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Validation and user experience of a dry electrode based Health Patch for heart rate and respiration rate monitoring

Jonathan C. J. Wei[1], Tim J. van den Broek[1], Jan Ubbo van Baardewijk[3], Robin van Stokkum[4], Regina J. M. Kamstra[1], Lars Rikken[2], Kaj Gijsbertse[3], Natallia Eduarda Uzunbajakava[2]✉ & Willem J. van den Brink[1]✉

Successful implementation of remote monitoring of vital signs outside of the hospital setting hinges on addressing three crucial unmet needs: longer-term wear, skin comfort and signal quality. Earlier, we developed a Health Patch research platform that uses self-adhesive dry electrodes to measure vital digital biomarkers. Here, we report on the analytical validation for heart rate, heart rate variability and respiration rate. Study design included $n = 25$ adult participants with data acquisition during a 30-minute exercise protocol involving rest, squats, slow, and fast cycling. The Shimmer3 ECG Unit and Cosmed K5, were reference devices. Data analysis showed good agreement in heart rate and marginal agreement in respiratory rate, with lower agreement towards higher respiratory rates. The Lin's concordance coefficient was 0.98 for heart rate and 0.56 for respiratory rate. Heart rate variability (RMSSD) had a coefficient of 0.85. Participants generally expressed a positive experience with the technology, with some minor irritation from the medical adhesive. The results highlighted potential of this technology for short-to-medium term clinical use for cardiorespiratory health, due to its reliability, accuracy, and compact design. Such technology could become instrumental for remote monitoring providing healthcare professionals with continuous data, remote assessment and enhancing patient outcomes in cardiorespiratory health management.

Remote monitoring including biometric parameters, vital signs as well as other biophysical and biochemical biomarkers is revolutionising healthcare enabling prevention, improving patient outcomes, reducing hospitalisations and hospital re-admissions as well as healthcare personnel workload[1]. The development and validation of digital biomarkers, actively relying on remote and continuous monitoring of biophysical and biochemical read-outs, is gaining a momentum and further accelerates the healthcare transformation[2]. A digital biomarker is defined as "an indicator of a (patho)physiological process, or a response to a (therapeutic) intervention collected by a wearable or a system of sensors and processed by algorithms, generating a real-time digital signal and enabling frequent, (quasi) continuous non-invasive monitoring under daily life conditions"[3]. In recent years, digital biomarkers have emerged in various fields such as cardiovascular disease, neurodegenerative diseases, diabetes, sleep medicine, oncology, and more. Some digital biomarkers are relatively straightforward, e.g., using pulse rate to detect atrial fibrillation[4]. Patterns of more than one vital signs (quasi) continuously and non-invasively collected over daily life could conceptually provide additional information on (patho)physiological processes[5], e.g. continuous data collection on heart rate patterns over daily life can define a digital inflammation biomarker[6]. Key vital signs such as heart rate (HR) and heart rate variability (HRV), already can shed light on a patient's cardiovascular health, autonomous nervous system and stress levels[7–9]. Expanding beyond HR and HRV, respiration rate (RR) is likely a useful biomarker for assessing respiratory and pulmonary health and overall well-being[10]. While these vital signs are viewed as standalone digital biomarkers, in a clinical context, they can be used synergistically to define intricate, multimodal digital biomarkers that can indirectly indicate various health conditions, such as inflammation and disease progression[11].

[1]Microbiology & Systems Biology, TNO (Netherlands Organisation for Applied Scientific Research), Leiden, The Netherlands. [2]Holst Centre, TNO (Netherlands Organisation for Applied Scientific Research), Eindhoven, The Netherlands. [3]Human Performance, TNO (Netherlands Organisation for Applied Scientific Research), Soesterberg, The Netherlands. [4]Risk Analysis for Products in Development, TNO (Netherlands Organisation for Applied Scientific Research), Utrecht, The Netherlands. ✉email: natallia.uzunbajakava@tno.nl; willem.vandenbrink@tno.nl

Quantitative parameters	Min-max	Mean ± SD
Age (years)	24–58	36 ± 11
Height (cm)	158–196	180 ± 11
Weight (kg)	50–104	77 ± 13
BMI (derived, kg/m^2)	20–29	24 ± 3
Categorical parameters	**Category**	**Tally (%)**
Gender	M	14 (56%)
	F	11 (44%)

Table 1. Demographics of the volunteers recruited for the study.

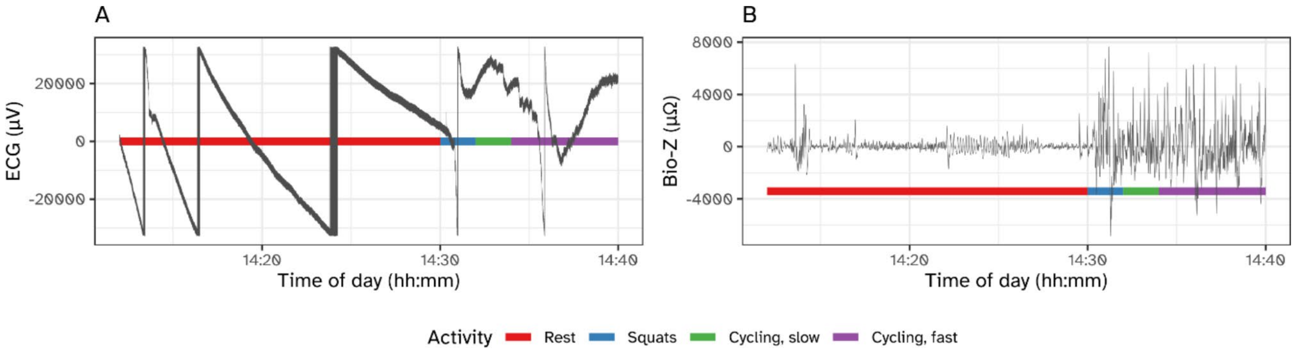

Fig. 1. Representative sample of raw ECG sensor output (**A**) and bioimpedance sensor output (**B**) from one participant (volunteer #12) during the entire period of the test, consisting of rest, squats, slow and fast cycling.

