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

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Summary/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, 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 if 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 to check if this is the case. This information is widely relevant to anyone seeking to purchase a home, clinic or ambulatory BP monitor, including individual consumers for use personally or those procuring monitors for use in health care systems, and retailers looking to stock only validated BP monitors.

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 (e.g. 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, 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, BP monitors 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. 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, 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 (i.e. patients, health professionals, procurement officers, general public) as they are faced with many hundreds of choices when it comes to purchasing a BP monitor, particularly online. The situation may be even worse in low-middle income countries where the regulatory environment is often poor. 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 if a monitor has been validated for accuracy. Thus, this paper aims to provide a guide for consumers on how to check if a BP monitor has been properly tested for accuracy (validation status). 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. This effort also coincides with the recent publication of the Lancet Commission on Hypertension Group position statement on improvement of accuracy standards for BP devices and the World Health Organisation on technical specifications for automated non-invasive cuff BP devices.

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

The easiest way to check if 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 by
reputable country-specific and international organisations 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 (e.g.
n=33 versus n=85). The way the registries define equivalence to previously validated
monitors also varies. Some registries (e.g. 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 (e.g. 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 if a BP monitor is 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. 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 if 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. 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 device under different model names or numbers in
different regions or countries. If a device is not found on the STRIDE BP site, it may be
worthwhile to cross-check the device for sale in one particular region on alternative sites to
determine if this is the case.

The Medaval registry (https://medaval.ie/blood-pressure-monitors/) is a listing that is not
affiliated with a specific scientific organisation. 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 (e.g. 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 recognised by
specific expert groups.

**Practical guide for consumers on how to check if 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, general public) on how to search online registries of validated BP
monitors (Figures 1-3). The document has also been translated to several languages other
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. These include a properly 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. There are many practical resources available on self-BP monitoring available from hypertension societies and public health organisations.

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.

References


**Figure legends**

**Figure 1.** How to check if 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 2.** How to check if 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 3.** How to check if 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

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Raj Padwal: Canadian representative to the ISO Sphygmomanometer committee and sits on the AAMI Sphygmomanometer committee. Co-Founder and CEO of a digital health company (mmHg Inc.), based at the University of Alberta.

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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.

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

<table>
<thead>
<tr>
<th>Society, organisation or company</th>
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<tr>
<td><strong>Regional registries</strong></td>
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<tr>
<td>American Medical Association</td>
<td><a href="https://www.validatebp.org/">https://www.validatebp.org/</a></td>
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<tr>
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<tr>
<td>German Hypertension Society*</td>
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<tr>
<td><strong>General registries</strong></td>
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<td>STRIDE BP (European based)</td>
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<tr>
<td>Medaval**</td>
<td><a href="https://medaval.ie/blood-pressure-monitors/">https://medaval.ie/blood-pressure-monitors/</a></td>
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*Only lists monitors that pass the German Hypertension League Quality Seal Protocol.24,25

**Medaval is not affiliated with a specific scientific organisation. 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.
Table 2. Practical guides on how to check if a BP monitor has been properly tested for accuracy in different languages.

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<th>Language</th>
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How to check that a blood pressure monitor has been properly tested for accuracy

Why do I need to use an accurate monitor?

Many inaccurate monitors exist. Over 200 blood pressure monitors are available but less than 10% of monitors have been properly tested.

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 to follow their instructions:

- Italy
- Ireland
- Canada
- Germany
- Japan
- United States of America

General registries

STB.BF: a registry of validated blood pressure monitors. Follow the detailed instructions on how to access this registry on page 4.

MobileLink: lists updated and new validated blood pressure monitors. Please are required for other or versions of this registry on page 6.
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 into your web browser.

02 SEARCH Entering the ID number of the monitor model will provide the results.

Alternatively, enter the monitor's model name and your search will be performed automatically.

If the model is not found, the model is not recommended to be used.

Don't be tempted by brands or prices or reviews

Tips:

The search function is very sensitive. If no match found, the monitor is not validated even if the model is not found. If no match found, the monitor is unlikely to be validated.
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.”

02 LOOK
Look for and click on the link with the Medaval evaluation of the device, ensuring any other advertising around the link may come up in the first few pages.

03 CHECK
Scroll down to the Medaval assessment report. Look for the Medaval recommendations.

Don’t be tempted by brands or prices or reviews.

Tips:
- If the make and model of a monitor cannot be found, the monitor is unlikely to be validated.
- Different monitoring systems may be used, and any properly validated monitor will be recommended irrespective of the number of stars.