Instructions for use of the Shen.AI medical device

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TABLE OF CONTENTS

1. Intended purpose 3
2. Indications and contraindications for the use of the Shen.AI device and expected clinical benefits 3
3. Operating principle 4
4. Measurement Conditions and Procedure 5
5. Performing the calibration procedure - mobile version 7
6. Performing a measurement - mobile version 15
7. Performing the calibration procedure - web version 20
8. Performing a measurement - web version 28
9. Results and accuracy of measurements 33
10. Interpretation of the measurement results 34
11. Hardware requirements 35

1. Intended Purpose

The Shen.AI medical device is intended for the measurement of physiological parameters, including heart rate (HR), heart rate variability (HRV), breathing rate (BR) and blood pressure (BP) (systolic and diastolic) for the purpose of assessing physiological status. Shen.AI enables convenient and contactless measurement of the above physiological parameters through a one-minute facial analysis using a digital video camera.

2. Indications and contraindications for the use of the Shen.AI device and expected clinical benefits

Indications for use of the Shen.AI medical device

The device, implemented in a mobile or web application, is intended for the measurement of physiological parameters in resting conditions including heart rate, heart rate variability, breathing rate and blood pressure as part of self-monitoring for generally healthy individuals over 18 years of age.

Additionally, Shen.AI is indicated for:

- Regular or occasional assessment of resting pulse, with reference to normal value ranges and previously recorded values, to assist in identifying potential abnormalities in heart rhythm and assessing the risk of cardiovascular disease.
- Regular or occasional assessment of breathing rate, with reference to normal value ranges and previously recorded values, to assist in identifying potential respiratory function abnormalities.
- Regular or occasional assessment of blood pressure (systolic and diastolic), with reference to normal value ranges and previously recorded values, to assist in identifying potential cardiovascular changes and assessing the risk of hypertension.
- Regular assessment of short-term pulse variability by monitoring trends in observed values to assist in evaluating levels of fatigue or stress.
- Contactless measurement of pulse and breathing rate rate in conditions or situations that require physical distancing.
- Regular assessment of blood pressure (systolic and diastolic), by monitoring trends in measured values over time, to assist in tracking changes associated with the risk of hypertension and supporting clinical follow-up of cardiovascular conditions.

Contraindications for the use of the Shen.AI device

The Shen.AI medical device should not be used by individuals:

- with cardiac arrhythmia, except for sinus bradycardia, sinus tachycardia or respiratory sinus arrhythmia,
- with a visible facial deformity (for example resulting from a tumor),
- who are unable to keep their head stable in the required position during the measurement,
- with impaired respiratory function presenting as shortness of breath or irregular or shallow breathing,
- with an implanted cardiac pacemaker,
- who require specialized medical supervision or continuous medical care,
- those in a life or health-threatening situation,
- pregnant,
- under 18 years of age.

Due to the characteristics of the measurement method based on optical detection of blood pulsations in the facial skin, Shen.AI technology cannot be used to measure physiological parameters in the following situations:

- extensive skin damage on the face (including abrasions, wounds or burns)
- a disease process involving a significant part of the face,
- extensive facial dressings
- extensive facial tattoos or face paint
- facial deformity (for example resulting from a tumor)
- facial paralysis, numbness or tingling
- facial tremors or muscle spasms including tics (except for eye or eyelid movements)
- inability to keep the head stable in the required position during the measurement
- temporary or persistent facial pallor
- moderate or severe anemia
- heart failure, impaired left ventricular systolic function, aortic valve stenosis or other cardiac or respiratory conditions that result in low stroke volume, low pressure amplitude or pulsus paradoxus

Expected clinical benefits resulting from the use of the Shen.AI medical device

- Since the device is intended for the measurement of selected physiological parameters in resting conditions, the primary benefit of its use is obtaining information about physiological status within the scope of the measured parameters including pulse (heart rate), heart rate variability, breathing rate and blood pressure (systolic and diastolic).
- As a result, the device allows users to monitor physiological status and may support the early identification of potential abnormalities in the measured parameters which must be confirmed through professional and comprehensive clinical evaluation.
- The possibility of using the device on widely available mobile devices may improve access to basic physiological measurements in settings where access to traditional measurement equipment is limited.
- The contactless nature of the measurement may enable the acquisition of physiological parameters in situations that require physical distancing.

The Shen.AI software, being a non-contact and software-based medical device, does not cause any direct physiological effects. Undesirable effects are limited to the possibility of inaccurate readings, which may occur if the instructions for use are not properly followed (e.g. improper lighting conditions, unstable head position or obstructions covering the face).

3. Operating principle

Shen.AI is software that analyzes the optical signal of remote photoplethysmography (rPPG) and remote ballistocardiography (rBCG) recorded by the video camera of a mobile device or computer. The software determines physiological values by analyzing changes in reflected light intensity from the facial skin caused by pulsatile blood flow in superficial vessels and by detecting subtle head movements associated with blood ejection into the carotid artery.

Measurement mechanisms:

- Heart rate and heart rate variability are determined by detecting blood pulsation and variability in the intervals between heartbeats.
- Breathing rate is determined by analyzing rhythmic changes in the amplitude of the rPPG and rBCG signals.
- Blood pressure is estimated algorithmically based on pulse wave characteristics including rise time, waveform shape, amplitude, variability and timing differences in blood arrival across different facial regions, without the use of a cuff.

4. Measurement Conditions and Procedure

The Shen.AI technology is designed to perform measurements in resting conditions in a seated position with appropriate lighting. With Multi-Tonal Sensing (MTS) technology, the measurement can be performed under varying lighting conditions, with slight head movements and for all skin tones.

During the measurement, the cardiovascular and respiratory systems should remain as stable as possible. Therefore the measurement should not be performed immediately after physical activity or a change in body position. It is recommended that the user remain relaxed for at least 5 minutes before starting the measurement to stabilize heart rate and breathing rate. Results obtained after a shorter resting period should not be considered representative of resting conditions.

During the measurement, the user should breathe normally, maintain a relaxed but stable head position, avoid speaking and avoid facial movements.

The available measurement mode includes self-measurement using the front-facing camera.

During the measurement, the user should follow the instructions displayed on the screen of the device used for the measurement.

Before starting the calibration, the user should:

- prepare an automatic blood pressure monitor with an upper-arm cuff
- sit comfortably and place the automatic blood pressure monitor on the left side in a position that allows easy access to the device
- place the device used for the measurement on a stand or support, or otherwise ensure that it is stabilized so that it remains steady during the measurement and the user's face is fully visible
- rest in a seated position for approximately 5 minutes before beginning the calibration

Preparation for measurement

Before starting the measurement, the user's face:

- should be positioned at the correct distance and angle relative to the camera so that it aligns with the marked frame displayed on the screen,
- should be dry and clean, without heavy makeup or visible dirt,
- should not be covered by hair, a mask, glasses or other objects - the user should remove the mask and glasses and move hair away from the forehead

To maintain measurement accuracy, the measurement should be performed under stable and consistent lighting conditions.

Measurement is not recommended while in motion, for example during transportation, due to vibration that may affect image stability and rapid changes in background or lighting.

Performing the measurement

During the measurement, the user should not chew gum, tobacco, food or any other products. The device used for the measurement should have a clean camera and remain in a stable position. Otherwise, the measurement may not be performed or may be associated with greater error compared to a fully stable measurement.

When using a mobile device (phone or tablet), it should be placed against a stable object or positioned on a stand or holder. Holding the device in unsupported hands is not recommended due to micro-movements that can negatively affect measurement accuracy.

When using a laptop, it is recommended to place it on a table or desk. Holding the laptop in the hands, on the lap or in any other unsupported position is not recommended due to micro-movements that can negatively affect measurement accuracy.

When using an external camera connected to a desktop computer or laptop, the camera should be attached to a stable object or otherwise kept steady. As with mobile devices, holding the external camera in the hands is not recommended due to micro-movements that can negatively affect measurement accuracy.

The face should be directed straight toward the camera. After the face is correctly positioned relative to the camera, the measurement can be started by pressing the START button. The measurement lasts approximately 1 minute and the progress is displayed as a bar that fills with a green color. The measurement can be stopped at any time using the STOP button. For calibration measurements, the blood pressure values obtained with the automatic blood pressure monitor must be entered into the device according to the calibration process shown on the screen.

The quality level of the measurement is indicated by five stars at the top of the screen. The more stars are filled, the better the measurement quality.

