Instructions for use of the Shen.AI Vitals medical device

Version 1.1, dated 04.04.2025

Manufacturer:
Shen.AI OÜ,
Lõõtsa tn 8a,
11415 Tallinn, Estonia,

Contact details:
Email: support@shen.ai
Website: https://www.shen.ai

ANVISA Registration Number: 81464750186

Registration Holder:
Domo Salute Consultoria Regulatória Ltda.

Avenida Cristóvão Colombo, 2948/411, 90540-072, Porto Alegre - Brazil

Technical Responsible Person: Eng. Diego Louzada
CREA/RS 16297

1. Purpose

The Shen.AI Vitals medical device is intended for the measurement of physiological parameters, including heart rate (HR), heart rate variability (HRV), and breathing rate (BR), to support the assessment of an individual's physiological status within the scope of self-monitoring or clinical examinations.

Shen.AI Vitals enables a convenient and non-contact measurement of the above-mentioned physiological parameters through a one-minute facial analysis performed with a digital video camera.

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

Indications for use of the Shen.AI Vitals medical device:

The measurement of physiological parameters using Shen.AI Vitals technology is intended for generally healthy individuals aged 18 years and older.

In addition, the Shen.AI Vitals is indicated for:

- Regular or ad hoc assessment of resting heart rate - pulse with reference to normal value ranges and previously recorded values to support the detection of potential cardiac abnormalities and the assessment of cardiovascular disease risk.
- Regular or ad hoc assessment of breathing rate with reference to normal value ranges and previously recorded values to support the detection of potential respiratory dysfunction.
- Regular assessment of short-term pulse variability to monitor trends in observed values, assisting in the evaluation of fatigue or stress levels.
- Long-term collection of resting pulse measurements for presentation to a physician to support cardiac diagnosis.
- Non-contact measurement of pulse and/or breathing rate in conditions or situations requiring physical distance.

Contraindications to the use of the investigational device:

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

- with cardiac arrhythmia (except sinus tachycardia, sinus bradycardia or respiratory sinus arrhythmia),
- with impaired respiratory function in the form of dyspnoea or irregular or shallow breathing,
- with an implanted cardiac electrostimulator,
- using cardiac assist devices,
- requiring specialised medical supervision or continuous medical care,
- those in a life or health-threatening situation.

In addition, due to the characteristics of the measurement method (optical detection of blood pulsations in the facial skin), Shen.AI Vitals technology cannot be used to measure physiological parameters in the following cases:

- extensive facial skin damage (including abrasions, wounds, burns),
- a disease process affecting a significant part of the face,
- presence of extensive dressing on the face,
- extensive facial tattooing or the application of face paint,
- facial deformities (e.g. due to a cancerous tumour),
- paralysis, numbness or tingling of the face,

- facial tremors or muscle spasms, including nervous tics (except eye or eyelid movements),
- inability to maintain a stable head position during measurement,
- temporary or persistent facial pallor,
- moderate or severe anaemia,
- heart failure, impaired left ventricular systolic function, aortic valve stenosis or other cardiovascular diseases or disorders leading to low stroke volume, low pressure amplitude or irregular pulse patterns ("odd pulse").

Expected clinical benefits of the Shen.AI Vitals medical device:

- The device is intended for the measurement of selected physiological parameters (in resting conditions at home), so the primary benefit of using the device is to obtain information on the physiological state (of oneself or the person being measured) in terms of the parameters measured, i.e. heart rate (HR), heart rate variability (HRV), and breathing rate (BR).
- Consequently, the device allows monitoring of the physiological state and can enable early detection of potential abnormalities in the measured parameters (which should be confirmed through professional and comprehensive diagnostics.
- The ability to use the device on widely available mobile devices may contribute to making measurement of basic physiological parameters more accessible in areas with limited access to classical measuring devices.
- The non-contact measurement method allows physiological parameters to be measured in conditions that require distance.

