

Manufacturer
630 Komas Drive | Suite 200
Salt Lake City | UT 84108 | USA
P +1 (801) 582-5533 | F +1 (801) 582-1509
www.blackrockmicro.com



Blackrock Research Arrays

Instructions for Use

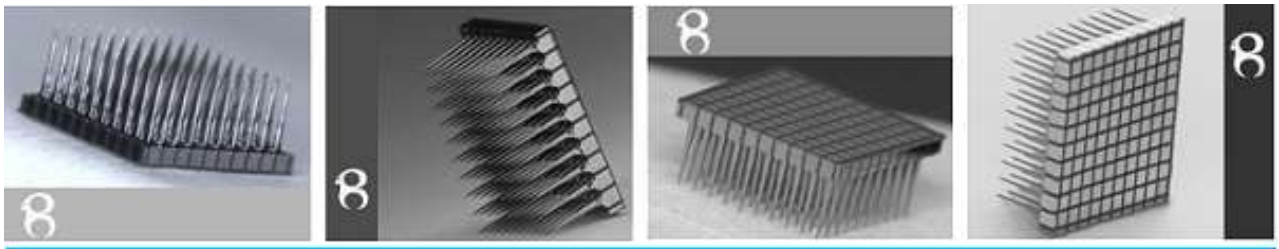


Table of Contents

What This Manual Covers	3
Warnings and Precautions	3
Symbols	4
Specifications	5
Overview of the Device	6
Unpacking the Device	8
<i>Unpacking of the Array Assembly</i>	8
How to Interpret The Datasheet Sent with Array Assembly ..	8
Sterilization.....	16
Cleaning and Maintenance	17
<i>Disposal</i>	18
Magnetic Resonance	18
Troubleshooting	18
Return Merchandise Authorization.....	19
Warranty.....	20
Support.....	20
<i>Complaints</i>	20

What This Manual Covers

The Blackrock Research Assemblies are all powered by the Utah Array. Blackrock Research Assemblies are silicon-based, multi-electrode arrays that can be implanted in both in-vivo and in-vitro research applications. The main purpose of the Blackrock Research Assemblies is to record/stimulate neural bio-potential activity in a specified subject area of research. Unlike depth electrodes, which penetrate deep into the brain, Blackrock Research Assemblies penetrate only the outer surface of the brain and are capable of detecting single unit and multi-unit neuronal activities, as well as local field potentials. Some applications of the Blackrock Research Assemblies include use in the peripheral nervous system, cardiovascular, digestive, respiratory, immune/lymphatic, urinary, and muscular systems.

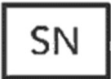
- Examples of Blackrock Research Assemblies types are shown in Section “How to Interpret the Datasheet Sent with Your Array Assembly” below.

This manual is not meant as a surgical guide. To learn more about surgical techniques contact sales@blackrockmicro.com to learn about upcoming workshops.

Warnings and Precautions

- **DO NOT** let any instruments touch the electrodes as they can break easily. The Blackrock Research Assemblies are delicate structures and can be damaged if not handled gently.
- **DO NOT** perform Scanning Electron Microscope (SEM) imaging on samples prior to implantation as this will alter and possibly degrade the array assembly causing the device to malfunction.
- **DO NOT** use any sterilization techniques that are not recommended by Blackrock Microsystems. Some sterilization methods can damage or degrade the array performance. Please refer to Section 5 for sterilization recommendations.
- **DO NOT** handle the electrode array directly with fingers.
- **DO NOT** ultrasonically clean the electrode array. This will damage the array.
- Map files sent with arrays assume analog configurations. If you are using custom adapters or our digital headstages, please contact support@blackrockmicro.com to confirm compatibility.

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.
5.1.6		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.
5.4.2		Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single subject 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.
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.

Specifications

The different types of assemblies powered by Blackrock Research Assemblies are:

Name	Dimensions	Testing Type
CerePort (128-ch)	16.5mm (height) 19mm (diameter base) 12mm (diameter neck)	Chronic
Cereport (256-ch)	16.5 mm (height) 19mm (diameter base) 10.7mm (diameter neck)	Chronic
ICS-96	18mm (height) 7mm (base length) 37mm (base width)	Acute
Omnetics	9mm (height) 7mm (base length) 13mm (base width)	Chronic

Overview of the Device

There are 3 device types:

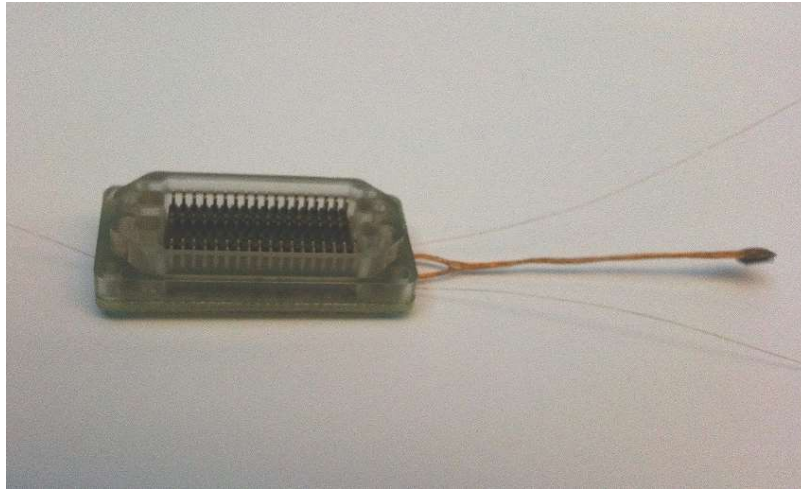
1. CerePort Array assembly: CerePort array assembly has four sub-components: the electrode array, the wire bundle, two reference wires, and the pedestal connector.



