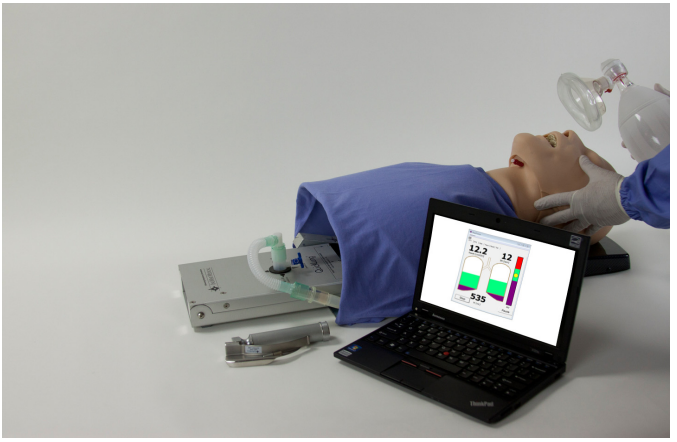
INGMAR MEDICAL

QuickLung®
RESPITRAINER
Advance

Manual Ventilation Task Trainer



USER'S MANUAL

Software 1.2

2nd edition 2014, © IngMar Medical, Ltd.

This page intentionally left blank

Legal Information

Product Warranty

Educational tools and test instruments manufactured or distributed by IngMar Medical Ltd. are fully warranted, covering materials and workmanship, for a period of one year from the date of shipment, except for products with stated warranties other than one year. IngMar Medical reserves the right to perform warranty service(s) at its factory, at an authorized repair station, or at the customer's installation.

IngMar Medical's obligations under this warranty are limited to repairs, or at IngMar Medical's option, replacement of any defective parts of our equipment, except fuses and batteries, without charge, if said defects occur during normal service. Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify both the model name and number, and the serial number as it appears on the equipment.

Improper use, mishandling, tampering with, or operation of the equipment without following specific operating instructions will void this warranty and release IngMar Medical from any further warranty obligations.

The above is the sole warranty provided by IngMar Medical, Ltd. No other warranty, expressed or implied, is intended. Representatives of IngMar Medical are not authorized to modify the terms of this warranty.

For factory repair service, call:

Toll free:	1-800-583-9910
International:	(412) 441-8228
Facsimile:	(412) 441-8404
or contact us via e-mail:	service@ingmarmed.com
Our shipping address:	IngMar Medical, Ltd. 5940 Baum Blvd. Pittsburgh, PA 15206 USA

Please note that a valid merchandise shipment authorization no. is always required before sending in any products for repair, calibrations, or updates.

Limitation of Liability
IngMar Medical Ltd.'s liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon above defined product warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to IngMar Medical, and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).
THE STATED EXPRESSED WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR NONINFRINGEMENT.
IngMar Medical, Ltd. shall not be liable for, nor shall buyer be entitled to recover, any special incidental or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

Trademarks
RespiTrainer™, RespiTrainer Advance™ and NeoLung™ are trademarks of IngMar Medical, Ltd.
QuickLung® is a registered trademark of IngMar Medical, Ltd.
Windows® and MS-DOS® are registered trademarks of Microsoft Corporation.
LabVIEW™ is a trademark of National Instruments Corporation.
Bluetooth is a trademark of the Bluetooth SIG, Inc. USA.
All other trademarks or registered trademarks are property of their respective owners.

Copyright

Software License Agreement

See also software envelope:

LICENSE AGREEMENT

DO NOT BREAK THE SEAL--UNTIL YOU CAREFULLY READ THE FOLLOWING TERMS AND CONDITIONS. OPENING THIS PACKAGE INDICATES THAT YOU, AS THE SINGLE END-USER, ACCEPT THESE TERMS AND CONDITIONS.

ENTIRE AGREEMENT
YOU ACKNOWLEDGE THAT YOU HAVE READ THIS AGREEMENT AND UNDERSTAND THIS AGREEMENT (THE "AGREEMENT") IS THE FINAL, COMPLETE AND EXCLUSIVE STATEMENT OF THE ENTIRE AGREEMENT BETWEEN INGMAR MEDICAL, LTD ("INGMAR") AND YOU. THIS AGREEMENT SUPERSEDES ANY PRIOR AND CONTEMPORANEOUS PROPOSALS, PURCHASE ORDERS, ADVERTISEMENTS, AND ALL OTHER COMMUNICATIONS IN RELATION TO THE SUBJECT MATTER OF THIS AGREEMENT, WHETHER ORAL OR WRITTEN. NO TERMS OR CONDITIONS, OTHER THAN THOSE CONTAINED IN THIS AGREEMENT, AND NO OTHER UNDERSTANDING OR AGREEMENT WHICH IN ANY WAY MODIFIES THESE TERMS AND CONDITIONS, SHALL BE BINDING UPON INGMAR UNLESS MADE BY A WRITTEN AGREEMENT, EXECUTED BY DULY AUTHORIZED REPRESENTATIVES OF BOTH INGMAR AND YOU.

SOFTWARE AND DOCUMENTATION LICENSE
1. IngMar hereby grants you a non-exclusive, non-transferable license to use the enclosed data acquisition and instrumentation software for the IngMar Medical RespiTrainer (the "Software") and any associated printed documentation (the "Documentation"), subject to the limitations set forth in this Agreement (the "License"). You may use the Software only on one central processing unit (Pocket PC or personal commputer) with one input terminal at any time. All right, title and interest to the Software and the Documentation are, and shall remain, in IngMar. You have no right of access to the source code of the Software. You are entitled to updates or upgrades of the Software or Documentation only as set forth in your purchase agreement for the RespiTrainer product.
2. You may not alter, assign, decompile, disassemble, distribute, lease, modify, reverse engineer, sublicense, transfer or translate in anyway the Software or Documentation except as provided in the following clause:
You may permanently and simultaneously transfer all of the Software, Documentation and the License if: a) you deliver to the transferee the Software and Documentation (including updates and upgrades) supplied by this Agreement; b) notify IngMar in writing of such transfer; and c) destroy any archival/backup copy. A transfer immediately terminates the License. You agree that the transferee must expressly accept all terms and conditions of this Agreement.
3. YOU MAY NOT COPY THE SOFTWARE OR DOCUMENTATION; provided, however, that you may make one (1) copy of the Software for archival/backup purposes.
4. If either the Software or Documentation is used in any way not expressly and specifically permitted by this License, then the License shall immediately terminate. Upon the termination of the License, you shall thereafter make no further use of the Software or Documentation, and you shall return to IngMar all licensed materials to IngMar, postage prepaid.
5. ANY SOFTWARE PROVIDED BY INGMAR MEDICAL IS NOT INTENDED TO BE USED FOR ACTUAL ANALYSIS AND DIAGNOSIS OF MEDICAL CONDITIONS OF HUMANS OR ANIMALS.

