INSTRUCTIONS FOR USE

BioScan ®

Software version 1.0

Medical Device Software (MDSW)

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CE

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1. Terms used

Algorithm: A set of computational procedures that BioScan uses to analyse optical signals obtained from a short video recording of the face and to estimate the values of selected physiological parameters.

Centring: A process in which the application guides the user to place their face in the centre of the marked frame.

Respiratory rate: Indicates the number of breaths (respirations) per minute. The unit of measurement is respirations per min (rpm).

eIFU: Electronic instructions for use.

Fitzpatrick scale (phototypes) I-VI: A commonly used scale for describing skin phototypes, i.e., its colouring and reaction to sunlight, divided into six grades from very light to very dark skin. In BioScan, it serves to describe the representation of different skin phototypes during algorithm validation.

Glycated haemoglobin (HbA1c): An indicative marker of long-term blood glucose (glycemia) levels. It indicates the average blood glucose level over the last 2–3 months based on the proportion of haemoglobin to which glucose is bound. The unit of measurement is mmol/mol.

Haemoglobin: A protein contained in red blood cells that binds and carries oxygen from the lungs to tissues and carbon dioxide from tissues back to the lungs. The unit of measurement is g/l.

Measurement history: A saved overview of previous measurement results available in the application for retrospective viewing and comparison.

Error message: A message displayed by the application informing the user of a problem that prevents the correct execution of a measurement or the functioning of the application.

Cardiovascular: Relating to the heart and blood vessels.

Blood pressure: A physiological parameter expressing the pressure that circulating blood exerts on the walls of the arteries. Blood pressure is given in two values: systolic blood pressure (SYS), i.e., pressure in the arteries during heart contraction (systole), and diastolic blood pressure (DIA), i.e., pressure in the arteries during heart relaxation (diastole). The unit of measurement is mmHg.

Signal quality: A measure of the suitability of the captured optical signal for reliable evaluation of physiological parameters.

MDR (Medical Device Regulation): Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, regulating the requirements for medical devices in the European Union.

MDSW (Medical Device Software): Software as a medical device – a designation that BioScan is software regulated as a medical device according to applicable legislation (MDR).

MEDDI App: The mobile application through which the BioScan medical device is made available to the user.

Measurement: The process of capturing and evaluating optical signals from the user's face for the purpose of estimating physiological parameters through the BioScan application.

Mobile device: A compatible electronic device (e.g., smartphone or tablet) on which the application is operated.

Incident: Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

Operating system (OS): The basic software of a mobile device that ensures its functioning and enables the application to run. BioScan is intended for compatible devices with the iOS or Android operating system.

Measurement conditions: A set of requirements for the environment, user position, and technical parameters of the device that must be met to achieve reliable results.

Reference range: A range of common values established based on a reference population.

rPPG (remote photoplethysmography): A non-contact method for measuring physiological parameters that uses a camera to detect subtle colour changes in the skin of the face caused by changes in blood flow in the vessels during the cardiac cycle.

Software: The software equipment of a medical device. In the case of BioScan, it is software running on a compatible mobile device that ensures the initiation and course of measurement, processing of obtained data, and display of results.

Measurement reliability: A relative indicator of result quality expressing to what extent the result can be considered trustworthy based on the analysed data.

Stable lighting: Lighting that is uniform during measurement and does not significantly change its intensity or colour character.

SÚKL: State Institute for Drug Control (Státní ústav pro kontrolu léčiv).

Pulse rate (heart rate): Indicates the number of heart contractions (beats) per minute. The unit of measurement is beats per min (bpm).

Artificial intelligence (AI): Technology that enables software to recognize patterns in data and, based on them, perform automated analysis or generate estimates.

User: A person who uses the BioScan application in accordance with its intended purpose.

Measurement result: The numerical value of a physiological parameter displayed by the BioScan application after completion of the measurement, including any verbal and graphical expression relative to the reference range.

Serious incident: Any incident that directly or indirectly led, might have led or might lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, a serious public health threat.

Serious public health threat: An event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

2. Information about the Instructions for Use

These instructions for use (hereinafter "instructions") are intended for users of the **BioScan®** medical device (hereinafter "medical device", "device", or "application"). The instructions provide important information on the safe and correct use of the medical device in accordance with its intended purpose. Failure to familiarize oneself with these instructions may result in incorrect use, inaccurate results, incorrect interpretation of results, and/or reduced performance of the medical device.

2.1 Form of the Instructions for Use

The instructions for use are available in electronic form (eIFU):

- Directly in the BioScan application at: https://www.meddiapp.com/bioscan-navod.pdf
- Directly in the application under the Menu – More – BioScan Instructions for Use tab.
- On the manufacturer's websites: www.meddi.com or www.meddiapp.com.

A printed version of the instructions for use can be provided to the user upon request.

2.2 How to Obtain a Printed Copy of the Instructions

A printed copy of the instructions for use can be requested from the manufacturer via:

- Technical support email: support@meddi.com.
- The contact form on the manufacturer's website.

A printed copy will be provided free of charge and delivered no later than 7 calendar days after receipt of the request.

3. Symbols used

Caution (Warning) – indicates a potentially dangerous situation associated with the use or reasonably foreseeable misuse of the system, which must be prevented as it could lead to health hazards or other serious adverse effects.

