LungTrainer Models MD2 & MD3

INSTRUCTIONS FOR USE

These instructions contain important information for safe use of LungTrainer MD2 & MD3 Positive Exhalation Pressure (PEP) therapy devices. Read the entire contents of the Instructions for Use, including Warnings, Cautions, and Notes, before using this product. Failure to properly follow warnings, precautions, and instructions could result in injury to the patient. It is the responsibility of the healthcare practitioner to assure that the instructions for use and maintenance are understood by and provided to the patient and user.

CONTENTS

READ BEFORE USE: WARNINGS & PRECAUTIONS

WARNINGS

- Do not use the device without authorization from a healthcare professional and training outlined in this IFU. A safety hazard may result from operating the device without proper training. More training materials can be found online at:

  https://lungtrainers.com/pages/get-started-ltmd

- Breathing ability can vary among sick and healthy patients. The initial use of this device, it's frequency of use, therapy level advancement, and the maximum therapy level should be only by prescribed by a healthcare professional. This determination should be done by evaluating each individual patient for their respiratory capacity using the standard clinical methods before prescribing any therapy level.

- All patients must start therapy at the lowest level when using the device for the first time and only advance to the next highest level of therapy only when prescribed by a healthcare professional. All patients must demonstrate to the healthcare professional that they can perform the easiest level therapy prior to starting any therapy program without clinical supervision in a home environment. This confirms successful training and prescription is not too demanding for the patient. The device must not be used with more weighted inserts and/or for more time or repetitions than what is prescribed by a healthcare professional. Applying too high levels of breath pressure/flow to the device may result in adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients.

- Do not continue therapy if the patient experiences lightheadedness, fatigue, or other discomfort while using the device OR if the patient is not able to produce the effort required to complete the therapy session that was prescribed by the healthcare professional. This may result adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients. Contact your healthcare provider so that the prescribed therapy level can be adjusted.

- No modification of this equipment is allowed. This may cause an electrical hazard for the patient.

- Always inspect the device for damage and foreign objects and obstructions before use. Do not use the device if it has been damaged. This may result in a system malfunction and safety hazards to the patient. Contact Lung Trainers for repair of damaged devices

- Do not attempt to repair the device. There are no user repairable parts inside the device. This may lead to an electrical hazard to the patient

- Do not assemble, operate, or store the device in an area that is accessible to children or pets. The device contains small parts and tubes which may be a choking or strangulation hazard. Additionally, children or pets may damage the system in a way that may be a safety hazard to the patient.

- Do not use the device or any accessories past its expected service life. Doing so may cause a safety hazard for the patient.

- Remove any food or gum before using the device. Never operate the device with anything in the mouth. Doing so may cause a choking hazard for the patient. Always clean hands before use.

- Do not use the Mouthpiece / Air Regulator with Flexible Air Tube among multiple patients. The device is a MULTIPLE PATIENT USE system, however, the Mouthpiece / Air Regulator and Flexile Air Tube are SINGLE PATIENT, MULTI-USE accessories. Using these parts among multiple patients may pose a risk of infection.

- Do not place the device mouthpiece into the mouth. The mouthpiece is designed for use on the exterior of the mouth and lips. Placing the mouthpiece in the mouth may present a choking hazard for the patient.

- Always clean the device after every use according to the instructions found in this document. Failure to clean the device may result in patient injury.

- The components of the device must be thoroughly cleaned. Thorough cleaning includes ensuring that all surfaces are cleaned according to the instructions found in this document. Failure to thoroughly clean the device may pose a risk of infection to patients.

- Visually inspect all the components of the device after cleaning according to the instructions found in this document. If any device is determined not to be visually clean after cleaning, repeat the relevant specified cleaning process. If following the cleaning processes found in this manual do not result in the device being visibly clean, safely dispose of the device, so that a visibly soiled device is not used again. Removal of residual soil ensures the effectiveness of the cleaning processes and reduces the risk of infection to patients.

- Do not attempt to clean the device system by any method other than those listed in this Instructions for Use. Do not use alcohol for cleaning the device as it will deteriorate the acrylic components (i.e. acrylic case and acrylic chamber). Alternate cleaning methods or chemicals may damage the equipment and may pose a safety hazard.

- Do not use the device if interference with other medical devices is possible. If interference with other medical devices is observed, then discontinue use.

- Do not use the device adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) and other RF emitters should be used no closer than 30 cm (12 inches) to any part of the LungTrainer device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Some examples of RF emitters that are known sources of electromagnetic disturbance are RFID readers, security systems, metal detectors, medical scanners, radar systems, mobile phones, cordless phones, and microwave ovens. Note that some of these RF emitters may be concealed (e.g., RFID systems) and still electromagnetically interference with the device's operation without the user being aware. In the case that any device performance degradation is observed (improper functioning of counters, controls, or indicators), relocate the equipment to an environment further away from the interfering RF equipment.

- Do not use the device with or near active high frequency surgical equipment, MRI, x-ray, or any other equipment that has high level RF emissions or is sensitive to RF fields.

- Do not use batteries other than those specified or provided by Lung Trainers with this device. This could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Do not attempt to connect the device with any other equipment or power sources. This may cause an electrical hazard for the patient.

- Do not attempt to perform maintenance on the device or change the batteries while it is in use with a patient. Do not use the equipment while the back access cover is open.

- Do not to operate, transport, or store the device in an environment exceeding the ranges specified in the technical specifications. Operating, transporting, or storing the device in an environment exceeding these ranges may cause the device to malfunction or cause a fire hazard for the patient.

- Do not set up or operate the device close to thermal ignition sources. This may cause a fire hazard for the patient.

- Allow the device to adjust to ambient temperature (68°F, 20°C) before setup for 24hrs after exposure to maximum or minimum storage temperatures. Failure to do so may cause the device to malfunction or may cause a thermal hazard for the patient

- Do not assemble, store, or operate the device in direct sunlight, in water, near radiant heat sources, or in an area with excessive lint, dust, children, pets, or pet dander. Always store the device with the Chamber Cover installed. These may cause a malfunctions that may pose a safety hazard.

PRECAUTIONS

- Only use the device mouthpiece over intact healthy skin. Do not use the mouthpiece over broken or unhealthy skin. Do not continue to use the device if any contact injuries or skin abnormalities such as rashes, irritation, or allergic reactions are observed after contacting the accessible parts of the device. This could pose a dermatologically hazardous situation for the patient.

- Do not use the device if it is missing any parts or accessories. Verify all connections are securely in place (i.e. Mouthpiece / Air Regulator and Flexible Air Tube and properly connected to device) before use. Use of an incomplete or incorrectly assembled system may be a safety hazard to the patient.

- Do not operate the device without the check valve bearing installed. Operating the device without the check valve operational may result in an infection hazard for the patient.

- Do not operate the device without the Chamber Cover firmly installed. This can cause an impact hazard for the patient. Always store the device with the tube cover installed.

- Do not attempt to use any accessories, detachable parts, or materials that are not described in this document with the system. Only use those that are described in these instructions for use. The use of any others not specified by Lung Trainers may cause damage to the system or may be a safety hazard to the patient.

- Do not set up the device on an inclined surface. The device requires a flat surface to operate. This may cause a tip hazard for the patient.

- Do not attempt to move or transport the device unless it is configured into the transport position where the floor stand is adjusted to the lowest position off the ground. Attempting to move or transport the system when not in this position may result in overbalancing and may cause a hazardous situation for the patient.

- Always place weighted inserts with the flat side down on a surface so that they don't roll or slide. It is recommended that the unused weighted inserts are stored in the in the holders located on the top of the device. The weighted inserts are heavy and may cause injury if they fall on a person.

NOTES

- Do not drop or damage weighted inserts. Damage to a weighted insert, such as chipped edges caused by dropping an insert, will damage the interior walls of the acrylic chamber. Due to the tight tolerance between the acrylic chamber and inserts, any damage or obstruction will prevent proper performance of the device.
- Patients who use this device with an insufficient therapy program will not benefit from it's use over the long term. Patient progress should be monitored by a healthcare provider for best results.
- Remove batteries from the device if the device is not going to be used for an extended period of time.
- Contact Lung Trainers for assistance, if needed, in setting up, using or maintaining the system
- Contact Lung Trainers in the event of unexpected behavior with the device.

DESCRIPTION OF THE SYSTEM, USERS, & COMPONENTS

INDICATIONS / INTENDED USE

The LungTrainer is intended to be used as (1) an expiratory breathing exerciser for respiratory muscles, and (2) to be used as an expiratory resistance device, providing positive expiratory pressure (PEP) to substitute for pursed lip breathing and to assist in mucus clearance. The LungTrainer device is intended for use in patients ages 12 years and up in a clinical or home use environment.

GENERAL DESCRIPTION

The LungTrainer is a device that enables its patient users to manipulate air flow and air pressure. It is intended for use as a therapy device for increasing lung capacity. The LungTrainer promotes proper breathing support by focusing on increasing lung capacity and diaphragmatic breathing. It uses a system that combines air flow and resistance to engage the core breathing apparatus; including the diaphragm and lungs and assisting anatomy to develop strong breathing techniques.

The LungTrainer device is not intended to serve as replacement for the standard method of care for patients who require critical or life-threatening therapy for breathing problems. This device is designed for use by patients who do not require breathing assistance but seek to enhance their maximum expiratory pressure gradually over a longer period. Not attaining their prescribed target level of therapy while using this device will only result in diminished returns over time and will not lessen or diminish their initial capacity to breathe.

