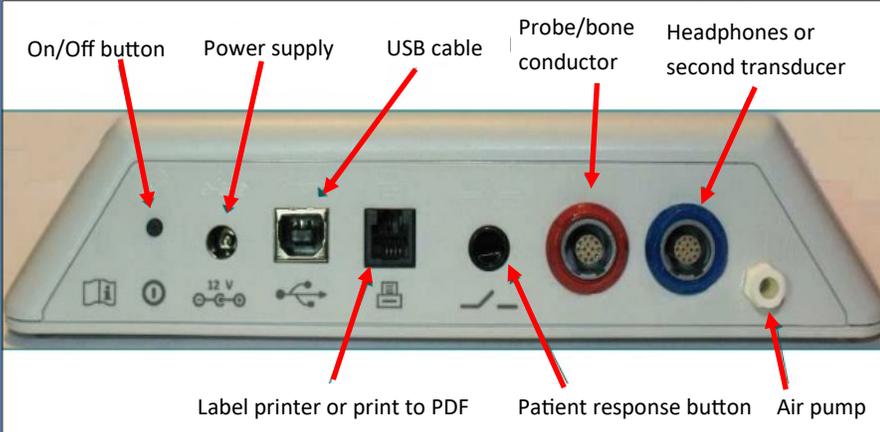


The Bio-logic AuDX PRO FLEX device enables a variety of audiology tests to be performed. Results can be saved to an AFHCAN case when devices are integrated with *AFHCANcarts or used with *AFHCAN cart client.

Device Overview

On/Off button & Socket Panel:



Accessory Boxes:



Include Ear Tips, Probe Tips, & Calibration Tools

Probe Tip:



Probe tips are **not** interchangeable. Correct size **MUST** be used.

Adult/Child: use PT-A probe tip (transparent with larger nozzle)

Infants <7 months: use PT-S probe tip (white with smaller nozzle)

Note: Always attach ear tip before placing in ear

Headset:



Patient Response Button:



Tympanometer Calibration Tool:



General Instructions for use with *AFHCANcart . *Version 8.4.5 or higher required.

First, prepare the AFHCANcart: log in, create case, select patient, select "Add to Case", then select "Audiology" button. **Note:** If no "Audiology" button, contact your local IT.



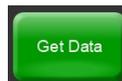
Steps 1-4 MUST be followed in order:

On the PATH Bio-logic:

1. **Verify correct patient is displayed.** Test will not save if patient name is not displayed.
2. **From the home screen, select and run all desired tests** (multiple tests can be saved at the same time). Follow testing instruction prompts for each test.
3. **Return to home screen** once all desired tests are complete.

On the AFHCANcart:

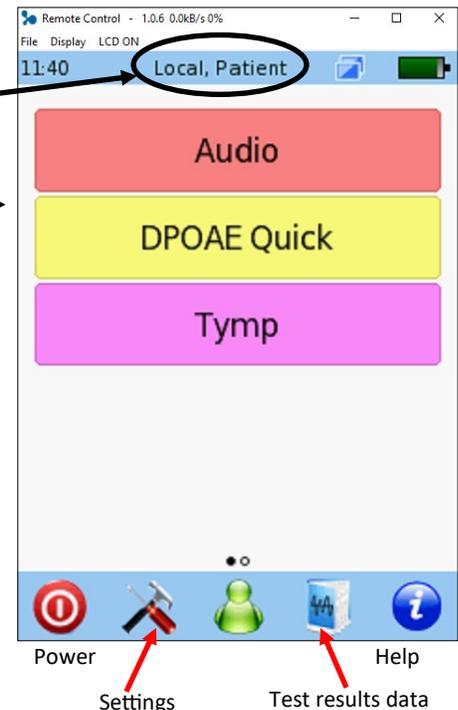
4. **Select "Get Data".**
5. Label, review and "Save" test data on the cart.



If additional testing is needed after getting data, select "Add to Case" button and repeat from Step 1.

6. Once all tests have been saved in AFHCAN, send the case to the desired recipient.

Home screen:



Audiometry— Audiometry tests the ability to hear sounds.

AudioScreen: Manual screening test

AutoDxAudio: Automated diagnostic test

ManualDxAud: Manual diagnostic test (use for patients unable to respond reliably to automated test)

Audiometry should be done in a **quiet space**. Make sure **patient is facing away** from the device during testing.

