MAXIM BLOOD PRESSURE TRENDING:

USER GUIDE

Rev. 2.0
***Platform**: MAXREFDES104*
***User Interface**: Maxim Wellness Suite 4.4.4*

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maxim integrated™

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FIGURES

1 Introduction

The subject device is not intended for diagnostic purposes, and medical/life critical applications to measure blood pressure. It is only intended for a device/system evaluation.

Maxim Blood Pressure Trending (MaximBPT) system is a non-invasive, cuff-less monitor embedded in an integrated hardware and software solution and it measures blood pressure by capturing physiological signals at the user's fingertip. Waveforms obtained by these sensors are analyzed by proprietary algorithms to determine systolic and diastolic blood pressure changes relative to calibration point.

This document provides guidance on general blood pressure measurement procedures and MaximBPT system for MAXREFDES104 evaluation kit.

The system is accessed by a user interface provided as Maxim Wellness Suite for Android platforms.

1.1 Device Connection

After installing the firmware and while MAXREFDES104 is powered up, the system can be connected to the Android application via Bluetooth.

As seen in Figure 1, the landing page of the Maxim Wellness Suite application allows for a Bluetooth scan for available devices. From the listed devices, please connect to the MAXREFDES104 that is in use.

After the Bluetooth connection is established, the application will be listing the available algorithms. This page has the links for *User Profile* and *Blood Pressure Trending*. First time users can start with creating a profile, and after that they can select their profile from the dropdown user selection menu (Figure 1). After creating a user profile, *Blood Pressure Trending* algorithm can be initiated.

The landing page of BPT has the measurement, calibration, BP history and reference device connection options.

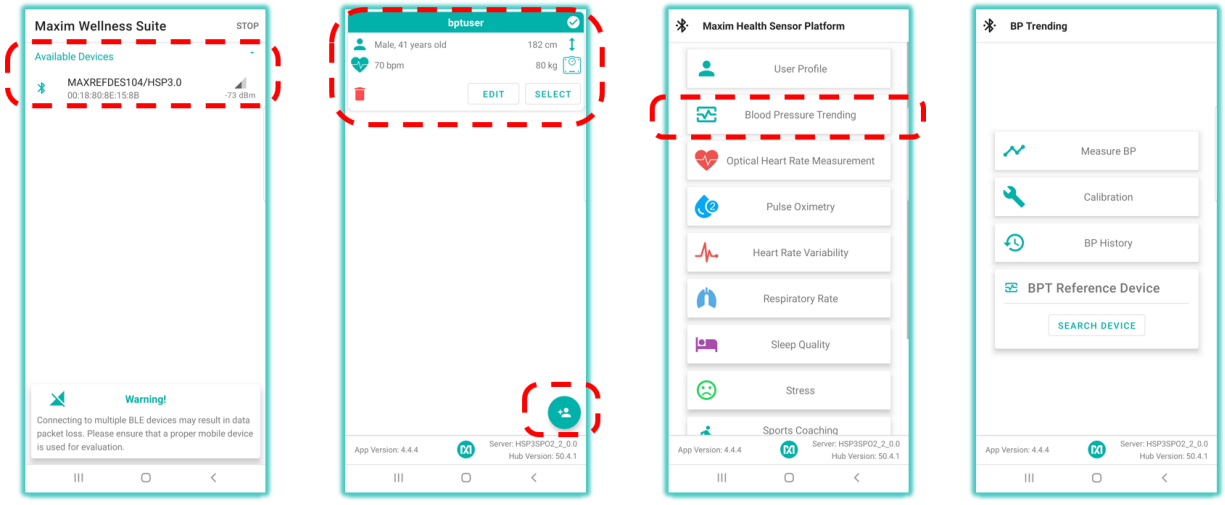

Figure 1. Bluetooth connection to the available device, user profile creation, and Blood Pressure Trending link, landing page.

2 Calibration Procedure

The goal is to record the PPG signal associated to a reference blood pressure value. Calibration is a critical step in which reference blood pressure measurements, tagged with PPG data, are taken.

These calibration reference values are valid for 4 weeks and thereafter re-calibration is required to use MaximBPT for blood pressure measurements. At least 3 distinct calibrations are recommended to get a better accuracy, yet the algorithm will function even with one calibration.

Calibration protocol have three main sections, a) subject preparation, b) reference BP measurement and c) PPG collection from fingertip. Calibration protocol is summarized in Figure 2, the phone application user-interface and relevant instructions are given in Figure 3.

