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Wearable pulmonary monitoring system with integrated functional lung imaging and chest sound recording: a clinical investigation in healthy subjects

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Supplementary material for this article is available online

Abstract

Objective. Current wearable respiratory monitoring devices provide a basic assessment of the breathing pattern of the examined subjects. More complex monitoring is needed for healthcare applications in patients with lung diseases. A multi-sensor vest allowing continuous lung imaging by electrical impedance tomography (EIT) and auscultation at six chest locations was developed for such advanced application. The aims of our study were to determine the vest's capacity to record the intended bio-signals, its safety and the comfort of wearing in a first clinical investigation in healthy adult subjects. *Approach.* Twenty subjects (age range: 23–65 years) were studied while wearing the vests during a 14-step study protocol comprising phases of quiet and deep breathing, slow and forced full expiration manoeuvres, coughing, breath-holding in seated and three horizontal postures. EIT, chest sound and accelerometer signals were streamed to a tablet using a dedicated application and uploaded to a back-end server. The subjects filled in a questionnaire on the vest properties using a Likert scale. *Main results.* All subjects completed the full protocol. Good to excellent EIT waveforms and functional EIT images were obtained in 89% of the subjects. Breathing pattern and posture dependent changes in ventilation distribution were properly detected by EIT. Chest sounds were recorded in all subjects. Detection of audible heart sounds was feasible in 44%–67% of the subjects, depending on the sensor location. Accelerometry correctly identified the posture in all subjects. The vests were safe and their properties positively rated, thermal and tactile properties achieved the highest scores. *Significance.* The functionality and safety of the studied wearable multi-sensor vest and the high level of its acceptance by the study participants were confirmed. Availability of personalized vests might further advance its performance by improving the sensor-skin contact.

1. Introduction

Due to the high prevalence of lung diseases in the worldwide population, the current intense research dedicated to mobile health (mHealth) often focuses on the patients suffering from such diseases and defines them as the target population for future mHealth solutions. Since pulmonary diseases are characterized by pronounced

morbidity, frequent chronic course and high mortality, the individual and societal burden of these diseases is immense. It is postulated that better monitoring of these patients, utilizing wearable medical devices suitable for remote use at patients´ homes, might not only improve the therapy and care management but also the patients´ outcomes with potential reduction of treatment costs.

It is therefore no wonder that numerous wearable systems for respiratory monitoring have already been developed and shown to provide reliable recordings of several parameters characterizing the lung function (Cruz *et al* 2014, Aliverti 2017, Costanzo *et al* 2022). The drawback of the current solutions is that they typically generate only basic parameters describing the breathing pattern. The two components of the breathing pattern are the tidal volume and the breathing rate. Thus, the available respiratory mHealth devices determine measures like the relative tidal volume, relative flow rate, inspiration and expiration times, inspiration-to-expiration time ratio, or respiratory rate. Such parameters are frequently used in sports sciences where they provide adequate information to continuously characterize the lung function of healthy athletes (Nicolo *et al* 2020, Miccinilli *et al* 2022). However, they are not always sufficient to capture the complex deterioration of lung function in patients with lung diseases.

To increase the clinical relevance of the information generated by the wearable respiratory monitoring devices, external devices like hand-held spirometers or pulse oximeters are added to provide quantitative values of lung volumes and capacities (e.g. forced expiratory volume in 1 s (FEV_1) or forced vital capacity (FVC)) and peripheral transcutaneous oxygen saturation, respectively. Another add-on method that might expand the information content generated by wearables in a remote setting employs electronic stethoscopes to register acoustic signals (Au *et al* 2022, Emokpae *et al* 2022). Through the stated add-on methods, the conventional pulmonary function parameters, the gas exchange efficiency and the presence of pathological lung sounds can be assessed. However, the full clinical pulmonary status assessment in pneumology patients also requires lung imaging which is not easy to be implemented in a wearable respiratory monitoring device.

Conventional radiological methods like chest radiography cannot be adopted because of their operational principle based on radiation. The only methods that could be considered are electrical impedance tomography (EIT) and ultrasound because they are both portable, not harmful to the examined subject or other subjects in the vicinity and suitable for prolonged use (Frerichs *et al* 2022). EIT determines regional changes in lung gas content by continuous measurement of thoracic electrical bio-impedance through an array of sensors placed on the chest circumference. These sensors are used to repetitively inject very small imperceptible alternating electrical currents into the body and to measure the resulting voltages. Since the EIT signals correlate with the volumetric changes in lung gas content (Ngo *et al* 2017, Mosing *et al* 2022) and EIT data is continuously acquired, EIT has the advantage that it can generate measures comparable with spirometry that are familiar to healthcare professionals (Frerichs *et al* 2016, Vogt *et al* 2019, Lasarow *et al* 2021, Ma *et al* 2022).

There exist just a few attempts to realize fully wearable EIT systems (Hong *et al* 2015, Rapin *et al* 2019, Frerichs *et al* 2020). Such systems do not require leads to connect the examined subject with an external processing and visualization unit unlike all commercial EIT devices. To the best of our knowledge, the only system designed to provide both EIT and chest sounds was the so-called WELCOME vest (Frerichs *et al* 2020). However, this vest failed to achieve its full functionality because of relatively low EIT image quality in some of the study participants and non-usability of the recorded acoustic signals for detection and analysis of lung sounds due to the low performance of the used acoustic transducer.

Therefore, a next-generation wearable was developed within the project WELMO funded by the European Commission in the years 2019–2022[8]. The WELMO vest was completely re-designed compared with the previous WELCOME model featuring different fabrics, new cutting and sewing, multi-layer textile design and a novel sensor-fixing solution using a removable harness. The sensors, based on the previously described cooperative sensor architecture (Rapin *et al* 2015, Rapin *et al* 2019), were also developed *de novo*, with a new powering solution, extended functionality and markedly reduced dimensions. The performance of this new wearable was tested for the first time under *in vivo* conditions in a pilot clinical investigation[9] on healthy human subjects. The aims of the study were to determine (1) the functionality of the WELMO vest, i.e. its capacity to record the intended bio-signals, download them to a mobile device for real-time visualization and upload them to a back-end server, (2) the vest safety and (3) the comfort of wearing. The results of this clinical investigation are reported in the current paper.

[8] https://cordis.europa.eu/project/id/825572

[9] The term 'clinical investigation' is used in accordance with the standard ISO 14 155 and the current European Union legislation specified in the 'Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC'

Figure 1. WELMO vests in different colour and size versions. Each vest contains 18 sensors for EIT and chest sound recording, an accelerometer is integrated in the 'master' unit which is responsible for powering and coordination of sensors, wireless communication, data concentration and storage (*black arrow*). The receptacle for the 'master' with a protective cover can be seen in the dark vest (*white arrow*).

2. Methods

The WELMO pilot clinical investigation was designed as an open, prospective, monocentric, single-arm study with a non-CE-marked medical device that required an extensive study approval by local and national authorities, insurance of the study participants and study registration.

The WELMO study was approved by the Ethics Committee of the Medical Faculty at the Christian Albrechts University (CAU) in Kiel, Germany (reference no. A104/21) and the German Federal Institute for Drugs and Medical Devices (reference no. 94.1.10-5660-13105). The WELMO medical device was registered in the European Database of Medical Devices (EUDAMED) (reference no. CIV-21-03-036204). The study was registered at the German Clinical Trials Register (DRKS) which is an open-access primary registry of clinical trials approved by the World Health Organization (record no. DRKS00023703). The study was carried out in the Department of Anaesthesiology and Intensive Care Medicine at the University Medical Centre Schleswig-Holstein (UKSH) in Kiel, Germany.

The primary end-point of the study was defined as the presence and plausibility of the signals generated by the WELMO vest (i.e. transthoracic electrical bioimpedance, auscultation and posture/activity signals). The secondary end-points were the safety of use and the comfort of wearing the WELMO vest. The former was determined by documentation of any adverse events and the latter by a survey among the study participants.

