The revised digital transcutaneous PCO2/SpO2 Ear Sensor is a reliable noninvasive monitoring tool in patients after cardiac surgery

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The revised digital transcutaneous PCO$_2$/SPO$_2$ ear sensor is a reliable non invasive monitoring tool in patients after cardiac surgery

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There were no financial or non-financial competing interests in the accomplishment of this study
Abstract

**Objective:** The aim of this study was to validate the revised SenTec V-Sign™ 2 sensor for combined non-invasive continuous assessment of pulse rate, pulse oximetry (SpO₂) and transcutaneous carbon dioxide tension (PtcCO₂) in adults after cardiac surgery.

**Design:** prospective clinical study

**Setting:** University Hospital, single-center

**Participants:** twenty adult patients after cardiac surgery, aged 36 to 84 years,

**Interventions:** SpO₂ and PtcCO₂ values of three V-Sign™ 2 sensors attached at the ear-lobe, forehead and cheek and SpO₂ values of the Nellcor Durasensor (model DS-100A) were compared with simultaneous measurements of blood gases and end-expiratory carbon dioxide.

**Measurements and Main Results:** Measurements were performed during periods of hyper-, normo- and hypocapnia and then at 30 min intervals up to 5 hours. Bland-Altman analysis and simple regression analysis were used.

**Results:** Detection failures for PtcCO₂ were 0.3 to 1.3%, for SpO₂ 10 to 25%, and for pulse rate 5 to 10%. The V-Sign™ 2 ear-lobe sensor provided the best results. Mean bias and limits of agreement for PtcCO₂ear and PaCO₂ were +1.1 and -3.4 / +5.5 mmHg. Drift of PtcCO₂ was negligible at all locations. Mean bias and limits of agreement of V-Sign SpO₂ear and SaO₂ as well as V-Sign pulse rate and ECG were -1.7% and -6.8 / + 3.9%, and 1.2 bpm and -3.3 / +5.8 bpm. End-expiratory carbon dioxide showed a weak correlation with PaCO₂ (r² = 0.47).

**Conclusions:** Transcutaneous capnometry using the revised V-Sign™ 2 sensor at the earlobe is a reliable monitoring tool during the recovery period of patients after cardiac surgery. This approach has the potential to reduce the number of arterial blood gas samples.

**Key Words:** non-invasive monitoring, combined transcutaneous PCO₂ and SpO₂, digital ear sensor, cardiac surgery intensive care unit
Introduction

Transcutaneous continuous partial carbon dioxide (PtcCO₂) sensors have been used more than twenty years [1] and the devices have been continuously improved. At present, all commercially available PtcCO₂ sensors are electrochemical in nature [2]. Initially, PtcCO₂ sensors were mainly utilized in neonatology and in critically ill infants in combination with the measurement of transcutaneous partial oxygen tension [3, 4]. Currently, combined assessment of PtcCO₂ and partial oxygen tension using a single earlobe clip sensor is increasingly used in adult patients during noninvasive mechanical ventilation [5], transportation of critically ill adults [6], bronchoscopy [7], sleep studies [8, 9] and pulmonary stress testing [10]. However, sensor preparation, positioning, taping, and the necessity for repeated calibration and repeated changes of the sensor’s location because of drifting of the PtcCO₂ signal made handling cumbersome [4]. Additionally, the results of recently performed studies in neonates, infants and adults are controversial in terms of the reliability of these devices [6, 11-13]. In adults, clip sensors at the earlobe are routinely used because of its intense capillary perfusion. During haemodynamic instability, however, reliability of PtcCO₂ earlobe clip sensors may be restricted because of centralisation of perfusion. Secondary to the earlobe, other skin locations such as the forehead and the cheek might provide adequate perfusion conditions for transcutaneous detection of PtcCO₂ and SpO₂ in critically ill adult patients.

