
From: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=941B714CDB1348168693DC704F0514EF-[redacted] [I/S]
Sent: 5/27/2021 2:31:15 PM
To: Queries, Devices [devices.queries@mhra.gov.uk]; [redacted] [I/S]
[redacted] [I/S]
CC: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) [redacted] [I/S]
Subject: OFFICIAL SENSITIVE CONFIDENTIAL Oxehealth
Attachments: Vital Signs-IFU-Instructions For Use-EN-UK-47.0.pdf

Please note this email contains official sensitive and personal information

Dear [redacted] [I/S] and MHRA Device colleagues

Following on from initial enquiries into the [Oxehealth system](#) we are raising the following concerns with you [the MHRA]. These points have been constructed from reports received through the NRLS and review of the [Oxehealth website](#) and IfU (attached):

- There is misrepresentation between medical claims on the website and the IfU using only the vital signs tracker as a medical device; the website materials suggest how it can be used to prevent falls, prevent self-harm, monitor COVID-19 patients.
- There is a high risk to patient safety if website materials imply to patients or staff that there are automatic alerting functionalities linked to vital sign parameters, which there are not.
- As you are aware, there are difficulties accessing the IfU of the vital signs component which you have had to specifically request on our behalf. This leaves users relying on website indications which do not include warnings, cautions and contraindications.
- There is no apparent information on the safe fitting of monitors to avoid ligature risk when monitors are linked to the medical device. Whilst Oxehealth appears to undertake fitting with its own engineers, there is still a need for clear instructions since trusts would have responsibilities for ensuring these were safe even if they had not installed them themselves. We are aware of a reported incident of unsafe fitting.

Please could you respond at your earliest convenience to the points made.

Kind regards

Sarah

Sarah Jennings | Patient Safety Clinical Lead (Medical Devices)

Supporting the NHS response to Covid-19 by producing relevant patient safety advice and guidance

NHS England and NHS Improvement



From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) [redacted] [I/S]
Sent: 25 May 2021 07:09
To: [redacted] [I/S]
Cc: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520) [redacted] [I/S]; Software

<software@mhra.gov.uk>

Subject: RE: Request for IFU information please

Hi [I/S]

That's really helpful

These look like end user instructions for use – would you be able to ask the manufacturers to confirm whether or not there are any other instructions for use e.g. for engineers fitting the devices, or for providers configuring any alarm settings within it, etc.? We note their own engineers fit these but presumably even so fitting instructions required.

And are you able to confirm which of these is their CE marked indication for use? thank you so much

The Oxehealth Vitals Signs device is a certified medical device in Europe. It is intended for non-invasive spot measurements of pulse rate and respiratory rate. It is a fixed-installed device for use within single occupancy rooms within hospitals, general care, domestic and secured environments where a framework exists which mandates period checks by a trained professional to ensure subject safety. See Instructions for Use for intended use, contraindications, warnings, cautions, usage directions and maintenance. The activity detection, fall risk, activity tracker and sleep products are activity trackers and do not have a medical purpose or functionality. They are not patient monitors or vital signs monitors. They cannot be used to make a medical or clinical decision.

The Oxehealth Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate. It is a fixed-installation device for use within single occupancy rooms within hospitals, general care, domestic and secured environments where a framework exists which mandates periodic checks by a trained professional to ensure subject safety. The Oxehealth Vital Signs device is indicated for use on humans 12 years of age or older with all skin types, who do not require critical care.

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] >

Sent: 24 May 2021 17:12

To: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) <

Cc: [I/S] (NHS ENGLAND & NHS IMPROVEMENT - T1520) <[I/S]>; Software

<software@mhra.gov.uk>

Subject: RE: Request for IFU information please

Dear Frances,

Please find attached the requested IFU.

Kind regards,

[I/S]

[I/S]

Senior Medical Device Specialist – Software, Apps and AI
Devices Safety and Surveillance

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: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520) ([I/S])

Sent: 24 May 2021 08:56

To: ([I/S])

Cc: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) ([I/S])

Subject: RE: Request for IFU information please

Dear ([I/S])

Thanks for your response and also for your continued assistance.

Please go ahead and request the IFU material, informing them that NHS England have requested a copy. Once you are in receipt, grateful if you could forward it to ([I/S]) and cc to me.

Thanks again

Sarah

Sarah Jennings | Patient Safety Clinical Lead (Medical Devices)

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From: ([I/S])

Sent: 20 May 2021 10:52

To: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520) ([I/S])

Subject: RE: Request for IFU information please

Dear Sarah,

My apologies for the late response. You might find it useful to know that medical devices are regulated differently to medicines. We do not usually have IFUs readily available to us and users normally contact the manufacturer for

questions regarding the device. However, I have spoken to the manufacturer requesting the IFU as they have not responded to you.

They informed me that they provide paper copies to the current users of their system. As the IFU contains detailed information about their system beyond the essential labelling information, they have concerns regarding the sharing of the full content of their IFU and would like to know who requested the IFU. Please let me know if you are happy with us telling them that NHS England have requested a copy.

