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Review

Review

Hypertension Canada Statement on the Use of Cuffless Blood Pressure Monitoring Devices in Clinical Practice

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BACKGROUND: Cuffless blood pressure (BP) devices are an emerging technology marketed as providing frequent, nonintrusive and reliable BP measurements. With the increasing interest in these devices, it is important for Hypertension Canada to provide a statement regarding the current place of cuffless BP measurements in hypertension management.

METHODS: An overview of the technology in cuffless BP devices, the potential with this technology and the challenges related to determining the accuracy of these devices.

RESULTS: Cuffless BP monitoring is an emerging field where various technologies are applied to measure BP without the use of a brachial cuff. None of the devices currently sold have been validated in static and dynamic conditions using a recognized validation standard. Important issues persist in regard to the accuracy and the place of these devices in clinical practice. Current data only support using validated cuff-based devices for the diagnosis and management of hypertension. Presently, readings from cuffless devices that are used for diagnosis or clinical management need to be confirmed using measurements obtained from a clinically validated BP device.

CONCLUSIONS: Cuffless BP devices are a developing technology designed to track BP in most daily life activities. However, many steps remain before they should be used in clinical practice.

Keywords: accuracy; blood pressure measurements; cuffless; hypertension; validation.

Blood pressure (BP) monitoring is one of the most fundamental approaches to assess cardiovascular risk. Decades of research have shown that hypertension is one of the most important modifiable risk factors, and that BP lowering significantly prevents cardiovascular diseases even when BP is below 120/80 mmHg.[1,2] Since 1905, when the Korotkoff sounds were described allowing the estimation of systolic and diastolic BP using an upper-arm cuff, the underlying principles for BP measurements have remained broadly the same. While the past years have seen automated oscillometric BP measurements supplant auscultatory BP measurements,[3,4] and the emergence of technologies such as central BP[5] and remote home BP monitoring,[6] these all rely on the use of a cuff. Importantly, all these measurements are performed under static conditions, where the wearer needs to be resting, correctly positioned and immobile. Only ambulatory BP measurements (ABPM) provide some degree of dynamic measurements, although the person wearing the device needs to keep their arm still and to relax during all measurements, and the number of readings obtained per day is limited.[7,8]

The past few years have seen rapidly growing interest in the development of cuffless wearable technologies to measure BP in a nonintrusive manner. The global market for cuffless BP monitors is expected to increase from USD 586 million in 2022 to USD 1.6 billion in 2032.[9] Cuffless BP devices can now easily be purchased online, often for a lower price than validated cuff-based devices. In a recent Australian audit of the online market,

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none of the wristband cuffless devices listed, estimated to be more than 500, were validated.[10] While the potential advantages of such technologies are appealing, many hurdles remain before cuffless BP measurements can be incorporated into routine clinical care, with the most important being concerns regarding clinical usefulness, accuracy and appropriate validation. Due to these concerns, in 2022 the European Society of Hypertension made a statement that they did not recommend the use of cuffless BP devices for the evaluation or management of hypertension.[11]

As the leading authority on BP management in Canada, Hypertension Canada's mission includes providing guidance on novel BP measurement technologies that could impact the lives of Canadians. As several comprehensive reviews are already available on cuffless BP monitoring,[11–16] the purpose of this statement is to provide a brief summary of the promises and concerns relating to these technologies and to propose recommendations on how and under which conditions cuffless BP measurements could be incorporated into the current Canadian context.

METHODOLOGY

All members of Hypertension Canada's Device Recommendation Committee participated in the preparation of this statement. This committee includes a diverse group of Canadian experts from across the country, with different backgrounds in clinical, research and implementation work. The first author is an expert in cuffless BP measurements external to the Committee and prepared the first draft with the last author after a literature review. Thereafter, all panel members reviewed the document and consensus was reached on all aspects discussed. As such, the statements listed represent official recommendations from Hypertension Canada's Device Recommendation Committee in regard to the routine use of cuffless BP measurement devices in clinical practice.

