NHS

Screening Programmes

Newborn Hearing

Protocol: Otoport

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1 NOTES

It is expected that screeners will familiarise themselves with the contents of the manufacturer's manual as this protocol is not designed to replace it.
In line with NHSP family friendly practice the probe will be referred to as the ear piece.
For AOAE this equipment uses TE (OAE) - Transient Evoked Oto-Acoustic Emission

2 OPERATING INSTRUCTIONS

2.1 Login

Switch on
When switching on, the Otoport defaults to the user name of the last person to login
Scroll across to select your user name and enter your password

The password must be 8 characters long and contain at least 1upper and 1 lower case letter and a number. Passwords must not be shared. A generic user must not be used and should not appear in the user list on the Otoport.

2.2 Quality Assurance tests

There are a series of tests and actions that must be carried out daily. QA test 1,2 and 3 are uploaded to eSP with the screening tests recorded in that session. These will show that the equipment was working correctly prior to testing.
Do not use equipment that fails any one of these tests but inform your local manager
Tests should be carried out in quiet surroundings as noise will increase the length of time it takes to carry them out.

Visual Inspection

Look at the AOAE earpiece and coupler to check for wax or damage
Change the coupler if required.
Check the device, lead and connecting plug for damage.

Data Upload

Make sure that all data has been uploaded before starting a new session. The local manager must be notified of any instrument with data that cannot be uploaded. That instrument must not be used until the problem has been resolved.

Probe Test

This shows that the loud speaker provides enough sound to evoke an AOAE and the microphone is sensitive enough to detect an AOAE.
Insert the earpiece into the test cavity
In Probe menu - Select 1. Probe test
The first measurements of a new probe are the reference point to which subsequent measurements are compared.
Subsequent results should NOT BE SAVED but should be recorded in the log book

The levels displayed on the Otoport screen, should be within the range shown in the table below
The first column of the table shows the 'stored' intensity levels
The second column shows what the intensity level is now
The third column shows 'pass' or 'fail' at each of the 3 frequencies tested

If the difference between the levels is >3dB the probe has failed

If the probe "fails" or the levels have fallen outside the range change the coupler and repeat the Probe test

Universal Values	(from September 2012)	
Frequency	**Lower limit**	**Upper limit**
1Khz	**71**	**83**
2Khz	**74**	**86**
4Khz	**71**	**83**

See manufacturers manual section 14.2

QA 1 Cavity Test.

This tests for artefacts that may give rise to a false AOAE
In the Probe menu – Select 2. QA Tests
Select 1. Cavity test
Check the AOAE earpiece is seated correctly in the test cavity and the environment is suitably quiet
The test outcome should be Cavity OK.
SAVE the result.
QA 1 = Fail If the Otoport result is 'artifacts' and the coupler is seated correctly and the probe cover and lid are assembled correctly
QA 1 = Fail if the result is 'Noisy' and you have tested in quiet conditions

QA 2 Occlusion Test.

This tests that the microphone cannot pick up the sound from the speaker
In the Probe menu – Select 2. QA Tests
Select 2. Occlusion test
Occlude the tip of the coupler with a finger or thumb
The test outcome should be Occlusion OK
SAVE the result
If this test fails, change the coupler checking that it is seated correctly over the loudspeaker and microphone and that the body and lid are assembled correctly
Test again

QA 3 Real Ear Test.

This is to check that the Otoport is able to record an AOAE from a hearing ear
In the Probe menu – Select 2. QA Tests
Select 3. Real Ear Test
Select an appropriate size adult soft eartip and fit the AOAE ear piece into an adult ear known to have a Clear response.
The test outcome should be Clear Response. In cases where the tester does not normally get a CR then the usual expected result will suffice.

2.3 Screening Test

Entering Demographic details

In the Test menu – Select Patient: 1. New
Enter the following data:
Those marked * are mandatory.

