LÖWENSTEIN medical MAGAZINE

May 2019 Issue

CARA FULL FACE

Face the day well-rested.

PRISMA JOURNAL

Data security in telemedicine.

SANDMAN.MD

Mobile anesthesia documentation.

CLAC 2.0

Familiar safety and reliability with optimized regulation algorithm.

HOSPITAL HOMECARE DIAGNOSTICS

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THE ELISA FAMILY

The future of intensive care ventilation.

- Innovative
- Intuitive
- Sustainable

DESIGN AWARD 2018

HOSPITAL HOMECARE DIAGNOSTICS

Dear Customers, Employees and Business Partners,

In this issue of the Löwenstein Medical Magazine we report on activities in all our business areas, namely Hospital, Homecare and Diagnostics. For us two things stand out. First, we see how important each of the three areas is for our business and second, how we as a company have to develop continuously and reinvent ourselves in order to endure in a highly dynamic environment. The three core areas are not just economically but also strategically important to us. We are absolutely certain that we can create synergies that are valuable for our customers.

We are the world's only manufacturer and service provider that links these three worlds. One example in Germany – the widely debated issue of discharge and weaning management of ventilation patients – shows how important this particular interface is.

Here we report on other such interface topics, including the digital anesthesia documentation Sandman in conjunction with our Leon devices; the enhanced CLAC 2.0 algorithm in our Leoni and our new ventilator prisma VENT50-C with High-Flow Oxygen mode; and the connection to a hospital's Patient Data Management System over Phillips IntelliVue patient monitor. All these subjects concern us because we have forged closer links among these worlds.

We also are occupied with the growing demand for digital support of processes and products. The opportunities that digitalization has opened up in many other business fields remain generally untapped by medical technology.

Our task in the coming years is to invest in this area and not only bring very good products to market, but also provide the right digital solutions that will further improve diagnostics and treatment of patients – no matter which medical field is involved – for patients and professional users. To that end, we have already made our Homecare products telemedicine-capable and believe in the enormous potential of telemetry in a clinical setting.

This summer's product highlight is our new and lightweight mask CARA Full Face, which we expect will build on the immense success of CARA. It is the best full face mask that we have ever made. We hope that you share our enthusiasm for the new mask.

All these projects and other activities are not empty promises. Right now we are investing 16 percent of our revenue in new development projects in all areas. The excitement continues into the future. We look forward to exchanging ideas and opinions on these subjects with you.

We hope you enjoy reading this issue.

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DIGITIZATION OF ANESTHESIA

The documentation of anesthesia data in the clinical process is a difficult and sometimes unpopular subject. According to law, all anesthesia records on the treatment of a patient must be documented and retained for up to 30 years. They include information that the doctor obtains from the patient during a pre-operative consultation, data recorded while anesthesia is in use and in the recovery room. Blood pressure, heart rate, respiration parameters and medication dosages are only some of the data the doctor has to document, sometimes by the minute. Moreover, all measures which the anesthesiologist carries out during the patient's stay in the OP area have to be documented too.

In most hospitals the entire documentation process, which includes data delivered by patient monitors and anesthesia equipment, involves handwritten reports by the anesthesiologist. The process not only demands too much time which could otherwise be spent on treating the patient, but also poses a risk to the patient because the notes may not be legible. For example, allergies may be incorrectly recorded or the related paper documents could be lost. Furthermore, false or missing documentation means that not all medical services can be invoiced in full.

Those problems are history at the University Hospital Frankfurt am Main, where anesthesia reports are no longer put on paper. For more than one year Frankfurt has been working with a digital solution for complete anesthesia documentation. Every medical employee in Anesthesia is equipped with an iPad over which all important information about the patient's treatment can be entered and retrieved. More than 150 iPads with the app Sandman.MD are now in use. All patient monitors and anesthetic equipment in the more than 30 centralized and decentralized operating rooms and intervention workstations, such as trauma room and diagnostic areas, deliver their data via Bluetooth to the iPads. Manual documentation activities are reduced to a minimum.

For Prof. Dr. Dr. Kai Zacharowski, Director of the Clinic for Anesthesiology, Intensive Care Medicine and Pain Therapy, the straightforward integration in OP devices and IT is an important factor.

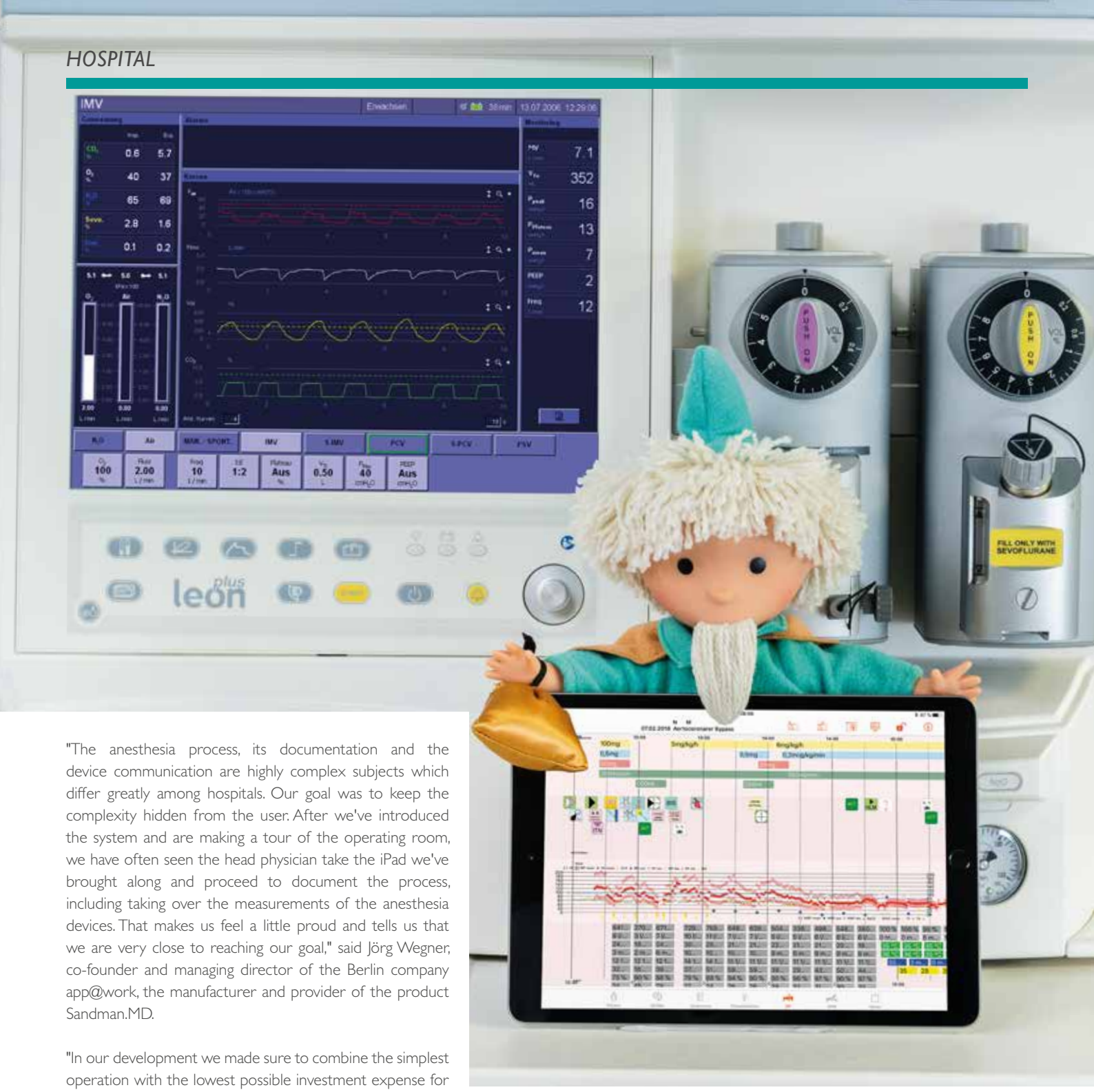
"What's special about Sandman.MD is the online documentation of data from OP devices via Bluetooth-based communication. That's particularly important to us because our patient monitors and anesthesiology devices are not integrated in the hospital network. But of course Sandman.MD with the iPad is integrated in our hospital IT infrastructure. Patient data are transmitted from our HIS (Hospital Information System) ORBIS to an anesthesia server and from there forwarded to the iPads. Pre-medication protocols, anesthesia records and recovery room logs are returned as PDF files to ORBIS, where they can be called up from every PC immediately after completion of each treatment step."

