
From: [I/S]
Sent: 2/10/2022 5:30:45 PM
To: [I/S]
CC: [I/S]
Subject: RE: Oxehealth

Thanks [I/S]

In my opinion it is reportable. The following statement is contentious..... *'This particular patient was not suffering from any condition that could cause them serious harm' and.....They are a mental health patient without any other physical conditions or illness'*

The patient could have suddenly developed an acute condition and just because they have a mental health condition it does not prevent them from developing an acuter illness, it also sounds like there may be issues with the parameters (operating range) of the device ?

Furthermore given the following statement *In general, research of the literature found that tachypnoea at this level was not found to be associated with conditions or diseases that could result in serious harm.* Why are they relying on literature ? there are many causes of tachypnoea and in this given situation a medical intervention should have occurred to rule out any immediate acute or developing illness.

All in all it meets the criteria for a vigilance report

A – an event occurred (low pulse rate recorded)

B - The manufacturer's device is suspected to be a contributory cause of the INCIDENT (The Customer took a reading of a very low pulse rate for a patient they verified was tachycardic. This was because the patient's breathing rate and pulse rate were both above the stated operating range maxima for the Vital Signs device)

C: The event led, or might have led, to one of the following outcomes:
death of a patient, USER or other person
serious deterioration in state of health of a patient, USER or other person (the patient could have developed a sudden acute illness)

I hope this is helpful, if they refuse then ask them to provide answers to A,B and C above to evidence why its not reportable. They need to be made aware that in reporting it does not attribute blame it just evidences they take vigilance and safety issues seriously and they can investigate and rule in / out the device. Finally they must be made aware that any software update would require a FSCA and NB approval

Kind regards

[I/S]

[I/S]

Senior Clinical Advisor
Clinical Governance and Audit Lead
Devices Clinical Team

[I/S]

[Read our guidance on coronavirus \(COVID-19\)](#)

Please note – I do not work on a Monday

Tel: [I/S]

Email: [I/S]

From: [I/S]

Sent: 10 February 2022 16:27

To: [I/S]

Cc: [I/S]

Subject: Oxehealth

Dear All,

I am seeking advice regarding whether an incident is reportable. I have previously updated SRM on Oxehealth as we have had some concerns from NHSEI. [I/S] has also raised concerns regarding data privacy which I have included in the questions sent to the manufacturer.

We have received a list of complaints were the manufacturer has indicated that they are not reportable. However, I disagree with one of the complaints as I believe it may be reportable and would appreciate your view on this. Please see below details of the incident and justification from Oxehealth on why it is not reportable.

Description	What has happened?	Could anyone have been seriously harmed as a result?	What action did Oxehealth take?
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Low pulse rate reported for patient believed to be tachycardic	The Customer took a reading of a very low pulse rate for a patient they verified was tachycardic. This was because the patient's breathing rate and pulse rate were both above the stated operating range maxima for the Vital Signs device at the same time, resulting in the breathing rate being mistakenly reported as a pulse rate. The patient's tachypnea and tachycardia were not associated with a condition or disease that could have directly resulted in harm to them in these circumstances (they are a mental health patient without any other physical conditions or illness).	No, the patient could not have been harmed, and subsequent risk analysis showed that the risk of harm to other patients would be negligible if this event were to recur. This particular patient was not suffering from any condition that could cause them serious harm. In general, research of the literature found that tachypnea at this level was not found to be associated with conditions or diseases that could result in serious harm.	Oxehealth communicated with the Customer regarding this occurrence with the patient so they can understand the nature of the error and act accordingly should they have such an extreme tachypnea again. Oxehealth carried out further investigation of the issue to detect occurrences for other patients, with some rare potential occurrences identified, but no further reports from customers. Longer term investigation and assessment of the benefit-risk of a potential fix that would also remove potentially valid readings in the 50-60 bpm pulse rate range has been carried out (results are a 10% lower yield of accurate values between 50 and 60 bpm, a 3 reduction overall, but no effect on the primary accuracy claim). Current Action: To implement the fix in the next release of software, as the benefit-risk ratio has been found to not be adversely affected (it is still worth using the device with the lower yield of accurate values). Regression tests for this issue will be added.
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Many thanks,

[I/S]

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

[I/S]

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