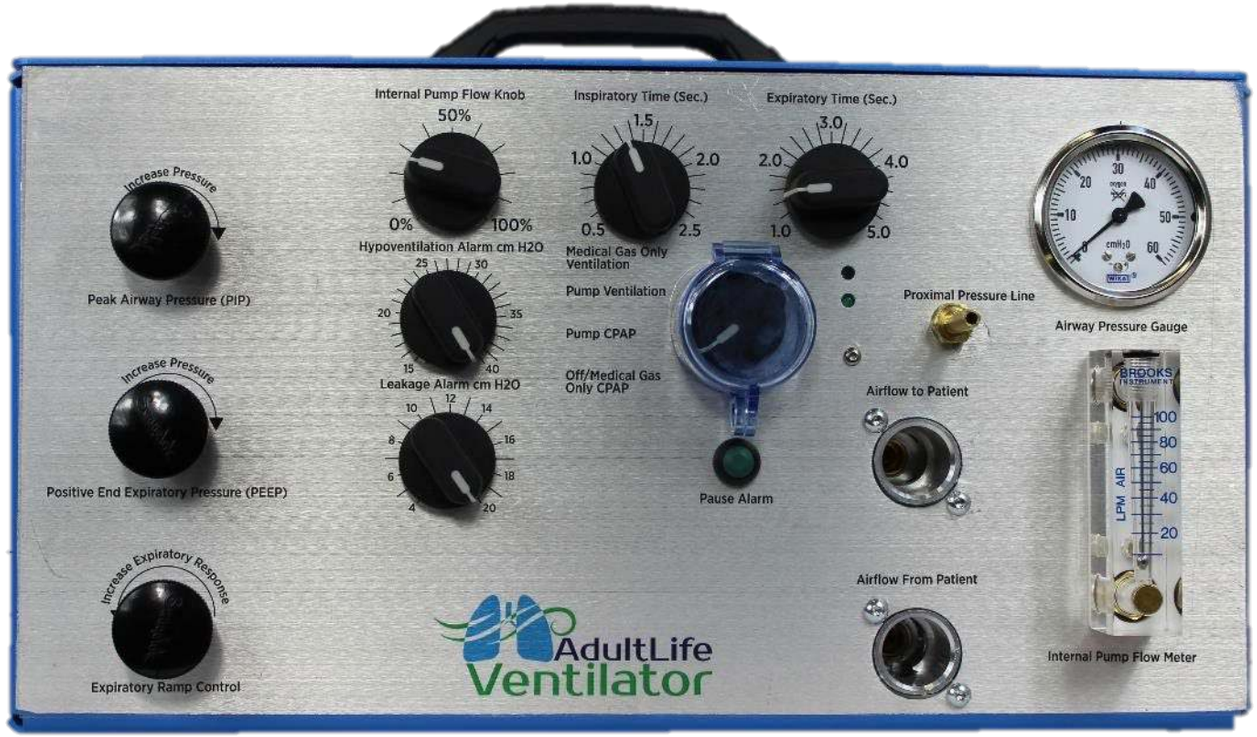
AdultLife Ventilator

saving lives is our mission

Introduction

- The AdultLife Ventilator is a pressure controlled, time cycled ventilator and CPAP device. Its simple yet effective and durable design allows for affordability, ease of use, and portability.
- AdultLife's Core Features
  - Internal Battery
  - Internal Air Pump
  - Low/High/Disconnect Pressure Alarm
  - Low Maintenance
  - Low Cost



Specifications

AdultLife Ventilator

- Peak Inspiratory Pressure (PIP)
  - 0 to 40cm H2O
- Positive End Expiratory Pressure (PEEP)
  - 0 to 20cm H2O
- Inspiratory Time (IT)
  - 0 to 2.5 Seconds
- Expiratory Time (ET)
  - 0 to 5 Seconds
- Breath Rate Per Minute (BPM)
  - 0 to 35 Breaths/Min
- Tidal Volume
  - 200-1000cc
- Oxygen Input/Medical Air Inputs
- Optional: Internal Pump (60L/min)
- Optional: Internal Battery (2-12 hr)
- Compatible with 22mm corrugated tubing and accessories (filter, humidifier, etc.)
- Internal Pressure Release Valves
  - Set at 40cm H2O
- Alarms:
  - Disconnect/Power Off Alarm
  - Max PIP Alarm
  - PEEP Alarm
  - Occlusion Alarm
  - Hypoventilation
- 110-240V Compatible (US Type B plug)

