Guest Commentary: How blood-pressure devices work

Eric Kinast - March 17, 2005

EDN's recent editorial misses the actual difference between analog and digital blood-pressure devices (see "Digital doesn't always mean better," by John Dodge, March 3, 2005). This is quite understandable, because most people (including some doctors) have no idea how these different types of blood-pressure devices really work.

What you are really looking at is not the difference between analog and digital implementations of the same thing, but rather the difference between devices based on entirely different operating principles. It is not just a matter of the accuracy of the pressure sensor, because unlike in a tire gauge, the pressure sensor in a cuff-type blood-pressure monitor doesn't sense your blood pressure at all. Rather, it reads the air pressure in the cuff, from which the instrument indirectly infers your blood pressure, often with an error much greater than that of the pressure sensor itself.

The different types of instruments use completely different inference mechanisms, which is why they sometimes get different readings, even if the pressure sensors themselves are accurately calibrated. This has nothing to do with analog versus digital, because over the long history of manual and automatic blood-pressure-monitoring devices, analog and digital methods have been applied to both commonly used inference mechanisms.

The mechanisms in question are called auscultatory and oscillometric. (Other mechanisms are used to a small extent in specialized applications.) The traditional manual method is called the auscultatory method. This is the one done with a stethoscope, but some automatic devices use this method, too (although not the ones mentioned in the editorial).

As the name implies, it works by sound. Your blood pressure has an alternating-current component, with the systolic pressure at the peak and the diastolic at the trough. When the cuff pressure is inflated higher than your systolic pressure, the artery in the arm, over which the stethoscope is placed, is completely flattened by the cuff pressure, and no blood is able to pass through. As the cuff pressure just drops below the systolic pressure, the artery briefly opens, and a spurt of blood flows through, at the peaks of the waveform. At this point, you begin hearing a thumping in the stethoscope, essentially due to a water-hammer effect as the artery closes when the blood-pressure waveform passes the peak. As you continue to deflate the cuff pressure, the artery stays open for a longer period of time, as more of the waveform is above the cuff pressure, and you continue to hear thumping. Finally, when the cuff pressure falls below the diastolic, the artery remains open for the full pressure cycle, and the thump caused by it opening and closing stops. (Some patients exhibit a phenomenon known as auscultatory gap, where the thumping seems to disappear briefly at intermediate pressures between systolic and diastolic, but soon returns.)
There are several ways to implement an auscultatory instrument, all of which have varying impacts on accuracy. First, regarding the pressure sensor, the traditional standard has been the mercury column, now being phased out due to toxicity. While mercury columns are reasonably accurate, errors exist due to the strong meniscus that forms at the top of the mercury, which adds about 1 mmHg of uncertainty, and the fact that they must be absolutely level to read correctly.

Alternatives include analog mechanical dial gauges and electronic gauges. In order to be legally sold in the USA, the gauge portion of the device must be accurate to better than 3 mmHg at room temperature over the range of 0 to at least 260 mmHg (see ANSI/AAMI standard SP10). The same standard of accuracy applies whether the gauge is digital, analog, or mercury. However, the accuracy of the gauge itself sometimes has little to do with the overall accuracy of the blood-pressure reading, as other sources of error often have a greater impact.

Next, there is assumption that the cuff pressure gets accurately transferred to the arterial wall. It turns out that this only happens reliably when the cuff has a certain aspect ratio (ratio of cuff width to arm circumference). Few doctors bother to consistently select the correct cuff, and some home units don't even come with an assortment of cuff sizes.

Finally, the detection and interpretation of the sounds, which can be accomplished by human or machine, plays a role. For machine reading, manufacturers place a microphone in a little pocket at the edge of the cuff. In various devices over the years, instruments have processed the microphone signal using analog, digital, and hybrid methods, with little difference in accuracy. This is due in part to the fact that the beginnings and endings of the sounds are usually fairly distinct, and fairly deterministically related to the relative pressure of the cuff and blood. Well-designed auscultatory machines and skilled human operators usually agree closely.

However, most automatic machines today do not use the auscultatory principle. The automatic instruments described in the editorial work by the oscillometric method, as do most automatic clinical instruments outside of special application areas like stress testing. This is a more indirect method, and such instruments are usually empirically calibrated against the auscultatory method.

These instruments have neither a stethoscope nor a microphone, and are therefore easy to use, because it is not necessary to position anything accurately over the artery—you just wrap the cuff around the arm (or wrist or finger in some home units). Further, they don't need the quiet environment necessary to detect the auscultatory sounds. They work on the principle that when the artery does open during a portion of the pressure cycle, a tiny perturbation, or oscillation, will be superimposed on the pressure inside the cuff. That is, the circumference of the arm will be enlarged infinitesimally by the surge of blood under the cuff.

