**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 analyze optical signals obtained from a short video recording of the face and to estimate the values of selected physiological parameters.

**Centering**: A process in which the application guides the user to place their face in the center of the marked frame.

**Respiratory rate**: Indicates the number of breaths per minute. The unit of measurement is breaths/min.

**eIFU**: Electronic instructions for use.

**Fitzpatrick scale (phototypes) I-VI**: A commonly used scale for describing skin phototypes, i.e., its coloring 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 hemoglobin (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 hemoglobin to which glucose is bound. The unit of measurement is mmol/mol.

**Hemoglobin**: 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.

**Unassessable measurement**: A measurement in which it was not possible to obtain high-enough quality data for calculating results.

**Adverse event**: 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 color 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 analyzed data.

**Stable lighting**: Lighting that is uniform during measurement and does not significantly change its intensity or color 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/min.

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

**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 adverse event**: An adverse event that directly or indirectly led, might have led, or may lead to any of the following: the death of a patient, temporary or permanent deterioration in a state of health, or a serious public health threat.
**Serious public health threat**: An event that may lead to an imminent risk of death, serious deterioration in a state of health, or significant morbidity or mortality in a population.

# 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 lead to incorrect use, inaccurate results, their incorrect interpretation, and/or a reduction in the 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, hemoglobin (Hb), and glycated hemoglobin (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 personal monitoring of selected physiological parameters in a non-clinical environment.

# 8. Contraindications or limitations of use

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

However, there are limitations of use that may reduce measurement reliability or cause the use of the medical device to be unsuitable 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 persons with involuntary movements or a limited ability to maintain a stable position (e.g., due to tremors or certain neurological diseases).
- Obstruction of the face in the captured area (e.g., thick beard, heavy makeup, mask, glasses, or medical covering), which may interfere with the capture of the optical signal.
- Inappropriate ambient lighting or direct light may distort the captured optical signal, thereby affecting measurement accuracy.
- Significantly reduced skin perfusion (e.g., in cases of low blood pressure, shock, or vasoconstriction), which may adversely affect the accuracy of the rPPG signal.
- Significant skin changes or atypical pigmentation in the facial area (e.g., extensive hemangiomas, 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, while walking, or if the device is held by hand 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 the capture of the optical signal and reduce measurement accuracy.
- Použití na mobilních zařízeních s nízkým rozlišením kamery, nestabilní snímkovou frekvencí nebo bez funkce automatického ostření může ovlivnit kvalitu snímaného signálu a spolehlivost měření.
- Use on mobile devices with low camera resolution, unstable frame rates, or without an autofocus function may affect the quality of the captured signal and measurement reliability.
- Use in persons with a skin tone or skin condition where the optical signal cannot be sufficiently captured in the red, green, and blue components (RGB). 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.
- Výkonnost prostředku byla validována pouze pro níže uvedená referenční rozmezí jednotlivých fyziologických parametrů na příslušných operačních systémech (iOS, Android); tato rozmezí se mohou podle operačního systému lišit. Použití mimo tato validovaná rozmezí může snížit přesnost měření:
- The performance of the device has been validated only for the reference ranges of individual physiological parameters listed below on the respective operating systems (iOS, Android); these ranges may vary according to the operating system. Use outside of these validated ranges may reduce measurement accuracy:

    - Pulse rate: 50.0–115.0 beats/min (iOS), 50.0–117.0 beats/min (Android)
    - Respiratory rate: 8.0–28.0 breaths/min (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).
    - Hemoglobin (Hb): 100.0–170.0 g/l (iOS), 100.0–160.0 g/l (Android).
    - Glycated hemoglobin (HbA1c): 20–64 mmol/mol (iOS and Android).

    The performance of the device outside of these validated ranges has not been established and is not declared by the manufacturer.

- Use in a clinical environment where continuous or high-precision monitoring of physiological parameters is required is not suitable, as certified medical devices of at least Class IIa are intended for such use.

# 9. Side effects

BioScan is a software medical device 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 lay users for self-measurement and personal monitoring of selected physiological parameters in a non-clinical environment.

The medical device does not provide a diagnosis and must not be used for clinical decision-making, for guiding treatment, 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 the accuracy of measurement declared by the manufacturer under all conditions. Performance may be influenced by factors such as user movement, lighting, facial obstruction, and the device's technical parameters. In case of health concerns, consult a qualified healthcare professional.

