Benefits of LungFit PH System Compared to Cylinder-based Systems

In this feature, Neonatal Intensive Care interviews clinicians and healthcare providers about the actual application of specific products and therapies. This interview is with Jeff Griebel, Director, Clinical Services, Beyond Air.

Tell us about your background.

Jeff Griebel, Director, Clinical Services, Beyond Air. Jeff Griebel has more than 30 years of experience working with iNO delivery systems. Prior to joining Beyond Air, he served as Clinical Program Director at medical device company, Spinal Stabilization Technologies and was Senior Manager of Clinical Device Innovation at Mallinckrodt Pharmaceuticals, a large specialized pharmaceutical manufacturer of generic pharmaceuticals and agents. Prior to Mallinckrodt, he held the positions of Field Manager of Medical Affairs and Country Manager on the US Clinical Specialist Team at IKARIA, Inc., a company acquired by Mallinckrodt. Mr. Griebel also spent 16 years as a Clinical Specialist on a research team at Children's Hospital Colorado working within the NICU/PICU and neonatal and adult transport teams.

Can you tell us about your career in respiratory care within the NICU and PICU and how this experience ties into your work focusing on clinical device innovation related to inhaled nitric oxide (iNO) delivery?

I worked as a clinician and clinical educator in the NICU/PICU, as well as working on neonatal and adult transport teams. I started working with iNO delivery systems before any commercial systems were available. As part of a research team at Children's Hospital Colorado we created very basic iNO delivery and monitoring systems. We used iNO in multiple clinical settings, including NICU, PICU, OR, transport, CAT scan, and MRI. I was involved in treating hundreds of patients receiving iNO therapy and gained experience in not only how to administer and monitor the therapy, but also valuable insights into how patients responded to the therapy. I also gained valuable insights from speaking to clinicians across the country and participating in clinical trials. I was often involved in discussions about what the ideal nitric oxide system should be while I was working in the hospital and later working in the medical device industry.

What drew you to Beyond Air?

I have known, been friends with, and worked alongside the inventors of Beyond Air's LungFit® systems for more than 20 years. They are also the inventors of the first commercialized iNO system in the US. Once I understood how the LungFit's Ionizer™ technology accurately controls and delivers iNO to patients using only room air and small pulses of electricity, combined with a very similar platform that clinicians already understand, I was intrigued. Combining the ability to produce an unlimited amount of iNO at the bedside with the simplicity of not having to deal with large, compressed gas cylinders—it made perfect sense to me. The sum of these factors made joining Beyond Air a natural fit.

What are the advantages of the LungFit PH System compared to cylinder-based systems?

I think you must look beyond just the obvious advantages of not having to manage cylinders. The weight, the storage requirements, and the constant movement of materials add to the labor cost. We estimate that each cylinder can take up to 1 hour of time: receiving them, moving them to the clinical area, attaching them to a delivery system, and returning the cylinders when the contents have been depleted. The advantage the LungFit system brings is familiarity and simplicity. Familiarity in that the LungFit is a universal delivery system, has the same basic connections clinicians have been using for more than 20 years, and also includes improved technology for flow sensing and monitoring. Simplicity in that there are really no other connections to make, no regulators to connect, and gas purges are never necessary. You basically turn on the device, make the few connections on the front of the device, and set a dose. The pre-use procedure is also very easy and only takes a few minutes. Once the device has been checked out (about 5 minutes) you can literally have the patients on therapy in less than 1 minute. We use a 12-hour filter to remove the NO_2 that is created in the iNO generation process; each filter weighs 2.5 oz and fits in the palm of your hand. The best part about the system is that you never run out of iNO since it is made at the bedside, on demand, from room air.

LungFit PH generates iNO from room air. How does this impact iNO supply and predictability of that supply compared to other iNO delivery systems?

Cylinder consumption can vary based on patient dose and ventilator flow. Clinicians need to keep track of inventory and plan ahead since shipping and delivery of high-pressure cylinders generally requires special handling, and it can be difficult if an emergency supply is needed for a surge in therapy. Being able to generate iNO from room air eliminates the concern regarding iNO supply. The NO_2 filter is a required accessory, but it is a lot easier to ship a box of filters (you can send weeks or months of supply in one shipment vs the space and handling characteristics of high-pressure cylinders). The filters require seconds to change

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Jeff Griebel, Director, Clinical Services, Beyond Air and the LungFit PH.

and last 12 hours, even at the maximum dose using high gas flows. You can basically set your watch to know how long a filter will last vs constantly checking the cylinder pressure and knowing what the pressure/volume relationship is for a specific cylinder size.