TECHNOLOGY

Cuffless BP measurement technologies rely on alternative physiological measurements combined with algorithms to compute BP in mmHg (**Figure 1**).[17] The European Society of Hypertension has summarized the various cuffless techniques,[11] and, to the authors' knowledge, no new technologies have emerged since this publication. Cuffless BP technologies are categorized based on whether they require individual user cuff calibration, or not (**Table 1**).

Calibration-free cuffless BP technologies (e.g., oscillometric finger pressing, ultrasound and volume control—*not to be confused with its precursor, the longstanding cuff-based volume clamping principle*[18]) have not been widely adopted, likely due to their inherent limitations. For instance, ultrasound methods can only measure pulse pressure and are not very convenient, while volume control methods require continuous application of external pressure to the finger to measure BP. The most common calibration-free cuffless BP technology is the oscillometric finger pressing method.[19,20] It allows BP measurements to be obtained via smartphones by having the user press their fingertip against a sensor to measure contact pressure and blood volume oscillations (similar to an oscillometric cuff), but it requires active user participation and can only provide discrete measurements. While it can enhance hypertension awareness and screening due to the widespread use of smartphones,[21] it cannot offer continuous and nonintrusive BP monitoring.

For cuffless BP measurements that require calibration, the most commonly measured physiological signals are extracted from the local arterial waveforms, generally assessed via photoplethysmography (PPG), tonometry or facial video, and the time delay for the pressure wave to travel between two arterial sites.[22–24] Estimating BP from arterial waveform features refers to pulse wave analysis, while estimating BP from the time delay between two arterial sites refers to pulse transit time, which is often estimated with the time delay between an electrocardiogram and an

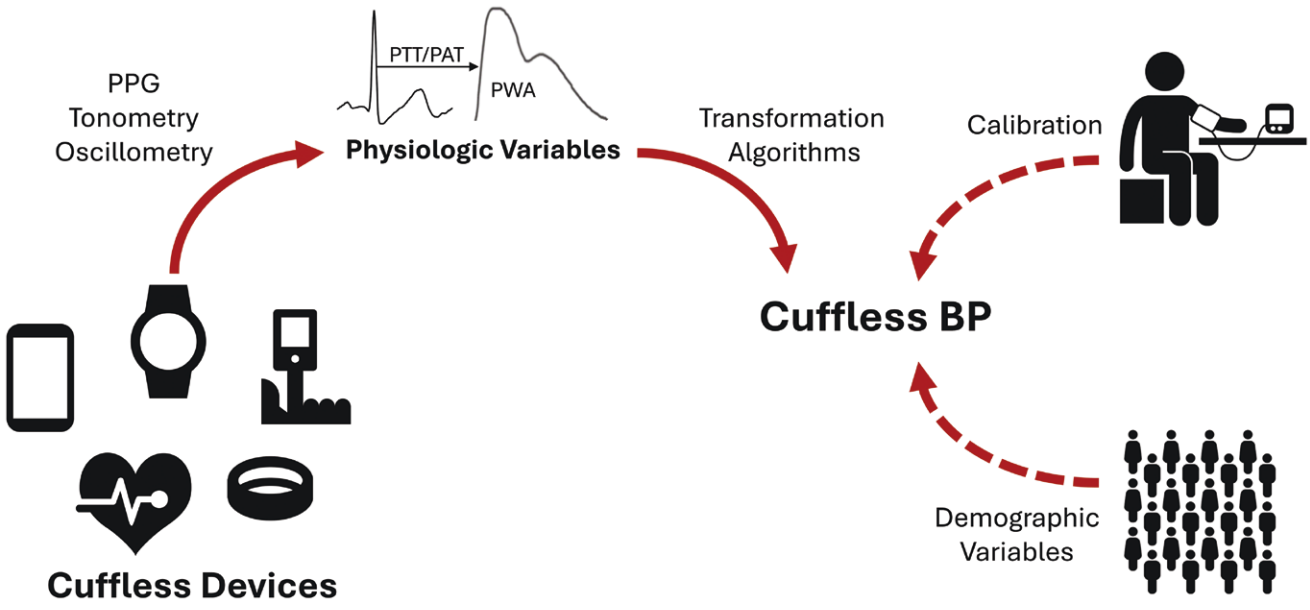

Figure 1. Underlying principles of cuffless BP measurements. Cuffless BP devices record physiological variables mostly from photoplethysmography, tonometry or oscillometric sensors. This data is then transformed using proprietary algorithms to derive an estimation of the BP. To provide accurate estimations, periodic calibration with cuff-based BP measurements and/or the inclusion of demographic variables is required. BP, blood pressure; PPG, photoplethysmography; PAT, pulse arrival time; PTT, pulse transit time; PWA, pulse wave analysis.