To ensure proper measurement performance, attention should be paid to the following:

a. appropriate facial lighting:
    - diffused natural or artificial light at an intensity suitable for comfortable reading
    - even illumination of the entire face without visible shadows
    - no visible reflections on the facial skin
b. proper camera conditions:
    - stable camera position
    - clean camera lens
    - no direct light hitting the camera lens, especially from behind the user
    - no other faces or persons in the camera frame
c. appropriate head position and unobstructed view of the facial skin:
    - the face should be positioned perpendicular to the camera with both cheeks equally visible
    - no obstruction of the facial skin by hair, glasses, masks, bandages or other objects
    - no heavy facial makeup
    - no visible moisture or dirt on the facial skin
    - stable head position
    - neutral facial posture avoiding talking and facial movements

If the lighting conditions are inadequate, an appropriate message will be displayed on the screen. To improve facial lighting, an additional light source may be used as long as the illumination remains even and no reflections appear on the facial skin.

If during recording the user's head or the camera changes position so that the face no longer aligns with the frame displayed on the screen, the frame will turn red to indicate the need to adjust the head position relative to the camera (for example by moving closer, farther or sideways).

If the exposure of clean and unobstructed facial skin is insufficient or if other circumstances prevent the measurement, a warning message will also appear at the bottom of the screen.

5. Performing the calibration procedure - mobile version

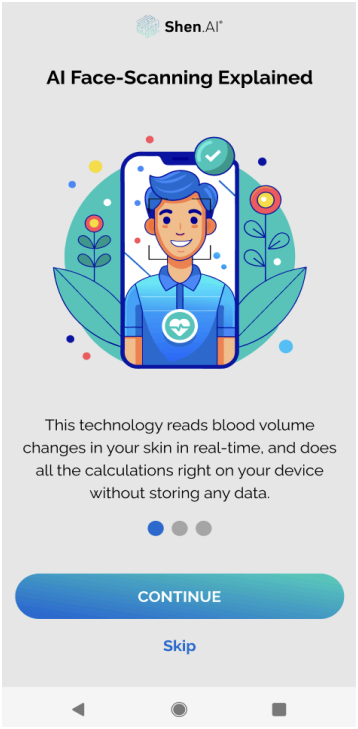
Onboarding screens
The app will guide you through a series of three onboarding screens that introduce you to the key features and technologies used in the app. Each screen presents important information that should be read carefully.

Screen 1 - AI Face-Scanning Explained

On the first onboarding screen, there is detailed information about the innovative technology, which allows real-time readings of changes in blood volume in the patient's skin.

After reviewing the information on the screen, select the **Continue** button to proceed to the next two onboarding screens, which will provide additional information.

The user has the option to skip the onboarding screens by clicking the **Skip** button at the bottom of the screen. **This is not recommended** as the information presented is crucial to fully understand the operation of the application and the technology used in the research.

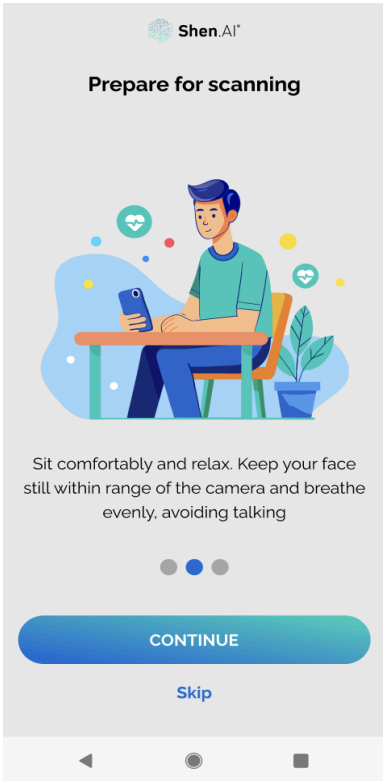


Screen 2 - Prepare for scanning

Preparing for the scan
At this stage the user will be asked to prepare for the scan. The screen will tell you to sit comfortably and relax. It is important to be in a stable, stationary position so that the scan can run properly.

Moving to the next step
When the user is ready, select the **Continue** button to proceed to the third onboarding screen.

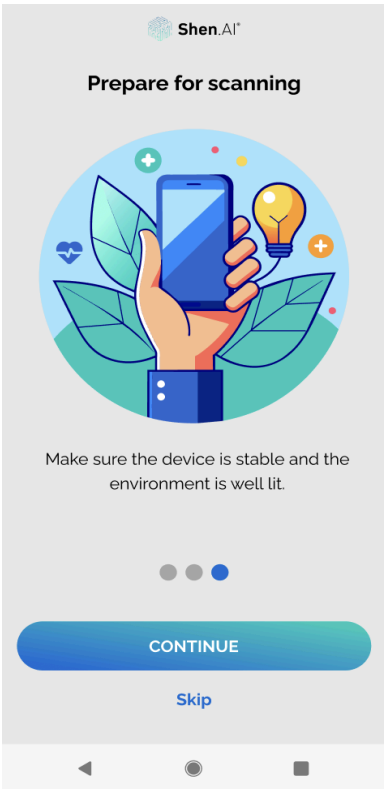
Possibility of omission
The **Skip** button allows you to skip the entire onboarding process.



Screen 3 - Prepare for scanning

The third onboarding screen provides guidance on optimising the environment for scanning.

After reviewing the information, select **Continue** to proceed, or use the **Skip** button to skip onboarding.



Onboarding screens - calibration

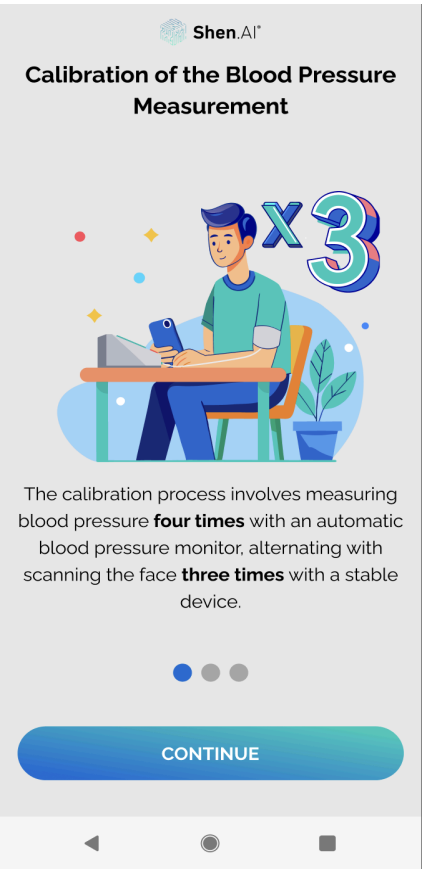
After a general introduction about the technology and preparation for measurement, there will now be three screens related to the introduction to the calibration process.

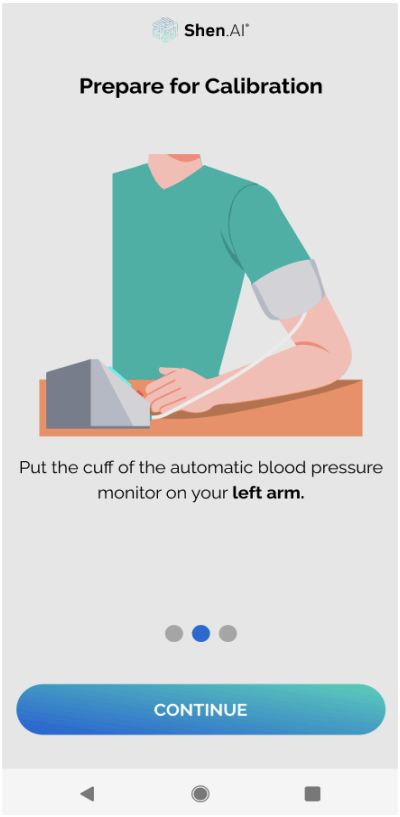
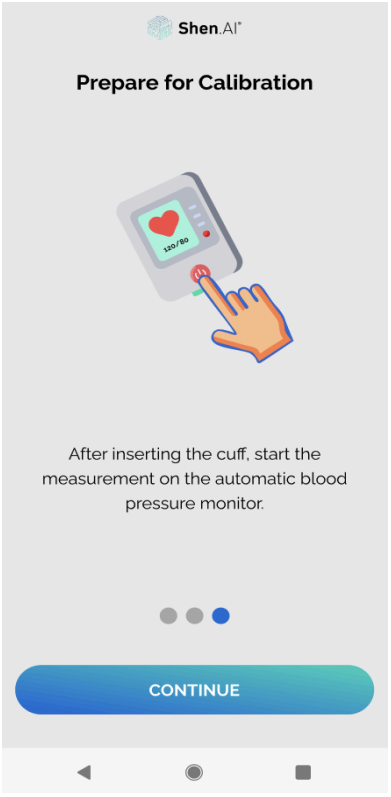
The following screens provide detailed information on the **calibration** process and **how to prepare for it.** Each screen will guide you step-by-step through the process, ensuring you are fully prepared to take measurements.

