LÖWENSTEIN medical

L Ö W E N S T E I N

MEDICAL MAGAZINE

Issue 11/2016

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INTRODUCTION

Dear employees,
customers and friends
of the Löwenstein Group,

eventful and challenging times are behind us.

Today, three years after our acquisition of the Weinmann Homecare division, we can call the venture a success. We have successfully integrated the company into our Group and have given it firm financial footing.

Of course, successful integration greatly depends on the willingness of employees to work together under new conditions. Everyone rose to the challenge. In the beginning we concentrated on establishing a new, state-of-the-art product portfolio. Our recent product innovations show our success in maintaining and expanding the company's innovative capacity. We also have opened up new international sales channels for these products, which complement our established export business in the hospital sector perfectly.

We make these claims with a good deal of modesty, fully aware that other challenges may lie ahead. Success is a moving target that demands our constant attention and unflagging effort.

The successful integration and cooperation will now be made more visible and transparent by the new name of the independent company – Löwenstein Medical Technology. The "Technology" in the name tells you our mission. We are investing in company headquarters in Hamburg to prepare the site for long-term development and production of high quality medical devices Made in Germany.

In other news, Heinen + Löwenstein, the largest company in our Group, recently reached a major milestone with the celebration of its 30th anniversary. In the competitive medical technology market, 30 years is a long time.

Sometimes it may be forgotten that our roots are in neonatology and anaesthesia. We have continued to pursue these business areas as a manufacturer and distribution company with great enthusiasm. At some point many of our competitors jumped into the new and rapidly growing fields of sleep medicine and ventilation. Now that the financial situation in sleep medicine has become much more difficult, we are very fortunate to be involved in a variety of successful business fields in Germany and abroad. As the technological boundaries between homecare and hospital treatment fade away, Löwenstein Medical Technology is the perfect addition to the Group.

We celebrated another addition with the opening of the new branch office building of Heinen + Löwenstein in Cologne. The previously rented space had become too small for us after just a few years of continuous growth. So we decided in favor of a completely new building in an attractive, accessible location, which creates better conditions for employees, customers, and patients.

Finally, we have given this magazine a new name to reflect the internationalization of our business. In recent years we have successfully established subsidiaries with the name Löwenstein Medical in several European countries. With this magazine we want to present ourselves as a Group in pursuit of the shared goal of focusing on the individual in medical technology.

Reinhard Löwenstein *Ulrich Brandenburg*

CONTENT

HIGH-FLOW – *Just a lot of hot air?*

High-flow therapy is broadly accepted in Intensive Care Units because it offers both medical benefits and economic advantages. In high-flow therapy, conditioned respiratory gas is delivered to the patient through a special nasal cannula at a defined flow rate. This delivery method greatly reduces the patient's respiratory effort, also known as the "work of breathing."

The innovative technology in the PRECISIONflow membrane cartridge permits delivery of respiratory gas in the form of molecular vapor with relative humidity of 100 percent. The fully saturated and warm respiratory air assists mucociliary clearance, increases secretolytic activity and improves lung compliance and alveolar gas exchange. For maximum patient comfort, the temperature can be set in increments from 33° to 43 °Celsius.

The PRECISIONflow high-flow system reduces nasopharyngeal dead space by washing out carbon dioxide with flow rates of 1 to 8 liters/minute in neonates and infants, and from 5 to 40 liters/minute in adults. This action effects the rapid removal of CO_2 and a significant increase in alveolar oxygen concentration. Unlike low-flow therapy using a conventional nasal cannula, high-flow delivery increases oxygen concentration and lets the patient exhale CO_2 more easily. With use of the Velocity nasal cannula recommended for PRECISIONflow, an unintended increase in respiratory tract pressure is prevented even at high flow rates because the small diameter of the nasal prongs takes up no more than 50 percent of the space in the nostrils. Early use of high-flow therapy often prevents extensive intubation and contributes to a considerably improved and less invasive therapy outcome. Thus, patient satisfaction is accompanied by an additional economic advantage.

High-flow therapy reduces the workload for physicians and nursing staff and improves outcome in Intensive Care Units.

High-flow therapy is expected to contribute to revenue in 2017.

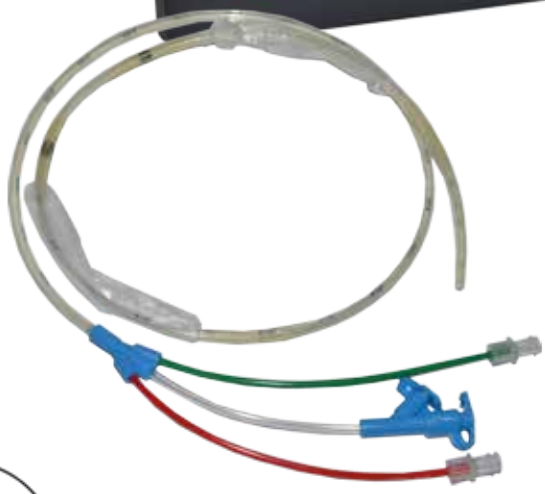
NutriVent - NEW WAYS TOWARD PERSONALIZED VENTILATION THERAPY

