

Inspiration

Löwenstein Medical Magazine

Autumn 2021 Edition

LÖWENSTEIN DEVELOPER SUMMIT

Four days of innovation and info sharing.

LÖWENSTEIN IS GROWING

Medigroba, WILAméd and SANIMED
expand the Löwenstein Group.

Samoa - SMART. SIMPLE. SMALL.

Polygraphy of the future.

With people
in mind.

LÖWENSTEIN
medical

b r e a t h e

difference

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Dear Readers,

We are pleased to present our latest issue of Inspiration, which appears in our new corporate design and contains interesting stories and developments all about Löwenstein. Even though we've been unusually busy with two events in recent months, we have packed this issue full of new inspiration and innovations.

Which two events? In the past 18 months, our organization has been dealing with two major happenings in our market which are unrelated, but which occurred one right after the other. The first is the significantly increased need of ventilators for many people and healthcare systems during the corona pandemic. The other is the temporary production freeze and subsequent recall of Philips Respironics home therapy products that led to a global bottleneck and with it, the urgent, immense processing effort for us and other service providers. As I see it, these two events have had such an outstanding impact on our organization and the entire market that the effect will linger and challenge everyone involved. We are filled with pride when we think of how our employees mastered both, despite handling many personal challenges at the same time.

Naturally, the Group—especially as a manufacturer—has profited financially from the events, but has expended a great deal of effort too. About 15 years ago, Löwenstein was the largest dealer of Respironics products in the world (excluding North America) and therefore had provided the affected devices to many patients, who now need replacements. We are hard at work on this matter.

I am very pleased that—despite the difficult circumstances and challenges—we are continuing our work on innovation projects, admittedly with some delays.

We are planning several new products for the upcoming three years and also are developing a medium-term innovation roadmap with a clear strategy of offering complete ecosystems intended to improve the quality and effectiveness of patient care for users, medical professionals and service providers. Both hardware and software are required. Solutions such as telemonitoring, cloud services and advising algorithms are erasing the boundaries between analog and digital therapy.

Besides our many innovations, we have expanded strategically with three acquisitions in 2020/2021. With WILAméd we are developing our manufacturing competence in breathing tube systems and humidifier technology. In Homecare, with medigroba in the south and SANIMÉD in the north, we will be a nationwide full-service provider in the care of respiratory patients.

Within the next two years, we will work on consolidating our newly acquired subsidiaries, figuring out how to use the knowledge and market share gained through corona and Philips Respironics, and devising ways to meet future challenges.

Kind regards,
Benjamin Löwenstein



The Löwenstein Academy has a new home

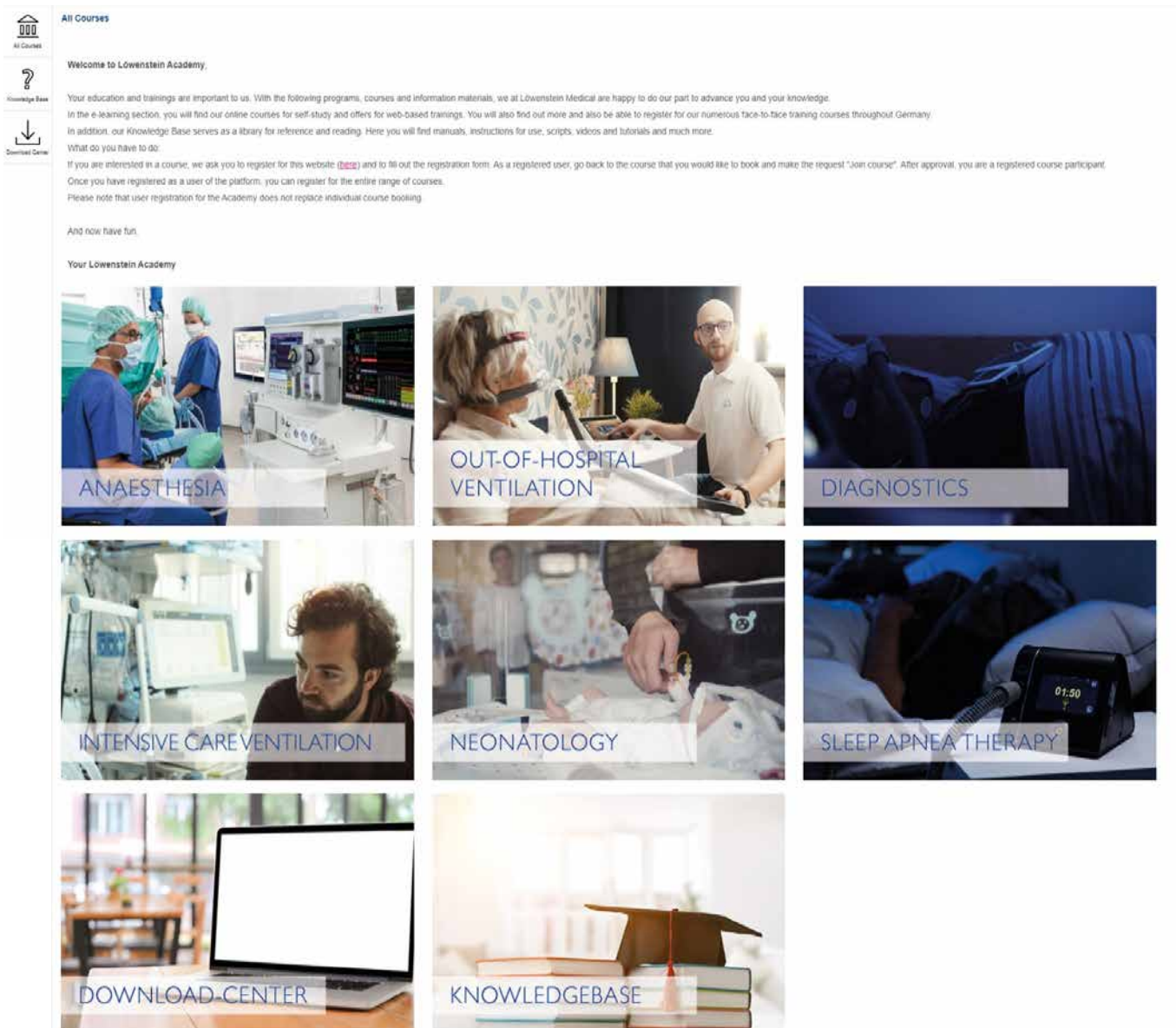
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"See the positive too." This simple sentence serves as both a building block for a new training program and the right philosophy for these times. We followed the advice by implementing ideas that benefit the company in many ways. In everyday life dominated by the coronavirus, we can find many examples of positive innovations and changes, especially in our professional environment. Like this one.

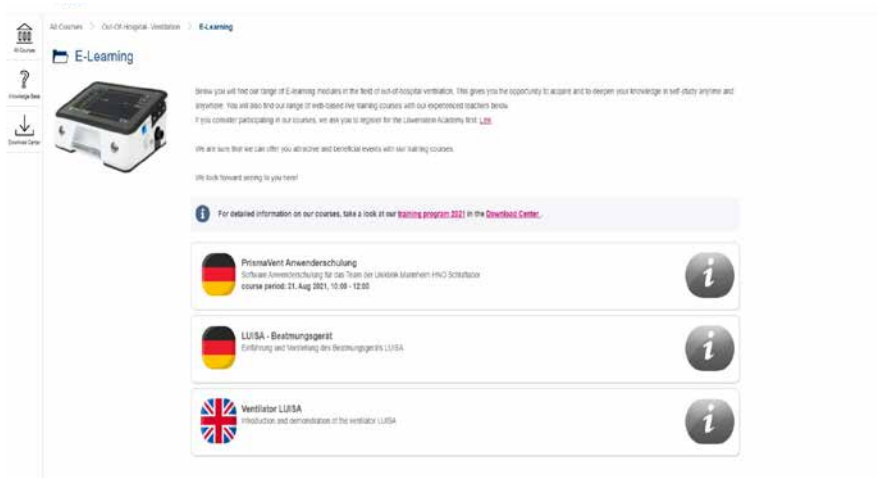
Löwenstein Medical has an excellent reputation not only as a developer and manufacturer of high-quality medical products, but also as a service provider and supplier of training, application consulting and knowledge transfer in a medical context. Demand is high for our training courses in all areas of the company and sessions fill up quickly. During a pandemic, however, classroom training is difficult or even impossible. So we seized the opportunity to set up our own

digital Löwenstein Academy and create an e-learning platform. Eventually, the Academy will present our entire training and continuing education program in an appealing and easily understood form. We've divided the training programs into the six areas of anesthesia, out-of-hospital ventilation, diagnostics, intensive care ventilation, neonatology and sleep respiratory therapy. Our customers and all other interested parties can read about our training offers,

register or take advantage of online self-study courses and Web-based training via the platform. Participant management for classroom training can now be organized digitally and centrally. We can offer "blended learning" with combined classroom and online training. For example, online tests can be used to ensure in advance that participants in a classroom training course meet minimum subject-matter requirements.



Löwenstein Academy training platform



Selection of training courses

The offer is rounded off with a "knowledge base", that is, a library with links to our YouTube channel, tutorials, product information, clinical studies and technical manuals. With a dedicated dashboard, participants can keep track of when and how well they completed courses in the past and which courses they have booked in the future. Acquired certificates are generated automatically and are available to the user as downloads, as are scripts of training sessions.

The first Academy training sessions took place at the end of February and beginning of March in the form of two Web-based user training courses. Our colleagues from Export, Simon Lehmler and Jörg Marschinke, trained medical technicians from Italy on the elisa 300 in a Webinar of several hours. Just one week later, a user training course on our Hamilton ventilators was conducted by our colleagues Julian Gö-

bel and Olaf Röber. On two mornings, 12 participants followed the live explanations and device use on their screens. Despite corona, we were finally able to hold our hospital user and technical training courses again this year for national and international participants. Lively interactive exchanges between instructors and participants and among participants are made possible by the training tool BigBlueButton, which we use for Webinars. It has numerous features such as chats, emojis, classrooms, interaction tools, shared notes, etc., and a recording function that saves sessions.

The training was very well received by the doctors and nurses and the Italian technicians even though they sorely missed making a personal visit to Bad Ems. The Academy survived its baptism by fire. Other Web-based training courses followed in March and April.

Since then the number of courses on our platform has grown steadily and now covers all areas of the company. The ultimate goal is to present Löwenstein's entire training and development offering there and to establish a knowledge library for our customers.

We invite anyone interested in further education to look around our Löwenstein Academy and take advantage of the growing range of further education and training courses on offer. Our courses are free of charge. We hope to provide you with a clear, appealing and helpful offer in this service line. Have fun!



This will take you to the Löwenstein Academy.

WE ARE THERE WHEN YOU NEED US.

That is a promise. Löwenstein is a technology leader in clinical ventilation and respiratory therapy. Innovation and experience make our ventilators into true partners. After all, everything is at stake.

Löwenstein.
Innovative Ventilation Technology.

