Gmail

Derek Lamb <liquidgands@gmail.com>

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

1 message

Franco Carrizo <fcarrizo@maxtec.com> 30 January 2020 at 19:42
To: helen.russelfisher@mft.nhs.uk
Cc: jemema.sharp@mft.nhs.uk, steve.nixon@viamed.co.uk, derek.lamb@viamed.co.uk, steve.hardaker@viamed.co.uk, Tammy Lavery <tlavery@maxtec.com>, Silvia Jones <sjones@maxtec.com>, Bruce Brierley <bruce@maxtec.com>, Almy Hollis <ahollis@maxtec.com>, Bob Kalish <bkalish@maxtec.com>

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

Franco Carrizo
Quality Assurance Associate

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2 attachments

Resend report email.pdf
40K

IncidentReport-2019-010-022-401-011.pdf
22K