Usability of a New Cuffless Device for Ambulatory Blood Pressure Measurement in Hypertension
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Word count: 4042
Number of tables: 2
Number of figures: 5
Abstract

Background: Frequent home blood pressure (BP) measurements result in a better estimation of true BP. However, traditional cuff-based BP measuring is troublesome for patients.

Objective: To evaluate the use and efficacy of a new cuffless device (Checkme) for ambulatory systolic blood pressure (SBP) measurement.

Methods: A mixed-method study in hypertensive patients. Reliability of Checkme SBPs was analyzed quantitatively by intra-user reproducibility and comparability to a classic home BP monitor. Correct use by the patients was checked with video. Patients reported experience with qualitative semi-structured interviews and user-friendliness was assessed using a validated questionnaire.

Results: 1020 Checkme SBP measurements were performed in 11 hypertensive patients. Duplicate SBPs showed a high intra-user correlation (R=0.86, p<0.01). SBP of the Checkme did not correlate well with those of the different home monitors being used (R=0.47, p<0.01). However, the mean SBP’s of the Checkme and of the home monitors over 3 weeks follow-up were highly correlated (R=0.75, p<0.01). 36.4% (n=4) of the participants performed the Checkme measurements without any mistakes. The mean SUS score was 86.4 (SD=8.3). The most important facilitator was the ease of use of the Checkme. Most important barriers included the absence of diastolic BP and the incidental difficulties in obtaining an SBP result.

Conclusions: Given the good intra-user reproducibility, user-friendliness and patient experience, which all facilitate patients to perform frequent measurements, cuffless BP monitoring may change the way patients are measuring their home BP in the context of ambulant hypertension management.

Key words
Ambulatory blood pressure monitoring; Home blood pressure monitoring; Cuffless blood pressure device; Hypertension.
Introduction
An elevated blood pressure (BP) is a major risk factor for cardiovascular morbidity and mortality.\[1\] BP is however a highly variable vital parameter, and circumstances under which measuring takes place may influence the result extensively.\[2-4\] Compared to office BP, home BP better predicts cardiovascular risk.\[5-8\] The predictive value increases progressively with the number of home measurements.\[9\] Thus, to improve prediction of the cardiovascular risk, BP needs to be monitored frequently, preferably at home.

For patients with hypertension, home blood pressure monitoring (HBPM) is easy to perform, reliable, and reproducible.\[10\] Therefore, it is recommended as a routine component of BP monitoring in the American Society of Hypertension and the American Heart Association guidelines.\[5\] The use of HBPM improves hypertension control and associated outcomes.\[11-14\] Home BP is predominantly measured with an oscillometric BP monitor which uses an arm cuff. In daily practice, patients use all sorts of different BP monitors of which most devices are not officially validated.\[15\] In a cross-sectional study by Ruzicka et al. 30% of the home BP monitors were inaccurate.\[16\] Although an automatic BP monitor is relatively easy to use and inexpensive\[5\], measuring BP is time-consuming and may be experienced as inconvenient. In addition, various factors may influence BP measuring accuracy, such as discomfort by inflation of the cuff\[17\], inappropriate cuff size and cuff position at the arm in relation to the heart level.\[18\]

A new technique has been developed to measure systolic BP (SBP) fast and easy without the use of a cuff, which is applied in new devices such as the Checkme Pro Health Monitor (Viatom Shenzen, China). An algorithm calculates the SBP based on the pulse transit time determined with an \text{SpO}_2 measurement, the electrical ECG signal and an individual’s arterial compliance.\[19\] For the latter the cuffless device needs a calibration procedure, by entering a classically obtained SBP. An SBP measurement with the Checkme takes less than 30 seconds, as a result of which the willingness of patients to measure more frequently could increase. Thereby, cuffless BP measuring is an emerging
technique, which may lead to an increased patient compliance in measuring BP at home and promoting a larger number of BP results for hypertension management.

Recently, we evaluated the validity of the Checkme’s SBP results by using criteria of the European Society of Hypertension (ESH) for validating new BP devices.[20] This validation protocol may be considered inadequate, since it lacks a consensus about the quality of the BP measurement to be used for calibrating cuffless devices. However, results obtained with the Checkme were promising over a wide range of BP levels.[20] A recent study showed promising results of vital parameter measurements in an inpatient setting.[21] Since the previous study by Schoot et al. was performed under demanded controlled circumstances, we felt the need to evaluate the performance of the Checkme in an uncontrolled home setting.

