Optimizing Simulation Results With Your SimCube Oscillometric NIBP Simulator

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Introduction

The SimCube NIBP simulator provides accurate NIBP simulation in an amazingly convenient, rugged, and affordable package. As you use your simulator on various patient monitors it is important to understand what sort of results to expect, what they mean, and how to optimize them.

NIBP Device Accuracy

The accuracy of NIBP devices is governed by an AAMI standard (SP-10). This standard specifies two different types of accuracy: static and dynamic.

The static accuracy represents the accuracy with which the internal pressure gauge in the device can measure cuff pressure and it is required to be within +/-3mmHg or +/-2%, whichever is greater. The static accuracy of the device can be easily checked by placing the monitor in cal or check mode and verifying the accuracy against the SimCube's manometer mode.

The dynamic accuracy represents the accuracy of the device in taking actual readings on patients, and it is specified in a relatively vague way. The AAMI specification calls for automated (device) readings to be taken on a large group of patients meeting certain criteria and the results to be compared with manual readings taken by nurses on the same patients. The manual and automatic readings are then compared statistically.

To be acceptable under the standard the mean error on systolic and diastolic readings must be no more than 5mmHg and the standard deviation of the error must be no more than 8mmHg.

What this means is that, under the specification, roughly 68% of all patients must be within 13mmHg of the manual readings, but 5% might be only within 21mmHg and 1% might be as far out as 29mmHg. While these specifications may seem very loose they can be quite difficult to meet.

The errors in the readings come from several basic sources:

1. Patient to Patient Physiological Variations: Different patients have different arterial pulse shapes, arterial compliance, flesh rigidity and other factors which simply make the BP cuff respond differently. The oscillometric signal is complex and changes not only in size but in shape with cuff pressure and it is simply slightly different from patient to patient. Additionally, a patient's actual BP values are often not perfectly stable, but change over time, often during a reading or a series of readings.
2. Extrinsic Noise: During the testing process patients may be moving or talking. The signal to noise ratio on the oscillometric signal is never very good and it does not take very much additional noise to affect readings.
3. Intrinsic Noise: Even on a perfectly still patient with perfectly static blood pressure there would still be significant reading to reading variations. The biggest factor on this is sampling error introduced by the cuff pressure bleed rate or step size. It is no accident that step-down NIBP monitors step in 8mmHg steps and the standard deviation of the error is specified at 8mmHg. In addition to this both bleeding and stepping introduce pneumatic noise which can affect the oscillometric signal.

NIBP Device Differences

In manual NIBP readings there is a published AHA standard for how the readings should be performed. In practice the process is somewhat subjective, but at least there is the intent of uniformity.

With automated NIBP readings the situation is quite different. The first companies in the Oscillometric market patented their technology and tried to exert some control on the market by aggressively pursuing patent litigation. The result of this was not that they were able to keep any other manufacturers out of the market, but rather that all manufacturers have been legally forced to use slightly different methods. Key differences in these methods include:

1. Different cut-off frequencies for the AC channel high pass and low pass filters.
2. Different metrics for measuring pulse size.
3. Different methods for averaging pulse size.
4. Different methods for finding the peak of the pulse size envelope.
5. Different methods for determining average cuff pressure on a given pressure step.
6. Different methods and coefficients for extracting systolic and diastolic pressure from the pulse size envelope.
7. Different methods of controlling cuff pressure such as step down, step up, bleed down, and bleed up.

Since the oscillometric signal is complex and different for different patients these design differences can lead to identical results on some patients and quite different results on others.

In addition to the design differences several other factors lead to differences in readings between manufacturers:

1. Every manufacturer has adjusted their system based on the data they measured on their test patient group. Of course, they used different test patient groups. In theory the groups are large enough that they should be statistically identical, but in practice they can still give different results.
2. Every manufacturer has adjusted their system based on data which was measured by the nurses they used to generate the manual values for comparison. Of course, they used different nurses. In theory the nurses are all using the standard method, but in practice the process is still subjective and different nurses get slightly different results.

The end result of these differences is that the various devices do yield similar but slightly different results on the average, and on any specific patient the results can be quite different.

SimCube Simulation Results

The SimCube uses a simple yet effective mechanism along with a sophisticated variable pulse shape approach to deliver accurate, repeatable NIBP simulation. Simulations can easily yield values within 10% of their labeled values and with careful setup this can usually be lowered to 5% or better. The following table shows values obtainable with careful setup:

ADULT MODE (120/80)

Vendor	Reading1	Reading2	Reading3
MDE	120/81	119/81	121/81
HP	121/79	122/80	121/80
Critikon	126/82	119/83	120/84
Datascope	119/76	120/75	118/75
CSI	122/78	123/77	122/77

NEO MODE (70/40)

Vendor	Reading1	Reading2	Reading3
MDE	68/42	67/38	67/43
HP	68/38	67/36	67/38
Critikon	71/42	70/42	71/45

HYPERTENSIVE MODE (190/120)

Vendor	Reading1	Reading2	Reading3
MDE	187/117	187/118	187/117
HP	206/124	200/128	199/124
Critikon	189/116	190/118	184/120
Datascope	185/106	187/106	186/106
CSI	197/106	197/111	195/109

Notes:

1. These results were obtained with SimCube 1.5 software. We are constantly improving the product so future software versions may give slightly different results.
2. These results represent data taken from specific models of these manufacturer's products. We normally expect a given manufacturer's results to be pretty consistent across their product line, but different models and even different software revisions may give different results. For example an HP OmniCare with software E.0.1 reads adult mode diastolic about 10mmHg lower than a HP Merlin with software 17.52.
3. The readings shown are actual random samples, but they do not necessarily reflect worst case.
4. MDE=Escort II SW 4.2.0, HP=Merlin SW 17.52, Critikon=Vitalnet 2200, Datascope=Accutorr 3, CIS=506DXNT

Optimizing Your Simulations

The following techniques will help you obtain the best possible simulation results.

