

Vitacam

VITAL SIGNS MONITOR INSTRUCTIONS FOR USE

NE DEVICE SW

Vitacam V1



0598

Software version: 0.10.1
Version number: 1.2.0
Latest update: 12/2021

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NE Device SW OY

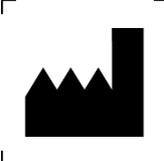
Teknologiantie 7b
90590 Oulu
Finland

<https://nedevicesw.com>
<https://vitacam.health>

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SYMBOLS

	CE marking which indicates that Vitacam fulfils 93/42/EEC-directive requirements. Includes the notified body ID number.
	Warning - Caution to be taken into consideration when using the application
	Name and address of the manufacturer
	Date of manufacturing [mm/yyyy]
	Consult instructions for use

CONTRAINDICATIONS AND PRECAUTIONS

Please read following carefully before start using the Vitacam system.



Warning

01. A dirty camera lens can impact measurement results. Ensure that the lens is clean before using the application.
02. The camera must not be closer than 1.5 metres from the patient.
03. Obstacles in the camera view or an incorrectly positioned patient can hinder or prevent measurements. Ensure that the camera view is obstacle-free, and the measuring environment is set up according to instructions.
04. Dark clothing can hinder or prevent respiratory rate measurements.
05. Insufficient lighting can hinder or prevent measurements. Ensure that the measuring environment is lit up between 360 - 1200 lux 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 face can hinder or prevent heart rate measurements.
06. Near skin tone colors in the background of the measuring environment can hinder or prevent heart rate measurements. Always measure the patient against a contrasting background.
07. Makeup that significantly alters or covers the base tone of the face can hinder or prevent heart rate measurements. This includes, but is not limited to, foundations, concealers and color correctors in a liquid, cream or powder formula.
08. Excessive movement by the patient can hinder or prevent measurements.
09. Respiratory rate lower than 8 breaths a minute may not be detected.
10. There can be difficulties in obtaining heart rate measurements from patients with Fitzpatrick skin types 5 and 6, if distance to camera is greater than 2m.
11. Vitacam reports values for approximately two-thirds of heart rate measurements compared to reference pulse oximeter



Caution

01. This device has not been tested with patient with arrhythmia, blood pressure disorders or other abnormal heart condition
02. This device has not been tested with patient with lung diseases
03. Do not use this device with a camera that does not fulfil the technical specification. Recommended camera is Logitech Brio camera.
04. Do not use as the sole basis for medical decisions. Vitacam must be used in conjunction with clinical signs and symptoms.
05. Do not use Vitacam on patient who might be in immediate danger.
06. Vitacam has been tested only on subjects with normal skin temperature.
07. Vitacam does not support measurements on patients under the age of 18. Only use the application on adult subjects.

Disclaimer

NE Device SW is responsible for Vitacam safety and performance only when the following condition applies:

- Vitacam is installed by NE Device SW personnel or other authorized personnel
- Vitacam is operated according to this document.

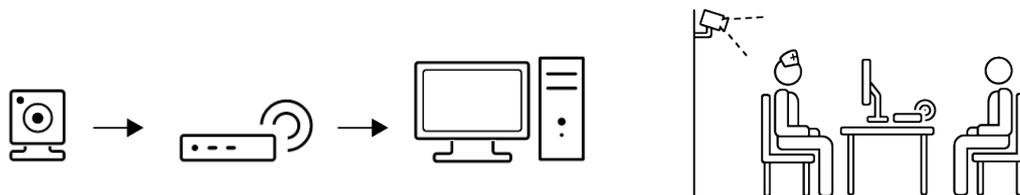
GENERAL INFORMATION

Vitacam is medical device software that measures a patient's respiratory rate (RR) and pulse [HR] by analyzing a livestream from a digital camera. The device is intended for healthcare professionals to be used in a triage scenario, to facilitate clinical decision-making. The system does not record images or video, nor does it gather any other measurement than the ones previously mentioned. The manufacturer (NE Device SW Oy) collects analytical data on the operation of the system for development purposes, but this data cannot be traced back to individual patients or their personal patient record.

How the system works

The Vitacam system is comprised of the server computer, the application and a mounted web camera. The camera is directed at the patient and connected to the server computer, which is responsible for processing the livestream and calculating a patient's vital parameters. The measurements and livestream image are then forwarded to the application installed on a computer used by the clinician.

