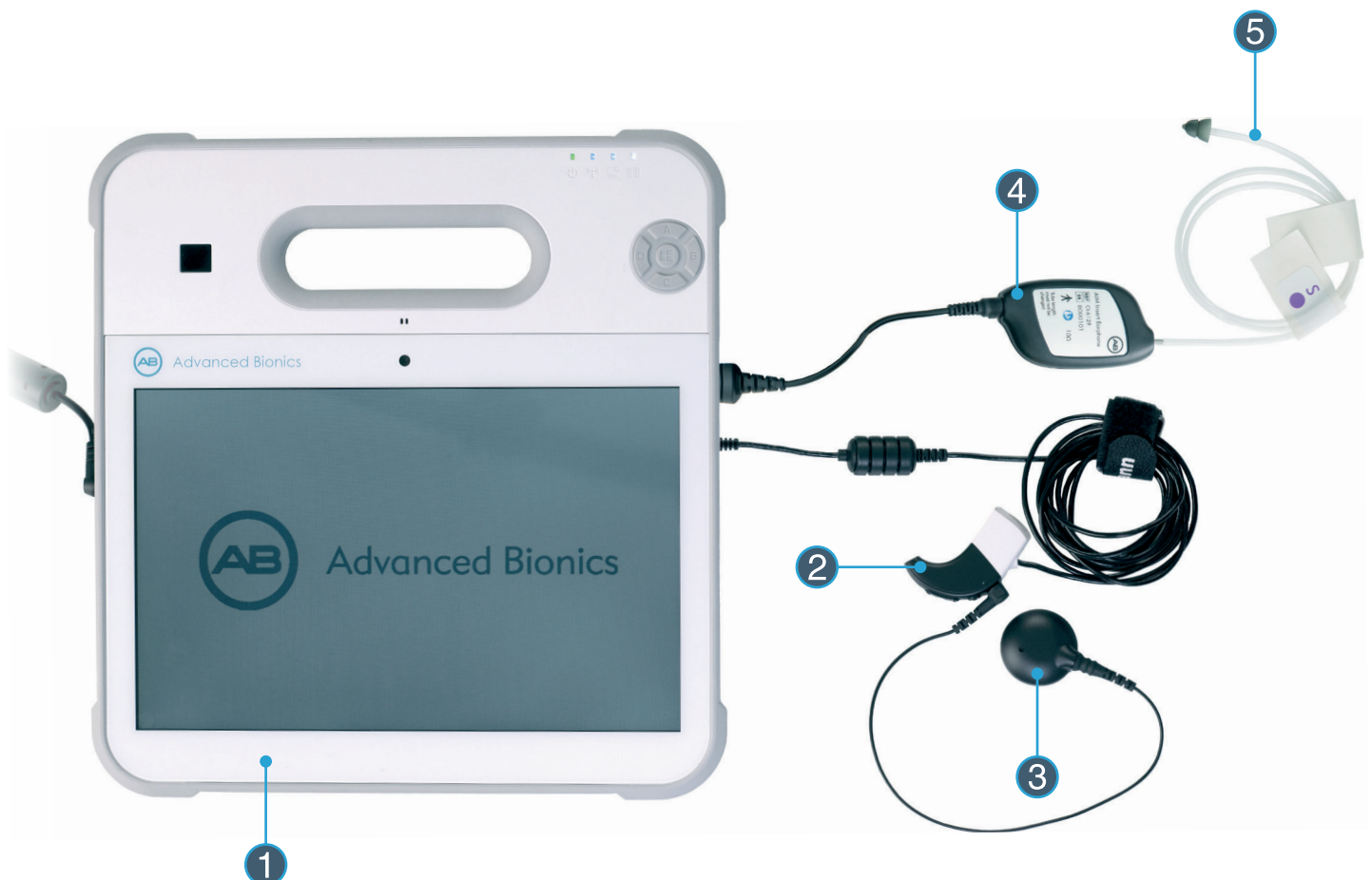


The **Active Insertion Monitoring (AIM) System** is a platform of electrophysiological measurements that can be used intra-operatively in the operating room (OR) and post operatively in a clinical setting. The intuitive touch screen tablet makes it easy to run objective measurements like Electrocochleography (ECoChG) using the Advanced Bionics cochlear implant. The system is fast, objective, convenient and can be operated by the audiologist, surgeon or supporting theatre nurse.

