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Clinical Safety Case Report for Oxevision/Oxevision Observation

Essex Partnership University Trust

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Document Management

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Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
[I/S]	Consultant Psychiatrist / Chief Clinical Information Officer		
[I/S]	Director of Nursing and Chief Nursing and AHP information Officer	23rd April 2025	
[I/S]	Chief Information Officer	29th April 2025	
Alex Green	Executive Chief Operating Officer	29th April 2025	

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Clinical Safety Oversight Group		29/04/2025	0.2
Project Board		30/04/2025	0.3
Safety care group			

Related Documents

These documents provide additional information and are specifically referenced within this document.

Ref	Doc Reference Number	Title	Version

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Introduction

The purpose of this clinical safety case report is to demonstrate compliance with the clinical safety standard DCB0 160 (Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems) and relates to the deployment of Oxevision/OxeObs within selected EPUT inpatient wards.

The Clinical Safety Case Report outlines EPUT governance process for evaluating Oxevision/OxeObs system, as configured within EPUT and confirms the residual risk levels after Go Live.

The Clinical Safety Objectives are:

- First and foremost, that Oxevision/OxeObs system is clinically safe for patients in the context of its intended purpose/use.
- To ensure that the clinical safety activities undertaken are in line with the EPUT Clinical Safety Governance Plan.
- To monitor any changes to the system through configuration and deployment, assess any potential risks and mitigate these through the risk assessment process.
- Identify and assess any clinical hazards/risks to maintain patient safety by following the risk assessment process.
- To review the Hazard Log, update it throughout full implementation and revisit/amend to ensure that it remains relevant and up to date.
- To highlight any residual risks on the Oxevision/OxeObs Hazard Log, that remain after mitigation has been put in place. Any residual risks will be on the Trust Risk Register
- Identify safety critical functionality of the system and evidence assurance activities in these areas to mitigate clinical risk and support the patient in feeling safe.
- co-produced our case for change for the Trust's move from risk stratification to a more personalised approach to risk and safety planning, which will be taken into 2025/26.

The Clinical Safety Case will ensure compliance to DCB0160 clinical safety standard for due diligence and the supplier's compliance with DCB0129 standard. Oxevision/OxeObs has supplied EPUT with their Clinical Safety Case Report and Hazard log version 12. dated 10 February 2025 to demonstrate compliance.

System Definition / Overview

System Description

The Oxevision software is a standalone software system, designed to run on standard, off-the-shelf computer hardware, and operated at a touchscreen terminal or using a mobile tablet. The software is deployed, configured and maintained by Oxehealth.

The Oxevision software is uniquely identified by a single software version number that is common to all products within the Oxevision module suite.

Intended Use

Oxevision is a fixed-installation system 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 patients remain safe. The Oxevision platform and related modules are intended for use within non-acute physical health clinical settings where patients are adults or adolescents, who would not be

expected to exhibit abnormal physiology or vital signs.

Modules of the Oxevision System

Oxevision Vital Signs

● The Oxevision Vital Signs is intended for non-invasive spot measurement of pulse rate and breathing rate. It is a Class IIa medical device, with a CE certificate of conformity.

● The Oxevision Vital Signs medical device has been validated as performing comparably (with pulse rate accuracy of ±3 bpm and breathing rate accuracy of ±2 breaths/min, comparable to current state of the art in monitoring devices and best practices for vital signs).

● The Oxevision Vital Signs provides pulse rate and breathing rate measurements to a clinically validated accuracy and is also not intended to be relied upon as the sole basis for clinical decision making.

● The Oxehealth Vital Signs device is for spot-check observations; it does not provide alerts for vital signs, for example high/low pulse and/or breathing rate.

Oxevision Activity Tracker (with location-based alerts) - Location based alerts are configured per ward - not all sites have all location-based alerts - please check what location-based alerts you have configured.

