

Inspiration

Löwenstein Medical Magazine.

Fall 2023 Edition

JULIA

Sweet dreams.

An inspiring family.

Living with spinal
muscular atrophy.

Neonatology.

Innovations for a good
start in life.



LEONI 4

Simply the best.
From day one.

LÖWENSTEIN
medical

At a glance.

Topics and innovations. People and stories.



Our topics.

Löwenstein pursues a holistic approach to patient care. From diagnostics through the patient's hospital stay to support for optimal homecare, our services and our products are there for you. The Löwenstein colors show you how we are organized. Dark blue stands for the company. Green for hospitals. Magenta for homecare. Light blue for diagnostics. We hope you enjoy reading about all these topics in this new edition of our magazine.

HOMECARE

- 6** JULIA. Sweet dreams.
- 10** Digital pathways for CPAP/APAP treatment.
- 14** Smart therapy networks.
- 16** An inspiring family.
- 20** News from the world of science.

HOSPITAL

- 24 LEONI 4 - Simply the best. From day one.
- 28 A passion for medical device development.
- 32 Preterm birth - a global problem.
- 38 Ventilation in neonates.
- 40 Individualized respiratory gas conditioning.
- 44 LM Flo₂

16 Everyday experiences.



6 The new JULIA.



COMPANY

- 46 Training with purpose at Löwenstein Medical.
- 50 Löwenstein Medical France.
- 52 Pleasingly high demand for classroom training.
- 54 Have you heard?
- 58 Publication details

28 Product development.



24 LEONI 4





Foreword



Dear Readers,

Finally, we can once again fully focus on innovation. Gone are the days of worrying about crippling bottlenecks in critical supply chains and global shortages. The past three years were ruled by an unceasing reaction mode, dynamics, little planning certainty, continuous surprises and frequent delays. This era has left its mark on us like very few others before it. We were forced to do a total rethink. Many things that once ran smoothly suddenly stopped working. The world is now a very different place and it is only fitting that we have changed and adapted. Consequently, we have gained many new markets, customers and colleagues. That's good news even though the changes bring challenges.

We manage change and master challenges as we develop. Through it all, we remain stable and reliable. As a mid-sized family-run business, we always think long-term, and show our customers, employees and partners that they can depend on us. That distinguishes our company from the world around us today. At Löwenstein, there is no sudden change of heart, no ad-hoc strategic realignment through new management, no unpredictable shifts in our priorities. At all times we strive to be fast, flexible and pragmatic. As we head toward a distant beacon, we need to rethink, adjust our course quickly and set our sails to take advantage of prevailing winds.

We are pleased to have the chance with this magazine to introduce our innovative products to be launched soon. In these pages we also report on our continuous development as a manufacturer, service provider and multi-talented organization.

In this edition, the focus is on digitalization and sustainability, two topics that have become as important as our core products and services. We underscore our reliability in the profiles of some of the employees who put their hearts and souls into their work. Of course we also keep you up to date with the latest scientific findings in our fields.

I hope you enjoy reading this new edition.

Yours,
Benjamin Löwenstein

JULIA. Sweet dreams.

We know all about masks. For more than 25 years, we've succeeded at developing innovative masks, always with patients in mind. We're now rethinking masks as we focus on sustainability. JULIA is the proof. A small, barely noticeable mask with an unobstructed field of vision.

By Tanja Derlien, Senior Product Market Manager

With the new JULIA mask, we rethought a tried-and-tested approach. Many details will be familiar at first glance, yet feel surprisingly different. The fit, for instance. The mounting surface of the mask cushion is the same as with CARA, our globally best-selling nasal mask. With a design adapted to the overall small shape of JULIA, the mask cushion looks even smaller.

The exhalation system lives up to the Löwenstein standard with a quiet and diffuse flow. Based on the established design, exhaled air flows through the slits under the elbow toward the mask tube and disturbs neither patient nor bed partner.

Mask and glasses? No problem!

Besides its proven attributes, JULIA offers something new. The mask has an unobstructed field of vision with no forehead support. The patient can keep to a favored evening routine of reading a book or watching TV while wearing glasses and a mask. It's possible to doze off without any discomfort.

Innovative headgear.

A good mask fit during sleep is the key to therapy success. The headgear plays a major role, especially when the mask has no forehead support. Stability is provided by the headgear frame of flexible, ergonomic 3D plastic. With help from the stable frame, the headgear and mask slip on easily and never twist. The frame also gives the mask system the holding power it needs to stay in place in every sleep position – back, side or stomach – without leaving any marks behind.

**JULIA is sustainable
and entirely
"Made in Germany".
A mask for the future.**



At Löwenstein Medical, we are working on medical devices for the future.





*Whatever the sleeping position
– on the side, back or stomach –
JULIA stays securely in place and
leaves behind no pressure marks.*

Designing a sustainable future.

Sustainability has become a regular part of our daily lives. We devote our time to issues such as packaging waste, solar energy and climate protection. We ask how we can make our own contribution to a more secure future.

It's a question we also put to the Patient Interface Team at Löwenstein Medical. We think about masks every day. How can we combine these important issues to develop a more sustainable mask?

Everyone was eager to get started. We got into discussions about how our products could be "resource-friendly", "renewable", "recyclable". Once we'd come up with the topics, we got into the details.

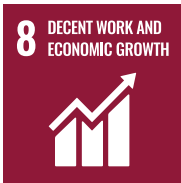
Conserving resources.

Mask production consumes electricity and water. But how much exactly? How can we conserve our resources and cut consumption? Many conversations with our suppliers revealed that sustainability was making inroads. Solar power was used in production, transport routes were shortened, packaging waste was prevented or reused. We turned our attention to the conventional production of dyed textiles, which uses vast amounts of water, electricity and chemicals.



Sustainable socially

Löwenstein is guided by these five United Nations Sustainable Development Goals.



We got to work on improving it. In the production of JULIA, we use a process that adds color pigments to the raw material before it's turned into yarn. It saves significant amounts of¹:

¹ Manufacturer's own figures



↓ -90%
Clean water



↓ -94%
Wastewater



↓ -66%
Energy consumption



↓ -70%
Chemicals

and responsible.

Use of renewable raw materials.

We start by reducing consumption and using renewable, i.e., sustainable raw materials. We imagine using only bioplastics for the mask some-day. Right now, that remains just a vision. Initial tests show that bioplastic material cannot meet the tough quality requirements that masks, which are classified as medical devices, are subject to. Even such setbacks help us make progress and give our suppliers additional knowledge they can put into improvements as we work together toward our shared goals.

One goal for packaging has been achieved. Eighty percent of the packaging for JULIA is made of sugar cane, a renewable raw material.

Recyclable.

During the project, we learned about “more circularity, fewer one-way streets.” In other words, generate as little waste as possible and keep raw materials for as long as possible in the circular economy. Each mask part should be made of a single material so it can be recycled separately. We designed JULIA for recycling. Each part can be fed into a specific channel in the recycling loop. Or rather, “could” be. Disposal laws differ among countries, so not every country allows medical devices to be put into the closed cycles.

Perhaps you now understand our interest in sustainability. We've put some of our ideas into practice while we continue to work on new ones that will take our masks into a sustainable future.

Our intensive care and neonatology ventilators help reduce mortality rates. Worldwide. We operate in crisis situations, supply devices where they are needed and donate medical technology in developing and emerging countries.

We use rainwater, purify wastewater and work with sanitary installations that save water.

We use green electricity and implement energy-saving measures. Motion sensors for lights, energy-saving lamps, and photovoltaics are just some examples.

Fairness and integrity are values enshrined in our code of conduct for employees and business partners.

We work together with our national and international subsidiaries on green tech in production, sustainable innovations and fair services.

Digitalization in CPAP/APAP treatment.

Telemedicine and apps to support patients: A contradiction or supplement to conventional care?

By Matthias Schwaibold, Chief Product Officer

Digitalization is an ever-present topic in our society. It is an unstoppable trend and like many innovations, offers opportunities. But it also poses risks. It can play an important role to support well-founded decision-making so that high-quality infrastructure and healthcare can be maintained despite the increasingly serious shortage of specialist staff. Indeed, digital pathways may even bolster aspects of sustainability. Yet, particularly in medical care, innovations are accepted haltingly, coming up against well-established structures, regulatory provisions and policies governing cost reimbursement.

What status has digitalization achieved in CPAP/APAP treatment? The devices keep up with technical progress and offer data transfer options such as cellular communication for telemonitoring by a Healthcare Provider (HCP). As a rule, the data channel is used to change device settings and comfort functions remotely. Studies have shown that telemedicine leads to increased CPAP usage and improves treatment outcomes. Furthermore, digitalization saves time and travel expenses and avoids CO₂ emissions.

Data alone cannot improve treatment. What matters is how the data are used in healthcare.

Some studies failed to demonstrate any benefits. In every case, the real-life implementation of a new method is critical. Simply sending data does not improve treatment. What happens with the data can. It's important to consider:

- which patients in which treatment phase receive support through telemedicine? **All of them? Those with initial difficulties? Those with specific comorbidities?**
- how the data are used to derive interventions. **Proactively based on specific thresholds? Reactively in response to reports of problems?**
- how telemedicine procedures are integrated into the healthcare process and combined with other components;
- which previous healthcare process the telemedicine is compared to. **A time-consuming, fairly costly one with a correspondingly good outcome or the opposite?**
- how reliable the technology is. Including data transmission and measurement of therapeutic efficacy by the CPAP devices, e.g., with validated detection of any remaining nocturnal respiratory events.



Another hard-to-answer question revolves around who assumes responsibility for remote care. In many healthcare systems, the CPAP provider is responsible for optimizing the device or mask, for example, and encouraging patient acceptance of the treatment. More HCPs use data transmission, despite additional costs, to improve their processes and services and thus increase their attractiveness.

As a rule, the physician makes the medical decisions.

The attending physician is not always on site to supervise CPAP therapy. The provider too needs access to the data and other patient information. In telemedicine, privacy and data security remain a challenge, but a solvable one. An even more serious barrier in many countries is the lack of reimbursement for incurred costs. Healthcare systems in which patients bear the cost of medical services can implement innovations faster. Even countries with reimbursement systems are introducing remuneration for telemedicine services or allowing existing reimbursable services to be provided over telemedicine channels.

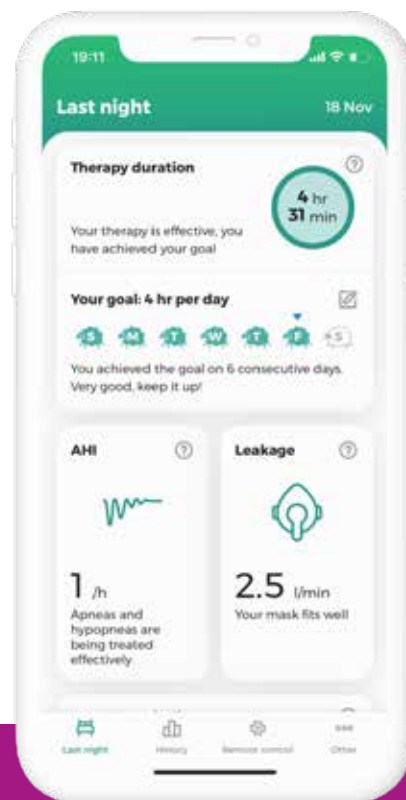
Digital tools offer an alternative.

Digital tools support the patient directly. Today they are available as apps for smartphones or tablets. The tools simplify device operation with touchscreen interfaces, e.g., allowing the patient to adjust the size of the display as needed. Digital features aim at increasing patient motivation for treatment and help to resolve simple questions – with no waiting times or the need to call on increasingly scarce qualified staff members. The prisma APP for the Löwenstein medical devices is a good example that lets us show how effective digitalization can be for improving adherence and treatment outcomes.

Are patient apps really competing with telemedicine? Are apps and telemedicine at odds with conventional care? Absolutely not! Rather, the smart combination of multiple components leads to modern, efficient CPAP care. A well-implemented patient app can help resolve simple questions and improve patient motivation for CPAP treatment. If assistance from the HCP or medical team is required, the app will say so and allow the patient to transmit data to the specialist. Then the time that specialists need will be used as effectively as possible.

Our recently published study demonstrates impressively the potential of the prisma APP for improving adherence to and efficacy of PAP treatment with no additional work for increasingly stretched specialist staff.

Christian Franke, Franziska Piezonna, Regina Schäfer, Alexander Grimm, Lisa-Marie Loris & Matthias Schwaibold (2023): Effect of a digital patient motivation and support tool on CPAP/APAP adherence and daytime sleepiness: a randomized controlled trial, <https://doi.org/10.1007/s41105-023-00479-9>



The smart combination of multiple components guarantees quick access to information, good decision-making criteria and ways to save time.

France is testing ground for digital pathways in CPAP treatment.

Reimbursement for the healthcare provider depends on the use of telemedicine. The patient’s treatment adherence with the support of telemedicine directly influences reimbursement. The data flows from the CPAP device to the device manufacturer’s cloud, typically to the HCP’s ERP software, which processes reimbursement settlements over a digital interface. Patient apps are being used to improve adherence

Early published criticism said that device settings did not get enough attention and that some patients still experienced many nocturnal respiratory events despite telemonitoring. Medical specialists and professional associations have been drafting recommendations with relevant intervention protocols. In some cases, the reimbursement rate for conventional house calls applies when physicians personally check on affected patients using telemedicine tools, i.e., video or telephone calls and digitally transmitted CPAP data.

Official data on the efficacy of the digitalized care system are not available.

