# BrainPort<sup>®</sup> Vision Pro



# Instructions for Use



Wicab, Inc. 8313 Greenway Blvd. Middleton, Wisconsin 53562 USA Intentionally Blank

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#### **Using this Manual**

This manual is intended for use after you have been trained on the operation of the BrainPort<sup>®</sup> Vision Pro. This manual serves as a reference to supplement your training and to address any questions you may have when you use the device at home.

The manual contains general information on safety, operation, and troubleshooting. Please read it thoroughly and become familiar with its contents.

This manual is written in an accessible format. This manual is also available electronically via Wicab's website or portable electronic storage media. As discussed with your trainer, you may use accessibility tools to access the document on your computer to read aloud the text that appears on the screen.

- Chapter 1 describes the BrainPort Vision Pro and the risks and benefits of using it.
- Chapter 2 explains how to use the BrainPort Vision Pro.
- Chapter 3 includes troubleshooting procedures to use in the event of problems with the BrainPort Vision Pro.
- Chapter 4 lists product specifications and technical references.



Attention, consult accompanying documents

This label is a reminder for you to consult this manual or other material you received with the device for important safety information.

# **CHAPTER 1**

## **General Information**

The BrainPort Vision Pro is an oral electronic vision aid that provides electro-tactile stimulation to aid profoundly blind individuals in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as the white cane or a guide dog. It translates digital information from a video camera to gentle electrical stimulation patterns on the surface of the tongue. Users describe the experience as streaming images drawn on their tongue with small bubbles. With training, users are able to interpret the shape, size, location and motion of objects in their environment. BrainPort Vision Pro is not used to diagnose or treat the underlying condition that led to the user's visual impairment.

# **i** Warning

The BrainPort Vision Pro does not replace the cane or guide dog. The BrainPort Vision Pro is intended to augment, rather than replace, other assistive technologies such as the white cane or guide dog.

Training is required before using the BrainPort Vision Pro.

## Purpose of Device (Indications for Use)

The BrainPort Vision Pro is an oral electronic vision aid that provides electro-tactile stimulation to aid profoundly blind patients in orientation, mobility, and object recognition as an adjunctive device to other assistive methods such as the white cane or a guide dog.

## Description of BrainPort® Vision Pro

#### Headset

The headset consists of the device controls, battery pack, and a digital video camera that is mounted on an eyeglass-type frame. It may be worn by itself or optionally with a pair of glasses or sunglasses. The camera's field of view is user-controlled and varies from narrow to wide angle views. The Intra Oral Device (IOD) is permanently attached to the left earpiece by a cable.

#### Intra Oral Device (IOD)

The IOD (tongue electrode array) contains electrodes that act as "pixels" for the tongue. The flat side with the electrodes should be in contact with the front top surface of the tongue. Close your lips around the thin stem, maximizing tongue contact with the electrodes. The stimulus pattern on the electrode array corresponds to the scene captured by the camera. There is one cable exiting the thin stem of the IOD that is permanently attached to the earpiece of the headset.

#### **Battery Charger**

A battery charger with factory instructions and two lithium-polymer rechargeable batteries are included.

#### **Training and Training PC**

Training is required before you use the BrainPort Vision Pro. The trainer may use a personal computer or mobile device (e.g.: smart phone) during training. When the computer/device is in use:

- Do not touch the personal computer or your trainer, and
- Do not come into contact with any device plugged into a wall circuit.

Your BrainPort Vision Pro does not include or require a personal computer or mobile device.

## When NOT TO USE the Device (Contraindications)

You should not use the BrainPort Vision Pro if you have the following condition:

 Any neurological condition that causes impaired sensitivity to your tongue or loss of consciousness

## **Risks of Use**

Potential risks arising from the use of the BrainPort Vision Pro include:

- Electrical and electromagnetic safety hazards associated with battery-operated devices
- Allergic reaction to the materials in the device
- Irritation of your tongue from the electrodes or excessive stimulation

You can manage these risks by setting the stimulus level according to your preferred comfort level, adhering to the instructions in this manual, and applying the training you received for the proper and safe use of the device.



- *Tongue Sensation.* The BrainPort Vision Pro should be not used with subjects experiencing numbress or lack of feeling of the tongue, or with subjects with a history of injury to the tongue resulting in impaired sensation or use of the tongue.
- Long-term use. Limited data are available on the long-term effects of electrical stimulation of the tongue. Long-term effects (beyond one year) have not been evaluated in clinical trials.
- Device Usage. Limited data is available on use of this type of stimulating device exceeding an average of between 250 and 400 minutes per month, and a maximum of 1550 minutes per month. Wicab recommends that you tailor your use of the device to be within these time limits since long-term effects (beyond one year) exceeding this usage have not been evaluated in clinical trials.
- Trainers. Potential trainers of users of the BrainPort Vision Pro should have relevant experience, such as experience working with the blind or visually impaired. Trainers may have professional credentials, such as certification as a Certified Low Vision Specialists (CLVS), Certified Orientation and Mobility Specialist (COMS) or Teachers of the Visually Impaired (TVI). All potential trainers will be trained by Wicab according to Wicab procedures and only those who have successfully completed the training will be considered qualified to train users of the BrainPort Vision Pro.
- Supervision. The BrainPort Vision Pro should only be used after you have completed training. Do not give the device to untrained individuals for use.
- Use only Wicab supplied components and procedures. Using controls, adjustments, components, or procedures other than those specified in this manual may damage the BrainPort Vision Pro, increase risk, or decrease benefit.
- Oral Health. Limited data is available on stimulation sensitivity for individuals with oral conditions such as oral ulcerations, herpes simplex, oral thrush, and geographic tongue. If use of

the device causes discomfort, discontinue use.