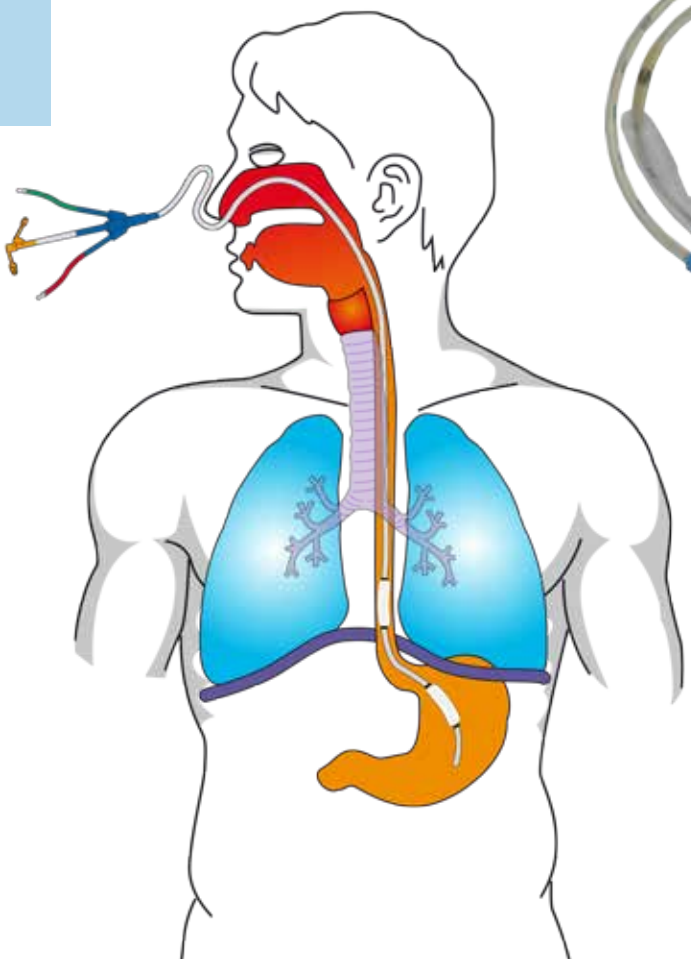
One of the central challenges in healthcare research is achieving the highest degree of therapeutic effectiveness while minimizing side effects. Thanks to the great advances in medicine, personalized therapy is becoming a reality. The NutriVent systems presented here are heading toward that goal.

The NutriVent nasogastric, multi-functional probe is a non-traumatic, flexible polyurethane catheter equipped with two balloons to measure transpulmonary and gastric pressure.

The NutriVent probe can be connected directly to a monitor or to a mechanical ventilator if the ventilator is equipped with a secondary port for pressure measurement.
The OptiVent monitor allows users to enter patient data and make settings simply and intuitively on the touch screen. The measurements made by the NutriVent esophageal catheter are displayed in a user-friendly way.

The combination of these two systems gives ideal support to users of ventilation therapy. They can use the recorded parameters to set the inspiratory pressure and PEEP to serve the specific needs of the patient and provide more effective therapy.





INTERVIEW

Heinen + Löwenstein demonstrates extreme flexibility and lives up to its motto of "focusing on the individual." Since 2015 Heinen + Löwenstein has employed a very special apprentice in business administration at the Schüttorf branch. Markus Foppe relies on non-invasive ventilation therapy and suffers from a disease which had previously prevented him from working under normal conditions.

Heinen + Löwenstein was not discouraged by his condition and rose to the challenge. The workplace was restructured to smooth the path to this apprenticeship. In the following interview, Mr. Foppe tells of his journey from consumer to apprentice.

"My name is Markus Foppe. I am 19 years old and come from Hörstel. After completing secondary school at a special needs school in Mettingen, I started an apprenticeship in office management at Heinen + Löwenstein on 1 August 2015. The apprenticeship consists of office work, which I am completing at the Schüttorf branch, and classroom instruction, which takes place in the Business School in Rheine."

Q: How did you become aware of our company? Why did you choose this occupation?

A: As I have been dependent on non-invasive ventilation for a long time due to my disease (Duchenne muscular dystrophy), I came in contact with Heinen + Löwenstein as a provider. When it was time for my practical school training, the possibility of a training position arose from a discussion with Maria Terwolbeck (Application Consultant) and a subsequent discussion with Dirk Doetkotte (Branch Manager).

After the practical training, which I very much enjoyed, I asked whether an apprenticeship at Heinen + Löwenstein would be an option for me.

Q: What steps were necessary to get this apprenticeship?

A: First it was important that I complete school and submit a proper application.

Of course, the Employment Agency, the Chamber of Industry and Commerce, and the Integration Office were involved, since the need for assistance had to be assessed. Technical and occupational assistance were necessary.

The company installed an elevator and installed a ceiling lift system and recliner in the existing handicapped WC. The same personnel provide occupational assistance and the accompanying healthcare service.

Q: What is your workday like? What are your duties?

A: At 7:15 a.m. I take a taxi to Schüttorf with my occupational assistant/caregiver. When I arrive, my work station is set up. My assistant connects the microphone for speech amplification and starts the computer. An infra-red interface allows me to use the joystick of my electric wheelchair to move the cursor and operate a specially installed keyboard.

My duties in the first apprenticeship year include scanning incoming mail, processing patient orders (delivery of accessories), and creating and sending certificates and letters to patients from the SAZ centers. I also enter patient data in the IT system and manage maintenance data/repairs and failures of the clinical devices in the North West region, which I obtain from service slips sent by sales professionals. My workday ends at 4:00 p.m.

Q: What do you like about your training? Is it fun?

A: What I like most is the opportunity to do this apprenticeship. I am very happy that I am able to participate in working life despite my severe disabilities.

Q: Did you have a lot to consider before you started the apprenticeship? Was there any special concern or any uncertainty?

A: Since I already knew the Schüttorf branch office and many employees from my practical training, my worries were within limits. I had greater concerns about going to vocational school since I had become accustomed to the learning situation at the special needs school. Everything is going very well now after a certain organizational period.

Q: What feelings did you have on the first day you came to work? What was your first impression?

A: I was excited that the day had finally arrived.

Q: Have you had to deal with any event that was especially difficult or stressful for you?

A: So far, not yet…

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Q: What has changed for you since you became an apprentice?

A: Since I started the apprenticeship, my daily schedule has become quite well planned since I have to attend healthcare appointments, physiotherapy, and logopedic therapy after work. Of course, I also have to find time to study the class material from vocational school and do the homework.

Q: What do you like about attending vocational school?