Over the last decade, medical-grade patch technology has emerged, allowing for wearable, wireless, user-friendly ECG monitoring[12]. Other wearable designs have also been explored, including a watch or ring format[13,14] and integration into textiles[15]. Essentially, innovation in vital signs patches for remote monitoring of ECG and vital signs has three key unmet needs: longer-term wear to capture the signals for two weeks' time and longer, skin comfort and high quality medical-grade signal. However, currently available medical grade vital signs patches mostly rely on gel electrodes and therefore have limited skin wear time, can cause skin irritation and discomfort and are prone to motion artefacts[16,17]. Self-adhesive dry electrode technology, designed for capturing bio-electric signals without using gel, shows promise in meeting these requirements. It can extend electrode wear time and enhance comfort compared to gel electrodes, and reduce motion artefacts via more secure skin attachment. Previously, a Health Patch research platform has been developed featuring self-adhesive dry electrodes for acquisition of ECG and bioimpedance for estimation of the heart rate and respiration rate. The Health Patch also includes three-axis accelerometry allowing activity monitoring and registration of motion artefacts. The ECG signal quality of the Health Patch has been evaluated and compared to the gold standard in a small pilot[18]. However, no analytical validation of the heart rate and respiration rate vs. gold standard was reported, while such validation is essential for medical-grade requirement before deriving digital biomarkers of cardiorespiratory health. To overcome these limitations and to further unveil the potential of such research platform for the development of medical-grade digital biomarkers, the primary objective of this study was to perform analytical validation of the Health Patch for monitoring of the heart rate vs. the gold standard reference devices on a larger cohort of participants, balancing where possible in key demographics such as gender. The secondary objective was to evaluate the accuracy of the device to measure heart rate variability and respiration rate vs. gold standard reference devices. Finally, the usability and experience of wearing and removing the Health Patch were evaluated.

Results

Study participant demographics

Demographics of the study participants are shown in Table 1. In total $n = 25$ participants were included, with the age range between 24 and 58 years and a body mass index (BMI) range of 20–29 kg/m^2. The number of male participants was slightly higher versus that of females (14 vs. 11, respectively), however the difference ($n = 3$ male subjects) is below one standard deviation of the sample size, assuming normal distribution. Most of the recruited subjects completed all the steps of the study and no drop offs occurred. Eight persons did not complete squats and another person did not complete fast cycling.

ECG and bioimpedance data processing flow

A representative sample of the raw ECG and bioimpedance data acquired on one participant is shown in Fig. 1. A drift was observed in the ECG data and an overflow was observed in certain areas of the data which was corrected during processing. An increase in magnitude of the bioimpedance signal was observed during the exercise period, compared to the resting period (Fig. 1B).

The heart rate and respiratory rate signals are shown in Fig. 2, where in particular a section of the normalised data is shown for one of the participants (volunteer #8). The peaks of the ECG signal corresponded to heart beats (see Fig. 2E) and the peaks of the respiratory rate data were assumed to be one breath (see Fig. 2F). It should be noted for clarity that the respiration rate data acquired by measuring bio-impedance does not take into account the volume of breath inhaled or exhaled.

Heart rate and respiration rate data

An exemplary and a representative dataset of extracted heart rate and respiration rate for one study participant (volunteer #8) during the study is shown in Fig. 3. Visual observation showed that the HR and RR acquired using a Health Patch follow that of reference devices, both during the resting and exercise periods. A visual good agreement was observed for the heart rate acquired using the Health Patch and the Shimmer reference. In case of the respiratory rate, the Cosmed reference measurement followed reasonably well (average trends), but both showed more scatter.

Heart rate and respiratory rate distributions combined over $n=25$ participants for each of the performed activity (rest, squats, cycling slow, cycling fast) are shown in Fig. 4 in violin plots, illustrating data distribution, spread and symmetry. For heart rate the combined data yielded reasonably good accuracy and statistical distributions similar to that of the reference method ($r^2=0.96$; mean absolute error (MAE) with 5th – 90th percentile = 2.6 (0.9–4.3) bpm). Higher heart rate values acquired using the Health Patch were consistent with that of the reference method (Shimmer) showing MAEs with their 5th – 90th percentiles of 1.6 (0.5–3.3) bpm, 4.7 (0.9–15.2) bpm, 5.8 (0.8–14.0) bpm, and 3.7 (0.5–6.4) bpm during all of the performed activities, i.e., rest, squats, cycling slow, and cycling fast, respectively.

For respiration rate, the differences between the two devices appeared larger ($r^2=0.35$; MAE with 5th – 95th percentile = 2.8 (1.2–4.5) rpm). Interestingly, respiratory rates acquired using the Health Patch were consistently lower vs. Cosmed, i.e. MAEs with their 5th – 90th percentiles of 2.6 (1.2–4.6) rpm, 4.1 (1.1–8.4) rpm, 3.3 (0.8–6.1) rpm, and 3.5 (1.1–9.1) rpm during rest, squats, cycling slow, and cycling fast, respectively.

Figure 5 presents the level of agreement for heart rate (Fig. 5a) and respiratory rate (Fig. 5b) in Bland-Altman plots to visualise a direct comparison of measurement error and to identify outliers and trends. A reasonably good level of agreement was observed for the heart rate (bias: 0.38 bpm, 0.15 bpm, 2.00 bpm, 1.83 bpm, 0.47 bpm; 95% SD LoA (limits of agreement) ± 9.9 bpm, ± 5.4 bpm, ± 14.9 bpm, ± 18.7 bpm, ± 9.8 bpm) overall, rest,

