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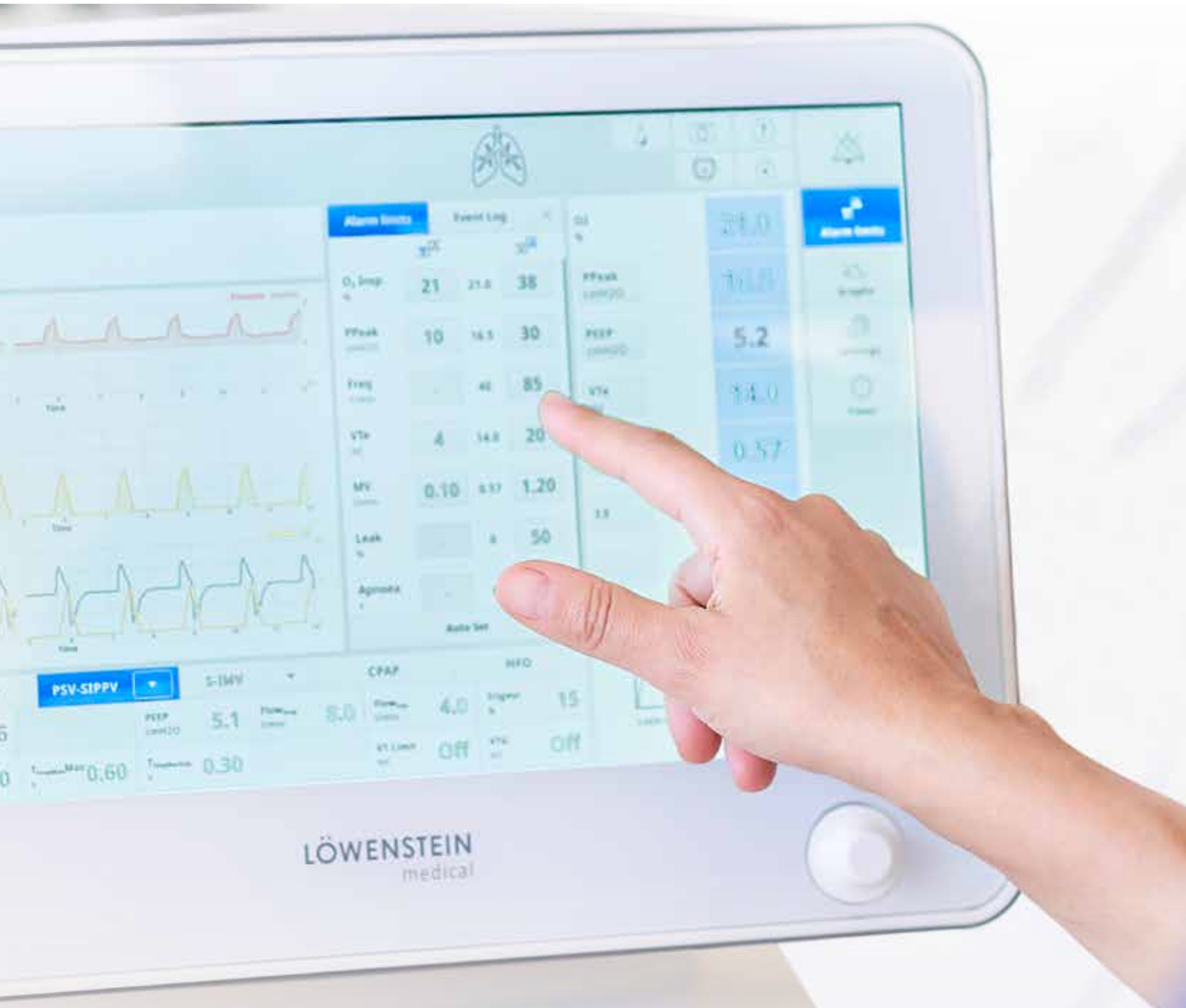
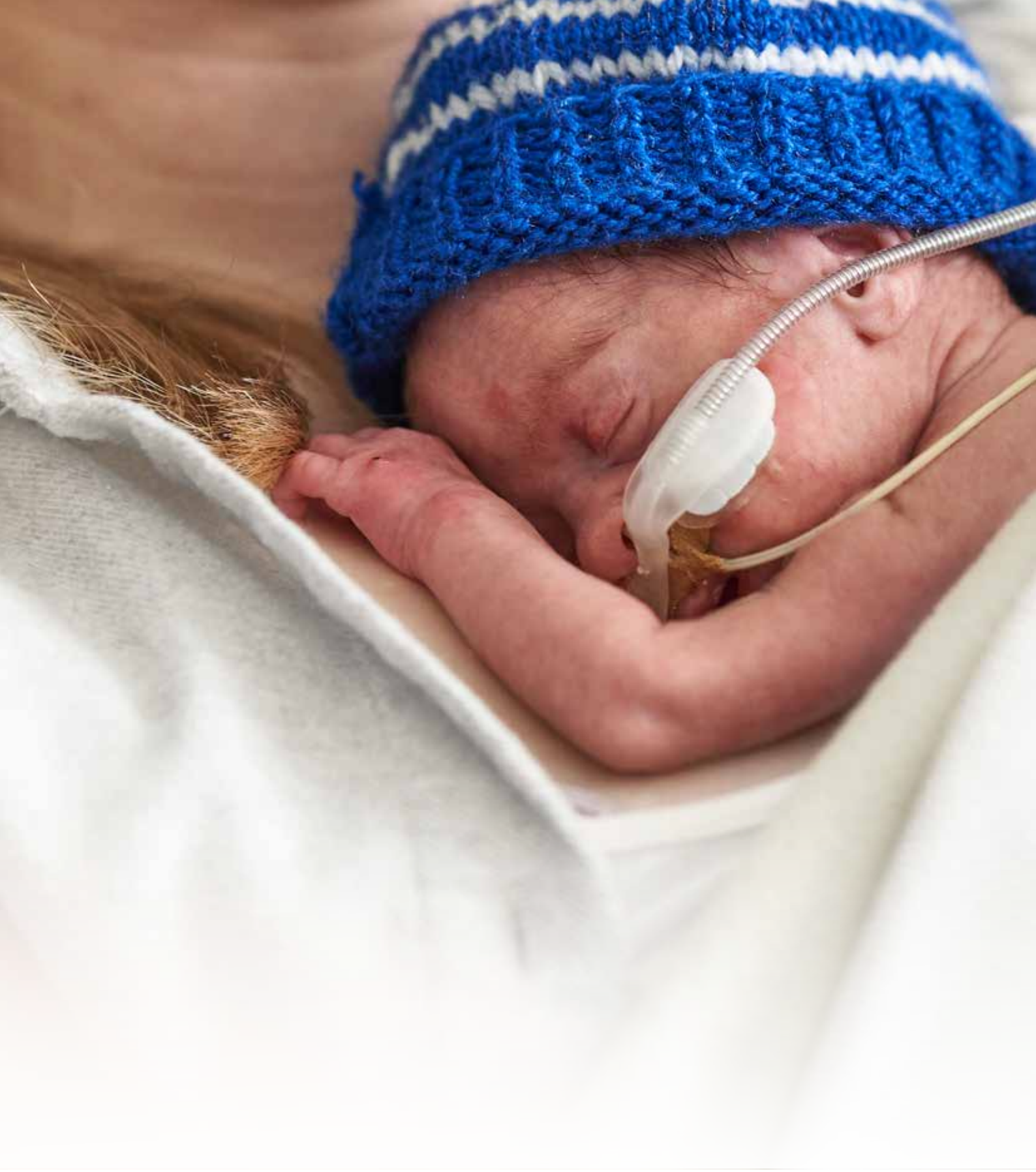
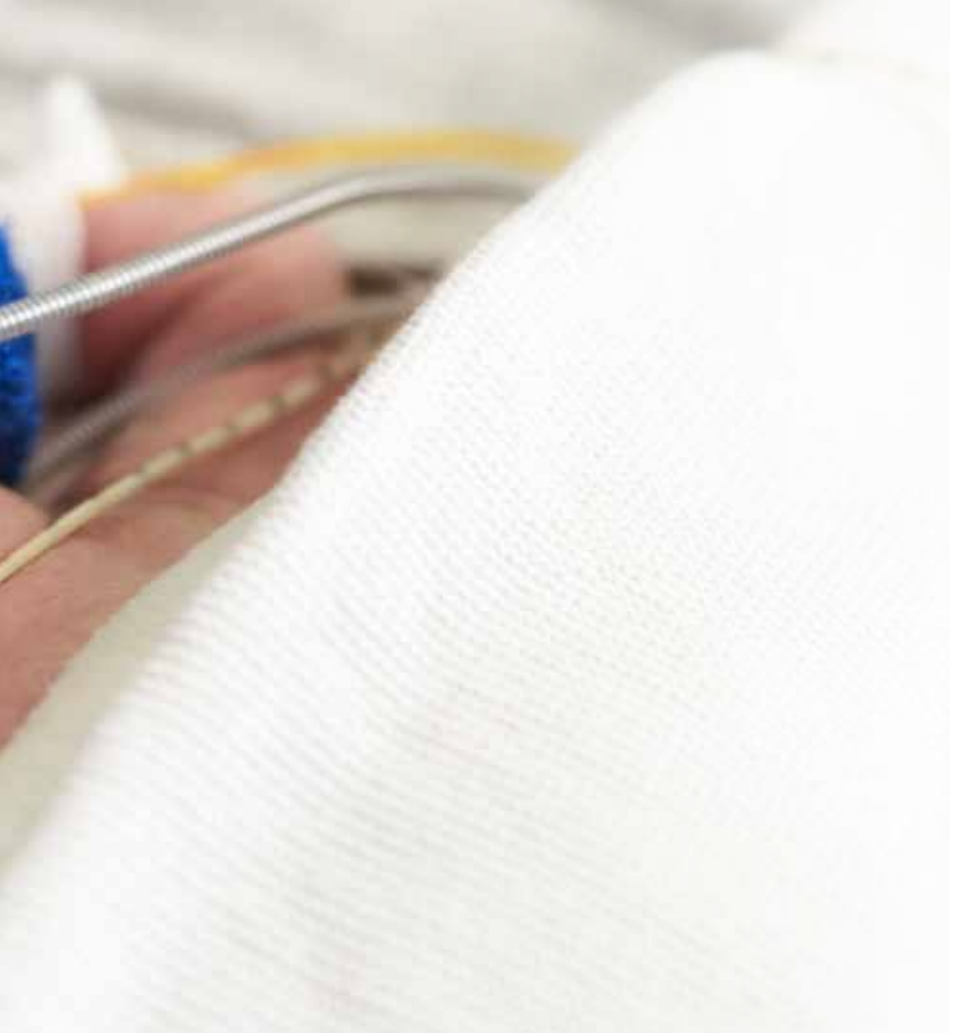


