



Second Sight

***Argus<sup>®</sup> II***  
***Retinal Prosthesis System***  
***Surgeon Manual***

**REF** 090001-004

**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<sup>®</sup> II***  
***Retinal Prosthesis System***  
***Surgeon Manual***

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# 1 Introduction

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This manual describes the Argus II Retinal Prosthesis (Implant) and the procedures associated with its implantation. Refer to the Argus II Product Insert for indications, contraindications, warnings, precautions, clinical considerations, safety and probable benefit data and other general information about the Argus II Retinal Prosthesis System.

## 1.1 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.

## 1.2 Training

Prior to implanting the device, you will receive training which covers patient selection, key surgical steps, how to properly handle the device during the implantation procedure, and reviews the instructions for use. As part of this training, you will also review a video of the procedure and receive hands-on training to practice handling the implant and tack with a surgical mock-up which replicates the primary structures and landmarks of the eye. Additionally, Second Sight requires that for the first implantation procedure conducted at each site, a vitreoretinal surgeon experienced in implanting the Argus II Implant be present during the surgery to guide the new implanting surgeon through the procedure.

## 1.3 Argus II Retinal Prosthesis System Components Overview

The Argus II System consists of the following main components:

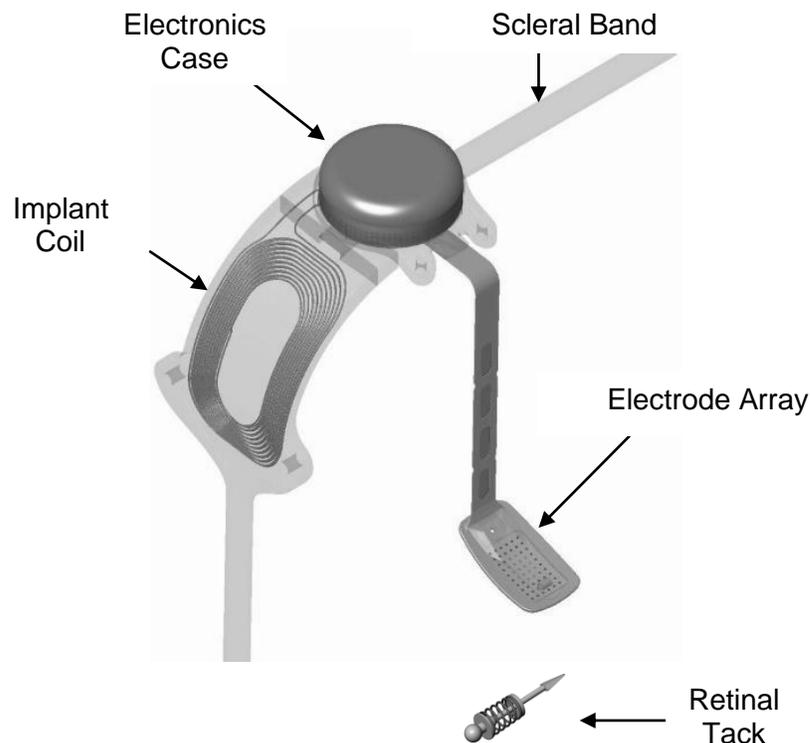
- **Argus II Implant:** A neural stimulation device that is implanted in the patient's eye. The implant is comprised of a coil and a case, which are placed around the eyeball using a scleral band, and an electrode array, which is tacked intraocularly on the surface of the retina.
- **Argus II Glasses:** Glasses that are specially fitted with a miniature video camera, radio-frequency (RF) coils and associated electronic circuitry. The glasses transmit electrical stimulation data along with power via telemetry to the implant. The Argus II Glasses are worn by the patient.
- **Argus II Operating Room (OR) Coil:** An RF coil that is used to test the functionality of the implant during the implantation procedure.
- **Argus II Video Processing Unit (VPU):** A battery-powered device that processes the video signal obtained from the video camera on the glasses and transforms it into electrical stimulation data. The electrical stimulation data and power are then sent to the Argus II Glasses for transmission to the implant. The VPU comes with a pouch that is worn by the patient.
- **Argus II Clinician Fitting System (CFS):** Laptop computer that is configured with a dedicated, PC-based software that, when connected to the VPU, enables tailoring of the electrical stimulation parameters for the patient (i.e. creating a video configuration

file), as well as monitoring and troubleshooting of the system. The CFS is used in medical facilities and clinical research settings and is operated by approved clinicians, researchers, and Second Sight personnel. Patients do not operate the CFS and do not use it at home.

## 1.4 Argus II Retinal Prosthesis (Implant)

The implant is a sterile medical device which is surgically placed within the orbit, partly outside and partly inside of the patient's eye. The implant is comprised of the following components: (1) the electronics case, (2) the implant coil, (3) the electrode array, and (4) the scleral band. The array is secured in place over the fovea using a retinal tack. Figure 1.1 shows an illustration of the Argus II Right Eye Implant and Retinal Tack. Table 1.1 and Table 1.2 provide descriptions of the components and accessories of the implant.

**Figure 1.1 Argus II Implant and Tack**



**Table 1.1 Implant Components**

<b>Component</b>	<b>Description</b>
Implant Coil	<p>This contains the receiver and transmitter antenna made of wire encased in silicone. The coil communicates with an external coil on the Argus II Glasses. The implant coil is connected to the electronics case. When implanted, the coil is affixed to the inferior temporal sclera via sutures through a tab located along the anterior edge of the coil.</p>
Electronics Case	<p>A cylindrical, hermetically-sealed case contains electronic components and an Application Specific Integrated Circuit (ASIC) for processing the received data and using the received power to generate the required stimulation output. The case is affixed to the superior temporal sclera via sutures through the tabs located along the anterior edge of the case.</p>
Electrode Array	<p>The means by which electrical stimulation is delivered from the case to the retina.</p> <p>The electrode array consists of a polymer cable that contains the wire conductors and an array of 55 enabled platinum electrodes where the conductors terminate. These electrodes are secured in place over the fovea using a retinal tack.</p> <p>The proximal end of the cable is connected to the package while the distal end (the array) is attached to the retina. In between, the cable traverses the eye wall through a pars plana incision.</p> <p>Silicone is used over much of the array to buffer the interface of the polymer with the retinal tissue.</p>
Scleral Band	<p>In addition to the sutures described above, a sclera band that is equivalent to a 240 band used in scleral buckling procedures is used to hold the implant on the eye. When implanted, the band is held around the eye with a silicone sleeve and is affixed to the sclera with a suture over the band (and/or scleral tunnel) in each of the nasal quadrants.</p>

**Table 1.2 Implant Accessories**

Component	Description
Retinal Tack	Modeled after a standard retinal tack, with the addition of an integrated spring, this tack is used to affix the array to the retina.
VPU-Implant Matching CD	A CD containing configuration information for pairing a VPU with a specific implant.

## 1.5 Argus II Glasses

Figure 1.2 shows the Argus II Glasses for the right eye implant. The glasses for the left eye implant are the same with the exception that the RF board and coil of the glasses are attached to the left side ear piece. Refer to the “Argus II Retinal Prosthesis System Device Fitting Manual” for a detailed description of the glasses components and associated accessories.

**Figure 1.2 Argus II Glasses**



## 1.6 Argus II Operating Room (OR) Coil

The Argus II Operating Room Coil is used to test the pre-operative and intra-operative functionality of the implant. The OR coil is shown in Figure 1.3. Table 1.3 provides a description of the components that make up the OR coil.

**Figure 1.3 Argus II OR Coil**



**Table 1.3 OR Coil Components and Accessories**

Component	Description
Operating Room Coil	This component is placed in a sterile sleeve for use in the surgical field to confirm intra-operative functionality of the implant.
Sterile Sleeve (not shown above)	Sterile sleeve for housing OR coil when placed in the surgical field.

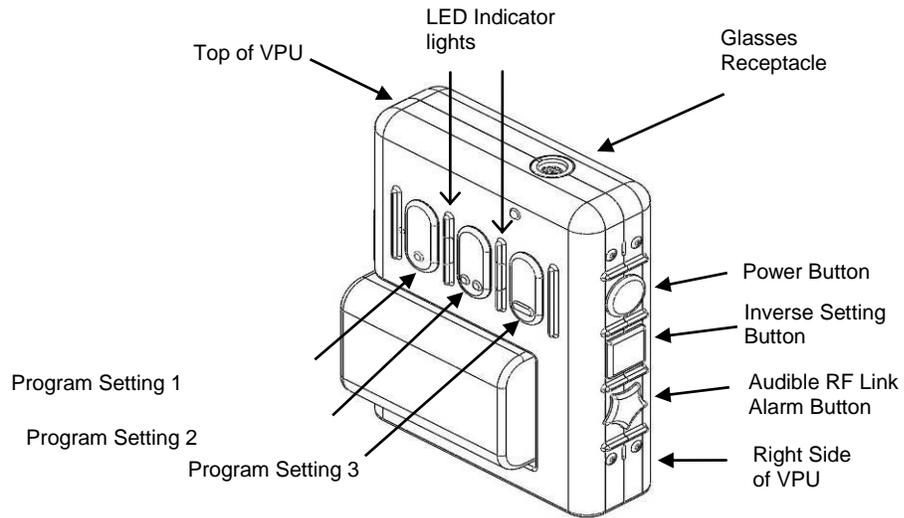
## 1.7 Argus II Video Processing Unit (VPU)

Figure 1.4 shows the Argus II Video Processing Unit (VPU). A multi-view illustration of the VPU is provided in Figure 1.5. Refer to the “Argus II Retinal Prosthesis System Device Fitting Manual” for a detailed description of the VPU components and the associated accessories.

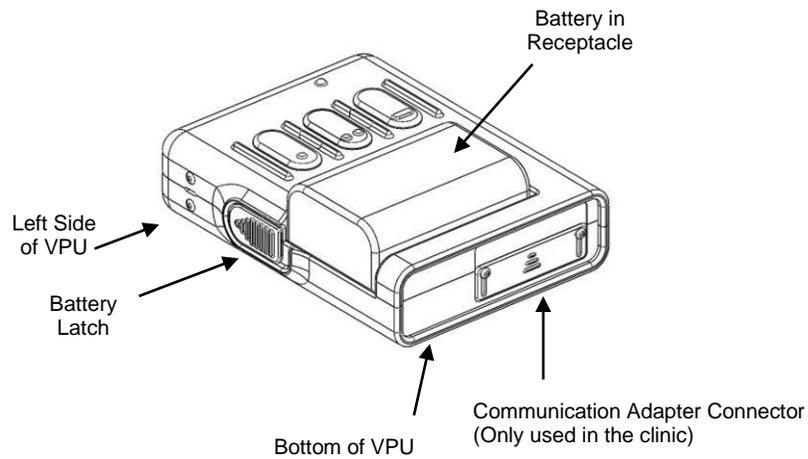
**Figure 1.4 Argus II VPU**



**Figure 1.5 Illustrations of the VPU and its Components**



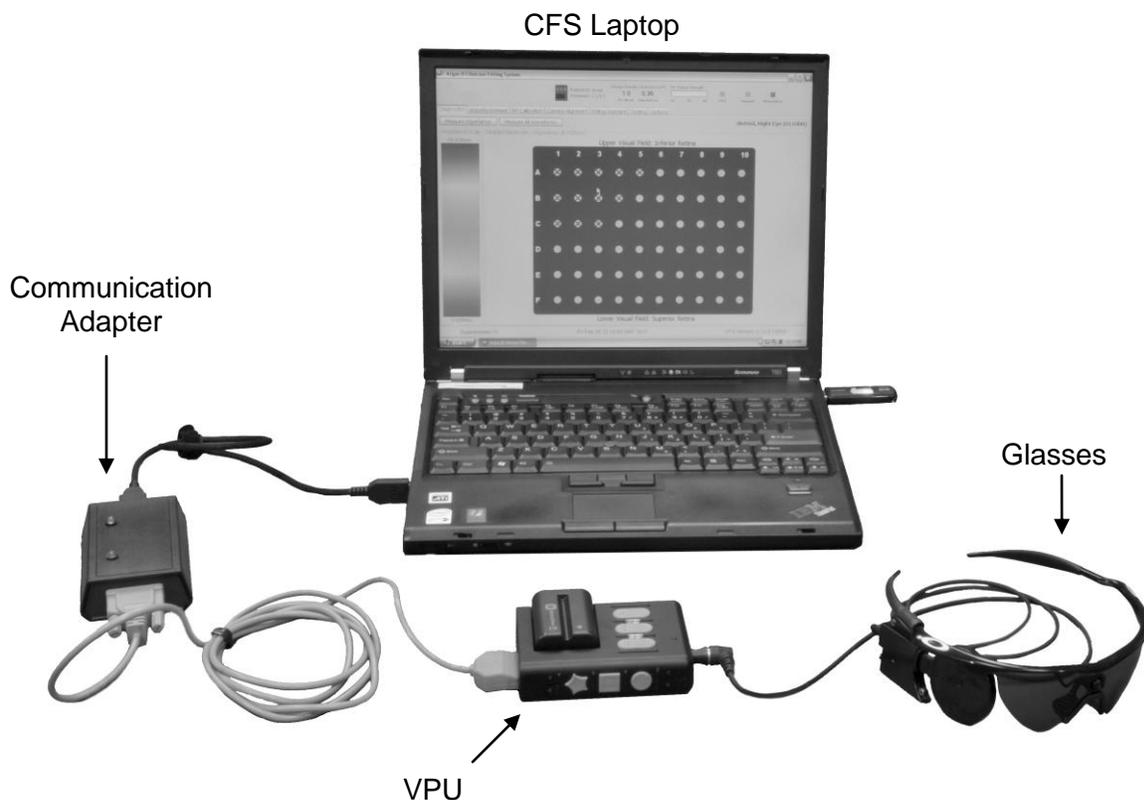
**Figure 1.6**



## 1.8 Argus II Clinician Fitting System (CFS)

The Argus II Clinician Fitting System (CFS) is used to configure the Argus II System stimulation parameters and video processing strategies for each patient. The CFS consists of custom software with a graphical user interface running on a dedicated laptop computer. Within the CFS are modules for performing diagnostic checks of the implant, loading and executing video configuration files (VCFs), viewing electrode voltage waveforms, and conducting psychophysical experiments. Figure 1.6 shows the components of the Argus II Clinician Fitting System. Refer to the “Argus II Retinal Prosthesis System Device Fitting Manual” for a detailed description of the CFS and the associated accessories.

**Figure 1.7 Clinician Fitting System (CFS)**



## 1.9 Surgical Supplies

The following lists contain products that may be used or consumed before or during the Argus II Retinal Prosthesis surgery. Contact Second Sight Customer Service for replacement parts. These lists may be updated periodically.

<b>Products Manufactured by Second Sight</b>	<b>Second Sight Catalog Number</b>
Argus II Retinal Prosthesis Kit, Right Eye	011013-K
Argus II Retinal Prosthesis Kit, Left Eye	011014-K
Argus II Retinal Tacks	011006
Argus II Surgeon Manual	090001
Argus II Device Fitting Manual	090002
Argus II Patient Manual	090000
Argus II VPU-Implant Matching CD (implant serial number specific)	011007
Argus II Operating Room (OR) Coil	012103
Argus II Clinician Fitting System	014003
Argus II Communication Adapter	014103
Argus II Video Processing Unit	013003
Video Processing Unit Battery (Small)	100200-001
Video Processing Unit Battery (Medium)	100200-002
Video Processing Unit Battery Charger	100200-004
Argus II CFS-CA Cable	014916
Argus II CA-VPU Cable	014913
Argus II USB Drive, Security	014984
Argus II Explant Kit (US)	011099

Surgical Supplies that may be purchased from Second Sight	Second Sight Catalog Number
OR Coil Sleeves	100705-006
Silicone Tipped Forceps	100705-005
Knife, 19 ga MVR	100705-003
Retinal Tack Forceps, Tip 19 ga	100705-002
Sutherland Handle NG	100705-001
Silicone Sleeve, Style 3083	100700-216
Synerfit™ Single Port Adapter	100710-006
Synerport™ Single Fiber Adapter	100710-005
Tano Diamond Dusted Membrane Scraper	100710-004
Illuminated 4.0mm Infusion Cannula, 19 ga	100710-003
Disposable Micro Serrated Eckhardt Forceps, Tip Only, 20 ga	100710-002
Syntrifugal™ Handle	100710-001

## 1.10 Where to Find Information

Information regarding indications, contraindications, warnings, precautions, clinical considerations, safety and probable benefit data, magnetic resonance imaging (including a summary of the MR sequences used), electromagnetic environments, recommended separation distances, wireless characteristics of the Argus II System, and other general information about the Argus II System can be found in the “Argus II Product Insert.” The product insert has been provided along with this Surgeon Manual.

Additional technical information about the Argus II Retinal Prosthesis System and detailed programming instructions can be found in the “Argus II Retinal Prosthesis System Device Fitting Manual.”

## 1.11 Symbols and Regulatory Classifications

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

**Table 1.4: Symbols**

Symbol	Meaning
	Catalog number
	Single use
	This product has been sterilized using ethylene oxide
	Use by date
	Serial number
	Lot number
	Date of manufacture
	Warning and/or consult accompanying documents
	Storage temperature range
	Keep Dry
	This device is susceptible to electrostatic discharge (ESD) damage and should be handled in an ESD safe manner
	Non-ionizing radiation (Radio frequency radiation)
	Manufactured by
	Type B Applied Part
	Fragile
	MR Conditional
	MR Unsafe

The Argus II System 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.

**Table 1.5: Regulatory Classifications**

Standards/Directives	Classifications
EN60601-1	Classification:  Internally Powered Type B Applied Part IPX0 Continuous Operation
R&TTE Directive	Classification:  <u>Product Type 1</u> - Inductive loop coil transmitter tested with an integral antenna  <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
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 domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes
IEC 60601-1-2 (Electromagnetic Immunity)	Classification:  The Argus II System may experience interference from ESD, power frequency magnetic fields, and conducted and radiated RF.

## 1.12 Acronyms Used in This Manual

Acronym	Meaning
ASIC	Application Specific Integrated Circuit
BIOM	Binocular Indirect Ophthalmo Microscope
CA	Communication Adapter
CD	Compact Disc
CFS	Clinician Fitting System
CT	Computed Tomography
ERG	Electroretinography
ESD	Electrostatic Discharge
FCE	Field Clinical Engineer
GUI	Graphical User Interface
ID	Identification
IOP	Intraocular Pressure
LED	Light Emitting Diode
MR	Magnetic Resonance
MVR	Microvitreoretinal
OCT	Optical Coherence Tomography
OR	Operating Room
PTS	Psychophysical Test System
RMA	Return Materials Authorization
RF	Radio Frequency
USB	Universal Serial Bus
VCF	Video Configuration File
VPU	Video Processing Unit

## 1.13 Contact Us

Second Sight Medical Products, Inc. is committed to providing the highest quality products and service to our customers. Please feel free to contact us for technical assistance or replacement parts.

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# 2 Pre-Operative Considerations

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## 2.1 Patient Screening

Clinical best practice should be employed when screening patients for eligibility to receive the Argus II Retinal Prosthesis System. Please refer to the Product Insert for indication and contraindication information.

When a patient is screened for the Argus II Implant, the following process is recommended (screening should be terminated at any step where the patient is deemed ineligible):

1. Confirm that the patient is at least 25 years old, has a diagnosis of retinitis pigmentosa, and a history of previous useful form vision.
2. Perform a visual function assessment to confirm that the subject has bare light or no light perception in both eyes. If the patient has no residual light perception, the retina must be able to respond to electrical stimulation. In cases where no measurable acuity is observed, residual light detection should be verified using full-field stimulus threshold measurements (for suitably-equipped ERG systems such as Espion Systems), or by reliable dark-adapted detection of a photo flash. Performance in subjects with visual acuity better than 2.3 logMAR has not been studied.
3. Perform a comprehensive eye exam (both eyes), assessing whether or not any contraindications are present.
4. Review the patient's medical history (including current medications and allergies) for the presence of contraindications. It is strongly recommended that preoperative psychosocial evaluation be performed to determine a patient's level of motivation, expectations of the device, ability to deal with potentially disappointing results, and the extent of their social support network.
5. Review the warnings, precautions and clinical considerations in the Product Insert, to confirm that the Argus II is still suitable for the patient.
6. Review with the patient their expectations for the system. Review the Patient Manual with the patient and his/her caregivers, if applicable, to give them an opportunity to ask questions about the anticipated risks and benefits of the Argus II System. Provide the patient with a paper and audio version of the Patient Manual.
7. Perform diagnostic testing and imaging to assist in patient assessment and planning. Typical assessments include: Ultrasound A-Scan (to measure the axial length of the implanted eye), Ultrasound B-Scan (to assess for abnormalities in the typical curvature of the eye, such as staphyloma), Fundus photography, Fluorescein angiography, and Optical Coherence Topography.

For patients who are successfully screened and who want to use the Argus II System, follow your institutional procedures for consenting, scheduling, and ordering.

## 2.2 Equipment and Supplies for Implantation

In addition to the standard equipment and supplies used in vitreo-retinal surgery, the following items are needed to implant the Argus II device.

### 2.2.1 Argus II Implant

Each kit contains:

- 1 Argus II Implant (sterile)
- 2 Argus II Retinal Tacks (sterile)
- 2 VPU-Implant Matching CDs (implant specific)
- Warranty Registration Form and Return Envelope
- Patient ID Card
- Argus II Surgeon Manual
- Operative Report Form

**NOTE:** Confirm that the correct implant configuration (i.e. right eye or left eye) has been selected for the patient.

**NOTE:** It is strongly recommended that a back-up implant and back-up tacks be available for each implant procedure.

### 2.2.2 Argus II External Devices (OR Configuration)

All external equipment is non-sterile. All external equipment should be tested prior to the start of the implant procedure to verify proper function.

- Argus II Operating Room Coil (OR Coil)
- Argus II Video Processing Unit (VPU)
- Argus II Communication Adapter (CA)
- Argus II Clinician Fitting System (CFS)
- Cables and accessories:
  - VPU battery (fully-charged)
  - Argus II CA-VPU cable
  - Argus II CFS-CA cable
- Argus II USB Security Drive (if this is the first time using the CFS)

**NOTE:** The VPU used during implantation must be configured for use in the Operating Room (OR). Section 2.3.2 provides the detailed description of the OR Configuration.

**WARNING**

Do not use a VPU configured for operating room use for purposes other than pre-operative or intra-operative testing unless instructed by Second Sight trained personnel. Unsafe stimulation may occur. If necessary, contact Second Sight to change the VPU configuration for normal clinic or at-home use.

**2.2.3 Standard Vitreo-Retinal Surgical Equipment**

- Vitrector
- Operating microscope (with inverter)
- BIOM with BIOM lens (or equivalent non-contact lens)
- Vitrectomy lens(es)
- Bipolar electrosurgical equipment
- Photocoagulation laser
- Anaesthesia machine with ventilator

**2.2.4 Surgical Instruments**

- Lid speculum
- Large artery clamp
- Small artery clamp
- Wescott blunt scissors
- Blunt curved scissors
- Big scissors (can be straight scissors)
- Fixation forceps
- (2) Blunt Alabama forceps
- Suture tying forceps
- Silicone-tipped forceps\*
- Plug forceps
- End-gripping forceps, 20 ga
- Retinal tack forceps, 19 ga
- Large fixation forceps
- (2) Muscle hooks, one plain, one with eyelet
- (1-2) Barraquer's needle holder
- Myringotomy (19 ga and 20 ga MVR)
- Calipers (millimeter increments or smaller)
- Vitreous cutter

- Endoillumination probe (light pipe)
- 19 gauge illuminated infusion cannula (4 mm length)\*
- B.P. blade handle
- Diamond dusted Tano Brush\*
- Soft-tipped cannula

\* Items marked with an asterisk may be purchased from Second Sight (See Section 1.9)

### 2.2.5 Surgical Supplies

- Silicone sleeves (Labtician Ophthalmics™, Oval Sleeve, Style # 3083)\*
- 9-0 Prolene™ monofilament sutures with micropoint spatulated needle (Johnson & Johnson, #1754G) or equivalent non-absorbable sutures
- 6-0 Vicryl sutures braided with spatula needle or equivalent absorbable sutures
- 5-0 Mersilene® sutures braided with spatula needle or equivalent non-absorbable sutures
- 2-0 silk sutures or equivalent muscle manipulation sutures
- 6-0 chromic sutures or equivalent biological sutures
- Processed pericardium or equivalent (approximately 400 µm thick)
- Sterile balanced salt solution
- Sterile sleeves / sterile camera drapes\*
- Spare tack for the electrode array\*
- Sterile powder-free and latex-free gloves or sterile silicone phaco test chamber
- General vitreoretinal surgical items

\* Items marked with an asterisk may be purchased from Second Sight (See Section 1.9)

## 2.3 Pre-Operative Preparation: The Day Before Surgery

The Argus II Retinal Prosthesis System operates in three configurations: Operating Room (OR) Configuration, Clinical Fitting /Testing Configuration, and Stand-Alone Configuration. The OR configuration will be described below. Refer to the Argus II Device Fitting Manual for the description of the other two configurations and further technical information.

It is strongly recommended that all Argus II External Equipment and the Argus II Implant be tested the day before the surgery to ensure that they are working properly. A spare set of external equipment and the back-up implant should also be tested at this time.

### WARNING



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

**WARNING**



The use of cables or batteries other than those supplied by Second Sight may result in the Argus II system being more effected by electromagnetic interference from other devices. Use of non-approved cables or batteries may also result in the Argus II System interfering with the performance of other electronic equipment.

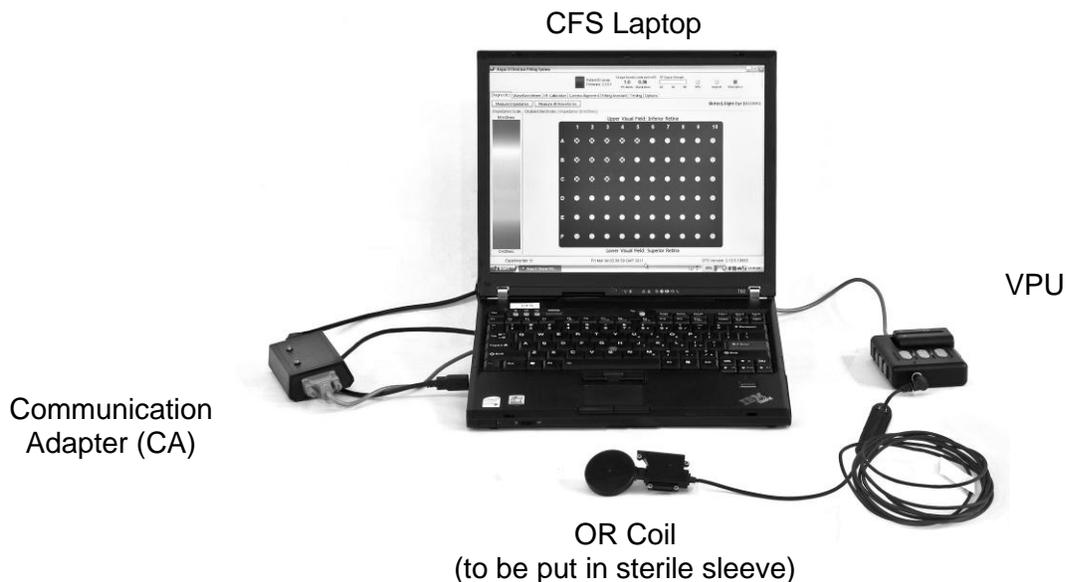
**2.3.1 Equipment Set-Up**

1. Obtain all of the Argus II External Equipment necessary for the operating room configuration as shown below in Figure 2.1.
2. If this is the first time using the clinician fitting system (CFS) computer at the site, perform the “Updating the Center Resource Identifier on CFS”. Second Sight trained personnel are required to perform this procedure.
3. Install a fully-charged battery in the video processing unit (VPU). Connect the OR coil to the VPU by inserting the plug on the OR coil cable into the glasses receptacle on the top of the VPU.
4. Connect the Communication Adapter (CA) to the VPU via the CA-VPU cable.

**NOTE:** To save battery life, the VPU should remain off until it is needed for the pre-operative test of the implant.

**CAUTION:** The CA should only be plugged in the USB port marked “CFS-CA Cable”. If not, it may result in interruption of normal use of the CFS.

**Figure 2.8 Operating Room Configuration**



### 2.3.2 Configuring the VPU for OR Use

In OR configuration, electrode impedance measurements are performed on-demand, as opposed to being automatically performed as usually occurs when VPUs are used in the clinic or at-home. Prior to using a VPU during the implantation procedure, the following steps must be performed:

**NOTE: Some of the following processes may only be performed by Second Sight trained personnel.**

1. On the CFS laptop open the Argus II CFS software by clicking on START and selecting “Argus II Clinician Fitting System” (CFS) in the program menu. The log-in screen will appear requesting a username and password. Enter user name and password to log in to CFS.
2. Configure the VPU for OR use or confirm that it has already been configured for OR use. Refer to the Argus II Device Fitting Manual “Configure the VPU for OR Mode” section for detailed instructions.

### 2.3.3 Pre-Operative Implant Testing Procedure

The functionality of the implant can be tested pre-operatively and intra-operatively by using an Argus II OR Coil that is placed in close proximity to the implant. The OR coil communicates the status of the implant to the Argus II VPU (configured for OR use) which is connected to the CFS laptop via a cable through the communication adapter. The configuration is shown in Figure 2.1.

1. Obtain the Argus II Implant Kit. Open the implant kit box, but leave the implant sealed in the inner box marked “Sterile”.
2. Perform VPU-implant matching. Each Argus II Implant has certain custom specifications. To optimize the performance of the system and for safety reasons, the VPU used with the implant must be configured or “matched” to the implant. To match a VPU to an implant, Second Sight personnel use the VPU-implant matching CD that is provided with each Argus II Implant.

**CAUTION: Always match the VPU to the patient’s implant. In order to provide the best control over stimulation parameters, the VPU is calibrated for the patient’s implant. The implant matching data for each implant is provided on a CD, and must be loaded into the patient’s VPU prior to use. Failure to do so could result in less accurate threshold measurements, distortion of the presented image, and discomfort to the patient.**

3. Program the VPU with the patient ID.
4. Using the operating room external equipment configuration, place the OR coil in the centre of the bottom of the Argus II Implant box.

5. Adjust the OR coil position (moving it lengthwise along the box if necessary) until link is obtained with the implant. The VPU will emit a periodic, audible beep until link is obtained.
6. Once link has been obtained, the audible beep will stop and the green LED indicator on the VPU will blink fast to indicate that the start-up tests are being conducted. These tests should last approximately 10 seconds.
7. Once the tests are complete, the VPU green LED will blink (approximately 1 blink/second) to indicate the implant passed the start-up tests.
8. On the CFS laptop select the 'Start Session' option from the main menu. Enter the patient ID when prompted.
9. Select "Patient Testing".
10. Ensure the "Diagnostics" tab is selected and click the "Measure Impedance" button to measure the impedance of the implant. The impedance values measured at this stage are typically high as the implant is dry.

#### **2.3.4 Repeating Preparation with Spare Equipment**

It is highly recommended that a complete set of spare equipment (including a second implant) be available, configured and tested the day before the surgery. Keeping the secondary implant in its sealed, unopened shipping container, match the secondary VPU with the secondary implant using the VPU-Implant matching CD provided by Second Sight personnel.

#### **2.3.5 Charging the Batteries**

Fully charge two VPU batteries. Follow the instructions supplied with the battery charger to charge the VPU batteries.

# 3 Surgical Procedures

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This chapter provides information for physicians and personnel who participate in surgical procedures involving the Argus II Implant. The activities described in this section require both aseptic and clean technique. The following topics are described in this chapter:

- How to handle the implant
- Intra-operative setup
- Implant procedure
- Recommended Medication Regimen
- Intra-operative implant testing procedure
- Post-implant evaluation and testing
- Re-interventions and Elective Revision Surgery
- Surgical removal of the implant

## 3.1 How to Handle the Implant

The Argus II Implant is made specifically for either the left eye or the right eye. Before opening the Argus II Implant package, carefully read the label and verify that the package contains the desired device.

**CAUTION:** Handle the Argus II Implant with extreme care, especially the electrode cable and array which are fragile. Do not drop the device or allow other objects to fall onto it as this can damage the device. Minimise touching the implant directly. Whenever possible, use soft-tipped instruments to manipulate the implant. Do not handle the device with electrical or sharp instruments as these may damage the device. The device may be safely handled by the scleral band, as shown in Figure 1.1.

Minimize flexure of the implant coil and its joint with the case. Handle the coil with fingers, silicone tipped forceps or flat forceps. Muscle hooks are an acceptable tool to handle the coil. Avoid the use of serrated or sharp ‘toothed’ forceps which can damage the silicone protection.

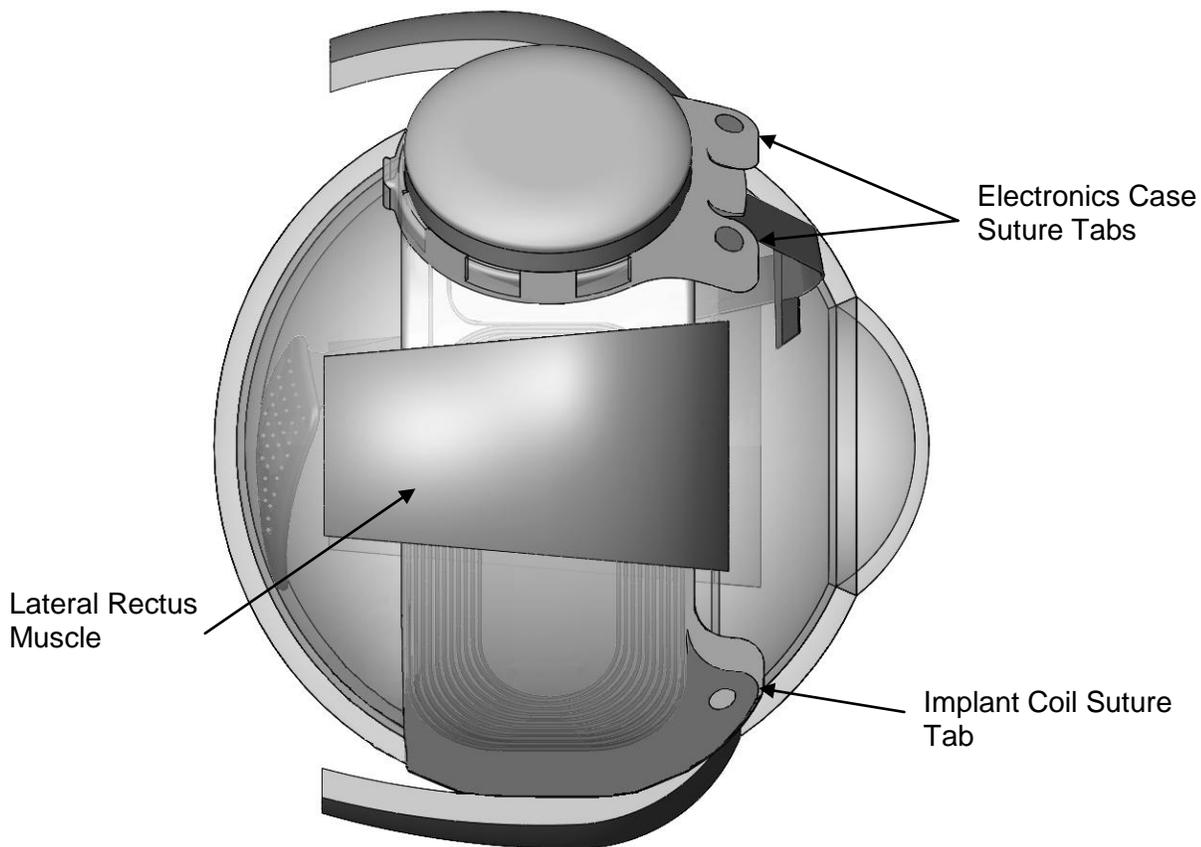
Do not lift the device by the electrode array or cable (shown in Figure 1.1) as this could result in tearing of the array or mechanical damage that could reduce the life of the device. The device may be safely handled by the scleral band. If the electrode array must be handled, use only silicone-tipped forceps on the cable or grip the electrode array by the handle on the back surface of the array. Avoid touching other parts of the array, especially the exposed electrode region.

**CAUTION:** During implantation, if an undesirable condition occurs when the Argus II Implant is electrically active, immediately turn off the VPU or move the OR coil away from the implant. Either of these actions will stop the VPU from delivering power to the implant.

The Argus II Implant is designed with features to aid its handling and surgical placement. To aid in securing the implant to the sclera, three suture tabs are provided, one on the implant coil and two on the electronics case.

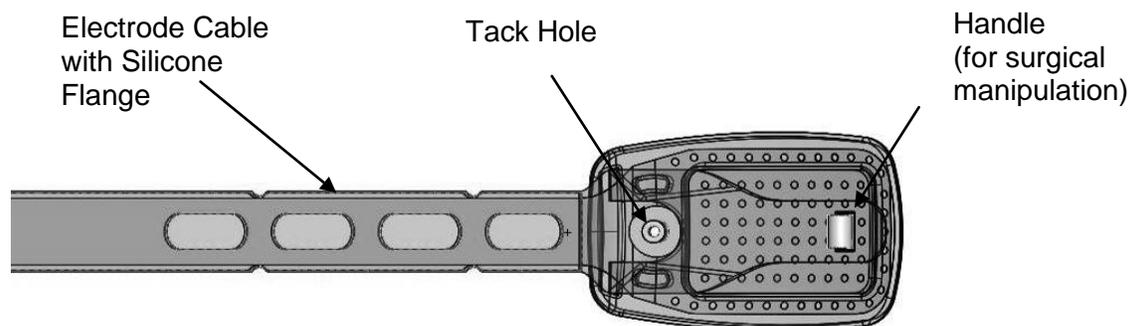
**Figure 3.9 Argus II Implant, Right Eye, in Position on the Eye (Temporal Side View)**

**Figure 3.10**



A “handle” on the distal end of the array (Figure 3.3) allows it to be grasped with intraocular forceps, inserted into the vitreous cavity, and positioned over the retina. A tack hole at the base of the electrode array site accepts a retinal tack. This tack secures the electrode array to the retina. The tack has a spring on it to keep the array in contact with the retina. For tissue protection, much of the retinal side of the electrode array has a covering of silicone.

**Figure 3.11 Landmarks for the Surgeon on the Electrode array**



## 3.2 Intra-Operative Setup

### Preparing the Second Sight-supplied equipment

Refer to the “Equipment Setup” section in Chapter 2 to set up the equipment for intra-operative device testing.

### Placing the OR Coil in the Sterile Sleeve

**CAUTION:** Take care to maintain the sterility of the OR coil when connecting it to the VPU.

1. Use two people (one sterile, one non-sterile) and proper sterile techniques. Have the sterile person open the sterile sleeve (camera drape or equivalent) and seal the bottom of the sterile sleeve, with a knot or tape, to prevent the coil from protruding from the opening (if an opening is present).
2. Have the non-sterile person hold the cable of the OR coil and carefully lower the coil end into the sterile sleeve. The coil should be positioned in the bottom of the sterile sleeve and the connected cable should exit from the open end of the sleeve through the telescoping ring. The sterile person then pulls on the telescoping ring to extend the sterile sleeve over the length of the OR coil cable.

**Note:** The outside surfaces of the sterile sleeve must remain sterile. The top (open edge) of the sleeve, where the non-sterile cable exits is to be considered non-sterile.

3. Place the OR coil, draped in the sterile sleeve, upon an instrument table within the sterile field. The OR coil cable should be extending outside of the sterile field for connection to the VPU. Clamp the sterile sleeve and cable near the perimeter of the sterile field so that the portion of the sleeve outside of the sterile field is not free to slide into and contaminate the sterile field.
4. Have the non-sterile person hold the plug of the OR coil cable and connect it to the VPU.

### Introducing the Implant into the Sterile Field

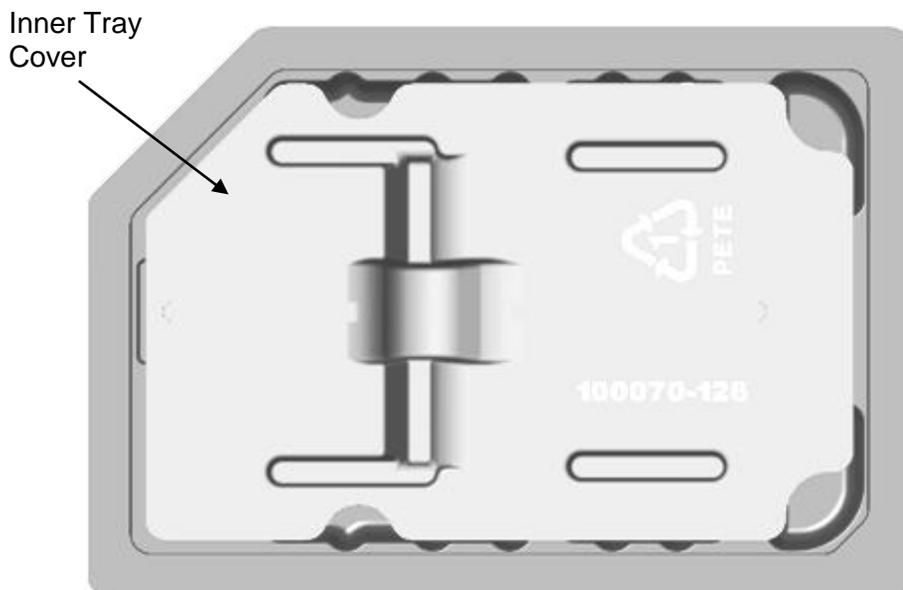
1. Obtain the Argus II Implant intended for implantation. Confirm that the VPU has been matched to this implant. It is recommended to hand over the implant with the complete package to the non-sterile nurse and instruct him/her about opening the implant package.
2. The non-sterile nurse will remove the device tray from the outer box. The implant is packaged in an inner tray (sterile) which is sealed inside an outer tray (non-sterile). The non-sterile nurse will use sterile technique to peel back the Tyvek lid from the outer tray and introduce the inner tray (which contains the implant and two retinal tacks) into the sterile field. The device should remain in its sterile tray, with the lid sealed, until instructed to be opened as described below.

### Preparing the Implant

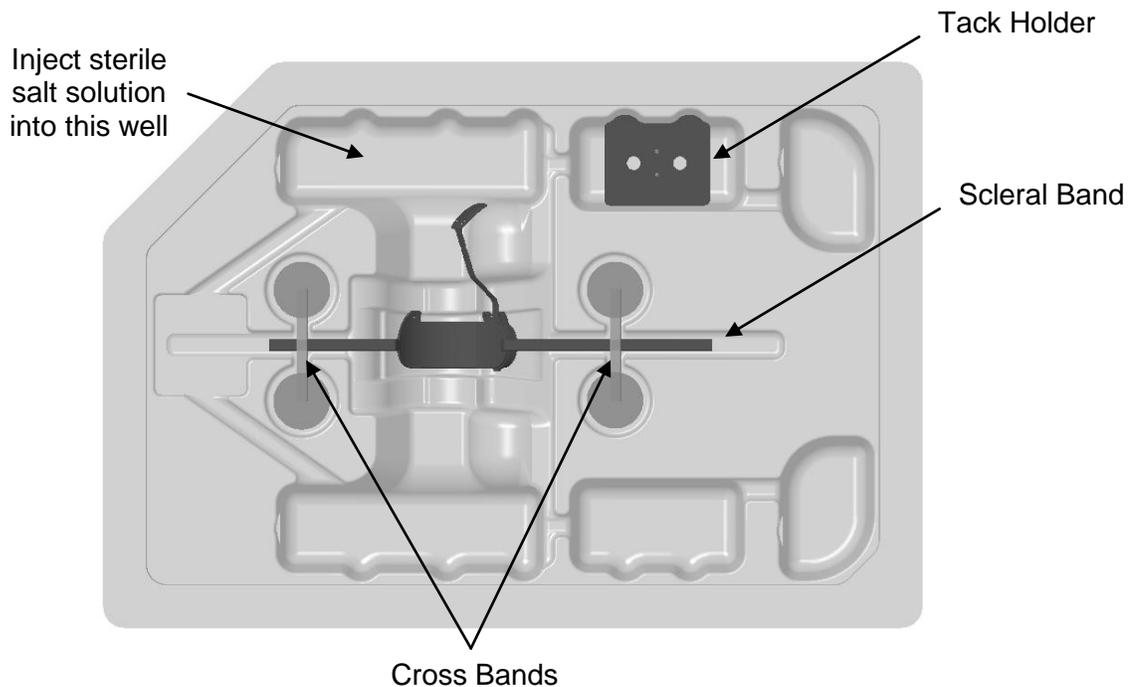
1. Using sterile technique, the sterile person opens the implant inner tray by carefully peeling the Tyvek lid off the tray.
2. Carefully remove the plastic cover from the inner tray by pulling the cover straight up (i.e. not to the side). The cover has cut out handles on the side to help with its removal. Do not discard the implant inner tray cover. See Figure 3.12.

**CAUTION:** To limit contamination of the implant, after the implant's sterile tray has been opened and before the implant is installed on the outside of the eye, the implant should be covered.

**Figure 3.12 Inner Tray with Cover On**



**Figure 3.13 Implant in Inner Tray with Cover Off**



3. The retinal tacks are fixed in a silicone holder. Using tweezers remove the silicone tack holder (keeping the tacks in the holder) and place it in a sterile location where the tacks will be easily accessible when needed. Alternatively, the tack holder may be left in the tray but care should be taken to ensure that the tray is not discarded once the implant has been removed.
4. Add 48 ml of sterile salt solution to the well of the tray where the implant is located. The entire implant device, including the electrode array, should be covered with solution. If necessary, push the electrode array under the salt solution using a soft-tipped sterile tool.
5. Perform the “Impedance Measurement in Solution” per the instructions in Section 3.5.
6. Replace the implant inner tray cover.

### **3.3 Implant Procedure**

Perform the surgical implantation procedure under sterile conditions using instrumentation and patient monitoring customary for vitreo-retinal surgical procedures.

The equipment and implant should already have been tested as instructed in Section 2.3.

**WARNING**

During the surgical procedure, do not use monopolar electro-surgical equipment.

**CAUTION:**

Bipolar electro-surgical equipment may be used with caution near the implant. Electro-surgical instruments are capable of producing radio frequency voltages of such magnitude that a direct coupling can effectively exist between the cautery tip and the implant electrodes. Induced currents could cause damage to the surrounding tissues and permanent damage to the implant.

To avoid infection adhere to scrupulous sterile technique and carefully prepare the eye region at the start of the case. Extra attention should be paid to eyelashes and removal of any debris. Adhere to sterile technique throughout the procedure by limiting the number of personnel in the OR, limiting the flow of personnel in and out of the room, and requiring all personnel to wear masks that cover the nose and mouth.

Avoid injections of viscoelastic solution into the eye as this may cause inflammation. If a viscoelastic solution is applied to the array or cable during the installation of the extraocular portion of the device, carefully rinse the array and cable with sterile salt solution prior to inserting it into the eye.

Avoid handling the implant coil with sharp 'toothed' forceps, or serrated forceps. Use fingers, blunted forceps, silicone-tipped forceps, or muscle hooks where possible.

Handle the array cable with silicone-tipped forceps only.

**Step 1. Preparation**

- a. Dilate the eye.
- b. Prepare for pars plana approach to the vitreous cavity paying particular attention to ensuring sterility of the eye lids and lashes and the general orbital area.
- c. Administer the following medications via IV infusion to the patient: 8 mg of Dexamethasone and 1 g of Cefazolin.
- d. Removal of Lens (for phakic only): If the patient is phakic, perform clear cornea phacoemulsification to remove the lens. Leave the patient aphakic after the procedure. Close the resulting wound.
- e. If the patient is pseudophakic, the IOL should be left in place unless it is subluxed or dislocated or has a high likelihood of becoming subluxed or dislocated, in which case it should be removed through a limbal incision. Close the resulting wound.

- f. Perform a 360-degree limbal conjunctival peritomy. Any radial relaxing incision(s) should be made in the nasal quadrant(s), or in line with the rectus muscles, to avoid regions that will be occupied by the implant.
- g. Isolate each of the rectus muscles.
- h. Using silicone-tipped tweezers, or forceps, remove the implant from the tray by sliding the scleral band out from under the two cross bands holding it in the tray.
- i. Rinse the implant with sterile salt solution.

## **Step 2. Extraocular placement**

**CAUTION: If a microscope is used to visualize the eye while installing the extraocular portion of the implant, use a corneal shield to prevent light toxicity from damaging the retina.**

- a. To protect the implant cable and array from contamination while the extraocular portion of the device is being installed on the eye, cover the cable and array with a sleeve (e.g. cut the finger tip from a small sterile talc-free glove to approximately 1 inch long or use a sterile silicone phaco test chamber tip). If employing a suture to hold the sleeve in place, pre-place the suture prior to inserting sleeve over the array to avoid potential damage to the array by the suture needle.
- b. Using your finger or blunt forceps (avoid serrated or sharp ‘toothed’ forceps which may damage the coil), insert the implant coil onto the temporal half of the eyeball, centered under the lateral rectus muscle. If difficulty is encountered in placing the extraocular portion of the device consider making a small lateral canthotomy to ease this placement.
- c. Pass the inferior part of the scleral band under the inferior and the medial rectus muscles, and the superior portion of the band under the superior rectus muscle.
- d. Fix the band with a non-absorbable suture in the inferior medial quadrant. Optionally, fix the band in this quadrant using a scleral tunnel.
- e. Adjust the superior/inferior position of the implant coil such that the case is centered in the superior lateral quadrant.
- f. Adjust the anterior/posterior position of the case and coil such that the limbus to suture tab distances coincide with the fitting table below.

Suture bites should be taken anterior to posterior, emerging at the intended suture tab hole setback distance provided in Table 3.1.

**Table 3.1: Extraocular Placement Fitting Table**

Patient Axial Length Range [mm]	Sclerotomy Setback [mm]	Suture Tab Hole Setback, Anterior Edge [mm]
20.5 – 22.7	3.0	7.5
22.8 – 24.1	3.5	7.0
24.2 – 25.4	4.0	6.5
25.5 – 26.0	4.5*	6.5

\* Ensure that ora serrata permits a sclerotomy 4.5 mm posterior of the limbus. If not, make the sclerotomy at 4.0 mm and note that this may not allow placement of the array exactly centered over the fovea. Similarly, ensure that a sclerotomy made 3.0 mm or closer to the limbus will not infringe upon the ciliary body. If there is infringement, move the sclerotomy posterior to the first safe position.

- g. Place 5-0 Mersilene sutures through the three suture tabs on the implant to hold the implant in the desired position on the sclera. Tie temporary knots, so that adjustments to the position of the device may be made if necessary following the next steps.
- h. Overlap the two ends of the band and secure them with a silicone sleeve in the superior nasal quadrant. Remove the slack in the band by pulling the ends of the band through the sleeve, but do not tighten the band beyond removal of the slack.
- i. Fix the band in place with a non-absorbable suture in the superior medial quadrant.
- j. Confirm suture tab hole positions and permanently tie the sutures attached through the three suture tabs. Rotate the suture knots so that the cut ends face toward the sclera as much as possible to minimize the risk of conjunctival abrasion.
- k. If you suspect that there may have been damage to the implant, perform an impedance test as instructed in the “Intra-Operative Implant Testing Procedure” in Section 3.5.

**Step 3. Intraocular placement**

- a. Install an infusion line in the inferior temporal quadrant. Suture the infusion cannula in a manner that permits the immediate closure of the wound upon removal later in the case.
- b. Create scleral ports for the vitrectomy. The temporal vitrectomy port should be approximately 3.5 mm from the limbus centered anterior to the lateral rectus muscle. The nasal vitrectomy port should be approximately 3.5 mm from the limbus centered anterior to the medial rectus muscle. (Alternatively you may elect to create a vitrectomy port centered in the inferior nasal quadrant, which aligns the tack tool with the long axis of the array).
- c. Perform a complete vitrectomy, with removal of the posterior vitreous. To facilitate visualization of the vitreous and retinal surface, Triamcinolone approved for intraocular use (e.g. Triesence™) may be injected into the eye. Also, carefully remove peripheral vitreous at the nasal port and in the superior temporal quadrant

by pressing on the sclera at those locations. Remove any epi-retinal membrane present in the region where the array is to be located. If the patient is aphakic remove any posterior capsule that remains.

**CAUTION: Orient the cutting blade perpendicular to the sclera when creating the sclerotomy. Avoid cutting into the ciliary body or vitreous base.**

- d. At the setback distance listed in Table 3.1 create a straight, 5 mm wide sclerotomy in the superior temporal quadrant with a No. 11 B-P blade or equivalent. Angle the cutting blade perpendicular to the sclera. If necessary, raise the infusion bottle to increase intraocular pressure.
- e. Remove the sleeve covering the cable and array. Rinse this portion of the device with sterile salt solution.
- f. Hold the electrode array with the end-gripping forceps at the handle on the electrode region of the array and insert the array into the mid-vitreous cavity. Angle the array perpendicular to the sclera during insertion. If there is significant resistance during insertion, widen the wound by another 0.5 mm. Insert the rest of the cable. Release the array in the mid-vitreous cavity. Push the remaining extraocular cable into the eye.
- g. Use sutures (e.g. 9-0 Prolene) to close the sclerotomy to the permissible limit around the array cable where it enters the sclerotomy. Begin with sutures closest to the cable and work outward. Check the integrity of the sclerotomy seal for leakage.
- h. If you suspect that there may have been damage to the implant, perform an impedance test as instructed in the “Intra-Operative Implant Testing Procedure” Section 3.5.
- i. Using intraocular end-gripping forceps, place the electrode array onto the retina so that it is centered over the fovea. This should result in the electrode rows being approximately diagonal at 45 degrees to the horizontal meridian. The ideal array location is such that the centre of the electrode grid is coincident with the fovea (note that this may result in a small non-electrode portion of the array overlapping the optic disc).
  - The initial location of the array is generally nasal of the macula, since some excess cable in the eye is desired. If the array appears flat when placed on the fovea and there is little or no twist in the cable, the surgeon should proceed with tacking.
  - If the array appears tilted when placed on the fovea or there is substantial twist in the cable, the surgeon should relocate the extraocular portion of the device to change the cable angle entering the sclerotomy. Note that it is most desirable to adjust the position of the extraocular device such that the sclerotomy does not need to be widened in either direction.
- j. When ready to proceed with tacking, load the tack into the tack insertion tool. Note that you may wish to align the dot on the handle with the activation lever of the tool so that you will know in which direction to slide the tool off to release the tack later. Rotate the loaded tack tool under the surgical microscope to confirm the tack is in line with the tool shaft. Carefully reload tack if necessary.

- k. Enlarge the nasal (or inferior nasal) vitrectomy port to 19 ga. In one smooth motion, insert the tack into the vitreous cavity through the port. Stop with the tack in the mid-vitreous.

**CAUTION: Raise the bottle height prior to tacking the array onto the retina. At least 80 cm bottle height (60 mmHg pressure) is recommended.**

- l. Raise the bottle height, and using the tack insertion tool, secure the electrode array over the macula with the retinal tack. Prior to applying pressure tilt the tool so that it is as nearly perpendicular to the retinal surface as possible. Apply pressure to the tack. You will know that the head to the tack is through the sclera when a “pop” is felt. If no pop is felt, pull gently on the tack to ensure that it is secure. There is a small dot on the handle (outside the eye) that remains aligned with the opening of the tack tool. To remove the tool from the tack head, depress the actuator and slide it off in the direction away from the dot.