Most recently a revised V-Sign™ sensor (V-Sign™ 2 sensor, SenTec Digital Monitoring System [SDM]; SenTec AG, Therwil, Switzerland) has been designed by the manufacturer. Earlobe clips as well as attachment ring-clips are available for sensor application at different sites of the body. The V-Sign™ 2 sensor measures PtcCO₂, pulse rate and arterial oxygen saturation (SpO₂) continuously and noninvasively. It combines the elements of a temperature-controlled Stow-Severinghaus pH-sensitive glass electrode and a conventional pulse oximetry
sensor. Severinghaus type electrodes always show a certain amount of drift over time, as the electrochemical measurement is influenced by a number of time-varying factors, including material selection. One biological reason for signal drift may be the increasing production of CO₂ in the skin areas surrounding the sensor during rewarming. The revised V-Sign™ sensor was improved by the material side and the data processing algorithm that characterizes and compensates the drift. Drift specific information is directly stored on the digital sensor itself (in vivo correction). Additionally the equilibration time has been reduced from until 20 min to 3 to 10 min with a mean equilibration time of 5 min. The sensor is heated up to 42°C to achieve local arterialization of the skin at the site of PtcCO₂ monitoring. Prior to application of the sensor to the patient’s skin, an automatic calibration of the sensor is performed in vitro. Afterwards, the sensor is mounted at the skin and the first measurement is performed after allowing a 10-min equilibration time.

The primary aim of this study was to validate the data acquired with the V-Sign™ 2 sensor at the earlobe, forehead and cheek in comparison to arterial carbon dioxide tension (PaCO₂) and arterial oxygen saturation (SaO₂), measured by co-oximetry, and pulse rate (PR) derived from the electrocardiogram in critically ill patients after cardiac surgery. The secondary aim was to investigate the safety, feasibility and medium term precision of the new V-Sign™ 2 sensor at the different sensor locations.
Material and Methods

With ethics committee approval and written informed consent, 20 patients scheduled for elective cardiac surgery were enrolled in this prospective single-centre trial. Exclusion criteria were non-German-speaking patients, unstable haemodynamics, arrhythmias, and age <18 years. Criteria for terminating a subject’s participation were unstable haemodynamics and/or significant arrhythmias, need for re-operation, a serious skin lesion at the measurement site and withdrawal of consent by the patient. Before surgery, standard instrumentation included a continuous 2-channel ECG (leads II and V5) (Delta Infinity Delta XL Kappa monitor (Dräger Medical Systems, Inc. Lübeck, Germany), continuous arterial blood pressure monitoring via a fluid-filled catheter system (Baxter Healthcare Corp. Cardiovascular Group Irvine) connected to the radial artery inserted at the nondominant hand, a triple-lumen central venous catheter (Arrow International, Reading, PA) and a 7.5-FG thermistor-tipped, flow-directed pulmonary artery catheter (IntelliCath Baxter Healthcare Corporation Edwards Critical Care Division), introduced through an 8.5-FG introducer (Arrow International), inserted into the right internal jugular vein and connected to a cardiac output vigilance® computer system (9520A Baxter Healthcare Corporation).

After arrival of the patient in the ICU, V-Sign™ 2 sensors were attached according to the manufacturer’s directions to the inside of the left earlobe using an adhesive Ear-Clip (PtcCO₂ear, V-Sign SpO₂ear, V-Sign PRear), to the forehead (PtcCO₂forehead, V-Sign SpO₂forehead, V-Sign PRforehead) and to the cheek (PtcCO₂cheek, V-Sign SpO₂cheek, V-Sign PRcheek) each affixed with an adhesive ring-clip. Each probe was connected to one of three SenTec Digital Monitoring Systems (SDMS, Software Prereleases SMB V7.0 / MPB V5.0, SentTec AG, Therwil, Switzerland). As reference method for non invasive, continuous measurements of SpO₂ and PR, a Nellcor Durasensor (Model DS-100A) was attached to the forefinger of the non cannulated hand and connected with the Nellcor’s N-595 Finger clip Pulse Oximeter.
Arterial blood samples (BS) were drawn from the indwelling radial artery catheter at time points specified in the study protocol. PaCO₂ was measured at a standard temperature of 37°C, and SaO₂ was determined by co-oximetry (multi-wavelength haemoximetry) (ABL 800, Radiometer Medical A/S, Akandevej 21 DK-2700 Bronshoj, Denmark).

All data generated by the three V-Sign™ 2 sensors, the Nellcor 595 device, and the vigilance computer system [continuous cardiac index and mixed venous oxygen saturation (SvO₂)] were continuously recorded by means of an online computing system for subsequent plotting and off-line statistical data analysis. The time points and the results of the respective blood gas and co-oximetry values were also documented in the online computing system.

In addition, at the time points of the arterial blood samples, all data were recorded off-line on a separate protocol sheet. Additional recordings included end-expiratory carbon dioxide tension (PECO₂), mean arterial pressure (MAP), bolus thermodilution cardiac index (BCI), blood temperature, peripheral skin perfusion (I = warm and dry; II = cool; III = cold) and skin status at the measurement sites where the V-Sign sensors were attached (0 = no reddening; 1 = slight reddening; 2 = reddening; 3 = intensive reddening; 4 = blister).

