

## LuMon™ OEM System – Neonates / Infants configuration (LMOS-N)

*SenTec EIT technology*

*Compact & Lightweight*

*Regional lung function monitoring at the bedside*

*Noninvasive & Radiation Free*

*Skin friendly & Easy to Use*



SenTec's LuMon™ OEM System (LMOS) 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™ OEM System (LMOS-N) is intended for patients, whose underbust girth is within approximately 17.0 to 52.0 cm. The LMOS-N comprises SenTec's integration-ready OEM EIT Modules, external LuMon™ Modules, LuMon™ Connectors to link SenTec's patented, textile LuMon™ Belts being available in seven sizes to either OEM customer products integrating OEM EIT Modules or external LuMon™ Modules being interfaced with an OEM customer product, as well as SenTec's NeoContactAgent serving as a medium for impedance coupling between a LuMon™ Belt and the patient's skin. SenTec EIT solutions offer flexibility in all clinical environments.

SenTec's EIT platform 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™ OEM 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

<b>Respiratory Rate (RR)</b>	
Measurement Principle	Impedance based
Units	Breaths per minute (bpm)
Measurement Range	4 – 138 bpm
Resolution	1 bpm
Accuracy (A <sub>rms</sub> )	± 2 bpm over 5 – 70 bpm ± 4 bpm over 71 – 120 bpm ± 5 bpm over 121 – 130 bpm
<b>End-expiratory lung impedance (EELI) / End-inspiratory lung impedance (EILI)</b>	
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
<b>Aeration</b>	
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
<b>Relative Tidal Stretch (RTS)</b>	
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%
<b>Center of Ventilation (CoV)</b>	
CoV-values are defined as the weighted geometrical center of ventilation distribution within the lung contours. CoV(v) and CoV(h) characterize the ventilation distribution in vertical and horizontal directions, whereas CoV(r) and CoV(vd) characterize the ventilation distribution in right-to-left and ventrodorsal directions, respectively. CoV(v) defines the position of the Horizon of Ventilation (HoV).	
Units	%
Measurement Range	0 – 100% for CoV(v), CoV(h), CoV(vd), CoV(r)
<b>Functional Lung Spaces / Silent Spaces</b>	
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] Rahtu 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 (customizable (12.5 or 25 Hz))
Feed Current	0.7 – 3.7 mA <sub>rms</sub> ; 200 kHz ± 10%
Configurable	Patient Mode (adult or neonatal), Analysis Mode (BB, TB-I or TB-II).
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.
Data available for various EIT Images	Dynamic Image (data updated with image rate); Tidal Image, Stretch Image with RTS histogram (both with 10 categories), Silent Spaces Image (with geometric center of lung contours, CoV and HoV). The Tidal Image, Stretch Image and the Silent Spaces Image data is updated breath wise in BB-Mode, once every 15-seconds in TB-I mode, and are not supported in TB-II mode.
Plethysmogram	Waveform displaying the time course of the sum of all impedance values of all lung-pixels. It reflects the relative breathing amplitude.
Various other data	RTS quartiles, belt time, connector & belt connection status.
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:	OEM EIT Module	10 to 65 °C
	LuMon™ Module	10 to 35 °C
	LuMon™ Connector	10 to 38 °C
	LuMon™ Belts	10 to 40 °C
	NeoContactAgent	10 to 40 °C
Storage:	OEM EIT Module	-20 to 60 °C
	LuMon™ Module	-20 to 60 °C
	LuMon™ Connector	5 to 40 °C
	LuMon™ Belts	5 to 40 °C
	NeoContactAgent	0 to 30 °C
Humidity		
Operation	OEM EIT Module	15 – 90% non-condensing
	LuMon™ Module	15 – 90% non-condensing
Storage	OEM EIT Module	10 – 95% non-condensing
	LuMon™ Module	10 – 95% non-condensing
Atmospheric pressure		
Operation	OEM EIT Module	660 to 1060 hPa
	LuMon™ Module	660 to 1060 hPa
Storage	OEM EIT Module	500 to 1060 hPa
	LuMon™ Module	500 to 1060 hPa
Ingress protection		
LuMon™ Monitor	IP22	
LuMon™ Connector	IPX1	
Compliance		
IEC 60601-1 (3 <sup>rd</sup> edition), IEC 60601-1-2 (4 <sup>th</sup> edition), ISO 10993-1 (2009)		
Classification according European Medical Device Regulation 745/2017		
Class IIa: LuMon™ Module, LuMon™ Connector		
Class I: LuMon™ Belt, NeoContactAgent		
Intra-System Compatibilities		
OEM EIT Modules/LuMon™ Modules with TIC-SW 1.6.x.000 and neonatal-mode selected support LuMon™ Connectors/LuMon™ Belts sizes 19 to 47.		

## Integration-ready OEM EIT Module (PN 100102-15x) (TIC-SW 1.6.x.000)

General	
The OEM EIT Module (also referred to as Tomographic Image Creation (TIC) Module) is the core component of SenTec EIT technology. Thanks to its compact size and low power consumption, the OEM EIT Module can be integrated into a wide range of host configurations. The OEM EIT Module is used in SenTec's LuMon™ Module and in SenTec's standalone EIT monitor called LuMon™ Monitor.	
Physical Characteristics	
Weight	< 150 g

Size	9.5 cm x 9.0 cm x 4.0 cm (3.7" x 3.5" x 1.6")
Interfaces	
Belt Connector Port (isolated with 2 MOPP from the other interface ports)	
1 LAN Port (100BASE-TX) – to connect the host device	
Electrical	
Powering Options	12 V (x = 5); 24 V (x = 0)
Power Consumption	max 10W
Electrical Safety (IEC 60601-1)	Suitable for continuous operation Type BF Applied Part (Belt Connector)

## LuMon™ Module (PN 2ST400-100) (TIC-SW 1.6.x.000)

General	
SenTec's OEM EIT Module (see above) is now also available as an external module, making it easier than ever to implement SenTec EIT with existing medical devices such as patient ventilators.	
Physical Characteristics	
Weight	< 1 kg (lightweight)
Size	18.3 cm x 12.6 cm x 7.4 cm (7.2" x 5.0" x 2.9")
Mountable	Various LuMon™ Module Mounting Adapters for wall railings, infusion stands or VESA 75x75 mounts
Interfaces	
Belt Connector Port (isolated with 2 MOPP from the other interface ports)	
1 LAN Port (100BASE-TX) – to connect the host device	

Electrical – Instrument	
External AC-Adapter 12 V (PN 100404-101)	100 – 240 V ± 10% (50/60 Hz); C14 AC inlet socket; various mains cables with different country-specific plugs available
Power Consumption	max 0.8 A at 230 V max 1.4 A at 100 V
Electrical Safety (IEC 60601-1)	Suitable for continuous operation Class I Type BF Applied Part (Belt Connector)

## 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
Host Connector	Redel SP Plug SAN.M13.NLA.5GZ; customizable

## 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			

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

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.

## 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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