WARRANTIES
1. LIMITED WARRANTY ON MEDIA. For a period of thirty (30) days following the date of delivery to you as the original licensee, if evidenced by your receipt as such, (the "Warranty Period") IngMar warrants the media on which the Software is embodied to be free from defects in materials and workmanship under normal use. The warranty is personal to you, and no warranty is made to your transferees. THE FOREGOING WARRANTIES ARE THE SOLE WARRANTIES ON THE MEDIA AND ARE IN LEIU OF ALL OF WARRANTIES OF ANY KIND, SUCH AS WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.
2. NO WARRANTY ON SOFTWARE OR DOCUMENTATION. INGMAR LICENSES THE SOFTWARE AND DOCUMENTATION SOLELY ON AN "AS IS" BASIS WITHOUT WARRANTIES OF ANY KIND, SUCH AS WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. THE ENTIRE RISK OF QUALITY AND PERFORMANCE IS WITH YOU. IF EITHER THE SOFTWARE, DOCUMENTATION OR BOTH PROVE TO BE DEFECTIVE, YOU ASSUME THE ENTIRE COST OF ALL SERVICING, CORRECTION OR REPAIR.

REMEDY FOR DEFECTIVE MEDIA
Your sole and exclusive remedy in the event of a defect in a warranted item is expressly limited to replacement of the defective media. To receive a replacement media, you must send the defective media, with proof of purchase, to IngMar at the address indicated below, postage pre-paid and postmarked within the Warranty Period.
IN NO EVENT SHALL INGMAR BE LIABLE FOR ANY OTHER OBLIGATIONS OR LIABILITIES INCLUDING WITHOUT LIMITATION LIABILITY FOR DAMAGES (WHETHER GENERAL OR SPECIAL, DIRECT OR INDIRECT, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY), OR FOR ANY CLAIM FOR THE LOSS OF PROFITS, BUSINESS OR INFORMATION, OR DAMAGE TO GOOD WILL EVEN IF INGMAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN ANY EVENT, INGMAR'S MAXIMUM LIABILITY SHALL BE LIMITED TO THE AMOUNT OF THE PURCHASE PRICE.

U.S. GOVERNMENT RESTRICTED RIGHTS LEGEND
The Software and Documentation have been developed exclusively at private expense, and are provided with RESTRICTED RIGHTS. Use, duplication or disclosure by the Government is subject to restrictions as set forth in subparagraph (c) of the Rights in Technical Data and Computer Software clause at DFARS 252.227-7013 or subparagraphs (c) (1) and (2) of the Commercial Computer Software-Restricted Rights at 48 CFR 52.227-19, as applicable. IngMar is the Contractor, and is located at 4719 Liberty Ave, Suite 2, Pittsburgh, PA 15224.

EXPORT RESTRICTIONS
The program or underlying information or technology may not be installed or otherwise exported or re-exported where prohibited by law.

MISCELLANEOUS
This Agreement shall be considered severable, and if for any reason any term or condition is determined to be invalid, illegal or unenforceable under current or future law, such invalidity shall not impair the operation of, or otherwise effect, the valid terms and conditions of this Agreement, so long as the intent of this Agreement is maintained.
This Agreement shall be governed by, construed and enforced in accordance with the laws of the Commonwealth of Pennsylvania, with the exception of its conflict of law provisions. The parties consent to the personal jurisdiction of the Commonwealth of Pennsylvania and agree that any legal proceedings arising out of this Agreement shall be conducted solely in such Commonwealth.
No action, regardless of form, arising out of this Agreement may be brought by either party more than one (1) year after a claim has accrued.

This page intentionally left blank

Contents

1 Introduction

1.1 Operator Safety

For correct and effective use of the product it is mandatory to read and to observe all instructions, WARNINGS, and CAUTION statements in this manual. If the product is not used as instructed, the safety protection provided may be impaired.

1.2 Definitions

1.2.1 Warnings and Caution Statements

WARNING!

Indicates a potentially harmful condition that can lead to personal injury.

CAUTION!

Indicates a condition that may lead to equipment damage or malfunction

NOTE: Indicates points of particular interest or emphasis for more efficient or convenient operation.

1.2.2 Nomenclature

Throughout this manual and in the software, the word “patient” is used occasionally to describe a simulated patient as defined by the lung model settings. This will correspond to the use of “patient” in respiratory mechanics patient monitoring in that the lung model is a representation of a patient receiving ventilatory assistance.

Definitions of breath parameters as they are calculated in the RespiTrainer Software can be found under
"Parameter Definitions", page 43.

1.3 Typing Conventions

For easy recognition within a sentence, file names are typed in italic font, e.g.:

...\mobile device\program files\RespiTrainer\Respi.exe

Buttons and controls in the software user interface are designated with < ..>, e.g. :

<Start>

Items on the page selection bar on the bottom of the PC screen or on the task bar are indicated by use of a bold font, e.g.:

<Options>

2 Intended Use

The IngMar Medical® RespiTrainer Advance™ and RespiTrainer® Infant have been specifically designed to develop and maintain skills for manual bag-valve mask (BVM) ventilation and intubation/ insertion of laryngeal masks or combi-tubes. This device is intended exclusively for the training of medical professionals, and is suitable for all typical training environments (allied health care schools, simulation centers, EMS training, etc.) and for all skill levels, from novice to expert. Combined with the QuickLung® precision test lung, it constitutes a task trainer that can easily be adjusted to represent different pathological scenarios. It is intended to assist trainees with applying appropriate airway pressure, rhythm, and minute ventilation once an appropriate airway connection has been established.

The device is an easy-to-operate and reliable tool which can not only assist beginners to get a feeling for proper manual bag ventilation without real patient exposure, but also is helpful when seasoned medical staff is working to improve the efficiency of their bagging technique.

WARNING!

Do not use RespiTrainer Advance as a patient monitoring device!

Background: Teaching the proper way of providing manual ventilation is particularly important, since recent studies have shown that ventilation is often not adequate and appropriate during resuscitation even when performed by seasoned staff.
Another point is the manual ventilation of children or infants, where it is of even more importance to not exceed the volume or pressure limits.

It is therefore mandatory to always follow approved guidelines and procedures for basic life support and manual ventilation.

IngMar Medical, Ltd. does not recommend any specific certification test for manual ventilation performed by medical staff and no portion of these instructions shall be construed as doing so.

2.1 Applications

2.1.1 Training and Certification of Medical Personnel (Paramedic/ EMT/nurse/respiratory therapist/ physician)

A primary application of the RespiTrainer Advance is the training of medical staff in the specialty of respiratory care. While not eliminating the need for learning from contact with real human patients and related special challenges, IngMar Medical's RespiTrainer Advance assists in delivering a number of teaching points critical to the proper performance of manual ventilation.

- Placing the head of an unconscious person into the "sniffing position" to open the airway.
- C-grip technique: Utilizing the TruCorp RespiTrainer Advance airway management training head, the RespiTrainer Advance allows the user to practice in a realistic fashion the correct grip for pressing the mask onto the face, including chin lift with both ring and little finger.
- Properly placing a laryngeal mask (LMA) when trying to provide added reliability to the interface between patient and bag
- Practicing the procedure of intubating a patient
- Manual ventilation management (correct pressure, inflation time, volume, and frequency): The RespiTrainer software provides real-time feedback on the PC for acquiring skills and learning proper technique, including a warning for excessive pressures that cause stomach insufflations.
- For certification testing within a timed framework, the software can also be used without showing performance feedback to the

student, but giving the teacher a summary of results of the timed test (see "Results" on page 31).