Therefore, Löwenstein Medical conducted a survey among HCPs and physicians in France. In response to the question of whether telemedicine had improved therapy adherence, 32% of HCP staff and 25% of physicians said the improvement was significant and 42% HCP staff and 75% of physicians said the improvement was minor. Just over 47% of HCP staff and 75% of physicians saw a major improvement in outcomes. Mixed responses were received to the question about whether telemedicine had increased or reduced costs. Around 80% of those surveyed in both professional groups said they would like to retain telemedicine.

Digital solutions from Löwenstein Medical are in use throughout France.

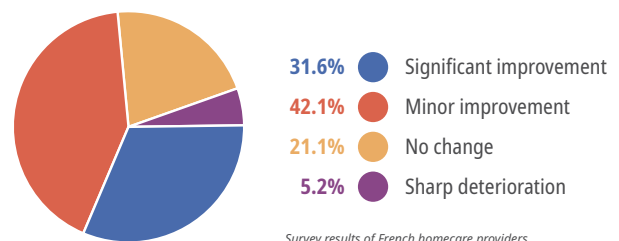
We learned a great deal from customer feedback from which other countries now can benefit. Our new generation of prisma devices includes telemedicine options for a mobile interface or Bluetooth™ interface. The devices are thus equipped for the future and ever-changing healthcare processes. With the telemedicine software prisma CLOUD, HCPs and medical specialists can provide care more flexibly in accordance with previously made service agreements. For example, data can be forwarded to ERP, practice or hospital software and combined with the other case data. The Bluetooth™ interface connects the devices with prisma APP, the digital assistant for patients. With the patient’s consent, the app communicates in the background with prisma CLOUD. The logo and contact address of the HCP or healthcare professional can be displayed optionally in the app.

Treatment data can be sent to the medical professional in prisma CLOUD via the prisma APP even in areas with no mobile reception. The prisma devices provide digital signal data to our Samoa, Scala, and Sonata diagnostic devices to make possible the best titration or treatment monitoring. Our prisma devices offer a vast array of options for modern CPAP care with digital components. Here we have purposely avoided specifying any one healthcare process via the technology. After all, many different routes lead to the goal. Depending on the healthcare system, available capacity and the reimbursement policy for services provided, users can select the appropriate options from our treatment portfolio for Sleep-Disordered Breathing. Elements of digitalization are expected to play an important role. In some countries they already do, but in others it may take several more years. We offer the necessary solutions and continuously develop them further.

i

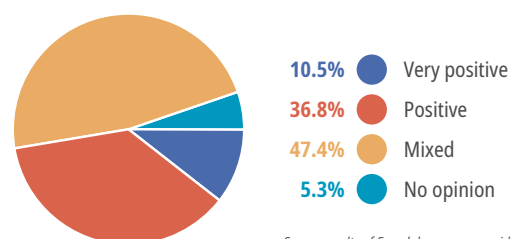
Interested in studies and guidelines on this topic? Contact Löwenstein directly.

How has patient compliance with treatment guidelines changed as a result of telemonitoring?



Survey results of French homecare providers

How do you rate patients’ satisfaction with telemonitoring?



Survey results of French homecare providers



Sleep well.

While you do, we worry about every bioparameter that can influence the quality of sleep. Small, smart, and easy to use – the sleep diagnostic devices from Löwenstein. All our technologies are compatible so that the best treatment can follow diagnosis.

Perfect interplay. Diagnosis and treatment.

Smart therapy networks.

Bluetooth® data exchange between polygraph and sleep therapy devices.

By Mats Schauerte, Junior Product Manager Homecare

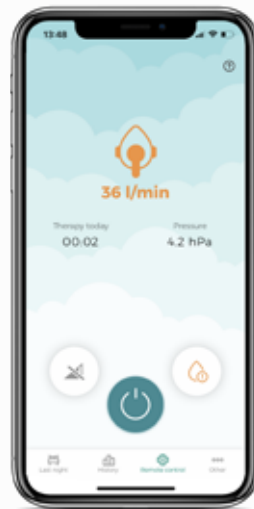
Wireless link for Löwenstein Medical sleep therapy and diagnostic products.

A recipe for success from Löwenstein? We offer the entire gamut of ventilation – from a single source. Driving this innovation is our constant entrepreneurial endeavor to effectively link the various product areas so that we can optimize user-friendly, efficient, and powerful diagnostic and therapeutic options.



The white sleep therapy devices in the prisma SOFT/SMART series with direct Bluetooth connection to the Samoa polygraphy system support simple, meaningful diagnostic and therapeutic monitoring options in the home environment. Both datasets are time-synchronized and can be viewed in the MiniScreenViewer (MSV) analysis software. Optional post-processing of data can save healthcare professionals valuable time and optimize data validity.

For patients, this eliminates long waiting times for appointments to undergo routine examinations. Instead, they can perform these routine tests in the comfort of their own home where they ultimately then also receive the therapy.



Add-ons for Löwenstein therapy support prisma APP.

Various studies have examined the options to improve patients' therapy adherence. Results show that individuals who actively engage with their therapy and can obtain information and support at any time are much more likely to adhere to what they are prescribed.

Further development of the prisma APP has incorporated the many new features outlined below:

- The integration of comprehensive FAQs on how to clean the device and accessories, options for PAP therapy and support for how to use the sleep therapy device.
- Support for better homecare provider contact options. Homecare providers now have the option of storing and personalizing contact details in the app. This makes it easier for patients to contact the HCP for support.
- Newly engineered to make it easier to view information on last night's therapy, the apnea-hypopnea index (AHI), the duration of use, and the deep sleep indicator. The sleep diary graphics for personal therapy support were redesigned.

Furthermore, the prisma APP can be linked directly via Bluetooth to the white devices in the prisma SOFT/SMART series. Comfort features can be changed and adjusted conveniently via the app. The prisma APP is available in the App Store and Google Play Store.



Want to find out more? Then read our white paper "Patient Self-Management in PAP Therapy."

An inspiring family.

At four weeks old, Fiorello Rizzuto was diagnosed with type I spinal muscular atrophy. The doctors gave him until his second birthday to live. Today, Fiorello Rizzuto is 15 years old, goes on holidays with his family and decides what they watch on television. A visit to a family that won't be beaten by a prognosis.

By Nadine Jaun and Bettina Recher, Marketing / Communication specialists at Löwenstein Switzerland

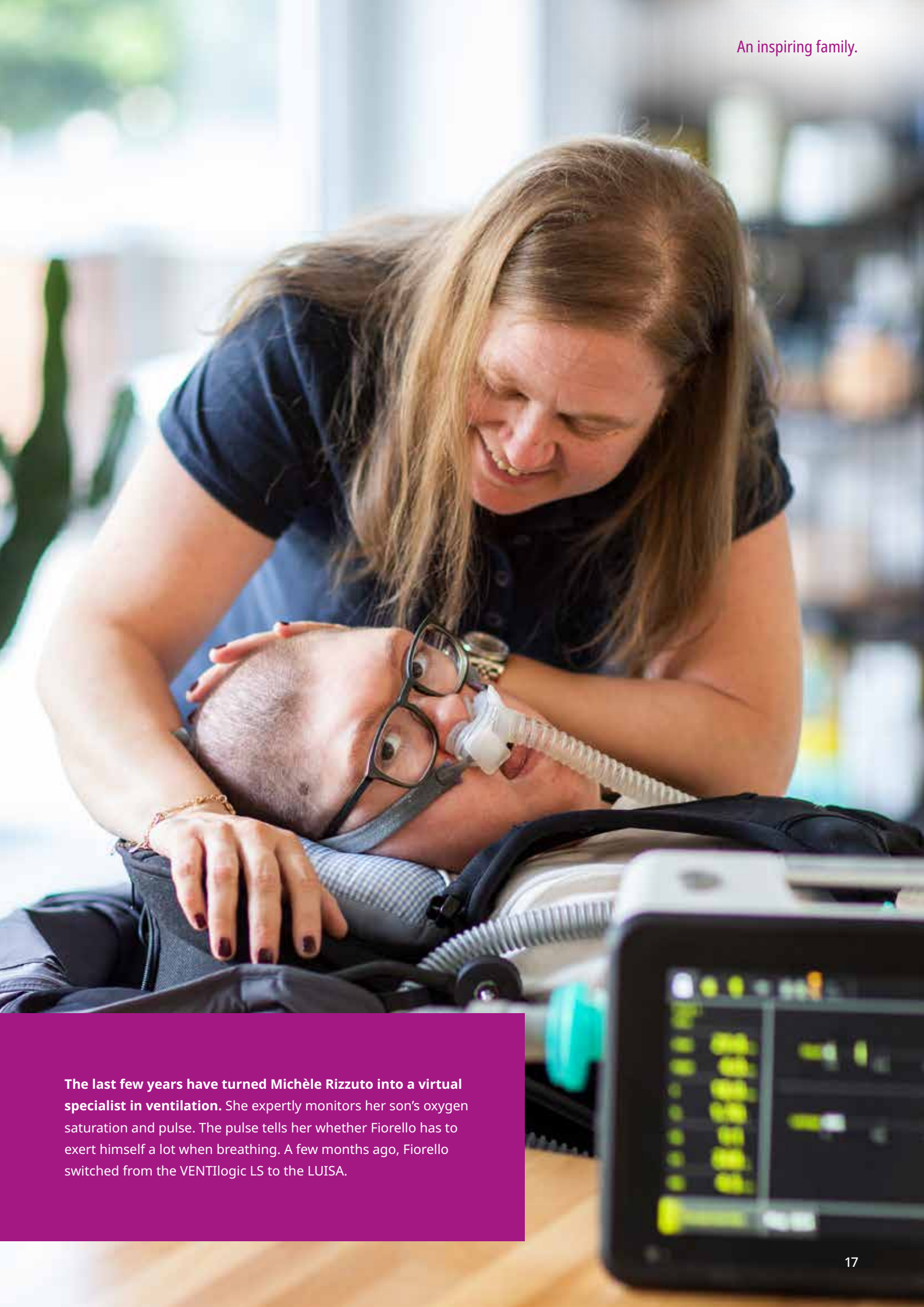
"Most people that visit us for the first time find the whole experience daunting," says Michèle Rizzuto at the start of our visit. With seeming effortlessness, she lifts her son out of the bed and into the wheelchair. Fiorello can barely move on his own. He's fed through a gastric tube. A LUISA ventilator takes care of his breathing. Only his eyes follow us closely throughout the entire conversation. Michèle Rizzuto is not daunted by everyday life or having to look after Fiorello. Quite the contrary. A sense of joy dominates the mood in the Rizzuto household.

The Rizzutos got the diagnosis Christmas Eve.

Fiorello was just four weeks old when the pediatrician performed one of the first checkups and found that Fiorello couldn't move his legs properly, recounts Michèle Rizzuto. On Christmas Eve, just a month later, he had his first respiratory arrest, face down on his mother's breast. "Go home, enjoy life," the doctors told her and her husband once they ascertained that Fiorello had type 1 spinal muscular atrophy (SMA). Fiorello will be lucky to reach his second birthday, was their prognosis. Type 1 SMA is, in fact, the most serious form of spinal muscular atrophy. It starts in early infancy and tends to cause death before the second year of life if untreated. SMA is a congenital, neurological disorder characterized by severe muscular weakness and atrophy. It is caused by the death of spinal cord neurons that control the muscles.

Giving up was never an option.

For Fiorello's parents, giving up was not an option they considered. "As long as Fiorello tolerates therapy and has no pain, we will do everything we can," says Michèle Rizzuto. Michèle and her husband looked into the subject of ventilation. At eight months, Fiorello was ventilated overnight for the first time. Thanks to untiring research, trying out various devices, and through a variety of connections, the Rizzuto family found its way to Löwenstein Medical Switzerland. "For me, it was clear from the outset that we were going to do everything to help this family," explains Erich Reithaar, Managing Director of the Swiss subsidiary. And now, that's where Fiorello gets ventilators, accessories and consumables. Their cooperation has been straightforward, approachable, and wonderfully friendly, says Michèle Rizzuto, "Before I had around 15 different suppliers, that number has meanwhile dropped substantially."



The last few years have turned Michèle Rizzuto into a virtual specialist in ventilation. She expertly monitors her son's oxygen saturation and pulse. The pulse tells her whether Fiorello has to exert himself a lot when breathing. A few months ago, Fiorello switched from the VENTIlologic LS to the LUISA.



Michèle Rizzuto is always there for her son. Is there something she'd wish for? Of course. It would be nice if other people approached Fiorello so openly and without fear.



The better batteries make life easier and we can go on trips up the mountain.

Michèle Rizzuto is impressed: “The runtime of the external batteries is simply great. That makes things a lot easier for us.” The better the batteries, the easier it is for us to plan the time when we don’t have access to a power socket, whether that’s going shopping or up on the Jungfrauoch, the Top of Europe. The family tries whatever they can to get Fiorello out of bed, the house, and into the outdoors to experience life. The family’s vehicle, a small van, was converted to accommodate a wheelchair. That way we can also go on holiday easily. “There’s nothing stopping us,” says Michèle Rizzuto. The next project involves fitting out the vehicle with roof-mounted solar panels to ensure an uninterrupted power supply for the ventilators and more independence.

What she’d also like to see is for people to approach Fiorello more openly. Many people tend to have major inhibitions, even avoid Fiorello altogether – it’s almost impossible for him to have contact with children of his own age. For that reason, “Brazil”, a service dog, recently joined the family. The black Labrador greets us with a friendly welcome as we arrive and doesn’t leave Fiorello’s side throughout the entire conversation.

