

Oxehealth

Instructions For Use For

Oxehealth Vital Signs

For use with Oxehealth Vital Signs versions:





1.14 to 1.19



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Symbols Used In This Manual

	<p>Read the instructions for use</p>		<p>Caution</p>
	<p>Manufacturer</p>		<p>CE Marking, made in conformance with EC Directive 93/42/EEC for medical devices</p>

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 Solution platform. For instructions on how to use other product modules within the Oxehealth Solution platform, refer to other instructions for use for those features.

Intended Use

The Oxehealth Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate¹. It is a fixed-installation device for use within single occupancy rooms within hospitals, general care, domestic and secured environments where a framework exists which mandates periodic checks by a trained professional to ensure subject safety.

The Oxehealth Vital Signs device is indicated for use on adults and adolescents² with all skin types, who do not require critical care.



Contraindications

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



Warnings

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 breathing rate in the ranges specified, and will not give accurate measurements outside these ranges.

¹ Please note that pulse rate and heart rate are used interchangeably in this and other Oxehealth documentation.

² 12 years and older, under 18 years

Oxehealth Vital Signs may not give measurements of pulse rate as specified 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 breathing rate as specified 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
- When the area to be observed contains a large number of high contrast features (e.g. highly patterned wallpaper, numerous ornaments or pictures). The installation validation procedure will identify where this may be the case.

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

- In subjects with tremor, alcohol withdrawal or motion disorders
- In subjects with pronounced sleep apnea or who are deliberately controlling their breath to make breathing observations difficult
- 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.

Oxehealth Vital Signs is not intended to give pulse rate or breathing rate measurements if a subject is moving. In situations where a subject is moving when you are preparing to take pulse rate or breathing rate 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 breathing rate measurements. Failure to do so may result in unreliable or inaccurate measurements.

Oxehealth Vital Signs measures pulse rate and breathing rate 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 unreliable or inaccurate measurements.

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.

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

Pulse rate measurement*	50 to 130 \pm 3 beats per minute
Breathing rate measurement*	8 to 39 \pm 2 breaths per minute

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

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 breathing rate of a subject. It is installed within a housing and so the cleanliness of the device housing must be maintained. The device housing is rated against the ingress of water, so it can be cleaned with warm soapy water. Do not use caustic or abrasive cleaners or abrasive cleaning materials on the glass front, as this may scratch the glass, 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, switch off the Oxehealth device 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

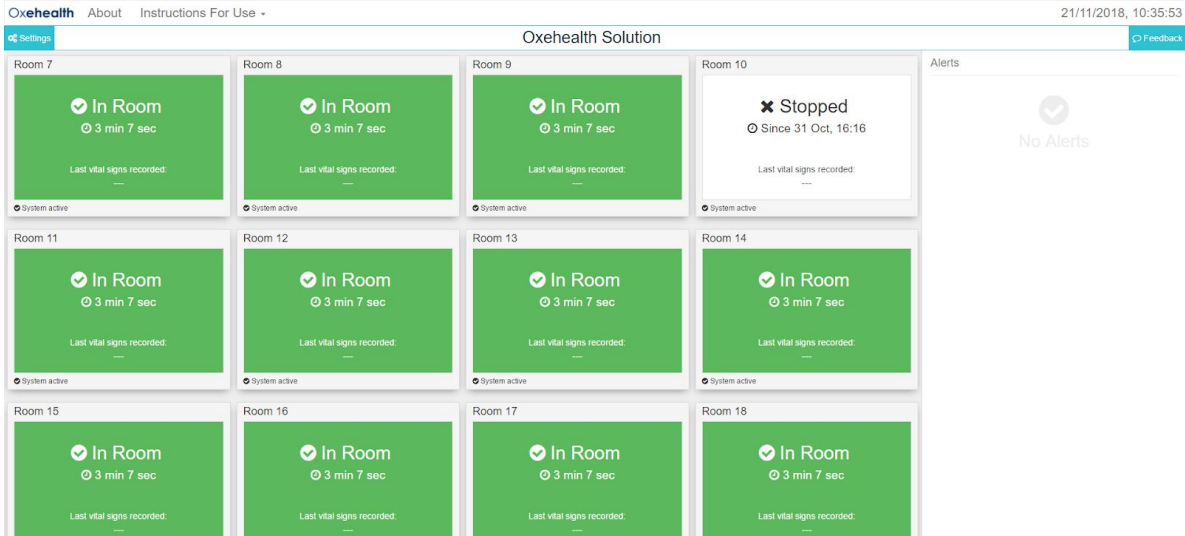
Maintaining the privacy of subjects, and protecting the confidentiality of their data is of the utmost importance. Ensure that you observe all of your organisation's safety and security policies and guidelines, and do not relocate any equipment that has been installed for the Oxehealth software, or change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

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.