2.1.2 Classroom Instruction

With the PC software, it is also possible to run a RespiTrainer Advance in a classroom and sending the data to a large display or projector, so that a larger group of students may watch the performance simultaneously.

2.1.3 Validating / Changing Trained Habits of Experienced Staff

As recent studies show, the ventilation technique of seasoned medical staff frequently is not appropriate to the newest guidelines, a finding with the possibility of profound implications for the patient.

Additionally, as medical science evolves, guidelines for manual ventilation techniques may be reconsidered from time to time. It is quite difficult to adapt to new guidelines, especially in stress situations, if you have practiced a manual task in a particular way for many years. Changing trained habits, therefore, becomes an important application for a task simulator such as the RespiTrainer Advance.

3 Description

3.1 Overview

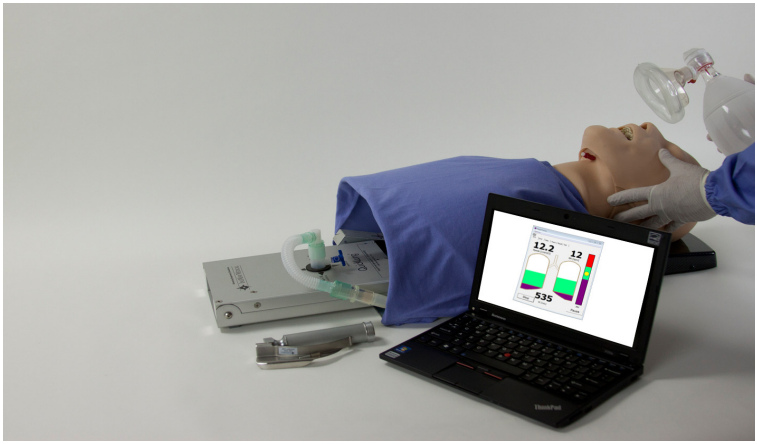


Figure 3-1

The IngMar Medical RespiTrainer Advance system consists of three main components, which are:

1) the lung model (QuickLung®),
2) the RespiTrainer Base integrated into the patient interface (intubation trainer/mannekin head), and
3) a notebook PC running Windows 7.

In addition, a resuscitation bag (not included) is needed for intended operation, as well as the medical instruments for patient intubation (laryngoscope, ET-tube, and LMA, not included).

Description

Overview

The precision test lung used is the IngMar Medical QuickLung®, which features linear response and the possibility to make reproducible changes in the resistance and compliance parameters. For further information regarding the operation of this component, please see the “QuickLung Precision Lung Model: User Quick Reference” (included) as well as the Quick Reference basic instructions printed on the bottom the QuickLung device itself. The optional leak setting must be in the OFF position for accurate volume calculations in the PC software.

For neonatal patient settings (C = 3 cmH_2O, R = 50 $cmH_2O/L/s$), the RespiTrainer infant can be ordered separately.

t should be used with both leak settings in the OFF position. Air will escape otherwise.

The RespiTrainer Base integrated into the RespiTrainer allows for capturing data in a realistic scenario for the assessment of skill levels of medical trained professionals. This helps to produce a realistic scenario for medically trained professionals. The RespiTrainer Advance requires the trainee to first bring the head into the “sniffing position” before beginning with the resuscitation. If this is not done properly, the system will generate a respective message in the software interface, but also present a significantly higher mechanical airway resistance simulating a (blocked airway), in this fashion providing feedback to the trainee if this maneuver is not performed. **Note:** This feature is not included in the newest RespiTrainer Infant models.

The PC receives data from measurements via Bluetooth from the Acquisition Module and performs the calculations for the different performance parameters. There are several screens showing the effectiveness of the artificial ventilation (see "Data Display", page 34).

NOTE: The software features and operation PC version of the RespiTrainer Advance conforms to the standard convention of menu selections at the top of an application window.

NOTE: The RespiTrainer software installed on a Windows PC may be used with either the Infant version of the RespiTrainer or with the RespiTrainer Advance. Both devices share the same data format and software-related feature set.

4 Operation

4.1 Setup for RespiTrainer Advance

Prerequisites
Bluetooth capable PC running Windows.

Carefully remove components from the soft-sided carrying case or hard case. Place QuickLung at the “neck end” of the head. Use the swiveling elbow connector (the optional leak adapter connector) on the QuickLung for unobstructed settings of Resistance. Make sure that the leak setting is turned off at this time.

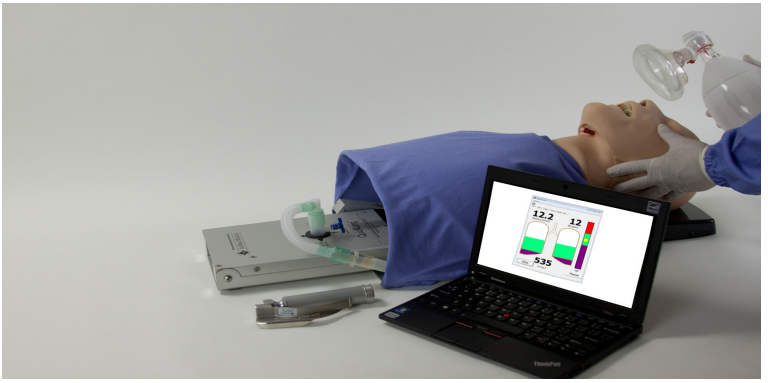


Figure 4-1

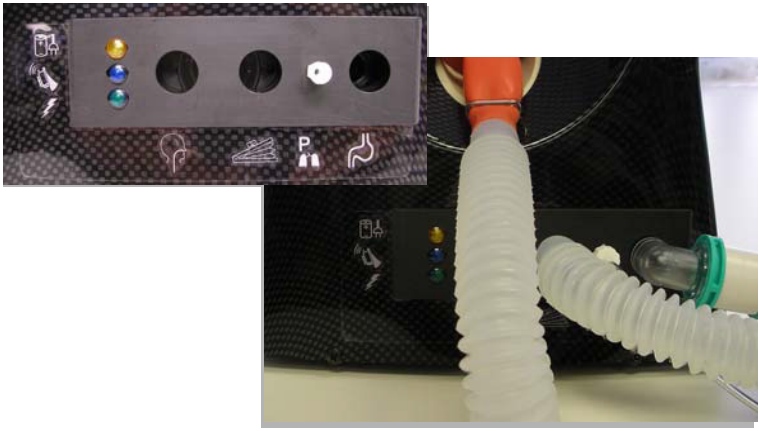


Figure 4-2

Make the following connections (please refer to Figure 4-2):

- Pressure line from the bottom panel of the QuickLung to the Lung Pressure port on RespiTrainer Base,
- 15 mm patient circuit from neck of mannekin head to port labeled on RespiTrainer Base,
- 15 mm patient circuit from QuickLung swivel connector to port labeled on RespiTrainer Base,
- "stomach bag" with 15mm connector elbow to port on RespiTrainer Base.

