Technology & Clinical
REPORT

Fall 2005 Vol. X, No. 1

Advances in pulmonary management of the critically ill infant

bunnell
INSPIRED INFANT CARE

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25 Years of "Inspired Infant Care"

by J. Bert Bunnell, ScD

I founded Bunnell Incorporated in 1980 when I realized the only way to successfully develop a High-Frequency Ventilator was on my own. I paid the last company I worked for $5,000 to buy back my ideas and the HFV prototype I was developing there. My early experiments with HFV at Massachusetts General Hospital in 1974 convinced me that this technique had significant promise, and I had to see it through to the end.

Dr. Tom Harris and I treated our first patient with HFV in 1982. The baby had BPD, and the device was a high-frequency positive-pressure ventilator, not a Jet. The prototype was quite sophisticated, even by today's standards. It measured exhaled tidal volume and could produce a quasi-static lung compliance measurement at the push of a button. However, we had to change its two HF valves every 72 hours. This was the only baby we treated with that device, because Dr. Joe Custer at the University of Michigan convinced us that jet ventilation was a better option.

We started treating babies with HFJV at Primary Children's Hospital in 1983. Using a pinch valve to create HFV and jetting the breaths into the ET tube was a more efficient and practical approach.

> ***"Half of the first 200 babies we treated survived, which was great considering their expected mortality was greater than 90%."***

Congenital diaphragmatic hernia and meconium aspiration patients were the most dramatic responders, but babies with PIE and other air leaks were the most frequent survivors. We could keep the CDH patients alive for days without surgery, and the Jet dramatically improved tracheal bronchial clearance in the MAS patients.

We initially thought the key to HFV success was to minimize all airway pressures. This approach was very effective in treating air leaks, but oxygenation was always difficult. Fortunately, we learned how to address the oxygenation issue from research presented at the Snowbird HFV Meetings.

It was Dr. Harris' idea to start an HFV meeting in 1983. The first one was held in Park City, Utah, where I had access to a condominium. Twelve people attended, and we all stayed in that one condo. Participants included Drs. Eduardo Bancalari, Greg Heldt, Neil Finer, and David Smith, Miki

Inglet, RRT, and five bioengineers and two marketing guys from my little start-up company and Mallinckrodt, Inc.. We spent two days discussing theory, early animal and clinical results, indications and contraindications, and potential complications.

In 1984 we met at the Snowbird Ski Resort for the first time. Attendees included neonatologists, pediatric intensivists, bioengineers, and RTs from across the US and Canada. Presenters were Drs. Don Null, Ron Goldberg, Alan Spitzer, Wally Carlo, Steve Donn, Steve Karl, Marty Keszler, Mark Mammel, Steve Boros, Joe Neu, and Ron Ariagno and RTs Bob Kopotic and Rob Chatburn. Don Null, Steve Karl, and Tom Harris volunteered to head up the organizing committee for the next annual meeting.

FDA Struggles and HFV Competition

Even though evidence was mounting that high frequency ventilators worked, it was increasingly difficult to convince the Food and Drug Administration (FDA) that HFV was here to stay. Certain key reviewers in Washington thought we would just fade away because the device approval process was so difficult. It took years of testing and multiple submissions, but I finally got a hearing with the FDA's clinical advisory board in 1986. The advisory board recommended approval.

It took two more years before we got our FDA approval in 1988 by which time we were on the verge of bankruptcy. Fortunately, orders for the Life Pulse quickly rolled in. We had survived and business was good until 1992.

With a two-year FDA approval lead on the competition, we fell into the trap of thinking that we had all the answers for HFV. Convinced that less pressure was the obvious way to avoid and treat barotrauma, it took a lot of data from the HFOV proponents to convince us that there was more to HFV than using lower airway pressure. Our biggest wake-up call came from the HiFi Study.

The HiFi Study was a large multicenter randomized trial, sponsored by the NIH, which compared early use HFOV (the Senko Hummingbird) to conventional ventilation in RDS patients. Results were negative: no demonstrated benefit and increased severe cerebral injuries. The HFOV camp concluded that the HiFi investigators failed to follow a "high lung volume" strategy, and we in the HFJV camp thought the results were particular to HFOV. Clearly, we all had more to learn about HFV.

We started listening more carefully to all the experts at the Snowbird HFV Meetings. Dr. Alan Spitzer reported that adding IMV breaths to HFJV was a huge benefit to oxygenation, and Drs. Robert deLemos and Alison Froese presented the most cogent arguments for the high-lung volume strategy with HFOV. Finally, Dr. Froese incorporated Dr. Spitzer's findings into a refined strategy for HFJV in the elegant animal experiments she presented at Snowbird in 1990.

