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Patient Cable with Filament Film NeuroPort Connector

Instructions for Use

Revision 3.00/LB-0349 – Patient Cable with Filament Film NeuroPort Connector IFU – November 2018

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What This Manual Covers

This manual is the instructions for use for the NeuroPort Patient Cable with Filament Film connector (referred to as the Patient Cable in this document). There are multiple models of Patient Cable offered by Blackrock Microsystems, the other cables offering a different number of channels (128 instead of 96) or a pogo-pin connector instead of the filament film connector. This Patient Cable has two revisions, one that has jumpers for selection of reference and one that utilizes dip switches for the same purpose.

The Patient Cable is provided Ethylene Oxide (EO) sterilized and is labeled as a single use device.

Intended Use and Indications for Use

The Patient Cable is intended to be used with the NeuroPort Biopotential Signal Processing System. It operates as a preamplifier for neural signals from the NeuroPort Electrode.

It is indicated for use in any patients or research participants that are implanted with a NeuroPort Electrode.

Contraindications, Warnings, Precautions

Contraindications

- The NeuroPort Electrode should not be used on any patient whom the physician/surgeon considers at an elevated risk of infection.
- The NeuroPort Electrode is a recording device and should not be used in applications involving stimulation.
- The NeuroPort Electrode is designed for single patient use and should not be reused.

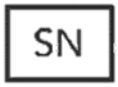
Warnings

- A thorough understanding of the technical principles, clinical applications and risks associated with neurosurgery is necessary before using this product.
- The NeuroPort Electrode is intended for use only by a trained and licensed neurosurgeon with expertise in stereotactically guided and functional neurosurgery procedures.
- Read this entire manual prior to using the device.
- Completion of the Blackrock Microsystems user training program is required prior to the use of the NeuroPort System.
- Once the NeuroPort Electrode has been implanted, the patient should not be exposed to electrocautery, therapeutic ultrasound or diathermy.
- Once the NeuroPort Electrode has been implanted, peripheral nerve stimulation should not be used.
- While the Patient Cable is disconnected from the amplifier, care should be taken to prevent excess force on the cable.
- The patient should not attempt to remove the Patient Cable themselves.
- The Patient Cable should not be bound to, or organized with, any other cables which allows the Patient Cable to lie parallel to another cable.
- The NeuroPort Neural Signal Monitoring System should be disconnected from the NeuroPort Electrode during cardiac defibrillation.

Precautions

- The NeuroPort Electrode is intended for use only with the NeuroPort Biopotential Signal Processing System.
- Do not use the NeuroPort Electrode if the sterile barrier packaging is damaged.

Symbols

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.
5.1.3		Date of Manufacture	Indicates date of manufacture and is accompanied by a date.
5.1.4		Use-by Date	Indicates the date after which the medical device is not to be used.
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 Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
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.
5.4.3		Consult Instructions for Use	Indicates the need for the user to consult the instructions for use, which you are currently reading.

ISO 15223-1: 2016 Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied			
Reference	**Reference**	**Reference**	**Reference**
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 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.
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	Sterile Patient Cable with Filament Film NeuroPort Connector
Part Number	6735
Channel Count	96 Channels
Compliance Standards	IEC 60601-1-1, IEC 60601-1-2
Mode of Operation	Continuous
Water Ingress Protection	Ordinary Equipment, Not Fluid Resistant; IPX0
Operating Environment	10˚C to 40˚C, 5% to 50% R.H. (non-condensing)
Storage Environment	10˚C to 40˚C, 5% to 20% R.H. (non-condensing)

Overview of Hardware

Filament Film Connector

The Patient Cable is designed to mate with the NeuroPort Electrode via the filament film NeuroPort connector. Signals are transferred from the pins on the Land Grid Array of the NeuroPort Electrode, through the anisotropic membrane of the filament film, and into the pins of the printed circuit board inside of the Patient Cable headstage housing.

The housing of the filament film connector, known as the NeuroPort Plug, may be removed for cleaning or troubleshooting purposes. The following image shows a plug detached from the Patient Cable.

