Otodynamics

Otoport OAE+ABR

User Manual for Otoport NHSP model

Otoport OAE+ABR

Otoport NHSP model

Issue 4.4

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Otodynamics Ltd
30-38 Beaconsfield Rd
Hatfield Herts AL10 8BB UK

EC REP MDSS GmbH Schiffgraben 41,
30175 Hannover, DE

www.otodynamics.com/IFU

CE 1639

MD

(01) 0 5060396 17244 1
(10) 4.4

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Contents

Section One General

1 Before use

1.1 Intended use

This Otodynamics Otoport OAE+ABR device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. ABR, TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization. Where the individual to be screened is healthy with no medical conditions related to the ear, as in the case of well-baby hearing screening, the user can be a trained screener. In all other cases the user should be an audiologist or medical professional.

The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose the device is intended to be used by audiologists or other audiologically skilled professionals. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.

1.2 What do OAEs test for

- OAEs test for problems in the peripheral auditory system. It is important to remember that OAEs do not test the whole hearing system, only cochlear function.
- Absence of OAE can be due to cochlear or middle ear dysfunction. Failure to detect any OAEs can also be due to high levels of noise or a blocked or badly fitted probe.
- The presence of OAEs indicates good middle ear function and good transmission of stimulation by outer hair cells inside the cochlea, at the tested frequency.

- Good OAEs do not exclude the possibility of auditory neuropathy or higher neural dysfunctions but these higher level dysfunctions are almost unknown in the well baby population. This is why OAEs have been used as an effective primary screen in hearing screening programmes for decades in many countries.
- Higher level disorders are occasionally present in ‘at risk’ and NICU babies and for this reason both OAE and ABR screening is recommended for this group.

1.3 Otoport setup

Before your Otoport can be used for testing, it must be configured with information supplied automatically from S4H.

After fully charging the Otoport, follow instructions in chapter 4 **Installing Otolink software** and chapter 5 **Configuring your Otoport.**

Note:

It will not be possible to transfer to S4H test results recorded before the Otoport has been configured.

1.4 Otoport features

The Otoport provides high quality OAE and ABR measurement features in a compact, handheld format.

The Otoport is simple to use and with powerful measurement features performs an automatic analysis of cochlear status within seconds. Set NHSP pass criteria control the test’s automatic stop mechanism. NHSP specific test outcomes are then clearly reported.

This Otoport has been specially configured for use in the NHS Newborn Hearing Screening Programme.

1.5 Terminology

In line with NHSP family friendly practice, wherever suitable the probe should be referred to as the earpiece and electrodes should be referred to as sensors. The terms are used interchangeably in this manual.

For AOAE (Automated OAE) test the Otoport uses TEOAE (Transient Evoked Otoacoustic Emissions).

1.6 General use precautions

Measuring OAEs and ABRs requires that the ear is exposed to sound. Whilst the level of this exposure is harmless under normal test conditions, it is not recommended that tests be allowed to continue indefinitely even if there is no result.

The Otoport includes ‘stop criteria’ which will automatically terminate the test when an OAE or ABR pass has been achieved or within ten minutes.

Whilst this limits the sound exposure in a single test, the user is responsible for limiting the number of separate tests performed on the same ear.

The Otoport has built in signal analysis proven to distinguish true OAEs and ABRs from artefactal signals. Checks should be performed daily to confirm the system continues to operate effectively.

In exceptional circumstances, either an equipment fault or failure to comply fully with the instructions in this manual may result in unreliable test results. Results with total OAE responses greater than 40 dB SPL should be considered highly suspect and should not be relied on.

The probe’s coupler tubes which carry sound to and from the ear canal are protected from contamination by the disposable tip. The probe should never be inserted into the ear without a disposable tip attached. Doing so risks damage to the ear by the probe body and contamination of the probe by the ear.

If contamination occurs the coupler tubes must be replaced.

Visually inspect the coupler tubes before use. A blocked sound delivery tube may prevent the Otoport from achieving its target stimulation level and so prevent testing. It may also attenuate certain frequencies and limit the number of pass bands. A blocked microphone tube will prevent the Otoport from sensing the stimulus level in the ear and from detecting the OAE. As a result the Otoport may apply a louder than normal sound to the ear.

Before inserting the probe, the ear should be inspected to ensure that the ear canal is clean and dry and also to establish that there are no contraindications to carrying out the test (see section 1.7 **Contraindications**).

If the ear is not clean and dry the probe may be damaged. This misuse is not covered by warranty.

All surfaces of the Otoport may be cleaned with an alcohol based wipe or cloth with antiseptic fluid. Dry the device immediately with tissue.

Do not allow liquid to enter the instrument.

If additional hygienic protection is required, clear plastic infection control sleeves designed to contain the Otoport during use are available from Otodynamics.

Otodynamics does not guarantee the accuracy of the test results, or the tests themselves, if accessories other than those supplied by Otodynamics are used.

1.7 Contraindications

The device should not be used by a trained screener (i.e. not an audiologist or doctor) if there is any medical condition affecting the outer ear or ear canal, unless instructed to do so by a medical professional after examination.

Contraindications to testing include discharge from the test ear, occlusion of the external auditory meatus by wax or other material, outer ear surgery and severe otitis externa.

Testing should not be performed in the case of deformity of the ear or ear canal sufficient to prevent the probe being comfortably fitted and acoustically sealed into the ear canal.

1.8 Safety

Caution

Connection of a patient to a high frequency (HF) surgical equipment and to the instrument in ABR mode simultaneously may result in burns at the site of the electrodes and possible damage to the instrument.

The Otoport should not be operated in close proximity to shortwave or microwave therapy equipment.

When one or more ABR electrodes are connected to the patient, take care to avoid any contact between the remaining electrodes and any conductive surfaces, such as other equipment. Failure to observe this precaution may result in harmful electrical currents flowing through the patient.

The ABR skin impedance measurement (via stimulation) function is not intended for trans-thoracic use – follow our guidance on electrode placement.

The Otoport should not be used on a patient with an implanted electronic device unless specialist medical opinion has first been obtained.

Anyone who combines charging devices, software, and IT equipment for use with the instrument configures a Medical System, and is therefore responsible for ensuring that the system complies with the safety requirements of the IEC 60601-1 standard.

Otodynamics Ltd. only selects materials for use in its instruments and accessories that have a proven track record of safe use in medical devices.

All materials used in the manufacture of the Otoport and applied parts meet the biocompatibility requirements of ISO 10993; in consideration of the likely nature and duration of contact of each material with both patient and user.

This device should be used only with the leads, electrodes, probes, ear cups and accessories recommended for use by Otodynamics Ltd. which will comply with medical device Biocompatibility/ Safety Standards (EN ISO 10993/ EN 60601-1).

Infants and children should not be left unattended with the Otoport or its accessories.

The Otoport instrument is not protected against liquid ingress (rating IPx0) - do not allow liquid to enter the instrument.

When connecting the Otoport with PCs, printers and servers a secured user network is required.

Observe good Information security management practices per EN ISO/IEC 27001 standard.

If in any doubt, or if further guidance is required, contact Otodynamics or your dealer for support.

1.9 The importance of setting the appropriate stimulus levels

The correct stimulus setting is vital for effective hearing screening with OAEs and ABR. The optimum stimulus level for your screening programme will be one that identifies the vast majority of infants with abnormal ears, but only rarely wrongly reports a healthy normal ear as needing to be referred.

Screening programs differ in their requirement to detect slight losses, and in their capacity to deal with false positives.

Over the decades in which TEOAE have been studied and used for newborn screening, a click stimulus level of '84dBpe' in the ear has been proved effective and efficient, and become the de facto standard for TEOAE screening. The parameter '84dBpe' indicates the peak sound pressure level of the brief click stimulus. It does not represent the hearing level or sensation level.

For DPOAE screening stimulus levels L1/L2 of 65/55dBSPL are most widely used and recommended in the literature as both sensitive to mild losses and as eliciting a robust response from normal ears. This stimulus decibel level does not indicative of the hearing level of the stimuli or the sensitivity to hearing loss.

Unlike for TEOAE and DPOAE the stimulus level for ABR screening is expressed relative to the threshold of hearing for healthy ears (indicated by 'dBHL). The stimulus dBHL must calibrated on a group of healthy young ears using the specific stimulus format actually delivered by the instrument. It has to be determined experimentally for each instrument and stimulus type. For ABR screening the stimulus level setting is made somewhat higher than the normal threshold level. This is to ensure that normal healthy responses are recordable in a reasonably short time and that the test is only sensitive to clinically significant losses.

Otoport ABR stimulus settings of both 35 and 40dBHL are widely for newborn screening. The 35dBHl setting gives exceptional sensitivity to slight losses with a somewhat lower specificity than the 40dBHL setting. The 40dBHL setting gives excellent sensitivity to mild losses and higher specificity i.e., there are fewer false positives. Stimulus levels outside of this range are not recommended for regular screening.

Note that the Otoport ABR is not intended for use in diagnostic use. In clinical testing with OAEs a wider range .

Never over-stimulate for infant screening.

Over-stimulation will result in mild and some moderate hearing losses being missed.

TEOAEs - never use stimulus levels above 87dBpe for screening,

DPOAEs - never use stimulus level of 70dBSPL or above for screening

AABR - never use stimulus level above 45dBHL for screening.

1.10 Auditory Brainstem Response

Auditory Brainstem Response (ABR) is an electrophysiologic response that measures the auditory system's response to sound. Three sensors are placed on the patient and a probe connected to an earcup is placed on the test ear. The equipment sends a soft clicking sound to the ears and the sensors pick up the nerve's response to that sound.

The cochlea or inner ear converts sound into electrical signal. These signals travel in sequence to the acoustic nerve, the brainstem, and finally to the cortical areas of the brain. These electrical responses are commonly known as auditory evoked potentials. One type of auditory evoked potential is the Auditory Brainstem Response, which occurs within approximately 3-20 ms of the onset of the stimulus (depending on frequency and intensity of the stimulus). Voltages (potentials) can be measured at the skin with surface sensors; the sensor montage consisting of three such sensors. As the amplitude of the ABR is very small compared to the 'noise' of other brain electrical activity (EEG), the signal to noise ratio is enhanced by averaging. The amplitude of the ABR is also quite small compared to voltages generated by myogenic (muscle) activity; therefore, ideally, children should be tested when sleeping. The ABR consists of a series of positive waves (at the vertex of the scalp) that are named by their relative order (waves I through V). ABR is typically elicited by click, brief tone, or chirp stimuli.

If EEG and myogenic artefacts are below a tolerable (noise reject) level, the Otoport ABR firmware will detect the ABR waves and give a simple Pass/Fail response to the user. The resultant waveforms may also be viewed, and results interpreted, manually if so desired.

1.11 Training

It is important that the operator of the Otoport is properly trained before using the instrument. The manual should be read before use and note taken of the sections marked with the training required symbol.

Where the training symbol is directly beneath a chapter title, it indicates that training is required for everything within the chapter. Where the symbol appears beneath a section heading, it indicates that training is required for that section only.

Where the device is to be used for other than the screening of healthy individuals, the user must be competent in the recognition of medical conditions associated with ears which may preclude testing (see **Contraindications**). Training for that purpose must be given by an audiologist or medical professional.

In all cases before application of the probe to the ear there must be an appropriate visual examination of the ear as specified by an audiologist or medical professional as part of training.

Training in operating the device is provided by Otodynamics Ltd in the UK. Training in the operation of the device elsewhere is via an approved dealer who has been trained by Otodynamics. Training on OAEs and use of the equipment may also be provided by previously trained staff and qualified audiologists.

Ensure your local policy for infection control is followed, as well as reading the recommendations in this manual (see section 12.6 **Use of the Otoport and cleaning**).

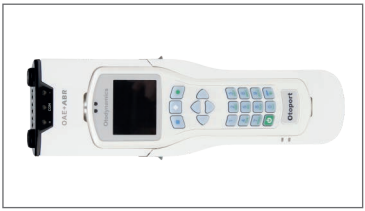
If a problem occurs during the operation of your Otoport or Otolink software or a message or warning appears that you don't understand, make note of the issue and messages provided. Refer these to Otodynamics for support.

2 Equipment identification

2.1 Supplied only in Otoport NHSP OAE+ABR kit

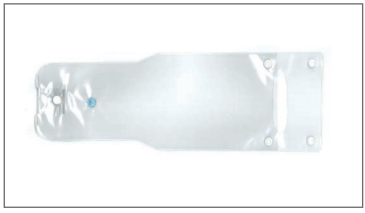
REF NHSP-OS-ST+ABR

Otoport NHSP OAE+ABR



REF ABR-INF

Infection control sleeve for Otoport OAE+ABR unit only



REF NHSP-PR-ABRLS

UGS TEOAE Serviceable probe for binaural use (BLUE)

1 meter cable

REF NHSP-PR-ABRRS

UGS TEOAE Serviceable probe for binaural use (RED)

1 meter cable

REF BGSL

BLUE BGS probe body and lid x 1

Supplied with Otoport NHSP

Re-order quantity: 10

REF BGSR

RED BGS probe body and lid x 1

Supplied with Otoport NHSP

Re-order quantity: 10

REF NHSP-ABR-CAV

Probe cavity and ABR cable tester

ABR Starter kit

REF ABR-E-TAB

ABR Tab Electrodes x 1 pack of 3

Re-order quantity: 60

REF ABR-CUP

ABR Ear Cups, 2x pairs

Re-order quantity: 20 pairs

REF NHSP-ABR-DS

ABR Desktop stand / Crib hook

Desktop stand / crib hook insert for ABR sleeve.

REF ABR-EC1

Tab electrode cables - 1m

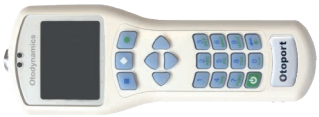
REF ABR-CAS

Equipment case for
Otoport NHSP OAE+ABR kit

2.2 Supplied only in Otoport NHSP OAE kit

REF NHSP-OS-ST

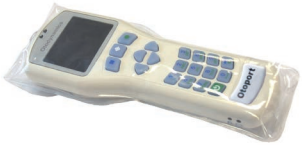
Otoport NHSP



REF OP-INF

Infection control sleeve for
Otoport only

Shown fitted



REF PR-UGS

UGS TEOAE probe

Supplied with Otoport NHSP

REF BGS

BGS probe body and lid x 1

Supplied with Otoport NHSP
Re-order quantity: 10

REF ABR-CAV

Probe cavity and
ABR cable tester

REF OP-CAS

Equipment case for Otoport
NHSP kit

2.3 Supplied in both kits

TPC probe coupler tubes x 5

Re-order codes:
REF TPC-10 (quantity: 10)
REF TPC-100 (quantity: 100)

REF TE-BOX

Sample probe tips

See section 2.10
for re-order codes

REF PR-POUCH

Drawstring probe pouch

REF PR-CLIP

Probe cable clip

REF OP-CHG

Charger and mains lead

Supplied with required country-specific plug adapter

REF OP-CAB

PC downoad cable

REF OTOLINK

Otolink software CD

Documentation pack

Includes instrument and software manuals, quickstart and probe use guides

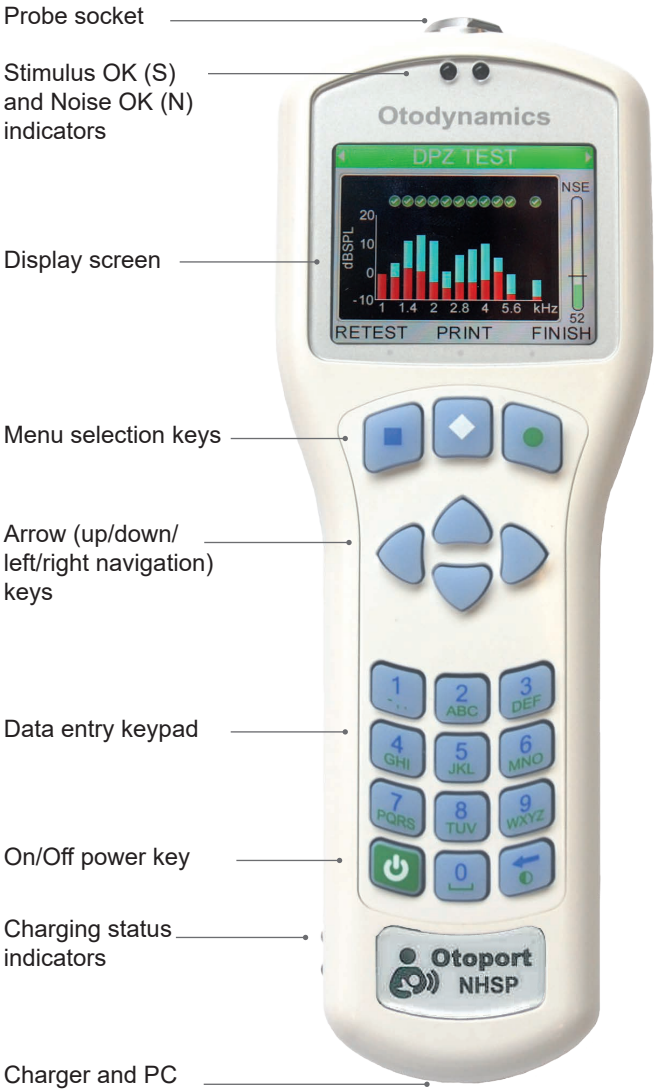
2.4 Optional accessories

REF ODS

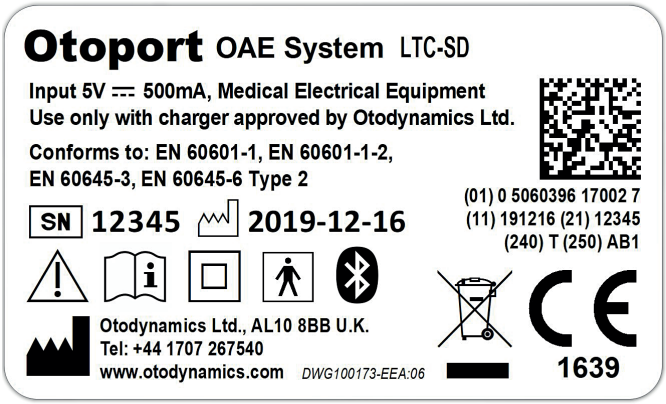
Docking station

Provides connections for charging and downloading to PC not compatiable with NHSP OAE+ABR

2.5 Controls, indicators and connections



2.6 OAE labelling



2.6.1 Symbols

The label uses one or more of the following symbols:

Symbol	Description	Where indicated
	DC	Product Label
	Serial Number	Product Label
	Date of Manufacture	Product Label
	**Bluetooth®** wireless technology enabled	Product Label
	Caution	Product Label
	Refer to user manual	Product Label
	Class II electrical protection (double insulated)	Product Label

continued ...

Symbol	Description	Where indicated
	Type BF applied part	Product Label
	Manufacturer	Product Label

Note:

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Otodynamics Ltd. is under license. Other trademarks and trade names are those of their respective owners

2.6.2 Serial number

The Otoport NHSP OAE system complies with the unique device identifier system to aid the identification of medical devices within the healthcare supply chain.

The fields in the serial number are made up of the following parts:

(01) Company prefix: Otodynamics, Item reference: Otoport NHSP OAE
(11) Production date: 31st January 2015
(21) Serial numbers: 1234 (Otoport)
(240) Additional product ID: BRT (used to identify any hardware modules fitted)
(250) Secondary serial number: AB1 (This is a proprietary electronic device identifier, called GSN).

This information is also contained in the adjacent barcode.

2.6.3 Certification or regulatory marks

The label features one or more of the following certification/regulatory marks:

Symbol	Description
CE 1639	CE Mark (with Notified Body number) (EEA)
	WEEE Directive applies (EEA)
	MET Mark

2.7

Otoport OAE+ABR controls, indicators and connections

Probe sockets and sensor sockets

Impedance check indicator LEDs

Locked clips

Otoport unit

Otoport controls and keypad

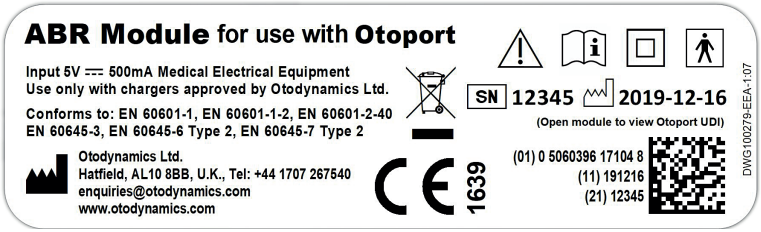
'USB/PSU' connected' and 'battery charging' indicator LEDs

Charger / PC cable socket

2.8 ABR labelling

2.8.1 System

2.8.2 Upgrade



2.8.3 Symbols

The label and device use the following symbols:

Symbol	Description	Where indicated
⎓	DC	Product Label
⚠	Caution	Product Label
🕮	Refer to user manual	Product Label
⧈	Class II electrical protection (double insulated)	Product Label

continued ...

Symbol	Description	Where indicated
	Type BF applied part	Product Label
	Manufacturer	Product Label
	Serial Number	Product Label
	Date of Manufacture	Product Label
	Consult Accompanying Documents (MANDATORY) *Safety information should be read and guidance followed, before instrument use.*	Device

2.8.4 Serial number

The Otoport NHSP OAE+ ABR system complies with the unique device identifier system to aid the identification of medical devices within the healthcare supply chain.

The fields in the serial number are made up of the following parts:

(01) Company prefix: Otodynamics, Item reference: Otoport NHSP OAE+ABR
(11) Production date: 31st January 2015
(21) Serial numbers: 1234 (Otoport) - 1234 (ABR) (if ABR module is supplied)
(240) Additional product ID: BRT (used to identify any hardware modules fitted)
(250) Secondary serial number: AB1 (This is a proprietary electronic device identifier, called GSN).

This information is also contained in the adjacent barcode.

2.8.5 Certification or regulatory marks

The label features one or more of the following certification/regulatory marks:

Symbol	Description
CE 1639	CE Mark (with Notified Body number) (EEA)
	WEEE Directive applies (EEA)
	MET Mark

2.9 Probe cable clip

The probe cable clip is provided to aid the practical aspects of positioning and securing the probe cable during OAE testing. Using the probe cable clip can improve your test times by reducing noise from cable rub and providing greater probe stability.

2.9.1 Using the cable clip

Push the plunger to open the cable grip.

Place the probe cable in the slot and release the plunger. The position of the clip on the cable can be adjusted if necessary.

Open the crocodile clothing clip.

Attach the probe cable clip to the patient's clothing.

If the cable slips through the grip, turn the head to grip the cable.

Use a sterile wipe to clean the clip.

2.10

Probe tips

Samples of tips are provided with your instrument. Further supplies may be obtained from Otodynamics.

T3E
REF T-T3E
Fits ~3mm ear canal
Small and premature newborns

T4.5C
REF T-T4.5C
Fits ~4.5mm ear canal
Small newborns

T5C
REF T-T5C
Fits ~5mm ear canal
Newborns

T5.5B
REF T-T5.5B
Fits ~5.5mm ear canal
Most newborns

T6.5B
REF T-T6.5B
Fits ~6.5mm ear canal
Large newborns and first year infants

T7M
REF T-T7M
Fits ~7mm ear canal
Infants and children

T8M
REF T-T8M
Fits ~8mm ear canal
Infants and small adult ears

T9M
REF T-T9M
Fits ~9mm ear canal
Most adult ears

T11M
REF T-T11M
Fits ~11mm ear canal
Large adult ears

T13M
REF T-T13M
Fits ~13mm ear canal
Extra large adult ears

2.10.1 Use of tips

All Otodynamics probe tips are disposable and MUST be discarded after each test. The probe coupler tubes should be visually examined for signs of contamination and the outer parts cleaned with an antiseptic wipe. Take care not to squeeze any cleaning fluid into the tubes.

The tip design leaves a ~0.5mm gap between the end of the coupler tubes and the end of the tip. Therefore, the tubes should never come into contact with the patient.

OAEs should NOT be conducted if there is evidence of fluid of any kind in the ear canal. Not only does this pose a contamination risk, but OAEs cannot be recorded through fluid.

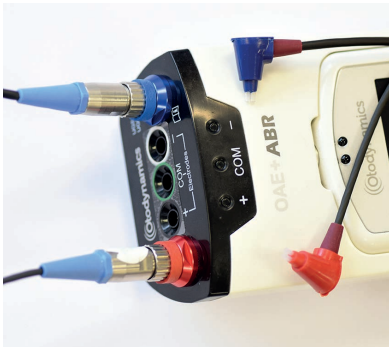
In the event of an accident with body fluids, the tip, coupler tubes and probe body must be changed.

3 Getting started

3.1 Connecting probes and sensor cables on the Otoport OAE+ABR

The connections panel for probes and sensor cables is found at the top end of the module.

3.1.1 Connecting the probes

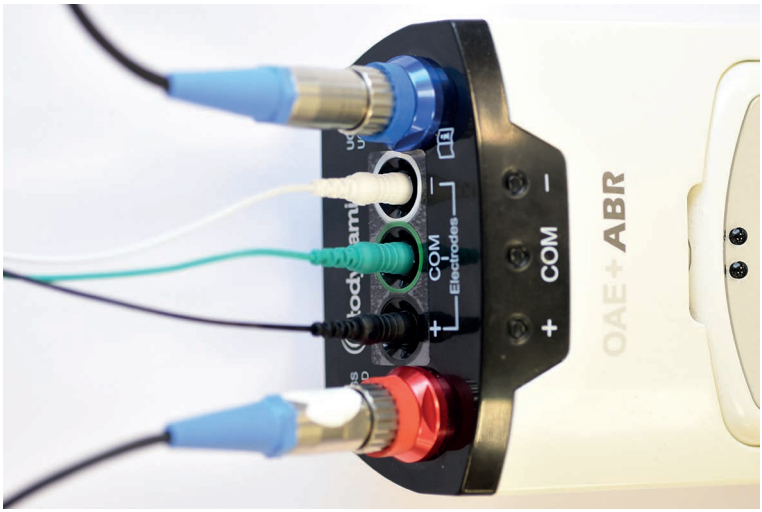


Follow instructions for connecting the probe to the Otoport in section 3.2.