Löwenstein Developer Summit

Four days of innovation and interaction with 240 developers from the entire Group

In March 2020 everything had been organized for the first Löwenstein Developer Summit. During the three-day event in Hamburg, 240 developers were to be given the chance to share info, discuss the latest trends, methods and technologies and generate lots of ideas. At the last minute the pandemic prompted us to cancel the conference. We could not risk the disaster of a COVID-19 outbreak among developers from all the Löwenstein Group locations.

At that point we thought we could simply postpone the conference until autumn. The course of the pandemic showed us just how wrong we were. Nevertheless, we did not want to abandon the idea of the conference or lose sight of the goals, so we decided to hold the summit online. From the Inno-Booster we tested suitable tools, developed concepts and finally implemented it all. Some IT challenges were jointly resolved. All participants were familiarized with the technology and tools in advance in OnBoarding.

The event went live on 22 February 2021 when the 240 participants at all the Löwenstein Group locations moved with their avatars into the virtual conference center.



Developer Summit

Inno



"A really cool developers' conference with lots of take-aways! We networked with colleagues from other locations. I see plenty of potential for knowledge transfer."

Benjamin Löwenstein officially opened the four-day conference program. He was followed by keynote speakers and technological masterminds. A general discussion provided a look at the different development sites. Later on, participants had a chance to get to know each other in a large-scale virtual speed dating setup.

Day Two was given over to small presentations (master classes) by participants and some external experts. In three consecutive time slots, 11 subjects were presented and then discussed. Participants could select the topics that interested them the most. With an avatar each participant had to enter different conference buildings and use media walls and flip charts, just like in real life. An accompanying digital white-

board could be used by all participants to visualize the subject matter and save results.

Day Three featured "Hands On" in an open space format, where once again the participants could choose which topics to pursue. This time each of the three time slots offered 10 parallel subjects. After a brief introduction, participants discussed the topics and developed them jointly. At the end of the day in the virtual event building, teams played a game in which they had to master a variety of challenges.

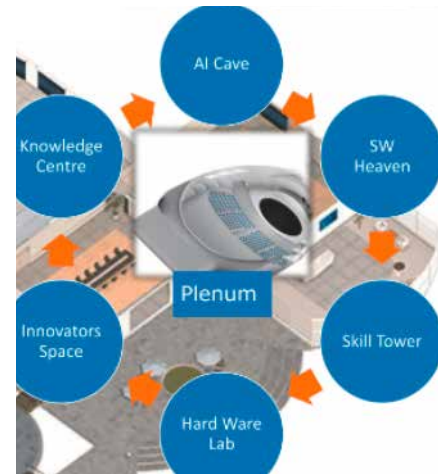
The event concluded on Day Four. Research & Development management fielded questions from participants, a few of whom bravely pitched new ideas to the jury in the hope of getting a posi-



Speed dating in the outdoor area



Avatar at a media wall



Event grounds

tive reaction. Two exceptional topics that were presented were subsequently given the green light.

The most critical moment of the entire event came when an excavator suddenly dug a hole in the very spot where the Internet line goes in our Hamburg building. Fortunately, disaster was averted. For such a situation the software developers had found out how they could redesign the entire conference building. So once a bonfire unexpectedly appeared on the stage or at another time a purple elephant.

The goals of the summit were to network the developers from all locations, to more effectively use the Group's accumulated knowledge and

experience, and to exploit synergies. Expectations were exceeded, participants were enthusiastic and the cornerstone was laid for further exchanges among the locations. Many initiatives arose during and after the summit aimed at joint resolutions of specific problems. Feedback from participants was overwhelmingly positive. We're already looking forward to the next summit.

"The keynote speakers were excellent and highly motivating. The cornerstone was laid for many new exchanges."



medigroba
site in Balingen

A warm welcome to medigroba

With the addition of medigroba in April 2021, the Löwenstein Group grew a bit more. Löwenstein and medigroba have long worked in close cooperation, which they intend to intensify.

The quiet city of Balingen with 35,000 residents and 13 districts is located south of Baden-Württemberg at the edge of the Swabian Alb region, midway between Stuttgart and Lake Constance. The next larger city is Tübingen, just 30 minutes away by car via the B27 highway. Balingen is best known as the starting point for many hikes and for its handball team, which for years has been a force to deal with in the first natural league. There's still another reason Balingen is on the map. Every year thousands of mostly young music fans from all over Germany head to the city for the well-known Bang Your Head!!! Open Air Festival.

Rise to local champ

In 1975 Heinz Allgayer founded medigroba, whose name is formed from the German words for medical wholesaler Balingen. The family-owned company with six employees provides wholesale supplies for medical practice needs and treatment of diabetes. At the beginning of the 1990s, the compa-

"Dauntless" commitment and great expertise make medigroba a reliable partner to patients and to all who have responsibility for patients.

ny was handed over to the second generation, which steered the company on an expansion course. Thus the wholesaler began providing patient supplies and moved into new, modern premises on Spessartstraße, where it still maintains headquarters.

In subsequent years the product range was expanded continuously and the medical aids for patients unit was developed into the main area of business. Then and now the strategy is to provide local partners (hospitals, nursing homes and nursing services) complete service, ranging from ventilators and cannulas to enteral nutrition and hospital beds. By following this strategy, medigroba became an important player in the region south of the A8 highway.

Successful cooperation with the Löwenstein Group

When medigroba expanded into the field of home ventilation at the start of the 2000s, initial contact was made with the Löwenstein Group. Over the years, medigroba intensified the contact, first as the local partner for Weinmann and later for Löwenstein Medical.

As the key supplier of breathing tubes and active humidification, WILAméd is a major player on the procurement side. In the CNI network (*Competenz Netzwerk außerklinische Intensivversorgung e.V.*) has been fighting alongside the company GMV for higher quality of supply and against price dumping in homecare ventilation.



The medigroba team

Dynamic growth

In 2016 the Allgayer family cited personal reasons for withdrawing from management of medigroba and gave the business shares to SHS Beteiligungsgesellschaft, a Tübingen-based specialist for investments in medical technology. Under the direction of SHS and new management, the emphasis was placed on national expansion, but the family character of medigroba was retained.

Today, medigroba, with its own sales team and logistical infrastructure, is active from North Rhine-Westphalia, Hesse, Rhineland-Palatinate to Saarland, throughout Baden-Württemberg, and in the western part of Bavaria. Particularly as a specialist for patients with multimorbidity and in pediatrics, medigroba has established a firm position in the care spectrum in the new region. With such a wide range of products and services, the company often works with other providers, such as the sales reps from Löwenstein. In addition to supplying medical aids, medigroba operates a certified training center in which 1,000 nurses are trained an-



medigroba transport

nually. Demand is growing. Another service offers hygiene concepts for nursing care facilities. Even during the corona-related lockdowns, medigroba employees have been sought-after partners in many facilities.

Prepared for the future

The strategic merger with the Löwenstein Group once again places medigroba in family hands and lays the foundation for the future. Now we can offer patients of the new affiliated companies a meaningful addition to the portfolio with product areas such as enteral nutrition or incontinence supplies. That makes it possible

to provide care completely from within the Group. The established trade name "medigroba" will be kept, as will the headquarters in Balingen. Management of the company remains in the hands of managing directors Frank Franzen and Bodo Weinitschke.

Samuel Amed

WILAméd joins the Group

Löwenstein Medical and WILAméd have been joined in long-term cooperation whose success story they will continue writing together. As of January 2021, WILAméd is part of the Löwenstein Medical Group.

Kammerstein in Middle Franconia has about 3,000 residents. It is a good 30 kilometers to Nuremberg via the B466 highway. The WILAméd headquarters, surrounded by forests and fields in the industrial park in the Barthelmesaurach district is just a stone's throw from the Löwenstein Medical branch office in Kammerstein. No one would guess that the modern building complex sporting corporate colors on the green meadow is home to a "Hidden Champion". After all, WILAméd is neither hidden nor as unknown as the well-intentioned but misleading designation suggests. Among its regular customers in more than 60 countries are dealers that provide patients with modern ventilation technology, humidifiers and tubing systems "Made in Germany". WILAméd is a specialist in respiratory medical technology, serving hospitals, intensive care units, patients from premature babies to adults, rehabilitation facilities and homecare patients. As a reliable manufacturer and dealer, WILAméd has become an established brand. It was a long journey to this position.



WILAméd in Kammerstein

Export from the family center

With a strong pioneering spirit, lifeblood, and a good dose of courage, Claudia Röttger-Lanfranchi and Hildegard Winkler wagered the leap into self-employment in 1997. At the end of the 1990s, the treatment of sleep disorders offered newcomers to the field good prospects for success. That was the driving force behind the founding and the two entrepreneurs were familiar with the clinical picture from earlier jobs with a joint employer. The company's name "WILAméd" was made up from their last names Winkler and Röttger-Lanfranchi.

In the beginning, everything was rather small scale. Their residence initially served as the operational hub and warehouse. Back then the staff was small too, made up of members of both founding families. The company initially focused on the sale of sleep apnea devices and the production of consumable materials such as air filters, mask headgear and breathing tubes.

Dynamic development

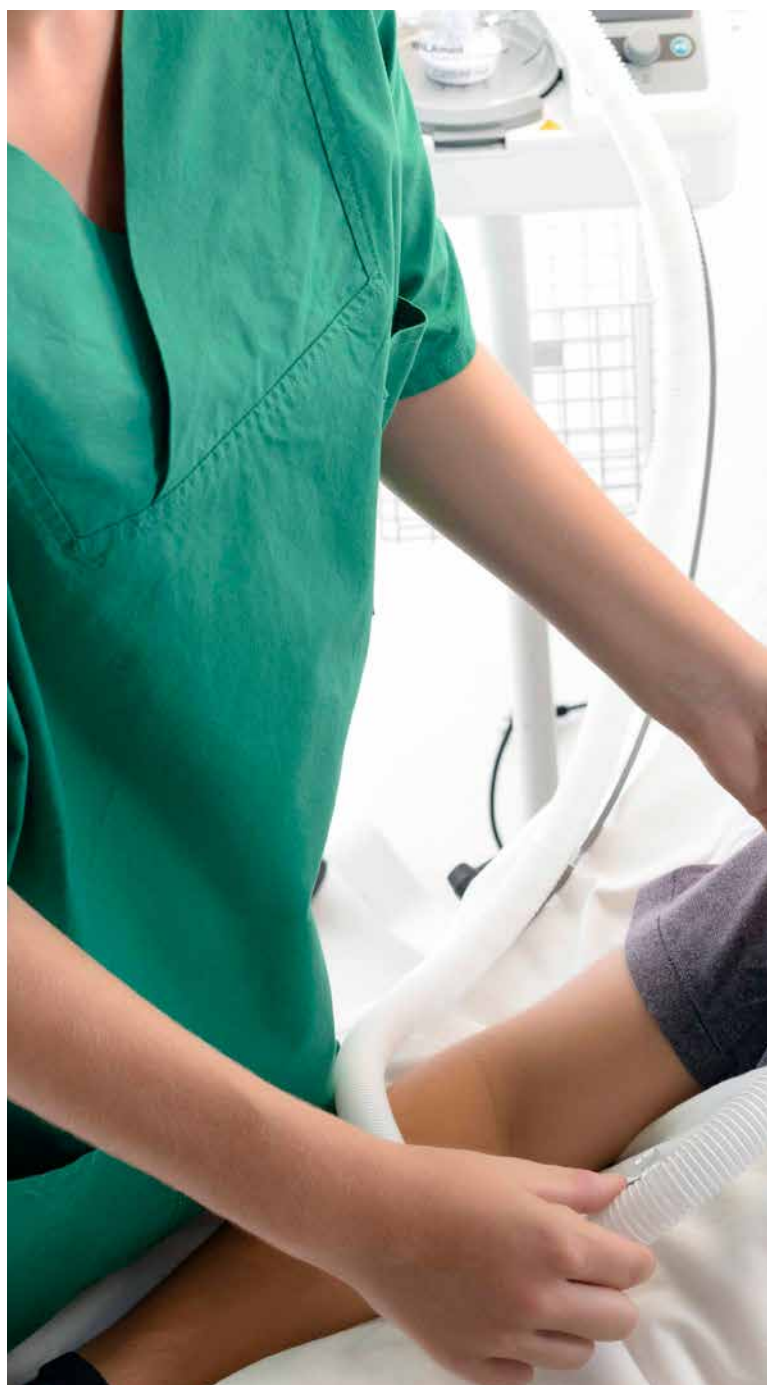
In the early years the new company frequently moved as the business and its space requirements grew. Encouraged by the positive developments, the management team decided in 2005 to acquire today's headquarters in the industrial park Barthelmesaurach and from then on to concentrate on the production and development of WILAméd's own medical products. Profit was regularly reinvested in the expansion of the in-house Research & Development department, modern technology and production facilities. From the start, WILAméd has followed a sustainability strategy and to date has received several awards for its commitment to energy efficiency and resource conservation.