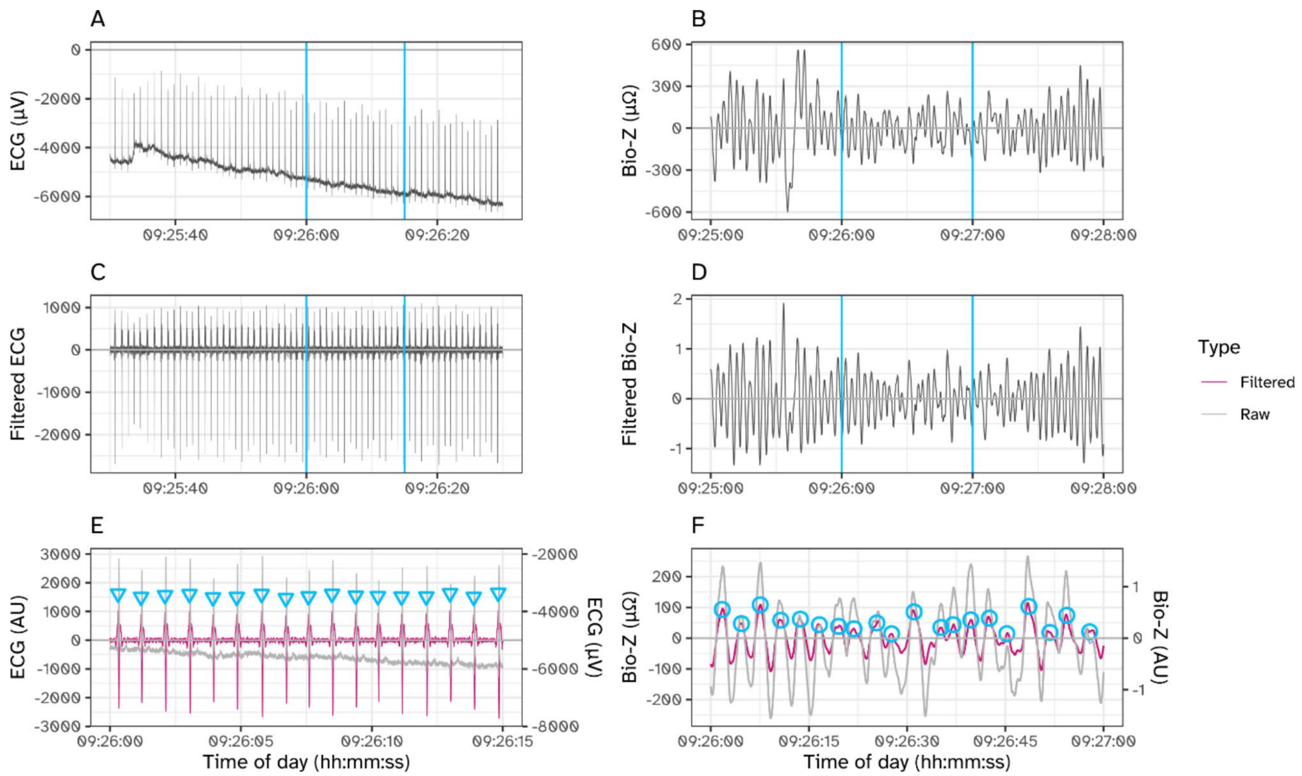

Fig. 2. Representative section of a recording sample (volunteer #8) from the study, taken during rest, showing (**A**,**B**) – raw ECG and bioimpedance signals, respectively; (**C**,**D**) – filtered ECG and bioimpedance signals; (**E**,**F**) - zoomed-in sections with pre-processed (grey) and processed (purple) data with drift eliminated, for ECG and bioimpedance signals; the detected peaks (light blue) were used to count the heart rate and respiratory rate, respectively. RMS normalized signal refers to scaling of the raw signal among the participants.

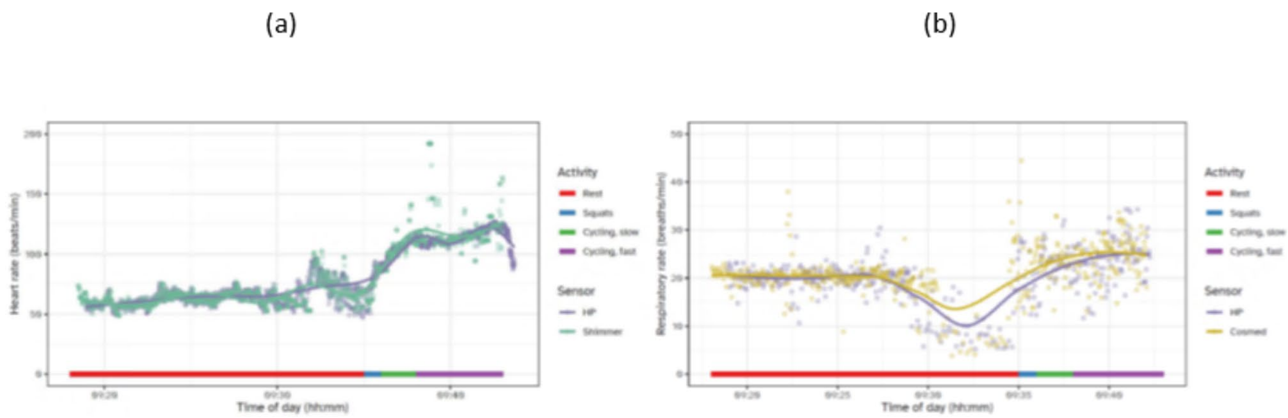

Fig. 3. An exemplary and a representative dataset of extracted heart rate (**a**) and respiration rate (**b**) for one study participant (volunteer #8). Scatter plots and moving average trendlines are shown for the data acquired using the Health Patch and using reference devices Shimmer for HR and Cosmed for RR, respectively. Activities performed by a participant, such as rest (red), squats (blue), slow cycling (green), fast cycling (purple) are annotated by the respective colours in the timeline on the X-axis.

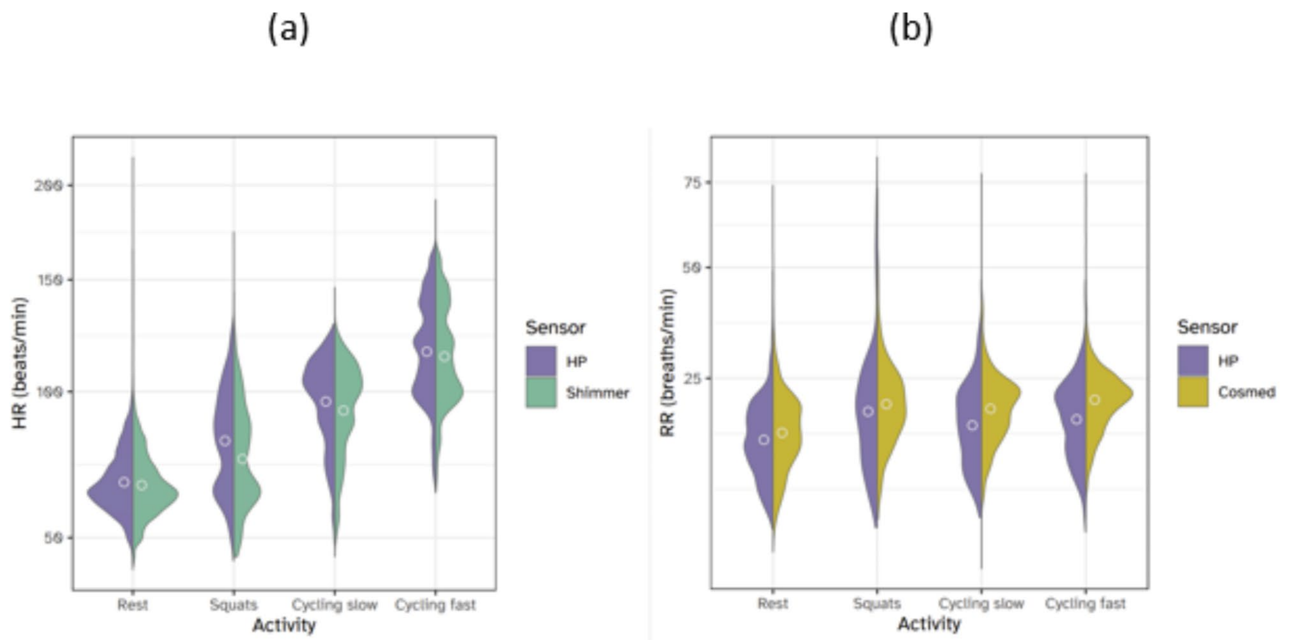

Fig. 4. Violin plots of combined data from 25 participants showing the spread of the (**a**) heart rate and (**b**) respiratory rate readings for each activity.

squats slow cycling and fast cycling, respectively. An acceptable level of agreement was observed for respiratory rate, with a slight underestimation by the Health Patch (bias: − 1.90 rpm, − 0.92 rpm, − 2.09 rpm, − 3.21 rpm, − 3.78 rpm; 95% LoA ± 8.6 rpm, ± 6.7 rpm, ± 12.2 rpm, ± 8.2 rpm, ± 10.2 rpm), also in the same respective order. While the agreement is consistent over the full range of measured heart rates, a small decreasing trend is observed towards higher respiratory rates (Fig. 5b).

