

Instructions for Use of the Shen.AI medical device

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Manufacturer:
Shen.AI OÜ,
Lõõtsa tn 8a,
11415 Tallinn, Estonia,
SRN: EE-MF-000050105
REF: SHENAI_MD

Contact: office@shen.ai
Website: <https://www.shen.ai>

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TABLE OF CONTENTS

1. Intended purpose	3
2. Indications and contraindications for the use of Shen.AI and expected clinical benefits	3
3. Principle of operation	4
4. Measurement conditions and procedure	5
5. Performing the measurement – mobile and web version	7
6. Results and measurement accuracy	9
7. Interpretation of measurement results	10
8. Hardware requirements	11
9. Legend of symbols used on the label	13

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 medical device (implemented within a mobile or web application) is intended for the measurement of physiological parameters at rest (heart rate, heart rate variability, breathing rate and blood pressure) for self-monitoring by generally healthy adults over 18 years of age. For the purposes of this Instructions for Use, a "generally healthy individual" means an adult who does not meet any of the device contraindications and is not in a condition requiring specialist medical supervision or immediate medical intervention. This term refers to the intended target population of the device and does not imply the absence of diagnosed chronic diseases as such.

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 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. Principle of operation

The Shen.AI medical device is software that analyses the optical signal of remote photoplethysmography (rPPG) and remote ballistocardiography (rBCG), recorded by a video camera on a mobile device or computer. The software determines physiological values based on the analysis of changes in the intensity of light reflected from the skin of the face caused by pulsatile blood flow in the skin vessels and the detection of head movement as a result of blood ejection into the carotid artery.

Measurement mechanisms:

- HR / HRV – determined based on the detection of blood pulsation and the variability of intervals between heartbeats,
- BR – determined by analysing rhythmic changes in the amplitude of the rPPG and rBCG signals,
- BP – estimated algorithmically based on pulse wave characteristics (rise time, shape, amplitude, variability, time difference in blood flow to different parts of the face), without the use of a cuff.

4. Measurement conditions and procedure

Shen.AI technology is designed to perform measurements under resting conditions, in a seated position and with adequate lighting. Thanks to MTS (Multi-Tonal Sensing) technology, measurements can be performed under various lighting conditions, with minor head movements, and across all skin tones.

During the measurement, the circulatory and respiratory systems should remain as stable as possible. Therefore, the measurement should not be performed immediately after physical activity or after a change in body position. Before starting the measurement, the user should remain as relaxed as possible for at least 5 minutes to allow the heart rate and breathing rate to stabilise. Measurement results obtained after resting for less than 5 minutes should not be considered representative of resting conditions.

Measurements should not be performed immediately after exposure to low temperatures. Before starting the measurement, the user should wait until the temperature of the facial skin has stabilised after returning to environmental conditions consistent with the intended use of the device.

During the measurement, the user should breathe normally, keep the head relaxed but as still as possible, refrain from talking and avoid facial movements or expressions.

The available measurement mode is self-measurement using the front-facing camera. To perform a measurement, the application must be granted access to the device's camera. Without access to the camera, the measurement cannot be performed.

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

Preparing for measurement

Before starting the measurement, the user's face:

- should be in the correct position and distance from the camera so that its view on the screen matches the marked frame.
- should be dry and free of heavy make-up and any dirt.
- should not be covered by hair, a mask, glasses or any other objects; remove the mask and glasses and move the hair away from the forehead.

In order to maintain measurement accuracy, ensure that the Shen.AI device is used in conditions of constant and, as far as possible, unchanging lighting.

It is not recommended to take measurements while in motion, e.g. while travelling by means of transport, due to the possibility of vibrations (difficult image stabilisation) and the possibility of dynamic changes in the background and lighting.

Performing the measurement:

During the measurement, do not chew gum, tobacco, food or other products. The device used for measurement should have a clean camera and be in a stable position (otherwise, the measurement may not be performed or will be subject to a greater error than a fully stable measurement).

When using a mobile device (phone, tablet), rest it against any stable object or place it on a stand, rack, etc. Holding the device in your unsupported hand(s) is not recommended due to micro-vibrations that may adversely affect the accuracy of the measurement.

