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NeuroPlex™ E

PN 10906, 10907, 10908, & 10909
Digital Data Cable: PN 11058 & 11404
Instructions for Use



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What This Manual Covers

Blackrock Microsystems' NeuroPlex™ E provides a compact interface from a NeuroPort™ Electrode to Blackrock's NeuroPort Bio-Potential Signal Processing Systems for up to 128 channels on the E128 or 96 channels on the E96. The NeuroPlex E is designed for high fidelity transmission and recording of extracellular spikes and local field potentials from the brain. Blackrock Microsystems' NeuroPlex E converts analog signals to digital format at the recording site which can reduce noise introduced to the signal during transmission.

This manual covers the intended use, warnings, precautions, technical specifications, pinout, cleaning, disinfection, sterilization, and maintenance instructions, and warranty of the NeuroPlex E digital headstage manufactured by Blackrock Microsystems.

Intended Use and Indications for Use

The NeuroPlex E supports recording, processing, and display of biopotential signals from user-supplied electrodes. Biopotential signals include, but are not limited to: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG), and Evoked Potential (EP).

Warnings and Precautions

The NeuroPlex E, as part of the NeuroPort BioPotential Signal Processing System, has the following warnings and precautions:

Warnings

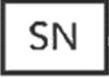
- Only connect NeuroPort System components to properly tested, grounded and dedicated AC outlets to reduce the risk of electrical shock. Do not use an adapter for ungrounded wall outlets.
- Do not connect the NeuroPort System to an outlet controlled by a wall switch.
- Do not use the NeuroPort System in the presence of flammable anesthetic agents.
- Avoid strong static discharges from sources like televisions or computer monitors because it can damage the electrical parts of the system.
- Keep the NeuroPort System away from liquids. Contact with water, shower spray, or wet surfaces can lead to the patient receiving an electrical shock.
- Connection of external instruments may compromise electrical safety compliance with IEC 60601-1.
- The Digital Data Cable is long and may snag on equipment in the room. Secure equipment in place and avoid placing in walkways or other traffic areas.
- The NeuroPlex E is attached to the NeuroPort Electrode percutaneous connector, force applied to the NeuroPlex E will be applied to this connector. Avoid large impacts to the device when it is attached to the patient. Consequences can include tearing of bone screws from skull.
- Do not use the NeuroPlex E (PN 10907, 10909) or Digital Data Cable (PN 11058) if the sterile barrier packaging is damaged.
- Only sterile NeuroPlex Es and Digital Data Cables should be used in the intraoperative environment. Non-sterile NeuroPlex Es and Digital Data Cables should only be used in the postoperative environment.
- Do not allow the Digital Data Cable to be pulled in such a way that it can apply force to the NeuroPlex E.
- Avoid spilling fluid onto or into the NeuroPlex E as doing so may cause electrical damage to the device and loss of function or electrical shock.

Precautions

- Read this entire manual prior to using the device.
- Do not allow any object to impact the NeuroPlex E while in use.
- Do not drop the NeuroPlex E when handling.
- Do not use the NeuroPlex E with damaged Digital Data Cables or Digital Data Cables that are not supplied by Blackrock Microsystems. Doing so may damage the device.
- When replacing the filament film of the device, avoid touching circuit board components as electrostatic discharge can cause damage to the device.
- When replacing the filament film, do not overtighten the screws. Overtightening the screws may cause poor connection between the device and the pedestal.
- Do not attempt to use the NeuroPlex E with connectors other than the NeuroPort pedestal connector.
- Do not plug the Digital Data Cable into devices other than the Digital Hub and Blackrock Microsystems approved headstage accessories.
- Avoid overtightening the NeuroPlex E when attaching to the NeuroPort Electrode. Device damage may result.
- Using the 'Wide-Band' filter mode on the device may cause a reduced signal to noise ratio.
- Swollen or degraded filament film may result in loss of signals.
- Do not immerse devices in liquid.
- Do not use a washing machine or an automated washing process (such as an automated washer/disinfector). Doing so may damage the devices.
- Do not allow contaminated devices to dry. All subsequent cleaning and steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used devices.