BCI was measured by injecting 10 ml of iced saline 0.9% with a closed injectate system (CI-set; Baxter Healthcare Corp.). Injections were distributed randomly throughout the respiratory cycle. Thermodilution curves were displayed on a recorder and accepted as correct if the shape of the curve fulfilled the criteria of Levett and Replogle [14] and if the injectate temperature was <10°C.

After haemodynamic stabilization in the ICU, arterial blood samples were taken before attaching the sensors (BS1), 7.5 min (BS2) and 15 min (BS3) after attaching the sensors (equilibration phase). Thereafter, duplicate samples were taken with an interval of 5 min after 20 min of hyperventilation (target PaCO₂ = 4.5 kPa) (BS4 and BS5); after 20 min of normoventilation (target PaCO₂ = 5.0 kPa) (BS6 and BS7) and after 20 min of hypoventilation.
(target PaCO2 = 6.5kPa) (BS8 and BS9). Subsequently, one sample was taken every half hour until five hours after starting the trial (BS10-BS16). Following data were simultaneously collected at the different time points: blood temperature, CCl, N595-ECG, N595-SpO2, PaO2, PaCO2, PE CO2, PR, SaO2, V-Sign PRear, V-Sign PRforehead, V-Sign Psheet, V-Sign SpO2ear, V-Sign SpO2forehead, V-Sign SpO2sheet, PtcCO2ear, PtcCO2forehead, PtcCO2sheet, and MAP. Before starting the trial and 2, 4, 8 and 12 h after removing the sensors, peripheral skin perfusion (I = warm and dry; II = cool; III = cold) and the local skin status (0 = no reddening; 1 = slight reddening; 2 = reddening; 3 = intensive reddening; 4 = blister) at the earlobe, the forehead and the cheek were documented.

Statistics

Power calculation revealed that 20 patients were necessary to estimate variation between and within subjects with an accuracy of at least 15%. Bland-Altman analysis [15] was applied to assess mean bias and limits of agreement (LOA) (±2 SD of bias) of PaCO2 and PtcCO2, SaO2 and corresponding values of SpO2, displayed by the V-SignTM 2 sensors and the Nellcor N-595 sensor as well as pulse rate derived from the ECG, the V-SignTM 2 sensors and the Nellcor N-595. According to the quality criteria for blood gas analyser devices variation in the mean bias of PtcCO2 and paCO2 of 3.5% and a variation of LOA of 12.5% was accepted as “good”. A mean bias ≤ ± 1 mmHg and LOA ≤ ± 3.5 mmHg were defined as “excellent”. Mean bias ≤ ± 1.5 mmHg and LOA ≤ ± 5 mmHg were defined as good agreement. Values outside of these definitions were considered “unsatisfactory”. For comparison V-Sign SpO2 with SaO2 a good agreement was defined with mean bias ≤ ± 1% and LOA ≤ ± 4%, based on the manufacturers precision of measurements of the Nellcor 595 device. Multiple regression analysis was performed to determine whether blood temperature, pulse rate, cardiac index, skin status mean arterial pressure, the used catecholamines and milrinone significantly influenced PtcCO2, PaCO2 and the difference between PtcCO2 and PaCO2 (PtcCO2-PaCO2). A
p-value less than 0.05 was considered significant. Repeated measures ANOVA were used to estimate between-subjects and within-subject variations. In addition, simple linear regression was performed to assess first differences in transcutaneous and arterial PCO$_2$. 
Results

Twenty patients were enrolled; their characteristics and procedural parameters are listed in Table 1. Repositioning of the sensors was necessary in five cases for the earlobe sensor, in three cases for the forehead ring clip sensor, in one case for the cheek ring clip sensor and in three cases for the Nellcor finger clip sensor. For on line data collection a cable bundle of all sensors used was build and placed close the head of the patient. Intensive movement the patients was the reason for repositioning the sensors in most of these cases. In two times a unrealized old membrane of the sensor had to be changed. Two-hundred-ninety-six data pairs of PtcCO$_{2\text{ear}}$ and PaCO$_2$, 297 data pairs of PtcCO$_{2\text{forehead}}$ and PaCO$_2$, and 299 data pairs of PtcCO$_{2\text{cheek}}$ and PaCO$_2$ were analysed. Median (range) PtcCO$_{2\text{ear}}$, PtcCO$_{2\text{forehead}}$, PtcCO$_{2\text{cheek}}$ and PaCO$_2$ were 38.8 (26.9-56.5) mmHg, 38.1 (28.9-56.4) mmHg, 38.0 (28.5-57.8) mmHg and 36.7 (27.3-54.7) mmHg, respectively, and PaCO$_2$ values were significantly lower than the PtcCO$_2$ values ($\leq$ 0.005).