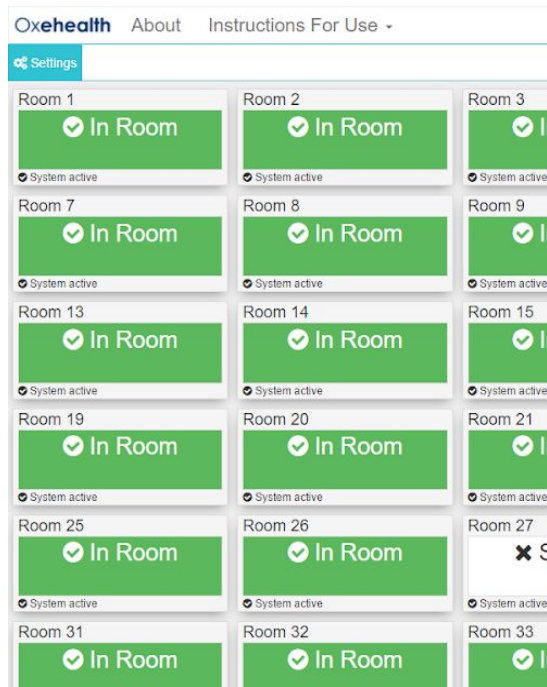
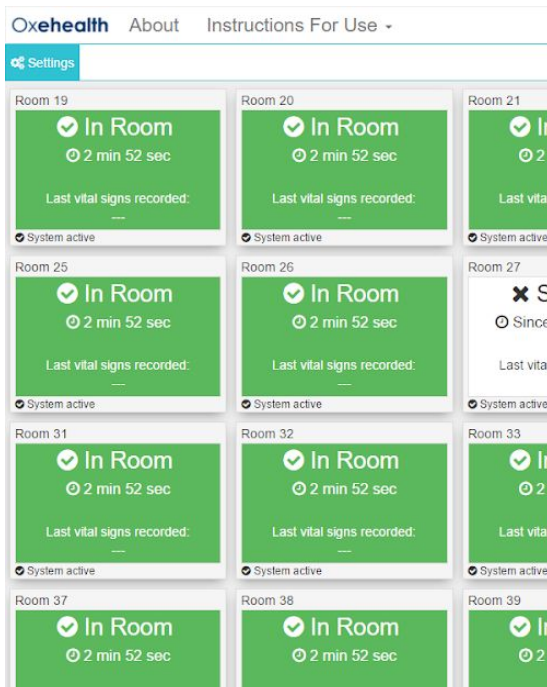
How To Use Oxehealth Vital Signs

The Overview Screen

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



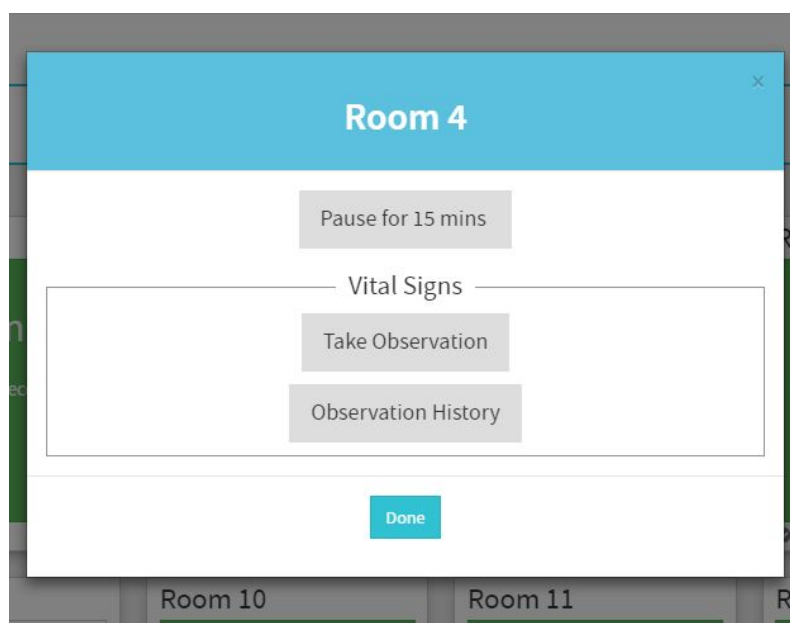
Depending on the number of rooms, the overview screen will show smaller panels for each room as shown below to keep all of the rooms visible:



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.