● The Oxevision Activity Tracker is intended to display a warning and/or set off a visual and audible alert if it detects activity in a room occupied by a sole occupant, having detected occupancy, and:

○ The activity suggests that an occupant is in a specified region within the room (such as a doorway), or remains in that region for a specified length of time;

○ The activity suggests that the occupant has entered a camera blind spot or an adjoining area out of the field of view (such as a bathroom), or remains in that area for a specified length of time;

○ The activity suggests that the occupant is making movements associated with leaving the bed region or has got out of bed, having already detected occupancy within the bed region.

○ The activity suggests that the occupant has left the room;

○ The activity suggests that a second occupant has entered the room

Seclusion and Health Based Place of Safety (HBPoS) rooms only

○ The 'No Activity Alert' is only available in these rooms due to them being secure rooms (often locked) and without large pieces of furniture in. The 'No Activity Alert' is designed to trigger a visual and audible alert if the system detects that the room is occupied but no activity (small or large movements) has been detected for longer than 50 seconds.

Oxevision Activity Tracker (without location-based alerts)

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● The Oxevision Activity Tracker (without location-based alerts) module provides a timeline summary of categories of activity detected by Oxevision Activity Tracker. It does not have a medical purpose or functionality. The product is designed to provide additional information in parallel to the authoritative human checks.

Oxevision Observations

● Oxevision Observations is intended for digitally recording the results of non-intrusive patient observations in situations where regular checks of patient location, presentation, and breathing status are required (normally referred to as “Level 1” and “Level 2” observations, “General Observations” or “Intermittent Observations”). The Observations product is for digitally recording patient observations and does not have any medical diagnosis or monitoring capability. The Oxehealth Observations software is not for use in situations where any immediate safety concerns exist that would require a patient to be on continuous or close observations (normally referred to as “constant eyesight” or “Level 3”, “constant arms-length” or “Level 4”, or more than one staff member observing a patient at a time, e.g. “2-to-1s”).

● The Oxevision Observations module can be used alongside the Oxevision Vital Signs module, to allow pulse rate and breathing rate measurements taken with the Vital Signs software to be digitally recorded with the other observations of patient location and presentation.

Oxevision Sleep System

● The Oxevision Sleep system module is intended for measuring time awake in bed compared to time asleep. It is a Class IIa medical device, with a CE certificate of conformity.

● The Oxevision Sleep system module provides periods of in bed and asleep measurements to a clinically validated accuracy and is also not intended to be relied upon as the sole basis for clinical decision making.

Oxevision API

Oxevision API is intended to provide access to Oxevision user interface usage data, Oxevision Activity Tracker alert data and installed hardware information via API. It does not have a medical purpose or functionality. It is a prototype provided as a one-off for a single trust as a trial.

Except for Oxevision Vital Signs, the Oxevision modules are not for monitoring health or vital signs, and their intended use is to supplement existing clinical practice, rather than their operation or outputs being solely relied upon in clinical decision making. We expect that in most environments, the Oxevision platform, the vital signs and sleep information obtained through the device will provide additional clinical information, rather than replacing existing traditional contact-based devices.

Further details of contraindications, warnings, cautions and performance specifications are available in the Instructions For Use (IFU’s) for each product.

Oxevision is currently on:

- 30 inpatient wards
- 4 HBPoS

- 8 seclusion/LTS
- 2 intensive care rooms

Clinical Risk Management System

Oxehealth maintains a risk management system that complies with ISO 14971:2019, and complies with the EU Medical Devices Regulation 2017/745, that is subject to audit by its notified body, as part of the Oxehealth QMS.

The Oxehealth Clinical Risk Management System (CRMS) and Clinical Risk Management Process (CRMP) describe how Oxehealth :

● Conduct Clinical Risk Management (CRM) to ensure patient safety with respect to the Oxevision platform.

● Align with the existing Quality Management System (QMS), documenting any warranted variations to standard practice.

● Complete interrelated and interactive activities that constitute the QMS.

● Meet the requirements of DCB0129 and enable Healthcare Organisations deploying the Oxevision platform to meet the obligations of DCB 0160.

The clinical risk management process involves:

● Ongoing involvement of the Clinical Safety Officer (CSO), in all appropriate product development activities.

● Passive monitoring of customer feedback for clinical hazards/clinical safety incidents.

● Active monitoring of all Oxehealth customers for clinical hazards/clinical safety incidents.

