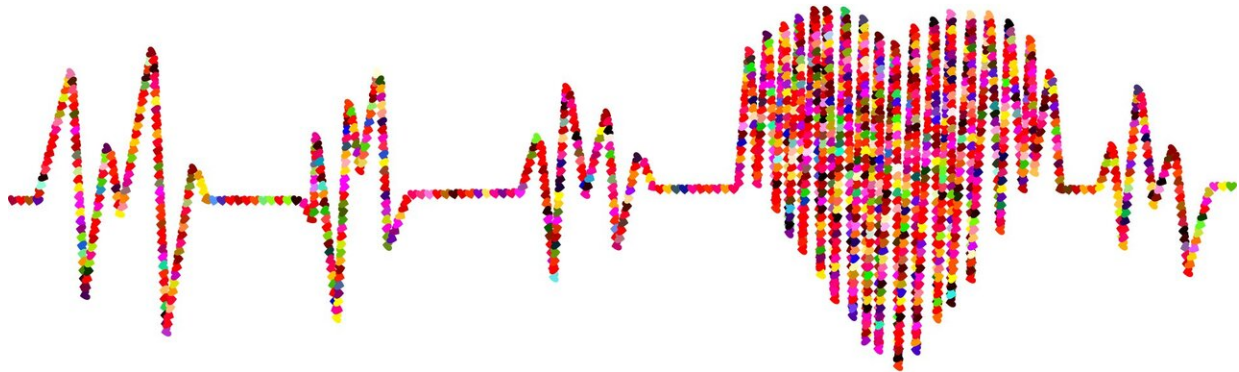


# Australian study: Many home blood pressure monitors not validated for accuracy

April 13 2020

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Most blood pressure devices sold for home monitoring in Australia—and possibly worldwide—may not have been validated for accuracy and could lead to misdiagnoses and inappropriate treatment, according to new research published today in *Hypertension*, an American Heart Association journal.

In this study, the researchers studied the online blood pressure [device](#)

marketplace in Australia, including large, multi-national, e-commerce businesses such as Amazon and eBay, which was the source of over 90% of the devices examined. Validating a blood pressure device means it has gone through rigorous testing to make sure it is measuring accurate blood pressure readings. The researchers found:

- Only 6% of the 972 models of blood pressure monitoring devices available for purchase had been validated;
- More than half of the blood pressure monitors on the market were wristband models, and none had been validated;
- Slightly over 18% of the upper-arm cuff blood pressure devices had been validated; and
- Non-validated devices were cheaper than those that had been tested for accuracy.

"People around the world monitor their blood pressure using home devices to help to effectively manage hypertension and to help determine their risk for heart attacks or strokes," said James E. Sharman, Ph.D., lead researcher for the study and deputy director at the Menzies Institute for Medical Research at the University of Tasmania in Australia. "If the devices haven't been properly validated for accuracy, treatment decisions could be based on incorrect information. We found non-validated devices dominate the Australian marketplace, which is a major barrier to accurate blood pressure monitoring and cardiovascular risk management.

"Inaccurate blood pressure measuring devices could have a major implication for public health. If blood pressure is incorrectly overestimated it could lead to unnecessary prescriptions or higher doses than needed of blood pressure lowering medications, which are usually prescribed for life. Medications are costly, have potential side effects and patients incorrectly labeled with [high blood pressure](#) could suffer unnecessarily. When blood pressure is incorrectly underestimated, people might remain at increased risk for a [heart attack](#) or stroke that

could otherwise be avoided with the appropriate medication and dose, and/or lifestyle changes," Sharman said.

"International policies need to be strengthened to ensure that home use medical devices are rigorously tested for accuracy before being cleared for sale by regulatory authorities. Currently, manufacturers of blood pressure devices conduct their own accuracy testing, an honor system with potential real-life consequences for patients," said Sharman.

Home blood pressure monitoring is recommended by the American Heart Association for people with high blood pressure because it provides more blood pressure readings rather than the occasional measurement in a doctor's office or health care clinic. The Association recommends using a [blood](#) pressure monitor with an upper-arm cuff that has been independently validated. In addition, the Association suggests taking the device to their healthcare provider to double-check it for accuracy.

The study may be limited because it only reviewed devices purchased via Australia's online marketplace. These suppliers also sell products in the U.S. and worldwide, however, the focus of this study is the Australian market, so it is not known if these same [blood pressure](#) devices are sold in the U.S. The FDA requires manufacturers to submit documentation that the devices are tested for precision before they can be available for sale in the U.S. However, the devices are not independently evaluated; rather, the manufacturers conduct their own [accuracy](#) tests.

**More information:** Dean S. Picone et al, Nonvalidated Home Blood Pressure Devices Dominate the Online Marketplace in Australia, *Hypertension* (2020). [DOI: 10.1161/HYPERTENSIONAHA.120.14719](https://doi.org/10.1161/HYPERTENSIONAHA.120.14719)

Provided by American Heart Association

Citation: Australian study: Many home blood pressure monitors not validated for accuracy (2020, April 13) retrieved 2 May 2024 from <https://medicalxpress.com/news/2020-04-australian-home-blood-pressure-validated.html>

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