CONTRAINDICATIONS

The device is not to be used by patient with the following conditions:

- Cardiovascular compromised
- Congestive heart failure, congenic heart disease, or cardiac abnormalities
- Untreated cardiac pathologies
- Myocardial ischemia
- Pulmonary barotrauma
- Worsening COPD
- Increased intracranial pressure
- Tympanic membrane rupture
- Inner ear lesion or pathologies
- Pneumothorax
- Active hemoptysis
- Active upper respiratory infection
- Active trauma, untreated trauma, or patients recovering from surgery to the skull, face, or mouth

RISKS

Adverse events that can be experienced by any patient are the following:

- Slight Discomfort,
- Temporary Dizziness
- Temporary Lightheadedness
- Fatigue
- Headache

- Hyperventilation
- Syncope, fainting
- Barotrauma (pulmonary, ears, eyes, sinus, groin)
- Pneumothorax

The following adverse events can be experienced if used by cardiovascular compromised patients:

- Myocardial ischemia
- Decreased venous return
- For increase in the inspiratory lung volume, air swallowing could cause nausea or vomiting
- Claustrophobia
- Skin damage around the mouth or bruising from use of the mouthpiece

BENEFITS

Patients may experience the following benefit from using the LungTrainer device:

- Increased lung capacity
- Enhanced maximum expiratory breathing pressure

USE ENVIRONMENT & CONSIDERATIONS

The following describes the use environment for the LungTrainer MD2 & MD3:

- For hospital (clinical) and home use environment.
- Indoor use only.
- Multiple patient use device.
- Single patient use at a time.
- A different mouthpiece and tube is to be used with each different patient.
- Reusable mouthpiece with and tube are to be used with the same patient only.
- Temperature range: 5°C to 40°C.
- Relative humidity range: 15% to 93% ± 3% non-condensing.
- Ambient pressure range: 700hPa to 1,060hPa.
- Altitude: ≤2,000m.
- Ambient luminance range: 100 lx to 1,500 lx.
- Not for use in shower, tub, sink, sauna, swimming pool

USER DESCRIPTION, REQUIRED TRAINING, REQUIRED SKILLS & ABILITIES, REQUIRED MATERIALS

The device is intended for use in a hospital or home healthcare environment. The patient is the intended user of the device. The LungTrainer is designed so that the patient can safely use all functions of the device and perform all maintenance activities.

Warning: *Do not use the device without authorization from a healthcare professional and training outlined in this IFU. A safety hazard may result from operating the device without proper training. More training materials can be found online at:*

https://lungtrainers.com/pages/get-started-ltmd

Training must take place prior to the use of this device. This includes a complete review of this Instructions for Use document and the training videos found online at www.lungtainers.com. All patient users must be capable of following instructions for Positive Expiratory Pressure Therapy. Review the diagrams and the product to become familiar with all the product features.

The minimum user abilities required for the normal use and maintenance of the device include the following. Using the device while not meeting these requirements or without these cleaning & disinfecting materials may result in harm to the user and patient.

Patient & User Requirements:

- Patients must be 12 years of age or older.
- Patients and users must have vision corrected to at least 20/40.
- Patient and users must understand hygiene, cleaning with soap and water, and how to use commercially available disinfection products.
- Patient must have the strength & dexterity in one hand to grip the mouthpiece and put fingers over the air flow regulator holes.
- Patient and user must be able to lift a 15lb (4.5kg) weight.

Required Cleaning & Disinfecting Materials:

- Lint-free microfiber cloth,
- Sink or wash basin with source of tap water,
- Mild liquid dish detergent (ammonia-free),
- Metrex brand CaviCide™ liquid surface disinfectant (for clinical environments).
- Metrex brand CaviWipes™ Bleach disinfecting towelettes (for clinical environments).

Information or instructions regarding the proper installation or use of the device can be found by visiting:

https://lungtrainers.com/pages/get-started-ltmd

Or by emailing media@Lungtrainers.com or by calling +1-786-286-4744.

OPERATING PRINCIPLE

The device uses a purely mechanical and remarkably simple mode of operation to administer Positive Expiratory Pressure (PEP) treatment. A treatment session is accomplished by the patient user blowing into a mouthpiece connected to the device. The applied expiratory breath lifts precisely weighted inserts that can slide freely within a clear vertical tube (Chamber). A maximum of two or three weighted inserts can be stacked atop each other for different levels of treatment. The amount of expiratory air pressure required to lift the inserts increases with more inserts that are used.

The mouthpiece has an incorporated air regulator in the form of three precisely drilled holes that the patient can cover with their fingers while they blow into the device. Covering and uncovering these holes changes the amount of airflow required to lift the weighted inserts. Leaving all three holes uncovered requires the patient to provide more airflow to lift the weights while covering all holes decreases the amount of airflow required.

The combination of number of weighted inserts used and number of covered air holes determines the therapy level. All patients are instructed to start using the device at the lowest therapy level. The progression to higher therapy level (when to advance to a higher level) as well as the maximum therapy level for each individual patient is to be prescribed by a healthcare provider.

Therapy Level & Effort

Most exercises are developed for use with only one (1) weighted insert. At this level, the amount of exhalation needed to lift the insert would be that of engaging the 'belly' breathing (using the diaphragm) apparatus in the abdominal region. This would take the same amount of exhalation force that belly breathing, or light laughing would take. More strenuous exercises may be performed with the use of 2-3 inserts and additional open holes on the air regulator for more pressure and air flow, respectively.

The treatment series steps are as follow:

1. The patient blows into the device applying a prescribed and configured levels of pressure and airflow to lift the weighted inserts so that they hover roughly in the center of the vertical air chamber.
2. The patient continues to blow these levels for a desired or prescribed amount of time (seconds).
3. The patient releases the applied breath and rests for a prescribed amount of time (seconds).
4. The patient repeats the process for a prescribed number of repetitions (reps).

The levels of pressure (number of weighted inserts), airflow, hold time, rest time, and number of repetitions are all controlled by the patient, but must be prescribed by a medical professional.

LT Advisor Functionality

The LungTrainer device also incorporates the functionality of the optional LT Advisor. This functionality is provided in the form of a battery powered display that provides qualitative feedback for the patient to achieve optimal therapy results. This includes electronic timers that count elapsed seconds for exhalation time, resting time in between repetitions ("reps"), and a "rep" counter. This functionality also provides applied pressure feedback in the form of four LED's that illuminate at the approximate pressures that correspond to the number of weighted inserts used for therapy. The LT Advisor functionality is optional for use. The patient visually maintaining the weighted inserts in the approximate centered position I the vertical air chamber is what gives the patient a true indication that the therapy is being completed correctly.

MODEL DIFFERENCES AND SYSTEM COMPONENTS

The Lung Trainer Models covered in this instruction for use document are:

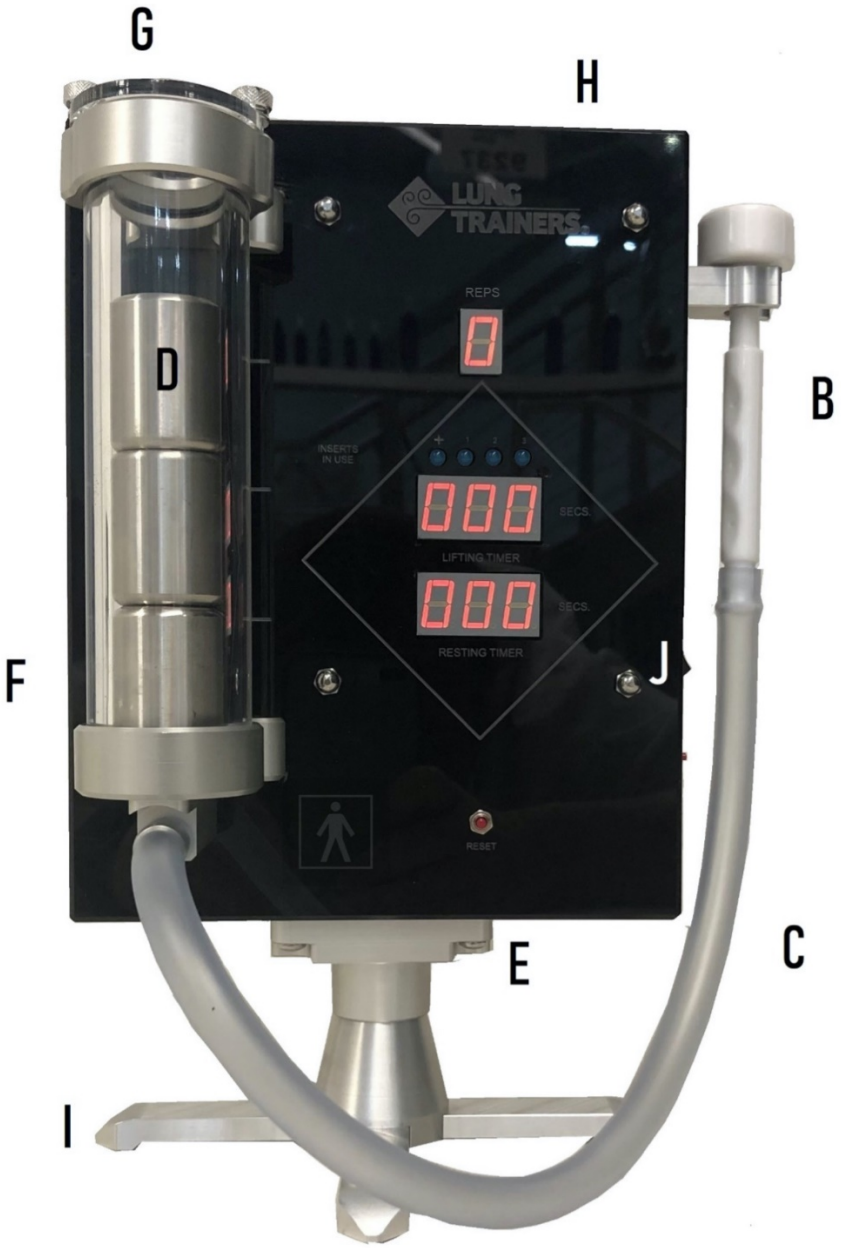
LungTrainer MD2
LungTrainer MD3

Where:

MD = “Medical Device”
Number 2 or 3 = Maximum number of weighted inserts

The device consists of the following (See following figures):

A. Device including Rep Counter, LED’s, Exhalation Timer, Resting Timer, Check Valve and Controls.
B. Mouthpiece / Air Regulator
C. Flexible Air Tube
D. Weighted Inserts (maximum two or three)
E. Floor stand to mount the Device. The floor stand height can be adjusted as desired by user (See following figures).
F. Vertical Chamber
G. Chamber Cover
H. Weighted Insert Holders
I. Table stand to mount the Device (this is an optional accessory, See Figure 3)
J. Power switch



LungTrainer Components
(See UNDERSTANDING THE LT ADVISOR CONTROLS & DISPLAYS section for explanations of controls & Displays.)

LungTrainer Device Mounted on Floor Stand,
Note Position of Hand Screws Identified with Red Arrows

POSITION OF OPERATOR / PATIENT & APPLIED PARTS

The device is to be setup according to the instructions found in this document. The patient is the operator of the device. The patient is intended to be seated or standing in front of and facing the device during use. The Device enclosure, Mouthpiece / Air Regulator, and Flexible Air Tube are the applied parts of the system.

