Development and Implementation of Continuous Blood Pressure Monitoring: A Study Utilizing Photoplethysmography (PPG) Sensor Technology.

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The primary objective of this study is to determine the accuracy of the technical performance of a newly developed non-invasive, continuous PPG-based BP algorithm by comparing absolute one-minute values of systolic (SBP) and diastolic (DBP) BP with...

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

Summary

ID

NL-OMON57073

Source
ToetsingOnline

Brief title
PRESSURE

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Respiratory tract therapeutic procedures

Synonym
elective surgery (cardiothoracic, major oncological, or major gastro-intestinal)

Health condition

Respiratoire aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: smartQare B.V.
Source(s) of monetary or material Support: Deze studie is onderdeel van het PRESSURE-project;gesubsidieerd door EFRO (Europees Fonds voor Regionale Ontwikkeling).

Intervention

Keyword: Blood pressure algorithm, Continuous monitoring, Development, Implementation

Outcome measures

Primary outcome

The primary endpoint of the study is the technical performance verification of

a PPG-based algorithm for continuous one-minute SBP and DBP values derived from

viQtor data, meeting standards set by the Association for the Advancement of

Medical Instrumentation (AAMI). This is deemed acceptable for clinical purposes

if the mean absolute error (MAE) <= 5 mmHg and the standard deviation (SD) of

the difference <= 8 mmHg between simultaneously paired measurements from viQtor

SQ-RD and the arterial line (White et al., 1993).

Secondary outcome

8.1.2 Secondary study parameters/endpoints

• Evaluate whether viQtor*s BP data adheres to at least Grade B of the BHS

standard.

o For clinical acceptability (minimum Grade B), the MEA and distribution of the

MAE between simultaneously paired measurements of both DBP and SBP between the

viQtor SQ-RD and the arterial line adhere to the following criteria.

Additionally, it is essential that at least 20% of these one-minute median BP

measurements obtained by the viQtor SQ-RD are available:

* <= 5 mmHg for 60% of the paired measurements (Grade A);

* <= 10 mmHg for 85% of the paired measurements (Grade A);

* <= 15 mmHg for 95% of the paired measurements (Grade A);

* <= 5 mmHg for 50% of the paired measurements (Grade B);

* <=10 mmHg for 75% of the paired measurements (Grade B);

* <=15 mmHg for 90% of the paired measurements (Grade B).

• Evaluate whether viQtor*s BP measurements meet the accuracy requirements of the 81060-2:2022 standard (ISO, 2018).

o For clinical acceptability, the MEA and SD between simultaneously paired systolic and diastolic BP measurements must adhere to the following criteria set by the 81060-2:2022 standard: Acceptable for clinical purposes if the MAE is <= 5 mmHg and the SD is <= 8 mmHg between simultaneously paired measurements from viQtor SQ-RD and the arterial line (ISO, 2018).

• Descriptive, MAE and SD between simultaneously paired measurements of mean arterial pressure (MAP) from viQtor SQ-RD and the arterial line.

o Acceptable for clinical purposes if MAE < 6 mmHg and SD is < 10 mmHg between simultaneously paired measurements from viQtor SQ-RD and the arterial line.

• Descriptive, ARMS between paired one-minute median values of DBP and SBP values estimated using a 2-point model-based method (using ear PPG and viQtor PPG) and invasive arterial line, in accordance with the AAMI standards (White

et al., 1993).

o Acceptable for clinical purposes if the MAE <= 5 mmHg and the SD of the difference between the estimated DBP and SBP values of the model and the arterial line is <= 8 mmHg (White et al., 1993).

• Comparison of ARMS and other relevant statistical outcomes between viQtor SQ-RD and the invasive arterial line, and between the 2-point model-based method and invasive arterial line.

• Descriptive, ARMS between simultaneously paired measurements of SpO2 from viQtor SQ-RD and ear SpO2 measurements from the Philips IntelliVue MX750 monitor.

o Acceptable for clinical purposes if the total ARMS is within 2%.

• Descriptive ARMS between simultaneously paired measurements of SpO2 from viQtor SQ-RD and SaO2 from blood gasses of the arterial line.

o Acceptable for clinical purposes if the total ARMS is within 2%.

• Descriptive, ARMS between simultaneously paired measurements of Heart Rate (HR) from viQtor SQ-RD and ECG-based of the Philips IntelliVue MX750 monitor.

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

• Descriptive, ARMS between simultaneously paired measurements of Respiratory Rate (RR) from viQtor SQ-RD and Capnography of the Philips IntelliVue MX750

monitor.

o Acceptable for clinical purposes if the total ARMS is within +/- 3

breaths/min.