Screen 1 - Calibrating the Blood Pressure Measurement

The screen describes the calibration measurement process.

After reviewing the information, select **Continue** to proceed to the next screen.



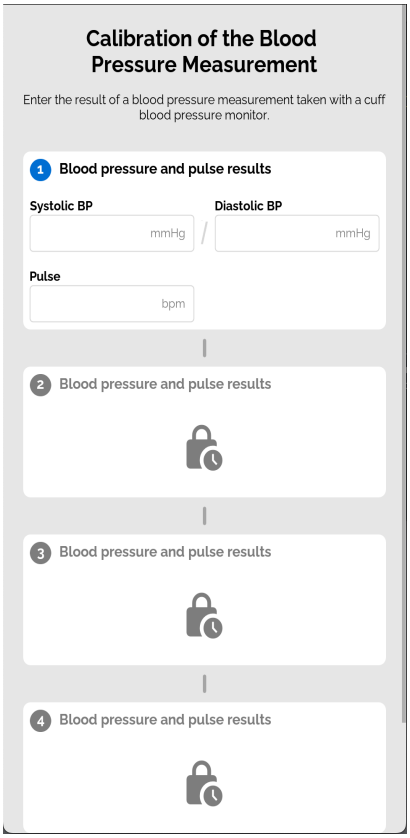
Screen 2 - Prepare for Calibration The screen will prompt you to put the cuff on the left arm. Once the cuff is in place, select **Continue** to proceed to the next screen.	
Screen 3 - Prepare for Calibration The screen displays instructions on how to take the measurement. After reviewing the information, select **Continue** to proceed to the next screen.	

Once the measurement has been completed, a screen is displayed allowing the first results obtained with the automatic blood pressure monitor to be entered.

The screen has a **Blood pressure and pulse results** section with three fields to edit: **Systolic BP** and **Diastolic BP**, as well as **Pulse.**

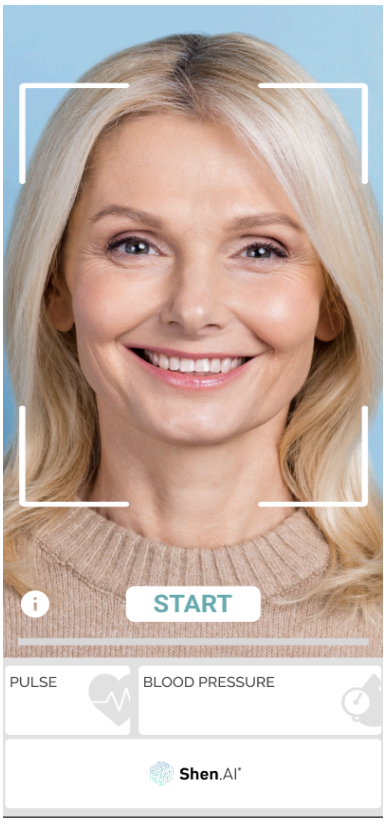
In the appropriate fields, enter the results obtained from the automatic blood pressure monitor. Once the data is entered, the **Save and Continue** button at the bottom of the screen will become active, allowing you to proceed to the next step.

Before saving, you can edit the data by clicking on the relevant field, which allows you to make changes.



After clicking **Save and Continue,** the measurement screen will appear.

To start the measurement, click on the **Start** button.



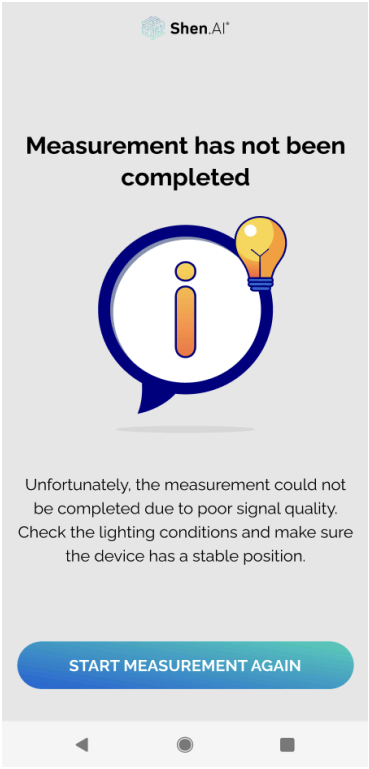
The remaining time until the end of the measurement is presented as a progress bar filling in green.

The quality of the measurement is presented in the form of stars and the measurement results are presented in windows at the bottom of the screen.

- **Pulse:**
  Starting from the 11th second of measurement, instantaneous pulse values are displayed every 1 second. At the end of the measurement, the average pulse value for the entire test period is presented.
- **Blood pressure:**
  During the measurement, the progress bar will gradually fill up in green. Once the progress bar is completely filled, it means the measurement has been successfully completed.

A PPG signal is additionally visible at the bottom of the screen. If a problem occurs during measurement, **an appropriate message will be displayed** in the field at the bottom of the screen instead of the PPG signal**.**
The measurement can be stopped at any time using the **Stop** button.

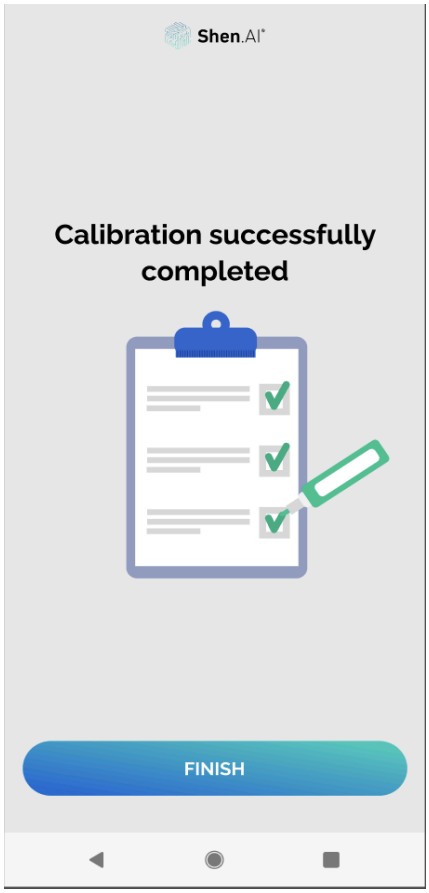
The measurement limit is 2 minutes. If the measurement time exceeds this limit, a message will appear on the screen indicating that the measurement has not been completed. In this case, click the **Start measurement again** button to resume the process.



After completing the first calibration step, which includes measuring blood pressure with the blood pressure monitor and a face scan, a screen will be displayed where the user will have to enter data from the blood pressure monitor. This will be followed by another face scan. Another screen will allow the user to enter the blood pressure monitor data again, followed by another face scan. Finally, a final screen will appear where the user will enter the blood pressure monitor data, finalizing the entire calibration process.

All measurements should follow one another without undue delay and the whole process should take no longer than 10 - 15 minutes. It is recommended that measurements be taken at 1 minute intervals.

When all steps of the calibration process have been successfully completed, a message will appear on the screen: **Calibration successfully completed.**



6. Performing a measurement - mobile version

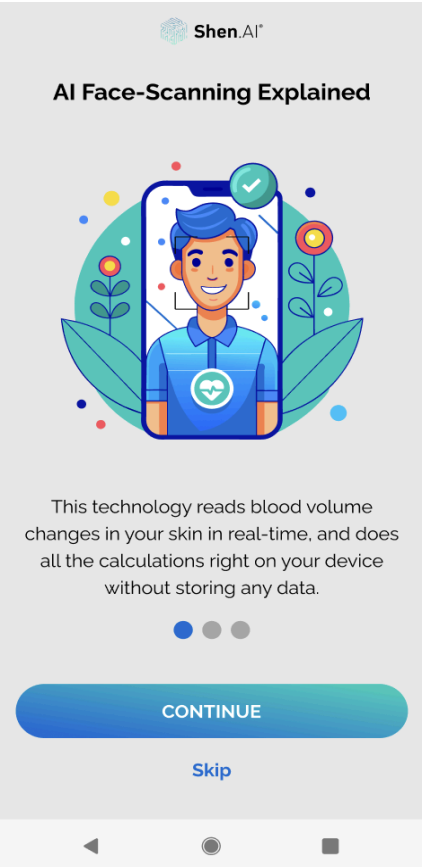
Onboarding screens
The app will guide you through a series of three onboarding screens that introduce you to the key features and technologies used in the app. Each screen presents important information that should be read carefully.