Patient in Sitting Position (left) with the Table-Top Stand and
Patient in Standing Position (right) with the Floor Stand

FREQUENTLY USED FUNCTIONS

The following are the frequently used functions with the device:

1. Adjusting the height of the device
2. Installing & unloading the weighted inserts
3. Installing & uninstalling the mouthpiece and tube set.
4. Operating the device
5. Cleaning the device
6. Transport & storing the device
7. Maintaining the device

MATERIALS

The Mouthpiece / Air Regulator are made of medical grade materials that have been evaluated for biocompatibility according to the ISO 10993 family of standards for contact with intact skin for up to 24hrs.

Caution: *Only use the device mouthpiece over intact healthy skin. Do not use the mouthpiece over broken or unhealthy skin. Do not continue to use the device if any contact injuries or skin abnormalities such as rashes, irritation, or allergic reactions are observed after contacting the accessible parts of the device. This could pose a dermatologically hazardous situation for the patient.*

TECHNICAL SPECIFICATIONS

<table>
<tr><th colspan="2">Technical Specifications</th></tr>
<tr><td>Operating Conditions:</td><td>5°C to 40°C (41°F to 104°F), 15% to 93% RH ± 3%, 700hPa to 1,060hPa</td></tr>
<tr><td>Transport & Storage Conditions:</td><td>-25°C to 70°C (-13°F to 158°F), 0% to 93% RH ± 3%, 700hPa to 1,060hPa

Note: Allow the device to adjust to room temperature for 24hrs before use after bringing it out of storage or transport. Not doing this may cause a malfunction.</td></tr>
<tr><td>Power Ratings:</td><td>6Vdc (4 x AA Alkaline Batteries)</td></tr>
<tr><td>Battery Life:</td><td>1 month.

Note: When the LT Advisor counters and indicators start to dim, it is time to replace the batteries.</td></tr>
<tr><td>Product Service Life:</td><td>Device: 5 years
Mouthpiece / Air Regulator, Flexible Air Tube: 1 year</td></tr>
<tr><td>Dimensions & Weight:</td><td>Weight: 9lbs / 4.1kg (Device, Mouthpiece / Air Regulator, Flexible Air Tube, & Stand)
Dimensions: Device: 8” x 6” x 14”, Stand: 12” radius, 26-48” adjustable height.</td></tr>
<tr><td>Accuracy:</td><td>The pressure required to raise inserts increases as the number of inserts is increased and as more holes, or larger holes, are left open by the patient. For example, with all three holes of the regulator closed (i.e., X-X-X), the pressure required to lift the weights is:

<table>
<tr><th></th><th>1 insert (cmH2O)</th><th>1.5 inserts (cmH2O)</th><th>2 inserts (cmH2O)</th></tr>
<tr><td>Minimum Pressure</td><td>31.46</td><td>45.30</td><td>62.60</td></tr>
<tr><td>Maximum Pressure</td><td>35.20</td><td>52.20</td><td>71.43</td></tr>
<tr><td>Mean Pressure</td><td>33.28</td><td>48.28</td><td>66.63</td></tr>
<tr><td>Standard Deviation (SD)</td><td>0.82</td><td>1.84</td><td>1.98</td></tr>
</table>

There is no difference in variability of the MD2 and MD3 models, because both models have identical specifications with regard to inserts and inner diameter of the clear acrylic tube where inserts move up and down.

Accuracy of the timers used for the lifting timer and resting timer are +/-3 seconds in 60 seconds (i.e., +/-5%).</td></tr>
<tr><td>Applied Parts:</td><td>The device has the following type BF applied parts:

Device Enclosure & Controls
Device Stand
Mouthpiece / Air Regulator
Flexible Air Tube</td></tr>
<tr><td>Essential Performance:</td><td>The device provides no essential performance to the patient.</td></tr>
<tr><td>Special Installation & Storage Requirements:</td><td>The device must be installed on a flat surface only. The device must never be set up or stored near children or pets. Also, the device must be configured into a transport position before moving when using it with the floor stand. Failure to do these things may result in a tipping hazard. See Setup section for more information.</td></tr>
</table>

<table>
<tr>
<td>Replaceable Parts (Approved Accessories):</td>
<td>The following approved accessories are replaceable when they reach the end of their service life:

<table>
<tr><th>Approved Accessory Description</th><th>Approved Accessory Part Number</th></tr>
<tr><td>Mouthpiece / Air Regulator</td><td>Lung Trainers PN: IBA412001MP</td></tr>
<tr><td>Flexible Air Tube</td><td>Lung Trainers PN: IBA412002AT</td></tr>
<tr><td>Check Valve Ball Bearing</td><td>Lung Trainers PN: LTMD2012BBC</td></tr>
<tr><td>Floor Stand</td><td>On-Stage PN: SM7211B</td></tr>
<tr><td>Table Stand</td><td>Lung Trainers PN: LTPT2012TS</td></tr>
<tr><td>Batteries</td><td>N/A (AA Alkaline cells)</td></tr>
</table>

Warning: These parts must only be replaced with identical parts that have been identified in this manual. Improperly replacing these parts may result in a hazardous situation for the patient.</td>
</tr>
<tr>
<td>Cleaning Methods, Materials & Substances:</td>
<td>All cleaning and disinfection must be conducted according to the instructions forum in the CLEANING & DISINFECTION INSTRUCTIONS section of this document. The mouthpiece and hose must be cleaned with ammonia-free, mild liquid dish detergent, water after each use. When used in a clinical environment, the enclosure of the device must be cleaned and subjected to a low-level disinfection after use with each patient with a microfiber cloth, and treatment with Metrex brand CaviCide™ liquid surface disinfectant and Metrex brand CaviWipes™ Bleach disinfecting towelettes. The mouthpiece, hose, and device enclosure are to be cleaned according to the instructions after every use. The device has been designed with materials that will withstand cleaning for the expected service life of the device without degrading in a way that will affect safety or performance. If any cosmetic changes occur, consult the DEVICE SERVICING, MAINTENANCE, & DISPOSAL section of this document for replacement parts.

Warning: Do not attempt to clean the device system by any method other than those listed in this Instructions for Use. Do not use alcohol for cleaning the device as it will deteriorate the acrylic components (i.e. acrylic case and acrylic chamber). Alternate cleaning methods or chemicals may damage the equipment and may pose a safety hazard.</td>
</tr>
</table>

WIRELESS INFORMATION

This device is intended to be used in a hospital or home environment. This device does not provide any essential performance that can be lost or degraded due to EM disturbances.

Warning: *Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.*

Warning: *Use of accessories other than those specified or provided by Lung Trainers of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

Warning: *Do not use batteries other than those specified or provided by Lung Trainers with this device. This could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

Warning: *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) and other RF emitters should be used no closer than 30 cm (12 inches) to any part of the LungTrainer device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Some examples of RF emitters that are known sources of electromagnetic disturbance are RFID readers, security systems, metal detectors, medical scanners, radar systems, mobile phones, cordless phones, and microwave ovens. Note that some of these RF emitters may be concealed (e.g., RFID systems) and still electromagnetically interference with the device's operation without the user being aware. In the case that any device performance degradation is observed (improper functioning of counters, controls, or indicators), relocate the equipment to an environment further away from the interfering RF equipment.*

Warning: *The device should not be used with or near active high frequency surgical equipment, MRI, x-ray, or any other equipment that has high level RF emissions or is sensitive to RF fields.*

Warning: *Do not use the device if interference with other medical devices is possible. If interference with other medical devices is observed, then discontinue use.*

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including any interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the LungTrainer and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Interference may occur in the vicinity of equipment marked with the following symbol:

WIRELESS COMPLIANCE INFORMATION

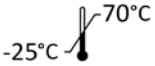
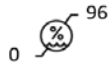
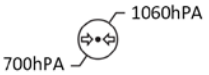
The following table shows the immunity test level for each immunity test and emissions compliance class and group that the device complies to:

Standards	Test Level
CISPR 11	Group 1, Class B
IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
IEC 61000-4-3	80MHz to 2.7Ghz at 10V/m Including proximity testing as per IEC 60601-1-2 clause 8.10
IEC 60601-1-2, Clause 8.10	Table 9

COMPLIANCE INFORMATION

Compliance Testing	
IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 & AAMI/IEC 60601-1:2005 + AMD 1:2012 & EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN ISO 10993-5:2009	Biological Evaluation: In Vitro Cytotoxicity
EN ISO 10993-10:2010	Biological Evaluation: Sensitization
EN ISO 10993-10:2010	Biological Evaluation: Intracutaneous Reactivity
EN ISO 14971:2019	Medical devices -Application of risk management to medical devices
IEC 62304:2006 & EN 62304:2006/A1:2015	Medical device software — Software life cycle processes
IEC 60601-1-11:2015 & EN 60601-1-11:2015	Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 62366-1:2015 & EN 62366:2008/EN 62366-1/2015	Medical devices — Part 1: Application of usability engineering to medical devices
UL 62368-1:2012 & EN 62366:2008/EN 62366-1/2015	Audio/video, information, and communication technology equipment - Part 1: Safety requirements
IEC 60601-1-6:2010 & EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-2:2014, 4th edition & EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
CISPR11 ed 5.0 (A1:2010)	Industrial, scientific, and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
FCC Part 15	Code of Federal Regulations – Part 15
FCC Part 18	Code of Federal Regulations – Part 18

CLASSIFICATIONS & SYMBOLS

Symbol Meanings & Classifications	
Type BF applied part (Mouthpiece / Air Regulator and Flexible Air Tube)	
Power switch: ON / OFF	I / O
Read the instructions before use	
Ingress protection rating: 2 particulate ingress, 2 water ingress	IP22
Minimum / maximum storage temperatures	
Minimum / maximum storage humidity	
Minimum / maximum atmospheric pressure	
Non-ionizing radiation	
Not for use in the vicinity of an MRI	
FCC compliance symbol	
Model Reference Number	
Serial number	
Prescription only	
Latex free	
Not provided sterile	
Manufacturer name & address	

DEVICE SETUP, DISSASSEMBLY, & TRANSPORT

Warning: *Do not assemble, operate, or store the device in an area that is accessible to children or pets. The device contains small parts and tubes which may be a choking or strangulation hazard. Additionally, children or pets may damage the system in a way that may be a safety hazard to the patient.*

Warning: *Do not assemble, store, or operate the device in direct sunlight, in water, near radiant heat sources, or in an area with excessive lint, dust, children, pets, or pet dander. Always store the device with the Chamber Cover installed. These may cause a malfunctions that may pose a safety hazard.*

Warning: *Do not set up or operate the device close to thermal ignition sources. This may cause a fire hazard for the patient.*

Warning: *Do not attempt to connect the device with any other equipment or power sources. This may cause an electrical hazard for the patient.*

Caution: *Do not attempt to transport the device unless it is configured into the transport position where the stand is adjusted to the lowest position off the ground. Attempting to move or transport the system when not in this position may result in overbalancing and may cause a hazardous situation for the patient.*

Caution: *Allow the device to adjust to ambient temperature (68F, 20°C) before setup for 24hrs after exposure to maximum or minimum storage temperatures. Failure to do so may cause the device to malfunction.*

Caution: *Do not drop or knock over the device. Doing so may cause damage to the device including, but not limited to, the acrylic casing, acrylic chamber, inserts, electronics displays, and/or other components and cause the device to malfunction.*

Caution: *Do not attempt to use any accessories, detachable parts, or materials that are not described in this document with the system. Only use those that are described in these instructions for use. The use of any others not specified by Lung Trainers may cause damage to the system or may be a safety hazard to the patient.*

Note: *Contact Lung Trainers if any assistance is needed in setting up, using, or maintaining the device.*

To setup the Device, simply follow the following steps.

