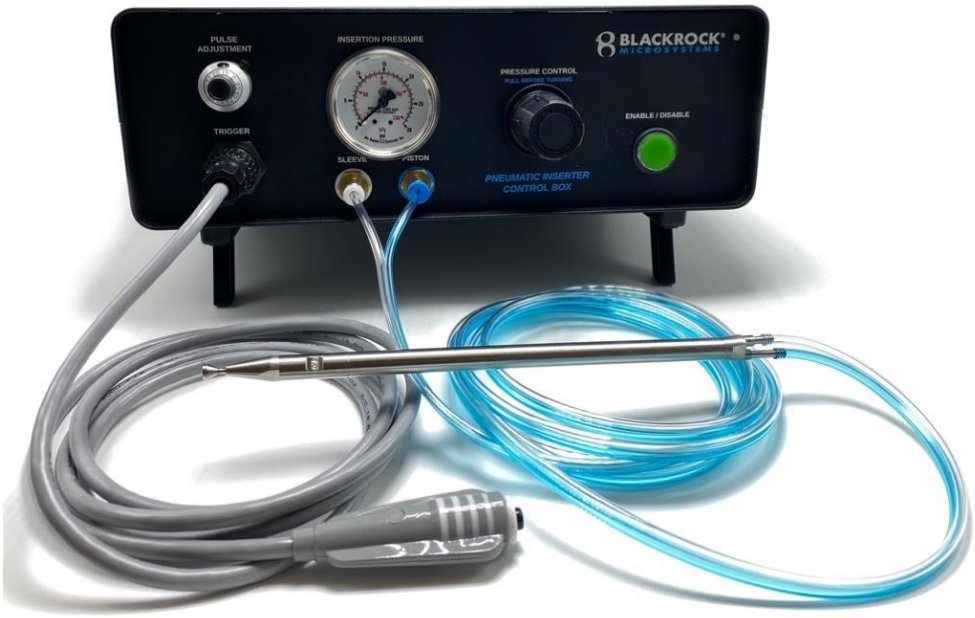
Manufacturer
630 Komas Drive | Suite 200
Salt Lake City | UT 84108 | USA
P +1 (801) 582-5533 | F +1 (801) 582-1509
www.blackrockmicro.com

NeuroPort Electrode Inserter System

User's Manual



Revision 1.00 / LB-0880 – Electrode Inserter IFU – 2021/11

Table of Contents

What This Manual Covers

This manual is intended as an informational tool for use of the NeuroPort Electrode Inserter System. This pneumatically-actuated impulse inserter is designed to deliver a repeatable momentum and travel to the electrode array to allow insertion into neural tissue.

This manual is not intended to teach general surgical skills, techniques, or principles. It is expected that those making use of this manual are trained in the surgical techniques they will be performing. It is recommended that they have also completed the Blackrock Utah Array surgical training program. While this manual provides a detailed description of the implantation device, it is not intended to be an instructional tool for implantation.

This manual covers the use of the inserter system and can be used to identify pieces of parts of the device and their respective function. This manual does not cover surgical procedure.

PN	Description
10730	NeuroPort Electrode Inserter Control System 110V
10731	NeuroPort Electrode Inserter Control System 220V
10623	NeuroPort Electrode Pneumatic Inserter Control Box
4468	Sterile Inserter Wand and Trigger 1.0 mm
4469	Sterile Inserter Wand and Trigger 1.5 mm
4273	Inserter Wand Holder
4484	Head Holder Adapter