Next, a comparison of the heart rate and respiratory rate as acquired using the Health Patch and reference devices using Lin's concordance correlation coefficient (CCC) is shown in Fig. 6. The CCC provides a quantitative measure of agreement that accounts for bias, precision, variability and potential nonlinearity on a scatter plot, with a line of reference with perfect agreement as a red dashed line. The correlation of the heart rate measurements appeared highly in agreement amongst the two devices at 0.98 (95% CI 0.98–0.98), 0.95 (95% CI 0.95–0.96), 0.88 (95% CI 0.83–0.91), 0.85 (95% CI 0.81–0.88), 0.97 (95% CI 0.97–0.98) for overall, rest, squats, cycling slow and cycling fast respectively (Fig. 6a). The Lin's concordance correlation coefficient for the respiration rate measured using the Health Patch and the Cosmed were 0.56 (95% CI 0.53–0.58) overall, 0.53 (95% CI 0.49–0.56) rest, 0.28 (95% CI 0.14–0.41) squats, 0.33 (95% CI 0.23–0.42) cycling slow and 0.42 (95% CI 0.36–0.48) cycling fast.

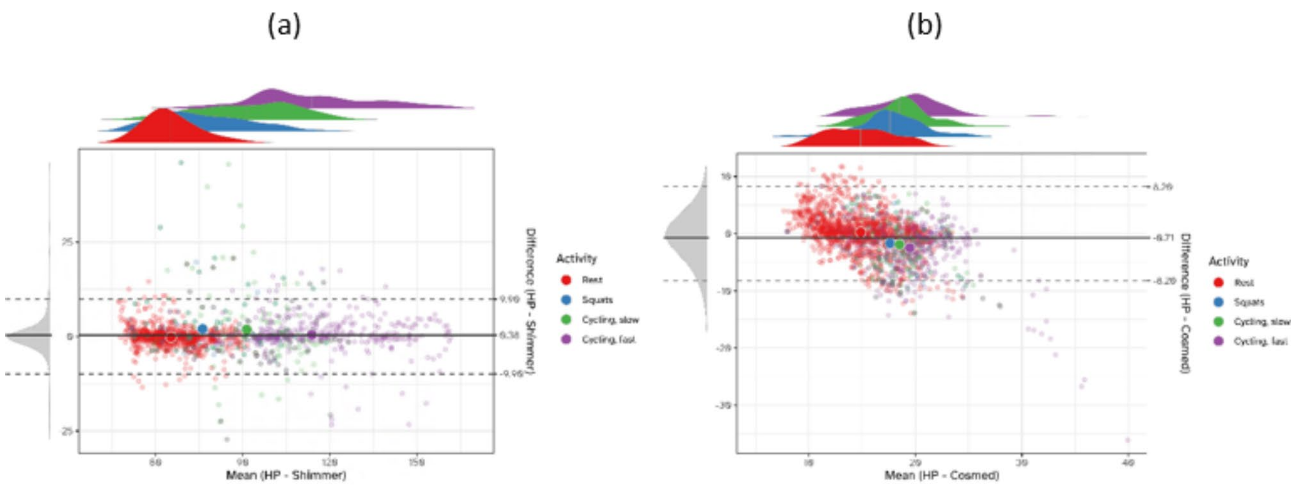

Fig. 5. Bland-Altman plots showing differences of (**a**) heart rate and (**b**) respiratory rate, measured with both the Health Patch and the respective gold standard device. The x-axes show the mean measurements, while the y-axes show the differences between the two devices. The horizontal dashed lines refer to the 95% limits of agreement.

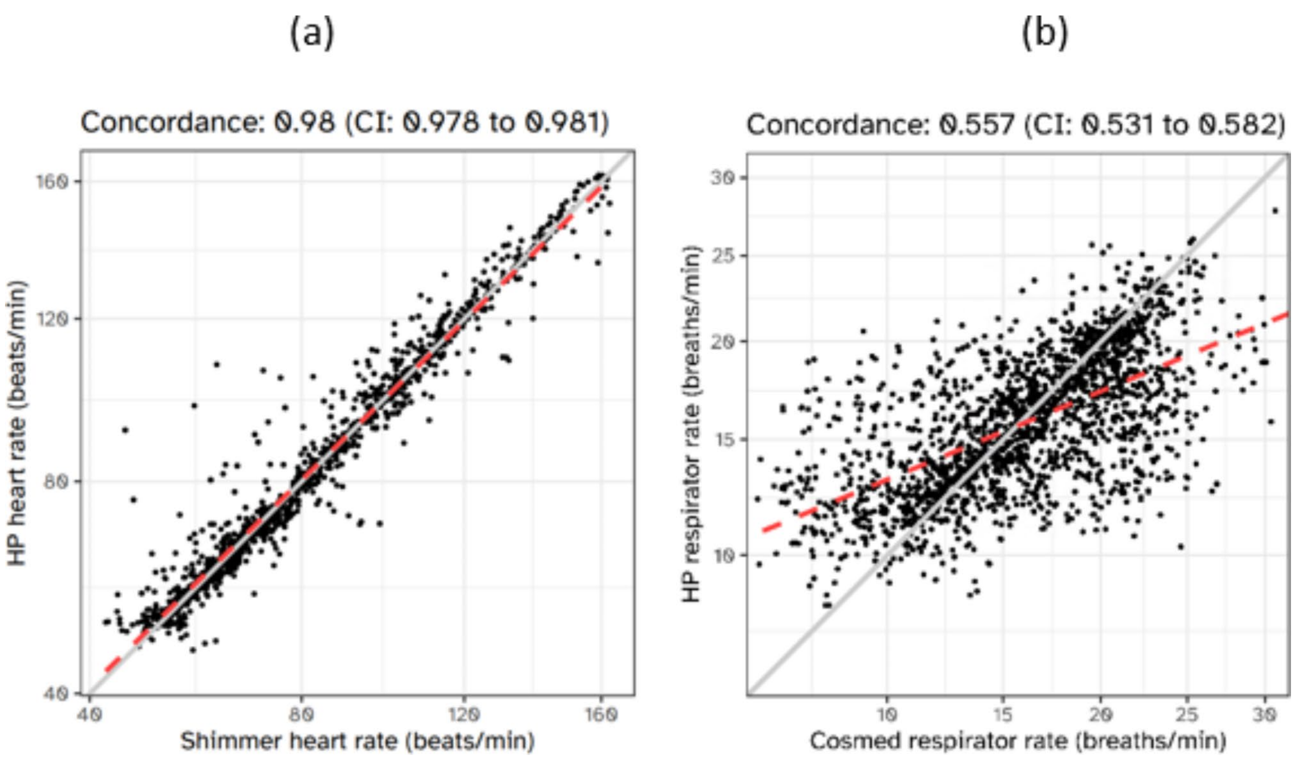

Fig. 6. (**a**,**b**) Lin's concordance coefficient plots of the Health Patch vs. the reference devices for heart rate and respiratory rate, respectively.

