



Instructions For Use For

Oxehealth Vital Signs

en-GB English

For use with Oxehealth Vital Signs versions:

1.61 to 2.4

Vital Signs Basic UDI-DI: 506075145VITALSIGNSFF

Alternative electronic instructions for use are available at the website below, or you can request further paper copies from Oxehealth using the contact information at the end of these instructions.












Website: www.oxehealth.academy/instructions-for-use



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Symbols Used In This Manual And On Product Labels

	Read the Instructions for Use		Caution
	Medical Device, according to the definition within Regulation (EU) 2017/745 on Medical Devices (as amended)		Unique Device Identifier
	Lot or batch number (in the case of Vital Signs, the software version number)		Date of manufacture
	Manufacturer		CE Marking, made in conformance with EC Directive 93/42/EEC for medical devices
	UKCA Marking, made in conformance with the UK Medical Devices Regulations 2002 (as amended)		

Instructions For Use For Oxehealth Vital Signs



Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in inaccurate readings of pulse rate or breathing rate.

These instructions for use are for the Oxehealth Vital Signs software medical device, which is a product module within the Oxehealth Oxevision platform. For instructions on how to use other product modules within the Oxehealth Oxevision platform, refer to other instructions for use for those features.

Before using Oxehealth Vital Signs, you must first be trained in its use. Oxehealth Vital Signs training will be made available from your organisation, or by Oxehealth.



IMPORTANT - please read carefully

If any serious adverse incident occurs when using the Oxehealth Vital Signs medical device, where a subject or user is or could have been seriously harmed, it is vital that you inform Oxehealth using the contact details at the end of these instructions.

Intended Use

The Oxehealth Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care, domestic and secured environments with professional healthcare oversight and where a framework exists which mandates periodic checks by a trained professional to ensure subject safety.

The Oxehealth system is intended for use by appropriately trained staff with a duty of care, and should not be used by untrained users.

The Oxehealth Vital Signs device is indicated for use on humans 12 years of age or older with all skin types, who do not require critical care.

The device is not intended to be the sole method of checking the physical health of a subject.



Warnings

The Oxehealth Vital Signs device must not be used with any subject receiving critical care.

The Oxehealth Vital Signs device must not be used in bed spaces that contain or may contain:

- Domestic animals
- A shower or significantly sized water feature

Oxehealth Vital Signs must not be used as the sole basis for making any decisions or recommendations relating to clinical diagnosis, subject care or treatment. Decisions or recommendations must be made by a clinician based on broader evidence than Oxehealth Vital Signs alone provides.

It is possible that the introduction of the Oxehealth Vital Signs device could affect the behaviour of individuals in your care. It involves the introduction of the Oxevision system including cameras and illuminators which could result in false perceptions of the capabilities, limitations and intended use of the software. It is essential that you engage with the individuals under your care and other interested parties to ensure that they fully understand the capabilities, limitations and the intended use of the software, using the training materials and subject information provided by Oxehealth. Failure to fully inform individuals could result in them becoming distressed or coming to serious harm.



Cautions

If the Oxehealth Vital Signs device fails to respond as described, discontinue use until the situation has been corrected. Contact Oxehealth for support through either the user interface, or the telephone number or address given at the end of this manual.

The Oxehealth Vital Signs device is designed to measure pulse rate and breathing rate in the ranges specified, and will not give measurements outside these ranges.

Oxehealth Vital Signs may not give measurements of pulse rate in the following circumstances:

- In subjects with low perfusion, anaemia, poor circulation or blood volume deficiency
- Where insufficient skin is visible to the camera
- Where visible skin is significantly scarred or tattooed
- Where visible skin has excessive make-up, sunscreen or other topical applications that hide the underlying skin applied

Oxehealth Vital Signs may not give measurements of pulse rate or breathing rate in the following circumstances:

- Where insufficient body area is visible to the camera
- If the area the camera sees of the subject is heavily saturated due to exceptionally bright illumination

Oxehealth Vital Signs may not give measurements of pulse rate or breathing rate, or may give inaccurate measurements of pulse rate or breathing rate in the following circumstances:

- In subjects with tremor, alcohol withdrawal or motion disorders
- When subjects are talking or are controlling their breathing
- Large airflows through the room
- Other sources of movement in the image
- If another living being is present in the image (including hidden from view, for example by sheets)
- Running, dripping or spraying liquids in the image
- Moving patches of light or shadow in the image
- In the presence of sources of flashing or variable light, including other Near Infrared illumination, for instance from an existing CCTV installation
- Sources of mechanical vibration, for example massage devices, in the image
- Vibration of the Oxehealth hardware, caused for example by drilling into a nearby structure at the time of the measurement.

The availability of pulse rate or breathing rate is thus affected by the circumstances of the measurement. If it is not possible to take a Vital Signs measurement using **Take Vital Signs**, wait until the circumstances have changed then attempt another measurement using **Take Vital Signs**, or use another method for obtaining a measurement.

Oxehealth Vital Signs is not intended to give pulse rate or breathing rate measurements if a subject is moving and measurements may not be available or may be inaccurate if this is the case. Vital signs

displayed by the **Vital Signs Trends** function may be affected in this way. When using the **Take Vital Signs** function, ensure that the subject is still before proceeding to obtain pulse rate and breathing rate measurements.

Oxehealth Vital Signs measures pulse rate and breathing rate from the skin and the body of a subject and measurements may not be available or may be inaccurate if suitable areas of the subject are not available. Vital signs displayed by the **Vital Signs Trends** function may be affected in this way. When using the **Take Vital Signs** function, ensure that Oxehealth Vital Signs is reading from suitable areas of the body of the subject you intend before proceeding to take measurements.

The **Vital Signs Trends** chart displays data gathered from a specified room so may show data for a subject who is not the subject currently occupying that room.

The **Vital Signs Trends** chart shows a summary of average vital signs to assist trend identification and cannot be used to measure or monitor pulse rate or breathing rate. To take a new measurement of pulse rate or breathing rate, use the **Take Vital Signs** function, or use other means to establish vital signs.

Please be aware that the Take Vital Signs functions such that:

- The system provides an estimated breathing rate (chest wall movements), rather than end tidal CO₂. It is not a replacement for end tidal CO₂ measurements.
- The system is not intended to detect the presence or absence of arrhythmias or to report measurements during an irregular arrhythmia.
- The system is not intended to be used as a continuous vital signs monitor.
- The system is not intended to be used as an apnea monitor.
- The accuracy of Oxehealth Vital Signs outputs has not been studied in patients with neuromuscular disorders.

The Oxehealth Vital Signs device analyses video captured from a video camera within a room illuminated by a Near Infrared Illuminator to measure pulse rate and breathing rate from the subject, and so obstruction of either of these parts of the device will severely compromise its operation. It is also possible that individuals will attack or attempt to damage the housing containing the camera and illuminator, and this can also result in compromising the operation of the system and the software. Ensure that the housing containing the camera and illuminator is kept free from obstruction according to the maintenance directions in the Vital Signs Instructions for Use, and inform Oxehealth of any attack on or interference with the housing.

Oxehealth software and related hardware installed inside or outside the room environment is not to be installed or maintained by anyone other than an Oxehealth trained representative. Any attempt by a non-Oxehealth representative to interfere with the hardware, operating system administration or software configuration outside that described in this manual may result in damage to the device performance.

If you make significant physical changes to a room, for instance visible structural changes or adding large items of furniture, this may affect the device performance and you should inform Oxehealth.

Specification

	Accuracy	Measurement Window
Pulse rate measurement*	50 to 130 \pm 3 beats per minute	9 seconds
Breathing rate measurement*	8 to 39 \pm 2 breaths per minute	30 seconds

* Reported accuracy uses the root-mean-square error (RMSE) criterion

Installation

Installation will be carried out by an Oxehealth approved installer, according to installation instructions and verification procedures provided by Oxehealth.

Maintenance

The Oxehealth Vital Signs device analyses video from an infrared illuminated room that has been captured by a video camera to measure the pulse rate and breathing rate of a subject. Hardware is installed within a housing and so the cleanliness of the housing must be maintained. When cleaning the housing unit and/or touch screen devices, do not use solvent based, ammonia, caustic or abrasive cleaners or abrasive cleaning materials on the clear front of the housing unit or on touch screen device displays, as this may scratch or fog the material, and potentially degrade the ability of the device or the user's ability to see the subject clearly and may reduce the reliability and accuracy of the readings.

If components within the sealed housing are directly exposed to liquids, vapours or dust then they may be damaged and cease to operate correctly. If this happens, stop using the Oxehealth Vital Signs software and inform Oxehealth.

In the event of failure of any part of the Oxehealth product, inform Oxehealth.

Only Oxehealth or Oxehealth trained maintenance personnel may make modifications to this device as these may affect device performance. If you are in doubt whether changes could affect the device, you should contact Oxehealth who can advise.

**IMPORTANT SAFETY AND SECURITY NOTICE - please read carefully**

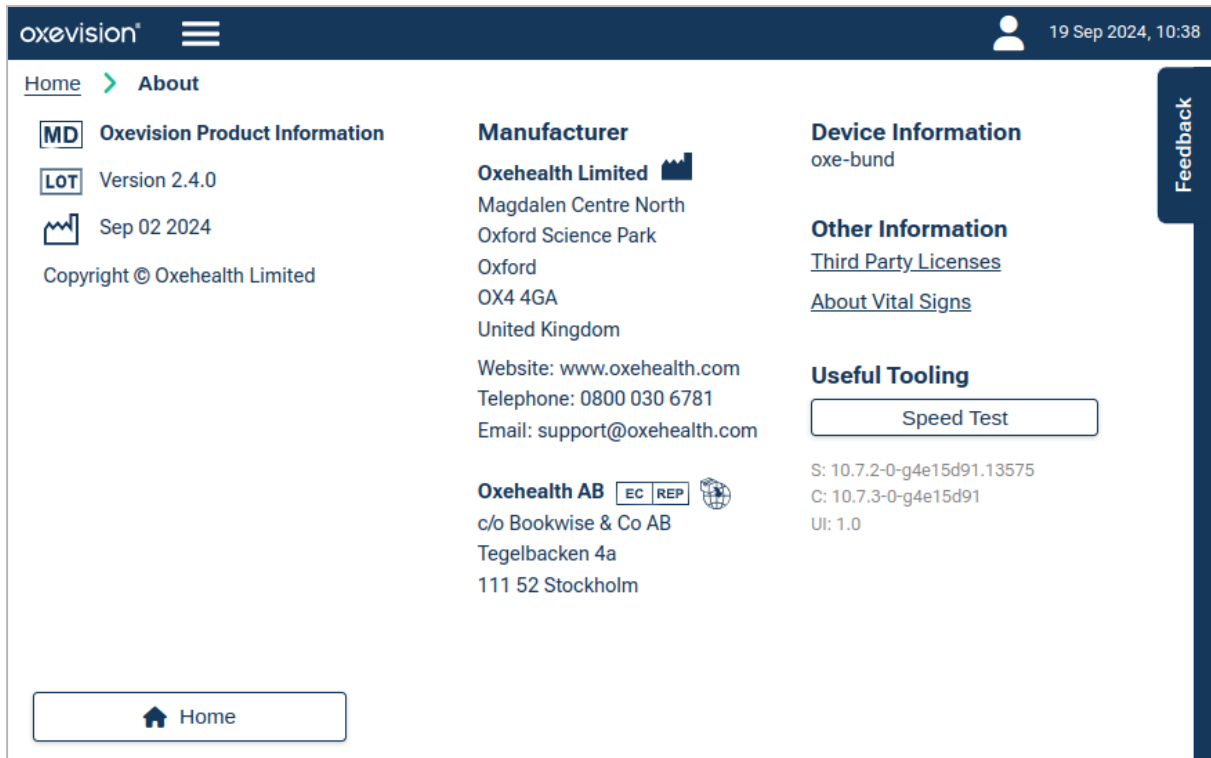
Maintaining the privacy of subjects, and protecting the confidentiality of their data is of the utmost importance. Ensure that you observe all of your organisation's safety, privacy and security policies and guidelines, and do not relocate any equipment that has been installed for the Oxehealth software, or change any security or access arrangements to the equipment without first informing Oxehealth.

If you are using any mobile devices to access your Oxehealth software, pay particular attention to ensuring these devices are used only by authorised and trained staff, using the devices as intended.

The Vital Signs software is not intended to be used as a surveillance tool, and you must use the functions to view the video feed in accordance with your organisation's privacy and security policies. Failure to do so puts you and your organisation at risk of violating individuals' rights, and data protection laws.

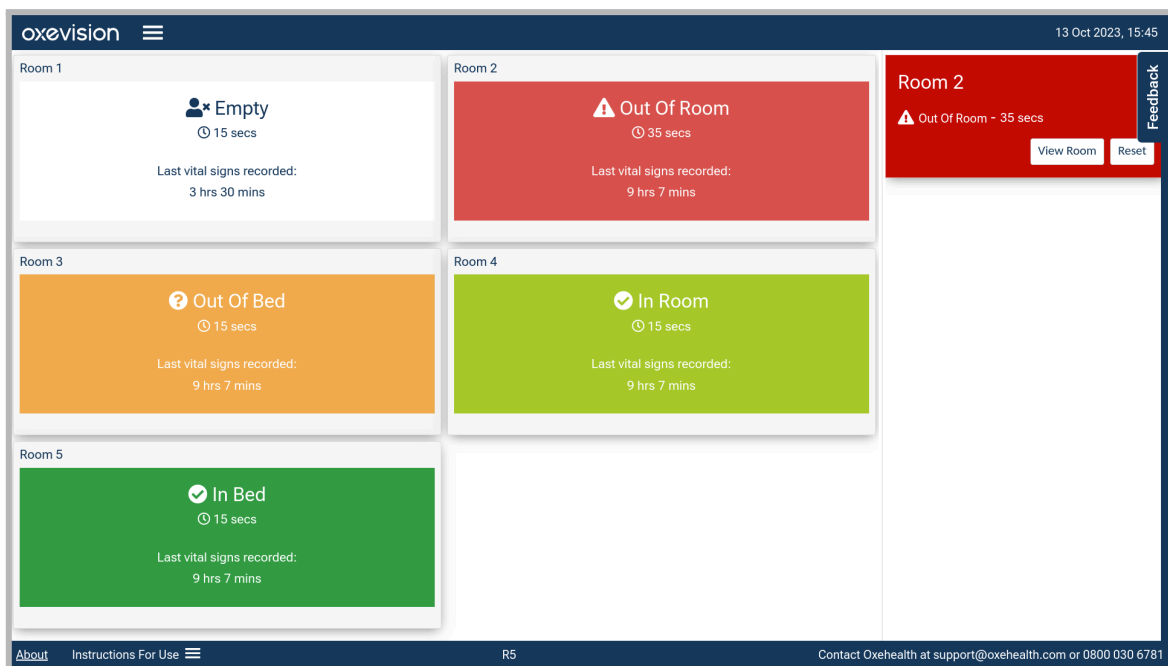
How To Use Oxehealth Vital Signs - UI Version 1.0

If your graphical user interface "About" screen displays "UI: 1.0", as illustrated below. Then please refer to this section, "How To Use Oxehealth Vital Signs - UI Version 1.0" on pages 8 to 41. Otherwise, refer to section, "How To Use Oxehealth Vital Signs - UI Version 2.0" on pages 42 to 74.

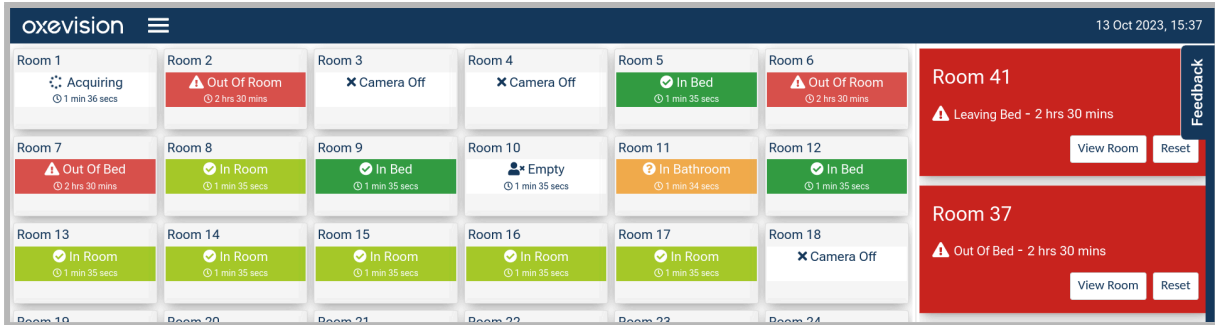
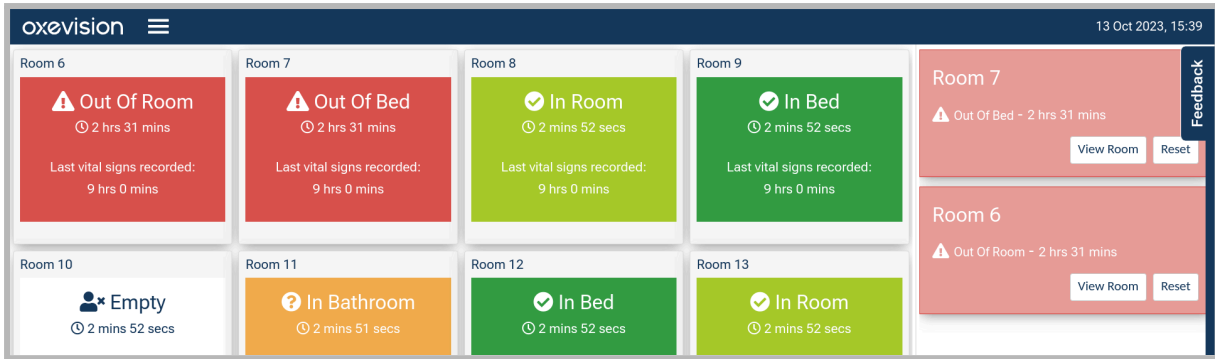


The Overview Screen

The **Overview Screen** shows all of the rooms connected to the Oxehealth Vital Signs software:



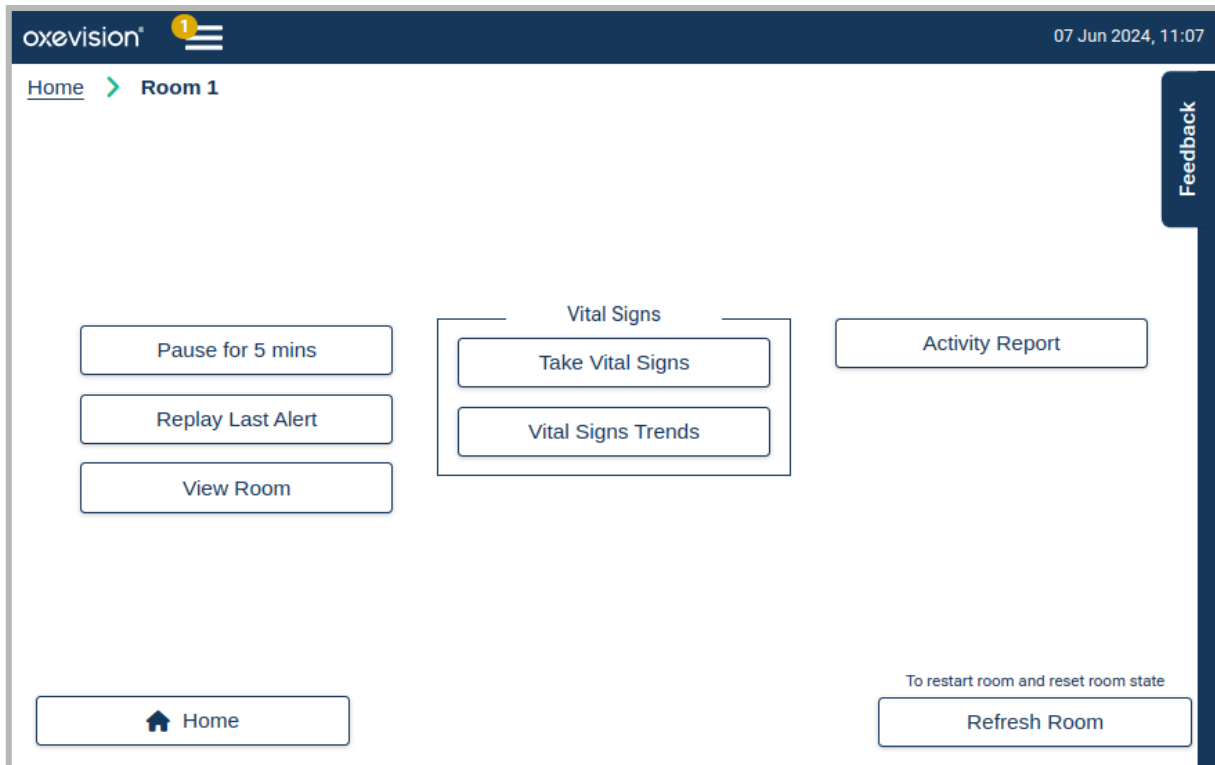
Depending on the number of rooms configured, the **Overview Screen** will show smaller panels for each room as shown below to keep all of the rooms visible and reduce the need for scrolling:



IMPORTANT - please read carefully

Depending on the number of rooms and layout chosen, you may need to scroll down to see all of the room tiles.

Each room is shown as a clickable panel on the Overview Screen, by clicking a room, this brings up the room **Action Menu** for that room:

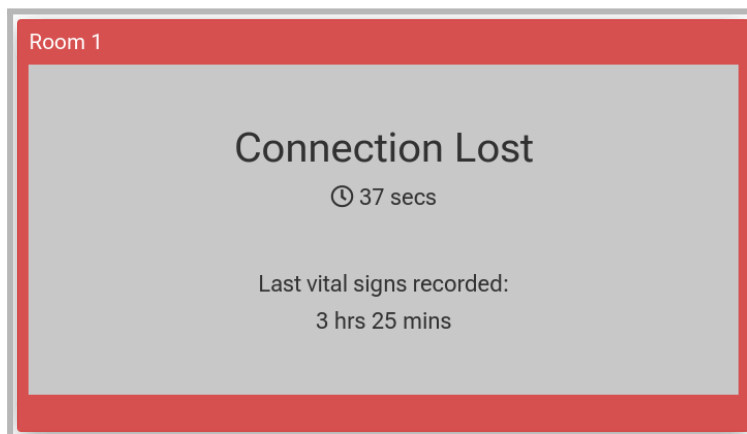


Note that the room **Action Menu** may include **Vital Signs Trends** depending on your software configuration. See the sections on [Viewing Vital Signs Trends](#) on how to use these functions.

The room **Action Menu** may include other menu items for other product modules (refer to other Oxehealth Oxevision product module instructions for use for information).

On the **Overview Screen**, the large icons indicate the status of the room as follows:

- **Connection Lost:** the Oxehealth Vital Signs software is not connected to the room.

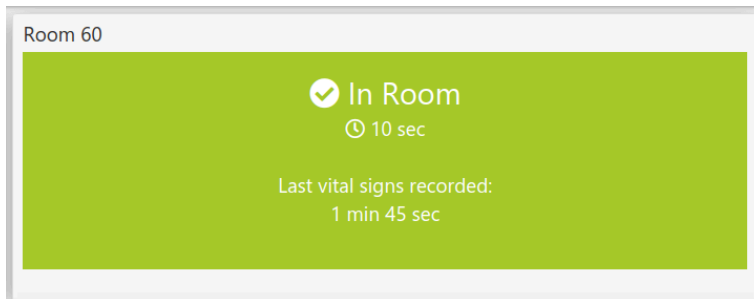


The main text in the room icon will display the nature of any software disconnection, and the time that the connection has been down.

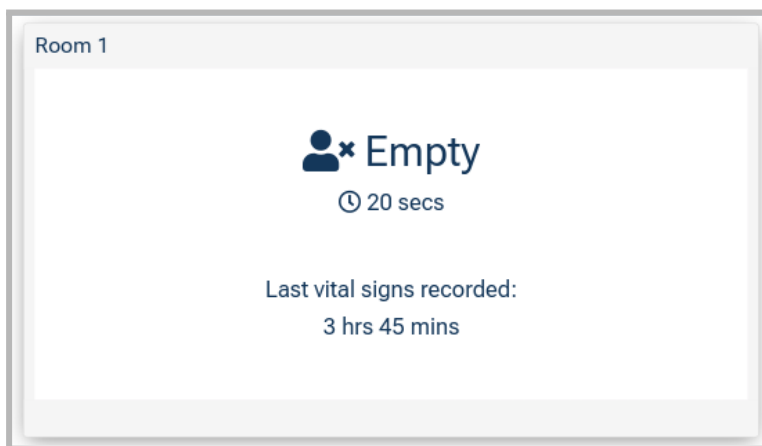
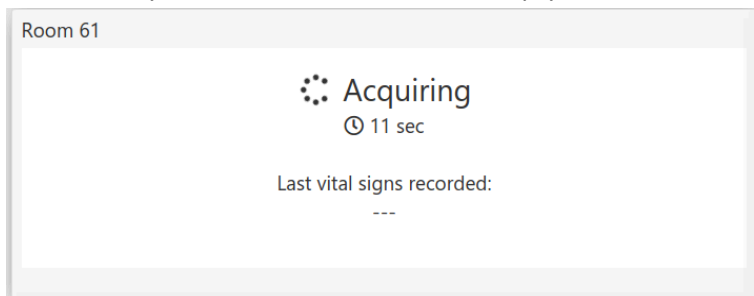
The **Last vital signs recorded** text on the room icon indicates how long it has been since anyone last used the **Take Vital Signs** function successfully for this room.

In this state, it will be possible to use the **Vital Signs Trends** functions on the **Action Menu**. In this state, it will not be possible to use the **Take Vital Signs** or **Pause** functions on the **Action Menu**.

- **Connected:** the Oxehealth Vital Signs software is connected to the room and running, such that the software is receiving video and making estimations.



The main text in the room icon will display non-medical information from other modules about what is happening in the room, and the time that the room has been in this state. Other modules may also modify the colour of the room icon while they are processing data, or when they determine the room to be empty.



Refer to other product module instructions for use for further information.

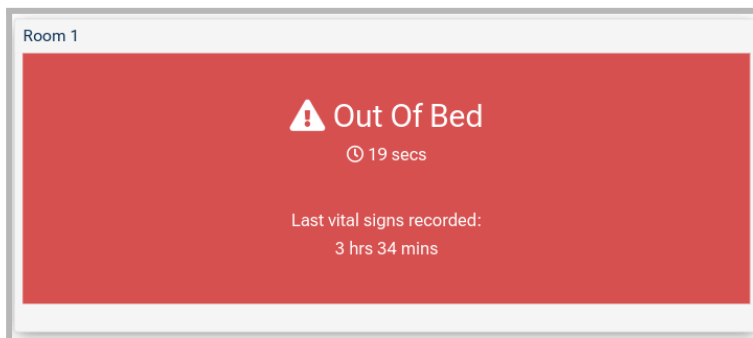
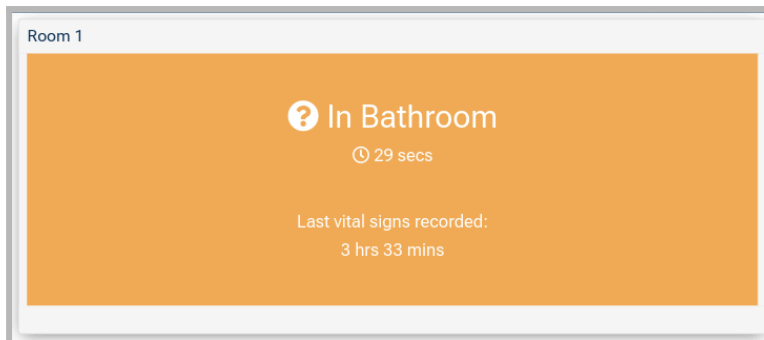
IMPORTANT - please read carefully

When other Oxehealth product modules are running and showing different non-medical information about what is happening in the room, the Oxehealth Vital Signs is still operational, and it is still possible to take vital signs.

The **Last vital signs recorded** text on the room icon indicates how long it has been since anyone last used the **Take Vital Signs** function successfully for this room.

In this state, it will be possible to use the **Take Vital Signs**, **Pause** and **Vital Signs Trends** functions on the **Action Menu**.

- **Alert State:** the Oxehealth Vital Signs software is connected to the room and running, such that the software is receiving video and making estimations. In this state, other product modules are producing a non-medical alert to prompt further checks in the room. These prompts may be informational (orange), or alerts (red) as the examples below show, and will be pre-configured to a scheme specific to your installation.



The main text in the room icon will display the nature of the non-medical alert, and the time that the room has been in this state. Refer to other product module instructions for use for information on these alerts.

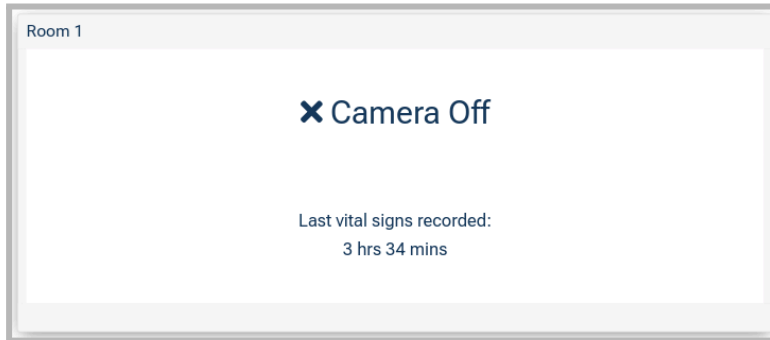
IMPORTANT - please read carefully

When other Oxehealth product modules are producing an alert, Oxehealth Vital Signs is still operational, and it is still possible to take vital signs.

The **Last vital signs recorded** text on the room icon will continuously update, and indicates how long it has been since anyone last used the **Take Vital Signs** function successfully for this room.

In this state, it will be possible to use the **Take Vital Signs**, **Pause** and **Vital Signs Trends** functions on the **Action Menu**.

- **Camera Off:** the Oxehealth Vital Signs software is connected to the room, but a user has chosen to stop measuring, such that the Oxehealth Vital Signs software has ceased receiving video and making estimations for this room.

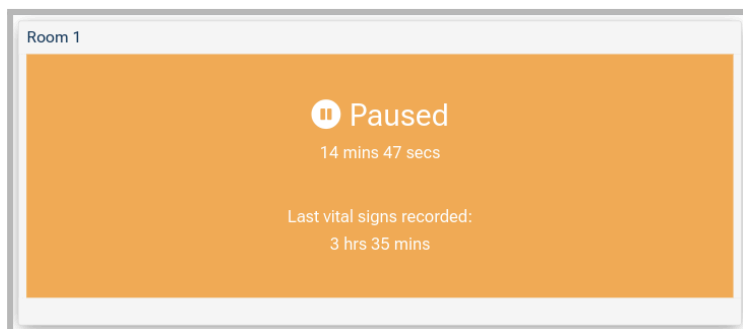


The timer indicates the time that the software has been stopped for the room.

The **Last vital signs recorded** text on the room icon will continuously update, and indicates how long it has been since anyone last used the **Take Vital Signs** function successfully for this room.

In this state, it will be possible to use the **Vital Signs Trends** functions on the **Action Menu**. In this state, it will not be possible to use **Pause** or **Take Vital Signs** function on the **Action Menu**.

- **Paused:** the Oxehealth Vital Signs software is connected to the room, but a user has chosen to pause measuring, such that the Oxehealth Vital Signs software has ceased capturing video and making estimations temporarily for this room.



The time for the room will continuously update, and is a countdown timer, indicating how long is left before Oxehealth Vital Signs automatically restarts capturing video and processing.

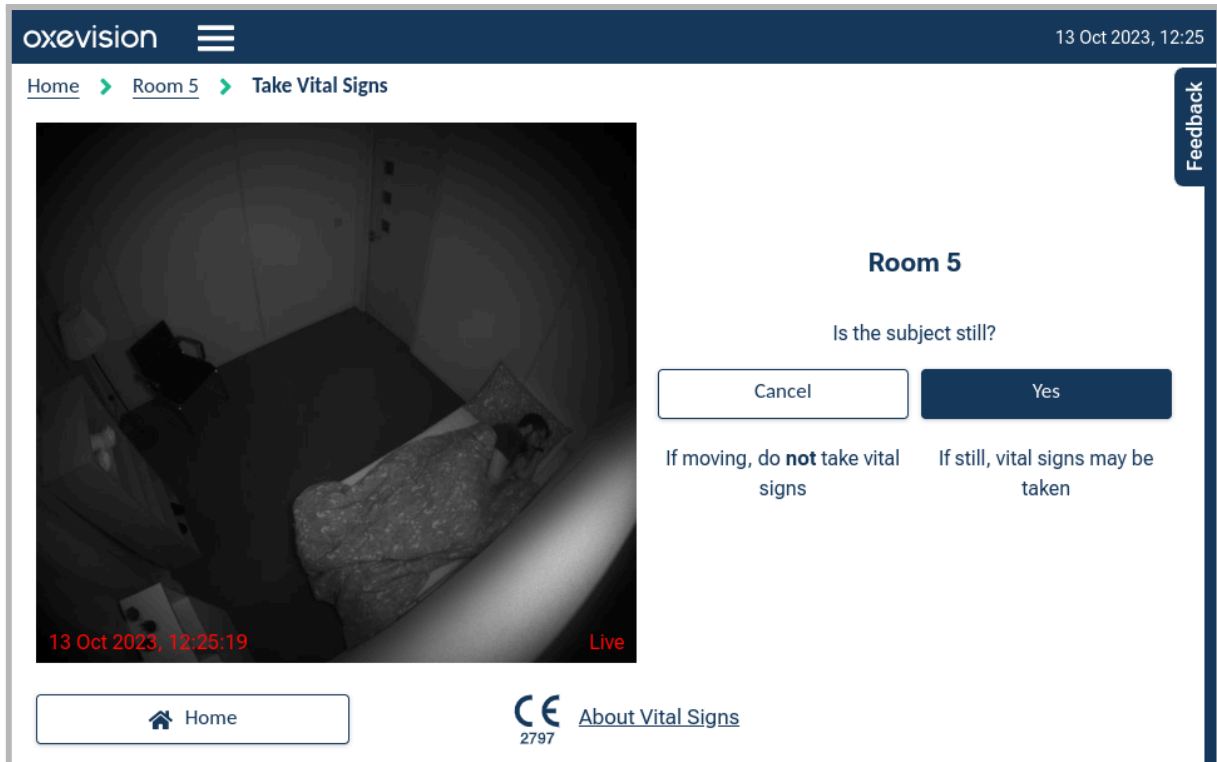
The **Last vital signs recorded** text on the room icon will continuously update, and indicates how long it has been since anyone last used the **Take Vital Signs** function successfully for this room.

In this state, it will be possible to use the **Extend Pause**, **Cancel Pause** and **Vital Signs Trends** functions on the **Action Menu**.


In this state, it will not be possible to use the **Take Vital Signs** function on the **Action Menu**.

Taking Vital Signs Observations

To take vital signs observations from a subject, click the room icon for the room the subject is in, then select **Take Vital Signs** from the **Action Menu**. You will then see the first **Take Vital Signs** screen below:



This screen will show live video of the room, and ask you if the subject is still. If the Oxehealth Vital Signs device software is not able to make any vital signs estimations at the current time, the **Yes** button will indicate **Acquiring Vitals**, and you will not be able to proceed:

Acquiring Vitals... 

If the subject is not still, the **Acquiring Vitals** button is shown, or if you do not wish to proceed for any reason, click **Cancel**, and you will return to the **Overview screen**.