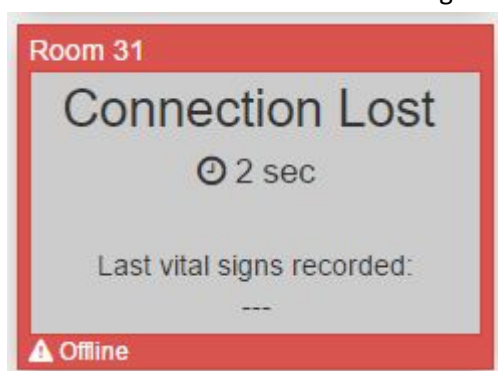
Each room is shown as a clickable panel, which brings up the room **Action Menu** for that room:



The **Action Menu** may include other menu items for other product modules (refer to other Oxehealth Solution 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.

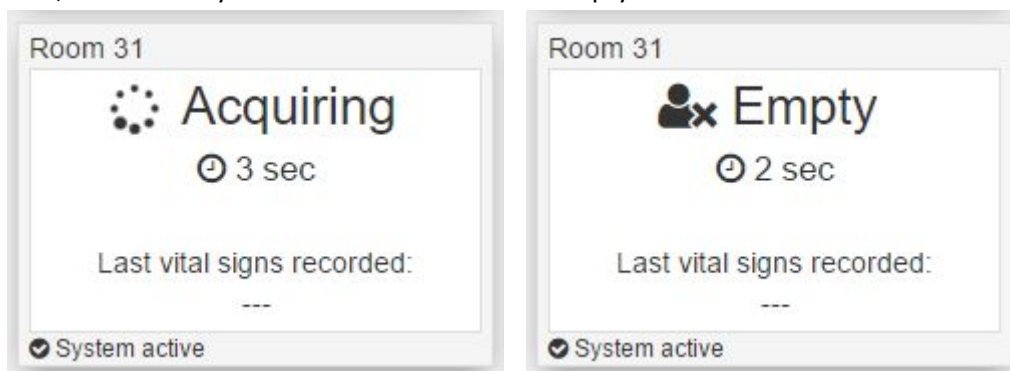
The **Last vital signs recorded** text on the room icon will continuously update, and indicates how long it has been since anyone last used the **Take Observation** function successfully for this room.

In this state, it will not be possible to use the **Observation History**, **Take Observation** 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

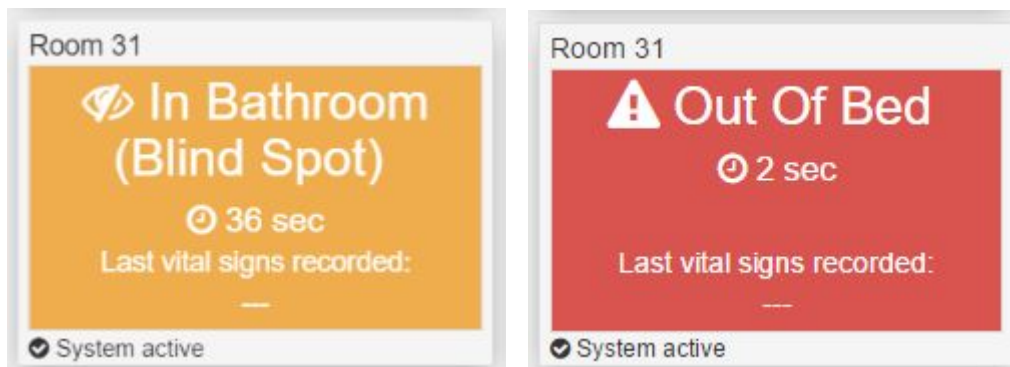
When other Oxehealth product modules are running and showing different non-medical information about what is happening in the room, the Oxehealth Vital Signs is still operational, and it is still possible to take vital signs.

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

In this state, it will be possible to use the **Take Observation**, **Pause** and **Observation 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 Observation** function successfully for this room.

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

- **Stopped:** 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.