This year Fiorello will turn 15 despite all the medical prognoses.

He receives regular home schooling and communicates with his environment via a computer that he controls with his eyes. But his mother understands him even without the technical aids – for instance what TV programs should be on in the evening. “Die Beatrice Egli-Show”, for instance, has become a must recently, Michèle Rizzuto explains laughing, “We found it boring, but he liked it.” It’s these small, beautiful everyday moments that she wouldn’t really appreciate, she says, without Fiorello. Thanks to him she’s become aware of what it means to live for the moment, to enjoy the moment.

“He’s the best thing that could have happened to us.”

News from the world of science.

In the following, we have compiled a selection of new publications on the topics of ventilation, respiratory therapy and diagnostics.

We'd be happy to receive your feedback on this selection or send us your own personal highlights from the literature.

By [Matthias Schwaibold, Chief Product Officer Homecare](#)

Telemedicine in sleep breathing therapy.

A recent study investigated the **reliability of our prismaLine devices** in determining the **residual apnea-hypopnea index (AHI)** under therapy. To this end, 50 patients were titrated manually under polysomnographic monitoring. The CPAP pressure was deliberately increased slowly to trigger phases with elevated residual AHI and also with good therapeutic efficacy. Respiratory events were scored according to AASM guidelines hypopnea criteria 1A and 1B. On average, the device AHI ranged between these two reference AHIs determined by polysomnography. The correlation coefficients for overall AHI and its obstructive elements between device and reference score were very high, as confirmed by Bland-Altman plots and ROC analyses. Central respiratory events occurred very rarely during treatment. Overall, the authors confirmed the high reliability of residual AHI determined by **prismaLine** devices to provide relevant data for both conventional and telemedicine care pathways.

Richter, M.; Schroeder, M.; Domanski, U.; Schwaibold, M.; Nilius, G. (2022): Reliability of respiratory event detection with continuous positive airway pressure in moderate to severe obstructive sleep apnea — comparison of polysomnography with a device-based analysis. In: Sleep and Breathing. DOI: 10.1007/s11325-022-02740-w.

Efficient pathways to successful therapy.

A **review article** describes the **therapy algorithms used by leading sleep therapy device manufacturers**. It also provides practical tips on the selection and optimization of the comfort settings.. These descriptions of different device technologies aim to improve user understanding and thus ensure more efficient and more effective pathways to successful therapy. The review examines numerous modes, including adaptive servoventilation and the associated settings and automatic functions.

Johnson, K. G. (2022): APAP, BPAP, CPAP and New Modes of Positive Airway Pressure Therapy. In: Advances in experimental medicine and biology 1384, p. 297–330. DOI: 10.1007/978-3-031-06413-5_18.

Daytime sleepiness with CPAP therapy.

Several working groups are once again looking at the issue of **residual daytime sleepiness with CPAP therapy**.

Two papers examine predictors and confirm the trend of the work quoted in our last edition. **Risk factors** for persistent daytime sleepiness include in particular a raised BMI, old age, lower adherence to the CPAP therapy, specific comorbidities such as PLM or cardiovascular disease and poor sleep hygiene. The level of residual AHI with CPAP appears to play a minor role.

Li, Z.; Cai, S.; Wang, J.; Chen, R. (2022): Predictors of the Efficacy for Daytime Sleepiness in Patients With Obstructive Sleep Apnea With Continual Positive Airway Pressure Therapy. A Meta-Analysis of Randomized Controlled Trials. In: Frontiers in Neurology 13, S. 911996. DOI: 10.3389/fneur.2022.911996.

Yassen, Ashraf; Coboeken, Katrin; Bailly, Sébastien; Burghaus, Rolf; Bušková, Jitka; Dogas, Zoran et al. (2022): Baseline clusters and the response to positive airway pressure treatment in obstructive sleep apnoea patients. Longitudinal data from the European Sleep Apnea Database cohort. In: ERJ open research 8, p. 132–2022. DOI: 10.1183/23120541.00132-2022.

Current study in cooperation with Löwenstein.

As yet unpublished data from a clinical study in collaboration with the Löwenstein Group show in the case of parameters that can be measured with CPAP devices that adherence is most relevant to residual daytime sleepiness, followed by the estimated **duration of deep sleep** and well behind residual AHI.

A European working group has summarized the knowledge on this issue and recommends **an algorithm for interventions** with raised persistent daytime sleepiness: initially, an increase of the PAP adherence and efficacy if this is still low; next, clarification of the comorbidities such as PLM or depression; followed by an assessment of the influence of existing medication, optimization of sleep hygiene and as a last step, targeted medication.

Craig, S. E.; Pépin, J. L.; Randerath, W. J.; Caussé, C.; Verbraecken, J.; Asin, J. et al. (2022): Investigation and management of residual sleepiness in CPAP-treated patients with obstructive sleep apnoea. The European view. In: European Respiratory Review 31. DOI: 10.1183/16000617.0230-2021.



Ventilation.

A few interesting articles look at the issue of **long-term ventilation of COPD patients**.

A paper from Germany shows that even with ventilation at higher pressures, the **sleep quality** of persons affected does not deteriorate, but **improves** slightly, especially among patients with coprevalent obstructive sleep apnea. **Daytime sleepiness, blood gases and health-related quality of life also improved** after three months as expected.

Wollsching-Strobel, M.; Bauer, I.; Baur, J. J.; Majorski, D. S.; Magnet, F. S.; Storre, J. H. et al. (2022): The Impact of Non-Invasive Ventilation on Sleep Quality in COPD Patients. In: Journal of clinical medicine 11, p. 5483. DOI: 10.3390/jcm11185483.

Still another study suggests that a reduction in the health-related quality of life, among ventilated patients as measured by the **SRI questionnaire**, is associated with a **raised risk of mortality**.

Ribeiro, C.; Jácome, C.; Castro, L.; C., Sara; Windisch, W.; Nunes, R. M. L. (2022): Long-term health-related quality of life in patients on home mechanical ventilation. In: BMC pulmonary medicine 22, p. 433. DOI: 10.1186/s12890-022-02236-z.

HEMECARE

For the **initiation and control of long-term ventilation of COPD patients**, a German research group proposed a **standardized, multilevel process**. The therapy parameters are optimized based on subjective information from the patient, daytime blood gas analyses and nocturnal ventilation based on a defined algorithm.

Cornelissen, Christian Gabriel; Winter, Stefan; Keuchel, Daniel; Spicher, Nicolai; Boeckmann, Britta; Stephan, Christian et al. (2022): Toward a digital decision- and workflow-support system for initiation and control of long-term non-invasive ventilation in stable hypercapnic COPD patients. In: *Therapeutic Advances in Chronic Disease* 13, p. 1–5. DOI: 10.1177/https://doi.org/10.1177/20406223221099338.

New findings on long-term ventilation in patients with neuromuscular disorders.

A retrospective cohort study on over 450 patients confirms that **ALS patients survive longer with non-invasive ventilation**: ventilation time ≥ 4 hours per day proves to be better than low therapy time.

Akrivo J., Hsu J., Hansen-Flaschen J., Elman L., Kawut S. (2021): Noninvasive Ventilation Use Is Associated with Better Survival in Amyotrophic Lateral Sclerosis. In: *AnnalsATS* 18 (3), p. 486–494. DOI: 10.1513/AnnalsATS.202002-169OC.

NIV initiation in ALS patients.

To investigate the best possible procedure for **timing and the approach to NIV initiation in ALS patients**, an expert panel compiled and published evidence-based recommendations. The panel updated criteria for initiating NIV, proposed a strategy to optimize NIV parameters for ventilation outcomes, interface selection and secretion management.

Georges, M.; Perez, T.; Rabec, C.; Jacquin, L.; Finet-Monnier, A.; Ramos, C. et al. (2022): Proposals from a French expert panel for respiratory care in ALS patients. In: *Respiratory Medicine and Research* 81, p. 100901. DOI: 10.1016/j.resmer.2022.100901.

Decision aids for mouthpiece selection.

A narrative review gives **recommendations on the procedure for mouthpiece ventilation**. The setting options of devices from leading manufacturers and various available mouthpieces are compared. A decision tree for the procedure during adjustment is presented and explained.

Toussaint, M.; Chatwin, M.; Gonçalves, M. R.; Gonzalez-Bermejo, J.; Benditt, J. O.; McKim, D. A. et al. (2021): Mouthpiece ventilation in neuromuscular disorders. Narrative review of technical issues important for clinical success. In: *Respiratory medicine* 180, S. 106373.

Device evaluation of home ventilation.

A **bench evaluation** compares the response of **home ventilation devices with auto-EPAP and target volume functions** to apneas and hypopneas and how they detect events. None of the devices fulfilled the authors' expectations for all criteria. prisma VENT achieved a very good overall result. The lack of an EPAP increase after simulated obstructive hypopnea can be explained by the sufficient therapy of simulated events through target tidal volume control.

Delorme, M.; Leroux, K.; Léotard, A.; Boussaid, G.; Prigent, H.; Louis, B.; Lofaso, F. (2022): Noninvasive Ventilation Automated Technologies. A Bench Evaluation of Device Responses to Sleep-Related Respiratory Events. In: *Respir Care* 68 (1). DOI: 10.4187/respcare.09807.

Study on ventilation cites influencing factors.

A study on ventilated patients showed how **apneas, hypoapneas, phases with hypoxemia or hypoventilation and patient-ventilator asynchrony negatively influence outcomes in long-term ventilation**.

Kleiven, A. L.; Markussen, H.; Skjønsberg, O. H.; Janssens, J.-P.; Aarrestad, S. (2022): Effect of Respiratory Events on Health-Related Quality of Life in Patients Treated with Long-Term Noninvasive Ventilation. In: *Respiration* 101, p. 1099–1109.

Monitoring ventilation efficacy.

To summarize current knowledge, an international group of experts compiled **recommendations on procedures for monitoring ventilation efficacy**. They recommended increasing adherence, monitoring mask leakage and using nocturnal pulse oximetry and capnography. In addition, ventilator and poly(somno)graphy data should be analyzed in case of doubt.

Janssens, J.-P.; Cantero, C.; Pasquina, P.; Georges, M.; Rabec, C. (2022): Monitoring Long Term Noninvasive Ventilation. Benefits, Caveats and Perspectives. In: *Frontiers in Medicine* 9, Article 874523. DOI: 10.3389/fmed.2022.874523.



Adaptive support ventilation (ASV) therapy.

A study of ASV patients showed that despite an increase in average pCO₂ compared to per day **in a few cases, hypocapnia** occurs during therapy or is at least not eliminated. This confirms the recommendation of measuring blood gas-/acid-base balance on ASV therapy. Changing the parameters of the ventilators reduced or eliminated hypocapnia in most cases.

Barleben, A.; Allrich, M.; Grüning, W. (2022): [Is ASV therapy a positive airway pressure or ventilation therapy? A comparison of acid-base balance per day and under ASV]. In: Pneumologie 76 (09), p. 606–613.

An analysis of the data from the **SERVE-HF study** revealed that with ASV therapy there was **no increase in ventricular ectopy or tachyarrhythmia** in patients with heart failure and LVrEF or with predominantly central sleep apnea. The suspicion of an increased risk has therefore not been substantiated.

Fisser, C.; Gall, L.; Bureck, J.; Vaas, V.; Priefert, J.; Fredersdorf, S. et al. (2022): Effects of Adaptive Servo-Ventilation on Nocturnal Ventricular Arrhythmia in Heart Failure Patients With Reduced Ejection Fraction and Central Sleep Apnea—An Analysis From the SERVE-HF Major Substudy. In: Frontiers in Cardiovascular Medicine 9. DOI: 10.3389/fcvm.2022.896917.

Acoustic respiratory monitoring.

An observational study showed the feasibility of acoustic monitoring of nocturnal lung sounds with LEOsound in patients **during and after an Acute Exacerbation of COPD (AECOPD)**. Specifically, the symptoms of wheezing and coughing that occurred frequently in this small patient cohort were monitored with high quality. The frequency across the selected time points during and after the AECOPD varied from patient to patient. This points to the potential of

this method for differentiating between individual pathophysiological mechanisms in AECOPD and personalizing the therapeutic strategy in subsequent steps.

Boeselt, T.; Kroenig, J.; Lueders, T.-S.; Koehler, N.; Beutel, B.; Hildebrandt, O. et al. (2022): Acoustic Monitoring of Night-Time Respiratory Symptoms in 14 Patients with Exacerbated COPD Over a 3-Week Period. In: Int J Chron Obstruct Pulmon Dis 17, p. 2977–2986. DOI: 10.2147/COPD.S377069.

Keep up-to-date with our tips, studies, and articles on key ventilation topics.





LEONI 4 – Simply the best. From day one.

For over 30 years, Löwenstein Medical has been dedicated to preterm neonatal care.

By Marco Meeß, Global Product Manager Neonatology

As early as 1947, the company Heinen GmbH was already a renowned specialist in pediatrics and neonatology. It pioneered clinical care with incubators, heated beds, ventilators, and SIDS monitors for home use. Since the beginnings of Heinen + Löwenstein in 1986, the Löwenstein Medical division has been developing, marketing, and providing technical support for specialized neonatal equipment. This commitment spans the fields of thermal therapy with heat lamps, heated beds and incubators, patient monitoring in both hospital and homecare settings. Phototherapy systems to manage neonatal jaundice and highly specialized ventilation to treat immature lungs in preterm babies are part of a broad product range.