Symbols

The following symbols may apply to the NeuroPlex E even if they do not appear on the physical product.

ISO 15223-1:2016 Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied			
Reference	Symbol	Title	Meaning
5.1.1		Manufacturer	Indicates the medical device manufacturer.
5.1.4		Use-by Date	Indicates the date after which the medical device is not to be used.
5.1.5		Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6		Catalog Number	Indicates the manufacturer's catalog number so that the device may be identified. For Blackrock Microsystems it is called the Part Number (PN).
5.1.7		Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
5.2.3		Sterilized Using Ethylene Oxide	Indicates that the device has been sterilized using ethylene oxide.
5.2.6		Do Not Resterilize	Indicates a medical device that is not to be resterilized.

ISO 15223-1:2016 Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied			
Reference	Symbol	Title	Meaning
5.2.7		Non-Sterile	To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized.
5.2.8		Do Not Use if Package is Damaged	Indicates that a medical device should not be used if the package has been damaged or opened.
5.4.2		Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.3		Consult Instructions for Use	Indicates the need for the user to consult the instructions for use, which you are currently reading.
5.4.4		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

IEC 60601-1, Edition 3.1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance			
Reference	Symbol	Title	Meaning
ISO 7010-M002		Follow Instructions for Use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
IEC 60417:2002 DB Graphical Symbols for Use on Equipment			
Reference	Symbol	Title	Meaning
5333		Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1.
5334		Electrostatic Sensitive Devices	To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge.
21 CFR 801. 109 (b) (1), 81 FR 38911 2016-09-13, U.S.A. FDA Guidance: Alternative to Certain Prescription Device Labeling Requirements 2000-01-21			
Symbol		Title	Meaning
		Prescription Only	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Specifications

Model Name	Blackrock NeuroPlex E128 Non-Sterile	Blackrock NeuroPlex E128 Sterile	Blackrock NeuroPlex E96 Non-Sterile	Blackrock NeuroPlex E96 Sterile
Model Number	10906	10907	10908	10909
Sterility	Non-Sterile	Ethylene Oxide Sterilized	Non-Sterile	Ethylene Oxide Sterilized
Number of Channels	128	128	96	96
Power Requirements	0 to 5 VDC, 150 mA maximum load			
Resolution	16-bit, at 250 nV per bit resolution			
Sampling Frequency	30 kpsps			
Mode of Operation	Continuous			
Input Hardware Filter (User selectable)	Normal mode: 0.3 Hz (1 st order) – 7.5 kHz (3 rd order) Wide-band mode: 0.02 Hz (1 st order) – 10 kHz (3 rd order)			
Input Filter Type	Butterworth			
Input Impedance	1300 MΩ @ 10 Hz, 13 MΩ @ 1 kHz			
Auto Impedance Measurement Range	5 kΩ – 1 MΩ			
Maximum Input Range	± 8.192 mV with respect to reference			
Ingress Protection	Ordinary Equipment, not fluid resistant, IP20			
Dimensions	L 24.9 mm x W 17.7 mm x H 17.9 mm			
Operating Environment	10° C to 40° C, 5 to 95% R.H. (non-condensing)			
Storage Environment	-20° C to 50° C, 5 to 100% R.H. (non-condensing)			

Hardware

Blackrock Microsystems NeuroPlex E Setup

The image below demonstrates how the NeuroPlex E connects with the Digital NeuroPort Biopotential Signal Processing System.

