Make sure the form has been signed and dated on the back by the volunteer (or by the parent or guardian if the volunteer is a minor).

3. Begin by having your volunteer take a deep breath and blow as hard as they can into the Peak Flow Meter. **Always use a new, disposable, One-Way Valve Mouthpiece per person** (See Figure 7).
4. Repeat the above step, and write down their highest peak expiratory flow measurement.

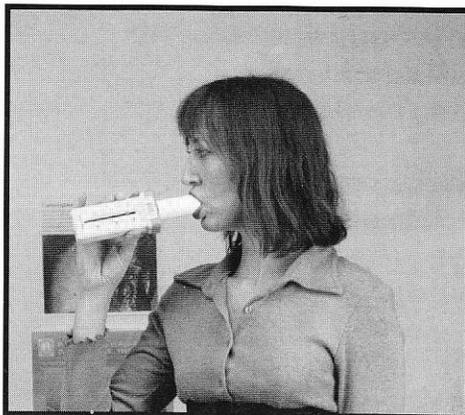


Figure 7 Volunteer blowing into the Peak Flow Meter

Install the three components of The Empathy Lungs™ on the Volunteer.

Note: As you install each component, ask the volunteer open-ended questions to find out what he/she is feeling, both physically and emotionally. Try to draw out the specific 8 symptoms presented in the introduction.

1. Have your volunteer hold the 2 weights (only 1 weight for the small simulator) over their abdomen, positioned just under their sternum and ribs. Ensure that the weight(s) is/are not on top of the ribs or the hips bones. As the instructor, estimate where to place and connect the weights onto the inside of the Torso Constrictor's soft pile Velcro® (figure 8).

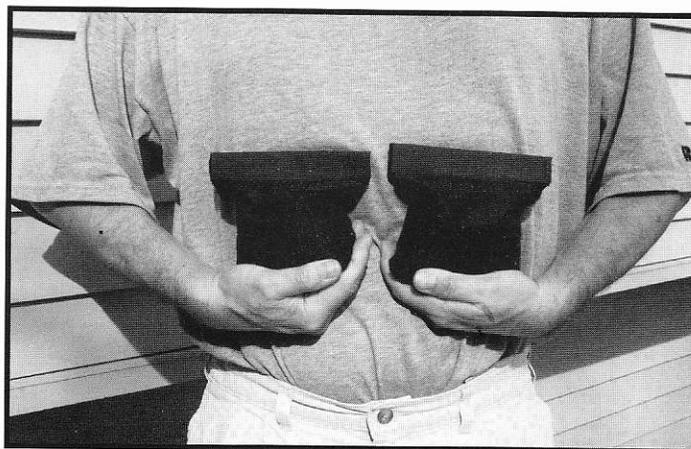


Figure 8 Volunteer correctly positioning the 2 weights

2. After you have connected the weight(s) onto the corresponding Velcro® of the Torso Constrictor, hold the simulator up to the volunteer's front torso, weights against their body and vinyl side facing you. Double check to be sure the weight(s) is/are over the upper abdomen and not over any lower ribs or hipbones; **reposition if necessary**.

Note: If your volunteer is male, tell him to position the bottom edge of the Torso Constrictor at his navel. If your volunteer is female, ask her to discreetly position the top edge of the Torso Constrictor just under (not over) her breasts.

3. Have the wearer hold up the Torso Constrictor (with attached weights) while you go to their back and buckle the bottom strap (D). Here is where you may need to adjust the length of the tightening strap with the floater (as explained in item #4 on page 6 of this manual).
4. After you have adjusted and buckled strap D, open the tightening strap and remove the floater. Pull on the end of the strap **very** firmly, locking the strap and floater into place about 1" from buckle. There may be excess strap depending on the size of the volunteer (See figure 9).

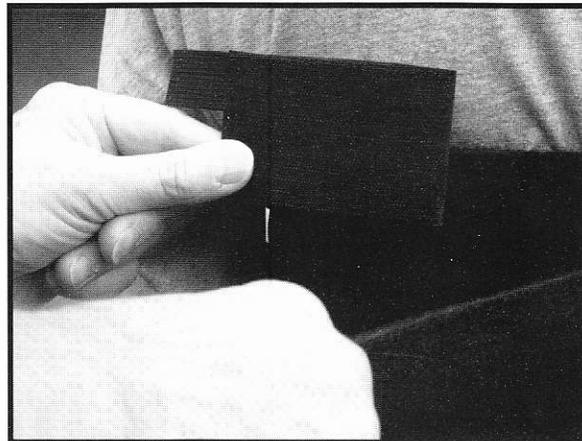


Figure 9 Positioning the strap and floater 1" from buckle

NOTE: After tightening the lower "D" strap snugly, the volunteer no longer needs to hold up the Torso Constrictor and weight(s).