A: Most of the class topics are really interesting. It was cool that I won a prize of € 100 with my suggestion for the name of the new school kiosk.

Q: What subject is the most fun for you?

A: I like the subjects 'Office Processes' and 'Business Processes,' depending on the particular topic, and English is okay.

Q: How do you get along with your colleagues? What do you like about the office environment?

A: My work colleagues are friendly and willing to help. I get support whenever I need it.

Q: What are you hoping for in the next two years of the apprenticeship?

A: I would be very happy if the apprenticeship continues to go as it has been up to now.

Q: What have you learned that has impressed you/ advanced you the most?

A: I think it is good that I am treated like any other employee at Heinen + Löwenstein – which includes all rights and responsibilities.

Q: How have you developed personally during your apprenticeship?

A: I think that I have become more independent.

Q: Due to your handicap, your life and activities are much more complicated from our perspective; do you feel overwhelmed or does the challenge motivate you?

A: My goal has always been to perform a meaningful job and to be able to lead a self-determined life. The apprenticeship at Heinen + Löwenstein takes me a lot closer to my goal.

NEW BRANCH IN COLOGNE

Cologne is a very special city and, according to natives, the most beautiful city of all, not only during Carnival season. Heinen + Löwenstein and Cologne apparently are a very good match since the largest branch office in Germany is now located there. The new building was officially dedicated at the end of August.

The history of Heinen + Löwenstein in Cologne began in the 1990s with a sales office in Bonner Strasse in the Bayenthal district. After several successful years, particularly in home respiratory therapy, the staff had outgrown the office. In 2010 operations were relocated to rented premises with 750 square meters of office and warehouse space in the Lindenthal district, close to University Hospital.

As the clinical and homecare division continued to grow, the Heinen + Löwenstein branches began developing from simple sales offices into regional centers which manage services for customers and patient care close to home in SAZ (sleep-respiratory) centers. The expanding branches require space for liquid oxygen filling stations, regional warehouses and patient consultation rooms along with convenient access to transportation connections and free parking. After a few more years, the branch in Lindenthal could no longer accommodate the growing business, so a new building was constructed in Cologne-Lövenich, not far from highway A1.

Like the other five German branches, the new building has an attractive and functional design. The architecture has since become a company trademark that customers and patients recognize from afar.

Management celebrated the grand opening with employees, customers, patients, and friends of the company. After the guests had found relief from the tropical temperatures with a refreshing cold drink, they listened to some brief speeches in the tightly packed reception area. Speakers looked back on the development of Heinen + Löwenstein in the Cologne area and looked ahead to upcoming opportunities and challenges. Upon conclusion of the official program, guests relaxed and spent a pleasant afternoon together.

MORE MOBILITY
THE WORLD'S ONLY CLICK & GO CONCEPT FOR EO-150

Medical technology for out-of-hospital ventilation continues to develop, bringing more benefits to patients and caregivers. In the early years, the technical challenge was to create therapy devices that could provide ventilation therapy without the external gas supply commonly used in hospitals. Later, non-invasive ventilation therapy became established and required access via a mask. Today most out-of-hospital ventilation can be administered non-invasively, thanks to the introduction of increasingly better masks.

In another technological development, the therapy device was designed to calculate and store a number of respiratory parameters. These data can be read and visualized with special software applications to give healthcare professionals information about the success of therapy in the home environment.

The clinical success of out-of-hospital ventilation therapy is nothing less than remarkable. For patients with chronic diseases involving respiratory failure, the treatment prolongs survival while it improves quality of life and reduces clinical symptoms. In particularly serious cases, ventilation is required over an extended period at night and during the day and sometimes continuously for life-sustaining purposes. What are the requirements for a state-of-the-art device for out-of-hospital life-sustaining ventilation?

Excellent ventilation performance is the top priority. The device must measure and record many different respiratory and ventilation parameters continuously and accurately. Error-free operation and economic efficiency over the course of several years are absolute prerequisites. Operating errors and misinterpretations of the ventilation situation can put patients in immediate danger in the out-of-hospital environment. The operating instructions for a therapy device should be clear and simple. An option for remote access to the device by an authorized medical expert is highly recommended.

Most ventilation patients want to lead an active social life within their personal capabilities. A modern therapy system should satisfy their desire for mobility by means of technology and simple operation.

The new EO-150 ventilator, which Heinen + Löwenstein exclusively launched this year in many markets in Europe, is a technological pioneer. The experienced development engineers at the French manufacturing firm EOVE designed the EO-150 with a unique click & go concept. They also implemented an innovative operating concept with a Bluetooth connection that allows data to be displayed and monitored on a tablet or a compatible smartphone.

Weighing only 1.8 kg, the compact ventilation module is the heart of the system and the actual life-sustaining unit. The ventilation module can be used on the docking station with an integrated tablet as a complete unit in the home or clinical environment. The tablet functions as a convenient display and graphical user interface.

For ventilation away from home, the ventilation module is simply removed from the side of the docking station. There is no need to interrupt patient ventilation as tubes and cables do not have to be disconnected for this purpose. In its compact form, the EO-150 gives patients the greatest possible mobility of all therapy devices and still provides all therapy options at all times. A large selection of accessories is available for this mobile application, including tablets, external batteries and various pocket concepts. Via the Bluetooth interface, users can monitor mobile use of ventilation on a tablet or smartphone. The patient and the healthcare professional can check the ventilation and therapy situation at any time. The EO-150 ventilator provides more mobility with the greatest possible level of safety.

MASK PRODUCTION BEGINS IN NEUHÄUSEL

In an important step for the Löwenstein Group, mask production began in Neuhäusel at the start of this year. In-house production makes it possible to respond to specific customer requests and requirements.

The production team consists of eight motivated and dedicated employees under the supervision of Löwenstein Medical Technology. Production takes place in a controlled area to minimize risks of contamination. Specifically, manufacturing is concentrated in specially defined areas which are subject to compliance with personnel and hygienic requirements.