To charge the NiMH battery in the data acquisition system as needed, connect 12V table top power supply to line power and plug the small connector into the DC input socket on the RespiTrainer Base as needed.
If the battery has been significantly depleted, an orange LED on the RespiTrainer Base will light, indicating the system is in rapid charging mode. After the battery is mostly charged, trickle charging will continue, but the orange LED will be off.

Setup for RespiTrainer Advance

If you acquired your PC through IngMar Medical, and the software was already preloaded, you are now ready to use the PC.

Switch RespiTrainer Advance ON with the switch on the RespiTrainer Base. Next, power on your PC and verify the external Bluetooth adapter is plugged into one of the USB ports.

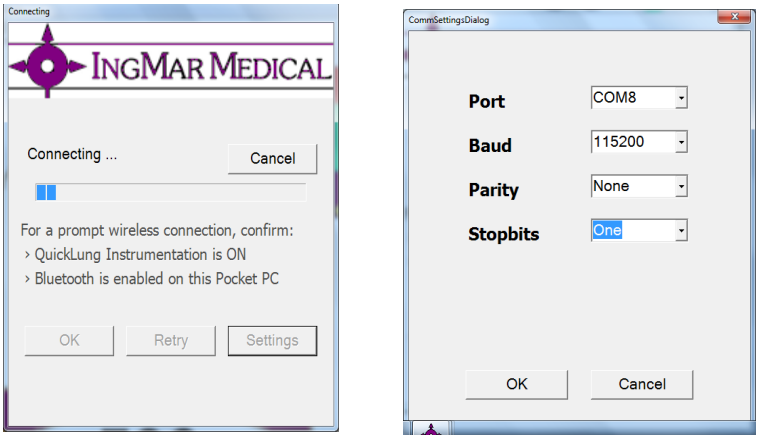


Figure 4-3

After a brief moment for loading the software, the system will attempt to connect to the RespiTrainer Base and a screen as depicted in Figure 4-3 (left) will be displayed.
When the first launching of the software, the PC has been preconfigured to communicate over the Bluetooth using the COM8 port. This COM port can be configured to a different port and the information will be saved to a configuration file.
You will then have the option to manually change the COM port to the correct setting. Choose the “Settings” button and select the desired COM-port from the drop down menu. Do not change any other settings. This step is only necessary once and the RespiTrainer software will retain this setting even after it has been

exited. Usually it is possible to find out which is the COM-port used by a PC's Bluetooth module by exploring the settings of the Bluetooth manager.

.

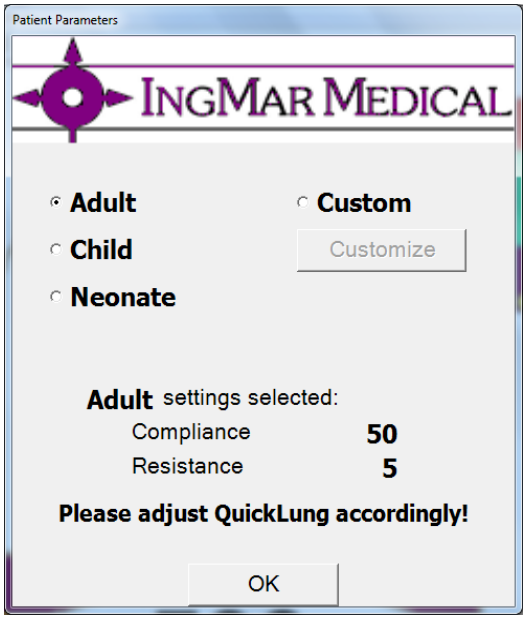


Figure 4-4

From the Connecting page, it is also possible to access the Patient Parameters page where the user may change the type of patient and the parameters to be set for the test lung. Alternatively, the user may use the last patient model and directly proceed to the RealTime1 screen (RT1) by selecting ok.

Besides a standard adult, pediatric, or neonatal patient, it is also possible to set up a customized patient model, with free choice of compliance and resistance. It is the user's responsibility to match the parameters indicated to the PC software with the actual parameters from a test lung.

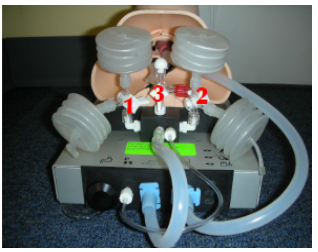
Setup for RespiTrainer Advance

For accurate results, the assumption of linear compliance and parabolic resistor characteristics must be valid.

The RespiTrainer Infant is a variant of the RespiTrainer Advance Manual Ventilation and Intubation Task Trainer dedicated to training the same skills in caregivers to the infant patient population. All instructions from the RT-Advance Manual may be used, respectively.

RespiTrainer Infant is available as part no. 15 30 500 and uses the same software and Bluetooth
connectivity as the other members of the RespiTrainer family. An intubation accessory kit is available (analogous to the RT-Advance kit, part no 15 30 740) as part no. 15 30 730.
Only the setup and the specifics of the model are different.

- The neonatal lung model is directly integrated into the base, no setup of a separate test lung is necessary
- The neonatal lung model can be set to compliance values of 1, 2, 3, or 4 [mL/cmH2O] based on the stopcock settings. See 1 and 2 in below image.
- Using the leak stopcock, the neonatal lung leak values can be set to Low (White leak cap engaged only), Medium (Red leak cap engaged only), and High (white and red leak caps engaged). See 3 in below image.
- For operation with a PC, at startup, the software option "Patient Parameters" needs to be set to "Neonate" for a 2-bellow system and to "Custom" for a 4- bellow system.



Neonatal Bellow:

1. Engage/Disengage Bellows

2. Engage/Disengage Bellows

3. Engage/Disengage Leak options

Figure 4-5

.
.

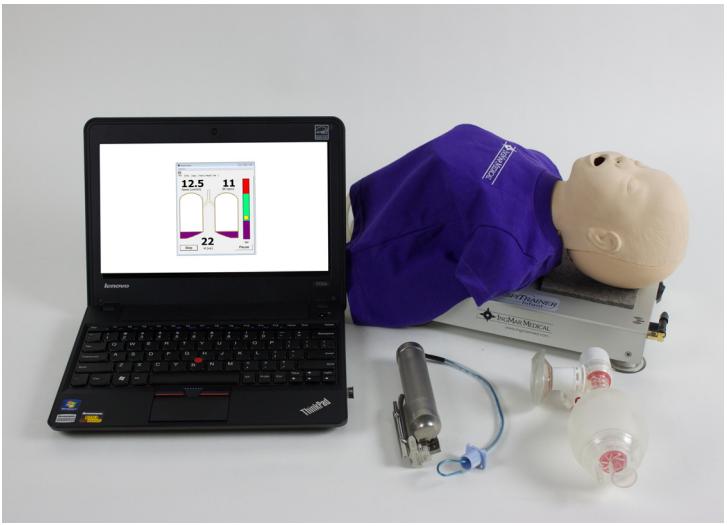
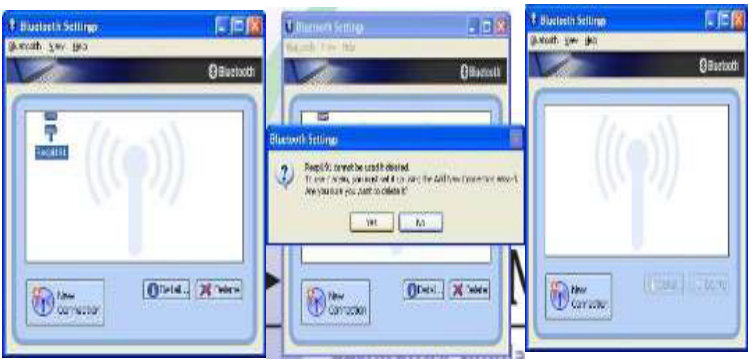


