Testing of the viQtor in postoperative patiënts: a study utilizing photoplethysmography (PPG) sensor technology

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In this prospective observational data-collection study with retrospective data analysis, 80 subjects, who have been admitted at the UMC Utrecht because of a surgery, will be recruited at the pre-operative screening clinic before surgery. Prior to...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON56569

Source
ToetsingOnline

Brief title
Testing of the viQtor

Condition

- Other condition

Synonym
Cardiac ablation, COPD, surgery

Health condition

vitale functie parameters worden vergeleken in postoperatieve patientengroepen

Research involving

Human

Sponsors and support

Primary sponsor: smartQare B.V.
Source(s) of monetary or material Support: bedrijf smartQare B.V.

Intervention

Keyword: Accuracy, Continuous monitoring, Testing, Vital signs

Outcome measures

Primary outcome

• Descriptive, ARMS between simultaneously paired measurements of RR from viQtor and Capnography (Spacelab type XPREZZON ® 91393) and in phase 2 also from real-time CO* waveforms collected with the Smart Advanced Capno-Line® H Plus EtCO* sampling line (Medtronic, Boulder, CO, USA).

Acceptable for clinical purposes if the total ARMS is within 3 breaths/min.

Secondary outcome

• Descriptive, ARMS between simultaneously paired measurements of PR from viQtor and ECG-based heart rate (Spacelab type XPREZZON ® 91393).

Acceptable for clinical purposes if the total ARMS is within 3 beats/min.

• Descriptive, ARMS between simultaneously paired measurements of SpO2 from viQtor and SpO2 measurements from a reference device: (Spacelab type XPREZZON ® 91393).

Acceptable for clinical purposes if the total ARMS is within 3%.

- To evaluate the number and type of artefacts of the algorithms: the number of low quality data during monitoring of the PPG values of each participant.

• Descriptive, quotient of the recorded data points versus the theoretical

maximum data points per patient.

• Descriptive, the responses to the abbreviated USE questionnaire: the

assessment of patient satisfaction and the impact on daily activities when

using the viQtor device and armband from the patient's perspective.

Study description

Background summary

In the pursuit of delivering optimal patient care while adhering to budget constraints, hospitals must maximize their resources, including staff members and available beds. This necessitates efficient management of patient
admissions and discharges, often aiming to transition patients to lower levels of care whenever possible. However, navigating these tasks can be complex and challenging. One valuable solution that can enhance patient management and triage is the utilization of wearable monitoring devices for continuous vital
sign measurements.

Continuous vital sign monitoring with wearable devices offers significant benefits in understanding patients' health conditions more comprehensively.
This deeper insight aids in effective triaging, allowing medical professionals to make informed decisions about the appropriate level of care for each patient2. At present, continuous monitoring is predominantly carried out in medium and intensive care units and recoveries, where (critically ill) patients are located. However, to effectively and timely detect deterioration, it is crucial to implement continuous monitoring for patients in general wards as well. By employing wearable devices, healthcare providers can continue monitoring patients even in lower care settings, reducing the urgency to keep patients within the hospital.

The peri-operative period, characterized by high incidences of respiratory and hemodynamic events, presents a critical time for patient monitoring. Continuous vital sign monitoring facilitated by wearable devices such as the viQtor* solution enables early detection of clinical deterioration, providing opportunities for prompt intervention and preventive adjustments to treatment.
In an ideal scenario, such monitoring would be ongoing, wireless, and independent of constant supervision.

By implementing wearable monitoring devices, such as the viQtor* solution, in hospital settings and outside, medical professionals gain a valuable tool to enhance patient care and

resource management. Continuous monitoring can offer a comprehensive view of patient health, aiding in effective triage on patient
admission and facilitating appropriate discharge decisions. Moreover, the ability to detect and address clinical deterioration early on through continuous monitoring contributes possibly to improved patient outcomes.

Given that viQtor* version 1.0 has a CE mark and has successfully undergone stringent tests for elec-trical safety and performance according to the ISO 60601 standards at an accredited testing facility, our focus shifts to
assessing the accuracy of measuring vital signs within a clinical environment, in patients who exhibit significant variability in vital functions. Therefore, we have opt-ed for postoperative patients as this group shows an increased risk of health deterioration. It is essential to understand how the viQtor* performs under these conditions to ensure its reliability and effectiveness in a clinical setting.