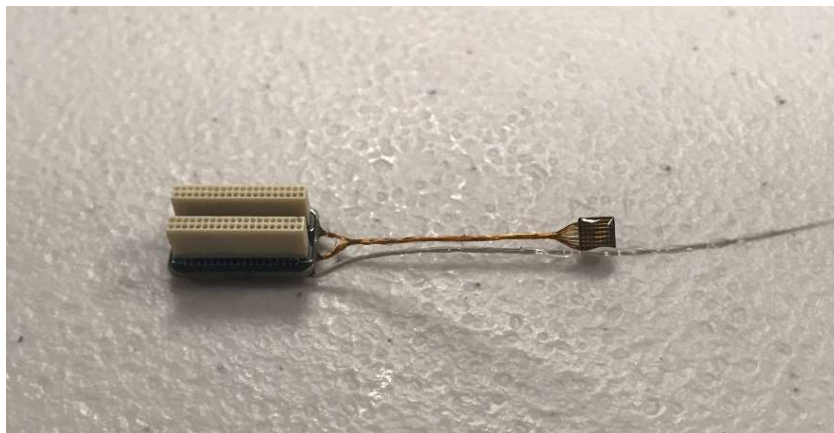
Figure 1–Top: CerePort Array with a single electrode array.
Bottom: CerePort 256-ch array with multiple electrode arrays (Multi-port).

Note that the device does not include the bone screws necessary for affixing the pedestal connector to the skull. The suggested screws are 6mm length, 2 mm diameter titanium Synthes self-tapping cranial cortex screws. Six to eight total screws are suggested. The device also ships with the Pedestal Cap with Viton O-Ring (Part Number 4301), an accessory used to protect the surface of the pedestal connector and to help prevent electrostatic discharge into the electrodes through that connector.

2. ICS-96 Array assembly: ICS-96 array assembly has five sub-components: the electrode array, the wire bundle, two reference wires, one ground wire and the connector.



3. Omnetics Array assembly: Omnetics array assembly has five sub-components: the electrode array, the wire bundle, the reference wires, one ground wire and the Omnetics connector.



Unpacking the Device

Unpacking of the Array Assembly

The array assemblies are shipped in a plastic jewel case.

To unpack the array assembly, remove the screws securing the connector to the box. See **Figure 2** for mounting screws location. Carefully spread the foam to release the array and the connecting wires, and remove the unit from the box. Ensure the array and wires (wire bundle, Reference and Ground) come free and do not catch on the packing foam (**Figure 3**).

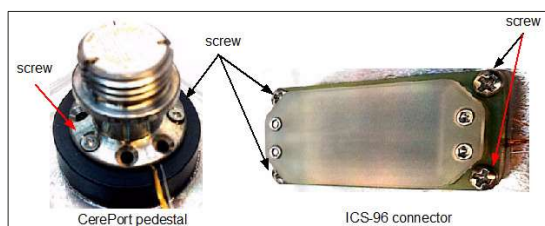


Figure 2–Removing Screws

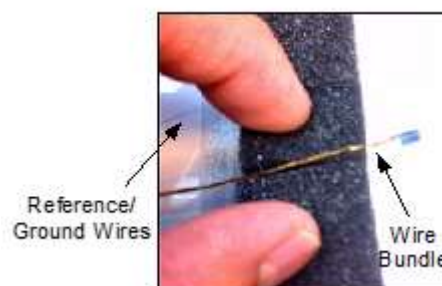


Figure 3–Removing Array and Wire Bundle

How to Interpret The Datasheet Sent with Array Assembly

The datasheets provided with your array indicate both electrode impedance values as well as the association between electrode numbers and pin numbers on the electrode connector. Further, electrodes come with mapfiles that can be loaded into our Central software to automatically label channels with their associated electrode numbers.

The array mapfile creates an association between electrode number and the connector pin/pad. Connector pins are associated into banks because most devices in the field process data in 32 channel banks/increments. For the example below, notice how electrode 33 is associated with connector pin B-01 (Pin 33) of the electrode connector. Pinouts of Blackrock's mating connectors are shown below to demonstrate which channel would be receiving that electrode's signal.