The smooth system integration in the hospital environment continues with the uncomplicated and intuitive operation on the iPad. Dr. von der Groeben, who oversaw the introduction of Sandman.MD in the University Hospital from the medical point of view, said: "We trained our colleagues in groups of five to 10 persons in the afternoon and on the following day they worked with the system in the OP. Throughout the process they had personal one-on-one support, which helped them to overcome initial difficulties and learn how to handle the system quickly and securely."

More than 200 anesthesiological steps, measures and activities, 200 questions and answers about medical history and 250 medications, which are pre-defined in the app, help to simplify standard procedures. Additionally, the iPads can be used to take photos, a new extra that provides a completely new quality in treatment documentation.

With just a click, users can add to the anesthesia record all kinds of documents, from the doctor's letter and the patient's signed consent form to the condition of patient's teeth prior to intubation or a photo of an allergic reaction. The documentation, along with standard boilerplate and plausibility checks, increases the level of safety for patients and for hospital personnel.

Sandman.MD



"The anesthesia process, its documentation and the device communication are highly complex subjects which differ greatly among hospitals. Our goal was to keep the complexity hidden from the user. After we've introduced the system and are making a tour of the operating room, we have often seen the head physician take the iPad we've brought along and proceed to document the process, including taking over the measurements of the anesthesia devices. That makes us feel a little proud and tells us that we are very close to reaching our goal," said Jörg Wegner, co-founder and managing director of the Berlin company app@work, the manufacturer and provider of the product Sandman.MD.

"In our development we made sure to combine the simplest operation with the lowest possible investment expense for the hospital. Because there are so many employees working in anesthesia in the operating rooms, hospitals incur high acquisition costs for conventional PC-based solutions," explained Dr. Stephan-Matthias Reyle-Hahn, head physician at the hospital for anesthesia and interdisciplinary intensive care in the Waldkrankenhaus Berlin-Spandau. A co-founder of app@work, Dr. Reyle-Hahn contributed his more than 30 years of practical experience in anesthesia to the product development.

When, as in Frankfurt, nearly 30,000 operations have been documented with this system, it is almost inevitable that the request for data analysis arises. That too is possible. In addition to standard analysis of OP process times, the user simply presses a key to document relevant activities for specialist medical training, display statistics of the use of hemodynamic monitoring or to evaluate the use of the drug Sugammadex for a specific medical field.

"Anesthesia documentation with EMR (Electronic Medical Record) systems can provide a very valuable data pool for economic and medical analyses," said Dr. Reyle-Hahn. "But most of all, it has to simplify the doctor's work and lead to more comprehensible, standardized processes. In the interest of improving intraoperative treatment quality and thereby providing better health care to the patient."

The best possible health care is a core goal for Prof. Zacharowski, also in his role as vice president of the European Society of Anesthesiology (ESA): "With Sandman.MD we have a tool that the work on the patient supports and does not hinder. It reduces documentation effort, which leaves more time for patients. And that means greater patient safety. Furthermore, our colleagues always have on hand the information required for treatment. We are making anesthesia documentation mobile. Because anesthesia must be mobile."

PRISMA VENT50-C

NOW WITH CONNECTION TO PATIENT MONITORING

In the Intensive Care Unit several medical devices are used for diagnostics, monitoring and treatment of seriously ill patients. Every one of the medical products positioned around the patient's ICU bed has to be set up specifically for the patient by hospital personnel. Additionally, information and data from each medical product have to be checked regularly and documented along with the patient's clinical symptoms.

Yet another complication is that hospital personnel have to register very quickly all relevant information provided by medical products. The situation demands that treatment-relevant information from other medical products are displayed on just one medical product if possible.

Bedside patient monitoring for the purpose of analyzing circulatory functions such as ECG, heart rate, blood pressure and oxygen saturation is a core component in the care of seriously ill patients. The process can be set up on a network so that circulatory-relevant data of all patients in an ICU can be checked via central monitoring in a nurses' station. Patient monitoring offers itself as a central medical product to display data from other medical products such as ventilators. Then, besides monitoring functions, therapy information too is available on a single workstation.

An appropriate interface and interface protocols are required so that ventilators can transmit data and patient monitors can receive data. As a rule, interfaces and protocols are proprietary, i.e., every manufacturer has its own standard. In the interface protocols the quantity and type of data and the data format are defined. Functioning like an interpreter, software drivers ensure smooth communication among medical products in accordance with the relevant interface protocols.

prisma VENT50-C, our ventilator for the treatment of respiratory insufficiency, is equipped with the interface that permits a connection to patient monitoring.

The first step has been taken to connect the prisma Philips driver to Philips monitors. Which data are involved in the connection? Which data from prisma VENT50-C should be presented on a Philips monitor for clinicians in order to generate added value?

Four categories of data are involved:

a) Settings, modes and ventilation pressures in particular
b) Measurements, e.g., tidal volume, respiratory minute volume and respiratory rate
c) Curves of ventilator pressures and flow
d) Alarms

When prisma VENT50-C emits an alarm, the alarm is transmitted via interface to patient monitoring in the nurses' station, where hospital personnel see it immediately and take any necessary measures. That saves time and increases patient safety.

Another task for personnel involves documenting patient-relevant data in the intensive care record, either in paper-based or digital form. A Patient Data Management System (PDMS) permits electronic and, in some cases, automatic documentation.

Data from ventilators, structured in ventilation protocols, must be documented by hand regularly. An online connection via an interface to PDMS makes possible automatic data transmission from a ventilator into PDMS. That too is valuable support for hospital personnel.

primsa VENT50-C also is prepared for connection to PDMS. In the future the prisma VENT50-C driver library will be expanded for other monitoring and PDMS manufacturers.

An important step into the future.

prisma VENT50-C with connection to a Philips monitor

CLAC 2.0 – REGULATION WITH NEW FUNCTIONS

The manual regulation of inspiratory oxygen (FiO_2) for premature babies is often complicated and time-consuming. In a joint project the University Hospital Tübingen, the Medical University of Vienna and Löwenstein Medical developed an algorithm for automated oxygen management for preterm infants called "CLAC" for Closed Loop Automatic Oxygen Control.

The effectiveness of CLAC was validated in multi-center studies for which the Löwenstein Medical neonatal ventilator Leoni plus CLAC was in daily clinical use.

The control algorithm and pulse oximetry measurement were integrated in Leoni plus CLAC to make operation of the CLAC controller as easy and intuitive as possible for the user while ensuring maximum safety. All operating functions, including visualization of the measurement data and alarm settings, are carried out via the ventilator's graphic user interface.

The use of unadulterated SpO_2 raw data from the device's own MASIMO® measurement technology guarantees previously unachieved measurement accuracy which is indispensable for precise and rapid regulation.

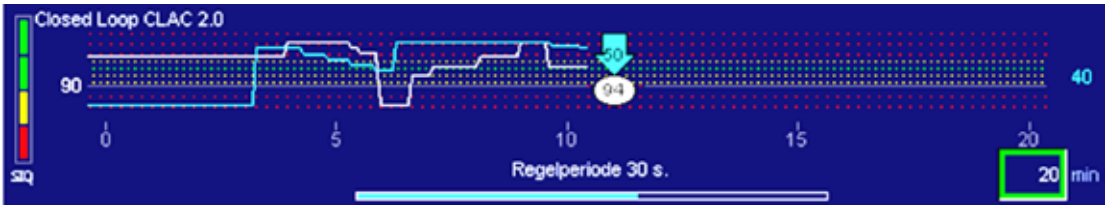
CLAC 1.1 took over the work of clinicians in the routine adjustment of inspiratory oxygen in respiratory gas (Fraction of Inspired Oxygen or FiO_2) in that it continuously monitored the patient's needs and condition and changed the device settings accordingly.