If you are using two probes, ensure that the probe head colour matches the probe socket; the probe with the red head should be conected to the red socket and the blue head to the blue socket.

3.1.2 Connecting the sensors

The Otoport OAE+ABR is supplied with a sensor cable loom featuring croc clip connectors for sensor attachment. Alternatively, any wired sensors that are terminated with 1.5mm 'Touchproof' DIN 42-802 connectors may be used.



Carefully align the sensor connector plug with the appropriate sensor socket (observe colour coding) and then push in firmly.

To disconnect the sensor connector, grasp the plug body and pull straight out from the socket.

Important note:

Do not unplug by pulling on the sensor cable as this may damage the cable/plug assembly.

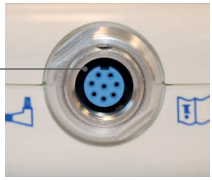
3.2 Connecting the probe on the Otoport OAE

Prior to the testing session, connect the probe to the Otoport.

The probe plug contains a ‘key’ that must be aligned with the ‘keyway’ in the probe socket on the Otoport.

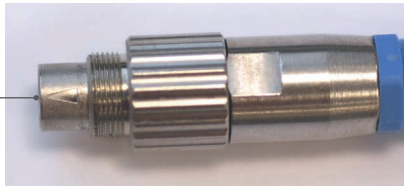
Probe key

Socket keyway



The arrow at the front of the probe plug indicates the position of the ‘key’ and should be aligned with the front of the Otoport.

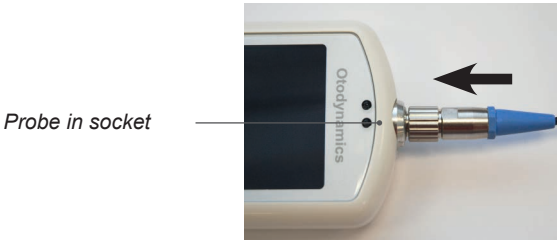
Arrow



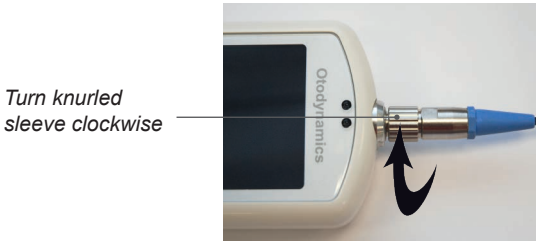
It is possible to feel when the probe key is aligned as the probe will mate with the socket easily.

Align arrow with front of Otoport

Push the probe into the socket until it hits the end stop. DO NOT force in the probe.

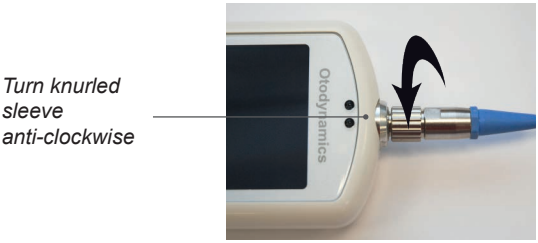


Screw up the **knurled sleeve** in a clockwise direction until finger tight.

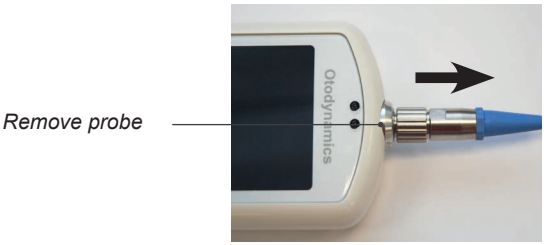


3.3 Disconnecting the probe

To disconnect the probe, unscrew the **knurled sleeve** in an anticlockwise direction until the thread is disengaged.

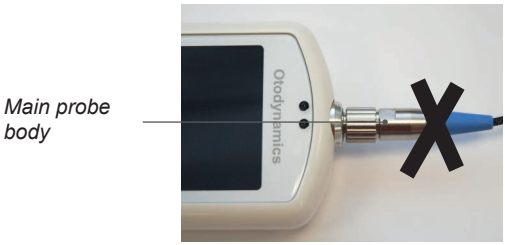


Then gently pull the probe out from the probe socket.



Important Note:

Do **NOT** attempt to screw or unscrew the probe by holding the main probe body (smooth chrome section).



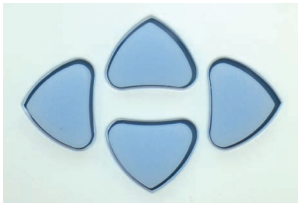
This will result in damage to the probe and will invalidate the probe warranty.

3.4 Using the keys and keypad

3.4.1 Control keys

The keys directly below the screen marked with a square, a diamond or a circle enable you to execute the functions offered on the screens. Their functions vary from screen to screen, but generally the right (circle) key provides affirmative options and the left (square) key provides negative options.

3.4.2 Arrow (navigation) keys



The arrow (navigation) keys provide **Left**, **Right**, **Up** and **Down** control and allow the user to move to options available on the screen. The selected option becomes highlighted.

The left and right arrow keys scroll through the main menu options.

3.4.3 Entering characters

Character entry is similar to a mobile phone where numbered keys can be pressed sequentially to select the required character.

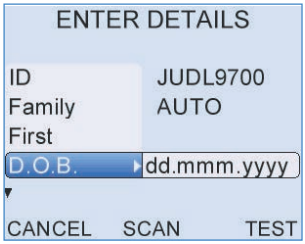
The order of the characters is dependent on context. For example when used to enter:

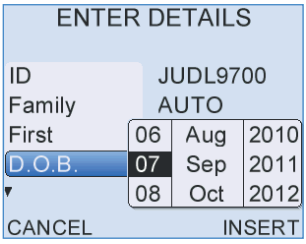
Patient ID
Numbers are presented first then capitals, e.g. 2ABC.

Family Name
For the first character capitals are presented first, then lower case then numbers, e.g. ABCabc2. For subsequent characters lower case is shown first, e.g. abcABC2.

More characters can be stored than can be displayed on the screen. Arrows are displayed to indicate that the string continues to the left or the right. Pressing the appropriate arrow navigation keys will display the hidden characters.

3.4.4 Entering dates





A right arrow symbol is shown at the end of a date field.

When the field is highlighted, press the right arrow key to access the calendar pop-up table. The day will be highlighted first and can be altered using the up/down arrow keys. Continue to use the left and right arrow keys to jump between the Day/Month/Year and the up and down arrow keys to select the required date.

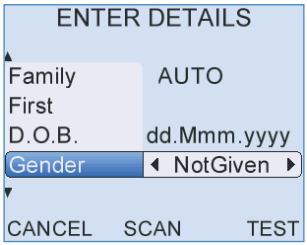
Select **Insert** to accept the date displayed or press **Cancel** to ignore the changes.

If the date has not been edited, it will remain as dd.mmm.yyyy.

For Date of Birth entry (**D.O.B**) the Otoport will not permit entry of a future date. **Invalid D.O.B.** will be displayed briefly at the top of the screen then the date of birth will revert to today's date. Re-edit and confirm the D.O.B. if necessary.

3.4.5 Choice bars

Left and right arrow keys are used to move through choice bar options. For example when entering patient details in the **Gender** field, pressing the right arrow key will rotate the selected option between **Not Given**, **Male**, **Female** and **Unknown**. Choice bar options are enclosed by arrow graphics.



3.4.6 Deleting characters

The bottom right hand key is the **Delete** key. If the cursor is at the end of a row of characters, press this key to delete the last character. The Contrast function indicated on this key is no longer available.

Left and right arrow keys can be used to scroll back through the text. The selected blinking character can be replaced using the keypad data entry function or deleted with the delete key. Continue to press delete to erase characters to the right of the cursor.

3.4.7 Brightness

The brightness of the screen can also be changed in in **System** setup (see chapter 18).

3.4.8 Backlight

The screen and keypad are backlit to assist testing in dimly lit environments. The back light stays on for 7 seconds (default) following any key press and remains on during testing. The timing can be changed in **System** setup (see chapter 18).

3.4.9 Stimulus and Noise OK indicators (blue LEDs)

The two blue LEDs above the screen on the Otoport give an indication of whether stimulus and noise levels are acceptable for data collection.

The Stimulus LED is highlighted with an S. It is lit when the stimulus level recorded by the probe microphone is within the expected range. It is extinguished if the stimulus is outside range. During testing this is 84+/-1dBpeSPL.

The Noise OK LED is highlighted with an N. It is lit when the noise level recorded by the probe microphone is below 52dBSPL.

3.4.10 Hard reset

In the unlikely event that the Otoport fails to respond to user control, hold the On/Off key down for 10 seconds, in order to reset the device. You may then switch on the device as normal.

4 Test preparation

4.1 General checks before testing

Ensure the Otoport is charged.

Ensure the Otoport daily checks have been carried out.

Do not run an OAE test if there is any discharge from the ear to be tested.

Choose a quiet room, without background noises.

Ensure the patient is comfortable and settled.

Ensure you can clearly see the ear to be tested.

4.2 Environment checks for ABR

Try to minimise any interference from electrical equipment. Turn off electrical equipment and florescent lighting if possible. If equipment cannot be turned off, try to move away from it.

Ensure that all necessary disposables (sensors, tips etc) are at hand and prepared for use.

Plan where the baby will be positioned, where you will place the Otoport so it will be visible and secure and how you will route the sensor and probe cables.

4.3 Tip selection and probe fitting

Tip selection and probe fit are essential to ensure successful OAE recordings. A good probe fit will help to block out external noise and enhance the OAE signal. When selecting a tip, first inspect the ear to be tested to assess its size and to check that it is clear and free from debris. If debris subsequently enters the probe sound tubes, do not attempt to clean them; the coupler tubes should be changed. The correct size tip will look slightly larger than the ear canal and should fit snugly, forming a complete seal with the ear canal wall.

4.3.1 Fitting for newborns

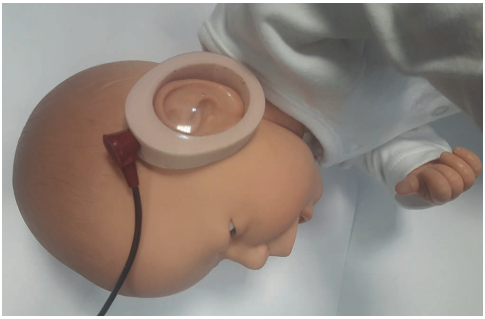
Gently lift the pinna upwards, away from the baby's head, and then towards the back of the head. This will open the ear canal.

Insert the probe at approximately 10 o'clock (for left ear) or 2 o'clock (for right ear).

Turn the probe to 12 o'clock.

Hold the probe for several seconds. Then release the pinna and let go of the probe.

4.3.2 Fitting for infants using ear cups



Only the Sanibel Infant Earcup^{tm} is approved for use with the Otoport ABR. Fit a tip to the probe before fitting the probe to the ear cup. The T7M tip for TE probes should be used; see section 2.10 for more information on probe tips. The probe may be inserted into the earcup before or after applying the earcup to the infant. Push the probe into the ear cup until the front face of the tip is flush with the inside wall of the ear cup.

4.4 Helpful hints

The most frequent cause of unsuccessful OAE recordings is failure to fit the probe correctly, so that it is deep enough in the ear canal, or without the correct size tip to seal the ear canal. The presence of fluid and debris in the ear canal or middle ear will also inhibit recordings.

If a pass result is not obtained, remove the probe and inspect the probe tip. Discard the tip if it has collected debris or moisture. Also check that the probe coupler tubes are clear and replace these if a blockage is noticed. Then refit the probe and try again. Problems of debris and middle ear fluid occur mostly in babies younger than 6 hours and are often cleared by feeding or turning the baby. If there is no success during the first OAE testing attempts, a second OAE testing session, when the ear has had time to clear, usually brings success.

Babies are best tested when they are sleeping or sleepy and successful OAE recordings are most often made one hour after a feed. The baby may settle down more easily if swaddled. Babies older than one month may be too active to test. When testing a child it can help to entertain them during the test, so they don't become too restless. Try to keep the probe cable out of their reach; using the probe cable clip may help. Instruct adults to be still and remain quiet.

Noises from the baby may not prevent successful recording, but will increase the test time. Constant environmental background noise, for example from air conditioning or machinery, may prevent a successful test. Testing should only be conducted in rooms where the noise level recording on the Otoport is mainly below the noise reject level when the probe is not fitted in the ear. Some intermittent noise can be tolerated, but constant high noise will inhibit successful recordings.

4.5 Sensor fitting

4.5.1 Skin preparation

The skin at the sensor sites must be prepared to ensure that the impedance is low enough for a good recording.

Use sensor skin preparation pads/tape, exfoliating pads (e.g. Dry Prep), or a swab coated with Nuprep™ to clean each of the areas - try to select hair-free sites. With your thumb and finger support the skin, holding it gently taut. Rub in a circular motion with 5-10 moderately firm strokes to abrade the skin to permit a satisfactory connection to the skin. Excessive caution with skin preparation can disturb the baby more than firmer strokes.

If using a wet prep, use a gauze pad to remove any residue and dry the area. Avoid touching the prepared area and, to ensure that the sensor is placed directly on the prepared area, it is preferable to prepare one site at a time and immediately apply a sensor. When all three sensors have been placed, check the impedances. If unacceptable impedance occurs, identify the electrode responsible and replace it by repeating the steps mentioned above to re-prep the skin. If impedance is still high, one sensor lead may be faulty and will need to be inspected and, possibly, replaced.

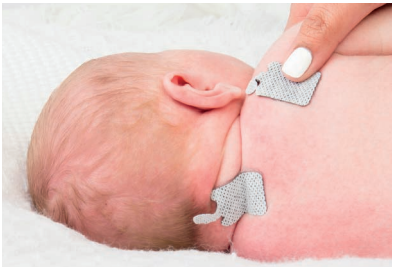
The use of wet gel sensors is recommended, as the conductive gel ensures a quick and reliable low-impedance contact with the skin. However, any wired sensors that are terminated with 1.5mm ‘Touchproof’ DIN 42-802 connectors may be used.

4.5.2 Placement (montage)

Sensors are placed at three sites: the high forehead, the nape of the neck, and a reference (common) sensor on the shoulder. In all locations avoid hair when possible. When using wet gel sensors the sticky area around the central gel should be pressed to the skin – not the central area itself.

High forehead

(positive ⊕ black)

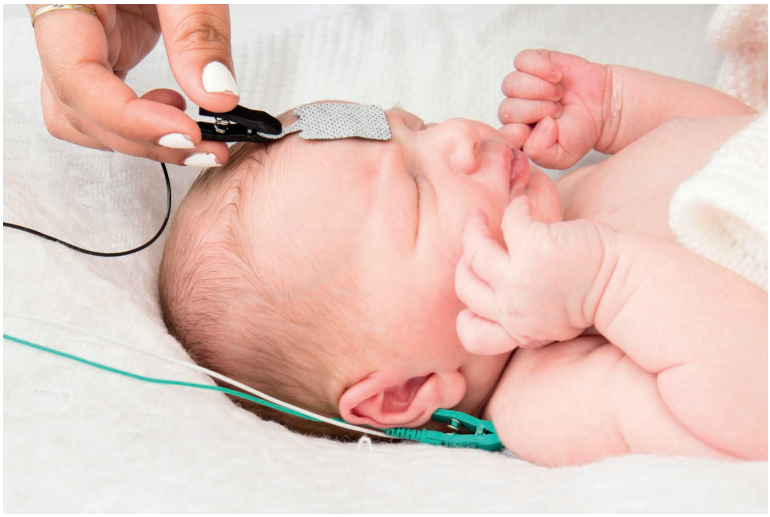


Shoulder
(common ● green)

and Nape of neck
(negative ⊖ white)

The sensor should be placed high on the forehead near the hairline, ideally avoiding hair if possible, and in the centre (not offset to the left or to the right). Prepare the skin and, whilst holding the skin taut, apply the sensor.

If using tab sensors, now connect the sensor cables to the sensors. Connect the black cable to the high forehead, the white cable to the nape of the neck and the green cable to the back of the shoulder.



Summary

Positive	Black	⊕	High forehead
Common	Green	⊖	Back of shoulder
Negative	White	●	Nape of neck

The Otoport may fail to recognise a valid ABR if an alternative place is used for the Positive (⊕) sensor.

5 Test troubleshooting

5.1 OAE test problems

The most frequent cause of unsuccessful OAE recordings is failure to fit the probe correctly, so that it is deep enough in the ear canal, or without the correct size tip to seal the ear canal. The presence of fluid and debris in the ear canal or middle ear will also inhibit recordings.

If a pass result is not obtained, remove the probe and inspect the probe tip. Discard the tip if it has collected debris or moisture. Also check that the probe coupler tubes are clear and replace these if a blockage is noticed. Then refit the probe and try again. Problems of debris and middle ear fluid occur mostly in babies younger than 6 hours and are often cleared by feeding or turning the baby. If there is no success during the first OAE testing attempts, a second OAE testing session usually brings success when the ear has had time to clear.

Babies are best tested when they are sleeping or sleepy and successful OAE recordings are most often made one hour after a feed. The baby may settle down more easily if swaddled. Babies older than one month may be too active to test. When testing a child it can help to entertain them during the test, so they don't become too restless. Try to keep the probe cable out of their reach; using the probe cable clip may help. Instruct adults to be still and remain quiet.

Noises from the baby may not prevent successful recording, but will increase the test time. Constant environmental background noise, for example from air conditioning or machinery, may prevent a successful test. Testing should only be conducted in rooms where the noise level recording on the Otoport is mainly below the noise reject level when the probe is not fitted in the ear. Some intermittent noise can be tolerated, but constant high noise will inhibit successful recordings.

5.2 ABR test problems

5.2.1 Impedance values are too high and the test will not run

Solutions:

Wait for about two minutes. During this time the sensors may connect better to the skin and, therefore, reduce the impedance values.

1. Check all sensor plugs are firmly inserted into the sockets of the ABR Module.
2. Make sure the sensors are in complete contact with the skin and are not lifting from corners.
3. Press firmly onto the sensors if impedance is only slightly high.
4. Remove and re-prep the sensor site that has high impedance. If that fails to work, re-prep all sites.
5. If re-prepping does not work, try a fresh set of disposable sensors (or clean reusable sensors).
6. 'Wet gel' sensors, such as the Ambu Neuroline 720, can dry out especially if the foil pouch they are kept in has been opened for some time. This can result in very high impedances. Check the expiry date on the sensor pouch and then open a fresh pouch if in doubt about how long the current pouch has been open.

5.2.2 High myogenic activity/artefact reject

The most common cause of electrical interference is myogenic (muscle) activity from a restless baby.

Solutions:

1. Check that all sensor and cable connections are secure.
2. Switch off lights in the test area.
3. Do not place the Reference (Common) sensor close to the heart (front or back of the patient). Noise can be generated by a large EKG response.
4. Smooth and swaddle the baby in an effort to calm him/her. Note that electric muscle artefacts may arise from non-moving but tensed muscles (isometric contraction) – pay particular attention to the nape of the neck with this condition.

5. Touch each sensor to identify which is causing the problem, try:

   • holding the skin around the sensor taut
   • maintaining light pressure on the sensor
   • gently stroking the baby's head
   • repositioning the baby's head

5.2.3 High environment electrical noise

Audible noise in the room as well as interference from other electrical equipment may trigger an artefact reject signal.

Solutions:

1. Check that all sensor and cable connections are secure.
2. Switch off any non-essential equipment in the room.
3. Do not use mobile (cellular) phones when operating the equipment.
4. Separate the sensor cables from the probe cable if intertwined.
5. Move to a quieter location if possible.

5.2.4 No response in ear with known normal hearing

Check sensor montage (placement). Using an incorrect montage can result in very small responses, or responses that have a low template correlation.

Check ear cup/probe fit. A probe that has very poor fit to the ear can result in very low stimulus levels and therefore a small or absent response.

5.3 OAEs and screening

OAE testing is commonly used as the primary hearing screen in newborns with no known hearing loss risk factors. Failure to show a strong OAE indicates that further testing or observation is necessary.

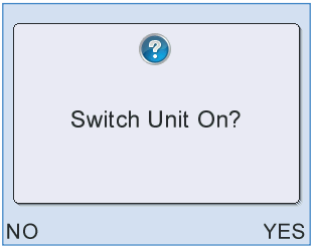
OAE testing is frequently used as the initial screen within the 'at risk' population. Passing the OAE test indicates that normal middle ear and cochlear function is present. The specific risks must be evaluated to determine whether ABR (auditory brainstem response) testing is necessary, even after a pass at OAE. Certain clinical conditions indicate the possibility of retro-cochlear/neurological disorders which the OAE test cannot detect.

Section Two Screeners

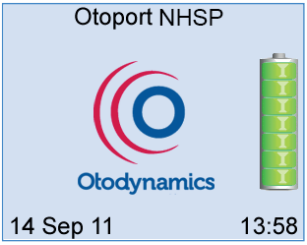
6 Switch on and Login

6.1 Switching on

Press the green On/Off button and select **Yes** to confirm.



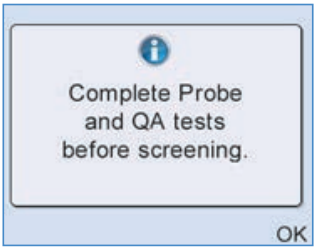
Following switch on, the logo screen is displayed whilst the Otoport performs system checks. In the event of a problem, an error message will be displayed. (See section 21.5 **Hardware fault messages** for details).



The battery level, date and time are also displayed.

6.2 QA checks reminder

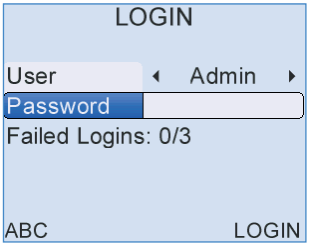
If the daily QA checks have not been run, a reminder message will be shown.



Use the Left/Right arrow buttons until you arrive at the **QA Area** then press **Select**.

The presence of a red "X" indicates that all the relevant Daily QA Checks need to be completed before accessing the **Test** *area*

6.3 Login



After 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 eight characters long and contain at least one upper and one 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.

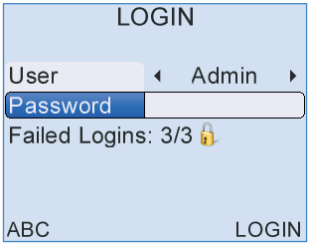
Select **Login**.

Password entry is case sensitive. Use the square control button to switch between upper case (**ABC**) and lower case (**abc**) entry.

To improve security during **Login**, a * symbol will replace each character as it is entered. To review characters that have been entered, simply scroll back through the * using the left/right arrow keys.

If the **Password** has been entered incorrectly, a warning message will appear as below:

A user will be locked out from accessing the device if three sequential attempts are made to **Login** with an incorrect **Password**. The following warning message will appear:



The locked **User** account can only be unlocked by an Administrator, via S4H. One or two incorrect login attempts for any user will be reset at midnight, so the next day all users will have three login attempts again. A locked user will not be reset.

7 Daily QA checks

QA checks are designed to identify faults or problems with the equipment.

These checks are mandatory on the Otoport and MUST all be completed with the 'expected' outcome for each QA test, as stipulated in the national guidelines, before the equipment can be used to screen babies each day. They ensure that the equipment is working correctly.

The Otoport will NOT allow access to the TEOAE and AABR tests until ALL relevant QA checks have been completed at least once each day on the probes used with the equipment. This restriction is enforced on the Otoport once every 24 hours from midnight.

All the tests should be carried out carefully in quiet surroundings. Noise will increase the length of time it takes to carry them out and may be misinterpreted as an equipment fault.

When checks do fail the fault is most likely to be with the probe, rather than the Otoport. If another probe is available, then you may change the probe and begin the QA tests from the beginning.

If the equipment fails any of the daily checks it must be removed from service until the fault is investigated and rectified. Inform your local manager/screening administrator.

Changing Couplers

Changing couplers can change the results of the probe test but is unlikely to significantly change the results of the other tests. Therefore, we recommend that the probe test is rerun following a change in coupler, the test should be run even if the coupler is changed outside of the QA tests.

Data Upload

Make sure that all screening data has been uploaded before starting a new session.

The local manager must be notified of any instrument found with data that cannot be uploaded.

That instrument must not be used until the problem has been resolved.

7.1 Visual Inspection

Look at the probe and its coupler tubes to check for wax or damage.

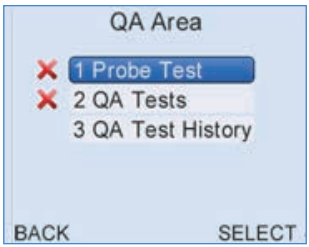
Change the coupler if required (see chapter 12 **Maintenance and Cleaning**).

Check the device, leads and connecting plugs for damage (it is not necessary to disconnect the probe to do this).

7.2 Probe test

This checks that the loudspeaker in the Probe is producing the correct stimulus level and that the microphone is correctly measuring it. The Otoport ABR will automatically test both left and right probes if they are both connected. A green tick is shown for each probe when the test completes successfully.

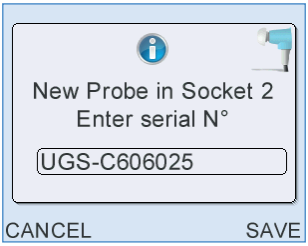
To run the test, find the **QA Area** screen (using the arrow keys) and press **Select**.



