Otodynamics

Otoport OAE+ABR

User Manual for Otoport Screener model

Otoport OAE+ABR
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Issue 3.5

User Manual for Otoport OAE+ABR

Otoport Screener model

Firmware Revision: 1.19.1.11 onwards

Doc Ref: MANOSC - Issue 3.5

15/08/2022

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 17243 4
(10) 3.5

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1 Introduction

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

The Otoport is simple to use and with powerful measurement features performs an automatic analysis of cochlear status within seconds. Customisable Stop criteria control the test's automatic stop.

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 General Guidance

Each test type provides evidence of normal peripheral hearing function objectively and non-invasively.

The screening functions of this instrument are especially suitable for use with infants. The ABR screening function uses conventional Fsp methodology to detect the response supported by waveform identification (Template Correlation) which is optimised for infants from 34 weeks to 6 months gestational age. Template-free pass criteria for ABR may be selected for use with patients outside this age range (see chapter 15 **Test Setup**, section 15.6.3, **ABR stop criteria**). OAE screening functions include Otodynamics classic Quickscreen TEOAE technology and Rapid DPOAE technology (depending on the model).

The device can be used in a wide range of different environments for example in the well-baby nursery, the NICU, a doctor's office, an audiology clinic, the outpatient clinic or in the home. For optimum results and short test times the room should be quiet and the patient should be very quiet and still during the test. The device will clearly indicate levels of acoustic noise and electrical interference (with ABR). Use this as a guide to improve the testing environment.

The screening functions of the device are intuitive and suitable for operation by trained screeners without specialized knowledge. Testing and interpretation is automated. The TEOAE and DPOAE analysis functions of the device are intended for clinical audiological investigations when objective non-invasive characterisation and monitoring of the functional status of the peripheral auditory function is required. These functions are intended for use as a part of the audiological diagnostic test battery, not as solitary diagnostic tests. The OAE analysis functions provided on some models are of particular interest to Audiologists, Ear, Nose and Throat specialists, Neurology specialists, researchers and other health professionals concerned with the differential diagnosis of hearing problems, the monitoring of changes to hearing, the conservation of hearing or the detailed measuring of peripheral auditory function.

1.4 General use precautions

The Otoport pass criteria are set in the **Test set-up** area (see section 15.6). It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

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 weekly and before each test session to confirm the system continues to operate effectively (see chapter 17 **QA Area**).

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 (see section 19.2 **Changing probe coupler tubes**).

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 1.4 **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.

1.5 Contraindications

This device should not be used for testing if there is discharge from the test ear, occlusion of the external auditory meatus by wax or other material,or if there is severe otitis externa.

Testing should also not be performed in the case of deformity of, or surgery to the ear or ear canal which might prevent the probe being comfortably fitted or acoustical sealed into the ear canal, unless examined and permitted by an audiologist or doctor.

1.6 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.

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

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.

1.7 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 used 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 of stimulation levels are used, especially for DPOAEs as part of the diagnostic process.

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.

See the **Test Setup** section of this manual for more detailed information.

1.8 Types of otoacoustic emissions

Otoacoustic emissions are sounds which can be recorded in the ear canal and which are created by the action of sensory cells within the cochlea. The sensory cells responsible are the outer hair cells.

Outer hair cells are nearly always damaged or inactive when there is cochlear hearing loss. Damaged outer hair cells do not produce emissions so cochlear hearing loss is associated with reduced or absent otoacoustic emissions.

Damage can occur to one part of the cochlea while other parts remain normal. This corresponds to hearing loss at some frequencies and not others. Similarly, otoacoustic emissions can be present at some frequencies, where hearing is intact, and absent at others, where there is a hearing loss.

The presence of otoacoustic emissions does not prove that the higher level auditory system is working normally. They only confirm that the cochlear environment and sensory outer hair cells are working normally at the frequencies tested.

The absence of otoacoustic emissions does not always indicate cochlear pathology. Otoacoustic emissions can be blocked by a malfunctioning middle ear, or obscured by excessive noise. Absent emissions with normal middle ear function and a properly conducted test very strongly indicate that hearing loss is present.

Otoacoustic emissions can be recorded in several different ways:

- Without stimulation it is possible to record Spontaneous Otoacoustic Emissions (SOAE)
- With a continuous pure tone stimulus and a special protocol it is possible to record Stimulus Frequency Otoacoustic Emissions
- With two continuous pure tone stimuli it is possible to record Distortion Product Otoacoustic Emissions (DPOAE)
- With a click or other brief stimulus it is possible to record Transient Evoked Otoacoustic Emissions (TEOAE)

The Otoport Advance currently records DPOAEs and TEOAEs, the Otoport Screener records TEOAEs only.

The difference between TEOAE and DPOAE measurements is largely in the means used to generate and measure the emission, rather than in the interpretation of emission. However each emission recording method has different advantages and disadvantages. In clinical use the methods are complementary.

The TEOAE test uses a click to briefly stimulate the cochlea across a wide frequency range and the instrument then records the sound made by the cochlea.

The DPOAE test uses a pair of pure tones of specific frequencies (f1 and f2) to stimulate the cochlea. The instrument records the distortion generated when outer hair cells respond to the stimulus combination. Pairs of f1 and f2 at different frequencies are used in turn to acquire emissions from different areas along the length of the cochlea.

The two measurement techniques have different characteristics and so lend themselves to different uses:

TEOAEs are rapidly acquired because emissions from all areas of the cochlea are collected simultaneously. They are sensitive to small depressions of hair cell function and therefore to small hearing losses because they record activity in the quiet period between clicks when the stimulation is minimal. TEOAEs are highly relevant to hearing communications problems because this response is normally strongest across the frequency range required for speech and language development. The TEOAE stimulus is brief and practical limitations prevent loud stimulation being applied. This means the TEOAEs cannot be obtained from ears with more severe pathology. All these properties have meant that TEOAE have been widely used and trusted in newborn hearing screening programmes. However the use of TEOAEs is not limited to newborn screening. In the clinic they can provide an early warning of cochlear deterioration and hearing loss, although their usefulness is limited above 4kHz.

DPOAEs allow testing at higher frequencies and at greater stimulus intensities than the TEOAE method. This has made DPOAEs valuable in the complete clinical assessment of cochlear status. The availability of stronger stimulation allows DP emissions to be recorded in patients with moderate hearing losses and this can be useful in establishing the extent of cochlear pathology. Recordings can be concentrated on selected frequency ranges.

When used with lower stimulus levels, DPOAEs are just as sensitive to slight hearing losses as TEOAEs, so they can be used for screening of newborns and adults. The test can take longer than for TEOAEs because each frequency has to be measured in turn, but this is acceptable with adults in return for higher frequency information.

Recording otoacoustic emissions below 2kHz can be more difficult with DPOAEs in noisy situations than with TEOAEs.

Otodynamics recommends a combination of both tests and a range of stimulus levels for clinical investigations.

1.9 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 is placed in 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 electrodes; the electrode montage consisting of three such electrodes. 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.

1.10 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 section 1.4 **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 chapter 20 **Care of the Otoport**).

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 your department lead, or directly to Otodyanmics or your dealer for support.

2 Equipment identification

2.1 Supplied only in Otoport OAE+ABR kit

REF SCR-ABR
Otoport Screener OAE+ABR

REF ABR-EC1
Snap electrode cables - 1m

REF ABR-EC2
Snap electrode cables - 2m

REF ABR-SK
Starter kit of snap electrodes (pack of 25), skin preparation gel, pack of cotton wool pads and ear cups

REF ABR-CAV
Probe cavity and ABR cable tester

REF ABR-DS

ABR Desktop stand / Crib hook

Desktop stand / crib hook insert for ABR sleeve.

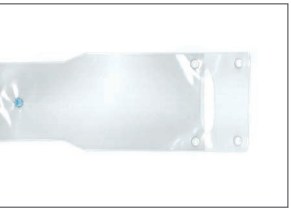
REF OP-CHG

Charger and mains lead

Supplied with required country-specific plug adapter

REF ABR-INF

Infection control sleeve for Otoport OAE+ABR unit only



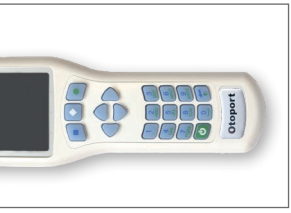
REF ABR-CAS

Equipment case for Otoport OAE+ABR kit

2.2 Supplied only in Otoport OAE kit

REF OS-ST

Otoport Screener



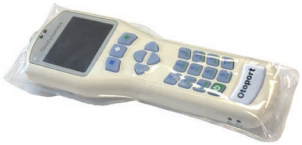
REF ABR-CAV

Probe test cavity

REF OP-INF

Infection control sleeve for Otoport only

Shown fitted



REF OP-CAS

Equipment case for Otoport OAE kit

2.3 Supplied in OAE and OAE+ABR kits

REF PR-UGS

UGS TEOAE probe

REF PR-POUCH

Drawstring probe pouch

Re-order quantity: 10

REF PR-CLIP

Probe cable clip

TPC probe coupler tubes x 5

See chapter 19 for fitting instructions

Re-order codes:

REF TPC-10 (quantity: 10)

REF TPC-100 (quantity: 100)

REF BGS

BGS probe body and lid x 1

Re-order quantity: 10

REF TE-BOX

Sample probe tips

See chapter 18
Probe, tips and accessories
for re-order codes

REF OP-CHG

Charger and mains lead

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 OPP-CAS

Large equipment case

For use with Otoport Screener OAE device, with additional compartment for printer

REF OMP

Otoport printer

Wired and wireless models available for Otoport Screener OAE device

REF EAR-CUP

Ear cups

Optional accessory for ABR screening as an alternative to direct probe use

REF ODS

Docking station

- Optional accessory for Otoport Screener OAE
- Not compatible with or supplied with OAE+ABR
- Provides connections for printing charging and downloading to PC

REF OP-CHG

Charger and mains lead

Optional for Otoport OAE kit
Supplied with required country-specific plug adapter

2.4.1 Printer accessories and consumables

REF OMP-CAB

Otoport printer cable

For use Otoport Screener OAE device (not for use with ABR)

REF OMP-CHG

Otoport printer charger

REF OMP-PAP

Otoport printer paper rolls

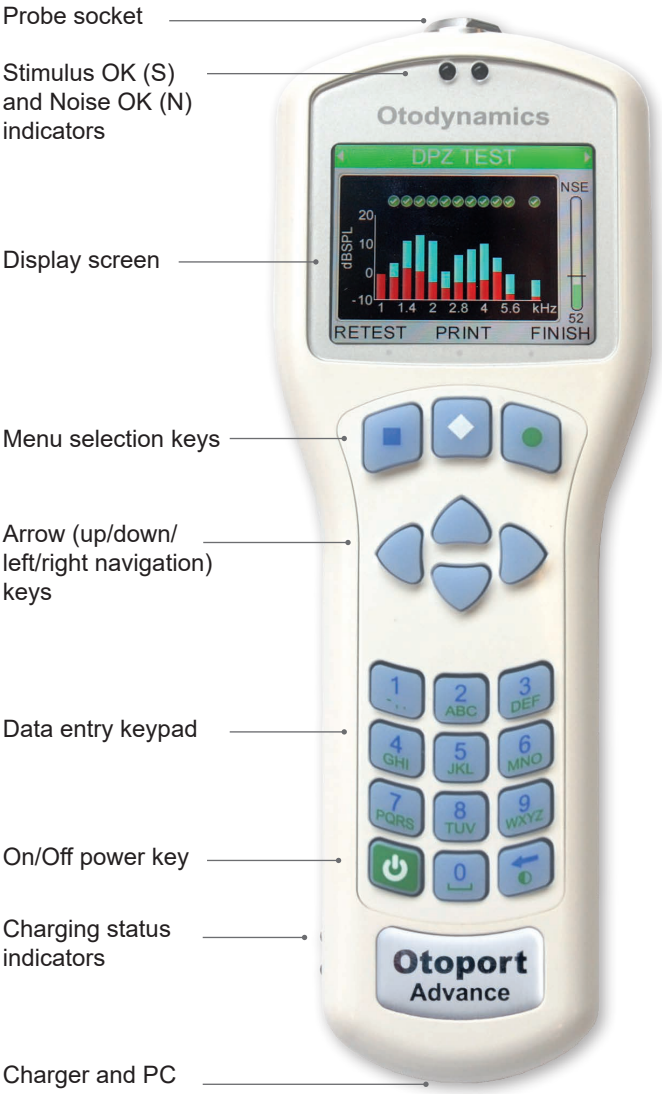
Quantity: 10

REF OMP-SA-PAP

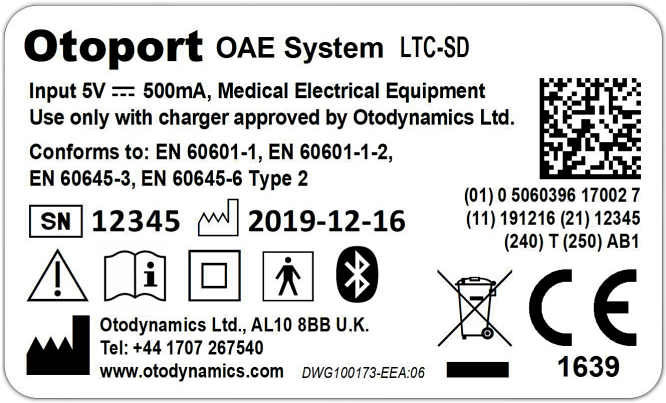
Otoport printer self-adhesive paper rolls

Quantity: 6

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 Screener 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 Screener 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 electrode sockets

Impedance check indicator LEDs

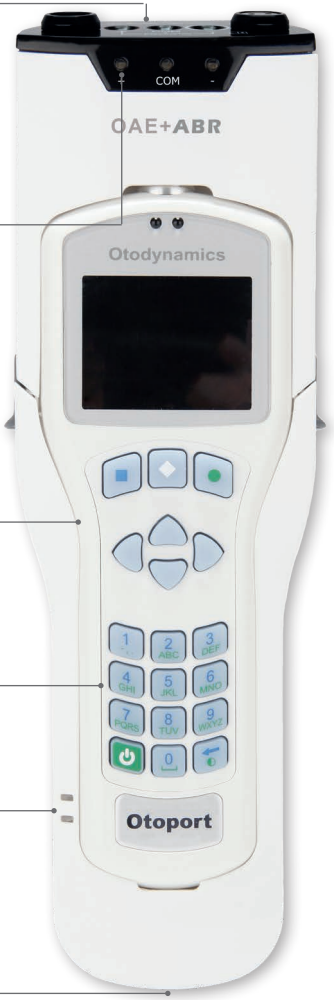
Quick-release clips

Otoport unit

Otoport controls and keypad

‘USB/PSU’ connected’ and
‘battery charging’ indicator LEDs

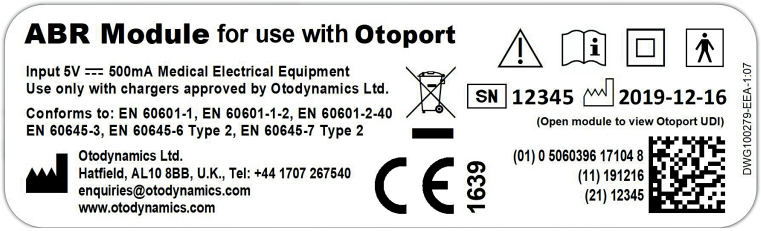
Charger / PC cable socket



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 Screener 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 Screener 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

3 Getting started

If you have purchased the ABR Module as an upgrade to your Otoport, you will first need to assemble the equipment, as follows.

3.1 Assembling the ABR Module with an Otoport

The ABR Module is designed to be fitted as a ‘sleeve’ to an Otoport unit, as described in the following instructions:

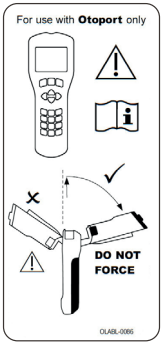
Do NOT force the Otoport into the ABR sleeve.

3.1.1 Lift up the clips on each side of the ABR Module.

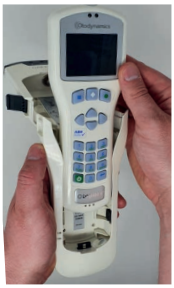
3.1.2 Hold the lower half of the ABR Module with one hand and use the other hand to slide the upper section up.

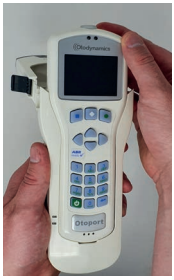
3.1.3 Slightly tilt the upper section back (see diagram on label inside Module).

Do NOT tilt it forwards and do NOT force it back.



3.1.4 Carefully insert the Otoport into the sleeve and slide it down until the connector at the bottom of the sleeve is inserted into the port at the bottom of the Otoport



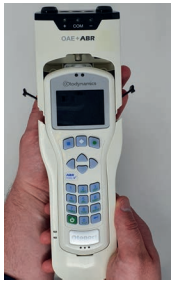


3.1.5 Tilt the upper section of the ABR Module forward (so that it is level with the Otoport)

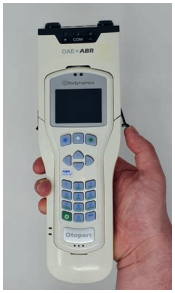
Please see next page for warning of possible damage if the Otoport is not inserted according to these instructions.

Do NOT insert the Otoport into the top of the module first, or insert into the bottom of the sleeve at an angle, as this may cause damage.

3.1.6 Lower the sleeve until the connector at the top of the ABR Module is inserted into the Otoport.



3.1.7 Close the clips.



3.2 Removing the Otoport from the ABR Module

If you need to remove the Otoport from the ABR Module at a later time, carefully follow these steps:

3.2.1 Open the clips on each side.

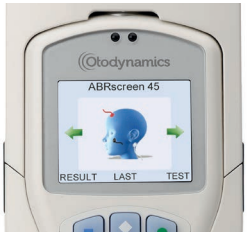
3.2.2 Slide the top half of the ABR sleeve up and and tilt it back.

3.2.3 Move the Otoport up to disconnect it from the port at the bottom of the sleeve and remove it from the Module. Do NOT tilt the Otoport forward. while lifting it up.

3.3 Otoport OAE+ABR with non-removable module

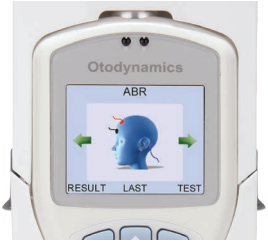
If you have purchased an Otoport OAE+ABR with a permanently fitted sleeve, sometimes referred to as ‘locked’, it is not possible to remove the Otoport from the module.

The clips on the side of the locked module are flat.



Non-release clips on ‘locked’ module

The clips on the unlocked module are shaped for ease of opening.



Quick-release clips on ‘unlocked’ module

3.4 Connecting probes and electrodes

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

3.4.1 Connecting the probe

Follow instructions for connecting the probe to the Otoport in section 3.8.

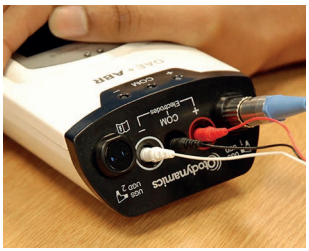
If you are using two probes, ensure that the probe head colour matches the probe socket; the probe with the red head should be conected to the red socket and the blue head to the blue socket.

Some Otoport models only allow a single probe connection to probe socket one. In this case, one probe socket will be blocked.

3.4.2 Connecting the electrodes

The Otoport OAE+ABR is supplied with an electrode cable loom featuring snap stud connectors for electrode attachment. Alternatively, any wired electrodes that are terminated with 1.5mm 'Touchproof' DIN 42-802 connectors may be used.

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



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

Important note:

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

3.5 Initial charge

Before using your Otoport for the first time, fully charge the unit. See chapter 21 **Otoport Power** for details.

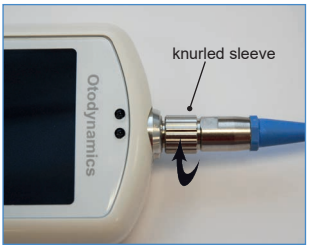
3.6 Quickstart guides

Quickstart guides for OAE and ABR tests, included as separate items in your document pack, are shown on the following pages.

OAE QUICKSTART

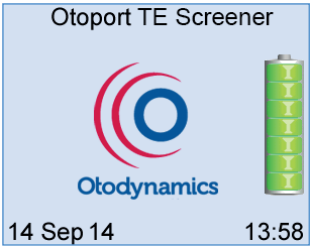
Otoport Screener

Step 1. Setting up your Otoport



1 With the arrow at the front, connect the probe and screw the knurled sleeve until finger tight.

2 Press the button to turn on the Otoport. Confirm within 2 seconds by pressing the button.

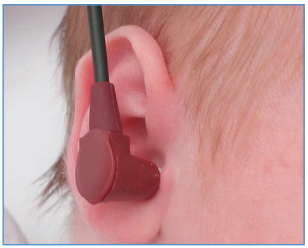


3 Date, time and battery status are displayed while system checks are performed.

Step 2. Fitting the earpiece

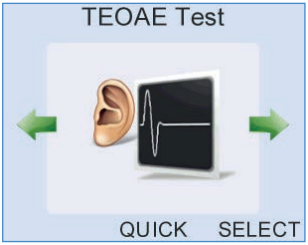
1 Select an appropriate tip.

2 Fit the tip to the earpiece.

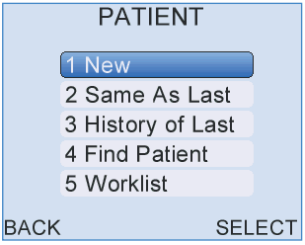


3 Fit the earpiece in the ear canal.

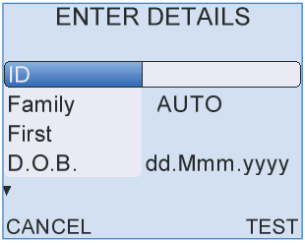
Step 3. Performing a TEOAE test



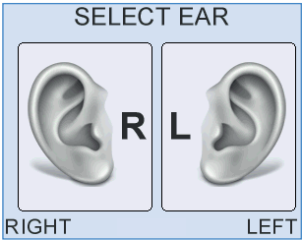
1 Use the arrow buttons to find the TEOAE screen. To run a **QUICK** test, press the button.



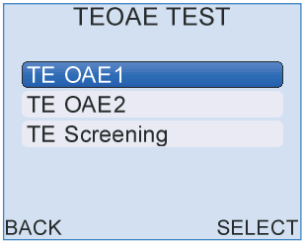
2 Select a stored patient or a **New** patient.



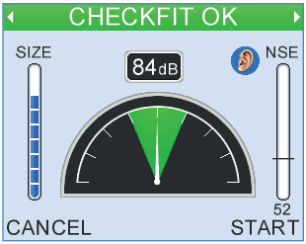
3 Enter patient details then select **Test** by pressing the button.



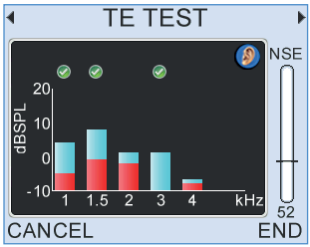
4 Select Right or Left ear using the and buttons. ABR tests can be performed on both ears.



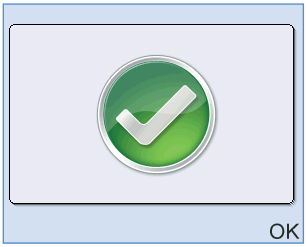
5 Select one of the TEOAE test modes.



6 Assess test conditions. When **CHECKFIT OK** is shown, press to start test.



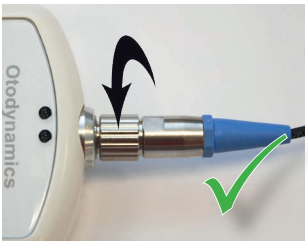
7 An OAE histogram is continuously updated during the test. The symbol indicates that a band meets pass criteria.