Dr. Froese skillfully taught us the importance of ventilator strategy. The key to successful use of the Jet was using optimal PEEP. Using IMV to recruit collapsed alveoli worked fine as long as PEEP was high enough to take advantage of its critical opening pressures. Once alveoli were opened, continuing IMV breaths with HFJV was unnecessary, and one could operate HFJV in a style similar to the high lung volume strategy with HFOV.

Dr. Froese helped us change our focus from technology to strategy. She increased our understanding of how to use HFV appropriately and for that we will forever be indebted to her.

The future of Bunnell and HFV looked bright. The June 1992 issue of FDA Consumer, the agency's public relations news magazine, ran a cover story on the Bunnell Life Pulse HFV touting its life-saving capabilities and the role FDA played in getting it on the market. Unbelievably, that very same month FDA faxed us a letter ordering us to notify our customers that they considered our device hazardous to the health of the babies it was being used to save.

FDA's action was prompted by a former Bunnell employee who told FDA that a defective Jet had led to the death of a baby in California. Fortunately, we had good records on that case (we were found to be faultless by a hospital inquiry into the matter), and we were finally able to convince FDA at our hearing that they had been grossly misled by a disgruntled former employee.

It took a two-day regulatory hearing and nearly a year to re-convince FDA that our product was safe and effective. In the process we upgraded our manufacturing documentation and procedures to FDA standards, which eventually made us a much stronger company. We now have top-notch regulatory and manufacturing people and are in good standing with FDA and all other regulatory bodies that oversee our operation.

The Slow Recovery and on to "Inspired Infant Care"

Most Jet users stuck with us during the FDA crisis, but some stopped using the Jet and switched to HFOV. Sales bottomed out in 1995, but they have steadily improved since then, particularly over the past four years with an average annual growth rate of 20% per year. We just finished the best year in the company's history with a remarkable 36% increase in sales.

Our clinical and device research continued to advance even during the difficult times thanks to some timely NIH grants and dedicated clinical collaborators and advisors such as Drs. Tom Harris, Alan Spitzer, Wally Carlo, Jonathan Davis, Steve Donn, Martin Keszler, Houchang Modanlou, Rita Ryan, Tony Clark, Philippe Friedlich, Ron Cohen, David Smith, Dick Bland, Dave Carlton, Kurt Albertine, and numerous other physicians and respiratory therapists including many friends in Canada, Australia, Poland, and the Czech Republic to whom we will be forever grateful. Many of these folks participated in the multicenter randomized trial on early intervention in infants with RDS, coordinated by Martin Keszler. This study demonstrated the benefits of using higher PEEP to improve oxygenation and decrease hyperventilation.

The culmination of 25 years of clinical experience, studies, and numerous discussions with our users have provided us with a much clearer understanding of how HFJV works for infants and children suffering from all kinds of injuries and pathophysiologies. We have learned the value of when to turn up the conventional ventilator in tandem with the Jet and when to turn it back down to allow HFJV to do its magic. We learned the value of not only optimizing PEEP, but also of using slower Jet rates with longer expiratory times for babies with chronic lung disease. Our newest multicenter randomized controlled study will focus on validating this newest treatment strategy for babies with "evolving BPD."

Our ongoing contact with clinicians, around-the-clock 800-Hotline service, and the two annual meetings, Snowbird in April and Tempe in November, provide us with opportunities to continually refine our understanding of the Jet and the training we provide our customers. We started several exciting new research projects in the past year with the help of many of you, and we look forward to many more years of providing *Inspired Infant Care*. Thank you all!!!!!!

> ***"We just finished the best year in the company's history with a remarkable 36% increase in sales."***

Snowbird HFV Conference '05

The High-Frequency Conference held at the Snowbird Resort, Utah was once again a great success. Attendance was 188 which represented 33 states as well as, Australia, Belgium, Canada, Poland, and Portugal. There were presentations on a wide range of topics, including conventional and high-frequency ventilation, and infant to adult applications. It was particularly exciting for Bunnell because we are celebrating our 25th Anniversary this year, as a ventilation company.

The highlight of our celebration was a party featuring a "Jeopardy" style game with questions about the Snowbird meeting, high-frequency ventilation, and Bunnell history. Our Clinical Specialist, Evan Richards created the game and it incorporated his quirky sense of humor. It was a perfect blend of educational information and hilarious anecdotes that keep everyone entertained.

The meeting started off this year with two presentations on the Bunnell Life Pulse HFV. The first one titled, "HFJV in Neonatal Respiratory Disease Unresponsive to HFOV" by Peter Dargaville, MD from Royal Hobart Hospital, Tasmania, Australia reported on 28 patients that were rescued from the SensorMedics 3100A over an 8 year period using the Life Pulse. The conclusion of this observational study was, "Initiation of HFJV in infants unresponsive to HFOV was consistently associated with better gas exchange, and particularly in those with MAS, ultimately led to survival. HFJV should be considered whenever HFOV is failing, and if used, should be initiated before the lung becomes irretrievably damaged."