2.1. Study vests

Four vests were provided for the WELMO pilot clinical investigation, two for women and two for men. The female vests had the sizes 75 and 80 (for subjects with an approximate chest circumference at the level of the bottom part of the sternum of 75 cm and 80 cm, respectively). The garments exhibited two different (light and dark) colour variations (figure 1). The male vests had the sizes 90 and 95 (for subjects with an approximate chest circumference of 90 cm and 95 cm, respectively). The male vests were also produced in two different colours. A long front zipper made it easy to put the vest on and to take it off. The vests were washable in laundry machine using a delicate wash and rinse cycle with low agitation speed. The used polyamide-elastane textile was tested for harmful substances and certified according to the OEKO-TEX[10] standards. Its production complied with the

[10] https://www.oeko-tex.com/en/

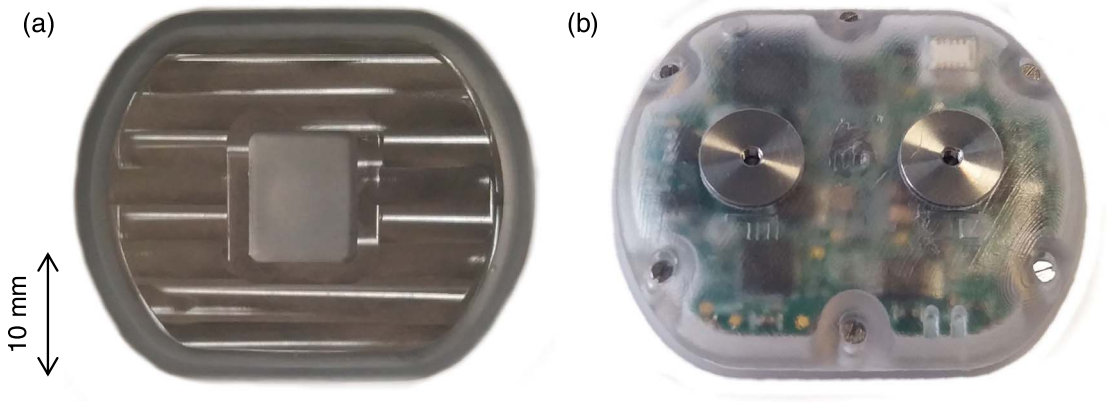

Figure 2. One of the WELMO sensors with combined EIT and chest sound recording function. The sensor side facing the skin of the examined subject (a) and the side fixed to a sensor harness integrated in the vest textile (b) are shown.

Organization Environmental Footprint and Product Environmental Footprint methodology. It also passed the biological compatibility, accelerated aging and washability tests.

The vests exhibited a multilayer structure. The inner layer primarily served the purpose of bio-signal acquisition, and the outer layer of communication and fitting. An array of 18 sensors, intended for direct contact with the skin, was integrated in each vest using a specific harness. The harness secured the precise locations of the sensors in relation to the chest. (The exact anatomical locations appropriate for EIT and lung sound acquisition were determined in a survey among health care professionals prior to the designing and production of the vests.) The harness was positioned between the two main layers of the vest textile and could be separated from the vest when needed through an opening at the back of the vest which was secured by a short zipper. Sixteen of the mentioned 18 sensors were located on the circumference of the lower chest when the vest was worn, two other sensors were placed in the right and left subclavicular region. To secure good skin contact of the subclavicular sensors, padding was applied below two textile patches (see the top part of the vests in figure 1). Further narrow padding was used in the back part of the vests near the backbone. The central unit, the so-called 'master', was attached using a specifically designed receptacle with a bayonet lock on the outer side of the vest (figure 1). The 'master' was not in contact with the skin.

2.2. Sensors

Different types of watertight and skin-friendly sensors were integrated into the WELMO vests. Sixteen sensors, placed on the chest circumference, were needed for the generation of the EIT data. These sensors were used to apply small excitation currents (100 μA, 40 kHz) to the body and measure the resulting voltages. Further technical details on these electrical bio-impedance measuring sensors are provided in Chételat *et al* (2022). Six sensors enabled the acquisition of chest sounds, two of these, located in the right and left subclavicular regions, were used exclusively for the acquisition of the acoustic signals. The other four allowed the combined sound and EIT recording (figure 2), thus, they were part of the 16-sensor array placed on the chest circumference. Two were placed at the front and two at the back of the chest. Further technical details on these chest sound measuring sensors, that function as miniature stethoscopes, are provided in Yilmaz *et al* (2020). The electrodes and sound transducers were dry and glue-free, i.e. the contact of the sensors with the skin was not enhanced by any solutions or gels in the course of the investigation. A guard and a reference electrode were implemented as foam-padded textile bands (about 15 cm $\times$ 2 cm each) to the left and the right of the front zipper about 5 cm below the EIT sensors. For a deeper insight into the functioning of the reference and the guard electrodes, the reader is referred to Rapin *et al* (2015). All 18 sensors (i.e. 12 with exclusive EIT functionality, 2 with exclusive sound recording functionality and 4 with combined functionalities), the guard and the reference electrode and the 'master' unit were connected to a two-wire parallel bus and functioned as cooperative sensors (Rapin *et al* 2015, Rapin *et al* 2019).

The central 'master' unit fulfilled multiple functions. It was responsible for the sensor synchronization and bidirectional communication with them. It recorded all the acquired bio-signals, i.e. the already mentioned electrical bio-impedance and the acoustic signals, and also the acceleration signal through an accelerometer (LIS2DW12, ST Microelectronics, Geneva, Switzerland) that was contained within its housing. The accuracy of the algorithms determining the wearer's posture and activity from accelerometry was first verified in Chételat *et al* (2015). The 'master' also provided the wireless communication (Bluetooth and WiFi). It was powered by a

rechargeable LiPo battery and secured the power supply of the cooperative sensors. (See (Chételat *et al* 2022) for further information.) The central unit was fixed to the outer front bottom part of the WELMO vest (figure 1).

Overall, the sensors integrated in the WELMO vest secured the measurement of the following bio-signals: EIT through 256 (16 × 16) channels at 40 Hz, skin-electrode contact through 16 channels at 40 Hz, chest sounds through 6 channels at 5 kHz and accelerometry through 1 channel at 0.2 Hz.

The design of the sensor vest was accompanied by a risk management guided by ISO 14971. Relevant paragraphs of the standard IEC 60601-1 and of collateral standards were included in the design requirements and verified prior to the study presented in the manuscript. These included, for example, the limitation of the auxiliary current and of leakage currents, protection against harmful ingress of water, electromagnetic compatibility regarding emission and immunity. The sensor materials in contact with the skin have been tested for skin tolerance according to the standards of the ISO 10993 series.

2.3. Data acquisition, download and upload

A Dell PowerEdge workstation was deployed at the pilot study site. The workstation carried an Intel Xeon Processor E3-1220v2 (3.10 GHz, 8 MB Cache, Turbo, 4C/4 T, 69 W). It was extended with 32 GB RAM and a 500 GB SSD hard disk in order to meet the requirements for the efficient operation of the system. The operating system (Ubuntu) as well as the platform required to run the WELMO applications and services (Docker Engine) were installed. The WELMO 'healthcare professional' application allowed the study investigator to create and review individual study subject accounts.

A SamSung Galaxy S5 Lite tablet was used as the connecting device between a back-end server and the WELMO vest. A dedicated Android WELMO 'patient' application was installed on the tablet and configured to the local hospital network via a remote session with a third device with support from the local IT department. Specific considerations for the proper operation in the internal restricted environment were considered. The configurations were aiming to enable unobtrusive communication between the tablet and the WELMO back-end server taking the lack of internet access from the devices into account.

The WELMO 'patient' application allowed the authentication of the user and established the connection with the WELMO vest. During a recording session, a screen was presented to the user providing the instantaneous information on the recorded data, namely a waveform of the global electrical bio-impedance or of the chest sound at one selected sensor (see supplementary figure 1). The quality of the skin-electrode contact on all 16 sensors with EIT functionality was also shown. Additionally, the state of charge of the 'master' unit battery and the duration of recording were displayed. The user was also provided with the option to annotate the recording.

In summary, a WELMO connector service running on the tablet was responsible for two major tasks, to retrieve the data from the WELMO vest and to communicate with the WELMO back-end. From the user's perspective, the operation was simple since the investigator only needed to press the 'Start Recording' button in the WELMO 'patient' application and the WELMO connector sent the 'Start Recording' and the 'Start Streaming' commands to the WELMO vest. The 'Start Recording' command initiated the measurement of all signals, the storage of the signals on the 'master' and the continuous transfer of the measured data to the tablet. Note that the bandwidth of the used Bluetooth Low Energy protocol was not sufficient to send all data in real-time to the tablet. Therefore, the 'master' transmitted in real-time the subset of the measured data described in the paragraph above upon reception of the 'Start Streaming' command. When the user pressed the 'Stop Recording' button, the WELMO connector sent the 'Stop Recording' and the 'Stop Streaming' commands to the WELMO vest and returned the user to the main screen of the application and waited for the downloading of all the session data from the WELMO vest to the tablet to finish. The synchronization process that uploaded the multiplexed data file of all recorded bio-signals, the recording session's metadata and the manual signal annotations to the WELMO back-end was also automatically triggered by the WELMO connector.

