

Response to MHRA Questions of 15 Nov 2021

Oxehealth, 20 Dec 2021

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.

Details on how the algorithm works for the vital signs trend, activity detection, fall risk, activity tracker and sleep products.

We have provided details of the principles of operation for Oxevision product modules as follows:

- Vital Signs
- Fall Risk Detection
- Location Risk Detection
- Activity Detection

The details provided for Vital Signs are taken directly from the Vital Signs medical device technical file as examined by our Notified Body, BSI, with additional material from the Vital Signs Instructions For Use. The details provided for the other product modules are taken from our internal design documentation for these non-medical devices.

We wish to clarify that Vital Signs Trends is not an Oxevision product module of its own: it is part of the Vital Signs medical device product module, and the principles of operation are presented as those of the Vital Signs medical device.

We also wish to clarify that we do not provide Oxevision “Sleep” or “Activity Tracker” product modules, and trust that the principles of operation provided for the other product modules are sufficient to describe how all of the product modules that detect some form of room activity work.

Vital Signs, including Vital Signs Trends

The following principles of operation are extracted directly from the medical device technical documentation for Vital Signs:

During operation the video camera captures images of the area to be observed then sends the raw, uncompressed video images to the Oxehealth Vital Signs video processing software that is running on the mini PC or server computer. The software performs an analysis which assesses the heart rate and breathing rate of any subject visible in the area to be monitored.

The Oxehealth Vital Signs software estimates vital signs from pixel intensities within the video images over time. For heart rate measurement, it derives the average pixel intensity of multiple regions in the video. The algorithm then identifies signals in the varying values of the intensities over time, and the locations of those signals in the images. For breathing rate, movements in the image are tracked through time so that breathing movement can be sensed.

The Oxehealth Vital Signs software is designed to capture physiological vital signs with the following performance characteristics:

- Heart rate is averaged over a sliding window, approximately nine seconds in length, and its values should be within 3 beats per minute of a reference CE-marked pulse oximeter (e.g., SOMNOscreen™ Plus manufactured by Somnomedics Ltd.).
- Breathing rate is averaged over a sliding window, approximately 30 seconds in length, and its values should be within 2 breaths per minute of a reference CE-marked breathing belt system (e.g., SOMNOscreen™ Plus manufactured by Somnomedics Ltd.).
- An outlier removal method is applied to the calculated heart rate and breathing rate to exclude any spurious measurements.
- The sliding window for heart rate measurement is moved forward one second at a time and so the Oxehealth Vital Signs software attempts to measure heart rate at a frequency of 1 Hz.
- The sliding window for breathing rate measurement is moved forward two seconds at a time and so the Oxehealth Vital Signs software attempts to measure breathing rate at a frequency of 0.5 Hz.
- The filters used within the algorithm determine the range of heart rates and breathing rates which can be measured by the device. The breathing rate and heart rate filters measure a range of 8 to 39 breaths/minute and 50 to 130 bpm, respectively.
- Heart rate measurement by the Oxehealth Vital Signs software relies upon it being fed images of the patient's skin (e.g. face, arms, and legs) and for the skin region to be trackable by the camera software.
- Breathing rate measurement by the Oxehealth Vital Signs software relies upon it being fed the video images of the subject containing regions of interest for which the small body movements associated with breathing can be detected and it requires these regions to be trackable by the camera software. The Oxehealth Vital Signs software algorithms are very sensitive to spontaneous natural breathing and can detect breathing even when skin is covered. Where coverings are excessively thick (e.g., multiple blankets) then the amplitude of the breathing signal may become too small for it to be distinguishable in the changes in the pixel intensities of the images; no breathing rate measurements will then be displayed.
- Where the level of motion of regions is too great for a heart rate and/or breathing rate to be reliably measured, then no values will be displayed for that vital sign. The Oxehealth Vital Signs software detects movements of regions in the images which are too large to be related to heart rate or breathing, and does not attempt to generate measurements at these times. Hence, for example, measurements will not be attempted from a subject who is walking around in the room.

The combination of image and signal processing techniques described above form one of the core operating principles of the software: that it only outputs readings that are likely to be human vital sign, and are not caused by or corrupted by spurious noise or other artefacts in the image.

Vital signs measurements by the Oxehealth Vital Signs software, together with video images are subsequently transmitted to the OxeServer software on the server computer of the secure local area network and made

available on the user interface. The images are not subsequently stored or transmitted over the secure wide area network via the internet to the OxeServer software, running on the Oxehealth server computer.

The values of the heart rate and breathing rate measured by the Oxehealth Vital Signs software, together with debug and log data and a stream of anonymised video images (a large kernel median filter is applied to make the subject in the images unidentifiable) are subsequently transmitted (regardless of whether or not a vital sign was measured by the trained user from the images) over the secure wide area network via the internet to the OxeServer software, running on the Oxehealth server computer, and stored in the secure Oxehealth databases. These anonymised images, heart rate and breathing rate values, debug and log data are subsequently used in continuous operational monitoring, post-market surveillance and clinical follow-up activities to ensure continued evaluation of the Oxehealth Vital Signs medical device and maintain optimal device operational performance.

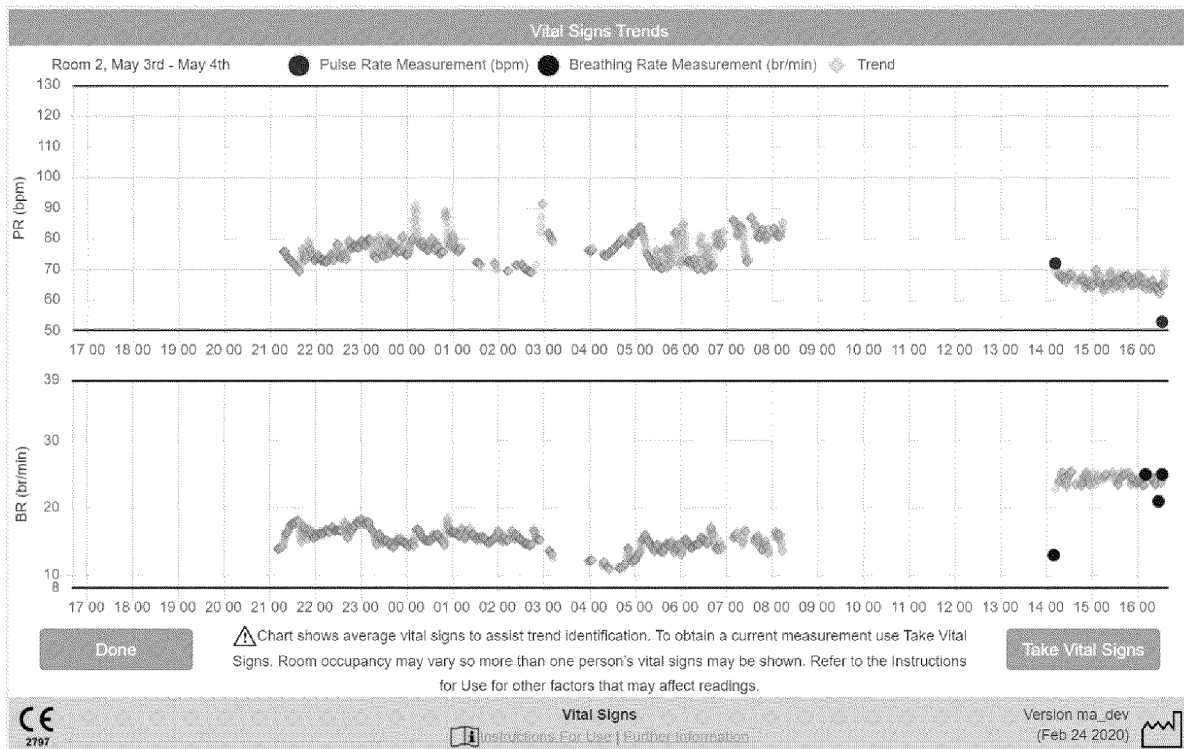
The software does not offer any “live” view of vital signs that regularly updates, and the user interface has instead been designed to offer routes to see either only readings at the time the software is operated (such that it is restricted to a spot-check observation), or historical readings.