Warnings and Precautions

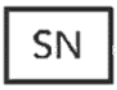
Warnings

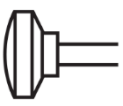
- If the electrode has been inserted incorrectly (skewed or incomplete insertion), do not attempt to reuse or reinsert the electrode. Explant the previous, incorrectly inserted electrode and use a new electrode.
- Ensure that the appropriate spacer is used for the given electrode. Failure to do so could result in under insertion of the array, leading to extrusion of the device from the cortex, over insertion causing cause central nervous system (CNS) injury to the subject or physical damage to the electrodes.
- Cleaning and Sterilization instructions provided have been validated by Blackrock Microsystems as capable of preparing the identified devices for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials, and personnel in the processing facility, achieves the desired result. Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. Blackrock Microsystems is not responsible for the consequences of reprocessing devices by any conditions other than those specified, and cannot attest to, or be held responsible for the functionality, cleanliness, or sterility of any devices so processed.
- Ensure that the wand is rigidly held during insertion or the impact during insertion. Failure to do so can cause skewed electrode insertion.
- There will be movement of the piston when the device is first turned on. To ensure that this piston movement does not unintentionally affect electrode implantation, ensure that the wand tip is at least 3mm away from the array when turning on the inserter control box.
- Ensure at least 20 seconds between each enable/fire cycle of the device. Otherwise, the piston may have a longer pulse time than intended due to insufficient vacuum pressure. Longer pulse values may result in a double fire of the inserter wand
- Only connect NeuroPort Electrode Inserter System components to properly tested supply mains with protective earth and dedicated AC outlets using only the Blackrock Microsystems provided power cable to reduce the risk of electrical shock. Do not use an adapter for ungrounded wall outlets.
- Do not connect the NeuroPort Electrode Inserter System to an outlet controlled by a wall switch, multiple socket-outlet or extension cord to avoid fires or other electrical hazards.
- Do not re-sterilize the Inserter Wand and Trigger if it has been provided sterile by ethylene oxide. The interaction between ethylene oxide and other sterilization methods has not been validated.

Precautions

- Failure to depressurize the inserter between uses can cause early failure of the device.
- Completion of a Blackrock Microsystems user training program is suggested prior to the use of this system.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- The Inserter Control Box contains parts that can wear out after use or degrade over time. It is recommended to have the Inserter Control Box serviced by the manufacturer, Blackrock Microsystems, once a year.
- If the inserter wand is disassembled, ensure proper reassembly of the inserter wand. Failure to do so may result in no insertion, incomplete insertion or damage to the electrode.
- Ensure there are no kinks, cracks, or cuts in the inserter wand tubing, loss of function may result.
- Do not shorten the inserter wand tubing. Loss of function may result.

Symbols

ISO 15223-1: 2021 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: 2021 Medical Devices – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied			
Reference	**Symbol**	**Title**	**Meaning**
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.
5.6.3		**Non-Pyrogenic**	Indicates that the product is non-pyrogenic.
ISO 7000:2019/IEC 60417:2002 DB Graphical Symbols for Use on Equipment			
Reference	**Symbol**	**Title**	**Meaning**
0137		**Compressor, Vacuum Pump**	Identifies the control or the indicator for a vacuum pump or compressor (for example, status, or to identify the compressor or vacuum pump).
0160		**Calibration**	Identifies the control for the release or adjustment of a calibration procedure. To identify the calibration reference marks on scales. To indicate that the equipment is in calibration mode.
0183		**Pressure Gage**	Indicates the control of a preselected pressure (for example, on a luminous signal indicating a disturbance).
0231		**Pneumatic Energy**	Indicates any source of pneumatic energy derived from the physical properties of permanent gases (for example, on controls or devices for starting or stopping the production or use of pneumatic energy).
0548		**Pressure Control**	Identifies a control for regulation pressure (for example, operating controls for pressure regulation).
0783		**Knob, Plunger**	Identifies a type of control either a knob or type of plunger.

ISO 7000:2019/IEC 60417:2002 DB Graphical Symbols for Use on Equipment			
Reference	**Symbol**	**Title**	**Meaning**
1360		**Vacuum**	Identifies the control for applying a vacuum.
5333		**Type BF Applied Part**	Identifies 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

The NeuroPort Electrode Inserter System is comprised of the Inserter Control Box, a pneumatic piston (called wand) and tubing, a push-button trigger cable, and the power supply. These specifications provide a section to easily see useful details about specifics of the inserter system.

