SimCube™ NIBP Simulator
Operator's Manual

PRONK TECHNOLOGIES

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SimCube™ Operation Instructions

Models SC-1, SC-2, SC-3, SC-4 and SC-5

Introduction

Your ***Pronk ™ SimCube ™ simulation system*** is quick to set up, easy to use and ready to go where you need to be. Your SimCube system comes with the following: The SimCube simulator, a small 6VDC/2 amp power supply and at least one adapter. For information on other accessories, visit our web site www.pronktech.com.

Getting Started

1. Plug the SimCube power supply into an AC outlet.
Warning: Use only the power supply provided with your SimCube system. The power supply provided is 6VDC, 1.8amp, center positive, 2.1mm jack.

2. Connect the power jack into the SimCube power receptacle. Many power supplies use the same plug, and connecting the SimCube simulator to the wrong power supply may damage it. Be sure the plug has a yellow SimCube flag on it prior to connecting it to the SimCube simulator.
3. Wait for the power-up sequence to complete. When complete, the display will show 000.0 on SimCube models SC-1, SC-2, SC-3 and SC-4 and SC-5 with SW versions up to 4.5. SC-5 SW version 5.0 or higher will display 0.0. During the power-up sequence, the SimCube simulator will zero its pressure, so please remove all connections from the NIBP bulkhead to allow the SimCube to accurately zero to atmosphere. This step may take up to 15 seconds to complete.
4. Select the desired mode by pressing the Yellow Mode button. Each time the **Mode** button is pressed, the mode will be changed and the LED indicating the new mode will be lit. If the SimCube transitions into sleep mode (after approximately 30 seconds of non-use) to conserve power, the first press of the **Mode** button will illuminate the display and a second press will be required to move to the next mode. The NIBP and, if available, ECG, RESP, and IBP values corresponding to each mode are printed on the front panel next to the LED, horizontally. For more detailed information on each mode, refer to each parameter section in this manual.
5. For dynamic NIBP testing, connect the SimCube simulator in line with the monitor's cuff and hose as shown in Fig. 1. Different monitors will require different adapters. A variety of adapters are available from Pronk Technologies Inc. and each SimCube system comes equipped with at least one. Using a SimCube Cuff Jacket can improve reading capture and consistency. Generally, the smaller cuff jacket sleeve volume is best for most monitors. In Neo mode, be sure to use a small cuff. To use the Cuff Jacket, wrap the cuff as described above and insert into the desired neo or large volume sleeve. If not using the Cuff Jacket, wrap cuff snugly around itself and place in an area safe from accidental motion.

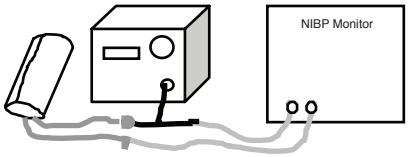


Fig. 1

6. Start the NIBP reading on the unit under test and wait for the reading to complete.

7. For static calibration, over pressure testing, and leak testing, connect the SimCube simulator and a manual pump bulb in line with the monitor's cuff and hose as shown in Fig. 2. All SimCube models include a manometer for performing static calibration. Some models include an Over Pressure (peak detect) mode for performing over pressure testing and some models include a Leak Test mode for performing leak tests.

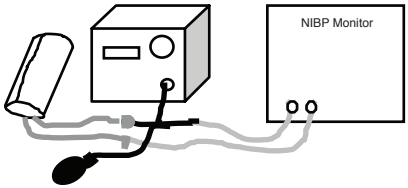


Fig. 2

8. For IBP testing, connect the IBP extension cable supplied with the SimCube system and the correct IBP adapter for the monitor under test to the SimCube simulator. A variety of IBP adapters are available from Pronk Technologies Inc. Select the '0' mmHg IBP simulation mode, zero the monitor, then select the desired simulation mode.

