

# Activity and heart rate monitor validation study

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The purpose of the activity and heart rate monitor is to measure and track movement (acceleration) and heartbeat, and derive a number of health-related parameters, which can serve as basis for behavioral change programs leading to e.g. a healthier,...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON19960

### Bron

Nationaal Trial Register

### Aandoening

Sedentary behavior, suboptimal physical fitness  
Sedentair gedrag, suboptimale lichamelijke fitheid

## Ondersteuning

**Primaire sponsor:** Joep Rous  
Head of Product Engineering  
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**Overige ondersteuning:** Fund=initiator=sponsor

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

measurement accuracy of energy expenditure<br>  
measurement accuracy of resting heart rate

## Toelichting onderzoek

### Achtergrond van het onderzoek

Background of the study: Klik voor meer informatie

The purpose of the activity and heart rate monitor is to measure and track movement (acceleration) and heartbeat, and derive a number of health-related parameters, which can serve as basis for behavioral change programs leading to e.g. a healthier, more active lifestyle, weight reduction, reduced risk of cardio-vascular disease, reduced risk of diabetes, or can be part of a disease or condition management program. In order for such a measurement/monitoring device to be able to lead to positive health benefits a preliminary requirement is that it measures the basic parameters in an accurate manner.

Objective of the study

The primary objective of this study is to determine the accuracy of energy expenditure and resting heart rate measurement. Secondary objectives include assessment of accuracy of other measures like sleep duration, steps counting, activity recognition, respiration rate at rest, heart rate recovery, interbeat interval and VO<sub>2</sub>max estimation. Last wear comfort of the device will be evaluated.

Study design:

The study follows a within-person paired measurement design. The study consists of an intake, 3 days free living monitoring, and measurement in a controlled environment of +/- 2.5 hours. From the free-living measurements data will be collected to estimate the resting heart rate, sleep duration measurements can be validated, sedentary behavior detection buzz can be checked, and heart rate recovery and VO<sub>2</sub> max assessment can be checked. The controlled measurement is used for the validation of the energy expenditure measurements and provides reference data for resting heart rate. Both of these datacollections will also be used for secondary purposes.

Study population:

The study will take place with 31 healthy volunteers who meet the following inclusion criteria:  
- Aged more than 18 years old . - Body mass index [body weight (kilograms)] / [height<sup>2</sup> (meters)] between 19 and 35 - Functionally capable If volunteers meeting one of the

following exclusion criteria, will be excluded from participation in the study: - Suffering from severe chronic disease for which a physician has contraindicated moderate intensity exercise without medical supervision - Function/mobility and or cognitive impairments preventing compliance with the study protocol - Having pacemaker or other implantable electronic devices - Skin issues or wounds in wrist area - Might be, or is, pregnant

Intervention (if applicable):

During the controlled measurements subjects are asked to complete various activities (eg. Walking and cycling). During the measurements the activity and heart rate monitor is worn and reference measurements are made.

Primary study parameters/outcome of the study:

The primary parameters of the study are: - measurement accuracy of energy expenditure - measurement accuracy of resting heart rate

Secondary study parameters/outcome of the study (if applicable):

Secondary parameters include assessment of accuracy of other measures: - heart rate - sleep duration - steps counting - activity recognition - respiration rate at rest - sedentary behaviour alert - heart rate recovery, interbeat interval and VO2max estimation yes/no Additionally the wear comfort of the device will be evaluated with a questionnaire.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

Anticipated clinical benefits : In the future the device will be used with programs users will have a clinical benefit, we are now testing the accuracy of the measurement device.

Anticipated adverse device effects: Not expected Residual risks associated with investigational device: Possibly contact allergy (skin redness, irritation) or skin irritation due to prolonged wearing. Risks associated with participation in clinical investigation: Minimal risks. There is risk on falling during the protocol because we ask participants to exercise. Risks are mitigated because of the use of good research and sporting materials and continuous observation by researchers. Privacy risk are mitigated by separating the personal data from the research data and data storage in a secured database by an external, certified clinical research organisation. Possible interactions with concomitant medical treatments: There are no interactions with concomitant medical treatments Steps that will be taken to control or mitigate risks: Information on the device will be given to the participants before start of the study.

## **Doel van het onderzoek**

The purpose of the activity and heart rate monitor is to measure and track movement (acceleration) and heartbeat, and derive a number of health-related parameters, which can serve as basis for behavioral change programs leading to e.g. a healthier, more active lifestyle, weight reduction, reduced risk of cardio-vascular disease, reduced risk of diabetes, or can be part of a disease or condition management program. In order for such a measurement/monitoring device to be able to lead to positive health benefits a preliminary requirement is that it measures the basic parameters in an accurate manner.

## **Onderzoeksopzet**

Participants will receive the device and instructions for use on day 1. On days 2-4 the device will be worn at home. On day 5 the device is returned and controlled measurements in the lab are completed.

## **Onderzoeksproduct en/of interventie**

During controlled measurements in a laboratory environment subjects are asked to complete various activities (eg. Walking and cycling). During the measurements the activity and heart rate monitor is worn and reference measurements are made.

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Aged more than 18 years old . '

Body mass index [body weight (kilograms)] / [height<sup>2</sup> (meters)] between 19 and 35

Functionally capable

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Suffering from severe chronic disease for which a physician has contraindicated moderate intensity exercise without medical supervision

- Function/mobility and or cognitive impairments preventing compliance with the study protocol

Having pacemaker or other implantable electronic devices

Skin issues or wounds in wrist area

Might be, or is, pregnant

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

## Deelname

Nederland  
Status: Werving gestopt  
(Verwachte) startdatum: 08-02-2016  
Aantal proefpersonen: 31  
Type: Werkelijke startdatum

## Ethische beoordeling

Positief advies  
Datum: 19-10-2015  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43960  
Bron: ToetsingOnline  
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL5270
NTR-old	NTR5552
CCMO	NL54374.028.15
OMON	NL-OMON43960

## Resultaten

### Samenvatting resultaten

Planned, none accepted to date