REF 012.002.001

Instructions for Use | OptiBP™ App

For Android

1. Introduction

Monitoring blood pressure just got easier. The OptiBP application enables easy, convenient, and fast blood pressure measurement using only a fingertip on a smartphone camera.



Please, read this manual carefully to acquire a complete understanding of the device's functions before using the product. It contains important safety and care information and provides step-by-step instructions for using the product properly.

For any additional information or support, please contact support@biospectal.com.

2. Product description

2.1. Intended Purpose

OptiBP is a software-only mobile medical application that is intended to be used in a compatible mobile computing platform (e.g. a smartphone or a tablet). OptiBP is intended to measure and display blood pressure (systolic and diastolic) based on a photoplethysmography (PPG) signal. The device extracts the PPG signal from optical data captured from capillary fingertip tissue, from a user's index or middle finger, when placed over the mobile platform's camera. The device is intended for use in adults aged 18 years and older. The blood pressure estimates displayed by OptiBP are intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without consultation from a qualified healthcare professional.

2.2. Indications for use

OptiBP is intended to measure and display systolic and diastolic blood pressure in adults over 18 years old

2.3. Warnings

OptiBP is not indicated for blood pressure measurement or monitoring in the following cases:

- Children and young adults under 18
- Pregnant women
- Heart rate below 40 beats/minute or above 120 beats/minute.

- Exercise: OptiBP is intended to be used only at rest and does not provide measurement of continuous blood pressure, or during motion.
- Unstable cardiac condition (such as myocardial infarction < 1 week, pulmonary embolism, cardiac arrhythmia, decompensated heart failure, etc.).
- Dysrhythmia like bigeminy, trigeminy, isolated VPB, atrial fibrillation.
- Abnormality of the user's fingertip (including but not limited to damaged/injured skin, known vascular malformation, Raynaud syndrome).
- Contact dermatitis (caused by metal allergens, notably nickel and chromium).
- In anesthesia, intensive care or emergency care situations.

2.4. Cautions

- Users must use the fingertip of their index or middle finger, which should entirely cover the camera lens of the smartphone (with a gentle, even pressure) and not cover the flash.
- OptiBP is not intended to be used as a self-diagnostic device.
- Users should not use OptiBP if the camera of their smartphone is scratched or broken.
- To ensure accuracy, users must calibrate their device at least every four weeks.
- Users should rest for 5 minutes before using OptiBP.
- Users should avoid talking and moving their body.
- Users should refrain from measuring when they are working out, smoking or drinking.
- The camera should be only used on healthy skin tissues of the finger.
- Users should avoid crossing their legs.
- Users should use the same finger and same sitting configuration for consistency.

2.5. Medical Conditions to be diagnosed/treated/monitored

- OptiBP is not intended to be used for diagnosing hypertension, other conditions, or checking for signs of a heart attack.
- OptiBP is not meant to replace traditional methods of diagnosis or treatment by a qualified healthcare professional.
- If patients think they are having a medical emergency, they should contact their local emergency services immediately.

2.6. Disclaimers

- OptiBP cannot diagnose hypertension, other conditions, or check for signs of a heart attack.
- OptiBP is not meant to replace traditional methods of diagnosis or treatment by a qualified healthcare professional. If you think you are having a medical emergency, contact your local emergency services immediately.
- DO NOT change your medications or dosage without first consulting your doctor.

- DO NOT interpret or take clinical action based on the Blood Pressure App estimations without first consulting with a qualified healthcare professional.
- DO NOT use OptiBP for Blood Pressure measurements if the app has been calibrated for use by another person.
- DO NOT take Blood Pressure measurements during any physical activity.
- DO NOT take Blood Pressure measurements during a medical procedure (for example, surgery or external defibrillation procedures).
- DO NOT cover the flash with your finger.
- OptiBP's range for blood-pressure readings is as follows:
    - Calibration Range - Systolic: 70–220 mmHg, Diastolic: 40–120 mmHg (note: upon setting up OptiBP, an initial calibration with an OTC cuff is required)
    - Measurement Range - Systolic: 70–220 mmHg, Diastolic: 40–120 mmHg

2.7. Risks and Side Effects

- There are no side effects associated with the use of OptiBP besides two potential unfavorable events:
    - Contact dermatitis (caused by metal allergens, notably nickel and chromium). Note that contact dermatitis is rather linked to the use of a smartphone than the use of OptiBP itself.
    - Flash may cause pain due to heat or might briefly annoy users if directed towards them.