Prior to starting, follow instructions from page 1: **General Instructions for use with AFHCANcart**

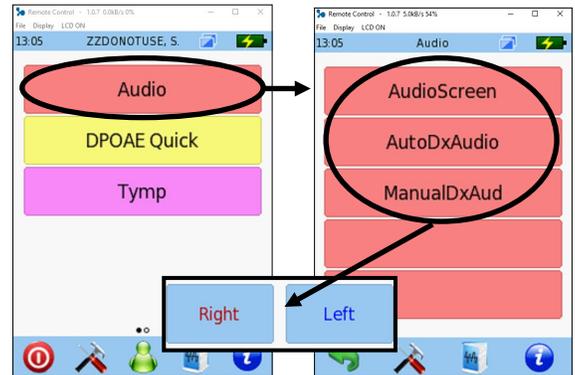
For ALL Audiometry Tests:

1. From device home screen, select “Audio”. Then choose desired test.

- Verify that the headset and patient response button are plugged-in to the correct ports on the device.
- Place headset on patient (**RED on RIGHT** ear).
- Explain the procedure and position patient away from device.

2. Right or Left: choose which side to test first.

During each test, patient will be listening carefully for a sound. Instruct them to press the patient response button when they hear it.



Specific Test Instructions:

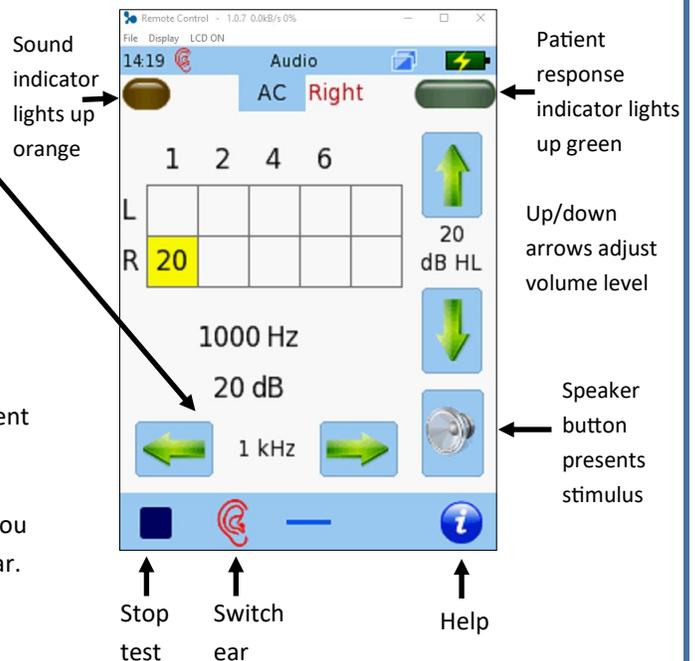
AudioScreen:

- Up/down** arrows adjust volume level
 - Left/right** arrows **toggle between frequency levels**
 - Speaker** button presents the stimulus (sound)
- The test starts by measuring the first frequency level (1000 Hz). **Press the speaker button to present the stimulus.** When patient responds, patient response indicator lights up in green.
 - *If patient responds, lower the volume & present the stimulus again.
 - *If patient does not respond, increase the volume and present the stimulus again.

2. Continue to adjust the volume and present the stimulus until you have reached the lowest volume dB HL the patient is able to hear.

NOTE: If no response, tap on the device screen and it will display NR=No response. Tap again and the square becomes blank.

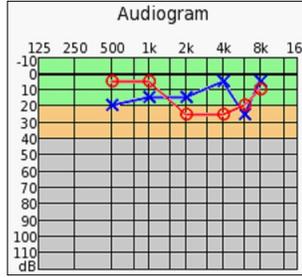
- Once the lowest volume level that the patient can hear has been recorded, **use the left/right arrows to move on to the next frequency level** and repeat.
- To switch ears:** click on the ear at the bottom of the screen.
- Once testing is complete, click on **Stop** test. Use the “back” arrow to return to the home screen.



Audiometry– continued

AutoDxAudio: automated diagnostic test

1. Select the play button  to start the test.
2. Once testing of the first ear is complete, the device will automatically switch to the other ear.
3. Once entire test is complete, device will display Audiogram results:



4. Click on the back arrow to return to Audio screen. Click the back arrow again to return to Home Screen.



Sound indicator lights up in orange

Patient response indicator lights up in green

Start test

Stop test Switch ear Help

ManualDxAud: manual diagnostic test. Use for patients who are unable to respond reliably to the automated test. Follow your clinical guidelines when performing this test.