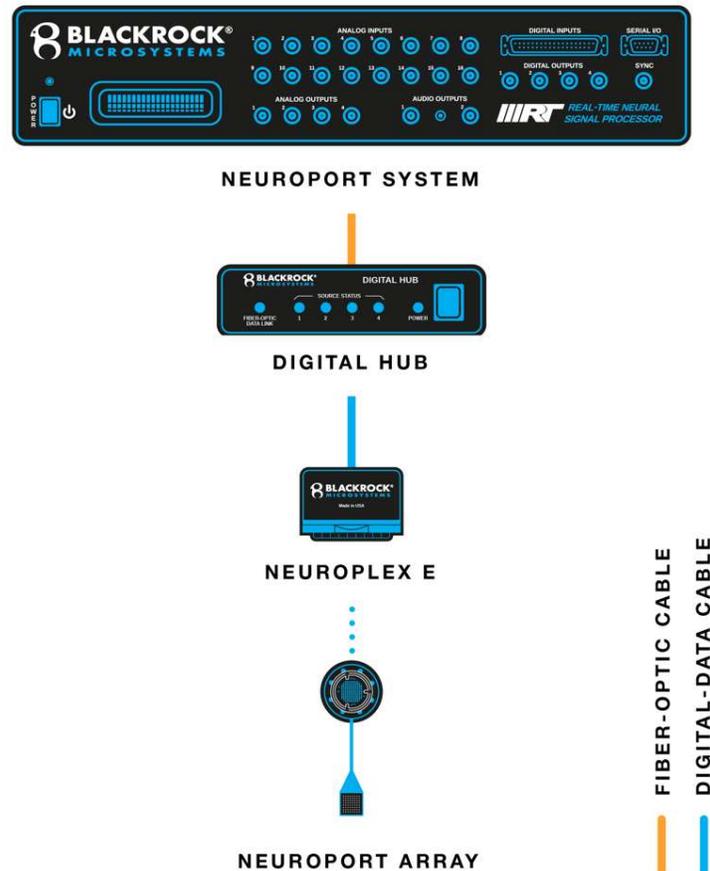


Figure 1–NeuroPlex E as part of the Digital NeuroPort Biopotential Signal Processing System

Blackrock Microsystems NeuroPlex E Pin-out

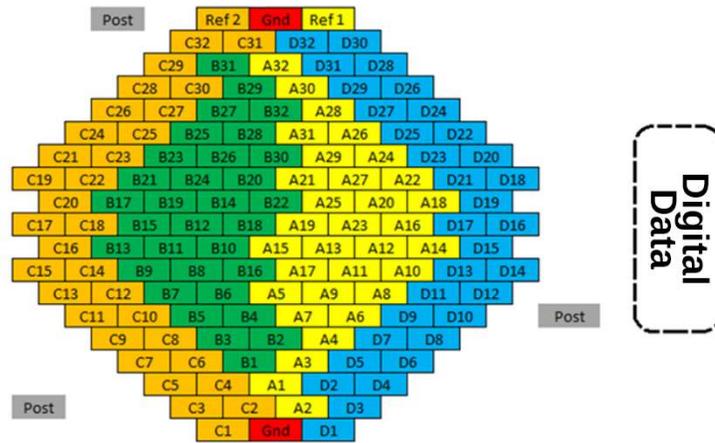


Figure 2–Pinout of NeuroPlex E128 (PN 10906, PN 10907)

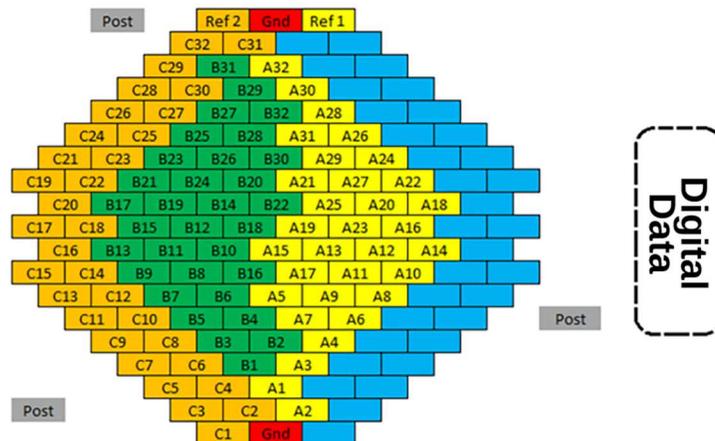


Figure 3–Pinout of NeuroPlex E96 (PN 10908, PN 10909)