- Oral Health. Individuals with high, narrow palatal vaults should discontinue use of the device if use causes discomfort
- Oral Health. Individuals with maxillary or mandibular tori that interfere with the IOD placement such that full contact with the tongue is prevented should seek additional training to gain the most benefit of the device.
- Dental Appliances (orthodontic appliances, removable partial or full dentures, lingual amalgam alloy restoration, metal crowns, etc.) Electrical stimulation of the tongue when metal appliances/surfaces are present may change results and/or cause unintended stimulation. If the stimulation causes discomfort, remove the IOD from your mouth and discontinue use of the device. If you notice a change in your dental device or appliance (warmth or looseness), discontinue the use of the device and contact your dentist.
- Dental Implants. The BrainPort device has not been thoroughly evaluated in the presence of dental implants. The safety of dental implants in BrainPort users is unknown. The use of this device potentially may cause heating of dental implants; chronic use of this device potentially may result in loosening and failure of dental implants.
- Condition of device. Before EACH use, tactilely inspect the device for damage, for example, anything rough or loose on the IOD, disconnected cables, worn cables, cracked or broken glasses, cracked or broken headset, etc. If you find these or similar issues, contact Customer Support and DO NOT use the device. Using a damaged device could expose sharp edges and/or the damage could prevent normal operation, thereby increasing the risk of use.
- *Proper environment for use*. The BrainPort Vision Pro is intended for use as a supplemental assistive device.
  - Do not use it in environments that could put you in danger.
  - Do not operate the device in hot or cold conditions (below 0°C/32°F or above 40°C/104°F). Maintain conditions between 5% and 95% relative humidity. The device is intended for operation under normal atmospheric pressures (700 hPa to 1060 hPa)

- If the headset becomes uncomfortably warm, or when the ambient temperature exceeds 35°C/95°F discontinue use of the device.
- The camera and other headset components are not waterproof. Do not use the device in environments that will allow liquids (such as rain and snow) to enter these components.
- Electrical shock. To avoid electrical shock, do not immerse the BrainPort Vision Pro or the battery charger in liquids.
- Do not use where flammable gases are present.
- Do not come into contact with any device which is plugged into a wall circuit or any person using such a device.
- Follow the guidance outlined in CHAPTER 4 Product Specifications and Technical References regarding the intended electromagnetic use environment.
- Contact Wicab if you have questions or concerns about a particular use environment.
- Discomfort. Using the BrainPort Vision Pro should not cause discomfort. If you experience any pain, numbness or discomfort including burning or stinging, please stop using the device. If the symptoms are temporary, you may resume using the device by reducing the stimulation level to a comfortable level. If the condition recurs, stop using the device and seek professional help.
- *Risk of Strangulation*. Take care in arranging cables to avoid the risk of strangulation. Small children may become entangled in the cables. Do not allow children to use the device without adult supervision. Store the device out of reach of small children.
- Choking. The BrainPort Vision Pro contains small parts. Check the device for loose or missing parts before each use. Do not use the device if parts are missing. Do not allow children to use the device without adult supervision. Store the device out of reach of small children.
- Discomfort. Use of the BrainPort Vision Pro may be contraindicated for young individuals or people with narrow dental arcades of the upper palate – it may be difficult to BrainPort Vision Pro Instructions for Use

comfortably place the IOD on the tongue for these individuals.

- *Care and Maintenance.* Use only the procedures in this manual to care for your device.
- *Intended Purpose*. Do not use the BrainPort Vision Pro for any purpose other than that stated in the Indications for Use.
- Personal Computer / Mobile Device. When using a personal computer or mobile device (remote device) with its power cord plugged into a power source:
  - Remove the BrainPort Vision Pro before touching the remote device;
  - Do not touch the remote device and the BrainPort Vision Pro at the same time;
- Magnetic Resonance (MR) Unsafe. The BrainPort Vision Pro has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of BrainPort Vision Pro in the MR environment is unknown. The BrainPort Vision Pro should be removed before entering an MR scan room or having an MR scan. Scanning a patient who has this device could result in patient injury.
- *Battery Charger*. The battery charger should be kept out of the patient environment. Remove the BrainPort Vision Pro before using the battery charger. Do not touch the battery charger and the BrainPort Vision Pro at the same time.

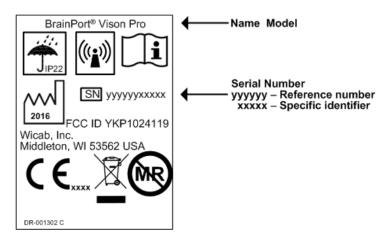
## Precautions

- Signal Stimulation. Adjust the stimulation to a comfortable level that allows you to clearly feel and respond to the signal. Increasing beyond this point does not improve effectiveness. If the stimulation causes discomfort, reduce the stimulation setting to a comfortable level. If discomfort continues, remove the IOD from your mouth and discontinue use of the device.
- Sensitivity to stimulation. Although the BrainPort Vision Pro is designed to minimize the risk of injury due to stimulation strength, if you react negatively to the stimulation from the BrainPort Vision Pro, remove the IOD from your mouth and discontinue use of the device.
- Oral health. If you currently have or develop open lesions, sores or abrasions in your mouth, discontinue use of the BrainPort Vision Pro until the situation has resolved.
- *Mouth injuries/Dental Trauma*. The IOD is intended to be held in the mouth during use. Take care so that the cables do not become entangled, pulling the IOD out of your mouth potentially injuring your mouth, teeth or lips.
- Choking. The IOD is intended to be held in the mouth during use. To minimize the risk of choking on the IOD, make certain it is securely connected to its flexible cable and that the IOD is positioned properly in the mouth. Do not use the device if the IOD is damaged.
- *Neck Trauma*. Take care so that you do not become entangled in the cables that run from the headset to the IOD. A sudden yank could cause neck trauma.
- *Batteries.* Do not use the device with the battery pack door open. Inspect the battery prior to use. Do not use the battery if it appears damaged, corroded, is leaking, or is swollen.
- *Pregnant or Nursing Women.* The BrainPort Vision Pro has not been evaluated in subjects who are pregnant. Users who are pregnant should consult with their doctor before using the BrainPort vision device.