Screen 1 - AI Face-Scanning Explained

On the first onboarding screen, there is detailed information about the innovative technology, which allows real-time readings of changes in blood volume in the patient's skin.

After reviewing the information on the screen, select the **Continue** button to proceed to the next two onboarding screens, which will provide additional information.

The user has the option to skip the onboarding screens by clicking the **Skip** button at the bottom of the screen. **This is not recommended** as the information presented is crucial to fully understand the operation of the application and the technology used in the research.

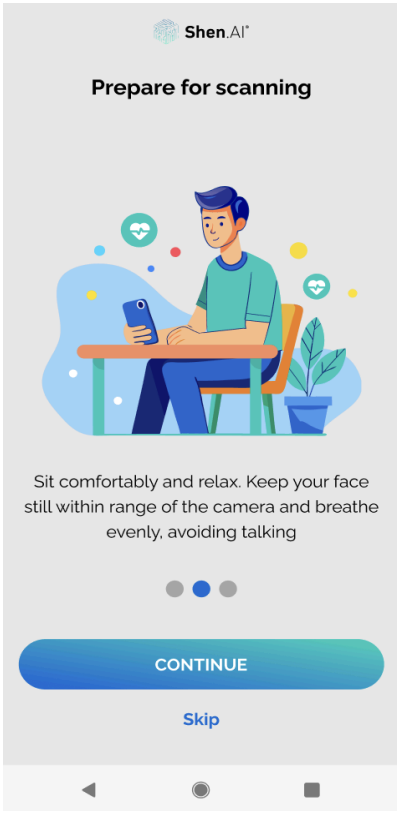


Screen 2 - Prepare for scanning

Preparing for the scan
At this stage the user will be asked to prepare for the scan. The screen will tell you to sit comfortably and relax. It is important to be in a stable, still position so that the scan can run properly.

Moving to the next step
When the user is ready, select the **Continue** button to proceed to the third onboarding screen.

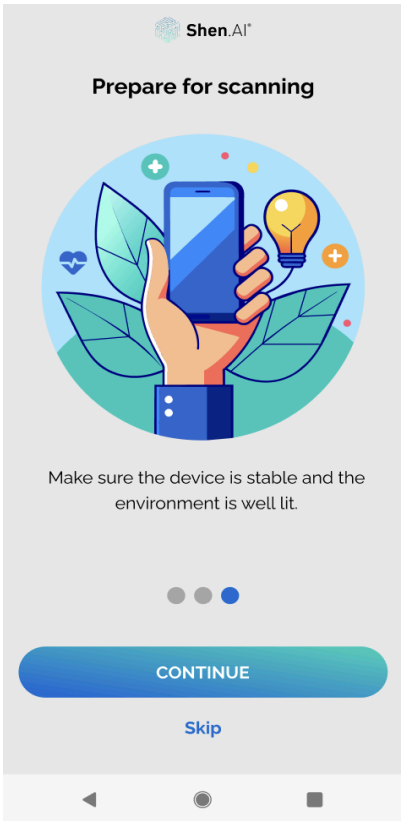
Possibility of omission
The **Skip** button allows you to skip the entire onboarding process.

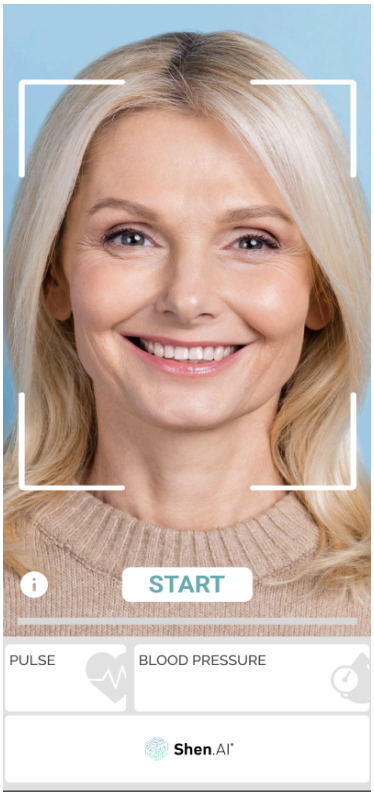


Screen 3 - Prepare for scanning

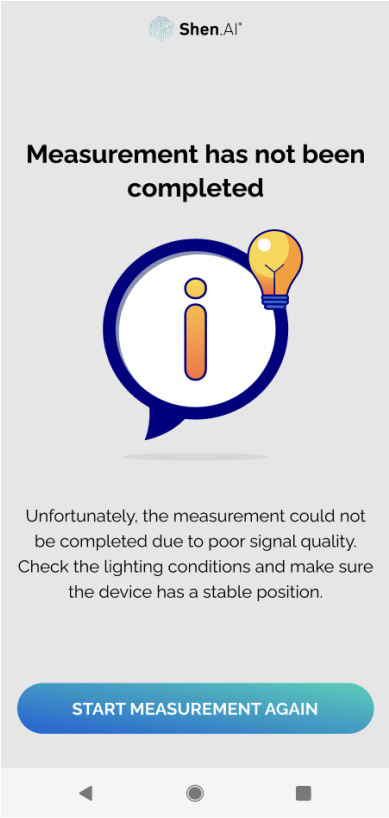
The third onboarding screen provides guidance on optimizing the environment for scanning.

After reviewing the information, select **Continue** to proceed, or use the **Skip** button to skip onboarding.



The first measurement screen will display a **Start** button, which must be clicked to start the measurement.	
The remaining time until the end of the measurement is presented as a progress bar filling in green. The quality of the measurement is presented in the form of stars and the measurement results are presented in windows at the bottom of the screen. ● **Pulse:** Starting from the 11th second of measurement, instantaneous pulse values are displayed every 1 second. At the end of the measurement, the average pulse value for the entire test period is presented. ● **Blood pressure:** Once the measurement is complete, the averaged systolic and diastolic blood pressure values from the entire test period appear. A PPG signal is additionally visible at the bottom of the screen. If a problem occurs during measurement, **an appropriate message will be displayed** instead of a pressure wave in the field at the **bottom of the screen.**	

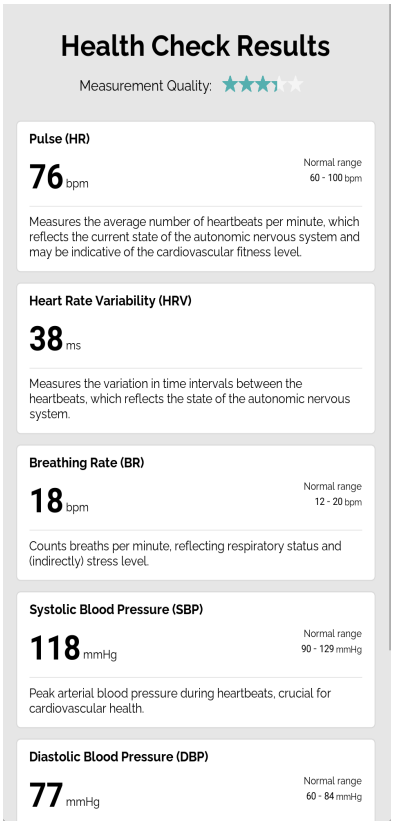
The measurement limit is 2 minutes. If the measurement time exceeds this limit, a message will appear on the screen indicating that the measurement has not been completed. In this case, click the **Start measurement again** button to resume the process.



When the measurement is complete, a summary of the results will appear on the screen. This will contain all the data obtained, together with descriptions that explain what each result relates to. Each result will be clearly assigned to the relevant parameter, making it easier to understand and interpret the measurement results.

Blood pressure values are displayed in basic mode (**uncalibrated** results).