Manufacturer

Read the electronic instructions for use.

Medical Device

Unique Device Identifier

The marking proves that the product was assessed before being placed on the market of the European Economic Area and meets EU legislative requirements.

Additional information for the user

4. Intended purpose

BioScan is a medical device software intended for user-initiated, non-invasive self-measurement of selected physiological parameters by laypersons using remote photoplethysmography (rPPG) via compatible mobile devices equipped with a camera. The device provides outputs for health awareness only and is intended to support personal self-monitoring of physiological parameters without clinical interpretation. It is not intended to provide a diagnosis, to replace medical examinations or professional medical advice, or to be used for clinical decision-making. The information provided may encourage users to consult a qualified healthcare professional if they have health-related concerns. It does not replace measurements obtained using clinically validated medical devices and/or methods used as part of established standards of care and shall not be used as a substitute for such devices and/or methods. The user is not intended to interpret or take clinical action based on the device output without consultation with a qualified healthcare professional.

5. Functionalities

Measurement of physiological parameters: blood pressure (SYS – systolic blood pressure, DIA – diastolic blood pressure), pulse rate, respiratory rate, haemoglobin (Hb), and glycated haemoglobin (HbA1c).

6. Intended users

The BioScan medical device is intended for laypersons (adults aged 18 years and older).

7. Indications

BioScan is intended for non-contact, non-invasive self-measurement and self-monitoring of selected physiological parameters in a non-clinical environment.

8. Contraindications or limitations of use

In the traditional sense, no clinical contraindications are known for BioScan.

However, there are limitations of use that may reduce measurement reliability or make the medical device unsuitable for use in certain situations, for certain users, or under certain environmental conditions.

The following situations are considered contraindications or limitations of use:

- Inability to remain still during measurement, including individuals with involuntary movements or limited ability to maintain a stable position (e.g., due to tremor or certain neurological conditions).
- Obstruction of the face within the scanned area (e.g., dense facial hair, heavy make-up, face masks, glasses, or medical dressings) that interferes with optical signal acquisition.

- Inadequate ambient lighting conditions or exposure to direct light sources that may distort the captured video signal and thereby affect measurement accuracy.
- Severely impaired skin perfusion (e.g., in cases of low blood pressure, shock, or vasoconstriction), which may affect rPPG signal accuracy.
- Significant skin changes or atypical pigmentation in the facial area (e.g., extensive haemangiomas, burns, implants, fillers, or tattoos), which may interfere with the capture of the optical signal and reduce measurement accuracy.
- Use during rapidly changing physiological states (e.g., during or immediately after intense physical activity), which may lead to transient instability of the measured parameters and reduce measurement accuracy.
- Use in environments with excessive movement or vibration (e.g., in moving vehicles, during walking, or when the device is handheld without stabilization), which may disrupt signal stability and reduce measurement accuracy.
- Use under lighting conditions causing flickering (fluctuation) of light, reflections, or glare (e.g., strong backlight or direct sunlight), which may interfere with camera-based signal acquisition and reduce measurement accuracy.
- Use on mobile devices with low camera resolution, unstable frame rates, or without an autofocus function may affect signal quality and measurement reliability.
- Use in persons with a skin tone or skin condition that does not allow sufficient capture of the optical signal in the red, green, and blue (RGB) channels. Although the algorithm has been validated across Fitzpatrick phototypes I–VI, the representation of the darkest skin tones was limited; therefore, the performance of the device in these subgroups may vary.
- The performance of the device has been validated only within the specific reference ranges listed below for each physiological parameter and operating system (iOS and Android). Use outside these validated ranges may reduce measurement accuracy:
    - Pulse rate: 50.0–115.0 bpm (iOS), 50.0–117.0 bpm (Android)
    - Respiratory rate: 8.0–28.0 rpm (iOS and Android)
    - Systolic blood pressure (SYS): 100.0–160.0 mmHg (iOS and Android).
    - Diastolic blood pressure (DIA): 60.0–100.0 mmHg (iOS and Android).
    - Haemoglobin (Hb): 100.0–170.0 g/l (iOS), 100.0–160.0 g/l (Android).
    - Glycated haemoglobin (HbA1c): 20–64 mmol/mol (iOS and Android).

    The device performance outside these validated ranges has not been established and is therefore not claimed by the manufacturer.
- Use in a clinical environment where continuous or high-precision monitoring of physiological parameters is required is not suitable, as such settings require certified medical-grade devices classified as class IIa or higher.

9. Side effects

BioScan is a medical device software that does not come into physical contact with the user. Therefore, the risk of any physical side effects associated with the use of the device can be excluded.

10. Warnings

BioScan is intended exclusively for self-measurement and self-monitoring of selected physiological parameters by laypersons in a non-clinical environment.

The medical device does not provide a diagnosis and must not be used for clinical decision-making, for therapeutic guidance, or as a substitute for a professional medical examination.

Measurements obtained outside the validated physiological reference ranges may be inaccurate or unreliable.

BioScan may, in some cases, provide incorrect or inaccurate results. The application does not guarantee claimed measurement accuracy under all conditions. Factors such as user movement, lighting, facial obstructions, and the device's technical parameters can affect performance.

