	Title:	Hearing - Audiometer		
	Version Date:	2019-SEP-03	Document Number:	SOP_DCS_0020
	Effective Date:	2019-OCT-15		
Data Collection Site (DCS)	Version:	3.3	Number of Pages:	7

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 administers 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:

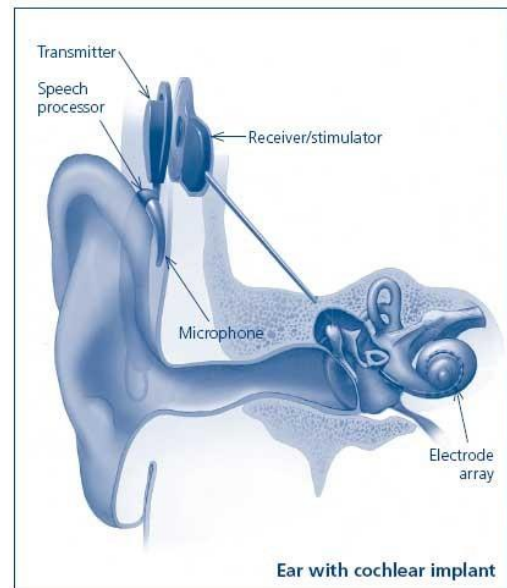
- **SOP_DCS_0044** – Audiometer - Calibration and Maintenance
- **SOP_DCS_0080** - Audiometer Transferring - Troubleshooting

5.0 Definitions:

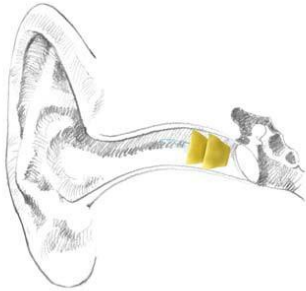
- **Bone anchored hearing aids:** a type of hearing aid that conducts sound through the bone, for people with conductive hearing loss, unilateral hearing loss, and mixed hearing losses. The sound processor typically clips onto the screw which has been implanted into the skull.



- **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 (nonalcoholic) wipes or cloth and cleaning solution;

8.0 Procedure Steps:

Contraindications:

- Wearing a Lyric hearing or bone anchored hearing aid;
- Current ear infection with discharge in one or both ears.

To Be Noted

In Onyx, note the following:

- Ear conditions that would affect the measurement of hearing;
- Burst ear drum;
- Facial structure/abnormalities such that the headphones cannot be worn with a reasonable seal; and,
- 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]**.

- c. 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. It is recommended that these windows be dragged 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.

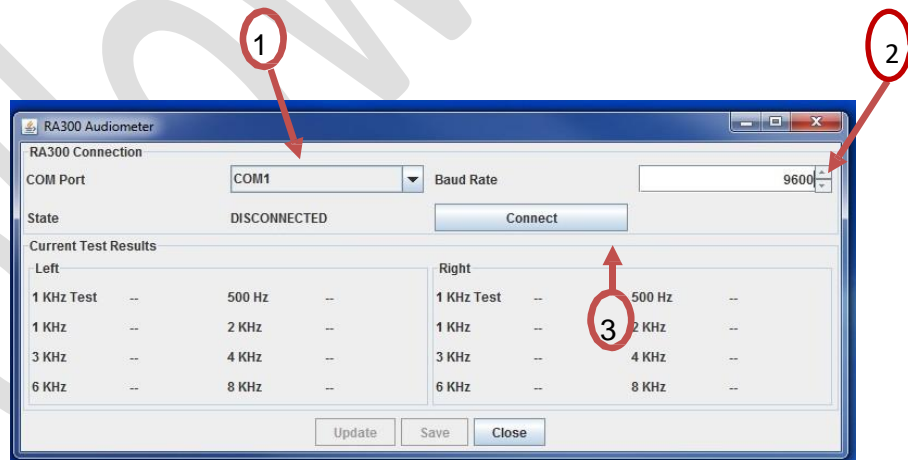
Step 3: **Scan** the interview ID barcode then click on **Continue**.

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, manually enter the participant ID and press **Enter**.

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 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: Ask the participant “Which ear they hear better with?”

Step 10: Set the test to start on the ear the participant hears better with, press **SPECIAL** then **4** and **Enter**. Answer the questions on the audiometer according to the participant’s preference. If the participant says both ears hear the same, then always test the left ear first.