- ID * 10 digit NHS number
- Hospital ID Mandatory field if NHS number is not available
- Family Name * Baby's surname
- DOB* Date of birth
- Gender Male/Female/Not known/Not given
- Risk factors Yes/No/Unknown.
- Location IP/OP/Home
- Facility lists local screening facilities
- NICU Yes/No
- Consent * Unknown/Full/Screen only

See manufacturers manual:

- Section 2.8.3 for entering characters
- Section 8.2 for patient details

Performing a test

The optimum test conditions are a settled baby in a quite environment.
Place an ear tip on the earpiece coupler. Choose a size that is large enough to provide a secure fit in the baby's ear.
Gently pull the pinna up and back to open the ear canal and insert the earpiece into the baby's ear.

Check patient details and select Test
Check fit - The stimulus level at the start of the test should be 84 dB but acceptable between 81 -87 dB. When stimulus is within range and the 2 blue lights are on - start the test.

Monitor the screening test:

The two blue lights should be on most/all the time
Noise bar indicates the level of noise
If the conditions become noisy once a screening test has been started you may pause the test by pressing the ■ blue button .
Reduce the noise
To resume press the ● green button
The vertical bars on the display, represents the AOAE signal (white) to noise (black) ratio.
A black dot appears when the NHSP criterion for signal to noise ratio is met for a frequency
The screen will stop automatically when the NHSP criteria for an outcome have been met
The test will time out after 5 minutes if the criteria have not been met

If the screening conditions deteriorate or the probe needs to be refitted the test may be stopped manually and the outcome will be Incomplete. **NB** It is important to note 'stim out of range' will appear if 'start' is pressed when the stimulus falls outside the accepted range. Press 'back' and readjust fit and attempt the screen again if protocol permits

See Otoport NHSP stop decision tree for details of test outcomes
Test outcomes:

Otoport – test result	eSP – test result
Clear Response	CR
No Clear Response	NCR
Too Few Bands	NCR
Incomplete	NC
Noisy	NC
Poor Probe Fit	NC

An outcome of CR or NCR should not be repeated
An outcome of NC may be repeated if the screen conditions can be improved.
A maximum of 3 screen attempts is permitted

Save the test to the appropriate ear.

2.4 Uploading into eSP

Each screener is responsible for the accuracy of screening data and ensuring that it is uploaded into eSP at the end of each screening session.
Data must be uploaded within 24 hours of the screen being done.

Switch the Otoport off
Connect the Otoport to the designated PC using download cable
Otolink (the intermediate software) will open automatically
Check that the number of 'screens' and 'patients' is correct
Click on the 'download' button
Successful download is confirmed

Disconnect the Otoport – Check all test data has been deleted. Click OK
If the upload is not successful (data should arrive within 5 minutes) please refer to document "SEDQ data not arriving in eSP"

3 MAINTENANCE AND CLEANING

3.1 Cleaning

The equipment should be cleaned before and/or after each baby following the manufacturer's recommendations.

Inspect the earpiece coupler regularly for contamination with debris or wax
Change the coupler if visibly contaminated.
If a coupler is changed during the course of the screening session a **Probe test** should be carried out to ensure that the new coupler hasn't affected the probe's output.

Ear tips: Use new tip for each baby
Protective sleeves for the Otoport are available from Otodynamics

All infection control procedures must be approved locally.

3.2 Battery

Charging

The battery level is displayed when the Otoport is switched on
Check battery level in the system menu
The battery when fully charged will allow over 250 screening tests.
Charging can take up to 4.5 hours
You cannot screen whilst the Otoport is charging

Top light on the side of the Otoport – Green – when connected to the mains
Bottom light – Orange - when charging
Bottom light – Green – when fully charged. A tick will also appear on the screen

Switch off after each screening session to ensure that all data has been saved and to conserve the battery.
If switched on but not in use – Otoport will enter standby mode
Press any key to start again
If left for a longer period of time the Otoport will 'beep' to remind the user it is switched on
If left on but not used the Otoport will eventually switch off (any unsaved data will be lost)

The Otoport will not start a screen with <5% battery power.
A warning screen appears when the battery is:

- ‘Low’ (10%/30 minutes usage remaining)
- ‘Critical’ (5%/10 minutes usage remaining)

Battery Conditioning

Once a year the battery should be conditioned:
Upload all data prior to conditioning
In the ‘System’ menu - select Battery
Press the ◊ key and allow the Otoport to discharge the battery completely
Re charge fully

3.3 Manufacturer Calibration

Calibration is due at 3 years, and every 3 years thereafter
Return to Otodynamics for a factory inspection, re-calibration and rechargeable battery change.
Calibration certificates must be kept for your records.

