Date: Thu, 24 Dec 2015 12:34:28 +0000

From: Steve Hardaker <steve.hardaker@viamed.co.uk>

Subject: Pulse oximetry sensors returned on SRS65192

To: R Pantry <R.Pantrey@nhs.net>

Bcc: Michael Green <michael.green@viamed.co.uk>, Jonathan Connor <jonathan.connor@viamed.co.uk>

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Dear Mr Pantrey,

I am contacting you with regards to the pulse oximetry sensors that you returned to us on SRS65192.

All 6 of the sensors have undergone a full QA testing procedure against a simulator that has been programmed with the correct 'R-curves' for the oximetry technology utilised by the sensors, and all have tested within specification. As such, we will return these to you; I have attached a summary of the test data for reference.

I note from the information that you provided that you sent these back to us based on the results of the 'Lightman' tester, I should point out that the results claimed by this device have long been disputed, and indeed discredited by a number of pulse oximetry technology manufacturers. An investigation by the MHRA in 2006 prompted the release of a statement (attached) which offers the following comment from them:

"The tester predicts the probes accuracy by measuring the spread of IR wavelengths. Annex AA.50.101.2.1 of BS EN ISO 99190:2005 states the accuracy of pulse oximeters cannot be characterized or validated by this type of tester."

The key word in this statement is PREDICTS: the measurements have no proven bearing on actual measured accuracy that we are aware of. Furthermore, Viamed has plenty of test data that proves that sensors that the Lightman has reported as having potential failures are actually perfectly within specification, both for sensors that Viamed manufactures and for a raft of OEM manufactured sensors.

I hope that this helps to reassure you that these sensors are perfectly within specification, if you have any queries, please feel free to contact me.

Regards,

Steve Hardaker
UK Sales Manager
Viamed Ltd.
http://www.viamed.co.uk
email: steve.hardaker@viamed.co.uk
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

Twitter: twitter.com/ViamedLtd
Facebook Page: Search for Viamed Ltd