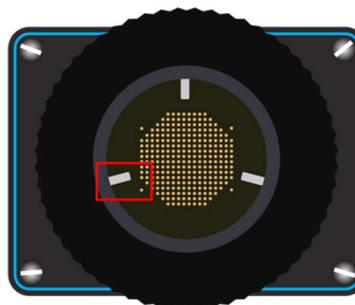


Figure 4–Bottom view of NeuroPlex E (128 & 96).
Red box indicates one of three guide posts

Instructions for Assembly

The NeuroPlex E is available in two configurations: either as a non-sterile device that may be reprocessed or an ethylene oxide sterilized, single-use device. If the device is delivered sterile, inspect the packaging for any punctures, damage, or defect prior to use. Peel open the sterile pouch only when ready for use. Note that the NeuroPlex E has double pouch layers to facilitate sterile transfer.

The NeuroPlex E is designed to mate with the pedestal connector of the NeuroPort Electrode (PN 6248, 6249, 4383, and 4382) or other electrodes that use the same connector. The NeuroPlex E is equipped with three guide posts that are visible in center pane of **Figure 4**. These guide posts must be aligned with the three available notches around the edge of the NeuroPort connector to facilitate a correct connection between NeuroPlex E and the NeuroPort Electrode. For a detailed procedure on how to connect the NeuroPlex E headstage to NeuroPort Electrode please refer to the following instructions:

1. Connect the NeuroPlex E to the Digital Hub (PN 10480) and Digital Data Cable (PN 11058 and 11404). See below **Figure 5**. Only one NeuroPlex E should be plugged into each Digital Hub of the Digital NeuroPort System.
2. Power on the Digital Hub.

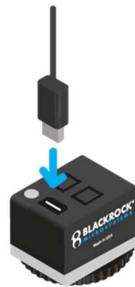


Figure 5–NeuroPlex E and cable

- The LED on the NeuroPlex E should light up as blue.
 - The LED on the Digital Hub corresponding to the Digital Data bank connected to the NeuroPlex E should light up green.
3. Roughly align the guide pins with the pedestal before attaching to the pedestal. See **Figure 6** below.



Figure 6–NeuroPlex E and pedestal alignment

4. Hold the NeuroPlex E housing with one hand and gently rotate the wheel clockwise with another hand. See below **Figure 7**.
5. While screwing down, slightly rotate the housing left or right until you feel the guide posts slide into the notches.
6. Once the NeuroPlex E is aligned with the pedestal, rotate the wheel until two fingers are no longer able to move the wheel any further.
Precaution: Avoid overtightening the NeuroPlex E when attaching to the NeuroPort Electrode. Device damage may result.
7. The blue LED will turn green when the NeuroPlex E is firmly mated with the NeuroPort Electrode and data should be visible in the Central software.



Figure 7—Instructions on connecting the NeuroPlex E to the NeuroPort Electrode

Description of Switches on the NeuroPlex E

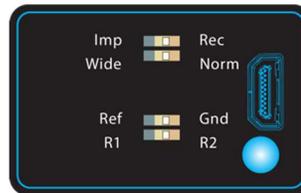


Figure 8–Available switches on the NeuroPlex E

Impedance and Recording Selector Switch

When the selector is positioned on “Imp” the NeuroPlex E enters impedance measurement mode. The impedance of each recording channel is measured with a 1 kHz, 10 nA sine wave. Impedance values are displayed in the Impedance Tester application of the Central Suite. To revert the NeuroPlex E headstage into the recording mode, simply toggle the switch to “Rec” position.

Frequency Range Selector: Wide & Norm

This switch toggles between two different hardware-based filter input settings. The “Wide” filter setting corresponds to an input frequency range from 0.02 Hz to 10 kHz. “Norm” (Normal) filter setting is between 0.3 Hz to 7.5 kHz.

