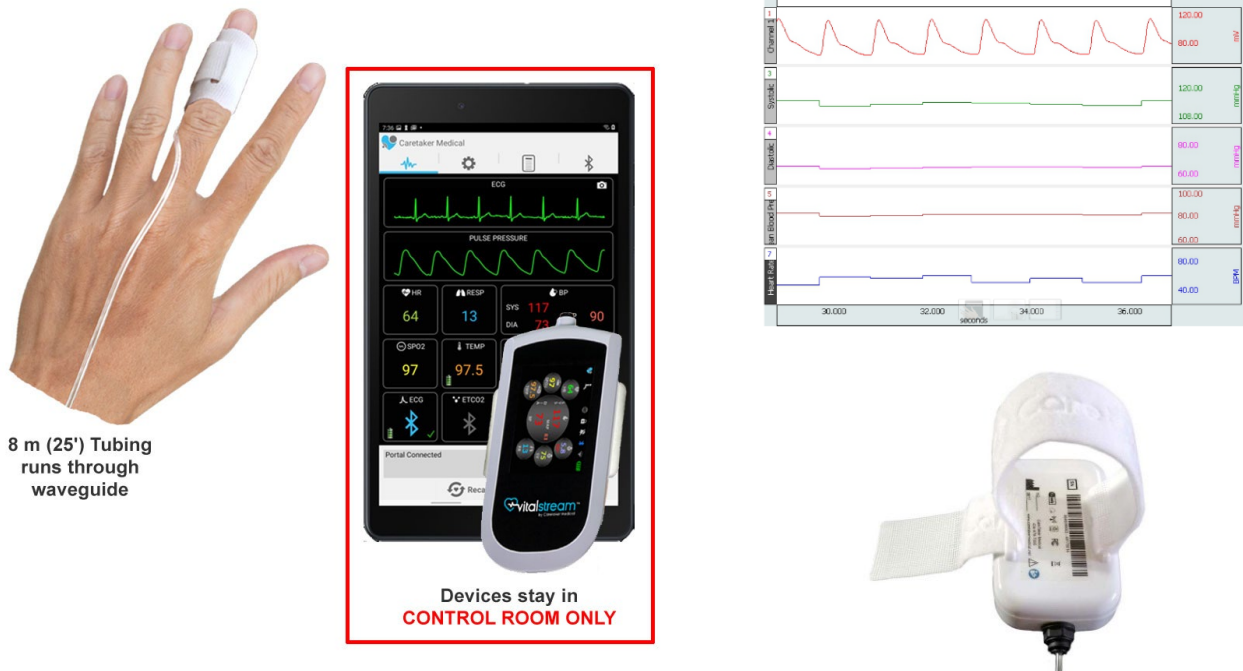


NIBP-B-MRI & RXNIBP-A-SENSOR

NONINVASIVE BLOOD PRESSURE MEASUREMENT IN THE MRI



The NIBP-B-MRI measures relative central arterial pressure in the MRI to provide continuous, noninvasive “Beat-by-Beat” Blood Pressure from at rest humans (≥ 15 kg). Measures include Diastolic, Systolic, Mean Arterial Pressure; heart rate (HR) data is available. The system uses the scientific method of Pulse Decomposition Analysis (“PDA”).

Key Features

- Continuous, noninvasive monitoring of “Beat-by-Beat” Blood Pressure (Diastolic, Systolic, Mean Arterial Pressure) and Heart Rate
- Wireless transmission of blood pressure data from VitalStream blood pressure processing unit (via Bluetooth) to a PC—tablet included
- Measurements captured using a single disposable finger cuff inflated to low pressure—can be worn for extended periods with no discomfort or loss of circulation in the finger
- Designed for use with MRI recordings
- easily export to AcqKnowledge research software for post-acquisition analysis
- Compact device with on-board display
- Automatic and manual calibration modes
- Integrated PDF report generation and alarms

System Components

- MRI-Compatible “VitalStream” Continuous Monitor
- Finger Cuff Transducers x 2
 - In general, Cuffs last ~100 hours of intermittent MRI use (max 3-5 days of continuous use)
 - additional or replacement sensors available as [RXNIBP-A-SENSOR](#)
- Tubing 8 m (25')
- Tablet computer
- Automatic Blood Pressure Calibration Unit
- Export Utility
- Bluetooth dongle
- Power Supply
- 1-Year Warranty

MRI Use: MR Conditional (NIBP-B-MRI only)

Condition: Unit remains in the control room and tubing passes through the waveguide to subject.

Calibration

VitalStream devices can be calibrated automatically using its self-calibration mode or manually with an included cuff. An export conversion utility is included to import calibrated pulse wave data to AcqKnowledge research.