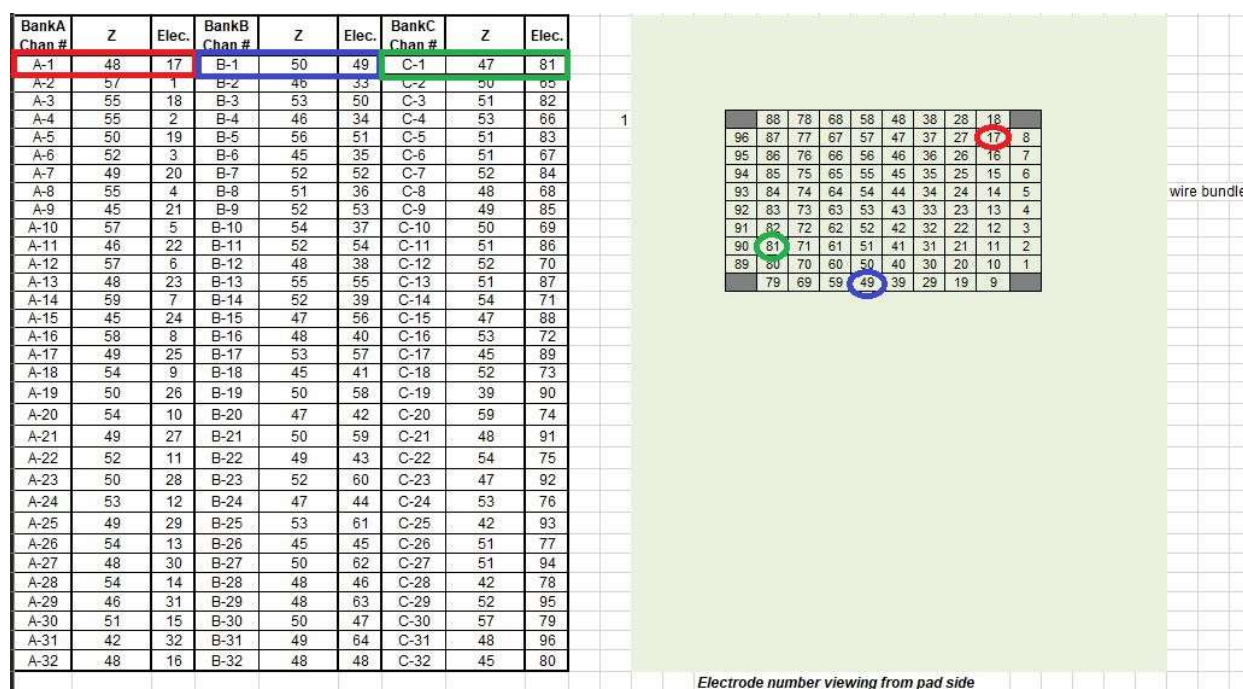


Figure 4–Interpreting electrode/channel mapping from the included datasheet

The following are examples of Blackrock Research Assemblies types and Impedance tables.

Please contact our support team at support@blackrockmicro.com if you have custom connectors, adapters, custom mappings, or digital headstages.

Note: Impedance readings are taken at room temperature and the impedance values are in kΩ. The temperature of the conductive testing medium (such as saline) will change the impedance values measured. The recommended testing solution is saline pH 7.0–7.2 warmed to 37°C. Only use equipment from Blackrock Microsystems for measuring the impedances. Any devices that outputs current higher than 10nA may damage the electrodes.

CerePort Array Assemblies

The CerePort Pedestal comes in two forms: a standard form with up to 128 neural channel contacts (with one ground channel and two reference channels), and a higher channel count form with up to 256 neural channels (including one ground channel and four reference channels). Both pedestals have the same form at the portion that attaches to the skull or a pedestal base. Both pedestals are shown side by side below:

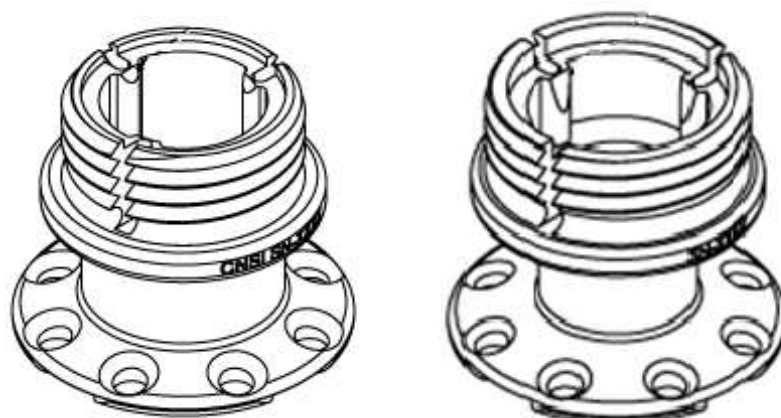


Figure 5-128 Channel Pedestal (Left); 256 Channel Pedestal (Right)

