
Urgent FIELD SAFETY NOTICE

Commercial name of the affected product:
Blackrock NeuroPort Biopotential Signal Processing System (Neuroport System)

FSCA-identifier 16-001
Type of action: Device Modification

Date: 2016-08-31

Attention: <Insert Name Here>

Details on affected devices:

Brand Name:

Blackrock NeuroPort Amplifier (Component of Blackrock NeuroPort Biopotential Signal Processing System)

Reference Catalog Number:

Part Number 5703 – 128 Channel Amplifier
Part Number 5747 – 32 Channel Amplifier
Part Number 5748 – 64 Channel Amplifier
Part Number 5749 – 96 Channel Amplifier

Batch/ serial numbers of affected devices:

All Serial Numbers of the listed devices are affected.

Number of affected devices:
Austria: 1
Switzerland: 3
Germany: 6
France: 3
Great Britain: 1
Italy: 1
The Netherlands: 2

Description of the problem:

Blackrock has identified two potential safety risks with the NeuroPort System:

(1) The NeuroPort Amplifier is currently labelled as a type CF Applied Part. According to IEC 60601:2005 3rd Edition, the maximum patient leakage current (single fault condition, mains voltage on the applied part) is 0.05mA for a type CF Applied Part. Measurements on devices currently in inventory and in the field indicate a mains on the applied part leakage of between 0.10 mA to 0.12 mA for systems rated for 240VAC, which is above the acceptable limit of 0.05 mA. The intended use of the NeuroPort Biopotential Processing System is:

> The Blackrock NeuroPort Biopotential Processing System supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP).

The intended use of the device does not include direct cardiac tissue contacting applications, and therefore the type BF Applied Part designation provides an acceptable level of protection against electrical shock for the intended use.

The incorrect label creates a potential hazard where the physician may incorrectly assume that the device can be safely used off-label in applications that require a type CF Applied Part (direct cardiac tissue contact). If the patient contacts a mains level external voltage source during this misuse of the device, then leakage current through the applied part could exceed safe limits.

(2) The NeuroPort Amplifier is labeled as a Floating Applied Part, and is currently configured with an accessible metal part. Blackrock has determined that a reasonably foreseeable misuse of the device could cause the floating applied part to become electrically connected to earth ground.

If this misuse were to occur either intentionally or accidentally, then the amplifier would no longer be a Floating Applied Part and leakage current through the applied part may exceed limits specified in IEC 60601-1.

Any possible risk to patients associated with previous use of affected devices.

Any potential hazards are expected to have immediate consequences. No risks to patients who have previously used the device are anticipated.

Advise on action to be taken by the user:

As long as the device is used in accordance with the provided instructions for use, there is no risk to the patient or end user. The device may continue to be used for all indications identified in labeling.

As is the situation for all devices, the device is not to be used for unapproved purposes.

- *method of modification of device*

Blackrock Microsystems will provide a corrected label for the NeuroPort Amplifier

Blackrock Microsystems will provide a protective enclosure for the NeuroPort Amplifier. Once properly placed within the enclosure, the amplifier will no longer provide an accessible metal part.

- *recommended patient follow up*

No follow-up with patients is required.

- *Timelines*

Correct labels will be provided within 2 weeks of confirmation by consignees of serial numbers of affected devices possessed by identified consignees.

Confirmation of the placement of the correct labels will be confirmed by either electronic delivery of photographs of the correct labels affixed to the amplifiers to Blackrock Microsystems.

Enclosures for the amplifiers will be provided within 90 days of confirmation by consignees of serial numbers of affected devices possessed by identified consignees.

Confirmation of the placement of the protective covers will be confirmed by either electronic delivery of photographs of the corrective covers in their correct location to Blackrock Microsystems.

Transmission of this Field Safety Notice:

This notification will be shared with all relevant National Competent Authorities and Blackrock's European Authorized Representative.

Please pass this FIELD SAFETY NOTICE to all those who need to be aware of it within your organization and to maintain awareness until all devices at your facility are modified.

Contact reference person:

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

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Signature