How does it improve NICU workflow and potentially improve patient care?

With a cylinder-based system, a clinician needs to maneuver the delivery system to gain access to the cylinders, often times in tight spaces. During therapy, there is nothing to access on the back of the LungFit PH since the small NO_2 filter is easily accessible on the front of the device.

Removing and replacing a large compressed gas cylinder on a delivery system can create a lot of stress on the body (especially the back muscles). There is a risk of injury any time you are moving a heavy cylinder.

You can keep several days' supply of NO_2 filters in a small drawer and, of course, you never have to worry about the iNO supply.

Once the cylinder is near empty, the clinician has to remove the cylinder from the delivery system and take the necessary steps to have it returned to the manufacturer for refilling. When the 12 hour NO_2 filter is depleted, a clinician can quickly replace the filter during the course of therapy and discard the old filter without using any special precautions.

LungFit PH employs a dual channel system, why was it designed this way?

From the earliest days of delivery system development, I felt a dual channel system was the safest and most accurate way to deliver iNO therapy.

A dual channel system basically means you have two separate systems, one to deliver and one to monitor the delivered gases (eg, iNO). One channel controls delivery and the second channel monitors the gases delivered to the patient (ie, iNO, NO_2 and O_2). The delivery is controlled by a mass flow sensor and a microprocessor that delivers a precise, proportional amount of iNO to the ventilator circuit to achieve the desired set dose. The whole delivery process is monitored and updated several times per second. The flow sensor is also on the dry side of the ventilator circuit, so no contamination from humidity or medications can affect the iNO delivery. The LungFit PH can accurately deliver the desired dose, even if the monitoring system completely fails.

Systems that rely on a monitoring system to adjust the iNO delivery are, in my opinion, far from ideal. All currently available systems use electrochemical cells to monitor the iNO dose delivered to a patient (including the LungFit PH). Electrochemical cells and sampling systems can be affected by humidity in the ventilator circuit (from condensation in the sampling circuit) and other contaminants such as medication. Also, in single channel systems, the response time of the sample system is measured in seconds which limits the response time of iNO delivery, and is slower than the response time of dual channel, gas flow sensor based systems. In both single and dual channel systems, the gas is sampled from the ventilator circuit, then the electrochemical cells need to respond, which takes a few more seconds. The cells can also become saturated with iNO causing them to respond less efficiently. There are a number of compensations that can be done with software to make the monitored values look better to the observer, but the bottom line is the sampling system is the weakest point of any delivery system. If you base your iNO delivery solely on a monitored value, you can have a single point of failure and the device is only as accurate as the previous iNO sensor calibration. A dual channel system can deliver an accurate dose even if the iNO calibration is inaccurate or the sample system fails.

What is the level of NICU team training required for LungFit PH compared to cylinder or cassette-based systems?

This is one of the strengths of the LungFit PH. Again, clinicians are making the same basic connections to the ventilator circuit they have been making for more than 20 years. After that, you just set the dose; there are no regulators to connect, and no purging needs to be done. There is also no need to calculate how long a cylinder or cassette will last, you just change a filter every 12 hours. You also do not have to check to see the remaining cylinder pressure when initiating iNO therapy, because the time remaining on an installed filter is always displayed on the LungFit PH screen and alarms at 30, 10, and 2 minutes, reminding you exactly how long you can use that filter. If you want to install a new one, you just remove the currently installed filter and pop in a new one. It is that easy. A frequent comment I hear following an in-service for the LungFit PH is that clinicians sometimes think they missed a step in the set up when they are first introduced to the device. I often have to say, I know it feels that way, but it really is so easy to set up it feels like you missed a step, especially if you are used to connecting cylinders and regulators and going through a leak test and purge routine. You will soon forget all about purging an iNO delivery system after spending a short time working with the LungFit PH. The device completely purges all iNO out of the system up to the point of delivery (ventilator circuit) within 6 seconds of stopping

therapy. The iNO is purged with the same room air that was used to generate iNO. Once the dose is set to zero, the Ionizer stops producing iNO and the room air passes though at the same flow rate into the ventilator circuit. The device will also purge the delivery lines if you turn it off without setting the dose to zero.

What has been the initial feedback from NICU teams and RTs who have used or evaluated LungFit PH?

Common comments I receive are: "the device is so easy to use, it does not require hours of training and retraining"; and "set up is so easy, I don't think we need a software wizard to assist with the setup." Staff love the fact that they don't have to manage cylinder logistics anymore.