CerePort Array Assembly

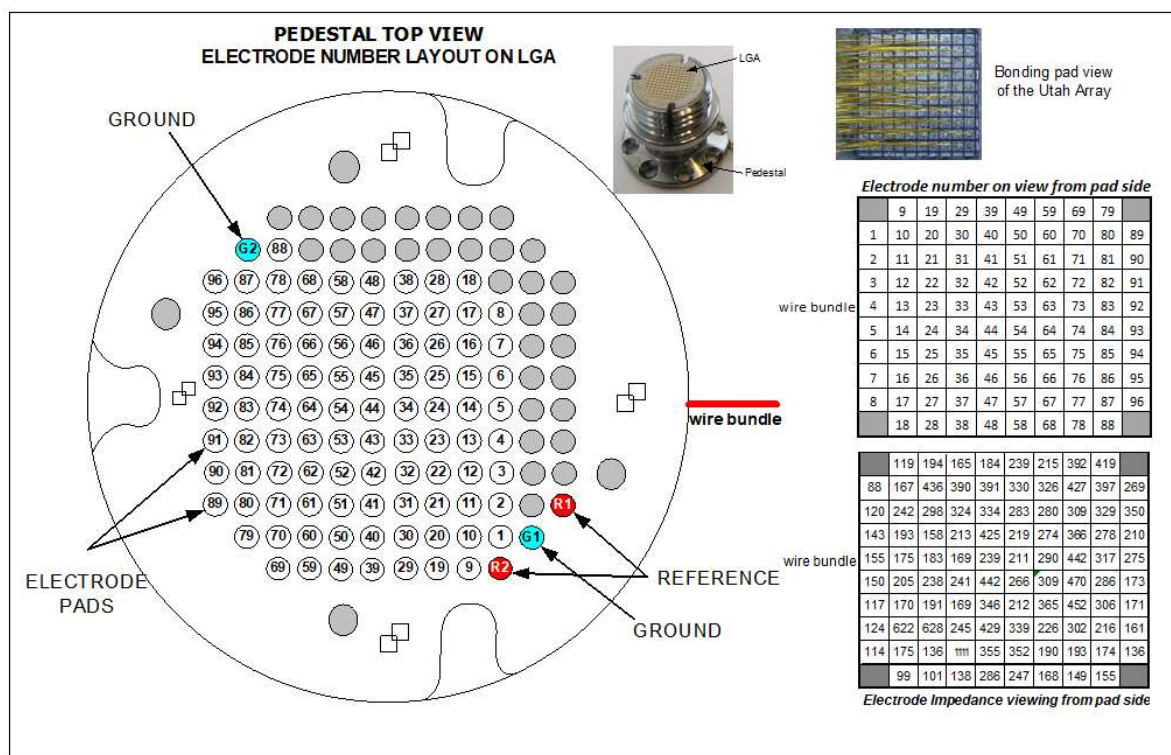


Figure 6-128 Channel Pedestal Layout

Please note that arrays are often highly customized and the exact channel mappings may vary from device to device. Please refer to the mapping datasheet included with your array to determine channel mappings.

CerePort 256 Array Assembly

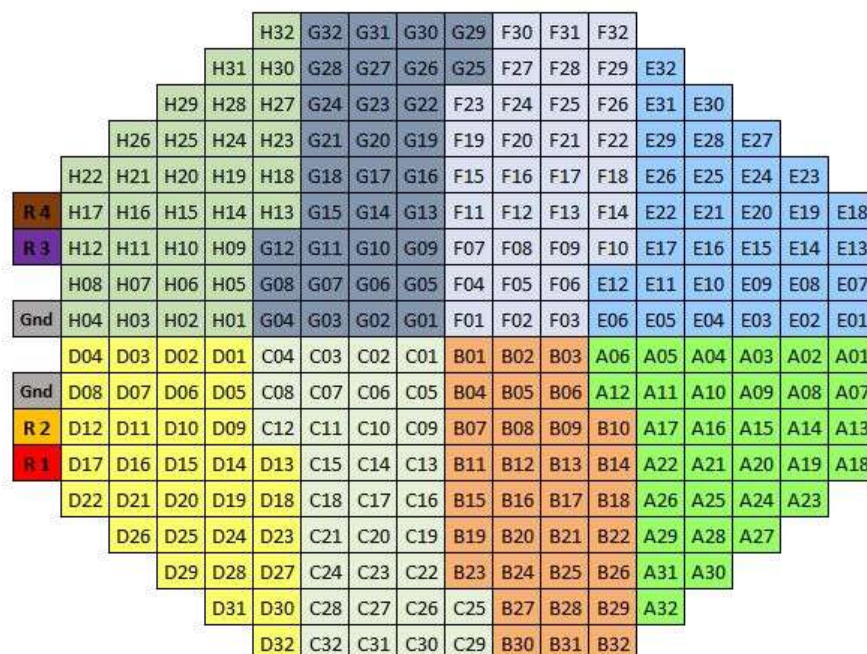


Figure 7-256 Channel Pedestal Layout

Please note that arrays are often highly customized and the exact channel mappings vary from device to device. Please refer to the mapping datasheet included with your array to determine channel mappings.