The "X" indicates that the test needs to be completed

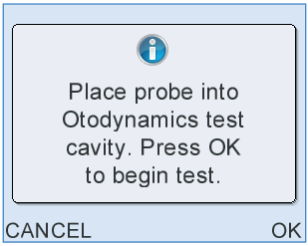
Once in the QA Area, select **1 Probe Test**.

If the probe has not been used with this Otoport before a message like this is shown:

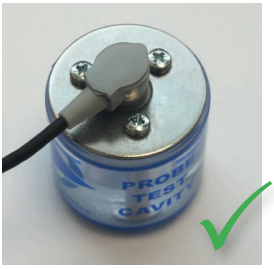


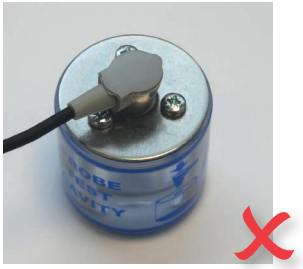
The number in the box should match that on the white label on the probe cable. If it does not then add the correct number. When it is correct press **Save**.

Then the message below will be shown:



Remove the tip from the probe and insert the probe into the test cavity. Make sure that probe is BETWEEN the two screws, and not over one (as shown below), as this may prevent full insertion. Press the probe firmly down into the cavity.





Press **OK** to begin the **Probe Test** or **Cancel** to return to the **Probe Menu** screen.

Two Probes

If two probes are connected to the Otoport, the probe test will run automatically on both in turn.

In the case of two probes insert both probes into test cavities before beginning the Probe Test.

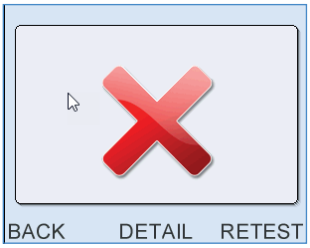
7.2.1 Results

The possible results of the test for each probe tested are:

Pass

The probe has passed the test. Both the microphone and speaker are working correctly.

Fail



If a **Fail** is shown on screen you must inspect the probe coupler tubes again for debris which can cause this failure. Replace the coupler if you see any debris or damage. Re-insert the probe in the cavity. Repeat the Probe Test, by selecting **Retest**.

If the probe continues to fail the test after you have changed the coupler, it must be removed from service until the reason is investigated and rectified. Record the results from the DETAIL screen, as described below, on the log sheet and inform your local manager.

Noisy

The Drum symbol means there was too much noise during the test to tell if the probe passed or failed. Check that the probe is properly fitted to the cavity. Try to reduce any noise in the room and then select **Retest**.

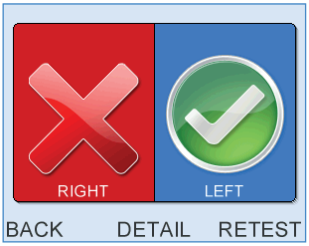
If the probe continues to show a Noisy result even if the room is very quiet, then inform your local manager.

Probe Query

A **Query** result is shown if the performance of the probe has changed. This often happens if the coupler is blocked. Inspect the probe coupler tubes again for debris which can cause this failure. Replace the coupler if you see any debris or damage. Re-insert the probe in the cavity and repeat by selecting **Retest**.

If the probe continues to show Query after you have changed the coupler then record the results from the DETAIL screen, as described below, on the log sheet. You may change the probe and repeat the QA process from the start. If an alternative probe passes all tests then remove the original probe from use. If the problem persists with the new probe you must remove the equipment and probe from use. Report the failure to the local manager.

Dual probe test result



If two probes are connected to the Otoport, both are tested automatically in sequence and a result is shown for each.

Detail

If you cannot achieve a pass result, then record the details of the test in the log. The full test results from any probe test can be viewed by selecting **Detail** from the test outcome screen. If you have tested two probes then the screen below allows you to select which result you wish to view:

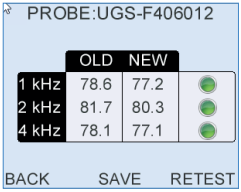
"X" indicates the Probes that need QA Testing

The detail screen shows the ID of the probe tested and the sound level recorded at each frequency.

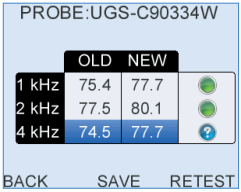
The column labelled **New** shows the results of the Probe Test which has just been completed. It is these **New** values that should be recorded in the log.

The column labelled **Old** shows the probe test results which are stored in the probe. These **Old** values are stored so that any change in the performance of the probe can be noted.

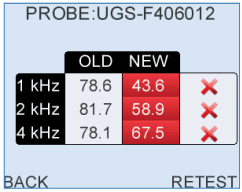
A typical details screen is shown below for three probe test outcomes, Pass, Query and Fail.



Pass: Probe sensitivity in range



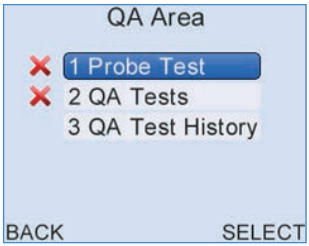
Query: Probe sensitivity in range but a frequency more than 3dB different from stored values

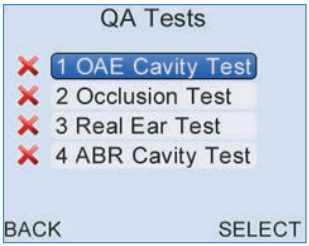


Fail: Probe sensitivity out of range

7.3 QA tests

7.3.1 QA 1 Cavity Test

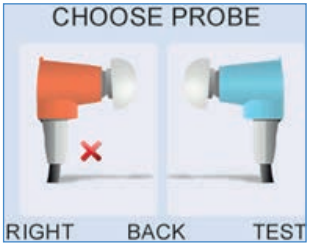




"X" indicates the QA Tests that need completion

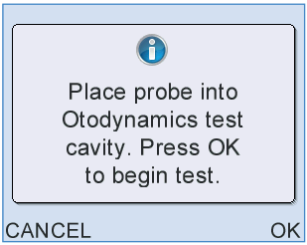
From the **QA Area** menu select **QA Tests** and then **1 OAE Cavity Test**.

If you are using two probes then the QA1 Cavity Test must be run on **each of them**; the screen below will be shown:

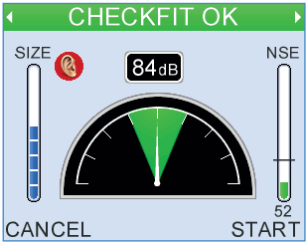


"X" indicates the Probe that needs QA Testing

Select the probe you wish to test (if you have a single probe connected then you will not see this message).

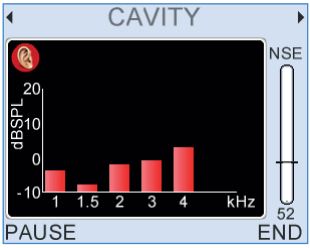


Place the probe in the OAE Test Cavity and select **OK**.



If test conditions are good the banner at the top of the screen will read **Checkfit OK** as in a normal OAE test. If not, then you may need to select the **Adjust** button on the middle key.

See that the stimulus level indication shows **84dB**.



An OAE test recording will be made. The test should be allowed to run until it stops automatically, and a test result is obtained. At the end of the test one of the screens below will be shown. Select **OK** then **Save** the result.

If the equipment is working correctly, no response should be recorded and the **Cavity OK** screen will be shown.

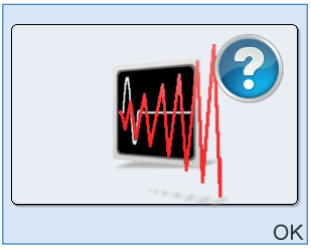
Cavity OK

The test result should be a green tick a green tick beside the cavity picture, pressing **OK** on this screen will show a banner reading **CAVITY OK**. Press **OK** and then **Save** this result.

The test checks that an ear with a hearing loss will not give a **Clear Response** outcome. The cavity, like a deaf ear, should not show a response. If it does show any response then the screen will show **Artefact?**. This can happen rarely by chance in working equipment.

If the cavity is NOT OK, then one of the following four warnings can be displayed:

Artefact?



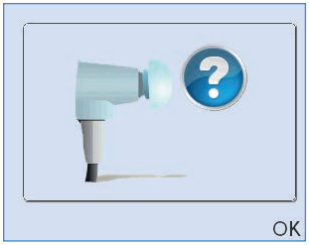
If **Artefact?** is shown at the end of the test, save and make sure the probe is complete with its cover and lid, and has been firmly pressed into the test cavity. A poor fit can sometimes cause this outcome. This outcome indicates that some signal that could be mistaken for an OAE was recorded in the test.

It is very important that you recheck the system if you see this outcome, as it will be interpreted as a clear response by the national IT system when it is uploaded. You may change the probe and refer it to your local manager for further checking (see chapter 24).

Noisy

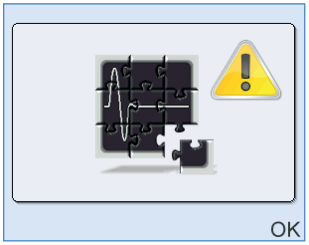
This result indicates that the test environment was too noisy, or that there is a fault with the equipment.

Poor Probe Fit



This result is shown if the probe fit changed during the test.

Incomplete



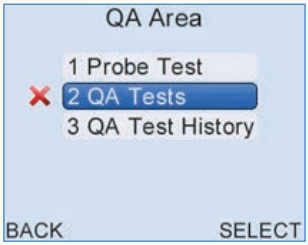
This result is shown if the test was ended by the user (rather than running until it stopped automatically).

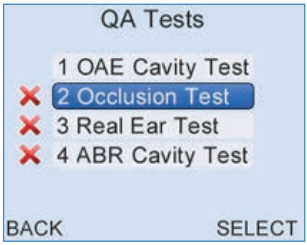
If any of these results are shown save the test, recheck the test conditions and retest, checking that the Probe is firmly inserted into the test cavity and that the noise conditions within the room are acceptable for a screening test to be conducted. After checking the test conditions repeat the test.

If you cannot record a CAVITY OK in this test then you may:

- Change the probe and repeat the QA process from the start.
- If an alternative probe passes all tests then remove the original probe from use.
- If the problem persists with the new probe you must remove the equipment and probe from use.
- Report the failure to your manager.

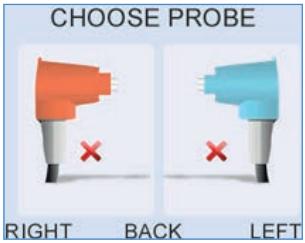
7.3.2 QA 2 Occlusion Test





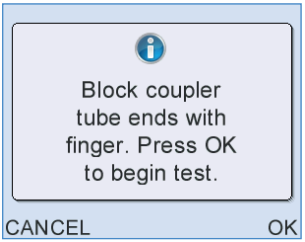
Select **QA Tests** then select **2 Occlusion Test**.

If you are using two probes, then the QA2 Occlusion Test must be run on each of them; the screen below will be shown:

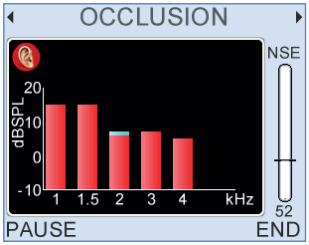


Select the probe you wish to test (if you have a single probe connected, then you will not see this message).

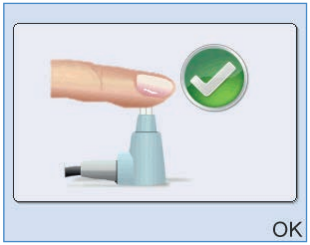
Occlude the tip of the coupler, without a probe tip, with a finger or thumb.



Press **OK** to begin test.



The test outcome will take about seven seconds to complete.

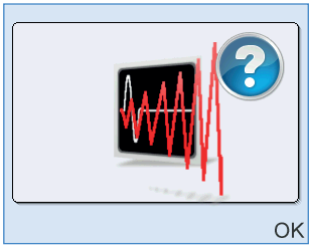


The test outcome should be **Occlusion OK**. Select **OK** then **Save** the result.

If you see any other outcome (shown below) then this test has failed. 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.

Artefacts?

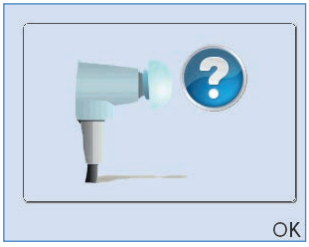


This outcome indicates that some signal that could be mistaken for an OAE was recorded in the test. This can be interpreted as a clear response by the national IT system when it is uploaded. This result can occur occasionally by chance, but a persistent result indicates a fault with the equipment.

Noisy

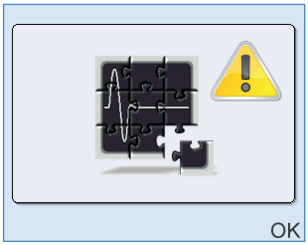
This result indicated that the test environment was too noisy (possibly because the probe was not held still during the test), or that there is a fault with the equipment. Please ensure to move the calibration away from PCs, fans, windows (to avoid traffic noise) or other sources of acoustic interference.

Poor Probe Fit



This result is shown if the probe fit changed during the test. The probe may not have been fully covered by the finger at the start or the end of the test.

Incomplete

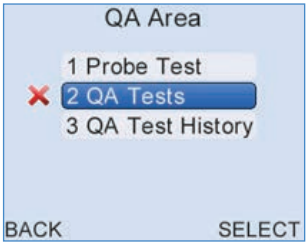


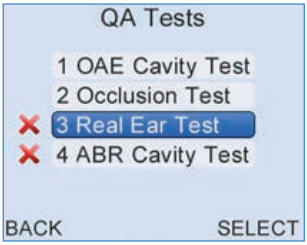
This result is shown if the test was ended by the user (rather than running until it stopped automatically).

If you cannot record an **OCCLUSION OK** result, then you may:

- Change the probe and repeat the QA process from the start.
- If an alternative probe passes all tests then remove the original probe from use.
- If the problem persists with the new probe you must remove the equipment and probe from use.
- Report the failure to your manager.

7.3.3 QA 3 Real Ear Test



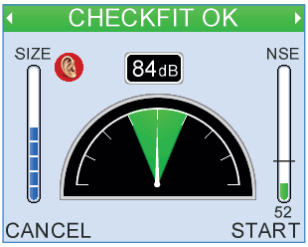


In **QA Tests**, select **3 Real Ear Test**.

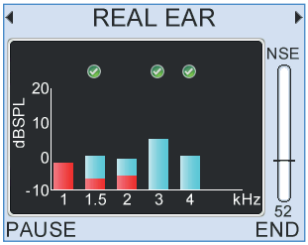
Select an appropriate size adult soft ear tip and fit the OAE probe into an adult ear known to have a Clear Response.

If you are using two probes, then the QA3 Real Ear Test must be run on each of them; the screen below will be shown:

Select the probe you wish to test (if you have a single probe connected then you will not see this message).

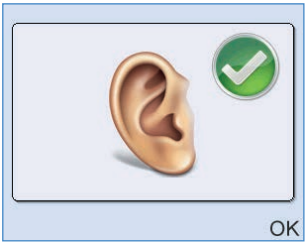


Select **Start** to begin the test.



The instrument will show the OAEs characteristic of the ear used in the test.

If the test ear used has sufficient OAEs and the equipment is working correctly, the test result will be **Real Ear OK**. The test may stop once sufficient OAE response has been detected at two frequency bands on the colour-screen Otoports and on three frequency bands on the legacy (black and white) Otoport models. Alternatively, the test will run to the max 260 sweeps.

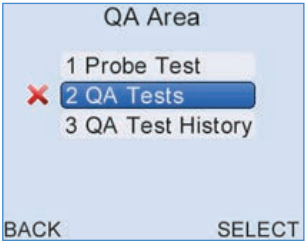


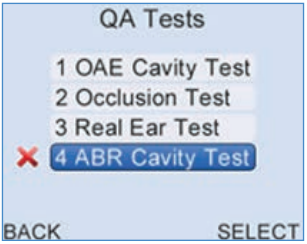
Select **OK** then **Save** the result.

In cases where the QA tester does not usually get a clear response on OAEs and there is no-one else available for testing, the usual expected results will suffice.

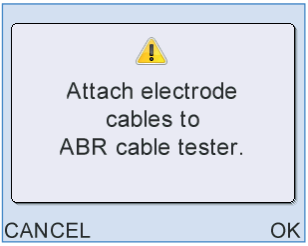
7.3.4 QA 4 ABR Cavity Test

This test checks electrode connectivity, and checks that the instrument is not generating artefacts that might be misinterpreted as a clear ABR response.





In QA Tests, select **4 ABR Cavity Test**.



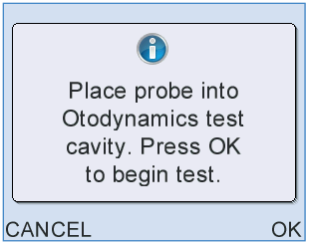
Attach the three electrode cable sensor clips to the top of the ABR test cavity as illustrated, then press **OK**.

The order and position they are attached in is not important.

QA4 checks the integrity of the electrode connectors and the functioning of the AABR test. QA4 does not check the functionality of the probe. It should be noted that, at this stage, both probes will have already been through rigorous evaluation through other QA tests.

QA4 will need to be run wth both probes, but only one probe at a time.

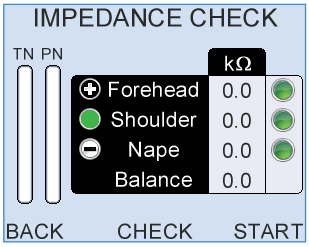
Select **Right** (the left probe can also be selected for the test but ensure to insert only the selected probe in the test cavity on the next step).



Insert the **Right** probe into a test cavity as illustrated above and press **OK** to begin the Impedance Check.

Impedance Check

All impedances should show 0k Ohms:

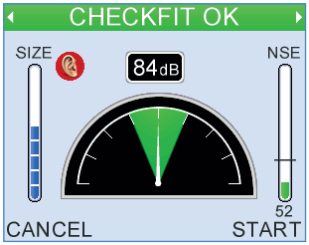


If the impedances are any higher than this, then check the connection of the cable to the test cavity and press **Check**. If after adjusting the impedances still do not show 0k Ohms then there may be a problem with the electrode cables. Remove these cables, connect alternative cables and retry.

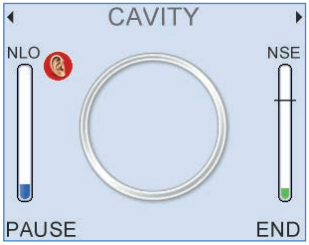
If the new set of electrode cables also fails to give zero impedances, there may be a fault in the instrument; remove the Otoport from service until the fault is investigated and rectified. Inform your local manager.

If all impedances are zero, select, **Start**.

The Checkfit screen will be briefly shown:

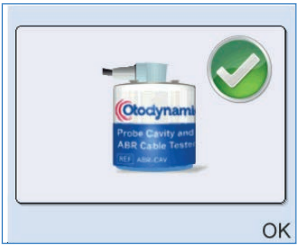


Test screens will follow:



Wait until the test stops. This may take some time while the instrument looks for any signs of an artefactual response.

QA4 Test results



Cavity OK
The test should terminate with **Cavity OK**, which means that no false ABR responses were found. **Save** the test.

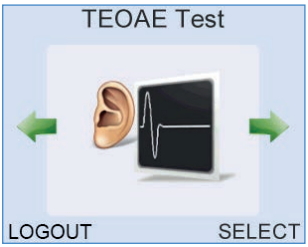
Other Outcomes

If the test results in **Noisy**, **Poor Probe Fit**, **Incomplete** or **Artefacts?** outcomes, save the test and retest after checking that the probe is firmly inserted into the test cavity and that the noise conditions within the room are acceptable for a test to be conducted.

If after adjustment, a **Cavity OK** result still cannot be obtained remove the instrument from service until the possible fault is investigated and rectified. Inform your local manager.

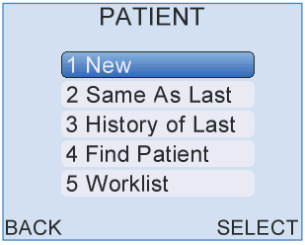
Each of the QA tests can be reviewed individually in the **QA Test History Area**.

8 TEOAE test



On the **TEOAE Test** screen, choose **Select** to go to the **Patient** menu.

8.1 Entering demographic data



Select **1 New** to enter details of a new baby to test.

The Otoport will check that the previous patient has test data for both the left and right ears. If only one test has been saved then a pop up message will appear stating **Only RIGHT/LEFT Ear Test Saved to Last Patient. Proceed with New?**. Select **Yes** to continue with a new patient or **No** to return to the **Patient** menu screen.

Enter the following data. Mandatory fields are marked with an asterisk.

*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	Full/Screen only

See Chapter 3, section 3.4.3 for guidance on entering characters.

8.2

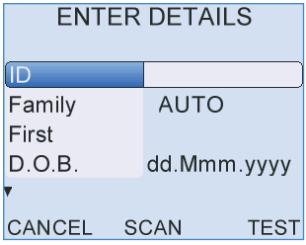
Preparing the baby

The optimum test conditions are a settled baby in a quite environment.

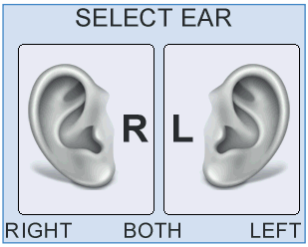
Place an ear tip on the probe coupler. Choose a size that is large enough to provide a secure fit in the baby's ear.

Gently pull the pinna up and back to open the ear canal and insert the probe into the baby's ear.

Check patient details and select **TEST**.

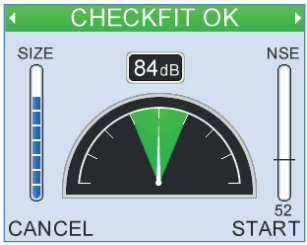


8.3 Selecting the ear



Select RIGHT or **LEFT** for the ear being tested.

8.4 Checking probe fit



It is important to perform a test in the appropriate conditions. The **Checkfit** screen allows a user to assess the testing environment. Conditions such as high ambient noise, poor fit of the probe in the ear (including leaks) and blocked probes can be detected before starting the test.

Excessive noise or a poor probe fit may mean that it is not possible to record OAEs.

Noise level indicator

On the right of the screen is the Noise Level Indicator. For good testing conditions the bar should be consistently below the Noise Reject Level which is the line across the Noise Level Indicator.

Use the up/down arrow keys to change the Noise Reject Level.

Ear canal size indicator

The bar on the left of the screen gives an estimate of ear canal size. . Baby ears should show as small (0-2 segments) if the probe fit is good.

Stimulus level indicator

The dial on the screen is a Stimulus Level Indicator, the number above shows the current stimulus level. With the probe in an ear, the Otoport will try to adjust the stimulus to 84dB. The stimulus is at the correct level when the needle points straight up. If the stimulus level remains very low, regardless of the position of the probe in the ear, it is likely that the probe has become blocked. In this case, inspect the probe coupler tubes and replace if necessary (see section 12.2 **Probe care**).

Autoadjust

The 'in-the-ear' calibration process on the Otoport compensates for different ear canal sizes, provided that the probe is fitted correctly (see section 4.3 **probe fitting**). During the Checkfit stage, if the probe fit is stable, the stimulus will automatically adjust the click stimulus level to the target stimulus setting of 84dB (±1dB). This will compensate for different ear canal volumes.

If the probe fit remains poor at the start of the Checkfit stage, an **Adjust** button may become available on the Otoport screen. This gives the user the opportunity to improve the probe fitting. After improving the probe placement, the user may select the **Adjust** button to retry the automatic stimulus adjustment process.

Test condition information

The message on the top of the screen varies showing:

Checkfit OK when the adjusted stimulus level is correct and the noise is consistently below the reject level.

Noisy when noise is high.

Check Probe Fit when the stimulus is out of range.

Ringing when the Stimulus Waveform continues for a long period after the initial positive and negative peaks.

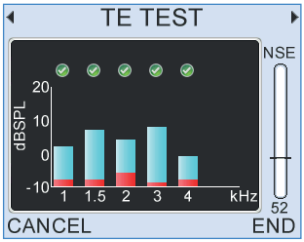
When **Checkfit OK** is shown, select **Start** to begin a test. If you need to stop testing for any reason, press **Cancel**.

The stimulus (**S**) and noise (**N**) LEDs above the screen are lit when the stimulus and noise levels are good for testing.

Additional information on checkfit is available in the **Administrators** section of this manual.

8.5

Monitoring the test



The two blue lights should be on most/all the time. The 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, represent the TEOAE signal (blue) to noise (red) ratio. A tick appears above a bar 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. Select **Back** and readjust fit and attempt the screen again if protocol permits.

Test condition information

The message on the top of the screen varies showing:

TE TEST when test conditions are good

Noisy when the noise level is above the noise reject level

Check Probe Fit when stimulus level is below 81dB or above 87dB. This mostly happens if the probe is falling out of the ear.

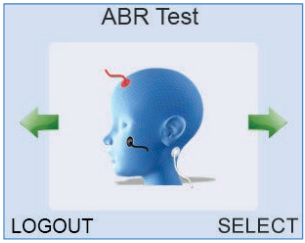
Additional information on monitoring the test is available in the **Administrators** section of this manual.

8.6 Test result

The Otoport NHSP test outcomes are:

S4H Test Result	Otodynamics Test Result	Result Description
CR	Clear Response 	The test met the NHSP criteria.
NCR	No Clear Response 	The test did not meet NHSP criteria and no problems were identified during the recording that may have prevented a Clear Response from being detected.
NC (Incomplete)		The test did not meet the NHSP criteria but problems were identified during the recording that may have prevented a Clear Response from being detected. Note: All of the stop reasons below will be reported as 'Incomplete' on S4H, not just tests cancelled by the user (which are labelled 'Incomplete' on the Otoport).
	Noisy 	There was too much acoustic noise to test. The 'Noisy' message would have been displayed during testing and the amount of rejected data (NHi) was three times the accepted data (NLo). The screener should attempt to reduce acoustic noise in the room or calm the baby and retest.
	Poor Probe Fit 	The fit of the probe in the ear changed significantly during testing, most likely because it fell out of the ear. Refit the probe and retest.
	Incomplete 	The screener cancelled the test.

