

User's Guide



For the LuMon™ System

GUI software 1.0.x.x/TIC software 1.6.x.xxx

LuMon™ Belts sizes 47 and smaller / SensorBelts

Warranty

The manufacturer warrants to the initial purchaser that each new component of the LuMon™ System will be free from defects in workmanship and materials. The manufacturer's sole obligation under this warranty is to at its own choice repair or replace any component – for which the manufacturer acknowledges the warranty cover – with a replacement component.

Warranty exclusions and system performance

SenTec AG can neither guarantee or verify instrument performance characteristics nor accept warranty claims or product liability claims if the recommended procedures are not carried out, if the product has been subject to misuse, neglect or accident, if the product has been damaged by extraneous causes, if accessories other than those recommended by SenTec AG are used, if the warranty seal on the lower side of the monitor is broken, or if instrument repairs are not carried out by *SenTec Authorized LuMon™ Technicians*.

CAUTION

Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Design/patents related to the LuMon™ System: Please refer to the specification sheets for the LuMon™ System: www.sentec.com/education/eit/plpm-eit

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While every effort is made to ensure the correctness of the information provided in this User's Guide, SenTec AG assumes no responsibility for errors or omissions. This User's Guide is subject to change without notice.



LuMon™ Monitor
SensorBeltConnector
LuMon™ Connector



SensorBelt
LuMon™ Belt
ContactAgent
NeoContactAgent

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1 INTRODUCTION

1.1 LuMon™ System

The LuMon™ System (LMS) is a compact and lightweight Electrical Impedance Tomography (EIT) system providing noninvasive monitoring of variations of regional air content/volume within a cross-section of the patient's lungs as well as patient respiration. It displays the results as real-time *EIT images, waveforms, parameters and indices.*

NOTE
The LuMon™ System is not intended for diagnosis, it is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

The LuMon™ System comprises LuMon™ Monitors (5.1), belt connectors (5.2) to link SenTec's textile EIT belts (5.3) being available in various sizes to the LuMon™ Monitor, as well as SenTec's contact agents (5.4) serving as a medium for impedance coupling between a belt and the patient's skin. Measuring tapes (5.5) permit the user to determine the recommended belt size, i.e. the size of the belt best fitting the respective patient.

The LuMon™ System is available in two configurations

- (👤) for adults and children illustrated in Table 1-1 with a family of belts supporting an underbust girth range of approximately 76 to 128 cm (abbreviated as LMS-A).
- (👶) for neonates and infants illustrated in Table 1-2 with a family of belts supporting an underbust girth range of approximately 17 to 52 cm (abbreviated as LMS-N).

Table 1-1: LuMon™ System — Adults/Children configuration (👤)

| LuMon™ Monitor - Adult | SensorBeltConnector | SensorBelt | ContactAgent |
|---|---|--|---|
|  |  |  |  |

Table 1-2: LuMon™ System — Neonates/Infants configuration (👶)

| LuMon™ Monitor - Neo | LuMon™ Connector | LuMon™ Belt | NeoContactAgent |
|---|---|--|---|
|  |  |  |  |

1.2 About this User's Guide

This User's Guide contains information needed to operate and maintain the LuMon™ System. Before attempting to operate the LuMon™ System, read this User's Guide and pay special attention to the safety information (2). Strictly observe all warnings and cautions.

LuMon™ System's indications and contraindications are provided in section 3. The principle of operation and limitations of EIT in general and SenTec EIT in particular are elucidated in 4. A brief description of the components of the LuMon™ System is provided in 5. Section 6 describes the Graphical User Interface (GUI) of the LuMon™ Monitor. How to install the LuMon™ System is explained in 7.

Section 8 explains how to apply the belts and to initiate monitoring, a description of the information displayed while monitoring is provided in 9, and how to pause or end monitoring is outlined in 10.

Maintenance and troubleshooting related information are provided in 11 and 12, respectively. The technical specifications for the LuMon™ System, finally, are provided in section 13.

NOTE

Statements in this User's Guide are only applicable for LuMon™ Monitors with the software versions indicated on the cover page, where "x" can be any number. The software versions of the LuMon™ Monitor – GUI and TIC (14.3) - are displayed in the 'system settings' area of ScoutView (Figure 6-8). If your LuMon™ Monitor has other software versions than those indicate on the cover page, please refer to the corresponding version of the User's Guide for the LuMon™ System (see www.sentec.com/education/eit/plpm-eit).

1.3 Symbols, terminology and abbreviations

Safety symbols and messages are defined in sub-section 2.1.

A glossary of symbols used on the products of the LuMon™ System (1.1), on their packaging and in the associated documentation is provided in sub-section 2.4.

A list of terms defined in this User's Guide is provided in sub-section 14.2.

- Table 14-1 defines generalized product terms for those products of the LuMon™ System that have different variants. Unless the differentiation between the product variants is of importance for a specific context, the generalized product terms will be used.
- Table 14-2 defines SenTec EIT related terms.

Notice that those terms being italicized and/or capitalized in Table 14-2 are *italicized* and/or Capitalized throughout the entire User's Guide.

Also notice that the symbol  identifies information and instructions being applicable only to the Adults/Children configuration of the LuMon™ System whereas the symbol  identifies information and instructions being applicable to its Neonates/Infants configuration only.

A list of abbreviations used in this User's Guide is provided in 14.3.

2 SAFETY INFORMATION

2.1 Safety symbols and messages

Safety symbols and messages are shown and defined as follows:

 **WARNING**
Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the patient, user, or environment.

 **CAUTION**
Cautions indicate a potentially hazardous situation, which, if not avoided, could result in minor or moderate injury.

 **NOTE**
Notes provide additional guidelines or information.

A comprehensive list of warnings and cautions are provided in 2.2. Some are repeated in other sections of the User's Guide to reinforce a specific safety topic. Notes are provided in sections where applicable.

2.2 Warnings and cautions

 **WARNING**
The LuMon™ System is to be operated by qualified health care personnel. Personnel operating the LuMon™ System should have read and understood this manual, accessory directions for use, all precautionary information, and specifications before use. Improper use of the LuMon™ System may result in injury, inaccurate measurements and/or damage to the device.

 **WARNING**
Use only equipment, accessories, disposables or parts supplied or recommended by SenTec AG. Use of other parts may result in injury, inaccurate measurements and/or damage to the device.

 **WARNING**
Only use SenTec's contact agents to wet the belt's striped fabric as directed herein. Do not use any other agents or liquids such as ECG or ultrasonic gel. Doing so may adversely affect the belt measurement and the performance of the LuMon™ System.

 **WARNING**
Measurements and displayed images of the LuMon™ System may be affected by patient manipulation or movement.

 **WARNING**
Do not use LuMon™ Monitors, belt connectors or belts that appear damaged or have a technical fault. Doing so may result in injury, inaccurate measurements and/or damage to the device.

 **WARNING**
To reduce the possibility of patient entanglement or strangulation, properly route and fix cables. Do not leave unapplied belts in reach of the patient.

 **WARNING**
To ensure patient safety, do not place the LuMon™ Monitor, mounted or unmounted, in any position that might cause it to fall or tip over on the patient. Ensure to properly fasten the LuMon™ Monitor, when mounting it on, for example, a roll stand or a wall mount/railing. Furthermore, do not lift the LuMon™ Monitor by the belt connector or the AC power cord because they could disconnect from the LuMon™ Monitor, causing it to fall on the patient.

 **WARNING**
Before cleaning the LuMon™ Monitor, always switch it off and disconnect it from AC mains power.

 **WARNING**
Apart from using cleaning and disinfection agents as recommended herein, do not spray, pour, or spill any liquid on LuMon™ Monitors (particularly on the openings of its chassis), belt connectors, belts and other accessories. Neither immerse any parts of the LuMon™ System nor allow water or other liquids to enter the device. Failure to do so increases the risk of electrical shock and/or may result in damage to the device. If a LuMon™ Monitor has been wetted accidentally, it must be removed from AC mains power, wiped dry externally, allowed to dry thoroughly, and inspected by qualified technician (e.g. a biomedical engineer) before further use.

⚠ WARNING

Do not expose the LuMon™ Monitor to heavy moisture and do not allow any fluids to enter the LuMon™ Monitor. Plugs and connectors have to be kept meticulously clean and dry at all times. Failure to do so increases the risk of electrical shock and/or may result in damage to the device.

ⓘ CAUTION

Dispose of the battery in accordance with local requirements and regulations for Lithium Ion batteries.

⚠ WARNING

Explosion and flammability hazards. Do not use the LuMon™ Monitor in the presence of flammable or explosive anesthetics/gases or other flammable or explosive substances. The LuMon™ Monitor is not rated for use in an oxygen rich environment.

⚠ WARNING

The ContactAgent is an extremely flammable aerosol. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Do not spray on an open flame or other ignition source. Pressurized container: Do not pierce, crush or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122°F. Failure to do so increases the risk of fire and/or explosion.

⚠ WARNING

Before using the LuMon™ System verify that it does not interfere with bioimpedance measurement devices such as impedance respiration monitoring or with ECG, EMG, EOG or EEG devices being connected to the same patient. Interference with such devices may adversely affect the monitoring of the patient.

⚠ WARNING

Do not use the LuMon™ System on patients with internal or external pacemakers or other active implants such as defibrillators. The LuMon™ System may affect the operation of such devices.

⚠ WARNING

The LuMon™ System is NOT rated for use with a defibrillator. Therefore, remove the belt from the patient before defibrillating a patient. Failure to do so may reduce the defibrillation effectiveness or cause device damage.

⚠ WARNING

This device has been tested and found to comply with the requirements for medical devices according to the IEC 60601-1-2. These requirements are designed to provide reasonable protection against harmful interference in a typical medical installation. When interpreting monitored data be aware that interferences that either affect the LuMon™ System and/or other devices may nevertheless occur and, hence, may adversely affect the monitoring of the patient. In case you witness or suspect interferences, contact a qualified technician, your local SenTec EIT representative or SenTec AG.

⚠ WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the LuMon™ System. Otherwise, degradation of the performance of the LuMon™ System could result.

⚠ WARNING

The LuMon™ Monitor should not be used adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If adjacent or stacked use is necessary, the LuMon™ Monitor should be observed to verify normal operation in the configuration it is to be used.

⚠ WARNING

High-frequency surgical equipment may influence the operation of the LuMon™ System and may not be operated in combination with the LuMon™ System.

⚠ WARNING

MR UNSAFE. Do not use the LuMon™ System with magnetic resonance (MR) equipment. Induced current in the belt and belt connector could potentially cause patient burns, and the MR image quality could be affected by the LuMon™ System and the LuMon™ System by the MR equipment.

⚠ WARNING

During normal operation (except intra-hospital transport), it is recommended that the monitor is always connected to AC mains power.

⚠ WARNING

If the monitor is operated on an AC mains power source with a depleted battery and the AC mains power is subsequently disconnected or lost, the monitor may shut down immediately.

⚠ WARNING

Do not connect the LuMon™ Monitor to an electrical outlet controlled by a wall switch, because the LuMon™ Monitor may be unintentionally disconnected from AC mains power and, once the battery is depleted, accidentally switch off.

⚠ WARNING

To avoid risk of electrical shock, this equipment must be connected to AC mains power with protective earth. Ensure that power and protective ground lines are connected correctly. As a precaution connect this equipment directly to fixed wall sockets within hospitals or hospital type facilities only. Neither connect it to portable sockets nor use extension cords or connect it to publicly accessible AC mains power.

For US, respectively Japan: Grounding reliability can only be achieved when the LuMon™ Monitor is connected to an equivalent receptacle marked HG (Hospital Grade), respectively HGJ (Hospital Grade Japan).

⚠ WARNING

Accessory equipment (e.g. a PC or an externally powered USB memory device) connected to the LuMon™ Monitor's data ports must be certified according to the applicable IEC standards (e.g. IEC 60601-1, UL60601-1, CSA C22.2 No. 601-1-M90, or IEC 60950). Furthermore, all resulting configurations must comply with the IEC standard 60601-1 systems requirements. Anyone who connects accessory equipment to the LuMon™ Monitor configures a medical system and is, therefore, responsible for ensuring that the resulting system complies with the IEC standard 60601-1 systems requirements and the electromagnetic compatibility standard IEC 60601-1-2. Connection of accessory equipment to the LuMon™ Monitor's data ports is to be performed by qualified personnel.

⚠ WARNING

SensorBelts and LuMon™ Belts, are for single patient use only — do not attempt to reuse, clean, disinfect, or sterilize. Using a belt on more than one patient increases the risks of infection and cross-contamination. Using a belt whose *belt time* has expired may compromise its biological integrity and functionality as well as the overall system performance. Dispose of the belt when the *belt time* has elapsed or after ending monitoring for a patient.

⚠ WARNING

Do not apply SensorBelts, LuMon™ Belts, ContactAgent or NeoContactAgent on open, uncovered wounds. Doing so increases the risks of infection and tissue irritation.

ⓘ CAUTION

Biological evaluation has been conducted in compliance with ISO 10993-1 on the belts and the contact agents for their use on the intact skin of an individual patient for up to 30 cumulative days. Nevertheless, on rare occasions erythema (skin redness) has been observed in neonates and infants on the skin area where the belt has been applied. Should skin redness occur, it will generally resolve within a few hours after belt removal. Reassess the patient's skin periodically as needed.

⚠ WARNING

Wipe off ContactAgent residue from the patient after belt removal.

⚠ WARNING

Clean and disinfect the reusable parts of the LuMon™ System as described in this User's Guide after ending monitoring for a patient and before use with a new patient, and regularly according to institutional policy during use with a single patient. Before each use, prepare the LuMon™ System as described herein. Failure to do so increases the risk of cross contamination and patient infection.

⚠ WARNING

All parts of or removed from the LuMon™ System must be considered potentially contaminated and a source of infection risk. Dispose of all parts removed from the device according to local regulations for medical waste.

⚠ WARNING

The SensorBeltConnector's ControlBox and MatchBox generate a small amount of heat and their surfaces can reach several °C above ambient temperature. Failure to adhere to the following points increases the risk of local skin burn:

- 1) Do not place the MatchBox directly on the patient and place the ControlBox in a way to prevent any skin contact with the patient.
- 2) Where possible do not cover the ControlBox or the MatchBox with linens or bed covers to avoid possible heating of the skin.
- 3) To minimize the pressure on the chest of the patient in prone position right there where the MatchBox is inserted in the SensorBelt's Docking Station and to allow convection to conduct heat away from the MatchBox place, for example, two small cushions on either side of the docking station.

⚠ WARNING

The LuMon™ Connector's ControlBox generates a small amount of heat and its surface can reach several °C above ambient temperature. Failure to adhere to the following points increases the risk of local skin burn:

- 1) Place the ControlBox in a way to prevent any skin contact with the patient.
- 2) Where possible do not cover the ControlBox with linens or bed covers to avoid possible heating of the skin.

ⓘ CAUTION

Be aware that a belt being applied to a patient may impair the quality of x-ray images (e.g. of chest x-rays).

ⓘ CAUTION

To avoid misinterpretation of results, be aware that in some situations Lung Impedance changes displayed by the *Plethysmogram* may be less related to breathing than to other sources such as cardiac activity, therefore one should not rely solely upon the visual representation of the *Plethysmogram*, i.e. the *Lung Impedance waveform*, to derive information on breathing.

⚠ WARNING

Data quality may be impaired, measurements incorrect and thus results may be misinterpreted if

- 1) the size of the connected belt does not match the recommended size
- 2) the belt is not applied and positioned as recommended
- 3) *rotation* and *inclination* displayed by the LuMon™ Monitor do not reflect the patient's position.
- 4) patient data, half/full underbust girth or belt displacement are not determined and entered correctly. Notice that these settings are reset to their defaults when starting up the monitor. You therefore must re-enter these settings after each restart of the monitor
- 5) an inadequate *Analysis Mode* is selected.

ⓘ CAUTION

In *TB-I mode* the minima and maxima and, hence, the maximal *Lung Impedance* changes detected within *Analysis Intervals* are, irrespective of the magnitude or rate of the *Lung Impedance* changes, assumed to be related to breathing, more specifically to end-expiratory and end-inspiratory time points. In order to avoid misinterpretation of data, be aware that *breathing-related EIT images and indices* generated in *TB-I mode* may consequently not always be physiologically meaningful.

ⓘ CAUTION

To avoid misinterpretation of results be aware that the *Dependent Silent Spaces*, the *Non-Dependent Silent Spaces* as well as the vertical and horizontal components of the *Center of Ventilation (CoV(v) and CoV(h))* are less meaningful, if the gravity vector is more or less perpendicular to the examined thorax cross-section being defined by the *belt plane*. This is, for example, the case, if the patient is standing or sitting upright.

ⓘ CAUTION

To avoid misinterpretation of results, it should be considered that the displayed *Thorax and Lung Contours* and associated thorax and lung models used by the LuMon™ System to evaluate the measured *EIT data* may deviate significantly from reality in case of patients with, for example, anatomic anomalies (e.g. after lung resection) or pathologies. Do not utilize the displayed *Thorax and Lung Contours* for diagnostic purposes or evaluation.

ⓘ CAUTION

Use of other cleaning and disinfection agents than recommended may cause damage and/or deterioration of the device's materials and device failure may result.

ⓘ CAUTION

Applying excessive mechanical force to the device during cleaning may damage the device's materials and device failure may result.

ⓘ CAUTION

Do not touch, press or rub the surfaces of the LuMon™ Monitor or belt connector with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with any that could scratch the surfaces of the LuMon™ Monitor or belt connector.

ⓘ CAUTION

Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the LuMon™ Monitor or belt connector. These substances can attack the device materials and device failure may result.

ⓘ CAUTION

The LuMon™ System and its accessories are provided non-sterile. Do not sterilize any parts of the equipment by irradiation, steam or ethylene oxide. Do not autoclave or pressure sterilize.

⚠ WARNING

There are no user serviceable parts inside the LuMon™ Monitor. The cover of the LuMon™ Monitor should only be removed by *SenTec Authorized LuMon™ Technicians*. Service as well as the complete safety and functionality test should be made by qualified technicians. Failure to do so could lead to injury, inaccurate measurements and/or damage to the device.

⚠ WARNING

Do not modify the LuMon™ System without express approval from SenTec. Modifications to the system by persons without the appropriate training or using unapproved parts could lead to injury, inaccurate measurements and/or damage to the device.

2.3 EMC-related safety information

The LuMon™ System is intended for use in the electromagnetic environment specified in [13.8](#).

2.3.1 Electromagnetic emissions

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used according to the User's Guide, may cause harmful interference with radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the users will be required to correct the interference at their own expense.

The LuMon™ Monitor has been tested and found to comply with the limits for a Class A digital device, pursuant to both Part 15 of the FCC rules and the radio interference regulations of the Canadian Department of Communications.

📌 NOTE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

2.3.2 Electrostatic discharge precautions

Always use proper electrostatic discharge (ESD) procedures, protection, and products when handling and before operating the device. Failure to use ESD procedures may damage electrostatically sensitive components in the device. Such damage to components is not covered by SenTec warranties. ESD can amount to a significant voltage that can damage PCBs (printed circuit board) or other system components. ESD damage is cumulative and may not be apparent at first, causing only degraded performance rather than a clear actual device failure. ESD is more likely to occur under low humidity conditions, or through contact with carpeting, linens, or clothing.

2.3.3 Electromagnetic susceptibility

The LuMon™ Monitor complies with IEC 60601-1-2 EMC (Electro Magnetic Compatibility) Collateral Standard. Certain transmitting devices (for example, cellular phones, walkie-talkies, cordless phones, paging transmitters), however, emit radio frequencies that could influence or disturb the operation of the LuMon™ Monitor.

2.4 Glossary of symbols

The table below summarizes symbols used on the LuMon™ System (including all its related parts), on the packaging and in the associated documentation. These symbols indicate information essential for proper use; the order of their appearance is not prioritized.

| | | | |
|---|--|---|--|
|  | Follow instructions for use |  | Equipotentiality terminal |
|  | Consult instruction for use |  | Ethernet connection |
|  | Manufacturer |  | Single-use |
|  | Date of manufacture |  | Single patient multiple use |
|  | EU authorized representative |  | Indicator of belt size (under bust circumference in cm) |
|  | 'Conformité Européene' means that the device is in conformance with the applicable European Regulations and Directives as stated in the declaration of conformity. |  | Use by date |
|  | Symbol for conformity to the aerosol directive 75/324/EEC |  | Nominal quantity information about content |
|  | Medical Device |  | Caution |
|  | Reference number |  | Extremely flammable aerosol |
|  | Serial number |  | Keep dry |
|  | Batch or Lot number |  | Keep away from sunlight |
| Rx only | Prescription Device (applies for USA) |  | Humidity limit |
| IP_{xy} | Ingress protection class xy |  | Pressure limit |
|  | Fuse |  | Temperature limit |
|  | Radio frequency transmitter |  | Upper limit of temperature |
|  | Applied part type BF (according to IEC 60601-1) |  | Do not use if package is damaged |
|  | Off (power) |  | Dispose of according to Council Directive 2012/19/EU |
|  | On (power) |  | Recommended user action(s) |
|  | USB connection |  | Information/instructions applicable to the Adults/Children configuration of LuMon™ System |
| IOIO | Serial port |  | Information/instructions applicable to the Neonates/Infants configuration of LuMon™ System |

3 INDICATIONS AND CONTRAINDICATIONS

3.1 Intended user

It is intended that the LuMon™ System (1.1) will be used only by licensed health care practitioners who understand its fundamental functioning and principle of operation (4).

 **NOTE**

Personnel operating the LuMon™ System should have read and understood this manual, accessory directions for use, all precautionary information, and specifications before use.

3.2 Intended use: General

The LuMon™ System (1.1) is intended for use in patients' requiring assessment or monitoring of respiration and (regional) lung function. This includes patients breathing spontaneously or requiring supplemental oxygen, breathing support or mechanical ventilation. It is also intended to monitor ventilation distribution in patients lying, for example, in supine, prone, and lateral positions, where regional lung volume distribution is of clinical interest.

The LuMon™ System is intended for use under direct supervision of licensed healthcare practitioners in professional health care facilities such as hospitals, hospitals-type facilities, or intra-hospital transport.

3.3 Intended use: Indications for Use

The LuMon™ System (1.1) – consisting of the LuMon™ Monitor and specified accessories — is a noninvasive, non-radiological monitoring device that provides an assessment of regional impedance variation within a cross-section of a patient's thorax. Graphical and numerical information is presented to the clinical user to support an assessment of respiration and of variations in regional air content within a cross section of a patient's lungs. The LuMon™ System provides no alarms and its measurements are only to be used as an adjunct to other clinical information. The LuMon™ System is not intended to be utilized as a primary vital signs monitor.

The SensorBeltConnector and the LuMon™ Connector are reusable adapters intended to link a SensorBelt or a LuMon™ Belt to the LuMon™ Monitor.

The SensorBelts and the LuMon™ Belts are non-sterile, single-patient use accessories, and are intended to be applied on the circumference of the patient's thorax on intact skin. Sequential application of SensorBelts and LuMon™ Belts on a single patient can be repeated for up to 30 cumulative days.

The SensorBelts are indicated for use in adults and pediatric patients with selection of an appropriate belt size based on the thorax circumference (underbust girth).

The LuMon™ Belts are indicated for use in adults through neonatal patients with selection of an appropriate belt size based on the thorax circumference (underbust girth).

The ContactAgent, the ContactAgent-II and the NeoContactAgent are contact liquids indicated for use with the SensorBelts and the LuMon™ Belts as a medium for impedance coupling between the belts and the intact skin of patients. The ContactAgent, the ContactAgent-II and the NeoContactAgent are non-sterile and are intended for use on the intact skin of an individual patient for up to 30 cumulative days.

The LuMon™ System is intended for use under the direct supervision of a licensed healthcare practitioner in professional healthcare facilities providing patient care.

U.S.A. specific statement: The LuMon™ System is for prescription use only.

3.4 Contraindications

Using the LuMon™ System (1.1) is contraindicated if any of the following conditions are present or are thought to be present:

- The patient has active implants (pacemaker or defibrillator).
- The patient has an external pacemaker or defibrillator.
- The patient has open/uncovered wounds in the area where the belt is applied, as for example an open thorax during/after heart surgery.

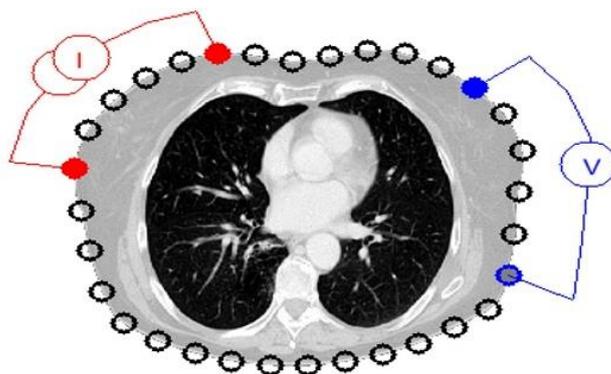
4 PRINCIPLE OF OPERATION AND LIMITATIONS

4.1 General principle of operation

SenTec EIT is based on the principles of Electrical Impedance Tomography (EIT), where weak alternating currents are applied and travel along the paths of least resistance through an object, and the electrical potentials resulting at the object's surface are continuously measured by an array of electrodes placed on the object. Typically, electrode arrangements are designed to sequentially pick up signals coming from different directions. In this way, the electrical "point of view" is constantly changing and images reflecting regional impedance within the object and variations thereof can be created with frame rates of typically 50 Hz.

Figure 4-1 illustrates this concept for a belt with embedded electrodes fastened around the chest of a subject. Very weak, harmless alternating current is applied to a pair of electrodes (in red). The current applications are successively shifting around the chest. For each current applied to a pair of electrodes, the voltages are measured by 32 pairs of electrodes (in blue).

Figure 4-1: Schematic drawing of the electrode locations for an EIT belt fastened around the chest of a subject.



4.2 Principle of operations when used for lung function monitoring

When a belt with embedded electrodes is fastened around the chest (Figure 4-1) it is possible to continuously monitor and visualize regional impedance variations within a cross-section of the subject's thorax. As impedance variations are primarily caused by lung function – i.e. air flowing in, distributing within, and flowing out of the lungs – and, to a lesser extent, perfusion and cardiac activity, it is possible to continuously monitor variations of regional air content/volume within the subject's lungs noninvasively, without radiation and at the bedside. Various images (e.g. images related to distribution of tidal volume), *waveforms* as well as a wide variety of *indices* and *parameters* can be derived and trended, including but not limited to:

- *Plethysmogram* (9.4) representing relative variations of *Lung Impedance*, related to relative lung volume/air content variations with breathing.
- *Impedance Respiratory Rate* (RRi) (9.6).
- *End-Expiratory Lung Impedance* (EELI) (9.8) related to end-expiratory lung volume, i.e. if exhaling against ambient pressure, to the Functional Residual Capacity (FRC), when breathing normally, or to the Residual Volume (RV), in a forced expiration.
- *End-Inspiratory Lung Impedance* (EILI) (9.8) related to end-inspiratory lung volume.
- *Tidal Variation* (TVi) (9.8), the difference between EILI and EELI, related to the volume inhaled in one breath, i.e. to the Tidal Volume (TV), when breathing normally, or to the Inspiratory Capacity (IC), in a forced inspiration.
- *Aeration* (9.8) defined as the mean *Lung Impedance* (MLI) over a preset *Analysis Interval* of a fixed duration of 15 seconds, related to mean lung volume.
- *Stretch Image* (9.9), displaying the regional distribution of *Relative Tidal Stretch* (RTS) and representing the regional distribution of Tidal Volumes (TV) within the lungs.
- *Center of Ventilation* (CoV) (9.10) characterizing the ventilation distribution and represented, for example, in vertical and horizontal direction, with the CoV vertical component (CoV(v)) defining the position of the *Horizon of Ventilation* (HoV).
- *Silent Spaces* (9.10), reflecting the distribution and percentage of lung areas with little or no impedance change during breathing. As such they are meant to represent the percentage of lung regions receiving little or no ventilation and are thus hypoventilated. Considering the influence of gravity on lung tissue and fluids within the lungs, *Silent Spaces* being localized above or below the HoV are further defined as *Dependent Silent Spaces* (DSS) and *Non-Dependent Silent Spaces* (NSS), respectively. *Silent Spaces* may be helpful to identify conditions such as displacement of the

endotracheal tube, pneumothorax, and pleural effusion 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.

- *Functional Lung Spaces (FLS)* (9.10) reflecting the distribution and percentage of lung areas with non-negligible impedance change during breathing. As such they are meant to represent the percentage of ventilated lung regions. They are related to what in literature is referred to as Functional Lung Size [1] or size of the available lung volume, i.e. the percentage of the aerated remaining lung.

For a more in depth description of the principle of operation of SenTec EIT, please refer to the respective Technical Bulletin available on <https://www.sentec.com/education/eit/tbwpcn-eit/>.

The EIT methodology has been an object of study for decades and there is plenty of literature on the subject; a summary description can be found for example in Costa et al.[2]. For more information on its clinical applications, please also refer to reviews available in literature, e.g. Frerichs et al. [3], Putensen et al.[4], Lobo et al.[5].

4.3 Particular features of SenTec EIT

SenTec EIT selects the thorax and lung models best adapted to the individual patient from a set of predefined, CT-derived thorax and lung models (9.1). These models are used for *EIT image* reconstruction and to determine corresponding *Thorax* and *Lung ROIs* respectively *Thorax* and *Lung Contours*. In Adults/Children configuration these models mainly depend on body mass index (BMI) for both genders. In Neonates/Infants configuration, where only one CT-derived thorax and lung model is used, the LuMon™ System accounts for the displacement of the electrodes around the thorax from their assumed default positions. It is herewith emphasized that, with the exception of the *Global Dynamic Image* (9.4), the LuMon™ System solely evaluates impedance values within the *Lung ROI*.

SenTec EIT also features a position sensor that continuously evaluates the patient's position (*rotation* and *inclination*) and permits the clinician to assess the influence of gravity on lung mechanics and ventilation distribution in the lungs (9.2).

As fully functional electrodes are important for the generation of *EIT data*, the LuMon™ System continuously evaluates the skin contact quality of all 32 electrodes integrated in the belt and categorizes the electrodes into those having adequate, poor, or insufficient contact, respectively impedance coupling to the skin, the latter referred to as *failing electrodes* (9.3). The LuMon™ System's advanced, unique image reconstruction algorithm can compensate up to six *failing electrodes*. When the belt to skin contact quality changes significantly or a change in the number of *failing electrodes* occurs, the LuMon™ System performs a calibration of its measurement setup and monitoring is briefly interrupted. In case of too many *failing electrodes* monitoring is not possible. Once data quality respectively signal quality (9.3) improves, for example, when there are fewer *failing electrodes*, monitoring resumes.

4.4 Limitations of EIT/SenTec EIT

The following clinical situations or factors may affect *EIT raw data* and thereof derived *EIT images*, *waveforms* and *indices* and may limit the accuracy of thereof derived *parameters* such as the *Respiratory Rate* (RRi).

- Mal-positioned or not properly applied belt — e.g. belt not positioned as recommended or not enough contact agent applied on belt (8).
- Conditions hindering sufficient belt to skin contact quality such as bandages in the area around the thorax where the striped fabric of the belts (8.1, 8.2) has to be placed.
- Conditions causing an abrupt or gradual deterioration of the belt to skin contact quality — e.g. (excessive) patient movement/manipulation or gradual loosening of the belt's fit around the chest.
- Conditions (transiently) causing impedance changes within the *EIT sensitivity region* not related to breathing — e.g. administration of fluids or movement of liquid and tissue (e.g. diaphragm) within the *EIT sensitivity region*.
- Use of *TB-I Analysis Mode* in very irregularly and/or very weakly breathing patients, in which the maximal *Lung Impedance* change within *Analysis Intervals* may not be *breathing-related* and, hence, *breathing-related EIT images and indices* generated in *TB-I mode* may not always be physiologically meaningful (8.4, 9.7).
- Use of SenTec EIT in patients after lung resection or having thoracic malformations — in this case, the models for thorax and lung may deviate significantly from reality, a fact that should be considered in the interpretation of the results.
- Use of SenTec EIT when it is contraindicated (3.4).
- Interferences caused by other devices such as high-frequency (HF) surgical equipment or devices emitting strong electromagnetic fields.
- The subdivision of *Silent Spaces* in *Dependent Silent Spaces* and *Non-Dependent Silent Spaces* as well as the vertical and horizontal components of the *Center of Ventilation* (CoV(v) and CoV(h)) are less meaningful if the *inclination* is big enough that the gravity vector is more or less perpendicular to the examined thorax cross-section being defined by the *belt plane*. This is, for example, the case if the patient is standing or sitting upright.

 **NOTE**

EIT does not measure the behavior of the entire lung but only the lung regions located within the *EIT sensitivity region*. *EIT images* and thereof derived *parameters* and *indices*, consequently, do not represent information being related the entire lung, but only information being related to the lung region located within the *EIT sensitivity region*.

Being centered around the *belt plane* the *EIT sensitivity region* is roughly lens-shaped: close to the body surface the thickness of the *EIT sensitivity region* corresponds to at least the width of the belt (Table 13-13) and increases towards the central region of the thorax to reach a thickness of roughly one half to two-thirds of the thorax width.