2.4. Study participants

The study participants were recruited using a flyer and by personal communication. The intended number of study participants was 20 subjects with women and men equally represented. The inclusion criteria were: (1) age $\geqslant$ 18 years, (2) capacity to give a consent, and (3) signed informed consent form. The exclusion criteria were: (1) thoracic deformities, (2) history of previous chest surgery, (3) severe obesity, (4) foreign objects in the chest (pacemaker, surgical screws, etc), (5) history or presence of pulmonary disease, (6) history or presence of cardiovascular disease, (7) history or presence of moderate or severe general disease, (8) skin injury, inflammation or disease, (9) pregnancy or breast-feeding in women, and (10) physical handicap.

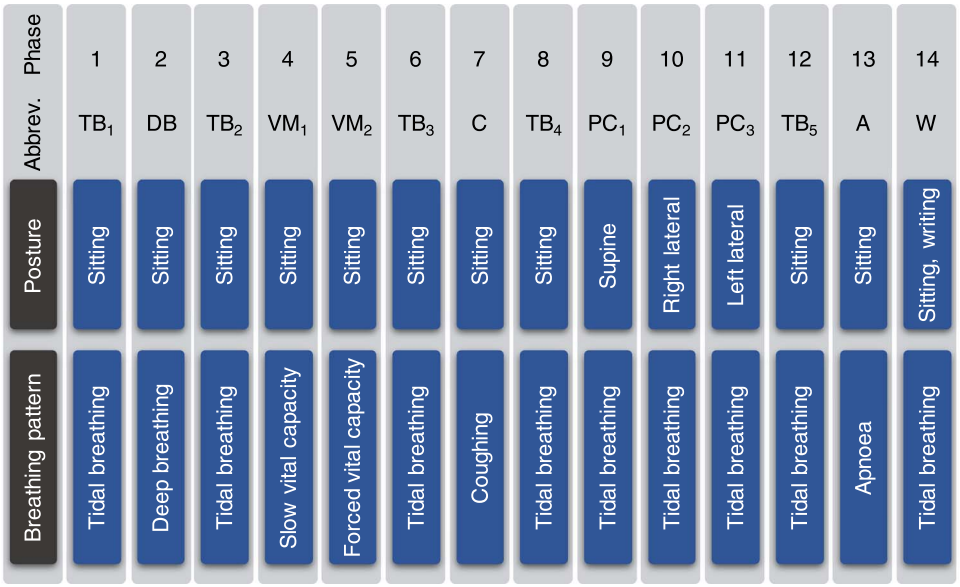

Figure 3. Study protocol. $TB_{1–5}$, quiet tidal breathing in sitting posture; DB, deep breathing in sitting posture; VM_1, slow full expiration manoeuvre in sitting posture; VM_2, forced full expiration manoeuvre in sitting posture; C, coughing in sitting posture; $PC_{1–3}$, quiet tidal breathing after posture change to supine, right and left lateral positions, respectively; A, apnoea in sitting posture; W, tidal breathing in sitting posture while filling out the questionnaire.

Table 1. Questionnaire for the assessment of vest properties and comfort of wearing.

Number	Survey statement
1	The garment is pleasant to wear on the skin.
2	I like the garment colour.
3	The vest is user-friendly.
4	The size and model fit to my body shape.
5	The vest has good temperature regulation.
6	The vest is pleasant to wear while sitting.
7	The vest is pleasant to wear while lying on the back.
8	The vest is pleasant to wear while lying on the side.
9	The putting on and taking off the vest causes no problems.
10	The vest can be worn with other clothes on top of it.
11	The vest does not limit my breathing.

2.5. Study protocol

Potential study participants were provided with an extensive oral and written information on the background, significance, aims, benefits, perspectives and possible risks of the WELMO pilot study. The signing of the information and consent form was the prerequisite for the inclusion in the study.

At the beginning of each individual examination, the study participants were allowed to familiarize with the WELMO vest. The subjects were trained regarding the individual steps of the study protocol that were later performed during the wearing of the vest. Afterwards the subjects put on the vest and assumed the initial upright sitting posture with their hands placed on their thighs and the examination with recording and streaming of data was started. Once the recording began no adjustments to the vest were performed. The individual steps of the study protocol are shown schematically in figure 3. The protocol comprised phases of quiet tidal and deep breathing, ventilation manoeuvres (slow and forced full expiration, coughing and apnoea). The subjects were studied in four different postures (sitting, supine, right and left lateral). In the final phase of the study protocol, the subjects´ perceptions regarding the vest properties and the comfort of wearing were acquired using a questionnaire. The survey comprised 11 statements (table 1) with an additional option of free text input. The scores were determined using the Likert scale with the following five response options: (1) strongly disagree, (2) disagree, (3) neither agree nor disagree, (4) agree and (5) strongly agree.

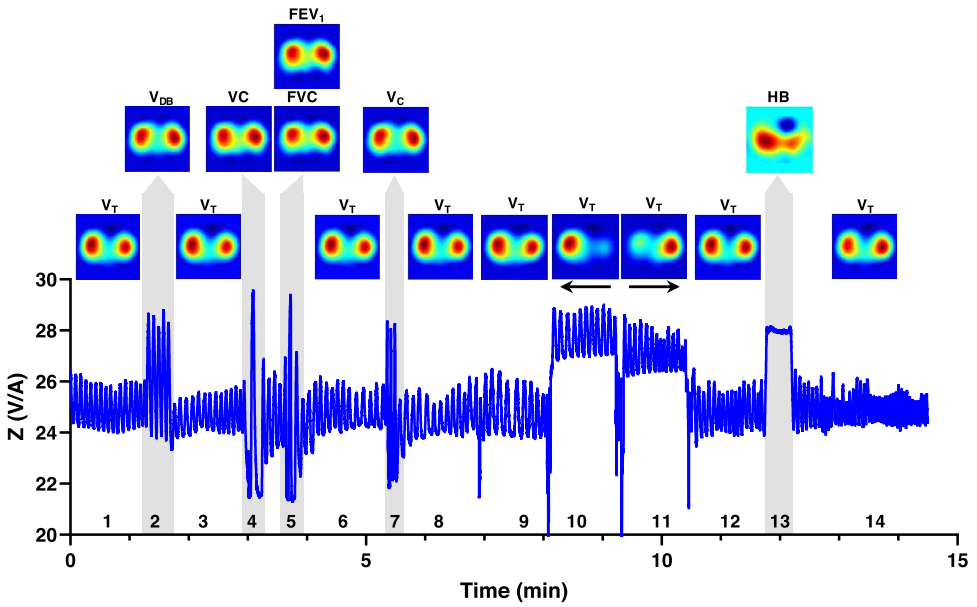

Figure 4. Global impedance (Z) waveform acquired in a 38 year old man during the whole study examination. The 14 phases of the study protocol are marked by numbers above the X axis. Autoscaled functional EIT images generated during each phase are shown at the top. The images visualize the distribution of ventilation during different types of breathing, with the exception of the image obtained during apnoea which shows the spatial distribution of heart-beat related impedance changes in the cardiac and pulmonary regions. The shifts in ventilation distribution toward gravity-dependent lung regions in the two lateral postures are indicated by arrows. V_T, tidal volume; V_{DB}, ventilated volume during deep breathing; VC, vital capacity; FEV_1, expiratory volume in 1 s; FVC, forced vital capacity, V_C, volume exhaled during coughing, HB, heart-beat related impedance variation.

After the completion of all study protocol steps, the subjects took the vest off. The upload of the recorded data from the central 'master' unit to the dedicated study tablet and the download of the session data from the tablet to the WELMO back-end server were automatically completed as described in section 2.3.

2.6. Data analysis

The EIT, chest sound and accelerometry data acquired during the clinical investigation was analyzed offline.

