



Clinical Excellence

Paediatric and hi-acuity patients
Highly accurate volume delivery and responsive trigger
Advanced monitoring capabilities providing detailed insight into the quality of ventilation



Versatility

Designed for Hospital, Home and Mobile use
Adaptable to patients needs and prescriber preferences
Easy to use thanks to intuitive user interface



Low Cost Of Ownership

Robust design
Cost-efficient service
Integrated monitoring capabilities
Short learning time



www.vivo60.com

* Vivo by Breas is a trademark of Breas Medical AB

© 2014 Breas Medical AB - All rights reserved.
Breas Medical AB reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.
Contact your Breas representative for the most current information.
The Breas logotype is a trademark of Breas Medical AB.

BREAS

Breas Medical AB · Företagsvägen 1 · SE-435 33 Mölnlycke · Sweden
Phone +46 31 86 88 00 · Fax +46 31 86 88 10 · www.breas.com

vivo

From Hospital to Home

by Breas

Dr. Kurt Wollinsky
INTERVIEW



Meeting the challenge

CARL VAN LOEY ← INTERVIEW

Mikael Tiedje: **THE ALGORITHM OF LIFE**



vivo60.com



EDITORIAL

EDITOR/WRITER: Paul Redstone
PRINT & PRODUCTION: Ineko AB
PHOTO: Sam Lindh, Grafia

VENTILATION

as part of a patient-centered approach to care

Today there is a growing movement toward patient-centered care, driven by the need to improve the quality of healthcare while simultaneously reducing costs. It is now well established that these aims are compatible. But how does home mechanical ventilation fit into this wider care picture?

One of the main principles of patient-centered care is that patients and family members are the best judges of how well their needs are being met, and their experience therefore determines an assessment of successful treatment¹.

Involving the patient and caregivers in defining the parameters for effective treatment is therefore a cornerstone of the approach, ensuring the clinician's assessment of the care matches the patient's experience.

A patient-centered approach can help improve clinical outcomes and satisfaction

levels. At the same time, savings are made because of reduced demand for prescriptions, hospitalizations, referrals, etc.²

Homecare is a natural component of patient-centered care, and many clinical decisions within homecare will be influenced by the approach. Having the right equipment available means more patients can be treated at home, where they are more likely to experience a better quality of life.

For a ventilator to effectively support patient-centered care, it must be user-friendly and robust enough for use in daily activities and under highly challenging conditions. It must meet

patients' changing needs, and have the accessories and autonomy needed for a life beyond the hospital or home. Equally important is that the ventilator is very quiet, allowing for a good night's sleep.

At the same time, the ventilator must give doctors the treatment modes they want, cover as wide a range of patients as possible, have a familiar interface, and offer the lowest possible cost of ownership.

Vivo* 60 is an important step forward in aligning life support ventilation with the aims of patient-centered care. It supports the critical balance between improving patients' quality of life and making better use of healthcare resources.

¹ Hudon C et al, Ann Fam Med 2011;9:155-164

² Felix S F Ram, Jadwiga A Wedzicha, John Wright, Michael Greenstone: Hospital at home for patients with acute exacerbations of chronic obstructive pulmonary disease: systematic review of evidence. BMJ, doi:10.1136/bmj.38159.650347.55 (published 8 July 2004)



Vivo 60 is the new flagship of the Breas range. It builds on the highly successful Vivo 50 platform, extending the treatment possibilities even further. But what can the clinician expect from the new ventilator in practice?

We asked Breas clinical specialist *Carl Van Loey*.

Meeting THE CHALLENGE

What sort of issues is Vivo 60 designed to address, and how? There are many pressures on medical staff, including high workloads, lack of time, staff shortages and budget restrictions. That's today's reality. We believe a medical device must help address these aspects. First and foremost, a life support ventilator has to be reliable. It should have the modes and functionality the clinician wants, but should also be easy to learn, and flexible enough to treat as many patients as possible.

The challenge is to create a device that allows comfortable treatment to maximize quality of life, without compromising on security. It's about combining the needs, wishes and expectations of medical staff with those of homecare providers, carers and patients.

What does Vivo 60 offer the clinician working with paediatric patients? One of the key developments in this ventilator is the ability to treat infants as small as 5 kg. It is an important step forward enabling infants to be treated at home as an increasing priority. This development also required considerable technical advancement. The margins involved are much smaller, so precision is everything.