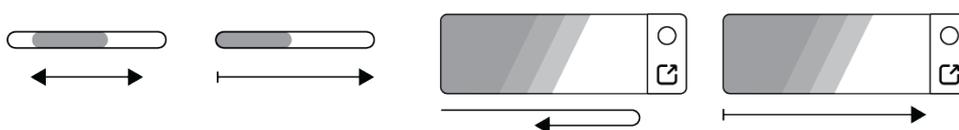
The application connects to the server computer at startup and is ready for use when the connection status light in the lower right corner of the application turns green and the adjacent connection status reads "Connected".



Once connected, the system is active and begins to automatically search for recognizable human faces in the camera view using face detection. Once a person has been found, their face and chest are mapped for landmarks. These trackable points are then used to analyze movements of the chest and tonal changes of the face to calculate respiratory rate and heart rate values. The measuring process is automatic and does not require any user-side action, if the face is detected successfully. If automatic detection of the face fails or is not possible, or more than one person are found in the live view, the application provides manual tools for selecting the correct patient.

The basics of patient measurement

When the system is ready for use, a progress bar can be seen in the bottom bar of the application window. While the program searches for a patient, this bar displays a back-and-forth animation to indicate no persons have been detected by the face detection. A similar animation can be seen if the application is minimized to its widget form.

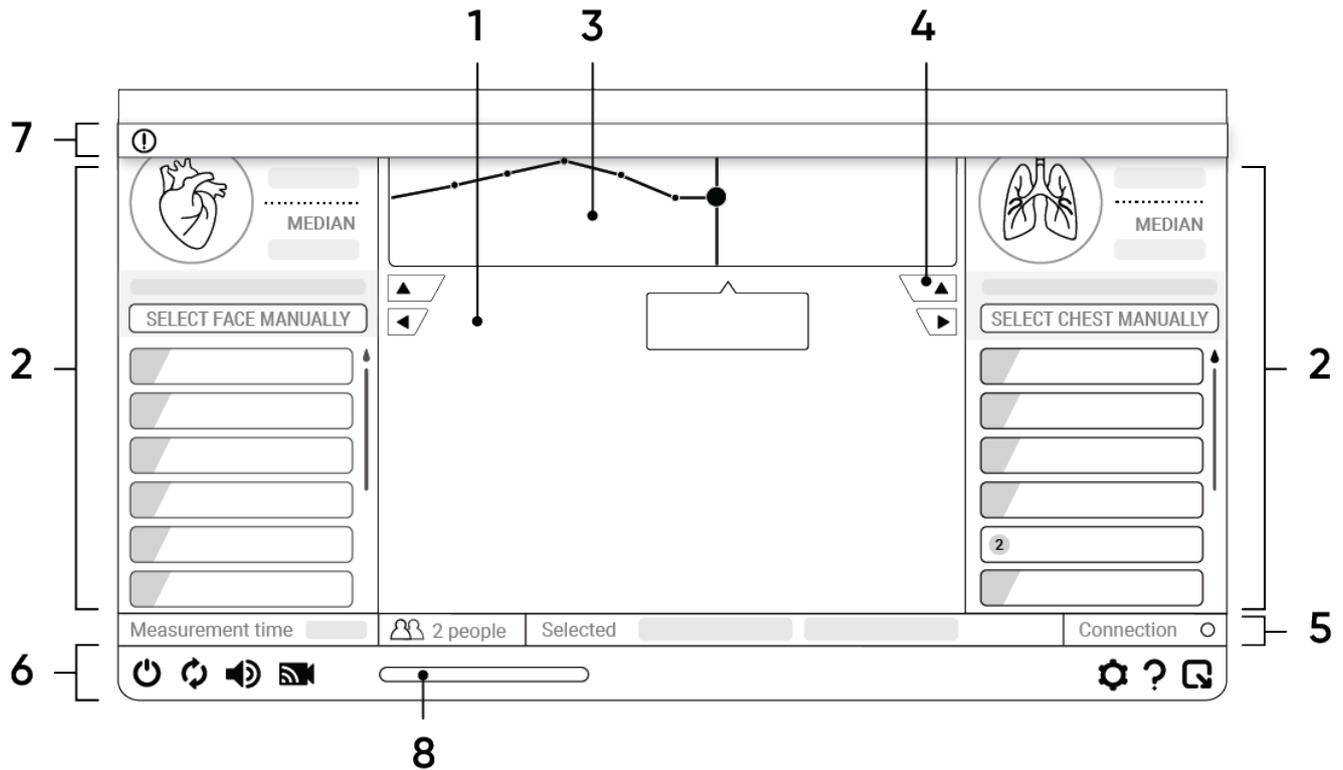


When the program finds a person, the measurement time on the information bar begins counting and the number of persons is updated. During the first calculation, the progress bar fills up to indicate the estimated time for the

calculation. The initial calculation usually takes anywhere from 15 to 30 seconds, after which results are updated on the screen every fifteen (15) seconds until the measurement process is reset or no patient is detected.