To assess the use and efficacy of the Checkme in an outpatient setting, we studied the reliability, user-friendliness and patient experience in participant’s home-situations.
Methods

Research design, setting and participants
We conducted a pilot study using a mixed-method approach. To determine reliability of the SBP measurement, we systematically assessed the reproducibility of the Checkme, the comparability to a home BP monitor and the performance of daily vital measurements with the Checkme using video analysis. A System Usability Scale (SUS) questionnaire was used to determine the user-friendliness. Patient experience was studied with a semi-structured interview following the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) framework. Participants were recruited from the hypertensive outpatient clinic of an academic hospital in The Netherlands from April 2017 to May 2017. The institutional review board approved the study (ID: 2017-3241). All participants signed informed consent after written and verbal information.

Inclusion and exclusion criteria
Patients were considered eligible if they met the following criteria: medical treatment for high blood pressure and accustomed to home blood pressure measurements with their own blood pressure meter, ≥18 years and the cognitive ability to understand instruction and perform measurements correctly after instruction. Patients with a pacemaker and pregnant females were excluded.

Checkme Pro Health Monitor
We evaluated the Checkme Pro Health Monitor (Viatom Technology, Shenzen, China), which measures SBP without the use of a cuff. The device also measures a one lead ECG, Heart Rate and SpO₂ in one measurement called ‘daily check’. The way these vitals are being measured with the Checkme is shown in figure 1. The right thumb, right middle finger and left palm are placed on ECG sensors. The right index finger is placed on the built-in SpO₂ sensor. To
increase accuracy of the results, the device needs to be held steady at heart level during the measurement. The latest version of the Checkme, used in this study, is FDA approved for measuring these vitals and has a CE mark.

Figure 1. Demonstration of an SBP measurement with the Checkme Pro Health Monitor (Viotom Technology, Shenzen, China). Right thumb and middle finger and left palm are placed on ECG sensors. Right index finger is placed on the built-in SpO\textsubscript{2} sensor. SBP measurement is performed in less than 30 seconds, holding the device steady at heart level.

Study procedures
The study timeline and procedures are shown in figure 2. Two trained researchers instructed the participants on the study procedures, how to perform the SBP measurement with the Checkme, and checked the way they performed their regular home SBP measurement using their own home BP monitor. Before the start of the study, the Checkme was calibrated for SBP measurement according to manufacturer’s instructions. To determine a reference SBP to calibrate the Checkme, a standard duplicate BP measurement was performed using a validated automatic BP monitor at the outpatient clinic (Vital Signs Monitor 300 series, Welch Allyn) after initial 5 minutes of rest. The participants performed the measurements with the Checkme in duplicate twice daily, in the morning and in the evening, for a period of
three weeks. They were instructed to perform the second measurement immediately after
the first measurement under the same circumstances.

In addition, the participants performed a regular BP measurement once weekly with their
own home BP device. Participants were asked to perform one duplicate SBP measurement
with the Checkme and one duplicate home BP measurement using their own conventional
BP monitor, in a random order.

After three weeks, the correct use of the Checkme by the patient was checked with a video
recording of the SBP measurement. The user-friendliness was assessed with a SUS-
questionnaire and the patient’s experience was determined with a semi-structured
interview.

Figure 2. Timeline of the study procedures. Dotted lines represent a variable time of 0-5 days
between day X and day 0, and 0-5 days between the end of the study period and day Y.

Analysis of reproducibility
To obtain the intra-user reproducibility of a duplicate SBP measurement, two values of one
duplicate measurement were correlated and the level of variation was categorized in < 5
mmHg, < 10 mmHg and > 15 mmHg. Both the Checkme and the home BP monitor were
tested for reproducibility. The paired SBP measurements with the Checkme and home BP
monitor were correlated to obtain the comparability. The mean difference and level of variation between the Checkme and home BP monitor SBP were calculated. In addition to the paired measurements, the mean of all SBP measurements with the Checkme and home BP monitor was correlated. For each participant, all measured SBP values with the Checkme, their home BP monitor and hospital monitor were plotted in a diagram to show the variation of SBP over time measured with different devices.

**Analysis of correct use of Checkme by the patient**
Two researchers independently assessed the use of the Checkme by the patient, by checking the video recorded measurements with a scoring sheet based on the principles of Gelbart et al.[22] and Van Der Heide et al.[23] Thirteen steps were distinguished for the SBP measurement with the Checkme. All items for the use of the Checkme were noted as ‘badly performed’, or ‘not done’ (0 points), ‘suboptimal’, or ‘to late’ (1 point), ‘perfectly done’ (2 points). Findings were compared and discussed until consensus was achieved.