9. For ECG and Respiration testing, connect the ECG cable from the monitor under test to the SimCube simulator. Snap locations for 3, 5 or 12 lead simulations are indicated on the side of the SimCube simulator and shown in Fig. 3. When using large snap heads or alligator clips, it may be necessary to use the ECG Extender Module, which is available from Pronk Technologies Inc.

SimCube Side View

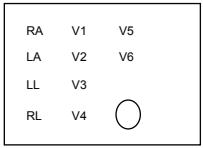


Fig. 3

User Interface Information

SC-4 SimCubes with software version 3.3 and SC-5 SimCubes with software version 4.3 and above include the 'Press and Hold' feature. This feature allows the user to advance through various simulations in a given mode. To place the SimCube into the Press and Hold mode, press and hold the Yellow **Mode** button for two seconds or until the **Mode** LED begins to flash. Each press of the Yellow **Mode** button will advance to the next waveform. As an example, when in HR Seq, by placing the SimCube in the Press and Hold mode, the HR Seq will stay at 30BPM until the Yellow **Mode** button is pressed. Then it will advance to 60BPM. Each subsequent press of the Yellow **Mode** button will advance to the next waveform in the sequence. To exit the Press and Hold mode, simply press and hold the Yellow **Mode** button for two seconds, or power cycle the SimCube.

NIBP Detailed Information

Before you begin, make sure you have your SimCube setup as described in 'Getting Started.' Available simulation modes are described below. Refer to the front panel of your SimCube simulator to determine which modes apply to your model.

- **NIBP Adult (120/80)**

Simulates a patient with blood pressure of 120/80mmHg, heart rate of 70 bpm, mean pressure of 97mmHg, and pulse volume of 1 ml.

- **NIBP Neo (70/40)**

Simulates a patient with blood pressure of 70/40mmHg, heart rate of 95 bpm, mean pressure of 51mmHg, and pulse volume of 0.25 ml. Requires use of a neo or pediatric cuff and the monitor under test should be placed in neonatal mode, if available.

- **NIBP High (190/120)**

Simulates a patient with blood pressure of 190/120mmHg, heart rate of 70 bpm, mean pressure of 142mmHg, and pulse volume of 1 ml.

- **NIBP Low (80/40) (SC-5 only)**

Simulates a patient with blood pressure of 80/40mmHg, heart rate of 70 bpm, mean pressure of 58mmHg, and pulse volume of 1 ml.

- **NIBP Peak Detect / Over Pressure (SC-3, 4 & 5 only)**

This mode is used to test the over pressure feature on patient monitors. The SimCube readout will latch the highest pressure value sensed (in 1mmHg steps). When the input pressure has returned to 0 mmHg for 15 seconds, the latched value is cleared. Typically the monitor must be

placed into a test mode so that the software will not release the cuff pressure prior to the over pressure activating. The trigger point on the over pressure feature of many patient monitors can depend on the inflation rate, so care should be taken to create an inflation rate which is similar to that produced by the monitor's pump with a typical cuff.

- **NIBP Manometer**

SC-1, SC-2, SC-3, and SC-4: Static Manometer readout displays pressures from 0 to +400mmHg in 0.1mmHg steps. NIBP simulation is OFF.

SC-5: Static Manometer readout displays pressures from –400 to +400mmHg in 0.1mmHg steps. NIBP simulation is OFF.

This mode can be used for performing static calibration of NIBP monitors. In many cases the monitor must be placed in a special test mode so that it will not release the cuff pressure.

- **NIBP Leak Test (SC-5 only)**

This mode is used for measuring leak rates in NIBP monitors, their cuffs and their hoses. Until it detects that cuff inflation is complete, leak test mode will simply display the cuff pressure. Once cuff inflation completion is detected (less then 8mmHg change in a 5 seconds window), leak test mode will start its elapsed timer. When the elapsed timer reaches 15 seconds (to allow for initial pressure settling), the display will begin to cycle every 5 seconds showing static pressure, indicated by P (in mmHg); leak rate, indicated by L (in mmHg per minute); and elapsed time (in Min:Sec). In many cases the monitor must be placed in a special test mode so that it will not release the cuff pressure.

