SunTech Medical: The Rationale for Clinical Monitors and Validation of the Oscillometric Method

SunTech Medical, Inc. is a leading global provider of blood pressure monitors and non-invasive blood pressure technologies (OEM). We have always recognized the need for highly specialized equipment for different markets and environments. Our sole focus on blood pressure for over twenty years has allowed us to study various patient populations and design equipment specific to the needs of that patient group.
We are the only company with proprietary algorithms for auscultatory, oscillometric, stress, transport motion, patient motion, veterinary, dialysis, pediatric, neo-natal, ambulatory, geriatric, and bariatric applications. Our Advantage series of modules accommodate many of these applications in a single, robust platform.

Our monitors and modules are used in almost every environment where accurate BP is required. SunTech does not design or manufacture any non-clinical BP monitors because there is little similarity between the requirements for a clinical grade device and a monitor for home use.

There are several criteria that distinguish a clinical grade device from a simple home monitor:

1. The first and most important criterion is that a clinical grade monitor must be accurate on a wide range of patient populations. Most home units will work well on healthy normotensive adults. The section of this paper on The Oscillometric Method explains the difficulties inherent in taking oscillometric blood pressure readings.
2. The development and part costs of home monitors will be significantly less than clinical monitors. Since clinical monitors have to work on patients ranging from healthy to critically ill, the algorithms are much more complex requiring higher power processors, more memory, and better performance pneumatic components.
3. In critical clinical situations, systolic and diastolic pressures can be extremely high and/or extremely low. In order to facilitate therapeutic interventions, it is very important for the monitor to be accurate throughout the entire measurement range.
4. The blood pressure monitor must be able to work on a wide range of arm sizes. Most home monitors will work with 1-3 different cuff sizes. This covers a range from about 18cm – 43 cm. A clinical monitor should work with a cuff range from at least 12cm – 50cm. The SunTech series of Advantage modules will work with the smallest neonate cuff through a thigh cuff.
5. Typical home monitors have no MTBF or expected life rating, and some are rated for less than 10,000 BP readings. SunTech Advantage modules are guaranteed for 30,000 readings and typically perform over 80,000 readings without a failure.
6. Clinical monitors regulated by the FDA or through CE marking must identify key components and provide traceability for these components in case of a recall. The manufacturer of the monitor must ensure that traceability extends from the key components in all subassemblies to the end device in the event of a latent defect and possible product recall.
7. The manufacturer of a BP monitor sold in the USA must have a 510(k) through the FDA; it is the manufacturer of the end device that is responsible for the safety of that device in the market place. The manufacturer of the end device must know if any changes are made to the hardware or software so that the changes can be validated. Also, the manufacturer may be required to submit a new 510(k) if the changes are major.
8. All SunTech monitors are calibrated to a digital pressure gauge that has an accuracy of better than +/- 1 mmHg. The calibration on this pressure gauge can be traced to a NIST standard as required by the FDA. Many Asian manufacturers calibrate to a mercury manometer that has an accuracy of +/- 3mmHg.
9. SunTech monitors have been designed and tested to meet the current EMC requirements for FDA clearance and CE marking. Many home monitors are tested to a lower standard and some are not tested to any EMC standard at all.

The Oscillometric Method

The basic method of taking an oscillometric blood pressure reading has not changed, however more sophisticated hardware and software has been developed to improve the accuracy and reliability of blood pressure readings. Most clinical grade oscillometric blood pressure monitors inflate a cuff on the upper arm to a pressure above the subject's systolic pressure to occlude the brachial artery. The cuff is slowly deflated until the cuff pressure approximates the subject's diastolic pressure. Then the cuff pressure is quickly exhausted and the subject's systolic pressure, diastolic pressure, and heart rate can be calculated from small pressure pulses collected during the cuff deflation. The diagram in Figure 1 shows a typical deflation cycle on a normal healthy adult.