2.8. Use Environment

OptiBP can be used at home, at work, or anywhere where it is possible to sit comfortably. Users should measure their blood pressure after a period of 5 minutes of rest.

3. Compatibility

The OptiBP Android application requires the Android 10 operating system or higher, and supported phone devices. The OptiBP smartphone application is available for download on the Google Play store.

OptiBP is intended only for compatible devices verified by Biospectal. If the user's device is not supported, they will see a warning ("Your device isn't compatible with this version") on the Google Play store application page.

OptiBP users will be notified when an update to the software and verified devices are available. The latest OptiBP application version can be found in the Google Play store.

4. OptiBP Setup

4.1. Download and Install OptiBP

The OptiBP mobile application can be downloaded from the Google Play Store. Open the Google Play Store app, search for “OptiBP” and download the app. An internet connection is required to download OptiBP. Once the download installation is complete, the app can be opened.

4.2. Setup an Account

Tap on the OptiBP app icon to open the OptiBP app. Select “sign with Google” and follow the instructions presented. Alternatively, you can create an account by entering your email address.

4.3. Activate Subscription

Activate a subscription via Google Play after a period of free trial to continue using OptiBP. When you start the free trial, instructions to create a personal profile will appear. Cancel a subscription at a later time by navigating to the account page via OptiBP’s ☰ utility “hamburger” menu designated by three stacked horizontal lines in the upper left of the app interface.

4.4. Calibrate OptiBP with a Cuff

Once the personal profile is set up, calibrate the app according to the user’s personal physiological parameters by taking two sample measurements with a cuff-based upper-arm blood pressure monitor.

Follow the onscreen instructions provided. To calibrate OptiBP you will take a measurement with your phone, and a comparative measurement with your cuff. You will repeat the process twice.

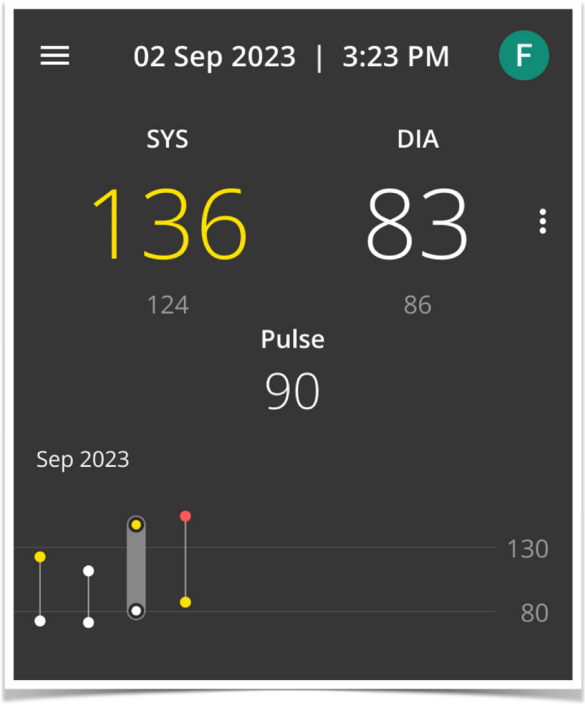
After calibrating, you will not need your cuff anymore to take blood pressure measurements using OptiBP.

However, OptiBP app is to be recalibrated every 30 days. You may calibrate OptiBP anytime before every 30 days by selecting ‘Calibrate OptiBP’ from the ☰ menu.

5. OptiBP Measurement

5.1. Performing a measurement

OptiBP uses the camera of your smartphone to record your fingertip blood flow beneath the skin for 30 seconds. Once the recording is complete, we calculate a blood pressure estimation and display a SYSTOLIC, DIASTOLIC blood pressure estimates and the calculated pulse rate.



5.2. Blood pressure estimate color coding

SYSTOLIC and DIASTOLIC blood pressure estimates are color coded according to the 2018 ESC/ESH Guidelines for the Management of Arterial Hypertension. Details concerning the ranges for hypertension including the user's measurement plots can be found by tapping on the "more information" three vertical dot menu to the right of the systolic and diastolic numeric display on the results screen.