FDA Compliance

- 3/23/2020 Proposed Emergency Use Approval (EUA) to FDA
- 3/25/2020 FDA Reviewed/Approved EUA Proposal and Requested Full Submission
- 4/6/2020 FDA EUA Submission*
- 6/17/2020 FDA EUA Approval**
- 10/15/2020 Estimated 510K Submission

* See appendix A for list of testing standards and medical review team

** https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas

Training Support

- The AdultLife Ventilator includes the following resources for training and support:
  - Detailed instructions for use (IFU) available in both English and Spanish
  - Available training videos
    - USA respiratory university professor instruction on how to properly operate AdultLife ventilators
  - Availability to schedule video chat for further instruction with AdultLife medical staff and/or engineers

AdultLife Applications

- Respiratory Failure
- Respiratory Insufficiency
- Pneumonia
- Acute Respiratory Distress Syndrome (ARDS)
- Asthma
- Sepsis
- Brain Injuries
- CNS/Neurologic Conditions
- Trauma
- Drug Overdose

Warranty

- AdultLife ventilation devices are provided with a 1 year or total duration of the FDA defined Emergency Use Authorization (EUA) period, whichever comes first. If the EUA is terminated by the FDA, the 1 year warranty will continue upon FDA 510k approval. The components below are covered on the following schedule:
  - Internal Pump: 1 year or 10,000 hours
  - Pressure Gauge: 1 year
  - Internal Batteries: 1 year or 300 cycles

AdultLife Options

AdultLife Ventilator

Base Model

AdultLife Ventilator
Wall Air/Cylinder Connectors
Patient Tubing
User Manual
Training Resources
1 Year Warranty

Complete

AdultLife Ventilator
Internal Pump
Internal Battery
Wall Air/Cylinder Connectors
Patient Tubing
User Manual
Training Resources
1 Year Warranty