In case of health concerns, seek advice from qualified healthcare professional.

Not following the instructions for use may lead to inaccurate measurement results, misinterpretation of results, or reduced performance of the application.

11. Other considerations

- As part of its functionality, BioScan uses artificial intelligence (AI) to analyse optical signals.
- Users must not share their login credentials (username, password, or access tokens) with others under any circumstances. Sharing of login credentials may compromise the integrity, confidentiality, and traceability of personal data and measurement results.

12. Description of the medical device, clinical benefit and validated measurement accuracy

12.1 Description of the device and its outputs

BioScan is a Class I medical device software. It enables non-contact and non-invasive self-measurement of selected physiological parameters from a short facial video acquired via the front-facing camera of a compatible mobile device. The measurement is based on remote photoplethysmography (rPPG). To analyse optical signals and estimate the values of selected physiological parameters, BioScan uses an algorithm based on computer vision, signal processing, and artificial intelligence, specifically pre-trained machine learning models. These models do not undergo further learning and are not independently updated after deployment. The outputs are intended only to support personal health awareness and personal self-monitoring of physiological parameters without clinical interpretation. The device is not intended to provide a diagnosis or to be used for clinical decision-making.

BioScan outputs:

- Blood pressure in mmHg
- Pulse rate in beats per minute (bpm)
- Respiratory rate in respirations per minute (rpm)
- Haemoglobin in g/l

- Glycated haemoglobin (HbA1c) in mmol/mol

Measurement duration: Under recommended conditions, the measurement usually takes less than 1 minute.

12.2 Clinical benefit of the medical device

Within the scope of its intended purpose, the clinical benefit of BioScan lies in enabling lay users to support personal self-monitoring and health awareness by providing accessible and reasonably accurate physiological parameter outputs generated from user-initiated, contactless and non-invasive rPPG-based self-measurement using compatible mobile devices.

The claimed clinical benefit of the device applies only within the limits of its intended purpose and under the conditions of use and limitations specified in these Instructions for Use.

The required accuracy was demonstrated for all evaluated physiological parameters in the clinical performance validation studies.

12.3 Validated measurement accuracy

The table below summarizes the validated measurement accuracy of BioScan for each physiological parameter within its validated measurement ranges; these ranges may vary depending on the operating system (iOS, Android). The stated values apply under the recommended conditions of use specified in these instructions for use. Performance of the device outside the stated ranges and specified measurement conditions has not been validated and is therefore not claimed by the manufacturer.

Measured parameter	Validated measurement accuracy	Required measurement accuracy achieved in	Validated measurement ranges by operating system
Pulse rate	± 3 bpm	99,8 % of measurements	iOS: 50,0–115,0 bpm; Android: 50,0–117,0 bpm
Respiratory rate	± 3 rpm	95,9 % of measurements	iOS and Android: 8,0–28,0 rpm
Systolic blood pressure	± 15 mmHg	87,9 % of measurements	iOS and Android: 100,0–160,0 mmHg
Diastolic blood pressure	± 10 mmHg	82,9 % of measurements	iOS and Android: 60,0–100,0 mmHg
Haemoglobin (Hb)	± 15 g/l	79,4 % of measurements	iOS: 100,0–170,0 g/l; Android: 100,0–160,0 g/l
Glycated haemoglobin (HbA1c)	approximately ±12 mmol/mol	73,3 % of measurements	iOS and Android: approximately 20–64 mmol/mol

13. Installation

13.1 System requirements

BioScan is a medical device software intended for use on commonly available mobile devices that meet the following minimum system requirements:

Operating system: iOS (version 13.0 or newer) and Android (version 10.0 or newer) on devices officially supported by Apple or Google.

Processing capability: The device must have sufficient performance to ensure stable video capture at a frequency of at least 30 frames per second (fps) while simultaneously processing data using artificial intelligence algorithms.

Front-facing camera: The device must be equipped with an integrated front camera for capturing the user's face. The minimum required parameters are a resolution of 1080p at 30 frames per second (fps). Lower resolutions (e.g., 720p) have not been validated and may not ensure correct measurement functionality. Devices that do not meet these parameters may provide inaccurate or incomplete results.

Memory (RAM): At least 3 GB of RAM is recommended to ensure the smooth running of the application and stability during measurement.

Battery status: A minimum of 20% battery capacity is required to ensure an uninterrupted measurement process.

Power-save mode: Energy saving mode must be turned off during measurement to avoid limiting device performance (e.g., reducing processor performance or camera frame rate).

Camera condition: The camera must be clean, undamaged, and unobstructed to correctly capture the signal.

Internet connection: A functional internet connection is required for the BioScan medical device to work correctly.

13.2 Access to the BioScan medical device

BioScan is available only within the MEDDI App (or partner applications based on the MEDDI App technology solution) and cannot be used independently. Before the first use, it is necessary to install the MEDDI App from an official distribution channel (App Store or Google Play) and create a user account through the registration process or log in. After registration and logging in, the user has access to the BioScan medical device.

BioScan can be accessed from the application’s home screen in two ways: via the large BioScan tile at the top of the screen or via the smaller BioScan tile in the Quick Actions section.

