

Instructions For Use For

Oxehealth Vital Signs

en-us English





For use with Oxehealth Vital Signs versions:

1.45 to 1.60

Table of Contents

Table of Contents	2
Symbols Used In This Manual And On Product Labels	3
Instructions For Use For Oxehealth Vital Signs	3
Intended Use	3
Warnings	4
Cautions	4
Specification	6
Installation	6
Maintenance	6
How To Use Oxehealth Vital Signs	7
The Overview Screen	7
Taking Vital Signs Observations	12
Viewing Vital Sign Observation History	18
Pausing Measuring	19
Extending and Cancelling a Pause	19
Rooms Settings	20
Sending Feedback to Oxehealth	21
Manufacturer	21

Symbols Used In This Manual And On Product Labels

	Read the instructions for use		Caution
	Manufacturer		Date of manufacture
R _x Only	Prescription only		

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 estimated breathing rate (chest wall movements).

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



CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a licensed healthcare practitioner.



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 and you may also inform the FDA.

For details of how to inform the FDA of an adverse incident, please visit <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>

Intended Use

The Oxehealth Vital Signs device is intended for noninvasive spot measurement of pulse rate and estimated breathing rate (chest wall movements) when the subject is still. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care 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 18 years of age or older who do not require critical care or continuous vital signs monitoring.

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 rooms 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.



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 the user interface or at the telephone number or address given at the end of this manual.

The Oxehealth Vital Signs device is designed to measure pulse rate and estimated breathing rate (chest wall movements) 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 Oxehealth Vital Signs device
- 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 estimated breathing rate (chest wall movements) in the following circumstances:

- Where insufficient body area is visible to the Oxehealth Vital Signs device
- If the area of the subject is heavily saturated due to exceptionally bright illumination

Oxehealth Vital Signs may not give measurements of pulse rate or estimated breathing rate (chest wall movements), or may give inaccurate measurements of pulse rate or estimated breathing rate (chest wall movements), 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 Vital Signs camera, caused for example by drilling into a nearby structure at the time of the measurement.

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

Oxehealth Vital Signs is not intended to give pulse rate or estimated breathing rate (chest wall movements) measurements if a subject is moving. In situations where a subject is moving when you are preparing to take pulse rate or estimated breathing rate (chest wall movements) measurements, do not proceed, but use other methods, or ensure that the subject is still before attempting to use Oxehealth Vital Signs to obtain pulse rate and estimated breathing rate (chest wall movements) measurements. Failure to do so may result in you obtaining no measurement or an inaccurate measurement.

Oxehealth Vital Signs measures pulse rate and estimated breathing rate (chest wall movements) from the skin and the body of a subject, and you must ensure that Oxehealth Vital Signs is reading from suitable areas of the body before proceeding to take measurements. Failure to do so may result in inaccurate measurements.

Please be aware 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 estimated breathing rate (chest wall movements) from the subject, and so obstruction of either of these parts of the device will severely compromise its operation.

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.

Specification

	Accuracy	Measurement Window
Pulse rate measurement*	50 to 130 \pm 3 beats per minute	9 seconds
Estimated breathing rate (chest wall movements) measurement*	8 to 31 \pm 2 breaths per minute	30 seconds

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

Pulse rate accuracy may be reduced when the subject has a pulse rate greater than 110 beats per minute.

Installation

Installation will be carried out by an Oxehealth trained 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 estimated breathing rate (chest wall movements) of a subject. Hardware is often installed within a housing and so the cleanliness of the housing must be maintained. When cleaning, pay attention to the manufacturer's instructions for cleaning, and in particular, do not use solvent based, ammonia, caustic or abrasive cleaners or abrasive cleaning materials on the clear front, as this may scratch or fog the material, and potentially degrade the ability of the device 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.



