

LÖWENSTEIN medical MAGAZINE



November 2018 Issue

SONATA

The new polysomnograph.

PRISMA CLOUD

Security in telemedicine.

HIGH-FLOW

The logical addition to respiratory therapy.



INTRODUCTION

Dear Patients, Customers, Employees and Friends,

More than one-quarter of the adult population suffers from chronic sleep disorders, which have clinical significance for the affected persons. More than 80 different clinical sleep disorders have been documented. It has been scientifically proven that some sleep disorders, e.g., sleep apnea, correlate with reduced life expectancy. Sleep medicine is a relatively young interdisciplinary specialty which has established thorough diagnostic investigations of sleep disorders and has achieved some spectacular treatment success. On both personal and social levels, sleep medicine has already become very important. It is expected that its value will continue to increase around the world.

Healthcare systems in countries around the world follow national policies. Given the great number of affected patients, it is no wonder that sleep medicine is developing in different ways in Germany and abroad. Sleep apnea services at a national level in France, for example, are evolving toward continuous improvement in quality. Modern approaches such as telemedical care at the patient's home play a major role in development there. In contrast, the design of patient care services in Germany is being left to the individual health insurance companies, which tend to favor the least expensive provider. Innovative diagnostic and treatment methods are hardly considered for reimbursement and are not even listed as benefits provided by health insurers. The German healthcare system, which is increasingly disconnecting itself from the progress made in medical and medical technology in this field, is falling behind in comparison to other European countries. Consequently, German medical technology companies like Löwenstein Medical are now successfully launching some of their innovative medical products in foreign markets, but not in the domestic market because the basis for compensation for medical centers and care providers is lacking.

Despite these difficulties, which may very well be temporary, we, as a company, are still certain that sleep medicine has glowing prospects. Our reasons are not based on the previously mentioned number of affected patients, but rather on the incredible trove of scientific findings whose relevance in the long term cannot be ignored by any healthcare system in a developed country. There is a higher logic in medicine which maintains that clinically successful diagnostic and treatment concepts always find their appropriate place in the long term, regardless of healthcare policies and economic obstacles. Support for this process in an open and modern society is bolstered by the patients' easy access to information.

In this issue we will report on some new developments and current findings in sleep medicine. We hope you enjoy reading our customer magazine.



THE ELISA FAMILY

The future of Intensive Care Ventilation

- Innovative
- Intuitive
- Sustainable



HOSPITAL HOMECARE DIAGNOSTICS

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SONATA – THE NEW POLYSOMNOGRAPH

What the future will bring to polysomnography is still unknown. We are certain, however, that Löwenstein Medical is very well prepared with the new 65-channel PSG system Sonata. We were motivated to develop this new PSG system by the desires and requirements of our customers and by more than 25 years of experience in sleep diagnostics. Sonata is a modern, attractively designed polysomnography system at the highest technical level with complete flexibility and extensive functionality. Of course Sonata also fulfills all AASM criteria. No matter what the examination models will look like in the future, Sonata offers diverse solutions for different areas of application. The focus is on greater patient comfort, reliable findings and effective management of hardware and software.

A special function of the system is the integrated differential pressure measurement, which can determine the patient's actual respiratory flow volume. The special T-Adapter used for this purpose has two pressure measurement points with an integrated, precisely defined cross-sectional constriction between them. The narrowing causes an increase in the speed of the flow and a decrease in static pressure. The resulting pressure difference is a measure of the flow volume.

FLEXIBILITY

We can no longer imagine our personal or professional lives without wireless connections. We are now facing strong demand for cable-free systems for polysomnographic examinations. Sonata gives the customer two options for conducting patient measurements (online). The test can be made via a WiFi connection or a hard-wired device. The main advantage for the user is that a switch can be made between WiFi transmission and hard-wired data transmission during a sleep recording without interrupting the recording. Even if there is a disruption in the WiFi, the data integrity will be maintained.

International markets have a variety of requirements for a PSG system. One of the most important is the possibility of making an offline polysomnography recording. Sonata meets the challenge with video and audio functions and recording and saving data from therapy devices.