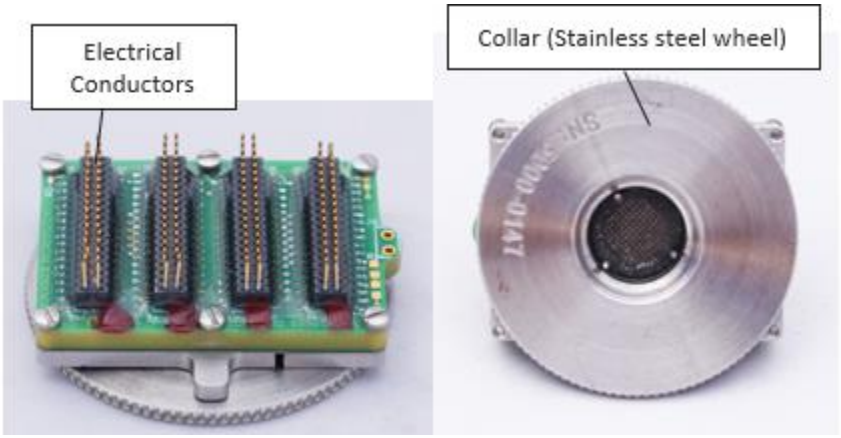


Figure 1 - Filament Film NeuroPort Plug

Headstage and Headstage Housing

The Patient Cable contains preamplification boards within the headstage housing. These boards buffer the neural signal using built-in unity gain voltage followers to protect the signals against external noise.

Figure 2 - Complete Patient Cable Highlighting Headstage Housing

Reference Selection

The Front End Amplifier has four 34-pin banks. Each bank consists of 32 channels, a bank reference pin, and a ground pin. The electrodes within each bank are differentially amplified with respect to the reference input of the same bank.

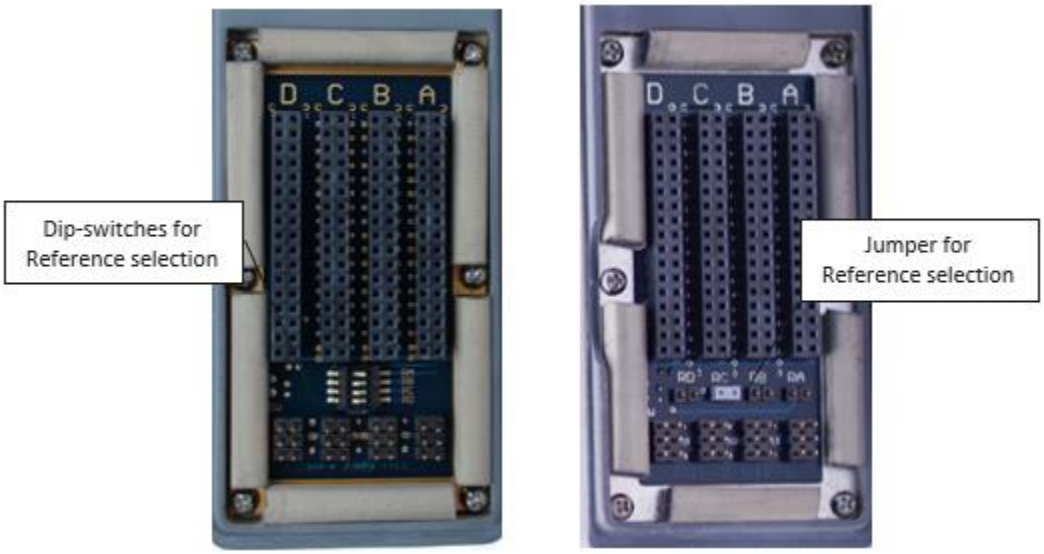


Figure 3 - Patient Cable connector termination board for newer versions of the Patient Cable (left) and older models (right)

When the Patient Cable is attached to the Front End Amplifier, the channels on all banks will be electrically measured with respect to a single input reference. This input reference can be determined by a small jumper connected to a desired reference input as shown

in the following picture. By default, there are two separate reference wires included in the NeuroPort or NeuroPort Electrode assemblies. These reference wires are referred to as R1 and R2. The reference selection scheme is described in the following table.

Location of the Jumper	Action
Jumper on RA Dip-switch A - ON	Selects Ref 1 as reference for all banks on the FEA
Jumper on RB Dip-switch B - ON	Signals are measured only with respect to ground
Jumper on RC Dip-switch C - ON	Selects Ref 2 as reference for all banks on the FEA
Jumper on RD Dip-switch D - ON	Signals are measured only with respect to ground

Table 1 - Patient Cable reference selection scheme

Impedance Measurement

The Patient Cable is equipped with an integrated impedance tester that allows users to measure impedance of the implanted electrodes. The impedance tester operates by injecting a low current sine wave (10 nA at 1 kHz) through the ground of the NeuroPort Electrode. The system then records one second of this sine wave on each channel and utilizes amplitude measurements to determine the impedance of each electrode. The system is capable of detecting impedance of 50 kOhms (at 1 kHz) or greater.