9 ABR test



The Auditory Brainstem Response (ABR) test records the electrophysiological response of the auditory system to sound.

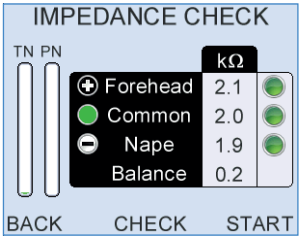
Find **ABR Test** from the scrolling modules using the arrow keys then press **Select**. The patient menu will be shown as for TEOAE test. When a patient has been selected, press **Test**.

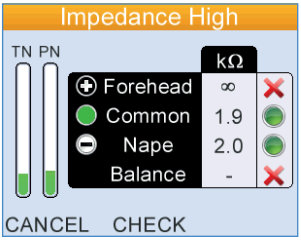
9.1

Impedance check

The Otoport checks the quality of the connection between the skin and each of the three sensors. This takes 2-3 seconds. A low impedance provides a good connection. Also, well 'balanced' electrodes (the difference between electrode impedance at forehead and nape) provides the best opportunity to reject noise and show an AABR response. Achieving optimum sensor impedance requires practice and experience.

The Otoport also checks the noise levels, marked TN and PN on the screen.





Good test conditions are necessary for efficient testing. Test conditions depend on sensor impedance and noise levels. The Otoport automatically decides if the test conditions are good, moderately good or poor:

If test conditions are good

The ABR test will start automatically if the sensor impedances are good and the electrical noise is low for a few moments.

If test conditions are moderately good

If test conditions are moderately good they are satisfactory for testing, but could be improved; the test will not start automatically. You have two alternatives: you may manually begin the test by selecting **Start**; or try to improve the test conditions (for example by reapplying the sensors or by settling the baby or by reducing the noise).

Observe the symbols next to each sensor on the screen. Green circles indicate the quality of the sensor connection. The more the green circle is filled the better the connection.

If you refit any sensors then you must select **Check** to re-measure the impedances.

If the test still does not start automatically, observe the two noise bars TN (EEG Noise), and PN (Powerline Noise). They may be high. For advice on how to reduce the noise see section 5.2 **ABR test problems**.

The test will start automatically when conditions are good.

If you are unable to improve test conditions then you may manually begin the test by selecting **Start**.

If test conditions are poor

If impedance or noise conditions are poor then the test will not start and it will not be possible to start a test manually. A message on the screen will show the problem. It will tell you if EEG Noise, Powerline Noise or Impedance are preventing the test from starting. Try to resolve the issue so that testing can start.

- If any sensor impedance is marked with X then refit that sensor
- If High EEG Noise is shown then try to settle the baby.
- If High Powerline Noise is shown and sensor impedances are good, then see if there is any electrical equipment in the room that can be turned off.

(See section 5.2 **ABR test problems** for more detail).

Select **Back** to cancel the test.

If required, further advice on electrical noise indicators and impedance assessment levels is provided on the next two pages.

Further advice on ...

Otoport impedance measurements

The impedance of each sensor, Forehead (+ve), Nape (-ve) and Common are shown in the Impedance Check panel.

Green circles are displayed for all impedance values where testing is possible.

The larger the green filled circle is the better the sensor connection (i.e. the lower the impedance). A red cross is shown at levels where impedance is poor and testing is not possible.

The ranges for each symbol displayed are:

- Less than 4 kΩ: Optimum ()
- 4 kΩ to 12kΩ: Good ()
- 12 kΩ to 16kΩ: Moderate ()
- More than 16 kΩ: Poor ()

The green LED lights on the top of the ABR unit will be lit if the connection of the sensor closest to that light is optimum, good or moderate. Autostart requires that all impedances are optimum or good.

The Balance result indicates the difference in the skin impedance between the Nape and Forehead sensors. Balances higher than 12 kΩ are Poor (X) and will prevent the test from starting.

If the impedance values are too high refer to 6.2 **ABR test problems**.

Note that testing is possible on the Otoport with moderate sensor impedances if there is sufficient balance between the sensors and the powerline interference is low. This is decided automatically by the Otoport.

Select **Check** to re-run the impedance check.

Further advice on ...

Electrical noise indicators

The bars on the left of the screen indicate the electrical noise levels. The lower the test noise the more rapidly an ABR response will be detected.

Electrical noise has multiple sources:

- Interference from other electrical devices (mains/powerline noise)
- Noise from muscle activity (myogenic noise)
- Noise from brain activity (EEG)

The right hand bar (labelled PN) estimates the level of noise from electrical wiring and other devices. This level is high if there is a lot of interference from electrical noise and/or one or more of the sensors is poorly connected (has high impedance). If impedance levels are acceptable but the PN noise level remains high try:

- Turning off or moving other electrical appliances (including lights)
- Moving to a different test location

The left hand bar (labelled TN) estimates the total level of noise from everything except other electrical devices. If this level is high it is likely that the baby is moving or is not relaxed. Try to settle the baby and ensure that the neck is supported and muscles are relaxed.

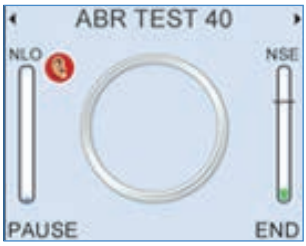
If either level remains high refer to 6.2 **ABR test problems**.

9.2 ABR Checkfit

The test stimulus in ABR tests can be provided either by applying an ear cup to the ear and inserting the probe into the ear cup or by inserting the probe directly into the ear, as for OAE testing. Which option is used, and how the probe checkfit functions, depends on the **Ear Cups** setting in **Test Setup** (see chapter 17).

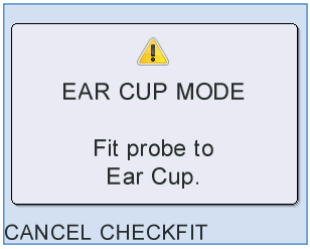
Note: Until advised otherwise, Screeners are permitted only the use of ear cups and **not** the probe fitted directly into the ear.

With **Ear Cups** set to **On** the Otoport will check whether the stimulus level recorded is consistent with ear cup use.



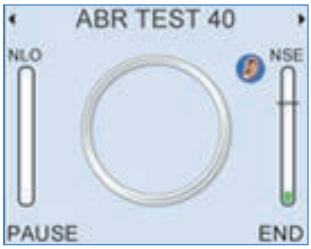
Checkfit in ear cup mode

If the levels are higher than those that would be expected in an ear cup (for example if the probe had been inserted into an infant ear canal) the stimulus is muted and this screen is shown:

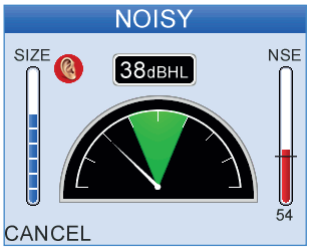


Selecting **Cancel** will cancel the test and **Checkfit** will recheck the stimulus.

The ear icon shown below indicates that the Otoport is in Ear Cups mode. If the levels are consistent and the noise level is low the test will start.



With **Ear Cups** set to **Off**, Checkfit proceeds as for OAE tests (see section 8.4 for details). The screen used in OAE Checkfit is shown if ear cup mode is off.



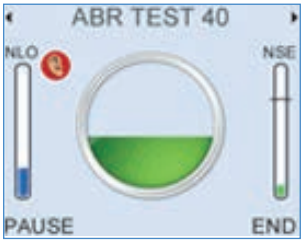
Checkfit in probe mode

9.3

ABR test

During the test the Otoport plays a series of clicks into the ear and records the electrical response from the sensors. The ABR signal is very small and difficult to distinguish from other electrical signals.

The ABR test screen shows progress towards the detection of an ABR response.



The circle indicates the probability that an ABR response is present. The circle is filled when there is 99% confidence that a response is present.

NLO is an indication of the amount of data accepted due to noise being below the noise reject level.

The test will end automatically when either the circle is filled (there is a ABR response present), when the blue NLO bar is filled (a full set of data has been recorded but no response has been detected), or when test noise (ABR noise) has become so low that any valid ABR would already have been detected and so further testing is redundant.

NSE is an indication of the amplitude of the current electrical noise level. The lower this value is, the faster the test will be. The data measured during this time will be ignored. If there is high noise for a consistent period then an impedance test is automatically run and the message 'Checking Impedance' will be displayed. If impedance levels have worsened significantly since the start of the test then the test will be automatically paused.

Pressing the left and right arrow keys displays the **Data Summary** and **Waveform Display** screens.

9.3.1 Test stop reasons

When the stop criteria have been met, the test will stop automatically and a single beep will sound for an ABR pass result or a double beep for any other result.

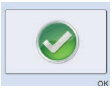
When the test stops a result graphic is displayed on the screen, see **ABR test results** 9.4 for more details. Select **OK** to accept the test stop reason. The result is then displayed at the top of the test screen.

Additional information on monitoring the test is available in the **Administrators** section of this manual.

9.4

ABR test results

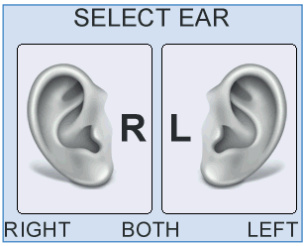
There are three basic types of test result, **Clear Response**, **No Clear Response** and **Incomplete**. The table below shows these results and the associated graphics shown on the Otoport.

S4H Test Result	Otodynamics Test Result	Result Description
CR	Clear Response 	The test met the NHSP criteria.
NCR	No Clear Response 	The test did not meet NHSP criteria and no problems were identified during the recording that may have prevented a Clear Response from being detected.
NC (Incomplete)		The test did not meet the NHSP criteria but problems were identified during the recording that may have prevented a Clear Response from being detected. There are several possible problems and the Otoport will report which has occurred so that the screener can try to resolve the issue and rerun the test. Note: All of the stop reasons below will be reported as 'Incomplete' on S4H - not just tests cancelled by the user (which are labelled 'Incomplete' on the Otoport).
	Noisy 	There was too much acoustic noise to test. The 'Noisy' message would have been displayed during testing. The screener should attempt to reduce acoustic noise in the room or calm the baby and retest.
	Poor Probe Fit 	The last stimulus level recorded changed from that recorded at the start of the test by >3dB, or the last acoustic noise level recorded was high. The fit of the probe in the ear should be adjusted and then retest.

Incomplete 	The screener cancelled the test before a decision was possible.
High Mains Noise 	Interference from electrical equipment invalidated the test. The screener should try to reduce the electrical noise in the environment by turning off any unnecessary electrical equipment or try to reduce sensor impedances and imbalance and then retest.
High EEG Noise 	Electrical noise during the test could have prevented an ABR from being recorded. This is most likely caused by the baby being unsettled during the test (myogenic interference). Retest when the baby is more settled.
High Impedance 	The sensor impedances measured at the end of the test were high and this may have prevented an ABR from being recorded. This could be caused by sensors becoming disconnected from the patient during testing. Check the sensors and retest.

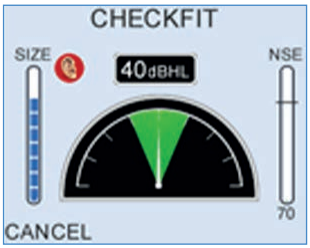
9.5

Bilateral ABR testing

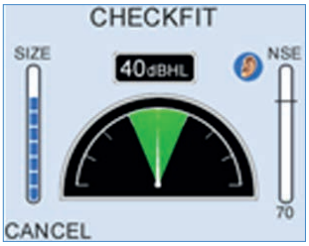


Bilateral ABR tests automatically run tests on both ears in sequence, right ear then left ear. Ear cups are recommended for bilateral testing and both ears should be prepared before testing commences. The current test ear is indicated during the test by a blue or red icon on the test screen.

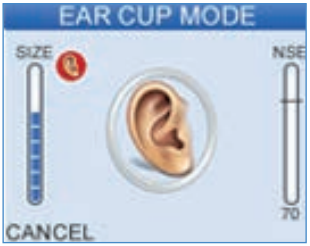
Checkfit and Test

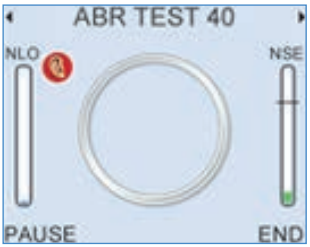


Right ear



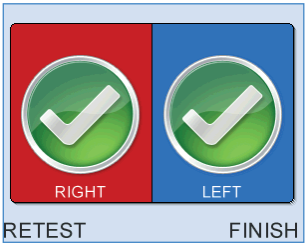
Left ear





When the right ear is completed the test result will be displayed briefly before testing on the opposite ear starts.

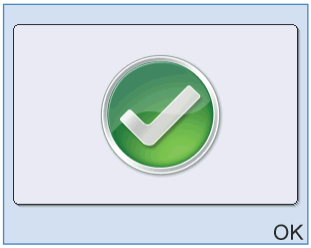
When both tests are complete, stop reason icons for both ears will be shown on the screen together. The same stop reason graphics used for single ear tests (see section 9.4 **ABR test results**) are used for the Right and Left ear results.



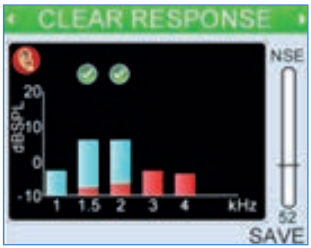
It is not possible to review bilateral ABR tests in detail at the end of test. If you wish to review the tests select the **History of Last** option from the patient menu (see chapter 22 **Records**).

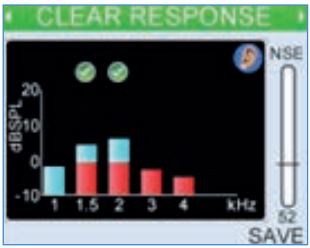
10 Saving tests

Once a test has finished the test result is displayed, **OK** is the only available option, select **OK**.

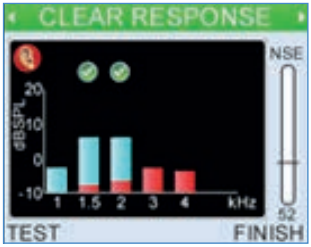


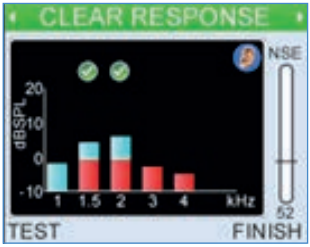
Save is the only available option from the Review screen, select **Save** to save the test result.





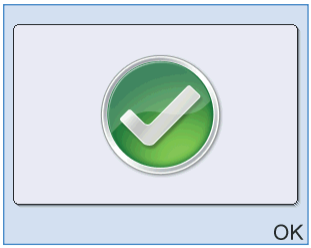
The options available from the saved result screen are **Test** and **Finish**. Select **Test** to perform another test on the same patient. This will navigate back to the ear selection screen, to select the test ear for the next test.

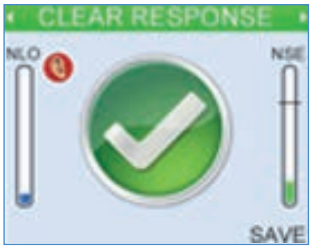


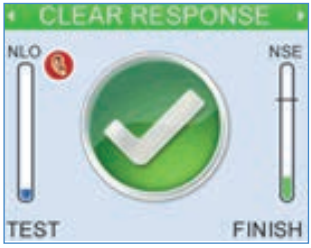


Select **Finish** to return to the main menu.

As above and now continuing for ABR.







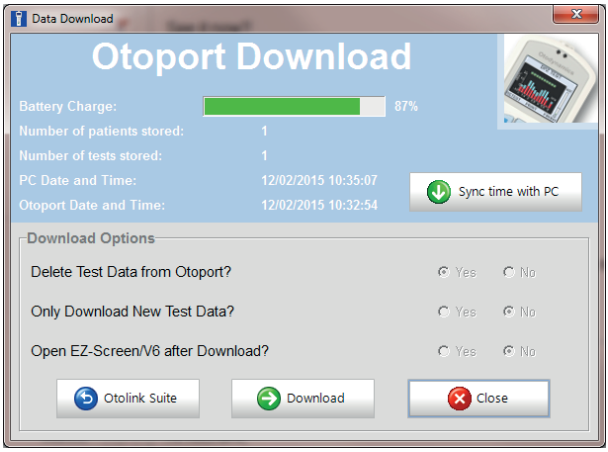
11 Uploading data to S4H

Each screener is responsible for the accuracy of screening data and ensuring that it is uploaded into S4H at the end of each screening session.

Data must be uploaded within 24 hours of the screen being done.

11.1 Downloading from the Otoport

- Switch the Otoport off.
- Connect the Otoport to the designated PC using the 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.

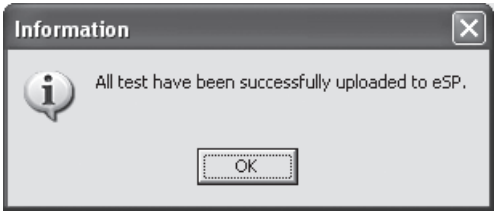


If the upload is not successful (data should arrive within 5 minutes) please refer to document “SEDQ data not arriving in S4H”.

11.2 Uploading to S4H

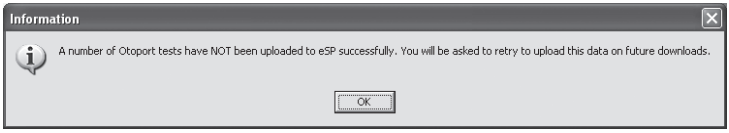
After downloading to the PC, upload to S4H is automatic. Data should arrive within five minutes.

When all data has been sent to S4H the following message will be displayed.



11.2.1 Upload errors

If data cannot be uploaded for any reason, an error message will be shown:



Tests which haven’t been uploaded are stored on the PC. You may view, export or delete the records using the Dataviewer (described later in this chapter).

11.2.2 Retrying transfer

Otolink will automatically retry the transfer the next time data is downloaded from the Otoport.

A transfer can also be attempted by right clicking the desktop or tray icons and selecting **Transfer S4H Data**.

12 Maintenance and cleaning

12.1 Summary

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

Inspect the probe 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 a new tip for each baby.

Protective sleeves for the Otoport are available from Otodynamics. All infection control procedures must be approved locally.

12.2 Probe care

Otodynamics does not recommend the use of bleaches such as sodium hypochlorite based cleansers.

The following is the suggested method of cleaning an Otodynamics probe. It should be noted that the probe is a precision assembly and, as such, care should be taken throughout in its handling and cleaning.

Cable - The cable may be cleaned with alcohol based antiseptic fluid or wipes.

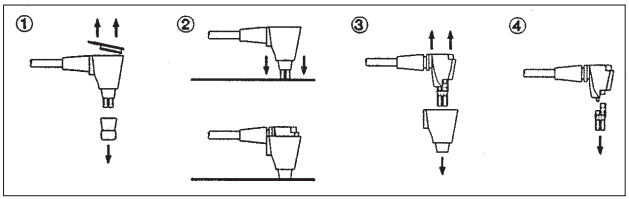
Probe casing - The probe casing may be cleaned using alcohol based antiseptic wipes and dried with a tissue immediately afterwards. Do not allow liquids to enter the sound tubes.

Coupler assembly - Each coupler assembly has two sound tubes. These are protected from ingress of foreign materials by wax guards in the tubes and by the disposable probe tip. There is a loudspeaker at the end of one tube and a microphone at the end of the other. Cleaning solution must not penetrate the tubes.

12.3 Changing probe coupler tubes

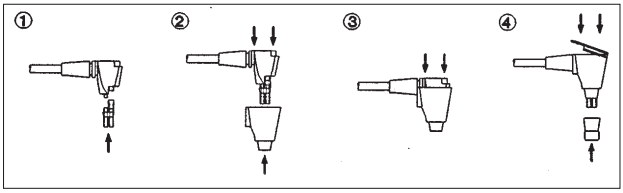
The probe has sound tubes combined into a single coupler assembly that can easily be replaced at regular intervals or when contaminated.

12.3.1 Disassembling the probe



First, unplug the probe from the instrument. Remove the tip and then the lid (fig. 1). Remove the coupler tubes by pushing the end of the tubes down onto a hard surface (fig. 2). Pull out the tubes by gripping them (fig. 3). Never remove them by pulling on the cable. Finally, pull the coupler tubes away from the probe (fig. 4).

12.3.2 Reassembling the probe



Fit the new coupler tubes to the probe assembly (fig. 1). Fit the outer shell (figs. 2 and 3), followed by the lid (fig. 4). Click the lid into place using firm finger pressure only. Finally, fit a new tip (fig. 4).

12.3.3 Notes:

- Fit a new tip for each baby.
- Check that the coupler tubes are not contaminated before fitting the tip.
- If the coupler tubes are contaminated, **replace them**. We recommend fitting new coupler tubes at regular intervals (approx every 20-40 tests) as a preventive measure.
- Perform daily QA tests.

12.4 Probe safety note

Probes are designed for use with an Otodynamics disposable tip. Use of a tip is essential.

Use without a tip will expose the ear canal to the hard plastic sound tubes and this **might cause injury**.

Use without a tip or with an incorrect or non-Otodynamics tip may also cause serious errors in measurement. This could invalidate the OAE recording.

12.5 Otoport care

The Otoport is robustly constructed but is a precision instrument, so should be handled with care. Be careful when connecting the probe, charger, PC cable or printer cable.

- Do not drop the Otoport
- Do not leave in strong sunlight
- Do not expose to high temperatures
- Do not touch the connector socket pins by hand
- Do not force the connection of the probe, the charger, the PC cable or the printer cable

12.6

Use of the Otoport and cleaning

The following is a suggested cleaning method for the Otoport and probe. The Otoport and accessories are precision assemblies, so care should be taken throughout handling and cleaning.

Cleaning of probe

Other than the probe and cable, the Otoport hardware should not come into contact with the patient being tested. Otodynamics probe tips are disposable and for single use only. A new tip should be used for each ear tested. The tip protrudes ~ 0.5mm beyond the end of the probe coupler, to prevent contact of the sound tubes with the patient.

Between patients, wipe the probe and cable with an alcohol based sterile wipe or cloth and antiseptic fluid. Dry the assembly with tissue immediately afterwards and do not let liquid pass down the coupler sound tubes. The probe is serviceable and its body, lid and coupler tubes can be replaced. The coupler tubes should be replaced weekly or after 20-40 tests, or if they have been contaminated. The body and lid should be replaced if contaminated. Visually check the probe for signs of dirt before each test.

Before fitting each tip, ensure the sound tubes are carefully examined for any sign of debris that may have entered them. Replace any part of the probe as necessary.

Ensure your hands are cleaned thoroughly between each patient tested.

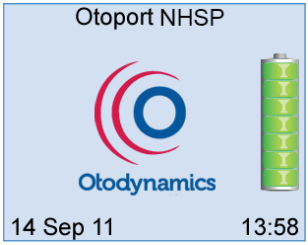
Cleaning of Otoport

Clean the Otoport each day before a testing session, or according to local requirements. Ensure the Otoport is cleaned if it becomes contaminated. Clean surfaces of the Otoport with an alcohol based sterile wipe or cloth and antiseptic fluid. Dry the Otoport with tissue immediately afterwards. Do not allow liquid to enter the instrument and do not immerse in fluid. Do not allow liquid to come into contact with the connection sockets. Do not poke any materials into either the probe or charger/pc cable sockets.

If additional hygienic protection is required, use the Otoport in an infection control sleeve. This can also be cleaned with a sterile wipe or cloth with antiseptic fluid. The sleeves are disposable, so should be replaced weekly or after approximately every 50 tests.

13 Otoport power

13.1 Battery life



The battery level is displayed when the Otoport is switched on.

The battery when fully charged will allow over 250 screening tests. To save power, the Otoport will go into standby mode after 90 seconds of inactivity.

Switch off after each screening session to ensure that all data has been saved and to conserve the battery.

If the Otoport goes into standby with a test result that has not been saved, then a beep will sound for five seconds in every minute to alert the user.

To resume from standby, press any key on the keypad. The Otoport will wake up and return to the previous screen displayed.

If the Otoport is left for 20 minutes in standby it will turn itself off (any unsaved data will be lost).

Low battery

When the battery power reaches less than 10% remaining a **Low Battery** warning message will be displayed. This equates to approximately 30 minutes of testing time.

Critical battery

When the battery power reaches 7% remaining a **Critical Battery** warning message will appear on screen. This equates to approximately 10 minutes of use. The Otoport will not start a screen with less than 5% battery power.

Auto switch off

The Otoport will automatically switch off when the battery is empty. It will be necessary to charge the Otoport before it will switch on again.

13.2

Charging the battery

Charging can take up to 4.5 hours

You cannot screen whilst the Otoport is charging.

Switch off the Otoport.

Plug the charger into a power socket and switch on the power. The green light on the charger will illuminate indicating it is powered.

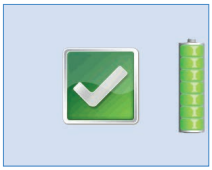
Then connect the slotted charger plug to the Otoport. Ensure the arrow is facing upwards.

There are two lights on the side of the Otoport.

Top light : Green when connected to the mains

Bottom light : Orange when charging, Green when fully charged

A tick will also appear on screen when the Otoport is fully charged.

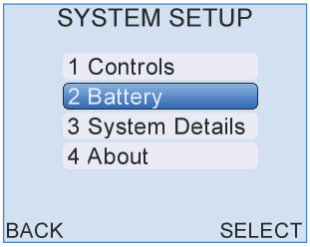


If the cable has release keys, squeeze to disconnect, otherwise just pull out the cable.