**CAUTION: Do not apply excessive force to the retinal tack and do not apply lateral force with the tool after tack penetration through the sclera.**

**If you need to remove the tack from the eye, inspect the tack after removal to make sure the spring and washer are still attached to the tack. If not, locate the spring and washer inside the eye and remove them.**

- m. After tacking the array perform an examination to determine if any retinal defects have been induced by this step. Begin lowering the pressure in the eye by approximately 10 mm Hg per minute until normal pressure is obtained.
- n. Perform an impedance measurement as instructed in the “Intra-Operative Implant Testing Procedure” in Section 3.5.

#### **Step 4. Closure**

- a. If the implantation result is acceptable, place a non-absorbable mattress suture (e.g. 9-0 Prolene) over the extraocular portion of the cable to secure it to the sclera.
- b. Close the remaining sclerotomies with sutures. Bury the knots in the sclera to reduce irritation of the overlying tissues.

**CAUTION: If the use of processed cadaveric tissue is not allowed, please consult with Second Sight on suitable alternatives.**

- c. Fix one piece of cadaveric human pericardium or equivalent allograft in an extraocular location over the array cable and electronics case suture tabs in the region between the implant and the limbus using absorbable sutures. The graft should proceed anteriorly just past the sclerotomy such that it is not too close to the limbus. The allograft should be sized such that it covers both of the suture tabs on the implant electronics case (approximately 9 mm x 7 mm).

- d. Reattach the tenons and conjunctiva at the limbus using closely-spaced interrupted sutures. Maximize the amount of tissue over the implant.
- e. Administer subconjunctival 1 cc Cefazolin (100 mg) and 1 cc Dexamethasone (2 mg) salt solution away from the implant (nasal).
- f. Administer subconjunctival approximately 2 cc of 4% Lidocaine away from the implant (nasal).
- g. Perform an impedance test as instructed in the “Intra-Operative Implant Testing Procedure” in Section 3.5 if you suspect that damage to the implant may have occurred.
- h. Patch and shield the eye and escort the patient to recovery.
- i. Clearly label the patient’s VPU with the implant serial number, and patient identification number. Change the patient’s VPU to Clinic Mode.

### 3.4 Recommended Peri-Operative Medication Regimen

		Initial Implantation	Revision Surgery	Explantation
<b>Pre-operative</b>		48 hours of full dose (oral) antibiotics fluoroquinolone or equivalent	Same as initial implantation	Same as initial implantation
<b>Intra-operative</b>	<b>Start of procedure</b>	Intravenous steroid Dexamethasone 8 mg (or equivalent)	Same as initial implantation	Same as initial implantation
		Intravenous antibiotic Cephazolin 1 g (or equivalent 1st generation cephalosporin)	Same as initial implantation	Same as initial implantation
	<b>End of procedure</b>	Subconjunctival antibiotics Cefazolin 100 mg (or equivalent 1st generation cephalosporin) and Dexamethasone 2 mg (or equivalent) away from the incision	Same as initial implantation	Same as initial implantation
		Subconjunctival Lidocaine 2 ml of 4% (or equivalent) away from the implant	Same as initial implantation	Same as initial implantation

	<b>Initial Implantation</b>	<b>Revision Surgery</b>	<b>Explantation</b>
<b>Post operative</b>	Full dose of (oral) antibiotics fluroquinolone or equivalent	Same as initial implantation	Same as initial implantation
	14 days of topical antibiotics Fluroquinolone (or equivalent) eye drops 1 drop 4 times per day	Same as initial implantation	Same as initial implantation
	14 days oral steroid Prednisolone (or equivalent) 60 mg daily for 14 days followed by 1 week of tapering dose*	Optional, depending on the nature and extent of the revision surgery	N.A.
	14 days topical steroid Prednisolone drops 1% (Pred Forte® or equivalent) 1 drop 4 times daily for at least 2 weeks and continue as needed.	Same as initial implantation	Same as initial implantation
	14 days topical drops Atropine 1% (or equivalent) 1 drop every day	Same as initial implantation	Same as initial implantation

\*Adjust dose of oral and/or topical steroid doses if necessary to manage side-effects such as high or low intraocular pressure, weight gain, insomnia or disturbance in blood glucose

## 3.5 Intra-Operative Implant Testing Procedure

### 3.5.1 Impedance Measurement in Solution

1. Have a sterile person pick up the OR coil by grasping it through the sterile sleeve. Place the OR coil within 1 cm of the implant coil. Be sure that the two coils are roughly parallel to each other (not at right angles).

**CAUTION:** Take care not to contaminate the sterile field with the unsterile cable while using the OR coil.

**For the OR coil to effectively transmit its signal to the implant coil there cannot be any metal objects within the immediate vicinity of the coil. If the implant does not get activated, remove all metal objects from the immediate vicinity.**

2. Power on the VPU and allow it to finish the start-up tests. If the VPU periodically beeps, this indicates that the OR coil has not established a good link with the implant. Adjust the position of the OR coil until the beeping stops. If the implant tray is resting on a metal table top, it may be necessary to lift the tray off the table and/or place it on a non-conductive surface (e.g. a stack of sterile drapes) in order to establish a link with the OR coil.
3. Allow the VPU to complete its start-up tests. Once the testing is complete, the VPU will flash a slow blinking green (about once per second).
4. Start the CFS software and log in using a valid username and password. Press the “Start Session” button and enter the patient ID when prompted, then press the “Patient Testing” button.

**Note: The VPU must be on and must complete its start-up tests prior to entering the “Patient Testing” module.**

5. Check the CFS to verify that the VPU connection indicator and the implant connection indicator located at the top of the window are illuminated green.
6. Once in the “Patient Testing” module, ensure that the “Diagnostics” screen is selected.
7. Click on the “Measure Impedance” button. The measurement takes less than 30 seconds. If the RF link is lost during the impedance measurement, the VPU will begin beeping indicating a loss of link. Once the link is reestablished, the impedance measurement will pick up where it left off.
8. The software will display a color-coded map of impedance values. Save the impedance map by capturing the screenshot and save it in another file.
9. If the impedance measurement indicates more than 20 electrodes with high impedance values ( $> 55 \text{ K}\Omega$ ), it is important to make sure the entire electrode array is immersed in salt solution and repeat the impedance measurement.

**Note:** If the problem persists, consult with the Second Sight surgical support personnel (if present), or contact Second Sight for guidance using the contact information provided in Section 1.12. This recommendation also applies to the following intra-operative measurement procedures.

If the VPU and CFS remain powered-on in this manner, you will hear a constant periodic beeping indicating loss of RF link. It is best to end the session and turn off the VPU when not in use.

### **3.5.2 Impedance Measurement after the Extraocular Placement (Optional)**

This measurement may be conducted when the device is secured extraocularly after the scleral band and fixation sutures are placed but before the sclerotomy is opened. Repeat the impedance measurement described in the previous section if you suspect that damage to the implant may have occurred.

If the impedance measurement indicates more than 20 electrodes with high impedance values ( $> 55 \text{ K}\Omega$ ), the array should be re-adjusted to ensure that the electrodes are “wet” and in contact with the eye (if applicable). Once this is done, repeat the impedance measurement again. Note that the use of a surgical glove finger tip to protect the array is likely to cause some electrodes with high impedance values. This is most likely an indication that the array is not sufficiently irrigated and the following attempts should be made: 1) add salt solution close to the array and repeat measurement; 2) if necessary, remove surgical glove finger tip and repeat the measurement.

### **3.5.3 Intraocular Impedance Measurement before Tacking (Optional)**

The closure of the sclerotomy is typically completed by suturing the sclerotomy before the retinal tack is placed.

Repeat the impedance measurement after the closure of the sclerotomy if you suspect that damage to the implant may have occurred.

### **3.5.4 Intraocular Impedance Measurement after Tacking**

Repeat the impedance measurement after the array is tacked to the retina.

### **3.5.5 Final Impedance Measurement after Closure (Optional)**

Repeat the impedance measurement after the final closure if you suspect that damage to the implant may have occurred.

## **3.6 Post-Implant Evaluation and Testing**

Following implantation, it is recommended that patients receive evaluation and testing as specified in the post-market study protocol for those enrolled in the study. Other patients should receive clinical follow-up and device testing on a regular basis. Second Sight recommends the following clinical follow-up schedule:

<b>Post Implant Visit Date</b>	<b>Recommended Evaluation and Testing</b>
Day 1	Eye exam (including measurement of IOP) No testing of device
Week 1	Eye exam (including measurement of IOP) Fundus imaging recommended Testing may begin
Week 2	Eye exam (including measurement of IOP)
Week 4	Eye exam (including measurement of IOP) Fundus and OCT imaging recommended
Month 3 (optional)	Eye exam (including measurement of IOP) Fundus and OCT imaging recommended
Month 6	Eye exam (including measurement of IOP) Fundus and OCT imaging recommended
Month 12 and every 12 months thereafter	Eye exam (including measurement of IOP) Fundus and OCT imaging recommended

Clinical examination should be conducted immediately if the patient reports any pain or other clinical complication.

**CAUTION:** To reduce the risk of infection during patient fitting sessions in the first month following implantation or any surgical intervention on the implanted eye, or if there is a potential breach in the conjunctiva or sclera, wear clean gloves and wipe any part of the Argus II Glasses which touches the tissue around the patient's eye with either alcohol or germicidal wipe. Allow the glasses to air dry before placing them on the patient.

### 3.7 Re-interventions and Elective Revision Surgery

The position of the Argus II Implant may be revised to address a variety of situations including, but not limited to:

1. Correct the position of the implant due to movement of the system.
2. Reposition the implant to improve functionality of the device including intra- and extraocular parts of the system.

The revision may include installing replacement or additional materials which were used in the original surgery to better secure the implant (i.e. sutures and tacks). The decision to revise an implant will be made by the surgeon, in consultation with Second Sight, if necessary. The procedure for performing the revision surgery will vary from patient-to-patient depending on the patient's particular situation. It is recommended that the surgeon consult with Second Sight as to how to perform the revision surgery.

**CAUTION:** If a laser is required to be used in the posterior segment, care should be taken to ensure that the laser beam does not contact any intraocular portion of the device.

Revision surgery may require re-opening of the sclerotomy through which the cable passes. In this case, exposure of the extraocular cable is likely required. Extreme caution should be taken when dissecting any fibrous capsule around the cable, as the cable can be easily damaged. If the extraocular cable is difficult to see prior to dissection use some means (i.e. trans-illumination) to aid in visualization.

Revision surgery may require repositioning of the extraocular portion of the device and it is likely that there will be a fibrous sheath that requires dissection. Care should be taken in dissecting this sheath to ensure that no portion of the device is damaged.

The polyimide cable outside of the eye should only be handled with silicone-tipped forceps.

If insertion of another tack into a part of the array that is not the tack hole is required, caution should be used to ensure that the sharp tip of the tack is inserted through silicone and not the polyimide portion of the array.

When removing a tack from the eye, inspect the removed tack to make sure the spring and washer are still attached to the tack. If not, locate the spring and washer inside the eye and remove them.

## **3.8 Surgical Removal of the Implant**

If there is a problem with the implant consult with Second Sight to decide whether the implant should be removed. If it is determined that the implant should be removed please request a Second Sight explant kit and Return Material Authorization (RMA) noting that hazardous materials are being returned.

### **3.8.1 Explant Procedure**

#### **Step 1. Extraocular portion**

- a. Dilate the eye.
- b. Perform a peritomy and pull the conjunctiva back to reveal the device.

- c. Install an infusion line in the inferior temporal quadrant, away from the implant coil suture tab.
- d. Create scleral ports for vitreous chamber access, preferably in locations that are different from the access ports created at the time of implant.
- e. Remove any fibrotic capsular material from around the implant coil, the electronics case, and the silicone sleeve of the scleral band.
- f. Perform vitrectomy if necessary.

### **Step 2. Retinal Tack, Intraocular Cable and Array**

- a. Inspect the tack and array for the presence of fibrosis or membranes. Dissect and remove any observed growth from the surfaces of the intraocular portion of the implant.
- b. Confirm that any sources of traction have been removed by gently lifting the handle at the distal end of the array.
- c. Temporarily raise the infusion bottle to increase intraocular pressure. At least 80 cm bottle height (60 mmHg pressure) is recommended.

**CAUTION: Raise the bottle height prior to removing the tack. At least 80 cm bottle height (60 mmHg pressure) is recommended.**

- d. Remove the tack from the posterior coats and array using a tack insertion tool inserted through the inferior nasal port.
- e. Pull up slowly on the tack until it extracts from the retina, then carefully pull the tack barb through the tack hole on the array, allowing the array to float in the mid-vitreous.
- f. Withdraw the tack from the eye.

**CAUTION: When removing a tack from the eye, inspect the removed tack to make sure the spring and washer are still attached to the tack. If not, locate the spring and washer inside the eye and remove them.**

- g. Reopen the sclerotomy used to insert the array and cable to about 5 mm. Withdraw the array through the sclerotomy using caution to avoid touching the retina.
- h. (Optional) Laser around the tack hole after removal to minimize the risk of bleeding and/or retinal detachment.

### **Step 3. Closure**

- a. Remove all sutures fixing the extraocular portion. Also remove the silicone sleeve.
- b. Close all incisions.
- c. Reattach the tenons and conjunctiva at the limbus using closely-spaced interrupted sutures.

d. Administer medications as appropriate.

**Step 4. Return the Explanted Unit for Warranty and Evaluation**

Return all surgically-removed implants to Second Sight for analysis. The Second Sight Explant Kit contains instructions, a specimen container, and packaging for biohazardous materials. Please contact Second Sight for instructions on how to store, package, and ship an explanted device.

# ***4 Special Handling of the Implant***

---

This chapter covers the special handling of the Argus II Implant and surgical-related products. For handling and maintenance of the Argus II external products and programming equipment, refer to the Argus II Device Fitting Manual. For service or to order parts, contact Second Sight using the contact information at the front of the manual.

## **4.1 Handling**

Severe impact could damage the storage pack which may, in turn, rupture the sterile packaging. The implant should be treated with the same care and attention appropriate to any implantable medical device.

## **4.2 Storage**

Store the packaged Argus II Implant at a temperature between -10°C and +55°C (+14°F to +131°F). Do not implant the device after the 2-year expiration date printed on the package label.

## **4.3 Maintenance**

No maintenance is required on the Argus II Implant. The implant is designed to be self-sustaining after implantation. The implant is electrically active only when an Argus II Video Processing Unit (VPU) is in communication with it. Otherwise, it is an inactive device.

Each time the implant is activated, the VPU performs diagnostic tests to ensure the implant is functioning properly. If improper function is detected, the VPU shuts off power to the implant, thus returning the implant to an inactive state. Depending upon the specific circumstances, it may be necessary to surgically remove an improperly-functioning implant.

If a problem is encountered with the implant that cannot be resolved, contact Second Sight Medical Products, Inc. using the contact information provided at the front of the manual.

## **4.4 Decontamination and Resterilization of the Surgical Tools**

Please follow the manufacturers' procedures for decontamination and resterilization of the re-usable surgical tools.

## **4.5 Handling the Explanted Device**

If the Argus II Implant is explanted for any reason, Second Sight must be contacted first except in the event of medical emergency. The explanted unit must be returned to Second Sight for evaluation and warranty purposes and disposition. You should request a biohazard (explant) kit from Second Sight (see contact information at the front of the manual) and return the explanted device to Second Sight.

The explant kit contains everything needed to safely ship the device except sterile normal salt solution. Use your standard sterile normal salt solution to ship the device back.

\*Be aware that shipments must arrive at Second Sight (Los Angeles, USA) on a weekday to be received. Please time shipping accordingly. If required, store the completed/sealed implant kit in a refrigerator until the day of shipping.

## **4.6 Disposal of Argus II System Components**

Do not dispose of any Argus II System components. Any explanted Argus II Implants or Tacks should be returned to Second Sight Medical Products, Inc.

All unused or damaged external equipment should also be returned to Second Sight Medical Products, Inc. Refer to the Argus II Device Fitting Manual for instructions on the proper disposal of rechargeable batteries.

## **4.7 Disposal of Packaging Material**

The Argus II System shipping carton, foam packing tray, and other packaging material should be disposed of according to local regulations.

# 5 Warranty

---

This chapter covers the manufacturer's warranty policy for the Argus II Retinal Prosthesis (Implant). Refer to the "Argus II Retinal Prosthesis System Device Fitting Manual" for the warranty policies of the external devices and clinician fitting system.

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

If an Argus II Implant fails to function within normal tolerances within 3 years from the date of implantation as a result of a failure to manufacture the Argus II Implant in accordance with Second Sight Medical Products, Inc.'s (Second Sight's) manufacturing specifications, Second Sight Medical Products, Inc. will provide a functionally equivalent Second Sight replacement implant. This warranty is limited to implant failures, and does not apply to out of specification performance due to surgical complications or the patient's medical conditions.

Claims under the Argus II Limited Warranty on Retinal Prosthesis (Implant) are subject to the following conditions and limitations:

1. The implant must be implanted before the end of the "Use By" date marked on the package.
2. The Implant Warranty Registration Form provided by Second Sight is completed and received by Second Sight.
3. Implant failure must be confirmed by Second Sight before explantation and replacement of the device.
4. The explanted unit must be returned to Second Sight for analysis within 15 days of explantation along with a report describing the circumstances of the removal. Explanted devices returned to Second Sight for analysis become the property of Second Sight.

### WARRANTY DISCLAIMER:

**SECOND SIGHT EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. SECOND SIGHT WILL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES CAUSED BY THE IMPLANT'S FAILURE TO FUNCTION WITHIN THE NORMAL TOLERANCES WITHIN 3 YEARS WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.**

Second Sight reserves the right, in its sole discretion, to provide a functionally equivalent Second Sight replacement implant even if the failure to perform within normal tolerances during the Three-Year Limited Warranty period is for reasons other than a failure to manufacture the implant in accordance with Second Sight's manufacturing specifications.

---

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**Date of Issue: FEB-2013**



Second Sight

***Argus<sup>®</sup> II***  
***Retinal Prosthesis System***

***Device Fitting Manual***

**REF** 090002-004

**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.

900030-001 Rev C

**Argus<sup>®</sup> II**  
**Retinal Prosthesis System**

**Device Fitting Manual**

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# 1 Before You Get Started

---

## 1.1 Introduction

This manual is intended for clinicians, technicians, and low vision specialists who work with Argus II Retinal Prosthesis patients. It contains the list of the system components (Chapter 1), detailed description of the system components and how they work (Chapter 2), the step-by-step device fitting procedure and patient data management (Chapter 3), preparation for patients to use the device outside the clinic (Chapter 4), product maintenance (Chapter 5), trouble shooting (Chapter 6), system specification (Chapter 7), and manufacturer's warranty (Chapter 8).

## 1.2 System Components

The Argus II Retinal Prosthesis System consists of the following items. This list may be updated periodically.

### 1.2.1 Argus II Patient Kit Contents

Description	Catalog/Product Number
Argus II Video Processing Unit (VPU) (including Patient Manual)	013003
VPU Battery	
Small size: Sony InfoLITHIUM M Series Model Number NP-FM500H	100200-001
Medium size: Sony InfoLITHIUM M Series Model Number NP-QM71D	100200-002
Argus II VPU Pouch	013931
Argus II Glasses, Dark Lenses, Right Eye	012011
Argus II Glasses, Clear Lenses, Right Eye	012012
Argus II Glasses, Dark Lenses, Left Eye	012013
Argus II Glasses, Clear Lenses, Left Eye (one pair of glasses is included in the kit)	012014
VPU Battery Charger, US	100200-004
Argus II Travel Case	012930

### 1.2.2 Argus II Clinician Fitting System (CFS) Contents

Description	Catalog/Product Number
Argus II CFS Computer	014003-R
Laptop Power Supply with Power Cord (USA)	130150-205
Argus II Communication Adapter (CA)	014103
Argus II CA – VPU Cable	014913
Argus II CFS – CA Cable	014916
Argus II Psychophysical Test System (PTS)	014202-R
Laptop Power Supply with Power Cord (USA)	130150-205
Argus II PTS – CFS Cable	014915
Argus II Touch Screen Monitor (ELO Touch Screen, 1928L, Contains EUR and US Power Cords)	014932
Logitech® Rumble Gamepad F510 (User Input Device)	130150-161
Argus II Device Fitting Manual	090002

### 1.2.3 Argus II Surgical Related Components Manufactured by Second Sight

Description	Catalog/Product Number
Argus II Retinal Prosthesis Kit, Right Eye	011013-K
Argus II Retinal Prosthesis Kit, Left Eye	011014-K
Argus II Retinal Tacks	011006
Argus II Surgeon Manual	090001
Argus II Device Fitting Manual	090002
Argus II Patient Manual	090000
Argus II VPU-Implant Matching CD (implant serial number specific)	011007
Argus II Operating Room (OR) Coil	012103

Refer to the Argus II Surgeon manual for a complete list of surgical supplies.

### **1.3 Where to Find Information**

The following sources provide information about the Second Sight Argus II Retinal Prosthesis System.

- Argus II Retinal Prosthesis System Surgeon Manual
- Argus II Retinal Prosthesis System Device Fitting Manual
- Argus II Retinal Prosthesis System Patient Manual
- Argus II Retinal Prosthesis System Product Insert

## 1.4 Acronyms used in this Manual

Acronym	Meaning
ASIC	Application Specific Integrated Circuit
CA	Communication Adapter
CDL	Charge Density Limit
CFS	Clinician Fitting System
ESD	Electrostatic Discharge
FCE	Field Clinical Engineer
GUI	Graphical User Interface
OR	Operating Room
PTS	Psychophysical Test System
RF	Radio Frequency
USB	Universal Serial Bus
VCF	Video Configuration File
VPU	Video Processing Unit

## 1.5 Symbols and Regulatory Classifications

Table 1.1 Symbols

Symbol	Meaning
	Catalog number
	Serial number
	Single use
	This product has been sterilized using ethylene oxide
	Use by date
	Lot number
	Date of manufacture
	Warning and/or consult accompanying documents
	Storage temperature range
	Keep Dry
	This device is susceptible to electrostatic discharge (ESD) damage and should be handled in an ESD safe manner
	Non-ionizing radiation (Radio frequency radiation)
	Manufactured by
	Type B Applied Part
	Fragile
	MR Conditional
	MR Unsafe

The Argus II System 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.

**Table 1.2 Regulatory Classifications**

Standard/Directive	Classifications
EN60601-1	<p>Classification:</p> <p>Internally Powered Type B Applied Part IPX0 Continuous Operation</p>
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>
IEC 60601-1-2 Classifications (CISPR 11 Electromagnetic Emissions)	<p>Classification:</p> <p><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.</p> <p><u>Class B Equipment</u> - equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.</p>
IEC 60601-1-2 (Electromagnetic Immunity)	<p>Classification:</p> <p>The Argus II System may experience interference from ESD, power frequency magnetic fields, and conducted and radiated RF.</p>

## 1.6 How to Contact Second Sight

Second Sight is committed to providing the highest quality products and service to our customers. Please feel free to contact us for technical assistance or replacement parts.

### Headquarters

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# 2 Product Description

---

## 2.1 Introduction

The Argus II Retinal Prosthesis System is intended to provide electrical stimulation of the retina to induce visual perception in blind patients. It is indicated for use in patient with severe to profound retinitis pigmentosa. Refer to the Product Insert for full indications and contraindications.

## 2.2 System Components Overview

This section provides a brief description of the system components. More detailed description will be provided in Section 2.3.

The Argus II System consists of the following primary components:

- **Argus II Retinal Prosthesis (Implant):** A neural stimulation device that is implanted in and around the patient's eye. The implant is comprised of a coil and an electronics case, which are placed around the eyeball using a scleral band, and a thin-film electrode array, which is tacked intraocularly on the surface of the retina.
- **Argus II Glasses:** The Argus II Glasses are worn by the patient and they are specially fitted with a miniature video camera, an external coil and associated electronic circuitry. The glasses transmit electrical stimulation data along with power via telemetry to the implant.
- **Argus II Operating Room (OR) Coil:** A coil that is used to test the functionality of the implant during the implantation procedure.
- **Argus II Video Processing Unit (VPU):** A battery-powered device that processes the video signal from the camera on the glasses and transforms it into electrical stimulation data. The electrical stimulation data and power are then sent to the Argus II Glasses for transmission to the implant. The VPU comes with a pouch and may be worn by the patient.
- **Argus II Clinician Fitting System (CFS):** Laptop computer that is configured with dedicated, PC-based software that, when connected to the VPU, enables tailoring of the electrical stimulation parameters for the patient (i.e. creating video configuration files) in addition to psychophysical testing and monitoring and troubleshooting of the system. The CFS is used in medical facilities and clinical research settings and is operated by authorized clinicians, researchers, or Second Sight personnel. Patients do not operate the CFS nor do they use it at home.
- **Psychophysical Test System (PTS):** Laptop computer that is connected to the CFS. It can be used to run performance evaluation software.
- **Argus II Communication Adapter (CA):** A device which provides data communication and electrical isolation between the VPU and the CFS.

Refer to Chapter 1 for a complete list of patient kit, clinician fitting components, and surgical components.

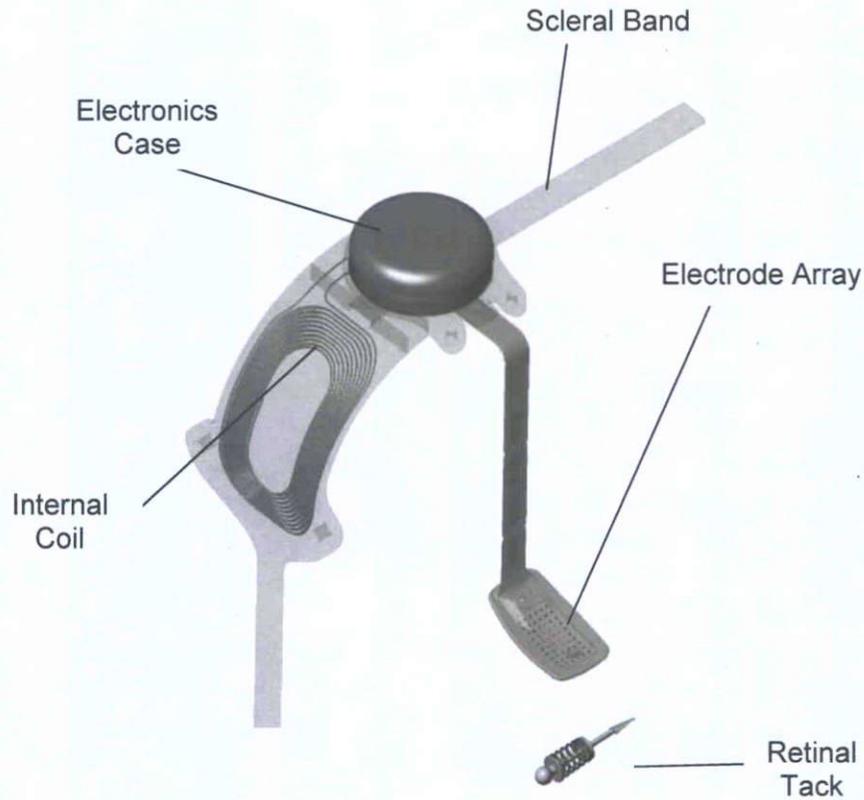
## 2.3 Description of System Components

### 2.3.1 Argus II Retinal Prosthesis (Implant)

The implant is a medical device which is surgically placed on the outside and inside of the patient's eye. The implant is comprised of the following components: (1) the electronics case, (2) the implant coil, (3) the electrode array, (4) the scleral band, and (5) the retinal tack. The array is secured in place over the fovea using a retinal tack. Figure 2.1 shows an illustration of the Argus II Right Eye Implant and Retinal Tack. Table 2.1 and Table 2.2 provide descriptions of the components and accessories of the implant.

**Figure 2.1 Argus II Implant (Right Eye)**

**Note:** Illustrations of the implant and tack are greatly enlarged to show detail.



**Table 2.1 Implant Components**

<p><b>Electronics Case</b></p>	<p>A cylindrical, hermetically sealed case that contains electronic components and an Application Specific Integrated Circuit (ASIC) for processing the received data and using the received power to generate the required stimulation output. The case portion of the implant is affixed to the sclera via sutures through the tabs located along the anterior edge of the case.</p>
<p><b>Internal Coil</b></p>	<p>Also known as the implant coil, it contains a receiver and transmitter antenna made of wire encased in silicone. The coil communicates with an external coil on the Argus II Glasses. The internal coil is also connected to and communicates with the implant electronics case. When implanted, the coil is affixed to the sclera via sutures through an inferior tab located along the anterior edge of the coil.</p>
<p><b>Electrode Array</b></p>	<p>The means by which electrical stimulation is delivered from the case to the retina.</p> <p>The electrode array consists of a polymer cable that contains the wire conductors and an array of 55 enabled platinum electrodes where the conductors terminate. The electrodes are secured in place centered over the fovea using a retinal tack.</p> <p>The proximal end of the cable is connected to the package while the distal end (the array) is attached to the retina. In between, the cable traverses the eye wall through a pars plana incision.</p> <p>Silicone is used over much of the array to buffer the interface of the polymer with the retinal tissues.</p>
<p><b>Scleral Band</b></p>	<p>In addition to the sutures described above, a biocompatible sclera band that is equivalent to a 240 band used in scleral buckling procedures is used to hold the implant on the eye. When implanted, the band is held around the eye with a silicone sleeve and is affixed to the sclera with a suture over the band (and/or sclera tunnel) in each of the nasal quadrants.</p>

**Table 2.2 Implant Accessories**

<b>Retinal Tack</b>	Modeled after a standard retinal tack, with the addition of an integrated spring, this tack is used to affix the array to the retina.
<b>VPU-Implant Matching CD</b>	CD containing configuration information for matching a VPU with a specific implant.

**2.3.2 Argus II Glasses**

Figure 2.2 shows the Argus II Glasses for the right eye implant. The RF board and coil of the glasses for the left eye implant are attached to the left side of the ear piece. Table 2.3 and Table 2.4 provide a description of the components that make up the glasses and the associated accessories.

**Figure 2.2 Argus II Glasses (Right Eye)**



**Table 2.3 Glasses Components**

<b>Glasses</b>	Provide a convenient and discrete way to house the video camera and equipment needed to power and communicate with the implant. The glasses are worn by the patient when he/she is using the Argus II System.
<b>Camera</b>	A miniature video camera is mounted in the center of the glasses frame, above the nose bridge. When the system is operating, the camera conveys a steady stream of video data to the Argus II VPU, via the glasses cable.  <b>Note:</b> Do not adjust the camera. Any adjustment of the camera may damage or affect the performance of the camera.
<b>RF Board / External Coil</b>	Contains receiver and transmitter antennae, and a radio frequency (RF) electronics board. The coil is mounted on the ear piece of the glasses, on the same side as the implanted eye. It communicates via telemetry with the internal coil on the implant and with the VPU via the glasses cable.  The external coil's position is adjustable in order to optimize alignment with the internal coil and to improve patient comfort.
<b>Glasses Cable</b>	Provides a connection between the Argus II Glasses and the Argus II VPU. It contains separate conductors for each of its three functions: (1) Convey power from the VPU to the camera and video signals from the camera to the VPU; (2) Convey data and power from the VPU to the external coil/RF board; (3) Convey implant status information from the external coil/RF board to the VPU.

**Table 2.4 Glasses Accessories**

<b>Travel Case</b>	A durable case provided to the patient to safely store and transport the glasses (as well as the VPU and batteries) when not in use.
--------------------	--

### 2.3.3 Argus II Operating Room (OR) Coil

The Argus II Operating Room (OR) Coil is used to test the pre-operative and intra-operative functionality of the implant. The OR coil is shown in Figure 2.3. Table 2.5 provides a description of the components that make up the OR coil.

**Figure 2.3 Argus II OR Coil**



**Table 2.5 OR Coil Components and Accessories**

<b>RF Board / External Coil</b>	This component is the same as the RF coil and board on the glasses. This component is placed in a sterile sleeve for placement in the surgical field to confirm the intra-operative functionality of the implant.
<b>Sterile Sleeve</b>	Sterile sleeve for housing OR Coil when placed in the surgical field. (not shown in the picture above)

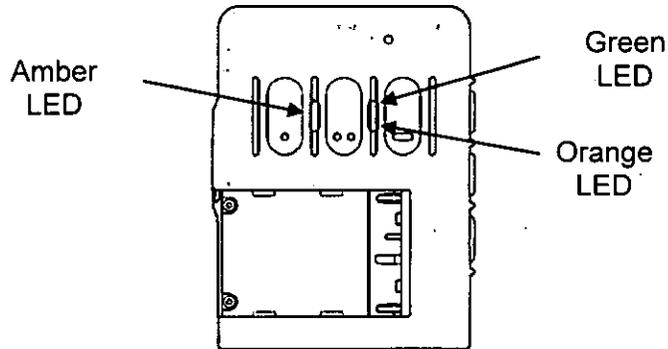
**2.3.4 Argus II Video Processing Unit (VPU)**

Figure 2.4 shows the Argus II Video Processing Unit (VPU). The VPU LED indicators are shown in Figure 2.5. The functions of the LEDs are described in Table 2.6.

**Figure 2.4 Argus II VPU Connections to CA and Glasses Cables**



**Figure 2.5 VPU LED Indicator Location**

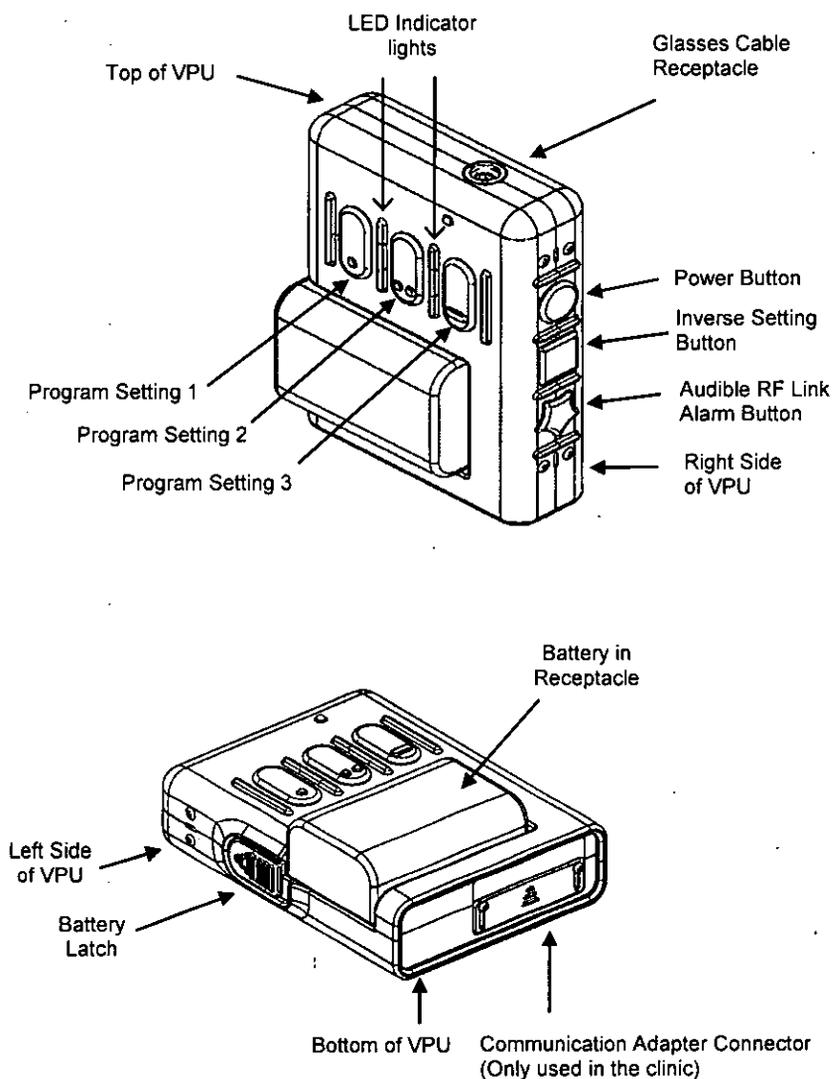


**Table 2.6 VPU LED Indicators**

Light Color	Light Flashing	Meaning
Green	Fast Periodic blinking	The VPU is going through system start-up diagnostic testing. The start-up testing takes approximately 30 seconds.
Green	Slow periodic blinking (1 per second)	The VPU is operating normally.
Green	Very slow periodic blinking (1 every 2 seconds). In addition, the amber LED is lit solidly.	The VPU or implant has a problem that was detected by the VPU at start-up. <b>Note:</b> This only occurs when the VPU is connected to the CFS.
Orange	Solid	Illuminates if the video signal from the camera is not being received by the VPU. The LED will stay on until the video signal is re-established.
Amber	Solid	There is a loss of communication between the implant and external coil (on the glasses) due to movement or removal of the Argus II Glasses while the system is operational or if the VPU detects a problem with the implant and shuts off power to the implant.
Amber	Blinking	There is intermittent communication loss between the implant and the external coil.

A multi-view illustration of the VPU is provided in Figure 2.6. The components of the VPU and its accessories are described below in Table 2.7 and Table 2.8.

**Figure 2.6 Illustrations of the VPU and its Components**



**Table 2.7 VPU Components**

<b>VPU Case</b>	The VPU case is approximately 11 cm x 7 cm (4" x 3"). It fits into the VPU pouch for easy carrying by the patient when the Argus II System is in use.
<b>Power Button</b>	A round-shaped button located on the right-hand side panel of the unit, this powers the VPU on and off. The button must be pressed down and held for at least two seconds to switch the VPU on and off.
<b>Program Setting Buttons</b>	The oval-shaped buttons located on the front panel of the unit that are used to select one of three program settings. The button with a single circle corresponds to Program Setting 1. The button with two circles corresponds to Program Setting 2 while the button with a small bar corresponds to Program Setting 3. The default setting is Program Setting 1. The VPU will default to use Program Setting 1 when powered on.
<b>Inverse Setting Button</b>	The square-shaped button located on the right-hand side panel of the VPU. This button is used to invert the image from black-to-white and white-to-black. Each time the button is pressed, the image is inverted.
<b>Battery Receptacle</b>	Located on the bottom third of the front panel, the receptacle is where the rechargeable battery is installed on the VPU. The receptacle has a keying mechanism that prevents incorrect installation of the battery.
<b>Battery Latch</b>	Located on the left side of the VPU, this two-position sliding latch automatically slides into the "locked" position when a battery is properly inserted into the receptacle. To remove a battery, the operator must first slide the latch to its "un-locked" position. Refer to the section "Changing a VPU Battery" in Chapter 5.
<b>LED Indicators</b>	Three LED indicator lights located on the front of the VPU in between the oval control buttons that give visual indication of operating status of the system. The different LEDs are described in Table 2.6.

<b>Audible RF Link Alarm Button</b>	The star-shaped button located on the bottom of the right side of the VPU is used to enable or disable the audible alarm that indicates if the communication link with the implant has been interrupted. The default setting is "RF link alarm on". It is set to the default every time the VPU is switched on.
<b>Audible Alarm</b>	An audible alarm creates seven distinct audible alerts to indicate various operational conditions of the system. The audible alerts are described in Table 2.9.
<b>Glasses Receptacle</b>	A round, recessed connector port on the top of the VPU that accepts the cable coming from the Argus II Glasses. The cable should be securely connected before the VPU is powered on. Refer to the section "Connecting the Equipment in Stand-Alone Mode" in Chapter 4.
<b>Communication Adapter (CA) Connector</b>	Located on the bottom of the VPU, this rectangular shaped connector accepts the cable coming from the communication adapter. It is protected by a metal door when not in use. To open the metal door, loosen the two screws on the metal door slightly until you can slide the door open. Close the door after the VPU is disconnected from the CA cable and tighten the screws.

**Table 2.8 VPU Accessories**

<b>Battery</b>	Sony InfoLITHIUM M Series Model Number NP-FM500H (small size) and NP-QM71D (medium size) are approved for use with the VPU. Refer to the "Battery Maintenance" Section in Chapter 5 for installation of battery. Depleted batteries can be recharged by using the battery charger. On average the small battery will last 2.5 to 3.5 hours and the medium battery will last 4 to 6 hours.
<b>Battery Charger</b>	<p>A battery charger is provided to the patient to recharge the battery.</p> <p><b>WARNING</b></p>  <p><b>Use only Second Sight-supplied rechargeable batteries to power the VPU and the Second Sight-supplied battery charger to recharge the batteries. Use of other batteries may damage the VPU or cause it to function improperly.</b></p>

<b>VPU Pouch</b>	The pouch allows the VPU to be worn on the body. It can be adjusted to hold the VPU in the most comfortable orientation.
<b>Travel Case</b>	A durable case provided to the patient to safely store and transport the VPU, glasses and batteries when not in use.

**Table 2.9 VPU Audible Alarms**

<b>Sound</b>	<b>Meaning</b>
Single short beep	A button has been pressed (for example, program setting adjustment).
One beep followed by a pause, followed by two short beeps	The VPU is turning off. This occurs when the power button is pressed while the VPU is on.
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)	Low battery voltage warning. The battery should be replaced as soon as this sequence is heard.
Slow periodic beep (1 every 2 seconds)	There is a problem with the video signal. Refer to Chapter 6 for troubleshooting.
Fast periodic beep (2 per second)	There is a loss of communication between the implant and external coils (on the glasses). This sound can be turned off by pressing the star-shaped button on the right side of the VPU, as shown in Figure 2.6. Refer to Section 3.8.2 to adjust the sensitivity of the RF link alarm.

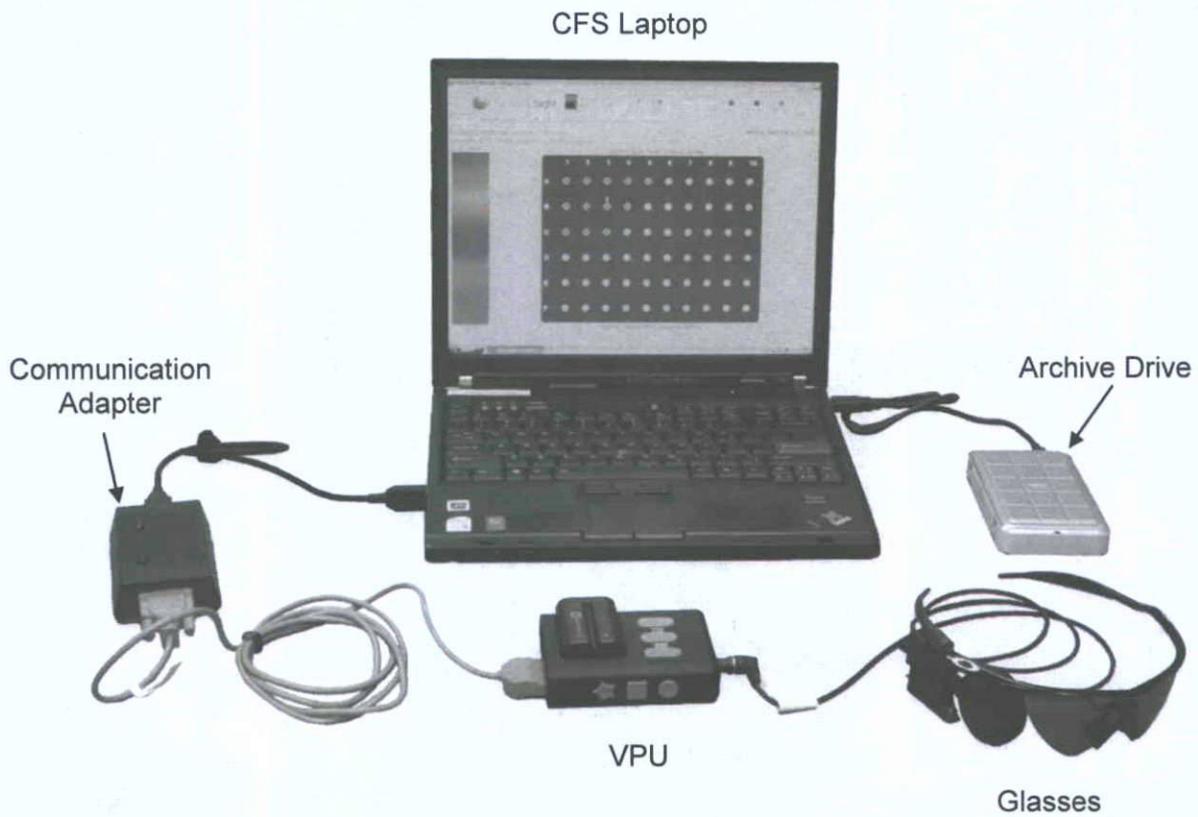
### 2.3.5 Argus II Clinician Fitting System (CFS)

Figure 2.7 shows the components of the Argus II Clinician Fitting System. In addition to the glasses and VPU, Table 2.10 provides a description of the components that make up this system.

**Table 2.10 CFS Components and Accessories**

<b>Clinician Fitting System (CFS) Laptop</b>	Used to customize and configure the patient's stimulation/fitting parameters, to electronically record data, to display VPU and implant status information, and to troubleshoot the Argus II System. CFS includes a laptop computer with dedicated Argus II clinician fitting software. Power supply unit for recharging the PC battery is also provided.
<b>Communication Adapter (CA)</b>	Provides an optically isolated communication channel between the CFS laptop and the VPU.  <b>CAUTION: The CFS-CA cable should only be plugged in the USB port marked "CFS-CA Cable". Plugging in other USB ports not marked "CFS-CA cable" may result in interruption of normal use of the CFS.</b>
<b>USB Archive Drive</b>	External USB Drive for archiving of files from the CFS laptop.
<b>USB Security Drive</b>	USB thumb drive containing security files to enable clinician's access to the CFS laptop. The security files contain encrypted login information for authorized users to access CFS and can be provided and updated by Second Sight.
<b>USB Video Settings Drive</b>	USB thumb drive containing video settings that can be loaded to the VPU.
<b>USB Data Transfer Drive</b>	USB thumb drive for transferring selected files from the CFS laptop to Second Sight for data analysis.
<b>CA-VPU Cable</b>	Cable providing connection between the CA and the VPU.
<b>CFS-CA Cable</b>	USB cable providing connection between the CFS laptop and the CA.
<b>Touch Screen Monitor</b>	Used during the camera alignment procedure or other tests to record the patient's responses.
<b>User Input Device (Logitech® Gamepad)</b>	A user input device used during psychophysical tests.

**Figure 2.7 External Components of the Argus II Clinician Fitting System (CFS) Configuration**



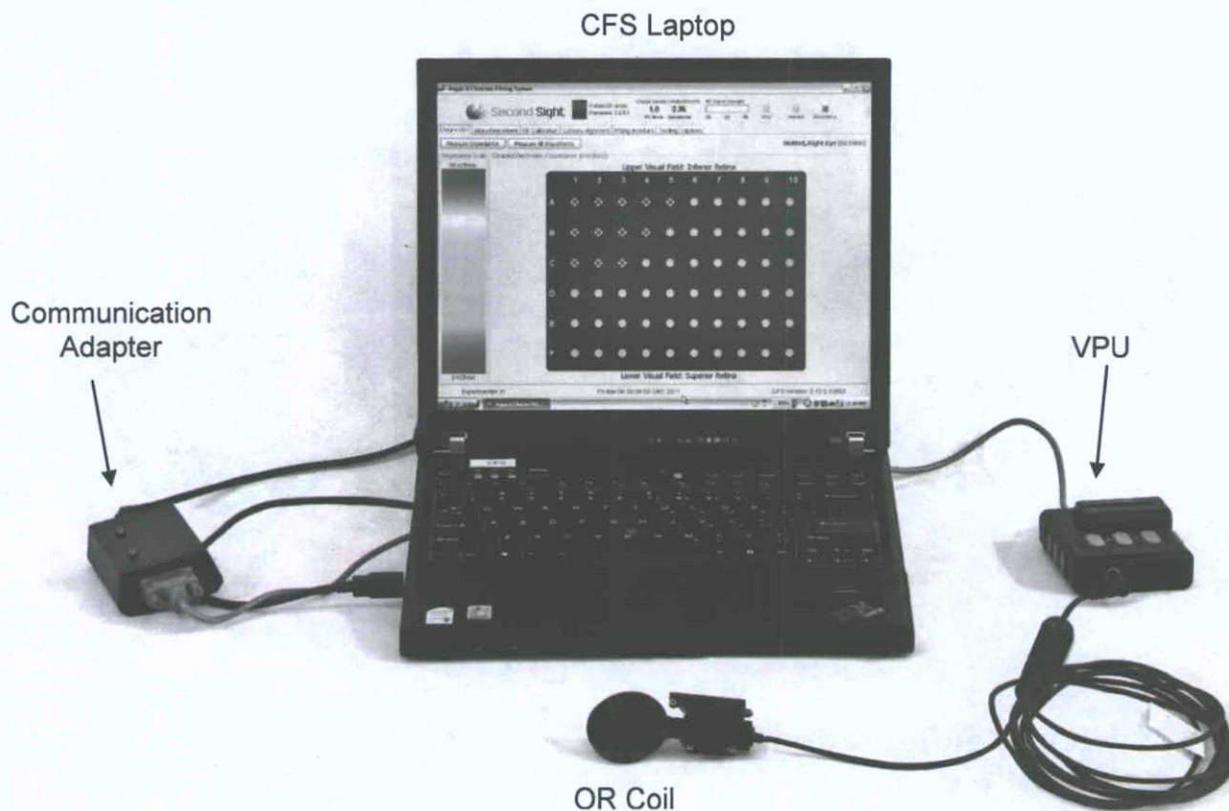
## 2.4 System Configurations

The Argus II Retinal Prosthesis System operates in three configurations. They are for surgery, device fitting, and use outside the clinic. Each of these is described below.

### 2.4.1 Operating Room (OR) Configuration (OR Mode)

The functionality of the implant can be tested pre-operatively and intra-operatively by using the Argus II OR Coil that is placed in close proximity to the implant. The OR coil communicates the status of the implant to the Argus II VPU (configured for OR use) which is connected to the CFS laptop via a cable through the Communication Adapter. The OR configuration is shown in Figure 2.8.

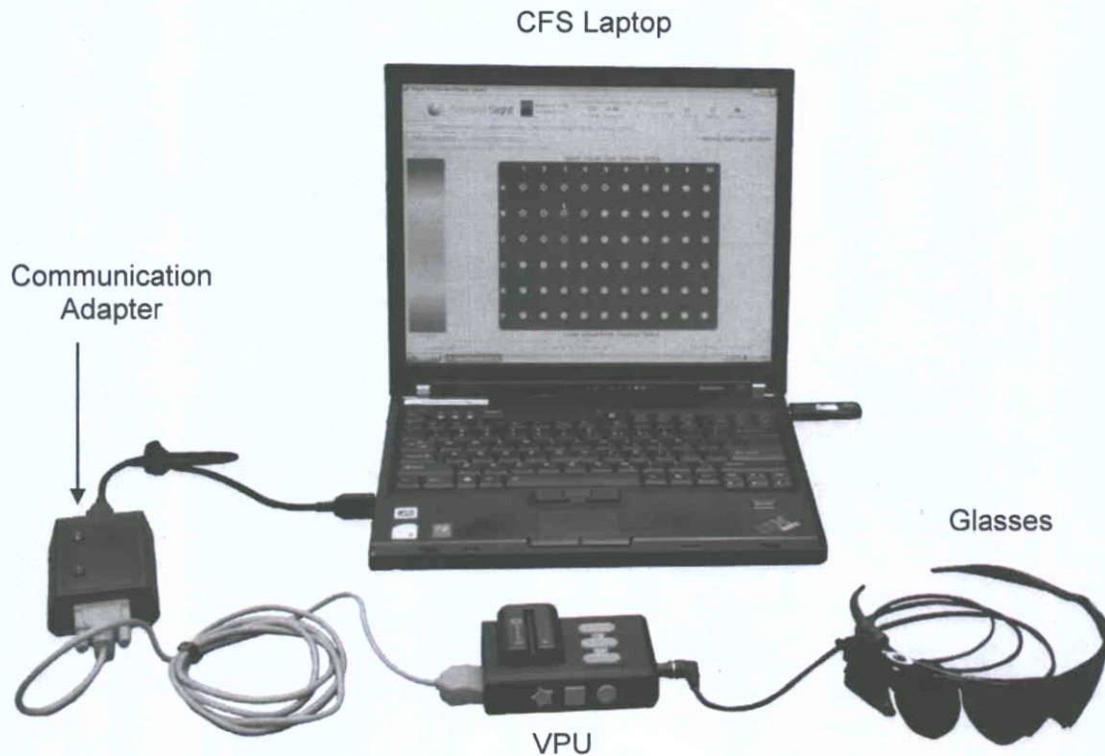
**Figure 2.8 Operating Room (OR) Configuration**



### 2.4.2 Clinician Fitting System Configuration (Clinic Mode)

The clinician fitting system configuration, also known as clinic mode, as shown in Figure 2.9, includes the glasses, the VPU, the CFS laptop, and the CA. This configuration enables diagnostic testing of the implant, the adjustment of various parameters to optimize the performance of the system, and psychophysical testing with a patient. The Argus II VPU is connected to the CFS laptop via cables through the communication adapter. Diagnostic tests can be run and programming parameters can be adjusted and downloaded to the VPU. This configuration allows sophisticated psychophysical testing and analysis to be performed by capturing patient responses to computer generated stimuli.

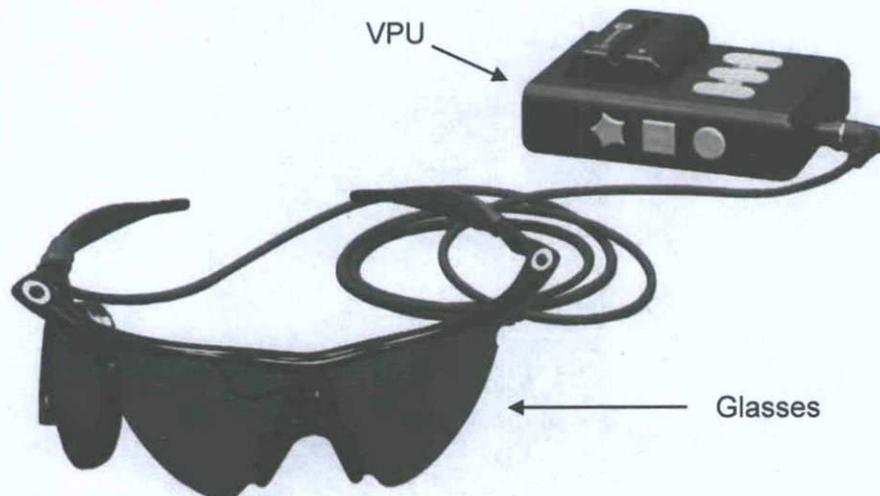
Figure 2.9 Clinic Mode Configuration



### 2.4.3 Stand-Alone Configuration

The stand-alone configuration, shown in Figure 2.10, consists of the Argus II Glasses and VPU. This configuration can be used in or outside the clinic. In this configuration, the video camera, which is attached to the Argus II Glasses, captures live video. The video signal is sent to the Argus II VPU (powered by a rechargeable battery), which processes the signal and subsequently transforms it into electrical stimulation patterns. The electrical stimulation data are then sent to the coil mounted on the glasses. The coil sends both data and power via radio frequency (RF) telemetry to the implant. The implant coil receives the RF commands which control an Application Specific Integrated Circuit (ASIC) which in turn delivers stimulation to the retina of the patient via an electrode array. **Note: The Argus II Implant is electrically active only when it is powered by the VPU; otherwise, the implant is a passive device.**

Figure 2.10 Stand-Alone Configuration



## 2.5 System Safety

### 2.5.1 Equipment Safety, Handling, and Storage

The CFS laptop is connected to the Argus II VPU using an optically isolated serial connection (Argus II Communication Adapter). Because it is optically isolated, the serial connection assures that no electric leakage current can flow from the Argus II Clinician Fitting System to the VPU and glasses.