Löwenstein Medical produces the masks according to a dual control principle in all production steps. After assembly, visual inspections and a quality check of flow measurements are made. Extensive testing of sub-assemblies is conducted at several intermediate stages. At full capacity, the facility yields a respectable production quantity.

The site currently produces the new clinical mask JOYCEclinic FF and the new homecare masks JOYCEone and JOYCEeasy next FF.

After completion, the manufactured products are sent from the main Heinen + Löwenstein warehouse in Neuhäusel for quick delivery to customers.

The Group plans to expand and enhance the facilities for the production of other types of masks. As part of its daily work, the Group focuses on continuous improvement of production quality and quantities. Direct market feedback from Heinen + Löwenstein customers and patients is taken into account for research and development by the engineers at Löwenstein Medical Technology.

JOYCEclinic FF, the single-patient-use mask for acute non-invasive ventilation features an innovative design, simple handling and attractive pricing. The masks provide a secure, comfortable fit at pressures of up to 50 hPa. The red quick-release cord can be used to disconnect the headband quickly and easily in case of emergency. With the four different, exchangeable angle adapters, the mask can be used in any situation. JOYCEclinic FF is supplied ready-to-use in the variants non-vented, non-vented with AAV (Leakage 1), and vented with AAV (Leakage 2). An endoscope adapter is available as a practical accessory.

MINISCREEN PRO – COMPACT, POWERFUL, AND SUCCESSFUL

THE SLEEP LABORATORY IS THE BACKBONE OF DIAGNOSTIC SLEEP MEDICINE

The outstanding care in sleep medicine in Germany is made possible to a large extent by the clinical sleep laboratories run by healthcare professionals with additional qualifications in sleep medicine. The overnight examination in the sleep laboratory, usually conducted with polysomnography, is the diagnostic gold standard for the investigation of clinical sleep disorders. Sleep-Disordered Breathing also can be detected in the sleep lab if a simple recording of nocturnal breathing (polygraph) has not done so.

The proven, diagnostic concept of polysomnography includes the recording of nocturnal sleep quality, breathing, motor function, and several cardiac and circulatory parameters. The examination is relatively complex; however, ongoing improvements of sensors and measuring devices have made the procedure safe and less stressful for patients. Thanks to considerable efforts by medical associations, the procedure itself and the subsequent analysis of polysomnography recordings have been standardized internationally. Now the examination results from sleep laboratories are comparable worldwide.

Although sleep labs have achieved a high quality standard, reimbursement for polysomnography has declined in Germany in recent years. As cost pressures increase, sleep labs are coming up with new market requirements for diagnostic devices. The equipment has to be reasonably priced and cost-efficient in operation. Furthermore, the devices should support automated work processes, especially with preliminary analyses of results and related administrative tasks.

SLEEP DIAGNOSTICS AT HEINEN + LÖWENSTEIN

Heinen + Löwenstein has been the leading supplier to clinical sleep laboratories in Germany for a long time. Last year too, the company was able to look back on a very positive sales trend. This notable success was made possible by attractive products and a strong orientation to customer needs. At a very early stage it was clear that a system provider could best support sales activities by offering comprehensive services in planning, support and training.

Modern sleep laboratory equipment includes polysomnography devices and related software, video recording systems and other diagnostic devices such as CO_2 monitors. Additional therapy devices are connected in order to present data from recordings during treatment in real time. The final step involves the transmission of findings to Electronic Medical Records (EMR) system in hospitals and medical practices. Given the complexity of the systems and their requirements, Heinen + Löwenstein carefully selects the products it distributes. In close collaboration with producers, the company then able to provide input into the products' further development.

After years of highly successful sales activities with MiniScreen 8 and MiniScreen Plus, polygraph devices that record nocturnal breathing, Heinen + Löwenstein launched a complete polysomnography system called "MiniScreen Pro". Developed and produced in Germany, the new device immediately claimed an excellent position in the market.

COMPACT DESIGN AND WIRELESS DATA TRANSMISSION

MiniScreen PRO, a compact polysomnographic device about the size of an eyeglasses case, is worn on the body while a recording is made. Its small size makes the device ideal for outpatient recordings, which are the preferred means in other countries. The system is equipped with optional wireless data transmission in real time via a local area network. This feature allows the patient to move about the room in the sleep lab before switching off the light and to make trips to the toilet during the night without having to deal with a tangle of connection cables.

MiniScreen PRO offers a comprehensive software package with the same user interface as the popular polygraph devices. Because the system conforms to national and international requirements of professional medical associations, its future usefulness is ensured. Free software updates that enhance system performance are offered at regular intervals for all MiniScreen systems.

DIGITAL PRISMA CONTROL (DPC)

With the new software version 5.16, MiniScreen PRO is breaking new ground. In a first for the technology and for this system, a digital interface is available between a polysomnographic device and prisma LINE, the modern therapy devices from Löwenstein Medical Technology.

The interface feeds all relevant therapy data from the recordings in the sleep laboratory, including pressure, airflow, and leakage directly into the system, in real time and without complex cable connections. Therapy data can then be visualized and analyzed with other signals to give the user valuable insights into the success of therapy.

CONNECTION TO THE HEINEN + LÖWENSTEIN SLEEP DATABASE

Another feature of the new software version is the optional integration of MiniScreen PRO into the familiar database environment for sleep laboratories that use Heinen + Löwenstein equipment. The sleep database, which has become one of the most successful applications in German sleep medicine centers, offers functions to manage findings for sleep laboratory patients and several auxiliary programs and tools to handle administrative tasks, such as creating documents and scheduling appointments. In addition, the sleep database is used as a platform for sending data on findings to hospital information systems and medical practice software via defined interfaces (HL7 and GDT). The new software version makes all functions available to all MiniScreen systems.

