

LuMon™ System – Neonates / Infants configuration (LMS-N)

Compact & Lightweight EIT system

Regional lung function monitoring at the bedside

Noninvasive & Radiation Free

Skin friendly & Easy to Use



The LuMon™ System (LMS) is a compact and lightweight Electrical Impedance Tomography (EIT) system providing noninvasive monitoring of patient respiration as well as of variations of regional air content within a cross-section of the patient's lungs. The **Neonates / Infants configuration** of the LuMon™ System (LMS-N) is intended for patients, whose underbust girth is within approximately 17.0 to 52.0 cm. The LMS-N comprises LuMon™ Monitors with Neonates / Infants configuration supporting neonatal-mode only, LuMon™ Connectors to link SenTec's patented, textile LuMon™ Belts being available in seven sizes to the LuMon™ Monitor, as well as SenTec's NeoContactAgent serving as a medium for impedance coupling between a LuMon™ Belt and the patient's skin.

The LuMon™ System is the world's only EIT system selecting the thorax and lung contours being best adapted to the individual patient from a set of predefined, CT-derived thorax and lung contours. It continuously evaluates the skin-contact quality of all 32 electrodes and its advanced, unique image reconstruction algorithms are able to compensate up to 6 electrodes having bad or no impedance coupling to the skin as well as inadvertent belt displacement around the patient's thorax. The LuMon™ System also features a patented position sensor continuously evaluating the patient's position and permitting the clinician to unambiguously assess the influence of the patient's position on the ventilation distribution in the patient's lungs.

EIT-based, regional lung function monitoring has the potential to optimize mechanical ventilation, to reduce ventilator-induced lung injuries and to shorten the duration of mechanical ventilation. For example, EIT is expected to help neonatologists in the choice between intubation and non-invasive ventilation, in assessing surfactant therapy or to identify potentially harmful conditions such as displacement of the endotracheal tube, pneumothoraxes, and pleural effusions [1, 2]. In comparison to standard care, use of EIT in preterm neonates is furthermore expected to result in cost-savings, lower mortality and BPD rates [3]. SenTec's skin-friendly textile LuMon™ Belts have been found to be suitable for patients whose skin require particular attention as for example preterm newborns [4].

System performance

Respiratory Rate (RR)	
Measurement Principle	Impedance based
Units	Breaths per minute (bpm)
Display Range	4 – 138 bpm
Resolution	1 bpm
Accuracy (A_{rms})	± 2 bpm over 5 – 70 bpm ± 4 bpm over 71 – 120 bpm ± 5 bpm over 121 – 130 bpm
End-expiratory lung impedance (EELI) / End-inspiratory lung impedance (EILI)	
EELI- and EILI-values are the sum of the impedance values of all lung-pixels measured at the end of expiration (start of inspiration) and end of inspiration, reflect the lung impedance at corresponding points in time and, consequently, are related to end-expiratory and end-inspiratory lung volume, respectively.	
Units	Arbitrary Units (AU)
Measurement Range	Not applicable
Aeration	
Aeration-values are the 15-seconds mean of the impedance values of all lung-pixels, correspond to mean lung impedance and, consequently, are related to mean lung volume.	
Units	Arbitrary Units (AU)
Measurement Range	Not applicable
Relative Tidal Stretch (RTS)	
Relative Tidal Stretch (RTS) is defined as a lung-pixel's impedance change during a breath with respect to the maximum pixel impedance change.	
Units	%

Measurement Range	0 – 100%
Center of Ventilation (CoV)	
CoV-values are defined as the weighted geometrical center of ventilation distribution within the lung contours. CoV(v) characterizes the ventilation distribution in vertical direction, whereas CoV(h) characterizes the ventilation distribution in horizontal direction. CoV(v) defines the position of the Horizon of Ventilation (HoV).	
Units	%
Measurement Range	0 – 100% for CoV(v) and CoV(h)
Functional Lung Spaces / Silent Spaces	
Functional Lung Spaces (FLS) are defined as lung-pixels with RTS-values greater than 10% during a breath, whereas the remaining lung-pixels are defined as Silent Spaces. Functional Lung Spaces, consequently, represent lung-areas that are well ventilated during a breath, whereas Silent Spaces represent lung-areas receiving little or no ventilation. Further, Silent Spaces being localized above or below the HoV are defined as Non-Dependent Silent Spaces (NSS) and Dependent Silent Spaces (DSS), respectively. Silent Spaces may be helpful to identify conditions such as displacement of the endotracheal tube, pneumothoraxes, and pleural effusions as well as conditions influenced by gravity such as collapsed, fluid filled or distended lung areas, with DSS reflecting the first two conditions and NSS the latter.	
Units	%
Measurement Range	0 – 100% whereby NSS + DSS + FLS = 100%