Use only Second Sight-supplied rechargeable batteries to power the VPU and the Second Sight-supplied battery charger to recharge the batteries. Use of other batteries may damage the VPU or cause it to function improperly.

Take care when storing and handling the CFS and other programming equipment, the VPU and glasses, as improper care or storage can result in damage to the equipment. Following the guidelines below can extend the lifetime of this equipment.

1. **Magnetically Sensitive Storage Devices.** Do not place magnetically sensitive storage devices (credit cards, computer floppy disks or hard disks) near the Argus II System while it is operating. The electromagnetic field generated by an operational system may corrupt the information stored on such devices.
2. **Unapproved Components.** Use only components and accessories supplied by Second Sight with the Argus II System. The use of unapproved components may cause damage to the equipment, resulting in loss of stimulation and/or injury. The unused ports and connectors of the fitting system are inaccessible without the use of a tool and should be accessed only by Second Sight personnel.
3. **Exposure to Liquid.** Do not expose the external equipment (VPU and glasses) to any liquid (for example, rain, shower, swimming pool, or ocean) as it may render the device inoperable.
4. **Storage of the Argus II VPU and Glasses.** Store the packaged Argus II VPU and glasses at temperatures between 0°C (32°F) and +45°C (113°F). Do not expose the external equipment to temperature below 0°C or above +45°C as this may render the device inoperable.
5. **Usage Temperature Range.** The temperature range for normal use should be between 0°C (32°F) and +40°C (104°F).
6. **Handling the Glasses.** Handle the glasses 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. The arms are not designed to be closed and trying to fold them may break them. Do not wrap the cable around the VPU or glasses since, over time, this may cause damage to the cable.
7. **Traveling with the External Equipment.** It is recommended that you store the VPU, glasses, and batteries in the travel case provided by Second Sight as this is designed to protect the equipment. It is also recommend that you uninstall the battery from the VPU during transit, so as to avoid accidentally turning on the VPU which could drain the battery. Do not place anything on top of the glasses or VPU.
8. **Interference.** The Argus II System may interfere with certain radio frequencies. If interference occurs, you should extend the distance between you and the radio, or turn off the Argus II VPU.

### 2.5.2 Data Handling

All patient data are stored on the hard disk of the computer. We recommend that all patient data be backed up after each fitting session to avoid data being destroyed or lost. The USB archive drive provided by Second Sight can be used for this purpose.

**Use of the CFS:** Do not use the Clinician Fitting System (including all the peripherals that attach to the CFS computer) to perform general purpose computing tasks. Do not load any unauthorized applications onto these computers or save any other data on the hard drives. These computers are dedicated solely for use with the Argus II System and are configured to support this dedicated use.

### 2.5.3 Patient Safety

The Argus II Retinal Prosthesis System is designed to protect the patient from hazardous stimulation using several safety measures for both the software and hardware. These safety measures include: a VPU start-up test to check the implant functionality, an electrode integrity test to ensure only functional electrodes are stimulated, a charge density limit for stimulation on each electrode, and a maximum simultaneous stimulation current limit for the system.

Any time stimulation is sent to the VPU, the stimulation parameters are checked to ensure that maximum charge per phase limits, charge balance, and power limitations are met before the test stimuli are sent to the VPU to make certain that stimulation is safe.

Although safety and precautionary measures have been implemented in the hardware and software to prevent unwanted stimulation, it is the clinician's responsibility to ensure that such stimulation is prevented. The following procedures should be followed to ensure safe stimulation of the system:

1. **Matching the VPU to the Implant.** Always configure a VPU for the patient's implant prior to using the VPU with the patient for the first time. This procedure is typically performed by Second Sight trained personnel. Failure to do so could result in less accurate threshold measurements, distortion of the presented image, and discomfort. When discomfort occurs the system should not be used, and settings should be analyzed and adjusted as needed.
2. **Matching the VPU to the Patient.** When providing an Argus II VPU to a patient, be certain that it is the correct VPU for that patient by checking the patient ID label on the VPU. If a patient uses another patient's VPU, they may experience pain, discomfort, or unsafe stimulation.

Troubleshoot promptly or contact Second Sight if the patient reports perceptual change or discomfort during the use of the device.

# 3 Argus II Retinal Prosthesis System Device Fitting

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## 3.1 Introduction

The Argus II Clinician Fitting System (CFS) is used to configure the Argus II System stimulation parameters and video processing strategies for each patient. Within the CFS are modules for implant diagnostics (impedance and electrode voltage waveform measurements), device fitting (ranging from perceptual threshold measurement, camera alignment, to creating customized video configuration files (VCF) for each patient), and video stimulation module. The video stimulation module can be used to change video filters, download video configuration files to the VPU and store them in the VPU memory.

Figure 2.7 provides a photograph of the external system in the clinician fitting system configuration.

## 3.2 Connecting and Powering on the Clinician Fitting System

**CAUTION:** Before connecting the CFS laptop or cables, ensure that the VPU is powered OFF.

CA should only be plugged in the USB port marked "CFS-CA Cable". If not, it may result in interruption of normal use of the CFS.

Before the first use of the system after implantation, make certain the VPU is configured for Clinic Mode and not OR Mode. Refer to Section 3.6 below.

**WARNING**



Failure to follow these recommended instructions for powering the fitting system could result in electric shock. The fitting system may require as many as three power supply units be connected to electrical outlets at the same time. While the fitting system is designed to provide user safety, use of a power strip to power all three power supply units may result in excessive currents flowing from the fitting system to earth creating a possible hazard. Ensure any power strip used is properly rated and not placed on the floor when in use. Additionally, in any fitting system configuration, it is important that the operator of the system not touch the patient and any component of the fitting system at the same time, as this may also present a path for excessive currents to flow. Only use the Lenovo AC adapter 92P1105 or 92P1156 power supply unit for the CFS and PTS laptops. Only use the HiTRON HES49-12040 power supply unit for the touch screen monitor.

**WARNING**

**Only use items that have been specified as part of the Clinician Fitting System including cables, power cords and power supplies.**

1. Install the battery into the VPU. To install, slide the VPU battery latch so that it opens and set the battery in the battery receptacle. Slide the battery in the receptacle across the front of the VPU until the battery latch can be released back down into its locked position.

**Note:** Do not power on the CFS until Step 6 and the VPU until Step 8.

2. Connect the CA to the USB port marked "CFS-CA cable" on CFS laptop using the CFS-CA Cable.
3. Connect the CA to the VPU using the CA-VPU Cable.
4. Connect the Psychophysical Test System (PTS) laptop to CFS using the CFS-PTS cable (optional).
5. Connect the glasses cable to the VPU.
6. Switch on the CFS laptop by pressing and holding down the power button. Switch on the PTS laptop (optional).
7. Have the patient put on the glasses. The patient should be informed that he or she may see percepts during the following tests.
8. Turn on the VPU by pushing down and holding the round-shaped power button located on the right side of the unit for at least two seconds. Four short beeps will signal that the system is turning on.

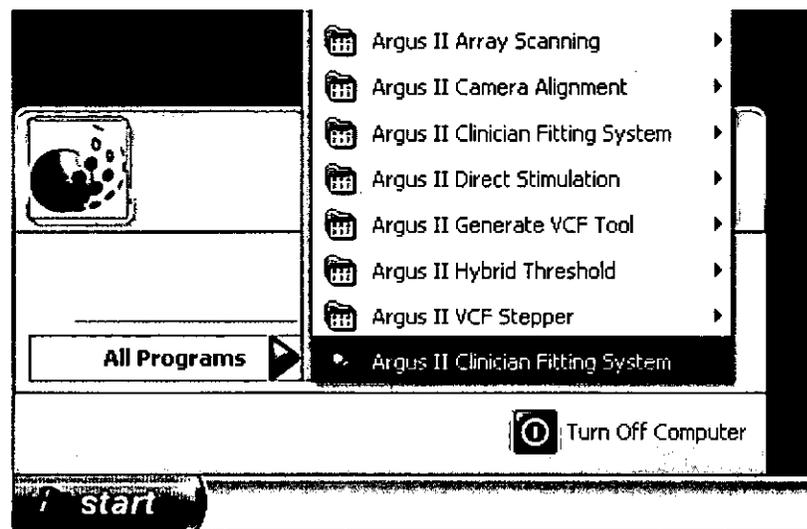
Immediately after the VPU is turned on, it performs a series of start-up tests. These tests will complete within 30 seconds. During this time the green LED indicator on the VPU will blink rapidly. Once these tests are complete, the green LED indicator will blink slowly to indicate that the system is in normal operation. Please refer to Chapter 6 Troubleshooting if the VPU is powered off after the start-up test.

**Note:** During these start-up tests, if the communication between the glasses and the implant is lost, the VPU will beep continuously. If this happens, adjust the position of the glasses until the beeping stops, indicating that link has been re-established. The glasses may be adjusted by either moving them up or down on the bridge of the patient's nose and/or by sliding the RF board/coil assembly forward or backward.

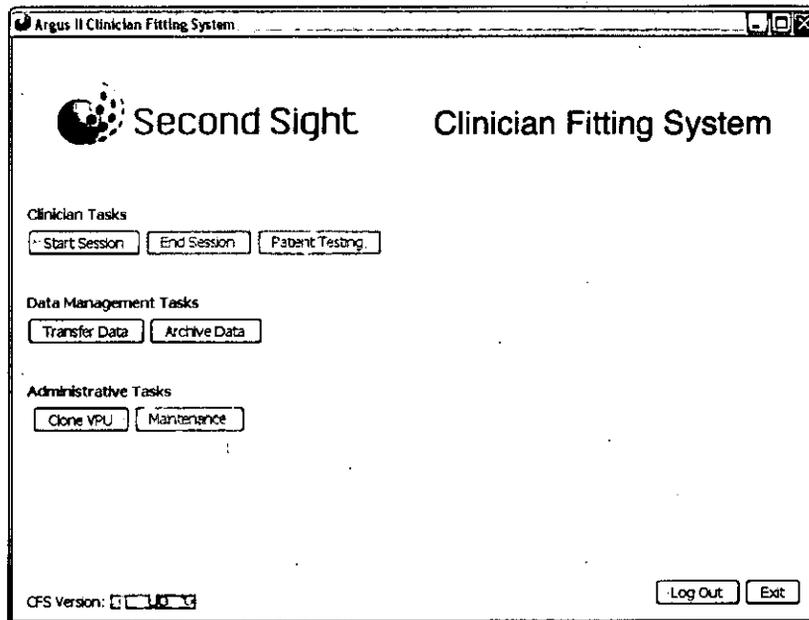
### 3.3 Starting the CFS Software

1. Follow the section "Connecting and Powering on Clinician Fitting System" in this chapter to connect the Argus II fitting equipment.
2. Prior to using the CFS software, confirm with Second Sight personnel that the correct security files which contain your encrypted login access have been loaded.
3. Switch on the VPU power button (refer to Figure 2.6) and wait for the start-up test to complete.
4. On the CFS laptop open the Argus II CFS software by clicking on START and selecting "Argus II Clinician Fitting System" in the "All Programs" menu, shown in Figure 3.1. The log in screen will appear requesting a username and password.
5. After entering the username and password; the main menu will be available, as displayed in Figure 3.2.

Figure 3.1 Starting CFS



**Figure 3.2 Clinician Fitting Main Menu**

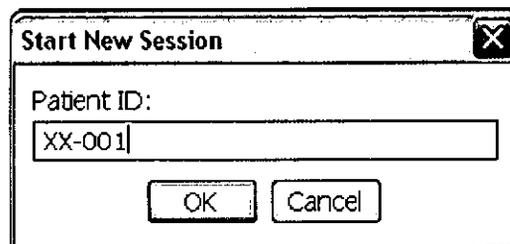


There are six options available on the CFS main menu startup screen:

1. Start Session
2. Transfer Data
3. Archive Data
4. Clone VPU
5. Log Out
6. Exit

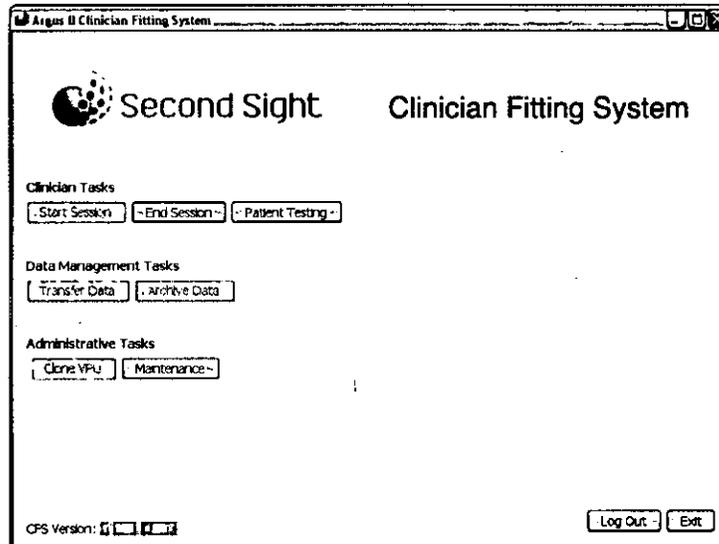
In order to obtain access to patient testing it is necessary to initiate a session by selecting the "Start Session" option from the main menu. The following screen will appear requesting the patient ID be entered (Figure 3.3). The patient ID should be in the format ##-### where ## represents the hospital and ### is a consecutive number to designate the patient (e.g., 97-003).

**Figure 3.3 Starting a New Patient Testing Session**



After the patient ID has been entered, the “End Session”, “Patient Testing”, and “Maintenance” buttons will be enabled, as shown in Figure 3.4. The software version number is displayed at the bottom left corner of the screen.

**Figure 3.4 Initiating Patient Testing**



“Patient Testing” is selected in order to perform device diagnostics and fitting.

“End Session” is selected to close a patient testing session without logging out (see below). Another patient testing session may be initiated by pressing the “Start Session” button.

“Maintenance” is selected in order to change the VPU configurations such as OR mode/Clinic mode, synchronizing the VPU clock, or changing the VPU audible alarm settings. Refer to Section 3.4 for detailed description on how to change VPU configurations.

“Log Out” allows the current user to log out of the testing session. A new user may log in to start a new testing session without closing the CFS software.

“Transfer Data” is selected when copying session data to a thumb drive for transfer to Second Sight.

“Archive Data” is selected when archiving all session data files on the CFS laptop to the external drive provided.

“Exit” is selected to exit CFS.

“Patient Testing”, “Maintenance”, “Transfer Data”, and “Archive Data” are described in more detail in this chapter.

## 3.4 Argus II Video Processing Unit (VPU) Configurations

Prior to using an Argus II Video Processing Unit (VPU) with a specific implant or patient, the VPU must be configured. There are two VPU configurable modes: Operating Room (OR) mode and clinic mode. In the clinic mode, if the impedance value of an electrode exceeds the specified normal range, the VPU will disable the electrode automatically. In the OR mode, the VPU does not disable electrodes automatically. This is because during the implant surgery, the impedance values may be out of range if the electrodes are not in contact with tissue or fluid.

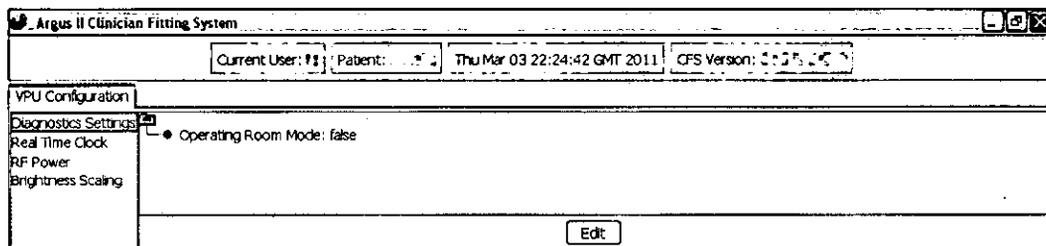
### 3.4.1 Configure the VPU for OR Mode

**Note:** Some processes may only be performed by trained Second Sight personnel.

Prior to using a VPU during the implantation procedure, the VPU must be configured to "OR mode". The following steps must be performed:

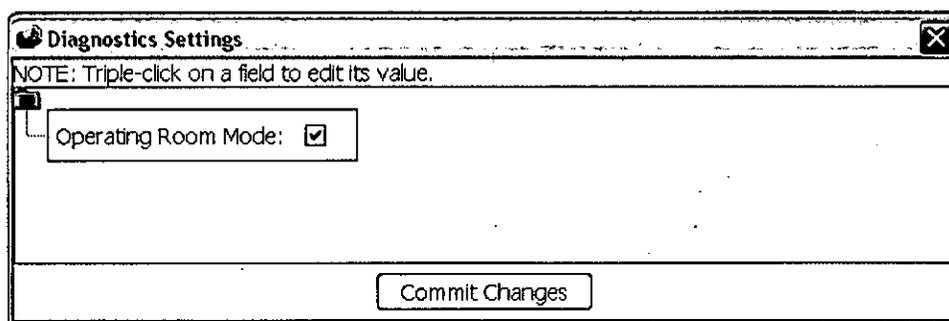
1. Log in and enter the patient ID.
2. Click on the "Maintenance" button under **Administrative Tasks**.
3. Select "Diagnostics Settings", the "Operating Room Mode" field will display, as shown in Figure 3.5. If the field is **true**, this means the VPU has already been configured for OR use. If the field is **false**, it means the VPU is not in OR mode.

**Figure 3.5 Change VPU Configuration in CFS Maintenance Screen**



4. Configure the VPU for OR use by clicking on the "Edit" button shown in Figure 3.5. Follow the instruction to triple-click on the field, and the OR mode check box will display, as shown in Figure 3.6. Check the box and click on the "Commit Changes" button.

**Figure 3.6 Change VPU Configuration to OR Mode**



5. Perform VPU-Implant Matching. Each Argus II Implant has certain custom specifications. To optimize the performance of the system and for safety reasons, the VPU used with the implant must be configured or "matched" to the implant. To match a VPU to an implant, the Second Sight personnel use the VPU-Implant Matching CD that is provided with each Argus II Implant, and program the VPU with the patient ID. **This process can only be performed by Second Sight personnel.**
6. Clearly label the VPU using the label provided by Second Sight with the following information: OR mode, implant serial number, and patient ID.

### 3.4.2 Configure the VPU for Clinic Mode

Prior to using a VPU with a new patient for the first time in the clinic, the following steps must be performed to configure the VPU:

1. Follow the steps in Section 3.4.1 to configure the VPU for clinic mode by changing the VPU OR mode to **False** in the maintenance screen and confirm the change.
2. Confirm with Second Sight personnel that the VPU is matched to the Argus II Implant (a copy of the VPU-Implant Matching CD is required for this step).
3. Confirm that the VPU is configured with the patient ID.
4. Confirm that the VPU is labeled with the VPU mode (i.e. clinic mode), the implant serial number and patient ID.

#### WARNING



**To reduce the risk of infection during patient testing sessions in the first month following any surgical intervention on the implanted eye, wear clean gloves and wipe any part of the Argus II Glasses which touches tissue around the patient's eye with either an alcohol or germicidal wipe. Allow the glasses to air dry before placing them on the patient.**

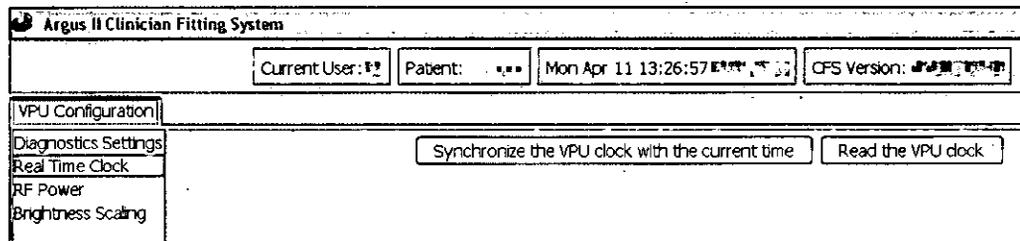
### 3.4.3 Synchronize the VPU Clock

**Note:** This procedure is only conducted if requested by trained Second Sight personnel.

The VPU has an internal clock which allows it to track some events such as when it is switched on and off, how well the implant and VPU function, and whether and when the communication between the implant and VPU is interrupted. This information is useful in monitoring the home usage of the device and advanced troubleshooting. It is loaded to CFS once the VPU is connected to CFS and can be transferred to Second Sight for further analysis. In order to track these events accurately, the VPU clock should be set correctly. The CFS software allows the user to synchronize the VPU clock with the CFS computer clock. To synchronize the VPU clock with the CFS clock, follow these procedures:

1. Make sure the clock on the CFS computer is set correctly to the Greenwich Mean Time (GMT) with automatic daylight savings adjustment disabled.
2. Connect the VPU to CFS and switch the VPU on.
3. Start CFS and log in. Click on "Start Session" and enter the patient ID.
4. Click on the "Maintenance" button and select the "Real Time Clock" tab, as shown in Figure 3.7. Click the "Synchronize the VPU clock with the current time" button to set the VPU clock to be the same as the CFS clock.

**Figure 3.7 Synchronize the VPU Clock**

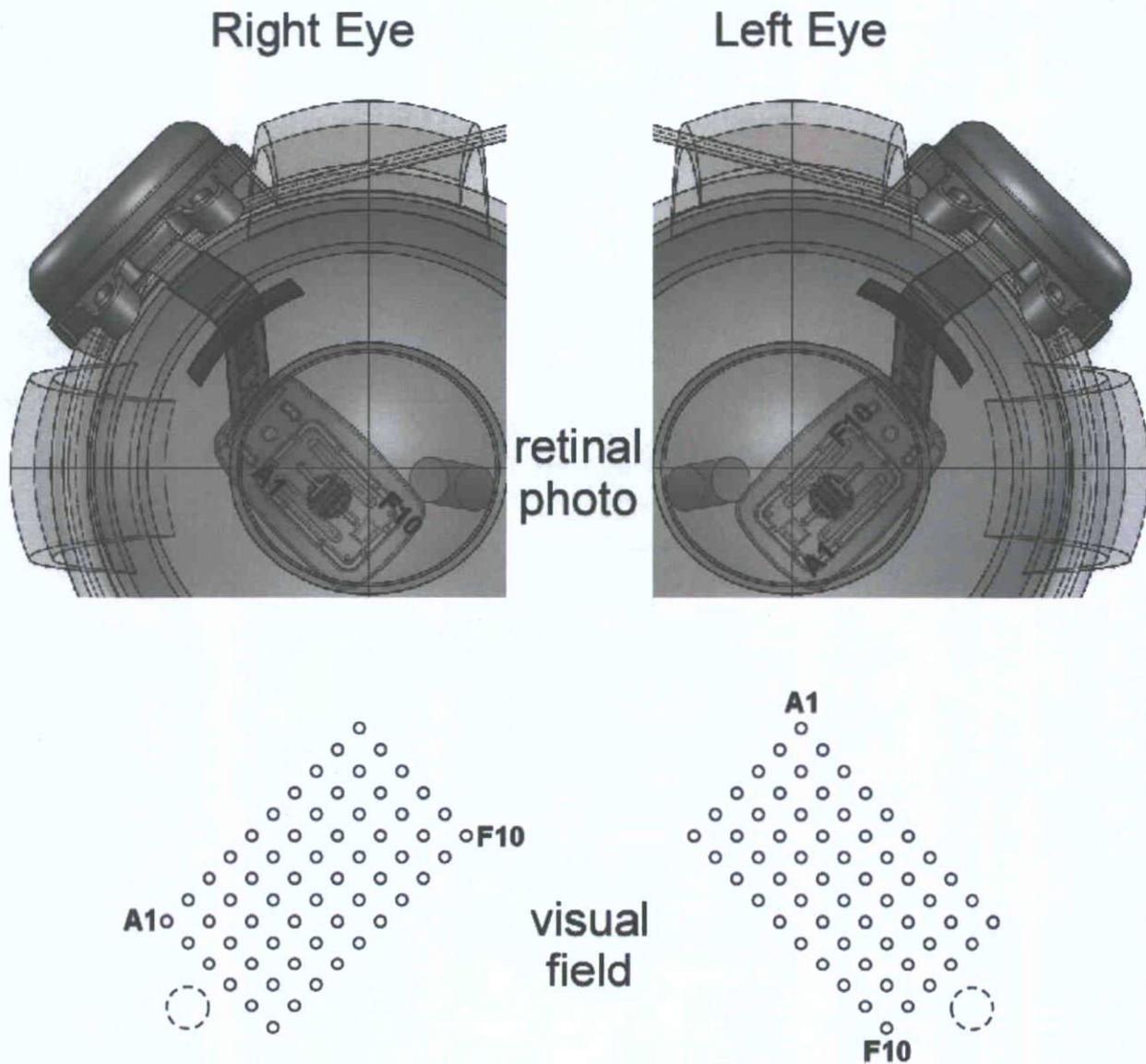


5. Once the software indicates the VPU clock is successfully set, click on the "Read the VPU clock" button to check whether the VPU clock matches the CFS clock.
6. If the VPU clock cannot be synchronized to CFS clock, contact Second Sight using the information provided in Section 1.6.

## 3.5 Left and Right Eye Electrode Array Position Reference for Post-Operative Procedures

When performing post-operative procedures, it may be important to note the position of particular electrodes on the Argus II Implant. The position of electrodes differs depending on whether the information is presented from the patient's visual field perspective or the perspective of looking into the patient's eye (retinal photo). These two perspectives are depicted in Figure 3.8.

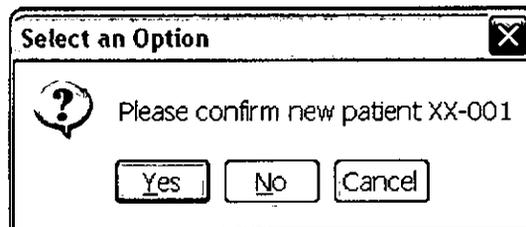
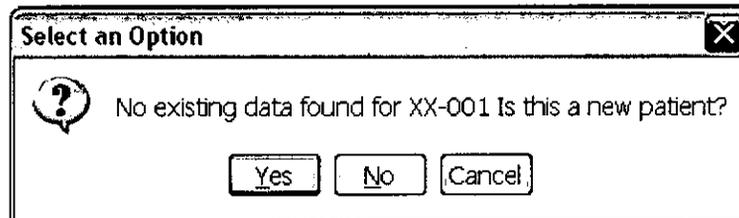
**Figure 3.8** Left and Right Eye Electrode Position Reference for Post-Operative Procedures



### 3.6 Initiating Patient Testing

1. Prior to initiating a "Patient Testing" session, the VPU must be on and must have completed its start-up tests by establishing an RF link with the implant. Have the patient put on the glasses. Turn on the VPU.
2. If the VPU emits a periodic audible beep indicating no RF link, adjust the glasses until link is obtained with the implant. The VPU will emit an audible periodic beep until link is obtained.

3. Once link has been obtained, the audible beep will stop and the green LED indicator on the VPU will continue to blink fast to indicate that the start-up tests are being conducted. These tests should last approximately 30 seconds. Tell the patient that he or she may see percepts during these tests.
4. Once the tests are complete, the VPU will blink moderately (approximately 1 blink/second) to indicate the implant passed the start-up tests. If the VPU is blinking slowly (approximately 1 blink every 2 seconds), then this indicates that there is a problem with the implant. Contact Second Sight if this occurs.
5. Log into CFS, press the "Start Session" button, enter the patient ID and then click on "Patient Testing".
6. If this is a new patient ID, the New Patient Screen will appear. Click "Yes" to accept the new patient. If the ID is entered in error, the software will display an error message and click No and re-enter the patient ID. A confirmation screen will appear. Click on "Yes" again to confirm.



## 3.7 Impedance and Waveform Measurements

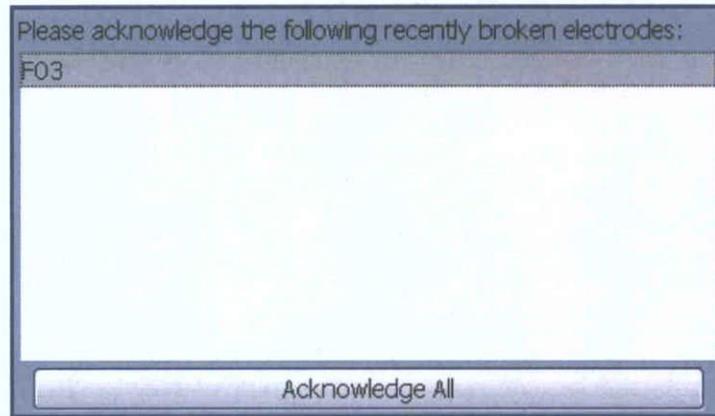
### 3.7.1 Diagnostics Module

After successfully initiating patient testing, a diagnostic application is automatically initiated to display the status of the implant. Through this application, an electrode integrity check is performed, electrode status is displayed and the impedance and waveforms for each of the electrodes can be measured. The diagnostic data (transferred from the CFS laptop to the USB Data Transfer thumb drive) will be sent to Second Sight for monitoring and analyzing the electrode function over time. The steps for performing the diagnostic checks are described in this section.

1. After beginning a testing session, a message box shown in Figure 3.9 will be displayed in the event that any newly disabled electrodes are detected since the previous session. If this message appears, click on "Acknowledge All" to

acknowledge any newly disabled electrodes. Contact Second Sight if the patient reports any decline in perception due to the new electrodes being disabled.

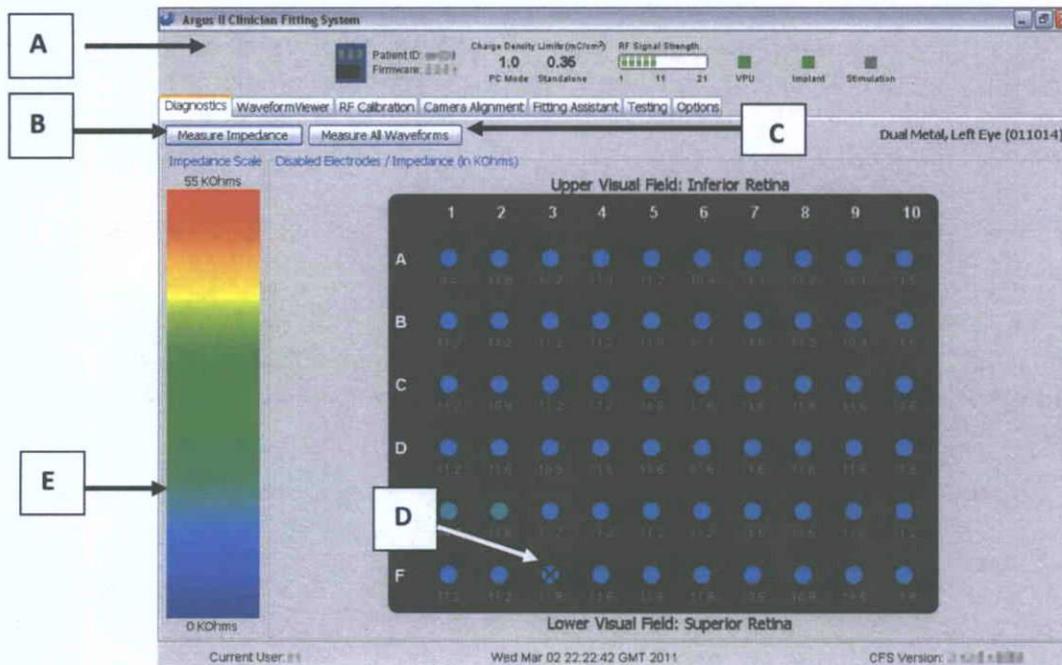
**Figure 3.9 Acknowledging Newly Disabled Electrodes**



If no newly disabled electrodes are detected, this message box will not appear and the Diagnostics Screen (Figure 3.10) will automatically appear.

The “Diagnostics” tab has an orange bar over the top to indicate that the Diagnostics Module has been initiated.

**Figure 3.10 Diagnostics Screen**



Diagnostic Module Screen Features

A. Session Information is located at the top and bottom of the Diagnostics Screen. The following session information is displayed:

- **Patient ID.**
- **VPU Firmware Version Number.**
- **Charge Density Limits (CDLs):** This displays the Charge Density Limit in mC/cm<sup>2</sup> for both the PC and standalone modes. The PC mode refers to the VPU being connected to CFS. The standalone mode refers to the VPU not being connected to CFS.
- The CDL for standalone mode is set at 0.35 mC/cm<sup>2</sup> by default. The CDL for PC mode is configurable by a Second Sight personnel. It is set to 1.0 mC/cm<sup>2</sup> by default.
- **RF Signal Strength Meter:** This displays the RF signal strength and the nominal value in the middle of the meter.
- **VPU:** This displays the status of the connection of the VPU to the CFS. It will be illuminated green if a connection is detected. If no communication is detected, the box will appear yellow.
- **Implant:** This displays the status of the communication of the implant to the CFS. It will be illuminated green if communication is detected. If no communication is detected, the box will appear yellow.
- **Stimulation:** This displays the status of stimulation (i.e., whether or not stimulation is occurring). When stimulation of the implant is occurring, the indicator box next to "Stimulation" will be green. When stimulation is not occurring the box will be grey.
- The **User, Date and Time, and CFS Version Number** are displayed on the bottom of the screen. The array type and right or left eye configuration is indicated on the right side.

B. "Measure Impedance" – Initiates impedance measurement for all electrodes

C. "Measure All Waveforms" –Initiates waveform measurement for all electrodes

D. Disabled Electrodes/Impedance (in kΩ) – a 10 x 6 electrode grid representing each of the implant electrodes. The view of the electrodes is from the perspective of the patient's visual field. The electrodes shown as "⊗" are designated as disabled (electrode F03 in Figure 3.10). When measuring impedance, the values will appear directly under each represented electrode.

**Note:** Impedances will be measured for electrodes designated as disabled, but no other stimulation will occur on these electrodes.

E. Impedance Scale - Color coded scale for impedance values. After measuring impedance, each of the represented electrodes in the grid will be color coded based on where its impedance value falls within the scale.

1. Verify that the indicator boxes above **VPU** and **Implant** are illuminated green. If the VPU indicator box is yellow, verify that the VPU is properly connected to the CFS via

the CA. If the **Implant** is yellow and/or the VPU is sounding an audible alert indicating that communication with the implant is not established, adjust the patient's coil on the glasses to establish link. If connection problems persist, refer to Chapter 6 (Troubleshooting) for additional information.

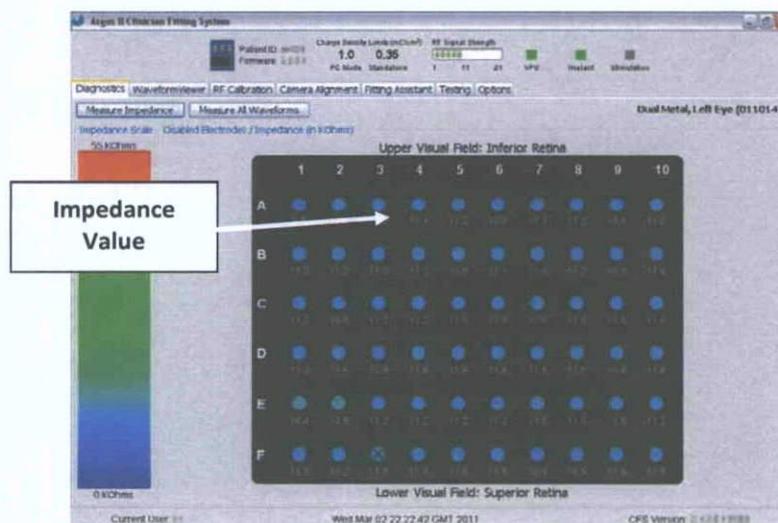
2. To measure impedance, click on the "Measure Impedance" button. The following message box will appear that indicates the progress of obtaining impedance measurements. This process should take less than 30 seconds. To cancel the impedance measurement prior to its completion, press the "Cancel" button.



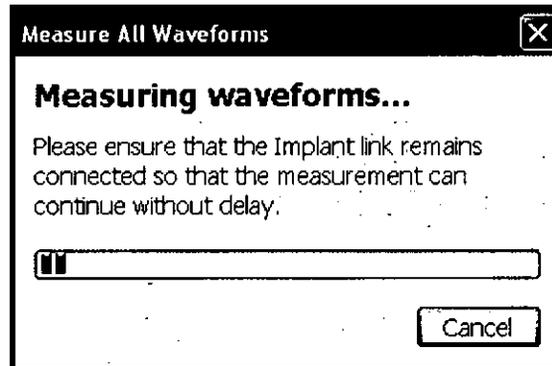
**Note:** The measurement of impedance requires a good link between the implant and the glasses throughout the measurement.

Once the impedance measurements are completed, the impedance values (in  $k\Omega$ ) will be displayed on the screen under each represented electrode (Figure 3.11). Each of the electrodes will be color coded based on where the impedance value falls within the impedance scale from 0 to 55  $k\Omega$ . The impedance values for the patient are automatically stored in a file on the CFS laptop. This file will be transferred to the data transfer thumb drive during Transfer and should be sent to Second Sight for further analysis (refer to Section 3.14.1 "Transfer Data").

**Figure 3.11 Impedance Measurement Screen**



3. To measure waveforms, click on "Measure All Waveforms." The following message box will appear that indicates the progress of the waveform measurements.



The indicator box for **Stimulation** (top of the screen) will flash green during measurement of waveforms.

**Note:** The measurement of waveforms requires a good link between the implant and the glasses throughout the measurement. It typically takes between 3 and 5 minutes for the waveform measurements to be completed.

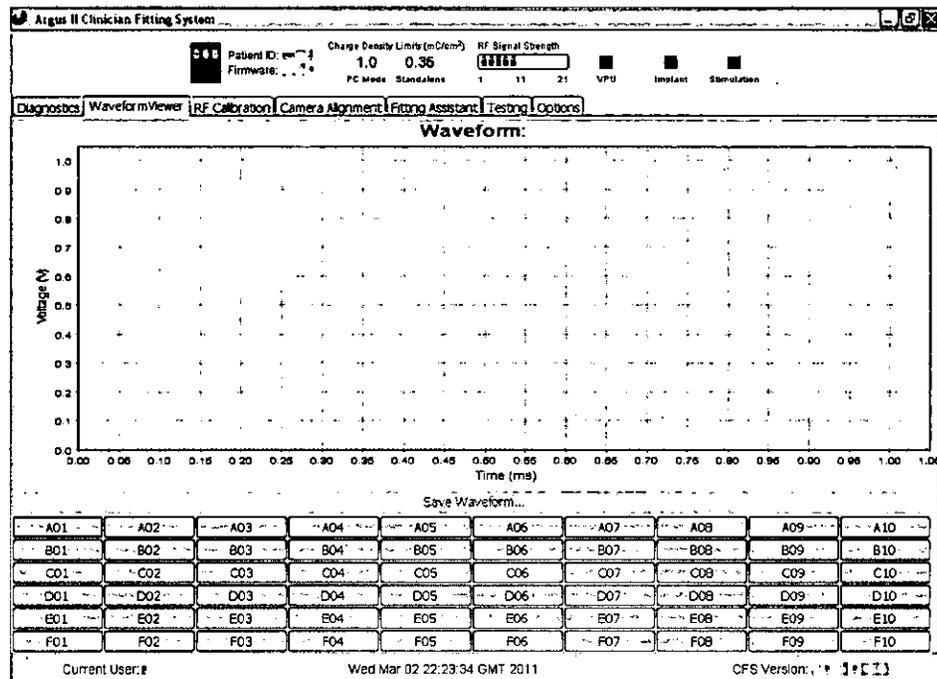
Once the measurements are complete, the message box will disappear and the stimulation indicator will stop flashing green. The waveform information will be stored in a file on the CFS laptop. This file will be transferred to the transfer thumb drive and can be submitted to Second Sight for analysis (refer to Section 3.14.1 "Transfer Data").

The waveforms for each of the electrodes can be viewed from the Waveform Viewer module.

The Waveform Viewer module is a utility that may be used to measure and view the waveform of a selected electrode.

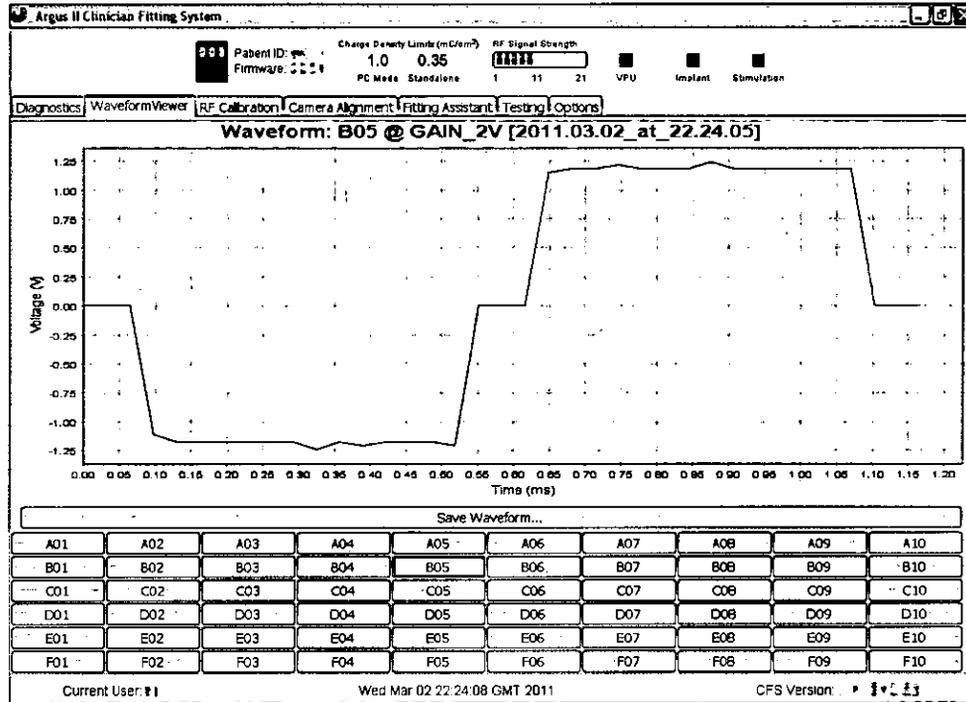
1. Click on the tab entitled "Waveform Viewer." The screen shown in Figure 3.12 will appear.

Figure 3.12 Waveform Viewer Screen



2. Verify that the indicator boxes above **VPU** and **Implant** are illuminated green. If not, refer to Chapter 6 (Troubleshooting) for additional information.
3. From the list of the electrodes at the bottom of the screen (displayed in a 10 x 6 configuration with their electrode names), click on the specific electrode for which you wish to measure the waveform. This will send a command to the VPU to record the waveform and to send back the information to the CFS so the waveform data may be presented on the screen. Figure 3.13 shows an example in which the waveform of B05 is measured during stimulation. By right clicking on the mouse, a pop-up window will appear that will allow you to zoom in and zoom out on the displayed waveform.

Figure 3.13 Example Waveform for Electrode B05

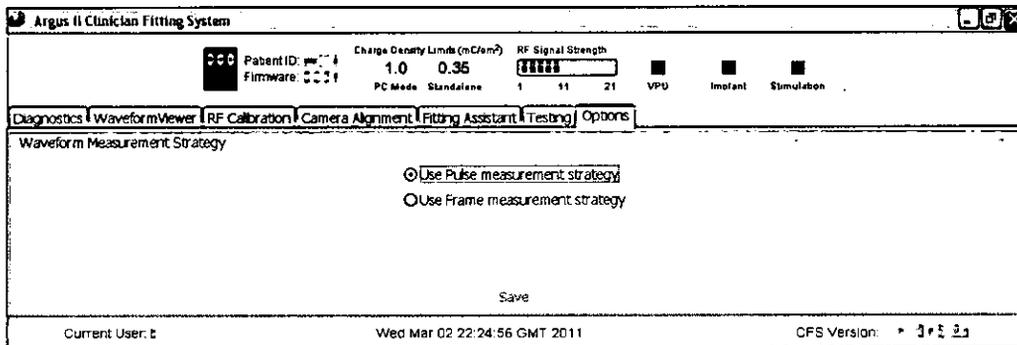


- To save the waveform, click on the “Save Waveform” button. A dialog box will then appear asking where you wish to save the file. Select the location and click “Save”.

### 3.7.2 Options

By selecting the “Options” tab in the CFS the user can choose either “Use Pulse measurement strategy” or “Use Frame measurement strategy” for measuring waveforms, as shown in Figure 3.14. The Pulse measurement only measures a portion of the waveform - the anodic and cathodic part of the waveform. The Frame measurement measures the entire waveform frame including the baseline. The default is Pulse measurement strategy. Pulse measurement strategy requires less time to complete.

Figure 3.14 Options Tab



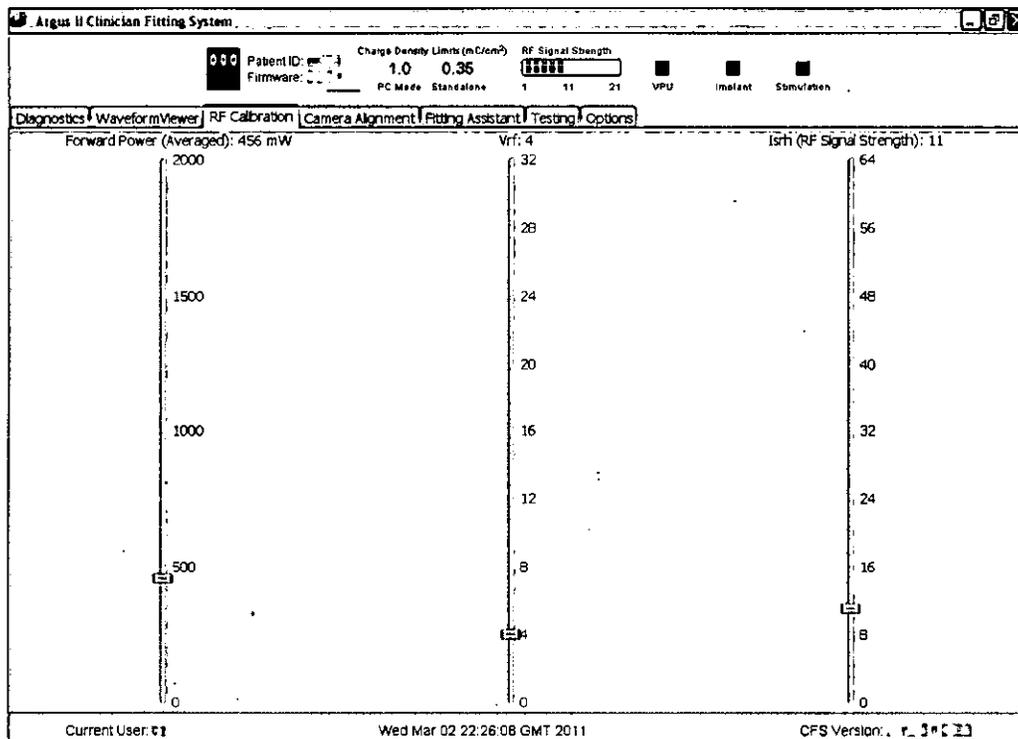
## 3.8 RF Calibration and RF Link Alarm Adjustment

### 3.8.1 RF Calibration

The stimulation data and power are transmitted in radio frequency (RF) from the external coil on the glasses to the implant coil. The distance between the coils and the relative angle between them governs the strength of this link. The RF calibration tab, shown in Figure 3.15, displays three parameters in real-time: **Forward Power**,  $V_{rf}$  and **Isrh**. **Forward Power** is the power that the VPU supplies for telemetry.  $V_{rf}$  is the RF voltage which corresponds with how much power the VPU is transmitting. The most critical is the **Isrh** parameter, which is a measure of how much power the implant is receiving. The position of the coil on the glasses and the glasses on the patient's head should be adjusted to maintain the **Isrh** value around the center of the horizontal RF Strength Meter bar located at the top of the screen, as shown in Figure 3.15, while subsequently trying to minimize  $V_{rf}$ .

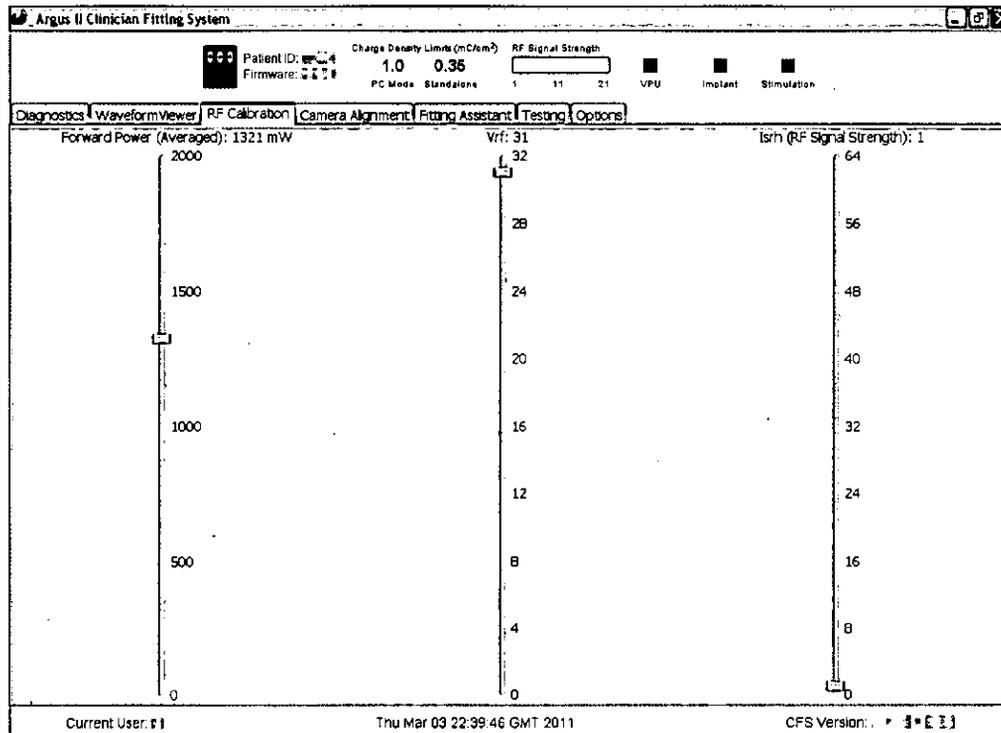
**CAUTION:** If the patient can feel the RF coil pressing against the superior-temporal region of the implanted eye in the area of the implant, the position of the RF coil should be adjusted. The RF coil should not exert any pressure or rub against the eye as this may cause discomfort or harm the patient.

Figure 3.15 RF Link Calibration – Nominal



When the distance and/or the angle between the coils is too large there will be a loss of RF link characterized by an audible alert from the VPU as well as a high  $V_{rf}$  value and a low **Isrh** value (Figure 3.16).

Figure 3.16 RF Link Calibration – Loss of Link



### 3.8.2 RF Link Alarm Adjustment

The VPU is in constant communication with the implant through the RF link. When the communication is temporarily interrupted, the audible RF link alarm will beep approximately twice per second to indicate the loss of communication with the implant. The star-shaped button on the VPU is a toggle switch to turn the VPU RF link alarm on or off.

The CFS allows the user to adjust a set of parameters that control how sensitive or fast the audible RF link alarm should react to the loss of RF link. The following three configurable parameters can be adjusted in 8.3ms increments (i.e., the actual time for each parameter is 8.3ms times the value shown on the screen). These parameters are:

**Implant Reconnect Time** (range 7 – 120, Default = 30): Reducing this parameter will decrease the time the system stops stimulation when the RF link is lost but will also reduce the battery life.

**RF Buzzer History Length** (0 – 1200, Default = 240): The amount of time the VPU looks back in time to see if the RF link has been maintained.

**RF Buzzer On Threshold** (0 – 1200, Default = 120): The amount of time during the history that the link must be lost to cause the RF link alarm to sound.

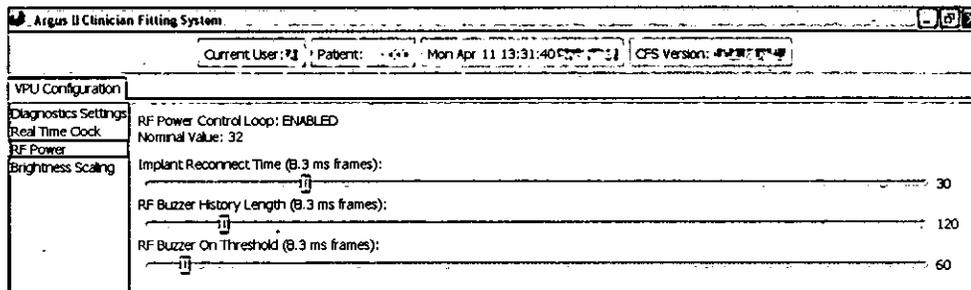
**Note:** The RF Buzzer on Threshold cannot be greater than the RF Buzzer History Length.

If the "RF Buzzer on Threshold" slider is set equal to the "RF Buzzer History Length", the RF link alarm will sound immediately upon loss of link.

Use the following steps to adjust these parameters:

1. Connect the VPU to CFS and switch the VPU on.
2. Start CFS and log in. Click on "Start Session" and enter the patient ID.
3. Click on the "Maintenance" button and select the "RF Power" tab, as shown in Figure 3.17.

**Figure 3.17 Audible RF Link Alarm configuration**



4. Adjust the parameters on the screen accordingly using the sliders.

If the patient would like to set the RF link alarm to be less sensitive to RF link loss, you can increase the "RF Buzzer History Length" and "RF Buzzer On Threshold" (e.g., RF Buzzer History Length = 1200; RF Buzzer on Threshold = 1198).

### 3.9 Fitting Assistant

The Fitting Assistant tool in CFS guides users through the fitting process, employing standard psychophysical techniques to measure the patient's perceptual responses to electrical stimuli, and using the resulting values to produce a patient-specific Video Configuration File (VCF) following standardized rules that are appropriate for most patients. Each of the modules in the Fitting Assistant, described below, has an "Advanced" mode that can be used to create non-standard VCFs in special circumstances. Advanced mode guidance is provided in Section 3.15; situations for which the advanced mode is appropriate are described at the end of this section.

**Note:** For clinical trial protocol testing, Array Scanning and Hybrid Threshold measurement should be done in the advanced mode as they require the inter-phase gap to be 0. If the VCF needs to be created using the protocol testing threshold values, it will be created using the Generate VCF Tool in the advanced mode too.