ECG/RESP Detailed Information

Before you begin, make sure you have your SimCube setup as described in 'Getting Started.' Available Simulation Modes are described below. Refer to the front panel of your SimCube simulator to determine which modes apply to your model.

• **ECG / RESP rate simulation modes (SC-4, -5 only)**
These modes produce NSR ECG waveforms at the rate indicated on the front panel. Respiration rates are also on the front panel.

• **ECG/RESP rate simulation modes (SC-2 only)**
These modes produce NSR ECG waveforms at the rate indicated below.

SC-2 ECG/Resp Values	
NIBP Manometer	**No ECG**
NIBP Adult (120/80)	**70/35**
NIBP Neo (70/40)	**94/47**
NIBP (190/120)	**70/35**
ECG Asystole	**0/0**
ECG Resp OFF	**70/0**
ECG Pacer ON	**70/35 w/pacer**

For ECG calibration purposes, the SimCube ECG waveform output is 1 mV on the following lead / configuration (software version is displayed on boot up):

Calibration point	SC-5 software version	SC-4 software version	SC-2 software version
1 mV on Lead I	Up to 4.1	Up to 3.1	Up to 1.9
1 mV on Lead II	4.2.X and later	3.2.X and later	1.10 and later

• **ECG Arrhythmia Simulation mode (SC-5 only)**

The Arrhythmia mode is designed to allow you to quickly check that all the life critical ECG alarms on a patient monitor are properly configured. The mode consists of a single cardiac failure sequence: 90 seconds of normal beats interspersed with PVCs and Runs, followed by approximately 30 seconds of VTACH, followed by 30 seconds of VFIB, concluding with 30 seconds of asystole. When the sequence is complete it restarts. RESP value stays at 00bpm.

• **ECG Pacer (SC-2, 4 & 5 only)**
NSR ECG at 70 bpm with pacer signal. RESP output rate is 35 bpm on SC-2 and SC-4 and 0 bpm on SC-5. This mode is designed to allow testing of a monitor's pacer detection and artifact stripping circuitry.

ECG/RESP HR Seq/Alarm Test mode (SC-4 and SC-5 only)

Paired ECG Heart rate and Respiration values will toggle every 30 seconds. ECG values: 30, 60, 90, 120, 45, 60, 160, 220. RESP values: 00, 30, 45, 60, 22, 30, 80, 110. This mode allows quick and complete testing of a monitor's cardiotach.

IBP Detailed Information (SC-5 Only)

Before you begin, make sure you have your SimCube setup as described in 'Getting Started.' The IBP interface to the SimCube simulator is a 6 pin mini DIN connector. For compact storage, each SimCube system is supplied with a single long (6') extension cable, which can be used with a variety of short (6") adapter cables that are sold separately. A variety of adapter cables are available from Pronk Technologies Inc. as is information to allow you to fabricate your own cables from the extension cable and an IBP cable you may have on hand. Wiring is as follows: + Excit = pin 1, - Excit = pin 4, + Sig = pin 3, -Sig = pin 6, which should be compatible with most other mini DIN IBP simulator cables. Contact Pronk Technologies Inc. at 800/541-9802 for more information.

• **IBP Dynamic Modes**

The pressure values of dynamic IBP modes match those of the NIBP values associated with the same mode and are indicated by the arrow ← on the front panel in the IBP column pointing towards the NIBP column.

• **IBP 0**

Use this mode to simulate atmospheric pressure and zero your monitor.

• **IBP 100**

The IBP 100 Mode will simulate a static 100mmHg which can be used for calibration.

• **IBP 200**

The IBP 200 Mode will simulate a static 200mmHg which can be used for calibration.

• **IBP Step**

The Step Mode will step through the following static values for 30 seconds each, then repeat the sequence: 0, 25, 50, 100, 150, 200, 250mmHg. This allows for a quick but complete check of the IBP channel over its entire range.