Vital sign measurements are only made by the software if the signal processing algorithms indicate that any signals in the video are likely to be human respiratory or pulse rate signals that have not been affected by human movement or residual potential confounding factors.

The software includes a workflow that the user may use to confirm that there is no human movement or other potential confounding factors that could affect the vital signs measurements.

Where this workflow is not used, additional post-processing algorithms to filter out non-human measurements are applied, and appropriate cautions are displayed to the user. Evaluation of the clinical data for vital signs estimates obtained without the workflow are addressed separately within the Oxecam-CER-Clinical Evaluation Report.

A history of vital signs can also be accessed from the main screen of the software user interface. This history includes the vital-sign observations successfully made by the user and can additionally display all automated vital signs measurements made by the software [the Vital Signs Trends]. The display of all vital sign measurements made by the software may filter the underlying data to reduce it to an underlying trend, and this is displayed in a distinctly different format to the user observations to prevent misinterpretation of this trend data as observation data. The software displays a historical chart in a manner that is again designed to not be misinterpreted as a vital signs monitor as shown below:



In addition to the detail provided in the Vital Signs medical device technical file, we include the following details of how Vital Signs Trends are calculated from the Vital Signs Instructions for Use:

Each grey trend point (◇) on this graph represents the average value of all collected pulse rates or breathing rates over a five minute period. Vital signs trend points are shown when measurements have been collected by the software for at least 75 seconds of the five minute period. The chart shows a period of one day to provide a balanced overview of the subject's recent state and so that underlying trends may become apparent. Rapid, short duration changes in pulse rate or breathing rate will not appear on the trend chart.

Fall Risk Detection

The Fall Risk Detection product module uses the following algorithm:

- The system identifies the location of the bed in the camera's field of view.
- The data from the camera are analysed each second to detect the locations of any movement in the field of view
- The algorithm uses movement in the bed location to establish whether the bed appears to be occupied
- If the bed is detected to change from occupied to unoccupied, based on the locations of movements, an Out Of Bed notification is generated
- If movement becomes concentrated near the edge of the bed region, having been concentrated near the centre of the bed region, after the bed has been detected as occupied, an Edge Of Bed notification is generated.
- If the movement suggests that a person is lying on the floor of the room, then a Fallen Person notification is generated.

Location Risk Detection

The Location Risk Detection product module uses the following algorithm:

- The system is configured with the locations of fixed regions in the camera's field of view (for example, a doorway).
- The data from the camera are analysed each second to detect the locations of any movement in the field of view
- The algorithm uses movement levels in the regions to establish whether the region appears to be occupied
- If the algorithm detects region occupancy which matches pre-specified notification criteria, chosen by the customer healthcare provider, a notification is generated. The criteria may require a region to be detected as occupied for longer than a predetermined time. For example, occupancy of a bathroom detected for a pre-specified number of minutes can trigger an "In Bathroom" alert. Occupancy detected for a pre-specified number of minutes dwelling in a doorway can trigger an "At Door" alert. Two regions of occupancy can indicate that there may be two people in the room, triggering a "Room Entry" alert.

Activity Detection

The Activity Detection module uses the following algorithm:

- The data from the camera are analysed each second to detect the locations of any movement in the field of view
- The algorithm uses movement levels in the room to establish whether the room appears to be occupied (including detecting whether a pattern of movement suggests that a person has entered or left the room).
- If no substantial movement is detected in the room for more than a prespecified period of time, but the room is still detected as occupied (i.e. prior movements have not suggested the person has left the room), an alert is generated.

You have mentioned that the system observes patients continuously and confidentially from a ceiling camera. Is this a continuous video stream? Are the images retained?

To briefly answer these two questions:

- **Is this a continuous video stream?**
 - Although the slides provided to you previously indicate that the system observes patients continually, there is not a continuous user-viewable CCTV-like video stream of personally identifiable data.
 - There is, however, a continuous stream of data from the camera sensor to the image processing software within Oxevision, upon which the software described in the previous section operates to produce the vital sign measurements and room activity alerts that the user may see on the user interface. This continuous stream of data is also transferred by the software to the retained “buffer” described in the next section.
- **Are the images retained?**
 - There is a continuous “buffer” of personally identifiable video data from the camera stored by the image processing software on the servers located on the customer site. This video “buffer” is not viewable by users of the Oxevision software or Oxehealth staff.
 - Short sections of this historical data are moved onto an attached storage platform for the following two processing purposes only:
 - For the Trust to investigate a clinical or safety incident, in which case, Oxehealth extracts an encrypted video of the requested period and provides it to the healthcare provider’s staff, or
 - Occasionally, for Oxehealth to investigate a software or site performance issue (including medical device complaints). Data of this type is only processed by Oxehealth where absolutely necessary and the data retained for the shortest period of time necessary for that purpose.
 - The retention and use of this data is under the instruction of the Trust acting as data controller, according to the service agreement between the Trust and Oxehealth (the data processor). Oxehealth reports to Trusts on its data holdings every 6 months.

Please provide the rationale used to justify why the modules Vital Signs Trend and reduce self-harm are not being considered to be medical devices?

We have treated the rationale for the medical device status of “Vital Signs Trend” and “reduce self harm” separately.

First, we would like to state that we do not believe that the Vital Signs Trends feature is not a medical device. When Oxehealth developed this feature, we recognised it would have a medical purpose and qualify as a software medical device, and given this analysis, chose to implement this as an optional extension to the existing Vital Signs Software medical device. The extension to the Vital Signs software medical device was made in consultation with our Notified Body, BSI, and was approved as being a change that was not substantial, did not change the intended use of the device, and has subsequently been subject to technical documentation audit by BSI.

In support of this, we have included relevant extracts from the change notification we submitted to BSI, which was subsequently approved prior to us placing Vital Signs Trends on the market.

Second, “reduce self-harm” is not a software product or software service that Oxehealth have produced, or placed on the market. Empirically, studies have shown that clinicians who use Oxevision within their system of care find themselves able to reduce self harm. For clarification, these findings are communicated through our website and other clinical benefit materials as an example of the kind of changes that clinicians have achieved when they have used Oxevision as part of their overall care regime, including all of their other sources of clinical information and existing care and risk reduction processes.

To provide details of our rationale for why product modules in Oxevision other than Vital Signs are not medical devices, we have included our analysis of their intended use and functions in relation to the UK and EU Medical Device Regulations definitions of a medical device. We have separated this out into the overall platform, Oxevision, and individual product modules, Activity Detection, Fall Risk Detection, Location Risk Detection, Activity Report and Seclusion.

Vital Signs Trends

The following are extracts from the change notification Oxehealth supplied to their Notified Body, BSI, prior to placing the updated Vital Signs medical device that incorporated the Vital Signs trends feature on the market:

Justification

Changes have been made to the claims made about the device but not its intended use, contraindications or warnings. The claim is that vital signs may be obtained from the device without executing a workflow that had previously been designed to verify that certain risk factors are not present. Where vitals signs are displayed that were not taken using this workflow then additional post-processing to filter out non-human readings and an additional caution shall be applied instead.

The accuracy claim is unchanged, and this continues to be substantiated by existing clinical trial data, using the original clinical evaluation protocol for statistical analysis of the data.

The principles of operation of the software remain the same, and no changes have been made to software architecture, the principles of design, implementation languages. The changes have been made to the user interface software components only, without changing the software components that extract vital signs from video.

The application of risk control measures has been modified, but no new hazards to the patient have been created, nor the risks associated with any existing hazards increased.

Compliance with the Essential Requirements of the MDD are unchanged.

Changes to the device have been made in response to demand and opportunity to assist existing NHS customers in their COVID-19 response. The intention is to give them the ability to see a much larger volume of accurate vital signs data without contact and therefore viral infection risk, that may allow them to identify trends that they previously could not have seen, while operating the Vital Signs product in a much more time efficient and expedient manner under the increased patient load that the decreasing staff numbers are experiencing.

These changes are not in response to any INCIDENT, complaint or negative trends in PMS data.