This is where our roots lie. We are committed to contributing to the care of these tenacious little fighters. Our aim is to conduct research, develop and deliver increasingly precise, customized ventilation and give the tiniest members of society the best possible start in life.

Designed, developed, and manufactured at our company headquarters in Bad Ems.

In 2003, our R&D department in Bad Ems embarked on the pioneering development of neonatal intensive care ventilators that became the LEONI family of products. Since 2007, these specialized products have been used in hospitals around the world.

With several thousand devices in over 80 countries, LEONI ventilators are considered among the best, most-established devices for specialized ventilation of preterm babies and

neonates. The “Made in Germany” seal of quality is a national and international guarantee of innovation and excellence, held in high esteem by our customers and partners worldwide.

LEONI 4 continues the tradition.

International research groups, consisting of leading development engineers, hospital staff and users, defined the requirements for this innovative ventilator. Decades of experience in innovation, coupled with pioneering technology, went into creating LEONI 4, the new premium class in neonatal ventilation.

LEONI 4 is expected to set new standards in user-friendliness with its excellent configurability and innovative operating concept, while significantly increasing operating safety.

Current key aspects such as hygiene, sustainability, ergonomics and communication will be implemented alongside functionality and high-performance ventilation. Particular emphasis is placed on comfort and safety.

Here are just a few features worth mentioning. Invasive and non-invasive high-frequency ventilation based on the double-diaphragm principle with active inspiration and exhalation improve CO₂ elimination. In addition, the oxygen supply supports lung-protective ventilation, even during spontaneous breathing.



Screensaver for the important and peaceful parent-child time



The system's unique architecture focuses on smart and intuitive operation, thereby substantially reducing acoustic and visual stimuli during parent-child interactions. Users, caregivers and the tiniest patients all benefit from a safe, calm and comfortable ventilation environment.

The improved system architecture of the LEONI 4 allows nearly silent operation, particularly at high amplitudes and rates during high-frequency oscillatory ventilation (HFOV).

Pre-launch event GNPI 2023 in Germany.

At the 49th Annual Congress of the Society of Neonatology and Pediatric Intensive Care (GNPI), LEONI 4 was unveiled to the public for the first time in the pre-launch.

Numerous visitors attended the unveiling ceremony at the Löwenstein Medical booth. The pre-launch was accompanied by an exclusive customer event with specialist presentations on the Elbe river and at the Löwenstein Medical Symposium

as part of the scientific Congress program. Over the next few days, our employees held a continuous round of conversations with numerous interested Congress attendees. The pre-launch proved a fantastic start for LEONI 4.

International debut of LEONI 4 at the ESPNIC Congress Athens 2023.

Shortly after the pre-launch event in Germany, LEONI 4 celebrated its international debut at the Annual Congress of the European Society of Paediatric and Neonatal Intensive Care. Here too, the new product generated lots of interest and the customer feedback was overwhelming.

In September, LEONI 4 was exhibited in Dublin at the INAC International Neonatology Association Conference.

Since then there have been some individual customer visits and training courses with all international branches and specialist dealers.

Market launch in Germany.

A controlled market launch is being prepared and gradually rolled out in Germany. Finally, the LEONI 4 registration will be completed before we can start registrations in non-CE mark countries outside Europe.

International marketing campaign.

An internationally focused marketing campaign accompanies the product launch of LEONI 4. The multilingual campaign includes communications activities for target groups. An image film, a teaser video, a landing page, product brochure, product calling card, rollup, and social media posts are some of the exciting contents.

Our image film for the LEONI 4 campaign

Worth taking a look at!



A passion for medical device development.

“Here, people are passionate about their work.” This is the answer Steffen Pattai, Head of the R&D department at Löwenstein Medical in Bad Ems, gave when asked what makes employees in his department contribute more than highly specialized, in-depth technical knowledge to their jobs.

By [Martina Ecke, Marketing Manager](#)



Löwenstein Medical
Bad Ems

Development work is teamwork.

Developers at Löwenstein Medical in Bad Ems work in small teams together on a single project. The team members take on different tasks that match their particular technical expertise. A development team is what you could think of as an island on which various experts work together intensively on a joint project over an extended period.

Independence and good humor.

Unlike at large enterprises, each employee at Löwenstein has the chance right from the start to assume a great deal of personal responsibility and to work independently. The upshot is a dynamic work culture, a good atmosphere, creativity, balance, and job satisfaction.

“The team in the R&D department is interested intensively in this issue. The high level of interest doesn’t stop when you’ve got a full daily workload,” says Britta Smoes, project and team manager.

And adds: “Development work sometimes stretches over several years. From the outside it is very difficult to comprehend the close intermeshing of subject experts and the complicated interplay within the team. It is difficult to explain the work in facts and figures. You can’t predict what results a development department will produce. Here every day is different,” Britta says. What is remarkable is that the very important and necessary teamwork was maintained during the COVID pandemic. What helped was that each team could do its work self-sufficiently and independently of other teams.

The young creative team accompanies highly complex medical technology products.

There is – for this sector – a balanced ratio of men and women. The expert teams accompany highly complex medical technology products, starting with the idea, the concept, through to market maturity.

Work also needs to be completed in the ongoing product life cycle. This can include product updates, software modifications, adaptation of new functions, implementation of customer requirements, and much more besides. In the department the key areas of “scientific work,” “research”, and “supporting subsidized projects” are also a top priority.





The LEONI 4 development team



Head of
R&D

Steffen Pattai

We'd like to know who you are! Could you briefly introduce yourself?

Hi, I'm Steffen Pattai. I live in Koblenz and have been working at Löwenstein Medical for the past eight years.

What is your current position at Löwenstein Medical?

I manage Research & Development at Löwenstein Medical in Bad Ems.

What does your resume look like?

After graduating as an engineer in Medical Technology, I started work in a research center in Bonn. I then set up a small company with three colleagues, which we later sold to a major manufacturer in the Netherlands. At the time, I was mainly involved in imaging, signal processing, electron optics, and software development. In addition, there were always lots of those little additional tasks you tend to find in a small company (IP, audits, sales, stakeholder management, exhibitions, production, etc.). Then, I focused on knowledge transfer and handover issues for a while. After that, I joined Löwenstein.

Was there one experience, one special moment in your professional career at Löwenstein Medical that you look back on fondly?

Yes, of course. More than anything else, it's the feeling that I had (and still have) in many situations of being able to leverage the power of a multinational company with the simplicity and speed of a start-up.

What would you like to give applicants and interested parties on their (professional) way?

If you relish the personal responsibility of working independently and creatively, then Löwenstein Medical is the place for you. I've come across very few other companies where you can have such an impact.

Many thanks!



Project manager

Britta Smoes

We'd like to know who you are! Could you briefly introduce yourself?

Britta Smoes, 32 years old. I grew up on a farm on the Dutch border. In my free time, I love to be outdoors, to make music, or paint with acrylics. I'm more of an introvert that just enjoys helping people in the background.

What is your current position at Löwenstein Medical?

Project manager for LEONI 4

What does your resume look like?

After graduating from high school in 2010, I studied Biomedical Engineering at Münster University of Applied Sciences where I earned a bachelor's and a master's degree. I wrote my bachelor thesis on computed tomography at what is now Siemens Healthineers in Forchheim, Germany back in 2013. To write my Master's thesis in a work-study program, I applied to Löwenstein Medical in 2015 where I completed my degree. They took me on after I earned my master's degree in 2016. After two years on the LEONI plus team, I was given the opportunity to set up my own team and lead my own project, which I still do to this day.

Was there one experience, one special moment in your professional career at Löwenstein Medical that you look back on fondly?

To have had the opportunity to lead my own project and team even though I had fairly little professional experience. Basically, the opportunity to bring your own ideas to the table and to shape the system with the team is what stands out for me.

What would you like to give applicants and interested parties on their (professional) way?

Even if the challenge is huge, don't let it prevent you from accepting it. You really learn a great deal simply by doing. Believe in yourself :)

Many thanks!



Software developer

Andreas Schwarz

We'd like to know who you are! Could you briefly introduce yourself?

My name is Andreas, I'm 36 years old and have been working at Löwenstein Medical since March 2020.

What is your current position at Löwenstein Medical?

I work as a software developer and am currently jointly responsible in the

LEONI 4 team specifically for the user interface.

What does your resume look like?

I graduated from the Goethe-Gymnasium university preparatory secondary school in Bad Ems before going on to complete a degree in Computer Science at the University of Koblenz. As a research assistant, after graduating I worked at the University of Koblenz teaching and doing research (topics: automotive sector, assisted driving, autonomous driving, driving maneuver planning). I found out through the XING platform that Löwenstein Medical was looking for a software developer. The family-run business, the super friendly and very pleasant interview along with the interesting field of medical technology convinced me to take on the job.

Was there one experience, one special moment in your professional career at Löwenstein Medical that you look back on fondly?

During the onboarding process, new employees have the opportunity to visit a hospital and see the daily work of those who use our devices, and seeing the devices live in action. For me personally it was visiting a neonatal intensive care unit that made a lasting impression on me. Joy and sorrow were so close together there. That once again showed me why research and development is so important in medical technology.

Another special moment during my time at Löwenstein Medical was when we assembled the first prototype of our device. The entire team was involved and together we managed to get the first working LEONI 4 including the housing up and running. Previously, all we had on our desks were wild assemblies with lots of circuit boards and cables, which looked super interesting and exciting for technology enthusiasts. But such assemblies have little to do with the finished device.

Installing everything into a housing gives you a much better feeling of the great things you achieve in the end and what goal you are aiming for.

What would you like to give applicants and interested parties on their (professional) way?

The field of medical technology is extremely multidimensional and exciting. For me personally, it motivates me enormously to develop products that can help people and even save lives. I enjoy working at Löwenstein Medical because the work environment is very informal, the topics are very varied, and decisions are made quickly thanks to the flat hierarchies.

Many thanks!

The R&D department in figures:

- In 2002, the development department for software, electronics, and mechanics was expanded
- In 2005, development of the Leon plus ventilation device was completed and the product went into production
- At the time Leon plus was finished, there were around two major development projects in the pipeline
- In January 2019, Steffen became Head of R&D
- Since 2023, almost 10 major projects have been worked on in parallel

Löwenstein Medical has six R&D sites with different key areas of emphasis. In this edition, we focus on Bad Ems to introduce the LEONI 4 project.

“I enjoy working at Löwenstein Medical as the work environment is very informal, the topics are very varied and decisions are made quickly, thanks to the flat hierarchies.”



A small insight into the world of work in product development

Would you like to be part of a strong team?

The Development department at Löwenstein Medical welcomes job starters after university. Lateral entrants can also join us.

For details on all our vacancies, requirements and contact details, visit:

www.loewensteinmedical.com/stellenangebote

By the way, we can supervise your thesis!



The team looks forward to your application!

Preterm birth – a global problem.

Preterm births happen the world over. But not all babies have the same chances of emerging from this phase of life healthy.

By [Dr. med. Cathrin Niedeggen, specialist in pediatric and adolescent medicine](#)

The WHO estimates worldwide premature births at 15 million annually. Preterm births are therefore a global problem. In all countries of the world, the rate of preterm births is between 5 and 18% of all infants born. The majority of preterm births take place in Africa and South Asia.¹

In Germany, around 60,000 infants are born prematurely every year, making one in 11 infants a “preemie.” Accordingly, preterm babies are the largest group of patients in the country.²

The less developed a premature baby is, the greater the risk of complications and of healthy survival. Preterm births can have many different causes, such as infections, multiple pregnancies, chronic diseases of the mother or complications during pregnancy, including diabetes or high blood pressure. Often though no precise cause can be identified. Complications surrounding preterm births are the most common cause of death among infants under five years old and were responsible for around one million deaths in 2015.⁴

Survival rates vary enormously worldwide.

There is a dramatic difference in survival rates for preterm babies depending on where they are born. For instance, more than 90% of preterm babies born before the 28th week of pregnancy in low-income countries die within the first days of life. Compare that with less than 10% of these infants that die in high-income regions.

Lack of affordable (primary) care.

The causes of high mortality rates in low-income countries include a lack of practical, affordable (primary) care such as heat supply/heat management, support with breastfeeding, basic care of infections and respiratory problems and no respiratory support. In high-income countries, almost all infants born after the 32nd week of pregnancy survive. In middle-income countries preterm infants who survive the neonatal period suffer a high burden of disability when the use of more advanced technology is suboptimal.

No two preterm babies are alike.

Preterm babies include infants born before the 37th week of pregnancy, normally weighing less than 2,500 grams at birth. Babies are then subdivided further, using weight, for example:³



(VLBWI = very low birth weight infant)

with a birth weight under 1,500 grams; (birth normally before the 32nd week of pregnancy) and

(ELBWI = extremely low birth weight infant)

with a birth weight of less than 1,000 grams; (birth normally before the 28th week of pregnancy).

Skin contact and CPAP to provide support.

Besides avoiding known factors that may lead to preterm births, and therapeutic options before the imminent premature birth (e.g., steroid therapy for the mother to help the baby's lungs mature or tocolytic therapy to inhibit labor), the WHO published new recommendations in November 2022 on the care of preterm babies. They reflect new insights that simple interventions such as kangaroo mother care straight after the birth, early commencement of breastfeeding, the use of continuous positive airway pressure (CPAP), and medication such as caffeine in response to respiratory problems can significantly reduce the mortality among preterm babies and babies with low birth weight.