In CLAC 2.0 the algorithm has been expanded with functions for rapid regulation of desaturation up to 70 percent, oversaturation and flexible setting of times for regulation periods.

With the optional "emergency regulation", CLAC 2.0 also regulates oxygen when SpO_2 falls below 70 percent by minimizing the regulation period and incrementally increasing the oxygen concentration.

So that the user is still relieved of routine work, CLAC 2.0 ensures that the algorithm will react reliably in critical situations too.

The user defines the extent of support provided by CLAC. Of course the user has the option of intervening in the automatic control if he/she wants to regulate the oxygen concentration manually.



All relevant information at a glance

nCPAP Generator of the latest generation

ABDOMINAL SENSOR

Monitoring a baby's diaphragm for breathing activities

Diaphragmatic or abdominal breathing is very pronounced in our littlest patients during the first months of life.

It is therefore appropriate to monitor the diaphragm for the infant's breathing activities and to use the signals obtained as a trigger for inhalation and exhalation.

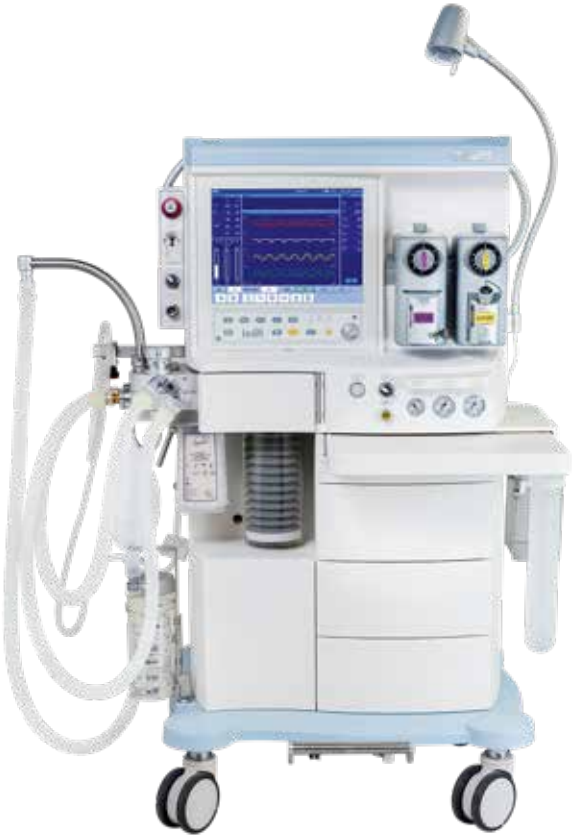
With the Löwenstein Medical abdominal sensor, it is possible to generate reliable trigger signals in non-invasive ventilation without direct intervention in the respiratory system, without adding weight to the patient interface and without increasing dead-space volume.

Leoni plus synchronizes non-invasive ventilation modes s-nIPPV and s-nCPAP with the optional abdominal sensor and simultaneously functions as apnea monitoring in both modes.

The abdominal sensor (Graseby Capsule), which is attached to the baby's abdomen, detects inspiratory and expiratory breathing efforts by means of pressure difference. On the basis of this signal, a trigger for synchronized breathing is created and apnea monitoring is made possible.

CLAC technology with abdominal sensor in use

CHERNOBYL HELP FROM HILDESHEIM



Ukrainian children want to live and breathe.
Aktion Tschernobyl-Hilfe e.V. of Hildesheim helps the children by delivering urgently needed medical devices to the Ukraine. Although the country is "just around the corner", the conditions in its hospitals are very challenging and far removed from what we know at home.

The aid association primarily supports the regional hospital in Lutsk, which is responsible for all seriously ill children of the Wolhynsker area, and delivers medical devices of all types, has them installed and shows doctors how to use them. Since healthcare reform was completed in the Ukraine, sick children from all parts of the country can be admitted and treated in this large children's hospital. Doctors from other hospitals travel to Lutsk for training.

The primary focus of the action is to help the Ukrainian medical personnel to help themselves. So the association invites doctors to Hannover and Hildesheim for intensive courses (in close cooperation with the Hannover Medical School), gives them medical assistance so that they can give the children in their country direct and fast support, change things and not feel as though they are asking for favors. We are pleased that Löwenstein Medical contributes to the efforts and supports association Chairperson Rita Limmroth in her work for children in the Ukraine.

Back in 2015 we delivered children's ventilators and an anesthesia device and in 2018 shortly before Christmas, two intensive care ventilators and diverse consumable articles, all of which were gratefully accepted. In 2019 we have already delivered another intensive care ventilator and a Leon plus anesthesia device.

Hildesheim, Germany

LÖWENSTEIN
medical

Leon mri

Advanced anesthesia support specifically for use in the cardiac catheterization or MRI

HOSPITAL HOMECARE DIAGNOSTICS

CARA FULL FACE – FACE THE DAY WELL-RESTED

Perhaps you remember reading in the last issue of the Löwenstein Medical Magazine: "The team has already begun working on the next mask. The working title, however, will remain a secret for now…" Really?
You might have already figured it out. After all, at Löwenstein Medical, the full face mask always follows the nasal mask.

CARA Full Face creates the CARA family.

THE FOCUS

The CARA family focus has not changed. CARA stands for a good fit, a quiet and diffuse exhalation system, a lightweight, small and nearly indestructible mask, whether it's a nasal or full face model. By its nature, the development of a full face mask poses a challenge – in the truest sense of the word. CARA had to provide a perfect fit around the nose and had to be comfortable yet stable. The lower part of the face had to be taken into consideration along with facial differences from one person to the next.

THE MASK CUSHION

The mask cushion had to have the answer. If it isn't any good, the entire mask fails the user's test and won't be used anymore. Then the question arose about whether we could simply take over the mask cushion from the CARA nasal mask. Yes, some parts. The upper portion of the mask cushion is similar to the nasal mask's. It is soft and supple, yet stable and cut somewhat wider across the bridge of the nose. A few adjustments were made here and there so that the upper portion matched the lower portion. Finished.

Almost. Now for the lower portion. Any special requirements? Of course! The mask cushion had to be airtight whether the patient's mouth was open or closed. Very often full face masks are worn by patients who use BiLevel devices, so they have to be able to withstand different pressures. The cushion had to fit every face, regardless of whether the face is gaunt or round, bearded or clean-shaven, with receding or strong chin, wrinkles or lines.

The answer came from market feedback and a simple idea of how the lower portion of the cushion had to look. Plain and simple, it needed a different surface than the upper portion's, i.e., soft and supple, but smooth and adherent. The jaw would then be held in place perfectly and the mask cushion could not slip off.

No matter whether the mouth was slightly open or the lower jaw dropped completely open.

THE PATIENT ACCEPTANCE TEST

We'd thought the theory through and completed the design of CARA Full Face. The time had come to put the theory to a practical test. After all, it does no good to develop a theory that doesn't work in practice. During the development phase some tests were conducted with patients. Now the final test was to be made.

It was intense. Several hundred patients took part, most of whom were looked after personally by the Team Patient Interface. The patients wore the masks through many nights and filled out questionnaires. A substantial amount of feedback made its way to us. The questionnaires were quantitatively analyzed and every personal comment was read and evaluated. It was a big job. If you glued all the questionnaires together, you'd have a paper trail several kilometers long.

Another lightweight mask in the family

THE FEEDBACK

In the end everything worked. The patients were very satisfied. The patient counselors received positive feedback and said they too were satisfied. Finally, all the positive feedback from patients and counselors went to the Team Patient Interface and made the team very happy.

Now we were off!