The Shen.AI Vitals 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

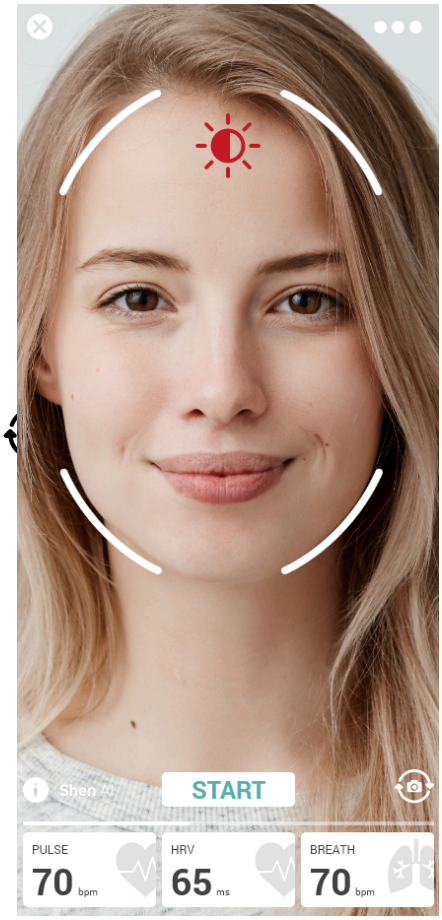
Shen.AI Vitals optically measures cyclic changes in blood volume within the blood vessels of the facial skin using remote photoplethysmography via a video camera. In contrast to classical photoplethysmography (used, for example, in finger pulse oximeters), diffuse white light (daylight or artificial light) is used to illuminate the skin, while the intensity of the light reflected from the skin is recorded by a video camera. The video signal is processed into signals showing the pulsation of blood in different parts of the face, the analysis of which allows the pulse rate, pulse variation indices as well as respiratory frequency to be determined. The processing and analysis of the video signal takes place on the device used during measurement. Advanced algorithms for tracking facial movement and position allow measurement even if the head moves slightly during measurement.

4. Conditions and course of measurement

The Shen.AI Vitals technology is designed to be measured under resting conditions in a sitting or lying position, with sufficient light to perform the measurement.

During the measurement, the cardiovascular and respiratory systems should work as steadily as possible, therefore, measurements should not be taken immediately after physical activity or after a change in body position. It is recommended that the user remain as relaxed as possible for at least 5 minutes before starting the measurement in order to stabilise the heart rate and breathing rate. Measurement results taken after a rest period of less than 5 minutes should not be considered as results obtained under resting conditions.

During the measurement, the user should breathe normally, maintain a relaxed but as stable head position as possible, not talk or make facial movements.



Two measurement modes are available:

- Self-measurement - takes place using the front camera.
- Measured by a second person (e.g. by a caregiver or medical staff) - this is done using a rear camera.

The medical device is considered correctly installed and can function correctly and safely if, upon logging in, the screen displaying the user's face along with the START button is visible (as shown in the reference screenshot except for parameters values).

The mode can be selected before starting the measurement by using the icon  .

During the measurement, follow the messages displayed on the screen of the device used for the measurement.

<u>Preparation for measurement</u>

Before the user's face is measured:

- the user should be in the correct position and distance from the camera so that its view on the screen aligns with the marked border,
- the skin should be dried and cleansed of heavy make-up and any dirt,
- the face should not be covered by hair, a mask, glasses or any other object, the mask and glasses should be removed and hair should be moved away from the forehead.

In order to maintain measurement accuracy, it must be ensured that the measurement of the Shen.AI Vitals device is carried out under constant and unchanging lighting conditions.

Measurement in motion, e.g. while moving on means of transport, is not recommended due to the possibility of vibrations (difficult image stabilisation) and the possibility of dynamic background and illumination changes.

<u>Carrying out the measurement:</u>

No gum, tobacco, chewed food or other products may be chewed during the measurement. The device used for measurement should be in a stable position (otherwise, the measurement may not be performed or will have a higher error compared to a fully stable measurement).

When using a mobile device (phone, tablet), it is recommended to rest it against any stable object or place it on a stand, holder, etc. (does not apply to measurements taken with the rear camera). Holding the device in the hand(s) is acceptable if the user is able to hold the device steadily during the measurement (it is recommended to hold the device in both hands and, if possible, support the hands on a stable surface).

When using a laptop, it is recommended to place it on a table, desk, etc. holding the laptop in the hands, on the lap or otherwise is acceptable if the user is able to hold the device steady during the measurement.