The Fitting Assistant includes the following modules:

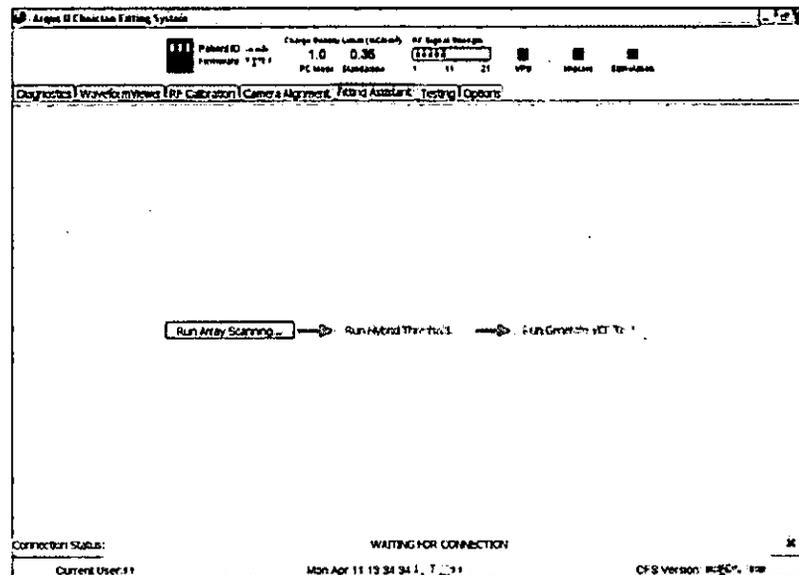
- Array Scanning – determines which electrodes yield a percept.

- Hybrid Threshold – measures the perceptual threshold (the minimum current required to produce a percept) for each electrode that yielded a percept in Array Scanning
- Generate VCF Tool – creates a VCF for the patient based on the electrode thresholds

To run the Fitting Assistant on a patient for the first time:

1. Confirm that the charge density limit (PC Mode) is set to 1.0 mC/cm<sup>2</sup>. If it is not, the threshold measurement and array scanning cannot be completed properly. Contact Second Sight to have someone change this value to 1.0 mC/ cm<sup>2</sup> if needed.
2. Ensure the Logitech® gamepad is connected to CFS and make sure the switch at the bottom of the gamepad is in the "Direct Input" position.
3. Ensure that CFS indicates "WAITING FOR CONNECTION" in the "Testing" tab. Select the "Fitting Assistant" tab.
4. This master screen, as shown in Figure 3.18, indicates the appropriate next step throughout the fitting process. The first step is to run the Array Scanning module.

**Figure 3.18 CFS Fitting Assistant Screen**



### 3.9.1 Array Scanning

Array Scanning determines which electrodes reliably yield percepts at different stimulation amplitudes in order to choose which electrodes should be tested for thresholds in the next step of the process (Hybrid Threshold). Array Scanning stimulates each active electrode up to three times at up to three amplitude levels at 234  $\mu$ A, 452  $\mu$ A, and 677  $\mu$ A. The amplitude levels correspond to charge densities of 0.34, 0.66, and 0.99 mC/cm<sup>2</sup>. If the patient does not detect phosphenes in at least two out of three stimulations at the lowest amplitude, the electrode will be stimulated at the next higher amplitude. Electrodes for which the patient experiences

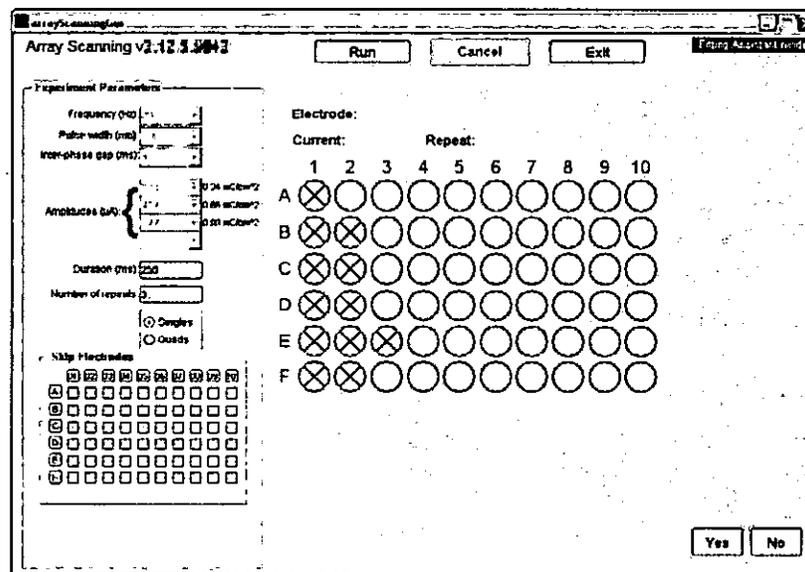
physical sensation or discomfort should be skipped at any time before or during this procedure. The process is self-paced by the patient who enters his or her response for each stimulation. The detailed procedure for Array Scanning is as follows:

1. Ensure that the Argus II Clinician Fitting System Software is running, the "Fitting Assistant" tab is selected, and the screen indicates that Array Scanning is the next appropriate step. Click the "Run Array Scanning..." button.
2. Log in using your username and password and the patient's ID.

In the Graphical User Interface (GUI) that appears (see Figure 3.19 below), the measurement parameters have been set. These values are not editable.

- **Frequency:** 20 Hz
- **Pulse Width:** 0.46 ms
- **Inter-phase gap:** 1 ms
- **Amplitude:** 234  $\mu\text{A}$  (for 0.34 CDL); 452  $\mu\text{A}$  (for 0.66 CDL); 677  $\mu\text{A}$  (for 0.99 CDL); 0
- **Duration:** 250 ms
- **Number of Repeats:** 3

**Figure 3.19 The Array Scanning GUI with the Default Parameters**



3. Choose "Singles" or "Quads" depending on whether you want to run Array Scanning with single electrodes or in groups of four (quad timing). For most patients, "Singles" will be the appropriate setting, however, if the patient has 20 or fewer electrodes yielding percepts up to 677  $\mu\text{A}$  (at 0.46 ms), you can run Array Scanning in quad timing mode. Instead of

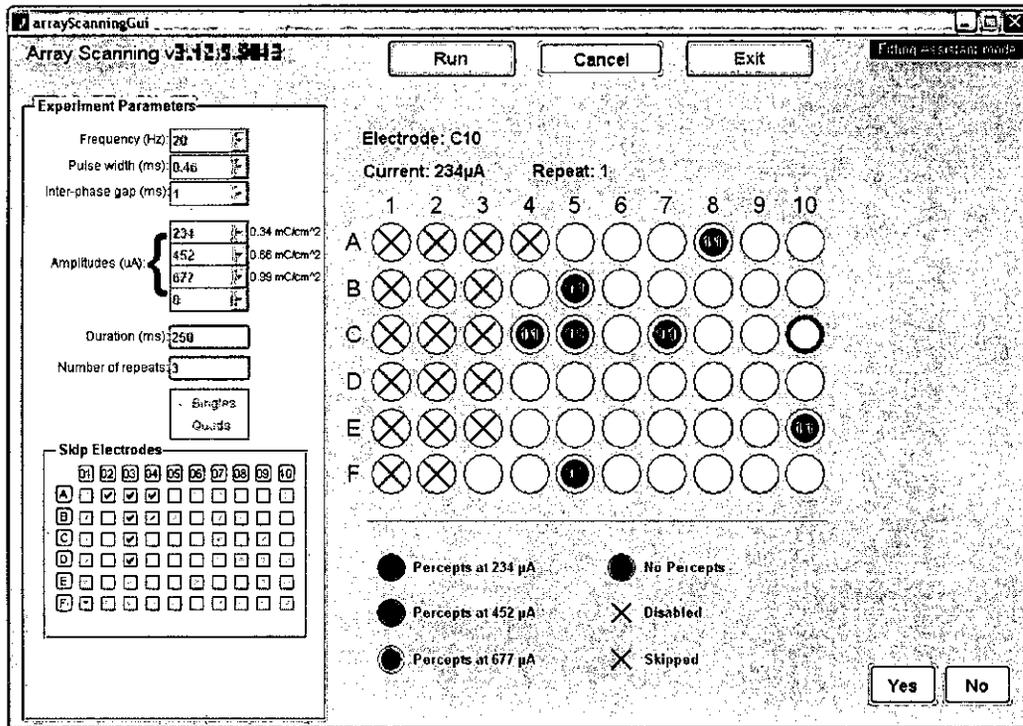
stimulating each electrode individually, a group of four adjacent electrodes (quad) will be stimulated simultaneously. A “quad” is four adjacent electrodes arranged in a 2x2 fashion as (A01, A02, B01, B02), (A03, A04, B03, B04)... (E09, E10, F09, F10). When electrodes are stimulated as a “quad”, it simply means they are stimulated simultaneously as one timing group. The quad is not equivalent to a single large electrode. They are not electrically connected or wired together.

For more information on quad VCF, see “Creating a Video Configuration File (VCF) with the Generate VCF Tool” in section 3.9.3.

4. Use the “Skip Electrodes” checkboxes to select electrodes to be skipped; these electrodes will not be stimulated in the remaining steps of the Fitting Assistant. Only skip electrodes if the patient reports an uncomfortable physical sensation or photophobia when a particular electrode is stimulated. Click on the letter or number boxes to skip entire rows or columns of electrodes.
5. Inform the patient about the measurement with the following suggested script:

“In this measurement, we’re going to be stimulating different electrodes one at a time (or, if running in Quads mode, “a few at a time”). Before each trial you will hear a beep; immediately after the beep, an electrode will be stimulated, and you should press the “yes” button if you saw something and “no” if you didn’t. The next trial will begin shortly after your response. We’ll be testing different electrodes, so you may see spots, lines or flashes in different places on different trials. You should not expect to see something on every trial. This test will take between 5 and 10 minutes.”
6. When the patient is ready, click “Run”. The measurement can be canceled at any time by clicking on the “Cancel” button.
7. A schematic of the array is shown on the GUI in Figure 3.20. Disabled electrodes are denoted by a black “X” in the circle; skipped electrodes are denoted by a grey “X”. Each time an electrode is stimulated, a sound is played, a green circle appears around that electrode in the schematic, and the electrode name appears at the top of the window. After each stimulation, the patient should enter his or her response by pressing the appropriate button for “yes” or “no” on the Logitech® gamepad. The two right buttons located at the top side of the gamepad correspond to “yes” and the two left buttons correspond to “no”. Alternatively, the clinician can enter the “Yes” or “No” buttons on the GUI or the “y” and “n” keys on the keyboard. The next trial will begin immediately after input.
8. If the patient answered “yes”, that electrode will be colored according to the legend (blue, green, or yellow depending on the amplitude) and a ratio will indicate how many ‘yes’ answers were given for that electrode out of the number of stimulations at the current amplitude. Figure 3.20 shows the GUI from a measurement in progress.

Figure 3.20 Array Scanning in Progress

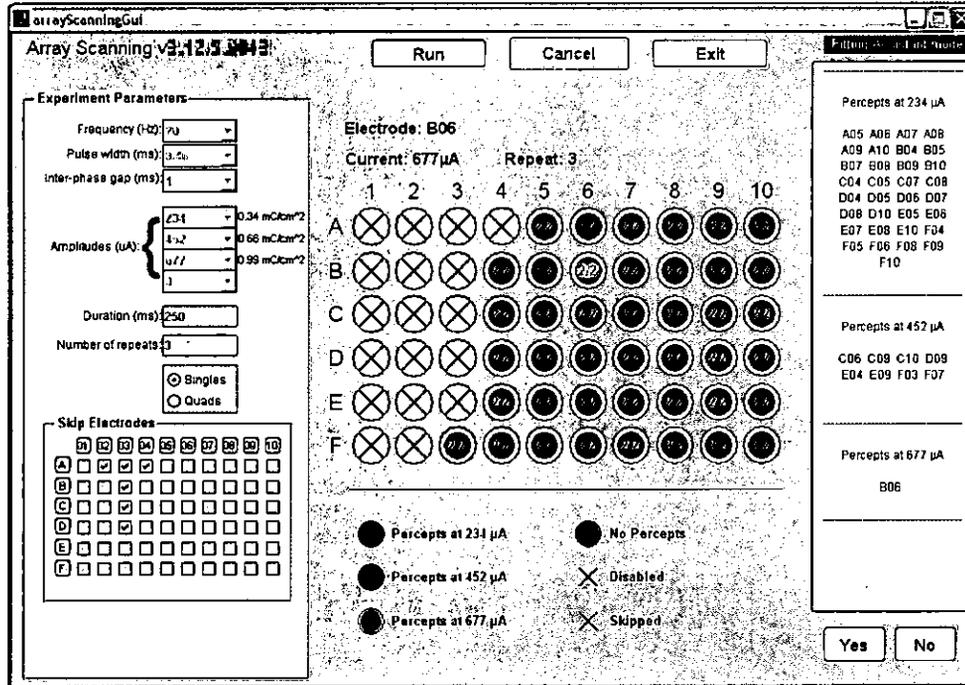


All electrodes that are not disabled or skipped will be stimulated in a random sequence that repeats up to three times at the lowest amplitude (if a percept is seen on an electrode only once after two stimulations, it is stimulated a third time). After the lowest amplitude is completed, the program continues to the next-highest amplitude according to the rules:

- If an electrode yielded a percept twice at the lower amplitude, it is not stimulated again and is color-coded according to the legend.
- If an electrode yielded a percept zero or one times, it is included in the next round of stimulations at higher amplitude. This ensures that electrodes are stimulated only at the lowest level needed to yield a reliable percept.

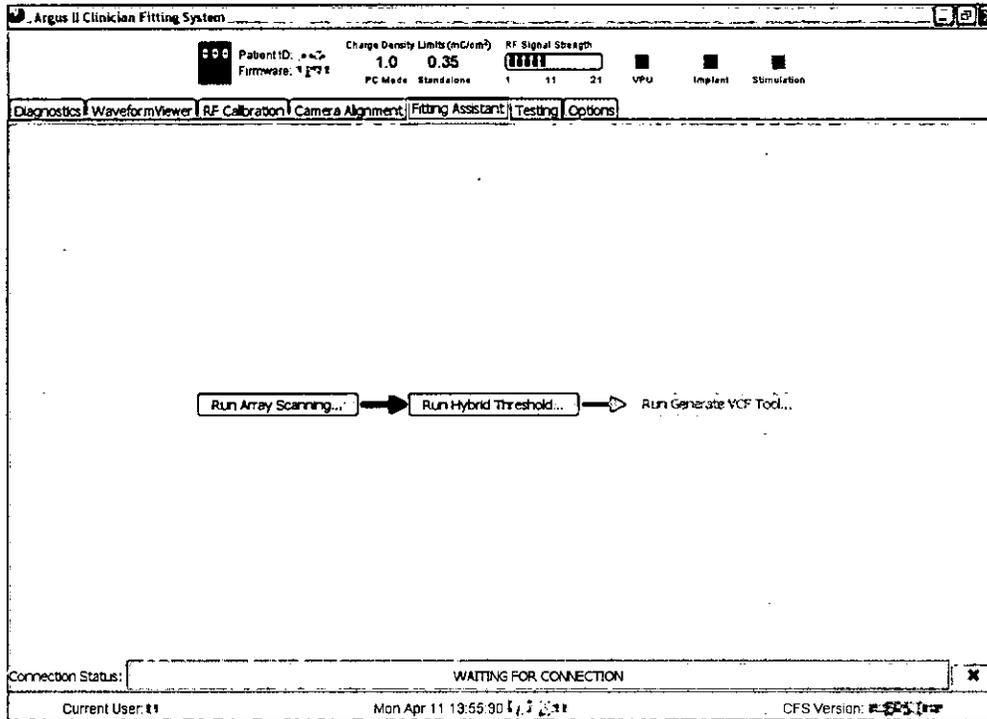
After the final round of stimulations at the highest amplitude, the final GUI is displayed in Figure 3.21. A list of the electrodes with at least two "yes" responses at any of the amplitudes will appear in the **Percepts** list on the right.

Figure 3.21 Final Array Scanning Result



9. If the measurement was canceled early, the list of percepts up to that point will still be reported on the GUI and a screenshot will be saved. However, a full run of Array Scanning is required before continuing to the next step in the Fitting Assistant.
10. Close the final screen by clicking on the red "x" at the top right of the window. The Fitting Assistant window will now indicate that the next step is to measure the threshold for each electrode using the Hybrid Threshold module (Figure 3.22).

**Figure 3.22 Fitting Assistant Window after Completion of Array Scanning**



### 3.9.2 Hybrid Threshold

The Hybrid Threshold program measures the perceptual threshold for electrical stimulation (the current at which the patient sees a percept 50% of the time) of individual electrodes. If the last run of Array Scanning was run in quads mode, Hybrid Threshold will measure the thresholds of groups of four electrodes (quads) stimulated simultaneously. The user selects up to six different single electrodes or quads to test in a single run. The run of six electrodes will take approximately 15 minutes to complete. In each trial, an audio prompt will be followed by stimulation of one of the electrode groups, selected pseudo-randomly out of the six groups, or no stimulation in the case of a catch trial. After the prompt, the patient must respond “yes” on the Logitech® gamepad if he or she saw a phosphene or “no” if he or she did not. Alternatively, the clinician can enter the “Yes” or “No” buttons on the GUI or the “y” and “n” keys on the keyboard.

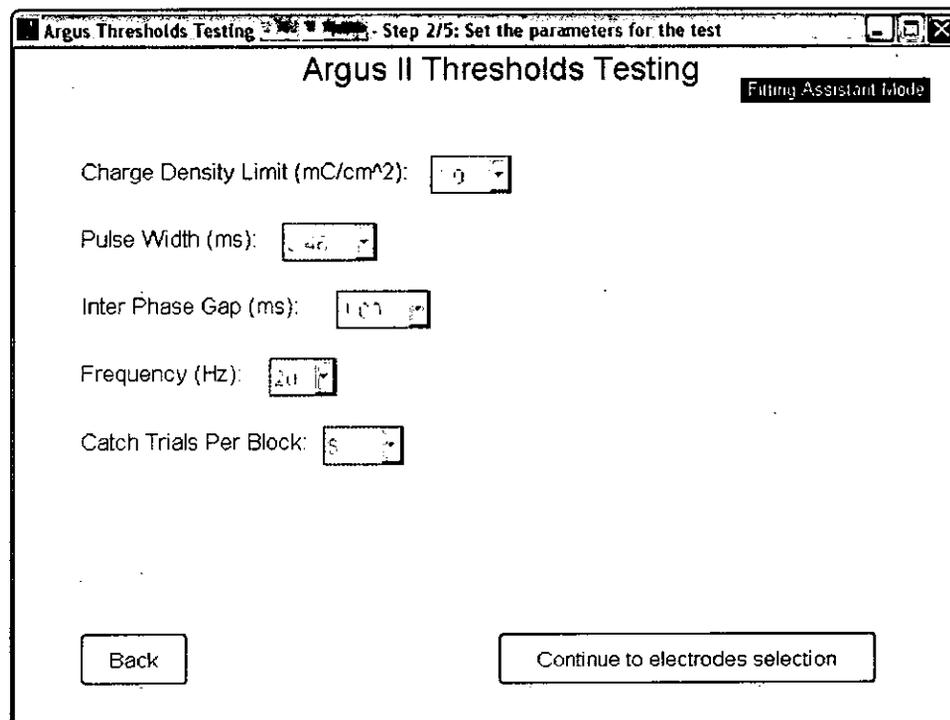
The trials are divided into blocks – up to five blocks of 12 trials are completed for each electrode group. After the first block, a maximum likelihood algorithm determines the range of the next block of stimulation amplitude values for each electrode group, based on all previous responses. If the confidence interval of the estimated threshold of an electrode group is narrowed to a pre-set level, trials for that electrode will terminate, but trials on the other electrodes will continue through a maximum of five blocks.

Most patients will need multiple runs of Hybrid Threshold to complete all measurements necessary to create a customized VCF (thresholds are measured for each electrode that resulted in a percept during the Array Scanning run). Each time Hybrid Threshold is run from the Fitting Assistant, the threshold values are saved; the Fitting Assistant screen will indicate when all electrodes have been measured.

Detailed Procedure:

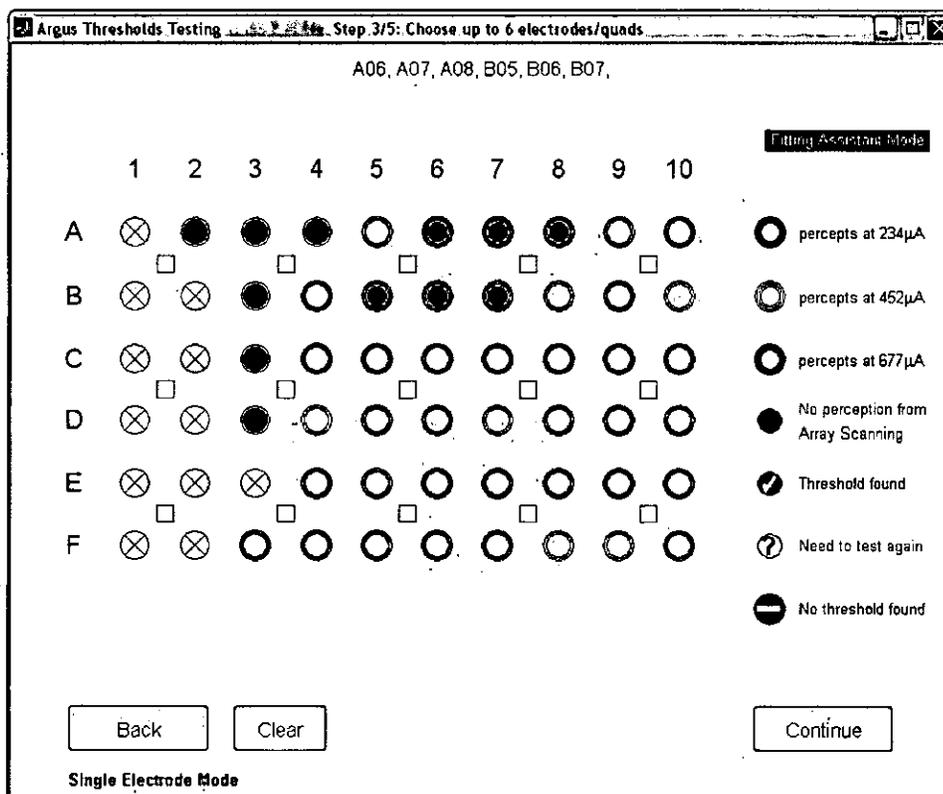
1. Confirm that the charge density limit (PC Mode) is set to 1.0 mC/cm<sup>2</sup>. If it is not, the threshold measurement cannot be completed properly. Contact Second Sight to have someone change this value to 1.0 mC/ cm<sup>2</sup> if needed.
2. Click the "Run Hybrid Threshold" button in the Fitting Assistant screen. Log in when prompted.
3. Stimulation parameters are indicated on the GUI, as shown in Figure 3.23.
  - **Charge density limit:** 1.0 mC/cm<sup>2</sup>
  - **Pulse width:** 0.46 ms
  - **Inter-phase gap:** 1.00 ms
  - **Frequency:** 20 Hz
  - **Catch trials per block:** 8

Figure 3.23 Hybrid Threshold Parameter Display GUI



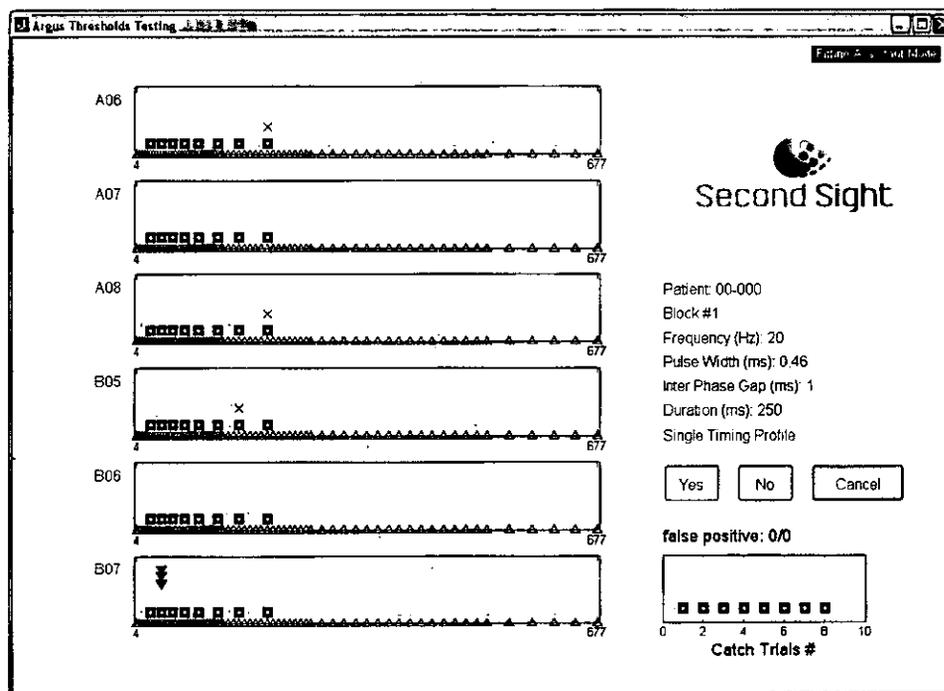
4. Click the button "Continue to electrodes selection" to continue.
5. In this GUI, electrode mode (singles or quads) is indicated and electrodes are color-coded to indicate at which current level a percept was reported in Array Scanning.
6. Choose up to six electrodes (or quads in Quad mode) to test in this run from the Electrode Selection GUI as shown in Figure 3.24. Any electrodes that have been disabled by the VPU are marked with an X; these are not selectable. Select individual electrodes by clicking in the corresponding circles. If this run is in Quads mode (indicated on the bottom left of the GUI), click in the squares between the four electrodes to select quads.
7. Choose the electrodes for the run according to the results of Array Scanning; wherever possible, choose electrodes that had percepts in the same current level (indicated with color coding) for the same run of Hybrid Threshold. Selected electrodes are highlighted in blue, and selected quads are highlighted with green lines. The names of selected electrodes/quads are also displayed in a list at the top of the window. Deselect any electrode or quad by re-clicking the circle or square. After selecting the electrodes, click on the "Continue" button to move to the next step.

**Figure 3.24 Electrode Selection GUI**



8. Set the maximum current for each electrode if necessary (this is not common; exceptions are discussed at the end of this section). Click "Continue" to move to the next step.
9. Ensure that the electrodes and parameters for the run are correct as displayed on the confirmation screen. Ensure that the Logitech® gamepad is connected and that the patient is ready to begin. Inform the patient that stimulation will start. Click "Start Block #1" to begin the measurement. Instruct the patient using the script for Array Scanning.
10. The main measurement GUI (Figure 3.25) displays a graph for each electrode, a separate graph for catch trials, and "Yes", "No", and "Cancel" buttons. Blue squares indicate individual trials; their x-axis position indicates the amplitude of the trial (except for catch trials, which have no amplitude).

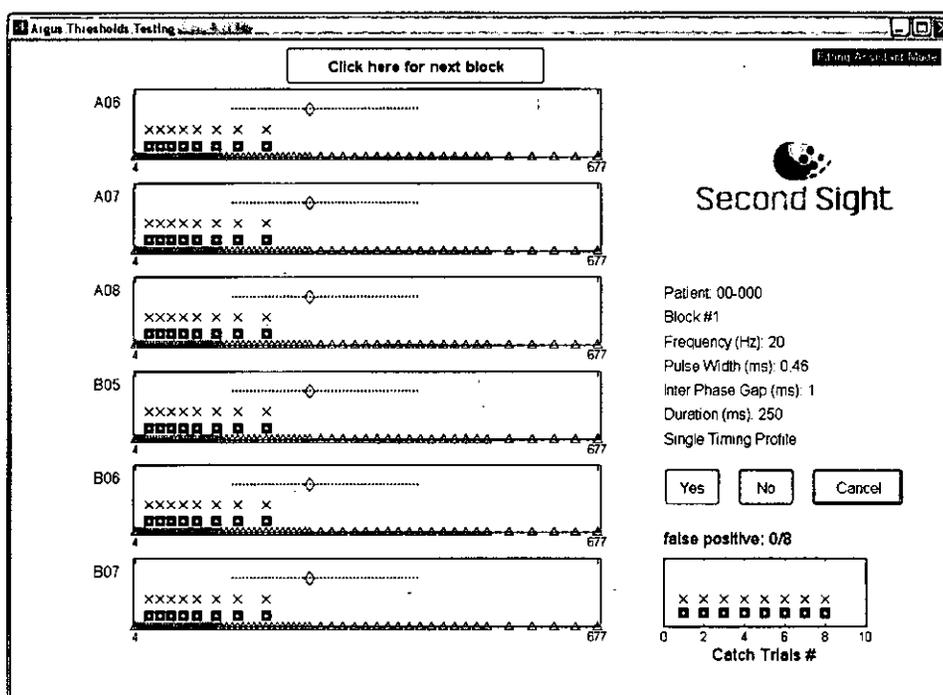
**Figure 3.25 Main Hybrid Threshold GUI**



11. In each trial, after an audio prompt, a single electrode or quad is stimulated and the patient must report whether he/she saw something. The order in which the electrodes are tested (stimulated) is random. The amplitude and electrode/quad stimulated on each trial are indicated by a black arrow pointing to the particular trial square.
12. In most blocks there are also catch trials. A catch trial is a trial in which the amplitude is zero but the audio prompt is still produced. Catch trials are used to estimate the false positive rate of the responses. The patient should NOT be informed that there are catch trials but they should know they might not see a phosphene in every trial.

13. After each trial, the patient should indicate his or her response by clicking the appropriate button on the Logitech® gamepad. Alternatively, the clinician can enter the “Yes” or “No” buttons on the GUI or the “y” and “n” keys on the keyboard. A blue circle will appear above the trial box if the response was “yes”, or a blue “x” will appear if the response was “no”.
14. When all the trials have been completed for the block, the program will pause to compute the trials for the next block. At this point, it will display a window showing the block results (Figure 3.26). On each plot, a blue diamond indicates the amplitude of the current threshold estimate for that electrode/quad, as well as the computed range for the next block (dotted line). To advance to the next block, click the button “Click here for next block.”

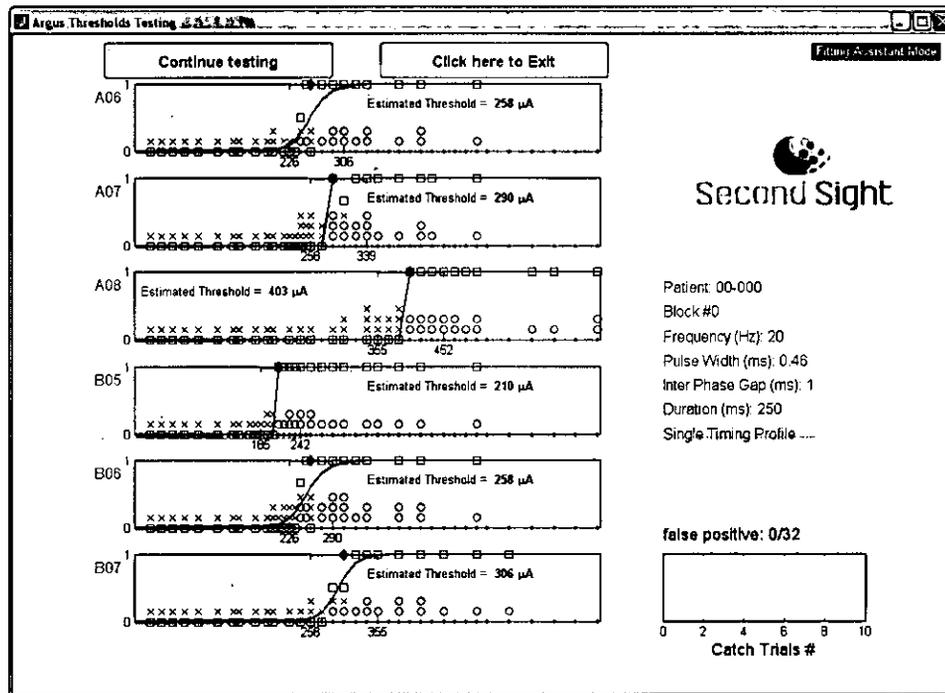
**Figure 3.26 Block Results GUI**



15. The measurement will continue through a maximum of five blocks; the measurements on some electrodes may terminate early (before block #5), if the confidence level of the threshold is relatively narrow.
16. If the number of false positives is high, a warning will pop up between blocks. More than 6 false positives in a run indicate unreliable results; if the patient exceeds this level during testing, the run should be canceled. Do not instruct a patient to change his or her criteria during the run; in between runs, the patient can be instructed to only press “yes” if he or she saw a percept that was well-synchronized to the auditory prompt, and/or to only press “yes” if they were sure there was a percept. If frequent false positives become a problem, contact Second Sight for alternative measurement strategies.

17. At the end of the run, a final GUI (Figure 3.27) displays the results for each electrode/quad, including the individual trial results, the psychometric curve for the threshold estimate, and the probability of each amplitude being seen (black squares). To continue measuring threshold for other electrodes or to re-measure thresholds, click "Continue testing." To close the program, click "Click here to Exit."

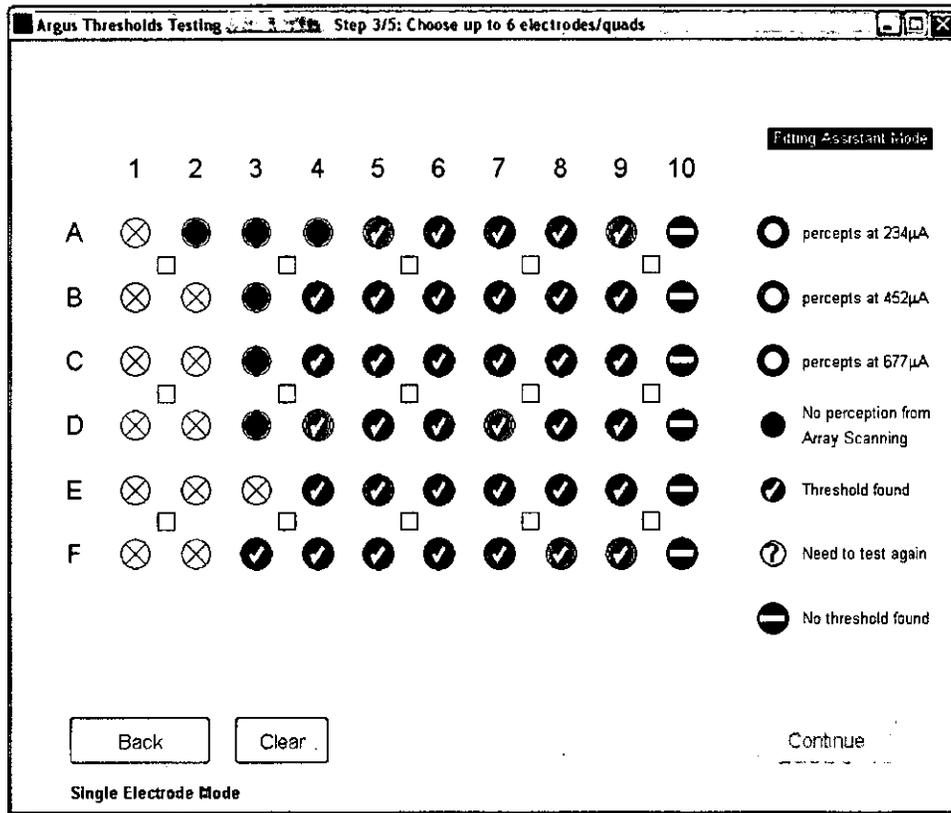
Figure 3.27 Final Results GUI



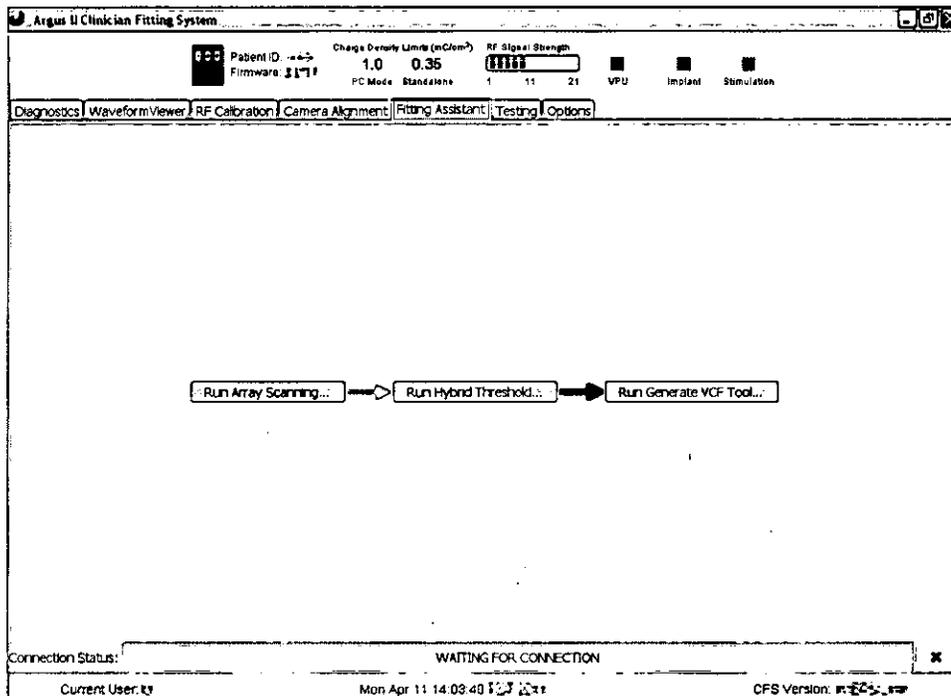
Continue to run Hybrid Threshold until all electrodes with percept at Array Scanning are measured. Once all electrodes have been measured, Hybrid Threshold pops up a window informing you that you are ready for Generate VCF Tool. If you click "Continue testing", as shown in Figure 3.27, then the electrode selection GUI will have check box for all functional electrodes or the symbol for "no threshold found" (Figure 3.28). If you choose "Click here to Exit", the software will return to the Fitting Assistant main screen which now indicates the next appropriate step "Run Generate VCF Tool", as shown in Figure 3.29.

It is not necessary to measure all electrodes in a single session with the patient; it is typical for this process to span multiple sessions. If the patient becomes tired, or if you run out of time in the clinic session, close all windows and quit CFS. The next time you log on to CFS and select the Fitting Assistant tab, the main screen will indicate that Hybrid Threshold is the appropriate step. Your results from the last session will be saved, and you can continue to measure thresholds on the remaining electrodes.

**Figure 3.28 Final Hybrid Threshold Result**



**Figure 3.29 Fitting Assistant Window after Completion of Hybrid Threshold**



### 3.9.3 Creating a Video Configuration File (VCF) with the Generate VCF Tool

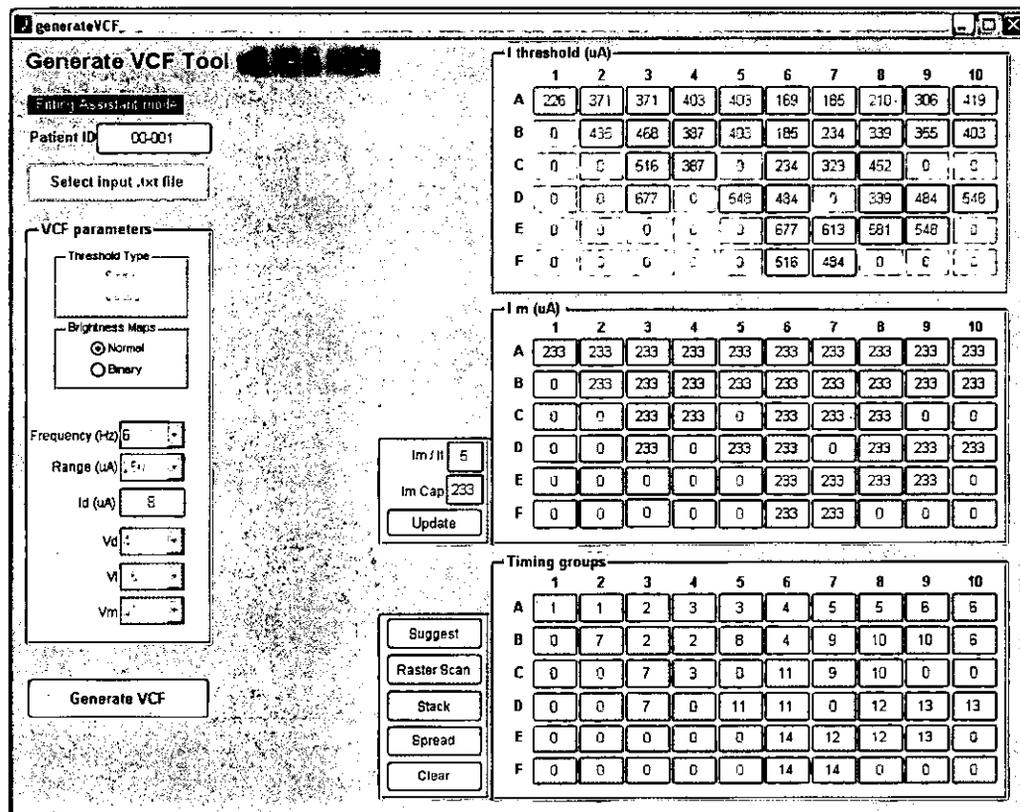
The Video Configuration File contains the information needed for the Argus II System to stimulate the patient's array according to real-time information gathered by the video camera on the glasses. It defines how the video signal is mapped to the electrical signal for individual or groups of electrodes. Each VCF is customized for the patient using the information gathered during the previous steps in the fitting process (Array Scanning and Hybrid Threshold).

Generate VCF Tool creates a VCF for the patient according to a set of rules that are appropriate for most Argus II patients. For strategies to use in off-nominal circumstances, see the end of this section.

#### Starting the Generate VCF Tool

- In the Fitting Assistant, click on the "Run Generate VCF Tool..." button, as shown in Figure 3.29. Enter the user name, password and patient ID. If the "Run Generate VCF Tool..." button is not highlighted, it means the previous steps in the fitting process (Array Scanning or Hybrid Threshold) are not completed and will need to be completed before proceeding with the Generate VCF Tool.
- The Generate VCF Tool GUI (Figure 3.30) will open, and the results from prior steps in the fitting process will automatically be loaded.

Figure 3.30 Generate VCF Tool GUI



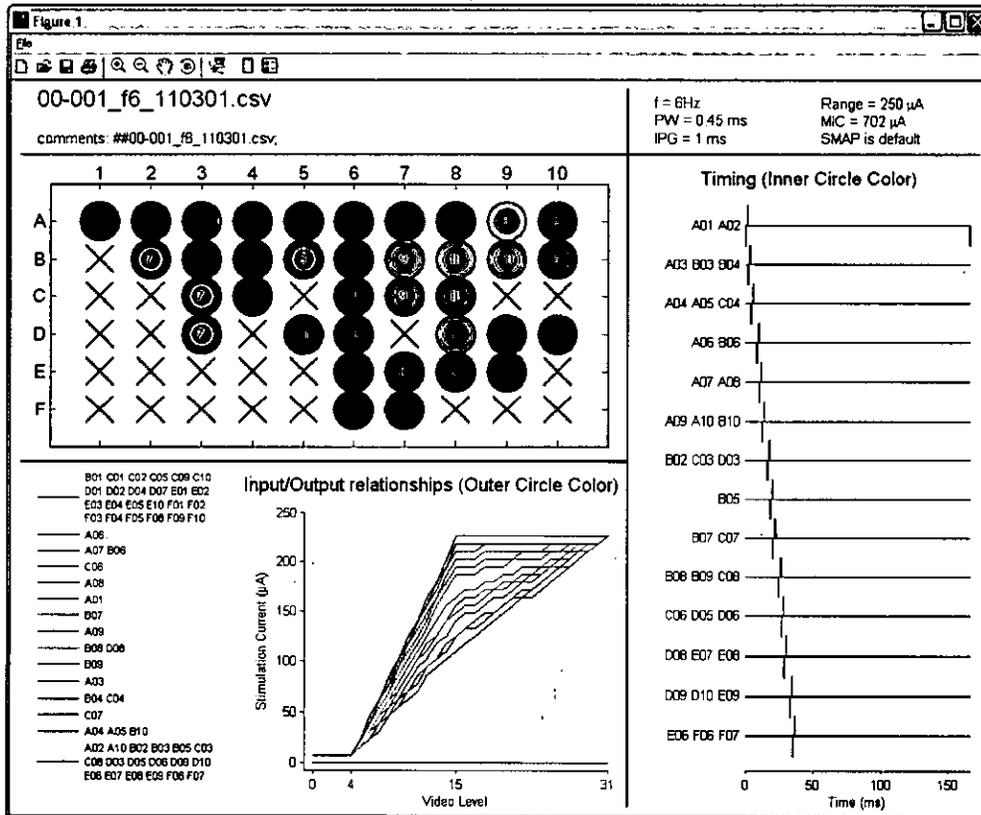
All parameters are set to the suggested values according to the standardized rules for creating VCFs. Many of these cannot be modified in the Fitting Assistant; see Section 3.15 for details on these parameters and how to use the advanced mode.

### Creating a new VCF

1. To create a VCF for the patient using all default settings, ensure that the Argus II Video Settings Drive is plugged in and that it contains a folder with the current patient's ID. The folder will automatically be created if it does not exist. Click the "Generate VCF" button. You will be prompted to save the VCF and provided with a default filename consisting of the patient ID, the frequency, and a date stamp in the form of 'yymmdd'.
2. Click "Save" to create a VCF in the video settings drive folder. Once created, you will be prompted to check the VCF for comfort using the VCF Stepper (see Section 3.10.1).

A figure summarizing the VCF will be generated (Figure 3.31). A copy of this figure will be saved on the video settings drive. (.emf format file).

Figure 3.31 VCF Summary Plot



## **Changing the VCF Parameters**

The default parameters should be appropriate for most patients. In some cases, however, adjusting various parameters may improve the performance and comfort of a VCF. An overview of the parameters that can be changed is provided below, followed by a list of ways to address various VCF related issues. To follow an alternative fitting strategy from the beginning of the Fitting Assistant, please see Section 3.9.5.

- **Binary/Normal VCF**

The shape of the function that defines the relationship between the brightness levels of the video input and amplitude of stimulation current can take two forms, "Normal" and "Binary". Binary VCFs are used in conjunction with special filter settings to provide improved edge detection. While normal VCFs provide a gradual dynamic range for brightness, binary VCFs provide only two brightness levels, so stimulation is either off (in darkness) or on at a chosen level of brightness. To create a binary VCF for Program Setting #3, click the "Binary" radio button before clicking the "Generate VCF" button. Leave all other parameters on their default values.

- **Different Frequencies**

This parameter is defined as the number of stimulation pulses sent to each electrode per second. It is a global parameter that applies to all electrodes. The larger the number of timing groups, the lower the frequency value. The default stimulation frequency is 6Hz. Other possible frequencies can be selected using the "Frequency" pull-down menu in **VCF Parameters**. In general, lower frequencies allow for more timing groups but create dimmer perception, while higher frequencies create brighter perception with reduced number of timing groups.

- **Changing the Maximum Stimulation Current  $I_m$  Cap**

The default maximum stimulation current is 233  $\mu$ A. This is the maximum allowable stimulation current for the pulse width used in the VCF (0.454 ms). Adjustment / reduction in the maximum stimulation current can be made to address VCFs that have excessive brightness or discomfort.

The maximum stimulation current can be lowered globally for the entire array or individually for selected electrodes. To lower the value globally, type the desired value into the  $I_m$  Cap text box and press "Update". The  $I_m$  table will update to the new values.

- **Changing the Ratio  $I_m/I_t$**

Additionally, you can adjust the ratio between the maximum stimulation current and the threshold stimulation current,  $I_m/I_t$ . The default value is 5, so for electrodes with a threshold of 20  $\mu$ A, the default  $I_m$  is 100  $\mu$ A. For example, if you change  $I_m/I_t$  to 7 and

click "Update", the  $I_m$  table will update its values for all electrodes to 7 times the threshold value or  $I_m \text{ Cap}$ , whichever is lower.

- **Changing the Maximum Current  $I_m$**

$I_m$  values in the table are maximum stimulation currents for each individual electrode. The values in this table are automatically populated based on the values in the threshold table, the  $I_m/I_t$  ratio, and the  $I_m \text{ Cap}$  value. The value in this table must be less than or equal to  $I_m \text{ Cap}$ . You can adjust the maximum current for individual electrodes by entering values into the  $I_m$  table. If you attempt to enter values above  $I_m \text{ Cap}$ , you will be prompted with a warning to adjust the values to appropriate levels.

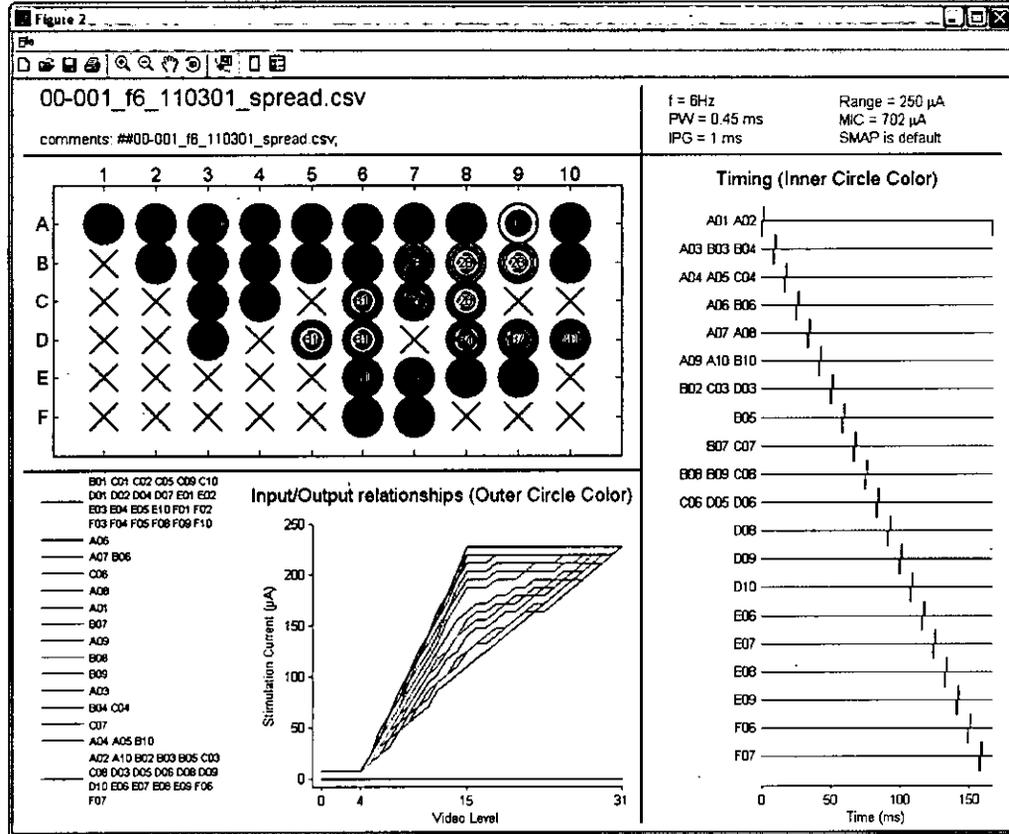
- **Changing the Timing Groups**

The timing groups define the temporal (time domain) stimulation pattern to which each electrode is assigned. The default pattern suggested by the software should be suitable for most VCFs. For VCFs with excessive brightness or discomfort, the timing groups can be adjusted to lessen the issues by dividing the larger timing groups into smaller groups and/or lowering the frequency of the VCF.

- The "Suggest" button populates the timing group table with suggested timing groups.
- The "Clear" button clears the table allowing manual entry into the table for the most flexibility.
- With values in the table, the "Raster Scan" button will rearrange the sequence of the timing groups to approximate a raster scanning pattern.
- The "Stack" button will eliminate any gaps in the sequence of timing groups, leaving a gap at the end of each stimulation cycle. This is likely to increase brightness of the VCF (by increasing current summation). By default, the Generate VCF Tool suggests the stack timing group pattern.
- The "Spread" button will maximally space out the timing groups over the time allotted by the desired frequency and create gaps in time between different timing groups. This is likely to decrease the brightness of the VCF (by reducing current summation).

An example of the modified "Spread" timing group table is shown in Figure 3.32.

Figure 3.32 VCF Summary Figure with the “Spread” Timing Groups



### 3.9.4 Notes on the Fitting Assistant

The Fitting Assistant is intended to guide the user through the entire fitting process, saving and loading the relevant data throughout. The Fitting Assistant will not allow you to advance until the data from a previous step are complete, but it will allow you to re-run a module multiple times. The specific flow control for each module is described below.

#### Array Scanning

Array Scanning can be run at any time; however, the Fitting Assistant always uses data from the most recent Array Scanning test. For example, suppose you run Array Scanning in single electrode mode and begin a run or two of Hybrid Threshold with those data. Then, before you finish all the runs of Hybrid Threshold and create a VCF, you re-start Array Scanning, this time measuring quads. Now when you next launch Hybrid Threshold, it will use the data from the quads run of Array Scanning (as this was the most recent), and begin measuring thresholds on quads. Therefore, you should complete the fitting process all the way through creating the VCF before re-starting Array Scanning unless you intend to overwrite the data.

## Hybrid Threshold

You can run Hybrid Threshold anytime after an Array Scanning run is completed. If you run Hybrid Threshold and re-measure thresholds on electrodes, the old data will be overwritten and the new data used in the Generate VCF Tool, so it is not recommended unless you have doubts about the previous measurements (for example, if a patient was tired or inattentive when their thresholds were measured).

## Generate VCF Tool

You can create more than one VCF using the same fitting data – the Fitting Assistant will allow you to launch Generate VCF Tool any time when there is a complete set of data currently saved. You can create several VCFs with different parameters without starting a new Fitting Assistant run. This is useful when you want to create both a Normal and Binary VCF for the same patient based on the same threshold values; similarly, if a particular VCF is too dim, too bright, or has other problems, you can re-run Generate VCF Tool using the same data but adjusting different parameters to create a new VCF.

### 3.9.5 Following Alternative Fitting Strategies

The Fitting Assistant tool will let you create customized VCFs that should be appropriate for most Argus II patients. However, all modules of the Fitting Assistant can be run in advanced mode, in which the user has more freedom to alter parameters and create non-standard VCFs. Details of how to use advanced modes are given in Section 3.15. As these programs can be quite complex, please contact Second Sight if you believe your patient requires non-standard VCFs created with the programs in advanced mode.

There are a few off-nominal circumstances that can be addressed in Fitting Assistant Mode:

- **Skipping electrodes or setting a lower maximum amplitude (in Array Scanning and Hybrid Threshold)**

Occasionally, a patient may report an uncomfortable physical sensation when an electrode is stimulated, or may report that the electrode produces percepts that are too bright. If the patient is uncomfortable with stimulation on a particular electrode during Array Scanning, select its checkbox in the “Skip Electrodes” section of the GUI. Any electrodes selected to be skipped here will be inactivated throughout the entire Fitting Assistant process.