By default, measurement results are displayed in the application for two (2) minutes after the patient has been lost. After this the application clears the displayed data and begins to search for a patient again. If a face is lost momentarily and found again within fifteen 15 seconds, the system compares the discovered face with the previous to determine whether the faces are the same. If the face is determined to be the same, the measurements continue. If the patient is different, the measuring process begins anew.

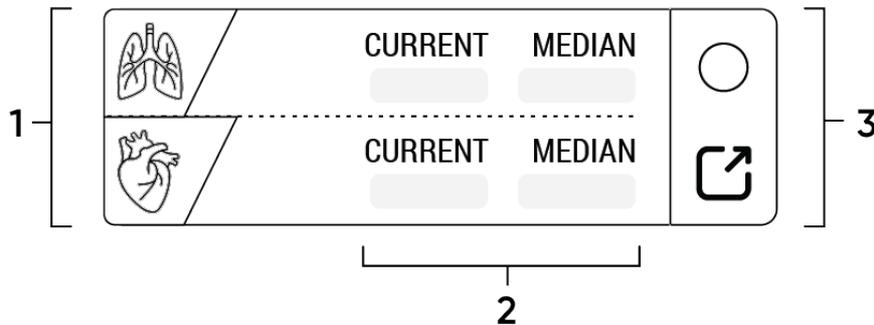
USER INTERFACE



1. Livestream	Live camera view
2. Lists	Measurement results as a vertical list of numerical values. Colour-coded in NEWS2.
3. Trends	Measurement results as a visual graph
4. Minimize list/Minimize trend	Minimizes and maximizes the trend or list the button is designated to,
5. Information panel	Information related to the ongoing measurement
6. Button panel	Buttons affecting base functionality, settings, user guide
7. Notification panel	Panel informing the user on system status and any action necessary
8. Progress bar	An UI element that appears when the application is searching for a patient or the system is calculating the first measurement. (back-and-forth movement – searching for patient, growing movement – first calculation in progress)

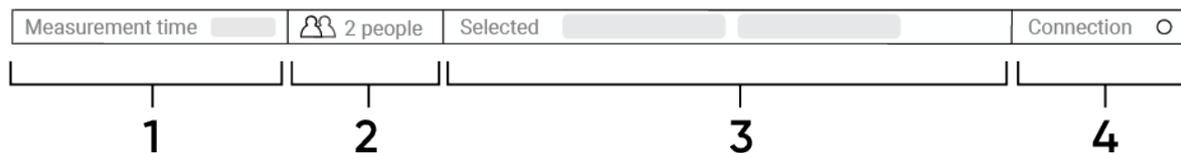
Widget

The program can be shrunk to a minimized widget format by pressing the 'minimize' button on the button panel. The widget displays the status of the application in a simplified format, displaying either the status of the progress bar or the latest measurement results. If the application requires user action in the main window, a yellow notification appears on the left side of the widget.



1. General widget status	Displays an icon of the measured vital parameter(s) or the status of the progress bar
2. Results	The most recent measurement and median result for each measured vital parameter.
3. Widget button panel	Connection status light and maximize button for returning to main view.

Information panel



1. Measurement time	Displays for how long the patient has been analyzed for. The timer begins once a face has been detected.
2. Person count	The number of persons detected in the live camera view.
3. Chosen value	A value selected from a trend or a list
4. Connection status light	Connection status to server computer. Red – No connection Yellow – Connecting Green - Connected