A good agreement of PtcCO$_2$ and PaCO$_2$ was only found with the ear lobe sensor with a mean bias of +1.1 mmHg and LOA of -3.4 / + 5.5mmHg (Table 2, Fig 1a-c), with the best agreement of PtcCO$_{2\text{ear}}$ and PaCO$_2$ during periods of hyper- and hypoventilation with a mean bias (LOA) of +1.4 mmHg (-2.3/+5.0 mmHg) and 0.5 mmHg (-3.4/+4.4 mmHg), respectively (Table 3).

In 7 patients an initial overshoot of PtcCO$_2$ was observed at all sensor locations until 8-25 min following calibration of the system. At the sample time 6h, PtcCO$_2$ showed no relevant drift at the three sensor locations as compared to PaCO$_2$ (Fig 2). Mean bias of PtcCO$_2$ and PaCO$_2$ did not correlate with pulse rate, cardiac index, skin status, MAP and blood temperature. No significant influence of the applied catecholamines and the milrinone was found to PaCO$_2$, PtcCO$_2$ at all locations and the mean bias of them, excepting the mean bias of PtcCO$_{2\text{ear}}$ and
PaCO₂, which was significantly influenced only by the dobutamine dose \( (r^2 = 0.09, \ p < 0.001) \).

First differences of PtcCO₂ and PaCO₂ for earlobe, forehead and cheek correlated well with \( r^2 \) of 0.81, 0.73 and 0.77, respectively (Fig 3a-c). The corresponding sensitivity/specificity to detect changes of PaCO₂ was 87/82 %, 79/78 % and 83/78 %, respectively. PtcCO₂ correlated only moderately with PaCO₂ and the agreement was poor (Table 2).

SpO₂ detection failures of the V-Sign™ 2 sensors at the earlobe, the forehead, the cheek and of the Nellcor finger clip sensor were observed in 10%, 19%, 25% and 2%, respectively (Table 2). Median (range) of V-Sign™ 2 SpO₂ear, V-Sign™ 2 SpO₂forehead, V-Sign™ 2 SpO₂cheek, N-595 SpO₂ and SaO₂ were 97.2 (81.7-100) %, 96 (86-100) %, 96.6 (85-100) %, 99.8 (87.8-100) % and 98.5 (89.2-100), respectively.

Agreement of V-Sign™ 2 SpO₂ and SaO₂ at all sensor locations was unsatisfactory and V-Sign™ 2 SpO₂ underestimated the corresponding SaO₂ values determined by co-oximetry, particularly in the lower SaO₂ range (Table 2, Fig 4a-c). However, the Nellcor device showed the smallest detection error and the best agreement with SaO₂, represented by a mean bias (LOA) of +0.41 (-2.38/+3.19)%, respectively.

Pulse rate detection failures of the V-Sign™ 2 sensors ranged between 5 to 10%, whereas only 2% detection failures were observed with the Nellcor device. V-Sign™ 2 PR showed a good agreement with the ECG at all sensor locations (Fig 5a-c), whereas the agreement of the Nellcor device with the ECG was poor (Table 2). No reddening or higher degrees of skin irritation were found in any patient neither during the study period nor following removal of the sensors even after 12 hours.

End-expiratory carbon dioxide correlated poorly with PaCO₂, had relevant bias and wide limits of agreement (Table 2).
Discussion

In this study we evaluated accuracy and precision of the recently revised V-Sign™ 2 sensor at three different sites of application on the head (earlobe, forehead and cheek) in adult patients during recovery from cardiac surgery.

The main results of the study were (i) the best site for PtcCO\textsubscript{2} measurement is the earlobe, (ii) at the earlobe, an excellent agreement was found between PtcCO\textsubscript{2} and PaCO\textsubscript{2} with only a slight overestimation of PaCO\textsubscript{2}, (iii) no statically significant drift was observed at either one of the three sensor locations, and the sensitivity and specificity to detect changes of PaCO\textsubscript{2} was good, (iv) the rate of detection failures of SpO\textsubscript{2} was high, and the agreement of SpO\textsubscript{2} values with SaO\textsubscript{2} was unsatisfactory (v) PR detected with the V-Sign™ 2 sensor showed an excellent agreement at all sensor locations with the ECG-derived PR, but detection failures were found in 5 to 10%, with the lowest rate of detection failure at the earlobe.