Small infants have different breathing patterns and require more accurate volumes. Volume deliveries are extremely accurate and stable in Vivo 60.

Furthermore, infants' needs change quickly over time. All this was taken into account in the design of Vivo 60. It also offers measurement of exhaled gases, which sometimes might be required for additional security.

"It's a game changer for sure!"

What are the key features and benefits of Vivo 60?

The goal was to achieve the highest level of clinical excellence. To this end we've incorporated a wide range of settings and setups, different circuit types, and the flexibility to use different interfaces. Its leakage algorithm also ensures accuracy of volume delivery and measurements. However, these clinical possibilities are not at the expense of ease of use. We only include treatment modes for which there is firm clinical evidence.

Some of the key benefits go beyond the ventilator itself. The importance of accessories and software to analyze and monitor treatment cannot be overemphasized.

What might clinicians see as the "number one" feature?

Besides its obvious clinical excellence, I see the monitoring possibilities as impressive. I believe they will be greatly appreciated. In addition to onscreen monitoring, you have the option to attach a range of sensors, allowing you to gather all treatment data into one memory package for easy analysis. This eliminates the need for multiple standalone devices. It's game changer for sure!

What about patients?

Vivo 60 is intended to support the patient in achieving a fuller life with more possibilities. While the top priority is of course a ventilator they can feel safe with, there are many details that make a big difference. The interface and menu system is simple and intuitive, without complicated sub-menus. And it's robust enough to take anywhere. The 4-hour internal battery combined with the 8-hour click-on battery provide a whole day of mobility. Moreover, click-on batteries can be changed without stopping the ventilator. We've had a lot of comments about its looks too. Performance is everything with a medical device of this nature. But let's face it, patients have to live with it all day every day, so a more attractive design is a little detail that makes a difference.

THE ALGORITHM OF LIFE

One of the biggest advantages of Vivo 60 is something that can't be seen or touched – the firmware and underlying algorithms that make it so precise and responsive. There's some serious number crunching involved. But as *Mikael Tiedje*, Team Manager Software, explains, every line of code is inspired by human feeling.

Creating a ventilator capable of responding to the breath demands of infants as small as 5 kg demands software wizardry of the highest order. It's easy to get lost in the technical details. But, Mikael says, it's really all about people. "The key is empathy," he says. "It's essential to understand the patient and their situation. That was the key to designing the core algorithm and safety features." The watchword for Vivo 60 was accuracy, and a great deal of work went into developing the trigger mechanism. "For paediatric patients we're talking about volumes as small as 50 ml," he says. "The difference between this and Vivo 50- 100 ml minimum volume doesn't sound much, but when you get down to these levels, you need a completely new approach." The responsive trigger mechanism also makes Vivo 60 ideal for treating

patients with a degenerative neuromuscular disease, where inspiration effort is very low due to muscle weakness. An important aspect of this accuracy is the new circuit to measure exhaled air volume, coupled with an advanced measuring approach called eSync*. "Vivo 60 measures and compares the characteristics in the inhaled and exhaled air," Mikael says. "This allows you to set up the whole breath as one entity. The inspiration and expiration phases are equally important." Another accuracy-enhancing feature is the ventilator's leakage compensation. Based on the ventilator settings and the attachments in use, this patented technology calculates the level of air leakage and automatically compensates. The patient-centered approach to software development ensures a lot of useful functionality. Vivo 60 supports up

to three profiles. Profiles can be created for day and night, for example, when the patient has different ventilation needs. A profile could also be set up to clear the lungs from secretions when a physiotherapist is not on hand to do this manually. "It all comes back to empathy," Mikael adds.



CUSTOMER-FOCUSED SUPPORT

A medical device should never be judged solely on the strength of the machine itself. Breas Product Applications Engineer Emilia Bjerke points out that factors such as the quality of service and support are also critical aspects that determine the overall value of the solution.