5. Repeat step #4 (above) with the three, remaining Tightening Straps A through C.

***Congratulations! You now have the Torso Constrictor put on correctly!
Now its time to really tighten the straps!!***

Retightening the Straps

NOTE: Whenever you are tightening the straps of the Torso Constrictor, have your volunteer steady his or her self by holding on to the back of a chair, desk or table; have the volunteer stand with knees bent and feet apart to help maintain his/her balance.

1. Beginning with strap "D", again separate the tightening strap from the Velcro® floater, remove the floater and set it within reach. **It is essential that you now instruct the wearer to inhale deeply and exhale as completely as possible, totally emptying his/her lungs and pull in their abdominal muscles. Quickly pull the strap as tightly as you possibly can!** (See figure 10), and lock into place with the floater (See figure 11).
2. Repeat step #1 (above) in exactly the same manner with straps "A" through "C".



Figure 10 Pulling the strap as tightly as you can



Figure 11 Locking strap into place with floater

3. Now locate the two "**V-Wings**" at the front of the Torso Constrictor (Figure 12).

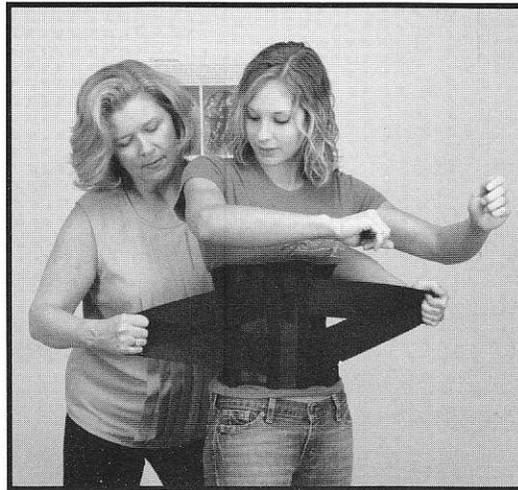


Figure 12 Locating the 2, elastic V-Wings

4. Just as you did with the 4 Tightening Straps, instruct the wearer to inhale deeply and exhale as completely as possible, totally emptying his/her lungs and pull in their abdominal muscles. Starting with the right side, quickly pull the V-Wing as tightly as you possibly can to the back of the Torso Constrictor and connect it to the soft pile Velcro® (See figure 13).

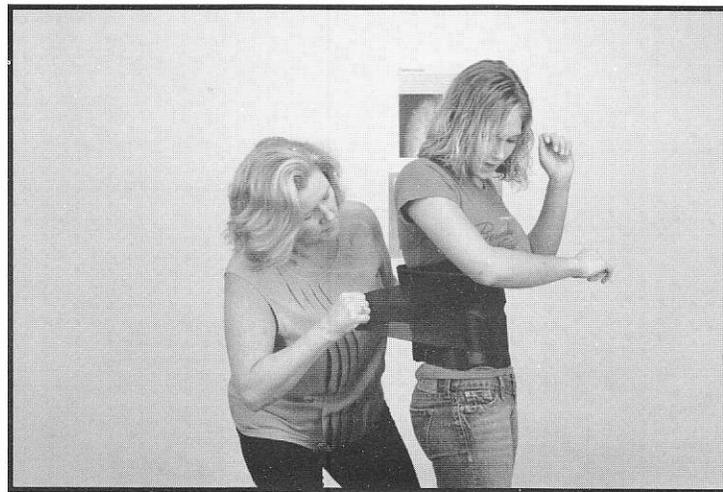
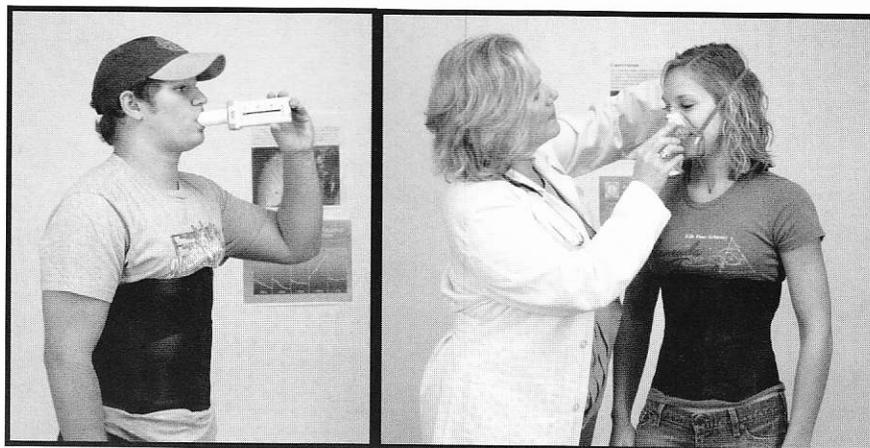