3.4 Repairs

Take care when inserting and removing the earpiece cable or download cable from the socket to avoid damage
Further information about the use care and maintenance can be found in the manufacturer’s manual
If the Otoport fails any of the QA tests or a fault is identified the Otodynamics NHSP support desk should be contacted to arrange for a repair .

4 Downloading Waveforms from eSP

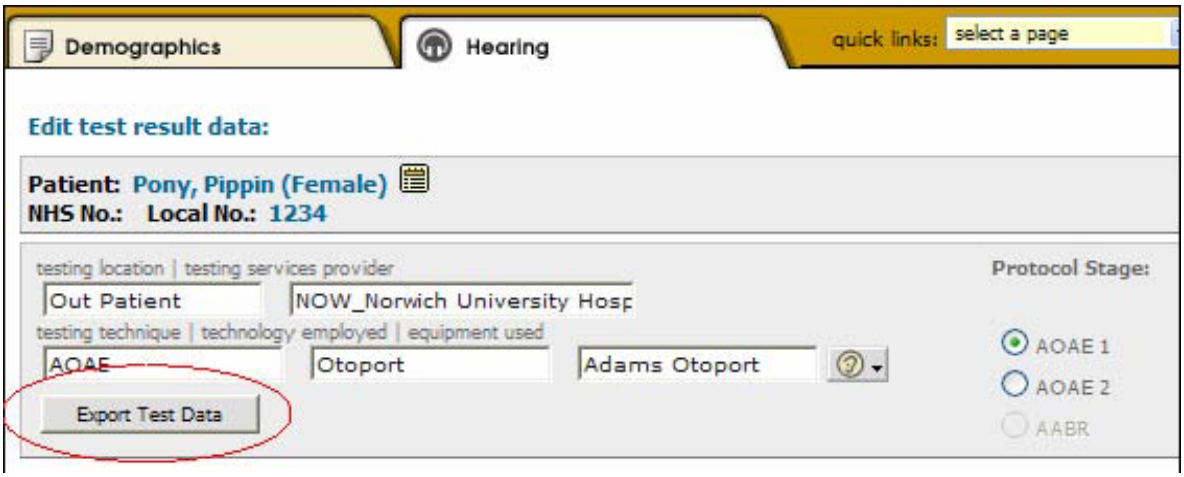
Details of each test, including the waveform, start and end times are stored in eSP with the baby record or within the QA test file. To view these data you will need.

- Waveform viewer software must have been installed.
- Export Test Data permission. These rights are generally allowed for managers or those responsible for monitoring data quality. If you can see the Export Test Data button on the hearing tab of a baby record then you do have the rights. eSP helpdesk will be able to help if you don’t have them
- WinZip version 9

NB this will not work with Windows XP proprietary uncompressor or powerarchiver.

Download data from a single screening test.