Figure 4-6

The RespiTrainer is normally paired to an individual netbook or PC prior to shipment from IngMar Medical Ltd. In some instances, for example the RespiTrainer is sent back to IngMar Medical Ltd. for repair without the netbook or PC. If this occurs, the end user may have to update the Bluetooth pairing with the repaired product. The instructions below describe the procedure for pairing to a RespiTrainer.

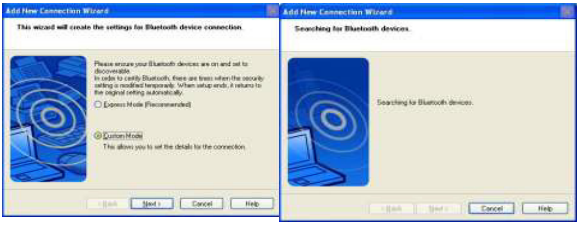
1) Turn on the netbook and make sure the Bluetooth “adapter” is inserted into the computer.
2) Right-click on the Bluetooth icon in the system tray (typically bottom right corner of the screen) and select **Bluetooth Settings**
3) When the Bluetooth settings window opens, the originally

paired RespiTrainer may be visible (Respi295, for example). Highlight the existing paired device and click on the **Delete** button. Select **Yes** when the window explains that the pairing will no longer be used.



4) Once the Bluetooth Settings window is clear, turn on the RespiTrainer. On the Bluetooth Settings window, click **New Connection**.

5) The next window will prompt the user to use "*Express Mode*" or "*Custom Mode*" to configure the Bluetooth device. Select "*Custom Mode*". Click **Next** and the computer will search for Bluetooth devices. NOTE: Custom Mode must be used to assure proper connectivity to the RespiTrainer. The COM port must be set to COM8.



6) When the search is complete (and the RespiTrainer is ON), a Respixxx should be visible (xxx = the serial number of the unit). Select the Respixxx device and click **Next**. Make sure the next window says *SPP* and click **Next** again.

7) The next window has a check in the box stating, "*Use default COM port*". Uncheck this box and click **Ok** on the pop-up window. Change the COM port to *COM8* and make sure the *Auto Connect* box is checked. Click **Next** to complete the COM setup.

8) Click **Next** to verify the connection name is Respixxx. Click **Next** again to complete the setup process. Finally, click **Finish** to close the setup wizard. Verify
the correct Respixxx is present in the **Bluetooth Settings** window.

Setup for RespiTrainer Advance

9) The computer and the RespiTrainer are now paired and ready for use

4.2 Use of the Software

The software offers tools to collect, display, and save performance data, as well as to configure the RespiTrainer Advance system for different simulation scenarios, including performance parameter thresholds and test setups.

The software operates from six basic tabs. Their functions are described in the following paragraphs. In addition, the **<Options>** tab on the task bar at the bottom of the screen allows for configuration, calibration, display settings, and simulated tests. It is also from the **<Options>** tab that the RespiTrainer Advance's service mode may be accessed.

RealTime 1 (RT1)

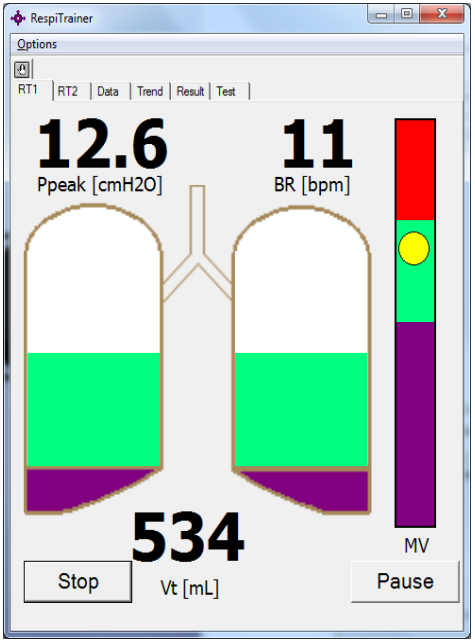


Figure 4-7

Use of the Software

RT1(Figure 4-7) is considered the Main Screen of the RespiTrainer software. The parameters displayed (pressure, breath rate, and tidal volume) are updated continuously in real time. The graphical display of the lungs fills and empties in synchrony with the ventilation attempts made, and the bargraph on the right will assist in finding the right level of minute ventilation for the chosen patient model.

Real Time 2 (RT2)

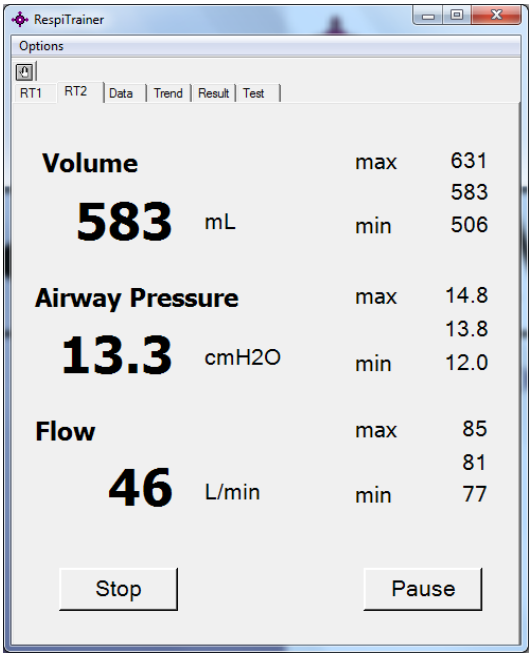


Figure 4-8

RT2 (Figure 4-8) shows real time parameters in numeric format only, without graphical visualization, giving, in addition, max, min, and current values of the parameters (Tidal) Volume, Peak Pressure, and (Insp.) Flow.