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Table 1. Existing cuffless BP technologies

Methods requiring calibration with cuff-based BP measurements	*Designed to estimate BP changes from calibration value*
Pulse transit time	Estimates blood pressure from the time delay between arterial waveforms detected at two distinct sites (proximal and distal); Requires two pulse sensors.
Pulse arrival time	Estimates blood pressure from the time delay between an arterial waveform detected at one site and the R-wave peak on an electrocardiogram; Requires one pulse sensor and electrocardiogram electrodes.
Pulse wave analysis	Estimates blood pressure from the changes in the pulse waveform; Requires one pulse sensor.
Facial video processing	Estimates blood pressure from pulse waveforms detected in the facial skin; Could be integrated in any devices with a camera; Very difficult to obtain high-quality waveforms.
Calibration-free methods	*Designed to directly estimate blood pressure values*
Oscillometric finger pressing	Estimates blood pressure by measuring contact pressure and blood volume oscillations; It could be integrated into smartphones with a pressure-photoplethysmography sensor unit.
Ultrasound	Estimates pulse pressure from blood velocity and arterial cross-sectional area; Requires an ultrasound probe.
Volume control	Estimates blood pressure from blood volume oscillations; Requires continuous external pressure application, which may not be comfortable.

arterial waveform (i.e., the pulse arrival time). While these physiological measures are somewhat correlated with BP, major challenges remain unresolved: the correlations are subject-specific,[25] change over time,[26] and are influenced by other factors[27] (i.e., they can change independently from BP, such as with smooth muscle contraction).

Currently, a way to overcome these challenges is through the use of machine learning algorithms and large datasets in the hope that BP information is possibility embedded in the waveform shape and/or the transit times. Periodic cuff-calibrations or demographic data correlated with BP (e.g., age, sex, and body size) are necessary to adjust the BP values computed by the algorithms.[17] This does not guarantee that the device can track BP changes in an individual since it does not personalize the algorithm.[28] Some user-specific algorithms have been proposed in the literature,[29–31] but they have not gained much popularity, likely due to the practical difficulties of developing these data-driven algorithms, which require many BP measurements.

THE PROMISE OF CUFFLESS BP

Cuffless BP monitoring has the potential to substantially change the landscape of hypertension management. It has several potential advantages compared to traditional cuff-based measurements (**Table 2**). With cuffless BP measurements, BP could be assessed repeatedly throughout the day, providing a wealth of data far beyond what is possible with ABPM. By foregoing cuff inflation, BP measurement would be more comfortable and less intrusive to daily life activities. Nocturnal BP could be easily assessed without the influence on BP from sleep disturbances. BP could be measured with no, or minimal, intervention by a device-wearer, at any times of the day in all situations. Cuffless BP devices have the potential to raise awareness of BP assessment and to determine the effect of emotions, work, rest, activities, and circadian rhythm on BP. There is also a potential for use in acute care settings, as is the case for volume clamp methods, foregoing the need of more invasive devices and monitors. In addition, by incorporating cuffless BP measurements into common accessories, such as phones, smart watches, bracelets or rings, significantly higher levels of hypertension awareness and diagnosis would be achievable. Of course, this can only become reality with a cuffless BP device that reports highly accurate and reproducible readings. To this day, no such device exists and several issues need to be addressed before cuffless BP can be incorporated into the outpatient and/or home setting.