- [1] Masner et al.: Electrical impedance tomography for neonatal ventilation assessment: a narrative review. IOP Conf. Series: Journal of Physics: Conf. Series 2019.
- [2] Rahu et al.: Early Recognition of Pneumothorax in Neonatal Respiratory Distress Syndrome with Electrical Impedance Tomography. Am J Respir Crit Care Med. 2019.
- [3] Voermans A, Mewes J, van Kaam A, Bayford R, Lepage-Nefkens I. Early cost-effectiveness analysis of continuous monitoring of lung-aeration with electrical impedance tomography in preterm neonates with respiratory distress syndrome. Presented at ISPOR Europe 2019, Copenhagen, Denmark.
- [4] Becher et al.: Feasibility and safety of prolonged continuous monitoring with electrical impedance tomography in neonates and infants with respiratory failure. Intensive Care Med. Exp. 2019 7 (Suppl 3):55, 209-210.

System characteristics, compliance and compatibilities

General EIT characteristics									
Number of Electrodes	32								
Image Rate	> 50 Hz								
Feed Current	0.7 – 3.7 mA _{rms} ; 200 kHz ± 10%								
Signal Quality Indicator	Indication of electrode-to-skin impedance coupling quality								
Lung Contours	Various sets of predefined, CT-derived thorax and Lung Contours. The set best fitting an individual patient is selected based on the patient's underbust girth.								
Patient Position (position sensor embedded in LuMon™ Belt)									
Rotation	Patient rotation around the longitudinal axis with the supine position being the zero-position.								
Inclination	Patient rotation around the transversal axis with the supine position being the zero-position.								
Environmental									
Temperature									
Operation:	<table border="1"> <tr> <td>LuMon™ Monitor</td> <td>10 to 35 °C</td> </tr> <tr> <td>LuMon™ Connector</td> <td>10 to 38 °C</td> </tr> <tr> <td>LuMon™ Belts</td> <td>10 to 40 °C</td> </tr> <tr> <td>NeoContactAgent</td> <td>10 to 40 °C</td> </tr> </table>	LuMon™ Monitor	10 to 35 °C	LuMon™ Connector	10 to 38 °C	LuMon™ Belts	10 to 40 °C	NeoContactAgent	10 to 40 °C
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LuMon™ Connector	10 to 38 °C								
LuMon™ Belts	10 to 40 °C								
NeoContactAgent	10 to 40 °C								
Storage:	LuMon™ Monitor -20 to 60 °C								

LuMon™ Connector	5 to 40 °C				
LuMon™ Belts	5 to 40 °C				
NeoContactAgent	0 to 30 °C				
Humidity					
LuMon™ Monitor	<table border="1"> <tr> <td>Operation</td> <td>15 – 90% non-condensing</td> </tr> <tr> <td>Storage</td> <td>10 – 95% non-condensing</td> </tr> </table>	Operation	15 – 90% non-condensing	Storage	10 – 95% non-condensing
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Ingress protection					
LuMon™ Monitor	IP22				
LuMon™ Connector	IPX1				
Compliance					
IEC 60601-1 (3 rd edition), IEC 60601-1-2 (4 th edition), ISO 10993-1 (2009)					
Classification according European Medical Device Regulation 745/2017					
Class IIa: LuMon™ Monitor, LuMon™ Connector					
Class I: LuMon™ Belt, NeoContactAgent					
Intra-System Compatibilities					
LuMon™ Monitors with activated Neonates / Infants configuration and GUI-SW 1.0.x.xxx/ TIC-SW 1.6.x.000 only support LuMon™ Connectors and LuMon™ Belts sizes 19, 22, 26, 30, 35, 40, 47.					