Data

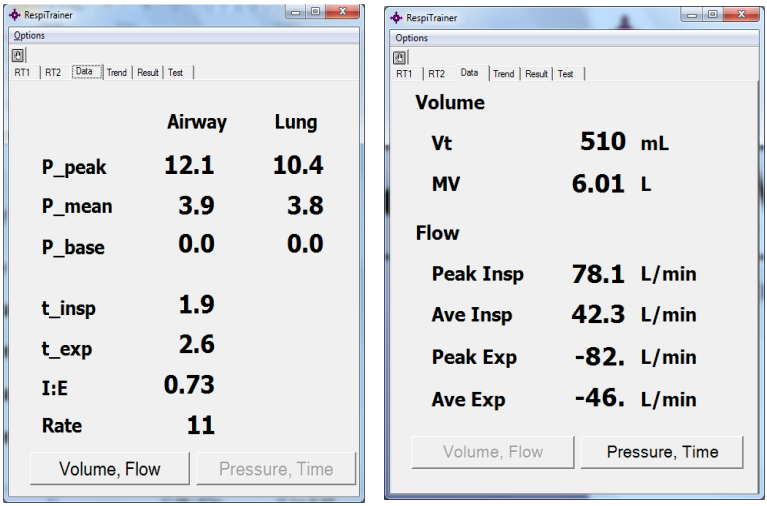


Figure 4-9

The data screen (Figure 4-9) is split into two pages, due to the screen limitations of a PC. Pressure and timing data are displayed first upon selecting "Data". The user may then toggle between this screen page and another, displaying flow and volume data.

Trends

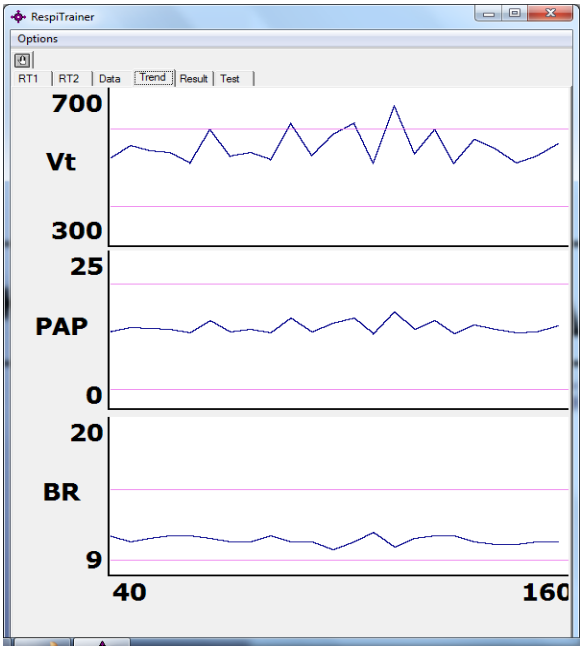


Figure 4-10

Graphic display of trends (Figure 4-10) for tidal volume, peak pressures, and breath rate are very useful when trying to evaluate student performance at a glance. The threshold values indicated for each of the three parameters make obvious during which part of a test a student's performance was acceptable or out of line with the requirements.

Results

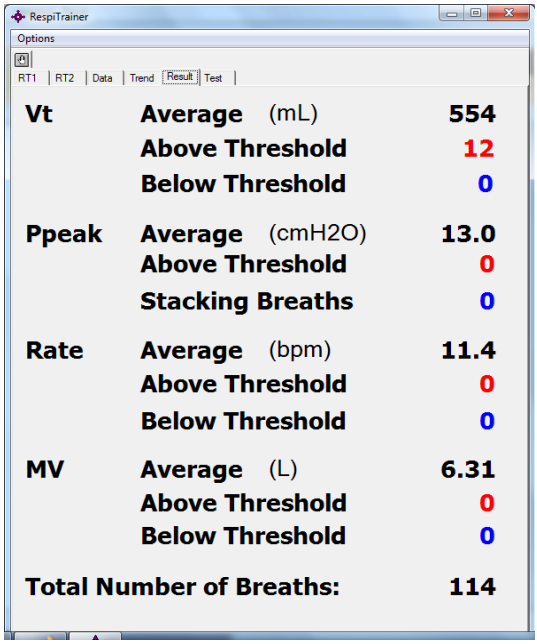


Figure 4-11

In the Result page (Figure 4-11), averages and threshold violations for the parameters tidal volume, peak pressure, breath rate, and minute ventilation are used to summarize the results of a timed test as well as of untimed data collection. In addition, the total number of breaths evaluated is also indicated.

Tests

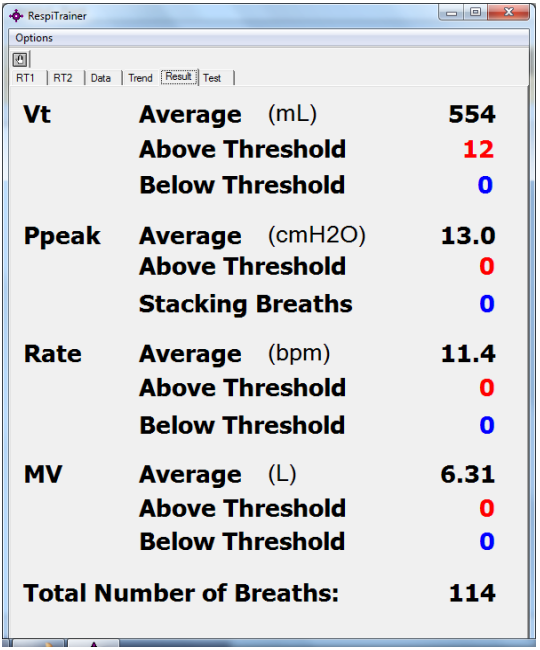


Figure 4-12

The Tests page (Figure 4-12) allows the user to setup, launch and stop a test. File names for data file recordings can be assigned in the Name field. Timed tests can conveniently be launched from this page, and a countdown timer will show the remaining test duration once a timed test is in progress.

The <Patient>, <Test Duration>, and <MV Sample> selection boxes will adjust the respective settings.

4.2.1 Application notes for software (general)

Data acquisition may be started from different points in the software. Most prominently this can be done after launching the software, from the RT1 screen. Besides this screen, data acquisition may be initiated from the Test page and from the **<Options>** menu. You may also tap on the clock symbol next to **<Options>** (at the top of the window in the PC software) to start, and tap the same key (which had changed to a hand symbol) to stop.

The selection between a timed test and free data collection is made under the **<Options>** menu (timed test indicated by checkmark). When launching data collection from the Test page, it will always start a timed test of the duration selected (Start timed test) and sets the checkmark on timed test in **<Options>**. When starting data collection from either the task bar toggle key, from the RT1 page, or from "Start Data" under **<Options>**, the type of test performed (timed or free) depends on the checkmark in **<Options>**

4.2.2 Test Setup

Timed tests are essential to the intended use of the RespiTrainer Advance as a feedback tool for a student practicing manual ventilation. It is on the Test page that you can select how to save a data file for further use as a reference or to document a student's progress. The user simply has to provide a data file name, which the software will then automatically increment for multiple tests, if so desired. Alternatively, each test may be given a different name manually. Saving of data is selected by the Save check box on the Test setup page. Data may be saved for timed tests as well as for untimed data collections.

The duration of a test is chosen from a drop down menu as 1,2,5,10,20, or 30 minutes.
Additionally, the number of breaths for averaging Minute Ventilation may be selected as 1,2,5, or 10 breaths.