LEONI 4

Best Chances. From the Start.

With people in mind





Little lionhearts. Tough, tiny warriors.

Pioneering technology in neonatology. For a safe start in life.

The premium class in neonatal ventilation. LEONI 4. With over 30 years of expertise and experience, this system is crafted to provide exceptional ventilation for the most delicate lungs and the tiniest patients. These incredible little fighters and their parents inspire us to keep on striving for improvement and excellence. They deserve our commitment to ventilating with ever-greater precision, personalization, and, above all, safety. Intuitive to use, life-saving, and designed to provide gentle, effective ventilation.

LEONI 4. Best Chances. From the Start.

LEONI 4

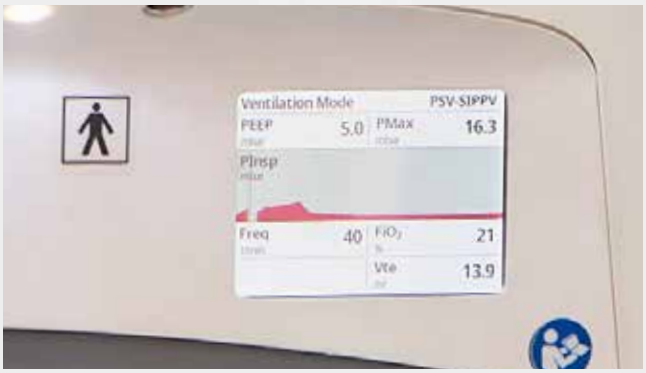
Made in Germany.

Designed, developed, and manufactured in Bad Ems, LEONI 4 delivers state-of-the-art technological safety essential for neonatology. And it goes one step further towards the future: with an agile system that keeps operation intuitive, configuration need-based and training requirements to a minimum.