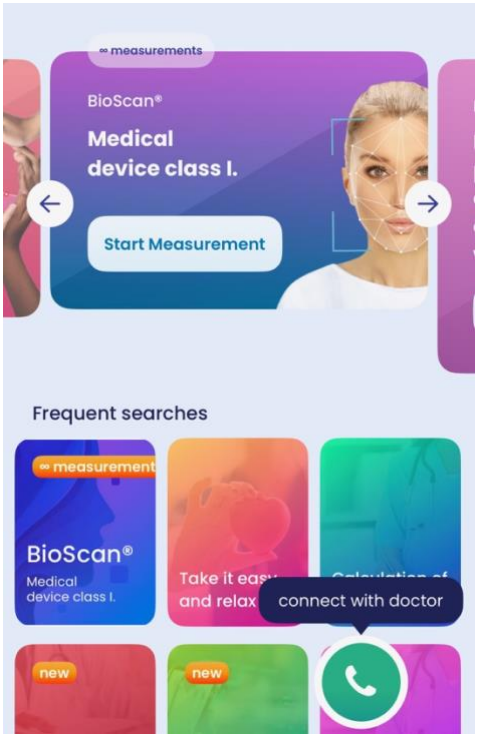

Figure 1: Access to the BioScan from the MEDDI App home screen – large tile at the top of the screen and a smaller tile in the Quick Actions section.

13.3 Identification of medical device

On the BioScan home screen, the medical device label is displayed. This label contains the device name, manufacturer details, the UDI, the software version, and a link to the current instructions for use.

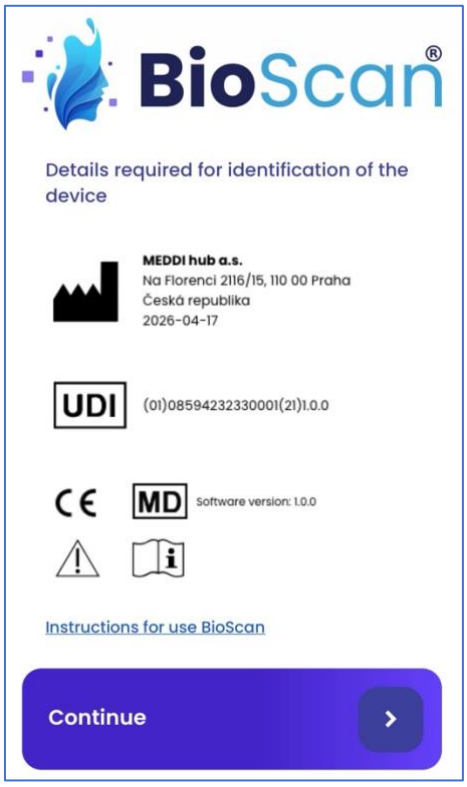

Figure 2: BioScan home screen with the medical device label.

Further details on the information provided on the medical device label:

- **YYYY-MM-DD** – the release date of the BioScan medical device version X.Y.
- **UDI – Unique Device Identifier**, which consists of UDI-DI and UDI-PI.
    - **(01)… – UDI-DI**, device identifier, specific to the manufacturer and the device.
    - **(21)… – UDI-PI**, device production identifier; for BioScan, this represents the identification of the specific software version, including sub-version.

14. Procedure for using the BioScan device

14.1 Selection of measurement and entry of input of data

After the medical device identification label is displayed, press the **[Continue]** button.

The following screen displays an overview of the health indicators (physiological parameters) that can be measured using BioScan. To start the measurement, press the **[Start BioScan]** button.

Before the measurement starts, you are prompted to enter the data required for the measurement. First, indicate whether the person being measured is you **[Yes, I am measuring myself]** or another person **[No, someone else]**.

If you choose the option **[Yes, I am measuring myself]**, enter your current body weight and save the data with the **[Save]** button.

If you choose the option **[No, someone else]**, enter the current body weight, age, and gender of the person being measured and save the data with the **[Save**] button.

