A Call to Regulate Manufacture and Marketing of Blood Pressure Devices and Cuffs: A Position Statement From the World Hypertension League, International Society of Hypertension and Supporting Hypertension Organizations

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Nearly all automated blood pressure (BP) measurement devices assess BP by the oscillometric technique.[1,2] Oscillometric BP readings are derived by measuring the maximal oscillations of the composite pulse wave in the BP cuff, which corresponds to the mean arterial pressure. Systolic and diastolic BP are then estimated by points along the composite pulse wave, using an algorithm that is proprietary to each manufacturer and device. Hence, there is a need to ensure that the estimated BP by automated oscillometric devices reflects BP measured by auscultation. A few automated devices use auscultation to assess Korotkoff sounds by using a microphone.[2] Microphones may capture different sound wave lengths and sound intensity than the human ear and there is a potential for sound artifacts to be recorded by automated devices as Korotkoff sounds. Therefore, automated devices that operate using microphones to assess Korotkoff sounds also require an assessment of their ability to estimate BP accurately.

An international validation standard and several protocols have been developed to test the ability of automated devices to assess BP accurately in the general public, as well as in special populations, such as children or pregnant women, and special conditions such as arrhythmias.[1,3–7] Factors that need to be considered for validation include microphone sensitivity, cuff size, appropriate algorithms, and the reliability and reproducibility of BP readings.

Many manufacturers have developed devices that have been rigorously tested by independent investigators by using one or more of these test procedures. Scientists, clinicians, and the public can be reassured that these devices are likely to be accurate in the populations tested. Other devices have been tested independently but the test results were not published.

Many government approval agencies do not require independent validation of accuracy according to established validation standards/protocols as mentioned above; rather, they rely only on the manufacturers to show that they have done accuracy tests internally. Furthermore, some validation testing may not include enough people with a wide range of arm sizes to ensure accurate readings in people with small or large arm sizes.[8] Thus, many devices currently available on the market for self-monitoring of BP at home or for professional use in the office or hospital have: (1) not been tested independently according to the international standard or a national protocol; (2) have failed independent validation studies; or (3) may not produce accurate readings in those with small or large arms but are still marketed.[2] The accuracy of these devices is not assured, and, for devices that fail validation standards, inaccurate BP readings and thereby incorrect treatment decisions are likely.

The manufacture and sale of BP measurement cuffs are also problematic. The issues apply not only to automated but also manual auscultatory devices. With the exception of cuffs that automatically adjust for a wide range of arm sizes,[9,10] an accurate BP assessment requires the selection of an appropriate cuff size according to the individual's arm circumference.[11] In general, this requires cuffs to be marked with the range of arm circumferences on which the cuff will be able to

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be used to assess BP accurately. However, some cuffs are not marked, and some may be inaccurately marked. Further, claims that "one size cuff fits all" may not have been validated in studies that had patients with a wide range of arm sizes. Clinicians can manually mark cuffs for the range of arm sizes on which they are likely to be accurate and can also manually assess individual arm circumferences to see what cuff would be proper. Unfortunately, these procedures are time-consuming and rarely done in clinical practice. Ensuring that all BP cuffs, when manufactured, are accurately marked for the range of arm sizes to be used for accurate BP assessment is a crucial and simple step for resolving this problem. Ensuring that the devices have a wide range of cuff sizes and that the devices are validated with the range of cuffs sizes available is also important.

Notwithstanding the relevant issues regarding arm sizes, the use of wrist devices to assess BP is becoming more popular. This is likely attributable to ease of use (eg, namely, no need to measure arm circumferences), cost, and usability in obese individuals with cone-shaped upper arms. There are, however, several challenges when using these devices, including that the wrist be held at heart level—an aspect that is not adhered to in many instances. Furthermore, a large proportion of these low-cost devices are not validated according to the described procedures, and, as a rule, are generally not advised to be used as a first option because of overestimation or underestimation of BP.

RECOMMENDATIONS FROM THE WORLD HYPERTENSION LEAGUE, INTERNATIONAL SOCIETY OF HYPERTENSION, AND SUPPORTING HYPERTENSION ORGANIZATIONS

Recommendation 1: Call on the private sector to manufacture and sell only: (1) automated BP devices that have been independently tested to meet the international validation standard or national protocols for accuracy with the detailed results either (a) published in peer-reviewed scientific journals, (b) publically accessible, or (c) verified by a government agency, and (2) arm size–marked BP cuffs that have been demonstrated to be accurate in people with arm sizes in the range indicated (Table).

Recommendation 2: Call on governmental organizations to develop policies and regulations to allow only the sale of: (1) automated BP devices that have been independently tested to meet the international validation standard or national protocols for accuracy with the detailed results either (a) published in peer-reviewed scientific journals, (b) publically accessible, or (c) verified by a government agency, and (2) arm size–marked BP cuffs that have been demonstrated to be accurate in people with arms sizes in the range indicated.

TABLE. Organizations Supporting the Position Statement to Regulate the Automated Blood Pressure Device Industry

Argentine Society of Hypertension
Belgian Society of Hypertension
Consortium for Southeastern Hypertension Control
HeartReach Inc.
Hong Kong College of Cardiology
Hypertension Canada
Indian Society of Hypertension
Israeli Society of Hypertension
Japanese Association of Hypertension
Japanese Society of Hypertension
Malaysian Society of Hypertension
Pakistan Hypertension League
Portuguese Society of Hypertension
Saudi Hypertension Management Society
Slovak League Against Hypertension
South African Hypertension Society
South Asia regional office of the World Hypertension League
Stroke Investigative Research & Educational Network (SIREN)
Swedish Society for Hypertension, Stroke, and Vascular Medicine

Recommendation 3: Continue to recommend upper-arm or brachial BP devices for BP measurement.

Recommendation 4: Call for the development of a simple and easy-to-understand branded symbol that would clearly identify automated BP devices with appropriate cuff sizes to be used by healthcare professionals and the public while recommendations 1 and 2 are being implemented. The use of the branded symbol should be provided to BP monitor manufacturers by an independent, not-for-profit body and to be used internationally.

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