Paired with Instant View Technology, which allows for immediate recognition of the current status and deviations at a glance, LEONI 4 sets new standards in the reliable ventilation of premature babies.

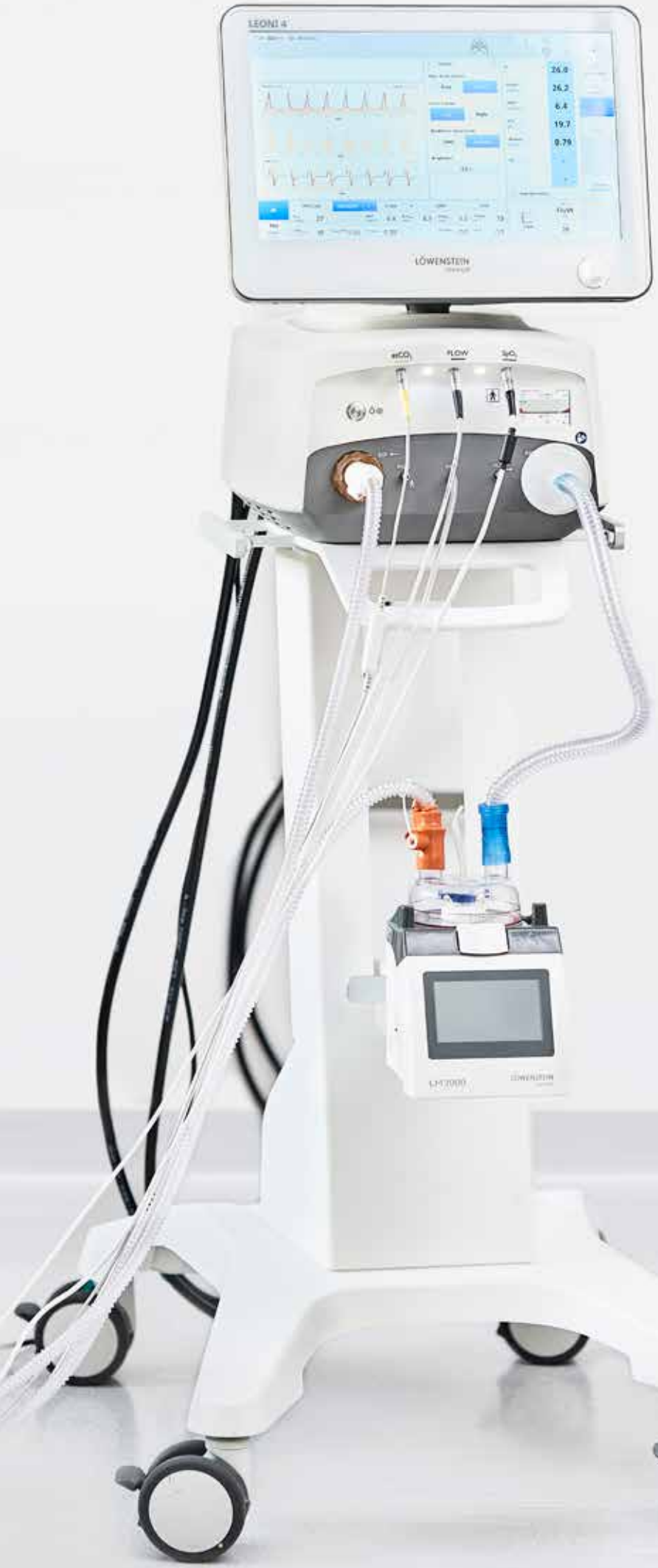
Ergonomics.

- All necessary connections are conveniently accessible on the front of the device, featuring dimmable LED illumination.
- The display can be rotated and tilted, providing an ergonomic workstation.
- The display includes a lock feature to facilitate cleaning.
- Programmable short cuts facilitate quick access to the most important functions.



Additional display.

Keep an eye on the key parameters at all times, even during quality between parent and child time.



Future-oriented platform

LEONI 4 is ready for the future. The latest and modern hardware serves as a platform for innovative developments in the future.

Hygiene

The optimized housing design minimizes potential hygiene concerns. The touch screen has a lock function for the cleaning process.

Service and maintenance

Cost efficiency is achieved through the optional maintenance-free paramagnetic O_2 cell and a service-friendly design.

