

VITACAM V2

INSTRUCTIONS FOR USE



Vitacam V2



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Liability disclaimer

Evondos Oy reserves the right to make modifications, enhancements, and other changes to the device and the related documentation without prior notice.

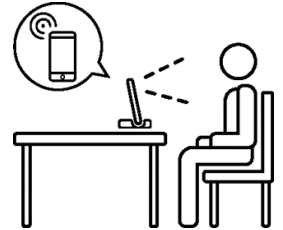
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INTENDED PURPOSE

Vitacam V2 is intended for non-invasive spot measurement of respiratory rate, pulse, pulse rate analysis and variability, and oxygen saturation.

Vitacam V2 is designed for use in a computer server, taking as input, a video clip, or a live video stream from a digital camera to spot-check or periodically measure vital signs in home-monitored adults or in ambulatory adult patients in a clinical setting.



The client's head and chest must be visible in the camera live view.

Vitacam V2 can support the clinical assessment of current condition and deterioration but is not intended to be the sole method of checking the physical health of a client.

Vitacam V2 can be used in:

1. Routine monitoring of clients' vital signs, including home care clients.
2. Monitoring the vital signs of ambulatory clients.

In all cases, whether used as part of a virtual consultation or home follow-up, the interpretation of the measurements should always be left to a healthcare professional.

Note before using:

Vital signs will fluctuate during the course of a day, in response to many factors including physical activity, stress, environmental conditions, diet, and fluid intake.

Measurements must be taken at rest, preferably having relaxed for at least five minutes prior.

For the best results, wait at least an hour after eating, smoking, drinking beverages with caffeine or alcohol, or exercise, as these may affect the results.

Contact a healthcare professional without delay if:

- You feel unwell, experience new or worsening symptoms (e.g., shortness of breath, chest discomfort, dizziness, or fatigue), regardless of the measurement result.
- Your measured vital signs are outside the normal or expected range provided in this manual.
- You receive repeated unusual or inconsistent measurement results, or you are unsure how to interpret your results.

Do not rely solely on Vitacam V2 measurements to make medical decisions. Always seek professional medical advice if you have concerns about your health.

Serious incidents:

- A serious incident is an event where Vitacam V2 may have caused, or could have caused, serious harm or danger to a patient or user.
- Any serious incident that has occurred in relation to Vitacam V2 should be reported to Evondos and the competent authority of the Member State in which the user and/or subject is established.

Disclaimer

Evondos Oy is responsible for the safety and performance of Vitacam V2 only when the following conditions apply:

- Vitacam is used according to its intended purpose.
- Vitacam is operated according to this document and instructions given in the application.

SAFETY SYMBOLS

	CE marking which indicates that Vitacam V2 fulfils EU MDR 2017/745 requirements. Includes the notified body ID number
	Contraindications to be taken into consideration when using Vitacam V2
	Warning to be taken into consideration when using Vitacam V2
	Caution to be taken into consideration when using Vitacam V2

	Notices to be taken into consideration when using Vitacam V2
	Name and address of the manufacturer
	Date of manufacturing (YYYY-MM-DD)
	Consult instructions for use before using
 vitacam.health/support	Consult the electronic instructions for use – which can be found on the website: https://vitacam.health/support/
	Indicates that Vitacam V2 is a medical device
	Unique Device Identifier

CONTRAINDICATIONS AND PRECAUTIONS

Read the following carefully before using Vitacam V2:



Contraindications

A condition, patient population, or situation in which Vitacam must not be used, as its use may pose an unacceptable risk or the risks outweigh the expected benefits.

01. Do not use Vitacam V2 in children (age < 18 years).
02. Do not use Vitacam V2 for monitoring clients under anesthesia, post-operative or intensive care, or emergency care.
03. Do not use Vitacam V2 on clients taking medication which lowers their breathing, such as strong opioids.
04. Do not use Vitacam V2 for diagnosing hypoxia or hypoxemia.
05. Do not rely on Vitacam V2 to measure pulse rate in those diagnosed with arrhythmia.
06. Do not use Vitacam V2 for monitoring or diagnosing sleep apnea.