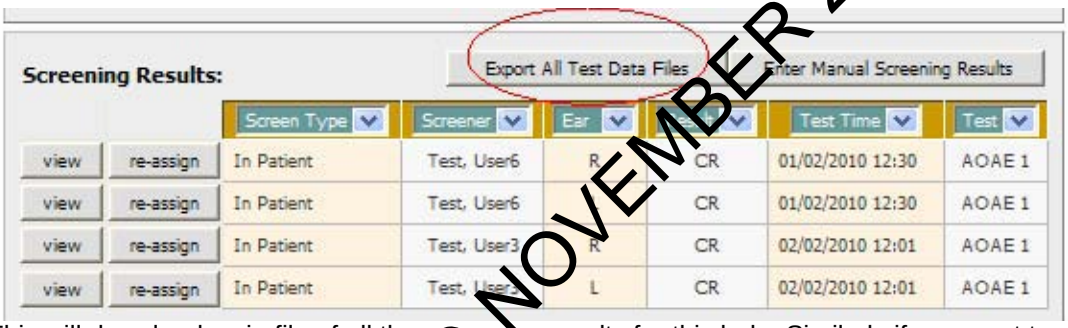
Access the record of the baby in eSP, click on the hearing tab and click the view button:



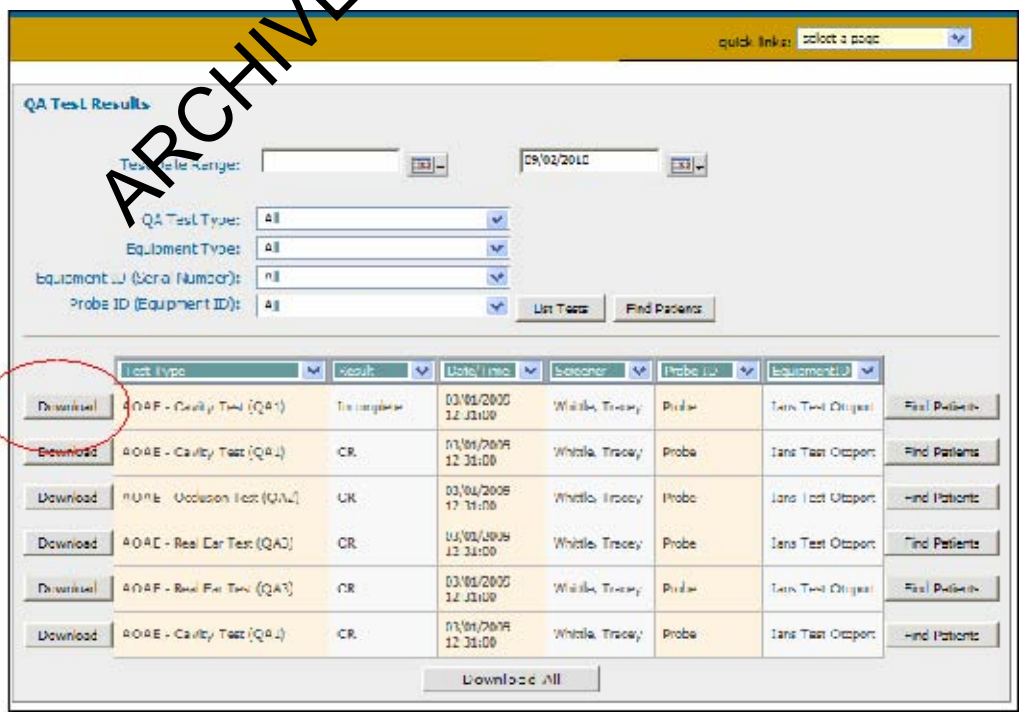
Click on the Export Test Data button and save the file.

