HEARTS in the Americas

Regulatory Pathway to the Exclusive Use of Validated Blood Pressure Measuring Devices

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PAHO Pan American Health Organization

World Health Organization Americas

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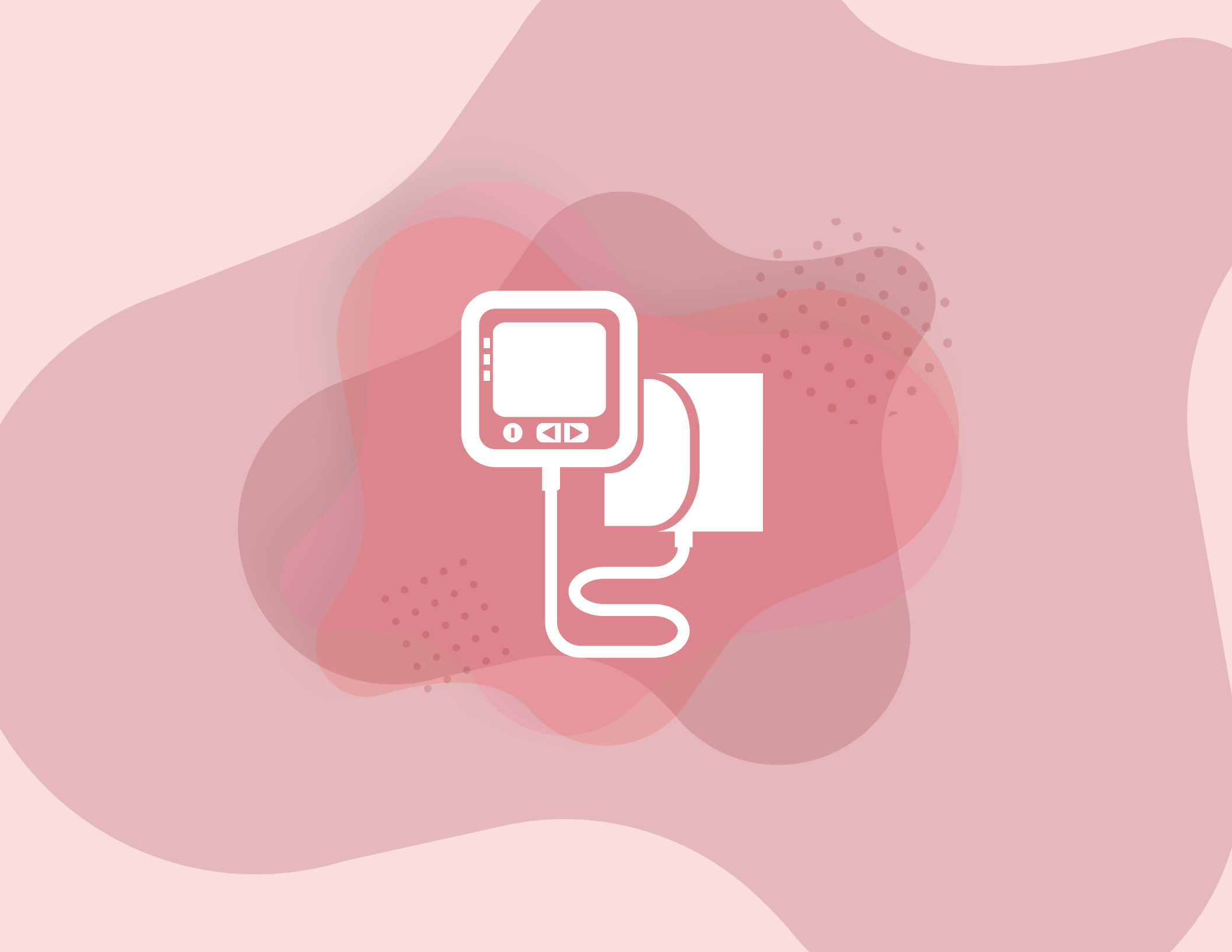
This document is the result of an extensive consultative process. Firstly, a draft document was developed taking into account the results of a survey conducted with countries on regulations of blood pressure measuring devices and countries' requests for guidance manifested during a technical meeting in Ecuador in March 2020. Secondly, the draft was submitted for review to technical experts in the area of blood pressure measurement and representatives of regulatory authorities and legal metrology departments of selected countries. After their comments were incorporated, the resulting draft was again submitted to technical experts for review. Finally, the revised document was then submitted to all the representatives designated by governments to participate in a virtual technical meeting in August 2021, and comments were received during the meeting. The final document incorporated those suggestions to the extent it was feasible. PAHO is grateful to all that participated in this process.



1. Introduction

Cardiovascular disease (CVD) is the leading cause of disease burden globally. According to the 2017 Global Burden of Disease estimates, there were 14 million new cases of CVD, 80 million people living with this condition, and nearly 1 million deaths attributed to CVD in the Americas (*1*). Hypertension is the major risk factor for CVD, causing half of the cases, and is highly prevalent, affecting one in four adults, including 40% of those over age 25 years (*2*). Fortunately, hypertension can be easily detected using correct measurement and controlled using an effective core set of medicines and/or lifestyle modifications.

To appropriately detect hypertension, accurate measurement of blood pressure (BP) is critical. Accurate BP measurement depends on the use of validated BP measuring devices (BPMDs), proper preparation of the patient, and use of a standardized protocol (*2, 3*). Therefore, guaranteeing the accuracy of BPMDs is key for improving hypertension control in populations, toward achieving Sustainable Development Goal Target 3.4: by 2030, reduce by one-third premature mortality from noncommunicable diseases through prevention and treatment.