## **Product and Package Labeling**

The labels on the back of the BrainPort Vision Pro battery pack and on its packaging provide important information. You will need the model name, model number, reference number, and serial number if you call Wicab for assistance. See the inside back cover of this manual for contact information.

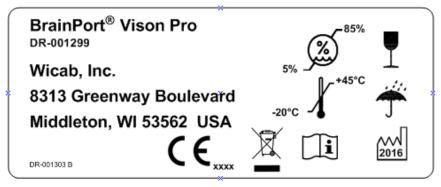
#### **Product Label**



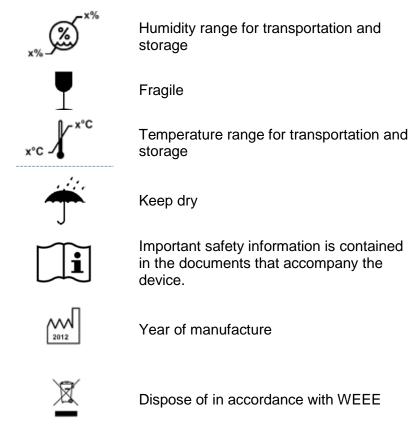
#### **Explanation of Symbols**

<b>1</b> 100	Keep the BrainPort Vision Pro dry.
(((*)))	The BrainPort Vision Pro includes RF transmitters
Ĩ	Important safety information is contained in the documents that accompany the device.
2012	Year of manufacture
SN	Serial Number
FCC ID	Identifier of RF transmitter

X	Dispose of in accordance with WEEE
8	MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment
CE	CE Mark



## **Explanation of Symbols**



## CHAPTER 2 Using the BrainPort<sup>®</sup> Vision Pro

This chapter explains how to set up and use the BrainPort Vision Pro.

(Refer to Figure 1: BrainPort Vision Pro and/or the verbal descriptions below)



Using procedures other than those specified in this manual may damage the BrainPort Vision Pro, increase risk of injury, and decrease benefits of use.



Before EACH use, tactilely inspect the device for damage, for example, anything rough or loose on the IOD, disconnected cables, etc. If you find any of these problems, contact Customer Support and DO NOT use the device.

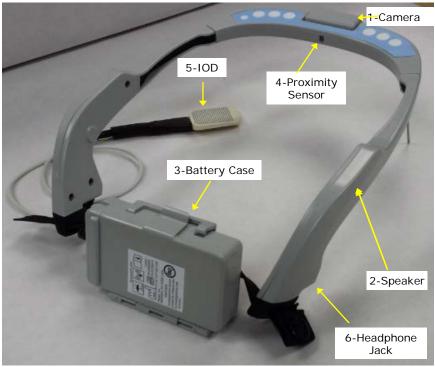


Figure 1: BrainPort® Vision Pro

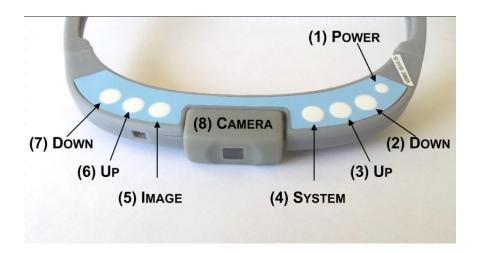
## **BrainPort<sup>®</sup> Vision Pro Device Components**

1. Camera	Used to capture the scene in front of the wearer. It is located at the front, center of the headset and faces outwards.
2. Speaker Provides audio feedback. It is located in the right-s ear piece.	
3. Battery Case	Contains the rechargeable battery. Mounted on the rear of the headset with an adjustable strap.
4. Proximity Sensor	Detects when headset is being worn. It is located at the front, center of the headset and faces inwards. The system will shut down after several minutes if the headset is not worn. Do not apply any material which might obstruct the sensor.
5. IOD	Contains the electrodes which present the stimulation patterns to your tongue.
6. Headphone Jack	Connection of external headphones/earbuds

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## **User Controls**

The User Controls are on the headset. The numbers in the descriptions refer to items in the figure below.



#### Power (1)

Device on/off button. To turn the device on or off, press the button.

#### SYSTEM (4)

This button scrolls through the **SYSTEM** features. The **UP (3)** and **DOWN (2)** buttons next to **SYSTEM** selects the specific action for that feature. **SYSTEM** features are:

**STATUS**: Up/Down will cycle through following status reports, announcing the information at each stop

- Battery charge level,
- Lighting condition detected by the device
- Language
- Version of the device software

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**VOLUME**: Up/Down will cycle through the following volume levels, changing the volume to the currently selected feature

- Mute (off),
- Low,
- Medium
- High.

Note that the mute function will not mute the status function.

**WIFI**: Use the Up or Down buttons to enable or disable the WiFi. Disabling the WiFi will help conserve battery life.

**TEST**: Use the Up and Down buttons to choose test patterns. Used for troubleshooting device operation.

#### **IMAGING (5)**

The **IMAGING** button scrolls through the Image features. Use the **UP (6)** and **DOWN (7)** buttons to choose the level you want for each feature. The Image features are:

**INTENSITY**: Stimulation intensity control. Use the Up and Down buttons to increase or decrease (respectively) the intensity of the stimulation on your tongue. The device will beep at the limits of stimulation (highest = 100, lowest = 0). At power up, stimulation intensity always resets to zero and must be increased to your comfort level.

**ZOOM**: Camera field of view (FOV) control. Use the Up and Down buttons to zoom in (smaller FOV) or out (larger FOV). Press the Up button to increase the camera zoom level (reducing the camera's effective field of view). Press the Down button to decrease the camera zoom (increasing the camera's field of view). The device will beep at the limits of zoom (widest = 48 degrees, narrowest = 3 degrees).

**INVERT**: Invert the stimulation intensity values, where the strongest becomes the weakest and vice-versa. Use the Up and Down buttons to toggle between whether bright

objects or dark objects in the field of view stimulate the tongue array.