Impressive balance sheet

Today the developed area in the Barthelmesaurach industrial park covers 10,000 square meters. More than 200 employees in Production and Administration work there on optimizing the treatment success of ventilated patients. In its core business, WILAméd, one of the leading manufacturers of humidification systems, supplies humidifiers (AIRcon Gen2, AIRniva, prisma VENT AQUA) for in-patient and outpatient use and produces related consumable materials such as humidifier chambers and heated/non-heated breathing tube systems.

Charting the course for the future

WILAméd opened up a new chapter in the company history with the strategic merger with the Löwenstein Medical Group. Both companies are certain that they can exploit synergies, bundle core competencies and free up productive capacity in joint pursuit of their goal, i.e., ensuring patient care with personalized, convenient and effective



therapy. The established brand WILAméd, the company's legal form and its headquarters remain unchanged. Founder Winkler retired at the end of 2020. Röttger-Lanfranchi is still entrusted with management of the business. In the spring of 2021, Andreas Bosch and Michael Goerlitz joined the top management team as managing directors.



Technologies for comprehensive solutions to respiratory gas conditioning

SANIMED comes on board

The Löwenstein Group welcomes yet another subsidiary – SANIMED with headquarters in Ibbenbüren. SANIMED and Löwenstein are linked by many years of cooperation, which should now be intensified.





Impressive development of SANIMED

Founded in 1983, SANIMED today is one of the market leaders in the healthcare sector with more than 20 business locations throughout Germany. SANIMED was part of the HARTMANN GROUP of Heidenheim from 2001 to 2020, a time of steady growth for the company. In 2017 the management team was expanded to include Michael Brauner, who still manages SANIMED alongside Karl-Heinz Westkamp. In 2020, the HARTMANN GROUP handed over SANIMED to palero capital, which has extensive experience in corporate development of medium-sized companies. In collaboration with palero, SANIMED increased its range of services and boosted further organic and inorganic growth. On 27 July 2021, the palero Group turned over SANIMED to the Löwenstein Group, whose portfolio of Homecare services will be expanded with the acquisition.

SANIMED – Partner for complete patient care

As a full-service provider, SANIMED wants chronically ill persons in need of care or with limited mobility to feel well cared for—whether at home or in a nursing home. In pursuit of that goal, the Homecare company provides a complete range of economically efficient medical aids from the areas of rehabilitation and medical technology. The portfolio is supplemented with mobil-



Certified professionals advise and network everyone involved in outpatient care

ity-enhancing products such as stair and wheelchair lifts. With its many locations and subsidiaries, SANIMED specializes in complete care of patients and offers an extensive range of products and services. By developing continuously, SANIMED aims to become the most successful full-service medical supplier in Germany.

Top-level supplier

SANIMED offers service reliability, optimum product choice and professional services. Trained and certified professionals provide consultation and assistance with product selection. Furthermore, they brief and train everyone involved—patients, family members and caregivers—to ensure ideal treatment. SANIMED has a strong network of health insurers, medical care services, nursing homes, hospitals and manufacturers, which it now brings to Löwenstein Medical.

Securing outpatient supply chain

With the expansion of the Medical Technology and Intensive Care business unit, the company has established several respiratory and follow-up care centers, which provide respiratory and oxygen therapy. The centers also offer products and services from the areas of Rehabilitation Technology and Medical Homecare.



Interdisciplinary competence goes into holistic care

Into the future together

By merging with the Löwenstein Group, SANIMED opens up a new chapter in its corporate history while retaining its legal form and management. Both companies hope to exploit many synergies that will help them to expand their respective market position.



Modern medical technology "Made in Germany"

A window on production in Hamburg

Löwenstein Medical Technology—formerly Weinmann Geräte für Medizin—has been a member of the Löwenstein Group since mid-2013. Homecare ventilators, sleep therapy devices and their masks are developed and assembled at the Hamburg headquarters. It was during the integration of Assembly and Logistics in late summer 2017 that the ultramodern "glass factory" was built on the site, conveniently located near the A7 federal highway.

When we became part of the Löwenstein Group, we were told by the Löwenstein family to bring Assembly and Logistics back to Hamburg and to integrate the departments in the buildings for Administration and Research & Development.

The shape of the available space on the Kronsaaßweg corner lot ruled out a rectangular addition. On top of that, the property sloped toward the neighboring stream, making construction difficult with the existing building at ground level. Creative thinking was called for as our planning group got to work.

In the end, we decided to extend the first upper floor of the old building and use part of it and the addition to house the factory. Now trucks drive over the side street Dörriesweg to the dock levellers at unloading height.

A garage underneath the Logistics area replaces some of the parking spaces elim-



View of Incoming Goods

inated by the extension. Two important questions remained: "How do we show visitors our technical expertise right away?" and "How can colleagues from outside the operations get a look at what's going on and feel a part of it without having to walk through the factory?"

The group came up with the idea of installing a window front across from the exhibition area to provide a view into the production area. Customers get the impression of how efficient the factory is and, for an even closer look, they can call up films on a small



View into the Production area

screen. Employees from all areas see and greet each other as they go by on the way to the canteen and conference rooms.

Six production lines for prismaLINE, prismaVENT and LUISA devices are visible behind the glass walls. There is still another clean room for sets of the devices' consumable articles and the hygienic reprocessing of devices assigned to new patients.

We made good use of the site for a second level with optimized workflow below Logistics and Assembly. The space there is used for customer device maintenance and other workstations for the packaging of sets and the assembly of older devices in the product discontinuation phase.

To link the two factory levels, a mobile robot was acquired and tested on the old site. Because the robot works so closely with us, we designated it a colleague, dubbed it "Giacomo" and added a moustache right

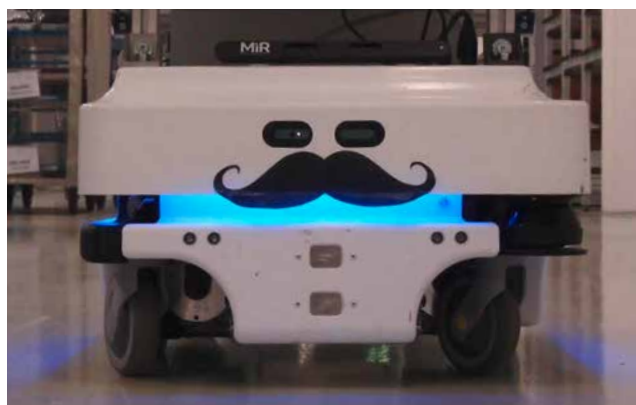
below its cameras and sensors. Via its own e-mail address, Giacomo entertains us now and again with success stories from its professional life.

Our colleague Giacomo is a self-propelled cart which, like a bus, makes regular stops along a route, and if needed, responds to e-mailed requests for pickups as a taxi does. Giacomo independently summons and operates the elevator so that it can supply the maintenance area for customer devices with the required materials from the storage area on the upper level.

The robotic cart also picks up empty containers from the assembly line and transports them to Logistics for refilling by placing them on the conveyor belt in front of the picking shuttle.

We figured out that Giacomo spares us from walking 1,200 kilometers a year, which is the distance from Hamburg to Genoa.

Our plans also called for gaining as much pallet space as possible in the industrial rack warehouse, which has a height of 7.5 meters, but only limited width. After weighing all the options, we decided in favor of a slide-in rack system for pallets. At any one



Giacomo in action

time, only one area of the system is opened to allow the forklift to drive through the open aisles. It is a little bit like the archives we have seen in crime series on TV or in films. First you crank open the area you want to enter.

The storage strategy for the slide-in racking system is based on an ABC analysis. The articles most frequently retrieved are made most easily accessible. Demand is regularly analyzed and adjusted as needed to minimize access frequency per aisle opening. With this solution we have gained an additional 280 pallet spaces in the same amount of storage area.

Our measurement technology is innovative too. We operate an instrument with optical magnification of 400x and a three-dimensional scanning mechanism. With this precision device, we have an efficient and trouble-free incoming goods process that assures our high level of quality and our ability to deliver at all times.

In the Continuous Improvement Process, teams in Assembly, Technical Service and Logistics are always working at optimizing processes to keep them efficient and lean. The CIP teams' accomplishments are visualized on bulletin boards, where the successful increases in our productivity serve as encouragement to all.

Today the factory and logistics center stand for absolute delivery reliability, customer-oriented flexibility with modern produc-



tion concepts in single-piece workflows with total usable area of 2,500 square meters.

The finished devices are checked completely by semi-automatic test benches to ensure our high quality. In addition, camera systems monitor sub-assemblies to minimize rework during device assembly. For that purpose, testing and production concepts are "tweaked" during development. Together we develop ideal processes for device production with the early involvement and good ideas of our colleagues from the areas of Testing Technology, Research & Development, Manufacturing Engineering, Quality Management, Technical Service, Assembly and Logistics.

Through the smooth interaction of people and technology and our colleagues' willingness to embrace change, we regularly reach important milestones on our shared way into the future.

We are still receiving very positive feedback on what we have achieved, particularly in the spring of 2020 during our baptism-by-fire with the mass production of ventilators to overcome the corona crisis.