For even more flexibility, Sonata is equipped with two freely configurable ExG channels. Depending on the customer requirements, they can be defined for EEG, EOG, EMG or ECG tracings so that specific issues can be investigated.



titration device prismaLAB

*Modern.
Flexible.
Diverse.
Future-proof.
Economical.*

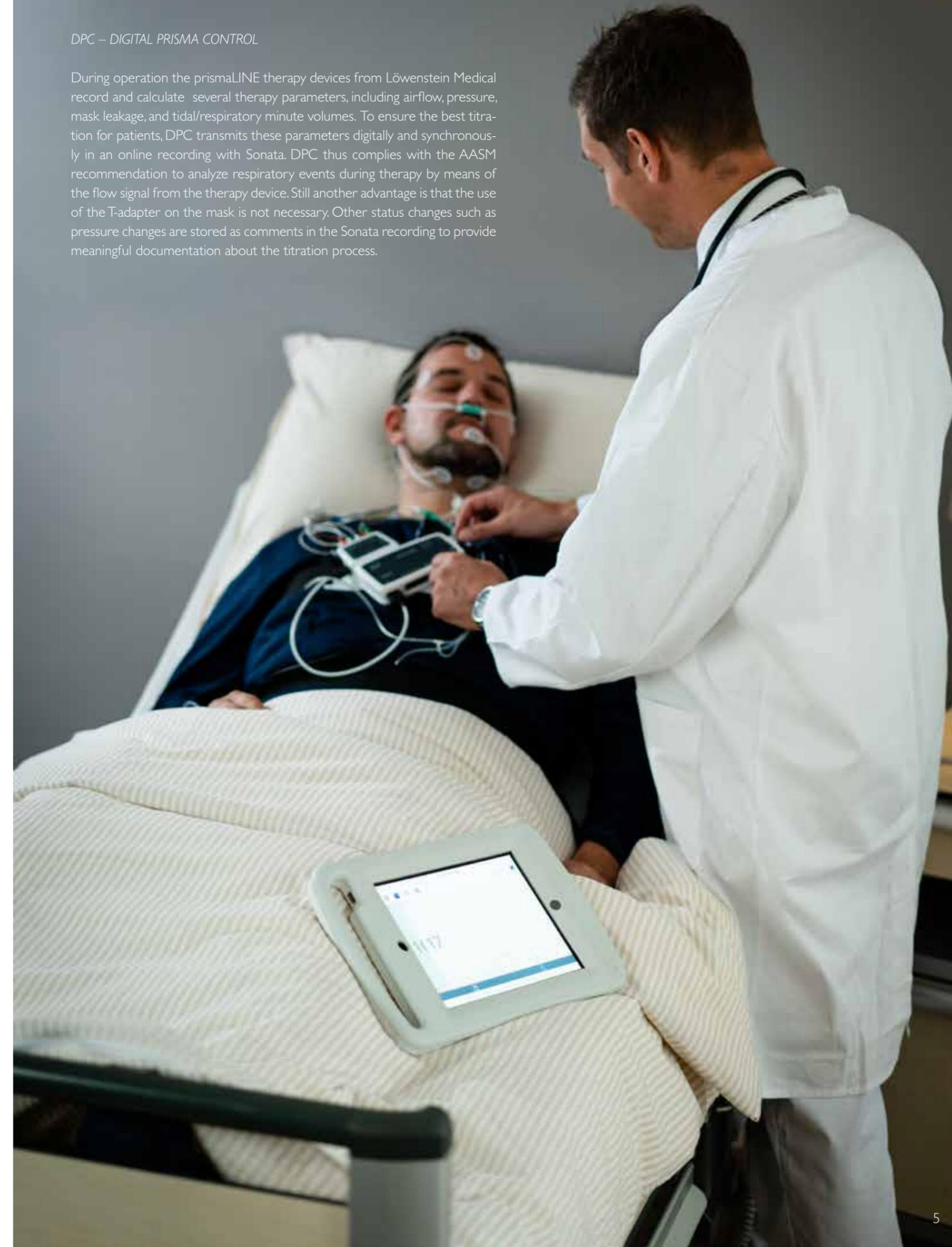
The device offers high-quality signal recording for ventilation monitoring of patients outside the hospital or for those treated with high and quickly changing pressures (BiLevel, ASV). The differential pressure measurement ensures that the patient's airflow is correctly registered even when mandatory ventilator breaths are administered. As registration of the exact airflow curve is reliable at high pressures, the device recognizes events with great precision.