Warning

A warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious personal injury

07. Do not use Vitacam V2 on a client who requires immediate care.
08. Do not use Vitacam V2 as the sole basis for medical decisions. Vitacam V2 must be used in conjunction with clinical signs and symptoms.
09. A respiratory rate lower than 6 breaths a minute will not be detected.
10. Oxygen saturation below 85%, such as with clients with severe COPD or lung cancer, will not be detected.
11. During arrhythmia, the pulse rate may be lower than the actual heart rate.



Caution

A caution indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or temporary impairment.

12. Vitacam V2 has not been tested with clients with arrhythmia, blood pressure disorders, or other abnormal heart conditions. Medication for such conditions will affect results.
13. Make sure that the timing of the measurement is agreed with the responsible nurse based on the treatment plan.
14. Do not rely solely on Vitacam V2 for measuring oxygen saturation if a client has low perfusion, i.e. below 2%.
15. Oxygen saturation has not been validated on clients with lung diseases or anemia.
16. Pulse and oxygen saturation measurement is not validated with very dark skin (Fitzpatrick type VI).
17. Vitacam V2 has only been tested with clients whose skin and body temperature is normal.
18. Vitacam V2 has not been validated on pregnant women and can only be used if recommended under clinical supervision.



Notice

A notice highlights important information to improve usability and ensure correct use.

19. Insufficient lighting can hinder or prevent measurements. Ensure that the measuring environment is lit up to 200 lux at least and no direct light source is facing the camera or placed within the camera's live view. Spotlights, shadows, and other lighting that alters the appearance of the client's face can hinder or prevent pulse or oxygen saturation measurements.
20. Do not use Vitacam V2 with a camera that does not fulfil the technical specification.
21. A dirty camera lens can impact measurement results. Ensure that the lens is clean before using the application. Use a fresh wet wipe to clean the camera if needed.
22. The camera must not be closer than 30 cm from the client and not further than one meter.
23. Obstacles in the camera view or the client's incorrect position can hinder or prevent measurements. Ensure that the camera view is obstacle-free, and the measuring environment is set up according to instructions.
24. Excessive movement, including tremors, can hinder or prevent measurements. Follow the guidance to be as still as naturally possible.
25. Makeup that significantly alters or covers the base tone of the face can hinder or prevent measurements. This includes foundations, concealers, and color correctors in a liquid, cream, or powder formula.
26. It is recommended to use wireless network when using Vitacam V2. Otherwise, data usage costs may be incurred.

HOW DOES VITACAM V2 OBTAIN VITAL SIGNS

Vitacam V2 analyzes a video recording of a client to obtain vital sign measurements.

The video must always include the head and upper chest of the client. These are the regions of the body used for the analysis. The analysis is performed on a computer server.

The respiratory rate is measured by analyzing the chest area over a 30 second period (Figure 1). The chest contracts and expands during breathing in and out. Vitacam V2 finds points on the chest to be used as regions of interest to estimate the magnitude and frequency of the chest movements.



Figure 1. Example of chest points used for respiratory rate measurement with Vitacam V2.

The pulse rate and pulse intervals are measured through a technique known as remote photoplethysmography (r-PPG). With this technique, blood volume variations in the microvascular facial tissue are detected from a video sequence (Figure. 2). The circulation of pulsatile blood causes the skin colour to become slightly more red. Haemoglobin in blood reflects red light, which is why blood appears red, but it absorbs green light strongly. These changes can be detected in Red-Green-Blue (RGB) channels which are used in digital imaging. A pulsatile signal showing the systolic and diastolic phases can be obtained, which is used to estimate the pulse and pulse variability. Analysis of different colours and their brightness is used to obtain the oxygen saturation (SPO₂). The technique is adapted and modified from photoplethysmography used in pulse oximeters.



Figure 2. Example of Regions of Interest for pulse and oxygen saturation calculations in Vitacam V2.

GETTING STARTED

There are several different ways to take Vitacam V2 into use:

1. As part of a system, where a digital camera records a video, which is then processed on the Vitacam V2 server.
2. As part of a digital platform, such as a remote care service that includes a smartphone app. Vitacam V2 functionality is integrated into that smartphone app.

