

## OEM MAXNIBP<sup>®</sup> - ND+ Module Accuracy

Meets: ANSI/AAMI SP-10 (1992 and 2002)

### ANSI/AAMI SP-10

The MAXNIBP ND+ module meets the 1992 and 2002 AAMI SP-10 requirements for accuracy (ANSI/AAMI American National Standards Institute/Association for the Advancement of Medical Instrumentation).

1992:  $\pm 5$  mmHg

Standard Deviation  $\leq 8$  mmHg

2002: More Restrictive Sliding Scale

As the mean difference increases, the allowable standard deviation decreases:

- at  $\pm 0$  mmHg - SD 6.95 mmHg
- at  $\pm 5$  mmHg - SD 4.81 mmHg

Mean Difference	Standard Deviation
0	6.95 or less
$\pm 0.5$	6.93 or less
$\pm 1.0$	6.87 or less
$\pm 1.5$	6.78 or less
$\pm 2.0$	6.65 or less
$\pm 2.5$	6.47 or less
$\pm 3.0$	6.25 or less
$\pm 3.5$	5.97 or less
$\pm 4.0$	5.64 or less
$\pm 4.5$	5.24 or less
$\pm 5.0$	4.81 or less

### British Hypertensive Society

The data gathered using the AAMI SP10 protocol was further analyzed using the British Hypertension Society grading criteria to determine the overall BHS rating.

The ND+ module achieved a grade of A for Systolic and A for Diastolic for an overall grade of A/A.\*

Grade	Absolute Difference Between Standard and Test Device		
	< 5%	<10%	<15%
A	60	85	95
B	50	75	90
C	40	65	85
D	Worse than C		

\*Data on File