Because of the large capillary network and good access way, the earlobe is the most favourite site in adults to attach a sensor that uses electrochemical technology for measuring carbon dioxide tension transcutaneously. It is well known, that cutaneous microcirculation shows a significant heterogeneity [16]. The supraorbital skin region, where the forehead sensor was attached, is supplied by the supraorbital artery, a branch of the internal carotid artery. The dependency of the supraorbital skin perfusion on the blood flow rate through the internal carotid was recently demonstrated by Hove and co-workers[17], using near infra-red spectroscopy in patients undergoing carotid endarterectomy. Supraorbital skin perfusion seems to be excluded from the centralization of blood flow accompanying low cardiac output states and might therefore be an optimal detection surface. For this reason we attached the sensors at the earlobe, the forehead and the cheek and expected better detection of PCO\textsubscript{2} and SpO\textsubscript{2} at the forehead. Thus it is surprising and not easily explicable that the earlobe appeared to be the best area for applying the electrochemical PtcCO\textsubscript{2} and conventional PaO\textsubscript{2} sensors in
the present investigation. The inflammatory response that was present postoperatively in most patients, the necessity of vasopressor support and the lack of centralization might be a possible explanation for this finding. Rodriguez and co-workers [11] recently evaluated PtcCO₂ monitoring in critically ill adults and reported that only major cutaneous vasoconstriction considerably influenced the accuracy of PtcCO₂ measurements, whereas application of catecholamines, respiratory support and mild hypothermia did not exert substantial interference. In the present study exploration of the skin status until 12 hours after removal the sensors showed no signs of low perfusion.

Monitors for combined continuous transcutaneous measurements of carbon dioxide tension and oxygen saturation have been investigated in recent years in healthy volunteers [18], during major surgery [19], in patients with severe pulmonary disease [5, 20] and in critically ill adults [11, 12, 21], but the results regarding reliability were not conclusive. In 13 spontaneously breathing, not intubated patients in the early postoperative period, Fanelli and co-workers [21] reported only a unsatisfactory agreement of PtcCO₂ measured with a previous version of the V-Sign™ 2 earlobe sensor and PaCO₂ measured by co-oxymetry. The study is however limited in its explanatory power, since a small and particularly heterogeneous group of patients was included and because of methodological confinement of blood sampling. In a previous study [12], using an older version of the V-Sign™ 2 earlobe sensor, we also found only unsatisfactory agreement of PtcCO₂ and PaCO₂ and a significant drift over the sampling time in patients after cardiac surgery. Contrary to these results, an excellent agreement of PtcCO₂ and PaCO₂ was found in the present investigation with the revised V-Sign™ 2 sensor attached at the earlobe. The only slight overestimation is in agreement with recent literature [5, 20] and is attributed primarily to the anaerobic factor, caused by heating the sensor area, and secondary to CO₂ production of living epidermal cells. During the 6 hours study period, 16 of the 20 patients were breathing spontaneously while being supported by a respirator, the lungs of two patients were ventilated, and two patients
were extubated three hours after admission. Intra-individual analysis of the agreement between PtcCO₂ and PaCO₂ data pairs collected after extubation of the two patients showed no considerable differences to the patients whose lungs were ventilated. These findings are supported by a study most recently published by Maniscalco and colleagues [22] and performed in severely obese and clinically unstable patients using the TOSCA device (Linde Medical Sensors AG, Basel, Switzerland). These authors reported good agreement of PtcCO₂ and PaCO₂ in both spontaneously breathing and ventilated patients.

A considerable drift of PtcCO₂ values over time has been reported by several investigators [12, 20, 23]. Storre and co-workers [5] demonstrated a considerably improvement in the accuracy of a previous version of the V-Sign™ 2 earlobe sensor using an off-line drift correction for PtcCO₂. Mean bias and limits of agreement of PtcCO₂ and PaCO₂ after retrospective drift correction were -2.9 mmHg and -0.8 / + 1.7 mmHg. Using the revised V-Sign™ 2 sensor in the present investigation we found no relevant drift at all three sensor locations during the 6 hours sample period. This finding might most probably be explained by the systematic revision of the algorithm of V-Sign™ technology by the manufacturer, including the integration of a new drift correction modus over time (in vivo correction). Using the revised V-Sign™ 2 sensor, an initial overshoot of the PtcCO₂ signal was observed in seven of the 20 patients that disappeared after 20 to 25 min. This finding was previously reported by several investigators [12, 24] and may be explained by mobilization of high tissue CO₂ that has accumulated before vasodilatation occurs during artificial heating of the sensor area. The short initial period of higher heating temperature of the sensor area incorporated into the revised V-Sign technology did not eliminate the overshoot phenomenon in all patients.