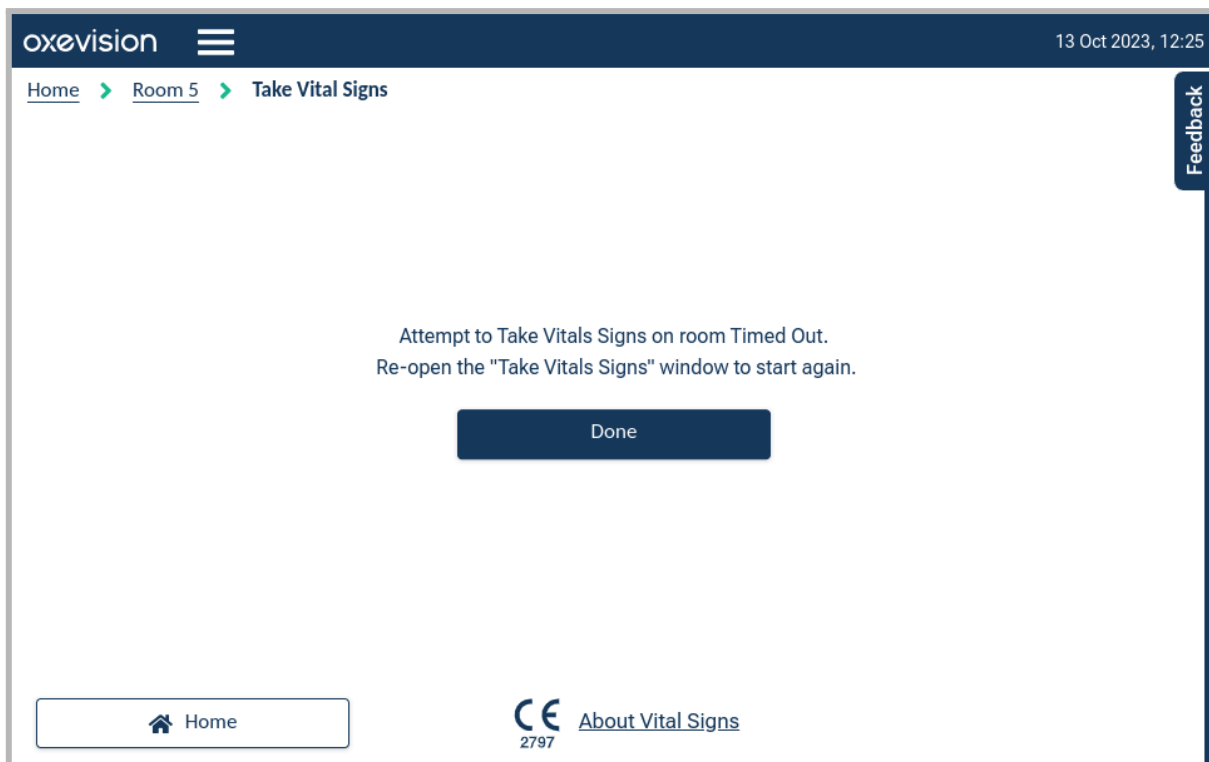
IMPORTANT - please read carefully

Oxehealth Vital Signs will not give pulse rate or breathing rate measurements if a subject is within a field of view where a privacy mask has been applied to cover an area such as a bathroom.

IMPORTANT SECURITY NOTICE - please read carefully

When taking Vital Signs observations, be careful to maintain the privacy of your subject by ensuring that your screen is not visible to any members of the public.

If you are unable to proceed for more than 15 seconds, the **Take Vital Signs screen** will automatically close and you will see the following display:



Click **Done**, and you will return to the **Overview screen**.

IMPORTANT - please read carefully

If the **Yes** button is available, you may proceed if the subject is still. If you are not sure the subject is still, do not proceed.

Guidelines for considering the subject to be still:

- Asleep in a bed, on the floor or in a chair
- Lying in bed awake, but not moving
- Sitting up in bed, a chair or on the floor awake, but not moving

Do not proceed if the subject is carrying out small repetitive movements, for example:

- Rocking while sitting or lying
- Having a seizure
- Visibly shivering
- Displaying tremors
- Standing or sitting still, but manually brushing teeth or washing
- Brushing hair
- Fidgeting
- Tapping their foot or hand


**CAUTION**

If you can see the subject, but insufficient skin is visible (e.g. they are partially covered by bed sheets), then you may proceed with caution. If a subject has covered most of their skin, then it may not be possible to take a pulse rate observation, but a breathing rate observation may still be possible.

If you judge the subject to be still according to these guidelines, and you want to proceed, click **Yes** and you will see the second **Take Vital Signs screen** below:

oxevision
13 Oct 2023, 12:25

Home >
Room 5 >
Take Vital Signs



13 Oct 2023, 12:25:19 Paused

Room 5

Are there blobs which do not touch the body?

If any blobs not on body, do **not** take vital signs

If all blobs on body, vital signs may be taken

Home

About Vital Signs

Feedback

The video of the room will now pause, and you will see the regions in the image from which the Oxehealth Vital Signs software is estimating breathing and pulse rate as coloured blobs, together with the question “**Are there any blobs which do not touch the body?**”

IMPORTANT - please read carefully

The blobs in the image represent the locations from which the software is estimating pulse rate and breathing rate, and it is important that you ensure that the software is extracting these from the body of the subject. You will see up to two circular blobs, but these may be touching or overlaid, so be sure that you have accounted for this before proceeding to answer **No** to the question.

Examples of blobs that are and are not touching the body are shown below:

Only one blob visible, not touching the body



Select "Yes"

Two blobs visible, both touching the body



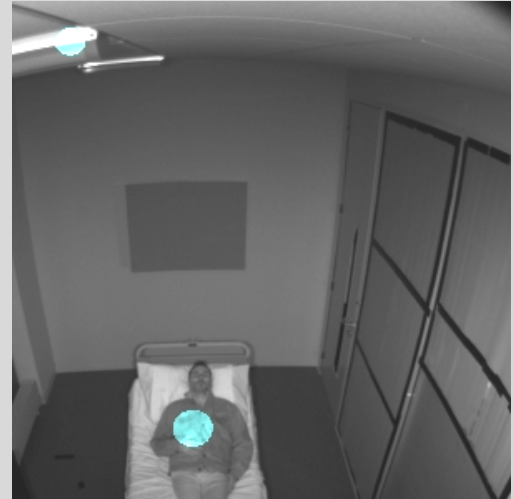
Select "No"

Only one blob visible and touching the body



Select "No"

Two blobs visible, one not touching the body



Select "Yes"

In the last of these examples (bottom right), note that one of the blobs is on the light fitting on the ceiling.

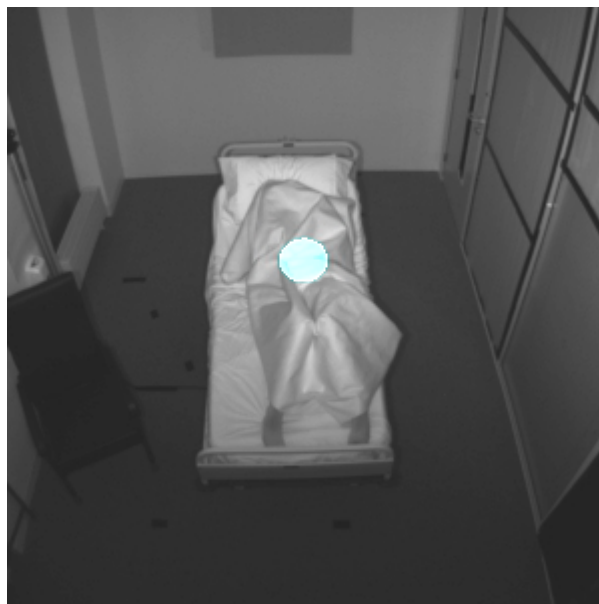


CAUTION

You must consider other means of obtaining vital signs observations if you have any cause for concern over the readings obtained by Oxehealth Vital Signs.

If you can see the subject, but they are covered, for example by bed sheets, then you may proceed with caution if you consider all of the visible blobs to be on the body of the subject.

An example of a subject being covered, but whose body can clearly be made out, with a blob touching is shown below:



If a subject has covered all of their skin, then it may not be possible to make a pulse rate observation, but a breathing rate observation may still be possible.

Remember, Oxehealth Vital Signs may not give reliable or accurate measurements from the subject if another living being or moving object is in the image, even if hidden, for example by sheets. Never proceed if the blobs touch another living being or moving object.

If there are any blobs which do not touch the body, or you do not wish to proceed for any other reason, click **Yes**, and you will return to the **Overview** screen.

Otherwise, click **No** and you will see the final **Take Vital Signs** screen below:

The screenshot shows the 'Take Vital Signs' interface for Room 5. The video feed is paused at 13 Oct 2023, 12:25:48. The vital signs displayed are Pulse Rate 89 bpm and Breathing Rate 22 br/min. A 'Please wait...' message is shown, indicating that vital signs are being submitted to the system. A 'Done' button is visible below the message. The bottom of the screen features a 'Home' button and a CE 2797 certification logo with a link to 'About Vital Signs'.

The video of the room will remain paused, and you will see the Oxehealth Vital Signs breathing and pulse rate. The Oxehealth Vital Signs device software indicates the vital signs as follows:

Pulse Rate indicates the pulse rate of the subject in beats per minute (bpm). (These may not be present if the Oxehealth Vital Signs software was not able to measure a pulse rate at the time that the video recording was paused.)

Breathing Rate indicates the breathing rate of the subject in breaths per minute (br/min). (These may not be present if the Oxehealth Vital Signs software was not able to measure a breathing rate at the time that the video recording was paused.)

While the **Take Vital Signs** screen is visible, a message is displayed indicating that the readings are being submitted to the system and saved in the Oxehealth Vital Signs software history, so they will then be available on the **Vital Signs Trends** chart.

Attempts to submit the vital signs may fail due to poor network connectivity. When using a mobile device it is important to move to an area with a strong WiFi signal.

If submitting the vital signs to the system fails, then you will see a warning message and an option to **Retry** as shown below:

The screenshot shows the Oxevision interface for 'Room 5'. The top navigation bar includes 'Home', 'Room 5', and 'Take Vital Signs'. The main content area displays a video feed of a patient in a bed, with a timestamp of '13 Oct 2023, 12:25:48' and a 'Paused' status. To the right, the 'Room 5' section shows 'Pulse Rate 89 bpm' and 'Breathing Rate 22 br/min'. Below this, a red error message states 'Vital Signs Failed to Submit' with the text 'There's been an issue sending the vital signs to Oxevision' and a 'Retry' button. A 'Done' button is also present. The bottom navigation bar includes a 'Home' button and a 'CE 2797 About Vital Signs' link. A 'Feedback' button is visible on the right side of the interface.

If you are using a mobile device, move to an area with a stronger WiFi signal and check that your WiFi is working before clicking Retry. The software will then attempt to submit the vital signs readings to the system to save them in the Vital Signs Trends chart again. If this fails again, you will see the same error message as shown above, and may click Retry again.

If submission continues to fail, your organisation may have support staff to help with a WiFi issue, or you may wish to contact Oxehealth using the contact details at the end of this manual.

Once the vital signs have been successfully saved in the Oxehealth Vital Signs software history you will see a success message as shown below:

The screenshot displays the Oxevision software interface for Room 5. The top navigation bar shows 'Home > Room 5 > Take Vital Signs' and the date '13 Oct 2023, 12:26'. A video feed on the left shows a patient in a room, with a timestamp of '13 Oct 2023, 12:25:48' and a 'Paused' status. To the right, under the 'Room 5' header, the vital signs are displayed: Pulse Rate 89 bpm and Breathing Rate 22 br/min. A green checkmark icon indicates 'Vitals Saved!' with the message 'The vital signs have successfully synced with Oxevision'. Below this, it states 'Vital Signs taken at: 13 Oct 2023, 12:25:47' and a 'Done' button is present. At the bottom, there is a 'Home' button, a CE 2797 logo, and an 'About Vital Signs' link. A 'Feedback' button is visible on the right side of the interface.

These vital signs observations have now been stored in the Oxehealth Vital Signs software history, and can be accessed using the **Vital Signs Trends** function on the **Action Menu** for this room.

NOTE

You should also now record these vital signs observations according to your subject observation protocols.

Click **Done**, and you will return to the **Overview screen**.

Viewing Vital Signs Trends

To view the history of vital signs measurements the software has automatically collected from a room, click the room icon, then select **Vital Signs Trends** from the **Action Menu**. You will then see the **Vital Signs Trends** screen below:



The history of vital signs measurements for the room is illustrated on the graphs as follows:

● **Red blobs (PR plot)** indicate the pulse rate observations made using Take Vital Signs in beats per minute (bpm). These may not be present at each attempted observation point if the user cancelled the operation at any point, or the software did not measure a pulse rate at that time.

● **Blue blobs (BR plot)** indicate the breathing rate observations made using Take Vital Signs in breaths per minute (br/min). These may not be present at each attempted observation point if the user cancelled the operation at any point, or the software did not measure a breathing rate at that time.

◇ **Grey diamonds (both plots)** indicate the average of automatic measurements made by the software without making spot-check observations using Take Vital Signs (see below).

Each grey trend point (◇) on this graph represents the average value of all collected pulse rates or breathing rates over a five minute period. Vital signs trend points are shown when measurements have been collected by the software for at least 75 seconds of the five minute period. The chart

shows a period of one day to provide a balanced overview of the subject's recent state and so that underlying trends may become apparent. Rapid, short duration changes in pulse rate or breathing rate will not appear on the trend chart.

Where no value is shown for a particular time, this may be because:

- There was too much movement in the room
- There was no subject in the room
- The Oxehealth Vital Signs device is designed to measure pulse rate and breathing rate in the ranges specified, and will not give measurements outside these ranges (see Cautions and Specification sections).



CAUTION

The **Vital Signs Trends** chart shows a summary of average vital signs to assist trend identification and cannot be used to monitor pulse rate or breathing rate. To take an accurate measurement of pulse rate or breathing rate, use Take Vital Signs, or use other means to establish vital signs.

The **Vital Signs Trends** plots have not been passed through the Vital Signs workflow therefore the readings may not have been taken from the subject and could be from another source (See cautions section of this document). As such the **Vital Signs Trends** information should not be used to inform clinical decisions.

NOTE

The chart displays data gathered from a specified room so may show data for a subject who is not the subject currently occupying that room.

Exporting a Vital Signs Trends Report

NOTE: This feature is only available on fixed screen and tablet devices

This feature allows you to export and send a **Vital Signs Trends** report to a recipient within your organisation by clicking the **Export** button situated in the top right part of the **Vital Signs Trends** screen for the selected room:



The **Choose Recipient** screen shown below will then appear prompting you to enter a recipient email address and the **Reason For Export**:

 A screenshot of a web application interface. At the top left is the "oxevision" logo and a hamburger menu icon. At the top right is the date and time "13 Oct 2023, 12:29". Below the header is a breadcrumb trail: "Home > Room 2 > Vital Signs Trends > Choose Recipient". On the right side, there is a vertical "Feedback" button. The main content area is divided into two columns. The left column has three sections: "Email" with a text input field containing "Recipient's email" and a dropdown menu showing "@oxehealth.com"; "Reason For Export" with a text area containing "Type your reason here..." and a character count "Characters remaining: 255"; and a note "This email will also be sent to the following default recipients for audit purposes: user.name@oxehealth.com.". The right column has a "Summary" section with three rows: "Exporting" (Vital Signs Trends), "For" (Room 2), and "Time Period" (12 Oct 2023 - 13 Oct 2023). At the bottom right of the form is a "Confirm Export" button.

Enter the email address you wish to send the report to in the **Email** field, and describe a reason for exporting in the **Reason for Export** field. These fields must be completed for the **Confirm Export** button to successfully send the report.

You will only be able to send the report to a recipient with an email address within your organisation, and you only need to enter the part of the email address before the '@' symbol. When you export a report, a copy may also be sent to other recipients that your organisation has chosen for audit purposes. The email address of this person will be indicated on the **Choose Recipient** screen shown above.

NOTE

Do not include any subject identifying information in the **Reason For Export** section, e.g. names, date of births.

To cancel this action from the **Choose Recipient** screen, click the **Back** button to return to the **Vital Signs Trends** screen or the Home button to return to the **Overview screen**.

When you are ready to export the report, click the **Confirm Export** button. A message will appear which reads "Submitted. A report email will be with you in the next 5 minutes". as shown below:

The screenshot shows the Oxevision interface at the 'Choose Recipient' step. A green banner at the top states: "Submitted. A report email will be with you in the next 5 minutes". The breadcrumb trail is: Home > Room 2 > Vital Signs Trends > Choose Recipient. The page title is "oxevision" and the date/time is "13 Oct 2023, 12:30".

Email

Reason For Export
 Do not include personally identifiable information, e.g. names, dates of birth, etc.

 Characters remaining: 221
 This email will also be sent to the following default recipients for audit purposes:
 user.name@oxehealth.com.

Summary

Exporting
Vital Signs Trends
For
Room 2
Time Period
12 Oct 2023 - 13 Oct 2023

Confirm Export

NOTE

Limitation on email size means that users should limit the number of rooms to export to no more than 15 rooms for 10 days or in other words, 150 room-days of information in one export.

If you are operating a mobile device and this has lost connection to WiFi, or the system encounters other errors attempting to send the email, you will see an error message as shown below:

oxevision 13 Oct 2023, 12:29

Home > Room 2 > Vital Signs Trends > Choose Recipient

Email failed. Please try again
Contact Oxehealth at support@oxehealth.com or 0800 030 6781

Email
ben @oxehealth.com

Reason For Export
Do not include personally identifiable information, e.g. names, dates of birth, etc.
Enter the "reason for export" here
Characters remaining: 221
This email will also be sent to the following default recipients for audit purposes:
user.name@oxehealth.com.

