Gmail

Derek Lamb <liquidgands@gmail.com>

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

1 message

Steve Hardaker <office@viamed.co.uk> 31 January 2020 at 16:35
Reply-To: steve.hardaker@viamed.co.uk
To: Franco Carrizo <fcarrizo@maxtec.com>
Cc: Steve Nixon <steve.nixon@viamed.co.uk>, Derek Lamb <derek.lamb@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>

Dear all,

This email is to provide you (Maxtec) with some background information with regards to the Field Safety Notice 2019/010/022/401/011 issued by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which was raised following an Adverse Incident Report that was submitted by Wythenshawe Hospital concerning EyeMax 2 phototherapy masks. This has not been circulated to the customer organisation or to the MHRA; it is a confidential communication to Maxtec to provide additional context.

As part of Viamed's post market surveillance and monitoring, we log all significant communications between ourselves and customers concerning products. Our records show that we have had contact with Sister Helen Russel-Fisher, the nurse that reported the incident, previously.

Specifically, on 8th December 2017, Sister Russel-Fisher called to ask if we have any reports of the Eyemax 2 slipping down when in use. She advised that they had observed one patient where it looked like the EyeMax 2 had slipped, not covering the patient's nose but enough to cause the clinical Staff to have to readjust it and she wondered if this was a common thing or if it was just a staff training issue.

At that time (and since, to date) we have had no other reports of masks slipping. In response, we discussed the correct use of the product and I suggested that the department reviews Staff training on the product, and I sent all of the instruction and pack inserts by email for reference.

I followed this up in January 2018 and Sister Russel-Fisher advised by email "*...we have highlighted the risk of the Imax* [sic] *masks slipping down and occluding the nostrils. Hourly signed for checks have been instigated and a picture and instructions of how to size and fit the mask has been attached to each bassinet.*"

My response dated 30th January 2018 was as follows: "*The Eyemax2 was designed with the section of headband that goes over the crown of the head specifically to reduce the possibility of the mask slipping down over the airway when correctly applied. The precautions that you have taken to address the correct positioning of the Eyemax2 will minimise the risk of incident and I fully expect that there will be no further cause for concern if your procedures are followed.*"

Although the Adverse Incident Report states "3 incidents in the last 2 years", no further incidents or concerns were reported to Viamed and, as such, the matter was closed. I judged this to be a training issue that was resolved by the review of the hospital's procedures and, as no other customers have reported any problems, this was not reported back to Maxtec as it did not appear to be a defect with the product itself.

For reference, Wythenshawe Hospital began purchasing Eyemax phototherapy masks in October 2013 and is still purchasing as of January 2020. They purchase R300P01 regular and R300P02 premie, but not the micro size.

Steve Nixon is working to identify batch numbers, but due to the time frame in which the customer has been buying these, it isn't possible to confirm whether the incident(s) involved newly supplied masks or ones that may have been in storage.

If you need any further information from me, or if you have any queries, please feel free to ask.

Best regards,

Steve Hardaker
Technical Support Manager
Viamed Ltd.

Website: www.viamed.co.uk
email: steve.hardaker@viamed.co.uk
Tel: +44 (0)1535 634542
Fax: +44 (0)1535 635582

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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

Franco Carrizo
Quality Assurance Associate

P: +1 (385) 549-8088

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