8 The test will auto-stop and a result graphic will be shown. Press the button to review the result.

9 The test result will be displayed at the top of the test screen. Press the button to **SAVE** the test.

Step 5. Disconnecting the probe



1 Unscrew the knurled sleeve.

2 Do NOT turn the main probe body.

3 Gently pull out the probe.

CE 1639

Otodynamics Ltd
30-38 Beaconsfield Rd Hatfield Herts AL10 8BB UK
www.otodynamics.com Email: support@otodynamics.com
US Toll free: 1 800 659 7776
International: +44 (0)1707 267667

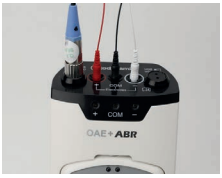
Ref: MOSCQ.3 May 2017

Otoport ABR QUICKSTART

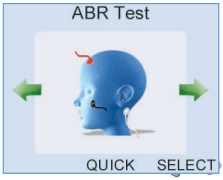
Step 1. Setting up your device

1 Ensure that the Otoport and the ABR module are tightly secured together.

2 Connect the OAE probe to the probe socket, aligning the 'key' and 'keyway.' Screw up the knurled sleeve until finger tight.



3 Plug the electrode connector leads into the appropriate sockets, following the colour coding. Push in firmly.

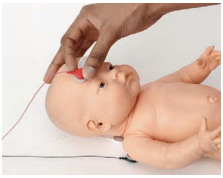


4 Press the button to switch on the Otoport. Use the and arrow buttons to navigate to the ABR screen.

Step 2. Getting ready to test

1 Prepare and clean the skin at the electrode sites to ensure low impedances. Apply electrode to high forehead.

2 Apply electrode to the nape of neck and (common) electrode to the back of the shoulder.

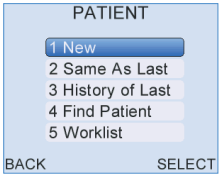


3 Attach , , and (common) electrodes.

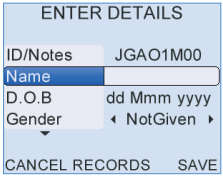
4 Fit an appropriate sized tip to the probe and insert the probe in the ear to be tested. Ensure electrodes are attached correctly.

Step 3. Performing the test

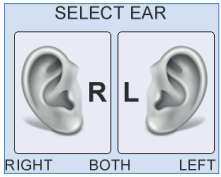
1 Press the button to proceed to the Patient menu.



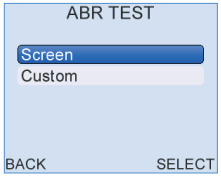
2 Select the required option.



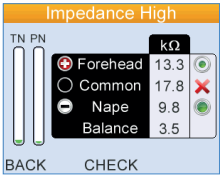
3 Enter patient and test details using the keypad and arrow buttons.



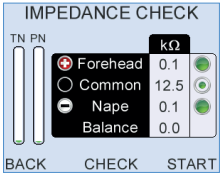
4 Choose the ear to be tested, or Both for a bilateral test.



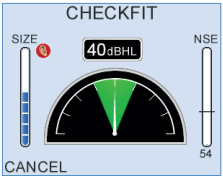
5 Select ABR test mode.



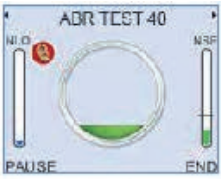
6 Check impedances, total noise (TN) and powerline noise (PN) are acceptable. Reapply electrode if an impedance is marked .

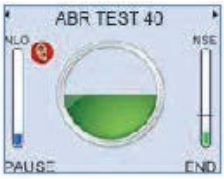


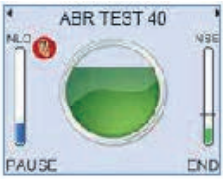
7 The test will autostart if conditions are good. Press the button to manually start the test.



8 The Checkfit screen shows the fit stability of the probe and acoustic noise (NSE). ABR will start automatically if conditions are acceptable.







9 The filling green circle represents the progress of the test towards a pass and the rising NLO bar represents the amount of data collected.

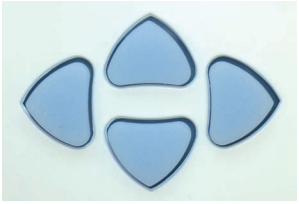
10 Use the ◀ and ▶ arrow buttons to switch between data viewing screens. To end the test, press the ✕ button. To save the test, press the + button.

3.7 Using the keys and keypad

3.7.1 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.

3.7.2 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.

3.7.3 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.

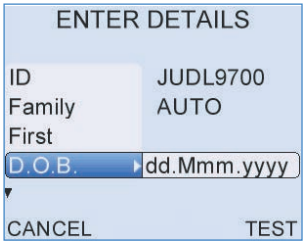
Family Name
For the first character capitals are presented first, then lower case then numbers, e.g. ABCabc2. For subsequent characters lower case is shown first, e.g. abcABC2.

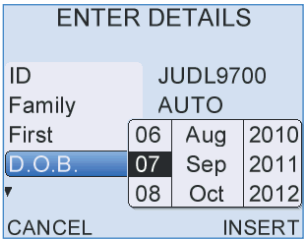
More characters can be stored than can be displayed on the screen. Arrows are displayed to indicate that the string continues to the left or the right. Pressing the appropriate arrow navigation keys will display the hidden characters.

3.7.4 Foreign character table

A foreign character pop-up table can be accessed by holding down the 1 key for 1.5 sec. Use the arrow keys to navigate around the table. Select **Insert** to enter the required character or select **Cancel** to close the table window.

3.7.5 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.

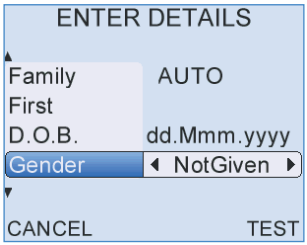
Select **Insert** to accept the date displayed or press **Cancel** to ignore the changes.

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.

3.7.6 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.



3.7.7 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.

3.7.8 Backlight

The screen and keypad are backlit to assist in 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 13).

3.7.9 Brightness

The brightness of the screen can also be changed in in **System** setup (see chapter 13).

3.7.10 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 the range defined in **Test setup** (see chapter 15).

The Noise OK LED is highlighted with an N. It is lit when the noise level recorded by the probe microphone is below the noise reject threshold. It is extinguished when the noise level is above the threshold.

3.7.11 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.

3.8

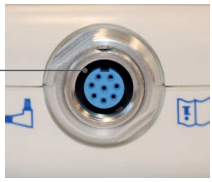
Connecting the probe

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.

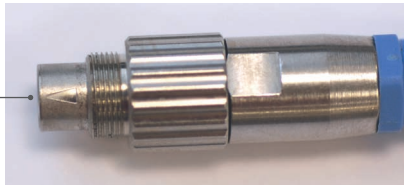
Probe key

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.

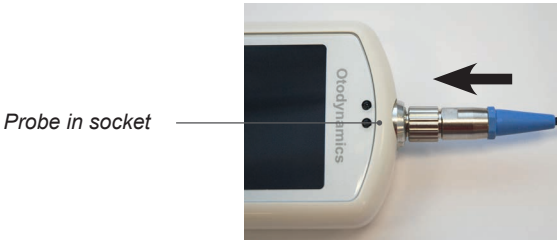
Arrow



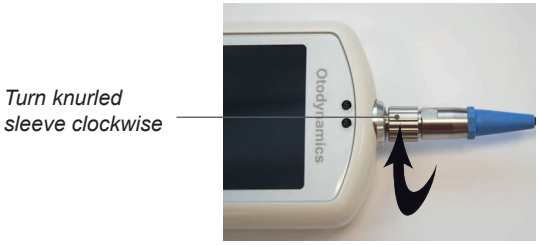
It is possible to feel when the probe key is aligned as the probe will mate with the socket easily.

Align arrow with front of Otoport

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

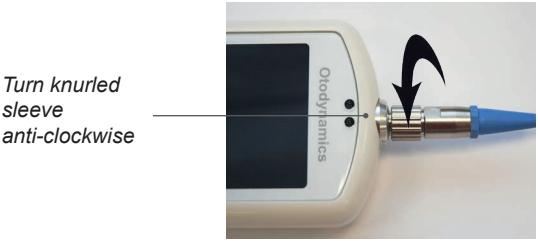


Screw up the **knurled sleeve** in a clockwise direction until finger tight.

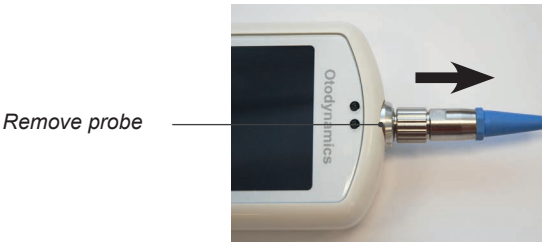


3.9 Disconnecting the probe

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

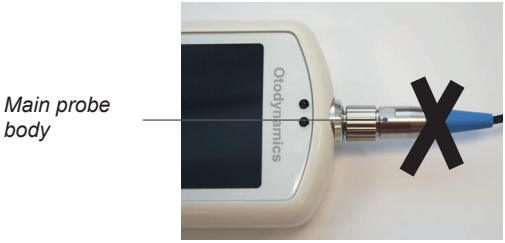


Then gently pull the probe out from the probe socket.



Important Note:

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

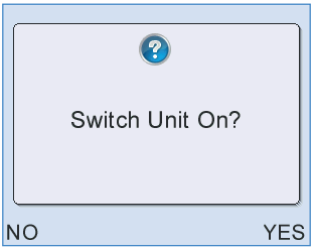


This will result in damage to the probe and will invalidate the probe warranty.

4 Switching on

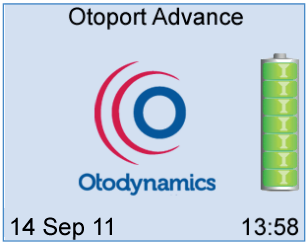
4.1 Switch on screen

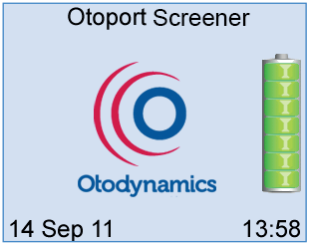
To switch on the Otoport press the green **On/Off power** key found at the bottom left of the keypad. The display screen will show **Switch Unit On?**.



Select **Yes** to confirm Otoport switch on, or **No** to turn the unit off again. If **Yes** or **No** are not selected within two seconds of pressing the on/off power key, the device will automatically turn off. The unit will turn off if any key other than **Yes** is pressed. This is to prevent accidental switch on during transit.

4.2 Logo screen





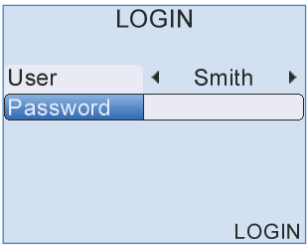
Following switch on, an Otodynamics logo animation is displayed whilst the device performs a series of hardware system checks. In the unlikely event of any of the systems checks failing, an error message will be displayed (see section 22.5 **Hardware fault messages** for details).

A battery graphic will appear to the right of the logo to provide an indication of the **Battery power** remaining. Please refer to chapter 22 **Otoport power** for battery information.

The date and time are also shown at the bottom of the screen and can be reset by an Administrator in the device **Management** module (see section 14.4 **Date and time**).

A prompt will be shown if the Otoport is due to be calibrated (see chapter 24 **Calibration**).

4.3 Login



If **Login** is **On** the login screen will be displayed and the user will be required to enter a name and password.

Use the left/right arrow keys to choose the correct user name from the choice bar.

Once the user is selected, use the data entry keypad to enter a corresponding **Password**, if required for that user.

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

When the **User** and **Password** have been chosen, select **Login** to access the device. If the **Password** has been entered incorrectly, a warning message will appear as below:

4.4

Scrolling modules

The **TEOAE Test** module screen is displayed following switch-on. The **ABR Test** screen and other module screens can be accessed using the left/right arrow keys. Choose **Select** to enter each menu.

5 Test preparation

Good preparation for testing will improve test results and make testing more efficient and less stressful for the baby, parents and tester.

5.1 General checks before testing

Ensure the Otoport is charged (see chapter 21 **Otoport power** for information).

Ensure the Otoport weekly checks are being regularly conducted (see chapter 17 **QA area** for information).

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.

5.2 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 electrode and probe cables.

5.3 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. The Otoport is supplied with a full range of tips to fit all ear canal sizes (see section 18.3 **Probe tips**). 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.

5.3.1 Fitting for newborns

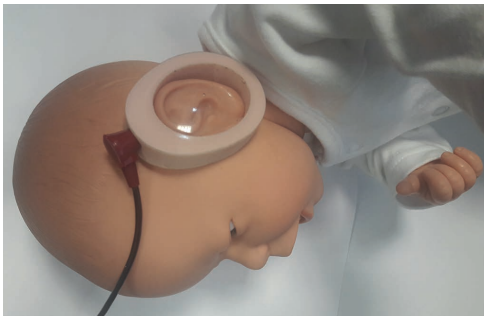
Gently lift the pinna upwards, away from the baby's head, and then towards the back of the head. This will open the ear canal.

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

Turn the probe ear piece to 12 o'clock.

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

5.3.2 Fitting for infants using ear cups



Only the Sanibel Infant Earcup^{tm} (www.sanibelsupply.com) 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 and the R7M tip for DP probes should be used; see section 18.3 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.

5.3.3 Fitting for children and adults

Line up the probe to 7 o'clock (for left ear) or 5 o'clock (for right ear).

Push the probe firmly into the ear canal at this angle.

Hold the probe for several seconds. Then release the probe.

No discomfort should be felt by the patient.

The weight of the probe cable should be supported to minimise the risk of the probe being pulled out during testing. Use the probe cable clip supplied, ensuring there is sufficient slack in the cable to allow for movement of the patient's head. If the correct tip is used, the probe should stay in place without aid. However, it is acceptable to hold the probe gently in the ear if the patient is restless.

5.4 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. 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 patient 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.

5.5 Electrode fitting

5.5.1 Skin preparation

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

Use electrode skin preparation pads/tape, exfoliating pads (e.g. Dry Prep), or a swab coated with Nuprep™ to clean each of the areas. With your thumb and finger support the skin, holding it gently taut. Swipe across the site with 3 to 4 moderately firm strokes in order to obtain 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. 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.

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

5.5.2

Placement (montage)

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

Shoulder (common ● black) and nape of neck (negative ⊖ white)

High forehead (positive ⊕ red)

The sensor should be placed high on the forehead near the hairline 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 snap stud electrodes, now connect the electrode cables to the sensors. Connect the red cable to the high forehead, the white cable to the nape of the neck and the black cable to the back of the shoulder.

Alternative electrode placements

The Otoport is optimised for the electrode placements described above. Alternative placements are possible, including:

	Recommended	Alternative 1	Alternative 2
Positive - Red ⊕	High forehead	High forehead	High forehead
Negative - White ⊖	Nape of neck	Nape of neck	Mastoid of test ear
Common - Black ●	Back of shoulder	Cheek	Mastoid of non-test ear

Note:

The Positive (⊕ Red) electrode MUST always be placed on the high forehead.

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

6 Test troubleshooting

6.1 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. 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 patient 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.

6.2 ABR test problems

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

Solutions:

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

1. Check all electrode plugs are firmly inserted into the sockets of the ABR Module.
2. Press firmly onto the electrodes if impedance is only slightly high.
3. Remove and re-prep the electrode site that has high impedance. If that fails to work, re-prep all sites.
4. If re-prepping does not work, try a fresh set of disposable electrodes (or clean reusable electrodes).
5. 'Wet gel' electrodes, 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 electrode pouch and then open a fresh pouch if in doubt about how long the current pouch has been open.

6.2.2 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 electrode and cable connections are secure.
2. Switch off lights in the test area.
3. Do not place the Reference (Common) electrode 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 electrode to identify which is causing the problem, try:
   - holding the skin around the electrode taut
   - maintaining light pressure on the electrode
   - gently stroking the baby's head
   - repositioning the baby's head

6.2.3 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 electrode 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 electrode cables from the probe cable if intertwined.
5. Move to a quieter location if possible.

6.2.4 No response in ear with known normal hearing

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

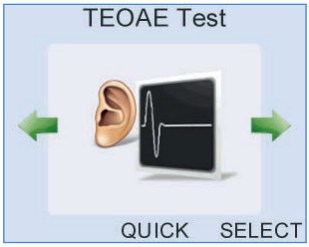
Check probe fit. A probe that has very poor fit to the ear can result in very low stimulus levels and therefore a small or absent response.

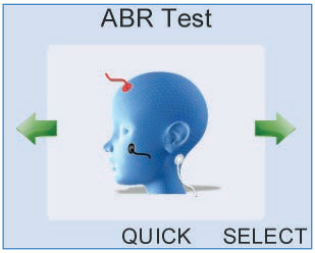
6.3 OAEs and screening

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.

7 Testing options





On the **Test** module screens, there are two options.

The **Quick** button will enable you to choose a test type and perform a test before entering patient details. This option gives the user flexibility when testing conditions are variable. At the end of the test, select **Save** to access the **Save Options** menu.

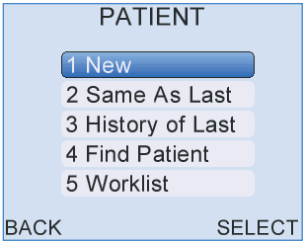
The **Select** button will enable you to enter patient details, or select a patient from the database, before choosing and performing a test.

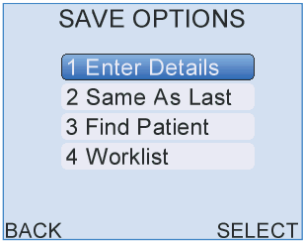
You will not be able to start a test if the Otoport is connected to a PC or charger.

8 Patient details

Choose **Select** on one of the test module screens to view the **Patient** menu. After selecting or completing patient details, select **Test**.

Select **Save** at the end of a **Quick** test to view the **Save Options** menu. After selecting a stored patient or saving details of a new patient, you will be asked to save the test results. See chapter 11, **Saving a test**.





New or Enter Details

Select **New** or **Enter Details** to enter details of a new patient.

The device 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.

Same as last

Select **Same As Last** to use the details of the last entered patient. Patient details will be displayed but cannot be edited. Select **Test** to begin the test. This option will not function if there is no patient information stored on the Otoport.

History of last

Select **History Of Last** to review test results of the last saved patient. This option will not function if there is no patient information stored on the Otoport.

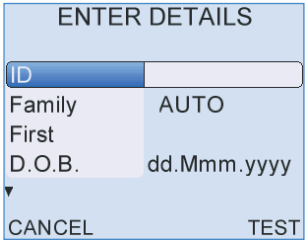
Find patient

Select **Find Patient** to search for a patient with records already stored in the database.

Worklist

Select **Worklist** to find a patient stored in the worklist.

8.1 Entering patient data



The **Enter Details** screen allows patient data to be entered and saved with the test record.

Patient details fields

Fields can be selected by pressing the up/down arrow keys. The field name becomes highlighted and a cursor flashes at the beginning of the line ready for data entry. Up and down arrows are present on the screen to indicate that other fields are available, but not currently visible.

An explanation of the patient details fields is shown in the table on the next page.

Mandatory patient details

The ID field is prefilled with a unique value and the name field prefilled with **Auto**. The prefilled values can be overwritten but the fields are mandatory and so the test cannot be saved if they are blanked.

Beginning a test

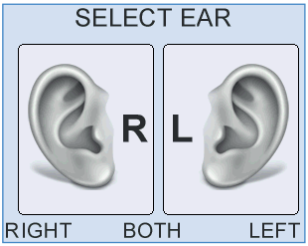
Select **Test** to enter the **Test Choice** screen. Please refer to the next chapter for details of TEOAE testing.

Field	Description	Max Number Characters
ID	The patient's ID number or local hospital number, prefilled with unique value	12
Family	The patient's family name, prefilled with 'Auto'	20
First	The patient's first name	20
D.O.B	The patient's date of birth	n/a
Gender	The patient's gender	n/a
Mother	The mother's maiden name	20
Notes	Any additional comments relating to the patient	15
Risks	15 risk factors (configure choices in **Management**) with options of Yes, No or Unknown (UKN)	n/a
Location	Either inpatient, outpatient or at home	n/a
Facility	The name of the hospital, clinic etc. where the test is being performed (configure choices in **Management**)	n/a
NICU	Is the patient in the Neonatal Intensive Care Unit, Yes or No	n/a
Consent	This option allows the consent to the test to be stored with the test details. Two levels of consent are provided, Full and Screen Only.	n/a

8.2 Beginning a test

Select **Test** to begin the OAE test once the correct patient details have been entered or **Cancel** to return to the **Patient** menu screen.

8.2.1 Select test ear



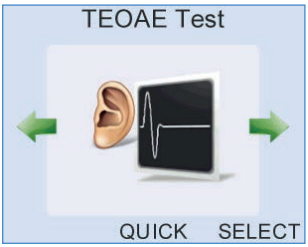
The **Select Ear** screen represents the patient facing you.

Press the right menu selection key or the right arrow key to select the **Left Ear** or press the left menu selection key or the left arrow key to select the **Right Ear**.

ABR tests run using ear cups may be run bilaterally (on both ears), so a third option **BOTH** can be chosen. Further information on bilateral ABR testing follows in chapter 10 **ABR test**.

If the patient's previous test was saved to the same ear, the pop-up message **Last Test Saved to Left/Right Ear. Save Test to Left/Right Ear Again?** will appear. Press **Yes** to accept the current ear choice or press **No** to return to the **Select Left/Right Ear** screen.

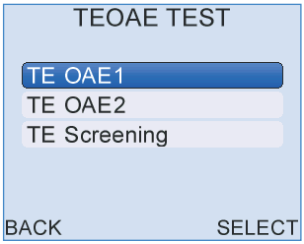
9 TEOAE test



Transient Evoked OAE testing involves exposing the ear to a brief sound and recording the response from the cochlea.

After choosing either the **Quick** option, or selecting **Test** on the patient details screen, the test choice screen is available.

9.1 Test choice

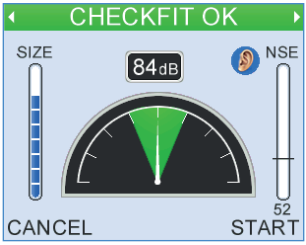


Choose a TEOAE test from the list using the arrow keys, then press **Select**. Descriptions of the test modes are given in section 15.10.1.

If the TE mode you wish to use is not displayed, refer to chapter 16 **test setup**.

9.2 TEOAE Checkfit

9.2.1 Checkfit display



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.

Ear canal size indicator

The bar on the left of the screen gives an estimate of ear canal size. This estimate is based on the click stimulus level required to give 84dBpe in the ear canal. Large ear canals, such as found in adults, require a large stimulus and fill the bar. Small ear canals, such as found in neonates, require only a small stimulus, indicated by only a small section of the bar filled.

If there is a disagreement between the size indicated and the ear canal size expected of your patient then there may be a problem with the probe or the probe fit. For example: an indication of a large ear canal in a neonate may occur if the probe has fallen out of the ear or if the probe is blocked; an indication of a small ear canal in an adult may occur because of wax blocking the canal. Size indication is only valid *after* the stimulus has adjusted to 84dBpe.

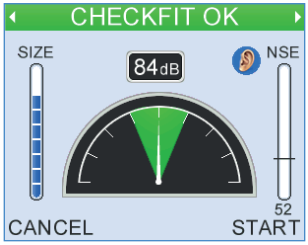
Stimulus level indicator

A **Stimulus Level Indicator** is shown in the centre of the **Checkfit** screen. With the probe in an ear, by default the device will attempt to adjust the stimulus to the set testing level. The indicator's needle and the numeric display above the arc show the change in stimulus level during adjustment. The stimulus is at the set testing level when the needle is vertical. 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 chapter 19 **Probe care**).

