# Evaluation of the *auto-cuff* response in outpatients with and without hypertension

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Does the *auto-cuff* response persist during automated consecutive blood pressure recording in patients who have been referred for out of office BP measurements as a potential explanation for the difference between HBPM (active-measurement) and ABPM...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON44268

**Source**
ToetsingOnline

**Brief title**
Evaluation of the *auto-cuff* response

### Condition

- Other condition

**Synonym**
high blood pressure, Hypertension

**Health condition**

Hypertensie

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Ambulatory Blood Pressure Measurement (ABPM), Auto-cuff response, Home Blood Pressure Measurement (HBPM), Hypertension

## Outcome measures

### Primary outcome

Main study parameter/endpoint:

The principal parameter is the difference in the average systolic BP, defined as the mean BP during self-measurement using continuous beat-to-beat BP registration, between semi-automated and fully-automated BP measurement compared to baseline values.

### Secondary outcome

Secondary study parameters/endpoints:

o Differences in average diastolic BP, defined as the mean BP during self-measurement using continuous beat-to-beat BP registration, between semi-automated and fully-automated BP measurement compared to baseline values;

o Differences in the maximal rise in BP (systolic and diastolic), defined as the maximum BP during the first 20 seconds of each self-measurement using continuous beat-to-beat BP registration;

o Differences in heart rate (HR), defined as the inverse of the interbeat interval, during each self-measurement using continuous beat-to-beat BP

registration;

o Differences in cardiac output (CO), defined as the stroke volume (SV) divided

by the interbeat interval, during each self-measurement using continuous

beat-to-beat BP registration;

o Differences in systemic vascular resistance (SVR) during each

self-measurement using continuous beat-to-beat BP registration calculated as

the ratio of MAP and CO.

# Study description

**Background summary**

The diagnosis of hypertension is hampered by intrinsic blood pressure (BP) variability and anxiety responses that may systematically influence BP measurement, such as the white coat effect. Both influence the diagnostic value of BP measurement and the prediction of cardiovascular disease. Recently we showed that ~20% of patients referred for out-of-office BP measurement have a significantly higher home and office BP compared to ambulatory measurement. The differences between home and ambulatory BP do not relate to hypertensive organ damage. In addition, patients with a difference between home and ambulatory BP more frequently had a white coat effect. This suggests that anxiety responses upon the self-measurement of BP may exist. Recently we have shown the existence of such an *auto-cuff* response during semi-automated self-measurement, however evidence regarding the possibility of such an *auto cuff * response based on fully-automated blood pressure measurement is lacking.

In theory, self-measurement of BP could evoke an anxiety response, similar to that observed with the white coat effect during office BP measurement. These *cuff responses* may be larger during active self-measurement compared to fully-automated measurements. Anticipating a BP reading could induce a pressor response at home as may happen in the clinic. Such an *auto-cuff* response may be less significant during fully-automated ambulatory BP measurement, where recording is nearly continuous and less influenced by emotional factors such as anxiety. Recently, we showed a significant increase in BP during self-measurement using a semi-automatic device compared to baseline in patients with a large difference (10 mmHg systolic and/or 5 mmHg diastolic) between home blood pressure measurement (HBPM) and ambulatory blood pressure measurement (ABPM), but also in patients without this difference. This increase in BP

during self-measurement was accompanied by both an increase in cardiac output (CO) and heart rate (HR) compared to baseline. Overall, BP decreased after repeated self-measurements but still remained higher compared to BP before self-measurement.
These results support the existence of an *auto-cuff* response during semi-automated self-measurement. Whether this *auto-cuff* response persists during fully-automated BP measurements remains to be determined. It*s important to know if this *auto-cuff* response also exist in fully-automated self-measurement, alias ABPM, to better understand the differences in HBPM and ABPM but more important to prevent patients misdiagnosed with hypertension.

**Study objective**

Does the *auto-cuff* response persist during automated consecutive blood pressure recording in patients who have been referred for out of office BP measurements as a potential explanation for the difference between HBPM (active-measurement) and ABPM (passive measurement)?

Primary Objective: To assess differences in average systolic BP response during semi-automated and fully-automated BP measurement in patients who are referred for out-of-office BP measurement.