Generally, preterm babies with an expected birth weight of under 1,500 grams (irrespective of the week of pregnancy) should receive care in specialized *perinatal centers*, on the basis of the relevant requirements.^{5,6} Especially extremely preterm infants whose lives are hanging by a thread need access to professional, experienced intensive and care.⁷ These centers are fitted out with appropriate specialist equipment and technically trained staff. Here, preterm babies receive appropriate (usually intensive medicine) care, with the relevant care preventing possible complications due to the particularly immature babies. As an example, there were just under 10,000 infants in Germany in 2020 with a birth weight of under 1,500 grams needing care in these specialized centers.⁸

Lifelong consequences possible.

Classic problems of premature birth affect almost all organs due to their immaturity: e.g., respiratory distress syndrome (RDS), bronchopulmonary dysplasia (BPD), necrotizing entero-

colitis (NEC), retinopathy of prematurity (ROP), and not least intraventricular hemorrhage (IVH), to name but a few. As already mentioned, the general supposition is that the lower the birth weight and the shorter the pregnancy, the higher the risk of complications.⁹ Many of the infants that survive suffer the consequences of complications of premature birth the rest of their lives in the form of disability, including learning disability, sight and hearing problems. Preterm births are not such a rare event as some would think, and are relevant to society as a whole not just due to the potential long-term consequences.

To draw attention to this global problem, *World Prematurity Day* has been held every year on November 17 since 2008. Through this day, parent representatives and associations aim to raise awareness of the concerns and problems of preterm babies and their families.¹⁰

¹ Preterm birth (who.int), accessed 12/22.

² Press kit – Bundesverband „das frühgeborene Kind“ e.V., last revised April 1, 2022.

³ Checkliste Neonatologie – 5th Edition, Geznel-Boroviczény, Ross et al.; 2015 Georg Thieme Verlag KG.

⁴ Perin, J.; Mulick, A.; Yeung D.; Villavicencio, F.; Lopez, G.; Strong, K.L. et al.: Global, regional, and national causes of under-5 mortality in 2000-19: an updated systematic analysis with implications for the Sustainable Development Goals. *Lancet Child Adolesc Health*. 2022;6(2):106-15. doi:10.1016/S2352-4642(21)00311-4.

⁵ <https://perinatalzentrum.org/informationen/faq/#collapse73>, accessed on January 17, 2023.

⁶ Guideline of the Joint Federal Committee concerning Quality Assurance Measures of the Care of Premature and Term Babies as per § 136 (1) number 2 SGB V (Social Security Code V) in conjunction with § 92 (1) sentence 2 number 13, SGB V; (Quality Assurance Guideline Premature and Term Babies/QFRRL), in the version dated September 20, 2005, published in the Federal Gazette 2005 (p. 15 684), entered into force on January 1, 2006, last amended on October 20, 2022 published in the Federal Gazette (BAnz AT December 1, 2022 B3), entered into force on January 1, 2023.

⁷ Press kit – Bundesverband „das frühgeborene Kind“ e.V., last revised April 1, 2022, accessed December 22, 2022.

⁸ IQTiG – Institute for Quality Assurance and Transparency in Healthcare – National Analysis 2020 – Neonatologie, last revised August 10, 2021.

⁹ Das neugeborene Kind – Wissen @ AMBOSS (accessed on January 12, 2023).

¹⁰ Warum ein solcher Tag? – World Prematurity Day (welt-fruehgeborenen-tag.de), accessed 12/22.

Kangarooing aims to give the preemie a bit of time and warmth. Time that they couldn't spend in the protected environment of the mother's womb.





Infants aren't little adults.



Ventilation for preterm babies.

Most preterm babies, as described above, require different levels of specialist care and provision by trained personnel for varying periods of time and devices tailored specifically to the needs of these small patients, such as neonatal ventilators – true to the motto that “infants aren't little adults.”

Intensive medical care.

Here invasive and noninvasive respiratory support plays a major role. Particularly the group of extreme preterm babies (<28th week of pregnancy) normally requires intensive medical care. Around 80% of these preterm babies receive invasive mechanical ventilation in highly developed countries.¹¹ Even if new therapy approaches and strategies try to avoid invasive mechanical ventilation¹² or to reduce usage time, and noninvasive ventilation of preterm babies has increased steadily over the past few years¹³, invasive ventilation therapy is still indispensable in neonatology and is associated with high morbidity and mortality despite general medical progress and is accompanied by acute and chronic lung damage (such as bronchopulmonary dysplasia, see above).¹⁴

In times of progressive digitalization and automation, not just in medicine (e.g., autonomous driving and assistance systems), there is particularly in this vulnerable area a desire to further optimize therapy, tailor it to the needs of the particular patients, and, due to the increasing shortage of personnel and lack of time, also a desire for increasing automation, not least in the area of ventilation.

CLAC® respiratory support.

Approaches exist for automating the ventilation strategy for preterm babies: Most preterm babies requiring respiratory support also frequently need additional oxygen and often experience intermittent hypoxemic and hyperoxemic episodes or are exposed to a higher risk.¹⁵ Hypoxemic episodes and the exposure to insufficiently high oxygen concentrations are known to increase the occurrence of lung and eye damage^{16,17} and are associated with an increased risk of retinopathy of prematurity (ROP)¹⁸, chronic lung disease (Bronchopulmonary Disease, BPD), necrotizing enterocolitis (NEC), neurodevelopmental impairment (NDI), and increased mortality.¹⁹

Manually adjusting oxygen settings is time-consuming.

The oxygen requirement and, in turn, the FiO₂ settings change almost regularly over the course of the day, entailing many manual adjustments of the oxygen supply. These have normally been made by the healthcare staff in the intensive care unit. Depending on the patient group, these adjustments can be difficult and time-consuming. In the face of notable staff shortages, particularly in these specialized areas, increasing automation of the FiO₂ settings can help improve patient care for certain infants. CLAC® – closed-loop automatic oxygen control – was developed with this goal in mind. The CLAC® algorithm adjusts the FiO₂ value according to preselected settings by the user to the prevailing SpO₂ value and assists the user with the FiO₂ settings.

Automation brings benefits for healthcare staff and infants.

The principle of automated FiO₂ control based on the SpO₂ value is not new but has been used for several years and has been proven to be effective and safe.^{20,21,22} For instance, Hallenberger et al. showed in their multicenter randomized, controlled crossover study that CLAC[®] can significantly improve SpO₂ therapy with preterm babies with mechanical ventilation or nCPAP: The SpO₂ values for the CLAC[®] infants were 10% more in the SpO₂ target range than for the infants that received purely manual control. The workload of the healthcare staff was also reduced as fewer SpO₂ adjustments were required than with conventional therapy.²³

In summary, it is evident that automatic control of the inspiratory oxygen fraction increases the proportion of time in which the oxygen saturation (SpO₂) is in the target range, thereby reducing the number and duration of hypo- and hyperoxemic episodes and the workload of caregivers. Effects on clinically important endpoints of infants (such as ROP, BPD, NEC, NDI, and mortality) and the long-term development of the preterm babies were not yet investigated in long-term studies in particular.^{24,25}

FiO₂-C study.

It is precisely here where the FiO₂-C study (closed-loop automatic control of FiO₂) starts. A randomized, controlled parallel group study with observer-blinded recording of outcomes aims to investigate the effectiveness of automatically adjusted FiO₂ usage compared with the manual control in terms of serious complications relating to hypoxemia and hyperoxemia. The study includes and investigates more than 2,300 preterm babies with a maturity between 23+0 and 27+7 weeks of pregnancy at 75 European sites with the highest levels of neonatal care.

The LEONI plus with CLAC[®] is also used here. The project aims to verify safety and the clinically significant impact of this technology with very immature preterm babies in a multicenter study.²⁶ This study differs in that the preemies are examined twice. The first takes place at a PMA of 36 weeks, i.e., normally just before being discharged from hospital, for indications of the previously mentioned complications and again at a corrected age of 24 months. In the follow-up, infants are examined for secondary outcome variables (death, speech and cognitive developmental delay, motor impairments and visual and hearing disabilities).

The study is currently underway and the results are eagerly anticipated. It will be interesting to see whether the partial automation of neonatal ventilation reduces the workload of medical staff and whether long-term results show a better outcome for premature babies and effective, lasting protection by reducing the complications of prematurity.

¹¹ Stoll, B.J.; Hansen, N.I.; Bell, E.F. et al.: Trends in Care Practices, Morbidity, and Mortality of Extremely Preterm Neonates, 1993–2012. *JAMA*. 2015;314(10):1039-1051. doi:10.1001/jama.2015.10244.

¹² Göpel, W. et al.: Avoidance of mechanical ventilation by surfactant treatment of spontaneously breathing preterm infants (AMV): an open-label, randomised, controlled trial. *The Lancet*. 2011 Nov; 378, 9803:1627–34.

¹³ Subramaniam, P.; Ho, J.J.; Davis, P.G.: Prophylactic or very early initiation of continuous positive airway pressure (CPAP) for preterm infants. *Cochrane Database Syst Rev*. 2021;10(10):CD001243. Published 2021 Oct 18. doi:10.1002/14651858.CD001243.pub4.

¹⁴ Thèbaud, B.; Goss, K.N.; Laughon, M. et al.: Bronchopulmonary dysplasia. *Nat Rev Dis Primers*. 2019;5(1):78. Published 2019 Nov 14. doi:10.1038/s41572-019-0127-7.

¹⁵ Martin, R.J.; Di Fiore, J.M.; Macfarlane, P.M.; Wilson, C.G.: Physiologic basis for intermittent hypoxic episodes in preterm infants. *Adv Exp Med Biol*. 2012; 758:351–8.

¹⁶ Saugstad, O.D.: Bronchopulmonary dysplasia: oxidative stress and oxidants. *Semin Neonatol*. 2003;8(1):39–49.

¹⁷ McColm, J.R.; Fleck, B.W.: Retinopathy of prematurity: causation. *Semin Neonatol*. 2001; 6(6):453–460.

¹⁸ Chow, L.C.; Wright, K.W.; Sola, A.: CSMC Oxygen Administration Study Group. Can changes in clinical practice decrease the incidence of severe retinopathy of prematurity in very low birth weight infants? *Pediatrics*. 2003 Feb;111(2):339-45. doi: 10.1542/peds.111.2.339. PMID: 12563061.

¹⁹ Maiwald, C.A.; Niemarkt, H.J.; Poets, C.F. et al.: Effects of closed-loop automatic control of the inspiratory fraction of oxygen (FiO₂-C) on outcome of extremely preterm infants – study protocol of a randomized controlled parallel group multicenter trial for safety and efficacy. *BMC Pediatr*. 2019;19(1):363. Published 2019 Oct 21. doi:10.1186/s12887-019-1735-9.

²⁰ Claire, N.; Bancalari, E.; D'Ugard, C.; Nelin, L.; Stein, M.; Ramanathan, R.; Hernandez, R.; Donn, S.M.; Becker, M.; Bachman, T.: Multicenter crossover study of automated control of inspired oxygen in ventilated preterm infants. *Pediatrics*. 2011 Jan;127(1):e76-83. doi: 10.1542/peds.2010-0939. Epub 2010 Dec 27. PMID: 21187305.

²¹ Poets, C.F.; Franz, A.R.: Automated FiO₂ control: nice to have, or an essential addition to neonatal intensive care? *Arch Dis Child-Fetal*. 2017;102(1):F5–6.

²² Mitra, S.; Singh, B.; El-Naggar, W.; McMillan, D.D.: Automated versus manual control of inspired oxygen to target oxygen saturation in preterm infants: a systematic review and meta-analysis. *J Perinatol*. 2018;38(4):351–60.

²³ Hallenberger, A.; Poets, C.F.; Horn, W.; Seyfang, A.; Urschitz, M.S.; CLAC Study Group: Closed-loop automatic oxygen control (CLAC) in preterm infants: a randomized controlled trial. *Pediatrics*. 2014 Feb;133(2):e379-85. doi: 10.1542/peds.2013-1834. Epub 2014 Jan 27. PMID: 24470641.

²⁴ Maiwald, C.A.; Niemarkt, H.J.; Poets, C.F. et al.: Effects of closed-loop automatic control of the inspiratory fraction of oxygen (FiO₂-C) on outcome of extremely preterm infants – study protocol of a randomized controlled parallel group multicenter trial for safety and efficacy. *BMC Pediatr*. 2019;19(1):363. Published 2019 Oct 21. doi:10.1186/s12887-019-1735-9.

²⁵ FIT Project (uni-tuebingen.de) accessed December 22, 2022.

²⁶ FIT Project (uni-tuebingen.de) accessed December 22, 2022.



CLAC® further development.

Existing systems can still be improved: Löwenstein Medical is constantly working to keep its neonatology products up to date to guarantee the best possible patient safety and high levels of user comfort. The CLAC® system is therefore constantly being further developed and is currently being tested and improved, for example, in collaboration with the Neonatal Department at Tübingen University Hospital under the guidance of PD Dr. Axel Franz²⁷. The aim is to optimize the system to further reduce the hypoxemic and hyperoxemic periods of the ventilated child. In addition, the team is also looking to reduce system alerts to improve comfort for users and to avoid “alarm fatigue,” i.e., users becoming desensitized to alarms.

Innovation through research.

Another innovative approach to automation in neonatal ventilation comes in the shape of the NANNI® project funded by the German Federal Ministry for Education and Research (BMBF): The funding initiative “Tiny Patients, Huge Need – Medical Technology Solutions for Child-Oriented Healthcare” supported the project to develop an innovative ventilation system for preterm babies designed to reduce the therapeutic effort and improve diagnosis quality. As described in

detail above, the invasive ventilation of preterm babies is a life-saving therapy, which unfortunately can also entail complications. As a rule it is a time-consuming, labor-intensive therapy that has to be adjusted frequently as the medical condition of the child can vary wildly in no time at all. Here the response is often time-critical.

