



QUICKLUNG BREATHER

QUICKLUNG BREATHER

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> 1. ABOUT THE USER'S MANUAL

This User's Manual is for IngMar Medical's QuickLung Breather, the Spontaneous Breathing Accessory for the QuickLung Precision Test Lung. It is recommended that you read this instruction manual carefully before using the QuickLung Breather.

This manual is divided into several main sections to help you easily access information and instructions you need.

1.1 Conventions Used in This Manual



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.

Use of the word "Patient"

Throughout this manual and in the software, the word "patient" is used to describe a simulated patient with specific lung model settings. This reference corresponds to the use of "patient" in a clinical setting who receives ventilator assistance.

> 2. SAFETY CONSIDERATIONS

2.1 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.

2.1.1 Intended Use

The QuickLung Breather is the spontaneous breathing option for the IngMar Medical QuickLung. It may be used in ventilator management training where the need for a spontaneously breathing respiratory simulator is essential while addressing topics of synchrony, patient support, and weaning. The QuickLung Breather may also be used effectively in ventilator performance verification procedures that require reproducible breath triggers.

IngMar Medical, Ltd. does not recommend any specific ventilator test or calibration procedures and no portion of these instructions shall be construed as doing so.

Always follow ventilator manufacturers' instructions and recommendations regarding performance verification procedures.



Do not allow aerosols to contaminate the bellows of the QuickLung. Contamination with aerosols may, over time, result in material degradation.



Use of the QuickLung Breather in the presence of flammable anesthetics may present an explosion hazard.



Electromagnetic Interference: Do not use the QuickLung Breather in patient rooms or other areas where life supporting equipment is in use.

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2.2 Summary of General Precautions



- Electrical Supply: Connect the power supply provided only to a properly grounded wall outlet providing 100 – 240 V AC, 50 – 60 Hz.
- Do not operate QuickLung Breather when it is wet due to spills or condensation. Never sterilize or immerse the device in liquids.
- Always use dry air or oxygen with the QuickLung. “Rainout” inside the bellows of the QuickLung may impair its function and may eventually cause damage.
- Do not operate the QuickLung Breather if it appears to have been dropped or damaged.



Fire Hazards related to the use of oxygen: When using the system with elevated concentrations of oxygen (ventilators set to $FiO_2 > 21\%$), observe all precautions applicable to the use of oxygen indoors.

- Always use extreme caution when using oxygen!
- Oxygen intensely supports any burning!
No smoking, no open fire in areas where oxygen is in use!
- Always provide adequate ventilation in order to maintain ambient O₂ concentrations < 24 %.
- Always secure O₂ cylinders against tipping, do not expose to extreme heat.
- Do not use oil or grease on O₂ equipment such as tank valves or pressure regulators
Do not touch with oily hands. Risk of fire!
- Open and close valves slowly, with smooth turns. Do not use any tools.

> 3. AN INTRODUCTION TO THE QUICKLUNG BREATHER

3.1 System Overview

The QuickLung Breather acts as a physical “cradle” for the QuickLung (standard or pediatric version “QuickLung Junior”) mounted on top of it.

3.2 System Features and Options

The QuickLung Breather offers features and options for the basic as well as the advanced user. The Pulmonary Mechanics Graphics Option (PMG Option) is designed specifically for users that need a graphical representation of flow, pressure and volume waveforms or flow/volume and pressure/volume loops. It operates with an external flow/pressure sensor and can effectively illustrate the interactions between a patient and a ventilator on a personal computer.

Standard features of the QuickLung Breather include:

- The ability to breathe spontaneously, making a small or large contribution to overall minute ventilation
- Predefined breathing patterns include:
 - Eupnea® (shallow breathing)
 - Cheyne-Stokes® (periodic breathing)
 - Biot's® (groups of quick, shallow inspiration)
 - Kussmaul's® (deep and labored breathing)
 - Apneusis® (deep, gasping inspiration with a pause) at full inspiration
- Apnea - the ability to breathe intermittently, with a preset or randomized ratio of breath to no-breath periods
- The ability to vary breath rate and tidal volume randomly with a mean target of minute ventilation

Please see **6 Using Different Modes of Spontaneous Breathing** for further details on the individual modes of spontaneous breathing and the adjustable parameters for each of the different patterns.