When using a laptop, it is recommended to place it on a table, desk, etc. Holding the laptop in your hands, on your lap or in any other way is not recommended due to micro-vibrations that may adversely affect the accuracy of the measurement.

When using an external camera connected to a desktop computer or laptop, it is recommended to attach the camera to a stable object or one that is held in a stable position. As with mobile devices, holding an external camera in your hand(s) is not recommended due to micro-vibrations that may adversely affect the accuracy of the measurement.

The face should be facing the camera directly. Once the face is correctly positioned in relation to the camera, the measurement can be started using the START button. The measurement takes about 1 minute, and the progress of the measurement is shown in the form of a bar filling with green colour. The measurement can be stopped at any time using the STOP button. The quality level of the measurement performed by the device is indicated by 5 stars at the top of the screen (the more stars filled in, the better the measurement quality).

In order to ensure that the measurement is performed correctly, pay particular attention to:

- a. adequate lighting of the face, i.e.:
 - Diffused daylight or artificial light of sufficient intensity to allow comfortable reading.
 - Uniform lighting of the entire face (without visible shadows).
 - No visible reflections on the skin of the face.
- b. appropriate camera operating conditions, i.e.:
 - Stable camera position.
 - Clean camera lens.
 - No direct light falling on the camera lens (especially from behind the user).
 - No other persons (faces) in the camera frame.
- c. Appropriate head position and unobstructed view of the facial skin, i.e.:
 - Face positioned perpendicular to the camera (both cheeks equally visible).
 - No obstruction of the facial skin by hair, glasses, mask, dressing or any other objects.
 - No heavy facial make-up.
 - No visible moisture or dirt on the skin of the face.
 - Stable head position.
 - Keep your face still (avoid talking and facial expressions).

In case of inadequate lighting conditions, a corresponding message will be displayed on the screen. In order to improve the lighting of the face, an additional light source may be used, maintaining even lighting of the face and avoiding reflections.

If, during recording, the user's head or the camera changes position so that the face in the frame no longer matches the border marked on the screen, the border will turn red, signalling the need to change the position of the head relative to the camera (i.e. move it closer, further away or in the appropriate direction).

In the event of insufficient exposure of clean and unobstructed facial skin, or in the event of other circumstances preventing measurement, a corresponding warning message will also appear at the bottom of the screen.

The language of the Shen.AI medical device interface depends on the application in which the device is available. By default, the interface is displayed in the system language of the device (e.g. phone, tablet or computer) or in the language set in the application.

5. Performing a measurement – mobile and web version

LOADING SCREEN (APPLIES TO THE WEB VERSION ONLY)

Licence check

The application automatically verifies the validity of the Shen.AI medical device license.

- If the license check is successful, the application will automatically proceed to the next screen.
- If a problem occurs during the license check, the following message will be displayed:
“Initialization failed. There is a problem with this application’s license. Please contact the application’s technical support team.”

In this situation, it will not be possible to start the measurement. Please contact the technical support team for the application that uses the Shen.AI medical device.

Loading screen

At the very beginning, a screen will appear informing you that the next stages of the process are loading. At this stage, the system processes the data and prepares the next steps.

Waiting for loading to complete

Please wait until the loading process is complete. The loading time may vary depending on your internet connection speed and system load.

Automatic transition

Once loading is complete, the system will automatically redirect you to the next screen.

ONBOARDING

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

Screen 1 – How face scanning technology works

The first onboarding screen provides detailed information about the innovative technology that allows real-time reading of changes in blood volume in the patient's skin.

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

You can **skip** the onboarding screens by clicking the **Skip** button at the bottom of the screen. **This is not recommended**, as the information presented is essential for a full understanding of how the application and the technology used in the tests work.

Screen 2 – Prepare for the scan

Preparing for the scan

At this stage, the user will be asked to prepare for the scan by taking a comfortable resting position and relaxing. It is important to be in a stable, stationary position for the scan to run correctly.