To achieve this, we have designed a comprehensive study with the aim of comparing vital signs data collected during standard postoperative monitoring with data obtained using the viQtor*.

Study objective

In this prospective observational data-collection study with retrospective data analysis, 80 subjects, who have been admitted at the UMC Utrecht because of a surgery, will be recruited at the pre-operative screening clinic before surgery. Prior to the surgery procedure, the treating doctor will inquire whether the researcher may contact the patients for potential participation in the study. If the participant is interested in participating, the researcher will approach the participant and provide them with the informed consent form at least 24 hours prior to the measurements. Participants will, thus, have 24 hour to consider participating in the study.
After the informed consent is signed and after surgery, the participant will be equipped with the viQtor device (SQ-RD or viQtor 2) on the upper arm and monitored simultaneously by a hospital reference monitor (Spacelab XPREZZON) in the recovery department for a minimum of 4 hours and a maximum of 24 hours until transition to a general ward of the UMCU. It is important to note that the ward staff will rely solely on the values measured by the hospital's monitoring device for the assessment of the patient's vital functions. The values measured by the viQtor SQ-RD and viQtor 2 will only be stored, and analyzed after the study, exclusively for the purpose of this study. More information about both viQtor devices and the reference hospital measurement devices can be found in Chapter 6.

At the end of the study period, following a maximum wear time of 24 hours or upon transfer to the general ward, the research nurse will ask the patient three questions about their experience with the viQtor device using a short 5-point Likert Scale questionnaire. During this interview, the nurse will inquire about the patient's satisfaction of the viQtor. This interview is expected to take about 3 minutes.

Measuring vital signs
Within the first phase of this study, measurement data will be collected, with the SQ-RD, from

a case mix of 40 postoperative patients in the recovery department of UMC Utrecht. The photoplethysmogram (PPG) data are needed for the determination of all three vital sign measurements (SpO2, PR, RR), as the performance of RR is directly related to the performance of the other two vital signs algorithms. These measurement data will be used to train/improve the technical performance of the RR algorithm, and possibly also for the training/improvement of the algorithms for SpO2 and PR. The training/improvement of the technical performance of the RR algorithm is based on comparing measurement values of the SQ-RD with the reference equipment (Spacelab type XPREZZON ® 91393) at UMC Utrecht.

Based on the collected measurement data in phase 1, the RR algorithm, and possibly also the PR and SpO2 algorithms, will be optimized by the manufacturer if needed, with the aim of improving technical performance.

In the second phase of the study, the clinical validation of the technical performance will take place for the new software version with viQtor 2, which includes the optimized RR algorithm, as well as previously validated algorithms for PR and SpO2, possibly with improvements. Measurements will be compared again with the reference device (Spacelab type XPREZZON ® 91393) at UMC Utrecht and also with the Smart Advanced CapnoLine® H Plus EtCO* sampling line (Medtronic, Boulder, CO, USA) to achieve more precise RR measurements. In this second phase, a new group of 40 postoperative patients will be involved to prevent bias from the test patient population. If a measurement lasts less than four hours or if the data become unusable due to technical issues with the reference device (Spacelabs XPREZZON® 91393), the participant will be replaced to ensure the statistically required total of 40 valid data points is achieved, without altering the study design or increasing the burden on participants.

Additionally, it is of ultimate importance that the various time clocks are set identically in the recovery room and the respective device. Within 2 minutes, both the viQtor device and the reference device must be initiated. The start time is manually annotated. Retrospectively, the time matching is determined based on the correlation of both datasets. The viQtor has a start delay of 1 minute, and there may be missing data points at the beginning. Therefore, we accept a maximum time difference of 5 minutes in the correlation of the data.

Within this study, the number and type of artifacts are also examined, such as "no data" or when recorded as an "invalid value." Classification into valid/invalid or missing data is determined retrospectively, including missing
data since the start of a measurement.

As an additional quality check on the reference measurements, RR annotations are performed by the research nurse in the recovery department, which are crucial for establishing and comparing the RR data of the viQtor and the Spacelab XPREZZON at the specified moments below.
The annotation is conducted through direct observation at three specific points in the study (5 minutes after the application of the viQtor, after 2 hours of wearing the viQtor, and during the last 5 minutes before the viQtor is
removed). The RR is manually annotated by counting the number of breaths per minute. Simultaneously, the research nurse manually records the results of the respiratory rate

measured by the Spacelab XPREZZON at that same moment to enable a comparison.