Noise level indicator

A Noise Level Indicator is shown on the right of the **Checkfit** screen. The bar moves in response to changes in noise. For good testing conditions the bar should be consistently below the Noise Reject Level which is represented by the horizontal line across the Noise Level Indicator. The bar is filled red if the level is above the threshold and green if it is below. The noise level shown is calculated from the peak sound level recorded within each response window. The threshold level is displayed numerically above the indicator. Use the up/down arrow keys to change the Noise Reject Level.

Test condition information



Checkfit OK will appear at the top of the screen if the adjusted stimulus level is correct and the noise is consistently below the reject level.

Noisy appears if high noise conditions cause the noise bar to be consistently above the reject level for a period of time.

Check Probe Fit is shown if the adjusted stimulus level falls outside the accepted stimulus range. The needle on the **Stimulus Level Indicator** will be outside the shaded area of the arc.

Ringing is displayed when there is obvious oscillation within the **Stimulus Waveform** after the initial positive and negative peaks instead of a flat line response.

The table below describes the highlighted message which will appear if more than one condition is met.

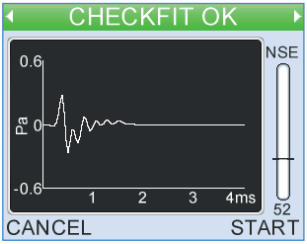
Consistent High Noise	Stimulus Out of Range	Stimulus Ringing	Highlighted Message
No	No	No	Checkfit OK
No	No	Yes	Ringing
No	Yes	No	Check Probe Fit
No	Yes	Yes	Check Probe Fit
Yes	No	No	Noisy
Yes	No	Yes	Ringing
Yes	Yes	No	Check Probe Fit
Yes	Yes	Yes	Check Probe Fit

When **Checkfit OK** is present on screen indicating conditions are suitable for testing, select **Start** to begin a test or **Cancel** at any point in **Checkfit** to return to **Patient Details**.

Stim out of Range will appear if **Start** is selected when the stimulus is outside the accepted range. It is advisable to select **Back** to return to **Checkfit** and readjust. Select **Continue** to test with the current stimulus level.

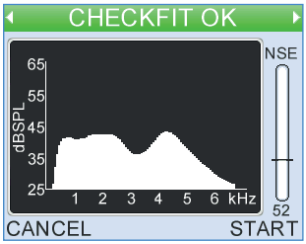
Additional checks on testing conditions are the stimulus (**S**) and noise (**N**) LEDs above the screen. Both LEDs are lit in ideal testing conditions.

9.2.2 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.

9.2.3 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.

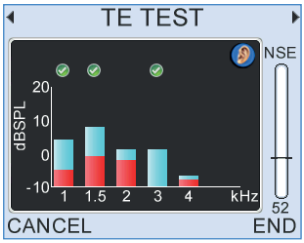
The stimulus spectrum should be a smooth, rounded curve. A jagged stimulus response in the low frequencies or a sharp peak in the mid-frequency range indicates a poor probe fit. Dips in the stimulus spectrum may be caused by standing waves in the ear canal. A dip indicates a drop in intensity at the 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. This can make it a useful tool for checking continuity of fit over separate testing sessions.

9.3 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.

9.3.1 Half-octave histogram



Test data is displayed graphically on the histogram screen in ½ octave bands: 1k, 1.5k, 2k, 3k, 4k and 6kHz (optional). The blue section of each band represents the OAE signal level within each band and the red section represents the noise level at that frequency.

A tick will appear above a bar if the TE in the half-octave band has met its Stop criteria. Please refer to the **Test Setup** (chapter 15) 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.

Brackets can be displayed to indicate normative ranges (see chapter 15 **Test setup**).

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.

Test condition information

When conditions are good for data collection **TE TEST** will be shown at the top of the screen. This fades in and out to show that a test is currently running.

Noisy appears if the noise level is above the noise reject level for a period of time.

Check Probe Fit is shown if the adjusted stimulus level falls outside the accepted range.

The following table describes the test condition information which appear if more than one condition is met:

Consistent High Noise	Stimulus Out of Range	Highlighted Message
No	No	TE TEST
No	Yes	Check Probe Fit
Yes	No	Noisy
Yes	Yes	Check Probe Fit

Noise level indicator

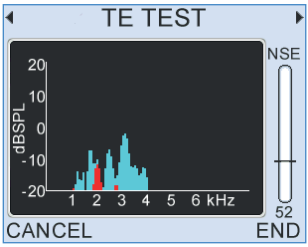
The noise level indicator allows continuous monitoring of the noise level during a test. The noise reject level is displayed numerically below the indicator. Use the up/down arrow keys to adjust the noise reject level.

Cancel and End

Select **Cancel** at any time during a test to pause the test. This may be useful if the ambient noise increases. **Cancel Test?** is displayed at the top of the screen and three options are provided. **Yes** will terminate the test; **No** will continue the OAE recording and **Checkfit** will restart the test at the Checkfit stage.

Select **End** at any time during a test to manually terminate the test.

9.3.2 Response spectrum



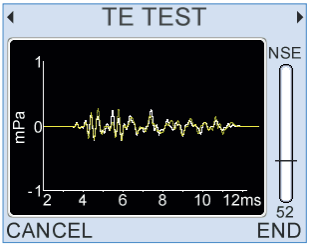
The response spectrum screen shows the signal and noise levels recorded in 80Hz frequency bands. This is the information which is summarised by the half-octave histogram but the response spectrum displays the data at a much higher frequency resolution.

The additional detail shown is often quite irregular and should not be interpreted as showing variation in cochlear health at a fine frequency resolution. However, changes in the detail may relate to changes in the cochlear status.

TEOAE responses sometimes include spontaneous OAEs and strong spontaneous OAEs can sometimes dominate the TEOAE response. Spontaneous OAEs occur at specific frequencies and can be observed in the response spectrum as very sharp large peaks at the frequency of the emission.

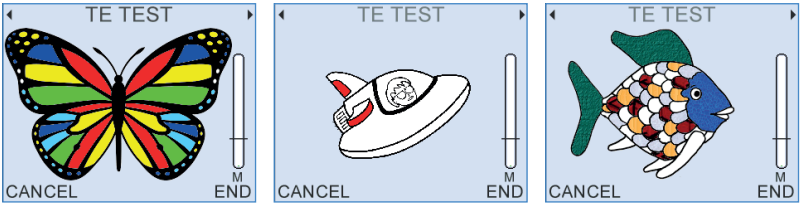
The OAE signal is shown in blue and noise is shown in red.

9.3.3 Response waveform



The response waveform screen displays the two interleaved OAE waveforms (named A and B). Waveform A is shown in white and waveform B in yellow. Waveforms that correlate well represent good quality recordings with low noise. Significantly different waveforms indicate a noisy recording. As the test continues the noise levels will be reduced by averaging and the two waveforms will show better agreement. Examining the waveforms can help troubleshoot testing problems. Typical TEOAE response waveforms have energy distributed across the response window with the higher frequencies appearing early in the response window and low frequencies later. Waveforms dominated by a single frequency may be the product of strong spontaneous OAEs. Waveforms dominated by a single frequency which decays rapidly may be due to a faulty probe or a ringing stimulus. If you are concerned about the performance of your Otoport, run the system QA test (see chapter 17 **QA area**).

9.3.4 Infant distraction screens



These screens are designed to encourage young patients to keep still and quiet during OAE testing.

They show a simple drawing that becomes more colourful if they are quiet. The quieter they are the more quickly the picture progresses. If they become noisy then the colour in the picture starts to fade.

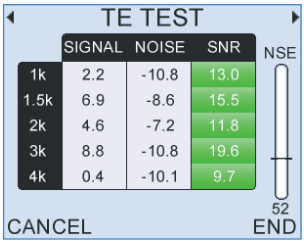
A number of alternative images are available. Choose between the images with the number keys (1-3)

9.3.5

Data tables

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

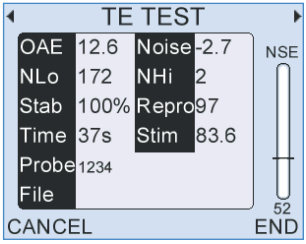
The first data table displays the dB levels at the specified half octave frequencies.



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.



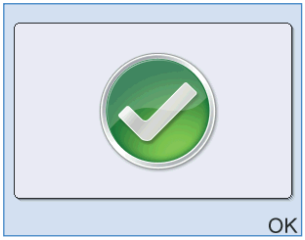
The following table describes each field in detail:

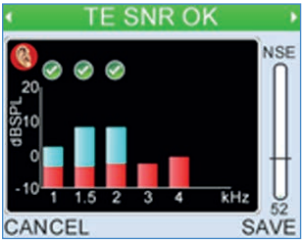
Field	Description	Units
OAE	The total OAE Signal level	dB SPL
Noise	The total Noise level	dB SPL
NLo	The amount of data accepted due to noise being below the noise reject level	n/a
NHi	The amount of data rejected due to noise being above the noise reject level	n/a
Stab	Stimulus stability shows the change 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)	

9.3.6 Test stop reasons

When Stop criteria have been met, the test will stop automatically and a single beep will sound for a positive OAE result or a double beep for a negative OAE result.

When the test stops a result is displayed on the screen (example below left). Select **OK** to accept the test stop reason. The result is then displayed at the top of the test screen (example below right).





The test can also be terminated manually with the **Cancel** or **End** options, as described before.

9.4

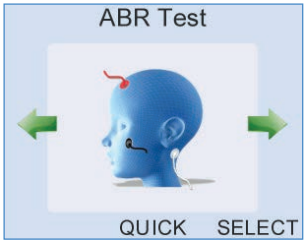
TEOAE test results

The following table lists all possible test results and gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
TE SNR OK 	The data collected has met the criteria set. The optimum test setting will depend on your application e.g. screening or clinical measurement (see chapter 15 **Test set-up**)
Note: The following results will only occur if a TE SNR OK is not obtained	
No Valid OAE 	The data collected has not met the set Stop criteria and the test conditions were acceptable
Noisy 	If the noisy data collected is three times greater than the low noise data collected
Poor Probe Fit 	If the final test stimulus level is outside the stimulus ok range or if the final stimulus stability value is < 85%
Too Few Bands 	If insufficient bands meet the set requirements
Stopped Too Soon 	If a user ends the test manually before the required minimum amount of data has been collected

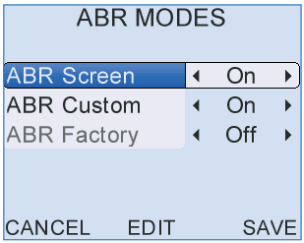
10 ABR test

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



Select **ABR Test** from the scrolling modules using the arrow keys. After choosing either the **Quick** option, or selecting **Test** on the patient details screen, the test choice screen is shown.

10.1 Test choice



Choose an **ABR** mode from the listed test modes using the arow keys, then press **Select** Descriptions of the test modes are given in section 15.10.1. If the ABR mode you wish to use is not displayed, refer to chapter 15 **Test setup**.

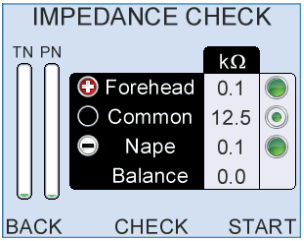
If only one ABR mode is **On** in the **Test setup** area (see chapter 15), the test choice screen will not appear and the test will start immediately.

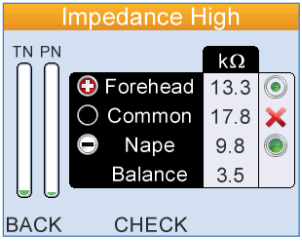
10.2

Impedance check

The Otoport checks the quality of the connection between the skin and each of the three electrodes. This takes 2-3 seconds. A low impedance provides a good connection. Achieving optimum electrode 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 electrode 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 electrode impedances are good and the electrical noise (EEG) 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 electrodes or by settling the baby or by reducing the noise).

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

If you refit any electrodes 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 6.2 **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 electrode impedance is marked with X then refit that electrode
- If High EEG Noise is shown then try to settle the baby.
- If High Powerline Noise is shown and electrode impedances are good, then see if there is any electrical equipment in the room that can be turned off.

(See section 6.2 **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 electrode, 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 electrode 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 electrode 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 electrodes. 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 electrode impedances if there is sufficient balance between the electrodes 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 electrodes 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 patient is moving or is not relaxed. Try to settle the subject and ensure that the neck is supported and muscles are relaxed.

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

10.3 ABR Checkfit

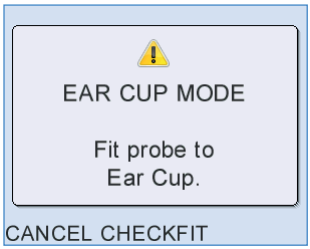
The test stimulus in ABR tests can be provided either by applying an ear cup to the ear and inserting the probe into the ear cup or by inserting the probe directly into the ear, as for OAE testing. Which option is used, and how the probe checkfit functions, depends on the **Ear Cups** setting in **Test Setup** (see chapter 15).

Ear Cup mode set to On

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:

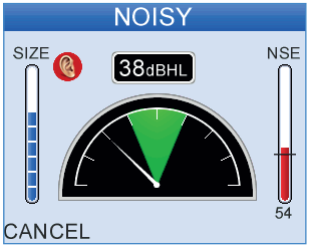


Selecting **Cancel** will cancel the test and **Checkfit** will recheck the stimulus.

The ear icon shown below indicates that the Otoport is in Ear Cup mode.

Ear Cup mode set to Off

With **Ear Cups** set to **Off**, Checkfit proceeds as for OAE tests (see section 9.3 for details). The screen used in OAE Checkfit is shown if ear cup mode is off.



Checkfit in probe mode

Ear Cup mode set to Auto

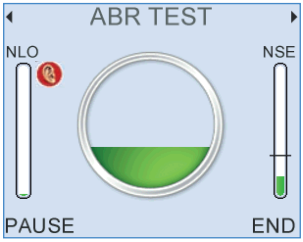
With Ear Cup mode set to **Auto** the Otoport will first assess size of the cavity the probe is in. If the cavity is large it will ask the user if ear cups are being used. If the user confirms ear cups are in use then the Otoport act as when **Ear Cup** mode is **On**. Otherwise (if the cavity is small, or the users says ear cups are not in use) the Otoport acts as when **Ear Cups** is set to **Off**.

10.4

ABR test

During the test the Otoport plays a series of clicks into the ear and records the electrical response from the sensors (electrodes). 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.

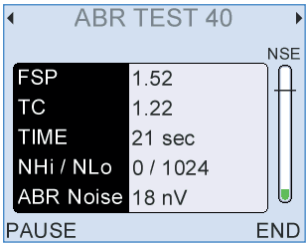
NLO is an indication of the amount of data accepted due to noise being below the noise reject level.

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.

10.4.1 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.

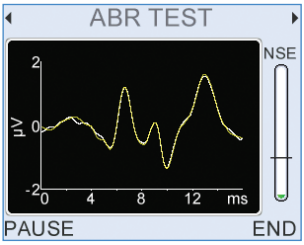
ABR Noise

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.

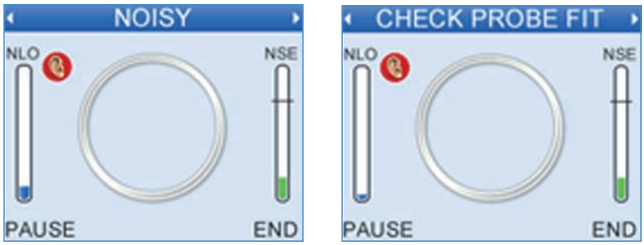
If ABR noise is too high (>85nV), a valid ABR cannot be detected, so the test will continue to run even if other pass criteria are met.

10.4.2 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. The screen shows both of the interleaved waveforms (in yellow and orange) and the average of the two (in white). Close agreement between the waveforms indicates that an ABR response is present, disagreement between them is a product of noise.

10.4.3 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.

10.4.4 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.

10.4.5 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, an electrode 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 10.2.2).

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.

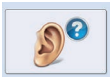
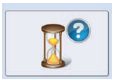
10.4.6 Test stop reasons

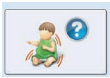
When the stop criteria have been met, the test will stop automatically and a single beep will sound for an ABR pass result or a double beep for any other result.

When the test stops a result 4raphic is displayed on the screen, see **ABR Test Results** 10.4.7 for more details. Select **OK** to accept the test stop reason. The result is then displayed at the top of the test screen.

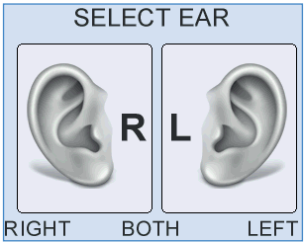
10.4.7 ABR test results

The following table lists all possible test results and associated graphics. The table gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
ABR Pass 	The data collected has met the criteria set. The optimum test setting will depend on your application, e.g. screening or clinical measurement (see chapter 15 **Test setup**).
Note: The following results will occur if a Pass is not obtained.	
No Valid ABR 	The data collected has not met the set pass criteria and the test conditions were acceptable.
Noisy 	The noisy data collected is three times greater than the low noise data collected.
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.
Stopped Too Soon 	The test has been ended manually before the minimum amount of data had been collected.
Atypical Waveform 	The template correlation (TC) is low but Fsp is high (only obtained in PC2 and PC3). An ABR has been detected but it did not match the neonate template. This might occur if an adult were tested or if electrodes were incorrectly connected.

High Mains Noise 	Interference from electrical equipment prevented the test from passing. The Fsp pass threshold was elevated due to this interference and the Fsp did not reach this higher threshold.
High Impedance 	The electrode impedances measured at the end of the test were high and may have prevented an ABR from being recorded. This could be caused by electrodes becoming disconnected from the patient during testing.
High EEG Noise 	Electrical noise during the test prevented an ABR from being recorded. This occurs when the noise at test end is above 40nV and is most likely caused by the baby being unsettled during the test (myogenic interference).

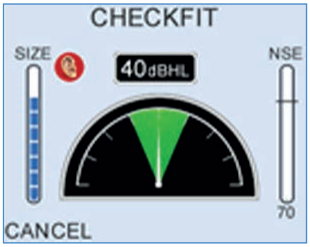
10.5 Bilateral ABR testing

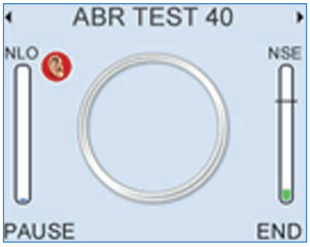


Bilateral ABR tests automatically run tests on both ears in sequence, right ear then left ear. Ear cups are recommended for bilateral testing and both ears should be prepared before testing commences. The current test ear is indicated during the test by a blue or red icon on the test screen.

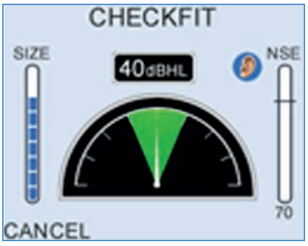
Checkfit and Test

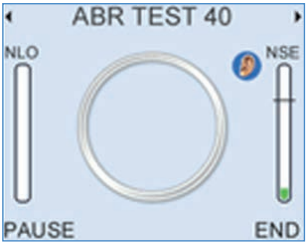
Right ear



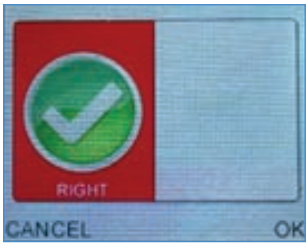


Left ear

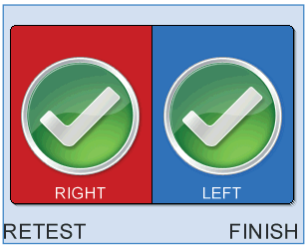




When the right ear is completed the test result will be displayed briefly before testing on the opposite ear starts.

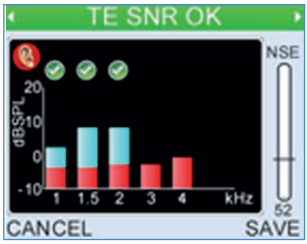


When both tests are complete, stop reason icons for both ears will be shown on the screen together. The same stop reason graphics used for single ear tests (see section 10.4.7 **ABR test results**) are used for the Right and Left ear results.



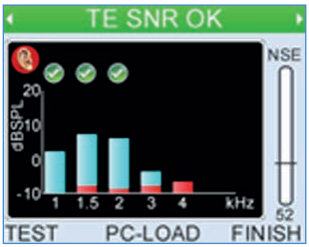
It is not possible to review bilateral ABR tests in detail at the end of test. If you wish to review the tests select the **History of Last** option from the patient menu (see chapter 8 **Patient details**).

11 Saving a test



When a test is completed, select **Save** to save the result (the display will vary depending on the type of test performed). Select **Cancel** to discard the result; a confirmation screen is provided which gives the option to restart the test at **Checkfit.**

11.1 Test review screens



When the test record has been saved to the database the test screens are displayed again to allow for further review of the data collected. The left/right arrow keys can be used to toggle between the test screen choices.

Select **Retest** to repeat the test.

Select **Print** or **PC-Load** to print or download the patient details and test result (see chapter 16 **Transfer** for further details).

Select **Finish** at any time to close the **Test Review Screens** and return to the **Patient Menu**.

12 Records

12.1 Records menu

Select **Find** to search for saved **Patient Records** within the database.

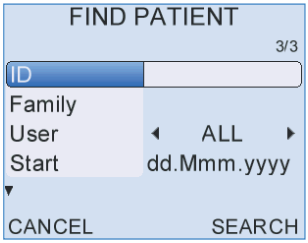
Select **Work List** to edit or add a new patient to the **Worklist.** The **Worklist** can be reviewed and a patient selected to test.

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

Select **Erase all** to delete all tests in the database.

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

12.2 Find patient



The Otoport provides powerful database search facilities. The **Find Patient** screen gives the option to search and filter the **Patient Records** by specific criteria.

Enter characters to filter for patients by **ID**, **Family** name, **First** name or **Mother**'s name.

Filter by **User** with the left/right arrow keys.

The **Start** and **End** dates provide the option to search for patient tests within the specified date range.

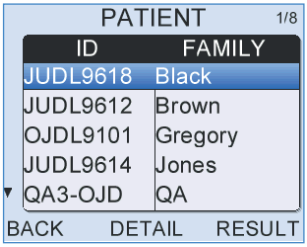
Enter a date in **D.O.B.** to filter by date of birth.

The number on the right at the top of the screen shows the number of patients in the database; the number on the left specifies the number of patients who match the search criteria entered. This number updates as search criteria change.

Select **Search** to display the **Patient List** meeting the search criteria.

Select **Cancel** at any time to return to the **Records Menu**.

12.2.1 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.

12.2.2 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.

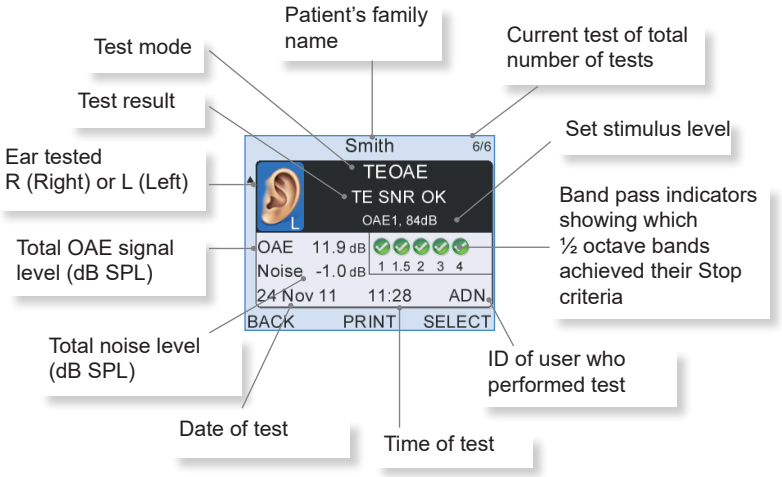
The number of tests currently saved to the patient is displayed in the top right of the screen. Press the up/down arrow keys to scroll between tests. The test number will increment accordingly.

