

FIELD SAFETY NOTICE



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| Subject | SHORT CIRCUITING POWER SUPPLY UNIT DC CONNECTOR |
| Date | February 06, 2020 |
| Affects | DIGORA Optime, Scan eXam, Express, GXPS-500 |

Dear KaVo Kerr Customer,

Palodex Group OY has identified an issue with Soredex DIGORA Optime, *KaVo Scan eXam, Instrumentarium Express, and Gendex GXPS-500 Imaging Plate Systems (later called IPS)*. According to our records, we have delivered to you one or more devices belonging to the serial number range defined in the table below. The Power Supply Unit (PSU) delivered with the device may have a fault requiring correction.

| Product | SN range begins | SN range ends |
|--------------------------------|------------------------|----------------------|
| Soredex DIGORA Optime | SJ1105219 | SJ1314421 |
| KaVo Scan eXam | KJ1208178 | KJ1314403 |
| Instrumentarium Dental Express | IJ1208217 | IJ1313309 |
| Gendex GXPS-500 | GJ1209488 | GJ1311722 |

Devices falling into these serial number ranges were delivered with PSU's having nine-digit serial numbers beginning with four digits as follows:

- 1143XXXXX**
- 1221XXXXX**
- 1224XXXXX and**
- 1229XXXXX**

Please Note: If the PSU serial number does not begin with 1143, 1221, 1224, or 1229, then no action is required.

In this letter we refer to DIGORA Optime, but instructions are applicable to all four makes listed in the table above.

Issue Description

Slow degradation of plastic insulation used in the PSU DC plug may result in short circuiting which may cause heating and melting. The melting may generate smoke and eventually cause the PSU to fail. Risk of fire or injury has been assessed to be low. As a result, Palodex Group OY is being proactive with our customers to have these identified Imaging Plates Systems corrected.

Appendix 1 consists of step-by-step instructions to identify and replace a potentially failing PSU.

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Please communicate this information to your local distributors and report the initiated Medical Device Correction to your local authorities if the local regulation requires distributors to do so. Palodex Group Oy as a manufacturer of the Imaging Plates Systems will take care of manufacturer's reporting to the relevant authorities.

Palodex Group Oy sincerely apologizes for the inconvenience this situation causes you and your customers. If you have any questions regarding this field action, please call Eric Schwandt at +358 10 270 2456 or e-mail Eric at eric.schwandt@kavokerr.com.

Sincerely,

Eric Schwandt
Regulatory Affairs Manager
Palodex Group Oy

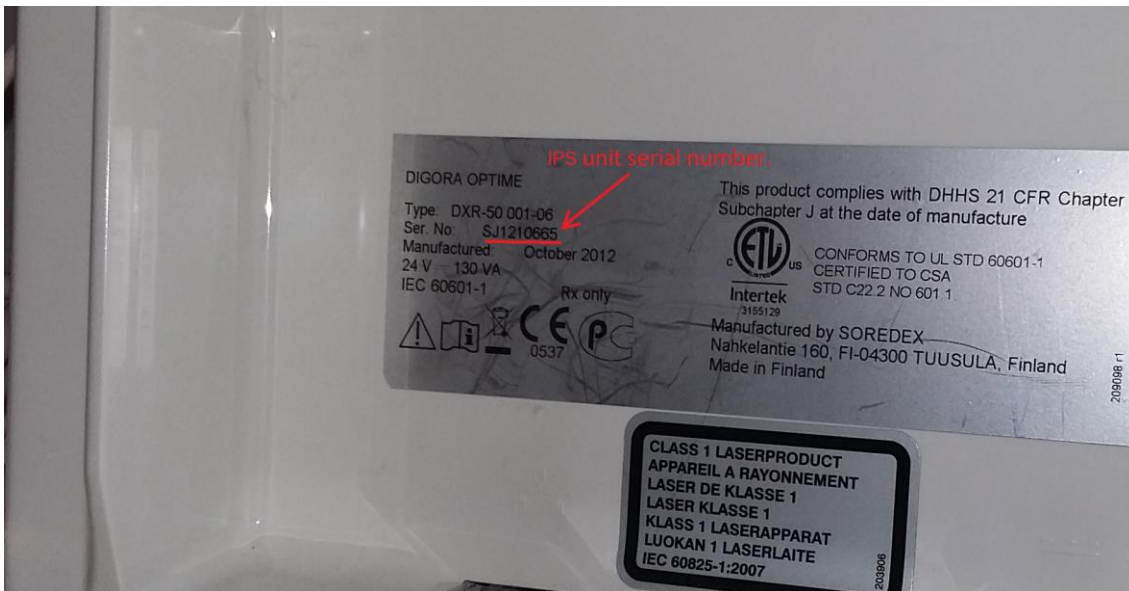
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Appendix 1