Study design

Within the framework of this study, the aim is to improve and validate the technical performance of a new algorithm for determining the respiratory rate (RR) of the viQtor. This research involves continuous collection of
photoplethysmogram (PPG) data (initially) and vital parameters including pulse rate (PR), respiratory rate (RR), and blood oxygen saturation (SpO2), from 80 post-operative patients. The data collection will span a minimum of 4 hours and a maximum of 24 hours during their stay in the recovery department. The study is divided into two phases, which are further explained below.

Phase 1:
The primary goal of this first phase is to collect measurement data from a case mix of 40 postoperative patients in the recovery department of the UMC Utrecht.
These measurement data will be used to train/improve the technical performance of the RR algorithm. During this phase, the viQtor research device (SQ-RD) will be utilized. The training/improvement of the technical performance of the RR algo-rithm is based on comparing the measurement values of the SQ-RD with the
reference equipment (Spacelab type XPREZZON ® 91393) at UMC Utrecht. PPG measurement data will be used for train-ing/improving RR, and possibly also for the training/improvement of SpO2 and PR. Vital parameters SpO2 and PR are also measured because the performance of RR is related to them. In this phase, the research group in terms of size and population will be equal to the group in phase 2, ensuring both groups have the same level of representativeness of the collected data.

Optimization:
Based on the collected measurement data in phase 1, if necessary, the RR algorithm will be optimized by the manufacturer with the aim of improving technical performance. If applicable, the technical per-formance of the PR and SpO2 algorithms will also be improved. The result of the optimization is a new software version that will be clinically validated for technical performance in phase 2 within a new group of postoperative patients. In phase 2, the viQtor device, equipped with the new, yet-to-be-certified, software version (viQtor 2) will be used. ViQtor 2 is identical to the current CE certified device (viQtor 1), with the only difference being that it contains new software that is not yet CE certified. This new software will have been verified according to the manufacturer's quality processes, including verification of technical performance in healthy subjects before phase 2.

Phase 2:
In the second phase of the study, the clinical validation of the technical performance of the new soft-ware version with viQtor 2, containing the optimized RR algorithm, as well as previously validated algorithms for PR and SpO2, will take place. Measurements will again be compared with the reference device (Spacelab type XPREZZON ® 91393) at UMC Utrecht. Additionally, in phase 2 of the study, we will connecting patients to the Smart Advanced Capno-Line® Plus EtCO* sampling line (Medtronic, Boulder, CO, USA) to achieve more precise

RR measurements. Literature and clinical practice indicate that capnography is the gold standard for measuring RR [1]. These capnography measurements complement ECG-based data by providing real-time respiratory insights directly related to ventilation quality and CO* exchange efficiency. In addition, to using the capo-line for RR measurements, we will continue to measure RR with the Spacelab system, but will give special attention to applying the electrodes. In this second phase, a new group of 40 postoperative patients will be involved to prevent bias from the test patient population. Postoperative patients are chosen due to the significant variability in vital functions within this group, allowing for a broader validation of the technical performance of viQtor 2.

After clinical validation, the obtained results of technical performance will be used to create a clinical evaluation report, which is part of the documentation for the modification of viQtor 2 (algorithm adjustment). This
report will then be submitted for approval for CE-certification to the Notified Body, as viQtor is a Class IIa medical device.

MDR 74.2:
This research is part of the conformity assessment according to MDR 74.2. The study is conducted with the aim of training and clinically validating the technical performance of the RR algorithm, and possibly also the algorithms for PR and SpO2 within the new intended application [2]. It involves assessing per-formance based on MDR-specified requirements within the new intended application [MDR Regulation (EU) 2017/745, Appendix II, Chapter 6]. For this purpose, the recovery department within UMC Utrecht has been selected, where the accuracy and reliability of viQtor can be well-established given the strongly varying vital measurement values.

[2] Intended application of viQtor 2 (only the bolded text contains a modification to the intended application):The intended use of the viQtor solution is to periodically transfer health data and events to a professional healthcare organization for assessment by healthcare professionals. It measures
SpO2, pulse rate (PR), respiratory rate (RR) of adult users(18 years and older) in hospitals, nursing homes, and home settings, allowing remote monitoring and assessment of trends by healthcare professionals. Ad-ditionally, viQtor monitors skin temperature, user activity and detects potential falls. In case of a possi-ble fall, the device sends a request for attention to a professional healthcare organization. The user also has the option to send a request for assistance to the professional healthcare organization by pressing the assistance request button.