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

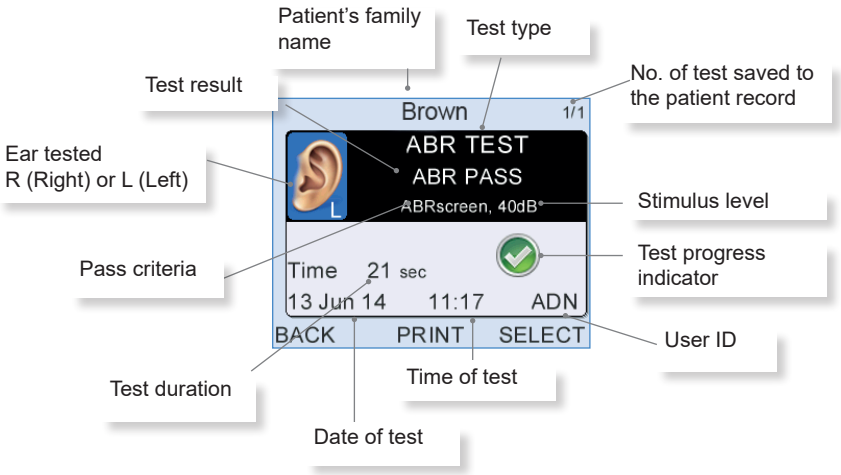
Choose **Select** on a **Test Summary** screen to analyse the test result in detail.

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



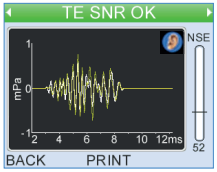
ABR test summary screen

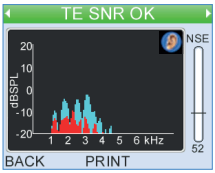


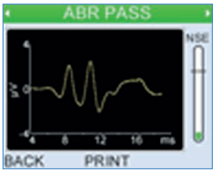
12.2.3 Detailed test review

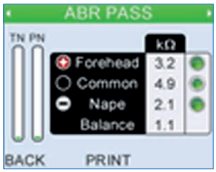
Test Results can be reviewed in detail by choosing **Select** on the **Test Summary** screen. The OAE test data is shown on various test screens. Please refer to chapters 7 and 8 for a full description of the screen displays for the relevant test type.

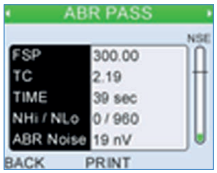
Use the left/right arrow keys to scroll between the screens.





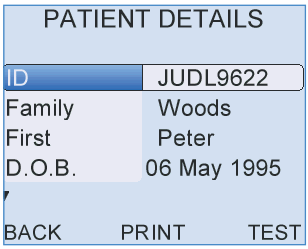






Select **Back** at any time to exit and return to the **Test Summary**.

12.2.4 Review patient details in database

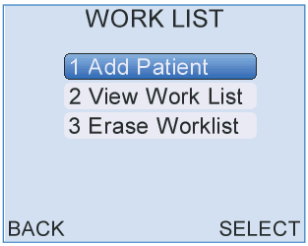


A non-editable version of highlighted **Patient Details** can be reviewed by selecting **Detail** in the **Patient List**. Please refer to chapter 6 **Patient Details** for a full description of the screen format.

Select **Test** to start the test for this patient. Please refer to chapter 9 **TEOAE Test** for an explanation on how to setup and perform a test.

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

12.3 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.

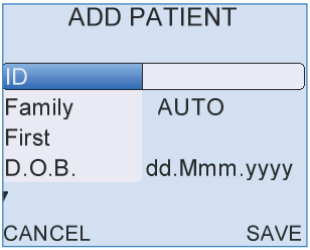
Select **Add Patient** to add a new patient to the work list.

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**.

12.3.1 Add patient

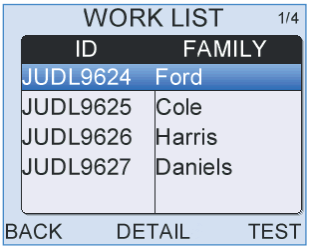


A new patient can be added to the current **Work List** by entering their **Patient Details** in the **Add Patient** screen. The screen format and data entry is identical to entering patient information when performing a test. Please refer to chapter 6 **Patient Details** for guidance on entering data 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.

12.3.2 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.

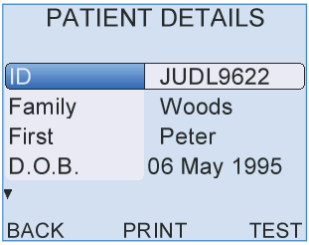
Select **Detail** to review the complete **Patient Details** of the highlighted patient.

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**.

12.3.3 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 7 **TEOAE Test** for an explanation on how to setup and perform a test.

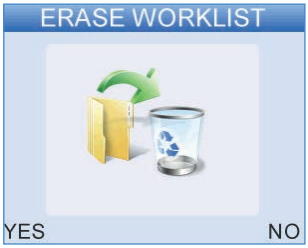
Select **Options** to view a pop-up menu giving a choice to **Edit** Patient Details or **Delete** the patient from the **Work List**.

Choose **Select** when **Edit** is highlighted to show an editable version of the **Patient Details**. Please refer to chapter 6 **Patient Details** 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.

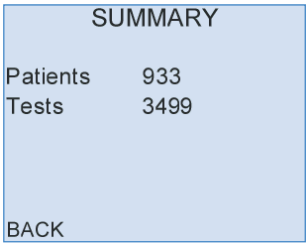
Select **Back** to return to the **Work List**.

12.3.4 Erase work list



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

12.4 Database summary

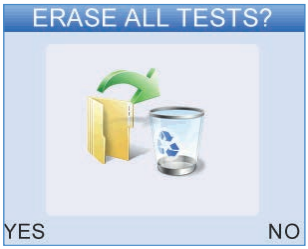


A database **Summary** can be accessed from the **Records Menu** screen. It details the present number of **Patients** and **Tests** saved to the database.

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**.

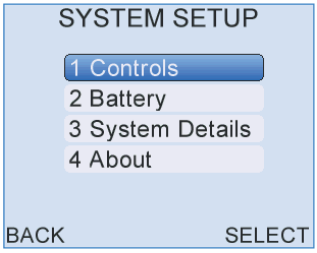
12.5 Erase all



The **Erase all** function will delete all tests stored in the database. It is then necessary to confirm the erase request to help eliminate accidental deletion.

Select **Yes** to **Erase all tests** or **No** to leave the records stored on the Otoport.

13 System



13.1 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.

13.2 Controls menu

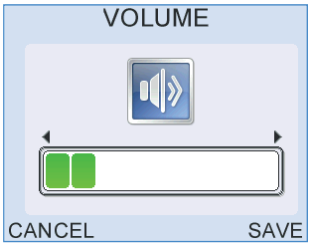
Select **Volume** to increase or decrease the unit's volume level or to turn sound off.

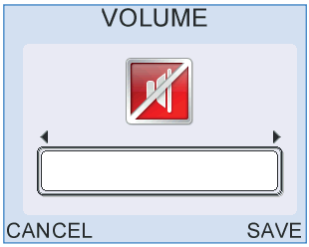
Select **Brightness** to adjust the brightness of the screen for varying light conditions.

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

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

13.2.1 Volume



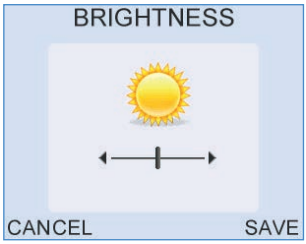


Use the left/right arrow keys to decrease or increase the **Volume** level. To turn the sound off press the left arrow key repeatedly until the red mute symbol appears in the centre of the display.

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

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

13.2.2 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**.

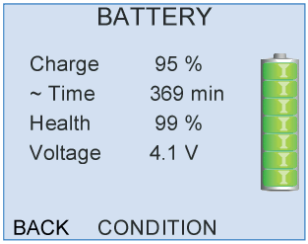
13.2.3 Backlight

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**.

13.3 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:

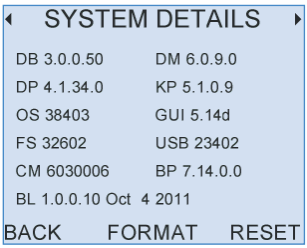
Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

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.

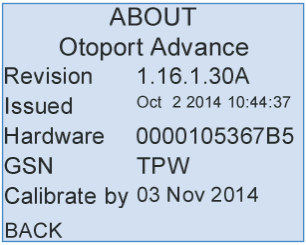
Select **Condition** to condition the Otoport battery. See chapter 21 **Otoport power** for more information.

13.4 System details



System Details displays information for Otodynamics engineers. The device performs electrical self-checks and any errors during these tests are displayed (see section 22.3 in **Troubleshooting** for further details).

13.5 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.

14 Management

14.1 Management menu

Select **Users** to add a **New User** or to review and edit the current **User List**.

Select **Facility & Risk** to enter custom **Facility** or **Risk Factor** options.

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.

14.2 Users menu

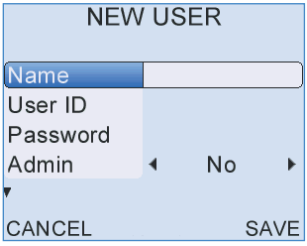
Select **Add New User** to enter details of a new user and save to the **User List**. Adding users to the Otoport allows test results to be attributed to individuals and allows password control of areas such as test setup.

Select **View Users** to review, edit or delete users from the current **User List**.

Select **Login** to turn the login function on or off.

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

14.2.1 Add new user



To add a **New User**, complete the field entries shown on the **New User** screen. The table on the next page describes the field choices available.

Field	Description	Max No. Characters
Name	User's name that appears at Login	8
User ID	The user's unique identification This is attached to a test record when saved to the database	3 (capitalised only)
Password	An alphanumeric password required for secure login.	8 (capitalised only)
Admin	Select **Yes** to give the new user administrator access rights Select **No** to restrict the user to user rights (described below)	N/A N/A
Location	Where the default test will be performed - either Inpatient, Outpatient or at Home	N/A
Facility	The default name of the hospital, clinic etc. where the test will be performed (configurable choices)	N/A
NICU	Are patients tested by this user predominantly in the neonatal intensive care unit, **Yes** or **No**?	N/A

The **User ID** is added to a saved test record to identify the user who performed the test. The **User ID** must therefore be unique and the message **Cannot Save! User ID already exists** will appear on **Save** if the chosen **User ID** is already associated with a current user. The device will return to the **New User** screen where the **User ID** field will be selected for editing.

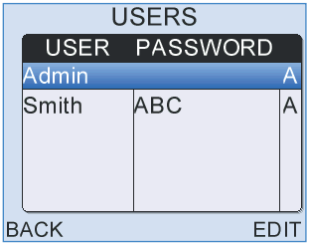
A new user is given a choice of two levels of access rights. If **Yes** is selected in the administrator field then the user will have full access to all modules of the device. Select **No** to restrict the user's rights to only **Test**, **Records**, **Probe**, **Print** and **System** modules.

Default **Location**, **Facility** and **NICU** options can be set for each user. On future login by the user, the **Patient Details** for each new patient will switch to these default options. If a test is not being performed in the normal testing location the default options can be easily changed when entering **Patient Details**.

Selecting **Save** will add the user to the **User List**. The **User List** will appear with the newly saved user highlighted on screen. The message **Cannot Save! Please enter Name and User ID** may appear on press of **Save** if either of these two fields have been left unfilled.

Select **Cancel** to cancel the addition of a **New User** and return to the **Users** menu screen.

14.2.2 View user list

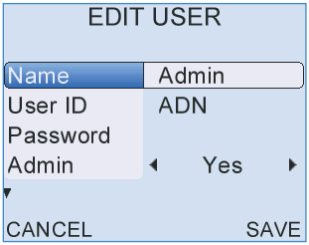


The **User List** displays the **Name**, **Password** and **Status** of all users currently saved to the device.

If a user has been assigned Administrator rights then an **A** will be present in the right hand Status column of the table.

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

14.2.3 Edit user



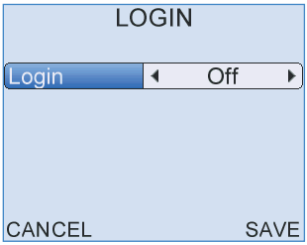
Select **Edit** to alter the details of a highlighted user.

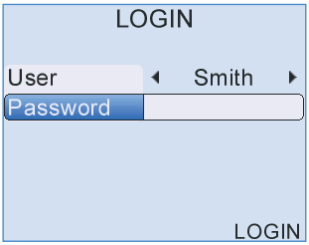
Select **Save** to save changes to the user's details and return to the **User List**.

Select **Delete** to remove the selected user from the **User List**. A confirmation message will appear at the top of the screen. Select **Yes** to confirm the deletion or **No** to retain the user and return to the **Edit User** screen. It is not possible to delete the default "Admin" user.

Select **Cancel** at any time to discard changes and return to the **User List**.

14.2.4 Login





The Otoport provides the option of User Login. When Login is switched on, the **Login** screen will appear automatically following device switch on.

Check that the correct **User** name is displayed. The Otoport will remember the last user of the device and automatically default to that user at the next login. Use the arrow keys to select a **User** from the choice bar if necessary.

Once a **User** is selected, use the arrow keys to return to the password entry row and the data entry keypad to enter a corresponding **Password**.

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

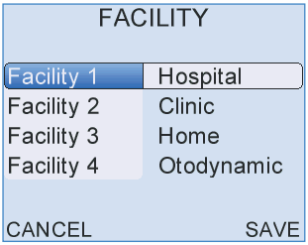
Once both **User** and **Password** have been added, select **Login** to access the device. If the **Password** has been entered incorrectly then a warning message will appear as below:

14.3 Facility and risk

Select **Facility** to edit the name of the hospitals or clinics where the device is commonly used.

Select **Risk Factors** to view or customise the list of 15 patient risk factor choices available.

14.3.1 Facility

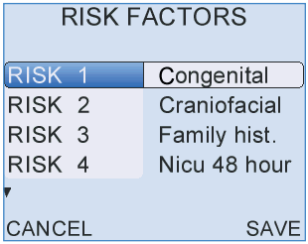


The **Facility** screen allows a user with administrator access to modify the choice of four **Facility** names. The name should be no longer than 10 characters and identify the hospital, clinic or other locality where the device is to be regularly used. These options are then presented in the **Facility** choice bar when entering new **Patient Details** and during the creation of a **New User** account. Please see relevant chapter entries for further information.

Select **Save** to save changes to the **Facility** list and return to the **Defaults Menu** screen.

Select **Cancel** to return to the **Defaults Menu** screen and discard changes made to **Facility** names.

14.3.2 Risk factors

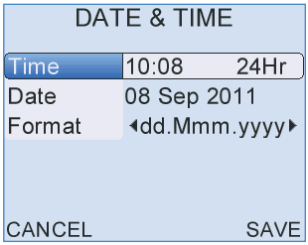


The **Risk Factors** screen allows a user with Administrator access to modify the list of 15 risk factors available. The name chosen to identify each risk factor should be no longer than 12 characters.

Select **Save** to save changes to the **Risk Factors** list and return to the **Defaults Menu** screen.

Select **Cancel** to return to the **Defaults Menu** screen and discard changes made to **Risk Factor** entries.

14.4 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.

The date format can be changed from dd.Mmm.yyyy to dd.mm.yyyy or mm.dd.yyyy for use in the USA.

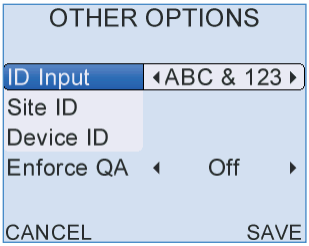
Select **Save** to set the current date and time settings and return to the **Management Menu** screen.

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.

14.5 Other options



Other Options are available to customise the use of the device within a specified testing environment.

14.5.1 ID Input

The **ID Input** choice bar can be used to alter the input format of the **Patient's ID** field. When adding new **Patient Details** characters will be restricted for Patient ID input according to the chosen format. Below is a table listing the options available.

ID Format	Description
123	Numeric only
123&ABC	Alphanumeric
ABC	Alpha only

14.5.2 Site ID

The **Site ID** is a three-letter site identifier and will be saved to each test record. The ID cannot be changed until all data has been downloaded from the database and the database has been cleared.

14.5.3 Device ID

The **Device ID** is a six-letter device identifier. This could be used to give simple identification of a unit if multiple units are used in one site, for example using colours to code such as yellow, blue etc. The **Device ID** will be saved to each test record so it cannot be changed until all data has been downloaded from the database and the database has been cleared.

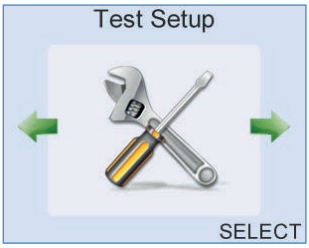
Select **Save** to save changes and return to the **Management Menu** screen.

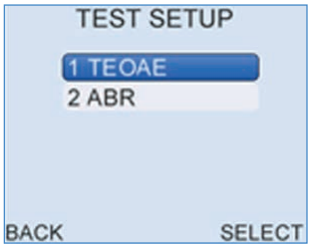
Select **Cancel** to discard changes and return to the **Management Menu** screen.

14.5.4 Enforce QA

Enforce QA offers users the ability to turn mandatory QA checks on or off, and thus enabling or disabling daily QA check's before performing patient testing (See section 17.5 QA area).

15 Test set-up





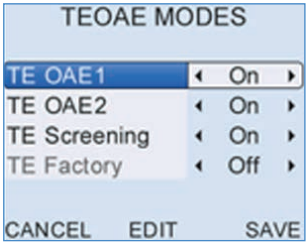
15.1 Test setup menu

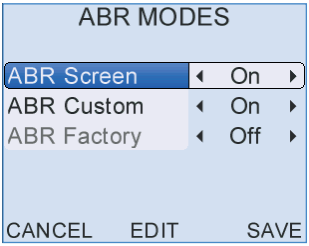
The Otoport provides comprehensive test configuration settings to enable you to tailor the device to specific testing requirements. Flexible programmable Stop criteria control the device's OAE/ABR detection logic, where the device will automatically end the recording when the criteria have been met.

There are 7 separate test modes (four TE and three ABR), that may be set by the user. The user may choose between any of these at the time of test. The factory modes are non-editable.

The test set-up area allows configuration of each mode and for the modes available at the time of test to be chosen.

Select **TEOAE** or **ABR** to view the test modes.





Modes which are **On** will be available for selection at the start of test. Modes which are **Off** will not be available. If only one mode is **On** then a test in this mode will begin automatically when a test is started. Scroll down using the arrow keys to see all the modes.

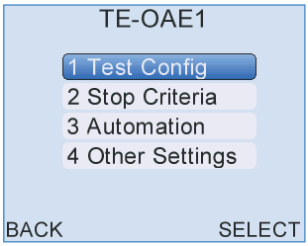
Switch each mode **On** or **Off** using the arrow keys.

Select **Save** to keep any changes you have made to the modes available at the start of a test. A message confirming the save will be shown briefly.

Select **Cancel** to return to the **Test Setup** menu screen without saving changes to the available test modes.

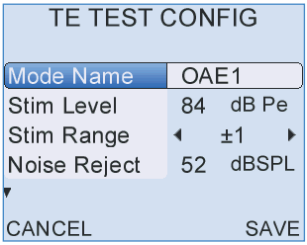
Select **Edit** to edit the highlighted mode. See the next section for further details.

15.2 Edit mode menu



The mode selected for edit is displayed at the top of the screen. The available parameters depend on the mode type (ABR or TE) selected. Choose the section to edit then **Select**. It is not possible to edit the ABR or TE factory modes.

15.3 Test config



Various test parameters can be configured in this area. Up and down arrows on the screen indicate other fields are available, but not currently visible. Use the up/down navigation keys to scroll up and down the settings and highlight a parameter to edit. The parameter variable will flash. Use the left/right arrow keys to change each setting. See the following tables for details of the settable test parameters.

15.4 Selecting the appropriate stimulus level

Otodynamics instruments differ in the facility to change stimulus levels.

Where the stimulus is pre-set and unchangeable on a screening instrument, the stimulus level will have been chosen on the basis of independent trials reported in the literature which reliably alerts to the possibility of a mild loss.

Where the stimulus level is changeable on an instrument it is important to select the stimulus level appropriate for your purposes. For screening, the level selected will affect the sensitivity of the device to mild losses. A stronger screening stimulus will result in some patients with mild cochlear losses passing a screening test. For clinical diagnostic purposes stronger stimulation can be useful in identifying residual outer hair cell function with mild to moderate losses.

15.5 Selecting levels for TEOAE screening

- For TEOAEs a peak equivalent stimulus level of 84dBSPL has been extensively tested in controlled screening trials and found to detect mild losses. This level is currently adopted by major infant screening programs, as the initial screen, followed up by AABR screening at either 35 or 40dBHL.

15.6

TEOAE test config

Field	Description
TE mode name	User settable mode name *Range: 8 characters max*
Stim level	Peak target stimulus level for testing *Range: 70-90 dB pe*
Stim range	Stimulus OK range – the permitted change in stimulus level during TEOAE testing before probe movement warnings are provided. If the stimulus is out of range, the Stimulus OK indicator will extinguish and the screen will display 'Check probe fit'. *Range: +/- 1, 2 or 3dB*
Noise reject	The threshold of noise permitted during a test above which causes data to be rejected from the final result. Reducing the noise reject level could result in better quality data collected, but less data will be accepted if there is noise, which could result in a longer test time. Increasing the noise reject level will allow more data to be collected in noisy conditions. This could have a negative affect on data quality as it could contain more noise and there is an increased risk of noise artefacts. *Range: 40-74 dB SPL*
Ring alert	Controls the sensitivity of a warning provided if the stimulus becomes oscillatory and rings. Stimulus ring only occurs in large ear canals, so is not an issue when making OAE measurements on newborns. A ringing stimulus can increase the risk of a stimulus artefact. The Otoport displays 'Ringing' during checkfit, to warn the users if the stimulus is ringing (see fig. 1). In most ears, the stimulus click becomes 'flat' following the click stim (see fig. 2), but in longer large ear canals the stimulus can oscillate for longer. The Ring alert displays the ratio in dB of the peak stimulus over the stimulus level recorded at 3 milliseconds. *Range:-10 to -30dB*

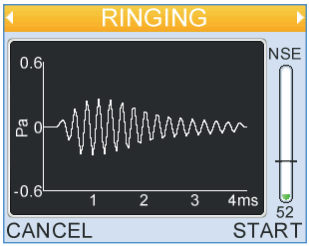


Fig 1

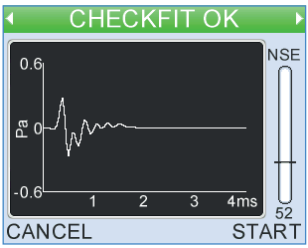


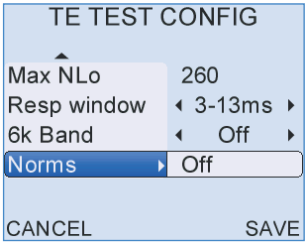
Fig 2

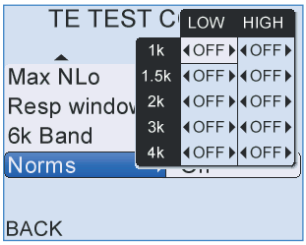
Field	Description
Max NLo	This is a test timeout function, which stops the test when the specified number of low noise data samples (when the noise present is below the reject level) has been collected. *Range: 10-990*
Max time	The maximum time the test will run before automatic stop. *Range: 10-900 secs*
TE response window	The TE response window sets how long after the presentation of the stimulus the recording of the measured response starts and ends. So, setting 'response window' to 3-13 ms means that the response is measurement begins 3ms and ends 13ms after the stimulus was presented. The structure of the cochlea means that low frequency OAEs occur longer after the stimulus than higher frequency OAEs. The 3-13ms response window captures TEOAE responses across a wide frequency range. The 3-9ms response window captures a narrower frequency range of emissions but includes the period in which the largest emissions are generally recorded. Because it includes only the period when emissions are strongest this setting can improve the Signal to Noise Ratio (SNR) of the recording. Used in combination with the narrow 1600-3200Hz noise filter the 3-9ms sometimes enables TEOAE testing to take place in noisy environments which prohibit testing with other settings.
6K Band	Sets whether waveform energy in the half-octave frequency region centred 6kHz is displayed. The 6kHz OAE response is often absent in waveforms recorded in normal ears as the emission occurs very early following the stimulus and is often lost within the stimulus waveform. However, 6kHz emissions can be recorded especially in neonate ears and their presence may be clinically significant. *Range: On or Off*

Note:

If the maximum test time specified is not long enough for the device to complete the max NLo requirement, then the test time is automatically reset to longer than the Max NLo.

