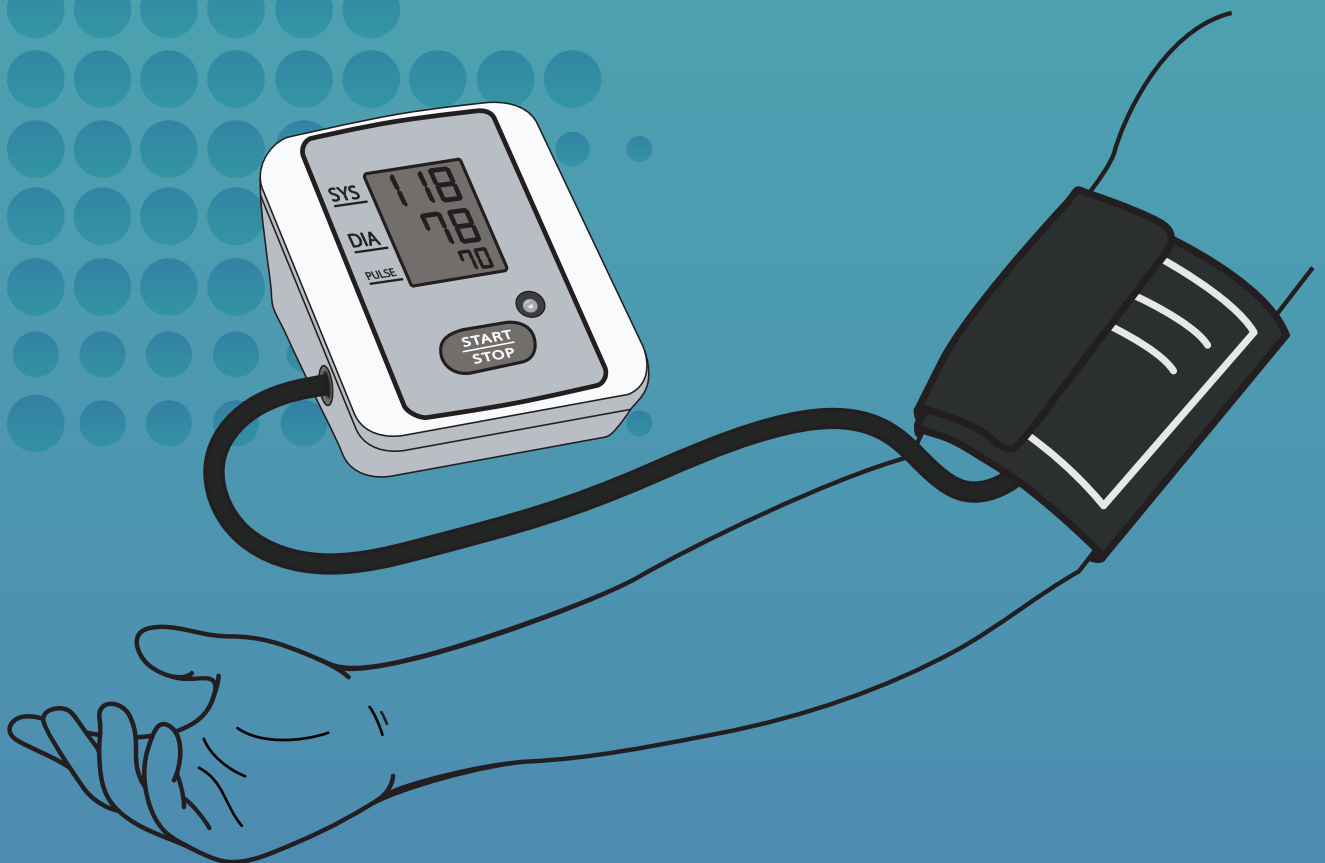


WHO TECHNICAL SPECIFICATIONS FOR AUTOMATED NON-INVASIVE BLOOD PRESSURE MEASURING DEVICES WITH CUFF

WHO MEDICAL DEVICE TECHNICAL SERIES



WHO TECHNICAL SPECIFICATIONS FOR AUTOMATED NON-INVASIVE BLOOD PRESSURE MEASURING DEVICES WITH CUFF

WHO MEDICAL DEVICE TECHNICAL SERIES

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

ISBN 978-92-4-000265-4 (electronic version)

ISBN 978-92-4-000266-1 (print version)

© World Health Organization 2020

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Illustrations by Margot Steiner