ICS-96 Array Assembly

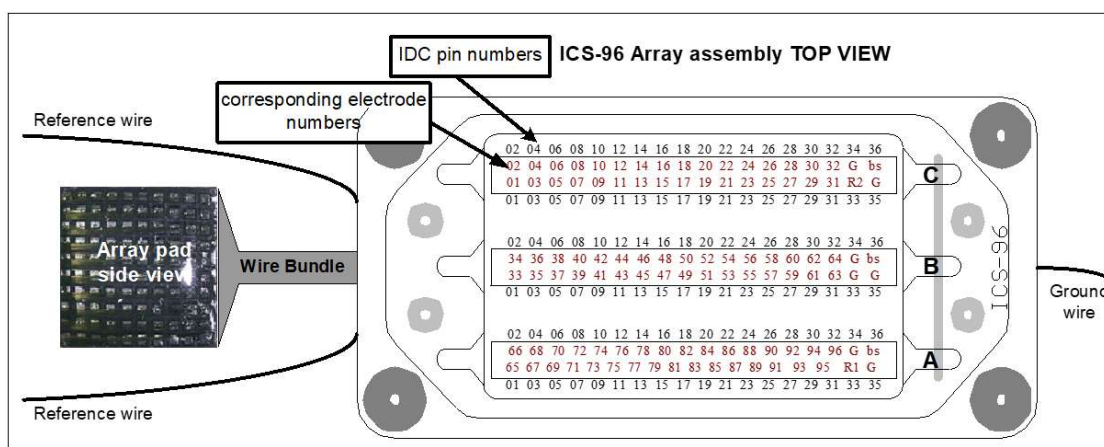


Figure 8-ICS-96 pin-out

Note: By default (i.e., bank A on ICS connected to bank A of the amplifier, bank B of ICS connected to amplifier's bank B, et cetera), pins 1-32 on Bank A will be channels 1-32 in Central, pins 1-32 on Bank B will be channels 33-64 in Central, and pins 1-32 on bank C will be channels 65-96 in Central.

Omnetics Array Assembly

The Omnetics array assembly comes in 6 different configurations: 1x16, 2x16, 3x16, 1x32, 2x32, and 3x32. Below are examples of these assemblies.

Omnetics Array Assembly 1x16

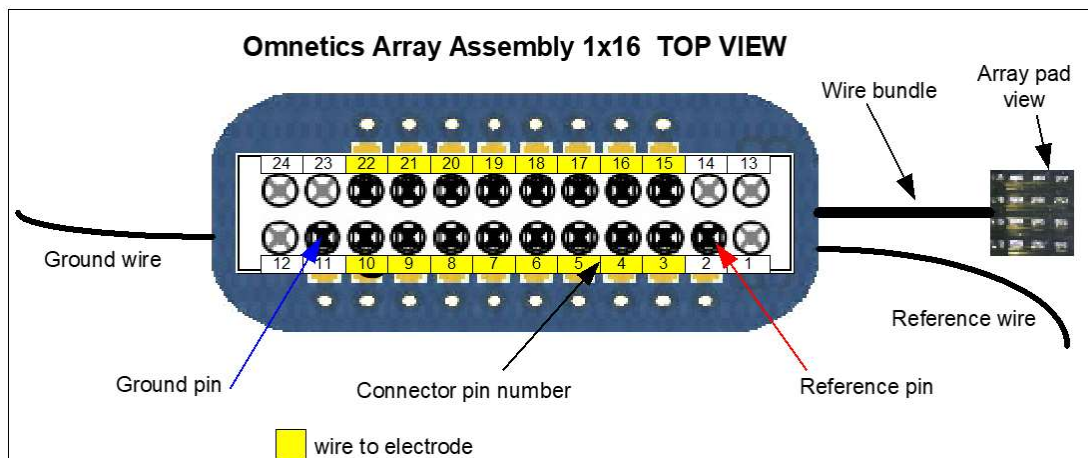


Figure 9–Omnetics 1x16 assembly pin-out

Connector pin number column		Electrode impedance column		Electrode number column
			Wire bundle direction	
Conn pin	elec	4290 Z	Calculated	Conn pin
1	NC	NC	NC	13
2	Ref	na	NC	14
3	1	110	111	15
4	2	120	121	16
5	3	130	132	17
6	4	140	142	18
7	5	150	152	19
8	6	160	163	20
9	7	170	173	21
10	8	180	183	22
11	Gnd	na	NC	23
12	NC	NC	NC	24

