

Smartphone application for blood pressure monitoring*

Country of origin		Switzerland
Primary use		Diagnosis/measurement/monitoring
Category		Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 5

Year of commercialization: N/A

Number of units distributed: 0

Currently marketed in: Austria, Bangladesh, France, Germany, Ghana, Kenya, Rwanda, South Africa, Switzerland and United Republic of Tanzania

Model: OptiBP™

Product description

Biospectral OptiBP uses cuff less blood pressure measurement using a fingertip on a smartphone camera along with optical algorithms on smartphones, transforming the device into an easy-to-use, accurate blood pressure monitor to manage hypertension, the silent killer and number one chronic health condition worldwide.

Product details

Accessories: N/A

Consumables: N/A

Warranty duration: N/A

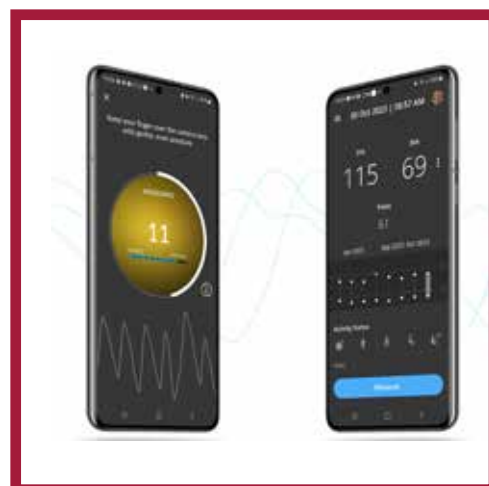
Lifetime: Annual software updates, but lifetime value

Energy requirements: Mobile phone

Facility requirements: N/A

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*** Information reported by manufacturer, October 2023**



WHO assessment**

Clinical



Clinical



Recommended with caution

Hypertension affects 1.3 billion people globally and is the leading risk factor for cardiovascular, cerebrovascular and chronic kidney disease. According to the most recent WHO Global Hypertension Report (2023), about 78% of adults with hypertension live in

LMICs. Globally, an estimated 54% of patients have been diagnosed with hypertension, and just over a fifth of them have had their blood pressure controlled.

This technology uses a smartphone camera to measure blood flow at the fingertip, which is analysed by photoplethysmography. Blood pressure is estimated from a specific algorithm, and initial calibration is performed with a standard blood pressure cuff. The device has been extensively tested in different settings (including LMICs) and different populations across the globe. Results have been encouraging and have validated the device's use in non-pregnant adults. Dissemination of this technology can facilitate blood pressure control in low-resource settings. Currently, OptiBP only works with a limited list of compatible Android smartphones. New models are regularly tested and included on the supported device list.

Comparison with WHO technical specifications

Cannot be verified.

The manufacturer has provided detailed technical documents, including the user manual in English. At the time of this report creation, WHO did not have any technical specifications document available to compare this software application for blood pressure monitoring.

Regulatory

 Pre-market assessment	 Proceed with caution
 Post-market assessment	 Proceed with caution
 Quality system assessment	 Proceed
 Security	 Proceed with caution






















Pre-market: This product is a class IIa medical device in the EU. The manufacturer declared that they have the design verification and validation of the product but did not submit these documents. Consequently, full premarket assessments could not be conducted to ensure the safety and performance of the product.

Post-market: The manufacturer declared that they have post-market documentation but did not submit the post-market surveillance and vigilance documentation. According to the submission, there have been no recalls or adverse events since the release of the product. Nevertheless, it is considered good regulatory practice to establish the PM system before introducing the product to the market.

Quality management system (QMS): The manufacturer has submitted a ISO13485:2016 valid until 17 January 2024. Based on the certification and standards for performance, the product is safe and effective.

Security: This technology could introduce a cybersecurity risk. The manufacturer did not submit risk management or information documentation on security management systems to ensure the safety and performance of the device.

Health technology assessment






Indicators	Evidence assessment	Innovation
 Medical		   
 Safety		
 Economy		
 Organizational		
 Legal		
 Social		
 Ethical		
 Green environment		

The technology enhances health outcomes by promoting better user adherence and integrating connected data with clinicians. Concurrently, it reduces costs by eliminating the necessity for supplying blood pressure cuffs in vulnerable health systems, while delivering the same quality as a medical-grade blood pressure cuff. Moreover, leveraging the extensive data collected through OptiBP can offer unprecedented epidemiological insights at a global scale.

Technology readiness level **9**

Technology evidence assessment **Recommended**

Health technology management

 Durability	N/A
 Ease of Use	→
 Ease of maintenance	N/A
 Environmental conditions	→
 Affordability	→
 Local access to technical support	→
 Ease of cleaning	N/A
 Infrastructure requirements	N/A

Health-care delivery platform



This smartphone app uses the phone's camera to detect and measure blood pressure and heart rate. It can be used on any smartphone. It needs to be calibrated with a sphygmomanometer, hence involvement of a health-care practitioner is required to begin. The app is easy to use and can serve both patients and health-care practitioners. The durability, ease of maintenance, ease of cleaning and infrastructural and environmental requirements depend on the phone used. The app is independent of those factors. Technical support is available through the app. The affordability will depend on the purchase price of the app but is estimated to be appropriate. Ownership of the phone and the app should be considered.

Intellectual property and local production

 Technology transferability	!
 Open source/access	🔒
 Local production	N/A

Intellectual property: This technology is protected by copyright and patents and has a registered trademark. The use of all intellectual property including any third-party-owned rights will require clearance.

Local production: This is a software algorithm.