If a customized patient model is desired, you can also access the "Customize Patient" page from the Test page. The initial parameters showing are those from the last time a customized patient model was used, and may be simply accepted or modified.

4.2.3 Data Display

Three different views of data are available as it is being collected. The two screen pages RT1 and RT2 offer updated data in real time. The first screen, considered the main or default view, shows updates of the parameters pressure, tidal volume, and breath rate numerically, in addition to colored bar graph representations of the filling of the lungs and Minute Ventilation. On these, a green target zone represents the parameter values within the set thresholds, whereas a red and purple zone indicate over- or under-performance, respectively. On the RT2 screen, all four parameters (P, Vt, Rate, MV) are also continuously updated in real time and are shown together with their set thresholds. The third view option, Data, shows parameters grouped by type on two separate screens, one for flow related parameters and the target of Minute Ventilation (MV) as well as pressure limit, and a second one for pressure and timing related parameters.

The Results screen is particularly helpful when performing timed tests. In this view, the parameters collected from a test run are characterized by their mean, as well as showing the number of threshold violations. This screen also indicates the total number of breaths performed in a test.

4.2.4 Saving Data

Saving of data is initiated from the Test Setup page (see "Test Setup" on page 33). Data is then written to the file specified there, in a tab-delimited ASCII file, suitable for further analysis via a spreadsheet program such as Excel or similar. The file location is always *Documents\Tests (in Win7)* or *My Documents\RespiTrainer\Tests (in WinXP)* may also be transferred to a PC and analyzed there.

4.2.5 Performing a Test

After initial setup has been made and the software has been launched on the PC, proceed to the Test page and select a file name for saving data. Also choose the test duration and the number of samples to be used for calculating minute ventilation (default =1).

For simulation of adult patients with RespiTrainer Advance, the mannekin head, at the beginning of the test should be down, which prompts the message about a blocked airway to appear.

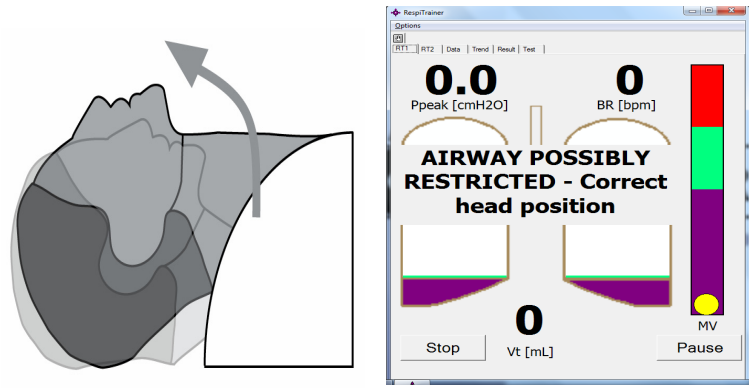


Figure 4-13

The student is then expected to position the head into the overstretched (“sniffing”) position, which will move the neck up on an arc on the head base. This will cause the message to disappear and also to open up the airway that was otherwise restricted.

4.3 Advanced Airway Interfaces

4.3.1 Simulation of a Patient Intubation

The RespiTrainer Advance intubation trainer head is designed to allow for a realistic experience when attempting an intubation. An 8 or 9 mm endotracheal tube is the appropriate size for ral intubation. **Note:** Do not use larger than 7mm size for nasal intubation or damage to the nasal passage of the RespiTrainer Advance head might result. It is recommended to use commercially available glycol-based lubricant on the ET-tube. Via the nipple below the chin, it is possible to inflate the tongue to create a difficult-to-intubate airway.

NOTE: The RespiTrainer Advance head is equipped with break-away teeth.

4.3.2 Placing a Laryngeal Mask

Thanks to the anatomically correct airway, the airway trainer may also be used to practice placement of an LMA. The appropriate size LMA is a #3.

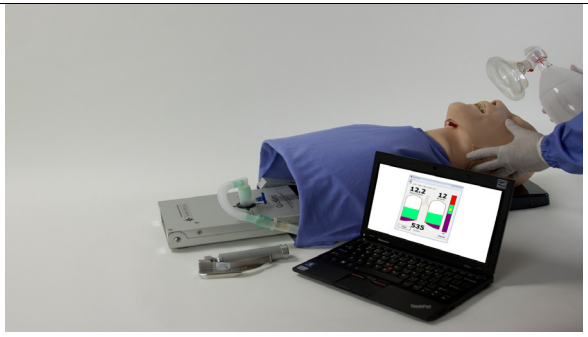


Figure 4-14

4.4 Options

4.4.1 ET-View Option

A stylet with a miniature video camera at its distal end is available as ET-View option. It allows the instructor (or other students) to see images from inside the airway on a PC screen and thus to follow currently in preparation. It will allow ITVA images to be viewed on the PC. This will allow an instructor to visually follow a student's progress in the intubation attempt.

4.5 Shut Down and Storage

After using the system, remove circuits from both the QuickLung and the RespiTrainer Base.

Exit the RespiTrainer software and turn PC off.
The blue light on the RespiTrainer Base will turn off.

Switch the RespiTrainer Base off, and unplug charger both from line power and from the RespiTrainer Base.

Place the RespiTrainer Advance head/ RespiTrainer Base inside the main bag compartment

Store the PC (and its charger, if used) in the smaller bottom pocket of the RespiTrainer Advance carrying case for optimum protection.

Place the QuickLung in the longer of the two bottom compartments in the carrying case.

Close the zippers on both bottom compartments to prevent items from falling out of the bag.

Place the circuits and other small parts into the main compartment of the carrying case and close the main zipper.

4.6 Installing/Updating Software on the PC

If your PC was not acquired through IngMar Medical together with the RespiTrainer Advance system or if you want to reinstall or update your PC software for the RespiTrainer Advance, first establish a connection for file transfer with a PC. The PC should have an available USB port into which you can then insert the USB memory stick delivered with the RespiTrainer Advance kit. Execute the file *RespiTrainer Advance.msi* which will install the software on the PC. After that, you should see the RespiTrainer Advance item and logo in the **<Start>** menu of the PC. If the item does not show in your **<Start>** menu, most likely it is already filled to capacity (8 items). In this case, you can either access the RespiTrainer software using File Explorer (*RespiTrainer Advance.exe* in the *\program files\RespiTrainer Advance* - directory), or manually place a shortcut into the Start menu folder after deleting one of the items in the list. To do this, you copy *RespiTrainer Advance.exe* from the *program files* directory and paste it as a shortcut onto the Desktop.

4.7 Pairing the RespiTrainer Base With Your PC

If your PC was not acquired through IngMar Medical, the process of “pairing” the Bluetooth connection should be performed by the user for a more convenient startup and if the PC is intended to be linked exclusively to one RespiTrainer Advance RespiTrainer Base.

For this purpose, start the PC and go to the Bluetooth Manager page which is part of your operating system.

Switch on the RespiTrainer Advance RespiTrainer Base.

