Field Safety Notice

OxyPrem 1.4

Risk of pressure marks during monitoring with OxyPrem 1.4 in preterm infants

FSN Reference: FSN Nr 2021-01
FSCA Reference: FSCA Nr 2021-01

Zurich, 10 January 2022

Dear OxyPrem 1.4 User,

With this Field Safety Notice, we would like to inform you about a Field Safety Corrective Action for the OxyPrem 1.4 device, which follows an analysis of pressure marks reported in preterm infants. You can continue to use your OxyPrem 1.4 device(s) in accordance with the Instructions for Use.

Affected Devices

Affected device	Catalogue Nr	Affected serial or lot number range
OxyPrem 1.4	REF 001	All OxyPrem 1.4 systems

Figure 1 The OxyPrem 1.4 system

The OxyPrem 1.4 is intended for use as an adjunct monitor of absolute haemoglobin oxygen saturation in tissue beneath the sensor in any individual. The device is intended to be operated by healthcare professionals in professional stationary healthcare environments and shall not be used as sole basis for diagnosis or therapy.

Description of the Problem

OxyPrem has received reports from users that pressure marks or pressure sores occurred during use of the OxyPrem 1.4 Sensor. The pressure marks occurred under the sensor, during prolonged continuous monitoring of cerebral tissue oxygenation with the OxyPrem 1.4 system in preterm infants. Preterm infants have a very vulnerable skin, and skin injuries due to pressure occur often in this patient group. In all cases, the device functioned as expected. Skin irritation or injury, during prolonged application without sensor repositioning, and in patients with vulnerable skin is a known complication of use of oximetry devices.

An investigation into the pressure mark cases showed the importance of regular skin checks and repositioning of the sensor, to minimize the risk of pressure sore occurrence. The OxyPrem 1.4 Instructions reflect this already, but will be adapted to further emphasize this important information.

Potential Risk to the Patients

The most severe complications with regard to skin injury in premature infants reported to OxyPrem were pressure sores grade 2, where partial dermis loss occurs (e.g. a shallow open ulcer with a red pink wound bed, without slough or bruising or an intact or open/ruptured serum-filled blister). Pressure sores of this grade usually need medical treatment to prevent permanent damage (scarring), but if treated, these generally heal completely without long term effects.
Regular skin checks, at an interval suitable for the sensitivity of the patient's skin, ensure that pressure marks are discovered at an earlier, less severe stage and can be adequately responded to.

Probability of Problem Arising

In 11.2% of the extremely preterm babies (under 28 weeks of gestational age at birth) monitored with OxyPrem 1.4, a pressure mark occurred. The observed rate of 11.2% is slightly higher than the initially estimated occurrence rate of 10%. In 3 cases (1.4%), a grade 2 pressure sore occurred in patients with perfusion problems, where the sensor had been in the same position for a longer duration than specified in the Instructions for Use. Two of these grade 2 sores occurred on different positions on the skin of the same infant.
The investigation showed, that if the existing warnings and precautions in the Instructions for Use are followed and skin integrity is checked regularly, the risk of a pressure sore grade 2 occurrence is very low.

Action To Be Taken by the User

Please take the measures listed below:
- Read this Field Safety Notice carefully and please consider in particular the two revisions of the Instructions for Use as detailed in the section Actions Being Taken by the Manufacturer.
- Ensure that all OxyPrem 1.4 users within your organization are informed of the Field Safety Corrective Action.
- If the OxyPrem 1.4 has been supplied to a third party, please transfer this Field Safety Notice to the other organisations on which this action has an impact.
- Complete the Customer Reply Form (see Appendix A) and send it back to OxyPrem AG by e-mail to support@oxyprem.com. Please reply within 14 days of receipt.
- Retain this document for your records.
- Report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Action Being Taken by the Manufacturer

The 'Warnings and precautions' section of the OxyPrem 1.4 Instructions for Use will be adapted, providing updated warnings and precautions to reduce the risk of pressure mark occurrence.
In the revised Instructions for Use, the following two precautions will be made more prominent and will be marked as warnings:

"Check sensor fixation and skin under the sensor at least every 4 hours. When signs of skin irritation skin damage are visible, move the sensor to a different spot. The checking frequency may have to be shorter for patients with vulnerable or poorly perfused skin such as neonates, after flap surgery or burn victims. Also check sensor fixation and adjust if needed. Stress to the patient due to increased handling should be considered."

"When fixating the sensor on the patient, make sure that it fits tightly to the skin surface, but only mild force is applied. Special attention should be given to fixation on the heads of the smallest infants. Depending on size, curvature and shape of the head, there might be an increased risk for pressure injuries of the skin or head deformation. In extreme cases, monitoring may have to be interrupted or stopped."

OxyPrem Support will contact you when the new Instructions for Use are available and a printed copy of the adapted Instructions for Use will be distributed to all users. The updated Instructions for Use will be distributed by the end of March 2022.

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
If you have any questions, or need any further support concerning this issue, please do not hesitate to contact us using the contact information provided below.

Sincerely,

Zurich, 10 January 2022

Alexander Nitsch
CEO
OxyPrem AG

Stefan Kleiser
CTO
OxyPrem AG

OxyPrem AG
c/o Universität Zürich
Klinik für Neonatologie
Frauenklinikstrasse 10
8091 Zürich
Switzerland

+41 43 508 34 82
www.oxyprem.com
support@oxyprem.com

Appendix A: Field Safety Notice Customer Reply Form

Appendix A: Field Safety Notice Customer Reply Form

Field Safety Notice Customer Reply Form

OxyPrem 1.4

Risk of pressure marks during monitoring with OxyPrem 1.4 in preterm infants

FSN Ref: FSN Nr 2021-01
FSCA Ref: FSCA Nr 2021-01
Date: January 2022

Please complete this form and return it to OxyPrem AG promptly upon receipt and no later than 14 days from receipt. This will confirm receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Healthcare Organisation Name:

Organisation Address:

Department/Unit (if applicable):

Contact Name:

Title or Function:

Email Address:

Telephone Number:

I confirm receipt of the Field Safety Notice and that I read and understood its content and that I performed all actions requested by the FSN. The information and required actions have been brought to the attention of all relevant OxyPrem 1.4 users.

Name

Signature

Date

Please return the completed form by scanning or taking a photo of the completed form and email it to support@oxyprem.com.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.