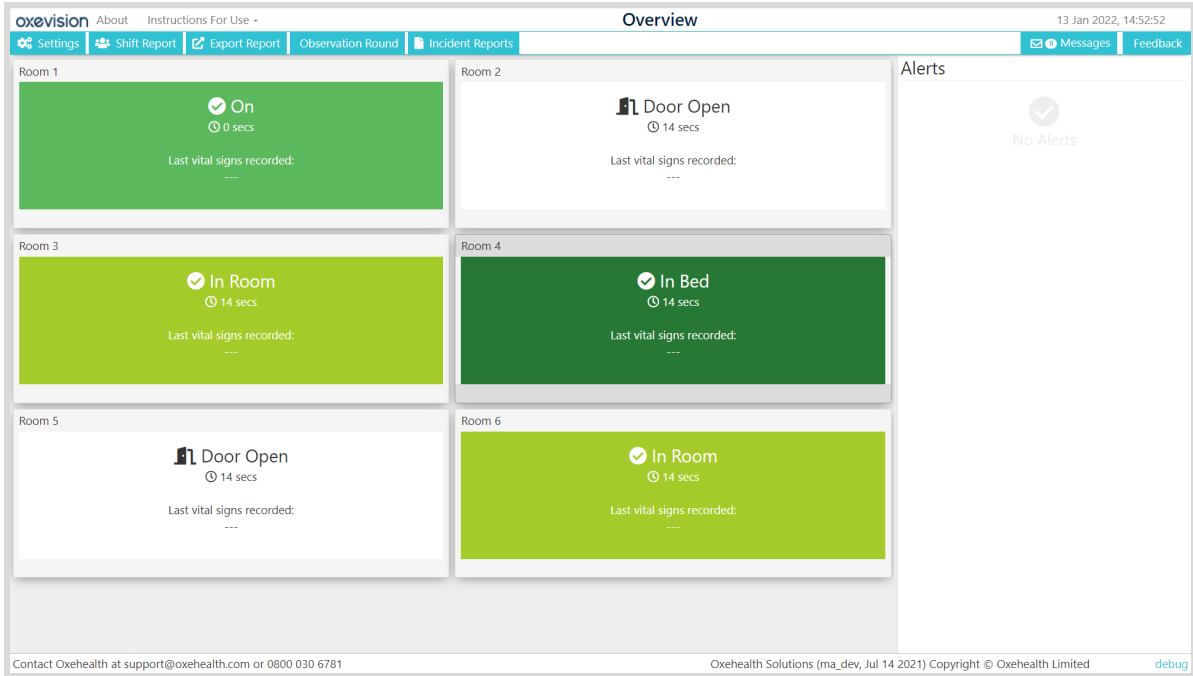
IMPORTANT SAFETY AND SECURITY NOTICE - please read carefully

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 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.

