

SunTech Medical: A Controlled Laboratory Comparison of three NIBP Devices on Cats and Dogs

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.

While there are no formal veterinary regulatory requirements or guidelines, SunTech Medical, Inc. has recognized the need and obligation to study veterinary populations. We have confirmed that human monitors utilizing oscillometric technology do not have the sensitivity or range to be accurate in animals. We therefore have focused on the Veterinary market and the unique requirements of taking blood pressure readings on patients unable to interact or communicate. The clinical environment is further complicated in the alert patient due to the stresses of being in an unfamiliar place surrounded by startling sounds and smells. Since animal types vary, structural, anatomical, physiological and pulse pressure properties further complicate accurate blood pressure monitoring even in sedated/anesthetized patients. Our Veterinary algorithm has been refined to accommodate these concerns and manage patient motion artifact thereby maximizing utility in both the awake and sedated patient.

Taking all these factors into consideration, we have identified specific characteristics which are essential for designing an oscillometric blood pressure system for veterinary applications.

- Since animal types vary, systolic and diastolic pressures can be very high and extremely low. Accuracy is required throughout the expanded range.
- The BP system must be easy to use since the training and skill level of veterinary technicians vary.
- The BP monitor must be able to obtain accurate results on almost every attempt.
- Taking a reliable reading on the first attempt is crucial since an alert animal may become increasingly agitated.

To put our Advantage 2 Veterinary module to the test, we conducted a controlled trial at the North Carolina State University College of Veterinary Medicine. Our vet NIBP algorithm was compared against a Cardell Model 9402 NL monitor and a Critikon Dinamap Plus 9720 monitor on both dogs and cats. The reference device was a Ultrasonic Doppler Flow Detector Model 811-B. While it can be argued that Doppler does not provide a diastolic value, the technology is universally accepted in Veterinary Medicine to

provide systolic values. A wide variety of animal subjects were used in this comparison to better replicate actual conditions in a Veterinary Clinic.

Methods

The data collection methodology included gathering pre and post Doppler measurements where oscillometric NIBP measurements were taken in between the pre and post Doppler measurements. The oscillometric NIBP measurements were performed simultaneously on contralateral limbs with the SunTech Advantage module on one and a competitive device on the other. Three simultaneous measurements were done. Both the pre and post Doppler values were calculated by performing three sequential Doppler measurements which were averaged together.

All measurements were performed on both alert and sedated/anesthetized dogs and cats. In general, most dogs were anesthetized and most cats were awake. Animal conditions varied from healthy to critical to more closely replicate real conditions in a veterinary environment. The majority of animals had some sort of health issue ranging from dental prophylaxis to brain surgery. Subject (cat and dog) blood pressures included hypotensive, normotensive and hypertensive.

Weights and ages for cats varied from 1.3 to 10 kg (2.9 to 22.0 lb) and 8 weeks to 17 years old. For dogs, weights were 8 to 44 kg (17.6 to 97 lb) and ages were 1 to 13 years old. A total of 29 cats and 48 dogs were involved in this comparison. The majority of subjects were included in the Cardell arm of the comparison (29 cats, 28 dogs). The remaining 20 dogs were included in the Critikon Dinamap comparison.

Since Doppler measurements only provide a systolic measurement, comparisons for diastolic, mean arterial pressure (MAP) and heart rate were not performed.



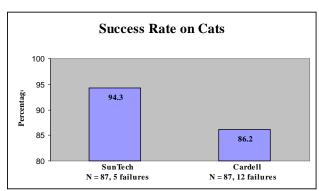
Results

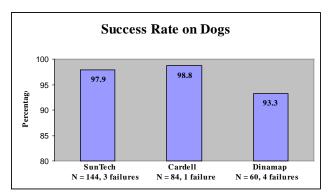
Table 1a & 1b: Systolic comparisons with Doppler reference on cats and dogs

SunTech - Cardell Systolic Accuracy Comparison			
Cats (n = 29)	Mean	Standard Dev	
SunTech Advantage	-2.7	28.1	
Cardell Monitor	15.5	34.5	
Dogs (n = 28)			
SunTech Advantage	3.0	18.1	
Cardell Monitor	4.7	21.4	

SunTech - Dinamap Systolic Accuracy Comparison			
Dogs (n = 20)	Mean	Standard Dev	
SunTech Advantage	1.1	11.7	
Dinamap Monitor	5.0	20.8	

Table 2a & 2b: Oscillometric device success rates on cats and dogs





While accuracy is, without question, an important attribute in NIBP monitoring, reliability and consistency are particularly valuable in Veterinary Medicine. Operator confidence in being able to get needed results with the Advantage Model 2 Veterinary module can facilitate interventions in these traditionally difficult to manage patients.

Consolidation of these data together with our experience from our ongoing research serves to optimize our algorithms facilitating continuous improvements. Our entry into the Veterinary marketplace, a logical extension of our core competency, confirms our credibility and commitment to our customers.