

	Title:	Hearing - Audiometer		
	Version Date:	2014-JUL-10	Document Number:	SOP_DCS_0020
	Effective Date:	2014-OCT-15		
Data Collection Site (DCS)	Version:	3.0	Number of Pages:	8

1.0 Purpose:

The purpose of this document is to describe the procedure for measuring a participant's hearing using the RA 300+ Digital Screening Audiometer.

2.0 Scope:

This document is to be used by the DCS staff who administer the hearing test to participants.

3.0 Responsibilities:

DCS staff are responsible for performing the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

- **SOP_DCS_0044** - Audiometer - Calibration and Maintenance

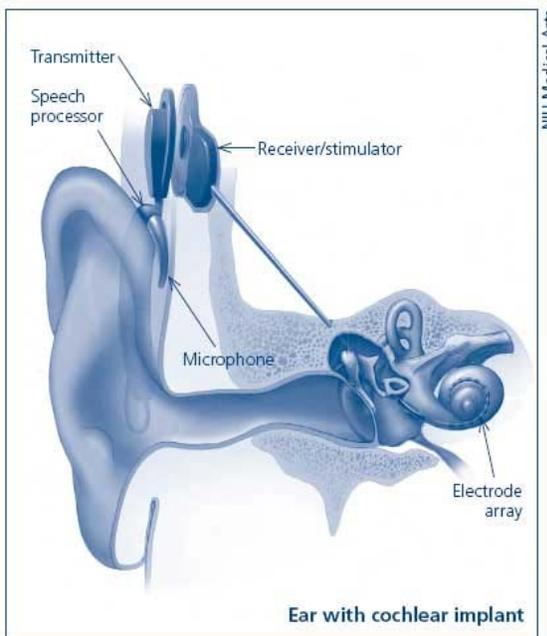
5.0 Definitions:

- **Bone anchored hearing aids:** a type of hearing aid that conducts sound through the bone, for people with conductive hearing loss, unilateral hearing loss, and mixed hearing losses. The sound processor typically clips onto the screw which has been implanted into the skull.

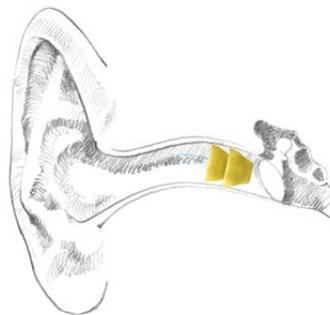


- **Cochlear implants (CI):** a surgically implanted electronic device that provides a sense of sound to a person who is profoundly deaf or severely hard of hearing. With a conventional CI, all residual hearing for the ear with the CI is absent because of complete or almost complete destruction of the cochlea. With a hybrid CI, the user typically has normal to moderately-severe hearing impairment in the low frequencies and profound hearing impairment in the higher frequencies. A hybrid CI operates by providing conventional amplification in the low frequencies and electrical stimulation in the high frequencies. For this surgery, the CI electrode is only partially inserted into the cochlea, thus destroying residual

cochlear abilities in the high frequencies, while maintaining cochlear abilities in the low frequencies. Note, hybrid CIs are far less common than conventional CIs.



- **External processor units:** the external parts of a hearing aid consisting of the microphone, the speech processor, and the transmitter. Users should know how to remove these as this is part of basic maintenance of the device. Please note that the external processing unit is typically worn on the ear, but there are body worn external processing units. It is not necessary to have the user remove a body worn external processor unit if the CI is turned off because it won't get in the way of further testing.
- **Lyric hearing aids:** a type of hearing aid placed deep in the ear canal and worn on a permanent or semi-permanent basis.



6.0 Equipment:

- Audiometer - Tremetrics RA300 with response button; and,
- Audiocup headphones.

7.0 Supplies:

- Disinfectant wipes; and,
- Sheet of paper to cover the audiometer screen.

8.0 Procedure Steps:

Contraindications:

- Lyric or bone anchored hearing aid

To Be Noted

In Onyx, note the following:

- Ear conditions that would affect the measurement of hearing;
- Tinnitus;
- Burst ear drum;
- Facial structure/abnormalities;
- Religious headgear affecting the headphones' proper placement.