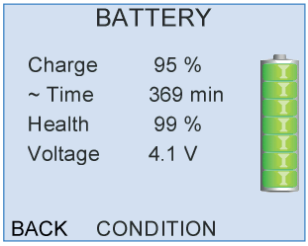
13.3 Conditioning the Otoport battery

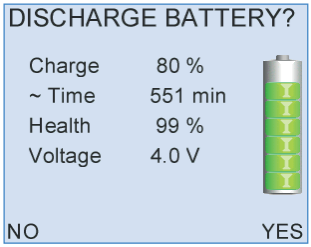
Once a year the battery should be conditioned. Upload all data prior to conditioning.

Go to the **System** screen, choose **Select** then **2 Battery** from the menu.



Press the key and confirm to discharge the battery completely. This will take up to six hours.





Re-charge fully before next using the Otoport.

14 Manufacturer calibration and repairs

Calibration is due at three years, and every three years thereafter.

Return the Otoport to Otodynamics for a factory inspection, re-calibration and rechargeable battery change.

Calibration certificates must be kept for your records.

Otodynamics highly recommends that the Otoport is serviced every three years (this is not a device safe operation requirement). During Otodynamics approved service the Otoport system will be thoroughly inspected and calibration will be checked; any system items with significant wear/tear or negatively affecting the system's calibration will be replaced at no additional charge.

The expected service life of the Otoport is ten years from the date of manufacture.

Take care when inserting and removing the probe cable or download cable from the socket to avoid damage.

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.

Otodynamics Ltd.
30-38 Beaconsfield Road
Hatfield
Hertfordshire AL10 8BB
UK

Section Three Administrators

15 Installing Otolink software

15.1 Introduction

There are several stages to Otolink installation and they should be conducted in the order detailed below. Prior to the installation close all programs running on your PC.

Note:

You will require Windows Administrator privileges to complete this installation. Please contact your IT administrator if you do not have this level of PC access.

To ensure smooth Otolink installation and operation, it is recommended that User account control (UAC) is turned off, or set to the lowest level on Windows Vista, W7 and W8.

15.2 Minimum PC specifications

Processor
Pentium III 1GHz

Operating System
Windows 10, 8, 7 and Vista

RAM
1024 MB minimum

Otolink installation
Hard disk: 50MB min free

V6 installation
Hard disk: 50MB min free

CDR / DVDR
Recommended for database archiving and backup

15.3 Installing ILO V6

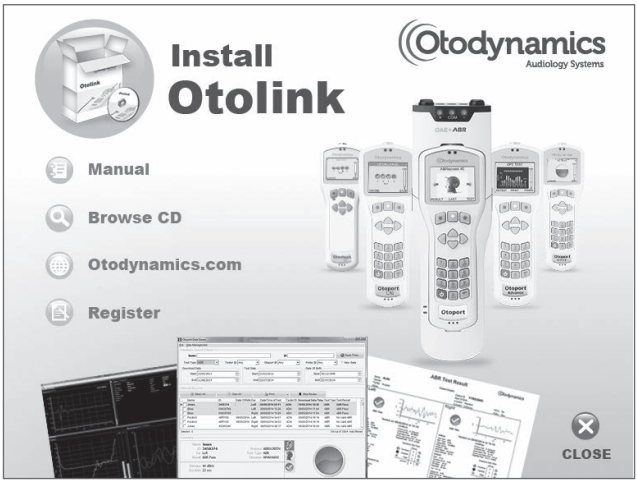
The Otoport you have purchased may be supplied with ILO V6 software as standard. This software is also available as an option. For most data types, ILO V6 is not essential for review of data on the PC as data can be viewed in Otolink. Otoport Advance TEOAE tests that include 6KHz band data and DP Growth tests can only be viewed in ILO V6. ILO V6 software can be used for clinical data review and data management.

If you are going to use ILO V6, it should be installed before Otolink is installed. Refer to the ILO V6 manual for installation instructions. If the installation is solely for viewing Otoport data, ensure that ILO V6 is installed with the **OAE instrument type** set to **Otoport Viewer / Training mode**.

15.4

Otolink CD menu

Insert the Otolink CD into your CD-ROM drive. The menu below will be displayed.



Select the various options using a left mouse click.

Install Otolink
This will begin the Otolink software installation.

Manual
This opens the Manual, for on-screen viewing.

Browse CD
This allows the contents of the CD to be viewed.

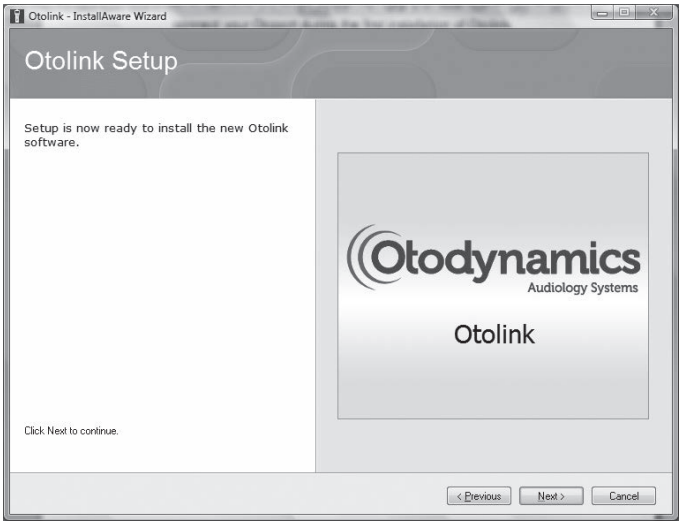
Otodynamics.com
This will open the Otodynamics website on your web browser (your PC will need to be connected to the internet).

Register
Select this option to register your software with Otodynamics.

15.5 Install Otolink

Select **Install Otolink** from the CD menu.

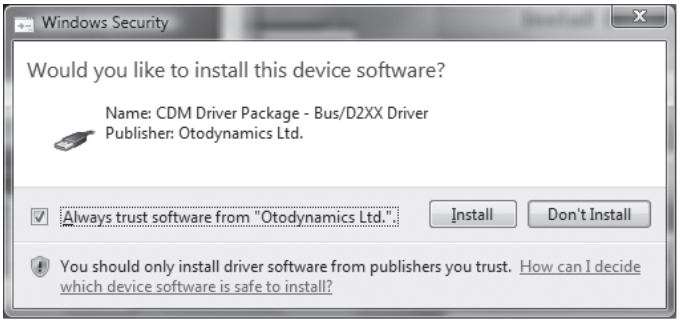
Otolink installation comprises a number of stages which vary according to whether Otolink has previously been installed on your PC. The installation process also installs the USB drivers required for the Otoport to communicate with the PC.



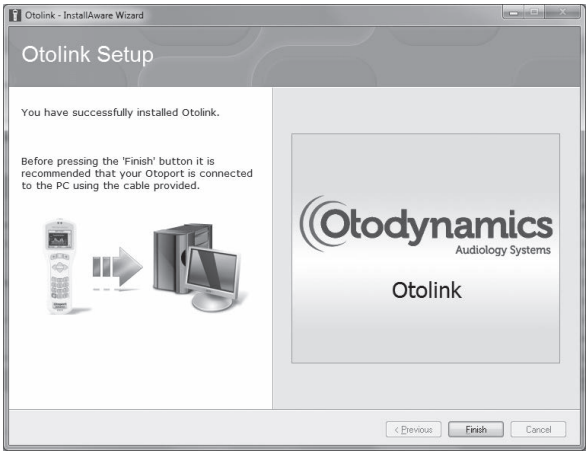
Follow the on-screen instructions, selecting **Next** when necessary.

Select the tick/check box to 'Always trust software from Otodynamics Ltd' and then click **Install**.

During installation, you may see the following message:

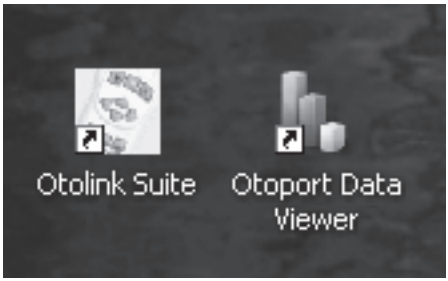


A message is displayed when installation is complete. Before pressing the **Finish** button, it is recommended that your Otoport is connected to the PC using the cable provided. Otolink will then automatically be configured for your Otoport type and where necessary drivers will be updated or installed.



Select **Finish**.

Following the installation, Otolink will automatically run. Shortcuts to the Otolink Suite and Otolink Data Viewer will be placed on your PC desktop. To start Otolink manually, double-click either icon.



Note:

If it is necessary to uninstall Otolink, re-start your PC following this process prior to reinstallation of the software.

15.6 Completing Otoport driver installation

Otoport drivers were loaded onto your PC during the Otolink installation. To complete the driver installation, follow the instructions below.

15.6.1 For Windows 10, 8, 7 and Vista

Connect the Otoport to the PC and Windows will automatically complete the driver installation process.

16 Configuring your Otoport

16.1 S4H setup

Before an S4H Otoport can be used for testing it must be configured with information from S4H. This procedure loads the users, facilities and risks that will be required by a particular Otoport. These lists are specific to a particular NHSP site.

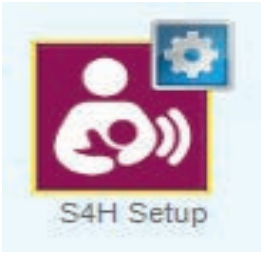
Before configuring your Otoport ensure:

- The Otoport machine ID (GSN) is registered on S4H for your site
- The PC you are using is connected to N3
- There is no data stored on the Otoport
- The Otoport is turned off

Plug your Otoport into your PC.

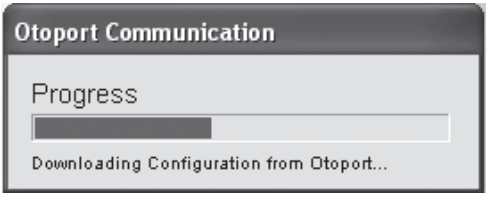
Open **Otolink Suite**.

Select **S4H setup**.



If the **S4H configuration** details **are correct** and the Otoport's machine ID (**GSN**) **is registered** on S4H for the selected Site name, Otolink will read the current settings on the Otoport.

This will take a few seconds and a window will indicate progress.

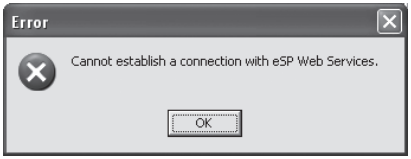


You are then presented with the **Login** window (see the next section).

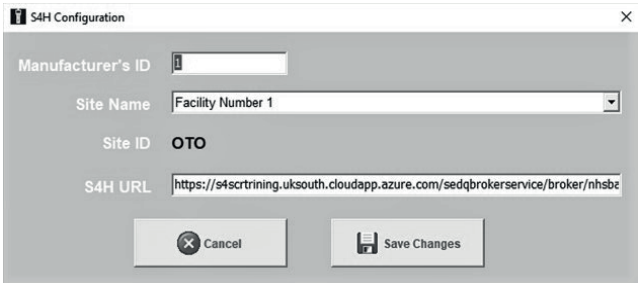
16.1.1 Connection problems

If the **S4H URL** (connection address) is **incorrect** the **S4H configuration** window will open.

If your Otoport's **GSN** is **not registered** at the currently selected site, or if there is a problem with your connection, you will see a message like this:



When you click on **OK** the S4H configuration window will open.



Click on the arrow next to the **Site Name** box. Ensure that your site is selected from the drop-down list.

Ensure that the manufacturer's ID is set to **1**.

Check the S4H URL is correct and carefully edit if necessary.

Correct S4H URL:

https://NWW.SMSNHSP.NHS.UK/csp/sedqpra/northgate.esp.sedq.bserv.ProxySEDQ.cls

Click on **Save Changes** when you have finished.

Click again on the **S4H setup** button to continue to **Login.**

Note:

If there is a problem connecting to S4H Setup, or the S4H Configuration details do not display a Manufacturer's ID of 1, then close Otolink by right clicking on the Tray Icon and selecting Exit from the dropdown menu.

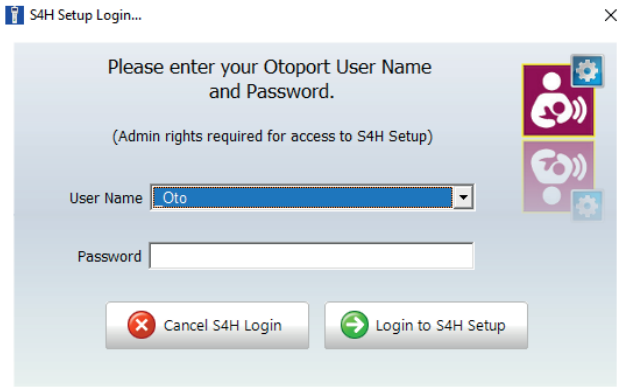
Now start Otolink by double clicking on the Otolink shortcut:

or by selecting Otolink from:

Start > All Programs > Otodynamics > Otolink.

Now re-attempt Otoport configuration.

16.2 Login



After the current settings have been read you will be prompted to select your Otoport **User name** and to enter your **Password**. User name should be chosen from the list displayed when the arrow besides the User name box is selected. You will need to have an administrator account in order to configure your Otoport.

When you have completed the User Name and Password click on **Login to S4H Setup**. Note that password entry is case sensitive.

First Use:

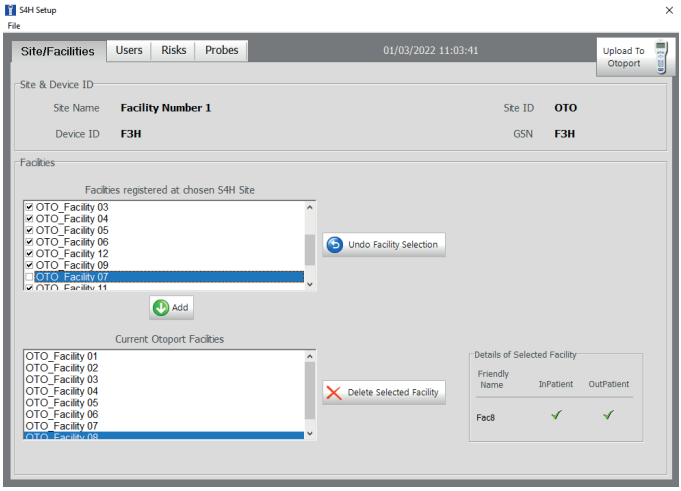
If this is the first time the otoport has been configured then the default Admin and Oto user name will be available. Select **Admin** then enter the password '**A**'. (**Oto** password = **Oto**)

The first time the Otoport is configured the default settings, including the Admin user account, must be deleted; you will receive a series of prompts as they are erased.

If there are any configuration options programmed on the Otoport that do not exist on the Site download list (such as users who have left NHSP and been deleted from the S4H system) then you will be informed that they have been deleted from the Otoport.

After a successful login you will be able to select the details you would like to be available on your Otoport. There are separate areas for selecting **Facilities**, **Users** and **Risks** and a section on probes registered on an Otoport. Each of these areas is described below.

16.3 Site/Facilities



The top section of this screen displays the **Site Name**, **Site ID**, **Device ID** and **GSN** that will be used with your Otoport. It is not possible to edit any of these details here but you may wish to check that they are correct or to make a note of them.

The lower section shows a list of all the **Facilities registered at chosen S4H Site** and a list of the **Current Otoport Facilities**.

Click on the box next to the facilities required on the Otoport so that a tick appears. When you are happy with your selection click on the **Add** button between the boxes. There is a maximum of 12 facilities per Otoport.

Current facilities may be removed from the Otoport by selecting the facility in the lower window and then selecting **Delete Selected Facility**.

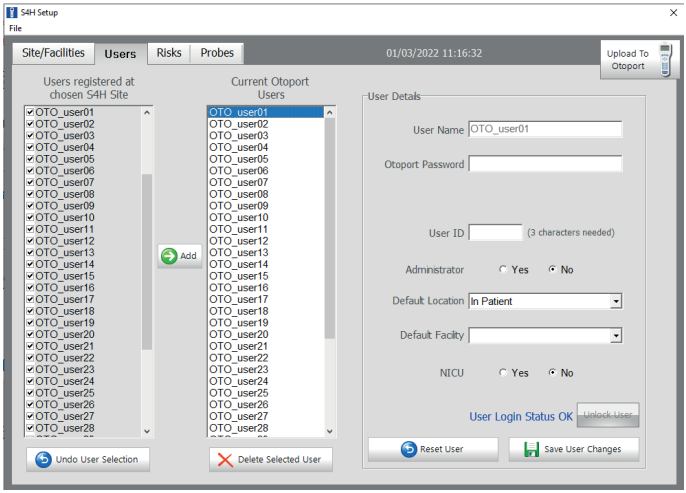
The **Details** of selected facilities are shown in a box on the right. Each facility is registered with S4H as an **Inpatient**, and / or an **Outpatient** location. The **Friendly Name** is the name which will be shown on the Otoport.

Note:

If you delete a Facility that is the default facility of an Otoport user, you will need to select a new default facility for that user before you can save configuration changes to the Otoport.

16.4

Users



Two columns display **Users registered at chosen S4H Site** (listed alphabetically by surname on the left) and **Current Otoport Users** (on the right). Select the users you wish to add to the Otoport by clicking on the box next to their name; a tick will then appear in the box. When you have selected all the users you wish to select click on the **Add** button between the columns.

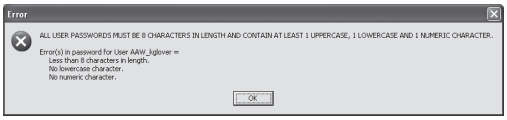
Clicking any of the **Current Otoport Users** names will display the **User Details** for that user in the box on the right of the screen.

For each of the **Current Otoport Users** you must enter an Otoport password, a User ID number, a default facility, a default location, whether this default is in NICU and select whether this user will have Administrator rights.

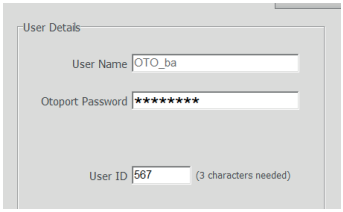
You may also **Unlock User** to reinstate access to users who have been 'Locked out' from using the Otoport. This occurs if three incorrect passwords have been entered by a user.

Notes:

Passwords must contain both upper and lower case and numeric characters and must be eight characters long. An error message will be displayed if any of these conditions are not met.



Changes in passwords must be confirmed by repeating the password in the **Confirm password** box. The confirm password box is only shown if a change is made to the Otoport password. The two passwords entered must match.

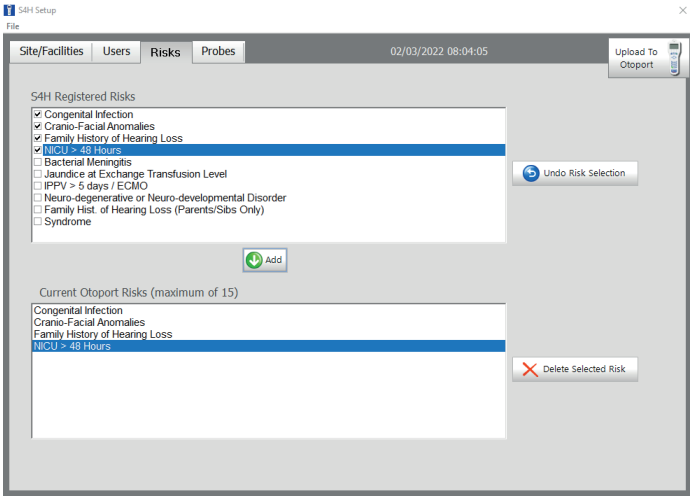


The User ID must be three characters.

The first user entered on the Otoport must have Administrator rights. In order that an Administrator who becomes locked out can have their account unlocked, **we recommend that at least two users are setup with Administrator rights**.

When a user's details have been completed select **Save User Changes**. The details for each **Current Otoport User** must be completed and saved before configuration can be saved to the Otoport. Up to 39 users may be registered on an Otoport.

16.5 Risks

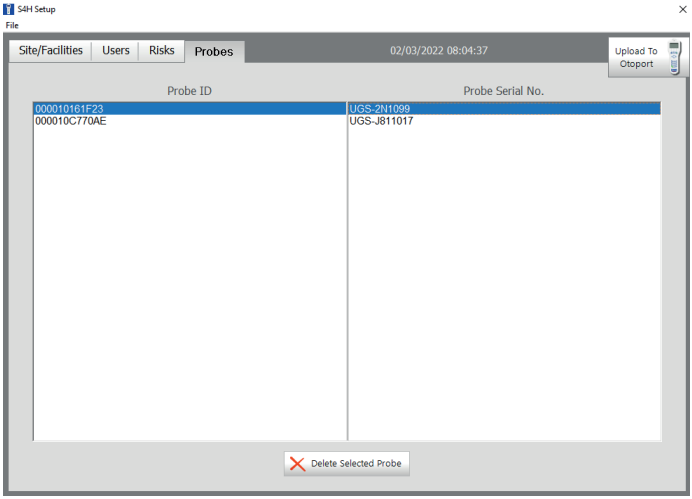


The **S4H Registered Risks** box lists all the risk factors registered on S4H for your site. Select the risks you wish to add to the Otoport by clicking on the box next to the risk; a tick will then appear in the box.

Selecting **Undo Risk Selection** will remove the ticks from all of the risks. When you have ticks next to all the new risks you require on the Otoport click on the **Add** button between the two boxes.

The **Current Otoport Risks** box lists all the risk factors that will be available on the Otoport when configuration is completed. A maximum of 15 risks can be made available on the Otoport at one time. Risks may be removed from the current list by selecting the risk and then clicking **Delete Selected Risk**.

16.6 Probes



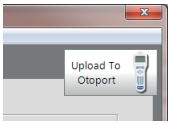
Probes stored on the Otoport will be listed. The electronic **ProbeID** is listed along with the **Probe Serial Number** that has been entered on the Otoport.

If there is an error in the probe serial number, then use the button to **Delete Selected Probe** and re-enter the correct serial number on the Otoport when starting a test.

Up to 10 probes can be stored on an Otoport.

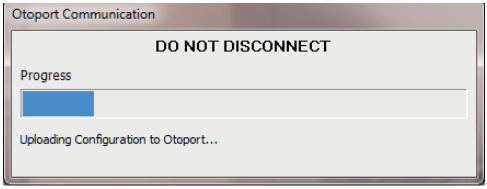
16.7

Saving configuration to Otoport



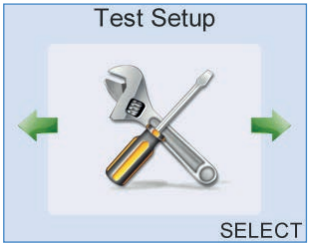
When you are happy with the changes you have made to the Otoport configuration click on the **Upload to Otoport** button in the top right corner. If there are any required fields you have failed to complete you will be prompted, otherwise the updated settings will be loaded on to the Otoport.

A window will indicate progress.

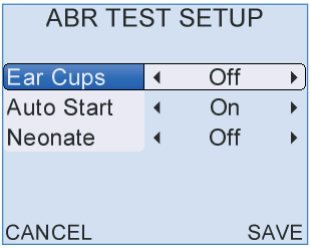


When this window closes configuration of the Otoport is complete. We suggest that the configuration be tested by performing a QA test and uploading the data to S4H.

17 Test setup



Test Setup allows users to change the setup for ABR tests. Only users with Administrator (A) rights have access to this area.



Setup for A users

The **Ear Cups** setting allows users to select whether they wish to use Ear Cups or insert the probe directly into the ear. **On** selects ear cup mode, **Off** selects direct insertion mode.

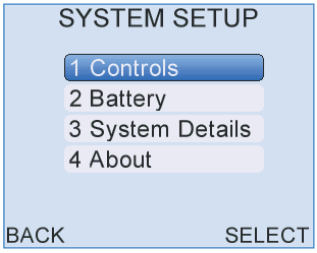
The **Auto Start** setting controls whether ABR testing will automatically start if impedance and electrical noise levels are good. With **Auto Start On** testing will begin automatically. With **Auto Start Off** testing will only begin when the user selects **Start**. Only users with Administrator rights have access to this setting.

With **Neonate** mode **On** and **Ear Cups** set to **Off** the user is warned if the response from the probe indicates a large ear canal. The warning message is displayed after Checkfit and before the test starts. Selecting **Checkfit** returns the user to Checkfit. **Cancel** returns the user to the main test screen.

Ear canal cavities greater than around 0.5cc will trigger the warning.

With **Neonate** setting **Off** (or if **Ear Cups** set to **On**), no warning message is displayed if a large ear volume is detected. Only users with Administrator rights have access to this setting.

18 System



18.1 System menu

Select **Controls** to adjust **Volume**, **Brightness** and timing of the **Backlight**.

Select **Battery** to view current battery status.

System Details displays information for Otodynamics engineers.

Select **About** for Otoport firmware revision number and issue date and device identification numbers.

Select **Back** to return to the **System** module screen.

18.2 Controls menu

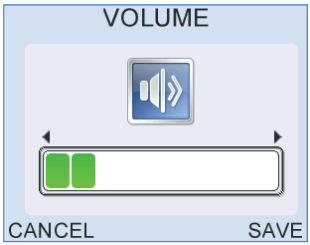
Select **Volume** to increase or decrease the unit's volume level or to turn sound off.

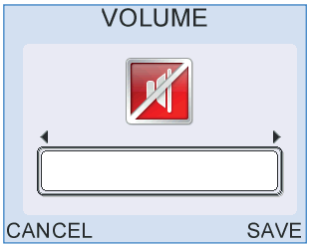
Select **Brightness** to adjust the brightness of the screen for varying light conditions.

Select **Backlight** to configure the status of the screen and keypad backlights.

Select **Back** at any time to return to the **System Menu**.

