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CerePlex E

PN: 7513, 10511 – E96

PN: 8010, 10510 – E128

PN: 10747 – E256

Instructions for Use



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What this Manual Covers

The CerePlex E is a Digital Headstage Accessory that provides a compact interface from electrodes bonded to a Blackrock CerePort pedestal to the Cerebus or CerePlex Direct data acquisition systems. The CerePlex E converts analog signals to digital format at the recording site, which can reduce noise introduced into the signal during transmission to the recording system.

This Instructions for Use will cover important information about the device including warnings, hardware settings, and maintenance activities.

There are several CerePlex E models that are available in different channel counts. These are outlined in the table below.

Model Name	CerePlex E96 v1	CerePlex E128 v1	CerePlex E96 v2	CerePlex E128 v2	CerePlex E256
Model Number	7513	8010	10511	10510	10747
Channel Count	96	128	96	128	256

Intended Use and Indications for Use

The CerePlex E is intended to be used with the CerePort pedestal for animal research only.

The CerePlex E supports 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

Warnings

- Only connect Cerebus 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.
- Use only the supplied Blackrock Microsystems components (Cerebus™ system, Digital Hub, CerePlex E HDMI Cable).
- Substitution of components not supplied by Blackrock Microsystems may affect system performance and patient/subject safety.
- Do not connect the Cerebus System to an outlet controlled by a wall switch.
- Do not use the CerePlex E in the presence of flammable anesthetic agents.
- Keep the CerePlex E away from liquids. Contact with water, shower spray, or wet surfaces can lead to the subject receiving an electrical shock.
- Connection of external instruments may compromise electrical safety compliance with IEC 60601-1.
- Always use antistatic or electrostatic discharge (ESD) safe gloves when connecting the CerePlex E.
- The CerePlex E 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. Pulled cables may cause damage to the CerePlex E and any other connected devices.
- When the CerePlex E is attached to the CerePort pedestal, force applied to the CerePlex E will be applied to this connector. Avoid large impacts to the device when it is attached to the subject.
- Do not leave the patient/subject connected to the CerePlex E when the data acquisition system is not in use.

Precautions

- Read this entire manual prior to using the device.
- Do not allow the digital data cable to be pulled and apply force to the CerePlex E.
- Do not allow any object to impact the CerePlex E while in use.
- Do not drop the CerePlex E when handling.
- Do not use the CerePlex E with damaged data cables or data cables that are not supplied by Blackrock, doing so may damage the device.
- When replacing the filament film of the device, avoid touching circuit board components as these can be easily broken and cause damage to the device.
- Do not attempt to use the CerePlex E with connectors other than the CerePort pedestal connector.
- Do not plug the digital data cable into devices other than the Digital Hub and Blackrock approved headstage accessories.
- Avoid spilling fluid onto or into the CerePlex E as doing so may cause electrical damage to the device and loss of function or electrical shock.
- Avoid strong static discharges from sources like televisions or computer monitors because it can damage the electrical parts of the system.
- Using the 'Wide-Band' filter mode on the device may cause a reduced signal to noise ratio. 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.
- Avoid overtightening the CerePlex E when attaching to the CerePort Electrode. Device damage may result.

Specifications

Model Name	CerePlex E96	CerePlex E128	CerePlex E256
Model Number	7513/10511	8010/10510	10747
Number of Channels	96	128	256
Power Requirements	0-5 VDC, 150 mA maximum load		0-5 VDC, 300 mA maximum load
Resolution	16-bit, 250 nV per step		
Sampling Frequency	30,000 Samples per Second		
Mode of Operation	Continuous		
Input Hardware Filter	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		
Impedance Measurement Range	5 kΩ – 1 MΩ		
Maximum Input Range	± 8.192 mV with Respect to Reference		
Dimensions	L 24.9 mm x W 17.7 mm x H 17.9 mm	L 24.9 mm x W 35.4 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)		
Water Ingress Protection	Ordinary Equipment, not fluid resistant, IP20		

Hardware

Blackrock CerePlex E Setup

Figure 1 demonstrates how the CerePlex E96/128 connects with the Digital Cerebus System or the CerePlex Direct in a lower channel configuration.