Description of Changes

The measurement function of the device currently requires the user to operate the following workflow to obtain a pulse rate and/or breathing rate that acts as a risk control for subject movement and potential sources of frequency within the area being monitored that could be mistaken for a vital sign:

1. The software attempts to estimate a vital sign from all possible signals in the area to be monitored once per second, and if no estimates are possible, the user is not allowed to start the workflow
2. They view a video and answer the question "is the subject still?"
3. If they indicate that the subject is still, they are then shown a still image with the areas highlighted from which the vital sign(s) were measured ("blobs") and asked the question "are there any blobs that do not touch the body?" (possible answers "yes" and "no")
4. If they answer "no", they are then shown the measured vital sign(s) and the time at which they were measured
5. The claim made is that pulse rate error is less than 3 beats/minute and breathing rate error is less than 2 breaths/minute (RMSD for all measurements taken)

We call this the "2 question workflow".

The change to the software allows the user to observe the graph of all vital sign measurements that were not taken using the 2 question workflow and instead apply post-processing to filter out non-human readings (identified using algorithms to detect measurements with little variance and measurements that are very short lived) and display a caution to the user. The clinical evaluation protocol and data captured to substantiate the original claim shows that the accuracy claim is still substantiated for measurements taken without the 2

question workflow. The risks that are controlled by the workflow and the replacement post-processing have been shown to be very low likelihood by post-market surveillance data (over 1,150,000 hours of debug data and over 117,000 vital sign observation attempts made by users), with no potential for harm to users having been reported.

New risks introduced by the changes are very low, with only a very minor risk of human vital signs being filtered out by the new post-processing algorithm. The benefit of showing all vital sign measurements that the software has taken is that the user may observe many more measurements than was previously possible, allowing them to see trends in the data. The risk control is therefore replaced with post-processing steps to filter out non-human readings that are likely to have been rejected by users and indications to the user (a caution) of the residual risk that subject movement and other sources of frequency content may affect readings, and to read the instructions for use.

Historical graphs of measurements of all vital signs obtained by the software may therefore be observed, but with post-processing to filter out non-human readings and the additional caution above.

Spot-check measurements of vital signs may therefore be taken without the 2 question workflow, but with post-processing to filter out non-human readings and the additional caution described above.

Subject to both of these changes, the device is still intended to be used as a spot-check measurement device and is not a vital sign monitor. Vital signs readings are not continuous, and the software is still designed to allow users to take direct spot-check measurements that include visual confirmation of the subject's situation, with all software functions retaining design features that avoid misuse of the device as a monitor.

Other non-medical device modules

We present our analysis according to the UK MDR and EU MDR definitions of medical devices and medical device accessories, as we assess during the regulatory planning phases of all product development at Oxehealth. Please note that we have chosen to not include reference to “control of conception”, as we believe it is abundantly clear that none of the Oxehealth products have this purpose. We first list the intended use of the various product modules, taken from the Instructions for Use that Oxehealth provides, and then describe the analysis of these intended purposes against the medical device and medical device accessory definitions:

Product Module	Indications for Use (from the published Instructions for Use documents)
Location Risk Detection	<i>The Location Risk product 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:</i> <i>• 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;</i> <i>• 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;</i> <i>• The activity suggests that the occupant has left the room;</i> <i>• The activity suggests that a second occupant has entered the room;</i>
Fall Risk Detection	<i>The Fall Risk Detection product 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:</i> <i>• If it detects that a person has left the bed area (“out of bed detection”);</i> <i>• If enabled, if it detects a person on the edge of the bed area and is making movements which would suggest that they are getting out of bed (“edge of bed detection”);</i> <i>• If enabled, if it detects that a person has been on the ground for an extended period (“fallen person detection”).</i>
Activity Detection	<i>The Activity Detection product is intended to set off a visual and audible alert if it cannot detect activity in a room occupied by a sole occupant, having detected occupancy.</i>
Activity Report	<i>The Activity Report product provides a timeline summary of categories of activity detected by Oxehealth activity tracking products.</i>
Seclusion	<i>The Oxehealth Seclusion product provides a timeline summary of categories of activity detected by Oxehealth activity tracking products, vital sign measurements from the Oxehealth Vital Signs product and indications of rapid tranquillisation events entered by clinicians.</i>

Definitions	MEDICAL DEVICE DEFINITION Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease	MEDICAL DEVICE DEFINITION Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability	MEDICAL DEVICE DEFINITION Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
Location Risk Detection	Not for direct diagnosis etc. of disease	Not for direct diagnosis etc. of injury or disability	Not a physiological or pathological process or state
Fall Risk Detection	Not for direct diagnosis etc. of disease	Not for direct diagnosis etc. of injury or disability, detection of a potential past fall event only based upon an assessment that a person appears to be on the floor, not impact or injury	Not a physiological or pathological process or state
Activity Detection	Not for direct diagnosis etc. of disease	Not for direct diagnosis etc. of injury or disability	Not a physiological or pathological process or state
Activity Report	Not for direct diagnosis etc. of disease	Not for direct diagnosis etc. of injury or disability	Does not report a physiological or pathological process or state
Seclusion	Not for direct diagnosis etc. of disease	Not for direct diagnosis etc. of injury or disability	Reports data from a medical device without modification, otherwise does not report a physiological or pathological process or state

Definitions	MEDICAL DEVICE ACCESSORY DEFINITION To be used together with a medical device to specifically enable it to be used in accordance with its intended purpose	MEDICAL DEVICE ACCESSORY DEFINITION To be used together with a medical device to specifically and directly assist the medical functionality in terms of its intended purpose
Location Risk Detection	Used alongside for a different purpose	Does not assist the Vital Signs medical device
Fall Risk Detection	Used alongside for a different purpose	Does not assist the Vital Signs medical device
Activity Detection	Used alongside for a different purpose	Does not assist the Vital Signs medical device
Activity Report	Used alongside for a different purpose	Does not assist the Vital Signs medical device
Seclusion	Summarises medical device outputs with other data, but not required to achieve the medical device purpose	Does not assist the Vital Signs medical device, as the medical device may be used without Seclusion to achieve its intended purpose

Details of customer complaints that you have received and why you consider that they may not be reportable to MHRA.

We have provided a detailed summary of all complaints received since the Vital Signs medical device was placed on the market in the Appendix. These summarise as follows:

- In total, 15 events have occurred that were classified as complaints.
- Of these 15 events, 4 were raised by Oxehealth through its live monitoring and PMS processes, and the remaining 11 were raised from customer feedback
- Of all of the complaints, only 3 related to events where the user could potentially obtain vital signs data in error. The remaining occurrences were all either failures of functions that could not affect patient safety, expected failure modes, security issues or issues where existing risk control measures would prevent any harm from occurring. These complaints have been highlighted.
- Detailed rationale is provided for all complaints according to the definitions of reportable INCIDENTS from MEDDEV 2.12/1 rev 8.
- Oxehealth has responded to all complaints with software fixes and other actions to correct any defects and ensure that risks are reduced as far as possible.

What actions have you taken to address the total risk presented by all of the components when used in health /mental health environment and other care settings?

First of all, we would like to summarise our approach to risk management of the Oxevision software:

- The risks presented by Oxevision and all of the Oxevision product modules (including vital signs) are assessed according to DCB0129. This risk analysis considers the risks presented by each product module, and also, the risks of the use of product modules together.
- We apply a medical device risk management system for the Vital Signs medical device according to the Medical Device Regulations (as per ISO 14971). The scope of the Vital Signs technical file and risk analysis includes all of the software components within Oxevision that enable and support the medical device, including the software framework and user interface that also enables and serves the other non-medical device product modules. This risk analysis also includes the risks presented by using the medical device alongside other Oxevision product modules. (The diagram below illustrates the scope of the medical device software, so the extent of medical device software risk control can be seen.)
- We apply the approaches we developed for medical device risk control to the whole of Oxevision and all other Oxevision product modules, as those approaches are mature, based on processes and systems already in place, and provide a greater degree of risk control and risk monitoring than a DCB0129 standard clinical risk management approach ordinarily would. The additional benefits of the medical device risk control regime are described below.