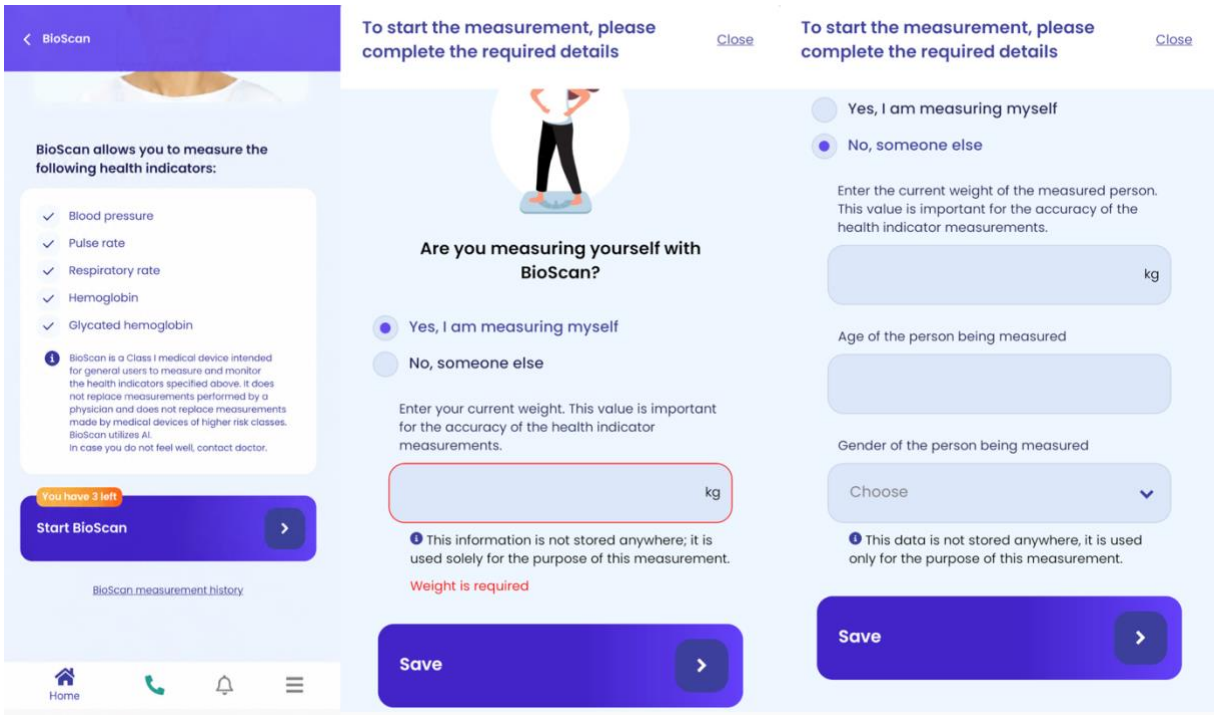

Figure 3: Overview of measured parameters and entry of input data before starting the measurement.

14.2 Preparation and correct execution of measurement

Before starting the measurement, read the instructions displayed in the application ("**How to measure correctly**") and follow them.

To ensure correct measurement, the following conditions must be met:

- Remain in a resting state for at least 2–3 minutes before the measurement.
- Perform the measurement while seated, with your feet placed freely on the floor.
- Place the mobile device in a stable position; it is recommended to lean it against a solid support or use a stand.
- The mobile device's battery must be charged to at least 20%.
- Power saving mode must not be turned on in the device during the measurement.
- The front camera must be clean, undamaged, and must not be covered.
- The face must be uncovered and fully visible (without covering, shadows, or heavy make-up).
- Look into the front camera of the mobile device throughout the entire measurement.
- Keep your face within the marked frame on the display.
- Keep your face at a distance of approximately 20–40 cm from the camera.
- Do not speak, move your head, or change your facial expression during the measurement.
- Perform the measurement in an environment with stable lighting (for the best result, it is suitable to sit under a single source of cool white light).
- There must be no direct sunlight, flickering lighting, coloured lighting, or multiple simultaneous light sources at the measurement site.
- Avoid movement in the background and reflective surfaces, such as mirrors or glass.

If these conditions are not met, the quality of the captured signal may be reduced, and the accuracy of the measurement results may be affected.

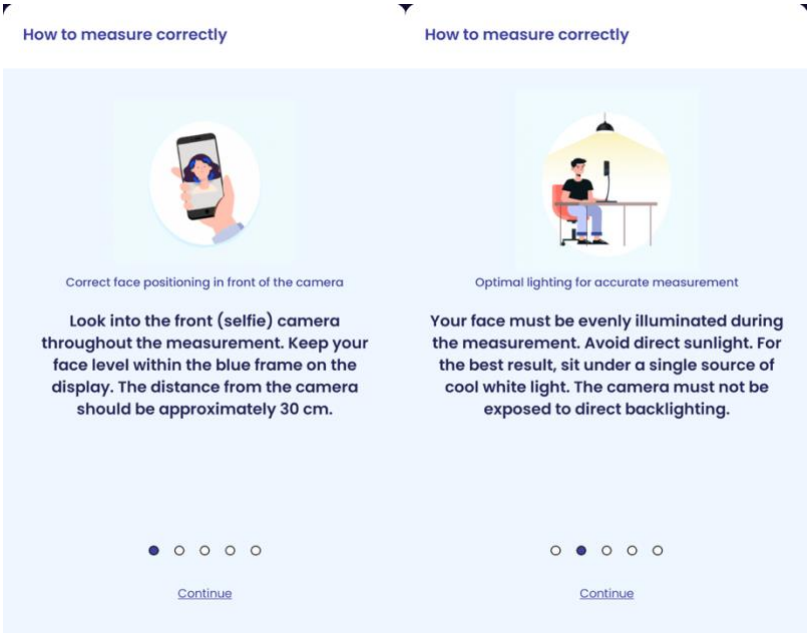

Figure 4: Examples of the "How to measure correctly" instructions displayed in the application before starting the measurement.

14.3 Starting the measurement

After reading the "**How to measure correctly**" instructions, a screen prompting you to start the measurement is displayed. To start the measurement, press the **[Start measurement]** button.