The channels to be recorded can be scanned with a sampling rate of up to 1,000 Hz with a 24-bit resolution. This ensures high signal quality and an exact recording of the patient signals. Good signal quality depends primarily on the stability of the electrodes throughout the recording period. The device is equipped with a continuous impedance measurement function to monitor the electrodes' placement and contact during the night. Sonata has a removable rechargeable battery, an integrated light sensor, and two actographs, which can be connected specifically for polysomnographic examinations of children.

For many years Löwenstein Medical has relied on pneumatic pressure pads in thorax and abdomen belts for the recording of respiratory effort for sleep diagnostics. Even though this price-conscious and high quality testing method has become firmly established, Löwenstein Medical offers induction effort belts too and leaves the choice up to the customer.

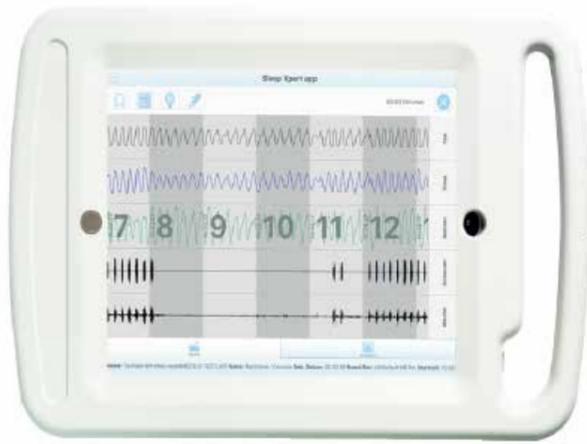
DPC – DIGITAL PRISMA CONTROL

During operation the prismaLINE therapy devices from Löwenstein Medical record and calculate several therapy parameters, including airflow, pressure, mask leakage, and tidal/respiratory minute volumes. To ensure the best titration for patients, DPC transmits these parameters digitally and synchronously in an online recording with Sonata. DPC thus complies with the AASM recommendation to analyze respiratory events during therapy by means of the flow signal from the therapy device. Still another advantage is that the use of the T-adapter on the mask is not necessary. Other status changes such as pressure changes are stored as comments in the Sonata recording to provide meaningful documentation about the titration process.



SLEEP XPERT APP

The Sleep Xpert App allows the user to conduct all important processes and tests during a sleep examination (recording start, impedance measurement, bio-signal calibration, signal monitoring and entry of comments) directly at the patient's bedside. During the course of a night, personnel no longer have to walk back and forth between patient room and analysis room. The specific patient room can be selected and managed in the app on a mobile device such as a tablet.



Tablet with Sleep Xpert App

SLEEP XPERT LAB

Sleep Xpert Lab is the software for displaying and processing the recorded data. Functionality, operating elements and views can be adapted to satisfy personal needs. Special features and functions include the freely configurable report, the easily set and transparent analysis criteria, automatic recognition of pressure modes (CPAP/BiLevel) and operating simplicity. The software is available in 11 languages. EDF data can be imported and exported with no trouble at all.



VIDEO EQUIPMENT

Two different high-quality network cameras are available for nighttime monitoring of patients. Both are equipped with an infrared spotlight and an intercom function.

The pan-tilt-zoom camera has a 30x optical zoom with auto focus, silent and smooth panning, tilting and zooming, and integrated phantom power for excellent audio quality.

The award-winning compact camera has a fixed focal length with 110° horizontal and 61° vertical field of view, which can be divided into visual ranges, integrated infrared lighting, microphone and speaker.



SONATA

The new polysomnograph.

- Modern
- Flexible
- Diverse
- Future-proof
- Economical



VENTILATION MONITORING OF PREMATURE BABIES – LEOTOM NEO CLOSES THE GAP

Infant Respiratory Distress Syndrome (IRDS) remains the most frequently cited cause of death in premature babies. Approximately one percent of all newborns develop IRDS. The incidence rises dramatically in relation to the number of weeks short of a full gestation period. Despite all the progress made in neonatology intensive care medicine with surfactant therapy and differentiated ventilation therapy, our youngest patients are still the most difficult to monitor. While adult ventilation patients can be closely monitored with a range of instruments, neonatology monitoring is generally limited to pulse oximetry and blood gas analysis by invasive means.