5 SYSTEM OVERVIEW

This section provides a brief description of each component of the LuMon™ System (1.1), which is available in a configuration for adults and children and in a configuration for neonates and infants.

The LuMon™ System comprises LuMon™ Monitors (5.1), belt connectors (5.2) to link SenTec's textile EIT belts (5.3) being available in various sizes to the LuMon™ Monitor, as well as SenTec's contact agents (5.4) serving as a medium for impedance coupling between a belt and the patient's skin. Measuring tapes (5.5) provided with the contact agents permit the user to measure the patient to determine the recommended belt size, i.e. the size of the belt best fitting the respective patient.

5.1 LuMon™ Monitor

The LuMon™ Monitor (Figure 5-1, Figure 5-2) is a portable, bedside stand-alone EIT monitor available in two configurations:

- (👤) The LuMon™ Monitor – Adult, i.e. the monitor's Adults/Children configuration, supports SensorBeltConnectors (5.2.1) and SensorBelts (5.3.1).
- (👶) The LuMon™ Monitor – Neo, i.e. the monitor's Neonates/Infants configuration, supports LuMon™ Connectors (5.2.2) and LuMon™ Belts (5.3.2).

NOTE
The monitor housing, connectors and graphical user interface are common to both monitor configurations and are described below.

Figure 5-1: LuMon™ Monitor – front panel (here a LuMon™ Monitor – Adult)

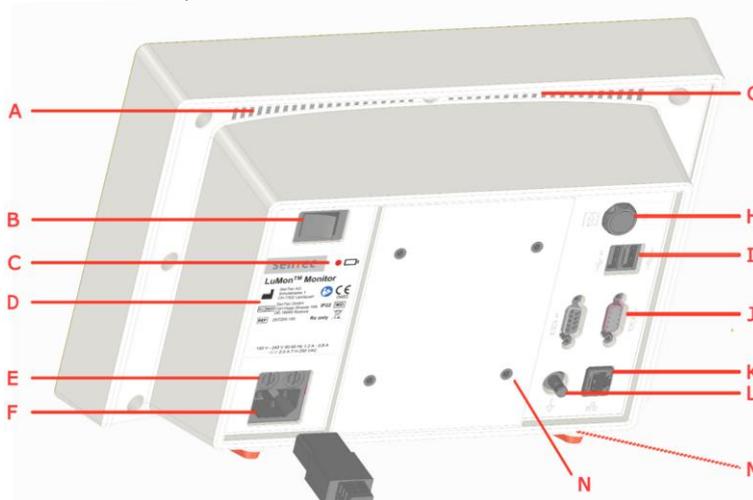


- A. Touch screen based Graphical User Interface – GUI (6).
- B. Support foot indicating the LuMon™ Monitor's configuration:
LuMon™ ADULT identifies the LuMon™ Monitor – Adult;
LuMon™ NEO identifies the LuMon™ Monitor – Neo.

NOTE
The LuMon™ Monitor screen supports finger touch operation only. The use of rigid or sharp instruments on the touch screen can permanently damage the display.

NOTE
The LuMon™ Monitor performs a calibration of its touch screen after it is switched on. To not disturb the calibration of the touch screen, do not touch the screen the first few seconds after startup.

Figure 5-2: LuMon™ Monitor — rear panel



- | | |
|---|--|
| <ul style="list-style-type: none"> A. Ventilation slot B. ON/OFF switch C. AC Power/Battery indicator D. Type label E. Fuse holders (2x) F. AC power inlet G. Integrated carrying handle H. Belt connector socket | <ul style="list-style-type: none"> I. USB ports (2x) – only for use with memory devices without external power supply J. Serial ports (2x) – factory use only K. Ethernet port – factory use only L. Equipotentiality terminal connector M. Ventilation slot N. VESA 75 compatible mounting holes (4x) |
|---|--|

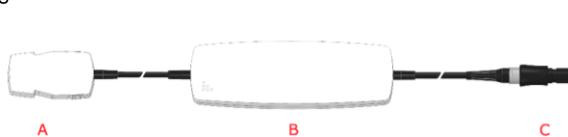
5.2 Belt connectors

The belt connectors are designed to link belts to LuMon™ Monitors. Belt connectors control the injection of very weak alternating currents into the patient’s thorax and the measurement of the voltages (electrical potentials) resulting at the skin of the patient’s thorax.

5.2.1 SensorBeltConnector

The SensorBeltConnector (Figure 5-3) links a SensorBelt (5.3.1) to a LuMon™ Monitor – Adult (5.1). The position sensor embedded in its MatchBox permits the LuMon™ System to measure and display the patient’s position (*rotation* and *inclination*) (9.2). If the SensorBeltConnector is properly connected to a LuMon™ Monitor in on-state, the status indicator LED of its MatchBox continuously lights green if a SensorBelt is connected.

Figure 5-3: SensorBeltConnector



- A. MatchBox (includes a position sensor and a status indicator LED) – connects to SensorBelts
- B. ControlBox (with integrated electronics and status indicator LED)
- C. Monitor plug – connects to the belt connector socket on the LuMon™ Monitor

5.2.2 LuMon™ Connector

The LuMon™ Connector (Figure 5-4) links a LuMon™ Belt (5.3.2) to a LuMon™ Monitor – Neo (5.1).

In contrast to the MatchBox of the SensorBeltConnector (5.2.1) the MatchBox of the LuMon™ Connector contains neither a position sensor nor a status indicator LED.

Figure 5-4: LuMon™ Connector



- A. LuMon™ MatchBox – connects to LuMon™ Belts
- B. ControlBox (with integrated electronics and status indicator LED)
- C. Monitor plug – connects to the belt connector socket on the LuMon™ Monitor

5.3 Belts

SenTec EIT's disposable single-patient use belts are adhesive-free, embody 32 electrodes in a striped fabric and are designed to ensure a snug fit between belt and patient without restricting patient breathing. In particular, the belts go around the chest following the ribs on a slightly oblique plane for belts used on adults and children or a transverse plane for belts used on neonates and infants. The belts must be used on intact skin, are for single-patient use and can be used for up to 72 hours. Sequential application of SensorBelts and LuMon™ Belts on a single patient can be repeated for up to 30 cumulative days

5.3.1 SensorBelt

SensorBelts (Figure 5-5) are available in four sizes (Table 13-14) and are intended for adults and children whose full underbust girth is within approximately 76 to 128 cm. Their shoulder straps help to properly position SensorBelts on the patient's thorax and, subsequently, help to avoid inadvertent displacement of the SensorBelt from its optimal position.

The oblique design enables the SensorBelt to follow the movement of the ribs and thus does not restrict breathing.

Figure 5-5: SensorBelt



- A. Shoulder straps with hook and loop fasteners
- B. Mid-line indicator – positioning aid (to be aligned with the spinal column)
- C. Striped fabric – adhesive-free, conductive cloth embedding 32 electrodes
- D. Docking station – for connection of the SensorBeltConnector
- E. Loops to attach shoulder straps
- F. Flap of SensorBelt

5.3.2 LuMon™ Belt

LuMon™ Belts (Figure 5-6) are available in seven sizes (Table 13-14) and are intended for neonates and infants whose underbust girth is within approximately 17 to 52 cm. The embedded position sensor permits the LuMon™ System to measure and display the patient's position (*rotation* and *inclination*) (9.2). The soft and expandable closure band prevents the chest from being constrained by the belt and, consequently, prevents restrictions to breathing and increased work of breathing.

Figure 5-6: LuMon™ Belt



- A. Striped fabric – adhesive-free, conductive cloth embedding 32 electrodes
- B. Soft and extensible closure band
- C. "Bear" – image to aid orientation of LuMon™ Belts – heads of bear and patient to be aligned – and to assess inadvertent belt displacement. The position sensor is underneath the bear.
- D. Connector plug – connects to the LuMon™ Connector

5.4 Contact agent

The ContactAgent and the NeoContactAgent serve as a medium for impedance coupling between the belts and the intact skin of patients. The contact agent has to be applied to the structured fabric of the belt before patient use (8.1, 8.2).

5.4.1 ContactAgent

The ContactAgent is provided in pressurized spray cans that allow fast and homogeneous application of the ContactAgent on SensorBelts, i.e. large-sized belts for adults and children (5.3.1). In particular, the foam that develops upon application of the ContactAgent provides a visual feedback on where the ContactAgent has been applied. The ContactAgent is supplied in kits containing six ContactAgent spray cans and six Measuring tapes – Adults/Children (5.5.1).



Figure 5-7: ContactAgent spray can

⚠ WARNING

The ContactAgent is an extremely flammable aerosol. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Do not spray on an open flame or other ignition source. Pressurized container: Do not pierce, crush or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122°F. Failure to do so increases the risk of fire and/or explosion.

5.4.2 NeoContactAgent

The NeoContactAgent is provided in spray bottles and is recommended for use with the LuMon™ Belts, i.e. the smaller-sized belts for neonates and infants (5.3.2). The NeoContactAgent is supplied in kits containing six NeoContactAgent spray bottles and six Measuring tapes – Neonates/Infants (5.5.2)



Figure 5-8: NeoContactAgent spray bottle

5.5 Measuring tapes

The measuring tapes permit the user to measure the patient to determine the recommended belt size, i.e. the size of the belt best fitting the respective patient.

5.5.1 Measuring tapes – Adults/Children

The Measuring tapes – Adults/Children (Figure 5-9) are included in the ContactAgent kits (5.4.1) to measure the half underbust girth of adults and children and indicate the recommended SensorBelt (5.3.1) size.



Figure 5-9: Measuring tape – Adults/Children

To assist size selection, predefined half underbust girth ranges on the Measuring tape – Adults/Children and packaging labels of corresponding belt sizes are color-coded. For example, on Measuring tapes – Adults/Children the half underbust girth range between 43 and 49 cm is marked blue and 92 is indicated as recommended SensorBelt size. Packaging labels of SensorBelts size 92 exhibit an area with the same blue color.

Refer to Table 13-14 for the full underbust girth range covered by each of the different available belts.

5.5.2 Measuring tapes – Neonates/Infants

The Measuring tapes – Neonates/Infants (Figure 5-10) are included in the NeoContactAgent kits (5.4.2) to measure the full underbust girth of neonates and infants and indicate the recommended LuMon™ Belt (5.3.2) size.



Figure 5-10: Measuring tape – Neonates/Infants

To assist size selection, predefined full underbust girth ranges on the Measuring tapes – Neonates/Infants and packaging labels of corresponding belt sizes are color-coded. For example, on Measuring tapes – Neonates/Infants the full underbust girth range between 32.5 and 37.5 cm is marked yellow and 35 is indicated as recommended LuMon™ Belt size. Packaging labels of LuMon™ Belts size 35 exhibit an area with the same yellow color.

Refer to [Table 13-14](#) for the full underbust girth range covered by each of the different available belts.

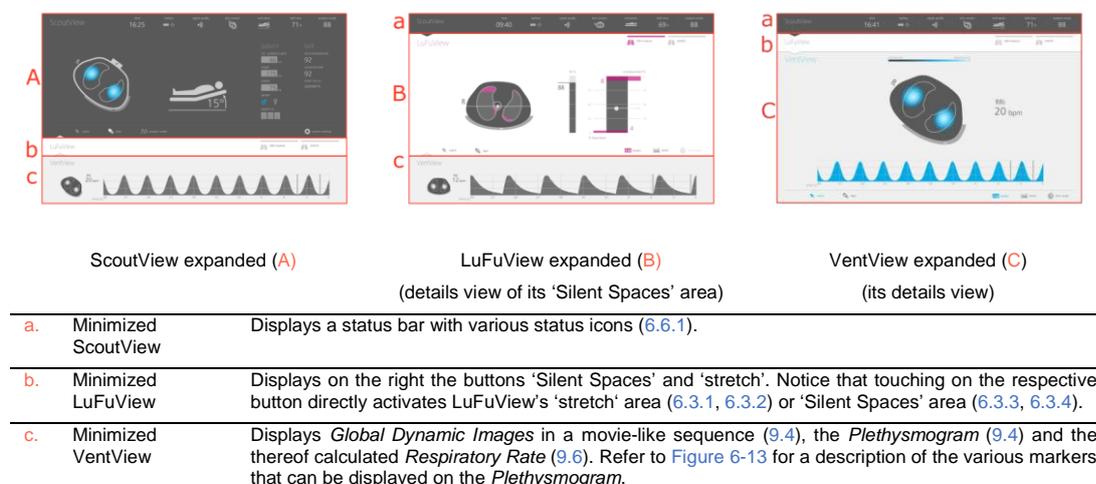
6 LUMON™ MONITOR – GUI

The LuMon™ Monitor (5.1) is controlled with a touch screen based Graphical User Interface (GUI). Sub-section 6.1 provides an overview of the LuMon™ Monitor’s GUI and its navigation. A detailed description of the three main screens called ScoutView, LuFuView and VentView is provided in 6.2, 6.3 and 6.4, respectively. Common elements and characteristics of *EIT images* and trends are summarized in 6.5. Various visual indicators such as status icons are described in 6.5. *Operator-adjustable parameters* are listed in 6.7.

6.1 GUI overview and navigation

ScoutView (6.2), LuFuView (6.3) and VentView (6.4) are the three main screens of the LuMon™ Monitor with ScoutView being the power-on default screen. Due to the arrangement of the main screens in layers, each main screen is always at least partially visible, with one of them expanded and the two others minimized or folded-in (Figure 6-1). Touching on a minimized main screen will cause it to expand and the expanded main screen to fold-in.

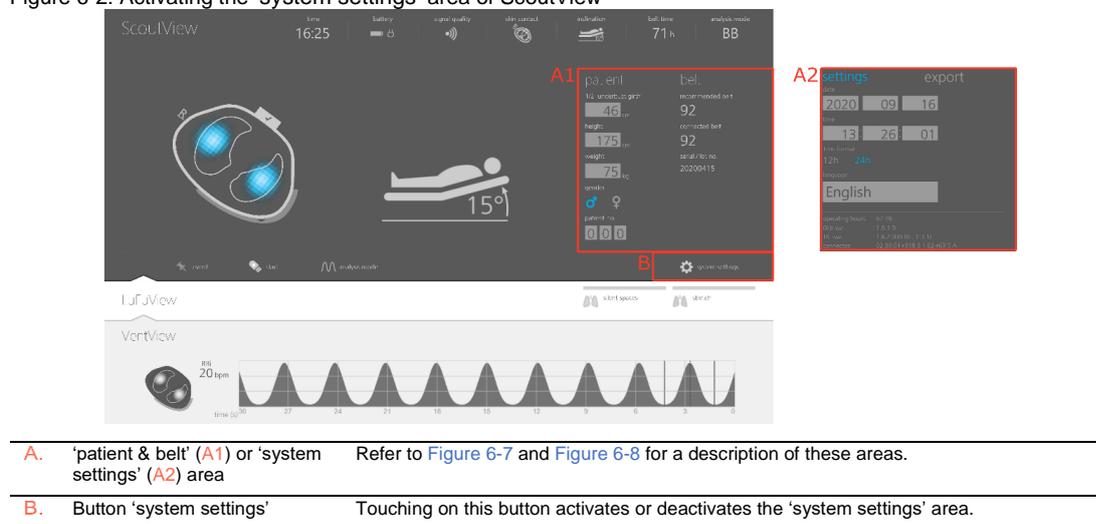
Figure 6-1: The three main screens of the LuMon™ Monitor.



NOTE
Buttons or symbols representing GUI elements or functions being active or selected, not being active or selected, or not being available or selectable are respectively displayed colored, in grey or dimmed grey.

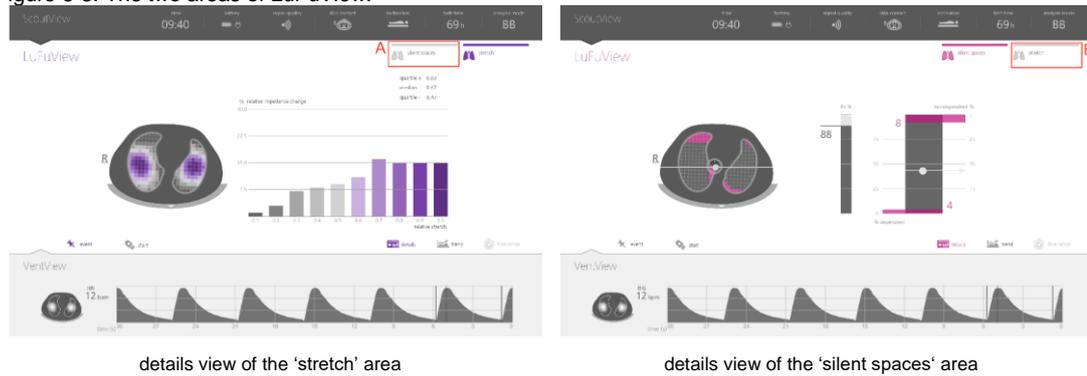
As illustrated in Figure 6-2, touching on the button 'system settings' on ScoutView (6.2) activates the 'system settings' area.

Figure 6-2: Activating the 'system settings' area of ScoutView



As illustrated in [Figure 6-3](#), touching on the button ‘stretch’ or the button ‘Silent Spaces’ on LuFuView permits to toggle between the ‘stretch’ area (6.3.1, 6.3.2) and the ‘Silent Spaces’ area (6.3.3, 6.3.4).

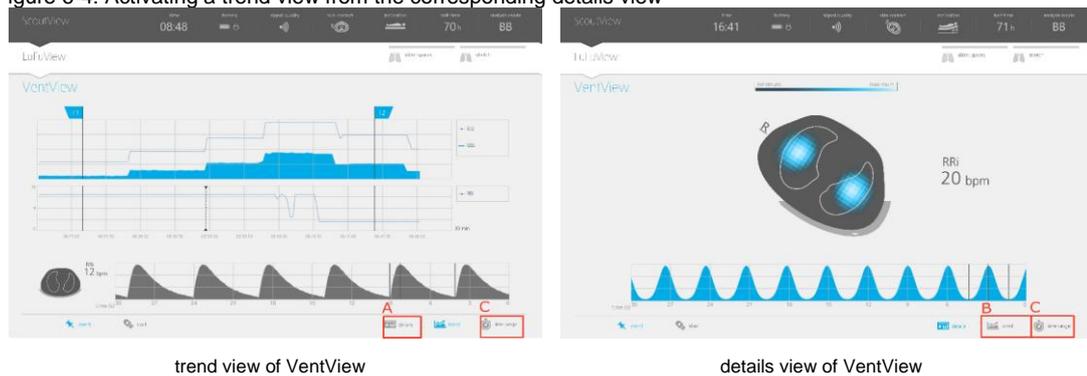
Figure 6-3: The two areas of LuFuView.



| | | |
|----|------------------------|---|
| A. | Button ‘silent spaces’ | Touching on this button activates LuFuView’s ‘silent spaces’ area |
| B. | Button ‘stretch’ | Touching on this button activates LuFuView’s ‘stretch’ area |

As illustrated in [Figure 6-4](#) for VentView, touching on the button ‘trend’ on the details views of VentView or of LuFuView’s ‘stretch’ or ‘silent spaces’ area, activates the corresponding trend view (6.3.2, 6.3.4, 6.4.2). Touching on the button ‘details’ when a trend view is active, re-activates the corresponding details view.

Figure 6-4: Activating a trend view from the corresponding details view



| | | |
|----|---------------------|--|
| A. | Button ‘details’ | Touching on this button activates the respective details view. |
| B. | Button ‘trend’ | Touching on this button activates the respective trend view. |
| C. | Button ‘time range’ | To change the displayed time range for <ul style="list-style-type: none"> • the <i>Plethysmogram</i> if VentView’s details view is active. • trends if a trend view is active. |

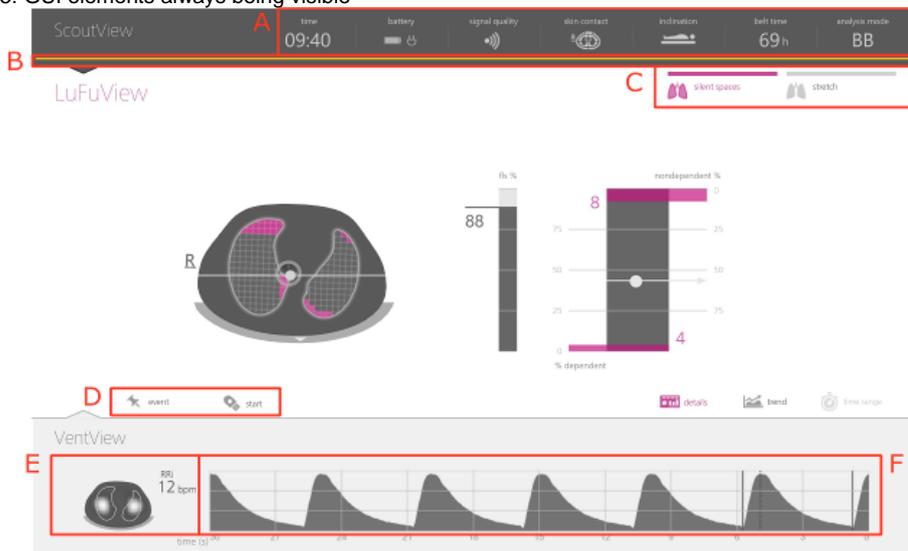
The button ‘time range’ ([Figure 6-4](#)) on the bottom right of all details views and trend views, finally, permits to adjust

- the displayed time range of the *Plethysmogram* if VentView’s details view (6.4.1) is active. Refer to [Table 6-8](#) for the respective time ranges and the power-on default time range.
- the displayed time range of trends if a trend view (6.3.2, 6.3.4, 6.4.2) is active. Refer to [Table 6-8](#) for the respective time ranges and the power-on default time range.

A description of the common characteristics of trends is provided in 6.5.2.

In addition to the three main screens, which are always visible at least in minimized form (Figure 6-1), the GUI elements or functions highlighted in Figure 6-5 are always visible.

Figure 6-5: GUI elements always being visible



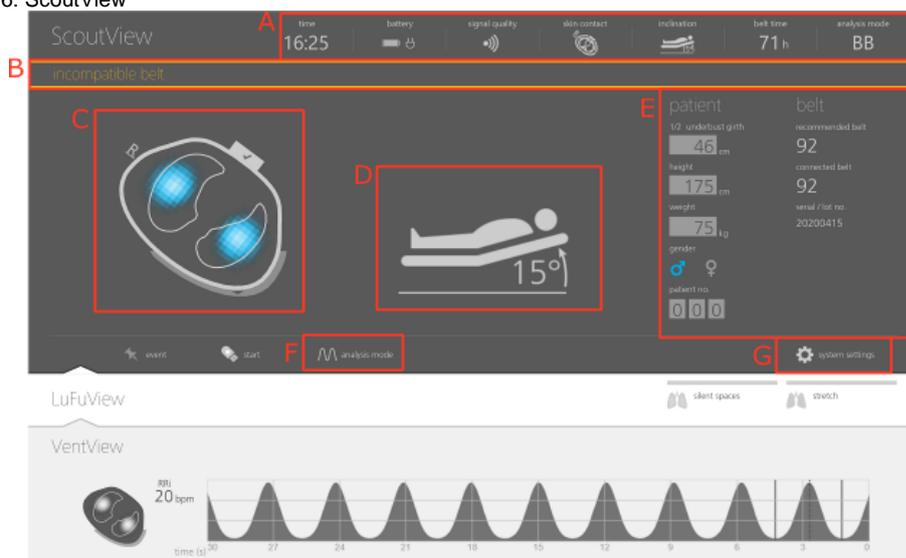
| | |
|--|---|
| A. Status bar | Refer to 6.6.1 for a description of the status icons provided in the status bar. |
| B. Status message indicator line | Horizontal yellow line displayed underneath the status bar when a status message (6.6.2) is displayed. |
| C. Buttons 'silent spaces' and 'stretch' | Refer to Figure 6-3 for a description of these buttons. |
| D. Buttons 'event' and 'record' | Refer to 9.11 and 9.12.1 for a description of these buttons. |
| E. Global Dynamic Image and Respiratory Rate | Refer to 9.4, 9.6 and Figure 6-13 for a description of this EIT image and this parameter, being displayed in larger size on the details view of VentView (Figure 6-13). |
| F. Plethysmogram | Refer to 9.4 and Figure 6-13 for a description of this waveform. |

6.2 ScoutView

ScoutView (Figure 6-6) is the power-on default screen of the LuMon™ Monitor. ScoutView displays status icons (6.6.1), status messages (6.6.2), data related to the connected belt and various other visual indicators providing information about the patient's position (9.2), the measurement quality/plausibility (9.3), and the general system status.

In ScoutView you can select the *Analysis Mode* (9.7) and enter data necessary for the selection of patient-specific, CT-derived thorax and lung models (Figure 6-7, 9.1). Furthermore, ScoutView provides access to the 'system settings' area where system *parameters* can be adjusted, system information such as software versions are indicated, or export of data stored in the internal memory of the LuMon™ Monitor can be activated (Figure 6-8, 9.11).

Figure 6-6: ScoutView



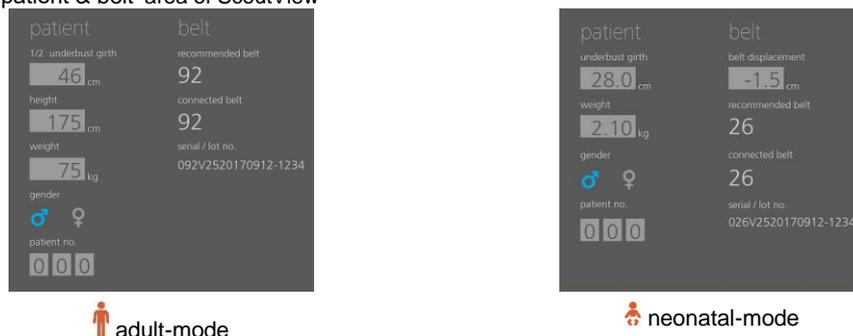
| | | |
|----|--|--|
| A. | Status bar | Provides various status icons (6.6.1). Remains visible if ScoutView is minimized. |
| B. | Status message field | Area displaying status messages (6.6.2). |
| C. | Global Dynamic Image | Refer to Figure 6-13 and 9.4 for a description of this <i>EIT image</i> . Note that on ScoutView, the connection status of the belt connector and belt (6.6.3) as well as the belt to skin contact quality around the thorax grouped in 12 electrode-segments (6.6.4) is indicated along with the <i>Global Dynamic Image</i> . |
| D. | Inclination indicator | Indicates <i>inclination</i> of the patient (9.2). |
| E. | 'patient & belt' or 'system settings' area | Refer to Figure 6-7 and Figure 6-8 for a description of these areas. |
| F. | Button 'analysis mode' | Touch this button to select the Analysis Mode (9.7). See Table 6-8 for possible selections and power-on default setting. |
| G. | Button 'system settings' | Touching this button activates or deactivates the 'system settings' area. |

Refer to Figure 6-5 for a description of the GUI elements being visible on all views.

The 'patient & belt' area of ScoutView (Figure 6-7)

-  permits to enter the measured half underbust girth and patient height, weight, and gender data which is used by the monitor for the selection of patient-specific, CT-derived thorax and lung models (9.1) best fitting the individual patient (see Table 6-5 for ranges and power-on defaults).
-  permits to enter the measured full underbust girth, patient data and the measured belt displacement which is used by the monitor to determine the position of the electrodes on the patient's thorax (9.1) as accurately as possible (see Table 6-6 for ranges and power-on defaults).
- displays the recommended belt size and the size of the connected belt, the latter highlighted in yellow if the size of the connected belt does not match the recommended size.
- displays the serial number (in case of SensorBelts) or lot number (in case of LuMon™ Belts) of the connected belt.

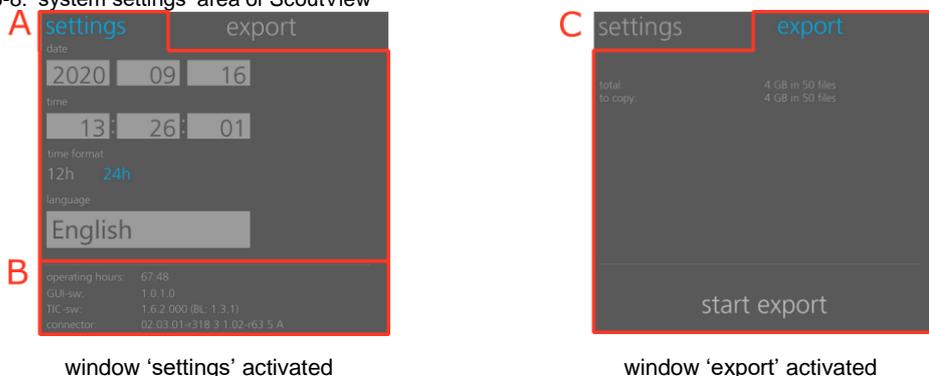
Figure 6-7: 'patient & belt' area of ScoutView



The 'system settings' area of ScoutView (Figure 6-8) has two windows:

- The window 'settings' permits to adjust various system settings (Table 6-7) and displays system related information such as software and hardware versions.
- The window 'export' permits to export data stored in the internal memory of the LuMon™ Monitor on a USB memory device connected to the LuMon™ Monitor (9.11).

Figure 6-8: 'system settings' area of ScoutView



| | |
|-------------------------------|--|
| A. System settings | Adjustable settings are date, time, time format, and language See Table 6-7 for ranges and power-on defaults. |
| B. System related information | The following system related information is displayed: <ul style="list-style-type: none"> • operating hours of the LuMon™ Monitor • software versions of the LuMon™ Monitor (GUI and TIC) • belt connector hardware and software versions |
| C. Data export | Touching on 'start export' starts data export on a USB memory device connected to the LuMon™ Monitor (9.11). |

Touch on the respective symbol to select the gender (Figure 6-7).

Touch the light grey field to adjust the corresponding *operator-adjustable parameter* (Figure 6-7, Figure 6-8). A number picker will open. Slide up- or downward to change the value. Click on 'ok' to save and, apart from language, enable the change.

NOTE
For 'weight' enter actual (not lean or ideal) body weight in kg.

NOTE
To enable the selection of a new language, the LuMon™ Monitor must be restarted.

NOTE
EIT data stored in the LuMon™ Monitor's internal memory will be deleted when changing its date/time. No further operator confirmation will be requested at the time of the change.

6.3 LuFuView

LuFuView has a 'stretch' area and a 'silent spaces' area, both areas with a details view and a trend view.

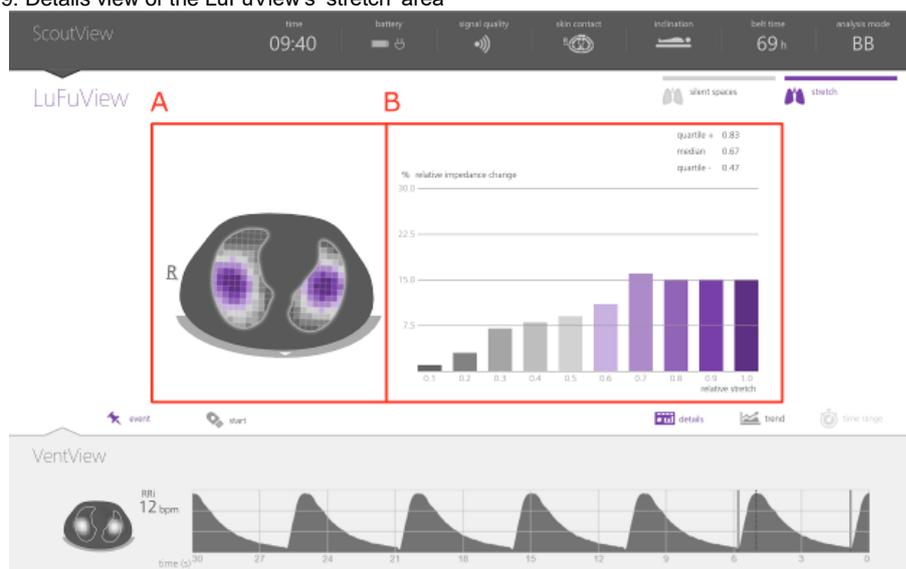
NOTE

LuFuView cannot be accessed in *TB-II mode*.

6.3.1 LuFuView – details view of its 'stretch' area

The details view of LuFuView's 'stretch' area (Figure 6-9) displays the *Stretch Image*, provides an associated weighted *Relative Tidal Stretch* histogram as well as quartiles of weighted *Relative Tidal Stretch* (9.9).