We look forward to an exciting future with innovative products that we develop and produce in Hamburg, deliver punctually for the well-being of customers and patients, and maintain for our customers during the usage phase.



Medigas Italia and Löwenstein Medical

A thriving German-Italian friendship



Covid-19 unit in an Italian hospital

Medigas Italia, founded in 1996, immediately established itself as an important player in the home health care sector. Since the early 2000s, it has continuously diversified and expanded its product and service portfolio. The company's pioneering approach has helped it to grow in highly specialized markets and attain a widespread presence in Italy.

Thanks to its high technological and quality standards, Medigas Italia is now recognized as a valid and reliable

provider in the hospital, clinical and private customer markets. Today it is part of the SIAD Group, which has been active for more than 90 years in the technical gas business and for many years in the engineering sector.

Since 2013 Medigas and Löwenstein Medical have been cooperating successfully in the fields of Sleep Therapy, Homecare Ventilation and, since 2018 in the field of Intensive Care Ventilation. The recently acquired company Wilamed, also a part of

the Löwenstein Group, has been working with Medigas since mid-2005.

In 2020 the COVID-19 pandemic turned all our lives upside down, including at Medigas. The coronavirus has forced people around the world to change their habits. This "tsunami" has overwhelmed us, forced us to stay at home to contain the spread of the virus and prompted us to look more closely at our lifestyles and how we work, play, travel and shop.

The pandemic has changed not only our lives in many ways, but also the face of our Italian cities, with downtowns emptied of tourists and many of the workers who populated them. Urban residential areas and the suburbs are not just places to sleep, but spaces for life and work for those who no longer have to commute long distances and can spend more time in their neighborhoods.

Among the areas that have suffered are restaurants, pubs and hotels, retail trade, sports activities and night-life sites, cinemas, theaters, which have been partially or completely closed.

In everyday life, more attention has been given to hand washing along with increased use of disinfectant gels and gloves, especially after being at work or on public transport. In Italy, with the gyms closed and access to parks restricted, many people have rediscovered workouts at home with online courses. Distance learning has become important, with Zoom, Microsoft Teams and other applications allowing schools and universities to continue programs. Now the implemented systems are considered fundamental to academic life and the world of business.

We all have had to review our habits. We have to maintain social distance, wear masks, use public transport (which carries fewer passengers) less often in favor of bikes and electric scooters, and avoid crowds. It is a long way back to normality.

The first COVID-19 pandemic lockdown imposed in January 2020 upset our planning and operations. The emergency situation demanded a rapid and coordinated response with contributions from all departments involved.

The area of Bergamo (in Lombardy) was particularly affected, with Hospital Papa Giovanni XXIII forced to manage 200 patients per day, compared to 30 in normal situations.

COVID-19 symptoms could be treated only with the administration of oxygen. Medigas had to modify logistics immediately to cope with the emergency, making available more than 1000 extra liquid oxygen systems on very short notice.

Based in Milan, which was then a corona hotspot, Medigas was in greater demand than ever as a provider of ventilators. The company's 100 employees did their best to meet the challenge.

Medigas coordinated the delivery of ventilators to many hospitals in which special COVID-19 and intensive care units were set up quickly for

the care of patients infected with the virus. From January to November of last year, more than 300 ventilators were installed. Despite the inadequate number of devices supplied by the manufacturers, Medigas was able to deliver ventilators because technicians had refurbished previously used devices. As soon as the supply chain resumed delivery of new ventilators, the old devices were replaced.

The quick reaction of Medigas to the urgent situation was made possible by extensive support from Löwenstein Medical, which delivered more than 200 intensive care ventilators. In addition, Löwenstein made deliveries via the German government to Italy. The ventilators were installed and supported by Medigas, the Italian partner and friend in the battle against the coronavirus.



Delivery of some ventilators

LENA. Reliable at high pressures too.

Most people breathe in and out without having to think about it. Patients with respiratory insufficiency or Sleep-Disordered Breathing need help with breathing. LENA – the new full face mask from Löwenstein – has been developed specially for ventilation. The primary focus is on a comfortable mask fit, particularly when high pressures are applied or when the pressure difference between inspiration and expiration is very big.

For effective ventilation, the three essential factors for an optimum mask fit are the mask cushion, the connection between cushion and mask body and the headgear.



Pressure stability



Large pressure range



Ventilation



In the hospital



At home



Day and Night



Can be disinfected and sterilized



Forehead cushion

- broad surface distributes pressure evenly

Forehead support

- easy-to-use sliding element permits almost infinite adjustment

Connection for O₂ feed

- no adapter required

Exhalation system

- quiet and diffuse flow for unimpaired wearing comfort

Elbow

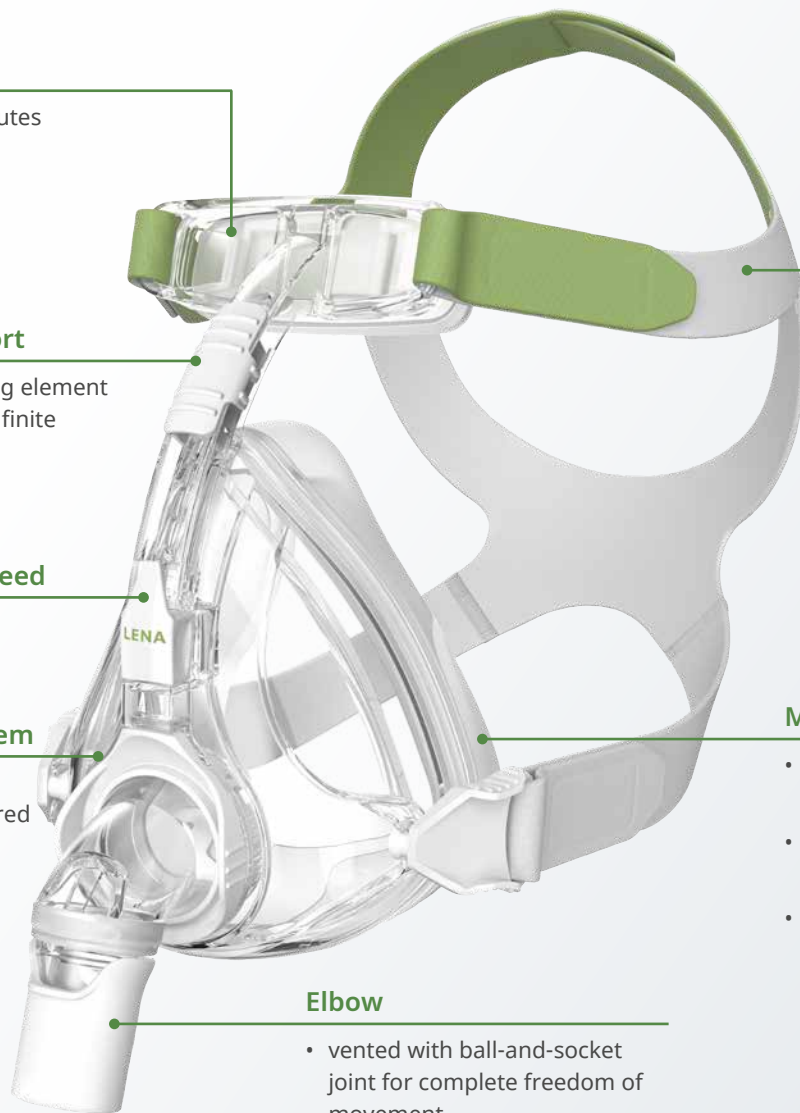
- vented with ball-and-socket joint for complete freedom of movement
- non-vented for valve circuit ventilation

Headgear

- withstands high pressures and big pressure differences
- color coding helps with correct mask assembly
- rounded edges leave no marks on skin

Mask cushion

- double lip for a perfect seal all around
- new design with anatomically rounded, soft edges
- varied structure on the surface ensures a good, lasting fit



Success factors for LENA

In an article about masks in a previous edition of our magazine, you read about the challenges in coming up with the perfect mask fit. From north to south and east to west, faces differ in shape and size. A mask cushion has to accommodate all types of faces—full or gaunt, young or old, bearded or clean-shaven.

To meet the challenges, we decided in favor of a "double lip" for the LENA **mask cushion**. The inner silicone lip stabilizes the mask cushion on the patient's face and the outer lip gives the mask a good seal. The therapy pressure generates an air buf-

fer, which seals the mask very effectively without causing any pressure marks on the face.

The significance of the second factor—the **connection between mask cushion and mask body**—is often underestimated or overlooked entirely. When subjected to high pressure differences, such as in Bi-Level mode, masks tend to "pump" on the face. With each breath, the mask is pushed away and then immediately pressed back onto the patient's face. A reliable connection between these two mask parts ensures a stable mask fit without any leaks. However, the mask should not have an excessively tight fit.

It should be easy to disassemble the connection so that the mask can be cleaned simply and thoroughly. A presumed paradox that LENA resolves very well.

The **headgear** completes the triad of essential factors. The strap material is sufficiently firm to ensure that the mask remains stable and does not leak or "pump" when subjected to big pressure differences. The individually adjusted forehead support with forehead cushion gives LENA extra hold.

Quiet and diffuse flow even at high pressures

Additional important details round off the mask concept. The integrated exhalation system in LENA, for example, has a pleasantly **quiet and diffuse flow** that disturbs neither patient nor bed partner. It is a special feature that distinguishes all Löwenstein masks from the rest. At increasing pressure, the noise level of the exhalation system rises. Wanting to avoid that at all costs, we optimized the exhalation system accordingly. Despite a higher flow, the sound remains at a pleasant volume and, along with the special Löwenstein **ball-and-socket joint**, lets the patient sleep soundly.

Simple use for everyone

Handling a ventilation mask is not left to the **patient** alone. Because **someone else** –a caregiver or family member–is often involved, the mask has to be simple to use. During development we made sure to sat-

isfy this requirement and conducted usability tests to confirm our success.

An **oxygen feed** directly into the mask can be helpful for patients at home. That is possible without an extra adapter.

Broad selection of variants and accessories

LENA can be used with all available NIV devices and patient circuits because LENA comes in vented and non-vented variants.

Mask accessories too play an increasingly important role. The **quick-release cord**, which originally served to detach the headgear from the mask, now makes the mask easier to use. Patients with muscular disorders or arthritic hands benefit from simplified handling.

Another helpful accessory is the **Endoscopy Adapter**. Attached to the mask in place of the non-vented elbow, the adapter allows a doctor to perform a bronchoscopy on the patient without interrupting ventilation. The patient suffers no shortness of breath, allowing the doctor to perform the procedure undisturbed.

With its variety and well thought out details, LENA satisfies many different needs and has proven itself in practice. The new mask adds more diversity to the Löwenstein mask portfolio. Try it yourself.





Research News

In this section we present a selection of especially interesting new literature on the subjects of ventilation, respiratory therapy and related diagnostics. You are welcome to give us your feedback on our choices or to tell us about your own literature discoveries.