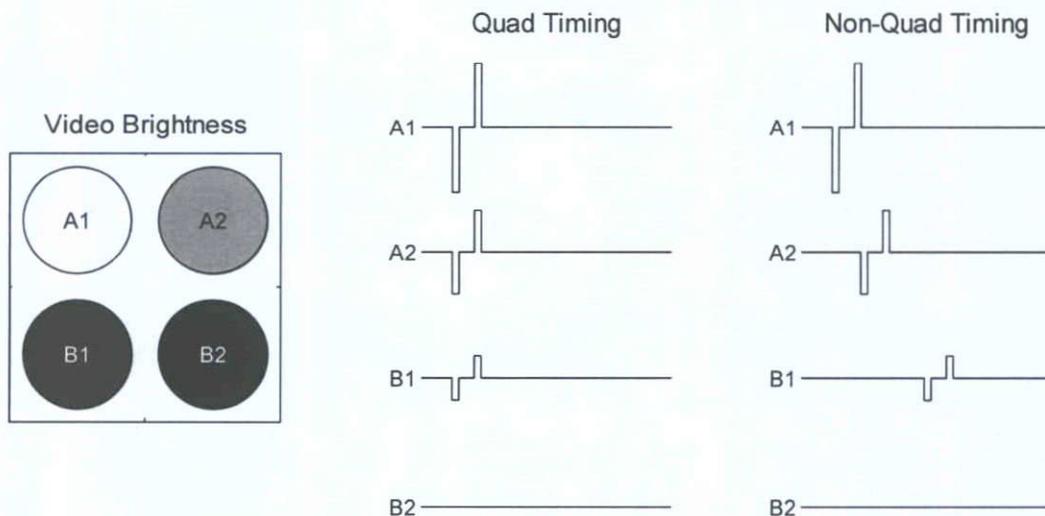
If the patient experiences discomfort on certain electrodes at certain stimulation levels, you can set the maximum current for individual electrodes in Hybrid Threshold. Choose a value at which stimulation is comfortable for the patient.

- **Quad VCFs**

Normally, VCFs are created using single electrode threshold data. However, if you have run Array Scanning and 20 or fewer electrodes yielded percepts up to 677  $\mu\text{A}$ , you can run Array Scanning in quad mode. Although stimulating a single electrode at an amplitude below its threshold would generally not result in a phosphene, stimulating multiple nearby electrodes simultaneously at amplitudes below their single-electrode thresholds may elicit phosphenes due to current summation. Restart Array Scanning and select "Quads." Array Scanning will proceed to measure the percepts on 15 quads. Hybrid Threshold will then measure the thresholds on those quads in which a percept was reported. Generate VCF Tool will then follow a quad-fitting strategy to produce a VCF. In the quad VCF, 2x2 "quads" of electrodes are placed in the same timing groups. In doing so, this may allow you to include more useful electrodes in the VCF from the less-sensitive regions of the electrode array. That is likely to be more useful to the patient than the one created using single electrode data.

A "quad VCF" really means a "quad timing" VCF. When electrodes are stimulated as a "quad", it simply means they are stimulated simultaneously as one timing group. The amplitude of stimulation for each electrode in the quad is governed by each electrode's corresponding video brightness, as shown in Figure 3.33. In a "standard" (or non-quad VCF), these electrodes could be in four different timing groups as indicated in the same figure. The amplitude of the pulses for a particular electrode is not different between the quad and non-quad scenarios, as can be seen in the timing illustrations.

**Figure 3.33 Quad and Non-Quad Stimulation**



### 3.9.6 VCF Troubleshooting

- Case #1: The VCF is too dim
  - Increase the frequency gradually, and create a new VCF
  - Generate a VCF with stacked timing groups
  - Increase  $I_m / I_t$
  - Use VCF Stepper to ensure the new VCF is not too bright or cause discomfort
- Case #2: The VCF is too bright
  - Lower the global maximum stimulation current ( $I_m$  Cap) and generate a new VCF
  - Generate a VCF with spread timing groups
  - Split electrodes that are in the same timing group into multiple timing groups
  - Lower  $I_m / I_t$
  - Lower the frequency
- Case #3: Individual electrodes are too bright or are causing discomfort
  - Lower the individual  $I_m$  on electrodes causing the problem or set  $I_m$  to 0 to disable the electrode completely.
  - Separate those electrodes from other electrodes in the same timing group by assigning new timing groups to these electrodes
- Case #4: The patient has  $\leq 20$  measurable single electrode thresholds under 677  $\mu\text{A}$ 
  - Run Array Scanning and Hybrid Threshold measurement using the Quad configuration.
  - Create a VCF with quad timing groups. Run VCF Stepper to ensure the Quad VCF does not cause any discomfort.

## 3.10 Video Stimulation

### 3.10.1 Testing a VCF using VCF Stepper

VCF Stepper is a compiled program installed on the Argus II Clinician Fitting System computer. It allows the clinician to evaluate the overall brightness and potential discomfort of a VCF prior

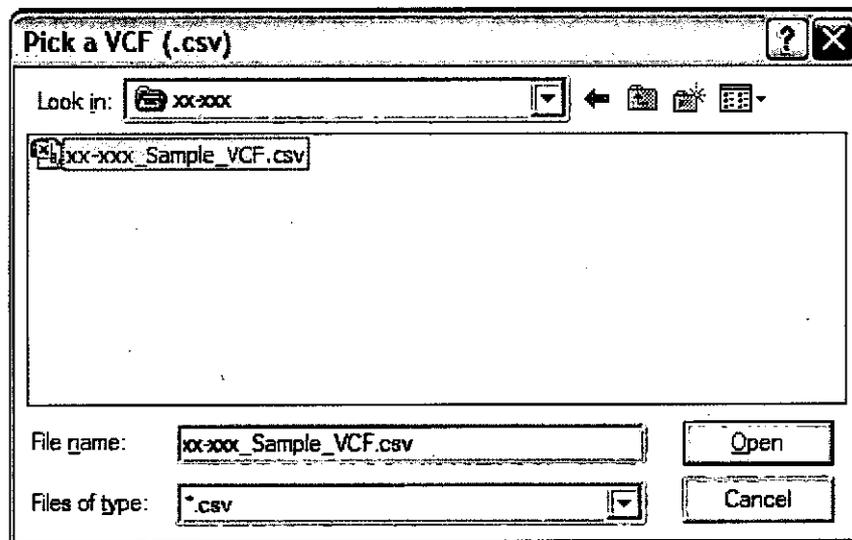
to loading the VCF onto the video processing unit (VPU). The patient can give verbal feedback regarding whether he or she perceives phosphenes, the relative brightness of phosphenes, and any physical sensation or discomfort at various video levels to allow the clinician to determine if the VCF is suitable for normal use.

The VCF Stepper stimulates all the electrodes with the stimulation parameters defined in the selected VCF. It takes a video image with a uniform brightness and the user can control the brightness level. Each electrode will be stimulated at the current level that matches the brightness level as set by the VCF.

The procedures are:

1. Ensure that the "Testing" tab is selected in Argus II Clinician Fitting System Software, and the software indicates "WAITING FOR CONNECTION".
2. Open "Argus II VCF Stepper" by clicking the icon in the start menu.
3. Log in using your username and password and the patient ID.
4. In the pop-up window, navigate to the patient ID directory on the Video Settings Drive: VideoSettingsDrive:\settings\patientID and select the VCF to be tested.

**Figure 3.34 Pop-up Window for VCF Selection**

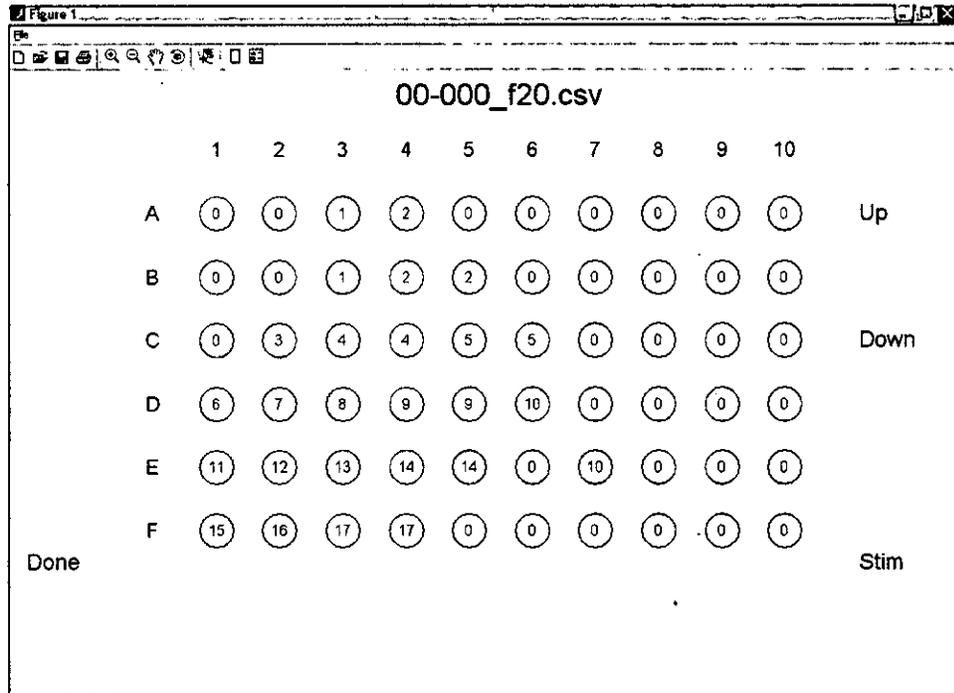


The user interface pops up with a schematic of the array, as shown in Figure 3.35. Each electrode is labeled with a number indicating the timing group of the electrode; once you increase the video level, the numbers indicate the current amplitude (in  $\mu\text{A}$ ) at which each electrode will be stimulated, as shown in Figure 3.36. The "Up", "Down", "Stim", and "Done" labels are as buttons when they are clicked.

- "Up": increases the video level (range from 0 to 31)

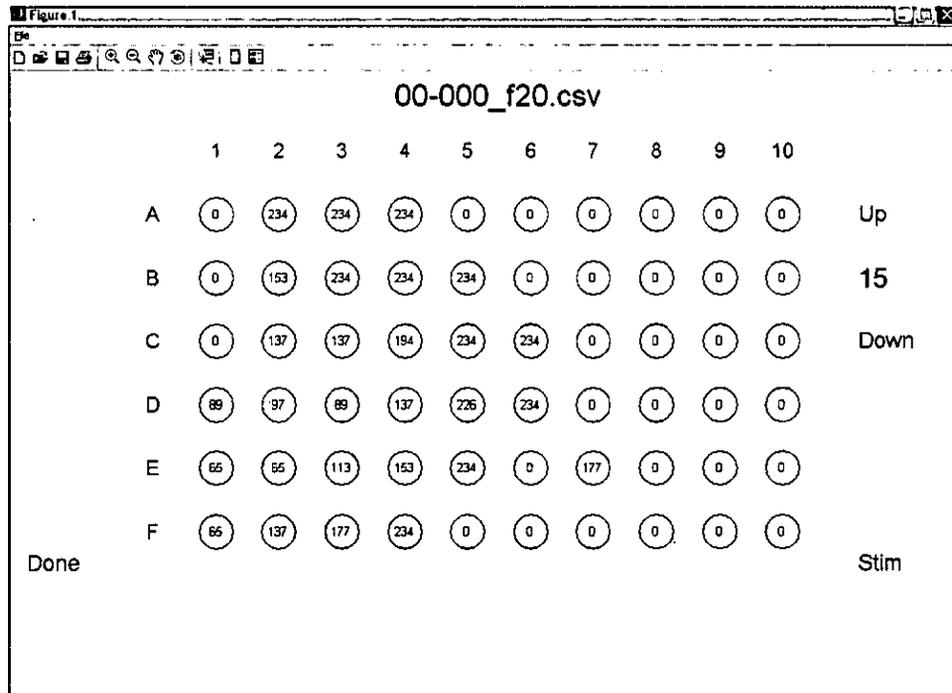
- “Down”: decreases the video level (range from 0 to 31)
- “Stim”: initiates stimulation
- “Done”: ends the procedure

**Figure 3.35 Initial user Interface Showing Timing Groups of all Electrodes**



5. Increase the video level to 10 and tell the patient that you will be stimulating the array. Press “Stim”; all electrodes in the VCF will be stimulated together for 2 seconds using the timing groups defined in the VCF. Obtain feedback from the patient regarding brightness and comfort level of the phosphene. Increase the video level and repeat this process until you either reach the maximum video level 31 or the patient reports discomfort or excessively bright stimulation.
6. If you reach level 31 and the patient reports that there is no discomfort and the phosphene seems comfortably bright, the VCF is appropriate to use. Load the VCF to the patient’s VPU (see Section 3.10.2). If the VCF is uncomfortable or too bright (or too dim), refer to the previous section to modify the VCF. Repeat the VCF Stepper procedure with the new VCF until a VCF suitable for home use has been created.
7. Click “Done” to complete the VCF Stepper procedure.

**Figure 3.36 User Interface Showing Stimulation Amplitudes in  $\mu\text{A}$  for Video Level 15**



### 3.10.2 Loading a VCF onto the VPU

Now that the VCF is created and tested, it can be loaded onto the VPU using the following procedure:

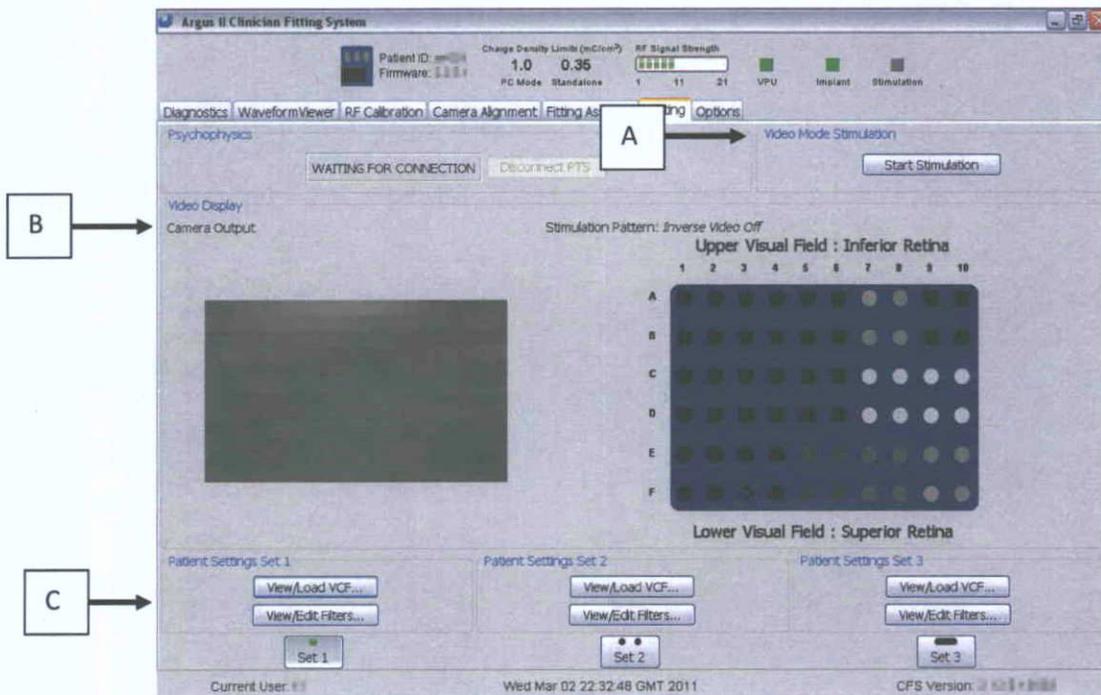
1. Click on the "Testing" tab in CFS. The "Testing" screen, shown in Figure 3.37, consists of three sub-sections related to video stimulation:
  - A. **Video Mode Stimulation** (to turn on/off the stimulation)
  - B. **Video Display**
  - C. **Patient Settings** (VCF + Filter Settings)

**Note:** The **Patient Settings** in Figure 3.37 is also referred to as **Program Settings** throughout the manual.

The **Video Display** section has two images. The image on the left represents the camera output, which has 20 x 12 pixels. The image on the right has 10 x 6 pixels and represents the filtered image sent to the electrode array. The **Inverse Video Off or On** status is also displayed.

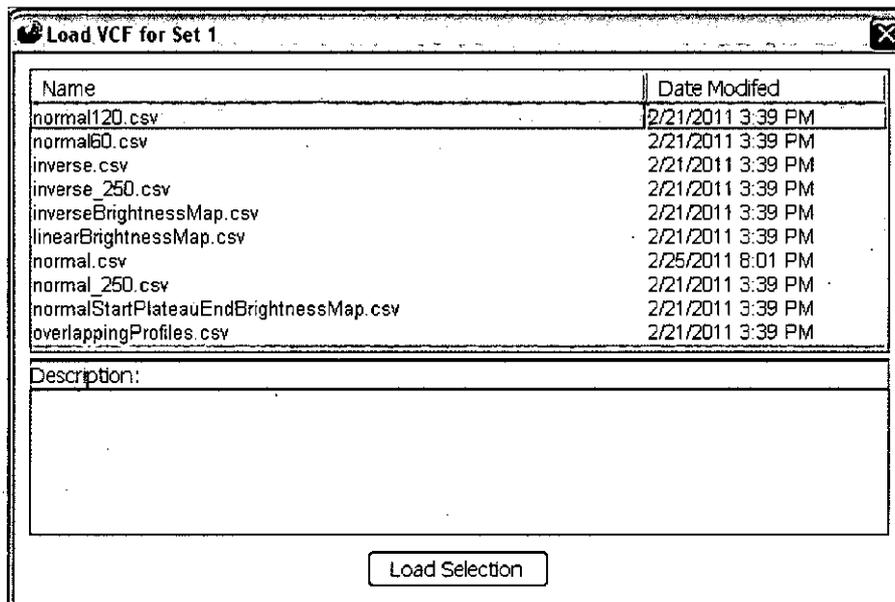
The **Patient Settings** section allows you to configure, load on to the VPU, and switch between three program settings. Each program setting is a combination of a VCF and a set of filter parameters.

**Figure 3.37 The Video Screen**



2. To load a video configuration file to the VPU for a particular Program Setting, connect the USB thumb drive labeled **Argus II USB Drive, Video Settings** to an empty USB port on the CFS computer.
3. Click the “View/Load VCF” button for the desired setting. Information about the currently-loaded VCF, including its name, when it was loaded, and a description, will be displayed.
4. Press the “Load new VCF...” button. A list of video configuration files contained in this patient’s folder within the “settings” folder on the thumb drive will be displayed, as shown in Figure 3.38.

**Figure 3.38 Load VCF Screen**



5. Clicking on a file in the list will display a description of that selected file in the description box provided that the description was included as part of the video configuration file.
6. When the desired video configuration file is located, click on "Load Selection" to transfer the selected VCF to the VPU. The file name, load date and time along with a brief description will be displayed in the **Video configuration** section on the Video Screen.

**Note:** The CFS will not allow any file that does not meet the necessary stimulation safety requirements to be downloaded to the VPU.

7. To configure the filter parameters for the program setting, click the "View/Edit Filters..." button, as shown in Figure 3.37.

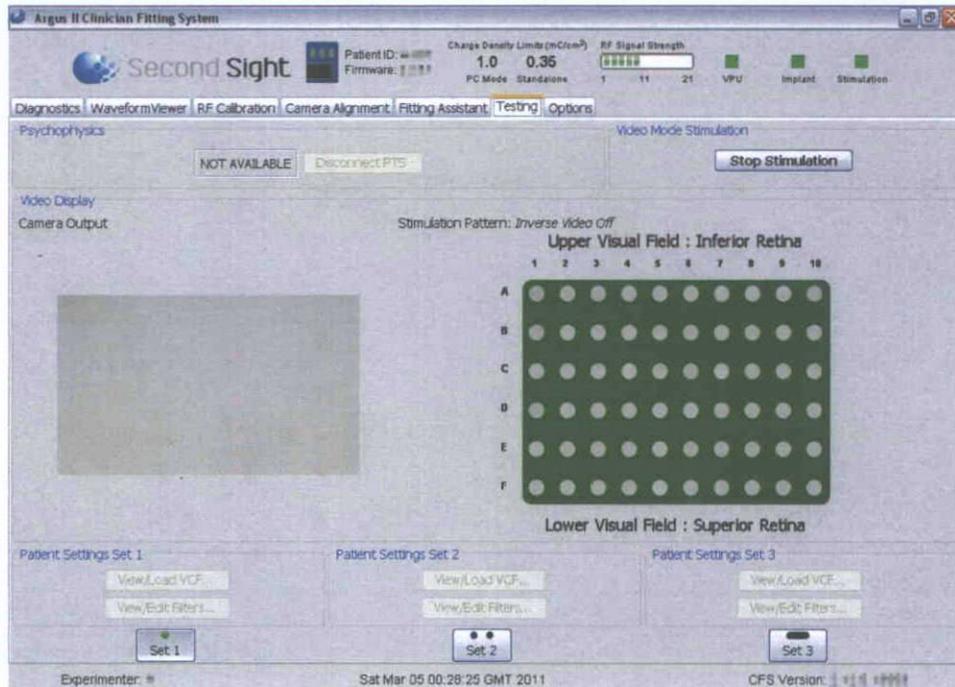
**Note:** Detailed information on filter parameters can be found in Section 3.10.3.

8. Once the desired VCF and filters are configured for a particular setting, ensure that the setting is selected by clicking one of the setting icons on the screen (a green light will appear in the selected setting icon), begin stimulation when the patient is ready by clicking "Start Stimulation." The background of the 10 x 6 image on the right will change from blue to green when the stimulation is on, as shown in Figure 3.39. Note that once the video mode stimulation is started the psychophysics module is indicated as **Not Available**, as shown in Figure 3.39.

**Note:** When the VPU is connected to the CFS, always use the setting buttons (Set 1, Set 2, or Set 3) on the CFS screen to change to different

programming settings and do not use the program setting buttons on the VPU to change the settings.

**Figure 3.39 Video Stimulation Window**



9. To stop stimulation, click the “Stop Stimulation” button.
10. The “Video Settings” thumb drive can be safely removed from the USB port after the desired VCF is downloaded to the VPU. To do this, click on the “Safely Remove Hardware” icon in the lower right hand corner of the screen. The message “Safely remove USB mass storage device” will appear. Click on this message and select the device to be removed. A message box will then appear that indicates that it is safe to remove the hardware device.

**CAUTION:** The CDL is set on the VPU independently for standalone and for PC use. For standalone the CDL must be set to  $0.35 \text{ mC/cm}^2$ . For PC mode (in the clinic), the CDL should be set to  $1.0 \text{ mC/cm}^2$  in order to perform array scanning and hybrid threshold measurement properly. The CFS will not allow the clinician to load a VCF that exceeds the PC use CDL. If the VPU is powered on in standalone mode with a VCF that exceeds the standalone CDL ( $0.35 \text{ mC/cm}^2$ ), the VPU will perform the startup tests, produce an audible warning, and power off.

### 3.10.3 Program Settings

The Program Settings are called “Patient Settings” in the CFS user interface. The Argus II VPU transforms the video image recorded by the camera into the level of stimulation current in each electrode in real time. First, the camera image is digitized and down sampled to a resolution of 20x12 pixels. The instructions for converting the down-sampled image to stimulation currents are contained in two components:

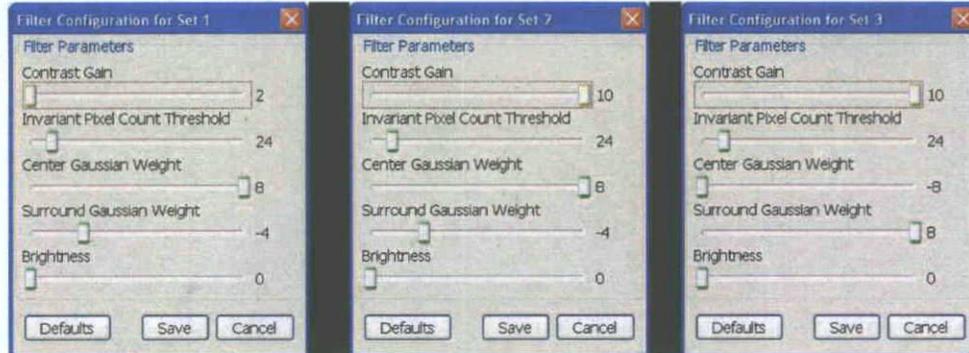
- (a) Video Filter – the filter enhances the digital sampled image of 20 x 12 (twice the electrode array resolution) and performs sub-sampling in order to convert the 20 x 12 image to a 10 x 6 image, emphasizing different aspects of the image depending on the filter settings.
- (b) Video Configuration File – a look-up table tailored for each patient that transforms the video levels at the output of the video filter to electrical current for each electrode.

The VPU can hold three programs (Program Settings). By default, each setting contains a set of parameters for a video filter and a video configuration file (see Figure 3.40). Press one of the three program setting buttons on the VPU to choose the corresponding program when the VPU is not connected to the CFS. Use the program setting buttons on the CFS screen when the VPU is connected to the CFS.

- Program Setting #1 (Normal contrast): This is the default setting every time the VPU is switched on. This default video filter setting uses a low contrast gain and Gaussian filter for spatial low pass (Contrast Gain = 2; Center Gaussian Weight = 8; Surround Gaussian Weight = -4). The software allows users to change any of the filter setting parameters. **You must load a VCF to Program Setting 1 before stimulation.** Create a normal VCF with the Fitting Assistant and load it to Setting #1.
- Program Setting #2 (Contrast enhancement): In this setting the video filter is set to enhance the contrast of the sampled image. The default video filter parameters are high gain and Gaussian filter for spatial low pass (Contrast Gain = 10; Center Gaussian Weight = 8; Surround Gaussian Weight = -4). Users can adjust the filter setting parameters. **You must load a VCF to Program Setting 2 before stimulation.** For this setting, you can use the normal VCF created with the Fitting Assistant. If it is too bright, reduce the gain to a value between 2 and 10.
- Program Setting #3 (Edge detection): In this setting the video filter is set to show only edges in the sampled image. An electrode will be turned on only if there is an edge at the respective field of the electrode. The default video filter parameters are high gain and Inverse Gaussian filter to emphasize the edges (Contrast Gain = 10; Center Gaussian Weight = -8; Surround Gaussian Weight = +8). **You must load a VCF to Program Setting 3 before stimulation.** For this setting, you should use a binary VCF created with the Fitting Assistant.

The default filter parameters for the three program settings are shown in Figure 3.40.

**Figure 3.40 Default Filter Settings**



The effect of the three sets of filters can be illustrated in the following figures:

Figure 3.41 is an outdoor image from the Argus II Camera pointing to the edge of the grass and concrete curb. The yellow rectangle represents the down-sampled output video window of the Argus II System.

**Figure 3.41 Argus II Camera Capturing the Grass and Curb**



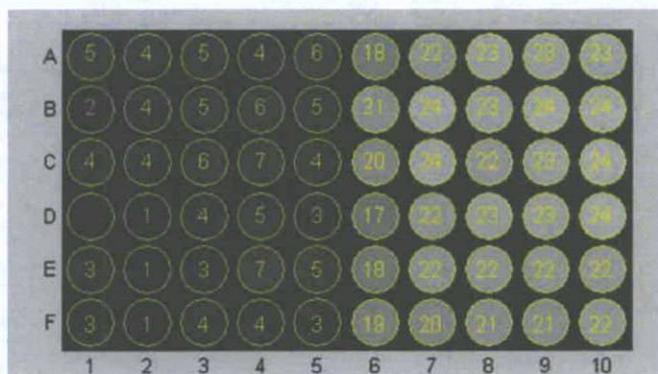
Figure 3.42a represents the video brightness levels (range 0 – 31) at the output of the default filter parameters for program setting 1.

Figure 3.42b represents the video levels at the output of the default filter parameters for program setting 2 (contrast enhancement). Note that the video levels on the left side of the video window are zero and on the right side are at the maximum level of 31.

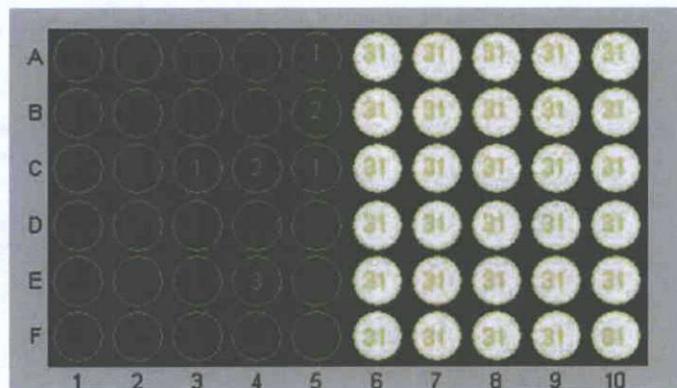
Figure 3.42c represents the video levels at the output of the default video filter parameters for program setting 3 (edge enhancement). Note that only the electrodes at the edge are turned on. The video levels for the rest of the image are relatively low and patient may not perceive

enough brightness with this setting. Therefore a binary VCF is recommended to increase the brightness levels of the edge.

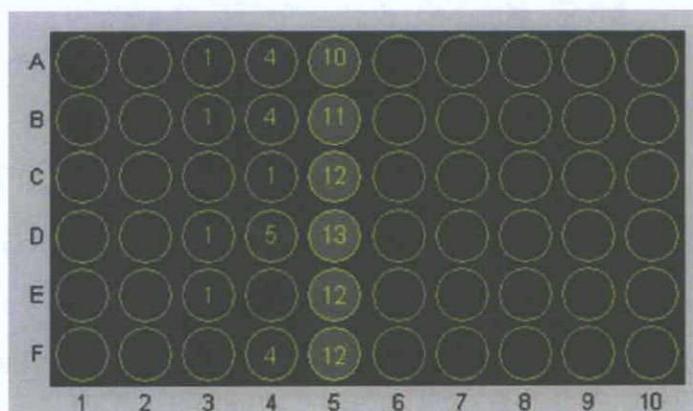
**Figure 3.42 Video Outputs from Three Different Filters**



a. Filter 1



b. Filter 2



c. Filter 3

Patients should be advised that when changing between different VPU Program Settings or if the light level of their environment undergoes a sudden change it may take their vision a few seconds to adjust to the new conditions.

### 3.11 Direct Stimulation

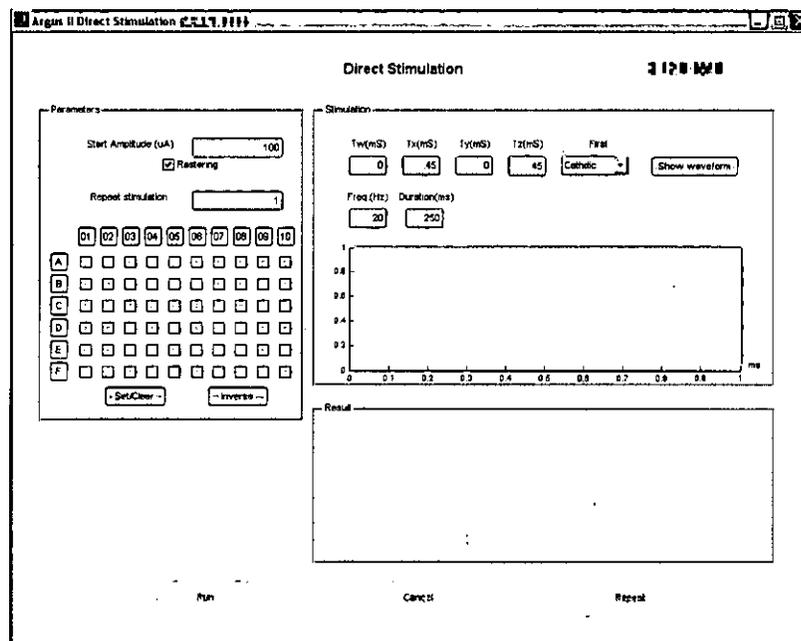
The Direct Stimulation Software is a program installed on the Argus II Clinician Fitting System computer. The aim of the program is to provide a tool for stimulating a single electrode or a group of electrodes using the stimulation parameters defined by the user. The Direct Stimulation Software is also used in the Camera Alignment procedure described in Section 3.12. To perform Direct Stimulation, follow the instruction below:

1. Log in to CFS, go to "Patient Testing" and select the "Testing" tab.
2. Run "Argus II Direct Stimulation" program from the Start menu on the CFS computer.
3. Enter the user name, password, and patient ID to log in.
4. The Direct Stimulation screen will appear, as shown in Figure 3.43.

**CAUTION: Choose the direct stimulation parameters carefully and increase the stimulation amplitude gradually to avoid discomfort or overly bright sensation.**

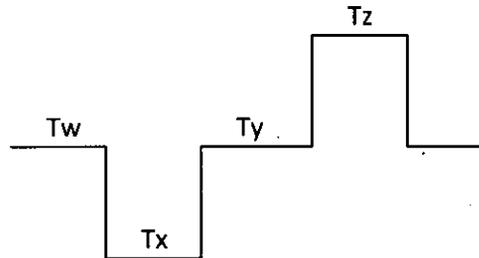
The PC mode charge density limit (CDL) set for the VPU connected to CFS will be used to control the maximum stimulation charge used during direct stimulation. By default, the PC mode CDL is set to 1.0 mC/cm<sup>2</sup>.

**Figure 3.43 Direct Stimulation Screen**



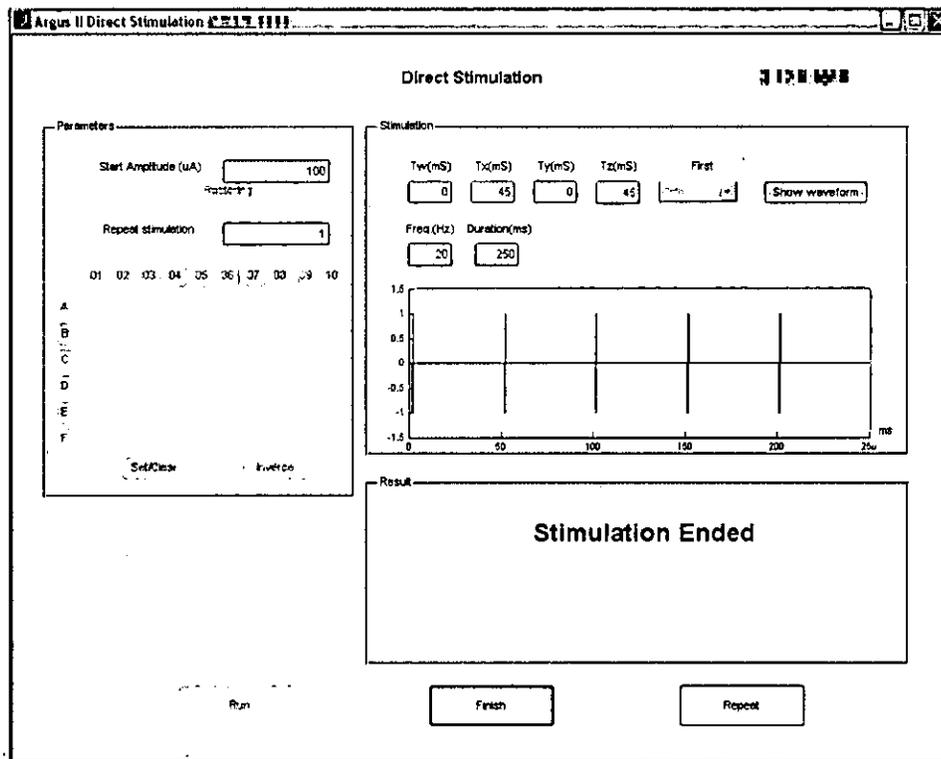
The following parameters can be specified or changed:

- **Start Amplitude:** Stimulation amplitude in  $\mu\text{A}$ . The default value is  $100 \mu\text{A}$ .
- **Rastering:** If this box is checked and multiple electrodes are selected, they will be stimulated in rastering order. If this box is unchecked, multiple electrodes will be stimulated simultaneously.
- **Repeat Stimulation:** The number of times stimulation will be repeated. The time delay between successive repetitions is approximately 0.5 seconds.
- **Electrode Selection:** The electrodes to be stimulated can be selected and unselected.
- **Frequency:** The number of pulses repeated per second on each electrode.
- **Duration:** The length of time for the stimulation.
- **Waveform Parameters:**
  - $T_w$  – The time between the start of frame and initiation of the first phase. The default value is 0.
  - $T_x$  – The duration of the first phase. This is also called the “pulse width”. The default is 0.45 ms.
  - $T_y$  – The inter-phase gap. The default value is 0.
  - $T_z$  – The duration of the second phase.  $T_z$  is always equal to  $T_x$  for a charge balanced biphasic pulse.



- **First:** Determines whether the first phase is negative (cathodic) or positive (anodic) current. The default setting is cathodic.
5. Click the “Show waveform” button to produce a graph that displays the waveform of the stimulus, as shown in Figure 3.44.
  6. Click the “Run” button to start stimulation.
  7. Click the “Repeat” button to stimulate again with the same parameters, and click the “Finish” button to end the current trial and/or stimulate with a new set of parameters.

**Figure 3.44 Direct Stimulation Screen Showing the Stimulation Waveform**



## 3.12 Camera Alignment

During the Argus II retinal implant surgery, the electrode array may be placed on the retina at an angle. The camera rotation adjustment allows for compensation of the implant electrode array rotation angle for each patient by rotating the camera mounted on the glasses accordingly. The software will assist the operator to adjust the camera to the appropriate rotational degree.

The camera tilting position (video window) adjustment allows for the selection of the sub-sampled field of view of the camera (or the output video window as shown in Figure 3.52) that corresponds to the perceptual location resulting from array placement on the retina.

The Camera Alignment Software is a compiled program installed on the Argus II Clinician Fitting System computer. The aim of the program is to provide a tool for accurate camera alignment. The program consists of two applications: 1) Camera rotation adjustment; and 2) Camera tilting position (video window) adjustment.

This section provides detailed procedures on camera rotation and tilting alignment. Before the camera alignment procedure is performed, it is important to ensure that the Argus II Touch Screen Monitor is calibrated.

### 3.12.1 Touch Screen Monitor Calibration

Use the following procedure to calibrate the touch screen monitor:

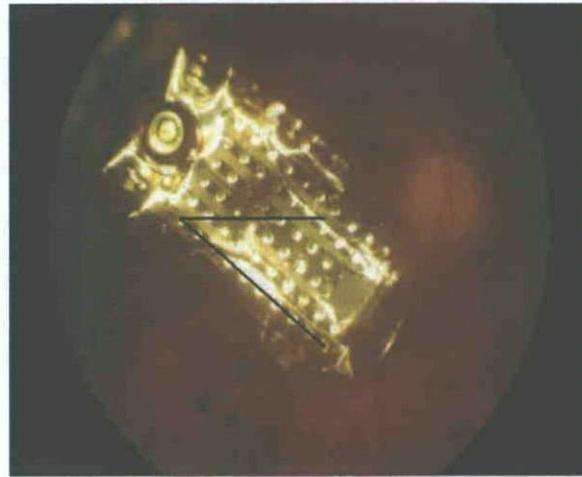
- 1) Connect the touch screen AC adaptor to the touch screen monitor.
- 2) Connect the appropriate power cord from the AC adaptor to the power supply output.
- 3) Connect the USB cable from the CFS laptop to the touch screen monitor.
- 4) Connect the VGA cable from the CFS laptop to the touch screen monitor.
- 5) Turn on the touch screen monitor. Right click on the Desktop of the CFS laptop.
  - i) If you see Graphics Properties on the Menu, use Graphic Properties to set the CFS laptop as the primary monitor and the touch screen monitor as secondary display using the extended desktop settings. Ensure that the screen resolution is set to 1024 x 768 and color quality = 32 bits for both the CFS laptop and the touch screen monitor.
  - ii) If you see the Catalyst (TM) Control Center on the Menu, use the Catalyst (TM) Control Center to set the CFS laptop as primary monitor ("Desktop 1") and the touch screen monitor as secondary monitor ("Desktop 2") using the Display Manager. You may need to right click on the "Desktop 2" icon to swap the displays. Select "Desktop 1" and "Desktop 2" separately, one at a time, and ensure that the screen resolution and color quality for both the CFS laptop and touch screen monitor are set to be 1024 x 768 (in the Desktop area) and 32 bits respectively.
- 6) Double click on the touch screen icon at the bottom right corner on the taskbar on the CFS laptop. Click on "Align". Targets will first appear on the CFS. Click the escape key once to transfer the targets from the CFS to the touch screen. Follow the on-screen prompts to complete the alignment process on the touch screen monitor.
- 7) On the CFS laptop, click on the sound tab under ELO touch screen properties, and uncheck "beep on touch". This step should be performed if you do not want an audio alert upon touching the touch screen. Click "Apply" and "OK".

### 3.12.2 Camera Rotation Adjustment

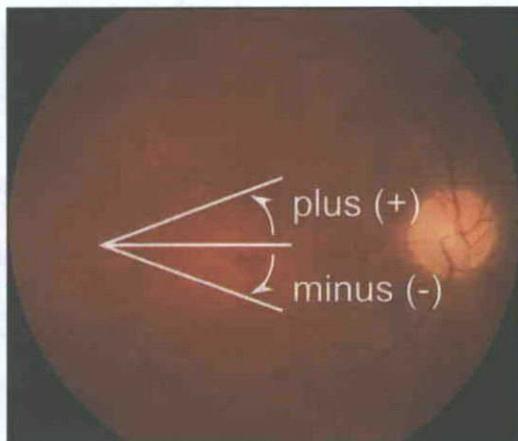
1. Ensure that the touch screen monitor is connected to the CFS computer. Set the CFS monitor as the primary monitor and the touch screen as the secondary monitor with a resolution of **1024 x 768**. Connect the Argus II Glasses containing the camera to be aligned to the VPU.
2. Log in to CFS and select the "Camera Alignment" tab.
3. Determine the rotation of the patient's array from a fundus photo of the implanted array by measuring the angle of a row of electrodes (e.g., A01 to A10) relative to the horizontal, as shown in Figure 3.45. This measurement can be made using a protractor with the fundus photograph or using the freely available software GIMP (<http://www.gimp.org/>). The definition of the array rotation angle is as follows: using the tack point on the fundus image as the point of rotation, if the array is rotated counter-clockwise (CCW) from horizontal, the rotation angle is defined to be CCW (+). If the array is rotated clockwise (CW) from horizontal, then the rotation angle is defined to be CW (-). (Note that the tack is on opposite sides for right and left implants, but the rotation is always given with respect to the tack site of a specific patient.) Figure 3.46 shows a fundus image with the definition of the orientation

polarity of the electrode array on the retina. For example, if the surgical placement angle of the array is 20 degrees CCW), the rotation angle will be +20 degrees.

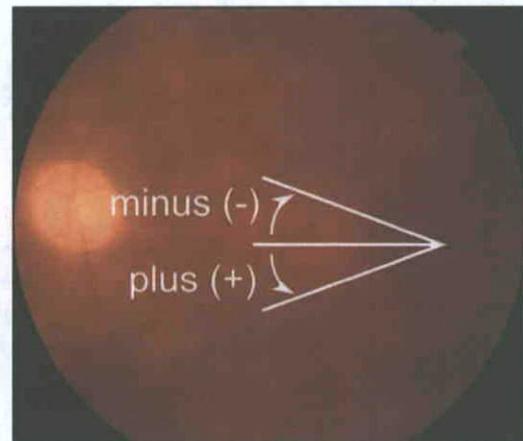
**Figure 3.45 Implant Rotation Angle**



**Figure 3.46 Implant Array Rotation Angles for Left and Right Eyes**



**Right Eye**

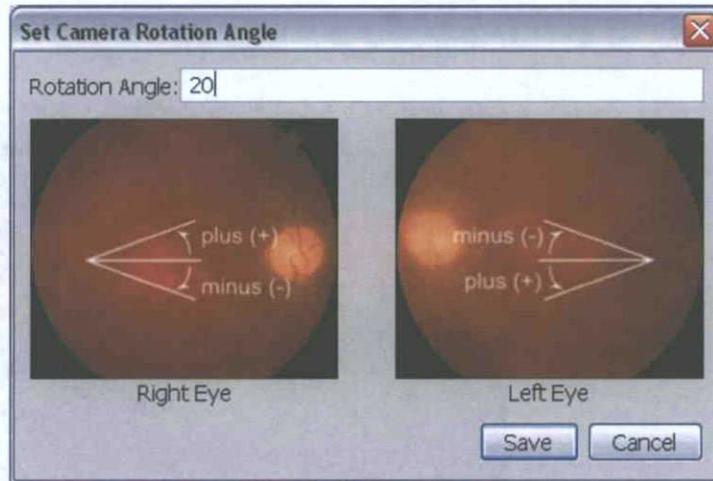


**Left Eye**

4. In CFS, click the "Edit" button under "Camera Rotation Angle" and set the rotation angle to the angle measured from the fundus photo, as shown in Figure 3.47. Click the "Save" button. This saves the patient's rotation angle in the VPU so if the glasses are replaced later, you can obtain the rotation angle from CFS rather than from the fundus photo.

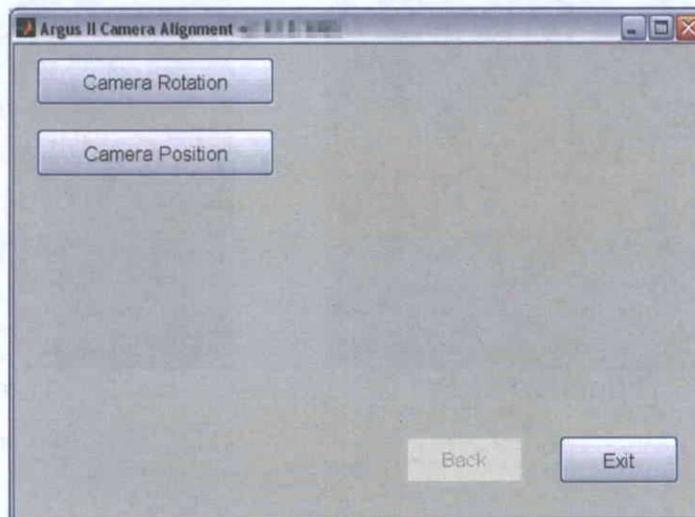
**Note:** The rotation angle may change over time. It is recommended that the rotation angle be updated based on the latest fundus image.

**Figure 3.47** Enter the Camera Rotation Angle in CFS



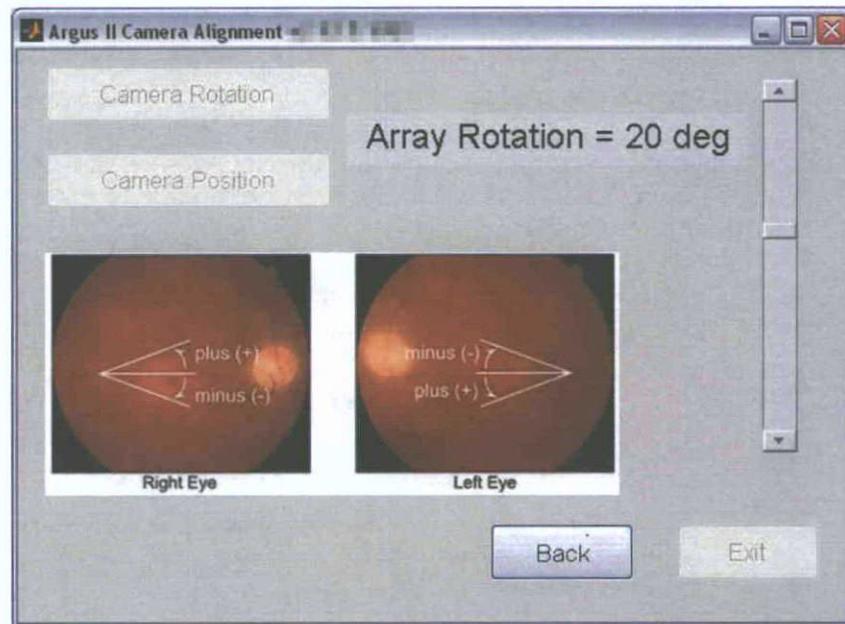
5. Run "Argus II Camera Alignment" program from the Start menu on the CFS computer. Select the "Camera Rotation" button, as shown in Figure 3.48:

**Figure 3.48** Camera Alignment Software Main Screen

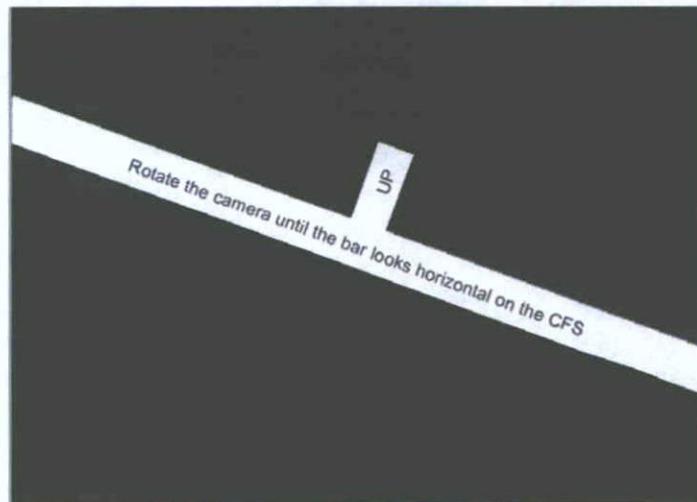


6. Adjust the slider to match the patient's array orientation. For example, if the surgical placement angle of the array is 20 degrees counter clockwise (CCW), set the slider to +20 degree, as shown in Figure 3.49. A white bar with the intended angle will appear on the touch screen, as shown in Figure 3.50.

**Figure 3.49 Camera Rotation Angle Adjustment**



**Figure 3.50 Camera Rotation Target Based on the Rotation Angle**

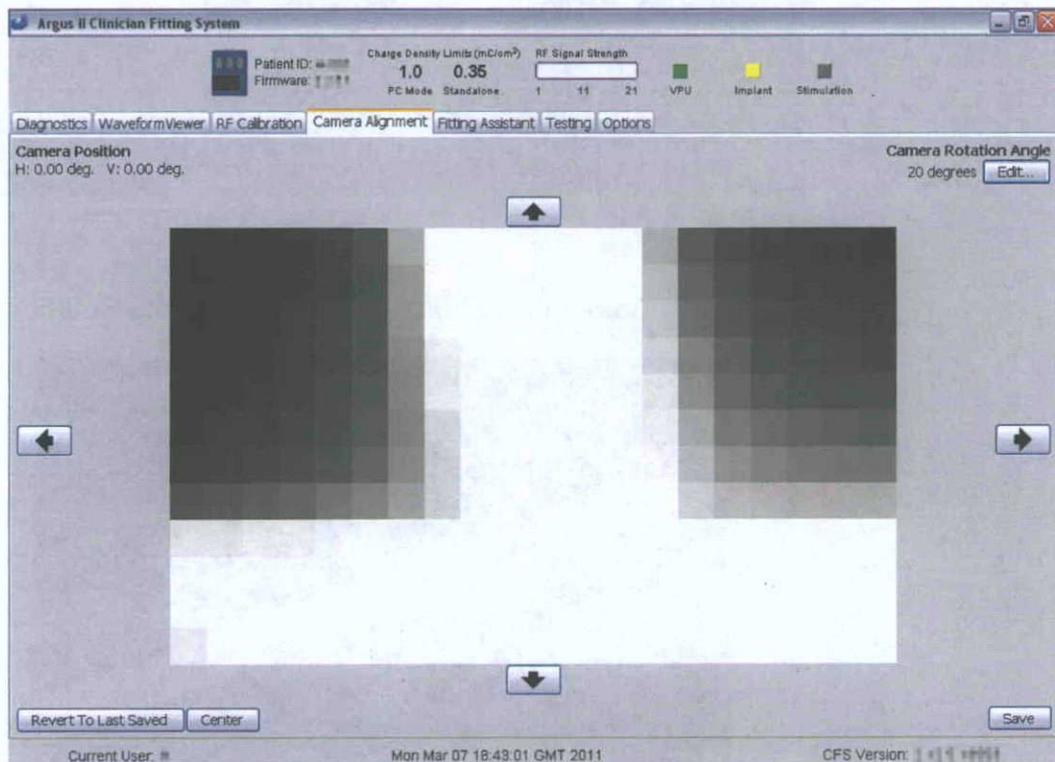


7. Position the patient so that the camera on the glasses is 12" (or approximately 30 cm) away from the center of the touch screen. Instruct the patient to look straight ahead while keeping their head position as still as possible.
8. Remove the glasses and keep them in the same orientation. Rotate the camera until the bar on the touch screen appears horizontal on the CFS Camera Alignment screen. (In the above example in which the angle of the array is 20 degrees counter-clockwise (CCW) and the slider is correspondingly set to +20 degrees, the camera

should be rotated in the counter-clockwise direction if you are facing the front of the camera.)

9. After the camera rotation, the line should appear horizontal on the CFS screen when the patient wears the glasses. If not, remove the glasses, adjust the camera rotation, and recheck the angle of the bar. Repeat this step until the longer bar on the touch screen appears horizontal and the "up" bar appears vertical on the CFS screen, as shown in Figure 3.51. This will rotate the video image to correspond to the rotation of the array on the patient's retina.
10. Use the hot glue gun to place a small spot of hot glue on each side of the camera to affix it to the lenses and allow adequate time for the glue to dry.

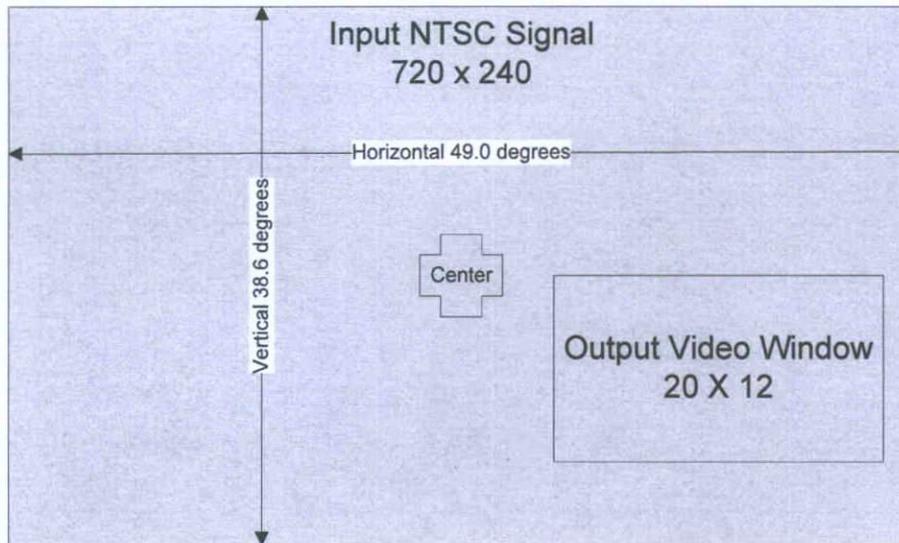
**Figure 3.51 Camera Rotation Angle Properly Adjusted as Indicated in CFS**



### 3.12.3 Camera Tilting Position Adjustment

The camera mounted on the glasses captures a field of view of approximately 49° horizontally and 39° vertically. The image is then cropped and down sampled to a 20 x 12 pixel image, which is twice the implant array resolution.

**Figure 3.52 Video Window**



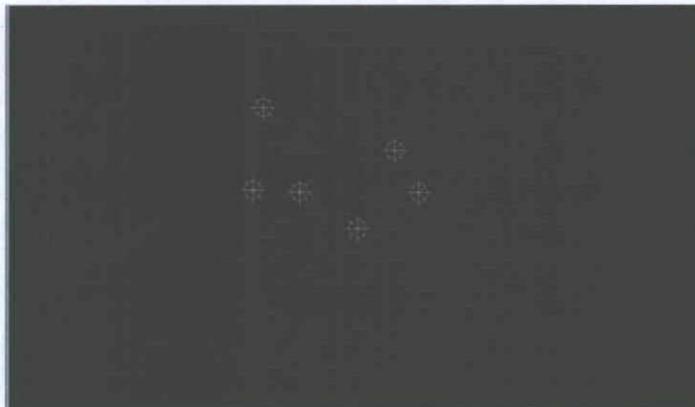
The field of view of the Output Video Window is approximately 17.9° x 10.8°. The down-sampled output video window can be moved horizontally and vertically from the center of the field of view of the camera, as shown in Figure 3.52. Adjusting the camera output video window is equivalent to adjusting the camera “tilting” in software.