List and trend

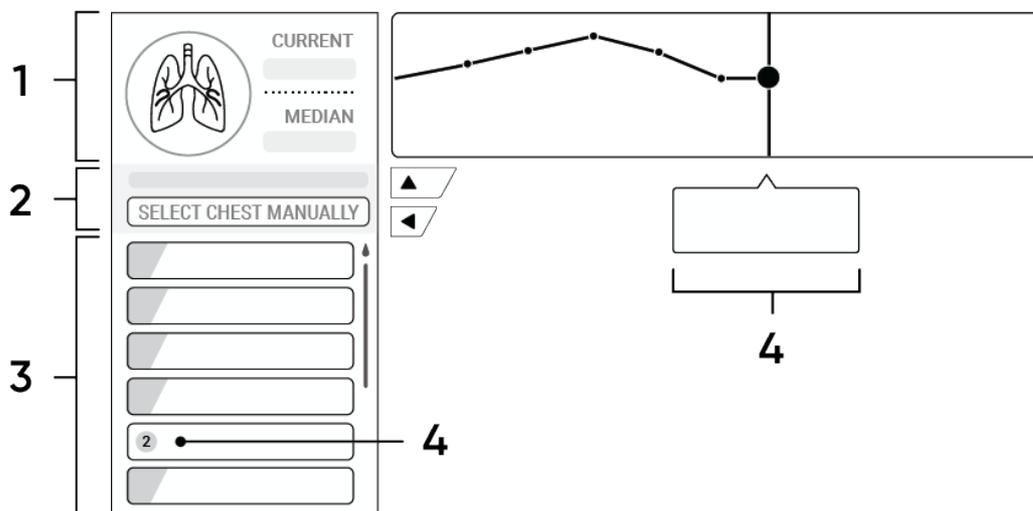
All gathered measurement results are displayed on the application main window through two user interface elements: lists and trends. Lists are situated on either side of the main window and display the measurements as a vertical timestamped list, with the newest result at the top.

Trends are situated above the live camera view between the lists and showcase the results as a visualized graph. Hovering over a measurement in the trend view reveals the exact measurement value and timestamp.

Each measurement is colour-coded according to the National Early Warning Score (NEWS2). In the list view the colour-coding can be seen in the left corner of a value and in the trend the colours are displayed on the background of the graph. A measurement result can be copied to clipboard by clicking on it either in the list or in the trend. The result can then be pasted (CTRL V) into another application, such as an electronic patient record.

In a situation where the program is unable to reliably measure the patient due to movement or other conditions, instead of a regular measurement value the list or trend displays an undefined result, void of data. Occasional undefined results are normal and require no corrective action, as they work as a visual feedback and a countermeasure against displaying inaccurate results. If the number of such results becomes very frequent, however, troubleshooting the issue may be necessary.

In addition to measurements, lists for both RR and HR display the patient detection mode currently active (automatic/manual) for each vital parameter, as well as the manual selection button to select the patient by hand. The manual selection for respiratory rate is done by drawing the rectangular indicator over the chest area, whereas the same is done for pulse by drawing the indicator over the face.



1. Key information area	Vital sign icon for the designated vital sign (changes colour according to the latest NEWS2 result), as well as the most recent result and median result.
2. Manual selection area	Current patient detection status (automatic/manual) and the manual selection button for the designated vital sign
3. Full list view	All measurements gathered so far, newest at the top
4. Undefined result	Empty value resulting from the program being unable to calculate the vital parameter reliably.

BUTTONS

The button panel contains buttons affecting many of the basic functionalities of the software. Additionally, it houses the navigation to the settings, the user guide and the troubleshooting.



Power on / Power off

Halts all functionality, clears collected measurement and analytics data associated with the most recent measurement session and disconnects the camera. A second press of the button reinitiates normal behavior.



Reset

Resets measurements and clears the application of gathered data. Patient detection mode is returned to automatic. After a reset the application can be used normally.



Sound on / Sound off

Enable or disable audio alerts. For more advanced audio settings, navigate to user settings.



Livestream on / Livestream off

Enable or disable livestream view. (measuring will still proceed as normal, however, we recommend keeping leaving setting on). For more advanced livestream settings, navigate to measurement settings.



User guide

Opens the application tutorial.



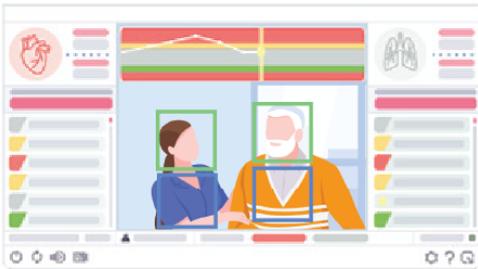
Minimize / Maximize

Switches the application to its widget mode or back to main view.