The consequences of errors in measurement of BP are observed at the population level, impacting the estimated rates of hypertension prevalence and control, as well as at the individual level, through incorrect diagnosis and treatment (*4*). For example, overestimation of blood pressure by 10/5 mm Hg can create a marked increase in perceived hypertension prevalence (22% vs. 53%) together with a large drop in perceived hypertension control (21% vs. 4%). Hence, inaccurate measurement of BP has important consequences for policies to address hypertension, as well as for patient safety and quality of care.

1.1. Purpose

This publication seeks to provide a practical tool for governments to improve their national regulatory frameworks to improve accuracy of BPMDs, in turn contributing to the exclusive use of validated automated BPMDs in primary health care (PHC) facilities by 2025. This publication can also guide the development of procurement mechanisms that will ensure exclusive availability of BPMDs in PHC facilities. Specifically, this publication will provide a brief background on the importance of using validated BPMDs and highlight key elements of regulations related to pre-market approvals to promote accurate BPMDs.

1.2. Scope

This publication refers exclusively to regulatory and procurement matters related to the accuracy of automated and semi-automated upper-arm cuff BPMDs and does not include other quality assurance or safety elements.

2. Background

2.1. World Health Organization position on medical devices and BPMDs

The Fourth World Health Organization (WHO) Global Forum on Medical Devices identified several critical issues related to medical devices (*5*). Among those issues were recommendations for increased regulation of medical devices in low- and middle-income countries and development of technical specifications to optimize procurement of priority medical devices. To implement the recommendations, WHO suggests that a medical devices needs assessment be undertaken at the country level, and that local workshops on health technology regulatory frameworks, assessments, and management be organized for relevant stakeholders. This is consistent with the World Health Assembly Resolution 67.20 (Regulatory system strengthening for medical products), which stresses the importance of regulation of medical devices for better public health outcomes and to increase access to safe, effective, and quality medical products (*6*). It calls for establishment and strengthening of regulatory capacity in developing countries for review of medical products; and for regulating the quality, safety, and efficacy of health products and medical devices.

In 2020, WHO published the technical specifications for automated cuff BPMDs (*7*). This document recommends that measurement of BP should be performed using an automated BPMD with an upper-arm cuff. This evidence-based document aims to assist regulatory authorities to prepare policies and regulations, by describing the performance and technical aspects of automated non-invasive BPMDs, and providing guidance on regulatory requirements, standards, and other elements related to accurate BP measurement. It also identifies the barriers to accessing accurate and affordable BPMDs in low- and middle-income countries. This WHO publication is the basis for many of the recommendations included in this current publication.

An expert committee chaired by the Pan American Health Organization (PAHO) developed a situational analysis of the regulatory capacities of individual countries (*8*). Among the conclusions, it was noted that the limited or complete lack of legal and organizational frameworks for regulatory systems in a number of countries is a cause for concern because populations will not all have access to safe, quality, and effective medicines. This is also highly relevant to medical devices such as BPMDs. The PAHO Directing Council has recommended that governments prioritize the development of legal and organizational frameworks to oversee the quality, safety, and efficacy of health technologies available on the market (*9*).

WHO has recently published the WHO List of Priority Medical Devices for Cardiovascular Health and Diabetes. The list

names BPMDs as one of the six essential technologies for early detection, diagnosis, and monitoring of noncommunicable diseases and as one of the seven general priority medical devices for clinical assessment intervention (*10*). In 2019, PAHO also published a list of priority medical devices for the first level of care (*11*). These documents reaffirm the importance of measuring BP with high-quality BPMDs to ensure optimal clinical decisions can be made.

2.2. Importance of regulating pre-market approval and procurement of BPMDs

Regulation is of critical importance to ensure that safe, rigorously tested medicines and medical devices are used in health care. Increased regulation and compliance with regulations may increase the costs of medicine or device development and manufacturing for companies. These costs would subsequently be passed onto healthcare providers and patients, making health care more expensive. Thus, increased regulations could have the unintended consequence of limiting access to adequate medical equipment. On the other hand, poor regulatory control of medical devices has resulted in the use of substandard devices (*12*), which is an unacceptable compromise. Beyond usual safety requirements, regulations of BPMDs should address accuracy, verified through clinical validation studies, as a crucial component of quality assurance.

[1] The term validation is used in this publication to mean clinical validation for accuracy.

Substandard BPMDs have been recognized by professional societies and academics as a threat to improving the control of hypertension. In a recent consensus statement, the Lancet Commission on Hypertension Group called for convergence toward a mandatory global regulatory requirement that BPMDs have undergone independent validation according to the universally accepted ISO Standard (ISO 81060-2:2018) (*13*). The Group recommended that before a BPMD is used clinically, it must undergo an independent clinical validation study. The results of the validation study should be publicly available; for example, through publication in a peer-reviewed scientific journal. Equally, one of the recommendations resulting from a meeting of various hypertension societies in Sao Paulo in 2019 was to advocate for policies, including regulation, to ensure the procurement and use of validated automated BPMDs (*2*). These recommendations follow on from other calls by international hypertension societies to strengthen the regulatory environment governing BPMDs (*14*).

