

# SPECIAL HEALTHCARE PROVIDER REPORT:

Ensuring Home Blood Pressure Monitors are Accurate for In-home Patient Use

## Executive Summary

Accuracy in blood pressure monitors for mass market consumption has never been more critical: as mass shortages of healthcare practitioners collide with an ever-growing population of patients, chronic disease rates rise and consumers demand to utilize technology to manage healthcare on their own, the home blood pressure monitor has become a critical tool of long-term health management.

But as healthcare providers look to recommend blood pressure devices for home use, two main factors remain omnipresent in ensuring long-term accuracy of results: 1) the use of legitimately clinically validated products, and 2) educating patients on the correct way to take blood pressure readings.

## Modern Protocols

Independent device accuracy assessment within a clinical setting is recommended before introduction and routine clinical use. Various protocols have been published to assess automated devices against a mercury sphygmomanometer during clinical use and these are referred to as clinical validation protocols.

### Hypertension Canada

Hypertension Canada recently re-launched its recommendation program to allow consumers and healthcare professionals a resource to easily identify blood pressure monitors that are validated in studies as accurate. Various standards exist globally to gauge the accuracy of blood pressure measurement devices. Those with a Gold rating meet the highest and most current international standards, and those with the Silver ratings meet the highest international standards available prior to their most recent updates. Both Gold and Silver levels are accepted as accurate



## Clinically Validated? Other Factors that Can Impact Blood Pressure Monitor Accuracy

### Each Product Must Be Validated

Occasionally, companies will claim a certain level of accuracy in their products, which have met all the clinical validation standards, but will then modify the design of the product in such a way that the original validation is no longer representative of the product.

As such, each new product and its peripheral components (cuffs, etc.) need to pass the standard clinical validation process.

### Assurance of Accuracy During Manufacturing

In order to make sure a clinically-validated product maintains its level of substantiated accuracy through the production process, the following should be in place:

- **Design Control:** the design, exactly as it is, is the one that needs to enter the production process.
- **Production Control:** From end-to-end, the product resourcing, testing, manufacture, sampling and packaging, should be in control of the manufacturer. Without that level of precise control, manufacturers have no way of knowing if design or production has resulted in the tweaking of the design in a way that would negate accuracy results.
- **Consistency:** The above manufacturing process as defined above needs to be tested for accuracy as well, to ensure long-term consistency in the production process.



## An Independent Validation of Accuracy

The market today for blood pressure monitors places a strong emphasis on independently validating the device accuracy and generating a study that is peer-reviewed for neutrality of conclusions.

The protocols process for validating accuracy hinges on a three-way correlation between the following, to prove the device under testing is operating as accurately as a highly-trained healthcare professional:

1. The device under testing; and
2. Two trained healthcare specialists conducting readings, who are blind to one another.

## Publication in a Peer-reviewed Journal

Following the independent validation, the full report of the validation study describing the process and results should be published in a peer-reviewed journal. This adds credibility to the validation study because the Journal would not include the report in its publication without the medical peers of the author(s) having found the techniques and quality of the outcome to be sound.

### Over 40 Years of Experience

LifeSource by A&D Medical has been perfecting blood pressure monitoring for over 40 years. Our blood pressure monitors used in clinics, hospitals and the home are clinically validated according to the standards above to assure that healthcare practitioners and patients can trust their results to better manage blood pressure. We design and manufacture all of our monitors to bring the highest quality and accuracy to all care settings.

## Clinical Validation: The Gold Standard?

For healthcare practitioners who want to advise patients on the right home blood pressure monitor to use – as well as utilize the data they provide for long-term management – suggesting the patient look for a product that has been “clinically validated” has always seemed to be obvious advice.

Why clinical validation? The accuracy of a blood pressure device or monitor is determined by comparing its measurement relative to the measurement of an observer using a mercury sphygmomanometer and stethoscope on a patient. Under this scenario, the trained healthcare practitioner uses the above tools in a controlled environment, with a prepared patient, and compares that reading to the blood pressure device in question. This careful comparative measurement is considered to be the gold standard for clinical validation.

But unfortunately, the phrase “clinically validated” has become as ubiquitous as other marketing claims because the process of clinical validation is not always followed to its fullest measure – or for each applicable product line. Patients need to understand the process of clinical validation in order to assess manufacturer claims.

To that end, clinical validation is comprised of a three major components:

1. Utilization of modern protocols;
2. Independent verification of accuracy; and
3. Publication in a peer-reviewed journal