



Technology Applications Center for Healthful Lifestyles

Quarterly Report in Remote Patient Monitoring

Report 1. Peripheral Devices for Blood Pressure Management



This report is intended to serve as a quick guide for clinicians, researchers, and innovators who are interested in using mobile-based blood pressure monitoring devices in their research or practice. Access to key references and information relating to FDA clearance, validation data, Bluetooth capability, and other parameters is helpful toward navigating decisions about what devices may have the most utility. Devices are typically developed for iPhone (iOS) users but data suggest that 65% of MUSC patients are Android users, indicating a need for devices that function well with both operating systems. For more information on how these devices could be used in your clinic/research, please feel free to contact the Director of TACHL, Dr. Frank Treiber, at treiberf@musc.edu.

Our next report, which we will make available in January 2017, will address Remote Patient Weight Monitoring.

Device	OS	Native App	Cuff Circumference	BLE	SCTA Approved Integration	FDA Cleared	Multiple Users	Validation*
A&D BP UA-651		A&D Connect	23-37 cm 31-45 cm	✓	✓	✓	✓	✓ ¹
iHealth BP5		iHealth MyVitals	22-42 cm 42-48 cm	✓	✓	✓	✓	✓ ²
Withings BP-800		Withings Health Mate	22-42 cm	✗	✓	✓	✓	✓ ³
Withings BP-801		Withings Health Mate	22-42 cm	✓	✓	✓	✓	✓ ⁴
Omron HEM-9200T BP		OMRON Connect	22-42 cm	✓	✓	?	?	✓ ⁵
Fora TN'G BP		iFora App	24-43 cm	✓	✓	?	✓	✓ ⁶

Note. OS = Mobile Operating System; BLE = Bluetooth Low Energy Enabled; SCTA = South Carolina Telehealth Association; * = The gold standard for measurement is intra-arterial blood pressure; typical validation procedures include a sphygmomanometer reading within 5 mmHg of intra-arterial blood pressure.

¹ = Device-mercury sphygmomanometer disagreement -0.4±4.4 mmHg for systolic blood pressure (SBP) and -1.3±3.5 mmHg for diastolic blood pressure (DBP) Benetti E, Fania C, Palatini P (2014). Validation of the A&D BP UA-651 device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010; *Blood Press Monit* **19**:50-53.

² = Device-mercury sphygmomanometer disagreement -1.21±5.87 mmHg for SBP and -1.04±5.28 mmHg for DBP Shang F, Zhu Y, Zhu Z, Liu L, Wan Y (2013). Validation of the iHealth BP5 wireless upper arm blood pressure monitor for self-measurement according to the European Society of Hypertension International Protocol revision 2010; *Blood Press Monit* **18**:278-281.

³ = Device-mercury sphygmomanometer -0.2±5.0 mmHg for SBP and 0.4±4.2 mmHg for DBP Topouchian J, Agnoletti D, Blacher J, Youssef A, Chahine M, Ibanez I,...Asmar R. Validation of four devices: Omron M6 Comfort, Omron HEM-7420, Withings BP-800, and Polygreen Kp-7670 for home blood pressure measurement according to the European Society of Hypertension International Protocol 2014; *Vasc Health Risk Manag* **10**:33-44.

⁴ = Predicate device Withings BP 800 and validation is based on Topouchian et al., 2014, *Vasc Health Risk Manag* **10**:33-44.

⁵ = Device-observer disagreement 2.5±4.6 for SBP and -1.2±4.3 for DBP based on predicate devices Omron M6 Comfort and Omron HEM-7420 Topouchian et al., 2014, *Vasc Health Risk Manag* **10**:33-44.

⁶ = Fora Website states ±3 mmHg or ±2% of reading, although no published studies are available at the time of this report.