Model Name	Blackrock Electrode Inserter System
Power Requirements	110 VAC 60 Hz 0.8A / 240 VAC 50 Hz 0.4A
Serviceable Fuses	5 x 20 mm, 250V, 1.0A, Normal Blow
Compliance Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26
Type of Protection Against Electrical Shock	Class I
Degree of Protection	Type BF Applied Part
Mode of Operation	Continuous
Ingress Protection	Ordinary Equipment, not fluid resistant, IPX0
Operating Environment	10˚C to 35˚C, 5 to 80% R.H. (non-condensing)
Storage Environment	-20˚C to 50˚C, 5 to 80% R.H. (non-condensing)
Inserter Wand Tube Length	8 Feet (2.4 m)
Inserter Trigger Cable Length	3 Feet (.9 m)
Max Pressure	30 psi (206.8 kPa)
Implantable Electrode Length	1.0 mm or 1.5 mm

Overview of the Hardware

The NeuroPort Electrode Inserter System is comprised of the Inserter Control Box, a pneumatic piston (called wand) and tubing, a push-button trigger cable and the power supply.

Inserter Control Box

The Inserter Control Box contains a pneumatic compressor, vacuum pump, and solenoids that control the delivery of air to the wand for pneumatic insertion. The box has controls for adjusting air pressure, duration of applied pressure, and switches for both power and enabling of the device in preparation for triggering a pneumatic impulse.

Figure 1: Inserter Control Box. Front panel components from left to right: pulse adjustment knob and trigger connector; pressure gauge and color-coded wand tube connectors; pressure control knob; enable/disable button

Inserter Wand and Trigger

The Inserter Wand is a pneumatically actuated piston for inserting the NeuroPort Electrode. The Inserter Wand has a spacer piece that determines whether it is used to insert electrodes with lengths of 1.0 mm or 1.5 mm.

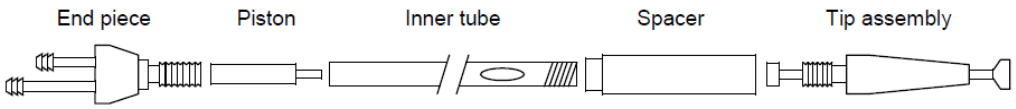
The Inserter Wand is connected to a dual lumen inserter tube labeled sleeve and piston that communicate the compressed air and vacuum from the Inserter Control Box.

A combination of compressed air and vacuum is used to control the movement of a piston mass in the shaft of the wand. The vacuum holds the mass at the top during standby. When the implantation is triggered, a pressure pulse is delivered to the piston line to propel the piston down to the inserter tip. When the piston mass strikes the tip, it quickly transfers its momentum to the tip, which pushes the array into the neural tissue in less than 1 ms.

The insertion depth is mechanically limited by the spacer positioned between the tip assembly and barrel. After the insertion, a vacuum is applied to return the piston mass to the top of the inserter wand, and the tip is retracted by a weak spring.

The outer sleeve is under vacuum immediately before and during insertion to prevent the wand from expelling air pressure pulses out onto the surgical field.

The Trigger is a push button trigger that connects to the Inserter Control Box. When the inserter is enabled, pressing this button will cause the insertion sequence to begin.



Exploded diagram of the wand (outer tube or sleeve omitted).

Figure 2: Wand and tubing (above) with schematic view of wand (below)

Figure 3: Trigger Assembly

Wand Holder and Head Holder Adapter

The Inserter Wand Holder is an assembly that attaches to a rigid fixation device typically used in neurosurgical procedures. Depending on the equipment used, an adapter may be used to ensure the wand holder can be adequately attached to the fixation device. The Inserter Wand Holder serves two key functions: precision control of the wand and prevention of recoil during the insertion process. This device is shipped non-sterile and is intended to be sterilized before use.