Figure 6-9: Details view of the LuFuView's 'stretch' area



- | | |
|--|--|
| A. Stretch Image | Image displaying the regional distribution of <i>Relative Tidal Stretch</i> within the <i>Lung ROI</i> (9.9). Refer to 6.5.1 for a description of the elements and characteristics common to <i>EIT images</i> . |
| B. Weighted Relative Tidal Stretch histogram | Ten-part bar chart providing the weighted <i>Relative Tidal Stretch</i> histogram associated with the <i>Stretch Image</i> (9.9). 25% quartile, median and 75% quartile of weighted <i>Relative Tidal Stretch</i> is displayed above the ten-part bar chart. Touch on one or more bars to highlight one or more corresponding clusters in the <i>Stretch Image</i> . Touch on the background of the ten-part bar chart to re-select all bars. |

Refer to Figure 6-3 for a description of the buttons 'silent spaces' and 'stretch'

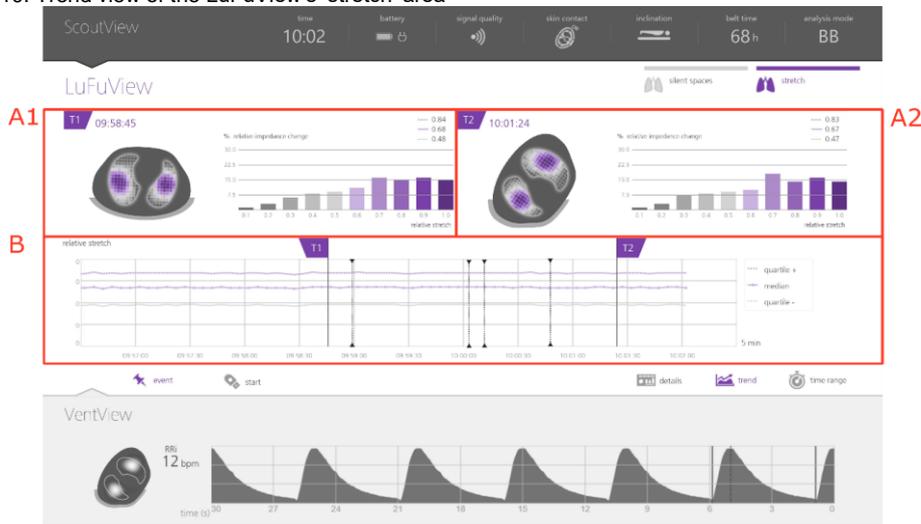
Refer to Figure 6-4 for a description of the buttons 'details', 'trend' and 'time range' (here, the last button dimmed grey)

Refer to Figure 6-5 for a description of the GUI elements being visible on all views

6.3.2 LuFuView – trend view of its ‘stretch’ area

The trend view of LuFuView’s ‘stretch’ area (Figure 6-10) provides trends of the quartiles of weighted *Relative Tidal Stretch*, i.e. of its center and spread.

Figure 6-10: Trend view of the LuFuView’s ‘stretch’ area

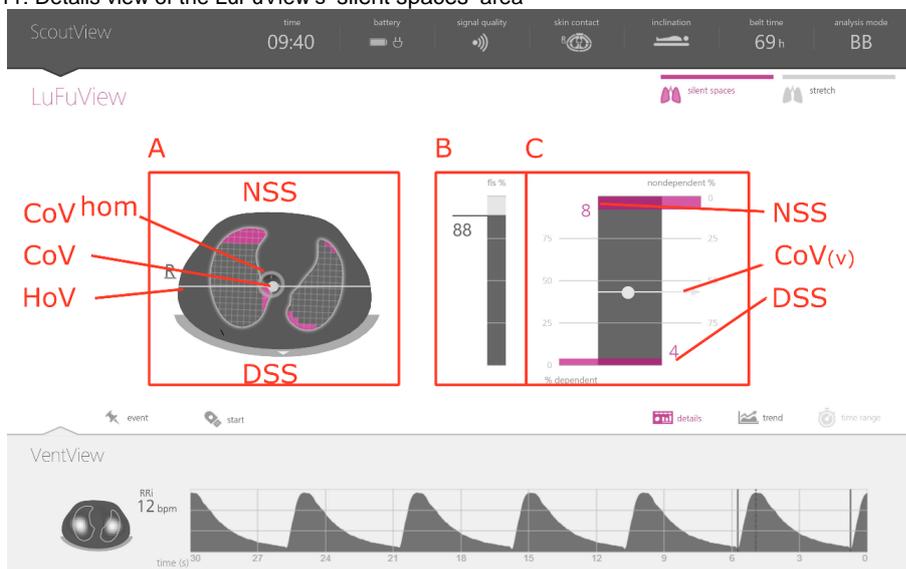


| | |
|---|--|
| <p>A. Miniaturized ‘stretch’ details views at flags T1 (A1) and T2 (A2)</p> | <p>Visualize at time T1 and T2</p> <ul style="list-style-type: none"> - the <i>Stretch Image</i> (also indicating <i>Rotation</i> at the respective time) - the weighted <i>Relative Tidal Stretch</i> histogram - the weighted <i>Relative Tidal Stretch</i> quartiles |
| <p>B. Trends of weighted <i>Relative Tidal Stretch</i> quartiles</p> | <p>The three trends represent the 25% quartile (lower dotted line), the median (solid middle line) and 75% quartile (upper dotted line) of weighted <i>Relative Tidal Stretch</i>.</p> <p>Refer to 6.5.2 for a description of the common characteristics of trends.</p> |
| <p>Refer to Figure 6-3 for a description of the buttons ‘silent spaces’ and ‘stretch’</p> | |
| <p>Refer to Figure 6-4 for a description of the buttons ‘details’, ‘trend’ and ‘time range’</p> | |
| <p>Refer to Figure 6-5 for a description of the GUI elements being visible on all views</p> | |

6.3.3 LuFuView – details view of its ‘silent spaces’ area

The details view of LuFuView’s ‘silent spaces’ area displays the *Silent Spaces Image*, the *Center of homogeneous Ventilation*, the *Center of Ventilation* and the *Horizon of Ventilation*. Furthermore, it provides the *Functional Lung Spaces* bar and the *Silent Spaces* bar (9.10).

Figure 6-11: Details view of the LuFuView’s ‘silent spaces’ area



| | |
|---|---|
| A. Silent Spaces Image | <p>Lung Pixels of the <i>Silent Spaces Image</i> colored in magenta represent the regional distribution of <i>Silent Spaces</i> (i.e. pixels with <i>Relative Tidal Stretch</i> values smaller or equal 10%) and those shown in grey the regional distribution of <i>Functional Lung Spaces</i> within the <i>Lung ROI</i> (9.10).</p> <p>The following elements overlie the <i>Silent Spaces Image</i>:</p> <ul style="list-style-type: none"> • grey hollow circle representing the <i>Center of homogeneous Ventilation</i> (CoV^{hom}) • whitish dot representing the <i>Center of Ventilation</i> (CoV) • whitish horizontal line perpendicular to the gravity vector through the CoV representing the <i>Horizon of Ventilation</i> (HoV), dividing the image into non-dependent (upper part of image) and dependent (lower part of image) areas. Correspondingly, the sub-sets of <i>Silent Spaces</i> being localized above and below the HoV are respectively referred to as <i>Dependent Silent Spaces</i> (DSS) and <i>Non-Dependent Silent Spaces</i> (NSS). <p>Refer to 6.5.1 for a description of the elements and characteristics common to <i>EIT images</i>.</p> |
| B. Functional Lung Spaces bar | Numerical and schematic representation of the <i>Functional Lung Spaces</i> (9.10). |
| C. Silent Spaces bar | <p>Numerical and schematic representation of</p> <ul style="list-style-type: none"> • <i>Dependent Silent Spaces</i> (DSS) (on left axis with 0% on the bottom) • <i>Non-Dependent Silent Spaces</i> (NSS) (on right axis with 0% on the top). <p>Schematic representation of</p> <ul style="list-style-type: none"> • <i>Horizon of Ventilation</i> (whitish horizontal line) • <i>Center of Ventilation</i> (CoV) (whitish dot) with its vertical component $CoV(v)$ displayed with respect to the right axis with 0% on the top (as indicated by the arrow going through the CoV pointing to the right). $CoV(h)$ is displayed without scale with respect to the width of the <i>Silent Spaces</i> bar with 0% at the left. |
| Refer to Figure 6-3 for a description of the buttons ‘silent spaces’ and ‘stretch’ | |
| Refer to Figure 6-4 for a description of the buttons ‘details’, ‘trend’ and ‘time range’ (here the last button dimmed grey) | |
| Refer to Figure 6-5 for a description of the GUI elements being visible on all views | |

6.3.4 LuFuView – trend view of its ‘Silent Spaces’ area

The trend view of LuFuView’s ‘silent spaces’ area provides trends of *Functional Lung Spaces (FLS)*, *Dependent Silent Spaces (DSS)*, *Non-Dependent Silent Spaces (NSS)*, and the vertical component of the *Center of Ventilation (CoV(v))* (9.10).

Figure 6-12: Trend view of LuFuView’s ‘silent spaces’ area



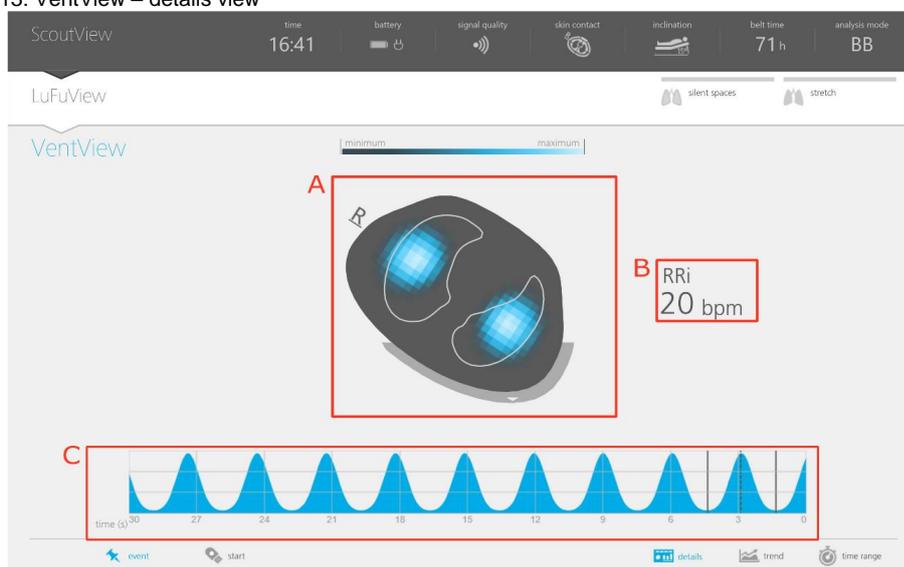
| | |
|---|--|
| <p>A. Miniaturized ‘silent spaces’ details views at flags T1 (A1) and T2 (A2)</p> | <p>Visualize at time T1 and T2</p> <ul style="list-style-type: none"> - the Silent Spaces Image (also indicating <i>rotation</i> at the respective time) - the Functional Lung Spaces bar - the Silent Spaces bar |
| <p>B. Trends of FLS, DSS, NSS and CoV(v)</p> | <p>The four trends represent</p> <ul style="list-style-type: none"> • with 0% at the bottom: <i>Functional Lung Spaces (FLS)</i> • with 0% at the top: <i>Non-Dependent Silent Spaces (NSS)</i> • with 0% at the top: <i>Vertical component of the Center of Ventilation (CoV(v))</i> |
| <p>Refer to 6.5.2 for a description of the common characteristics of trends.</p> | |
| <p>Refer to Figure 6-3 for a description of the buttons ‘silent spaces’ and ‘stretch’</p> | |
| <p>Refer to Figure 6-4 for a description of the buttons ‘details’, ‘trend’ and ‘time range’</p> | |
| <p>Refer to Figure 6-5 for a description of the GUI elements being visible on all views</p> | |

6.4 VentView

6.4.1 VentView – details view

The details view of VentView displays the *Global Dynamic Image* (9.4), the *Plethysmogram* (9.4) and the calculated *Respiratory Rate* (9.6).

Figure 6-13: VentView – details view



- | | |
|-------------------------|--|
| A. Global Dynamic Image | Image visualizing the regional impedance distribution within the <i>Thorax ROI</i> . Displayed in real-time as continuously updated series of images in a movie-like sequence (9.4). Refer to 6.5.1 for a description of the elements and characteristics common to <i>EIT images</i> . |
| B. Respiratory Rate | Impedance based <i>Respiratory Rate</i> (9.6). If the LuMon™ System is unable to detect a breath, the last calculated value continues to be displayed for up to 40 seconds and is then replaced by "--". |
| C. Plethysmogram | Auto-scaled <i>Lung Impedance waveform</i> moving from right to left with zero (0) being the current time and, for example, the signal at 10 seconds corresponding to the <i>Lung Impedance</i> measured 10 seconds ago (9.4). Solid black vertical lines identify the start and end of the most recent completed <i>Analysis Interval</i> , i.e. the last detected breath in <i>BB mode</i> and a 15-seconds interval in <i>time-based</i> modes; broken black vertical lines identify end-inspiratory and end-expiratory time points within the last completed <i>Analysis Interval</i> (9.7). Dotted black vertical lines with triangles at both ends (if any) identify operator events (9.11). Touching the <i>waveform</i> changes from a full <i>waveform</i> style to a line style and vice versa. |

Refer to Figure 6-4 for a description of the buttons 'details', 'trend' and 'time range'

Refer to Figure 6-5 for a description of the GUI elements being visible on all views

6.4.2 VentView – trend view

The trend view of VentView displays trends of

- *End-Expiratory Lung Impedance (EELI)* (9.8), *End-Inspiratory Lung-Impedance (EILI)* (9.8) and *Respiratory Rate (RRi)* (9.6) in *BB* and *TB-I* modes.
- *Aeration* (9.8) and *RRi* (9.6) in *TB-II* mode.

Figure 6-14: VentView – trend view



| | | |
|----|---|---|
| A. | Trends of EELI and EILI in <i>BB</i> and <i>TB-I</i> modes or of <i>Aeration</i> in <i>TB-II</i> mode | In <i>BB</i> and <i>TB-I</i> modes the upper line and the lower shaded area respectively represent trends of EILI and EELI In <i>TB-II</i> mode the line represents the <i>Aeration</i> trend. |
| B. | Trend of RRi | <i>Respiratory Rate</i> trend. |
| C. | VentView real-time data | Displays the same information as the minimized VentView (Figure 6-1), i.e. <i>Global Dynamic Images</i> , <i>Respiratory Rate (RRi)</i> and the <i>Plethysmogram</i> . |

The vertical axis of the above-mentioned trend charts is auto-scaled between the flags T1 and T2.

Refer to 6.5.2 for a description of the common characteristics of trends.

Refer to Figure 6-4 for a description of the buttons 'details', 'trend' and 'time range'

Refer to Figure 6-5 for a description of the GUI elements being visible on all views

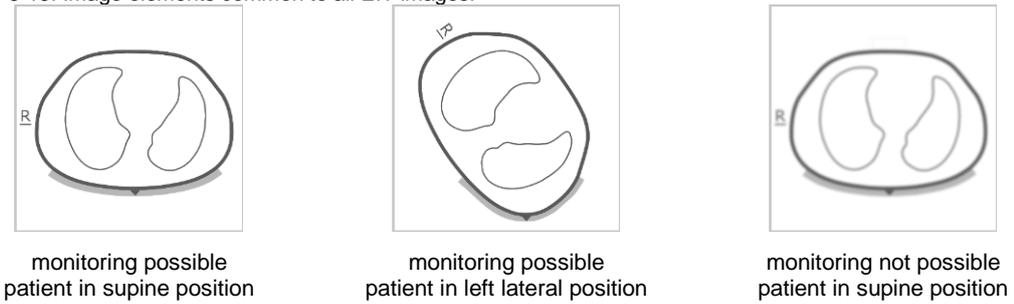
6.5 Common aspects of EIT images and trends

6.5.1 Common image elements and characteristics of EIT images

As illustrated in Figure 6-15 all *EIT images* displayed on the LuMon™ Monitor have the following common elements and characteristics:

- Visualization of the *Thorax* and *Lung Contours* associated with the patient-specific, CT-derived thorax and lung models (9.1). Per definition the patient-specific models, those of the image pixels located within the *Thorax ROI* are likely to represent areas within the patient's thorax and those within the *Lung ROI* areas within its lungs.
- The 'R' at the side of the *Thorax Contour* indicates the right side of the patient.
- To indicate *rotation* (9.2), the *EIT images* rotate with the patient.
- The thick grey line, being displayed at the "bottom" of the *Thorax Contour* irrespective of *rotation*, schematically visualizes the bed.
- The black triangle points in direction of gravity.

Figure 6-15: Image elements common to all EIT images.

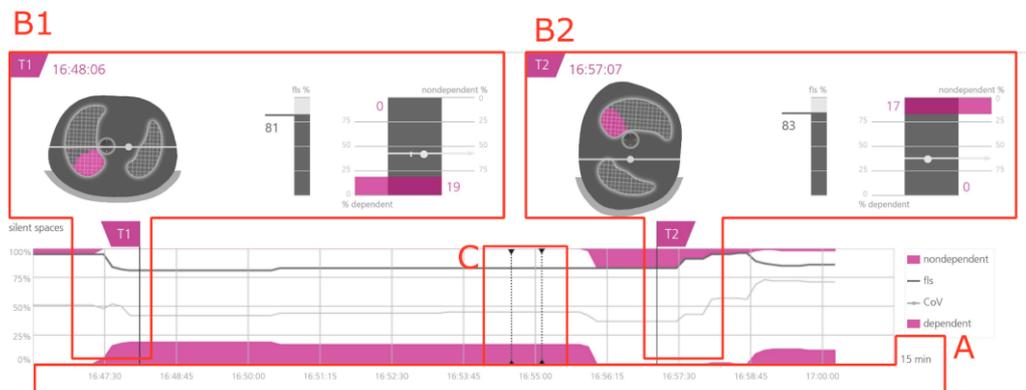


If monitoring is not possible (e.g. in case of insufficient belt to skin contact or while the system is calibrating (6.6.4) if no belt connector or belt is connected (6.6.3) or in case of various system errors or faults (6.6.2) all common EIT image elements are displayed blurred (in certain cases without Lung Contours).

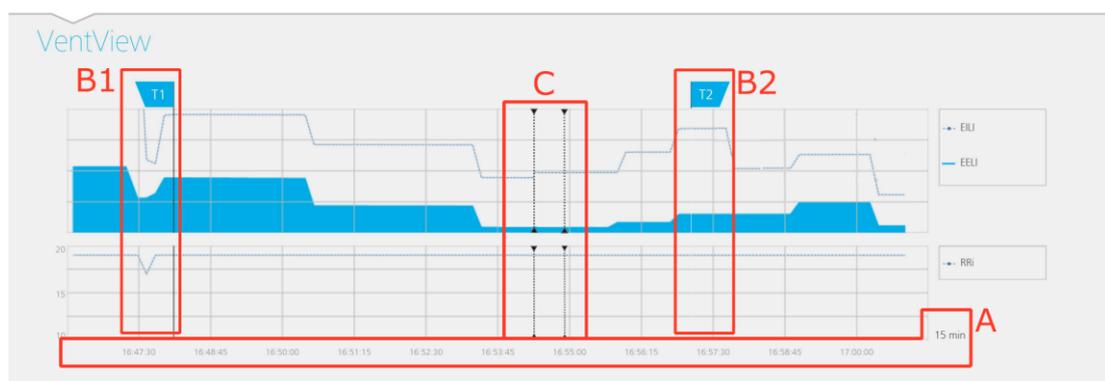
6.5.2 Common characteristics of trends

As illustrated in Figure 6-16 the trends available on LuFuView's and VentView's trend views (6.3.2 6.3.4, 6.4.2) have the following common characteristics:

Figure 6-16: Common characteristics of trends



Trend view of LuFuView's 'silent spaces' area



Trend view of VentView

- A. The trended values move from right to left with zero (0) being the current time and, for example, the signals at 5 minutes corresponding to those measured 5 minutes ago. The displayed time range is indicated on the bottom right of the trends.
- B. Moving the T1 (B1) or (B2) T2 flag in one trend view, will also move the corresponding flag in the two other trend views to the same time.
- C. Dotted black vertical lines with triangles at both ends (if any) identify operator events (9.11).

NOTE
 If monitoring is possible and if the time range for trends is 5 min in neonatal mode and 5 or 15 min in adult-mode a new point is plotted:

- for *Respiratory Rate* once per calculated value
- for all other *indices* once per detected breath in *BB mode* or once every 15 seconds in *time-based Analysis Modes* (9.7).

For larger time ranges multiple trend points are averaged to a single trend point using a median filter (in adult mode: 3 in case of 30 min and 1 h, 9 in case of 6 h, 27 in case of 24 h ranges; in neonatal mode 3 in case of 15 min, 9 in case of 30 min, 27 in case of 1 h, 81 in case of 6 h, 243 in case of 24 h ranges)

If monitoring was not possible during the selected trend period (6.6.2, 6.6.3, 6.6.4) the respective trend will be displayed with blank spaces.

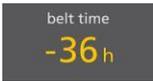
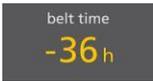
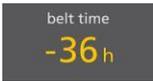
6.6 Visual indicators

6.6.1 Status icons

The Status bar corresponds to the part of the ScoutView that remains visible when ScoutView is minimized. From left to right it provides the status icons in the sequence as listed in Table 6-1.

Table 6-1: Status icons

| Status icon | Description/possible states of the icon |
|---|--|
| Current time | Indicates the monitor's current time (12 h or 24 h format). |
| AC Power/ Battery | Indicates whether the monitor is connected to AC mains power and whether the battery is charging or discharging |
| Battery discharging (7.2.2) | 91-100% 61-90% 31-60% 0 – 30% |
| Monitor connected to AC mains power battery charging (7.2.1) | Fully charged 91-100% 51-90% 0-50% |
| Battery status unknown | |
| Signal quality | Indicates the <i>signal quality index</i> (9.3), influenced, among other, by the belt to skin contact quality. |
| | Strong Adequate Weak Insufficient Status Message "Calibrating" Status Message "tech error 0001" |
| Belt-connection/ Skin-contact/ Rotation | This 'multipurpose' icon provides three types of status information: |
| Belt connection status (6.6.3) | Belt connected to LuMon™ Monitor Belt connector or belt not connected to LuMon™ Monitor |
| Belt to skin contact quality – grouped in quadrants (6.6.4.9.3) | Quadrants with no or the only <i>failing electrode</i> in the belt display in grey. Quadrants with one <i>failing electrode</i> highlighted yellow in case of at least 2 <i>failing electrodes</i> in the belt Quadrants with at least two <i>failing electrodes</i> highlighted red |

| | | | | | | | | | | | | | | | |
|---|--|---|--|---|--|--|---|--------------|---------------|--------|---------------------------|------------------|---------------------------|-----------------------------|-------|
| | <p>Rotation – ‘R’ indicates the right side of the patient</p>  | | | | | | | | | | | | | | |
| Inclination | <p>Indicates <i>inclination</i> of the patient.</p>  <table border="1"> <tr> <td>-90° to -11°</td> <td>-11° to 10°</td> <td>10° to 23°</td> <td>23° to 38°</td> <td>38° to 68°</td> <td>68° to 123°</td> <td>123° to 270°</td> </tr> <tr> <td>Trendelenburg</td> <td>Supine</td> <td>Supine, slightly inclined</td> <td>Supine, inclined</td> <td>Supine, strongly inclined</td> <td>Upright sitting or standing</td> <td>Prone</td> </tr> </table> | -90° to -11° | -11° to 10° | 10° to 23° | 23° to 38° | 38° to 68° | 68° to 123° | 123° to 270° | Trendelenburg | Supine | Supine, slightly inclined | Supine, inclined | Supine, strongly inclined | Upright sitting or standing | Prone |
| -90° to -11° | -11° to 10° | 10° to 23° | 23° to 38° | 38° to 68° | 68° to 123° | 123° to 270° | | | | | | | | | |
| Trendelenburg | Supine | Supine, slightly inclined | Supine, inclined | Supine, strongly inclined | Upright sitting or standing | Prone | | | | | | | | | |
| Belt Time | <p>Indicates the remaining time a belt can be used.</p> <table border="1"> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td><i>Belt time</i> not elapsed, here the belt can be used for another 71 hours</td> <td><i>Belt time</i> elapsed, here since 57 hours.</td> <td>Belt data not available, e.g. if no belt is connected</td> </tr> </table> |  |  |  | <i>Belt time</i> not elapsed, here the belt can be used for another 71 hours | <i>Belt time</i> elapsed, here since 57 hours. | Belt data not available, e.g. if no belt is connected | | | | | | | | |
|  |  |  | | | | | | | | | | | | | |
| <i>Belt time</i> not elapsed, here the belt can be used for another 71 hours | <i>Belt time</i> elapsed, here since 57 hours. | Belt data not available, e.g. if no belt is connected | | | | | | | | | | | | | |
| Analysis Mode | <p>Indicates the currently selected Analysis Mode (9.7).</p> <table border="1"> <tr> <td></td> <td></td> <td></td> </tr> <tr> <td><i>BB mode</i></td> <td><i>TB-I mode</i></td> <td><i>TB-II mode</i></td> </tr> </table> |  |  |  | <i>BB mode</i> | <i>TB-I mode</i> | <i>TB-II mode</i> | | | | | | | | |
|  |  |  | | | | | | | | | | | | | |
| <i>BB mode</i> | <i>TB-I mode</i> | <i>TB-II mode</i> | | | | | | | | | | | | | |

6.6.2 Status Messages

On ScoutView (6.2), status messages are displayed in yellow between two horizontal yellow lines just underneath the status bar.

NOTE

Status messages are only visible if ScoutView is expanded. If ScoutView is minimized only the status message indicator line (the top of the two yellow lines) is visible (Figure 6-5).

Only one status message is displayed at a time. In case two or more conditions that require the display of a status message occur concurrently, the LuMon™ Monitor displays the status message associated with the condition that last occurred. If no status message is displayed, the field is empty, and the two yellow lines are not displayed.

Table 6-2 lists all status messages in alphabetical order and provides for each status message a short description.

Table 6-2: Status messages

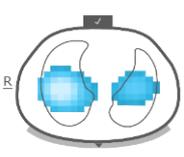
| Status message | Description |
|-------------------|--|
| belt fault | <p>Displays if the LuMon™ System has detected a belt fault.</p> <p>Monitoring is not possible.</p> <p>Aside from the message, the LuMon™ System shows the identical behavior as if a belt connector is connected to the LuMon™ Monitor, but no belt is connected to the belt connector (6.6.3).</p> <p> Obtain a different belt.</p> |
| calibrating... | <p>Displays while the LuMon™ System performs a system calibration (6.6.4). Usually, calibration is accomplished within a few seconds.</p> <p>Monitoring is not possible (briefly interrupted).</p> <p> If calibration does not end within approximately 10 seconds, refer to 8.3 to improve the belt to skin contact quality around the thorax.</p> |
| connect belt | <p>Displays if no belt is connected to the LuMon™ Monitor or the connected belt is defective (6.6.3).</p> <p>Monitoring is not possible.</p> <p> Connect a belt or a different belt.</p> |
| connect connector | <p>Is displayed if no belt connector is connected to the LuMon™ Monitor or the connected belt connector is defective (6.6.3).</p> |

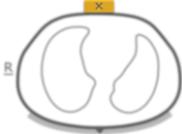
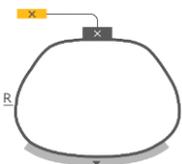
| Status message | Description |
|--|--|
| | Monitoring is not possible.  Connect a belt connector or a different belt connector |
| connector fault | Is displayed if the LuMon™ System has detected a belt connector fault. Monitoring is not possible. Aside from the message, identical behavior as if a belt connector is not connected to the LuMon™ Monitor (6.6.3).  Obtain a different belt connector. |
| incompatible belt | Is displayed if the connected belt is not compatible with the configuration of the LuMon™ Monitor (5.1). Do not use the LuMon™ System if this message is displayed.  Obtain a belt being compatible with the configuration of the LuMon™ Monitor. |
| incompatible connector | Is displayed if the connected belt connector is not compatible with the configuration of the LuMon™ Monitor (5.1). Do not use the LuMon™ System if this message is displayed.  Obtain a belt connector being compatible with the configuration of the LuMon™ Monitor. |
| insufficient skin contact | Is displayed if there are more <i>failing electrodes</i> than the LuMon™ System is able to compensate for (6.6.4). Monitoring is not possible (interrupted as long as there are too many <i>failing electrodes</i>).  Refer to 8.3 to improve the belt to skin contact quality around the thorax. |
| monitor fault, contact the technical support | Is displayed if the LuMon™ System has detected a monitor fault. Monitoring is not possible. Aside from the message, identical behavior as if no belt connector is connected to the LuMon™ Monitor (6.6.3).  Contact a qualified technician, your local SenTec EIT representative or SenTec AG. |
| tech error 0001 | Is displayed if the LuMon™ System has detected severe interferences likely caused by a third-party device impairing the LuMon™ System's measurements. Alternatively, the belt or belt connector may be defective. Monitoring is not possible The image elements common to all <i>EIT images</i> (Figure 6-15) are blurred and all bars of the 'Signal quality' icon as well as all quadrants of the 'Belt-connection/Skin-contact/Rotation' icon are displayed in red.  In case of severe interferences from other devices switch off the other devices (if possible). Also check if use of a different belt and/or belt connector resolves the problem. If unresolved, contact a qualified technician, your local SenTec EIT representative or SenTec AG. |
| tech error 0002 | Is displayed if the LuMon™ System has detected a fault of an internal component (TIC module). Monitoring is not possible. <i>EIT images</i> are not displayed (not even the image elements common to all <i>EIT images</i> (Figure 6-15)), Apart from the message, the behavior of the LuMon™ System is otherwise as if no belt connector is connected to the LuMon™ Monitor (6.6.3).  Restart the LuMon™ Monitor. If this does not resolve the problem, contact a qualified technician, your local SenTec EIT representative or SenTec AG |

6.6.3 Indication of the connection status of the belt connector and the belt

On ScoutView (Figure 6-6) the connection status of the belt connector and the belt (Table 6-3) are indicated along with the *Global Dynamic Image*.

Table 6-3: Belt connector and belt connection status

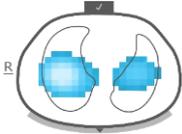
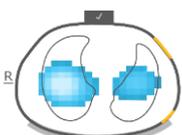
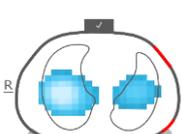
| Visual indication | Status | Description of visual indication on ScoutView |
|---|---|--|
|  | Belt connector connected to LuMon™ Monitor | The belt connection symbol on the ventral side of the thorax displays a check mark on grey background. |
| | Belt connected to belt connector | |
| | Monitoring possible (if belt properly applied on patient and no error (6.6.2)); Signal quality weak, adequate or strong | |

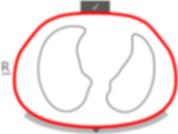
| Visual indication | Status | Description of visual indication on ScoutView |
|---|---|---|
|  | Belt connector connected to LuMon™ Monitor Belt not connected to belt connector Monitoring not possible; Signal quality insufficient | The belt connection symbol on the ventral side of the thorax displays an "x" on yellow background. The status message "connect belt" (6.6.2) is displayed and the image elements common to all EIT images (6.5.1) are blurred. |
|  | Belt connector not connected to LuMon™ Monitor Connection status of belt not known Monitoring not possible; Signal quality insufficient | The belt connector symbol displays an "x" on yellow background. The belt connection symbol on the ventral side of the thorax displays an "x" on grey background. The status message "connect connector" (6.6.2) is displayed and the image elements common to all EIT images (6.5.1) are blurred, whereby the Lung Contours are not displayed. The 'Belt-connection/Skin-contact/Rotation' icon displays all quadrants in red. |

6.6.4 Indication of the belt to skin contact quality

In order to visualize the overall belt to skin contact quality around the thorax (9.3), on ScoutView the 32 electrodes are subdivided in 12 segments being arranged on the *Thorax Contour* of the *Global Dynamic Image* (three segments of three and one segment of two electrodes per quadrant). Segments whose electrodes have all adequate skin contact are displayed in grey, those with at least one electrode with poor skin contact in yellow and those with at least one *failing electrode* (i.e. having insufficient skin contact) in red. The display of the belt to skin contact quality is updated in real-time. Table 6-4 summarizes how on ScoutView the belt to skin contact quality around the thorax is visualized.

Table 6-4: Visualization of the belt to skin contact quality around the Thorax Contour

| Visual indication | Status | Description of visual indication on ScoutView |
|---|--|---|
|  | All electrodes with adequate skin contact Monitoring possible; signal quality strong | All 12 electrode-segments on the <i>Thorax Contour</i> are displayed in grey. |
|  | Electrodes with poor skin contact Monitoring possible; signal quality strong | Electrode-segments along the <i>Thorax Contour</i> with at least one electrode having poor skin contact are highlighted yellow. |
|  | Up to 6 compensated <i>Failing electrodes</i> Monitoring possible; signal quality weak or adequate | Electrode-segments along the <i>Thorax Contour</i> with at least one <i>failing electrode</i> are highlighted red. |
|  | System is calibrating after a significant change of the belt to skin contact quality, after a change in the number of <i>failing electrodes</i> or after changing patient data causing the selection of a different thorax and lung model. Monitoring not possible (briefly interrupted); signal quality insufficient | Electrode-segments along the <i>Thorax Contour</i> with at least one <i>failing electrode</i> are highlighted red. In this case the status message 'calibrating' (6.6.2) is displayed and the image elements common to all EIT images (6.5.1) are blurred. |

| Visual indication | Status | Description of visual indication on ScoutView |
|---|--|--|
|  | Too many <i>failing electrodes</i> Monitoring not possible (interrupted); signal quality insufficient | All 12 electrode-segments on the <i>Thorax Contour</i> are highlighted red. The status message 'insufficient skin contact' (6.6.2) is displayed and the image elements common to all <i>EIT images</i> (6.5.1) are blurred. |

NOTE
The 'Belt-connection/Skin-contact/Rotation' icon (6.6.1) displays the belt to skin contact quality in similar manner grouped in four quadrants of eight electrodes each.