Respiratory Medicine in the time of COVID-19:

- A current publication compiles the state of knowledge and recommendations on **diagnostics and treatment of COVID-19**. (available only in German)

Kluge, S.; Janssens, U., Welte, T.; Weber-Carstens, S., et al. (2021): S3 Guideline – Recommendations on in-patient treatment of patients with COVID-19. In: AWMF Register-Nr. 113/001. Weblink: <https://www.awmf.org/leitlinien/detail/II/113-001.html>

Chalmers, J. D.; Crichton, M. L.; Goeminne, P. C.; Cao, B.; Humbert, M.; Shteinberg, M. et al. (2021): Management of hospitalised adults with coronavirus disease 2019 (COVID-19). A European respiratory society living guideline. In Eur. Respir. J 57 (4). DOI: 10.1183/13993003.00048-2021.

Bein, B.; Bachmann, M.; Huggett, S.; Wegemann, P. (2021): SARS-CoV-2/COVID-19 – updated recommendations on diagnostics and treatment. In Anästhesiol Intensivmed Notfallmed Schmerzther. 56: pages 277–287.

Grasselli, G.; Cattaneo, E.; Florio, G.; Ippolito, M.; Zanella, A.; Cortegiani, A. et al. (2021): Mechanical ventilation parameters in critically ill COVID-19 patients. A scoping review. In Crit. Care 25 (1). DOI:10.1186/s13054-021-03536-2.

- The AASM has published data from a survey on the impact the **COVID-19 pandemic** has had on **sleep medicine practices**. Nearly 400 responses were returned from 18 countries, with the majority from the USA. Almost all sleep medicine centers reported stopping all or nearly all sleep testing; diagnoses in homecare were continued in part. The majority put measures in place for protection from infection, e.g., hygiene measures for equipment, protective gear for personnel or COVID tests, from symptom screening and temperature screening to PCR tests. A notably high number of centers offered telemedicine and many of them expect to continue with virtual office hours after the pandemic. It appears as though sleep medicine is adapting to the changing situation and is making more patient care possible again.

Johnson, K. G.; Sullivan, S. S.; Nti, A.; Rastegar, V.; Gurubhagavatula, I. (2021): The impact of the COVID-19 pandemic on sleep medicine practices. In: J. Clin. Sleep Med. 17 (1), pages 79–87. DOI:10.5664/jcsm.8830.

- In January 2021 the German Society for Pulmonology and Respiratory Medicine (DGP) published a statement regarding the regulation on the use of **FFP and surgical masks by the general public**. The DGP is in favor of the initiative by the federal and state governments that puts face masks on the front line of protecting the wearer from infection. A mask's most important characteristics include high filtration of infectious particles, low air resistance and a good seal with minimum leakage. The objectives sometimes conflict with each other. FFP and surgical masks, which were originally developed for other purposes, represent a currently available compromise. Proper use and a good fit are critical. Patients with heart and/or lung diseases should have a stress test with a mask so that doctors can assess and minimize medical risks. The statement also expressed approval of the new development of masks which are optimized for infection protection requirements and widespread use among the general public.

Dellweg, Dominic; Lepper, P. M.; Nowak, D.; Köhnlein, T.; Olgemöller, U.; Pfeifer, M. (2021): Statement of the German Society for Pulmonology and Respiratory Medicine Regarding the Regulation to Use FFP and Surgical Masks in the General Population. (abstract in English, statement only in German) Available online at: <https://pubmed.ncbi.nlm.nih.gov/33598902/>.

CPAP/APAP-Therapy:

- The AASM has published an update to its position paper on the use of **telemedicine** for the diagnosis and treatment of **sleep disorders**. Above all, the COVID-19 pandemic has shown that telemedicine is an tried and tested means of maintaining medical care. The position paper recommends retaining some of the digital practices, such as video consultations.

Shamim-Uzzaman, Q. A.; Bae, C. J.; Ehsan, Z.; Setty, A. R.; Devine, M.; Dhankikar, S. et al. (2021): The use of telemedicine for the diagnosis and treatment of sleep disorders. An American Academy of Sleep Medicine update. Published in J. Clin. Sleep Med. DOI: 10.5664/jcsm.9194.

- The InterfaceVent study examined the occurrence of **mask problems** in almost 1,500 **CPAP patients** and their effect on adherence and sleepiness. No correlation was seen between patient-reported leaks and CPAP device-reported leaks. However, a connection was found between the patient-reported leaks and patient's reduced adherence (complaints of dry mouth), residual daytime sleepiness (attributed to leakage problems, loud mask noise, dry nose and discomfort causes by headgear). The study shows how important it is to ask patients for their subjective mask complaints and to fit them properly with a high-quality, quiet mask.

Rotty, M.-C.; Suehs, C. M.; Mallet, J.-P.; Martinez, C.; Borel, J.-C.; Rabec, C. et al. (2021): Mask side-effects in long-term CPAP-patients impact adherence and sleepiness. The InterfaceVent real-life study. Published in Respiratory Research 22 (1). DOI: 10.1186/s12931-021-01618-x.

ASV Treatment:

- A meta analysis examined the effect of **Adaptive Servo-Ventilation (ASV)** in major adverse cardiovascular events in patients with **Central Sleep Apnea (CSA) and heart failure**. ASV treatment has a protective effect on patients with Left Ventricular Ejection Fraction (LVEF) > 33%, but not on those who with heart failure, defined as LVEF ≤ 33%. The findings confirm the contraindication of ASV in cases of severely reduced ejection fraction, but also reinforce the recommended use of ASV treatment in cases of CSA and less severe heart failure.

Wang, J.; Covassin, N.; Dai, T.; Fan, Z.; Yisilamu, P.; Sun, D. et al. (2021): Therapeutic value of treating central sleep apnea by Adaptive Servo-Ventilation in patients with heart failure. A systematic review and meta analysis. Published in *Heart & Lung: The Journal of Cardiopulmonary and Acute Care* 50 (2), pages 344–351. DOI: 10.1016/j.hrtlng.2021.01.012.

- A conference paper from France and Belgium reports on the examination of the effect of **ASV treatment on cardiac outcomes**. The ASV patients were divided into different clusters. It was confirmed that patients with heart failure with reduced ejection fraction and Central Sleep Apnea (CSA) have the worst prognosis. Other patient clusters, particularly those with heart failure with preserved ejection fraction, benefited from ASV treatment. Overall ASV showed a protective effect. We eagerly await the full publication.

Damy, T.; Tamisier, R.; Davy, J.; Verbraecken, J.; Bailly, S.; Lavergne, F. et al. (2021): FACE. Phenotyping analysis of Chronic Heart Failure (CHF) patients with Sleep Disordered Breathing (SDB) indicated

Adaptive Servo-Ventilation (ASV): two-year follow-up results. Published in: *Archives of Cardiovascular Diseases Supplements* 13 (1), page 35. DOI: 10.1016/j.acvdsp.2020.10.106.

Ventilation:

- A review summarizes the findings on **long-term non-invasive ventilation** of children. The number of cases in the past 30 years has risen sharply. Besides the benefit for quality of life and the reduction of subsequent medical expenses, the paper covers indications and contraindications, practical challenges in general and specifically in times of COVID-19.

Praud, J.-P. (2020): Long-Term Non-invasive Ventilation in Children. Current Use, Indications, and Contraindications. Published in *Frontiers in Pediatrics* 8. DOI: 10.3389/fped.2020.584334.

- An extensive review of **long-term non-invasive ventilation in COPD** discusses current practices and recent trends, ventilation strategies and novel developments in technology. A separate article on the subject presents the European guidelines on long-term NIV for COPD.

Majorski, D. S.; Duiverman, M. L.; Windisch, W.; Schwarz, S. B. (2021): Long-term non-invasive ventilation in COPD. Current evidence and future directions. In *Expert Rev. Respir. Med.* 15 (1), pages 89–101. DOI: 10.1080/17476348.2021.1851601.

Wollsching-Strobel, M.; Windisch, W.; Majorski, D. S. (2021): European guidelines on noninvasive long-term ventilation for chronic obstructive pulmonary disease. In *Der Pneumologe* 18, pages 13-19.

- The Swiss Society of Pulmonology also has published a **paper with recommendations for long-term ventilation** that offers a good overview of ventilation, including interfaces, modes, setting parameters, indications, accessories such as manually assisted cough techniques, practical aspects, success criteria and blood gas analysis. The publication is very well suited for beginners in long-term ventilation.

Janssens, J.-P.; Michel, F.; Schwarz, E. I.; Prella, M.; Bloch, K.; Adler, D. et al. (2021): Long-Term Mechanical Ventilation. Recommendations of the Swiss Society of Pulmonology. In Respiration 99 (10), pages 867–902. DOI: 10.1159/000510086.

- Another paper from Switzerland reports on an observational study regarding **multidisciplinary care of ALS patients**.

Sukockiene, E.; Iancu, F. R.; Truffert, A.; Héritier, B.A.-C.; Genton, L.; Viatte, V. et al. (2020): Multidisciplinary care in amyotrophic lateral sclerosis. A 4-year longitudinal observational study. In Swiss Med Wkly 150 (23-24). DOI: 10.4414/sm.w.2020.20258.

Diagnosics:

- An American team took up the research question "In comparison with the Apnea-Hypopnea Index (AHI), how does sleep apnea-specific hypoxic burden predict incident heart failure?" Samples were derived from the Sleep Heart Health Study. Particularly clear connections were found between the hypoxic burden and heart failure (only in males), a heightened pulse rate response to respiratory events and cardiovascular disease, including mortality, and prolonged circulation time and mortality (examined in older males). The results

underscore the relevance of sleep apnea as a cardiovascular risk factor.

Azarbarzin, A.; Sands, S. A.; Taranto-Montemurro, L.; Vena, D.; Sofer, T.; Kim, S.-W. et al. (2020): The Sleep Apnea-Specific Hypoxic Burden Predicts Incident Heart Failure. In Chest 158 (2), pages 739–750. DOI: 10.1016/j.chest.2020.03.053.

Azarbarzin, A.; Sands, S. A.; Younes, M.; Taranto-Montemurro, L.; Sofer, T.; Vena, D. et al. (2021): The Sleep Apnea-specific Pulse Rate Response Predicts Cardiovascular Morbidity and Mortality. In Am. J. Respir. Crit. Care Med. DOI: 10.1164/rccm.202010-3900OC.

Kwon, Y.; Sands, S. A.; Stone, K. L.; Taranto-Montemurro, L.; Alex, R. M.; White, D. P. et al. (2020): Prolonged Circulation Time is Associated with Mortality Among Older Men with Sleep Disordered Breathing. In Chest. DOI: 10.1016/j.chest.2020.10.025.

- The **ESADA database** examined **phenotypes** in 23,000 **OSA patients** and found eight distinct clinical phenotypes. Two clusters were made up exclusively of males or females, with the remaining clusters of mixed genders, predominantly male. The factors of age range, BMI, AHI and comorbidities differed among the clusters. The preferred therapeutic approach also differed for the clusters. The impact of these clusters on long-term treatment adherence or prognosis are still to be studied in ESADA follow-up data.

