
From: [I/S] [I/S]
Sent: 9/9/2022 12:02:20 PM
To: [I/S] [I/S]; [I/S] [I/S]; [I/S]
[I/S] [I/S] [I/S] [I/S]
Subject: RE: Oxevision Activity Tracker

Flag: Follow up

Hi [I/S]

Thanks for updating and for sight of their response. I would agree with your conclusion and proposed response.

Kind regards,

[I/S]

[I/S]

Device Borderline Specialist
Healthcare, Quality & Access

From: [I/S]
Sent: 07 September 2022 17:53
To: [I/S] [I/S] >; [I/S] [I/S] >; [I/S]
[I/S] [I/S] >; [I/S] [I/S]
Subject: RE: Oxevision Activity Tracker

Hi All,

Oxehealth has responded to the questions that [I/S] has asked, please find attached.

They have indicated that the Activity Tracker can function without the Vital Signs Module as when the AT is deployed on its own, it has its own cameras and computing hardware, video processing software and GUI(s). The Vital signs module can also be used independently of the AT tool. Therefore, this would not meet the definition of an accessory. In regards to the breathing-like movement signals, this is used to confirm subject activity within a room and the AT does not measure breathing.

As said previously, the claims do not specify the patients condition/ disease however, it does mention that it provides information for clinical decisions which could impact care & treatment of patients with known condition. As the intention behind this tool was due to our comments on their "reducing self-harm" claims, I can inform the manufacturer that as it stands, the activity tool is unlikely to qualify as a medical device as the alerts generated from the AT would need to be for medical purposes, and to explicitly include this information in their intended use if they want to market their product as a medical device.

Please let me know your views from their response.

Kind regards,

[I/S]

From: [I/S] [I/S]
Sent: 24 August 2022 13:31
To: [I/S] [I/S] > [I/S] [I/S] > [I/S]
[I/S] [I/S] > [I/S] < [I/S]
Subject: RE: Oxevision Activity Tracker

Hi [I/S]

Sorry for the delay in responding on this.

Like others, I am somewhat confused by where the boundary lies between the Activity Tracker versus the Vital Signs software. They state that they see the AT as an accessory to VS, however, p15 of the Regulatory Plan both shows a diagram where the two are presented completely separate from each other:

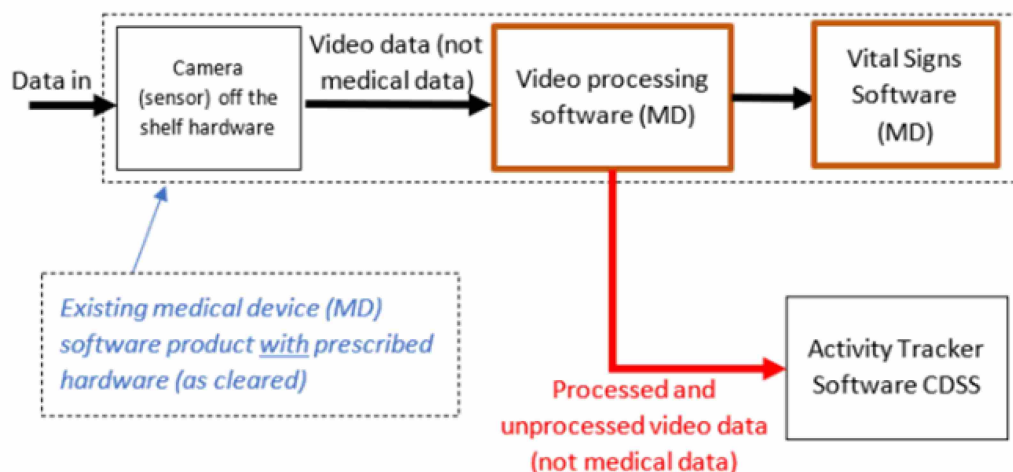


Figure 3: Oxevision Activity Tracker Relationship to and Separation from Oxevision Vital Signs

and the statement that the AT “is both separate from the Vital Signs device and relies on data from it”. What data is it reliant on from Vital Signs? Can they be used separately? The IFU for the AT suggests that VS may not need to be enabled for it to work, as it implies that the Vital Signs readings are not presented to every user depending on their software configuration.

If the Activity Tracker IFU is complete and correct otherwise, then the only functions clearly attributable to AT (and not fed in by running alongside a VS module) are that it identifies where a person is likely to be within the room, allows staff to run through video feeds, and alerts if the patient is out of sight of the camera for a longer period of time. As [I/S] has already flagged, surveillance and location tracking, detecting falls etc. are not usually considered to be medical purposes and software with only this function/claim would not qualify as a medical device.

Regarding their claims about self harm – this appears to be related to issues such as the alerts for patients being in a blind spot. The software and the rest of the system does not actually reduce the drive to self harm, treat the underlying condition etc. – only limits the opportunity to do so available to the patient. The actual infliction of self harm falls more under “injury” than “disease” (the instigating mental illness would be the “disease” component) and there is no “prevention of injury” in the definition of a medical device so I feel that prevention/reduction of self harm, in this particular case, would not be a clear medical claim.

