



Adverse Incident Report

About you

Your name	Helen Russel-Fisher
Position/Occupation	Nurse
Organisation	RMCH
Your address	Starlight ward Wythenshawe Hospital M239LT
Your telephone number	0161 291 5628
Your email address	helen.russelfisher@mft.nhs.uk
Email Copy To	jemima.sharp@mft.nhs.uk
Local reference number	2093734
Consultant in charge	Dr J sharp
Type of device	General Report Form / All other devices
Incident Number	2019/010/022/401/011

Device & Incident details

Type of injury	Minor
Type of device	infant eye mask
Model	Eyemax 2 premie
Manufacturer name	SGS (notified body) / Viamed Ltd (supplier)
Manufacturer phone number	
Catalogue number	
Serial number	
Lot or batch number	
Date of manufacture	
Expiry date	
Quantity defective	
Current location of device	
Has the manufacturer / supplier been contacted?	Yes
Is the device CE Marked?	Yes
Date of incident	11 Oct 2019

Details of incident / nature of device defect test

We have had 3 incidents in the last 2 years when the eye goggles have slipped down and obstructed the infants nose and mouth. The first 2 incidents appeared to have resulted in an increase in the work of breathing (including sternal recession). This third incident that happened last week on infant was born at 36 weeks and 17 days old on admission and the eyemax 2 premie caused the apnoea alarm to go off. The infant had shallow breathing appeared to recover but 40 minutes later had a respiratory arrest. We can't be sure the two events are linked but it is a worrying coincidence.

Since the previous incidents we have added an hourly checklist that the mask is in the correct position and on each bassinet there are instructions on the fitting and application of the mask.

Details of injury (to patient, carer or healthcare professional):

See above

Action taken (includes any action by patient, carer or healthcare professional, or by the manufacturer or supplier)

See above

Attachments