Figure 13 Pulling the right V-Wing and connecting to Velcro® at the back

5. Ask the volunteer to take another deep inhale and exhale and repeat step #4 (above) with the left V-Wing.

Note: When put on correctly, the volunteer should feel very uncomfortable, they should say they can only achieve “shallow, upper chest breathing”, or any of the other 8 symptoms typically simulated by The Empathy Lungs™. (See page 1 of this manual).

6. After resetting the Peak Flow Meter to zero, again have the volunteer take a deep breath and blow as hard as they can into it. If you have put the simulator on correctly there will typically be a reduction of 200 liters or more from their initial blow (See figure 14).
7. Now put an unused Disposable Air Way Restriction Mask on your volunteer. These masks are designed to be tightened at either the back of the head, or wrapped over the volunteer's ears and tightened under their chin. Have the volunteer pinch the metal nosepiece snugly over the bridge of their nose. Securely fit the bottom of the mask over the volunteer's chin (See figure 15).



*Figure 14 Re-Measuring Post
Peak Expiratory Flow Rate*

*Figure 15 Putting on the Disposable Air Way
Restriction Mask*

8. Give the volunteer the appropriately sized **Cover Up Shirt** to wear over the simulator. Briefly describing each hand-out, give the volunteer the pamphlet "**The ABC's of Smoking**" and the brochure from the National Lung Health Education Program which features "**The 20 Most Frequently Asked Q and A's About COPD**". Ask him/her to review these carefully while wearing the simulator.
9. Instruct the volunteer to continue wearing The Empathy Lungs™ for the next 15 to 30 minutes; tell them to remain either standing or pacing in order to bring out the full effects simulated by The Empathy Lungs™.

Take "The Empathy Lungs"™ COPD Simulator off of your volunteer.

1. Have the volunteer hold the simulator and weights as they did before you tightened the straps. Disconnect the tightening strap "D" from the Velcro® floater and **slowly** allow the strap to loosen. Reconnect the strap to its Velcro® floater.
2. Repeat this step with straps A, B and C. Now that the 4 straps are loosened, unbuckle them and have the volunteer gently set the simulator on a table.
3. Ask your volunteer and audience about their emotional reactions and insights regarding the impact of COPD on their daily lifestyle and values.

Appendix

- *Informed Consent Release Form*
- *Cleaning*
- *Replacement of Disposable Components*
- *Sewing Repairs, Lost or Worn Out Parts*
- *One-Year Limited Product Warranty*

INFORMED CONSENT RELEASE
for
“The Empathy Lungs”™ C.O.P.D. Simulator

Based on the results of extensive field testing, “The Empathy Lungs”™ C.O.P.D. Simulator (U.S. and Foreign Patents Pending) has been found to be a highly effective, beneficial and safe teaching aid when handled or worn by individuals who are in reasonably good health, and who behave in a correct and careful manner while handling or wearing this teaching aid. Since you (or your child) are being offered the educational opportunity to use The Empathy Lungs™, you are hereby provided with full information regarding this product’s intended and potential effects, benefits, avoidable risk factors, and reasonable precautions to be maintained while handling or wearing this product. **As a prerequisite to handling or wearing the Empathy Lungs™, carefully read and complete this form.**

