

How to check whether a blood pressure monitor has been properly validated for accuracy

Dean S. Picone PhD¹  | Raj Padwal MD, MSc²  | Norm R. C. Campbell MD³  |
 Pierre Boutouyrie MD, PhD⁴ | Tammy M. Brady MD, PhD⁵  | Michael Hecht Olsen MD^{6,7} |
 Christian Delles MD⁸ | Cintia Lombardi ScD⁹ | Azra Mahmud MD, PhD^{10,11,12}  |
 Yaxing Meng MClInMed¹ | Gontse G. Mokwatsi PhD^{13,14} | Pedro Ordunez MD, PhD⁹  |
 Hoang T. Phan MD, PhD^{1,15} | Giacomo Pucci MD, PhD¹⁶ | Aletta E. Schutte PhD^{13,14,17} |
 Ki-Chul Sung MD, PhD¹⁸ | Xin-Hua Zhang MD, PhD¹⁹ | James E. Sharman PhD¹ |
 for the Accuracy in Measurement of Blood Pressure (AIM-BP) Collaborative

¹Menzies Institute for Medical Research, University of Tasmania, Hobart, Australia

²Department of Medicine, University of Alberta, Edmonton, AB, Canada

³Department of Medicine, Physiology and Pharmacology and Community Health Sciences, O'Brien Institute for Public Health and Libin Cardiovascular Institute of Alberta, University of Calgary, Calgary, AB, Canada

⁴Department of Pharmacology, European Georges Pompidou Hospital, Assistance Publique Hôpitaux de Paris, Inserm UMR 970, Université de Paris, Paris, France

⁵Division of Pediatric Nephrology, Johns Hopkins University School of Medicine, Baltimore, MD, USA

⁶Department of Internal Medicine, Holbaek Hospital, Holbaek, Denmark

⁷Centre for Individualized Medicine in Arterial Diseases, Department of Regional Health Research, University of Southern Denmark, Odense, Denmark

⁸Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, UK

⁹Department of Non-Communicable Diseases and Mental Health, Pan American Health Organization, Washington, DC, USA

¹⁰King Abdul Aziz Cardiac Center, King Abdul Aziz Medical City, Riyadh, Saudi Arabia

¹¹National Guard Health Affairs, Riyadh, Saudi Arabia

¹²King Abdullah International Medical Research Center & King Saud bin Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia

¹³Hypertension in Africa Research Team (HART), North-West University, Potchefstroom, South Africa

¹⁴Medical Research Council Unit for Hypertension and Cardiovascular Disease, North-West University, Potchefstroom, South Africa

¹⁵Pham Ngoc, Thach University of Medicine, Ho Chi Minh City, Vietnam

¹⁶Unit of Internal Medicine at Terni University Hospital, Department of Medicine, University of Perugia, Perugia, Italy

¹⁷School of Public Health and Community Medicine, University of New South Wales, The George Institute for Global Health, Sydney, Australia

¹⁸Division of Cardiology, Department of Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, Korea

¹⁹World Hypertension League, Beijing, China

Correspondence

James E. Sharman, Menzies Institute for Medical Research, University of Tasmania, Private Bag 23, Hobart, 7000, Australia.
 Email: james.sharman@utas.edu.au

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Abstract

Hypertension guidelines recommend that blood pressure (BP) should be measured using a monitor that has passed validation testing for accuracy. BP monitors that have not undergone rigorous validation testing can still be cleared by regulatory authorities for marketing and sale. This is the situation for most BP monitors worldwide. Thus, consumers (patients, health professionals, procurement officers, and general public) may unwittingly purchase BP monitors that are non-validated and more likely to be

inaccurate. Without prior knowledge of these issues, it is extremely difficult for consumers to distinguish validated from non-validated BP monitors. For the above reasons, the aim of this paper is to provide consumers guidance on how to check **whether** a BP monitor has been properly validated for accuracy. The process involves making an online search of listings of BP monitors that have been assessed for validation status. Only those monitors that have been properly validated are recommended for BP measurement. There are numerous different online listings of BP monitors, several are country-specific and two are general (international) listings. Because monitors can be marketed using alternative model names in different countries, if a monitor is not found on one listing, it may be worthwhile cross-checking with a different listing. This information is widely relevant to anyone seeking to purchase a home, clinic, or ambulatory BP monitor, including individual consumers for use personally or policy makers and those procuring monitors for use in healthcare systems, and retailers looking to stock only validated BP monitors.