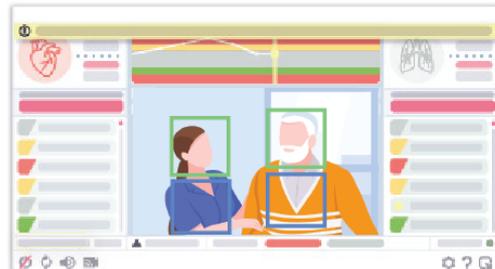
OPERATING SITUATIONS

Multiple patients in camera view

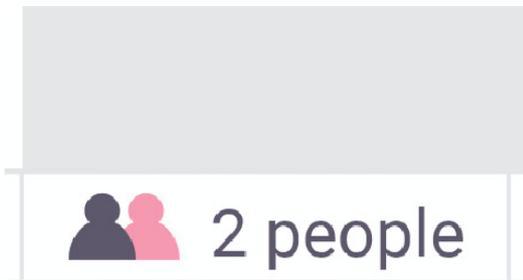
In a situation where the program finds more than one human face in the livestream, the application notifies the user via a message in the notification bar and the number of patients in the information panel is updated. In such a situation, the user must tell the software which patient to measure by selecting them in the livestream view. To select a patient, tap the rectangular indicators on the patient's face or chest in the livestream. After a successful selection, the indicators for the undesired targets will disappear and the first measurement will begin.



The system has identified two persons in the live camera view. Both have been marked with square-shaped indicators.



Notification panel appears at the top of the window and informs the user of multiple persons found.



The person count in the information panel is updated to match the number of persons detected.



User makes a selection by clicking on the indicators over the intended person.



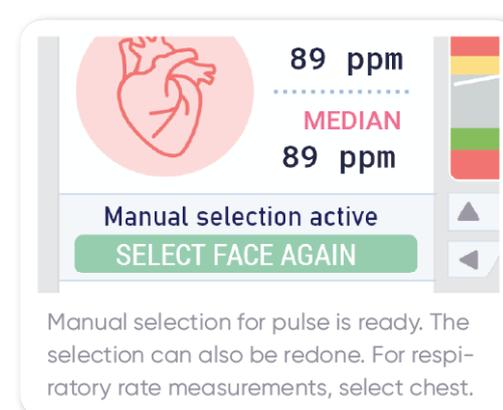
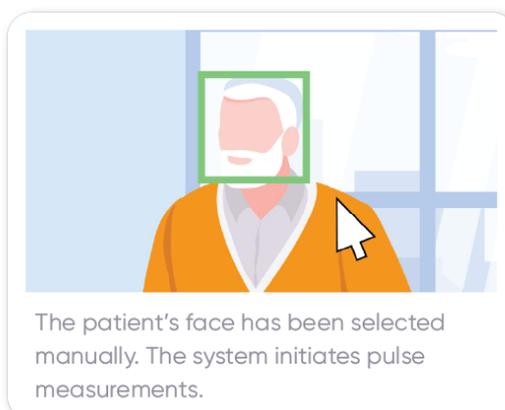
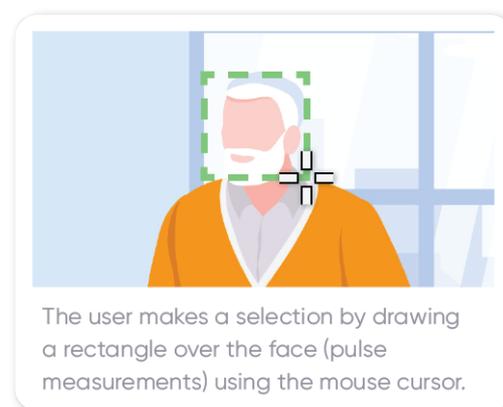
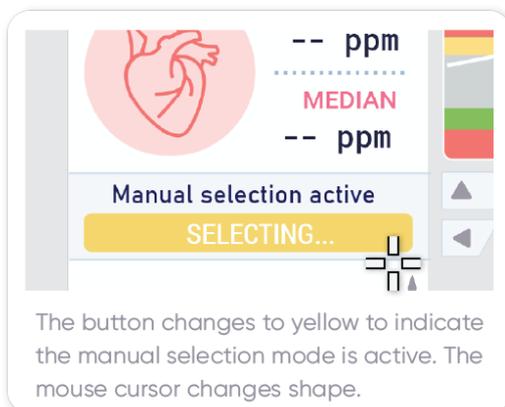
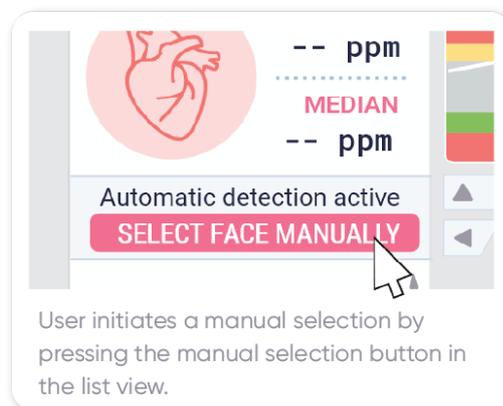
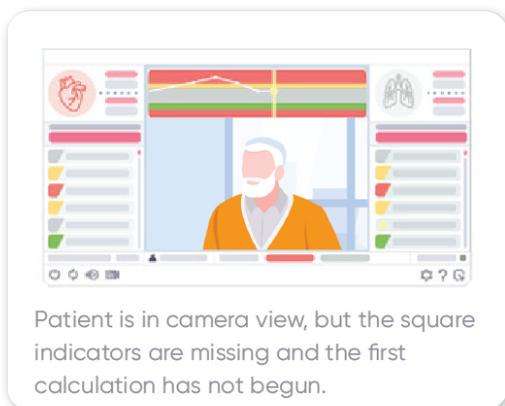
Patient has been selected successfully. Other indicators disappear.