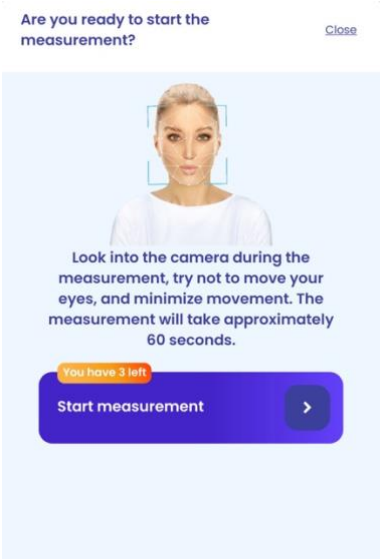

Figure 5: Starting the measurement.

Once the measurement starts, the screen shows a front-camera preview, a marked frame for positioning the face, and the continuously updated percentage indicating the measurement progress.

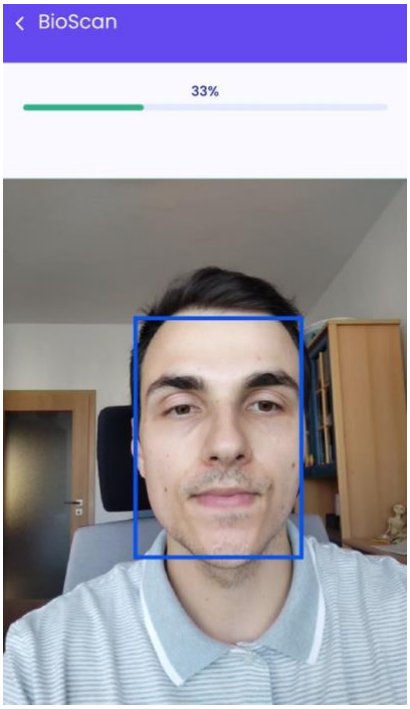

Figure 6: Measurement progress – front camera preview with a marked frame for face positioning and a continuously displayed percentage indicating the measurement progress.

During the measurement, BioScan automatically verifies key measurement conditions, in particular correct face positioning within the marked frame, appropriate distance from the camera, movement restriction, and the quality of the captured signal. If these conditions are not met, the user may be prompted to adjust the position/conditions, or to repeat the measurement (see Chapter 14.5).

14.4 Displaying, saving and sharing of measurement results

Presentation of outputs: Upon completion of the measurement, the BioScan application displays each measured physiological parameter in a standardized form, which includes a numerical value with the unit specific to the given parameter and a neutral descriptive indicator (“lower”, “normal”, “higher”) derived from predefined reference ranges. A colour-coded gauge visually shows where the value lies in relation to the parameter-specific reference range.

Confidence level (of the measurement): For selected parameters, specifically pulse rate and respiratory rate, the measurement confidence level is additionally displayed in the form of a scale (low, medium, high), supplemented by a sliding indicator expressing the relative reliability of the result. The application is designed to ensure that results with a 'Low' or 'Unknown' confidence level are not presented as valid outputs; in such a case, the user is prompted to repeat the measurement.

Educational information: For each parameter, users may optionally view a brief explanation of the parameter and, where relevant, an overview of common ranges or value categories in the general population. This information is intended only to support a general understanding of the result. It does not constitute a clinical interpretation, is not tailored to the individual user or to the specific measurement result and does not replace consultation with a qualified healthcare professional.

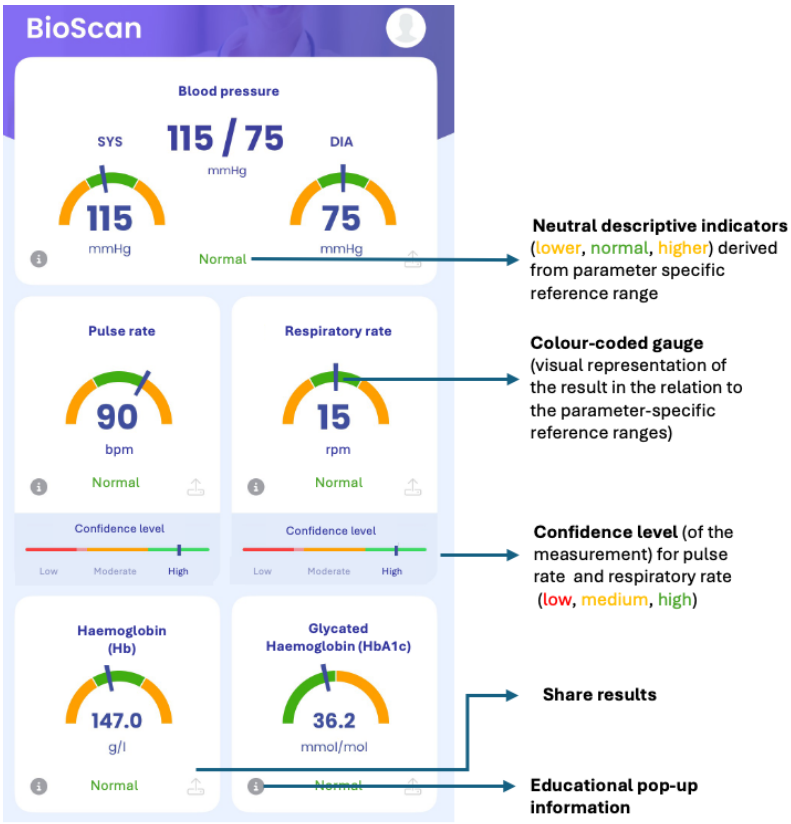

Figure 7: Standardized presentation of measurement outputs in the BioScan application.

