
From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Sent: 3/17/2022 8:37:41 AM
To: [I/S] [I/S]
Subject: [I/S] FW: Oxehealth Responses to Queries- [I/S]

Frances

Dr Frances Healey, PhD, RN, RN-MH (NMC 80D1205E)

Deputy Director of Patient Safety (Insight)

NHS England & NHS Improvement

T [I/S]

E [I/S]

From: [I/S] [I/S]
Sent: 16 March 2022 11:27
To: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Cc: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Subject: RE: Oxehealth Responses to Queries- [I/S]

Hi Frances,

Thank you for your email and your comments.

I agree that they need to provide sources to link to the claims they have in the promotional material. Once we have this we will be able to determine what they are exactly claiming. I am hoping to send out our questions by tomorrow so we can have a quick response back.

I have also seen your other emails and will be discussing with the team.

It has been great working with you Frances and I wish you the best for the future.

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: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Sent: 11 March 2022 08:10
To: [I/S]; JENNINGS, Sarah (NHS IMPROVEMENT - [I/S])
[I/S]
Subject: RE: Oxehealth Responses to Queries- [I/S]

Hi [I/S]

They do seem to be shifting a little but seems a bit limited – adding a caveat after saying ‘not us but other people say it prevents self-harm’ etc. Better than current materials but will rely on your regulatory knowledge to say whether putting on your website that other people say it prevents self-harm and falls plus an asterisk that only as part of wider care package means that it isn’t making a claim for use as a medical device. The existing lower tech falls alarms are the parallel I understand – clearly they don’t prevent falls unless someone responds to the alarm, but are still registered as medical devices.

In their response they say they have recognised the risk of harm if patients believe it can function it ways it doesn’t, and that appears to be on a corporate risk register, but not clear on what steps they have taken to reduce that risk.

It’s not a regulatory issue but very odd for them to say it is not used for viewing 15 seconds unless people have purchased the viewing mode, only for spot pulse and respiration measurement, because if you have the spot measurement module you can view 15 seconds whenever you like and either take - or not take - a spot measurement.

I don’t understand at all when they say users can choose between an anonymised video feed and a non-anonymised feed, they need to explain that more clearly. May mean pixelated?

Seems no clear end date for how long they store video. They say stored at least 24 hours but the GDPR issue is ‘and always deleted no later than xx hours’ which doesn’t seem stated. The reports we have seen include ones implying the video was requested and received more retrospectively than 24 hours (e.g. needs authorisation from someone who would not be working weekends)

The doorway aspects still not clear to me so would think not clear to users - needs to be clear in user instructions and training whether they need to set room-by-room parameters to require the equipment to alarm if patient is near a doorway for more than x minutes or whether it does so automatically and if this applies to all doors (door out of bedroom or just en suite door). The reports we have seen include ones where there appeared no alarm despite a patient ligaturing using a door and from their condition having been there for longer than 30 seconds.

We’d like the user guidance to very clearly emphasize the continuous pulse and respiration monitoring will NOT automatically alert staff in any way – not if the pulse and respiration increase, decrease or cease.

On the falls mode - Oxehealth when we met appeared to agree with the picture we saw in incident reports that it will not alarm if patient rolls/slips out of bed, rather than sits up before standing. This would need to be emphasised in the training materials.

‘Reminder’ materials are purely technical – would improve safety if they also provided reminders of what the system can and can’t do

Likewise the competency materials – they again are purely technical rather than ensuring staff know what the device will and will not do.

These materials all seem intended for use after purchase – it is not clear what materials they are giving trusts considering purchase.

The fitting guidance is too weak on the ligature risk – only says you ‘may’ want to use anti-pick mastic to avoid the fitting being a ligature risk. Needs to say must be fitted in this way if used in an environment where patients vulnerable to self-harm are cared for. The case they describe underlines the need for this – they provided these instructions saying you didn’t have to use it then had to raise the alarm that it wasn’t used. Note I am almost certain they said earlier there were no fitting instructions as their engineers undertook it all.

I don’t think you have been shown fitting instructions for the part they do install (which includes the registered medical device) only the fitting instructions for the housing.

There continue to be many % claims in the materials you’ve sent and on the website with no apparent source. If these claims are made need linking to a footnote or another document that describes their source.

At this point in time it is probably helpful if you share our review with them – could you send it when you send your extra questions? And add a note that we are happy to look at an application for data sharing if they contact nrls.daterequests@nhs.net. I’ll send a separate email you can forward to them.

To note our MH policy colleagues dealing with an issue whereby a patient complained about the privacy aspects – he had consented to use when acutely unwell but on recovery was very distressed to realise he had done so. That raised a wider issue regarding the capacity of acutely ill MH patients to meaningfully consent. Their planned way forward is to produce national patient information (for Oxehealth and similar devices). This would link to your work, as for patients to give valid consent/not consent they need know what the device benefits are/are not, which helps with our safety concern of patients believing it will automatically summon help if pulse changes etc. They’ll take this forward in summer I understand.

I’m retiring the end of this month so Sarah will be your key contact here onwards – I’m so grateful for your patient and skilled progression of this important safety issue and know it is in safe hands.

All best

Frances

Dr Frances Healey, PhD, RN, RN-MH (NMC 80D1205E)

Deputy Director of Patient Safety (Insight)

NHS England & NHS Improvement

T: [I/S]

E: [I/S]

From: [I/S] <[I/S]>

Sent: 09 March 2022 16:58

To: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]; JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]

Subject: FW: Oxehealth Responses to Queries-[I/S]

Dear Both,

Please find attached Oxehealth’s responses to our questions. They have also informed us that the complaint regarding “low pulse rate reported for patient to be tachycardic” will be reported to us as a vigilance report.

We will be asking some further questions so, please let me know if you have any further comments.

Many thanks,

[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]

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From: Iain Charlton <[I/S]>

Sent: 02 March 2022 12:05

To: [I/S] <[I/S]>

Subject: RE: Oxehealth Responses to Queries- [I/S]

Dear [I/S],

We have finished putting together our answers and supporting material to your questions. We are keen to discuss these with you to ensure that you have all of the information you and NHSEI need, and that our approach to the changes we are making to our public website and promotional materials address the concerns raised.

We would welcome a meeting at the earliest opportunity to discuss these matters, and look forward to hearing from you.

Kind Regards,

Iain

Iain Charlton
Head of Engineered Compliance
Oxehealth

M [I/S] T [I/S]

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

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

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

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

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