
From: [I/S]
Sent: 9/28/2022 3:44:53 PM
To:
CC: [I/S]
Subject: RE: STED

Flag: Follow up

Dear [I/S]

Many thanks for your response.

We appreciate your detailed review of the Oxevision Activity Tracker and it is very helpful to receive your assessment that you deem it "unlikely to be a medical device".

Given we have received this feedback from you, we now intend to de-register the device and continue to carefully market it as a non-device CDSS. Please would you confirm you are happy for us to proceed in this way?

We very much value the constructive dialogue that you and our NHS partners have entered into with us. Your scrutiny and feedback enables us to ensure that we continue to market and produce safe and effective products.

We look forward to maintaining this positive and constructive relationship going forward.

Regards

[I/S]

From: [I/S]
Sent: 12 September 2022 15:15
To: [I/S]
Cc:
Subject: RE: STED

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Dear [I/S]

Thank you for your email.

Based on the information you have provided, the activity tool as it stands is unlikely to qualify as a medical device. The alerts generated from the tool would need to be for medical purposes, and this needs to be explicitly stated in the intended use to market the product as a medical device.

If Oxehealth does decide to market the product as a medical device, it will not meet the definition of an accessory as the Activity tool and the Vital Signs Module can be used independently of each other. This is because the Activity tracker does not enable the parent device (Vital Signs Module).

Please let me know if you have any questions.

Many thanks,

[I/S]

Technical Specialist – Software, Apps and AI

[I/S]

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Please note my normal working days are Monday - Thursday

From: [I/S]

Sent: 02 September 2022 12:44

To: [I/S]

Cc:

Subject: RE: STED

Dear [I/S]

Thank you for your questions. **Apologies** for the delay in response, different colleagues were away as a result of the bank holiday weekend, so it has taken me some time to organise a response.

To address your questions regarding the device as an accessory:

What Data is it reliant on from the Vital Signs?

Where the Activity Tracker is deployed alongside the Vital Signs device, it needs to receive unprocessed video data and processed video data (data giving information about detected breathing-like movement signals which may come from a human and their location in the video image) derived from some of the software and prescribed hardware components of the Vital Signs software medical device.

Can it function without this data and what happens without it?

We do not deploy the Activity Tracker without the software component that generates breathing-like movement signals which may come from a human as and when they are detected.

Can the Activity Tracker be used completely independently of the Vital Signs Module and vice versa?

The Activity Tracker can be used completely independently of the Vital Signs device. The Vital Signs device can be used completely independently of the Activity Tracker device. Both devices can be used together.

How is this the case? The same hardware (including camera), video processing software and GUI components are required to deliver the Vital Signs device and the Activity Tracker, whether or not one or both software devices are enabled for the user:

1. At sites where the Activity Tracker is deployed on its own, camera(s) and computing hardware, video processing software and GUI(s) that could form part of the Vital Signs device are deployed and activated but the Vital Signs Software is not enabled and so the user does not receive the Vital Signs device or its outputs.
2. Likewise, identical camera(s) and computing hardware, video processing software and GUI(s) will be deployed at sites where the user is to receive the Vital Signs device and its outputs but not the Activity Tracker. On these sites, the Activity Tracker will not be enabled so the users will not receive the Activity Tracker or its outputs.

3. In fact, the vast majority of sites choose to receive both the Vital Signs device and the Activity Tracker. In these cases, the camera(s) and computing hardware, video processing software and GUI(s) are used by both the Vital Signs device and the Activity Tracker.

The meaning of the statement in the Activity Tracker's IFU about apnoeic/breath-holding patients – how/why does lack of breathing affect Activity Tracker's readings and what exactly is the Activity Tracker detecting/measuring in relation to breathing?

The Activity Tracker detects activity, posture, presence and location. The Activity Tracker does not measure breathing. It uses the information about the location of breathing-like movement that may come from a person derived from the processed video data described above as one of several methods of locating and confirming subject activity within a room. In the case of the Vital Signs device, that device contains additional software components (not used by the Activity Tracker device) to further process and validate the breathing-like movements in order to deliver validated breathing rate measurements to the user.

In the event that the patient exhibits lack of breathing movement (for example during breath holding or apnoea), the Vital Signs device (or, where the Activity Tracker is deployed without the Vital Signs device, the relevant video processing software components) will not provide the relevant breathing-like movement signals to the Activity Tracker. If the Activity Tracker also fails independently to detect human movement from an occupied room using the other techniques it makes use of, then the Activity Tracker may fail to correctly "determine activity, posture, presence and location" and consequently "over alert" or "under alert" (either incorrectly alert or miss an alert respectively) as detailed in the Instructions for Use. We have reduced this risk as far as possible and have communicated the risk to the user in the Instructions for Use.