6.6.5 Display of information requiring operator awareness

Information requiring operator awareness or operator response is displayed in yellow. Examples include

- the status messages (6.6.2)
- the status message indicator line (Figure 6-5)
- the indication of the *belt time* in the 'belt time' icon if *belt time* has elapsed (Table 6-1)
- electrode-segments around the *Thorax Contour* having at least one electrode with poor skin-contact in the *Global Dynamic Image* on ScoutView (Table 6-4).

NOTE
Those electrode-segments (Table 6-4) with at least one *failing electrode* and those quadrants of the 'Belt-connection/Skin-contact/Rotation' icon (Table 6-1) with at least two *failing electrodes* are highlighted in red.
The 'AC Power/Battery' icon (Table 6-1) is displayed in red if the approximate remaining battery capacity is below 30% (7.2.2).
The 'Signal quality' icon (Table 6-1) is displayed in red if 'tech error 0001' occurs (6.6.2).

NOTE
The LuMon™ Monitor has no alarm system

6.7 Operator-adjustable parameters

6.7.1 Patient related operator-adjustable parameters

Table 6-5: Patient related operator-adjustable parameters –  Adults/Children configuration. Refer to Figure 6-7.

| Parameter | Range | Power-on default |
|------------------------|-----------------|------------------|
| ½ underbust girth (cm) | 38 – 64 | 46 |
| Height (cm) | 140 – 210, test | 175 |
| Weight (kg) | 40 – 200, test | 75 |
| Gender | Female/male | Male |
| Patient no. | 0 - 999 | 0 |

Table 6-6: Patient related operator-adjustable parameters –  Neonates/Infants configuration. Refer to Figure 6-7.

| Parameter | Range | Power-on default |
|------------------------|----------------|---|
| Underbust girth (cm) | 17 – 52 | 28 |
| Weight (kg) | 0.5 – 13, test | 2.1 |
| Gender | Female/male | Male |
| Belt displacement (cm) | -5.5 – +2.5 | Approx. 1.5 cm – depending on the difference between belt size and entered underbust girth. |
| Patient no. | 0 - 999 | 0 |

NOTE

For the  Adults/Children monitor configuration, the half underbust girth (e.g. from spine to sternum) is measured and entered; for the  Neonates/Infants monitor configuration, the full underbust girth is measured and entered.

NOTE

Entering 'test' for the patient's height or weight will select round *Lung Contours*, which should only be used for troubleshooting and not during monitoring. Enter actual (not lean or ideal) body weight in kg.

6.7.2 System related operator-adjustable parametersTable 6-7: System related operator-adjustable parameters. Refer to [Figure 6-8](#).

| Parameter | Range | Power-on default |
|-----------------|---|---|
| Time (hh:mm:ss) | - | Last setting |
| Date (YY-MM-DD) | - | Last setting |
| Time format | 12h/24h | Last setting – 24h is the factory default |
| Language | dansk, deutsch, english, español, français, italiano, nederland, norsk, português, svenska, suomi, türkçe, japanese | Last setting — English is the factory default |

NOTE

EIT data stored in the LuMon™ Monitor's internal memory will be deleted when changing its date/time. No further operator confirmation will be requested at the time of the change.

6.7.3 Measurement related operator-adjustable parametersTable 6-8: Measurement related operator-adjustable parameters. Refer to [Figure 6-4](#) and [Figure 6-6](#).

| Parameter | Range | Power-on default |
|------------------------------|--|------------------|
| Analysis Mode | BB/TB-I/TB-II | BB |
| Time range for trends | 5/15/30 min 1/6/24 h Refer to Figure 6-4 for information on when new trend points are plotted. | 5 min |
| Time range for Plethysmogram | 10/30/60/300 s | 30 s |

7 INSTALLATION AND PREOPERATIONAL CHECK

The LuMon™ Monitor (5.1) is a portable, bedside stand-alone EIT monitor. Optionally it can be mounted on SenTec's Roll Stand for the LuMon™ Monitor (14.1) and on most VESA 75x75 mounts able to support at least 4 kg. To mount the LuMon™ Monitor on any of those mounting options use SenTec's LuMon™ VESA Screw Set (14.1) and refer to the instructions provided with the respective mounting options.

Sub-section 7.1 provides information about the use of the LuMon™ Monitor's equipotentiality terminal connector. 7.2 describes how to connect the LuMon™ Monitor to AC mains power and provides important information regarding its operation on AC mains power or on its internal battery. How to switch the LuMon™ Monitor on and how to check/adjust its system settings is explained in 7.3. Sub-section 7.4 describes a simple preoperational check that should be performed as a last installation step and, subsequently, each time before initiating monitoring (8) for a new patient.

7.1 Using the equipotentiality terminal connector

The LuMon™ Monitor has an equipotentiality terminal connector on its rear side (Figure 5-2). If required by the institution or local regulations, connect the equipotentiality terminal connector of the LuMon™ Monitor to the equipotentiality grounding system. This may, for example, be the case in rooms classified as 'cardiac protected' electrical areas. For additional information about the use of equipotentiality terminal connectors, refer to IEC 606001-1 or other national or international standards.

7.2 Power supply

The LuMon™ Monitor can be powered by AC mains power or by its internal Li-Ion battery.

7.2.1 Connecting the LuMon™ Monitor to AC mains power/operation on AC mains power

To connect the LuMon™ Monitor (5.1) to AC mains power proceed as follows:

- Plug the power cord into the AC power inlet on the rear of the monitor (Figure 5-2).
- Plug the power cord into an earthed AC mains power outlet.
- Verify that the AC Power/Battery indicator on the rear side of the monitor is lit (Figure 5-2).

NOTE

The LuMon™ Monitor will automatically adapt to the applicable local voltage: 100 – 240V~ (50/60 Hz).

NOTE

If the AC Power/Battery indicator on the rear side of the LuMon™ Monitor (Figure 5-2) is not lit when the monitor is connected to AC mains power, check the power cord, accessible fuses, and the AC mains power outlet. Replace any defective parts with SenTec original parts. Refer to 11.3 to replace the fuses of the LuMon™ Monitor.

The AC Power/Battery indicator on the rear side of the LuMon™ Monitor (Figure 5-2) provides color-coded information about the AC mains power connection status of the monitor and the charging status of its battery:

- green: indicates that the monitor is connected to AC mains power and its battery is not charging (either battery is fully charged, or charging is paused because of high temperature)
- yellow: indicates that the monitor is connected to AC mains power and its battery is charging
- off: indicates that the monitor is not connected to AC mains power (i.e. it is powered by internal battery).

If the LuMon™ Monitor is switched on, the 'AC Power/Battery' icon in the status bar of the GUI (Table 6-1) also indicates its AC mains power connection status, the charging status of its battery if connected to AC mains power and the approximate remaining battery capacity if not connected to AC mains power.

NOTE

Whenever the LuMon™ Monitor is connected to AC mains power, its internal battery is being charged. Therefore, it is recommended that the LuMon™ Monitor remains connected to AC mains power when not in use. This will ensure a fully charged battery whenever it is needed.

7.2.2 Operating on internal battery

The LuMon™ Monitor (5.1) is equipped with a rechargeable internal Li-Ion battery that can be used to power the monitor during intra-hospital transport or when AC mains power is not available. A new, fully charged battery provides up to 1 hour of operating/monitoring time.

The 'AC Power/Battery' icon in the status bar ([Table 6-1](#)) indicates the LuMon™ Monitor's AC mains power connection status, the charging status of its battery if connected to AC mains power and the approximate remaining battery capacity if not connected to AC mains power.

If the LuMon™ Monitor is not connected to AC mains power, the 'AC Power/Battery' icon highlights:

- yellow when the remaining battery capacity is below 60% (i.e. if 30 or fewer minutes of operating/monitoring time is available on the existing battery charge)
- red if it is below 30% (i.e. 15 or fewer minutes remain until the monitor shuts down if not connected to AC mains power)

Charging a low or depleted battery takes approximately 5 hours. 80% of the battery capacity is available after approximately 3.5 hours of charging.

 **NOTE**
As the battery is used and recharged over a period of time, the amount of time between the onset of the display of the 'AC Power/Battery' icon in red and the instrument shut-off may become shorter.

 **NOTE**
It is recommended, that *SenTec Authorized LuMon™ Technicians* check and – if needed – replace the internal battery every 24 months. Used batteries should be disposed of in accordance with local ordinances.

7.3 Switching the LuMon™ Monitor on and checking its system settings

Switch the LuMon™ Monitor on by pushing the ON/OFF switch on its rear side ([Figure 5-2](#)). The startup screen, indicating a progress bar and the monitor's GUI software version, is displayed while the LuMon™ Monitor starts up all internal processes and performs a 'Power-on Self-Test'. The startup of the LuMon™ Monitor can take up to three minutes.

 **NOTE**
The LuMon™ Monitor performs a calibration of its touch screen after it is switched on. To not disturb the calibration of the touch screen, do not touch the screen the first few seconds after startup.

Once the startup is completed, the default ScoutView ([Figure 6-6](#)) is displayed.

Check the LuMon™ Monitor's approximate remaining battery capacity ([7.2.2](#)) displayed in the 'AC Power/Battery' icon in the status bar of its GUI ([Table 6-1](#)). If necessary, connect the monitor to AC mains power ([7.2.1](#)).

To check the LuMon™ Monitor's system settings (e.g. its date/time) and software versions, access system settings in ScoutView ([Figure 6-6](#), [Figure 6-8](#)). If necessary, adjust the settings.

 **NOTE**
EIT data stored in the LuMon™ Monitor's internal memory will be deleted when changing its date/time. No further operator confirmation will be requested at the time of the change.

7.4 Preoperational check

Perform the preoperational check as a last installation step and, subsequently, each time before initiating monitoring ([8](#)) for a new patient.

A. Required items:

-  LuMon™ Monitor – Adult ([5.1](#)) and a SensorBeltConnector ([5.2.1](#)).
-  LuMon™ Monitor – Neo ([5.1](#)) and a LuMon™ Connector ([5.2.2](#)).

B. Switch the LuMon™ Monitor on

Switch the LuMon™ Monitor on without a belt connector being connected and verify that the status message 'connect connector' displays on ScoutView ([Figure 6-6](#)).

C. Access system setting in ScoutView ([Figure 6-8](#)):

- Check and if necessary, synchronize the monitor's date/time with, for example, your institution's date/time.
- Verify that the field on the right of 'connector' is empty.

D. Connect the belt connector to the LuMon™ Monitor and verify that:

- the field on the right of 'connector' displays a number (encodes hardware and software versions of the connected belt connector).
- the status message 'connect belt' is displayed on ScoutView.

If the preoperational check passed, you can initiate monitoring (8). If it failed or in case of belt connector related error messages (6.6.2), do not use the belt connector you used during the preoperational check. In this case, repeat the preoperational check with another belt connector.



NOTE

It is recommended to synchronize the LuMon™ Monitor's date/time (Figure 6-8, Table 6-7) with the date/time of your institution as otherwise the date/times indicated in the trends of the LuMon™ Monitor or of stored/exported data, e.g. for marked operator events (9.11), may differ from those noted in your records.



NOTE

Seasonal time changes are not automatically adjusted by the LuMon™ Monitor.



NOTE

EIT data stored in the LuMon™ Monitor's internal memory will be deleted when changing its date/time. No further operator confirmation will be requested at the time of the change.

8 BELT APPLICATION AND INITIATING MONITORING

Sub-sections 8.1 and 8.2 respectively describe for adults and children and for neonates and infants how to determine the belt size best fitting the patient, how to properly apply the belt to the patient, and how to initiate monitoring.

How to verify proper setup and adequacy of the selected *Analysis Mode* after initiating monitoring and, subsequently, at least every 8 hours while monitoring the patient (9) is explained in 8.3 and 8.4, respectively. A description of the different available *Analysis Modes* is provided in 9.7.

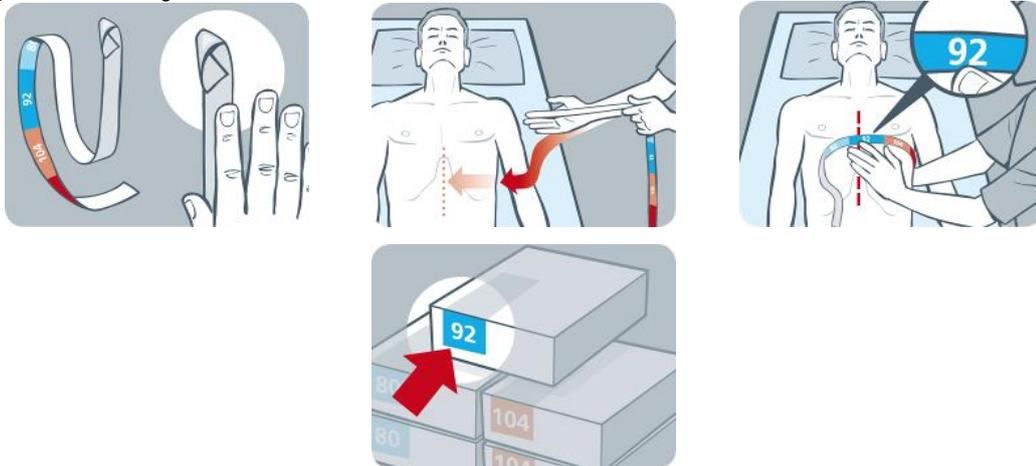
8.1 SensorBelt application and initiating monitoring for adults and children

To initiate monitoring for adults and children, perform the following steps by referring to the figures in this sub-section. For quick recall, the Quick Reference Guide for Adults/Children (14.1) provides a condensed version of the information provided in this sub-section and the instructions included in the packaging of the SensorBelt (14.1) provide the same figures without explanatory text.

Before initiating monitoring for a **new** patient, ensure the patient meets the criteria for EIT monitoring (3, 4.4) and obtain a LuMon™ Monitor – Adult (5.1) and a SensorBeltConnector (5.2.1) to perform the preoperational check including the verification of the monitor date/time (7.4).

Remove all material and wipe away any fluids around the thorax where the striped fabric of the SensorBelt (Figure 5-5) will be placed.

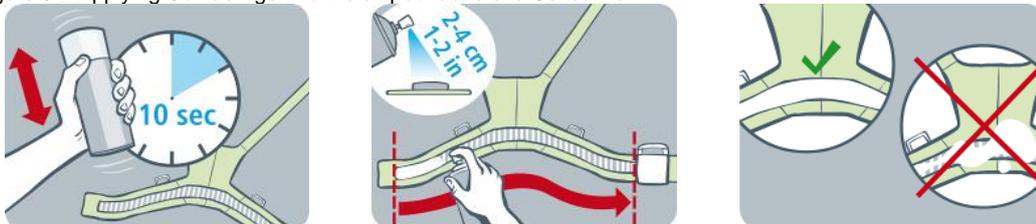
Figure 8-1: Selecting the SensorBelt size for adults and children



By using a Measuring tape – Adults/Children (5.5.1) included in the ContactAgent kit (5.4.1) measure the patient's half underbust girth (from spine to mid sternum just below the breast line) and determine the size of the SensorBelt (5.3.1) best fitting the patient as shown in Figure 8-1. Predefined colored half underbust ranges on the Measuring tape – Adults/Children indicate the size of the recommended SensorBelt. To assist size selection, packaging labels of correspondingly sized belts exhibit an area with the same color. Refer to Table 13-14 for available SensorBelt sizes.

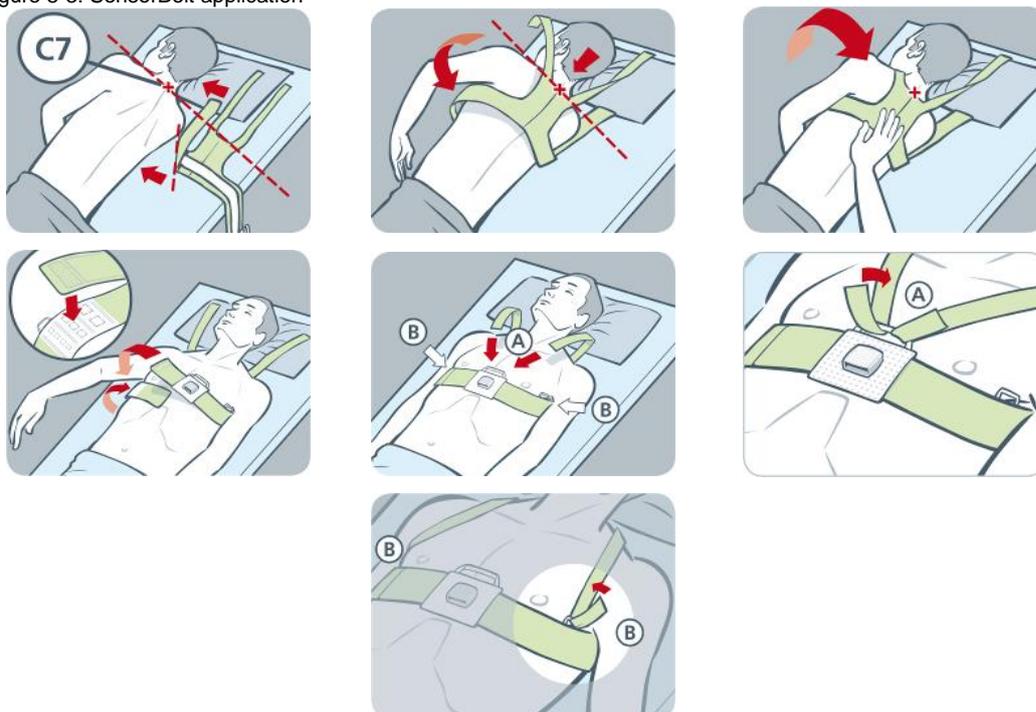
Obtain a SensorBelt of the recommended size and open its package and place the SensorBelt with the striped fabric embedding the electrodes (Figure 5-5) facing upwards onto a flat surface.

Figure 8-2 Applying ContactAgent to the striped fabric of a SensorBelt



Shake the ContactAgent spray can (5.4.1) for at least 10 seconds and apply ContactAgent to the SensorBelt striped fabric on the patient-facing side as shown in Figure 8-2. Repeat the spraying until the striped fabric is wetted evenly and entirely. Where possible avoid spraying any ContactAgent outside the strip fabric area.

Figure 8-3: SensorBelt application



Apply the SensorBelt to the patient as shown in [Figure 8-3](#), which shows the SensorBelt application first around the patient's left side and then the right:

- Turn the patient to the right side.
- Identify the 7th cervical vertebra (C7) being highlighted by a red "x" in [Figure 8-3](#). C7 has a large, easily identifiable spinous process that protrudes posteriorly at the back of the neck.
- Place the belt aside the patient with the striped fabric of the left belt flap facing upwards and oriented away from the patient and with the right belt flap folded up with the striped fabric facing downwards. Hereby align the top-end of the mid-line on the SensorBelt's back part with C7 as indicated by the black solid and red broken lines.
- Flip the left belt flap over the left chest of the patient.
- Position the belt such that the mid-line on its back part is aligned with the spinal column, its top-end remains close to C7 and the left belt flap follows the ribs along the 5th/6th intercostal space (ICS).
- Pay attention to maintain the SensorBelt in this position when turning the patient to the left side.
- Once the patient is on the left side, take the right belt flap and flip it over the right chest of the patient.
- Ensure that the mid-line on the SensorBelt's back part is still aligned with the spinal column, its top-end remains close to C7 and that the right belt flap is also following the ribs along the 5th/6th ICS.
- Pay attention to maintain the SensorBelt in this position when turning the patient back into supine position.
- When closing and tightening the SensorBelt ensure that the striped fabric of both belt flap still follows the ribs along the 5th/6th ICS (intercostal space) on an oblique plane with the top-end of the mid-line of the SensorBelt's back part close to C7 and that it fits snugly on the patient's skin but does not restrict breathing. The shoulder straps of the SensorBelt can either be fastened centrally (A) or laterally (B).

NOTE

For applying the SensorBelt, first on the right side and then on the left proceed in corresponding manner.

Enter the measured half underbust girth and the patient data in the 'patient & belt' area of ScoutView ([Figure 6-7](#)) to select the thorax and lung model ([9.1](#)) best fitting the individual patient. Enter actual (not lean or ideal) body weight.

Connect the SensorBeltConnector to the SensorBelt to initiate monitoring. After a few seconds, a green light should appear in the SensorBeltConnector's MatchBox ([Figure 5-3](#)) to indicate that the SensorBelt is properly connected to the LuMon™ Monitor and monitoring is initiated.

⚠ WARNING

To reduce the possibility of patient entanglement or strangulation, properly route and fix cables. Do not leave unapplied belts in reach of the patient.

⚠ WARNING

The SensorBeltConnector's ControlBox and MatchBox generate a small amount of heat and their surfaces can reach several °C above ambient temperature. Failure to adhere to the following points increases the risk of local skin burn:

- 1) Do not place the MatchBox directly on the patient and place the ControlBox in a way to prevent any skin contact with the patient.
- 2) Where possible do not cover the ControlBox or the MatchBox with linens or bed covers to avoid possible heating of the skin.
- 3) To minimize the pressure on the chest of the patient in prone position right there where the MatchBox is inserted in the SensorBelt's Docking Station and to allow convection to conduct heat away from the MatchBox place, for example, two small cushions on either side of the docking station.

On ScoutView, verify that the size of the connected SensorBelt matches the recommended size (Figure 6-6, Figure 6-7). In case of a mismatch verify the measured half underbust girth. If necessary, either adjust the respective entry on the monitor or select a belt of recommended size.

Check proper setup (8.3) and select an *Analysis Mode* being adequate for the patient's breathing pattern (8.4) initially and at least every 8 hours while monitoring the patient (9).

⚠ WARNING

Data quality may be impaired, measurements incorrect and thus results may be misinterpreted if

- 1) the size of the connected belt does not match the recommended size
- 2) the belt is not applied and positioned as recommended
- 3) *rotation* and *inclination* displayed by the LuMon™ Monitor do not reflect the patient's position.
- 4) patient data or half underbust girth are not determined and entered correctly. Notice that these settings are reset to their defaults when starting up the monitor. You therefore must re-enter these settings after each restart of the monitor
- 5) an inadequate *Analysis Mode* is selected

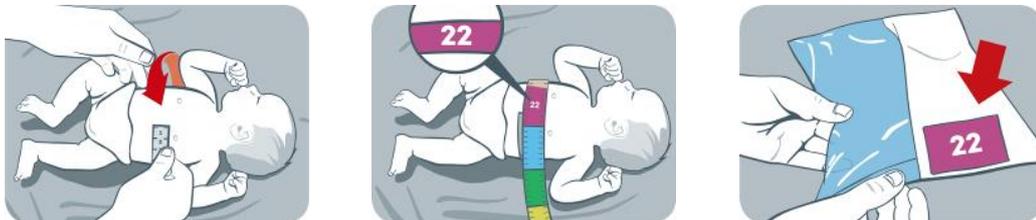
8.2 LuMon™ Belt application and initiating monitoring for neonates and infants

To initiate monitoring for neonates and infants, perform the following steps by referring to the figures in this sub-section. For quick recall, the Quick Reference Guide for Neonates/Infants (14.1) provides a condensed version of the information provided in this sub-section and the instructions included in the packaging of the LuMon™ Belts (14.1) provide the same figures without explanatory text.

Before initiating monitoring for a **new** patient, ensure the patient meets the criteria for EIT monitoring (3, 4.4) and obtain a LuMon™ Monitor – Neo (5.1) and a LuMon™ Connector (5.2.2) to perform the preoperational check including the verification of the monitor date/time (7.4).

Remove all material and wipe away any fluids around the thorax where the striped fabric of the LuMon™ Belt (Figure 5-6) will be placed.

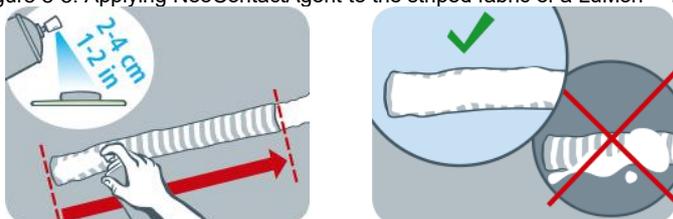
Figure 8-4: Selecting the LuMon™ Belt size for neonates and infants



By using a Measuring tape – Neonates/Infants (5.5.2) included in the NeoContactAgent kit (5.4.2) measure the patient's full underbust girth just below the breast line and determine the size of the LuMon™ Belt (5.3.2) best fitting the patient as shown in Figure 8-4. Predefined colored full underbust ranges on the Measuring tape – Neonates/Infants indicate the size of the recommended LuMon™ Belt. To assist size selection, packaging labels of correspondingly sized belts exhibit an area with the same color. Refer to Table 13-14 for available LuMon™ Belts sizes.

Obtain a LuMon™ Belt of the recommended size, open its package and place the LuMon™ Belt with the striped fabric embedding the electrodes (Figure 5-6) facing upwards onto a flat surface.

Figure 8-5: Applying NeoContactAgent to the striped fabric of a LuMon™ Belt



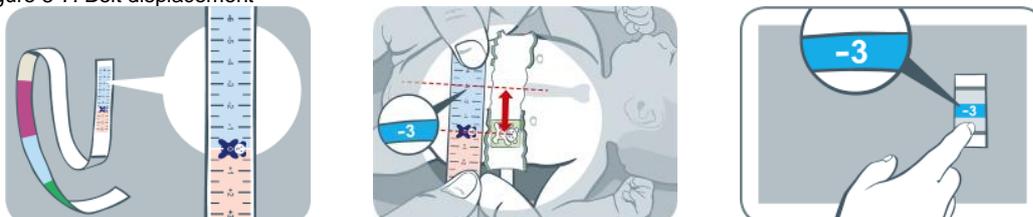
Apply NeoContactAgent (5.4.2) to the LuMon™ Belt striped fabric on the patient-facing side as shown in Figure 8-5. Repeat the spraying until the striped fabric is wetted evenly and entirely. Where possible avoid spraying any NeoContactAgent outside the strip fabric area. To increase patient comfort, you may warm up the NeoContactAgent to normal body temperature prior to use.

Figure 8-6: LuMon™ Belt application



Apply the LuMon™ Belt to the patient as shown in Figure 8-6. The head of the bear on the LuMon™ Belt (Figure 5-6) and that of the patient have to be oriented identically. Attach the belt around the patient's chest just under its breast line and then tighten the belt with the soft and extensible closure band. When closing and tightening the LuMon™ Belt ensure to center the sternum between the two ends of the striped fabric. Also verify that the LuMon™ Belt follows the ribs along the underbust on a transverse plane and that it fits snugly on the patient's skin but does not restrict breathing.

Figure 8-7: Belt displacement



By using a Measuring tape – Neonates/Infants, measure the belt displacement, i.e. the distance between the sternum and the bear on the LuMon™ Belt, as shown in Figure 8-7. Align the bears on the belt and on the measuring tape with their heads being oriented identically and read the belt displacement from the measuring tape.

Enter the measured full underbust girth, the patient data and the measured belt displacement in the 'patient & belt' area of ScoutView (Figure 6-7) to determine the position of the electrodes on the patient's thorax (9.1) as accurately as possible. Enter actual (not lean or ideal) body weight.

Connect the LuMon™ Connector to the LuMon™ Belt to initiate monitoring.

⚠ WARNING

To reduce the possibility of patient entanglement or strangulation, properly route and fix cables. Do not leave unapplied belts in reach of the patient.

⚠ WARNING

The LuMon™ Connector's ControlBox generates a small amount of heat and its surface can reach several °C above ambient temperature. Failure to adhere to the following points increases the risk of local skin burn:

- 1) Place the ControlBox in a way to prevent any skin contact with the patient.
- 2) Where possible do not cover the ControlBox with linens or bed covers to avoid possible heating of the skin.

On ScoutView, verify that the size of the connected LuMon™ Belt matches the recommended size (Figure 6-6, Figure 6-7). In case of a mismatch verify the measured full underbust girth. If necessary, either adjust the respective entry on the monitor or select a belt of recommended size.

Check proper setup (8.3) and adequacy of the selected *Analysis Mode* being adequate for the patient's breathing pattern (8.4) initially and at least every 8 hours while monitoring the patient (9).

⚠ WARNING RISK

Data quality may be impaired, measurements incorrect and thus results may be misinterpreted if the size of the connected belt does not match the recommended size

- 1) the belt is not applied and positioned as recommended
- 2) *rotation* and *inclination* displayed by the LuMon™ Monitor do not reflect the patient's position.
- 3) patient data, full underbust girth or belt displacement are not determined and entered correctly. Notice that these settings are reset to their defaults when starting up the monitor. You therefore must re-enter these settings after each restart of the monitor
- 4) an inadequate *Analysis Mode* is selected

8.3 Checking the proper setup

Check the proper setup after initiating monitoring (8) and at least every 8 hours while monitoring the patient (9). To check proper setup for adults and children refer to 8.3.1 and to 8.3.2 to check proper setup for neonates and infants.

8.3.1 Checking the proper setup for adults and children

For quick recall, the Quick Reference Guide for Adults/Children (14.1) provides a condensed version of the information provided in this sub-section.

A. Checking belt time

Check the *belt time* displayed in the 'belt time' icon (Table 6-1).



💡 If expired, remove and dispose of the old belt and obtain a new belt of the same size to continue monitoring for the same patient (10.2).

B. Checking belt positioning for adults and children

Verify belt positioning and a snug fit of the belt on the skin.



💡 If necessary, adjust the belt position and tighten its fit. If tightening the fit of the belt, ensure not to restrict breathing.

The SensorBelt is positioned correctly (8.1) when

- the belt's striped fabric follows the ribs along the 5th/6th intercostal space (ICS) on an oblique plane with the top-end of the mid-line of the SensorBelt's back part close to C7.
- the belt's docking station is aligned with the patient's sternum

C. Checking for correct data entry on monitor for adults and children

Verify that the half underbust girth and patient data entries on the monitor correspond to those of the actual patient.

💡 If necessary, adjust the respective entries in the 'patient & belt' area of ScoutView (Figure 6-7). Enter actual (not lean or ideal) body weight.

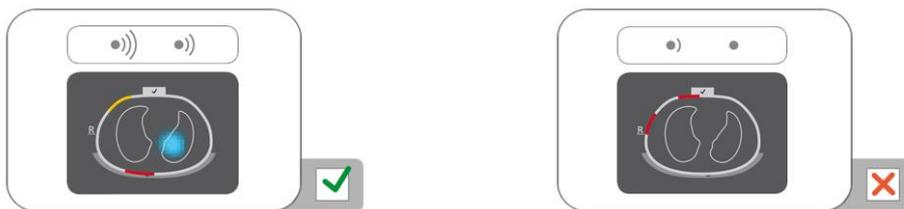
D. Checking displayed patient position for adults and children

Verify that the displayed *rotation* and *inclination* images reflect the patient's position – acceptable is within +/- 10° of the displayed rotation image for *rotation* and for *inclination* of the angle range spanned by the displayed state of the 'inclination' icon (6.6.1).

💡 If necessary, verify the belt positioning. Particularly, ensure that the belt is not distorted.

E. Checking signal quality and belt to skin contact quality

Verify the signal quality and the belt to skin contact quality around the thorax (Table 6-1, Table 6-4). Though monitoring is possible if the signal quality is weak, the signal quality should preferably be adequate or strong and there should preferably be no *failing electrodes* (9.3).



 If necessary, remove any material such as bandages between the belt and the patient's skin and adjust the belt fit to the patient by softly pressing on the belt and by tightening the belt. If this does not resolve the problem, remove the belt, re-apply contact agent to the striped fabric of the belt and re-initiate monitoring (10.2).

F. Checking that breathing-related impedance changes are mainly within the Lung Contours

Verify that the movie-like display of *Global Dynamic Images* on ScoutView (Figure 6-6) and on VentView's detail view (Figure 6-13) reflects breathing-related impedance changes mainly within the *Lung Contours* (9.4).



 If necessary, ensure that the belt is applied as recommended. If applied too far caudally the measurements may be influenced by the diaphragm, if applied too far cranially, the movie-like display of *Global Dynamic Images* tends to exhibit impedance changes as illustrated in the right figure below.

G. Checking that Global Dynamic Images and Plethysmogram reflect breathing

Verify that the *Global Dynamic Images* and the *Plethysmogram* on VentView's detail view (Figure 6-13) reflect the breathing pattern of the patient. Interferences from other devices, particularly from bioimpedance measurement devices such as impedance respiration monitoring may periodically cause the *Global Dynamic Image* to flutter and the *Plethysmogram* to exhibit irregular spikes.

 In case of interferences from other devices switch off the other device (if possible) or in case of impedance respiration monitoring through ECG electrodes, reposition the electrodes further away from the belt. If this does not resolve the problem, contact a qualified technician, your local SenTec EIT representative or SenTec AG.

