



Second Sight

**Argus® II**  
**Retinal Prosthesis System**

**Patient Manual**

**[REF]** 090000-002

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

**HUMANITARIAN DEVICE:** Authorized by Federal (U.S.) law to provide electrical stimulation of the retina to induce visual perception in blind patients with severe to profound retinitis pigmentosa and bare light or no light perception in both eyes. The effectiveness of this device for this use has not been demonstrated.



# **Argus® II**

## **Retinal Prosthesis System**

### **Patient Manual**

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# Chapter 1: Glossary

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Term	Definition
Choroid{ XE "choroid" }	A thin layer of cells between the retina and the sclera that contains pigments and blood vessels that bring oxygen and nutrients to the retina (See Figure 1)
Communication Adapter (CA)	A device that is connected to the Video Processing Unit (VPU) when the VPU is hooked up to a computer in the clinic
Conjunctiva{ XE "conjunctiva" }	A thin layer of tissue that covers the white part of the eye and the inner surface of the eyelids (See Figure 1)

Term	Definition
Cornea{ XE "cornea" }	The clear layer of tissue, shaped like a dome, that lies on top of the iris and the pupil. The cornea is the eye's outer lens. It gives the eye its major focusing ability. (See Figure 1)
Cyst	A closed sack of abnormal tissue which may contain air, fluids, or semi-solid material
Diagnosis	The identification of disease by its symptoms and signs
Electrode Array	A rectangular grid of electrodes used to stimulate the retina
Electrical Stimulation	A technique that uses electrical currents to activate nerve fibers

Term	Definition
Electromagnetic Interference{ XE "electromagnetic interference (EMI)" } (EMI)	A field of energy (electrical, magnetic, or both) created by electronic equipment. This field of energy may be strong enough to interfere with the normal operation of your Argus II System.
Electrostatic Discharge (ESD{ XE "electrostatic discharge (ESD)" })	A momentary unwanted flow of electrical current that can cause damage to electronic equipment
Incision	The surgical cut created in your eye by the doctor so that the Argus II Implant can be placed in your eye

Term	Definition
Iris{ XE "iris" }	<p>The iris is the round structure in the eye that gives someone his or her eye color. For example, blue-eyed people have a blue iris while brown eyed people have a brown iris. The center of the iris is an opening called the pupil. The iris controls the size of the pupil when it reacts to the amount of light that is present.</p> <p>(See Figure 1)</p>
Radio Frequency{ XE "Radio Frequency (RF)" }	<p>Any electromagnetic frequency within the range used for wireless communication</p>
Retina{ XE "retina" }	<p>A thin layer of nerve cells at the back of the eyeball which converts light into nerve impulses that travel to the brain</p> <p>(See Figure 1)</p>

Term	Definition
Sclera{ XE "sclera" }	The white outer coating of the eye made of tough tissue which allows the eye to keep its shape and helps to protect the delicate inner parts of the eye (See Figure 1)
Therapy	Treatment of disease or disorders
VPU{ XE "VPU" } (Video Processing Unit)	The part of the Argus II System that processes the information that is sent to and from the implant inside your eye

**Figure 1: Parts of the Human Eye**

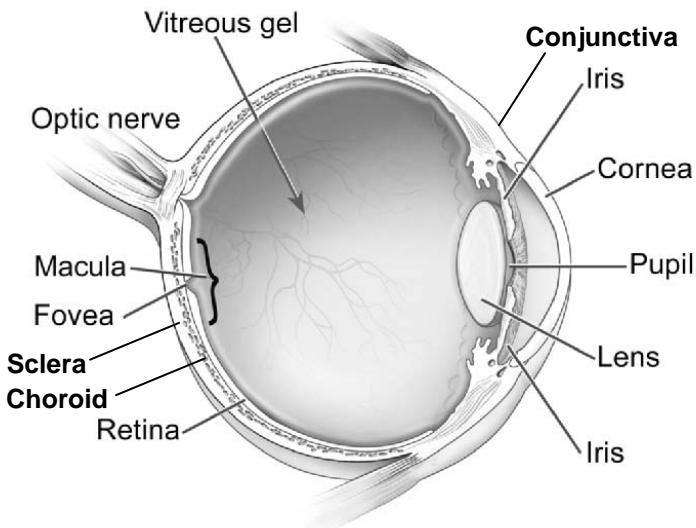


Image courtesy of the National Eye Institute,  
National Institutes of Health

## **Chapter 2: Descriptive Information**

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### **Indications for Use{ XE "indications for use" }**

The Argus II Retinal Prosthesis System is intended to provide electrical stimulation of the retina to induce visual perception in blind patients. You are eligible for the Argus II system if you have severe to profound retinitis pigmentosa and you meet the following criteria:

- You must be an adult, age 25 years or older.
- You must have bare light or no light perception in both eyes. If you do not have any remaining light perception, your doctor will test your eye to make sure it will respond to electrical stimulation.
- You need to have been able to see objects, shapes and lines in the past.
- In the eye that will be implanted, you either need to have an artificial lens or no lens at all. (If the eye that will be implanted still has a natural lens, your doctor will remove this lens during the implant surgery.)
- You must be willing and able to follow the recommended schedule of clinical follow-

up, device programming and visual rehabilitation after you are implanted.

Your doctor will implant the Argus II Implant in only one of your eyes, most likely the eye that has the worse vision. Your doctor will discuss with you which eye is best for the implant before your implant surgery.

## **Device Description**

The Argus II Retinal Prosthesis System consists of the following main parts and accessories:

- Argus II Retinal Prosthesis (Implant)
- Argus II Video Processing Unit (VPU)
- Argus II Glasses (Glasses)
- Accessories:
  - VPU Rechargeable Battery
  - VPU Battery Charger
  - VPU Pouch
  - Travel Case

**WARNING**



**Do not use any equipment with your Argus II System other than that supplied by Second Sight.**

**If you use cables or batteries not supplied by Second Sight, your Argus II system may be more likely to experience interference from other electronic devices. The use of non-approved cables or batteries may also cause the Argus II System to interfere with other electronic equipment.**

Refer to the Appendices A and B for more information about interference with other electronic equipment.

### *How Does the Argus II System Work?*

You will have the Argus II Retinal Prosthesis implanted in and around your eyeball. To turn on and use the implant, you need to wear the glasses and VPU.

When you are using the system, a miniature video camera on the glasses captures images in real time. The glasses send these images to the VPU. The VPU converts these video images into electrical signals and send them back to the glasses. The coil on the glasses sends the signals wirelessly to the implant. The implant then sends out small pulses of electricity to the retina in your eye. These pulses stimulate your retina. Your retina sends the nerve signals along the optic nerve to your brain. You perceive these pulses as patterns of light. Over time, you may learn how to

interpret these visual patterns as objects and shapes.

Note: The implant is on only when you are wearing the glasses and have the VPU turned on. Otherwise, the implant is off.

The sections below describe each of the parts of the Argus II System.

### **Argus II Retinal Prosthesis (Implant)**

The implant consists of four parts: (1) the electronics case (2) the implant coil, (3) the electrode array, and (4) the scleral band.

Figure 2 shows the implant as it looks after it has been implanted. Part of the implant sits on the outside of your eye and part goes inside your eye. The implant is not visible to other people.

The electronics case, the implant coil and the scleral band sit on the outside of the eye. The scleral band wraps around your eye and holds the implant in place. A thin layer of tissue that covers the white part of the eye also covers the parts of the implant that sit on the outside of the eye.

A cable connects the electronics package to the electrode array. This cable enters your eye through an incision made during surgery. At the end of cable is the electrode array. The electrode

array is attached to the surface of your retina with a retinal tack.

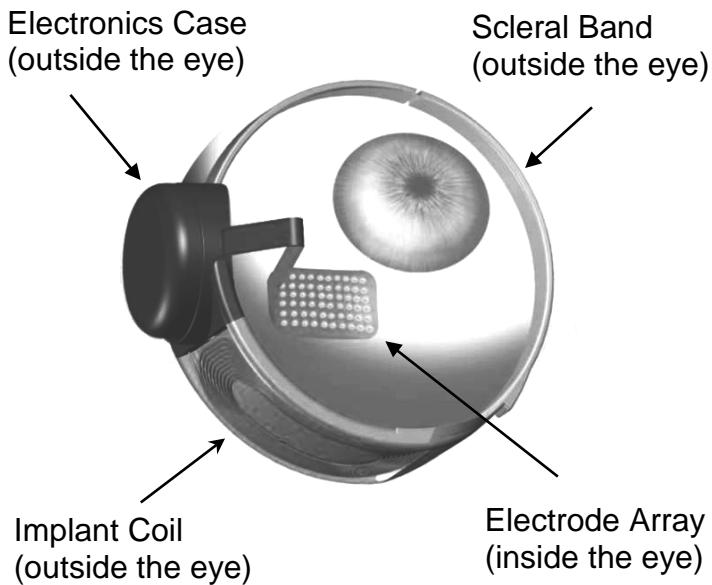
The electrode array provides electrical stimulation to your retina. It has 60 electrodes arranged in a rectangular grid. Fifty-five of these electrodes are turned on at the time of implant. Up to 5 of the remaining electrodes may be functional and could be turned on to replace an electrode that is not working.

#### *Patient Contacting Materials of the Implant and Tack*

The implant and retinal tack are made of following materials:

- Niobium
- Platinum
- Polyimide (plastic)
- Silicone Rubber
- Titanium

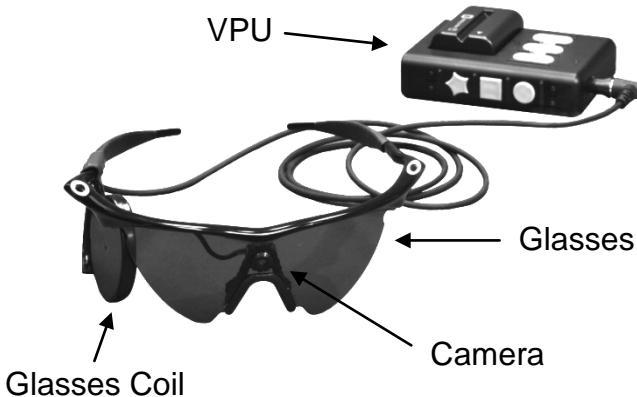
**Figure 2: Implant on a Right Eye  
(looking at your eyeball)**



## External Equipment

Figure 3 shows the VPU, glasses, and battery{ XE "external equipment" }.

**Figure 3: External Equipment**



### *Video Processing Unit (VPU){ XE "VPU" }*

The VPU allows you to turn stimulation on and off. Using the buttons on the VPU, you can change the stimulation program to suit your current environment. The VPU buttons are large and have distinct shapes so that you can easily identify them by touch.

The VPU connects to the glasses using a cable. The cable from the glasses plugs into the glasses receptacle on the VPU to connect these two parts. You must wear both the VPU and glasses for the system to work.

The VPU keeps track of when you turn it on and off, and it keeps a record of how well your implant and VPU are functioning. The VPU also records when there is break in the wireless link between the implant and glasses. Your clinician can check all of this information when you visit the clinic.

There is a “communication adaptor connector” on the bottom of the VPU. Your clinician will use this connector in the clinic to connect the VPU to a computer. A metal door covers this connector. The VPU with the battery weighs about half a pound (0.23 kilograms). See Figure 4 for a diagram of the VPU.

**Figure 4: VPU{ XE "VPU" }**

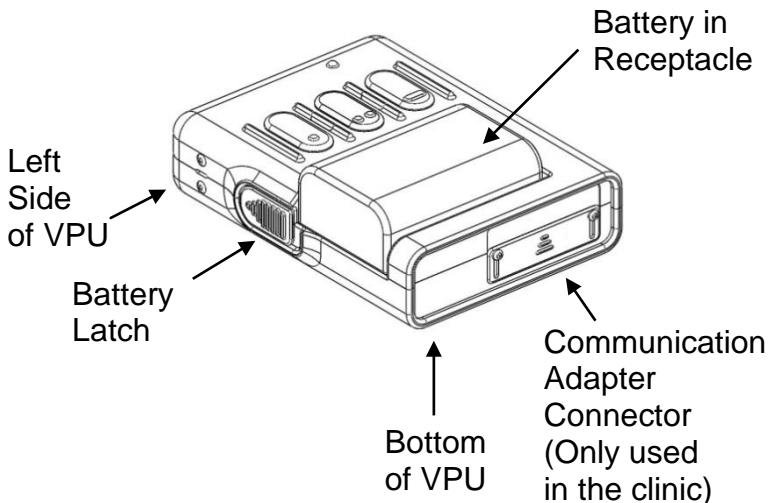
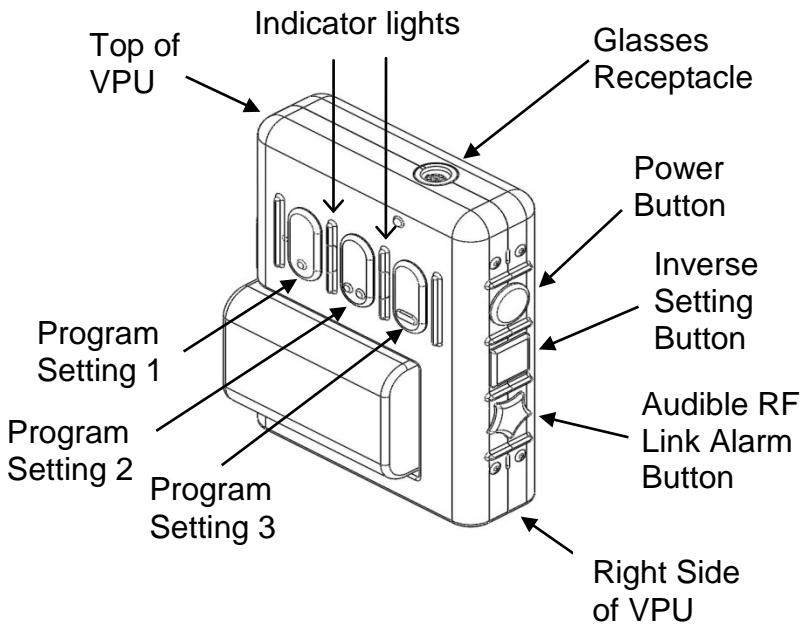


Table 1 describes the parts of the VPU. Table 2 describes the accessories that you use with the VPU.