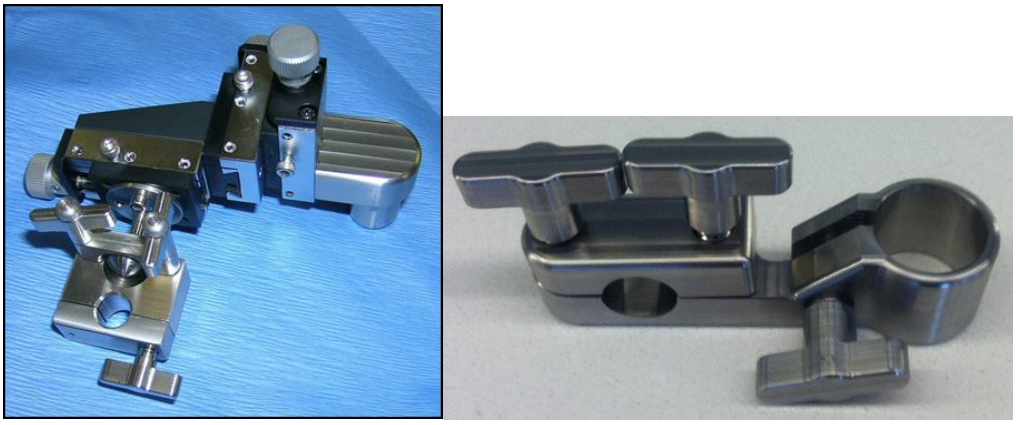


Figure 4: Wand and head holder adapter

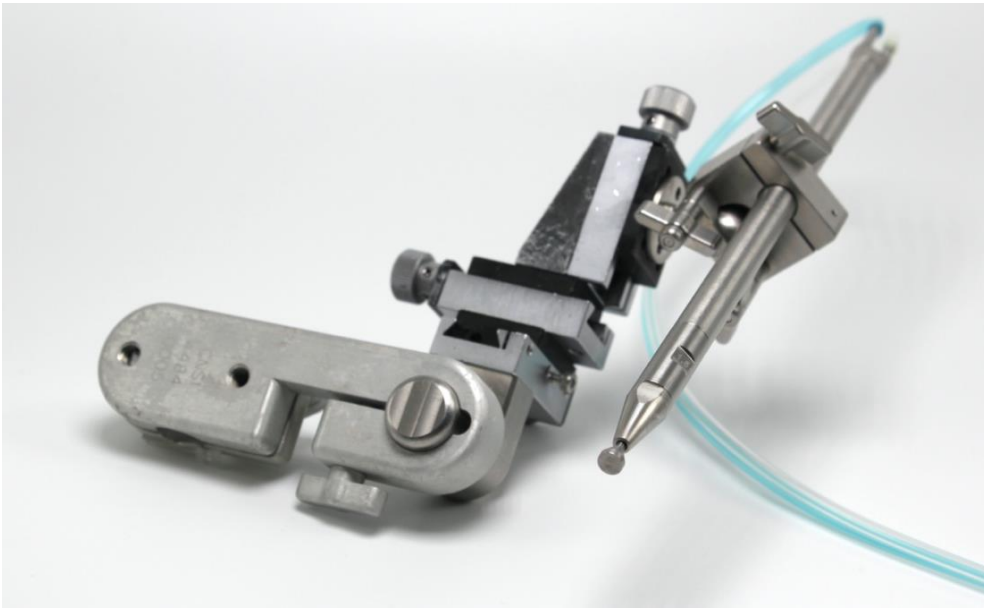


Figure 5: Wand Holder, Inserter Wand, and Head Holder Adapter assembled

Assembling the Inserter System

The inserter system is comprised of the Inserter Control Box, a pneumatic piston (called wand) and tubing, a push-button trigger cable, and the power supply. These parts should be connected before connecting power to the Inserter Control Box. The wand ships fully assembled but may be taken apart for repair or maintenance.

Connect the Trigger to the Control Box

Align the keyed connector of the trigger with the connector labeled ‘Trigger’ on the Inserter Control Box. Push the trigger connector straight into the box and then twist the collar on the trigger cord to the right (clockwise) to engage the threads and secure the cable to the box.