2.3. Regulatory environment in relation to BPMDs in countries implementing HEARTS in the Americas

A recent study examined regulatory frameworks related to BPMDs in countries implementing HEARTS in the Americas (15). The study found that most countries lacked an appropriate regulatory framework to ensure that BPMDs approved for sale and used in PHC facilities had been accuracy validated. Most countries (10 out of 13) had a medical devices law, or the foundation in law stipulating

responsibilities of the regulatory bodies, but only six had regulations that applied specifically to BPMDs, and just two used accuracy-validation as criteria for pre-market approval. Seven countries had government bodies responsible for the enforcement of medical devices regulations, and seven had mechanisms to remove devices from market that did not comply with regulations. Regarding procurement of medical devices, seven countries had a centralized (or national) system of acquisition of BPMDs in place, while acquisition was regulated in only six countries. In summary, in most countries in the Region of the Americas, BPMDs can be approved for sale without evidence of passing an internationally accepted scientific validation standard. Altogether, this indicates that BPMDs used in PHC facilities of countries implementing HEARTS in the Americas are not guaranteed to have been rigorously tested for accuracy, even though this is critically important for the optimal diagnosis and treatment of hypertension.

3. Concepts Related to Clinical Validation of BPMDs

3.1. Types of blood pressure measuring devices

Automated (electronic) upper-arm cuff BPMDs are now recommended for clinical BP measurement in place of traditional manual BPMDs (*7*). This is because automated BPMDs have some user-independent functions, which helps to eliminate some operator-errors, including digit bias and hearing problems (*16*). Automated BPMDs are either fully or semi-automatic. Fully automated BPMDs inflate at the press of a button and the cuff deflation speed is electronically regulated to ensure BP is correctly measured. On the other hand, semi-automatic BPMDs require manual cuff inflation using a bulb before automatic deflation and BP measurement. Automated BPMDs use proprietary algorithms to estimate BP. The algorithms are designed to estimate BP equivalent to manual (mercury or non-mercury) sphygmomanometry, the gold-standard reference BP measurement. Other details on all types of BPMDs, including advantages and disadvantages, can be found in the recent WHO technical specifications (*7*).

3.2. Accuracy validation of automated BPMDs

Information contained in this section is not intended to provide guidance for conducting validation studies of BPMDs, because this is generally not required at the country level. Instead, the purpose is to provide sufficient background on accuracy validation of BPMDs so that the recommendations related to regulatory frameworks can be implemented.

Validation studies are defined as the rigorous clinical testing of an automated BPMD against a gold standard to determine accuracy (*17*). Validation studies should be conducted by independent investigators (separate from the BPMD manufacturer) and must follow a scientifically accepted validation protocol. A validated BPMD is one that has met or exceeded the accuracy requirements of a protocol (*7*). Validation studies are essential for ensuring that automated BPMDs are accurate (*18–21*). Unfortunately, most automated BPMDs available for purchase have not been validated for accuracy, and one study from Australia showed that this included those sold through community pharmacies (*22*). Barriers to conducting validation studies may include cost, the technical expertise required, and lack of incentive, because the validation testing just described is not currently required by regulatory authorities as part of pre-market approval, even if some accuracy testing is required.

Many validation protocols are available from different scientific and standards organizations, including the U.S. Association for the Advancement of Medical Instrumentation (AAMI) (*23*), International Organization for Standardization (ISO) (*24*), British Hypertension Society (*25*), and European

Society of Hypertension (ESH) (*26, 27*). In 2018, the AAMI, ESH, and ISO developed a universal standard for the validation of BPMDs to resolve differences and confusion related to multiple validation protocols (*28*). This protocol is referred to as the AAMI/ESH/ISO protocol, ISO 81060-2:2018 standard, or "universal standard." It was designated that it would become the mandatory international validation standard for BPMDs one year after publication (*29, 30*). Therefore, all new validation studies of BPMDs should use ISO 81060-2:2018. As future universal validation standards supersede ISO 81060-2:2018, validation and procurement of BPMDs should be based on validation to the most recent standard, with a five-year lag to allow for BPMDs to be validated according to the most up-to-date protocol.

Briefly, the ISO 81060-2:2018 protocol must enroll at least 85 subjects with specific requirements for participant BP range, sex distribution, and arm circumference. There are also strict requirements for the number of BP measurements taken with the test BPMD and reference BPMD. Further detail is beyond the scope of this publication, and readers are referred to other documents on this topic (*29*). Within a regulatory framework, it is important to note that accuracy validation studies are different from market acceptability assessments, where safety and other non-accuracy related features of BPMDs may be tested (*31*).

3.3. Evidence on higher accuracy of validated BPMDs

Validated BPMDs have less variability and are more accurate than non-validated ones (*18–20*). Clinical testing of automated BPMDs used by patients for home BP measurement found that validated BPMDs were accurate 65% of the time compared with 15% of the time for non-validated BPMDs (*20*). Other studies report similar results or show greater dispersion of BP values (greater variability) among non-validated BPMDs compared with validated BPMDs (*18, 19*). Static (non-clinical) testing of home BPMDs found 96% of validated versus 64% of non-validated BPMDs were accurate to ± 3 mm Hg across different pressure ranges (*21*).

3.4. Registries of validated BPMDs

Reliable information on the validation status of BPMDs is available from several online registries (*32*). Each registry has specific methods and may include a panel of experts that either examines peer-reviewed scientific literature for validation studies or evaluates the findings or submission of validation studies by manufacturers and performs expert review to determine if they were acceptably performed. Automated BPMDs that have passed validation studies are then added to the registry. In some registries, non-validated BPMDs or those BPMDs that have failed validation studies are included, and there are definitive statements on the registries that these are not recommended for use. Practical guidance on how to use the registries to identify validated BPMDs was recently published and is available in a number of languages from https://bit.ly/ResourcesBP. Further details on using the registries to identify validated BPMDs are provided in Annex A (*32*).