Failure to comply with the instructions for use may lead to inaccurate measurement results, incorrect interpretation of results, or reduced application performance.

# 11. Additional information

- BioScan utilizes artificial intelligence (AI) to process and analyze optical signals.
- Users must not share their login credentials (username, password, or access tokens) with other persons under any circumstances. Sharing 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 software medical device. It enables non-contact and non-invasive self-measurement of selected physiological parameters from a short video recording of the face captured by the front camera of a compatible mobile device. Measurement is based on the remote photoplethysmography (rPPG) method. To analyze optical signals and estimate the values of selected physiological parameters, BioScan uses an algorithm based on computer vision methods, signal processing, and artificial intelligence, specifically on pre-trained machine learning models. These models do not learn further or update themselves independently during operation. Outputs are intended only to support personal health awareness and to support personal monitoring of physiological parameters without clinical interpretation. The device is not intended for establishing a diagnosis or for clinical decision-making.

**Outputs from BioScan:**

- Blood pressure in mmHg
- Pulse rate in beats per minute (beats/min)
- Respiratory rate in breaths per minute (breaths/min)
- Hemoglobin in g/l
- Glycated hemoglobin (HbA1c) in mmol/mol

**Measurement time:** A measurement under recommended conditions usually takes less than 1 minute.

## 12.2 Clinical benefit of the medical device

The clinical benefit of BioScan within its intended purpose lies in allowing lay users to personally monitor selected physiological parameters and supporting personal health awareness. This benefit is achieved by the device providing accessible and sufficiently accurate measurement outputs of selected physiological parameters obtained from user-initiated, non-contact, and non-invasive self-measurement based on the rPPG method using compatible mobile devices.
The declared clinical benefit of the device applies only within the limits of its intended purpose and under the conditions and limitations of use stated in these instructions. For all evaluated physiological parameters (within clinical performance validation studies), the required accuracy was achieved.

## 12.3 Validated measurement accuracy

The table below summarizes the validated measurement accuracy using BioScan for individual physiological parameters within their validated measurement ranges; these ranges may vary depending on the operating system (iOS, Android). The stated data apply under the recommended conditions of use specified in these instructions for use. The device's performance outside the specified ranges and established measurement conditions has not been validated and is not declared by the manufacturer.

| Měřený parametr | Validovaná přesnost měření | Požadované přesnosti měření bylo dosaženo u | Validované rozmezí měření podle operačního systému |
|---|---|---|---|
| **Pulse rate** | ± 3 beats/min | 99,8 % measurements | iOS: 50,0–115,0 beats/min; Android: 50,0–117,0 beats/min |
| **Respiratory rate** | ± 3 breaths/min | 95,9 % measurements | iOS and Android: 8,0–28,0 breaths/min |
| **Systolic blood pressure** | ± 15 mmHg | 87,9 % measurements | iOS and Android: 100,0–160,0 mmHg |
| **Diastolic blood pressure** | ± 10 mmHg | 82,9 % measurements | iOS and Android: 60,0–100,0 mmHg |
| **Hemoglobin (Hb)** | ± 15 g/l | 79,4 % measurements | iOS: 100,0–170,0 g/l; Android: 100,0–160,0 g/l |
| **Glycated hemoglobin (HbA1c)** | approximately ±12 mmol/mol | 73,3 % measurements | iOS and Android: approximately 20–64 mmol/mol |

# 13. Installation

## 13.1 System requirements

BioScan is a software medical device 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.

**Device computing power**: 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 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.

**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 saving 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 Accessing 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 is accessible on 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.

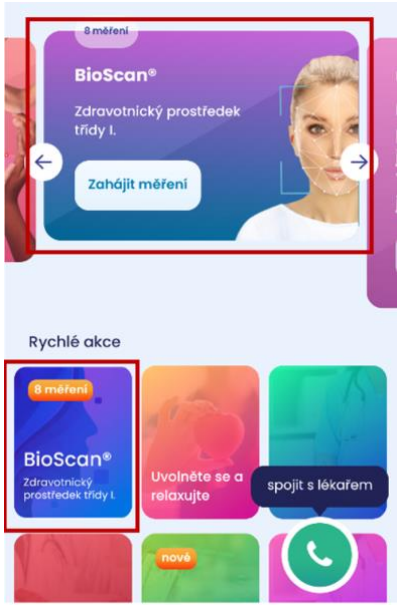


*Figure 1: Access to the BioScan device from the MEDDI App home screen – large tile at the top of the screen and a smaller tile in the Quick Actions section.*

## 13.3 Identification of medical device

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


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

More detailed information on the medical device label markings:

- **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 parts.
  - **(01)… – UDI-DI**, device identifier, specific to the given manufacturer and device.
  - **(21)… – UDI-PI**, device production identifier; for BioScan, this represents the identification of the specific software version, including sub-versions.

