

Field safety notice

Product	DIGORA Optime	Type DXR-60	July 22 th , 2013
Subject	Important service note for the new DIGORA Optime, DXR-60		
Affected devices	DXR-60 unit SN: SL1300505 to SL1300927 293 pcs		

Dear SOREDEX Partner,

We have identified a possibility of a safety risk for service technicians working with the new version of DIGORA Optime (DXR-60) imaging plate system (ref Technical information number 1171). This issue affects units from SN: SL1300505 to SL1300927 (293 pcs).

In situations where the DIGORA Optime displays an "error 3" message requiring service, there is a remote risk that the laser light inside the unit illuminates continuously, even if the enclosure has been removed and the enclosure safety switch has been deactivated. If the Image Plate Carrier is then moved, the service technician could unexpectedly be exposed to the laser beam.

There is no risk for the user of the device and units can continue to be used normally. However, in situations where any service action is required to address an "error 3" message, service technicians need to use caution to avoid exposure to the laser beam.

In the event that service is required, it is important that all safety precautions and service instructions are followed during the service operations to avoid this unexpected exposure. Specifically, service technicians need to ensure the following:

- The unit should only be serviced by a qualified service technician.
- The unit shall not be connected to mains voltage during the service actions.
- The unit shall not be powered during the service actions.
- The Imaging Plate Holder, which blocks the laser beam, should not be moved during servicing.
- Good service practices need to be followed when working on lasers to avoid looking directly at the beam.

As a correction, SOREDEX released an updated service manual including modified instructions for the "error 3" message. The new service manual can be downloaded from the SOREDEX extranet site <https://extranet.soredex.com>.

A field corrective action has been initiated and the devices shall be updated to include an extra shield, that will be permanently affixed to the inside of the unit, to prevent any inadvertent exposure to the laser beam during service.

SOREDEX is requesting that each of our dealers make all of their service technicians immediately aware of this safety concern to ensure safe handling until the additional shield is made available for

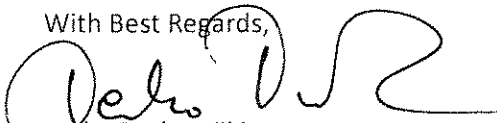
Field safety notice

installation. SOREDEX will also be sending you a service kit for each unit that you have distributed. The kit will contain a shield, adhesive and instructions for its addition to the unit. As valued business partners, SOREDEX is requesting the following actions:

1. Familiarize yourself with this letter.
2. Notify all of your service technicians of the issue immediately.
3. Send the attached acknowledgement (Appendix 1) letter to SOREDEX after reading and acknowledging this field safety notice
4. Modify the affected devices according to the modification instructions (210380)
5. Send attached acknowledgement (Appendix 2) letter to SOREDEX after performing the instructed device correction per provided instructions

We regret the inconvenience caused by this issue. If there are any questions, feel free to contact us at SOREDEX.

With Best Regards,



Terho Turkumäki

QA & RA Manager

terho.turkumaki@soredex.com

Mika Anttila

mika.anttila@soredex.com

Field safety notice



Appendix 1

Acknowledgement letter

We _____ (dealer name), confirm that, we have been read and understood the Field Safety Notice's information and we have informed our Service Technician(s) for this issue.

Service Technician(s) has also understood the severity of the issue and will take the extra attention when repairing/servicing/maintaining the DIGORA Optime (DXR-60) unit.

Date: _____

Dealer's representative signature: _____

Dealer's representative name: _____

Please return fulfilled acknowledgement letter back to SOREDEX by mail or email, after Field Safety Notice is read and understood.

RETURN TO:

Jussi Tanskanen, Nahkelantie 160, 04300 Tuusula, Finland

or

jussi.tanskanen@palodexgroup.com

Field safety notice



Appendix 2

Confirmation letter

We _____ (dealer name) confirm that, we have upgraded the DIGORA Optime (DXR-60) xxxx--- we will add the list of SN's per dealer here when FSN is approved.....

Date: _____

Device serial number: _____

Dealer's representative signature: _____

Dealer's representative name: _____

Please return fulfilled confirmation letter back to SOREDEX by mail or email once all the devices have been modified as requested.

RETURN TO:

Jussi Tanskanen, Nahkelantie 160, 04300 Tuusula, Finland

or

jussi.tanskanen@palodexgroup.com