



# HEARTS

IN THE AMERICAS

## Technical Note

# Technical resources relevant to the accuracy of blood pressure measurement

*Prepared by*  
*Cintia Lombardi, ScD, and Pedro Ordunez, MD, PhD*  
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Hypertension is a global health challenge that must be tackled on many fronts. As it is the largest modifiable risk factor for cardiovascular disease, appropriate devices to screen for hypertension and measure BP are important to ensure that hypertension is accurately diagnosed and treated.

*WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff*

# Purpose and audience

In this note we present a compilation of the most relevant available technical resources in the three key components of the HEARTS blood pressure measurement strategic area. The resources listed include links to scientific articles, and technical and communication materials developed by PAHO and other institutions.

The purpose is to provide resources that can be useful for policy makers, health professionals, regulatory agencies, professional societies and the public. Many of these resources can be found at the HEARTS webpage:

<https://www.paho.org/en/hearts-americas/hearts-americas-blood-pressure-measurement>

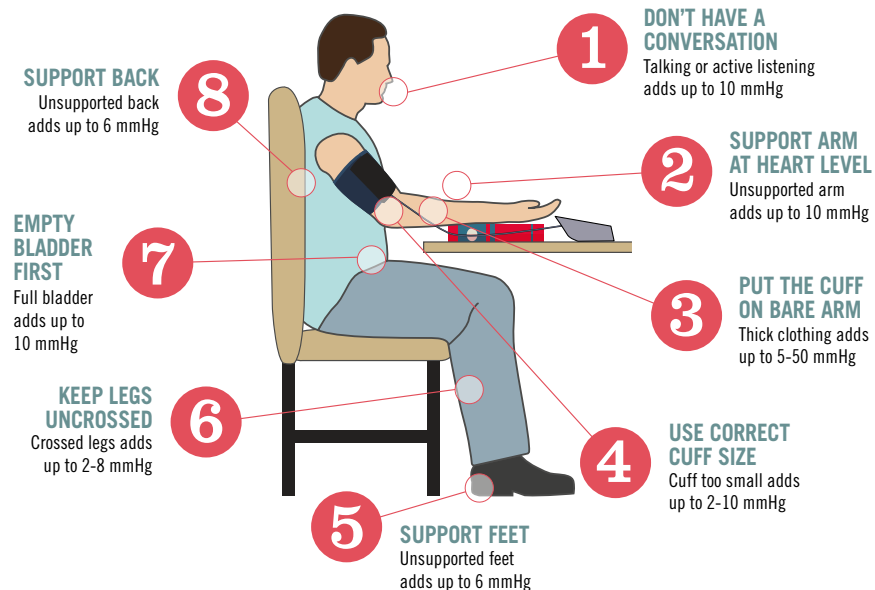
# Background

Global Hearts is an initiative spearheaded by the World Health Organization involving various global actors, including the Centers for Disease Control and prevention of the United States (CDC) and the Initiative Resolve to Save Lives. The Pan American Health Organization (PAHO) leads the implementation of HEARTS in the Region of the Americas, ensuring that implementation actions are aligned with the strategic priorities of the region, particularly with the universal health coverage resolution, strengthening of health systems based on primary care and with the Sustainable Development Goals 2030, specifically those related to the prevention and control of noncommunicable diseases (NCD).

HEARTS in the Americas is sustained by six technical pillars or strategic areas, blood pressure measurement being one of them, since accurate blood pressure measurement is essential for the diagnosis and management of hypertension.

The key components of this strategic area are: 1) use of an appropriate measurement protocol and proper patient preparation, 2) use of automated blood pressure measuring devices validated for accuracy, and 3) strengthening of regulatory frameworks relevant to measurement accuracy, such as pre-market approval and procurement.

# Resources on measurement techniques



## Infographic and banner

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Requirements for obtaining an accurate blood pressure reading

The posters with the infographic are available in print-ready formats in two sizes.

<https://www.paho.org/en/node/70200>

<https://www.paho.org/en/documents/banner-requirements-obtaining-accurate-blood-pressure-reading>

## Social media GIF

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<https://www.paho.org/en/documents/gif-how-get-accurate-blood-pressure-reading>

## Videos

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Automated Blood Pressure Device:

[https://www.youtube.com/watch?time\\_continue=68&v=vqhpbf8U9E&feature=emb\\_logo](https://www.youtube.com/watch?time_continue=68&v=vqhpbf8U9E&feature=emb_logo)

(Resolve to Save Lives)

Preparing an individual for blood pressure measurement:

<https://bit.ly/2Wwc0Qq>

<https://bit.ly/2JUu1RX>

(Johns Hopkins Bloomberg School of Public Health)

## PAHO virtual campus

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Virtual course on the implementation of the HEARTS Technical Package in Primary Health Care  
<https://www.campusvirtualsp.org/en/node/27083>

## Articles

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Padwal R, Campbell NRC, Schutte AE, et al. Optimizing observer performance of clinic blood pressure measurement: a position statement from the Lancet Commission on Hypertension Group. *J Hypertens*. 2019;37(9):1737-1745.