When **Norms** is set to **On** a pop up table enables configuring of **Low** and **High** norms for each frequency test point. Use the up/down arrow keys to select the parameter to edit and to move between the **Low** and **High** columns and left/right arrow keys to edit the settings. Move down at the bottom of the **High** column to edit the **Low** column. Select **Back** and then **Save** to save changes to the table settings. Select **Cancel** to discard changes.





15.7 ABR test config

Field	Description
Mode name	User settable mode name *Range: 8 characters max*
Stim type	Stim type sets the stimulus type used in the ABR test. The types available are ‘click’ and ‘chirp’. See chapter 25 **Mode of operation** for further details of these stimulus types. The chirp stimulus has been demonstrated to give a larger ABR response for the same stimulus level.
Stim level	Peak target stimulus level for testing. *Range: 5-60 dBHL* In ear cup mode, the stimulus level limits are 40dBHL when the stimulus type is chirp and 30dBHL when the stimulus type is click.
Max NLo	This is a test timeout function, which stops the test when the specified number of low noise data samples (when the noise present is below the reject level) has been collected. *Range: 1,920 to 32,000 sweeps*
Max time	The maximum time the test will run before automatic stop. *Range: 600-990 secs*

15.8 Stop criteria

The test stop logic is controlled in this section. Up and down arrows on the screen indicate that other fields are available, but not currently visible. Use the up/down arrow keys to scroll up and down the settings and highlight a parameter to edit. The parameter variable will flash. Use the left/right arrows to change each setting.

15.8.1 OAE Stop criteria

When **Setup Bands** is selected a pop up table enables the edit of each band criteria. Use the up/down arrows to select the parameter to edit and to move between the **SNR** and **RQRD** (required) columns and left/right arrows to edit the settings. Move down at the bottom of the **SNR** column to edit the **RQRD** column. Select **Save** to save changes to the table settings. Select **Cancel** to discard changes (DP tests only).

See the following tables for details of the settable Stop criteria.

TEOAE Stop criteria

Field	Description
Min NLo	The minimum number of low noise data samples (when the noise present is below the reject level) required for autostop that has to be collected. *Range: 10 to 222*
Min OAE sig	The minimum total OAE signal level required. *Range: -10 to 20 or Off*
Min SNR	The minimum required total signal to noise ratio (the difference in the total noise and total signal required). *Range: 0 to 20 or Off*
Min band sig	The minimum level of OAE signal required in each band. *Range: -10 to 20 or Off*
Pass bands	The minimum number of band passes required in order to meet the overall Stop criteria. *Range: 1 to 5*
Setup bands:	
Min SNR	The minimum signal to noise ratio required for a band pass. *Range: 1 to 1 or Off*
RQRD	Controls which bands are mandatory for a pass to be achieved. Scroll down past the bottom of the SNR column to reach the RQRD column. *Range: Yes/No*

Note:

It is possible to turn off some settings, which means the parameter will not be included in the Stop criteria logic.

15.8.2 ABR Stop criteria

Pass criteria

Pass criteria sets the conditions in which the ABR test will give a pass result.

Pass criteria is based on a statistical measure similar to signal to noise ratio known as Fsp, and a measure of the extent to which the averaged response waveform resembles a typical neonate ABR, a value referred to as template correlation (TC).

Fsp is the principle determinant of a Pass. It must achieve a minimum *fixed Fsp* or *dynamic Fsp* level. The *dynamic Fsp* threshold rises if power line noise is a large part of the electrical noise measured in order to account for any possible contribution of the powerline noise to Fsp (to ensure that the powerline noise is not mistaken for an ABR). The minimum *fixed Fsp* threshold is higher than the largest Fsp ever likely to be achieved by chance in EEG noise.

The *minimum TC* requirement should be achieved when recording an ABR waveform from a neonate (34 weeks to 6 months gestational age). The *strict TC* requirement is higher than largest TC ever likely to be achieved by power line interference.

The two measures Fsp and TC are combined in four different ways as follows:

PC1 requires:

Fsp level exceeds the dynamic Fsp with no template requirement

PC2 requires:

Fsp level exceeds the dynamic Fsp and TC exceeds the minimum TC level

PC3 requires:

Fsp level exceeds the dynamic Fsp and TC exceeds the minimum TC level

Or

Fsp level exceeds the minimum Fsp and TC exceeds the strict TC level

PC4 requires:

Fsp level exceeds the dynamic Fsp with no template requirement

Or

Fsp level exceeds the minimum Fsp and TC exceeds the strict TC level

When to use each PC

PC1 is ideal for performing an ABR test on adult subjects and is the default setting for ABRcustom mode. It is useful for training, demonstration and clinical investigations.

PC2 is designed for neonate screening and is the default setting for the ABRscreen mode.

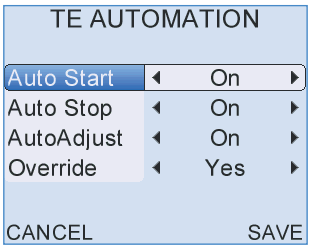
PC3 and PC4 may give higher specificity in challenging noise environments, potentially passing healthy ears securely even when interference levels are high. Both are designed for neonate screening but PC4 can also be used with adult ears.

15.9 Automation

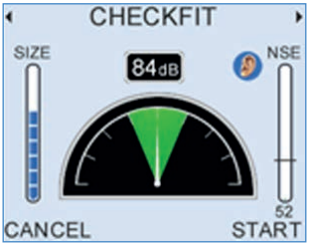
The Otoport has programmable automation logic to enable the user to configure the test routine to their preference. The test process can be set to be fully automated or manually operated, depending on the desired control over the test.

All settings have an **On/Off** or **Yes/No** option. Use the up/down arrows to highlight a setting and use the left/right arrows to change the choice bar setting.

15.9.1 TE automation



Auto Start



With **Auto Start On**, the stimulus level will automatically be adjusted to the testing target stimulus and the test will commence automatically. The device will check if the probe fit is stable and will not adjust or start the test until a good probe fit is obtained.

With **Auto Start Off**, it is necessary for the user to select **Start** to begin recording from the **Checkfit** stage.

Auto Stop

With **Auto Stop On**, the test will stop when the Stop criteria are met.

With **Auto Stop Off**, the test will timeout in accordance with the maximum NLo figure (amount of data accepted into the result, when the noise present is below the reject level) set in **Test Config**.

Autoadjust

If **Autoadjust** is set to **On**, during the test Checkfit stage the click stimulus will automatically adjust its level to the target stimulus set, compensating for different ear canal volumes. The stimulus will only adjust when the probe fit is stable. Select **ADJUST** to manually initiate stimulus adjustment.

If **Autoadjust** is **Off** it is necessary for the operator to select **ADJUST** during the test Checkfit stage. This will initiate the stimulus adjustment process.

Override

When **Auto Start** is **On**, the **Override** setting controls the option for the user to manually start the test overriding the **Auto Start** function.

If **Override** is **On**, the **Start** option is available on the Checkfit screen to force a test start, when the conditions are not optimum and the Otoport has not automatically started the test.

If **Override** is **Off**, the **Start** option override is not provided to start the test manually.

15.9.2 ABR Automation

Auto Start

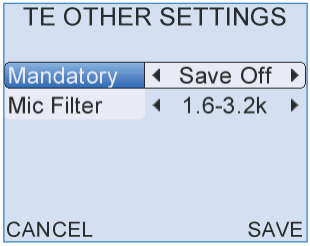
If **Auto Start** is ON then the ABR test will proceed from the Impedance Check screen to data collection (autostart) without any action from the tester if test conditions are good.

If **Auto Start** is OFF the tester determines when to proceed from Impedance Check to data collection (manual start).

Auto Stop

The **Auto Stop** setting controls whether the test automatically stops when the pass criteria are met. If Stop is turned OFF, the test will run for longer, but the ABR levels will be more accurately measured. If Stop is ON when screening, the test will be as short as possible.

15.10 OAE Other settings



15.10.1 Mandatory

The **Mandatory** save setting controls whether tests started have to be saved. This option may be useful if you would like to save all tests performed. This can be useful for statistical purposes if you wish to collect information, for example on the number of test attempts conducted per patient.

Set **Mandatory Save On** to save all tests. During the test it will be possible to **Pause** the recording, but not **Cancel** and it will not be possible to conduct another test without saving the data.

With **Mandatory Save Off**, it is possible to **Cancel** the test or abort the data saving process.

15.10.2 TEOAE Mic filter

It is possible to select various **Mic Input Filters** on the Otoport, which can be helpful when testing in various environmental noise conditions.

There are four filter settings provided. Frequencies outside the filter range will be attenuated.

The best filter to use depends on both the noise level in the test environment and on the purpose of the test.

A narrower filter allows easier testing in noise, while a wider filter gives a better indication of OAE signal level across all frequencies. Narrower filters are most useful in screening while wider filters are preferred in diagnostic applications.

Environmental noise is normally greatest at low frequencies while the TEOAE signal is normally strongest in the middle frequencies. This means that filtering out low frequencies reduces noise levels more than OAE

signal levels making it easier to record OAEs in noisy environments. There is also some advantage in filtering high frequencies. However, a narrower filter range reduces the OAE signal levels recorded at high and low frequencies. The attenuation at high and low frequencies does not affect the signal to noise ratio (SNR) obtained at these frequencies as both signal and noise are equally attenuated.

0.4-6.4k (400-6400Hz): Collects data at the widest frequency range and should be used if the **6k Band** (see 15.3 **Test configuration**) is turned on as it gives the least high frequency attenuation.

0.8-4.8k (841-4757Hz): Attenuates OAE signal and noise collected at 1 and 4Khz, by a few dB. This works well in most diagnostic environments.

1.2-4.8k (1189-4757): Signal and noise will be attenuated by around 6dB at 1 kHz and 3dB at 1.5khz. Data at 4kHz is also attenuated by a few dB. This filter works well in screening applications where frequency specific information is required and in noisy diagnostic environments.

1.6-3.2k (1600-3200Hz): Signal and noise are significantly attenuated in the 1, 1.5 and 4kHz bands. This filter provides poor frequency specific information. Ideal for screening in noisy environments with a pass criteria based on overall OAE level rather than ½ octave band passes (see 15.6 **Stop criteria**).

15.11 ABR Other settings

15.11.1 Neonate mode

With **Neonate** mode **On** the user is warned if the response from the probe indicates a large ear canal. This provides an additional check of probe fit for users who are testing only babies.

The warning message is displayed after Checkfit and before the test starts.

Selecting **Start** will start the test as normal. 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.

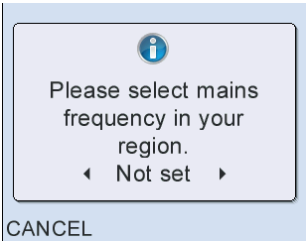
With **Neonate** setting Off, no warning message is displayed if a large ear volume is detected.

15.11.2 ABR Mains

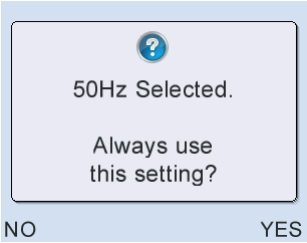
ABR mains sets the ABR test configuration for optimum test recording in mains (powerline) noise. The mains frequency varies in different countries. Set **50Hz** if the mains in your region is 50Hz and **60Hz** if your region is 60Hz. Set **Not Set** if you are unsure of the mains frequency in your region.

Setting ABR mains from the main menu

If ABR mains is Not Set then you will be prompted to set it when an ABR test is selected from the main menu:



Use the arrow keys to choose 50Hz or 60Hz then press Select. You will be prompted to confirm whether to 'Always use this setting?':



Select No if you are unsure of this setting and wish to leave ABR mains Not Set. Select Yes to permanently change the ABR Mains setting.

Note that changing the setting of ABR mains in one test mode will also change the setting in other ABR test modes.

15.11.3 Ear cups

This setting allows the use of ear cups and it can be set in three different ways:

Off - Will always go into test assuming ear cups are not being used.

Auto - Will detect whether ear cups are being used and prompt the user before test if ear cups are being used or not.

On - Will always go into test assuming ear cups are being used.

15.12 Test setup defaults

15.12.1 Default Mode descriptions

Below is a description of each of the default modes available with the mode settings detailed in the tables following.

TE Modes

Screening mode is designed for rapidly detecting the presence of TEOAE in poor testing conditions. It is fully automated, stopping when an OAE has been detected. The TEOAE response is recorded over narrow frequency and time windows. The total OAE recorded across frequencies (not the levels recorded in half-octave bands) is used as a stop criteria. The filters used mean that the TEOAE recorded at frequencies above 3.2kHz and below 1.6kHz are reduced so this mode should not be used if frequency specific information is required. The mode is similar to that used in the Otodynamics Echocheck.

OAE1 mode is designed for general clinical TEOAE measurement in the range 1-4kHz. Users manually start and end the test. At test end three half-octave bands are required for a pass.

OAE2 is a replication of the settings used for the Universal Newborn Hearing Screening Programme in England. It is similar to OAE1 but requires only two half-octave bands for a pass and does not included 1kHz among possible pass bands. The **Mic Filter** setting is narrower than OAE1 reducing the TEOAE recorded at 1kHz.

Factory mode cannot be edited and is designed for Quality Assurance purposes.

ABR Modes

The ABR Screen mode is intended for newborn hearing screening.

The default setting is 40dBHL. You should set this level only if directed to you by your screening program manager.

The stimulus level should be set to the lowest value compatible with the aims and targets of the hearing screening program. For high sensitivity detection of even slight hearing impairments the Otoport 35dBnHL setting has been successfully used. At this stimulus level the number of unnecessary referrals (i.e., false positives) will be higher than with 40dBHL stimulation. Many major infant screening programs (e.g., UK English, and

Welsh national programs) use the 40dBHL setting. They find it gives both good sensitivity to mild and clinically significant losses with an easily manageable refer rate. Typically, in the well-baby population, an OAE test fail is immediately followed up by an AABR screen using the Otoport. Note that screening with stimulus levels significantly above 40dBnHL is likely to miss some mild hearing losses.

- The **ABR Custom** mode is not intended for diagnostic use or ABR threshold determination.
- Stimulus levels higher than 45dBnHL can be useful in training sessions and in instrument function confirmation testing to allow more rapid acquisition of ABR in noisy environments. These levels should not be used for infant screening as they will miss mild to moderate losses.
- Fine adjustments of the stimulus level (1dB steps) are intended for the setting of precise (custom) stimulus levels e.g. for compatibility with prior screening practice.
- Low stimulus levels (down to 5dBnHL) can be used for the audiological confirmation (subjective testing) of the instrument's hearing level setting calibration

Notes:

The Otoport OAE+ABR dynamically adjusts the delivered sound pressure level to achieve the selected normal hearing level (nHL) for each test. The instrument will achieve the selected dBnHL in all sizes of ear including, for screening levels (30-45dBnHL), adult ears up to the volume of a neonate screening ear cup.

The Otoport OAE+ABR is capable of recording ABR responses from patients of all ages provided a non-template (Fsp only) pass criteria is selected (PC1 or PC4). However the specificity of the device has only been established for neonates and therefore it is not intended for use as screen for hearing loss in older children or adults.

TEOAE Test Setup Parameters

Mode Name	Screening		OAE 1		OAE 2		Factory (locked)	
TE Test Config								
Stim Level	84dB pe		84dB pe		84dB pe		84dB pe	
Stim Range	± 1dB		± 1dB		± 1dB		± 1dB	
Noise Reject	52dB SPL		52dB SPL		52dB SPL		52dB SPL	
Ring Reject	-20dB		-20dB		-20dB		-20dB	
Max NLo	260		260		260		260	
Max Time	300s		300s		300s		300s	
Response Window	3-9ms		3-13ms		3-13ms		3-13ms	
Norms	OFF		OFF		OFF		OFF	
6k Band	OFF		OFF		OFF		OFF	
TE Stop criteria								
Min NLo	30		30		40		40	
Min OAE Sig	0dB SPL		0dB SPL		0dB SPL		0dB SPL	
Min SNR	6dB		OFF		OFF		OFF	
Min Band Sig	-5dB		-5dB		-5dB		-5dB	
Pass Bands	1		3		2		3	
Band Settings	SNR	Rqrd	SNR	Rqrd	SNR	Rqrd	SNR	Rqrd
1K	6	NO	6	NO	OFF	NO	6	NO
1.5K	6	NO	6	NO	6	NO	6	NO
2K	6	NO	6	NO	6	NO	6	NO
3K	6	NO	6	NO	6	NO	6	NO
4K	6	NO	6	NO	6	NO	6	NO
TE Automation								
Autoadjust	ON		ON		ON		ON	
Autostop	ON		OFF		OFF		OFF	
Autostart	ON		OFF		ON		OFF	
Override	YES		N/A		YES		N/A	
TE Other Settings								
Mandatory	SAVE OFF		SAVE OFF		SAVE OFF		SAVE ON	
Mic Filter	1.6-3.2kHz		0.8-4.8kHz		1.2-4.8kHz		0.8-4.8kHz	

ABR Test Setup Parameters

Mode Name	Screen	Custom
ABR Test Config		
Stim Type	Chirp	Chirp
Stim Level	40dBHL	45dBHL
Max NLo	10240	10240
Max time	600 sec	600 sec
ABR Automation		
Autostart	On	On
Autostop	On	Off
ABR Stop Criteria		
Pass Criteria	PC2	PC1
ABR Other Setting		
Mandatory	Save Off	Save Off
Neonate mode	On	Off
Ear Cups	Off	Auto or On

16 Transfer

(printing and downloading)

Test results can be printed on the optional Otoport mini-printer or downloaded to PC for printing, archive or export. Wireless (via Bluetooth wireless technology) and wired (via supplied cables) connections are available for both functions.

The Transfer module sets up and initiates transfers.

16.1 Bluetooth wireless technology enabled printing and download

Wireless printing and downloading are only available on Bluetooth wireless technology enabled Otocheck ABR and Otoport instruments. If a Bluetooth module is fitted, a Bluetooth symbol (shown above) is included on the product label. Downloading can also be performed with a wired connection, using the cables supplied.

However, the Bluetooth connection supports *either* printing *or* downloading, not both (see **Transfer Menu below** to select which function is available). The softkey **Print** or **PC-Load** is shown on screen whenever the function is available.

Download via Bluetooth wireless technology requires that Otolink software is installed and that your Otoport is paired with your PC. The password for pairing is 4679. See your Otolink manual for full instructions.

When the connection to the PC is ready to send data the **PC-Load** text on the Otoport screen is green:

If the connection is not complete then the **PC-Load** text on the Otoport screen is black.

Bluetooth printing is described throughout this chapter.

Bluetooth is disabled when the Otoport is connected to a power supply (non US models only).

16.2 Wired downloading

Wired download is available at any time when a test is not in progress and the Otoprt database is not open. See the Otolink manual for details.

16.3 When you can print and download

The Otoport provides flexible options to print or download from various areas of the user interface, including at the end of the test, from the patient database and via a dedicated menu.

16.3.1 Printing or downloading at the end of a test

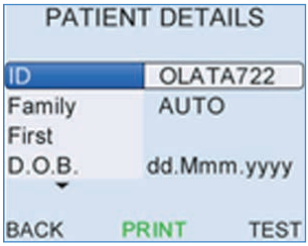
When the recording is finished and the result has been saved, select **Print** or **PC-Load** for a printout or download of the patient details and test

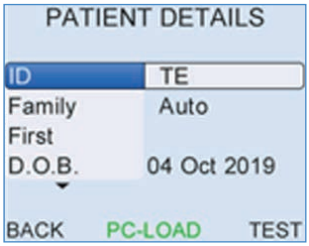
results.

16.3.2 Printing or downloading from records

Results can be printed or downloaded from the Otoport **Records** area. Select the patient for whom you would like to print results (see the section 12 **Records** for details of how to retrieve specific records from the database).

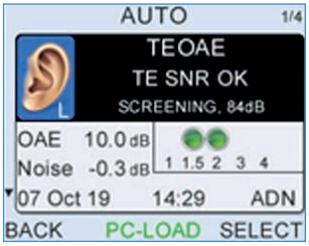
To print or download patient details and all test results for that patient,

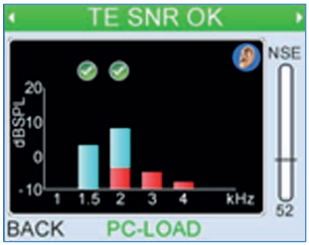




select **Print or PC-Load** on the **Patient Details** screen.

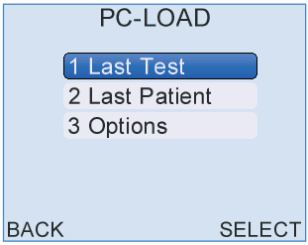
To print or download patient details and the result of a specific test, select the **Results** summary screen, scroll through the different tests for the patient (using the up and down arrow keys) and select **Print** or **PC-Load**,





or **Select** the test details and then **Print** or **PC-Load**.

16.4 # Transfer menu



From the Otoport **Transfer** screen, choose **Select** to open the Transfer menu, where it is possible to initiate prints or downloads for the **Last Test**, or **Last Patient**, as well as configuring **Options**.

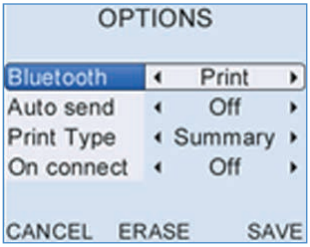
16.4.1 ## Last test

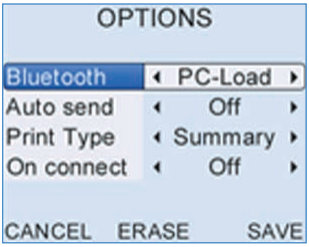
This transfers the last test recorded including the associated patient details.

16.4.2 ## Last patient

This option transfers all the test results for the last patient including their patient details.

16.4.3 Transfer options





Bluetooth wireless technology

Bluetooth sets how the Otoport's wireless communication will be used.

If **Bluetooth** is set to **PC-Load** then the Otoport can use Bluetooth communication to send test results to a PC. Details of how to set up wireless download to PC are included in your Otolink manual.

If **Bluetooth** is set to **Print** then the Otoport can use Bluetooth communication to send test results to the mini-printer.