1. Test is pre-set to begin at 40dB HL at 1000Hz. **Press the speaker button to present the stimulus.** When patient responds, the patient response indicator lights up in **green**.
*If patient **does not** respond, increase volume & present stimulus again.
*If patient **does** respond, decrease volume & present stimulus again.

Use the “bracketing” process (down 10 dB, up 5 dB) to isolate the patient’s true hearing threshold at each frequency.

2. When you have determined the lowest dB HL the patient can hear for each frequency, **tap on the device screen to mark the results.** Tapping on the device screen **twice** indicates “No Response”.
3. Once you have marked the results for the first frequency level, **use the left/right arrows** to move on to the next frequency level and repeat step 2 until you have tested all desired frequency levels.
4. To switch ears, click on the ear icon at the bottom of the screen.
5. Press the **Stop** button to stop the test.
6. When done, device will display Audiogram results.
7. Click on the back arrow to return to Audio screen. Click the back arrow again to return to Home Screen.



Sound indicator lights up orange

Patient response indicator lights up green

Up/down arrows adjust volume level

Speaker button presents stimulus

Stop test Switch ear Help

Key:	
Right Ear	Right Ear, No Response
	
Left Ear	Left Ear, No Response
	

Distortion Product Otoacoustic Emissions (DPOAE Quick)- reflects outer hair cell integrity and cochlear function. When used appropriately, they are an effective diagnostic tool and can detect hearing loss with accuracy.

OAE Screen: Screening assessment

Dx OAE: Diagnostic assessment– use if patient fails the OAE Screen

Prior to starting, follow instructions from page 1: **General Instructions for use with AFHCANcart**

Ear Tip Selection: Select an ear tip that will fit on the appropriate probe tip. It should fit in the ear comfortably and securely without leakage. You may need to try more than one to get a proper fit. Ear tips are disposable and should never be re-used on different patients.

Adult/Child: Use ear tips that begin with ET or PM with the PT-A (adult/child) transparent probe tip.

Infant <7months: Use ear tips that begin with ET-S with the PT-S (infant) white probe tip.

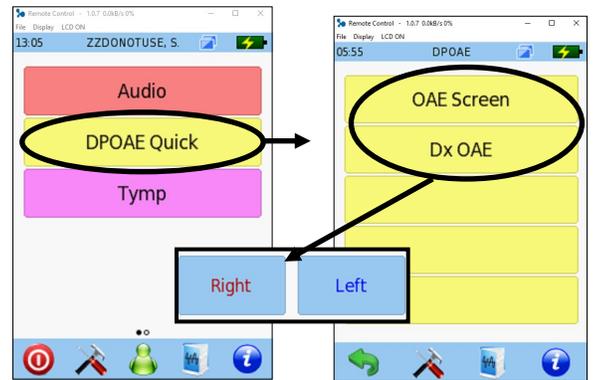
For ALL OAE Tests:

1. From device home screen, select “DPOAE Quick”. Then choose desired test.

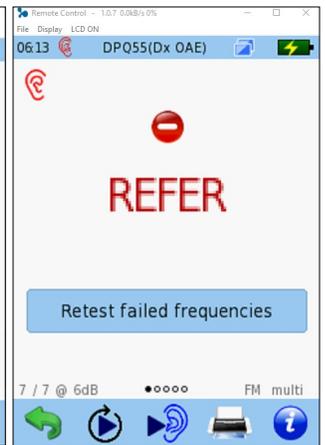
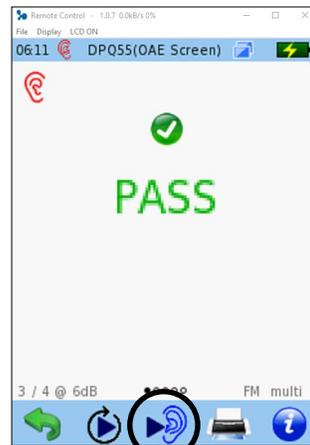
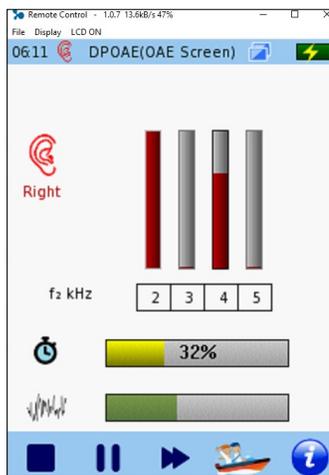
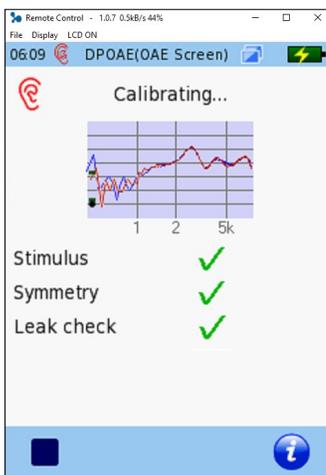
- A. Verify that the probe is plugged-in to the correct ports on the device.
- B. Select appropriate ear tip size and place on end of probe.
- C. Insert probe in ear, ensuring proper fit. Do not hold in place if possible. Consider gently resting cord on top of patient’s head.