● Audit of clinical risk management activities and clinical incidents annually.

● The Oxehealth CSO is responsible for reviewing the clinical safety/risk documentation with input from other key individuals in the Oxehealth team.

This allows product safety to be dealt with in a systematic manner, in particular to enable the early identification of hazards and hazardous situations associated with the Oxevision system.

The Clinical Risk Management Process forms part of this overall risk management system, generating the necessary clinical risk management file documentation.

Risk Management Team

The responsibility for the risk management process ultimately lies with the manufacturer, Oxehealth Leadership Team. The Risk Management Team assigned by them shall consist of the following members:

Role	Assigned Personnel	Responsibilities
Risk Management Lead	**[I/S]** Head of Compliance	Risk management process oversight

		Risk management file documentation Risk identification and assessment Risk control and verification Incident identification and assessment
Clinical Safety Officer	[I/S] Head of Patient Safety and Quality, RMN	Risk management process review Risk identification and assessment Incident assessment Clinical risk management file documentation review
Director – Product & Customer Success	[I/S]	Join clinical risk management reviews
Product Manager	[I/S]	Join clinical risk management reviews
VP of Engineering	[I/S]	Join clinical risk management reviews
Information Security & Privacy Manager	[I/S]	Join clinical risk management reviews
Head of Product Engineering	[I/S]	Join clinical risk management reviews

The Oxehealth Leadership Team is responsible for reviewing the suitability of the risk management process; this is done as part of the periodic Quality Management review (QMR).

Clinical Risk Analysis

Clinical Risk Management File

The process for maintaining the Clinical Risk Management File (CRMF) is built upon the ISO 14971:2019 risk management system, and involves the following:

1. All risks associated with the Oxevision system and modules are considered as part of the ISO 14971 risk management system.

2. The clinical hazards are identified from the overall risk analysis and added to the Clinical Hazard Log and assigned a likelihood of the harm occurring.

3. The Clinical safety case (Including the Hazard log) is discussed and approved in the Clinical Safety Oversight Group and the project board.

4. The CSCR is built upon the overall residual risk and risk/benefit analysis.

5. The CSCR is updated following verified completion of risk management activities.

EPUT Clinical Safety Officer has been engaging with relevant practitioners to complete the DCB0160 documentation mentioned above. The documentation is then discussed in the Clinical Safety Working group, approved by the project board, and signed off by the Clinical safety Oversight group.

Clinical Risk Evaluation

The clinical risk matrix, evaluation and management process used is defined below and can also be found in more detail within the appendix. The hazard assessment process will follow the standard *Clinical Risk Management System* [*Ref 1*] approach.

Hazards may be identified in other ways during the development and use of the Oxevision/OxeObs such as:

- Discovery during design of a solution by supplier or NHS Organisation;
- Testing of amended functionality;
- Ad hoc testing of live service functionality;
- Reporting of an incident or problem within the live service; and
- Identification by a member of staff within the supplier or NHS Organisation

For each identified hazard, the following information will be defined and recorded on the Hazard Sheet and summarised on the Hazard Log:

- Hazard number;
- Hazard name;
- Hazard description;
- Potential clinical impact – this will describe the effect of the hazard in the care setting and potential impact on the patient;
- Possible causes – these may be technical, human, error etc. A hazard may have several causes; and
- Existing controls – these are identified existing controls or measures that are currently in place and will remain in place post implementation that provide mitigation again the hazard, i.e. will be used as part of the initial Hazard Risk Assessment.

Each Hazard will be discussed by the Oxevision/OxeObs Clinical Safety team and any other appropriate people. They will perform the following tasks and record the outcome in the Hazard Sheet and a summary in the Hazard Log:

- Estimation of clinical risks;
- Clinical risk evaluation; and
- Clinical risk control option management.

Estimation of clinical risks.

For each identified hazard estimation will be made of the clinical risk. This will include the severity of the hazard, the likelihood of the hazard and the resulting clinical risk. The estimation process will follow that established by the safety processes defined in DCB0129. A copy of the risk assessment matrix is provided in the appendix.