Wireless printing and download are only available on Bluetooth wireless technology enabled Otoports. You can tell if a Bluetooth module is fitted, as a Bluetooth symbol is included on the product label on the back of the Otoport.

The function of the **Auto Send** and **End Data** options below are dependent on this setting.

Auto Send

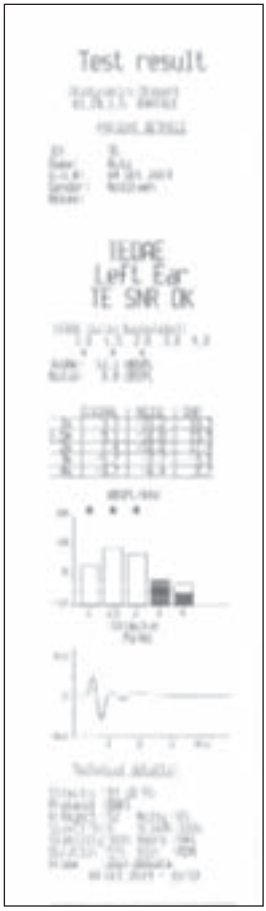
If **Auto Send** is set to **On** then the test result is automatically printed/ downloaded after the test is saved.

If **Auto Send** is set to **Off** then the user has the option to print/download the test after save.

Print type

There are two printing formats provided on the Otoport - **Summary** and **Detailed**. The Summary format prints core patient details and the test results. The Detailed format prints all the test details and a fuller set of patient details.

Example printout shown is of a TEOAE test.



On connect

On connect printing allows printing to be initiated as soon as a wired printer is connected. This is particularly useful if the Otoport is used with a Docking Station as it allows results to be printed as soon as the Otoport is dropped into the docking station.

On connect may be turned **Off** or set to print the last **Test**, all unprinted tests for the last **Patient**, or **All** unprinted tests.

Printing will only start if the Otoport is on and displaying one of the main module screens (see section 4.4).

If **Cancel** is selected during the print, three options are available:

If **Cancel Print** is selected, the Otoport will not attempt to automatically print the test(s) again (test may still be selected to be printed manually).

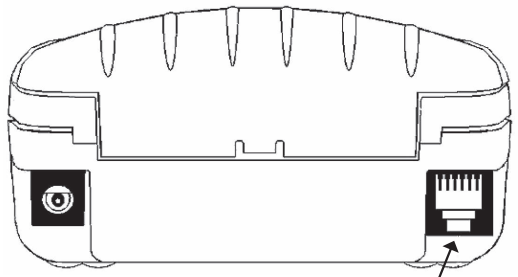
If **Retry** is selected then printing will recommence.

If **Stop On Connect** is selected then the **On connect** setting is turned off and the Otoport will not attempt to print tests on connection in future.

16.5

The printing process

If you are using the wired printing method ensure the printer is connected to the Otoport using the printing cable provided. Connect the flat connector to the Otoport with the arrows facing upwards and the square connector to the back of the printer.



Printer cable socket

The wireless printing method has a range of up to 10m in direct line of sight. It is recommended that the printing distance is reduced to 5m to help ensure robust communication. Remain within this range for the duration of the printout. Printouts will not complete if wireless communication is lost.

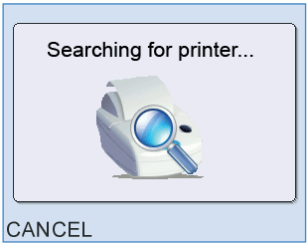
The **Print** option on the Otoport screen will be shown in green if the Otoport is currently connected to a printer wirelessly. Otherwise, the **Print** option is shown in black.

Note:

When using multiple Otoports with wireless connection to a single printer, the last Otoport to print must disconnect from the printer before another Otoport can print. To disconnect from the printer, exit the **Printing** menu, **Records** area or finish the test sequence.

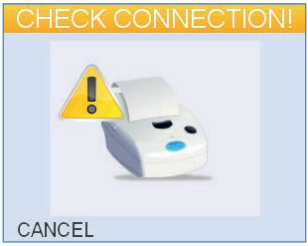
The printer is powered from batteries, or can be connected to mains power when printing. Prior to printing, switch on the printer, using the power key on the top. When the printer is powered, a green light will be displayed. To save power, the printer will automatically switch off after 30 minutes of inactivity. If it is connected to mains power, the printer will remain on indefinitely.

When a print is initiated, the Otoport will establish communication with the printer. The screen **Searching for Printer** will be displayed.

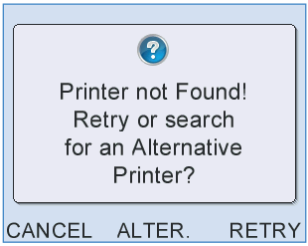


The printout will then commence. The screen will display **Printing** during the print process. Select **Cancel** to terminate the printout. When the printout is completed, the screen from which the print was initiated will be displayed.

If there is a problem connecting to the printer using the wired method, the message **Check Connection!** will be shown briefly and then the screen from which the print was initiated will be displayed. Check the printer is connected correctly and switched on then re-try. If the printer continues to fail to connect, switch the Otoport off, then on and press the black key on the printer to feed the paper through.



If there is a problem connecting to the printer using the wireless method, the following screen will be displayed providing options to **Cancel**, search for an alternative (**Alter.**) or **Retry**.



To **Retry** the print, ensure the printer is switched on and is within range (5m). Then select the **Retry** key.

If printing wirelessly and you have an alternative printer available, or if **Retry** is unsuccessful, select **Alter.** The Otoport will search for all available printers, taking up to 30 seconds.

Up to five available printers will now be listed in order of signal strength. The first number displayed on the screen corresponds with the serial number printed on the bottom of the printer. The second number indicates signal strength.

Select the printer required with the navigation keys and then **Select**. Printing will then commence.

To cancel the printout, select the **Cancel** key.

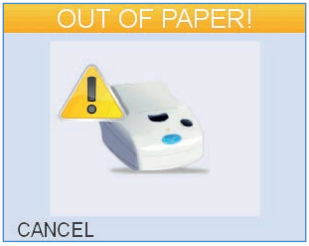
When your print has completed, pull the paper sharply towards you across the serrated tear bar to remove the printout and store it with your patient records.

16.6

Printer fault detection

The printer can detect if the paper roll has run out, or if the lid is open.

Under these circumstances the Otoport will report the printer is out of paper and the following message will be displayed.



The printer will store (spool) the print job and flash the green light during this process. When the printer problem has been rectified, the printout should complete automatically.

If the printout does not complete automatically, select **Continue** to resume printing or **Cancel** to cancel the print job.

Note:

The printer memory is not large enough to print a complete **Detailed** print. **Summary** prints can be completed. If a print job is not completed by the printer, re-initiate the print on the Otoport.

16.7

Printer light summary

The light at the front of the printer has a number of colour combinations, which indicate various conditions:

Constant green: Normal operation, running on battery power

Flashing green: The printer is storing print information (spooling) that cannot be printed at the time (e.g. no paper, or printer lid open)

Flashing green/orange: Battery is being charged

Red: Low battery or other problem

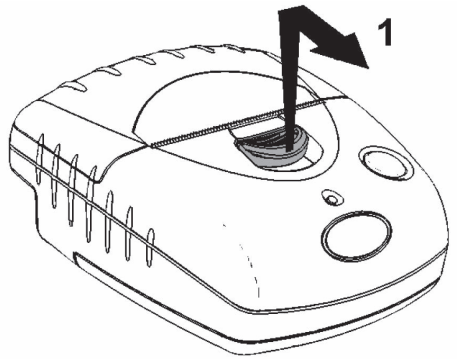
No light: Unit is in sleep mode, has a flat battery, or the battery is not connected

16.8

Paper

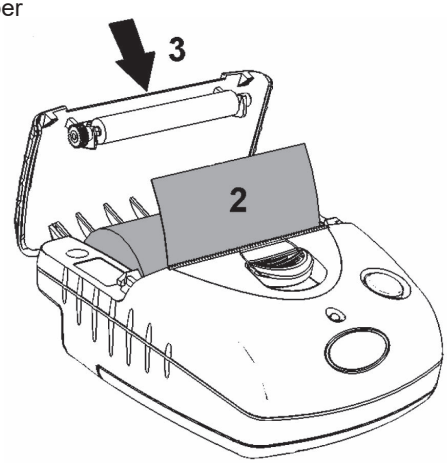
When the printer is switched on, the key provides a paper feed function. A double press of the key will initiate a test print.

The printer is supplied with spare paper rolls. To change the printer roll, pull the lid release catch (1) forwards with your thumb and the paper roll lid will spring open.



Unwind a small amount of paper from the roll. Insert the new roll (2) ensuring the paper will pass through the paper feed (3) and close the cover with a click.

After loading, check that the paper advances properly using the paper feed function, and tear off any excess by pulling the paper sharply towards you across the serrated tear bar. In the event of a jam or other paper loading problem, release the lid and straighten the paper before closing again.

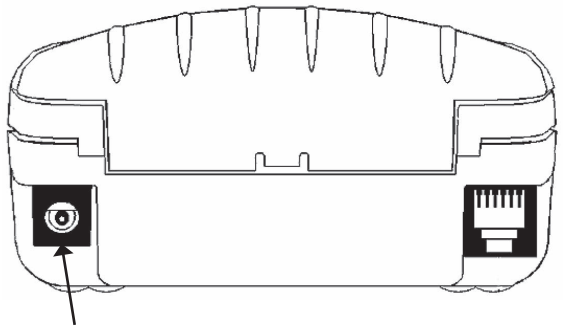


Self-adhesive paper rolls are also available and may be used in the same way as standard paper, but can be stuck to your patient records.

16.9

Charging the printer

To charge the printer, plug the charger into a mains outlet socket and insert the charger jack plug into the rear of the printer. The light on the printer will flash green/orange to show the printer is on charge. The red charger light



will also illuminate. A full charge will take approximately 15 hours.

Charger jack plug socket

The printer can be used as normal whilst charging.

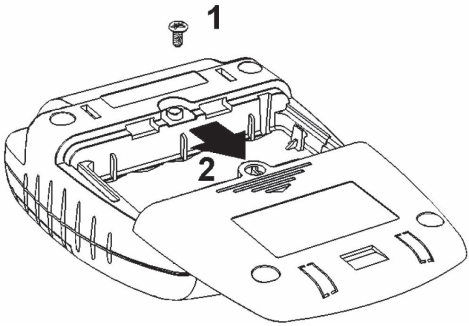
Once fully charged, the printer has enough power for around 10 hours standby use. The batteries should provide enough power to print several rolls of paper. The printer light will flash green/red when the batteries are low.

Note:

The printer charger is not medically approved. The Otoport must not be in patient contact if connected to the printer whilst the printer is charging.

16.10

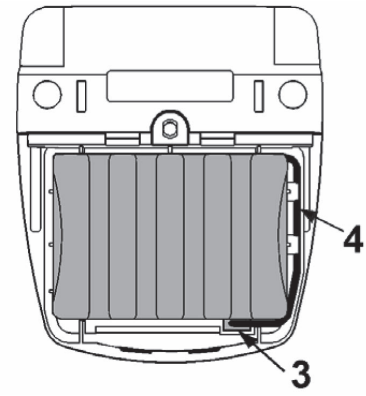
Changing the battery



The printer battery will provide up to 500 charge and discharge cycles. If the battery performance deteriorates the batteries will need to be changed. A spare battery cradle, which takes 4 AAA batteries, is provided with the printer. Alternatively a new battery pack can be obtained from your dealer or Otodynamics.

To change the battery pack:

Remove the screw (1) from the battery compartment cover.



Push down, and slide back the battery compartment cover (2).

Remove the old battery pack and disconnect the battery pack connector, noting its orientation.

Fit the battery pack connector (3) taking care to insert it correctly.

Fit the battery pack ensuring wires (4) are not trapped.

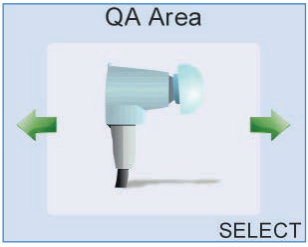
Slide back the battery compartment cover and replace the screw.

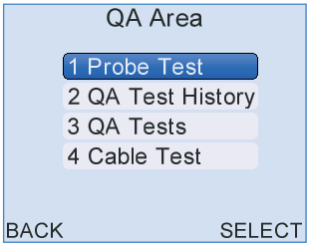
Important Note:

Only charge the printer if it contains an approved battery pack, supplied by your dealer or Otodynamics Ltd.

17 QA area

17.1 QA area menu





The probe menu provides system functional checks which should be conducted weekly or if a fault is suspected.

Probe test

Select **Probe Test** to check the calibration performance of a probe.

QA test history

Select **QA Test History** to review previously performed system checks.

QA tests

Select **QA Tests** to conduct system checks to ensure the device is functioning correctly.

Cable test

Select **Cable Test** to check the ABR electrode cables.

Select **Back** at any time to return to the main menu screens.

17.2

Probe test

A **Probe Test** should be performed weekly to monitor the calibration of the probe's output stimulus level and microphone response.

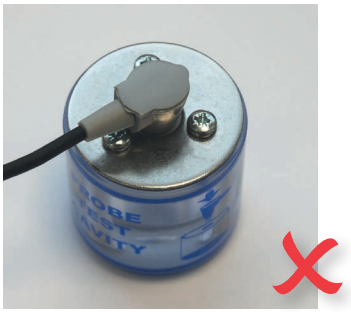
Note:

Probes supplied with a new Otoport systems are tested with the system and Probe Test levels are stored. These levels form a baseline to compare future tests against in order to monitor any calibration drift. It is not necessary to save a new baseline level for these probes.

Replacement probes supplied should be tested with your Otoport system and new Probe Test results saved as a baseline reference.

On selecting **Probe Test** the message **Place Probe into Otodynamics Test Cavity. Press OK to begin test** will appear on screen.

Remove the tip from the probe and place the cavity on a flat surface. Insert the probe into the test cavity at a 90 degree angle to the top of the cavity, between the screws, as shown below left. Press the probe firmly into the cavity until the shoulder of the probe touches the top of the cavity. When released, the probe will rise a little to its natural position and the shoulder may no longer touch the cavity. Inserting the probe at the wrong angle or with the probe head over one of the screws may result in incorrect test results.



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

The probe outputs sound at 1, 2 and 4kHz via its loud speaker(s). There is one loud speaker in the UGS (TEOAE) probe and two in the UGD (DPOAE) probe. The Otoport compares the response at each frequency against an absolute range and probe specific values stored on the probe connected.

Checking the probe response against the absolute range determines if the probe is OK for use. Checking the probe response against the probe specific values is more sensitive and provides a warning if the response of the probe has changed.

17.2.1

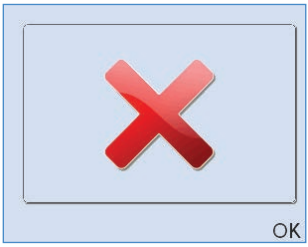
Results

The possible results of the test are:

Pass

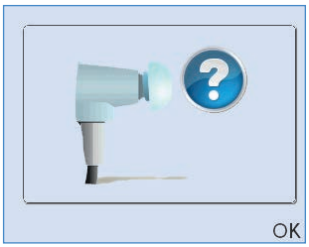
The levels recorded at all frequencies are within the absolute range and within ± 3dB of the probe specific values.

Fail



One or more of the levels recorded are outside the absolute range specified for the probe. If a Fail is shown on screen inspect the probe coupler tubes for debris, replace the coupler if necessary and repeat the Probe Test, by selecting **Retest**, ensuring the ear piece is firmly inserted in the test cavity. If the test continues to fail there may be a fault with the probe or system. Contact your dealer or Otodynamics for advice.

Probe Query



The levels recorded at all frequencies are within the absolute range but one or more frequencies is more than ± 3 dB of the probe specific values. If a Query is shown inspect the probe coupler tubes for debris, replace the coupler if necessary and repeat the Probe Test by selecting **Retest**, ensuring the ear piece is firmly inserted in the test cavity. A Query result indicates that there have been changes in the probe but that these changes are not large enough to invalidate testing. It may be possible for the probe calibration to be adjusted if the probe is returned to Otodynamics.

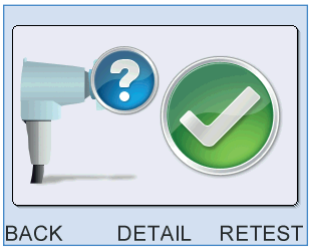
Noisy

There was significant noise during the calibration test. This noise may have influenced the levels recorded so a **Retest** should be performed.

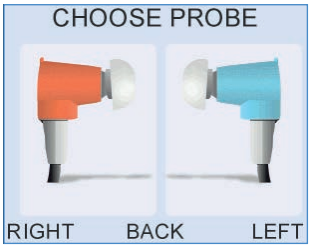
Select **Back** to exit the probe test and return to the Probe Menu screen.

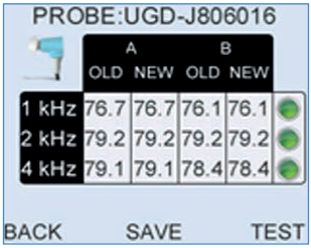
Dual probe result

If two probes are connected to the Otoport, both are tested and a test result for each is shown:



The full test result for either can be selected when **Detail** is selected and a probe icon will show which probe result is displayed.

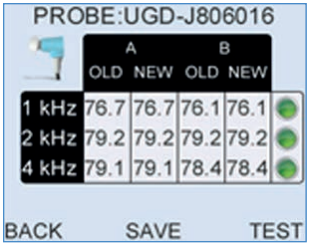




Detail

The full test result can be viewed by selecting **Detail**. The details screen shows the levels recorded from the probe loud speaker at each frequency tested. The NEW column shows the levels just recorded and the OLD results are the levels that are stored in the probe.

Results are given for each frequency tested:



Pass - Tick/Check mark (✓) – The **NEW** and **OLD** (stored) data for each of the two channels are within ± 3dB and are within the absolute limits.

Query - Question mark (?) - Values differ by more than ± 3dB. The NEW and OLD levels are highlighted.

Fail - Cross (X) - Values are outside the absolute range. The NEW level only is highlighted.

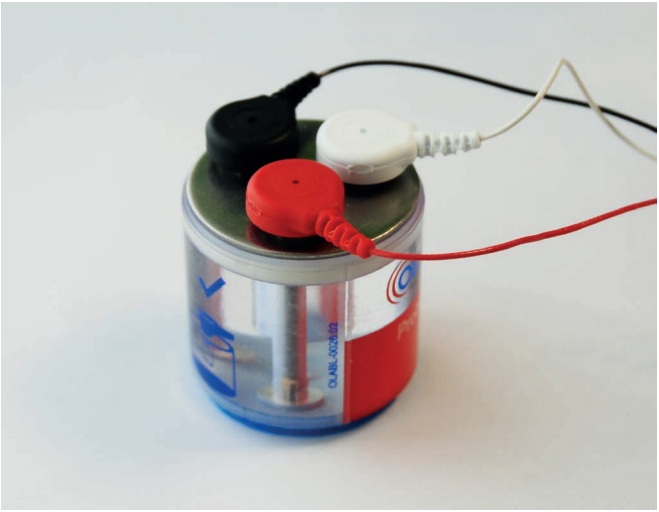
The 1, 2 and 4kHz values may not be stored in the probe if a new probe is being used with the system. To save new data, run a Probe Test, record the values for each frequency and repeat by selecting **Retest.** Check that the values from two sequential tests are within ± 0.5dB before selecting **Save**.

Save is only available to admin users. It is not available if the test was noisy or if the levels were outside the absolute range.

On selecting **Save**, the screen title **Overwrite Stored?** will be shown highlighted. Select **Yes** to save the new data or **No** to keep the current stored values which may be blank for a newly registered probe. Before entering Probe Test the user will be prompted to register the probe with the Otoport.

Select **Back** to exit the Probe Test detail screen and return to the Probe test result screen.

17.3 ABR cable test



The ABR cable test checks the continuity of the electrode cables.

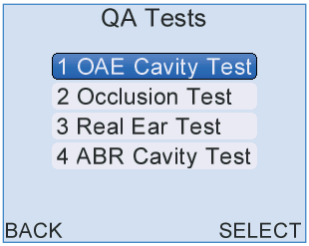
Attach the probe snaps to the top of the cable tester as illustrated. Select **ABR Cable Test** and wait for the result to be displayed. If the electrode cables are OK then a large tick is displayed on the screen. If any of the cables fails the test, a large cross is displayed.

Select **Details** to see the results for each cable. The impedances should show zero for all cables.

If any cable shows a cross, check that it is properly connected to the Otoport and retest. If it continues to fail, then replace the cable.

17.4

QA test menu



Each QA type tests for different types of probe fault.

OAE Cavity test

Select **OAE Cavity Test** to run a test in the test cavity.

Occlusion test

Select **Occlusion Test** to check for sound leakage within the probe ear piece.

Real ear test

Select **Real Ear Test** to ensure the device measures OAEs correctly.

ABR cavity test

ABR cavity tests should be run weekly to ensure that the Otoport is working correctly.

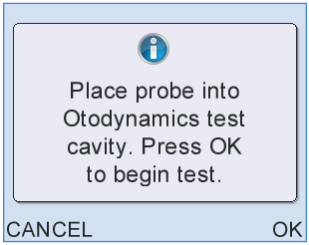
Select **Back** at any time to return to the main menu screens.

17.4.1

OAE Cavity test

Cavity tests should be run weekly to ensure that the Otoport is working correctly.

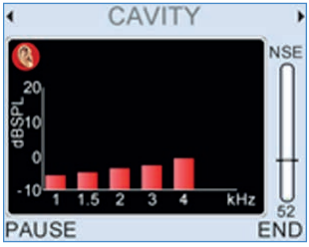
On selection of **Cavity Test** from the **QA Tests Menu**, the message **Place Probe into Otodynamics Test Cavity. Press OK to begin test** will appear on screen.



Follow the instructions in **Probe test** for inserting the probe into the test cavity.

Select **OK** to enter the standard **Checkfit** screen and begin the **Cavity Test** or **Cancel** to return to the **QA Tests Menu** screen.

Follow the **Checkfit** and **Test** screen sequences until the test stops. In a cavity the testing stimulus level should adjust to 84dB. Please refer to **Checkfit** and **Test** chapters for a detailed description of how to perform a standard test.



Data collected during the **Cavity Test** is analysed against set Stop criteria. The following table lists all possible test results and gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
Artefact?	The data collected has met the set OAE Stop criteria according to the locked Factory protocol.
Artefact?	If one band has > 6dB SNR and an absolute signal level > -5 dB SPL in acceptable conditions OR if two or more bands have greater than 3dB SNR with an absolute signal level > -5 dB SPL in acceptable conditions.
Noisy	If Noise is greater than -5 dB SPL in any band.
Poor Probe Fit	If the final test stimulus level is outside the stimulus ok range or if the final stimulus stability value is < 85%.
Cavity OK	The data collected is acceptable and in good environmental conditions.
Incomplete	If a user ends the test manually.

If the result **Noisy**, **Poor Probe Fit** or **Incomplete** is achieved, save the test and retest checking that the probe ear piece is firmly inserted into the test cavity and that the noise conditions within the room are acceptable for a test to be conducted. Continue to retest until the result **Cavity OK** is given.

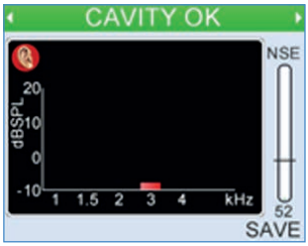
If **Artefact?** is shown at the end of the test, save and retest making sure the ear piece has been firmly pressed into the test cavity.

Consistent artefact or noisy outcomes may be the result of a fault with the probe, the test cavity or with the Otoport. Check the top of the test cavity and ensure that it is securely attached to the clear plastic part of the test cavity. If the resources are available, repeat the test with a different test cavity and then with a different probe. This will identify which component is responsible for the problem.

