



Instructions For Use For

Vital Signs

en-GB English

Vital Signs Basic UDI-DI: 506075145VITALSIGNSFF













Applicable for versions 3.0 to 3.1

Physical Instructions For Use are available upon request, please contact LIO.

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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 (MDR) EU 2017/745 for medical devices
	UKCA Marking, made in conformance with the UK Medical Devices Regulations 2002 (as amended)		Authorised Representative in the EU.
	Importer		Prescription use only - sale by or on the order of a licensed healthcare practitioner only

Instructions For Use For 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 measurements of pulse rate or breathing rate.

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

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

IMPORTANT

If the platform is not performing as expected or looks different in any way please contact LIO using the contact details at the end of these instructions.

If any serious adverse incident occurs when using the Vital Signs medical device, where an individual or user is or could have been seriously harmed, it is vital that you inform LIO using the contact details at the end of these instructions and you may also inform the appropriate regulatory authorities for your jurisdiction (FDA, MHRA, or TGA)

Product Description

The platform gives you the ability to take contactless spot-check vital signs measurements of **pulse and breathing rate** within the ranges stated in the specification table.

The device is not intended to be the sole method of checking the physical health of an individual.

Specification Table

	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 Mean Absolute Error (MAE) criterion

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



Warnings

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

- Domestic animals,
- A shower or significantly sized water feature.

Vital Signs does not provide alarms to irregular or cessation to breathing or other signs of life. It should not be relied upon to notify care professionals of any immediate health or safety hazards, risks of harm, or health of the individual, and must not be used as the sole basis for making any decisions or recommendations relating to clinical diagnosis, individual care, or treatment.

Always revert to your local Standard Operating Procedures (SOPs) for establishing health and safety of individuals.

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 platform.

Cautions

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

- When individuals are moving
- If another individual is present in the image (including hidden from view, for example by sheets)
- If the individual is a large distance from the camera
- In individuals with low perfusion, anaemia, poor circulation or blood volume deficiency
- Other sources of movement or vibration in the image - Clothing or fabric e.g. curtains, loosely fitted clothing, air mattresses or CPAP machines
- When individuals are talking or are displaying a non-typical breathing pattern (e.g coughing and sleep apnoea) or controlling their breathing
- Large airflows through the room (e.g. fans)
- If the camera sees any of the following:
 - The image is heavily saturated due to exceptionally bright illumination,
 - Sources of flashing or variable light, including other Near Infrared illumination (e.g. CCTV, TV, etc)
 - Other moving patches of light and shadow (e.g. sunlight)
- Where visible skin is significantly scarred or tattooed
- Where visible skin has excessive make-up, sunscreen or other topical applications applied that hide the underlying skin
- When the individual is obscured (e.g covered by excessive bedding, or otherwise not viewable to the camera)

Limitations

- It is not a replacement for end tidal CO₂ measurements
- It is not intended to detect the presence or absence of arrhythmias or to report measurements during an irregular arrhythmia

- It is not intended to be used as a continuous vital signs monitor
- It is not intended to be used as an apnea monitor
- The accuracy of the Vital Signs device outputs has not been studied in patients with neuromuscular disorders
- The platform cannot verify a person's identity, and data is generated on a room by room basis so may show data for an individual who is not the individual currently occupying the room

Maintenance

In the event of failure of any part of the LIO platform, contact LIO.

Only LIO or LIO trained maintenance personnel may make modifications to the platform. If you are in doubt whether changes could affect the device, you should contact LIO who can advise.

Do not relocate any equipment that has been installed for the LIO platform, or change any security or access arrangements to the equipment without first informing LIO.

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 platform and contact LIO.

When cleaning the housing unit or touch screen devices, do not use solvent based, ammonia, caustic or abrasive cleaners or abrasive cleaning materials on the clear front panel of the housing unit or on touch screen device displays. These substances can scratch or cloud the surface, impairing visibility of the individual and potentially reducing the device's reliability and measurement accuracy.

Using Vital Signs

The platform gives you the ability to take contactless spot-check vital signs measurements of **pulse and breathing rate** within the ranges stated in the performance table.

It is not possible to use the **Vital Signs** function while the room is in the following states:

- Camera Off
- Camera Paused
- Acquiring
- Interfered With
- Connection Lost/System Error
- Blind Running

For more information on each room state including how to turn a camera on or off or unpause a room please refer to the Activity Tracker instructions for use.

Taking A Vital Signs Measurement

To take an individual's vital signs measurement, follow these steps. Please ensure the screen is not visible to anyone else and ensure that you observe all of your organisation's safety, privacy and security policies and guidelines.