Heart rate variability

We also performed analysis on the heart rate variability (HRV), more specifically, the R-R intervals variability using the data acquired with the Health Patch and compared it to that of the reference apparatus (Shimmer). This resulted in $r^2 = 0.82$, MAE = 9.1 ms and a bias of − 8.2 ± 19 ms overall, − 6.58 ± 14.8 ms rest, − 14.1 ± 29.2 ms squats, -9.2 ± 13.1 ms cycling slow and − 11 ± 26.1 ms cycling fast. Figure 7a shows a Bland-Altman plot of the HRV as acquired using the Health Patch and the reference equipment (Shimmer). One can see that most of the data points are located below zero with some beyond the 1 SD threshold, meaning that the HRV calculations using the Health Patch results into lower HRV values vs. the reference for the same paired dataset. Good correspondence can also be seen in the CCC graph (see Fig. 7b) and while there is bias, still a good degree

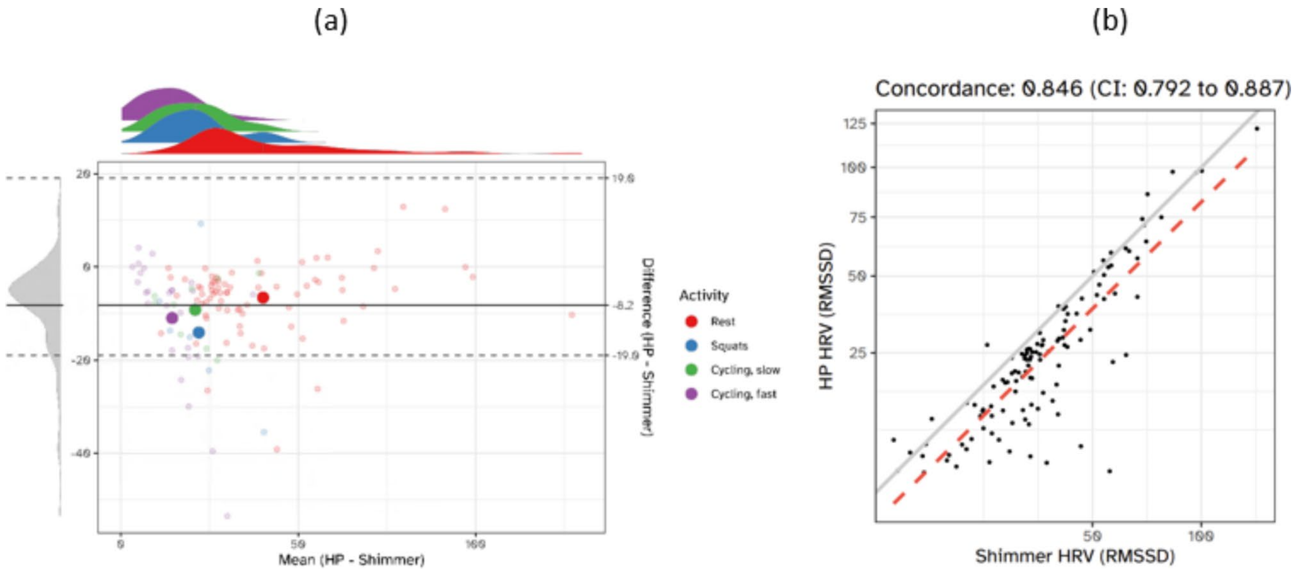

Fig. 7. Health Patch vs. Shimmer (**a**) HRV Bland-Altman plot; (**b**) Lin's concordance correlation coefficient (RMSSD) of the, axes shown as log(2).

Parameter	Number of answers given (max 25)	Average score (from not at all (1), to very much so (10), or yes/no ratio
Skin dryness (mean ± SD)	25	2.0 ± 1.3
Skin sensitivity (mean ± SD)		1.6 ± 1.4
General discomfort during Health Patch removal (mean ± SD)	24	2.9 ± 2.3
Itch (y/n)	24	5/19
Extent of itch if reported (mean ± SD)	5	3.4 ± 1.9
Pain during Health Patch removal (mean ± SD)	24	2.0 ± 2.2
Willingness to wear a Health Patch again (y/n)	25	24/1
Health Patch adhesive wetness through perspiration (y/n)	25	8/17

Table 2. A summary of the participants' responses to the use of the Health Patch post exercise protocol.

of overall concordance was obtained (0.85). For rest, squats, cycling slow and cycling fast, these were reported as 0.91, 0.19, 0.53 and 0.14 respectively. In the same order, CIs were 0.79–0.89, 0.86–0.94, − 0.28-0.58, − 0.09-0.80, − 0.06-0.33.

Respiration rate variability was unable to be compared due to the reference equipment (Cosmed) which only provides averaged data (updated every 3–5 min).

Health Patch wear and removal comfort

Health Patch comfort during its wear and removal was assessed using an in-house developed questionnaire. A summary of the self-reported responses is given in Table 1. Of the 25 participants, skin dryness, sensitivity, discomfort, and pain during Health Patch removal were minor (all below 3 on the scale from 1 to 10 ranging from 'not at all' to 'very much so'). Itching due to the adhesive was reported by 5 participants, and the average score for itch given by them was 3.4 out of 10. It was also observed that during this short exercise protocol, approximately a third of the participants' Health Patch adhesive became wet through sweating by visual observation. All but one participant responded positively on the question if they would use the device again (Table 2).

Discussion

The objective of this work was to evaluate the accuracy of heart rate, heart rate variability, and respiratory rate acquired by the novel Health Patch featuring self-adhesive dry electrodes technology. To achieve this goal, a study was designed and performed on 25 healthy male and female adult volunteers comparing the estimation of HR, HRV and RR acquired using the Health Patch with clinical reference devices (Shimmer and Cosmed) under both under resting and different exercise conditions. This is an important assessment for the monitoring of cardiovascular health and the prediction of (patho) physiological conditions[19].