**CONTRAST**: Image contrast control. The Up and Down buttons toggle between normal contrast (default) and high contrast mode. High Contrast will enhance the difference between light and dark regions in the camera image.

**EDGE ENHANCE**: Enable/disable edge enhancement. Use the Up and Down buttons select the following functions:

- Off
- Edge Enhancement 1: the camera image is processed to show just edges
- Edge Enhancement 2: the camera image is processed to overlay enhanced edges on the image

**CAMERA (8)**: The camera can be adjusted to point straight out from the headset or can be tilted down (to about 45 degrees) to reduce neck fatigue.

**BATTERY CASE**: The battery case is attached at the rear of the Vision Pro headset. Simple elastic straps are used to tighten or loosen the headset for your comfort.

A fully charged battery should always be used at the start of each session.

**HEADPHONE JACK**: The BrainPort Vision Pro includes an audio jack (3.5mm) at the right-rear housing, below the strap holder. If you wish to use your own headphones in lieu of the embedded headset speaker, insert the headphone connector into the jack. Audio will be routed to your headphones instead of the Vision Pro speaker. If you remove the headphone connector, audio will again be output to the Vision Pro speaker.

## Quick Start: Turning on the BrainPort Vision Pro

- 1. Fully charge the batteries included with your device prior to using your BrainPort Vision Pro for the first time.
- 2. Insert a fully charged battery into the back of the Battery Pack.
- 3. Wicab recommends that you thoroughly clean the IOD before using it for the first time. Use the alcohol towelette (included with your device) to clean the IOD. Allow to air dry. Thoroughly rinse the IOD with tap water. Your IOD is ready for use after the rinse. See "Care and Maintenance" for detailed instructions on how to clean the IOD.
- 4. Place the headset onto your head and make any adjustments for comfort.
- 5. Verify that the Camera is at its home position by manually rotating it up until it reaches its stop position (do not force past the stop point).
- Press the **Power (1)** button once to turn the BrainPort Vision Pro on. The system will emit a 'tick' about once per second while the unit is booting. After successful power-up, the system announces "Starting... Welcome BrainPort Vision Pro... Battery xx%.... Ready"
- There are two ways to use the BrainPort Vision Pro: in standalone mode, or in Wi-Fi mode to connect to the companion vRemote software. The Vision Pro starts in WiFi mode by default.

#### Standalone Mode

After power-up, the system announces "Ready". Press the **SYSTEM (4)** until WiFi is selected. Press the **Down (2)** button to disable WiFi. The system will announce "Wi-Fi disabled".

#### WiFi Mode

The BrainPort Vision Pro starts in Wi-Fi mode automatically. If WiFi has been disabled and you wish to re-enable it, press the **SYSTEM (4)** button until *WiFi* is selected. Press the **UP (3)** button to enable WiFi. The system will announce "Wi-Fi enabled".

WiFi mode is necessary if you wish to allow remote

connections for the companion webpage display.

- 8. Place the IOD in your mouth.
- Press the IMAGING (5) button until Intensity is selected. Press the UP (6) button to increase the stimulation intensity to the desired level. The system will announce the intensity setting for each button press. Press the Down (7) button to decrease the stimulation intensity.
- 10. The camera field of view (zoom) will default to a medium field of view (24 degrees). This can be changed by using the IMAGING (5) button until *Zoom* is selected. Press the UP (6) button to increase the zoom, magnifying a smaller portion of the scene. Press the Down (7) button to zoom out, viewing more of the scene. The system will announce the zoom setting for each button press.
- 11. Press the **Power (1)** button turn off the BrainPort Vision Pro. The Vision Pro will emit a series of 'ticks' as it powers down.

## Accessing the Companion View

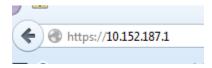
Your trainer or a sighted companion can use a web browser to view Vision Pro camera images and basic status information. Using a MOBILE DEVICE with WiFi capability (laptop, tablet, or smartphone), your sighted companion can follow the instructions below to establish a WiFi connection with the Vision Pro and display a webpage with the image and status information.

- 1. Establish a WiFi connection with the BrainPort Vision Pro device:
  - a. Start the Vision Pro in WiFi mode (this is the default start-up mode).
  - b. Using the MOBILE DEVICE, Open the wireless connection interface
  - c. Connect to the Vision Pro wireless network. The Vision Pro Network ID is specified on a label affixed to the battery pack door.

The Network ID will usually start with 'V200-'

Currently connected to:	•		
Wnidentified network No Internet access			
Wireless Network Connection			
V200-3312M00940	E		
Information sent over this network might be visible to others.			
Connect automatically			
BPV-000024			
Other Network			
wwap 🗙	-		
Open Network and Sharing Center			

- d. Wait for the MOBILE DEVICE to indicate that the connection has been made.
- 2. Open the Vision Pro Web Page:
  - a. Using your device's web browser, Enter the Secure URL Web Address: <u>https://10.152.187.1</u>



b. If this is the first time connecting to the Vision Pro, you may see several pages asking you to verify that you

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want to display this webpage. You should select the answers that allow you to proceed (each browser type may have a unique way of presenting the requests):

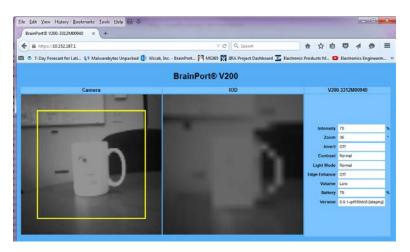
- i. Select "I Understand the Risks"
- ii. Select "Add Exception"
- iii. Select "Confirm Security Exception"

	You have asked Firefox to connect securely to 10.152.187.1, but we can't confirm that your connection is secure.
	Normally, when you try to connect securely, sites will present trusted identification to prove tha you are going to the right place. However, this site's identity can't be verified.
	What Should I Do?
	If you usually connect to this site without problems, this error could mean that someone is try to impersonate the site, and you shouldn't continue.
	Get me out of here!
	Technical Details
Г	I Understand the Risks