Clinical Risk Control

*T*he table below provides an overview of the status of the Hazards and mitigation relevant to the use of Oxevision/OxeObs. The Hazard log provides detail description. *(NB: Due to the overlap of certain hazards, some explanations cover more than one):*

Hazard Number	Hazard explained	Mitigation	Status (RAG)
Oxe1 to Oxe4	On the office monitor, there is no ability for staff to login the system, hence it cannot recognise who has taken any actions from the monitor such as: - Vital signs - Who silenced the monitor or turned the volume down - Who used the functionality of 'Stop room function' (Turning off Oxevision/Oxehealth functionality in a room)	Staff should be aware of processes as described in the SOP	
Oxe5	Staff enters the patient's room/ opens the room door when the bathroom alert is triggered while the patient is in the bathroom. When the staff leave the room/closes the door, the room status change to 'Empty', i.e the bathroom timer has been overridden by the entry and exit	Staff need to complete a face-to-face intervention when the alarm is triggered, after the intervention, the staff must reset the alarm. There will be no re-alerts following the initial alert reset. This situation has been	

	of a second person in the room and will no longer cumulate. The patient remains in the bathroom out of view of the camera, the room state remains 'Empty' until the patient comes out of the bathroom into the room, then the room state changes to 'In Room'.	highlighted as a risk and articulated in the SOP with the action to reset the alarm. Staff should not solely rely on the system for this purpose and should remain vigilant. The SOP stipulates that the system is an assistive technology. The bathroom alert reminder sheet has been updated to explicitly mention this behaviour and is available for reference on OxeAcademy	
Oxe 6	Staff can use the system without completing mandatory training	All staff need to have completed their mandatory training before using Oxevision. Mandatory training is part of the Trust contract requirement for all staff. This is part of the SOP. Staff performing the allocation need to ensure staff are trained before allocating to Oxevision	
Oxe7	Staff using the device as a replacement for a face-to-face engagement	Staff allocation is undertaken following handover. Oxeacademy instructions for use of the device and the SOP highlights the fact that the device is an assistive technology not a replacement to face to face engagement.	
Oxe8	While vital sign is being taken, the device gives a clear video image of the patient in their room for 15 seconds. This impacts on their privacy.	Oxevision is discussed with patient on admission and recorded on the admission checklist. Patient are given a information leaflet about Oxevision in addition there are posters on the ward about the usage. If patients does not consent to Oxevision, they can request for it to be switched off. The Oxevision system can be individually isolated by the Nurse in charge turning the camera off. The action to turn the camera off should only occur if the Nurse In Charge	

		deems the action clinically safe to do so prior to an MDT decision making meeting.	
Oxe 09	The Oxevision system is not a live feed to the electronic patient record	Any information about the live observation recording can be accessed via a device. This is documented in the SOP.	
Oxe10/ Oxe11	If devices are not operational for any reason.	The staff will revert to paper until the devices are operational as per BCP plan	
Oxe12	Sometimes patient can be created with the wrong details in the EPR hence impacting on Oxevision	Staff must check patient's credentials before registering the patient in the EPR. If wrongly created, amendment will be done in the EPR and the correction will be done within Oxevision as per SOP guidance	
Oxe13	OxeObs documentation is manually uploaded to the EPR systems within 24 hours except the weekend.	The live data is available on the Oxevision device. The upload to the EPRs follows on	
Oxe14 Oxe15	The device can be used as a weapon or if snatched from a staff, patient could view other patient's details	Staff must assess the risk prior to taking the device into any environment and follow the trust risk policy. If a patient has managed to see another patient's details. IG policy must be followed. The tablets do have a time out of 2 minutes	
Oxe16	Training guides has been replaced by 'Information for use' (IFU)	'Information for us' remains available on each Monitor, device and Oxeacademy and contain the same information as the training guides.	
Oxe17 Oxe18	If the clear video data (CVD) is not requested within 24 hours, the CVD is lost due to staff not following the request process within 24 hours.	Ward managers must ensure the staff follows the correct process as indicated in the SOP to access the CVD. This is part of the mandatory training requirement. It is also on the competency checklist staff must complete on their induction. An audit trail of who accessed the system can be obtained and the	