The viQtor solution is not intended:
o to detect acute life-threatening situations
o for use in high-acuity environments, such as ICU or operating rooms.
o for use on acutely ill (cardiac) patients with the potential to develop life threatening deterioration, like arrhythmias or very fast atrial fibrillation.
These patients should be monitored using a device with continuous ECG. The
viQtor solution is not a substitute for an ECG monitor.

Intended use of the viQtor solution for this study is:
The SQ-RD and viQtor 2 (equipped with the new, yet-to-be-certified, software version) are specifically designed for use in a clinical setting, focusing on a diverse population of postoperative patients, including those with COPD, which have undergone various surgi-cal procedures such as cardiac ablation. The intended application is to capture and analyze data related to vital functions, including PR, RR, and SPO2, for the detection of cardiac arrhythmias and decreased oxygen saturation during the postoperative period. To facilitate a comprehensive evaluation of both the device and the software across various usage environments, we have decided to conduct the study in a postoperative setting at the UMC Utrecht with a diverse group of patients. The selection of
post-operative patients is driven by the substantial variability in vital functions due to an increased risk of health deterioration, allowing for testing of the medical device across a broad spectrum within the dynamic range of the device.

Estimated study timelines
First Subject enrolled: February 2024 (pending IRB approval)
Enrolment Period: 1 month
Follow-up duration: min 4 hours and max 24 hours per participant
Total study duration: 2 months
Data cleaning/close out: 3 months

Intervention

In this study, two viQtor devices are used: a derived research device (SQ-RD) based on the currently CE-certified viQtor device (viQtor 1), and the viQtor 2. The viQtor 2 is equipped with the new software version, which is still pending certification. The viQtor 2 is identical to the current CE-certified device, with the only difference being the inclusion of the new, not yet CE-certified, software.

Study burden and risks

The viQtor wearable will be placed on the upper arm with a band which can be easily adjusted for comfort. The study participants will wear the viQtor* wearable 24/7 in the hospital for a minimal of 4 hours and a maximum of 24 hours but this will not affect their clinical care nor impact their activities. Additionally, in phase 2 of the study, we propose connecting patients to the Smart Advanced Capno-Line® H Plus EtCO* sampling line to achieve more precise RR measurements. Research has shown that this capnography line is comfortable for patients. To minimize patient burden, they will be connected to the capnoLine for a minimum of 2 hours and up to a maximum of 6 hours. The capnoLine will be placed immediately after surgery while the patient is often still sedated, ensuring they experience minimal discomfort from its placement. Besides potential skin irritation, there is no further burden to the patient.

Measurements obtained with the viQtor* will not be viewed nor analyzed during the study, and consequently, no clinical decisions will be made based on these measurements.

In addition, participation in the study incurs a minimal time commitment. The study participant wears the viQtor device only during their hospital stay. Additionally, we ask the participant to answer a set of questions at the end of the study, which are also administered within the hospital setting. The interview typically takes about 3 minutes.

Participation in the study does not impact the standard care/treatment that the participant receives at the hospital. Participants receive the regular treatment or assessments for the condition for which they have been admitted to the UMC Utrecht.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Adolescents (16-17 years)

Inclusion criteria

- Adult (age 18+) - equal mix regarding gender and age
- Post-operative connection to patient monitors
- No cognitive impairments
- Hospitalized because of moderate/major surgery
- Fluent in the Dutch language
- Willing and able to sign informed consent

Exclusion criteria

- Patients with known extremely sensitive skin, or allergies to metal or plastics.
- Patients with significant upper arm deformities, swelling, irritation, injuries, degenerative changes, infectious diseases, or oedema at the moment of inclusion
- cuff, or IV line).
- Patients with tremors or convulsions (e.g. Parkinson).
- Patients with tattoos on the upper arm where the device*s PPG sensor will be placed.
- Patients with upper arm sizes outside the wearable*s fitting range.
- Emergency (surgical) patients, as obtaining true informed consent may not be feasible.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-04-2024
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	viQtor
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	22-02-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-06-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-12-2024
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85372.000.23