The second presentation by Andora Bass, MD from Duke University Medical Center reported on bench data that validated the accuracy of using the Life Pulse to monitor the SensorMedics Oscillator. Her data showed that the Life Pulse was more accurate than the $NICO_2$ Respiratory Profile Monitor (Respironics Inc.). This study was done to see if there was a convenient way to determine PIP and PEEP settings when switching from HFOV to HFJV that would result in a mean air-

way pressure (Paw) that was similar to that on HFOV. She concluded, " HFJV accurately monitors pressure delivery during HFOV. These measurements can then be successfully used to calculate the predicted PEEP necessary to match Paw on the two types of high-frequency ventilators. Replicating the Paw with adequate PEEP on HFJV will simplify the transition between ventilators and may result in improved oxygenation."

The afternoon of the second day, Hooshang Baghaee, RRT, a senior therapist from Georgetown University Hospital, Washington, DC, presented a retrospective review of their 5 years of experience using the Life Pulse with the INOvent. The purpose of the review was to evaluate the feasibility and safety of this application during transport and NICU use. The 44 patients they treated represented 3724 hours of HFJV and iNO therapy, including 30 hours during transport. No device failures occurred and there were no mechanical problems with either device. Abstracts of these presentations are available upon request by contacting Dave Platt at plattdr@bunl.com or 800.800.4358 ext.15.

The "Call for Abstracts" for the 2006 HFV Conference will be mailed in August and due on December 12, 2005. If you would like to receive a submission form, contact Carolyn Smith at 801-588-3861 or carolyn.m.smith@ihc.com. If you need help or support to put a presentation together, contact Dave Platt at Bunnell (contact information listed above). The Snowbird meeting offers a unique opportunity to share clinical observations and research data, with a ventilation focus. Even if you don't have a presentation to share you should plan on attending the meeting, Mar. 29 – Apr. 1,

2006. It's a fun and friendly atmosphere where you'll learn clinically relevant strategies from leading experts in the field of ventilation and have an opportunity to ski some of the best snow on the planet.

New Clinical Specialist

Kari Woodruff (formerly Kari Brandenburg), BSRC, RRT-NPS is our newest clinical specialist. She came to us from Presbyterian/St. Luke's Medical Center in Denver, CO where she was a therapist for 7 years and the Neonatal and Pediatric Clinical Coordinator for 2 years. She was also coordinator for the neonatal/pediatric transport team as well as an ECMO team

member. In addition to her many accomplishments in the clinical realm, Kari distinguished herself as a member of the Colorado State Sputum Bowl teams from 2000 to 2004. The Colorado team reached the finals in 2003 and 2004 finishing in 2nd place. Kari is currently the Vice President for the Colorado Society for Respiratory Care.

Kari will be providing training and sales support for us in the following states: Nebraska, Kansas, Oklahoma, Texas, Wyoming, Colorado, and New Mexico. If you work in one of these states and have any sales or training needs, please feel free to contact Kari directly at kari.woodruff@bunl.com.

Infant Star™ Trade-In Program

Bunnell Incorporated is offering a Trade-In Program for the Infant Star™ High-Frequency ventilator. A $5000 credit can be applied toward the purchase of a Bunnell Life Pulse High-Frequency ventilator with the trade-in of a fully functioning Infant Star™ High-Frequency ventilator. This is a one-for-one, limited time offer!

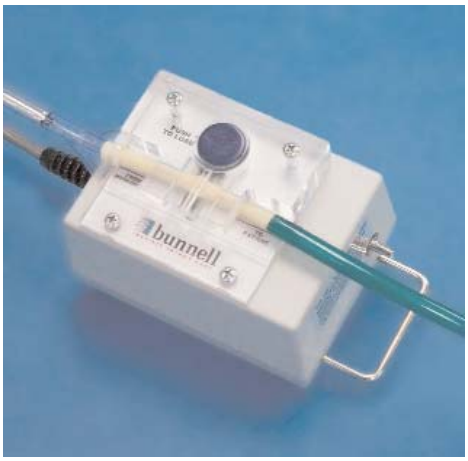
Because of the huge trade-in discount being offered, rental credits will not be applied to the same purchase. The Infant Star trade-in program will be in effect for a limited time.

To qualify for the Infant Star credit, the Infant Star must be received by Bunnell Incorporated within two weeks of delivery of the Life Pulse. Some restrictions may apply. For additional information contact Ken Hekking at 800.800.4358 ext. 13 or khekking@bunl.com.

"WhisperJet" PB News

The WhisperJet (Model# 312 Patient Box) is a great improvement over the original patient box, particularly when you consider how quiet it is. Here's what Tom Shaw, MD from DeVos Children's Hospital has to say about the WhisperJet, "We think the WhisperJet boxes are

significantly quieter and make an already great ventilator even better." As with every new product, we have learned a few things about the WhisperJet since it was release for clinical use.