Only on setup

- Initialize the Audiometer with **[SPECIAL 0]**. Proceed through the steps 'Special 1' and 'Special 2' in sequence. These two steps are used to initialize the Audiometer. After entering the information required for Special 1 and Special 2, this information is permanently entered in memory and does not have to be re-entered at power on.
- Verify the correct time and date using **[SPECIAL 1]**.
- Select the stimulus using **[SPECIAL 2]**. Stimulus must be selected to Pulsed to accept the current stimulus, press **[YES]** or **[ENTER]**.

Be aware that this equipment is attached to a computer that has two screens, the Interviewer screen and the Participant screen. Some of the windows will automatically come up on the Participant screen. You are recommended to drag these windows to the Interviewer screen for ease of viewing.

Each day, before administering any hearing tests, perform the daily calibration check as per the *SOP_DCS_0044 - Audiometer – Calibration and Maintenance*.

Step 1: At the *Interview Tab* in Onyx, look for "Hearing" measurement in the list of stages. Then select **Start** in the "Actions" in that row.

Step 2: The "Hearing: Start" window will pop up

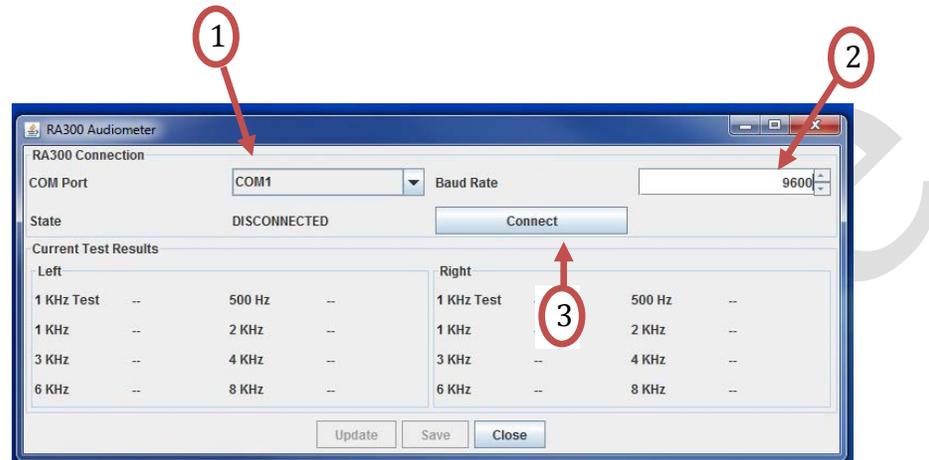
Step 3: **Scan** the Interview ID barcode then click on **Continue**.

Step 4: Click **Start** in Onyx, the RA300 software will start up. The software notification screens may appear on the Touch Screen near the participant.

Step 5: On the Audiometer, press **New Tests**.

Step 6: When prompted with "Test Daily Biological?", press **No**. When the display shows "Set up for a new test?", choose **Yes**. When the prompt to "Enter subject ID#" appears, press **Enter**. **Manually enter the participant ID.**

Step 7: On the RA300 software screen check to be sure that **com4** (may vary by site) is the port and that the baud rate is **9600**.



Press **Connect**. Wait to be sure the instrument is connected.

→ If the connection fails, then the warning will show on the screen, press **OK**. you may have to try to connect again.

NOTE: The status on the RA300 software screen will indicate whether the machine is connected to Onyx.

Step 8: Explain to the participant that "The purpose of the test is to measure how low a sound you can hear. Guessing is allowed, and you can press the button no matter how low the pulse sound is. Before we begin, I need to ask if you are currently using any type of hearing aid".

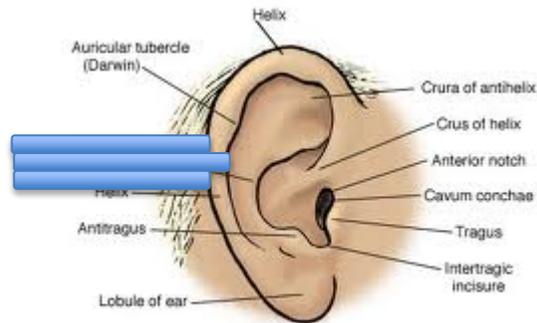
NOTE: This is an unaided threshold test. **Hearing aids/sound processors** need to be removed once instructions for the test are given.