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> 4. ASL QUICKLUNG BREATHER SETUP

4.1 Installing the QuickLung

Before attempting to install the QuickLung, ensure that the lift arms on the side of the QuickLung breather are in a downward position.



Make sure that the downward position of the lift arms is not beyond the marking indicated on the side of the QuickLung Breather chassis.



If you already own a QuickLung that does not have the side rails or the “wing” panel installed, please contact IngMar Medical to obtain the correct part.

On the rear of the Breather, there is a spring-loaded pin used to secure the QuickLung test lung into place.

- Pull and twist the spring-loaded pin so that the QuickLung can be installed.
- Set the QuickLung onto the Breather by sliding the front of the lung under the Breather locking brackets and lowering onto the Breather surface.
- Release the spring-loaded pin to secure the lung.

4.2 Electrical Connections

The first step for getting started is to establish safe and proper electrical connections following the instructions in this section.

- Connect the DC power output cord of the power supply to the DC input jack in the back of the QuickLung Breather.
- Connect the QuickLung Breather power adapter to line power supplying 100 - 240 V AC, 50/60 Hz with the power cord for your specific country supplied in the package.



Electrical Supply: Connect only to a **properly grounded** wall outlet providing **100 - 240 V AC, 50 - 60 Hz**.

1. Plug DC barrel connector into its socket on the back panel of the QuickLung Breather.

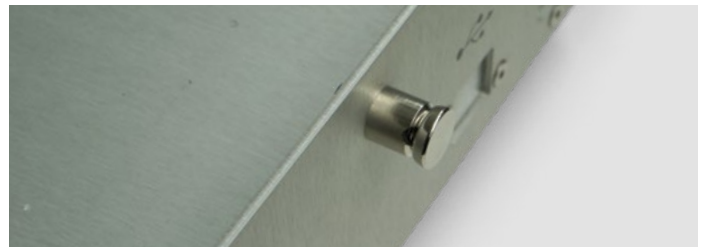


Figure 4 1:
QuickLung Locking Pin in the Released and Locked Positions



Figure 4 2:
Electrical Connections

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5. RUNNING A SIMULATION

After safely making the electrical connections and installing the QuickLung, you are now ready to run your first simulation.

To begin, turn on the system:

1. Flip the power switch at the back of the QuickLung Breather to the ON (I) position.



Figure 5.1:
Turning On the Device

On the front panel, the LCD display will light up and show the QuickLung Settings window.

2. Using the left <+/-> buttons on the front panel, set the QL Model to Adult or Junior, matching the actual QuickLung that is installed on the QuickLung Breather.
3. Using the right <+/-> buttons to set the Apnea mode to Enable or Disable.
4. When complete, press Mode Select to continue.

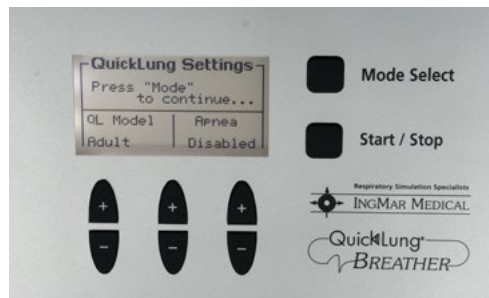


Figure 5.2:
QuickLung Settings Menu

The last setup window appears, where Resistance and Compliance can be set. Also, the baseline Offset value is set for tidal volume accuracy.

It is important that the values entered for Res. (Resistance) and Compl. (Compliance) match the settings of the QuickLung as it is installed. The values are needed to correctly limit spontaneous breathing settings in the different modes.

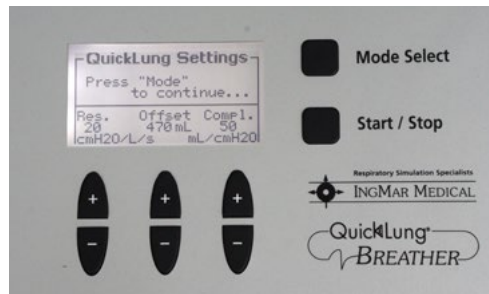


Figure 5.3:
Offset and R/C Settings Menu

! If the QuickLung Breather is set to take excessive breaths (considering the compliance and/or resistance present), the motor drive will slip and could potentially be damaged.