STA.	This Connection is Untrusted
- 2	You have asked Firefox to connect securely to 10.152.187.1, but we can't confirm that your connection is secure.
	Normally, when you try to connect securely, sites will present trusted identification to prove that you are going to the right place. However, this site's identity can't be verified.
	What Should I Do?
	If you usually connect to this site without problems, this error could mean that someone is trying to impersonate the site, and you shouldn't continue.
	Get me out of here!
	Technical Details
	<ul> <li>I Understand the Risks</li> </ul>
	If you understand what's going on, you can tell Firefox to start trusting this site's identification. Even if you trust the site, this error could mean that someone is tampering with your connection.
	Don't add an exception unless you know there's a good reason why this site doesn't use busted identification.
	Add Exception



c. The browser will then display the Vision Pro webpage and the Vision Pro will announce "Wi-Fi connect"



## **Device Announcements**

During use, the device will produce a variety of announcements following each button press. These announcements let the user know which button was pressed and what changes have been made to the camera or IOD. Sometimes the device may detect change in environmental conditions.

#### Low Light

In low light conditions, the device will announce "low light" one time per session. Use the Status button to reveal whether the conditions remain low light. This announcement is used to remind users to optimize their lighting conditions (i.e. turn on a light) in order for the camera to capture a useful image.

#### LOW BATTERY

When the battery level decreases to a low level, the device will repeatedly announce "low battery". This announcement acts as a reminder that a fully charged battery should be inserted in order to continue using the device.

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#### ACTIVE MODE

If the device transitioned to "standby mode" due to an irregularity, the device will announce "active mode" when it returns to active mode after the irregularity has been addressed. The device is ready for use while in active mode.

#### WI-FI MODE

The device will announce "Wi-Fi enabled" upon activation of the Wi-Fi module and completion of start-up testing. The device is available for webpage connections while in Wi-Fi mode.

When a remote webpage establishes a connection, the device will announce "Wi-Fi connect". When the webpage is closed, the device will announce "Wi-Fi disconnect".

#### STANDBY MODE

To ensure that the user of the Vision Pro receives accurate real time information representative of the scene captured by the camera, the device self-monitors and transitions from "Image" active mode to standby mode whenever an irregularity occurs. In this case, transitioning to standby mode is the normal and intended behavior of the device as it ensures that the user of the Vision Pro does not act upon potentially compromised or significantly time delayed information. The user is required to take action to return the Vision Pro to active mode. The system prevents a return to image mode if the irregularity persists. Degradation of performance, including loss of power, is acceptable device behavior.



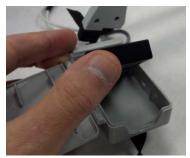
The BrainPort Vision Pro does not replace the cane or guide dog. The BrainPort Vision Pro is intended to augment, rather than replace, other assistive technologies such as the white cane or guide dog.

### **Batteries**

The system uses a single rechargeable Lithium-Polymer battery. When fully charged, a battery provides approximately three hours of standard usage (WiFi enabled, stimulation intensity set at 75%). A given battery has an expected life of more than 500 charge cycles. A fully charged battery should always be used at the beginning of each session. The BrainPort Vision Pro includes a charger and charging instructions.

To replace the battery, open the door on the back on the Battery

Pack by inserting a finger under the clip and swinging the door open. To remove the battery, grip the top of the battery and pull outward. To replace the battery, align the exposed metal connectors to the metal connectors in the Battery Pack, snap the battery into place, and close the door.



To test the battery power while using

the BrainPort Vision Pro, press the **System** button. The device will report the approximate percentage of charge remaining for the installed battery. When the battery charge gets very low, the device may shut down automatically to avoid improper operation.

Avoid direct contact with the gold contacts located in the Battery Pack and on the battery.

- If you will not be using the BrainPort Vision Pro for a period of more than 5 days, remove the battery.
- Storage and Transportation Conditions:
  - Temperature: -20°C/-4°F to +45°C/113°F
  - Humidity: 5% to 85%



The nearby figure shows the location of the Battery Manufacturer Part Number.

BrainPort Vision Pro Battery Specifications			
Wicab Part Number	DR-000839		
Manufacturer Part Number	56446 702 099		
Battery Type	Rechargeable Li-Polymer		
Electrical Specification	- 3.7V - 2260mAh - 8.4Wh		
Charge Cycles	> 500		

### **Battery Charger**

A copy of the battery charger manual is provided with your BrainPort Vision Pro. Follow the manufacturer's instructions when charging your battery.

Avoid direct contact with the gold contacts located in the pocket of the charger. Do not power the charger using a power strip or extension cord.

## **Battery Precautions**

- Avoid short circuits
- Do not heat the batteries above 60°C
- Do not dispose of batteries in fire
- Do not solder directly to the battery
- Do not charge with more that 1C and above 4.2V
- Do not charge below 0°C or above 45°C
- Do not discharge with more than 1C and below 2.7V
- Do not discharge below -20°C or above 60°C
- Do not disassemble the batteries
- Do not insert the batteries in reverse polarity
- WARNING: FIRE, EXPLOSION, AND SEVERE BURNS HAZARD



Personal injury can occur if the battery is handled carelessly or improperly. For your safety, follow these instructions for proper battery handling:

- The battery can ignite or explode if not handled properly. If you notice any deformities, cracks, or other abnormalities in the battery, immediately discontinue use of the battery and contact the manufacturer.
- Use only authentic, manufacturer-recommend battery chargers and charge the battery only by the method described in this user manual.
- Do not place the battery near heating devices or expose to excessively warm environments, such as the inside of an enclosed car in the summertime.
- Do not place the battery in a microwave oven.
- Avoid storing or using the battery in hot, humid places, such as spas or shower enclosures

## **Care and Maintenance**

- If you will not be using the BrainPort Vision Pro for a period of more than 5 days, remove the battery.
- Thoroughly rinse the IOD with tap water as needed to remove contaminants. You may use it immediately following such a rinse.
- Wicab recommends that you clean the IOD once a week. Use the cleaning solutions listed in Appendix A on a cotton ball or cotton swab to gently wipe the surfaces of the IOD. DO NOT SCRUB! Thoroughly rinse the IOD with tap water to remove any residual cleaning solution and allow it to air-dry.
- As needed, use a cloth slightly damp with water to wipe the exterior of the headset and battery charger. DO NOT rinse or immerse the headset or the battery charger. After cleaning, allow the headset and battery charger to dry completely before use. DO NOT allow liquid to touch the headset
- DO NOT store or transport the device in extreme hot or cold conditions (except for batteries see above section).