Use the following steps to adjust camera tilting:

1. Place the patient in front of the touch screen monitor. Ensure that the touch screen monitor is set to the secondary monitor with a resolution of 1024 x 768.
2. If it is not open, launch the “Argus II Camera Alignment” program from the Start menu on the CFS computer. Click on the “Camera Position” button. A blank screen will appear on the touch screen monitor.
3. Select the “Testing” tab in CFS and then launch “Argus II Direct Stimulation” program from the Start menu of the CFS computer.
4. In the Direct Stimulation Screen, stimulate a small group of electrodes in the center of the array with the default parameters, and increase the stimulation amplitude and the number of stimulating electrodes until the patient clearly sees a localized bright phosphene.
5. Adjust the patient’s seating position and the touch screen monitor in order to align the camera to the center of the touch screen and about 12” (30 cm) away from the screen. Instruct the patient to look straight ahead while keeping their head position as still as possible. Use a chin rest if necessary. Generate a phosphene using Direct Stimulation and ask the patient to point the location of the phosphene on the touch screen without moving their eyes or their head. If the position of the phosphene is outside the touch screen, move the touch screen or adjust the height of the patient’s chair so that the response is on the monitor. Verify that a gray

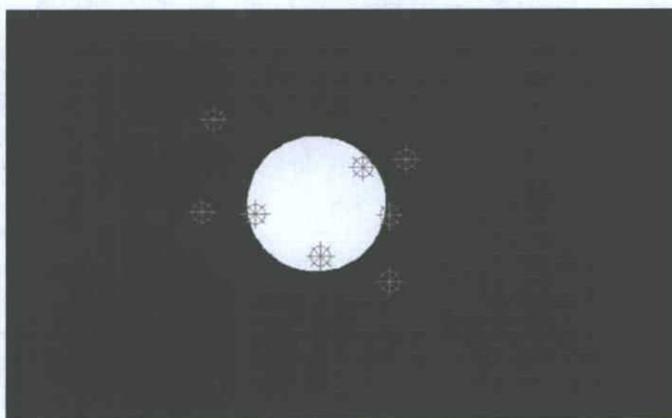
symbol appears on the touch screen at the location indicated by the patient, as shown in Figure 3.53.

**Figure 3.53 Touch Screen Monitor Display Patient's Responses During Camera Tilting Adjustment**



6. Repeat the stimulation and gather the response 8 times. The touch screen will display all the outputs from the patient. Click the "Undo last trial" button to remove the last responses from the patient if necessary. Click the "Back" button to go back to the main screen and click the "Exit" button to exit the program. If the touch screen monitor or the patient seating is adjusted during this step, repeat the step to collect 8 responses again.
7. The program will calculate the average position of the responses and present an alignment target (a white circle) centered at this position on the touch screen, as shown in Figure 3.54.

**Figure 3.54 Camera Tilting Adjustment Target Created Based on Patient's Responses**



8. Exit Direct Stimulation. Select the "Camera Alignment" tab in CFS. Instruct the patient to look straight ahead and to carefully maintain the same head and body position as during the data collection phase. The alignment target should appear in



**Figure 3.56 CFS Record Signature Screen**



Close Session  
Please Sign This Session

Username:

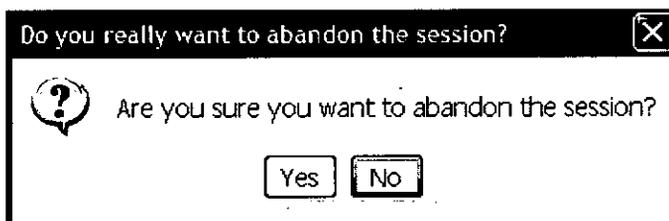
Password:

Comment:

Abandon Session Sign Session

2. Enter the same username and password as used at the beginning of the session. The username and password serve as an electronic signature.
3. Click on "Sign Session", as shown in Figure 3.56. This will bring the user back to the CFS main screen.
4. The session can also be abandoned by clicking on the "Abandon Session" button. Abandoning the session will indicate that the data should not be considered valid for the purposes of data analysis but it will still be archived and transferred. If this option is used the following message will appear asking the user for verification.

**Figure 3.57: CFS Abandon Session message**



Press "No" to return to the CFS user record signature screen. Press "Yes" to abandon the session.

**CAUTION:** The session should be ended by clicking the "End Session" button prior to the VPU being turned off at the end of a testing session.

## 3.14 Managing Patient Data

At each fitting session, all the patient-specific parameters for the three program settings (VCFs and filter parameters), electrode integrity information, camera alignment parameters, and other parameters) are downloaded to the patient's VPU.

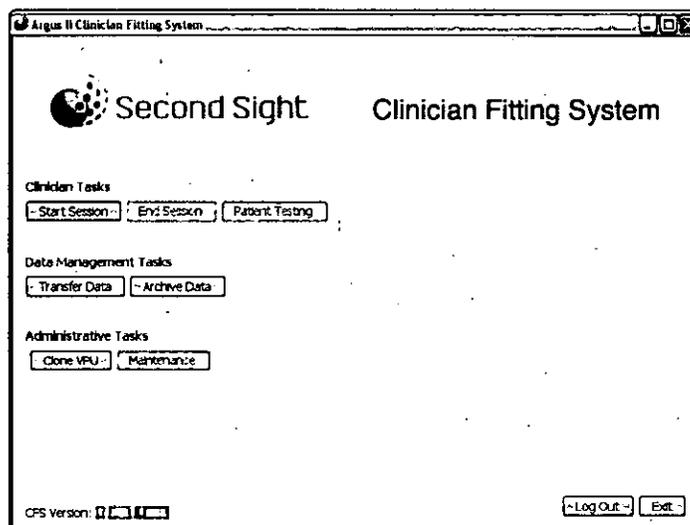
During normal use of the system outside the clinic, the VPU tracks certain events such as when the VPU is turned on/off, which buttons are pressed and when they are pressed, when the communication between the VPU and implant is temporarily lost. The VPU also does a series of safety checks including electrode impedance measurement when it is switched on and it can disable electrodes with impedance values exceeding the normal range. All these data are saved on the VPU and are uploaded to CFS once the VPU is connected to CFS.

### 3.14.1 Transfer Data

At the end of each fitting session, the patient-specific diagnostic and programming data can be transferred onto a USB thumb drive and used for analysis. It is recommended that the files be transferred after each session using the following steps:

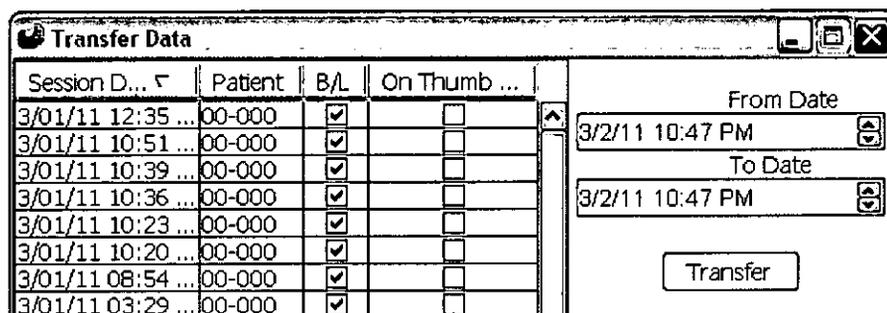
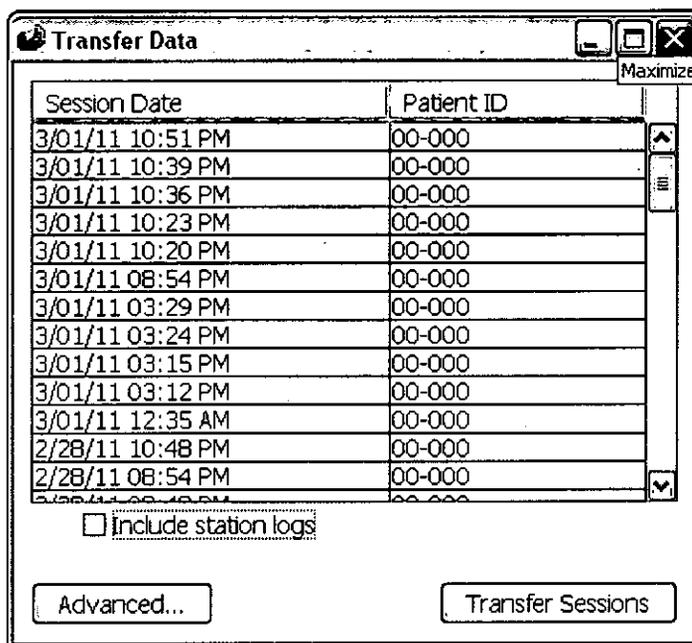
1. Connect the thumb drive labeled "Argus II USB Drive (Data Transfer)" to an open USB port on the CFS.

Figure 3.58 CFS Main Menu



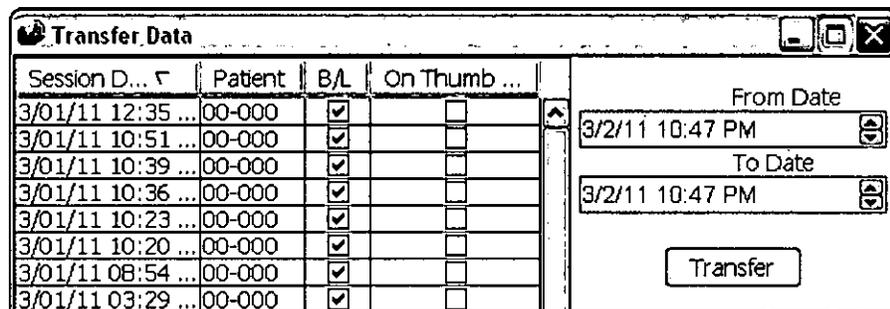
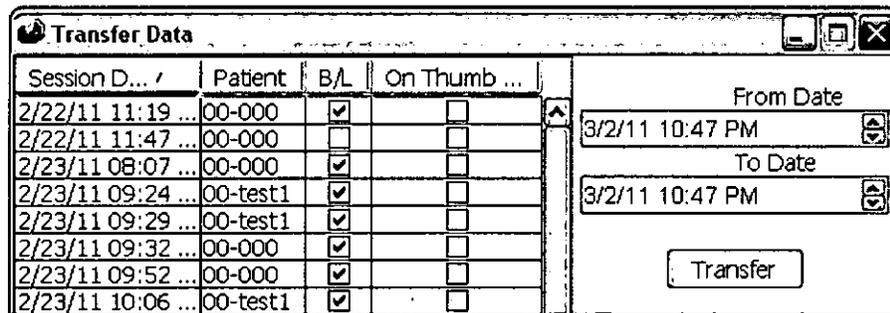
2. Click on "Transfer Data" as shown in Figure 3.58. This will bring up the Transfer Data screen as shown in the top graphic of Figure 3.59. A list of files will appear with each of the files identified by the session date, time and patient ID. All the sessions for which the "Transfer Data" has not previously been completed will be listed. Click on "Transfer Sessions" to transfer the data for the sessions listed.

**Figure 3.59 Transfer Sessions**



3. If you need to transfer the data from sessions other than the ones listed, click on the "Advanced" button and a new screen will appear as shown in the bottom graphic of Figure 3.59. A complete list of files will appear with each of the files identified by the session date, time and patient ID. To the right of the patient ID are check boxes under the headings **B/L** and **On Thumb Drive**. A checked box in the **B/L** column indicates that the particular file is in the backlog and has never been transferred. A checked box in the **On Thumb Drive** column indicates that the particular file is currently stored on the "Data Transfer" USB thumb drive.
4. The data transfer packages can be sorted in ascending or descending order by clicking on the column labels (**Session Date**, **Patient**, **B/L**, **On Thumb D...**). In 0 the top graphic has the packages sorted by ascending order using the **Session Date** and the bottom graphic is in descending order.

**Figure 3.60 Sorting Transfer Sessions**



- Using the mouse, select the sessions to download to the thumb drive by highlighting them under the **Session Date** heading. Alternatively, you can select the sessions within a particular time frame by identifying the "From Date" and "To Date". You can also select multiple files by holding down the control or shift keys while clicking on additional sessions.
- Once you have identified the file(s) you wish to transfer, click "Transfer" to download the files onto the thumb drive. When the transfer is in-progress an hourglass will appear. Once the hourglass turns to an arrow, the download is complete. The files transferred will now have a check mark in the box in the **On Thumb Drive** column.

**Note:** Transferring files whose box for the **On Thumb Drive** column is already checked will simply overwrite the existing files on the thumb drive.

- Close the Data Transfer screen by clicking the "X" in the upper right hand corner. Safely remove the thumb drive from the USB port. To safely remove the thumb drive, click on the "Safely Remove Hardware" icon in the lower right hand corner of the screen. The message "Safely remove USB mass storage device" will appear. Click on this message and select the device to be removed. A message box will then appear that indicates that it is safe to remove the hardware device.

The transfer files include the following patient-specific data:

- VPU Event log (Includes error messages from the VPU and implant, when the VPU is switched on/off, what buttons are pressed on the VPU, etc)

- Patient ID (in the format ##-### where ## represents the hospital and ### is a consecutive number to designate the patient)
- Results from any stimulation testing performed with the patient (e.g. measurements of electrode stimulation thresholds, results from visual acuity testing, etc.)
- VPU serial number and firmware version.
- Implant diagnostics data such as the electrode impedance values, waveforms, and implant coil diagnostics.
- VPU programming parameters including VCFs, filter parameters, and camera alignment parameters.

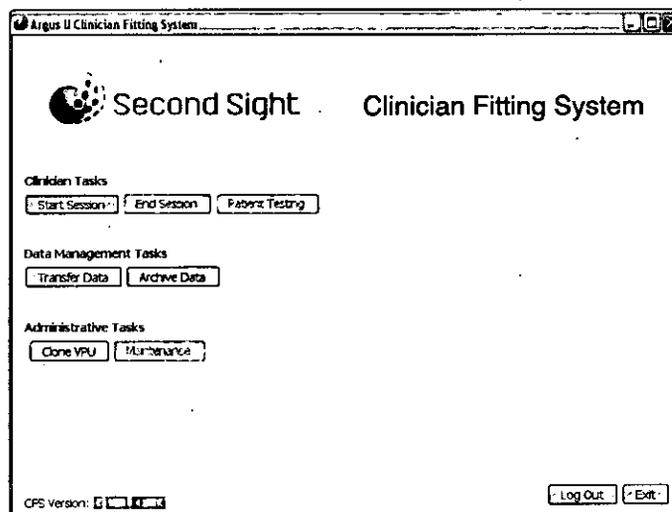
**Note:** It is recommended that transfer files be sent to Second Sight for device monitoring, data analysis, and troubleshooting. To transfer, email the compressed transfer files to [cds@2-sight.com](mailto:cds@2-sight.com) with a subject line of **upload**.

### 3.14.2 Archive Data

This section describes how to download all patient data onto the Argus II USB Archive Hard Drive for back-up purposes. This procedure should be done after the completion of each testing session and without the patient being present.

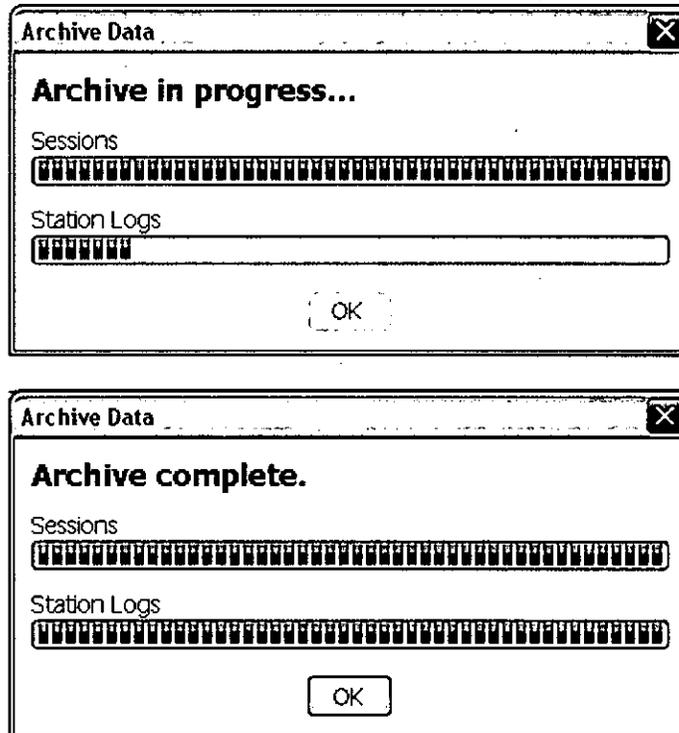
1. Connect the Argus II Archive Drive to an open USB port on the CFS computer.
2. Open "Argus II Clinician Fitting System" software and log in. The main menu, as shown in Figure 3.61, will appear.

**Figure 3.61 Clinician Fitting System Main Menu**



3. Click on "Archive Data". This will copy all patient data on the CFS hard drive onto the Argus II Archive Drive. When the archiving is in-progress an hourglass will appear. Once the hourglass turns to an arrow the download is complete. If the Archive drive is not connected and powered on then the following error message will appear: "Media is not attached or required content is missing. Please insure media is properly prepared." If the archive drive is attached then a progress bar will appear indicating the progress of the archiving process first for the transfer sessions and then for the station logs.

**Figure 3.62 Archive progress bars**



4. If you need to disconnect the archive drive from CFS, safely disconnect it from CFS by clicking on the "Safely Remove Hardware" icon in the lower right hand corner of the screen. The message "Safely remove USB mass storage device" will appear. Click on this message and select the device to be removed. A message box will appear that indicates that it is safe to remove the hardware device.
5. Click on this message and select the device to be removed. A message box will appear that indicates that it is safe to remove the hardware device.

### 3.14.3 Clone a VPU

#### WARNING



Do not connect the VPUs to the glasses, OR coil or any type of reference implant device at any time during the cloning process as this will result in incorrect cloning of the VPU. Incorrectly cloned VPU may result in incorrect stimulation. During the cloning process, the VPU should only be connected to the CFS.

The “Clone a VPU” function is designed to transfer all the patient-specific parameters stored on the VPU or on CFS to a new or replacement VPU. A fully-programmed VPU contains many patient-specific parameters including but not limiting to the following settings:

- Patient ID
- Implant-specific settings from the matching CD
- Electrode integrity setting and information
- 3 program settings (including 3 video configuration files (VCFs) and 3 sets of filter parameters)
- Camera setting
- VPU mode
- Other VPU configurations

The CFS software allows the user to copy or “clone” the above patient-specific settings to another VPU should the patient need a replacement VPU.

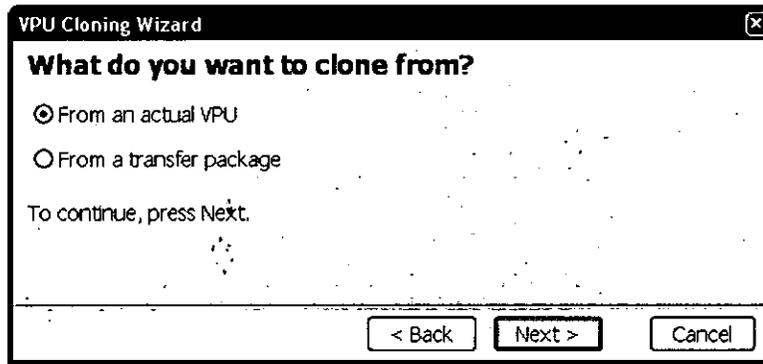
There are two ways to copy the settings to a new VPU. You can either transfer the settings from an existing source VPU, or from the transfer files on the CFS computer which contain the last saved VPU settings. The latter is used when the original VPU fails to communicate with CFS.

#### **Clone a VPU from Source VPU**

Use the following steps to clone a VPU from the source VPU:

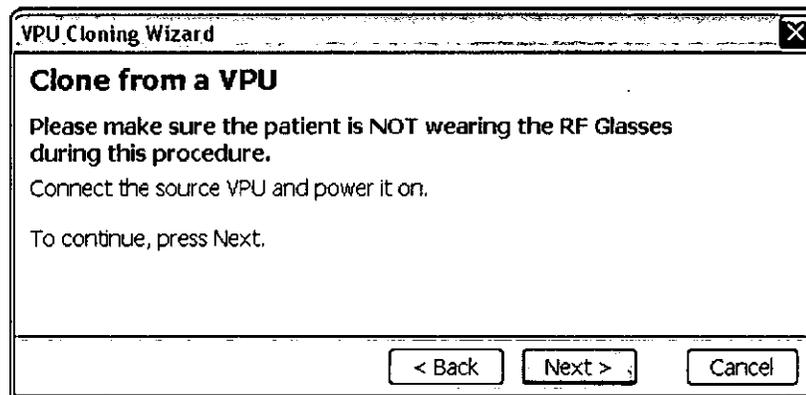
1. Start CFS and log on. Click on the “Clone VPU” button, as shown in Figure 3.2.
2. The **VPU Cloning Wizard** screen will pop up. Click on the “Next” button.
3. Choose whether you want to clone “From an actual VPU” or “From a transfer package”. It is recommended that you choose “From an actual VPU” if the source VPU is able to communicate with CFS. If the source VPU fails to communicate with CFS or you suspect that the source VPU may be corrupted, then you should choose “From a transfer package”, as shown in Figure 3.63.

**Figure 3.63 VPU Cloning Selection**



4. Click on the "Next" button. Make sure to follow the instruction shown in Figure 3.64.

**Figure 3.64 VPU Cloning – Make Certain the Glasses or the OR Coil are not Connected to the VPU**



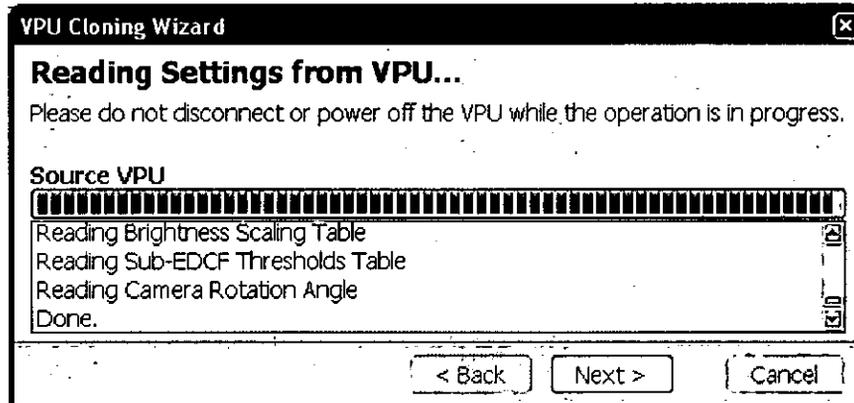
**WARNING**



**It is important to follow the instruction above and disconnect the glasses or OR coil from both the source and destination VPU prior to and throughout the entire cloning process.**

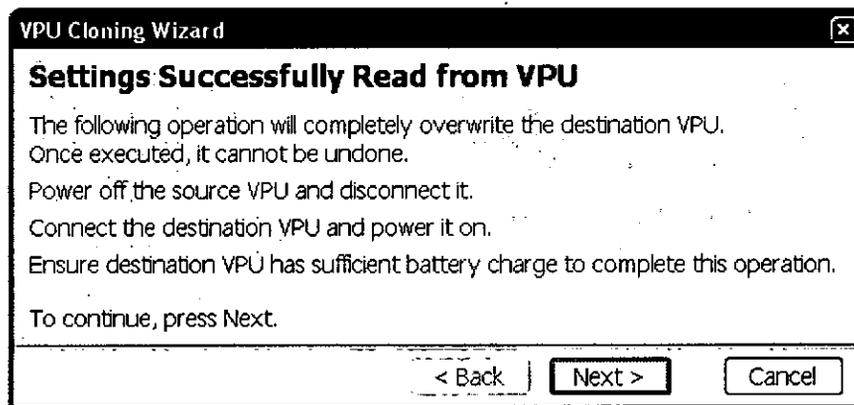
5. Follow the instructions on the screen to connect the source VPU to CFS.
6. Click on the "Next" button. CFS will start to read all the settings from the source VPU until it is completed, as shown in Figure 3.65.

**Figure 3.65 Reading Settings from the Source VPU**



7. Click on the “Next” button and follow the instructions on the screen to power off and disconnect the source VPU, connect and power on the destination VPU, as shown in Figure 3.66.

**Figure 3.66 Disconnect the Source VPU and Connect the Destination VPU**



8. Follow the instructions until the cloning procedure is completed.
9. **Check the Cloned VPU:** If the patient is present, run the VCF Stepper software to ensure the VCFs on the new VPU are appropriate and will not cause any discomfort. Allow the patient to use the new VPU in stand-alone mode to make sure the new VPU functions the same as the patient’s original VPU.

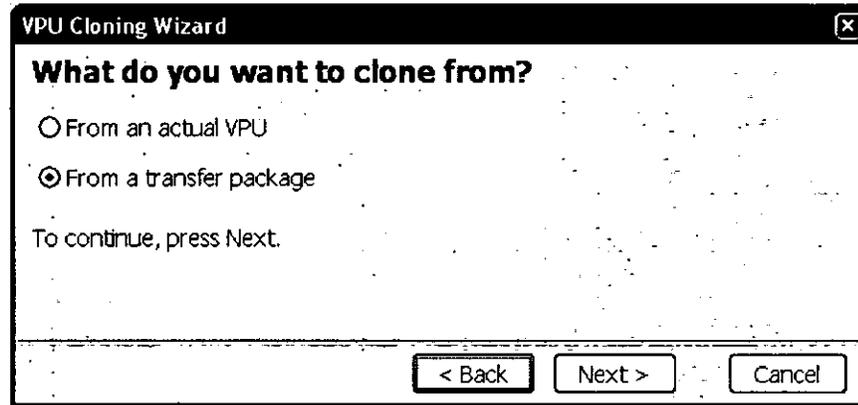
If the operation is not successful during any of the above steps, repeat the step or go back to Step 4.

### **Clone a VPU from the Data on CFS**

To clone a VPU from the data on CFS, use the following steps:

1. Select cloning "From a transfer package", as shown in Figure 3.67.

**Figure 3.67 Cloning a VPU from a Transfer Package**



2. Select "The most recent valid transfer package on this computer", as shown in Figure 3.68. This is the recommended selection.

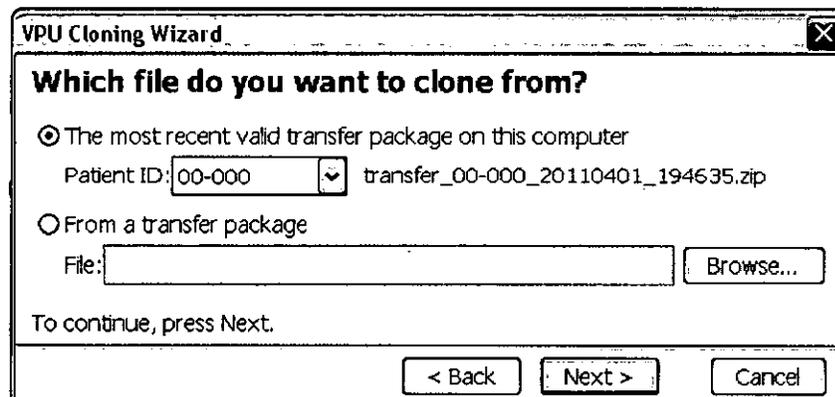
**WARNING**



**It is important to disconnect the glasses or OR coil from both the source and destination VPU prior to and throughout the entire cloning process.**

Click "Next" and follow the instructions until the cloning procedure is completed.

**Figure 3.68 Select a Transfer Package for Cloning**



**WARNING**



**Make sure the correct patient ID is selected during this step. Selecting an incorrect patient ID will cause the wrong files to be copied to the new VPU and may result in discomfort or overstimulation to the patient.**

3. After cloning, keep the new VPU connected to CFS. Select the “Start Session” button in the CFS main screen, enter the correct patient ID. If the patient ID entered does not match the patient ID on the VPU, CFS will display a message to indicate the patient ID mismatch. Repeat the cloning procedure if you suspect the wrong patient ID was selected during cloning and ensure the correct patient ID is chosen.
4. **Check the Cloned VPU:** Run the VCF Stepper software if the subject is present to ensure the VCFs on the new VPU are appropriate and will not cause any discomfort. It is recommended that the subject also try all the programming settings in stand-alone mode before he or she takes the new VPU home.

### 3.15 Fitting in Advanced Mode

The three modules employed in the Fitting Assistant (Array Scanning, Hybrid Threshold, and Generate VCF Tool) all have an “Advanced” mode that can be used to perform psychophysical testing using a set of non-standard parameters or to create non-standard VCFs. The advanced mode is designed to provide flexibility for advanced fitting.

The detailed differences of these three modules in the advanced mode and Fitting Assistant mode and when to use the advanced mode will be described in this section.

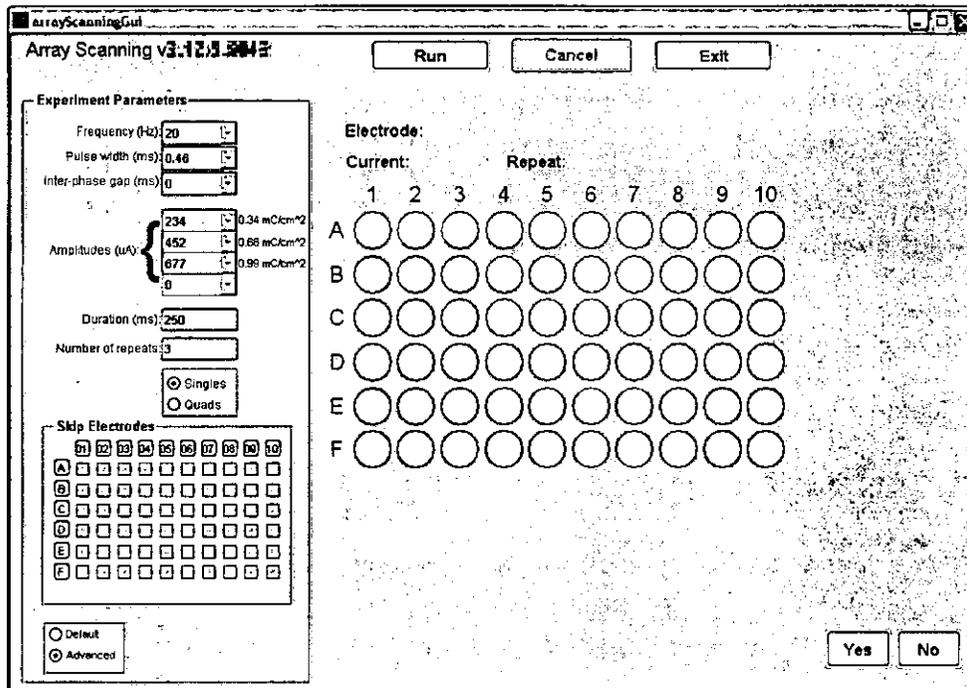
**Note:** For clinical trial protocol testing, Array Scanning and Hybrid Threshold measurement should be done in advanced mode as they require the inter-phase gap to be 0. If the VCF needs to be created using the protocol testing threshold values, it will be created using the Generate VCF Tool in advanced mode too.

#### 3.15.1 Array Scanning in Advanced Mode

To start Array Scanning in the advanced mode:

1. Confirm that the charge density limit (PC Mode) is set to 1.0 mC/cm<sup>2</sup>. If it is not, the array scanning cannot be completed properly. Contact Second Sight to have someone change this value to 1.0 mC/ cm<sup>2</sup> if needed.
2. Ensure that the “Testing” tab is selected in Argus II Clinician Fitting System Software, and the software indicates “WAITING FOR CONNECTION”.
3. Open Argus II Array Scanning by clicking the icon in the Start menu.
4. Log in using your username and password and the patient ID.
5. In the GUI, select the “Advanced” Radio button and select “Yes” in the dialog box to enter advanced mode (Figure 3.69).

Figure 3.69 Array Scanning in Advanced Mode



6. The following parameters can be modified in the advanced mode by choosing values from the pull down menus:

- **Frequency:** the frequency at which stimulation will be provided. Allowed values range from 1 Hz to 120 Hz. For clinical trial protocol testing, the frequency should be set to 20 Hz.
- **Pulse width:** the duration of the cathodic and anodic phases of the waveform. Allowed values range from 0.04 ms to 2.99 ms. For clinical trial protocol testing, the pulse width should be set to 0.46 ms.
- **Inter-phase gap:** the duration between the cathodic and anodic phases of the waveform. The inter-phase gap must be less than  $6 \text{ ms} - (2 \times \text{pulse width})$ . For clinical trial protocol testing, the inter-phase gap should be set to 0.
- **Amplitudes:** The amplitudes at which the stimulation will be provided. Allowed values are constrained by the charge density limit of  $1.0 \text{ mC/cm}^2$ . To skip amplitudes, set the value to 0.
- **Duration:** The duration of the stimulation. For clinical trial protocol testing, the duration should be set to 250 ms.

- **Number of repeats:** the maximum number of times each electrode will be stimulated at each amplitude level. For clinical trial protocol testing, it should be set to 3.
7. Proceed through the steps to complete the Array Scanning as laid out in Section 3.9.1, steps 3 – 10.

The final result is saved as a JPEG file on C:\Program Files\Second Sight Medical Products\Argus II Array Scanning\Data\[Patient ID].

### 3.15.2 Hybrid Threshold in Advanced Mode

**Note:** In advanced mode, the Hybrid Threshold results are saved in the transfer package for the session. Analysis of these data is performed by Second Sight. The user should manually track the results to ensure all functional electrodes in the array are tested.

To start Hybrid Threshold in the advanced mode:

1. Log in to CFS -> "Start Session" -> Patient ID. Select the "Testing" tab and ensure the software indicates "WAITING FOR CONNECTION".
2. Open "Argus II Hybrid Threshold" program in the advanced mode by clicking the icon in the Start menu.
3. Confirm that the charge density limit (PC Mode) is set to 1.0 mC/cm<sup>2</sup>. If it is not, the threshold measurement cannot be completed properly. Contact Second Sight to have someone change this value to 1.0 mC/ cm<sup>2</sup> if needed.
4. Enter the user name, password, and patient ID to log in. The Hybrid Threshold GUI screen will appear, as shown in Figure 3.70.

Figure 3.70 Hybrid Threshold GUI in the Advanced Mode

Argus II Thresholds Testing

Step 2/5: Set the parameters for the test.

Charge Density Limit (mC/cm<sup>2</sup>): 1.0

Pulse Width (ms): 0.46

Inter Phase Gap (ms): 1000

Frequency (Hz): 20

Catch Trials Per Block: 8

Check this box for protocol testing parameters

Back Continue to electrodes selection

- **Protocol testing parameters check box:** By default, the clinical trial protocol testing parameters check box is checked for measuring thresholds on clinical trial subjects over time.

**Note:** Always use Hybrid Threshold in advanced mode and check this box for protocol testing parameters when measuring thresholds for clinical trial protocol.

If this box is unchecked, all the parameters in the GUI can be modified.

- **Charge Density Limit:** It is recommended to use a charge density limit of 1.0 mC/cm<sup>2</sup>. For patients who have sensitive electrodes or experience discomfort at certain stimulation levels, the maximum current for each electrode can be adjusted later.
- **Pulse Width:** In the Fitting Assistant, the pulse width is fixed at 0.46 ms. In advanced mode, the pulse width can be adjusted in the range of 0.10 ms to 2.0 ms. If an electrode has no measurable threshold at the highest current level for a specific pulse width (e.g., the highest stimulation current is 677  $\mu$ A for pulse width at 0.46 ms without exceeding 1.0 mC/cm<sup>2</sup> charge density), wider pulse widths can be tried.
- **Inter-Phase Gap:** In the Fitting Assistant, the Inter-Phase Gap is fixed at 1 ms. In advanced mode, it can be modified within the range of 0 – 3.8 ms.

- **Frequency:** In the Fitting Assistant, the frequency is fixed at 20 Hz. In the advanced mode, it can be modified within the range of 3 – 120 Hz.
  - **Catch Trials per Block:** In the Fitting Assistant, the Catch Trials per Block is fixed at 8. In the advanced mode, it can be modified to 8, 4, 2, or None. Additionally, “Auto” lets the software determine the number of catch trials based on the number of electrodes being tested.
4. Click the “Continue to electrode selection” button to continue.

Choose up to six single or six quad electrodes to test in this run from the Electrode Selection GUI. Mixing singles and quads is not permitted. Click on the “Continue” button to move to the next step.

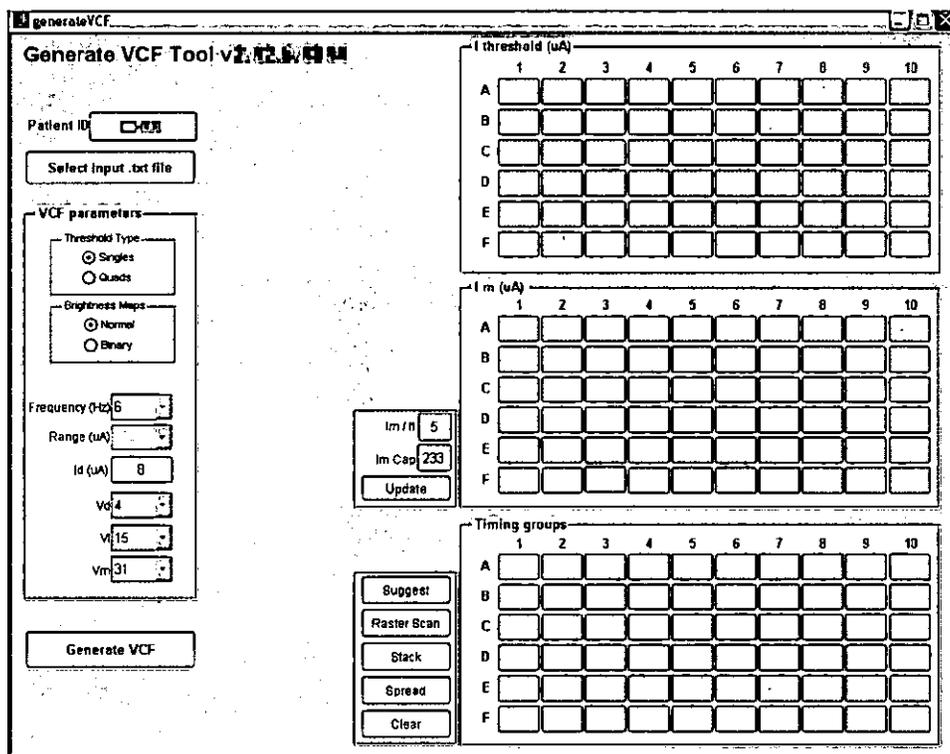
5. Set the maximum current for each electrode or quad if necessary. If the patient is comfortable with stimulation on a certain electrode up to a point, but you do not wish to stimulate up to 677  $\mu$ A in Hybrid Threshold, you can set the maximum current for individual electrodes in Hybrid Threshold. Choose a value at which stimulation is comfortable for the patient.
6. Proceed through the steps to complete the Hybrid Threshold measurement as laid out in Section 3.9.2 Steps 8 - 16.

### 3.15.3 Generate VCF in Advanced Mode

To start Generate VCF Tool in the advanced mode:

1. Open the “Argus II Generate VCF Tool” by clicking the icon in the Start menu. It is not necessary to have Argus II Clinician Fitting System Software running. The GUI will open with no data (Figure 3.71).

Figure 3.71 Generate VCF Tool in Advanced Mode



- Click on "Select input .txt file". Select the desired .txt file that contains the threshold values for the patient and click "Open". The threshold data will be populated in the **I threshold** table along with suggested  **$I_m$**  and **Timing Groups**. The .txt file must contain thresholds in the following format: the first line contains the header text **Label,SingleThreshold,QuadThreshold**; the subsequent 60 lines contain each electrode label in sequence followed by the single and quad threshold values for that electrode separated by commas. For example,

```

Label,SingleThreshold,QuadThreshold
A01,468,65
A02,73,65
A03,121,65
A04,,65
A05,,
.
.
.
F10,52,28
    
```

**Note:** Disabled electrodes or electrodes with no measurable single or quad thresholds are listed with no values (e.g., A04 in the above list has no measurable single threshold; A05 is either disabled, not measured, or has no measurable threshold). It is required to have commas separating each field.

3. In addition to all the parameters described in Section 3.9.3, the following parameters can be modified in the advanced mode:
- **Threshold Type:** The VCF uses threshold data to define the stimulation amplitude in response to the video signal. The thresholds are either measured as “Singles” or “Quads”. You can choose to use either the single or quad threshold values from the .txt file.
  - **Range:** The current range is the maximum stimulation current that can potentially be delivered to each electrode. The VCF can support the current ranges of 125  $\mu\text{A}$ , 250  $\mu\text{A}$ , 500  $\mu\text{A}$ , and 1000  $\mu\text{A}$ . The appropriate setting for this parameter is made automatically based on the maximum stimulation current required.
  - **$I_{\text{dark}}$  ( $I_{\text{d}}$ ):** is the minimum current amplitude on a single electrode or a quad (a constant stimulation level when there is no information in the image). Default is 8  $\mu\text{A}$  if all thresholds are above 40  $\mu\text{A}$ , otherwise it is 0  $\mu\text{A}$ . If the patient reports that he or she can see phosphenes even in a very dark place when the system is in use, you can lower the  $I_{\text{d}}$  level. Allowed values range from 0 to the lowest threshold value contained in the .txt file.
  - **$V_{\text{d}}$ :** is the video level below which information will be ignored. Allowed values range from 1 to 31.
  - **$V_{\text{t}}$ :** is the video level at which an image that fills the field of view of a single electrode will elicit a percept 50% of the time. Allowed values range from  $V_{\text{d}}$  to 31.
  - **$V_{\text{m}}$ :** is the video level above which changes in brightness is not coded. Allowed values range from  $V_{\text{t}}$  to 31.
  - **I threshold:** The threshold values from the most recent measurements of Hybrid Thresholds are automatically populated. They can be manually adjusted.
4.  $I_{\text{m}}$  values in the  $I_{\text{m}}$  table and the timing groups can be modified in the same way as in Fitting Assistant.

# 4 Prepare and Train Your Patient for Device Use

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## 4.1 Introduction

The Argus II Retinal Prosthesis System is typically used in stand-alone mode (a) in the clinic to perform testing or training that requires mobility and (b) when the patient is using the system outside the clinic. The stand-alone configuration is described in Section 2.4.3. The VPU components and the switch positions are described in Section 2.3.4. The instructions below describe the following:

- Connecting the Equipment in Stand-Alone mode
- Basic VPU Settings

## 4.2 Connecting the Equipment in Stand-Alone Mode

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

1. **Confirm that a battery with sufficient charge is installed in the VPU.** Prior to turning on the VPU, make sure the battery has enough charge left or install a newly charged battery. Refer to Chapter 5 Product Maintenance, for instruction on checking battery charge level for the medium size battery, removal of battery, and installation of battery.
2. **Wearing the VPU.** 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). Insert the battery into the receptacle and secure the VPU in place with the other Velcro® strap. The VPU pouch can be worn on the body. It can be adjusted to hold the VPU in the most comfortable position.
3. **Connect the Glasses to the VPU.** The glasses are equipped with a cable that is inserted into the glasses receptacle located at 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. 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.
  - b. Locate the round-shaped glasses receptacle on the VPU.
  - c. Insert the cable plug into the glasses receptacle. Ensure that the cable end of the plug is pointed 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, the plug will insert into the glasses receptacle.

- d. Push the plug firmly into the receptacle until you hear a click. Note that the plug does not lock.
4. **Disconnecting the Glasses from the VPU.** Always turn off the VPU 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.

5. **Have the Patient Put on the Glasses.** Instruct the patient to use both hands and gently put on the glasses as one would a normal pair of glasses. The VPU pouch strap and glasses cable should be adjusted so that they are comfortable and do not catch on anything (for example, the patient's arms or clothes). The cable may be threaded inside the patient's clothing to prevent it from getting caught on objects while moving.
6. **Adjust the Coil Position.** If necessary, adjust the coil position to optimize the communication with the implant. The coil position is adjusted by adjusting the screws on the RF board/coil assembly and sliding the assembly horizontally along the arm of the glasses. Once a good position is found, the screws should be tightened in place.

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

### 4.3 Basic VPU Settings

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

1. **Turning on the VPU.** To turn on the VPU, press and hold the circular power button on the side of the VPU for approximately two seconds. Four short beeps will signal that the system is starting up.
2. **System Start-up Diagnostic Tests.** Immediately after the VPU is turned on, the system performs a series of diagnostic tests. These tests last approximately 30 seconds. During this time the green LED indicator will blink quickly. Once these tests are complete, stimulation will begin and the green LED indicator will blink more slowly to indicate that the system is operating properly.
3. **Changing Program Settings.** The VPU has three program settings. Each program setting can have its own VCF and a specific set of filter parameters. The program can be changed by pressing one of the three program setting buttons on the front of the VPU to find the best program for the environment in which the device is being used. Every time the VPU is switched on, it defaults to Program Setting 1.

4. **Inverse Setting.** The square-shaped button located on the right-hand side of the VPU is used to invert the image from black-to-white and white-to-black. Each time the button is pressed, the image is inverted. The default setting is in “non-invert” mode. It is set to the “non-invert” mode every time the VPU is switched on.
5. **RF Link Audible Alarm Toggle Switch.** The star-shaped button located on the right-hand side of the VPU is used to switch off /on the RF link alarm. Patients may want to switch off the RF link audible alarm in public or social settings.
6. **Turning off the VPU.** To turn off the VPU, press the power button and hold it down for approximately two seconds. One beep followed by a pause, followed by two short beeps will signal that the system is turning off. Once the VPU is off, all LED indicators on the VPU will be off.

## 4.4 LED and Audible Indicators

The VPU uses both visual and audible indicators to provide information about the status of the VPU and glasses and problems that can occur with the Argus II System. These indicators are described in detail in Tables 2.8 and 2.9 located in Chapter 2.

## 4.5 Training Your Patient to Use the Argus II System

The vision that a patient receives with the Argus II System is different from the vision he or she used to have; there are several important concepts and basic visual skills that the patient has to learn in order to use the system effectively. Once system fitting is complete, it is important to teach the patient these basic skills and to help him or her integrate the skills into daily life. This training can be supplemented by rehabilitation work with low vision therapy specialists.

### 4.5.1 Basic Skills for Using the Argus II System

#### **Skill 1: Eye Movement and Phosphene Location Awareness**

The location in space of phosphenes created by the Argus II System is affected by two factors: 1) the location of the array on the retina and 2) the patient's eye position at the time of stimulation. When Argus II patients scan their camera across a scene, it is vital that they do not move their eyes relative to their heads in order to properly localize objects. Patients often have difficulty keeping their eyes in the proper position, as they have no visual feedback for where their eyes are pointed. In addition, they do not always understand how their eye position relates to where they see the phosphenes.

This training procedure was developed to help patients and clinicians understand the relationship between eye position and phosphene location. A better understanding of the importance of controlling their eye movements may lead to an improvement in performance when Argus II patients are localizing objects using the system.

This procedure requires a tactile target with a single white square on a black background. Seat the patient with the tactile target on his or her lap; describe the target and ask the patient to feel the square. Then, with the Argus II System and camera on (either in stand-alone mode or in PC mode), ask the patient to scan his or her head left to right such that the field of view captures the square (if the system is being stimulated through CFS, you can watch the display to see

when the camera crosses the square). The first time the patient scans, ask him or her to keep the eyes straight with the head (if the patient is wearing clear glasses, you can watch the eyes to make sure they stay straight while scanning). Ask the patient to pay attention to where the percept appeared. Next, ask the patient to repeat the scan, but this time, keep the eyes pointed down (if the RF link stays connected). Ask the patient if the square appeared in a different place (it should have looked as if it were lower the second time, although the square remained in the same place). Practice a few times with the patient until you are sure he or she understands how the position of the eyes affects the location of the percept.

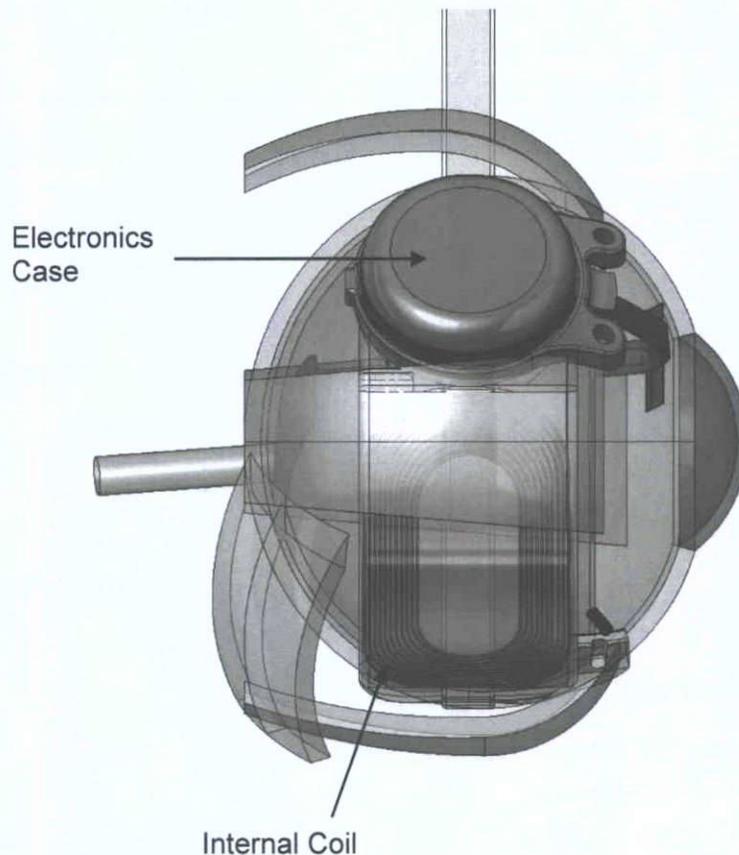
### **Skill 2: Eye Position and RF Link Awareness**

As described above, it is important for patients to keep their eyes straight with their heads while using the Argus II system, in order for them to see percepts in the correct place. In addition, the eyes must remain in the same position relative to the head in order to keep a continuous RF link so data and power continue to flow to the array. The Argus II Implant is driven by the external coil housed on the Argus II Glasses. Shifting of the internal coil (on the patient's eye) relative to the coil on the Argus II glasses may result in a decrease or loss of stimulation.

Show the patient where the RF coil is by asking them to feel the coil while they are wearing the glasses. The coil can be adjusted by tilting it closer to the head, and it can be adjusted slightly forward or backward on the ear piece by sliding the RF board gently back and forth. The coil can also be tucked inside the lens of the glasses or left outside (inside is often preferred). During this training, experiment with the patient to find the best position for the RF coil (the position most likely to keep a steady link). If the VPU is in PC mode and CFS is running, the information on the "RF Calibration" tab can help monitor the patient's link while the patient adjusts the coil to find the best position. (See Section 3.8 RF Calibration)

Explain to the patient that the corresponding coil is located internally – it is secured to the outside of the eyeball, as shown in Figure 4.1.

**Figure 4.1 Argus II Implant, Right Eye, in Position on the Eye (Temporal Side View)**



The internal coil must be in close proximity to the external coil on the glasses. When the eyes move in the head, the internal coil is moved relative to the external coil. Pointing the eyes straight in the head is usually the best position to maintain RF link. Ask the patient to move his or her eyes all the way to the right, then the left, then up, then down. Determine the limits of movement that allow the RF link to be maintained (if the link is broken, the audible alert will sound). Remind the patient that while head scanning, the eyes must stay in the same position relative to the head to maintain link.

### **Skill 3: Head Scanning**

In addition to understanding and controlling eye movements, Argus II patients must also adapt to visually scanning with their head rather than their eyes, as the camera is fixed to the glasses. Therefore, they will not be able to locate an object in space unless they scan their head until the field of view of the camera crosses the object. This is further complicated by the camera alignment – in some cases, the camera may not be pointing straight ahead relative to the forehead. In a case where the camera is pointed down, for example, the patient must move his or her head higher than they might expect to bring the field of view of the camera up to the object. To help the patient locate the field of view of the camera, suggest that he or she wave a hand in front of it until the patient sees the hand motion or blocks the light.

Have the patient practice head scanning using the tactile target boards. Connect the system in video mode and, when the patient is ready, start stimulation. Ensure that the room lights are on and/or there is enough natural illumination in the room. Begin with the white square on the back background. Hold the target board about 12" (30 cm) in front of the patient and ask the patient to scan slowly back and forth with their head until he or she sees a percept. (You can watch the video screen of the CFS computer to ensure that when the patient is reporting seeing a percept, the camera (and array) field of view is over the square.) Ask the patient to touch the square, feeling where it is positioned on the board. Move the position of the target board so the square is in a different place, and repeat the task. If the patient is having trouble understanding where the camera is pointed (if the alignment is non-intuitive or the patient is not well aware of his or her head position) it may help to have the patient keep a finger on the square while scanning. Repeat this training with the small white square until the patient has a good understanding of how to scan efficiently to locate the square. Remind the patient that it is important to keep his or her eyes in line with the head while scanning, as demonstrated in skills 1 and 2. Some strategies that might help:

Tell the patient to imagine he or she is looking through a cardboard tube or binoculars and scanning back and forth to locate and track a bird. The reduced visual field of the tube requires that the eyes sweep along with the head movements.

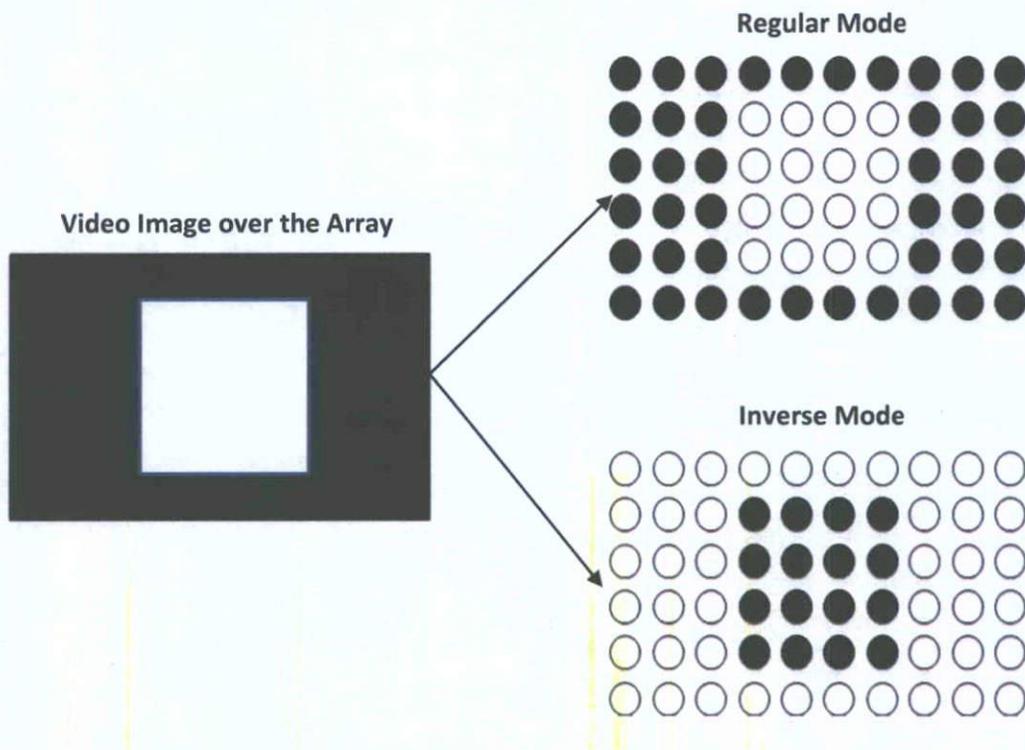
Similarly, patients can imagine they are using a magnifying glass, which is swept back and forth with their head and eyes.

