

## LuMon™ System – Adults / Children configuration (LMS-A)

*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 **Adults / Children configuration** of the LuMon™ System (LMS-A) is intended for patients, whose underbust girth is within approximately 76 to 128 cm. The LMS-A comprises LuMon™ Monitors with Adults / Children configuration supporting adult-mode only, SensorBeltConnectors to link SenTec's patented, textile SensorBelts being available in four sizes to the LuMon™ Monitor, as well as SenTec's ContactAgent serving as a medium for impedance coupling between a SensorBelt 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. 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, it has been proven useful in optimizing ventilator settings in critically ill patients suffering from ARDS [1]. It has also been shown helpful in assessing lung collapse and lung over-distention [2, 3] and therefore can play an important role in the individualization of patients' PEEP settings [4, 5]. Furthermore, EIT can also help to reduce postoperative atelectasis or to guide protective ventilation strategies [6].

### System performance

Respiratory Rate (RRI)	
Measurement Principle	Impedance based
Units	Breaths per minute (bpm)
Display Range	4 – 66 bpm
Resolution	1 bpm
Accuracy ( $A_{rms}$ )	$\pm 2$ bpm over 5 – 60 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] Bachmann et al.: Electrical impedance tomography in acute respiratory distress syndrome. Critical Care 2018: 22-263.
- [2] Gómez-Laberge et al.: A unified approach for EIT imaging of regional overdistension and atelectasis in acute lung injury. IE EE Trans Med Imaging. 2012 Mar; 31(3):834-42.
- [3] Spadaro et al.: Variation of poorly ventilated lung units (silent spaces) measured by electrical impedance tomography to dynamically assess recruitment. Critical Care 2018: 22-26.
- [4] Zhao et al.: Positive end-expiratory pressure titration with electrical impedance tomography and pressure-volume curve in severe acute respiratory distress syndrome. Ann. Intensive Care 2019: 9-7.
- [5] Ukere et al.: Perioperative assessment of regional ventilation during changing body positions and ventilation conditions by electrical impedance tomography. British Journal of Anaesthesia 2016: 228-35.
- [6] Pereira et al.: Individual positive end-expiratory pressure settings optimize intraoperative mechanical ventilation and reduce postoperative atelectasis. American Society of Anesthesiologists 2018.

## System characteristics, compliance and compatibilities

General EIT characteristics	
Number of Electrodes	32
Image Rate	> 50 Hz
Feed Current	0.7 – 3.7 mA <sub>rms</sub> ; 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 gender, weight and height.
Patient Position (position sensor embedded in SensorBeltConnector)	
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:	<div>LuMon™ Monitor 10 to 35 °C</div> <div>SensorBeltConnector 10 to 35 °C</div> <div>SensorBelts 10 to 35 °C</div> <div>ContactAgent, ContactAgent-II 10 to 40 °C</div>
Storage:	LuMon™ Monitor -20 to 60 °C

SensorBeltConnector	5 to 40 °C
SensorBelts	5 to 40 °C
ContactAgent, ContactAgent-II	0 to 25 °C
Humidity	
LuMon™ Monitor	<div>Operation 15 – 90% non-condensing</div> <div>Storage 10 – 95% non-condensing</div>
Atmospheric pressure	
LuMon™ Monitor	<div>Operation 660 to 1060 hPa</div> <div>Storage 500 to 1060 hPa</div>
Ingress protection	
LuMon™ Monitor	IP22
SensorBeltConnector	IP54 / 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™ Monitor, SensorBeltConnector	
Class I: SensorBelt, ContactAgent, ContactAgent-II	
Intra-System Compatibilities	
LuMon™ Monitors with activated Adults / Children configuration and GUI-SW 1.0.x.xxx/ TIC-SW 1.6.x.000 only support SensorBeltConnectors and SensorBelts sizes 80, 92, 104, 116.	

## LuMon™ Monitor (PN 2ST200-100-01) (GUI-SW 1.0.x.xxx; TIC-SW 1.6.x.000; with activated Adults / Children 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 and belt related data; 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, EILI, Aeration, RRI, RTS-quartiles, DSS, NSS, FLS, and CoV(v).
Languages	dansk, deutsch, english, español, français, italiano, japanese, nederlandse, 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)
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Data Management	
Non-volatile internal memory providing at least 4 hours of data	
Possibility to mark events	
Possibility to store screenshots on a USB memory stick (if connected)	
Possibility to store data on a 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 Consumption	<div>max 0.3 A at 230 V</div> <div>max 0.6 A at 100 V</div>
Electrical Safety (IEC 60601-1)	<div>Suitable for continuous operation</div> <div>Class I (if connected to mains)</div> <div>Class II (if operated on battery)</div> <div>Type BF</div>
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

## SensorBeltConnector (PN 1ST101-100)

Physical Characteristics	
Dimension	9 mm x 59 mm x 36 mm / 142 mm x 51 mm x 18 mm
Lengths of Cable	Approximately 2.5 m

Weight	Approximately 200 g
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## SensorBelts (PN 1ST20x-100)

Size	x	Underbust girth in cm
80	3	76-86
92	4	86-98
104	6	98-112
116	7	112-128

Its patented oblique design makes the SensorBelts follow the movement of the ribs without restricting patient breathing, which would be highly undesirable in patients suffering from respiratory insufficiency. The textile SensorBelts 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 SensorBelts on a single patient can be repeated for up to 30 consecutive days.

## ContactAgent Kit (PN 1ST224-100) / ContactAgent-II Kit (PN 1ST226-100)

Characteristics	
Content Spray Can	100 ml
Kit Content	6 spray cans & 6 measuring tapes
Microbial Status	Non-sterile

The ContactAgent / ContactAgent-II serves as a medium for impedance coupling between a SensorBelt and the patient's skin. The ContactAgent / ContactAgent-II has to be used on intact skin and can be used for up to 30 consecutive days.

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