Bailly, S.; Grote, L.; Hedner, J.; Schiza, S.; McNicholas, W. T.; Basoglu, O. K. et al. (2021): Clusters of sleep apnoea phenotypes: A large pan-European study from the European Sleep Apnoea Database

(ESADA). Published in *Respirology* 26 (4), pages 378–387. DOI: 10.1111/resp.13969.

- Another study based on the ESADA database examined the improvement of sleepiness and blood pressure under treatment. The patients were divided into four groups according to the severity of clinical symptoms and comorbidities. Membership in one of the groups had a greater influence on the treatment outcome than the baseline AHI. The **Baveno classification** allows a better **stratification of the OSA population** and may provide better guidance for therapeutic decisions in OSA.

Randerath, W. J.; Herkenrath, S.; Treml, M.; Grote, L.; Hedner, J.; Bonsignore, M. R. et al. (2021): Evaluation of a multicomponent grading system for obstructive sleep apnoea. The Baveno classification. Published in *ERJ open research* 7 (1). DOI: 10.1183/23120541.00928-2020.

- A current study with **SOMNOcheck micro** shows that the Apnea-Hypopnea Index, Oxygen Desaturation Index and the pulse wave-based Cardiovascular Risk Index (CRI) all independently predicted high **cardiovascular risk** in sleep apnea patients. However, in a prediction model that took age, gender and Body Mass Index into consideration, only CRI improved the performance of cardiovascular risk prediction. The findings indicate the potential of **pulse wave analysis** in risk stratification.

Strassberger, C.; Zou, D.; Penzel, T.; Fietze I.; Hedner, J.; Ficker J. H.; Randerath, W.; Sanner, B.; Sommermeyer, D.; Grote, L.(2021): Beyond the AHI–pulse wave analysis during sleep for recognition of cardiovascular risk in sleep apnea

patients. In *J Sleep Res.* DOI: 10.1111/jsr.13364.

- A series of reviews in *Sleep Medicine Clinics* gives an overview of the current state of knowledge on sleep-related movement disorders, including Restless Legs Syndrome, bruxism and REM sleep behavior disorder.

Garcia-Borreguero, D. (2021): Movement Disorders in Sleep. Published in *Sleep Medicine Clinics* 16 (2), pages 223-408. <https://www.sciencedirect.com/journal/sleep-medicine-clinics/vol/16/issue/2>.

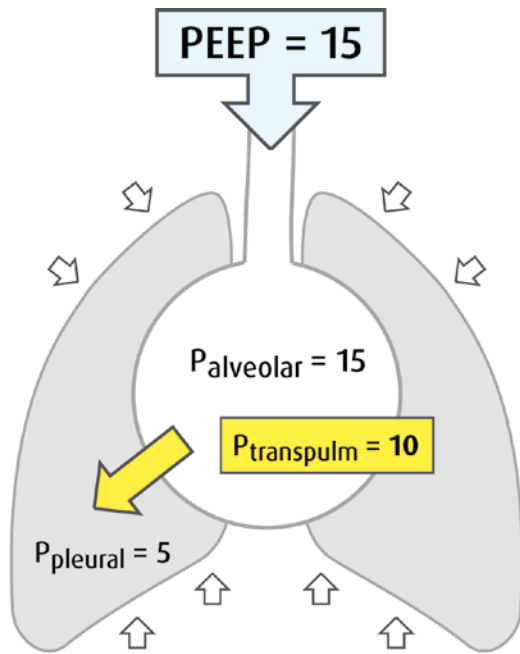


Question for Experts

What does lung-protective ventilation mean?

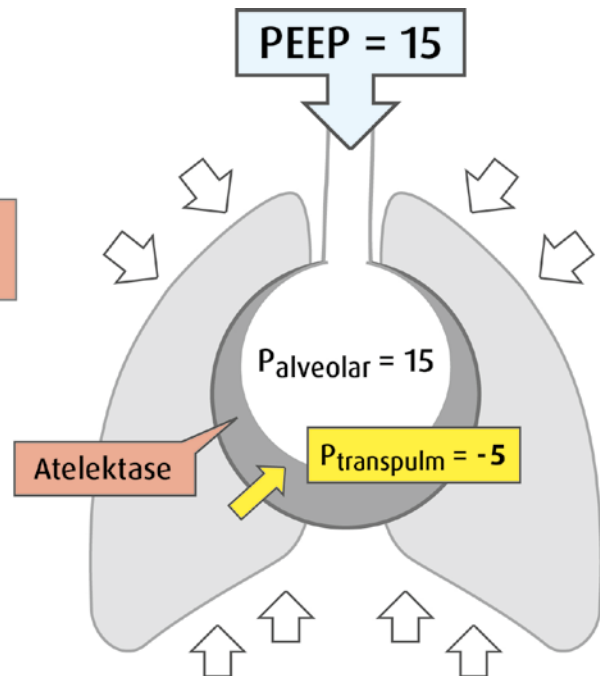
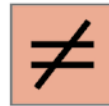
Mechanical ventilation is the most invasive intensive care measure to ensure an adequate oxygen supply and CO₂ elimination in patients with acute respiratory insufficiency. As with any type of treatment, ventilation therapy has side effects. Reports were made in the 1970s of barotrauma, that is, the rupture of lung tissue caused by high ventilation pressures. In the past 20 years, different damaging mechanisms have been identified and renamed "Ventilator-Induced Lung Injury (VILI)". Among them are the previously mentioned baro-

trauma, volutrauma (overdistension of alveoli) and atelectrauma (shear stress from atelectasis). A concept for lung-protective ventilation strategy was developed to reduce VILI. The goal is to keep the mechanical pressure and volume load on the lungs as low as possible. Because the application of ventilation therapy to damaged lungs is a highly dynamic process, at regular intervals the ventilation settings have to be adjusted to the specific regional lung function and the ventilation needs of the patient evaluated.



$$TPP_{insp} = \text{Plateau} - P_{es}$$

$TPP_{insp} \approx \text{Dehnung („strain“)}$



$$TPP_{exsp} = PEEP - P_{es}$$

$TPP_{exsp} \approx \text{Alveolarkollaps („stress“)}$

"Lung-protective" ventilation significantly improves the survival rate of patients with Acute Respiratory Distress Syndrome (ARDS). In ARDS patients, atelectrauma with breath-synchronous collapse and re-opening of lung regions is a major factor in VILI and an independent risk factor in increased mortality. An optimum setting of Positive End Expiratory Pressure (PEEP), an important lung-protective ventilation measure, should help to reduce the opening and collapsing of lung regions. Excessively low PEEP settings cause damage to lung com-

partments through atelectrauma, while excessively high PEEP damages lung areas through overdistension. This gravity-dependent process is not homogeneously distributed in the lungs, causing atelectasis to occur predominantly in the dorsal regions and overdistension in ventral lung regions. Transpulmonary Pressure (TPP) greatly affects the extent of mechanical stress on the alveoli and for VILI. Contrary to frequently made assumptions, the influencing factor is not the inspiratory plateau pressure set on the ventilator. TPP is defined as the dif-

ference between alveolar pressure (P_{alv}) and pleural pressure (P_{pl}). Because neither the alveolar pressure nor the pleural pressure can be determined directly by the ventilator, a surrogate measure is used.

In the case of P_{alv} , one can presume that the end-inspiratory plateau pressure and the end-expiratory PEEP represent the inspiratory and expiratory P_{alv} as there is no gas flow present at that point (no-flow phase). Given the anatomical proximity of the pleura to the lower third of the esophagus, the pleural pressure is transferred to the esophagus. The changes in esophageal pressure (P_{es}) during a breathing cycle, as measured by an esophageal catheter (Pesocatheter), reflect the changes in pleural pressure. These days nearly all modern intensive care ventilators permit minimally invasive transpulmonary pressure monitoring to be conducted by means of novel balloon catheters. Valuable information about the current ventilation status is delivered by such catheters. For example, the same inspiratory pressure in patients with elevated intra-abdominal pressure may be associated with less VILI than in patients with normal abdominal pressure. In the presence of elevated intra-abdominal pressure (e.g., caused by obesity, ileus, ascites), patients can tolerate a higher inspiratory plateau pressure as long as the inspiratory TPP is not accompanied by a potentially dangerous increase. The expiratory TPP can be used for PEEP optimization. A PEEP at which the end-expiratory TPP is positive indicates opened lung regions. Under PEEP optimization based on transpulmonary pressure, it was shown that the occurrence of atelectrauma was minimized and oxygenation and compliance of the respiratory system were improved. Even in the small number of ARDS cases (60 patients), a clinically significant association was shown between survival rate and PEEP optimization

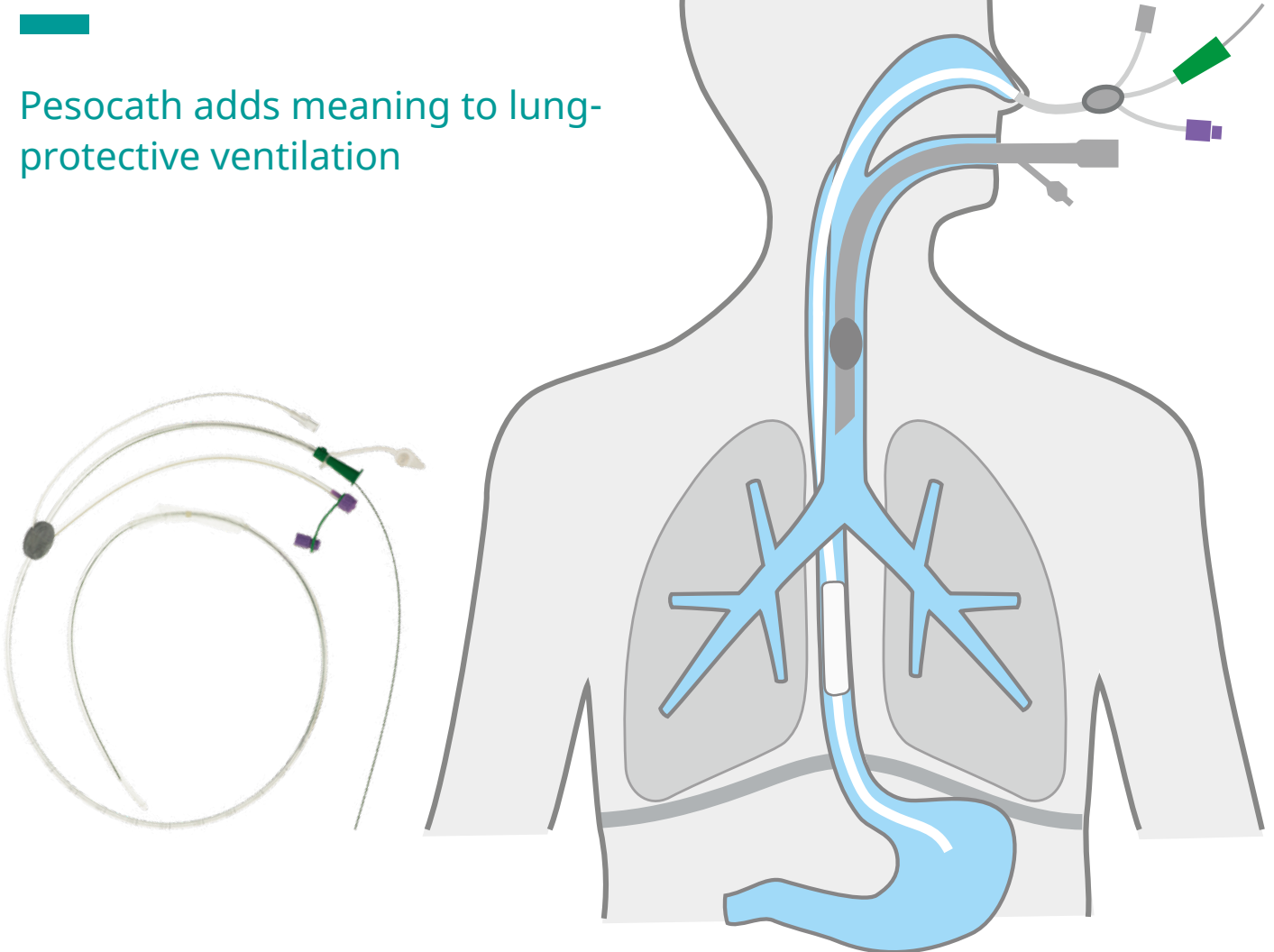
based on TPP, compared to a PEEP setting based on ARDS network tables. Lung-protective ventilation is more than low tidal volume, the limitation of plateau pressure and the PEEP setting based on table values. Transpulmonary pressure monitoring involves continuous PEEP adaptation to regional lung function and makes personalized lung-protective ventilation possible.