Storage and Transportation Conditions:

- Temperature: -25°C/-13°F to +70°C/158°F
- Humidity: 5% to 95%
- DO NOT bend, fold, or crush the IOD cable as this may permanently damage the IOD.
- Always protect the IOD. To avoid damaging the IOD, follow these instructions:
  - o Do not drag the IOD electrode surface across an object;
  - o Do not strike the IOD against a hard object;
  - Do not allow the IOD to come in contact with other electrical equipment such as cell phones, cell phone chargers, portable music players, etc.

## CHAPTER 3 Troubleshooting

This chapter describes steps you can take if the BrainPort Vision Pro does not seem to be working properly. You may need the assistance of a sighted individual to help with troubleshooting. If the troubleshooting procedures do not help, if you need further assistance, or if you think the device may need service, use the information on the inside back cover of this manual to contact Wicab.

The BrainPort Vision Pro has no user-serviceable parts and does not require routine adjustment or calibration. You will void your warranty if you attempt to service the BrainPort Vision Pro.



DO NOT attempt to repair the BrainPort Vision Pro yourself.

To ensure that you receive accurate real-time information representative of the scene captured by the camera, the device selfmonitors and transitions from active mode to standby mode (stimulation disabled) whenever an irregularity occurs. These irregularities might be caused by electromagnetic interference, insufficient battery charge to continue operation, or other reasons. This is the normal and intended behavior of the device as it insures that you do not act upon potentially compromised or significantly time-delayed visual information. You must take action to return to active mode. The device prevents a return to active mode if the irregularity persists. Simply turning the power off, then restarting the device as usual will typically restore normal operation.

If the device emits 3 warning beeps and stops functioning, simply turn the power off, then restart the device as usual.

## **Problems with Battery Power**

The BrainPort Vision Pro battery status reports the estimated percentage of power remaining, assuming a fully charged battery was installed at the beginning of the session. In cases where a partially charged battery is used, the battery report may be approximate and put the device into low battery states more quickly than expected.

When the battery in the BrainPort Vision Pro nears the end of its useful life it may take longer to recharge and the duration of use following a recharge may be shorter. If you notice these changes, or suspect that you have other battery related problems, execute the steps below before contacting Wicab.



The BrainPort Vision Pro uses a rechargeable battery that contains electronic components that address safety requirements and that increase its useful life. These electronic components are not present in over-the-counter batteries. Using any other battery may damage the device and increase risk of use.



The battery charger supplied with the BrainPort Vision Pro is specifically designed for use with the battery of the BrainPort Vision Pro. Using any other battery charger may damage the device and increase risk of use.

Do not use the device with the Battery Pack door open.

Perform the following steps to identify the source of a battery power problem.

- 1. Follow the instructions in the battery charger manual to ensure the charger is working properly. If the behavior of your battery charger does not match the operation described in the manual, the problem is most likely to be with the battery charger. Use the information on the inside back cover of this manual to contact Wicab to report the charger problem.
- 2. If the charger functions correctly, fully charge a battery. Once charged, place the battery into the BrainPort Vision Pro Battery

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Pack and attempt to power up the device. If the device does not complete its startup sequence, repeat the prior test with your second battery. If the device still does not begin its startup sequence, the problem is most likely with the device. Use the information on the inside back cover of this manual to contact Wicab to report the device problem.

If, however, the startup sequence begins with one, but not the other, of your batteries, the problem is most likely with the battery that fails to power up the device. Use the information on the inside back cover of this manual to contact Wicab to report the battery problem.

- 3. With the fully charged battery inserted, turn your system on and note the time. If after two hours of continuous operation the device is still functioning correctly, your battery is functioning as expected. Repeat the two hour test on your second battery. Should either battery fail to operate the device for two hours or more, the battery is likely nearing the end of its natural life. Use the information on the inside back cover of this manual to contact Wicab for replacement batteries.
- 4. If you reach this point, your batteries are mostly likely functioning properly. If you continue to have problems with your device, proceed to the device troubleshooting section below.

## Headset Troubleshooting

Perform the following steps if you suspect a malfunction with the headset. If you identify a problem with the headset and contact Wicab, the support staff may ask for the serial number of the headset. This is found on the system label on the rear of the Battery Pack (see Product Label in Chapter 1).

- Place a fully charged battery into the Battery Pack and attempt to power up the headset. You should hear the unit 'ticking' until headset completes its startup sequence (by announcing "Starting" after about 15 seconds). If you don't hear either of these audio cues, go through the battery power troubleshooting procedure described above before continuing with troubleshooting the headset.
- 2. If the headset does not produce the ready for operation announcement of *"Ready*", the problem is most likely to be with the headset. Use the information on the inside back cover of this manual to contact Wicab to report the headset problem.
- 3. If the headset successfully completes the startup operation, depress each of the buttons and dials in turn. The headset should announce the setting with each depression. If it does not, the problem is most likely to be with the headset. Use the information on the inside back cover of this manual to contact Wicab to report the headset problem.
- 4. If the headset successfully recognizes button presses, increase the intensity and verify that you feel stimulation on your tongue from the IOD. If you do not feel any stimulation, the problem is most likely to be with the headset. Use the information on the inside back cover of this manual to contact Wicab to report the headset problem.