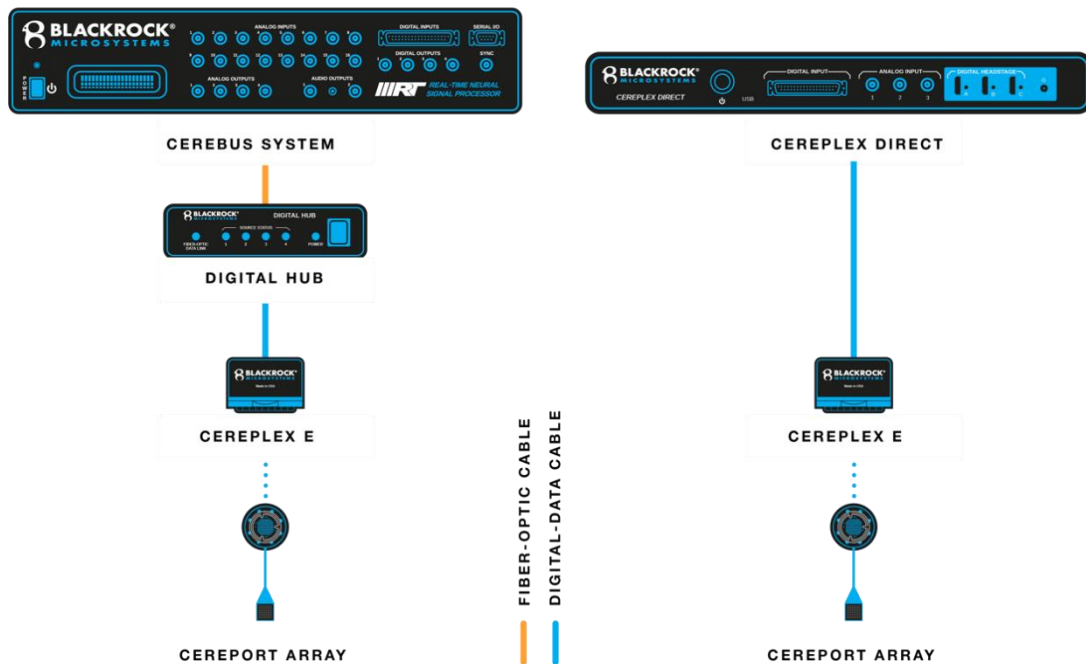


Figure 1–System Diagram of CerePlex E96/128 Connected to the Cerebus System or the CerePlex Direct.

Figure 2 demonstrates how the CerePlex E 256 connects with a 256-channel Digital Cerebus System or the CerePlex Direct in a 256-channel configuration.