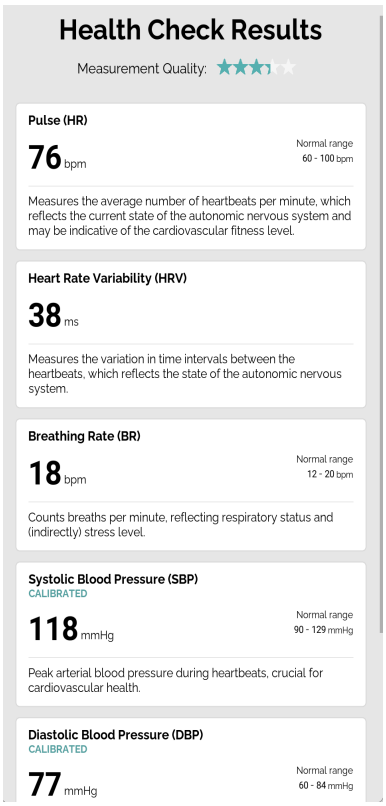
In a situation where the quality of the measurement was insufficient to calculate a result for a parameter, the message **Uncertain measurement** may appear on the screen instead of the result**.** Such a message indicates that a result could not be provided due to insufficient measurement quality.



When the measurement is complete, a summary of the results will appear on the screen. This will contain all the data obtained, together with descriptions that explain what each result relates to. Each result will be clearly assigned to the relevant parameter, making it easier to understand and interpret the measurement results.

Blood pressure values are displayed in advanced mode (**calibrated** results).

In a situation where the quality of the measurement was insufficient to calculate a result for a parameter, the message **Uncertain measurement** may appear on the screen instead of the result**.** Such a message indicates that a result could not be provided due to insufficient measurement quality.



7. Performing the calibration procedure - web version

Loading
screen At the very beginning, you will see a screen indicating that the next steps in the process are being loaded. At this stage, the system processes the data and prepares the next steps.

Waiting for the loading process to finish
The duration of the loading process may vary depending on the speed of your internet connection and the load on your system.

Automatically move on
When loading is complete, the system will automatically redirect to the next screen.

Onboarding screens
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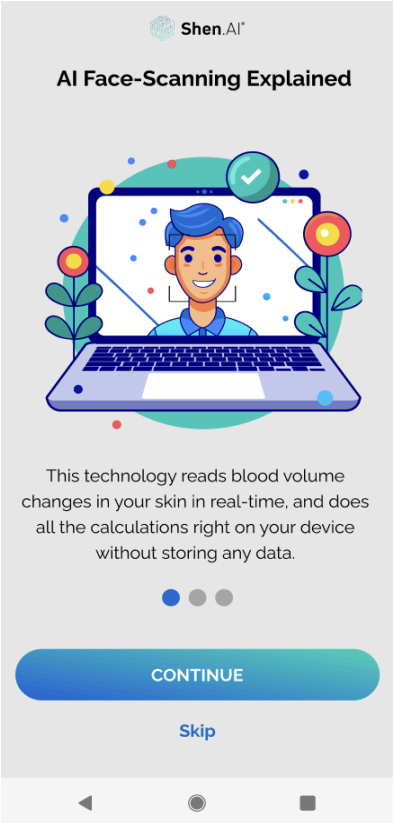
Screen 1 - AI Face-Scanning Explained

On the first onboarding screen, there is detailed information about the innovative technology, which allows real-time readings of changes in blood volume in the patient's skin.

After reviewing the information on the screen, select the **Continue** button to proceed to the next two onboarding screens, which will provide additional information.

The user has the option to skip the onboarding screens by clicking the **Skip** button at the bottom of the screen. **This is not recommended** as the information presented is crucial to fully understand the operation of the application and the technology used in the study.

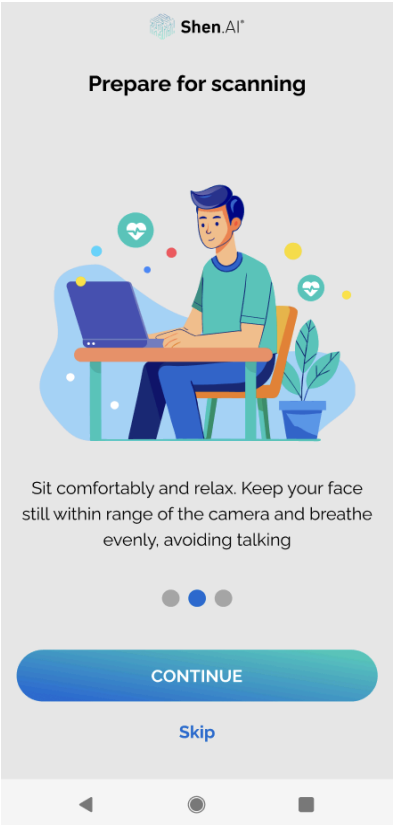


Screen 2 - Prepare for scanning

Preparing for the scan
At this stage the user will be asked to prepare for the scan. The screen will tell you to sit comfortably and relax. It is important to be in a stable, stationary position so that the scan can run properly.

Moving
on to the **next step**
When the user is ready, select the **Continue** button to proceed to the third onboarding screen.

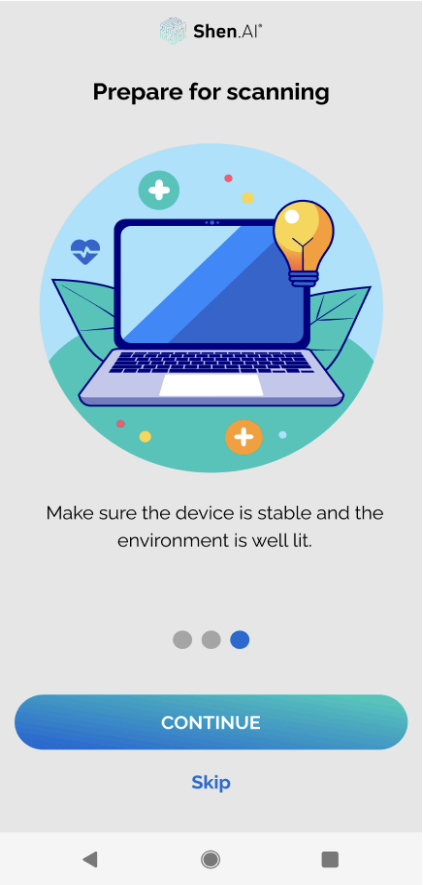
Possibility of omission
The **Skip** button allows you to skip the entire onboarding process.



Screen 3 - Prepare for scanning

The third onboarding screen provides guidance on optimizing the environment for scanning.

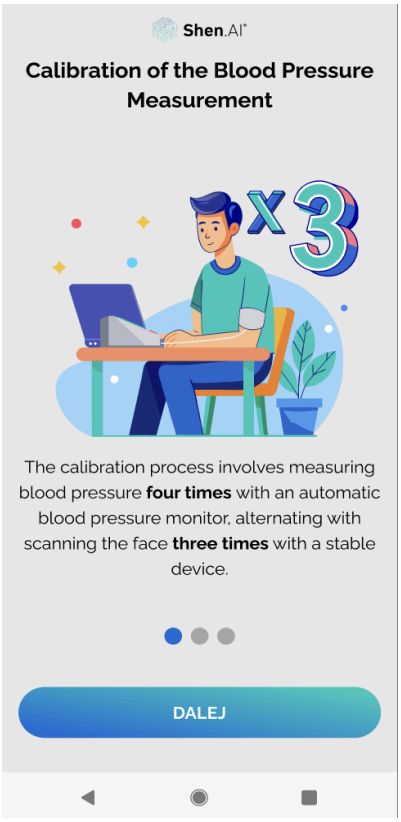
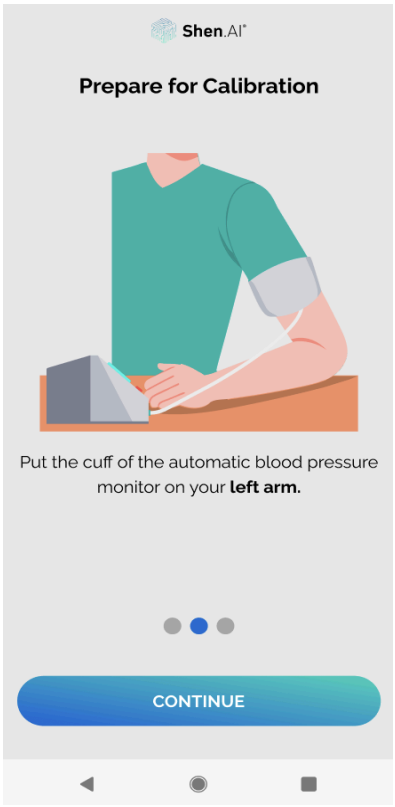
After reviewing the information, select **Continue** to proceed, or use the **Skip** button to skip onboarding.