1. Use the left <+/-> to match Res. to the resistance setting of the QuickLung.
2. Use the right <+/-> to match Compl. to the compliance setting of the QuickLung.



NOTE on Offset:

For correct estimates of the spontaneously inhaled volume, Offset should be adjusted so that, at rest, the lift arms are just touching the “wing” (bracket) from below. This is necessary as the characteristics that make up the QuickLung rubber bellow are not exact. The offset allows the user to create a “zero” position of the lift-arms such that increased accuracy is attained when dialing in a tidal volume.

3. Use the center <-> to set the Offset value to zero (0).
4. Press Start/Stop. This places the lift-arms at the “absolute” zero position.
5. Use center <-> to increase the Offset value, and then press Start/Stop again to verify position of the lift-arms. Repeat as necessary until the lift-arms are just touching the QuickLung wing.

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6. When complete, press Mode Select to cycle through and select one of the pre-defined breath patterns. Use the <+/-> to adjust the settings of each pattern.
7. Press Start/Stop to start a simulation with the preselected mode and settings of that mode.
8. The symbol ■ then turns into ▶, to indicate the system is running.



All settings for a particular breath pattern are retained when you switch to a different mode and will be effective again when the original mode is chosen.

The basic patterns available are depicted in the Figure below. For details on using the different modes of breathing patterns, please see the next section of this manual.



Figure 5.4:
Offset Not Adjusted (Left) and Properly Adjusted (Right)

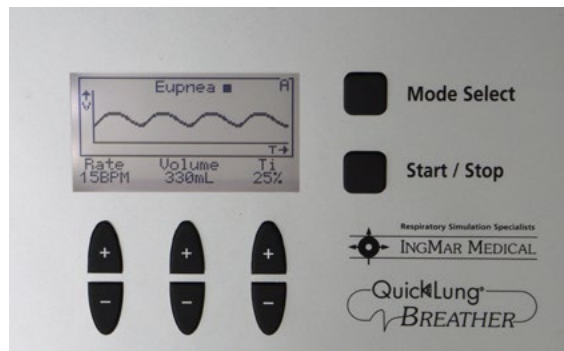


Figure 5.5:
Eupnea Breathing Pattern Settings

- Eupnea
- Cheyne-Stokes
- Biot's
- Kussmaul's
- Apneusis

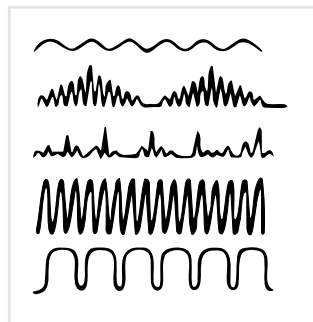


Figure 5.6:
Eupnea Breathing Pattern Settings

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6. USING DIFFERENT MODES OF SPONTANEOUS BREATHING

The following section describes the different breathing patterns available in the QuickLung Breather, together with the respective ranges of breath rate, I:E-ratio, flow rate, and the maximum spontaneous tidal volume possible.



Vt indicated in this context is representative only for applications where no PEEP is present that would require the Offset to be adjusted, diminishing the maximum available tidal volume.

Generally, high Resistance settings and small Compliance settings limit the range of flow and volume.

	R = 5 cm H ₂ O	R = 20 cm H ₂ O	R = 50 cm H ₂ O	C = 50 ml/cm H ₂ O	C = 20 ml/cm H ₂ O	C = 10 ml/cm H ₂ O
Max. Flow	80 L/min	40 L/min	20 L/min			
Max. Vt				720 ml	500 ml	300 ml

For the QuickLung Junior, the the respective values are:

	R = 5 cm H ₂ O	R = 20 cm H ₂ O	R = 50 cm H ₂ O	C = 15 ml/cm H ₂ O	C = 6 ml/cm H ₂ O	C = 3 ml/cm H ₂ O
Max. Flow	80 L/min	40 L/min	20 L/min			
Max. Vt				215 ml	150 ml	90 ml

6.1 Eupnea

Eupnea is the mode setting with which to simulate “normal” breathing. Wikipedia defines Eupnea as “normal, good, unlabored breathing, sometimes known as quiet breathing or resting respiratory rate. In eupnea, expiration employs only the elastic recoil of the lungs”.