Connect the Wand to the Control Box

The color-coded tubes on the Inserter Control Box (light blue and clear/white) match the colors of the dual lumen tubing. Remove the vinyl protector tubes from the ends of the Inserter Wand tubing, if present. Push the blue and clear tubes into the blue and white plastic connectors respectively on the front of the Inserter Control Box. Be sure to press on the tubes until they will not go in any further. Gently pull on each tube to ensure that it is seated firmly in the box.

When properly connected, the longer of the two metal tubes on the wand are connected to the socket marked ‘Piston’ on the Inserter Control Box via the blue tube and the shorter metal tube on the wand is connected to the socket marked ‘Sleeve’ on the control box via the clear tube.

To remove the tubes, press the colored connector towards the Inserter Control Box while simultaneously gently pulling on the tube.

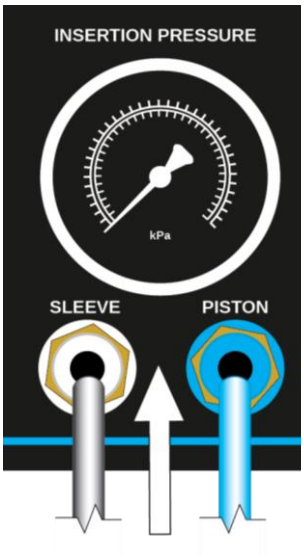


Figure 6: Close-up of tube placement on inserter

Preparing the Wand Holder

Connect the inserter wand holder to the patient’s head holder using an adapter or use another method that provides stability for the inserter wand. Ensure that the wand is rigidly held during insertion or the impact during insertion. Failure to do so can cause skewed electrode insertion.

After the wand holder is secured to the frame, place the inserter wand into the clamp portion of the wand holder, ensuring that the inserter wand size matches the size of the electrode. The inserter wand size is engraved on the outside of the spacer (**Figure 7**). Failure to use the correct inserter wand size can cause central nervous system injury to the subject or physical damage to the electrodes.

Figure 7: Close-up of wand spacer. Spacer length in mm is engraved on the spacer. 1.5 mm

Connect Power

Check that the power switch at the back of the Inserter Control Box is in the off (0) position. Attach the power cord to the control unit.

There will be movement of the piston when the device is first turned on. To ensure that this piston movement does not unintentionally affect electrode implantation, ensure that the wand tip is at least 3mm away from the array when turning on the Inserter Control Box.

Testing and Calibration

Before turning on the pressure to the inserter control box, unlock the pressure control knob by pulling it away from the control box, then turn the pressure control knob to the left (counter-clockwise) until resistance is met; this will ensure that the compressor starts with low load. Ensure that the pressure reading on the dial is zero before powering the device on.

Power the device on and then slowly turn the pressure control knob clockwise until a pressure of around 20 psi is reached on the insertion pressure gauge. Let go of the control knob and let the inserter run for 10-20 seconds to ensure that pressure remains stable. Adjust the pressure until it remains stable at 20 psi. If the inserter cannot maintain a pressure that does not jitter by more than 1 psi, then it may have a leak in the internal pneumatics. Check the troubleshooting section for more detail.

Once the pressure remains stable at 20 psi, set the pulse adjustment to 3. Hold the wand vertically with the wand tip facing downward. Place a gloved finger lightly underneath the tip of the wand. Press the Enable/Disable button to enable to the trigger, the button should light up.

Press the button on the end of the trigger cable to activate the inserter trigger and feel if the inserter tip moves. If it does not move, then the insertion pressure or pulse duration may be too low and the vacuum is being activated before the piston can strike the insertion tip. If the piston hits your finger twice during the pulse, then it is possible that the insertion pressure or pulse duration is too high and the piston is bouncing against the spacer. Consult the graph below for more information. These values are typical, but there may be minor variations from on inserter to another, thus testing this is recommended.