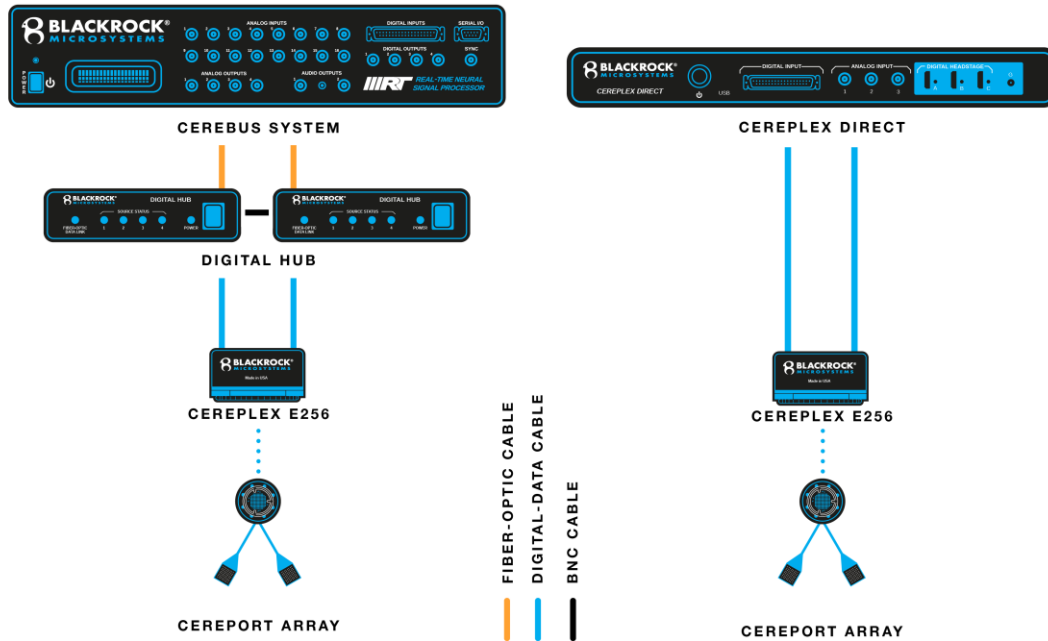


Figure 2–System diagram of CerePlex E256 connected to the Cerebus System or the CerePlex Direct.

Instructions for Assembly

Note: In order to use the CerePlex E 256 with a Cerebus system, two modified Digital Hubs will be needed. If you are unsure if you have the necessary modified equipment, contact Blackrock Support by emailing support@blackrockmicro.com.

The CerePlex E is designed to mate with the CerePort pedestal attached to Blackrock or third-party electrodes. The CerePlex E is equipped with three guide posts. These guide posts must be aligned with the three available notches around the edge of the CerePort pedestal to facilitate a correct connection between the CerePlex E and the implanted electrodes. For a detailed procedure on how to connect the CerePlex E headstage to CerePort pedestal please refer to the following instructions:

1. Connect the CerePlex E to either a CerePlex Direct or Digital Hub through an HDMI A-D cable (see **Figure 3**).
- For the E 256, HDMI Connector A is associated with banks A, B, C, and D of the LGA connector and HDMI Connector B is associated with banks E, F, G, and H of the LGA connector. To maintain proper channel numbering on an E 256, the HDMI A-D cable going to HDMI Connector A should be plugged into a lower numbered HDMI port on the Direct or Hub than the HDMI A-D cable going to HDMI Connector B.

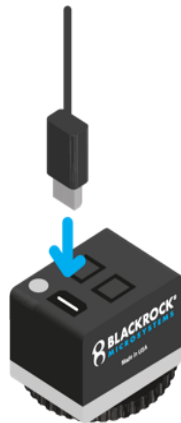


Figure 3–HDMI connection to the CerePlex E (E96/128 shown)

2. Power on the connected host device.
3. The LED on the CerePlex E should light up as blue.

4. Roughly align the guide pins with the pedestal before attaching to the pedestal (see **Figure 4**).



Figure 4—Proper orientation of the CerePlex E relative to the CerePort Pedestal. Note how the notches in the Pedestal align with the guide pins in the CerePlex E when

5. Hold the CerePlex E housing with one hand and gently rotate the wheel clockwise with another hand (see **Figure 5**).



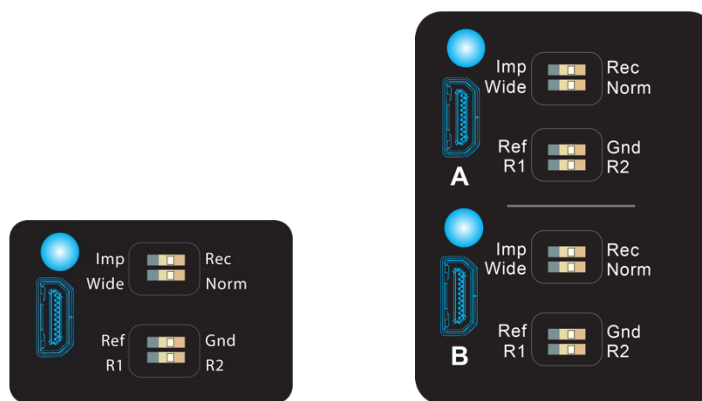
6. While screwing down, slightly rotate the housing left or right until you feel the guideposts slide into the notches.
7. Once the CerePlex E is aligned with the pedestal, rotate the wheel clockwise until the device is secured to the pedestal (see **Figure 5**).
 - Precaution: Avoid overtightening the CerePlex E when attaching to the CerePort Electrode. Device damage may result.
8. The blue LED will turn green when the device is firmly mated with the CerePort Electrode and data should be visible in the Central software.