# 14. Procedure for using the BioScan device

## 14.1 Selection of measurement and input of data

After displaying the identification label of the medical device, press the **[Continue]** button. The following screen displays an overview of the health indicators that can be measured using the BioScan device. To start the measurement, press the **[Start BioScan]** button. Before starting the measurement, you will be prompted to complete the data required for the measurement. First, choose whether you are performing the measurement yourself **[Yes, I am measuring myself]** or if it is 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.

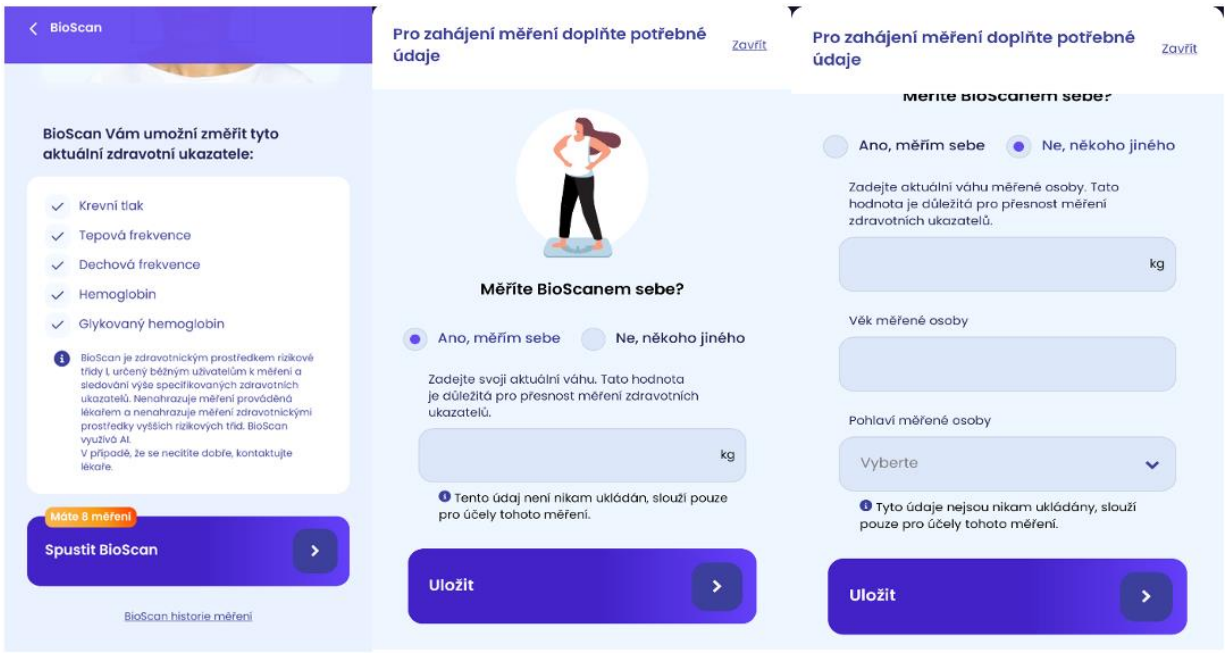


*Figure 3: Overview of measured parameters and input of data before starting the measurement.*

## 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 perform the measurement correctly, observe the following conditions:

- 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, colored lighting, or multiple simultaneous light sources at the measurement site.
- Avoid movement in the background and reflective surfaces, such as mirrors or glass.

Failure to comply with these conditions may reduce the quality of the captured signal and affect the accuracy of the measurement results.