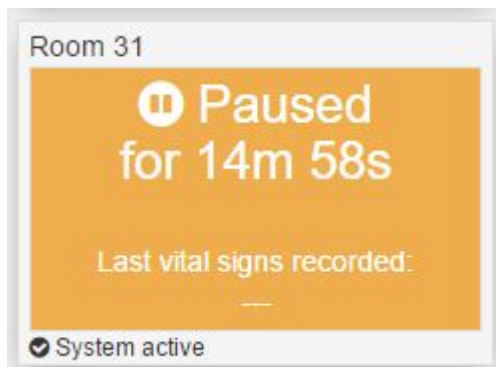
The timer indicates the time that the software has been stopped for the room.

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 Observation** function successfully for this room.

In this state, it will be possible to use the **Observation History** function on the **Action Menu**.

In this state, it will not be possible to use **Pause** or **Take Observation** 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 Observation** function successfully for this room.

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

In this state, it will not be possible to use the **Take Observation** 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 Observation** from the **Action Menu**. You will then see the first **Take Observation screen** below:



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

Acquiring Vitals... 

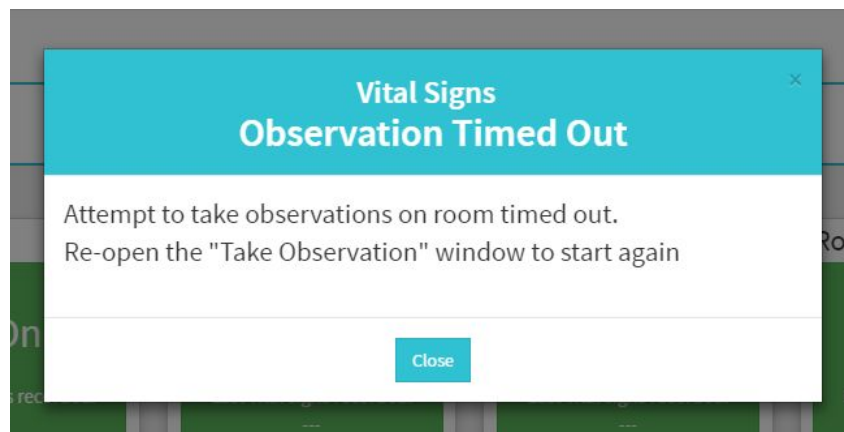
If the subject is not still, the **Acquiring Vitals** button is shown, or you do not wish to proceed for any reason, click **Cancel**, and you will return to the **Overview screen**.



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 Observation** screen will automatically close and you will see the following display:



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

IMPORTANT - please read carefully

If the **Ready for Observations** 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:

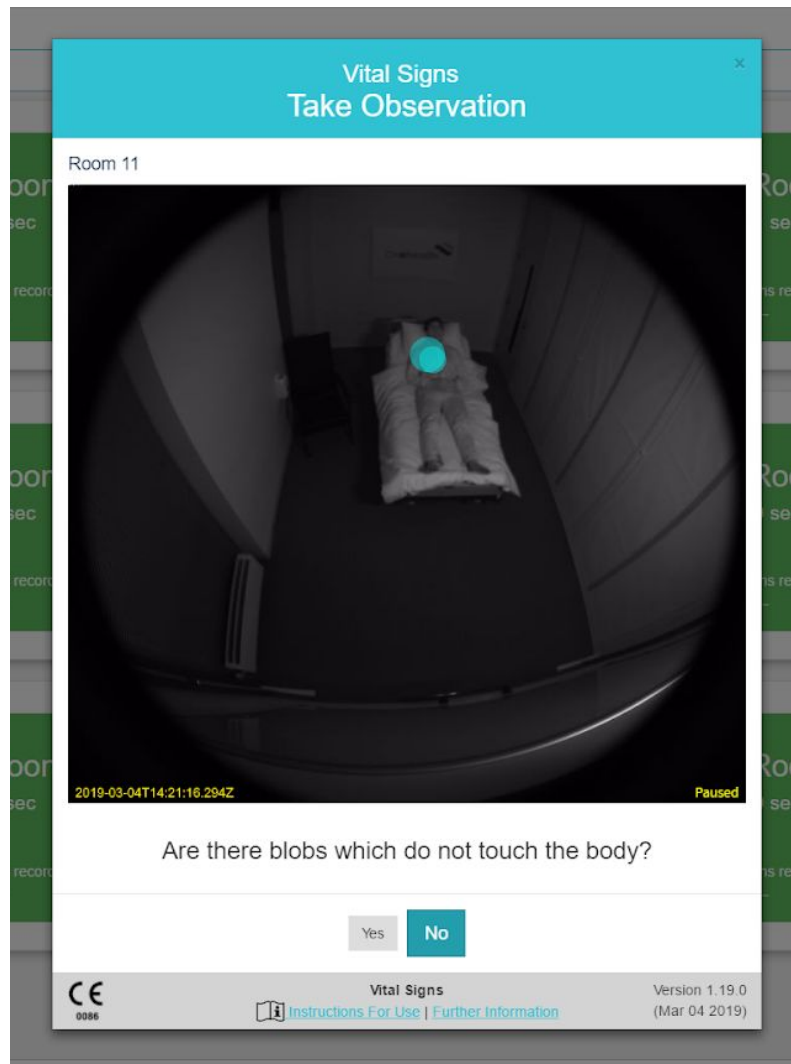
- Rocking while sitting or lying
- Having a seizure
- Visibly shivering
- Displaying tremors
- Standing or sitting still, but manually brushing teeth or washing
- Brushing hair
- Fidgeting