3. On a personal smartphone after the user has downloaded the 'Vitacam V2' app under the direction of a healthcare professional.

In the case of (1.), the user does not need to take any actions to use Vitacam V2. The functionality is triggered automatically in the background and no further actions are required.

In (2.), the functionality is available as part of a third-party app and no actions are required.

In (3.), the user must download the 'Vitacam V2' app from either the Apple App Store for iPhones and iPads or the Google Play Store for Android devices. The app has the logo shown on the right side. This is also the icon for the app on the smartphone.



Obtaining credentials

For the Vitacam app, you should receive credentials from a healthcare professional, whose organization has a license to distribute Vitacam V2.

If you are a healthcare professional who wishes to test Vitacam V2, please contact info@vitacam.health.

If you are using Vitacam V2 functionality as part of another system or digital platform, there is no separate login required.

Getting an initial reference measurement

During the onboarding of Vitacam V2 to a client, the healthcare professional must take an initial reference measurement of the oxygen saturation using a CE-marked pulse oximeter, approved for clinical use. As per normal practice, the measurement should be stable for at least 30 seconds. The measured value shall be entered into the back-end system and transmitted to the Vitacam servers, where it is used to calibrate Vitacam V2's oxygen saturation measurements for that client.

The measured value can be entered through a client device, available to the healthcare professional, in a system where Vitacam V2 is a component.

Understanding and accepting how your data is processed

Note that if you are using Vitacam V2 as part of a physical system, the data is processed entirely on the system and the data protection policy, as described below, does not apply.

In the case of using Vitacam V2 as part of a digital platform, it is still worth reading the description below as both the Evondos Oy and the operator of the platform would act as data processors.

You must read and accept the data protection notice before using the Vitacam app which is concerned with the handling of the data.



Your data is processed according to the General Data Protection Regulation 2016/679 (GDPR), which applies across the European Economic Area. In the United Kingdom, the processing is done according to the Data Protection Act 2018.

No video data is ever stored on any server. All videos sent will be deleted immediately upon processing and within a 24-hour period in the unlikely event that the video was uploaded but not processed.

Your activity on the app and the results cannot be shared with any third-party.

The date and time of your logins and the measurements themselves are stored in the Vitacam V2 server which is hosted by Google Cloud and is in Hamina, Finland. The healthcare provider acts as the data controller which means that it owns the data and decides what is done with it, including how long it is stored. Evondos Oy is a data processor, so it can view and process this data, on behalf of the healthcare provider.

Your rights to the data and its processing are implemented in accordance with the GDPR, subject to the rights of the healthcare provider, which can prevent the erasure of health data.

For more information about how the data is handled and processed, consult the data protection notice at <https://vitacam.health/privacy-policy/> and send any questions to info@vitacam.health.

Logging in (Vitacam app only)

For the Vitacam app, it is necessary to log in using the credentials provided.



You can enable biometric login depending on the capabilities of your smartphone. It is possible to set up a fast login with iPhones using Face ID or Touch ID, and similar biometric methods on Android. Look for the face login or the fingertip icon.



The next time you log in, tap **Use secondary login** or the face login icon.

To ensure the protection of your data, you are automatically logged out after a few minutes of continuous inactivity.

In case you forget your credentials, contact your healthcare provider.

Onboarding tutorial

The Vitacam app includes an onboarding tutorial that automatically opens the first time you access it. You can also open the material by tapping the **Question mark (?)** button that is always visible on the bottom of the screen.

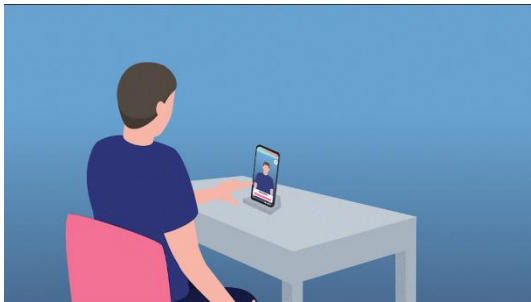
The onboarding tutorial explains the basics of how the app works, how the data is processed, and how to use it:

- Ensuring sufficient lighting.
- Being seated for the measurement.
- Using a stand for the smartphone or letting it lean against an object.
- It is important to take any face masks off while before using the application.