Hypertension Category	**Color**	**Systolic (mmHg)**	**Diastolic (mmHg)**
Low	Gray	Under 90	Under 60
Optimal & Normal	White	90-129	60-89
Elevated	Yellow	130-139	90-94
High	Red	140+	95+

Blood pressure estimates displayed by OptiBP are intended for informational use only. The user is not intended to interpret, diagnose, or take clinical action based on the device output without follow up testing and consultation from a qualified healthcare professional.

5.3. Error Message Definitions

In certain situations, OptiBP may not be able to provide blood pressure estimates and provide error messages:

Message Title	Explanation
High Heart Rate	A heart rate over 100 bpm was calculated and OptiBP was unable to estimate your blood pressure.
Irregular Pulse Detected	OptiBP identified an irregular heart rhythm two or more times during the measurement and is unable to estimate your blood pressure.
Weak Signal Strength	OptiBP was not able to estimate your blood pressure due to weak signal amplitude.
Unable to Calculate Blood Pressure	OptiBP was not able to estimate your blood pressure using your recorded signal.

5.4. OptiBP Measurement History

To view a detailed measurement history, select 'History' from the three horizontal bar "utility" ≡ menu.

The measurement history can be exported and shared by tapping the icon.

You can also sync your blood pressure history with Health Connect. By enabling OptiBP to share and store your blood pressure data in Health Connect, you can effortlessly access it in other health apps like Google Fit or Samsung Health, making it easier to track your overall health and wellness.

6. Renewal and Disposal

6.1. Changing Smartphones

To enable OptiBP in a new smartphone, download the application, sign-in to the appropriate OptiBP account from the previous phone, and past blood pressure recordings will be uploaded to your new smartphone.

If your new smartphone is a supported device, blood pressure measurement will be available after completing a new calibration.

6.2. Expired Subscription

To continue measuring using OptiBP, you need an active subscription. Tap 'Measure' and follow the instructions presented to renew your subscription via Google Play.

6.3. Terminating a Subscription

You can cancel your subscription by navigating to your account page via the ≡ menu. Once terminated, you will maintain access to OptiBP and your past blood pressure measurements.

6.4. Deleting an OptiBP Account

To delete an OptiBP account, open the OptiBP app and go to the Account page via the ≡ menu. Select Logout & Delete your account. This action will delete all of your measurements and your profile information.

7. Applicable Symbols

The symbols below are included in the OptiBP smartphone application labelling

	*Consult instruction for use* *Refers to content you should carefully follow to avoid any use issues or hazardous situations or inaccurate measurements using OptiBP*
CE	*CE mark symbol* *Signifies that the product meets all the legal requirements for CE marking and can be sold throughout the EEA*
MD	*Medical device symbol* *Symbol for "This equipment is a medical device"*
UDI	*Unique Device Identifier* *Allows the unambiguous identification of this specific medical device. The unique identifier includes information on the manufacturer, the product, and its version*

REF	*Catalog number* *Indicates the manufacturer's catalog number so that the medical device can be identified*
	*Date of manufacture* *Specifies the app version and the date of its release*
	*Manufacturer* *Indicates the legal manufacturer of the OptiBP app in Europe*
EC REP	*European Authorised Representative* *Indicates information of authorised representatives for the EU*

8. Contact Details

For more information or questions, please check our FAQ at www.biospectal.com. You may request a printed copy of this document by emailing at support@biospectal.com.

Serious incidents that have occurred in relation to the use of OptiBP shall be reported to:

(1) The legal manufacturer via support@biospectal.com
(2) The local competent authority

Manufacturer

Effectum Medical AG, Kirchgasse 11, 4600 OLTEN, Switzerland

E-mail: info@effectummedical.com
Web: www.effectummedical.com

EU Authorised Representative

MED-RAS GmbH, Eichenallee 8H, 21521 WOHLTORF, Germany

UK Responsible Person

Emergo Consulting (UK) Limited, c/o Cr360 – UL, International Compass House, Vision Park Histon, CAMBRIDGE CB24 9BZ, United Kingdom

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