Selecting the patient manually

If the built-in automatic detection is unable to detect the patient in the camera view, the desired target can also be selected manually by the user. Manual selection is a good tool in situations where face recognition does not work reliably, for example due to a strong beard or a face mask used by the patient.

Manual selection is initiated by pressing the manual selection button in the list view of either vital sign. Once the selection is initiated, the program guides the user in drawing a rectangle over either the face or the chest of the patient by dragging the mouse cursor over the intended area in the livestream view.

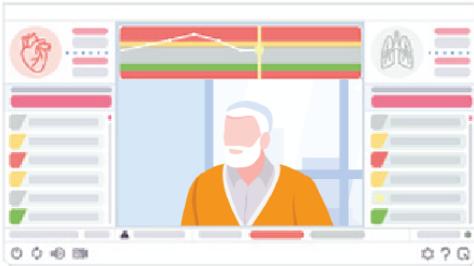
Please note that manual selection must be concluded for both vital parameters separately to gain both HR and RR measurements. Drawing a rectangle over the chest area is intended for respiratory rate measurements whereas drawing a rectangle over the face enables heart rate measurements. The two should not be mixed. Manual selection can be reinitiated by pressing the manual selection button again. After a measurement conducted using manual selection, resetting the application using the reset button is necessary (see page "buttons").



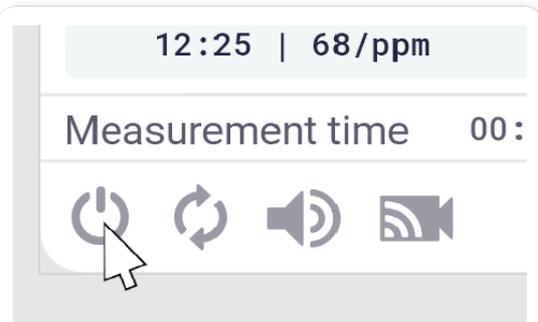
Shutting down Vitacam temporarily

In a situation where it is desired to temporarily stop the Vitacam system, the user can do so by pressing the “start / stop” button on the button panel. This functionality is particularly intended for situations, where a patient does not wish to be measured or objects to the camera. This functionality turns off the camera, disconnects the server computer from the camera and **deletes all measurement and analytics data** collected in relation to most recent session. Aside from vital upkeep, all data transfer between the different parts of the system ceases.

The system can be returned to normal mode by pressing the button again.



Patient informs the user they do not wish to be measured using the Vitacam system.



The user presses the “Power on/Power off” -button in the button panel of the main window.



The measurements are halted, all data is erased. The notification panel and a related tooltip appear to inform the user.

SETTINGS

Measurement settings

Time to clear data

For how long the application displays collected measurement results after a patient is no longer detected. After set time, the data is cleared automatically.

User settings

Update audio ranges

Select the measurement values that prompt an audio alert.

Livestream with landmarks

Hide or display the visual aids drawn over the livestream, namely the square-shaped indicators and landmarks over the chest area.

Vital signs mode

Select for which vital sign(s) the measurements are gathered for.

Application on top

Maintains the Vitacam application on top, even if another window was selected as active.

Select language

Select English, Finnish or Swedish as the application language.

Factory settings

Resets all custom settings to default. Does not affect the server computer.

About the application

Basic information about the application and its licenses.