Electromagnetic interference is an ‘invisible’ source of noise, so if there are persistent problems and other hardware issues have been eliminated, try to move to another location to perform the tests.

Contact your dealer or Otodynamics for further advice.

If the result **Cavity OK** is displayed when the test stops, the test has passed. Save the test and perform the other QA tests if required or exit the **QA Tests Menu** screen.



On selecting **Save**, **Patient Details** are automatically entered and the test is allocated a unique date/time stamp.

Patient Details Field	Cavity Test Default
ID	QA1
Name	QA
First	Cavity

Each test can be reviewed individually in the **QA Occlusion Test History** area.

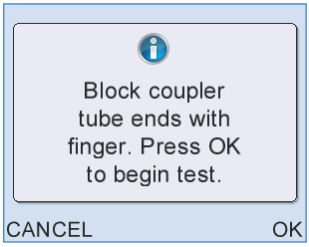
Note:

If an artefact is reported in the test cavity, ensure that five successful cavity tests are performed on the Otoport before returning it to use. Refit the probe in the cavity between each test.

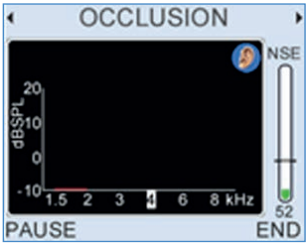
17.4.2 Occlusion test

If the probe coupler is not fitted correctly, sound may leak between the probe loudspeaker and microphone. The **Occlusion Test** helps to check that the probe is assembled and is performing correctly.

On selection of **Occlusion Test** from the **QA Tests Menu**, the message **Block Coupler Tube ends with Finger. Press OK to begin test.** will appear on screen. To occlude the probe place a finger firmly over the end of the coupler tubes, which will stop sound from being emitted from the ear piece and prevent ambient noise from being detected by the microphone.



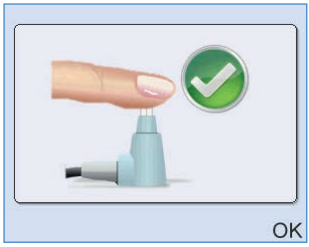
Select **OK** to begin the test.

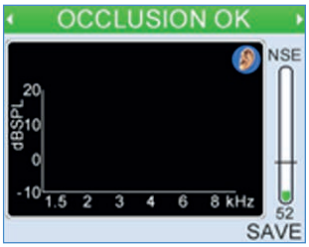


Data collected during the **Occlusion Test** is analysed against set Stop criteria. The following table lists all possible test results and gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
Artefact?	If one band has > 6dB SNR and an absolute signal level > -5 dB SPL in acceptable conditions OR if two or more bands have greater than 3dB SNR with an absolute signal level > -5 dB SPL in acceptable conditions.
Noisy	If there is three times more noisy data recorded than good quality low noise data, OR if Noise is greater than -5 dB SPL in any band. Final test stimulus level is > 60dBSPL in a TE test or > 40dBSPL in a DP test.
Occlusion OK	The data collected is acceptable and in good environmental conditions.
Incomplete	If a user ends the test manually.

If the result **Noisy**, **Poor Probe Fit** or **Incomplete** is achieved, save the test and retest checking that the coupler tubes are fully occluded by a finger and that the noise conditions within the room are low. Continue to retest until the **Occlusion OK** result is given.





If **Artefact?** is shown at the end of the test, save and retest making sure again that a finger is pressed firmly over the end of the coupler tubes and the testing stimulus level is below 40dB at the start of the test.

Consistent artefact or noisy outcomes may be the fault of the probe coupler tubes, the probe earpiece or the Otoport. Check that the coupler is correctly attached to the probe, then try changing the coupler (see **Probe care** chapter for details). If one is available then repeat the test with another probe.

Electromagnetic interference is an ‘invisible’ source of noise, so if there are persistent problems and other hardware issues have been eliminated, try to move to another location to perform the tests.

If the result persists, contact your dealer or Otodynamics for further advice.

On selecting **Save**, **Patient Details** are automatically entered and the test is allocated a unique date/time stamp.

Patient Details Field	Occlusion Test Default
ID	QA2
Name	QA
First	Occlusion

Each test can be reviewed individually in the **QA Occlusion Test History** area.

Note:

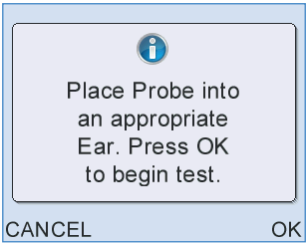
If an artefact is reported in the occlusion test, ensure that five successful occlusion tests are performed on the Otoport before returning it to use.

17.4.3

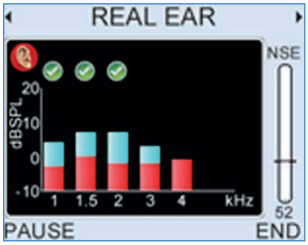
Real ear test

Testing with a known good ear checks that the Otoport correctly detects OAE responses.

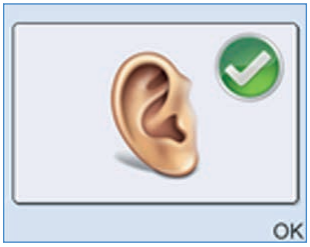
On selection of **Real Ear Test** from the **QA Tests Menu**, the message **Place Probe into an appropriate Ear. Press OK to begin test.** will appear on screen.



The **Real Ear Test** utilises the identical test sequence as a standard test.



The test will not autostop if an OAE is detected, but will always run for 260 NLo low noise sweeps (for TE tests) or until the maximum test time (for DP tests) has been reached.



The result logic for a **Real Ear Test** is set to the locked factory mode. Please refer to chapter 7 **TEOAE** for descriptions of stop results.

On selecting **Save**, **Patient Details** are automatically entered and the test is allocated a unique date/time stamp.

Patient Details Field	Real Ear Test Default
ID	QA3
Name	QA
First	Ear

Each test can be reviewed individually in the **QA Real Ear Test History** area.

Some adult ears with no significant hearing loss produce little or no OAE. If possible, the Real Ear Test should be performed on an ear which is known to have strong OAEs. Ideally, the same ear will be consistently used for the tests so that changes in response can be easily seen, which may indicate a change in the Otoport performance.

If a **Real Ear OK** result cannot be achieved in an ear which is known to have OAEs, then:

- Check that the subject has no middle or outer ear problems, such as a cold or wax blockage, which might prevent OAE recording.
- Check that a good probe fit has been achieved.
- Check that the probe coupler tubes are not blocked.
- Check that the probe still passes the probe calibration test (see above).
- Try recording emissions from another subject.

If a **Real Ear OK** result still cannot be achieved and if the resources are available, a recording should be performed with a different probe or with a different Otoport to help identify the problem. If the problem persists, contact your dealer or Otodynamics.

17.4.4 ABR Cavity test

ABR cavity tests should be run weekly to ensure that the Otoport is working correctly.

On selection of **ABR Cavity Test** from the QA Tests Menu, the message **Attach electrode cables to ABR cable tester** will be shown. Attach the probe snaps to the top of the cable tester as illustrated below then press **OK**. Then the message **Place Probe into Otodynamics Test Cavity. Press OK to begin test** will is shown.

Follow the instructions in **Probe test** for inserting the probe into the test cavity (two cavities are required, one to connect the electrode cables and one to connect the probe). Select **OK** to start the ABR impedance test. All impedances should show 0 kOhms.

Follow the **Checkfit** and **Test** screen sequences until the test stops. Please refer to the **ABR Test** chapter for a detailed description of how to perform a standard test.

Data collected during the **Cavity Test** is analysed against set Stop criteria.

The following table lists all possible test results and gives an explanation of the circumstances under which each result would be shown.

Test Result	Description
Artefact?	The data collected indicates that there is a possibility of an Artefact pass when testing with this equipment.
Noisy	The test data collected included too much electrical noise for the test to complete correctly.
Poor probe fit	The final test stimulus level is outside the stimulus ok Fit range.
Cavity OK	The data collected is acceptable.
Incomplete	The user ended the test manually.

If the result **Noisy**, **Poor Probe Fit** or **Incomplete** is achieved, save the test and retest checking that the probe ear piece is firmly inserted into the test cavity and that the noise conditions within the room are acceptable for a test to be conducted. Continue to retest until the result **Cavity OK** is achieved.

If **Artefact?** is shown at the end of the test, save and retest making sure the ear piece has been firmly pressed into the test cavity.

Consistent artefact or noisy outcomes may be the result of a fault with the probe, the test cavity or with the Otoport. Electromagnetic interference is an 'invisible' source of noise, so if there are persistent problems and other hardware issues have been eliminated, try to move to another location to perform the tests.

Contact your dealer or Otodynamics for further advice.

If the result **Cavity OK** is displayed when the test stops, the test has passed. Save the test and perform the other QA tests if required or exit the **QA Tests Menu** screen.

On selecting **Save**, **Patient Details** are automatically entered and the test is allocated a unique date/time stamp.

Patient Details Field	Cavity Test Default
ID	QA4
Name	QA
First	Cavity

Each test can be reviewed individually in the **QA Occlusion Test History** area.

17.5 # Enforced QA checks

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

If enforced (switch on and off using 'Other options – **Enforce QA**' section **14.5.4**) these checks become mandatory on the Otoport and MUST all be completed with the 'expected' outcome for each QA test, before the equipment can be used to screen patients. Performing these checks ensures that the equipment is working correctly and gives confidence to the results which the screener will then achieve from the patient. 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. To ensure that you get a quick and accurate QA check result we recommend that all tests are carried out carefully in a quiet environment.

When checks do fail the fault is most likely to be with the probe, rather than the Otoport. In this regard we ask that if a QA check fails you attempt the following steps and then repeat the tests:

- Change the probe coupler.
- Change the electrodes.
- Check that the probe is fully connected to the device.
- Check to ensure that the cavity is in good condition.

If the QA checks continue to fail, please contact Otodynamics.

17.5.1 ## Visual inspection

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

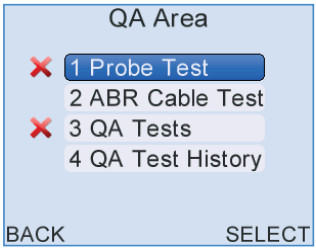
Change the coupler if required (see chapter 19 **Probe care**).

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

17.5.2 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.

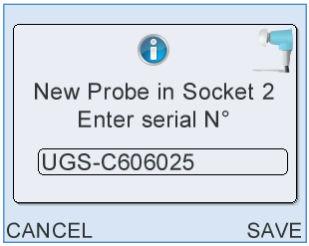
To run the test, find the **QA Area** > Probe Test screen (using the arrow keys) and press **Select**.



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

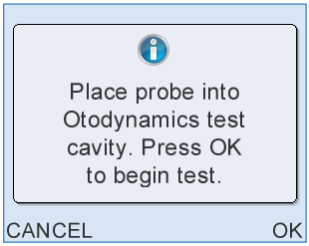
Once in the QA Area, select 1 **Probe Test**.

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 inserted LEVEL and BETWEEN the two screws, and not over one (as shown below). 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

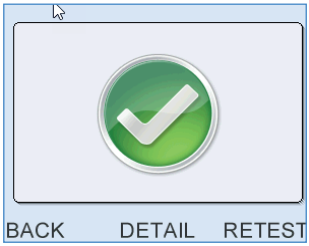
If two probes are connected to the Otoport, the probe test will run automatically on both in turn.

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

17.5.3 Probe test results

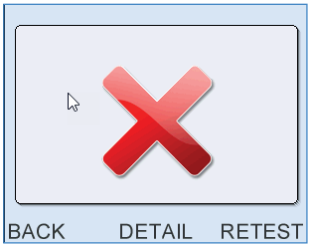
The possible results of the test for each probe tested are:

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**.

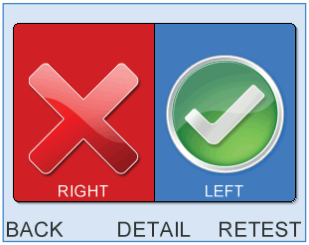
Noisy

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**.

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**.

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:

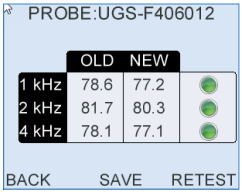
"X" indicates the Probes that need QA Testing

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

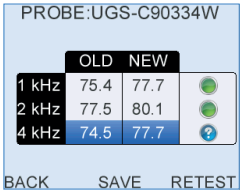
The column labelled **New** shows the results of the Probe Test which has just been completed. It is these **new** values that should be recorded in the log.

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.

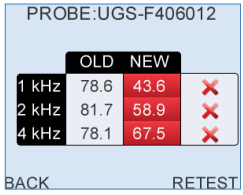
A typical details screen is shown below for three probe test outcomes, Pass, Query and Fail.



Pass: Probe sensitivity in range



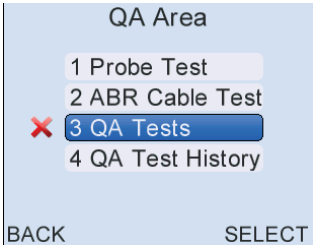
Query: Probe sensitivity in range but a frequency more than 3dB different from stored values

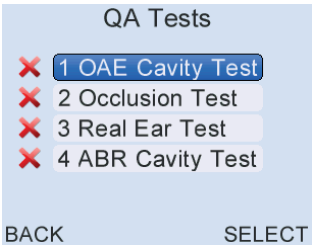


Fail: Probe sensitivity out of range

17.5.4 QA tests

17.5.4.1 QA 1 Cavity test

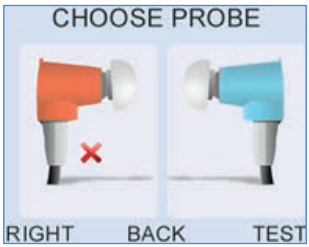




"X" indicates the QA Tests that need completion

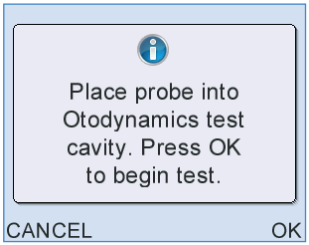
From the **QA Area** menu select **QA Tests** and then 1 OAE **Cavity Test.**

If you are using two probes, then the QA 1 Cavity Test must be run on e**ach of them**; the screen below will be shown:

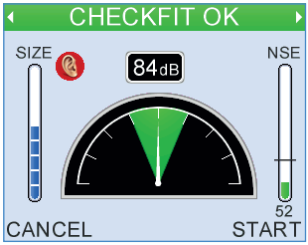


"X" indicates the Probe that needs QA Testing.

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

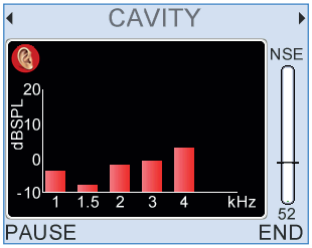


Place the probe in the OAE Test Cavity and select **OK**.



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 o**n the** middle key.

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

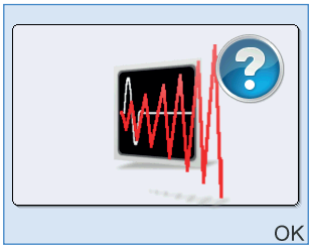


An OAE test recording will be made. The test should be allowed to run until it stops automatically, and a test result is obtained. At the end of the test one of the screens below will be shown. Select **OK** then **Save** the result.

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

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

Artefact?

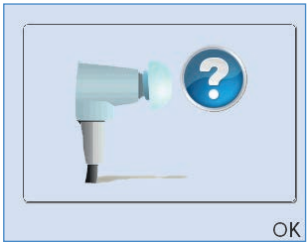


If **Artefact**? is shown at the end of the test, save and make sure the probe is complete with its cover and lid, and has been firmly pressed into the test cavity. A poor fit can sometimes cause this outcome. This outcome indicates that some signal that could be mistaken for an OAE was recorded in the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

Noisy

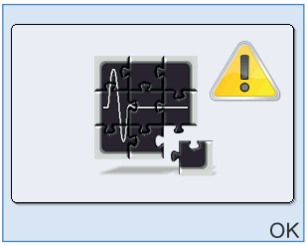
This result indicates that the test environment was too noisy, or that there is a fault with the equipment.

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:

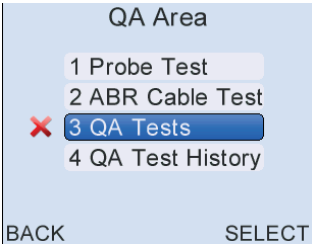
• Change the probe and repeat the QA process from the start.

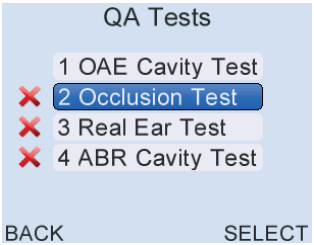
• If an alternative probe passes all tests then remove the original probe from use.

• If the problem persists with the new probe you must remove the equipment and probe from use.

• Report the failure to your Otodynamics.

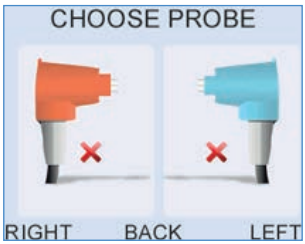
17.5.4.2 QA 2 Occlusion test



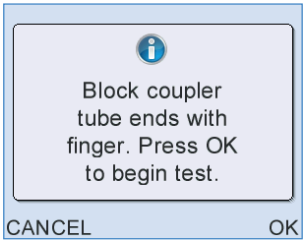


Select **QA Tests** then select **2 Occlusion Test**.

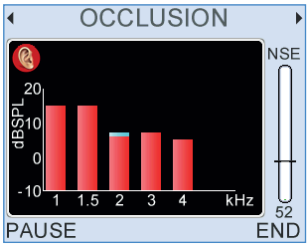
If you are using two probes, then the QA2 Occlusion Test must be run on each of them; the screen below will be shown:



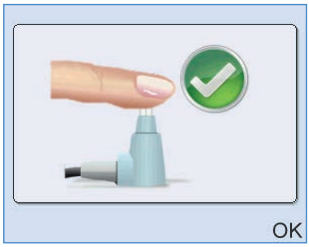
Select the probe you wish to test (if you have a single probe connected, then you will not see this message). Occlude the tip of the coupler, without a probe tip, with a finger or thumb.



Press **OK** to begin test.



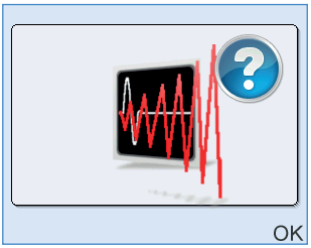
The test outcome will take about seven seconds to complete.



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.

Artefact?

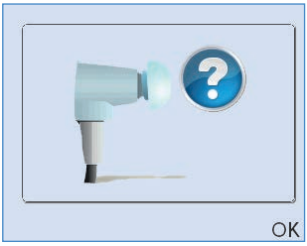


If **Artefact**? is shown at the end of the test, save and make sure the probe is complete with its cover and lid, and has been firmly pressed into the test cavity. A poor fit can sometimes cause this outcome. This outcome indicates that some signal that could be mistaken for an OAE was recorded in the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

Noisy

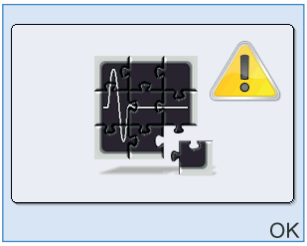
This result indicates that the test environment was too noisy, or that there is a fault with the equipment.

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 tip is fully occluded 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 **PASS** in this test then you may:

• Change the probe and repeat the QA process from the start.

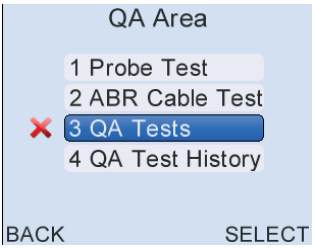
• If an alternative probe passes all tests then remove the original probe from use.

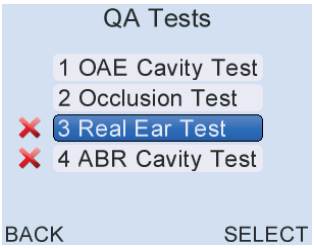
• If the problem persists with the new probe you must remove the equipment and probe from use.

• Report the failure to Otodynamics.

17.5.4.3

QA 3 Real Ear Test



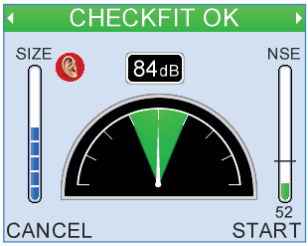


In **QA Tests**, select 3 **Real Ear Test**.

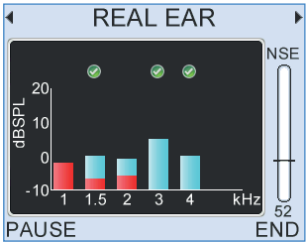
Select an appropriate size adult soft ear tip and fit the OAE probe into an adult ear known to have a Clear Response.

If you are using two probes, then the QA 3 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).

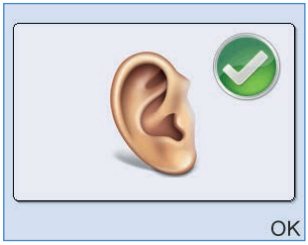


Select **Start** to begin the test.



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.

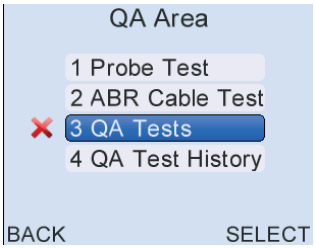


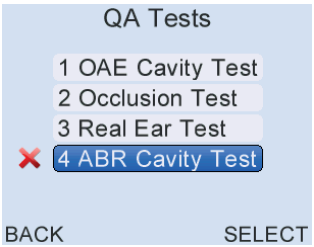
Select OK then Save the result. In cases where the QA tester does not usually get a clear response on OAEs and there is no-one else available for testing, the usual expected results will suffice.

17.5.4.4

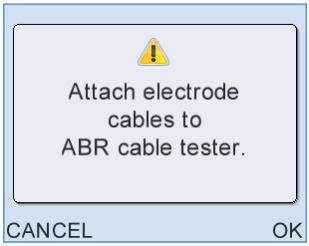
QA 4 ABR cavity test

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

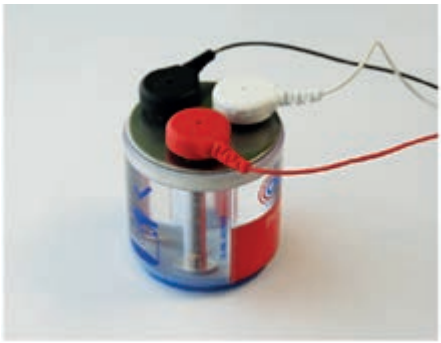




In QA Tests, select **4 ABR Cavity Test**.



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

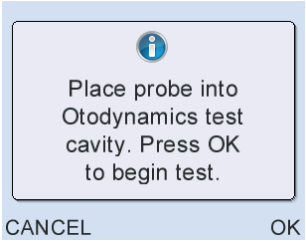


The order and position they are attached in is not important.

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 with both probes, but only one probe at a time.

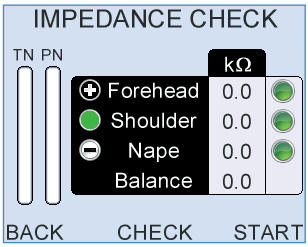
Select Right (the left probe can also be selected for the test but ensure to insert only the selected probe in the test cavity on the next step).