Reference and Ground Selector

This switch allows the user to toggle the reference used in the monopolar recordings. If the switch is toggled to “Gnd”, subject ground will be used as the input reference to the amplifier. Setting the switch position on “Ref” (Reference) will use one of the implanted reference wires (R1 or R2) as input reference.

R1 and R2 Reference Selector

Use this switch to select which of the two available reference wires to use as the input reference when the Reference and Ground switch is set to “Ref”. A switch position set to R1 selects reference wire number 1 as the input reference. The R2 position selects the reference wire number 2.

Cleaning, Disinfection, Sterilization, Maintenance, and Disposal

Sterilization

The NeuroPlex E (PN 10907 and 10909) and Digital Data Cable (PN 11058) are delivered in sealed, labeled, sterile barrier packaging. The NeuroPlex E and Digital Data Cable are validated to achieve a sterility assurance level of 10^{-6} when sterilized with Ethylene Oxide by Blackrock Microsystems.

When the NeuroPlex E (PN 10906 and 10908) and Digital Data Cable (PN 11404) are provided non-sterile, the device should be cleaned and disinfected according to the below Cleaning, Disinfection, and Maintenance section.

Warning: Only sterile NeuroPlex Es and Digital Data Cables should be used in the intraoperative environment. Non-sterile NeuroPlex Es and Digital Data Cables should only be used in the postoperative environment.

Cleaning, Disinfection, and Maintenance

The NeuroPlex E and Digital Data Cable should be disinfected and cleaned with CaviWipes and CaviCide. Dust and debris on the exterior connectors/ports may be removed with compressed air. Cleaning and disinfection should be done as soon as possible after the device use to help facilitate ease of soil removal and prevent continued microbial growth.

The collar assembly underneath the NeuroPlex E should be inspected before each use and cleaned every time after use. To clean and disinfect the collar and filament film, follow the instructions below. To clean and disinfect the Digital Data Cable, follow steps 1 through 3 below.

1. Using CaviWipes and CaviCide, wipe and spray the articles to remove visible soil for a minimum of 10 minutes.
2. Use additional CaviWipes and CaviCide spray as necessary to ensure visible soil is removed.
3. Pay special attention to crevices, mated surfaces, connectors, and hard-to-reach places. Use a soft-bristled brush to aid in the removal of soil from these locations for a minimum of 2 minutes.
4. Visually inspect the connector. Remove any particles if present.
5. Visually inspect the film. If the film is swollen or degraded, follow the section titled "Filament Film Disassembly and Replacement" (see below) to replace the film.
6. Clean the connector. Do not let the cleaning solution pool. Allow the solution to dry before use.
7. The connector and the film must also be cleaned after use. Do not allow the solution to pool. Allow the solution to dry before storage.

Filament Film Disassembly and Replacement

The filament film which is visible from under the NeuroPlex E, provides a conductive and uniform medium in between the input pins of the NeuroPlex E and the connectors on top of the NeuroPort Electrode pedestal. The filament film is conductive in the vertical direction with respect to the film surface, connecting the contacts on the NeuroPlex E input and the pins on the NeuroPort Electrode pedestal connector, while being insulative horizontally, eliminating cross talk. After repeated usage, dust or biological matter can accumulate on the filament film which can affect the signal quality on the NeuroPlex E.

It is recommended to regularly check the condition of the filament film before use and replace it at least once a year or whenever there is a degradation in signal quality. Follow the procedures below to replace the filament film.

1. Loosen the four screws on the NeuroPlex E by turning them counterclockwise with a flathead screwdriver.
2. Hold the bottom three plates together and lift them away from the cover.
3. Remove the old filament film and clean the nearby area on the plate and the PCB.
4. Place a new filament film onto the plate. Make sure the holes on the film are aligned with the pins on the plate. You may use a pair of flat-mating or rubber-tipped tweezers to manipulate the film.
5. Replace the assembly.
6. Hold the three plates together as you lower them onto the NeuroPlex E body.
7. Fasten the four corner screws clockwise.
8. Visually inspect the film placement and cleanliness. Confirm that the four corner screws are fastened securely.