ASSEMBLING THE FLOOR STAND

1. Place the floor or table stand in an area that is away from children and pets, radiant heat sources, and direct sunlight. Ensure that the surface is level.

Caution: *Do not set up the device on an inclined surface. The device requires a flat surface to operate. This may cause an impact hazard for the patient.*

2. If using the floor stand, turn lower knob on base stand counterclockwise to loosen and then extend the three legs outward as far as possible. See MODEL DIFFERENCES AND SYSTEM COMPONENTS Figure 2 for reference.

3. Place the stand on a flat level surface. If using the floor stand, tighten the lower knob by turning clockwise. Ensure that the stand is solid and secure before proceeding.

4. If using the floor stand, turn the upper knob on the floor stand counterclockwise to loosen and extend the pole upward to the desired height. The height of the Device should be approximately at eye level with the patient. Tighten the upper knob by turning clockwise. Ensure that it is secure before proceeding.

MOUNTING THE DEVICE TO THE STAND (BOTH FLOOR & TABLE STAND)

1. Mount the device to the floor or table stand by aligning the mounting hole on the bottom of the LungTrainer to the top of the stand's pole. Ensure that the top of the stand pole is seated as far as possible into the mounting bracket. For table stand, see MODEL DIFFERENCES AND SYSTEM COMPONENTS Figure 3 for reference.

2. Secure the device to the stand by tightening the thumbscrew on the back of the LungTrainer. Ensure that it is secure.

3. Once the device has been installed on the stand, ensure that the device powers on by switching the power switch from "O" to "I". Once switched to the on position, the LED displays should illuminate. Power off the device after performing this check.

Failure to Power On

If the device does not power on, check that the batteries were not dislodged during shipping, handling, or storage. Do this by following the instructions in the Device Servicing, Maintenance, & Disposal section and follow the steps for Replacing the Batteries. If the batteries are properly installed and the device still does not power on, or powers on and the displays are dim, then the batteries may need to be replaced.

ADJUSTING THE HEIGHT OF THE DEVICE WHEN USING THE FLOOR STAND

1. With the device mounted on the floor stand, ensure that the thumbscrew that fastens the device to the pole is tight.

2. Grip with one hand the vertical support pole just below the device.

3. With the other hand, slowly loosen the tightening screw that secures vertical support pole at the desired height. See MODEL DIFFERENCES AND SYSTEM COMPONENTS Figure 2 for reference.

4. Gently lift the vertical support pole to the desired height.

5. While still holding the pole in position, re-tighten the tightening screw that secures the floor stand into the desired height with the other hand.

INSTALLING THE CHECK VALVE BEARING

1. Gain access to the acrylic Chamber by sliding open the Chamber Cover. Do this by removing one (1) of the two Chamber Cover Screws by turning it counterclockwise. Once removed, place the removed thumbscrew to the side and do not lose. See MODEL DIFFERENCES AND SYSTEM COMPONENTS Figure 1 for reference.

2. Loosen, but do not remove, the second Chamber Cover Screw. This will allow the Chamber Cover to rotate freely. Rotate the Chamber Cover to the side so that the acrylic chamber is open and exposed. Remove the check valve bearing from its shipping packaging if it is installed and discard it.

3. The check valve bearing is a shiny metal ball. If it is not already installed, drop the check valve bearing into the vertical acrylic Chamber. Ensure that the bearing is seated properly in position at the lowest part of the metal cone in the Chamber Bottom Endcap.

4. Close the Chamber Cover by rotating it back to its original position. Then secure the Chamber Cover by replacing the thumbscrew and tightening in a clockwise motion. Be sure to tighten both (2) Chamber Cover Screws such that the Chamber Cover is secure to prevent ejection of any weighted insert(s). Do not to overtighten the Chamber Cover Screws.

Caution: *Do not operate the device without the check valve bearing installed. Operating the device without the check valve operational may result in an infection hazard for the patient.*

INSTALLING THE WEIGHTED INSERT(S)

1. Gain access to the acrylic Chamber by sliding open the Chamber Cover. Do this by removing one (1) of the two Chamber Cover Screws by turning it counterclockwise. Once removed, place the removed thumbscrew to the side and do not lose. See MODEL DIFFERENCES AND SYSTEM COMPONENTS Figure 1 for reference.

2. Loosen, but do not remove, the second thumbscrew. This will allow the Chamber Cover to rotate freely. Rotate the Chamber Cover to the side so that the top of the acrylic chamber is open and exposed.

3. Inspect the weighted insert and ensure that it is free from any dust, deformations, liquids and oils. Carefully take the insert in hand and drop it into the acrylic chamber.

Note: *Do not drop or damage weighted inserts. Damage to a weighted insert, such as chipped edges caused by dropping an insert, will damage the interior walls of the acrylic chamber. Due to the tight tolerance between the acrylic chamber and inserts, any damage or obstruction will prevent proper performance of the Device.*

4. Close the Chamber Cover by rotating it back to its original position. Then secure the Chamber Cover by replacing the thumbscrew and tightening in a clockwise motion. Be sure to tighten both (2) thumbscrews such that the Chamber Cover is secure to prevent ejection of any weighted insert(s). Do not overtighten the thumbscrews, as overtightening may break the acrylic Chamber Cover.

5. Place unused weighted insert(s) into holders on the top of the unit.

Caution: *Always place weighted inserts with the flat down on a surface so that they don't roll or slide. It is recommended that the unused weighted inserts are stored in the in the holders located on the top of the Device. The weighted inserts are heavy and may cause injury if they fall on a person.*

Caution: *Do not operate the device without the Chamber Cover firmly installed. This can cause an impact hazard for the patient. Always store the device with the tube cover installed.*

INSTALLING THE MOUTHPIECE, & TUBE

Caution: *Do not use the device if it is missing any parts or accessories. Verify all connections are securely in place (i.e. Mouthpiece / Air Regulator and Flexible Air Tube and properly connected to device) before use. Use of an incomplete or incorrectly assembled system may be a safety hazard to the patient.*

1. No parts of the device are not provided sterile and no parts are to be sterilized. Clean the Mouthpiece / Air Regulator, and flexible Air Tube kit prior to first time use. See CLEANING section of this document for instructions.

2. Grip the Flexible Air Tube with one hand and grip the device with the other.

3. Slide the tube onto the access point on the Chamber Bottom Endcap. Ensure that it is secure before proceeding.

4. Grip the other end of the Flexible Air Tube and slide it over the smaller end of the Mouthpiece / Air Regulator by pressing them together. Ensure that the connections are secure and air-tight before proceeding.

UNLOADING THE WEIGHTED INSERTS – METHOD 1: INVERSION (RECOMMENDED)

1. Remove any weights that are in the holders on the top of the device and place them on a flat surface with the flat side facing down so they do not roll.

Caution: *Always place weighted inserts with the flat down on a surface so that they don't roll or slide. It is recommended that the unused weighted inserts are stored in the in the holders located on the top of the Device. The weighted inserts are heavy and may cause injury if they fall on a person.*

2. Remove one (1) of the two thumbscrews, which secure the Chamber Cover at the top of the acrylic chamber, by turning it counterclockwise. Once removed, place the removed thumbscrew to the side and do not lose.

3. Loosen, but do not remove, the second thumbscrew. This will allow the Chamber Cover to rotate freely.

4. Rotate the Chamber Cover completely so that top of the acrylic chamber is completely exposed.

5. Loosen the thumbscrew that secures the device to the floor stand.

6. With two hands, carefully lift the device up from the floor stand.

7. Continue to hold the device with one hand, while taking the other hand and cupping it over the opening at the top of the acrylic chamber.

8. Taking extreme precaution not to drop a weighted insert, slowly tilt the device upside down so that the insert(s) slide down and out of the acrylic chamber, into the cupped hand. Carefully place the insert(s) safely down on a flat surface.

9. Ensure the check valve ball bearing is seated correctly at the bottom of the Chamber Bottom Endcap. If the check valve bearing becomes removed from the Chamber Bottom Endcap, re-install it according to the INSTALLING THE CHECK VALVE BEARING section.

10. Re-mount the device back on the floor stand and tighten the thumbscrew. Ensure that it is tight and secure.

11. Close the Chamber Cover by rotating it back to its original position. Then secure the Chamber Cover by replacing the thumbscrew and tightening in a clockwise motion. Be sure to tighten both (2) thumbscrews such that the Chamber Cover is secure to prevent ejection of any weighted insert(s).

UNLOADING THE WEIGHTED INSERTS – METHOD 2: EXHALATION (ADVANCED)

Advanced Unloading Method

This method for unloading/removing weighted inserts should only be used by (1) an individual who has previously used the device, (2) who is an experienced user, and (3) who is well coordinated and able to expertly control their air.

1. Remove one (1) of the two thumbscrews, which secure the Chamber Cover at the top of the acrylic chamber, by turning it counterclockwise. Place the removed thumbscrew to the side and do not lose.

2. Loosen, but do not remove, the second thumbscrew. This will allow the Chamber Cover to rotate freely.

3. Rotate the Chamber Cover completely so that top of the acrylic chamber is completely exposed.

4. Ensure that the Mouthpiece / Air Regulator, Flexible Air Tube are properly installed according to the previous section in these instructions.