Comparison of the estimated HR by the Health Patch acquired by ECG followed by the signal processing/de-noising and R-R peak detection vs. the reference equipment (Shimmer) resulted in high level of agreement (98% based on Lin's concordance correlation coefficient, MAE = 2.6 bpm overall). This compares well to several other wearable devices using different type of sensors for heart rate that reported MAEs. For example, a study by Bent et al. to consumer-grade wearable devices using an optical sensor for PPG, from which the heart rate was extracted mentioned MAE between 7 and 14 bpm (rest and activities)[20]. Nelson and Allen investigated a wearable watch and an optical sensor for heart rate reported MAE between 1.8 and 3.5 bpm (rest and activities – sitting, walking, running, chores)[21]. Morgado Areia et al. used the FDA cleared and CE marked VitalPatch for ECG recording with a subsequent heart rate extraction reported an MAE of 0.72 bpm at rest and minor activities – sit to stand, tapping, drinking, turning pages and using a tablet[22].

Comparison of the estimated respiratory rate by the Health Patch acquired by bioimpedance followed by the signal processing/de-noising and R-R peak detection vs. the reference equipment (Cosmed) resulted in acceptable level of agreement (51% based on Lin's concordance correlation coefficient, MAE 3.2 rpm). MAE values are close, but higher as compared with other studies. One study reported a home sleep measuring device with an MAE of 0.93 rpm[23], while another study reported an MAE of 2.7 rpm in a consumer device vs. laboratory device test[24]. The VitalPatch reported a MAE of 1.89 rpm for RR, when compared to their chosen gold standard device, the Philips MX 450 [22]. The authors of the VitalPatch study also pointed out similarly on higher scatter in the respiratory rate data when compared to their gold standard device. The aggregated respiratory rate generally exhibited fair agreement within a reasonable range and the larger disagreements tended to appear in the higher ranges of the measured values – during exercise where motion artefacts[25] and tissue conductivity changes are present, and thus impacts bioimpedance measurements and as a result also respiratory rates values. We suggest that inertial measurement unit (IMU)-based motion sensing of respiration (or a combination of both IMU and impedance) may allow for motion artefact compensation and for additional redundancy, improved signal clarity and improvement for derivation of respiratory rate. Furthermore, the sensing modality (bioimpedance vs. air flow) and thus the sensitivity to breathing patterns between the control and Health Patch devices are different. Others have combined multiple sensing modalities based on lung volume with bioimpedance, intrathoracic pressure reflected in PPG, and chest movements based on IMU sensors, leading to more accurate estimations of respiratory rate under resting conditions. In addition, Cosmed only provided averaged data over 1-minute intervals. This implies that the data may have been smoothed out and direct comparisons are therefore not straightforward. Nevertheless, numerous studies have demonstrated that bioimpedance based respiratory rate measurements is comparable to airflow-based methods, including those from Cosmed, and suitable for measurements at home[25–27]. We believe that the main reason for the discrepancy is related to the suboptimal position of the patch under the armpit, which was based on usability and comparability with other studies focusing on continuous heart rate monitoring. This position is suboptimal for bioimpedance-based respiratory monitoring, as only a small part of the lung is covered and sensitivity to respiration may be compromised, especially in some individuals that showed a high degree of bias. Given the clean raw bioimpedance signal, it is expected that proper positioning of the patch, i.e. on the middle of the chest, will significantly improve the sensitivity of the two bioimpedance electrodes to respiration and, hence, the underestimation of respiratory rate estimation from the Health Patch. In any case, it is important to highlight that the studies mentioned in this context were using different gold standard devices, making direct comparison challenging due to different methodologies.

As user comfort is crucial for compliance to wear health monitoring patches, this study also included a questionnaire to gather subjective feedback from the participants. Overall, the majority of participants indicated a positive perception of the Health Patch during a short wear time as well as during Health Patch removal. These findings are similar to what has been previously reported about this research platform in a study with a smaller number of participants but for a 5-day duration of use ($n=6$), indicating the utility of dry-electrode for long-term wear beyond the current maximum of 3 days with standard wet-electrode technology[28]. In this particular study, however, mild skin itch was reported by 5 out of $n=25$ individuals. This highlights the need for skin compatibility evaluation during prolonged use of the Health Patch research platform in a larger group of participants.

This study has several limitations. First, the recruited volunteers all had a military background and therefore may differ from the average population, e.g., in terms of body fat content and body shape. These factors might influence the ECG and bio-impedance readings and hence might influence the accuracy and precision of the heart rate and respiration rate.

Second, the study duration was relatively short, less than one hour with relatively low maximum heart rate activities which may not generalize to all other contexts of use, e.g., those of sports medicine. Future research should also address accuracy of the respiration rate measurements. It is recommended that clinical studies consider including a panel of volunteers representing a wider population demographics eventually extending to specific patient groups. Furthermore, it is being recommended that a future study considers a longer Health Patch wear period and includes a mixture of high and low intensity activities for the participants.

Conclusions

This study presents a thorough analysis of a novel, dry electrode adhesive-based, wearable Health Patch device for long-term monitoring HR, HRV and RR in comparison to clinical reference devices. The results demonstrated promising potential of this wearable technology for short-to-medium term clinical use in cardiorespiratory health monitoring. The study involved 25 female and male adult participants and showed good agreement with a Lin's CCC of 0.98 for HR and of 0.85 for HRV between the Health Patch and Shimmer reference. RR was reported with a Lin's CCC of 0.56 when compared to the Cosmed. Despite the lower coefficient, especially at higher respiratory rates, this study provides valuable insights into the technology's performance, capabilities, limitations, and room for future improvements. Furthermore, user feedback was generally positive with minor discomfort reported, confirming earlier results after 5-day monitoring. Together, these findings support the use of the Health Patch for digital biomarker development, with the potential for researchers, healthcare professionals and patients that benefit from continuous vital sign monitoring and health management, thereby improving patient outcomes.

Methods

Ethics approval statement

The study plan was approved by the Institutional Review Board of TNO (15 August 2022, approval number 2022-054). All study participants signed an informed consent. The study was conducted in accordance with the Declaration of Helsinki in October 2022.

Study design and procedures

Male and female adult participants were recruited via the Centre for Man and Aviation (CML), Soesterberg, the Netherlands, from the military personnel. Exclusion criteria from the participation were sensitive skin, skin lesions on the upper left chest, known allergy to silicone, acryl, or medical gels, cardiorespiratory disease, or wearing cardiac pacemakers or other implantable powered devices. Chest hair was shaved if present prior to the test, and a photo of the area prior Health Patch application was taken as a baseline. The Health Patch was applied on the left side of the body under the armpit in a modified lead V5 configuration (see Fig. 8). Then, the cardiorespiratory measurement system (K5, Cosmed, Pavona RM, Italy) and a 3-lead ECG (Shimmer3 ECG Unit, Shimmer, Dublin), Ireland were also applied and connected. Health Patch placement was selected to capture ECG and respiration rate (due to changing impedance of the thoracic cavity, which varies with each inhalation and exhalation) as well as to allow for placement of 3-lead ECG reference device.