EUPNEA	Rate [BPM]	Volume [ml]	I:E ratio [%]	MV [L]	Insp. Hold [%]
QuickLung	4...60 (12)	80...720 (300)	20...80 (33)		
QL Junior	4...60 (20)	24...216 (150)	20...80 (33)		

Eupnea mode is very flexible and can be considered a default and starting point for many simulation applications.

6.2 Cheyne-Stokes

Cheyne-Stokes respiration “is an abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in a temporary stop in breathing called an apnea. The pattern repeats, with each cycle usually taking 30 seconds to 2 minutes. [1] It is an oscillation of ventilation between apnea and hyperpnoea with a crescendo-diminuendo pattern”

The range of parameters that are available is depicted in the table below:

EUPNEA	Rate [BPM]	Volume [ml]	I:E ratio [%]	MV [L]	Insp. Hold [%]
QuickLung	4...40 (12)	200...720 (720)*	Fixed (50)		
QL Junior	4...40 (12)	60...216 (216)*	Fixed (50)		

* Vmax in a group of breaths

6.3 Biot's

“Biot's respiration is an abnormal pattern of breathing characterized by groups of quick, shallow inspirations followed by regular or irregular periods of apnea.” [2]

The range of parameters that are available is depicted in the table below:

EUPNEA	Rate [BPM]	Volume [ml]	I:E ratio [%]	MV [L]	Insp. Hold [%]
QuickLung	12...60* (18)	8...720 (600)		0.1...9.9 (6.0)	
QL Junior	12...40* (18)	24...216 (216)		0.3...2.9 (2.9)	

* fmax

¹ Cheynes–Stokes Respiration“, WebMD LLC. Retrieved 2010-10-05.

² Biot respiration“ in Dorland's Medical Dictionary

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6.4 Kussmaul's

"Kussmaul breathing is a deep and labored breathing pattern often associated with severe metabolic acidosis, particularly diabetic ketoacidosis (DKA) but also kidney failure. It is a form of hyperventilation, which is any breathing pattern that reduces carbon dioxide in the blood due to increased rate or depth of respiration." [3]

The range of parameters that are available is depicted in the table below:

EUPNEA	Rate [BPM]	Volume [ml]	I:E ratio [%]	MV [L]	Insp. Hold [%]
QuickLung	18...60 (18)	200...720 (720)	40...60 (50)		
QL Junior	18...60 (30)	60...216 (216)	40...60 (50)		

6.5 Apneusis

"Apneustic respiration (a.k.a. apneusis) is an abnormal pattern of breathing characterized by deep, gasping inspiration with a pause at full inspiration followed by a brief, insufficient release." [4]

The range of parameters that are available is depicted in the table below:

EUPNEA	Rate [BPM]	Volume [ml]	I:E ratio [%]	MV [L]	Insp. Hold [%]
QuickLung	4...40 (12)	80...720 (450)	60...75*		20...50 (25)
QL Junior	4...40 (20)	24...216 (150)	60...75*		20...50 (25)

* set by algorithm

^{3,4} Wikipedia.org

6.6 Using the Apnea Feature

You can control how apnea enters into the breathing patterns of your simulated patient by selecting the number of breaths taken (**Breaths**) and omitted (**NoBr**). Additionally, you can enter quasi-randomization into the pattern for more realism. Randomization takes the values of **Breaths** and **NoBr** as median values and allows the actual number of breaths taken and omitted over time to vary in the range of +/-30%. A seed value for the random number generator starts the pattern. The quasi-random apnea pattern can thus be repeated based on the set **Seed** value. Numbers between 1 and 999 are allowed. Setting the **Seed** value to zero (0) forces the QuickLung Breather to use the set **Breaths** and **NoBr** as fixed values, without any random fluctuations.

If **Apnea** is enabled at startup in the **QuickLung Settings** window, the Apnea Settings window will appear when **Mode** is pressed.

1. Set the (median) value of the number of breaths that you want your patient to take before an apnea occurs.
2. Set the (median) value of the number of breaths for which you want your patient to make no effort (duration of the apnea).
3. Adjust the **Seed** value to either 0 (no randomization) or a different number for randomization.
4. When complete, press **Mode Select** button to continue.
5. When Apnea is active in any of the breath patterns, it is indicated by the letter **A** in the top right corner of the display.

