



Evaluation of patient and user interfaces for Electrical Impedance Tomography – Swisstom's BB² system

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Summary: This white paper provides information about Swisstom's BB², a commercially available and clinically usable electrical impedance tomography system.

1. Introduction: Electrical impedance tomography (EIT) is a novel monitoring method for lung and heart and provides moving images which show functions rather than structures. For this purpose, an array of 32 electrodes is applied on the human thorax. Weak alternating currents are injected via these electrodes and travel along the paths of least electrical impedance through the body, creating electric potentials at the body surface. The potentials are being measured by the electrodes and converted into images that show the distribution of electrical impedance within the body. Since electrical impedance distribution is changed by ventilation and hemodynamics, EIT images allow continuous visualization of lung and heart function 24 hours a day, 7 days a week. Clinicians are finally able to observe the lung during breathing online, in real-time and color. The resulting images contain important information never available before. Unlike traditional medical imaging methods (e.g., computed-tomography or CT), EIT images are available right at the bedside, continuously.

EIT is not yet established in intensive care medicine in contrast to cardiology, where methods based on impedance measurement are well established and several devices have been on the market for many years. However,

pertinent literature shows, that EIT in intensive care medicine is on the verge of becoming a method of choice:

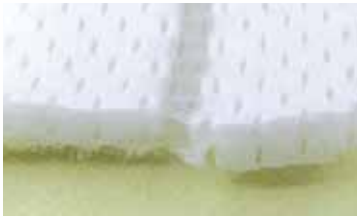
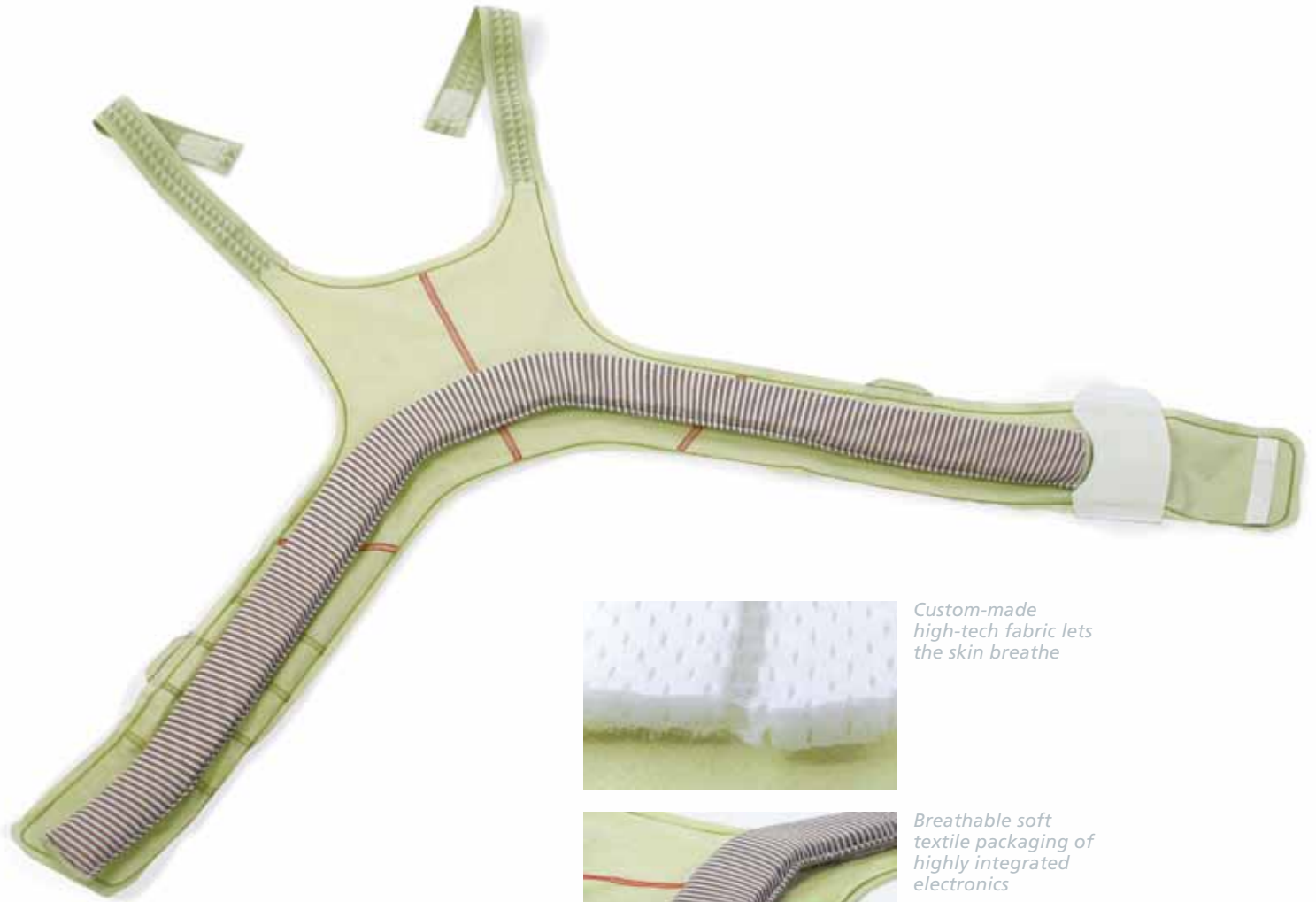
„There is growing evidence that supports EIT usage as a bedside measure to individually optimize ventilator settings in critically ill patients in order to prevent ventilator-induced lung injury.“ (Moerer et al.; 2011)