**Analysis of patient experience**
The semi-structured interviews following the Unified Theory of Acceptance and Use of Technology 2 (UTAUT2) framework[24] (figure 3) were conducted in Dutch with the participants. The UTAUT2 framework consists of four major themes: performance expectancy, effort expectancy, social influence and facilitating conditions. Performance expectancy is defined as the degree to which an individual believes that using the Checkme will help him or her. Effort expectancy is defined as the degree of ease associated with the use of the Checkme. Social influence is defined as the degree to which an individual perceives that important others believe he or she should use the Checkme. Facilitating
conditions are defined as the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the Checkme.[25]

**Figure 3. UTAUT2 interview framework.**

Interviews were audio recorded and transcribed verbatim using qualitative data analysis software (ATLAS.ti 7.1). Transcripts were independently analyzed by two investigators to identify barriers, facilitators, and positive and negative effects of the use of the Checkme. Findings were discussed until consensus was achieved. The barriers and facilitators were rewritten into general statements and subdivided according to the themes of the UTAUT2 interview framework. The magnitude of each statement was determined by the number of interviews the statement was mentioned in. A validated Dutch translation[26] of the SUS questionnaire[27] on the usability of the Checkme was used to determine the user-friendliness. A score between 0-100 was calculated as described by Brooke et al.[27] The interpretation of the SUS score was in accordance with Bangor et al.[28] A score above 90,9 was considered ‘best imaginable’, a score above 85,5 ‘excellent’, a score above 71,4 ‘good’ and a score above 50,9 ‘sufficient’. A score below 50,9 was considered ‘poor’.
Statistical analyses
All statistical analyses were performed by using IBM SPSS version 22.0. Normally distributed data were presented with mean and SD. Descriptive statistics were presented with median and quartiles in case of non-normally distributed data. Differences were tested with T-test in case of normal distribution of the data, or non-parametric Wilcoxon's test in case of non-normally distributed data. Correlations were calculated with Spearman's rank correlation coefficient.
Results
User statistics
One of twelve participants enrolled in the study was excluded from participation and analysis due to repeated failure of BP calibration. One participant did not own a BP monitor and visited the hospital for weekly BP measurements. Average instruction time was between 20-40 minutes. The characteristics of the eleven participants who completed the study period are summarized in table 1.

The SBP readings of the participants' home BP monitors highly correlated with the automatic hospital BP monitor at baseline (R=0.88, p<0.001). Eleven participants performed a total of 1020 measurements with the Checkme. In 209 measurements (20.4%) the Checkme was not able to measure an SBP. The success rate for SBP measurement varied among participants, with a mean success percentage of 71%, ranging from 42% to 100%.

Table 1. Participant characteristics.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Study population (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>4 (36%)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>7 (64%)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian, n (%)</td>
<td>10 (91%)</td>
</tr>
<tr>
<td>Black, n (%)</td>
<td>1 (9%)</td>
</tr>
<tr>
<td>Age (years), mean ± SD</td>
<td>57 (11.5)</td>
</tr>
<tr>
<td>Systolic BP (mmHg), mean ± SD*</td>
<td>140.7 (13.7)</td>
</tr>
<tr>
<td>Diastolic BP (mmHg), mean ± SD**</td>
<td>86.3 (11.0)</td>
</tr>
<tr>
<td>Use of BP lowering medication, n (%)</td>
<td>9 (82%)</td>
</tr>
<tr>
<td>Use of home monitor, n (%)</td>
<td>10 (91%)</td>
</tr>
<tr>
<td>Brand (n)</td>
<td>Withings (3), Microlife (2), Omron (1), Beurer (1), A&amp;D Medical (1), Medion (1), Cresta (1)</td>
</tr>
<tr>
<td>Frequency/month (SD)</td>
<td>6.8 (6.2)</td>
</tr>
</tbody>
</table>