Troubleshooting

No connection to the server computer detected - the connection status light is red

Restart the program. Close the application window and then reopen it by double-clicking the application icon. If restarting the program does not correct the problem, shut down the server computer by pressing and holding the power button for five (5) seconds. Once the device has been turned off, turn it on again.

No real-time livestream

Press the livestream button to hide the livestream. Then press the button again to reactivate the stream.

I cannot hear the application audio alerts

Make sure the application sound alerts are turned on using the audio on/off button on the button panel. Then navigate to the user settings in the settings menu and make sure that the audio ranges for alerts are set correctly.

If the problem persists, test system sounds using the “Test audio” feature in the user settings. If you do not hear sound, verify that the computer's audio devices are properly configured and turned on, and that system sounds are not muted.

The patient is not automatically detected, or the patient is found and lost multiple times

Make sure the patient is facing the camera. If the problems persist, select the patient manually.

The program has difficulty obtaining reliable measurement results

1) If the yellow landmarks on the patient's chest disappear frequently (e.g., every few seconds), improve the illumination of the measurement area. Dark clothing can also negatively affect the mapping of landmarks.

2) If the yellow landmarks do not disappear but move considerably as a result of such as hand movements, instruct the patient to sit more calmly for a while.

3) If the yellow landmarks do not disappear, but something (e.g., a bag held in the patient's lap) obscures the view of the camera, instruct the patient to lower or move the obstructing objects to the side during the measurement.

4) Make sure that the camera lens is clean. If the surface of the lens is dirty, clean it with a damp cloth.

Previous solutions did not work and there are still problems with the measurement, or the values obtained are unreliable.

While we do our best to ensure the measuring process is effortless and the measurements provided are accurate, it is possible to encounter a situation where the system is unable to provide reliable measurements. In such situations, use other methods of measuring such as pulse oximetry, ECG or a visual assessment to measure the patient.

The patient objects to the camera

The application can be temporarily shut down by pressing the Power on / Power off button in the button panel. In order to proceed with measurements, press the Power on button again.

TECHNICAL REQUIREMENTS

Technical specifications / Server

CPU support:	CPU core i7
RAM memory:	Minimum 4GB, recommended 8GB
LAN:	1x RJ-45 fast Ethernet
Operating system:	Ubuntu 20.04 LTS (Linux)
Connectivity:	1 x USB 3.0
Environmental requirements:	360 lux-1200 lux

Technical specifications / Application

CPU support:	CPU core i3/i5
RAM memory:	Minimum 4 GB, recommended 8 GB
LAN:	1x RJ-45 fast Ethernet or Wi-fi
Operating system:	Windows 10
Connectivity:	LAN access to server

Technical specifications / Camera

Resolution:	1920x1080p or higher
Framerate:	30 fps
Accuracy:	Zoom support from 1 to 5 meters.
Connectivity:	1 x USB 3.0