The detailed study design and procedures is depicted in Fig. 9a. Participants first remained in resting conditions for 15 min (normal breathing, sitting still, no movement). Then, participants executed 10 squats followed by 2 min of cycling warming up, 5 min of intensive cycling (heart rate 130–160 bpm) and 2 min of recovery period. After the tests, the Shimmer ECG, Cosmed K5 and the Health Patch were removed, after which another image of the Health Patch application skin area was taken. The participant fill in an in-house developed questionnaire on Health Patch usability and experience during its wear and removal.

Data collection and signal processing

Device and data collection

The Health Patch consists of a re-usable recorder unit, and a disposable patch with self-adhesive dry electrodes (Fig. 8b). The device allows for battery-powered data logging of electrocardiography (ECG), 4-lead bioimpedance (BIO-Z) to derive respiratory rate and 3-axial accelerometer (ACC) for G-force data at 256 Hz, 32 Hz, and 64 Hz, respectively. Recorded data is retrieved by connecting the recorder to a computer via a proprietary docking station that is connected via USB. When connected, a software can download and export the recorded data. The same software is used to setup a new measurement. Alternative to the USB interface, a Bluetooth Low Energy interface is also available for live streaming signals.

ECG acquired using a reference device was processed using the corresponding dedicated Consensys software (Shimmer, Dublin, Ireland), which returned heart rate values (in bpm) at a sampling frequency of approximately 256 Hz. Reference respiratory rate (bpm) acquired using a reference method, calculated over 1-minute intervals, was retrieved from the generated spreadsheets by the corresponding dedicated software of the Cosmed device. Raw signals are processed and analysed as shown in Fig. 9b.

Fig. 8. (**a**) The Health Patch research platform adhered to the left side of the chest on a participant. (**b**) The Health Patch components such as a disposable part and re-usable part positioned alongside a coin to illustrate their size relative to a scale).

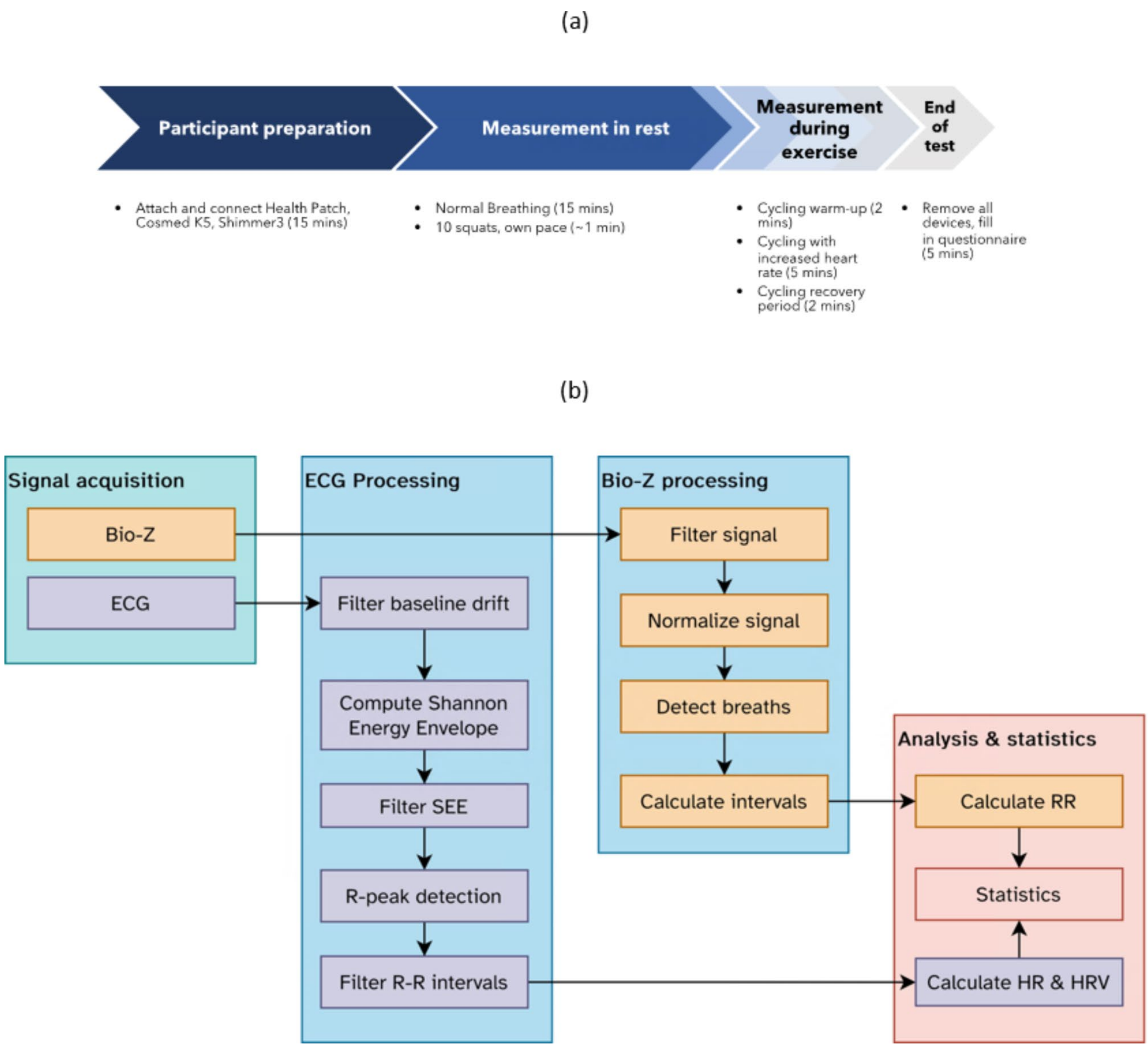

Fig. 9. (**a**) Timeline of the study protocol and procedures for the participants. (**b**) Flowchart of the signal and data processing for both heart rate and respiratory rate analysis. *ECG* electrocardiogram, *SEE* Shannon energy envelope, *R-peak* R wave in an ECG, *HR* heart rate, *HRV* heart rate variability, *RR* respiratory rate.

Performance metrics

To evaluate signal quality acquired using the Health Patch, we used key performance metrics, which included Mean Absolute Error (MAE), Bland-Altman analysis (BAA), and Lin's Concordance Correlation Coefficient (CCC). The MAE quantifies the average absolute differences between the measured differences between Health Patch and the gold standard measurements. A lower MAE indicates that the Health Patch's measurements are closer to the gold standard, implying higher accuracy. The Bland-Altman analysis plots show the difference between the paired measurements on the y-axis against their average on the x-axis to visualise bias or systematic error and trends. Finally, the CCC provides how well the data are correlated, and in addition, how well they conform to a perfect agreement (closer to 1). These metrics were applied on the heart rate (HR), heart rate variability (HRV) and respiratory rate (RR) data.