CAUTION

If you can see the subject, but they are covered, for example by bed sheets, then you may proceed with caution. If a subject has covered all of their skin, then it may not be possible to take a pulse rate observation, but a breathing rate observation may be possible.

If you judge the subject to be still according to these guidelines, and you want to proceed, click **Ready for Observations** and you will see the second **Take Observation** screen below:

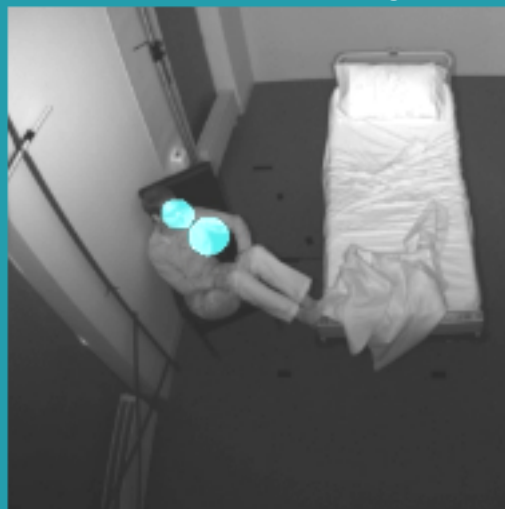


The video of the room will now pause, and you will see the regions in the image from which the Oxehealth Vital Signs software is estimating breathing and pulse rate as coloured blobs, together with the question **“Are there any blobs which do not touch the body?”**

IMPORTANT - please read carefully

The blobs in the image represent the locations from which the software is estimating heart 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 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:

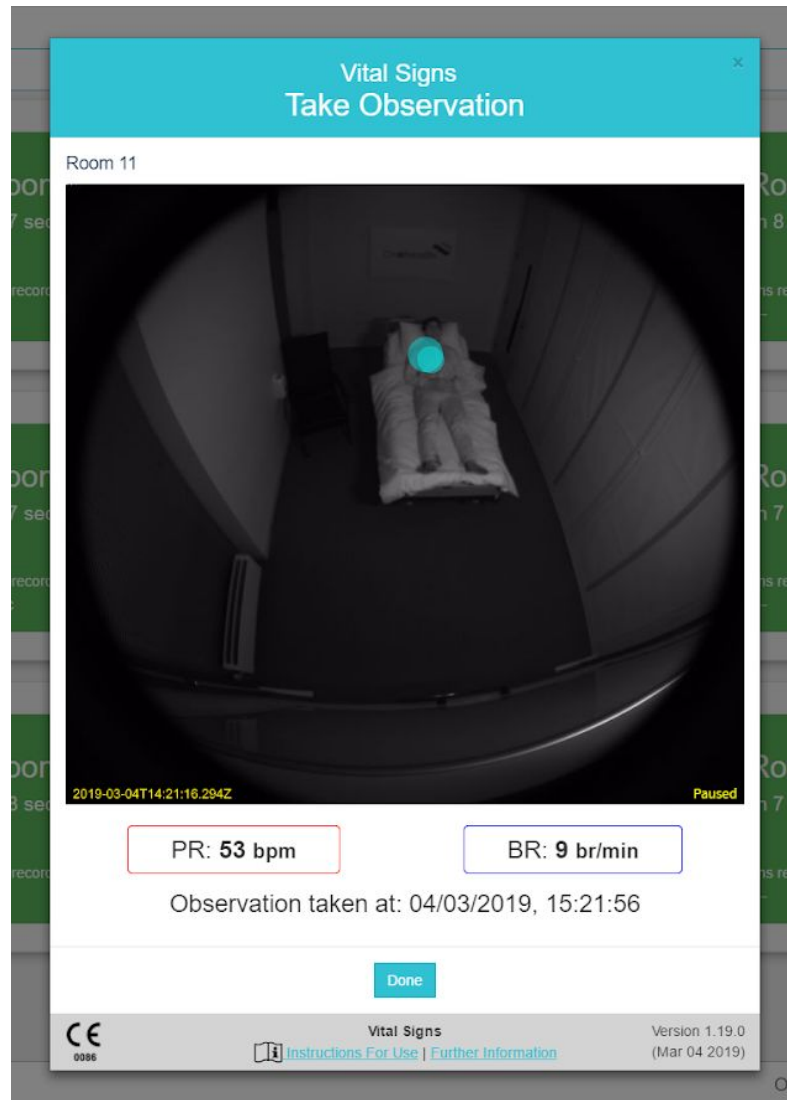


If a subject has covered all of their skin, then it may not be possible to make a pulse rate observation, but a breathing rate observation may be possible.

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 Observation 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:

PR 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.)

BR 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.)

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

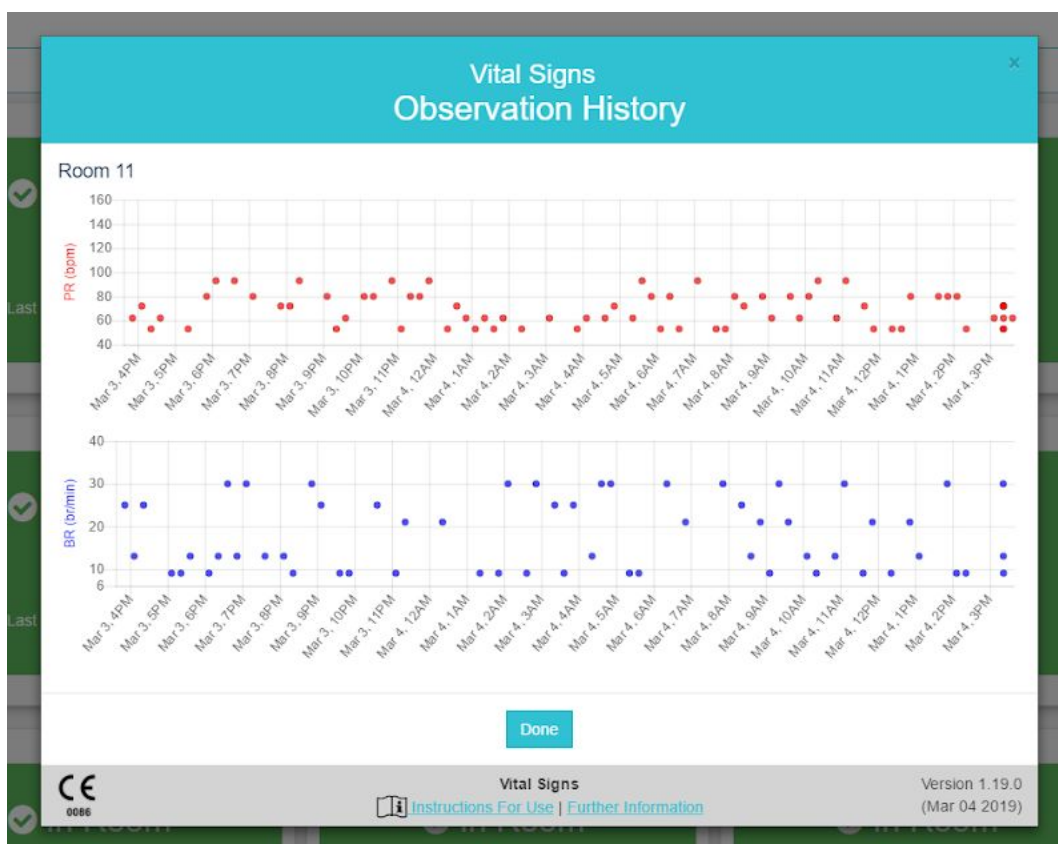
NOTE

You should also now record these 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 observations you have taken from a room, click the room icon, then select **Observation History** from the **Action Menu**. You will then see the **Observation History** screen below:



The History of 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 the that time.