#### **Skill 4: Inverse Mode and Filter Settings**

Train the patients on how to switch between modes and filters, and in what conditions they might prove useful. For more information on the default filters and how to adjust them, see section 3.10.3.

In inverse mode, dark areas in the visual field of the camera will be converted to bright areas, and bright areas will be dark. In other words, if the patient is looking at a white square on a dark background in normal mode, electrodes coinciding with the white square will be stimulated, while electrodes coinciding with the dark background will not. In inverse mode, electrodes coinciding with the square will not be stimulated, while those coinciding with the background will be stimulated, as shown in Figure 4.2.

**Figure 4.2 Schematic of Array Stimulation to the Same Camera Image in Regular Mode and Inverse Mode**



Inverse mode can be useful outdoors on a sunny day, when much of the environment is bright, and most of the contrast is provided by dark objects. Switching to inverse mode in this case will reduce the stimulation to only coincide with the dark objects.

Different program settings are useful in different environments and when performing different tasks. The default filter parameters in Program Setting 2, high contrast enhancement, are particularly useful in low-light conditions. To demonstrate it, reduce the lighting in the room and ask the patient to find the white square on the tactile target; try the task in both Setting 1 and Setting 2. The default filter parameters for Program Setting 3, edge enhancement, combined with a binary VCF, may be useful to some patients who can use their system to see lines. Use the tactile targets with black and white stripes to explore this setting.

# **5 Product Maintenance**

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## **5.1 Service**

For service or to order parts, contact Second Sight. See "How to Contact Second Sight" in Chapter 1, "Before You Get Started", of this manual.

## **5.2 Argus II Implant**

### **5.2.1 Storage**

Store the packaged Argus II Implant at a temperature between -10°C and +55°C (+14°F to +131°F). Do not use the device after the 2-year expiration date printed on the package label.

### **5.2.2 Maintenance**

No maintenance is required on the Argus II Implant. The implant is designed to be self-sustaining after implantation. The implant is electrically active only when an Argus II Video Processing Unit (VPU) is in communication with it. Otherwise, it is an inactive device. If the patient experiences a direct impact near the implant and perceptual change after the impact, please contact the clinic or Second Sight.

Each time the implant is activated, the VPU performs diagnostic tests to ensure the implant is functioning properly. If improper function is detected, the VPU shuts off power to the implant, thus returning the implant to an inactive state. Depending upon the specific circumstances, it may be necessary to surgically remove an improperly functioning implant.

If a problem is encountered with the implant that cannot be resolved, contact Second Sight. Refer to the Contact Information provided in Chapter 1 of this manual.

## **5.3 Argus II VPU and Glasses**

### **5.3.1 VPU Upgrade**

VPU firmware upgrades are required when a new version of CFS software is released. VPU upgrades may only be performed by trained Second Sight personnel with specific upgrade instructions provided by Second Sight.

### **5.3.2 VPU Replacement**

If a patient's VPU needs to be replaced, contact Second Sight Customer Service for a replacement VPU. Once the replacement VPU is received, follow the VPU Cloning procedure described in Section 3.14.3 to transfer the patient-specific settings to the replacement VPU.

### 5.3.3 Routine Handling and Storage

Take care when storing and handling the VPU and glasses, as improper care or storage can result in damage to the equipment. Following the guidelines below can improve the lifetime of this equipment.

- The VPU and glasses are designed to be stored and used at a temperature between 0°C and 45°C ( 32°F and 113°F), and a relative humidity between 5 and 95%.
- The frame of the glasses are fitted with sensitive electronic equipment, including a miniature video camera above the nose bridge and electronic circuits on the earpiece next to the implanted eye. Handle the glasses with care as they are fragile.
- Handle them with care when putting them on or taking them off.
- Use care when attaching or removing any cables or connectors as rough handling can damage the cables or equipment.
- It is recommended that the VPU, glasses, and batteries are stored in the travel case provided by Second Sight as this has been designed to protect the equipment. It is also recommend that you uninstall the battery from the VPU during transit, so as to avoid accidentally turning on the VPU which could drain the battery.
- Do not wrap the cable around the VPU since, over time, this may cause damage to the cable.
- Do not place anything on top of the glasses or VPU.
- 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. The arms are not designed to be closed and trying to fold them may break them.
- Do not expose the external equipment (VPU and glasses) to water (for example, rain, shower, swimming pool, or ocean) as water may render the device inoperable.

### 5.3.4 Routine Cleaning

To clean the battery contacts, follow the instructions in the battery package.

Clean the surfaces of the glasses and electronics board whenever necessary. To clean the VPU, glasses or cables, follow the instructions below.

- Use a clean, slightly damp cloth or an alcohol or germicidal wipe to clean the equipment. Gently rub the areas that require cleaning.
- Use a clean, dry cloth to dry the equipment after cleaning it.
- Use a can of compressed air to remove dust and debris from the system. Use as directed by the compressed air manufacturer.

- Use a soft cloth to remove minor smudges and fingerprints from the glasses. Use compressed air to clean the camera lens on the glasses.

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

### 5.3.5 Cleaning Between Patients

If the glasses are to be used with different patients, ensure they are adequately cleaned with an alcohol or germicidal wipe before use. Allow the glasses to air dry prior to placing them on the patient.

## 5.4 Battery Maintenance

**CAUTION:** Use only Second Sight-supplied rechargeable batteries to power the VPU and the Second Sight-supplied battery charger to recharge the batteries. Use of other batteries may damage the VPU or cause it to function improperly.

It is recommended to always keep at least one spare battery in a fully-charged condition, so that it is immediately available when a replacement is needed.

### 5.4.1 Recharging Batteries

The Argus II System is supplied with a small and a medium sized battery. Use the VPU Battery Charger to recharge the battery. Follow the instructions supplied with the charger to charge the batteries.

### 5.4.2 Changing a VPU Battery

When the battery in use needs recharging, the VPU indicates this by giving a repeating audible signal consisting of four fast beeps, followed by a pause. To remove a depleted battery from the VPU and to replace it with a fully-charged battery, do the following:

1. Remove the battery by sliding 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 slide it out of the receptacle. Release the latch.
2. Install the rechargeable battery, by sliding the VPU battery latch so that it opens. Holding the latch open set the battery in the battery receptacle of the VPU. Slide the battery in the receptacle away from the latch until the battery latch can be released back down into its locked position.
3. Confirm that the battery is properly installed by gently pulling it. If the battery comes loose, it was not properly installed. Repeat steps 1-2 again to properly re-install the battery.

### 5.4.3 Disposal of Batteries

The VPU uses rechargeable batteries. Dispose of a battery or battery charger when it reaches the end of its life. Use battery disposal procedures that comply with local regulations.

**WARNING**



**Do not dispose of the VPU batteries or the battery charger in a fire as this may cause an explosion and/or the release of toxic fumes.**

### 5.4.4 Battery Life

Actual battery life may vary based on settings, usage patterns, and environmental conditions. On average the small rechargeable battery will last 2.5 to 3.5 hours and the medium battery will last 4 to 6 hours when fully-charged. Battery capacity will drop gradually with use of the device and over time. When the available battery time is shortened considerably, a probable cause is that the battery has reached the end of its life.

## 5.5 Upgrading the Argus II Clinician Fitting System (CFS)

The Argus II Clinician Fitting System (CFS) software is pre-installed on a dedicated laptop computer. Software upgrades may only be performed by trained Second Sight personnel with specific upgrade instructions provided by Second Sight.

The CFS computer should be kept free of dust at all times. The computer may be cleaned with a soft cloth dampened with water. Do not use detergent or any other chemical agents on the CFS.

## 5.6 Argus II Communication Adapter (CA)

The CA should be kept free of dust at all times. Take care so that the cables do not become twisted or pinched. The CA may be cleaned with a soft cloth dampened with water. Do not use detergent or any other chemical agents on the CA.

## 5.7 Argus II Cables

The cables of the Argus II System should be kept off the floor and free of dust. Take care that the cables do not become twisted or pinched, as broken wires can result. The connector and plug-in ends of the cables are vulnerable to damage. When connecting/disconnecting cables, use a steady, firm pressure, but never force a cable into a connector. Cables may be cleaned with a soft cloth dampened with water. Make sure that the connector ends do not become wet. Do not use detergent or any other chemical agent on the cables.

## 5.8 Disposal of Argus II System Components

### VPU and Glasses

Do not dispose of the VPU or glasses. Always return this equipment to the Second Sight (see address below). If an exchange or replacement of equipment is occurring through your clinician, they will ensure that the equipment is properly returned.

### 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 or battery charger when it reaches the end of life. Follow procedures that comply with your local regulations and the package insert to safely dispose of a battery or battery charger. Batteries and chargers can be disposed of according to local electronics waste regulations.

#### **WARNING**



**During transport, storage and handling for disposal, the following safety precautions should be considered:**

**Do not dispose of the VPU batteries or the 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.**

**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 generated heat may ignite flammable wastes and cause a fire.**

## Argus II Implant

If the Argus II Implant is explanted for any reason, Second Sight must be contacted first except in the event of medical emergency. The explanted unit must be returned to Second Sight for evaluation and warranty purposes and disposition. Your clinician should request a biohazard explant kit from Second Sight.

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

12744 San Fernando Rd., Building 3  
Sylmar, CA 91342 USA  
Phone: +1 818 833 5000

## **5.9 Disposal of Packaging Material**

The shipping carton for the Argus II System components and accessories and packaging materials should be disposed of according to local regulations.

# 6 Troubleshooting

This chapter provides instructions for clinicians and personnel on how to fix a problem if one is encountered.

Troubleshooting symptoms are provided in the left column and the "Cause and/or Corrective Action" is provided for each is provided in the right column. If you cannot find the problem in this chapter or if the recommendations do not fix the problem, please contact Second Sight using the information provided in Section 1.6 of Chapter 1.

## 6.1 Troubleshooting, VPU & Glasses

Symptom	Cause and/or Corrective Action
The VPU does not start.	<ol style="list-style-type: none"><li>1. Check that the battery is installed properly. If it is not installed properly, refer to instructions in Section 5.4.2 of Chapter 5.</li><li>2. Install a fully-charged battery.</li><li>3. Ensure that the correct button is being pressed. The power button is the circular-shaped one on the right side panel of the VPU.</li><li>4. Ensure that the power button is being pressed for at least two seconds. If the button is pressed for less than a second, the VPU will not turn on.</li><li>5. If the above steps do not fix the problem, contact Second Sight using the information provided in Chapter 1.</li></ol>
The VPU produces an audible warning (2 or 3 short beeps) and shuts off suddenly	<ol style="list-style-type: none"><li>1. Turn on the VPU to see if this occurs again.</li><li>2. If the problem persists, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li></ol>
The VPU shuts off suddenly without an audible warning	<ol style="list-style-type: none"><li>1. Install a fully charged battery.</li><li>2. Turn on the VPU to see if this occurs again.</li><li>3. If the above steps do not fix the problem, contact Second Sight using the information provided in Chapter 1.</li></ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but the patient does not see anything</p>	<ol style="list-style-type: none"> <li>1. Make sure the VPU RF link alarm is not muted. Ensure that the VPU is not making any audible alarms. If it is, check that the glasses cable is properly plugged into the VPU glasses receptacle.</li> <li>2. Gently press the coil mounted on the glasses closer to the patient's eye. If the audible alarm stops beeping and resumes beeping when you stop pressing the coil, this indicates that the external coil on the glasses needs to be adjusted to ensure the communication between the external coil and the implant is reliable.</li> <li>3. Ensure that nothing is blocking the video camera on the glasses. If there is something blocking the video camera, try to remove the obstruction.</li> <li>4. Ensure that the lens on the camera is clean. Refer to Section 5.3.2 "Routine Cleaning" in Chapter 5.</li> <li>5. Ensure that there is adequate lighting.</li> <li>6. Ensure that you are using the correct stimulation setting. Switch between the normal/invert settings by pressing the square-shaped invert button.</li> <li>7. Ensure that the intended program setting is being used to provide the optimum perception by experimenting with the different program settings.</li> <li>8. If the VPU is connected to the CFS, ensure that the correct VCF is loaded on the VPU in the intended program setting.</li> <li>9. Switch off the VPU for 5 minutes and switch it back on.</li> <li>10. If the above steps do not fix the problem, contact Second Sight using the information provided in Chapter 1.</li> </ol>
<p>The VPU is on, but the image seems distorted</p>	<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 to Section 5.3.2 Routine Cleaning in Chapter 5.</li> </ol> <p>If the above steps do not fix the problem, contact</p>

Symptom	Cause and/or Corrective Action
	<p>Second Sight using the information provided in Chapter 1.</p>
<p>The VPU is on, but the patient's perception is dimmer than usual</p>	<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 to Section 5.3.2 "Routine Cleaning in Chapter 5.</li> <li>3. Ensure that there is adequate lighting.</li> <li>4. Ensure that you are using the correct stimulation setting. Switch between the normal/invert settings by pressing the square-shaped invert button.</li> <li>5. Ensure that the intended program setting is being used to provide the optimum perception by experimenting with the different programming setting buttons.</li> <li>6. Switch off the VPU and let the patient rest for 10 minutes and switch it back on.</li> </ol> <p>If the above steps do not fix the problem, contact Second Sight using the information provided in Chapter 1.</p>
<p>The coil on the glasses seems warmer than usual</p>	<ol style="list-style-type: none"> <li>1. Adjust the glasses to see if the coil cools down to its usual operating temperature.</li> <li>2. If the problem is persistent or the coil is getting unusually warm, contact Second Sight using the information provided in Chapter 1.</li> </ol>
<p>There is a clicking sound from the area of the RF board on the glasses</p>	<p>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</p>	<p>Turn the glasses over and lay them on a flat surface so that the top of the frame is in contact with surface. Take the nosepiece and place it on the underside of the lens where the nosepiece should be attached. Press firmly to lock the nosepiece back in place. This step should be conducted by a sighted person.</p>

## 6.2 Troubleshooting, VPU Visual Indicators

The VPU uses both visual and audible indicators to provide information about the status of the VPU and glasses and problems that can occur with the Argus II System. Refer to Table 2.6 of Chapter 2 for the meaning of the visual indicators.

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The green LED is not blinking	<ol style="list-style-type: none"> <li>1. Install a fully charged battery.</li> <li>2. Turn off the VPU and turn it back on again to see if the problem is fixed.</li> <li>3. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
The orange LED turns on (loss of video signal)	<ol style="list-style-type: none"> <li>1. Ensure that the green LED is still blinking.</li> <li>2. Check that the glasses cable is properly connected to the glasses receptacle on the VPU. Refer to Section 4.2 in Chapter 4 for connecting the glasses to the VPU.</li> <li>3. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
The amber LED turns on (loss of RF link)	<ol style="list-style-type: none"> <li>1. Ensure that the green LED is still blinking.</li> <li>2. Adjust the glasses to improve RF link (see Section 3.8.1) and see if the amber LED goes off.</li> <li>3. If the above step does not fix the problem, check that the glasses cable is properly connected to the glasses receptacle. Refer to Section 4.2 of Chapter 4 for connecting the glasses to the VPU.</li> <li>4. The patient may need to restrict the eye movement to maintain the link between the implant and the external coil.</li> <li>5. If the above steps do not fix the problem, replace the glasses or contact Second Sight for the replacement glasses using the information provided in Section 1.6 of Chapter 1.</li> </ol>

### 6.3 Troubleshooting, VPU Audible Indicators

The VPU uses both visual and audible indicators to provide information about the status of the VPU and glasses and problems that can occur with the Argus II System. Refer to Table 2.9 in Chapter 2 for the meaning of the audible indicators.

Symptom	Cause and/or Corrective Action
<p>The VPU shuts off suddenly emitting three short beeps (error induced VPU shutdown)</p>	<ol style="list-style-type: none"> <li>1. Turn on the VPU to see if this occurs again.</li> <li>2. If the VPU continues to shut itself off, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
<p>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)</p>	<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 Section 5.4.2 of Chapter 5 for changing a VPU battery.</li> <li>3. Turn on the VPU and allow the VPU to finish the start-up test. Ensure the same beeping pattern does not occur after the start-up test.</li> <li>4. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
<p>The VPU emits a slow periodic beep (loss of video signal)</p>	<ol style="list-style-type: none"> <li>1. Ensure that the green LED 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 Section 4.2 in Chapter 4 for connecting the glasses to the VPU.</li> <li>3. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU emits a fast periodic beep about 2 per second (loss of RF link)</p>	<ol style="list-style-type: none"> <li>1. Ensure that the green LED is still blinking approximately 1 blink per second.</li> <li>2. Adjust the glasses to improve RF link (see Section 3.8.1) and see if the amber LED goes off.</li> <li>3. Advise the patient to limit their eye movements and look straight ahead.</li> <li>4. If these measures are unsuccessful in correcting the problem, check that the glasses cable is properly connected to the glasses receptacle – if not, follow instructions in Section 4.2 in Chapter 4 for connecting the glasses to the VPU.</li> <li>5. This fast periodic beep can be turned off by pressing the star-shaped toggle switch on the VPU when in stand-alone mode.</li> </ol>
<p>The VPU does not operate as intended, but the patient does not hear any audible alarms</p>	<ol style="list-style-type: none"> <li>1. Press the star-shaped audible RF link alarm toggle switch to ensure the RF link alarm is “on”.</li> <li>2. If the patient still cannot hear the audible alarm, check whether the amber or the orange LED is on. If not, the patient will not hear any audible alarms. If the amber or the orange LED is on and an audible alarm is present, ensure that the VPU is within the patient’s hearing range.</li> <li>3. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
<p>The VPU operates as intended, but the patient hears an unexpected audible alarm</p>	<ol style="list-style-type: none"> <li>1. Refer to Table 2.9 in Chapter 2 of the manual for an explanation of the audible alarms.</li> <li>2. If you still cannot recognize the audible indicator, turn off the VPU. Install a fully-charged battery and turn it on to see if this sound occurs again.</li> <li>3. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>

## 6.4 Troubleshooting, Clinician Fitting System (CFS)

Symptom	Cause and/or Corrective Action
Unable to log in to CFS	<ol style="list-style-type: none"> <li>1. Be sure you are using the correct username, password, and patient ID.</li> <li>2. Re-try login.</li> <li>3. Check that the security file is loaded. This requires assistance from Second Sight</li> <li>4. Click on the "Argus II Clinician Fitting System" folder in the "Start" menu and select the "Remove running.txt File" option.</li> <li>5. If the above steps do not fix the problem, restart the computer.</li> <li>6. If the problem persists, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
The VPU-implant matching CD does not release from the CD-RW/DVD-ROM drive	<ol style="list-style-type: none"> <li>1. Go to the Windows Explorer. Right click on the CD/DVD drive and click on "Eject".</li> <li>2. If this does not work, close the CFS program.</li> <li>3. Turn the CFS computer off and then back on again.</li> <li>4. Try to eject the CD again.</li> <li>5. If steps 1-4 do not work, push a straightened paperclip into the hole near the eject button on the CD/DVD drive on the side of the computer. This should eject the CD.</li> <li>6. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The VPU is accidentally turned off during the middle of a patient testing session	<ol style="list-style-type: none"> <li>1. Sign out of the CFS application.</li> <li>2. Turn off all equipment (i.e. CFS, and VPU).</li> <li>3. Re-start all equipment.</li> <li>4. Re-start testing session.</li> </ol>
The CFS computer will not turn on	<ol style="list-style-type: none"> <li>1. Unplug the power cord.</li> <li>2. Uninstall and then reinstall the battery.</li> <li>3. Plug the power cord in again.</li> <li>4. Try turning the computer on again.</li> <li>5. If the above steps do not fix the problem, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>
In the process of archiving the sessions the following error message is received, "Application shut down due to internal error"	Shut down the application and then retry.
The CFS cannot be launched	This typically happens after the CFS has crashed or was not closed normally. Click on the "Argus II Clinician Fitting System" folder in the "Start" menu and select the "Remove running.txt File" option. After deleting the "running.txt" file, restart the CFS.
When changing the program setting buttons on the VPU, sometimes the setting buttons on the CFS screen does not seem to change accordingly.	Always use the setting buttons on the CFS screen ("Set 1", "Set 2", or "Set 3") to change the program settings when the VPU is connected to the CFS.

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The CFS displays an error message indicating that "PreVdolsrhTestFailure" is true</p>	<p>This could be an indication that the glasses coil is too close to the implant coil.</p> <ol style="list-style-type: none"> <li>1. Log out of CFS, shut down the VPU, wait for 10 seconds and restart the VPU.</li> <li>2. Log in to CFS and the error message should not be displayed. If the error message persists, log out of CFS and shut down the VPU.</li> <li>3. Adjusting the coil in the glasses by moving it backward (away from the eye). Once the coil is in its new position, restart the VPU.</li> <li>4. Log in to CFS and the error message should not be displayed. If the error still persists, contact Second Sight using the information provided in Section 1.6 of Chapter 1.</li> </ol>

## 7 Electrical Specifications

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Parameter	Specification
Pulse Amplitude*	0-1000 $\mu$ A 4 current ranges (0-125, 0-250, 0-500, 0-1000) each with 31 discrete steps
Pulse Width*	32.5 $\mu$ s – 3.0 ms (in increments of 32.5 $\mu$ s)
Pulse Rate* (Frequency of Stimulation)	0.25 Hz – 120 Hz (only selected discrete frequencies are supported in this range)
Carrier Frequency	3.156 MHz
Maximum Compliance Voltage	6.8 V
Maximum Charge Density per phase in stand-alone mode	0.35 mC/cm <sup>2</sup>
Maximum Charge Density per phase in PC mode	1.0 mC/cm <sup>2</sup>
Maximum Current per Electrode	1.0 mA

\* Maximum values of all parameters are not obtainable simultaneously on all electrodes owing to safety limitations.

# 8 *Warranty*

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

If an Argus II Implant fails to function within normal tolerances within 3 years from the date of implantation as a result of a failure to manufacture the Argus II Implant in accordance with Second Sight Medical Products, Inc.'s (Second Sight's) manufacturing specification, Second Sight Medical Products, Inc. will provide a functionally equivalent Second Sight replacement implant. This warranty is limited to implant failures, and does not apply to out of specification performance due to surgical complications or the patient's medical conditions.

Claims under the Limited Warranty on Argus II Retinal Prosthesis (Implant) are subject to the following conditions and limitations:

1. The implant must be implanted before the end of the "Use By" date marked on the package.
2. The Implant Registration Form provided by Second Sight is completed and received by Second Sight.
3. Implant failure must be confirmed by Second Sight before explantation and replacement of the device.
4. The explanted unit must be returned to Second Sight for analysis within 15 days of explantation along with a report describing the circumstances of the removal. Explanted devices returned to Second Sight for analysis become the property of Second Sight.

### **WARRANTY DISCLAIMER:**

**SECOND SIGHT EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. SECOND SIGHT WILL NOT BE LIABLE FOR ANY DIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES CAUSED BY THE IMPLANT'S FAILURE TO FUNCTION WITHIN THE NORMAL TOLERANCES WITHIN 3 YEARS WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.**

Second Sight reserves the right, in its sole discretion, to provide a functionally equivalent Second Sight replacement implant even if the failure to perform within normal tolerances during the Three-Year Limited Warranty period is for reasons other than a failure to manufacture the implant in accordance with Second Sight's manufacturing specifications.

## 8.2 Limited Warranty on Argus II External Equipment

Second Sight warrants to the purchaser of a new Argus II Video Processing Unit (VPU) or glasses or Operating Room Coil (OR coil) that it is free from defects in workmanship and materials for a period of one year from the date of initial VPU fitting (or time of purchase if purchased separately).

Second Sight further warrants to the purchaser of a new Argus II VPU that the supplied battery charger (including charger base and AC adaptor) and rechargeable batteries are free from defects in workmanship and materials for a period of 3 months from the date of initial VPU fitting (or time of purchase if purchased separately).

The exclusive remedy for breach of this warranty is: (a) repair or replacement of the defective VPU, glasses, OR coil or Charger with a functionally equivalent Second Sight replacement product, or (b) at Second Sight's option, full credit equal to the original purchase price of the defective VPU, glasses, OR coil or charger to be applied towards the purchase of a new replacement component.

**SECOND SIGHT EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE. Any accessory items included with the VPU are warranted for a period of 3 months from initial VPU fitting (or time of purchase if purchased separately).**

Product claims under Second Sight Limited Warranty on External Equipment are subject to the following conditions and limitations:

1. The product registration forms for the VPU and glasses must be completed and returned to Second Sight within 30 days of initial fitting or receipt of the product in order to receive the benefits of this warranty.
2. Items covered by this warranty that are the subject of the warranty claim must be returned to Second Sight (or its authorized agent) within 30 days after receipt of replacement part (s).
3. Second Sight must be able to confirm the component failure.
4. This warranty specifically excludes defects caused by: (a) fire, floods, lightning, natural disasters and other calamities defined as "Acts of God;" (b) accident, misuse, abuse, negligence, water immersion damage, improper fitting or connecting of components or failure to operate the VPU, glasses or Charger in accordance with the manufacturer's instructions; (c) wear and tear resulting in cosmetic or exterior damage; (d) attempts to repair, maintain, or modify the equipment by the customer or any third party not authorized by Second Sight; (e) performance problems caused by attachment of any component of an Argus II VPU, glasses or OR coil to any equipment or device not supplied by Second Sight without the prior approval of Second Sight; (f) cable breakage (appropriate care should be taken to prevent forces from damaging cables); (g) 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); or (h) 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 the purchaser.

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

For information regarding the above warranties or in the event of suspected device failure, please contact Second Sight using the contact information provided in this manual.

### **8.3 Limited Warranty on Argus II Clinician Fitting System (CFS)**

Second Sight warrants to the purchaser of a new Argus II Clinician Fitting System (CFS) that it is free from defects in workmanship and materials for a period of 12 months from the date of purchase. The Argus II CFS includes the CFS laptop computers and the USB and external drives provided by Second Sight to use with the CFS, the Argus II Communication Adapters and cables, and other accessories used for programming the device.

The exclusive remedy for breach of this warranty is: (a) repair or replacement of the defective CFS with a functionally equivalent Second Sight replacement product, or (b) at Second Sight' option, full credit equal to the original purchase price of the defective CFS to be applied towards the purchase of a new replacement CFS.

**SECOND SIGHT EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE.**

Product claims under Second Sight' Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Second Sight within 30 days of receipt of the product in order to receive the benefits of this warranty.
2. The CFS that is the subject of the warranty claim must be returned to Second Sight (or its authorized agent) within 15 days after discovery of the defect.
3. Second Sight must be able to confirm the CFS failure.
4. This warranty specifically excludes defects caused by: (a) fire, floods, lightning, natural disasters and other calamities defined as "Acts of God;" (b) accident, misuse, abuse, negligence, water immersion damage, improper fitting or connecting of components or failure to operate the CFS in accordance with the manufacturer's instructions; (c) wear and tear resulting in cosmetic or exterior damage; (d) attempts to repair, maintain, or modify the equipment by the customer or any third party not authorized by Second Sight; (e) performance problems caused by attachment of any component of an Argus II CFS to any equipment or device not supplied by a Second Sight without the prior approval of Second Sight; (f) cable breakage (appropriate care should be taken to prevent forces from damaging cables); (g) 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); or (h) accessories not listed with this limited warranty.

5. For a replacement CFS, the warranty will run only to the end of the warranty period for the original component that was replaced.

### **Outside the United States**

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

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**Date of Issue: FEB-2013**



Second Sight

**Argus<sup>®</sup> II**  
**Retinal Prosthesis System**

**Product Insert**

**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.

900007-003 Rev C

**Argus<sup>®</sup> II**  
**Retinal Prosthesis System**  
**Product Insert**

**Second Sight Medical Products, Inc.**

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## DEVICE DESCRIPTION

The Argus II Retinal Prosthesis System (hereinafter referred to as "Argus II System") consists of implanted and external components. The implant is an epiretinal prosthesis that includes a receiver, electronics, and an electrode array that are surgically implanted in and around the eye. The array has 60 electrodes arranged in a rectangular grid, of which 55 are enabled. It is attached to the retina over the macula with a retinal tack. The external equipment includes glasses, a video processing unit (VPU) and a cable. The glasses include a miniature video camera, which captures video images, and a coil that transmits data and stimulation commands to the implant. The VPU converts the video images into stimulation commands and is body-worn. The cable connects the glasses to the VPU. The Argus II System operates by converting video images into electrical energy that activates retinal cells, delivering the signal through the optic nerve to the brain where it is perceived as light. The Argus II Clinician Fitting System (CFS) and Psychophysical Test System (PTS) are used in the clinic to test and program the Argus II Implant and External Equipment.

## 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. It is indicated for use in patients with severe to profound retinitis pigmentosa who meet the following criteria:

- Adults, age 25 years or older.
- Bare light or no light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
- Previous history of useful form vision.
- Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
- Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

The Argus II implant is intended to be implanted in a single eye, typically the worse-seeing eye.

## CONTRAINDICATIONS

- Ocular diseases or conditions that could prevent the Argus II System from working (e.g. optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, severe strabismus, etc.).

- Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g. extremely thin conjunctiva, axial length <20.5 mm or >26 mm, corneal ulcers, etc.).
- Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the eye (e.g. corneal opacity, etc.).
- Inability to tolerate general anesthesia or the recommended antibiotic and steroid regimen associated with the implantation surgery.
- Metallic or active implantable device(s) (e.g. cochlear implant) in the head.
- Any disease or condition (e.g. significant cognitive decline, etc.) that prevents understanding or communication of informed consent, fitting of the Argus II System, or post-operative follow-up. A pre-operative psychological evaluation may be recommended to confirm the patient is not contraindicated based on this criterion.
- Predisposition to eye rubbing.

## WARNINGS

- Failure to follow the recommended surgical procedure for implanting the Argus II Implant may increase the risk of adverse events and damage to the implant.
- **Individuals implanted with an Argus II Implant should not undergo short wave or microwave diathermy.** High currents induced in the implant electrodes can cause tissue damage or serious injury. Diathermy may also cause permanent damage to the implant.
- **Individuals implanted with an Argus II Implant should not undergo electroconvulsive therapy (ECT)** as ECT may cause tissue damage or permanent damage to the implant.
- If **lithotripsy or high output ultrasound** must be used, do not focus the treatment beam near the Argus II Implant. Exposure of the Argus II Implant to these therapies may harm the patient or damage the implant.
- The Argus II Implant has been classified as an **MR Conditional** device. Individuals with an Argus II Implant may undergo a **magnetic resonance imaging (MRI)** procedure **ONLY** if it is performed using a 1.5 or 3.0 Tesla MRI System and **ONLY** following the MRI Instructions provided later in this insert. Individuals with an Argus II Implant should not enter a room housing an MRI System that has a rating other than 1.5 or 3.0 Tesla, even if the Argus II System is not being used. The external equipment (i.e. VPU and glasses) should remain outside

the MR system room, as **severe harm to people in the MR system room could occur**. If any pain is experienced during the MRI procedure the patient should be instructed to notify the technician immediately.

- The Argus II System may interfere with the operation or accuracy of **medical monitoring, diagnostic or life support equipment**. Do not use the Argus II System within 3 feet (0.9 meters) of this type of equipment. If interference occurs, turn off the Argus II VPU or extend the distance between yourself and the affected equipment.
- Do not use **monopolar electrosurgical equipment** in individuals with an Argus II Implant. Monopolar electrosurgical equipment may cause damage to the implant or to tissue surrounding the implant.

## PRECAUTIONS

- In the event of any **undesirable sensation** when using the Argus II System (for example, pain), immediately halt operation of the system by removing the Argus II Glasses or turning off the Argus II VPU.
- At any time after implantation, Argus II patients have a risk of conjunctival complications which, if left untreated, may result in conjunctival erosion which could lead to endophthalmitis. Argus II recipients should be vigilant in reporting any new symptoms of foreign body sensations, tearing and/or pain promptly to their eye care professional. Long-term professional monitoring for late conjunctival issues is necessary.
- The long-term effects of **chronic electrical stimulation** are unknown. Such effects may include deterioration of the retina or optic nerve. These effects may lead to deterioration of residual native vision and/or visual response to the Argus II System and could preclude subsequent replacement of the Argus II Implant with another retinal implant.
- Individuals with an Argus II Implant should **only use a VPU that has been specifically programmed for them** by their clinician or Second Sight personnel. Use of a different VPU may be ineffective in providing visual information and may cause physical discomfort from overstimulation.
- To avoid unsafe stimulation, do not use a **VPU configured for Operating Room** use for anything other than pre-implantation testing, testing during implantation, or initial fitting testing.
- Individuals with an Argus II Implant should **avoid physical impact or extreme direct pressure to the eye** as this

may result in eye trauma, movement or damage to the Argus II Implant. If this occurs, consult your physician.

- Individuals with an Argus II Implant should **avoid eye rubbing** as this may dislodge the implant or cause eye irritation.
- Individuals with an Argus II Implant should continue to use their other **mobility aids** (e.g. canes, dogs, etc.) at all times.
- Use of the Argus II System during **pregnancy and nursing** has not been evaluated.

## **Precautions Regarding Other Medical Procedures**

### **General Information (applicable to all procedures)**

- Individuals needing to undergo any of the procedures listed below, should inform his or her doctor about the existence of a retinal prosthesis in the eye. The doctor should contact Second Sight at 1-818-833-5060 for more information.
- **Before having any medical or test procedure that involves the use of other medical equipment, individuals with an Argus II Implant should remove the Argus II Glasses and VPU.**
- Once the procedure is complete, that individual should have the Argus II Implant tested 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)** – Refer to the Warnings section above and the MRI Information section below for more information about MRI.
- The use of **laser, phacoemulsification, or fragmatome** may damage the Argus II Implant. If these procedures must be used in an implanted eye, do not direct the laser beam at the implant. Extra caution should be used when performing these procedures intraocularly as visualization of the implant may be obscured.
- The use of **bipolar electrosurgical equipment** may damage the Argus II Implant. Use caution when using this equipment near the implant.
- **CT Scans or Diagnostic Ultrasound** may be performed in individuals with an Argus II Implant. However, if a scan or ultrasound is performed in the region where the Argus II Implant is located, the implant may create an image artifact making the scan unreadable in this region.
- Use of **defibrillators or therapeutic ionizing radiation to the head** may permanently damage the Argus II Implant. However, this should not preclude or change the way in which these treatments are delivered. The Argus II Implant should be tested by a qualified clinician or Second Sight personnel as soon as possible following the procedure or defibrillator activation to confirm that it is still functioning properly. Damage to the implant may not be immediately detectable.

- The effects of **cobalt treatment and linear acceleration** techniques on the implant are unknown.

### **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 the Argus II System. The Argus II System meets international standards for electromagnetic compatibility and is designed to continue to operate in a "safe mode" in the presence of any electromagnetic interference which would normally be encountered during every day use of the Argus II System. It is important to note, however, that in certain circumstances, electromagnetic interference could cause the following:

- **Serious injury.** Exposure of the implant to EMI may result in the implant heating and damaging nearby retinal tissue. See "Warnings" on page 2.
- **Damage to the 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 2.
- **Unexpected Turning off of the Argus II VPU.** EMI may cause the VPU to turn off unexpectedly.
- **Interruption of Stimulation.** EMI may cause a momentary interruption of stimulation.

Argus II System users should be advised that upon entering an environment which maybe causing interference with the Argus II System, they should move away from the equipment or object thought to be causing the interference, if possible, turn off the equipment or object causing the interference, tell the equipment operator or the doctor what happened and, if they continue to experience interference or think that the Argus II System is not working as well as it did before they encountered the interference, to contact their doctor.

## Possible Interference with Other Electronic Devices

- **Theft or metal detectors** (such as those located in entrances to public buildings and department stores) and **airport or security screening devices** may temporarily interrupt Argus II stimulation if the Argus II System is used within 1 yard (0.9 meters) of them. Normal operation will resume when you move away from these items. When possible, it is best to avoid these devices or turn the VPU off when passing through these systems. Individuals with an Argus II Implant should show their ID card to any attendant in the area who may be able to assist them in bypassing the devices. If unavoidable, walk through the scanner and promptly move away from the area. Do not lean on these scanners or linger in their path.
- **Electronic Article Surveillance (EAS) systems, EAS Tag Deactivators, and Radiofrequency identification (RFID) systems** may temporarily interrupt Argus II stimulation if the Argus II System is used within 3.5 yards (3.2 meters) of them. Normal operation will resume when you move away from these items. RFID systems and EAS systems and tag deactivators send out energy fields that wirelessly communicate with tags that are attached to objects such as merchandise, materials and people. These systems are used for security, theft prevention, tracking and inventory control and they are usually found in retail stores, libraries, government buildings, warehouses and offices. For example, security tags attached to clothing contain RFID tags.
- **Electrostatic Discharge (ESD)** may interfere with normal operation or cause damage to the electrical components of the Argus II System. Common situations that create static electricity include putting on or removing clothes, or dragging feet across a carpet or rug when there is less than 30% relative humidity. Care should be taken to avoid handling the VPU and glasses when static electricity is present.
- The Argus II System may interfere with the normal operation of some models of **hearing aids**. Hearing aids should be tested prior to implantation, to ensure proper functioning of both the Argus II System and the hearing device.
- Some **home appliances** (for example, microwaves ) and some **devices with antennae** (for example, cell phones, and cordless phones) may temporarily interrupt Argus II stimulation if the Argus II System is being used near them.

The table below lists the distance at which interruption of stimulation may occur with these systems.

**Table 1: Separation Distances**

Type of device	Interruption of stimulation may occur if device is operated within this distance of 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 device	1 inch (2.5 cm)
Microwave oven	1 inch (2.5 cm)
WiFi Access Point	8 inches (20 cm)
Wireless Router	8 inches (20 cm)

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

- The Argus II System operates using wireless technology which could interfere with the safe operation of an **airplane**. Patients should not turn on the Argus II System on an airplane.
- **Commercial electrical equipment** (such as arc welders, induction furnaces or resistance welders), **communication equipment** (such as microwave transmitters, linear power amplifiers and high-power amateur transmitters), **high voltage lines, power lines or generators, electric steel furnaces, or large magnetized speakers** may temporarily interrupt Argus II System function. Normal operation will resume when you move away from these items.

For additional information on specific environments and recommended separation distances please see the tables provided in the Electromagnetic Environments section of this insert.

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

**CAUTION:** The Argus II System operates using wireless technologies that could interfere with the safe operation of an airplane and should not be turned on or used on an airplane.

When travelling and not using the Argus II System, individuals should be advised to store the external equipment in the travel case. International travel may require the use of adapters to be able to plug the VPU battery charger into an electrical outlet. Individuals with the Argus II System should be advised to both bring their patient identification card with them to assist in going through security systems and to turn off the VPU. If individuals with the Argus II System are experiencing any medical complications before traveling, they should be advised to speak with a doctor to determine if it is safe for them to travel, especially on a plane. They also may wish to obtain the name of a local ophthalmologist, in the event of any complications during their travels.

## **Precautions in the Event of Change in Device Performance**

If there is a notable change in performance with the Argus II System, the patient should contact his or her clinician for assistance. A visit to the clinic for troubleshooting, diagnostic tests, or re-programming may be required.

## **CLINICAL CONSIDERATIONS**

- The Argus II System is not intended to slow or reverse the progression of the disease.
- The Argus II System provides "artificial" vision; it does not restore normal vision.
- The Argus II Implant is intended to be implanted in a single eye. In general, the Argus II Implant should be implanted in the worse-seeing eye. If both eyes have equivalent residual vision and are equally suitable for implantation, the patient's preference for the implanted eye should be respected.
- The Argus II Implant is made specifically for either the left eye or the right eye. Before opening the Argus II Implant package, carefully read the label and verify that the package contains the desired device.
- Abnormalities in the typical curvature of the retina (e.g. staphyloma), especially significant protrusions or depressions in the area centralis, could affect how well the

Argus II Implant fits against the retina. If the implant does not fit well against the retina, the patient's performance with the device may not be optimal.

- It is strongly recommended that a preoperative psychosocial evaluation be performed to determine a patient's level of motivation, expectations of the device, ability to deal with potentially disappointing results, and the extent of their social support network.
- The patient should have the cognitive and physical ability to operate the Argus II VPU and glasses.
- If the patient is severely hearing impaired, prior to implantation the clinician should test to see if the patient can hear the VPU's audible alerts using a hearing aid or other assistive listening devices. If the patient cannot hear these audible alerts when aided, the clinician should confirm that the patient has someone who can assist them in hearing and understanding these alerts. In addition, the clinician should be able to adequately communicate with the patient in order to program the Argus II System.
- Based on the spacing of the electrodes, the theoretical limit of resolution of the Argus II is 2.1 logMAR. However, in the clinical trial, one subject achieved a resolution better than this (i.e. 1.8 logMAR), likely due to head scanning.
- Each Argus II implant has 60 electrodes, of which 55 are enabled. Up to 5 of the remaining electrodes may be functional and could be enabled to replace an electrode if it fails post-implant.
- Patients should live within a distance (or be willing to temporarily relocate to a distance) that will allow their full participation in recommended post-operative clinical follow-up, device fitting and training, and visual rehabilitation.

## **REPORTED ADVERSE EVENTS**

A total of 30 subjects were implanted with Argus II in a clinical trial (14 were implanted in the United States and 16 were implanted in Europe). Follow-up time ranged from 2.6 to 4.8 years (average was 3.5 years). One subject's device was explanted at 1.2 years due to recurrent conjunctival erosion and refractory hypotony.

### *Definition of Adverse Events*

In the study, serious adverse events (SAEs) were medical occurrences that:

- Necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure; OR

- Caused permanent impairment of a body function or permanent damage to body structure; OR
- Required hospitalization or prolonged hospitalization.

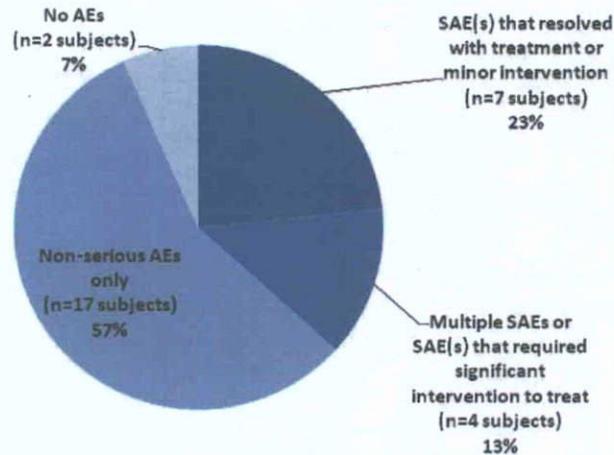
Events not meeting the above criteria were considered non-serious. All device-related or surgery-related events are summarized below.

### Overview of Safety Experience

Nineteen (19) subjects (63%) experienced no, or only non-serious, adverse events. These non-serious events were treated routinely with medication or observation only. An additional 7 subjects experienced SAEs that resolved with treatment or minor interventions.

The remaining 4 subjects were distinct from the other subjects in that they had a higher rate of adverse events due to a cascade of related events. In total, these 4 subjects accounted for 57% of all serious adverse events (SAEs) and 24% of all non-serious adverse events. Refer to Figure 1.

Figure 1: Overview of Safety Experience  
(n=30 subjects)



### Serious Adverse Events

Nineteen subjects did not have any device- or surgery-related serious adverse events (SAEs). Eleven subjects experienced a total of 23 device- or surgery-related SAEs (Refer to Table 2). Ten of the 23 events were considered to be related to the Argus II device and the remaining 13 were considered to be related to a surgical procedure. SAEs were generally treated with a surgical re-

intervention, with the exception of endophthalmitis, keratitis, and uveitis which were treated with topical and/or intravitreal antibiotics. Infective corneal melt was treated with antibiotics, steroids and cross-linking.

Certain trends were observed in SAEs. First, the majority of SAEs occurred within the first few months post-implant (more than 60% occurred within the first 6 months and 35% occurred within the first 6 weeks). Second, SAEs tended to be clustered in a few subjects. Two subjects accounted for almost half of all SAEs (10/23). In these cases, the main event either required multiple interventions to treat it or the subject experienced a cascade of inter-related events.

**Table 2: Serious Adverse Events  
(Device- or Surgery-Related)**

Event	# of Subjects	# of Events	% Subjects (n=30)
Conjunctival dehiscence	3	3	10.0%
Conjunctival erosion	3	4	10.0%
Corneal Melt - infective	1	1	3.3%
Corneal Opacity	1	1	3.3%
Fibrotic events:	3	3	10.0%
RD - rhegmatogenous	1	1	3.3%
RD - tractional and serous	1	1	3.3%
Retinal Tear	1	1	3.3%
Hypotony	4	4	13.3%
Intraocular inflammatory events:	3	4	10.0%
Endophthalmitis - infective	3	3	10.0%
Uveitis	1	1	3.3%
Keratitis - infective	1	1	3.3%
Re-tack	2	2	6.7%

RD = retinal detachment

#### *Non-Serious Adverse Events*

Any adverse event that did not meet the definition of an SAE was considered to be a non-serious adverse event. These events normally resolved on their own or were treated with medical management (i.e. they did not require surgical re-intervention to treat). There were 140 non-serious device-or surgery-related adverse events (in 28 subjects), of which 78 were device-related and the remaining 62 were surgery-related. The following non-serious events were reported (number of events is indicated in parentheses): ocular pain (17), conjunctival congestion (11), epiretinal membrane (11), elective revision surgery (7), non-serious hypotony (7), suture irritation (7), choroidal detachment (6),

uveitis (6), inflammatory conjunctivitis (5), retinal thickening with cystoid macular edema (CME) (5), ocular inflammation (4), retinal thickening with no cystic changes (4), vitreous hemorrhage (4), headache (3), high intraocular pressure (3), hyphema (3), keratic precipitates (3), corneal vascularization (2), epiphora (lacrimation) (2), and foreign body sensation (2). There was one reported case of each of the following events: 360° circumferential vitreous band traction, choroidal effusion, conjunctival cyst, conjunctival dehiscence, conjunctival erosion, corneal abrasion, corneal dryness, corneal epithelial defect, corneal filaments, corneal fold, corneal suture broken, decrease in light perception, fibrosis around the tack, filamentary keratitis, nausea, nystagmus increase, ocular fibrin, proliferative vitreo-retinopathy, ptosis, serous retinal detachment, tractional retinal detachment, retinal folds, retinoschisis, rubeosis, scleral patch displacement, scleritis, sub-conjunctival eyelashes, and vertigo.

### *Surgical Re-Interventions*

Nine (9) subjects required a surgical re-intervention(s) to treat a device- or surgery-related adverse event(s). Seven (7) subjects had elective revision surgery. Refer to Table 3. In cases where it was necessary to remove all or part of the implant and/or tack (i.e. 1 case of explant and 3 cases where the retinal tack was removed to reposition the implant during an elective revision surgery), no adverse sequelae occurred.

**Table 3: Surgical Re-Interventions**

	# of Subjects	# of Events	% Subjects (n=30)
Re-intervention to treat an AE:	9	28	26.7%
Conjunctiva repair	5	12	16.7%
Corneal scraping with EDTA	1	1	3.3%
Device explant	1	1	3.3%
RD repair	2	4	6.7%
Re-tack	2	2	6.7%
Treatment of hypotony	2	4	6.7%
Laser - Retinal tear	2	3	6.7%
Cross linking for corneal melt	1	1	3.3%
Elective revision surgery	7	7	23.3%

RD = retinal detachment

EDTA = Ethylenediaminetetraacetic acid

## POTENTIAL ADVERSE EVENTS

The following device-related or implant surgery-related adverse events were not observed during the clinical trial, but could potentially occur:

- Facial nerve stimulation, transient electrical shock, skin burn due to excessive heating of the external equipment, or retinal tissue damage due to mechanical trauma, excessive stimulation or excessive heating of the implant.
- Failure or damage to the Argus II Implant requiring it to be explanted.
- Fall or bump resulting from use of the Argus II System.
- Risks known to be associated with standard vitreo-retinal surgery, peeling of an epiretinal membrane and use of a scleral band: suprachoroidal hemorrhage, intrusion/extrusion of the scleral band, and macular hole.
- Risks known to be associated with the removal of the lens using clear cornea phacoemulsification: cortical drop in vitreous or vitreous prolapse.
- Risks known to be associated with canthotomy: improper apposition of the eyelids, chronic irritation at the lid margin.
- Risks known to be associated with the use of general anesthesia, steroids and antibiotics: chest pain, urinary retention, myocardial infarction, pulmonary embolism, deep vein thrombosis, respiratory failure, blood loss requiring transfusion, systemic infection, prolonged hospitalization, and allergic reaction to anesthesia.

## PROBABLE BENEFIT

The Argus II System provided all 30 subjects with benefit as measured by visual function tests, although this level of benefit was variable. All 30 subjects were able to see visual percepts when the Argus II was electrically activated.

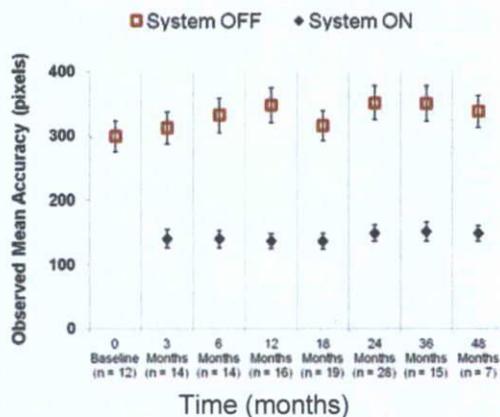
On the Square Localization test (i.e. object localization), subjects were consistently able to perform better with the System ON versus System OFF over the course of the study. Figure 2 displays the observed mean accuracy which indicates the subjects' mean distance from the center of the target square. Error bars represent the mean of the standard error.

On the Direction of Motion test, subjects were consistently able to perform better with the System ON versus System OFF over the course of the study. Figure 3 displays the observed mean accuracy which indicates the mean response error between the angle

displayed and the subject's response. Error bars represent the mean of the standard error.

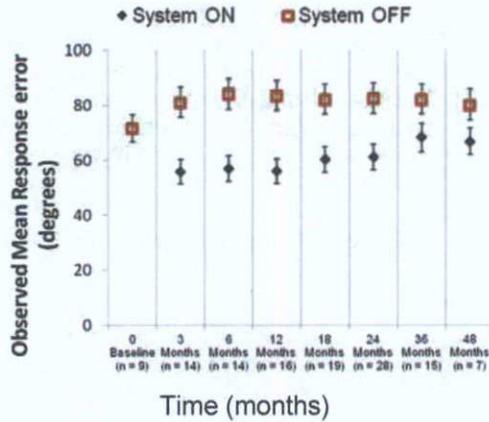
On the Grating Visual Acuity test, the most difficult of the 3 tests, 27% of subjects were able to reliably score on the scale (between 1.6 and 2.9 logMAR with a confidence interval within the scale) at least once with the System ON, while none of the Argus II subjects were ever able to score on the scale with the System OFF in either eye. (Table 4)

Figure 2: Square Localization Results



NOTE: Since this test was introduced midway through the study, the Baseline to 12-month results were only from subjects enrolled in 2009. Subjects enrolled in the study in 2007 and 2008 first performed this test at either their 18- or 24-month follow-up visit.

Figure 3: Direction of Motion Results



NOTE: Since this test was introduced midway through the study, the Baseline to 12 month results were only from subjects enrolled in 2009. Subjects enrolled in the study in 2007 and 2008 first performed this test at either their 18 or 24 month follow-up visit.

Table 4: Grating Visual Acuity (n=30)

	% of Subjects Whose Visual Acuity Improved to Less Than 2.9 LogMAR*
System ON	27% (n=8)
System OFF Implanted Eye	0% (n=0)
System OFF Fellow Eye	0% (n=0)

\* Best result at any follow-up visit.

The Argus II System was also able to provide subjects with benefit as measured by objectively-scored, partially-controlled functional vision tests. Subjects consistently performed better with the Argus II System ON vs. OFF on orientation and mobility tests (finding a door and following a line, Figure 4 and Figure 5, respectively).

Figure 4: Door Task Results

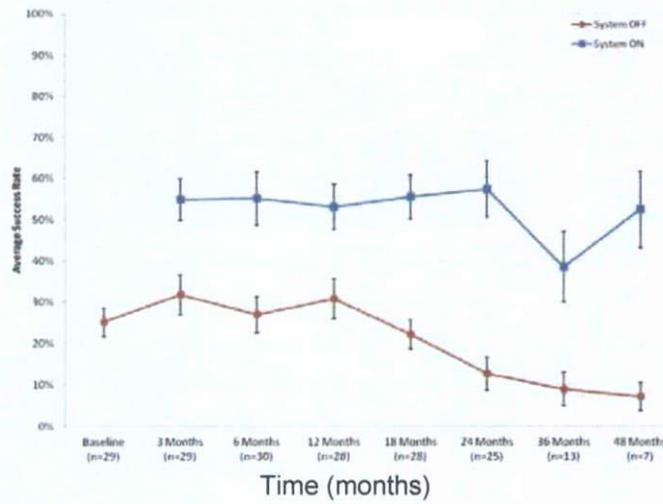
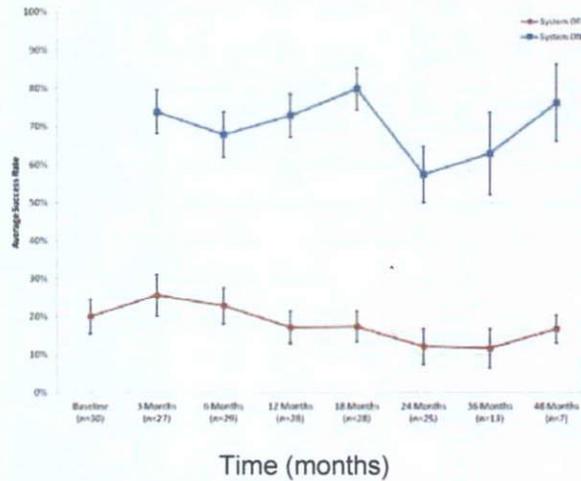


Figure 5: Line Task Results



Self-report questionnaires of activities of daily living and quality of life indicated mild improvement (Massof Activity Inventory) or no change (VisQOL), respectively.

An assessment of Argus II subjects in and around their home by independent, certified low vision rehabilitation specialists was also performed. This assessment, called the Functional Low-vision

Observer Rated Assessment (FLORA) was designed to evaluate how the Argus II System affected subjects' well-being and functional vision. It was added to the study in 2010 at which time subjects' length of follow-up ranged from 1.4 to 3.7 years post-implant. In no cases did the assessors report that the Argus II System had a negative impact on subjects. In 77% of cases, assessors using the FLORA determined that the subject was receiving (or had received at one time) functional vision and/or well-being benefit from the Argus II System. Refer to Table 5.

**Table 5: Summary of FLORA Results  
(n=26 subjects)**

Effect	Number of Subjects
Positive	9 (35%)
Mild Positive	7 (27%)
Prior Positive	4 (15%)
Neutral	6 (23%)
Negative	0 (0%)

Note: 4 subjects did not participate in the FLORA.