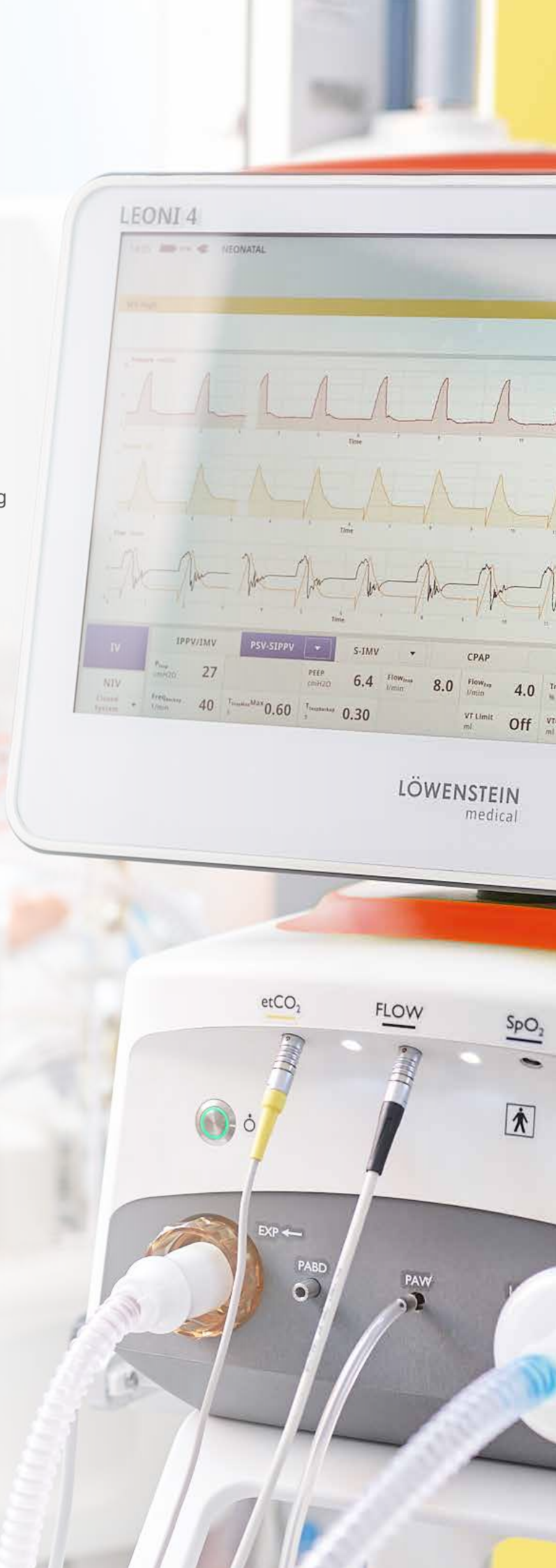
Sustainability

All components are interchangeable. The modular design guarantees a long service life. Transportation routes are kept short, and components are manufactured in Germany. Fresh gas consumption is significantly reduced by the HFO double diaphragm.

Functions and operation

With LEONI 4, all key functions are now even more advanced and secure. Comfortably familiar, yet innovatively ahead of the curve.

To make everyday routines faster and smoother, freeing up time for what truly matters: a comforting touch for our youngest patients or a reassuring conversation with their parents.



High-frequency oscillation ventilation.

Lung-protective HFO enables spontaneous breathing without pressure peaks in invasive and non-invasive ventilation under HFO.

LEONI 4 delivers the highest performance in high-frequency ventilation through the innovative double diaphragm principle. The optional volume guarantee provides the child with a constant breathing volume. Spontaneous breathing and volume limitation during HFO can be applied at any time.

Recruitment maneuvers under HFO recruit short-term alveolar capacities and keep them open through an adequately high PEEP.

Mainstream CO_2.

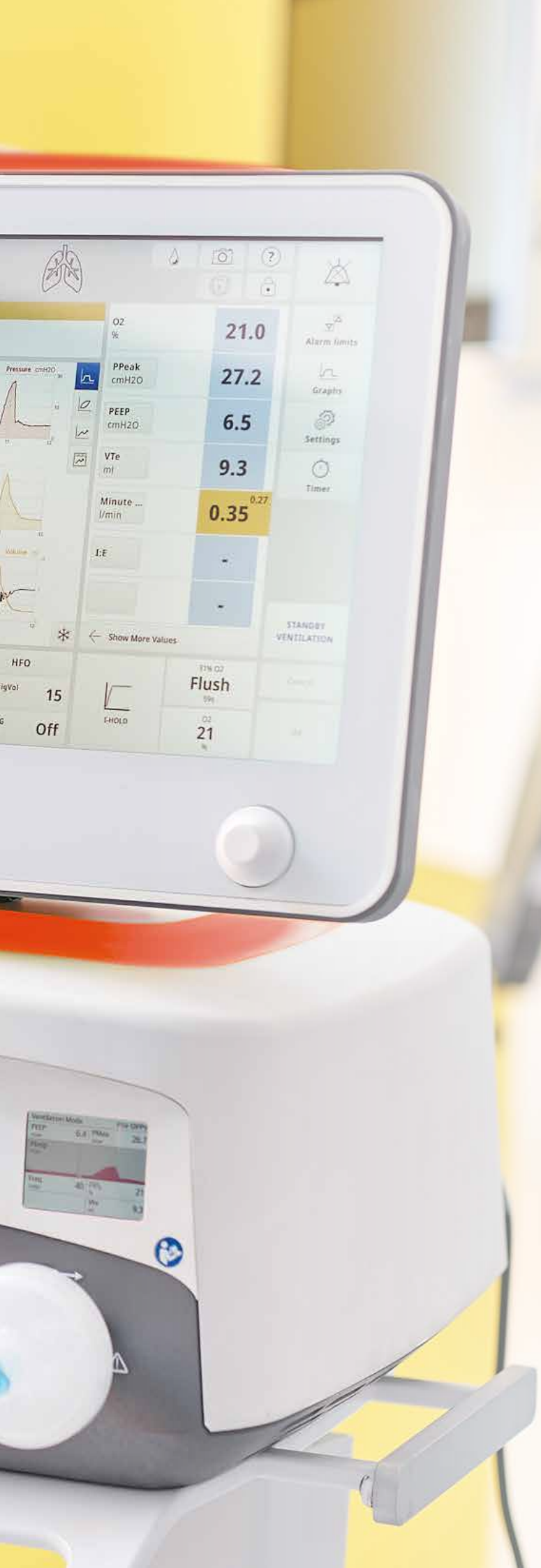
Continuous real-time measurement of the CO_2 partial pressure in the breathing gas through end-tidal CO_2 measurement.

Tube concept.

All ventilation modes can be performed with the same tube system. All without the need for time-consuming or risky system changes.

Neonatal and pediatric mode.

Settings and alarms can be individually programmed and saved for the neonatal and pediatric patient groups.



Battery concept.

The permanently installed battery can be supplemented by two additional optional batteries. Hot-swappable: safe battery replacement during operation.
The remaining time in battery mode is reliably displayed and adapted to the respective ventilation mode.
This allows for off-grid ventilation for approximately 6 hours in conventional modes and 3 hours in HFOV.

Modern interface communication.

Secure and flexible communication with external information systems.

Automatic system test.

The automatic system test independently checks and monitors all critical components.

Functions and operation

NIV trigger

Synchronized breathing support for spontaneous breathing efforts. Studies show the benefit of synchronized NIV by reducing reintubation rates, decreasing the frequency of desaturations, bradycardias and central apnea episodes. [1; 2]

Nasal high-flow therapy.

Effective and non-invasive respiratory support.
The functional dead space is minimized. No separate tubing system required. [3]

Ventilation performance.

Tidal volumes as low as 0.1 ml enable ventilation for even the smallest premature infants.
Volume guarantee and volume limitation protect the sensitive lungs of premature and newborn babies. [4; 5]

Abdominal sensor.

In the first few months of life, diaphragmatic or abdominal breathing is very pronounced in our smallest patients.

What could be more natural than monitoring children's breathing activity at the diaphragm and using the signals gathered to trigger inhalation and exhalation?

With the Löwenstein abdominal sensor, it is possible to generate reliable trigger signals for non-invasive ventilation without direct intervention in the breathing mechanics, without additional weight on the patient interface and without increasing the dead space.