The impedance measurement software must be started using the Central Software Suite. The software will prompt the user to enable impedance mode on the headstage. This is controlled by the switch on top of the amplifier-side housing of the Patient Cable. The '+' symbol is used to indicate that impedance mode is enabled. An image of the switch on the housing is shown below.

Figure 4 - Impedance mode switch

Do not enable impedance mode during recording as the sine wave signal will appear in the data channels, preventing proper signal acquisition.

Attaching the Patient Cable

When attaching the Patient Cable, it is important to take care to avoid electrostatic discharge into the Patient Cable or the NeuroPort Electrode contacts. To avoid this, wear sterile, antistatic and ESD safe gloves during attachment and touch the stainless steel wheel of the Patient Cable filament film connector to the skin of the patient to equalize built up charge.

After the electrostatic preparations listed above, connect the Patient Cable by aligning the three guide pins with the three slots on the NeuroPort Electrode, as shown in the image below. Then, while holding the headstage housing with one hand, use the other to screw down the Patient Cable onto the contacts using just two fingers on the wheel of the Patient Cable connector.

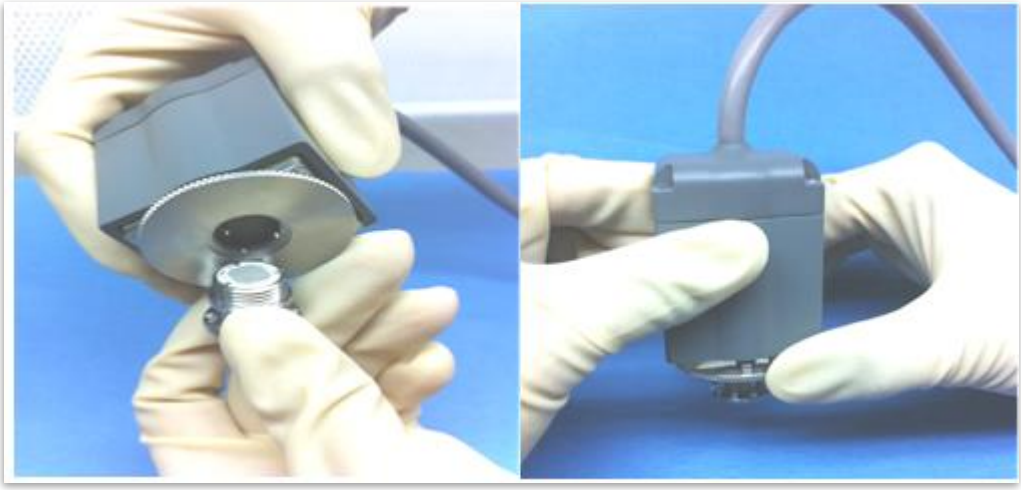


Figure 5 - Attaching the Patient Cable

After the cable is connected, there should be slack in the Patient Cable between the head and the amplifier, and the amplifier should be securely mounted. In the unlikely event of a physical pull/jerk/impact to the Patient Cable when it is connected to the head of the subject, the Patient Cable will break off at the connection point between the headstage housing and the top cap assembly, leaving the implanted pedestal and the filament film NeuroPort Connector still intact.

Cleaning, Maintenance, Storage, and Disposal

Cleaning

The Patient Cable is shipped EO sterilized, and it is labeled as single use only. That said, one may want to occasionally clean the Patient Cable during use.

The case of the Patient Cable may be cleaned with distilled water, isopropyl alcohol (70%), or 96% ethanol. The connectors of the Patient Cable may be cleaned using isopropyl alcohol (70%). If cleaning the connectors, ensure that the connector has dried completely before connecting the Patient Cable to the Front End Amplifier or the NeuroPort Electrode.

Maintenance

The Patient Cable does not require any regulator calibration.

Over time, the filament film inside of the connector can become damaged or dirtied. It is suggested that this film is replaced approximately every 12 months to ensure proper conductivity of the membrane. To initiate the replacement of this film, please contact Blackrock Microsystems Support using the contact information at the bottom of this document.

Storage

When not in the use, the Patient Cable must be stored at temperatures between 10˚ C and 40˚ C (50˚ F to 104˚ F) with 5% to 20% relative humidity (non-condensing).