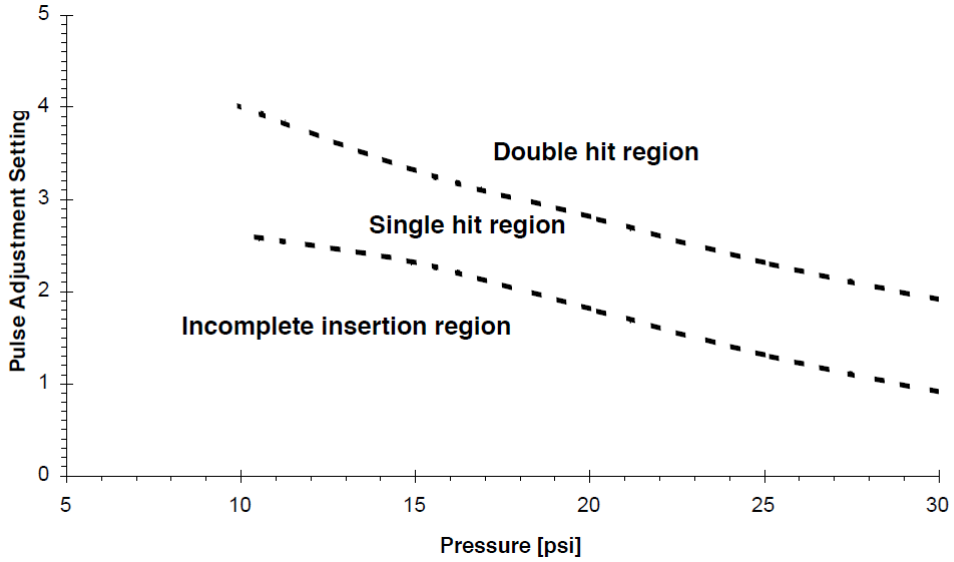


Figure 8: Pressure vs pulse adjustment with estimated piston response

To find the single hit region, it is recommended to start at a pressure of 20, and a duration of 0, then slowly increment the duration by 0.5 each test until you sense a hit, then turn the dial an additional half turn.

If the test succeeds, repeat the test without changing the position of the wand. If the test is successful again, the inserter is ready for use. Lock the dial by toggling the small black lever away from the top of the dial.

Inserter Operation

During inserter operation, ensure that the wand is rigidly held during insertion or the impact during insertion. There will be movement of the piston when the device is first turned on. To ensure that this piston movement does not unintentionally affect electrode implantation, ensure that the wand tip is at least 3mm away from the array when turning on the inserter control box. Confirm that the pulse widths and pressure are at the recommended levels determined during testing and are stable.

After verifying the pulse width and pressure, enable the inserter and press the trigger to insert when ready. If inserting multiple arrays, ensure at least 20 seconds between each enable/fire cycle of the device, otherwise the piston may have a longer pulse time than intended due to insufficient vacuum pressure, possibly resulting in a double hit of the inserter wand.

Depressurizing the Inserter System

After use, turn the pressure control knob counterclockwise until the insertion pressure gauge reaches zero. After the pressure reaches zero, turn off the inserter control box. Failure to reduce the pressure after use can cause stress on the inserter that can cause it to fail.

Before storing the inserter, unplug the dual lumen tubing and trigger cable.

Magnetic Resonance

The NeuroPort Electrode Inserter System has not been evaluated for safety and compatibility in the MR environment. The NeuroPort Electrode Inserter System has not been tested for heating, migration, or image artifact in the MR environment.

Cleaning, Sterilization, Reprocessing, and Disposal

Each subcomponent of the system has different instructions for cleaning, reprocessing, maintenance, and disposal. The specifics of each are detailed below.

Inserter Control Box

The Inserter Control Box may be cleaned with standard cleaning solutions such as alcohol and bleach-based cleansers used on non-sterile devices. Store the control box with the power cord, wand, tubes, and trigger detached. Ensure that the inserter pressure control knob is turned completely counterclockwise so that the pressure gauge reads zero.

The Inserter Control Box contains parts that can wear out after use or degrade over time. It is recommended to have the Inserter Control Box serviced by the manufacturer, Blackrock Microsystems, once a year. To request service for the control box contact Blackrock Support using the information found at the end of this manual or at www.blackrockneurotech.com/research.