5. Cage one hand over the opening at the top of the acrylic chamber.

6. Grip the Mouthpiece / Air Regulator with a free a free hand and position three fingers over the air regulator holes. Cover all the air regulator holes. Press firmly to cover holes completely to form a good seal.

7. Taking extreme precaution not to drop a weighted insert, gently blow into the Mouthpiece to lift the insert(s) up and out of the acrylic chamber, one at a time. Grip the weighted inserts as they come out of the tube with the caged hand over the opening.

Caution: *Do not place the weighted inserts on a surface so that they will roll or slide. It is recommended that the unused weighted inserts are stored in the in the holders located on the top of the device. The weighted inserts are heavy and may cause injury if they fall on a person.*

Note: *Do not drop or damage weighted inserts. Damage to a weighted insert, such as chipped edges caused by dropping an insert, will damage the interior walls of the acrylic chamber. Due to the tight tolerance between the acrylic chamber and inserts, any damage or obstruction will prevent proper performance of the device.*

8. Once the desired number of weighted inserts has been removed, close the Chamber Cover by rotating it back to its original position. Then secure the Chamber Cover by replacing the thumbscrew and tightening in a clockwise motion. Be sure to tighten both (2) thumbscrews such that the Chamber Cover is secure to prevent ejection of any weighted insert(s).

DISCONNECTING & DISASSEMBLING THE MOUTHPIECE / AIR REGULATOR FROM FLEXIBLE AIR TUBE

The Mouthpiece / Air Regulator, and Flexible Air Tube should be disconnected from the device and cleaned after a patient training session is complete. These parts should also be disassembled before storing the device. To do so, complete the following steps:

1. To begin, Follow the INSTALLING THE MOUTHPIECE, & TUBE section steps in reverse. Take the Flexible Air Tube by one hand, wrapping the fingers around the section closest to the end connected to the device.

2. With the other hand, grab the device enclosure for support. This will prevent the device from falling over and causing damage to the device while removing the Air Tube.

3. With both hands in place, gradually pull the tube until it disconnects from the device. (Use the thumb to disengage from the Chamber).

4. Using two hands, gently pull apart the mouthpiece and tube so that they are individual pieces.

5. If cleaning the device, see CLEANING INSTRUCTIONS section for the cleaning procedure.

SYSTEM SHUT DOWN, TRANSPORT & FLOOR STAND STORAGE POSITION

The device should be stored in a safe place after use. The device must be configured into transport and storage position before being moved when mounted to the floor stand.

Warning: *Do not to operate, transport, or store the device in an environment exceeding the ranges specified in the technical specifications. Operating, transporting, or storing the device in an environment exceeding these ranges may cause the device to malfunction or cause a hazardous situation for the patient.*

Warning: *Do not assemble, operate, or store the device in an area that is accessible to children or pets. The device contains small parts and tubes which may be a choking or strangulation hazard. Additionally, children or pets may damage the system in a way that may be a safety hazard to the patient.*

Warning: *Do not assemble, store, or operate the device in direct sunlight, in water, near radiant heat sources, or in an area with excessive lint, dust, children, pets, or pet dander. Always store the device with the Chamber Cover installed. These may cause a malfunctions that may pose a safety hazard.*

Caution: *Do not attempt to move or transport the system when using the floor stand unless it is configured into the transport position where the stand is adjusted to the lowest position off the ground. Attempting to move or transport the system when not in this position may result in overbalancing and may cause a hazardous impact for the patient.*

Note: *Remove batteries from the device if the device is not going to be used for some time.*

1. After the device is used for therapy, it should be powered down by moving the power switch to the “O” position. This will shut off the LT Advisor functionality and the displays will go dark.

2. With the device mounted on the floor stand, grip with one hand the vertical support pole just below the device to prevent it from falling.

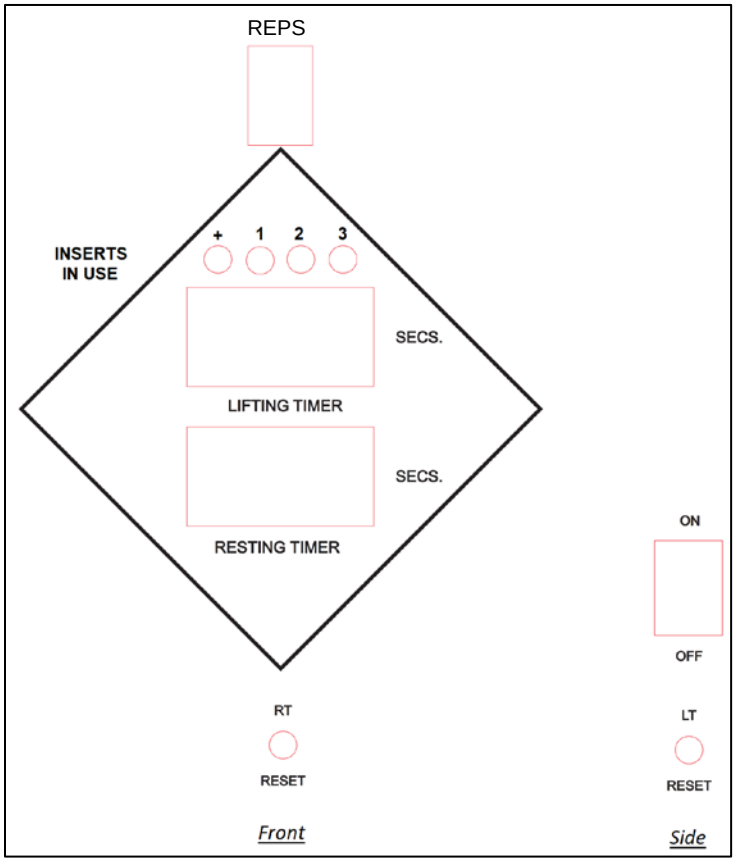
3. With the other hand, slowly loosen the knob that secures vertical support pole.

4. Slowly lower the floor stand to the lowest possible position.

5. Re-tighten the knob that secures floor stand into the desired height.

6. The device is now ready to move to a storage location

UNDERSTANDING THE LT ADVISOR CONTROLS & DISPLAYS



LT advisor displays & controls

REPS: This repetition counter increases in increments of one (1) once a patient's breath is detected. This is a single digit display that counts "reps". A rep is the application of patient breath, an exhalation hold time, and the removal of breath. This display provides the total number of "reps" that the patient has completed during a set. This number is increased by one every time the device senses the initial application of patient applied exhalation pressure. A patient may complete several reps in a therapy session.

INSERTS IN USE: These are four LED's that illuminate at pre-set pressure levels to provide feedback to the patient during therapy. The proper applied breath pressure will illuminate the LED that corresponds to the number of weighted inserts in use. The "+" LED illuminated when any breath pressure is detected. These are only intended to act as a guide for the patient. Proper applied exhalation pressure is determined by observing the position of the weighted inserts in the Chamber (they should hover approximately in the middle of the two air chamber brackets). The indicators are factory set to illuminate at specific pressure levels (See UNDERSTANDING PRESSURE USING WEIGHTED INSERTS AND LED LIGHTS section)

LIFTING TIMER: This timer shows the cumulative elapsed lift time for the training session in seconds. This is a three-digit timer that displays the patient exhalation time in seconds. This timer provides the patient a display of the cumulative exhalation time of all the completed reps. This display increases by one ever second once the device initially detects of the application of the patient's breath. This display stops increasing as soon as breath is removed. The Lifting Timer will once again continue to count upwards in one (1) second increases once pressure is once again detected in the tube (the start of the next set), adding to the last value that was displayed.

RESTING TIMER: This timer shows the elapsed resting time once a rep has been completed in seconds. This is a three-digit timer that displays the patient's resting time in seconds from the end of the last rep to the beginning of the next rep. This display increases by one every second and starts from zero once the device detects the removal of the patient's breath (the end of a rep). This display stops increasing as soon as breath is re-applied and is reset to zero (the beginning of a set).

LT RESET: This button resets the rep counter and the lifting timer back to zero.

RT RESET: This button stops the resting timer from counting and resets it to zero. After pressing this button, the counter will stay at zero, and no longer increases.

ON / OFF (I/O): This switch powers on and off the device.

GENERAL OPERATING INSTRUCTIONS

Warning: *Do not use the device without authorization from a healthcare professional and training outlined in this IFU. A safety hazard may result from operating the device without proper training. More training materials can be found online at:*

https://lungtrainers.com/pages/get-started-ltmd

Warning: *Breathing ability can vary among sick and healthy patients. The initial use of this device, it's frequency of use, therapy level advancement, and the maximum therapy level should be only by prescribed by a healthcare professional. This determination should be done by evaluating each individual patient for their respiratory capacity using the standard clinical methods before prescribing any therapy level.*

Warning: *All patients must start therapy at the lowest level when using the device for the first time and only advance to next highest level of therapy only when prescribed by a healthcare professional. All patients must demonstrate to the healthcare professional that they can perform the easiest level therapy prior to starting any therapy program without clinical supervision in a home environment. This confirms successful training and prescription is not too demanding for the patient. The device must not be used with more weighted inserts and/or for more time or repetitions than what is prescribed by a healthcare professional. Applying too high levels of breath pressure/flow to the device may result in adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients.*

Warning: *Do not continue therapy if the patient experiences lightheadedness, fatigue, or other discomfort while using the device OR if the patient is not able to produce the effort required to complete the therapy session that was prescribed by the healthcare professional. This may result adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients. Contact your healthcare provider so that the prescribed therapy level can be adjusted.*

The LungTrainer device is designed to gradually strengthen the patient's lungs by allowing for a controlled increase of required lung effort during therapy sessions. Effort is increased by configuring the device to require first more air flow and then more back pressure to lift the weighted inserts.

The combination of number of weighted inserts used and number of covered air holes determines the therapy level. All patients must start at the lowest therapy level and only advance to the next level after they have built up the lung strength to comfortably exert the amount of effort required to complete a therapy session without fatigue. When to advance to the next therapy level as well as the highest recommended therapy level is prescribed by a healthcare provider.

