

Response to MHRA Questions of 09 Feb 2022

Oxehealth, 2 Mar 2022

This document is shared in confidence with the MHRA and NHSE&I for the purposes of answering queries raised by the agencies about the Oxehealth Oxevision software and its product modules. This material is Oxehealth confidential and is not to be used or shared for any other purpose.

Oxehealth welcome the opportunity to discuss any of these matters further, to ensure all details have been fully clarified, and particularly to assess any actions being undertaken by Oxehealth to address concerns.

The answers refer to a number of attachments as follows:

- Attachment 1-Secure Housing Guidance
- Attachment 2-Oxehealth - Hardware Installation Acceptance Form - Mental Health
- Attachment 3-Oxehealth Staff Information Presentation Master_v3
- Attachment 4-Oxehealth_Reminder Sheet_v2
- Attachment 5-Oxevision training checklist_v1

1) In response to our question regarding whether there is a continuous video stream and if the images are retained, you have mentioned that Oxehealth is not a continuous user-viewable CCTV like video stream. However, we are aware of occasions where users have looked at the monitor before responding to patient calls and using the system to monitor patients. Also, when taking a measurement, to ensure the patient is still, the user reviews a live video feed. Please would you explain where there is a live video stream or not and if so, please could you confirm the arrangements for accessing that video stream and the storage arrangements for the data.

The user can view a live, identifiable video stream for a maximum of 15 seconds before the video feed is automatically closed when using the following software functions:

1. When taking a vital sign observation, in which case they are presented with the live feed, so they can assess if the patient is moving, and perform a visual check on the patient, and
2. When using the “view room” function, to allow a live visual check without disturbing the patient.

The latter of these two functions is an optional feature used by very few customers, and is only allowed when there is a clear customer request that has been approved via that customer’s clinical governance process. It can be offered with an anonymised video feed rather than a personally identifiable video feed if desired. In the UK it is only in use in 24 rooms across 3 wards of 2 NHS Trusts.

In the interest of clarity, the feature that allows users to view live or recorded video from a room in response to an alert always uses an anonymised video feed (so does not include personal data). Anonymised video may only be viewed under these circumstances if Oxevision is showing a room alert, and recorded anonymised video is shown only for the period that the alert has been detected.

The arrangements for accessing the videos feed are through the Oxevision user interface, which can only be operated on the “fixed screen” provided in a suitably secure ward office, or on mobile tablets, which have security PIN controls to prevent access by unauthorised users.

The identifiable video feed is temporarily stored in a buffer on the Oxehealth provided on-site server, located in an appropriately secure location (e.g. a data centre) on customer property. Only authorised Oxehealth staff may access these servers, with multiple layers of network and access security preventing unauthorised access. The buffer is designed to store at least 24 hours of data, such that in circumstances where the Trust instructs Oxehealth to retain the data for the investigation of a serious incident in a bedroom, it can be transferred to the Trust and/or Oxehealth for such an investigation. The stored video data is deleted after the buffering period, and video data is encrypted using AES256 prior to storage. Decryption keys are held securely by Oxehealth in a different location.