“The Empathy Lungs”™ C.O.P.D. Simulator is a unique and powerful tool for smoking prevention and cessation. Intended for use only as serious teaching aid, it is comprised of a custom designed Torso Constrictor (a truss-like garment) that is strategically weighted -- and worn around the wearer’s torso – along with a customized Airway Mask which, when worn together will temporarily simulate the pronounced “shortness of breath” or “breathlessness” that characterizes **Chronic Obstructive Pulmonary Disease** (which is comprised primarily of Emphysema and/or Chronic Bronchitis), as well as that of Asthma, and Lung Cancer. This unique, hands-on simulator has been engineered for one-time, short term use of just fifteen to thirty minutes, during which time it will safely enable the wearer to physically experience COPD’s typically strenuous, labored, shallow, “upper-chest breathing only”, as well as the subsequent fatigue, irritability and emotional distress that inevitably results from the feeling of “not getting enough air”. Wearing The Empathy Lungs™ also measurably reduces the wearer’s lung capacity, as evidenced by the “before and after” measurements of their **Peak Expiratory Flow** rates; these **PEF** rates are quickly measured by an easy-to-use Peak Flow Meter (included). Such an experience invariably impacts the wearer with a realistic “sneak preview” of the eventual, debilitating effects of smoking, which is the primary cause of COPD -- currently affecting over 45 million patients as of 2005. COPD is the 4th leading cause of death in the U.S., and is projected to become the 3rd leading cause of death by 2020. Since The Empathy Lungs™ simulator can be worn by both males and females, ranging in age from 12 to 82, it finally gives teachers and medical professionals a hands-on, uniquely effective approach to motivate adolescents to never begin smoking, and to help current smokers gain an emotional “gut-level” determination to quit smoking for good. Furthermore, in many instances, wearing this simulator will motivate a smoker to finally go to their family physician for simple Spirometer testing that reveals their current lung function, and learn what practical changes they can make to preserve their remaining lung health. Handling or wearing The Empathy Lungs™ is to be done on a strictly voluntary basis, and will be done only while under the careful supervision of a trained and authorized instructor. Recommended wearing time is 15 to 30 minutes.

Individuals who weigh less than 100 pounds, or more than 300 pounds, should NOT use this device. Handling or wearing The Empathy Lungs might put individuals with certain medical conditions or pre-existing injuries at risk™. The following checklist is intended to help identify such individuals who might be put at risk, and who should therefore **NOT** use this device. If you (or your child) desire to handle or wear The Empathy Lungs™, **indicate here if you (or your child) currently have any of the following medical conditions or health impairments:** (Check either YES or NO)

	<u>YES</u>	<u>NO</u>
1. Confirmed pregnancy, or the possibility of pregnancy.....	_____	_____
2. Chronic back pain, or disorders of your back, spine, neck or pelvis including, but not limited to, scoliosis, sciatica, slipped or ruptured discs, etc.....	_____	_____
3. Any fractured or broken bones, especially of the ribcage, spinal vertebra, or pelvis.....	_____	_____
4. Any serious strains (muscle-tendon damage) or serious sprains (ligament damage) of torso....	_____	_____
5. Serious weakness or brittleness (e.g. osteoporosis) of your ribcage, neck, pelvis or spine.....	_____	_____
6. Dizziness, fainting, vertigo, or uncontrolled hypertension (high blood pressure).....	_____	_____
7. Uncontrolled symptoms of asthma, bronchitis, emphysema, lung cancer, or difficulty breathing.	_____	_____
8. History of heart problems or disease including, but not limited to, heart attack, stroke, angina...	_____	_____
9. Uncontrolled epilepsy or history of convulsions.....	_____	_____
10. Urinary tract or bladder disorders, weakness or infection.....	_____	_____
11. Any serious skin bruises, wounds, or recent scars on the front or back torso, or abdomen.....	_____	_____
12. Any serious weakness or disorder of your abdomen’s internal organs, including, but not limited to, hernia, enlargement of liver or spleen, colon disease, or serious abdominal infections.....	_____	_____
13. Any other medical condition for which your physician has advised you to avoid strenuous activity	_____	_____

(Continued)

WARNING: Handling or wearing of this product in the presence of any of the above conditions may cause them to get much worse or may cause injury. If you have answered YES to ANY of the above questions, or if you (or your child) have any other abnormal health condition that you believe might put you (or your child) at risk, then YOU (OR YOUR CHILD) ABSOLUTELY SHOULD NOT HANDLE OR WEAR The Empathy Lungs™ COPD Simulator.

The respiratory changes common in COPD (and in the simulation of COPD) naturally impose significant physical demands on the human body. While experiencing any strenuous activity, especially those involving the handling or wearing of weighted components, there is always the possibility of a strain-sprain injury, particularly if an individual does not behave cautiously. MISUSE of The Empathy Lungs™ could cause serious, permanent damage. Therefore, to minimize any risk of injury while wearing The Empathy Lungs™, **the wearer should understand and maintain the following precautions:**

1. **DO NOT** wear any component of The Empathy Lungs for more than 15 to 30 minutes.
2. **DO NOT** simultaneously twist side to side while bending over.
3. **DO NOT** make any abrupt, jerky or swift movements in any direction.
4. **DO NOT** bend over without bending knees (use squatting position).
5. **DO NOT** bounce, jump or run.
6. **DO NOT** act recklessly or frivolously.
7. **DO NOT** engage in any strenuous activity or over-exertion (standing and slow pacing are recommended).
8. **HANDLE CAREFULLY** all weighted components of this device at all times.
9. **IMMEDIATELY DISCONTINUE WEARING THIS DEVICE** (by using the device's release zipper) if you feel any sudden pain, dizziness, panic response, or other adverse effect. Consult a physician if necessary.