[2] Semi-automated devices may also be included in some registries

Most registries of validated BPMDs are country-specific, which means the information may not be generalizable globally. Even the two registries that are designed for global use have limitations because of differences in model numbers for BPMDs between countries and/or that BPMDs sold in specific regions may not be listed. Moreover, it may be difficult to find BPMDs that are sold in Latin America and the Caribbean (LAC) countries on the global listings. This is a problem that needs resolution by engaging with existing registries to add validated BPMDs from LAC countries or the development of a region-specific registry for the Americas. As an initial step, a list focused on automated BPMDs available for sale in the region for clinical use could be developed.

Key points:

concepts related to clinical validation of BPMDs

- Validated, automated upper-arm BPMDs are recommended for clinical measurement of BP.
- Validation studies are used to perform rigorous accuracy testing of automated BPMDs. Only those BPMDs that has met or exceeded the accuracy requirements of a scientifically accepted validation protocol should be considered validated.
- Many non-validated BPMDs are available for procurement because validation testing is not required for pre-market clearance.
- New validation studies should be conducted according to the ISO 81060-2:2018 protocol.
- Procurement of BPMDs that have been validated according to the most recent standard is recommended, with a five-year lag to allow BPMDs to be validated according to the most up to date protocol.

4. Key Elements of Regulations and Recommendations for Pre-market Approval of BPMDs

4.1. Inclusion of accuracy validation-related components in the development or updating of regulations of BPMDs

Regulatory frameworks should require evidence that, as part of the quality assurance process, a BPMD has passed an internationally accepted standard before pre-market approval. Only those BPMDs that fulfill the requirements below should be approved:

- Devices that have been validated using the ISO 81060-2 2018 standard and 2019 cuff amendment (1:2019-09-12) or the most recent version of this international standard;
  OR
- Devices that have been validated using an older protocol than ISO 81060-2 2018. These include: a) 2013 American Association for Medical Instrumentation (AAMI) (*23*); b) 2010 European Society of Hypertension (ESH) (*26, 27*); and c) 1993 British Hypertension Society (BHS) (*25*). It is recommended that this allowance be discontinued by January 2024 and from that point forward, only devices validated with ISO 81060-2 2018 standard or the equivalent, most recent internationally accepted standard be accepted. This allows an appropriately lengthy time for manufacturers to transition toward the most recent internationally accepted standard.

As described above, BPMDs that are already in use and that have been validated using an older validation protocol (e.g., not ISO 81060-2:2018; see Table 2), should still be considered validated. But, newly procured automated BPMDs should be validated according to the ISO 81060-2:2018 standard.

Figure 1 presents a flowchart that summarizes the steps recommended for inclusion in regulatory frameworks that would provide the basis for approval of BPMDs with regard to validation status.

4.2. Approval by regulatory agencies of other countries

Approval or clearance by regulatory agencies of other countries should not constitute proof of accuracy validation, even if the country is a member of the International Medical Device Regulators Forum (IMDRF). Only when another country requires independent clinical validation of a BPMD for pre-market approval (as per this document), and other regulatory standards are met, is it reasonable for a country to rely on other country's regulatory approval or clearance. Harmonization of regulations of BPMDs that require clinical validation would not only enable but also strengthen reliance on pre-market approval by other agencies, as recommended by the Pan American Network for Drug Regulatory Harmonization (*33*).

Table 1. Main parameters considered in validation protocols

Item	Universal Standard	British Hypertension Society	European Society of Hypertension
Number of participants	85	85	33
Test cross-cuff range	Requirement for testing each cuff	No requirement for testing each cuff	No requirement for testing each cuff
Reference measurement	Any sphygmomanometer, with maximum error ± 1 mm Hg. Can also use invasive devices	Mercury sphygmomanometer	Mercury sphygmomanometer
Pass criteria or value	Mean overall difference ± 5 mm Hg, standard deviation within 8 mm Hg Mean difference among patients based on mean difference in BP and standard deviation	Proportion of BP measurements (test reference) overall and among patients with 5, 10 and 15 mm Hg	Proportion of BP measurements (test reference) overall and among patients falling within 5, 10 and 15 mm Hg