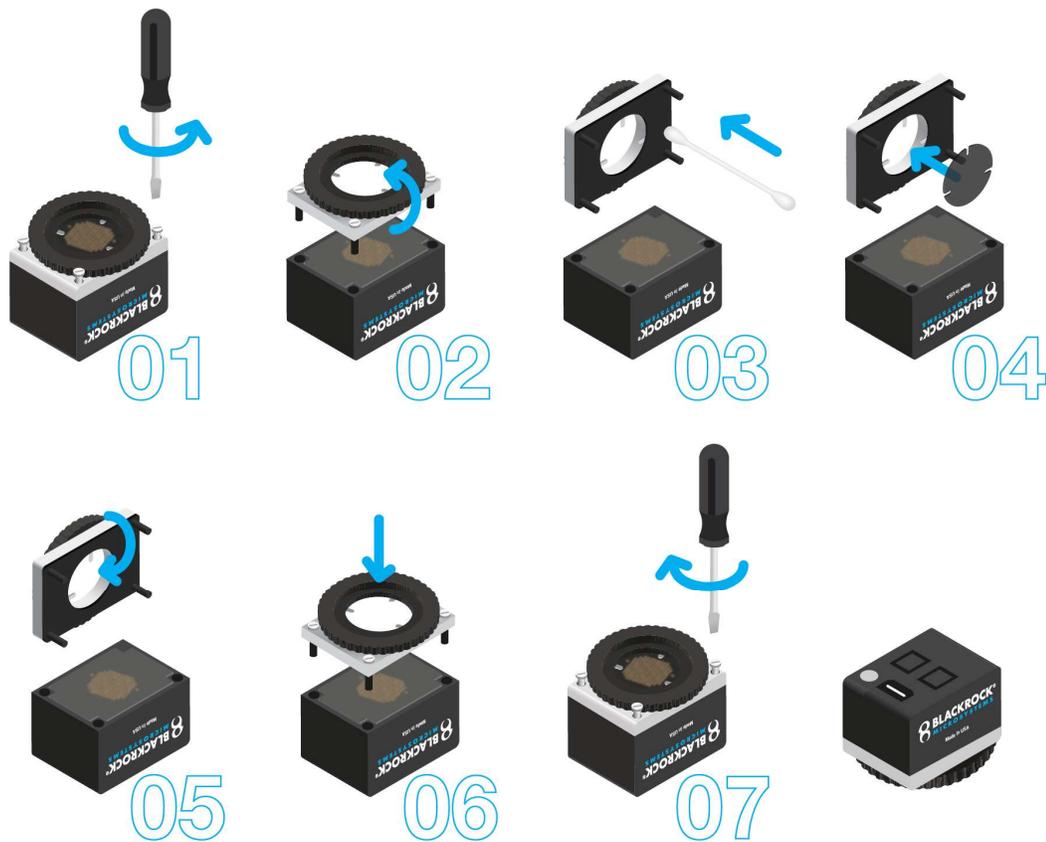


Figure 9–Replacing the Filament Film

Disposal

The NeuroPlex E may have incidental contact with bodily fluids. Follow institutional procedures for disposing potentially infectious or biohazardous devices when disposing of the NeuroPlex E.

Magnetic Resonance

The NeuroPlex E has not been evaluated for safety and compatibility in the MR environment. The NeuroPlex E has not been tested for heating, migration, or image artifact in the MR environment.

Troubleshooting

Non-Green Indicator Light on NeuroPlex E

The indicator light on the NeuroPlex E should be illuminated green if the headstage is receiving power and connected to a NeuroPort Electrode.