THE SUCCESSFUL MARKET LAUNCH OF prisma VENT

FUNCTIONAL DESIGN AS A FEATURE IN VENTILATORS

Right on schedule on 2 May 2016, series production began of prisma VENT, the new generation for out-of-hospital ventilation from Löwenstein Medical Technology. In years of development, which was built on the huge market success of the familiar ventilators VENTImotion and VENTIlogic, the experienced developers came up with a new technology platform. The previous Weinmann devices were known for outstanding ventilation performance and straightforward design. With the prisma VENT, functional design moved to the forefront.

Several studies had shown how important it is to give medical professionals or clinical users a user interface which offers immediate orientation and intuitive operation. That's where prisma VENT comes into play. The device series combines the previously available technical expertise in ventilation with state-of-the-art design, which is geared to the actual task of the device, i.e., making out-of-hospital ventilation for patients and users as effective, simple, comfortable and safe as possible.

THE DEVELOPMENT PROCESS AND ITS RESULTS

Heinen + Löwenstein achieved that goal with prisma VENT30 and prisma VENT40 by testing and re-testing during development and by questioning many respiratory experts, including medical professionals and patients. The valuable information obtained went directly into the ongoing development process and resulted in excellent functional design.

The large high-resolution display, for example, is razor sharp. The brilliantly displayed interactive graphics make sure that users are always aware of the current respiratory status and patient needs. In an acute clinical situation, it's important to be able to read the screen from all angles. The simple and clear design of the menu helps the user to find required therapy functions quickly. For rapid and precise settings in ventilation, the 360-degree easy-turn knob came out ahead in test applications. Together the display and menu permit reliable, intuitive operation even under time pressure.

The noise level and dimensions of the therapy device are of concern to patients who are treated out of hospital. In addition to being extremely compact and lightweight, prisma VENT is whisper-quiet. Mobility and flexibility are ensured by the optional internal battery, which sets new standards in its class with an operating time of up to 12 hours.

Data management of ventilators is becoming more important in routine clinical settings as a method of obtaining insight into home therapy. As with all devices in the prisma series, the prisma TS software is available for prisma VENT. The software reliably monitors therapy success and provides clinical documentation of therapy initiation.

NO COMPROMISES IN VENTILATION PERFORMANCE

Although new medical devices to maintain or support patients' vital functions always generate a lot of interest, they also give rise to a great deal of skepticism at first. That's also true with a complete redesign. In this case the new devices were put through intense and thorough clinical tests. Healthcare professionals quickly realized that even though the development work was focused on the user's point of view, no compromises had been made in the ventilation technology. The devices provide all classic modes and several innovative ventilation functions. Equipped with powerful blowers and precision measurement and monitoring technology, the ventilators can be set precisely to perform reliably even in severe clinical cases or under changing conditions. Validated automatic algorithms for the fine adjustment of individual ventilation parameters assist the work of respiratory therapists.

SILENT COMEBACK
THE RETURN OF ADAPTIVE SERVO-VENTILATION

THE SERVE-HF STUDY AND ITS RESULTS

A shock wave went through the sleep medicine world about 18 months ago. The highly anticipated results of the international Serve-HF study showed a statistically significant increased risk of cardiovascular death for patients with central sleep apnea and chronic systolic heart failure with reduced ejection fraction who were treated with Adaptive Servo-Ventilation (ASV). Although ASV effectively reduced sleep apnea, it did not improve functional outcomes or quality of life. Medical experts were astonished; the opposite results had been expected.

The validity of this study is still being examined by scientists and medical publications, a fact which does not make the assessment and implementation of results any easier for routine clinical practice. Nevertheless, the results should be taken seriously and precautionary measures taken in the interest of patient safety. All manufacturers agreed that ASV therapy should no longer be used for the patient group with systolic heart failure. Regulatory authorities instructed manufacturers to tell their customers about the contraindications even if they, like Löwenstein Medical Technology and Philips, had not been involved in the study. Treating physicians and providers such as Heinen + Löwenstein were then faced with the task of identifying the patients for whom these study results were important. The number was estimated to be only about 10 to 15 percent of the total number of patients treated with ASV therapy in Germany.

Since providers do not have the patients' relevant clinical data for data protection reasons, they had to write to all patients using ASV therapy. Patients were urged to contact the treating physician or sleep laboratory without delay to check whether their ASV therapy could be continued. Such information always unsettles patients. This response, however, was minimized by the professional approach and good communication used by medical associations, physicians and suppliers.

As expected, only a small portion of the total number of patients fell within the risk group. They were offered alternative means of therapy while other patients were allowed to continue ASV therapy. A considerable number of patients from the risk group reported that they had benefited greatly from ASV therapy and wanted to continue.

THE RESULTS OF THE NEW TREATMENT WITH ASV THERAPY

After publication of the study results, ASV therapy was rarely prescribed for new treatment cases even though it had been proven superior to other methods in eliminating respiratory disorders. Lost in the ongoing discussion about the validity of the Serve-HF study was the fact that most candidates for ASV therapy do not present systolic heart failure. The unaffected patients, therefore, may have been denied very effective therapy even though they faced no increased risks. Professional medical associations and researchers recognized the issue fairly quickly and went to work to clarify matters for the potential patient group. The number of new cases is now rising as ASV is being recommended for patients to whom the contraindications do not apply.

CHEYNE-STOKES RESPIRATION AND ADAPTIVE SERVO-VENTILATION

Sleep-Disordered Breathing (SDB) includes Cheyne-Stokes respiration, a type of periodic breathing. It is characterized by periods of gradually increasing and decreasing tidal volumes interrupted by periods when breathing ceases entirely (apneas). In simple terms, the patient alternates between breathing too little and far too much. This respiratory disorder was named for John Cheyne and William Stokes, the physicians who classified it in the 19th century. Many, but not all patients with Cheyne-Stokes respiration have decreased cardiac output often associated with certain arrhythmias. In other patients, neurological underlying or accompanying diseases are present, but no causes for the disorder can be identified. Cheyne-Stokes respiration may be accompanied by severe sleeping problems. The task of the sleep laboratory or the sleep medicine specialist is to confirm the diagnosis of Cheyne-Stokes respiration, recognize the effect on the sleep cycle, assess possible underlying and accompanying diseases and make treatment decisions based on this information. Thus far, no comprehensive data allow for an evidence-based therapy decision for all possible case constellations and patients.