• Descriptive, ARMS between simultaneously paired measurements of MAP, DBP and

SBP values from the viQtor SQ-RD and the cuff-based sphygmomanometers.

o Acceptable for clinical purposes if the MAE <= 5 mmHg and the SD of the

difference is <= 8 mmHg between the simultaneously paired measurements from

viQtor SQ-RD and the cuff-based measurements (White et al., 1993).

• Evaluate the correlation and the ability for prediction of treatment related

complications with the absolute measurements and trends from the various

non-invasive measured parameters with the viQtor SQ-RD and the occurrence.

Study description

Background summary

This study, supported by EFRO (European Regional Development Fund), responds to the limitations of conventional blood pressure (BP) measurement methods, like cuff-based sphygmomanometers and invasive arterial catheterization. Effective blood pressure (BP) management is vital for maintaining cardiovascular health and detecting potential health issues early. Traditional BP monitoring methods, including cuff-based sphygmomanometers and invasive arterial lines, are widely used but come with significant limitations. Photoplethysmography (PPG) technology emerges as a promising alternative, providing a cost-effective, continuous, and non-invasive solution for BP monitoring. smartQare B.V.*s developed viQtor wearable, which uses PPG technology, provides a novel approach aimed at addressing these challenges associated with current BP measurement methods. This clinical study aims to develop, optimize, and technically verify the performance of a PPG-based BP algorithm within the viQtor. The goal is to develop a user-friendly, accurate, and durable wearable device, suitable for

widespread use in both hospitals and outpatient care settings, thereby enhancing patient care and reducing healthcare personnel burden.

Study objective

The primary objective of this study is to determine the accuracy of the technical performance of a newly developed non-invasive, continuous PPG-based BP algorithm by comparing absolute one-minute values of systolic (SBP) and diastolic (DBP) BP with the continuous invasive arterial DBP and SBP data. The study*s objective adheres to standards set by the Advancement of Medical Instrumentation (AAMI) standards (White et al., 1993).

Study design

The study is a prospective data-collection study, with a primary focus on the development, optimization, and technical performance verification of a new PPG-based algorithm for continuous BP measurements within the viQtor device. It involves the continuous collection of raw PPG data and vital signs, such as BP, heart rate (HR), respiratory rate (RR), and blood oxygen saturation (SpO2), from a total of 55 perioperative ICU patients at Catharina Hospital Eindhoven (CZE). Data collection periods will vary for each patient, ranging from 30 minutes to 48 hours. This study gathers raw PPG and BP data from 55 ICU patients using the viQtor research device (viQtor SQ-RD), the Ear Pulse Oximeter, and an invasive arterial line. Subsequently, these raw data will be used to develop, optimize, and technically verify the performance of the BP algorithm by applying machine learning techniques and manual features by the research team.

Study burden and risks

The data protocol employed in this study does not interfere with the standard clinical care provided to perioperative ICU patients with an invasive arterial line, ensuring it runs concurrently without adding any extra burden. A total of 55 participating patients will wear the viQtor SQ-RD on their upper arm for a duration ranging from a minimum of 30 minutes to a maximum of 48 hours. Since continuous monitoring of BP, HR, RR, and SpO2 is part of standard care, the additional gathering of PPG data via the viQtor SQ-RD introduces minimal risk. The device*s strategic placement on the upper arm, especially in sterile environments like operating rooms, avoids stringent sterility protocols by being positioned under the operating table drape, thereby reducing infection risks. The potential of skin reaction or irritation from extended wear is acknowledged, presenting a slight risk. Overall, this study is designed to ensure minimal risk and burden to the participating patients.

Contacts

Public
smartQare B.V.

Kapteynstraat 1
Noordwijk 2201BB
NL
Scientific
smartQare B.V.

Kapteynstraat 1
Noordwijk 2201BB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

To be eligible to participate in this study, a subject must meet the following criteria:
- must be 18 years or older.
- must be admitted to the ICU at the Catharina Hospital Eindhoven postoperatively.
- must have a clinical indication for continuous BP measurement with an arterial line.
- must be willing and able to provide informed consent.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded

from this study:
- Patients with known extremely sensitive skin or allergies to metal or plastics.
- Patients with significant deformities, swelling, irritation, injuries, degenerative changes, infectious diseases, or edema on the upper arm where the device's PPG sensor will be placed. If these conditions affect only one arm, it is recommended to wear the device on the healthy arm.
- Patients with tremors and/or convulsions (e.g. Parkinson).
- Patients with tattoos on the upper arms where the device's PPG sensor will be placed. If tattoos are present on only one arm, wearing the device on the arm without tattoos is recommended.
- 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:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	55
Type:	Anticipated

Medical products/devices used

Generic name:	viQtor
Registration:	No

Ethics review

Approved WMO Date:	24-10-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86036.000.24