8.3.2 Checking the proper setup for neonates and infants

For quick recall, the Quick Reference Guide for Neonates/Infants (14.1) provides a condensed version of the information provided in this sub-section.

A. Checking the belt time

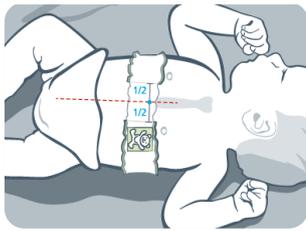
Check the *belt time* displayed in the 'belt time' icon (Table 6-1).

 If expired, remove and dispose of the old belt and obtain a new belt of the same size to continue monitoring for the same patient (10.2).



B. Checking belt positioning for neonates and infants

Verify belt positioning and a snug fit of the belt on the skin.

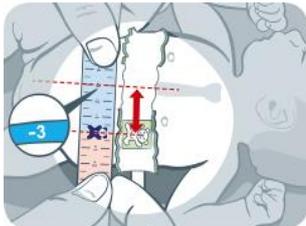


If necessary, adjust the belt position and tighten its fit. If tightening the fit of the belt, ensure not to restrict breathing

The LuMon™ Belt is positioned correctly (8.2) when

- the head of bear on the belt and that of the patient are oriented identically;
- the sternum is centered between the two ends of the belt's striped fabric;
- the belt follows the ribs along the underbust on a transverse plane.

C. Checking for correct data entry on monitor for neonates and infants



Measure the belt displacement (8.2).



If necessary, adjust the respective entry on the monitor (Figure 6-7).

Verify that the full underbust girth and patient data entries on the monitor correspond to those of the actual patient.



If necessary, adjust the respective entries in the 'patient & belt' area of ScoutView (Figure 6-7). Enter actual (not lean or ideal) body weight.

D. Checking displayed patient position

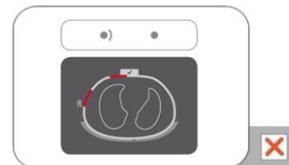
Verify that the displayed *rotation* and *inclination* images reflect the patient's position – acceptable is within +/- 10° of the displayed rotation image for *rotation* and for *inclination* of the angle range spanned by the displayed state of the 'inclination' icon (6.6.1).



If necessary, verify the belt positioning. Particularly, ensure that the belt is not distorted, the sternum is centered between the two ends of belt striped fabric and the belt is neither too small nor too large.

E. Checking signal quality and belt to skin contact quality

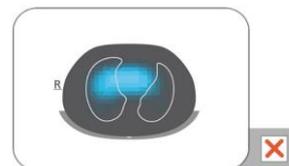
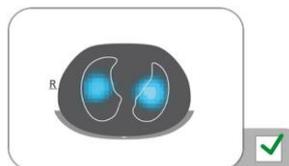
Verify the signal quality and the belt to skin contact quality around the thorax (Table 6-1, Table 6-4). Though monitoring is possible if the signal quality is weak, the signal quality should preferably be adequate or strong and there should preferably be no *failing electrodes* (9.3).



If necessary, remove any material such as bandages between the belt and the patient's skin and adjust the belt fit to the patient by softly pressing on the belt and by tightening the belt. If this does not resolve the problem, remove the belt, re-apply contact agent to the striped fabric of the belt and re-initiate monitoring (10.2).

F. Checking that breathing-related impedance changes are mainly within the Lung Contours

Verify that the movie-like display of *Global Dynamic Images* on ScoutView (Figure 6-6) and on VentView's detail view (Figure 6-13) reflects breathing-related impedance changes mainly within the *Lung Contours* (9.4).



If necessary, ensure that the belt is applied as recommended. If applied too far caudally the measurements may be influenced by the diaphragm, if applied too far cranially, the movie-like display of *Global Dynamic Images* tends to exhibit impedance changes as illustrated in the right figure below.

G. Checking that Global Dynamic Images and Plethysmogram reflect breathing

Verify that the *Global Dynamic Images* and the *Plethysmogram* on VentView's detail view (Figure 6-13) reflect the breathing pattern of the patient. Interferences from other devices, particularly from bioimpedance measurement devices such as impedance respiration monitoring may periodically cause the *Global Dynamic Image* to flutter and the *Plethysmogram* to exhibit irregular spikes.



In case of interferences from other devices switch off the other device (if possible) or in case of impedance respiration monitoring through ECG electrodes, reposition the electrodes further away from the belt. If this does not resolve the problem, contact a qualified technician, your local SenTec EIT representative or SenTec AG.

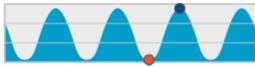
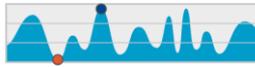
8.4 Checking the adequacy of the selected Analysis Mode

This sub-section and in particular [Table 8-1](#) provide guidance to check adequacy of the selected *Analysis Mode* (9.7). The adequacy of the selected *Analysis Mode* must be checked

- after initiating monitoring (8)
- while monitoring the patient (9) before evaluating *breathing-related EIT images and indices* or at least every 8 hours
- when reviewing trend data.

In the examples shown in [Table 8-1](#) the displayed time range is 15 seconds, i.e. the rate of the illustrated breathing-related and cardiac-related *Lung Impedance* changes is approximately 16 bpm and 96 bpm respectively. The dark blue and red dots mark local maxima and minima of the *Plethysmogram* and help to visualize maximal *Lung Impedance* change. The *Plethysmogram* (9.3) is displayed auto-scaled on the LuMon™ Monitor and therefore only shows relative *Lung Impedance* changes. Consequently, the absolute magnitude of breathing- or cardiac-related *Lung Impedance* changes are not displayed, however their relative magnitude can be visualized in relation to each other as shown in [Table 8-1](#).

Table 8-1: Guidance to verify adequacy of the selected Analysis Mode. See color key below the table.

| Breathing pattern | regular | irregular and/or weak | not visible or none |
|---|--|--|--|
| Maximal Lung Impedance changes <i>Plethysmograms</i> in the examples and on the LuMon™ Monitor are auto-scaled. | (a) mainly breathing-related  cardiac-related changes not visible | (c) mainly breathing-related  cardiac-related changes not visible | (e) mainly related to lung volume changes  cardiac-related changes visible; breathing-related changes not visible |
| | (b) mainly breathing-related  cardiac-related changes visible | (d) breathing- & cardiac-related  breathing- and cardiac-related changes visible | (f) mainly cardiac- or noise-related  breathing-related changes not visible |
| Breaths detected | frequently | frequently to infrequently | infrequently |
| RRi values available | frequently | frequently to infrequently | infrequently |
| BB mode <i>Breathing-related EIT images and indices</i> available for each detected breath | no data available | | |
| TB-I mode <i>Breathing-related EIT images and indices</i> available every 15 seconds | | | available data may not be meaningful |
| TB-II mode <i>Aeration</i> available every 15 seconds | | | |

Color key:

| | |
|--|-----------------------------|
| | mode generally adequate |
| | mode generally not adequate |

BB mode is adequate to analyze episodes during which the *Plethysmogram* (9.4) reflects quite regular breathing, basically, when most breaths can be detected (9.5) reliably and RRI values (9.6) are frequently available. This is usually the case in mechanically ventilated patients or spontaneously breathing patients with regular breathing patterns characterized by regular *Respiratory Rates* and tidal volumes. The less regular and/or the weaker breathing-related *Lung Impedance* changes are, the fewer breaths the LuMon™ System detects and the less appropriate the selection of *BB mode* is.

TB-I mode is adequate to analyze episodes during which the minima and maxima of the *Plethysmogram* (9.4) and, hence, the maximal *Lung Impedance* changes detected within *Analysis Intervals* are frequently related to breathing. In addition to episodes during which use of *BB mode* is appropriate, this also includes episodes during which the *Plethysmogram* reflects breathing patterns that present (significant) variations in amplitude and/or frequency. This can, for example, be the case in spontaneously breathing patients with irregular breathing rate and/or varying tidal volumes or in patients breathing rather shallowly. In such conditions, breath detection (9.5) may be hindered and RRI computation (9.6) may often not be possible.

TB-II mode is always adequate, even to analyze episodes during which the minima and maxima of the *Plethysmogram* (9.4) and, hence, the maximal *Lung Impedance* changes detected within *Analysis Intervals* are not related to breathing. In addition to episodes during which use of *TB-I mode* is appropriate, this also includes episodes during which the *Plethysmogram* exhibits very weak or no clear breathing pattern and instead is dominated by non-breathing-related *Lung Impedance* changes such as cardiac-related *Lung Impedance* changes. This can, for example, be the case in very shallowly breathing patients, in patients being ventilated at frequencies above a few Hz or on extracorporeal lung support or during apnea or breath holds. In such conditions, breath detection (9.5) and RRI computation (9.6) are typically not possible.

In *BB mode* breathing-related *EIT images and indices* are only calculated when a breath is detected, whereas in *TB-I mode* these data are calculated every 15 seconds, i.e. even if maximal *Lung Impedance* changes detected within *Analysis Intervals* are not breathing-related. Be aware that if this is the case, *breathing-related EIT images and indices* generated in *TB-I mode* may not always be physiologically meaningful. Also be aware, that *breathing-related EIT images and indices* obtained with *BB mode* may differ from those obtained with *TB-I mode*. Moreover, *breathing-related EIT images and indices* are not available in *TB-II mode*, *Aeration* is shown instead.

ⓘ CAUTION

In *TB-I mode* the minima and maxima and, hence, the maximal *Lung Impedance* changes detected within *Analysis Intervals* are, irrespective of the magnitude or rate of the *Lung Impedance* changes, assumed to be related to breathing, more specifically to end-expiratory and end-inspiratory time points. In order to avoid misinterpretation of data, be aware that *breathing-related EIT images and indices* generated in *TB-I mode* may consequently not always be physiologically meaningful.

In order to assess the adequacy of an *Analysis Mode* as outlined above and summarized in [Table 8-1](#) use VentView's trend view ([Figure 6-14](#)). Irrespective of the currently selected *Analysis Mode* this view displays:

- the *Plethysmogram* (9.4)
 - with, in *BB mode* ([Figure 9-9](#)),
 - two solid black vertical lines identifying the start and end of the last detected breath, also identifying the two most recent expiratory time points and the corresponding minima of the *Plethysmogram*
 - a broken black vertical line identifying the end-inspiratory time point and the corresponding maximum of the *Plethysmogram* within the last detected breath
 - with, in *time-based modes* ([Figure 9-10](#), [Figure 9-11](#)),
 - two solid black vertical lines identifying the start and end of the most recent completed *Analysis Interval* of 15 seconds duration
 - two broken black vertical lines identifying the minimum and maximum of the *Plethysmogram* within the *Analysis Interval*
- RRI (either the last calculated value or "--" if no value can be calculated (9.6))
- the RRI trend where gaps – if any - represent episodes during which no RRI value could be calculated.

A. If, as in the case of examples (a) and (b) in [Table 8-1](#),

- the minima and maxima identified by the above mentioned broken black vertical lines and, hence, the maximal *Lung Impedance* changes are mainly breathing-related,
- the *Plethysmogram* reflects a regular breathing pattern,
- breaths are frequently detected (respective markers only visible in *BB mode*)
- RRI is frequently available, and
- the patient's breathing pattern is unlikely to become less regular and/or weaker, then all three modes are adequate **with BB mode being recommended**.

- B. If, as in the case of examples (c) and (d) in Table 8-1,
- the minima and maxima identified by the above mentioned black vertical lines and, hence, the maximal *Lung Impedance* changes are breathing-related,
 - the *Plethysmogram* reflects an irregular breathing pattern and/or weak breathing pattern with cardiac-related *Lung Impedance* changes also being clearly visible,
 - breaths are detected frequently to infrequently (respective markers only visible in *BB mode*)
 - RRI is available frequently to infrequently, and
 - the patient's breathing pattern is unlikely to become less regular and/or weaker, then both *time-based modes* are adequate **with TB-I mode being recommended**.
- C. If, as in the case of examples (e) and (f) in Table 8-1,
- the minima and maxima identified by the above mentioned black vertical lines and, hence, the maximal *Lung Impedance* changes are not breathing-related,
 - the *Plethysmogram* does not reflect a breathing pattern
 - breaths are infrequently detected (respective markers only visible in *BB mode*)
 - RRI is infrequently available, and
 - the patient's breathing pattern is unlikely to become more regular and/or weaker, then **only TB-II mode is adequate**.

 **NOTE**
If in *TB-I mode* the *Stretch Image* (Figure 6-9) or *Silent Spaces Image* (Figure 6-11) every 15 seconds updates in an apparently arbitrary manner, then it is likely, that the maximal *Lung Impedance* changes being detected within *Analysis Intervals* are not breathing-related. In this case, consider using *TB-II mode*.

 **NOTE**
Irrespective of the currently selected *Analysis Mode*, the LuMon™ System in the background permanently analyzes the measured *EIT raw data* with all *Analysis Modes* and stores or outputs the results obtained with each mode. The selection of the *Analysis Mode* only determines for which mode the calculated results are displayed in real time and currently accessible in the trends for review. By selecting a different *Analysis Mode*, it is, consequently, possible anytime to review the results obtained with other modes in the trends. Should the selected *Analysis Mode* not have been adequate during a monitoring episode, this feature permits to review the trend data calculated with another, for the respective monitoring episode, possibly more appropriate *Analysis Mode*.

In order to assess the adequacy of an *Analysis Mode* to review an episode of previously recorded trend data first review the RRI trend in the corresponding time range. If within the time episode under review RRI is

- frequently available, then all three modes are adequate.
- only available often to rarely or even never, *BB mode* is more and more inadequate, *TB-I* may be, and *TB-II* is adequate. To check whether in this case use of *TB-I mode* is also adequate, open the trend view of the LuFuView's 'stretch' area (Figure 6-10) and slowly move one of the flags through the time episode to be reviewed. If the *Stretch Image* displayed in the respective flag's miniaturized 'stretch' details view changes in an apparently arbitrary manner when moving the flag, then *TB-I mode* is not adequate to review the respective episode.

9 WHILE MONITORING THE PATIENT

Monitoring starts when a belt, properly applied on a patient, is linked through a belt connector to a LuMon™ Monitor in the on-state (8).

NOTE

The LuMon™ System is not intended for diagnosis, it is intended only as an adjunct in patient assessment. It must be used in conjunction with other clinical signs and symptoms.

As an introduction to this section, sub-sections 9.1, 9.2, and 9.3 address several particular features of the LuMon™ System or more generally SenTec EIT. Sub-section 9.1 provides information about the patient-specific, CT-derived thorax and lung models used by the LuMon™ System. Why the LuMon™ System determines and how it visualizes the patient's position (*rotation* and *inclination*) is covered in 9.2. Sub-section 9.3 describes how the LuMon™ System continuously evaluates and visualizes the quality of the measured *EIT raw data* and of the thereof derived *EIT data*.

Sub-section 9.4 introduces the *Global Dynamic Image* and the *Plethysmogram*. *Global Dynamic Images* provide a movie-like display that visualizes regional impedance variations within the *Thorax ROI*. Considering *Lung Pixels* only, the *Plethysmogram* displays relative variations of *Lung Impedance* (i.e. the sum of impedance of all *Lung Pixels*) over time. Breath detection (9.5) is based on dynamics of the *Plethysmogram*, the determination of *Respiratory Rate* (9.6) and, with the exception of *Aeration*, of all other *EIT images* and *indices* provided by the LuMon™ System is based on detected breaths. The determination of the aforementioned data based on detected breath is herein referred to as *breath-based* (BB) analysis and the hereby determined *EIT images* and *indices* as *breathing-related EIT images and indices*. To determine *breathing-related EIT images and indices* the operator can also select a *time-based* (TB) analysis, e.g. when breaths are not easily detected. The different, selectable *Analysis Modes* are described in 9.7. Sub-sections 9.8, 9.9 and 9.10 describe the *breathing-related EIT images and indices*.

The possibility to mark operator events, to store screenshots on a USB stick and to record or export data on a USB stick are covered in sub-sections 9.10 and 9.11.

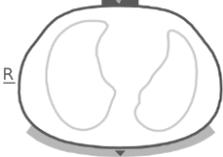
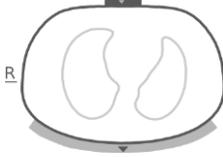
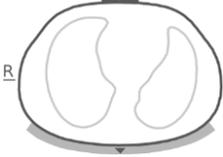
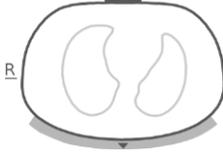
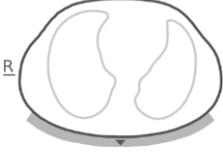
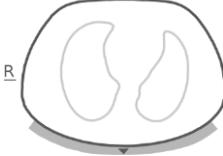
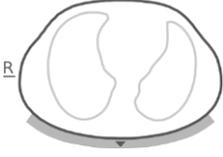
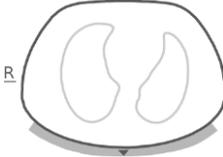
9.1 Selection of patient-specific, CT-derived thorax and lung models

The LuMon™ System makes use of thorax and lung models that have been derived from computed tomography (CT) to optimize the measured and displayed images as described below. On the one hand, anatomically enhanced *EIT image* reconstruction has been shown to be superior to non-individualized reconstruction [5]. On the other hand, using *Thorax* and *Lung ROIs* corresponding to the thorax and lung model best adapted to the individual patient's objective data, permits the LuMon™ System to determine those image pixels that most likely represent areas inside the patient's thorax and, most importantly, areas within the lung. Herein, pixels located within the *Thorax ROI* and the *Lung ROI* are respectively referred to as *Thorax Pixels* and *Lung Pixels* (14.2). It is herewith emphasized that, with the exception of the *Global Dynamic Image* (9.4), the LuMon™ System solely evaluates the impedance of *Lung Pixels* in order to determine the displayed data. *Lung Impedance*, for example, is the total impedance within the *Lung ROI* for a given image frame, i.e. the sum of the impedance values of all *Lung Pixels* (14.2).

In Adults/Children configuration, various CT-derived thorax and lung models covering a wide body mass index (BMI) range are available for both women and men.

Figure 9-1 illustrates for a few models the associated *Thorax* and *Lung Contours*, i.e. the borders of the *Thorax* and *Lung ROIs*. As can be seen from the examples, the *Thorax* and *Lung Contours* for females and males are different and their sizes and shapes mainly depend on BMI for both genders. As the width of the *Thorax Contour* is always scaled identically in the *EIT images*, the size of the displayed *Lung ROI* decreases with increasing BMI, though in this case mainly the size of the thorax increases in reality. For the same reason the size and shape of the *Thorax* and *Lung Contours* are similar in patients with similar BMI but different heights.

Figure 9-1: Illustration of Thorax and Lung Contours associated with different thorax and lung models.

| Gender | Height | BMI approx. 14.5 | BMI approx. 40.5 |
|--------|--------|---|---|
| Female | 165 cm |  |  |
| Female | 195 cm |  |  |
| Male | 165 cm |  |  |
| Male | 195 cm |  |  |

To select the thorax and lung model being best adapted to an individual patient in Adults/Children configuration, the patient's gender, actual (not lean or ideal) body weight, and height must be entered in the 'patient & belt' area of ScoutView (Figure 6-7) when initiating monitoring for a new patient (8.1). In Neonates/Infants configuration, only one CT-derived thorax and lung model is used and, consequently, the *Thorax and Lung Contours* used for the various *EIT images* are identical for all patients.

The thorax and lung models used by the LuMon™ System also assume specific positions of the 32 electrodes on the patient's thorax. In order to obtain optimal data, it is therefore very important to apply belts of recommended size to the patient properly (8.1, 8.2) and to check belt positioning regularly (at least every 8 hours) during monitoring (8.3). To avoid an inadvertent belt displacement around the patient's thorax, which would result in undefined electrode positions, belts for adults and children (SensorBelts (5.3.1)), have shoulder strips. Belts for neonates and infants (LuMon™ Belts (5.3.2)), do not have shoulder strips and it is therefore possible that in neonates and infants the belt is inadvertently rotated or displaced around the thorax from its optimal position. In order to assess the electrode positions on the thorax of neonates and infants as accurately as possible, it is therefore important to measure and enter the so-called belt displacement in the 'patient & belt' area of ScoutView (Figure 6-7) when applying a LuMon™ Belt (8.2), check it regularly (at least every 8 hours) and eventually update it during monitoring (8.3). Moreover, in Neonates/Infants configuration, the LuMon™ System also factors in the size of the connected belt and the patient's full underbust girth to determine the electrode positions. The full underbust girth is also to be measured and entered by the operator in the 'patient & belt' area of ScoutView (Figure 6-7) when applying the belt and initiating monitoring in Neonates/Infants configuration (8.2).

9.2 Accounting for the patient's position

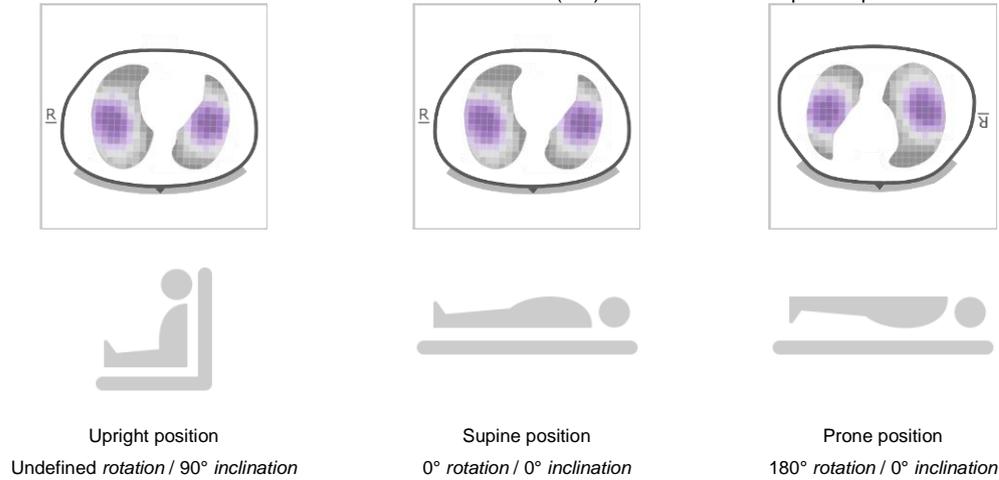
It is well known that physiological and pathophysiological phenomena are influenced by gravity (e.g. [6]). In order to facilitate the user with the possibility to better account for the influence of gravity on lung mechanics and ventilation distribution when evaluating monitored data displayed in real-time or retrospectively in the trends, the LuMon™ System continuously measures, visualizes and records patient position (*rotation* and *inclination*). Furthermore, the LuMon™ System considers the measured *rotation* when calculating the *Dependent Silent Spaces* (DSS), the *Non-Dependent Silent Spaces* (NSS) as well as the vertical and horizontal components of the *Center of Ventilation* (CoV(v) and CoV(h)). To this aim a position sensor is embedded in SensorBeltConnectors (5.2.1) and in LuMon™ Belts (5.3.2).

To indicate the measured *rotation*, all *EIT images* and the 'Belt-connection/Skin-contact/Rotation' icon in the Status Bar (6.6.1) rotate with the patient. *Inclination* is indicated with the 'Inclination' icon in the status bar (6.6.1) and on ScoutView (6.2). Figure 9-2 illustrates how patient position is indicated on ScoutView. The 'R'

While monitoring the patient

at the side of the *EIT image* indicates the right side of the patient. Refer to 6.5.1 for a description of the other common image elements and characteristics of *EIT images*.

Figure 9-2: Rotation and inclination as indicated on ScoutView (6.2) illustrated for three patient positions.

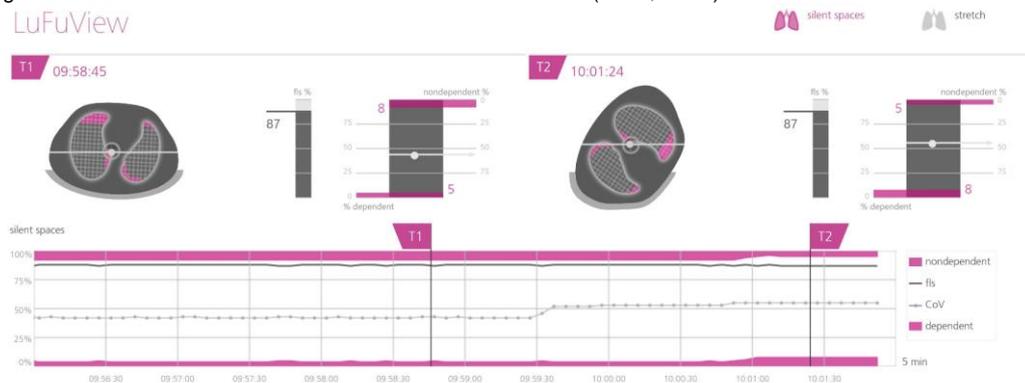


NOTE

The displayed *rotation* and the angle range spanned by the displayed state of the 'Inclination' icon (6.6.1) are meant to approximate patient position within +/- 10°.

As illustrated in Figure 9-3 for the trend view of LuFuView's 'silent spaces' area, the *EIT images* displayed within the miniaturized details views of LuFuView's trend views (6.3.2, 6.3.4) show the *rotation* at times T1 and T2. In the example shown, the patient was in supine position at T1 and in left lateral position at T2. By placing the two flags at time points with different *rotation*, the effect of the corresponding *rotation* change on the respective *EIT images* and *indices* and, hence, on ventilation distribution can be assessed.

Figure 9-3: Indication of rotation in the trend views of LuFuView (6.3.2, 6.3.4)



Finally, yet importantly, be aware that the subdivision of *Silent Spaces* into *Dependent Silent Spaces* (DSS) and *Non-Dependent Silent Spaces* (NSS) as well as the determination of the vertical and horizontal components of the *Center of Ventilation* (CoV(v) and CoV(h)) depend on displayed *rotation* (see also Figure 9-17).

CAUTION

To avoid misinterpretation of results be aware that the *Dependent Silent Spaces*, the *Non-Dependent Silent Spaces* as well as the vertical and horizontal components of the *Center of Ventilation* (CoV(v) and CoV(h)) are less meaningful, if the gravity vector is more or less perpendicular to the examined thorax cross-section being defined by the *belt plane*. This is, for example, the case, if the patient is standing or sitting upright.

9.3 Quality of calculated EIT data

The LuMon™ System continuously evaluates the quality of the measured *EIT raw data* and of the *EIT images*, *indices* and *Respiratory Rate* derived thereof. The results of this evaluation are used to set the quality of the displayed *EIT data* and/or to display status messages and various quality indicators.

As fully functional electrodes are important for the generation of *EIT data*, the LuMon™ System continuously evaluates the skin contact quality of all 32 electrodes integrated in the belt and categorizes the electrodes into those having adequate, poor or insufficient skin contact, the latter referred to as *failing electrodes*. Due to excessive skin contact impedance, EIT measurements are not performed with *failing electrodes*.

As shown in [Figure 9-4](#), the evaluated belt to skin contact quality around the thorax is visually presented in two ways:

- in quadrants of 8 electrodes each in the 'Belt-connection/Skin-contact/Rotation' icon ([6.6.1](#)). Quadrants with:
 - no or only one *failing electrode* (and no other *failing electrodes* in the other quadrants) are displayed in grey
 - one *failing electrode* (and at least another *failing electrode* in the other quadrants) are displayed in yellow
 - at least two *failing electrodes* are displayed in red
- with twelve electrode-segments being arranged on the *Thorax Contour* of the *Global Dynamic Image* on ScoutView ([6.6.4](#)). Electrode-segments:
 - whose electrodes have all adequate skin contact are displayed in grey
 - with at least one electrode with poor skin contact are displayed in yellow
 - with at least one *failing electrode* (i.e. having insufficient skin contact) are displayed in red.

Figure 9-4: Visual presentation of the skin contact quality around the thorax



Skin contact quality as indicated in the 'Belt-connection/Skin-contact/Rotation' icon ([6.6.1](#)). In the example shown, there are at least two *failing electrodes* in the ventral-right quadrant



Skin contact quality as indicated along the *Thorax Contour* of the *Global Dynamic Image* on ScoutView ([6.6.4](#)). In the example shown, two electrode-segments have at least one *failing electrode* and one segment has at least one electrode with poor contact

The more *failing electrodes* are in the belt, the fewer voltage measurements the LuMon™ System can use per image frame to generate *EIT images*. The 'signal quality status' icon ([6.6.1](#)) visualizes the *signal quality index*, i.e. the number of usable voltage measurements per image frame as a fraction of the possible voltage measurements. Monitoring is possible if the signal quality is strong, adequate, or poor. If it is insufficient, monitoring is not possible. This is the case, if there are more *failing electrodes* than the LuMon™ System is able to compensate for, or while the LuMon™ System is calibrating after a significant change of the belt to skin contact quality or a change in the number of *failing electrodes* ([4.3](#), [6.6.4](#)).

If monitoring is not possible (e.g. in case of too many *failing electrodes* or while the system is calibrating ([6.6.4](#)), if no belt connector or belt is connected ([6.6.3](#)) or in case of various system errors or faults ([6.6.2](#))), the LuMon™ System classifies all displayed *EIT data* to be invalid and

- blurs the elements common to all *EIT images* ([6.5.1](#))
- stops to update/display the *Global Dynamic Image* and the *Plethysmogram*
- continues to display the last measured *Stretch* and *Silent Spaces Images*, related histograms and bars as well as values of *indices* and *Respiratory Rate* for up to 40 seconds. Thereafter, the *Stretch* and *Silent Spaces Images*, related histograms and bars and all *indices* are removed from display and the last measured *Respiratory Rate* value is replaced by "--".

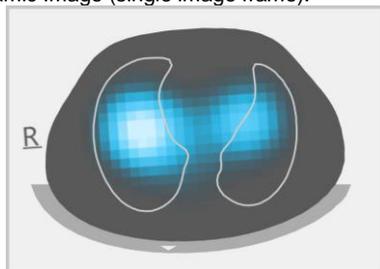
In conditions in which monitoring is possible, but the LuMon™ System is unable to detect a breath ([9.5](#)) or if the *Respiratory Rate* is outside its specified display range ([13.1](#)), the last calculated *Respiratory Rate* value continues to be displayed for up to 40 seconds and is then replaced by "--" in all *Analysis Modes*. If in this case the LuMon™ Monitor is operated in *BB mode*, the last measured *Stretch* and *Silent Spaces Images*, related histograms and bars and all values of *indices* continue to be displayed for up to 40 seconds and thereafter are all removed from display.

9.4 Global Dynamic Images and Plethysmogram

The details view of VentView (6.4.1) and the minimized VentView (Figure 6-1) display *Global Dynamic Images* and the *Plethysmogram*. *Global Dynamic Images* are also displayed on ScoutView (Figure 6-6). The *Plethysmogram* is displayed auto-scaled. The displayed time range for the *Plethysmogram* can be adjusted between 10 seconds and 5 minutes (Table 6-8).

About 50 times per second the LuMon™ System derives the impedance distribution within the *EIT sensitivity region* from the measured *EIT raw data*, maps those impedance distributions on the *belt plane* and then displays the resulting regional impedance distributions within the *Thorax ROI* as continuously updated series of *Global Dynamic Images* in a movie-like sequence. For visualization purposes, individual *Global Dynamic Images* (Figure 9-5) display the regional impedance distribution within the *Thorax ROI* with respect to a moving baseline impedance distribution with dark bluish colors reflecting small and brighter whitish colors reflecting larger impedance differences with respect to this baseline.

Figure 9-5: Example of a Global Dynamic Image (single image frame).

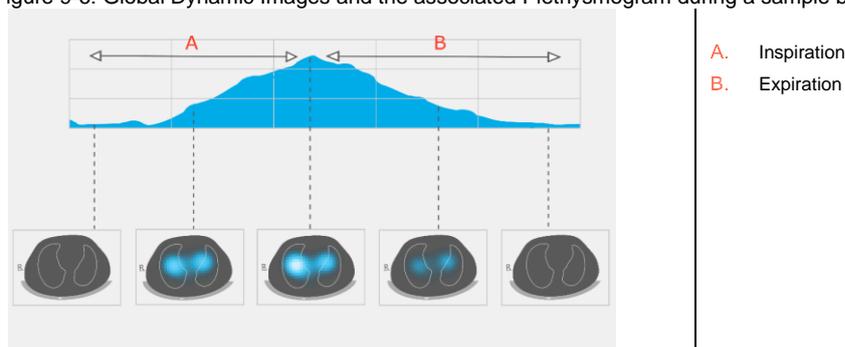


NOTE

The *Lung Contours* are superimposed in *Global Dynamic Images* for a better visualization of *rotation*. As breathing-related impedance changes should mainly occur within the *Lung ROI*, the display of the *Lung Contours* in *Global Dynamic Images* is furthermore useful to assess measurement quality/plausibility (9.3).