- **Saving of results (reports)**: All measurement results are stored in the application, allowing the user to review previous measurements.
- **Sharing of results**: The BioScan application allows users to share selected measurement results through a secure messaging function integrated into the mobile phone. This function enables measurement results to be shared in a structured format for informational purposes.

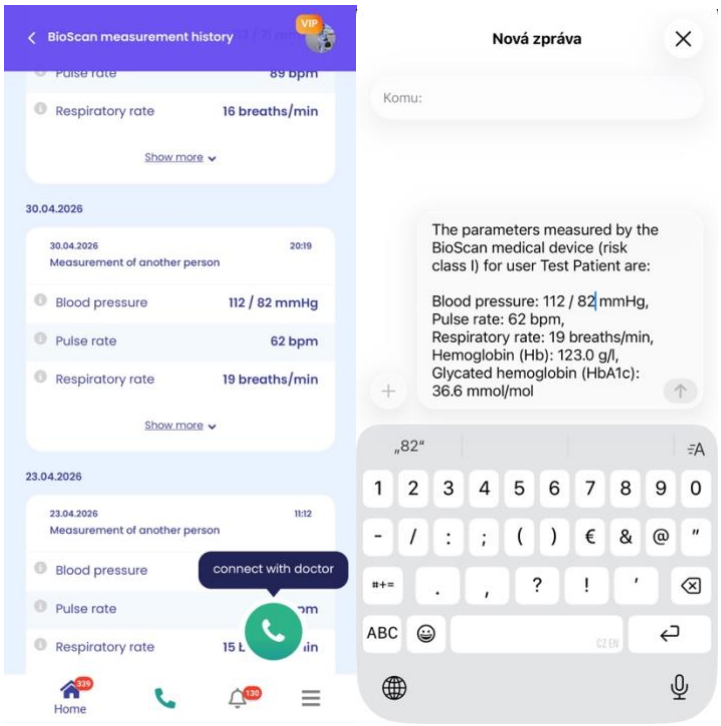

Figure 8: Measurement history and sharing of results.

14.5 Alerts during measurement and measurement interruption

Alerts during measurement

During the measurement, BioScan may display alerts if the conditions necessary for proper performance of the measurement and for obtaining a signal of sufficient quality are not met. These alerts are intended to allow the user, while the measurement is in progress, to adjust the position of the face, the position or orientation of the mobile device, or the environmental conditions (lighting).

During the measurement, BioScan automatically verifies, in particular, correct positioning of the face within the marked frame, the distance of the face from the camera, movement of the head and face, the orientation of the mobile device, and the quality of the captured signal. If any of these conditions is not met, the application displays a corresponding alert.

Examples of typical alerts displayed during measurement include:

Figure 9: Examples of alerts displayed during measurement.

If any of these alerts is displayed, follow the on-screen instructions and adjust the measurement conditions accordingly. If sufficient signal quality cannot be achieved, the measurement may be interrupted or evaluated as invalid. In such a case, the application displays information that the measurement was unsuccessful and recommends repeating it.

Measurement interruption

The measurement may be interrupted if, even after an alert has been displayed, the conditions necessary for proper performance of the measurement and for obtaining a signal of sufficient quality cannot be ensured, or if a technical problem occurs with the mobile device or the application.

In such a case, the application displays information about the interruption of the measurement and a recommendation to repeat it.

Figure 10: Examples of messages displayed when the measurement is interrupted.

15. Service and maintenance

The BioScan module does not allow for independent servicing by the user. If any such service is required, MEDDI hub a.s. will release an updated version of the application.

15.1 Troubleshooting

Try the quick steps below first. If the problem persists, see the **Contact and Support** section.

1) App cannot be installed/opened
Quick check

- Verify that your device and OS are supported (see System Requirements).
- Check that you have sufficient free storage space and a stable internet connection.
- Restart the device and try again.

If the issue persists

- Update the device OS to a supported version.
- Reinstall the app only from the official app store (App Store/Google Play).

2) Cannot log in / forgotten password
Quick check

- Check that the email address and password are entered correctly.
- Turn off CAPS LOCK and try again.

Reset

- Tap on "Forgotten Password" and follow the instructions sent to your email.
- If you do not receive the email, check your spam folder or try again after 15 minutes.

3) No internet connection / synchronization failed
Quick check

- Switch between Wi-Fi and mobile data.

If it still does not synchronize

- Re-link the data source (log out/log in at the provider).
- Check the provider's service status.

4) Measurement failed
Quick check

- Follow the on-screen instructions; remain still and quiet.
- Remove the phone case if it blocks camera; clean the camera lens.
- Ensure adequate lighting and sufficient battery charge (> 20 %).

Try again

- Close other applications using the camera.
- Restart the app and repeat the measurement.

Still not working?

- Check the system requirements (the device/OS may not be supported).
- Contact support with the error code/screenshot.