Secondary Objectives: To assess differences in average diastolic BP, heart rate (HR), cardiac output (CO) and systemic vascular resistance (SVR) during self-measurement. To assess the maximal increase in systolic and diastolic BP during self-measurement.

**Study design**

This study is designed as a single centre, one visit, cross-over study. After screening for eligibility and given informed consent, all subjects will receive cardiovascular risk assessment. Two groups will be randomly made using a computerized randomization scheme. Thereafter, all subjects will undergo a 30 minutes continuous non-invasive finger arterial BP recording with Nexfin (BMEYE, Amsterdam, The Netherlands) at the dominant arm. A finger cuff will be placed on the mid phalanx of the middle finger, the arm will be placed in a sling at the height of the heart.

After 5 minutes of rest while seated, participants will be asked to perform three semi-automated and three fully-automated BP measurements using the Microlife watch BP device with an in-build possibility to measure blood pressure in a full- and semi-automated way. Each participant will receive a blood pressure cuff at the non-dominant arm in order to perform blood pressure measurements. The order of the measurements will be randomized. After 5 minutes rest, the second measurement will be made. During the semi-automated

measurement, the patient uses the semi-automated mode to perform three blood pressure readings by actively pressing the button. In the fully-automated mode, patients will press the button once and the device will automatically perform three blood pressure measurements after a 5 minute waiting period. The study consists of a single visit of approximately 45 minutes.

The sequence will be randomly assigned using www.random.org. Participants and the executive researcher are aware of the classification. In order to mark the start of a semi-automated record or a fully-automated record the researcher will use a stopwatch and shall keep an eye on the participant from another room.

Continuous non-invasive measurement with Nexfin
Devices for continuous non-invasive finger arterial BP measurement, like Nexfin (BMEYE, Amsterdam, The Netherlands), have been largely validated in a variety of clinical settings and resulted to be as reliable as previously used invasive methods in detecting BP changes and autonomic responses. The measurement of BP is performed with an inflatable finger cuff with a build-in plethysmograph using the volume clamp method. The cuff pressure follows the finger arterial pressure to keep the finger arterial blood volume constant which is controlled by the plethysmograph, and supported by the automatic physiological calibration technology and the measurement of the difference in hydrostatic pressure between the finger and the heart. Then, the arterial BP in the brachial artery will be reconstructed from the finger arterial BP, with adjustment for finger pressure distortion and brachial finger pressure decrement. BP measures obtained with Nexfin are acceptably accurate as compared to measures obtained using the common auscultatory as well as the intra-arterial (invasive) methods. Continuous measurement of BP is the basis for the estimation of haemodynamic parameters. These estimates are comparable with measures obtained using the worldwide accepted invasive thermodilution method.

Heart rate variability (HRV) is a phenomenon of oscillations of both RR-interval and instantaneous heart rates and is used to investigate the autonomic influences on the functioning of the heart. The heart rate (HR) is defined as the inverse of the interbeat interval. Indices of blood pressure variability (BPV), expressing arterial BP fluctuations, provide further parameters used to investigate the autonomic influence on the cardiovascular system. To calculate the cardiac output (CO), the stroke volume (SV) will be determined by the pulse contour method (Nexfin CO-trek). CO is defined as SV divided by the interbeat interval and the systemic vascular resistance (SVR) will be calculated as the ratio of mean arterial pressure (MAP) and CO. All these indexes have been used in literature to evaluate autonomic responses to certain stimuli.

**Study burden and risks**

The results of this study will contribute to improve the quality of BP

monitoring and to better understand the characteristics of self-BP measurement and ABPM responses in order to better identify susceptible subjects. Individual subjects will gain no direct benefit from this study. The risk and burden of participating in this study is negligible since all the measurements that will be performed are safe and non-invasive and the study comprises only one visit of approximately 45 minutes including questionnaire and measurements. This visit will be combined with an out-clinic visit.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

- Aged *18 years;
- Patient visiting the outpatient clinic of the Department of Vascular Medicine at the AMC.

### Exclusion criteria

- Pregnancy;
- Severe heart rate irregularities of any cause;
- Severe uncontrolled hypertension (mean BP>200/120 mmHg in the clinic);
- Not able to follow instructions for BP measurement for any reason;
- Recently changed BP lowering medication (<4 weeks);
- Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 27-10-2017 |
| Enrollment: | 50 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 13-10-2017 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL62859.018.17 |