The following sections explain the following:

- How to hold the mouthpiece / air regulator
- How to operate the air regulator holes
- How the weights affect the therapy session
- How to configure the device for operation at the starting level
- When and how to advance to the next therapy level

STARTING THERAPY LEVEL CONFIGURATION

Warning: *All patients must start therapy at the lowest level when using the device for the first time and only advance to next highest level of therapy only when prescribed by a healthcare professional. All patients must demonstrate to the healthcare professional that they can perform the easiest level therapy prior to starting any therapy program without clinical supervision in a home environment. This confirms successful training and prescription is not too demanding for the patient. The device must not be used with more weighted inserts and/or for more time or repetitions than what is prescribed by a healthcare professional. Applying too high levels of breath pressure/flow to the device may result in adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients.*

All patients are to start using the device at the lowest therapy level which corresponds to the following setup configuration. The patient must demonstrate they can perform the easiest level therapy prescribed before they begin a therapy program without clinical supervision in a home environment. This confirms successful training and prescription is not too demanding for the patient.

Lowest Therapy Level Configuration

- One half-sized weighted insert only installed in the vertical air chamber, and
- All three air mouthpiece/ air regulator holes covered (see following sections for instructions)

The patient should use the device at this level for the time prescribed by a clinician. As the patient continues to use the device at this level, they will build lung strength and will be able to lift the weights for longer amounts of time. The patient shall only advance to the next therapy level when prescribed by a clinician.

The optional LT Advisor repetition counter and timers can be used to help track the approximate amount of lift time and rest time between repetition as well repetitions completed.

ADVANCING TO THE NEXT THERAPY LEVEL & MAXIMUM THERAPY LEVEL

Warning: *Breathing ability can vary among sick and healthy patients. The initial use of this device, it's frequency of use, therapy level advancement, and the maximum therapy level should be only by prescribed by a healthcare professional. This determination should be done by evaluating each individual patient for their respiratory capacity using the standard clinical methods before prescribing any therapy level.*

Note: *Patients who use this device with an insufficient therapy program will not benefit from it's use over the long term. Patient progress should be monitored by a healthcare provider for best results.*

Advancing a patient to a higher therapy level is only to be done at the time when prescribed by a clinician. Advancing to the next level is to be done by first by uncovering one additional hole on the air regulator.

When the patient needs to advance to the next therapy level after using the device at a therapy level with all the air regulator holes open, more weighted insert must into the vertical air column, and the device must be used with all air regulator holes must be covered. These steps should be followed until the maximum prescribed therapy level is attained.

The following steps describe the process of advancing to the next therapy level.

1. The patient shall initially use the device at the lowest therapy level at a frequency prescribed by a clinician (Example: Two therapy sessions a day, each consisting of 10 repetitions, 5 seconds lift time per repetition with all holes covered and ½ sized weighted insert).

2. Once the patient has used the devices for the prescribed amount of time and has achieved their target therapy level, they may advance to next level of therapy but only when prescribed by a clinician.

3. Advancing to the next therapy level is first done by opening (uncovering) an additional regulator hole to require more airflow to lift the weighted inserts. This should continue in the sequence shown in the diagram in the following section.

4. Once the patient is using the device with a certain number of weighted inserts and all the holes uncovered, the clinician may prescribe the patient to increase the therapy level by adding an additional half-weight (example: moving from a ½ sized weighted insert to a full-size weighted insert) and starting once again with all air regulator holes covered.

Examples of Therapy Level Advancement:

- If a patient is to advance to the next therapy level from the staring level configuration of all holes covered with one half-size weighted insert, the patient shall use the device with the same weighted insert and the hole closest to the mouthpiece uncovered.

- If a patient is to advance to the next therapy level from all holes open and one half-sized weighted insert, the patient shall remove the half sized weighted insert, replace it with a full-sized weighted insert, and use the device with all regulator holes covered.

- If a patient is to advance to the next therapy level from using the device with all holes open with one full-sized weighted insert, the patient shall add the half-sized weighted insert so that it is stacked on top of the full-sized weighted insert that is already installed, and use the device with all holes covered.

HOW TO HOLD & COVER THE MOUTHPIECE / AIR REGULATOR HOLES FOR EACH THERAPY LEVEL

The LungTrainer MD series of devices come with a Mouthpiece that has an incorporated Air Regulator. The mouthpiece is designed to be held by one hand (left or right) during a session but can be held in both hands if desired.

The patient must hold the mouthpiece in a way so that one fingertip can be placed over each hole during use. The patient must press firmly enough to cover holes completely to form a good seal to keep air from escaping while breathing into the mouthpiece.

To facilitate this, the mouthpiece has slight indentations to accommodate three of the patient's fingertips. Each hole is designed to be covered by one finger. It is not recommended that a patient cover more than one hole with one finger or cover the holes with other parts of the hand or other methods.

The suggested way of holding the mouthpiece with one hand while covering the holes is shown in the picture below. Level advancement is accomplished by lifting one additional finger as described in the previous section.

Holding the Mouthpiece with One Hand, Smallest Hole Open

OPERATING THE AIR REGULATOR (COVERING HOLES)

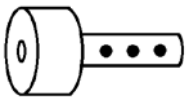
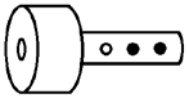
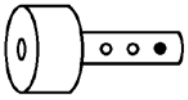
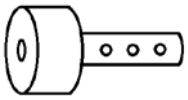
The mouthpiece has three precision molded regulator holes that can be covered with the fingers during use. Each hole is a different size and corresponds to a different level of required airflow from the patient. This affects the amount of exhalation effort required. The Air Regulator operates as follows:

- The lowest level of required effort results from covering all the holes with the tips of three fingers.
- Uncovering one additional hole will increase the amount of exhaled airflow necessary to advance to the next higher therapy level.
- Leaving all the regulator holes uncovered will require the most amount of effort to lift the weighted inserts that are installed in the vertical column.

Which Hole to Uncover to Advance Therapy Level

- *When uncovering the holes to advance to the next level of therapy, uncover them in sequence.*
- *Start with the smallest hole closest to the mouthpiece then the center hole, then the hole closest to the air hose.*

The figure below shows the different configurations that correspond to the available therapy levels (a higher airflow corresponds to a higher required amount patient effort corresponds to higher therapy level).

Required Airflow (Therapy Level)	Number of Open-Air Regulator Holes	
LOWEST ⇕ HIGHEST		**All Holes Covered**
		**1 Open Hole**
		**2 Open Holes**
		**3 Open Holes**

Regulator Holes vs. Therapy Level

NUMBER OF WEIGHTS DURING USE

When & How to Add More Weighted Inserts

- *Additional weighted inserts should be added for therapy only after advancing to the next therapy level with the air regulator holes first as prescribed by a clinician.*
- *Increasing the therapy level with the weighted inserts should be done in half sized weighted insert increments.*

The number of installed weighted inserts in the LungTrainer device's vertical air column determines the required amount of applied breath pressure to complete a therapy session. The required pressure increases as more weighted inserts are used.

Increasing weights should be done in ½ weight increments, but only when directed by a clinician. Do ONE of the following steps to increase weight:

- **Remove & Replace Weights:** Remove the existing weight(s) and replace it with a heavier weight, (Example, remove the ½ sized weighted insert, and replace it with one full size weight),

  OR

- **Add Weight:** Add an additional 1/2 sized weight on top of the installed weight(s) by simply stacking the additional weight on top of the weight that is currently installed in the vertical air column.

Choose whichever method to increase the amount of weighted inserts in the column by a ½ weight increment. See INSTALLING THE WEIGHTED INSERT(S) and UNLOADING THE WEIGHTED INSERTS sections for instructions on how to add or remove weighted inserts.

The LungTrainer MD series devices come with either two or three full-sized weighted inserts as well as a half-sized weighted insert. The maximum number of weighted inserts that can be used during a therapy session is listed below for each model:

Model	Maximum Number of Weights
MD2	2 full-sized weighted inserts
MD3	3 full-sized weighted inserts

COMPLETING A THERAPY SESSION

Warning: *Do not use the device without authorization from a healthcare professional and training outlined in this IFU. A safety hazard may result from operating the device without proper training. More training materials can be found online at:*

https://lungtrainers.com/pages/get-started-ltmd

Warning: *Breathing ability can vary among sick and healthy patients. The initial use of this device, it's frequency of use, therapy level advancement, and the maximum therapy level should be only by prescribed by a healthcare professional. This determination should be done by evaluating each individual patient for their respiratory capacity using the standard clinical methods before prescribing any therapy level.*

Warning: *All patients must start therapy at the lowest level when using the device for the first time and only advance to the next highest level of therapy only when prescribed by a healthcare professional. All patients must demonstrate to the healthcare professional that they can perform the easiest level therapy prior to starting any therapy program without clinical supervision in a home environment. This confirms successful training and prescription is not too demanding for the patient. The device must not be used with more weighted inserts and/or for more time or repetitions than what is prescribed by a healthcare professional. Applying too high levels of breath pressure/flow to the device may result in adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients.*

Warning: *Do not continue therapy if the patient experiences lightheadedness, fatigue, or other discomfort while using the device OR if the patient is not able to produce the effort required to complete the therapy session that was prescribed by the healthcare professional. This may result adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients. Contact your healthcare provider so that the prescribed therapy level can be adjusted.*

USING THE LUNGTRAINER DEVICE IN A CLINICAL ENVIRONMENT

Warning: *Do not use the Mouthpiece / Air Regulator with Flexible Air Tube among multiple patients. The device is a MULTIPLE PATIENT USE system, however, the Mouthpiece / Air Regulator and Flexile Air Tube are SINGLE PATIENT, MULTI-USE accessories. Using these parts among multiple patients may pose a risk of infection.*

When the LungTrainer device is used in a clinical environment, clinician or technician should take precautions to minimize chances of the device becoming cross contaminated by different users. The following guidelines must be observed:

- All LungTrainer device setup and configuration steps must be completed only by a clinician or technical staff while wearing protective gloves prior to use by a patient.
- The LungTrainer device controls (power switch and LT Advisor buttons) must only be touched and operated by the clinician or technical staff while wearing protective gloves.
- The patient must minimize contact with the device enclosure during use and should only handle the vertical air chamber if needed to best position the device.
- All cleaning and disinfection steps must be completed by the clinician or technical staff while wearing protective gloves immediately after each patient use according to the instructions found in the CLEANING & DISINFECTION INSTRUCTIONS section of this document.