THE COMMUNICATION

Almost. The chairman of the board at a pharmaceutical company once said, "Medications consist of 30 percent chemicals; the rest is communication." We had completed 30 percent and now for the communication. Okay, to tell the truth, mask development is more than 30 percent, but communication is nevertheless essential.

So we worked out a communication concept, signed up our "CARA patients" and organized a photo shoot and a video shoot. For some time now Löwenstein Medical has relied on "moving pictures" that can be seen on our Löwenstein Medical YouTube channel. Videos and tutorials demonstrate in a simple way the use of the product and provide tips and tricks.

Now, CARA Full Face needed moving pictures, so we got started. The storyboard for the video was written, equipment and props in the CARA Full Face palette were obtained and pretty soon the videos were shot over the course of demanding but productive and successful days of filming.

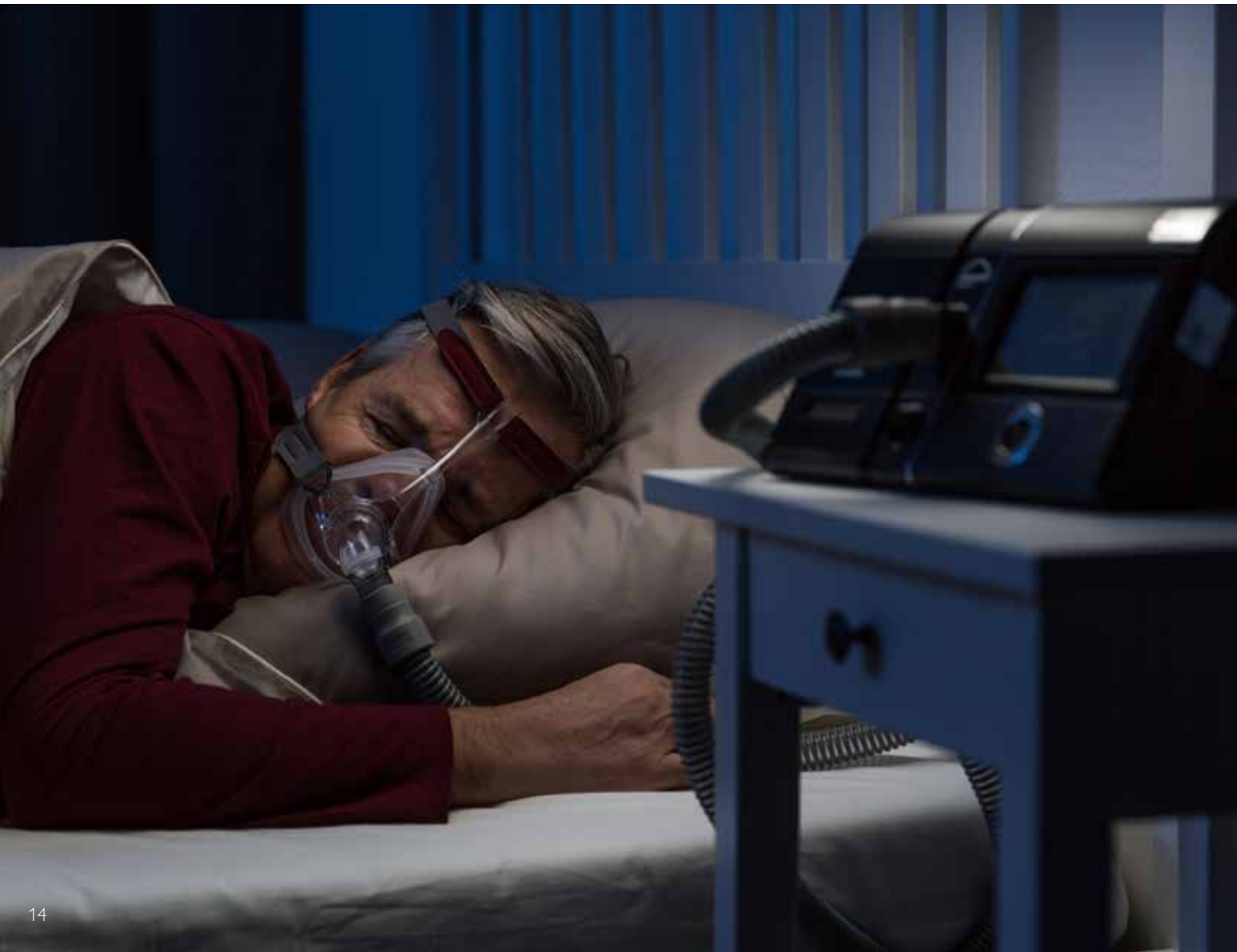
In the communication concept we also specified which brochures and information materials had to be prepared. We wrote the copy and worked on the graphic design, translated everything into different languages and went into production.

THE FINAL SPRINT

All set? Yes! All that's left is to wrap up the development process with all its regulatory requirements, make sure the material supply chain is in place and then production of CARA Full Face can begin.

THE RESULT

CARA Full Face, the best full face mask we have ever developed and produced for our customers. CARA Full Face is certain to repeat the success achieved by CARA.



NEU
CARA
Full Face

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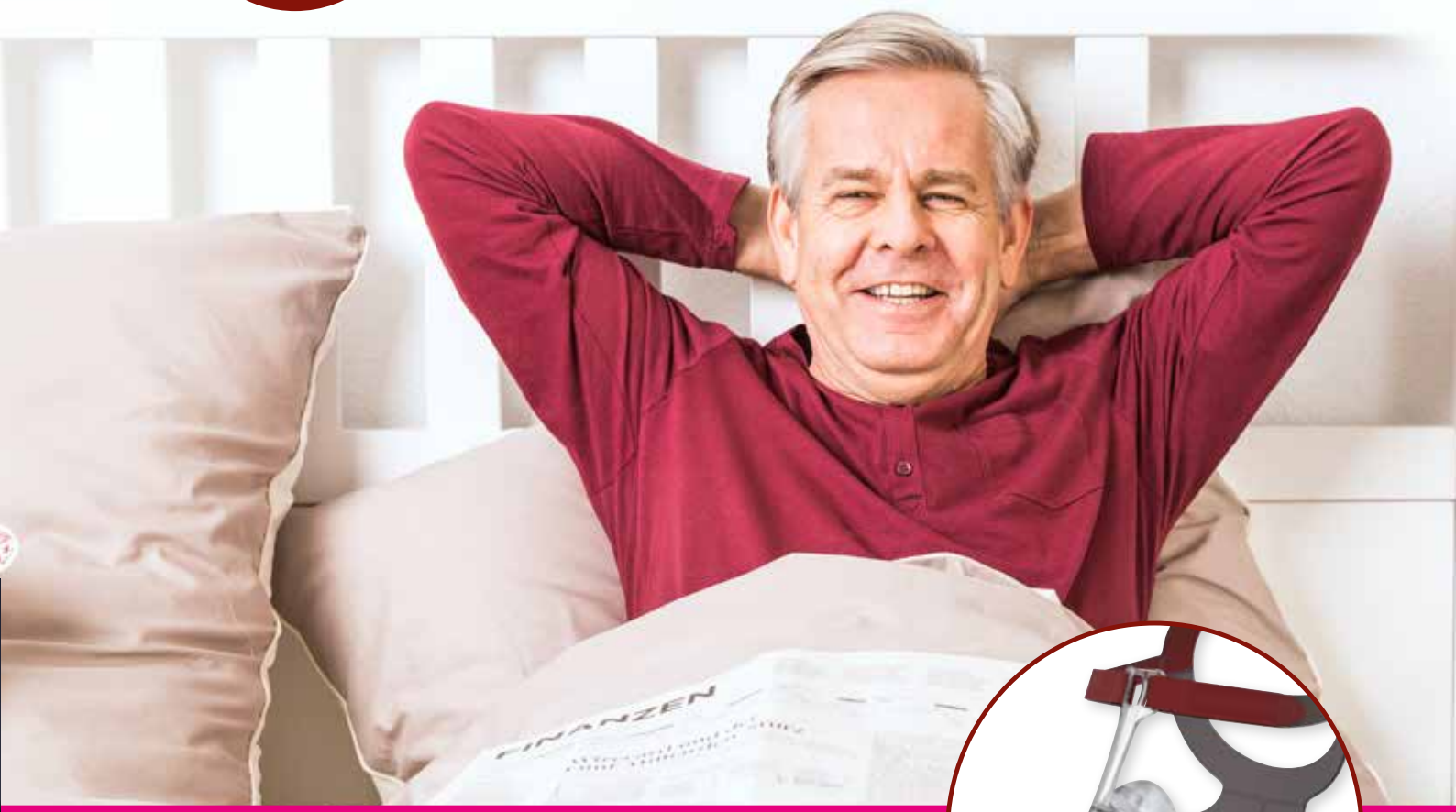


CARA Full Face

Face the day well-rested.