Step by step instructions to identify and change a potentially failing PSU

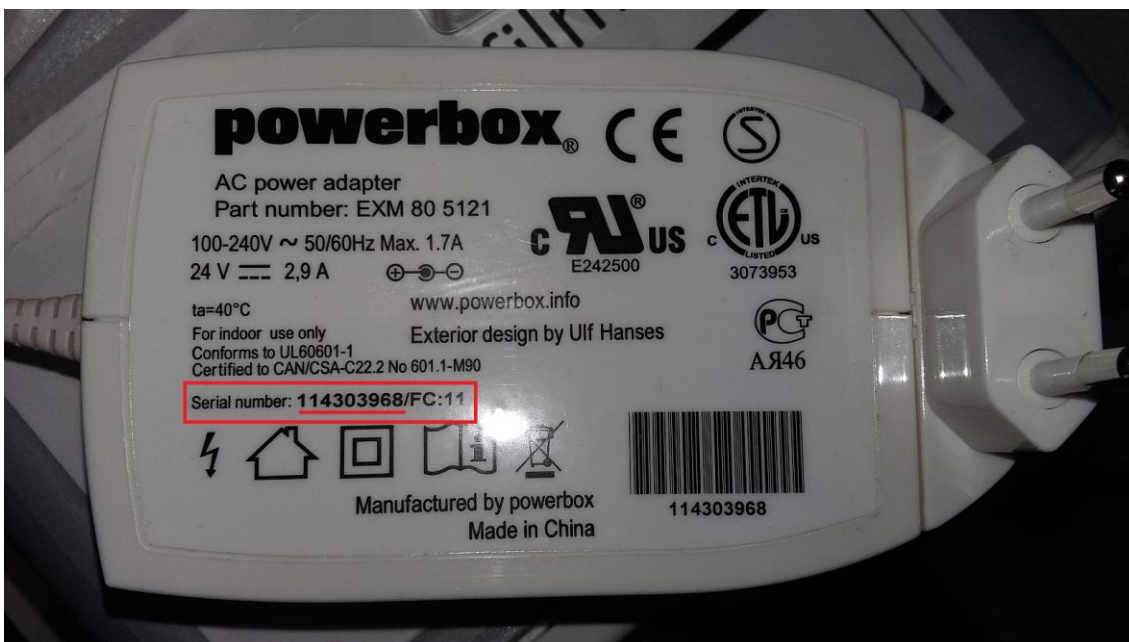
How to identify potentially failing IPS or PSU

The affected IPS unit can be identified by looking at the serial number on the scanner display or the type label at the back of the unit as shown in Picture 1.



Picture 1: The serial number of the IPS unit is located on its type label at the back of the unit.

Please locate the PSU serial number on the label shown in Picture 2.



Picture 2: The serial number of the PSU is located on its type label.

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Appendix 1



Corrective and preventive actions

Palodex Group OY is proactively requesting you to do the following actions:

- Identify the affected devices according to the instructions above
- If the PSU serial number is within the range informed above, please contact Quality and Regulatory Engineer Mr. Jussi Tanskanen for the delivery of replacement PSU free of charge. He can be reached by regular mail, phone or email as follows
Mr. Jussi Tanskanen
Palodex Group Oy, Nahkelantie 160, 04300 Tuusula, Finland
Phone: +358 10 270 2188
Email: jussi.tanskanen@kavokerr.com
- Unplug the PSU and replace it with the new one
- Dispose of the old PSU as Electronic Waste according to the local regulatory requirements.
- Send attached Confirmation Letter (Appendix 2) with your signature to jussi.tanskanen@kavokerr.com after performing the PSU replacement and disposing of the old PSU.
- You can provide information for several replacements made during one month in one Confirmation Letter
- The replacement shall be done for all the IPS devices / PSU units which are within the serial number range during the next 12 months.

We regret the inconvenience caused by this issue. Please contact the undersigned in case you need more information.

Sincerely,

Eric Schwandt
Regulatory Affairs Manager
Palodex Group Oy, Kavo Kerr Group Finland
eric.schwandt@kavokerr.com

Jussi Tanskanen
Quality and Regulatory Engineer
Palodex Group Oy, Kavo Kerr Group Finland
jussi.tanskanen@kavokerr.com

Confirmation Letter

We _____ (customer name) confirm that, we have upgraded the following IPS (Imaging Plate System) with a new PSU (Power Supply Unit) and disposed of the old PSU according to instructions provided by Palodex Group Oy:

Date: _____

IPS serial number(s): _____

PSU serial number(s): _____

Customer's representative signature: _____

Customer's representative name: _____

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

RETURN TO:

Jussi Tanskanen

jussi.tanskanen@kavokerr.com