Time (mins)	1	2	3	4	5	6	7	.	t2	t2+1	.....	tn	tn+1
Subject State	 RELAX during whole protocol					Ref. 01	PPG Data		Ref. 02	PPG Data		Ref. N	PPG Data
Reference Measurements (LEFT arm)													
PPG Sensor Data (RIGHT fingertip)													

Figure 2. Overview of the calibration procedure

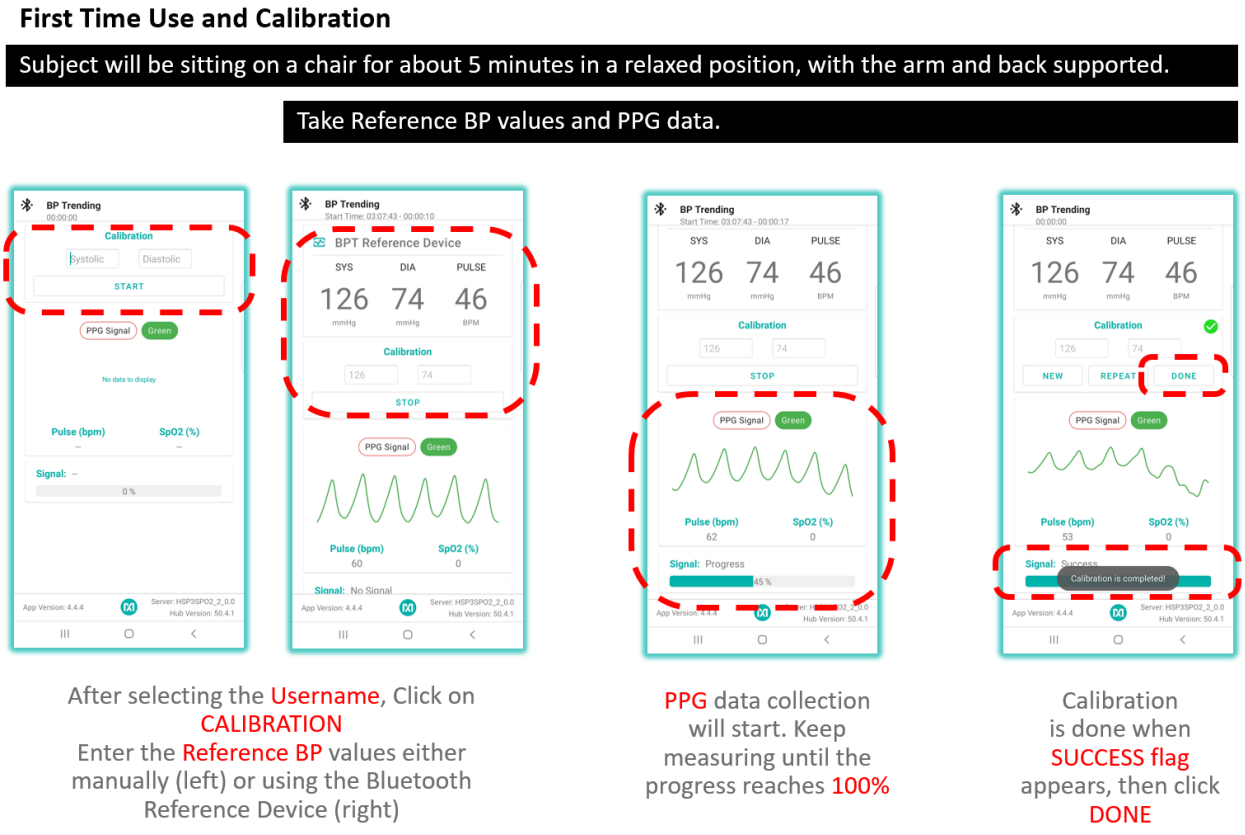

Figure 3. Android application user interface and relevant instructions in calibration procedure

2.1 Subject Preparation

- **Please follow the common procedure of subject preparation as described in Section 4 .**

2.2 Calibration Point References

- **Please follow the common procedure of reference blood pressure measurement procedure as described in Section 4 .**

Take three reference blood pressure measurements (like, Ref1, Ref2 and Ref3) and record systolic and diastolic blood pressure in mmHg units. For each reference measurement, collect PPG data from the wrist using the phone application. Follow additional instructions as described in reference device manual for accurate measurements.

The user is allowed to take measurements after a single calibration point. However, to achieve the accuracy metrics claimed, it is suggested to have at least 3 calibration points (Figure 4). Also, the user can take more than 3 reference measurements.