18.2.1 Volume



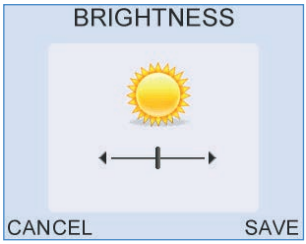


Use the left/right arrow keys to decrease or increase the **Volume** level. To turn the sound off press the left arrow key repeatedly until the red mute symbol appears in the centre of the display.

Select **Save** to accept the new **Volume** level.

Select **Cancel** to ignore changes and return to the **Controls Menu**.

18.2.2 Brightness



The screen **Brightness** can be altered by pressing the left/right arrow keys.

Select **Save** to accept the adjusted **Brightness** level.

Select **Cancel** to ignore changes and return to the **Controls Menu**.

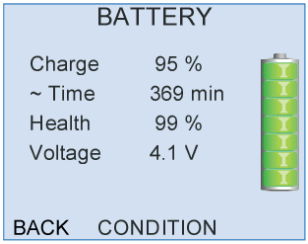
18.2.3 Backlight

Use the left/right arrow keys to toggle between the **Backlight** control choices for the screen and keypad. The backlight can be configured to be either always **on** or **off**, or **on** for a limited period of time (7, 10, 20 or 30 seconds) after a key press. Reduction in the backlight time will help to preserve battery charge during operation.

Select **Save** to accept the **Backlight** setting.

Select **Cancel** to ignore changes and return to the **Controls Menu**.

18.3 Battery



The **Battery** screen provides information on the current battery status. The total **Battery Power** remaining is displayed as a percentage and as an approximate operation time. The calculated time is only an approximate indication as the power requirements will vary depending on the mode of operation.

The remaining operation time may fluctuate during review of the **Battery** screen if the **Backlight** is set to time out after a limited period of time. When the screen **Backlight** turns off the operation time will increase as a consequence of a change in power requirement. This difference in calculated time will show the benefit to battery life of a reduced **Backlight** time.

The **Battery** graphic on the right of the screen conveys the total remaining **Battery Power**. The battery segments are shaded according to the following criteria:

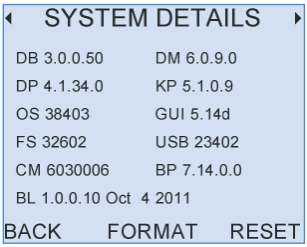
Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

The **Battery Voltage** and **Health** are provided as diagnostic tools.

The battery graphic is also displayed on the **Logo** screen to inform the user of the **Battery Power** every time the device is switched on.

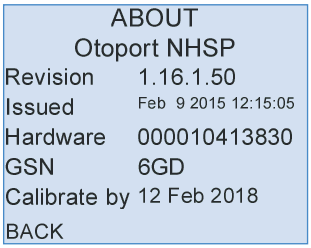
Select **Condition** to condition the Otoport battery. See chapter 13 **Otoport power** for more information.

18.4 System details



System Details displays information for Otodynamics engineers. The device performs electrical self-checks and any errors during these tests are displayed (see chapter 18).

18.5 About



The **About** screen details information relating to the Otoport's identification and mode of operation. The firmware revision number and issued date is stated, together with the unit's unique hardware ID. The next scheduled Calibration Due date is also shown. A dash is shown if no calibration date has been set.

19 Management

19.1 Management menu

Select **Users** to review the current **User List**. The **Facility & Risk** option is not available to Otoport NHSP users.

Select **Date & Time** to adjust the date and time settings.

Select **Other Options** to alter patient ID format, add a site and device identification which are then saved to **Test Records**.

Select **Back** to return to the **Management** module screen.

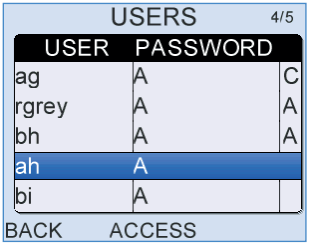
19.2 Users menu

Add New User is not available on this device. New users must be added via Otolink.

Select **View Users** to review the current **User List**.

Select **Back** to return to the **Management** menu screen.

19.2.1 View user list



The **User List** displays the **Name**, **Password** and **Status** of all users currently saved to the device.

If a user has been assigned as a User, then nothing appears in the right-hand column.

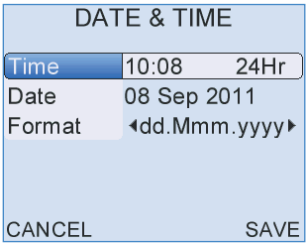
To grant or remove Cup rights from a user, use the up and down arrow keys to highlight the user in the list then select **Access**.

Select **Back** to exit the **User List** and return to the **Users Menu**.

19.3 Facility & Risk

The **Facility & Risk** menu is not available to Otoport NHSP users. Configuration is via Otolink.

19.4 Date and time



The date and time set on the device can be altered in the **Date & Time** screen. The Otoport displays the time in a 24-hour format.

When the **Date** field is highlighted press the right arrow key to access the calendar pop-up table. By default, the day will be highlighted first and can be altered using the up/down arrow keys. Continue to use the left/right arrow keys to jump between the **Day/Month/Year** and the up/down arrow keys to select the required date.

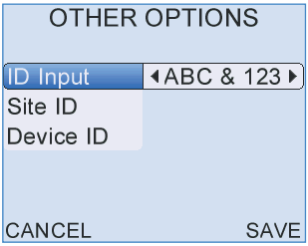
Select **Save** to set the current date and time settings and return to the **Management Menu** screen.

Select **Cancel** to discard changes made to date and time settings and return to the **Management Menu** screen.

Important Note:

Do not set the date on the Otoport to an earlier date, if there is data stored on the device.

19.5 # Other options



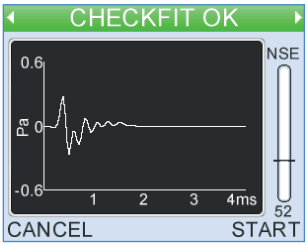
These fields cannot be changed by the user on the Otoport NHSP.

20 Test details for Local Managers

This chapter describes the OAE and ABR tests in more depth than is typically relevant to the screener. A fuller understanding of the information available on the Otoport may help to resolve issues and improve test practice.

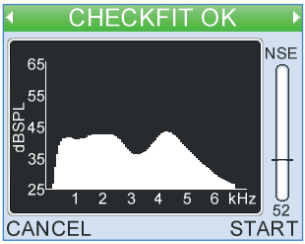
20.1 TEOAE Checkfit

20.1..1 Stimulus waveform display



Press the left/right arrow keys during **Checkfit** to access the **Stimulus Waveform** display. This shows a real time view of the stimulus waveform. With a good probe fit the waveform should have an initial large positive then negative peak followed by a flat line response.

20.1.2 Stimulus spectrum display

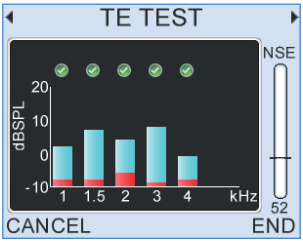


Press the left/right arrow keys during **Checkfit** to access the **Stimulus Spectrum Display**. This shows how the energy in the stimulus waveform is distributed over frequencies. This distribution is dependent on the fit of the probe and the geometry of the individual ear canal.

The stimulus spectrum should be a smooth, rounded curve. A jagged stimulus response in the low frequencies or a sharp peak in the mid-frequency range indicates a poor probe fit. Dips in the stimulus spectrum may be caused by standing waves in the ear canal. A dip indicates a drop in intensity at the probe microphone but may not necessarily indicate a dip in the stimulus intensity at the eardrum. Longer adult ear canals are more likely to show these standing wave effects.

Stimulus spectrum is very sensitive to probe fit.

20.2 TEOAE recording



Following **Checkfit,** the OAE recording begins and data is collected and displayed on a choice of four test screens - two OAE histograms and two data tables. The screens are continually updated to give a real time representation of the OAE response. The histogram is the default screen shown at the beginning of a test and the left/right arrow keys can be used to toggle between the screen choices when a test is in progress.

20.2.1 Half-octave histogram

Test data is displayed graphically on the histogram screen in ½ octave bands: 1k, 1.5k, 2k, 3k and 4 kHz. The clear section of each band represents the OAE signal level within each band and the shaded section represents the noise level at that frequency.

A tick will apear above a bar if the TE in the half-octave band has met its pass criteria. Please refer to the **Test Setup** (chapter 17) for further information on the band Stop criteria.

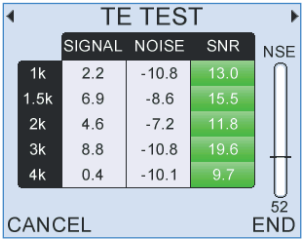
If either the OAE signal or noise level at a frequency band is greater than 20dB SPL, an up arrow will appear above the band to the right of the tick to show the level is off the graphical scale.

If no data has been collected, then a histogram will not be drawn and diamond symbols will be shown instead.

Common to all three screens is a noise level indicator to the right of the display, the title bar at the top of the screen and the **Cancel** and **End** options.

20.2.2 Data tables

During the test the two data tables are accessed by pressing the left/right arrow keys.

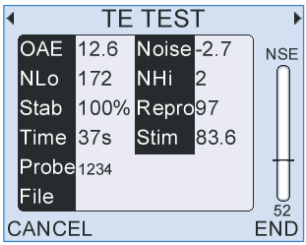


The first data table displays the dB levels at the specified half octave frequencies.

The following table describes each field:

Field	Description
Signal	The **signal** level recorded in dB SPL
Noise	The **Noise** levels recorded in dB SPL
SNR	The **Signal-to-Noise Ratio (**signal minus noise dB). If the OAE at this frequency has met the set criteria then the SNR value is shown on a green background

The second data table lists other statistics required for test analysis.

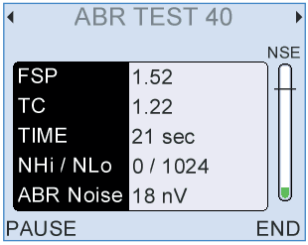


The following table describes each field in detail:

Field	Description	Units
OAE	The total OAE Signal level	dB SPL
Noise	The total Noise level	dB SPL
NLo	The amount of data accepted due to noise being below the noise reject level	n/a
NHi	The amount of data rejected due to noise being above the noise reject level	n/a
Stab	Stimulus stability shows the change in probe fit during a test; it is calculated by comparing the most recent stimulus with the stimulus recorded just before data collection began	%
Repro	The correlation of the two OAE waveforms	%
Time	Test time	seconds
Stim	The Checkfit Stimulus level	dB pe
Probe	The probe serial number	n/a
File	The unique test file name (populated on Save)	

20.3 ABR testing

20.3.1 Data summary



Fsp

The Fsp is a measure of the likelihood that a response is present (see *Eberling C., Don M. Scand Audiol 1984;13:187-197*).

TC

Template correlation (TC) is a measure of the similarity of the current waveform to a template constructed from the responses of 30 neonates aged 0 to 6 weeks.

Time

Shows the duration of the test.

NHi/NLo

NLo shows the number of sweeps accepted into the average. NHi shows the number of sweeps rejected due to high electrical noise levels.

Accepted

Shows the number of sweeps accepted into the average.

Rejected

Shows the number of sweeps rejected due to high electrical noise levels.

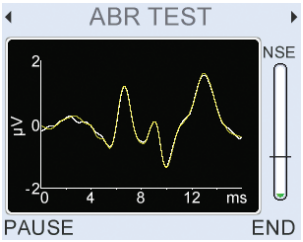
ABR Noise

Shows the estimate of residual noise in the averaged response that is used in the Fsp calculation.

If ABR noise is low (<15nV), and there is no progress in the test, the test will stop automatically with a No Valid ABR result as continuing the test would not find an ABR present.

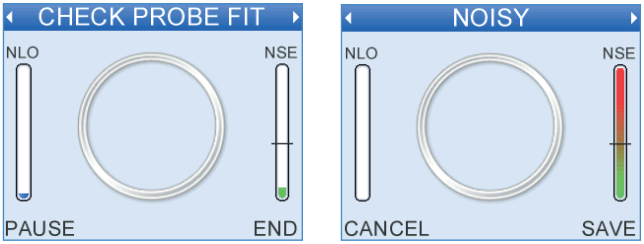
If ABR noise is too high (>85nV), a valid ABR cannot be detected, so the test will continue to run even if other pass criteria are met.

20.3.2 Waveform display



This screen shows the averaged ABR waveforms collected. Two waveforms are collected from interleaved averages so that the correlation between the two can be assessed. Close agreement between the waveforms indicates that an ABR response is present, disagreement between them is a product of noise.

20.3.3 Stimulus monitoring



At intervals during the testing the acoustic stimulus level is checked. If the stimulus level has changed the 'Check Probe Fit' message is shown. If the environment has become too noisy to test the 'Noisy' message is shown. In either case data collection is suspended until stimulus and noise levels are within range again. The Otoport will beep to warn the user if either **Check Probe Fit** or **Noisy** conditions persist.

If the 'Check probe fit' message is shown, it is most likely because the probe has fallen out of the ear. Adjust the probe fit until the message goes away; data collection will automatically restart.

20.3.4 Impedance monitoring

During the test, if progress towards ABR detection is slow, the impedance levels are automatically checked in the background.

- If impedance levels are low, the test will continue.
- If impedance levels are high, the test is paused and the 'Impedance Check' screen will be displayed.

20.3.5 Pausing the test

Select **Pause** to temporarily stop data collection. You may wish to do this if the test environment worsens (for example the subject becomes temporarily active, a sensor becomes detached or the probe falls out of the ear). If a test is paused an impedance check is automatically run and electrical noise is monitored (as in section 11.1).

Failure to measure discernible ABR data within the defined test time, and within acceptable NLO range, will return a Refer result.

Failure to measure discernible ABR data within the defined test time, and within acceptable NLO range or before ABR noise target is reached, will return a **No Valid ABR** result.

20.3.6 Test extension

If an ABR test is close to passing when it comes to the end of the normal test period then the test will be automatically extended to collect more data. When a test has been extended an 'E' will be shown on the screen.

21 Troubleshooting

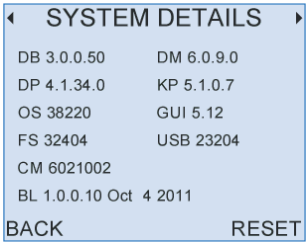
21.1 Otoport lock-up

In the unlikely event of an Otoport lock-up and it is not possible to control the device, turn the unit off and switch it on again. If this is not possible, hold down the **On/off** power key for 10 seconds; this will force the unit to switch off. Turn on the Otoport again.

21.2 Switch on

During switch on, the Otoport conducts a series of system checks. If the Otoport will not switch on and complete its start up sequence, check that it is charged and try again. If the Otoport still fails to complete its start up sequence then contact your distributor or Otodyamics for support.

21.3 System details

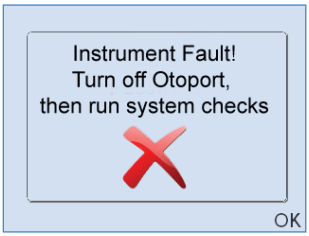


The **System** main menu area includes **System details**. This screen provides information for Otodynamics engineers relating to the Otoport hardware. If your device is not functioning correctly or you suspect a fault, go to the **System details** menu and press the left or right arrow keys until the screen tittled **Errs**: is displayed. Check the error numbers reported and when the error occurred. For support regarding a fault, report error numbers to your dealer or Otodynamics.

Select **Reset** to reset the Otoport to factory default settings. Changes from the default setting and any users or worklist patients added to the device will be lost. No test data will be removed.

21.4 Instrument fault message

In the event of an instrument fault, the following message will be displayed at the start a test.



Instrument fault, turn off Otoport then run system checks.

No stimulus will be delivered from the Otoport probe and you will not be able to start a test. Turn off the device and then switch it on again.

Important note:

The **Instrument Fault** message can be triggered by a partially connected probe. Ensure that the probe is fully connected and the knurled sleeve screwed up correctly. (See section 3.2).

Run the probe checks (see chapter 7). If the tests are 'OK' the device is functioning correctly and can be used for OAE testing again.

If you receive the **Instrument fault** message again, contact Otodynamics for support.

21.5 Hardware fault messages

The Otoport performs a series of hardware tests when it is first turned on. In the event of a fault being detected the following message will be displayed:

The error number displayed indicates the type of error detected. You should make a note of this error number. The Otoport should then be turned on and off a number of times to ensure that the error doesn't reoccur.

If you receive the hardware fault message again, contact your distributor or Otodynamics for support.

Error 2

The above message indicates that excessive noise was detected during start up. The noise may have been detected through the probe, if it was connected. Noise detected through the probe does not indicate a fault. If this message is displayed, turn the unit off, disconnect the probe and then turn it back on. If the message is consistently displayed with the probe disconnected, then contact Otodynamics.

21.6 Otolink communication problems

If Windows starts the New Hardware Wizard, or indicates that Otoport drivers are not present, then manually install the USB drivers by following the instructions in section 21.7.

Otolink installation problems can arise from a number of different areas. A good starting point is to examine the status of the USB controllers using the windows Device Manager with the Otoport plugged into the PC (accessed from My Computer>Properties>Hardware).

If the Otoport is not listed in Device Manager then Microsoft Windows has not detected the Otoport hardware. USB devices are dynamically detected each time they are connected to a PC, not just the first time of connection.

Some of the reasons that the Otoport USB will not be detected include:

Otoport is not connected to the user's PC

Connect to the PC and check to see if Windows now detects new hardware following the installation instructions in the Otoport manual.

The USB socket on the PC is faulty

Try another USB socket on the PC and check to see if Windows now detects new hardware following the installation instructions in the Otoport manual.

The USB cable being used to connect the Otoport is faulty

Try another USB cable to connect the Otoport to the PC and check to see if Windows now detects new hardware following the installation instructions in the Otoport manual.

User's PC is faulty or incorrectly set up

A good check would be to connect the Otoport to another PC (ideally a different make/brand of PC) and start the installation process from the beginning.

Fault with the Otoport USB

A good check would be to connect the Otoport to another PC (ideally a different make/brand of PC) and start the installation process from the beginning. If the device is still not detected there may be an issue with the Otoport system.

If the Otoport is listed on the Device Manager next to a yellow question mark, it means the device drivers have not been installed properly. Ensure the Otolink CD is placed in your CD-ROM drive then right click on the listed Otoport device and select Update Driver. The 'Install hardware wizard' will be initiated. Follow the instructions in section 2.3 to progress through the driver installation. Remember the Otoport drivers need to be installed twice, once for each USB communication channel.

If the Otoport is listed correctly on the Device Manager but does not function then some part of the driver or Otolink software may not have installed correctly. Try removing and then reinstalling the software drivers or Otolink software.

If your problems persist, please contact your local IT Support, your Otodynamics distributor or Otodynamics Support.

21.7 Manual driver installation

If automatic installation of USB drivers has not been successful then drivers can be installed via the new or update hardware wizards.

Connect your Otoport to the PC.

The **New Hardware** wizard should start automatically when the Otoport is connected. If it does not then the **Update Hardware** wizard can be started by navigating to **Device Manager**, right clicking on **Otodynamics Otoport-ChanA/B** and selecting **Update driver**.

This example installation is for Windows XP. Installation for other operating systems may vary.

Important Note:

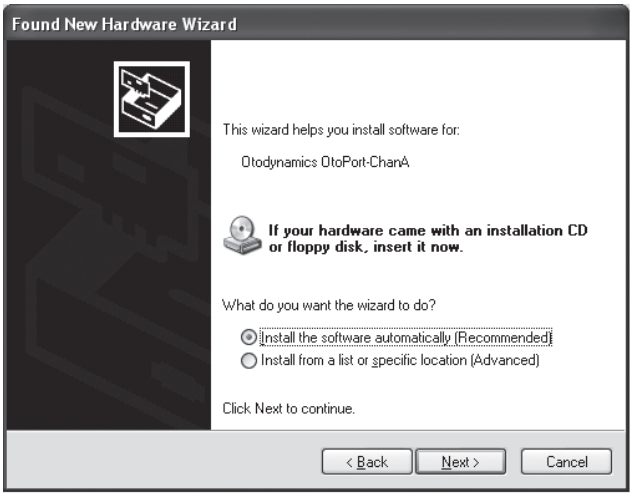
The Otoport contains an advanced USB PC communications chip, which requires driver installation on both its A and B communications channels. **The driver installation process must therefore be conducted twice, once for each channel.**

If you fail to install both channels you may see a USB driver error message. This may be remedied by simply plugging the Otoport into the PC then unplugging it and following the steps below. If this does not work then see section 21.6 **Otolink communication problems**.

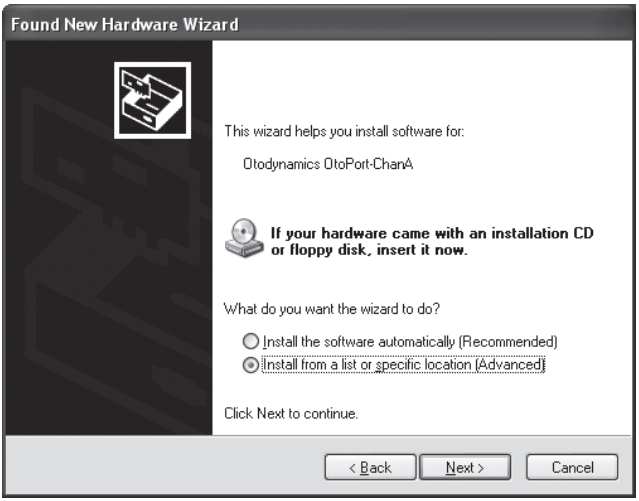
When the Otoport is connected it will be detected by your PC and a message will pop up to acknowledge the detection of new hardware.

The found new hardware wizard will automatically start.

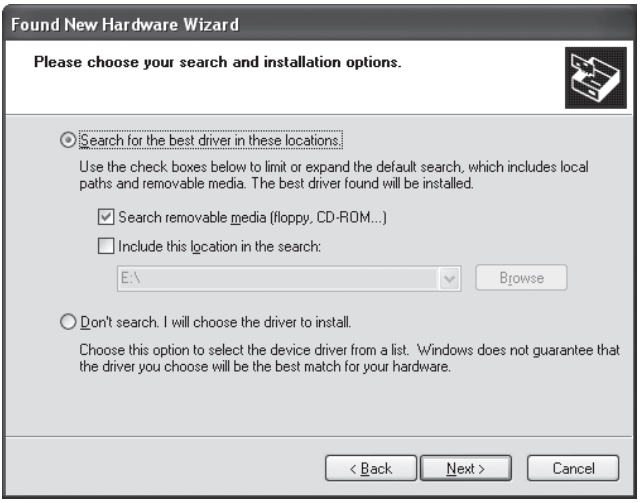
Select **No, not this time** and click **Next**.



Accept the option to **Install the software automatically**. This should find the Otodynamics Otoport drivers on the CD already in your CD-ROM drive.



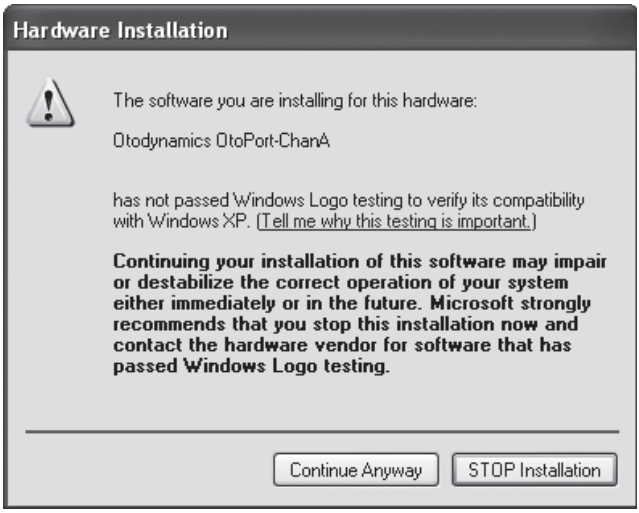
If the driver is not found during the automatic search, click **Back** and select **Install from a specific location** then **Next**.



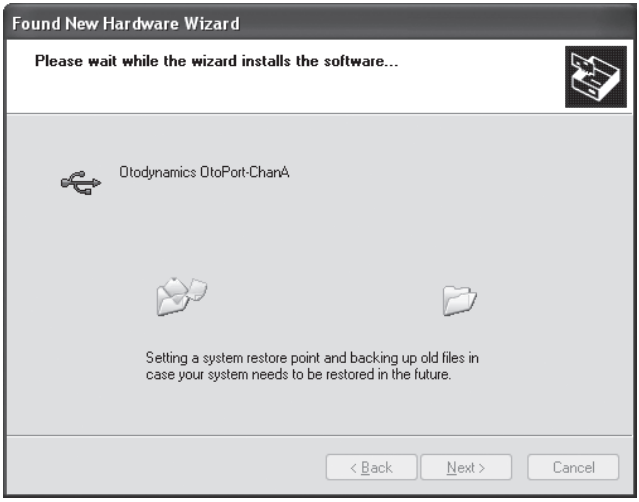
Select **Search removable media** and click **Next**.

If the CD is not available, the drivers can also be installed by selecting **Include this location in the search** and browsing to the folder **C:\Program Files\Otodynamics\Otolink\Drivers**.

Windows will search for the correct drivers.



When the drivers have been found Windows will prompt that the drivers have not passed Windows logo testing. The drivers have been certified for use by Otodynamics engineers. Select **Continue Anyway**.



Windows will then install the drivers.

Once complete click **Finish**. The driver installation for Otoport channel A is now complete.

Repeat the installation again for channel B.

Once complete, again click **Finish**. The driver installation for the Otoport is now complete and the hardware is ready to communicate with the Otolink PC software.