The finding, that dobutamine has an impact on the bias PtcCO₂ear and PaCO₂ might be explained by improvement of the microcirculation at the ear lobe, which leads to a higher PtcCO₂, caused by higher tissue CO₂ production. Since dobutamine in this study was only
applied in the low dose range, it is not excluded, that doses of dobutamine above the low range may significantly interfere with the accuracy of the PtcCO2 measurement at the ear lobe.

P_{\text{E}}CO_2 correlated only moderately with PaCO_2 and with PtcCO2 and the agreements were poor, indicating that PtcCO_2 better detects changes in the ventilation state of the patients than P_{\text{E}}CO_2 during the recovery period.

Most investigators focused their reports on accuracy and precision of PtcCO2, whereas the reliability of oxygen saturation measurements was not or less discussed. Rohling and co-workers [25] reported excellent agreement of transcutaneously measured SpO2 using the TOSCA device and SaO2 in anaesthetized adult patients. Similar results were found in anaesthetized pediatric patients by Dullenkopf and co-workers [26] with a mean bias and limits of agreement of -0.63% and -3.4 / +2.1% respectively. In patients assessed for long-term oxygen therapy, Schafroth Török and colleagues [20] recently confirmed these results using a previous version of the V-Sign\textsuperscript{TM} 2 sensor. However, this investigation was performed in medical patients with presumably constant body temperature attending lung function tests for assessment of home oxygen therapy. In a previous study [12] using the same sensor as Schafroth Török and colleagues [20] we reported unacceptably high limits of agreement for SpO2 and SaO2 in patients with stable haemodynamics during recovery after cardiac surgery. Although detection of transcutaneous oxygen saturation and pulse rate was considerably improved with the revised V-Sign\textsuperscript{TM} 2 sensor, the rate of detection failure still ranged between 10 to 25% and thus was too high at all sensor locations. Additionally, the limits of agreement of SpO2 did not meet predefined criteria. The best results were found when the revised V-Sign\textsuperscript{TM} 2 sensor was attached at the earlobe, but the rate of detection failures was still 10%.

In healthy adult volunteers, Mannheimer and colleagues [27] reported statistically significant degradation of reading accuracy of SpO2, measured by reflectance pulse oximetry. They recommended to attach the sensor at the lower part of the forehead directly over the eyebrow.
and slightly lateral to the eye to avoid possible impact of vasculature on SpO2 readings. In the current investigation we cannot exclude that pulsatile vasculature at the forehead and cheek had an impact on accuracy of SpO2 detection. Remarkably, the rate of detection failure for pulse rate, measured with the revised V-Sign™ 2 sensors, ranged between 5 to 10% and, thus, was considerably lower than that for SpO2. The lowest rate of detection failure of 5% and a good agreement with a bias of +1.2 bpm and limits of agreement of -3.3 and +5.8 were found with the revised sensor attached to the earlobe. The lowest rate of detection failure of 2% for SpO2 and PR and an excellent agreement of SpO2 and SaO2 were found with the Nellcor N-595 device using a finger clip. These findings confirmed the results of our previous study [12].

In conclusion, the revised SenTec digital V-Sign™ 2 device attached at the earlobe showed considerable improvement in accuracy of PtcCO2 detection. The V-Sign™ 2 earlobe sensor is a reliable tool for monitoring the ventilation status in respirator dependent and spontaneously breathing patients during recovery after cardiac surgery.
Figure legends

Fig 1a-c Agreement of PtcCO\textsubscript{2} and PaCO\textsubscript{2} at the earlobe, the forehead and the cheek with n = 296/297/299, mean bias +1.1/ +1.8/+1.5 mmHg and limits of agreement of -3.4/+5.5/-2.4/+7.8/-3.9/+6.9 mmHg, respectively