VITACAM V2 VIDEO MEASUREMENT

How to conduct a Vitacam V2 video measurement

To begin a Vitacam V2 video measurement, tap the **Take measurements** button on the front page of the app. The button leads to a guided step-by-step process of recording a video and sending it for processing.



The first screen provides an animation showing how to be seated for the measurement. You can select the front or rear camera, and the animation changes accordingly. The front camera is best if you want to measure yourself, while the rear camera is ideal if you want to measure someone else.

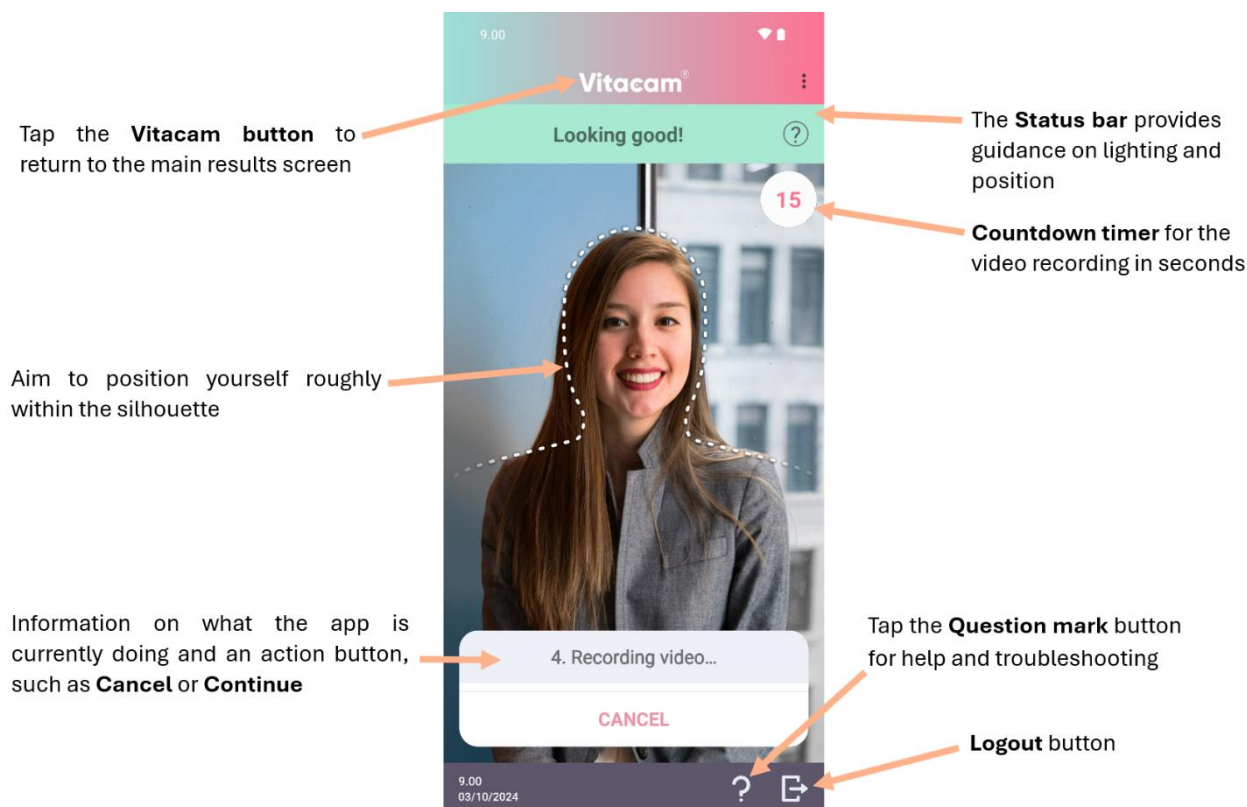
After you are correctly positioned, tap **Proceed**. The camera turns on and the live view is displayed on the smartphone screen with instructions and a silhouette. The colored text banner on top of the

screen shows instructions if you need to get closer or further to the camera or adjust the lighting.

Place yourself or the client within the silhouette until the top text banner turns green. In case you do not succeed, you can still proceed with the recording.