For example: to change to the right ear when it was left

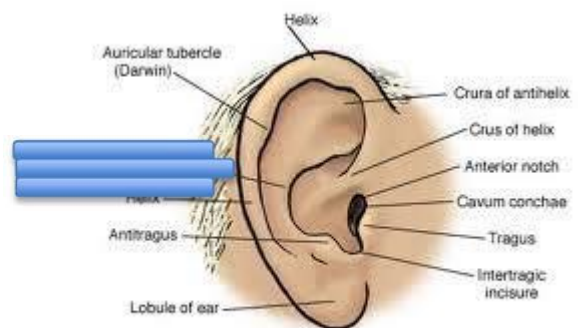
TEST LEFT EAR FIRST- enter N

TEST RIGHT EAR FIRST- enter Y

NOTE: Steps 9 and 10 must be done for every participant as the ear preference does not revert to left default.

Step 11: 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 12: 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 13: Remove hearing aids if required.

Step 14: Eliminate all obstructions between earphone and participant (hair, eyeglasses, earrings, hearing aids, etc.). This will make it more comfortable to wear the headphones and may also ensure that there is a good seal between the headphone and the participant's head. If a person cannot or will not remove these items then the possible effects on the test should be noted by the tester.

Step 15: Fully extend the headband of the headphones. Carefully place the Audiocup headphones on the participant's head.

Step 16: 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!
NOTE: 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 17: When the headphones have been positioned, hold them in place and slide the top of the headphones down so that it rests solidly on the top of the participant's head

Step 18: Ensure that the participant can't see the computer screen as the results will be displayed.

Do a final visual inspection to make sure that the headphones exert firm pressure on each ear and form a good seal with the head of the participant.

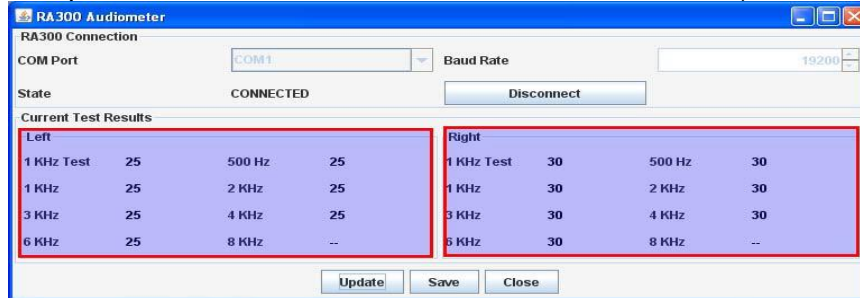
Step 19: Press **RUN TEST** on the Audiometer. The participant will now press the response button as they hear the sounds in their headphones.

Step 20: When the test is done you will hear two audible beeps from the Audiometer (without the headphones).

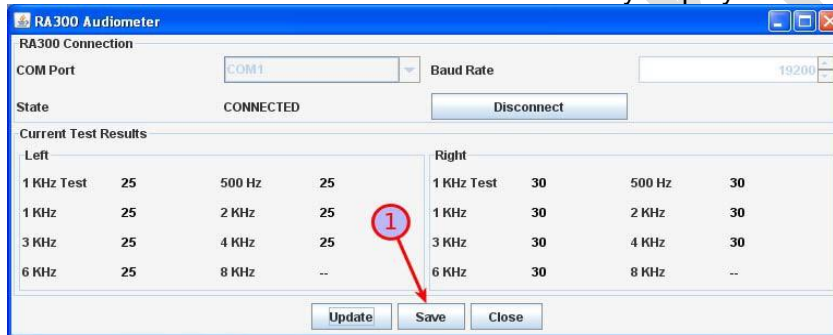




Step 21: When done, press the **Update** button on the software and the display will update to show the values read from the Audiometer (as shown below).



Step 22: Press the **Save** button to send the currently displayed values to Onyx.



Step 23: Press **OK**, then **Close**, to exit the software.



Step 24: Press **Next** on the Onyx screen, **ensure that the results transferred into Onyx**, then click **Finish**.

Step 25: The *Hearing – Finish* screen will pop up, click **Continue**.

Step 26: Open the *Hearing Questionnaire* and document the quality of the test by answering the reliability question.

Step 27: Indicate the status of the canal for both ears.

Step 28: When complete, click on **Next**, **Finish** and **Continue**, as they appear.

Step 29: 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.

F2 Revision History:

New Version #	Revision Date	Revision Author	Content Approval
3.3	2019-SEP-03	Lorraine Moss	Harriet Sauve
Summary of Revisions			
Updated Contraindications and to be noted section			
New Version #	Revision Date	Revision Author	Content Approval
3.2	2019-MAY-13	Lorraine Moss	Harriet Sauve
Summary of Revisions			
Highlighted step 19 – 22 as important.			
Ensure that the results transferred into Onyx in Step 22.			
In step 11, added “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 9 was changed to ask which ear the participant hears better with.			
Step 10 was updated to reflect the participants choice in step 9.			
Added the NOTE under step 9.			