5) Results appear incorrect / Do not correspond to how you feel

- The results are for informational purposes only. If they do not correspond to your symptoms, trust how you feel.
- Repeat the measurement under appropriate conditions and make sure the data are up to date.
- If symptoms persist or the results are unusual, consult a qualified healthcare professional.

If you experience symptoms requiring immediate medical attention, call 155 (or 112) or contact your physician immediately. Do not rely on the application.

6) Notifications are not working

Quick check

- Enable notifications in Device Settings → Notifications → MEDDI App.
- Keep the app updated and allow background activity/data.

7) App is slow / Crashes

- Check the available free space and close resource-intensive applications.
- Restart the device.
- Update the app to the latest version.

If the problem persists, contact support and provide the device model, OS version, app version, and a description of the issue.

8) Unable to find IFU / Product information (About the app)

- In-app: BioScan tile
- Web version: https://www.meddiapp.com/bioscan-navod.pdf
- If the information is not available, update the application to the latest version.

Common Error messages (examples)

- „Network error " → Check your internet connection/Wi-Fi and tap on „Try again".
- „Unsupported device/OS" → See the system requirements and update the OS.
- „Camera is not available " → Close other apps and allow camera access.
- „Insufficient storage " → Free up storage space and try again.

Contact and support

- Support e-mail: support@meddi.com
- Operating hours: 24 hours a day, 7 days a week

Please provide: App version (found in "About"), device model, OS version, screenshots, time of the issue, steps to reproduce it, and any error codes.

Data and Privacy notes (brief)

- Do not share your password or verification codes.
- If you suspect unauthorized access, change your password and contact support.
- For details, see the Privacy Policy and Terms of Use.

16. Reporting of a suspected serious incident

If, in connection with the use of the BioScan medical device, you suspect that a serious incident has occurred, report it without undue delay to MEDDI hub a.s., the manufacturer of the medical device.

A suspected serious incident may also be reported to the competent authority of the Member State in which the user is established. In the Czech Republic, the competent authority is the State Institute for Drug Control (SÚKL).

What is considered a serious incident?

A serious incident is an incident that directly or indirectly led, might have led, or might lead to any of the following consequences:

- the death of a user or other person,
- the temporary or permanent serious deterioration of a user's or other person's state of health,
- a serious public health threat.

What to do immediately?

- If the situation is urgent, call 155 (or 112) or contact your physician immediately.
- Stop using the application until you are sure that it is safe to continue using it.
- If possible, record important information about the event, such as the time, circumstances, any error message, or take screenshots.
- Report the incident to the medical device manufacturer and, where appropriate, to SÚKL.

How to report a suspected serious incident to the manufacturer (MEDDI hub a.s.)

- In-app: Menu → Help → Report a problem
- E-mail: support@meddi.com
- Web form: www.meddi.com/cz/kontakt

If possible, include the following in the report:

- Your name and contact details,
- The date and time of the incident,
- A brief description of what happened,
- Information about what you were doing in the application immediately before the incident occurred,
- Application version (Menu → About the app), device model, and operating system (OS) version,
- Any error message or code,
- Screenshots or other available supporting materials.
- If medical care was provided in connection with the suspected serious incident, state this fact; if the outcome or consequence of the event is known, provide this information to the extent necessary.

Your report will be assessed and, if necessary, you may be contacted to provide additional information.

Quick email template (you can copy and paste):
Subject: Report of a suspected serious incident – MEDDI BioScan – date: [DD/MM/YYYY] / time: [HH:MM]
Text:
Name and contact details: …
App version (Menu → About the app): …
Device and OS: …
What happened (briefly): …
Steps leading to the issue: …
Did any harm occur / did you seek medical attention? …
Screenshots attached: Yes/No
Connected devices/data sources: …

Reporting a suspected serious incident to the State Institute for Drug Control (SÚKL)

You may also report a suspected serious incident to the State Institute for Drug Control (SÚKL). The SÚKL website provides information on the content of the report, the method of submission, and a form for reporting by a patient. Reports may be submitted via data box, email, or post.

17. Other technical problems, deficiencies, and complaints

If, while using the application, you experience a technical issue, error, ambiguity, or other deficiency that is not related to a suspected serious incident, please report it to the manufacturer. This may include, for example:

- malfunctioning of the application or crashes,
- problems with starting, performing, or completing measurement,
- problems with displaying, saving, or viewing the history of results,
- error messages or unexpected behaviour of the application,
- unclear, incorrect, or missing information in the application or in the instructions for use,
- problems with the application's access to device functions required for its proper operation.

18. Manufacturer and support

Manufacturer

Name: MEDDI hub a.s.
Address: Na Florenci 2116/15, 110 00 Praha 1 – Nové Město
Web: www.meddi.com
Contact: info@meddi.com / phone number 00420 603 807 777

Support

- E-mail: support@meddi.com
- Operating hours: 24 hours a day, 7 days a week
- **Reporting suspected serious incidents and other technical problems**: In the application: Menu → Help → Report a problem
- Public URL/QR for eIFU: https://www.meddiapp.com/bioscan-navod.pdf

MEDDI hub a.s.
Na Florenci 2116/15
110 00 Praha 1 – Nové Město

BioScan ®

Medical Device – software (MDSW)

Software version: 1.0

Email: info@meddi.com
Company website: www.meddi.com