Onboarding screens - calibration

After a general introduction about the technology and preparation for measurement, there will now be three screens related to the introduction to the calibration process.

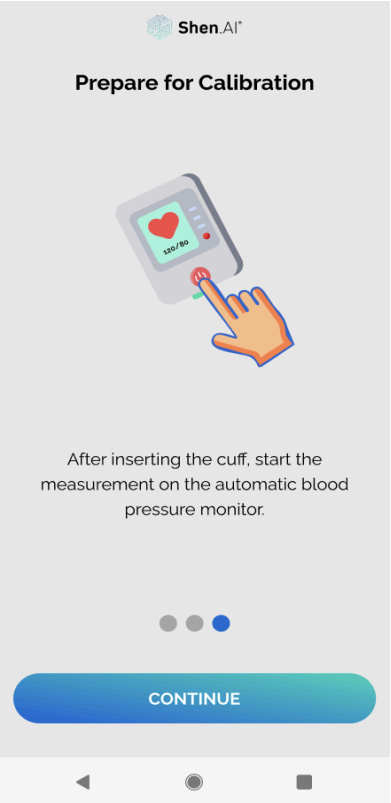
The following screens provide detailed information on the **calibration** process and **how to prepare for it.** Each screen will guide you step-by-step through the process, ensuring you are fully prepared to take measurements.

Screen 1 - Calibrating the Blood Pressure Measurement The screen describes the calibration measurement process. After reviewing the information, select **Continue** to proceed to the next screen.	
Screen 2 - Prepare for Calibration The screen will prompt you to put the cuff on the left arm. Once the cuff is in place, select **Continue** to proceed.	

Screen 3 - Prepare for Calibration

The screen displays instructions for taking the measurement.

After reviewing the information, select **Continue** to proceed.

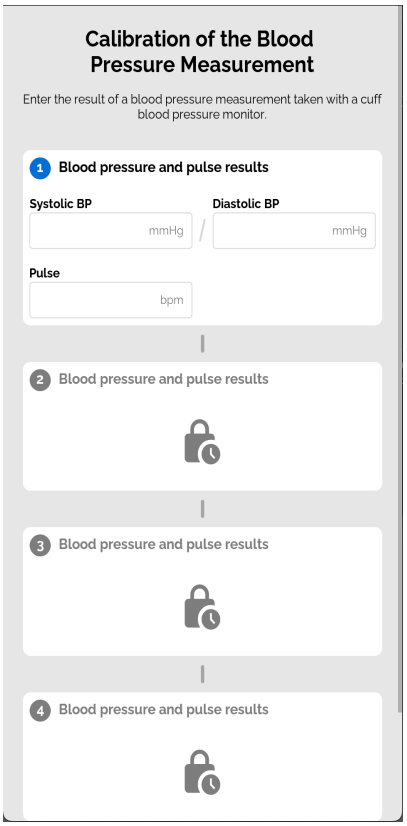


Once the measurement has been completed, a screen is displayed allowing the first results obtained with the automatic blood pressure monitor to be entered.

The screen has a **Blood pressure and pulse results** section with three fields to edit: **Systolic BP** and **Diastolic BP**, as well as **Pulse.**

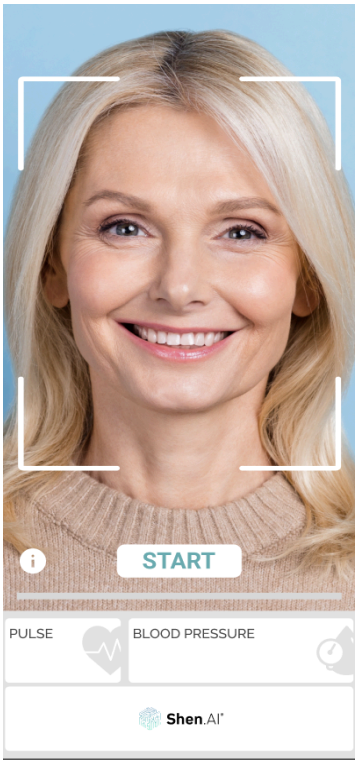
In the appropriate fields, enter the results obtained from the automatic blood pressure monitor. Once the data is entered, the **Save and Continue** button at the bottom of the screen will become active, allowing you to proceed to the next step.

Before saving, you can edit the data by clicking on the relevant field, which allows you to make changes.



After clicking **Save and Continue,** the measurement screen will appear.

To start the measurement, click on the **Start** button.



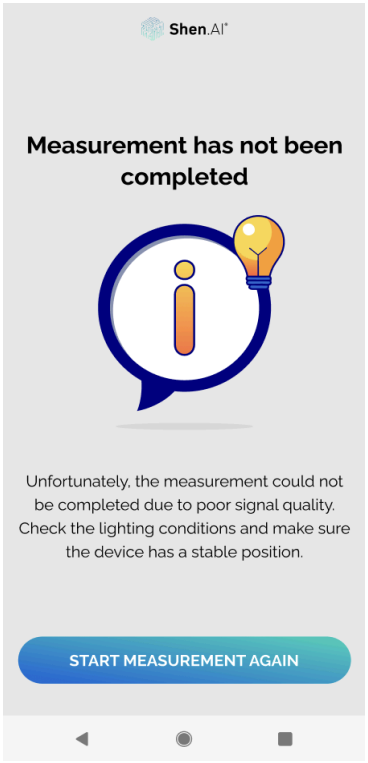
The remaining time until the end of the measurement is presented as a progress bar filling in green.

The quality of the measurement is presented in the form of stars and the measurement results are presented in windows at the bottom of the screen.

- **Pulse:**
  Starting from the 11th second of measurement, instantaneous pulse values are displayed every 1 second. At the end of the measurement, the average pulse value for the entire test period is presented.
- **Blood pressure:**
  During the measurement, the progress bar will gradually fill up in green. Once the progress bar is completely filled, it means the measurement has been successfully completed.

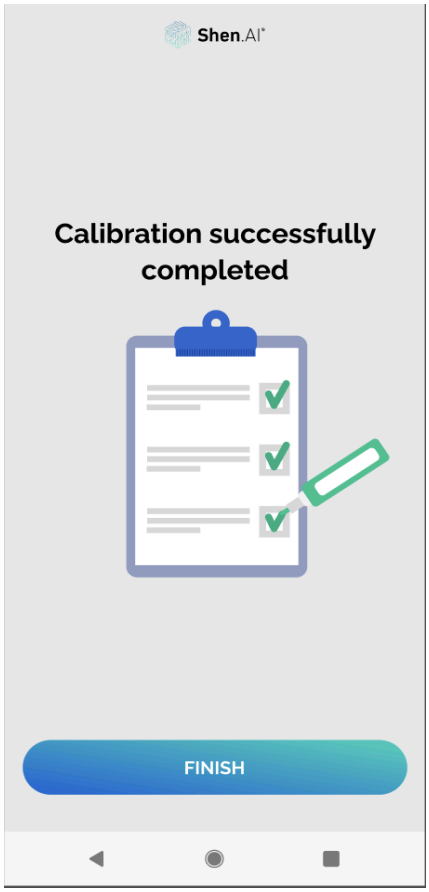
A PPG signal is additionally visible at the bottom of the screen. If a problem occurs during measurement, **an appropriate message will be displayed** in the field at the bottom of the screen instead of the PPG signal**.**

The measurement can be stopped at any time using the **Stop** button.

The measurement limit is 2 minutes. If the measurement time exceeds this limit, a message will appear on the screen indicating that the measurement has not been completed. In this case, click the **Start measurement again** button to resume the process.	

After completing the first calibration step, which includes measuring blood pressure with the blood pressure monitor and a face scan, a screen will be displayed where the user will have to enter data from the blood pressure monitor. This will be followed by another face scan. Another screen will allow the user to enter the blood pressure monitor data again, followed by another face scan. Finally, a final screen will appear where the user will enter the blood pressure monitor data, finalizing the entire calibration process.

All measurements should follow one another without undue delay and the whole process should take no longer than 10 - 15 minutes. It is recommended that measurements be taken at 1 minute intervals.