Heart rate calculation

The raw ECG signal is first processed to remove a baseline drift introduced by respiration, movement, and variations in skin conductance to reliably extract R peaks (the R wave in an ECG) values of the QRS complexes in varying conditions. To achieve this, a proprietary algorithm was made, based on a modified version of the routine from Lee et al.[29]. In brief, first, the signal baseline is obtained by applying a second order Savitzky-Golay filter on the raw ECG signal with a window width of 250 ms. The choice of filter order and window width ensured that the smoothing scale is larger than even the widest possible QRS complex so that higher frequency information in the QRS complexes is preserved while the slower varying noise components were effectively removed. Then, the signal baseline was subtracted from the raw signal, resulting in a baseline-corrected signal. The signal was then processed further for R-peak detection. In the first step, the Shannon Energy Envelope (SEE) of the baseline-corrected signal was computed by taking the squared absolute real part of the inverse Fourier transform of the Hilbert-transform of the baseline-corrected signal.

Next, a fifth-order Savitzky-Golay filter was applied to the SEE to smooth the energy envelope. Our algorithm then identified parts of the signal where the filtered envelope exceeds an adaptive threshold. This adaptive threshold was calculated by convolution of the filtered energy envelope with a Gaussian kernel. The segments that exceeded the threshold corresponded to the extracted QRS complexes. Segments that were within 200 ms of each other were regarded as a single QRS complex. Finally, the R-peaks were identified as the point of the maximum amplitude in each of the QRS segments.

The resulting R-R intervals were then converted to N-N intervals by filtering R-R interval values using a combination of filtering strategies adapted from Saleem et al.[30]. The goal was to remove or mitigate the impact of (technical and movement related) artefacts and noise, particularly ectopic beats, without distorting the underlying physiological information. This filtering step improved signal to noise ratio in the detected R-R intervals, which was important for subsequent accurate HR and HRV estimation. First, a signal-dependent rank ordered mean (SDROM) was used to filter spurious R-R intervals caused by ectopic beats and artefacts. The SDROM filter algorithm was designed to eliminate impulsive noise in data sequences using a sliding window approach.

Our algorithm applied a sliding window of an odd number of samples to the R-R interval data. Within these windows, the algorithm calculated a rank-ordered mean, based on the sorted data points excluding the centre value. The differences between the centre value and other values within the window were computed. These differences were compared against corresponding empirical thresholds. If any computed difference surpasses its corresponding threshold, the data point associated with that iteration was deemed anomalous. The corresponding R-R interval was then removed from the data, resulting in a sequence of N-N intervals.

The resulting N-N interval data was then used to calculate heart rate. Heart rate in beats per minute was calculated by multiplying the reciprocal of the N-N intervals by 60.

Heart rate variability calculation

Heart rate variability for both the Health Patch and Shimmer datasets was calculated as the Root Mean Square of Successive Differences (RMSSD). This is the most robust measurement to reflect parasympathetic nervous system (PNS) activity with limited influence from respiration from Shaffer & Ginsberg[31]. It was calculated based on the previously obtained N-N intervals for both the Health Patch and Shimmer data as follows in Eq. (1):

$$RMSSD = \sqrt{\frac{1}{N-1}\sum_{i=1}^{N-1}\left(NN_{i+1} - NN_i\right)^2}. \tag{1}$$

To calculate the heart rate variability, the root mean square of successive differences (RMSSD) calculation was applied to continuous five-minute windows of N-N interval data, a common technique used as per Shaffer & Ginsberg[31]. This calculates the square root of the mean squared differences between the adjacent normal to normal intervals.

Respiratory rate calculation

To process the respiratory rate data, first a Butterworth bandpass filter was applied to the bioimpedance signal, focusing on frequencies between 0.1 Hz and 5 Hz. This range effectively removed unwanted muscle movement artefacts, allowing the respiratory information to be extracted. After the filtering process, the resulting signal was normalised by dividing it by its root mean square value. This normalisation step ensured that the signal's amplitude was consistent across different recordings, facilitating accurate analysis. The bioimpedance signal oscillated around zero and the algorithm used this characteristic for detection of respiratory rate. It determined when the normalized signal exceeds zero, indicating potential respiratory events. Within each positive segment, the algorithm identified the peak by locating the maximum normalised signal value. After detection of the peak values, respiratory rate in respirations per minute (rpm) was calculated by multiplying the reciprocal of the peak-to-peak time in seconds by 60. The reason was because respiratory rate is generally reported in rpm instead of time between respirations.

Statistical analyses

As the acquisition of the data using a Health Patch and reference standards was not synchronized in hardware, time synchronisation after the signal acquisition was necessary. Data from the different devices with different sampling rates were synchronised using a 1-minute sliding window with a 20-second overlap. Mean measurements of the respective measurements within each window were computed to create a synchronised dataset, allowing comparative analysis by aligning the measurements temporally. Subsequently, mean absolute error (MAE) was calculated per participant and a Bland-Altman analysis was carried out to investigate the accuracy and precision of the Health Patch HR and RR measurements as compared to gold standard measurements. Mean statistics and 5th and 90th percentiles were reported for the MAE to evaluate the interindividual variation in performance of the Health Patch. Lin's concordance correlation coefficient (CCC) was used to evaluate how well the Health Patch dataset conformed to the gold standard device dataset[32]. It is a modification of the Pearson correlation coefficient by not only calculating the spread of the data from the line of best fit, but additionally assessing the deviation from the 1:1 line representing perfect agreement. Mean and standard deviation was used to describe the usability and user experience of the Health Patch and skin condition after use.

Data availability
De-identified raw and processed data can be shared upon request by the corresponding author.

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Author contributions
JCJW – writing the manuscript. TvdB – data processing, graphical representation, conclusions formulation, reviewing the manuscript. JUvB – data processing, graphical representation, reviewing the manuscript. RvS – data processing, reviewing the manuscript. RJMK – setting up and conducting the study, reviewing the manuscript. LR - setting up and conducting the study, reviewing the manuscript. KG - setting up and conducting the study, reviewing the manuscript. NEU - conceptualisation, study design, writing and reviewing the manuscript. WvdB – conceptualisation, writing and reviewing the manuscript.

Declarations

Competing interests
All authors are employees of TNO. TNO was the research organisation that developed the Health Patch. There has been no financial support for this work that could have influenced its outcome.

Additional information
Correspondence and requests for materials should be addressed to N.E.U. or W.J.B.

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