According to clinical studies, Electrical Impedance Tomography (EIT) has been used successfully in neonatology to optimize differentiated ventilation strategies for spontaneously breathing newborns. Now with the new leotom neo system, EIT is available in neonatology. Right at the bedside, it creates real-time images without radiation exposure and allows continuous assessment of the ventilated lungs. The leotom neo monitor was designed for premature and newborn infants with a minimum weight of 500 grams. Special cloth belts, which can be adjusted to fit the tiny patients, eliminate the risk of cross contamination.

The EIT measuring method involves repetitive feeds of a low-frequency alternating current between two electrodes and then measuring the resulting voltage on the surface of the remaining pair of electrodes.

After a measurement has been made, the neighboring pair of electrodes is used for the electricity feed and the remaining electrodes measure the resulting changes in voltage. From the measured voltage changes at the end of a measurement cycle, a mathematical reconstruction algorithm generates a two-dimensional cross-sectional image of the thorax. In contrast to other medical imaging methods, EIT monitors body functions, not corporal structures. The system delivers real-time images for use in ventilation monitoring and the detection of potential complications. With leotom neo in neonatology, EIT technology has moved beyond purely scientific applications.

Besides the ongoing optimization of ventilation settings for individual pulmonary situations, some theoretically conceivable uses, such as reduced sampling for blood gas analysis or visual management of surfactant therapy, are highly promising.

leotom neo closes the gap in monitoring mechanically ventilated premature and newborn infants.

HIGH-FLOW THERAPY – THE LOGICAL ADDITION TO RESPIRATORY THERAPY

In High-Flow Therapy (HFT) heated and humidified respiratory gas is delivered to the patient at a high, defined flow rate via a special nasal cannula. The Work of Breathing is significantly reduced and the therapy is generally well tolerated by patients. The High-Flow Therapy generates a moderate Positive End-Expiratory Pressure (PEEP) and reduces respiratory effort by washing out CO₂ and causing a related decrease in anatomical dead space.

Recent clinical studies show that HFT can be considered an alternative to standard methods such as invasive and non-invasive ventilation in the care of patients with acute respiratory failure in hospital or rescue services, depending on the clinical pictures and severity of the disorder. In some cases, early application of high-flow therapy may prevent intubation of the patient and allow a less invasive therapeutic regime, resulting in both clinical and economic benefits.

Treatment of acute respiratory failure by means of Non-Invasive Ventilation (NIV) often poses problems for the conscious patient's adaptation to the respiratory mask and the required ventilation settings. Furthermore, when NIV is used long-term, patients can develop mask-caused pressure points on the face. For the right medical indication successful treatment with High-Flow Therapy in hospital can lead to reduced

need of nursing care, less work for caregivers, a shortened stay in the intensive care unit and, subjectively and objectively seen, to a very good clinical outcome.

In addition to its use in hospital, High-Flow Therapy offers a range of potential applications in outpatient or homecare treatment. Here too recently published clinical studies report highly promising therapy results in certain clinical situations. According to the current state of knowledge, High-Flow Therapy will reasonably supplement outpatient therapy of chronic respiratory failure and find its place beside ventilation, oxygen therapy and secretion management. Despite the supporting data, the costs for outpatient High-Flow Therapy are not yet assumed across the board by health insurers in some countries, including Germany.

Löwenstein Medical offers innovative products for High-Flow Therapy for both inpatient and outpatient treatment. The extremely compact device charisma was developed for special clinical cases, such as emergency admissions or perioperative care, in which continuous positive pressure is delivered to the patient's airways (CPAP). Used with the high-performance Aircon humidifier, the device has a high-flow option with or without a supply of oxygen.



prisma VENT50-C during the day and prisma VENT AQUA in High-Flow Therapy



charisma

A unique treatment concept in the outpatient area is behind the therapy device prisma VENT50-C from Löwenstein Medical. For the first time ever, a single system can provide Non-Invasive Ventilation, Invasive Ventilation or High-Flow Therapy to accommodate the varied needs of patients during the day and at night. The less restrictive HFT can be used when the patient is awake. A switch is then made to ventilation when the patient sleeps as higher pressures are frequently required to keep upper airways open, something HFT cannot do. The patient can then follow a customized therapy plan without having to use different devices. Ultimately, that saves money. The high-performance humidifier prisma VENT AQUA can be used in both modes.



prisma VENT 50-C at night as ventilator

LÖWENSTEIN MEDICAL TECHNOLOGY MASK PORTFOLIO

The Perfect Fit - Or why it is so hard to find!