When all steps of the calibration process have been successfully completed, a message will appear on the screen: **Calibration successfully completed.**	

8. Performing a measurement - web version

Loading screen
At the very beginning, you will see a screen indicating that the next steps in the process are being loaded. At this stage, the system processes the data and prepares the next steps.

Waiting for the loading process to finish
The duration of the loading process may vary depending on the speed of your internet connection and the load on your system.

Automatically move on
When loading is complete, the system will automatically redirect to the next screen.

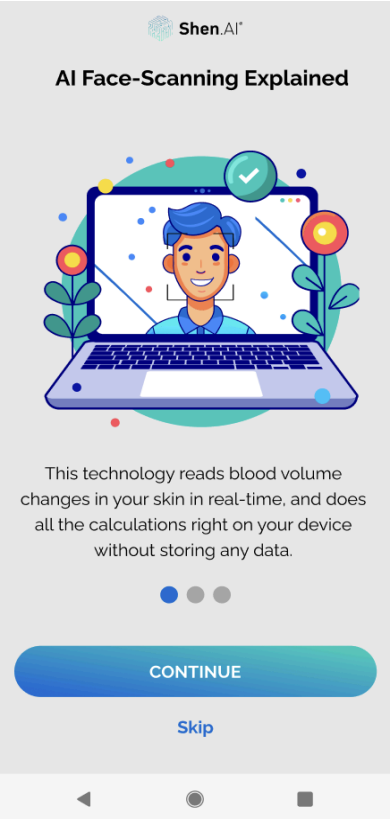
Onboarding screens
The app will guide you through a series of three onboarding screens that introduce you to the key features and technologies used in the app. Each screen presents important information that should be read carefully.

Screen 1 - AI Face-Scanning Explained

On the first onboarding screen, there is detailed information about the innovative technology, which allows real-time readings of changes in blood volume in the patient's skin.

After reviewing the information on the screen, select the **Continue** button to proceed to the next two onboarding screens, which will provide additional information.

The user has the option to skip the onboarding screens by clicking the **Skip** button at the bottom of the screen. **This is not recommended** as the information presented is crucial to fully understand the operation of the application and the technology used in the research.

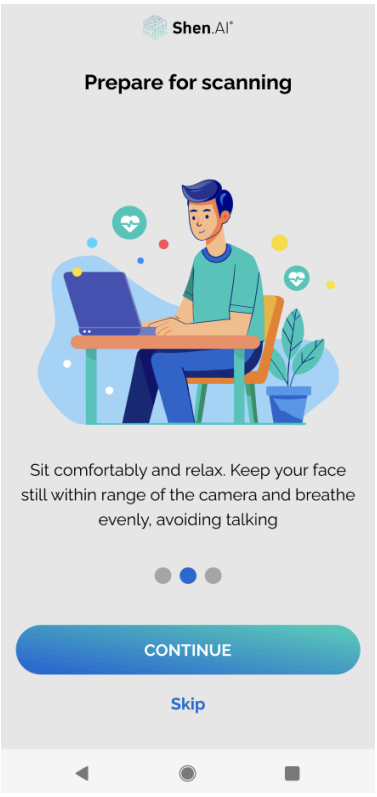


Screen 2 - Prepare for scanning

Preparing for the scan
At this stage the user will be asked to prepare for the scan. The screen will tell you to sit comfortably and relax. It is important to be in a stable, still position so that the scan can run properly.

Moving to the next step
When the user is ready, select the **Continue** button to proceed to the third onboarding screen.

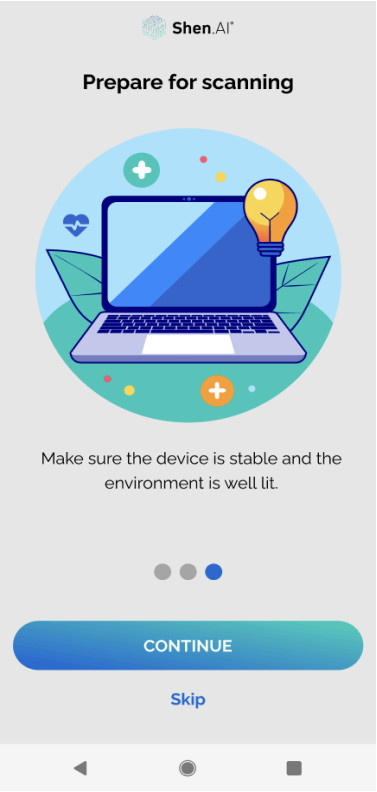
Possibility of omission
The **Skip** button allows you to skip the entire onboarding process.



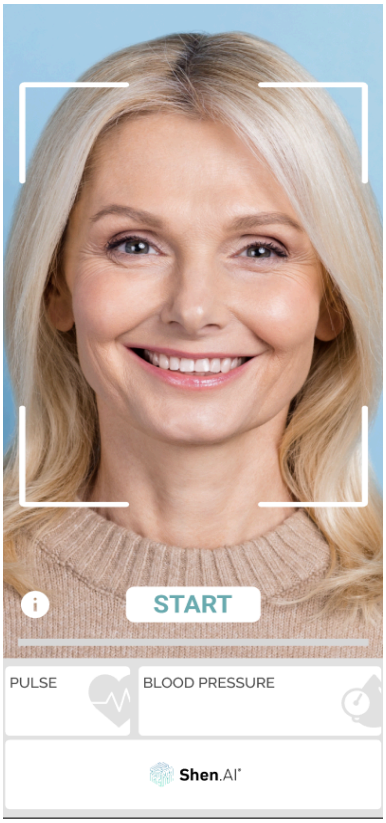
Screen 3 - Prepare for scanning

The third onboarding screen provides guidance on optimizing the environment for scanning.

After reviewing the information, select **Continue** to proceed, or use the **Skip** button to skip onboarding.



The first measurement screen will display a **Start** button, which must be clicked to start the measurement.



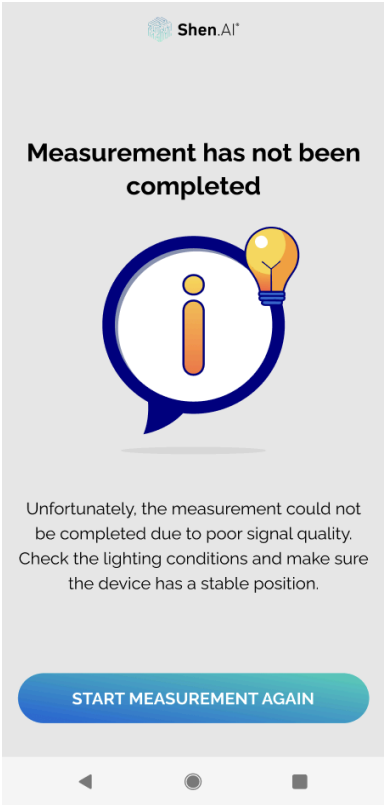
The remaining time until the end of the measurement is presented as a progress bar filling in green. .

The quality of the measurement is presented in the form of stars and the measurement results are presented in windows at the bottom of the screen.

- **Pulse:**
  Starting from the 11th second of measurement, instantaneous pulse values are displayed every 1 second. At the end of the measurement, the average pulse value for the entire test period is presented.
- **Blood pressure:**
  Once the measurement is complete, the averaged systolic and diastolic blood pressure values from the entire test period appear.

A PPG signal is additionally visible at the bottom of the screen. If a problem occurs during measurement, **an appropriate message will be displayed** in the field at the bottom of the screen instead of the PPG signal**.**
The measurement can be stopped at any time using the **Stop** button.

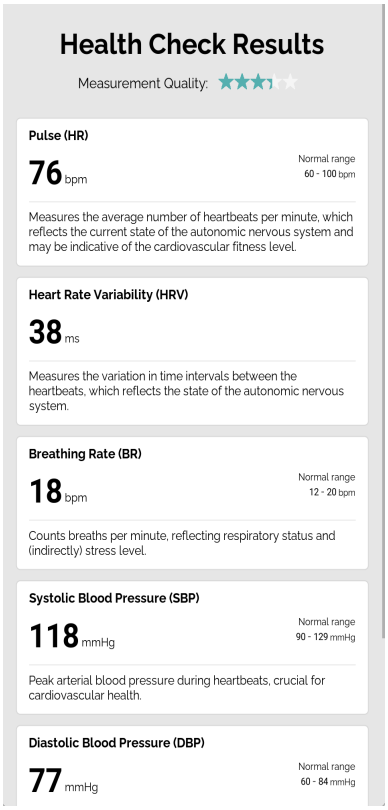
The measurement limit is 2 minutes. If the measurement time exceeds this limit, a message will appear on the screen indicating that the measurement has not been completed. In this case, click the **Start measurement again** button to resume the process.