Summary

Exporting
Vital Signs Trends

For
Room 2

Time Period
12 Oct 2023 - 13 Oct 2023

Confirm Export

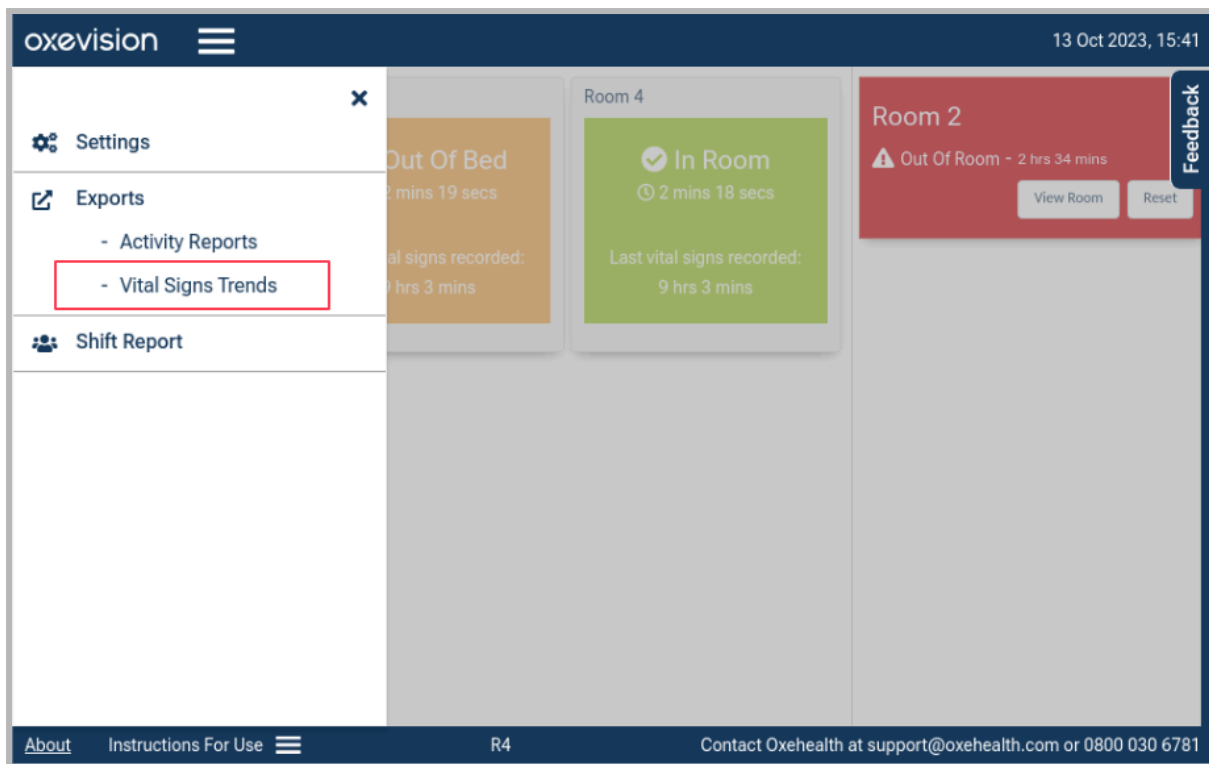
To ensure the reports can be sent, move to a place where your mobile device has a good Wifi connection and click **Confirm Export** again. If the problem persists, please contact Oxehealth using the details on the screen.

Once successful, an email will be sent to the address you provided, with the report attached as a PDF file. An additional copy of the report will also be sent to the other email addresses shown on the screen for audit purposes. The Vital Signs Trends Report will contain one page per day for the selected room.

Emails will be received by the recipient, and default recipient(s) for the device group, within 5 minutes.

If you have not completed the **Email** and **Reason for Export** fields, error messages will be shown and the report will not be sent. After successfully exporting, you will then be returned to the **Overview Screen**.

Alternatively, you can export Vital Signs Trends Reports for a number of rooms over a selected date range by clicking the **Vital Signs Trends** link in the navigation menu on the **Overview Screen**:



You will then see the **Select Rooms** screen shown below, allowing you to choose multiple rooms to export the reports for:




All rooms available to the device will be shown as multi-select options on the **Select Room** page. One or more rooms can be selected by clicking on the room name button. Clicking the **Select All** checkbox will select all rooms available. Selected rooms will be displayed in a solid (green) colour. Unchecking the **Select All** checkbox will deselect all rooms.

The **Choose Dates** button will be disabled until at least one room is selected.

To go back to the **Exports** screen to change the reports being exported, click the **Exports** button at the top left.


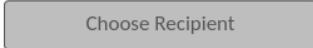
After selecting the rooms you would like to export Vital Signs Trends Reports for, click **Choose Dates** , and you will then see the **Choose Dates** screen shown below:

oxevision  13 Oct 2023, 12:33

Home > Select Rooms > Choose Dates

You are exporting Vital Signs Trends Reports for 2 Rooms

Start End

 Home  Choose Recipient

Feedback

The time frame for the export can be selected using the **Start** and **End** date dropdown boxes from the **Choose Dates** screen.

The **Choose Recipient** button will be disabled until at least one date is selected.

The maximum date range is 14 days. If invalid dates are selected, an error message will be displayed and the **Choose Recipient** button will continue to be inactive.

To go back to the **Select Rooms** screen to change the rooms being exported, click the **Select Rooms** button at the top left.

Once you have selected the date range you would like to export, click the **Choose Recipient** button and you will then see the **Choose Recipient** screen below:

The screenshot displays the 'Choose Recipient' interface. At the top, the breadcrumb trail is 'Home > Select Rooms > Choose Dates > Choose Recipient'. The 'Email' section has a text input with 'Recipient's email' and a dropdown menu showing '@oxehealth.com'. Below this is the 'Reason For Export' section, which includes a warning: 'Do not include personally identifiable information, e.g. names, dates of birth, etc.' and a text area with the placeholder 'Type your reason here...'. A character count of 'Characters remaining: 255' is shown. A note states: 'This email will also be sent to the following default recipients for audit purposes: user.name@oxehealth.com.' On the right, a 'Summary' panel lists 'Exporting Vital Signs Trends', 'For Room 2, Room 4', and 'Time Period 04 Oct 2023 - 11 Oct 2023'. A 'Feedback' button is located on the right side of the screen. At the bottom, there are two buttons: 'Home' and 'Confirm Export'.

Enter the email address you wish to send the reports to in the **Email** field, and describe a reason for exporting in the **Reason for Export** field. These fields must be completed for the **Confirm Export** button to successfully send the reports.

You will only be able to send the report to a recipient with an email address within your organisation, and you only need to enter the part of the email address before the '@' symbol. When you export a report, a copy may also be sent to other recipients that your organisation has chosen for audit purposes. The email address of this person will be indicated on the **Choose Recipient** screen shown above.

NOTE

Do not include any subject identifying information in the **Reason For Export** section, e.g. names, date of births.

To go back to the **Choose Dates** screen to change the dates being exported, click the **Choose Dates** button at the top left. To cancel this action from the **Choose Recipient** screen, click the **Home** button to return to the **Overview screen**.

A summary of the export is displayed on the right of the **Choose Recipient** screen which shows details of:

- **Exporting** - The type of report being exported;
- **For** - The rooms selected and;
- **Time period** - The time frame selected.

The export options can be edited by selecting the edit icons within the Summary section. Selecting an edit icon will return you to the respective Exports, Select Rooms or **Choose Dates** screens. Follow the earlier instructions for editing the information on these screens.

When you are ready to export the report, click the **Confirm Export** button. A message will appear which reads "Submitted. A report email will be with you in the next 5 minutes" as shown below:

oxevision 13 Oct 2023, 12:30

Home > Room 2 > Vital Signs Trends > Choose Recipient

Submitted. A report email will be with you in the next 5 minutes

Email

ben @oxehealth.com

Reason For Export

Do not include personally identifiable information, e.g. names, dates of birth, etc.

Enter the "reason for export" here

Characters remaining: 221

This email will also be sent to the following default recipients for audit purposes:
user.name@oxehealth.com.

Summary

Exporting
Vital Signs Trends

For
Room 2

Time Period
12 Oct 2023 - 13 Oct 2023

Confirm Export

If you are operating a mobile device and this has lost connection to WiFi, or the system encounters other errors attempting to send the email, you will see an error message as shown below:

oxevision 13 Oct 2023, 12:29

Home > Room 2 > Vital Signs Trends > Choose Recipient

Email failed. Please try again
Contact Oxehealth at support@oxehealth.com or 0800 030 6781

Email
ben @oxehealth.com

Reason For Export
Do not include personally identifiable information, e.g. names, dates of birth, etc.
Enter the "reason for export" here

Characters remaining: 221
This email will also be sent to the following default recipients for audit purposes:
user.name@oxehealth.com.

Summary

Exporting
Vital Signs Trends

For
Room 2

Time Period
12 Oct 2023 - 13 Oct 2023

Confirm Export

To ensure the reports can be sent, move to a place where your mobile device has a good Wifi connection and click Confirm Export again. If the problem persists, please contact Oxehealth using the details on the screen.

Once successful, an email will be sent to the address you provided, with the reports attached as individual PDF files (one per room). An additional copy of this email will also be sent to the other email addresses shown on the screen for audit purposes. Each Vital Signs Trends Report will contain one page per day for one room.

Emails should be received by the recipients, and default recipient(s) for the device group, within 5 minutes.

If you have not completed the **Email** and **Reason for Export** fields, error messages will be shown and the report will not be sent. After successfully exporting, you will then be returned to the **Overview Screen**.

Pausing Rooms

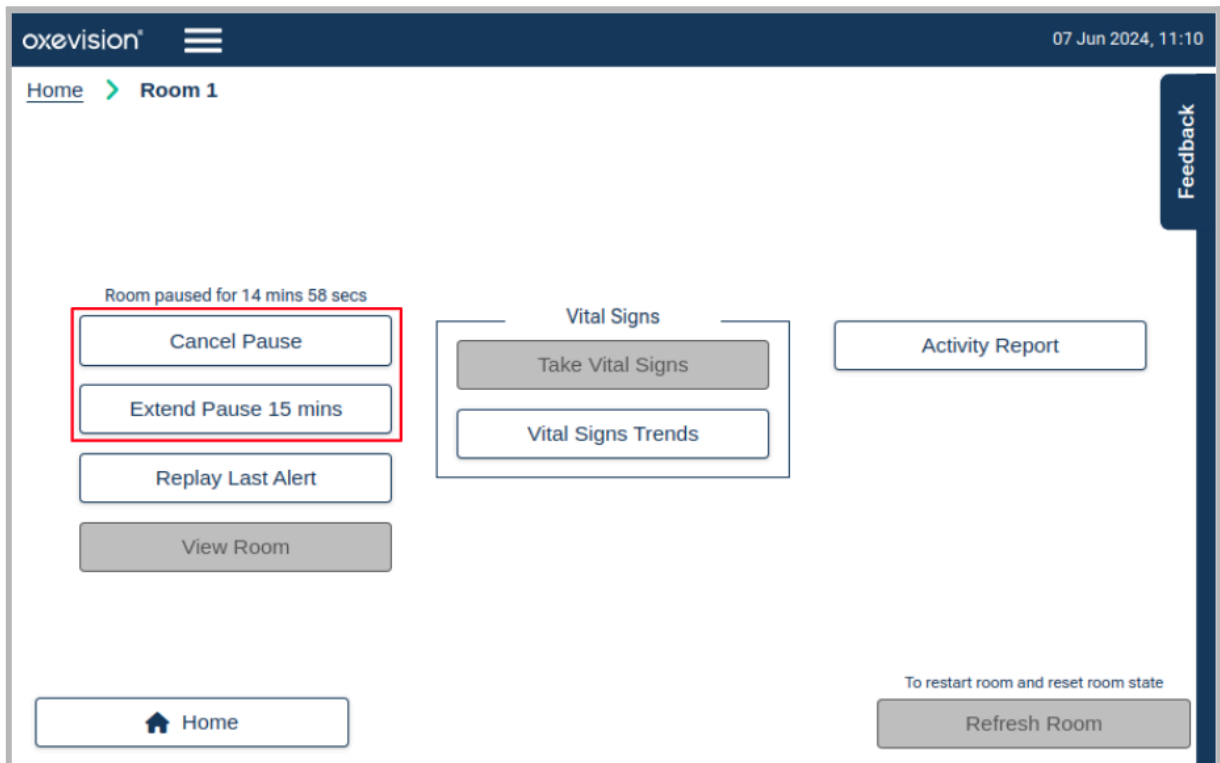
To pause any room, click the room icon for the room the subject is in, then select **Pause for 15 Minutes** from the **Action Menu**.

NOTE

The duration of the pause may not be 15 minutes if the default pause duration for this room has been changed. For instance, if the default pause duration has been changed to 45 minutes, the button will read **Pause for 45 Minutes**.

Extending and Cancelling a Pause

If you want to keep a room paused, or cancel the action and reconnect the room, click the room icon for the room the subject is in, and the **Action Menu** will look as it does below:



To Cancel the pause and reconnect the room, click **Cancel Pause**.

To extend the pause for another 15 minutes, click **Extend Pause 15 Minutes**. The room will now remain paused for the time that previously remained, plus the time added.

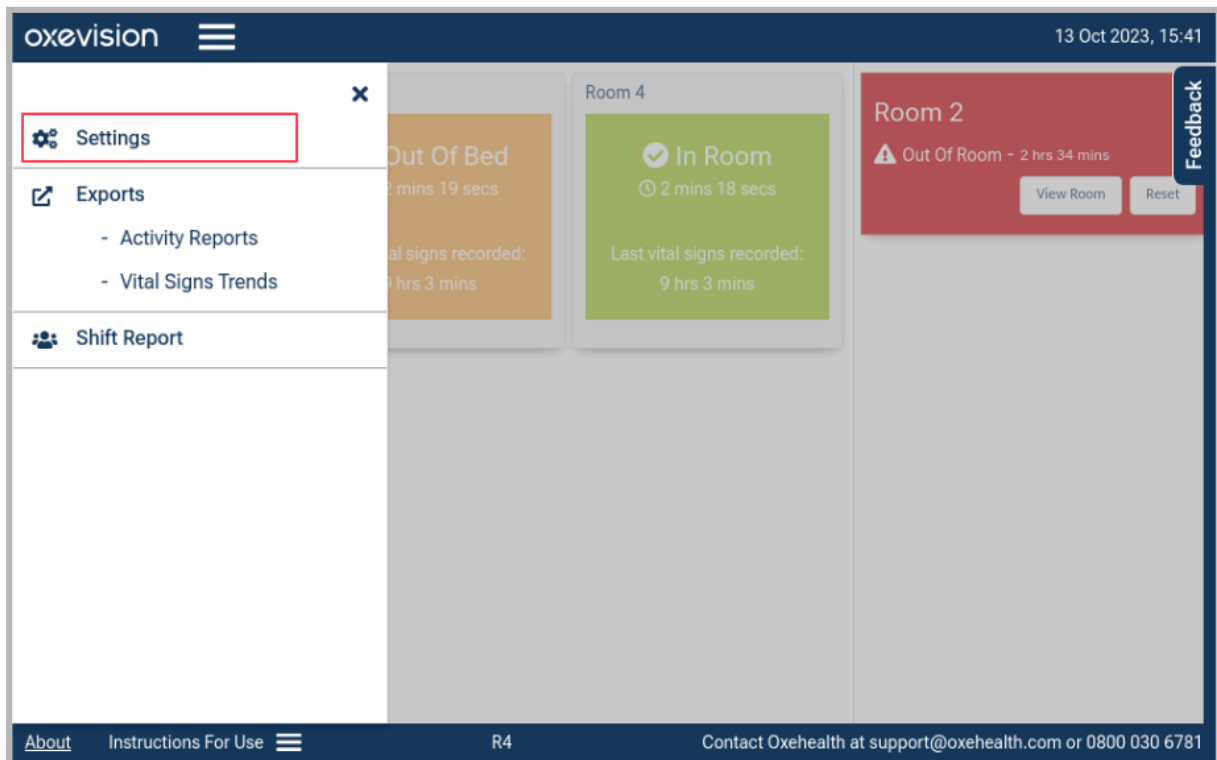
Click **Home** to return to the **Overview screen**.

NOTE

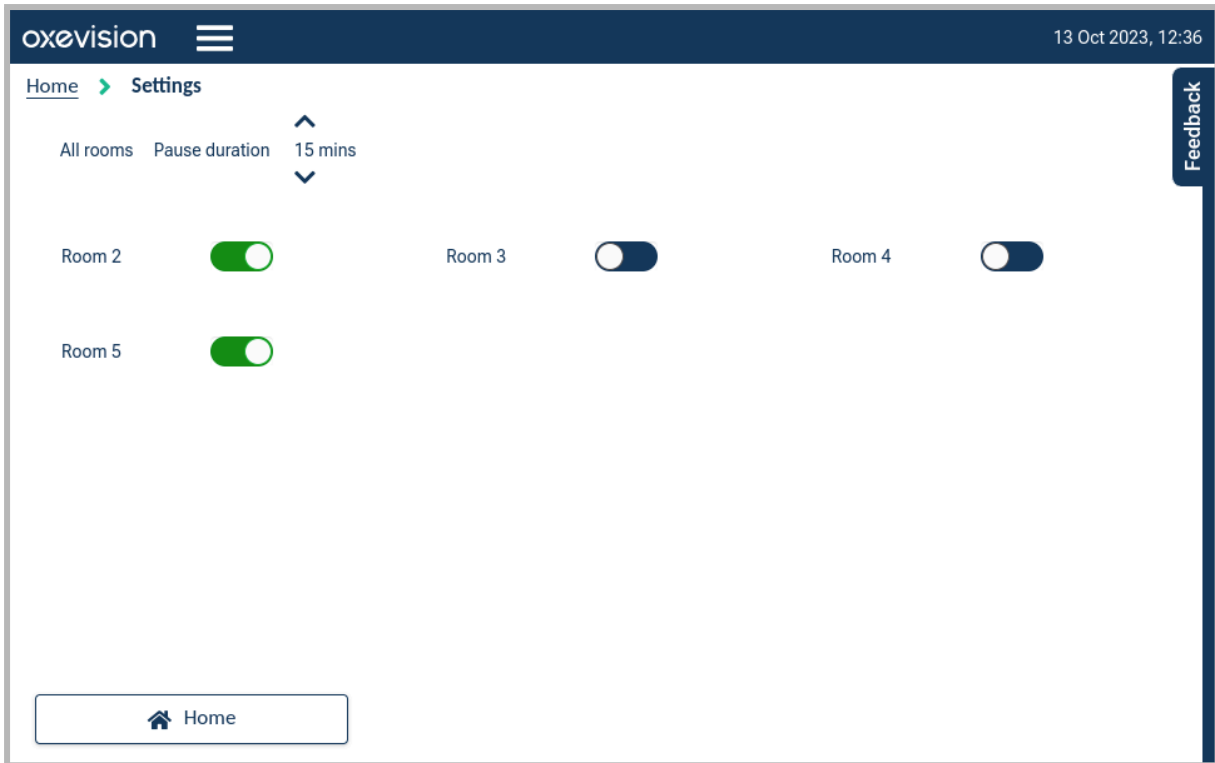
The extension of the pause may not be 15 minutes if the default pause duration for this room has been changed. For instance, if the default pause duration has been changed to 45 minutes, the button will read **Extend Pause 45 Minutes**.