After the setup is complete, tap **Start recording** to record a video. There is a three-second countdown for any final adjustments, after which the recording begins and a 30-second timer will appear on the screen. You or the client must stay still during this period. After the recording is finished, tap **Send video** to send it for processing. In case you are concerned that there were too many disturbances in the video, tap **Preview video** it to inspect it. Tap **Try again** to record the video again.

The Recording screen



The status of the upload process is shown live in the app. After the upload, the subsequent processing is also shown with a similar progress bar until the results are ready to be displayed. Meanwhile, the video is permanently and automatically deleted.

READING THE RESULTS

NOTE: You do not need to act on any of the measurements you see. These are sent automatically to remote care teams through our partner and platform integrations.

You can refer to the results when discussing with a healthcare professional.

When the results from a measurement are ready, the results screen appears automatically.

The screen includes a status card divided into five tiles with each displaying the result for a specific parameter:

- Pulse
- Respiratory rate (breathing)
- Pulse analysis

- Pulse rate variability (the Root Mean Squared Difference of successive inter-beat intervals, commonly known as RMSSD)
- Oxygen saturation.

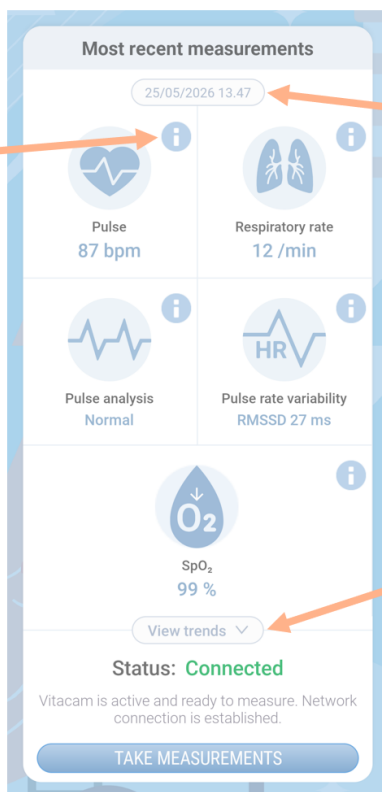
Tap the **Information** button for further information on each parameter

For example, tap the **Information** button on **Pulse** to see the following:

Pulse
24/09/2025 11.07

Pulse is the number of times your heart beats in a minute (bpm) and is linked to the number of times the blood vessels expand and contract in one minute.