As in all cases requiring positive airway pressure ventilation, the medical specialist takes into account the effect that applied pressure has on the thorax and the positive or negative consequences for cardiac output. Moreover, an evaluation is made as to whether an existing sleep disorder improves under positive airway pressure ventilation. Polysomnography examinations are designed and required for assessment.

HOW ADAPTIVE SERVO-VENTILATION WORKS

Adaptive Servo-Ventilation is based on a simple but ingenious idea that the therapy device should act as a kind of mirror image of the impaired, periodically fluctuating respiratory stimulus of the patient. The device measures the patient's breathing continuously. When breathing decreases, the device ventilates the patient immediately in the servo-mechanism. If the patient is in the phase of sufficient or excessive breathing, however, the device stops ventilation or pressure support immediately. By adapting continuously to the patient's breathing, the device effectively counteracts Cheyne-Stokes respiration.

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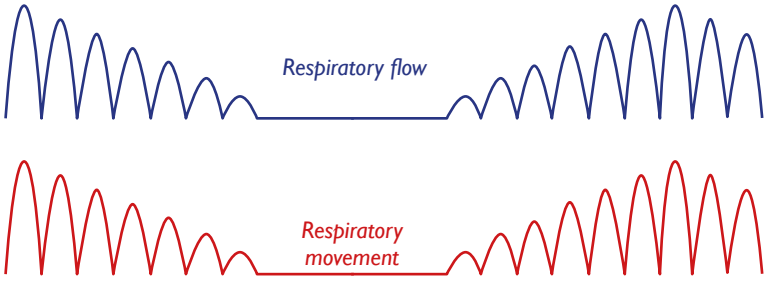
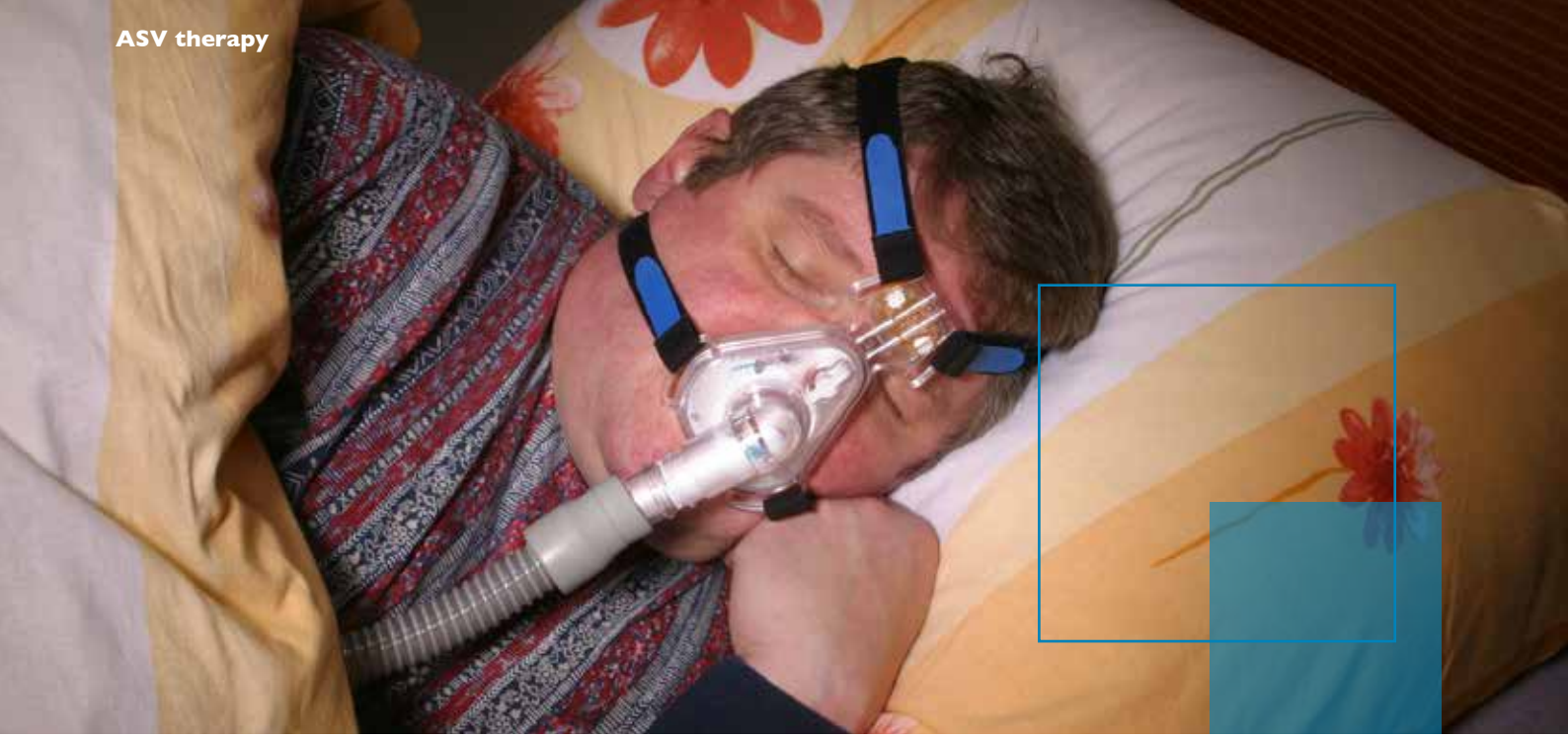


Cheyne-Stokes respiration



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MIXED PATTERNS OF SLEEP-RELATED RESPIRATORY DISORDERS AS INDICATION FOR ASV THERAPY

Development of ASV technology was focused initially on treatment of Cheyne-Stokes respiration combined with decreased cardiac output. Broader application of the therapy came about 15 years ago and since then a few German research centers have taken the lead in scientific work on the subject. According to study results, ASV therapy is superior to all other methods in the elimination or reduction of Cheyne-Stokes respiration. The good treatment option with ASV has led to more intense study of Cheyne-Stokes respiration and associated SDB in recent years. The results of these investigations showed central respiratory disorders linked to an obstruction or narrowing of the upper airways in a mixed pattern of sleep-related respiratory disorders.