**Table 1: VPU{ XE "VPU" } Components**

Component	Description
Case	The case is the outside of the VPU.
Power Button	The power button is a round-shaped button located on the right side of the VPU. You use this button to turn the VPU on and off.
Program Setting Buttons	The Program Setting buttons{ XE "VPU:program setting buttons" } are the three oval-shaped buttons located on the front of the VPU. You press these buttons to select a stimulation program. The button with a single circle is Program Setting 1. The button with two circles is Program Setting 2. The button with a small bar is Program Setting 3. The VPU starts in Program Setting 1 each time you turn it on.

Component	Description
Inverse Setting Button	<p>The inverse button is the square-shaped button located on the right-hand side of the VPU. You use this button to invert{ XE "VPU:invers setting button" } the image from black-to-white and white-to-black. Each time you press it, the VPU inverts the image. The VPU starts in “non-invert” mode each time you turn it on.</p>
Link Alarm Button{ XE "VPU:RF link alarm" }	<p>The link alarm button is the star-shaped button located on the bottom of the right side of the VPU. You use this button to turn the audible link alarm on and off. This alarm sounds if the VPU loses communication with the implant. Each time you turn the VPU on, the VPU starts up with the link alarm on.</p>
Battery Receptacle	<p>The battery receptacle holds the battery in place on the VPU. It is located on the front panel below the program setting buttons.</p>

<b>Component</b>	<b>Description</b>
Battery Latch	The battery latch is located on the left side of the VPU. The latch holds the battery in place. To remove the battery, you must first slide the latch to its “un-locked” position.
Indicators Lights	Three indicator lights are located on the front of the VPU between the program setting buttons. These give a visual indication of the status of the VPU. For example, the orange light will come on if the glasses cable is not properly connected to the VPU. Refer to Table 7 on page 76 for a description of each of these lights.
Glasses Receptacle	The glasses receptacle is a round connector on the top of the VPU. You attach the glasses to the VPU by plugging them in to this receptacle.

Component	Description
Communication Adapter (CA) Connector	The Communication Adapter Connector is rectangular connector located on the bottom of the VPU. A metal door covers this connector. To program the VPU, your clinician connects a computer to your VPU using this connector.

**Table 2: VPU Accessories**

Accessory	Description
Battery{ XE "battery" }	Rechargeable batteries power the VPU. You can choose to use either small or medium sized rechargeable batteries. Only use rechargeable batteries provided to you by Second Sight.
Battery Charger	Recharge the batteries using the battery charger provided with the Argus II System.
VPU Pouch	The pouch allows you to wear the VPU rather than carrying it. With the pouch, you can wear the VPU on your belt or over your shoulder.

## Glasses

The glasses{ XE "glasses" } have a miniature video camera in the bridge above the nose. The glasses also have a coil on one of the earpieces. The coil sends power to the implant and communicates wirelessly with it. The glasses connect to the VPU with a cable. See Figure 5. Table 3 provides a description of the parts of the glasses and the storage case for the Argus II System components.

**Figure 5: Glasses for the Right Eye**



### *Patient Contacting Materials of the Glasses*

The glasses{ XE "glasses:materials" } are mostly made of plastic and include the following materials:

- Acrylonitrile Butadiene Styrene (ABS)
- Aluminum

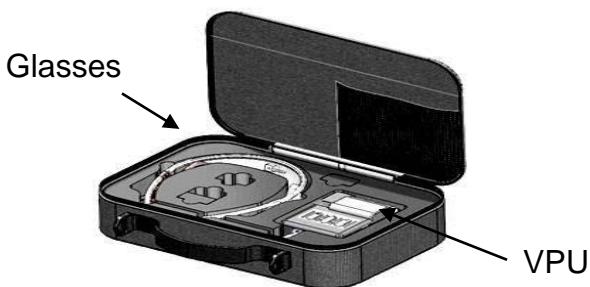
- Carbon fiber
- Nylon
- Polycarbonate
- Polyvinyl chloride (PVC)
- Thermoplastic Elastomeric

**Table 3: Glasses Components and Accessories**

Component	Description
Glasses	The glasses{ XE "glasses" } are a pair of sunglasses that have a miniature video camera and coil attached to them.
Camera	A miniature video camera{ XE "camera" } is located in the center of the glasses frame directly above the nose bridge. The camera sends video images to the VPU.
Glasses Coil	The glasses coil contains the receiver and transmitter antennae. The coil is located on the arm of the glasses on the side where the implant is located. The Argus II system uses the coil to communicate wirelessly with the implant.

Component	Description
Cable	The cable connects the glasses to the VPU. The cable is part of the glasses. Do not attempt to remove the cable from the glasses.
Travel Case{ XE "travel case" }	Use the travel case to safely store and transport the VPU, glasses and batteries. See Figure 6.

**Figure 6: Travel Case**



## Argus II System Wireless Information

The Argus II Glasses use wireless technology{ XE "wireless technology" } to power the implant and to send and receive information from the implant. Table 4 below summarizes information about the wireless technology used in the Argus II System.

**Table 4: Wireless Technology Specifications**

Frequency (to the implant)	3.156 Megahertz (MHz)
Frequency (from the implant)	473 – 490 Kilohertz (KHz)
Bandwidth (to the implant)	13 Kilohertz (KHz)
Bandwidth (from the implant)	20 Kilohertz (KHz)
Power (to the implant)	Amplitude modulation (AM) Less than 1.2 watts
Power (from the implant)	Frequency shift keying (FSK) Less than 10 microwatts
Wireless Link Performance	The system maintains wireless link more than 90% of the time when the coil is approximately 1 inch (2.5 cm) or closer to the implant.

## *How to Achieve Wireless Link with the Glasses*

Wear the glasses as you would a typical pair of glasses. Your clinician positions the glasses coil to ensure that it has good wireless link with the implant. The glasses and the implant automatically connect and operate when the glasses are placed on your head and the VPU is turned on. Refer to “Wearing the Glasses” on page 71 for more details.

## *Wireless Security*

The Argus II implant only operates if it is within a very short distance from the coil on the glasses. The Argus II System uses coded signals to make it harder for outside sources to accidentally or intentionally control the System. The Argus II System does not store or send any information, such as your name, that would allow you to be identified.

## *Quality of Service*

In order for your Argus II System to work, the Glasses and VPU cannot lose the communication link with the implant. The glasses and VPU communicate with the implant through a wireless link. For the wireless link to work, the glasses coil must be close to the implant. To make sure the system works properly, wear your glasses in the same position as they were when you were fitted

in the clinic. When the wireless link between the glasses and implant is broken, an alarm will sound and will continue to sound until the wireless link is restored. You may lose the link in the presence of strong magnetic or radio fields. Refer to the section entitled “Possible Interference with Other Electronic Devices” on page 39 and Appendices A and B for more information on interference related to the wireless system.

For Troubleshooting regarding link loss, see page 97.

## Argus II Patient Catalog

The following items are included in your Argus II Retinal Prosthesis Patient Catalog{ XE "catalog numbers" }:

**Table 5: Patient Catalog**

Description	Catalog / Product Number
Argus II Video Processing Unit{ XE "VPU" } including Patient Manual	013003
VPU Batteries: VPU Battery{ XE "VPU battery" } (small) VPU Battery (medium)	100200-001 100200-002
Argus II Glasses{ XE "glasses" }: Glasses, Right Eye, Dark Lenses Glasses, Right Eye, Clear Lenses Glasses, Left Eye, Dark Lenses Glasses, Left Eye, Clear Lenses	012011 012012 012013 012014
VPU Battery Charger{ XE "battery charger" }	100200-004

<b>Description</b>	<b>Catalog / Product Number</b>
Argus II Travel Case{ XE "travel case" }	012930
Argus II VPU Pouch{ XE "VPU pouch" }	013931

## **When the Device Should Not be Used (Contraindications)**

You should not have the Argus II Retinal Prosthesis{ XE "contraindications" } implanted if you:

- Have an eye disease or condition that could prevent the Argus II System from working properly. { XE "strabismus" }
- Have an eye structure or condition that could make it difficult to successfully implant the Argus II Implant or recover following surgery. For example, if you have a very long or very short eye, you may not be eligible for the Argus II Implant.
- Have eye diseases or conditions that make it difficult for your doctor to see inside your eye. For example, if you have a cloudy cornea, you may not be eligible for the Argus II Implant.
- Are unable to undergo general anesthesia{ XE "anesthesia" }{ XE "general anesthesia" }
- Are unable to take the recommended antibiotic{ XE "antibiotic" } and steroid{ XE "steroid" } medications that you need to take before and after implant surgery.
- Have a metallic or active implantable device in your head. For example, if you have a

cochlear implant, you are not eligible for an Argus II Implant.

- Have any disease or condition that prevents you from understanding or giving your informed consent. For example, if you have difficulty remembering things, you may not be eligible for an Argus II Implant. Your doctor may ask you to have a psychological evaluation to make sure you are qualified for this device.
- Have any disease or condition that prevents you from having medical follow-up or having the VPU programmed.
- Tend to rub your eye a lot.

## **General Warnings and Precautions**

### **Warnings**

Once you have an Argus II Implant:

- **Do not** undergo **short wave or microwave diathermy**{ XE "diathermy" }. These procedures could cause high electrical current in the implant electrodes that could cause tissue damage or serious injury. Diathermy may also cause permanent damage to the implant.
- **Do not** undergo **electroconvulsive therapy (ECT)**{ XE "electroconvulsive

therapy (ECT)" }. ECT may damage your eye or your Argus II Implant.

- **Avoid lithotripsy{ XE "lithotripsy" } or high output ultrasound{ XE "ultrasound" }.** These procedures may harm you or damage the implant. If you need one of these procedures, inform your doctor that you have this implant. Your doctor should contact Second Sight Medical Products for instructions on how to perform these procedures in someone who has an Argus II Implant.
- **Do not enter a room housing a magnetic resonance imaging (MRI){ XE "magnetic resonance imaging (MRI)" } System that has a rating other than 1.5 or 3.0 Tesla,** even if you are not using Argus II System.

The only part of the Argus II System that has been tested for use with MRI is the implant. The **Argus II Implant is classified as an MR Conditional{ XE "magnetic resonance imaging (MRI):MR conditional" }** device.

If you have an Argus II Implant, you may undergo an MRI procedure ONLY if it is performed using a 1.5 or 3.0 Tesla MRI System and ONLY following special instructions. Before having an MRI procedure, tell your doctor that you have

the Argus II Implant. Your doctor should contact Second Sight Medical Products for these instructions on how to perform an MRI in someone who has an Argus II Implant.

If you feel any pain{ XE "pain" } during the MRI procedure, tell the technician immediately.

**Do not take the VPU or glasses into the MR system room. The VPU and glasses are MR Unsafe. Severe harm to people in the MR system room or damage to this equipment may result.**

- **Do not** use the Argus II System within 3 feet (0.9 meters) of **medical monitoring, diagnostic or life support equipment**. Using the Argus II system near this equipment may cause the equipment to function improperly. If someone notices that interference is occurring, turn off the Argus II VPU or extend the distance between yourself and the equipment.
- **Do not** receive treatment with **monopolar electrosurgical equipment{ XE "electrosurgical equipment" }**. Monopolar electrosurgical equipment may damage the implant or the tissue around the implant.

## **General Precautions**

- **Stop** using the Argus II System if you experience any uncomfortable feeling such as pain{ XE "pain" }. Should this occur, immediately take off the Argus II Glasses or turn off the Argus II VPU. Then contact your doctor or programming clinician to report the problem.
- Contact your doctor promptly if you feel any pain or watering in your implanted eye or if you have the feeling that something is in your implanted eye. This may be a sign that you have a complication on the outside or inside of your eye. If your doctor does not examine your eye when you have these symptoms, you may develop an infection in your eye or have other serious complications.
- The long-term effects of electrical stimulation are unknown. It may cause damage to the retina or optic nerve. This sort of damage could lead to a decline in your normal remaining vision and/or how well you see with the Argus II System. It could also prevent you from getting a replacement Argus II Implant or another type of retinal implant or treatment in the future.
- **Do not** use anyone else's VPU. Only use the VPU that your clinician programmed for you. Using someone else's VPU may limit

how well you see with the Argus II System. It could also cause you pain{ XE "pain" } if it provides stimulation that is too strong.