2.7. EIT

Primary EIT images were generated from the raw EIT data using the GREIT image reconstruction algorithm (Adler *et al* 2009). The global EIT waveforms were inspected for the presence of baseline drifts, step-like and spike-like artifacts (Yang *et al* 2022) in each phase of the 14-step study protocol. Functional EIT images were generated from the data acquired during each of these 14 phases (figure 4) and inspected for the presence of 'streak' and 'blob' artifacts (Adler *et al* 2009). If the physiological EIT signal variation associated with breathing and heart beat and none of the described artifacts were present in the waveform then the corresponding data of the respective protocol phase were classified as 'undisturbed'. Similarly, if the functional images visualized the lung regions and no artifacts were present then the corresponding image was classified as 'undisturbed'.

The following criteria were used to assess the quality of the whole recording comprising the 14-step examination period. If the EIT waveforms and functional EIT images of 13 to 14 phases were undisturbed the recording was classified as 'excellent', with 10 to 12 undisturbed phases as 'very good', with 7 to 9 undisturbed phases as 'good', with 4 to 6 undisturbed phases as 'fair', and with 0 to 3 undisturbed phases as 'bad'.

To assess the reproducibility of the EIT findings obtained with the WELMO vest, regarding the ventilation distribution in the chest cross-section, three functional EIT parameters, (1) the centre of ventilation in the ventrodorsal direction (CoV_{vd}), (2) the centre of ventilation in the right-to-left direction (CoV_{rl}), and (3) the coefficient of variation (CV) of pixel tidal impedance variation were calculated from the five phases where the subjects were repeatedly breathing quietly in the sitting posture. All three parameters were computed according to the consensus definitions of functional EIT parameters (Frerichs *et al* 2017). To evaluate the capacity of the WELMO vest to capture the gravity-dependent redistribution of ventilation, CoV_{vd}, CoV_{rl}, and CV were determined from the three examination phases where the subjects changed their body position from lying on their backs to the right and left sides. Repeated measures one-way ANOVA with Tukey's multiple comparisons test was applied to check if any significant differences existed between the different phases of the examination using GraphPad Prism v. 9.5.0 (GraphPad Software Inc., San Diego, CA, United States). Each p value was adjusted to account for multiple comparisons.

2.8. Chest sounds

All acoustic signals acquired by the six sensors with chest sound recording capacity were processed identically as follows. Since the original sound exhibited an interference from the system (remote powering of the sensors at 500 Hz), a comb filter to remove this interference and its harmonics was applied first. Afterwards an 8th-order high-pass filter with a cut-off at 100 Hz was applied to the comb-filtered sound to remove most heart sounds and low-frequency noises as the main frequencies of interest for the analysis of respiratory sounds are between 100 and 2000 Hz (Sarkar *et al* 2015).

The sounds were then divided into excerpts corresponding to the 14 phases of the study protocol. Three audio descriptors were extracted from the power spectrum (window size: 2 s; overlap: 50%) of the high-pass filtered sounds of each excerpt, namely the spectral flatness, roll-off, and centroid. Spectral flatness was defined as the ratio of the geometric mean to the arithmetic mean of a power spectrum and it was a measure of the noisiness of a spectrum (i.e. the flatter a spectrum, the noisier the signal was). Spectral roll-off estimated the amount of high frequency in the signal by finding the frequency value below which 95% of the total spectral energy was contained. Spectral centroid was the geometric centre of the spectrum's distribution.

Quantitative analysis of the sounds was based on the median values of these audio descriptors. An excerpt was deemed too noisy/disturbed if its spectral flatness was higher than 10% or its spectral centroid was higher than 1000 Hz or its spectral roll-off was higher than 2100 Hz. Spectral flatness quantified the similarity of the sound with ideal white noise (Agus *et al* 2018) whereby at the threshold of 10% about 25% of white sound would be present. Since most respiratory sound frequencies are lower than 1000 Hz (Bohadana *et al* 2014, Sarkar *et al* 2015), this threshold value was chosen in the case of the spectral centroid descriptor. The spectral roll-off threshold was set to 2100 Hz to ensure that the spectral energy was below the interesting frequency range (with a 100 Hz buffer). The criteria used to assess the quality of the sound recordings during the whole 14-step examination period (excellent to bad) were the same as in case of EIT.

Because the study was performed on healthy subjects with lacking pathological lung sounds like crackles or wheezes, we additionally analyzed the sound signals regarding the presence of the physiological heart sounds as follows. First, the comb-filtered sounds were band-pass filtered between 20 and 200 Hz to consider the most intense frequencies (Reichert *et al* 2008). Then, the sound signals were split into the 14 excerpts representing each phase of the study protocol and the auto-correlation peaks between 60 and 120 Hz were computed in each phase. This approach allowed the identification of a stable heartbeat between 60 and 120 beats per minute as previously shown (Yuenyong *et al* 2011, Deng and Han, 2016). Finally, if any peak exceeded 5% then the corresponding excerpt was found to contain audible heart sounds. The quality classification of the whole recordings followed the same criteria as mentioned above.

2.9. Accelerometry

The accelerometer signal could assume five categorical values: 0: unclassified signal (recorded during, e.g. position changes), 1: lying position, 2: upright position, 3: walking, 4: running. Thus, it could determine the body position and activity. The value of the accelerometer signal was determined in each of the 14 examination phases and the correct identification of the three lying positions and the eleven upright positions was checked. The assessment of the overall quality of posture identification followed the same rules as in case of EIT and chest sound recordings.

2.10. Questionnaire

The individual scores for each statement of the paper-based questionnaire were transferred to an electronic data sheet and analyzed using GraphPad Prism v. 9.5.0 (GraphPad Software Inc., San Diego, CA, United States). The survey results are reported as histograms of the ratings and median values. In addition, fractions of positive scores representing the ratings 'Agree' with a value of 4 and 'Strongly agree' with a value of 5 were calculated.

3. Results

3.1. Study cohort

Twenty-seven healthy adults were screened. Seven subjects were discarded because the study sensor vests were too small for their bodies and because of a history of thoracic surgery in one subject, which was one of the study exclusion criteria. Twenty subjects (10 women and 10 men) with a mean age $\pm$ SD of 39 $\pm$ 12 years were included in the study. The oldest study participant was 65 years, the youngest 23 years old. The body weight of the subjects was 67 $\pm$ 9 kg (range 50–82 kg), the body height was 173 $\pm$ 8 cm (range 158–185 cm) and the body mass index (BMI) was 22.3 $\pm$ 2.0 kg m^{-2} (range 19.1–26.7 kg m^{-2}).

3.2. Study duration

The average duration of the participant's examinations from the inclusion till the end was 49 ± 9 min. The variation of this time was mainly related to the differences in the time needed to explain the study goals, the function of the WELMO vest and the study protocol to the participants. The time during which the WELMO vests recorded the data in the subjects according to the study protocol was shorter. The average duration was 934 ± 59 s. The maximum duration was 1054 s and the minimum 811 s. The major factor affecting the duration of the recording was the time of the survey, which represented the final phase of the study protocol. All 20 study participants completed the full study protocol.

3.3. Study data acquisition

All female and male WELMO vests provided for the pilot clinical examination were utilized during the study. The female vest size 75 was used four times, the female vest size 80 six times, the male vest size 90 five times and the male vest size 95 five times. The use of the vests within the study was smooth and not associated with any problems, except for the male WELMO vest size 90, in which a wire connecting the guard/reference electrode with the central 'master' unit broke. This was detected after the examination of participant number 14 in whom the streamed EIT and sound signals exhibited no ventilation-related modulation. The measurements of EIT and sound signals in this subject but also in the subject 8, who wore the same vest on the previous occasion, were affected and could not be used for further analysis.

The WELMO 'health care professional' and 'patient' applications were fully operational in all 20 study participants. They secured the following core tasks in the pilot: (1) the user authentication, (2) the control of the WELMO vest operation, (3) the download of all recorded data to the tablet with live visualization of the EIT or sound waveform and sensor contact quality, and (4) the upload of the recorded data to the WELMO back-end server. The data upload to the back-end was finished 3–4 min after the end of each recording session.

3.4. Primary outcome

The primary outcome of the pilot clinical investigation of the WELMO wearable documents the presence and plausibility of the bio-signals recorded by the vests. The following three text sections describe the results obtained regarding the EIT signals, the chest sounds, and the body position/activity signal.