1 | INTRODUCTION

Raised blood pressure (BP) is the leading risk factor for morbidity and mortality and is responsible for >10 million deaths globally each year.¹ Accurate identification of hypertension and initiation of BP-lowering strategies (eg, lifestyle modification, antihypertensive medication) considerably lowers the risk of heart disease, stroke, and other adverse clinical events.² Thus, accurate measurement of BP has been described as one of the most important tests in clinical medicine.³

Worldwide, hypertension guidelines state that it is essential for automated BP monitors to be validated for accuracy.⁴⁻⁷ Validation testing of BP monitors should be conducted by investigators independent of the manufacturer with strict adherence to a standardized international validation protocol,^{4,5,8-10} and the results should be published by peer-review journals. The validation protocol involves comparisons with a reference standard BP measurement (mercury manometers and auscultatory method) in a population of people of different sex, body size, and BP level. A monitor is regarded as validated for accuracy if the BP measurements meet or surpass the stipulated accuracy requirements of the designated protocol.

Since regulatory authorities mainly focus on ensuring that BP monitors are safe, they are often cleared for sale without undergoing rigorous, independent validation testing for accuracy. Consequently, of the BP monitors available on the market, only between 6% and 15% are validated.¹¹⁻¹³ This is quite problematic and a major cause for concern because non-validated BP monitors are more likely to be inaccurate compared with validated BP monitors,^{14,15} and if these non-validated BP monitors are used for clinical decisions there is a higher likelihood for incorrect medical management.

These problems are relevant to all consumers (ie, patients, health professionals, procurement officers, and general public)⁴ as they are

faced with many hundreds of choices when it comes to purchasing a BP monitor, particularly online. Policy makers also need to consider actions that can be taken to address these problems. The situation may be even worse in low-middle income countries where the regulatory environment is often weaker.¹⁶ Critically, there is a lack of reliable information on validation status at the point of purchase (in-store or online), and thus, buyers may unwittingly purchase non-validated monitors that are not recommended for use. There is also little guidance for consumers on how to check **whether** a monitor has been validated for accuracy.¹⁷ Thus, this paper aims to provide a guide for consumers on how to check **whether** a BP monitor has been properly tested for accuracy (validation status). The paper is also relevant to policy makers seeking to ensure clinical use of validated BP devices and retailers seeking to stock only validated BP devices. This work is aligned with ongoing efforts to advocate for and improve knowledge on the importance of accurate BP monitoring, and has been written for the Accuracy in Measurement of BP (AIM-BP) collaborative.¹⁸ This effort also coincides with the recent publication of the Lancet Commission on Hypertension Group position statement on improvement of accuracy standards for BP devices¹⁹ and the World Health Organisation on technical specifications for automated non-invasive cuff BP devices.²⁰

2 | HOW TO CHECK THAT A BLOOD PRESSURE MONITOR HAS BEEN PROPERLY VALIDATED FOR ACCURACY

The easiest way to check **whether** a BP monitor is validated for accuracy is to search an online registry (Figure 1). However, users need to know the characteristics of such registries and how to choose the most appropriate one. Indeed, there are several registries managed

How to check that a **blood pressure monitor** has been properly tested for accuracy



Why do I need to use an accurate monitor?
Inaccurate blood pressure measurement could lead to incorrect diagnosis and inappropriate treatment.
The chance to reduce the risk of heart attack or stroke could also be missed.



Many inaccurate monitors exist
Over 3000 blood pressure monitors are available but less than 15% of these have been properly tested for accuracy.



ONLY USE MONITORS THAT ARE RECOMMENDED BY THE (FREE) REGISTRIES BELOW

Choose a registry from your country or a general registry

Country-specific registries

Click the relevant country and follow their instructions.

- [Britain](#)
- [Ireland](#)
- [Canada](#)
- [Germany](#)
- [Japan](#)
- [United States of America](#)

General registries

[STRIDE BP](#) is a registry of validated blood pressure monitors. Follow the detailed instructions on how to search this registry on page 2.

[Medaval](#) lists both validated and non-validated blood pressure monitors. Follow the detailed instructions on how to search this registry on page 3.