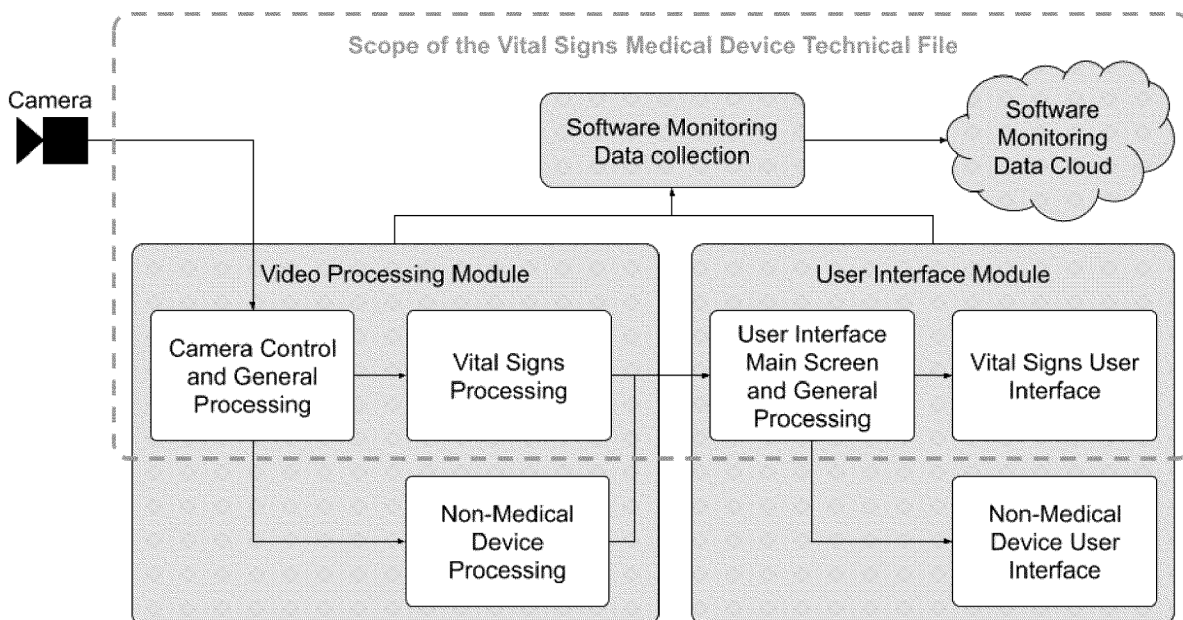


Illustration of the extent of the Vital Signs medical device technical file

The additional benefits of applying a risk control regime developed for the Vital Signs medical device to the rest of Oxevision and the other Oxevision modules which are not medical devices include:

- Having a structured formative and summative usability evaluation approach to software usability based on the IEC 62366 family of standards.
- Including quality process controls as part of transferring software from design to production, leading to the creation of:
 - Sales controls for qualifying customer use cases against the indications for use
 - Pre go-live validation of an installation to control environmental risks before it is placed into service
 - User training prior to placing into service
- Engagement with Trust patient safety and data governance as part of the sales process.
- Post market surveillance (PMS), including extensive live monitoring, data collection and analysis, and customer feedback analysis designed to continually inform Oxehealth of risks, such that the benefit-risk analysis may be continually updated, customers informed of any emerging risks and the product improved to further reduce risks.
- Post market clinical follow-up (PMCF), including a periodic review of the benefits and effects of the adoption of Oxevision with all customers as part of the service, and ongoing research activities with customers and academic partners to evaluate the safety, effectiveness and benefits of the software.

The specific risk control measures we have applied are elaborated in the following sections as extracts from our Clinical Risk Management File for Oxevision (including all Oxevision product modules, including Vital Signs), detailing:

- Software design controls (inherent safety by design)
- The approach to risk management of the live software
- Additional risk controls applied since placing the software into service

Software Design Controls (Inherent Safety by Design)

We have included an extract from the latest version of the Oxevision Clinical Safety Case Report (part of the DCB0129 Clinical Risk Management File), to indicate the various risk control measures that Oxehealth have designed into the Oxevision software (including all Oxevision product modules, including Vital Signs), and into the processes it uses to design, produce, deliver, monitor and maintain the software. The extract includes design controls intended to address the following categories of risks:

- Technical failures of software and hardware
- Usability and human factors
- Environmental factors
- Patient condition and behaviour
- Deployment and installation
- The use of the Vital Signs medical device alongside the other non-medical product modules

These design controls include those that were designed as part of the Vital Signs medical device.

Please note that the risk controls describe the “Assisted Observations” product module, which is currently a pilot product module undergoing service evaluation in a very small number of Trusts alongside existing nurse observations protocols. The product module is intended to provide a unified way for nurses to enter patient observations alongside using the Vital Signs product module. The module is fully risk analysed, designed,

produced, tested and deployed using the full risk management process, such that all risks have been considered and reduced as far as possible, but the pilot usage is restricted to where the normal nurse observation protocols continue to be used as the primary method of planning and giving care. Please note the working internal project name for this module was “Oxehealth Assisted Observations” and so the quoted text calls it “Assisted Observations”. In fact no assistance is rendered to the user so the launch name will be “Oxevision Observations”, which connotes its true nature - an data input system.

The extract from the Clinical Safety Case Report now follows:

Risk controls were identified for the clinical hazards according to the risk management process, as follows:

1. *Inherently safe design of the software;*
2. *Protective measures in the software itself or in the implementation process;*
3. *Information for safety (provided in the Instructions for Use);*

Software features designed to mitigate the risks are as follows:

- ***The primary workflow feature, to ensure that users verify the patient is still, and that vital signs are being estimated by the software from areas on the body; and***
- ***Software feature to ensure the user cannot wait for more than a reasonable period while attempting to take a vital sign;***
These features mitigate the risks associated with environmental factors, a second occupant, or patient movements that the software could mistake as the patient's pulse rate or breathing rate, by forcing the user to verify that the patient is safe, still, and that the areas in the image that the software is detecting vital signs within are on the body of the patient.
- ***Post-processing to remove non-human readings that are either very constant or occur for only very short periods of time;***
This feature mitigates risks associated with environmental factors and failure modes in optical hardware that could lead to errors in pulse rate or breathing rate by filtering out readings that are either very constant (and therefore very likely to have a mechanical cause), or occur for very short periods of time (and are therefore likely to have been caused by a transient environmental factor).
- ***Software identification of image stream properties that could lead to erroneous vital signs (frame rate and dropped frames); and***
- ***Software controls to configure and validate camera settings;***
These features mitigate failure modes in optical hardware that could lead to errors in pulse rate or breathing rate, as well as mitigating risks of these readings being unavailable.
- ***Software controls to fail safe in event of partial system failure; and***
- ***Software data and communications design includes timing information, with data and time synchronisation of all hardware, to prevent the display out of date data; and***
- ***Use of communications protocols robust to loss of data by design;***
These features mitigate the risks of hardware, software and communications failure modes that may cause a delay in communications of data, resulting in the user observing an old reading.
- ***Software features to ensure safe restoration of function following hardware failures;***
This mitigates the risks that the software is continually unavailable to the user.
- ***Security design requirements to mitigate all known pre-market vulnerabilities; and***

- **Encryption and authentication of all communications within the Oxecam solution; and**
- **Encryption of all data stored on devices; and**
- **Mobile device management controls to prevent unauthorised access; and**
- **User authentication as an option for features that allow carers to view confidential data; and**
- **Optional timeout of patient video viewing function;**

These features mitigate the risks associated with malicious, intrusive activity (potential interference causing errors in readings, unavailability of the software, or a loss of data confidentiality).

- **Clear segregation by name, and separate labelling of the Vital Signs product from the non-medical Activity Detection, Location Risk and Activity Report products;**

This design approach mitigates the risks of foreseeable misuse or misinterpretation of the non-medical parts of the Oxevision product suite leading to the user either failing to, or being unable to obtain vital signs.

- **Use of database software and integration patterns that limit the likelihood of corruption;**

This design choice ensures that the risks of corruption of Assisted Observations records are minimised, reducing the risk of users reviewing data that is incorrect.