2. Right or Left: choose which side to test.

3. Calibration will begin automatically. Once seal is obtained, screen will advance and the OAE test will begin automatically.



4. Once test is complete, results will show either “PASS” or “REFER”.



5. To switch ears, click on the ear at the bottom of the screen and repeat.

6. Click on the back arrow to return to DPOAE Quick screen. Click the back arrow again to return to Home Screen.

Tympanometry— an acoustic evaluation of the condition of the middle ear eardrum and the conduction bones. The test works by creating variations of air pressure in the ear canal, measuring energy transmission through the middle ear.

TympScreen— Screening assessment

TympReflex— Tympanometry with reflex: use if the patient fails the TympScreen (full measure)

Infant <7mo— Use for patients under 7 months of age

Prior to starting, follow instructions from page 1: **General Instructions for use with AFHCANcart**

Ear Tip Selection: Select an ear tip that will fit on the appropriate probe tip. It should fit in the ear comfortably and securely without leakage. You may need to try more than one to get a proper fit. Ear tips are disposable and should never be re-used on different patients.

Adult/Child: Use ear tips that begin with ET or PM with the PT-A (adult/child) transparent probe tip.

Infant <7months: Use ear tips that begin with ET-S with the PT-S (infant) white probe tip.

For ALL Tympanometry Tests:

1. From device home screen, select “Tymp”. Then choose desired test.

- A. Verify that the probe is plugged-in to the correct ports on the device.
- B. Select appropriate ear tip size and place on end of probe.
- C. Insert probe in ear, ensuring proper fit. Do not hold in place if possible. Consider gently resting cord on top of patient’s head

2. **Right or Left:** choose which side to test.

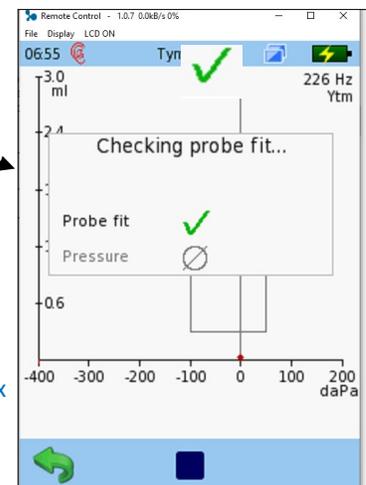
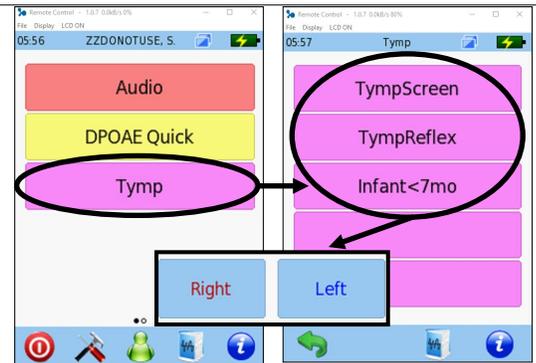
3. System will check probe fit and wait for the pressure build up.

NOTE: The LED light on the probe will pulse at a steady rate to indicate a correct fit. If unable to make proper seal, try using a different ear tip.

4. Once a proper seal has been obtained, the test will proceed automatically and a tympanometry test will be performed. If you have chosen the TympReflex test, a reflex measurement will also be included.