So, why is EIT still not used in clinical practice? A recent review on EIT points out the reasons. Particularly the poor patient interface of traditional systems is a concern:

„... there is a requirement for improved patient interfaces which allow EIT electrodes to be placed quickly, reliably and easily.“ (Adler et al.; 2012). And further: „The user interface must be designed with such clinical interactions and use in mind. Displayed parameters must be easy to interpret and preferably be in physiological units.“ Finally, the authors demand uncompromised quality: „Specifically, any errors in electrode contact or incorrect placement should be detected and, if possible, automatically corrected, to avoid the resulting serious image artefacts.“ Swisstoms BB² appears to address all of the issues raised above and this white paper provides answers to the following questions: What is the benefit of EIT (the „So What?“ question)? Does Swisstom BB² solve the above technical challenges?

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Conflict of interest: both authors are employees and shareholders of Swisstom AG

WHITE PAPER ON NOVEL EIT INTERFACES



Custom-made high-tech fabric lets the skin breathe



Breathable soft textile packaging of highly integrated electronics



Single cable with easy-to-use SensorBeltConnector



Comfortable SensorBelt fits like a second skin

2. Benefit of EIT (the „So What?“ question)

Recent studies show that 15% of mechanically ventilated patients in Intensive Care Units (ICU) develop Acute Lung Injury (ALI), mainly caused by progressively collapsing lungs. Although recovery procedures are well known, ALI is still treated inadequately with a reportedly high mortality of thirty-nine percent (Rubenfeld et al.; 2005).

It is well accepted that to improve this situation, a real-time lung monitoring system is needed to make impending lung collapse immediately visible in order to conduct appropriate treatment. Today, however, only very limited and incomplete monitoring options exist and treatment is still largely inadequate, leaving undue burden on patient, family, and the healthcare system. The EIT monitoring system Swisstom BB² allows physicians to continuously monitor intra-thoracic impedance changes. These impedance changes are closely related to regional ventilation. EIT enables the monitoring of regional lung function and thus provides real-time monitoring which was hitherto unavailable.

EIT has proven to be feasible. Several hundred patients and animals were studied in the past with different EIT devices. A number of different uses for EIT in connection with mechanical ventilation were identified, the result of a pubmed search in August 2013 is given in Table 1.