These calibration measurements can be taken at different times and are not required to be consecutive. Each reference measurement will have its own timestamp and expiration date (Figure 4).

2.3 PPG Data Collection by the Android Application

Follow the MaximBPT Android application instructions for calibration (select a username and insert calibration reference values to text boxes). Please see Figure 3.

The users are expected to keep **the wrist steady**, and they should **avoid talking** during data collection.

MaximBPT Android application will show the progress and then return a ***success*** flag, once the calibration PPG data collection is complete. This takes about 20-60 secs depending on the PPG signal quality.

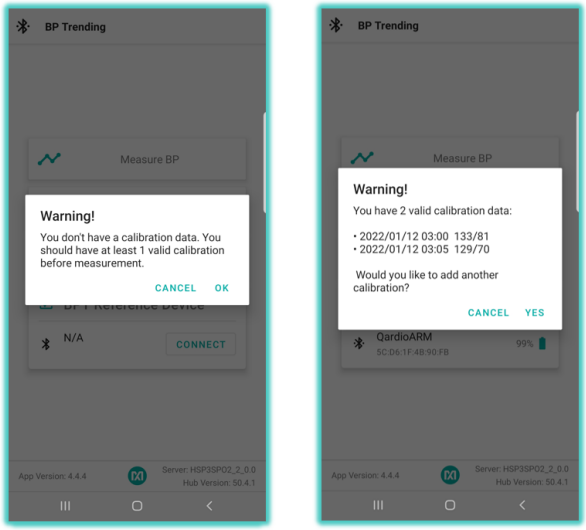

Figure 4. Android application warning message examples to guide the user during calibration process.

3 Measurement Procedure

This is the **rest-to-rest use-case protocol**, where MaximBPT system estimates the user's blood pressure trending values. Phone application user-interface and relevant instructions are given in Figure 5.

❖ **Please follow the common procedure of subject preparation as described in Section 4 .**