Such mixed patterns of sleep-related respiratory disorders are characterized by disorders in the respiratory stimulus (central component) overlaid with an obstruction in the upper airways (obstructive component). Complex sleep-related respiratory disorders are often associated with disorders of nocturnal blood gas levels and non-restorative sleep. During the night patients experience numerous waking and activation responses (arousals) which interrupt the natural sleep cycle and lead to increased tiredness and fatigue during the day. The prevalence of such mixed patterns, however, has not yet been clearly defined for gender and age groups. The exact composition of respiratory disorders can change over time.

ASV therapy can be effective in the presence of mixed symptoms only when the upper airways are kept open. In the technology's early days, users had to set the required pressure manually on first generation devices. Advanced development of the technology for the second and third generations automated the adaptation. In addition to the intrinsic servo-mechanism to reduce the central respiratory disorder, an auto-CPAP algorithm was introduced in order to keep the airways open reliably at all times during the night.

SUMMARY AND OUTLOOK

Adaptive Servo-Ventilation is an exceptionally effective ventilation method for the elimination or reduction of central sleep respiratory disorders and mixed patterns of Sleep-Disordered Breathing. The technical challenges for therapy devices are relatively high. Currently, only three manufacturers in the world (ResMed, Philips Respironics and Löwenstein Medical) offer therapy systems which are clinically recognized and scientifically validated.

The Serve-HF study showed that ASV therapy can be associated with increased risk of cardiovascular mortality for patients who suffer from central respiratory disorders and reduced ejection fraction (chronic systolic heart failure). ASV therapy should therefore no longer be used for this group of patients, which is clearly defined and relatively small. For the majority of patients with central respiratory disorders or mixed patterns of sleep-related respiratory disorders, ASV therapy remains a very effective and low-risk therapy option. Based on information provided by professional medical associations and medical experts, ASV therapy is again being prescribed much more often for such cases. A sleep specialist should make therapy decisions on a case-by-case basis with consideration given to clinical and polysomnographic data.

ACENDIS MARKET LAUNCH OF NEW INTENSIVE CARE VENTILATORS IN TURKEY

Leoni plus CLAC and Elisa 800VIT, high-end intensive care ventilators from Heinen + Löwenstein, were presented in Istanbul for the first time.

Acendis, the main representative of Heinen + Löwenstein in Turkey, successfully distributes the entire range of products throughout the country.

At a conference in December 2015, the latest developments of high-end intensive care ventilators for neonates and adults were introduced to the Turkish market. Top-ranking medical professionals, technical directors and executive officers from the most prominent hospitals in Turkey were in attendance. The latest intensive care ventilation technology from Heinen + Löwenstein was demonstrated and explained in detail.

The Elisa 800VIT ventilator has the world's first integrated EIT system in an intensive care respirator. With non-invasive lung monitoring by Elisa 800VIT, ventilation-associated complications are made visible for the first time and effectively treated by the device. Thus, ventilation becomes even more transparent and manageable.

The neonatology ventilator Leoni plus HFO with integrated CLAC (CLOSED-LOOP AUTOMATIC OXYGEN CONTROL) was developed specifically for premature infant care and neonatology. The device is the first in the world to provide automatic regulation of ventilation with measurement of oxygen saturation in the blood. With this feature, new therapy options are made available and patient safety is increased considerably.

The business partnership that Heinen + Löwenstein started with Acendis 20 years ago has since turned into friendship. Acendis opens doors in Turkey for the implementation of new technological developments by Heinen + Löwenstein.

