

# Caretaker4<sup>®</sup> Clinical Specifications Datasheet

<b>NON-INVASIVE BLOOD PRESSURE (NIBP) STANDARDS &amp; COMPLIANCE DATA (SELF CALIBRATION)</b>			
Compliance Standard	ANSI/AAMI/ISO 81060-2:2013 Non-Invasive Sphygmomanometers – Part 2: Clinical Investigation Of Automated Measurement Type		
Principle Of Operation	Oscillometry		
Systolic	Range:	60 – 240 mmHg	
	Accuracy:	Mean Error < ± 5 mmHg, Std. Dev. ≤ 8 mmHg	
	Resolution:	1 mmHg	
Diastolic	Range:	40 – 160 mmHg	
	Accuracy:	Mean Error < ± 5 mmHg, Std. Dev. ≤ 8 mmHg	
	Resolution:	1 mmHg	
Mean Arterial Pressure	Range:	50 – 185 mmHg	
	Accuracy:	Mean Error < ± 5 mmHg, Std. Dev. ≤ 8 mmHg	
	Resolution:	1 mmHg	
Validation Study	Standard-Compliant Simultaneous RRK Readings By Two Clinicians 49 m / 77 f, Mean Age: 45.3 y, SD: 14.6 y, Mean Weight: 87.6 kg, SD: 24.3 kg		
	Systolic Specifics		Diastolic Specifics
Sample Size:	331 Data points		
Mean:	-1.42 mmHg	2.24 mmHg	
Standard Deviation:	6.68 mmHg	6.46 mmHg	
Correlation:	0.90	0.88	
Upper 95% Limits Of Agreement (+1.96 SD):	11.67	10.42	
Lower 95% Limits Of Agreement (-1.96 SD):	14.51	14.90	
<b>CONTINUOUS NON-INVASIVE BLOOD PRESSURE (cNIBP) &amp; VITAL SIGN STANDARDS &amp; COMPLIANCE DATA</b>			
Compliance Standard	ANSI/AAMI/ISO 81060-2:2013 Non-Invasive Sphygmomanometers – Part 2: Clinical Investigation Of Automated Measurement Type		
Principle Of Operation	Pulse Decomposition Analysis		
Systolic	Range:	60 – 240 mmHg	
	Accuracy:	Mean Error < ± 5 mmHg, Std. Dev. ≤ 8 mmHg	
	Resolution:	1 mmHg	
Diastolic	Range:	40 – 160 mmHg	
	Accuracy:	Mean Error < ± 5 mmHg, Std. Dev. ≤ 8 mmHg	
	Resolution:	1 mmHg	
Mean Arterial Pressure	Range:	50 – 185 mmHg	
	Accuracy:	Mean Error < ± 5 mmHg, Std. Dev. ≤ 8 mmHg	
	Resolution:	1 mmHg	
BP Accuracy Validation Study	ICU-Based Cohort With Radial Artery Catheter 23 m / 11 f, Mean Age: 44.05 y, SD: 13.9 y, Mean Weight: 95.3 kg, SD: 27.4 kg		
Heart Rate	Tracking Accuracy: Heart Rate < 2 BPM, Beat By Beat Inter-Beat Interval < 6 ms, Range 30 – 200 bpm		
	Systolic Specifics	MAP Specifics	Diastolic Specifics
Sample Size:	99,432 Data Points		
Mean:	-0.36 mmHg	1.50 mmHg	-0.52 mmHg
Standard Deviation:	7.66 mmHg	6.77 mmHg	6.98 mmHg
Correlation:	0.91	0.81	0.83
Upper 95% Limits Of Agreement (+1.96 SD):	14.65	11.77	13.16
Lower 95% Limits Of Agreement (-1.96 SD):	15.37	14.77	14.20