Our LEONI 4 neonatal ventilator synchronizes the non-invasive ventilation modes s-nIPPV and s-nCPAP with the optional abdominal sensor and simultaneously functions as apnea monitoring in both ventilation modes. [6]

CLAC®: Closed- Loop Automatic oxygen Control CLOSED- LOOP AUTOMATIC OXYGEN CONTROL

Löwenstein has developed a unique algorithm for automated oxygen control in premature and newborn babies (CLAC: Closed-Loop Automatic Oxygen Control) and integrated it into LEONI 4.

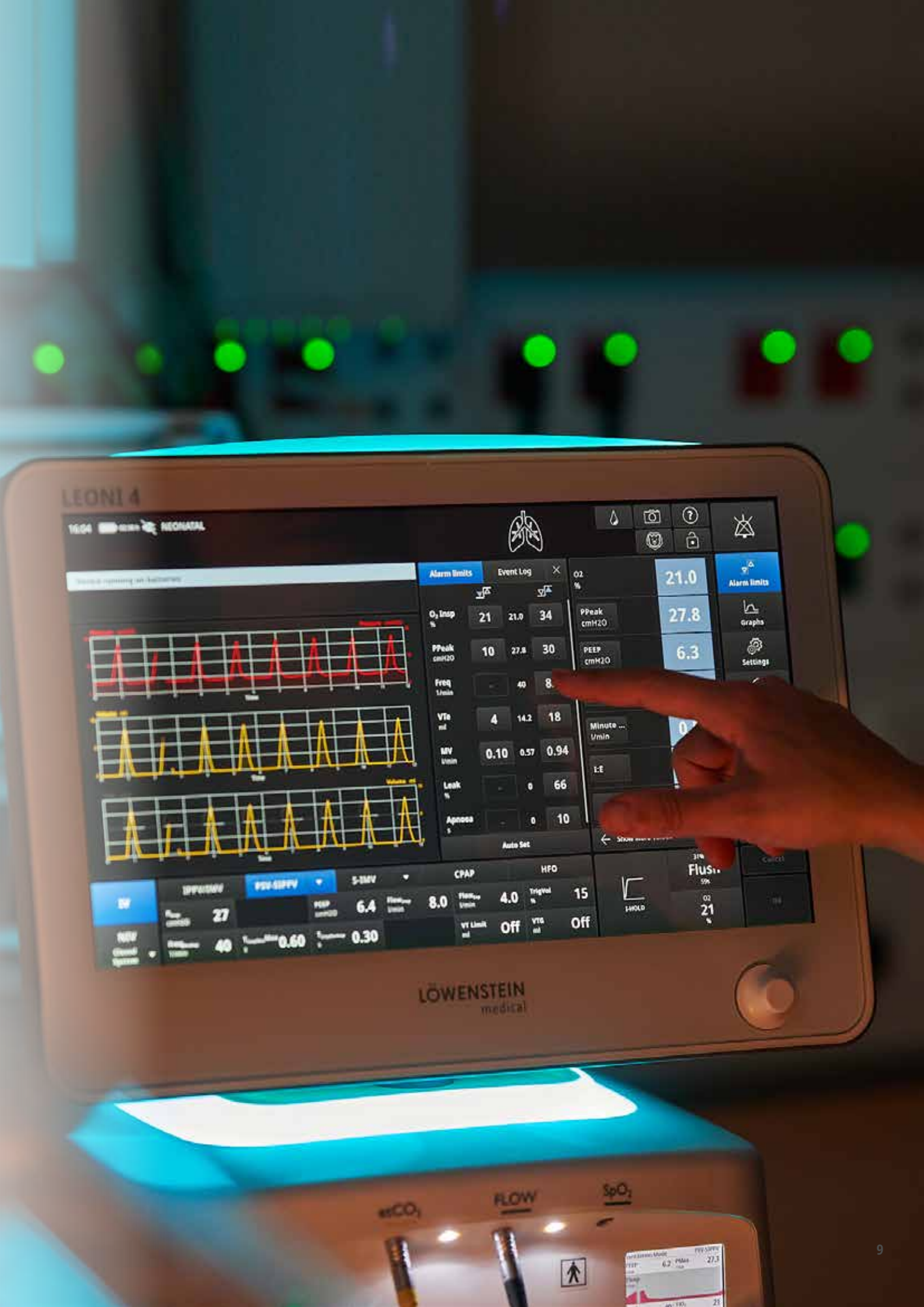
The entire operation, including the visualization of measurement data and alarm settings, is managed through the ventilator's user interface. The user can quickly assess the patient's current status through the graphically displayed overview.

CLAC relieves users of the routine adjustment of inspiratory oxygen in the breathing gas (FiO_2) by continuously monitoring the patient's demand and condition and adjusting the device settings accordingly. [7]

Manual intervention is always possible whenever needed.

Löwenstein Medical selected Masimo SET (Signal Extraction Technology) for its "best-in-class" SpO_2 algorithm performance to ensure reliable measurements under challenging monitoring conditions (low perfusion and motion artifact), which is essential for the functionality of the CLAC option.

The publications on the device functions listed here [1-7] can be found on our website.


LEONI 4
NEONATAL
Alarm limits
Event Log
O2
21.0
PPeak
cmH2O
27.8
PEEP
cmH2O
6.3
Graphs
Settings
Minute ...
l/min
I:E
Auto Set
CPAP
HFO
LÖWENSTEIN
medical
FLOW
SpO2

Screen and user interface

The interface between people and technology should be simple and intuitive to use.
See, feel, hear, and then respond.

LEONI 4 provides security thanks to its user-friendly and clear operability.
And the reassurance of knowing that nothing vital to life is being overlooked.

InstantView technology - resolution & display size.

The Full HD resolution of the 15.6" display shows all parameters, curves and loops in great detail. Intuitive detection of patient situations and changes from almost any position in the room.

Configurability.

The customizable content allows a focus on what truly matters. Security through clarity and selective data selection.

Measuring curves and loops.

Thanks to the high-precision display and the freezing curves function, curves and loops can be measured in detail.

Detachable display.

The detachable display is used to position the display independently of the ventilation unit. It enables individual bed space configuration.

Display of spontaneous breathing efforts and display of assisted breaths.

Spontaneous inspiratory efforts of the child and assisted breaths are visualized.