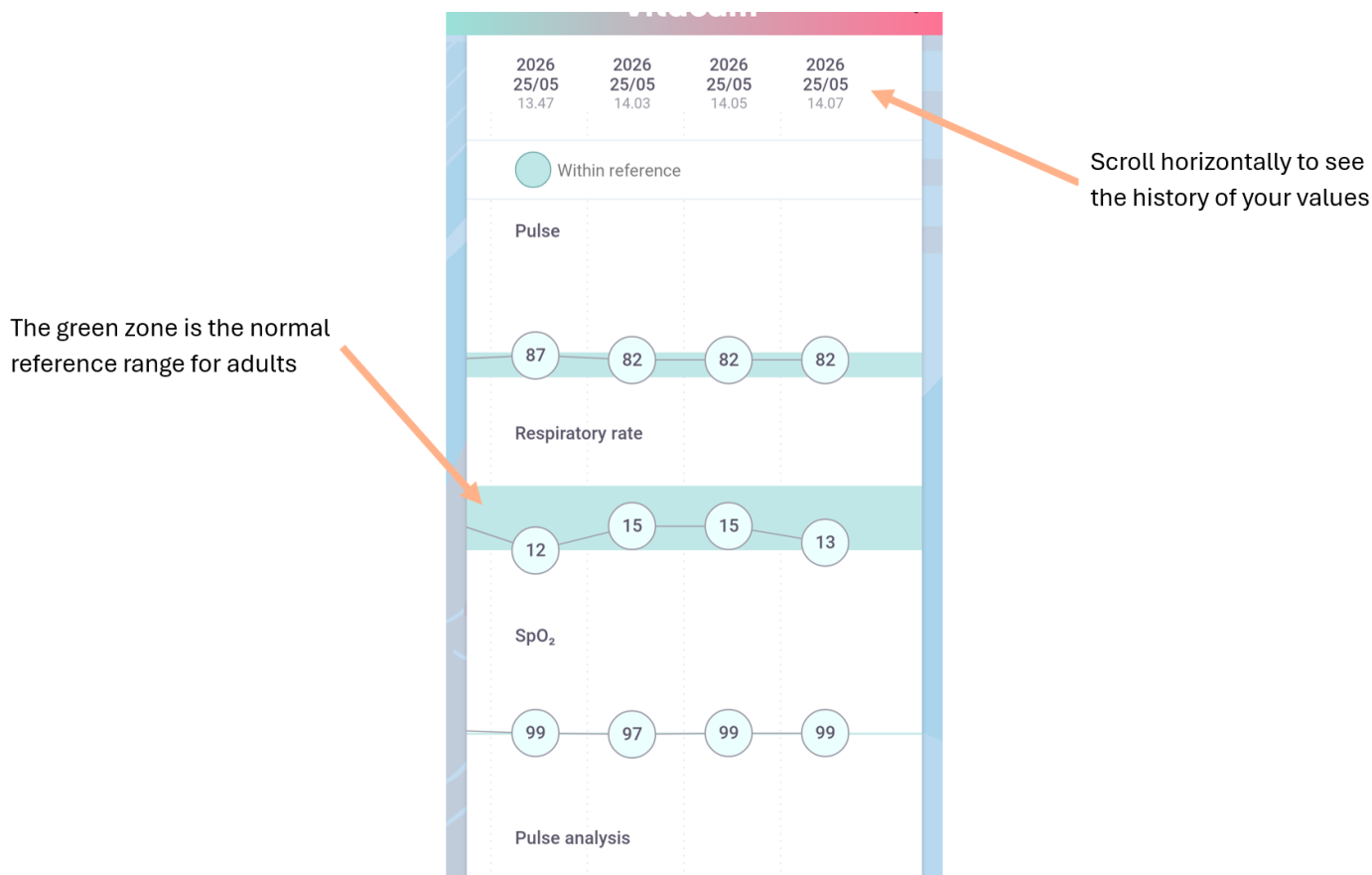
Your result
86 bpm
Within reference
Your pulse appears normal.



The date and time of the last measurement

Tap the **View trends** button to see patterns in your readings for all the parameters

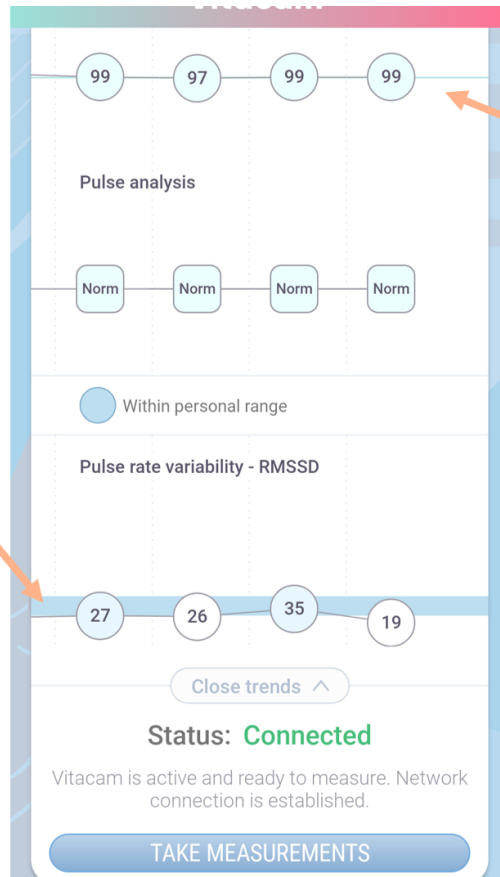
You can see the trends for each parameter by tapping the **Information** button next to a measurement or the **View trends** button.



For interpretation, the trend chart is colored green according to the reference range for normal values from the National Early Warning Score (NEWS2). NEWS2 is used for analyzing observations as part of routine clinical practice in many countries. The scoring is not intended for lay-users and it is not used or explicitly referred to in the Vitacam app.