- **Software feature to "lock down" Assisted Observations within 1 minute of them first being taken, preventing overwriting; and**

- **No user or administrative features for modifying or deleting Assisted Observation records;**

These design features mitigate the risk of foreseeable misuse where users may mistakenly overwrite existing patient observations and later review data that is incorrect. The 1 minute editing period is intended to allow users to complete making a set of observations and potentially perform immediate adjustments.

- **Distinctly different indicators on the trend chart for observations taken by the users and trend points, with prominent key to indicators;**

This is a direct usability design control, to ensure that the likelihood of misinterpretation the vital signs trends chart is as low as possible. The indicators on the chart for observations the user has taken continue to be bright red and bright blue solid circles to maintain consistency with the vital signs observations chart, and trend points are indicated as light grey diamonds. A prominent key is included at the top of the chart to indicate the meaning of the data points.

- **Prominent caution on the Vital Signs Trends chart to inform users of the risk of readings coming from other occupants; and**

- **Prominent caution on the Vital Signs Trends chart to inform users that the chart is not a monitor; and**

- **Prominent indication to the user directly on the Vital Signs Trends chart that the values are averaged and to use take Vital Signs for current observations;**

These cautions are displayed on the Vital Signs Trends chart user interface, in order to inform the user directly of the residual risks associated with readings coming from other occupants, that the chart is not a monitor and to use the Take Vital Signs function to obtain current pulse rate and breathing rate.

- **Prominent display of room name on all screens; and**

- **Touch/click visualisation and room selection indication;**

This is to reduce the likelihood of a user slip or failure in touchscreen hardware leading to the wrong room being selected when using the software.

- **Only timings of tranquiliser administration are recorded, rather than dose, forcing users to consult other records;**
This is to reduce the likelihood of the Seclusion product being misused as a medication record.
- **Restriction preventing use of User Authentication with Vital Signs history and trends;**
This mitigates the risk of human error and system error when using user authentication from preventing users from accessing historical health data, thus delaying appropriate care from being given.
- **Combined audio and visual alerts;**
This mitigates the risk of users being unaware of alerts, maximising the chance that alerts can always be seen or heard.
- **User Interface locked to Oxevision app, preventing user access to operating system volume controls; and**
- **Device level volume control set by app on mobile devices;**
These controls limit the ways in which the user can accidentally reduce the volume on touch screen and mobile devices, ensuring that audible alerts can always be heard.
- **Installation with user disable/pause features is possible, preventing users from disabling the system;**
The features that allow users to disable or pause processing in rooms may be selectively switched off, such that users will be unable to silence alerts.
- **Observation values are presented in recognised clinical units (bpm, br/min); and**
- **Units are displayed with all readings (observations and graphs); and**
- **Time is displayed in the accepted increasing time to the right format;**
These controls are intended to minimise the risk of user misinterpretation of the vital signs data presented.
- **Swing room design feature to ensure rooms appear on only one set of configured user terminals/mobile devices for a single location;**
This feature has been designed to ensure that, where users can assign a room to different locations depending on the way the room is being managed, that it must exist on one and only one configured user "location", such that it cannot be mistakenly missed from all user displays, and appears on only the displays of those users with responsibility for the room.

All the design features of the software are verified through controlled product verification and validation according to the Oxehealth ISO 13485 QMS. Each new release of software is subject to verification of the implementation of all design specifications, and validation of all required system functionality prior to a software release being made available for delivery to customers.

Further protective measures were not considered to be possible within the software, however protective measures have been applied to the implementation and deployment processes for the software as follows:

- **Live operational monitoring features of the software, allowing Oxehealth to continually monitor the performance, behaviour and usage of the software; and**
- **Post-market surveillance and clinical follow up activities to continually evaluate the effective and safe use of the software, and the benefit-risk profile;**
This provides further control and monitoring of most risks, by providing Oxehealth with live monitoring data and additional evaluation data to help quantify existing risks, and identify emerging hazardous situations and potential usage patterns and issues with the software.

- **Product qualification through software and hardware soak and stress testing;**
This controls many of the hazards relating to performance of hardware, by ensuring that the repeated verification and validation testing of the software includes prolonged testing on the hardware platforms.
- **Usability engineering activities to ensure the user interface is easily interpretable; and**
- **Usability testing of Assisted Observations under supervision, alongside an existing safety observation regime, to verify that design minimises misuse;**
This usability study is intended to assess and mitigate the risks of misuse of the Oxehealth Assisted Observations product, and may result in further design, testing, installation, training or other controls being put in place prior to the product being placed on general release.
- **Provision of electronic and paper copies of instructions for use; and**
- **On-site training to be provided for ward staff prior to any Oxehealth Oxevision software being made live;**
This further mitigates the risks of foreseeable misuse or misinterpretation of the user interface leading to the user being unable to obtain vital signs, with controlled sign-off of all customer installations requiring training to be complete.
- **Controlled installation, installation qualification and operational qualification procedures (including the requirement that a fixed terminal user interface is installed); and**
- **Installation by a qualified and trained engineer;**
These processes mitigate many software and hardware performance risks, by ensuring that the software is operating according to specification prior to use, with controlled sign-off of all customer installations requiring these processes to be complete.
Furthermore, the procedures require that a “fixed terminal” user interface is installed to mitigate risks associated with mobile device battery life, ensuring that users will always have a fallback option for operating the system in the event of mobile devices switching off.
- **Only approve hardware through confirmed performance testing; and**
- **Ensure the use of hardware that is approved only through controlled installation procedures;**
These processes result in Oxehealth having an approved hardware list, and installation processes that ensure only approved hardware is installed prior to the software being deployed to customer sites.
- **Clear communication of the scope of the Oxehealth Vital Signs product and its claims in sales and marketing handover material; and**
- **Control of sales and marketing to avoid deployment where contraindications and confounding factors may be present;**
These controls ensure that the risks of environmental factors potentially leading to users taking wrong readings are avoided, by controlling the sales process.
- **Clear communication of the scope of the Activity Detection, Falls Risk and Location Risk products and their claims in sales and marketing handover material; and**
- **Control of sales and marketing to avoid deployment where contraindications and confounding factors that could contribute to over alerting may be present;**
These controls ensure that the risks of environmental factors potentially leading to over alerting are avoided, by controlling the sales process. Avoiding over alerting subsequently reduces the risk of alert fatigue and user disabling the system.
- **Clear communication of the scope of the Falls Risk Detection product fallen person feature and its claims in sales and marketing handover material; and**

- **Control of sales and marketing to avoid deployment of the fallen person feature where contraindications and confounding factors may be present;**
The sales and marketing controls are used in this instance to prevent deployment of the fallen person feature where confounding factors would likely lead to a low detection rate of a fallen person. A particular example is wheelchair use.
- **Control of sales and marketing to avoid deployment of the Vital Signs software contrary to labelling for use in single occupancy rooms;**
These controls ensure that the commercial team are fully aware of the Vital Signs medical device indications for use in single occupancy rooms only, and of criteria for establishing if any foreseeable occasional multiple occupancy would pose any clinical risk to the patient (see further note on Controlling for Use in Single Occupancy Rooms for details of how this is applied).
- **Deployment controls to prevent deployment of a non-released product, and configuration updates that would affect performance, safety or security adversely;**
This process prevents Oxehealth staff from re-configuring the Oxevision software in a way that might affect patient safety or data confidentiality, with controlled sign-off of all modifications to customer installations required in order for these processes to be completed.
- **Oxhealth operates an ISO 27001 certified information security management system that mandates and monitors:**
 - **Ongoing security testing; and**
 - **Ongoing post-market vulnerability monitoring to inform software updates and patches;**
These processes form part of Oxehealth's audited Information Security Management System (ISMS), and control for emerging security risks that might affect the patient confidentiality breach hazard.
- **Installation controls for ensuring best practice hardware and network security setup;**
This control forms part of the controlled installation process designed to ensure medical device safety by communicating best practice security guidelines when clients provide their own network and IT setup, and Oxehealth verification of the controls put in place.
- **The use of Oxehealth Assisted Observations is, at present, limited to demonstration and service evaluation trials, which are supervised by Oxehealth and allowed to only take place alongside existing safety checking regimes;**
This approach is taken while usability testing and evaluation of the effectiveness of the Oxehealth Assisted Observation software is being carried out. Further design, testing training and other risk controls may be applied as a result of these evaluations.