Changing Room Settings

To enable or disable Oxehealth Vital Signs device processing in any of the rooms, or change the default pause duration, Click the **Settings** link from the Navigation Menu.





You will then be shown the **Settings** screen below:



On the settings screen, you can control which rooms are connected, and set the default pause duration.

This screen shows the on or off status for each room, which is operated as follows:

<p>Room 1 System </p>	<p>The room is chosen to be connected, such that the Oxehealth Vital Signs device software is receiving video, and making estimations for this room.</p> <p>To disconnect the room (stop the software from running, such that the software is not receiving or processing video), click the green toggle switch. The toggle switch should then look like the picture below.</p>
<p>Room 4 System </p>	<p>The room is chosen to be disconnected, such that the Oxehealth Vital Signs device software is not receiving video, or making estimations for this room.</p> <p>To connect the room (start the software, such that the software is receiving and processing video), click the black toggle switch. The toggle switch should then look like the picture above.</p>

To change the **Default Pause** duration, click the up arrow above the pause duration to increase the pause duration **minutes** and click the down arrow below the pause duration to decrease the pause duration **minutes**.

Click **Home** to return to the **Overview screen**.

Sending Feedback to Oxehealth

To send feedback of any sort to Oxehealth, click the **Feedback** tab in the top right corner of the screen. You will then see the **Feedback screen** below:

Select the **Feedback Type** (if this is available) and fill in the **Message** text field with the information you would like to share, your issues, suggestions or questions and click **Send Feedback** to send the information to Oxehealth. Please also provide your name and contact details, if available, as this will help a support representative to contact you if you require assistance. We will then receive your message automatically, and the Feedback form will be closed

The screenshot shows the Oxevision interface. At the top, the logo 'oxevision' and a menu icon are on the left, and the date and time '13 Oct 2023, 12:41' are on the right. Below the header, the navigation path is 'Home > Room 2 > Vital Signs Trends'. A warning icon and text state: 'Chart shows average vital signs to assist trend identification. Room occupancy may vary so more than one person's vital signs may be shown. Other factors that may affect readings.' Two charts are displayed for the period '12 Oct - 13 Oct'. The top chart is 'Pulse Rate Measurement (PR) (bpm)' with a y-axis from 40 to 130 and an x-axis from 13:00 to 22:00. It shows several red data points between 20:00 and 22:00. The bottom chart is 'Respiratory Rate (BR) (br/min)' with a y-axis from 6 to 40 and the same x-axis. It shows several blue data points between 20:00 and 22:00. A vertical 'Feedback' tab is visible on the right side of the charts. A large white box with a green checkmark and the text 'Thank you!' and 'Your feedback has been sent to Oxehealth.' is overlaid on the right side of the interface. At the bottom left, there is a 'Home' button and a CE mark with the number '2797'.

If you do not wish to send feedback, click on the **Feedback tab** and the feedback form will close



CAUTION

Do not include any subject identifying information in the feedback, e.g. names, date of births.

Manufacturer



Oxehealth Limited

Magdalen Centre North
Oxford Science Park
Oxford
OX4 4GA
United Kingdom

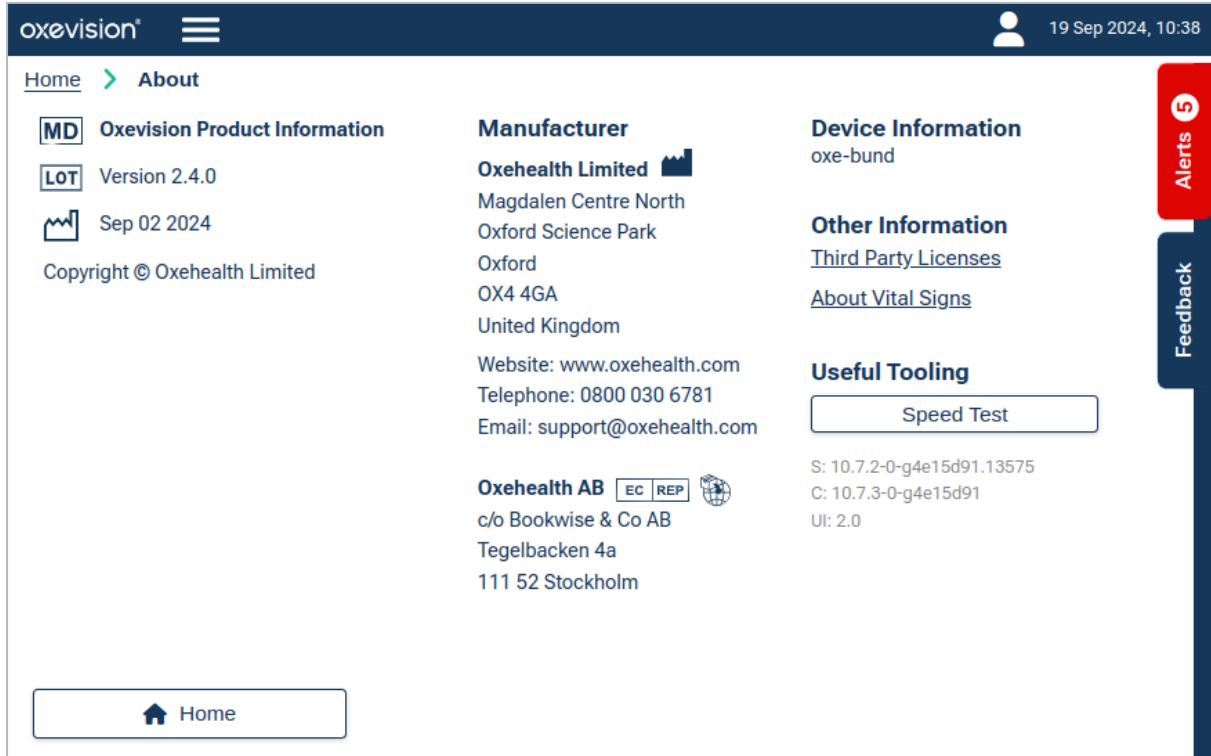
Telephone: 0800 030 6781

Website: www.oxehealth.com

Email: support@oxehealth.com

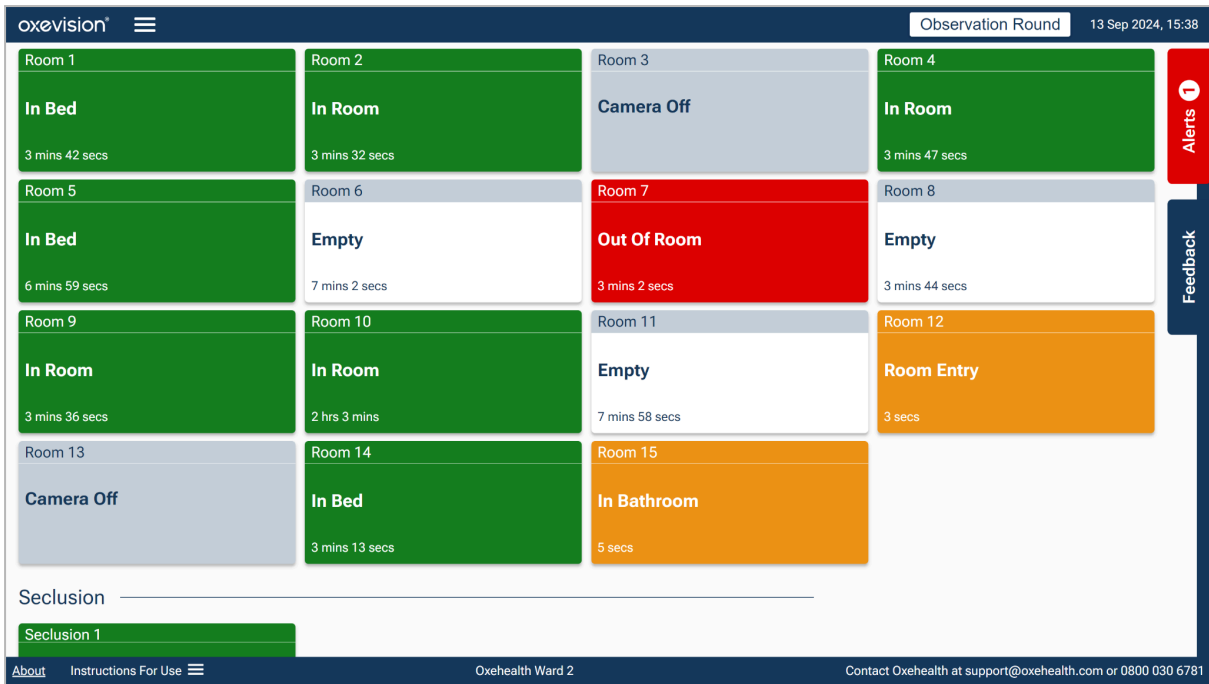
How To Use Oxehealth Vital Signs - UI Version 2.0

If your graphical user interface “About” screen displays “UI: 2.0”, as illustrated below. Then please refer to this section, “How To Use Oxehealth Vital Signs - UI Version 2.0” on pages 42 to 74. Otherwise, refer to section, “How To Use Oxehealth Vital Signs - UI Version 1.0” on pages 8 to 41.



The Overview Screen

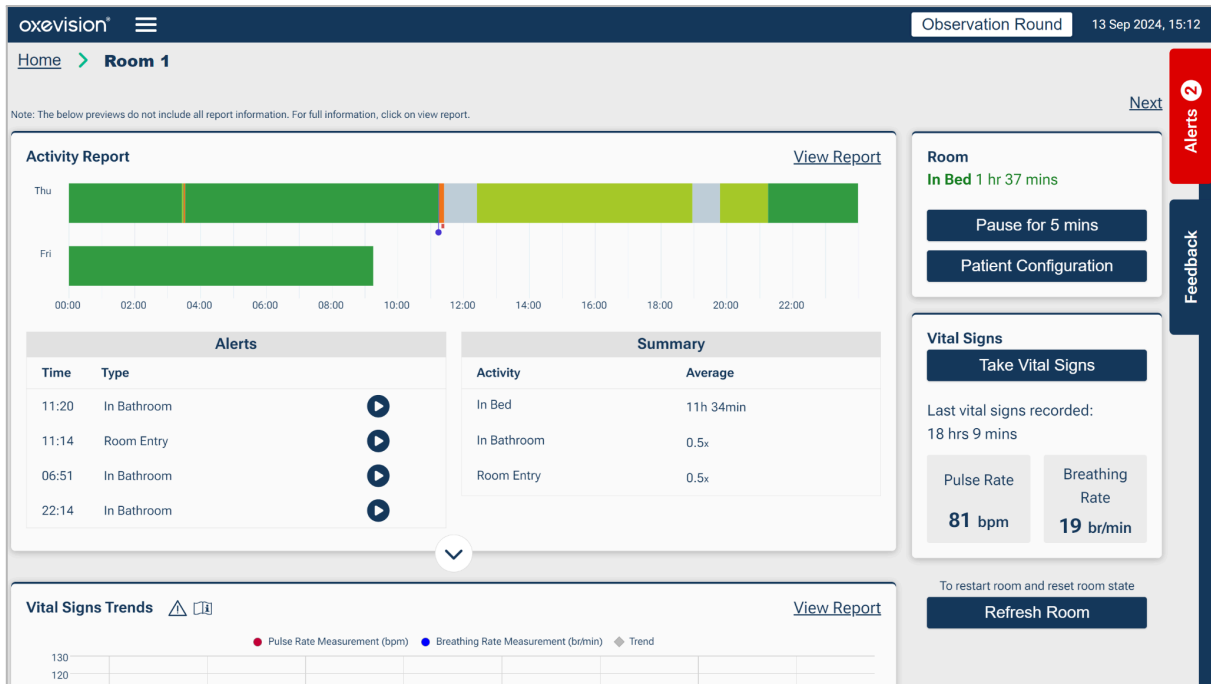
The **Overview Screen** shows all of the rooms connected to the Oxehealth Vital Signs software:



IMPORTANT - please read carefully

Depending on the number of rooms and layout chosen, you may need to scroll down to see all of the room tiles.

Each room is shown as a clickable panel on the Overview Screen, by clicking a room, this brings up the room **Room Dashboard** for that room:

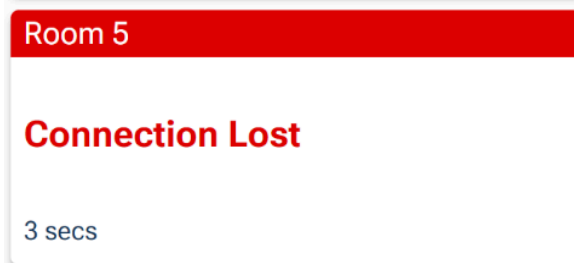


Note that the **Room Dashboard** may include **Vital Signs Trends** depending on your software configuration. See the sections on [Viewing Vital Signs Trends](#) on how to use these functions.

The **Room Dashboard** may include other menu items for other product modules (refer to other Oxehealth Oxevision product module instructions for use for information).

On the **Overview Screen**, the large icons indicate the state of the room as follows:

- **Connection Lost:** the Oxehealth Vital Signs software is not connected to the room.

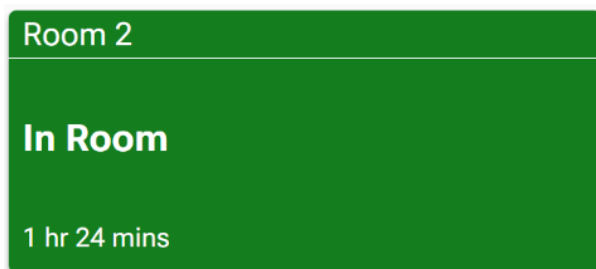


The main text in the room icon will display the nature of any software disconnection, and the time that the connection has been down.

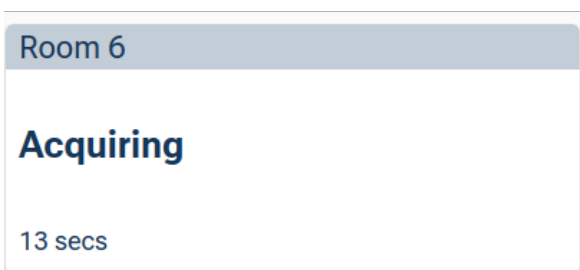
In this state, it will be possible to use the **Vital Signs Trends** functions on the **Room Dashboard**.

In this state, it will not be possible to use the **Take Vital Signs** or **Pause** functions on the **Room Dashboard**.

- **Connected:** the Oxehealth Vital Signs software is connected to the room and running, such that the software is receiving video and making estimations.



The main text in the room icon will display non-medical information from other modules about what is happening in the room, and the time that the room has been in this state. Other modules may also modify the colour of the room icon while they are processing data, or when they determine the room to be empty.



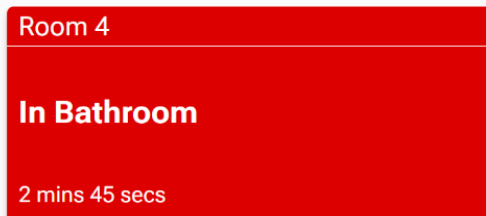
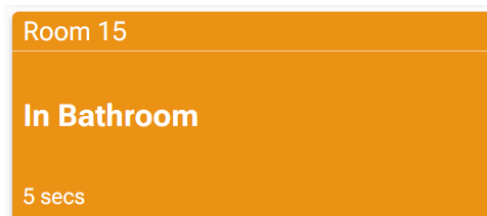
Refer to other product module instructions for use for further information.

IMPORTANT - please read carefully

When other Oxehealth product modules are running and showing different non-medical information about what is happening in the room, the Oxehealth Vital Signs is still operational, and it is still possible to take vital signs.

In this state, it will be possible to use the **Take Vital Signs**, **Pause** and **Vital Signs Trends** functions on the **Room Dashboard**.

- Informational and Alert States:** the Oxehealth Vital Signs software is connected to the room and running, such that the software is receiving video and making estimations. In this state, other product modules are producing a non-medical alert to prompt further checks in the room. These prompts may be informational (orange), or alerts (red) as the examples below show, and will be pre-configured to a scheme specific to your installation.



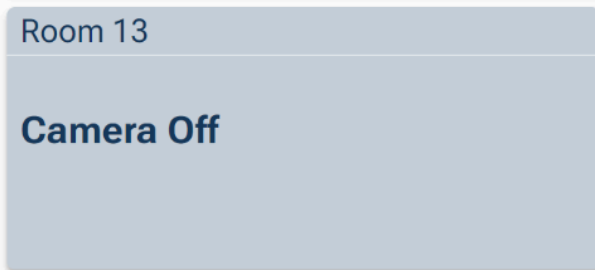
The main text in the room icon will display the nature of the non-medical alert, and the time that the room has been in this state. Refer to other product module instructions for use for information on these alerts.

IMPORTANT - please read carefully

When other Oxehealth product modules are producing an alert, Oxehealth Vital Signs is still operational, and it is still possible to take vital signs.

In this state, it will be possible to use the **Take Vital Signs**, **Pause** and **Vital Signs Trends** functions on the **Room Dashboard**.

- **Camera Off:** the Oxehealth Vital Signs software is connected to the room, but a user has chosen to stop measuring, such that the Oxehealth Vital Signs software has ceased receiving video and making estimations for this room.



The timer indicates the time that the software has been stopped for the room.

In this state, it will be possible to use the **Vital Signs Trends** functions on the **Room Dashboard**.

In this state, it will not be possible to use the **Pause** or **Take Vital Signs** function on the **Room Dashboard**.

- **Paused:** the Oxehealth Vital Signs software is connected to the room, but a user has chosen to pause measuring, such that the Oxehealth Vital Signs software has ceased capturing video and making estimations temporarily for this room.

The time for the room will continuously update, and is a countdown timer, indicating how long is left before Oxehealth Vital Signs automatically restarts capturing video and processing.