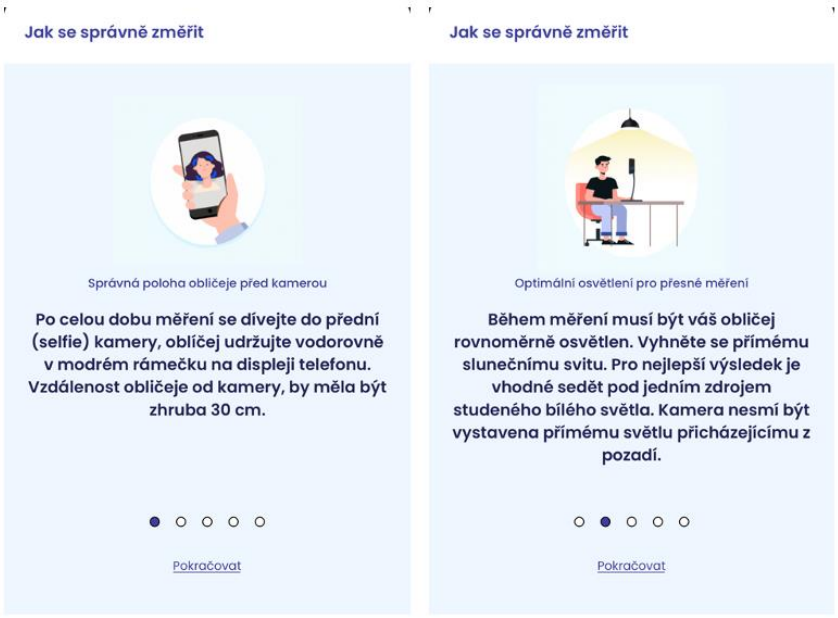


*Figure 4: Examples of the "How to measure correctly" instructions displayed in the application before starting the measurement.*

## 14.3 Starting the measurement

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

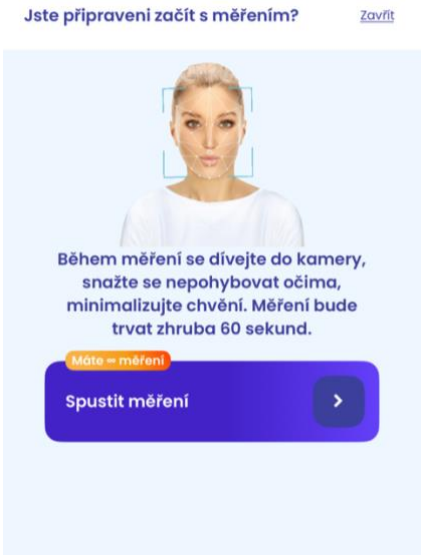


*Figure 5: Starting the measurement.*

After starting the measurement, a screen will be displayed showing a preview from the front camera, a marked frame for face placement, and a continuously updated percentage of the measurement's completion.

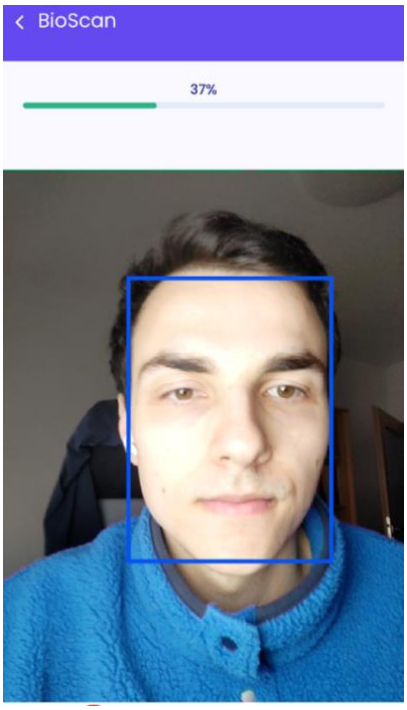


*Figure 6: Measurement progress – preview from the front camera with a marked frame for face placement and the continuously displayed percentage of measurement completion.*

During measurement, BioScan automatically verifies key measurement conditions, particularly the correct placement of the face within the marked frame, its distance from the camera, movement restriction, and the quality of the captured signal. If measurement 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 a unit specific to the given parameter and a neutral descriptive label (“lower”, “normal”, “higher”) derived from pre-determined reference ranges. A color-coded scale with a position indicator visually illustrates where the value is located relative to the relevant reference range.
**Measurement reliability level:** For selected parameters, specifically pulse rate and respiratory rate, the measurement reliability 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 so that results with a “low” or “unknown” reliability level are not presented as valid outputs; in such a case, the user is prompted to repeat the measurement.
**Educational information:** For individual parameters, a brief explanation of the parameter and, where relevant, an overview of common ranges or categories of values in the general population can optionally be displayed. This information serves only for a general understanding of the result, does not represent a clinical interpretation, is not tailored to a specific user or a specific measurement result, and does not replace consultation with a qualified healthcare professional.

