

LungFit® PH

Category:

Best Medical Technology

Company Name:

Beyond Air, Inc.

Product/Solution Name:

LungFit® PH

Compound/Tech Name:

LungFit® PH

Trade Name:

LungFit® PH

Corporate Name:

Beyond Air, Inc.

Date of Approval:

2022-06-28

Indications:

In the United States and around the rest of the world, NO from the LungFit® PH System is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

Outside the U.S., in addition to its approved indications in the United States, LungFit® PH is also CE Mark certified for the treatment of peri- and post-operative pulmonary hypertension in patients aged 0-17 years and adults undergoing heart surgery, to selectively decrease pulmonary arterial pressure and improve right ventricular function.

Intended Use

The LungFit® PH is intended to deliver nitric oxide (NO), a vasodilator, generated by the device into the inspiratory limb of the patient breathing circuit of a ventilator in a way that provides a constant concentration of nitric oxide, as set by the user, to the patient throughout the inspired breath. The LungFit® PH provides continuous integrated monitoring of inspired oxygen (O₂), nitrogen dioxide (NO₂) and nitric oxide (NO), and a comprehensive alarm system. The LungFit® PH includes an integrated backup NO delivery system that is a completely independent backup NO generating system; it has its own NO generator and gas flow delivery system.

Therapeutic Areas:

Respiratory Medicine

Persistent pulmonary hypertension of the newborn (PPHN) is a life-threatening condition requiring intensive care intervention. Inhaled nitric oxide (iNO) is the gold standard treatment, but conventional delivery systems rely on high-pressure cylinders that are costly, logistically complex, and could potentially pose safety risks to patients and medical staff. Beyond Air's LungFit® PH is a groundbreaking, tankless iNO delivery system that generates nitric oxide directly from room air, offering a more sustainable, portable, and user-friendly solution. Designed to streamline clinical workflows and expand access across critical care, LungFit® PH addresses a significant unmet need in neonatal respiratory medicine, redefining how iNO therapy is delivered across healthcare settings.

General Information File Document upload:

**[Beyond AirLungFit
PH_ApplicationForm_BESTMEDTECH_USAGallienAwards_FINAL.pdf](#)**

Background information and need for drug / device:

Persistent pulmonary hypertension of the newborn (PPHN) is a life-threatening condition requiring intensive care intervention. Inhaled nitric oxide (iNO) is the gold standard treatment, but conventional delivery systems rely on high-pressure cylinders that are costly, logistically complex, and could potentially pose safety risks to patients and medical staff. Beyond Air's LungFit® PH is a groundbreaking, tankless iNO delivery system that generates nitric oxide directly from room air, offering a more sustainable, portable, and user-friendly solution. Designed to streamline clinical workflows and expand access across critical care, LungFit® PH addresses a significant unmet need in neonatal respiratory medicine, redefining how iNO therapy is delivered across healthcare settings.

Background File Document upload:

History of the development of the solution/product:

Inhaled Nitric Oxide (iNO) has been an established therapy for over two decades, approved in the United States and globally for the treatment of hypoxic respiratory failure associated with pulmonary hypertension in neonates as well as other indications. While the clinical efficacy of iNO is well documented, traditional delivery systems have presented significant operational and safety inconveniences due to their reliance on high-pressure gas cylinders.

Recognizing this gap, Beyond Air developed LungFit® PH - a next-generation, tankless iNO delivery system that generates nitric oxide directly from ambient air using only a standard electric outlet. This innovation eliminates the need for storage, transport, and handling of compressed gas cylinders, reducing logistical burden and environmental waste, while enhancing safety and ease of use for hospital staff.

The development of LungFit® PH was guided by a commitment to improve the delivery of nitric oxide. Preclinical validation demonstrated equivalence in nitric oxide output and purity compared to traditional systems.

The LungFit® PH system received FDA approval in 2022 for the treatment of term and near-term neonates with hypoxic respiratory failure, commonly referred to as persistent pulmonary hypertension of the newborn (PPHN) and has since been adopted by leading institutions across the United States. CE Mark approval followed, expanding the device's reach and indications outside the U.S. to include broader perioperative use in both pediatric and adult patients.

Today, LungFit® PH represents a paradigm shift in nitric oxide therapy - maintaining the clinical standard of care while addressing long-standing limitations in delivery. With its portable body, user-friendly interface, and sustainable design, LungFit® PH supports better outcomes not only for patients, but also for the respiratory therapists, nurses, and physicians who deliver this life-saving therapy every day.

LungFit® PH significantly reduces time to treatment compared to traditional cylinder-based nitric oxide systems. Users report a setup time of under 6 minutes with LungFit® PH, versus 20-30 minutes for cylinder-based delivery. By eliminating the management and logistics associated with high-pressure gas tanks, LungFit® PH streamlines initiation of therapy - freeing up clinicians to focus more time on direct patient care.

Additionally, LungFit® PH generates nitric oxide directly from ambient air and does not require supplemental oxygen or humidification. This simplifies setup, reduces equipment dependencies, and enhances portability in the hospital.

Development File Document upload:

Beyond AirLungFit PH_Gas Composition Comparison of LungFit PH and Gas Composition Test Report_FINAL.pdf

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

LungFit® PH is a tankless inhaled nitric oxide (iNO) delivery system that generates nitric oxide directly from room air using patented Plasma Pulse Technology™, powered by only a standard electric outlet. It delivers iNO at user-set concentrations from 0.1 to 80 ppm, with real-time monitoring of NO, NO₂, and O₂ concentrations in the ventilator breathing circuit. The system supports ventilator flow rates up to 100 L/min for doses up to 40 ppm, and up to 80 ppm at 50 L/min when used with a mechanical ventilator.

The device supports three delivery modes - main, backup, and bagging (manual ventilation) - each ensures precise dosing and continuous monitoring. An integrated battery provides up to 4 hours of operation, and a fully independent backup NO delivery system ensures uninterrupted therapy at the flip of a switch in the event of primary system failure.

Key design features include front-facing quick connect ports for the Nitric Oxide Delivery Module (NDM) cable, nitric oxide injector line, gas sample line and automated purge cycles to ensure clean resumption of iNO between modes. A smart NO₂ filter system, with automatic usage tracking and advance replacement alerts, lasts 12 hours regardless of NO dose or flow, giving medical staff certainty of filter life (takes 5 seconds to replace). In contrast, competitive systems show large variability in cylinder change timing, making them unreliable, cumbersome and inefficient for staff. Compact and portable at approximately 19" tall and 44 lbs, LungFit® PH is optimized for both bedside and interhospital use.

LungFit® PH represents a paradigm shift in respiratory care by eliminating the need for traditional gas cylinders and enabling on-demand generation of inhaled nitric oxide from ambient air. This tankless technology reduces logistical burdens, enhances patient and provides safety, and lowers the environmental footprint of therapy. Its compact design and ease of use empower hospitals of all sizes to deliver life-saving care more efficiently. Beyond neonatal use, the LungFit® platform holds promise across multiple indications and age groups, paving the way for broader research into nitric oxide's therapeutic potential and setting a new standard for sustainable medical innovation.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

www.lungfitph.com

www.beyondair.net

References File Document upload:

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