When using an external camera connected to a desktop or laptop computer, it is recommended to attach the camera to a stable or hold in a stable position object. Analogous to mobile devices, holding the external camera in the hand(s) is acceptable if the user is able to hold it steady during measurement.

The face should be directed in front of the camera or the face of the person taking the measurement, in the case of a rear camera measurement. Once the face is correctly positioned in relation to the camera (or camera in relation to the face), the measurement can be started using the START button. The measurement takes approximately 1 minute and the degree of measurement progress is represented graphically at the bottom of the screen. The measurement can be stopped at any time using the STOP button.

The quality level of the photoplethysmographic signal extracted from the video image by Shen.AI Vitals algorithms is indicated by an icon ••• at the top of the screen (the more filled circles, the better the signal quality).

In order to ensure correct measurement, special attention should be paid to:

1. adequate facial lighting, i.e:
    - Diffuse daylight or artificial lighting at an intensity that allows comfortable reading.
    - Uniform illumination of the entire face (no visible shadows).
    - No visible reflections on facial skin.
2. suitable operating conditions for the camera, i.e:
    - Camera position stability.
    - Camera lens clarity.
    - No direct light falling on the camera lens (especially from behind the subject).
    - No other people (faces) in the camera frame.
3. an appropriate head position and an unobstructed view of the facial skin, i.e:
    - Position the face perpendicular to the camera (both cheeks visible equally).
    - No obscuring of facial skin with hair, glasses, mask, dressing or any other objects.
    - No heavy facial make-up.
    - No visible moisture or dirt on facial skin.
    - Stable head position.
    - Stable facial expressions (avoiding talking and facial movements).

In the event of inadequate lighting conditions, an icon  will be displayed on the screen in order to improve the illumination of the face, an additional light source can be used, with an even illumination of the face and no reflections.

If, during the recording, the subject's head or the camera changes position so that the outline of the face in the frame no longer coincides with the outline marked on the screen, the outline will turn red to signal the need to change the position of the head relative to the camera (i.e. zoom in or out).

In the event of insufficient exposure of clean and uncovered facial skin, or if there are other circumstances preventing measurement, an icon  and an audible warning will be displayed on the screen.

To exit the Shen.AI Vitals measurement module, use the icon  at the top of the screen.

5. Results, measurement ranges and accuracy of measurements

The measurement results are presented at the bottom of the screen:

- Pulse (heart rate) - starting from the 11th second of measurement, pulse values are displayed every 1 second (averaged over the last 10 seconds of full heart cycles, with a 1-second delay), at the end of the measurement the average pulse value from the whole measurement period is displayed,
- HRV (heart rate variability index) - a value displayed at the end of the measurement indicating the level of heart rate variability during the entire measurement,
- Breath (breathing rate) - value displayed at the end of the measurement (average over the measurement).

An indicator of pulse variability is:

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

Measurement ranges

The device can detect and classify pulse, HRV and breath within the following ranges:

Parameter	Unit	Range
Average pulse (average value of the whole measurement)	bpm (beats per minute)	40 - 120 bpm
Instantaneous pulse (average value over the previous 10 s)	bpm (beats per minute)	40 - 120 bpm
HRV (SDNN)	ms (milliseconds)	3 - 125 ms
Breath	bpm (breaths per minute)	9 - 28 bpm

Accuracy of the measuring function

Parameter	Unit	Measurement accuracy*
Average HR (average value of the whole measurement)	bpm (beats per minute)	± 0.3 bpm
Instantaneous HR (average value over the previous 10 s)	bpm (beats per minute)	± 0.4 bpm
HRV (SDNN)	ms (milliseconds)	± 6.3 ms
Breath	bpm (beats per minute)	± 2.3 bpm

*root mean square error (the measurement result falls within the specified error limit in approx. ⅔ of the cases)

6. Interpretation of measurement results

Test parameter	Range of normal values	Unit	Comment
Pulse (heart rate)	60 - 100	bpm (beats per minute)	The lower the pulse (within the normal range), the better. Physically active people, particularly those involved in endurance sports, may have a pulse rate well below the accepted lower limit of normal values. A pulse above 80 bpm, although it is within the range of normal values, is a risk factor for cardiovascular disease.
Breath (breathing rate)	12 - 20	bpm (breaths per minute)	In the elderly (over 65 years of age), 28 breaths per minute is taken as the upper limit of the normal range (Rodriguez-Molinero et al, Journal of American Geriatrics Society, 2013).
HRV - SDNN (heart rate variability)	non-applicable	ms (milliseconds)	Due to the numerous factors influencing pulse variability indices, no strictly defined ranges of normal values have been established for them.