22 Records

22.1 Records menu

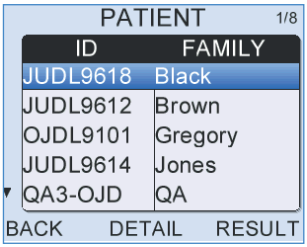
Select **Find** to search for saved patient records within the **Patient List**.

Select **Work List** to edit or add a new patient to the **Worklist.** The **Worklist** can be reviewed and a patient selected to test.

Select **Summary** for information on the current records in the database.

Press **Back** to return to the main **Menu** screens.

22.2 Patient List



The **Patient List** will display **Patient Records** that meet the search criteria or will list all the patients in the database if no search criteria were specified.

The **Patient List** displays patients alphabetically from the **Family** name field and also shows the patient **ID**. The up and down arrow indicators to the left of the **Patient List** show that there are other **Patient Records** not currently visible on screen.

Use the up/down arrow keys to scroll through the list one **Patient Record** at a time. A selected patient will be shown as highlighted in the list.

Use the left/right arrow keys to skip through the **Patient List** ± 5 records at a time.

Select **Detail** to review the complete **Patient Details** of the highlighted patient.

Select **Result** when a patient is highlighted to inspect the patient's saved **Test Records**. A summary of each test will be shown.

Select **Back** at any time to exit the **Patient List** screen and return to **Find Patient** to begin a new search.

22.2.1 Test summary

When reviewing **Results**, a summary of each of the patient's tests is given on screen. The diagrams on the next page detail all features of the **Test Summary** screens.

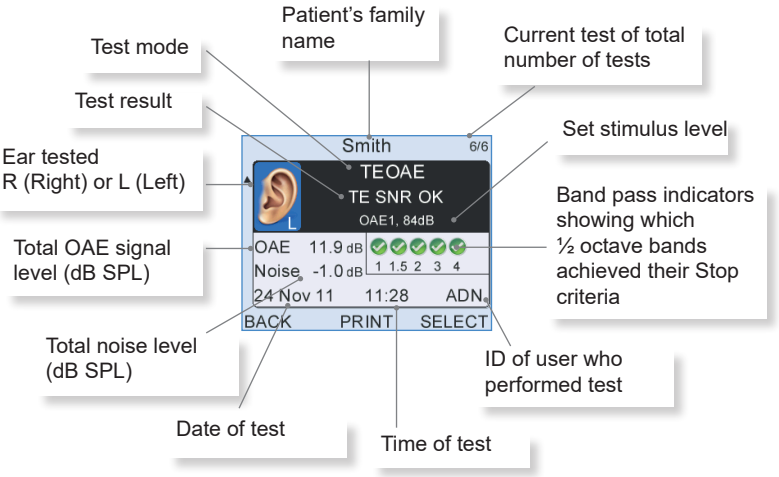
The number of tests currently saved to the patient is displayed in the top right of the screen. Press the up/down arrow keys to scroll between tests. The test number will increment accordingly.

The up and down arrow indicators to the left of the screen show that other **Test Results** are available.

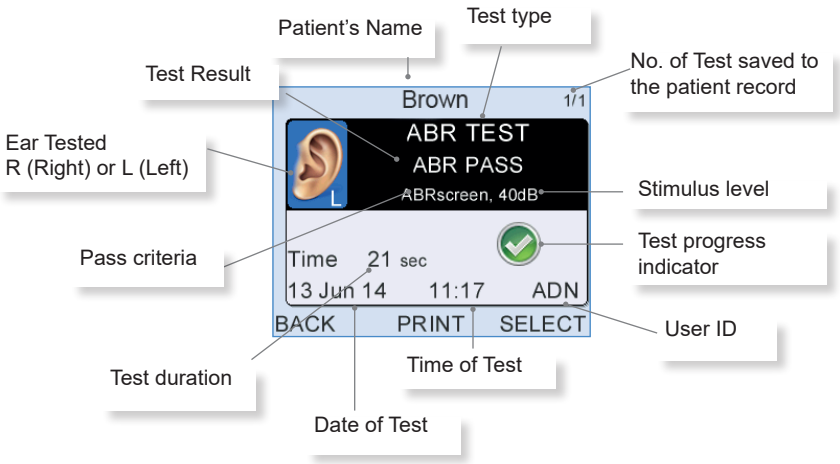
Choose **Select** on a **Test Summary** screen to analyse the test result in detail.

Select **Back** at any time to exit the **Test Summary** screens and return to the **Patient List** to review tests of another patient.

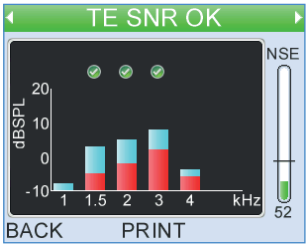
TEOAE test summary screen



ABR test summary screen



22.2.2 Detailed test review

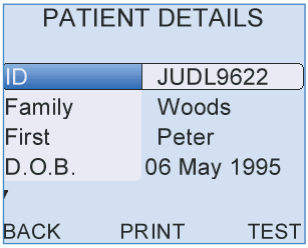


Test Results can be reviewed in detail by choosing **Select** on the **Test Summary** screen. The OAE test data is shown on various test screens. Please refer to chapters 7 and 8 for a full description of the screen displays for the relevant test type.

Use the left/right arrow keys to scroll between the screens.

Select **Back** at any time to exit and return to the **Test Summary**.

22.2.3 Review patient details in database

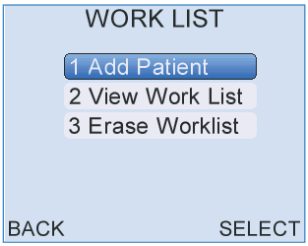


A non-editable version of highlighted **Patient Details** can be reviewed by selecting **Detail** in the **Patient List**. Please refer to chapter 6 **Patient Details** for a full description of the screen format.

Select **Test** to start the test for this patient. Please refer to chapter 7 **TEOAE Test** or 8 **DPOAE Test** for an explanation on how to setup and perform a test.

Select **Back** to exit **Patient Details** and return to the **Patient List**.

22.3 Work list



The **Work List** facility allows for **Patient Details** to be entered and saved prior to the test, to reduce data entry time during the testing session.

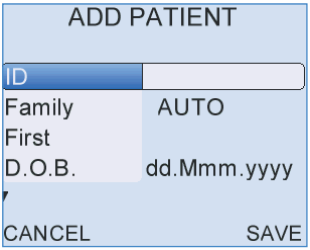
Select **Add Patient** to add a new patient to the work list.

Select **View Work List** to review, edit or test a patient on the current **Work List**.

Select **Erase Work List** to erase all the patient details currently held in the worklist. The user will be prompted to confirm the erase before the operation is completed.

Select **Back** to return the **Records Menu**.

22.3.1 Add patient

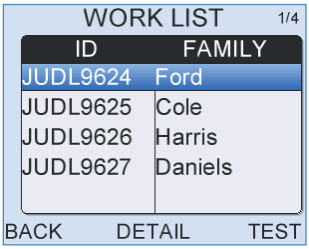


A new patient can be added to the current **Work List** by entering their **Patient Details** in the **Add Patient** screen. The screen format and data entry is identical to entering patient information when performing a test. Please refer to section 9.2 **Entering patient data** for guidance on entering data in fields and mandatory requirements before saving.

Once the correct patient details have been entered select **Save** to add the patient to the **Work List** or select **Cancel** to return to the **Work List Menu** screen and discard entered data.

A warning will appear if the patient added to the **Work List** is already present in the Otoport database. In this case, it is necessary to edit the **Work List** entry and then select **Save** again.

22.3.2 View work list



The **Work List** displays the **ID** and **Family** name of each patient to be tested. The format of the **Work List** is identical to the **Patient List**. Use the up/down arrow keys to scroll between patients and the left/right arrow keys to jump 5 patients at a time.

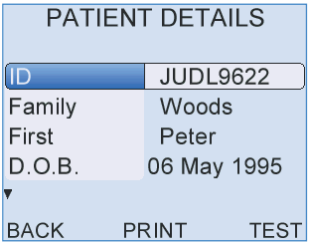
Select **Detail** to review the complete **Patient Details** of the highlighted patient.

Select **Test** to test the highlighted patient.

When a patient on the **Work List** has been tested and saved to the database the name is automatically removed from the list.

Select **Back** at any time to return to the **Work List Menu**.

22.3.3 Review patient details in work list



Selecting **Detail** on the **Work List** screen displays the selected **Patient Details** in a non-editable format.

Select **Test** to run a test on this patient. Please refer to chapter 8 **TEOAE Test** or 9 **ABR Test** for an explanation on how to setup and perform a test.

Select **Options** to view a pop-up menu giving a choice to **Edit** Patient Details or **Delete** the patient from the **Work List**.

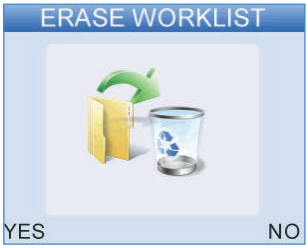
Choose **Select** when **Edit** is highlighted to show an editable version of the **Patient Details**. Please refer to section 9.2 for guidance on field entry and format. Select **Save** when changes to the **Patient Details** have been made. A pop-up message may appear if edits to mandatory fields (e.g. **ID** and **Family name**) prevent the **Patient Details** from meeting the requirements for saving a patient. The screen will return to **Edit Patient** for modifications to be made.

Choose **Select** when **Delete** is highlighted to remove the patient from the **Work List**. The message **Delete Patient?** will appear at the top of the screen. Select **Yes** to delete the **Patient Details** or **No** to cancel the deletion and return to the **Edit Patient** screen.

Select **Back** to return to the **Work List**.

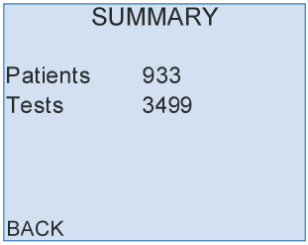
Note: All patients in the **Work List** who have not been tested should be deleted prior to any download of data.

22.3.4 Erase work list



The complete **Work List** can be deleted by selecting **Erase work list**.

22.4 Database summary



A database **Summary** can be accessed from the **Records Menu** screen. It details the present number of **Patients** and **Tests** saved to the database.

The Otoport can store up to 1024 patient records and over 5000 test results. An individual patient record can store up to 256 test results.

Select **Back** to return to the **Records Menu**.

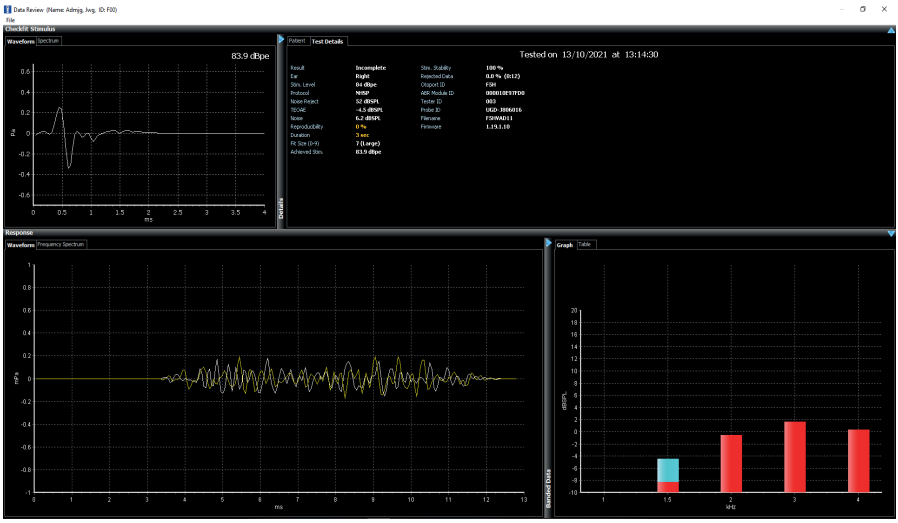
23 Downloading Waveforms from S4H

Details of each test, including the waveform, start and end times are stored in S4H with the baby record or within the QA test file. Please follow your national IT systems guidance on downloading screening data.

23.1 Veiwing downloaded screening data through Otolink

Screening data will be downloaded as a zip file. Once fully downloaded you must extract the files to a location of your choice. After the files have been extracted double click on the file of interest and the test will automatically be opened in Otolink's data viewer.

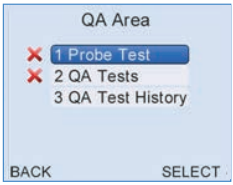
2

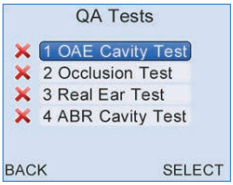


24 Notes on QA for Local Managers

ALL QA checks are mandatory on the Otoport. It should be noted that the Otoport will NOT allow access to the screening tests until all relevant QA checks have been adequately completed with the expected outcome, as per the national guidelines.

The following screens with red “X” indicate that the daily QA checks have not been completed for one or both probes. Upon successful completion of the QA checks, the “X” will be removed. The restriction will reset, and the “X” will reappear at midnight, and the QA checks will be required to be completed again.





Any failed QA test which persists following the suggested adjustments should be reported to the Site Administrator. The following provides additional information for Administrators receiving reports of failed QA tests.

24.1 Probe Test

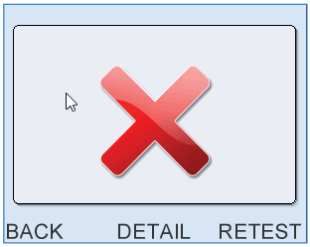
24.1.1 Query result

This result indicates that the probe is working and the levels recorded at all frequencies are within the absolute useable limits. The probe is still useable but there has been a change at one or more frequencies of more than +/- 3dB when compared with previously saved values for this probe. This can be due to a debris in the coupler. Replace the coupler if necessary, replace firmly into the test cavity and repeat the Probe Test.

If the query result persists then select **Detail** to see the numerical values (see below).

Probe performance can vary over time and the absolute limits ensure that performance is adequate to screen effectively. The query result is designed to draw attention to small changes so that the condition of the probe can be checked. As an Administrator, if you are happy with the condition of the probe, you can save the new values and return the probe to service.

24.1.2 Fail



This means one or more of the stimulus levels recorded are outside the absolute limits specified for the Probe for screening use. If a **Fail** is shown on screen you must inspect the probe coupler tubes again for debris which can cause this failure. Replace the coupler if you see any debris or damage. Re-insert the probe cavity and ensure environment is quiet. The performance of probes that fail on the absolute range are not effective for screening and must be withdrawn from service.

24.1.3 Noisy

If a **Noisy** result is repeated when the room is quiet, and the probe is well fitted to the cavity, this may indicate a fault with the probe or instrument. Remove the probe from service. Use another probe. If the replacement good probe gives the same **Noisy** result, withdraw the instrument from service.

If the replacement probe passes, then you must begin all the QA tests again with the replacement probe.

24.1.4 Probe Calibration Limits

These are the absolute limits of probes suitable for screening.

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

24.2 QA 1 Cavity Test

When QA 1 test does NOT show **CAVITY OK** it means that too much noise or artefact is present in the recording. The coupler should be checked and changed as necessary. This may correct the problem.

If **CAVITY OK** is obtained on retesting the probe it is still necessary to confirm that the probe is fit for service. A further four QA1 Cavity Tests must be undertaken and ALL should pass with **CAVITY OK**.

If any one of the additional QA1 Cavity Tests fails, the probe must be withdrawn from service and guidance sought from Otodynamics.

If all 5 additional cavity tests give CAVITY OK then the problem was clearly with the coupler or test conditions and probe and instrument can be returned to service.

If you remain concerned seek guidance from Otodynamics. They may require the Cavity Test data files.

The **Artefacts?** outcome is an indication that a fault with the equipment may increase the Clear Response rate in OAE testing. All other faults would be expected to reduce the Clear Response rate. Because of this it is most import to take equipment that has given **Artefacts?** outcomes out of service as testing using such equipment could result in the screening programme missing an ear with a hearing loss.

Note:

When a probe is returned to service after a QA alert, all QA checks will need to be repeated.

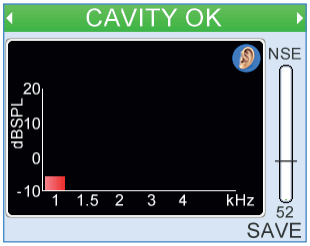
Note

When a probe is withdrawn from service, the replacement probe must pass all QA tests when connected to the Otoport in question, before that Otoport can be returned to service.

QA1 Details

At the end of the test the indications of possible response (blue) and noise (red) should be below the -5dBSPL level.

The test outcome should be **Cavity OK**. **Save** the result.



25 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 five stop reasons are:

- Clear response
- No clear response
- 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 “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 probe fit is acceptable, environmental noise levels were too high to detect the presence of an OAE 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.

Advice should be around finding ways to avoid testing in noisy conditions and improving probe 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.

Section Four Technical

26 Mode of operation

26.1 TE Test

Parameter	Description
Stimulus	**Idle** 80µs positive broadband square wave pulse with an intensity of 64dB pe (peak equivalent) in a 1cc cavity. **Adjusted** 80µs positive broadband square wave. **Test** 300µs biphasic broadband triangular pulse.
Sample rate	20kHz
Stimulus pattern	Each sweep presents 8 stimuli responses with the stimulus presentation pattern: A A A B -A -A -A -B Where: B = -3A
Noise rejection calculation	The noise level for noise reject is calculated from the difference between consecutive sweeps.
Averaging	The responses from each stimuli in a sweep are summed and averaged. Averaging this stimulus pattern removes artefacts which scale linearly leaving only the OAE signal which is non linear. These sub averages are alternately added to two separate averages. These separate averages are referred to as waveforms A and B.

Signal and noise calculation
Measures of signal and noise levels are based on the correlation and differences between waveforms A and B.

Stimulus repetition rate
One stimulus every 13ms, approximately 80 stims per second.

Response window
3-13ms or 3-9ms after start of stimulus presentation. Cosine filtered with rise and fall time of 2ms

Response frequency bands
Half octave, centred at 1, 1.4, 2, 2.8, 4 and 5.6kHz

Response frequency range
841-4757Hz

Microphone input filter
Configurable:
400-6400, 841-4757,1189-4757 or 1600-3200Hz
The attenuation at these frequencies is 3dB.
Attenuation increases by 80dB/decade below and 40dB/decade above these frequencies.

26.2

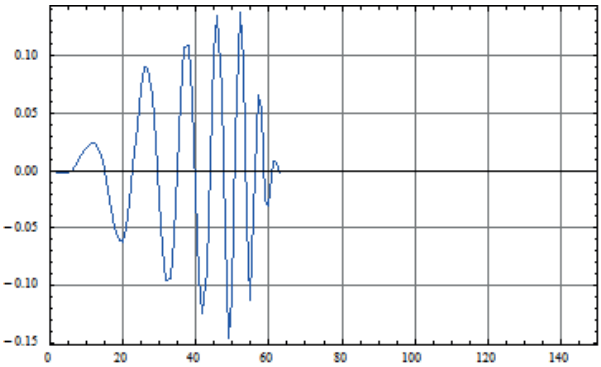
ABR test

Stimulus level	40dBHL
Stimulus rate	51.8Hz
Stimulus polarity	Alternating
Stimulus type	Chirp (see below)
Evaluation method	Fsp & Template Correlation
Sampling rate	25.6 kHz
Frame length	18.8ms
Amplifier gain	75dB
Amplifier CMRR	> 60dB at 100 Hz
Input impedance	1MΩ || 10 nF
Amplifier noise	20 nV / Hz @ 0.1-1 kHz
Input bandwidth	150-1000 Hz
Notch filter	None
IImpedance sense Waveform	For the measurment of impedance, the device delivers a 400Hz square wave giving in a worst-case (in to zero ohms) RMS current of <5uA with a <5uA DC component. The complete impedance measurement takes 2-3 seconds and consists of four bursts of 400Hz square wave. The first burst is 0-700mS long and the following three are 300-700mS long. Additionally, there are transient currents produced at device switch on and shut down. These have a peak current of less than 100uA with a duration of less than 0.5 secs.
Impedance test range	0 to 99 kΩ
Display	EEG-level, ABR detection probability

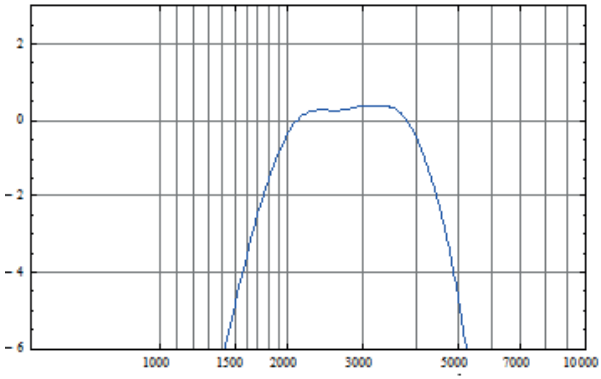
Electrodes	Disposable wet gel electrodes (FDA 510(k) cleared)
Electrode Montage	
Positive electrode	Forehead
Negative electrode	Nape of neck
Common electrode	Back of shoulder

26.2.1

Stimuli description



Chirp stimuli: 2.5ms duration of alternating polarity. The frequency



dispersion of the chirp is defined by the delay at frequency $T(f)= k * f^{-d}$ with k=0.0920, and d=0.4356.

The wide band chirp waveform was cosine filtered in the time domain to give the required duration and a frequency range of 1686 to 4614Hz (-3dB points). The waveform and spectra of the short chirp are illustrated below.

Short Chirp time domain (x-axis in samples at 25.6kHz):

Short Chirp frequency domain:

26.2.2 Hearing level determination

The hearing threshold for these stimuli was determined in a group of 20 subjects with normal hearing aged <25. The stimuli were measured in a Brüel & Kjær Ear Simulator Type 4157. The differences between the dBppSPL recorded in the B&K stimulator and the dBHL set on the Otoport (with ear cup mode off) were noted:

	Click dB	**Chirp dB**
Otoport HL to ppeSPL conversion	34.2	29.8

26.2.3 Sensitivity

The sensitivity of a hearing screening test relates to the ability of the device to detect ears with hearing loss (the true positive rate). Sensitivity is measured as the probability of a 'No Clear Response' result being correctly reported by the device when no ABR is actually present. Departure from the desired 100% sensitivity figure indicates false passes caused by the device misinterpreting electrical noise (biological and/or environmental) as an ABR. The sensitivity of a device must therefore be measured with the device operating in its screening test mode and exposed to all the differing levels of EEG noise and power line interference in which the device can be used, but without any ABR actually being present.

It is important to note that the measured sensitivity of an instrument relates to the outcome of tests where there is no ABR present. When there is a hearing loss we can assume that no ABR is present only if the stimulus level is below the elevated threshold. The demonstrated instrument sensitivity therefore only applies to the detection of hearing losses greater than the hearing level of the applied stimulus. It is the applied stimulus level that determines the range of hearing losses that will be detectable and to which the sensitivity figure applies. For example if only a small hearing loss is present such that the hearing threshold is still lower than the hearing level of the applied stimulus, then a true ABR will be present. The instrument may correctly detect that response and not detect the hearing loss.

Otoport ABR Sensitivity was established from the outcome of 'no stimulus' trials on well baby ears. This was organised and conducted by an independent audiological scientist. In this study NO false negatives (false passes) were reported in 127 no-stimulus tests newborn baby ears. This high sensitivity (better than 99.2%) exceeds the essential requirements of the NHSP, which is that no more than three false responses should occur in 120 tests (or 97.5% sensitivity).

The high sensitivity of the Otoport ABR was further quantified by our own laboratory tests. These tests used pre-recorded EEG noise from newborns recorded in a real in a screening environment. This pre-recorded noise signal was replayed into the Otoport ABR electrode inputs and 2122 complete tests were performed with the instrument. No valid ABR actually existed in this signal. The study established a false pass probability rate of 0.06%, which is equivalent to a sensitivity of 99.94%.

26.2.4 Specificity

ABR Specificity

The specificity of an ABR hearing screening instrument quantifies the ability of the device to identify ears with normal hearing (the true negative rate). When there is no hearing loss, we can assume that an ABR is present. 'Specificity' is the probability of a 'Valid ABR', (a pass), result when an ABR is truly present. In practice patient and environmental can obscure a true ABR response. This means that in practice ABR screening test specificity is variable and dependent on both the size of the individuals ABR at the electrodes and the levels of noise occurring during the test. Both vary according to the individual, electrode connection, position, resting state of the infant and the environment.

Otoport ABR Specificity

The specificity of the Otoport ABR screener was established by analysing the results of real screening tests conducted with the Otoport ABR instrument on 1004 well babies with no suspected hearing loss, according to the results of a prior independent hearing screening test performed on them. Data was collected from 13 facilities with differing screening environments in the UK and overseas*. Each test site used the Otodynamics' ABR short chirp delivered to the ear canal at either 35dBHL or 40dBHL, chosen according to the regular protocol in operation at the site. Otoport ABR's specificity under these realistic screening conditions was 95%.

The data was collected by users new to the instrument. Only a single test attempt was allowed if the result was either Clear Response or No Valid ABR. A retest was allowed only if there was a problem with the test conditions as called out by the Otoport e.g., 'incomplete test' or too much noise' . With more experience with the equipment, it is likely that a specificity higher than 95% can be achieved.

The inherent or 'potential' specificity of the Otoport ABR in perfect conditions as established by statistical analysis of the detection algorithm, and the normal distribution (spread) of ABR amplitudes from an historical study of 3200 well baby ABRs**, 270 ABR wll baby recordings on the Otoport ABR and the average EEG noise level present in quiet infants in ideal test conditions. Our finding was that in perfect conditions ABR responses in newborns with normal hearing would be detectable in 99.4% of cases.

This inherent specificity is eroded in routine usage by noise, movement of the baby and by sub-optimum screening skills.

All the data above relates to the specificity of individual tests, and not to the specificity of the whole screening protocol.