Board Viewing from pad side

18	12	8	4
15	11	7	3
14	10	6	2
13	9	5	1

Electrode number viewing from pad side

267	225	183	142
266	215	173	132
246	204	163	121
235	194	152	111

Electrode Impedance

Omnetics Array Assembly 1x32

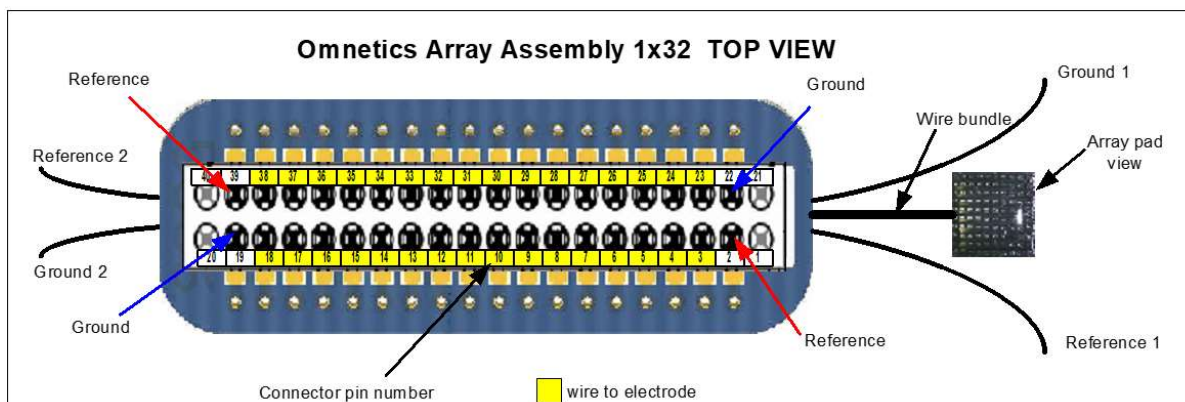


Figure 10–Omnetics 1x32 assembly pin-out

Wire bundle direction

Conn pin	elec	4290 Z	Calculated	Calculated	4290 Z	elec	Conn pin
1	NC	NC	NC	NC	NC	NC	21
2	Ref1	na	na	na	na	Gnd1	22
3	1	110	111	277	270	17	23
4	2	120	121	288	280	18	24
5	3	130	132	299	290	19	25
6	4	140	142	309	300	20	26
7	5	150	152	320	310	21	27
8	6	160	163	331	320	22	28
9	7	170	173	341	330	23	29
10	8	180	183	352	340	24	30
11	9	190	194	363	350	25	31
12	10	200	204	373	360	26	32
13	11	210	215	384	370	27	33
14	12	220	225	395	380	28	34
15	13	230	235	406	390	29	35
16	14	240	246	417	400	30	36
17	15	250	256	428	410	31	37
18	16	260	267	438	420	32	38
19	Gnd2	na	na	na	na	Ref2	39
20	NC	NC	NC	NC	NC	NC	40

Board Viewing from pad side

28	22	16	10
32	27	21	15
31	26	20	14
30	25	19	13
29	24	18	12
23	17	11	5

Electrode number viewing from pad side

395	331	267	204
438	384	320	256
428	373	309	246
417	363	299	235
406	352	288	225
341	277	215	152

Electrode Impedance Values

Reference and ground wires on Omnetics Array Assembly Board (Viewing From Pad Side)

Figures below show reference and ground wires layout on Omnetics assembly boards (Figures 11 and 12).

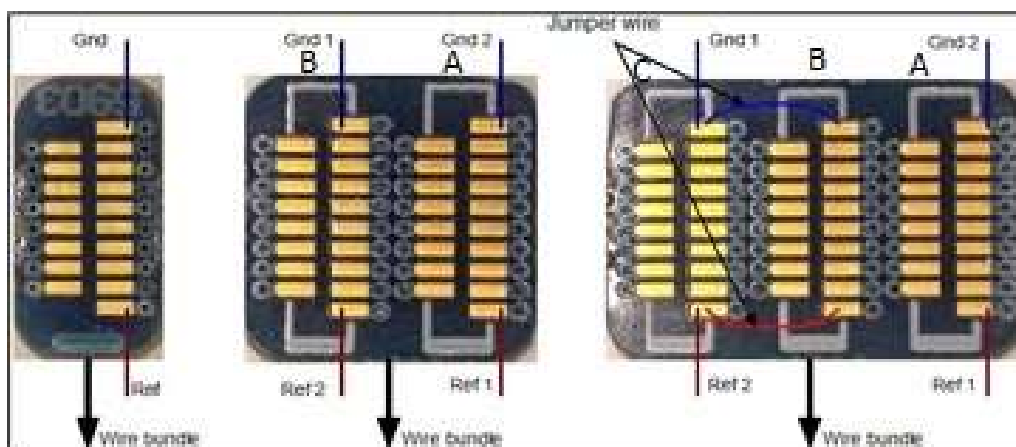


Figure 11–Reference and ground wires layout on 16 channels Omnetics connector board