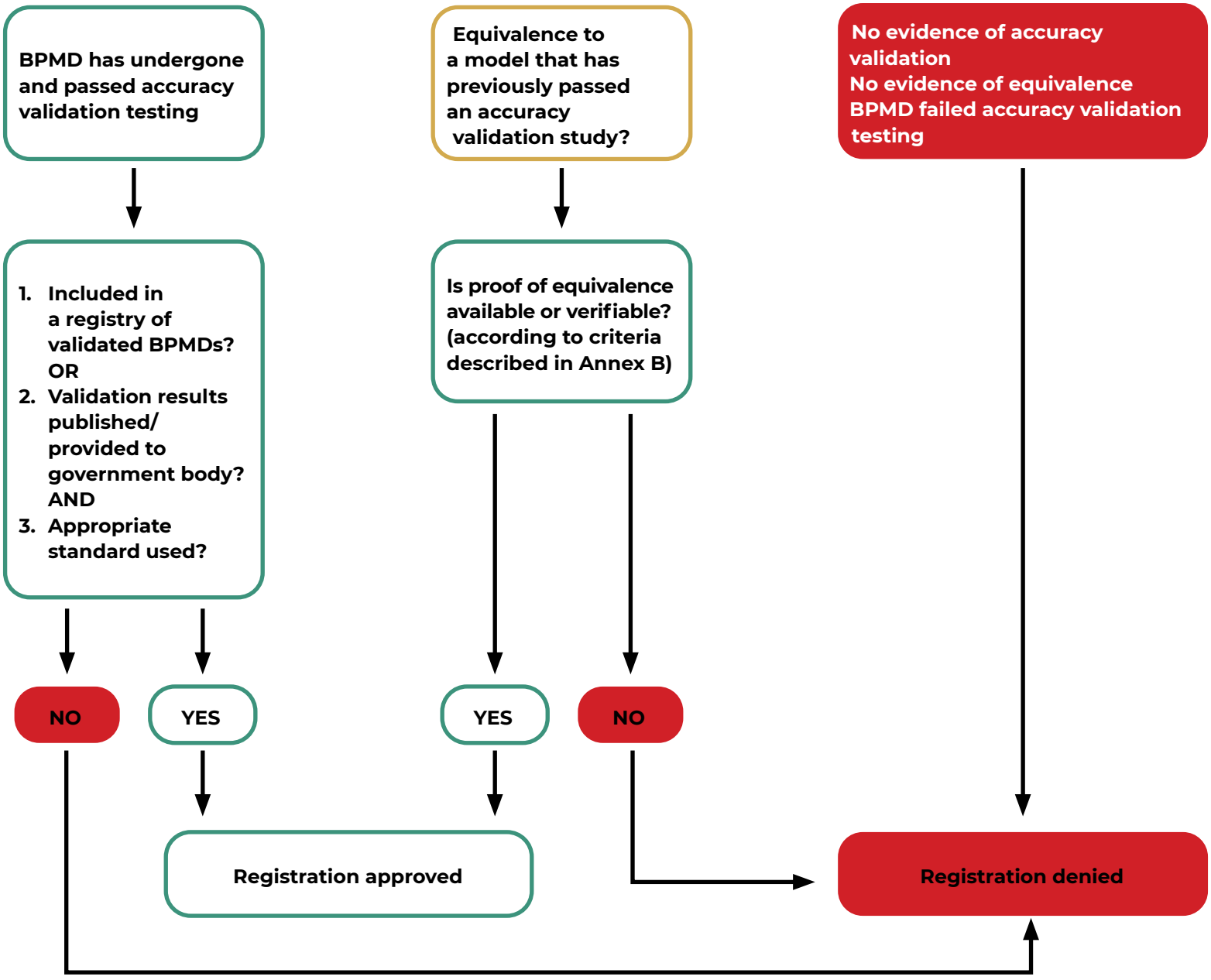
Source: World Health Organization. WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. Geneva: WHO; 2020.

Table 2: Requirements for various parameters of the universal validation standard (ISO 81060-2)

Parameter	Requirement
Efficacy measure	Threshold for accepting accuracy of BP measurement at estimated probability of tolerable error (≤ 10 mm Hg) ≥ 85%
Sample size	≥ 85 participants
Participating populations	A general population study: participants aged ≥ 12 years. Special populations (age < 3 years; age 3 to 11 years; pregnant women; arm circumference > 42 cm; atrial fibrillation; others may be added). Pregnant women: N = 45 (15 normotensive, 15 gestational hypertensions, 15 pre-eclampsia). Children aged 3–12 years. 35 participants can be included and analyzed together with 50 older participants; results reported separately.
Cuff sizes	Minimum number of participants per cuff size, depending on number of test device cuffs. Requirement for arm circumference distribution according to range of use of test device.
Reference BP	Mercury sphygmomanometer or accurate non-mercury devices.
Data collection	Sequential BP measurements on the same arm are preferred.
Pass criteria	Average difference in BP and standard deviation criteria 1 and 2 of universal method. Absolute difference in BP ≤ 5, 10, and 15 mm Hg and scatterplots presented.

Source: World Health Organization. WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff.

Figure 1. Flowchart of requirements related to accuracy validation of BPMDs for pre-market approval



4.3 Conflict of interest and accuracy validation testing

Conflict of interest in scientific work influences findings in favor of industry throughout other areas of health care. Therefore, independent accuracy validation testing of BPMDs is crucial to ensure unbiased results. Pre-market approval of BPMDs must only be granted to those that have passed accuracy validation testing which was performed independently by institutions identified as capable by regulatory entities (7) and by research groups or investigators that do not have conflict of interest with manufacturers or distributors. The regulatory agencies responsible for approval of BPMDs should not include or be influenced by experts who represent medical device manufacturers or institutions interested in the marketing of medical products (34). If approval is sought for a BPMD that is not included in one of the reputable online registries mentioned earlier, then the validation testing report that is provided to regulators should include information on:

- Funding by manufacturers;
- Conflict of interest by the researchers, research groups, or institutions that conducted the validation study;
- A copy of the peer-reviewed validation study.

4.4. Presentation of accuracy validation study results

Before pre-market approval of a BPMD is granted, the results of the accuracy validation study must have been disseminated through one or more of the following mechanisms:

- Study results published in a reputable peer-reviewed journal (i.e., not a predatory or “pay-to-publish” journal) and confirmed to have been conducted according to an approved protocol;
- BPMD registered in an accepted repository;
- Validation study findings and research protocol, including any negative findings, made available to both the government (regulatory authority and/or legal metrology body) and the public.