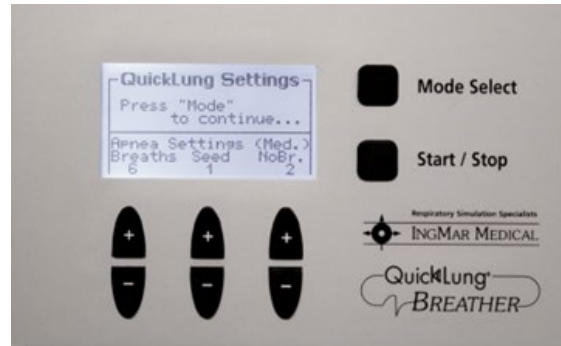


Figure 6.1:
QuickLung Settings Menu

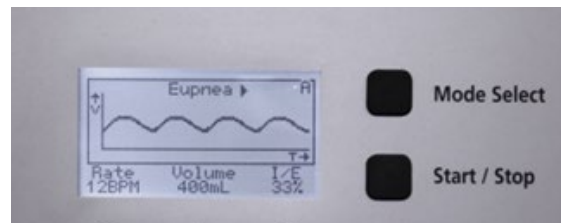


Figure 6.2:
Eupnea Breathing Pattern with Apnea

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> 7. MAINTENANCE

When inquiring about maintenance, always have the serial number of your device available. Additional reference information can be found on the label on the bottom of the instrument a copy of which is included also in the product binder supplied with each instrument.



The QuickLung Breather does not contain user-serviceable components or parts. Unauthorized opening of the device will void the warranty.

> 8. TECHNICAL DATA

8.1 Performance Specifications

Volumes

Total Volume (QuickLung)	1.2 L (400 ml for Junior)
Spontaneous Tidal Volume	0 to 720 ml (0 to 215 ml for Junior)

Frequencies

Spontaneous Breath Rate	4 to 60 BPM based on breath pattern
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Flows

Peak Flow	80 L/min
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Lung Settings

Resistance	5, 20, 50 cm H ₂ O/L/s
Compliance	50, 20, 10 ml/cmH ₂ O (15, 6, 3 ml/cm H ₂ O for Junior)

8.2 Electrical Specifications

Power Requirements	Universal input 100 to 240 V AC, 50/60 Hz
DC Output	24 V 3.0A

8.3 Physical Specifications

Dimensions

QuickLung with Wing	11" x 8.5" x 2.25" (276.4 x 215.9 x 57.2 mm)
QuickLung with Breather	14" x 8.5" x 6.5" (355.6 x 215.9 x 165.1 mm)

Weight

QuickLung Breather	Approx. 22 lbs. (10 kg)
QuickLung	3.5 lbs. (1.6 kg)

Materials Used Inside the QuickLung Precision Test Lung

Bellows	Hypalon®, Stainless Steel
Bellow End Plates	Aluminum, Silicone Sealant
Connector	Delrin

8.4 Environmental Specifications

Storage	Temperature: -10°C to 50°C (allow device to reach approximate room temperature before use)
	Humidity: 10 to 95%, non-condensing
Operation	Temperature: +10°C to 40°C
	Humidity: 10 to 95%, non-condensing

Specifications are subject to change without notice.

QUICKLUNG BREATHER

> 9. LEGAL INFORMATION

Product Warranty

Educational tools and test instruments manufactured or distributed by IngMar Medical come with a limited warranty, 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. Software, fuses and batteries are excluded from this warranty. System components such as computers are supplied with the factory warranty of the original manufacturer. IngMar Medical reserves the right to perform warranty service(s) at its factory, at an authorized repair center, 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 the purchased equipment, 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.

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Patents

The device is protected under US patent 5975748 which IngMar Medical, Ltd. uses under exclusive license.

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QUICKLUNG BREATHER

> 10. REPLACEMENT PARTS

QuickTrigger Module	1025219
QuickLung Swivel Elbow	1025202
QuickLung Standard Elbow Adapter	1025201
QuickLung Protective Case	1025206
QuickLung Spring Replacement Kit	1025203
QuickLung Spring Holder	1025204
QuickLung Rubber Feet	1025205

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QuickLung Breather System for Adult Patients	1025192
QuickLung Breather System for Pediatric Patients	1025193
QuickLung Precision Test Lung, pediatric	1025189
QuickLung Precision Test Lung, adult	1025188
QuickLung® Breather Option	1025207

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