## WiFi/Webpage Troubleshooting

- Delayed camera image: due to Wi-Fi limitations an occasional delay in the camera image may occur. To minimize delay the distance between the REMOTE DEVICE and Headset should be less than 6 meters (20 feet).
- 2. Intermittent connection problems: replace the battery with a fully charged battery in the Headset.
- 3. Device WiFi identifier is not listed in the "Wireless Connection" dialog on the REMOTE DEVICE: replace the battery with a fully charged battery in the Headset.

If you continue to experience difficulties with the device or WiFi connection, contact Wicab for assistance.

### CHAPTER 4 Product Specifications and Technical References

This chapter provides technical reference material that may be useful to you, your doctor, your trainer, or local, state, and national regulatory agencies.

#### **General Specifications**

Ŕ	Type BF Equipment	
Physical	Length 22.9 cm (9.0 in) width 16.5 cm (6.5 in) height 6.35 cm (2.5in) weight <199 g (0.44 lb, including battery)	
Power	Internally powered by a lithium polymer rechargeable battery (3.7V, 2260mAh, 8.4Wh)	
Output Waveforms	Monophasic Capacitive coupling	
Pulse Frequency	200 Hz	
Pulse Width	25 μs	
Surface Area	0.46 mm <sup>2</sup> (per electrode)	
Voltage	0 to 1.2 V rms (per electrode) 0 to 11.8 V rms (device)	
Current	0 to 6.0mA rms (per electrode) 0 to 17.0 mA rms (device)	
Energy/pulse	0.5 μJ (see note below)	
Materials	The BrainPort Vision Pro is not made with natural rubber latex	
Disposal	Many localities have recycling requirements for batteries, electronic equipment, and packaging. Recycle or dispose of the device and its packaging in accordance with local ordinances.	
Environmental Conditions	Operating Conditions: - Temperature Range: 0°C to +40°C (32°F to +104°F) - Humidity Range: 5% to 95% - Atmospheric pressure range of 700 hPa to 1060 hPa Storage and Transportation Conditions (except batteries):	

	<ul> <li>Temperature Range: -25°C to +45°C (-13°F to +113°F)</li> </ul>		
	- Humidity Range: 5% to 95%		
	Storage and Transportation Conditions (batteries):		
	<ul> <li>Temperature Range: -20°C to +50°C (-4°F to +122°F)</li> </ul>		
	- Humidity Range: 5% to 85%		
IP Classification	The BrainPort Vision Pro is classified as IP22. The device is protected against solid foreign objects over 12 mm. Regarding 60601-1-11 8.3.1: Other than the IOD assembly, the Vision Pro is not designed to prevent ingress of water or other liquids per test of IEC 60529:1989 for IPX2. However, in all cases the device maintains BASIC SAFETY and ESSENTIAL PERFORMANCE (which may include cessation of operation) after undergoing the test. The IOD assembly is IPX4 rated (protection against splashing water)		
Intended Conditions for Use	<ul> <li>Non-Sterile</li> <li>Used in the home environment</li> <li>Used to augment white cane or guide dog.</li> <li>Does not replace white cane or guide dog.</li> <li>Typical duration of use: multiple sessions per day, usually less than an hour per session</li> </ul>		
Part Numbers	Headset: DR-001269 (Large) or DR-001270 (Small) Battery: DR-000839 (56446 702 099)		

Note: Stimulation is voltage controlled and limited to 16.7 Volts. Stimulation current depends on variations in user physiology and with the pressure of the tongue against the electrode array. Values given for current and energy per pulse are at maximum voltage into a 2770  $\Omega$  load, for a single electrode. Up to four electrodes may be active at any given time.

#### **User Profile**

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User	For use by individuals who are profoundly blind.
Education	Completed traditional blindness rehabilitation: white cane, and/or guide dog, and rehabilitation in activities of daily living
Knowledge	Minimum: ability to understand verbal training instructions Reading and comprehension at 10 <sup>th</sup> grade level
Experience	All users must participate in a minimum of 10 hours of supervised training per Wicab's training protocol prior to unsupervised use of the device
Permissible Impairments	Diagnosis of no light perception or light perception Blindness may be acquired or congenital Absence of oral sensory impairments

#### **Electromagnetic Compatibility**

Medical electrical equipment needs special precautions regarding electromagnetic compatibility. The BrainPort Vision Pro should be used according to the electromagnetic compatibility information provided below.



NOTE: The BrainPort Vision Pro (DR-001269, DR-001270) uses WiFi and an antenna. The following information is included for reference.

Your BrainPort Vision Pro contains a Wi-Fi transmitter and receiver with the following characteristics:

FCC ID	YKP1024119
Description	DM3730/AM3703 Torpedo + Wireless SOM
Model No.	SOMDM3730-32-2780AKCR

Other equipment may interfere with this device, even if that other equipment complies with CISPR emission requirements.

This equipment has been designed to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try the correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver
- Consult the dealer or an experienced radio/TV technician for help.

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The BrainPort Vision Pro has been designed to conform to IEC 60601-1-2 and is intended for use in the electromagnetic environment specified in the following tables. **However, the device has not yet been tested for compliance to this standard.** If you must use the BrainPort Vision Pro in close proximity to other electronic equipment, observe the device to verify normal operations before starting use.

#### **Table 1: Electromagnetic Emissions**

The user of the BrainPort Vision Pro should ensure that it is used in the intended environment, as specified below.

# Guidance and manufacturer's declaration – electromagnetic emissions

The BrainPort Vision Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the BrainPort Vision Pro should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The BrainPort Vision Pro must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The BrainPort Vision Pro suitability for use in all establishments, including
Harmonic emissions IEC 61000-3-2	Not applicable (internally powered)	domestic establishments and those directly connected to the public low- voltage power supply network, which
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable (internally powered)	supplies power for buildings used for domestic purposes has not been verified.

### Table 2: Electromagnetic Immunity

The user of the BrainPort Vision Pro should ensure that it is used in the intended environment, as specified below.