The new CARA Full Face now offers all full face mask wearers the comfort of the successful CARA nasal mask and completes the CARA family.

Experience perfect fit, great wearing comfort, a gentle, quiet exhalation and good skin compatibility. Let us convince you of the lightness, the soft, supple mask cushion, adjustable headgear and many other clever details.

HOSPITAL HOMECARE DIAGNOSTICS

prisma JOURNAL

The importance of compliance

Given the symptoms and prevalence of Sleep-Disordered Breathing (SDB), the disease has both clinical and health economics significance. More than five percent of the adult population in Germany is affected by SDB. Major symptoms range from extreme daytime sleepiness to an involuntary propensity to fall asleep, a problem that greatly increases the risk of accidents. Furthermore, untreated sleep-related respiratory disorders can lead to serious secondary diseases of the cardiovascular system and to reduced life expectancy.

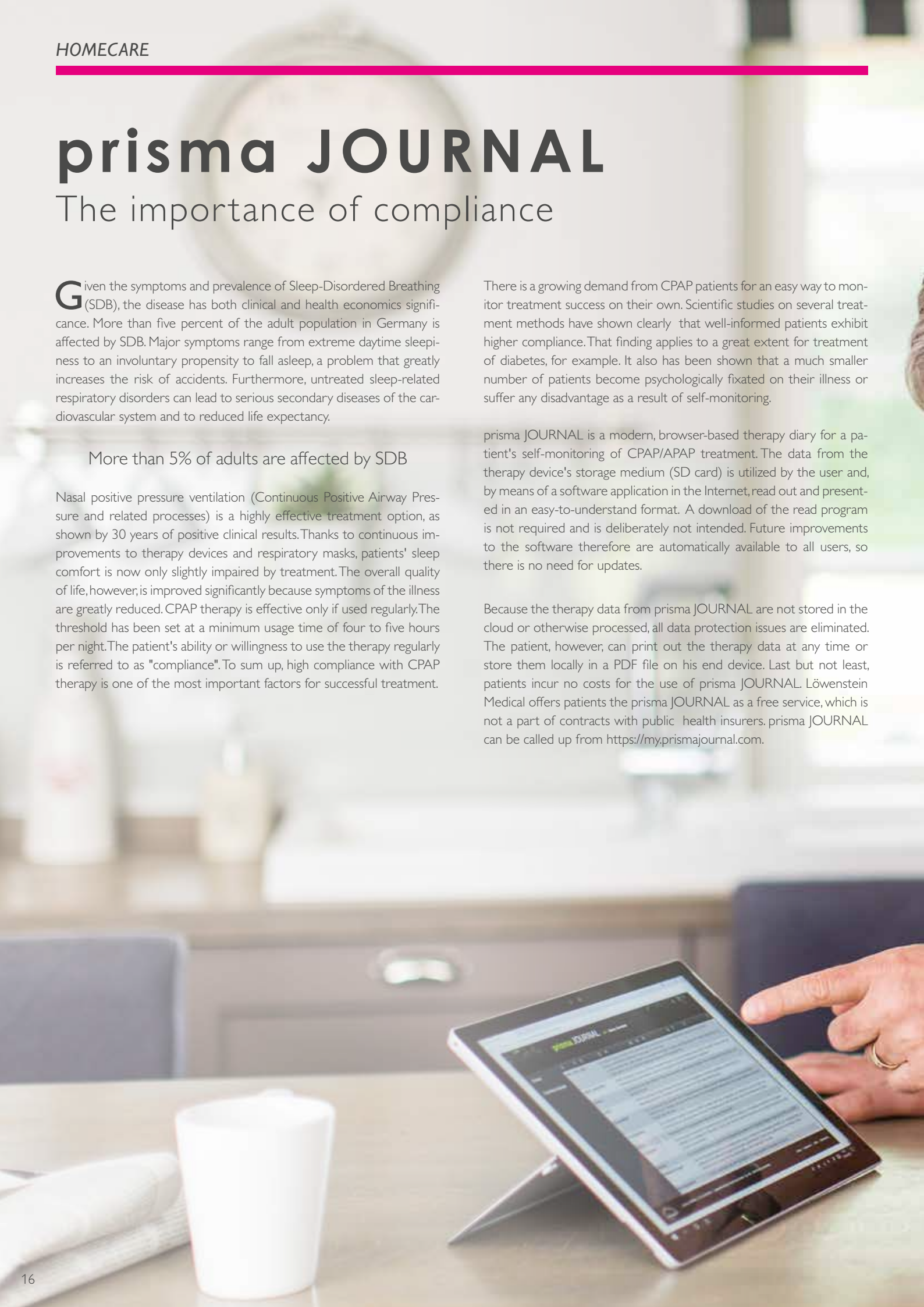
More than 5% of adults are affected by SDB

Nasal positive pressure ventilation (Continuous Positive Airway Pressure and related processes) is a highly effective treatment option, as shown by 30 years of positive clinical results. Thanks to continuous improvements to therapy devices and respiratory masks, patients' sleep comfort is now only slightly impaired by treatment. The overall quality of life, however, is improved significantly because symptoms of the illness are greatly reduced. CPAP therapy is effective only if used regularly. The threshold has been set at a minimum usage time of four to five hours per night. The patient's ability or willingness to use the therapy regularly is referred to as "compliance". To sum up, high compliance with CPAP therapy is one of the most important factors for successful treatment.

There is a growing demand from CPAP patients for an easy way to monitor treatment success on their own. Scientific studies on several treatment methods have shown clearly that well-informed patients exhibit higher compliance. That finding applies to a great extent for treatment of diabetes, for example. It also has been shown that a much smaller number of patients become psychologically fixated on their illness or suffer any disadvantage as a result of self-monitoring.

prisma JOURNAL is a modern, browser-based therapy diary for a patient's self-monitoring of CPAP/APAP treatment. The data from the therapy device's storage medium (SD card) is utilized by the user and, by means of a software application in the Internet, read out and presented in an easy-to-understand format. A download of the read program is not required and is deliberately not intended. Future improvements to the software therefore are automatically available to all users, so there is no need for updates.

Because the therapy data from prisma JOURNAL are not stored in the cloud or otherwise processed, all data protection issues are eliminated. The patient, however, can print out the therapy data at any time or store them locally in a PDF file on his end device. Last but not least, patients incur no costs for the use of prisma JOURNAL. Löwenstein Medical offers patients the prisma JOURNAL as a free service, which is not a part of contracts with public health insurers. prisma JOURNAL can be called up from https://my.prismajournal.com.




my.prismajournal.com

The prisma JOURNAL can be used with all modern CPAP and APAP devices (prisma SOFT and SMART, prisma 20C and 20A) from Löwenstein Medical. For technical reasons, prisma JOURNAL cannot be offered for BiLevel devices at this time.

The following therapy criteria are displayed in prisma JOURNAL: usage (hours), Apnea-Hypopnea Index (AHI), pressure needs and mask leakage. In prisma SOFT and prisma SMART devices of the newest design, for the first time an indicator for restorative deep sleep during therapy also will be given. The straightforward design of the software ensures intuitive use. Should users require help, however, the software contains detailed instructions (tutorial) in which all operation steps are explained.