Attention!

A normal pulse or respiratory rate measurement should not be a reason to forget a medical consultation if any worrying symptoms appear. If users suspect they are experiencing a medical emergency, they should immediately contact their local emergency services.

If a measurement result falls outside the normal range, it is recommended to repeat the measurement at least twice to confirm the result.

Measurement results that deviate from normal values should not be used as a basis for self-diagnosis, are not a substitute for medical consultation and should not influence further diagnostic and therapeutic management without medical consultation.

The results of heart rate variability measurements (both single measurements and observed trends in HRV indices) should not be used for self-diagnosis and should not influence therapeutic management without medical consultation.

7. Hardware requirements

The minimum hardware requirements are shown in the table below:

Android operating system (smartphones and tablets)	Android Version: Android 8.0 (API level 26) or newer CPU architecture: arm64-v8a or higher RAM: at least 2 GB OpenGL ES version: at least 3.0 Sensors: accelerometer, gyroscope, camera
Operating system iOS (smartphones and tablets)	Phone model: iPhone X or higher Operating system: IOS 13 or higher
Web browser (computers)	Requirements: ● Support for SharedArrayBuffer One of: ● Support for requestVideoFrameCallback ● Support for MediaStreamTrackProcessor (preferable) ● Support for WebGL 2.0 ● Support for OffscreenCanvas
Supported browser types on computers	● Chrome (from version 94) ● Edge (from version 94) ● Opera (from version 80)

Interoperability and Compatibility:
This device is compatible with Android (version 8.0+) and iOS (version 13+). It is not compatible with jailbroken or rooted devices.
Compatible browsers: Chrome v94+, Edge v94+, Opera v80+. Not compatible with non-standard web browsers or outdated systems.

Working environment:

- Recommended antivirus software.
- Recommended malware protection software.
- Firewall recommended.
- Network allowing SSL transmission encryption.

An internet connection is required to use the Shen.AI Vitals product.

Summary of medical device risk profile and associated IT security objectives:

- The medical device only processes the patient's medical data in terms of measurement results.
- The operating system requirements are included in the instructions for use.
- The activities needed to ensure the integrity and validation of the software take place without the involvement of the end user.
- The instructions for use define the minimum hardware requirements that must be met for the product to function as intended.
- The assumed environment of use of the medical device is the home environment.
- Use of the device outside the intended environment of use may lead to inappropriate medical conclusions.
- Additional security in the form of anti-virus and anti-malware software is recommended on the workstations (hardware) on which the medical device is used.
- The process of making backups and, if necessary, restoring the state of the product from these backups is carried out without the involvement of the end user.

Cybersecurity Information:

- Data Protection: All data is encrypted during transmission.
- Software Updates: Automatic updates are applied when connected to the internet.

Software Update Procedure:

- Updates are automatically prompted within the app. Users are advised to keep the device connected to Wi-Fi for seamless updates.

The label and all instructions for use of the product (current and archive versions) are stored electronically on the https://drive.google.com/drive/folders/19XWCLh9dVcUh5pqWOYRahDXiO8hRBdFF.

8. Contact details

Manufacturer:

Shen.AI OÜ, Lõõtsa tn 8a, 11415 Tallinn, Estonia.

Please send any comments, objections, complaints to the following email address: support@shen.ai.

Registration Holder:
Domo Salute Consultoria Regulatória Ltda.

Avenida Cristóvão Colombo, 2948/411, 90540-072, Porto Alegre - Brazil

Technical Responsible Person: Eng. Diego Louzada CREA/RS 162977

ANVISA Registration Number: 81464750186

Emergency Procedures:
If the device malfunctions, stop use immediately and contact technical support at support@shen.ai.

Any serious incident related to the device should be reported to the manufacturer and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.