Table 2. Potential advantages of cuffless BP monitoring

Continuous beat-to-beat BP measurements
BP readings accessible at all times
Activation of the device with minimal interventions by the wearer
BP measurements without awareness of the wearer
Detection of rapid BP changes during normal activities
Increased hypertension awareness and diagnosis
Improved recognition of white coat and masked hypertension
Easily integrated into common accessories such as smart watches, phones and rings
Prevent alarm reactions
Undisturbed measurements of nighttime BP

Abbreviation: BP, blood pressure.

ISSUES RELATING TO CAPTURE METHODS

As described above, a variety of physiological measurements and capture methods can help derive BP from cuffless devices. In this regard, several issues have been raised which may limit the accuracy of these capture methods (**Table 3**). First, several devices measure pulse transit time or PAT, which relate to transit times and as such, are highly dependent on distance (height and arm length) and speed (pulse wave velocity or arterial stiffness). Body habitus is obviously highly variable, resulting in a large variability of transit times across individuals. Although this should be compensated with user-specific cuff calibration, it has been previously shown that height can influence the accuracy of cuff-based oscillometric BP devices,[32] therefore may lead to compound errors. As for arterial stiffness, it has been known for decades that it increases with age and in the presence of cardiovascular comorbidities, but also with smooth muscle contractions when measured at the periphery.[33–36] Furthermore, the relationship between pulse transit time and BP appears to be affected by blood density and arterial diameter.[16] As all these variables can differ between subjects, a generalized algorithm may only provide accurate results on an averaged population level, and possibly less so on an individual level. Second, PPG use light-emitting diodes and sensors to detect volume changes in blood vessels. This may be problematic in people with darker skin tones, as is well described for pulse oximetry,[37,38] although there is (yet) no evidence that PPG technology used in cuffless BP devices is influenced by skin color.[39–42] Third, most cuffless BP devices measure BP on body parts even more distal from the heart than the upper arm, such as the wrist or fingers. However, the degree to

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Table 3. Accuracy issues specific to cuffless devices

Generalizability of the estimation algorithm may be problematic in various populations (upper/lower ranges of height and weight, elderly, increased arterial stiffness)
Measurement in distal sites may be overly affected by systolic BP amplification when pulse wave analysis is used to estimate BP
The use of the ideal reference standard (intra-arterial BP) for validating continuous devices is not feasible in the ambulatory setting
Photoplethysmography may be less accurate on darker skin tones
Need to test in various dynamic conditions
Pseudo-precision around the calibration value
Calibration with oscillometric upper-arm cuff BP measurement may compound errors due to cuff-based and the cuffless procedures

Abbreviation: BP, blood pressure.

which systolic BP and pulse pressure amplify (or increase) from proximal to distal arteries varies greatly between individuals.[43] This has already been shown to influence brachial cuff-based BP accuracy.,[43–45] and it is likely to be even more pronounced in more distal arteries (such as the radial artery where most cuffless BP devices capture BP), it may be more pronounced in more distal arteries with certain devices.

ISSUES RELATING TO CALIBRATION

Most cuffless BP devices require calibration with upper-arm cuff-based BP measurements before any BP can be measured. To limit the drift phenomenon, where the measured BP shifts away from the calibrated BP over time, most devices recommend periodic calibration. Importantly, cuff-based calibration measurements are subject to all the same potential errors as routine home-based BP measurements and need to be performed under optimal conditions with an approved protocol and a validated cuff-based device.[3] However, even with high-quality cuff-based BP calibration, any errors and variabilities in accuracy will be compounded by the cuffless procedure. Furthermore, when accuracy is tested immediately following calibration, the displayed cuffless BP will be highly similar to the cuff-based calibration BP, which may result in pseudo-precision where a device appears to be accurate when it only reproduces its cuff calibration.[11,15,46] To illustrate this phenomenon, Hu and colleagues[15] described the "File Card Analogy," where a cuffless device only displaying BPs identical to the cuff-based calibration value will always appear to be highly accurate and precise, whereas this approach provides no useful clinical information beyond what is obtained only with the calibration value. In the Microsoft Research Aurora Project, none of the tested cuffless BP devices provided any useful information in predicting the next-day BP beyond what was achievable with the calibration BP alone.[23,24] This has also been shown in a recent study testing a marketed cuffless BP device, where the authors showed that the device failed to track BP changes that diverge away from the calibration value.[46] All of this suggests cuffless BP measurements may only be as useful as the cuff-based measurement used for calibration. This defeats the purported promise of increasing access, ease, and widespread use of cuffless BP measurement for public health.