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Chief Physician
Klinik und Poliklinik für Anästhesiologie
und Intensivtherapie
University Hospital Rostock

PESOCATH

Pesocath adds meaning to lung-protective ventilation



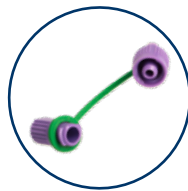
WIRE-IN-WIRE SYSTEM

Insertion wire with innovative WIRE-IN-WIRE technology. Simplifies the withdrawal of the insertion wire.



SAFE & RELIABLE IN AN EMERGENCY

Direct channel for emergency suction, auscultation and sampling of gastric juice



ENTERAL NUTRITION LATEST STANDARD

Direct connection to the latest standard for connectors as per DIN EN ISO 80369, with practical cap



VENTILATOR INTERFACE

Connector for esophageal and transpulmonary pressure monitoring or position-dependent gastric pressure



BALLOON CATHETER

Flexible, atraumatic catheter with radiopaque marking

Expiratory Flow Limitation

A great challenge in homecare ventilation.

Expiratory Flow Limitation (EFL) is a condition in which expiratory flow is limited by a dynamic collapse of small airways.¹ EFL represents a severe mechanical constraint caused by different mechanisms and observed in different conditions, but it is more relevant in terms of prevalence and negative consequences in obstructive lung diseases and particularly in chronic obstructive pulmonary disease (COPD). The prevalence and severity of EFL vary. The development of EFL in humans depends on the factors of aging, body position, exercise, hyperpnea-tachypnea, low-volume breathing, and airflow reduction, alone or more often combined together.² EFL occurred in 37.4% of test subjects with COPD.³ Flow-limited patients had higher BMI and a higher intrinsic Positive End Expiratory Pressure (PEEPi), which indicates positive pressure in the lungs at the end of expiration.^{4,5}

Dynamic tidal flow-volume loops are captured in order to identify EFL (see Figure 1). The flow-volume loops of a healthy subject show a steep increase in the expiratory phase and then a relatively uniform decrease. These subjects increase tidal volume without reaching maximum flow rates but with more stable or increased inspiration capacity. In contrast, the breathing loop in persons with COPD is always flatter than in a physiological case. The reason is the increased flow resistance caused by a reduced diameter of the airways. For the same flow, those patients have to generate greater volumes through movement in the thorax.⁶

Initially, flow limitation is present only at maximum respiratory effort, but as pulmonary disease progresses, EFL can develop in many affected patients while they are at rest. The consequences of EFL can be an in-

¹ Junhasavasdikul, D.; Telias, I.; Grieco, D. L.; Chen, L.; Gutierrez, C. M.; Piraino, T.; Brochard, L. Expiratory Flow Limitation During Mechanical Ventilation. *Chest* 2018; 154(4): 948-962.

² Tantucci, C. Expiratory flow limitation definition, mechanisms, methods, and significance. *Pulm. Med.* 2013 DOI: 10.1155/2013/749860.

³ Dean, J.; Kolsum, U.; Hitchen, P.; Gupta, V.; Singh, D. Clinical characteristics of COPD patients with tidal expiratory flow limitation. *Eur. Respir. J.* 50 2017; 12: 1503-1506.

⁴ Volta, C.A.; Dalla Corte, F.; Ragazzi, R.; Marangoni, E.; Fogagnolo, A.; Scaramuzza, G.; Grieco, D.L.; Alvisi, V.; Rizzuto, C.; Spadaro, S. Expiratory flow limitation in intensive care: prevalence and risk factors. *Critical Care* 2019; 23: 395.

⁵ Armaganidis A, Stavrakaki-Kallergi K, Koutsoukou A, et al. Intrinsic positive end-expiratory pressure in mechanically ventilated patients with and without tidal expiratory flow limitation. *Crit Care Med.* 2000;28: 3837-42.

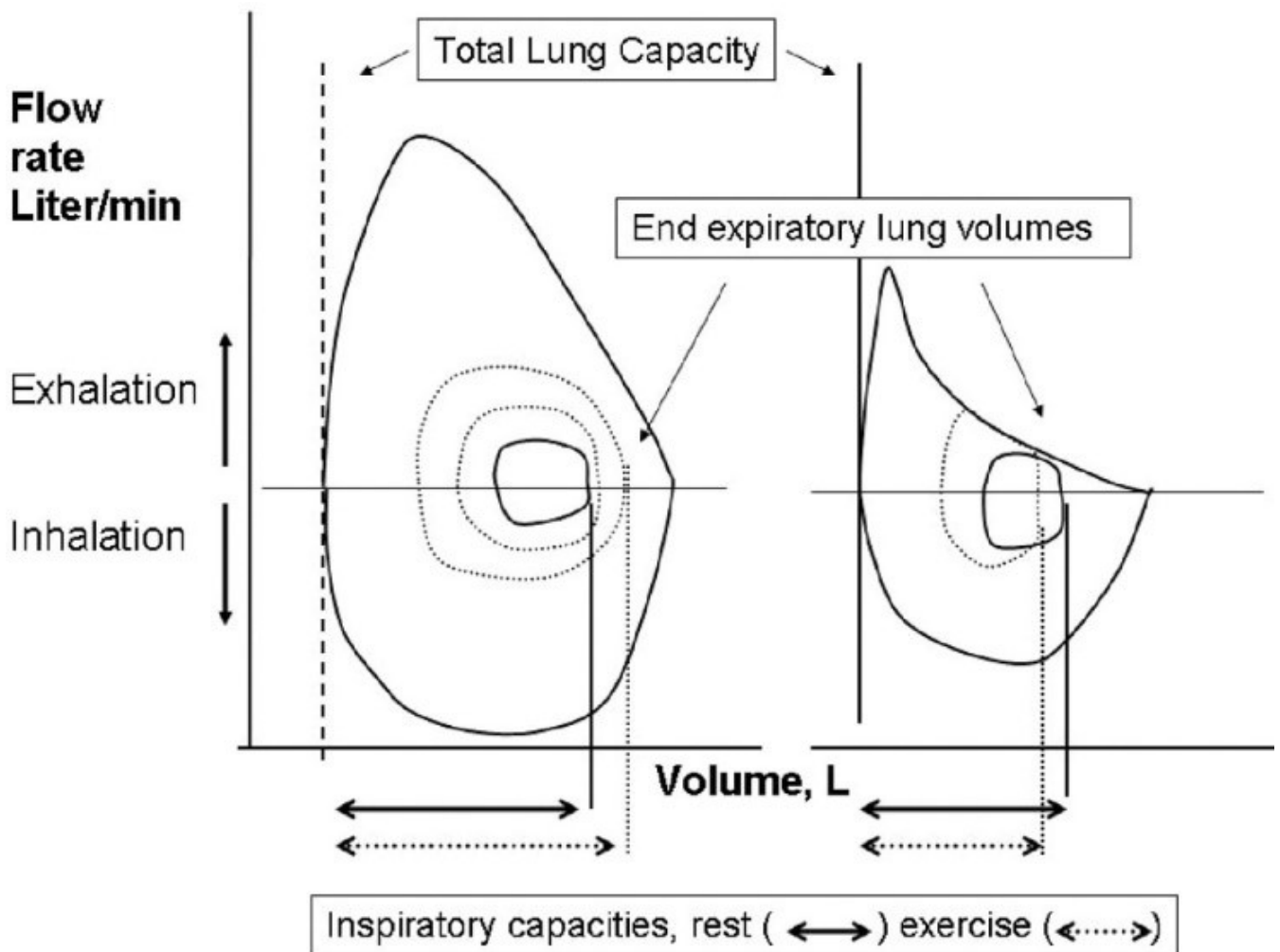


Figure 1: Spontaneous tidal flow-volume loops at rest (inner solid lines) and exercise (dotted lines) and maximal flow-volume loops measured before exercise (outer solid lines) for a normal subject (left) and a patient with chronic obstructive pulmonary disease (right).⁶

crease in obstructions or dynamic hyperinflation of the lungs, which is accompanied by breathlessness during physical exertion.^{3,7,8} An increased risk of later exacerbations and of all-cause mortality also have been associated with EFL.⁹

The success of mechanical ventilation may be compromised by EFL and an elevated PEEP_i, which cause patient-ventilator dyssynchrony, additional damage to the diaphragm or a drop in blood pressure.^{1,2,10,11}

⁶ Balady GJ, Arena R, Sietsema K, Myers J, Coke L, Fletcher GF, et al. Clinician's Guide to Cardiopulmonary Exercise Testing in Adults: A Scientific Statement From the American Heart Association. *Circulation* 2010; 121: 191–225.

⁷ Celli BR, MacNee W. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. *Eur Respir J* 2004; 23: 932–946.

⁸ Gibson GJ. Pulmonary hyperinflation: a clinical overview. *Eur Respir J* 1996; 9: 2640–9.

⁹ Aarli B, Calverley PMA, Jensen R, Dellacà R, Eagan TML, Bakke P, Hardie J. The association of tidal EFL with exercise performance, exacerbations, and death in COPD. *Int J Chron Obstruct Pulmon Dis* 2017; 12: 2179–2188.

¹⁰ Alvisi V, Romanello A, Badet M, Gaillard S, Philit F, Guérin C. Time course of expiratory flow limitation in COPD patients during acute respiratory failure requiring mechanical ventilation. *Chest* 2003; 123(5): 1625–1632.