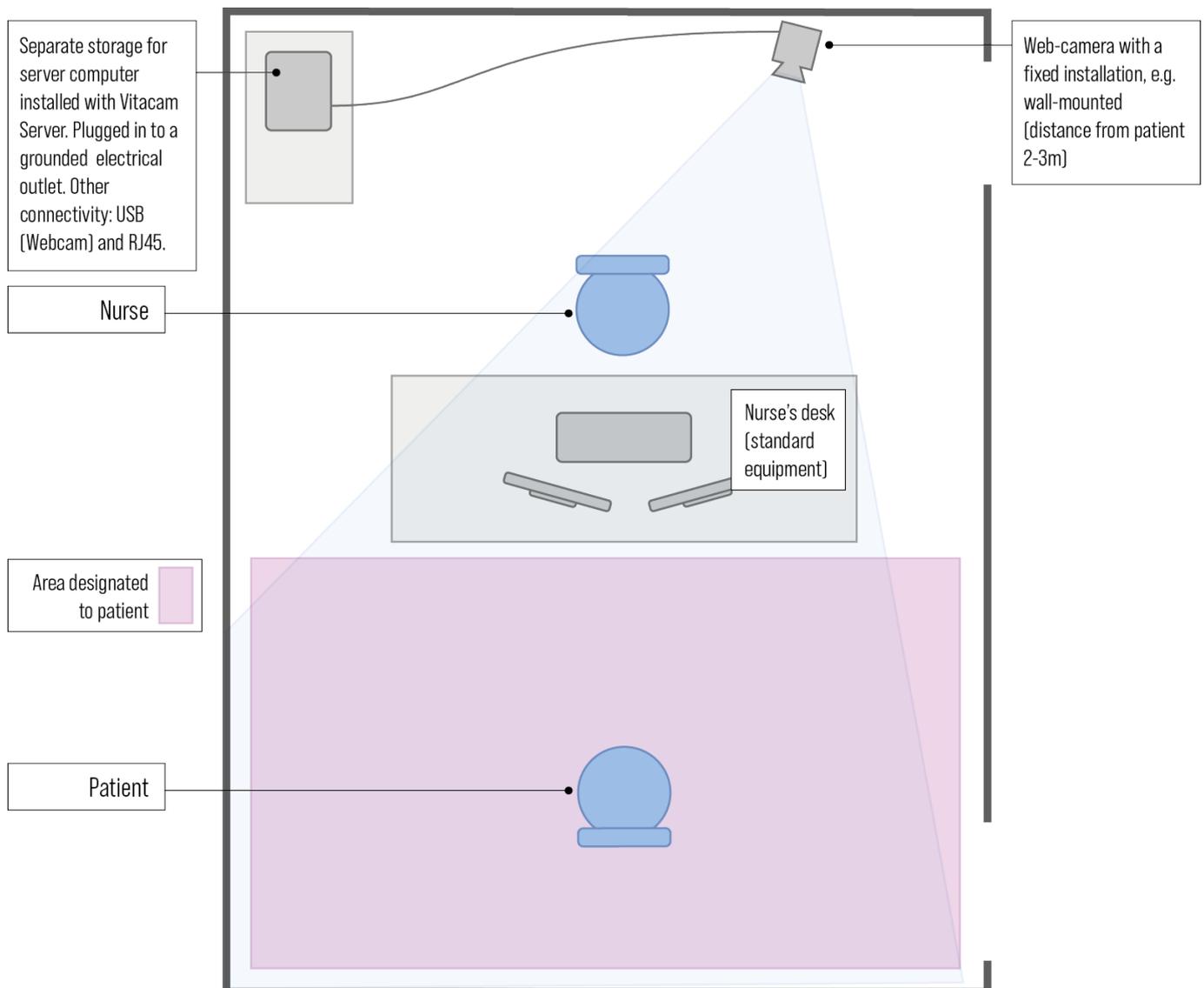
Measurement specifications

Respiration rate			
Condition	Range	Group	Accuracy
No Motion	6-60 / min	Adults, ≥ 18 yr	+3

Heart rate			
Condition	Range	Group	Accuracy
No Motion	30-240 / bpm	Adults, ≥ 18 yr	+5

Installation

Vitacam solution is installed by NE Device SW in cooperation with client facility personnel. NE Device SW staff ensures that the installation is successful, and all requirements set for proper deployment are met.



Uninstalling Vitacam application

Uninstallation should do only by authorized personnel.
There are different ways to remove apps and programs.

Uninstall from the Start menu

1. Select **Start** and look for the Vitacam
2. Press and hold (or right-click) on the Vitacam, then select **Uninstall**.

Uninstall from the Settings page

1. Select **Start**, then select **Settings > Apps > Apps & features**.
2. Select Vitacam and then select **Uninstall**.

Uninstall from the Control Panel (for programs)

1. In the search box on the taskbar, type **Control Panel** and select it from the results.
2. Select **Programs > Programs and Features**.
3. Press and hold (or right-click) on the Vitacam and select **Uninstall** or **Uninstall/Change**. Then follow the directions on the screen.

Service and repair

Vitacam is standalone medical device software product and therefore does not need regular or any another physical servicing. NE Device SW will update, correct and fix Vitacam software on a regular basis. NE Device SW personnel will be in touch with you concerning new software updates and installation.

Support

For additional questions and help, please contact Vitacam support:

Email: vitacam.support@neddevicesw.com

Phone: +358 50 486 8749

Warranty

NE Device SW offers warranty for Vitacam software, as described in the customer's commercial contract. Warranty is effective for whole product lifetime and includes support and maintenance of the Vitacam software. The total lifetime of the product is considered to be five years.

COMPLIANCE WITH REGULATORY STANDARDS AND CLASSIFICATIONS

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

SFS-EN ISO 14971:2019 Medical devices. Application of risk management to medical devices

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

IEC 62304:2015 Medical device software –software life cycle processes

Certificate of conformity

NE Device SW hereby declares that Vitacam is in compliance with the essential requirements of Directive 93/42 / EEC. The full Certificate of Conformity can be found at <https://vitacam.health>