THERAPY SESSION INSTRUCTIONS

Warning: *Always inspect the device for damage and foreign objects and obstructions before use. Do not use the device if it has been damaged. This may result in a system malfunction and safety hazards to the patient. Contact Lung Trainers for repair of damaged devices*

Warning: *Do not share the Mouthpiece / Air Regulator, Flexible Air Tube among multiple patients. The Device is a MULTIPLE PATIENT USE system, however, the Mouthpiece / Air Regulator, Flexible Air Tube are SINGLE PATIENT, MULTI-USE accessories.*

Warning: *Do not assemble, operate, or store the device in an area that is accessible to children or pets. The device contains small parts and tubes which may be a choking or strangulation hazard. Additionally, children or pets may damage the system in a way that may be a safety hazard to the patient.*

Warning: *Do not to operate, transport, or store the device in an environment exceeding the ranges specified in the technical specifications. Operating, transporting, or storing the device in an environment exceeding these ranges may cause the device to malfunction or cause a hazardous situation for the patient.*

Caution: *Do not use the device if it is missing any parts or accessories. Verify all connections are securely in place (i.e. Mouthpiece / Air Regulator and Flexible Air Tube and properly connected to device) before use. Use of an incomplete or incorrectly assembled system may be a safety hazard to the patient.*

The device is easy to use and simple to maintain. To complete a therapy session, the patient must simply follow the steps listed below.

1. Setup the device according to the instructs in this manual while paying attention to all the applicable warnings & cations. Configure the therapy level according to what was prescribed for the patient by the healthcare professional. If using the device for the first time, configure it to the Starting Level Configuration.

2. Face the assembled device in either a sitting or standing position. The device display should be as close to eye level with the patient as possible. The patient should be close enough to grab the mouthpiece and hold it to his/her mouth without the unit tipping.

3. Ensure that the check valve bearing is installed and that the proper number of weighted inserts have been installed into the Chamber and that the Chamber Cover is installed with the two thumbscrews firmly tightened in place. Consult the INSTALLING THE CHECK VALVE BEARING & INSTALLING THE WEIGHTED INSERTS sections in the previous section for instructions.

Caution: *Do not operate the device without the check valve bearing installed. Operating the device without the check valve operational may result in an infection hazard for the patient.*

Caution: *Do not operate the device without the Chamber Cover firmly installed. This can cause an impact hazard for the patient. Always store the device with the tube cover installed.*

4. Power on the device by pushing the on/off switch toward the ”I” position. The three digital number displays should illuminate and display all zeros.

Failure to Power On

If the device does not power on, check that the batteries were not dislodged during shipping, handling, or storage. Do this by following the instructions in the Device Servicing, Maintenance, & Disposal section and follow the steps for Replacing the Batteries. If the batteries are properly installed and the device still does not power on, or powers on and the displays are dim, then the batteries may need to be replaced.

To reset The LT Advisor after the device is being used after another patient or previous session, and the unit is already powered on, then do the following:

- *Press the LT Reset button, then*
- *Press the RT Reset button.*
- *Alternatively power off, then back on again.*

After pressing these buttons, the resting counter will display zero (0), and no longer increase, and the set and exhalation timers all display zero (0).

5. Grip the Mouthpiece / Air Regulator with a free hand and position three fingers over the air regulator holes. Cover only the number of holes for the desired level of therapy. Press firmly to cover holes completely to form a good seal.

6. Place the Mouthpiece / Air Regulator to the exterior of the mouth and lips and start to blow.

Warning: *Remove any food or gum before using the device. Never operate the device with anything in the mouth. Doing so may cause a choking hazard for the patient. Always clean hands before using the device.*

Warning: *Do not place the device mouthpiece into the mouth. The mouthpiece is designed for use on the exterior of the mouth and lips. Placing the mouthpiece in the mouth may present a choking hazard for the patient.*

Caution: *Only use the device mouthpiece over intact healthy skin. Do not use the mouthpiece over broken or unhealthy skin. Do not continue to use the device if any contact injuries or skin abnormalities such as rashes, irritation, or allergic reactions are observed after contacting the accessible parts of the device. This could pose a dermatologically hazardous situation for the patient.*

If the optional LT Advisor functionality is turned on, the following will be observed:

- *The left most blue LED + will illuminate to indicate that the device has detected the patient's breath and that a set is in progress.*
- *The set counter will increase by one as soon as the pressure is detected in the chamber.*
- *The Lift Timer will start counting upwards in one (1) second increments.*

7. Slowly exhale / blow in a controlled manner with more force until the weighted insert(s) begin to rise.

   Continue to maintain the amount of force necessary to raise the weights so that it (they) hover in place approximately in the middle of the vertical air Chamber in between the top and bottom metal brackets.

How Hard to Blow

- *Do not apply so much force that so that the weighted insert(s) lift to the point where they contact the Chamber Cover.*
- *If the weighted inserts contact the Chamber Cover, reduce force until it (they) hover in place in the middle of the Chamber.*

Continue to exhale / blow for the prescribed amount of time.

***Warning:** Do not continue therapy if the patient experiences lightheadedness, fatigue, or other discomfort while using the device OR if the patient is not able to produce the effort required to complete the therapy session that was prescribed by the healthcare professional. This may result adverse effects such as discomfort, fatigue, dizziness, syncope, or barotrauma like pneumothorax for some patients. Contact your healthcare provider so that the prescribed therapy level can be adjusted.*

8. Stop exhaling / blowing into the device to start the rest phase. Once exhalation pressure has stopped, the weighted insert(s) will slide down to the lowest level in the Chamber.

   If the optional LT Advisor functionality is turned on, the following will be observed:

   - *The left most blue LED + will no longer illuminate as soon as it has been detected that exhalation pressure has been removed.*
   - *The Lifting Timer will stop counting, and the Resting Timer will start counting upwards in increments of one (1) second.*

9. Once the prescribed amount of rest time has been reached, exhale / blow once again into the Mouthpiece / Air Regulator as before to start the next repetition.

   If the optional LT Advisor functionality is turned on, the following will be observed:

   - *The Resting Timer will return to zero,*
   - *The Lifting Timer will continue to count upwards in one (1) second increments once pressure is once again detected in the tube (and will display total cumulative time)*

10. Repeat the above steps until the prescribed number of repetitions and exhalation time has been completed.

LT Advisor Control Buttons

- *To reset the optional Resting Timer, press the RT Reset Button.*
- *To reset the Lift Timer counters, press the LT Reset buttons. Alternatively, the power switch can be turned to the off "O" position and then back to the on "I" position. This can be done at any time.*

USING THE OPTIONAL LT ADVISOR LED PRESSURE INDICATORS

When the device is used with the optional LT Advisor functionality enabled it provides applied breath pressure feedback to patient in the form of four blue LED's. The LED's are set to illuminate once an approximate pressure level has been detected that corresponds to the number of weighted inserts being used.

These LED's are intended to provide a general indication of real time pressure level to patient to indicate if more or less pressure is needed to be applied to lift the weighted inserts for PEP therapy to be as effective as possible. The use of these LEDs is optional and their meaning is described below:

Table A: Pressure & LED Indicator Illumination Meaning

LED	Meaning
Blue +	Patient breath expiration detected
Blue 1	Approximate pressure detected to lift 1 weighted insert
Blue 2	Approximate pressure detected to lift 2 weighted inserts
Blue 3	Approximate pressure detected to lift 3 weighted inserts

Pressure Indicator Accuracy

Slight variation may be observed among the LungTrainers MD-2 & MD-3 models concerning the required backpressure and airflow to lift the weights, the pressure levels at which the LED indicators illuminate, and the elapsed times indicated by the resting and lifting timers.

This variation may be due to the manufacturing process as well as differences in the ambient conditions (temperature, humidity, and barometric pressure of the environment) in which they are used.

The LungTrainer MD devices are intended to show relative improvement to the user when compared to their previous therapy session. As these devices are intended to provide only qualitative feedback related to the output of a therapy session (i.e. Better / Worse), no accuracy is claimed for these models. Any values indicated by these models should not be interpreted as an accurate quantitative measurement of a therapy session.

SHUT DOWN & STORAGE PROCEDURE

Once a patient therapy session has been completed, following the following steps to shut down the device and prepare it for storage.

1. If the LT Advisor functionality is enabled, power it off by pressing the switch into the ”O” position. The illuminated displays will no longer illuminate.

2. Follow the DISASSEMBLY procedure in the previous section to remove the Mouthpiece / Air Regulator and Flexible Air Tube from the device.

3. Follow the CLEANING AND DISINFECTING INSTRUCTIONS of this document to clean the device and accessories after every use.

4. Follow the TRANSPORT & STORAGE procedure in the previous section to store the device for later use if required.

Transport & Storage Conditions

-25°C to 70°C (-13°F to 158°F), 0% to 93% RH ± 3%, 700hPa to 1,060hPa

Allow the device to adjust to room temperature for 24hrs before use after bringing it out of storage or transport. Not doing this may cause a malfunction.

CLEANING & DISINFECTING INSTRUCTIONS

Warning: *Do not attempt to clean the device system by any method other than those listed in this Instructions for Use. Do not use alcohol for cleaning the device as it will deteriorate the acrylic components (i.e. acrylic case and acrylic chamber). Alternate cleaning methods or chemicals may damage the equipment and may pose a safety hazard.*

Warning: *Always clean the device after every use according to the instructions found in this document. Failure to clean the device may result in patient injury.*

Warning: *The components of the device must be thoroughly cleaned. Thorough cleaning includes ensuring that all surfaces are cleaned according to the instructions found in this document. Failure to thoroughly clean the device may pose a risk of infection to patients.*

Warning: *Visually inspect all the components of the device after cleaning according to the instructions found in this document. If any device is determined not to be visually clean after cleaning, repeat the relevant specified cleaning process. If following the cleaning processes found in this manual do not result in the device being visibly clean, safely dispose of the device, so that a visibly soiled device is not used again. Removal of residual soil ensures the effectiveness of the cleaning processes and reduces the risk of infection to patients.*

Caution: *Do not place the weighted inserts on a surface so that they will roll or slide. It is recommended that the unused weighted inserts are stored in the in the holders located on the top of the device. The weighted inserts are heavy and may cause an impact injury if they fall on a person.*

Note: *Do not drop or damage weighted inserts. Damage to a weighted insert, such as chipped edges caused by dropping an insert, will damage the interior walls of the acrylic chamber. Due to the tight tolerance between the acrylic chamber and inserts, any damage or obstruction will prevent proper performance of the device.*

CLEANING THE MOUTHPIECE / AIR REGULATOR & FLEXIBLE AIR TUBE

The device mouthpiece / regulator and air tube assembly are to be cleaned after the completion of each treatment session. These instructs apply to cleaning the device after use in a clinical environment as well as in a patient's home environment

To clean, follow these steps:

1. Detach the Mouthpiece / Air Regulator and Flexible Air Tube assembly from the Device following the disassembly instructions in the DEVICE SETUP, DISSASSEMBLY, & TRANSPORT section of this document.