What you will need to use the AIM System intra-operatively:

1. The AIM System tablet.
2. Naída CI Q90 sound processor and long programming cable (provided with the AIM System).
3. Cable and headpiece with the highest strength magnet for optimal retention.
4. AIM Insert Earphone.
5. AIM Sterile Insert with acoustic tube (each package contains a small, medium or large insert).
6. Draping equipment (not supplied by AB or shown in the figure below):
 - » Surgical drapes.
 - » Sticky drapes (e.g. 3M Ioban™).
 - » Surgical tape (e.g. Tegaderm or SteriStrips).
 - » Sterile plastic sleeve for the non-sterile headpiece, processor and cable.
 - » Bone wax (optional).



1. SURGICAL PREPARATION



1a. Cleaning the ear canal

a. Make sure the ear canal is clean and unobstructed

- Perform otoscopy.
- Ensure the ear canal is free of wax which could block the acoustic stimulus and impede the measurements (figure 1a).
- If using antiseptic liquids, ensure the ear canal is suctioned out and kept clear.



1b. Ensure a tight seal of the sterile insert

b. Select the appropriate Sterile Insert size to ensure a tight seal in the ear canal

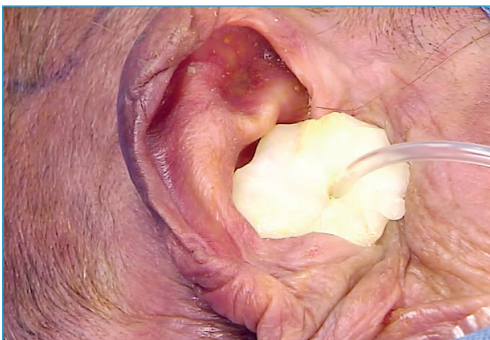
- Sterile Inserts are provided in small, medium and large sizes within each pack.
- Have a look at the patient's ear canal to estimate which insert size is most appropriate. If unsure, then start with the medium insert and check the fit in the ear canal. Try the small or large insert, if these offer a better seal of the ear canal.
- Ensuring a tight seal in the ear canal (figure 1b) will avoid dislodgement and prevent sound leakage which would impede the measurement.



1c. Wide draping

c. Draping

- Route the tubing and tape it down so that it does not displace during the surgery.
- Drape widely (figure 1c) so that you will have minimal separation between the implant coil and the headpiece. This is important for good magnetic retention between the headpiece and implant.
- The thickness of the drape and skin flap should be less than 7.0 mm.



1d. Insertion of the bone wax plug

d. Bone wax plug (optional)

- Some clinics may wish to use a bone wax plug to help further secure the insert in place and avoid dislodgement during the surgery (figure 1d).



1e. Apply the sticky drape

e. Fold the pinna

- Fold the pinna part way forward, ensuring you can see that the insert is still in place.
- Apply the sticky drape over the site, not too tightly to ensure there is no kinking of the acoustic tube (figure 1e).
- The sterile acoustic tubing length is 610 mm. It should not be cut, as it has been calibrated for the system at this length.
- Continue to drape as usual.
- Connect the sterile acoustic tubing to the non-sterile insert earphone. Ensure the insert earphone is outside the sterile field. Connect the insert earphone to the AIM tablet by plugging in the audio jack.



1f. Alternative draping

NOTE: If the above preferred draping approach was not done at the beginning of the surgery, the following steps will apply:

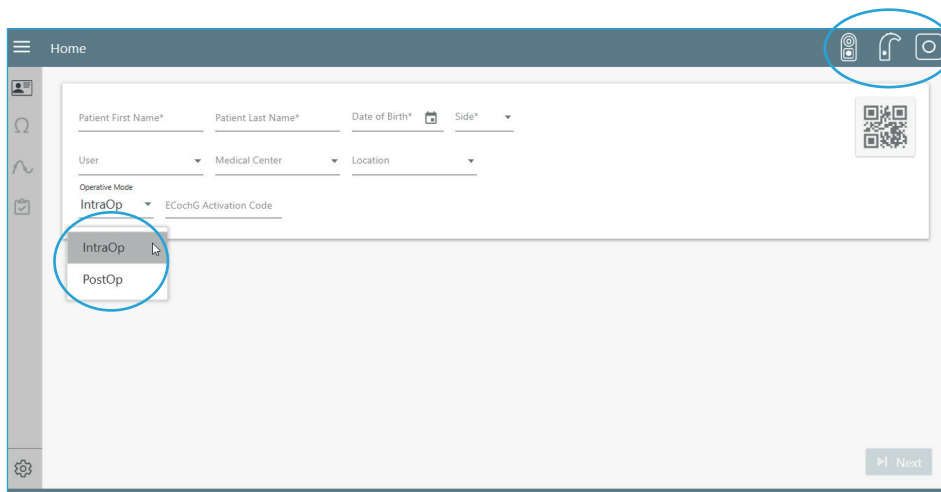
- The scrub nurse or surgeon would cut through the drapes (figure 1f) and introduce the sterile insert into the sterile field, placing it in the ear canal and ensuring a tight seal.
- Run the insert earphone and sterile tubing over the top of the head to maintain sterility.
- Connect the sterile tubing to the non-sterile insert earphone off the sterile field and connect it to the AIM tablet.

2. SURGICAL STEPS BEFORE ECOCHG MEASUREMENT

- Place and secure the implant package. Complete the cochlear implant surgery to the point of inserting the electrode array into the cochlea.
- Irrigate the implant package to ensure a good ground connection during the measurements.
- Suction out any fluid in the middle ear prior to electrode insertion, to ensure the fluid does not affect the measurement.

3. PERFORM THE AIM SYSTEM MEASUREMENTS

- Place the non-sterile headpiece and sound processor in the sterile plastic sleeve.
- Verify all equipment is properly connected.
- Use the highest headpiece magnet strength to ensure good headpiece lock stability.
- Launch the OM Suite application (figure 3a).
- Check the hardware is visible in the hardware chain.
- Enter the patient's demographic information on the “Home” screen.
- Select Mode: “IntraOp” for use in the OR.
- Scan the QR Code or manually enter the ECochG Activation Code located on the Sterile Insert Package, to enable the ECochG measures, i.e., ECochG Insertion, Electrode Sweep, and ECochG Threshold (figure 3b).



3a. OM Suite showing hardware connections and intra-op mode

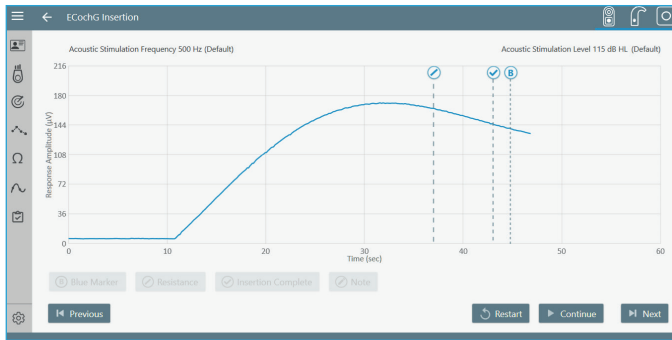


3b. QR code on sterile insert package

4. THE AIM SYSTEM MEASUREMENTS

- a. ECochG Insertion
- b. Electrode Sweep
- c. ECochG Thresholds
- d. Impedances
- e. Neural Response Imaging (NRI)
- f. Electric Stapedius Reflex Thresholds (ESRT)

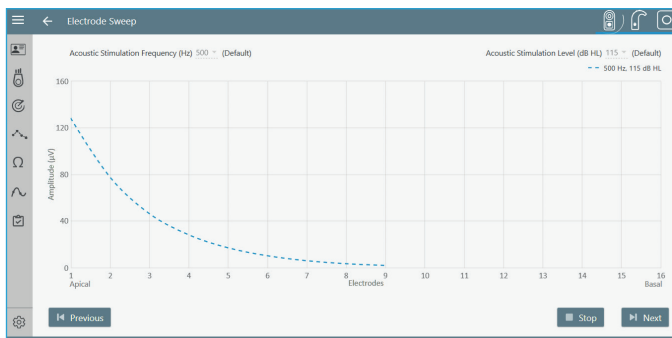
Simply click “Start” to begin the ECochG measurement and “Next” to advance to the next desired measurement. Click “Measure” to begin each measurement, or “Stop” to abort. The navigation panel can also be used to jump to the desired measurement.



