



Accurate Mini

World 1st FDA Approved Over the Counter Use Calibration-free Cuffless Blood Pressure Monitor.

Accurate Mini Blood Pressure Monitor is the world's first monitor able to read blood pressure straight from the pulse without the need of calibration. By using the FDA approved sensor system, each pulse waves inside the radial artery can be read, and precise results can be delivered quickly.

Measurements can be sent directly to the Dr. Pulse mobile app via Bluetooth for daily health management, and be uploaded to the Vital2Doc tele-medicare platform for you to review and share with the cardiologist of your choice.



Calibration-Free

Stash the old BP monitors, and forget about the annoying weekly calibrations.



App & Cloud Integration

Review, manage, and utilize your data with Dr. Pulse app and Vital2Doc telemedicare platform.



Wireless Data Transfer

The measurement results can be transferred to mobile app via Bluetooth and tele-medicare platform via internet.



Precise & Reliable

Our FDA approved sensor set uses mature technologies to provide reliable and precise results.



Rechargeable

A full charge is sufficient for 500 measurements, and can be charged with included USB Type-C cable.



Multi-Vital Sign Monitor

Besides the blood pressure, body temperature and blood oxygen are also measurable.



Small and Portable

Mini is small and portable. Bring it wherever you go, and measure whenever you want.



Fast Measurement

It takes just 25 seconds for the Mini to measure blood pressure and more.





Product Feature

Classification	Class II
Device Dimension (L) x (W) x (H)	L 2.7 in x W 1.7 in x H0.8 in L 69 mm x W 43 mm x H 21 mm
Weight	34.5 ±2 g (net), 46.2 ±2 g (with band) 1.22 ±0.2 oz (net), 1.63 ±0.2 oz (with band)
Display	1.2 inch TFT LCD
Pulse Sensor	Piezoelectric sensor x 2
Optical Sensor	Near Infrared Spectroscopy (NIRS)
Wireless Transmission	Bluetooth
Battery Type	340 mAh rechargeable Lithium-ion battery
Battery Service Life	Approx. 350 measurements
Memory Capacity	Approx. 500 measurements
Charging Port	DC 5V, 2A USB Type-C connector
Charging Protection	Built-In
Product Life	3 years
Battery Shelf Life	3 Years
Warranty	1 Year

Blood Pressure Measurement

Measurement Method	Pulse Transition Time with Hemodynamic
Mode of Operation	Spot Checking
Measurement Site	Radial Artery at the Wrist
Measurement Time	Approximately 25 seconds
Measurement Unit	Millimeters of mercury (mm Hg)
Blood Pressure Range	Systolic: 60 to 260 mm Hg Diastolic: 40 to 215 mm Hg
Blood Pressure Accuracy	±5 mm Hg
Pulse Rate Range	40 to 250 beats/minute
Pulse Rate Accuracy	±5% of the display reading

Environment conditions

Operating Conditions	41° F to 104° F (5° C to 40° C)
Storage Conditions	-4° F to 131° F (-20° C to 55° C)
Transportation Conditions	-4° F to 131° F (-20° C to 55° C)
Relative Humidity	10% to 95% RH (non-condensing)
Atmospheric Pressure	70 to 106 kPa
Water/Dust Protection	IP22

Regulatory Compliance

Performance	IEC 80601-2-30:2018
Electric Safety	IEC 60601-1:2012 IEC 60601-1-11:2015
EMC	IEC 60601-1-2:2014