- **Avoid** physical impact or extreme direct pressure to the eye. This could cause injury to your eye, movement of the implant in your eye, or damage to the implant.. If this occurs, contact your physician.
- **Avoid** rubbing your implanted eye. This may dislodge the implant or cause eye irritation.
- **Do not** rely on the Argus II System as your only aid when walking. The Argus II System will not provide you with enough vision to walk safely without any other aids. Even though you have the Argus II Implant, continue to use your other mobility aids (for example, canes, dogs) at all times.
- **Do not** use the Argus II System during pregnancy or when nursing a baby. Second Sight has not evaluated the use of the Argus II System by women who are pregnant or who are nursing a child{ XE "pregnancy and nursing" }.

### **Electromagnetic Interference (EMI){ XE "electromagnetic interference (EMI)" }**

Electromagnetic interference is a field of energy (electrical, magnetic, or both) created by

equipment found in public environments that may be strong enough to interfere with the normal operation of your Argus II System.

The Argus II System meets international standards for electromagnetic compatibility (See Chapter 8 and Appendix B for more information). The Argus II System continues to operate in a “safe mode” in the presence of any electromagnetic interference that you would encounter during your normal everyday activity.

It is important to note, however, that in certain circumstances, electromagnetic interference could cause:

- Serious injury. Exposure of your implant to EMI may result in your implant heating and damaging nearby retinal tissue. See “Warnings” on page 29.
- Damage to your Argus II Implant. Damage to the implant may require replacement; or result in loss of, or irreversible change in the performance of the Argus II System. See “Warnings” on page 29.
- Unexpected shutdown of the Argus II VPU. EMI may cause your VPU to turn off unexpectedly.
- Interruption of Stimulation. EMI may cause a momentary interruption of stimulation.

If you suspect that electronic equipment is causing interference with your Argus II System, you should do the following:

1. Move away from the equipment or object thought to be causing the interference.
2. If possible, turn off the equipment or object causing the interference.
3. Tell the equipment operator or your doctor what happened.

If you continue to experience interference, or if you think that your Argus II System is not working as well as it did before you encountered the interference, please contact your doctor.

The following sections provide additional information regarding potential sources of electromagnetic interference:

- *Precautions Regarding Other Medical Procedures*
- *Possible Interference from Other Electronic Devices*
- *Air Travel, General Travel and International Use*

The potential effects of EMI from devices or procedures are summarized in Appendix A.

Additional information about electromagnetic compatibility is included in Appendix B.

## Precautions Regarding Other Medical Procedures

### General Information (applicable to all procedures)

- If you need to undergo any of the procedures listed below, please inform your doctor that you have a retinal prosthesis in your eye. Your doctor should contact Second Sight at 1-818-833-5060 for more information.
- **Do not wear or use your Argus II Glasses or VPU when undergoing a medical test or procedure, unless you are having a vision test.** Using or wearing the Argus II Glasses or VPU during these procedures could cause you harm. It might also make it difficult for your doctor to understand the results of the test. Finally, it could damage the Argus II equipment.
- Once the procedure is complete, you should have your clinician test your Argus II Implant as soon as possible to make sure it is still functioning properly. Damage to the implant may not be immediately detectable.

### Information about Specific Procedures

- **Magnetic Resonance Imaging (MRI)** {  "magnetic resonance imaging (MRI)" } –

Refer to section “Warnings” on page 29 for information about MRI.

- **Avoid the use of **laser**{ XE "laser" }, **fragmatome**{ XE "fragmatome" } or **phacoemulsification**{ XE "phacoemulsification" }** in your implanted eye. These procedures may damage the Argus II Implant.
- **Avoid the use of **bipolar electrosurgical equipment**{ XE "electrosurgical equipment" }** in your implanted eye. This equipment may damage the Argus II Implant.
- You may undergo computed tomography scan{ XE "computed tomography scan (CT scan)" } **(CT Scans)** or **Diagnostic Ultrasound**. However, if you need a scan or ultrasound{ XE "ultrasound" } in the area where the Argus II Implant is located, the implant may block or blur the image making the scan unreadable in this area.
- Use of **defibrillator**{ XE "defibrillator" }s or **radiation therapy**{ XE "therapeutic ionizing radiation" } to the head may permanently damage the Argus II Implant. However, this should not stop you from receiving these treatments if necessary.
- The effects of **cobalt treatment**{ XE "cobalt treatment" } or **linear acceleration**{ XE }

"linear acceleration" } **techniques** on the implant are unknown.

## Possible Interference from Other Electronic Devices

- **Avoid Theft{ XE "detector:theft" } or metal{ XE "detector:metal" } detectors** (such as those located in entrances to public buildings and department stores) and **airport{ XE "airport" } or security screening{ XE "security screening" } devices**. If unavoidable, turn off your VPU, walk through the scanner, and quickly move away from the area. **Do not** lean on these scanners or linger in their path. These devices may temporarily interrupt Argus II stimulation if you are using the Argus II System within 1 yard (0.9 meters) of them. Your Argus II System will start operating normally when you move away from these items. You should show your patient identification card to any attendant in the area who may be able to assist you in bypassing these devices.
- **Avoid Electronic Article Surveillance{ XE "electronic article:surveillance" } (EAS) systems, EAS Tag Deactivators{ XE "electronic article:deactivator" }, and Radiofrequency identification (RFID){ XE "radiofrequency identification (RFID)" }**

systems. These systems may temporarily interrupt Argus II stimulation if you are using your Argus II System within 3.5 yards (3.2 meters) of them. Your Argus II System will start operating normally when you move away from these items. RFID systems, EAS systems and tag deactivators send out energy fields that wirelessly communicate with tags attached to objects such as merchandise, materials and people. Business uses these systems for security, theft prevention, tracking and inventory control. Retail stores, libraries, government buildings, warehouses and offices often use these systems. For example, security tags attached to clothing contain RFID tags.

- **Avoid** handling the VPU and glasses if you suspect there may be **static electricity**{ XE "static electricity" } present. Static electricity may interfere with normal operation or cause damage to the Argus II System. For example, walking across carpet in a low humidity environment can cause you to build up static electricity.
- The Argus II System may interfere with the normal operation of some models of **hearing aids**{ XE "hearing aids" }. If you wear a hearing aid, you should have it tested with the Argus II System before implant surgery to make sure both the

hearing aid and Argus II System will function properly.

- **Avoid home appliances**, such as microwaves,{ XE "microwaves" } and some **devices with antennae**, such as cell phones, when using the Argus II System. Home appliances and devices with antennae may temporarily interrupt Argus II stimulation. The table below lists the distance at which interruption of stimulation may occur with these systems.

**Table 6: Separation Distances**

Type of device	Distance from the Argus II System
Another Argus II System	7 inches (17.5 cm)
Cell phone	1 inch (2.5 cm)
Cordless phone	1 inch (2.5 cm)
Bluetooth{ XE "bluetooth" } device	1 inch (2.5 cm)
Microwave oven	1 inch (2.5 cm)
WiFi{ XE "WiFi" } Access Point	8 inches (20 cm)
Wireless Router{ XE "wireless router" }	8 inches (20 cm)

Devices with antennae may be marked with the following symbol:



Normal operation will resume when you move away from these items.

- **Do not** turn on the Argus II System on an **airplane**{ XE "airplane" }. The Argus II System operates using wireless technology that could interfere with the safe operation of an airplane.
- **Avoid** commercial electrical equipment, communication equipment, high voltage lines, power lines or generators,{ XE "power generators" } electric steel furnaces, or large magnetized speakers. These types of equipment may temporarily interrupt Argus II System function. Normal operation should resume when you move away from these objects.

Examples of commercial electrical equipment include arc welders, induction furnaces and resistance welders. Examples of communication equipment include microwave transmitters, linear power amplifiers and high-power amateur transmitters.

## **Air Travel, General Travel and International Use**

**CAUTION: Do not turn on the VPU or use the Argus II System on an airplane**{ XE "airplane" }. The Argus II System operates using wireless

**technologies that could interfere with the safe operation of an airplane.**

You may want to travel with your Argus II System. When travelling and not using the Argus II System, store the Glasses and VPU in the travel case.

If you will be traveling outside the United States, you may need an adapter to plug the VPU battery charger into the electrical outlet.

Bring your patient identification card with you to assist in going through security systems. The section below describes the patient identification card. Turn off the VPU when you go through security.

If your eye is experiencing any medical complications before your trip, speak with your doctor to determine if it is safe for you to travel, especially on a plane. You may also wish to speak with your doctor in advance of your trip to obtain the name of a local ophthalmologist in the event of any complications during your trip.

For more information about travel, contact the Transportation Security Administration (TSA):{ XE "Transportation Security Administration (TSA)" }

Website: [www.tsa.gov](http://www.tsa.gov)

Email: [TSAContactCenter@dhs.gov](mailto:TSAContactCenter@dhs.gov)

TSA General Phone Number: 866-289-9673

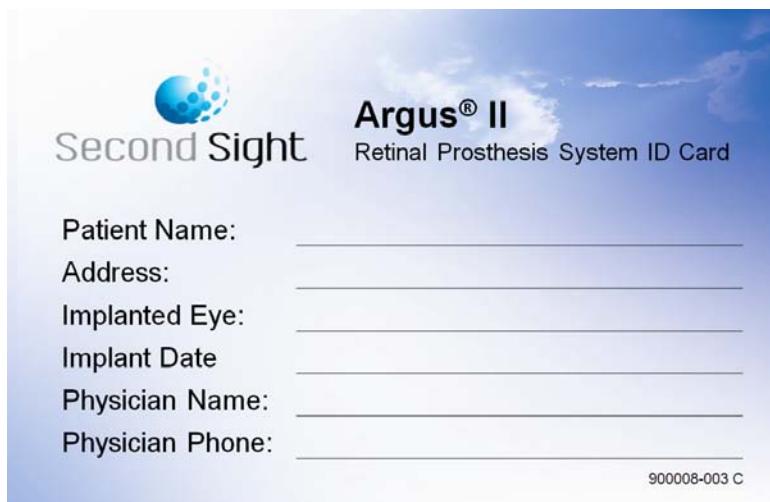
TSA Cares Phone Number: 855-787-2227

TSA Cares is a toll free helpline designed to assist travelers with disabilities and medical conditions, prior to getting to the airport{ XE "airport" }. You should call TSA Cares 72 ahead of traveling so that the TSA has the opportunity to coordinate checkpoint support with a TSA Customer Service Manager located at the airport when necessary.

## **Your Patient Identification Card**

You will receive a patient identification (ID){ XE "patient identification (ID) card" } card after your implant surgery. This card provides basic information about your implant and lists your doctor's name and telephone number. The information is important for others to know in case you need to bypass a security system or in the event of a medical emergency. Keep this card with you at all times. To assist you in locating the card in your wallet, the plastic covering for the card has two clipped corners on one side that you will be able to feel. Refer to Figure 7 below for an example of a patient ID card. This figure does not show the plastic covering with the clipped edges.

**Figure 7: Patient ID Card**



If you change your address or doctor's information, contact Second Sight to obtain a new card. Include the current information and indicate the changes. You may either call 1-818-833-5060 with the information or send it to the following address:

Second Sight Medical Products, Inc.  
Device Registration  
12744 San Fernando Rd., Bldg. 3  
Sylmar, CA 91342, USA

In addition to your Patient Identification Card, you may want to wear a Medical Alert Bracelet{ XE "medical alert bracelet" }. If you choose to purchase one of these bracelets, you should include the following information on it:

Active Implantable Device on (right or left) Eye  
See Patient ID Card in my wallet  
Doctor's Phone is (XXX) XXX-XXXX

# Risks and Probable Benefits

## Risks

There are risks{ XE "risk" } to having surgery and risks of having the Argus II Implant. Listed below are many of the problems you might come across having and using the Argus II System. Some of the risks listed happened to patients in the clinical trial{ XE "clinical trial" }, some did not. Some patients experienced more than one event. Some events are minor, some more severe. Certain events are more likely to occur than others are. For information about the risks experienced by patients in the clinical trial, please refer to Chapter 6.

### *Surgical Risks*

To receive the Argus II System, you will need to have surgery{ XE "risk:surgery" }. During this surgery, your doctor will implant the Argus II Implant in and around the eye. You will need to have general anesthesia. Any surgery where you are under general anesthesia carries some risk.

The following are rare but possible general risks of surgery:

- Blood clots in the legs or lungs (pulmonary embolism or deep vein thrombosis)
- Blood loss requiring transfusion

- Difficulty to urinate
- Chest pain{ XE "pain" }, heart attack, or respiratory failure
- Allergic reaction to the anesthetic

After the surgery, your eye will need to heal. You may have side effects from the medicine you need to take after the surgery.