Finally, one area for potential process change in order to safely adopt the use of the Oxehealth Oxevision software when using the Vital Signs product module is suggested, relating to the indications for use in single occupancy rooms only:

- **In order for the Vital Signs software to be deployed in accordance with the indication for use in a single occupancy room, any potential multiple occupancy must be occasional, and the users must have awareness, ability to monitor, and control over such instances;**
These criteria are to ensure that the adoption of Oxehealth Vital Signs may be in accordance indications for use in single occupancy rooms only (see further note on Controlling for Use in Single Occupancy Rooms for details of how this must be implemented).

These protective measures in Oxehealth's production and QMS processes are verified in two ways:

- Where the effectiveness of control measures form part of the wider Oxevision and Vital Signs product requirements (for example, the use of Instructions For Use in training), verification is carried out using appropriate techniques as part of product verification and validation prior to a new software release being made available to customers; and
- Processes that form part of the Oxehealth QMS and ISMS, these are verified as effective through process review, internal audit and external audit;

Finally, information regarding residual risks is communicated to users through the software Instructions For Use as follows:

- Environmental and patient movement factors are identified as cautions for use;
- The primary workflow is described in detail, with a caution indicating the importance of correctly ascertaining that the patient is still, and the software is taking pulse rate and breathing rate readings from the body;
- Areas of potential misuse are identified in the descriptions of how to use the device;
- Risks of unauthorised to patient identifiable images and healthcare data are highlighted, with a prominent caution;
- Users are warned against using the Seclusion product as a medication record for planning or reviewing patient tranquilisation;

Oxehealth's processes for handling user training are controlled, such that all safety information included in the Instructions For Use is included in all communications, with controlled sign-off of any new or modified material prior to the release of the material to users.

Completeness of the risk control activities is established prior to a software release being made available for delivery to customers in the following manner:

1. Each hazard is considered to have been reduced as far as possible;
2. A risk/benefit analysis has been made for each hazard, and the benefit the patient deemed to outweigh any residual risk;
3. An overall risk/benefit analysis of all residual risks has been made, and the benefit the patient deemed to outweigh the total residual risk;
4. Residual risks have been communicated to the users where required;

This evaluation is completed by the risk management team, requiring sign-off from the team and any other appropriate reviewers who were identified during the risk management process prior to a software release being made available for delivery to customers.

Controlling for Use in Single Occupancy Rooms

The key criteria for ensuring that the Oxehealth Oxevision software is installed in accordance with the indications for use in single occupancy rooms are to ensure that the users have awareness, ability to monitor, and control over such instances, and they are as follows (if all may occur, then this would be contrary to labelling):

- When other occupants may routinely remain still for extended periods and may therefore create automated vital signs trend measurements instead of the intended subject; and
- Such an occupant does not have the ability to provide the care and monitoring the subject would otherwise require; and
- The users are unlikely to be aware of secondary occupancy and may therefore misinterpret vital signs measurements from them in the view of vital signs trends;

Risk Management Following Production and Placing into Service

The following is an extract from the Oxevision Clinical Safety Case Report (part of the DCB0129 Clinical Risk Management File), to summarise the approach being taken to further monitor and analyse risks in the post-production period:

Clinical Risk Management in Post Production

Risk management in post production is provided as follows:

- A “Post Market Surveillance Plan” describes how Post Market Surveillance (PMS) and Post Market Clinical Follow Up (PMCF) will be carried out for the Vital Signs medical device as part of the Medical Device Risk Management Process. This plan is used in conjunction with the PMCF plan indicated below for Oxevision and other Oxevision product modules, and the Post Market Surveillance (PMS) Process within the Oxehealth Quality Manual, which includes procedures to revisit risk assessment in response to feedback data;
- Revision of the measured likelihood and severity of risks in the Clinical Hazard Analysis is carried out following PMS and PMCF activities. The hazard analysis is updated with post-market analysis information and indications of whether risk likelihood and/or severity are to be updated in response to the data;
- The Risk Management Process is revisited under the Change Management Procedure within the Oxehealth Quality Management System as the result of during any proposed modifications to the product;

Oxevision PMCF Plan

As part of ongoing PMCF, Oxehealth draws on all PMS data gathered from Oxevision, and includes other activities to study the safety, effectiveness and risks associated with Oxevision and the Oxevision product modules. Much of this is focussed on the overall benefits and risks of Oxevision as is used in health and mental health trusts, but the PMCF plan is not limited to this.

PMCF activities include the following:

- A report is prepared for all customers on the implementation of Oxevision based on the particular benefit case for each customer;
- Further feedback is solicited through ongoing customer engagement and proactively seeking user feedback and clinical feedback;
- Ongoing clinical evaluation through research studies carried out with research and development partners allow the capture of new data for research and product extensions and improvements using the systems described for capturing post market data;

- *Usability analysis is ongoing and revisited when Oxehealth determines that there has either been sufficient net change to aspects of design, or if evidence gathered through PMS and PMCF activities suggests there are factors that have not previously been seen previously;*
- *A variety of peer reviewed journal articles, case studies and conference presentations are prepared with research and development partners; and*
- *The Post Market Surveillance (PMS) Process within the Oxehealth QMS describes the monthly algorithm review forum, which monitors and manages continuing research activity including:*
 - *Identifying new research in the field, including the periodic re-running of literature searches identified in medical device clinical evaluation reports; and*
 - *Issues identified in new data captured and emerging from ongoing research studies;*

Actions following PMS and PMCF

As a result of our ongoing PMS and PMCF of the whole Oxevision solution highlighted above, we further reduced risks through investigation into monitoring data, customer feedback and complaints, and PMCF.

The following is a summary of additional risk control measures taken in response to the feedback, complaints, PMS and PMCF activities:

- Degradation of touch screens was found to be occurring due to non-recommended cleaning procedures with alcohol. A new “click event” animation was added to mitigate against this risk caused by misuse of hardware (provided by other manufacturers).
- Improvements have been made to Activity Detection, Location Risk Detection and Fall Risk Detection based on data collected from the field in response to cases of false positive and false negative alerts.
- The Location Risk Detection product function to detect whether a patient is dwelling in a doorway was developed in response to PMCF that found this behaviour to be of interest in some mental health settings, as it may provide insight into potentially self harming behaviour for clinicians.
- More information to users has been provided around rooms being disabled for maintenance or investigative reasons, to avoid confusion or misinterpretation.
- Messages to users have been added to Oxevision, to allow Oxehealth customer support staff to more directly communicate information about software maintenance, new features or any safety issues to users directly.

What information is provided to staff about the functionality of the system – who is responsible for ensuring that staff know the limitations of the equipment?

Oxehealth's approach to ensuring that the capabilities and limitations of Oxevision are understood at all levels and at all stages of the implementation of Oxevision with a Trust are as follows:

- As part of the sales process, Oxehealth ensures that the use case is qualified, such that the key indications for use regarding an existing care regime, non-reliance upon Oxevision, single occupancy, non-critical care and patient age are met.
- We have developed Instructions for Use for all software modules following the conventions and processes developed for medical device Instructions for Use, and these instructions are intended to be sufficient to educate users in the use of the system were they solely relied upon. Safe use of the Vital Signs medical device by untrained users following only reading the Instructions for Use was validated as part of summative usability evaluation.
- Latest versions of Instructions for Use are always available to staff in printed form as well as through the software interface, and these are controlled such that Oxehealth can deploy any required updates rapidly, and staff can never mistakenly use old or out of date instructions.
- Oxehealth is mindful of ensuring that these are fully understood and used appropriately by the product users and so Oxehealth always provides training to users prior to the use of Oxevision, to help staff obtain the benefit of the system rapidly and reinforce the intended use, capabilities and limitations of Oxevision.
- As part of staff training, Oxehealth provides information additional to the Instructions for Use through a training presentation and a staff reminder sheet that summarises key software user guides. This training material is designed and delivered through a process of review with Oxehealth medical device and clinical risk management to ensure all important indications, cautions and limitations are communicated.