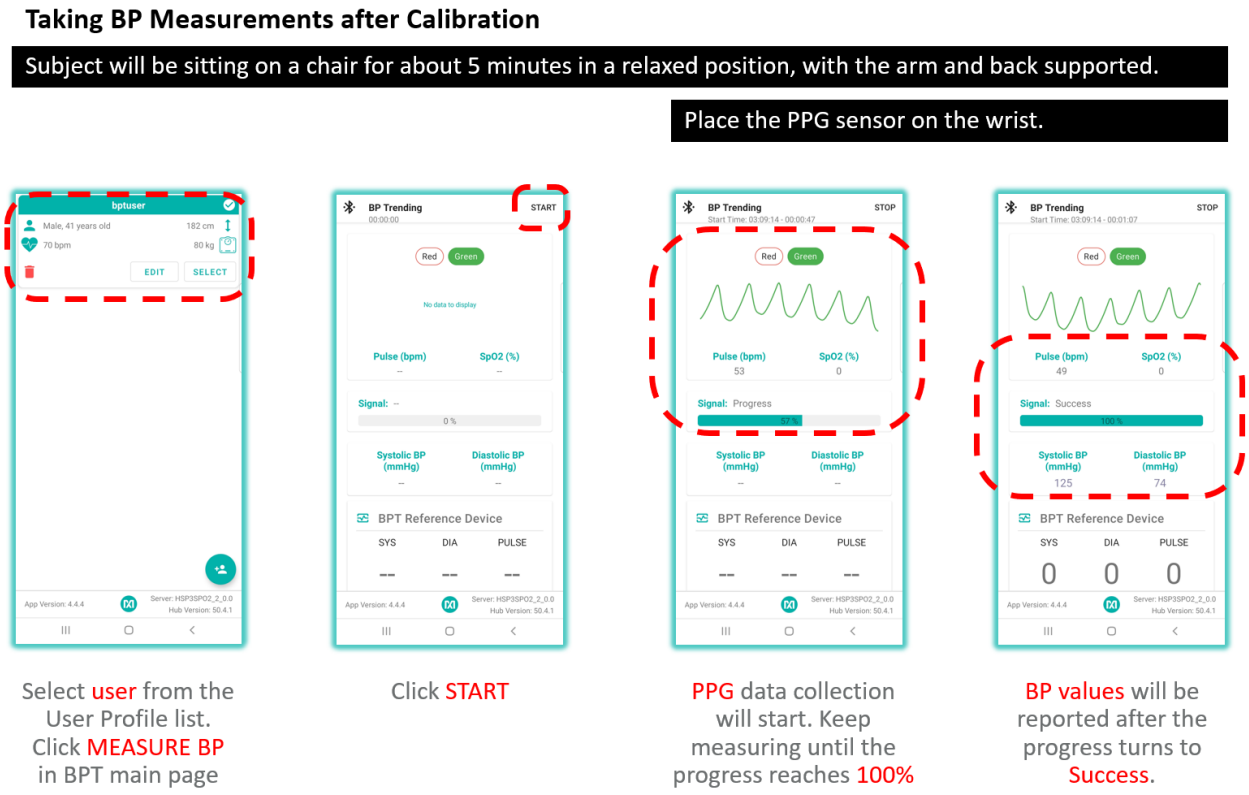

Figure 5. Android application user interface and relevant instructions during regular measurement

3.1 Blood Pressure Measurement

Follow the MaximBPT application instructions for measurement (place the PPG sensor on the wrist, then click on measurement button). The users are expected to keep **the wrist steady**, and they should **avoid talking**.

PPG data collection will start, and the progress will be displayed on the application user interface screen. Blood pressure outputs are displayed on the screen (Figure 6, left). If there is a Bluetooth reference device connected to the system, it will be initiated after the algorithm estimates and the reference measurement values will be displayed on the screen (Figure 6, middle)

All blood pressure calibration and measurement values for the selected user are reported in the ***BP History*** screen (Figure 6, right).

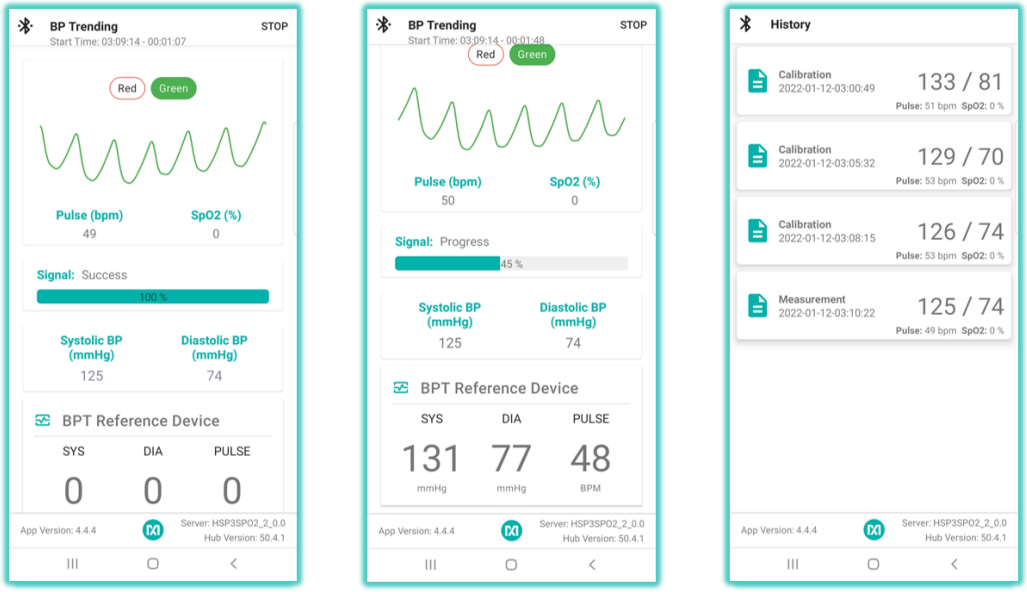

Figure 6. Android application user interface reporting the blood pressure trending values, reference device output values and BP History page to access previous measurement values.

4 General Procedure for Blood Pressure Measurement

1. **At the beginning of each measurement or calibration, the subject should rest quietly for 5 minutes in a seated position with the elbow resting on a table, slightly below the level of the heart. And the same procedure will continue during the measurements as well.**
   - The palm should be turned upward, with the hand remaining open and relaxed.
   - The arms, back, and feet should be supported and in a relaxed position.
   - The legs should remain uncrossed.
   - The subject should avoid talking.

2. **The reference measurements will be taken at a stable rest condition from the left arm.**
   - The reference measurements can be executed by a trained medical professional using medical grade blood pressure devices available at a healthcare facility or by self-measurement using an FDA cleared, cuff-based blood pressure measurement devices.

3. **MaximBPT sensor will be placed on the wrist.**
4. **Conduct the appropriate measurement steps as described in Section 2 and Section 3 .**