Fig 2 PtcCO\textsubscript{2}ear (thick solid line), PtcCO\textsubscript{2} forehead (thin solid line), PtcCO\textsubscript{2} cheek (thick dashed line) and PaCO\textsubscript{2} (thin dashed line) at the 16 sample points. Median [25/75\% percentile] of PtcCO\textsubscript{2} at the earlobe, forehead and cheek, PaCO\textsubscript{2} were recorded at the sample times (n = 20 for each sample time)

Fig 3a-c First differences of PtcCO\textsubscript{2} and PaCO\textsubscript{2} at the earlobe (r\textsuperscript{2} = 0.81, p < 0.001) the forehead (r\textsuperscript{2} = 0.73, p < 0.001) and the cheek (r\textsuperscript{2} = 0.77, p < 0.001)

Fig 4a-c Agreement of V-Sign SpO\textsubscript{2} and SaO\textsubscript{2} at the earlobe, the forehead and the cheek with n = 270/244/225, mean bias -1.68/-2.40/-2.04 \% and limits of agreement of -6.81/+3.45/-7.38/+2.57/-6.60/+2.53 \%, respectively

Fig 5a-c Agreement of V-Sign PR and PR measured by ECG with n = 285/269/294, mean bias +1.22/+1.61/+1.18 bpm and limits of agreement of -3.31/+5.75/-2.52/+5.73./-4.21/+6.58 bpm, respectively
References


Table 1 Patients characteristics and hemodynamic data

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<thead>
<tr>
<th>No. of Patients</th>
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<tr>
<td>Age, year</td>
<td>62 ±13.2 (36-84)</td>
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<tr>
<td>Male/female</td>
<td>16/4</td>
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<tr>
<td>BMI, kg/m²</td>
<td>26.2 ±4.1 (20.3-36.4)</td>
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<td>Type of surgery</td>
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<td>CABG</td>
<td>6</td>
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<td>Valve</td>
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<tr>
<td>Combined</td>
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</tr>
<tr>
<td>Cardiac index, liter/min/m²</td>
<td>2.57 ±0.77 (1.0-4.4)</td>
</tr>
<tr>
<td>Mean arterial pressure, mmHg</td>
<td>71 ± 7.6 (58-92)</td>
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<td>Ventilation time, min</td>
<td>297 ± 52 (210-390)</td>
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<td>Intraoperative drug support:</td>
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<td>*Norepinephrine, µg/kg/min</td>
<td>0.07 ± 0.14 (0-0.69)</td>
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<tr>
<td>**Epinephrine, µg/kg/min</td>
<td>0.04 ± 0.03 (0-0.09)</td>
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<tr>
<td>***Dobutamine, µg/kg/min</td>
<td>1.76 ± 1.76 (0-4.71)</td>
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<tr>
<td>°Milrinone, µg/kg/min</td>
<td>0.11 ± 0.08 (0.04-0.33)</td>
</tr>
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</table>

*values are expressed as mean ±SD (range). Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; *(n = 19 patients), **(n = 3 patients), *** (n = 7 patients), °(n = 3 patients)
Table 2. Agreement between values of non-invasive measurement (V-Sign\textsuperscript{TM} 2, Nellcor N-595) and those of invasive measurements, using linear regression ($r^2$) and Bland-Altman analysis

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>$r^2$</th>
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<th>LOA</th>
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<tr>
<td>PtcCO$_2$ear - PaCO$_2$, mmHg</td>
<td>296</td>
<td>0.92</td>
<td>+1.1</td>
<td>-3.4/+5.5</td>
</tr>
<tr>
<td>PtcCO$_2$forehead - PaCO$_2$, mmHg</td>
<td>297</td>
<td>0.85</td>
<td>+1.8</td>
<td>-2.4/+7.8</td>
</tr>
<tr>
<td>PtcCO$_2$cheek - PaCO$_2$, mmHg</td>
<td>299</td>
<td>0.88</td>
<td>+1.5</td>
<td>-3.9/+6.9</td>
</tr>
<tr>
<td>P$_e$CO$_2$ - PaCO$_2$, mmHg</td>
<td>165</td>
<td>0.47</td>
<td>+5.3</td>
<td>-10.9/+21.5</td>
</tr>
<tr>
<td>V-Sign SpO$_2$ear – SaO$_2$, %</td>
<td>270</td>
<td>0.59</td>
<td>-1.68</td>
<td>-6.81/+3.45</td>
</tr>
<tr>
<td>V-Sign SpO$_2$forehead – SaO$_2$, %</td>
<td>244</td>
<td>0.56</td>
<td>-2.40</td>
<td>-7.38/+2.57</td>
</tr>
<tr>
<td>V-Sign SpO$_2$cheek – SaO$_2$, %</td>
<td>225</td>
<td>0.64</td>
<td>-2.04</td>
<td>-6.60/+2.53</td>
</tr>
<tr>
<td>N-595 SpO$_2$ – SaO$_2$, %</td>
<td>294</td>
<td>0.73</td>
<td>+0.41</td>
<td>-2.38/+3.19</td>
</tr>
<tr>
<td>V-Sign PR$_{ear}$ – ECG, bpm</td>
<td>285</td>
<td>0.98</td>
<td>+1.22</td>
<td>-3.31/+5.75</td>
</tr>
<tr>
<td>V-Sign PR$_{forehead}$ – ECG, bpm</td>
<td>269</td>
<td>0.98</td>
<td>+1.61</td>
<td>-2.52/+5.73</td>
</tr>
<tr>
<td>V-Sign PR$_{cheek}$ – ECG, bpm</td>
<td>282</td>
<td>0.98</td>
<td>+1.18</td>
<td>-4.21/+6.58</td>
</tr>
<tr>
<td>N-595 PR – ECG, bpm</td>
<td>294</td>
<td>0.78</td>
<td>+1.00</td>
<td>-16.5/+18.5</td>
</tr>
</tbody>
</table>