This project aims to extend automatic functions. Additional sensor technology also optimizes the ventilation quality and allows conclusions to be drawn about the neonate's physiological condition. This procedure is designed to improve ventilation quality and outcomes while reducing ventilation-associated complications.²⁸

The initial phase of the project is complete and results have been published.

We managed to get the paper's authors to provide a short guest article that you can read below. Essentially, it focuses on automated CO₂ control,²⁹ which is even more complicated than automated oxygen control. However, it is no less effective, as paCO₂ extremes and fluctuations of the paCO₂ within a short period of time are associated with severe intracranial bleeding in preterm babies³⁰. This constitutes a serious and feared complication of prematurity and can cause serious lasting damage for the child.

²⁷ FIT Project (uni-tuebingen.de), Research Information Tübingen (FIT), accessed on December 22, 2022.

²⁸ From project sketch NANNI Version 1, 09/2017.

²⁹ M. Buglowski et al.: “Closed-Loop Control of Arterial CO₂ in Mechanical Ventilation of Neonates,” 2022 44th Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC), 2022, pp. 4991-4995, doi: 10.1109/EMBC48229.2022.9871185.

³⁰ Altaany, D.; Natarajan, G.; Gupta, D.; Zidan, M.; Chawla, S.: Severe Intraventricular Hemorrhage in Extremely Premature Infants: Are high Carbon Dioxide Pressure or Fluctuations the Culprit? *Am J Perinatol.* 2015 Jul;32(9):839-44. doi: 10.1055/s-0034-1543950. Epub 2015 Jan 21. PMID: 25607222.

Lots of potential but major challenges too.

Even if this constitutes a good initial approach to upgrading automation, other problems arise, such as measuring the relevant parameters. In the past, continuous monitoring of paCO_2 or continuous regular mainstream measurement of the etCO_2 has not been possible in preterm babies, as the current sensors are poorly suited to this specific group of patients due to often large amounts of dead space. Certain obstacles therefore need to be overcome in the search for ventilation automation.



Besides special and ideally “smart” ventilation devices and tools with automation algorithms, neonatology will require automation algorithms and more tailored applications and sensor systems in the future if it is to address the needs of these tiny patients more effectively.

Ventilation in neonates.

Control of arterial CO₂ partial pressure.

[By Mateuz Buglowski, Valerie Pfannschmidt, André Stollenwerk, Chair of Computer Science 11 – Embedded Software, RWTH Aachen; Mark Schoberer, Neonatology Section, RWTH Aachen University Hospital, Department of Pediatric and Adolescent Medicine, guest authors](#)

The control of arterial carbon dioxide partial pressure is an important aspect, particularly for the mechanical ventilation of preterm babies and neonates. Fluctuations and relevant deviations from the physiological standard range can cause lasting damage to the immature brain.

Adjustment of ventilation at certain intervals.

Healthcare staff regularly adjust ventilation to the patient's needs. Physicians and caregivers are normally responsible for several patients at a time and are unable to make adjustments continuously. Rather, they make them at certain intervals. This task is also challenging and time-consuming. User support could free up valuable resources for other patient care tasks. The problem here is that the existing methods of continuous measurement of the carbon dioxide partial pressure (paCO₂), such as transcutaneous measurement, do not always provide reliable values and the end-tidal CO₂ (etCO₂) can often not be measured with the tiniest patients due to the dead volume of the measuring cuvettes.



Joint project between hospital and Löwenstein.

In a joint project with the Neonatology Section in the Department of Pediatric and Adolescent Medicine at RWTH Aachen University Hospital, the Chair of Computer Science 11 – Embedded Software at RWTH Aachen, and Löwenstein Medical, we set out

to close this gap in care and develop an automated solution – as an add-on to the well-established CLAC® function of the oxygen equipment.

The aim of our work is to develop a control system that continuously adapts the ventilation so that the paCO₂ lies in a target range specified by the medical staff and the patient is ventilated at the same time with the least possible strain on the lungs. The paCO₂ control covers various modes in accordance with established mechanical ventilation practice. These modes map pressure- and volume-controlled ventilation.



Our goal is to improve the quality of measurement systems now commercially available for use with preemies and neonates. We expect that this high-quality etCO₂ measurement can lead to a breakthrough in mechanical ventilation for preterm babies.

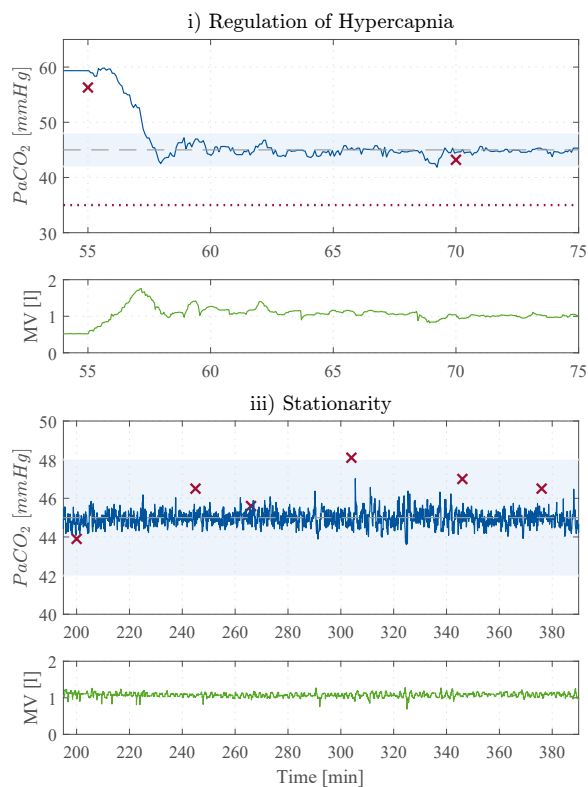


Figure 1 - Estimated $paCO_2$ curve and BGA reference measurements with the ventilation of premature lambs.¹
©IEEE 2022

Control is also envisaged that aims to achieve the ideal operating point of respiratory rate and tidal volume. The $etCO_2$ measurement is used as input value for the control. Compared with commercially available measurement systems for preterm babies and neonates, we aim to improve the quality of the measurement. We expect that this high-quality $etCO_2$ measurement can lead to a breakthrough in mechanical ventilation for preterm babies.

Control of the minute volume (MV) based on estimated $paCO_2$ value.

The control is based mainly on measuring the $etCO_2$ close to the tube connector. This value is used to estimate the $paCO_2$, which in practice is hampered by various technical and medical complications, such as a slipped tube, and requires further research. This estimate of the actual value is then compared with the $paCO_2$ target value so as to then define a minute volume (MV) for the ventilation. In a further algorithm step, this MV is translated into the specific therapy parameters of peak inspiratory pressure (PIP) and respiratory rate (RR).

Testing the control in an animal model.

To test the control in an animal model, LEONI plus ventilators were upgraded to be able to specify control commands for PIP and RR via a serial interface and to support capnometry in the respiratory gas. This setup enabled premature lambs to be ventilated from birth in SIMV therapy mode and with CLAC® support.

The first animal trials show the efficacy of the control. To this end, two ventilation situations were examined whose course is shown in Figure 1. In the first scenario, a hypercapnia was produced with hypoventilation and the controller then set to a $paCO_2$ target value of 45 mmHg and a target range of ± 3 mmHg. Through blood gas analysis (BGA) a reference value of 59 mmHg at the start of control was measured. After 2.5 minutes the target value was reached and then maintained by automatic adjustments of the MV in the target range. A BGA 15 minutes after the start of the test confirmed a $paCO_2$ value of 43.2 mmHg, which represents a minimal deviation from the estimated value of 44.5 mmHg. In the second part, the $paCO_2$ estimated from the $etCO_2$ was maintained constantly in the target range over a period of three hours. Reference measurements using BGA indicated only minor deviations of the actual $paCO_2$ from 0.2 mmHg to 3.73 mmHg.

Thereby, we were able to show that $paCO_2$ can be controlled on the basis of the measured $etCO_2$ concentration and that acute hypocapnic and hypercapnic states can be compensated in under 15 minutes.

Automatic control of the $paCO_2$ for enhanced safety.

The automatic control of the $paCO_2$ with ventilation in neonates therefore has the potential to increase safety for patients and reduce the workload of staff. Until the solution is deployed in practice, the estimate of the $paCO_2$ in particular needs to be more robust so that regulation cannot cause incorrect ventilation. The focus of further development will also look at integrating control with the spontaneous breathing of the neonates.

¹ Buglowski, M.; Pfannschmidt, V.; Becker, S.; Braun, O.; Hutten, M.; Ophelders, D.; Oprea, C.; Pattai, S.; Schoberer, M. and Stollenwerk, A. (2022, July): Closed-Loop Control of Arterial CO_2 in Mechanical Ventilation of Neonates. In Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual International Conference (Vol. 2022, pp. 4991-4995). DOI: 10.1109/EMBC48229.2022.9871185.

Individualized respiratory gas conditioning.

Between dogmas, secretion, and excessive formation of condensation.

By Christian Woll, Specialist in Internal Medicine & Pneumology, Intensive Care and Emergency Medicine, Section Leader Pneumology Fürst-Stirum Hospital Bruchsal, guest author

The development of HME filters (heat and moisture exchanger) and, in turn, the possibility of passive respiratory gas conditioning almost 50 years ago sparked a kind of philosophical war on the type of respiratory gas conditioning.

In favor of active respiratory gas conditioning.

The advocates of active respiratory gas conditioning point to the contraindications of the HME solutions and cite the negative effects during ventilation in relation to a reduction of the alveolar ventilation with additional dead space, additional flow resistance, and increased respiratory effort in the weaning process.

In favor of passive respiratory gas conditioning.

The supporters of passive respiratory gas conditioning cite an increased rate of pneumonia associated with ventilation due to frequent manipulation of the breathing tubes as a downside of the active respiratory gas conditioning. In addition, this technology is much more expensive and technically more complicated than the HME filter technology.

There is, however, general consensus regarding the need for respiratory gas conditioning. In the case of intubated and tracheostomized patients, the upper airways are bypassed. Consequently, the nasal, oral, and pharyngeal cavities cannot fulfill their physiological task of cleaning and heating the inhaled air.

As the nasal mucous membrane is well perfused and moist, the inhaled air is warmed and humidified by evaporation and convection. Condensation causes moisture during exhalation that is reabsorbed and stored. During the next inspiration, the stored moisture can be released. Cold and dry gases absorb a large portion of the existing heat and moisture. This can cause a substantial moisture imbalance in the airways and substantially impair respiratory gas conditioning.

Situation with mask ventilation and high-flow O₂ therapy.

The aforementioned problems occur even with mask ventilation and high-flow O₂ therapy (HFOT). Although the upper airways (nasal, oral, and pharyngeal cavities) are not eliminated, the high gas flows and the system and mouth leakages regularly cause the airways to dry out. In the case of HFOT, the continually high respiratory gas flow causes a similar effect. Even after a short time, the mucous membranes dry out, disrupting the mucociliary clearance function with demonstrable histological damage to the mucociliary and epithelial cells, thus promoting bacterial colonization.

The blocking of the tracheal cannula or main bronchi by viscous secretion constitutes a much-feared complication of the ventilation therapy. As a result, the ventilation can be severely compromised and requires rapid intervention, through aspiration for instance. The respiratory gas conditioning that heats and humidifies the administered respiratory gases is designed to maintain the mucociliary clearance and prevent damage to the cilia.

Active respiratory gas conditioning.