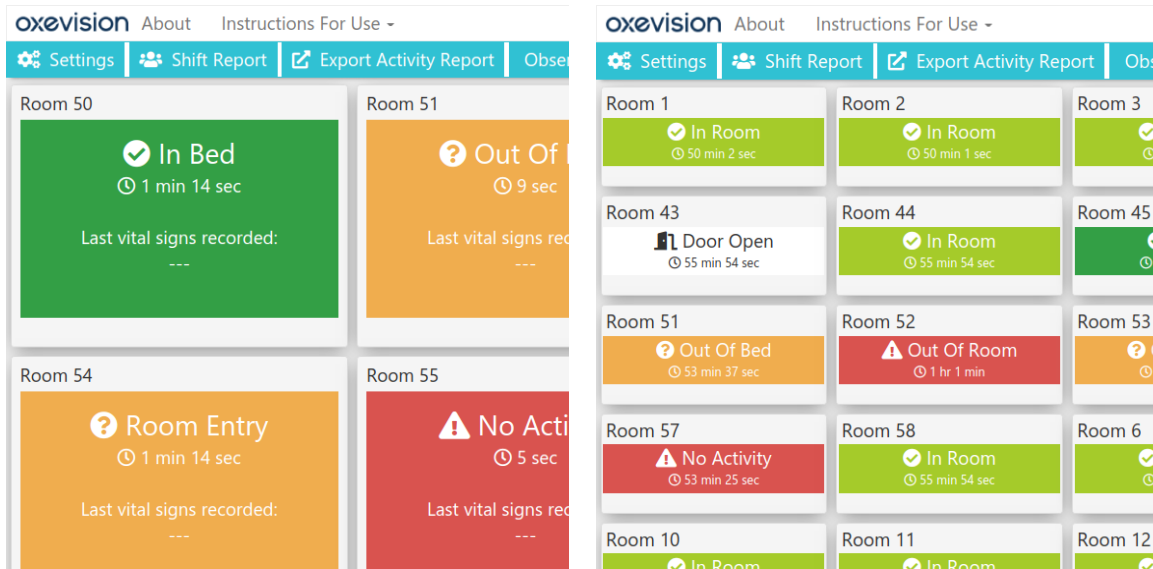
How To Use Oxehealth Vital Signs

The Overview Screen

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



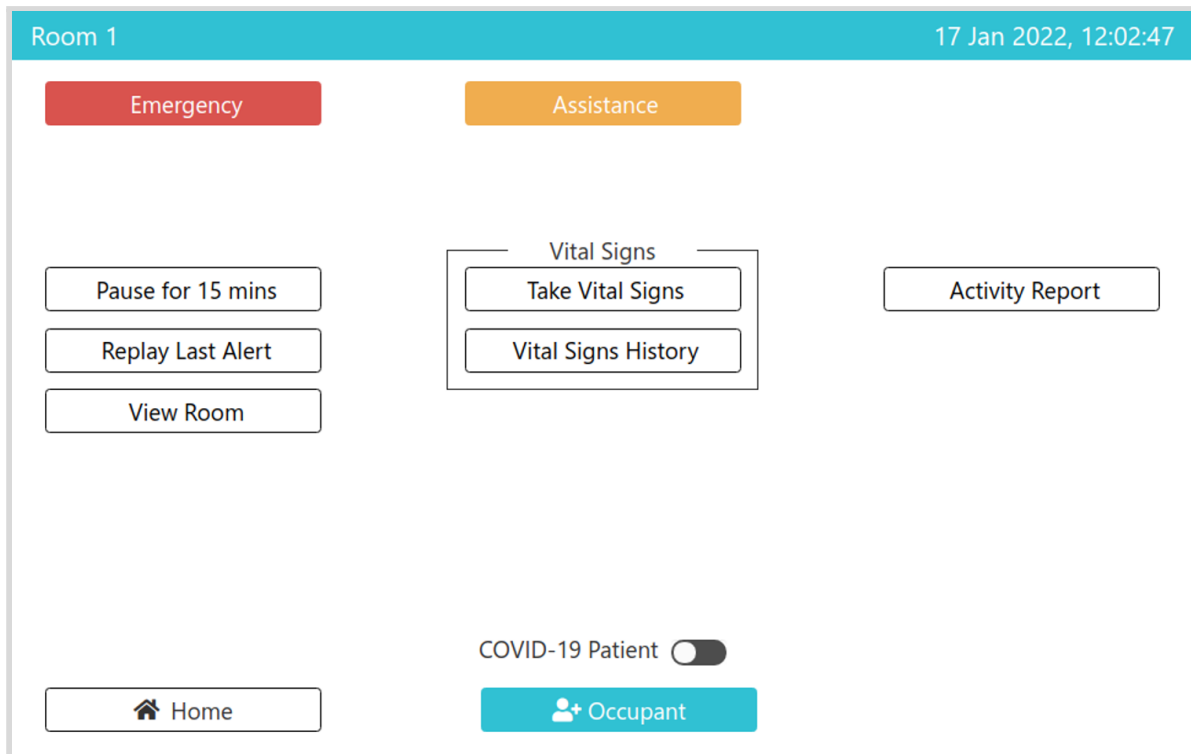
Depending on the number of rooms, the overview screen will show smaller panels for each room as shown below to keep all of the rooms visible:



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 cards.