When the measurement is complete, a summary of the results will appear on the screen. This will contain all the data obtained, together with descriptions that explain what each result relates to. Each result will be clearly assigned to the relevant parameter, making it easier to understand and interpret the measurement results.

Blood pressure values are displayed in basic mode (**uncalibrated** results).

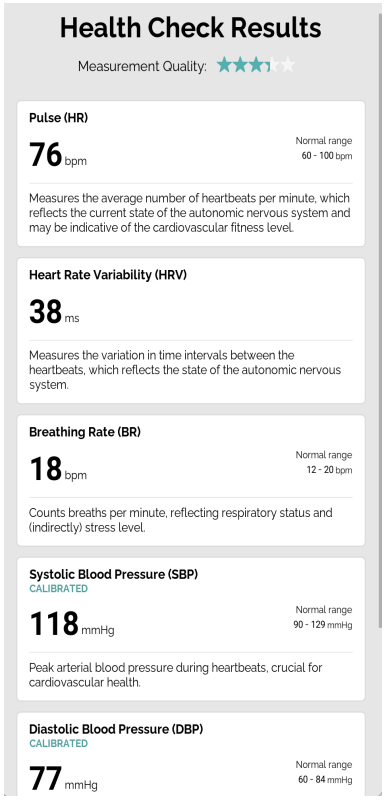
In a situation where the quality of the measurement was insufficient to calculate a result for a parameter, the message **Uncertain measurement** may appear on the screen instead of the result**.** Such a message indicates that a result could not be provided due to insufficient measurement quality.



When the measurement is complete, a summary of the results will appear on the screen. This will contain all the data obtained, together with descriptions that explain what each result relates to. Each result will be clearly assigned to the relevant parameter, making it easier to understand and interpret the measurement results.

Blood pressure values are displayed in basic mode (**calibrated** results).

In a situation where the quality of the measurement was insufficient to calculate a result for a parameter, the message **Uncertain measurement** may appear on the screen instead of the result**.** Such a message indicates that a result could not be provided due to insufficient measurement quality.



9. Results and accuracy of measurements

All measurement results are presented on the Health Check Results screen:

- Pulse (HR) - starting from the 11th second of the measurement, instantaneous pulse values are displayed every 1 second. These values are averaged based on complete cardiac cycles recorded over the preceding 10 seconds with a 1-second delay. After completion of the measurement, the average pulse value for the entire measurement period is displayed.
- Heart rate variability (HRV) - the value displayed after completion of the measurement representing the level of heart rate variability over the entire measurement period.
- Breathing rate (BR) - the value displayed after completion of the measurement representing the average breathing rate over the measurement period.
- Blood pressure (BP) - after completion of the measurement, the averaged systolic and diastolic blood pressure values calculated over the entire measurement period are displayed.

The heart rate variability indicator used is:

- SDNN (standard deviation of normal-to-normal interbeat intervals) - the standard deviation of the time intervals between successive blood pulsations.

Measurement function accuracy

HEART RATE (HR)

Range	MAE [bpm]	SD [bpm]
HR (10 s)	0,41	0,92
HR (1 min)	0,14	0,41

Measurement range: 40 – 120 bpm

HEART RATE VARIABILITY (HRV)

Parameter	MAE [ms]	SD [ms]	ME (bias) [ms]
SDNN	4,02	6,54	–1,29

Measurement range: 0 – 150 ms

BREATHING RATE (BR)

Metric	Value	Unit
MAE	1,40	bpm
SD	2,31	bpm
ME (bias)	–0,22	bpm

Measurement range: 10 – 28 bpm

BLOOD PRESSURE (BP)

Range	ME [mmHg]	SD [mmHg]
Systolic BP without calibration	4,82	11,76
Diastolic BP without calibration	2,77	7,27
Systolic BP with calibration	12,01	9,58
Diastolic BP with calibration	3,47	6,76

Measurement range: Systolic BP: 90–170 mmHg, Diastolic BP: 60–100 mmHg

10. Interpretation of the measurement results

Measured parameter	Normal value range	Unit	Comment
Pulse (heart rate)	60-100	bpm (beats per minute)	The lower the pulse (within the normal range), the better. Physically active individuals, especially those involved in endurance sports, may have a pulse significantly lower than the lower limit of the normal range. A pulse above 80 bpm, although within the normal range, is considered a risk factor for cardiovascular disease.
Heart rate Variability (HRV - SDNN)	Not defined	ms (milliseconds)	Due to the multiple factors influencing heart rate variability indices, no strictly defined normal value ranges have been established.
Breathing rate (BR)	12 - 20	bpm (breath per minute)	In older adults (over 65 years of age), the upper limit of the normal range is considered to be 28 breaths per minute (Rodriguez-Molinero et al., *Journal of the American Geriatrics Society*, 2013).
Blood pressure (BP)	Systolic BP: 90 - 129 Diastolic BP: 60 - 84 mmHg	mmHg (millimeters of mercury)	The values provided are consistent with the guidelines of the European Society of Cardiology (ESC). In general, normal blood pressure is considered to be below 120/80 mmHg.

Warning!

A normal result of the measured physiological parameters should not be used as a reason to refrain from medical consultation if any concerning symptoms occur.

If a measurement result falls outside the normal value range, it is recommended to repeat the measurement at least twice to confirm the result. The device performs measurements only within the defined measurement ranges.

Measurement results that deviate from reference values do not constitute a basis for self-diagnosis, do not replace medical consultation and should not be used to make diagnostic or therapeutic decisions without prior consultation with a physician.

The device is not intended to be used for making diagnostic or therapeutic decisions without medical supervision.

11. Hardware requirements

The minimum hardware requirements are listed in the table below:

Android operating system (smartphones and tablets)	• Android version: Android 8.0 (API level 26) or higher • Processor architecture: arm64-v8a or higher • RAM: at least 2 GB • OpenGL ES version: 3.0 or higher • Sensors: accelerometer, gyroscope, camera
iOS operating system (smartphones and tablets)	• Device model: iPhone X or higher • Operating system: iOS 14 or higher
Web browser (computers)	• Support for SharedArrayBuffer • Support for requestVideoFrameCallback or MediaStreamTrackProcessor • Support for WebGL 2.0 • Support for OffscreenCanvas
Supported desktop browsers	• Chrome (version 94 or later) • Edge (version 94 or later) • Opera (version 80 or later)

Working environment:

- Recommended use of antivirus software.
- Recommended use of anti-malware software.
- Recommended use of a firewall.
- Network enabling SSL-encrypted data transmission.

An internet connection is required to use the Shen.AI medical device:

- during installation of the mobile application containing the device,
- when using the device via a web application,
- for licensing purposes.

Summary of the medical device risk profile and related IT security objectives:

- The medical device processes patient medical data only within the scope of measurement results.
- Operating system requirements are specified in the instructions for use.
- Activities necessary to ensure software integrity and validation are performed without involvement of the end user.
- The instructions for use define the minimum hardware requirements that must be met for the device to operate according to its intended purpose.
- The intended operating environment of the medical device is a controlled environment without external disturbances.
- The medical device is intended for use both for patient self-monitoring and in the context of medical examinations.
- Use of the device outside the intended operating environment may lead to incorrect medical conclusions.
- On workstations where the medical device is used, additional security measures such as antivirus and anti-malware software are recommended.

Cybersecurity information:

- All processing of measurement data is performed locally on the user's device.The device does not require user login and no measurement or personal data are transmitted to external servers.
- Software updates to the SDK are provided via official distribution channels and may require an internet connection.

Access to measurement data is protected locally by the security mechanisms of the user's operating system. If the user stops using the device, uninstallation from the device is recommended. User data can be deleted at any time by resetting the application.

The device label and all instructions for use, including the current and archived versions, are stored electronically on the manufacturer's website at a stable network location:
https://shen.ai/medical-instructions.

Any comments, concerns or complaints should be reported to: complaints@shen.ai.

Any serious incident related to the device should be reported to:

1. The manufacturer (contact details provided on page 1 of the instructions for use),
2. For regulatory purposes, the incident must also be reported to Agência Nacional de Vigilância Sanitária (ANVISA) and to DOMO Salute Consultoria Regulatória, the registration holder in Brazil, in accordance with applicable legislation.