In summary, the information provided by Oxehealth about the functionality of the system consists of:

- Instructions for use for all product modules, developed to a standard and style Oxehealth developed for the Vital Signs medical device. These are made available in printed form and also continually through the software user interface, and are kept up to date by Oxehealth.
- An instructional presentation for users, delivered prior to the system being handed over, summarising the key capabilities, limitations and how to use the software. This covers Oxevision and all product modules being put into use in one cohesive presentation.
- A staff reminder sheet, that summarises how to use Oxevision and all product modules in use.

The responsibilities for ensuring staff understand Oxevision summarise as follows:

- During the training prior to handover, Oxehealth is responsible for working with specifically identified "Ward Champions", who become the training contact within their ward. The approach taken is "train the trainer", allowing training to be further disseminated, in particular given the challenges of staff turnover and temporary staff.

- During the training prior to handover, Oxehealth is also responsible for training all staff who are made available for the initial training sessions.
- Following handover of the system, the Trust, in particular the Ward Champions, are then responsible for training new or temporary staff. Some Trusts have chosen to introduce a staff competency self assessment, but this is at their own election.
- Oxehealth are responsible for retraining staff and Ward Champions as and when significant new features that have not been previously used by staff are introduced in the installed software, or other new training needs arise (for instance whether it is appropriate to use the system on patients with Covid). Such re-training is given prior to new features being put into use, or as soon as Oxehealth has new guidance available.
- The Trust are responsible for ensuring there are Ward Champions available to train new and temporary staff, who have been appropriately trained. Oxehealth will train new staff into this role when requested.

Appendix: Complaint Log

The following table summarises all issues that Oxehealth has encountered while the Vital Signs product has been on the market that have been classified as complaints. Oxehealth uses the following definition for a complaint (taken from the Oxehealth Quality Manual Feedback and Complaints Procedure):

An issue is considered to be a complaint if the following are true:

- *The problem has been identified as occurring on a live customer site (by anyone, not just the customer themselves);*
- *A failure or deficiency in the medical device software (Vital Signs), its labelling, or Instructions for Use is suspected to exist;*

The data in the table below summarises the issues, what happened, and the criteria Oxehealth uses to identify whether a reportable medical device INCIDENT had occurred, and finally, a summary of the actions Oxehealth carried out to rectify any deficiency. The criteria Oxehealth uses for identifying any reportable INCIDENT are as follows (taken from the Oxehealth Quality Manual Feedback and Complaints Procedure):

According to MEDDEV 2.12/1 (rev 8), a MEDICAL DEVICE INCIDENT is defined as:

“Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or USER or of other persons or to a serious deterioration in their state of health.”

Further definitions from MEDDEV 2.12/1 (NOTE: see also MEDDEV 2.12/1 for further detailed considerations for whether the incident is reportable):

A "serious deterioration in state of health" is defined as including (non exhaustive list):

- a) life-threatening illness,*
- b) permanent impairment of a body function or permanent damage to a body structure,*
- c) a condition necessitating medical or surgical intervention to prevent a) or b).*

Examples: - clinically relevant increase in the duration of a surgical procedure, - a condition that requires hospitalisation or significant prolongation of existing hospitalisation.

- d) any indirect harm (see definition under section 4.11) as a consequence of an incorrect diagnostic or IVD test result or as a consequence of the use of an IVF/ART device when used within MANUFACTURER's instructions for use (use errors reportable under section 5.1.5.1 must also be considered).
- e) foetal distress, foetal death or any congenital abnormality or birth defects.

It is also stressed that "serious deterioration" may also be the result of INDIRECT-HARM, where:

Examples of indirect harm include

- Misdiagnosis,
- delayed diagnosis,
- delayed treatment,
- inappropriate treatment,
- absence of treatment
- transfusion of inappropriate materials.

Indirect harm may be caused by

- imprecise results
- inadequate quality controls
- inadequate calibration
- false positive or
- false negative results.

At this stage, a potential issue with the software performance, effectiveness or functionality has already been established, so this means that it is a MEDICAL DEVICE INCIDENT if all of the following are true:

1. Some form of event has occurred; AND
2. The event led, or might have led to either:
 - a. The death of a patient, device user, or other person; OR
 - b. A serious deterioration in state of health of a patient, user, or other person; AND
3. A failure or deficiency in the medical device software (Vital Signs), its labelling, or Instructions for Use is suspected to directly or indirectly be a contributory cause;

The complaints are listed in the following table, with those that could have potentially led to a user taking a vital sign reading in error highlighted:

Created	Source	Description	What has happened?	Could anyone have been seriously harmed as a result?	Was Vital Signs a contributing factor (including any deficiency in labelling or instructions for use)?	What action did Oxehealth take?
22/Jul/21	Live Monitoring	Software configuration issues preventing upload of cloud data for product surveillance	Oxehealth discovered they were not receiving all post-market surveillance data from live software. This occurred following a software upgrade.	No, an absence of post-market surveillance data is not a software deficiency that can have any direct effect on the use of the medical device.	N/A	Immediate reconfiguration of affected systems to work around the deficiency and restore the upload capability. Subsequent software fix for affected system configurations.
14/Jun/21	Customer	Mobile tablets made available to users with security not fully configured	The Customer found that some of their mobile tablets were not "locked" to Oxevision - otherwise, Oxevision and Vital Signs were operating exactly as required.	No, as other security measures to protect mobile tablets from unauthorised access and violation of patient privacy were in place and functioning correctly.	N/A	Immediate reconfiguration to remove the error and restore normal operation of the tablets in "locked" mode. Further improvements to tablet management processes to reduce further issues, to record the security status of all tablets as they are configured and added to sites, so engineers can routinely check if there are any tablets still requiring configuration in the field.

29/Apr/21	Live Monitoring	Live software performance degradation causing minor latency in vital signs display	Oxehealth found that the software was performing poorly due to non-critical components causing platform slowdown, potentially allowing the reporting of old vital signs (up to 15 seconds old before other software safety features prevent this). This occurred as the result of a software upgrade with the non-critical software misconfigured. No Customer issue was reported.	No, a latency of 5 seconds maximum was found in the monitoring data prior to the issue being addressed, in which time variations in vital signs not being spotted are not at all likely to result in serious harm to a patient. Other risk controls prevent the latency from exceeding 15 seconds, in which time variations in vital signs not being spotted are not at all likely to result in serious harm to a patient.	N/A	Immediately addressed by removing non-critical component processing to bring the platform back to within its operational performance tolerances.
29/Apr/21	Live Monitoring	Software failures intermittently preventing upload of cloud data for product monitoring	Oxehealth discovered they were not receiving all post-market surveillance data from live software. This occurred following a software upgrade.	No, an absence of post-market surveillance data is not a software deficiency that can have any direct effect on the use of the medical device.	N/A	Software upgrade was halted for other sites immediately. A fix to the configuration tooling was created and tested, prior to being used to correct the affected sites and further roll out other sites with the issue addressed. A further fix to software to avoid the need for re-configuration was applied in the following release of the software. Regression tests for this

						issue were added.
07/Apr/21	Customer	Vitals Signs Trends function available despite being configured to be off during certain periods of the day	The Customer found that they could access features at times of day they did not expect: they have a configuration schedule set that should prevent staff from obtaining vital signs at night (as a matter of preference, rather than control for any risk).	No, as the system is still qualified to operate correctly at all times of day, and vital signs trends would still operate correctly when accessed outside the desired operating schedule.	N/A	Immediate deployment of a software re-configuration that reinstated the software operation schedule. Further fix of the software in the following release to avoid the need for re-configuration. Regression tests for this issue were added.
13/Jan/21	Customer	Low pulse rate reported for patient believed to be tachycardic	The Customer took a reading of a very low pulse rate for a patient they verified was tachycardic. This was because the patient's breathing rate and pulse rate were both above the stated operating range maxima for the Vital Signs device at the same time, resulting in the breathing rate being mistakenly reported as a pulse rate. The patient's tachypnea and tachycardia were not associated with a condition or disease that could have directly resulted in harm to them in these circumstances (they are a mental health patient without any other	No, the patient could not have been harmed, and subsequent risk analysis showed that the risk of harm to other patients would be negligible if this event were to recur. This particular patient was not suffering from any condition that could cause them serious harm. In general, research of the literature found that tachypnea at this level was not found to be associated with conditions or diseases that could result in serious harm. <u>NOTE: MEDDEV 2 12-1 (rev 8) under 5.1.3.6</u> <u>NEGLECTIBLE LIKELIHOOD</u>	N/A	Oxehealth communicated with the Customer regarding this occurrence with the patient so they can understand the nature of the error and act accordingly should they have such an extreme tachypnea again. Oxehealth carried out further investigation of the issue to detect occurrences for other patients, with some rare potential occurrences identified, but no further reports from customers. Longer term investigation and assessment of the benefit-risk of a potential fix that would also remove potentially valid readings in the 50-60 bpm pulse rate