Table 1. Summary of studies on EIT with respect to lung function (status August 2013)

	Adults	Infants	Animals
Number of subjects	471	114	248
Number of studies	27	7	28

According to these studies, lung over-distention and lung collapse can be monitored by EIT (Luecke et al.; 2012; Costa et al.; 2009) which can also be used to eventually optimize mechanical ventilation (Gomez-Laberge et al.; 2012). Recently, previous findings were confirmed by the first outcome study using EIT as guidance for mechanical ventilation. The authors concluded (Wolf et al.; 2013):

„Electrical impedance tomography-guided ventilation resulted in improved respiratory mechanics, improved gas exchange, and reduced histologic evidence of ventilator-induced lung injury in an animal model.“

3. Challenges

3.1. Patient interface

The first mandate of a clinically usable EIT system is to make the electrode assembly, i.e. patient interface skin-friendly for the patient and user-friendly for the nursing staff (Adler et al.; 2012). In Swisstom BB², 32 electrodes are integrated into the SensorBelt and wrapped in textile. One cable leads from the buckle of the SensorBelt (Docking Station) to the analysis modules. This arrangement can be considered user and patient friendly because of its textile nature and quick and easy fitting of the electrical connections.

Swisstom’s SensorBelt is made of soft textile and the electrodes are woven into this textile with silver yarn. However, contact with the skin is difficult to achieve with dry electrodes and therefore the BB² solution suggests contact enhancement by use of a special skin care lotion (ContactAgent). Table 2 shows the effect of the ContactAgent on contact impedance with the patient’s skin. Before application, the contact with the skin is insufficient as evidenced by high contact impedance (higher than 1000 Ohm). After application of ContactAgent, the resistance dropped to 325 Ohm on average, and remained low even after one hour of continuous skin contact.

No breathing restriction

The tailored shape of the SensorBelt was designed such that the SensorBelt follows the extension of the ribs from the upper back towards the lower front. The SensorBelt is uplifted with every breath but remains essentially un-stretched. In other words, Swisstom’s SensorBelt does not restrict breathing by virtue of its design.

Table 2. Effect of ContactAgent on skin-contact impedance, measured in Ohm, expressed as the composite impedance of two contact pads in series on healthy male volunteers. This means that the actual contact impedance of one electrode is about half of the value shown in the Table.

	Height in cm	Weight in kg	Age in y	Before application of ContactAgent [Ohm]	After application of ContactAgent [Ohm]	After one hour [Ohm]
	183	85	50	1235	244	566
	172	76	57	2328	313	534
	170	72	53	2069	361	400
	178	72	30	2371	382	429
	179	65	37	2626	553	532
	171	90	39	1196	278	428
	178	73	26	1927	333	460
	179	60	28	2505	285	272
	183	85	34	2110	248	492
	192	104	32	2191	256	276
Median	179	75	36	2151	299	445
Mean	179	78	39	2056	325	439
SD	6	12	10	464	88	97

Pressure ulcer prevention

Pressure ulcers are a known complication of bed-ridden patients. Body areas with a high prevalence of pressure ulcers in acute care are reported to be heels, coccyx, and ears. Risk factors include poor fecal management, incontinence, acidosis, inadequate support surfaces, steroids, poor perfusion and poor nutritional status (Wilczweski et al.; 2012). Incidentally, the duration of mechanical ventilation appears to be an important risk factor, too (Manzano et al.; 2010) while the most important measure to prevent pressure ulcers are pressure reducing devices and nursing interventions (Shahin et al.; 2009). However, according to a meta-analysis (*Pressure ulcer prevention: an evidence-based analysis; 2009*), there is very little evidence that actually supports any of the above mentioned measures: *„There is moderate quality evidence that an alternative foam mattress is effective in preventing the development of pressure ulcers compared with a standard hospital foam mattress. However, overall there remains a paucity of moderate or higher quality evidence in the literature to support many*

of the preventive interventions. Until better quality evidence is available, pressure ulcer preventive care must be guided by expert opinion for those interventions where low or very low quality evidence supports the effectiveness of such interventions.“

A review of the Cochrane Library on *Support Surfaces* leads to the conclusion that there is little evidence that the bed support structure reduces severity or incidence of pressure ulcers (McInnes et al.; 2011). It appears that the bed structure does not play an overly important role. This includes the linens used in beds and the kind of textiles used in the SensorBelt. In other words, the textile SensorBelt is unlikely to increase pressure ulcer formation.