We look forward to supporting you in this matter and would be happy to meet with you to answer any questions if you feel that would be helpful.

Regards

[I/S]

From: [I/S]

Sent: 25 August 2022 13:14

To: [I/S]

Cc:

Subject: RE: STED

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Dear [I/S]

I have asked for the rationale as in the document it is stated that you see the Activity Tracker as an accessory to the Vital Signs Module however, pg 15 of the Regulatory Plan both shows a diagram where the two are presented completely separate from each other:

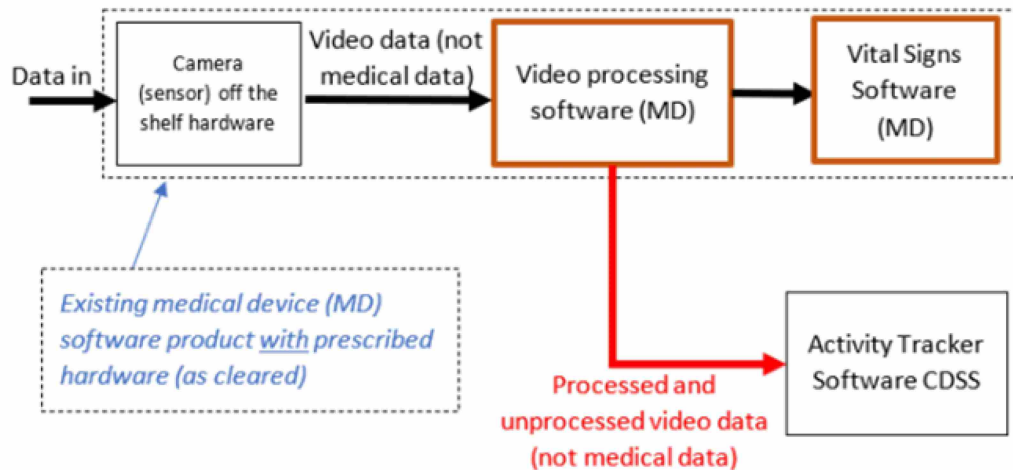


Figure 3: Oxevision Activity Tracker Relationship to and Separation from Oxevision Vital Signs

The document also includes the statement that the Activity Tracker is “both separate from the Vital Signs device and relies on data from it”. Therefore, please could you clarify:

- what data is it reliant on from the Vital signs? Can it function without this data and what happens without it?
- can the Activity Tracker be used completely independently of the Vital Signs Module and vice versa;
- the meaning of the statement in the Activity Tracker’s IFU about apnoeic/breath-holding patients – how/why does lack of breathing affect Activity Tracker’s readings and what exactly is the Activity Tracker detecting/measuring in relation to breathing;

I would also like to mention the feedback you received from MHRA were related to the claims regarding ‘reducing self-harm’ which were previously stated in Oxehealth’s marketing material.

Kind regards,

[I/S]

Technical Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[I/S]

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Please note my normal working days are Monday - Thursday

From: [I/S]

Sent: 23 August 2022 14:53

To: [I/S]

Cc: [I/S]

Subject: RE: STED

Dear [I/S]

Thank you for your questions.

1. The Intended Use statement is detailed in the STED Device Description and Regulatory Plan (pages 11 and 12) and is repeated in the Instructions for Use (page 4). We state that the device is “for the purpose of risk management and care planning” and “to be used to augment existing forms of monitoring (including direct in-person checks) as an additional risk management system”. Classification of the product as a medical device is consequently detailed on page 13 of the STED Device Description and Regulatory Plan. These documents have been prepared in response to the MHRA’s request for medical device Technical File. In the STED Device Description and Regulatory Plan page 15 we had recorded *“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”*.

2. Our rationale on how the activity tracker qualifies as an accessory is detailed in page 15 of the STED Device Description and Regulatory Plan.

If, having reviewed the documentation your conclusion is that the product is neither a medical device or a medical device accessory we would be happy to deregister it from your portal and to remove the UKCA mark from the product. Please would you confirm that this is an appropriate course of action?

Many thanks

[I/S]

From: [I/S]

Sent: 22 August 2022 15:54

To: [I/S]

Cc:

Subject: RE: STED

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Dear [I/S]

We would like to request some further information regarding the activity tracker:

- In the IFU, the intended use claims cover monitoring patients for injury and not for disease. Could you please clarify how the activity tracker fits within the definition of a medical device as currently the claims are for prevention of injury.
- Please could you provide your rationale on how the activity tracker qualifies as an accessory

Many thanks,

[I/S]

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Please note my normal working days are Monday - Thursday

From: [I/S]

Sent: 09 August 2022 17:36

To: [I/S]

Subject: RE: STED

Dear [I/S]

Thank you for ensuring that we remain aligned. In the call we requested further information of the intended claims and device function to better understand the functionality of the device. Majority of the team are away on annual leave, once they are back we will be able to provide our position on this.