			physical conditions or illness).	<u>OF OCCURRENCE OF DEATH OR SERIOUS DETERIORATION IN STATE OF HEALTH states:</u> <i>"INCIDENTs where the risk of a death or serious deterioration in state of health has been quantified and found to be negligibly small need not be reported if no death or serious deterioration in state of health occurred and the risk has been characterised and documented as acceptable within a full risk assessment. If an INCIDENT resulting in death or serious deterioration in state of health has happened, the INCIDENT is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains negligible small previous INCIDENTs of the same type do not need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Changes in the trend, usually an increase, of these nonserious outcomes</i>		range has been carried out (results are a 10% lower yield of accurate values between 50 and 60 bpm, a 3% reduction overall, but no effect on the primary accuracy claim). <u>Current Action:</u> To implement the fix in the next release of software, as the benefit-risk ratio has been found to not be adversely affected (it is still worth using the device with the lower yield of accurate values). Regression tests for this issue will be added.
--	--	--	----------------------------------	---	--	---

				<i>must be reported."</i> Oxehealth performed and documented such a risk analysis and found the likelihood of serious harm to be negligible and not reportable, as our risk analysis found a range of likelihood figures of this recurring and resulting in serious to be from 1 in 750,000 to 1 in 7,500,000 (i.e 1 vital sign in every 0.75 to 7.5 million taken may be affected and this result in serious harm).		
05/Jan/21	Live Monitoring	Vital Signs Trends screen shows more data than expected	Oxehealth found that the Vital Signs Trends chart was showing more data than expected while carrying out routine support on a customer site. This occurred following a software upgrade. The Vital Signs Trends chart had not been used by any Customer by the time that the issue was discovered and rectified.	No, as Oxehealth found the error and reconfigured all sites to hide Vital Signs Trends prior to any use of the software feature, meaning that no user used Vital Signs Trends while this deficiency was present. <u>NOTE: MEDDEV 2 12-1 (rev 8) under 5.1.3.1 DEFICIENCY OF A DEVICE FOUND BY THE USER PRIOR TO ITS USE states: "Regardless of the existence of provisions in the instructions for use provided</u>	N/A	Oxehealth immediately prevented the use of Vital Signs Trends on all sites where it could be used (5 sites, all sites reconfigured the same day). A software fix was put in place in the following release. Regression tests for this issue were added and testing processes for identifying issues such as this were updated to include a broader range of test data,

				<i>by the MANUFACTURER, deficiencies of devices that are always detected (that could not go undetected) by the USER prior to its use do not need to be reported under the vigilance system."</i> Oxehealth interprets <i>itself</i> finding a deficiency prior to use as in the same category as a failure found by the user prior to use.		and the new test system "gamed" with attempted Vital Signs bug creation to assess its effectiveness.
07/Dec/20	Customer	Vital Signs Trends screen not displaying any data	The Customer reported that the Vital Signs Trends chart was showing no data. This occurred following a software upgrade.	No, as a lack of Vital Signs Trends data could not cause indirect harm through delayed diagnosis in the indicated use cases for Vital Signs (i.e. it is not to be used where patients require critical care).	N/A	A software fix was put in place in the following release. Regression tests for this issue were added.
06/Nov/20	Customer	Mobile tablets made available to users with security not fully configured	The Customer found that their mobile tablets are not "locked" to Oxevision - otherwise, Oxevision and Vital Signs were operating exactly as required.	No, as other security measures to protect mobile tablets from unauthorised access and violation of patient privacy were in place and functioning correctly.	N/A	Immediate reconfiguration to remove the error. Improvements to tablet roll out processes to reduce further issues (alongside the other issue reported very recently), allowing customer operations to deploy tablets more independently to the full "go-live" process and add new tablets to the field without this issue.

21/Oct/20	Customer	On screen information to users showing the time since "last vital signs taken" can be wrong	The Customer found that the timer that indicates "Last Vital Taken xxx Ago" was showing a negative value on some mobile tablet devices. This could also appear as a positive time that is less than the real time since the vital signs were taken. This was due to a clock synchronisation error.	No, this is not a feature of the medical device intended to inform any diagnosis activity, and is not expected to be misused as such. There can therefore be no resulting indirect harm from any delayed or wrongful diagnosis.	N/A	A workaround to correct the clock synchronisation was communicated with the Customer. A software fix was put in place in a subsequent release to address the clock synchronisation error. Regression tests for this issue were added.
06/Oct/20	Customer	Vital signs workflow video showing standard time (GMT) instead of British Summer Time	The Customer found that the clock in the Vital Signs workflow was not adjusted for British Summer Time, and was therefore one hour behind the main screen clock and other clocks/watches.	No, the 1 hour difference could not cause any direct or indirect harm, as it is not clinical data that can affect a diagnosis. Software risk controls to prevent old data from being displayed to the user were functioning, which would ensure that only current data was seen by users.	N/A	A software fix was put in place in a subsequent release to address the clock error. Regression tests for this issue were added.
11/Sep/20	Customer	Mobile tablets made available to users with security not fully configured	The Customer found that their mobile tablets are not "locked" to Oxevision - otherwise, Oxevision and Vital Signs were operating exactly as required.	No, as other security measures to protect mobile tablets from unauthorised access and violation of patient privacy were in place and functioning correctly.	N/A	Immediate reconfiguration to remove the error. Improvements to tablet roll out processes to reduce further issues (alongside the other issue reported very soon after), allowing customer operations to deploy tablets more

						independently to the full "go-live" process and add new tablets to the field without this issue.
02/Sep/20	Live Monitoring	In-software customer feedback forms sent with no message body	Oxehealth discovered they were not receiving the body text within customer feedback messages (part of the post-market surveillance capability of the software). This occurred following a software upgrade.	No, an absence of post-market surveillance data is not a software deficiency that can have any direct effect on the use of the medical device.	N/A	A fix to software was applied in the next release of the software. Regression tests for this issue were added.
01/Nov/19	Customer	Vital signs workflow freezing and preventing use	The Customer found that the Vital Signs software could occasionally "freeze" when attempting to take a vital sign, preventing them from proceeding beyond the "is the patient still?" stage.	No, this issue is in fact a safe failure mode, preventing the use of the medical device following the loss of video input during the workflow, however the intended safe failure is to black out the video, rather than have it freeze. <u>NOTE: See also MEDDEV 2 12-1 (rev 8) 5.1.3.4 PROTECTION AGAINST A FAULT FUNCTIONED CORRECTLY</u>	N/A	A fix to software was applied in the next release of the software. Regression tests for this issue were added.

09/Apr/19	Customer	Software deployed with camera frame rate control incorrectly configured	Oxehealth customer support staff found that the Oxevision Vital Signs feed did not appear optimal. This was due to the software risk control feature to prevent operation in the event of unreliable frame rate not operating correctly on this site and a small number of other sites, and allowing video at unreliable frame rates to be processed. This was in turn the result of this software risk control being misconfigured on the affected sites, due to default configuration being too relaxed.	No, as the investigations into the maximum frame rate errors being allowed to occur could result in an error of up to 4% only (and in addition, relatively infrequently), which could result in the video processing to extract vital signs producing an error of 5.2 bpm in pulse rate, or 1.6 breaths/min in breathing rate, neither of which could result an error in diagnosis to an extent that could cause serious harm.	N/A	Immediate reconfiguration of all sites was carried out to correctly configure the risk control. A fix to software was applied in the next release of the software to change the default configuration to "always on". Regression tests for this issue were added.
-----------	----------	---	---	---	-----	--