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FIGURE 1 How to check **whether** a blood pressure (BP) device has been validated for accuracy. An overview of regional and general registries of validated BP devices is included. This figure with live links can be downloaded at <https://www.menzies.utas.edu.au/documents/pdfs/Blood-pressure-devices.pdf> figure

by reputable country-specific and international organizations that track the validation status of BP monitors (Table 1 and Figure 1). Each country-specific registry is focused on BP monitors available in that particular country or region, whereas the general (international) registries aim to provide more global coverage. There are differences in the processes for determining validation status between the registries. For example, the American Medical Association registry does not list monitors validated with the European Society of Hypertension protocols due to their smaller sample size compared to other protocols (eg, $n = 33$ vs $n = 85$).²¹ The way the registries define

equivalence to previously validated monitors also varies. Some registries (eg, British or Canadian) accept a monitor as valid if it is a derivative of a previously validated one and the vital BP measurement componentry remains identical. Other registries (eg, Medaval) require that derivative devices are in accordance with European Union Medical Device Regulation 2017/745. Taken altogether, these differences explain potential variation in recommendations of validated BP monitors between each registry.

There are two general (international) registries, STRIDE BP and Medaval, that can be used to check **whether** a BP monitor is

TABLE 1 Online registries of blood pressure monitors that have been tested for accuracy according to best practice scientific protocols

| Society, organization or company | Weblink |
|--|---|
| Regional registries | |
| American Medical Association | https://www.validatedbp.org/ |
| British and Irish Hypertension Society | https://bihsoc.org/bp-monitors/ |
| Hypertension Canada | https://hypertension.ca/bpdevices |
| German Hypertension Society ^a | https://www.hochdruckliga.de/messgeraete-mit-pruefsiegel.html |
| Japanese Society of Hypertension | http://www.jpnsh.jp/com_ac_wg1.html |
| General registries | |
| STRIDE BP (European based) | https://stridebp.org/ |
| Medaval ^b | https://medaval.ie/blood-pressure-monitors/ |

^aOnly lists monitors that pass the German Hypertension League Quality Seal Protocol.^{24,25}

^bMedaval is not affiliated with a specific scientific organization. As well as listing validated monitors, the Medaval registry details those monitors available for purchase that are not validated, with a warning that these monitors are not recommended.

validated. To search either registry, the manufacturer name and model of the monitor are needed. This information should be marked on the box or casing of the BP monitor. If a BP monitor is missing this fundamental information, it is unlikely to have been validated.¹³ Locating manufacturer name and model information for BP monitors may be more difficult when shopping online compared with in-store.

The STRIDE-BP registry (<https://www.stridebp.org/bp-monitors>) can be searched by typing the precise model of the BP monitor into the search box (Figure 2). The manufacturer name can also be entered, and the results can be scanned to check **whether** the BP monitor of interest is listed. If the monitor is listed, then it has been validated and can be used for BP measurement. STRIDE BP also uses a series of rules to label “Preferred Devices” with a ribbon icon. Preferred devices are those that are upper-arm cuff monitors, have had a validation study published in the last 10 years and, for home BP monitors, have the capacity for automatic data storage or data transfer to smartphones/computers.²¹ However, any properly validated monitor will be listed on STRIDE BP as validated. If there are “No Results Found” from the search, then it is possible that the monitor is not validated and thus not recommended for use. Occasionally, manufacturers will market a monitor under different model names or numbers in different regions or countries. If a monitor is not found on the STRIDE BP site, it may be worthwhile to cross-check the monitor for sale in one particular region on alternative sites to determine **whether** this is the case.

The Medaval registry (<https://medaval.ie/blood-pressure-monitors/>) is a listing that is not affiliated with a specific scientific organization. Nevertheless, Medaval currently has the largest repository of information on both validated and non-validated monitors and provides recommendations as to whether the BP monitor should be used. The registry also references to BP monitor assessments made by other listings, where relevant. Due to sensitivities in the Medaval search engine, the easiest way to access the Medaval registry is to use a general search engine (eg, Google) and type in the manufacturer name and model of the monitor, as well as the term “medaval” (Figure 3). In the Internet search results click the link to the Medaval registry for the BP monitor of interest. Find the “Assessment” section, and if the monitor is recommended, then it is validated. Medaval also assigns a five star rating scale to monitors (<https://medaval.ie/medaval-star-rating-criteria/>), but importantly, any properly validated monitor will be recommended, irrespective of the number of stars. If the monitor is “Not recommended” in the assessment section, the BP monitor is not validated and therefore is not recommended for use.