The Accurate Mini
Model No.
AMB-001

Material Used

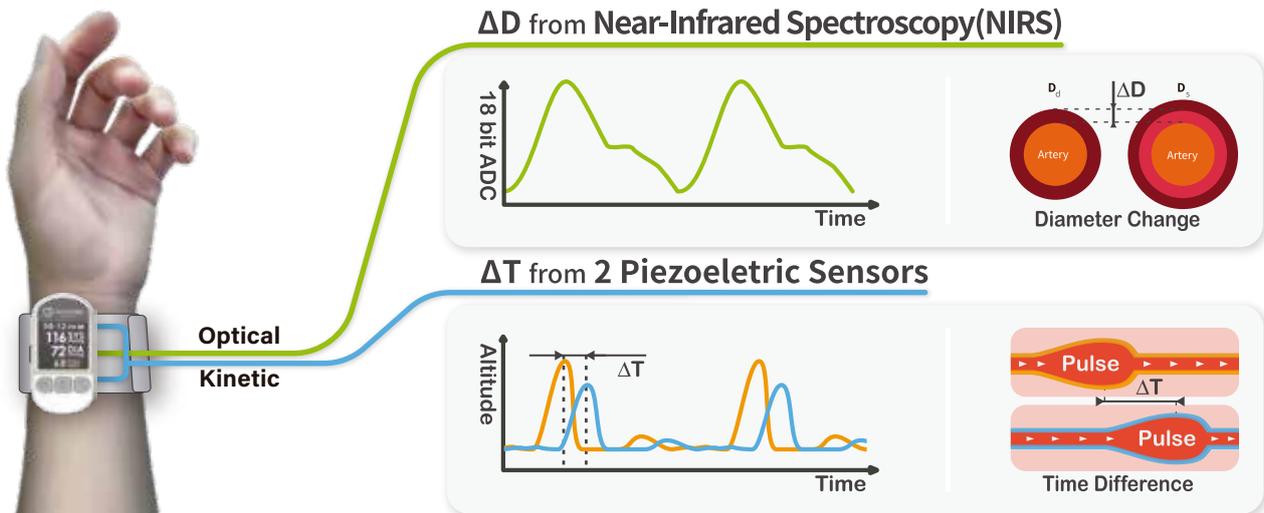
- Rubber Sensor Tips:**
Natural Rubber, bio-compatible.
- Optical Window:**
Polycarbonate (PC), bio-compatible.
- Device Case and Buttons:**
Acrylonitrile-Butadiene-Styrene (ABS), bio-compatible.
- Electronic:**
PCB with active and passive components powered by a rechargeable battery.
- Display Cover:**
Polyvinyl chloride (PVC), bio-compatible.

Primary Functions

The device features one touch full-auto measurement for blood pressure, heart rate, and blood oxygen. It is capable of measuring body temperature with the dedicated thermal dongle. The device can upload measurement data to the Dr. Pulse, a mobile app on App Store, via Bluetooth.

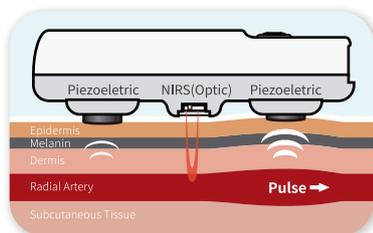
Principles used by the device

The device senses each pulse going through the radial artery by using 2 piezoelectric and 1 Near Infrared Spectroscopy (NIRS) sensor. The collected parameters, such as pulse transmission time (PTT), are calculated according to the Moens-Korteweg formula, and result in SYS, DIA and the heart rate (HR).



A. The physics behind blood pressure measurement.

- The physics of blood pressure involves many parameters from the wall tension and distensibility of the artery to fluidity of blood and the transmission speed of a pulse wave.
- In order to measure these parameters needed for determining blood pressure inside the artery, we utilize two piezoelectrics as stethoscopes to listen to the same pulse wave for the velocity. Also, a Near-Infrared Spectroscopy (NIRS) is used as a radar to detect any change of distensibility in radial artery.