### *Risks of the Argus II System*

Once you have the implant, there are risks associated with having an implant in your eye. There are also the risks{ XE "risk:Argus II specific" } of having electricity stimulate the nerve cells in your eye.

The following are risks specific to the Argus II Implant:

- The implant or the sutures{ XE "suture" } holding the implant in place on your eye could wear through the layer of tissue that covers the eye. If the implant or the sutures wear through this tissue, you may feel pain{ XE "pain" } or discomfort. This type of event can also lead to an infection in your eye. Sometimes surgery is required to re-cover the exposed parts to protect the other tissues of your eye and prevent more pain or infection. If surgery cannot resolve the

problem, your doctor may need to remove the implant from your eye.

- One or more of the wound{ XE "wound" }s from the surgery could open. This can cause discomfort and can lead to an infection in the eye. If surgery cannot repair the opening in the tissue, your doctor may need to remove the implant from your eye.
- Infection{ XE "infection" } in the eye is serious. You would need to get any infection treated quickly. Normally, your doctor would inject medicine into your eye to treat the infection. If this does not work, your doctor may need to remove the implant from your eye. In rare cases, if you have an infection that cannot be resolved you may need to have your eye removed.
- Your eye pressure may get too high or too low. Normally, your doctor would give you medication to treat this. Your doctor may also need to inject air or oil into your eye. In more severe cases, you may need surgery to return your eye pressure to normal. In rare cases, if the eye pressure gets extremely low, you may need to have your eye removed.
- Separation of the layers of the eye, or a tear in the retina{ XE "tear in the retina" } (the innermost layer) may need surgery or

treatment with a laser{ XE "laser" } to fix. In some cases, these events may affect how well the Argus II System works.

- Large-scale growth of cells{ XE "growth of cells" } in the eye that pull on the retina or growth of strands of tissue that pull on the inner lining of the eye may lead to separation of the layers of the eye. If this happens to you, you may need surgery to repair this problem.
- The implant could move or the retinal tack{ XE "retinal tack" } holding the implant could become loose. You may need surgery to adjust the position of the implant in your eye or to re-tack it to your retina.
- The implant could stop working due to mechanical or electrical problems. Surgery, physical impact to the eye, or exposure to harmful levels of energy could also damage the implant. If the implant stops working, you may need surgery to remove the device.
- You may need to have surgery to move the implant to a new position to improve how well it functions.
- The implant could cause electric shock{ XE "electric shock" }. A skin burn{ XE "skin burn" } could also occur due to too much heating of the glasses or VPU. Contact your doctor

or programming clinician right away if you experience these events. There may be a malfunction in your Argus II System.

- Some pain{ XE "pain" } in or around the eye may occur right after surgery. This pain usually goes away in a few days or weeks. If you have any pain in the eye or headaches after you have recovered from the eye surgery, report it to your doctor. Note that this pain may occur while you are using the Argus II System or when the system is off. Usually, your clinician can adjust the program on your VPU to eliminate any discomfort that occurs when the system is on.
- After implantation surgery, you may notice some decrease{ XE "decrease in light perception" } in how much light you can see. If this happens, you should tell your doctor. While this problem may go away on its own, it is possible that this change could be permanent.
- An eyelash{ XE "eyelash" } caught under the conjunctiva{ XE "conjunctiva" } can cause discomfort. Your doctor will use a pair of tweezers to remove the eyelash if this occurs.
- Damage to or interference with the eye muscles or eyelids, including drooping of

the eyelid{ XE "drooping of the eyelid" } may occur. Often, this does not require any treatment. In severe cases, you may need surgery to repair the damage.

- Implantation of this device may prevent you from receiving future treatments{ XE "future treatments" } for retinitis pigmentosa in the implanted eye. Your other eye, however, will be available for alternative treatments.
- There is a possibility of damage to your retina due to injury, too much stimulation{ XE "over-stimulation" }, or heating of the implant.
- The implant could affect how the nerves in your face work. This could cause twitching in your face or could affect how the muscles in your face work. This could affect how you do things such as smile or frown.
- The implant could wear through the layers of tissue beneath it. If part of the implant moves into the eye, you might need surgery to either repair the tissue or remove the implant.
- Your body may have an allergic reaction{ XE "allergic reaction" } to the materials in the implant or glasses. The following materials in the implant{ XE "materials in the implant" } contact the tissues and fluids in your eye: niobium, titanium, polyimide, silicone

rubber, and platinum. The materials in the glasses{ XE "materials in the glasses" } contact your skin. These materials include the following: carbon fiber, polycarbonate, plastic elastomeric, acrylonitrile butadiene styrene (ABS), thermoplastic elastomeric, aluminum, polyvinyl chloride (PVC) and nylon. If the reaction is severe, you may need to have the implant removed or stop using the Argus II System.

- The Argus II System could distract you from noticing cues from your other aides. You could fall or bump into something even while using the system. **Do not** rely on the Argus II System as your only aid when walking.

The following events may occur occasionally and typically resolve on their own or with medication:

- Infection{ XE "infection" } outside the eye
- Redness and irritation in or around the eye
- Irritation caused by the sutures
- Separation of the choroid from the sclera
- Bleeding{ XE "bleeding" } in the eye
- Clouding, thinning, scraping, or folding of the cornea{ XE "cornea" }
- Blood vessels, deposits, rough spots, "threads" or mucus on the cornea

- Dryness of the cornea
- Dry eye{ XE "dry eye" } or watering eye{ XE "watering eye" }
- Cyst{ XE "cyst" }s on the eye
- Nausea{ XE "nausea" } or dizziness{ XE "dizziness" }

The following events may occur occasionally and typically do not require any treatment:

- Swelling of the retina or choroid
- Splitting of the layers of the retina
- Fold(s) in the retina
- Growth of blood vessels on the iris
- Formation of scar tissue in the eye
- Fluid building up in the choroid
- Feeling that something is in the eye
- Movement of the tissue patch used to cover the implant
- Increase in eye movements that you cannot control

*Possible "Cascade{ XE "risk:possible \"cascade\" of events" }" of Adverse Events*

There is the risk that one event could lead to another. One event could cause other events to get worse. If this happens, it may take several

visits to your doctor, several treatments, and/or surgery to treat. If the events do not resolve, you may need to have the implant removed. In the extreme case, your doctor may have to remove your eye.

## **Probable Benefits and Limitations of the Argus II System**

The Argus II System{ XE "probable benefit" }{ XE "limitations of the Argus II System" } provides a form of vision that differs from the vision you used to have. It does not restore normal vision. It does not slow or reverse the progression of your disease. In addition, it will not replace your normal visual aids. You will have to learn how to use the Argus II System with your other aides (such as a dog or a cane) and techniques. When you are not using the Argus II System, your vision will return to its original impaired state.

When first using the system, you may not be able to tell exactly what you are looking at. Learning to understand the signals from the device and use it in your everyday life may be a challenging process. You will need training to learn how to interpret the vision provided by the Argus II System.

### *How Much Field of View Can the Argus II System Give Me?*

The Argus II System{ XE "field of view" } delivers electrical signals to your retina that will allow you to see spots of light. The implant is designed to give you a visual field{ XE "visual field" } of about 3.5 inches by 6.5 inches (9 by 16.5 centimeters) at arm's length, or slightly larger than a standard 3 x 5-inch index card. However, the actual size of light you see when the system turns on all the electrodes together may be larger or smaller.

Each implant has 60 electrodes. Not every electrode in the array will be able to allow you to see a spot of light on its own. For most subjects in the clinical trial{ XE "clinical trial" } (28 out of 30) the number of electrodes that could do this was less than 60. If fewer than 20 of the 60 electrodes produce spots of light on their own, your clinician may change the program on the VPU to turn on groups of electrodes at the same time. A "quad" is when four electrodes next to each other on the array stimulate at the same time.

It is possible that not all of your electrodes will be used and, as a result, your visual field may be reduced. In addition, the total number of electrodes that provide spots of light can decrease over time. A single electrode could stop working or parts of your retina could stop responding to the signal sent by that electrode.

*What will the spots of light look like to me?*

Electrodes in the Argus II System do not always create circular spots of light. Sometimes the light looks like a line or a wedge. During the clinical trial{ XE "clinical trial" }, three subjects were asked to draw what they saw when a single electrode was activated. In these three subjects, the spots of light ranged in length from 0.75 inches (1.9 cm) (if they were being viewed from an arm's length away) to 18 inches (45.7 cm).

The first subject reported a non-circular shape in 20 of the 29 electrodes tested. The second subject reported a non-circular shape in 24 of the 24 electrodes tested. The final subject reported a non-circular shape in 16 of the 29 electrodes tested.

In these three subjects, the size of the individual light spots ranged from less than 1 square inch (6.5 square centimeters) in size (if they were being viewed from an arm's length away) to 46 square inches (297 square centimeters). Most of the electrodes created spots of light that were less than 5 square inches (32.3 square centimeters) in size.

## *What Are the Probable Benefits of the Argus II System?*

The Argus II System{ XE "probable benefit" } may help you do tasks visually, rather than by touch. During the clinical trial{ XE "clinical trial" }, some subjects were able to locate lights and windows, follow lines in a crosswalk, or avoid running into things as they walked. Some subjects could sort laundry or determine where other people were located in a room. About half of the subjects were able to read very large letters (about 9 inches high viewed from 1 foot away or about 23 centimeters high viewed from 0.3 meters away). A few subjects were able to read smaller letters (about 1-2 inches high viewed from 1 foot away or about 2.5-5 centimeters high viewed from 0.3 meters away) and short words. In addition, many subjects reported enjoying seeing light and motion after being blind for many years and having a greater feeling of connection to their environment and to other people.

Results varied among clinical trial{ XE "clinical trial" } subjects. While the majority of subjects received a benefit from the Argus II System on multiple tests and exams, some subjects reported receiving no benefit.

# **Chapter 3: What to Expect Before, During and After Surgery**

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## **Before Surgery**

Two days before surgery{ XE "surgery" }, you will start taking antibiotics.

## **The Day of Surgery**

Below is general information about how the Argus II System is implanted.

1. On the day of surgery, you will come to the hospital. The surgical procedure will generally last four hours, but it may be shorter or longer. During the implant procedure, you will undergo general anesthesia{ XE "anesthesia" }.
2. If you have a natural lens in your eye, your doctor will remove it before inserting the implant. If you have an intraocular lens in your eye, your doctor will likely leave it in place.
3. Your doctor will pull back the conjunctiva (the thin tissue that covers the white part of your eye and the inside of your eyelid). If your eye orbit is small, your doctor may need to make a small cut at the outer corner of the eyelids to make it easier to place the device.

4. Your doctor will then place the implant around your eye. Your doctor will adjust the implant so that it fits snugly against your eye. Your doctor will secure the band on the implant around your eye using a small silicone sleeve. Your doctor will stitch the implant to your eye to hold it in place.
5. Your doctor will then make small hole in the wall of your eye and will remove all of the gel-like fluid inside your eye. Your doctor will replace the fluid with a saline solution.
6. If you have a thin layer of tissue over your retina, your doctor may remove this by gently peeling it off the retina.
7. Your doctor will then attach the electrode array of the implant to your retina with a small retinal tack. Your doctor will test the implant to make sure it is functioning properly.
8. If the device is functioning properly, your doctor will close all of the cuts in your eye. Your doctor will then place a thin layer of tissue (from a human donor) over a small portion of the implant on the outside of your eye.
9. Your doctor will close the conjunctiva with stitches that will dissolve over time.
10. Your doctor will patch your eye and you will be escorted to the recovery room.

11. After you recover from surgery, you will leave the hospital with instructions to take oral medication and use eye drops to control swelling, infection{ XE "infection" }, and pain{ XE "pain" }.
12. Your doctor may elect to admit you overnight to the hospital for observation, or could discharge you the same day as the surgery.

## **After Surgery**

After you have the Argus II Implant, you will need to return several times to the clinic for clinical follow-up{ XE "clinical follow-up" }, device programming{ XE "device programming" }, and visual rehabilitation{ XE "visual rehabilitation" }. You should consider living close enough to the clinic or temporarily relocate closer to the clinic to allow you to fully participate in the recommended follow-up.

## **Recovering from Surgery**

After your surgery and discharge from the hospital, your doctor or nurse will provide you with instructions on how to recover. These instructions will include information about what medications you will need to take and when you will need to return for follow-up visits. Always follow these instructions.

If you experience any medical complications with your implant, it is important to follow the instructions provided by your doctor for how to treat these complications.

It may take several weeks for you to recover from surgery. During this time, you may feel discomfort around your eye. If you notice unusual symptoms, contact your doctor.

### **Clinical Follow-Up{ XE "clinical follow-up" }**

The day after surgery, your doctor will examine your eye. You will return to the hospital one week later to have your eye checked again. At this time, if the doctor feels that you have recovered well enough from your surgery, you will begin to have your Argus II System custom programmed for you (See Device Programming section below).

You will need to continue to return to the hospital periodically so that your doctor can check the health of your eye. These periodic visits will continue as long as the Argus II Implant remains in your eye. A typical follow up schedule might include visits at 2 weeks, 1 month, 3 months, 6 months, and 12 months followed by annual or semi-annual visits.