The instructions above are also detailed in one of the Blackrock training videos which can be accessed online from the Blackrock Microsystems website under How-to Videos.

CerePlex E Channel Mapping

The high channel density of the CerePort pedestal can cause some channels to have crosstalk or difficulty mating with the CerePlex E. You can refer to the mapfile delivered with your Blackrock-manufactured implant assembly to the mapping of LGA and Central channels, as well as complete electrode mapping to Central channels. If this file is not available to you, contact Blackrock Support by emailing support@blackrockmicro.com.

Description of Switches on the CerePlex



Impedance and Recording Selector Switch

When the selector is positioned on “Imp” the CerePlex E enters impedance measurement mode. This mode enables users to measure impedance of electrodes via Blackrock’s Central Suite. For information regarding impedance measurement, please refer to the document titled “LB 0574 Central IFU,” which is available for download from the Blackrock Microsystems website. To revert the CerePlex E headstage into the recording mode, simply toggle the switch to “Rec” position (recording).

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 select between different sources to use as the input reference. If the switch is toggled to “Gnd” mode, 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 can be selected by another switch adjacent to reference and ground selector (see below).

R1 and R2 Reference Selector

Use this switch to select which of the two available reference wires to use as the input reference. This selection is only relevant when the Reference and Ground selector switch is in the “Ref” position. A switch position to R1 selects reference wire number 1 as the input reference. The R2 switch selects the reference wire number 2 as shown in **Figure 5**. The Ref/Gnd switch must be in Ref mode for this switch to be effective. For the CerePlex E 256, the switches closest to HDMI Connector A affect Banks A-D (Channel 1-128) and the switches closest to HDMI Connector B affect Banks E-H (Channel 129-256). Depending on how reference wires are connected to the 256-ch CerePort pedestal that is mated with the CerePlex E 256, selecting R1 or R2 for both switches may result in different references being used for channels 1-128 and 129-256.

Cleaning & Maintenance Instructions

Sterilization

While not generally required, the device may be sterilized by both Vaporized Hydrogen Peroxide and Ethylene Oxide Gas. Note that Vaporized Hydrogen Peroxide may significantly discolor the case of the device. Newer models (PNs 10510, 10511, and 10757) have a new case that should not discolor.

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.