Service and support is an area that makes a major contribution to both clinical performance and cost of ownership. It's a key focus for Breas. "We provide thorough training," Emilia says, "as well as giving easy access to resources such as tools, test equipment and service manuals. All of this reduces complication and saves time, which in turn contributes to the bottom line." Simplicity is the key. "We make it all easy," Emilia says. "From ordering parts, to working on the machine, to notifying about available upgrades. Everything is accessible and clear, with useful little details such as color-coded tubing. There are few parts and servicing is easy with minimal disruption. The annual service requires no more than a filter change

and a quick functionality test, which can be carried out in the patient's home. It's a win-win for both the patient and the service provider." Furthermore, all the information and resources the service technician needs are available on a dedicated extranet site, which distributors are given access to on completion of training. Support is an area where the Breas spirit provides some natural advantages. "Our long-term focus on patients and customers ensures it is always a top priority." Emilia says. "The Breas commitment to simplicity and ease of use comes from starting as a small company. We know the customers, and they know us – it's a relationship based on trust. We understand how important it is to ensure short delivery times and to be available whenever we are needed." This simplicity is partly the result of Breas involving the support team in the development process from an early stage. This ensures a product with minimized maintenance time and easy serviceability. But whatever the reasons, it all adds up to a great customer experience and a lower cost of ownership.

"It all comes back to empathy"

VIVO 60 AT A GLANCE

Vivo 60 is designed to meet the needs both of medical staff and a wide range of patients. It combines comfortable and controllable ventilation with excellent mobility.

Features such as precise synchronization, accurate volume delivery, leakage compensation and flexible monitoring possibilities make it suitable both for adults and for young children, and help shorten the hospital stay. Vivo 60 is easy to learn and operate, saving time for medical staff and homecare providers. Furthermore, its robustness and easy servicing contribute to a lower cost of ownership.



Roger Nyström, Product Manager

QUICK FACTS:

Pressure and volume

60 mbar maximum pressure.
50 ml minimum volume.

Circuits

Single limb with leakage port or exhalation valve.
Dual limb circuits enabling exhaled volume measurement.

Trigger

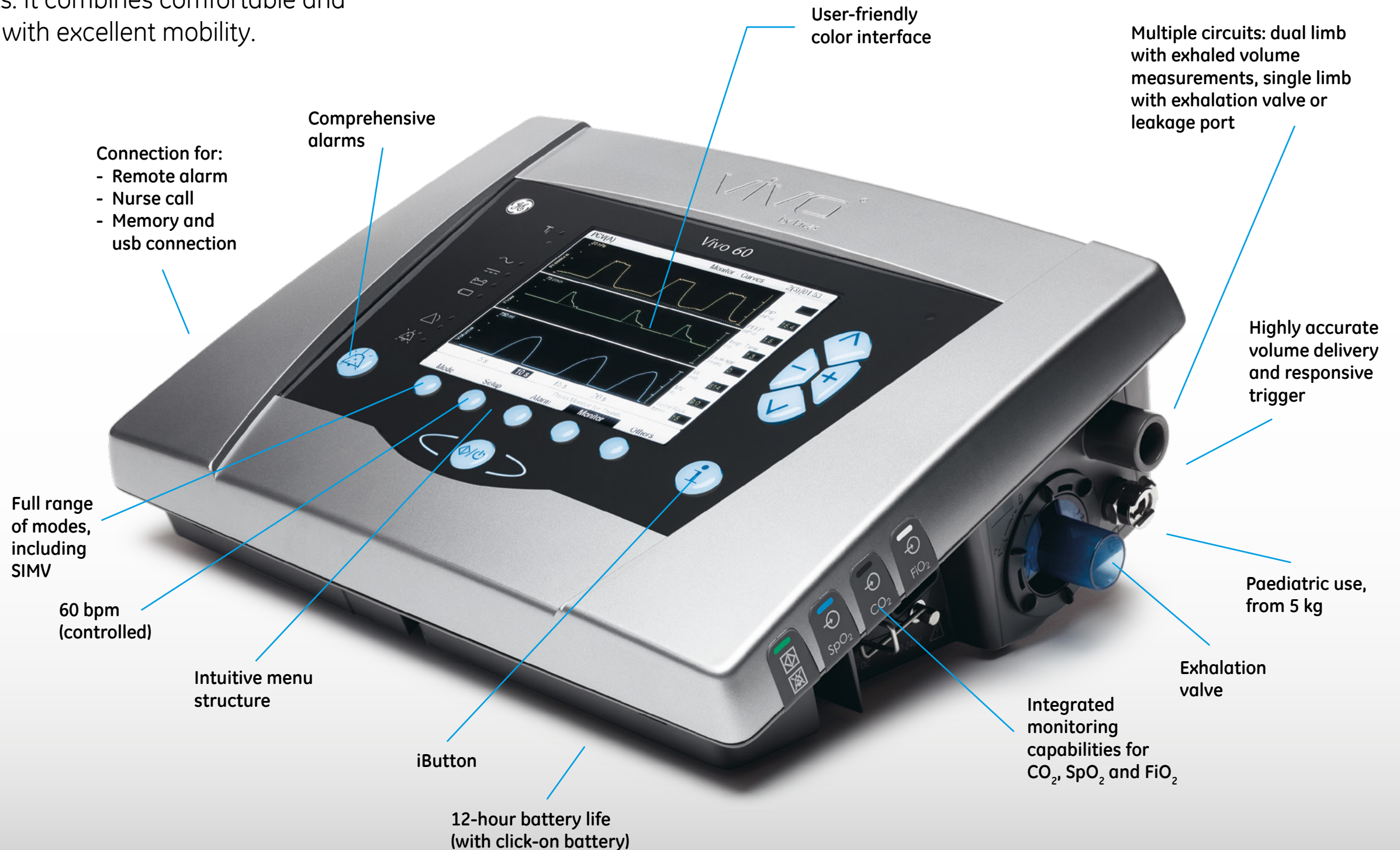
Responsive trigger to cope with the needs of the most sensitive patients.