3.4.1. EIT

A total of 675 240 primary EIT images were acquired in the study. As shown in an example recording of one of the studied subjects (figure 4), the WELMO vests ware able to measure the instantaneous changes in chest electrical bio-impedance, to capture the typical ventilation-related impedance variation associated with breathing at various dissimilar breathing patterns and to visualize the ventilation distribution in the chest cross-section. As expected, EIT signals obtained during quiet breathing exhibited the least number of disturbances in all examined body postures compared with those recorded during the two full expiration manoeuvres and coughing (figure 5(a)). Consequently, also the functional EIT ventilation images generated from the periods of quiet breathing in both upright and lying postures exhibited hardly any disturbances (figure 5(b)).

The overall assessment of the quality of the acquired EIT data revealed that 89% of the recorded EIT waveforms were of good to excellent quality (figure 6). Similarly, 89% of the generated functional EIT images exhibited good to excellent quality (figure 6). The functional tidal ventilation images obtained repetitively under identical quiet breathing conditions in sitting posture revealed comparable ventilation distribution in all five phases as quantified by CoV_{vd}, CoV_{rl} and CV (supplementary figure 2). Posture change to the right and left side induced a redistribution of ventilation toward the dependent lung which was correctly identified by the WELMO vests (supplementary figure 2).

3.4.2. Chest sounds

Noisy acoustic signals were detected in only a small number of the studied subjects (figure 7 and supplementary figures 3–8). The highest incidence of noisy signals (in 2 to 6 subjects, depending on the sensor location) was found during the last phase of the study protocol when the subjects were filling in the questionnaire. As expected, the presence of signals with audible heart sounds was lower than that of non-noisy signals (figure 7 and supplementary figures 3–8). The results pertaining to the overall quality of sound recording for the whole study period are presented in figure 8. The highest proportion of heart sounds with excellent quality was observed in the recording obtained by the sensor located at the front left bottom part of the chest.

3.4.3. Accelerometry

The posture/activity recording did not correctly identify the body positions in the WELMO study participants number one to three. This was caused by a mistakenly used older version of the algorithm which calculated the

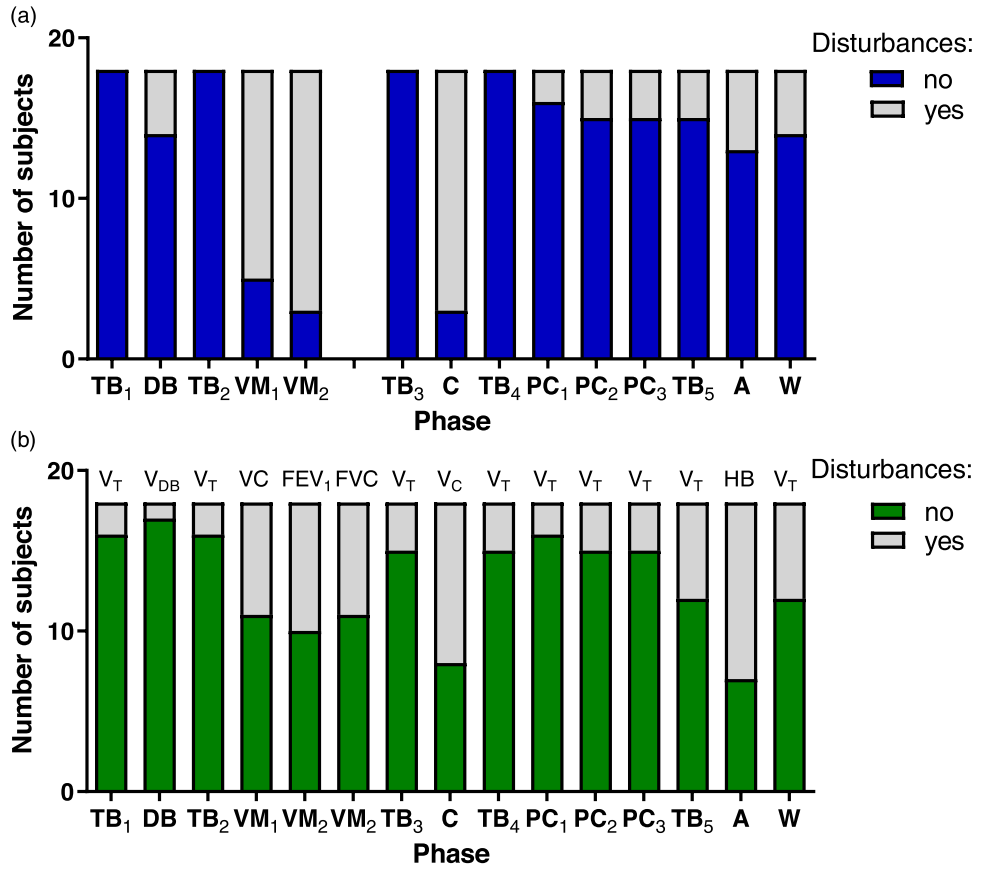

Figure 5. Presence and absence of disturbances in the EIT waveforms (a) and functional EIT images (b) in 18 study subjects during all 14 phases of the study protocol. TB_{1-5}, tidal breathing in sitting position; DB, deep breathing in sitting position; VM_1, ventilation manoeuvre with slow full expiration from total lung capacity in sitting position; VM_2, ventilation manoeuvre with forced full expiration from total lung capacity in sitting position; C, coughing in sitting position; PC_1, tidal breathing after posture change to supine position; PC_2, tidal breathing after posture change to right lateral position; PC_3, tidal breathing after posture change to left lateral position; A, apnoea in sitting position; W, tidal breathing during writing in sitting position; V_T, tidal volume; V_{DB}, ventilated volume during deep breathing; VC, vital capacity; FEV_1, expiratory volume in 1 s; FVC, forced vital capacity, V_C, volume exhaled during coughing, HB, heart-beat related impedance variation.

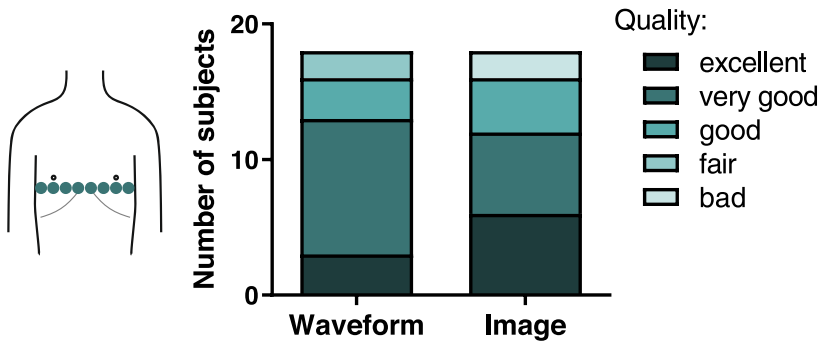

Figure 6. Overall quality assessment of the EIT recordings regarding the EIT waveforms and functional images. The location of the sensors for EIT measurement is shown in the schematic drawing of the upper torso.

orientation of the 'master' from the data acquired by the accelerometer sensor. The mistake was corrected and the identification of body posture became highly reliable in the subsequent 17 subjects (figure 9). Consequently, the overall quality of the accelerometer signals was rated as excellent (figure 10).

3.5. Secondary outcomes

The secondary outcomes document the safety of the WELMO vests and the comfort of wearing and their acceptance by the end-users.