B. Methods for Determining the pulse transmission speed.

- In general, pulse wave transmission speed is determined by the time a pulse wave takes to travel from one point to the other. Therefore, pulse wave transmission speed can be measured by monitoring the time difference of the same pulse travel through two points of the artery.
- In the case of Mini, the two piezoelectric sensors are positioned in a fixed distance to listening to the same pulse wave inside the radial artery mechanically.
- By comparing the time difference of the same wave heard by the two piezoelectric sensors, the Mini is able to determine the Pulse Wave Velocity (PWV) by finding ΔT . Then, the blood pressure can be calculated with the Moens-Korteweg equation when the arterial parameters are factored in from the NIRS sensor.

C. Key differences between most cuffless and the Mini.

- Most cuffless blood pressure devices rely on measuring Pulse Arrival Time (PAT), which includes Pulse Transit Time (PTT) and Pre-Ejection Period (PEP). While PTT is crucial for blood pressure calculation, the PEP is not.
- Since PEP is difficult to tell from PAT, users of PAT based cuffless devices are obligated to provide measurements from credible cuff devices weekly for the PAT based cuffless devices to find the users' PEP by reverse calculation, subtract PEP from PAT for PTT, and adjust the measurements accordingly. This process is known as "calibration".
- While Mini is a cuffless device, it needs neither user information nor calibration because Mini is a local Pulse Wave Velocity (PWV) based device capable of finding PTT and other parameters needed for blood pressure calculation directly from the radial artery.



Front and Rear Views

- A** Display
- B** Buttons
- C** Piezoelectric Sensor 1
- D** Near Infrared-Spectroscopy(NIRS)
- E** Piezoelectric Sensor 2



Performance Validation

The most critical step to validate the performance, useability and safety of medical devices with international standards recognized by U.S. FDA., and eliminate possible issues before the release of our products.

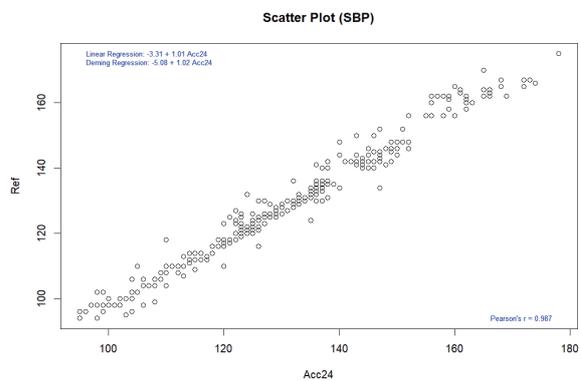
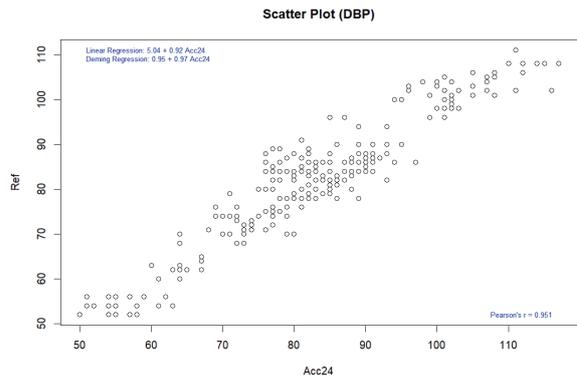
Procedure

The procedure used in this study follows the ISO 81060-2:2018 Clause 5.2.4.1.1. By compare results of reference and subject device using sequential method repeatedly to gain 3 sets of valid readings from the same arm of the same patient to minimal external interferes and change in the patient's physiological condition.

In order to be considered as a valid set of blood pressure readings, the differences between the reference and our device should be within 12 mmHg for the systolic, and within 8 mmHg for the diastolic.

Result

The complete validation procedures should be conducted in at least total of 85 subjects, as specified in the ISO 81060-2 standards, with at least 255 BP determinations having a mean error magnitude ≤ 5 mmHg and a standard deviation ≤ 8 mmHg.



Intended Use

- The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI < 40.
- The Accurate Mini Blood Pressure Monitor is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and is able to obtain results. The measurement results store in the device locally.
- The Accurate Mini Blood Pressure Monitor measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

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