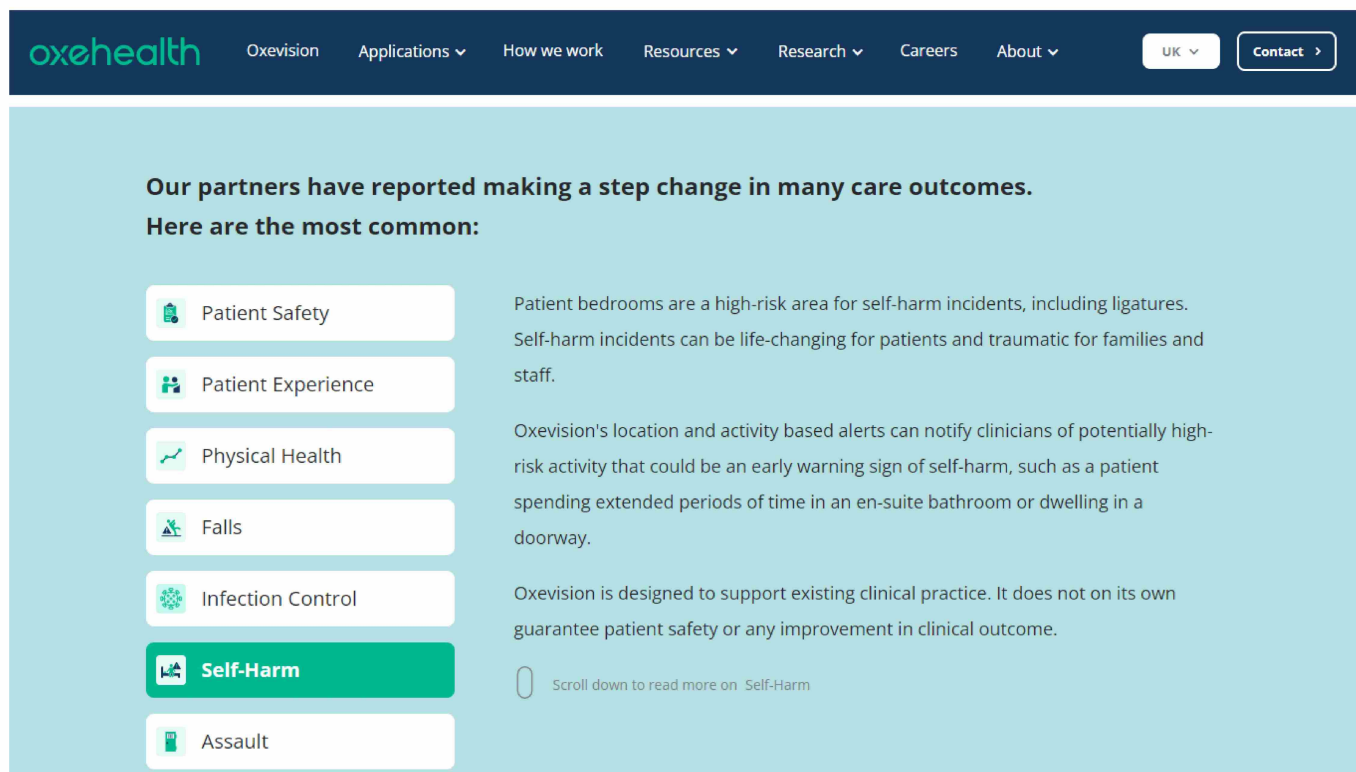
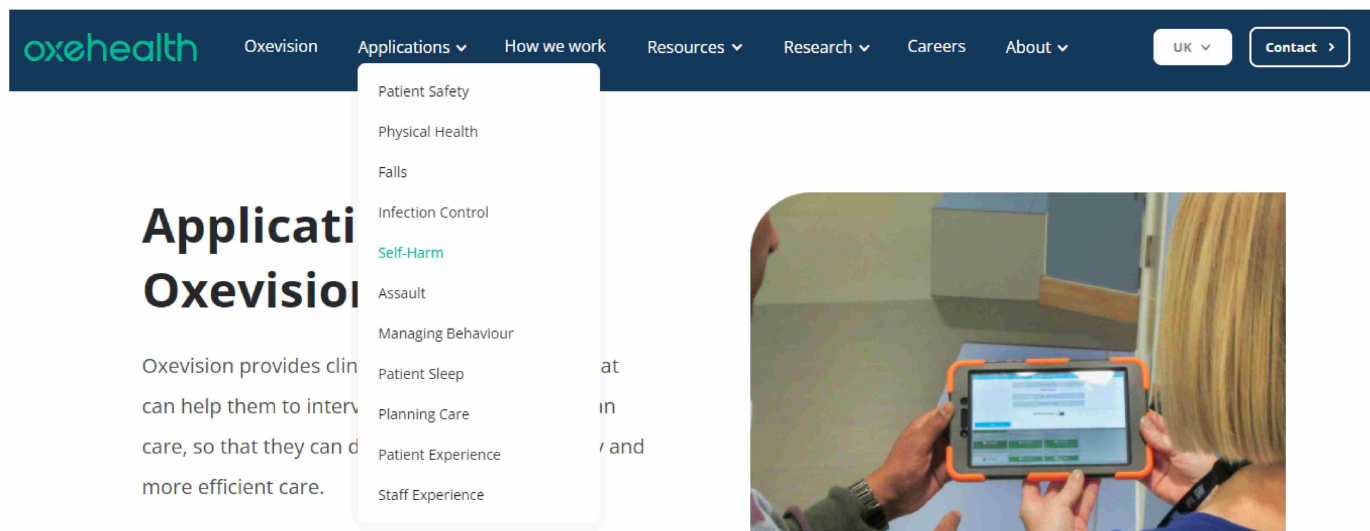
2) The justification for the claim “reduce self-harm” not being considered to be a medical device was that this was not a software product or software service that Oxehealth has produced. However, as this claim does have a medical purpose and the wording is included in the product literature and on the promotional material, then the MHRA would consider this to fall within the scope of a medical device. There is a risk that patients and users might think that the system will be able to alert staff to any self-harm attempt, which is not the case. Therefore, for this claim to be included in the product literature and advertising materials, it should meet the requirements of the Medical Devices Regulations and be included in the scope of the CE marking. Alternatively, we believe that the claim should be removed from the list of benefits of the system and in promotional materials until such time that it can be properly evidence as part of the medical device regulatory requirements.