- **Cochlear implants** need to be turned off and ear-worn external processor units need to be removed once instructions for the test are given. Other other body worn external processor units do not need to be removed.
- Users of hearing aids by "**Lyric**" need clinical assistance to re-insert their hearing aids, so participants with these aids should not be asked to remove them. These participants cannot do the test and staff should add the comment "could not test".
- **Bone anchor hearing aids** can be turned off, but the CLSA doesn't have the correct set-up to run the test. These participants cannot do the test and staff should add the comment "could not test".

Step 9: Explain what participants will need to do. They will be wearing headphones and they will hear pulsed sounds (This is a group of 3 beeps). When they hear any part of the pulsed beeping, they are to click the button once on the hand-

held response gauge. This is to be repeated for each group of 3 beeps (at any point during the beeping) that they can hear.

Step 10: Prior to placing the Audiocup headphones on the participant, check for collapsing hearing canals. Gently press the back part of the external ear (with your three fingers) while looking at the ear canal to see if it collapses (no otoscope needed). Also take note if there is a lot of wax in the canal or any other issue that may affect the results of the hearing test. Once the hearing test is complete, please document these issues in the Hearing Questionnaire in Onyx.



Step 11: Remove hearing aids if required.

Step 12: Carefully place the Audiocup headphones on the participant's head.

Step 13: The headphone centre should be directly placed over the ear canal. The red plug goes on the right ear and the blue goes on the left ear! **Be sure to place a sheet of paper or a binder over the small screen on the RA300 to block the participant's view or move the chair so the participant faces away from the screen. The participant must not see the small screen because it will give clues as to when they should be pressing the response button.**

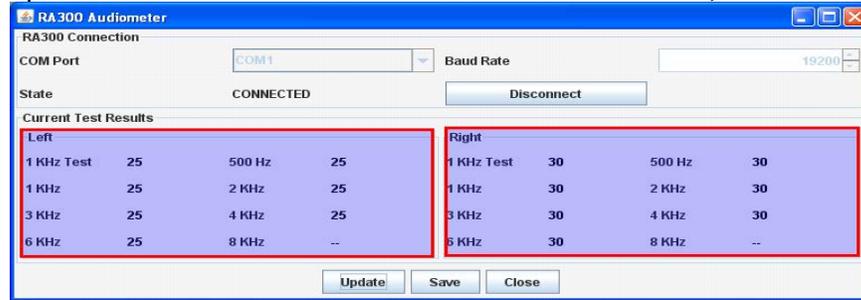
Step 14: Ensure that the participant can't see the computer screen as the results will be displayed.

Step 15: Press **RUN TEST** on the Audiometer. The participant will now press the response button as they hear the sounds in their headphones.

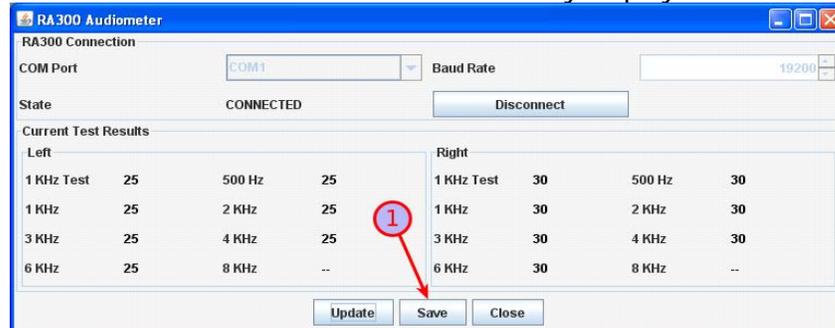
Step 16: When the test is done you will hear two audible beeps from the Audiometer (without the headphones).



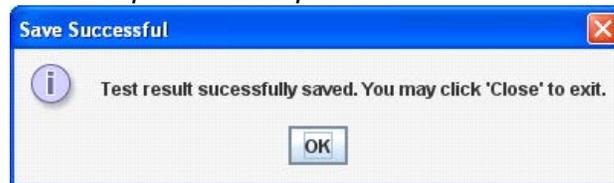
Step 17: When done, press the **Update** button on the software and the display will update to show the values read from the Audiometer (as shown below).



Step 18: Press the **Save** button to send the currently displayed values to Onyx.



Step 19: Press **OK**, then **Close**, to exit the software.