### **Implant Failures**

One Argus II Implant experienced an intermittent communication link beginning at 10 months post-implant which led to a significant decline in the functionality of the device.

This device eventually failed approximately 4 years post-implant; however, the device remained implanted.

## MRI INFORMATION



The Argus II Implant is MR Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. Non-clinical testing demonstrated that the Argus II Implant meets the MR Conditional classification.

**WARNING** Do NOT take the Argus II VPU or glasses into the MR system room. The VPU and glasses are MR Unsafe. The VPU and glasses were not tested in the MRI environment and are not permitted to be worn by the patient in the MR system room. Severe harm to the patient and/or damage to the external equipment may occur.



An individual with an Argus II Implant may safely undergo an MRI procedure under the conditions specified below:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e. per pulse sequence)
- Normal Operating Mode of operation for the MR system

### MRI-Related Heating, 1.5-Tesla

In non-clinical testing, the Argus II Implant produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 1.5-Tesla (1.5-Tesla/64-MHz, Symphony, Siemens Medical Solutions, Erlangen, Germany) MR system: Highest temperature change was +0.6°C.

Therefore, the MRI-related heating for the Argus II Implant at 1.5-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 3.5-W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +0.6°C.

### **MRI-Related Heating, 3-Tesla**

In non-clinical testing, the Argus II Implant produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in a 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change was +2.1°C.

Therefore, the MRI-related heating for the Argus II Implant at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +2.1°C.

### **Artifact Information**

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Argus II Implant. Therefore, optimization of MR imaging parameters to compensate for the presence of the implant may be necessary.

**Table 6: MRI Artifact Information**

<b>Pulse Sequence</b>	<b>Imaging Plane</b>	<b>Maximum Signal Void size - mm<sup>2</sup></b>
T1-SE	Parallel	979
T1-SE	Perpendicular	959
GRE	Parallel	2,242
GRE	Perpendicular	3,381

### **During the MRI Procedure**

The MRI technologist should tell the patient to notify the MRI system operator if pain or unusual sensation occurs during the MRI examination. If the patient experiences any pain or unusual sensation, the MRI procedure should be stopped immediately and the source of the problem should be investigated.

### **Device Functionality**

In non-clinical MRI tests, the Argus II implant was exposed to eight different pulse sequences (see

Table 7 below) using 1.5-T/64MHz (Symphony, Siemens Medical Solution, Erlangen, Germany) and 3.0-T/128MHz Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR systems. The results indicated that exposing the Argus II implant to

these MRI conditions did not damage or alter the function of the device nor did it have adverse effects on the device's functionality. However, it is strongly recommended that the Argus II Implant be tested by a qualified clinician or Second Sight personnel as soon as possible following an MRI procedure to confirm that it is still functioning properly.

**Table 7: Summary of MR Imaging Pulse Sequences Used**

Sequence #	1	2	3	4	5	6	7	8
Pulse Sequence	T1-SE	T2-SE	T1-FSE	T2-FSE	GRE 3D	FGRE 3D	GRE MTC	EPI
TR (msec)	700	3,000	700	5,000	20	3.7	628	3,400
TE (msec)	10	100	12	113	2.7	1.2	10	103
Flip Angle	N/A	N/A	N/A	N/A	25	8	5	N/A
Field of View (cm)	30	30	30	30	30	30	10	30
Section Thick (mm)	10	10	10	10	3	3	10	1
Imaging Plane	Axial	Axial	Axial	Axial	Volume	Volume	Axial	Axial

T1-SE, T1-weighted spin echo; T2-SE, T2-weighted spin echo; T1-FSE, T1-weighted fast spin echo; T2-FSE, T2-weighted fast spin echo; GRE, gradient echo; 3D, three-dimensional; FGRE, fast gradient echo; MTC, magnetization transfer contrast; EPI, echo planar imaging; N/A, not applicable; GRE, gradient echo; SE, spin echo

## ELECTROMAGNETIC ENVIRONMENTS

<b>Guidance and manufacturer's declaration – electromagnetic emissions</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.		
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		

<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>
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 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0,5 cycle  40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles  70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles  <5 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 5 s	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 <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<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> <p><math>d = 1.17 P</math></p> <p><math>d = 1.17 P</math> 80 MHz to 800 MHz</p> <p><math>d = 2.33 P</math> 800 MHz to 2.3 GHz</p> <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>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, 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.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**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.

## WIRELESS INFORMATION

The Argus II Glasses use wireless technology to communicate with and power the Implant.

Wireless 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	Wireless link active more than 90% of the time when the coil is approximately 1 inch (25 mm) or closer to the implant.
Wireless Security	The wireless system is designed so the implant will only operate if it is within a very short distance of the glasses. The Argus II System uses a proprietary communication protocol to reduce the likelihood of inadvertent control or malicious "hacking" of the System. No identifiable personal data are transmitted by the Argus II System.

<b>Wireless Specifications</b>	
<b>Quality of Service</b>	<p>In order for the Argus II System to operate, the external system must be in constant communication with the implant. This communication is achieved through a wireless link between the glasses and the implant. For the wireless link to function, the glasses coil must be in close range (0.78 inches or 20 mm) to the implant. This link does not depend on any other system to function. To better ensure proper functioning of the Argus II System, the glasses should be worn in the same position as they were when they 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. The link may not function in the presence of large magnetic or radio fields.</p>

## **STORAGE AND USE**

Store the Argus II Implant at temperatures between -10° to 55° Centigrade (14° to 131° Fahrenheit).

Store the Argus II Externals (VPU and glasses) at temperatures between 0° to 45° C (32° to 113° F). Only operate the Argus II Externals at temperatures between 0° to 40° C (32° to 104° F).

## **HANDLING**

The Argus II Implant packaging should be handled with care appropriate to any implantable medical device. Severe impact could damage the storage pack and rupture the sterile packaging.

The Argus II Externals should also be handled with care to avoid dropping, crushing, severe impact, and exposure to water.

## **SHELF LIFE**

A "Use Before" date is located on the Argus II Implant packaging. This date is two years from the date of sterilization.

## **STERILIZATION**

The Argus II Implant and Argus II spare Tacks are supplied sterile with indicators of sterilization. They are sterilized using ethylene oxide. Sterile packs should be carefully inspected to confirm that they have not been compromised. Sterility cannot be guaranteed if the sterile package is damaged or opened. These devices are for single-use only; do not re-sterilize or re-use them.

## **DIRECTIONS FOR USE & REQUIRED TRAINING**

The following are the main steps required to use the Argus II System:

1. Device Implantation
2. Post-Operative Clinical Follow-Up
3. Device Fitting and Training
4. Vision Rehabilitation

In addition to this product insert, several manuals are provided with the Argus II System to provide more detailed instructions for use.

A *Surgeon Manual*, a video describing the surgical procedure and implantation of the Argus II Implant, and hands-on training are provided by Second Sight to all surgeons prior to implantation. The

Surgeon Manual also provides instructions for how to screen potential patients for eligibility for the Argus II System and provides a recommended clinical follow-up schedule. Surgeons must undergo this training in order to implant the Argus II Implant.

A *Device Fitting Manual* is provided to all clinical centers and is included with the Argus II Clinician Fitting System. The Device Fitting Manual provides instruction on how to use all components of the Argus II System. Clinicians and/or technicians must be knowledgeable about state-of-the-art Argus II System fitting procedures. These personnel must be fully trained and qualified by Second Sight in the fitting of the Argus II System.

A *Patient Manual* is provided in print and audio formats to all patients implanted with the Argus II Implant. The Patient Manual describes how to use the external equipment of the Argus II System that is provided to the patient. Argus II System recipients should receive training on all aspects covered in the Patient Manual prior to taking the Argus II External Equipment home for everyday use. A *Visual Rehabilitation Guide* and hands-on training is provided to low vision therapists who will provide visual rehabilitation to Argus II patients post-implant.

For more information, contact Second Sight using the contact information provided on the front page of this insert.

#### **INTELLECTUAL PROPERTY INFORMATION**

Second Sight products (including the Argus II Retinal Prosthesis, Argus II Glasses, Argus II OR Coil, Argus II Video Processing Unit and Argus II Clinician Fitting System) are covered by one or more of the following patents:

United States:

5,109,844, 5,935,155, 5,944,747, 6,165,192, 6,507,758, 6,533,798, 6,718,209, 6,858,220, 6,920,358, 6,949,253, 6,974,533, 7,079,900, 7,097,775, 7,103,416, 7,127,286, 7,133,724, 7,142,909, 7,149,586, 7,181,287, 7,190,051, 7,211,103, 7,224,300, 7,228,181, 7,257,446, 7,263,403, 7,266,413, 7,291,540, 7,314,474, 7,338,522, 7,379,000, 7,480,988, 7,482,957, 7,483,750, 7,483,751, 7,493,169, 7,499,754, 7,527,621, 7,539,544, 7,565,202, 7,565,203, 7,571,004, 7,571,011, 7,574,263, 7,631,424, 7,638,032, 7,645,262, 7,666,523, 7,668,599, 7,676,274, 7,904,164, 7,904,163, 7,904,148, 7,894,911, 7,893,909, 7,881,799, 7,877,866, 7,835,798, 7,835,794, 7,818,064, 7,813,796, 7,776,197, 7,818,064, 7,765,009, 7,750,076, 7,749,608, 7,738,962, 7,734,352, 7,725,191, 7,709,961, 7,706,893, 7,691,252, 7,887,681, 7,908,010, 7,908,011, 7,912,556, 7,914,842, 7,925,354, 7,926,221, 7,937,153, 7,941,224, 7,957,810, 7,957,811, 7,962,221, 7,989,080,

7,991,478, 8,000,000, 8,010,202, 8,010,206, 8,014,868, 8,014,869,  
8,014,878, 8,019,428, 8,034,229, 8,036,751, 8,036,752, 8,046,078,  
8,060,211, 8,060,216, 8,068,913, 8,078,284, D565,082, D567565,  
D599, 313 D600,440

Australia:

2004235629, 2004235627, 2006202503, 2007201542,  
2009204164, 776879, 2004205105, 2006202583, 2002252113,  
2007201497, 751995, 2003234174, 2003220590, 739523,  
2006306658, 2006239178, 2006208146, 2006214142,  
2006292220, 2006306660, 2006241404, 2007243163,  
2007243164, 2007261384, 2006311850, 2007284422

Europe:

1171188, 1061996, 1061874, 2219728

Japan:

4384363, 3926564, 4411088, 4290566, 3929701

Canada:

2,323,550, 2,323,551

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**Second Sight Medical Products, Inc.**

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Phone: +1 818 833 5000  
Fax: +1 818 833 5067

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

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**Date of Issue: JAN-2013**

## Appendix E – Product and Package Labels for Argus II System

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1. Implant Labels



**Second Sight**

**ARGUS® II  
RETINAL PROSTHESIS KIT**

---

 **Manufactured by**  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA, www.2-sight.com

Quantity	Contents
1	Argus II Retinal Prosthesis, Left Eye, with 2 Retinal Tacks
2	Argus II VPU-Implant Matching CDs
1	Warranty Registration Form
1	Patient Identification Card

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**  **Caution:** Refer to Accompanying Documents Before Use

 Store between 14°F and 131°F

 Fragile

Catalog Number  011014-002-K

Serial Number  \_\_\_\_\_

Use By Date  \_\_\_\_\_



**Second Sight**

**ARGUS® II RETINAL PROSTHESIS KIT**

 011014-002-K  \_\_\_\_\_ 

900118-001 Rev B



**Second Sight**

**ARGUS® II  
RETINAL PROSTHESIS KIT**

---

 **Manufactured by**  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA, www.2-sight.com

Quantity	Contents
1	Argus II Retinal Prosthesis, Right Eye, with 2 Retinal Tacks
2	Argus II VPU-Implant Matching CDs
1	Warranty Registration Form
1	Patient Identification Card

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**  **Caution:** Refer to Accompanying Documents Before Use

 Store between 14°F and 131°F

 Fragile

Catalog Number  011013-002-K

Serial Number  \_\_\_\_\_

Use By Date  \_\_\_\_\_



**Second Sight**

**ARGUS® II RETINAL PROSTHESIS KIT**

 011013-002-K  \_\_\_\_\_ 

900116-001 Rev B

Second Sight CONFIDENTIAL

261

1.1. Retinal Prosthesis

REF 011014-002

BN

ARGUS® II RETINAL PROSTHESIS



**Second Sight**

**ARGUS® II**  
RETINAL PROSTHESIS

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II Retinal Prosthesis, Left Eye
2	Argus II Retinal Tacks

Catalog Number REF 011014-002

Serial Number SN

Date of Manufacture 

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution:**  
Refer to Accompanying Documents Before Use

 Single Use

 Store between 14°F and 131°F

 Fragile

 MR Conditional

 ESD Sensitive

[www.2-sight.com](http://www.2-sight.com)  
900117-001B

REF 011013-002

BN

ARGUS® II RETINAL PROSTHESIS



**Second Sight**

**ARGUS® II**  
RETINAL PROSTHESIS

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II Retinal Prosthesis, Right Eye
2	Argus II Retinal Tacks

Catalog Number REF 011013-002

Serial Number SN

Date of Manufacture 

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution:**  
Refer to Accompanying Documents Before Use

 Single Use

 Store between 14°F and 131°F

 Fragile

 MR Conditional

 ESD Sensitive

[www.2-sight.com](http://www.2-sight.com)  
900115-001B

1.2. Retinal Tack

REF 011006-001

ARGUS® II RETINAL TACKS

BN

REF 011006-001



**Second Sight**

**ARGUS® II**  
**RETINAL TACKS**

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

Quantity	Contents
2	Argus II Retinal Tacks

Catalog Number    REF 011006-001

Serial Number        SN

Date of Manufacture    

**Rx Only**

 **Caution:** Refer to Accompanying Documents Before Use

 Single Use

 Store between 14°F and 131°F

 Fragile

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

www.2-sight.com  
90019-001B

1.3. Sterilization Label for Retinal Prosthesis and Retinal Tack

STERILE EO



900102-001 B

Second Sight CONFIDENTIAL

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1.4. VPU-Implant Matching CD

**ARGUS® II VPU-IMPLANT  
MATCHING CD**

  
**Second Sight**  
  
SECOND SIGHT MEDICAL  
PRODUCTS, INC.  
SYLMAR, CA 91342 USA

IMPLANT ID

REF

011007-001

LOT

  
  
2013-01

SUBJECT ID

**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.

 **Rx Only**  
902402-001 B

2. Labels for External Subsystem

2.1. Video Processing Unit (VPU)

ARGUS® II VIDEO PROCESSING UNIT REF 013003-002 SN 	 <b>Second Sight</b>	<b>ARGUS® II</b> <b>VIDEO PROCESSING UNIT</b>				
	Manufactured by Second Sight Medical Products, Inc. Sylmar, CA 91342 USA					
	<table border="1"> <thead> <tr> <th>Quantity</th> <th>Contents</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td>Argus II Video Processing Unit</td> </tr> </tbody> </table>		Quantity	Contents	1	Argus II Video Processing Unit
	Quantity	Contents				
1	Argus II Video Processing Unit					
Catalog Number    REF 013003-002 Serial Number        SN Date of Manufacture 						
<p><b>HUMANITARIAN DEVICE:</b> 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.</p>		<p><b>Rx Only</b></p> <p> <b>Caution: Refer to Accompanying Documents Before Use</b></p> <p> Store between 32°F and 113°F</p> <p> Keep Dry</p> <p> Type B Applied Part</p> <p> MR unsafe</p>				
Argus, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.		www.2-sight.com 900210-001B				

 <b>Second Sight</b>	<b>ARGUS® II</b> <b>VIDEO PROCESSING UNIT</b>
Second Sight Medical Products, Inc. Sylmar, CA 91342 USA www.2-sight.com	
REF 013003 SN 	Use only with Sony battery: NP-QM71D, 2760 mAh, or NP-FM500H, 1650 mAh, Rated 7.2V
<p><b>HUMANITARIAN DEVICE:</b> 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.</p>	
 32°F	Rx Only 900209-001B

 <b>Second Sight</b>
<b>ARGUS® II</b> <b>VIDEO PROCESSING UNIT</b>
900211-001 B

Patient ID: \_\_\_\_\_  
 Implant Serial #: \_\_\_\_\_  
 The Argus II VPU and glasses are MR Unsafe. Do not take the VPU or glasses into a room with an MR system.  
 The Argus II Implant is MR Conditional.  
 002701-001 B

2.2. VPU Pouch



**ARGUS® II  
 VIDEO PROCESSING  
 UNIT POUCH**

---

**Second Sight Medical Products, Inc.**  
 Sylmar, CA 91342 USA

  **Med Pass International Ltd.**  
 Gloucester, United Kingdom

Contents / Contenu / Inhalt / Contenido / Contenuto / Inhoud:  
 1 Pouch / Poche / Beutel / bolsa / sacca / buidel

**REF** 013931-001                      **LOT**

**CE** 0344

Argus, Second Sight and the Second Sight logo are registered trademarks of Second Sight Medical Products, Inc. 901701-001 C

2.3. Glasses

**REF** 012014-001

**ARGUS® II GLASSES**

**SN**





**Second Sight**

**ARGUS® II  
 GLASSES**

---

**Manufactured by**  
**Second Sight Medical Products, Inc.**  
 Sylmar, CA 91342 USA  
 www.2-sight.com

Quantity	Contents
1	Argus II Glasses Left Eye, Clear Lenses

Catalog Number    **REF** 012014-001

Serial Number        **SN**

Date of Manufacture 

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution:** Refer to Accompanying Documents Before Use

 Store between 32°F and 113°F

 Keep Dry

 Emits Non-ionizing Radiation

 Type B Applied Part

 MR Unsafe

900329-001B

REF 012013-001

ARGUS® II GLASSES

SN



**Second Sight**

**ARGUS® II  
GLASSES**

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA  
www.2-sight.com

**Quantity Contents**  
1 Argus II Glasses  
Left Eye, Dark Lenses

Catalog Number REF 012013-001

Serial Number SN

Date of Manufacture 

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution:** Refer to Accompanying Documents Before Use

 Store between 32°F and 113°F

 Keep Dry

 Emits Non-ionizing Radiation

 Type B Applied Part

 MR Unsafe

900325-001B

REF 012012-001

ARGUS® II GLASSES

SN



**Second Sight**

**ARGUS® II  
GLASSES**

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA  
www.2-sight.com

**Quantity Contents**  
1 Argus II Glasses  
Right Eye, Clear Lenses

Catalog Number REF 012012-001

Serial Number SN

Date of Manufacture 

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution:** Refer to Accompanying Documents Before Use

 Store between 32°F and 113°F

 Keep Dry

 Emits Non-ionizing Radiation

 Type B Applied Part

 MR Unsafe

900327-001B

 <b>Second Sight</b>	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>ARGUS® II GLASSES</b> </div>						
REF 012011-001  SN  	<p style="writing-mode: vertical-rl; transform: rotate(180deg);"><b>ARGUS® II GLASSES</b></p>						
Manufactured by Second Sight Medical Products, Inc. Sylmar, CA 91342 USA www.2-sight.com							
<table border="0" style="width: 100%;"> <tr> <td style="width: 30%;"><u>Quantity</u></td> <td style="width: 30%;"><u>Contents</u></td> <td style="width: 40%;"></td> </tr> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">Argus II Glasses Right Eye, Dark Lenses</td> <td></td> </tr> </table>		<u>Quantity</u>	<u>Contents</u>		1	Argus II Glasses Right Eye, Dark Lenses	
<u>Quantity</u>	<u>Contents</u>						
1	Argus II Glasses Right Eye, Dark Lenses						
Catalog Number    REF 012011-001 Serial Number        SN Date of Manufacture 							
<p><b>HUMANITARIAN DEVICE:</b> 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.</p>							
Argus, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.							
Rx Only Caution: Refer to Accompanying Documents Before Use Store between 32°F and 113°F Keep Dry Emits Non-ionizing Radiation Type B Applied Part MR Unsafe							
900323-001B							

REF 012014-001			
SN		<b>ARGUS® II Glasses</b>	
  <b>Rx Only</b>		SECOND SIGHT MEDICAL PRODUCTS, INC. 900323-001 B	

REF 012013-001			
SN		<b>ARGUS® II Glasses</b>	
  <b>Rx Only</b>		SECOND SIGHT MEDICAL PRODUCTS, INC. 900324-001 B	

REF 012012-001			
SN		<b>ARGUS® II Glasses</b>	
  <b>Rx Only</b>		SECOND SIGHT MEDICAL PRODUCTS, INC. 900325-001 B	

REF 012011-001			
SN		<b>ARGUS® II Glasses</b>	
  <b>Rx Only</b>		SECOND SIGHT MEDICAL PRODUCTS, INC. 900322-001 B	

**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. 905000-001 B

2.4. OR Coil

REF 012103-001 SN 	 <b>Second Sight</b>	<b>ARGUS® II</b> OPERATING ROOM COIL				
	Manufactured by Second Sight Medical Products, Inc. Sylmar, CA 91342 USA	<b>Rx Only</b>  <b>Caution:</b> Refer to Accompanying Documents Before Use				
	<table border="1"> <thead> <tr> <th>Quantity</th> <th>Contents</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td>Argus II Operating Room Coil</td> </tr> </tbody> </table>	Quantity	Contents	1	Argus II Operating Room Coil	Store between 32°F and 113°F  Keep Dry  Emits Non-ionizing Radiation
	Quantity	Contents				
1	Argus II Operating Room Coil					
Catalog Number    REF 012103-001 Serial Number        SN Date of Manufacture 	<b>HUMANITARIAN DEVICE:</b> 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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.		www.2-sight.com 901205-001B				

<table border="1"> <tr> <td>REF</td> <td>012103-001</td> </tr> <tr> <td>SN</td> <td></td> </tr> </table>	REF	012103-001	SN		<b>ARGUS® II</b> OR COIL
REF	012103-001				
SN					
  <b>Rx Only</b>	SECOND SIGHT MEDICAL PRODUCTS, INC. 901204-001 B				

**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. 905000-001 B

3. Labels for Fitting Subsystem

3.1. Clinician Fitting System (CFS)

 <b>ARGUS® II CLINICIAN FITTING SYSTEM</b> 	 <b>Second Sight</b>	<b>ARGUS® II CLINICIAN FITTING SYSTEM</b>	
	Manufactured by Second Sight Medical Products, Inc. Sylmar, CA 91342 USA.		
	<b>Quantity</b>	<b>Contents</b>	<b>Rx Only</b>  <b>Caution: Refer to Accompanying Documents Before Use</b>
	1	Argus II Clinician Fitting System (Reconditioned)	Store between 32°F and 113°F
	1	Power Supply Battery	 <b>Keep Dry</b>
Catalog Number  014003-002-R Serial Number  Date of Manufacture 			
<p><b>HUMANITARIAN DEVICE:</b> 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.</p> <p style="font-size: small;">Argus, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc. <span style="float: right;">www.2-sight.com 900511-001B</span></p>			

 <b>Second Sight</b>	<b>ARGUS® II Clinician Fitting System</b>				
Second Sight Medical Products, Inc. Sylmar, CA 91342 USA					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;"><b>REF</b></td> <td style="text-align: center;"><b>014003-R</b></td> </tr> <tr> <td style="text-align: center;"><b>SN</b></td> <td style="text-align: center;"> </td> </tr> </table>	<b>REF</b>	<b>014003-R</b>	<b>SN</b>		   <b>Rx Only</b> 900510-001B
<b>REF</b>	<b>014003-R</b>				
<b>SN</b>					

**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. 905000-001B

3.2. Psychophysical Test System (PTS)

REF 014202-002-R

ARGUS® II

PSYCHOPHYSICAL TEST SYSTEM



**Second Sight**

**ARGUS® II**

**PSYCHOPHYSICAL TEST SYSTEM**

Manufactured by  
 Second Sight Medical Products, Inc.  
 Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II Psychophysical Test System (Reconditioned)
1	Power Supply
1	Battery

Catalog Number REF 014202-002-R  
 Serial Number SN  
 Date of Manufacture [ ]

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution:**  
 Refer to Accompanying Documents Before Use

 Store between 32°F and 113°F

 Keep Dry

www.2-sight.com  
900606-001B



Second Sight

**ARGUS™ II**

**Psychophysical Test System**

Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

REF 014202-R

SN [ ]





**Rx Only**

900606-001A

**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.

905000-001 B

3.3. Communication Adapter (CA)

 014103-002  	 <b>Second Sight</b>	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>ARGUS® II</b>                  COMMUNICATION ADAPTER             </div>								
	Manufactured by Second Sight Medical Products, Inc. Sylmar, CA 91342 USA									
	<table border="0" style="width: 100%;"> <tr> <td style="width: 30%;"><u>Quantity</u></td> <td style="width: 30%;"><u>Contents</u></td> <td style="width: 40%; text-align: right;"><b>Rx Only</b></td> </tr> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">Argus II Communication Adapter</td> <td style="text-align: right;">  <b>Caution:</b> Refer to                      Accompanying                      Documents                      Before Use                 </td> </tr> </table>		<u>Quantity</u>	<u>Contents</u>	<b>Rx Only</b>	1	Argus II Communication Adapter	 <b>Caution:</b> Refer to Accompanying Documents Before Use		
	<u>Quantity</u>	<u>Contents</u>	<b>Rx Only</b>							
1	Argus II Communication Adapter	 <b>Caution:</b> Refer to Accompanying Documents Before Use								
<table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Catalog Number</td> <td style="width: 30%;">  014103-002                 </td> <td style="width: 40%; text-align: right;">  Store between                      32°F and 113°F                 </td> </tr> <tr> <td>Serial Number</td> <td>  </td> <td style="text-align: right;">  Keep Dry                 </td> </tr> <tr> <td>Date of Manufacture</td> <td>  </td> <td></td> </tr> </table>		Catalog Number	 014103-002	 Store between 32°F and 113°F	Serial Number		 Keep Dry	Date of Manufacture		
Catalog Number	 014103-002	 Store between 32°F and 113°F								
Serial Number		 Keep Dry								
Date of Manufacture										
<p><b>HUMANITARIAN DEVICE:</b> 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.</p>										
Argus, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.		www.2-sight.com 900405-001B								

 <b>Second Sight</b>	<div style="border: 1px solid black; padding: 5px; display: inline-block;"> <b>ARGUS® II</b>                  Communication Adapter             </div>				
Second Sight Medical Products, Inc. Sylmar, CA 91342 USA					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20px; text-align: center;"><b>REF</b></td> <td style="text-align: center;"><b>014103-002</b></td> </tr> <tr> <td style="text-align: center;"><b>SN</b></td> <td style="text-align: center;"> </td> </tr> </table>	<b>REF</b>	<b>014103-002</b>	<b>SN</b>		   45°C
<b>REF</b>	<b>014103-002</b>				
<b>SN</b>					
<b>Rx Only</b> 900404-001 B					

<p><b>HUMANITARIAN DEVICE:</b> 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.</p>	905000-001 B
---	--------------

3.4. CFS-CA Cable



**Second Sight**

**ARGUS® II**  
CFS-CA CABLE

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

**REF** 014916-002

**ARGUS® II CFS-CA CABLE**

**LOT**

Quantity	Contents
1	Argus II Clinician Fitting System - Communication Adapter Cable (CFS - CA Cable)

Catalog Number    **REF** 014916-002

Lot Number         **LOT**

**Rx Only**

 **Caution:** Refer to  
Accompanying  
Documents  
Before Use

 Store between  
32°F and 113°F

 Keep Dry

**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, Second Sight and the Second Sight Logo are  
registered trademarks of Second Sight Medical Products, Inc.

www.2-sight.com  
900805-001C

<b>REF</b>	014916-002
<b>LOT</b>	



**Rx Only**

**ARGUS® II**  
**CFS-CA Cable**

SECOND SIGHT MEDICAL  
PRODUCTS, INC.  
300804-001 B



3.6. CFS-PTS Cable

**REF** 014915-001

**ARGUS® II CFS-PTS CABLE**

**LOT**



**Second Sight**

**ARGUS® II**  
**CFS-PTS CABLE**

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

**Quantity Contents**

1 Argus II Clinician Fitting System -  
Psychophysical Test System Cable  
(CFS - PTS Cable)

Catalog Number **REF** 014915-001

Lot Number **LOT**

**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, Second Sight and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

**Caution:** Refer to Accompanying Documents Before Use

Store between 32°F and 113°F

Keep Dry

[www.2-sight.com](http://www.2-sight.com)  
900905-001B

<b>REF</b>	014915-001
<b>LOT</b>	



**Rx Only**

**ARGUS® II**  
**CFS-PTS Cable**

SECOND SIGHT MEDICAL  
PRODUCTS, INC.  
900904-001 B

3.7. Security Drive



**Second Sight**

**ARGUS® II**  
USB SECURITY DRIVE

---

**Manufactured by**  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II USB Security Drive

Catalog Number    REF 014984-001

Lot Number         LOT

**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®, Second Sight® and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution: Refer to Accompanying Documents Before Use**

www.2-sight.com  
901912-001C

**Second Sight Medical Products, Inc.**

**ARGUS® II USB SECURITY DRIVE**

<b>REF</b>	014984-001		<b>Rx Only</b>
<b>LOT</b>			

3.8. Video Settings Drive



**Second Sight**

**ARGUS® II**  
USB VIDEO SETTINGS DRIVE

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II USB Video Settings Drive

Catalog Number    REF 014986-001

Lot Number         LOT

**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®, Second Sight® and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.

**Rx Only**

 **Caution: Refer to Accompanying Documents Before Use**

www.2-sight.com  
901914-001C

**Second Sight Medical Products, Inc.**

**ARGUS® II USB VIDEO SETTING S DRIVE**

<b>REF</b>	014986-001		<p><b>Rx Only</b></p> <p>901917-001 B</p>
<b>LOT</b>			

3.9. Data Transfer Drive



**ARGUS® II**  
**USB DATA TRANSFER DRIVE**

---

 **Manufactured by**  
 Second Sight Medical Products, Inc.  
 Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II USB Data Transfer Drive

Catalog Number    REF 014985-001

Lot Number            LOT

**Rx Only**

 **Caution: Refer to**  
 Accompanying  
 Documents  
 Before Use

**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.

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901913-001C

**Second Sight Medical Products, Inc.**

**ARGUS® II USB DATA TRANSFER DRIVE**

<b>REF</b>	014985-001		<b>Rx Only</b>
<b>LOT</b>			

901916-001 B

3.10. Archive Drive

REF 014931-001

ARGUS® II ARCHIVE DRIVE

LOT



**Second Sight**

**ARGUS® II**  
**ARCHIVE DRIVE**

---

Manufactured by  
Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

Quantity	Contents
1	Argus II Archive Drive

Catalog Number    REF 014931-001

Lot Number            LOT

Date of Manufacture    

**Rx Only**

 **Caution:** Refer to Accompanying Documents Before Use

 Store between 32°F and 113°F

 Keep Dry

**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®, Second Sight® and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc. www.2-sight.com  
902203-002 B



Second Sight

**ARGUS™ II**  
**ARCHIVE DRIVE**

---

Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA  
www.2-sight.com

REF 014931-001

LOT





**Rx Only**

902203-002 A

**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. 905000-001 B

Second Sight CONFIDENTIAL

279

3.11. Touch Screen Monitor

ARGUS® II TOUCH SCREEN MONITOR REF 014932-001 LOT	 <b>Second Sight</b>	<b>ARGUS® II</b> TOUCH SCREEN MONITOR
	Manufactured by Second Sight Medical Products, Inc. Sylmar, CA 91342 USA	
	Quantity: 1 Contents: Argus II Touch Screen Monitor	<b>Rx Only</b>  <b>Caution:</b> Refer to Accompanying Documents Before Use   Store between 32°F and 113°F  Keep Dry Type B Applied Part
	Catalog Number: REF 014932-001 Lot Number: LOT	<b>HUMANITARIAN DEVICE:</b> 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®, Second Sight® and the Second Sight Logo are registered trademarks of Second Sight Medical Products, Inc.		www.2-sight.com 903100-002 B

 Second Sight	<b>ARGUS® II</b> Touch Screen Monitor
Second Sight Medical Products, Inc. Sylmar, CA 91342 USA	
REF 014932-001 LOT	   32°F 113°F <b>Rx Only</b> 903100-002 C

**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. 905000-001 B

4. Patient ID Card

**Second Sight** **Argus™ II**  
Retinal Prosthesis System ID Card

Patient Name: .....

Address: .....

Implanted Eye: .....

Implant Date: .....

Physician Name: .....

Physician Phone: .....

Place product sticker  
here with  
model/serial number

Customer Service:  
(818) 833-5060

**AIRPORT SECURITY/THEFT PREVENTION DEVICES:** Metal detectors, x-ray machines, security scanners and other security devices may cause interruption of stimulation. The implant may also activate metal detector alarms. **CAUTION:** Turn off VPU prior to passing through or exposure to these devices. Walk through them promptly and do not linger in their path.

**WARNING:** Contact your doctor before having any medical procedures including, but not limited to: MRI, CT Scan, diathermy, electrocautery, electroconvulsive therapy (ECT), radiation therapy, lithotripsy, ultrasound, cobalt treatment, linear acceleration and any of the following procedures in the eye: laser, phacoemulsification, vitrectomy, fragmatome or any surgical eye procedure. **For MRI:** A person with an Argus II implant may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe injury or device malfunction. You should remove the Argus II Glasses and VPU before entering the MR system room. Full MRI safety information is available in the Argus II System product insert.

900008-003C1

## 5. Packaging Inserts



Before using this device refer to the Patient Manual and Product Insert provided with the Argus<sup>®</sup> II Video Processing Unit for instructions for use and important safety information.

900009-002 A



Before using this device refer to the Device Fitting Manual and Product Insert provided with the Argus<sup>®</sup> II Clinician Fitting System for instructions for use and important safety information.

900010-002 A



Before using this device refer to the Surgeon Manual and Product Insert provided with the Argus<sup>®</sup> II Retinal Prosthesis for surgical instructions and important safety information.

900011-002 A



Second Sight

**Argus<sup>®</sup> 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.

900028-001 Rev C

**Argus<sup>®</sup> II**  
**Retinal Prosthesis System**

**Patient Manual**

**Second Sight Medical Products, Inc.**  
12744 San Fernando Rd., 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)  
Visit us at [www.2-sight.com](http://www.2-sight.com)

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Second Sight Medical Products, Inc.

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are registered trademarks of  
Second Sight Medical Products, Inc.

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## Chapter 1: Glossary

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Term	Definition
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	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	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 (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)	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	<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 (RF)	<p>Any electromagnetic frequency within the range used for wireless communication</p>
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>

<b>Term</b>	<b>Definition</b>
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 (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**

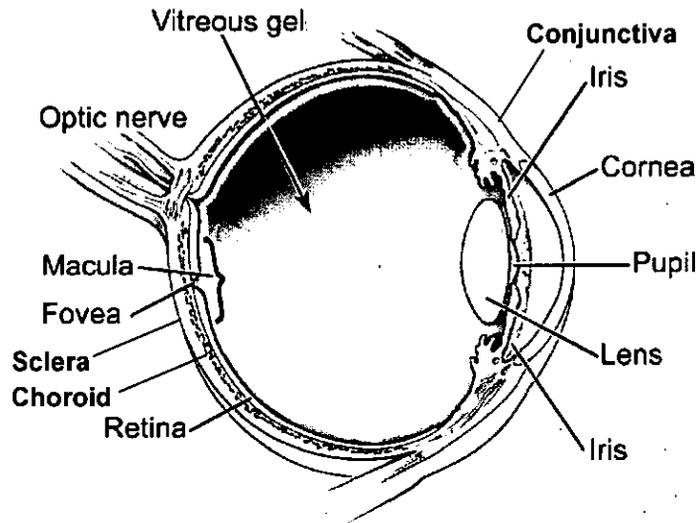


Image courtesy of the National Eye Institute,  
National Institutes of Health

## **Chapter 2: Descriptive Information**

### **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.

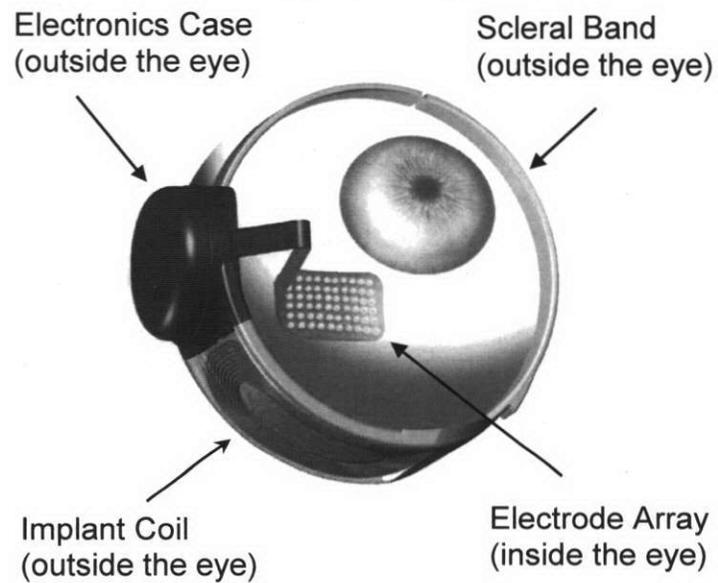
The electrode array provides electrical stimulation to your retina. It has 60 electrodes arranged in a rectangular grid. Fifty-five of these electrodes are turned on at the time of implant. Up to 5 of the remaining electrodes may be functional and could be turned on to replace an electrode that is not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

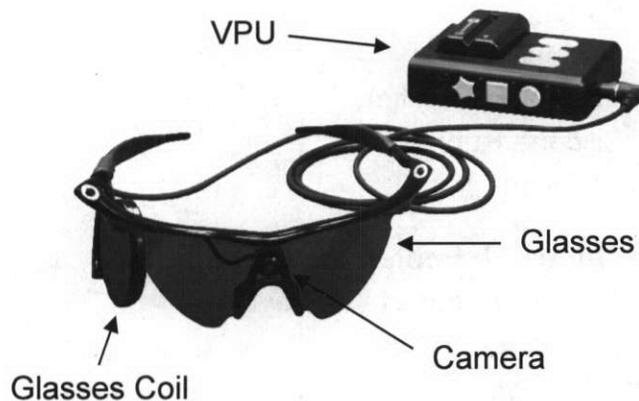
**Figure 2: Implant on a Right Eye  
(looking at your eyeball)**



## External Equipment

Figure 3 shows the VPU, glasses, and battery.

**Figure 3: External Equipment**



### *Video Processing Unit (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**

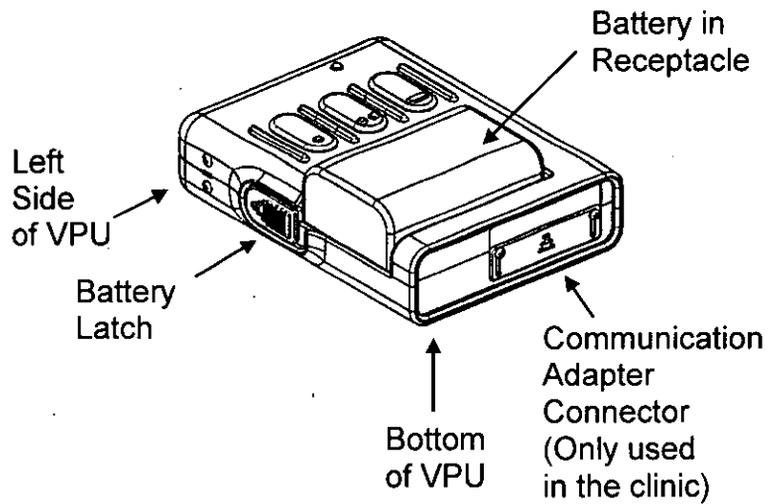
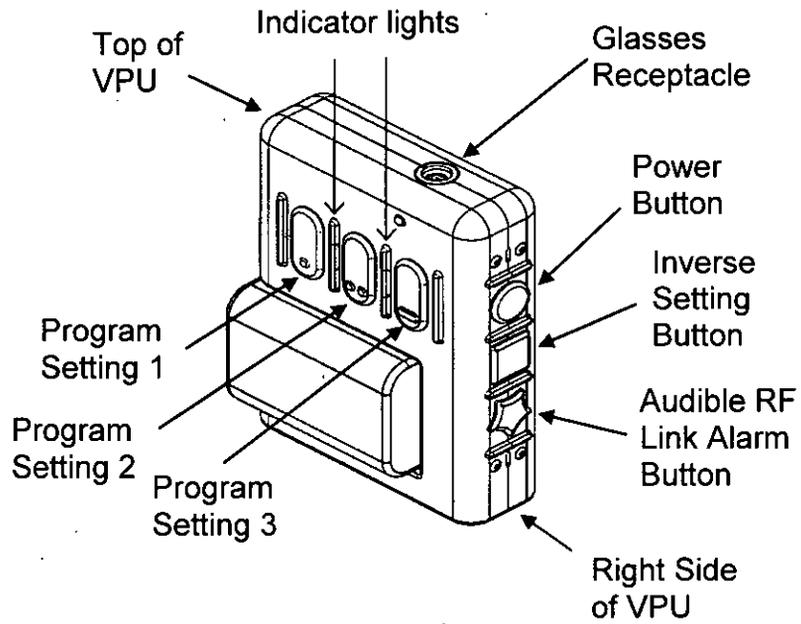


Table 1 describes the parts of the VPU. Table 2 describes the accessories that you use with the VPU.

**Table 1: 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	<p>The 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.</p> <p>The VPU starts in Program Setting 1 each time you turn it on.</p>

<b>Component</b>	<b>Description</b>
Inverse Setting Button	The inverse button is the square-shaped button located on the right-hand side of the VPU. You use this button to invert 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.
Link Alarm Button	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.
Battery Receptacle	The battery receptacle holds the battery in place on the VPU. It is located on the front panel below the program setting buttons.

<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 73 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.

<b>Component</b>	<b>Description</b>
Communication Adapter Connector (CA)	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**

<b>Accessory</b>	<b>Description</b>
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 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 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 are a pair of sunglasses that have a miniature video camera and coil attached to them.
Camera	A miniature video 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	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 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 68 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 36 and Appendices A and B for more information on interference related to the wireless system.

For Troubleshooting regarding link loss, see page 92.

## Argus II Patient Catalog

The following items are included in your Argus II Retinal Prosthesis Patient Catalog:

**Table 5: Patient Catalog**

<b>Description</b>	<b>Catalog / Product Number</b>
Argus II Video Processing Unit including Patient Manual	013003
VPU Batteries: VPU Battery (small) VPU Battery (medium)	100200-001 100200-002
Argus II 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	100200-004
Argus II Travel Case	012930
Argus II VPU Pouch	013931

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

You should not have the Argus II Retinal Prosthesis implanted if you:

- Have an eye disease or condition that could prevent the Argus II System from working properly.
- 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
- Are unable to take the recommended antibiotic and 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**. 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)**. ECT may damage your eye or your Argus II Implant.
- **Avoid lithotripsy or high output 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) 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 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 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.** 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. 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 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.

### **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 27.
- 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 27.
- 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)** – Refer to section “Warnings” on page 27 for information about MRI.
- **Avoid** the use of **laser, fragmatome or phacoemulsification** in your implanted eye. These procedures may damage the Argus II Implant.
- **Avoid** the use of **bipolar electrosurgical equipment** in your implanted eye. This equipment may damage the Argus II Implant.
- You may undergo computed tomography scan (**CT Scans**) or **Diagnostic Ultrasound**. However, if you need a scan or 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 **defibrillators or radiation therapy** 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, or linear acceleration techniques** on the implant are unknown.

## **Possible Interference from Other Electronic Devices**

- **Avoid Theft or metal detectors** (such as those located in entrances to public buildings and department stores) and **airport or 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 (EAS) systems, EAS Tag Deactivators, and 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** 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**. 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, 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 device	1 inch (2.5 cm)
Microwave oven	1 inch (2.5 cm)
WiFi Access Point	8 inches (20 cm)
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**. 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, 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. 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):

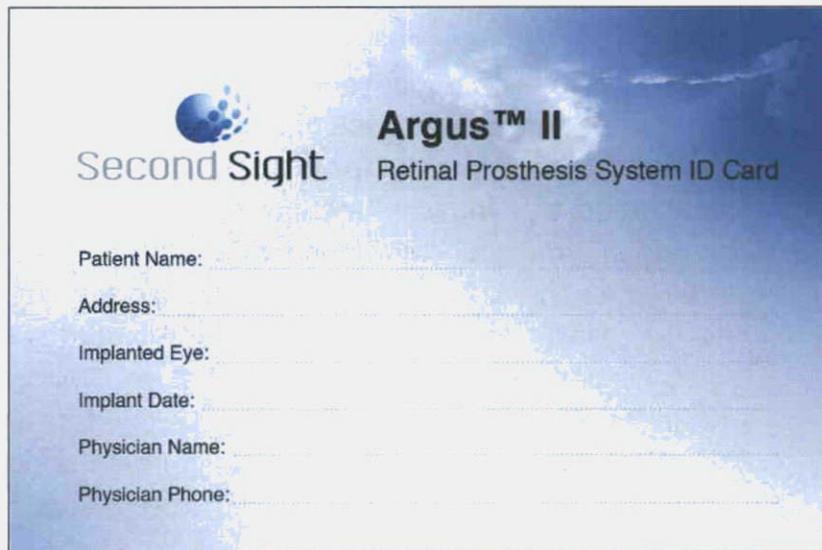
Website: [www.tsa.gov](http://www.tsa.gov)  
Email: [TSA-ContactCenter@dhs.gov](mailto:TSA-ContactCenter@dhs.gov)  
TSA General Phone Number: 866-289-9673  
TSA Cares Phone Number: 855-787-2227

TSA Cares is a toll free helpline designed to assist travelers with disabilities and medical conditions, prior to getting to the airport. 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) 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



The ID card features the Second Sight logo (a blue globe with dots) and the text "Argus™ II Retinal Prosthesis System ID Card". Below the header, there are seven fields for patient information, each followed by a dotted line for text entry:

Patient Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Implanted Eye: \_\_\_\_\_  
Implant Date: \_\_\_\_\_  
Physician Name: \_\_\_\_\_  
Physician Phone: \_\_\_\_\_

Place product sticker here with model/serial number

**Customer Service:**  
**(818) 833-5060**

Second Sight Medical Products, Inc.  
Sylmar, CA 91342 USA

**AIRPORT SECURITY/THEFT PREVENTION DEVICES:** Metal detectors, x-ray machines, security scanners and other security devices may cause interruption of stimulation. The implant may also activate metal detector alarms. **CAUTION:** Turn off VPU prior to passing through or exposure to these devices. Walk through them promptly and do not linger in their path.

**WARNING:** Contact your doctor before having any medical procedures including, but not limited to: MRI, CT Scan, diathermy, electrocautery, electroconvulsive therapy (ECT), radiation therapy, lithotripsy, ultrasound, cobalt treatment, linear acceleration and any of the following procedures in the eye: laser, phacoemulsification, vitrectomy, fragmatome or any surgical eye procedure. **For MRI:** A person with an Argus II implant may be safely scanned with MRI only under very specific conditions. Scanning under different conditions may result in severe injury or device malfunction. You should remove the Argus II Glasses and VPU before entering the MR system room. Full MRI safety information is available in the Argus II System product insert.

900008-003C1

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. 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 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, 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. 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, 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 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 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 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 wounds 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 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 (the innermost layer) may need surgery or treatment with a laser to fix. In some cases, these events may affect how well the Argus II System works.

- Large-scale 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 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. A 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 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 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 caught under the 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 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 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, 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 to the materials in the implant or glasses. The following materials in the implant contact the tissues and fluids in your eye: niobium, titanium, polyimide, silicone rubber, and platinum. The 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 outside the eye
- Redness and irritation in or around the eye
- Irritation caused by the sutures
- Separation of the choroid from the sclera
- Bleeding in the eye
- Clouding, thinning, scraping, or folding of the cornea
- Blood vessels, deposits, rough spots, "threads" or mucus on the cornea
- Dryness of the cornea
- Dry eye or watering eye
- Cysts on the eye
- Nausea or 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" 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 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 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 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 (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, 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 may help you do tasks visually, rather than by touch. During the 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 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, 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.
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, and 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, device programming, and 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**

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**

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") at the same time. If the clinician chooses to use quad stimulation, the clinician 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.**

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.

Your 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 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. 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**

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 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.

## Chapter 4: Using Your Device

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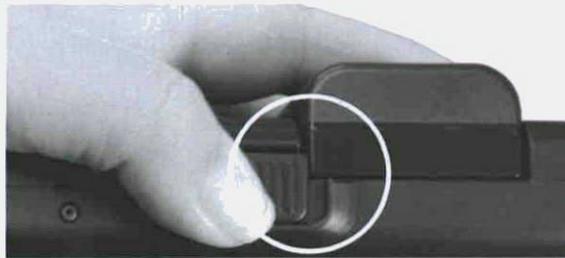
### Setup Instructions

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

- 1. Charge the battery.** 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.** 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.** 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 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 to the VPU.** 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 from the VPU.**  
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.** 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.** 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 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. Each time you press this button, the image will invert and the VPU will beep.
- 7. 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.** 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 Indicator Light Colors**



**Table 7: Indicator Light Colors**

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

<b>Sound</b>	<b>Meaning</b>
Single short beep	A button 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 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, 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 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 contacts, follow the instructions in the battery package.

To clean your VPU, glasses 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 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 and glasses. 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.** 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.** 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.** 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.** 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 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.** The temperature range for normal use should be between 32°F (0°C) and 104°F (40°C).
- 7. 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 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. 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.** 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 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 or glasses. 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 or battery charger 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 explanted 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 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, 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 or discomfort) related to the Argus II System, please contact your doctor or programming clinician immediately.

**Table 9: Troubleshooting**

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The VPU 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)	<ol style="list-style-type: none"> <li data-bbox="781 485 1170 689">2. Install a fully-charged battery. Refer to instructions provided in Chapter 4, "Install the battery."</li> <li data-bbox="781 697 1149 987">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).</li> <li data-bbox="781 995 1170 1285">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.</li> </ol>
The VPU produces an audible warning (three short beeps) and shuts off suddenly	<ol style="list-style-type: none"> <li data-bbox="781 1308 1162 1591">5. Turn on the VPU to see if this occurs again. If the problem persists, contact either your clinician or your Second Sight representative.</li> </ol>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU shuts off suddenly without an audible warning</p>	<ol style="list-style-type: none"> <li>1. Install a fully-charged battery. Refer to instructions "Install the battery" provided in Chapter 4.</li> <li>2. Turn on the VPU to see if this occurs again.</li> <li>3. If the VPU fails to restart, remove the battery for at least 5 minutes. Then, install again.</li> <li>4. Put on glasses. Turn on the VPU again and stimulation should restart.</li> <li>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</p>	<ol style="list-style-type: none"> <li data-bbox="781 478 1170 764">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="781 772 1170 1142">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="781 1150 1170 1646">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>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>5. Ensure that the lens on the camera is clean. Refer to "Cleaning" in Chapter 4.</li> <li>6. Ensure that your surroundings have adequate lighting.</li> <li>7. Try inverting the image (from black-to-white or white-to-black) by pressing the square-shaped settings button.</li> <li>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	<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	<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>

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
<p>The VPU is on, but my perception is dimmer than usual (continued)</p>	<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>
<p>The coil on the glasses seems warmer than usual</p>	<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>
There is a clicking noise from the area of the coil on the glasses	8. This is part of the normal operation of the glasses and does not indicate a failure of any kind.
Nosepiece comes off the glasses	<ol style="list-style-type: none"> <li>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>2. Take the nosepiece and place it on the underside of the lens where the nosepiece should be attached.</li> <li>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.</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 problem, check that the glasses cable is properly</li> </ol>

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

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

**Table 11: Audible Alarms**

<b>Symptom</b>	<b>Cause and/or Corrective Action</b>
The VPU shuts off suddenly emitting three short beeps (error-induced VPU shutdown)	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 information provided in Chapter 7.

Symptom	Cause and/or Corrective Action
<p>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)</p>	<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>
<p>The VPU emits a slow periodic beep once every 2 seconds (loss of video signal)</p>	<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 the glasses to the VPU."</li> </ol>

Symptom	Cause and/or Corrective Action
<p>The VPU emits fast periodic beeps about 2 per second (loss of RF link)</p>	<ol style="list-style-type: none"> <li>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>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>3. Limit your eye movements and look straight ahead.</li> <li>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>5. This fast periodic beeping related to the temporary loss of</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>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="769 478 1159 680">1. Refer to Table 6 from Chapter 4 of the manual for an explanation of the audible alarms.</li> <li data-bbox="769 688 1159 932">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="769 940 1159 1142">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**

### **Clinical Studies**

#### **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 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 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 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 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
  - 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 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, 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, 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 60 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 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 (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 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.**

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[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 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 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**

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

<b>Standards / Directives</b>	<b>Regulatory Classifications</b>
IEC 60601-1-2 Classifications (CISPR 11 Electromagnetic Emissions)	<p>Classification:</p> <p><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.</p> <p><u>Class B Equipment</u> Equipment suitable for use in all establishments including your home.</p>

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

**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	
Airport screening device			✓	Page 36
Bipolar electrosurgical equipment		✓		Page 35
Bluetooth device			✓	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>	
Cell phones or cordless phones			✓		Page 38
Computed tomography (CT) Scan				✓	Page 35
Commercial electrical equipment (for example, arc welders, induction furnaces, resistance welders, etc.)			✓		Page 38
Communication equipment (such as microwave transmitters, linear power amplifiers and high-power amateur transmitters)			✓		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>	
Defibrillator		✓			Page 35
Diagnostic Ultrasound				✓	Page 35
Diathermy	✓	✓			Page 27
Electric steel furnaces			✓		Page 38
Electroconvulsive therapy (ECT)	✓	✓			Page 27

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
Electronic article surveillance (EAS) systems and EAS tag deactivators			✓		Page 36
Fragmatome		✓			Page 35
Hearing aids			✓		Page 37
High output ultrasound	✓	✓			Page 38
High voltage lines, power lines or generators			✓		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>	
Home appliances			✓		Page 37
Large magnetized speakers			✓		Page 38
Laser		✓			Page 35
Lithotripsy	✓	✓			Page 27
Magnetic resonance imaging (MRI)	✓	✓		✓	Page 28
Metal detector			✓		Page 36

Device or procedure	Potential Effect:				Additional Information
	Patient injury	Damage to the Argus II System	Temporary Interruption of Stimulation	Image Artifact <sup>a</sup>	
Microwave oven			✓		Page 38
Phacoemulsification		✓			Page 35
Radiofrequency identification (RFID) systems			✓		Page 36
Theft detector			✓		Page 36
Therapeutic ionizing radiation to the head		✓			Page 35
WiFi access point			✓		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>	
Wireless router			✓		Page 38

<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

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<b>Guidance and manufacturer's declaration – electromagnetic emissions</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.

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		

<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>
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 % <i>UT</i> (>95 % dip in <i>UT</i> ) for 0,5 cycle  40 % <i>UT</i> (60 % dip in <i>UT</i> ) for 5 cycles  70 % <i>UT</i> (30 % dip in <i>UT</i> ) for 25 cycles  <5 % <i>UT</i> (>95 % dip in <i>UT</i> )	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 <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<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> <p><math>d = 1.17 P</math></p> <p><math>d = 1.17 P</math> 80 MHz to 800 MHz</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p><math>d = 2.33 P</math> 800 MHz to 2.3 GHz</p> <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>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, 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.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**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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