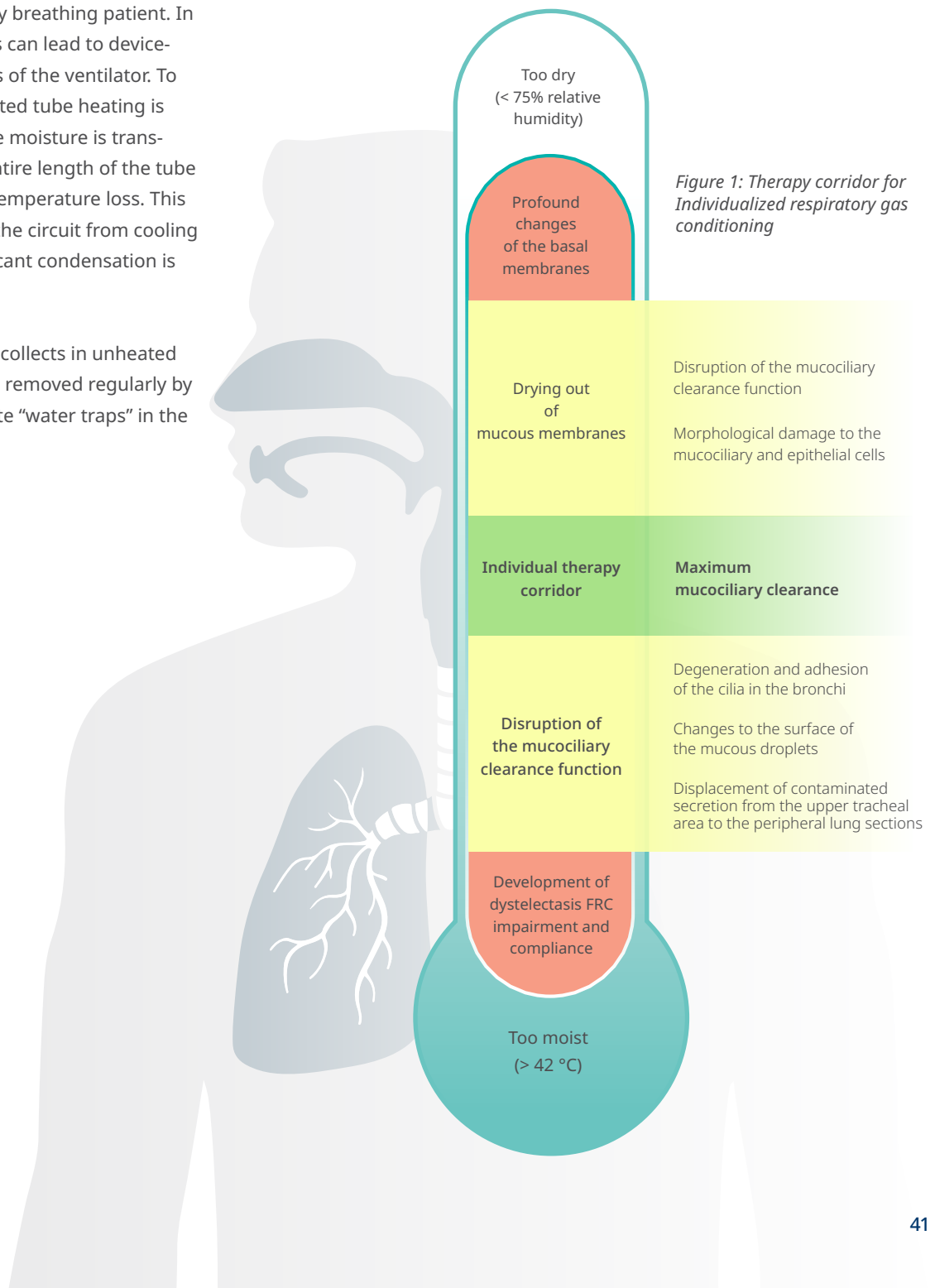
Active respiratory gas conditioning uses surface humidifiers in many cases. The mixture of gas for inspiration is directed over a heated water surface and saturated with heat and water vapor in the process. The aim is to achieve a respiratory gas temperature below the tip of the tube of almost 37 °C. The requirements for active respiratory gas conditioning systems have been specified as performance data in a binding standard since 2009. In accordance with the standard, the water content of the inhaled air must be at least 33 mg/l and the maximum inspiration temperature must not be more than 42°C. The individual setting of the active respiratory air humidifier must take into account both the bronchial secretion situation of the person being ventilated and

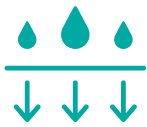
the condensation in the circuit. Ambient factors such as room temperature, direct sunlight, heat output of other devices, and the placement of the respiratory air humidifier directly next to a radiator or air-conditioning unit also influence the amount of liquid in the ventilation circuit.

Starting at a certain quantity of condensation, the flow resistance in the circuit is increased and so too the respiratory effort of the spontaneously breathing patient. In an extreme case this can lead to device-related malfunctions of the ventilator. To prevent this, integrated tube heating is used. As a result, the moisture is transported across the entire length of the tube without significant temperature loss. This prevents the gas in the circuit from cooling down and no significant condensation is generated.

Condensation often collects in unheated circuits. The water is removed regularly by draining intermediate “water traps” in the tube.

The frequent manipulation of breathing tubes was recognized in the 1990s as the main cause of a higher rate of pneumonia. With modern devices used for active respiratory gas conditioning, there is no evidence of ventilating-associated pneumonias.





Usual humidification capacity

HME filter (heat and moisture exchanger)

24.9 – 33.2 mg H₂O per 1,000 ml air (depending on the product)

Active respiratory air humidifier (heated humidifier)

44 mg H₂O per 1,000 ml air

Contraindications

- strong secretion formation
- existing exsiccosis
- high unintentional leakage
- COPD (dead space)
- long-term ventilation
- neonates

- overheating of the respiratory gases with inadequate settings

Side effects

- Additional dead space:
- reduction of the alveolar ventilation
 - increase in paCO₂
- Additional flow resistance:
- increased respiratory effort
 - influence of ventilation (especially with simultaneous mesh nebulization)

- formation of condensation (especially in interaction with air-conditioning system or other medical devices)

Figure 2: Passive and active respiratory gas conditioning compared

If the patient is ventilated with dry and warm respiratory gases due to the failure to top up the water, reference is made to the “Sahara effect,” which damages the epithelium. To identify this phenomenon in good time, modern respiratory air humidifiers have a water shortage alarm. Just like excessively dry respiratory gases, excessively moist respiratory gases compromise the person being ventilated. The effects range from a reduction of the mucociliary clearance function, changes to the surface of the mucous droplets, to undesired washing away of contaminated secretion from the upper tracheal area into the deep lung, which may impair gas exchange and cause infections.

Passive respiratory gas conditioning.

Passive respiratory gas systems (sometimes called “artificial noses”) are often described as a heat and moisture exchanger (HME). They remove heat and moisture from the patient’s exhaled air, store it reversibly in the inner material, and feed it into the dry respiratory gases with the next inspiration. At the same time, they act as an antimicrobial barrier for microorganisms. The use of tube heating and the

prevention of condensation with the earlier need of frequent draining of the water traps eliminates the hygienic benefit of HME filters.

Modern respiratory air humidifiers allow personal settings of the temperature profile. This also substantially reduces the amount of condensation generated. Due to the design of an HME filter and the associated shelf life, use with long-term ventilation is contraindicated.

Likewise, the use of HME filters must be seen as potentially critical in the case of acute respiratory insufficiency. The increased additional anatomic dead space reduces CO₂ washout and alveolar ventilation, which has been shown to increase mortality in ARDS. Ventilation with lung-protective parameters also proves more difficult as a result. An increased secretion load and tracheobronchial bleeding constitute exclusion criteria for the use of an HME filter. The increase in respiratory effort renders usage counterproductive in the context of more difficult weaning. Quality differences of the various manufacturers have an influence on ventilation.

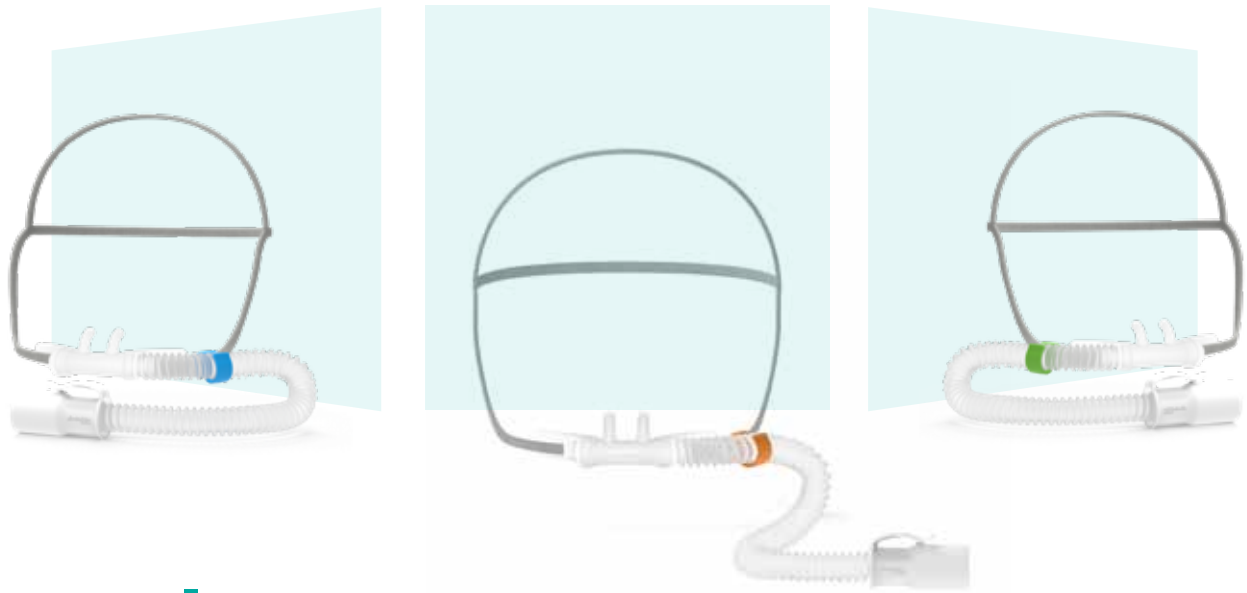
The greater flow resistance of the HME filter substantially increases the patient's required respiratory effort. HME filters with flow resistances of less than 2 mbar with a flow of 60 liters per minute are ideal.

Given the current data available, there is no clear recommendation for or against the usage of passive or active systems. Rather, there is a need to estimate the planned usage time, the current situation of the lung, and possible contraindications of HME filters. Such systems eliminate the need to simultaneously use bedside filters in combination with active humidification.

Conclusion: The Individualized respiratory gas conditioning is a key component in ventilation therapy. Thanks to technical innovations, active respiratory air humidifiers have become established over the past few years. The setting of individual temperature profiles, tube heating, and the alarm technology put the major criticisms of these systems into perspective.

Figure 3: Problem solutions in connection with active respiratory air humidification

Situation	Actions
Increased condensation on inspiration arm	Adjust chamber temperature (reduce where necessary). Patient temperature should remain constant unless the unheated path (e.g., tube extension) is longer than 20 cm.
Increased condensation on the exhalation arm	Increase exhalation temperature.
High-flow O ₂ therapy with high flows	Temperature must make physiological sense.
NIV ventilation	Select reasonable physiological temperature (e.g., patient 34 °C; chamber 30.5 °C).
Difficult disruptive factors	Temperature in the chamber should be at least 2 °C lower than the bedside temperature. Temperature must make sense physiologically.



LM Flo₂

Promoting successful High Flow Therapy.

Löwenstein Medical has developed in close collaboration with specialist medical staff the high-flow nasal cannula LM Flo₂ for this form of therapy. This cannula is available in three different sizes for adult and pediatric patients.

[By Andreas Specht, International Product Specialist](#)

Nasal High Flow Therapy (NHFT) has established itself as an important respiratory support measure for adult and pediatric patients with mild to moderate respiratory distress syndrome.

During High Flow Therapy, the respiratory effort is reduced by a continuous flow of fresh gas. Heating and humidification of the respiratory gas and a high-quality high-flow nasal cannula are decisive for successful High Flow Therapy. NHFT is being used successfully not only in intensive care units but also in the homecare setting.

Development of high-flow nasal cannula LM Flo₂

Löwenstein developed the high-flow nasal cannula LM Flo₂ in close collaboration with specialist medical staff. It offers a high degree of safety and comfort. The flexible and supple smooth-fit prongs are kink-proof. With their soft fit, they

prevent any type of skin irritation, decisively helping to alleviate pressure ulcers. The anatomically curved nose piece and the very light and elastic head strap ensure a high level of wearing comfort.

The possibility of connecting the tube intuitively on both sides to the high-flow nasal cannula LM Flo₂ increases the patient's freedom of movement. The Quick-Clip and the circuit holder ensure correct positioning and secure fit of the prongs.

We make careers. With a purpose.

Are you looking for meaningful work rather than just some job or other?
Then we should get to know each other.

We offer a wide range of occupational fields and professional opportunities.
Our goal every day is to improve the quality of life for patients in each of
these areas, to give them hope and to be there for our customers when
they need us.

Become part of our team.



We look forward to hearing from you and receiving your
application via our career portal at loewensteinmedical.com.

Training with purpose at Löwenstein Medical.

Löwenstein Medical has a long-standing tradition of training young people. Training has always been hugely important at this family-run business.

By [Martina Ecke](#), [Marketing Manager](#)

In the period between 2005 and 2020, 65 young people were trained at Löwenstein Medical in Bad Ems. Of these, 41 received an employment contract afterward – a ratio of 63%. This is testimony to the high-quality training received from the employer Löwenstein.

Employees remain loyal.

The figures for long-standing employees who once started out training at Löwenstein Medical attest to the attractiveness of the employer Löwenstein Medical in Bad Ems.

Wiebke Debus and Marcel Klauer, who we present in this edition, are just two of our employees that demonstrate how initial training at Löwenstein Medical can propel a career.



Team Leader

Wiebke Debus

We'd like to know who you are! Can you briefly introduce yourself?

My name is Wiebke Debus. I'm 38 years old and have been at Löwenstein Medical for 22 years.

What is your current position at Löwenstein Medical?

Team manager, office-based sales team for exports. In total there are eight of us working in exports and we support our branches and customers worldwide in coordination with our regional sales managers in the hospital and sleep diagnosis sectors. The role

includes tender preparation and submission of quotations up to shipment and drafting of the relevant customs documents. We ship our devices to over 130 countries worldwide.

How did you end up here? What training did you decide to follow at Löwenstein Medical?

I started my training as an industrial management assistant on August 1, 2001 at Heinen + Löwenstein in Bad Ems. Even then, I spent more time than usual in exports during my apprenticeship. I also assisted Technical Procurement at the same time. Since the export business continued to grow and we needed more support, two more people joined the team, which has continued to grow ever since.

Over the years I've specialized in the area of Export/International Business. This includes training courses to become a foreign-language correspondent (Chamber of Industry and Commerce) and export manager (Chamber of Industry and Commerce). I also attended various in-house and online training courses on specific export issues such as export controls and credit processing. At the end of the year I'm about to do a new course from the Chamber of Industry and Commerce.

Was there one experience, one special moment in your training that you look back on fondly?

Passing the exam, knowing that I'd be taken on after my training and would be given the opportunity to develop and grow here in the company. The first order I processed entirely on my own that time was a major project for a Turkish group of private hospitals.