Guidance – elec	tromagnetic immuni	ty	
			nvironment specified below. The is used in such an environment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Not Yet Tested	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output Lines	Not Yet Tested	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable (internally powered)	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11		Not applicable (internally powered)	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not Yet Tested	Magnetic fields from common appliances are not expected to affect the BrainPort Vision Pro.
Note: $U_{\rm T}$ is the a.c. main	ns voltage prior to application	on of the test level.	•

### Table 3: Electromagnetic Immunity

Users of the BrainPort Vision Pro should ensure that it is used in the intended environment, as specified below.

Guidance – ele	ectromagnetic immu	nity	
The BrainPort Vision Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the BrainPort Vision Pro should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to the BrainPort Vision Pro, including cables, than the recommended separation distance calculated from the equation that applies to the transmitter's frequency.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms; 150 kHz to 80 MHz	Not Yet Tested	d =0.58√P
Radiated RF IEC 61000-4-3	3 V/m; 80 MHz to 2.7 GHz	Not Yet Tested	<i>d</i> =0.35√ <i>P</i> 80 MHz to 800 MHz
			<i>d</i> =0.7√ <i>P</i> 800 MHz to 2.5 GHz
			Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and $d$ is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>
			Interference may occur in the vicinity of equipment

marked with the fo symbol:
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Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- <sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider doing an electromagnetic site survey. If the measured field strength in the location in which the BrainPort Vision Pro is used exceeds the applicable RF compliance level above, observe the BrainPort Vision Pro to verify normal operation. If you detect abnormal performance, additional measures may be necessary, such as reorienting or relocating the BrainPort Vision Pro.
- $^{\rm b}$  Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

#### **Table 4: Recommended Separation Distances**

Users of the BrainPort Vision Pro should ensure that it is used in the intended environment, as specified below.

## Recommended separation distances between portable and mobile RF communications equipment and the BrainPort Vision Pro.

The BrainPort Vision Pro is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BrainPort Vision Pro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BrainPort Vision Pro as recommended below, according to the maximum output power of the communications equipment. In the event that proximity of Vision Pro to a non-WiFi user of this spectrum causes unacceptable interference, increase the separation distance between the devices.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter Meters (m)		
W	<b>150 kHz to</b> <b>80 MHz</b> <i>d</i> = 0.58√ <i>P</i>	80 MHz to 800 MHz d = 0.35√P	800 MHz to 2.5 GHz d = 0.70√P
0.01	0.06	0.04	0.07
0.1	0.18	0.11	0.22
1	0.58	0.35	0.70
10	1.8	1.1	2.2
100	5.8	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

#### Warranty

Limited Product Warranty. Wicab, Inc. (the "Company") warrants to the purchaser ("Purchaser") (limited to the original Purchaser and to no other person) that the Product and the component parts thereof manufactured and distributed by the Company will meet the specifications stated on the Product specification sheets and shall be free from defects in workmanship and materials for a period of two years (Service Life) measured from the date the Product does not conform to these specifications, the Company will, at its sole discretion, as its sole and exclusive liability and as to the Buyer's sole and exclusive remedy, repair or replace the Product with a new or factory reconditioned Product at no charge or refund the cost of the Product; provided that notice of nonconformance (setting forth in reasonable detail the nature of the nonconformance) is given the Company within the Warranty Period and within 30 calendar days of the discovery of the defect or nonconformance.

This warranty limits the Company's liability to the repair or replacement of Product or refund of the cost of Product. No other warranties of any kind, express or implied, including without limitation, an implied warranty of merchantability or fitness for a particular purpose or noninfringement, are provided by company. Company shall in no event be liable for personal injury or property damage or any other loss, damage, cost of repair, or direct, indirect, incidental, special, consequential, or punitive damages of any kind, whether based upon warranty, contract, strict liability, negligence, or any other cause of action, arising out of the sale, use, results of the use or inability to use product or its components. The foregoing shall apply, without limitation to losses of profits, business interruption, damages to purchaser's reputation or any other such damages.

**Limitation of Liability**. With respect to any Company liability not legally subject to the foregoing terms, the Company's liability shall not exceed the amount paid by Purchaser to the Company for the Product.

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#### **Appendix A Cleansers**

Wicab recommends that you clean the IOD once per week using the cleansers listed in the table below. If the cleanser is in solution, wet a cotton ball or cotton swab and gently wipe the surfaces of the IOD. DO NOT SCRUB! Thoroughly rinse the IOD with tap water to remove any residual cleanser and allow it to air-dry.

The cleansers listed below have been tested and shown to be compatible with the materials used in the IOD. Follow the manufacturer's directions regarding safe use and disposal for the cleanser.

Please visit our website for the most recent list of approved cleansers. Cleansers are added to the list as they are tested and shown to be compatible with the IOD.

Cleanser	Source
70% isopropyl alcohol (rubbing	Over the Counter (local pharmacy)
alcohol)	May be in solution or as 'wipes'



The IOD may be damaged by bleach or oxidizing agents. Do not use any product that contains chlorine, sodium hypochlorite, calcium hypochlorite, hydrogen peroxide, sodium percarbonate, sodium perborate, or similar chemical. Household bleach and over-the-counter whitening agents will damage the IOD.

### **User Assistance**

If you need assistance setting up, using or maintaining the BrainPort Vision Pro, or to report unexpected operation or events, please contact Wicab, Inc. by mail, telephone, or e-mail:

#### North America

Wicab, Inc. Attn: Customer Support 8313 Greenway Blvd. Suite 100 Middleton, WI 53562 USA

Telephone:	1.608.829.4500
Fax:	1.608.829.4501
E-Mail:	customersupportus@wicab.com
Internet:	www.wicab.com

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#### Correct Disposal of This Product (WEEE - Waste Electrical & Electronic Equipment)

This marking on the product, accessories or literature indicates that the product and its electronic accessories should not be disposed of with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled

waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources.

Household users should contact either the distributor where they purchased this product or their local government office for details of where and how they can take these items for environmentally safe recycling.

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