The measurements will be appropriately coded for clinical use through third-party integrations.

Vital sign parameters fluctuate throughout the day and in response to activity. Values may occur outside the reference range without being a cause for concern.



As **Pulse rate variability** (RMSSD) is a wellness feature and not a clinical indicator, there is no reference range. Instead, a personal range is used based on your or client's own individual history.

TROUBLESHOOTING & FAQ

Please read through the contraindications and precautions section to find out if your issue is related to items listed there.

The app is using the wrong camera (front or rear)

Tap the **Camera** button on the top-left corner of the screen when preparing for measurement to switch between the front and rear camera.

During Vitacam V2 measurement or preparation phase, the top of the screen guidance flickers or remains yellow or red (e.g. face not detected or issue with lighting conditions)

Environmental factors and the heavy movement of the client can affect the ability of the app to reliably detect the face. The lighting may also be insufficient.

If you think that the face is properly positioned within the defined silhouette and lighting conditions are good, you can continue and send the video for processing. After the recording, you can also visually check the video yourself to see if it is looking fine. In most cases, it is enough to follow the in-app guidance.

Video measurements are inaccurate or incomplete

Ensure that you are following the in-app guidance and aim to stay still within the defined silhouette. If the issue persists, try to switch to a location with better ambient lighting.

Who can be measured using Vitacam V2?

Vitacam V2 is certified to be used with adult subjects over the age of 18 who are not in immediate danger or in need of critical care.

App displays a camera error

Try closing other apps which may be using smartphone cameras. You can also try restarting your smartphone.

App displays a network error

Try checking if your smartphone is connected to the network by opening the web browser and opening any site. In case there is no network, try switching from wireless network to mobile data or from mobile data to wireless network.

Are the recorded videos handled in a secure manner? What happens to the videos?

The videos are sent through secure channels to the server which processes the content using computer vision algorithms. The process is completely machine-based and the videos are never viewed by a human. The video is automatically erased from the mobile device after it is uploaded and from the server once the results have been calculated. In case of any malfunction in which you are not receiving any results of the video, the video is still deleted within 24h or before if processing can be carried out successfully.

What happens to my measurements? Is it retained and for how long?

Under GDPR, your measurements are processed according to the policy of the data controller, who is typically a healthcare provider, for the minimum period necessary for health records. They must follow national retention periods which can be up to 20 years but vary between countries.

What happens if I delete the app? How can I delete all the measurements?

In case you delete the app, your measurements are still stored according to the data controller.

Contact your healthcare provider to request the deletion under your GDPR rights.

Measurement specifications

	Condition	Validated Range	Display range	Accuracy
Respiration rate	Seated or reclining, Minimal Motion	8–25 / min	6–60 / min	±1.7 breaths per minute
Pulse rate	Seated or reclining, Minimal Motion	50–100 / min	30–240 / min	±1.13 beats per minute
Pulse analysis	Seated or reclining, Minimal Motion	As above	Tachycardic: >100bpm Bradycardic: <60bpm	±1.13 beats per minute
Pulse rate variability	Seated or reclining, Minimal Motion	30–130 ms	0– 300 ms	10– 20ms
Interbeat intervals	Seated or reclining, Minimal Motion	600–1400 ms	400–1500 ms	±35.26ms
Oxygen saturation	Seated or reclining, Minimal Motion	85–100%	85–100%	±3.77 percentage points

The stated accuracy reflects the expected range for most measurements under typical conditions, but individual readings may occasionally fall outside this range due to natural variability and real-world factors.

The **Validated range** is the range where the device has been independently tested and confirmed to give accurate and reliable results.

The **Display range** is the wider range of values that the device is technically able to show on the screen. However, values outside the validated range have not been independently proven to be reliable.

Accuracy is measured as:

- The **Root Mean Square Error (RMSE)** for respiratory rate, pulse and interbeat intervals
- The **Average Root Mean Square (ARMS)** Error for oxygen saturation
- The **Mean Error** for Pulse Rate Variability.