The resulting color changes observable in the movie-like display of *Global Dynamic Images* visualize regional impedance variations over time within the *Thorax ROI*. As an example, Figure 9-6 at the bottom shows five *Global Dynamic Images* illustrating typical color changes observable during a sample breath when breathing normally, i.e. with relatively constant rate and inspiratory volume yielding normal minute ventilation. At the start of inspiration (image at the left) all image pixels appear darkish. During inspiration, most pixels located within or close to the *Lung Contours* gradually appear brighter and appear brightest at the end of inspiration (image in the center). During subsequent expiration, the appearance of the pixels gradually darkens and at the end of expiration (image at the right), all image pixels appear again darkish.

Figure 9-6: Global Dynamic Images and the associated Plethysmogram during a sample breath (see text).

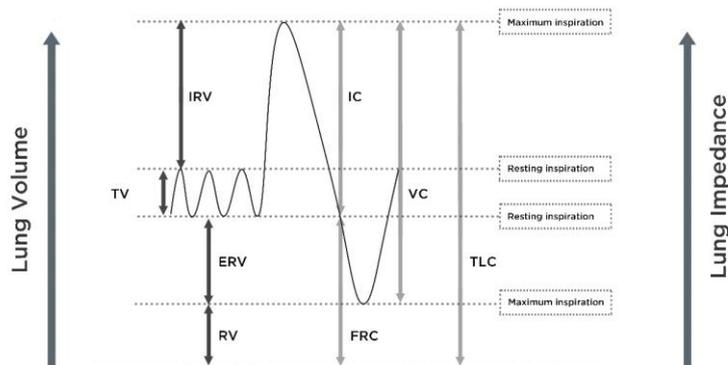


The *Plethysmogram* displayed on top of the five *Global Dynamic Images* in Figure 9-6 shows how *Lung Impedance* changes during the aforementioned sample breath. Starting from a minimum at the start of inspiration, *Lung Impedance* increases during inspiration to reach a maximum at the end of inspiration. During expiration, *Lung Impedance* decreases to reach a renewed minimum at the end of expiration.

It is well known [4] that impedance variations within the thorax and particularly within areas represented by the *Lung ROI*, are primarily caused by lung function – i.e. air flowing in, distributing within, and flowing out of the lungs – and, to a lesser extent, perfusion and cardiac activity. Therefore, in case of normal breathing as shown in the example of Figure 9-6, the color-changes observable in the movie-like display of *Global Dynamic Images* can be put in relation with variations of regional air content/volume within the lungs. Correspondingly, the variations of *Lung Impedance* with time displayed by the *Plethysmogram* are, in case of normal breathing, mainly related to lung volume/air content variations. If we follow inspirations and expirations, as in Figure 9-7, the *Plethysmogram* will indeed reflect corresponding changes in *Lung Impedance*, increasing with increasing lung volumes and vice versa. If exhaling against ambient pressure the local minima that will be observable in

the *Plethysmogram*, for example, will be related to the functional residual capacity (FRC) during normal breathing, or to the residual volume (RV) after a forced full expiration.

Figure 9-7: Representation of lung volumes during normal breathing and forced full inspiration and expiration (image adapted from [8]). The measured Lung Impedance increases with lung volume, and vice versa.



Cardiac-related *Lung Impedance* changes have up to approximately 1/10 of the magnitude of *Lung Impedance* changes caused by normal breathing and therefore might also be visible in the *Plethysmogram*. In Figure 9-6, where smaller *Lung Impedance* changes are superposed on the *Lung Impedance* change caused by a breath when breathing normally, this is indeed the case. It is quite evident that with decreasing tidal volume the magnitude of cardiac-related compared to breathing-related *Lung Impedance* changes will gradually increase. In case of very small or no tidal volumes - as this may be the case in very shallowly breathing patients, in patients being ventilated at frequencies above a few Hz or on extracorporeal lung support or during apnea or breath holds – cardiac-related *Lung Impedance* changes will typically dominate the *Plethysmogram*.

CAUTION
To avoid misinterpretation of results, be aware that in some situations *Lung Impedance* changes displayed by the *Plethysmogram* may be less related to breathing than to other sources such as cardiac activity, therefore one should not rely solely upon the visual representation of the *Plethysmogram*, i.e. the *Lung Impedance* waveform, to derive information on breathing.

NOTE
The LuMon™ Monitor displays the *Plethysmogram* auto-scaled and therefore only shows relative *Lung Impedance* changes. Consequently, the absolute magnitude of breathing- or cardiac-related *Lung Impedance* changes are not displayed, however their relative magnitude can be visualized in relation to each other.

NOTE
If in doubt whether the *Lung Impedance* changes displayed by the *Plethysmogram* are predominantly breathing-related, cardiac-related or mixed, consider comparing the *Plethysmogram* with other breathing or cardiac-related waveforms or data available for the same patient measured by other devices such as ventilators or patient monitors.

NOTE
As the LuMon™ Monitor partially filters out frequencies above a few Hertz the *Plethysmogram* displayed on the LuMon™ Monitor does not show the small tidal volumes typically encountered in patients under high-frequency oscillatory ventilation (HFOV) or under other high-frequency ventilation modalities.

NOTE
The ability of the LuMon™ System to detect lung volume changes depends on the dimension of the lung with respect to the thorax. As this relationship is similar across all age groups, the LuMon™ System can detect much smaller absolute lung volume changes in neonates than in adult patients.

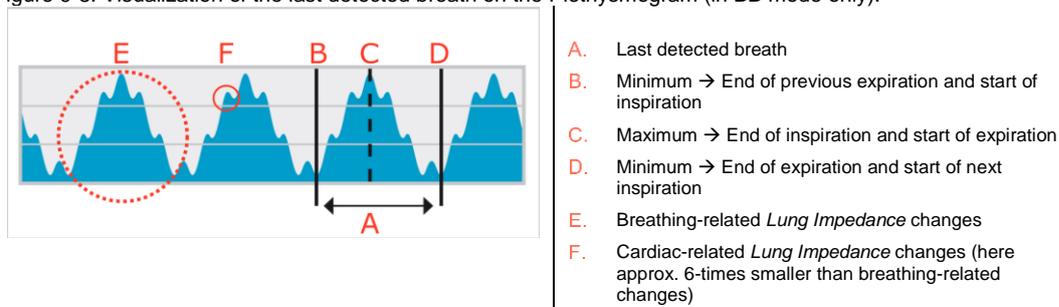
9.5 Breath detection

In order to identify breaths, the LuMon™ System continuously evaluates the course of the *Plethysmogram* irrespective of the selected *Analysis Mode* (9.7). As can be seen from Figure 9-7 the *Plethysmogram* is expected to display an increase during the inspiratory phase of a breath and a decrease during the expiratory phase. Pairs of consecutive increase and decrease of the *Plethysmogram* are potential breaths. Those that fulfill a set of predefined criteria are assessed as breaths, all others are rejected. As illustrated in Figure 9-8, the LuMon™ Monitor in *BB mode* (9.7.1) marks the last detected breath on the *Plethysmogram* with two solid black vertical lines.

The predefined criteria the LuMon™ System uses to detect breaths are selected so that, in mechanically ventilated patients or spontaneously breathing patients with regular breathing patterns characterized by regular

respiratory rates and tidal volumes, practically all pairs of consecutive increase and decrease of the *Plethysmogram* will be assessed as breaths. If, however, the *Plethysmogram* reflects breathing patterns that present (significant) variations in amplitude and/or frequency, only a varying number of the identified patterns (most to almost none) will be assessed as breaths and reliable breath detection may be hindered. This can be the case in spontaneously breathing patients with irregular breathing rate and/or varying tidal volumes or in patients breathing rather shallowly. If the *Plethysmogram* exhibits very weak or no clear breathing pattern and instead is dominated by non-breathing-related *Lung Impedance* changes such as for example cardiac-related *Lung Impedance* changes, the LuMon™ System will typically detect no breaths. For example, this may be the case in very shallowly breathing patients, in patients being ventilated at frequencies above a few Hz or on extracorporeal lung support or during apnea or breath holds.

Figure 9-8: Visualization of the last detected breath on the Plethysmogram (in BB mode only).



9.6 Respiratory Rate

The details view of VentView (6.4.1) and the minimized VentView (Figure 6-1) display *Respiratory Rate* (RRi). The trend view of VentView provides an auto-scaled RRi-trend (6.4.2).

On the basis of detected breaths (9.5) the LuMon™ System calculates and displays RRi irrespective of the selected *Analysis Mode* (9.7). The calculation of a *Respiratory Rate* value requires at least three consecutive detected breaths that are similar to each other and the displayed RRi value is a moving average over the last four detected breaths.

If the LuMon™ System is unable to detect a breath, for example if a patient is breathing rather shallowly, or if the calculated *Respiratory Rate* is outside its specified display range (13.1), then the last calculated *Respiratory Rate* value continues to be displayed for up to 40 seconds and is then replaced by "--" in all *Analysis Modes*.

9.7 Analysis Modes

The *Analysis Mode* can be selected in ScoutView (Figure 6-6).

The LuMon™ System features three operator adjustable modes to analyze the *Plethysmogram*, specifically, to determine end-expiratory and end-inspiratory time points needed for the calculation of *breathing-related EIT images and indices* as well as the mean of the *Plethysmogram* over an *Analysis Interval*. Furthermore, the extent of available *EIT data* depends on the selected *Analysis Mode*. Available *Analysis Modes* are *breath-based* (BB) mode and *time-based* (TB-I and TB-II) modes with *BB mode* being the power-on default mode.

It is important to check the adequacy of the selected *Analysis Mode*

- after initiating monitoring (8)
- while monitoring the patient (9) before evaluating *breathing-related EIT images and indices* or at least every 8 hours
- when reviewing trend data.

Sub-section 8.4 and in particular Table 8-1 provide further guidance.

NOTE
Breathing-related EIT images and indices are available in *BB mode* and *TB-I mode*, whereby those obtained with *BB mode* may differ from those obtained with *TB-I mode*. Moreover, *breathing-related EIT images and indices* are not available in *TB-II mode*, *Aeration* is shown instead.

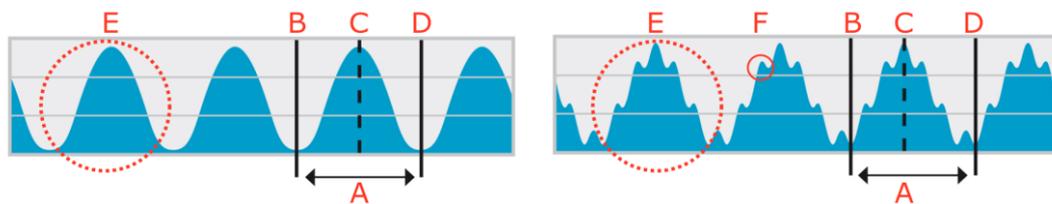
NOTE

Irrespective of the currently selected *Analysis Mode*, the LuMon™ System in the background permanently analyzes the measured *EIT raw data* with all *Analysis Modes* and stores or outputs the results obtained with each mode. The selection of the *Analysis Mode* only determines for which mode the calculated results are displayed in real time and currently accessible in the trends for review. By selecting a different *Analysis Mode*, it is, consequently, possible anytime to review the results obtained with other modes in the trends. Should the selected *Analysis Mode* not have been adequate during a monitoring episode, this feature permits to review the trend data calculated with another, for the respective monitoring episode, possibly more appropriate *Analysis Mode*.

9.7.1 Main characteristics of BB mode

In *BB mode* the *Analysis Interval* corresponds to the duration of detected breath cycles. The start and end of the last detected breath is marked on the *Plethysmogram* (Figure 9-9) with two solid black vertical lines. These two lines also identify the two most recent end-expiratory time points. The broken black vertical line identifies the end-inspiratory time point within the last detected breath. The corresponding values of the *Plethysmogram* are the *End-Expiratory Lung Impedance* (EELI) and the *End-Inspiratory Lung Impedance* (EILI) (9.8).

Figure 9-9: Markers on the Plethysmogram in BB mode



Lung Impedance changes regular and breathing-related, cardiac-related changes not visible – see example (a) of Table 8-1

Lung Impedance changes regular and mainly breathing-related, cardiac-related changes visible – see example (b) of Table 8-1

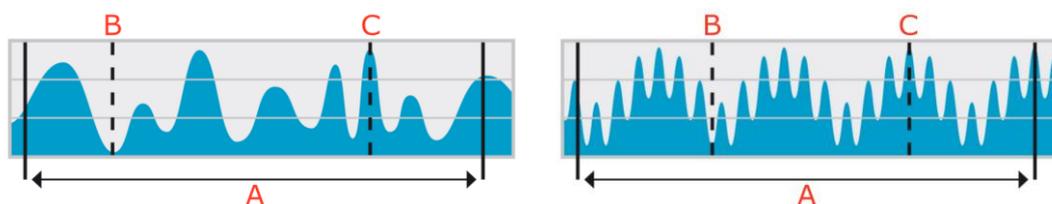
- A. Last detected breath/last *Analysis Interval*
- B. Minimum (end of previous expiration) → *End-Expiratory Lung Impedance* (EELI)
- C. Maximum (end of inspiration) → *End-Inspiratory Lung Impedance* (EILI)
- D. Minimum (end of expiration) → *End-Expiratory Lung Impedance* (EELI)
- E. Breathing-related *Lung Impedance* changes
- F. Cardiac-related *Lung Impedance* changes (here approx. 6-times smaller than breathing-related *Lung Impedance* changes)

In *BB mode*, all *breathing-related EIT images and indices* are calculated for each detected breath. This includes the *Stretch Image*, the *Silent Spaces Image* and *indices* such as EELI, EILI, *Functional Lung Spaces*, *Silent Spaces*, *Dependent Silent Spaces*, *Non-Dependent Silent Spaces* and the *Center of Ventilation* (9.8, 9.9, 9.10).

9.7.2 Main characteristics of TB-I mode

In *TB-I mode* the *Analysis Interval* has a fixed, preset duration of 15 seconds. The most recent completed *Analysis Interval* is marked on the *Plethysmogram* (Figure 9-10) with two solid black vertical lines. Two broken black vertical lines identify the minimum and maximum of the *Plethysmogram* within the most recent completed *Analysis Interval*. The minima and maxima within *Analysis Intervals* can occur in any order. Assuming that the marked maximum and minimum are nevertheless related to breaths, their occurrences are interpreted as end-expiratory and end-inspiratory time points of not necessarily the same breath and the corresponding values of the *Plethysmogram* are interpreted as *End-Expiratory Lung Impedance* (EELI) and the *End-Inspiratory Lung Impedance* (EILI) (9.8).

Figure 9-10: Markers on the Plethysmogram in TB-I mode



Lung Impedance changes irregular and breathing-related; cardiac-related changes not visible – see example (c) of Table 8-1

Lung Impedance changes 'weak & regular'; breathing- and cardiac-related changes visible – see example (d) of Table 8-1

- A. Last completed Analysis Interval of 15 seconds duration
- B. Minimum within last completed Analysis Interval (in TB-I mode assumed to be breathing-related) → End-Expiratory Lung Impedance (EELI)
- C. Maximum within last completed Analysis Interval (in TB-I mode assumed to be breathing-related) → End-Inspiratory Lung Impedance (EILI)

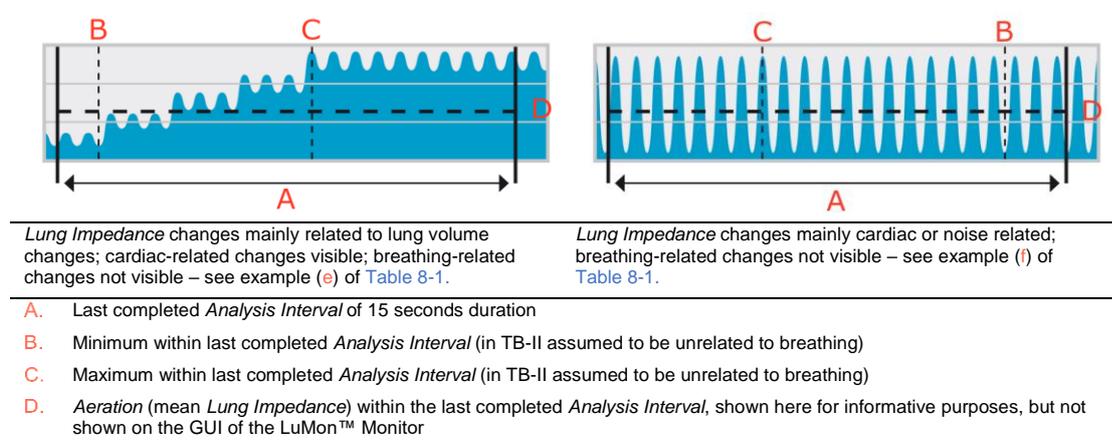
In TB-I mode, all breathing-related EIT images and indices are calculated for each Analysis Interval, i.e. every 15 seconds. This includes the Stretch Image, the Silent Spaces Image and indices such as EELI, EILI, Functional Lung Spaces, Silent Spaces, Dependent Silent Spaces, Non-Dependent Silent Spaces and the Center of Ventilation (9.8, 9.9, 9.10).

CAUTION
 In TB-I mode the minima and maxima and, hence, the maximal Lung Impedance changes detected within Analysis Intervals are, irrespective of the magnitude or rate of the Lung Impedance changes, assumed to be related to breathing, more specifically to end-expiratory and end-inspiratory time points. In order to avoid misinterpretation of data, be aware that breathing-related EIT images and indices generated in TB-I mode may consequently not always be physiologically meaningful.

9.7.3 Main characteristics of TB-II mode

In TB-II mode the Analysis Interval has a fixed, preset duration of 15 seconds. The most recent completed Analysis Interval is marked on the Plethysmogram (Figure 9-11) with two solid black vertical lines. A broken black vertical line marks the minimum and a second broken black vertical line the maximum of the Plethysmogram within the most recent completed Analysis Interval. In TB-II mode breathing-related EIT images and indices are not available and, consequently, LuFuView (6.3) is not accessible. Instead Aeration, i.e. the mean of Lung Impedance over an Analysis Interval, is determined every 15 seconds. Note that for informative purposes a broken black horizontal line visualizes Aeration in Figure 9-11, whereas on the LuMon™ Monitor Aeration is not visualized on the Plethysmogram.

Figure 9-11: Markers on the Plethysmogram in TB-II mode.



9.8 Trends of EELI, EILI and Aeration

The LuMon™ Monitor only displays trends of End-Expiratory Lung Impedance (EELI), End-Inspiratory Lung Impedance (EILI) and Aeration, the respective real-time values are not displayed. In BB and TB-I modes the trend view of VentView (6.4.2) displays trends of EELI, EILI and Respiratory Rate (RRi), and in TB-II mode it displays trends of Aeration and RRi.

EELI is the minimum of Lung Impedance within Analysis Intervals and interpreted as the Lung Impedance at end-expiratory time points. EELI is related to the end-expiratory lung volume (EELV) if exhaling against a PEEP and, if exhaling against ambient pressure, to the Functional Residual Capacity (FRC), when breathing normally, or the Residual Volume (RV), in forced expiration (Figure 9-7). Correspondingly, EILI is the maximum of Lung Impedance within Analysis Intervals and interpreted as the Lung Impedance at end-inspiratory time points. EILI is related to end-inspiratory lung volume and, therefore, the difference between EILI and EELI is related to tidal volume. Aeration, finally, is the mean Lung Impedance within Analysis Intervals and is related to mean lung volume.

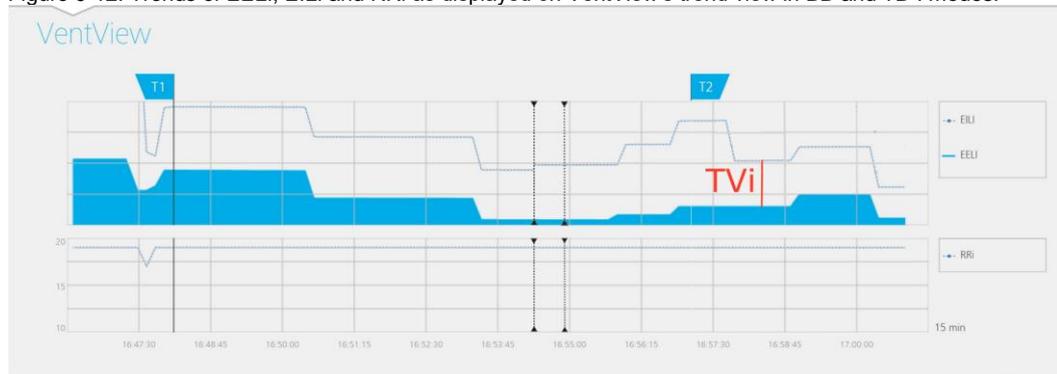
In **BB mode** and as illustrated in [Figure 9-9](#) for the last detected breath, EELI corresponds to *Lung Impedance* measured at the beginning and the end of detected breaths, i.e. at start inspiratory respectively end-expiratory time points. EILI corresponds to *Lung Impedance* measured at end-inspiratory respectively start-expiratory time points within detected breaths. In *BB mode*, EELI and EILI are determined for each detected breath.

In **TB-I mode** and as illustrated in [Figure 9-10](#) for the last completed *Analysis Interval*, EELI and EILI correspond to the minimum and maximum of the *Plethysmogram* within *Analysis Intervals*, respectively. The minima and maxima within *Analysis Intervals* can occur in any order. Their occurrence nevertheless is assumed to be breathing-related and to correspond to end-expiratory and end-inspiratory time points of not necessarily the same breath. In *TB-I mode* EELI and EILI are determined every 15 seconds, i.e. even if maximal *Lung Impedance* changes detected within *Analysis Intervals* are not breathing-related. Be aware that if this is the case, EELI and EILI may not always be physiologically meaningful. Also be aware, that EELI and EILI values obtained with *BB mode* may differ from those obtained with *TB-I mode*.

In **TB-II mode** and as illustrated in [Figure 9-11](#) for the last completed *Analysis Interval*, *Aeration*, i.e. the mean *Lung Impedance* within *Analysis Intervals*, is determined every 15 seconds.

As illustrated in [Figure 9-12](#), the trend view of VentView ([6.4.2](#)) displays the trends of EELI, EILI and RRi in *BB* and *TB-I modes*. In the upper graph, the upper border of the shaded area and the upper line represent the EELI and EILI trends, respectively. The line in the lower graph is the RRi trend. An increase or decrease of EELI and/or EILI is related to an increase or decrease of end-expiratory lung volume and/or end-inspiratory lung volume. The difference between the EILI and EELI trend is related to *Tidal Variation (TVi)*, i.e. *Lung Impedance* change due to tidal ventilation. An increase or decrease in this difference is related to an increase or decrease of the Tidal Volume.

Figure 9-12: Trends of EELI, EILI and RRi as displayed on VentView's trend view in BB and TB-I modes.



In *TB-II modes* and as illustrated in [Figure 9-13](#), the trend view of VentView ([6.4.2](#)) displays trends of *Aeration* and RRi. *Aeration* is displayed in the upper and RRi in the lower graph. An increase or decrease of *Aeration* represents an increase or decrease of the mean lung volume.

Figure 9-13: Trends of Aeration and RRi as displayed on VentView's trend view in TB-II mode.



9.9 Stretch Image – Relative Tidal Stretch

The details view of LuFuView's 'stretch' area ([6.3.1](#)) displays the *Stretch Image*, the associated weighted *Relative Tidal Stretch* histogram and quartiles of weighted *Relative Tidal Stretch*. The trend view of LuFuView's 'stretch' area ([6.3.2](#)) provides trends of the quartiles of weighted *Relative Tidal Stretch*, i.e. of its center and spread.

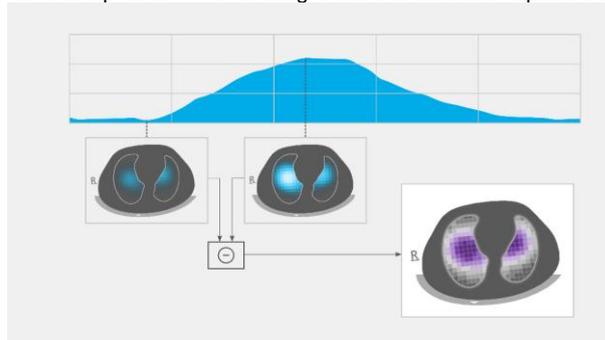
As illustrated in [Figure 9-14](#), a *Stretch Image* is obtained for every *Analysis Interval*:

- by first subtracting the EELI distribution (on the right) from the EILI distribution (on the left) (yielding as an intermediate result the change in *Lung Impedance* distribution between the respective time points),
- and then by normalizing for each *Lung Pixel* the corresponding impedance change with the maximum *Lung Pixel* impedance change.

In the example of [Figure 9-14](#) the *BB mode* calculation of the *Stretch Image* is shown, i.e. the last detected breath is taken as the current *Analysis Interval* and the preceding EELI distribution is subtracted from the associated EILI distribution.

The *Lung Pixel* values of the resulting *Stretch Image*, i.e. *Lung Pixel* impedance change due to tidal ventilation normalized to maximum *Lung Pixel* impedance change, are referred to as *Relative Tidal Stretch* (RTS). The *Stretch Image*, hence, displays the regional distribution of *Relative Tidal Stretch* within the *Lung ROI*.

Figure 9-14: Illustration of the concept of the Stretch Image. The calculation is explained in the text.

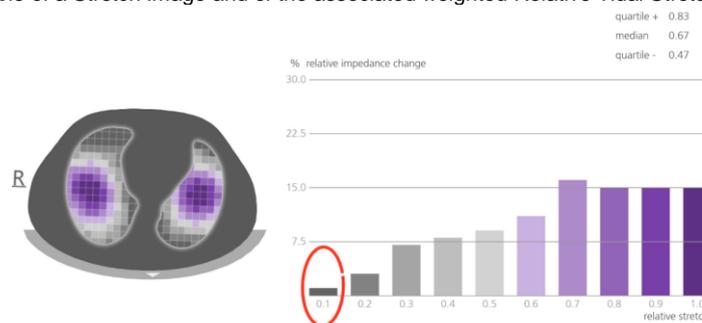


In *BB mode*, a *Stretch Image* is determined for each detected breath and is related to the regional distribution of the tidal volume inhaled during this breath within the lungs.

In *TB-I mode*, a *Stretch Image* is determined every 15 seconds and is related to the regional distribution of the largest lung volume change as a proxy of the regional distribution of (inhaled or exhaled) tidal volume during intervals of 15 seconds. Be aware that in *TB-I mode* *Stretch Images* are calculated even if the maximal *Lung Impedance* changes detected within intervals of 15 seconds are not breathing-related. If this is the case, *Stretch Images* may not always be physiologically meaningful. Also be aware that *Stretch Images* obtained with *BB mode* may differ from those obtained with *TB-I mode*.

The *Stretch Image* ([Figure 9-15](#)) has *Lung Pixel* values between 0 and 100% being subdivided into ten 10%-wide clusters with similar *Regional Tidal Stretch*. Clusters with large *Relative Tidal Stretch* values, reflecting better ventilation, are shown in violet colors, and those with small *Regional Tidal Stretch* are displayed in greyish colors. To visualize how much each cluster contributes to the *Lung Impedance* change between the end-inspiratory and end-expiratory time points, the associated weighted *Relative Tidal Stretch* histogram is displayed as a ten-part bar chart on the right of the *Stretch Image*. Each bar represents a cluster of *Lung Pixels* with similar *Regional Tidal Stretch*, whereby the first bar shows those *Lung Pixels* with *Regional Tidal Stretch* values between 0% and 10% and the last bar those between 90% and 100%. The height of each bar is the ‘% relative impedance change’ or, in other words, the percent contribution of a cluster to the total *Lung Impedance* change caused by tidal ventilation. The *Lung Pixels* belonging to the first bar, in [Figure 9-15](#) highlighted with an oval, constitute the so-called *Silent Spaces*, representing those regions within the lung that exhibit little or no impedance change. The rest of the *Lung Pixels* constitute the so-called *Functional Lung Spaces* (FLS), related to the concept of Functional Lung Size [1]. The 25% quartile, median and 75% quartile of weighted *Relative Tidal Stretch* displayed above the ten-part bar chart provide summary statistical information about both the center and the spread of weighted *Relative Tidal Stretch*.

Figure 9-15: Example of a Stretch Image and of the associated weighted Relative Tidal Stretch histogram.

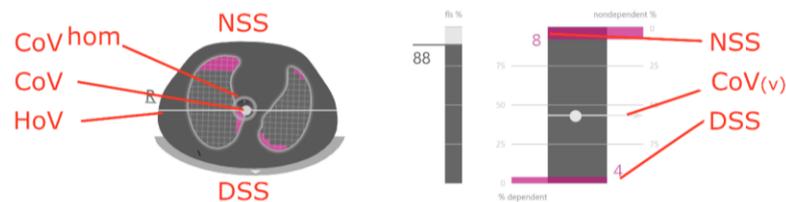


9.10 Center of Ventilation, Silent Spaces and Functional Lung Spaces

The details view of LuFuView's 'silent spaces' area (6.3.3) displays the *Silent Spaces Image*, the *Center of homogeneous Ventilation*, the *Center of Ventilation* and the *Horizon of Ventilation*. Furthermore, it provides the *Functional Lung Spaces* bar and the *Silent Spaces* bar. The trend view of LuFuView's 'silent spaces' area (6.3.4) provides trends of *Functional Lung Spaces* (FLS), *Dependent Silent Spaces* (DSS), *Non-Dependent Silent Spaces* (NSS), and the vertical component of the *Center of Ventilation* (CoV(v)).

From the *Stretch Image* (9.9), the corresponding *Silent Spaces Image*, displayed on the left of Figure 9-16, is obtained, by simply coloring in magenta all *Lung Pixels* with RTS-values smaller or equal than 10% and in grey all other *Lung Pixels*. The resulting *Silent Space image* hence displays the regional distribution of *Silent Spaces* and *Functional Lung Spaces* within the *Lung ROI* respectively in magenta and grey. *Silent Spaces* reflect the lung areas with little or no impedance change during breathing. As such they are meant to represent the percentage of lung regions that receive no or little ventilation and are thus hypoventilated. Correspondingly, *Functional Lung Spaces* reflect lung areas with non-negligible impedance change during breathing. As such they are meant to represent the percentage of ventilated lung regions and, hence, are related to the Functional Lung Size [1], i.e. the percentage of the aerated remaining lung sometimes referred to as the size of the available lung volume.

Figure 9-16: Example of Silent Spaces Image, Functional Lung Spaces (FLS) bar and Silent Spaces bar.



From the *Stretch Image* it is also possible to compute the *Center of Ventilation* (CoV) by weighing each *Lung Pixel Relative Tidal Stretch* value. So, the CoV is the weighted geometrical *Center of Ventilation* distribution within the *Lung ROI*. Within the examined thorax cross-section CoV is a point whose position indicates in which lung regions ventilation predominantly takes place [3]. In Figure 9-16, the whitish dot, overlying the *Silent Spaces Image*, represents the CoV. For the sake of comparison, the *Center of homogeneous Ventilation* (CoV^{hom}), i.e. the CoV if ventilation is homogeneously distributed within the *Lung ROI*, is also computed and displayed as a grey hollow circle.

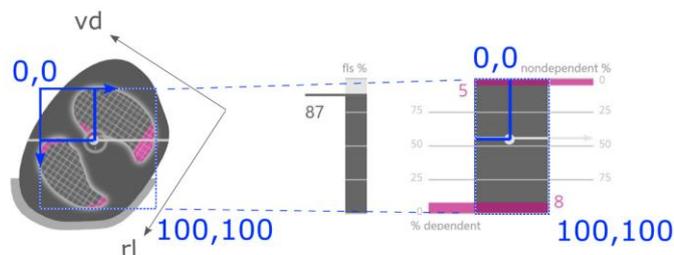
The whitish horizontal line perpendicular to the gravity vector through CoV represents the *Horizon of Ventilation* (HoV). HoV divides the image into non-dependent (upper part of image) and dependent (lower part of image) areas. Correspondingly, the *Silent Spaces* below the *Horizon of Ventilation* are called *Dependent Silent Spaces* (DSS). The *Silent Spaces* above the *Horizon of Ventilation* are called *Non-Dependent Silent Spaces* (NSS). Being located on the "bottom" of the lungs (dependent regions) and influenced by gravity, there is a certain probability that *Dependent Silent Spaces* represent lung regions that are closed, collapsed, or filled with fluid. *Non-Dependent Silent Spaces*, instead, being located in the upper regions, are more likely to represent already distended, maybe even overdistended, lung regions [9]-[11].

To express the position of the CoV in coordinates, the LuMon™ System uses the coordinate system with respect to gravity illustrated in blue in Figure 9-17. In this coordinate system,

- the coordinate CoV(v) characterizes the ventilation distribution in vertical direction and is expressed as a fraction of the vertical *Lung ROI* height.
- the coordinate CoV(h) characterizes the ventilation distribution in horizontal direction and is expressed as a fraction of the horizontal *Lung ROI* width.

In the former case, values towards 0% imply that ventilation is predominantly directed towards non-dependent lung regions, in the latter one towards the left of the gravity vector (i.e. towards the right lung if the patient is in supine position and towards the left lung if the patient is in prone position).