Likewise, a simulation study suggested that the addition of a waveform measurement (as used by cuffless devices) results in lower accuracy than using only the calibration BP.[47] The authors also showed that cuffless BP waveform data resulted in lower BP measurement accuracy compared to using either the populational BP average or using only baseline demographic characteristics (sex and age) to predict BP. This is not to say that cuffless devices using demographic characteristics for calibration should work better than the cuff-calibrated ones. On the contrary, it demonstrates that merely using populational BP averages or demographic characteristics without actual BP measurement can also predict individual BP with an acceptable accuracy.[47]

ISSUES RELATING TO ACCURACY AND VALIDATION

To be legally sold in Canada, all medical devices require a Canadian Medical Device Licence. This regulatory clearance relates to a device's safety, effectiveness and quality, often through demonstration of equivalency to already marketed devices. However, no demonstration of accuracy, validation, or clinical utility is needed, and equivalency can be shown to a completely different device and technology. Cuffless BP devices are particularly problematic in this regard as most are sold online where unregulated devices can be easily purchased or where Canadian customers can be mislead by claims of "FDA approval" whereas no Canadian regulatory clearance has been obtained. Furthermore, manufacturers often promote this "FDA-approved" label as a gauge of quality, when no data on accuracy has been obtained and only safety and relative equivalency to other devices is demonstrated.

To be deemed accurate, a BP device must meet the accuracy standard as defined in recognized validation protocols. In 2018, the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018) was published and this protocol is now viewed as the most comprehensive tool available to validate cuff-based BP measuring devices.[48] Now more than ever, patients and providers have access to resources to easily identify devices that have passed an accuracy validation protocol. Hypertension Canada has always been a pioneer in this domain,[49] and was one of the first to provide a listing of recommended devices on its website (https://hypertension.ca/healthcare-professionals/recommended-devices).

The AAMI/ESH/ISO 2018 universal standard (with the subsequent amendments), and its precursors, was designed only to test cuff-based devices in static conditions, where the subject is resting and remains immobile throughout the procedure. The main purpose of cuffless BP devices is to provide continuous or intermittent BP measurements in all daily life situations with minimal regard to the measuring conditions. Therefore, protocols to validate cuff-based devices in static conditions are not applicable to test the accuracy of cuffless BP devices. Due to a lack of a better alternative, most devices currently claiming accuracy have either passed a recognized validation protocol designed to test a cuff-based device[50–55] or a non-standard "in-house" protocol, all with only static measurements.[56–61] This is problematic as calibration of the cuffless device before the validation procedure will produce BPs that are closely matched to the BP used for calibration, which can artificially suggest high accuracy,[11,15,16] as stated above. Any condition that drives BP away from the calibration BP may affect the accuracy. This issue has been illustrated with a marketed device that is considered a highly accurate wrist-based cuffless device under static conditions,[53] but its ability to track BP reduction from antihypertensive drug initiation remains to be demonstrated.[46] Therefore, the accuracy of cuffless BP devices will need to be tested with specific validation protocols aimed at replicating various conditions that influence BP that may arise in daily life to reflect the intended use of the device.

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CURRENT STATE OF CUFFLESS BP VALIDATION STANDARDS

In 2014, the Institute of Electrical and Electronics Engineers published the first standard to assess the accuracy of cuffless BP devices, which was then amended in 2019.[62,63] This standard uses manual auscultatory BP as a reference method for both intermittent and continuous cuffless BP measurements. It requires validation immediately postcalibration, in different positions, after inducing BP changes and before recalibration is required. While advancing the field, this standard is difficult to apply as the methods for inducing BP changes are not described, therefore not standardized and left to the manufacturer's discretion. In 2022, ISO published a validation protocol for continuous (measurements every < 30 s) BP measurements against intra-arterial measurements.[64] However, this standard is only applicable to devices used in emergency, surgical or intensive care settings, hence not for cuffless BP devices intended for home or outpatient clinic use.

