

Urgent Field safety Notice

Power supply (LPS) for LCD monitor (Version 1.0 and 1.1)

FSCA Identifier: **20180705**

Type of action: Device replacement

Dear User,

NordicNeuroLab AS is conducting a recall of the above device. We are contacting you as a potentially affected product has been identified to have been supplied to your organization.

Details of affected devices:

This recall is relevant for LCD Powers Supply units with serial numbers LPS-1.0-yyyy-xxx and LPS-1.1-yyyy-xxx. These units were provided with a Kensington lock for securing the power supply to a cabinet or wall as safety precaution.

Description of the problem:

This is to notify that NNL AS has received 3 separate cases with the version of the power supply unit (LPS) (1.0 and 1.1) being dragged into the magnet bore (MR Scanner). These products were originally manufactured and shipped between 2011 until 2013 and contained a ferrous transformer. Precautions for safety had been taken to avoid these models being dragged into the magnet bore (MR Scanner) but have been deemed insufficient as incidents has re- occurred. Our internal investigation has led to the conclusion that this could occur in more sites across the globe as the MRI scanners that the original LCD 32" has been installed on, are getting replaced and internal site staff are performing de-installations/installations on the systems themselves. Due to this and the serious nature of the potential consequences, we have decided to perform a full recall and replacement on all remaining 1.0 and 1.1 LPSs in the field.

Action to be taken by user:

- Please immediately check your stock without removing the device from the magnet room and notify us. If it is not in the magnet room, safely quarantine the device.
- Immediately complete the attached Acknowledgement form even if you do not have any affected stock and return the scanned copy by email.
- Ensure relevant staff members are informed of this recall, including inwards goods, credit returns staff, biomedical engineers, relevant radiologists, research fellows who may need to monitor for adverse events, as applicable.

- If you have supplied any potentially affected product to another organization please advise that organization of this recall and contact us so we can follow up with them

Action Plan

NNL will upgrade all existing models with a safer design of the LCD Power Supply unit. Due to the nature of this recall, NNL will send engineer / trained personnel on site to remove the old LPS and replace it with the safer version. The replacement will either be brought with the engineer or shipped in advance of a site visit. This will only take place once we have received the completed acknowledgment form below.

Once the affected device has been replaced it can be disposed at user site or shipped back to manufacturer.

For further information please call please contact the NordicNeuroLab customer service.

Email: ProductSolution@nordicneurolab.com

Phone America: +1 262 337 2909

Phone Europe, Asia, ROW: +47 55 70 70 95

Thank you for your assistance in helping us to manage this recall.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

On behalf of NordicNeuroLab AS we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused.

Yours sincerely,

[Redacted signature]

[Redacted signature]

User Reply Form

Please COMPLETE and E-MAIL to NNL AS

User Contact Information

Note: Please list all site locations and names if responsible for more than one site or if your site is known by other names. Thank you

Site name		Site contact	
Secondary Location			
Street address		City	
State		Postal Code	Country
Phone		Email	

By signing below, I acknowledge receipt of the letter and I accept to comply with the safety instructions. Please record below the date on which your facility received this information.

Name and Title	Date
Signature	

Email to

ProductSolution@nordicneurolab.com

Attention:

NordicNeuroLab AS
5009, Bergen
Norway