As with all parameters, the patient can see the usage hours of therapy in a period from one month up to one year and thereby determine his personal compliance.

Display of usage

Another important point for self-monitoring of therapy is mask leakage. Under the menu item "Leakages" the portion of therapy time with a critically high leakage is shown. Low leakage is very important for effective and comfortable treatment. Therefore, to allow unrestricted device reaction and ensure high therapy effectiveness, the phases with high leakage should be reduced to a minimum or prevented entirely. When the portion of therapy time with critical leakage exceeds five percent, the fit and air-tightness of the mask should be checked.

The display of pressure needs is particularly interesting for patients who use Automatic Positive Airway Pressure (APAP) devices. During APAP treatment the therapy devices continuously analyze the patient's nighttime breathing and, on the basis of the results, independently adjust the pressure to be delivered to the mask. The treating physician can set a pressure limit which the device may not exceed or fall below. For purposes of therapy monitoring, prisma JOURNAL reports the maximum pressure which was sufficient for 90 percent of the time; in 10 percent of the time the pressure was higher. Many clinical studies have proven that the pressure applied for 90 percent of the time is adequate for APAP therapy. If the patient sees, for example, that the 90-percent value increases significantly at certain times, he may conclude that the therapy conditions changed. Under CPAP therapy the patient sees the permanently set pressure.

A key criterion for therapy success is the Apnea-Hypopnea Index (AHI), which provides the number of sleep-related respiratory disruptions. Apnea is defined as a complete cessation in breathing, while hypopnea is a phase of diminished breathing. If over the course of several nights, AHI is greater than 10, it could be an indication that the therapy should be optimized.

Display of Apnea-Hypopnea Index

CPAP or APAP therapy is particularly effective when the patient achieves good sleep quality with the mask and reaches recuperative deep sleep phases. To estimate deep sleep, the therapy device analyzes certain respiratory parameters during therapy and shows the result as the deep sleep indicator. If the patient still feels tired during the daytime despite therapy and no deep sleep phases are shown for the majority of the nights, it could indicate a problem with sleep quality.

Under certain circumstances the patient may have questions about self-monitoring of therapy with prisma JOURNAL which cannot be answered by the previously mentioned tutorial. For help with medical questions, such as mask leakage, the first contact for the patient is the counselor at the medical technology company that supplied the device.

KNOWLEDGE GAINED FROM 37 YEARS OF PAP THERAPY

WHAT DO WE KNOW ABOUT THE BENEFITS?

[1] Patil SP, Ayappa IA, Caples SM, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2019;15(2):301–334.

[2] Randerath W, Bassetti CL, Bonsignore R, et al. Challenges and perspectives in obstructive sleep apnoea : report by an ad hoc working group of the Sleep Disordered Breathing Group of the European Respiratory Society and the European Sleep Research Society. Eur Respir J. 2018; 52(3)

[3] Yagihara, F.; Lorenzi-Filho, G.; Santos-Silva, R. Patients with obstructive sleep apnea are perceived as younger after treatment with continuous positive airway pressure. Chest 2019; DOI: 10.1016/j.chest.2019.03.015.

The first reports about CPAP therapy for Obstructive Sleep Apnea were published in 1981. Now a task force of the American Association of Sleep Medicine (AASM) has systematically reviewed the studies published up until 2018 in order to present the knowledge accumulated since then [1].
In introductory remarks, the task force estimates the prevalence of OSA in the USA at 26 percent of the adult population and 10 percent for moderate to severe OSA. Established consequences mentioned include increased risk of sleepiness, impaired quality of life, cardiovascular diseases and accidents. Does PAP therapy counteract the disorder and, above all, its consequences?

26% of adults in the USA suffer from Obstructive Sleep Apnea

Using the PICO method, the task force conducted a search of the literature and weighted the articles found according to their relevance, quality and degree of evidence. Of the articles retrieved, 184 fulfilled the minimum criteria. Among other things, the following statements could be derived from the publications:

Found to be effective in the treatment of Obstructive Sleep Apnea, PAP therapy reduces the **Apnea-Hypopnea Index** *(AHI) to an average of four remaining events per hour. Evidence is high.*

PAP therapy reduces **subjective sleepiness** *to a mean 2.4 points in the Epworth Sleepiness Scale. Those patients who exhibit above average tiredness prior to the introduction of therapy obtain greater benefits from treatment. As expected, patients who are not tired despite sleep apnea see no benefit with regard to sleepiness. Evidence is high.*

PAP therapy improves sleep-related **quality of life**. *Evidence is moderate to high. Because the studies are heterogeneous, no numerical value is provided.*

PAP therapy reduces **blood pressure** *by 2-4 mmHg on average in similarly very heterogeneous studies with regard to design, inclusion criteria, measurement methods, etc. There are indications that the effect's intensity depends largely on the level of a patient's initial blood pressure and AHI and also on PAP compliance.*

PAP therapy potentially reduces the risk of **cardiovascular events** *right up to mortality. On this issue, however, the studies yielded different results. Supporting evidence until today is low to moderate. Similar findings were reported for neurocognitive and psychological impairments (e.g., anxiety disorders and depression), for the risk of accidents, limitations of LVEF in heart failure and the number of hospital stays.*

In total **the benefits of PAP therapy clearly outweigh the potential side effects**. *A proper patient briefing prior to therapy and an ideal selection of accessories (e.g., a humidifier) can reduce any possible side effects. Evidence to date is rather low.*

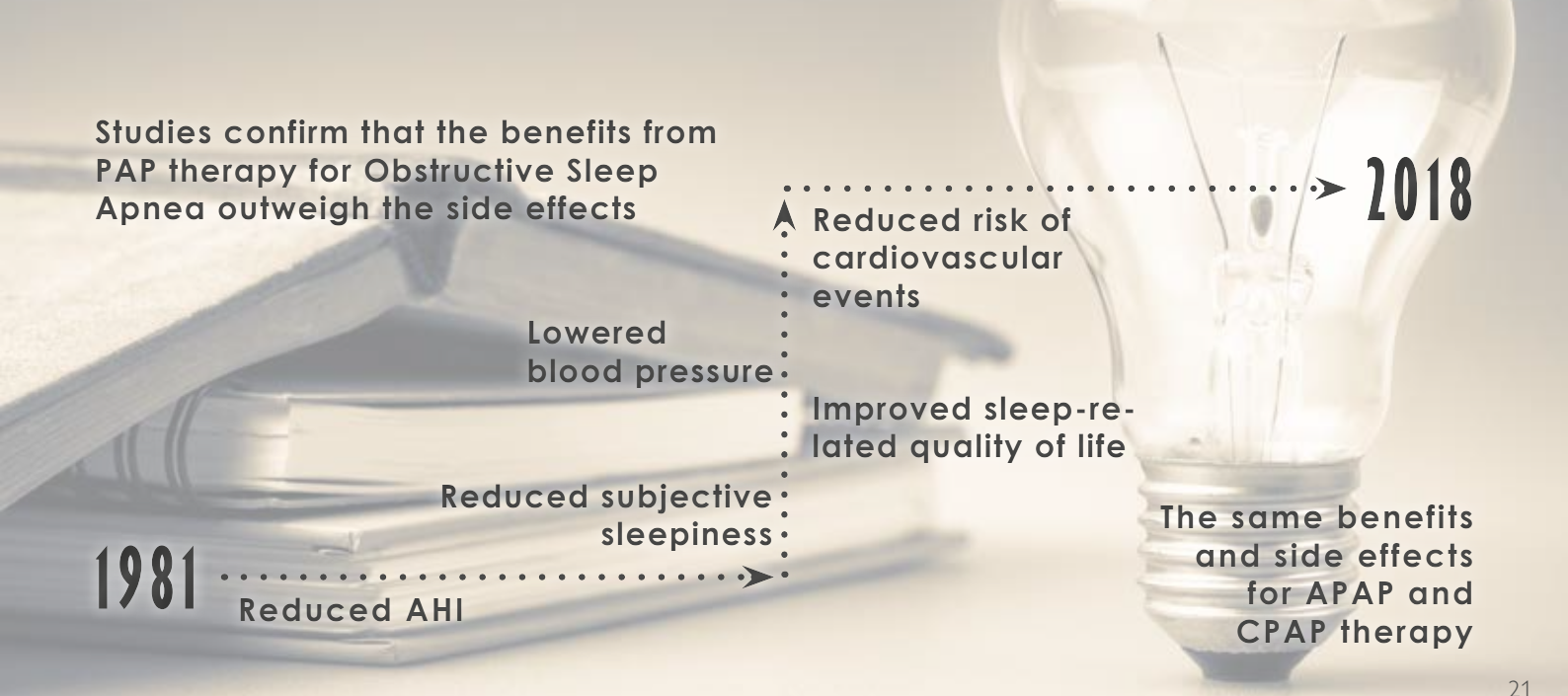
APAP *and* **CPAP** *therapy are of equal value with regard to benefits and side effects. Nevertheless, some patients prefer one type of therapy over the other. Evidence is moderate to high.*