Figure 9-17: Coordinates of the CoV

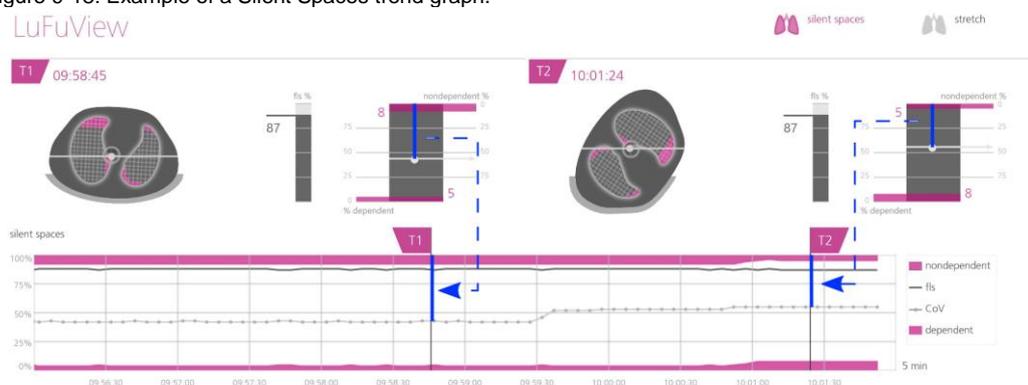


It is important to note that, thanks to the position sensor, DSS and NSS as well as the coordinates CoV(v) and CoV(h) are always automatically defined if *rotation* changes, thereby allowing to directly assess the influence of the patient's position on the ventilation distribution. Only in supine position, the coordinates CoV(v) and CoV(h) used by the LuMon™ System are aligned with the coordinates defined by the patient's main body directions typically used in literature [3],[8] and illustrated in black in Figure 9-16, namely the right-left and ventrodorsal coordinates, CoV(rl) and CoV(vd) respectively.

The FLS bar (in the center of Figure 9-16) represents the percentage of FLS with respect to the total lung area, and the *Silent Spaces* bar (on the right of Figure 9-16) represents the respective percentages of NSS and DSS (FLS, DSS and NSS together totaling 100%). Here CoV is also displayed as a whitish dot for contextualization, with its vertical coordinate represented on the right vertical scale with 0% on the top (its horizontal coordinate being also displayed but without a scale).

These percentages and the vertical coordinate of CoV are also shown in the corresponding trend graph as illustrated in Figure 9-18. Two time points, T1 and T2, are set for comparison. DSS, NSS, CoV(v) and FLS are shown in the trend graph in percentage values. The values of NSS and CoV(v) can be visualized considering 0% on the top, those of DSS and FLS considering 0% on the bottom.

Figure 9-18: Example of a Silent Spaces trend graph.



Finally, yet importantly, be aware that the subdivision of *Silent Spaces* into *Dependent Silent Spaces* (DSS) and *Non-Dependent Silent Spaces* (NSS) as well as the determination of the vertical and horizontal components of the *Center of Ventilation* (CoV(v) and CoV(h)) depend on displayed *rotation* (see also Figure 9-17).

CAUTION

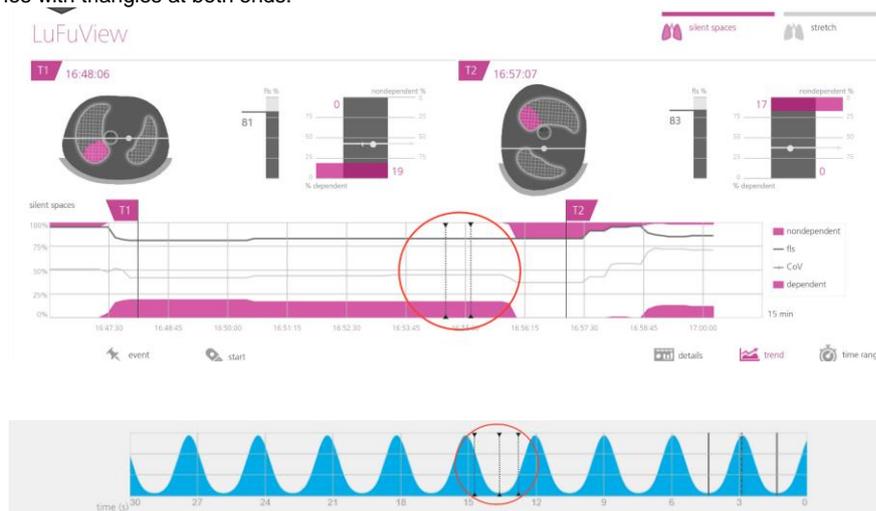
To avoid misinterpretation of results be aware that the *Dependent Silent Spaces*, the *Non-Dependent Silent Spaces* as well as the vertical and horizontal components of the *Center of Ventilation* (CoV(v) and CoV(h)) are less meaningful, if the gravity vector is more or less perpendicular to the examined thorax cross-section being defined by the *belt plane*. This is, for example, the case, if the patient is standing or sitting upright.

9.11 Operator events and screenshots

Pressing the button 'event' – which is available on all views (Figure 6-5) – will mark an operator event. As illustrated in Figure 9-19 dotted black vertical lines with triangles at both ends identify operator events in the trends and on the *Plethysmogram* (9.4).

If a USB memory device is connected to the LuMon™ Monitor when pressing the button 'event' a screenshot of the Graphical User Interface (at the time the button is pressed) is additionally stored on the USB memory device. Screenshots are stored in standard JPG image format and can be read by standard image viewer software. The filename of a screenshot corresponds to the date/time when the button 'event' was pressed (yyyymmddhhmmss.jpg).

Figure 9-19: Operator events in trends (top) and on the Plethysmogram (bottom) are identified by dotted black vertical lines with triangles at both ends.



9.12 Recording or exporting data

9.12.1 Recording data on a USB memory device

Pressing the button 'record' – which is available on all views (Figure 6-5) – when it is displayed in grey and indicates 'start' activates online recording of *EIT* data on the USB memory device connected to the LuMon™ Monitor. To indicate that recording is in progress the button 'record' is displayed in blue and a white dot flashes in the button 'record'. Touching on the button 'record' when it is displayed in blue and indicates 'stop' stops data recording.

NOTE

The button 'record' is not active (dimmed grey) if no USB memory device is connected to the LuMon™ Monitor. If the free space on the USB memory device is less than 1GB then the button remains inactive and 'not enough space' is displayed.

On the USB memory device *EIT* data are recorded in the three different binary files, whose filenames follow "yyyymmddhhmmss.xxx", with yyyymmddhhmmss referring to the time where the specific file was created:

- "Electrical Impedance Tomography" (*.eit) files contain the measured *EIT* raw data, notably "Differential Voltage", "Voltage Injection" and "Position" signals.
- "Zero Reference Images" (*.zri) files contain reconstructed zero reference images (i.e. the regional impedance distribution within the Thorax ROI for a given image frame) and the Plethysmogram (9.4).
- "Lung Function Values" (*.lfv) files contain *EIT* images (Stretch Image, Silent Spaces Image), values for Respiratory Rate and various indices such as EELI, EILI, Aeration, DSS, NSS, FLS, CoV(v), and CoV(h) as well as operator events (9.6, 9.8, 9.9, 9.10, 9.11).

Other than the gender, weight, height, and underbust girth, these files do not contain patient data.

NOTE

In long recordings (>15 minutes), the recorded data might extend over multiple files to avoid excessively large file handling.

NOTE

Irrespective of the currently selected Analysis Mode (9.7), the LuMon™ System in the background permanently analyzes the measured *EIT* raw data with all Analysis Modes and stores or outputs the results obtained with each mode.

9.12.2 Exporting EIT data from the internal memory of the LuMon™ Monitor

During monitoring the LuMon™ Monitor continuously stores the measured *EIT* data and operator events (9.11) in its non-volatile, internal memory according to the FIFO (First In First Out) principle. The memory capacity of 20 GB provides at least 4 hours of monitoring data.

The *EIT* data and operator events are stored in so-called "LuMon™ backup" (*.lbk) files whose filenames follow "yyyymmddhhmmss.lbk", with yyyymmddhhmmss referring to the time where the specific file was created. *.lbk files contain the same data as *.zri and *.lfv files (9.12.1).

To export a “LuMon™ backup” (*.lbk) file from the internal memory of the LuMon™ Monitor on a USB memory device connected to the LuMon™ Monitor

- activate the window ‘export’ in the ‘system settings’ area of ScoutView (Figure 6-8) and touch on ‘start export’ to activate data export (note that ‘start export’ is dimmed grey if no USB memory device is connected)
- data export progress will be indicated in a progress bar. Wait until the data export is finished or touch on ‘stop export’ to abort.
- ‘Done’ will be displayed once data export is finished

The “LuMon™ backup” (*.lbk) file may also be used for troubleshooting purposes (12) and you may be asked to send it to SenTec. Other than the gender, weight, height, and underbust girth, it does not contain patient data.



NOTE

EIT data stored in the LuMon™ Monitor’s internal memory will be deleted when changing its date/time. No further operator confirmation will be requested at the time of the change.

9.12.3 Exporting the event Log file from the internal memory of the LuMon™ Monitor

The LuMon™ Monitor stores in its internal memory a log of the occurrence of, among others, status messages, errors, system settings or system status changes in the so-called “eitMonitorLog.zip” file. Each time a USB memory device is connected to the LuMon™ Monitor the “eitMonitorLog.zip” file is copied onto the USB memory device.

The “eitMonitorLog.zip” file will mostly be used for troubleshooting purposes (12) and you may be asked to send it to SenTec. Other than the gender, weight, height, and underbust girth, it does not contain patient data.

9.12.4 Available software for data analysis

EIT Data and operator events stored on the USB memory stick can subsequently be imported into different analysis tools as briefly summarized below:

- ibeX Software can import *.zri and *.lbk files for subsequent display, analysis and reporting. Sequences can be selected from the *Plethysmogram*. The main *Analysis Modes* are: “*Region of Interest*”, ‘silent spaces’, and ‘stretch’. It features advanced analysis tools such as custom filters, and can export result as PDF, XLS or video. ibeX Software is currently for research use only, and some of the *indices* it displays may differ from values computed and shown by the LuMon™ Monitor. Contact SenTec EIT for additional information on ibeX Software.
- STEM Light Software can import and replay *.eit files. The quality of the measurement can be evaluated with the following views: electrode contact impedance bar chart, U-shape average plot, voltage *Plethysmogram*, IQ plot and voltage spectrum plot. STEM Light Software also includes a simplified image reconstruction and image display feature. STEM Light Software is currently for research use only. Contact SenTec EIT for additional information on STEM Light Software.
- EIDOORS can import *.eit files. EIDOORS is an open-source Matlab-based scripts package developed and maintained by the EIT community (<http://eidors3d.sourceforge.net/index.shtml>).

10 PAUSING OR ENDING MONITORING

How to pause monitoring without removing the belt is explained in [10.1](#). [10.2](#) explains how to pause monitoring with belt removal and [10.3](#) how to end monitoring for a patient.



NOTE

Patient data and (♂) half underbust girth or (♀) full underbust girth and belt displacement are reset to their defaults when starting up the monitor. These settings therefore must be re-entered after each restart of the monitor.

10.1 Pausing monitoring without belt removal

To pause/interrupt monitoring for a patient without belt removal proceed as follows:

- Disconnect the reusable belt connector from the disposable, single-patient use belt without switching the monitor off (see note above). To disconnect a SensorBeltConnector from a SensorBelt press both release buttons on either side of the SensorBelt Docking Station ([Figure 5-5](#)) with one hand, grasp the SensorBeltConnector's MatchBox ([Figure 5-3](#)) with the other hand and then gently pull on it to disengage. To avoid damage of the SensorBeltConnector do not pull at its cable. To disconnect a LuMon™ Connector from a LuMon™ Belt grasp the LuMon™ Belt's connector plug ([Figure 5-6](#)) with one hand, the LuMon™ Connector's MatchBox ([Figure 5-4](#)) with the other hand and then gently pull with both hands to disengage. To avoid damage of the LuMon™ Connector and LuMon™ Belt do not pull at their cables.
- To continue monitoring re-connect the belt connector to the belt. To avoid impaired data quality check proper setup ([8.3](#)) and select an *Analysis Mode* being adequate for the patient's breathing pattern ([8.4](#)) initially and at least every 8 hours during monitoring.

10.2 Pausing monitoring with belt removal and/or replacement

To pause/interrupt monitoring for a patient with belt removal proceed as follows:

- Disconnect the reusable belt connector from the disposable, single-patient use belt without switching the monitor off (see note above). To disconnect a SensorBeltConnector from a SensorBelt or a LuMon™ Connector from a LuMon™ Belt proceed as described in [10.1](#).
- Remove the belt from the patient.
- Wipe off contact agent residue from the patient with a disposable cloth or tissue.
- If the used belt is still able to be used, with adequate *belt time*, re-apply ContactAgent or NeoContactAgent prior to applying the used belt as described in [8](#).
- Dispose of the used belt if its *belt time* has expired or if it is soiled or not functioning. Follow local regulations for disposal of medical waste. To apply a new belt, follow the instructions provided in [8](#).

For cleaning and disinfection instructions for the LuMon™ Monitor and belt connector, refer to [11.2](#).

10.3 Ending monitoring

To end monitoring for a patient, proceed as follows:

- Disconnect the reusable belt connector from the disposable, single-patient use belt. To disconnect a SensorBeltConnector from a SensorBelt or a LuMon™ Connector from a LuMon™ Belt proceed as described in [10.1](#).
- Remove the belt from the patient and dispose of the belt according to local regulations for medical waste.
- Wipe off contact agent residue from the patient with a disposable cloth or tissue.
- If desired, review or export trend data ([9.11](#)) for the monitored patient before turning off the monitor.
- Switch the monitor off and perform cleaning and disinfection actions ([11.2](#)) on the LuMon™ Monitor and belt connector before use on the next patient ([8](#)).

11 MAINTENANCE

During normal operation, the LuMon™ System does not require any internal adjustments or calibrations. However, to guarantee continuous performance, reliability and safety of the LuMon™ System, routine checks and preventive maintenance procedures (including cleaning/disinfection) as well as safety checks should be performed regularly.

11.1 Routine Checks, Preventive Maintenance and Safety Checks

The following checks and maintenance procedures should be performed regularly (at least as often as stated below or in accordance with institutional, local or governmental ordinances or regulations):

- Perform the preoperational check (7.4) each time before initiating monitoring for a new patient (8).
- Dispose of the belt (11.4) when the *belt time* has elapsed or after ending monitoring for a patient (10.3).
- Clean and disinfect the belt connector and LuMon™ Monitor (11.2) after ending monitoring for a patient (10.3) and before use with a new patient, and regularly according to institutional policy during use with a single patient.
- Check the LuMon™ Monitor, its power cord and the belt connector for mechanical or functional damage at least once a month. Replace any defective parts with SenTec original parts. Refer to 11.3 to replace the fuses of the LuMon™ Monitor.
- Check the expiry date of disposables (belts and contact agent) at least once a month. Replace any expired products.
- Initiate a complete safety and functionality check for the LuMon™ System regularly (recommended every 12 months but at least once every 24 months). Respective instructions are provided in the Service Manual for the LuMon™ System. Hereto contact a qualified technician (e.g. a biomedical engineer), your local SenTec EIT representative or SenTec AG.

WARNING

There are no user serviceable parts inside the LuMon™ Monitor. The cover of the LuMon™ Monitor should only be removed by *SenTec Authorized LuMon™ Technicians*. Service as well as the complete safety and functionality test should be made by qualified technicians. Failure to do so could lead to injury, inaccurate measurements and/or damage to the device.

NOTE

To perform a safety and functionality check and for service or repair, contact a qualified technician (e.g. a biomedical engineer), your local SenTec EIT representative or SenTec AG.

NOTE

Repair and service procedures which require opening the cover of the LuMon™ Monitor must be performed by *SenTec Authorized LuMon™ Technicians*.

NOTE

Instructions for disinfection, repackaging and shipping when equipment and accessories are to be returned for a safety check and/or service/repair are provided in sub-section 11.5.

11.2 Cleaning and disinfection

Due to the nature and seriousness of infectious diseases, it is important that equipment and accessories which can come into contact with human tissues or fluids should always be regarded as potentially contaminated and therefore hazardous.

Contaminated equipment and accessories must be decontaminated. Decontamination must be carried out by a properly trained person. The directions for cleaning and disinfection vary from hospital to hospital. If you are in any doubt regarding contamination or decontamination, consult your local infection control authority/hygiene department.

The agents listed below may be used to clean and/or disinfect the surfaces of LuMon™ Monitors and of belt connectors after ending monitoring for a patient (10.3), and before use with a new patient, and regularly according to institutional policy during use with a single patient. However, other cleaning/disinfection procedures may be applied as often as required per institutional ordinances.

As the number of available cleaning and disinfection agents varies from country to country and from hospital to hospital, it is not possible to provide a complete list of all suitable cleaning and disinfection agents. The below listed name brand products may be substituted by other name brand products of equivalent composition. Refer to the instructions for use of the respective manufacturer for preparation, application and disposal of the cleaning agents.

To clean the LuMon™ Monitor and the belt connector proceed as follows:

- Gently wipe the surfaces of the monitor and belt connector and cable using the listed agents with a soft cloth, and do not allow excessive fluid or moisture to enter the monitor or connector ports.
- Surfaces should be cleaned prior to disinfection.
- Allow surfaces to dry fully before placing cleaned items into service or prior repackaging when shipping them (11.5).

A. Surface cleaning & low level disinfection

| Name brand/ manufacturer | Composition | Recommended procedure |
|--|------------------------------|--|
| Mikrozid (Schülke Mayr) pre-soaked wipes | 25% Ethanol, 35% Isopropanol | Carefully wipe the outer surfaces with alcohol wipes and allow to dry. |
| WEBCOL Alcohol Prep Pads (Kendal) | 70% Isopropanol | |

B. Low level disinfection

| Name brand/ manufacturer | Composition | Recommended procedure |
|---------------------------------|---|--|
| Terralin Protect (Schülke&Mayr) | 22 % quaternary ammonium compounds (Benzyl-C12-16-alkyldimethyl-, Chloride), 17 % 2-Phenoxyethanol, 0,9 % Aminoalkylglycine, 5 – 15% non-ionic tensides. | Prepare a 2% solution (e.g. 980 ml deionized water plus 20 ml Terralin Protect). Carefully wipe the outer surfaces. Wait 15 min. Perform a final wipe using using 70% Isopropanol or presoaked Mikrozid wipes. Allow to dry. |

⚠ WARNING
Before cleaning the LuMon™ Monitor, always switch it off and disconnect it from AC mains power.

⚠ WARNING
Do not expose the LuMon™ Monitor to heavy moisture and do not allow any fluids to enter the LuMon™ Monitor. Plugs and connectors have to be kept meticulously clean and dry at all times. Failure to do so increases the risk of electrical shock and/or may result in damage to the device.

ⓘ CAUTION
Use of other cleaning and disinfection agents than recommended may cause damage and/or deterioration of the device's materials and device failure may result.

ⓘ CAUTION
Applying excessive mechanical force to the device during cleaning may damage the device's materials and device failure may result.

ⓘ CAUTION
Do not touch, press or rub the surfaces of the LuMon™ Monitor or belt connector with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with any that could scratch the surfaces of the LuMon™ Monitor or belt connector.

ⓘ CAUTION
Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the LuMon™ Monitor or belt connector. These substances can attack the device materials and device failure may result.

ⓘ CAUTION
The LuMon™ System and its accessories are provided non-sterile. Do not sterilize any parts of the equipment by irradiation, steam or ethylene oxide. Do not autoclave or pressure sterilize.

💡 NOTE
The LuMon™ Monitor screen supports finger touch operation only. The use of rigid or sharp instruments on the touch screen can permanently damage the display.



NOTE

Belts are specified for single-patient use only and must be discarded after use according to local regulations for medical waste.

11.3 Replacing the fuses of the LuMon™ Monitor

Before replacing the fuses of the LuMon™ Monitor, end monitoring (10.3), switch the LuMon™ Monitor off and disconnect the LuMon™ Monitor from AC mains power.

To replace the fuses, open the fuse holder (Figure 5-2) with a screwdriver and replace the fuses with specified fuses only (14.1).

11.4 Disposal of parts of or removed from the LuMon™ System

Dispose all parts of or removed from the LuMon™ System according to your institution's protocol. Follow all local, state, or national regulations with respect to environmental protection.



WARNING

All parts of or removed from the LuMon™ System must be considered potentially contaminated and a source of infection risk. Dispose of all parts removed from the device according to local regulations for medical waste.



NOTE

Dispose all parts of or removed from the LuMon™ System according to your institution's protocol and/or local regulations. Products containing electronic parts (LuMon™ Monitor, its power cord, belt connectors, and belts) require special disposal. Incorrect disposal may lead to serious environmental pollution.



NOTE

SenTec is dedicated to helping protect the natural environment and to helping ensure the continued safe and effective use of this product through proper support, maintenance, and training. Therefore, SenTec's products are designed and manufactured to comply with relevant guidelines for environmental protection. If the product is properly operated and maintained, it presents no environmental risks. However, the product may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential to performing the functions of the product, and to meeting statutory and other requirements.

11.5 Instructions for repacking and shipping

Please contact your local SenTec EIT representative or SenTec AG prior to returning any material.

The following instructions apply to all shipments of the LuMon™ System or any part of it to your local SenTec EIT representative or SenTec AG:

- Unless otherwise instructed please ship only the LuMon™ Monitor and/or belt connector, but without any disposables such as belts or contact agent.
- Devices must be properly disinfected (11.2) prior to shipment. The completed forms "Certificate of Disinfection" and, if applicable, the "Repair Request Form" must be provided to SenTec AG per Email and must accompany the shipment outside the package box, e.g. in a documents pouch. PDF-copies of these forms are available from SenTec AG upon request (info-eit@sentec.com).
- Items must be shipped in the original packaging or in other packing providing the same degree of protection. Use sanitized packing material only.



NOTE

Any shipment to your local SenTec EIT representative or SenTec AG lacking the "Certificate of Disinfection" and, if applicable, the "Repair Request Form" or shipments sent without written authorization by your local SenTec EIT representative or SenTec AG may be returned unopened or disinfected at the sender's expense.



NOTE

It is recommended to ship the LuMon™ Monitor with a fully charged battery. If possible, charge the battery before shipping LuMon™ Monitor.



NOTE

Unless otherwise instructed, do NOT ship ContactAgent spray cans. ContactAgent spray cans are pressurized, and therefore must be declared as "dangerous goods", a special IATA form is required, and special packing instructions apply.

12 TROUBLESHOOTING

If you suspect a problem with any individual measurement, read this User's Guide and doublecheck that you have set up the system correctly. In particular, verify proper setup (8.3) and adequacy of the selected *Analysis Mode* (8.4). To resolve the problem(s) that may be associated with a displayed status message, refer to 6.6.2 for recommended corrective action(s).

If you cannot resolve the suspected problem with individual measurements or associated with the displayed status message or in case of suspected device related problems, contact a qualified technician (e.g. a biomedical engineer), your local SenTec EIT representative or SenTec AG. A complete and accurate problem description will help the technician or service engineer to pinpoint the problem.

You may be asked for system configuration related information such as:

- Configuration of the LuMon™ Monitor (LuMon™ Monitor – Adult or LuMon™ Monitor – Neo) indicated on its support foot (Figure 5-1)
- Serial number of the LuMon™ Monitor indicated on its type label (Figure 5-2)
- The software versions of the LuMon™ Monitor – GUI and TIC (14.3) - displayed in the 'system settings' area of ScoutView (Figure 6-8).
- Serial number of the belt connector indicated on its type label being located on the MatchBox (Figure 5-3, Figure 5-4)
- 'Connector' number displayed in the 'system settings' area of ScoutView (Figure 6-8) encoding hard- and software versions of the belt connector being connected to the LuMon™ Monitor.
- Serial or lot number of the belt(s) indicated on the respective type label or – for the belt linked to the LuMon™ Monitor - displayed in the 'patient & belt' area of ScoutView (Figure 6-7)

Furthermore, you may be asked to provide the following:

- Screenshots of the Graphical User Interface (9.11), possibly being helpful to document the suspected problem
- the "LuMon™ backup" (*.lbc) file (9.12.2)
- the "eitMonitorLog.zip" file (9.12.3)

When equipment is forwarded to qualified technicians or *SenTec Authorized LuMon™ Technicians* for further analysis and/or repair, please follow the repacking and shipping instructions provided in 11.5.



NOTE

Detailed troubleshooting is provided in the Service Manual for the LuMon™ System. It describes problems, possible causes and the recommended corrective action(s) the operator, qualified technicians or *SenTec Authorized LuMon™ Technicians* may perform to resolve the problem.

The Service Manual for the LuMon™ System is available at www.sentec.com/education/eit/plpm-eit/.

13 TECHNICAL SPECIFICATIONS

13.1 System performance

Table 13-1: System performance

| Parameters/Indices/functions | Properties | Specifications | |
|---------------------------------------|-----------------------|--|--|
| Respiratory Rate (RRi) | Measurement principle | Impedance based | |
| | Units | Breaths per minute (bpm) | |
| | Display range | | 4 – 66 bpm (Adults/Children configuration) |
| | | | 4 – 138 bpm (Neonates/Infants configuration) |
| | Resolution | 1 bpm | |
| Accuracy (Arms) | | Adults/Children configuration ± 2 bpm over 5-60 bpm Neonates/Infants configuration ± 2 bpm over 5-70 bpm ± 4 bpm over 71-120 bpm ± 5 bpm over 121-130 bpm | |
| End-Expiratory Lung Impedance (EELI) | Units | Arbitrary Units (AU) | |
| End-Inspiratory Lung Impedance (EILI) | Measurement range | Not applicable | |
| Aeration | | | |
| Relative Tidal Stretch (RTS) | Units | % | |
| | Measurement range | 0 – 100% | |
| Center of Ventilation (CoV) | Units | % | |
| | Measurement range | 0 – 100% for CoV(v) and CoV(h) | |
| Silent Spaces | Units | % | |
| Functional Lung Spaces (FLS) | Measurement range | 0 – 100% | |
| Dependent Silent Spaces (DSS) | | whereby DSS + NSS = Silent Spaces | |
| Non-Dependent Silent Spaces (NSS) | | and DSS + NSS + FLS = 100% | |

NOTE
The RRi accuracy specifications were validated via a bench test involving a *waveform* simulator for both configurations. Furthermore, in case of the Adults/Children configuration, these specifications were met with a high margin in a study on healthy, adult volunteers over a wide range of *Respiratory Rates*. The LuMon™ System's RRi readings were compared to the RR values corresponding to the *waveforms* displayed on screen as a guide for the volunteers. RRi accuracy is expressed as Arms (root-mean-square). The indicated variation equals plus or minus one standard deviation which encompasses 68% of the population.

13.2 System characteristics, compliance and compatibilities

Table 13-2: General EIT characteristics

| General EIT characteristics | Specifications |
|-----------------------------|---|
| Number of electrodes | 32 |
| Image rate | > 50 Hz |
| Feed current | 0.7 – 3.7 mA _{rms} ; 200 kHz ± 10% |
| Signal quality index | 0-100% |
| Thorax and lung models | Various sets of predefined, CT-derived thorax and lung models (9.1). The set best fitting an individual patient is selected based on the patient's gender and body-mass index (BMI) in Adults/Children configuration. In Neonates/Infants configuration, where only one CT-derived model is used, the LuMon™ System accounts for the displacement of the electrodes around the thorax from their assumed default positions. |

Table 13-3: Patient position

| Properties | Specifications |
|------------|--|
| Rotation | Measurement Range 0-360° The supine, right lateral, prone, or left lateral position respectively correspond to a <i>rotation</i> angle of 0°, 90°, 180° or 270° (or – 90°). |

| Properties | Specifications |
|-------------|---|
| Inclination | Measurement Range 0-360° To indicate <i>inclination</i> , the 'Inclination' icon has 7 states, each spanning a specified <i>inclination</i> angle range (6.6.1). |

Table 13-4: Environmental conditions

| Environmental conditions | Properties | Part | Specifications |
|-----------------------------------|-----------------|---------------------|--|
| Temperature | Operation: | LuMon™ Monitor | 10 °C to 35 °C |
| | | SensorBeltConnector | 10 °C to 35 °C |
| | | LuMon™ Connector | 10 °C to 38 °C |
| | | SensorBelts | 10 °C to 35 °C |
| | | LuMon™ Belts | 10 °C to 40 °C |
| | | ContactAgent | 10 °C to 40 °C |
| | | NeoContactAgent | 10 °C to 40 °C |
| | Transport: | LuMon™ Monitor | -20 °C to 60 °C |
| | | SensorBeltConnector | -20 °C to 70 °C |
| | | LuMon™ Connector | -20 °C to 65 °C |
| | | SensorBelts | -25 °C to 70 °C |
| | | LuMon™ Belts | -25 °C to 70 °C |
| | | ContactAgent | ≤ 50 °C, keep away from sun light |
| | | NeoContactAgent | ≤ 60 °C |
| | Storage: | LuMon™ Monitor | -20 °C to 60 °C |
| | | SensorBeltConnector | 5 °C to 40 °C |
| | | LuMon™ Connector | 5 °C to 40 °C |
| | | SensorBelts | 5 °C to 40 °C |
| | | LuMon™ Belts | 5 °C to 40 °C |
| | | ContactAgent | 0 °C to 25 °C keep away from sun light |
| | NeoContactAgent | 0 °C to 30 °C | |
| Atmospheric pressure | Operation: | LuMon™ Monitor | 660 to 1060 hPa (10.15 to 15.37 psi) |
| | Transport: | LuMon™ Monitor | 500 to 1060 hPa (7.25 to 15.37 psi) |
| | Storage: | LuMon™ Monitor | 500 to 1060 hPa (7.25 to 15.37 psi) |
| Relative humidity | Operation: | LuMon™ Monitor | 15 to 90% non-condensing |
| | Transport: | LuMon™ Monitor | 10 to 95% non-condensing |
| | Storage: | LuMon™ Monitor | 10 to 95% non-condensing |
| Ingress protection (IEC 60529) | | LuMon™ Monitor | IP22 |
| | | SensorBeltConnector | IP54 (MatchBox), IPX1 (ControlBox) |
| | | LuMon™ Connector | IPX1 |

Table 13-5: Intra-system compatibilities

| System | Intra-system compatibilities |
|-------------------------|---|
| LuMon™ Monitors – Adult | only support SensorBeltConnectors and SensorBelts |
| LuMon™ Monitors – Neo | only support LuMon™ Connectors and LuMon™ Belts |

13.2.1 Compliance/standards

The LuMon™ System was developed in accordance with following standards.

