

# Atlantis BaroVent

## Pneumatic/Mechanical Hyperbaric Ventilator

*Specifically developed for full range Hyperbaric Chamber Utilization*



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# History of Hyperbaric Ventilation

*During the last 40 years, physicians desirous of providing mechanical ventilation for critically ill patients requiring hyperbaric chamber therapy, have had to rely on ventilators that:*

- Would not provide adequate ventilation above 2.0 + ATA
- Needed to be modified to operate minimally during HBC therapy
- Are no longer in production and have no spare-parts availability
- Fails mechanically during actual procedures
- Have never been cleared by the FDA for hyperbaric chamber use in the USA

# Status Quo

*Physicians, practitioners and administrators must assume liability for the use of a non-cleared medical device if ventilation is used in a hyperbaric chamber*

- Current status of hyperbaric ventilation
  - Ventilator modified by manufacturers
  - Ventilators modified by practitioners
- Both resulting in physicians and other practitioners assuming liability for informed consent from patients before using a non-cleared medical device in their treatment
- Take responsibility to consult with their insurance carriers and internal Risk Management before using a non cleared medical devise

# Market Forces

*Major ventilator manufactures have declined to address the specific needs of the hyperbaric market by failing to produce a true hyperbaric ventilator {bar}*

- Major mechanical ventilator manufacturers spent serious time and effort researching whether it made economic sense to engineer, gain government clearances, manufacture and market hyperbaric chamber-capable ventilators and came to the conclusion that the expenses versus the monetary returns were not justifiable: the hyperbaric market seems too small to them, yet the need and challenges remain.
- Several noteworthy Physicians and their Associates requested that we make the effort to produce such a device for the hyperbaric community.

# Hyperbaric Community Requirements

*Addresses all requirements for ventilation for all hyperbaric Indications*

We began the research and found that the hyperbaric community asked for ventilator that had the following capabilities:

- developed specifically for hyperbaric chamber use
- had minimal operational/technical output controls (semi-automatic functions)
- was capable of ventilating pediatric through adult patients
- would provide full capabilities up to at least 6 ATA
- was mechanically reliable, easy to maintain and long-lasting
- An FDA approved device

# Methods and Materials

*Use proven technology and precision components to produce a rugged and reliable hyperbaric chamber ventilator*

- The engineering process was developed using the desires of the hyperbaric community, and deciding what mechanical components were best-suited to the tasks.
- Utilizing specific ventilator components with proven long-term reliability.
- Special components to enable the ventilator to perform semi-automatically throughout hyperbaric pressure ranges desired.
- In addition to our company's rigorous engineering practices, we utilize the FDA-mandated criteria for development and testing of acute-care ventilators, which include recommendations from ASTM, FPA and other recognized standards groups.

# Market Forces

*The Atlantis Hyperbaric Ventilator meets the diverse and demanding requirements presented by the Hyperbaric community and regulatory agencies.*

- The Atlantis is pneumatically driven and built using proven, high reliability components to offer many years of trouble free operation.
- Eliminates risk of using electronics in a high oxygen environment and relieves users from the extensive safety protocols that would be associated with using electronics in a hyperbaric chamber.
- The design of the Atlantis enables the ventilator to perform semi-automatically throughout hyperbaric pressure ranges of 1 to 6 ATA.

# Testing

*The Atlantis was tested with both mono-place and multi-place chambers as well as laboratory simulations of chamber pressures utilizing both air and oxygen as the driving gases over a two-year period of time.*

- Over 2,000 hours of chamber and laboratory testing was completed.
- The first live patients (adult pigs) were ventilated with the Atlantis first outside a chamber then later, inside a chamber at pressures up to and including 6 ATA.
- The initial patients thrived both during hyperbaric therapy as well as after removal from the chamber and ventilator.





# FDA Clearance

*The Atlantis offers the assurance of a 510(k) cleared Medical device*

- the Atlantis received FDA 510(k) clearance and is now available in the market.
- The FDA clearance of the Atlantis benefits the hyperbaric community by providing a fully functional solution that provides ventilation into any hyperbaric treatment scenario.
- The Atlantis eliminates the patient informed consent standards statutorily required for the use of non-FDA cleared medical devices. This is particularly important in the use of a hyperbaric ventilator, as many patients requiring hyperbaric ventilation may not be able to give informed consent.
- Practitioners are relieved of any requirement to inform their insurance carriers that they use non-FDA medical devices in their practice.

# Mono and Multi place Chamber Compatibility

*The Atlantis was tested with both mono-place and multi-place chambers.*



# Multi-place Chamber Compatibility

*The design of the Atlantis allows it to be used effectively inside a multi-place chamber or external to a mono-place.*



# Indications addressed by Hyperbaric Ventilation

*The Atlantis ventilator is a valuable tool in treating at least half of the 16 Indications for the use of HBO Therapy by UHMS.*

- Air or gas embolism
- Carbon monoxide and or cyanide poisoning
- Crush injury, compartment syndrome and other acute traumatic ischemias
- Decompression Sickness
- Exceptional Anemia
- Intracranial Abscess
- Thermal Burns
- Randomized clinical trials
- Side effects and complications

# Summary - Q & A

*At this time the Atlantis represents the only FDA-Cleared ventilator for use in hyperbaric chambers in the USA and presents a contemporary and safe mechanical ventilator for the practitioner to use with a wide-range of chamber pressures in either mono or multi place chambers.*

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