One of the greatest **challenges** *involves the patient's motivation to use the therapy when he or she does not suffer from daytime sleepiness. More attentive* **patient care** *provided through traditional means or telemedicine (e.g., digital feedback) can increase therapy adherence to an average level.*

Thus far, less evidence is available for all **alternative types of therapy** *than for PAP therapy.*

The European associations ERS and ESRS also have assembled the knowledge gained to date on Obstructive Sleep Apnea. [2]. The work takes into consideration additional aspects such as sleep diagnostics and looks to the future. What scientific emphasis is needed to put the focus on personalized therapy in which the ratio of benefits to side effects can be improved?

In recent weeks some additional studies have been published which could not be included in the reviews of the medical associations and thereby further increase the evidence for the benefits of PAP therapy. Current scientific key topics are improvement in kidney function, certain cardiac arrhythmia and the risk of cardiovascular events. Furthermore, there are indications that OSA patients look younger after only one month of PAP therapy – which in isolated cases can serve to increase patient motivation [3].



HAVE YOU HEARD?

In the new category "Have you heard?" we inform you quickly and concisely of interesting facts on many different subjects involving the entire Löwenstein Group.

YOUTUBE CHANNEL

On our YouTube channel you'll find not just videos on our newest products but also user tips and tutorials about the correct use of our products. See for yourself how varied our activities are and subscribe to our channel!

OUR LOGISTICS CENTER CONTINUES TO GROW

The first expansion of our logistics center at our Neuhäusel site was completed in 2015 and now the next expansion plans are moving full steam ahead. Within the next two years, the warehouse area is to be increased by two-thirds of the current space to improve our delivery capability and delivery times for our customers.

LARGEST SINGLE ORDER IN POLYGRAPHY

A single order for almost 200 polygraph devices is the largest order in the history of Löwenstein Medical. It came about when we were developing a customized solution for our customer Viollier in Switzerland.

NEWSLETTER

You're always well informed by our newsletter. We tell you all about our three main business areas of Homecare, Hospital and Diagnostics. From our newsletter you'll also get information about product innovations. Receive our newsletter once per quarter and read about subjects that interest you.

RESPIRATORY CENTER ANSBACH CELEBRATES

Our first respiratory center opened on 1 September 2003 in Ansback and so celebrated its 15th anniversary at the end of last year. From the very beginning our patient care concept has been well received by our patients. It is especially important for us to look after our patients competently at local sites. Have you heard that we are now represented throughout Germany by about 180 Sleep-Respiratory Centers and 30 branch offices? That means we have more business locations than any other competitor!

SALVIA MEDICAL IS NOW ...

Löwenstein Medical Innovation. As of 1 January 2019, the company's name shows that it belongs to the Löwenstein Group. Today our manufacturer in Kronberg goes by the name Löwenstein Medical Innovation. How was the name chosen? The name says what the company does. LMI works every day on innovations in intensive care ventilation. In addition, LMI is planning the construction of a new building in Steinbach in Taunus.

THE WAIT WILL SOON COME TO AN END

Production of our new intensive care ventilator elisa 500 has begun. We look forward to the delivery of the first devices. Equipped with the most efficient turbine now on the market, elisa 500 impresses with its completely configurable, agile Graphical User Interface. Learn more about our new device with the QR code.

ELISA 800 VIT MOVES INTO THE MIDDLE EAST

Excitement was in the air when the intensive care ventilator elisa 800 VIT was presented in Saudi Arabia at the beginning of this year. We are hoping for the device's success in the Middle East. Saudi Arabia is a market with great potential. Of course we want to succeed with our local partner Azeer.

IRAQ – MEDICAL TECHNOLOGY "MADE IN GERMANY" IS IN DEMAND

Following up on the largest single order for hospital ventilators ever, we recently received large orders worth millions for anesthesia devices, patient monitors, compressors and much more. Through the use of devices in several university hospitals, our installed base stretches across the entire Iraq territory (including Kurdistan).

COMPLEXITY REDUCTION FOR OUR ANAMED PATIENTS

By 1 June 2019 Anamed will transfer all business operations and supply contracts to Löwenstein Medical. The objective of this reorganization is to reduce complexity for our patients. Effective immediately, there is just one contact for all patients throughout Germany – and that is Löwenstein Medical.

GROUNDBREAKING EXCHANGE AT MATHILDE ESCHER HEIM SYMPOSIUM

The second Mathilde Escher Heim Symposium on 7 March 2019 was innovative in many ways. It was the first time Löwenstein Medical Schweiz worked with Prof. Dr. Konrad Bloch, vice director of Pulmonology at the University Hospital Zürich, to organize an event of this size. Renowned experts in pulmonology from Switzerland, Germany and Denmark presented new findings on long-term ventilation which can revolutionize treatment of patients with chronic respiratory insufficiency.

HOME FOR PATIENTS WITH MUSCULAR DYSTROPHY

The Mathilde Escher Heim, which served as host on that day, offered the ideal setting for the event. The home in the center of Zurich specializes in people with Duchenne muscular dystrophy. The light-filled, completely wheelchair-accessible rooms accommodate up to 46 children, teens and adults in different resident groups. The subject of respiratory insufficiency frequently comes up here. Given the episodic, progressive deterioration of muscles in this severe illness, sooner or later all Duchenne patients rely on respiratory support devices. "Thanks to the use of these devices, the life expectancy of our clients with Duchenne muscular dystrophy has been increased markedly," said Jürg Roffler, manager of the Mathilde Escher Heim, in his presentation about the safety issues involved in treating ventilated patients. Looking after such clients makes high demands on the development of safety standards. "We need devices that are suitable for external mobile use. That means they have to be vibration, impact, heat and water resistant," he told the manufacturers. Moreover, it is imperative to have a secure tube connection that prevents inadvertent disconnection.

QUALITY OF LIFE DESPITE LONG-TERM VENTILATION

Leading into the subject of long-term ventilation, Anne-Christin Stöwhas, senior physician at University Hospital Zürich, spoke about the practical aspects of non-invasive and tracheostoma ventilation of Duchenne patients. In his presentation, Prof. Dr. Wolfram Windisch, head physician in pulmonology in the Kliniken der Stadt Köln, addressed the topic of non-invasive ventilation in cases of Chronic Obstructive Pulmonary Disease (COPD). His summary: "There is clear evidence for non-invasive ventilation in COPD if ventilation is oriented toward reducing increased $PaCO_2$" (i.e., partial pressure of carbon dioxide in arterial blood).

Windisch also promoted the idea of using high ventilation pressures of more than 20 millibar, a technique he said was initially met with scepticism.

Dr. Dan Adler and Dr. Jean-Paul Janssens from the University Hospital Genf discussed the clinical and physiological monitoring of patients with non-invasive ventilation. For those patients Adler developed a monitoring questionnaire that covered the three areas of airway symptoms, sleep quality and treatment-related side effects, subjects which are essential for the quality of life for such patients.