Blue blobs (BR plot) indicate the breathing rate 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 a breathing rate at the 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

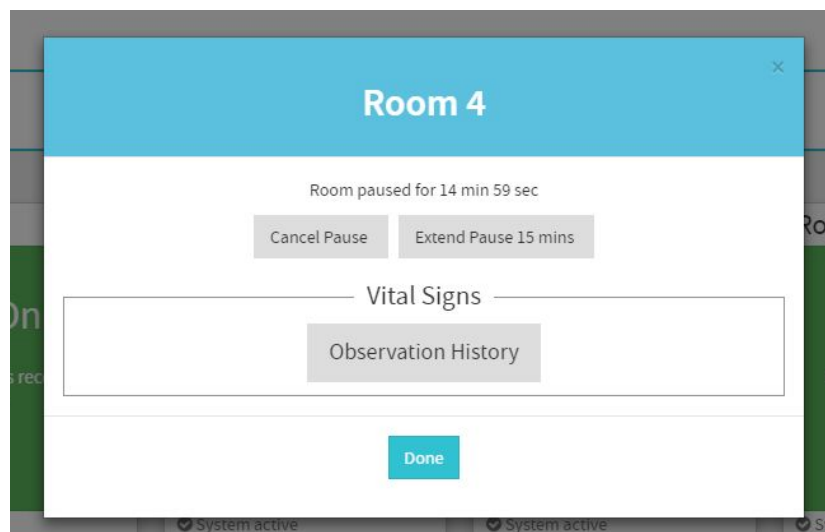
To pause measuring in any room, click the room icon for the room the subject is in, then select **Pause for 15 Minutes** from the **Action Menu**.

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.

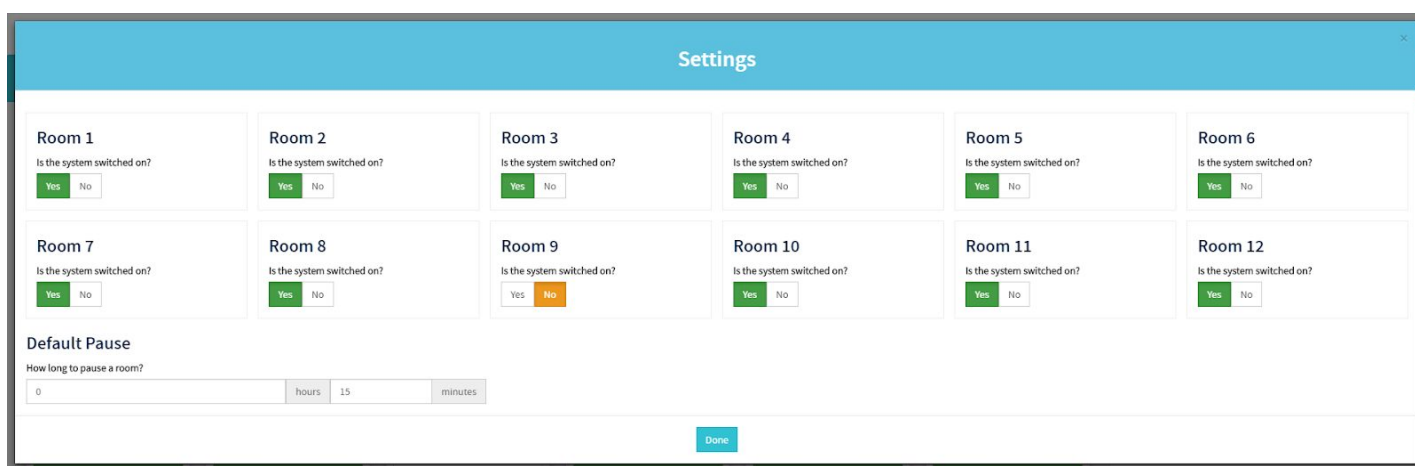
Click **Done** to return to the **Overview screen**.

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**.