Note: Publication of results on a manufacturer or other website shall not be considered sufficient for proof of a BPMD passing a validation study. Moreover, validation studies submitted to pre-print servers are not sufficient because they have not been peer-reviewed.

4.5. Other considerations

4.5.1. Labeling

Labeling includes the label, instructions for use, and information related to the identification, technical description, intended purpose, and proper use and maintenance of the BPMD (35) and can be placed in the packaging, device, and inserts. The brand or trade name and the model number of the BPMD should be easily identifiable to allow differentiation from similar BPMDs.

The regulatory authority should require that labeling requirements include validation status and standard used in

a clearly visible manner in both the packaging and the BPMD itself. A badge issued by the metrology body or regulatory authority could be used, and the location and proportion of the packaging area to be covered by the badge or stamp should be one that allows for high visibility.

The labeling might include a summary of the clinical validation study to demonstrate conformance with regulatory review principles and the clinical performance of the BPMD for its intended use. This summary should include, but may not be limited to, a summary of the investigation and outcome data, and should be presented in such a way as to accurately reflect the performance of the BPMD. If not contained in the instructions for use, a reference should be included as to where such information may be accessed. Information on validation status should facilitate the gradual process of ensuring that all BPMDs sold in the country have been accuracy validated. Claims of accuracy should not be authorized for labeling of non-validated BPMDs. Other labeling principles are detailed elsewhere (*35*).

4.5.2. Promotion and advertising

The claims made by manufacturers of BPMDs in commercial communications must be controlled by regulators in order to avoid misleading advertising and unfair competition and to ensure a high level of consumer protection. Therefore, market opportunities for validated BPMDs could be increased as a function of legitimate accuracy claims and consumer preference. Provisions might go further and restrict any promotion and advertising of non-validated BPMDs, but this would be dependent on the legal system of each country.

4.5.3. Internet sales

Internet purchase of goods, including health and medical products, is growing in popularity, which means there is greater access to a wider variety of products than ever before. This may create opportunities to gain access to a greater proportion of validated BPMDs than some countries may previously have had available. On the other hand, Internet purchasing may also increase the availability of BPMDs that have not undergone appropriate validation testing. Therefore, regulations that apply to the sales of BPMDs by distributors and at bricks-and-mortar stores, such as pharmacies, should extend to the Internet, including entry into the country of products acquired through the Internet. Innovative methodologies are needed to develop strong systems for surveillance of online sales.

4.5.3. Considerations for telemedicine

In some settings, telemedicine may be of considerable value. One randomized controlled trial of patients with hypertension conducted in Honduras and Mexico found the intervention group, who received a home BPMD and telemedicine advice, had significantly greater improvements in BP than the control group (36). Automated BPMDs that are designed for home use are most appropriate

for telemedicine. Some home BPMDs can directly transfer data to mobile phone applications and onward to clinicians. This can increase the reliability of the BP measurement data; however, these types of devices may not be suitable in all settings; for example, those in which mobile Internet access is lacking. In these settings, telemedicine via phone or SMS may be most appropriate, and standard automated home BPMDs would be sufficient. The recommendations in this document for regulatory frameworks related to validation of BPMDs are relevant and can also be applied to automated home BPMDs. Only validated automated home BPMDs should be used for telemedicine.

Key points:

Key elements of regulations and recommendations for pre-market clearance of BPMDs

- Regulatory frameworks should require evidence that, as part of the quality assurance process, a BPMD has passed an internationally accepted standard before pre-market approval.
- Clearance by regulatory agencies of other countries should not constitute proof of accuracy validation unless that country requires independent clinical validation of a BPMD for pre-market approval and all other regulatory standards are met.
- Pre-market approval of BPMDs must only be granted to those that have passed accuracy validation testing which was performed independently by institutions identified as capable by regulatory entities (7) and by research groups or investigators that do not have conflict of interest with manufacturers or distributors.
- Before pre-market approval of a BPMD, the results of the accuracy validation study must have been disseminated through a reputable peer-reviewed journal and/or registered in an accepted repository and/or the validation study findings made available to the regulatory body and general public.
- Commercial communications related to the accuracy of BPMDs, including validation, must be controlled by regulatory bodies.
- Regulations should extend to internet sales of BPMDs, as well as distributors and conventional bricks-and-mortar stores like pharmacies.

5. Life cycle of BPMDs—Technical Aspects for Consideration

There are factors other than validation that contribute to the level of accuracy of BPMDs. Throughout the life cycle of a BPMD, it needs to undergo calibration and maintenance checks to ensure optimal performance is maintained. This section briefly introduces key concepts related to calibration and maintenance of BPMDs and is based on the WHO technical specifications for automated BPMDs (*7*).

5.1. Maintenance

Over time, components of BPMDs will inevitably be subject to wear and tear, and this can contribute to reduced measurement accuracy. Therefore, through the life cycle of BPMDs, maintenance is essential to ensure ongoing safety and optimal performance. Maintenance can be considered as routine and preventative. Routine maintenance includes cleaning the BPMD and replacement of components that no longer function as required. Preventative maintenance should be performed at least once a year and should be undertaken by technical staff or a clinical engineer (*7*).

An important component of the maintenance schedule is calibration. The WHO technical specifications of automated BPMDs recommend calibration every one or two years; however, this can vary; for example, according to manufacturer specifications or the frequency the BPMD is used. A BPMD that is used in a busy clinic would require more frequent calibration than one which is only used once a month. Static (non-clinical) calibration should be undertaken by technical experts. Calibration checks should also include examination of vital measurement components, such as cuffs and tubing. If these are damaged, they should be repaired or replaced. It is important to always use the cuff recommended by the manufacturer and not generic replacements. This is because validation studies are conducted with the recommended cuff type, and it is unknown how use of a non-recommended cuff could influence BP measurement accuracy. It is vital to keep formal records of all the maintenance performed for BPMDs.

