



Instructions For Use For

Sleep

en-GB English

Sleep Basic UDI-DI: 506075145SLEEP9J













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 Sleep



Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in incorrect activity alerts or misunderstanding of the platform status or alerts.

These instructions for use are for the LIO Sleep 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 Sleep, you must first be trained in its use. Sleep training will be made available from 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 Sleepmedical 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

Sleep uses pulse and breathing rate, alongside location and movement to monitor sleep. It can tell the difference between when individuals are awake or asleep in bed. This is because an individual's pulse and breathing rate slow down when you sleep.

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

Specification Table

Bed State Outputs	Sleep State Outputs		
Accuracy	Overall Agreement	Positive Agreement	Negative Agreement
>95%	>82%	>88%	>55%



Warnings

Sleep must not be used with any individual receiving critical care.

Sleep must not be used in rooms that contain or may contain:

- Domestic animals
- A shower or significantly sized water feature

Sleep must not be used as the sole basis for making any decisions or recommendations relating to clinical diagnosis, individual care or treatment.

Cautions

If Sleep fails to respond as described, discontinue use until the situation has been corrected. Contact LIO for support using the contact details at the end of these instructions.

The Sleep Report may omit bed-occupancy or sleep periods, or may present them inaccurately, under the following conditions:

- 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
- 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)
- Other sources of movement or vibration in the image - Clothing or fabric e.g. curtains, loosely fitted clothing, air mattresses or CPAP machines
- In the presence of sleep disorders, e.g. REM sleep disorders, periodic limb movement or parasomnias, or other disorders or syndromes or any abnormal movement or breathing patterns during sleep

Limitations

- Displays data gathered from a specified bed space so may show data for any individual occupying that bed space
- Is not a real-time sleep monitor
- Does not give any indication of the health or safety of an individual
- Provides estimated sleep status. It is not a replacement for measurements of brain activity
- Cannot be used to diagnose or monitor abnormal breathing such as sleep apnoea
- The accuracy of Sleep has not been studied in individuals with movement disorders
- If you make significant physical changes to a room, for instance visible structural changes or adding large items of furniture, this may affect the performance and you should inform LIO

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 Sleep

The platform uses movement, activity, and physiological data (pulse and breathing rates) to provide a breakdown of an individual's sleep patterns of up to 7 days.

As detailed within the Activity Tracker instructions for use, you will not receive any data, including Sleep Data, for the duration of time a room is in the following states:

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

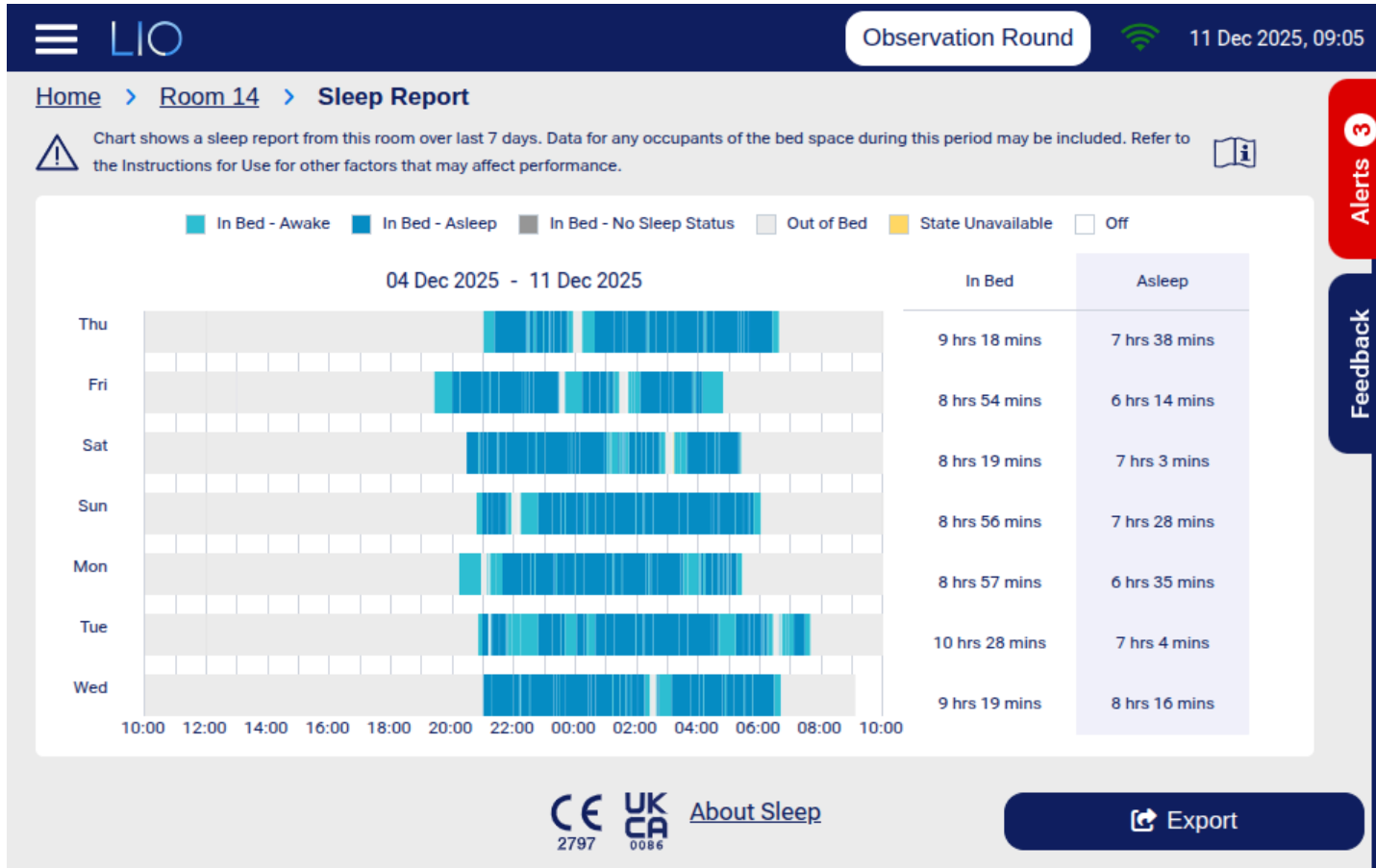
For more information on each room state including how to turn a camera on or off or unpause a room please refer to the Activity Tracker instructions for use.

Viewing the Sleep Report

To view a room's sleep report, select the respective room tile on the Overview Screen to navigate to the Rooms Dashboard. Here you can scroll down to see a preview of the Sleep Report. To access the full Sleep Report select the arrow located in the top-right corner of the preview. To return to the Overview Screen, select the Home button.

The Sleep Report

The Sleep Report includes 24-hour timelines, over 7 days showing an individual's sleep and bed occupancy patterns, and the operational status of the platform over the reporting period.. Each timeline will include the periods when an individual was detected to be in the bed space awake or asleep.



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



IMPORTANT

Data included in the Sleep Report is taken from the bed space only, and will not show sleep status if an individual is not occupying the bed space.

The data included in the Sleep Report is retrospective, this report will not show if an individual is currently asleep or awake, and will be generated at a configured time daily.

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 via the following methods.

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'. 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

Oxevision Sleep system

Intended Use

The Oxevision Sleep System is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring.

The device's intended use is to analyze subject activity, movement and physiological sign data associated with movement during sleep and to extract information about certain sleep parameters from these movements and physiological sign data. The device provides a timeline of periods when a bed space is occupied, and periods when a subject is asleep when the bed space is occupied.

The Oxevision Sleep System is software assessing video footage from a fixed-installation device for use within single occupancy bed spaces within hospitals, general care and secured environments.

The Oxevision Sleep System is indicated for use on subjects 18 years of age or older.

R_x Only

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



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