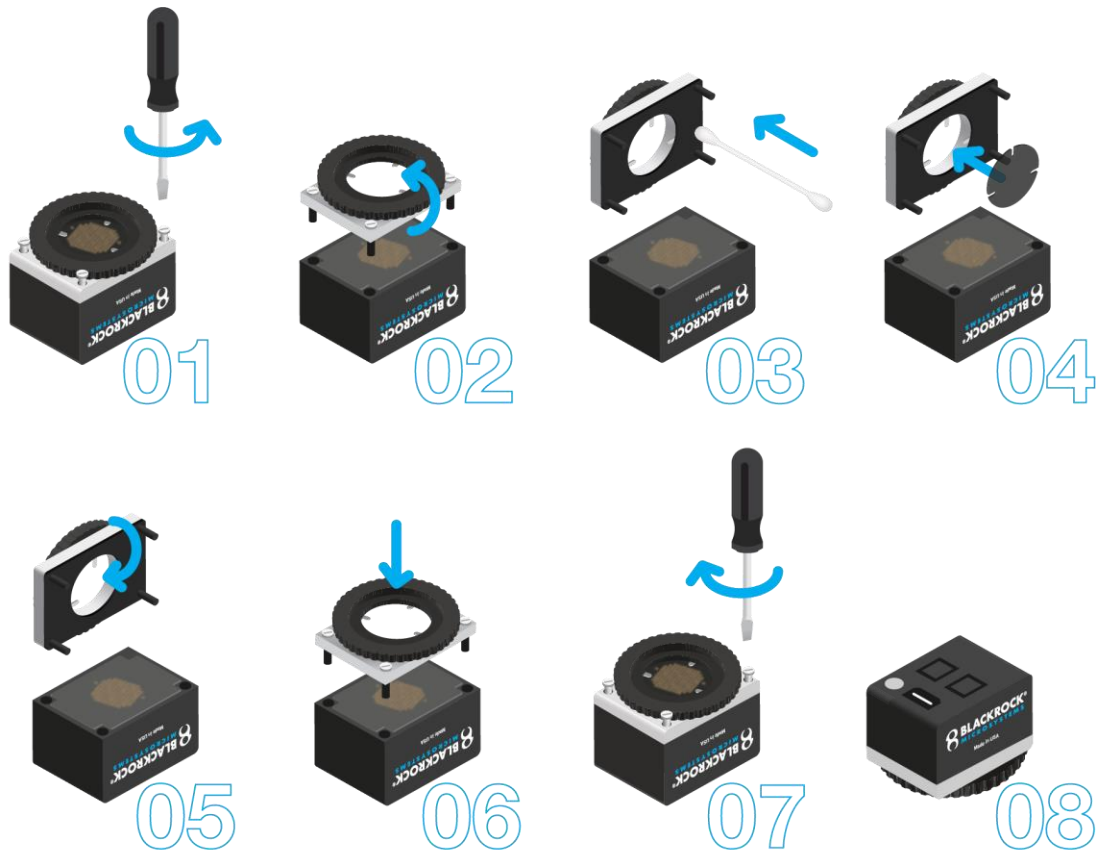
Filament Film Disassembly and Replacement

The filament film which is visible from under the CerePlex E (See , bottom panel) provides a conductive and uniform medium in between the input pins of the CerePlex E and the connectors on top of the CerePort pedestal. The filament film is conductive in the vertical direction with respect to the film surface, connecting the contacts on the CerePlex E input and the pins on the CerePort 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 CerePlex 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 CerePlex 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 with cotton swab and 70% isopropyl alcohol.
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 CerePlex 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.



Disposal

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

Magnetic Resonance

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

Troubleshooting

Some common error states and their respective resolutions are listed below. For further information please contact Blackrock Support at support@blackrockmicro.com.

Problem	Symptom	Failure	Potential fix
Non-green indicator light on CerePlex E	Blue light will not turn green after mating with pedestal	Bad mating technique Lack of power Only 1 or 2 HMDI cables connected	Make sure Hub or Direct is powered on Apply more force to wheel of E to tighten the E-pedestal mate Verify guide pins are aligned with notches on pedestal Verify the filament film is clean and free of debris For E256, make sure both HDMI cables are connected
Poor signal to noise ratio or signal quality	No spikes appear High-passed noise band is greater than $\pm 30 \mu\text{v}$	Bad reference configuration Poor contact between E and pedestal Incorrect recording band is being used Poor patient/subject grounding Excessive noise in operating environment Use of unsynced Digital Hubs	Try using different references, or using ground as reference, by toggling the E's reference switches (see Figure 6) Apply more force to wheel of E to tighten the E-pedestal mate Add ground connections from the patient/subject to the Patient Ground connection on the Direct/Digital Hub Turn off unnecessary lab equipment If you are using and E256 with Digital Hubs, make sure the Hubs are synced by contacting Blackrock Support
Problem	Symptom	Failure	Potential fix

Non-green light on Direct/Digital Hub	HDMI indicator lights on Direct/Digital Hub are either dark, red, or orange	Incompatible Direct/Digital Hub Bad cables Bad Direct/Digital Hub HDMI port	Try another Blackrock-supplied HDMI cable Try plugging in the HDMI cable into a different Direct/Digital Hub HDMI port Contact Blackrock Support for compatibility check
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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 that 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 performed 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

The CerePlex E is not intended for use on human subjects.