Abbreviations: LOA, limits of agreement; PtcCO$_2$X, transcutaneous carbon dioxide tension measured with V-Sign sensor at the corresponding measurement site X (ear, forehead, cheek); PaCO$_2$, arterial carbon dioxide tension; V-Sign SpO$_2$X, oxygen saturation measured with V-Sign\textsuperscript{TM} 2 sensor at the location X (ear, forehead, cheek); SaO$_2$, arterial oxygen saturation; N-595 SpO$_2$, oxygen saturation measured with the finger clip sensor of Nellcor N-595 pulse oximeter; V-Sign PR$_X$, pulse rate measured with V-Sign\textsuperscript{TM} 2 sensor; at the location X (ear, forehead, cheek) ECG, electrocardiography; N-595 PR, pulse rate measured with the finger clip sensor of Nellcor N-595 pulse oximeter.
Table 3. Agreement of PtcO₂ and PaCO₂ during various ventilation states analysed with linear regression ($r^2$) and Bland-Altman.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>$r^2$</th>
<th>Mean bias (mmHg)</th>
<th>LOA (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperventilation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PtcCO₂ear - PaCO₂</td>
<td>67</td>
<td>0.82</td>
<td>+1.4</td>
<td>-2.3/+5.0</td>
</tr>
<tr>
<td>PtcCO₂forehead - PaCO₂</td>
<td>70</td>
<td>0.65</td>
<td>+2.6</td>
<td>-1.1/+6.4</td>
</tr>
<tr>
<td>PtcCO₂cheek - PaCO₂</td>
<td>70</td>
<td>0.65</td>
<td>+2.3</td>
<td>-1.7/+6.3</td>
</tr>
<tr>
<td>Normoventilation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PtcCO₂ear - PaCO₂</td>
<td>192</td>
<td>0.75</td>
<td>+1.1</td>
<td>-3.6/+5.7</td>
</tr>
<tr>
<td>PtcCO₂forehead - PaCO₂</td>
<td>190</td>
<td>0.65</td>
<td>+1.8</td>
<td>-4.4/+7.8</td>
</tr>
<tr>
<td>PtcCO₂cheek - PaCO₂</td>
<td>192</td>
<td>0.71</td>
<td>+1.4</td>
<td>-4.3/+7.1</td>
</tr>
<tr>
<td>Hypoventilation:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PtcCO₂ear - PaCO₂</td>
<td>36</td>
<td>0.76</td>
<td>+0.5</td>
<td>-3.4/+4.4</td>
</tr>
<tr>
<td>PtcCO₂forehead - PaCO₂</td>
<td>36</td>
<td>0.60</td>
<td>+0.1</td>
<td>-7.3/+7.4</td>
</tr>
<tr>
<td>PtcCO₂cheek - PaCO₂</td>
<td>36</td>
<td>0.74</td>
<td>+0.3</td>
<td>-5.0/+5.6</td>
</tr>
</tbody>
</table>

Abbreviations: LOA, limits of agreement; PtcCO₂X, transcutaneous carbon dioxide tension measured with V-Sign™ 2 sensor at location X (ear, forehead, cheek); PaCO₂, arterial carbon dioxide tension.