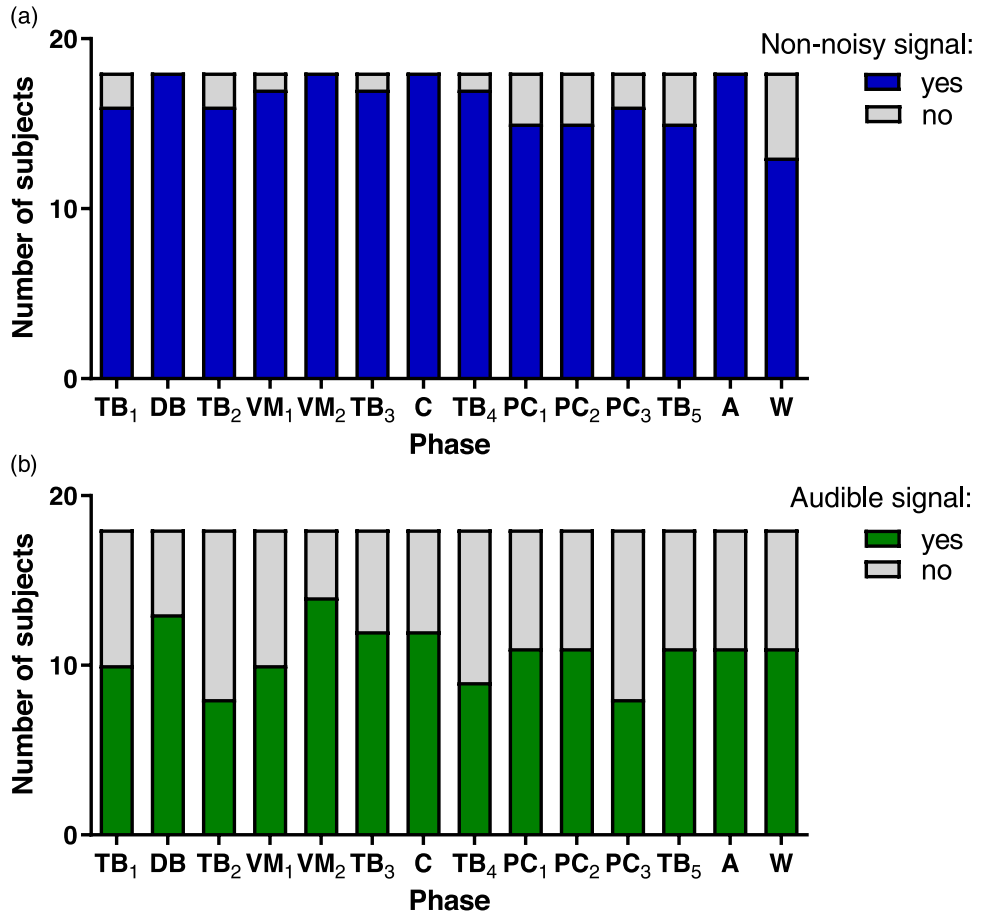

Figure 7. Presence and absence of non-noisy chest sounds (a) and acoustic signals with audible heart sounds (b) at the sound-recording sensor located at the top left front chest in 18 study subjects during all 14 phases of the study protocol. TB_{1-5}, tidal breathing in sitting position; DB, deep breathing in sitting position; VM_1, ventilation manoeuvre with slow full expiration from total lung capacity in sitting position; VM_2, ventilation manoeuvre with forced full expiration from total lung capacity in sitting position; *C*, coughing in sitting position; PC_1, tidal breathing after posture change to supine position; PC_2, tidal breathing after posture change to right lateral position; PC_3, tidal breathing after posture change to left lateral position; *A*, apnoea in sitting position; *W*, tidal breathing during writing in sitting position.

The WELMO vests were considered safe because no adverse events occurred in any of the studied subjects during the whole investigation.

All 20 study participants filled in the questionnaires with the survey. The quantitative results are presented in figure 11. The overall scores were high with the median values not smaller than 4, with the highest possible score being 5. The highest scores were obtained regarding the quality of the garment and the pleasantness of the skin sensation while wearing the vest with a median value of 4.5 and the absence of any effect restricting the breathing with a value of 5. The percentages of positive and highly positive responses to the survey statements ranged from 60% to 90%. The highest fractions of positive and highly positive scores were noted for the tactile and thermoregulatory properties of the garment, both with 90%. The lowest score with a value of 1, indicating strong disagreement with a survey statement, was crossed only twice in the whole survey. In both cases this was related to the colour of the vest. The male subjects 7 and 17 did not like the grey colour of the male vest in size 95.

4. Discussion

The first clinical investigation of the WELMO vest, a new wearable device with advanced respiratory monitoring, was successfully conducted in a cohort of healthy adult subjects with equal gender participation. The WELMO 'health care professional' and the WELMO 'patient' applications were operational in the course of the whole study. The functionality of the WELMO system was generally confirmed and all intended bio-signals were recorded. (However, it needs to be mentioned that one of the study vests ceased functioning during the study because of a broken wire between the central 'master' unit and the guard electrode.) The safety of the WELMO vests was verified. The properties of the vest and the comfort of wearing were positively rated by the study participants.

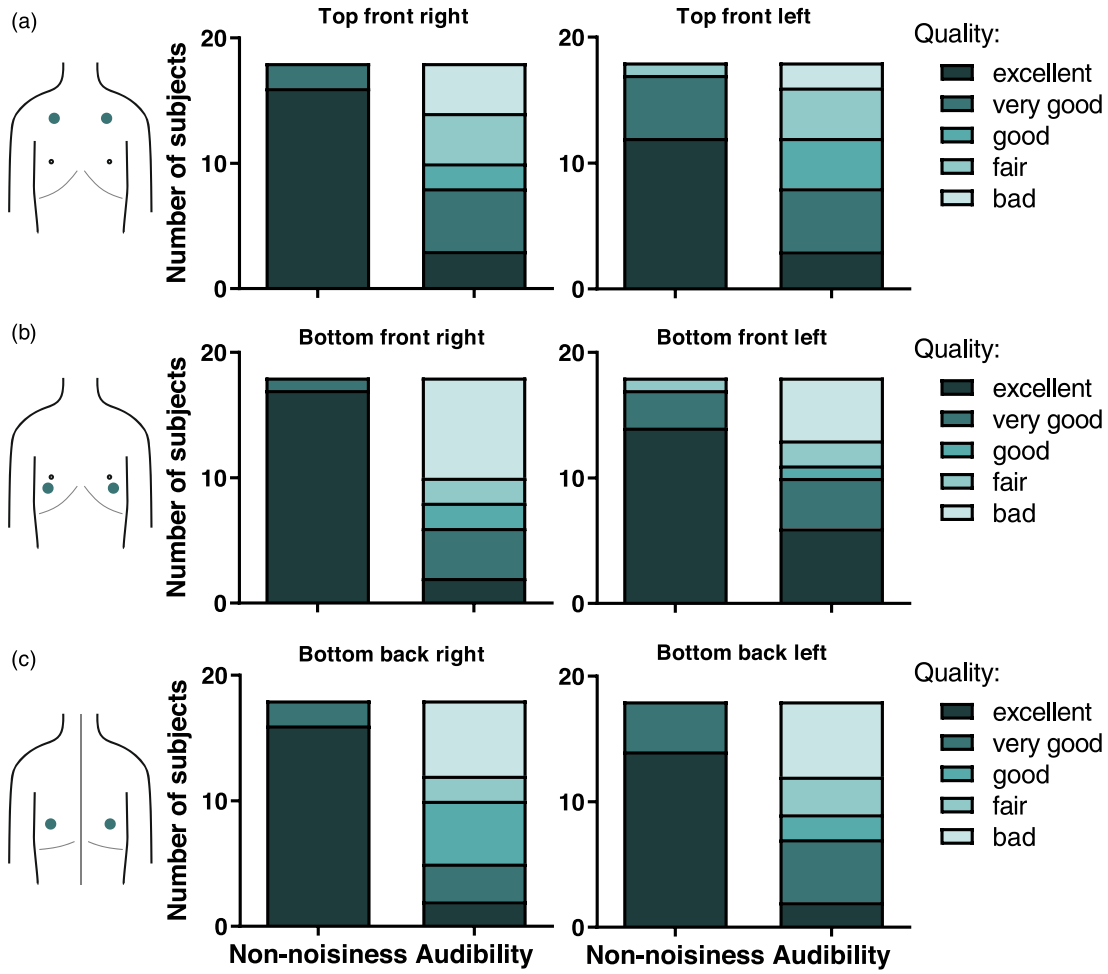

Figure 8. Overall quality assessment of the chest sound recordings for the whole study cohort at the two top front chest sensor locations (a), the two bottom front chest locations (b) and the two bottom back chest locations (c). The respective locations of the sensors are marked in the schematic drawings of the upper torso left to the diagrams.