Kind regards,

[I/S]

From: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520)

[I/S]

Sent: 06 May 2021 17:15

To: Software <software@mhra.gov.uk>

Subject: RE: Request for IFU information please

Thank you [I/S]

Would MHRA be able to confirm what this device (a type II medical device) is licensed for? There are both hardware and software elements (optical reading of skin changes for pulse) which are licenced here, not overseas however when I requested a link to the medical device disclaimer, which is not provided on the website, I was sent this

<https://www.oxehealth.com/us/fda-release>

Previously there has also been the caveat below as a footnote within one of the PDFs on the Oxehealth website but it is not readily available or obvious on their website. Also the wording *See Instructions for Use for intended use, contraindications, warnings, cautions, usage directions and maintenance* doesn't actually link into anything to give that information.

The Oxehealth Vitals Signs device is a certified medical device in Europe. It is intended for non-invasive spot measurements of pulse rate and respiratory rate. It is a fixed-installed device for use within single occupancy rooms within hospitals, general care, domestic and secured environments where a framework exists which mandates period checks by a trained professional to ensure subject safety. See Instructions for Use for intended use, contraindications, warnings, cautions, usage directions and maintenance. The activity detection, fall risk, activity tracker and sleep products are activity trackers and do not have a medical purpose or functionality. They are not patient monitors or vital signs monitors. They cannot be used to make a medical or clinical decision.

I have requested a copy of the IFU from the website although haven't received any confirmation or acknowledgement. We just want to see that users are fully informed and aware that the measurements of pulse rate and respiratory rate are not used to make a medical or clinical decision. If you are still unable to provide any additional insight then I will continue to follow up again with the MFR to see their supporting literature.

Kind regards

Sarah

Sarah Jennings | Patient Safety Clinical Lead (Medical Devices)

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Help us help you
get the treatment
you need.

NHS

From: Software <software@mhra.gov.uk>

Sent: 04 May 2021 17:03

To: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520)

[I/S]

Subject: RE: Request for IFU information please

Dear Sarah,

I appreciate your explanation and I can understand that you would need more information to explore the devices capabilities. However, we do not keep IFUs of devices and as we have not had any concerns regarding this device, I will not be able to provide any more information.

Please do not hesitate to contact me if I can be of any further assistance on this matter.

Kind regards,

[I/S]

Senior Medical Device Specialist – Software, Apps and AI
Devices Safety and Surveillance

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: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520)

[I/S]

Sent: 04 May 2021 15:48

To: Software <software@mhra.gov.uk>

Subject: RE: Request for IFU information please

Dear [I/S]

Thanks for your email. At this stage it is challenging to explain our concerns as we are unable to access any Instructions for Use, intended purpose, contraindications, warnings, cautions, usage directions and maintenance etc for the device. The website also provides no information on what training or instruction is given to staff and as such we approached you (the MHRA) to see if you had any additional insight which we could then review against the information received.

Until we have more understanding on the device capabilities and properties then we are unable to explore or respond. We hoped that you may be able to provide the insight on IFU, licensing etc as opposed to approaching the manufacturer as this could alarm them to concerns that may turn out to be unnecessary.

Hopefully that explains our position further but happy to discuss with you if needed.

Kind regards

Sarah

Sarah Jennings | Patient Safety Clinical Lead (Medical Devices)

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From: Software <software@mhra.gov.uk>

Sent: 04 May 2021 15:32

To: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520)

[I/S]

Subject: RE: Request for IFU information please

Dear [I/S]

Thank you for your email. In order for us to be able to assist you with your request, please could you provide more information regarding your concerns about the device.

Kind regards,

[I/S]

[I/S]

Senior Medical Device Specialist – Software, Apps and AI
Devices Safety and Surveillance

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: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520)

[I/S]

Sent: 26 April 2021 14:38

To: [I/S]

Cc: Queries, Devices <Devices.Queries@mhra.gov.uk>

Subject: Request for IFU information please

Please note this email contains official sensitive and personal information

Hi [I/S]

I was wondering if you are able to source some IFU for the team here relating to [Oxevision - Oxehealth](#).

We have a few concerns and would like to understand more about what this is licensed for and what is stated in the IFU, without contacting the manufacturer directly. The webpage doesn't provide any additional insight although does state *The Oxehealth Vitals Signs device is a certified medical device in Europe. It is intended for noninvasive spot measurements of pulse rate and respiratory rate.*

Is there any way you can source the IFU and more information for us?

Many thanks for any additional insight and happy to talk this through too if that's more appropriate.

Many thanks

Sarah

Sarah Jennings | Patient Safety Clinical Lead (Medical Devices)
NHS England and NHS Improvement

M 0 [I/S]
Skipton House, 5th Floor Area D, 80 London Road, London SE1 6LH
w: www.england.nhs.uk and www.improvement.nhs.uk

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