Blower

Innovative design for Vivo 50 and Vivo 60 with advanced energy preservation technology.

Modes

Pressure and volume ventilation with SIMV mode added in response to customer requests.



Dr. Kurt Wollinsky is a senior physician at the Clinic for Anaesthesiology, Intensive Care and Analgesic Therapy, RKU Ulm University and Rehabilitation Hospitals, Germany. The hospitals have a focus on orthopedics, spinal cord injury and neurology. We talked to Dr. Kurt Wollinsky about ventilation of adult and pediatric patients, as well as his experience with some of the Breas ventilators.

FROM HOSPITAL TO HOME – AND BEYOND

What type of issues do you deal with on a daily basis?
We treat many adolescent and adult patients with neuromuscular issues from either spinal cord injury, scoliosis, amyotrophic lateral sclerosis, or muscle disease such as Duchenne muscular dystrophy. The nature of these conditions means we are often treating adult patients with acute and chronic respiratory insufficiency who cannot be weaned from the ventilator.
We also treat children and infants with spinal muscular atrophy and chronic respiratory insufficiency. This was first made possible by the BREAS PV 403 ventilator some years ago.

Is homecare an important part of the regime?
Where possible we aim for patients to be supported at home in order to give independence and the best quality of life, and to prevent respiratory degradation. We have outpatients from 10 months to 80 years old who use ventilators. Many go to kindergarten, school or university, or have jobs. Mobility is an essential criterion here. The requirement is for stable ventilation with a modern turbine-driven ventilator, convenient ventilation patterns, alarm functions and good battery supply.

What advantages have you found with Vivo 50 when it comes to homecare?
We use it extensively and appreciate it very much. Vivo 50 gives us a wide

range of possibilities when it comes to respiratory modes and target volume. It is robust and the battery is excellent, which is very important for long-term patients using wheelchairs, who of course will not always have access to an external power supply. The ventilator will follow the patient everywhere, in different kinds of temperatures and weather conditions. It is a very quiet ventilator – an important consideration for restful sleep at home. Furthermore, the modern design is often appreciated.

What special considerations are there when treating paediatric patients?
Paediatric ventilators need a broad variation of respiratory rates, short inspiration times and extremely sensitive triggers for inspiration and expiration, small tidal volumes, and assisted spontaneous modes. The option of either an open leakage system or a closed circuit system with valve is offered for ventilation. Alarm functions are also important due to the low tolerance for hypoxemia compared to adult patients. Young infants are sometimes on invasive ventilation. Sufficient leakage compensation is very important for uncuffed ventilation via tracheal tubes. Premature babies with bronchopulmonary dysplasia need long-term ventilation at home after discharge from the ICU or paediatric hospital.