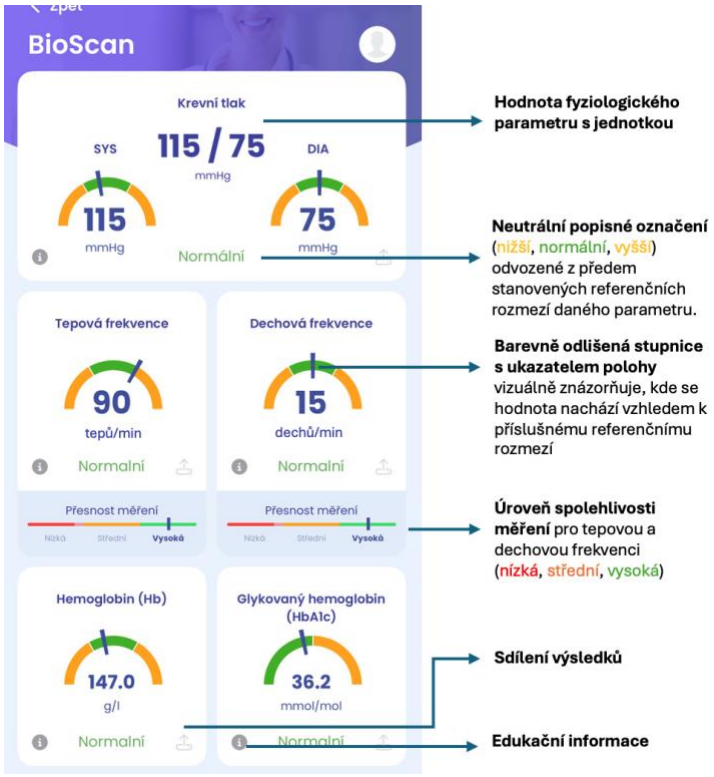


*Figure 7: Standardized presentation of measurement outputs in the BioScan application.*

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

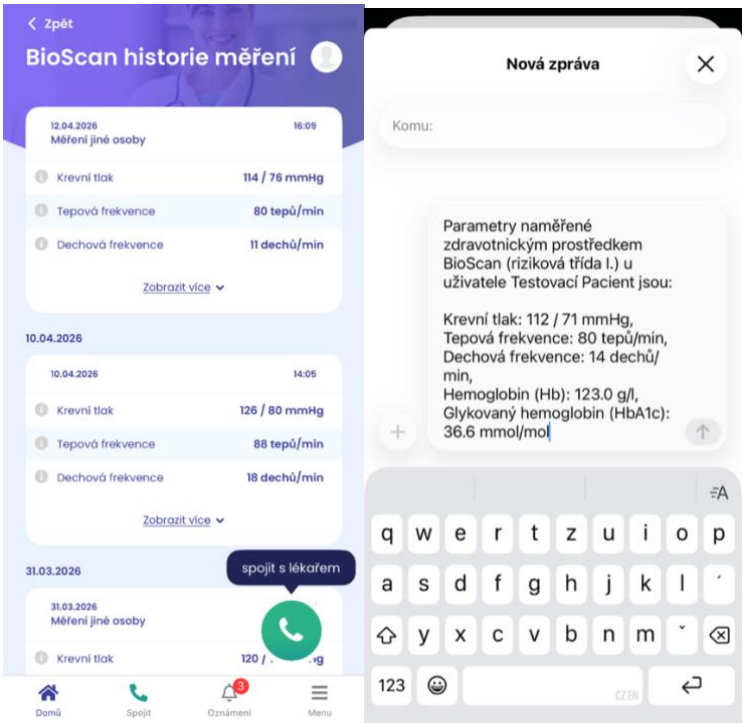


*Figure 8: Measurement history and sharing of results.*

## 14.5 Alerts during measurement and interruption of measurement

**Alerts during measurement:**

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

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

Typical alerts during measurement include, for example:

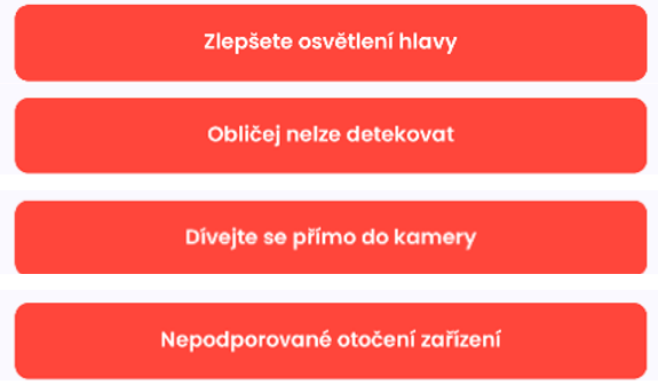


*Figure 9: Examples of alerts during measurement.*

If any of these alerts appear, follow the instructions on the screen and adjust the measurement conditions. If it is not possible to ensure sufficient quality of the captured signal, the measurement may be interrupted or evaluated as invalid. In such a case, the application will display information about the unsuccessful measurement and recommendations for repeating it.