Table 13-6: Compliance/standards

| Properties | Parts | Standards |
|-------------------------------------|--------------------------------------|---|
| Safety approvals | | IEC 60601-1 (3 rd edition) |
| Electromagnetic compatibility (EMC) | LuMon™ Monitor | IEC 60601-1-2 (4 th edition) |
| | SensorBeltConnector/LuMon™ Connector | |
| | SensorBelt/LuMon™ Belt | |
| Applied part BF | SensorBelt/LuMon™ Belt | IEC 60601-1 (3 rd edition) |

| Properties | Parts | Standards |
|---|------------------------|---------------------------------------|
| Biocompatibility | SensorBelt/LuMon™ Belt | ISO 10993 |
| Microenvironments of pollution degree 2 | | IEC 60601-1 (3 rd edition) |

13.3 LuMon™ Monitor

Table 13-7: Physical characteristics

| Properties | Physical characteristics | | | | |
|----------------------|--|------------|-----------------|----------------------|---------------------------|
| Weight | < 4 kg | | | | |
| Dimensions | 30.8 cm x 21.8 cm x 10.1 cm (12.1" x 8.6" x 4.0"), also see Table 13-9: Sound pressure level | | | | |
| | <table border="1"> <thead> <tr> <th>Properties</th> <th>Characteristics</th> </tr> </thead> <tbody> <tr> <td>Sound pressure level</td> <td>< 40 dBA during operation</td> </tr> </tbody> </table> | Properties | Characteristics | Sound pressure level | < 40 dBA during operation |
| Properties | Characteristics | | | | |
| Sound pressure level | < 40 dBA during operation | | | | |
| Mountable on | SenTec's Roll Stand for the LuMon™ Monitor Most VESA 75x75 mounts (e.g. roll stand, wall mounts/railings) | | | | |
| Portable | Integrated carrying handle | | | | |

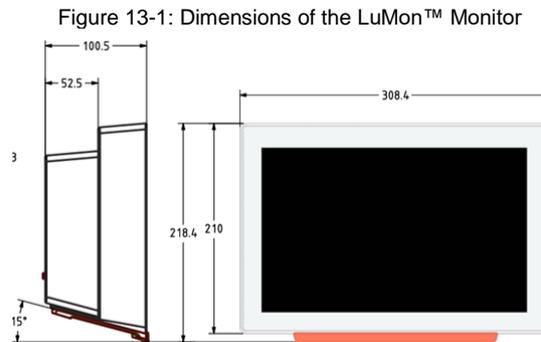


Table 13-8: Display/indicators

| Properties | Characteristics |
|--------------------|---------------------|
| Display size | 30.7 cm/12.1 inches |
| Display resolution | 1280 x 800 pixels |
| Display type | TFT touch display |

Table 13-9: Sound pressure level

| Properties | Characteristics |
|----------------------|---------------------------|
| Sound pressure level | < 40 dBA during operation |

13.3.1 Electrical specifications of the LuMon™ Monitor

Table 13-10: Electrical specifications

| Properties | Specifications |
|-------------------|--|
| Input power | 100 to 240 VAC ±10%, 50/60 Hz |
| Power consumption | Max 0.3 A at 230 V Max 0.6 A at 100 V |
| Internal battery | Type Rechargeable, sealed Lilon battery |
| | Capacity Up to 1 hour (new, fully charged battery) |
| | Charging time Approximately 5 h |

| Properties | Specifications |
|-------------------|-----------------------------------|
| Mode of operation | Suitable for continuous operation |

13.3.2 Communication interfaces

Table 13-11 Communication interfaces

| Communication interfaces | Description |
|--------------------------|--|
| Belt connector port | To connect the SensorBeltConnector/LuMon™ Connector to the LuMon™ Monitor BF applied part, Isolated with 2 MOPP from the other interface ports. |
| 2 x USB ports | USB 2.0 Standard-A port (Type A) To be used with memory device (≥ 1 GB), without external power only. To export data and screenshots and for software upgrade. |
| 2 x serial ports | RS /EIA-232 For service use only |
| 1 x LAN port | 100BASE-TX For service use only |

13.4 Belt connectors

Table 13-12: Physical characteristics connectors

| Properties | SensorBeltConnector | LuMon™ Connector |
|-----------------|---------------------------------------|--------------------------------------|
| Dimensions | See Figure 13-2 | See Figure 13-3. |
| Weight | Approximately 200 g | Approximately 200 g |
| Length of cable | Approximately 2.5 m | Approximately 2.5 m |
| Compatibility | LuMon™ Monitor - Adult SensorBelts | LuMon™ Monitor - Neo LuMon™ Belts |

Figure 13-2: Dimensions of the SensorBeltConnector

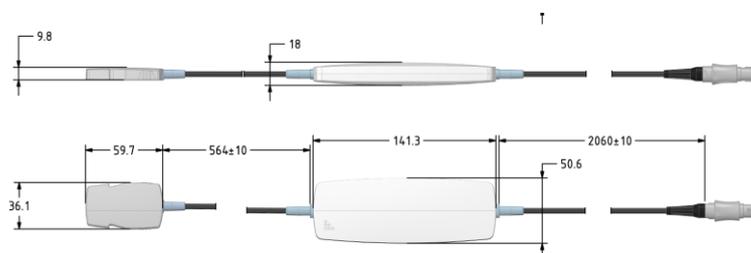
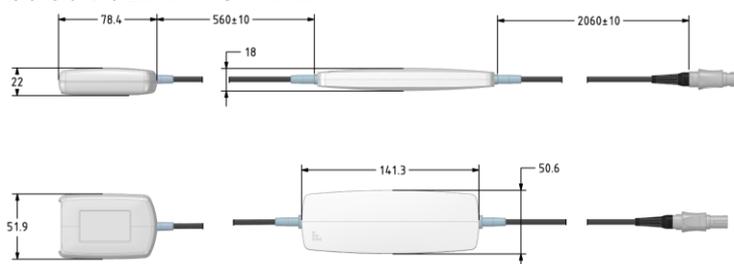


Figure 13-3: Dimensions of the LuMon™ Connector



13.5 Belts

Table 13-13: Physical characteristics belts

| Properties | SensorBelt | LuMon™ Belt |
|---------------|---|--|
| Sizes | See Table 13-14 . | See Table 13-14 . |
| Width (cm) | Approx. 4.0 | Approx. 2.8 |
| Compatibility | LuMon™ Monitor - Adult SensorBeltConnector | LuMon™ Monitor - Neo LuMon™ Connector |

Table 13-14: Belt sizes

| SensorBelt | | LuMon™ Belt | |
|------------|----------------------------|-------------|----------------------------|
| Size | Full underbust girth in cm | Size | Full underbust girth in cm |
| 80 | 76-86 | 19 | 17.0-20.5 |
| 92 | 86-98 | 22 | 20.5-24.0 |
| 104 | 98-112 | 26 | 24.0-28.0 |
| 116 | 112-128 | 30 | 28.0-32.5 |
| | | 35 | 32.5-37.5 |
| | | 40 | 37.5-43.5 |
| | | 47 | 43.5-52.0 |

Biological evaluation has been conducted in compliance with ISO 10993-1 on the SensorBelts and LuMon™ Belts.

13.6 Contact agent

Table 13-15: Characteristics of contact agent

| Properties | ContactAgent | NeoContactAgent |
|--------------------------|--|------------------------------------|
| Content spray can/bottle | 100 ml | 25 ml |
| Ingredients (INCI) | Aqua, Dimethyl ether, Alcohol denat., Panthenol, Helianthus annuus seed oil, Urea, Glycerin, Cyclopentasiloxane, Cetearyl alcohol, Cetearyl glucoside, Laureth-9, Cyclohexasiloxane, Phenoxyethanol, Butane, Hexyldecanol, Hexyldecyl laurate, Disodium laureth sulfosuccinate, Propane, Isobutane, Ethylhexylglycerin, Lactic acid, Tocopherol. | Aqua, Glycerol and Sodium chloride |

Biological evaluation has been conducted in compliance with ISO 10993-1 on the ContactAgent and the NeoContactAgent.

13.7 Devices classification

According to the European directive 93/42/EEC and the European Regulation 2017/745

- LuMon™ Monitor, SensorBeltConnector and LuMon™ Connector are classified as Class IIa devices.
- SensorBelt, LuMon™ Belt, ContactAgent and NeoContactAgent are classified as Class I devices.

NOTE

A copy of the declaration of conformity can be requested from the manufacturer (SenTec AG, Kantonstrasse 14, 7302 Landquart, Switzerland).

13.8 EMC declaration

The LuMon™ System is intended for use in the electromagnetic environment specified below.

Table 13-16 Electromagnetic emissions - Guidance and manufacturer's declaration

| Emission test | Compliance | Electromagnetic environment - guidance |
|---------------|------------|---|
| RF emissions | Group 1 | The LuMon™ System uses RF energy only for its internal functions. |

| Emission test | Compliance | Electromagnetic environment - guidance |
|---------------|------------|---|
| CISPR 11 | | Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment. |
| | Class A | The LuMon™ System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

Table 13-17 Electromagnetics immunity - Guidance and manufacturer's declaration

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|--|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 15 kV air | ± 8 kV contact ± 15 kV air | Floors should be wooden, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Electrostatic discharge may cause measurement artefacts, or the measurement may be temporarily interrupted. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines | ± 2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment. Electrical fast transients may cause measurement artefacts, or the measurement may be temporarily interrupted. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) ± 2 kV line(s) to ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s | <5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the LuMon™ System requires continued operation during power mains interruptions, it is recommended to provide the LuMon™ Monitor with power from an uninterruptible power supply or a battery. |
| Note: U_T is the a.c. mains voltage prior to application of the test level. | | | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 100 A/m | 100 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms 150 kHz to 80 MHz | Conducted RF disturbances may cause measurement artefacts, or the measurement may be temporarily interrupted. |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.7 GHz 9-28 V/m 385 MHz-5.785 GHz | 3 V/m 80 MHz - 2.7 GHz 9-28 V/m 385 MHz-5.785 GHz | Radiated RF disturbances may cause measurement artefacts, or the measurement may be temporarily interrupted. |

14 ANNEX

14.1 LMS related Accessories, Key Spare Parts and Documents

For a list of LuMon™ System related accessories, key spare parts and documents, please refer to the Product Catalogue for the LuMon™ System available on www.sentec.com/education/eit/plpm-eit

⚠ WARNING

Use only equipment, accessories, disposables or parts supplied or recommended by SenTec AG. Use of other parts may result in injury, inaccurate measurements and/or damage to the device.

14.2 Terminology

Table 14-1: Product variants related terminology

| Term | Definition – product variants |
|---------------------|---|
| LuMon™ System (LMS) | LuMon™ System – Adults/Children configuration (LMS-A), comprising: <ul style="list-style-type: none"> • LuMon™ Monitor – Adult • SensorBeltConnector (SBC) • SensorBelt (SB) • ContactAgent (CA) • Measuring tape – Adults/Children LuMon™ System – Neonates/Infants configuration (LMS-N), comprising <ul style="list-style-type: none"> • LuMon™ Monitor – Neo • LuMon™ Connector (LMC) • LuMon™ Belts (LMB) • NeoContactAgent (NCA) • Measuring tape – Neonates/Infants |
| LuMon™ Monitor | LuMon™ Monitor – Adult (with activated Adults/Children configuration) LuMon™ Monitor – Neo (with activated Neonates/Infants configuration) |
| belt connector | SensorBeltConnector (to link SensorBelts to the LuMon™ Monitor – Adult) LuMon™ Connector (to link LuMon™ Belts to the LuMon™ Monitor – Neo) |
| belt | SensorBelt (for adults and children/available in 4 sizes) LuMon™ Belt (for neonates and infants /available in 7 sizes) |
| contact agent | ContactAgent NeoContactAgent |
| measuring tape | Measuring tape – Adults/Children Measuring tape – Neonates/Infants |

Table 14-2: SenTec EIT related terminology

| Term | Definition/Measurement units (if applicable) | Available/determined |
|---|---|---|
| <i>Aeration</i> (MLI) | Mean of the <i>Plethysmogram</i> over an <i>Analysis Interval</i> of a fixed, preset duration. Aeration is related to the mean lung volume. Quantified in arbitrary, not displayed, units. Auto-scaled trend display. | <i>Index</i> calculated once per <i>Analysis Interval</i> — <i>TB-II mode</i> . |
| <i>Analysis Interval</i> | Time interval over which the LuMon™ System determines the minimum, the maximum or the mean of the <i>Plethysmogram</i> . | - |
| <i>Analysis Mode</i> | Modes used by the LuMon™ System to analyze the <i>Plethysmogram</i> , specifically, to determine end-expiratory and end-inspiratory time points needed for the calculation of breathing-related <i>EIT images</i> and <i>indices</i> as well as the mean of the <i>Plethysmogram</i> over an <i>Analysis Interval</i> . Furthermore, the extent of available <i>EIT data</i> depends on the selected <i>Analysis Mode</i> . Available <i>Analysis Modes</i> are <i>breath-based</i> (BB) mode and <i>time-based</i> (TB-I and TB-II) modes. See 9.7. | - |
| <i>BB mode</i> | One of the available <i>Analysis Modes</i> . See 9.7.1 | - |
| <i>belt plane</i> | The plane defined by a belt being applied to a patient's chest. A slightly oblique plane for belts used on adults and children; a transverse plane for belts used on neonates and infants See.5.3 | - |
| <i>belt time</i> | The remaining time a belt can be used. When a new belt is connected to a LuMon™ System, a timer begins to count down from the preset belt time to zero. The countdown interrupts if the belt is disconnected and resumes when reconnected. An icon on the LuMon™ Monitor indicates the belt time and highlights if the belt time has elapsed. Quantified in hours. | - |
| <i>breath-by-breath</i> or <i>breath-based</i> (BB) | Either a designation of one of the <i>Analysis Modes</i> or a statement used to describe that something occurs or is done for each breath. | - |
| <i>breathing-related EIT images and indices</i> | <i>EIT images</i> and <i>indices</i> for whose determination i) data being available at end-expiratory or end-inspiratory time points is used or ii) data being available at end-expiratory time points is subtracted from data being available at associated end-inspiratory time points within <i>Analysis Intervals</i> . In <i>BB mode</i> , these time points correspond to the start and the end of inspirations of detected breaths. In <i>TB-I mode</i> , the minima and maxima within 15 seconds intervals, that can occur in any order, are assumed to be related to breaths, their occurrences are interpreted as end-expiratory and end-inspiratory time points of not necessarily the same breath. Examples include the <i>Stretch Image</i> , the <i>Silent Spaces Image</i> and <i>indices</i> such as EELI, EILI, FLS, <i>Silent Spaces</i> , DSS, NSS and the CoV. | - |
| <i>Center of homogeneous Ventilation</i> (CoVhom) | Center of Ventilation if ventilation is homogeneously distributed within the <i>Lung ROI</i> , In case of homogeneous ventilation, it is assumed that the <i>Relative Tidal Stretch</i> values of all <i>Lung Pixels</i> are the same and contribute equally as weights in the computation of the <i>Center of Ventilation</i> . Notice that CoV ^{hom} coincides with the geometrical center of the <i>Lung ROI</i> . Represented as an image point. Coordinates are not displayed. | <i>Index</i> calculated when data are entered, that are required to determine the <i>Thorax ROI</i> and <i>Lung ROI</i> best fitting the specific patient — <i>BB</i> and <i>TB-I modes</i> . |
| <i>Center of Ventilation</i> (CoV) | Weighted geometrical Center of Ventilation distribution within the <i>Lung ROI</i> , computed by weighing each <i>Lung Pixel's Relative Tidal Stretch</i> value. The <i>Center of Ventilation</i> is a functional EIT measure used to quantify the distribution of ventilation. The vertical component of the Center of Ventilation (CoV(v)) (9.10) characterizes the ventilation distribution in vertical direction and is expressed as a fraction of the vertical <i>Lung ROI</i> width. The horizontal component of the Center of Ventilation (CoV(h)) (9.10) characterizes the ventilation distribution in horizontal direction and is expressed as a fraction of the horizontal <i>Lung ROI</i> width. Notice that CoV(v) defines the position of the <i>Horizon of Ventilation</i> (HoV). Represented as an image point. Coordinates quantified in % of <i>Lung ROI</i> width and shown in scale. | <i>Index</i> calculated once per <i>Analysis Interval</i> . CoV(v) and CoV(h) are additionally calculated upon each <i>rotation</i> change — <i>BB</i> and <i>TB-I modes</i> |
| <i>Dependent Silent Spaces</i> (DSS) | The subset of <i>Lung Pixels</i> having RTS-values smaller or equal than 10% and being localized below the HoV, i.e. <i>Silent Spaces</i> being localized in dependent lung areas. Quantified in % of <i>Lung ROI</i> area. | <i>Index</i> calculated once per <i>Analysis Interval</i> and upon each <i>rotation</i> change — <i>BB</i> and <i>TB-I modes</i> . |
| <i>EIT raw data</i> | Voltages obtained during EIT measurement, i.e. the voltages resulting at a subject's surface upon application of very weak alternating currents. | - |
| <i>EIT data</i> | <i>EIT raw data</i> and all thereof derived <i>EIT images</i> , <i>waveforms</i> , <i>indices</i> and <i>parameters</i> . | - |
| <i>EIT image</i> | Any kind of image reconstructed/derived from <i>EIT raw data</i> . | - |

| Term | Definition/Measurement units (if applicable) | Available/determined |
|--|---|--|
| <i>EIT sensitivity region</i> | <p>The intrathoracic volume the impedance changes of which contribute to the generated <i>EIT data</i> (i.e. the intrathoracic volume probed by EIT).</p> <p>Being centered around the <i>belt plane</i> the <i>EIT sensitivity region</i> is roughly lens-shaped: close to the body surface the thickness of the <i>EIT sensitivity region</i> corresponds to at least the width of the belt (Table 13-13) and increases towards the central region of the thorax to reach a thickness of roughly one half to two-thirds of the thorax width.</p> | |
| <i>End-Expiratory Lung Impedance (EELI)</i> | <p>Minimum of the <i>Plethysmogram</i> within an <i>Analysis Interval</i>. Assuming that the occurrence of the minimum corresponds to the end of an expiration, this minimum can be interpreted as <i>Lung Impedance</i> at an end-expiratory time point, therefore <i>End-Expiratory Lung Impedance</i>.</p> <p>EELI is related to the end-expiratory lung volume (EELV) if exhaling against a PEEP and, if exhaling against ambient pressure, to the Functional Residual Capacity (FRC), when breathing normally, or the Residual Volume (RV), in forced expiration.</p> <p>Quantified in arbitrary, not displayed, units. Auto-scaled trend display.</p> | <i>Index</i> calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |
| <i>End-Inspiratory Lung Impedance (EILI)</i> | <p>Maximum of the <i>Plethysmogram</i> within an <i>Analysis Interval</i>.</p> <p>Assuming that the occurrence of the maximum corresponds to the end of an inspiration, this maximum can be interpreted as <i>Lung Impedance</i> at an end-inspiratory time point, therefore <i>End-Inspiratory Lung Impedance</i>.</p> <p>EILI is related to end-inspiratory lung volume and, therefore, the difference between EILI and EELI to tidal volume.</p> <p>Quantified in arbitrary, not displayed, units. Auto-scaled trend display.</p> | <i>Index</i> calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |
| <i>failing electrode</i> | Electrode with insufficient skin contact respectively impedance coupling to the skin. Due to the associated, excessive skin contact impedance, current injection and voltage measurements are not possible with this electrode. | - |
| <i>Functional Lung Spaces (FLS)</i> | <p>The subset of <i>Lung Pixels</i> having RTS-values greater than 10%.</p> <p><i>Functional Lung Spaces</i> reflect the percentage of lung areas with non-negligible impedance change during breathing. As such they are meant to represent the percentage of ventilated lung regions. They are related to what in literature is referred to as Functional Lung Size [1] or size of the available lung volume, i.e. the percentage of the aerated remaining lung.</p> <p>Quantified in % of Lung ROI area.</p> | <i>Index</i> calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |
| <i>Global Dynamic Image</i> | <p>Image (tomogram) displaying, for a given image frame, the regional impedance distribution within the <i>Thorax ROI</i> (i.e. the <i>zero reference image</i>) with respect to a moving baseline impedance distribution.</p> <p>Typically, not shown as an individual image but as real-time display of continuously updated series of tomograms in a movie-like sequence. The movie-like display of Global Dynamic Images provides visual feedback about measurement quality and plausibility.</p> <p>Pixel values quantified in arbitrary units and represented in color scale.</p> | Calculated once per image frame — all modes. |
| <i>Horizon of Ventilation (HoV)</i> | <p>The horizontal plane through the <i>Center of Ventilation</i>, perpendicular to the gravity vector. The horizontal line through the <i>Center of Ventilation</i> displayed in certain <i>EIT images</i> corresponds to the line of intersection of the <i>belt plane</i> with the HoV.</p> <p>HoV divides <i>EIT images</i> into non-dependent (upper part of image) and dependent (lower part of image) areas.</p> | Calculated once per <i>Analysis Interval</i> and upon each <i>rotation</i> change — <i>BB</i> and <i>TB-I</i> modes. |
| <i>inclination</i> | <p>Patient rotation around the transversal axis, i.e. the intersection of the frontal and transversal planes.</p> <p>The supine position is the zero-position. Inclination angles increase if the patient is inclined in direction of the upright position — the inclination is 90° if the patient is upright.</p> <p>Quantified in angle degrees.</p> | Updated upon each <i>inclination</i> change |
| <i>index – indices</i> | <p>A typically numeric output variable calculated from <i>EIT raw data</i>. Indices provide additional information to the clinical user.</p> <p>Examples of indices derived from <i>EIT raw data</i> include EELI, EILI, NSS, DSS, or RTS.</p> | - |
| <i>Lung Contours</i> | Contours of the <i>Lung ROI</i> . | Updated whenever the <i>Lung ROI</i> is calculated — all modes. |
| <i>Lung Impedance (LI)</i> | <p>Total impedance within the <i>Lung ROI</i> (i.e. the sum of the impedance values of all <i>Lung Pixels</i>) for a given image frame, whereby impedance values are taken from the <i>zero reference image</i>.</p> <p>Changes in <i>Lung Impedance</i> are related to changes in lung volume.</p> <p>Quantified in arbitrary, not displayed, units. Auto-scaled waveform display (see <i>Plethysmogram</i>)</p> | <i>Index</i> calculated once per image frame. |

| Term | Definition/Measurement units (if applicable) | Available/determined |
|--|--|---|
| <i>Lung Pixel</i> | An image element inside the <i>Lung ROI</i> . | Updated whenever the <i>Lung ROI</i> is calculated — all modes. |
| <i>Lung ROI</i> | CT-derived, anatomy-related <i>Region of Interest</i> representing the lung in the <i>belt plane</i> of a belt applied to a patient as recommended. Based on patient specific data the <i>Lung ROI</i> and, hence, the <i>Lung Contours</i> best fitting an individual patient is selected from a set of predefined <i>Lung ROIs</i> . Impedance changes within the <i>Lung ROI</i> are expected to be primarily related to lung volume changes caused by lung-function (i.e. air flowing in, distributing within, and flowing out of the lungs) and, to a lesser extent, perfusion and cardiac activity | Calculated when data are entered, that are required to determine the <i>Thorax ROI</i> and <i>Lung ROI</i> best fitting the specific patient — all modes. |
| <i>Non-Dependent Silent Spaces (NSS)</i> | The subset of <i>Lung Pixels</i> having RTS-values smaller or equal than 10% and being localized above the HoV, i.e. <i>Silent Spaces</i> being localized in non-dependent lung areas. Quantified in % of <i>Lung ROI</i> area. | <i>Index</i> calculated once per <i>Analysis Interval</i> and upon each <i>rotation</i> change — <i>BB</i> and <i>TB-I</i> modes. |
| <i>operator adjustable parameter</i> | An input variable of the LuMon™ Monitor that can be adjusted or entered by the operator. For example, the gender and underbust girth of the patient, the time range for trends or for the <i>Plethysmogram</i> . | - |
| <i>parameter</i> | A typically numeric physiological variable that can be derived from <i>EIT raw data</i> and validated against a clinical reference method. Currently, the only example in the LuMon™ System is the <i>Respiratory Rate</i> . | - |
| <i>Plethysmogram</i> | <i>Waveform</i> representing relative <i>Lung Impedance</i> variations over time. Reflects relative lung volume variations over time. Auto-scaled display. | Calculated once per image frame |
| <i>preset belt time</i> | The factory-preset duration a belt can be used. Quantified in hours. | - |
| <i>Region of Interest (ROI)</i> | An area within an <i>EIT image</i> on which further analysis can be performed for example to derive and display regional information such as regional <i>waveforms</i> or regional <i>indices</i> . The ROIs currently used by SenTec EIT are the <i>Thorax ROI</i> and the <i>Lung ROI</i> . | - |
| <i>Relative Tidal Stretch (RTS)</i> | <i>Lung Pixel Tidal Variation</i> normalized to maximum <i>Lung Pixel Tidal Variation</i> . Quantified in % of maximum <i>Lung Pixel Tidal Variation</i> . | <i>Index</i> calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |
| <i>Respiratory Rate (RRi)</i> | Respiratory Rate derived from the <i>Plethysmogram</i> Quantified in breaths per minute (bpm). | <i>Parameter</i> calculated once per breath. |
| <i>rotation</i> | Patient rotation around the longitudinal axis, i.e. intersection of the sagittal and frontal planes. The supine position is the zero-position. Rotation angles increase if the patient is rotated in direction of the right lateral position — the rotation is 90° if the patient is lying on its right-hand side. Quantified in angle degrees. | Updated upon each <i>rotation</i> change |
| <i>SenTec Authorized LuMon™ Technician</i> | Qualified technician — e.g., a biomedical engineer — having successfully completed a “LuMon™ System Service & Repair Training” and being authorized (documented by a respective certification issued by SenTec EIT (or a hereto authorized third-party)) to perform repair procedures for the LuMon™ Monitor that do require opening of its cover and to install software updates and software upgrades on LuMon™ Monitors. | - |
| <i>signal quality index</i> | The number of usable voltage measurements per image frame as a fraction of the 928 possible voltage measurement. Quantified in % of the 928 possible voltage measurements | Calculated once per image frame — all modes. |
| <i>Silent Spaces</i> | The subset of <i>Lung Pixels</i> having RTS-values smaller or equal than 10%. <i>Silent Spaces</i> reflect the percentage of lung areas with little or no impedance change during breathing. As such they are meant to represent the percentage of lung regions receiving no or little ventilation. Quantified in % of <i>Lung ROI</i> area. | <i>Index</i> calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |
| <i>Silent Spaces Image</i> | Image displaying the regional distribution of <i>Functional Lung Spaces</i> and <i>Silent Spaces</i> , with the latter being subdivided in <i>Dependent Silent Spaces</i> and <i>Non-Dependent Silent Spaces</i> . | Calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |
| <i>Stretch Image</i> | Image displaying the regional distribution of <i>Relative Tidal Stretch</i> within the <i>Lung ROI</i> . <i>Stretch Images</i> are meant to represent the regional distribution of Tidal Volumes (TV) within the lungs. Pixel values quantified in % of maximum <i>Lung Pixel Tidal Variation</i> and represented in color scale. | Calculated once per <i>Analysis Interval</i> — <i>BB</i> and <i>TB-I</i> modes. |

| Term | Definition/Measurement units (if applicable) | Available/determined |
|------------------------------|--|--|
| <i>TB-I mode</i> | One of the available <i>Analysis Modes</i> . See 9.7.2. | - |
| <i>TB-II mode</i> | One of the available <i>Analysis Modes</i> . See 9.7.3. | - |
| <i>Thorax Contour</i> | Contour of the <i>Thorax ROI</i> . | Updated whenever the <i>Thorax ROI</i> is calculated — all modes. |
| <i>Thorax Pixel</i> | An image element within the <i>Thorax ROI</i> . | Updated whenever the <i>Thorax ROI</i> is calculated — all modes. |
| <i>Thorax ROI</i> | CT-derived, anatomy-related <i>Region of Interest</i> representing the thorax in the <i>belt plane</i> of a belt applied to a patient as recommended. Based on patient specific data the <i>Thorax ROI</i> and, hence, the <i>Thorax Contour</i> best fitting an individual patient is selected from a set of predefined <i>Thorax ROIs</i> . | Calculated when data are entered, that are required to determine the <i>Thorax ROI</i> and <i>Lung ROI</i> best fitting the specific patient — all modes. |
| <i>Tidal Variation (TVi)</i> | Difference of <i>Lung Impedance</i> between end-inspiratory and end-expiratory time points within an <i>Analysis Interval</i> or, in other words, the <i>Lung Impedance</i> change due to tidal ventilation. As <i>End-Inspiratory</i> and <i>End-Expiratory Lung Impedance</i> values are related to end-inspiratory and end-expiratory lung volumes, TVi is related to (in <i>BB mode</i>) or approximates (in <i>TB-I mode</i>) the volume inhaled in one breath, i.e. the tidal volume (TV) when breathing normally, or the inspiratory capacity (IC), in a forced inspiration. Quantified in arbitrary, not displayed, units. | Only indirectly available <i>index</i> as the difference between the EILI and EELI trend. |
| <i>time-based (TB)</i> | Either a designation used for two <i>Analysis Modes</i> — TB-I and TB-II — or a statement used to describe that something repeatedly occurs or is done per time interval, whereby the time interval has a fixed, preset duration. | - |
| <i>waveform</i> | The change of an <i>index</i> or <i>parameter</i> as a function of time. An example of a waveform derived from <i>EIT raw data</i> is the <i>Plethysmogram</i> . | - |
| <i>zero reference image</i> | Image reconstructed from the <i>EIT raw data</i> providing the regional impedance distribution within the <i>Thorax ROI</i> for a given image frame. Pixel values quantified in arbitrary units. | Calculated once per image frame – all modes. |

14.3 Abbreviations used in this User's Guide

Abbreviations are sorted alphabetically:

14.3.1 Abbreviations related to SenTec EIT, EIT in general and clinical terms

| | | | |
|--------------------|--|----------|--|
| BB | Breath-based | HFOV | High Frequency Oscillatory Ventilation |
| BMI | Body mass index | | |
| bpm | breaths per minute | HoV | <i>Horizon of Ventilation</i> |
| CA | ContactAgent | IC | Inspiratory Capacity |
| CoV | <i>Center of Ventilation</i> | ICS | Intercostal Space |
| CoV(h) | Horizontal component of CoV | LI | <i>Lung Impedance</i> |
| CoV ^{hom} | <i>Center of homogeneous Ventilation</i> | LMB | LuMon™ Belt |
| CoV(v) | Vertical component of CoV | LMC | LuMon™ Connector |
| CT | Computed Tomography | LMS | <i>LuMon™ System</i> |
| DSS | <i>Dependent Silent Spaces</i> | LMS-A | LuMon™ System - Adults/Children configuration |
| ECG | Electrocardiogram | LMS-N | LuMon™ System - Neonates/Infants configuration |
| ECMO | Extracorporeal membrane oxygenation | LuMon | Lung Monitor |
| EEG | Electroencephalography | LuFu | Lung Function |
| EELI | <i>End-Expiratory Lung Impedance</i> | LuFuView | Lung Function View |
| EELV | End-Expiratory Lung Volume | MLI | <i>Mean Lung Impedance</i> |
| EILI | <i>End-Inspiratory Lung Impedance</i> | MRI | Magnetic resonance imaging |
| EIT | Electrical Impedance Tomography | NCA | NeoContactAgent |
| EMG | Electromyography | NSS | <i>Non-Dependent Silent Spaces</i> |
| EOG | Electrooculography | ROI | <i>Region of Interest</i> |
| FLS | Either Functional Lung Space or Functional Lung Size | RTS | <i>Relative Tidal Stretch</i> |
| FRC | Functional Residual Capacity | RV | Residual Volume |
| | | RR | <i>Respiratory Rate</i> |

| | | | |
|-------|--|----------|------------------------------|
| RRi | <i>Respiratory Rate derived from Lung Impedance waveform</i> | TIC | Tomographic imaging creation |
| SB | SensorBelt | TV | Tidal Volume |
| SBC | SensorBeltConnector | TVi | <i>Tidal Variation</i> |
| TB-I | <i>Time-based I</i> | VentView | Ventilation View |
| TB-II | <i>Time-based II</i> | | |

14.3.2 Other abbreviations

| | | | |
|-------|---|------------------|--|
| % | Percent | INCI | International Nomenclature of Cosmetic Ingredients |
| A | Ampere | IP | Ingress Protection |
| AC | Alternating current | ISO | International Organization for Standardization |
| AU | Arbitrary units | kg | Kilogram |
| Arms | Root mean square accuracy | kHz | Kilohertz |
| C | Celsius | kV | Kilovolt |
| CISPR | Comité international spécial des perturbations radioélectriques International (Special Committee on Radio Interference) | mArms | Miliampere rms |
| cm | Centimeters | m | Meter |
| dBA | A-weighted decibels: Expression of the relative loudness of sound in the air – perceived by the human ear. | MHz | Megahertz |
| DC | Direct current | min | Minutes |
| EMC | Electromagnetic compatibility | ml | Milliliter |
| EN | European standard | mm | Millimeter |
| ESD | Electrostatic discharge | MOPP | Means of Patient Protection (electrical safety standard) |
| FCC | Federal Communications Commission Depending on Safety | LAN | Local area network |
| FIFO | First-in First-out | psi | Pounds per square inch |
| g | gram | RF | Radio frequency |
| GB | Gigabyte | rms | Root mean square |
| GHz | Gigahertz | s | Seconds |
| GUI | Graphical User Interface | USB | Universal Serial Bus |
| h | Hour | V | Volt |
| hPa | Hectopascal | V _{rms} | Voltage rms |
| HF | High frequency | VAC | Voltage Alternating Current |
| Hz | Hertz | W | Watt |
| IEC | International Electro technical Commission | WEEE | Waste electrical and electronic equipment |
| | | µt | Symbol for microtesla (unit of magnetic flux density) |

14.4 References

- [1] Amato MB et al. "Driving pressure and survival in the acute respiratory distress syndrome". N Engl J Med. 2015; 372(8):747-55.
- [2] Costa EL et al. "Electrical impedance tomography". Curr Opin Crit Care. 2009; 15(1):18-24.
- [3] Frerichs I et al. "Chest electrical impedance tomography examination, data analysis, terminology, clinical use and recommendations: consensus statement of the TRanslational EIT developmeNt stuDy group". Thorax. 2017; 72(1):83-93.
- [4] Putensen C. et al. "Electrical Impedance Tomography for Cardio-Pulmonary Monitoring". J Clin Med. 2019; 8(8):1176.
- [5] Lobo B. et al. "Electrical impedance tomography". Ann Transl Med. 2018; 6(2):26.
- [6] Thürk F et al., "Effects of individualized electrical impedance tomography and image reconstruction settings upon the assessment of regional ventilation distribution: Comparison to 4-dimensional computed tomography in a porcine model". PLoS One 2017; 12(8):e0182215.
- [7] West J et al. "West's Respiratory Physiology: The Essentials", Wolters Kluwer 2016.
- [8] Lutfi MF. "The physiological basis and clinical significance of lung volume measurements". Multidiscip Respir Med. 2017; 12:3.
- [9] Frerichs I et al. "Simple Electrical Impedance Tomography Measures for the Assessment of ventilation Distribution". Am J Respir Crit Care Med. 2020; 201(3):386-8.
- [10] Costa EL et al. "Bedside estimation of recruitable alveolar collapse and hyperdistension by electrical impedance tomography". Intensive Care Med. 2009; 35(6):1132-7.
- [11] Luepschen H et al. "Protective ventilation using electrical impedance tomography". Physiol Meas. 2007; 28(7):S247-60.
- [12] Borges JB et al. "Reversibility of lung collapse and hypoxemia in early acute respiratory distress syndrome". Am J Respir Crit Care Med. 2006; 174(3):268-78.

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