Monitoring possibilities are also particularly important for treating children, since we need precise control over ventilator data. There are a number of

parameters to monitor depending on the diagnosis, such as pressure, connection alarms, frequency control, oxygen saturation and CO₂.
You treat patients with quite different respiratory needs. How important is versatility in a ventilator?
It is important. Efficiency and safety are improved when there is only one ventilator to learn that can treat a broad spectrum of patients, including adults, children and infants from 5 kg, with both high and low pressures.

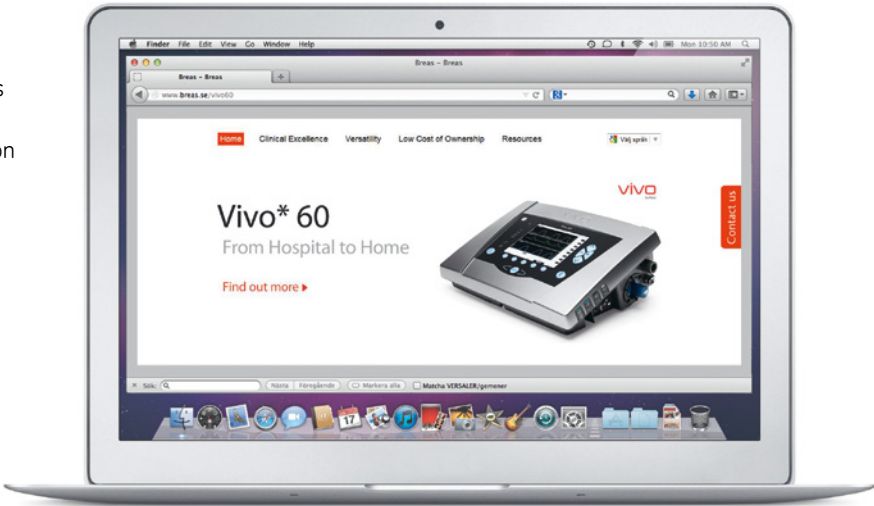
What other features are important for you?
Quick access to information and controls. A large display with a clear presentation of all essential ventilation parameters, alarms, etc. on a single screen. Everything you need should be right there, so you know the status at a glance without the need for additional steps. Vivo 50 and 60 are good examples of such a display. The availability of help and troubleshooting is important for the nursing team and families during ventilation at home.
Another very useful feature is the possibility to change modes without stopping the ventilator, as some patients are not able to tolerate a pause in the ventilation.
In the end it all comes down to supporting the patient's needs. The improvements we have seen in Breas ventilators over the years have made an enormous difference in terms of independence and quality of life.

vivo60.com

Take the opportunity to visit our new dedicated Vivo 60 web site! Just like Vivo 60 itself, we have kept the design simple and user-friendly, with few menus and easy-to-access controls.

- You can find everything you want to know on the new web site, such as:
- A clear overview of features and benefits
 - Contact shortcuts for booking a meeting with a representative, request information and more.
 - Downloadable resources such as the product specification and the Vivo 60 Magazine
 - A concise presentation film: "Vivo 60 in 60 Seconds"
 - Films on monitoring
 - Links to other information sites in different languages

We will continue to add resources to the site, so do check back regularly for updates.
Go to www.vivo60.com



Q AND A WITH IBB JESSEN

Principle Engineer, Breas Medical

How big of an advancement is Vivo 60?

Big! The development of Vivo 50 and 60 involved more than 50 man years of engineering with a team of up to 25 people.

Over 200,000 lines of code were written. It's the biggest investment Breas has ever made.

What was the biggest technical challenge?

From the beginning, the blower design. A great deal of work went into perfecting the housing design. It was a crucial innovation in order to achieve the highly precise volumes we needed. The fan unit is also an innovative piece of work, featuring a highly advanced Swiss-made motor. It's tiny,

but it would be easily powerful enough to drive a vacuum cleaner! The impeller design was crucial – it's very lightweight but can handle 50,000 rpm with every breath. Advanced power technology recovers energy when the blower slows down, putting it into use the next moment to accelerate the blower.

Anything else?

After establishing Vivo 50, the team did a great job further developing and refining the algorithms that are required to treat small children and adults with very severe conditions.

What are you most proud of?

The teamwork that made it possible.