From this question, we understood that you interpreted some of the statements on our website to indicate that our product delivers the clinical benefit of reducing self-harm. It was not our intention to state such a clinical benefit, and we very much appreciate this potential for misinterpretation being pointed out.

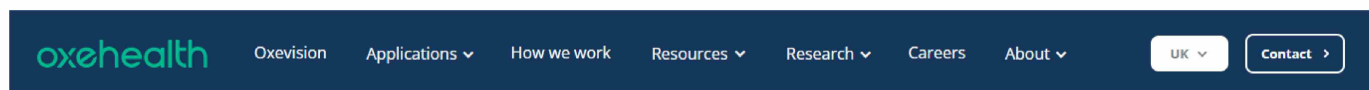
We have taken this matter very seriously, and it is a top corporate priority across many Oxehealth functions to update our marketing material to address the concerns. We have taken immediate action to update our website, and are undertaking further action to ensure that all relevant promotional, public and marketing material are reviewed.

The live <https://www.oxehealth.com/> website was updated on 23 February 2022, and we are keen to confirm whether the changes have addressed the concerns raised. In particular, we no longer include short statements that were intended to describe benefits clinicians had achieved having added Oxevision to their systems of care but which could have been taken out of context, such as “reduce self harm”; we instead present “applications of Oxevision”, describing the features of Oxevision that may be useful to clinicians, removing any text that could be misinterpreted as suggesting any direct reduction of self harm by the Oxevision software (as well as other direct beneficial changes in patient or care outcomes).

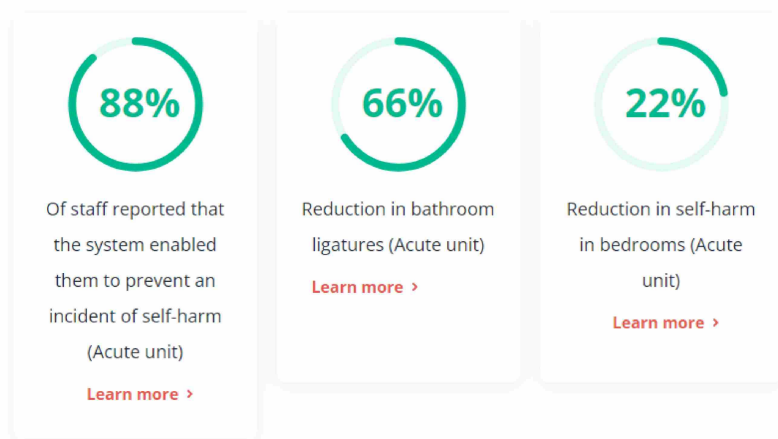
The screen captures below indicate these changes to the relevant sections of the website:



A further general change we have made is that where we present data from customers about how their changed clinical practices have affected care outcomes, it is made explicit that any improvements have been in response to clinician led changes as shown below:



Partners who have augmented their existing clinical practice with Oxevision insights report:



We also agree patients and users could in principle misinterpret the capabilities of the system, including thinking incorrectly that the system may be able to alert staff to any self-harm attempt. Our clinical hazard analysis of this risk is as follows:

- We treat this in general as a hazard of “misconception of system capability” by users and patients;
- The risks of system misuse caused by user misconceptions have historically been recognised and treated;
- The risks of patient misinterpretation are included and include other potential minor forms of harm (for instance distress caused by a misconception that they will have less contact with staff);
- Treatment of all of these potential hazards has used established processes for the provision of training by Oxehealth, marketing messaging training to control promotional and public information, and our usability engineering process where appropriate;
- In particular, risks of user and patient misconceptions are treated specifically in our early engagement materials and user training, including that customers and users should involve and inform patients and examples of how other customers have gone about this; and
- We are further strengthening risk treatment with the ongoing review of promotional and public material mentioned above. The updates to the Oxehealth website and Oxehealth’s standard training material that have already taken place included the removal of some text and quotations to reduce the risk of patient and user misconception.

3) NHSEI have highlighted concerns regarding the risk of the whole system when used in mental health care settings. In particular there are physical risks related to the fixing materials being used as ligature anchor points and it is unclear if the fitting instructions are sufficiently clear to address this risk. As fittings instructions are not provided and the fitting of the system is carried out by Oxehealth engineers, please could you inform us how you ensure the whole system is safe when installed in each room.

We would like to clarify the following aspects of the installation process, including how Oxehealth ensure that the hardware installed in each room is of an acceptable safety standard to the customer:

- The housing for the equipment is not installed by Oxehealth: this is provided to the customer, who then install this using their own staff or subcontractors;
- Oxehealth provide an installation plan to the customer, including guidance for housing installation as shown in Attachment 1 (note that anti-pick mastic is strongly recommended by Oxehealth but that ultimately it is up to the customer's own risk assessment and internal decision as to what type of mastic is used);
- Oxehealth subsequently install the camera and illuminator into the housing according to an internal installation guide; and
- Oxehealth requires a customer representative to sign a hardware acceptance form following completion of installation, to ensure that they have inspected the installation and have assessed it for safety according to all of their own requirements for their environment (see Attachment 2).

4) NHSEI have advised us that they reported an incident involving the fitting with wrong mastic which introduced a high ligature point in the room of multiple patients deemed at high risk of suicide. Please could you provide more details as this was not included in the list of incidents provided.

Our records indicate how Oxehealth staff have encountered and handled one event during the installation process for one customer. On this occasion, Oxehealth staff noticed incorrect mastic usage by a customer's installation staff (in this instance, a subcontractor chosen and procured by the NHS' trusts estates team) on a ward early in the installation process and immediately reported this to the customer and the installation staff, allowing the error to be corrected by the customer's installation staff prior to final installation inspection.

On this topic, we would be keen to discuss how sources of information available to and used by NHSEI that are not readily available to Oxehealth could be used in future as sources for feedback and post-market surveillance. Specifically, Frances Healey mentioned on the call we had in October 2021 that NHS England's Patient Safety team would be interested and willing to share relevant information that they receive through their national monitoring activities. We would like to explore this and other potential options that will enable us to continuously improve our post-market surveillance and risk management activities.

5) As Oxehealth is responsible for training the users, please provide more details on what this training covers.

We have provided our template training materials as attachments, which are used during Oxehealth's training of users during the installation process as follows:

- A presentation on the capabilities of Oxevision and its safe and correct use is given to users as part of the training prior to the system being made live (see Attachment 3), and
- A staff information sheet is provided with this training, which is left with staff, to remind them of the key software functions (see Attachment 4).

As we highlighted in our previous answer, following the initial training provided by Oxehealth, the customer is responsible for training any new or temporary users, providing this via their trained staff using the training presentation that Oxehealth prepared for initial training (a copy and recording of the presentation is given to the customer trainers). We are also using a training checklist with several Trusts, to ensure that the Trust can be confident that further staff training satisfies their requirements as well as Oxehealth's (see Attachment 5).

In addition to these training materials, Oxehealth have recently introduced the "OxeAcademy" website, which provides online training material to registered Oxevision users. This resource is for use by trained users after the system is put into use.

Oxevision Instructions for Use are also continually available to the users from within the software at all times.