Battery Operation

SimCube models SC-3, SC-4 and SC-5 may be operated on battery power using the Battery Boost Option. The Battery Boost allows the user to switch between AC power and four “AA” batteries and it easily integrates with the SimCube padded carrying case. The Battery Boost is designed to operate with alkaline batteries for simplicity and convenience, however, please note that using NiMH batteries will provide the highest battery performance. Simulating only NIBP, the SimCube simulator can perform 100-200 NIBP simulation readings on a set of fresh NiMH batteries. While rechargeable batteries may be used, an external charger is required to recharge these batteries.

SC-5 models with software version 5.0 or higher include enhancements to help extend battery life while using the Battery Boost Option. Please note the following battery saving features in your new SC-5 as compared to any previous versions you may have:

• The display will be slightly dimmer.
• The SimCube will go into "sleep" mode when the NIBP functions are not in use, the display will go blank and the green Mode LED will flash.
• When the batteries are depleted, the Battery Level indicator on the Battery Boost will illuminate a red LED and the SimCube may re-boot to further indicate the need to replace the batteries.

1. CRITICAL OPERATION NOTES. PLEASE READ FIRST!

• You may use NiMH rechargeable batteries, but the Battery Boost does not charge them. Rechargeable batteries must be charged outside of the SimCube system.

• When the Battery Level indicator lamp is red your simulator may continue to operate, but values should not be trusted. Always confirm the Battery Level LED is green when doing a simulation on battery power.

• When your SimCube simulator is not in use, switch the Battery Boost to the “Batt OFF” position to avoid draining your batteries.

2. Installation

a. Connect the gray power cable from the Battery Boost to your SimCube simulator.
b. Insert four “AA” batteries into the battery carriage.
c. Position the switch on the battery module to “Batt ON.” The SimCube simulator will power on.

3. Operation Guide

a. Battery Operation

Simply Install batteries (alkaline or rechargeable) into Battery Boost and switch to “Batt ON” position. When you are done using your SimCube simulator switch to “Batt OFF.” When Batt level LED changes from green to orange, make sure you have a spare set of batteries on hand. When the Batt Level LED changes from orange to red, change the batteries. The Batt Level LED will turn orange when approximately 25% battery life remains (about 50 readings). Always double check that the switch is in the “Batt OFF” position when you are done; the numeric display on the SimCube simulator is blanked under certain conditions to conserve power so you cannot rely on that to indicate that the unit is off.

b. AC Operation

When AC power is available, simply plug the SimCube power supply into an AC outlet. The Battery Boost will automatically switch over to AC and your batteries will not be drained, regardless of whether the battery boost slide switch is in the on or off position. The “AC ON” indicator lamp will light continuously while the AC power supply is connected to a viable AC outlet, but when AC power is disconnected and the battery is switched on, the “AC ON” lamp may still emit a short flash every few seconds. During AC operation, the Batt Level LED may not accurately reflect the state of the batteries.