* BP measured by trained investigator with Welch Allyn Automatic BP monitor at day=0
# Data shown for n=10
Reproducibility
The paired results of duplicate SBP measurements of the Checkme correlated well over the whole range of BP levels (R=0.86, p<0.001). Of 420 complete duplicate SBPs, paired results of 374 (89%) duplicates varied within 10 mmHg, of which 286 (68% of total) varied within 5 mmHg. Paired results of 22 (5%) duplicate SBPs varied more than 15 mmHg. Variations of the paired results of duplicates are shown in figure 4. Of the 22 duplicates with a difference more than 15 mmHg, 11 were obtained by only two participants. The paired results of duplicate SBP measurements with the home BP monitors correlated strongly (R=0.91, p<0.001). Of 40 complete duplicate SBPs, 38 (95%) varied within 10 mmHg, of which 27 (67% of total) varied within 5 mmHg. No measurement exceeded a variation of 15 mmHg. For each participant, all measured SBP values with the Checkme (twice daily), the home BP monitor (once weekly) and hospital monitor (once) were plotted in figure 5.

Figure 4. Frequency of the difference within duplicate SBP measurements.
the Checkme and home BP monitors was in 7 pairs (22%) <5 mmHg, in 18 pairs (56%) <10 mmHg, and 26 pairs (81%) <15 mmHg.

The mean SBP of both devices over three weeks correlated highly (R=0.75, p<0.01). The Checkme had a mean systematic difference of 0.26 mmHg (7.66 SD) for mean SBP over three weeks compared to the home BP monitors. 36.3% of the mean SBP with the Checkme and home BP monitors varied within 5 mmHg, 90.9% varied within 10 mmHg. No measurement exceeded a variation of 15 mmHg.

**Figure 5.** SBP during follow-up for each participant, measured with Checkme (○), home BP monitor (♦) or hospital BP monitor (◊).

**Correct use of the Checkme**

36.4% (n=4) of the participants performed the measurement with the Checkme correctly (‘well done’) in all 13 items, in 54.5% (n=6) with one mistake and in 9.1% (n=1) with two mistakes. No
participants had more than 2 mistakes. The most frequent mistake was not keeping the Checkme at heart level (5 of 11). During video recording, one out of eleven participants did not receive a valid SBP result. The hands of this participant were shaking due to medication side-effects and he did not find support by resting his arms on the table. However, at home this participant achieved a valid SBP in 80 of 104 measurements (77%).

**Patient experience**
Interviews lasted 15-35 minutes. All perceived barriers and facilitators could be subdivided into one of the five themes of the UTAUT2 interview framework. Most significant barriers and facilitators are described here, all barriers and facilitators are summarized in table 2. Performance expectancy could be divided into two subsequent topics: the features and possibilities of the Checkme and the measurement results produced by the Checkme. For the possibilities of the Checkme, six participants perceived the inability of the Checkme to measure diastolic BP (DBP) as a barrier. They considered DBP to be as important as SBP. At times, the Checkme did not report a result for SBP, which was a barrier for seven participants. This sometimes was perceived as bothersome, since the cause was unclear and the measurement had to be repeated. Another barrier mentioned by three participants, was the occasional big difference in SBP measured with the Checkme compared to home or hospital BP monitor. This reduced their trust in the Checkme’s reliability. One participant on the other hand, reported that the Checkme and home BP monitor correlated well, which increased trust in the Checkme.

Effort expectancy was defined through two topics: performing measurements and the design of the Checkme. For performing the measurements, all participants considered the Checkme easy to use and could quickly perform a measurement (four participants). Three participants perceived it as a facilitator that the Checkme can measure SBP without the use of an arm cuff, mostly because the arm
cuff on their home BP monitor was uncomfortable. On the design of the Checkme, the most significant facilitator perceived was the small size of the Checkme, reported by four participants. In addition, three participants thought the Checkme would be unsuitable for elderly, because of decreased fine motor skills. Automatic synchronization of results would be preferred by eight participants, either to their medical record or an online application to be able to monitor the results of medication, diet and/or physical activities and to be able to discuss results with their doctor. Two other suggestions were increasing the font size and addition of a backlight to the screen.

Five participants would like to use the Checkme in the future instead of their own home BP monitor. Three other participants would only use the Checkme in the future on certain conditions, for example if the Checkme reports reliable results. The remaining three participants did not want to use the Checkme in the future. Eight participants would recommend the Checkme to other patients. Participants gave the Checkme a median mark of 7.5 (IQR: 5.0-8.0) on a scale of 1 to 10, with individual marks ranging from 1.0 to 9.0. Mean SUS score was 86.4 (SD=8.3) with a range of 72.5 to 97.5, which indicates high user-friendliness.

