Gmail **Derek Lamb <liquidgands@gmail.com>**

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

1 message

Steve Nixon <office@viamed.co.uk> 31 January 2020 at 15:59
Reply-To: steve.nixon@viamed.co.uk
To: Franco Carrizo <fcarrizo@maxtec.com>
Cc: Steve Hardaker <steve.hardaker@viamed.co.uk>, Derek Lamb <derek.lamb@viamed.co.uk>, Bruce Brierley <bruce@maxtec.com>, Bob Kalish <bkalish@maxtec.com>, Tammy Lavery <tlavery@maxtec.com>, sjones@maxtec.com, ahollis@maxtec.com

Dear Franco

If you wish, I can send you a list of the batches that were supplied to this hospital. This should provide a reasonable indication of when the units were used, but no guarantee, as it is reliant on the stock control of the department.

Regards

Steve

On Thu, 30 Jan 2020 at 19:42, Franco Carrizo <fcarrizo@maxtec.com> wrote:

> Hello Helen,
>
> I am sorry to hear you experienced issues with our product and especially for what happened with the patient. In order to understand the circumstances and investigate further, I need additional information. Please answer my questions below as best you can.
>
> - Part and Lot Number of the unit that was used:
> - Did the person who placed the EyeMax 2 do it according to the instructions? Was this person trained? Was this a usual operation for this person?
> - Was the correct size EyeMax 2, did you measure the occipital-frontal circumference? What was the documented occipital-frontal circumference?
> - Was the EyeMax 2 overstretched at any time?
> - Was the EyeMax 2 used on a single patient? How long had the EyeMax 2 been in use on the patient concerned?
> - At the time of the reported incident, how often was the position of the EyeMax 2 checked?
> - In you report you mentioned that there were 2 additional incident in the last 2 years, have all of those cases been related with the Preemie Size?
>
> I am very grateful for your help and for any additional information that you can provide to deepen our investigation.
>
> Regards
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>
> **Franco Carrizo**
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>
> **MAXTEC.COM**
> FACEBOOK | TWITTER | NEWSLETTER
>
>  **How did I do today?**

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Steve

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