Moving on to the next step

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

Option to skip

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

Screen 3 - Prepare for the scan

The third onboarding screen provides tips on how to optimise the environment for scanning.

After reading the information, select **Continue** to continue or use the **Skip** button to skip onboarding.

MEASUREMENT PROCESS

The first measurement screen will display a **Start** button, which you should click to begin the measurement.

The time remaining until the end of the measurement is displayed as a progress bar that fills with green.

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

- **Heart rate:**

Starting from the 11th second of the measurement, the instantaneous pulse values are displayed every second. After the measurement is complete, the average pulse value for the entire measurement period is displayed.

- **Blood pressure:**

After the measurement is complete, the average systolic and diastolic blood pressure values for the entire test period are displayed.

The PPG signal is also visible at the bottom of the screen. If problems occur during the measurement, **a corresponding message will be displayed in the field at the bottom of the screen** instead of the wave.

RESULTS SCREEN

Results screen

After the measurement is complete, a summary of the results will appear on the screen. It will contain all the data obtained, with a description for each parameter readily accessible to the user. Each result will be clearly assigned to the appropriate parameter, which will facilitate understanding and interpretation of the measurement results.

If the parameter value is outside the range specified in point 6 of the instructions, or if the result cannot be determined due to insufficient measurement quality, the message "err" may be displayed on the screen instead of the parameter value. In this case, it is recommended to repeat the measurement after ensuring appropriate measurement conditions.

After reviewing the results, you can finish (finish button) or perform the measurement again (measure again button).

6. Results and measurement accuracy

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

- Heart rate (pulse) - starting from the 11th second of the measurement, the instantaneous pulse values are displayed every second (averaged values based on the recorded complete heart cycles over the last 10 seconds, with a 1-second delay), while after the measurement is completed, the average pulse value for the entire measurement period is displayed
- HRV (heart rate variability index) - value displayed after the end of the measurement, indicating the level of heart rate variability during the entire measurement
- Breathing Rate (BR) - value displayed after the measurement is completed (average value for the measurement period)
- Blood pressure - after the measurement is completed, the average systolic and diastolic blood pressure values for the entire measurement period are displayed.

The heart rate variability indicator is:

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

Accuracy of the measurement function

HEART RATE (HR)

Range	MAE [bpm]	SD [bpm]
HR (10 s)	0.41	0.92
HR (1 min)	0.14	0.41

Measuring range: 40–120 bpm

HEART RATE VARIABILITY (HRV)

Parameter	MAE [ms]	SD [ms]	ME (bias) [ms]
SDNN	4.02	6.54	–1.29

Measuring range: 0–150 ms

BREATHING RATE (BR)

Metrics	Value	Unit
MAE	1.40	brpm
SD	2.31	brpm
ME (bias)	–0.22	brpm

Measuring range: 10 – 28 brpm

BLOOD PRESSURE (BP)

Range	ME [mmHg]	SD [mmHg]
Systolic BP	4.82	11.76
Diastolic BP	2.77	7.27

Measuring range:

- Systolic BP: 90–170 mmHg
- Diastolic BP: 60–100 mmHg

Explanation of the metrics used:

- ME (*Mean Error*) describes the average difference between the results obtained with the device and those obtained with the reference method. The sign of the ME value indicates whether the device results were, on average, higher or lower than the reference method results.
- MAE (*Mean Absolute Error*) describes the average magnitude of the differences between the device results and the reference method results, regardless of the direction of those differences.
- SD (*Standard Deviation*) describes the extent to which the individual differences between the device results and the reference method results vary around the mean difference.

7. Interpretation of measurement results

Parameter tested	Normal range	Unit	Comment
Pulse (heart rate)	60-100	bpm (beats per minute)	The lower the pulse (within normal limits), the better. Physically active people, especially those who participate in endurance sports, may have a pulse significantly lower than the accepted lower limit of the normal range. A pulse above 80 bpm, even if it is within the normal range, is a risk factor for cardiovascular disease.
HRV (SDNN) Heart rate variability	none	ms (milliseconds)	Due to the multitude of factors affecting pulse variability indicators, no strictly defined normal ranges have been established for them.
Breathing Rate	12-20	brpm (breaths per minute; number of breaths per minute).	In older people (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 American Geriatrics Society, 2013).
Blood pressure (BP)	Systolic blood pressure 90 - 129 Diastolic blood pressure 60 - 84 mmHg	mmHg (millimetres of mercury)	The values given are in accordance with the guidelines of the European Society of Cardiology (ESC) and the Polish Society of Hypertension. In general, blood pressure below 120/80 mmHg is considered normal.

