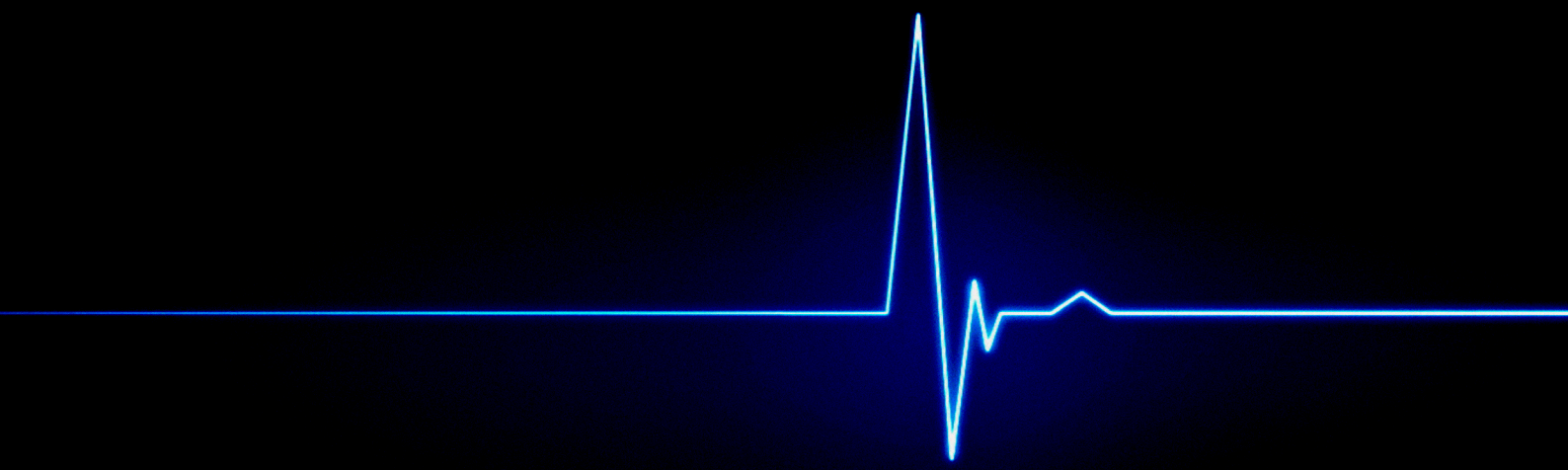
Heart rate, heart rate variability and blood pressure evaluation, conditions and procedure



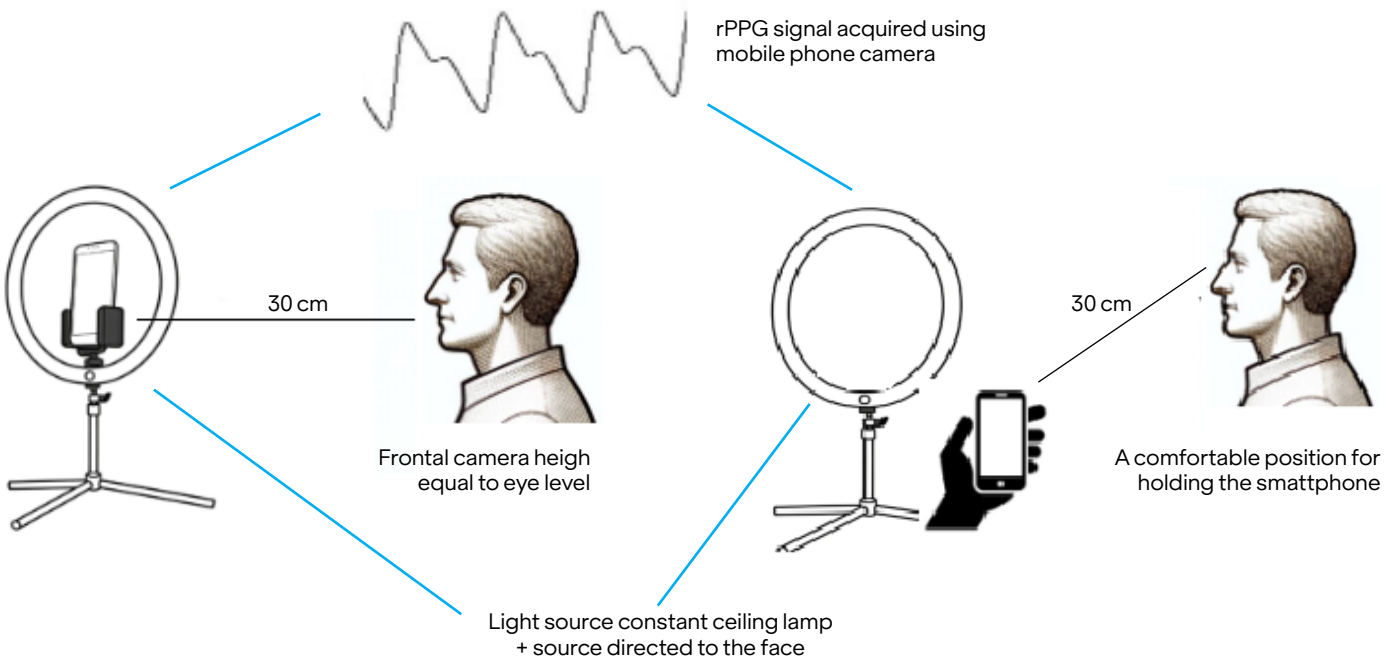
shen ai

TRIAL PREPARATIONS

All conditions that are mentioned below should be obtained during evaluation of aforementioned parameters.