In this state, it will be possible to use the **Extend Pause**, **Cancel Pause** and **Vital Signs Trends** functions on the **Room Dashboard**.

In this state, it will not be possible to use the **Take Vital Signs** function on the **Room Dashboard**.

Taking Vital Signs Observations

To take vital signs observations from a subject, click the room icon for the room the subject is in, then select **Take Vital Signs** from the **Room Dashboard**.

The screenshot shows the 'Room 1' dashboard in the oxevision interface. At the top, it displays 'Observation Round' and the date '13 Sep 2024, 15:12'. The main area is divided into several sections:

- Activity Report:** A horizontal bar chart showing activity levels for Thursday and Friday. A 'View Report' link is present.
- Alerts:** A table listing recent alerts:

Time	Type
11:20	In Bathroom
11:14	Room Entry
06:51	In Bathroom
22:14	In Bathroom
- Summary:** A table showing activity averages:

Activity	Average
In Bed	11h 34min
In Bathroom	0.5x
Room Entry	0.5x
- Vital Signs:** A section with a 'Take Vital Signs' button. It shows 'Last vital signs recorded: 18 hrs 9 mins' and current readings: Pulse Rate **81 bpm** and Breathing Rate **19 br/min**. A 'Refresh Room' button is also present.
- Vital Signs Trends:** A line graph area with a legend for Pulse Rate Measurement (bpm) and Breathing Rate Measurement (br/min).

You will then see the first **Take Vital Signs** screen below:


The screenshot shows the 'Take Vital Signs' screen for 'Room 5'. It features a large live video feed of a subject in a bed, timestamped '18 Sep 2024, 11:39:13'. Below the video is a confirmation dialog:

Room 5
Is the subject still?

If moving, do **not** take vital signs If still, vital signs may be taken

At the bottom, there is a 'Home' button, a note 'Exclusively For Clinical Investigation', and a link 'About Vital Signs'.

This screen will show clear live video of the room, for up to 15 seconds, and ask you if the subject is still. If the Oxehealth Vital Signs device software is not able to make any vital signs estimations at the current time, the **Yes** button will indicate **Acquiring Vitals**, and you will not be able to proceed:

Acquiring Vitals... 

If the subject is not still, the **Acquiring Vitals** button is shown, or if you do not wish to proceed for any reason, click **Cancel**, and you will return to the **Overview screen**.

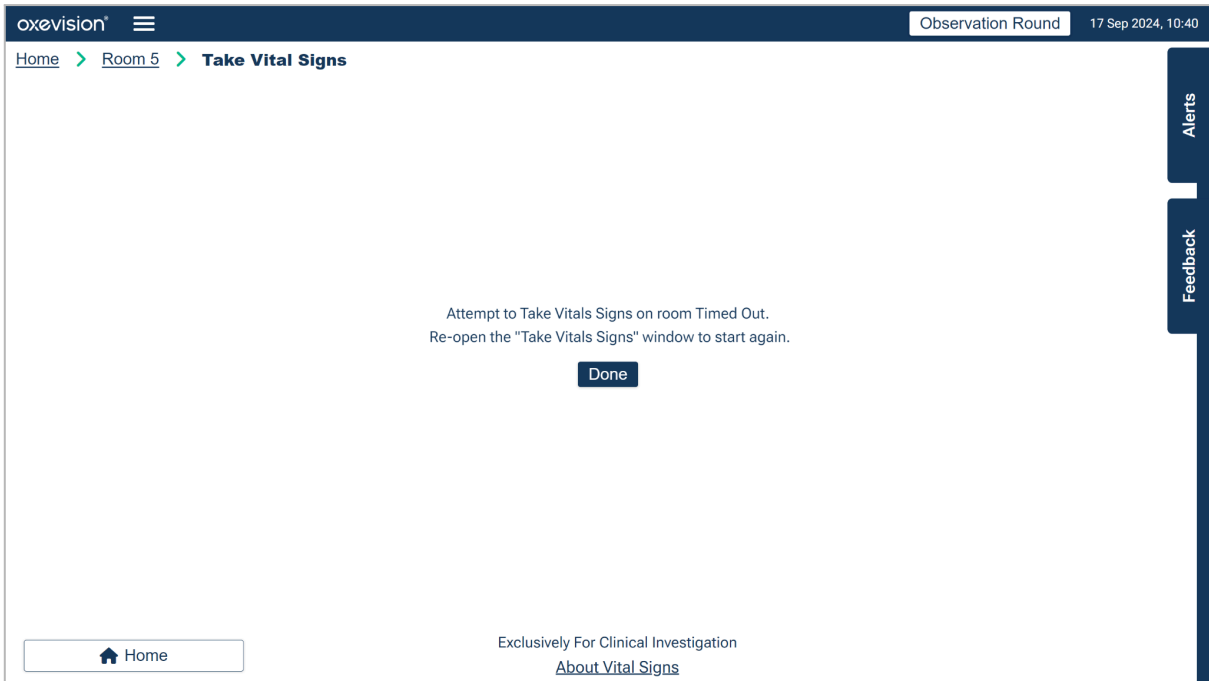
IMPORTANT - please read carefully

Oxehealth Vital Signs will not give pulse rate or breathing rate measurements if a subject is within a field of view where a privacy mask has been applied to cover an area such as a bathroom.

IMPORTANT SECURITY NOTICE - please read carefully

When taking Vital Signs observations, be careful to maintain the privacy of your subject by ensuring that your screen is not visible to other people.

If you are unable to proceed for more than 15 seconds, the **Take Vital Signs screen** will automatically close and you will see the following display:



Click **Done**, and you will return to the **Overview screen**.

IMPORTANT - please read carefully

If the **Yes** button is available, you may proceed if the subject is still. If you are not sure the subject is still, do not proceed.

Guidelines for considering the subject to be still:

- Asleep in a bed, on the floor or in a chair
- Lying in bed awake, but not moving
- Sitting up in bed, a chair or on the floor awake, but not moving

Do not proceed if the subject is carrying out small repetitive movements, for example:

- Rocking while sitting or lying
- Having a seizure
- Visibly shivering
- Displaying tremors
- Standing or sitting still, but manually brushing teeth or washing
- Brushing hair
- Fidgeting
- Tapping their foot or hand

**CAUTION**

If you can see the subject, but insufficient skin is visible (e.g. they are partially covered by bed sheets), then you may proceed with caution. If a subject has covered most of their skin, then it may not be possible to take a pulse rate observation, but a breathing rate observation may still be possible.

If you judge the subject to be still according to these guidelines, and you want to proceed, click **Yes** and you will see the second **Take Vital Signs screen** below:

Home > Room 2 > Take Vital Signs

18 Sep 2024, 14:54:39 Paused

Room 2

Are there blobs which do not touch the body?

Yes No

If any blobs not on body, do **not** take vital signs If all blobs on body, vital signs may be taken

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Exclusively For Clinical Investigation
[About Vital Signs](#)

The video of the room will now pause, and you will see the regions in the image from which the Oxehealth Vital Signs software is estimating breathing and pulse rate as coloured blobs, together with the question “**Are there any blobs which do not touch the body?**”

IMPORTANT - please read carefully

The blobs in the image represent the locations from which the software is estimating pulse rate and breathing rate, and it is important that you ensure that the software is extracting these from the body of the subject. You will see up to two circular blobs, but these may be touching or overlaid, so be sure that you have accounted for this before proceeding to answer **No** to the question.

Examples of blobs that are and are not touching the body are shown below:

Only one blob visible, not touching the body



Select "Yes"

Two blobs visible, both touching the body



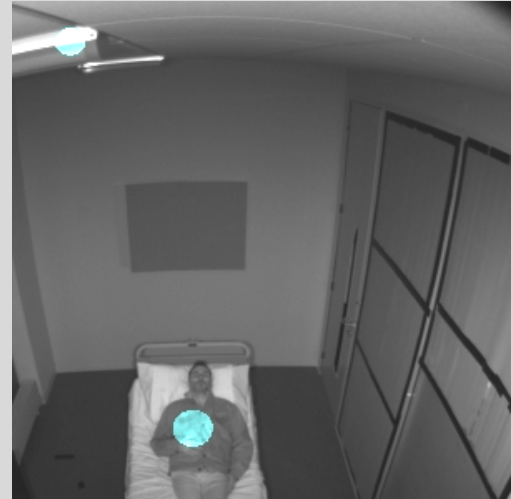
Select "No"

Only one blob visible and touching the body



Select "No"

Two blobs visible, one not touching the body



Select "Yes"

In the last of these examples (bottom right), note that one of the blobs is on the light fitting on the ceiling.

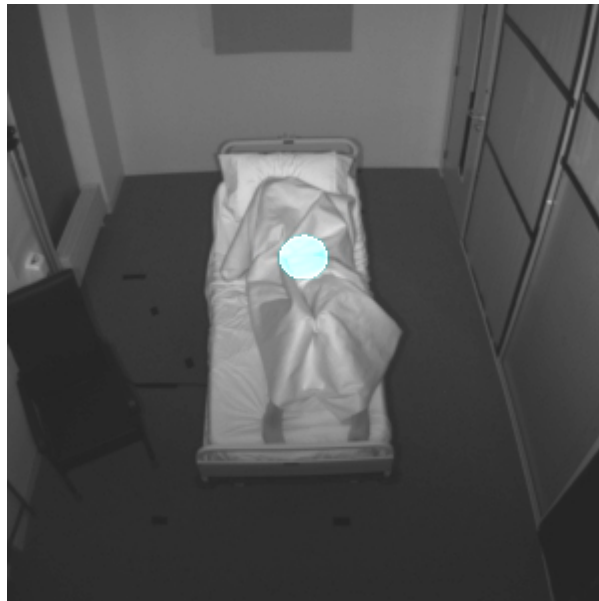


CAUTION

You must consider other means of obtaining vital signs observations if you have any cause for concern over the readings obtained by Oxehealth Vital Signs.

If you can see the subject, but they are covered, for example by bed sheets, then you may proceed with caution if you consider all of the visible blobs to be on the body of the subject.

An example of a subject being covered, but whose body can clearly be made out, with a blob touching is shown below:



If a subject has covered all of their skin, then it may not be possible to make a pulse rate observation, but a breathing rate observation may still be possible.

Remember, Oxehealth Vital Signs may not give reliable or accurate measurements from the subject if another living being or moving object is in the image, even if hidden, for example by sheets. Never proceed if the blobs touch another living being or moving object.

If there are any blobs which do not touch the body, or you do not wish to proceed for any other reason, click **Yes**, and you will return to the **Overview screen**.

Otherwise, click **No** and you will see the final **Take Vital Signs** screen below:

The video of the room will remain paused, and you will see the Oxehealth Vital Signs breathing and pulse rate. The Oxehealth Vital Signs device software indicates the vital signs as follows:

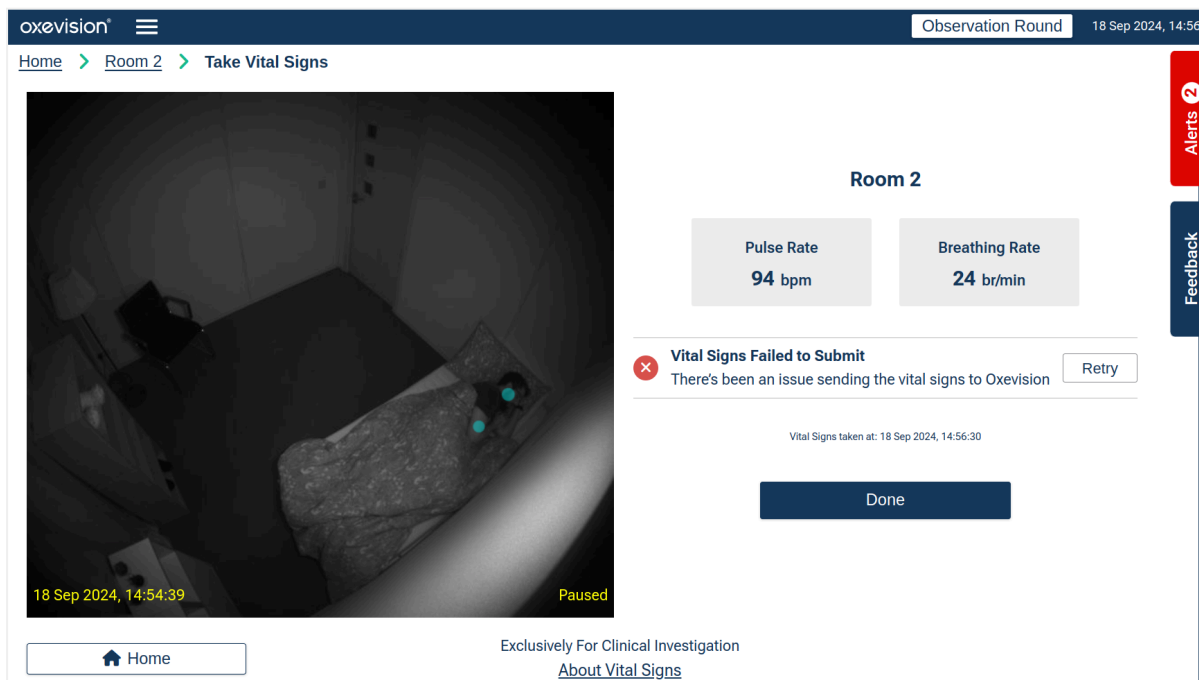
Pulse Rate indicates the pulse rate of the subject in beats per minute (bpm). (These may not be present if the Oxehealth Vital Signs software was not able to measure a pulse rate at the time that the video recording was paused.)

Breathing Rate indicates the breathing rate of the subject in breaths per minute (br/min). (These may not be present if the Oxehealth Vital Signs software was not able to measure a breathing rate at the time that the video recording was paused.)

While the **Take Vital Signs** screen is visible, a message is displayed indicating that the readings are being submitted to the system and saved in the Oxehealth Vital Signs software history, so they will then be available on the **Vital Signs Trends** chart.

Attempts to submit the vital signs may fail due to poor network connectivity. When using a mobile device it is important to move to an area with a strong WiFi signal.

If submitting the vital signs to the system fails, then you will see a warning message and an option to **Retry** as shown below:

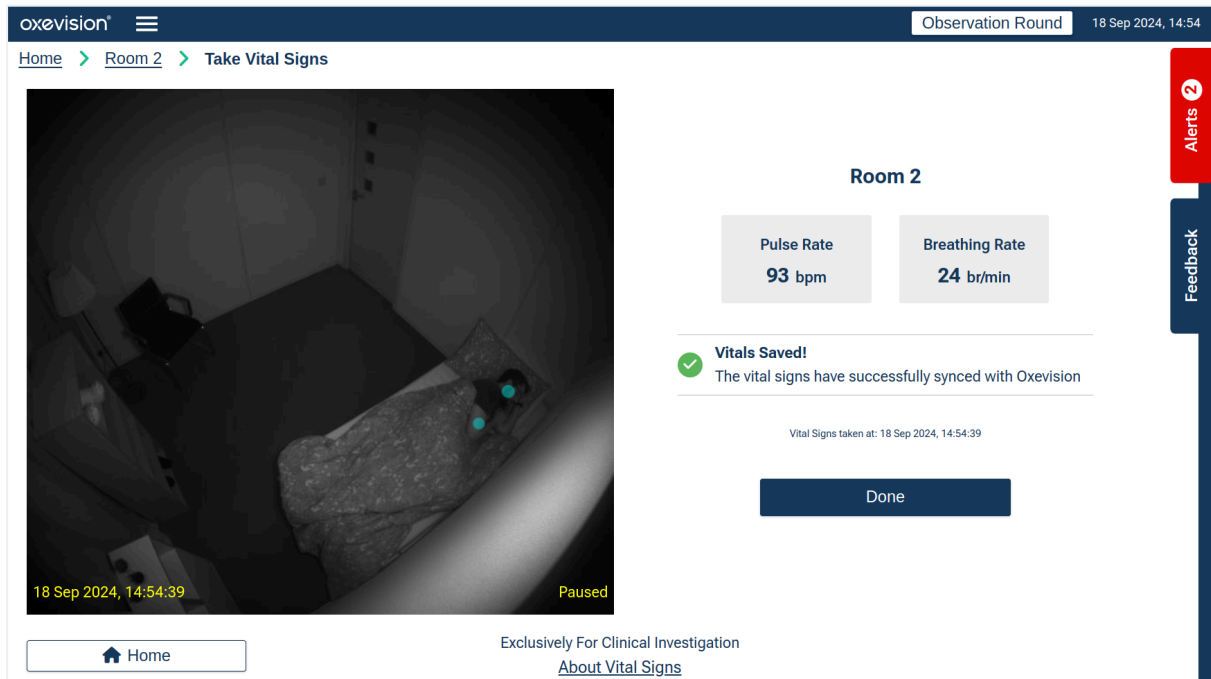


The screenshot displays the Oxevision interface for 'Room 2'. The top navigation bar includes the Oxevision logo, a menu icon, and the text 'Observation Round' and '18 Sep 2024, 14:56'. Below the navigation bar, the breadcrumb trail shows 'Home > Room 2 > Take Vital Signs'. On the left, a video feed shows a patient in a bed with a sensor on their chest, timestamped '18 Sep 2024, 14:54:39' and labeled 'Paused'. To the right of the video, the 'Room 2' vital signs are displayed: Pulse Rate at 94 bpm and Breathing Rate at 24 br/min. A red warning message states 'Vital Signs Failed to Submit' with a red 'x' icon, followed by the text 'There's been an issue sending the vital signs to Oxevision' and a 'Retry' button. Below the message, it indicates 'Vital Signs taken at: 18 Sep 2024, 14:56:30' and a 'Done' button. On the far right, there are vertical buttons for 'Alerts 2' and 'Feedback'. At the bottom of the interface, there is a 'Home' button and the text 'Exclusively For Clinical Investigation' with a link to 'About Vital Signs'.

If you are using a mobile device, move to an area with a stronger WiFi signal and check that your WiFi is working before clicking Retry. The software will then attempt to submit the vital signs readings to the system to save them in the Vital Signs Trends chart again. If this fails again, you will see the same error message as shown above, and may click Retry again.

If submission continues to fail, your organisation may have support staff to help with a WiFi issue, or you may wish to contact Oxehealth using the contact details at the end of this manual.