**Interruption of measurement**

The measurement may be interrupted if, even after an alert is displayed, the conditions required for correct measurement execution and obtaining a captured 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 will display information about the interrupted measurement and recommendations for repeating it.


*Figure 10: Examples of messages during measurement interruption.*

# 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 for sufficient free space and a stable internet connection.

- Restart the device and try again.

**If it still doesn't work**

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

**2) Cannot log in / forgotten password**

**Quick check**

- Verify the accuracy of the email and password.
- Turn off CAPS LOCK and try again.

**Reset**

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

**3) No internet connection / synchronization failed**

**Quick check**

- Switch between Wi-Fi and mobile data.

**If it still doesn't sync**

- 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 calm and quiet.
- Remove the phone case if it blocks sensors; clean the camera/sensor lens.
- Ensure good lighting and sufficient battery (> 20 %).

**Try again**

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

**Still not working**

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

**5) Results look incorrect / Do not match how you feel**

- Results are informative only. If they do not match your symptoms, trust your own judgment.
- Repeat the measurement under appropriate conditions and ensure data is up to date.
- In case of long-term issues or unusual results, contact a healthcare professional.

**Symptoms requiring immediate medical attention?** Call 155 (or 112) or your doctor. 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 usage.

**7) App is slow / Crashes**

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

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

**8) Cannot find IFU / Product information (About the app)**

- In-app: BioScan tile
- Web version: https://www.meddiapp.com/bioscan-navod.pdf
- Pokud chybí, aktualizujte aplikaci na nejnovější verzi.
- If information is missing, update the app to the latest version.

**Common Error messages (examples)**

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

**Contact and support**

- Support E-mail: support@meddi.com
- Operating hours / Response: 24 hours

**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**

- Do not share your password or verification codes.
- If you suspect unauthorized access, change your password and contact support immediately.
- See the Privacy Policy and Terms of Use for more information.

# 16. Reporting a suspected serious incident

Any suspected serious incident that has occurred, or could have occurred, in connection with the use of the BioScan application must be reported without undue delay to MEDDI hub a.s. as 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, this 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:

- Death of a user or another person,
- Temporary or permanent serious deterioration of the state of health of a user or another person,
- A serious public health threat.

**What to do immediately?**

- If the situation is urgent, call 155 (or 112) or contact your doctor immediately.
- Stop using the application until you are certain that it is safe to continue its use.
- If possible, record important information about the incident, such as the time, circumstances, error messages, or take screenshots.
- Report the incident to the medical device manufacturer or to SÚKL (State Institute for Drug Control).

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

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

**In the report, if possible, include:**

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

We will evaluate your report and, if necessary, may contact you for additional information.

**Quick email template (you can copy/paste)**
**Subject:** Reporting a suspected serious incident – MEDDI BioScan – date: [DD/MM/YYYY] / time: [HH:MM]

**Text:**
Name and contact: …
App version (Menu → About the app): …
Device and OS: …
What happened (briefly): …
Steps leading to the issue: …
Was there an injury / did you seek medical care?: …
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). Information regarding the content of the report, the method of submission, and a reporting form for patients are available on the SÚKL website. Reports can be submitted via data box, email, or post.

# 17. Other technical problems, deficiencies, and complaints

If you encounter a technical problem, error, ambiguity, or other deficiency while using the application 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 starting, performing, or completing measurements,
- Problems displaying, saving, or viewing the history of results,
- Error messages or unexpected application behavior,
- Unclear, incorrect, or missing information in the application or instructions for use,
- Problems with the application's access to device functions required for its correct 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 00420 603 807 777

**Support**

- E-mail: support@meddi.com
- Operating hours / Response time: 24/7 / response within 48 hours.
- Reporting suspected serious incidents and other technical problems: In the application: Menu → Help → Report a problém
- 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)**

**Version of softwaru:** 1.0

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