1. **Cuff Size Selection.** Many vendors are immune to variations in cuff size, but some are not. For example we find that some Datascope Accutorr monitors produce systolic values about 2mmHg higher and diastolic values about 6mmHg higher with a 400ml cuff volume rather than a 200ml cuff volume, while some Critikon monitors show about a 6mmHg drop in systolic values when changing to the 400ml cuff volume. We recommend using something close to a 400ml cuff volume for adult mode simulation. This can be achieved by wrapping an adult cuff on itself to form a cylinder approximately 3 inches in diameter. If you want to quantify the volume of a rolled cuff you can do this by injecting a measured amount of air into an unrolled, empty cuff using a syringe and a check valve. Once you have injected the desired amount of air, roll the cuff tightly. SimCube adult mode simulation will normally work with a broad range of test volumes, but with smaller test volumes you may see more vendor to vendor reading differences.
2. **Be prepared to throw out the first reading.** We find that some vendors sometimes produce a first reading that is substantially different than later readings.
3. **Take an average of several readings.** We suggest using a minimum of 3 to 5 readings.
4. **Make sure there are no leaks.** You can usually see leaks just by watching the SimCube manometer during the reading. On step down systems the cuff pressure may normally drop a bit during the first few steps, but after a few steps it should be flat or even rise slightly during

the step. This is because the air in the cuff is cooled by the rapid step deflation and warms up again during the step holding period causing the pressure to rise slightly. A leak on a step down system will appear as drop in pressure on all steps. Bleed down systems should normally bleed at about 2 to 6mmHg per second. A leak on a bleed down system will appear as a faster than normal bleed rate. Since the SimCube's NIBP simulation creates pulses which are several mmHg in size it is easiest to check for leaks with the SimCube in manometer mode. Be sure to watch for leaks on the SimCube's manometer rather than the monitor's cuff pressure display as the SimCube has a much faster sample rate and display update rate than most NIBP monitors.

5. **Make sure the monitor is in calibration.** On monitors with quickly updating cuff pressure displays you can do a rough cal check by simply placing the SimCube on top of the monitor, placing the SimCube in manometer mode, and starting a reading. The two pressure gauges should track tightly, although the monitor's display may be noticeably delayed. On some monitors, however, the displayed pressure may represent the intended pressure for the pressure step rather than the actual pressure. If this is the case you cannot use this method.

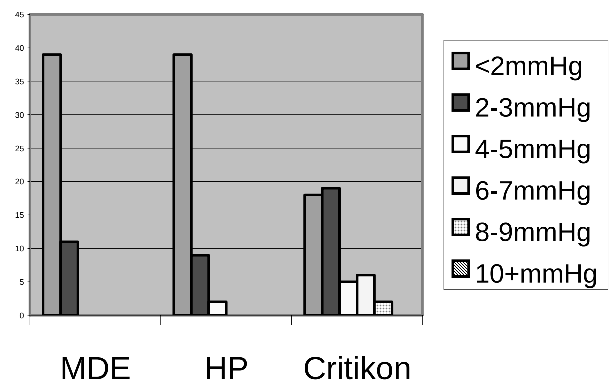
Neo Mode Simulation Setup

In a neonatal NIBP setup the patient cuff may represent just a few ml of volume, while the patient hose may represent 50 ml or more of volume. Since the SimCube operates by pulse volume (about 1/4 ml at peak in neo mode) the pressure pulses can be much larger on single lumen than on dual lumen systems. Some single lumen systems do not have enough dynamic range to reliably capture the pulses produced by the SimCube with a #1 neo cuff. While we have had good results with a #2 neo cuff, we recommend using a loosely wrapped #3 neo cuff for neonatal simulation on single lumen systems. Dual lumen systems should work reliably with a #1 neo cuff.

Due to the reduced pulse size of our neonatal simulation many monitors will not be able take readings on this simulation if the monitor is in adult mode or if you are using an adult cuff. We strongly recommend using a neonatal cuff and placing the monitor in neonatal mode. However, if you do not have access to a neonatal cuff, any volume in the range to 15 to 75ml will work with most monitors. This can be achieved with an infant cuff or, in some cases, with a tightly rolled child cuff. Also, a length of tubing can be used. A rough but handy approximation is that a 1 inch length of 1/8 inch I.D. tubing is around 1ml in volume.

Reading to Reading Variations

Even with the best setup there is still variation from reading to reading. Sometimes a reading will be produced which is quite far off target and it is difficult to know if this represents a problem with the monitor or not. The AAMI spec says that 1% of readings can be as much as 29mmHg off, but under simulation, and using the techniques we have described you should see much less than that. The following chart shows some typical error distributions. These represent the difference from 120mmHg systolic using SimCube's adult mode with a 400ml Cuff, discarding the first reading, for 50 readings. On some monitors systolic and diastolic have similar error distributions, while on others they are quite different.



About The Author

Karl Ruiter has been an engineer, a manager, and a director at a Los Angeles-based medical device manufacturer where he designed a NIBP algorithm which is in use in tens of thousands of units worldwide. This algorithm has been shown by competing manufacturers to be one of the most consistent and noise-immune on the market. In 2003 he helped to found Pronk Technologies Inc, which bases its product line on the concept that biomedical engineers do important work and they should have really good tools. He was the lead engineer on the SimCube product.

More Info

More information about the SimCube and NIBP simulation can be found at www.pronktech.com, by email at sales@pronktech.com, or by phone at (800) 609-9802.