Complete Plus

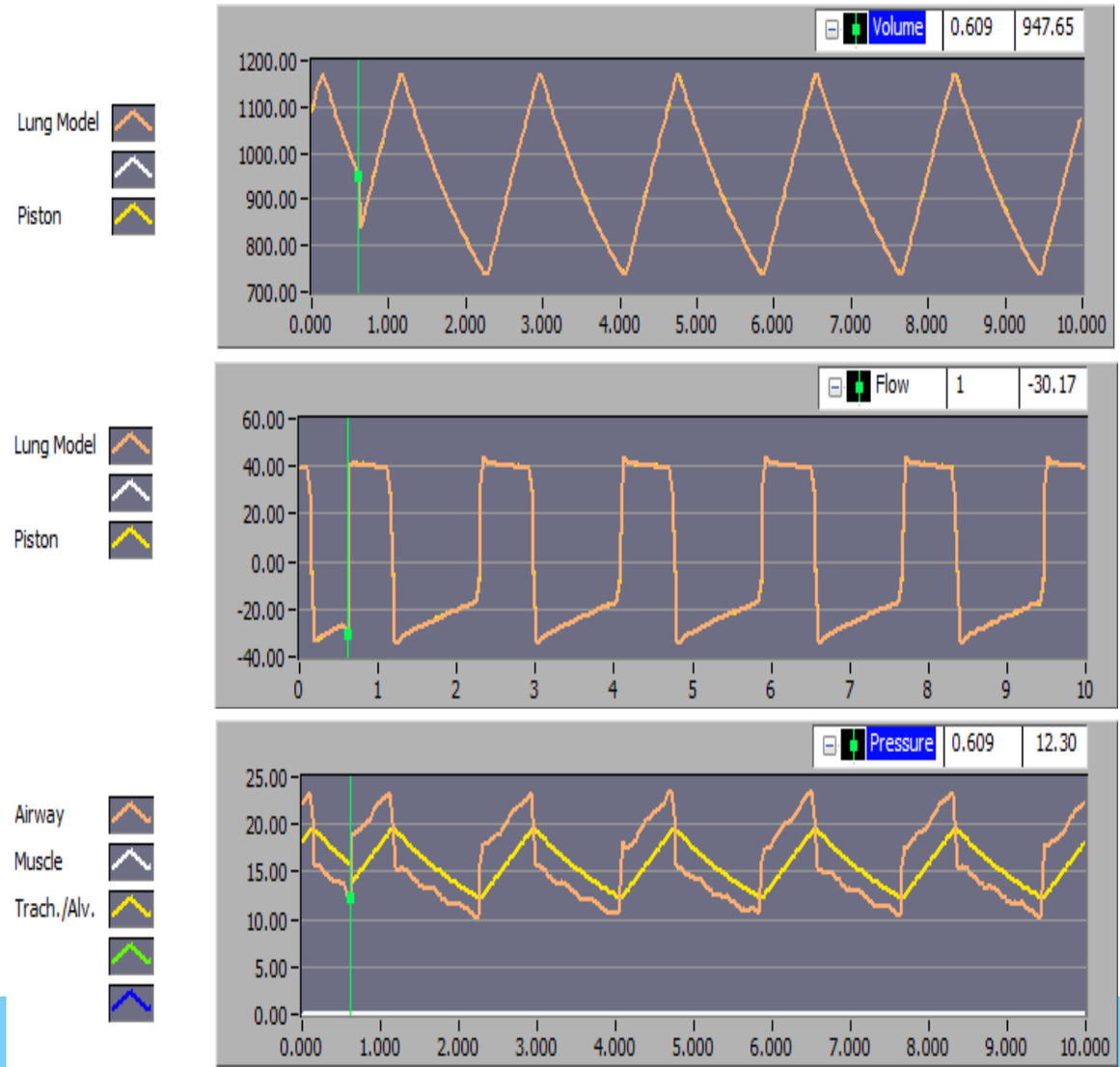
AdultLife Ventilator
Digital Monitoring System
Internal Pump
Internal Battery
Wall Air/Cylinder Connectors
Patient Tubing
User Manual
Training Resources
1 Year Warranty

Digital Monitoring System

A digital monitoring system is available with the AdultLife Pro Ventilator - Complete Plus.

This monitoring system allows for digital reading of tidal volume, pressure range, and wave form data. The system includes the following components:

- Digital Monitor
- Computer + Software Package
- Pressure Sensor System



Manufacturing Capabilities

AdultLife Ventilator

- Manufactured in USA in compliance with ISO 13485 and 21 CFR part 802
- All components are sourced in the USA

- Limited quantities are available in stock for immediate fulfillment, please contact your representative for details.
- Orders under 500pcs can be fulfilled within 45 days.
- Orders under 1000pcs can be fulfilled within 60 days.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Appendix A: Testing Standards and Medical Review

21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*
ISO 18562-1 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process*
ISO 18562-2 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*
ISO 18562-3 First Edition 2017: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*
ISO 18562-4 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate*
ISO 80601-2-12 First Edition 2011-04-15: *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators [Including: Technical Corrigendum 1 (2011)]*
ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*
Additionally, we have had our medical team review for useability testing--something that is required for FDA 510K approval.

Medical Review Team:
Janelle Gardiner (Professor of Respiratory Care/Respiratory Therapist 15yrs exp.)
Phil Thaut (Lead Respiratory Therapist ICU--35+ yrs exp)
Clark Bishop (Pulmonologist)
Robert Guenter (Respiratory Therapist--former director of respiratory therapy at Utah Valley Hospital, 40+ yrs exp.)
David Eitel (Respiratory Therapist, current director of respiratory at Utah Valley Hospital, 15+ yrs exp.)