		anonymise video data is available.	
Oxe19	Patient can be unaware of the use of Oxevision. This could potentially breach a patient's human rights.	Oxevision discussion is a requirement that staff must complete with the patient as part of admission. A checklist is available to support with the admission. The Oxevision aspect of the admission checklist is then published in a clinical dashboard accessible to all staff. If it is not completed, this will be highlighted in the clinical dashboard. There are posters on the ward explaining the system. Oxevision is part of the patient welcome pack received on admission to the ward. All patients have to provide consent for the use of Oxevision. The subject of consent is part of the mandatory training. Staff are required to routinely visit the use of Oxevision for each patient. It is also discussed in the community meeting with the patients. The SOP, the training and education covers all the above. Tendable audits contain a stand-alone Oxevision audit to be completed fortnightly by Qualified staff/ Health Care Assistant by each inpatient ward that has the Oxevision System installed. Additional control is being implemented to have an audit of the completion of the checklist. Focus groups with the patient will take place quarterly to	

		support the use of the Oxevision System, promote positive practice and enhance patient experience and care.	
Oxe20	The Oxevision/Oxeobs function is unavailable during the handover process.	The observation will have to be done manually as per Business Continuity Plan. A face- to-face check will be done to ensure patient safety as per handover process.	
Oxe21	If a staff fails to log out of a tablet and someone else complete an entry, this will be logged against the wrong staff name.	Staff must follow the SOP and IG policy when using the device	
Oxe22	Staff can log on the system with a different staff name and email address	This would be deemed an IG Breach and action taken as per policy. Sop process need to be followed.	
Oxe23/24	By rearranging furnishing in the room, the patient might create a blind spot. This could happen with the refurbishment of the room.	Staff needs to be aware of the implications of moving furniture in the room or refurbishment of the room. This is part of the Oxeacademy, in the vital signs of the IFU and in the SOP. Estate team should be trained on how Oxevision is set up in a room. The Ward manager should be aware of the impact of any alteration to the room, Ensure the Estate team are aware and alert the Oxe lead to ensure the room is reconfigured post refurbishment.	

Hazard Log

Link to Hazard Log V1.0 : DCB0160

Test Issues

Oxehealth does user acceptance testing (UAT). If new functionalities are being added to the system, they do proof of concept and testing first. The testing can be within EPUT or other organisations. If functionality is tested within EPUT, it will initially be piloted on a few wards before being implemented across all wards. Oxehealth follows a strong product development process, with clinical involvement being a key aspect. EPUT does have RAID logs (Trial issue log that is maintained and updated throughout the trial phase. Any threats and concerns will be logged and rated throughout the process. The project board will approve any trials, and a report is produced for the Executive Team.

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Summary Safety Statement

Clinical Risk Management activities have been completed in alignment with the Clinical Risk Management Plan. The Oxevision system is a suite of modules including Oxevision Vital Signs, Oxevision Activity Tracker (with location-based alerts), Oxevision Activity Tracker (without location-based alerts), Oxevision Observations, Oxevision Sleep System and Oxevision API. The Oxevision Vital Signs and Oxevision Sleep device system are registered Class IIa medical devices with a CE certificate of conformity. In accordance with the EU Medical Device Regulations (2017/745), Oxehealth are required to adhere to a rigorous process of risk management, which complies with ISO 14971. Oxehealth do supply us with a copy of the DCB0129 and we complete our responsibility by adhering to the requirements of the DCB0160

Current hazard risk status: there is one hazard in the red and two ambers at present. EPUT is working closely with Oxehealth to further mitigate the risk.

Quality Assurance and Document Approval

The Hazards are discussed in a Hazard workshop, It is reviewed by the Digital Oversight Group, discussed in the project board and agree on the resolution and make recommendations to Executive Team. The safety care group will ratify the Clinical safety case and provide a progress reports to the Safety of care group.

Configuration Control / Management

Strict version control has been used on all governance documents so that changes can be clearly tracked. The different version is kept on sharepoint.

Link below:

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