### **Device Programming{ XE "device programming" }**

In order for you to see anything from the Argus II System, it will need to be custom programmed, or “fitted” for you. Someone other than your doctor will likely perform this programming. This person, a “programming clinician” could be another doctor, nurse or technician.

### *Initial Programming Sessions*

The purpose of the initial programming sessions is simple: to find suitable stimulation levels so that the first visual program can be set on your VPU. To do this, you will need to come to the clinic where your clinician will connect the VPU to a special computer. The programming clinician will provide electrical stimulation to one electrode at a time. Your clinician will record your response to the stimulation. Your clinician will use these responses to create custom programs. Your clinician will download these programs to your VPU so you can use your Argus II System.

In case stimulating one electrode at a time is determined to be insufficient, the clinician may choose to stimulate groups of four electrodes next to each other (called a “quad{ XE “quad(s)” }”) at the same time. If the clinician chooses to use quad stimulation, the clinical will divide the entire array into 15 quads arranged in 3 rows of 5 columns. For people who need quad stimulation, quad electrode stimulation usually results in brighter perception than single electrode stimulation. Also,

a larger region of your array may become usable with quad stimulation, resulting in a larger field of view. These features may allow you to make better use of the device even if single electrode stimulation gives you little vision.

**CAUTION: Please note that the effect of using quad stimulation compared to single electrode stimulation was not specifically studied during the clinical trial{ XE "clinical trial" }.**

Depending on your results, this initial programming may take one visit lasting one to two hours, or it may take a few such visits.

#### *Preparing for Using the Argus II System at Home*

Once your clinician downloads the programs to your VPU, your clinician will turn on the VPU. You will then start to see spots of light. Your clinician will then adjust the camera position to line it up with how the implant is located inside your eye.

You clinician will show you how to connect the glasses to the VPU, how to operate the controls and switches on the VPU, and how to understand the alarms and indicator lights. Your clinician will train you how to perform simple troubleshooting and how to care and maintain your Argus II System.

You will need to come to the clinician many times in the 4-6 weeks after surgery to have your system programmed and to receive training. Once you complete these two activities, you will be able to start using your Argus II System at home. Typically, patients in the clinical trial{ XE "clinical trial" } started home use of the System one to three months after their implant surgery.

### *Follow-up Programming*

After the initial programming sessions, you may need to visit your programming clinician on a regular basis for a tune up{ XE "follow-up programming" }. The brightness of perception and the number of electrodes that can give you perception may decrease over time. If your perceptual experience with the device changes, you should contact your programming clinician for a follow-up programming session.

### **Visual Rehabilitation{ XE "visual rehabilitation" }**

It is important to learn how to use the device to fit your specific needs. Second Sight has a recommended visual rehabilitation program. This rehabilitation program will allow you to improve your use of the system. It should increase your ability to perform daily activities and help reach your goals for using the Argus II System. A typical rehabilitation program may include five to ten one hour sessions. These might take place at the

hospital, at another institution, in your home, at your work, or some combination of these settings. Your doctor can provide more details about your rehabilitation program.

As part of this rehabilitation program, you may receive some items to take home with you to help you practice and learn more about the system. It is important to spend time practicing in order to maximize the benefit that you get from the system.

### **The Importance of Following a Care Regimen**

The following guidelines about your Argus II System will help to ensure that you receive the safest and most beneficial treatment.

Always tell any medical personnel that you have an implant in your eye and tell them where it is located. If they have any questions, they should contact your doctor or Second Sight at 1-818-833-5060.

If you experience any unusual symptoms that you think are related to your Argus II Implant, contact your doctor.

If you have a family member or caregiver, ask them to read this manual along with you. There may be situations where you will need their assistance.

Go to all follow-up appointments. This will ensure that you get the best care.

## **When to Call Your Doctor**

Call your doctor if any of the following situations occur:

- You are experiencing any pain{ XE "pain" } or discomfort in your implanted eye.
- You feel any discomfort during stimulation. First, turn off your Argus II System (by shutting off the VPU or taking off your glasses), then call your doctor.
- You are having any difficulty operating your Argus II System or any of the components break.
- You feel like the information/stimulation you receive from your Argus II System is getting worse.
- You experience any unusual symptoms that you think electromagnetic interference is causing{ XE "detector:theft" }.

# Chapter 4: Using Your Device

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## Setup Instructions

To set up the equipment for use, follow the instructions below.

### 1. Charge the battery{ XE "battery:charging" }.

Before using the battery for the first time, charge it fully. To charge the battery, plug in the battery charger and place the battery in the receptacle of the charger. It takes approximately three hours to fully-charge a battery. A sighted individual can help you check if the battery is fully charged. When the battery is charging, the orange charge light is on. When the battery is fully charged, the light will be off.

### 2. Install the battery{ XE "battery:installation" }.

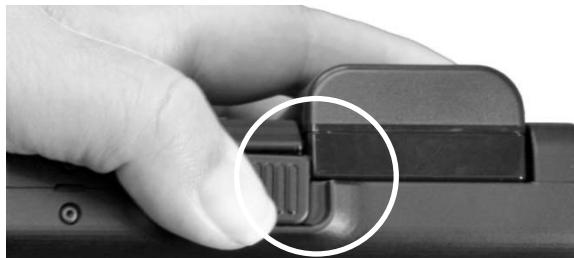
To install the rechargeable battery, slide the VPU battery latch so that it opens (as shown in Figure 8 below). While holding the latch open, slide the battery in the receptacle away from the latch until the battery latch automatically slides into its locked position.

### 3. Remove the battery{ XE "battery:removal" }.

To remove the battery, slide the VPU battery latch so that it opens (toward the top of the VPU). Holding the latch open, slide the battery

as far as you can toward the latch and lift it out of the receptacle. Release the latch.

**Figure 8: Battery Latch{ XE "battery:latch" }  
Being Held Open**



4. **Confirm proper installation of the battery.** Confirm that you have installed the battery correctly by gently pulling it. If the battery comes loose, re-install it by performing Step 2 again.

**CAUTION: Do not use any batteries with the VPU other than those given to you by Second Sight. Use of other batteries may damage the VPU or cause it to function improperly and void the manufacturer's warranty.**

5. **Wearing the VPU.** If you would like to wear the VPU, you will need the VPU pouch. Place the VPU in the pouch and lock it in place using the Velcro® strap near the right side of the VPU next to the star-shaped button. Secure the VPU in place with the other Velcro strap.

Once the VPU is in the pouch, you can wear the VPU.

**6. Connecting the glasses{ XE "glasses:connecting" } to the VPU{ XE "VPU:connecting" }.** The glasses are equipped with a cable that you insert into the glasses receptacle located on the top of the VPU. To connect the glasses to the VPU, perform the following steps:

- (a) Always make sure the VPU is turned off before connecting the glasses.
- (b) Grasp the cable and hold it by the rubber piece at the end. Notice that the rubber piece makes an L-shape. This L-shape aids in proper orientation of the plug.
- (c) Locate the round-shaped glasses receptacle on the VPU.
- (d) Insert the cable plug into the glasses receptacle. Point the cable end of the plug towards the right side of the VPU where the circular power button is located. Apply pressure to insert the plug into the glasses receptacle. If the plug does not insert, gently rotate it for proper alignment while trying to insert it. Once aligned, insert the plug into the glasses receptacle.
- (e) Push the plug firmly into the receptacle until you hear a click. Note that the plug does not lock.

**7. Disconnecting the glasses{ XE "glasses:disconnecting" } from the VPU{ XE "VPU:disconnecting" }.** Always turn the VPU off before disconnecting the glasses. If you need to disconnect the glasses from the VPU, hold the VPU firmly in one hand. Using the other hand, grasp the L-shaped plug at the end of the glasses cable and gently pull it straight away from the VPU.

**CAUTION: Do not pull the glasses cable out of the VPU at an angle as this may damage the receptacle or the VPU.**

**8. Wearing the glasses{ XE "glasses:wearing the glasses" }.** Using both hands, gently put on the glasses as you would a typical pair of glasses. Adjust the cable so that it is comfortable and does not catch on anything such as your arms or clothes. You can thread the cable inside your clothing to prevent it from getting caught on objects while you move.

**CAUTION: Do not adjust the position of the glasses coil. The coil position is set by your clinician to optimize performance of the device. Changing the coil position may cause loss and/or interruption of stimulation. Contact your clinician if your VPU audible alarm beeps frequently.**

**CAUTION: Use care when putting on the glasses. Do not over-extend the glasses arms as this could break them.**

**CAUTION: Do not attempt to adjust the camera mounted on the glasses as you may damage the camera or glasses. You could also alter the alignment of the camera.**

## **Operating Instructions**

**CAUTION: Do not exchange your VPU with another patient's VPU. If you use another patient's VPU, you could have uncomfortable stimulation.**

**CAUTION: If you experience any discomfort during the use of the device, please contact your clinician or Second Sight promptly.**

To use the VPU and glasses, follow the instructions below.

- 1. Lighting Conditions.** The Argus II System uses the camera in the glasses to capture the video image that it sends to your implant. Since the camera does not work well in dimly lit environments, make sure that you have enough light in your surroundings when you are using the System. If you are inside, you should always make sure the lights are on in the room. If possible, a sighted individual should confirm that your lights are working properly.
- 2. Turning on the VPU{ XE "VPU:turning on" }.** Put the glasses on as described above. To turn on the VPU, press the circular power button on the side of the VPU and hold it down for approximately two seconds until you hear four short beeps.
- 3. VPU Start-up tests.** Immediately after the VPU turns on, it performs a series of tests. These tests last approximately 30 seconds. During these 30 seconds, the green indicator light will blink quickly. You may or may not see something during these tests. Once these tests are complete, stimulation will begin and the green indicator light will blink more slowly (1 blink per second) to indicate that the VPU is operating properly.

4. **Possible clicking noise from the glasses coil.** You may hear a clicking noise from the glasses. This is part of the normal operation of the glasses and does not indicate a failure of any kind.
5. **Changing program settings.** The VPU{ XE "VPU:changing program settings" } has 3 program settings that you can select by pressing one of the three oval-shaped buttons on the front of your VPU. The button with a single circle is Program Setting 1. The button with two circles is Program Setting 2. The button with a small is Program Setting 3. You may change the program you are using to adjust for different lighting or contrast conditions. When you first turn the VPU on, it defaults to Program Setting 1. Each time you change the Program Setting, the VPU will produce a short beep.
6. **Inverting the image.** To invert the image from black-to-white and white-to-black, press the square button located in the middle of the right-hand side of the VPU{ XE "VPU:inverting the image" }. Each time you press this button, the image will invert and the VPU will beep.
7. **Audible RF link alarm{ XE "VPU:audible RF link alarm" }.** To turn the RF link alarm on or off, press the star-shaped button next to the inverse button. The RF link alarm tells you

when the communication link with the implant has been temporarily lost.

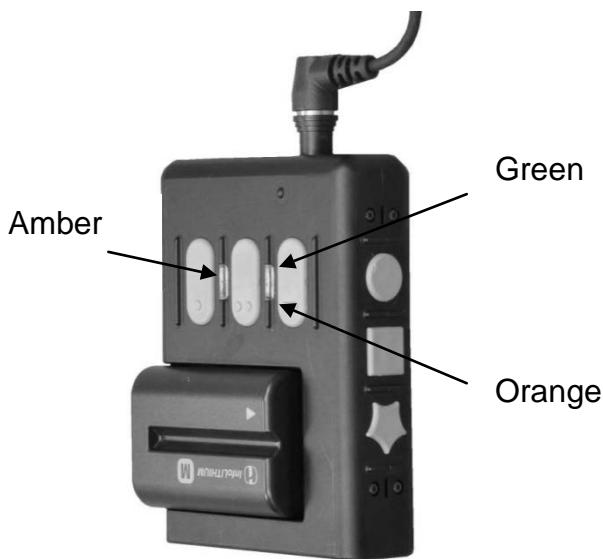
## **8. Turning off the VPU{ XE "VPU:turning off" }.**

To turn off the VPU, press the power button and hold it down for approximately one second. When the VPU is turning off, it will sound one beep followed by a pause, followed by two short beeps. Once the VPU is off, all indicator lights on the VPU will be off.

## **Indicators and Audible Alarms**

The VPU uses both visual and audible indicators to provide you with information about the status of the VPU and glasses and to tell you about problems with the Argus II System. Table 5 and Table 6 summarize the meaning of these indicators. Figure 9 below shows the location of the indicator lights on the VPU.

**Figure 9: VPU{ XE "VPU:indicator lights" }**  
**Indicator Light Colors**



**Table 7: Indicator Light Colors**

Indicator Light Color	Light flashing	Meaning
Green	Fast periodic blinking	The VPU is going through its start-up diagnostic testing.

Indicator Light Color	Light flashing	Meaning
Green	Slow periodic blinking (1 per second)	The VPU is operating normally.
Orange	Solid	There is a problem with the video signal. (For example, the glasses cable is not properly connected to the VPU).
Amber	Solid	There is a loss of communication between the implant coil and glasses coil.
Amber	Blinking	There is intermittent communication between the implant coil and the glasses coil.