Design and layout by L'IV Com Sàrl

Printed in Switzerland

Contents

Acknowledgements	iii
Acronyms and abbreviations	iv
Glossary	v
Executive summary	vii
1. Introduction	1
2. Global burden of hypertension	3
2.1 BP measurement	3
3. Non-invasive BPMDs with cuff	5
4. Automated non-invasive BPMDs with cuff	9
4.1 Description	9
4.2 Measurement principles	9
4.3 Regulatory requirements and standards	11
4.4 Accuracy	12
4.5 Calibration	14
4.6 Maintenance	15
4.7 Accessories and consumables	17
4.8 Guidance on procurement	17
4.8.1 International commercial terms	18
4.8.2 Nomenclature	18
4.8.3 Donations	19
4.8.4 Other relevant considerations	19
4.9 Decontamination	20
4.10 Decommissioning	21
4.11 Technical specifications of automated non-invasive BPMDs with cuff	22
5. Measuring BP	25
5.1 General standardized procedure for proper electronic BP measurements	25
5.2 Specific advice for different settings	27
5.3 Sources of error	28
5.4 Importance of training personnel	29
6. Innovation and research	30
7. Conclusions	33
References	35

Annex 1	
Phasing out mercury	38
Annex 2	
Meeting participants – Consultation for technical specifications for automated non-invasive BPMD with cuff, 25–26 June, 2019	40
Annex 3	
Universal standard for the validation of blood pressure measuring devices	41
Annex 4	
Procedures for laboratory and accuracy testing	43
Annex 5	
Online resources from professional societies	48
Annex 6	
Technical specifications and use of aneroid manual blood pressure measuring devices with cuff	49
1. Description	49
2. Measurement principles	51
2.1 Mercury sphygmomanometer	51
2.2 Aneroid sphygmomanometer	51
3. Regulatory requirements and standards	51
4. Calibration	52
5. Maintenance	52
6. Nomenclature	54
7. Technical specifications for manual BPMDs	54
8. General standardized procedure for proper manual BP measurements	57

Acknowledgements

The document is part of the WHO Medical device technical series. The overall guidance was prepared jointly by the WHO Management of Noncommunicable Diseases and the Medical Devices and in Vitro Diagnostics teams under the coordination of Cherian Varghese and Adriana Velazquez.

The document updates WHO's 2005 guidance on blood pressure measuring devices (BPMs) (1). It also responds to concern about the lack of accurate, good-quality devices, especially in low-and middle-income countries (LMIC), which was expressed at a workshop on blood pressure (BP) measurement during the 4th WHO Global Forum on Medical Devices held in India on 13–15 December 2018.

Laura Patricia López Meneses, a WHO consultant, drafted the document, which was discussed at an expert consultation on technical specifications for automated non-invasive BPMs with cuff, that took place in Geneva, Switzerland, from 25–26 June 2019. The meeting further discussed the scope and content of this publication and steps for implementation. The document then underwent external review. The technical experts who participated in the consultation, and provided technical review to the document, were: Aletta E Schutte (North-West University, South African Medical Research Council, South Africa; University of New South Wales; The George Institute for Global Health, Australia; International Society of Hypertension), Tammy Brady (Johns Hopkins University, USA), Margaret Farrell (Resolve to Save Lives an initiative of Vital Strategies, USA), Norm Campbell (University of Calgary, Canada), Mulugeta Mideksa (Biomedical Engineer, Ethiopia), Marc Jaffe (Resolve to Save Lives an initiative of Vital Strategies and Kaiser Permanente, USA), Oommen John (The George Institute for Global Health, India), Mohammad Ameen (WHO Collaborating Centre for Priority Medical Devices and Health Technology Policy, Ministry of Health and Family Welfare, India) and Laura Alejandra Velez (WHO Operations Support and Logistics). All participants declared any conflicts of interest, which were reviewed by the WHO compliance unit.

After the expert consultation, a second draft was prepared with input from WHO consultants: George Schmidt, Eunice Lorenzo and Jennifer de Francesco, with organizational support and compilation by Valeria Montant, WHO intern.

WHO also acknowledges the technical input of members of the team for Management of Noncommunicable Diseases: Allison Goldstein, Taskeen Khan, and Hongyi Xu, as well as Sheila Nakpil, Sophie Schmitt and Joel Tarel, who provided administrative support for the project.

Special acknowledgment to Nicola Toffelmire, Laura Patricia Lopez Meneses and Valeria Montant who did final compilation of comments.

WHO thanks Resolve to Save Lives, an initiative of Vital Strategies, for financially supporting the preparation of this publication.

The publication was edited by Elisabeth Heseltine. Designed by L'IV Com Sàrl.

Acronyms and abbreviations

ANSI	American National Standards Institute
BP	Blood Pressure
BPMD	Blood Pressure Measuring Device
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
LED	light-emitting diode
LMIC	low- and middle-income countries
MAP	Mean Arterial Pressure
UNDP	United Nations Development Programme
WHO	World Health Organization

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_24677