The **Root mean square error (RMSE)** represents the typical difference between Vitacam’s measured values and the reference values. Lower RMSE indicates higher accuracy. RMSE gives a truer measure of accuracy compared to mean error as it penalizes larger errors more and ignores whether the error is positive or negative.

ARMS is the term used for RMSE specifically in pulse oximetry.

Mean error is the average difference between the device's measured values and the true values, indicating whether the device tends to overestimate or underestimate.

These accuracy measurements have been obtained from two scientific studies to validate the accuracy of Vitacam V2's measurements compared to a nurse manual counting respiration rate, an Electrocardiogram reference for the heart rate and interbeat intervals and a clinical pulse oximeter for oxygen saturation.

TECHNICAL REQUIREMENTS, SERVICE AND SUPPORT

Technical specifications / Application

Mobile OS: Android 8.0 or newer, iOS 15.6 or newer

The smartphone must have a functional camera with a resolution of at least 1920×1080 pixels and internet connectivity enabled either over wireless network or mobile data. The minimum internet data throughput for download and upload is 2Mbps and 10Mbps for smooth experience.

Permissions to use features, such as the camera, will be asked from the client upon need and must be accepted for the app to function as intended.

Installation of the app

The official sources for Vitacam are:

- Google Play store
- Apple App store

The app is updated periodically. It is recommended to turn on automatic updates under your smartphone's **Settings**.

Tap the question mark symbol on the bottom of the screen and scroll down to see the version number of the app.

Network requirements

Vitacam V2 requires a stable connection to the internet to function. The minimum connection speed required is 0.128 megabits per second upload and 0.128 megabits per second download. For the software to run as intended, the connection to the wireless network must be secure and protected from unauthorized access.

Service and repair

Vitacam V2 is a standalone medical device software product and does not need any physical servicing. Evondos Oy will update, correct, and fix Vitacam V2 software on a regular basis. Updates are provided automatically in case the smartphone has been set to automatically receive app updates and without incurring additional costs.

Obtaining a paper copy of the Vitacam V2 instructions for use

To obtain a paper copy of these instructions for use, send an email to info@vitacam.health. A paper copy will be provided at no additional cost within seven (7) working days.

Support

For additional questions and help, please contact Vitacam V2 support:

Email: info@vitacam.health

Warranty

Evondos Oy offers warranty for Vitacam V2 software, as described in the customer's commercial contract. Warranty is effective for whole product's lifetime and includes support and maintenance of the Vitacam V2 software. The total lifetime of the product is five years.

COMPLIANCE WITH REGULATORY STANDARDS AND CLASSIFICATIONS

EN ISO 13485:2016+A11:2021: Medical devices --Quality management systems --Requirements for regulatory purposes

EN ISO 14971:2019 +A11:2021: Medical devices. Application of risk management to medical devices

EN IEC 62304:2006+A1:2015: Medical device software –software life cycle processes

EN IEC 62366-1:2015+A1:2020: Medical devices –Part 1: Application of usability engineering to medical devices

EN ISO 14155:2020: Clinical investigation of medical devices for human subjects. Good clinical practice

EN ISO 15223-1:2021+A1:2025: Symbols to be used with medical device labels, labelling and information to be supplied

EN ISO 80601-2-61:2019 - requirements for basic safety and essential performance of pulse oximeter equipment (partially applied). There is no compliance with clauses related to:

- Performance across SpO₂ of 70–100% (Vitacam V2 claims performance in 85-100%)
- Alarms
- Electromechanical devices, as Vitacam V2 is software
- Hardware, packaging and accessories, as Vitacam V2 is software.

Classification of the device

Vitacam V2 is classified as a class IIa medical device, which corresponds to a low or medium risk level. This means that Vitacam V2 is suitable for routine monitoring, but not for clients in immediate danger, such as those who require emergency care or are in intensive care.

According to MDR 2017/745, Annex VIII Rule 11, software intended to monitor vital physiological processes is classified as class IIa. These are situations where the nature of variations of those parameters could not result in immediate danger to the client.

Certificate of conformity

Evondos Oy hereby declares that Vitacam V2 is in compliance with the general safety and performance requirements of the EU Medical Device Regulation (MDR) 2017/745. The full Certificate of Conformity can be found at <https://vitacam.health>