**Table 8: Audible Alarms**

Sound	Meaning
Single short beep	A button{ XE "VPU:audible

<b>Sound</b>	<b>Meaning</b>
	alarms" } has been pressed (for example, a Program Setting or Inverse Setting Button).
One beep followed by a pause, followed by two short beeps	The VPU is turning off.
Four short beeps	The VPU is starting up.
Three short beeps	An error has occurred and the VPU is about to shut down automatically.
Periodic beeping pattern (3 short beeps followed by 1 long beep, followed by 3 short beeps, followed by a long pause)	The battery level is low.
Slow periodic beep (1 every 2 seconds)	There is a problem with the video signal.
Fast periodic beep (2 per second)	There is a loss of communication between the implant coil and glasses coil. This alarm can be temporarily turned off by pressing the star-shaped button on the right side of the VPU (the Audible RF Link Alarm Button).

## Battery Life

On average, the small battery will last 2.5 to 3.5 hours and the medium battery will last 4 to 6 hours. Actual battery life{ XE "battery:battery life" } may vary. Once the battery runs out of charge you will need to recharge it.

VPU settings as well as when and where you use your device will all affect how long the battery charge lasts. Battery capacity will also drop gradually over time with use of the VPU. If your battery charge is not lasting very long each time you charge it, the battery has probably reached the end of its life. Contact your clinician or Second Sight for a replacement battery.

### **Recharging the Batteries**

One small rechargeable battery{ XE "battery:recharging" }, one medium rechargeable battery and one battery charger are provided with the Argus II System. Follow the instructions supplied with the charger to recharge the battery. Additional batteries may be purchased from Second Sight.

### **Checking the Function of the Device**

It is important that you periodically check the Argus II System for normal wear and tear. If you notice any exposed wires on the glasses or loose or broken parts{ XE "broken parts" } on the glasses or VPU, contact your doctor. In addition, if you

notice a decline in the link between the implant and glasses (for example, if the RF link alarm is beeping more frequently than normal), contact your doctor.

## **Cleaning**

To clean the battery{ XE "battery:cleaning" } contacts, follow the instructions in the battery package.

To clean your VPU{ XE "VPU:cleaning" }, glasses{ XE "glasses:cleaning" } or cables, follow the instructions below:

1. Use a can of compressed air to remove dust and debris from the equipment. Use the compressed air as directed by the manufacturer.
2. Use a clean, slightly damp cloth to clean the equipment. Gently rub the areas that require cleaning.
3. Use a clean, dry cloth to dry the equipment after cleaning it.
4. Use a soft cloth to remove minor smudges and fingerprints from the glasses and camera lens on the glasses.

**CAUTION: Do not use any cleaning solutions or solvents to clean the equipment as this may damage the equipment or its labels.**

## Maintenance

The Argus II System{ XE "glasses:maintenance" }{ XE "VPU:maintenance" } does not contain any user serviceable parts.

**CAUTION: If your VPU or glasses are not working properly, contact either your clinician or Second Sight for assistance. Do not try to fix the equipment yourself as you may experience an injury, violate the product warranty, or damage the equipment.**

## Handling and Storage

Take care when storing and handling the VPU{ XE "VPU:handling and storage" } and glasses{ XE "glasses:handling and storage" }. Improper care or storage can result in damage to the equipment. Following the guidelines below can improve the lifetime of this equipment.

- 1. Magnetically-sensitive storage devices{ XE "magnetically-sensitive storage devices" }.** Do not place magnetically-sensitive storage devices near the Argus II System while it is operating. Examples of these storage devices include credit cards, computer floppy disks and hard disks. The electromagnetic field generated by the Argus II System may damage

or erase the information that is stored on magnetically-sensitive storage devices.

2. **Metal objects**{ XE "metal objects" }. Do not allow any metal objects within 6 inches (15.2 cm) of the glasses coil while the VPU is in use. If metal objects get too close to the coil, the coil could overheat, which would cause the VPU to turn off. The VPU will not work until reset by trained personnel.
3. **Unapproved components**{ XE "glasses:unapproved components" }{ XE "VPU:Unapproved components" }. Use only components and accessories supplied by Second Sight with the Argus II System. If you use unapproved components, you may damage the equipment, resulting in loss of stimulation and/or injury. If you use unapproved components, you will also void the manufacturer's warranty.
4. **Exposure to liquid**{ XE "glasses:exposure to liquid" }{ XE "VPU:exposure to liquid" }. Do not expose the VPU and glasses to water (for example, rain, shower, swimming pool, or ocean) or other liquids. Liquids may damage the VPU or glasses. The glasses may be exposed to light rain, but the VPU may not.
5. **Storage**{ XE "glasses:storage" }{ XE "VPU:storage" } **of the Argus II VPU and**

**Glasses.** Store the packaged Argus II VPU and glasses at temperatures between 32°F (0°C) and 113°F (45°C). Do not expose the VPU and Glasses to temperatures below 32°F (0°C) or above 113°F (45°C) as this may damage the Glasses or VPU.

6. **Usage temperature range{ XE "VPU:usage temperature range" }{ XE "glasses:usage temperature range" }.** The temperature range for normal use should be between 32°F (0°C) and 104°F (40°C).
7. **Handling{ XE "glasses:handling" } the glasses.** The glasses are fragile. Handle them with care, especially when putting them on or taking them off. Do not over-extend the arms of the glasses when putting them on or taking them off as this may break them. Do not fold the arms of the glasses to shut them since trying to fold them may break them. Use care when attaching or removing any cables or plugs as rough handling can damage the cables or equipment. Do not wrap the cable around the VPU since, over time, this may damage the cable.
8. **Traveling{ XE "travel" } with the external devices.** Store the VPU, glasses, and batteries in the travel case provided by Second Sight as this is designed to protect the equipment. Uninstall the battery from the VPU during

transit, to avoid accidentally turning on the VPU which could drain the battery. Do not place anything on top of the glasses or VPU.

**9. Loss of RF link.** The coil on the Glasses powers the implant.{ XE "VPU:loss of RF link" } Moving the coil on the glasses more than approximately 1 inch (2.5 cm) away from the Implant may result in a decrease or loss of stimulation. Additionally, you may need to restrict your eye movements to maintain the link between the implant coil and glasses coil.

**10. Interference{ XE "interference" }.** The Argus II System may interfere with certain radio frequencies. If interference occurs, you should extend the distance between you and the source of interference, or turn off the Argus II VPU.

## **Expected Failure Time and Mode and Its Effect on You**

The Argus II Implant was designed to operate for at least five years. Laboratory testing has demonstrated that the implant should last that long. Insufficient time has elapsed in actual clinical use to provide proof that the device will function properly for more than five years, but performance to date and laboratory testing suggest that it will.

One possible failure mode of the implant is that it could stop responding to signals from the glasses and thus stop stimulating. If it fails in this manner, you should not experience any harmful effects. The implant may be removed and replaced, if desired.

The VPU and glasses are much more susceptible to handling and breakage than the implant. This equipment may be replaced if necessary.

Wearing out of the rechargeable battery is described in the "Operating Instructions" section of this chapter.

## **How to Safely Dispose of the Device**

Follow the safety precautions below when you are transporting, storing or disposing of any components of the Argus II System. During transport, storage and handling for disposal, the following safety precautions should be considered:

### **WARNING**



**Do not dispose of the VPU batteries{ XE "battery:disposal, handling, storage and transport" } or battery charger in a fire as this may cause an explosion and/or the release of toxic fumes.**

**Do not dismantle the battery as some ingredients can be**

**flammable or harmful.**

**Store used batteries for disposal in a clean dry environment out of direct sunlight and away from extreme heat.**

**Dirt and wetness may cause short-circuits and heat. Heat may cause leakage of flammable gas which may result in fire, rupture or explosion.**

**WARNING**



**Store used batteries in a well-ventilated area. If used batteries are short-circuited, abnormally-charged or force-discharged, leakage of flammable gas may be caused possibly resulting in fire, rupture or explosion.**

**Do not mix used batteries with other materials. If the batteries are short-circuited, abnormally-charged or force-discharged the heat generated may ignite flammable wastes and cause a fire.**

**VPU and Glasses**

Follow local and state regulations regarding the proper disposal of electronics to dispose of the

VPU{ XE "VPU:disposal" } or glasses{ XE "glasses:disposal" }. If you are exchanging or replacing your equipment through your clinician, your clinician will be responsible for following these regulations.

## **Rechargeable Batteries and Battery Charger**

The VPU uses rechargeable batteries. If you detect any leakage of fluid from the battery, stop using it and replace it with a new one. Dispose of a battery{ XE "battery:disposal" } or battery charger{ XE "battery charger:disposal" } when it reaches the end of life. Follow procedures that comply with your local regulations and the package insert of the battery or battery charger for proper disposal methods.

## **Argus II Explant**

If you have the Argus II Implant{ XE "implant disposal" } explanted{ XE "explant" } for any reason, contact Second Sight immediately except in the event of medical emergency. Your doctor must return the explanted device to Second Sight for evaluation, warranty purposes and final disposition. Your doctor should request a biohazard (explant) kit from the Second Sight office (see contact information in Chapter 7).

## **Disposal of Packaging Material**

Dispose of the shipping carton{ XE "packaging material disposal" } and packaging materials for the Argus II System components according to local regulations.

## Chapter 5: Troubleshooting

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If you encounter a problem with any part of your Argus II System{ XE "troubleshooting" }, look for the problem in Table 9 below. Instructions for how to fix the problem are provided in the table.

If you cannot find the problem in the tables below or if the recommendations do not fix the problem, then contact your doctor or programming clinician or use the information provided in Chapter 7 of this manual to contact Second Sight.

**CAUTION: If you encounter a clinical or physical problem (such as eye pain{ XE "pain" } or discomfort) related to the Argus II System, please contact your doctor or programming clinician immediately.**

**Table 9: Troubleshooting**

Symptom	Cause and/or Corrective Action
The VPU{ XE "VPU:does not start, troubleshooting" } does not start	1. Check that the battery is installed properly. If it is not installed properly, refer to instructions in Chapter 4, "Install the battery."

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The VPU does not start (continued)	<p>2. Install a fully-charged battery. Refer to instructions provided in Chapter 4, "Install the battery."</p> <p>3. Ensure that you are pressing the correct button. The power button is the circular-shaped one on the right side panel of the VPU (see Figure 3).</p> <p>4. Ensure that you are pressing the power button for at least two seconds. If the button is pressed for less than two seconds, the VPU will not turn on.</p>
The VPU produces an audible warning{ XE "VPU:produces an audible warning" } (three short beeps) and shuts off suddenly	<p>5. Turn on the VPU to see if this occurs again. If the problem persists, contact either your clinician or your Second Sight representative.</p>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU shuts off suddenly{ XE "VPU:shuts off suddenly" } without an audible warning</p>	<ol style="list-style-type: none"> <li data-bbox="497 246 872 442">1. Install a fully-charged battery. Refer to instructions "Install the battery" provided in Chapter 4.</li> <li data-bbox="497 450 830 573">2. Turn on the VPU to see if this occurs again.</li> <li data-bbox="497 581 856 777">3. If the VPU fails to restart, remove the battery for at least 5 minutes. Then, install again.</li> <li data-bbox="497 785 866 948">4. Put on glasses. Turn on the VPU again and stimulation should restart.</li> <li data-bbox="497 956 866 1357">5. If the problem persists or occurs again randomly when the battery is charged, contact either your clinician or your Second Sight representative for advanced troubleshooting.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but I don't see anything{ XE "VPU:VPU is on, but I don't see anything" }</p>	<ol style="list-style-type: none"> <li data-bbox="444 246 832 524">1. Confirm that the VPU is on by pressing any button on the VPU other than the power button. If a beep is heard, then the VPU is on.</li> <li data-bbox="444 540 832 916">2. Ensure that the VPU is not making any audible alarms. Check if the audible RF link alarm switch is on. If it is, check that the glasses cable is properly plugged into the VPU glasses receptacle.</li> <li data-bbox="444 932 832 1406">3. Gently press the coil mounted on the glasses closer to your eye. If the audible alarm stops beeping and resumes beeping when you stop pressing the coil, this indicates that your external coil needs to be adjusted to ensure the communication</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but I don't see anything (continued)</p>	<p>between the external coil and the implant is reliable.</p> <ol style="list-style-type: none"> <li data-bbox="494 372 881 654">4. Ensure that nothing is blocking the camera on the glasses. If there is something blocking the camera, try to remove the obstruction.</li> <li data-bbox="494 666 881 829">5. Ensure that the lens on the camera is clean. Refer to "Cleaning" in Chapter 4.</li> <li data-bbox="494 840 814 960">6. Ensure that your surroundings have adequate lighting.</li> <li data-bbox="494 971 881 1205">7. Try inverting the image (from black-to-white or white-to-black) by pressing the square-shaped settings button.</li> <li data-bbox="494 1216 789 1291">8. Try changing the program setting.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The VPU is on, but the image seems distorted{ XE "VPU:is on, but the image seems distorted" }	<ol style="list-style-type: none"> <li>1. Ensure that nothing is blocking the camera on the glasses.</li> <li>2. Ensure that the lens on the camera is clean. Refer to Chapter 4, "Cleaning."</li> <li>3. Try using one of the other program settings to see if there is an improvement.</li> </ol>
The VPU is on, but my perception is dimmer than usual{ XE "VPU:is on, but my perception is dimmer than usual" }	<ol style="list-style-type: none"> <li>1. Ensure that nothing is blocking the camera on the glasses. If there is something blocking the camera, try to remove the obstruction.</li> <li>2. Ensure that the lens on the camera is clean. Refer Chapter 4, "Cleaning."</li> <li>3. Ensure that your surroundings have adequate lighting.</li> <li>4. Ensure that you are using the correct stimulation setting.</li> </ol>