There are some caveats to the above registries which mean that a monitor may be searched and incorrectly deemed non-validated. First, on registries where users need to type the monitor name or model number, input errors may lead to the incorrect assumption that a monitor is non-validated. Second, new monitors may be validated but have not been added to a registry. Third, as mentioned above, some manufacturers use different names or monitor model numbers in different countries. This could mean people that search for a monitor on a registry find that it appears non-validated when in fact an identical monitor with a different monitor model number has been validated. Last, a monitor may have been validated following a proper protocol, but the data remain unpublished, despite being recognized by specific expert groups.

3 | PRACTICAL GUIDE FOR CONSUMERS ON HOW TO CHECK WHETHER A BP MONITOR HAS BEEN PROPERLY TESTED FOR ACCURACY (VALIDATION STATUS)

A practical document has been developed to guide consumers (patients, health professionals, procurement officers, and general public), policy makers and retailers on how to search online registries of validated BP monitors (Figures 1-3). The document has also been translated to several languages other than English to facilitate global dissemination. Links to the translated document are available in Table 2.

4 | CONSIDERATIONS BEYOND MONITOR VALIDATION FOR PROPER BLOOD PRESSURE MEASUREMENT

Accuracy of BP measurement is also contingent on other factors beyond validation of the BP monitor.³ These include a properly



How to check that a **blood pressure monitor** has been **properly tested for accuracy** using the **STRIDE BP registry**

STEP BY STEP GUIDE

01 TYPE www.stridebp.org/bp-monitors into your web browser.

02 SEARCH by typing the precise model of the monitor into the search box.

Alternatively, enter the monitor manufacturer name and scroll through the results until you find the model of the monitor listed.

If the monitor is listed under the 'Device Description', then **it has been validated.**

Blood pressure monitors

Search: ABC-123

| Device Description | Measurement site |
|--------------------|------------------|
| BrandX ABC-123 | Upper arm |

If **"No results found"** under 'Device Description' then the monitor **is not recommended to be used.**

Don't be tempted by brands or prices or reviews

Tip: The search function is **very sensitive.** Any minor errors in the manufacturer name or model of the monitor will mean the monitor is **not found, even if it is validated.**



Tip: If the manufacturer name or monitor model cannot be found, **the monitor is unlikely to be validated.**






FIGURE 2 How to check **whether** a blood pressure (BP) device has been validated for accuracy using the STRIDE BP registry. This figure with live links can be downloaded at <https://www.menzies.utas.edu.au/documents/pdfs/Blood-pressure-devices.pdf> figure

prepared patient in a quiet, comfortable location, using a correctly sized BP cuff and following a proper BP measurement protocol. Without following these steps, there is a greater likelihood of inaccurate BP measurement.^{7,23,24} There are many practical resources available on self-BP monitoring available from hypertension societies and public health organizations. A free online certification course on measuring BP has also recently been developed.²⁵

In conclusion, hypertension remains a leading risk factor for death and disability, and accurate measurement of BP is crucial for optimal management. Most BP monitors are not validated for

accuracy, which makes them unsuitable for clinical or home use. The current paper provides a guide to using online validated BP monitor registries and is relevant to anyone seeking to buy a BP monitor.

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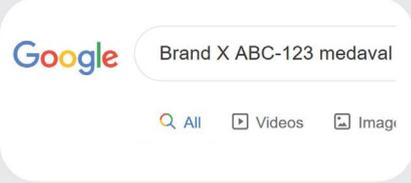
How to check that a **blood pressure monitor** has been **properly tested for accuracy** using the **Medaval registry**

STEP BY STEP GUIDE

01 SEARCH

Google* the make and model of the blood pressure monitor, together with the word "Medaval".

*or any other search engine



02 LOOK

Look for and click on the link with the Medaval evaluation of the monitor. Ignore any other advertising material that may come up in the first few hits.

medaval.ie > device > abc-123

Brand X ABC-123 Blood Pressure Monitor - Medaval

The **Brand X ABC-123** is a clinically validated taken from the upper arm and it is intended fo

03 CHECK

Scroll down to the accuracy assessment report. Look for the Medaval assessment and Recommendation.

