

Electronic (Oscillometric) Blood Pressure Monitors

Suggested Requirements for External Validation Studies

WHY IS EXTERNAL VALIDATION REQUIRED?

- Oscillometric blood pressure (BP) monitors sense waveforms (generated by arterial pulses) and estimate BP using algorithms applied to a processed version of these waveforms.
- Algorithms are proprietary and kept secret. They differ between manufacturers and, possibly, between devices.
- Consequently, devices using new or unstudied algorithms require validation. In addition, if critical elements of the device are new (pressure transducer, waveform filtering and processing, cuff), revalidation should be done.
- Companies typically perform internal testing – usually on employees or healthy subjects. This consists of comparing device readings to auscultation and/or use of a simulator that generates waveform signal with a known BP. Internal testing is important to ensure that the device is giving reasonable results. However, internal testing may not be rigorously performed and simulators, while useful, are not a substitute for human testing.

WHAT IS INVOLVED IN AN EXTERNAL VALIDATION STUDY?

- External validation involves comparing device measurements to blinded, two-observer auscultation. For auscultation, mercury sphygmomanometers are preferred, but well calibrated aneroid devices are acceptable (mercury has been banned in many jurisdictions). In general, the validation process involves performing sequential measurements taken in the same arm, alternating between auscultation and the device-under-test. Mean results are calculated for each method and compared according to a protocol-based recommended analytic plan.
- Should be performed by an arms-length investigator and team, preferable with experience because the process is not straightforward and the study must be conducted with diligence.

- Two major types of entities perform validation studies – academic investigators (see Annex I for a list of recommended investigators) and research teams (usually University based) and contract research organizations. The former are preferred because they tend to publish their results in peer-reviewed journals, which adds an extra layer of scrutiny and ‘face validity’.
- Although it is always preferable to have multiple validations conducted for a device, this is costly and time consuming. One well conducted external validation study should be considered sufficient.
- Ideally, validation should be performed in the population in whom use is intended. Practically, such data are rarely available because study samples are derived from local populations residing near the validation site (a validation study in Athens may be performed for a device used primarily in China).
- Further to the point above, BP devices are often intended to be used in patients with cardiovascular disease (very elderly, obese, coronary disease, kidney disease, cerebrovascular disease, etc.) yet validation studies often do not contain such individuals. There is concern that validation results generated from a healthy study sample don’t generalize well to patients with disease. For now, we have to accept this as a limitation. More study is needed of this important issue.
- An external validation is conducted according to an accepted protocol. These include:
 - British Hypertension Society (BHS): Most rigorous and most time consuming. 85 subjects tested. Primary assessment criteria based on the proportion of measurements falling within 5, 10 and 15 mmHg.
 - Association for the Advancement of Instrumentation (AAMI)/International Standards Organization (ISO): 85 subjects. Primary assessment based on the mean and

standard deviation. A major criterion is that the mean difference between the device-under-test and auscultation should fall within 5 mmHg and the standard deviation of this difference within 8 mmHg.

- European Hypertension Society International Protocol (ESH IP): 33 subjects. Developed to make the validation process easier; however, many have concerns that the protocol is of insufficient rigor. Primary assessment criteria based on the proportion of measurements falling within 5, 10 and 15 mmHg. Thus, it is being phased out in favor of a revised and combined AAMI/ISO/ESH protocol.

WHEN SHOULD EXTERNAL VALIDATION BE PERFORMED?

- New device and algorithm
- Revised algorithm
- Changes in the device pressure transducer, technique for filtering/processing oscillometric waveforms, device cuffs

WHEN SHOULD REVALIDATION NOT BE REQUIRED?

- As it is common for manufacturers to sell different models, each with slightly different features, changes in a device that don't affect the measurement should not require re-validation.
- Examples include changes in casing, electronic cords, displays, extra features (e.g., Bluetooth or WiFi modules).

ANNEX I: LIST OF RECOMMENDED INVESTIGATORS THAT PERFORM VALIDATION STUDIES

This roster is current as of 18 Aug, 2018.

Any individual or organization wishing to be added to this roster may contact info@resolvetosavelives.org to explore this possibility.

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