From the Bluetooth Manager menu, go to <**Paired Devices**> and ask the PC to add a device. Tap on the magnifying glass symbol next to the <Device> field to search for Bluetooth devices in the vicinity. The RespiTrainer Advance should be on the list of devices found. Tap on its entry (Respinnnn) to initiate pairing. The Passkey value to be entered is "1234". Click OK in the top right corner of the screen to add the selected RespiTrainer Advance to the list. After successful pairing, the RespiTrainer Advance connection will be automatic whenever the RespiTrainer software is launched.

If no pairing is performed, the user will be directed to the Bluetooth browser after launch of the RespiTrainer software allowing to manually select a RespiTrainer Advance.

5 Care

5.1 Cleaning

Head
For cleaning the head, use mild detergent to remove stains and visible dirt. Disinfect face as necessary with isopropyl alcohol.

NOTE: It is not possible to remove the face from the head.

Base surfaces (plastic)
Wipe with damp cleaning rag and a mild detergent

Circuits
Bath-disinfect as needed using a disinfecting agent compatible with silicone circuits.

Battery
NiMH batteries will be losing their charge if not used for extended periods of time. It is therefore recommended to charge the RespiTrainer Advance battery occasionally (approximately once a month).
Alternatively, if the system is used regularly, keeping the charger plugged in and connected to line power will not negatively affect the life of the battery. Only a trickle charge will be performed to keep the “battery” topped “off”.

5.2 Maintenance

Both the RespiTrainer Advance RespiTrainer Base and the QuickLung are designed to be maintenance-free.

WARNING !

Only replace with original 1650 mAh NiMh battery pack, IngMar Medical part no. 15 30 007.
Using other than the specified battery pack may cause a fire hazard.
Do not place into a fire. Explosion hazard!

CAUTION!

Follow all Federal, State, and local environmental regulations when disposing of batteries.

6 Principle of Operation RespiTrainer Advance

The RespiTrainer Advance™ RespiTrainer Base measures pressure in two locations, in the airway and inside the simulated lung. Because of the readily documented behavior of the QuickLung, flow and volume can be calculated based solely on the chosen resistance and compliance parameters. **Note:** It is the user's responsibility to make sure the PC software is informed properly about the selected patient parameters in the initial “patient select” screen, at the time of program start or whenever a change to the test lung parameters is made

6.1 Data Sampling and Exchange With The PC

The RespiTrainer Base incorporates a Bluetooth wireless card that transmits data from two pressure transducers to the PC. Pressure is sampled at a port inside the RespiTrainer Base and in the test lung. With the known compliance of the test lung, volumes can be determined from the lung pressure at zero flow condition. Flow can be calculated from the pressure differential across the known resistance of the test lung. The raw data is transmitted at a sampling rate of 100 Hz after which averaging (oversampling) is applied for a net data update rate of 10 Hz.

All parameters displayed carry performance thresholds that can be altered for adapting to different patient models. For peak pressure there exists a second (fixed) threshold set to 20 cmH_2O. At that pressure, a valve to the stomach bag opens. The primary upper pressure threshold (user adjustable) triggers the counting of high pressure events and the display of the respective “Stomach insufflation" message. By default, its setting is also 20 cmH_2O.

A low pressure threshold serves the purpose of identifying the stacking of breaths. If pressure does not drop below this threshold, a full exhalation was not possible and this event is also recorded. There is, however, no screen message associated with this event.

Tidal volume thresholds are present for high and low Vt. The same is true for minute ventilation. Its thresholds correspond to the limits of the green zone of the MV bar graph.

6.2 Parameter Definitions

V_t Tidal volume is calculated from lung pressures as (P_{peak}-P_{min})/Compliance

P_{peak} Peak pressure is the highest value of pressure during a breath.

BR Breath rate is determined as the quotient of 60 s and the momentary value of breath cycle time (inspiration + expiration).

MV Minute ventilation is calculated as the prorated average tidal volume per minute from a sample of 1,2, or 3 breaths (user-adjustable).

Averages and standard deviations: The assumption is made that the parameters are approximately normally distributed and the calculation of average and standard deviation is therefore justified.

7 Troubleshooting/FAQs

Wireless connection not established
Does the Windows PC have Bluetooth powered on?
Is the RespiTrainer Advance RespiTrainer Base switched on?
Is the RespiTrainer software using the correct COM-port (the COM-port assigned to serial service by the Bluetooth manager)?

No volume delivered to the test lung
Make sure that Resistance on the QuickLung is not set to OFF.
Are all connections made properly into the respective ports on the RespiTrainer Base and the head?

Large leak present
Check that the stomach bag is connected or that the respective port on the RespiTrainer Base is plugged. Make sure that the leak setting on the optional QuickLung swivel elbow adapter is set to “No Leak”. Check other circuit connections for leaks.

8 Technical Data

8.1 QuickLung Specifications

For specifications of the IngMar Medical QuickLung, please refer to the separate QuickLung Quick Reference Guide

8.2 RespiTrainer Advance Specifications

Power Requirements	
	Wide range input AC/DC tabletop charger. Input: 100 - 240 V AC, 50/60 Hz Output: 12 V DC, 2 A, regulated
Battery	7.2 V 1600 mAh NiMH battery nominal time of operation with a full charge: 8 h
Data Communicat.	
Wireless	Bluetooth Class I
Range	max 10m (30') distance between PC and RespiTrainer Base
Data sampling rate	100 Hz with 10 x oversampling (averaging) between data points
Volumes	
Tidal	dependent on test lung used Adult (QuickLung): 1.2 L Infant: 100 mL
MV	50 mL to 50 L /min

RespiTrainer Advance Specifications

Breath Rates

dependent on test lung used
0 to 150/min, calculated as real time from previous breath

Flows

Peak flow	> 270 L/min

Respiratory Mechanics

Resistance	dependent on test lung used Rp5 to Rp200 $cmH_2O/L/s$ parabolic characteristics assumed
Compliance	2 to 50 mL/cmH_2O
Leak	no lung leak condition assumed

Pressure Measurement

Airway	error < 1% fso (100 cmH2O)
Lung	error < 1% fso (100 cmH2O)

Physical Characteristics

Dimensions (W x L x H)	185 x 330 x 267 mm (7.3 x 13 x 10.5 inch)
Data Acquisition Base	185 x 310 x 55 mm (7.3 x 12.2 x 2.2 inch)
Carrying Case	280 x 356 x 318 mm (11 x 14 x 12.5 inch)
Weight	6.1 kg (13.5 lbs), complete system including QuickLung and carrying case, without PC

NOTE: Specifications are subject to change without notice.

9 Ordering Information

Description	Part No.
RespiTrainer® Advance standard.	15 30 600
QuickLung	15 00 100
10" Netbook Control Module	26 00 500
RespiTrainer® Advance Intubation Package	15 30 740
ETView™ Intubation Video Assistant	15 30 790
ETView™ ET Tube ADULT Camera	15 30 901
ETView™ Monitor	15 30 903
RespiTrainer® INFANT Intubation Trainer	15 30 500
10" Netbook Control Module	26 00 500
RespiTrainer® INFANT Intubation Pkg	15 30 730
ETView™ ET Tube INFANT Camera	15 30 493

Index

Index