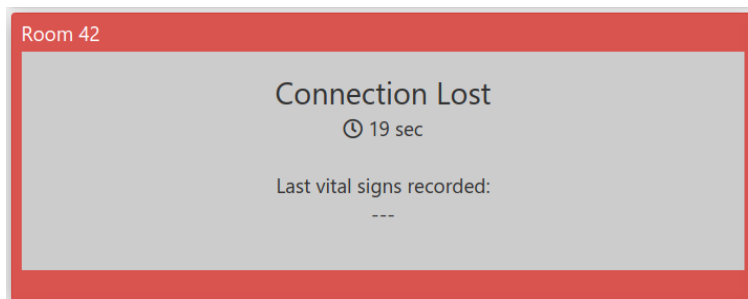
Each room is shown as a clickable panel, which brings up the room **Action Menu** for that room:



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

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

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

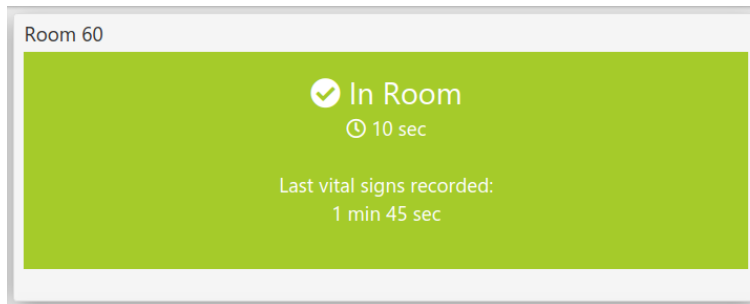


The main text in the room icon will display the nature of any software disconnection, and the time that the connection has been down.

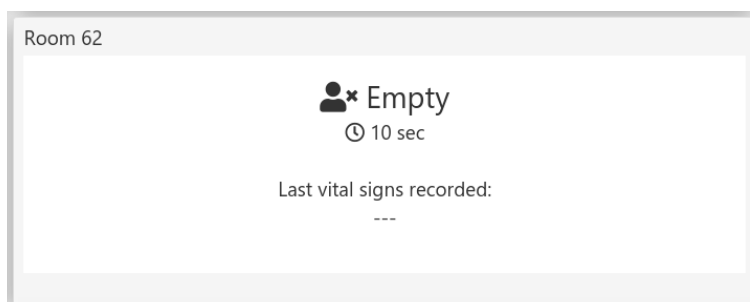
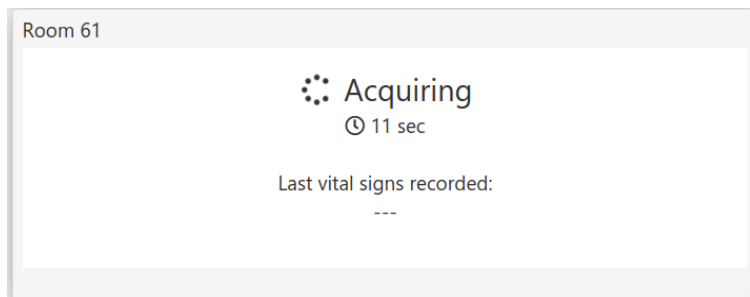
The **Last vital signs recorded** text on the room icon will continuously update, and indicates how long it has been since anyone last used the **Take Vital Signs** function successfully for this room.

In this state, it will not be possible to use the **Vital Signs History**, **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 color 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.