SimCube System Troubleshooting Tips

SYMPTOM	SOLUTION
Readings inconsistent or no reading at all	If using Battery Boost, be sure the Batt On/Off switch is ON and the Batt Level LED is green. If the Level LED is Red or dark, replace the batteries with a fresh set.
Readings inconsistent, error message (C05) on Welch Allyn 52000	Reduce/Control cuff volume and movement by inserting the cuff into the small sleeve of the Pronk Cuff Jacket Duo.
During NIBP simulation, monitor continually inflates cuff without reading	Check for leak in hose and cuff. Use standard adult size cuff only for adult and hyper modes. Neo mode requires size 3 or 4 (8-13cm) cuff to be effective. Reduce/Control cuff volume and movement by inserting either adult or neo size cuff into the small sleeve of the Pronk Cuff Jacket Duo.
Alaris / IVAC 4410 does not get readings	This device calculates diastolic during inflation. Wait until it is done with its first inflation cycle; it will automatically restart inflation and will get reading.
IVAC 4200 does not get readings	The IVAC 4200 is primarily an auscultatory blood pressure monitor, in fact there is a microphone built into the cuff itself. However, these monitors also have an oscillometric algorithm and will get consistent readings if you remove the cuff from the hose and connect the hose directly to the SimCube simulator.
Can't get RESP waveform on Datascope	Reconfigure snaps to the following: black lead to white RA, red lead to black LA and white lead to green RL.
Battery Boost Option does not charge batteries	This is by design. In order to allow customers to use off the shelf alkaline batteries, no charge current is applied to the batteries being used.
Readings are always high/low on specific model/manufacturer	Each model of monitor has a different algorithm for calculating NIBP values; therefore different models, even from the same manufacturer, can yield different results. Use the SimCube Sample Reading Chart as a reference.
Respiration does not count	The amplitude of the respiration signal was carefully selected to ensure that monitors will not count if 60hz noise is present. Some monitors may require an adjustment to increase resp size in order to get an accurate respiration rate.

SimCube won't read 0 (shows ––) at power up	During power on initialization, SimCube auto zeroes pressure itself. Therefore, vent circuit to atmosphere at power up and wait 15 seconds for auto zero to complete, signified by 000.0 on display of SimCube models SC-1, SC-2, SC-3 and SC-4 and SC-5 SW version up to 4.5. SC-5 version 5.0 or higher will display 0.0 when zeroed to atmosphere.
Can't connect 12 Leads to snaps	Order ECG snap extender, part number ECG EXTEND.
No heart rate on EASI configured Telemetry	When viewing AVR or V2 lead, change the V lead to V6 snap.
ECG is Noisy	The noise may point to a ground loop issue. Check for ground loop noise by running the SimCube on battery power to see if the noise still exists. If it is present, check to see that the monitor under test has its A/C filter(s) enabled. Please note that monitors may have more than one filter that filter out of different frequencies.
Unable to resolve problem	**Contact Pronk Technologies' Technical Support at:** (800) 541-9802

Accessories

P/N	DESCRIPTION
ADAPT-D	**DINAMAP/Critikon style**: A threaded screw-on connector, used on Critikon and MDE monitors.
ADAPT-M	**Marquette style**: A freely-rotating twist-on connector, used on GE/Marquette monitors.
ADAPT-Q	**Quick Disconnect**: A push-pull quick disconnect connector used on HP monitors.
ADAPT-L	**Luer**: A friction-based connector used on Spacelab monitors and most neonatal monitors.
ADAPT-B	**Bulb Adapter**: This hand bulb adapter is utilized in static calibration, as well as in Over Pressure Mode for SimCube models SC-3, SC-4 and SC-5.
ADAPT-FP	**Welch Allyn Flexiport style:** A snap connector, used on any monitor with Welch Allyn Flexiport cuff.
ECG Extend	**ECG Snap Extender**: If using 12-lead clips or banana plugs instead of snaps to connect to the SimCube, the ECG Extender Module is recommended.