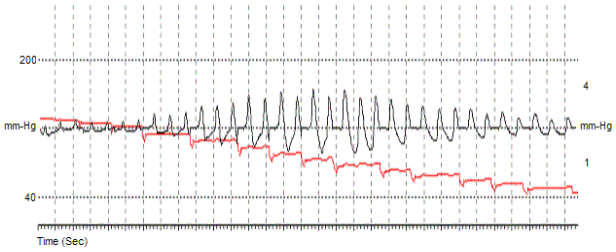

Figure 1

The red line shows the cuff pressure and the black line shows the oscillometric pulses. The cuff pressure and the oscillometric pulses are on different scales; the cuff pressure starts at approximately 140 mmHg on the left and decreases to about 50 mmHg on the right. The amplitude of the oscillometric pulses are shown much larger so that they can clearly be seen. The amplitude of the oscillometric pulses on the far left are less than 1 mmHg, the pulses increase in amplitude to approximately 4 mmHg in the center of the diagram, and the pulses then decrease to less than 1 mmHg on the right side of the diagram. Once the cuff deflation is completed and the oscillometric pulses from systolic to diastolic are recorded an envelope curve is created using the amplitude of the oscillometric pulses. The diagram in Figure 2 shows the envelope curve for the oscillometric pulses shown in Figure 1.

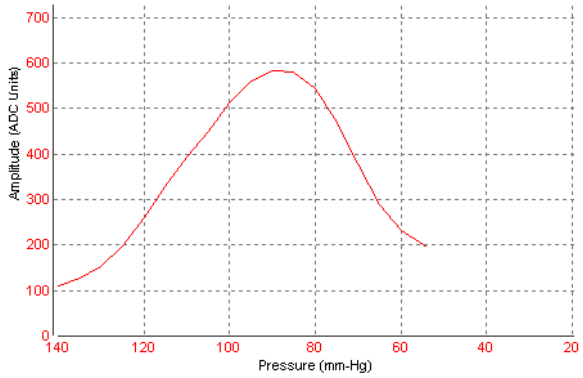

Figure 2

The oscillometric pulses start increasing in amplitude around 140 mmHg, they continue to increase in amplitude to a maximum just below 90 mmHg, then start to decrease and they continue to decrease below 60 mmHg. The pressure at the peak of the curve represents the Mean Arterial Pressure (MAP). From this envelope curve the systolic and diastolic pressures are calculated using coefficients on the rising side of the curve for systolic and coefficients on the falling side for diastolic. The maximum point on the curve (MAP) is easy to detect and the changes in the slope throughout the curve are gradual. A clearly defined MAP and correct determination of the slope are key factors for calculating systolic and diastolic blood pressures.

The curve shown in Figure 2 is a good example of data collected on a healthy, relatively motionless adult. Under these conditions most blood pressure monitors are capable of producing accurate readings.

Oscillometry on Hypertensive Patients

The next sets of curves in Figure 3 and Figure 4 are from hypertensive patients at a dialysis clinic.