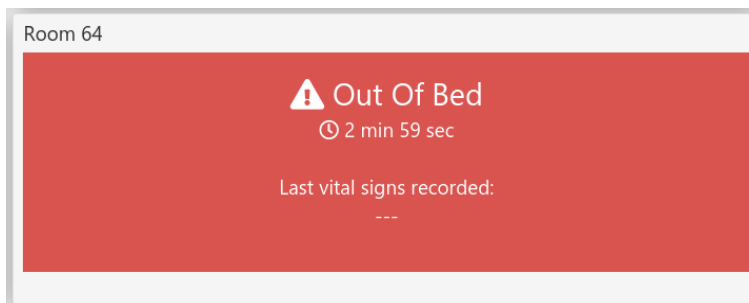
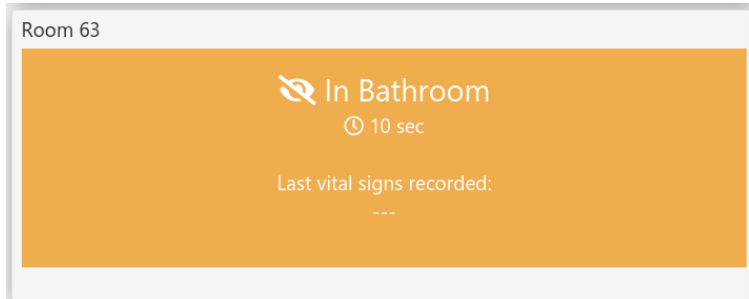
IMPORTANT - please read carefully

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 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 History** 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.

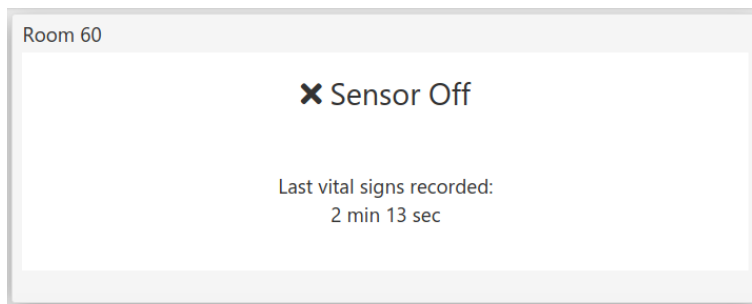
IMPORTANT - please read carefully

When other Oxehealth product modules are producing an alert, 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 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 History** functions on the **Action Menu**.

- **Sensor 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.

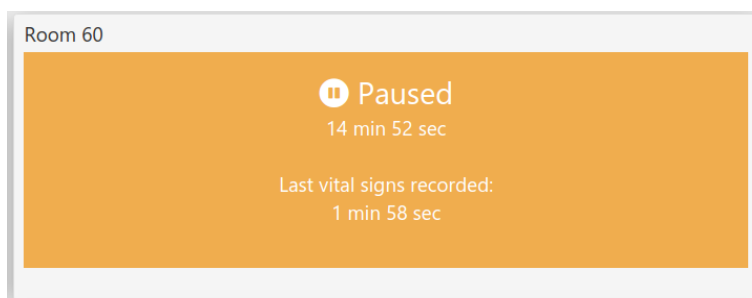


The timer indicates the time that the software has been stopped for the room.

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 History** function 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 **Paused for** text on 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 History** 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 asks 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 you do not wish to proceed for any reason, click **Cancel**, and you will return to the **Overview screen**.



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




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 an estimated breathing rate (chest wall movements) 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:

Room 43
Take Vital Signs
14 Jan 2022, 17:10:23



14 Jan 2022, 17:10:21 Paused

Room 43

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

Home

[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 rate (chest wall movements) and pulse rate as colored 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 estimated breathing rate (chest wall movements), 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.