“It’s been an amazing journey”

A spirit of
INSPIRATION

Breas has been one of the pioneers in homecare ventilation and sleep therapy for over 20 years and the founding spirit is still just as strong. CEO *Nicke Svanvik* describes what drives the company.

Breas has been motivated by the desire to improve patients’ lives and help clinicians since 1991, when the company started up in Gothenburg. From humble beginnings, it has grown into a significant player in bi-level and home mechanical ventilation across Europe.

“It’s been an amazing journey,” Nicke says. “Today we are recognized as one of the leaders when it comes to versatile innovation and industrial design for the homecare market. Our brand is based on the same values we started up with – quality, a focus on patients and customers, and a commitment to innovation.”

With the move into GE Healthcare, he says, Breas came of age. “GE enabled us to mature as a global medical device com-

pany, for example strengthening our design control procedures to ensure compliance with global regulatory requirements”.

Breas is strong in Europe, but is also well positioned to grow in selected homecare markets worldwide. Breas already has a significant presence in Japan and recently Vivo 50 was cleared for sales in the US.

Nicke sees ventilation as an area where the company can make a vital difference. “Everything we do is about bringing patients from the hospital to the home,” he says. “We have special competence in combining advanced clinical treatment modes, mobility and monitoring in order to bring true value to patients and customers. And now we have a product range

that offers even greater possibilities.” To make our vision a reality, Breas works closely with customers. Many years of collaboration have built up a natural source of design input that influences all the company’s activities – from R&D to marketing, customer support and service.

“When you visit our site in Molnlycke, Sweden, you can feel the spirit and the passion for listening to our customers,” Nicke says.

He adds that Breas is never content to stand still. “We’re always looking to combine present customer requirements with innovations that will enable the products of the future. Vivo 60 will enable chronically ill or disabled children to live a fuller life. Few things create a greater sense of purpose than that.”

OUR RANGE OF PRODUCTS



iSleep 20/20+/20i

The Breas range of sleep devices includes a basic CPAP, a CPAP with pressure reduction at exhalation, and an auto-CPAP. Common for all devices is their user-friendly interface, design and robustness.



iSleep 22/25

iSleep 22 and 25 are bi-level devices with different levels of functionality. They are an excellent choice for more severe OSA patients or OHS patients. The user interface has the same intuitive menu structure as the other devices in the range.



Vivo 30

Vivo 30 can be used to treat various hypoventilation conditions. It provides non-invasive ventilation to patients over 30 kg with spontaneous breathing. The Vivo range is appreciated for its intuitive user interface and Scandinavian design.



Vivo 40

Vivo 40 bi-level ventilator is equipped with adult and paediatric modes, internal battery and target volume. It can be used for invasive and non-invasive ventilation in patients from 10 kg and up. Vivo 30 and 40 were upgraded in 2013, further enhancing functionality and giving an attractive new look.



Vivo 50

Vivo 50 is an advanced life-support ventilator for patients of 10 kg and above. It provides a wide range of modes, settings and alarms to ensure effective and comfortable ventilation. Integrated monitoring options, combined with alarms and PC software, provides extensive monitoring capabilities for better insight into the quality of ventilation. Vivo 50 can be used in the hospital, at home or on the move thanks to its 12-hour autonomy (using the click-on battery) and a wide range of accessories.



Vivo 60

Vivo 60 provides clinical excellence, versatility and low cost of ownership. Intended for patients from 5 kg, it takes ventilation treatment to a new level while maintaining the intuitive user interface and other appreciated features of the Breas range.

VIVO 60



Is a life-support ventilator intended for paediatric and adult patients requiring highly secure and reliable ventilation in the hospital or at home. Vivo 60 offers clinical excellence, versatility and a low cost of ownership

Clinical excellence

To treat patients under some of the most challenging circumstances, care givers require security and clinical excellence. Vivo 60 is developed to meet these demands by offering:

- Intended use for paediatric (from 5 kg) and adult ventilator-dependent patients.
- Effective and comfortable ventilation thanks to highly accurate volume delivery and responsive trigger.
- Improved insight in the quality of ventilation using the advanced monitoring capabilities. These include integrated SpO₂, CO₂ and FiO₂ monitoring, numeric values and Pressure, Flow and Volume wave forms on display, comprehensive alarms and PC software.