5.2. Energy sources

Most high-quality clinic-grade automated BPMDs use mains power or rechargeable batteries as energy sources. BPMDs designated for home use are more likely to require multiple single-use batteries. Some BPMDs need professional maintenance when batteries require replacement. The availability of reliable mains power as well as ongoing costs and environmental impact of the energy source of BPMDs should be considered before procurement of automated BPMDs..

Key points:

Life cycle of BPMDs—technical aspects for consideration

- Routine and preventative maintenance of BPMDs, including calibration, is crucial to ensure ongoing safety and optimal performance.
- The energy requirements of automated BPMDs should be considered as part of the procurement process..

6. Process to Facilitate Implementation of Regulations

Features that may facilitate the process of development and implementation of a regulation, and ensure its effectiveness, include:

a. **Early adoption strategy:** A strategy where the government takes action instead of waiting for voluntary measures by the manufacturers and distributors (self-regulation). This strategy may motivate the industry to promote BPMDs that have been validated, and thus use it as a marketing strategy, generating a win-win situation.

b. **Gradual implementation:** In order to facilitate acceptance and provide time for a realistic substitution of BPMDs, including avoiding excessive costs, preventing challenges by manufacturers and distributors, regulations must be designed in such a manner as to allow for implementation over time. A grace period for procurement may help in that process.

c. **Timeframe:** Establishing a timeframe to debate the regulation, adopt it, and fully implement it may reduce the potential for the regulation lagging.

d. **Flexibility:** It is hard to change medical devices laws, but the regulation must be flexible enough as to allow for modifications and adjustments as needed. New standards for accuracy validation and other scientific evidence, when available, must be incorporated swiftly to increase its effectiveness. A system to recognize standards faster than modifying regulations should be adopted in order to include a rapid revision of international standards.

e. **Sustainability:** To ensure sustainability, regulation must be a component of a national strategy on cardiovascular health and be linked to laws on medical devices.

f. **Advocacy:** The regulation can be promoted as a tool for protecting patient safety and improving quality of health care. Support by key stakeholders, such as professional societies and academia, can greatly facilitate its implementation if they see it as an improvement in health care practices instead of as a constraint to continuing the established medical practices and professional autonomy.

g. **Monitoring and evaluation:** In order to measure the impact of the implementation of a regulatory framework, and correct its course if needed, implementation should be monitored and evaluated. This process must be linked to procurement of BPMDs for use in PHC facilities.

h. **Enforcement:** Mechanisms, roles of responsible government bodies, and budget for monitoring and enforcement of compliance, including use of sanctions, need to be defined. Coordination with other government sectors (e.g., trade, customs) must be set in place, especially since most BPMDs are imported.

7. Procurement

Guidance on procurement was recently published in the WHO technical specifications (7). In addition to the WHO guidance, procurement officials should verify that BPMDs have passed appropriate accuracy validation testing. The setting that the BPMD will be used in is also an important consideration. For example, will the BPMD be used in a busy PHC facility, hospital, or even telemedicine. Automated BPMDs designed for clinical use will be most suitable in PHC and hospital settings, whereas automated home BPMDs would be suited to telemedicine. Other considerations include whether multiple cuff sizes are available for the BPMD, energy source, lifespan, and maintenance schedule required.

Importantly, PAHO has adapted the guidance above for use by the PAHO Strategic Fund presented in Annex C (*PAHO Technical Specifications for the Procurement of Automated BPMDs with Cuff (First Level of Care)*) and which can be adapted to be used by governments for the procurement of devices for use in PHC facilities.

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Annex A: How to Check if a Device is Validated for Accuracy

1. Verify if BPMDs have passed accuracy validation by searching online registries.

If a BPMD has previously been appropriately clinically validated for precision and accuracy[1] then it does not need further testing. If a device has not been validated, then it should not be approved for sale until an appropriate validation test has been performed (see Figure 1).

The easiest and most reliable way to verify if an automated BPMD has been validated is to search for the device on a reputable registry. There is not currently a dedicated listing for Latin American and Caribbean countries, so the most useful sources of accuracy validation information are the general registries STRIDE BP (https://www.stridebp.org/) and Medaval (https://medaval.ie/). There are country-specific listings for Canada, Germany, Japan, United Kingdom and Ireland, and the United States of America.

Practical guidance on how to use these listings has been recently published.[2] In summary, the first step is to identify the manufacturer name and model number. These two details should be available on the packaging of the BPMD, from the business selling the BPMD, or directly through the manufacturer. If the manufacturer name and/or model number are unavailable, it is unlikely the BPMD will be validated. Once these details have been found, follow the guidance available from the practical infographics available from https://www.menzies.utas.edu.au/education/blood-pressure-resources (available in a number of languages). If the device is not found on one registry, it is worthwhile searching on a different registry for confirmation.

2. Verify equivalence to a previously validated device.

New automated BPMDs that are equivalent to those that have been previously validated do not need to undergo validation testing. Equivalence is defined as a new BPMD, when compared to a previously validated BPMD, having exactly the same critical measurement apparatus and algorithms. Manufacturers and distributors should provide data relating to devices for which they are claiming equivalence, in order to justify their claims of equivalence. See Annex B for specific equivalence criteria.