LEONI PLUS CERTIFIED FOR TRANSPORTT

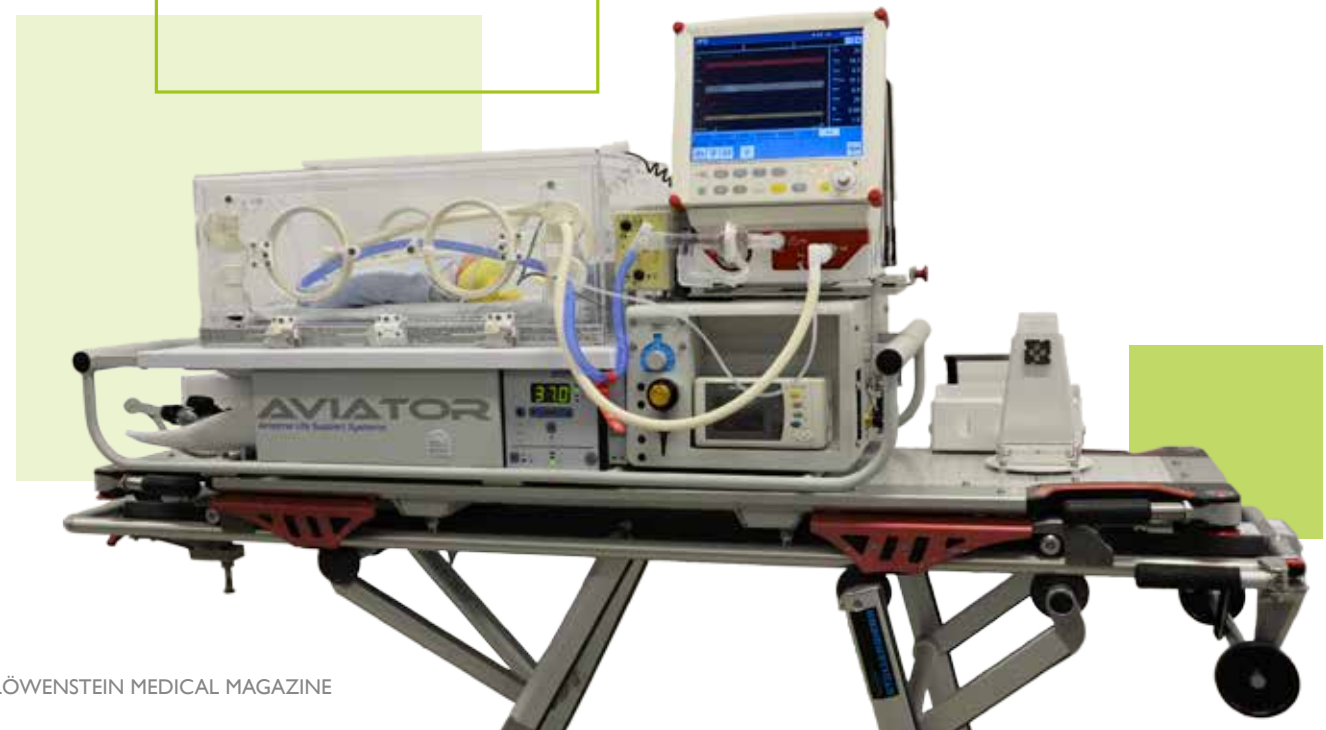
Heinen + Löwenstein is dedicated to providing ideal care for the smallest patients in all situations. So it was only logical to make the outstanding features of Leoni plus available for the transport of neonates too.

Product developers at Heinen + Löwenstein responded to users' growing demands for approved use of Leoni plus in ground and airborne ambulances with Leoni plus Transport.

To meet the standards, the device has to pass rigorous tests that go far beyond normal use. They include the following:

- Spraying water test: a simulation to assess the device's protection level and operational readiness in heavy rainfall.
- Vibration and shock: test of device's ability to withstand vibration during transport. Special shock tests expose Leoni plus Transport and the transport holder to stress levels with acceleration of up to 20 times greater than gravitational force.
- Temperature and pressure: Leoni plus Transport must perform reliably under the most extreme conditions. This test simulates conditions likely to arise during air transport, such as temperatures ranging from -30 °C to +70 °C. During these tests, no function or ventilation errors may occur.

Certification for ground transport has been obtained for Leoni plus Transport and approval for air transport is expected soon.



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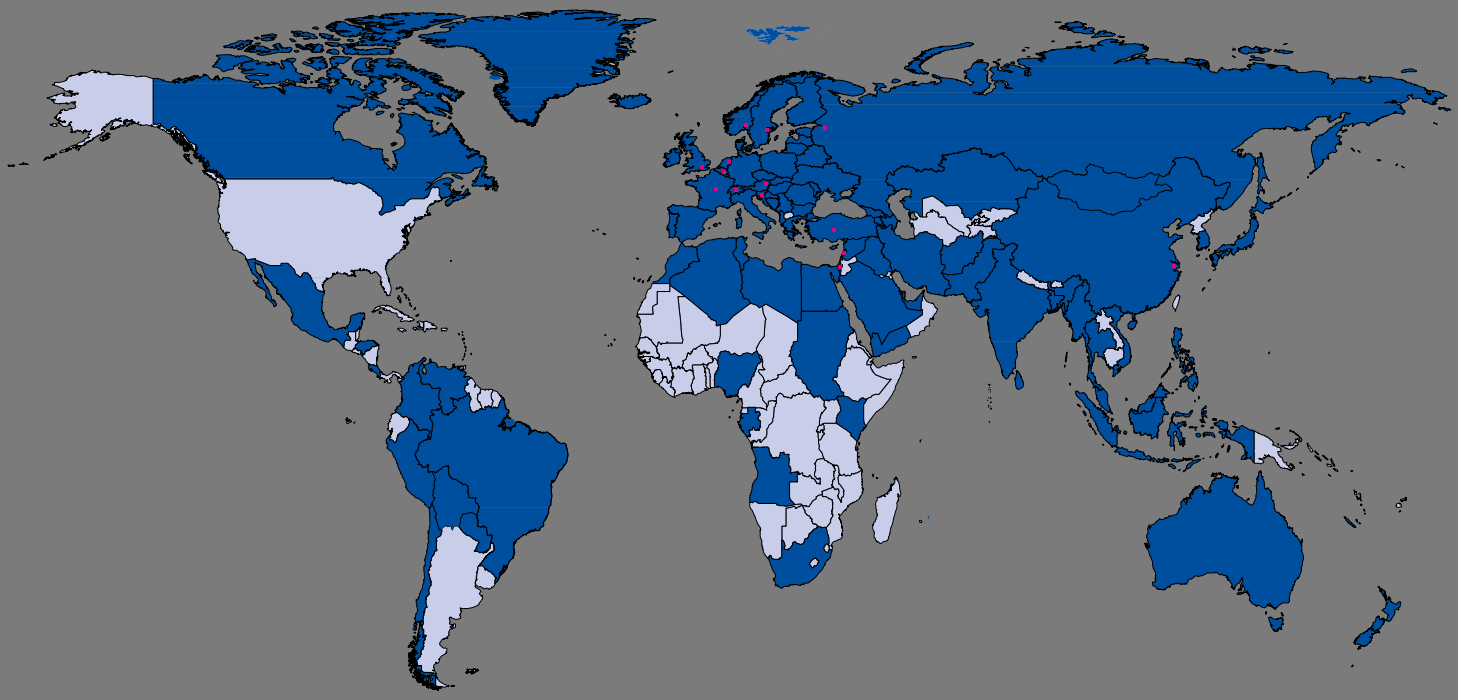

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