The amplitude of these oscillometric signals waxes and wanes over the course of the deflation of the cuff. However, even when the cuff pressure is much higher, or much lower, than the blood pressure, there is still some interaction between the blood and the cuff, so the amplitude never drops to zero, unlike the sounds in the stethoscope. The sequence of amplitudes seen as the cuff deflates is as follows:

1. Cuff air pressure well above systolic: small amplitude
2. Cuff pressure approaching, but just above, systolic: increasing amplitude
3. Cuff pressure passing through systolic: rapidly increasing amplitude
4. Cuff pressure intermediate between systolic and diastolic: maximum amplitude
5. Cuff pressure approaching but above diastolic: decreasing amplitude
6. Cuff pressure at diastolic: moderate amplitude
7. Cuff pressure below diastolic: moderate amplitude, slowly decreasing with further cuff pressure
reduction.

(Some instruments work by gradually inflating, instead of deflating, the cuff, in which case the sequence is reversed.)

Although I have shown seven stages, the oscillation amplitude profile is actually a continuous, smooth variation. The maximum amplitude in No. 4 occurs at something called the mean arterial pressure, or MAP. Very early commercial oscillometric instruments could measure MAP, but often not systolic and diastolic. For example, the popular DinaMAP device (manufactured by Critikon, today a Johnson & Johnson division) takes this name because in the very beginning it measured just MAP.

With time, it became possible to reliably correlate points on the waxing and waning amplitudes on either side of MAP with the systolic and diastolic pressures. Although there is sound theory as to why this should be, the actual amplitudes observed do not always agree completely with the theory. Subsequent versions of oscillometric devices looked for oscillation amplitude of certain fractions of the maximum amplitude at MAP, defining one fraction as the systolic point and another as the diastolic point. The designers defined these fractions based on empirical calibration.

Over the years, engineers have developed more advanced criteria for finding the systolic and diastolic points. For example, some clinical devices today use a combination of the amplitude, the slope of the increase or decrease, and some other complex factors to find these points. Further, they may use several methods, and then select the results that best meet certain integrity checks.

The important thing to realize is that in the auscultatory method, the systolic and diastolic points are fairly well defined by the sudden appearance and disappearance of sounds (although the disappearance is less distinct), while in the oscillometric method, they are somewhat ill-defined points on a continuously varying amplitude profile that never goes fully to zero.

In order to evaluate their choice of points for the systolic and diastolic, manufacturers of oscillometric instruments must go through a calibration protocol. The standard cited above (ANSI/AAMI SP10) defines how to validate the calibration for the US market. Although two possible methods exist, in practice the process usually relies on comparison with the auscultatory method.

As John Dodge noted in his editorial, he and his wife observed that two different operators, particularly if not highly experienced, can get different auscultatory results. To eliminate this variability, the persons providing the auscultatory reference must meet certain qualifications as to professional experience and hearing acuity. Second, they both listen to the same pressure measurement at the same time, using a special dual stethoscope. The standard requires a certain statistical tolerance on the agreement between the two persons, or the data cannot be used. The test is preferably performed so that the auscultatory measurement is made at the same time, on the same limb, as the automatic oscillometric measurement. With some oscillometric devices, it is possible to do this by just tucking the stethoscope under the edge of the oscillometric cuff, but other devices deflate the cuff in such a way (for example, by steps or too fast) as to make this impossible.

If an oscillometric device agrees within margins considerably larger than those allowed for the pressure sensor itself, it is considered to be properly calibrated against the auscultatory reference, and may be submitted to the FDA for approval for legal sale. For the systolic and diastolic pressures evaluated individually, the standard allows the following:

1. The mean of all measurement disagreements (between the device readings and the auscultatory measurements) must not exceed ±5 mmHg; and
2. The standard deviation of the disagreements must not exceed between 4.8 and 7 mmHg, according to how far off the mean was.

The inclusion of a standard-deviation specification provides a clue that some individual readings are permitted to be fairly far off, much more than the mean error. The reason for this is that the correlation between the indirect oscillometric method and the more deterministic auscultatory method varies somewhat between different individuals, and may vary according to the same individual's condition. Thus, these statistical measures of accuracy demonstrate that over a large population of patients, the unit under test agrees fairly well on average with the reference method, and that the readings have a reasonable scatter. It does not guarantee that there are not extreme outliers. Therefore, any individual person can expect to see a deviation between the methods.

Again, this has little to do with analog versus digital, or even the accuracy of the pressure sensor itself. Instead it represents a manifestation of the degree of correlation between two indirect methods, each producing a different approximation by different means. Various manufacturers use different methods for picking the systolic and diastolic points on the oscillometric amplitude profile, or "envelope," as it is called. Some of these methods show less variation as a function of differing patients than do others.

Home oscillometric units often use simple methods (for example, fixed percentages of the amplitude at MAP). These units may be very accurate on some people, and considerably in error on others. The more sophisticated algorithms used in better clinical-grade oscillometric devices often contain features designed to minimize this variability, usually by taking into account other factors in addition to amplitude.

So the blame for the different readings lies not on analog implementation versus digital, but on trying to compare an apple with an orange.

About the author

Eric Kinast is an EE and a fellow with the Patient Monitoring division of Datascope Corp., a New Jersey-based manufacturer of products for clinical healthcare markets in interventional cardiology and radiology, anesthesiology, cardiovascular and vascular surgery, emergency medicine, and critical care. He has spent about 12 years in the design of patient-monitoring devices, prior to which he worked in the scientific-instrumentation field.