SunTech Medical: NIBP Simulator Limits with the Advantage OEM NIBP Module Series

When potential customers evaluate the Advantage NIBP module with a view to developing manufacturing procedures, often an NIBP simulation or group of simulations are performed using an NIBP simulator. Some will ask for expected values. These values are dependent on several factors including the type of simulator, settings, age of the instrument, software version, pneumatic setup and module configuration bytes. Thus it is difficult to provide meaningful min/max values without testing under identical conditions.

This application note provides general limits expected for 5 simulator brands at various settings. These limits were derived using specific equipment arranged in a precise manner. If these data are to be relied upon, we recommend the test conditions be replicated exactly. Even so, results may vary due to the vagaries of the specific instrument.

Protocol

It is important that the equipment and procedures described in this section be replicated as closely as possible. Deviating from them may result in acquired data inconsistent with these published performance limits.

The five NIBP simulators we chose are most commonly used by NIBP developers, medical monitoring companies and biomedical engineering departments throughout the world. They are as follows:

- Fluke Biomedical Cufflink, software 3.21
- Bio-Tek BP Pump, software 3.32
- Fluke Biomedical BP Pump 2, software 1.15
- Metron QA-1290, software 1.70E, hardware 4.01
- Clinical Dynamics SmartArm, software 7.19A

This is not a comprehensive list as we are aware of other NIBP simulators on the market. In the future, we may develop additional information for other instruments.
Four preset simulations were chosen – hypotensive, normotensive, hypertensive and a neonatal setting. These settings represent a broad spectrum and fit into most evaluation and manufacturing procedures. The actual simulator target values for each setting are in table 1. For most settings, there is a slight variation in target values between simulators.

Table 1a

Simulator	**Hypertensive HR= 80 bpm**
Cufflink	200/150/165
BP Pump	200/150/166
BP Pump 2	200/150/166
Metron QA-1290	200/140/167
SmartArm	200/136/166

Table 1b

Simulator	**Normotensive HR= 80 bpm**
Cufflink	120/90/80
BP Pump	120/80/93
BP Pump 2	120/80/93
Metron QA-1290	120/80/95
SmartArm	120/80/95

Table 1c

Simulator	**Hypotensive HR= 80 bpm**
Cufflink	80.50/62
BP Pump	80/50/60
BP Pump 2	80/50/60
Metron QA-1290	80/48/58
SmartArm	80/50/60

Table 1d

Simulator	**Neonatal HR= 120 bpm**
Cufflink	60/30/40
BP Pump	60/30/40
BP Pump 2	60/30/40
Metron QA-1290	60/30/40
SmartArm	60/30/40

Artifact settings were not selected since they typically are not utilized during general manufacturing.

Ten Advantage Model 2 OEMNIBP modules were used to derive the performance limits for these NIBP simulators. Each simulator setting was performed three times per module for a total of 30 simulations per setting. Statistical analysis was done by calculating the mean (average) and standard deviation for each group of 30 simulations. The mean shows the shift from the target value and the standard deviation was used to determine the span between the minimum and maximum limits. The limits are based on 4 standard deviations. Thus low quality NIBP simulators have wider limits and high quality NIBP simulators have tighter limits.

Setup

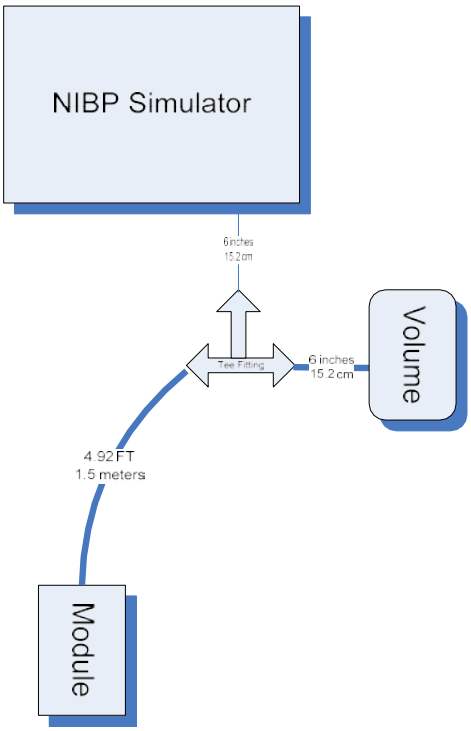
When applicable, no internal volumes were engaged. For all adult simulations, a 500mL rigid volume was attached to the pneumatic setup. Neonatal simulations were performed with a #3 neonate cuff wrapped tightly around a rigid cylinder within its range.