Step 1: Select the relevant room tile on the Overview Screen, then select 'Take Vital Signs' from the Room Dashboard.

Vital Signs

Take Vital Signs

If User Auth is enabled you may be prompted to 'Sign In' via your organisation's single sign on page. For more information on User Auth please refer to the Activity Tracker instructions for use.

Step 2: A clear, live video into the individual's room will be displayed, which will automatically close after 15 seconds.

Home > Room 2 > Take Vital Signs

Room 2

Is the subject still?

Cancel Yes

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

11 Dec 2025, 10:32:35 Live

CE 2797 UK CA 0086 About Vital Signs

You will be prompted to answer the following question:

'Is the subject still?'

If the individual is still, select 'Yes'.

If the individual is not still or the platform is not able to obtain any vital signs measurements, the 'Yes' button will be replaced by 'Acquiring Vitals', and you will not be able to proceed:

Acquiring Vitals

If you do not wish to proceed for any reason, select 'Cancel', and you will return to the Overview screen.

IMPORTANT

If you are unsure if the individual is still, do not proceed.

Guidelines for determining when an individual is considered still:

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

Guidelines for determining when an individual is not considered still:

- 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

Step 3: The clear, live video has been paused. The platform has placed up-to two blue blobs onto the image, which indicate where the platform will take the vital signs measurements from.

You will be prompted to answer the question:

'Are there blobs which do not touch the body?'

You may see one or two blobs on the image. If all blobs are located on the individual, select 'No' to proceed. If a blob is located off the individual, or you do not wish to proceed for any other reason, select 'Yes'. You will return to the Overview Screen.

IMPORTANT

Blobs represent the locations from which the platform is measuring pulse and breathing rate, and it is important that you ensure that the platform is extracting these from the individual. You will see one or two blobs if the platform is able to take a vital signs measurement.

Examples of blobs that are and are not touching the individual 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"

CAUTION

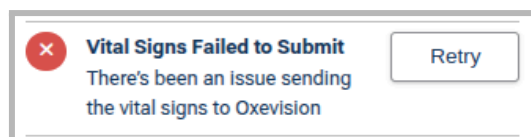
You must consider other means of obtaining vital signs measurements if you have any cause for concern over the measurements obtained by the vital signs device.

Step 4: The video of the room will remain paused, and the platform will display the vital signs as follows:



Once a vital sign measurement has been taken, a message is displayed indicating that the measurements are saved by the platform and will be available on the **Vital Signs Trends**.

If submitting the vital signs to the platform when a failure has occurred, you will see a warning message and an option to **Retry** as shown below:



Failure to submit a Vital Signs measurement can be due to poor network connectivity. When using a mobile device it is important to move to an area with a strong WiFi signal, to ensure the vital signs measurement can be saved.

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

Vital Signs Attempts Notification (VSAN)

If enabled by your organisation, the Vital Signs Attempts Notification appears when a user has made a predefined number of attempts to record a vital signs measurement for a room. This notification will be shown at the top of the screen on all devices.

An example can be found below:



Multiple Vital Sign Attempts Made
Room 8 starting at 17:49

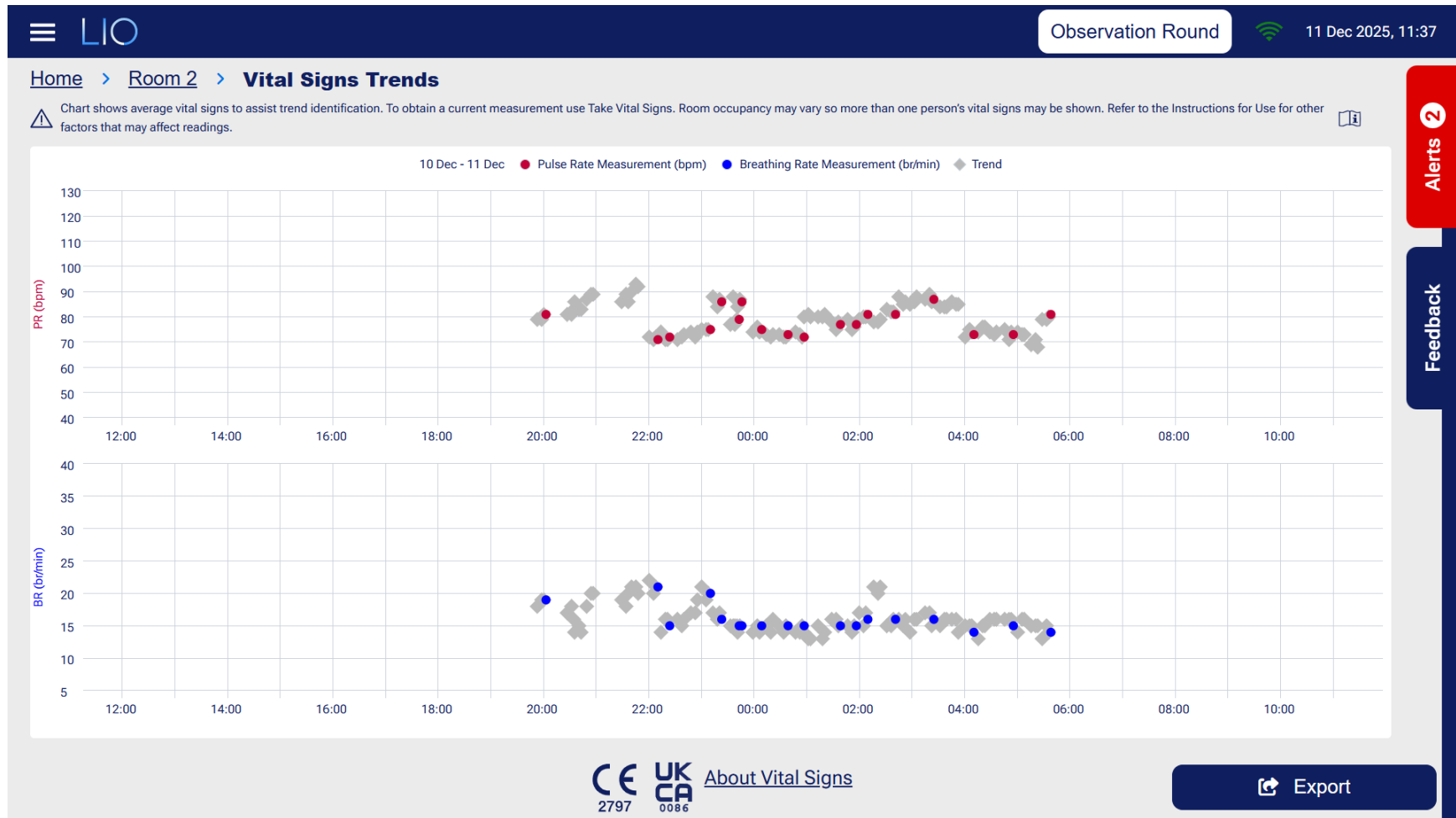


In the event this notification is displayed, an automated email will be sent to a predefined individual at your organisation.

To dismiss this notification, select the small cross in the top right.

Vital Signs Trends

The Vital Signs Trends preview can be accessed via the Room Dashboard. To access the full 24hr report select the arrow located in the top-right corner of the preview.



● Red blobs (PR plot)

Spot-check pulse rate measurements taken by a user via the take vital signs workflow in beats per minute (bpm).

● Blue blobs (BR plot)

Spot-check breathing rate measurements taken by a user via the take vital signs workflow in breaths per minute (br/min).

◇ Grey diamonds (both plots)

Represent the average value of all collected pulse rates or breathing rates over a five minute period.

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

- There was too much movement in the room
- There was no individual in the room
- The room was off or the camera was paused
- The Vital Signs medical 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).

The Vital Signs Trends may contain more than one individual's data, if there has been more than one individual present in a room.

Please note: this report is exportable. To find out more, please refer to the Activity Tracker Instructions For Use.

Contacting LIO

LIO has a dedicated customer support team who are available 24/7, 365 days a year. If you have any issues or questions about the platform, you can contact LIO using the information below

Feedback Form

Select the Feedback tab in the top right corner of the screen. Complete the relevant fields with your information, issues, suggestions, or questions then select 'Send'. Please provide your name and contact details, if available, this will help a support representative reach out if further assistance is required. After sending, you will automatically be returned to the Overview screen.

If you prefer not to send feedback, select 'Clear' to return to the Overview screen.

CAUTION

Do not include any person identifying information when contacting LIO , e.g. names, date of births.

Regulatory Information

Device name

Vital Signs

Intended Use (US)

The Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate 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 system is intended for use by appropriately trained staff and should not be used by untrained users. The Vital Signs device is indicated for use on subjects 12 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.

Intended use (GB)

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.

R_x Only

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

Manufacturer



Oxehealth Limited

Bee House
Eastern Avenue
Milton
Abingdon
England
OX14 4SB

Telephone: US: +1 (888) 871-8108
Telephone UK: +44 (0) 1865 900 599
Website: www.liohealth.com
Email: support@liohealth.com