Case SC-5 OxSlim	**Large Nylon Carrying Case –** This case is for use with the **SimCube** and all accessories. It is large enough to hold all the IBP adapter cables, Battery Boost Module, NIBP adapters and more.
CUFF JACKET DUO SLEEVE	**Cuff Jacket -** Slide the NIBP cuff inside our patented Cuff Jacket to create a controlled and repeatable cuff volume without the need for bulky mandrels. Use of the Cuff Jacket is suggested for optimum repeatability on most monitors. The small Cuff Jacket sleeve is required on some NIBP monitors such as Welch Allyn 52000 series.
IBP-EXT CABLE	**IBP Extension Cable –** This six foot long extension cable allows you to use any of the interface cables below.
IBP-PHILIPS	**IBP Interface Cable for HP Merlin/Philips Monitors -** This cable has a six pin mini-DIN to Merlin style connector. It is six inches long and works with the IBP-Extension cable.
IBP-DATASCOPE	**IBP Interface Cable for Datascope Monitors -** This cable has a six pin mini-DIN to Datascope connector. It is six inches long and works with the IBP-Extension cable.
IBP-GE	**IBP Interface Cable for GE/Marquette Monitors -** This cable has a six pin mini-DIN to GE style connector. It is six inches long and works with the IBP-Extension cable.
IBP-MDE	**IBP Interface Cable for MDE/Spacelabs Monitors -** This cable has a six pin a mini-DIN to MDE/Spacelabs style connector. It is six inches long and works with the IBP-Extension cable.
IBP-Datex	**IBP Interface Cable for Datex Ohmeda Monitors -** This cable has a six pin mini-DIN to Datex Ohmeda style connector. It is six inches long and works with the IBP-Extension cable.
IBP-Draeger	**IBP Interface Cable for Draeger Monitors -** This cable has a six pin mini-DIN to Draeger style connector. It is six inches long and works with the IBP-Extension cable.
IBP-Fukuda	**IBP Interface Cable for Fukuda Denshi Monitors -** This cable has a six pin mini-DIN to Fukuda Denshi style connector. It is six inches long and works with the IBP-Extension cable.
IBP-NK	**IBP Interface Cable for Nihon Kohden Monitors -** This cable has a six pin mini-DIN to Nihon Kohden style connector. It is six inches long and works with the IBP-Extension cable.

Services (Please Call For Pricing)

SERVICE ITEM NUMBER	DESCRIPTION
SC-1/3 Upgrade Service	SC-1 to SC-3 Upgrade
SC-1/4 Upgrade Service	SC-1 to SC-4 Upgrade
SC-2/4 Upgrade Service	SC-2 to SC-4 Upgrade
SC-2/5 Upgrade Service	SC-2 to SC-5 Upgrade
SC-3/4 Upgrade Service	SC-3 to SC-4 Upgrade
SC-4/5 Upgrade Service	SC-4 to SC-5 Upgrade
Warranty-SC-1	Extended Warranty* – 1 year
Warranty-SC-2	Extended Warranty* – 1 year
Warranty-SC-3	Extended Warranty* – 1 year
Warranty-SC-4	Extended Warranty* – 1 year
Warranty-SC-5	Extended Warranty* – 1 year
Calibration Service SC-1 / SC-3	Full checkout and calibration including certification
Calibration Service SC-2 / SC-4	Full checkout and calibration including certification
Calibration Service SC-5	Full checkout and calibration including certification
Rejuvenation	SimCube Rejuvenation Service: - Complete checkout, calibration including certificate, and replacement of visually worn parts.
Check Out Service	Non-warranty repair estimate

*Pronk Technologies recommends an annual calibration interval.

*Extended Warranty (up to 5 years total) may be purchased only at time of original sale or with purchase of Rejuvenation Service

Warranty and Service Information

SimCube Limited Warranty

The SimCube NIBP Simulator with optional ECG/Respiration and IBP feature is warranted against defects in materials and workmanship for a period of forty-eight (48) months from the date of shipment to the original purchaser. Warranty is valid only to the original buyer. Defective equipment should be returned freight prepaid to Pronk Technologies Inc. Equipment returned with defective parts and assemblies shall be either repaired or replaced at the manufacturer's sole discretion. This warranty is not applicable if the unit has been opened, if repair has been attempted, if the unit has been damaged due to operation outside the environmental and power specifications for the product, or due to improper handling or use.

If any fault develops, notify Pronk Technologies (see Returns and Repairs, below) giving full details of the difficulty, and include the model and serial number of the device. Upon receipt of shipping instructions, forward the device prepaid and repairs will be made at the factory.
The foregoing warranty is in lieu of all other warranties expressed or implied, including but not limited to any implied warranty or merchantability, fitness or adequacy for any particular purpose or use. Pronk Technologies shall be liable only for repair or replacement of the SimCube NIBP Simulator and optional features. Pronk Technologies shall not be liable for any incidental or consequential damages.