Symptom	Cause and/or Corrective Action
The VPU is on, but my perception is dimmer than usual (continued)	<p>Switch between the normal/invert settings by pressing the square-shaped invert button.</p> <p>5. Ensure that the intended Program Setting is being used to provide the optimum perception by experimenting with the different Program Setting buttons.</p> <p>6. Switch off the VPU for 10 minutes and switch it back on.</p>
The coil on the glasses seems warmer than usual{ XE "glasses:coil seems warmer than usual" }	<p>7. Re-adjust the glasses to see if the coil cools down to its usual operating temperature. If the problem is persistent or the coil is getting unusually warm, contact Second Sight using the contact information provided in Chapter 7.</p>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>There is a clicking noise{ XE "glasses:clicking noise" } from the area of the coil on the glasses</p>	<p>8. This is part of the normal operation of the glasses and does not indicate a failure of any kind.</p>
<p>Nosepiece comes off the glasses{ XE "glasses:nose piece" }</p>	<ol style="list-style-type: none"> <li data-bbox="444 592 821 796">1. Turn the glasses over and lay them on a flat surface so that the top of the frame is in contact with surface.</li> <li data-bbox="444 805 821 1009">2. Take the nosepiece and place it on the underside of the lens where the nosepiece should be attached.</li> <li data-bbox="444 1017 821 1172">3. Press firmly. This should lock the nosepiece back in place.</li> </ol>

If the problem persists, contact your clinician or use the information in Chapter 7 to contact Second Sight.

**Table 10: Indicator Lights**

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The green light is not blinking	<ol style="list-style-type: none"><li>1. Change to a fully charged battery{ XE "VPU:indicator lights, troubleshooting" }.</li><li>2. Turn off the VPU and turn it back on again to see if the problem is fixed. If it is not fixed then contact Second Sight using the contact information provided in Chapter 7.</li></ol>
The orange light turns on (loss of video signal)	<ol style="list-style-type: none"><li>1. Ensure that the green light is still blinking.</li><li>2. Check that the glasses cable is properly connected to the glasses receptacle on the VPU. Refer to Chapter 4, "Connecting the glasses to the VPU."</li></ol>
The amber light turns on (loss of RF link)	<ol style="list-style-type: none"><li>1. Ensure that the green light is still blinking.</li><li>2. Re-adjust the glasses to see if the light turns off.</li><li>3. If step 2 does not fix the</li></ol>

Symptom	Cause and/or Corrective Action
The amber light turns on (loss of RF link, continued)	<p>problem, check that the glasses cable is properly connected to the glasses receptacle. Refer to Chapter 4, "Connecting the glasses to the VPU."</p> <p>4. You may need to restrict your eye movement to maintain the link between the implant coil and the glasses coil.</p>

If the problem persists, contact your programming clinician or use the information in Chapter 7 to contact Second Sight.

**Table 11: Audible Alarms{ XE "VPU:audible alarms, troubleshooting" }**

Symptom	Cause and/or Corrective Action
The VPU shuts off suddenly emitting three short beeps (error-induced VPU)	<p>Try powering up the VPU to see if this occurs again. If the VPU continues to shut itself off, contact your programming clinician. You may also contact Second Sight using the contact</p>

Symptom	Cause and/or Corrective Action
shutdown)	information provided in Chapter 7.
The VPU emits the following periodic beeping pattern: 3 short beeps followed by 1 long beep, followed by 3 short beeps, followed by a long pause (low battery voltage warning)	<ol style="list-style-type: none"> <li>1. Turn off the VPU.</li> <li>2. Install a fully-charged battery onto the VPU. Refer to instructions provided in Chapter 4, "Install the battery."</li> <li>3. Power up the VPU; allow the VPU to finish the start-up test and ensure the same beeping pattern does not occur after the start-up test.</li> </ol>
The VPU emits a slow periodic beep once every 2 seconds (loss of video signal)	<ol style="list-style-type: none"> <li>1. Ensure that the green light is still blinking approximately 1 blink per second.</li> <li>2. Check that the glasses cable is properly connected to the glasses receptacle on the VPU. Refer to Chapter 4, "Connecting</li> </ol>

Symptom	Cause and/or Corrective Action
	the glasses to the VPU.”
The VPU emits fast periodic beeps about 2 per second (loss of RF link)	<ol style="list-style-type: none"> <li data-bbox="434 344 821 589">1. Allow the VPU to finish the start-up test and ensure that the green light is blinking approximately 1 blink per second.</li> <li data-bbox="434 589 821 801">2. Re-adjust the glasses and gently press the external coil closer to your eye to see if the amber light turns off.</li> <li data-bbox="434 801 821 916">3. Limit your eye movements and look straight ahead.</li> <li data-bbox="434 916 821 1373">4. If steps 2 and 3 are unsuccessful in correcting the problem, check that the glasses cable is properly connected to the glasses receptacle – if not, follow instructions in Chapter 4, “Connecting the glasses to the VPU.”</li> <li data-bbox="434 1373 821 1422">5. This fast periodic</li> </ol>

Symptom	Cause and/or Corrective Action
<p>The VPU emits fast periodic beeps about 2 per second (loss of RF link, continued)</p>	<p>beeping related to the temporary loss of communication with the implant can be turned off by pressing the star-shaped switch on the right side of the VPU.</p>
<p>The VPU is not operating as intended, but I do not hear any audible alarms</p>	<p>Press the star-shaped audible RF link alarm switch to ensure the RF link alarm is “on”. If you still cannot hear any audible alarms, a sighted person should check whether the amber or the orange light is on. If not, you will not hear any audible alarms. If the amber or the orange light is on, ensure that the VPU is within your normal hearing range. To test it, you may want to put it next to your ear.</p>

Symptom	Cause and/or Corrective Action
The VPU operates as intended, but I hear an unexpected audible alarm	<ol style="list-style-type: none"> <li data-bbox="434 246 811 442">1. Refer to Table 6 from Chapter 4 of the manual for an explanation of the audible alarms.</li> <li data-bbox="434 453 811 698">2. If you still cannot recognize the audible indicator, turn off the VPU and try turning it on to see if this sound occurs again.</li> <li data-bbox="434 710 811 911">3. Install a fully-charged battery. Refer to instructions provided in Chapter 4, “Install the battery.”</li> </ol>

If the problem persists, contact your programming clinician or use the information in Chapter 7 to contact Second Sight.

# **Chapter 6: Additional information**

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## **Clinical Studies{ XE "clinical trial" }**

### **Introduction**

Second Sight performed a clinical study to test the Argus II System. In this study, thirty subjects were implanted with the Argus II Implant. Fourteen of these subjects lived in the United States and sixteen lived in Europe.

As of March 2012, subjects had been implanted for an average of 3.5 years. The shortest length of implant was 1.2 years and the longest length of implant was 4.8 years.

One subject had the Argus II Implant removed at 1.2 years after implant due to a complication. The Argus II Implant failed in one subject at 4 years after implant. In the other 28 subjects, the Argus II Implant was still implanted and working.

### **Side Effects and Complications**

During the study, 28 of the 30 subjects experienced at least one side effect or complication related to the Argus II System or the surgery to implant the device. Two subjects had no side effects.

Of the 28 subjects, 17 had non-serious side effects that either were treated with medication or did not require any treatment at all. Six subjects had one serious complication that was treated with medication or a simple surgery (for example, repairing a suture used to close the wound in the eye). Five subjects had multiple serious complications, some of which were treated with surgery. Of these last five subjects, four had a "cascade" of events, meaning that one complication led to another complication.

### *Serious Complications*

Below is a list of the serious complications{ XE "clinical trial:serious complications" } during the study. Of the 30 subjects:

- 4 subjects had a decrease in the pressure of the eye, making the eye soft
- 3 subjects had an opening of the surgical wound where the eye tissue covers the implant.
- 3 subjects had a portion of the implant wear through the tissue that covers it, leaving that part of the implant uncovered.
- 3 subjects had an infection{ XE "infection" } in the eye
- 2 subjects had a partial separation of their retina from the eye wall
- 2 subjects had their retinal tack come out of the retina requiring a re-tack procedure

- 1 subject had a thinning and clouding of the cornea caused by an infection in the cornea
- 1 subject had an infection in the front chamber of the eye
- 1 subject experienced a tear in his retina

Serious complications were treated with surgery, unless they were a severe infection. Severe infections were treated by either giving the subject a shot of medication into the eye or by giving the subject medicated eye drops.

As mentioned above, some subjects had several serious complications. More than half of the serious complications happened within 6 months of implant surgery, although two happened as late as 2 years after implant.

### *Other Side Effects*

Below is a list of other side effects{ XE "clinical trial:other side effects" } that occurred during the study as of March 2012. Some of these side effects needed no treatment and others were treated with medication. Some subjects had several of these side effects. Of the 30 subjects:

- 11 subjects had a thin layer of tissue grow on the retina
- 10 subjects had redness of the conjunctiva

- 9 subjects had pain{ XE "pain" } in or around the eye
- 9 subjects had swelling of the retina
- 7 subjects had surgery to adjust the position of the implant in the eye to improve how well it worked
- 7 subjects had a decrease in the pressure of the eye, making the eye soft
- 6 subjects had irritation caused by the sutures
- 6 subjects had fluid collected under the choroid
- 4 subjects had redness or irritation of the conjunctiva ("pink eye")
- 9 subjects had redness or irritation inside the eye
- 4 subjects had bleeding in the back part of the eye
- 3 subjects had blood in the front of the eye
- 3 subjects had headaches
- The following side effects occurred in 2 subjects each:
  - Increase in pressure of the eye{ XE "pressure of the eye" }
  - Blood vessels growing on the cornea
  - Watering eye
  - "Threads" on the cornea
  - Redness and irritation due to deposits on the cornea
- The following side effects occurred in 1 subject each:

- Large-scale growth of cells in the eye that pulled on the retina
- Growth of strands of tissue that pulled on the inner lining of the eye
- The feeling that something is in the eye
- Build-up of fluid in the choroid
- Scar tissue inside the eye
- Scar tissue around the tack used to hold the implant to the retina
- Cyst{ XE "cyst" } on the conjunctiva
- An opening of the surgical wound where the eye tissue covers the implant
- A portion of the implant wore through the tissue that covers it, leaving that part of the implant uncovered.
- Scraping of the cornea
- Dryness of the cornea
- Rough spot on the cornea
- Folding of the cornea
- Torn suture
- Decrease in how much light the subject could see
- Increase in uncontrolled eye movements
- Drooping of the eyelid
- Fluid causing partial separation of the retina from the choroid

- Partial separation of the retina from the choroid due to pulling or shrinking of the retina
- Folds in the retina
- Splitting of the layers of the retina
- Growth of blood vessels in the iris
- Movement of the tissue patch used to cover the implant
- Redness and irritation of the sclera
- Eyelash below the conjunctiva
- Nausea
- Dizziness

## Device Function

During the clinical trial{ **XE** "clinical trial" }, most subjects experienced changes in the number of electrodes that were programmed in the VPU. As of March 2012, this number ranged from as few as 8 electrodes in some subjects to as many as 60 electrodes in other subjects. The average number of electrodes programmed for stimulation in the VPU was 38.

The stimulation limit was lower for home use than for clinical testing. Because of this, some electrodes that were programmed for stimulation in the VPU were not able to independently produce light perception during home use. As of March 2012, the number of electrodes that produced light perception when they were stimulated one-at-a-time at the lower home use

level ranged from 0 electrodes in some subjects to as many as 60 electrodes in other subjects. The average number of electrodes that produced light perception when they were stimulated one-at-a-time at the lower home use level was 13.4.

During the clinical trial{ **XE** "clinical trial" }, 13 subjects had fewer than 20 electrodes that produced perception of light when stimulating one electrode at a time. 8 of these 13 subjects did not have any individual electrodes that, on their own, produced perception of light. The clinician changed the VPU programming to quad stimulation in some of these subjects in order to allow them to have perception over a larger part of the electrode array. Refer to page 63 for a description of quad stimulation. As of March 2012, 6 of these 13 subjects were using quad stimulation. In the clinical trial, no attempt was made to directly compare whether quad stimulation provided better vision than single electrode stimulation.

## Probable Benefit

### *Tests of Vision*

All 30 subjects were able to see spots of light when the Argus II System{ XE "probable benefit" } was on.