Compatibility

[MRI and fMRI setups](#)

NIBP-B-MRI Technical Specifications

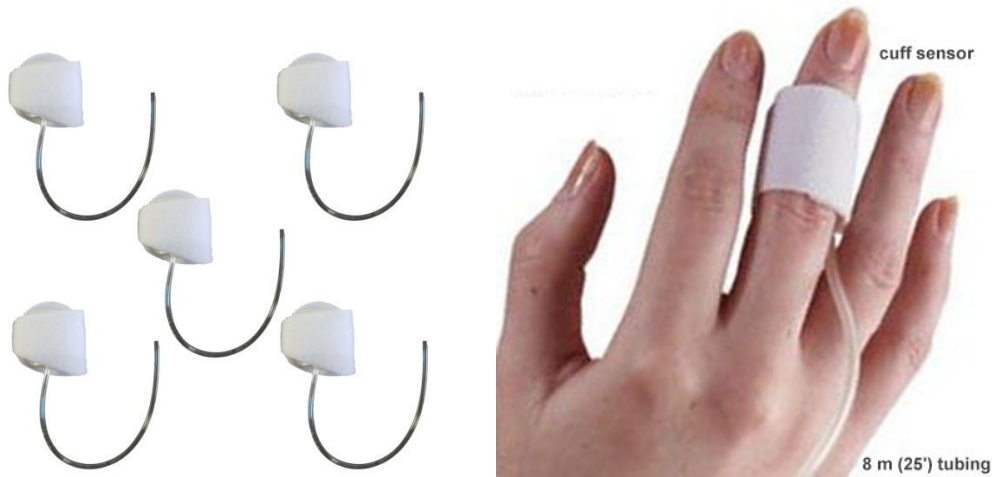
Physical Specifications:	
Device Dimensions:	3.4 x 6.4 x 9.6 cm
Weight:	198 Grams
Operating & Storage Conditions:	
Storage Temp:	-20 °C to +70 °C
Operating Temp:	0 °C to 40 °C
Operating Humidity:	0 to 95% non-condensing
Operating/Storage Pressure:	70 – 101 kPa
Operating/Storage Elevation:	0 – 3000 meters
Operating System Pressure:	-10 mmHg to +250 mmHg
Infection Control:	Wipe with Super Sani-Cloth or other disinfectant wipe
Liquid Ingress Rating:	IP52
Parameter Measurement Ranges:	
Heart Rate Range:	30 – 200 BPM
Heart Rate Resolution:	1 BPM
Heart Rate Accuracy:	±3 BPM
Heart Rate Averaging:	10 second moving average
Continuous Noninvasive Blood Pressure Method ("CNIBP"):	Pulse Decomposition Analysis ("PDA")
CNIBP Systolic Range:	80 – 250 mmHg
CNIBP Diastolic Range:	50 – 150 mmHg
CNIBP MAP Range:	60 – 185 mmHg
CNIBP Accuracy:	±5 mmHg, Std. dev. < 8 mmHg
CNIBP Calibration:	Automatic (oscillometric sweep via finger cuff) or Manual (user input parameters)
CNIBP Recalibration Update Interval:	User configurable
CNIBP Measurement Update Interval:	User configurable and fixed intervals (0 seconds to 15 minutes)
Respiration Range:	6 – 32 breaths/minute
Respiration Accuracy:	±3 breaths/minute
Respiration Method:	Proprietary PDA, IBI, spectral analysis
User Interface Information:	
Integrated Liquid Crystal Display:	128 x 128 pixels
Clinical App Tablet Based Display:	8" diagonal LCD (Caretaker provided hardware)
Waveforms Displayed:	Continuous pulse rate, continuous pulse pressure, individual pulse shape
Audible Alarms:	None
Battery & Charging Information:	
Battery Type & Certification:	2000 mAh lithium polymer UL certified
Operating Time:	8 – 24 hours, depending on use mode
Charging Time:	2 – 4 hours using provided wall charger
Charger Type & Certifications:	5 VDC barrel jack, UL, IEC
Charger Current & Voltage:	150 – 400 mAh @ 5 – 12 VDC
Communications:	
Bluetooth Frequency:	Bluetooth Low Energy ("BLE"), 2400 – 2483.5 MHz ISM band
Bluetooth Communications Range:	10 meters line of sight from host/display

Security Encryption:	AES 128-bit encrypted data stream
Disposable Finger Cuff & Wrist Strap:	
Finger Cuff Dimensions:	3.8 mm x 14.2 mm
Finger Cuff Diameter Range:	12 – 30 mm
Wrist Cuff Dimensions:	346 mm x 38 mm
Cuff Materials:	Hypoallergenic polyurethane
Cuff Infection Control:	Single use only, dispose after each use

NIBP-B-MRI Clinical Specifications

Noninvasive Blood Pressure (NIBP) Standards & Compliance Data (Self-Calibration):		
Compliance Standard:	ANSI/AAMI/ISO 81060-2: 2013 Noninvasive 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

Continuous Noninvasive Blood Pressure (cNIBP) & Vital Sign Standards & Compliance Data:			
Compliance Standard:	ANSI/AAMI/ISO 81060-2: 2013 Noninvasive 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

RXNIBP-A-SENSOR

This is a 5-pack of 8 m Finger Cuff Sensors for MRI Research with the NIBP-A-MRI and NIBP-B-MRI Systems.

Sensor life: ~100 hours of intermittent MRI use

Finger Cuff Dimensions: 3.8 mm x 14.2 mm

Finger Cuff Diameter Range: 12 mm – 30 mm

Tubing: 8 m

Interface: NIBP-A-MRI and NIBP-B-MRI

Cuff Materials: Hypoallergenic polyurethane

Cuff Infection Control: Single use only, dispose after each use

(Non-FDA Cleared)