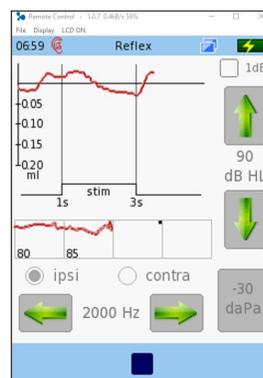
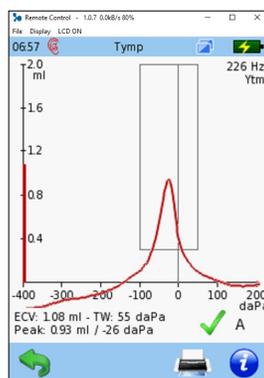
5. Once testing is complete, use the back arrow to return to home screen.

6. Repeat steps to complete test on other ear if indicated/ desired.



Tympanometry

Tympanometry with reflex

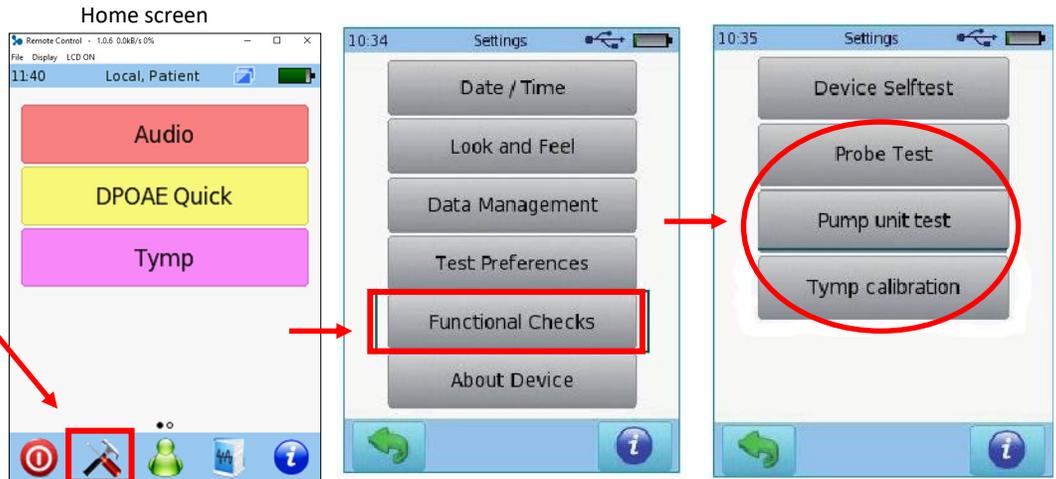


Device calibration as instructed below should be done regularly, or if the device is not working as intended.

Annual device calibration should be done at least once per year by the manufacturer. To schedule annual device calibration, call Natus at 855-283-7978 to set this up. All cables, cords, power supplies, probes and transducers that come with the equipment must be sent in with the machine (make sure to save tracking information), and note that there is a fee involved.

For ALL Calibration Tests:

1. Make sure ALL cables (including clear air tube) are plugged-in to the correct ports on device.
2. From home screen, click on the Settings button
3. Select "Functional Checks"
4. Choose the calibration test you wish to perform.



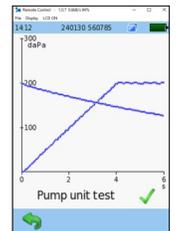
Probe Test:

1. Insert **adult size (transparent) probe tip** firmly into **RED** test cavity found in accessories box
2. Select "Probe Test"
3. Test will run automatically. Results will either be green **Probe OK** or red **Probe Failed**.
4. If Probe Test fails, check connections to ensure they are secure and reinsert probe tip into test cavity and retry Probe Test.



NOTE: If test still fails try moving clear plastic probe tip by squeezing the top and bottom, then retest. If test still fails, contact your IT support for further troubleshooting.

Pump Unit Test: Use **infant size (white) probe tip** with calibration tool. Pump unit test begins automatically, select "Pump unit test" to start the test.



Tymp Calibration:

1. Insert **infant size (white) probe tip** firmly into calibration tool.
2. Select "Tymp calibration"
3. As the test begins, follow the prompts: Press the "Re-calibrate" button to initiate calibration. For each cavity, press the corresponding button (0.5 mL, 2 mL, 5mL) and the test will run, asking you to remove and insert the probe tip into each calibration cavity.
4. Results will either be **Calibration completed successfully**, or **Calibration failed**.