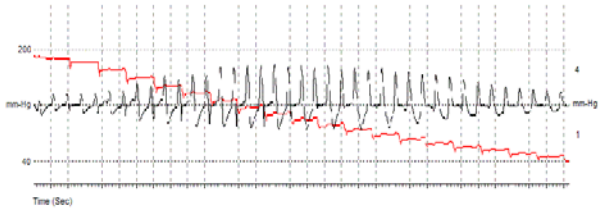

Figure 3

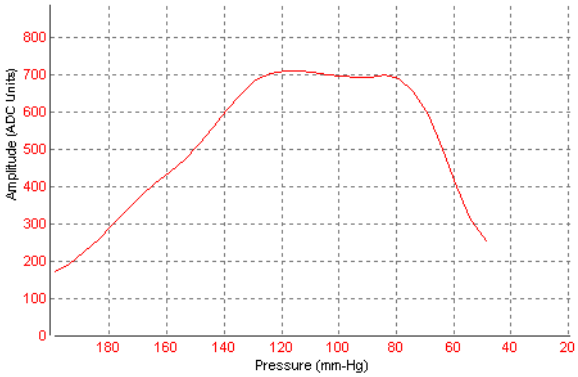

Figure 4

The oscillometric pulses shown in Figure 3 are large and easy to detect, and there is no motion artifact to interfere with collecting all of the pulses. However, the envelope curve shown in Figure 4 is very different than the curve of the healthy patient in Figure 2. This difference is due to structural changes (progressive hardening of the arteries) in many geriatric patients. In Figure 4, the curve has no clear maximum point, the maximum point measured by the algorithm could be anywhere between 120 mmHg and 80 mmHg. This uncertainty could lead to a 40-mmHg error in the systolic or diastolic measurement.

In another hypertensive patient (Figure 5), the maximum point on the curve is easier to measure, but the rising edge of the curve does not have a gradually increasing slope and then a decreasing slope until it reaches its maximum point.

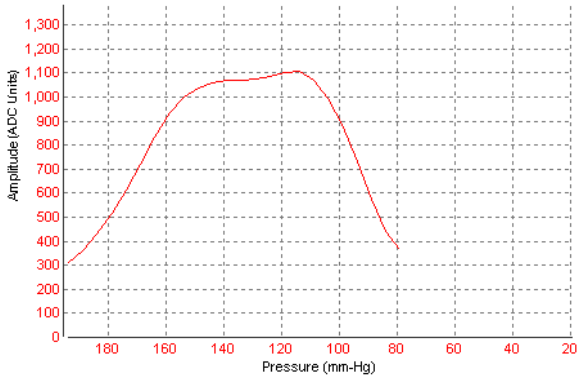

Figure 5

Current validation protocols do not require blood pressure monitors to be validated on any specific types of patients. Consequently, most are validated on readily available, healthy volunteers with a small sample of hypertensive and hypotensive patients. In this regard, SunTech's efforts exceed most of its competitors by including thousands of readings on hypertensive, hypotensive and notably, dialysis and diabetic patients. Some manufacturers will even go out of their way to exclude patients with any health issues.

Consolidation of these data together with experience gained from our ongoing research in emergency medicine systems (EMS), ambulatory blood pressure and cardiac stress monitoring serves to continually optimize our algorithms. This minimizes the effects of poorly defined MAP and non-linear slope thereby ensuring reliable, accurate readings on a more diverse patient population.

Data Collection/Validation Summary

SunTech Medical has conducted a significant number of domestic and international data collections and validations in order to secure an accurate representation of diverse patient populations. Data collection at local clinics gives us convenient access to hundreds of patients. Efforts in several other states and internationally, expand the breadth of our patient database and minimize any geographical effects on patient distribution.

Over the past several years SunTech has completed blood pressure studies on a variety of patient populations and in several different environments. These studies include:

- Dialysis patients during dialysis treatment (3)
- Diabetic patients
- Motion tolerant studies in ambulances
- Motion tolerant studies in helicopters
- Neonate validation (0 – 30 days)
- Infant validation (30 days – 3 years)
- Pediatric validation (3 – 12 years)
- Veterinary study (cats, dogs, & horses)
- AAMI SP10:1992 (6 separate validations)
- BHS Protocol (2 separate validations)
- International Protocol (2 separate validations)

A home monitor may only have a single validation to AAMI SP10 or to the BHS protocol. Since the protocols require very little diversity in the patient population the manufacturer is given a large amount of freedom selecting the subjects for the study. The manufacturer could screen the subjects for the study by not admitting subjects with weak pulses, very large or small arms, irregular heart beats, etc… This is acceptable in most of the protocols if these conditions are clearly defined. This explains why many home monitors will have excellent scores on one validation and then do poorly on a validation performed by an independent 3rd party.

SunTech has also created an excellent system to independently control every OEM customer's product. Each customer's module is given a separate part number with hardware and software revision control. These controls are built into our production test and QA system. This ensures that we build each system per the customer's requirements. Also, our system does not allow any revision changes without customer approval.