4a. Real-time ECoChG measurements

a. Real-time monitoring of ECoChG potentials during electrode insertion

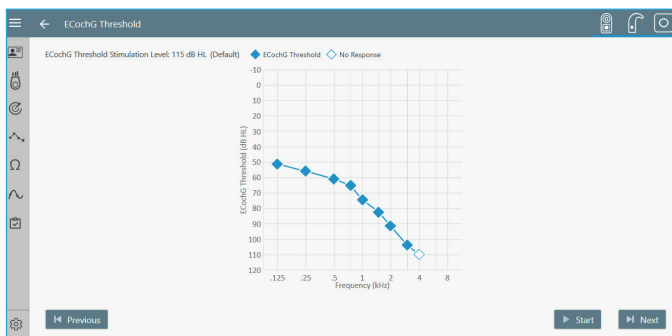
- This measurement (figure 4a) is only available when using the system in “IntraOp” mode.
- With the system fully assembled, click “Start” to begin the ECoChG measurement.
- Acoustic stimulation parameters are displayed on the ECoChG Insertion Screen. These values can be modified in settings when the system is not performing a *live* measurement.
- Real-time audio feedback is provided to the surgeon during the electrode insertion. To enable, go to: Settings > ECoChG > Audio On
- Use the buttons at the bottom of the screen to annotate the measurements as desired. Click “Note” to add any custom notes during the measurement or if resistance is felt during the electrode insertion click on the “Resistance” button to mark the position.
- Click “Stop” to end the ECoChG Insertion measurement and “Next” to advance to the Electrode Sweep or use the navigation panel to select the desired measurement.



4b. Electrode Sweep

b. Electrode Sweep

- Acoustic stimulation parameters are displayed on the Electrode Sweep screen (figure 4b) and may be adjusted here.
- Measurements that are not significantly above the noise floor are displayed as open symbols.



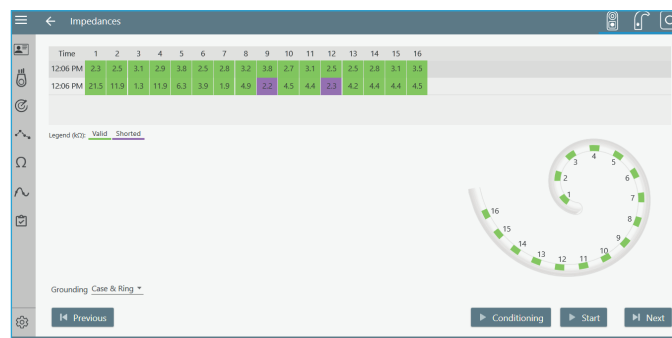
4c. ECoChG Threshold

c. ECoChG Threshold

- Acoustic stimulation level is displayed on the ECoChG Threshold screen (figure 4c), this may be adjusted in the settings.
- Measurements that are not significantly above the noise floor are displayed as open symbols.

d. Impedances

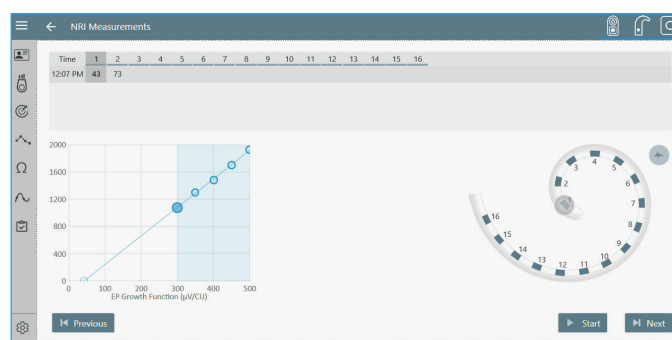
- Conditioning will be performed prior to the first impedance measurement.
- Click “**Conditioning**” to rerun conditioning and measure impedances.
- Click “**Start**” to remeasure the impedances.
- Table of impedances will show the values for the last three measurements only.
- Color coded legend indicates **Valid**, **Shorted** or **Open impedances** (figure 4d).