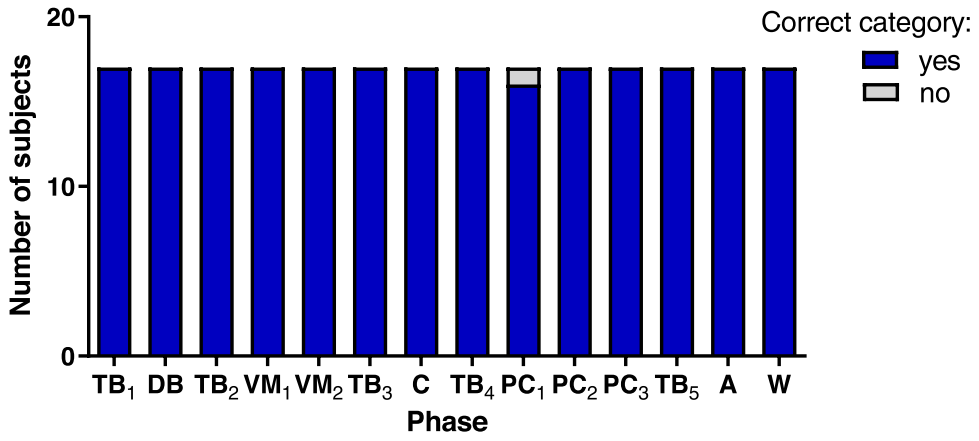

Figure 9. Presence and absence of correctly categorized accelerometer signals in 17 study subjects during all 14 phases of the study protocol. TB_{1-5}, tidal breathing in sitting position; DB, deep breathing in sitting position; VM_1, ventilation manoeuvre with slow full expiration from total lung capacity in sitting position; VM_2, ventilation manoeuvre with forced full expiration from total lung capacity in sitting position; *C*, coughing in sitting position; PC_1, tidal breathing after posture change to supine position; PC_2, tidal breathing after posture change to right lateral position; PC_3, tidal breathing after posture change to left lateral position; *A*, apnoea in sitting position; *W*, tidal breathing during writing in sitting position.

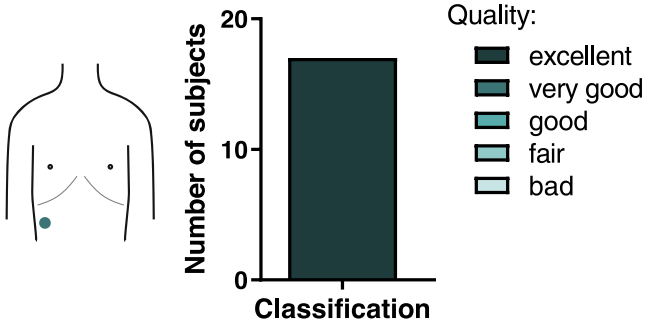

Figure 10. Overall quality assessment of the body position and activity recordings in 17 study subjects. The location of the accelerometer is marked in the schematic drawing of the upper torso.

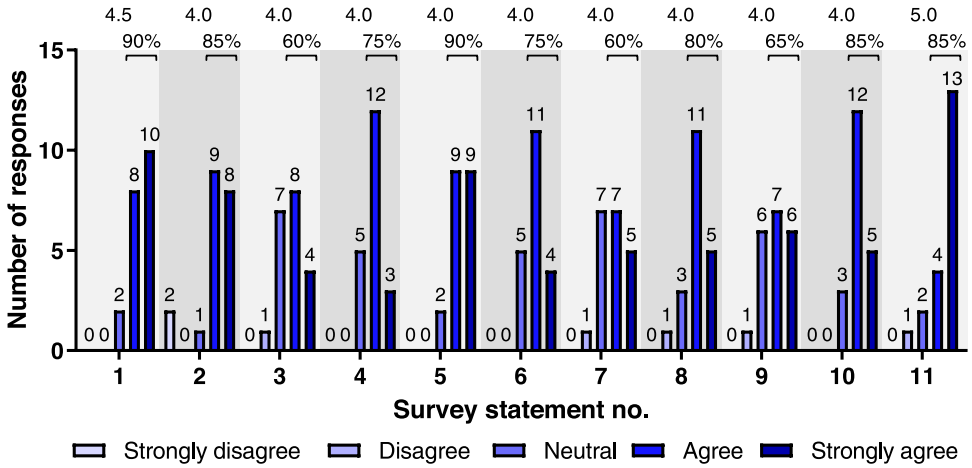

Figure 11. Results of the survey on vest properties and comfort of wearing conducted among all study participants. (See table 1 for the 11 statements of the questionnaire). The numbers in the top part of the diagram show the median values of the Likert scale ratings and the percentages of positive responses to each statement. The numbers directly above the individual columns indicate the numbers of subjects providing the respective response.

4.1. Data streaming

One of the positive findings of the study was that data streaming and download were fully operational and user-friendly. The waveform of the global EIT or chest sound signal was presented to the examiner in real time on the tablet screen and the quality of the electrode-skin contact at all sensors involved in EIT data acquisition, as an important feedback information, was also continuously visualized. The download of data from the central 'master' unit and the upload to the back-end server were completed within just a few minutes after the completion of the examination. The applications required only minimum inputs from the user and they never crashed during the study.

This is a significant progress compared with the previous WELCOME vest (Frerichs *et al* 2020). That wearable device did not provide a real-time visualization of the EIT and sound signals and the quality of electrode-skin contacts of only half the sensors involved in EIT measurement was shown to the user. The procedures of data download and upload of the former device lasted more than one hour and they were instable. Besides, they needed to be separately initiated by the user. Because of a higher power consumption than in the current WELMO vest, the central unit of the older WELCOME vest needed to be recharged between the download and upload of the data. All the stated differences in the performance of the connector functions of the current and former wearable highlight the improvements achieved and the reliability of the present WELMO system.

4.2. Primary outcome

The primary end-point was achieved. All intended bio-signals (electrical bio-impedance, chest sounds, posture/activity signal) were recorded.

The quality of the EIT data acquired by the WELMO vest was much higher than in the former WELCOME vest: 89% of the waveforms and 89% of the functional ventilation images exhibited good to excellent quality whereas only 68% of the waveforms and 46% of the images obtained by the WELCOME vest were undisturbed. Multiple factors contributed to this improved EIT signal quality. The WELMO sensors were about 30% smaller and 40% lighter (Chételat *et al* 2022) than the old WELCOME sensors. Thanks to these reduced dimensions and weight the sensors could more easily establish and keep their position on the chest with a stable contact with the skin despite breathing movements. The unreliable snap buttons, used to fix the sensors in the older WELCOME vest, were replaced by dedicated circuit boards integrated in a special harness which additionally ensured an excellent skin contact. The contact was further improved by the new multi-layer structure of the garment using elastic fabrics in a new design with added padding at those sensor locations with potentially higher probability of losing contact, like near the backbone. Besides, the examiner had the possibility to check the quality of the skin-electrode contact of all sensors with EIT functionality before the initiation of recording. Thus, if low contact quality was detected in any of the sensors a slight repositioning by hand from the outside could be performed before data acquisition to improve it. Finally, the EIT image resolution of the WELMO system was higher than of the WELCOME system (supplementary figure 9). The WELMO vest offered 256 (16 × 16) independent measurements of transthoracic bio-impedance per each scan cycle whereas the former vest only performed 64 (8 × 8) measurements (Rapin *et al* 2019) which often resulted in confluent right and left lung regions (Frerichs *et al* 2020).

The EIT recordings showed ventilation-related impedance changes during all types of breathing in all study participants except for the two subjects who wore the male vest with the broken wire connecting the 'master' unit with the guard electrode. The tidal impedance variation was smaller during quiet tidal breathing than during deep breaths and the largest impedance variation was observed during the two full expiration manoeuvres. The fraction of waveforms with excellent quality was lower than that of the images (figure 6). This is attributable to the fact that signals with occasional disturbances, like spike artifacts, could still render excellent images if they were not disturbed during exactly those timepoints needed for the functional image calculation. Ventilation distribution between the right and left lung regions was symmetrical in the upright and supine positions. In the two lateral body positions, the WELMO vest identified a significant shift in ventilation toward the dependent lung which corresponded to the known physiological gravity-dependent redistribution of ventilation in these postures (Kaneko *et al* 1966, Milic-Emili *et al* 1966). The ventilation distribution under identical conditions of quiet breathing and sitting posture was reproducible. During apnoea, no ventilation-related impedance changes were present, only the much smaller heart-beat related impedance variation was detectable, as expected.

Our study confirmed that the WELMO vests were able to record the chest sounds at all six chest locations in parallel. This was a major improvement compared with the WELCOME vest since the sound signals recorded by that wearable were of such a low signal quality that no ventilation-related signal modulation was detected and no sound analysis was feasible at all. In spite of much better signal quality, the capacity of the WELMO vest to detect pathological lung sounds could not be tested in our pilot clinical investigation because it was conducted in healthy subjects. A different cohort of patients suffering from lung diseases, in whom such abnormal sounds are present, needs to be recruited for that purpose in a future study. The results of the quantitative and qualitative sound analysis of the current sound data imply that continuous adventitious sounds, like wheezes, can be expected to be detectable in patients. However, discontinuous adventitious sounds, like crackles with short durations typically below 20 ms (Rocha *et al* 2019), might be harder to differentiate from the possible underlying noise. This became evident especially in one of the current male participants (subject 7) with excessive chest hair in whom the acoustic signals were noisy with inaudible physiological sounds. Coughing was detectable in all study participants.