No cross contamination

Cross contamination is a serious issue especially with multi-patient use devices. The BB² SensorBelt is single patient use and can be worn for up to 72h continuously. By definition, single patient use makes cross contamination impossible.

3.2. The caregiver's interface

The second mandate of a clinically usable EIT system is to provide meaningful information to the caregiver and not just display blurry pictures (Moerer et al.; 2011). The Swisstom BB² implements a novel approach to presenting EIT information which includes the calculation of pulmonary function indices such as regional volume change and related relative stretch. The Swisstom BB² puts this information in the context of lung and heart position within the chest by virtue of image fusion technology.

The touch user interface screen of Swisstom BB² is divided into three main sections which overlap on the screen. The selected view displays detailed information on a large area. At the same time, the other two sections are shown in a compact view. They display any relevant data in reduced form so that it is still possible to keep an overview of the entire situation. A new view can be selected by simply tapping it: the area expands, moving the previous view to the background. This clear structure allows for a fast operation of Swisstom BB² even within the stressful intensive care environment.

The user interface of Swisstom BB² has three views: **ScoutView**, **VentView**, and **LuFuView**. All views include monitoring of the patient's position. Patient position is fundamental in the assessment of lung collapse and thus an important part of Swisstom's BB².

The **ScoutView** provides the user with an overview of the patient's general data and indicators of monitoring quality. The **ScoutView** also shows whether the electrodes of the belt are in sufficient electrical contact with the patient's skin. Once a SensorBelt of appropriate size for an individual patient has been determined, the user enters height, weight and gender using the number picker on the screen. From these inputs Swisstom BB² automatically selects reference contours of thorax and lungs that best match the individual patient. Swisstom BB² then displays the breathing lungs directly within these contours on the screen.

The **VentView** displays continuously and in real-time the amount of ventilation within the lungs during breathing. By taking the lungs' contours into account, the user can immediately recognize lung zones in which ventilation is reduced or even absent.

The **LuFuView** shows breath-by-breath parameters which are calculated and updated with each new breath. The unique way lung function indices are calculated and displayed allows the user to visually identify patterns of health and disease. Next to their spatial distribution, the frequency of each parameter-expression is made available as a histogram for in-depth analysis.

3.3. Quality assessment

Every SensorBelt contains 32 electrodes with integrated electronics to measure as close to the patients skin as possible. Swisstom is the only company that can provide this technology. In contrast to other technologies, Swisstom's on-skin electronics results in images that are virtually unaffected by cables and artifacts caused by the handling of cables. On top of this, a second measurement channel monitors the performance of each electrode. If a given electrode fails to make sufficient contact with the skin, the Swisstom BB² will identify this electrode, remove it from the measurement chain and compensate for its removal. This results in extremely reliable and stable measurements.

Leading edge technology brief:

(i) 32 electrodes are integrated into a textile SensorBelt which contains 32 electronic circuits to drive each electrode. Competitive devices use single passive gel or silicone electrodes which connect to electronic circuits by long cables thereby inducing artifacts and noise.

(ii) The SensorBelt is composed of custom made fabrics with conductive stripes and sewn onto a non-stretchable flexprint which carries the 32 electronic circuits. This unique assembly is optimized for patient comfort.

(iii) Each electrode on the SensorBelt is controlled by a unique electronic bus system which enables highly flexible scanning patterns. Competitive devices are hard-wired.

(iv) The shape of the (non-stretchable) SensorBelt follows the ribs and thus allows free breathing. Competitive devices use a circumferential straight elastic silicone chest belt which may restrict breathing if attached tightly.