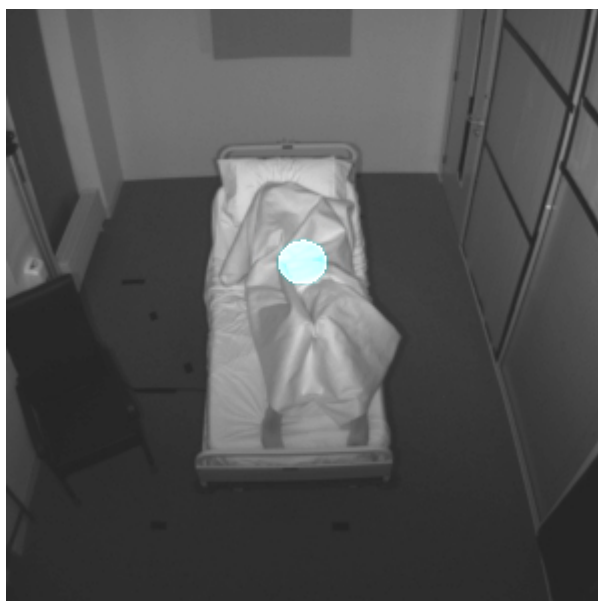


CAUTION

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 an estimated breathing rate (chest wall movements) 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:

Room 43 Take Vital Signs 14 Jan 2022, 17:10:26

Room 43

Pulse Rate:
74 bpm

Breathing Rate:
22 br/min

Vital Signs taken at: 14 Jan 2022, 17:10:20

Done

14 Jan 2022, 17:10:21 Paused

Home

CE 2797 About Vital Signs

The video of the room will remain paused, and you will see the Oxehealth Vital Signs estimated breathing rate (chest wall movements) 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 estimated breathing rate (chest wall movements) 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 an estimated breathing rate (chest wall movements) at the time that the video recording was paused.)

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

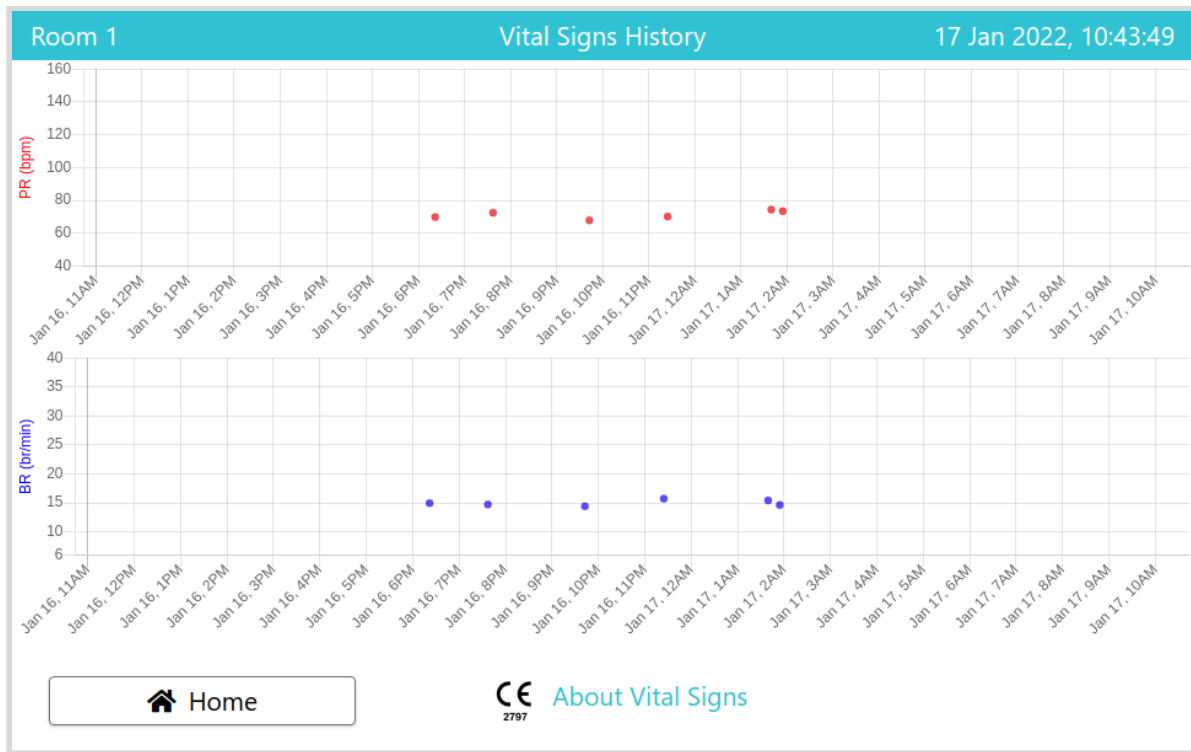
NOTE

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 Sign Observation History

To view the history of vital signs observations you have taken from a room, click the room icon, then select **Vital Signs History** from the **Action Menu**. You will then see the **Vital Signs History** screen below:



The History of vital signs observations for the room is illustrated on the graphs as follows:

Red blobs (PR plot) indicate the pulse rate observations made 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 estimated breathing rate (chest wall movements) observations made 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 an estimated breathing rate (chest wall movements) at that time.

The history chart shows 24 hours of readings as its default setting. This is configurable and your Oxehealth trained installer can change this at install or a later date.

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.

Pausing Measuring

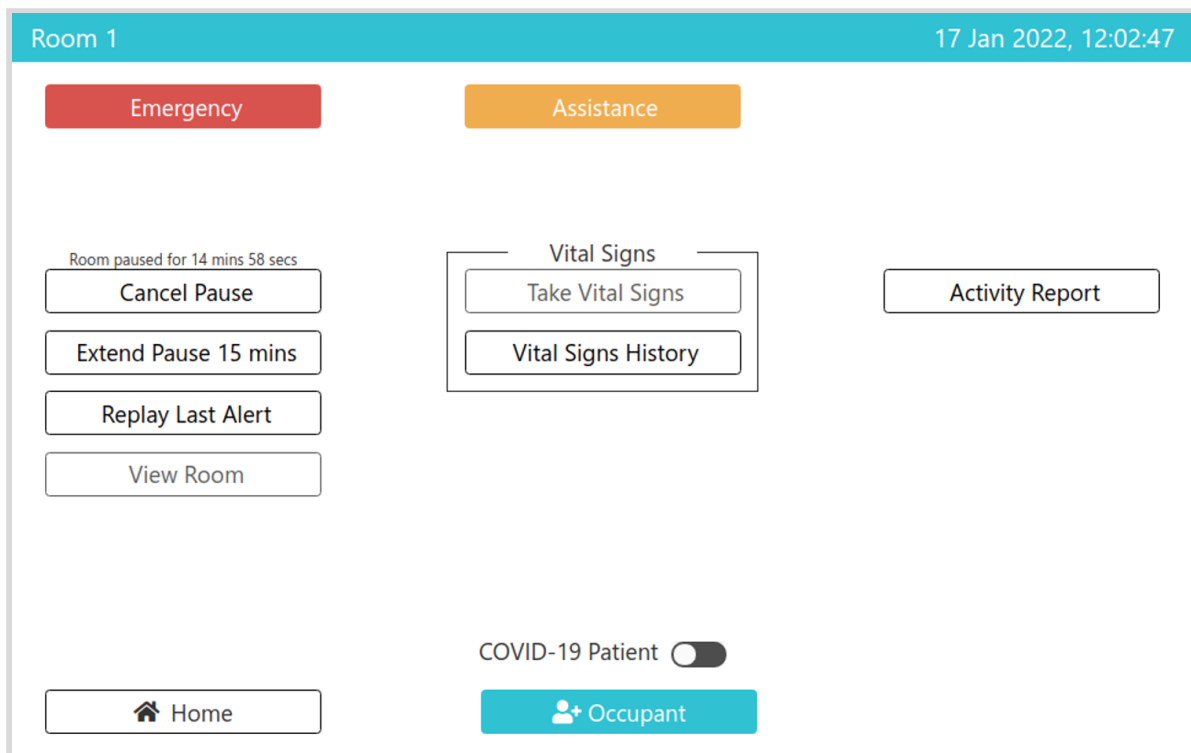
To pause measuring in any room, click the room icon for the room the subject is in, then select **Pause for 15 Minutes** from the **Action Menu**.

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.

