



Derek Lamb <liquidgands@gmail.com>

Re: MHRA Adverse Incident Report - Maxtec EyeMax 2 (Premie)

1 message

Bob Kalish <bkalish@maxtec.com>

29 January 2020 at 16:54

To: Steve Nixon <steve.nixon@viamed.co.uk>

Cc: Derek Lamb <derek.lamb@viamed.co.uk>, Steve Hardaker <steve.hardaker@viamed.co.uk>, Tammy Lavery <tlavery@maxtec.com>, Matthew Marumoto <mymarumoto@maxtec.com>, Silvia Galvan <sjones@maxtec.com>

Hi Steve,

I hate to hear about something like this. I have copied our regulatory folks on this email to respond accordingly.

**Bob Kalish**

OEM and International Sales Director

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How did I do today?

On Wed, Jan 29, 2020 at 11:16 AM Steve Nixon <office@viamed.co.uk> wrote:

MHRA Adverse Incident Report - Maxtec EyeMax 2 (Premie)

Hi Bob

Can you please provide feedback and advice from Maxtec regarding the attached adverse incident report received from the MHRA. We have just learned of this and we need to construct a response ASAP either from Maxtec or from Viamed (on behalf of Maxtec).

Initial quick thoughts:

- a) Did they affix the EyeMax 2 in accordance with the instructions?
- b) Did they used the correct size EyeMax 2, did they measure the occipital-frontal circumference? What was the documented occipital-frontal circumference?
- c) Was the EyeMax 2 overstretched at any time?
- d) Was the EyeMax 2 used on a single patient? How long had the EyeMax 2 been in use on the patient concerned?
- e) At the time of the reported incident, how often was the position of the EyeMax 2 checked?

Regards

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Steve

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Director - Viamed Ltd.

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2 attachments**Resend report email.pdf**

40K

**IncidentReport-2019-010-022-401-011.pdf**

22K