Assessment

The technology used in the Brand X ABC-123, to measure blood validation study, in a general population, according to a recognised st published in a peer-reviewed publication.

| Accuracy Assessment | Recommendation |
|---------------------|--|
| Medaval | ★ ★ Recommendation <small>Re re</small> |

Don't be tempted by brands or prices or reviews

Tip: If the manufacturer name or monitor model cannot be found, **the monitor is unlikely to be validated**



Tip: Different star ratings are used by Medaval, but **any properly validated monitor will be recommended**, irrespective of the number of stars.






CRICOS Provider Code 00358B

FIGURE 3 How to check **whether** a blood pressure (BP) device has been validated for accuracy using the Medaval registry. This figure with live links can be downloaded at <https://www.menzies.utas.edu.au/documents/pdfs/Blood-pressure-devices.pdf> figure

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CONFLICT OF INTEREST

Aletta E Schutte: Her University has received equipment and funding from manufacturers of BP devices including IEM and Omron. Azra Mahmud has received equipment and research funding from manufacturers of BP devices including AtCor Medical and IEM but has no personal commercial interests in these or any other BP companies. Raj Padwal: Canadian representative to the ISO Sphygmomanometer committee and sits on the AAMI Sphygmomanometer committee.

TABLE 2 Practical guides on how to check **whether** a BP monitor has been properly tested for accuracy in different languages

| Language | Weblink |
|-----------------------|---|
| Afrikaans | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Afrikaans_final.pdf |
| Arabic | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Arabic_final.pdf |
| Chinese (simplified) | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Chinese_simplified.pdf |
| Chinese (traditional) | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Chinese_traditional.pdf |
| Danish | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Danish_final.pdf |
| Dutch | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Dutch_final.pdf |
| English | https://www.menzies.utas.edu.au/documents/pdfs/Blood-pressure-devices.pdf |
| French | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/French.pdf |
| German | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/German_final.pdf |
| Italian | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Italian_final.pdf |
| Korean | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Korean_final.pdf |
| Portuguese | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Portugese_final.pdf |
| Setswana | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Setswana_final.pdf |
| Spanish | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Spanish_final.pdf |
| Vietnamese | https://www.menzies.utas.edu.au/documents/pdfs/blood-pressure-devices/Vietnamese_final.pdf |

Co-Founder and CEO of a digital health company (mmHg Inc), based at the University of Alberta. James E Sharman: His university has received equipment and research funding from manufacturers of BP devices including AtCor Medical, IEM and Pulsecor (Uscom). He has no personal commercial interests related to BP companies. Cintia Lombardi and Pedro Ordunez are staff members of the Pan American Health Organization. The authors alone are responsible for the views expressed in this publication, and they do not necessarily represent the decisions or policies of the Pan American Health Organization. Tammy Brady: is Co-Chair of the Association for the Advancement of Medical Instrumentation (AAMI) Sphygmomanometer Committee and is a nominated expert on the IEC (International Electrotechnical Commission)/ISO (International Organization for Standardization) joint working group on non-invasive blood pressure monitoring devices. The remaining authors have no disclosures.

AUTHOR CONTRIBUTIONS

Each of the listed authors (DSP, RP, NRCC, PB, TMB, MHO, CD, CL, AM, YM, GGM, PO, HTP, GP, AES, KS, XZ, and JES) meet the criteria for "Authorship" in accordance with the ICMJE recommendations as

outlined below: (1) Substantial contributions to the conception or design of the work; (2) Drafting the work or revising it critically for important intellectual content; (3) Final approval of the version to be published; (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

ORCID

Dean S. Picone  <https://orcid.org/0000-0002-4760-1634>

Raj Padwal  <https://orcid.org/0000-0003-3541-2817>

Norm R. C. Campbell  <https://orcid.org/0000-0002-1093-4742>

Tammy M. Brady  <https://orcid.org/0000-0002-1315-6747>

Azra Mahmud  <https://orcid.org/0000-0002-1927-8139>

Pedro Ordunez  <https://orcid.org/0000-0002-9871-6845>

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