Once the vital signs have been successfully saved in the Oxehealth Vital Signs software history you will see a success message as shown below:



The screenshot displays the Oxehealth Vital Signs software interface. At the top, the header shows 'oxevision' with a menu icon, 'Observation Round', and the date '18 Sep 2024, 14:54'. Below the header, the breadcrumb navigation reads 'Home > Room 2 > Take Vital Signs'. The main content area is split into two sections. On the left is a video feed of a patient in a hospital room, with a timestamp '18 Sep 2024, 14:54:39' and a 'Paused' indicator. On the right, under the heading 'Room 2', there are two data cards: 'Pulse Rate 93 bpm' and 'Breathing Rate 24 br/min'. Below these is a green checkmark icon and the text 'Vitals Saved! The vital signs have successfully synced with Oxevision'. A smaller timestamp 'Vital Signs taken at: 18 Sep 2024, 14:54:39' is visible. A 'Done' button is located at the bottom of this section. On the far right, there is a vertical sidebar with 'Alerts 2' and 'Feedback' buttons. At the bottom of the interface, there is a 'Home' button and a disclaimer: 'Exclusively For Clinical Investigation About Vital Signs'.

These vital signs observations have now been stored in the Oxehealth Vital Signs software history, and can be accessed using the **Vital Signs Trends** function on the **Room Dashboard** for this room.

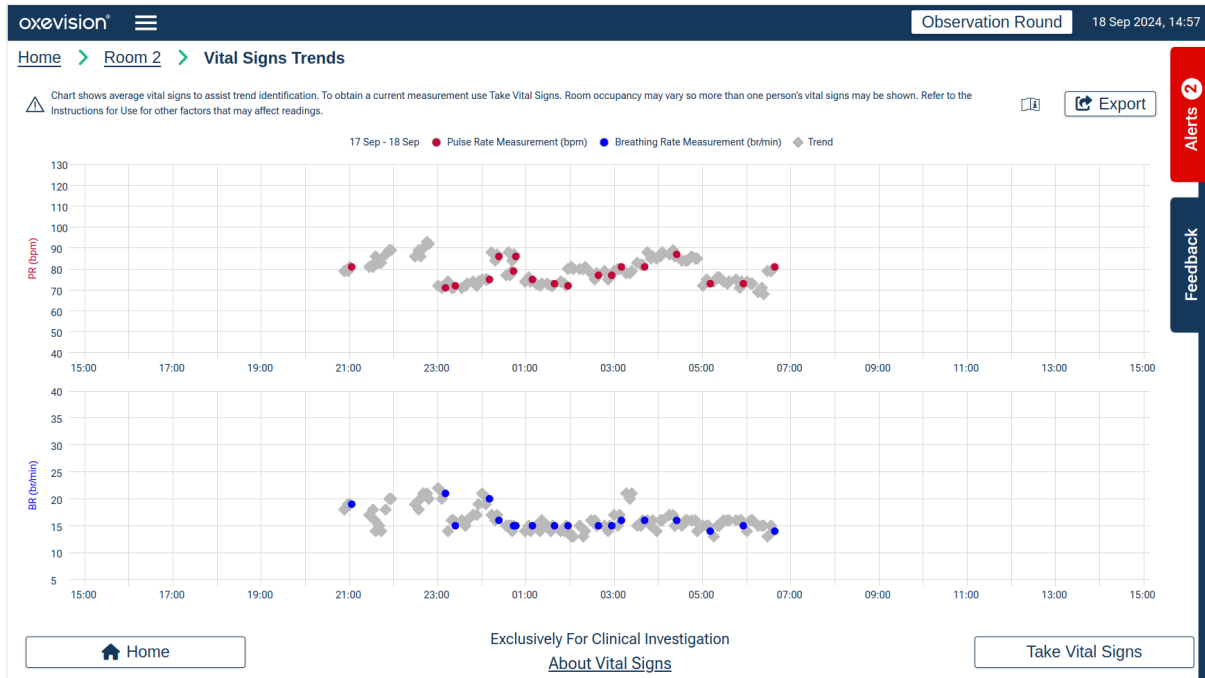
NOTE

You should also now record these vital signs observations according to your subject observation protocols.

Click **Done**, and you will return to the **Overview screen**.

Viewing Vital Signs Trends

To view the history of vital signs measurements the software has automatically collected from a room, click the room icon, then select **Vital Signs Trends** from the **Room Dashboard**. You will then see the **Vital Signs Trends** screen below:



The history of vital signs measurements for the room is illustrated on the graphs as follows:

● **Red blobs (PR plot)** indicate the pulse rate observations made using Take Vital Signs in beats per minute (bpm). These may not be present at each attempted observation point if the user cancelled the operation at any point, or the software did not measure a pulse rate at that time.

● **Blue blobs (BR plot)** indicate the breathing rate observations made using Take Vital Signs in breaths per minute (br/min). These may not be present at each attempted observation point if the user cancelled the operation at any point, or the software did not measure a breathing rate at that time.

◇ **Grey diamonds (both plots)** indicate the average of automatic measurements made by the software without making spot-check observations using Take Vital Signs (see below).

Each grey trend point (◇) on this graph represents the average value of all collected pulse rates or breathing rates over a five minute period. Vital signs trend points are shown when measurements have been collected by the software for at least 75 seconds of the five minute period. The chart shows a period of one day to provide a balanced overview of the subject's recent state and so that

underlying trends may become apparent. Rapid, short duration changes in pulse rate or breathing rate will not appear on the trend chart.

Where no value is shown for a particular time, this may be because:

- There was too much movement in the room
- There was no subject in the room
- The Oxehealth Vital Signs device is designed to measure pulse rate and breathing rate in the ranges specified, and will not give measurements outside these ranges (see Cautions and Specification sections).



CAUTION

The **Vital Signs Trends** chart shows a summary of average vital signs to assist trend identification and cannot be used to monitor pulse rate or breathing rate. To take an accurate measurement of pulse rate or breathing rate, use Take Vital Signs, or use other means to establish vital signs.

The **Vital Signs Trends** plots have not been passed through the Vital Signs workflow therefore the readings may not have been taken from the subject and could be from another source (See cautions section of this document). As such the **Vital Signs Trends** information should not be used to inform clinical decisions.

NOTE

The chart displays data gathered from a specified room so may show data for a subject who is not the subject currently occupying that room.

Exporting a Vital Signs Trends Report

NOTE: This feature is only available on fixed screen and tablet devices

This feature allows you to export and send a **Vital Signs Trends** report to a recipient within your organisation by clicking the **Export** button situated in the top right part of the **Vital Signs Trends** screen for the selected room:



The **Choose Recipient** screen shown below will then appear prompting you to enter a recipient email address and the **Reason For Export**:

 A screenshot of a web application interface. At the top, there's a dark blue header with the "oxevision" logo, a menu icon, and the text "Observation Round" and "18 Sep 2024, 14:58". Below the header is a breadcrumb trail: "Home > Room 2 > Vital Signs Trends > Choose Recipient". The main content area is split into two columns. The left column has an "Email" section with a text input field containing "Recipient's email" and a dropdown menu showing "@oxehealth.com". Below that is a "Reason For Export" section with a warning: "Do not include personally identifiable information, e.g. names, dates of birth, etc." and a large text area with the placeholder "Type your reason here...". Below the text area, it says "Characters remaining: 255" and "This email will also be sent to the following default recipients for audit purposes: ben.underwood@oxehealth.com.". The right column has a "Summary" box with three sections: "Exporting" (Vital Signs Trends), "For" (Room 2), and "Time Period" (17 Sep 2024 - 18 Sep 2024). On the far right, there's a vertical sidebar with "Alerts 2" and "Feedback" buttons. At the bottom right of the main content area is a "Confirm Export" button.

Enter the email address you wish to send the report to in the **Email** field, and describe a reason for exporting in the **Reason for Export** field. These fields must be completed for the **Confirm Export** button to successfully send the report.

You will only be able to send the report to a recipient with an email address within your organisation, and you only need to enter the part of the email address before the '@' symbol. When you export a report, a copy may also be sent to other recipients that your organisation has chosen for audit purposes. The email address of this person will be indicated on the **Choose Recipient** screen shown above.

NOTE

Do not include any subject identifying information in the **Reason For Export** section, e.g. names, date of births.

To cancel this action from the **Choose Recipient** screen, click the **Vital Signs Trends** button to return to the **Vital Signs Trends** screen or the **Home** button to return to the **Overview** screen.

When you are ready to export the report, click the **Confirm Export** button. A message will appear which reads "Submitted. A report email will be with you in the next 5 minutes". as shown below:

The screenshot shows the Oxevision interface for the 'Choose Recipient' step. At the top, the breadcrumb trail is 'Home > Room 2 > Vital Signs Trends > Choose Recipient'. A green notification banner at the top states: 'Submitted. A report email will be with you in the next 5 minutes'. Below this, the 'Email' section has a text input field containing 'recipient.email' and a dropdown menu showing '@oxehealth.com'. The 'Reason For Export' section includes a warning: 'Do not include personally identifiable information, e.g. names, dates of birth, etc.' and a text input field with 'reason for export'. Below the input field, it says 'Characters remaining: 237' and 'This email will also be sent to the following default recipients for audit purposes: some.email@oxehealth.com'. On the right, a 'Summary' box displays: 'Exporting: Vital Signs Trends', 'For: Room 2', and 'Time Period: 17 Sep 2024 - 18 Sep 2024'. A 'Confirm Export' button is located at the bottom right. On the far right, there is a vertical sidebar with 'Alerts 2' and 'Feedback' buttons.

NOTE

Limitation on email size means that users should limit the number of rooms to export to no more than 15 rooms for 10 days or in other words, 150 room-days of information in one export.

If you are operating a mobile device and this has lost connection to WiFi, or the system encounters other errors attempting to send the email, you will see an error message as shown below:

The screenshot shows the Oxevision interface for exporting Vital Signs Trends. At the top, the breadcrumb trail is Home > Room 2 > Vital Signs Trends > Choose Recipient. The date and time are 18 Sep 2024, 15:04. A red error banner at the top states: "Email failed. Please try again. Contact Oxehealth at support@oxehealth.com or 0800 030 6781". Below this, the "Email" field contains "recipient.email" and "@oxehealth.com". The "Reason For Export" field contains "reason for export". A summary box on the right shows: "Exporting: Vital Signs Trends", "For: Room 2", and "Time Period: 17 Sep 2024 - 18 Sep 2024". A "Confirm Export" button is at the bottom right. On the far right, there are vertical buttons for "Alerts 2" and "Feedback".

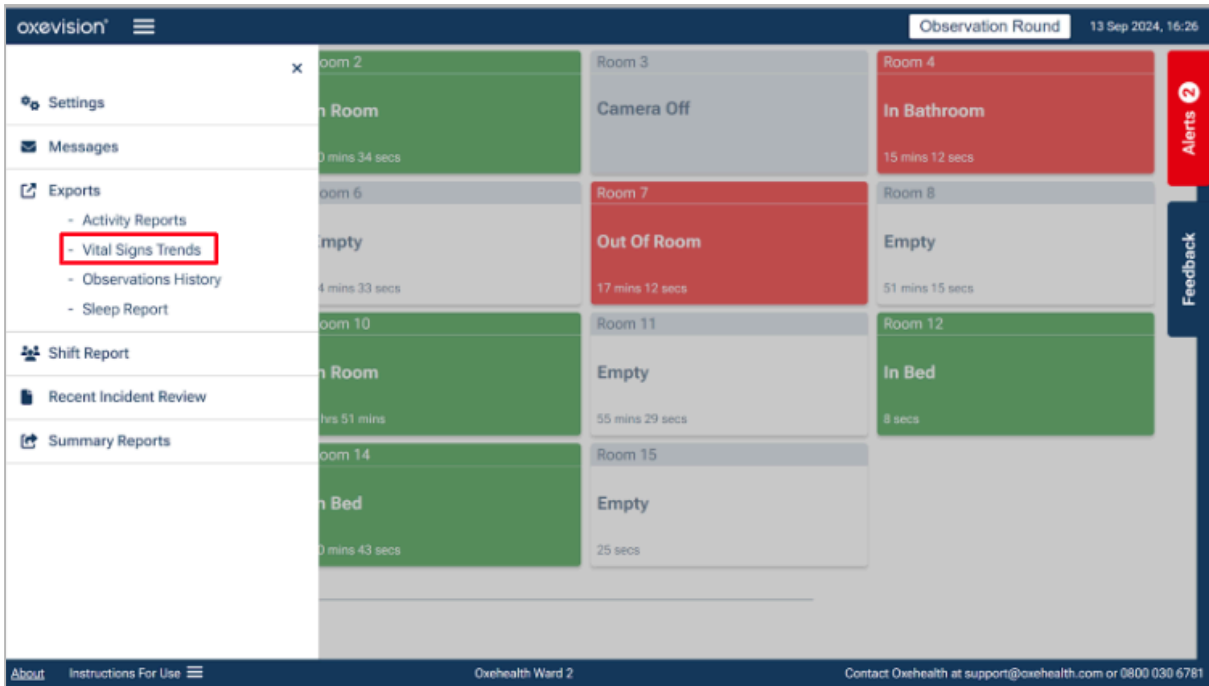
To ensure the reports can be sent, move to a place where your mobile device has a good Wifi connection and click **Confirm Export** again. If the problem persists, please contact Oxehealth using the details on the screen.

Once successful, an email will be sent to the address you provided, with the report attached as a PDF file. An additional copy of the report will also be sent to the other email addresses shown on the screen for audit purposes. The Vital Signs Trends Report will contain one page per day for the selected room.

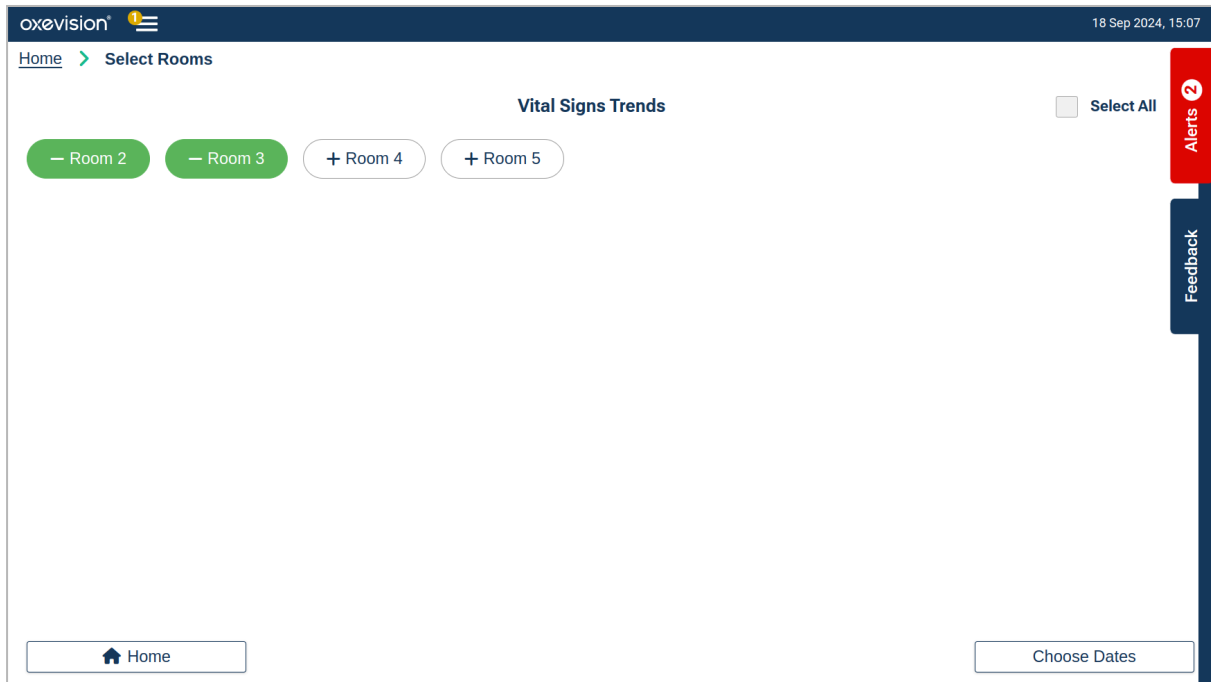
Emails will be received by the recipient, and default recipient(s) for the device group, within 5 minutes.

If you have not completed the **Email** and **Reason for Export** fields, error messages will be shown and the report will not be sent. After successfully exporting, you will then be returned to the **Overview Screen**.

Alternatively, you can export Vital Signs Trends Reports for a number of rooms over a selected date range by clicking the **Menu**, then **Vital Signs Trends** in the navigation menu on the **Overview Screen**:



You will then see the **Select Rooms** screen shown below, allowing you to choose multiple rooms to export the reports for:



All rooms available to the device will be shown as multi-select options on the **Select Room** page. One or more rooms can be selected by clicking on the room name button. Clicking the **Select All** checkbox will select all rooms available. Selected rooms will be displayed in a solid (green) colour. Unchecking the **Select All** checkbox will deselect all rooms.

The **Choose Dates** button will be disabled until at least one room is selected.

To go back to the **Exports** screen to change the reports being exported, click the **Exports** button at the top left.

After selecting the rooms you would like to export Vital Signs Trends Reports for, click **Choose Dates**, and you will then see the **Choose Dates** screen shown below:

oxevision 18 Sep 2024, 15:07

Home > Select Rooms > Choose Dates

You are exporting Vital Signs Trends Reports for 2 Rooms

Start End

[Home](#) [Choose Recipient](#)

Alerts 2
Feedback

The time frame for the export can be selected using the **Start** and **End** date dropdown boxes from the **Choose Dates** screen.

The **Choose Recipient** button will be disabled until at least one date is selected.

The maximum date range is 14 days. If invalid dates are selected, an error message will be displayed and the **Choose Recipient** button will continue to be inactive.

To go back to the **Select Rooms** screen to change the rooms being exported, click the **Select Rooms** button at the top left.