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

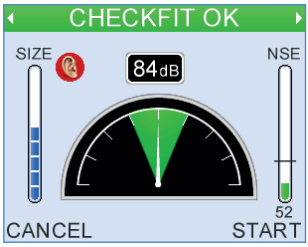
Impedance Check

All impedances should show 0k Ohms:

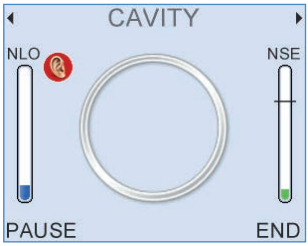


If the impedances are any higher than this, then check the connection of the cable to the test cavity and press **Check**. If after adjusting the impedances still do not show 0k Ohms, then there may be a problem with the electrode cables. Remove these cables, connect alternative cables, and retry.

If 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.

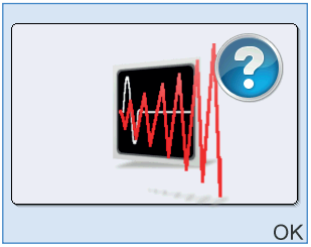
QA 4 Test results

Cavity OK

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

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

Artefact?

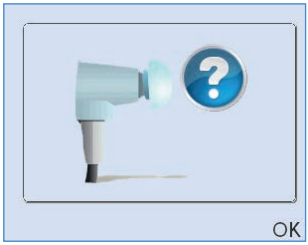


If **Artefact**? is shown at the end of the test, save and make sure the probe is complete with its cover and lid, and has been firmly pressed into the test cavity. A poor fit can sometimes cause this outcome. This outcome indicates that some signal that could be mistaken for an OAE was recorded in the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

Noisy

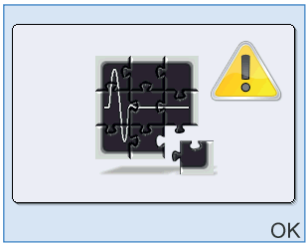
This result indicates that the test environment was too noisy, or that there is a fault with the equipment.

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 **PASS** 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 Otodynamics.

18 Probe, tips and accessories

18.1 Probe and service accessories

Your kit will include a TEOAE probe, with appropriate sample coupler tubes and spare probe body/lid, depending on the Otoport model purchased. See chapter 2 **Equipment identification** for details.

18.2 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.

18.2.1 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.

18.3

Probe tips

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

18.3.1

TEOAE tips

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

Large foam tip
REF T-T200L

Small foam tip
REF T-T200S

18.3.2 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 TEOAE 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.

19 Probe care

19.1 Cleaning

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.

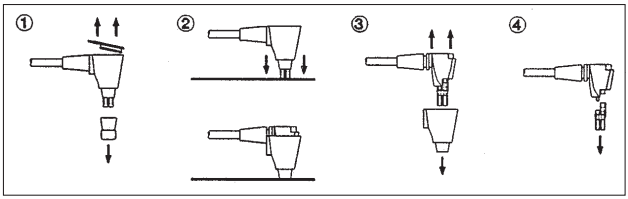
19.2 Changing probe coupler tubes

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

19.2.1

Disassembling the probe

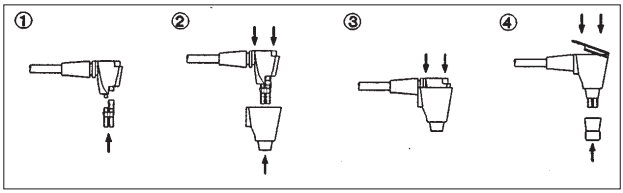
First, unplug the probe from the instrument. Remove the tip and then the lid (fig. 1). Remove the coupler tubes by pushing the end of the tubes down onto a hard surface (fig. 2). Pull out the tubes by gripping them (fig. 3). Never remove them by pulling on the cable. Finally, pull the coupler tubes away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



19.2.2

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).



Illustrations show TPC (TEOAE) coupler tubes.

19.2.3

Notes:

As with all probes it is important to:

- Fit a new tip for each test.
- 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 weekly probe QA tests (see chapter 17 **QA area**).

19.3

Probes 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.

20 Care of the Otoport

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
- Do not expose to moisture (keep it dry)

20.1 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.

Other than the probe ear piece 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 ear piece 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 ear piece 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 ear piece 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 ear piece as necessary. (See chapter 19 **Probe care** for details)

Ensure your hands are cleaned thoroughly between each patient tested.

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 no 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.

21 Otoport power

Important Note:

Only charge your Otoport with the charger, charging cradle, or docking station supplied by Otodynamics.

21.1 Battery life

The Otoport is powered using an internal rechargeable battery. The battery will provide enough power for over 250 tests from a single charge. With built in power save functions and by switching the device off for the periods between tests, the battery will provide enough power for over a week of intense use.

21.2 Initial charge

The Otoport is fully charged before it leaves the Otodynamics factory. However, the battery will discharge slowly, even if the device is switched off. It is therefore recommended that an initial charge is provided to fully charge the battery before using your Otoport for the first time.

21.3 Standby

To save power, the Otoport will go into standby mode after 90 seconds of inactivity.

The Otoport will not go into standby if a test is being performed.

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 off.

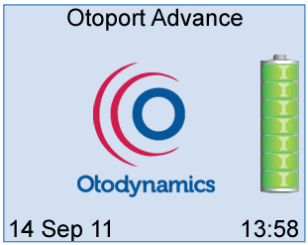
Notes:

Following an OAE recording, always save test data, as data that has not been saved prior to auto switch off will be lost.

Over time batteries will wear and lose their capacity, resulting in quicker discharge. The batteries may therefore need replacing around every 4 years of use.

21.4

Battery charge

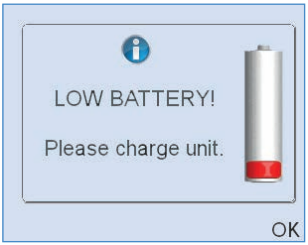


When the Otoport is switched on, the opening screen shows a battery indicator which displays the remaining level of battery charge.

The indicator has 7 segments which convey the total Battery Charge remaining. The battery segments are shaded according to the following criteria.

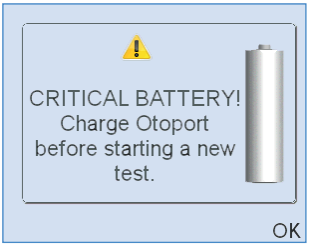
Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

21.4.1 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. Select **OK** to accept the message and return to the previous screen. This screen will continue to appear every minute, as a reminder to charge the battery.

21.4.2 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. Select **OK** to accept the message and return to the previous screen. It will not be possible to start a new test when the Otoport has reached this level of charge. The Otoport should be charged as soon as convenient.

21.4.3 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.

21.5 Charging the Otoport

It is recommended that when the Otoport is not in use, it is placed in the Docking Station, which should be plugged into the mains electricity supply, thereby ensuring that the Otoport is always fully charged and ready for use.

If the Docking Station is not used, observe the on-screen battery indicators to determine when to charge your Otoport.

There are two alternative ways in which the Otoport may be charged, by using the charger supplied, or by using the PC cable connected to a PC.

Note:

Do not charge more than one Otoport on the same PC at any one time.

21.5.1 Connecting the Otoport for charging

Switch off the Otoport prior to charging.

Connect the mains lead to the charger and plug the mains lead 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.

Notes:

If forced it is possible to insert the charger connector into the Otoport the wrong way up. In this position the Otoport will not charge.

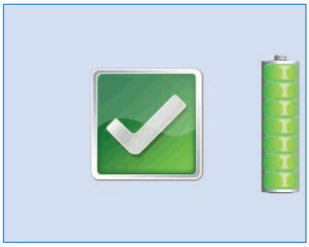
Disconnect the connector and re-insert with the arrow facing upwards.

If the cables provided with your Otoport have a locking connector, as shown below, squeeze the release keys at the sides of the connector when removing the plug.

When the Otoport is connected the display will show the current battery level. This screen is updated every minute to show how the charge is progressing.

A full charge will take up to 4 ½ hours.

When the device is fully charged a large tick will appear on the screen.



21.5.2

Additional charge indicators

There are additional charge indicators on the side of the Otoport.

Power light - The green light above the plug symbol shows that the device is powered.

Charging light - The orange light above the battery symbol will illuminate when the device is being charged.

Note:

If the device appears fully charged, with a tick displayed on screen, but the charging light is still on, if convenient, allow the device to continue to charge until the charge light goes out.

It is possible to leave the charger connected to the Otoport for extended periods, even if the device is fully charged. This may be convenient if you wish to leave the device charging overnight.

When powered by any of the above methods, the Otoport is powered from the attached device and not its internal batteries.

When being charged it is possible to switch on and control the Otoport but it is not possible to run a test.

When connected to Otolink PC software, it is not possible to control the Otoport. If the Otoport is on when it is connected to Otolink, the current screen displayed will remain until the device is unplugged again.

21.5.3 Disconnecting the Otoport

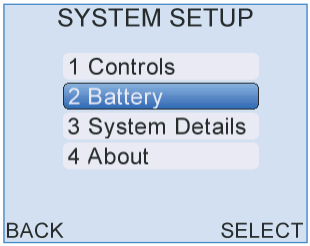
If the cable has release keys, squeeze to disconnect, otherwise just pull out the cable.

The power light will extinguish on the Otoport and if the Otoport was off prior to the charging session, the screen will return to blank. If on during the charging session the current screen will remain displayed.

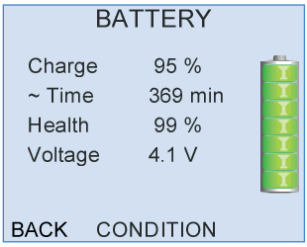
21.6 Conditioning the Otoport battery

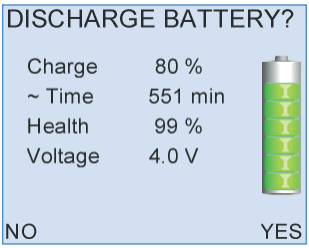
In order maintain the Otoport batteries and keep them at optimal performance you should condition the battery once per year, or if the unit batteries appear to run down more quickly than expected. This process involves completely discharging the battery and then fully charging the device.

To initiate the battery condition, enter the **System** main menu and select **Battery**.



Select **Condition** and **Yes** on the confirmation screen. The device will automatically be set to full power to drain the battery.





This process can take up to 6 hours. The conditioning process may be stopped during this period by selecting **Cancel**. The Otoport will automatically switch off when the battery has been fully discharged. Now fully charge the Otoport to complete the battery condition cycle. Wait for the tick on the screen and for the charge light to extinguish, to confirm a full charge.

21.6.1 Additional battery care

If the Otoport is not in regular use, in order to maintain the battery, fully charge the device every two months.

22 Troubleshooting

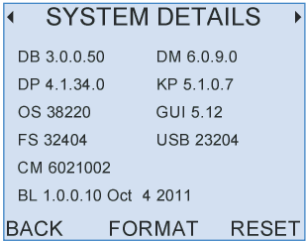
22.1 Otoport lock-up

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.

22.2 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.

22.3 System details



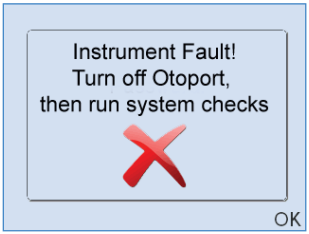
The **System** main menu area includes **System details**. This screen provides information for Otodynamics engineers relating to the Otoport hardware. If your device is not functioning correctly or you suspect a fault, go to the **System details** menu and press the left or right arrow keys until the 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.

Select **Format** to reformat the Otoport database. Any records held on the device will be irrecoverably lost.

The **Format** and **Reset** options are only available to users with Admin rights.

22.4 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 **Connecting the probe** in the **Getting started** section).

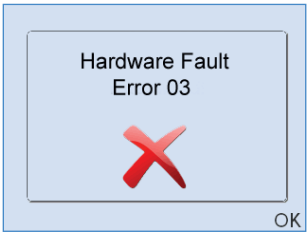
Run the probe checks (see chapter 17). If the tests are 'OK' the device is functioning correctly and can be used for OAE testing again.

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

22.5

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 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.

23 Obtaining service

Otodynamics or its authorised distributor will replace or service, free of charge, this Otoport during the period of warranty, where the fault is not associated with misuse. Servicing after that period will be provided at reasonable cost.

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.

Probes failing because of faulty construction will be replaced subject to inspection. Probes must be treated with care. Do not allow cleaning fluid to enter the sound tubes.

When sending equipment to Otodynamics for service or repair, please ensure all items, particularly the OAE instrument and probe, are clean and free from contamination. Otodynamics cannot guarantee the equipment will be contamination free when returned to you and suggest that it is cleaned in accordance with your infection control protocols before being put back into use.

Please contact your distributor or Otodynamics for advice before returning an item for repair. You will be asked for your instrument serial number, which can be found on the back of the Otoport.

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

Tel: +44 1707 267540
Fax: +44 1707 262327
E-mail: support@otodynamics.com

www.otodynamics.com

24 Calibration

The Otoport is a precision instrument designed to make accurate measurements of OAE and ABR responses. Before it leaves Otodynamics, each system supplied is calibrated using high quality acoustic measuring equipment traceable to national standards.

Users should conduct the recommended weekly checks (see section 17.2) to ensure the instrument is working correctly. In addition to this, the calibration of the instrument should be periodically checked with laboratory equipment. Otodynamics advises regular calibration checks at intervals not exceeding 3 years and ideally annually.

The **About** screen displays the Calibration Due date for your Otoport, if a date has been set (see section 13.5 **About**). A prompt when turning on will warn that calibration is due from 30 days before the due date.

Contact your dealer or Otodynamics to arrange a calibration check.

25 Mode of operation

25.1 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.

25.2 ABR test

Stimulus level	5-60 dBHL
Stimulus rate	51.8-57.9Hz
Stimulus polarity	Alternating
Stimulus type	Click or Chirp (see below)
Stimulus repetition rate	51.8-57.9 Hz
Evaluation method	Fsp & Template Correlation
Sampling rate	25.6 kHz
Frame length	17.3-18.8ms
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
Impedance 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	Ipsilateral mastoid or nape of neck
Common electrode	Back of shoulder, cheek, or contralateral mastoid

25.2.1

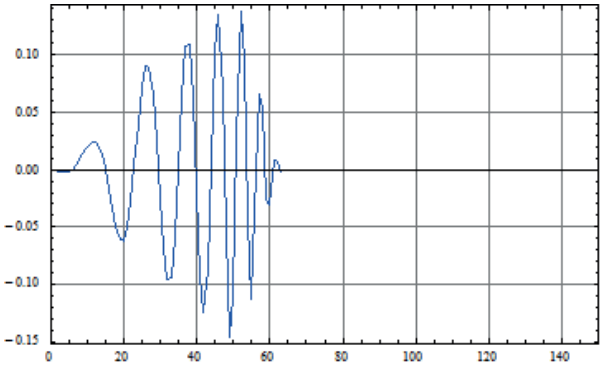
Stimuli description

Click stimuli: 80µS duration square pulse of alternating polarity.

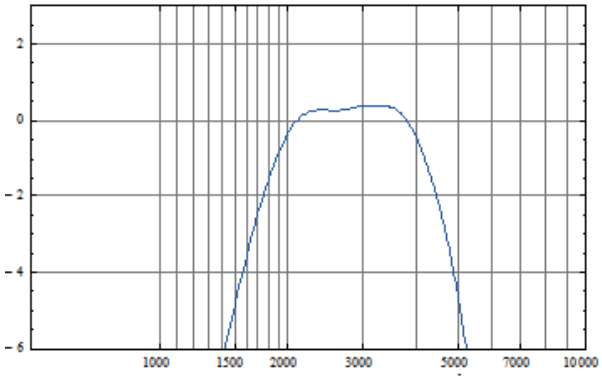
Chirp stimuli: 2.5ms duration of alternating polarity. The frequency dispersion of the chirp is defined by the delay at frequency $T(f)= k * f^{-d}$ with k=0.0920, and d=0.4356.

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:



25.2.2

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 were noted:

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

25.2.3

Screening test sensitivity

The 'sensitivity' of a hearing screener relates to the ability of the device to detect ears with hearing loss (i.e., the true positive detection rate). Sensitivity is measured as the probability of a 'No Valid response' result being correctly reported by the device when no response is actually present. Departure from the desired 100% sensitivity figure would indicate a false passes caused by the device misinterpreting electrical noise (biological and/or environmental) as a true response. This must be avoided even at the expense of unnecessarily referring some patients with normal hearing.

The sensitivity of a device is best measured with the screening device operating in its screening test mode in a real screening environment and exposed to all the differing levels of interfering noise in which the device can be used (e.g., EEG noise and power line interference of ABR and acoustic noise for OAEs). But crucially without any real response actually

being present, this is achieved by not supplying any stimulus during the test.

It is important to note that the measured sensitivity of an instrument relates to the outcome of tests where there was definitely no response is present. When there is a hearing loss, we can assume that no ABR is present below a certain stimulus level at which a clear response IS detectable in most normal healthy ears. This demonstrated measurement of Otoports sensitivity therefore only applies to the detection of hearing losses greater than a specific amount. It is the applied stimulus level that determines what range of hearing losses that will be detectable and to which the sensitivity figure applies.

For example, if the patients hearing is only slightly impaired and the stimulus level is adequate then a true response may still be recorded.

It is therefore recommended that the stimulus level is set to the lowest value which delivers the sensitivity required consistent with a manageable false positive rate. Stimulus levels between 35 and 40dBHL have been found appropriate on the Otoport ABR, with the 40dBHL level giving both high sensitivity to mild losses and low false positive results.

Sensitivity of the Otoport OAE+ABR for ABR screening

The sensitivity of the Otoport OAE+ABR for ABR hearing screening was measured using 349 recordings from 30 neonates (3 days to 4 weeks old). For the purpose of determining sensitivity to hearing loss in a realist screening environment with infants, the test was conducted with no stimulus delivered to the babies. All had passed an actual screening tests, but the absence of any stimulation meant there could be no true response present during the sensitivity test. A clear response would indicate to the possibility of missing an impaired ear.

For the experiment the instrument was configured to generate its default short chirp stimulation at a level of 35dBnHL at the default repetition rate for 50Hz powerline environments. However, the stimulating probe was fitted to a closed cavity near to the baby's ear, but so that no sound entered the ear and so no ABR was actually generated by the baby. The real-time electrical signals received by the Otoport from the electrodes on the baby were digitally recorded through the device for many minutes to collect a large amount of real EEG and EMG signals. These electrode signals were then replayed at their original level back into the Otoport OAE+ABR and a total of 3257 virtual ABR further tests run. This procedure ensured that the instrument was exposed all possible statistical combinations of noise

and instrument timings. Each of the 3257 ABR test results were evaluated by each of the four pass criteria (PC1-4) of the Otoport ABR. The results below describe the rate of false (artefactual) passes obtained in when a realistically wide range of neonate electrode noise signals (i.e., from sleeping to restless) is processed by the device. As no acoustic stimulation actually reached the ear, no real ABR was present, so all 'passes' are false. This data shows that the sensitivity of the Otoport ABR is between 99.79% and 99.94%, which is very good.

	Pass Criteria			
	PC1	PC2	PC3	PC4
Tests	3257	3257	3257	3257
Passes	7	2	2	7
Pass probability (%)	0.21	0.06	0.06	0.21
CI(Hi) (%)	0.44	0.22	0.22	0.44
CI(Low) (%)	0.09	0.01	0.01	0.09
Sensitivity (1 - Pass prob)	99.79%	99.94%	99.94%	99.79%

Confidence Interval (CI) measurements are given at 95%.

Very high sensitivity of the instrurment is demonstrated with each pass criteria. Pass criteria PC2 and PC3 showed the highest sensitivity, exceeding 99.9%. This would be expected because PC2 and PC3 require that the response correlates with the neonate ABR template. PC1 and PC4 only require that an Fsp statistical criteria is met and so showed a slightly lower sensitivity of 99.79%.

Since the acoustic stimulus was not delivered to the ear, this sensitivity data is valid for all stimulus settings and levels up to a level where electrical artefacts from the probe might create an artefactual pass. Rigorous tests showed that no artefactual passes occurred due to electrical stimulus artefacts up to the maximum stimulus level of the instrument, for both click and short chirp stimuli.

25.2.4 ABR test 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 noise 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.

To determine specificity the mean ABR amplitudes from 270 infants was determined from healthy normally hearing baby's ABR recorded by the Otoport OAE+ABR using our short chirp stimulus at a level of 35dBnHL at the default repetition rate. The noise levels recorded by the Otoport OAE+ABR instrument during tests when the baby was considered quiet enough to test, were averaged, to give a realistic benchmark noise level against which ABRs must be detected.

To supplement the measurement of ABR amplitudes seen on the Otoport we incorporated range (i.e., the spread) of ABR amplitudes determined by an historic controlled study of 3200 infant ABR recordings at 30dBHL*. This helped determine the probability of there being exceptionally small ABR amplitude from normal ear, not captured in our smaller 270 infant trial.

Using this data and applying the Pass Criteria built into the Otoport OAE+ABR, we determined the probability of the Otoport OAE+ABR identifying the ABRs present in the normal population. This included the correct proportion of the weakest ABRs present on the normal population detectable against fluctuating noise based on the average amplitude present in 'quiet' babies. This provided a robust measure of specificity. Results are shown in the table below

	All Pass Criteria
Pass probability (%)	99.70
CI(Hi) (%)	99.75
CI(Low) (%)	99.59
Specificity	99.79%

Important Notes:

- High EEG, myogenic or powerline noise levels can greatly reduce specificity.
- Testing with active infants will reduce specificity, depending on the movement noise.

- Testing with higher stimulus levels will increase specificity because the response will be larger but will reduce the range of threshold elevations to which the instrument is sensitive (according to the stimulus dBnHL used).
- Using 40dB HL stimulation instead of 35dBHL will increase specificity and decrease sensitivity to only slight hearing losses while maintaining sensitivity to mild losses. Using lower than 35dB HL stimulation will further decrease specificity and increase sensitivity to slight hearing losses.
- Testing with a 60Hz powerline setting rather than 50Hz will have an no significant effect on specificity since the ABR response size change is minimal between 50 and 60 Hz stimulus rates (Less than 1dB).
- Testing with a click stimulus rather than our short chirp will slightly decrease specificity because click stimuli generate a slightly smaller ABR response than a chirp of identical hearing level (due to reduced synchronisation). The typical ABR amplitude reduction for clicks relative to short chirps is of the order of 3dB for near threshold stimulation. This translates to a decrease in specificity to 98.6% with click stimuli.

*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

26 Response detection

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.

26.1 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 26.2.2 below.

26.1.1 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

26.1.2 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

26.1.3

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.

26.2 Conclusions

26.2.1 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.

26.2.2 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.

27 Technical specifications

27.1 General

Note:

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

27.1.1 Physical

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

27.1.2 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)

27.1.3 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

27.1.4 Keypad

19 key alphanumeric with cursor control and soft keys

27.1.5 Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

27.1.6 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%

27.1.7 Hardware Option

Bluetooth wireless printing

27.1.8 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

27.1.9 Analogue performance

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

27.1.10 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.

27.1.11 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.

27.1.12 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.

27.2 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.

27.2.1 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.

27.2.2 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.

27.2.4 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.

27.3 Electromagnetic compatibility - Technical Description

27.3.1 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.

27.3.2 Deviations from the standard

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

27.3.3 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.

27.3.4 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.

27.3.5 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.

27.3.6 Specific Absorption Rate SAR

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

27.3.7 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.

27.3.8 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.

27.4 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 ear piece 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

27.5 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.

27.5.1 Physical

Hand-held module:	278mm x 84mm x 38mm
Weight:	240g (490g with Otoport fitted)

27.5.2 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

27.5.3 Indicators

Data display:	Data is displayed via Otoport (refer to section 22.1)
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

27.6

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.

27.7 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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