Easy Access Bar, manual encoder, touchscreen.

The option to operate directly via the touch display, use the haptic encoder wheel, or the Easy Access Bar on the user interface ensures quick and secure selection and adjustment of setting parameters, providing intuitive user guidance and a clear focus on the essentials.

Number of curves.

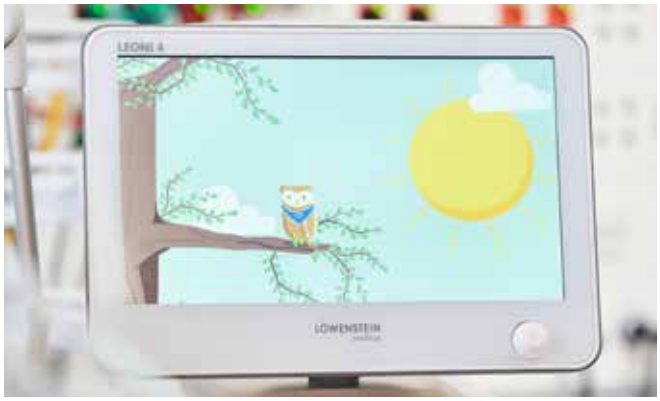
LEONI 4 enables up to 8 ventilation curves to be displayed at the same time. The display, parameters, curve color and prioritization of the curves can be determined by the user.
The curves can be displayed overlapping.

Screenshot function.

The user interface content, along with curves and loops, can be saved on a PC for later evaluation and transferred to external media.

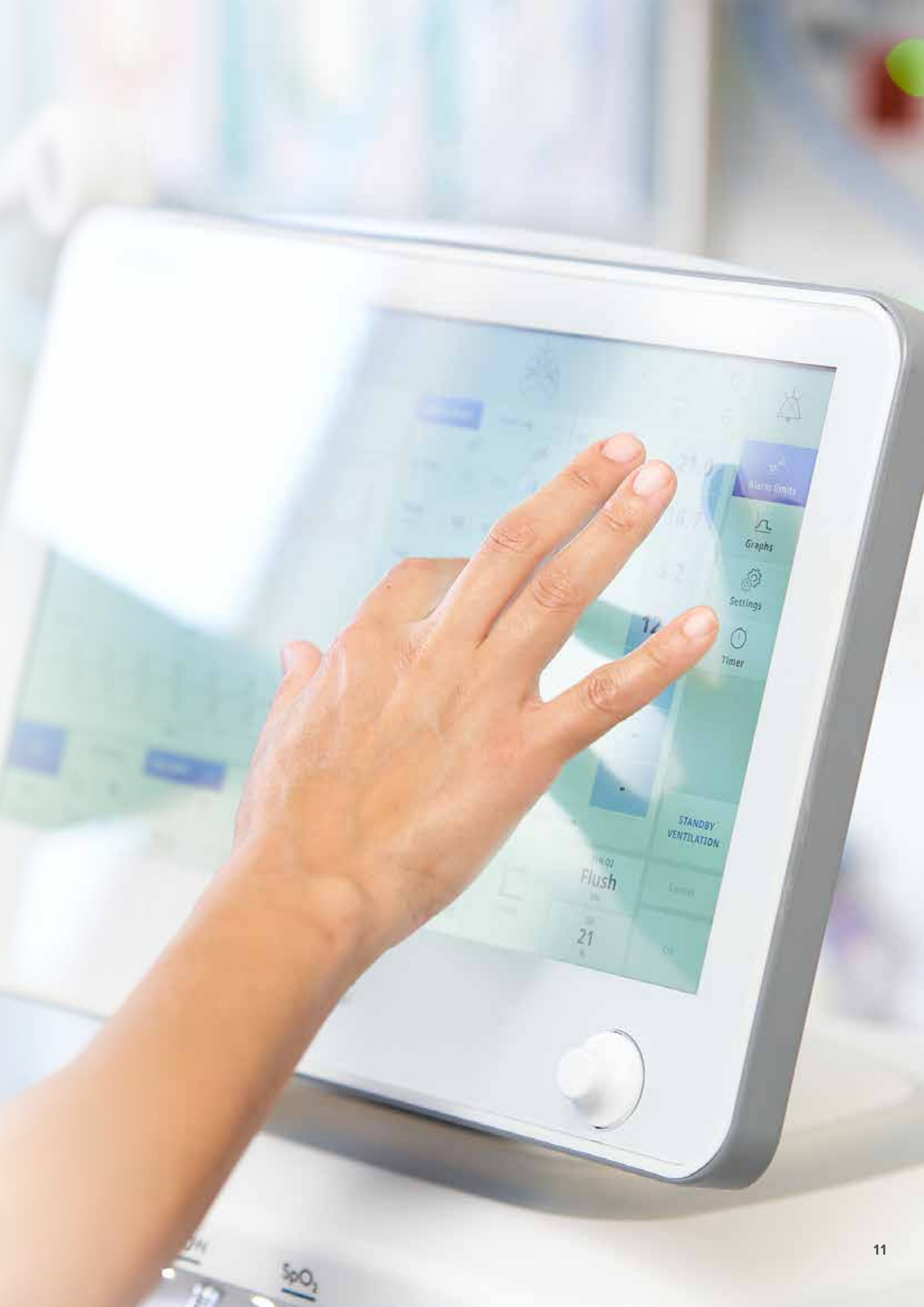
Help function.

The help function supports the user with solutions to problems. Like plain text descriptions for alarms, for example.



Screensaver.

For those precious and peaceful moments of parent-child bonding. Safety through additional display.


Graphs
Settings
Timer
STANDBY
VENTILATION
Flush
21

Comfort and safety

Life in the womb is safe and shielded. A premature baby loses all of this abruptly, and far too soon. This makes it all the more important that nothing frightens, disturbs, or unsettles these little warriors as they learn to breathe and adapt to their new environment. With LEONI 4, sound and light effects are used softly and consistently to foster a sense of calm and security.

Touch display with Easy Access Bar and additional encoder.

Safe operation via the touch display or the rotary-push encoder. Quick operation from the front. The baby and the device remain in focus at the same time.

Day-night changeover.

Distracting light impressions are reduced, creating a pleasant environment and improving the readability of the display content.

Alarm management.

Alarms, priorities, and delays are programmable and can be transmitted to external devices. Various alarm tones can be selected.