Note 1: The SmartArm neonatal mode produces a pulse amplitude that is too large therefore the 500mL volume was used to ensure proper pulse amplitude.

Note 2: The Cufflink neonatal mode produces a pulse amplitude that is too large so the gain had to be reduced to 80%.

The NIBP module being tested was connected to the volume and simulator using a 5 ft (1.5m) length of polypropylene tubing patient hose which is the same type of hose provided in the Advantage development kits. It has a durometer of 80 Shore A and inner diameter of 0.125 inches (3.2mm). It is strongly advised not to use tubing that is lower in durometer, inner diameter or vary the length by more than 20 inches (0.5m). Tubing to the volume and simulator was 6 inches (15.2 cm) and was the same silicone tubing used as the exit tubing on the module manifold. This tubing has a durometer of 50 Shore A and inner diameter of 0.094 inches (2.4mm). Similar tubing material, durometer, inner diameter and length should be used. Do not decrease the durometer below 50 Shore A and do not increase each length beyond 10 inches (25.4 cm).

Figure 5



Results

The performance limits provided are for the latest SunTech firmware (LM3.395) in the Advantage module series. If you are testing modules with previous firmware versions, please contact SunTech Medical to see if these limits apply to your version.

Limits are provided for both measured MAP and calculated MAP. The module measures MAP during its data collection process but can output either measured or calculated MAP depending on the customer's preference. This is set at the factory and is not user-selectable.

When evaluating your own results, it is important to remember the following NIBP simulator guidelines:

1. NIBP simulator target values should never be considered as a standard of accuracy. All NIBP simulator manuals explain or should explain that the target values are approximations and should only be used for measuring repeatability and agreement. Accuracy is only measured using human subjects and accuracy requirements and test methods are given in the AAMI SP10 Standard for Automated Sphygmomanometers. This standard does not apply at all to measurements done with NIBP simulators.

2. The Advantage module usually provides measurement values EVEN IF AN ERROR CODE OCCURS. For all error codes, these measurement values should be disregarded and considered unusable during any type of evaluation.

3. NIBP modules from different manufacturers will usually give different results on the same simulator setting. This is normal and expected primarily due to a number of algorithm differences between manufacturers. THE OEM NIBP MODULE THAT BEST MATCHES UP WITH TARGET VALUES IS NOT NECESSARILY THE BETTER MODULE. Remember, NIBP simulators cannot be used to measure clinical accuracy.

4. On many NIBP simulators, the Advantage module will output significantly higher BP values on hypertensive settings. This is normal and expected due to differences in oscillation amplitude ratios in NIBP simulators and the Advantage BP algorithm. Many NIBP simulators choose to have the same ratio throughout the entire pressure range. Our clinical evidence shows this is not true on humans so we developed a dynamic ratio that changes based on pressure. The net effect of this difference is that for some NIBP simulator settings, the Advantage module BP results will be somewhat different than the target values.

5. The Advantage module will provide different results on different NIBP simulators for the same setting. This is normal and expected due to simulator differences.

Cufflink, SW Ver. 3.21

	SYS	DIA	Meas. MAP	Calc. MAP	HR
Setting	200	150	165	n/a	80
Mean	209	151	165	170	81
Sd Dev	1.03	2.52	1.29	1.55	0.90
Hypertensive Limits					
Min	205	140	160	164	77
Setting	120	80	90	n/a	80
Mean	117	82	92	94	81
Sd Dev	1.17	1.41	1.07	1.04	0.50
Normotensive Limits					
Min	112	77	87	90	78
Setting	80	50	62	n/a	80
Mean	77	52	60	60	81
Sd Dev	*1.54*	*0.78*	*0.66*	*0.71*	*0.65*
Hypotensive Limits					
Min	71	49	56	57	78
Setting	60	30	40	n/a	120
Mean	60	33	40	42	121
Sd Dev	1.84	1.11	0.85	0.74	0.91
Neonatal Limits (80% Gain)					
Min	52	28	36	38	117
Max	67	37	44	46	125