I am unsure about the meaning of the lines regarding apnoea and breath-holding, but understood these to be related to how the software identifies a living being on camera – perhaps identifying the small regular movements associated with breathing is a necessary part of detecting the patient, and therefore the warning is in reference to apnoeic or breath-holding patients effectively “disappearing” as far as the software is concerned and giving inaccurate room empty/blind

spot alerts. If the software is not measuring a breathing rate, then just the presumptive detection of breathing movements as a way of identifying a person on camera would not itself be a medical function (compare to e.g. GPS wandering trackers for the elderly, which include a fitbit-style heartrate monitor solely as a way of being able to confirm the product is being worn). Worth clarifying the meaning of their statement about breathing and what Activity Tracker is doing here (vs if anything being fed in by Vital Signs).

Any claims for the Activity Tracker alone appear mostly non-medical, and Vital Signs appears to be capable of being used independently of AT.

The Activity Tracker does have the claim you have flagged *“Oxevision Activity Tracker is intended to inform healthcare professionals of subjects’ activity and locations within the healthcare facility (any room where subjects are intended to sleep) for the purpose of risk management and care planning”* which suggests that data provided by the tracker is likely to affect the patients’ care and treatment. The website also has the following:

What care reports does Oxevision provide?

Vital sign and activity data are presented to inform care planning. Key reports are:



Sleep

Sleep is crucial to well-being and recovery. Assess the sleep opportunity a patient has experienced using reports of location and activity to anticipate their energy levels, care needs and likely behaviour during the day.

[View applications >](#)



Review overnight activity

Know how often the patient goes to the bathroom, how long they spend in bed and whether they left the room during the night. Use activity reports to assess this objective behavioural data to create personalised care plans for your patients.

[View applications >](#)

- the graphic above appears to more clearly link information from the activity data to a clinical purpose i.e. changes in care provided.

All in all, I would say that the Activity Tracker does appear to have a handful of likely medical claims, however the majority of the function appears to be non-medical. I cannot see from the current information that it meets the definition of an “accessory” to Vital Signs, nor does it appear to fall under Rule 10 as the alerts only seem to relate to non-medical issues such as patient location/failures to obtain readings and it does not seem to measure breathing/heart rate itself.

I would recommend clarifying:

- whether the Activity Tracker can be used completely independently of Vital Signs and vice versa;
- the meaning of the statement in AT’s IFU about apnoeic/breath-holding patients – how/why does lack of breathing affect AT’s readings and what exactly is AT detecting/measuring in relation to breathing;
- clarification of the statement that the AT “is both separate from the Vital Signs device and relies on data from it”. What data is it reliant on from Vital Signs? Can it function without this data and what happens without it?

Hope this is helpful and sorry that as usual it is not a clear-cut yes or no answer!

Kind regards,

[I/S]

[I/S]

Device Borderline Specialist

From: [I/S] [I/S] >
Sent: 10 August 2022 14:49
To: [I/S] [I/S] >; [I/S] [I/S]
[I/S] [I/S] > [I/S] [I/S]
Subject: RE: Oxevision Activity Tracker

Hi All,

Thank you for your comments. [I/S] I have also attached the IFU.

[I/S] we discussed the Oxehealth applications in our Software monthly meeting and we came to a conclusion that 'reducing self-harm' had a medical purpose due to the intended user and the nature of these claims. They activity tracker software has been on the market and in use as a non-medical device software product since 2018. They have now changed the product (definition of an Indications for Use, UKCA/CE labelling, minor technical changes to meet applicable performance standards) so that it meets the requirements applicable to a medical device (per UK Legislation). The activity tracker software has now been registered as a class I device and they will apply the UKCA mark to the device in the field via a version update

I would appreciate your views on whether the activity tracker indication for use statement has a medical purpose as Frankie and I are leaning more towards that it has a medical purpose. It was also mentioned that the software is an accessory however, as mentioned below it does not enable the parent device. Therefore, can the activity tracker device qualify as standalone software as the tool heavily relies on the technology used for the vital signs module.

Please let me know if you require any further information as the product is registered with us.

Kind regards,

[I/S]

[I/S]

Technical Specialist – Software, Apps and AI

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From: [I/S] [I/S] >
Sent: 19 July 2022 14:14
To: [I/S] [I/S] > [I/S] [I/S] >; [I/S]

[I/S]

Subject: RE: Oxevision Activity Tracker

The indications for use statement states the following which I thought leaned it towards medical purpose...:

"Oxevision Activity Tracker is intended to inform healthcare professionals of subjects' activity and locations within the healthcare facility (any room where subjects are intended to sleep) for the purpose of risk management and care planning."

"Oxevision Activity Tracker is intended to provide information to inform clinical decisions but not to direct therapy or diagnosis."