LuMon™ Monitor Neo (PN 2ST200-100-02) (GUI-SW 1.0.x.xxx; TIC-SW 1.6.x.000; with activated Neonates / Infants configuration)

Physical Characteristics	
Weight	< 4 kg (lightweight)
Size	30.8 cm x 21.8 cm x 10.1 cm (12.1" x 8.6" x 4.0")
Mountable on	SenTec's Trolley for the LuMon™ Monitor; most VESA 75x75 mounts (e.g. roll stands, wall mounts/railings)
Portable	Integrated carrying handle
Alarm System	
The LuMon™ Monitor currently has no alarm signals	
Display / Indicators	
Size / Resolution	30.7 cm (12.1") / 1280 x 800 pixels
Type	TFT touch display
Status Bar / LED Indicator	Various status icons (e.g. AC power, battery, patient rotation/inclination, belt time, signal quality) and status messages. AC Power/Battery Indicator (LED)
Scout View	Possibility to enter patient/ belt related data and belt displacement around the patient's thorax; indication of patient rotation/inclination, connector & belt connection status and electrode-skin-impedance coupling quality around the thorax.
Measurement Views	Various pre-configured, measurement views displaying Dynamic Image, Plethysmogram (reflecting relative breathing amplitude), Stretch Image with RTS-histogram aside (both with 10 categories); Silent Spaces Image also displaying the geometric center of the lung contours, CoV, and HoV; values and/or online trends for EELI, EILL, Aeration, RRI, RTS-quartiles, DSS, NSS, FLS, and CoV(v).
Languages	dansk, deutsch, english, español, français, italiano, nederlands, norsk, português, svenska, suomi, türkçe

Configurable Analysis Mode (BB, TB-I, TB-II), time range for online trends (5 min, 15 min, 30 min, 60 min, 6 h, 24 h), Plethysmogram time range (10 s, 30 s, 60 s, 300 s), Date&Time, Time format (12 h, 24 h)

Data Management	
Non-volatile internal memory providing at least 4 hours of data	
Possibility to mark events	
Possibility to store screenshots on an USB memory stick (if connected)	
Possibility to store data on an USB memory stick (if connected) for subsequent display, analysis and reporting within ibeX (SenTec's PC-based EIT data analysis and viewing software (for research use only)).	
Interfaces	
Belt connector port (isolated with 2 MOPP from the other interface ports)	
2 USB 2.0 Standard-A ports (Type A) - only supporting USB memory sticks	
2 Serial ports (RS/EIA-232) – for service use only	
1 LAN Port (100BASE-TX) – for service use only	
Electrical – Instrument	
AC Power	100 – 240 V ± 10% (50/60 Hz)
Power	max 0.3 A at 230 V
Consumption	max 0.6 A at 100 V
Electrical Safety	Suitable for continuous operation
(IEC 60601-1)	Class I (if connected to mains)
	Class II (if operated on battery)
	Type BF
Electrical – Internal Battery	
Backup battery to bridge power interruptions	
Type	Rechargeable, sealed LiIon Battery
Capacity	Up to 1 hour (new fully charged battery)
Charging Time	Approximately 5 hours

LuMon™ Connector (PN 1ST110-100)

Physical Characteristics	
Dimension	22 mm x 79 mm x 52 mm / 142 mm x 51 mm x 18 mm

Lengths of Cable	Approximately 2.5 m
Weight	Approximately 200 g

LuMon™ Belts (PN 1ST26x-100)

Size	x	Underbust girth [cm]	Size	x	Underbust girth [cm]
19	2	17.0-20.5	35	6	32.5-37.5
22	3	20.5-24.0	40	7	37.5-43.5
26	4	24.0-28.0	47	8	43.5-52.0
30	5	28.0-32.5			

ensures a tight fit between belt and patient without restricting patient breathing. The textile LuMon™ Belts have to be used on intact skin, are for single-patient use and can be used for up to 72 hours. Use of sequentially applied LuMon™ Belts on a single patient can be repeated for up to 30 consecutive days.

The gentle textile belt is suitable for patients whose skin require particularly attention as for example preterm newborns. Its extensible closure band

NeoContactAgent Kit (PN 1ST232-100)

Characteristics	
Content Spray Bottle	25 ml
Kit Content	6 spray bottles & 6 measuring tapes
Microbial Status	Non-sterile

The NeoContactAgent serves as a medium for impedance coupling between a LuMon™ Belt and the patient's skin. The NeoContactAgent has to be used on intact skin and can be used for up to 30 consecutive days.

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