Disposal

The Patient Cable may have incidental contact with bodily fluids and therefore should be disposed of as a biohazard.

Magnetic Resonance Safety

The Patient Cable has not been evaluated for safety and compatibility in the magnetic resonance environment. The Patient Cable has not been tested for heating, migration, or image artifact in the magnetic resonance environment.

Troubleshooting

Signal from the Cable is Noisy

Ensure that the Patient Cable has a secure connection between the ground of the amplifier and the patient. Patient ground is communicated through the housing of the NeuroPort Electrode pedestal connector and through the wheel of the Patient Cable. This can be done by ensuring that the pedestal is screwed into bone and that the connection between the Patient Cable and pedestal is tight. After ground is secured check the reference settings of the Patient Cable. Only one reference switch or jumper should be in the ‘On’ position. One may try different references

to see if they result in better signal. If none of the above configurations results in clean signal, contact Blackrock Support.

The Patient Cable is Not Detecting Impedances

Detecting impedances requires good reference, ground, and channel connections. Ensure that all three connections have good connection to the patient and that reference is set as RC or RA. Ensure that the impedance switch is in the correct position. Ensure that the software is in 'Patient Cable' mode for impedance detection.

Testing the Patient Cable

Sometimes, it is useful to test the Patient Cable in a more generic and complete way as a method of troubleshooting. To test the Patient Cable in saline, follow the instructions below.

Step 1 - Verify patient ground connection

- Connect Patient Cable to pedestal on the Digital Neural Signal Simulator (DNSS) and to Front End Amplifier.
- Use Ohm meter to measure resistance between the pedestal or the wheel of on the plug to the Front End Amplifier ground connector.
- This resistance should be around 50 Ohms if there is a good connection.
- An open circuit indicates a failure in the ground path from patient to amplifier. Could be:
    - Wires connecting inside the array assembly that link the pedestal to LGA board
    - Patient Cable wiring
- Recording could be improved by directly connecting the NeuroPort plug wheel to the amplifier ground to bypass the troubled ground connection. However, this will eliminate the ability to record impedances.

Step 2 – Test the internal impedance board

- Connect Patient Cable to Front End Amplifier.
- Open Spike Panel in Central and load default map file to display all 128 channels.
- Set the voltage scale for all channels to maximum (8191 uV).
- Turn Patient Cable into the impedance mode (Switch to + sign).
- Channels 125 and 126 should show a large sine wave signal.
- If they show noise, there is a problem with the internal impedance board of the Patient Cable.
- If they show large sine wave, proceed to Step 3

Step 3 - Verify reference connections

- Connect the Patient Cable to the Front End Amplifier and to Array or the DNSS.
- If the array is implanted in a subject or a DNSS, proceed to next step. If testing with saline, place the array and reference wires in the saline, and make a connection from

the pedestal body to the saline using an alligator clip and an external electrode, such as a paper clip.

- Set Patient Cable to impedance mode and open Spike Panel to show all 128 channels.
- Set voltage scale for all channels to maximum (8191 uV).
- Verify that channels 127 and 128 show a large sine wave. If step 2 passed, and either channel 127 or 128 does not show a large sine wave, then the corresponding references in the above table require attention.
- If one reference is good, set the jumper on the Patient Cable to that reference.

Step 4 - Verify that the reference jumper

- Identify a good reference connection, and set the jumper to that reference position
- As in previous steps, connect Patient Cable to the amplifier and an array, set Patient Cable to the impedance mode, and show all 128 channels in Spike Panel
- Set voltage scale for all channels to a maximum (8191 uV)
- Channel 123 should show a large sine wave
- If channel 123 does not show a large sine wave, but the corresponding reference channel (127 or 128) does, then there is a problem with:
    - The reference jumper
    - Internal wiring of the Patient Cable

Channel ID	Description
123	Reference selected by the Jumper position. This is the reference signal used for recordings.
124	Not Connected (NC).
125	1kHz sine wave generated by impedance board. This is independent of a connection to the animal, so this signal should appear in Central even if the Patient Cable is not connected to an array/subject.
126	Same as 125.
127	Signal recorded on Reference C.
128	Signal recorded on Reference A.

Table 2 - Signal information by channel

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

Issues or Questions

www.blackrockmicro.com/technical-support

support@blackrockmicro.com

U.S.: +1 (801) 582-5533

Complaints

For any serious incident or adverse event, please report the complaint to the manufacturer and the competent authority of your member state.

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.

CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.