Table 2. Barriers and facilitators for use of the Checkme and the number of interviews these were mentioned in. Subdivided following the themes of the UTAUT2 interview framework and subsequent topics.

<table>
<thead>
<tr>
<th></th>
<th>Barriers</th>
<th>Facilitators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Performance expectancy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Possibilities Checkme</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td>1.1 The device measures only SBP</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>2. Outcomes Checkme</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>2.1 At times, the Checkme did not report a result for SBP and/or SpO₂</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>2.2 The big/small difference between the home BP monitor and the Checkme leads to less/more trust in the Checkme</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td><strong>Effort expectancy</strong></td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td>3. Performing measurements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 The Checkme is easy to use</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>3.2 With the Checkme, a measurement is quickly performed</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>3.3 BP can be measured with the Checkme without the use of an arm cuff</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.4 Daily check cannot be performed with cold hands</td>
<td>1</td>
</tr>
<tr>
<td>---</td>
<td>------------------------------------------------------</td>
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</tr>
<tr>
<td>4. Design of the Checkme</td>
<td>4.1 The Checkme is small and can be taken everywhere</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>4.2 The Checkme does not have a backlight in the touch screen</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>4.3 The Checkme is not a standard BP monitor, which decreases trust in results</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>4.4 The font size of the results screen is very small</td>
<td>1</td>
</tr>
<tr>
<td>Social influence</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Measuring BP with the Checkme can be done without any help</td>
<td>1</td>
</tr>
</tbody>
</table>
Discussion
This study delivers new information about the use, efficacy, reliability and patient experience of an FDA approved cuffless BP measuring device in patients who are used to measuring their blood pressure at home. Adequate intra-user reproducibility of cuffless SBP was observed in the majority of participants, and the use of the Checkme was well adopted in the home setting. Patient indicated an increased willingness to take their BP measurement because of the ease of use. It was concluded that the large variety of cuff-based BP monitors currently used by patients in home BP monitoring does not necessarily serve as a gold standard to compare new devices for home monitoring with. In addition, the easily obtained large number of Checkme SBP's may be a better picture of actual BP variation over time, which can be easily missed by having just one home measurement every week.

The majority of participants could produce series of valid measurement results, and most of the unsuccessful SBP measurement attempts were observed in a small number of participants. Failure to produce valid SBP readings may be caused by several factors. Since the cuffless technique requires an ECG and SpO\textsubscript{2} signal to produce an SBP result, factors influencing ECG and SpO\textsubscript{2} accuracy may lead to unsuccessful measurements with no SBP results. These factors include poor perfusion (cold fingers) and skin color.[29, 30] Performance related factors, such as moving during the measurement or applying too much pressure on the sensors[31] may disturb the SpO\textsubscript{2} signal and thereby influencing the SBP result, which suggests proper user instructions are necessary. Technical factors such as system failure, incorrect calibration procedure or imperfections in the algorithm may also influence BP results.

Another issue of cuffless BP measurement technique is the need of a classic reference BP measurement in order to calibrate the calculating algorithm for individual vascular compliance. An international standard for this calibration procedure is still lacking in existing protocols for new BP device validation.[32] Schoot et al. recently performed a pragmatic validation study with the Checkme, using standardized measurement conditions, which revealed promising results. The SBP
with the Checkme was considered comparable to an in-hospital reference monitor, with a mean difference of $2.6 \pm 12.1$ mmHg.[20] Other studies compared different cuffless SBP measuring devices to a reference monitor. Poon et al.[33] described a difference of $0.6 \pm 9.8$ mmHg and Boubouchairiropoulou et al.[34] found a difference of $3.2 \pm 6.7$ mmHg, which is to a great extent comparable to the results in the present study. Also, this study showed that currently an unrestricted range of BP monitors from different manufacturers are being used for home monitoring, which each have their own accuracy. Both the variety of home BP monitors and the uncontrolled use in a home setting may contribute to the observed differences. Although home BP devices should ideally come from a list of validated monitors and the circumstances under which measurements are taken should be standardized, the added value of home BP monitoring is rather the increasing number of results than the absolute value of each of them.[35] Robust hypertension management is rather being based on the average of a large series of BP measurements than on a single clinic measurement.[35]