It also includes the following which I think is incorrect as the IFU has many mentions of 'warnings and alerts'

"Oxevision Activity Tracker does not provide alarms and is not intended to be relied upon to notify healthcare professionals of any immediate health or safety hazards to subjects."

From: [I/S] <[I/S]>
Sent: 19 July 2022 14:00
To: [I/S] <[I/S]>; [I/S] <[I/S]>; [I/S]
[I/S]
Subject: RE: Oxevision Activity Tracker

[I/S]

The 'Indication for Use Statement' says what the product doesn't do but I can't see what medical purpose it has.

Tracking activity on its own isn't a medical purpose, it just appears to be a surveillance tool.

Regards, [I/S]

[I/S] MSc MIPeM

Technical Lead, software devices and MRI

Devices/Q&A, MHRA

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From: [I/S] <[I/S]>
Sent: 19 July 2022 12:49
To: [I/S] <[I/S]>; [I/S] <[I/S]>; [I/S]
[I/S]
Subject: RE: Oxevision Activity Tracker

Hi all,

I agree that the relationship between the Oxevision Vital Signs medical device and the Oxevision Activity Tracker is not clear therefore it is not clear what should be an accessory, separate medical device or system.

From figure 3 in the technical file, it is not clear whether the Vital Signs medical device consists of the camera, video processing software and vital signs software? It seems that these three components can work without the Oxevision Activity Tracker therefore suggesting that the activity tracker is not an accessory to the Oxevision vital signs. It seems

that the Oxevision Activity Tracker does require the camera and video processing software which may be part of the Oxevision Vital Signs medical device therefore the Oxevision Vital Signs medical device could be described as an accessory to the Oxevision Activity Tracker?

Agree with [I/S] point that as they seem to share the same user interface, this could be the accessory to both products or the whole system as a single device. Agree it would be good to know whether the 2 can be supplied separately?

To [I/S] other point, it is borderline as to whether the Oxevision Activity Tracker is a medical device in its own right. As per page 12, section on principles of operation, in the technical file, it does sound as though this software is performing analysis which could be complex and this analysis is being used to inform patient management and therefore I am leaning towards it being a medical device....If it is a medical device, then surely it would be a class IIa as per EU MDR rule 11 - Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause?

I hope that helps and am happy to discuss.

Kind regards,

[I/S]

From: [I/S] [I/S]
Sent: 15 July 2022 10:12
To: [I/S] [I/S] <> [I/S] [I/S] [I/S]
[I/S]
Subject: RE: Oxevision Activity Tracker

[I/S]

The Oxevision Activity Tracker doesn't appear to qualify as a device in its own right as far as I can see.

Could you ask for a copy of the IFU for the Oxevision Vital Signs medical device please, I'm not convinced that their argument about it being an accessory is correct as it does not appear to 'enable' the parent device.

Also, do you know where this is from:

"Since the device has been moved from a "non-medical device" status to that of a "medical device clinical decision support system" in response to feedback from the UK MHRA, the classification review of the device includes the determination of whether it is an accessory or not."

As it shares the same user interface, I would consider the interface to be an accessory to both products or the whole system a single device. Can the two be supplied separately?

Regards, [I/S]

[I/S]

MSc MIPEM

Technical Lead, software devices and MRI

Devices/Q&A, MHRA

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From: [I/S] [I/S]
Sent: 14 July 2022 17:45
To: [I/S] [I/S] <> [I/S] [I/S] <> [I/S]

[I/S]

Subject: Oxevision Activity Tracker

Hi All,

I have been reviewing the documents that Oxehealth have sent for their Oxevision Activity Tracker medical device. I have attached their IFU for a better understanding of the device. I have also attached the device description which includes their rationale for classification under the UK MDR 2002 and EU MDR. Under both classification the device is a class I which I am inclined to agree as the software is to inform care planning and risk management and not indicated to drive clinical decisions (pages 13 & 14). The clinical benefit of the device can be seen through various improvements which could include reduced falls, decreased self-harm, improved sleep, better patient response as the device is enabling better informed care.

They have mentioned that the clinical decision support software is an accessory to the Oxevision Vital Signs medical device. Since the device requires data from a medical device (the Oxevision Class IIa Vital Signs device) and cannot function without that data, it is therefore an accessory to that device. The description of the device includes that it analyses video data produced by the pre-existing class IIa Oxevision Vital Signs device. The Oxehealth Activity Tracker device also shares the same processing, storage and display hardware of the class IIa Oxevision Vital Signs device. It is viewed through the same web browser as the Oxevision Vital Signs device. Lastly, in the IFU under caution it includes "In subjects with pronounced sleep apnoea or who are deliberately controlling their breathing" which would indicate that the activity tracker is also analysing the patients breathing rate.

The main question I wanted to ask was whether the activity tracker would also be classified as a class IIa as it is using data from the vital signs module therefore, the whole system would need to be the same classification. I would appreciate your views on this or whether we need more information.

[I/S]

Technical Specialist – Software, Apps and AI

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