Although not primarily part of respiratory monitoring, the recorded chest sound signals produced audible heart sounds of good to excellent quality in 44% to 67% of the subjects, depending on the sensor location. The proportion of excellent heart sound quality was the highest over the left bottom front part of the chest which was anticipated based on the heart vicinity. The WELMO vest was developed with the main aim of proving that EIT and chest auscultation can be achieved in parallel in a fully wearable design suitable for remote monitoring but the addition of automated heart sound analysis along with ECG recording and heart rate measurement could be easily added to allow combined assessment of both respiratory and cardiovascular events. This was successfully realized in earlier wearable devices (Rapin *et al* 2019, Frerichs *et al* 2020) where the sensors were locally powered (i.e. each sensor had a battery) but omitted in the WELMO vest to minimize the considerable development risks linked to the implementation of novel central powering of all sensors from a single battery placed inside the 'master'.

The accelerometer sensor was functioning properly in the current study and the changes in body posture during the study protocol phases 9–11, when the study participants changed their position from sitting to three lying positions, were correctly identified. The posture/activity signal showed the categorical value of 0 (i.e.

unclassified position/acceleration) only during the very short transitions between body positions and occasionally during the forced ventilation or coughing in those subjects who temporarily moved their torsos forward.

4.3. Secondary outcomes

The study confirmed that no safety concerns existed related with the use of the WELMO vests. No adverse events were observed in the whole study cohort.

General performance and comfort of wearing of the WELMO system was positively rated. The survey revealed positive assessments of the wearing comfort in all body positions, easy putting on and taking off the vest, pleasant tactile perception and good thermoregulatory properties of the used textile. The survey also demonstrated that the WELMO vests for women and men fitted well to the female and male bodies of various sizes and shapes and that they did not limit the chest movement during breathing. This confirmed the proper function of the harness that secured good sensor contact with the skin but at the same time did not induce any sensations of restricted ventilation movements. With this respect, the WELMO vest scored by one point higher than the older WELCOME vest, which induced a feeling of chest restriction in a higher proportion of subjects but still without securing reliable skin-electrode contact.

In spite of the overall positive outcome of the survey, the perceptions of the users need to be obtained also from frail patients with chronic respiratory diseases whose feedback might differ from the healthy subjects and provide information for further design improvements. A previous study has demonstrated differences between healthy subjects and patients by showing a reduction of objective lung function measures by the silicone EIT electrode belt of a commercial non-wearable EIT device only in patients but not in healthy subjects (Zhang *et al* 2020). The wearing of a well-fitting vest is essential for the favourable subjective assessment of the vest properties and the quality of the recorded bio-signals. Personalized vests produced for individual patients can be expected to improve both of these aspects in the future.

4.4. Comparison with other respiratory monitoring systems with EIT and electronic stethoscopes

The comparison of the WELMO wearable with its direct predecessor, the WELCOME vest, was provided in detail in the above sections of the Discussion. In short, the WELMO vest outperformed the WELCOME vest in the majority of its features. The quality of the EIT and acoustic signals was improved and the resolution of the EIT images and audibility of physiological sounds was increased. The vest properties were positively evaluated by the study participants, in those assessments that were common in the surveys on the two wearables, the WELMO vest always received higher or identical scores. The WELMO connector services were functional and user-friendly. The download of full signal data occurred in near real-time and the upload was quick and automated.

To the best of our knowledge, there exist no other wearable devices providing both the EIT and chest sound recording functionality. However, patients with chronic lung disease might benefit from such extended monitoring with included imaging. As evidenced by the recent initiative towards earlier and more precise diagnostics of COPD and its exacerbations (Stolz *et al* 2022), advocating abandoning the 'over-reliance on spirometry', the role of lung imaging needs to be advanced. EIT, as a non-invasive and radiation-free method with a capacity to detect the increased ventilation heterogeneity in COPD patients, might contribute to limiting the burden of COPD. Although the commercial EIT devices are not large and they are placed on wheels, the examined patients need to be directly connected with them. In that sense, the existing devices are moveable but certainly not wearable and not suitable for mHealth applications. Also, the commercial EIT interfaces have been optimized for the specific use in lying, immobile and mechanically ventilated patients not in upright, moving and spontaneously breathing subjects. Except for the current WELMO and the former WELCOME vest, other wearable EIT devices were introduced by Hong *et al* (2015) and Zouari *et al* (2022). The former device uses a silicone electrode belt and a mobile phone, however, the two need to be connected by a USB cable. The latter device uses a belt into which sticky electrodes for single use are inserted before application on the chest and a mobile phone connected with a cable. A certain disadvantage of these two solutions is that the users might not place the belts at an identical chest plane during repetitive intermittent examinations on separate days. This will affect the reproducibility and the comparability of results because of the known dependence of EIT findings on the examination plane (Reifferscheid *et al* 2011, Karsten *et al* 2016, Braun *et al* 2018, Zhao *et al* 2022). This drawback does not exist in the WELMO vest, where the anatomical sensor locations are always the same thanks to the direct integration of sensors into a wearable garment. This was checked by inspecting the faint imprints of the sensors on the skin at the end of each examination with no signs of shifted position detected. Besides, the wearables proposed by Hong *et al* (2015) and Zouari *et al* (2022) do not offer multimodal bio-signal acquisition but only EIT.

The acquisition of acoustic signals in parallel to EIT is a meaningful approach since it can detect continuous and discontinuous abnormal lung sounds and coughing. This may contribute to an early diagnosis of an acute

exacerbation and/or failing therapy in a chronic lung disease in case of longitudinal patient examinations. The stored sound signals moreover allow an objective user-independent computerized analysis. Previously described wearable stethoscope systems offer respiratory sound recordings at only one or two locations in parallel (Au *et al* 2022, Emokpae *et al* 2022). By using simultaneously six sensors for acoustic recordings, the WELMO vest covers multiple lung lobes. Besides, the WELMO vest guarantees the sound signal sampling at exactly the same locations using dry sensors which is not necessarily given in case of the adhesive sensors of the other two mentioned wearables that need to be attached separately, possibly with the help of another person.

4.5. Study limitations

Our clinical investigation was carried out on a relatively small cohort of 20 subjects. This was considered a convenient sample for the initial functional validation of the WELMO vest design. It was also associated with the availability of only a limited number of vest prototypes and other time and funding constraints related to a multi-party consortium project. Because the study was designed as the first pilot, it was only conducted in healthy subjects with normal BMI. (Only one subject had a BMI >25 kg m^{-2}). In order to verify the full functionality of the sound recordings to detect pathological lung sounds, a clinical study on patients with acute and/or chronic lung diseases is needed. Such a cohort will also be necessary to confirm the capacity of the WELMO vests to detect longitudinal changes in ventilation inhomogeneity and presence of pathological lung sounds in the course of either deterioration of a lung disease or therapy in contrast to the current study where the subjects were examined only on a single occasion. Finally, the WELMO vest generates EIT images only from the caudal and not cranial lung regions. This is comparable to all commercial EIT devices that also offer the placement of the EIT electrode interface in just one plane. Although the principle of multiplane or 3D EIT has been described decades ago (Metherall *et al* 1996) the practical realization is still lacking. However, further miniaturization of the sensors with reduced power consumption can be expected to offer the possibility of increasing the overall number of sensors integrated in the wearable and extending the chest sections assessed by EIT in the future.

5. Conclusion

Our study confirmed the basic functionality, safety and user acceptance of a novel wearable device for advanced respiratory monitoring with included functional lung imaging by EIT and chest sound recordings at six locations in parallel. The also contained accelerometry determined reliably the body posture. The WELMO vests obtained the intended bio-signals during quiet breathing and a variety of breathing patterns, including deep breathing, slow and forced full ventilation manoeuvres and apnoea in four different postures. The WELMO system provided a fully functional download and upload of recorded data and is thus suitable for remote monitoring.

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Data availability statement

The data cannot be made publicly available upon publication due to legal restrictions preventing unrestricted public distribution. The data that support the findings of this study are available upon reasonable request from the authors.

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