[1] In addition to passing other tests related to accuracy such as those related to the effects of static pressure, variation in temperature, and ambient humidity.

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Annex B: Equivalence of Devices

The criteria below were developed by the British and Irish Hypertension Society (BIHS).[1]

Derivative Devices

Devices that are listed on the BIHS validated BPMD listing as being derivative of other models have been approved on the basis of information supplied to the BIHS by the manufacturer. Other organizations, such as Hypertension Canada and the American Medical Association Validated Device Listing, also require a signed, notarized affidavit attesting that there are no differences between the BPMD that is claimed to be an equivalent and previously validated BPMD.

In declaring equivalence, manufacturers should state if there are any changes in any of the following items:

1. Cuff characteristics.
2. Transducer, amplifier, and any signal processing carried out prior to digitization.
3. Cuff inflation.
4. Cuff deflation.
5. Digitization (sampling frequency and number of bits), and digital signal processing.
6. Interpolation. The oscillometric pulses occur only every heartbeat and it is not uncommon for designers to interpolate between pulses to increase the accuracy and reduce the measurement variability while increasing the cuff deflation rate (or inflation rate for those devices that measure during cuff inflation) to reduce the measurement time.
7. Algorithm.

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Annex C: PAHO Technical Specifications for the Procurement of Automated BPMDs with Cuff (First Level of Care)

Automated Non-Invasive Blood Pressure Measuring Devices with Cuff	
Description	An electrically powered device designed to non-invasively measure BP, with a self-contained software program to regulate automatic arm-cuff inflation and measurement cycles. It typically displays current heart rate and mean arterial pressure in addition to systolic and diastolic BP; it may have memory to store values and may sound an alarm if BP exceeds pre-set limits.
General technical requirements	**Measurement ranges** Systolic (mm Hg): • 60–250, 290 preferred for adults • 30–160 for children Diastolic (mm Hg): • 30–180 adults • 10–150 paediatric Mean arterial pressure (mm Hg) • 30–250 adults • 30–160 children Pulse (beats per min): • 30–150 adult and children Inflation pressure (mm Hg) • 150–260 adults **Cuff sizes** • Paediatric • Small, adult • Adult • Large, adult • Extra large, adult **Cuff characteristics** • Latex free • Cuff arm fixing method must allow ease of use • Ease of cleaning and low dirt attraction • Cuff material must be removable and washable • Connection tube to be detachable from other parts, allowing periodic cutting of decayed ends • Connection tube length ≥ 30 cm

General technical requirements	**Cuff markings** • Markings that indicate proper placement and helps the user to determine if arm size appropriate **Equipment alarms required:** • Cuff leak, cuff disconnect • Failure to take successful reading • Low-battery notice **Equipment alarms, preferable:** • Hose leak • Inflation error • Deflation error Automatic 0 required Display may include tabular and/or graphic trends (user preference) For adults: the sphygmomanometer must automatically deflate if the cuff pressure reaches 300 mm Hg
Displayed parameters	**The unit must display the following numerical values:** • Systolic pressure • Diastolic pressure • Pulse rate • Other parameters, such as mean arterial pressure, are optional. The unit must alert the operator, either visually or audibly, when the blood pressure measurement has finished
User adjustable settings	• Inflation pressure must be adjustable or automatically set
Physical characteristics	• Dimensions (l x w x h): 15 x 10 x 10 cm, approximately • Weight: 300 g, approximately
Accessories/Consumables	• Blood pressure cuff child • Blood pressure cuff small adulto • Blood pressure cuff adult • Blood pressure cuff thigh Quantities and types must be confirmed with the user
Labeling and user manuals	• All supporting documentation, operation, service and user manuals must be presented in the official language of the country in which the equipment will be used
Power supply	• Operates from AC power electric line: 100-240 V ~, 60 Hz. (if aplicabble) • DC: Rechargeable battery (3.6 V or approximately 300 measurements) or single-use battery

Regulatory compliance/ Certification	• Free sales certificate (FSC) or certificate for exportation of medical device provided by the competent authority in the manufacturing country • Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE])
Standards for the manufacturer	• Certified quality management system for medical devices (e.g. ISO 13485) • Application of risk management to medical devices (e.g. ISO 14971)
Accuracy validation standards	• AAMI/ESH/ISO 81060-2 Universal Standard for the Validation of Blood Pressure Measuring Devices Noninvasive Sphygmomanometers – Part 2: Clinical investigation of automated measurement type (only standard to be accepted after 2024, unless replaced by an equivalente universal standard. • Until 2024 the following standards will be accepted: 2013 American Association for Medical Instrumentation (AAMI);2010 European Hypertension Society (ESH), and 1993 British Hypertension Society (BHS)
Other standards for the product performance	Compliance to the following international standards or to regional or national equivalent, (including the technical tests for safety and performance from accredited laboratories or third parties). Compliance to the current version of the standards is recommended: • ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice • IEC 80601-2-30 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers • ISO 16142-1 Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards • ISO/IEEE 11073-10407 Part 10407: Device specialization – Blood pressure monitor (if applicable) **Regional/local standards** • ANSI/AAMI SP10:2002 and A1:2003 and A2:2006 (Manual, electronic or automated sphygmomanometers) blood pressure measuring system.
Warranty	• Minimum 2 years • Availability of accessories, consumables and spare parts for at least 2 years

PAHO

Pan American Health Organization

World Health Organization

REGIONAL OFFICE FOR THE Americas