Download all screening data for a baby

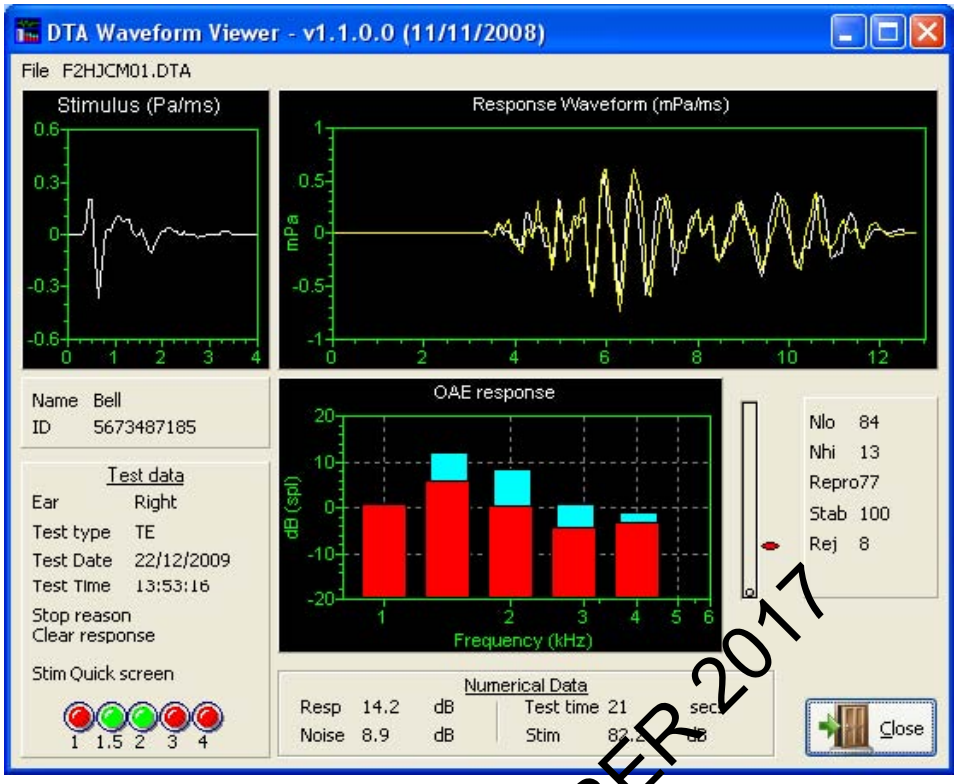
WinZip is needed for this function.



This will download a zip file of all the screening results for this baby.Similarly if you want to download the waveform for a QA test, from the QA Test Results screen, click on the download button.



Once saved, double click on the file and the test will automatically be opened in the DTA Waveform Viewer



5 Data governance.

Waveform-viewer data may be needed to monitor quality. Screener activity reports for individual screeners should be monitored for any indication of poor practice which could reduce the sensitivity or specificity of the screening test. Indication of where there may have been poor practice would be screeners with:

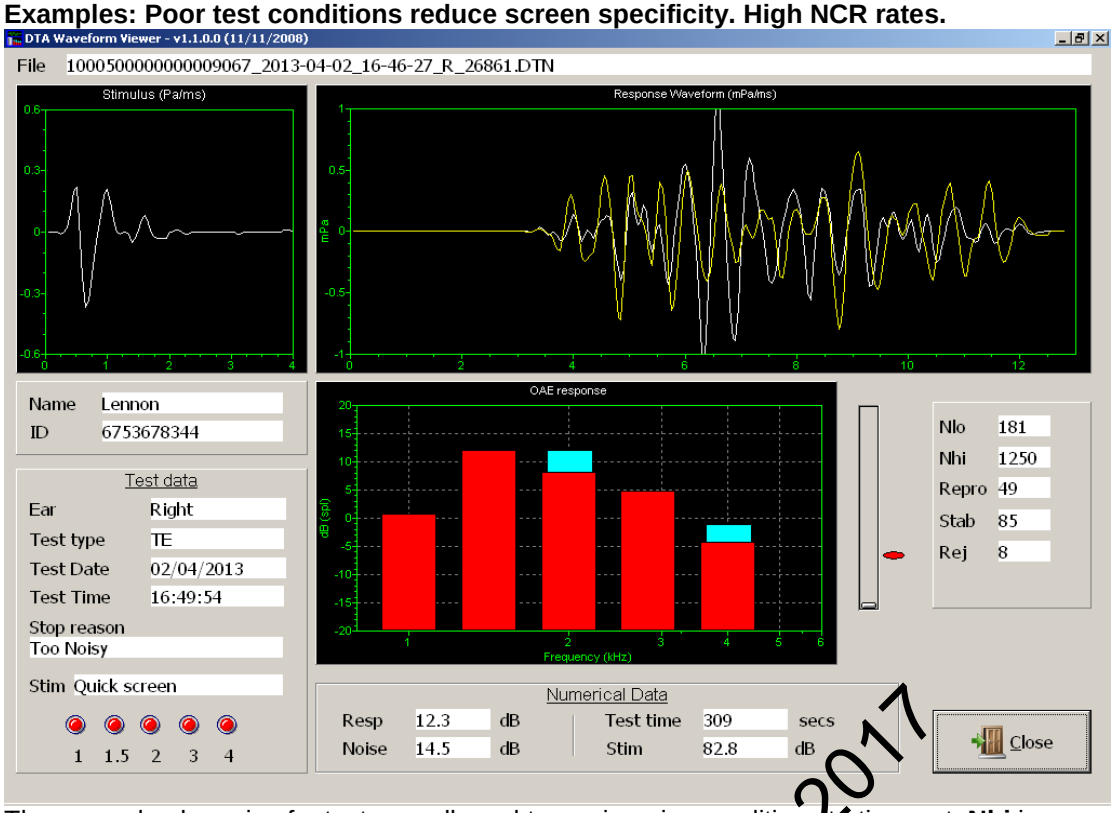
- High NCR rate.
- High NC rate.
- High (~100%) CR rate.
- Very short time interval between tests.