Versatility

Versatility is a requirement equally important to patients, care givers and homecare providers. Vivo 60 provides multiple benefits to make it a truly versatile ventilator.

- Designed for Hospital, Home and Mobile use, thanks to its attractive Scandinavian design, low noise level, 12-hour autonomy (with click-on battery) and wide range of accessories.

- An extensive set of modes and settings, three profiles, the choice of single and dual limb circuits with leakage or exhalation valve and invasive and non-invasive use, make Vivo 60 highly adaptable to patient needs and prescriber preferences.
- A highly intuitive User Interface, which is easy to use, easy to learn and helps reduce the risk of mistakes.

Low cost of ownership

Demands for cost-effective treatment and service are continuously increasing. Therefore, Vivo 60 has been developed to offer an attractive cost of ownership to hospitals and homecare providers.

- Robust design and durable accessories.
- A modular technical design for quick and cost-efficient service. There are synergies with Vivo 50 regarding spare parts and technical training.
- The integrated monitoring capabilities reduce the need for external monitoring equipment.



The exhalation valve is a key component in Vivo 60. It can be inserted easily into the ventilator. The dedicated paediatric exhalation valve assures that volumes can be measured accurately down to 50 ml.

Vivo 60 Technical Specifications

Settings/Performance				
Ventilation Modes		• PSV • PCV • PCV(A) • VCV	• PSV(TgV) • PCV(TgV) • PCV(A+TgV) • VCV(A)	• SIMV PCV • SIMV VCV • CPAP
Patient Modes		• Adult • Paediatric		
Device Modes		• Home • Clinical		
SIMV		4 to 60 bpm		
Inspiratory Pressure		4 to 60 cm H ₂ O		
PEEP		0 cm H ₂ O to 30 cm H ₂ O for Adult / 20 cm H ₂ O Paediatric Inspiratory Pressure - 2 cm H ₂ O or Min Insp Pressure -2 H ₂ O		
Breath Rate (PCV, VCV)		4 to 60 bpm		
Inspiratory Time		0.3 to 5 s		
Backup Inspiratory Time		0.3 to 5 s (PSV)		
Rise Time		1 to 9 (PSV & PCV) 50 - 90 %, Off (VCV)		
Inspiratory Trigger		1 to 9 (PSV, PCV & VCV), Off (PCV & VCV)		
Expiratory Trigger		1 to 9 (PSV)		
Minimum Inspiratory Time		Off, 0.3 to 3 s		
Maximum Inspiratory Time		0.3 to 3 s, Off		
Backup Rate (PSV)		4 to 60 bpm		
Target Volume		50 to 2500 ml		
Tidal Volume		50 to 2500 ml		
Flow Pattern		Square, decelerating		
Sigh function		On/Off, rate (every 50-100-150-200-250 breaths), sigh% (125, 150, 175, 200%)		
Power Supplies		Monitoring		
Mains supply	100 to 240 V AC	Displayed data	Ppeak, PEEP, Pmean, Leakage, MVe/MVi, Vte/Vti, FiO ₂ , % in TgV, Total Rate, Spont Rate, % Spont, SpO ₂ , Pulse Rate, EtCO ₂ , InspCO ₂	
External battery	24 V DC	Waveforms	Pressure, Flow, Volume and CO ₂	
Click-on battery	8 hours	Trends over 1, 6, 24 and 48h	Ppeak, PEEP, Total Rate, Spont Rate, Vt, Leakage, SpO ₂ , EtCO ₂	
Internal battery	4 hours			
Main Alarms		Dimensions		
High Pressure, Low Pressure, High PEEP, Low PEEP, High Vte/Vti, Low Vte/Vti, High MVe/MVi, Low MVe/MVi, High Breath Rate, Low Breath Rate, Apnea, Disconnection, Rebreathing, High FiO ₂ , Low FiO ₂ , High SpO ₂ , Low SpO ₂ , High EtCO ₂ , Low EtCO ₂ , High InspCO ₂ , High Pulse Rate, Low Pulse Rate, Low Last Power Source.		W x H x D	343 × 125 × 264 mm (343 × 125 × 285 mm with click-on battery)	
		Weight	5.2 kg	
		Noise level (at 10 cmH ₂ O constant pressure)	Less than 30 dB(A)	