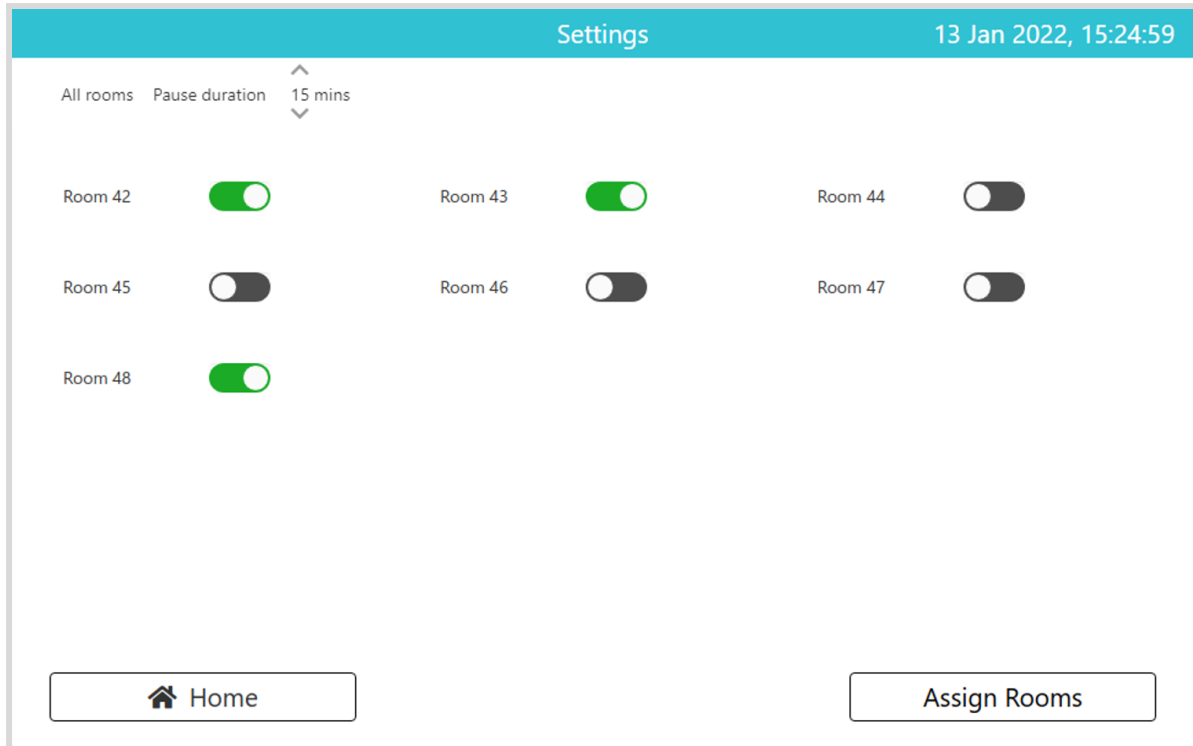
Click **Home** to return to the **Overview screen**.

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**.

Rooms Settings

To enable or disable Oxehealth Vital Signs device processing in any of the rooms, or change the default pause duration, Click the **Settings** button in the top left corner of the screen. 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 **Is the system switched on?** status for each room:

<p>Room 1 System <input checked="" type="checkbox"/></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 <input type="checkbox"/></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 **Back or Home** to return to the **Overview screen**.

Sending Feedback to Oxehealth

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

Feedback

Name	Contact email
<input type="text" value="Enter your name"/>	<input type="text" value="name@example.com"/>
Feedback Type	
<input type="text" value="General query"/>	
Do not include personally identifiable information, e.g. names, dates of birth, etc.	
Message	
<input type="text" value="Enter your message here"/>	
<input type="button" value="Home"/>	<input type="button" value="Send Feedback"/>

Fill in the 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. We will then receive your message automatically, and you will be returned to the **Overview screen**.

If you do not wish to send feedback, click **Home** and you will be returned to the **Overview screen**.



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: +44(0)800 030 6781

Website: www.oxehealth.com