Waveform-viewer shows the raw screening data including indicators of test conditions and reasons why the test stopped. This data can be used to ascertain reasons behind multiple attempts or where testing has been done in less than optimum conditions.
The 6 stop reasons are:

- Clear response
- No clear response
- Too few bands
- Too noisy
- Poor probe fit
- Incomplete

Test condition indicators are:
Nlo – The number of sweeps that have been accepted due to noise being below the noise reject threshold level. The minimum is 40 sweeps and maximum 260.
Nhi – The number of sweeps that have been rejected due to noise above the noise reject threshold level. “Too Noisy” stop reason results if Nhi is greater than 3 times Nlo.
Stab – A numerical representation of the stability of the testing stimulus. The figure given is a comparison of the stimuli at the start of the test and the last stimuli recorded. A “Poor Probe Fit “stop reason will result if it falls below 85%.
Stim – The recorded stimulus level at the start of the test. The target is 84 dB but acceptable between 81-87 dB. If the stimulus level is outside this range “Stim out of range” will appear. A Clear Response result obtained in these conditions is acceptable but these conditions could give rise to a “Too few bands” or “No Clear Response” result.
Test time – duration of the test in seconds. Tests will time out after 300 seconds, but will only run for that long when test conditions are less than optimum.

Examples: Poor test conditions reduce screen specificity. High NCR rates.



The example above is of a test was allowed to run in noisy conditions to time out. **Nhi** is more than 3 times **Nlo** resulting in a stop reason of "Too Noisy". The stimulus level is within the acceptable range but stimulus stability is only just. This means that while ear piece fit is acceptable, environmental noise levels were too high to detect the presence of an AOAE if there was one.

The example below is of a test carried out with a poor probe fit as indicated by **Stab** < 85%. This gives a stop reason of "Poor Probe Fit".

Both examples are of testing in sub optimum conditions resulting in incomplete test outcomes. Testing in poor conditions such as this may also result in a "Too Few Bands" stop reason. Advice should be around finding ways to avoid testing in noisy conditions and improving ear piece fit. Both these measures would contribute to reducing testing time and improving screen specificity.

Example – Screen sensitivity

Screener activity reports that show close to 100% CR rates and/or high levels of NC may be an indication that screen sensitivity is compromised and should therefore be investigated. Screeners may have repeated tests with a NCR outcome or may have stopped the test before the stop criteria were met and started again several times. Waveform-viewer data can show that test conditions have been good and there should be no need to repeat. The

example below shows a test with a NCR outcome but all the test conditions were good. Stimulus stability (**Stab**) is 100%, the stimulus (**Stim**) is within range and the number of noisy responses (**Nhi**) was low. This test must not be repeated.