The most comprehensive validation protocol to evaluate cuffless BP device accuracy has been developed by a working group of the European Society of Hypertension and published in 2023.[14] This standard details the procedures to validate intermittent cuffless BP devices (BP readings every > 30 s—usually every 30–60 min) with a combination of manual auscultatory and 24-h oscillometric ABPM as reference methods. Its framework is based on the AAMI/ESH/ISO 2018 universal standard protocol to test accuracy following various physiological and pharmacological changes in BP. With this validation standard, to be deemed accurate, a device needs to pass different validation tests (**Table 4**) designed to replicate common situations where BP may increase or decrease. As this standard has only been recently published, no cuffless BP device currently available for purchase has passed all six validation tests. Recently, it was also announced that a new ISO standard is under development (ISO 81060-7: noninvasive sphygmomanometers—Part 7: Clinical performance verification of intermittent or repeated intermittent cuffless measurement) to provide guidance on intermittent cuffless BP device validation.

HYPERTENSION CANADA STATEMENTS

Regarding cuffless BP monitoring, Hypertension Canada issues the following statements and recommendations:

1. Cuffless BP monitoring is a rapidly evolving field that may ultimately allow improvements in hypertension awareness and management.
2. As various technologies exist, all cuffless BP devices will need to be independently validated for accuracy before routine clinical use can be considered, as is required for all cuff-based devices.
3. Once proven to be accurate, a cuffless BP device will need to demonstrate clinical utility before it can be integrated into routine clinical care.
4. At this time, no diagnosis or treatment decisions should be made solely based on cuffless BP measurements. Current data only supports using validated cuff-based devices for these purposes and all readings from cuffless BP measurements need to be confirmed using validated BP measurements devices.
5. To be listed on Hypertension Canada's List of Recommended Devices, a cuffless BP device will be required to pass all required validation tests described in the ESH 2023 validation protocol[14] until the upcoming ISO 81060-7 standard is published, at which point this requirement will be reassessed.

After lingering for most of the 20th century, BP measurement now appears to finally embrace the technological age with the development of remote home BP monitoring, noninvasive central BP devices and cuffless BP measurements. However, it is still unclear whether these new technologies will change hypertension diagnosis and management beyond what is possible using standardized automated cuff-based BP measurements. Although the potential advantages of cuffless BP monitoring are appealing, many steps are needed before these devices can be used in routine clinical practice, notably resolving important issues around information capture, calibration, accuracy and validation. At this time, Hypertension Canada finds there is insufficient evidence to support the use cuffless BP measurements for clinical decision-making.

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CONFLICT OF INTEREST

C.L. is an inventor on patent applications submitted by the University of Pittsburgh that covers smartphone-based blood

Table 4. Examples of validation tests required to test cuffless BP monitoring device accuracy

Validation test	Reasoning	Description
Static test	Absolute accuracy testing	Universal standard
Device position test	Accuracy with hydrostatic pressure changes	Universal standard in a position different from the calibration position
Treatment test	Accuracy with pharmaceutical BP lowering	Universal standard 1–4 weeks after antihypertensive drug initiation or increase
Awake/asleep test	Accuracy with circadian BP changes	Comparison to 24-h ambulatory BP monitoring
Exercise test	Accuracy with BP increase	Universal standard during exercise
Recalibration test	Calibration stability	Universal standard immediately before cuff recalibration is required

Universal standard refers to the testing procedure and accuracy criteria designed to test intermittent cuff-based BP devices, as described in the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018).
Abbreviation: BP, blood pressure.

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pressure measurement techniques. R.T.T. has received arm's length investigator-initiated research funds from Merck, Sanofi, AstraZeneca, and Pfizer and has been a consultant for Shoppers Drug Mark, Emergent Biosolutions and Novo Nordisk in the past. J.R. is a shareholder of mmHg Inc., a digital health company. She is participating in clinical trials with Astra Zeneca and Mineralys. S.H. serves on the Board of NephJC, an educational nonprofit, a voluntary position. He is the chair of the Hypertension Canada Blood Pressure Device Recommendation Committee.

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