Dimmable LEDs.

Brightness-adjustable lighting enables safe work, even in darkened surroundings.

Reduced noise emissions.

The intelligent architecture of LEONI 4 reduces the noise emission to the outside.

Parent-child time.

The screensaver function creates a calm and relaxed atmosphere for the important parent-child time. The additional display shows the most important parameters for safety.

Adaptation to the ambient volume.

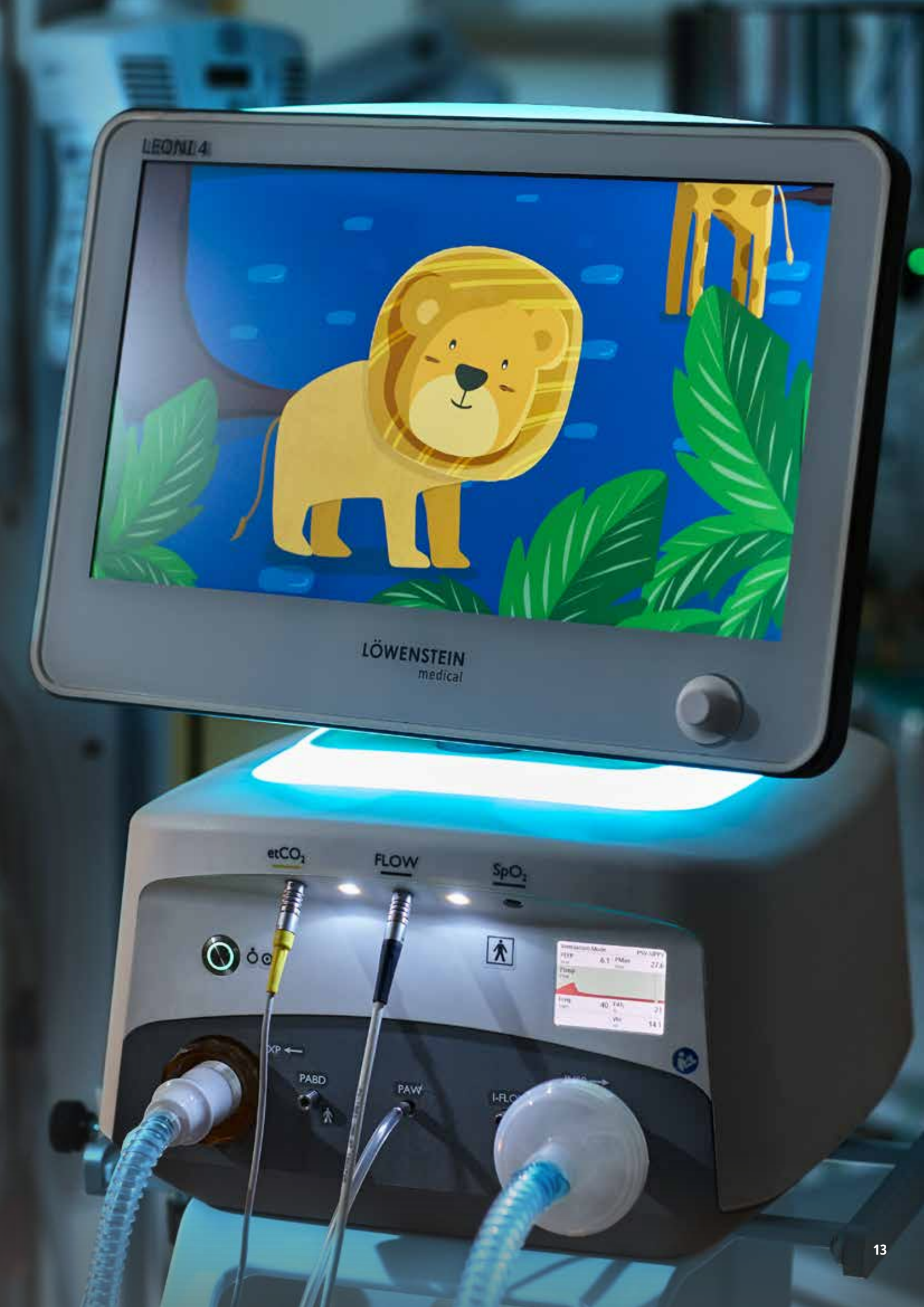
Low noise emission. Our contribution to stress reduction for children, users and parents.

Mains-independent operation.

The remaining time in battery mode is reliably displayed and adapted to the respective ventilation mode.

Input of patient data.

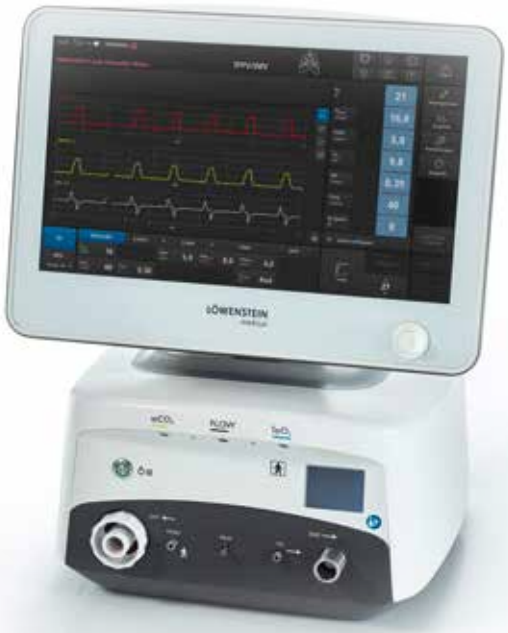
Patient data can be gathered and stored for clear identification and comprehensive documentation. The body surface area can also be calculated.


LEONI 4
LÖWENSTEIN
medical
etCO2
FLOW
SpO2
PABD
PAW

Technical specifications

The LEONI 4 ventilator is a device for invasive and non-invasive ventilation in intensive care.

LEONI 4 can be used for the ventilation of premature infants, newborns, term infants and children with a body weight of up to 30 kg.