- To get the best results with Shen.AI technology, make measurements in a sitting position and good lighting (approx. 400 - 500 lx).
- Make sure that you choose hardware that fits Shen.AI requirements.
- The measurements should be taken in seated position, with phone being stable - either held by hand, or on tripod
- Face should be not covered with hair, glasses, a mask, a dressing or any other object; no heavy makeup on the face; no visible moisture or dirt on the face
- The face should be illuminated evenly, ideally when sitting in front of the window, avoiding strong light behind, shadows or direct sunlight
- During the measurement the person must avoid talking and moving
- Before starting, make sure your face is at the right distance from the camera so that it fits within the frame on the screen. Once you're ready, just press the START button.
- **APPLIES TO BLOOD PRESSURE:** To get the reference measurement of **Blood Pressure**, make sure that the person is steady, not moving, and has been resting for at least 3 minutes. The cuff should be on the arm from the very beginning (further body movements influence the BP).

EXAMPLES OF EQUIPMENT SET:



Polar H10

RRi from ECG signal acquired for reference (using Polar H10 or other certified equpment)

Video measurement notes

1. Direct, but not overly strong light (avoid reflections on the skin).
2. The face should be uncovered: hair should be tied back, and items such as glasses or a protective mask should be removed.
3. The face position should be perpendicular to the camera (both cheeks equally visible).
4. Participants must not move, speak, or make facial expressions.
5. Participants' hands should rest on the table.
6. The phone on the tripod should be positioned below head level, allowing the person to look down on it. This corresponds to the typical measurement position when holding the phone in hands, on a table.

PROCEDURE:

For HR and HRV evaluation, an ECG signal is required. Our recommendation is to use either **Polar H10 device**, or professional medical device such as **Finapress Nova**, with 4-lead ECG connection with **NovaScope software to export data**.

The best way to compare **the basic metrics (HR, RR intervals, HRV)** is to measure individual beat-to-beat intervals, and save them to a **CSV** file.

To get estimated intervals from Shen.AI your implementation should allow saving the interval data, described here as list of heartbeats. Each heartbeat has **its beginning, end and duration (timing), in milliseconds**.

It is crucially important to plot each set of intervals (measured by Shen.AI and those from the reference device) and **make sure** the plot (tachogram of intervals) **roughly matches the other**. We have had situations in the past, where researchers compared heartbeats that were not aligned in time, which looked like an inaccuracy (**which it was not**).

APPLIES TO BLOOD PRESSURE:

For Blood pressure evaluation our recommendation is to use **Omron M4 Intelli IT blood pressure monitor** (link)

To get the reference measurement of **Blood Pressure**, make sure that the person is steady, not moving, and has been resting for 3 minutes. The cuff should be on the arm from the very beginning (further body movements influence the BP).

Both measurements (Shen.AI and reference) should be done at the same time. To achieve this, press the buttons on the phone **and, after three seconds, on the blood pressure monitor** (the measurement on the blood pressure monitor will finish earlier).

It is crucial to understand that blood pressure is never constant and can fluctuate continuously. Here are a few important points to consider:

PLEASE REMEMBER:

If Your trial includes more than one measurement per patient, make at least 1 minute break between measurements.

- **Fluctuations in Blood Pressure**: Blood pressure can vary by approximately 10mmHg every 5-10 seconds. This means that the readings obtained at different times may differ due to these natural fluctuations.
- **Continuous Measurement**: Shen.AI utilizes advanced technology to measure blood pressure continuously over a period of 60 seconds. The readings provided by Shen.AI represent an average value over this duration, unlike traditional cuff-based sphygmomanometers that provide a snapshot measurement at a specific moment.
- **Potential Discrepancies**: The method and timing of blood pressure measurement can affect the results. Factors such as movement, talking, or behavior can significantly influence blood pressure. For example, even the act of moving your hand to operate the cuff can cause fluctuations in your blood pressure.
- **Potential Variations**: It is important to note that there may be variations between blood pressure measurements obtained through Shen.AI and those obtained using reference cuffbased sphygmomanometers. The typical standard deviation of errors in such reference devices is reported to be around 3-5 mmHg.

Please keep these factors in mind when interpreting blood pressure readings obtained through **Shen.AI**. If you have any concerns or questions, we recommend consulting a healthcare professional for further guidance and clarification. We strive to provide accurate and reliable measurements, but it is essential to understand the limitations and potential variations that can occur. Your understanding and cooperation are greatly appreciated as we work to improve blood pressure measurement technology.

DATA ANALYSIS:

For comparing accuracy, we recommend these statistical metrics, which we always use ourselves:

- SD (ang. Standard deviation)
- RMSE (ang. Root mean square error)
- MAE (ang. Mean square error)

Below You may find a link to a blank table prepared for aforementioned calculations: **Please note**, that You should provide to this table values that are analyzed already regarding duration of **matched** intervals in milliseconds and **values** of appropriate heart rate and blood pressure.

Table includes examples and blank spreadsheets to be used in **Your analyzes**.