Caution!



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



Normal results of physiological parameters should not be a reason to forgo a medical consultation if any concerning symptoms appear.



Measurement results that deviate from the reference values do not constitute a basis for self-diagnosis, do not replace a medical consultation and should not influence diagnostic or therapeutic decisions without prior consultation with a doctor.

If the message “err” or “–” is displayed, indicating that a result could not be determined, including because the value is outside the defined measurement range or the measurement quality is insufficient, the user should:



- ensure appropriate measurement conditions and repeat the measurement at least twice,
- if the message “err” or “–” is displayed again, verify the blood pressure using another medical device intended for blood pressure measurement,
- consult a physician if any concerning symptoms occur.

The device performs and displays measurements only within the measurement ranges specified in Section 6. Outside these ranges, the device does not display a numerical value, and no claim is made regarding measurement accuracy.

8. Hardware requirements

The minimum hardware requirements are presented in the table below:

Android operating system (smartphones and tablets)	Android version: Android 8.0 (API level 26) or newer Processor architecture: arm64-v8a or newer RAM: at least 4 GB OpenGL ES version: 3.0 or higher Sensors: accelerometer, gyroscope, camera
iOS operating system (smartphones and tablets)	Phone model: iPhone X or newer Operating system: iOS 14 or higher
Web browser (computers)	Requirements: • SharedArrayBuffer support • Support for requestVideoFrameCallback or MediaStreamTrackProcessor • WebGL 2.0 support • OffscreenCanvas support
Supported browser types on computers	• Chrome (from version 94) • Edge (from version 94) • Opera (from version 80)

Working environment:

- Recommended antivirus software.
- Recommended malware protection software.
- Recommended use of a firewall.
- Network permitting SSL transmission encryption.

To use the Shen.AI medical device, an Internet connection is required:

- when installing the mobile application with the medical device,
- when using the medical device in 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 in relation to measurement results.
- The instructions for use contain requirements for the operating system.
- The actions necessary to ensure the integrity and validation of the software are performed without the involvement of the end user.
- The instructions for use define the minimum hardware requirements that must be met for the device to function as intended.
- The intended environment for use of the medical device is a controlled environment without environmental interference.
- The medical device is intended for use both for patient self-monitoring and for medical examination purposes.
- Use of the medical device outside the intended environment of use may lead to incorrect medical conclusions.
- It is recommended that additional security measures in the form of antivirus and anti-malware software be used on workstations (equipment) where the medical device is used.

Access to measurement data is protected locally by the user's operating system security measures. The medical device does not require login and does not store personal data on the manufacturer's server.

If you stop using the device, it is recommended that you uninstall it from your device. User data can be deleted at any time by resetting the application.

The label and all instructions for use of the medical device (current and archived versions) are stored in electronic form on the manufacturer's website in a stable network location:

<https://shen.ai/medical-instructions>.

Upon request, the instructions for use can be provided in paper form at no additional charge.

To receive the instructions in paper form, please contact the manufacturer using the contact details provided on the first page of these instructions. The paper instructions will be delivered no later than 7 calendar days after receipt of the request.

Reporting serious incidents:

Any serious incident related to the medical device should be reported to the manufacturer (contact details can be found on the first page of the Instructions for Use) and to the competent authority of the Member State in which the user and/or patient resides.

Please send any comments, concerns or complaints to the following e-mail address: complaints@shen.ai

9. Legend of symbols used on the label



Manufacturer



Date of manufacture



UDI code



Medical device



REF number



eIFU: shen.ai/medical-instructions

Electronic instructions for use
Read the instructions for use before using the device



CE mark with the number of the notified body



Caution