* Report on the performance of Otoport ABR. Otodynamics Ltd, 2016

**Norton, SJ, Gorga M P, Widen, JE, Folsom, RC, Sininger, YS, Cone-Wesson, B, Vohr, BR and Fletcher, KA. Identification of Neonatal Hearing Impairment: Summary and Recommendations, Ear & Hearing, 21:5, pp 529-535, 2000

27 Response detection

27.1 OAEs

OAE response detection is based on the Signal to Noise ratio (SNR) at each test frequency (for DPOAE tests) or across a specific frequency range (for TEOAE tests). Dependent upon the statistical nature of the noise, even with the probe in a cavity, there is a finite probability that data at the measurement frequency appears above the noise and will be considered as a 'signal' (i.e. a positive SNR). For both test types the larger the SNR the greater the confidence that the signal detected is not a noise artefact.

The number of required frequencies for a screening pass influences the SNR required for a given level of confidence. Once the level of confidence and number of frequencies is decided the necessary SNR can be computed.

By running many repeat cavity tests the occurrence rates of different SNR levels in these tests were used to generate the confidence levels shown in the tables reported below. These confidence levels can then be used to determine positive predictive value and the negative predictive value (NPV or false pass rate) which gives an essential measure of the chances of missing an ear with a significant hearing impairment.

27.2 Confidence levels in TEOAE tests

In the case of TEOAE measurements, data points are aggregated in to frequency bands. Normally this banding is performed as some proportion of octaves. Because of this logarithmic banding of data there is a frequency variance in the SNR required for any given level of confidence. This leads to a more complex table for the SNR required for a single band. Furthermore, this additional complexity is factored into the multiband tables found in section 27.1.2 below.

27.2.1 Confidence for a single ½ octave band

	Minimum SNR required for confidence level in a single band					Average of all bands
Confidence	**1kHz**	**1.5kHz**	**2kHz**	**3kHz**	**4kHz**	
99%	7dB	5dB	4dB	4dB	2dB	5dB
99.9%	11dB	8dB	6dB	6dB	4dB	8dB
99.99%	14dB	9dB	7dB	8dB	7dB	11dB

27.2.2 Confidence for multiple ½ octave bands

Most TEOAE test criteria test across all five ½ octave bands, between 1-4kHz:

	Minimum SNR required for confidence level			
Confidence	**2 of 5 bands**	**3 of 5 bands**	**4 of 5 bands**	**5 of 5 bands**
99%	2dB	0dB	0dB	0dB
99.9%	4dB	2dB	0dB	0dB
99.99%	8dB	4dB	2dB	0dB

However, in some screening protocols the 1kHz band is not used (for example in the UK newborn hearing screening programme). The table below shows the data for this situation where only 4 bands are analysed.

	Minmum SNR required for confidence level		
Confidence	**2 of 4 bands**	**3 of 4 bands**	**4 of 4 bands**
99%	2dB	0dB	0dB
99.9%	3dB	1dB	0dB
99.99%	5dB	3dB	1dB

27.2.3 Confidence for single band pass mode

A separate screening mode can be selected on the Otoport where the pass criteria is judged by the signal and noise across all frequencies. The default settings for this mode use a input filter of 1600-3200Hz and a shorter response window (4-10ms). The SNR required for various confidence levels with these results are:

Confidence	**Minimum SNR required for confidence level**
99%	2dB
99.9%	6dB
99.99%	8dB

Note:

All of the above data were derived empirically from laboratory studies using Otodynamics equipment in the presence of noise recorded from real clinics.

27.3 Conclusions

27.3.1 How to use this data in relation to OAE screening?

The test confidence percentage is a statistical indicator of how likely the test will correctly identify an ear with no OAE in response to the selected type and level of stimulus. Typically the population under test has a low prevalence of ears with no OAE. Therefore when considering the effect of a given pass protocol on the test outcome, it is more useful to examine the false pass rate or negative predictive value, as this indicates the likelihood of a subject with no OAE erroneously being identified as having a normal OAE.

27.3.2 False pass rate (or Negative Predictive Value NPV)

The false pass rate for a test depends on both the confidence in the results of an individual test and the incidence of the disorder tested for. The incidence of permanent hearing loss (>40 dB HL) has been estimated:

Neonate:	1-6/1000 (0.1-0.6%)*
At aged 3:	1.07%
Aged 9-6:	2.05%**

** www.asha.org/public/hearing/Prevalence-and-Incidence-of-Hearing-Loss-in-Children/*

*** Fortnum et al BMJ 2001;323:536*

The incidence rate of OAEs being falsely detected for those tested in a population with the stated prevalence rates (assuming all ears with significant hearing loss have absent OAEs) is estimated below:

	Incidence of permanent hearing loss		
Confidence	**0.1%**	**1%**	**2%**
99%	1 in100,000	1 in 10,000	1 in 5,000
99.9%	1 in 1,000,000	1 in 100,000	1 in 50,000
99.99%	1 in 10,000,000	1 in 1,000,000	1 in 500,000

For example, with a birth rate 600,000 per annum, screening with TEOAE in a well-baby neonate population (assume 0.3% incidence), a screening protocol of 2 bands from 4 with a minimum 5dB SNR stipulation we could predict that the screening process would 'miss' one baby with a detectable hearing impairment every 5 years. It is safe to assume that this is below the rate at which human error factors would interfere with the screening efficacy.

28 Technical specifications

28.1 General

Note:

The Otoport has no user serviceable parts. Any required servicing must be conducted by Otodynamics Ltd or authorised service facilities only

28.1.1 Physical

Hand-held device:	197mm x 70mm(max) x 30mm Weight 0.55lbs (250g) (max)
Charger:	90mm x 38mm x 28mm – Weight 120g

28.1.2 Interfaces

Probe connector compatible with Otodynamics UGx probes (8 pin)
Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1or 2.0) via Data Cable
Bluetooth® wireless print (option)

28.1.3 Indicators

Data Display:	Resolution: QVGA (320 x 240 pixels), 166 dpi Technology: Colour LCD, 16 bit (displaying 65K colours) Viewable Area: 46.5mm x 36.5mm
Backlight:	White - intelligent control
Probe fit: Noise OK:	Blue LED (‘N’)
	Stimulus OK: Blue LED (‘S’)
Power/Charge:	Power OK: Green LED
	Fast charge: Amber LED
Audible:	Wide range speaker provides audio feedback of status

28.1.4 Keypad

19 key alphanumeric with cursor control and soft keys

28.1.5 Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

28.1.6 Power

Li-Polymer Battery
Intelligent multi-level power control for charging/testing/idle/sleep/shutdown:
After 1.5 minutes unit will enter sleep mode
After 20 minutes in sleep mode unit will shut down

Sleep time:	20 hours minimum (with fully charged battery)
Running time:	6 hours minimum (continuous data collection)
Battery voltage operating range:	3-4.2V
Max consumption when testing:	1W (Otoport) or 1.3W (Otoport ABR)
Max consumption when charging:	2.5W
Source:	1000mAh lithium polymer internal rechargeable cells
Charge time:	3 hours to 90% capacity Approximately 4 hours to 100%

28.1.7 Hardware Options

Bluetooth® wireless printing

28.1.8 Hardware processing and storage

Embedded microcontroller plus dedicated hardware DSP engine
4GB of non-volatile memory for storing programs, configuration, patient details and test results

28.1.9 Analogue performance

Output channels:	2 x 16bit resolution
Input channels:	1 x 16bit resolution
Sample rate:	Variable
Frequency response:	Electrical – 160Hz to 12KHz

28.1.10 Accuracy

The Otoport measures the sound delivered to the ear as a stimulus and automatically adjusts its level to be equal to the nominal value set. This 'in-the-ear' calibration process compensates for different ear canal sizes. It is most effective below 3kHz. Above this frequency sound levels may depart slightly from nominal due to individual ear acoustics. The device complies with the relevant standard (60645-6:2010 - 5.3.3) which requires that in a standard ear simulator/coupler any inaccuracy in stimulation level must not exceed ± 3dB for frequencies up to 4kHz or ± 5dB for frequencies above 4kHz.

Our OAE probe contains a microphone which is used to both calibrate the stimulus sound level and detect the otoacoustic emission. This ensures that the same accuracy applies to both applied stimulus and the recorded OAE sound levels. All our probes are factory tested and calibrated to be within these limits.

28.1.11

Environmental

Protect from heat and radioactive sources

Keep dry

If the environment changes rapidly in temperature, humidity/pressure environments do not use the device for six hours following the change.

Transport and storage:

Temperature range: 0 to 40 Celsius

Pressure: 23KPa to 120KPa

Humidity: 10% to 90% non-condensing

Protect Otoport Product from heat and radioactive sources
Keep Otoport Product dry

Operation:

Indoor use
Temperature range: 5 to 40 Celsius
Normal atmospherics pressure conditions with extremes in the range of 80-120kPa *

Relative Humidity: Noncondensing: 10% to 90%

Warm-up time: <10s when unit is stored within stated temperature range

*Otodynamics instruments and probes are calibrated at an ambient pressure of 101kPa (standard atmospheric pressure at sea level). Lowering the ambient pressure significantly (e.g. when operating at altitude) alters the acoustic response of the probe. For instance, at an ambient pressure of 80 kPa (standard atmospheric pressure at 2000m) changes of up to 2 dB can be observed in the response of the probe around 2KHz. This could cause the probe to fail standard calibration tests.

The Otoport Medical Device is not intended to operate in oxygen rich environments and is not to be used in conjunction with flammable agent.

28.1.12 Classifications and standards

Device Classification:

Class IIa under rules 5 and 10 of Medical Device Directive [93/42/EEC] & [MEDDEV 2. 4/1 Rev. 9].

The Otoport and Otoport+ABR products are declared to be in compliance with the council directives 93/42/EEC Annex II (excluding Section 4), 93/68/EEC, 2001/104/EC and 2007/47/EC and new Regulation (EU) 2017/745 of 5 April 2017 on medical devices at the product level (taking account of the intended purpose of the devices concerned).

In addition, the Otoport and Otoport+ABR meet the requirements of the Registration, Evaluation, Authorisation and Restriction of Chemicals - REACH Regulation (EC) No 440/2008 and (EC) No 1907/2006; of the Waste Electrical & Electronic Equipment - WEEE Directive 2012/19/EU; and of the Restriction of Hazardous Substances - RoHS Directive 2011/65/EU and Packaging / Packaging Waste Directive 94/62/EC.

Declared Conformity:

Otoport and Otoport+ABR products do not contain any of the restricted substances in concentrations and applications not permitted by the RoHS Directive (maximum concentration values tolerated by weight in homogeneous materials):

- Cadmium (Cd- 0.01 %); Lead (Pb – 0.1 %); Hexavalent Chromium (Cr6+- 0.1 %); Mercury (Hg- 0.1 %);

  PBB's (Polybrominated biphenyls) (PBB- 0.1 %); PBDE's (Polybrominated diphenyl ethers) (PBDE 0.1 %);

- Adaptation of RoHS Directive issued (2015/863/EU) for the four additional phthalate substances:

  Bis (2-ethylhexyl) phthalate (DEHP – 0.1%); Butyl benzyl phthalate (BBP – 0.1%); Dibutyl phthalate (DBP – 0.1%);

  Diisobutyl phthalate (DIBP – 0.1%). Otodynamics Otoport and Otoport+ABR products do not contain phthalates.

- No Ozone Depleting Substances are used by Otodynamics / its Products.

- None of the following are used by Otodynamics in its Products: Polychlorinated Biphenyls (PCBs); Chlorinated Paraffins; brominated flame retardants, asbestos, chlorofluorocarbons (CFC's), hydrochlorofluorocarbons (HCFC's), hydrofluorocarbons (HFC's), Tributyl Tin (TBT); Triphenyl Tin (TPT) and Tributyl Tin Oxide (TBTO).
- Otodynamics products do not contain Latex and do not contain Materials Derived from Animal Sources.
- Materials used in the manufacturing processes for the Otodynamics products are not Substances of Very High Concern (SVHC) and are in line with REACH regulations.
- Otoport and Otoport+ABR packaging is recyclable.
- The Otoport and Otoport+ABR medical device / system is not supplied sterile or intended to be sterilized by the user. It is recommended that probe tips, electrodes and ear cups are for SINGLE PATIENT use only.

Otoport and Otoport+ABR Declared Conformance relating to the following above and other standards:

RoHS / Other: EN 50581:2012; EN 50419:2006; EN 60601-1-9:2008+A1:2013; EN ISO 14001:2015; ISO 14040: 2006; EN ISO 10993-1:2009/AC:2010.

QMS: EN ISO 13485:2016 & EN ISO 14971: 2012.

Safety: EN 60601-1:2006+ A12:2014; EN 60601-1-6:2010+ A1:2015; EN 62366-1:2015; EN 60601-2-40:1998 (IEC 60601-2-40:2016); EN 62304: 2006+ A1:2015. IEC 60601-1:2005+A1:2012, CAN/CSA-C22.2 No. 60601-1:14, ANSI/AAMI ES60601-1: 2005(R) 2012, UL 60601-1 and KS C IEC 60601-1.

EMC: EN 60601-1-2:2015; IEC 60601-1-2:2014, ed. 4.0; ETSI EN 301 489-17 V3.2.0; ETSI EN 301 489-1 V2.2.0

Other: EN 60645-3:2007; EN 60645-6:2010; EN 60645-7:2010; EN 50419:2006; EN ISO/IEC 17050-1:2010; EN 1041:2008+ A1:2013; EN ISO 15223-1:2016; EN ISO 14155:2011; ISO/IEC 27001:2013; EN ISO 27799:2016; ISO/IEC 27032:2012.

Note: The Otoport and Otoport+ABR products' Declaration of Conformity (DoC) can be provided on request.

28.2 Electromagnetic compatibility - User Guidance

The Otoport has been tested and certified to the medical electromagnetic compatibility standard EN 60601-1-2:2015. This standard limits both: the electromagnetic emissions generated by the Otoport; and the susceptibility of the Otoport to electromagnetic disturbances at the levels found in its intended environment.

In order that the instrument operates safely it should be put into service according to the Electromagnetic Compatibility (EMC) information provided here.

28.2.1 Suitable environments for operation

The Otoport is designed for use in a professional healthcare facility only. It must not be used near high frequency (HF) surgical equipment or in the Radio Frequency (RF) shielded room of medical equipment systems for magnetic resonance imaging.

28.2.2 Essential performance

Electromagnetic (EM) immunity of this Otoport was tested by exposing it to the EM disturbances detailed in the medical EMC standard EN 60601-1-2:2015. These EM disturbances are the maximum level normally expected in the Otoport's specified operating environment. During these tests the Otoport was shown to:

(i) not indicate a 'PASS' result when a stimulus is applied but there is no physiological response to the stimulus;

(ii) remain electrically safe;

In higher levels of EM disturbance than tested for, or for different types of EM disturbance, the user can expect so see increasingly large proportions of measurement data rejected. However, for reasonably foreseeable levels of EM disturbance it is improbable that electrical safety is compromised or that damaging levels of sound are generated. In these circumstances the increased rejection rate, and the operation of the detection algorithms, will ensure probability of falsely detecting a false OAE or ABR will not increase. However, at very high levels it will become impossible to record any data. If this occurs, you are advised to reduce or move away from the source of the EM disturbance.

Warning

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating normally.

28.2.3 Cables that may affect electromagnetic compatibility

To ensure electromagnetic compatibility this equipment should only be used with the following cables:

(i) UGD or UGS probe, as supplied by Otodynamics;

(ii) charger and mains lead, as supplied Otodynamics;

(iii) PC download cable, as supplied by Otodynamics;

(iv) electrode cables, as supplied by Otodynamics or equivalent. Maximum length 2m.

Warning

Use of accessories, transducers and cables other than those specified or provided by Otodynamics could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Otoport including cables specified by the manufacturer. Otherwise, degradation of the performance of this instrument could result.

28.3 Electromagnetic compatibility - Technical Description

28.3.1 Compliance levels

The Otoport has been tested and certified to the medical electromagnetic compatibility standard EN 60601-1-2:2015. Compliance levels are as below:

(i) Electromagnetic emissions - complies with:

CISPR 11:2015
EC 61000-2:2014
IEC 61000-3:2013

The instrument is group 1, class B for the purposes of CISPR 11. Radio emissions limits are as given in tables 4 and 7 of CISPR 11:2015.

(ii) Electromagnetic immunity - complies with:

IEC 61000-4-2:2008
IEC 61000-4-3:2013 + amendment 1:2007 + amendment 2:2010
IEC 61000-4-4:2012
IEC 61000-4-5:2014
IEC 61000-4-6:2013
IEC 61000-4-8:2009
IEC 61000-4-11:2004 + amendment 1:2017

All immunity test levels as in tables 4 to 9 of IEC 60601-1-2:2014 for medical EMC testing. The 'professional healthcare facility environment' immunity levels apply.

28.3.2 Deviations from the standard

The Otoport shows no deviations from the EN 60601-1-2:2015 EMC standard.

28.3.3 Maintaining essential performance for the expected service life

No special measures need to be taken to maintain basic safety and essential performance with regard to electromagnetic disturbances for the device's expected service life.

28.3.4 Details of radio receivers

The instrument contains the following intentional RF receivers:

(i) **Bluetooth® receiver**. Operates in frequency range of 2.4000-2.4835GHz with a bandwidth of 1MHz hopping pseudo-randomly in the frequency range.

(ii) **RFID**. Operates at 13.56MHz. ETSI EN 300-330-1 defines a transmit mask that is -65dB down at ±0.9Mhz from the carrier. Therefore the -65dB bandwidth is 1.8Mhz.

28.3.5 Details of radio transmitters

The instrument contains the following RF transmitters:

(i) **Bluetooth®**. Operates in frequency range of 2.4000-2.4835GHz with a bandwidth of 1MHz hopping pseudo-randomly in the frequency range. The maximum radiated power is 20dBm. The modulation is Gaussian frequency shift keying or phase shift keying.

(ii) **RFID**. Operates at 13.56MHz. ETSI EN 300-330-1 defines a transmit mask that is -65dB down at ±0.9Mhz from the carrier. Therefore the -65dB bandwidth is 1.8Mhz. The effective radiated power is not meaningful as this is a near field device. The maximum magnetic field generated is 60dB re uA/m. The modulation is amplitude shift keying.

28.3.6 Specific Absorption Rate SAR

The SAR is a measure of the rate at which radio frequency (RF) energy is absorbed by the human body.

28.3.7 RF Exposure

The Otoport / Bluetooth® technology complies with CE/FCC/IC RF exposure limits for general population / uncontrolled exposure. The Bluetooth® module “WT11i” or “WT11u” in Otoport and Otoport+ABR devices comply with SAR regulatory requirements. Otoport and Otoport+ABR can be used as hand-held devices with the WT11i or WT11u Bluetooth® module with the current antenna position of 8mm from the edge of the Otoport case and firmware setting output power level to 13dBm. Measurements confirm that the Otoport and Otoport+ABR maximum RF Energy output is below the limits set forth for CE, FCC and IC compliance.

28.3.8 Regional Standards

Europe

Radio Equipment Directive (2014/53/EU)
CE marking certification
Silicon Labs Declaration of Conformity - DoC for WT11i and WT11u.

Otodynamics Otoport and Otoport+ABR 3rd Body Test House Validation Safety & EMC measurements.

The WT11u is Bluetooth® qualified and the declaration ID is B016141 (QDID 22298).

SIG Listing
The Bluetooth® - SIG, Declaration ID: D034915.

US

Federal Communication Commission (FCC)
This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions. (1) This device may not cause harmful interference. (2) This device must accept any interference received, including interference that may cause undesired operation.

FCC ID for WT11i Bluetooth® - module currently used for Otoport / Otocheck USA: QOQWT11

FCC ID for WT11u Bluetooth® module alternative/future use for Otoport / Otocheck USA: QOQWT11U.

Canada

Industry Canada (IC)
This radio transmitter (IC: 5123A-WT11U) has been approved by Industry Canada to operate with the embedded chip antenna. Other antenna types are strictly prohibited for use with this device. This device complies with Industry Canada's license-exempt RSS standards. Operation is subject to the following two conditions. (1) This device may not cause interference. (2) This device must accept any interference, including interference that may cause undesired operation of the device.

Japan

MIC Japan
The WT11u module in certified for Japan. Certification number: 209-J00232 Since September 1, 2014.

28.4

EN60645-3 conformance notes

These notes are provided in compliance with EN60645-3 “Electroacoustics audiometric equipment - Part 3: test signals of short duration.”

(a) Types of short duration stimuli:

The Otoport TEOAE test uses short duration stimuli. During test setup a ‘rectangular stimulus’ is used. During data collection a ‘bipolar stimulus’ is used. The rectangular is a unipolar pulse of 78uS length. The bipolar stimulus is 1 cycle of a triangle waveform of 240uS period. Both stimuli are low pass filtered by a 10kHz anti-alias filter, which ‘rounds’ any ‘sharp edges’.

(b) Transducers and headband force:

The stimulus is delivered to the patient’s ear using a UGS or UGD Otodynamics probe. The probe tip holds the probe in the ear canal, with no headband or other retaining device required.

(c) Sound field system:

The sound field is generated by the probe sealed in the ear canal by its tip.

(d & e) Calibration cavity and measurement type:

For the purposes of EN60645-3 calibration was performed in an occluded ear canal simulator conforming to IEC 60711 (Bruel and Kjear type 4157). The probe was mounted in a DB2012 adaptor using an Otodynamics probe tip. The sound ports of the probe were aligned with the 4157 reference plane. A UGD probe was used for the calibration. Sound levels from the 4157 ear simulator were measured in dB SPL peak-to-peak equivalent, as defined in EN60645-3.

(f) Signal levels:

The following conversion factors convert between the stimulus level reported on the Otoport screen and the signal level in the IEC 60711 occluded ear simulator:

rectangular stimulus: -6.1dB
bipolar stimulus: -7.1dB

The following conversion factors convert between the signal level generated in the ear simulator by the Otoport stimulus and the level that would be generated by a ‘reference stimulus’ of the same peak to peak electrical drive. (The ‘reference stimulus is a 100uS unipolar rectangular pulse, as defined in EN60645-3.):

rectangular stimulus: +3.0dB
bipolar stimulus: +2.4dB

Suppose, for example, that a stimulus level of 90dB is reported by the Otoport during stimulus setup (rectangular stimulus). If this stimulus was replaced by the reference stimulus, of the same amplitude, the level generated in a IEC 60711 ear simulator would be:

90dB + -6.1dB + 3.0dB = 86.9 dB SPL peak-to-peak equivalent.

(g) Polarity of stimulus:

The polarity of the stimulus varies between positive and negative, according to the TEOAE test sequence.

(h) Repetition rate:

The stimulus is repeated every 12.5mS during standard Otoport TEOAE setup and testing.

(i) Covered in (a) above

(j) Covered in (f) above

28.5 ABR Module

Note:

The ABR Module has no user serviceable parts. Any required servicing must be conducted by Otodynamics Ltd or authorised service facilities only.

28.5.1 Physical

Hand-held module:	278mm x 84mm x 38mm
Weight:	240g (490g with Otoport fitted)

28.5.2 Interfaces

Probe connectors compatible with Otodynamics UGS and UGD probes (8 pin)
Electrode connectors compatible with 1.5mm 'Touchproof' DIN 42-802 connectors
Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1or 2.0) via Data Cable

28.5.3 Indicators

Data display:	Data is displayed via Otoport (refer to section 23.1)
Probe Fit:	Indicators on Otoport: Noise OK - Blue LED ('N') Stimulus OK - Blue LED ('S')
Impedance check:	Impedance OK - Green LED (one for each electrode socket)
Power/Charge:	Power OK - Green LED
Fast charge:	Amber LED
Audible:	Audio feedback via Otoport speaker

28.6 End of life management

The Otoport/ABR meets the requirements of the Waste Electrical & Electronic Equipment- WEEE Directive 2012/19/EU; and of the Restriction of Hazardous Substances- RoHS Directive 2011/65/EU and of Packaging/ Packaging Waste Directive 94/62/EC.

When the Otoport product is discarded, the item must be sent to separate collection facilities for recovery and recycling.

- No hazardous materials are included in the Otoport/ABR.
- No Ozone Depleting Substances are used by the Otoport/ABR.
- No Latex is included in the Otoport/ABR. The Otoport/ABR does not contain any phthalates.
- Local guidance for disposal of medical devices should be followed, for example in the UK follow the NHS Healthcare (clinical) Waste National guidelines.
- When sending Otoport/ABR equipment that is no longer required for disposal, please ensure all items, particularly the instrument and probe(s)/ cables, are clean and free from contamination (cleaned in accordance with your infection control protocols).
- Prior to battery recycling, handling precautions and prohibitions for Li Ion Batteries must be read and understood. Follow VARTA Handling and Safety Precautions for LiIon & LiPolymer batteries.
- Otoport/ABR shipping package is recyclable; the Otoport/ABR is recyclable (Electronic Waste Recycling/ Plastics recycling); Battery Recycling
- In some territories, total waste management solutions are available and should be used for the the Otoport/ABR and accessories; these allow nationwide collection service and a sustainable licensed recycling solution with full traceability. Otherwise, all electrical and electronic products, batteries, and accumulators must be taken to separate collection facilities at the end of their working life. This requirement applies in the European Union.
- Do not dispose of these products as unsorted municipal waste.
- You can return your device and accessories to Otodynamics, or to any Otodynamics supplier.
- You can also contact your local authorities for advice on disposal.

28.7

Symbol explanations

Symbol	Description
	Class II
	Type BF
	Bluetooth® enabled
	Caution
	USB 1.1
	When discarded, the item must be sent to separate collection facilities for recovery and recycling
	Probe socket
	Battery charging indicator
	Power supply connection
S	Stimulus OK indicator
N	Noise OK indicator

Symbol	Description
	Refer to operating instructions
	Otodynamics' factory address
	Product catalogue number
	Product date of manufacture
	Product serial number
	RF transmitter
	Training required

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Symbols

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