Available at <https://pubmed.ncbi.nlm.nih.gov/31034450/>

Padwal R, Campbell NRC, Schutte AE, Olsen MH, Delles C, Etyang A, et al. Optimización del desempeño del observador al medir la presión arterial en el consultorio: declaración de posición de la Comisión Lancet de Hipertensión. *Rev Panam Salud Publica*. 2020;44:e88.

Available at: <https://iris.paho.org/bitstream/handle/10665.2/52467/v44e882020.pdf?sequence=4&isAllowed=y>

# Resources on validation of blood pressure measuring devices

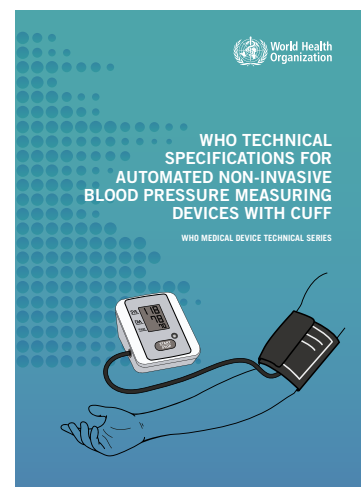
## WHO document

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PAHO's work on this area is consistent with the *WHO Technical specifications for automated non-invasive blood pressure measuring devices with cuff*, published in 2020 and found at:

<https://apps.who.int/iris/bitstream/handle/10665/331749/9789240002654-eng.pdf>

This document emphasizes the importance of clinical validation for accuracy and precision conducted by investigators independent of the manufacturer following a standardized international validation protocol.



## **Lists of validated automated blood pressure measuring devices**

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Lists of devices that have been independently validated for accuracy and precision using established validation protocols (AAMI, ESH, BHS and ISO 81060-2:2018).

<https://www.paho.org/en/documents/lists-validated-automated-blood-pressure-measuring-devices>

## **Instructions on how to use lists of validated devices**

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Step-by-step guidance on how to use two international lists or registries (STRIDE BP and Medaval).

<https://www.menzies.utas.edu.au/documents/pdfs/Blood-pressure-devices.pdf>

[https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Spanish\\_final.pdf](https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Spanish_final.pdf)

[https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Portugese\\_final.pdf](https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Portugese_final.pdf)

## **Articles**

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Sharman JE, O'Brien E, Alpert B, et al. Lancet Commission on Hypertension group position statement on the global improvement of accuracy standards for devices that measure blood pressure. *J Hypertens*. 2020;38(1):21-29.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6919228/>

Sharman JE, O'Brien E, Alpert B, et al. Declaración de posición del Grupo de la Comisión Lancet de Hipertensión con respecto a la mejora mundial de las normas de exactitud para los dispositivos de medición de la presión arterial. *Rev Panam Salud Publica*. 2020;44:e88.

<https://iris.paho.org/handle/10665.2/51862>

Stergiou GS, Palatini P, Asmar R, et al. Recommendations and Practical Guidance for performing and reporting validation studies according to the Universal Standard for the validation of blood pressure measuring devices by the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO). *J Hypertens*. 2019;37(3):459-66.

[https://journals.lww.com/jhypertension/Fulltext/2019/03000/Recommendations\\_and\\_Practical\\_Guidance\\_for.2.aspx](https://journals.lww.com/jhypertension/Fulltext/2019/03000/Recommendations_and_Practical_Guidance_for.2.aspx)

## **ISO standard**

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ISO 81060-2:2018. Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type

This document specifies the requirements and methods for the clinical investigation of equipment used for the intermittent non-invasive automated estimation of blood pressure at home and health care facilities. It is considered the single universal protocol for the validation of BP monitors and is intended to replace the previous ones.

<https://www.iso.org/standard/73339.html>

# Resources on regulatory frameworks

## Articles

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Lombardi C, Sharman JE, Padwal R, et al. Weak regulatory frameworks on automated blood pressure measuring devices pose a major impediment for the implementation of HEARTS in the Americas and hypertension control. Under revision by J Clin Hypert (2020)

Campbell NR, Gelfer M, Stergiou GS, et al. 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. J Clin Hypertens (Greenwich). 2016;18(5):378-380.

<https://pubmed.ncbi.nlm.nih.gov/26852890/>

## Recommendations

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Recommendations from the HEARTS in the Americas Workshop on Regulatory Frameworks and Procurement of Blood Pressure Measuring Devices for Use in Primary Health Care

<https://www.paho.org/en/documents/recommendations-hearts-americas-workshop-regulatory-frameworks-and-procurement-blood>

## WHA resolution on regulations of medical devices

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World Health Organisation. Regulatory system strengthening for medical products. Sixty-Seventh World Health Assembly resolution WHA67.20. Geneva, Switzerland: World Health Organisation; 2014.

[https://www.who.int/healthsystems/WHA60\\_29.pdf](https://www.who.int/healthsystems/WHA60_29.pdf)



**PAHO**