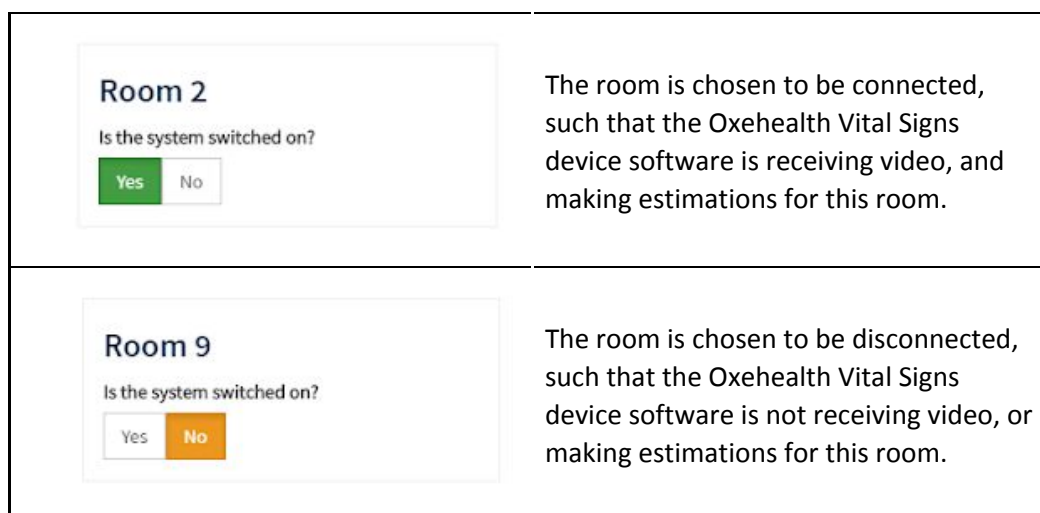
Rooms Settings

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:



To disconnect a connected room (stop the Oxehealth Vital Signs device software from running, such that the software is not capturing video or making estimations), click the **No** button under the **Is the system switched on?** text for the room you want to disconnect. The **No** control should now be highlighted in orange.

To connect a disconnected room (start the Oxehealth Vital Signs device software, such that the software is capturing video and making pulse rate and breathing rate estimations), click the **Yes**

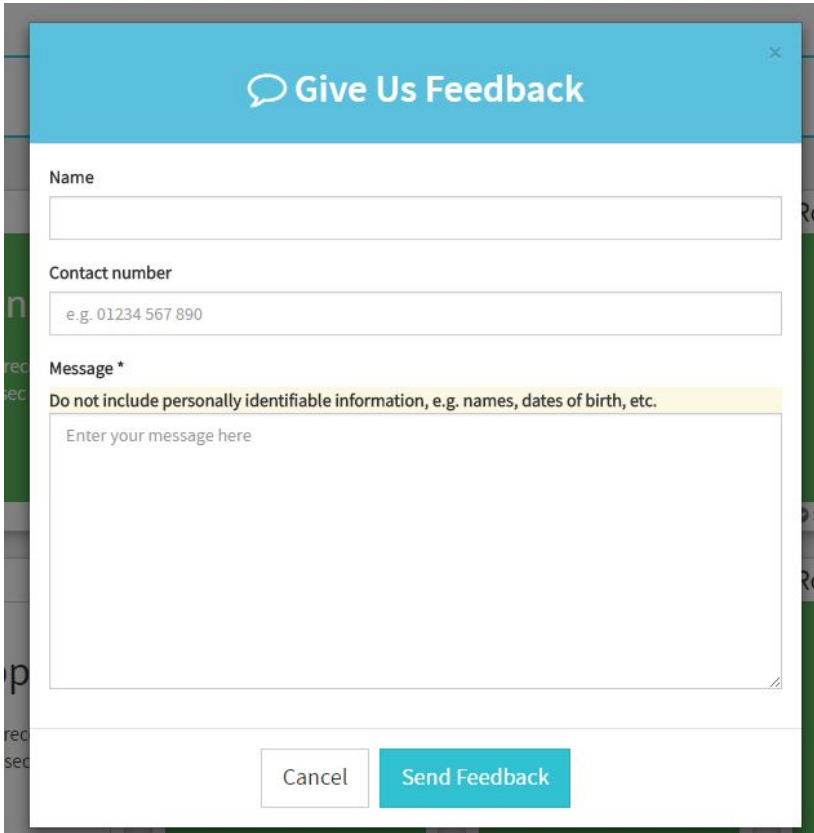
button under the **Is the system switched on?** text for the room you want to connect. The **Yes** control should now be highlighted in green.

To change the **Default Pause** duration, enter the number of **hours** and **minutes** in the boxes.

Click **Done** 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:



The screenshot shows a 'Give Us Feedback' dialog box. It contains the following elements:

- Name:** A text input field.
- Contact number:** A text input field with a placeholder example: 'e.g. 01234 567 890'.
- Message *:** A larger text area with a placeholder 'Enter your message here'. A yellow highlight above the text area contains the instruction: 'Do not include personally identifiable information, e.g. names, dates of birth, etc.'
- Buttons:** 'Cancel' and '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 **Cancel** 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

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