2. Disassemble the mouthpiece and hose by pulling the tubes apart from the mouthpiece and inline valve. Do this pulling the tubes away from the barb fittings until they are all individual parts.

3. Prepare a clean sink or basin of soapy water. Use an ammonia-free, mild liquid dish detergent, mixing approximately two (2) tablespoons of detergent per one (1) gallon water.

4. Manually clean the mouthpiece and tubing sections by submerging them in the soapy water to remove all visible contaminants. Swirl all parts around for about five minutes.

5. Rinse each part thoroughly with clean tap water for one (1) minute. Shake out excess liquid from the mouthpiece and then place it in a normal resting position. Shake out excess liquid from the tube and hang it over a shower rod or a towel rack to ensure all the water drips out.

6. Allow the parts to air dry completely before re-assembling.

   If small amounts of water are still visible on the mouthpiece or tube after cleaning, shake them vigorously and allow them to completely dry before re-assembling them.

CLEANING THE DEVICE EXTERIOR, WEIGHTED INSERTS, & STAND

The device's exterior surfaces are to be cleaned after the completion of each patient treatment session. These instructs apply to cleaning the device after use in a clinical environment as well as in a patient's home environment. To clean follow these steps:

1. Detach the Mouthpiece / Air Regulator, Flexible Air Tube from the device following the disassembly instructions in the DEVICE SETUP, DISSASSEMBLY, & TRANSPORT section of this document.

2. Ensure that the vertical air chamber is tightly closed the by rotating the chamber cover back so that it is covering the top of the chamber. Ensure that it is secured by the two (2) thumbscrews and if necessary, tighten them in a clockwise motion.

3. Remove the uninstalled weighted inserts from the holders on the top of the device and place them on a hard flat surface.

4. Pre-clean the exterior surfaces of the uninstalled weighted inserts, acrylic casing, exterior of acrylic chamber, and the stand (table or floor stand) of the device using a clean dry lint-free microfiber cloth. Ensure that all visible contaminants have been removed.

5. Place unused weighted inserts into the holders on the top of the device when done.

DISINFECTING THE DEVICE EXTERIOR, WEIGHTED INSERTS, & STAND (CLINICAL ENVIRONMENT)

Understanding Disinfection

*The device is to be disinfected after the completion of each patient treatment session only when used in a clinical environment by following the **SPRAY – WIPE – SPRAY** methods described in this section.*

When used in a clinical environment, the device exterior is to be disinfected with the following **spray - wipe - spray** method after the completion of each patient treatment session.

To disinfect follow the following steps:

1. Follow the cleaning instructions of the previous section but do not place the unused weighted inserts into the holders on the top of the device when done.

2. Once cleaning has been completed, liberally spray all exterior surfaces of the uninstalled weighted inserts, acrylic casing, exterior of acrylic chamber, and the stand (table or floor stand) of the device with Metrex brand CaviCide™ liquid surface disinfectant. Completely saturate all areas that are handled during use such as the

entire surface of the vertical air chamber and aluminum brackets which can serve as a handle for positioning during use. Also saturate crevices, and difficult to reach areas including where the acrylic vertical air chamber meets the metal brackets, and the controls.

3. Allow the disinfected surfaces and weighted inserts to sit for a minimum of ten minutes.

4. Next, wipe the uninstalled weighted inserts, acrylic casing, exterior of acrylic chamber, and the stand (table or floor stand) with Metrex brand CaviWipes™ Bleach disinfecting towelettes. Again, ensure that the areas of the device that are handled during use are wiped such as the entire surface of the vertical air chamber and aluminum brackets which can serve as a handle for positioning. When done, immediately dispose of the used towelettes in accordance with Federal, State, and local regulations for infectious materials disposal.

5. Again, allow the disinfected surfaces and weighted inserts to sit for a minimum of ten minutes.

6. Finally, once again liberally spray all exterior surfaces of the uninstalled weighted inserts, acrylic casing, exterior of acrylic chamber, and the stand (table or floor stand) of the device with Metrex brand CaviCide™ liquid surface disinfectant. Completely saturate all areas that are handled during use are treated such as the entire surface of the vertical air chamber and aluminum brackets which can serve as a handle for positioning during use. Also saturate crevices, and difficult to reach areas including where the acrylic vertical air chamber meets the metal brackets, and the controls.

7. Again, allow the disinfected surfaces and weighted inserts to sit for a minimum of ten minutes.

8. After cleaning, allow all parts to completely dry. Any visible residue left behind by the disinfectants can be removed with a lint free microfiber cloth.

9. Place unused inserts into the holders on the top of the device.

DEVICE SERVICING, MAINTENANCE, & DISPOSAL

Warning: *No modification of this equipment is allowed. This may cause an electrical hazard for the patient*

Warning: *Do not attempt to repair the device. There are no user repairable parts inside the device. This may lead to an electrical hazard to the patient.*

Warning: *Do not attempt to connect the device with any other equipment or power sources. This may cause an electrical hazard for the patient.*

Warning: *Do not attempt to perform maintenance on the device or change the batteries while it is in use with a patient. Do not use the equipment while the back access cover is open.*

Warning: *Do not use batteries other than those specified or provided by Lung Trainers with this device. This could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

Note: *Remove batteries from the device if the device is not going to be used for an extended period of time.*

All personnel performing maintenance or service on the system must meet the requirements listed in the USER DESCRIPTION & TRAINING section of this document.

Inspect the device enclosure for the following and do not use the device if any of the following are observed:

- Vertical air chamber for cracks and damage before using,
- Ensure that all tubing fittings are secure and do not leak air, and
- Inspect the weights for chipped edges or deformations that would cause them to be obstructed in the acrylic chamber.

If any of the above is observed, contact LUNG TRAINERS, LLC for repair or replacement parts.

REPLACING THE MOUTHPIECE & TUBING SET

The Mouthpiece / Air Regulator, Flexible Air Tubing set must be replaced after 1 year of use. Only the specific designated replacement parts must be use with the device. To order replacements, contact Lung Trainers.

REPLACING BATTERIES

The device is powered by four (4) AA batteries. It is time to change the batteries when the digital displays start to dim, or the digital displays do not operate properly. To replace the batteries, do the following:

1. Remove the back-acrylic cover from the casing of the LungTrainer device. To do so, use a hex key screwdriver to unscrew the four (4) screws located in each of the four corners.

2. Remove the four (4) AA alkaline batteries by pulling the plus (+) end first from the battery compartment.

3. Insert four (4) new AA batteries, using the plus (+) and minus (-) guides in the AA battery pack battery compartment to insert the batteries in the proper direction. Be sure to insert the minus (-) end first when replacing the batteries in the battery compartment.

4. Secure the back-acrylic cover to the casing of the device using the four (4) screws and a hex key screwdriver.

REPAIR

> ***Warning:*** *Do not attempt to repair the device. There are no user repairable parts inside the device. This may lead to an electrical hazard to the patient*

There are no user serviceable or repairable parts in the device. In the case that the device requires repair or servicing, contact LUNG TRAINERS, LLC.

DISPOSAL & END OF SERVICE LIFE

The device and accessories must be disposed of after reaching the end of its service life in accordance with local laws and regulations concerning medical waste.

If desired, contact LUNG TRAINERS, LLC to receive a complimentary shipping label for return shipment and disposal of the LungTrainer.

EXPECTED SERVICE LIFE

> ***Warning:*** *Do not the device or any accessories after their expected service life. Doing so may cause a safety hazard for the patient.*

Assuming the manufacturer recommended cleaning protocol is followed, the device and approved accessories should have expected service lives as follows:

Approved Accessory Description	Approved Accessory Part Number	Expected Service Life
Device & Stand	LungTrainer MD2, MD3	5 Years
Mouthpiece / Air Regulator	IBA412001MP	1 year
Flexible Air Tube	IBA412002AT	1 year
Check Valve Bearing	LTMD2012BBC	5 Years

UNDERSTANDING PRESSURE USING WEIGHTED INSERTS AND LED LIGHTS

To understand how much pressure (cmH_2O) is required to lift a weighted insert(s) in the Acrylic Chamber using exhaled air, refer to Table A: Converting Weighted Inserts to Required Lift Pressure. To understand how much pressure (cmH_2O) is required in order to illuminate each LED on the device, refer to Table B: Converting LT Advisor Illuminated LED Lights to Detected Input Pressure.

Table A: Converting Weighted Inserts to Required Lift Pressure Using the Device with all Regulator Holes Closed)

No. of Weighted Inserts in Acrylic Chamber	Required Pressure PSI (±0.1psi)	Approx. Required Pressure cmH_2O
1	0.44 psi	38 cmH_2O
2	0.88 psi	73 cmH_2O
3	1.32 psi	108 cmH_2O

Table B: Converting LT Advisor Illuminated LED Lights to Detected Input Pressure (Using the Device with all Regulator Holes Closed)

LED	LED Illuminates at PSI (±0.1psi)	LED Illuminates at Approx. cmH_2O
Blue +	0.25 psi	18 cmH_2O
Blue 1	0.44 psi	38 cmH_2O
Blue 2	0.88 psi	73 cmH_2O
Blue 3	1.32 psi	108 cmH_2O

TROUBLESHOOTING

Problem	Resolution
The device does not power on when the power switch is activated.	Ensure that the internal AA batteries are properly seated.
	Replace the 4xAA alkaline batteries with new cells.
The weighted inserts do not rise when breath is applied to the mouthpiece.	Check the mouthpiece and tube for a tight and secure connection.
	Allow the device to acclimate to room temperature for 24 hours.
	Inspect the acrylic Chamber for obstructions or residues.
The acrylic Chamber tube is not large enough to install the weighted inserts into.	Allow the device to acclimate to room temperature for 24 hours.
Additional guidance for above problems, or any other problems.	Call LungTrainers Customer Service or email info@lungtrainers.com.

CONTACT INFORMATION

LUNG TRAINERS, LLC
8000 NW 7th Street, Suite 202
Miami, FL 33126, USA
Phone: +1-786-286-4744
www.LungTrainers.com
Email: info@LungTrainers.com