Basic data LEONI 4

Classification in accordance with Regulation (EU) 2017/745	Class IIb
IP classification	IPX1
CE	0197
Dimensions (WxHxD)	40 cm x 50 cm x 40 cm (incl. display)
Weight	17.2 kg with one permanently installed battery, each additional battery (up to two additional batteries) 0.65 kg*
Display	
Display	15.6" capacitive color touch display
Display resolution	Full HD 1920 x 1080 px Display is removable and can be attached to round tube or standard side rail with optional holder*
Electrical data	
Power supply	100 – 240 VAC, 50/60 Hz
Mains-independent operation - internal battery - with two additional batteries*	 2 h conventional, 1 h HFOV 6 h conventional, 3 h HFOV
Power consumption - in standby - Max.	 31 W 250 W
Protection class	1 according to DIN EN 60601-1
Gas connections	
Compressed air	2.0 – 6.5 bar; medical compressed air
Oxygen	2.0 – 6.5 bar; medical oxygen; concentration 93% – 100%
O_2 sensor	Fuel cell; paramagnetic*

Ambient conditions during operation	
Temperature	-10 – 45 °C
Air pressure	600 – 1060 hPa
Relative humidity	10% – 90%, non-condensing
Ports	
Serial port	2 x RS232
Ethernet	2 x RJ45
Universal Serial Bus	3 x USB
Digital Multimedia Interface	1 x HDMI
Sensor interfaces	4 (Flow, $etCO_2$, SpO_2, NN)
High frequency oscillation ventilation	
Principle	Integrated double membranes with positive and negative amplitudes
Setting range - Oscillation - Medium pressure - Frequency	 5 – 100 mbar 0 – 40 mbar 5 – 20 Hz
Ratio range	1:1 to 1:3
Recruitment function	yes
Gas mixer	
Flow principle	Constant flow, VIVE (variable inspiratory and variable expiratory flow)
Gas mixture	Proportional valve mixer
Inspiratory O_2 concentration	21% – 100%
Oxygen shower	22% – 100%; adjustable from 30 – 120 sec.

**paid option*

Ventilation modes, monitoring, parameters

Invasive ventilation modes
Systematic code according to DIN ISO 19223

IPPV / IMV (CMV-PC)	Intermittent Positive Pressure Ventilation
IMV (IMV-PC)	Intermittent Mandatory Ventilation
IPPV / IMV + VT Limit	Intermittent Positive Pressure Ventilation / Intermittent Mandatory Ventilation with tidal volume limitation
S-IPPV (SIMV-PC)	Synchronized Intermittent Positive Pressure Ventilation
S-IPPV + VT limit	Synchronized Intermittent Positive Pressure Ventilation with tidal volume limitation
S-IPPV + VTG	Synchronized Intermittent Positive Pressure Ventilation with tidal volume guarantee
S-IPPV + VT limit / VTG	Synchronized Intermittent Positive Pressure Ventilation with tidal volume limitation / tidal volume guarantee
SIMV (SIMV-PC/ES)	Synchronized Intermittent Mandatory Ventilation
SIMV + Psupport	Synchronized Intermittent Mandatory Ventilation with Pressure Support
SIMV + VT limit	Synchronized Intermittent Mandatory Ventilation with tidal volume limitation
SIMV + VTG	Synchronized Intermittent Mandatory Ventilation with tidal volume guarantee
SIMV + Psupport + VTG / VT Limit	Psupport + VTG / VT Limit are freely configurable
PSV - SIMV (SIMV-PC\PS\ES)	Pressure Support Ventilation (PSV) in connection with SIMV
PSV- SIPPV (SIMV-PC\PS)	Pressure Support Ventilation (PSV) in connection with SIPPV
PSV-SIMV + Psupport + VT limit / VTG	Psupport + VTG / VT Limit are freely configurable
PSV -SIPPV + VT limit / VTG	VTG / VT Limit are freely configurable
CPAP (CPAP)	Continuous Positive Airway Pressure
HFO (HFOV)	High Frequency Oscillation can be combined with Tidal Volume Guarantee, I:E Ratio, Recruitment Maneuver

Non-invasive ventilation modes
Systematic code according to DIN ISO 19223

nCPAP (CPAP)	Nasal Continuous Positive Airway Pressure
S-nCPAP* (CPAP)	Synchronized Nasal Continuous Positive Airway Pressure (with abdominal sensor)
nIPPV (CMV-PC)	Nasal Intermittent Positive Pressure Ventilation
S-nIPPV* (SIMV-PC)	Synchronized Nasal Intermittent Positive Pressure Ventilation (with abdominal sensor)
nHFO (HFOV)	Nasal High Frequency Oscillation
HiFlow LM*	HFOT High Flow Oxygen Therapy

Parameters

Inspiratory Peak pressure	4 – 60 mbar
PEEP / CPAP	0 – 30 mbar
Frequency	2 – 200 1/min
Inspiration time	0.1 – 2 sec.
Expiration time	0.2 – 30 sec.
Inspiratory flow	2 – 32 l/min
Expiration flow	2 – 10 l/min
HiFlow	2 – 60 l/min

Monitoring

Ventilation charts	Pressure, flow, volume, $etCO_2$*, Abdomen*, plethysmogram* (optional with CLAC),
Ventilation loops	Flow/pressure, volume/pressure, flow/volume, $etCO_2$/volume
Pulmonary function	Compliance, dynamic compliance, C20/C - stress index, resistance, DCO_2
O_2 measurement	21% – 100%
Alarms	Plain text message in three large alarm windows incl. help text
Trend	Display of numerical values and curves Resolution 2 sec.
Logbook function	40,000 events; transfer to USB medium possible
Screenshot function	10,000 images internal memory; Transfer to USB medium possible
CLAC	Closed loop automatic oxygen control*
$etCO_2$ measurement	Main stream measurement*
NIV trigger	Abdominal sensor*
Screen saver	Yes
Compact Display – Additional Display	Yes
Battery indicator	Yes, in mains operation State of charge in % in battery operation; remaining running time in minutes adapted to the mode
Body surface area calculation	Yes

**paid option*

All invasive and non-invasive ventilation modes can be combined with the optional pulse oximetry-controlled ventilation CLAC (Closed Loop Automatic Oxygen Control).

Made in Germany

LÖWENSTEIN medical

Sales + Service
Löwenstein Medical
Arzbacher Straße 80
56130 Bad Ems, Germany
T. +49 2603 9600-0
F. +49 2603 9600-50
info@loewensteinmedical.com
loewensteinmedical.com

Svensk distrubitör:

Medu
SVERIGE

www.medu.se
08-31 00 46
info@medu.se

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