All 30 subjects did better on tests of their vision when they were using the Argus II System compared to when they were not using the System. However, the extent that each subject's vision improved varied. Three tests were used to measure subjects' vision with the Argus II System.

In the first test, called "Square Localization," subjects had to touch a white square that appeared on a black computer screen. On average, subjects did better on this test with the Argus II System on versus when the System was off at each time point. At one year after implant, 15 of 16 subjects tested did better on this test with their Argus II System on versus with the System off.

The second test was harder than the first test. In the second test, called "Direction of Motion," subjects watched a computer screen where a white bar moved across the screen in different directions. Subjects had to draw on the screen the direction that they thought the bar was moving. On average, subjects did better on this test with the

Argus II System on versus off at each time point. At one year after implant, 10 of 16 subjects did better on this test with their Argus II System on versus with the System off.

The third test was the hardest of the three tests. In the third test, called “Grating Visual Acuity,” black and white stripes with decreasing width were shown on a computer screen. The stripes were drawn in one of four directions, either up and down, left to right, diagonally to the left or diagonally to the right. Subjects had to say which direction the stripes were drawn. When using the Argus II System, 8 of the 30 subjects could correctly tell the direction of the stripes. When not using the Argus II System, none of the subjects could do this test correctly.

### *Line and Door Tests*

The line and door tests were used to test how well subjects could follow a white line on the ground and find the door in a room. At every follow-up visit after implant, subjects were better at doing these tasks when using the Argus II System versus when they were not using the Argus II system.

### *Use of Argus II System in Daily Life and Quality of Life*

Subjects completed two surveys to measure the effect of the Argus II System on their quality of life

and their everyday life. One survey, the Massof Activity Inventory, showed that during the study, subjects reported a small improvement in how easy it was for them to do everyday tasks. The other survey showed no change in quality of life during the study.

A low-vision therapist also spoke with the subjects and visited their homes to judge what affect the Argus II System was having on subjects' lives. These therapists found that 20 of the 26 participating subjects received benefit from the Argus II System, while the remaining 6 subjects were not getting benefit from the system.

## **Conclusions**

The results of this clinical study showed that the probable benefits of the Argus II System are greater than its risks for patients with loss of vision due to retinitis pigmentosa.

## Information about Retinitis Pigmentosa

Retinitis pigmentosa{ XE "retinitis pigmentosa" } (RP) is an eye disease which causes damage to the retina. This damage results in a loss of vision. The retina is the layer of tissue at the back of the inside of the eye. The cells in the retina convert light into signals to nerve cells which send signals to the brain. The brain then tells us what we see. The disease is named for the dark deposits which appear in the retina.

RP can be caused by a genetic defect which will cause it to run in families. Early symptoms of the disease often are first experienced in childhood (loss of the ability to see at night or in very low light). Later the disease may lead to blurring of vision, tunnel vision, loss of central vision or loss of the ability to see colors. In many cases, these severe vision problems do not occur until early adulthood. In advanced stages of the disease, RP can lead to a person being able to see only very bright flashes of light. In the worst case, the person may experience total blindness.

## **Warranty**

### **Argus II Limited Warranty on Retinal Prosthesis (Implant)**

This warranty{ XE "warranty" } applies to a person implanted with an Implant (You). This warranty is provided by Second Sight Medical Products, Inc. (Us, We, or Our).

If an Argus II Implant stops working within 3 years from the date of implant, due to Our not making the Argus II Implant within specifications, We will replace Your Implant. This warranty is limited to Implant failures. This warranty does not apply to failures due to surgical problems. This warranty does not apply to failures due to Your medical condition. An Implant failure must be confirmed by Us before it is explanted.

### **WARRANTY DISCLAIMER:**

**WE EXPRESSLY DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. WE WILL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES CAUSED BY THE IMPLANT'S FAILURE TO FUNCTION WITHIN THE NORMAL TOLERANCES WHETHER THE CLAIM IS**

**BASED ON WARRANTY, CONTRACT, TORT  
OR OTHERWISE.**

If we choose, we may replace the Implant even if the failure is not covered.

**Argus II Limited Warranty on External Devices**

External Devices include the video processing unit (VPU), glasses, battery, battery charger base and battery charger AC adaptor.

We warrant that the Argus II VPU and Glasses will be free from defects in workmanship and materials for 1 year from the date of first VPU fitting (or date of purchase if bought separately).

We further warrant that the supplied battery charger and rechargeable batteries are free from defects in workmanship and materials for 3 months from the date of first VPU fitting (or time of purchase if bought separately). The battery charger includes the charger base and AC adaptor.

We will repair or replace a defective External Device, or at Our option, provide full credit equal to the purchase price of the defective External Device. You may apply the credit towards the purchase of replacement components.

**WE EXPRESSLY DISCLAIM ALL IMPLIED  
WARRANTIES, INCLUDING BUT NOT LIMITED**

## **TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE.**

Product claims under Our Limited Warranty on External Devices are subject to the following conditions:

1. The product registration forms for the VPU and glasses must be completed and returned to Us within 30 days of first programming or receipt of the product.
2. Warranty claim items must be returned to Us within 30 days after receipt of replacement part(s).
3. We must be able to confirm the failure.
4. This warranty excludes defects caused by: fire, floods, lightning, natural disasters and other calamities defined as "Acts of God;". This warranty excludes defects caused by accident, misuse, abuse, negligence, water damage, improper fitting or failure to operate the External Device according to Our instructions. This warranty excludes defects caused by wear and tear resulting in cosmetic or exterior damage. This warranty excludes defects caused by attempts to repair, maintain, or modify the equipment by You or anyone else. This warranty excludes defects caused by attachment of an External Device

to any device not supplied by Us without Our prior approval. This warranty excludes defects caused by cable breakage. Appropriate care should be taken to prevent forces from damaging cables. This warranty excludes defects caused by battery cell depletion, which may occur during the warranty period and is not considered a defect in workmanship or material—The batteries have a specified capacity, which may deplete at different rates depending on the settings used and failure to recharge as specified in the operator's manual. Note: Per operator instructions, batteries should be used promptly after receipt, should not be stored for future use, periodically recharged and must be kept within temperature range. This warranty excludes defects caused by accessories not listed with this limited warranty.

5. For a replacement component the warranty will run only to the warranty period for the original component that was purchased by You.

The terms and conditions of this warranty limitation may be different in each country depending on local laws.

For information on Our warranties or if You believe a device is not working properly, please contact Us using the contact information in Chapter 7.

## **Chapter 7: User Assistance Information**

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Second Sight Medical Products welcomes your comments about the Argus II Retinal Prosthesis System or your suggestions to improve the product. Please feel free to contact us for technical assistance, replacement parts, or your suggestions.

### **Second Sight Medical Products, Inc.**

12744 San Fernando Road, Building 3  
Sylmar, CA 91342 USA  
Phone: +1 818 833 5000  
Fax: +1 818 833 5067

E-mail: [service@2-sight.com](mailto:service@2-sight.com)  
[www.2-sight.com](http://www.2-sight.com)

## **Write important telephone numbers here**

<b>Resource</b>	<b>Telephone number:</b>
Clinic	
Physician	
Device disposal contact:	

# Chapter 8: Symbols and Regulatory Classifications

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## Symbols

The following symbols{ XE "symbols" } appear on components of the Argus II System. The symbols and their meanings are described below.

**Table 12: Symbols**

Symbol	Meaning
	Catalog number
	Serial number
	Lot number
	Date of manufacture
	Warning and/or consult accompanying documents
	Storage temperature range
	Keep Dry
	Non-ionizing radiation (Radio frequency radiation)

Symbol	Meaning
	Manufactured by
	Type B Applied Part
	MR Conditional
	MR Unsafe

## Regulatory Classifications

The Argus II System{ XE "regulatory classifications" } meets the requirements of several international standards and directives. The table below indicates how the Argus II System is classified according to each of these standards and directives. For detailed information regarding electromagnetic environments, please see Appendix B.

**Table 13: Regulatory Classifications**

Standards / Directives	Regulatory Classifications
IEC 60601-1	Classification:  Internally Powered Type B Applied Part IPX0 Continuous Operation

Standards / Directives	Regulatory Classifications
IEC 60601-1-2 Classifications (CISPR 11 Electromagnetic Emissions)	Classification:  <u>Group 1 Equipment</u> Equipment in which there is intentionally generated and/or used conductively coupled radio frequency energy which is necessary for the internal functioning of the equipment itself. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  <u>Class B Equipment</u> Equipment suitable for use in all establishments including your home.

Standards / Directives	Regulatory Classifications
IEC 60601-1-2 (Electromagnetic Immunity)	<p>Classification:</p> <p>The Argus II System may experience interference from ESD{ XE "electrostatic discharge (ESD)" }, power frequency magnetic fields, and conducted and radiated RF.</p>

Standards / Directives	Regulatory Classifications
R&TTE Directive	<p>Classification:</p> <p><u>Product Type 1</u> - Inductive loop coil transmitter tested with an integral antenna</p> <p><u>Receiver Class 2</u> - Function critical Short Range Device (SRD) communication media; i.e. when a failure to operate correctly causes loss of function but does not constitute a safety hazard.</p>

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## Appendix A: Potential Effects of Electromagnetic Interference (EMI)

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### Information for Users (FCC Rules)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for 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 and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, 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 to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

- Consult the dealer or an experienced radio/TV technician for help

Any changes or modifications not expressly approved by Second Sight Medical Products, Inc. could void the user's authority to operate the equipment.

**Table 14: Potential effects of EMI from devices or procedures**

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
Airport{ XE "electromagnetic interference (EMI):index of potential effects" } screening device			✓		Page 39
Bipolar electrosurgical equipment		✓			Page 38
Bluetooth device			✓		Page 41
Cell phones or cordless phones			✓		Page 41

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
Computed tomography (CT) Scan				✓	Page 38
Commercial electrical equipment (for example, arc welders induction furnaces, resistance welders, etc.)			✓		Page 42
Communication equipment (such as microwave transmitters, linear power amplifiers and high-power amateur transmitters)			✓		Page 42
Defibrillator		✓			Page 38
Diagnostic Ultrasound				✓	Page 38

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
Diathermy	✓	✓			Page 29
Electric steel furnaces			✓		Page 42
Electroconvulsive therapy (ECT)	✓	✓			Page 29
Electronic article surveillance (EAS) systems and EAS tag deactivators			✓		Page 39
Fragmatome		✓			Page 38
Hearing aids			✓		Page 40
High output ultrasound	✓	✓			Page 42

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
High voltage lines, power lines or generators			✓		Page 42
Home appliances			✓		Page 41
Large magnetized speakers			✓		Page 42
Laser		✓			Page 38
Lithotripsy	✓	✓			Page 30
Magnetic resonance imaging (MRI)	✓	✓		✓	Page 30
Metal detector			✓		Page 39
Microwave oven			✓		Page 41

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
Phacoemulsification		✓			Page 38
Radiofrequency identification (RFID) systems			✓		Page 39
Theft detector			✓		Page 39
Therapeutic ionizing radiation to the head		✓			Page 38
WiFi access point			✓		Page 41
Wireless router			✓		Page 41

<sup>a</sup> If the medical procedure is being performed to evaluate the area where the Argus II Implant is located, the implant may block or blur the image making it unreadable in this area.

# Appendix B: Electromagnetic Environments

## Guidance{ XE "electromagnetic interference (EMI):electromagnetic environments" } and manufacturer's declaration – electromagnetic emissions

The Argus II system is intended for use in the electromagnetic environment specified below. The customer or the user of the Argus II system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Argus II system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Argus II System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable*	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable*	

\* Not Applicable – The Argus II System is Battery Powered

Guidance and manufacturer's declaration – electromagnetic immunity			
The Argus II system is intended for use in the electromagnetic environment specified below. The customer or the user of the Argus II system should assure that it 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	± 6 kV contact  ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle  40 % UT (60 % dip in UT) for 5 cycles  70 % UT (30 % dip in UT) for 25 cycles  <5 % UT (>95 % dip in UT)	Not Applicable	
Power frequency (50/60 Hz) magnetic field  IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The Argus II system is intended for use in the electromagnetic environment specified below. The customer or the user of the Argus II system should assure that it is used in such an environment.			
<b>IMMUNITY test</b>	<b>IEC 60601 Test Level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
Conducted RF IEC 61000-4-6  Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz  3 V/m 80 MHz to 2.5 GHz	3 V  3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Argus II system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.17 P$ $d = 1.17 P \text{ 80 MHz to 800 MHz}$ $d = 2.33 P \text{ 800 MHz to 2.3 GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>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></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.</p>			

a 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Argus II system is used exceeds the applicable RF compliance level above, the Argus II system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Argus II System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the Argus II system**

The Argus II system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Argus II system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Argus II System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = [ 3.5 ] PV1$	80 MHz to 800 MHz $d = [ 3.5 ] PE1$	800 MHz to 2.5 GHz $d = [ 7 ] PE1$
0.01	0.0117	0.0117	0.0233
0.1	0.117	0.117	0.233
1	1.17	1.17	2.33
10	11.7	11.7	23.3
100	117	117	233

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 rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 Hz, 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.

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