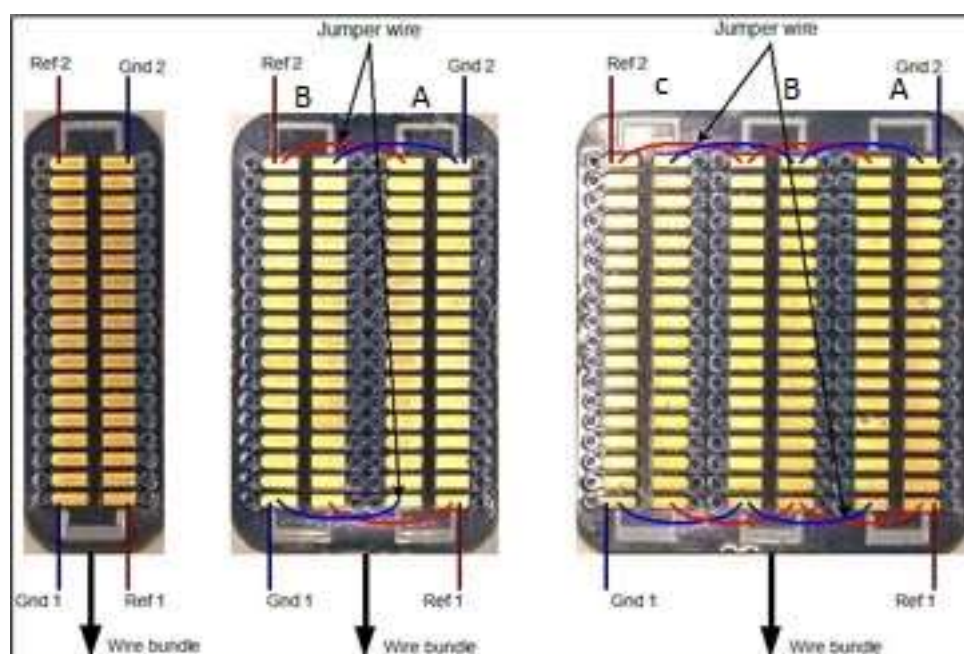


Figure 12–Reference and ground wires layout on 32 channels Omnetics connector board

Omnetics Board Orientation

When connecting the Omnetics connector assembly, please check for the orientation of the assembly connector (**Figure 13**).

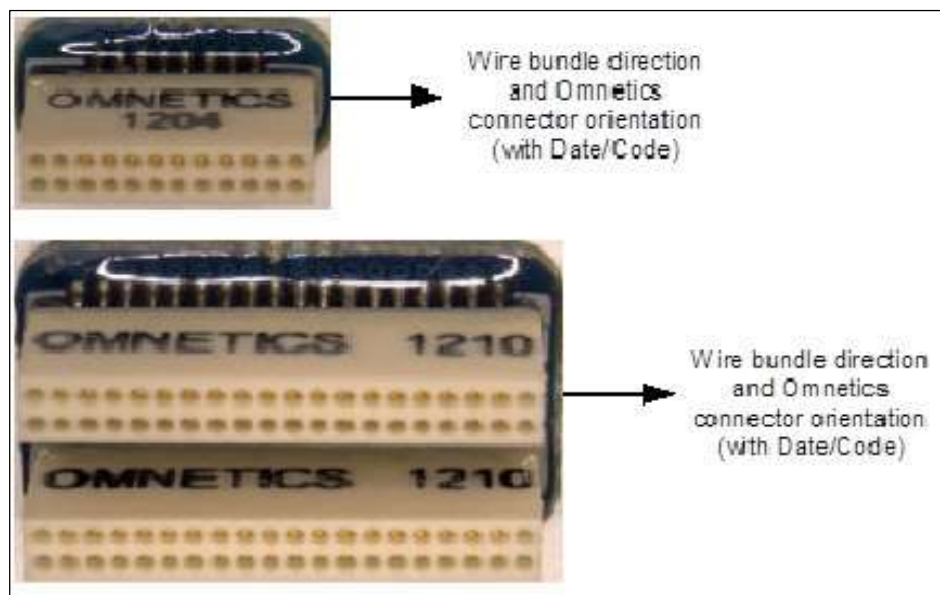


Figure 13–Omnetics Array Assembly

Sterilization

Blackrock recommends ETO sterilization according to the protocol below (Table 1). **Do not use other methods of sterilization, as these may damage the integrity of the array.** Contact Blackrock Support (support@blackrockmicro.com) with additional questions.

Table 1: ETO Processing Parameters

		Set Point	Minimum	Maximum
Preconditioning	Temperature:	110°F	105°F	120°F
	Relative Humidity:	65%	45%	75%
	Time:	24Hrs 0Min	24Hrs 0Min	72Hrs 0Min
Process Temperature		125°F	115°F	135°F
Vacuum A Approx. Rate: 0.7"/min				
	Evacuate To:	5.8 inHgA	5.3 inHgA	6.3 inHgA
Nitrogen Dilution Approx. Rate: 0.7"/min	Humidity Pressure Rise:	inHgA	inHgA	inHgA
	N2 Inject To:	25.3 inHgA	24.8 inHgA	25.8inHgA
	Evacuate To:	5.8 inHgA	5.3 inHgA	6.3 inHgA
Humidification Approx. Rate: 0.7"/min				
	Pressure Rise:	1.4 inHgA	0.9 inHgA	1.9 inHgA
Humidity Dwell	Dwell Time:	30 Min	29 Min	35 Min
	Maintain Pressure At:	7.2 inHgA	6.7 inHgA	7.7 inHgA
Gas A Approx. Rate: 0.7"/min				
	Gas Pressure-Inject To:	17.9 inHgA	17.4 inHgA	18.4 inHgA
Gas Dwell Maintain Pressure: Yes Sterilant / Inert: Sterilant	Temperature:	125°F	120°F	130°F
	Time:	4hrs 0min	3hrs 59min	4hrs 40min
	At:	17.9 inHgA	17.4 inHgA	18.4 inHgA
After Vacuum Approx. Rate: 0.7"/min	Evacuate To:	7.8 inHgA	7.3 inHgA	9.3 inHgA
	Vacuum Hold Time:	1Hrs 00Min	0Hrs 59Min	1Hrs 4Min
Gas Wash A Inject Type: Inert Approx. Rate: 0.7"/min	Inject To:	24.8 inHgA	24.3 inHgA	25.3inHgA
	Evacuate To:	5.8 inHgA	5.3 inHgA	7.3 inHgA
	Vacuum Hold Time:	30Min	29 Min	34 Min
	Number of Cycles	0 (1 total)		
Gas Wash B Inject Type: Inert Approx. Rate: 0.7"/min	Inject To:	24.8 inHgA	24.3 inHgA	25.3inHgA
	Evacuate To:	5.8 inHgA	5.3 inHgA	6.3 inHgA
	Number of Cycles	2 (3 total)		
Release Approx. Rate: 0.7" / Min				
	Release To:	24.8 inHgA	inHgA	inHgA
Heated Aeration	Temperature:	110°F	100°F	135°F
	Time:	36 Hrs	36 Hrs	N/A

