Vital Signs Camera Medical Library

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Primary objective:• To assess the clinical safety and effectiveness of Pulse Rate (PR) and Respiration Rate (RR) measuredwith the VSC-MEDlib within the intended use compared to the gold-standard reference devices.Exploratory objective:• To assess...

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

Summary

ID

NL-OMON56074

Source
ToetsingOnline

Brief title
VSC-MEDlib

Condition

- Other condition

Synonym
non-invasive contactless measurement of heart rate and respiratory rate

Health condition

niet-invasieve contactloze meting van hartslag en ademhalingsfrequentie

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Philips

Intervention

Keyword: Pulse Rate, remote Photoplethysmography, Respiration Rate, VitalSigns Camera

Outcome measures

Primary outcome

Primary Endpoint:

•The clinical safety and effectiveness of the non-invasive and contactless measurement of PR and RR by the VSC-MEDlib within the intended use. The effectiveness of the VSC-MEDlib will be presented in RMSE in beats and breaths per minute of the PR and RR respectively and compared to the PR and RR measured with the reference devices. It is expected that the 95% upper confidence limit of the RMSE will be <= 3 BPM for PR and RR measured by VSC-MEDlib compared to the reference devices.

Secondary outcome

Exploratory Endpoint:

•The clinical safety and effectiveness of the non-invasive and contactless measurement of PR and RR by the VSC-MEDlib during suboptimal circumstances (outside the scope of the intended use).

•Availability of the non-invasive and contactless measurement of PR and RR by the VSC-MEDlib within the intended use and during suboptimal circumstances. Availability is the percentage of valid measurements from the VSC-MEDlib: 100% x [number of valid measurements]/[total number of measurements].

•Precision of the non-invasive and contactless measurement of PR and RR by the VSC-MEDlib within the intended use and during suboptimal circumstances. Precision is the percentage of valid measurements from the VSC-MEDlib that

differ from the reference device by <= 3 BPM: 100% x [number of valid

measurements with Absolute Error <= 3 BPM]/[number valid of measurements].

Study description

Background summary

VitalSigns Camera Medical library is a software library that can be integrated into a customer application for use during virtual consults or health screening. It is intended for a point in time measurement/spot check of Pulse Rate (PR) and Respiration Rate (RR) in an automatic contactless manner as a data point in the overall assessment of the patient. It can be used either in the home or in a clinical environment, when the person is still and positioned properly in front of the camera, which is placed on a stable surface in an adequately lit environment. Both PR and RR are measured simultaneously on the same video data.
Remote photoplethysmography (rPPG) is a technique that measures a blood pulsation signal on a piece of human skin tissue from an image sequence recorded by a video camera. This blood pulsation signal is extracted by analyzing minute color differences on the skin that are caused by blood volume variations induced by each heart beat. These color differences are not visible to the naked eye. VSC-MEDlib uses advanced image and signal processing algorithms to measure the blood pulsation signal on the facial skin tissue of a human subject and derive the subject*s pulse rate (PR). Respiration rate (RR) is extracted from the same sequence of video images by analyzing the motion of the human subject*s torso induced by respiratory movement.

VSC-MEDlib should be used by original equipment manufacturers and system integrators for calculating a single HR and RR value, i.e., a spot check value, from a video recording of a patient. Typically, a reliable HR and RR measurement will be obtained within a recording duration of 1 minute.

VSC-MEDlib does not output PR or RR measurements that are of low confidence. As described in the intended use, VSC-MEDlib should not be prescribed for persons who do require critical care. It is not intended as a continuous patient monitoring system or as the sole method of checking the physical health of the patient, but as a part of a framework which mandates periodic checks by a healthcare professional to ensure appropriate clinical diagnosis and treatment can be reached. If an accurate pulse rate and respiration rate reading cannot be obtained during the measurement, the healthcare professional should direct the patient to report to a doctor*s office or other healthcare location to obtain measurements for pulse rate and respiration rate via traditional methods.

For a more detailed description of the investigational device including safety precautions and handling, see the Instructions for Use. This study will be performed to provide evidence for the claims as stated in the IFU and to show that our risk mitigation works for use cases outside of our intended use.

During this study the influence of different suboptimal condition on the recording by the VSC-MEDlib will be tested. The tests include the subjects wearing make-up as this make-up might affect the rPPG signal and therefore the PR measurement due to the fact that it reduces the amount of light penetrating into and reflecting from the skin. Wearing sunglasses or a medical face mask may affect this as well as they cover part of the face and may affect the function of the face tracker. In another tests, the camera settings, the minimum hardware requirements, the effect of a damaged lens of the smartphone used, and the effect when the subjects' face is outside the test frame will be tested.