The centerpiece of non-invasive ventilation – the mask – serves as the interface between patient and machine. If a mask leaks or exerts pressure on the skin, the patient is not adequately cared for. That's what makes the fit the most important detail in a ventilation mask.

You might think that a good fit could be developed very quickly, but you'd be wrong. Did you know that there is a "north-south divide"? Northern Europeans, including some Germans, demonstrably have the narrowest and shortest noses. The further south you go, the more likely you are to see longer and somewhat broader noses. The tendency is even more pronounced in Southern Europe.

Noses have completely different shapes in Asia. Sometimes the nasal root is very flat and broad, as are the wings of the nose. But only sometimes. Other shapes have a small root and a high bridge, making the nose appear narrower overall.

On the American continent the patient clientele is highly diverse. There you see European and Asian face and nose shapes and many Afro-Americans, who generally have larger faces and noses, flat bridges and broad nasal wings. In Central and South America we encounter a mixture of European immigrants and native peoples with high cheekbones and narrow nasal bridges.

In addition to these ethnic characteristics, the clinical picture plays a decisive role. Are we speaking about ventilation patients with slender to gaunt faces or the sleep apnea with an obese face?

You can see that different shapes of noses and faces demand a great degree of flexibility.

LÖWENSTEIN medical MASKEN-PORTFOLIO



More than 10 years ago Löwenstein Medical Technology invested in a scanner in order to set up an extensive database which has since grown to hold more than 1000 patient faces. The device uses light to scan the contours of a face. With several scans from different angles, Löwenstein Medical Technology employees generate a computer-based 3-D face. On a computer screen, the three-dimensional image is then used to examine the design of mask cushions for pressure points and leaks. By means of a CAD (Computer-Aided Design) program, the fit of the mask cushion is simulated on the patient face. Pressure points and/or leaks are indicated by the program. The process makes it possible to optimize mask cushions for different facial shapes and lengths on the computer.

Once the groundwork has been done, it's time to switch from theory to practice. The first functional models are constructed with a 3-D printer in the Rapid Prototyping Center at Löwenstein Medical Technology. A negative form is printed into which members of the Research & Development department pour silicone by hand to produce a mask cushion. The negative mold is made from a material which the 3-D printer stacks in layers from the bottom up and then binds together with heat. Because the surface of this mask cushion is very rough, it's too early to think about testing it on a patient. However, Patient Interface team members test the cushions on themselves and, based on years of experience, evaluate the first prototypes. As a rule, several runs are required in order to get a satisfactory new fit. That can take many months.

If the Patient Interface Team members are satisfied, an aluminum form is milled in the Rapid Prototyping Center. This is a more time-consuming and expensive process, but it has the advantage of producing a surface that corresponds to a real mask cushion that can be worn by every patient throughout the night.



Professional 3-D printer for the production of functional models

The Löwenstein Group now offers new possibilities and synergies for testing mask cushion prototypes on a variety of patients here and abroad. At one time the manufacturer Löwenstein Medical Technology had no direct contact to patients. These days the Patient Interface product manager can contact Sleep-Respiratory Centers (SRCs) and international branches and discuss the tests. With background knowledge of the different nasal and facial shapes in Germany, the product manager and other parties pay attention to the regional distribution of test subjects and make sure a heterogeneous patient group is selected. Joint invitations go out to suitable patients for tests in the SRCs or branches. Contact is made only with experienced patients who already wear the type of mask (nasal, full face, nasal pillows) to be tested. The patient groups are made up of different ages and both sexes in order to ensure a balanced test.

Next, the entire Patient Interface Team of product manager and developers, armed with test masks and questionnaires, travel to the SRCs or branches and discuss the tests with the patients personally. It is important to Löwenstein Medical Technology that employees have direct contact with the mask users. Second or even third-hand reports can lead to serious misinterpretations and errors in judgment. Now everyone involved can draw his or her own conclusions about the test and patient while the test mask is adjusted and explained. The patient can try out the mask over the course of several nights. A questionnaire filled out by the patient makes it possible to analyze the findings systematically. International markets use a similar procedure.