- If the light is not illuminated: check that the Digital Hub is powered on and that the digital data cable is firmly connected to the Hub and NeuroPlex E.
- If the light is illuminated blue, the headstage is receiving power, but is not connected to the NeuroPort Electrode: Verify that the guide pins of the NeuroPlex E are aligned with the guide holes of the NeuroPort Electrode, that the wheel is tightened firmly with two fingers, and that the filament film and pedestal LGA surface are both clean and free of debris.

Poor Signal to Noise Ratio / Noisy Signal

A typical high-passed noise band is less than +/- 30 microvolts or approximately 60 microvolts peak to peak (roughly 10 root mean squared). If the signal that you are receiving is noisier than this, it could be due to a number of factors:

- Poor reference configuration: Try changing the reference setting of the device.
- Poor contact between device and pedestal connector: Try the troubleshooting steps above for 'Non-Green Indicator Light on NeuroPlex E'.
- Wideband configuration: Try changing the filter range to standard instead of wideband.
- Electrode connections: Ensure the electrode has good ground contact with the patient. The pedestal is the ground contact for the NeuroPlex E. Check that the reference wires are exposed to tissue.

Non-Green Light on Digital Hub Bank

The indicator light on the Digital Hub for the bank that the NeuroPlex E is attached to should be green.

- If it is not green, it could mean that your NeuroPlex E device is damaged or malfunctioning or it could mean that you are using an unapproved or damaged Digital Data Cable between the Digital Hub and the NeuroPlex E. Try changing the Digital Data Cable to a Blackrock Microsystems' Digital Data Cable. Finally, it could mean that the Digital Hub is malfunctioning. Try changing which bank that the NeuroPlex E is connected to. If the problem persists, contact Blackrock Microsystems Support for assistance.

Return Merchandise Authorization

In the unlikely event that your device needs to be returned to Blackrock Microsystems for repair or maintenance, do not send any equipment back without a Return Merchandise Authorization Number (RMA). An RMA number will be issued to you by a Blackrock representative. If you need to obtain an RMA number, you may contact a product support representative at +1 (801) 582-5533 or by emailing support@blackrockmicro.com.

Once an RMA number has been issued, it is important to safely pack the returned item for shipping back to Blackrock. It is preferred that you save the original boxes and packing materials that your system arrived in for return shipment. Please address the package as follows:

Blackrock Microsystems, LLC
ATTN: RMA#
630 S. Komas Dr., Suite 200
Salt Lake City, UT 84108 USA
Tel: +1 (801) 582-5533

Warranty

Blackrock Microsystems (“Blackrock”) warrants its products are free from defects in materials and manufacturing for a period of one-year from the date of shipment. At its option, Blackrock will repair or replace any product that does not comply with this warranty. This warranty is voided by: (1) any modification or attempted modification to the product done by anyone other than an authorized Blackrock employee; (2) any abuse, negligent handling or misapplication of the product; or (3) any sale or other transfer of the product by the original purchaser.

Except for the warranty set forth in the preceding paragraph, Blackrock provides no warranties of any kind, either express or implied, by fact or law, and hereby disclaims all other warranties, including without limitation the implied warranties of merchantability, fitness for a particular purpose, and non-infringement of third-party patent or other intellectual property rights.

Blackrock shall not be liable for special, indirect, incidental, punitive, exemplary or consequential damages (including without limitation, damages resulting from loss of use, loss of profits, interruption or loss of business or other economic loss) arising out of non-compliance with any warranty. Blackrock’s entire liability shall be limited to providing the remedy set forth in the previous paragraph.

Support

Blackrock prides itself in its customer support. For additional information on this product or any of our products, you can contact our Support team through the contact information below:

Manuals, Software Downloads, and Application Notes

www.blackrockmicro.com/technical-support

Complaints

When filing a complaint, please provide the product description, product number, software version, lot number, complainant's name and address, and the nature of the complaint.

Issues or Questions

www.blackrockmicro.com/technical-support

support@blackrockmicro.com

Tel: +1 (801) 582-5533

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.