(v) Swisstom's unique ContactAgent which is based on a skin ointment provides immediate and excellent electrical connection. Competitive devices use salty liquids or gels which dry out the skin and may cause its breakdown.

4. Conclusions

In conclusion, and based on the available information, Swisstoms BB² addresses the needs of a clinically useful EIT monitor. It holds great promise to dramatically change the way mechanical ventilation is governed in the ICU. Controlled EIT studies demonstrating the clinical benefits of EIT can now be conducted safely and easily with the device from Swisstom.

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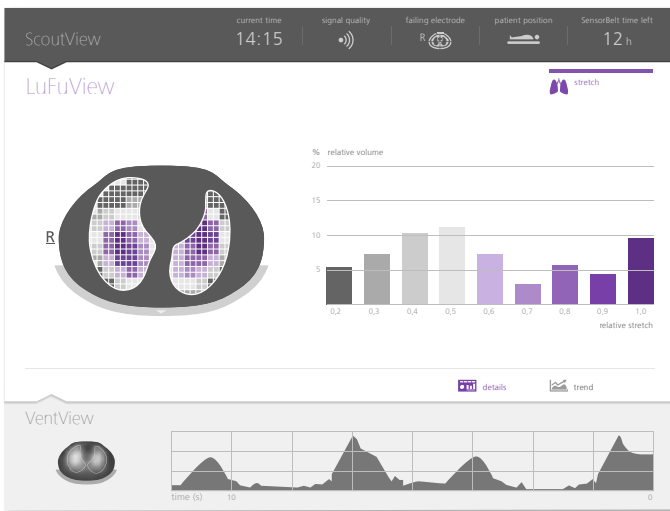
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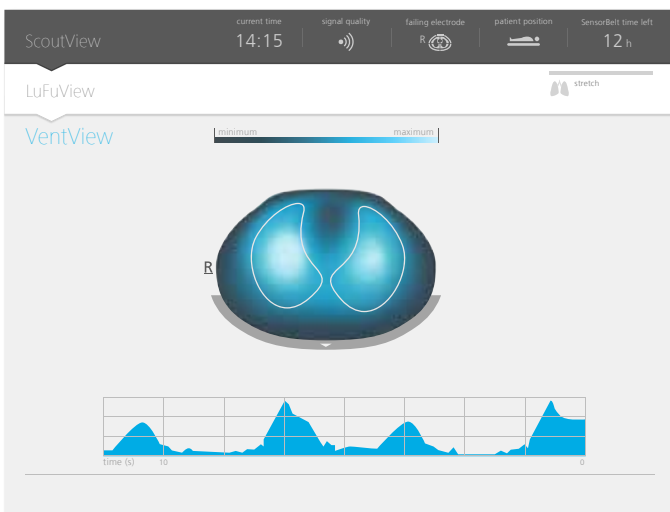
swisstom
Now I can see.



The ScoutView contains graphics that show the patient's body position and indicate whether the electrodes of the belt are in sufficient electrical contact with the patient's skin



The LuFuView visualizes both, parameter values in individual lung regions as well as their relative frequencies



The VentView lets the users watch the lungs breathe

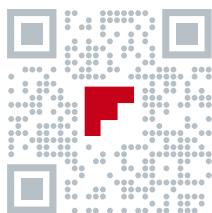
Real-time tomographic images for organ function monitoring and diagnosis



electrical impedance tomography



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Swisstom AG, located in Landquart, Switzerland, develops and manufactures innovative medical devices. Our new lung function monitor enables life-saving treatments for patients in intensive care and during general anesthesia.

Unlike traditional tomography, Swisstom's bedside imaging is based on non-radiating principles: Electrical Impedance Tomography (EIT). To date, no comparable devices can show such regional organ function continuously and in real-time at the patient's bedside.

Swisstom creates its competitive edge by passionate leadership in non-invasive tomography with the goal to improve individual lives and therapies.