After about six to eight weeks the tests are completed and analyzed. The Patient Interface Team from Löwenstein Medical Technology will presumably repeat the tests many times until a new mask cushion is created that can satisfy the tough demands made by the highly diverse patients around the world.



Milling machine for the production of aluminum forms



3D-face



PRISMA CLOUD – THE TELEMEDICINE SOLUTION WITH VERY HIGH SECURITY STANDARDS

Around the world everyone is talking about digitalization, which is pushing into our daily lives a little bit more every day. We have already integrated many digitalization-driven changes in our routines. Our communication has been altered by social networks like Facebook and Whats App in ways that were unimaginable just a few years ago. Mobility too is changing. Today in our large cities, car services which can be ordered via app are making personal mobility convenient for people who don't drive or own automobiles. As the convenience and availability of such offers increase, so does the store of customer data held by service providers. We are disclosing more data about ourselves whether we want to or not.

The speed at which our familiar everyday lives are changing is dizzyingly fast. We are in danger of losing the big picture or failing to understand how the world around us is changed by digitalization – that is, if we do not delve into the material. The same goes for the data which we are always sharing with others. We have to trust that the providers of digital solutions and products ensure the security and protection of their offerings. That works well in most cases. Nevertheless, we hear again and again about gaps in security, misuse of data or system hacking. You could presume that one or the other short-term security problems did not cause any major damage to individual users, with potential data loss limited to the latest update on a social network, for example. The risks and damages, however, increase with the sensitivity of the stored data.

Particularly where personal medical data is involved, a gap in the security structure which would allow intruders to gain access to systems is never acceptable. It is the provider's responsibility to look after the security of customer information. Security is not only in the interests of the customer or the provider. Lawmakers have written security requirements for sensitive data which have to be observed under all circumstances. That is a good thing.

Telemedicine is a subsection of healthcare services in which the treating physician or therapist can provide diagnostics and therapy to a certain extent when the patient is not on site at the medical facility. For some time Löwenstein Medical Technology has offered a solution for doctors and patients with its prisma CLOUD system, which is certified as a medical technology product. Today our customers can use functions to transmit up-to-date information from sleep therapy devices and retrieve data from the CLOUD anywhere in the world, allowing them to monitor patients' therapy closely and professionally. The patient-related therapy data can then be assessed by the treating physician or medical caregiver at any time after login in the Internet portal. Our solution targeted to the patient – prisma JOURNAL – helps to positively influence therapy success by making information about sleep therapy available to the interested patient.



prisma CLOUD was developed to satisfy requirements for confidentiality, integrity and availability. We also implemented control mechanisms to ensure that the data we store and process for our customers have the best protection possible. That includes a risk management process and regularly scheduled penetration tests, which we have carried out by external security experts. In those penetration tests, experts attempt to find vulnerable points in our systems. We concentrate on the functional areas of service, e.g., data transmission, data storage and access to data over our Internet portal.

Data transmission between devices and prisma CLOUD is protected by mutual authentication between the devices and the service. A SIM card specially produced and registered for us is used in this process. It prevents unauthorized devices from gaining access to our communication channels. Data are encrypted and transmitted via a private access point that serves as entry to a VPN (Virtual Private Network) tunnel. Data transmission takes place completely separate from the public network and its risks.

Löwenstein Medical Technology does not store data in the cloud. We work instead with respected providers who have been specially certified for the processing of medical data. We benefit from their knowledge and subject ourselves to strict security examinations which the providers require before we can become their partner.

In addition to our use of standard encryption, firewalls and the division of medical and personal data on physically separated servers, we have our program code checked by external experts for inadvertent security weaknesses.

All data are encrypted, with access permitted only to encrypted data. We rely on encryption technologies that the banking industry has used successfully for years and has continued to develop. A hierarchical user administration ensures that visibility of stored data is limited only to users who are authorized to look at medical information. The defined password guidelines stipulate the use of secure passwords that have to be changed at regular intervals. Two-factor authentication offers additional protection.

Our administrators and algorithms continuously monitor prisma CLOUD for unusual activities or threats. We regularly make updates to keep our security concept prepared to deal with the changing dangers on the Internet. We invest time and effort in the protection of our customers' data because we want to maintain the same high quality standards for our digital products as for our therapy devices and software. For data protection and security have to be the top priority in the digitalization of the healthcare industry.



prisma CLOUD is a telemedicine solution available for all therapy devices in the prismaLINE.