Bio-Tek BP Pump, SW Ver. 3.32

	SYS	DIA	Meas. MAP	Calc. MAP	HR
Setting	200	150	166	n/a	80
Mean	213	155	169	174	80
Sd Dev	2.47	2.20	1.36	1.73	1.19
Hypertensive Limits					
Min	203	146	163	167	76
Max	223	164	174	181	86
Setting	120	80	93	n/a	80
Mean	123	84	94	97	80
Sd Dev	1.48	0.83	0.83	0.68	0.86
Normotensive Limits					
Min	116	80	90	94	77
Max	129	87	98	101	84
Setting	80	50	60	n/a	80
Mean	78	53	60	61	81
Sd Dev	1.10	0.91	0.68	0.70	0.81
Hypotensive Limits					
Min	74	49	57	58	78
Max	83	57	63	65	84
Setting	60	30	40	n/a	120
Mean	63	33	42	43	120
Sd Dev	1.01	0.67	0.92	0.57	1.05
Neonatal Limits					
Min	59	30	38	40	115
Max	67	37	45	46	124

BP Pump 2, SW Ver. 1.15

	SYS	DIA	Meas. MAP	Calc. MAP	HR
Setting	200	150	166	n/a	80
Mean	210	154	167	173	80
Sd Dev	3.72	2.43	1.55	2.03	0.50
Hypertensive Limits					
Min	195	144	161	165	78
Max	225	167	174	181	83
Setting	120	80	93	n/a	80
Mean	121	85	94	97	81
Sd Dev	2.07	1.25	1.23	1.23	0.86
Normotensive Limits					
Min	113	79	89	92	77
Max	129	90	99	102	85
Setting	80	50	60	n/a	80
Mean	78	55	62	62	81
Sd Dev	0.82	0.86	0.78	0.71	0.51
Hypotensive Limits					
Min	74	51	58	59	78
Max	82	58	65	66	83
Setting	60	30	40	n/a	120
Mean	58	34	41	42	120
Sd Dev	3.05	1.38	1.00	0.86	1.50
Neonatal Limits					
Min	46	29	37	38	112
Max	71	40	45	46	126

Metron QA-1290, SW Ver. 1.70E, HW Ver. 4.01

	SYS	DIA	Meas. MAP	Calc. MAP	HR
Setting	200	140	167	n/a	80
Mean	199	146	162	164	80
Sd Dev	5.04	2.88	2.33	3.05	0.63
Hypertensive Limits					
Min	179	134	152	152	77
Max	220	157	171	177	83
Setting	120	80	95	n/a	80
Mean	118	83	94	95	80
Sd Dev	3.79	2.25	1.71	2.24	1.03
Normotensive Limits					
Min	103	74	87	86	76
Max	133	92	101	104	85
Setting	80	48	58	n/a	80
Mean	75	50	59	58	80
Sd Dev	2.41	2.64	1.54	1.91	0.86
Hypotensive Limits					
Min	65	40	52	51	77
Max	84	61	65	66	84
Setting	60	30	40	n/a	120
Mean	55	35	41	42	120
Sd Dev	1.59	2.62	2.52	2.02	1.86
Neonatal Limits					
Min	49	25	31	34	113
Max	62	46	51	50	128

SmartArm, SW Ver. 7.19A

	SYS	DIA	Meas. MAP	Calc. MAP	HR
Setting	200	136	166	n/a	80
Mean	201	142	156	162	81
Sd Dev	1.80	2.65	1.48	1.52	0.62
Hypertensive Limits					
Min	193	132	150	156	78
Max	208	153	162	168	84
Setting	120	80	95	n/a	80
Mean	125	83	94	97	81
Sd Dev	1.20	0.85	0.83	0.74	0.86
Normotensive Limits					
Min	120	80	91	94	77
Max	129	87	98	101	85
Setting	80	50	60	n/a	80
Mean	83	54	61	63	80
Sd Dev	2.00	1.11	0.93	0.99	0.57
Hypotensive Limits					
Min	75	49	58	59	77
Max	91	58	65	67	84
Setting	60	30	40	n/a	120
Mean	64	32	41	42	120
Sd Dev	1.27	1.35	1.28	0.98	0.72
Neonatal Limits (Adult Volume)					
Min	59	26	35	38	117
Max	69	37	46	46	124

Conclusions

Lesser quality NIBP simulators can produce greater variability in a set of measurements which is revealed by the standard deviation. Higher standard deviations will also have wider min/max limits.

Based on our testing, we recommend using the Fluke Biomedical Cufflink or the Clinical Dynamics SmartArm. The BP Pump is also an acceptable instrument, however, it is no longer commercially available. We do not recommend the Fluke Biomedical BP Pump 2 and the Metron QA-1290.

We provide these limits and recommendations to assist anyone using NIBP simulators with the Advantage series of modules. While we have collaborated in the past with an instrument manufacturer, our performance assessments are completely independent. All recommendations herein are based solely on scientific principles and actual acquired data as well as significant clinical experience with our Advantage series of OEM NIBP modules.