Cleaning and Maintenance

1. Remove the array from the subject and immediately place it in clean distilled water until it will be cleaned.
2. Secure the connector on a lab stand. Immerse the electrode array and wire bundle in warm (30-35°C) distilled water or enzymatic cleaner for 15 to 60 minutes. **Figure 14** shows one way to suspend the electrode array in a beaker of cleaning solution with a heating and stirring plate for SLOW stirring.

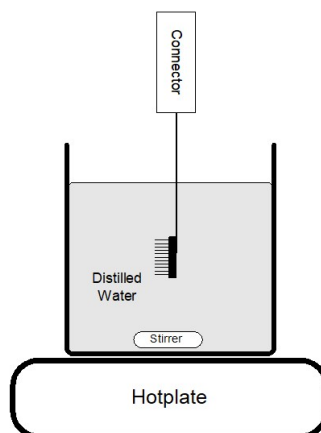


Figure 14–Cleaning array assembly in distilled water

3. Under a microscope, check for debris stuck in the array. If necessary, remove the debris with a small soft artist's brush or use a syringe to gently squirt cleaning solution into the array.
4. Rinse with distilled water. When using detergent cleaning solution (such as Enzyme/distilled water mixture), soak the array in warm (30-35°C) distilled water for an additional 30 minutes and rinse again.
5. Let the array air dry at room temperature. You may wick away excess rinse water with soft KimWipe or filter paper by touched gently to the side of the electrode array (**Figure 15**).

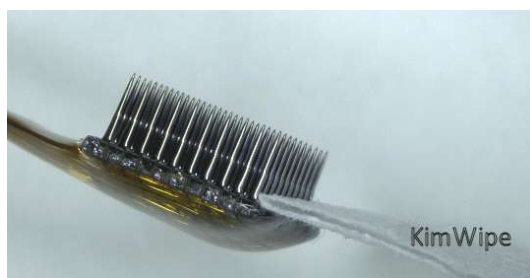


Figure 15–Wick away excess water with KimWipe

6. If possible, test the assembly impedance in solution (such as saline pH 7.0–7.2) at 37°C. Impedance values are typically in the range of:
 - a. 20 K Ω – 800 K Ω for Pt tip array
 - b. 1 K Ω – 80 K Ω for SIROF tip array

Disposal

The device is an implantable electrode for cerebral cortex. Follow institutional procedures for disposing potentially infectious or biohazardous implantable devices when disposing the device.

Magnetic Resonance

The Electrode Array has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The Electrode Array has not been tested for heating, migration, nor image artifact in the MR environment.

Troubleshooting

Problem	Symptom	Failure	Potential fix
Unsure of electrode:channel mapping of my array assembly	NA	Unexpected stimulation response, or unexpected channels have neural recordings	Make sure you have loaded the mapfile delivered with your array assembly into your stimulation and/or recording software Confirm correct mapfile is being used by emailing support@blackrockmicro.com with your array assembly serial number
Poor signal quality or signal to noise ratio	No spikes appear High-passed noise is greater than $\pm 30 \mu V$ Signal has 50/60-Hz noise	Bad hardware connection Bad referencing or grounding Inadequate recovery time after surgery Failing channels on assembly	Confirm your system components are fully connected by connecting your headstage to a signal simulator instead of an implanted array. If signal quality is still poor, check for loose connections at each point in the signal stream Use a pure noise channel as a software reference to try to remove 50/60-Hz noise common to all channels Change which reference channel you are using for recordings Ground nearby equipment to the system ground Add another ground connection from the subject to the data acquisition system

Problem	Symptom	Failure	Potential fix
			Recordings fluctuate 2-3 weeks after implantation. See if recordings improve after this window Measure impedances with your headstage. See your headstage IFU for instructions on how to take this measurement with your specific headstage. If channels show impedances higher or lower than you expect, those channels may be failing. These channels cannot be fixed after implant.

To learn more about noise troubleshooting techniques, visit support.blackrockmicro.com or contact support@blackrockmicro.com.

Return Merchandise Authorization

In the unlikely event that your device needs to be returned to Blackrock 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

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

CAUTION

Device for investigational use in laboratory animals or other tests that do not involve human subjects.