LÖWENSTEIN MEDICAL ACADEMY – ALL ADVANCED TRAINING UNDER ONE ROOF



The use of ultra-modern medical technology has become part of everyday work in clinics and hospitals. Users are required to have more and more knowledge, not least of all because staff organizations and responsibilities are continuously changing. Innovative device development and the resulting new treatment methods are positive signs of medical progress, but are also indications of the need for staff training in order to ensure the highest degree of safety for patients.

Particularly in the fields of sleep medicine and ventilation, Löwenstein Medical has a long history of continuing education in German-speaking areas. Within the past two decades, the company has set standards for training program content and the number of participants. To date, more than 20,000 participants have learned about our products and acquired medical background information in approximately 1000 workshops and seminars.

Within the scope of our corporate development, we established a noteworthy continuing education series devoted to the Hospital business. Through the years respected experts have designed and conducted multi-day workshops in which they convey detailed information on the subjects of anesthesia, intensive care ventilation and neonatology.

Last but not least, multi-day workshops on ventilators and sleep therapy devices from Löwenstein Medical are held regularly at our location in Hamburg. Participants have the opportunity there to talk about the products with product specialists and developers.

By bundling all these training events in the Löwenstein Medical Academy, we are putting our successful continuing education program in the areas of Hospital, Diagnostics and Homecare under one roof. At the same time we are expanding the content and the number of training events. In the first half of 2019 alone, we will offer about 40 workshops and seminars.

We are certain that with our training program we are making an important contribution to the safe and optimum use of our medical devices on patients.

Our current training programs for Hospital, Homecare and Diagnostics can be found on our homepage www.hul.de.

PRISMA LINE

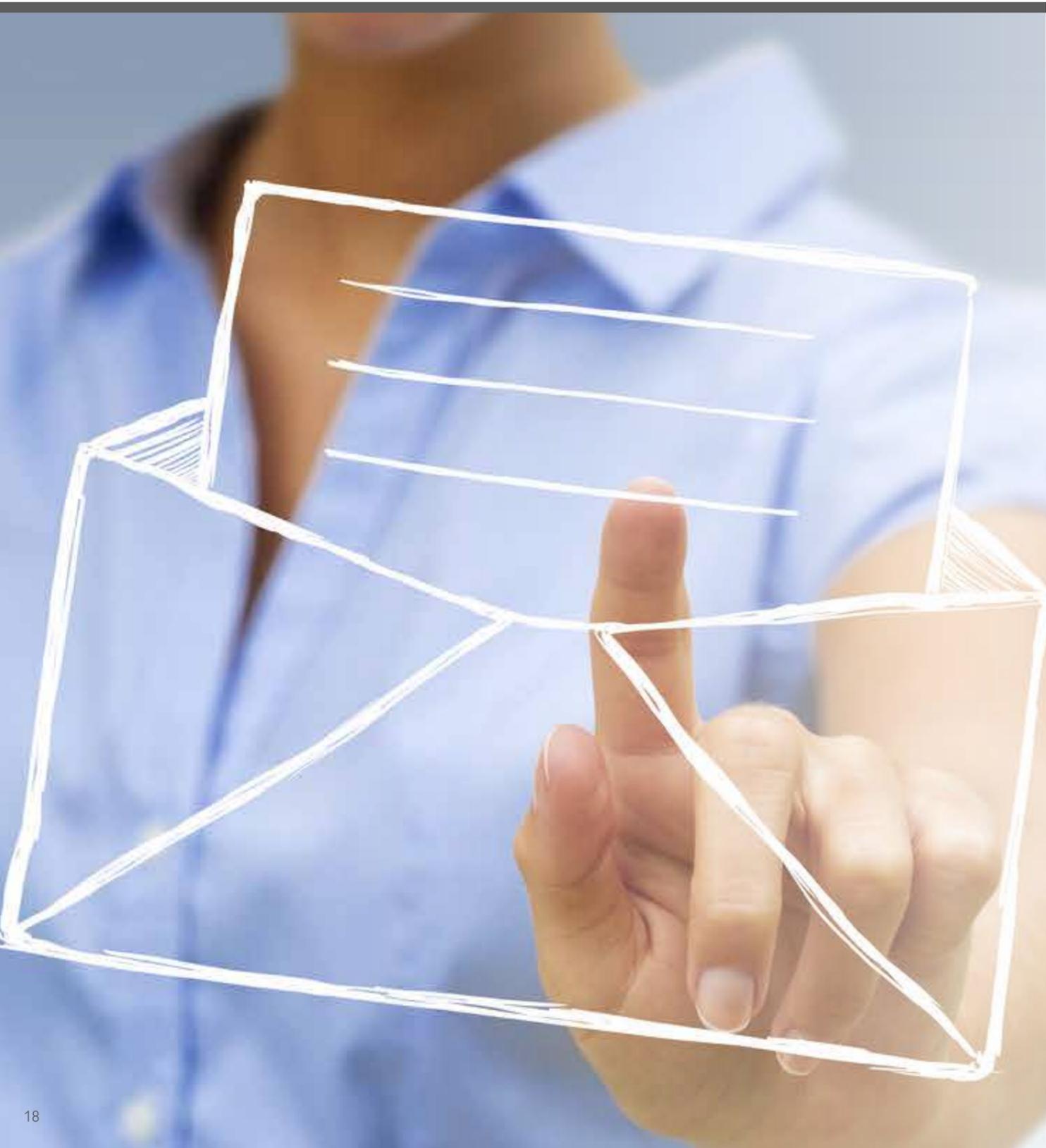
Trust the entire product line.