Order Cancellation and Refund Policy

You may return your item within 14 days of delivery for a full refund. We are unable to exchange items (however, if you received a defective or incorrect item, we will be happy to make an exchange). Item(s) returned for refund must be in its original condition, undamaged and with no missing parts, packed in its original packaging, and include both the original receipt and an RMA number.
We will notify you via e-mail or fax of your refund once we have received and processed the returned item. You can expect a refund in the same form of payment originally used for purchase within 7 to 14 business days of our receiving your return.

Returns and Repairs

Please call Pronk Technologies' Service Department at 800-541-9802 to obtain a Return Merchandise Authorization (RMA) number and the shipping address. Returns should be packaged securely in the original packaging materials. The RMA number should be clearly marked on the packaging. If the return is for a new item and is a result of our error, we will make arrangements for payment of return shipping. Otherwise, items should be returned freight prepaid to Pronk Technologies.

Optimizing Simulation Results With Your SimCube Oscillometric NIBP Simulator *by Karl Ruiter, Pronk Technologies Inc.*

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.

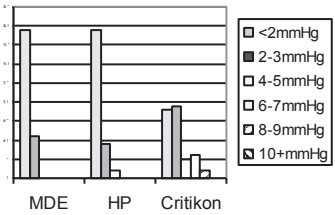
Neo Mode Simulation Setup

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:

On the Web at:	www.pronktech.com
By email at:	sales@pronktech.com
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SimCube Sample Readings

Different manufacturers, different models and sometimes even different software versions can give quite different readings, but the following are some average values obtained from a variety of devices.

Model	Systolic	Diastolic	Systolic STD Dev	Diastolic STD Dev
Alaris 4410	128.7	77.7	3.0	3.7
Alaris 4510	120.3	79.0	4.6	1.8
Colin BP8800C	116.8	78.0	1.3	1.2
Critikon 8700	118.3	78.9	2.8	3.0
Critikon 1846SX	117.0	79.0	0.7	0.0
CAS	117.1	85.3	1.2	0.7
CSI	123.0	82.0	N/A	N/A
Datascope Accutor	119.9	73.0	4.2	2.9
Datascope Passport	118.5	72.6	0.8	2.3
Draeger	119.7	79.0	0.6	1.0
Fukuda Denshi	118.6	78.5	0.5	0.4
GE Dash 3000	120.3	78.7	2.9	1.2
GE Pro200	107.0	82.6	2.9	4.0
GE Pro 400	113.1	73.6	5.0	5.2
GE Pro 400 V2	120.0	80.9	4.0	1.0
GE Procare 400	120.6	79.2	1.9	1.4
GE/Marquette Solar 8000	119.8	81.3	1.0	1.7
HP Merlin	113.0	74.0	3.1	4.3
HP Viridia	120.0	72.7	1.5	2.2
IVAC4200	118.5	82.0	0.7	1.4
J & J	117.0	79.0	N/A	N/A
Marquette Eagle	114.2	78.7	1.8	0.7
MDE E300	117.9	78.8	1.5	1.0
MDE Prism	119.0	82.6	1.2	0.7
Nihon Khoden	110.1	80.1	0.8	1.2
Nonin Avant	116.7	73.2	2.9	0.9
Philips Heart Smart	108.1	77.1	2.8	1.0
Phillips Intelliview	119.7	80.7	1.2	4.2
Phillips M8007	116.7	77.7	0.6	1.5
Phillips VS-1	121.9	78.0	1.8	1.7
Phillips VS-3 and VM-6	115.9	83.7	1.8	0.9
Spacelabs 90369	114.9	78.3	0.9	0.8
Welch Allyn 52000	121.4	83.8	2.8	2.8
Welch Allyn VS	116.1	83.1	3.2	3.2
Welch Allyn Spot VS LXi	117.2	81.4	1.0	0.8
Zoll Defib M Series	108.8	77.2	1.3	0.77