Many thanks,

[I/S]

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[I/S]

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Please note my normal working days are Monday - Thursday

From: [I/S]

Sent: 05 August 2022 11:25

To: [I/S]

Cc:

Subject: RE: STED

Dear [I/S]

Thanks for getting back to me. I am keen to ensure that we remain aligned. I thought we had communicated what our action plan was on the call with you and [I/S] and in subsequent emails and had not received any communication or guidance from you that an alternative course of action was needed. Please could we schedule a call so we can fully understand your position and ensure we are supporting your work in any way we can?

Regards

[I/S]

From: [I/S]
Sent: 04 August 2022 17:27
To: [I/S]
Cc: [I/S]
Subject: RE: STED

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Hi [I/S]

I hope you are well too.

Yes unfortunately there was a miscommunication. I will discuss with the team and get back to you soon.

Many thanks,

[I/S]

Technical Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

[I/S]

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Please note my normal working days are Monday - Thursday

From: [I/S]
Sent: 02 August 2022 12:36
To: [I/S]
Cc: [I/S]
Subject: RE: STED

Dear [I/S]

I hope you're well and that you had a good holiday.

I called yesterday and today but I expect you're very busy, so please can we schedule a time for a call to align please? My concern is that your request not to register came in to us **after** the point when we'd registered. I had said that we would register promptly after sending you the last of the documents but clearly there was a disconnect between us and we've end up mis-aligned.

I wanted to talk to discuss what to do now, the product is registered and on the market with the UKCA mark as a class I.

I will make myself available to talk to you whenever you wish so please let me know when suits.

Thanks

[I/S]

From: [I/S]

Sent: 19 July 2022 17:13

To: [I/S]

Cc:

Subject: RE: STED

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Dear [I/S]

Thank you for sending over the documents.

As we are currently reviewing the documents, we are requesting a hold on registering the device on our portal.

This will allow us to evaluate whether the intended claims provided in the IFU has a medical purpose, and whether the activity tracker device can be registered as a standalone software as the tool heavily relies on the technology used for the vital signs module.

I would also like to mention that I will be going on annual leave from tomorrow and will be back on the 1st August.

Kind regards,

[I/S]

Technical Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

[I/S]

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Please note my normal working days are Monday - Thursday

From: [I/S]

Sent: 08 July 2022 07:12

To: [I/S]

Cc:

Subject: STED

Dear [I/S]

I hope you're well.

Please find attached the final elements of the Activity Tracker device STED. This is the V&V section of the STED with the supporting software documents.

I believe we have supplied a complete STED in line with the IMDRF guidance and so won't be sending you further documents unless (of course) you request them. A summary of the documents provided is below.

STED Section (from IMDRF guidance)			Document	Status
Device Description	Device Description	General description	Detailed regulatory plan	Supplied to MHRA
		Intended patients		
		Principles of operation		
		Risk classification		
		Novel features		
		Accessories		
		Variants		
		Description of functional elements		
		Key functional materials		
	Product Spec			
	Reference to similar or previous devices			
Labelling	Device		Refer to IFU	Supplied to MHRA
	Instructions for Use		IFU	
	Marketing		Various sales/marketing documents	
Device Design	Device Design		Product design (output) summary narrative	Supplied to MHRA
	Manufacturing process			
	Design and manufacturing sites			
ER Checklist			ERC	Supplied to MHRA
Risk Management Report			RMR	Supplied to MHRA

STED Section (from IMDRF guidance)			Document	Status
V&V		Software V&V requirements-test matrix	Requirements to V&V matrix + underlying test reports + software classification	Supplied to MHRA
		DoC to 62304	DoC + summary	
		DoC to 14971	DoC plus RMR submitted (above)	
		DoC to 62366	DoC plus summary report	Supplied to MHRA
		Clinical evidence	CER	Supplied to MHRA
	Biocompatibility		N/A	N/A
	Medicinal Substances		N/A	
	Biological safety		N/A	
	Sterilisation		N/A	
	Software V&V		Software classification rationale + matrix (submitted above)	
	Animal Studies		N/A	
	Clinical evidence		CER (submitted above)	
DoC			Draft product DoC	Supplied to MHRA

We will be registering the device on your portal next week.

Please let me know if you have any questions. I will follow up in a few weeks with you to give you time to review the docs.

Have a nice weekend.

Regards

[I/S] COO

[I/S]

w: www.oxehealth.com

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