I have studied and understand all of the teacher training materials provided by the manufacturer concerning the correct, effective and safe usage of the teaching aid, "The Empathy Lungs"™ COPD Simulator. I have been specifically authorized as a qualified instructor to handle and demonstrate this device. I agree to follow all instructions and precautions of the manufacturer. I agree to carefully supervise the below named individual at all times while he/she is wearing The Empathy Lungs™.

Supervising Instructor's Printed Name Signature Date

I have read and understand the above description of "The Empathy Lungs"™ COPD Simulator, its intended and potential effects, benefits, avoidable risk factors, and the reasonable precautions to be maintained while wearing this teaching aid. I voluntarily agree (or permit my child) to wear The Empathy Lungs™ for purposes of my (or my child's) own benefit. I (or my child) agree to follow the instructions and precautions stated above. I assume all risk and liability for any injury or damage to me (or my child) that might arise out of my (or my child's) handling or wearing of The Empathy Lungs™. I hereby release and forever discharge the manufacturer of The Empathy Lungs, the purchaser and the instructor, from all claims of injuries or suits of any kind arising from my (or my child's) use of The Empathy Lungs™.

Wearer's Printed Name Signature Date
(Or if Minor, Signature of Parent/Legal Guardian)

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"The Empathy Lungs"™ C.O.P.D. Simulator

Cleaning

The fabric components of The Empathy Lungs™ can be cleaned according to the following instructions.

To clean the fabric side of the Weighted Pouches, or to clean the Torso Constrictor's vinyl surface, elastic straps, or soft pile Velcro® straps:

- Damp wipe only, using a mild soap if necessary
- Smooth by hand, dry flat, and air dry **thoroughly** before using or storing
- **DO NOT machine wash or machine tumble dry**
- **DO NOT iron, wring or twist**
- Pick out by hand any accumulated lint from the sharp, **hook** side of the Velcro®

To clean the “cover-up” shirts:

- Machine wash separately in cold water, on normal cycle
- To minimize fabric shrinkage, line dry, dry flat, or machine tumble dry on **low** heat
- Press with steam if needed

Replacement of Disposable Components:

Call the distributor from whom you purchased The Empathy Lungs™, or call the manufacturer Birthways Inc. at (800) 882-3559 or (206) 463-9572, if you wish to purchase any of the disposable components of The Empathy Lungs™, such as the:

- **One-Way Valve Mouthpieces** (Item #: 50-DM)
- **Custom-made, Airway Restriction Masks** (Item #: 50-DARM)
- **“The ABC’s of Smoking” Booklets** (Item #: 50-ABC)
- **Brochures from The National Lung Health Education Program** that contain “The 20 Most Frequently Asked Questions About COPD” (Item #: 50-NLHEP)

Sewing Repairs, Lost, or Worn Out Parts :

Call the manufacturer, Birthways Inc., at (800) 882-3559 or (206) 463-9572, to discuss the options available to you for repairs or replacement parts.

One-year Limited Product Warranty

This product is of the highest quality and is inspected twice before shipment. It is guaranteed against faulty or defective parts and/or workmanship for one (1) year from the date of the original purchase, provided the product has been used in strict accordance with the manufacturer's full directions for correct usage as supplied at the time of delivery. The manufacturer's only obligation shall be limited to the repair or replacement of the defective product. The manufacturer shall not be liable for any injury, loss or damage to person(s) or property, direct or consequential, arising out of the use or misuse of the product. The buyer shall determine the suitability of the product for the buyer's intended use, and the buyer assumes all risk and liability whatsoever in connection therewith.

**The Empathy Lungs™ C.O.P.D. Simulator
Teaching Module
(U.S. and Foreign Patents Pending)**

**Made in the U.S.A.
Manufactured by Birthways, Inc.**

Birthways, Inc.
P.O. Box 2069
Vashon, WA 98070-2269

Phone: (800) 882-3559
Or (206) 463-9572
Fax: (206) 463-6837

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