We learned early on that the WhisperJet works better when it is driven by a slightly higher voltage than the original box. This issue was addressed by sending out valve driver regulator (VDR) boards (versions 1 & 2). You should be running VDR version 2. Please make sure the VDR upgrade paperwork has been completed and returned. If you have any questions about the VDR in your Life Pulse contact our customer service department.

The WhisperJet also requires a more complete test set-up to pass the Self Test. The Life Pulse circuit must be connected to a LifePort adapter and an ET tube with test lung in order to pass the purge valve check portion of the Self Test. Without the proper test set-up you get a Ventilator Fault 02 during the Self Test.

If you are using an appropriate test set-up, as described above, and you get a Ventilator Fault 02, please contact us via our 800.800.4358 Hotline number. One of our clinical specialists can help you determine the cause of the Ventilator Fault 02. We have identified a few WhisperJets that were manufactured with purge valves that were a little sluggish responding to the purge drive signal. These valves will sometimes fail the Ventilator Fault 02 test because the purge doesn't occur fast enough (the requirement is 10 milliseconds). The purge valve in these boxes can be replaced to eliminate the problem.

The last news item related to the WhisperJet is a cautionary note. We have received several WhisperJets from customers reporting a range of symptoms from Ventilator Fault 02 to "stopped working", only to discover that the WhisperJet box had been dropped. The WhisperJet is a precision device, which does not respond well to dropping. The handle on the WhisperJet was designed so there is a convenient way to secure the WhisperJet during transport. Please use caution when handling or moving the WhisperJet so it does not find its way to the floor.

If you have any questions or concerns about your WhisperJet patient boxes, please contact our customer service department at 800.800.4358.

Have You Seen Our New Colors?

This new friendlier, more contemporary look is not only available on new Life Pulse ventilators. It is also available as an update for older Jets as well. Any Life Pulse serial number 2169 or greater can be updated by replacing the front panel and the two case halves. The cost is $1800.00. This update is also available, at no charge, with the purchase of a two year service contract.

For more details or to make arrangements to update your Life Pulse contact Ken Hekking at 800.800.4358 ext 13 or khekking@bunl.com.

Using a UPS with the Life Pulse

Many of you know that Bunnell has long recommended using an uninterruptible power supply (UPS) in conjunction with the Life Pulse. A UPS is a sophisticated power conditioner with a built-in battery. You may use one at home or in the office to protect your computer from power irregularities.

A UPS provides the same kind of protection for the Life Pulse. It regulates the power going to the Life Pulse so the microprocessor does not lock-up while the system is running on a patient.

Power fluctuations are more common in older hospitals and hospitals that are undergoing renovation. They can be the result of checking the back-up power system or electrical storms. Regardless of the cause, they have the potential to interrupt any microprocessor driven device.

Bunnell distributes one brand of UPS, which is made specifically for hospital use. There are a number of companies that make hospital grade UPSs. If you would like additional information about UPSs, contact our customer service department at 800.800.4358.

If you are running the Life Pulse whether it's yours or a rental, we suggest you run it in conjunction with a UPS!

Wanted: "Jet" Clinical Specialist

With the Life Pulse being used more than ever, requests for training have increased. Training clinicians is one of the most important services Bunnell provides. We are always looking for bright, enthusiastic respiratory therapists with "Jet" experience to add to our family of clinical specialists.

Clinical Specialists are used for in-service training, demos, evaluations, emergency clinical support and regional conferences. Bunnell provides extensive training and certifies clinical specialists before utilizing them in the field.

Clinical Specialists must have the flexibility to travel. Trips are usually one to two days. Reimbursement is on a per diem basis with all expenses paid.

If you're looking for a new challenge and want to share your knowledge of the Life Pulse with other clinicians, contact Evan Richards at 800.800.4358. ext. 37 or evanr@bunl.com. We're looking for a few good therapists!

iNO & the One-way Valve

If you are currently delivering iNO via the Life Pulse using the INOvent, you may want to consider adding a one-way valve between the injector module and the humidifier. The one-way valve will prevent water in the humidifier from reaching the injector module and causing problems.

For more information about how to implement a one-way valve into your iNO – Life Pulse set-up contact Dave Platt at plattdr@bunl.com or 800.800.4358 ext.15.

Hi-Lo Jet ET Tubes are No More

As many of you may already know, Mallinckrodt Medical Inc. is no longer manufacturing the Hi-Lo Jet ET tubes. We only have a limited supply of the 3.5-mm, 5.5-mm, and 6.0-mm I.D. sizes left in stock.

If you are interested in ordering any of these Hi-Lo tubes, contact our customer service department at 800.800.4358 ext. 6.