
From: [I/S]
Sent: 11/18/2021 3:39:29 PM
To: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) [I/S] J [I/S] (NHS ENGLAND & NHS IMPROVEMENT - T1520) [I/S]
CC: [I/S]
Subject: FW: MHRA, NHSEI & Oxehealth Meeting

Hi Both,

MHRA colleagues and I have put together a list of questions which we have sent to the manufacturer of Oxehealth. We are hoping to have a response soon.

Kind regards,

[I/S]

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Tel [I/S]

Email [I/S]

gov.uk/mhra

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From: [I/S]
Sent: 15 November 2021 15:11
To: [I/S]
Subject: RE: MHRA, NHSEI & Oxehealth Meeting

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Dear Iain,

Thank you for providing the slides. We would like to request some further clarity on the following:

1. Details on how the algorithm works for the vital signs trend, activity detection, fall risk, activity tracker and sleep products.
2. 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?
3. 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?
4. Details of customer complaints that you have received and why you consider that they may not be reportable to MHRA.
5. 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?
6. 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?

Thank you and kind regards,

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Tel [I/S]

Email [I/S]

[gov.uk/mhra](https://www.gov.uk/mhra)

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From: [I/S]

Sent: 28 October 2021 16:26

To: [I/S]

Subject: RE: MHRA, NHSEI & Oxehealth Meeting

Dear [I/S]

Here are the slides we presented on Wednesday for reference. Please feel free to share these with all meeting attendees. We have made only one change, removing sensitive company revenue information from one of the slides.

Kind Regards,

Iain

[I/S]

**Head of Engineered Compliance
Oxehealth**

M [I/S]

Magdalen Centre North, The Oxford Science Park, Oxford, OX4 4GA

Patient Safety Awards 2019 – Winners [“Best HealthTech Solution for Patient Safety”](#)

Laing Buisson Awards 2019 – Winners [“Innovation in Technology”](#)

Journal of mHealth – [Global Digital Health 100 2019 & 2020](#)

UK Tech Nation – [Upscale Cohort 4.0 2019](#)

Design In Mental Health Awards 2019 – Nominee [“Product Innovation of the Year”](#)

HealthInvestor Awards 2019 – Nominee [“IT Innovator of the Year”](#) & [“Technology Provider of the Year”](#)

Royal Academy of Engineering – Winners [Colin Campbell Mitchell Award 2017](#)

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From: [I/S]
Sent: 27 October 2021 17:19
To: [I/S]
Cc: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) <[I/S]>
Subject: MHRA, NHSEI & Oxehealth Meeting

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Dear [I/S]

Thank you for your time today, it was an insightful meeting.

We will be getting in touch soon for further clarity on the areas discussed today.

Kind regards,

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

Tel: [I/S]

Email [I/S]

gov.uk/mhra

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