What would you like to share with future apprentices and interested readers to further their professional careers?

Ask questions, ask questions, ask questions, be thirsty for knowledge, and be enthusiastic about what's involved and, of course, medical technology is incredibly interesting and, more than that, it's a worthwhile sales area.

Many thanks!

Wiebke is the responsible "export team manager" in Bad Ems and started an apprenticeship as an industrial management assistant some 22 years ago at Löwenstein Medical. Wiebke's professional career and progress in the company are paved with many internal and external training courses. The acquired expertise in exports coupled with excellent foreign-language skills make Wiebke an indispensable employee for Löwenstein Medical. You can see just how much Wiebke enjoys the job during the photo shoot for this edition. Her positive charisma and high spirits have a noticeable effect on the friendly atmosphere in the Export team.



Production manager

Marcel Klauer

We'd like to know who you are! Can you briefly introduce yourself?

I'm Marcel Klauer, 37 years old and have been at Löwenstein Medical for 17 years.

What is your current position at Löwenstein Medical?

I manage production and procurement for hospital products.

How did you end up here? What training did you decide to follow at Löwenstein Medical?

After graduating from high school and subsequent basic training with the German Armed Forces, I started my apprenticeship as an industrial management assistant in August 2006 and completed it in 2009. I spent the whole first year of my apprenticeship in sleep diagnostics and then moved to Regina Bilo in Production Procurement and Production Planning. I spent the rest of my time there, with the exception of the mandatory accounting component, because they urgently needed somebody.

Initially, I also helped out a bit in Export and attended a relevant training course, but the issue of Procurement and Production Planning always interested me more. In 2016, I completed a certificate course in Supply-Chain Management at RWTH Aachen and various in-house training courses on our products and other topics such as QM (MDR, MDSAP), purchasing negotiations, etc. Most recently I took part in a workshop focusing on the corporate due diligence obligations in supply chains, which we as Löwenstein Medical have recently had to meet and implement in Procurement and QM.

Was there one experience, one special moment in your training that you look back on fondly?

I can't remember whether it was still during my apprenticeship or just after, but the first visit to one of our suppliers sticks in my mind because it was really exciting of course.

As an apprentice, I really enjoyed helping out with inventory in the warehouse. Most of the other apprentices were also there lending a hand.

What would you like to share with future apprentices and interested readers to further their professional careers?

There's no such thing as a silly question. If you don't understand something, the only way to find out is to ask. It's better to ask three times than to get it wrong three times.

Particularly with medical technology, regardless of whether it's with the hospital products in our segment or in the other segments of Löwenstein Medical, not everything is always self-explanatory. Whether that involves the function of a

product or the processes.

If you ask questions, things will be explained to you and you'll find out how everything interrelates.

They might even be questions that no one's ever asked before and that can improve something.

Many thanks!

Marcel holds the position of "Head of Production and Procurement Hospital." "The fact that I was able to take on so much responsibility so young is what makes this company so special," says Marcel.

He started out at Löwenstein Bad Ems training as an industrial management assistant and was given the opportunity to move ahead in his career following the departure of his superior. Marcel's career bears testimony to how

such a high level of personal commitment and dedication pays off.

During our photo shoot it quickly became clear that Marcel is blessed with a positive approach. He always has a smile on his face – an important characteristic considering the many discussions and negotiations held on- and offline.

Looking for an apprenticeship that serves a purpose?

Training with prospects.

The company Löwenstein strives to encourage the young people trained in-house to stay after their training is complete. The examples of Wiebke and Marcel show that training pays dividends – and that training is a springboard for professional progress and a career.

The company Löwenstein promotes its employees with internal and external training. People trained in-house are ideal candidates for managerial positions.

Now it's YOUR turn:

Would you like to become part of the Löwenstein family? Are you looking for a suitable apprenticeship at the Bad Ems site or at one of the other sites? You will find all apprenticeships available for 2024, broken down by site, at

loewensteinmedical.com/schueler

LÖWENSTEIN
medical

**Become
part
of our
team.**

loewensteinmedical.com

A wide range of apprenticeship opportunities will also be available for 2024:

- > IT specialist for system integration (male/female/non-binary)
- > Warehouse specialist/warehouse logistics specialist (male/female/non-binary)
- > Industrial management assistant (male/female/non-binary)
- > Management assistant in the healthcare system (male/female/non-binary)
- > Dual course of studies B.Sc. Business Administration (male/female/non-binary)
- > Apprenticeship for industrial management assistant (male/female/non-binary)



Click here for the
Löwenstein Medical
careers portal.

**The Löwenstein team
looks forward to your
application!**

Löwenstein Medical France.

Employees from Löwenstein France pursue the ambitious goal of turning Löwenstein Medical France into the reference company for ventilation.

By Christophe Hentze, Managing Director

The French subsidiary of the Weinmann Group was founded in 1996 in Igny, a city in the Paris region. At the time, the company's two sales teams sold homecare products (CPAP devices, ventilators, polysomnography devices, breathing masks) and emergency products (ventilators and defibrillators).

The French subsidiary underwent restructuring in 2013 when Löwenstein took over the homecare activities of Weinmann. It currently serves two different markets, one for ventilators and sleep medicine devices for the homecare segment and, since 2017, a second for the hospital segment. Both teams were gradually merged to leverage synergies between activities. At present, the company with headquarters in Massy manages its business with 60 employees.

Löwenstein Medical France has invested a great deal of energy in defining a business plan and strategy with the involvement of the workforce and customers and reviews this plan annually, as the current markets are subject to rapid fluctuations.

The company's clearly defined purpose is to provide innovations "Made in Europe" to professional health institutions, combined with "excellent" service quality so that they can dedicate themselves to their patients without worries.

A relaxed yet performance-enhancing leadership culture.

With a purposeful mix of delegation, subsidiarity, project orientation, and the atmosphere of a start-up, Löwenstein Medical France has a very special leadership style. All processes are geared to ensuring that efficiency, creative thinking, responsiveness, personal development and job satisfaction are an integral part of the company. The financial

performance of the company is not a goal in itself, but the consequence of the well-being and dedication of the employees.

Everything revolves around the team on the ground.

The 60 committed employees that make up the Löwenstein Medical France team are spread out across the subsidiary's site and its training center. Before being recruited, they had to demonstrate their skills to ensure that their experience, their pragmatism, their modest and creativity met the requirements of this very special medium-sized enterprise. This team is the strength behind the company and makes all the difference. The team is well-established, pulls together, and accepts all challenges, even the most complicated tasks that stump competitors.

The environment.

Every month an internal event on a topic is organized that has nothing to do with the business. This brings the team together (cooking, sport, leisure activities, etc.) and promotes team spirit.

In the morning, employees enter the office in high spirits and aren't expected to stay late in the evening: Efficiency replaces long workdays. All Löwenstein employees are encouraged to create their personal motivating and structured working environment in which they recognize, respect, and promote the talent of other employees. Three goals should be kept in mind – well-being in the company, self-realization and satisfying customers.

Environmental protection and carbon footprint.

The environmental aspect of Löwenstein Medical France is a priority. Just because a company grows quickly doesn't mean that it can forget about the environment, quite the opposite in fact. A Corporate Social Responsibility program is currently being developed.

And, last but not least, all of our partners and customers.

By forging a close working relationship with our clients on all levels of the company, we achieved #2 ranking on the market.

We firmly believe that we must place the users of our product and service solutions at the center of our considerations and that service is now more important than the product itself and its price. That's why, for so many years, we have strongly anchored in our self-image the wish to do everything systematically to keep offering our customers the kind of "excellent" service quality that makes all the difference.

Always keep an eye on the long-term plan

The decisive success factors at Löwenstein Medical France:

Top priority goes to top results in customer surveys with internal and external customers

Remain modest and professional and always stick to your objectives

Trust employees. They have the best ideas.

Involve your customers as much as possible in all your projects. You ultimately know your own wishes best.



Pleasingly high demand for classroom training.

Before the COVID-19 pandemic, our customers always valued classroom training from all Löwenstein Medical segments. Both interest and demand were phenomenal.

By Alexander Hubert, Team Manager Product Management/Application Diagnosis

At the height of COVID-19 we were all forced to adjust quickly to new situations. Unfortunately, people were not permitted to gather in a confined space. Löwenstein Medical rolled soon out its web-based Löwenstein Academy as an alternative training medium.

Even though we managed to maintain the number of people attending our webinars, wanted to return to classroom training. The personal and direct interaction with our customers is hugely important in the company.





Record numbers attend classroom training.

For the past year or so we have offered classroom training courses again. As a result, we were rewarded with outstanding numbers of participants signing up for the courses.

All of the training courses in 2023 in the field of diagnostics were fully booked and in some cases overbooked. During the courses we learned that many participants started working in a sleep lab during the coronavirus pandemic and recently had their first opportunity to attend a classroom-based training course.

All those involved really enjoy the chance to talk to each other personally and take many new, useful insights back to their daily work.

It's what we see as our mission and motivation.

For 2024 we will once again be offering interesting topics both as classroom-based sessions and as webinars in the field of sleep and ventilation medicine for anyone interested.

Find out more about our training offer:



Have you heard?

The “Have you heard?” section provides you with a quick roundup of interesting facts from many different subject areas at Löwenstein.



Sustainability projects.

Many small steps gradually lead to more sustainability. Löwenstein is adopting photovoltaic systems that convert sunlight into electric current at its sites in Hamburg, at Löwenstein Medical Technology, and in Kammerstein, at WILAmEd GmbH.

The new blue transport crates used to transport goods between various Löwenstein sites, e.g., between Hamburg and Neuhäusel, also promote sustainability.

The use of electric charging stations is another step: Following in the footsteps of Dortmund as the pilot project, the new building in Hennigsdorf near Berlin will be the second site to be fitted with electric charging stations. Löwenstein Medical Fleet Management is doing its bit to make work at Löwenstein more sustainable and to reduce carbon emissions.



Löwenstein video podcast.

Senior management communicates company news to Löwenstein employees in the form of informative video podcasts, the intranet blog, emails, notice boards and townhall meetings.

This newly established internal communications channel proved effective during the coronavirus pandemic and is currently an integral part of ongoing internal corporate communications.



International growth course.

With the newly founded subsidiary Löwenstein Medical Iberia for the markets Spain and Portugal, Löwenstein continues its strong international growth.

New international employees joined us on the Iberian peninsula and also in Japan, Canada, the Middle East and South America.



Donation to Project HOPE.

Löwenstein Project HOPE is providing a Lifetherm warming bed and three other warming beds at cost for the project in Strumica, northern Macedonia. In the future, neonates will receive optimum care in the clinical environment.

Project HOPE focuses in particular on setting up effective healthcare in the countries of Eastern Europe. Besides initiatives relating to healthcare and setting up basic medical care, a great deal of importance is attached to the professional training of doctors and nurses.

Details of other projects can be found on the Project HOPE homepage: www.projecthope.de



Employee milestones 10, 15, 20 and 30 years.

Seventy-six employees in Germany celebrated a milestone in the first half of 2023, including:

41 employees 10 years
24 employees 15 years
9 employees 20 years and
2 employees 30 years.

Senior management expresses its sincere thanks for their many years of loyalty to the company and wishes those celebrating anniversaries all the best, both privately and professionally, good health and continued happiness, satisfaction and success in their careers.

Take a deep breath.

The air in Bad Ems is very special. Pure, fresh, and infused with nature. Not everyone is lucky enough to breathe fresh air. Löwenstein Medical develops top-quality ventilation technologies.

In Bad Ems. And worldwide.

LÖWENSTEIN

medical



With people in mind

Publication details

Inspiration is the Löwenstein Medical Magazine

(as per January 2024)





Publisher

Löwenstein Medical SE & Co. KG
Arzbacher Strasse 80
56130 Bad Ems, Germany
loewensteinmedical.com

Reader service

marcom@loewensteinmedical.com

Editorial

Julia Gundlach (resp.)
Martina Ecke

Employees in this edition

Julia Bodewig
Mateuz Buglowski
Wiebke Debus
Tanja Derlien
Wiebke Diebold
Martina Ecke
Anne Grünewald
Christophe Hentze
Alexander Hubert
Christoph Jaschke
Nadine Jaun
Marcel Klauer
Dr. Peter Kremeier
Benjamin Löwenstein
Paulina Lungen
Marco Meeß
Dr. Cathrin Niedeggen
Steffen Pattai
Valerie Pfannschmidt
Bettina Recher
Mats Schauerte
Mark Schoberer
Matthias Schwaibold
Andreas Schwarz
Britta Smoes
Andreas Specht
Julia Stahlhofen
André Stollenwerk
Christian Woll

Design

WILDDESIGN GmbH
wilddesign.de

Proofing

Isolde Kring
isoldekring.de

Translation

beo Gesellschaft für Sprachen
und Technologie mbH
beo-doc.de
Kate Simmons

Printing

Druckerei Hachenburg
PMS GmbH
Saynstrasse 18
57627 Hachenburg, Germany
druckerei-hachenburg.de

Print run

1000 (quarter 1/2024)

The publisher accepts no liability for the correctness of the information provided despite a careful review by the editorial team. No part of this publication may be reproduced in any form or processed using electronic systems without the publisher's express consent.

Help us make the next edition of Inspiration even better!

As with our products, we want to improve this magazine. What should we include? Share your suggestions and feedback by writing to: marcom@loewensteinmedical.com

Thank you and see you in the next issue!



With people in mind



loewensteinmedical.com



p10309en2401