Despite its easy to use concept, accurate self-measuring with the Checkme was not completely adequate after a single instruction at the start of this study. This phenomenon was also observed in studies with conventional BP monitors, which reported that 52-65% patients missed at least one step of a correct BP measurement.[36, 37] Milot et al. found that only 18% of the patients performed the classic BP measurement with cuff excellent,[38] and a study of Wagner et al. found that none of the participants performed BP measurement completely correct.[39] Compared with these observations in classical cuff based BP measurement, the correct use of the Checkme in our study was much better. Actually, the only observed mistake was not holding the device at heart level, which has minor effect on the SBP result.[20] Other mistakes concerning the use of the Checkme were not observed. This is in contrast to the observation during classic BP measurement, in which various other errors, with respect to cuff usage and position, can occur. An important finding of the present study is that user instruction needs attention both at the start and probably during long-term use as well to increase the quality of BP readings. This may be achieved by optimizing the patient instruction by using the protocol described by Mengden et al. as a guide,[40] or using video instructions.[41]
Performance expectancy and effort expectancy were most mentioned in the interviews, and only a few barriers and facilitators were mentioned on social influence and facilitating conditions. This can be explained by the short follow-up period and the Checkme being an unknown new device. The two most prominent issues of performance expectancy for participants are that the Checkme only measuring systolic and not the diastolic BP, and that the Checkme sometimes failing to produce a valid SBP result. The cuffless BP measurement technique is currently unable to determine DBP accurately. However, it is internationally accepted that SBP is the primary target in managing cardiovascular risk in most patient groups, except in elderly people.[42] Some participants also suggested to improve the design of the Checkme. Five requirements for medical devices have been described by Korhonen et al., including reliability and durability, looks and unobtrusiveness, user identification, communication, and zero maintenance and fault recovery.[43] Cuff-based home BP monitors meet the first and last requirement. The Checkme formally meets the second, third and fourth criteria with its size, personal user profiles and ability to share readings, respectively. This study also provides new information about reliability by the evaluation of intra-user reproducibility of the Checkme in home monitoring. The memory capacity of the Checkme and the ability to automatically share saved readings bypasses the imprecision of self-reported BP readings by patients, which appeared to range from 0% to 100% in a study with 30 hypertensive patients.[44] Further, it enables physicians to intervene and adjust medication since patients are often not able to interpret the readings of SBP correctly.[45, 46]

Strengths and weaknesses
The strength of this pilot study is that cuffless derived SBP with the Checkme is studied in a home-based setting. This is the first study in which the use and efficacy of a cuffless BP measuring device in a home monitoring setting was assessed using a mixed-method study design. We obtained a large number of home measurements in both morning and evening, as recommended by ESH/ESC,[47] in well-instructed patients who were involved in self-management. Patient experience and performance were evaluated by a widely used and reliable questionnaire to determine the feasibility of different
products, and all interviews followed an interview guide derived from a well-known interview framework.[28, 48] Possible weakness of this study was the small study sample, which may not guarantee complete saturation in all qualitative aspects. The relative short follow-up may also have led to an incomplete user experience. To confirm the current results, this study should be repeated on a larger scale. Some adjustments of the methods need to be taken into consideration, including more explicit user instructions and providing a restricted set of validated home BP monitors as a reference. Another study should focus on the cause and mechanisms of failures to measure SBP with Checkme in some patients or situations. Furthermore, an international validation protocol for the calibration procedure of a cuffless device is needed.

**Implications for practice**

It is highly possible that the use of cuffless SBP devices will become part of common practice in hypertension and cardiovascular risk management in the near future. Therefore, healthcare professionals should be aware of this development and familiarize themselves with the specific characteristics of these devices. They could explore possibilities such as smart data analysis and connectivity with electronic health records. Patients and their relatives should not hesitate to discuss the possibilities in home monitoring with their healthcare professionals. If they start using these devices, it may provide them with better insight in their health status and/or recovery, with a minimum effort.

**Conclusion**

As confidence in the validity of BP measurement results continues to increase and if international consensus on the calibration process is reached, cuffless BP monitoring devices such as the Checkme may change the way patients are measuring their home BP in the context of ambulant hypertension and cardiovascular risk management. Major advantage of the Checkme above the current use of cuff-based BP home monitors is that it stimulates the patient in doing larger numbers of BP readings, because of its easy to use design.
Conflicts of interest
The authors report no specific funding in relation to this research and no conflicts of interest.

Abbreviations
BP: blood pressure
SBP: systolic blood pressure
DBP: diastolic blood pressure
HBPM: home blood pressure monitoring
SUS: system usability scale
UTAUT2: unified theory of acceptance and use of technology 2
References