4d. Impedances

e. Neural Response Imaging (NRI)

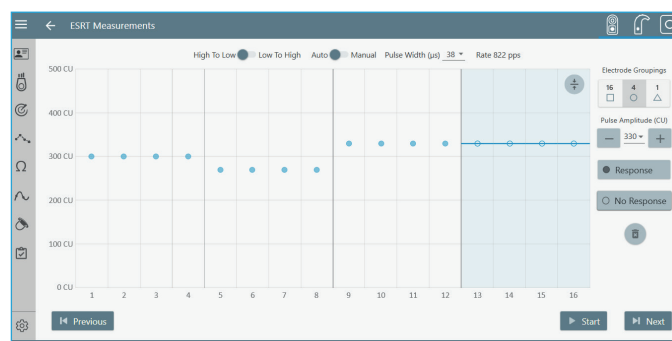
- Electrode impedances must be measured prior to the start of NRI.
- tNRI will be estimated for all selected contacts that have a valid impedance value.
- Compliance limit is represented with a yellow vertical line in the NRI Growth Function graph when relevant.
- By clicking on the view button the user can switch between looking at the electrode array image and the individual response curves (figure 4e).



4e. NRI measurements

f. Electric Stapedius Reflex Thresholds

- The AIM system provides the stimulation for ESRTs and the intra-op response can be determined visually by observing the stapedius muscle.
- The user may select within settings to “**Measure High to Low**” (default in intra-op mode).
- ESRT can be measured with Electrode Groupings of 1, 4, or 16 contacts (figure 4f). When channels are not selected or have invalid impedances these channels will be omitted from the Electrode Grouping of 16.
- To make a measurement, all electrodes need to be in compliance. This can be managed by reducing the pulse amplitude, increasing the pulse width, or deselecting electrodes with low compliance levels.
- The blue horizontal line indicates the selected pulse amplitude. This may be adjusted using the “-” and “+” buttons, using the drop down value for Pulse Amplitude, or by clicking and dragging the line indicating the current Pulse Amplitude.
 - » The step size for changes in Pulse Amplitude can be modified in the ESRT Settings.
- Clicking on the view button reveals the compliance limit for each contact and provides the ability to select or deselect contacts.



4f. ESRT measurements

- Description of Auto measurements:
 - » With auto enabled, clicking **“Start”** will begin the measurement.
 - » The specified number of stimulation cycles will be presented.
 - » User will have an opportunity to click **“Response”** or **“No Response”** to indicate what was observed during stimulation. However, it is not required that the user click either of these two buttons.
 - » When threshold is being estimated by going high to low, stimulation will be stopped when the first **“No Response”** is recorded.
 - » When threshold is being estimated by going low to high, stimulation will be stopped when the first **“Response”** is recorded.
- Description of Manual measurements:
 - » With **“Manual”** enabled, clicking **“Start”** will begin the measurement.
 - » The specified number of stimulation cycles will be presented.
 - » User may indicate a response or no response by clicking on the corresponding buttons, or click **“Start”** again to present stimulation at the same level an additional time.
 - » User may change stimulation parameters, e.g., increase or decrease pulse amplitude, and click **“Start”** to present stimulation.
- Deleting marked Response/No Response:
 - » Response/No Response symbols can be deleted by placing the blue line, current pulse amplitude line over the symbols that the user desires to delete.
 - » The user then clicks on the **“Trash”** button and this opens a list of the Response/No Response symbols that are covered by the blue line. Clicking on the desired symbol will result in its deletion.

5. SAVING AND EXPORTING DATA

Click **“Export”** to export and save the recorded data, if desired. A comprehensive PDF report is also generated which shows a summary of the measurements.

6. CLEANING

Always clean the AIM System with an isopropyl alcohol wet wipe after OR use i.e. AIM tablet, non-sterile insert earphones, processor, cables, etc. Ensure the system is turned off and disconnect the power supply prior to cleaning.

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