Intuitive operating interface, validated algorithms for therapy management and telemedicine processes with high data integrity, prisma builds confidence in respiratory therapy.

Developed and manufactured at our innovative facilities in Hamburg and Karlsruhe for the worldwide requirements of tomorrow.



ALWAYS WELL INFORMED – WITH THE LÖWENSTEIN MEDICAL NEWSLETTER



Newsletters are everywhere these days. For many they are a nuisance, as online offers are often linked to your willingness to receive a newsletter, which then lands in your already overflowing incoming mail.

On the other hand, newsletters give you the chance to receive specific information targeted to you or your field of interest. That's very important to us with our newsletter! We want to provide news and information relevant to you, the medical supplies distributor, doctor, MTA or patient. Your feedback also is important to us. Are you interested in a particular subject or do you have questions or criticisms?

With our newsletter we offer you the chance to get news several times a year about our main topics in the fields of neonatology, anesthesia, intensive care ventilation, sleep medicine and homecare ventilation.

We inform healthcare professionals about neonatology, anesthesia, intensive care ventilation, sleep therapy, home ventilation and patient interface. Our major subjects are new products, advanced development of our devices, software and firmware updates, clinical studies, device training as well as important trade fairs and conventions.

Patients and self-help groups receive from us product information from the areas of sleep therapy, homecare ventilation and masks. We report on our new masks, for example, and on further developments which are often prompted by patient feedback. We also produce user videos and provide information about them in our newsletter addressed to patients.

Have we aroused your interest? Then sign up now!

To the hospital newsletter for healthcare professionals:



www.hul.de/newsletter/

To the homecare newsletter for patients or healthcare professionals:



www.loewensteinmedical.de/en/lm-newsletter/

FEEDBACKS

Dear Sir or Madam,

Thank you for the newsletter. With this information you'll keep us patients up to date.

The presentation of the CARA mask and the JOYCEeasy mask regarding the new design and improvement was very interesting for me.

I have some questions about the headgear for the JOYCE mask:

What are the materials used in its production? Are they eco certified?

Thank you for taking the time to answer my questions.

Kind regards,

Dear Team
at Löwenstein Medical,

As a patient, I am very interested in the newsletter and am already looking forward to the next one.

Kind regards,

Hello Löwenstein-Team,
Yes, we like it!

Dear Sir or Madam,
The content of your newsletter is very interesting. I would like to receive information of this type even more frequently.

Best regards,



bad ems
GERMANY



igny
FRANCE



bad ems
GERMANY



shanghai
CHINA



barneveld
NETHERLANDS



hamburg
GERMANY



bracknell
ENGLAND



salzburg
AUSTRIA



wien
AUSTRIA



istanbul
TURKEY



neuenhof
SWITZERLAND



rødovre
DENMARK



boston
USA



kronberg
GERMANY

