

# An accuracy study for the DINAMAP SuperSTAT NIBP technology for neonatal/infant population

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## INTRODUCTION

The purpose of this clinical study was to determine the accuracy of the DINAMAP\* SuperSTAT blood pressure technology in neonatal/infant subjects according to the ANSI/AAMI SP-10:2002 Standard. Systolic, diastolic, mean arterial pressure (MAP), and pulse rate (PR) were compared to intra-arterial blood pressure (IBP). The study took place in neonatal intensive care units and cardiac catheterization laboratories. Institutional Review Board (IRB) approvals were granted and informed consent was obtained.

## METHOD

Data were collected according to the ANSI/AAMI SP-10:2002 Standard specifications, utilizing static and dynamic calibration procedures to ensure the accuracy of the IBP. A computer program recorded the SuperSTAT NIBP simultaneously with the IBP. A sample of 15 neonatal and 6 infant subjects was in the data analysis. NIBP determinations were taken using a blood pressure cuff on the neonate's calf or infant's upper arm. Six sizes of blood pressure cuffs were used; neonatal CRITIKON\* SOFT-CUF\* cuff sizes 2, 3, 4, and 5, as well as CRITIKON DURA-CUF\* infant and child size cuffs.

## RESULTS

The differences between the SuperSTAT algorithm and the IBP reference were analyzed according to the ANSI/ AAMI SP-10:2002 Standard. see Table 1.

Parameter	Mean	Standard Deviation
Systolic difference (mmHg)	3.35	4.54
Diastolic difference (mmHg)	-0.92	3.51
MAP difference (mmHg)	-0.80	3.20
Pulse rate difference (bpm)	-0.17	1.28

Table 1. Mean differences between SuperSTAT NIBP and the IBP reference:

## CONCLUSION

The SuperSTAT NIBP algorithm met the ANSI/AAMI SP-10:2002 Standard accuracy specifications of  $\pm 5$  mmHg for mean difference and  $\leq 8$  mmHg standard deviation for the neonatal/infant population.

## ADDITIONAL RESOURCES

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