The device should not be disposed with household waste. Return to a recycling point for electric and electronic devices.

Wand and Tube

The wand and tube can be cleaned with mild bleach, enzymatic cleaners, or any other non-corrosive cleaning agents.

The wand and tube are exposed to ethylene oxide sterilization.

This device may have incidental contact with bodily fluids. Follow institutional procedures for disposing potentially infectious or biohazardous devices when disposing of the inserter wand and connected tube.

Trigger Assembly

The trigger can be wiped with mild bleach or mild soap solutions, but it should not be immersed in fluid.

The trigger assembly is exposed to ethylene oxide sterilization.

The device should not be disposed with household waste. Return to a recycling point for electric and electronic devices.

Wand and Head Holder Adapter

The Wand Holder and Head Holder Adapter can be damaged by alkaline (pH> 10) detergents and solutions. Cleaning in an ultrasonic bath may cause cosmetic defects but does not affect function.

The Wand and Head Holder Adapter are both able to be sterilized by autoclave.

	Temperature	Cycle Time (Minutes)	Dry Time (Minutes)
Gravity Displacement	134°C	18	15-30

After cleaning or sterilization, apply a small amount of Teflon lubricant to all moving parts and threads. Afterwards, check for smooth movement of each slide.

If necessary, the device may be disposed of in household waste or recycled at any facility accepting steel and chrome-plated brass.

Troubleshooting

The NeuroPort Electrode Inserter System is a critical device to any NeuroPort Electrode surgery. Many researchers choose to have a second device on hand to mitigate cost and risk in case of a failure. Whenever possible, the inserter system should be tested before surgery and periodically.

Inserter will not reach 20 psi.

Insertions should not, generally, occur at pressures greater than 25 psi. If the inserter will not reach over 20 psi, there may be an issue with the compressor or there may be a loose pneumatic tube inside the inserter control box. It is possible to increase the pulse adjustment up to 7.0 to account for a slightly low insertion pressure. Insertion should never be done below 15 psi. If your inserter cannot reach a pressure of 25 psi, contact Blackrock support to arrange for service of the device.

The enable button will not light up when pressed.

It is possible that the connections on the button have disengaged. Contact Blackrock Support to arrange for service of the device.

The piston does not return to starting position after the inserter is used once with the wand vertically pointed down.

This indicates a weak vacuum. Check that the tubes are connected to the Inserter Control Box properly, see **Figure 6**. Reseat the tubes in the Inserter Control Box Sleeve and Piston connectors. If the problem persists, contact Blackrock Support to arrange for service of the device. As a temporary workaround, the wand can be turned upside down to re-seat the piston on the vacuum. This would need to be repeated for each insertion.

The pulse adjustment dial will not turn.

Ensure that the sliding lock on the upper right of the dial is disengaged. The lock should be engaged after choosing the proper duration and disengaged when setting the duration. If the dial will still not turn, clean the dial with a warm, mild detergent and try

again. If the problem persists, please contact Blackrock Support to arrange for service of the device.

The pressure control knob will not turn.

Disengage the lock by pulling the knob away from the Inserter Control Box before turning. The pressure control knob should always be locked after setting the pressure by pushing the knob into the inserter control box.

I have tried the above calibration technique, but the wand will still not perform a single hit insertion.

Likely, the wand must be replaced, but occasionally, temperature changes or impacts can cause the piston to get stuck in the wand due to the tight specifications. Disassembly, cleaning, and reassembly of the wand can occasionally correct this. Note that failure to maintain the required pressure consistently or a failure for the piston to return to can also be caused by incorrectly reassembling the wand. Refer to the schematic view in **Figure 2** for the correct orientation of parts. Care should be taken to avoid contaminants inside the wand when reassembling.

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@blackrockneuro.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.blackrockneuro.com/research/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.blackrockneuro.com/research/support
support@blackrockneuro.com
U.S.: +1 (801) 582-5533

Caution:

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