Experts have tried different approaches to increase the success of ventilation in the presence of EFL by using settings optimized to counteract the condition.

- Attempts have been made to prolong the expiration time (i.e., reduce respiratory frequency). However, the small additional exhaled volume gained from prolonging the expiratory time (achieved by reducing the respiratory rate) might not be worth the sacrifice of overall minute ventilation.¹
- It has been shown that high Positive End Expiratory Pressure (PEEP) during ventilation decreases inspiratory muscle effort, normalizes breathing patterns, improves blood gases and reduces asynchrony between patient and ventilator.^{12,13,14} With external PEEP applied, the work of breathing to activate the inspiration trigger decreases when the patient can initiate

a breath at a higher starting point. In the end, this approach does not reduce EFL or potential hyperinflations of the lungs, but simply adapts the ventilation to the problem. Depending on the patient's comorbidity, an increased end-expiratory pressure can have a negative effect on blood dynamics and stroke volume.^{15,16,17} Therefore, the pressure should be increased on a case-by-case basis and, ideally, manually under medical supervision. Moreover, in some patients the intrinsic PEEP increases further when the ventilator offers a higher external PEEP. In this case the external PEEP may worsen the situation.¹

- Higher pressure at the end of expiration acts as a splint to keep lower airways open and thus contributes to more effective expiration. Therefore, it appears to make more sense to increase ventilation pressure at the start of expiration and during the expiratory

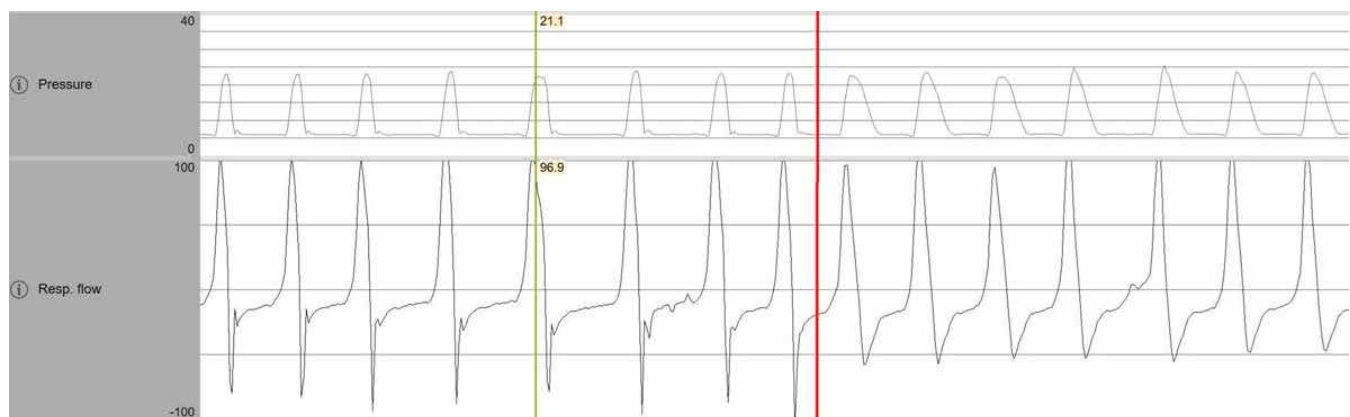


Figure 2: Pressure and respiratory flow of a patient with EFL under mechanical ventilation with prismaVENT, IPAP 21 hPa, EPAP 6 hPa. expiratory slope first at Level 1 (steep), from the red line, Level 4 (flat).

¹¹ Puente-Maestu, L.; Stringer, W. W. Hyperinflation and its management in COPD. *Int J Chron Obstruct Pulmon Dis* 2006; 1(4): 381–400.
¹² Elliott MW, Mulvey DA, Moxham J, Green M, Branthwaite MA. Inspiratory muscle effort during nasal intermittent positive pressure ventilation in patients with chronic obstructive airways disease. *Anaesthesia* 1993;48: 8–13.
¹³ Nava S, Bruschi C, Fracchia C, Braschi A, Rubini F. Patient-ventilator interaction and inspiratory effort during pressure support ventilation in patients with different pathologies. *Eur Respir J* 1997;10: 177–183.
¹⁴ Appendini L, Patessio A, Zanaboni S, et al. Physiologic effects of positive end-expiratory pressure and mask pressure support during exacerbations of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1994;149: 1069–1076.

peak flow than at the end of expiration during the relevant phase for blood dynamics. It could be shown that blood dynamics could even be improved with a flatter expiration slope.¹⁸ The study was conducted with the homecare ventilator prisma VENT, in which the expiratory slope can be set manually at four different levels. As a secondary measure, PEEP can be increased manually if, despite a flat expiratory slope, the lungs cannot be ventilated sufficiently. Figure 2 shows the flow curves of a patient with EFL. At the moment the switch is made from a steep expiratory slope (prisma VENT, Level 1) to a flat slope (Level 4), there is an immediate improvement in the expiratory flow curve. When the expiratory slope is set too flat, the duration of the of EPAP pressure application could be severely shortened, depending on the I:E ratio and expiration time. The settings could result in an elevated external PEEP. As a countermeasure, a new firmware version for prisma VENT offers the "max" level for the expiratory slope which automatically adjusts the slope so that EPAP is reached after 50% of the expiration time. The setting maximizes

the time available for pressure reduction to hold open the lower airways and thus decrease EFL, ventilate the lungs and reduce hyperinflation. Figure 3 shows the setting option "max" for the expiratory pressure ramp.

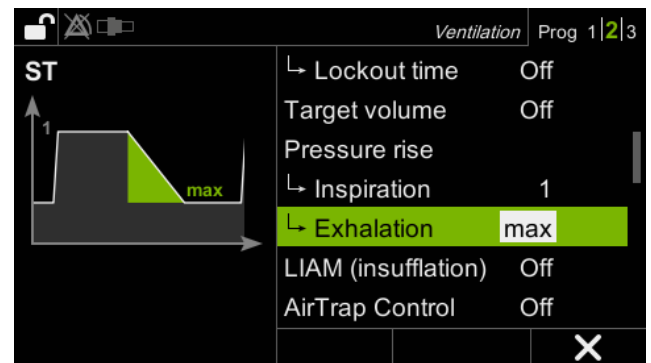


Figure 3: Setting option for expiratory pressure ramp to level "max" in prisma VENT

In any case, ventilating patients with expiratory flow limitations poses a special challenge. It is up to the treating physician to select the most effective therapy options available in modern ventilators which are capable of improving hypercapnia, dyspnea and patient adherence and tailor the treatment to meet each patient's particular needs.

¹⁵ Ranieri VM, Giuliani R, Cinnella G, et al. Physiologic effects of positive end-expiratory pressure in patients with chronic obstructive pulmonary disease during acute ventilatory failure and controlled mechanical ventilation. *Am Rev Respir Dis* 1993;147: 5–13.

¹⁶ Baigorri F, de Monte A, Blanch L, et al. Hemodynamic responses to external counterbalancing of auto-positive end-expiratory pressure in mechanically ventilated patients with chronic obstructive pulmonary disease. *Crit Care Med* 1994;22: 1782–1791.

¹⁷ Ambrosino N, Nava S, Torbicki A, et al. Haemodynamic effects of pressure support and PEEP ventilation by nasal route in patients with stable chronic obstructive pulmonary disease. *Thorax* 1993;48: 523–528.

¹⁸ Bouchra Lamia, Olivier Pasquier, Sandrine Pontier, Arnaud Prigent, Claudio Rabec, Jesus Gonzalez-Bermejo, Expiratory slope variations induce physiological changes in stroke volume during non invasive ventilation in hyperinflated COPD patients. (abstract only) *European Respiratory Journal* 2018 52: PA1678.

Samoa

Smart. Simple. Small.

Polygraphy of the future.

After the resoundingly successful launch of Scala last summer, the next development from our Diagnostics area awaits its unveiling. Intended for standardized use in the diagnostic and therapeutic area, the polygraphy device Samoa boasts the advantages of being smart, simple & small.

Smart

The integrated Bluetooth interface allows wireless data transmission to the newest generation of sleep therapy devices from Löwenstein Medical. Both device platforms – polygraphy and therapy – wirelessly exchange information about patient treatment. As soon as the devices are physically close to each other and set to recording or treatment mode, they connect via Bluetooth. When used in the patient's home, they connect in offline mode. The signals required for therapy monitoring and settings, such as flow, pressure, leakage and tidal volume are transmitted from the therapy device to Samoa. Later these data are time-synchronized with other polygraphic parameters such as respiration, SpO₂, pulse and position, read from Samoa and then displayed on a computer.

The advantage for the patient is that no T-Adapter is needed to record pressure and flow. For the medical user, the main advantage is being able to see all the therapy parameters together with the polygraph data. As a rule, it is not possible to obtain important information, such as the leakage signal, by means of a T-Adapter. The Samoa supply schedule is rounded off with a removable battery and the option of using the integrated connection for a thermistor to record air flow.



Simple

The use of Samoa is self-explanatory, thanks to the integrated color display and intuitive plug-in and connection options. After the sensors have been applied to the patient, the signal quality of the measurement parameters can be checked on the display and improved if necessary. Status information on battery capacity, the ongoing recording and the device can be called up on the display. A recording can be programmed in advance with an automatic start or can be started manually by pressing a key on the device.

Small

With its small dimensions and comparably low weight, Samoa offers patients greater wearing comfort. The patient hardly feels the device at all throughout the nighttime recording. A stable cloth bag is available for transport of the little device.



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Löwenstein Anniversaries

CONGRATULATIONS

Löwenstein Medical congratulates employees who are celebrating job anniversaries and thanks them for their engagement and loyalty through the years: Bernward Palenta, Gregor Czerwinski and Bernd Brand for **30 years** of service; Sven Schäfer and Barbara Kohr for **25 years**; and Daniel

Ozekker, Robert Schützen-dorf, Patrick Stahlhofen, Oliver Koch, Barbara Strelow, Rüdiger Best, Heike Kaiser, Doris Kunz, Jürgen Reppert, Alexander Schulte, Bianca Größer, Henrik Heine and Wiebke Debus for **20 years**. We look forward to continued close cooperation.



Corporate Benefits

OUR OFFER TO EMPLOYEES AT LÖWENSTEIN MEDICAL
Effective immediately, we offer our employees special advantages in the form of discounts from top suppliers. On a convenient platform, employees can find products and services at attractive conditions. We wish all Löwensteiners lots of fun!



USA

LUISA GOES TO THE USA
We continue working on internationalization. In 2021 we look forward to entering the USA market with our new ventilator LUISA in partnership with Biophysics Corporation. It's the kick-off into an important and promising market for Löwenstein.



Fantastic Order

LÖWENSTEIN DEVICES ARE GOING TO VIETNAM
Years of cooperation with our partner TNT Trading have led to the largest single order for intensive care ventilators in the history of Löwenstein in Asia. The major order from the Vietnamese Ministry of Health supports hospitals in the fight against COVID-19 and smoothes the way for us to a strategic partnership.



With people in mind