In addition to the measurements under sub-optimal conditions, heart rate and respiration are also measured after heart rate and respiration have been increased by an exercise test. The volunteer is asked to practice on a spinning bike for 10 minutes, followed by a 20-minute rest period. During this rest period, 10 video recordings of 1 minute each are made.

Study objective

Primary objective:
• To assess the clinical safety and effectiveness of Pulse Rate (PR) and Respiration Rate (RR) measured
with the VSC-MEDlib within the intended use compared to the gold-standard reference devices.

Exploratory objective:
• To assess the clinical safety and effectiveness of Pulse Rate and Respiration Rate measured with the
VSC-MEDlib during suboptimal circumstances (outside the scope of the intended use), compared to the
gold-standard reference devices.

Study design

This study is a single center, prospective clinical investigation which is balanced for gender, age, Body Mass Index (BMI) and skin color. The study will be performed at the High Tech Campus 37, 5656 AE, Eindhoven, the Netherlands. Simultaneous measurements of PR and RR on study participants will be collected in conditions described in IFU [REF-1] and various suboptimal conditions. The study participants will be recorded with the VSC demo app (together with a compatible camera and computing hardware) and reference devices. PR and RR data

to be collected by the VSC demo app, will be post-processed after the clinical investigation and compared with the reference devices. To compare the PR measured from the VSC-MEDlib with the reference device, there is an three lead ECG recording that will be executed with the Philips MP50 monitor. The ECG is used to record the electrical activity of the heart which is directly correlated to the heart rate (in BPM). To compare the RR measurement from the VSC-MEDlib with the reference device, there is a capnography recording that will be executed by an oral/nasal canula, which is connected to the Philips Respironics LoFlo sidestream. Capnography is used to measure the CO2 level during the expiratory phase and is directly correlated to the respiration rate of the study participant. Persons who are willing to participate will be asked to provide their consent.

Intervention

Not applicable

Study burden and risks

Simultaneous measurements of PR and RR in study participants will be collected under conditions described under various sub-optimal conditions (e.g. wearing make-up, measuring with a broken lens). This is a total of 10 test/recordings. Recordings from the study participants will be recorded by the VSC demo app and reference devices. As described in this protocol, study participants are requested to sit still for a maximum of 2 minutes per recording. Heart rate and respiration data collected by the VSC demo app will be analyzed after the study and compared to the reference devices.
In addition to the measurements under sub-optimal conditions, heart rate and respiration are also measured after heart rate and respiration have been increased by an exercise test. The volunteer is asked to practice on a spinning bike for 10 minutes, followed by a 20-minute rest period. During this rest period, 10 video recordings of 1 minute each are made. The entire examination will take approximately 2 hours.

Potential risks associated with the study include:
1. Study participants use makeup that may cause skin irritation
2. Study participants use makeup that can cause cross-contamination
3. Study participants will be exposed to viruses during the clinical study
4. The exercise is too intense for the study participants, which may cause syncope
5. The ECG electrodes used during the clinical examination cause skin irritation

The outcome of the risk analysis for this clinical trial, including the use of the research equipment (VSC-MEDlib), is that the risks are acceptable. Due to the non-invasive and non-contact measurement of the VSCMEDlib/VSC demo app, the risks for the study participant lie in the external factors (e.g. make-up,

viruses). The conclusion is that these risks are mitigated where possible and acceptable.

Contacts

Public
Philips

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NL
Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Persons with ASA I or II classification
• Adult population (age >18 years old)
• BMI >= 18 - <= 40 kg/m2
• Able to intensively exercise for 10 minutes
• Persons willing to give informed consent
• Willingness to have vital signs measured by a medical mobile application
• Willingness to follow study protocol (e.g., put on sunglasses, facial

make-up, medical face-mask and sitting still up to 2 minutes)

Exclusion criteria

• Vulnerable populations (e.g., age <18 years old, not able to consent by themselves, or immunecompromised
or pregnant women)
• Cardiac arrhythmias (e.g., Atrial Fibrillation, Supraventricular Tachycardia, Ventricular arrhythmia,
regular ectopic beats)
• Persons present signs of infection
• Participant has known allergic reactions to make-up and/or make-up remover
• Persons with positive COVID 19 test in last 14 days
• Participant who exhibit irregular or excessive movement such as tremors, tics, shaking and/or shivering
• Participant is Philips employee or their family members residing with this Philips employee

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-02-2024
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Philips Vital Signs Camera Medical library (VSC-MEDlib) version 2.3

Registration:	No

Ethics review

Approved WMO Date:	05-12-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
ClinicalTrials.gov	NCT06140433
CCMO	NL85241.000.23