From a clinical perspective, Janssens underscored the importance of regular, standardized monitoring of patients, which includes a thorough medical history, documentation of symptoms, blood gas analysis, nocturnal oxygen saturation and ventilation software.

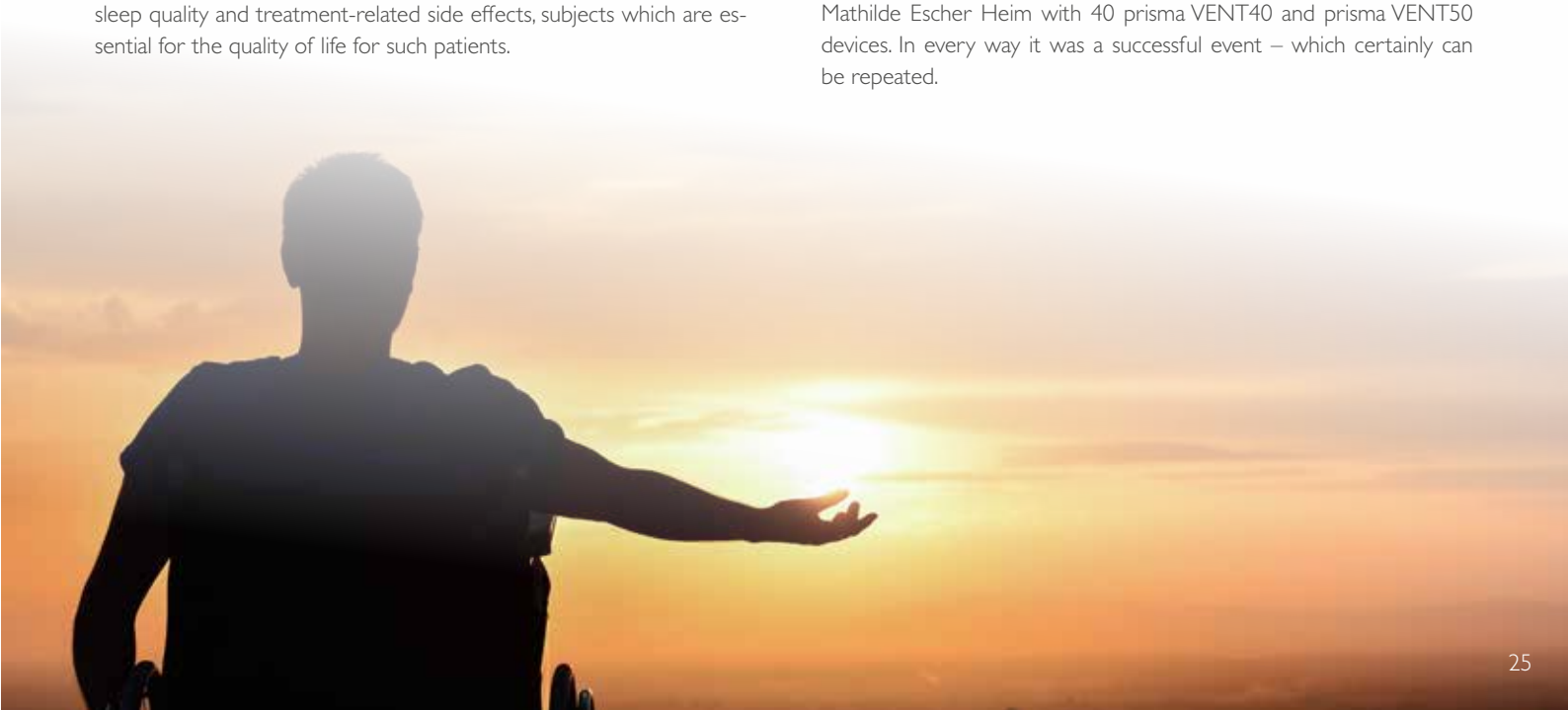
HIGH-FLOW: SUITABLE BEYOND INTENSIVE CARE

In his lecture, the pulmonologist Dr. Bloch spoke about a new type of treatment, High Flow Oxygen (HFO) therapy, and reported on clinical experience with it in an acute care setting. In HFO respiratory gas is enriched with oxygen, humidified, heated and then applied at a high flow via a special nasal cannula. "High-flow therapy reduces the work of breathing, generates a slightly positive pressure in the upper airways and decreases the dead-space ventilation," said Bloch. Because HFO effectively treats hypoxemia patients with high oxygen needs, whether the patient breathes through nose or mouth, the therapy is a valuable treatment option for patients with advanced respiratory insufficiency.

Until now high-flow was used primarily in intensive care and neonatology, but is now being applied more often in cases of chronic respiratory illnesses. In a 12-month study a team which included Prof. Dr. Ulla Weinreich of Denmark, Dr. Line Hust Storgaard, Dr. Hans-Ulrich Hockey and Dr. Brigitte Schantz Laursen investigated the effect of High-Flow therapy on COPD (Chronic Obstructive Pulmonary Disease) patients. It is the only long-term study conducted to date in the homecare area. Some of the examined patients were successfully treated with HFO. Among other things, there was a reduction in symptoms of AECOPD (Acute Exacerbation of COPD) and with it a reduction in the hospitalization rate. In addition, treated patients were capable of walking longer distances. As a result, the subjectively assessed quality of life was significantly higher.

NUMEROUS VISITORS AND A COMMITMENT

More than 100 visitors including pulmonologists, nurses, medical practice assistants and representatives from all over Switzerland attended the symposium. The lively discussions and many questions prove the timeliness of the studies presented and the relevance of the discourse on the subject of High-Flow Therapy. In a perfect ending, Löwenstein Medical received the commitment to equip Duchenne patients in the Mathilde Escher Heim with 40 prisma VENT40 and prisma VENT50 devices. In every way it was a successful event – which certainly can be repeated.



ADDED VALUE FROM VIDEOS FOR INFORMATION DISSEMINATION

The distribution and use of video material are moving toward the media forefront. Will companies jump onto this train? Does this method for disseminating information really bring added value for customers and business partners?

In times of unending information overload, complex subjects in particular do not get much attention when presented only in written form. Videos, however, offer a way to reduce the complexity of topics requiring explanation. Especially when clinical pictures, causes, side effects, treatment methods and therapy algorithms are concerned, the medium of a video is interesting for the relevant target group.

"With almost two million monthly users, YouTube is the world's largest video-sharing website."

Videos also help the user to recall the message by tapping emotions and telling stories. They simultaneously engage two receptors (auditory and visual senses) to take in the information.
The advantages of video are clear. Now to the question of information dissemination. Above all, the target group should be able to find information almost everywhere and call it up at any time. The video-sharing Website YouTube is the world's second-largest search engine, right behind Google. The platform has nearly two billion users. Every minute 400 hours of video material is uploaded. The YouTube user structure covers a broad spectrum.

"400 hours of video material uploaded every minute."

Many analyses claim that the target group of every company and of every industry can be reached via the platform. Because the target groups of the healthcare industry are highly diversified and possibly not comparable to other industries, we determined to form our own picture of user behavior in our target group. For a detailed analysis, we limited our investigation to our patient base in the field of sleep therapy.

The results of the analysis were very positive. More than two-thirds of our patients already use the platform, that is, the information medium of video. Of those patients, a majority use the medium to search for information on health topics. We also discovered that interest in this group is very high when it comes to videos about sleep therapy. To sum up, the analysis confirmed for us the previously described advantages of video as an information medium and the usefulness of making videos available on the YouTube platform.

"YouTube is the world's second-largest search engine after Google."

Since then we have continued working on new videos on a very broad range of topics from product introductions and tips on product use to hygienic reprocessing and much more. We conclude from the statistics that videos about the use of respiratory masks and the operation of sleep therapy devices generate a lot of interest. Our objective is to fill the channel with interesting content. You can stay up-to-date when you subscribe to our YouTube channel. It's easy to do with your Google account.

From here you can go directly to our YouTube channel:

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