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SPECIAL HEALTHCARE PROVIDER REPORT:

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

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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.

The International Protocol of the European Society of Hypertension and the protocol of the British Hypertension Society are widely accepted, and most commonly used in publications, although similar protocols exist in Germany and the U.S. In addition, European Committee for Standardization (CEN) standards including clinical validation protocols are available for manufacturers to use.

A recent protocol to evaluate the accuracy of a blood pressure device against the gold standard of a trained healthcare practitioner is ISO 81060-2. This is the protocol currently endorsed by the Food and Drug Administration (FDA) and gaining wide spread acceptance.

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

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.

Once Clinical Validation is in Place: Educating Patients is Key

In November of last year, the American Heart Association (AHA), the American College of Cardiology and nine other groups redefined high blood pressure: The new parameters now reflect hypertension to be a reading of 130 over 80, down from 140 over 90.

This change means that almost half – **46 percent** – of all U.S. adults are considered hypertensive.

According to the AHA, lowering the definition of high blood pressure will allow for earlier intervention to prevent further increases in blood pressure and complications related to hypertension. They are hoping healthcare providers and patients alike will consider home monitoring of blood pressure levels (in addition to those taken during clinical visits), in order to gain accurate readings across a broader spectrum of time and to mitigate errors in readings that might take place in a physician's office.

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 Mass Production Accuracy

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.

Therefore, in addition to advising around the full clinical validation process, providers should look to use the office visit as a time to educate patients on the proper procedure for blood pressure monitoring.

For those who want to take that educational process one step further, the *American Medical Association (AMA)* states clinicians should encourage patients to bring their home blood pressure monitor to their clinical office to measure its accuracy against a mercury sphygmomanometer.

They provide a simple version of the European Society of Hypertension International Protocol, which can be done quickly by the physician or other healthcare clinician and the patient.

1. Have the patient sit down with his or her arm at heart level (the arm should be completely relaxed).
2. Allow the patient to rest for five minutes.
3. Avoid any conversation during the measurements to prevent an increase in blood pressure.
4. Take a total of five sequential same-arm blood pressure readings, no more than 30 seconds apart.
    a. Have the patient take the first two readings with his or her own device.
    b. Take the third reading, preferably with a mercury sphygmomanometer or comparable device.
    c. Have the patient take the fourth reading.
    d. The fifth and final reading should be taken by the health care clinician.
5. Compare the difference between the readings from the two cuffs:
    a. BP readings will usually decline over the five measurements. The final systolic blood pressure reading may be as much as 10 mm Hg lower than the first.
    b. If the difference is 5 mm Hg or less, the comparison is acceptable.
    c. Do the step #4 again if the difference is greater than 5 mm Hg but less than 10 mm Hg (the device may not be accurate if the difference is greater than 10 mm Hg.).
6. Repeat this procedure annually.

Though there is no established target for how close the readings from the patient's cuff should be to those from the clinician's cuff, the above exercise can provide a general sense of the device's accuracy, which can be taken into consideration for future measurements recorded at home.

To further ensure accuracy, the clinic and home devices can be calibrated following the *National Health and Nutrition Examination Survey (NHANES)* Health Tech/ Blood Pressure Procedures Manual.