Step 20: Press **Next** on the Onyx screen, then click **Finish**.

Step 21: The "Hearing – Finish" screen will pop up. Click **Continue**.

Step 22: Open the "Hearing Questionnaire" and document the quality of the test by answering the reliability question.

Step 23: Indicate the status of the canal for both ears.

Step 24: When complete, click on **Next**, **Finish** and **Continue**, as they appear.

Step 25: Clean the Audiocup headphones and the response button with a disinfectant wipe after each participant.

9.0 Documentation and Forms:

- CRF_DCS_0020 - Hearing Case Report Form

10.0 References:

- Tremetrics RA300 & RA300 Plus Operations Manual. Minnesota: Hawkwa, Inc.; 2011.

Baseline Revision History:

New Version #	Revision Date	Revision Author	Content Approval
3.0	2014-JUL-10	Lorraine Moss	Mark Oremus
Summary of Revisions			
SOP format updated			
Wording of Scope, Purpose and Responsibilities updated and clarified.			
Added 'Sheet of paper to cover the audiometer screen' in Supplies			
Reformatted Contraindication and Setup instructions under Procedure section			
Step 4 clarified to state The software notification screens may appear on the Touch Screen near the participant.			
Divided Step 5 into the following: (renumbered steps following) Step 5: On the Audiometer, press New Tests Step 6: When prompted "Test Daily Biological?", press No , then the display shows "Set up for a new test?" Choose Yes . Then a prompt to "Enter subject ID#" shows, press Enter . Manually enter the participant ID			
Added Step 9 (renumbered steps following): Also explain what they need to do. They will be wearing headphones and they will hear pulsed sounds (This is a group of 3 beeps). When they hear any part of the pulsed beeping, they are to click the button once on the hand-held response gauge. This is to be repeated for each group of 3 beeps (at any point) that they can hear			
Added Step 11 (renumbered steps following): Remove hearing aids if required			
Divided Step 12 into the following (renumbered steps following): Step 12: Carefully place the Audiocup headphones on the participant's head. Step 13: The headphone centre should be directly placed over the ear canal. The red plug is for the right ear and the blue goes on the left ear! Be sure to place a sheet of paper or a binder over the small screen on the RA300 to block the participant's view or move the chair so the participant faces away			
Added Step 14 (renumbered steps following): Ensure that the participant can't see the computer screen as the results will be displayed			
Added Step 17 (renumbered steps following): When done press the Update button on the software, the display will update to show the values read from the Audiometer as shown below			
Added Step 19 (renumbered steps following): Press OK then Close to exit the software			
Divided Step 22 in the following (renumbered steps following): Step 22: Open the "Hearing Questionnaire" and document the quality of the test by answering the reliability question Step 23: Indicate the status of the canal for both ears Step 24: When complete click on Next, Finish and Continue , as they appear			
New Version #	Revision Date	Revision Author	Content Approval
2.1	2012-Jun-12	Lorraine Moss	Mark Oremus
Summary of Revisions			
Added to Step 7, NOTE: This is an unaided threshold test. Hearing aids/sound processors need to be removed. Cochlear implants need to be turned off and ear-worn external processor units need to be removed. It is not necessary to remove other body worn external			

processor units. Users of hearing aids by "Lyric" need clinical assistance to re-insert their hearing aids, and therefore, should not be asked to remove their aids.

Added **Definitions** of Bone anchored hearing aids, Cochlear implants and external processor units, and Lyric hearing aids.

New Version #	Revision Date	Revision Author	Content Approval
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2.0	2012-Dec-17	Lorraine Moss	Mark Oremus
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Summary of Revisions

Contraindication added

Paragraph one of **Step 6** of section **6.0 Procedure Steps** updated to com4

Paragraph 2 of **step 6** of section **6.0 Procedure Steps** updated to read: Press **Connect**. Wait to be sure the instrument is connected.

→ If it fails the warning will show on the screen, press **OK**. It may be necessary to try to connect again.

NOTE: The status on the RA300 software screen indicates if the machine is connected to Onyx

Step 12 of Section **6.0 Procedure Steps** updated to read: The **Save** button can be pressed to use the currently displayed values to send to Onyx. The following dialog will then be:

Step 5 – changed the last sentence to read "**Manually enter the participant ID.**"

Various grammatical and spelling corrections throughout the document