Once you have selected the date range you would like to export, click the **Choose Recipient** button and you will then see the **Choose Recipient** screen below:

The screenshot shows the 'Choose Recipient' interface. At the top, the breadcrumb trail is 'Home > Select Rooms > Choose Dates > Choose Recipient'. The 'Email' section has a text input field with 'Recipient's email' and a dropdown menu showing '@oxehealth.com'. Below this is the 'Reason For Export' section, which includes a warning: 'Do not include personally identifiable information, e.g. names, dates of birth, etc.' and a text area with the placeholder 'Type your reason here...'. A character count shows 'Characters remaining: 255' and a note: 'This email will also be sent to the following default recipients for audit purposes: some.email@oxehealth.com.'. On the right, a 'Summary' box displays: 'Exporting: Vital Signs Trends', 'For: Room 2, Room 3', and 'Time Period: 17 Sep 2024 - 18 Sep 2024'. At the bottom, there is a 'Home' button on the left and a 'Confirm Export' button on the right. A vertical sidebar on the far right contains 'Alerts 2' and 'Feedback' buttons.

Enter the email address you wish to send the reports to in the **Email** field, and describe a reason for exporting in the **Reason for Export** field. These fields must be completed for the **Confirm Export** button to successfully send the reports.

You will only be able to send the report to a recipient with an email address within your organisation, and you only need to enter the part of the email address before the '@' symbol. When you export a report, a copy may also be sent to other recipients that your organisation has chosen for audit purposes. The email address of this person will be indicated on the **Choose Recipient** screen shown above.

NOTE

Do not include any subject identifying information in the **Reason For Export** section, e.g. names, date of births.

To go back to the **Choose Dates** screen to change the dates being exported, click the **Choose Dates** button at the top left. To cancel this action from the **Choose Recipient** screen, click the **Home** button to return to the **Overview screen**.

A summary of the export is displayed on the right of the **Choose Recipient** screen which shows details of:

- **Exporting** - The type of report being exported;
- **For** - The rooms selected and;
- **Time period** - The time frame selected.

The export options can be edited by selecting the edit icons within the Summary section. Selecting an edit icon will return you to the respective Exports, Select Rooms or **Choose Dates** screens. Follow the earlier instructions for editing the information on these screens.

When you are ready to export the report, click the **Confirm Export** button. A message will appear which reads “Submitted. A report email will be with you in the next 5 minutes” as shown below:

oxevision 18 Sep 2024, 15:11

Home > Select Rooms > Choose Dates > Choose Recipient

Submitted. A report email will be with you in the next 5 minutes

Email
recipient.email @oxehealth.com

Reason For Export
Do not include personally identifiable information, e.g. names, dates of birth, etc.
reason for export
Characters remaining: 238
This email will also be sent to the following default recipients for audit purposes: some.email@oxehealth.com.

Summary

Exporting
Vital Signs Trends

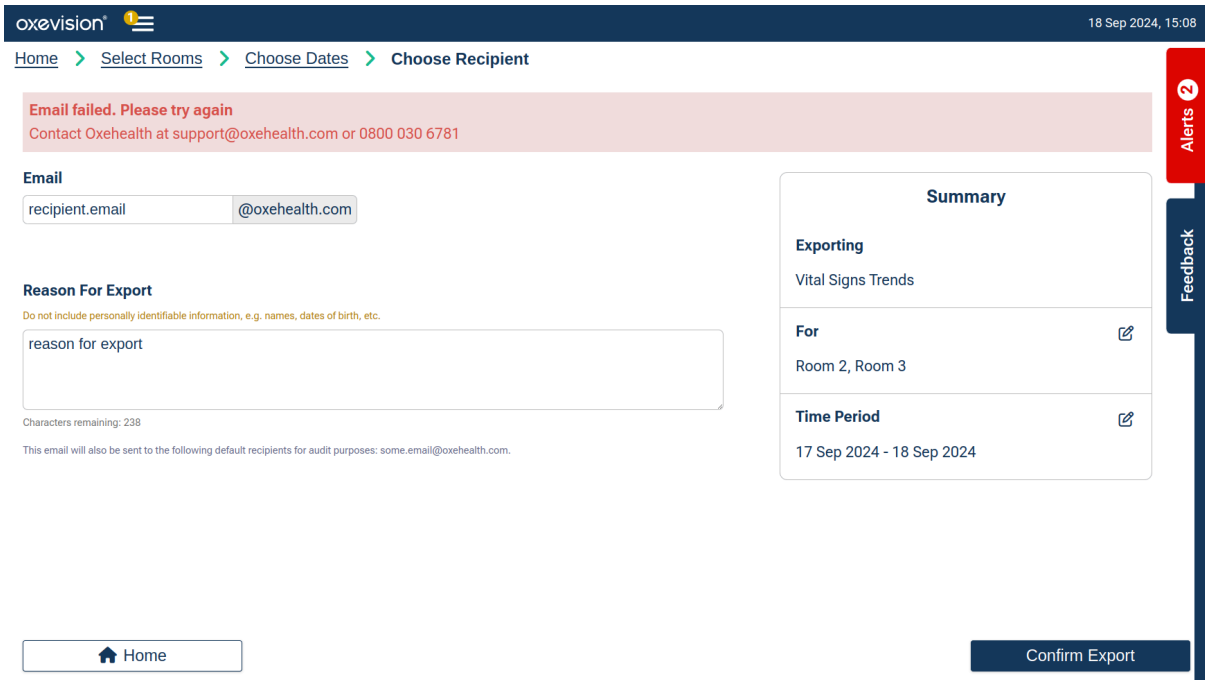
For
Room 2, Room 3

Time Period
17 Sep 2024 - 18 Sep 2024

Home Confirm Export

Alerts 2
Feedback

If you are operating a mobile device and this has lost connection to WiFi, or the system encounters other errors attempting to send the email, you will see an error message as shown below:



To ensure the reports can be sent, move to a place where your mobile device has a good Wifi connection and click Confirm Export again. If the problem persists, please contact Oxehealth using the details on the screen.

Once successful, an email will be sent to the address you provided, with the reports attached as individual PDF files (one per room). An additional copy of this email will also be sent to the other email addresses shown on the screen for audit purposes. Each Vital Signs Trends Report will contain one page per day for one room.

Emails should be received by the recipients, and default recipient(s) for the device group, within 5 minutes.

If you have not completed the **Email** and **Reason for Export** fields, error messages will be shown and the report will not be sent. After successfully exporting, you will then be returned to the **Overview Screen**.

Pausing Rooms

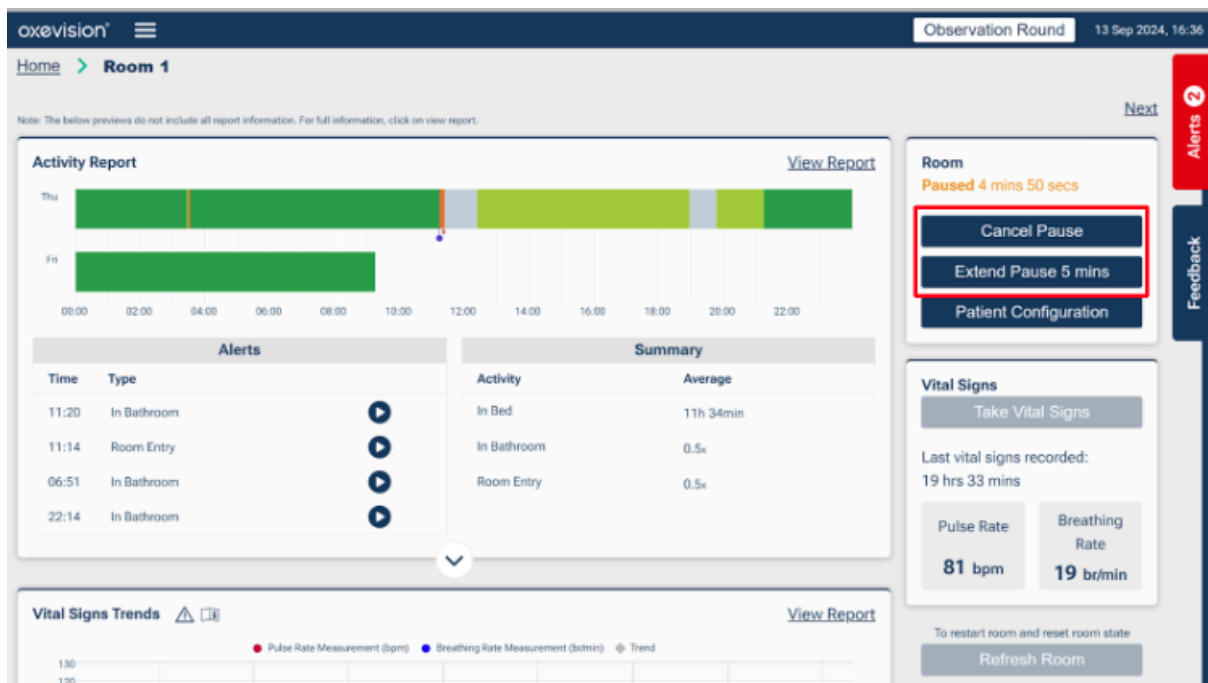
To pause any room, click the room icon for the room the subject is in, then select **Pause for 15 Minutes** from the **Room Dashboard**.

NOTE

The duration of the pause may not be 15 minutes if the default pause duration for this room has been changed. For instance, if the default pause duration has been changed to 45 minutes, the button will read **Pause for 45 Minutes**.

Extending and Cancelling a Pause

If you want to keep a room paused, or cancel the action and reconnect the room, click the room icon for the room the subject is in, and the **Room Dashboard** will look as it does below:



To Cancel the pause and reconnect the room, click **Cancel Pause**.

To extend the pause for another 15 minutes, click **Extend Pause 15 Minutes**. The room will now remain paused for the time that previously remained, plus the time added.

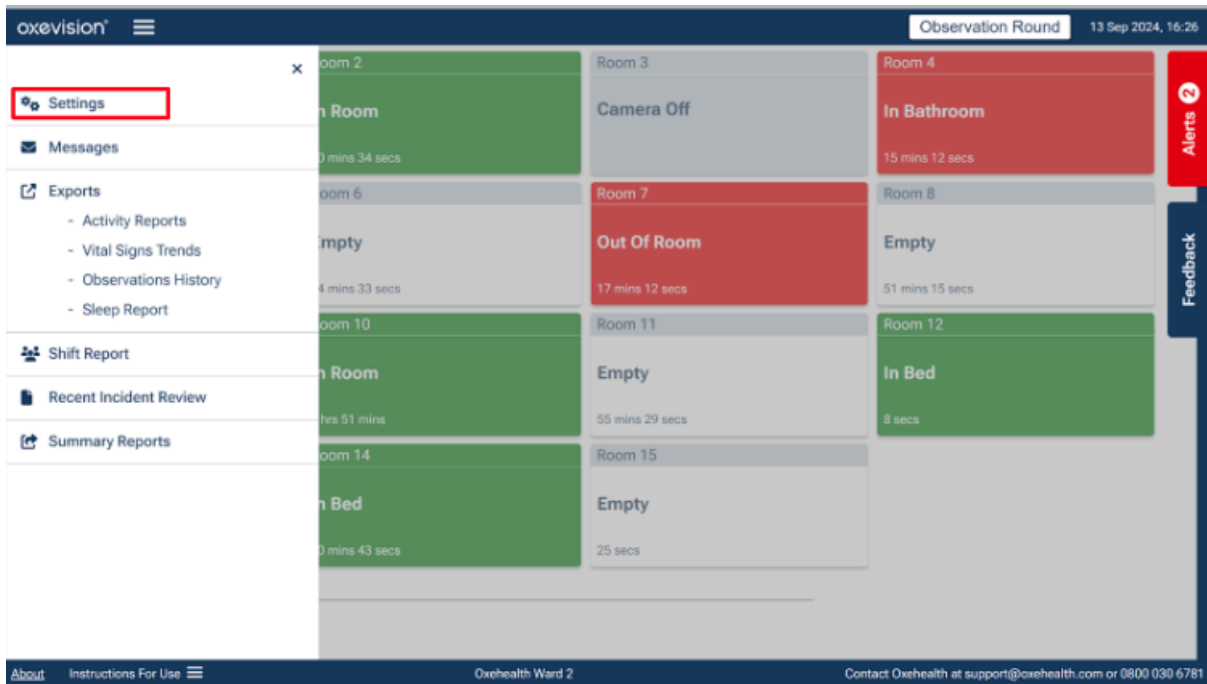
Click **Home** to return to the **Overview screen**.

NOTE

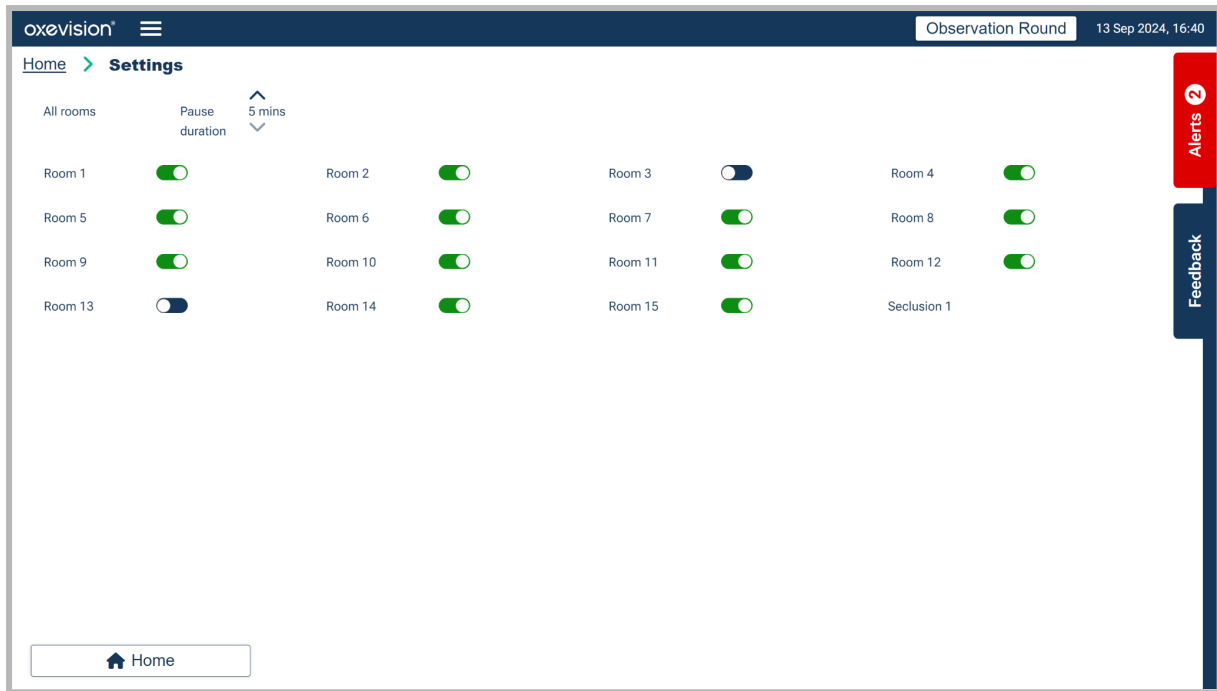
The extension of the pause may not be 15 minutes if the default pause duration for this room has been changed. For instance, if the default pause duration has been changed to 45 minutes, the button will read **Extend Pause 45 Minutes**.

Changing Room Settings

To enable or disable Oxehealth Vital Signs device processing in any of the rooms, or change the default pause duration, Click the **Settings** link from the Navigation Menu.





You will then be shown the **Settings** screen below:



On the settings screen, you can control which rooms are on and off, and set the default pause duration.

This screen shows the on or off status for each room, which is operated as follows:

<p>Room 1 </p>	<p>The room is chosen to be switched on, such that the Oxehhealth Vital Signs device software is receiving video, and making estimations for this room.</p> <p>To turn the room off (stop the software from running, such that the software is not receiving or processing video), click the green toggle switch. The toggle switch should then look like the picture below.</p>
<p>Room 1 </p>	<p>The room is chosen to be switched off, such that the Oxehhealth Vital Signs device software is not receiving video, or making estimations for this room.</p> <p>To turn the room on (start the software, such that the software is receiving and processing video), click the black toggle switch. The toggle switch should then look like the picture above.</p>

To change the **Default Pause** duration, click the up arrow above the pause duration to increase the pause duration **minutes** and click the down arrow below the pause duration to decrease the pause duration **minutes**.

Click **Home** to return to the **Overview screen**.

Sending Feedback to Oxehealth

To send feedback of any sort to Oxehealth, click the **Feedback** tab in the top right corner of the screen. You will then see the **Feedback screen** below:

The screenshot displays the Oxehealth interface. On the left, a grid of room status cards is visible, with Room 6 in an 'Acquiring' state and others in 'In Room' states. On the right, the 'Feedback' form is active, featuring input fields for 'Name', 'Contact number', and 'Feedback Type', a large text area for 'Message', and 'Clear' and 'Send' buttons. A disclaimer note is present: 'Do not include personally identifiable information, e.g. names, dates of birth, etc.'

Select the **Feedback Type** (if this is available) and fill in the **Name**, **Contact Number** and **Message** text field with the information you would like to share, your issues, suggestions or questions and click **Send** to send the information to Oxehealth. Please provide your name and contact details, as this will help a support representative to contact you if you require assistance. We will then receive your message automatically, and the Feedback form will be closed.

The screenshot shows the Oxevision interface. At the top left is the 'oxevision' logo and a menu icon. At the top right is the date and time '18 Sep 2024, 15:14'. The main area is a grid of 16 room cards. Room 6 is greyed out and labeled 'Acquiring' with a timer of '13 mins 51 secs'. Rooms 7, 8, 10, 11, 12, 14, 15, and 16 are green and labeled 'In Room' with a timer of '13 mins 50 secs'. On the right side of the grid are two vertical tabs: 'Alerts' (top) and 'Feedback' (bottom). The 'Feedback' tab is active, and a white feedback confirmation box is overlaid on the right side of the screen. The box contains a green checkmark icon, the text 'Thank you!', and 'Your feedback has been sent to Oxehealth.' At the bottom of the interface is a dark blue footer with links for 'About', 'Instructions For Use', 'R12', and 'Contact Oxehealth at support@oxehealth.com or 0800 030 6781'.

If you do not wish to send feedback, click on the **Feedback tab** and the feedback form will close



CAUTION

Do not include any subject identifying information in the feedback, e.g. names, date of births.

Manufacturer



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