Otodynamics
Audiology Systems

Otoport Screener

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Otoport Screener
User Manual Issue 15

Otoport Screener

Issue 15 : September 2012

Otoport Screener v1.13.0.0 onwards

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Contents

1 Introduction

1.0.a The Otoport Screener provides high quality OAE measurement features in a compact, handheld format.

1.0.b The Otoport Screener is simple to use and with powerful measurement features performs an automatic analysis of cochlear status within seconds. Customisable pass criteria control the test's automatic stop mechanism and a clear Pass/Refer indication is provided.

1.0.c The Otoport Screener's impressive list of features includes:

- TEOAE Quickscreen testing
- Ultra fast interactive graphic display
- ILO Gold Standard data format
- Frequency band or waveform analysis
- Mobile phone type keypad
- 1000 patient secure database
- Long battery life
- Data transfer allowing viewing and analysis on PC

1.0.d Options include:

- Integral barcode or RFID card reader
- Wireless printer

1.1 General use precautions

1.1.a Measuring OAEs 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.

1.1.b The Otoport includes 'stop criteria' which will automatically terminate the test when an OAE pass has been achieved or after a pre-determined time set by the user, which has a default of five minutes and may be set by the user to a maximum of 15 minutes.

1.1.c 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.

1.1.d The Otoport has built in signal analysis proven to distinguish true otoacoustic emissions from artefactal signals. Checks should be performed weekly and before each test session to confirm the system continues to operate effectively (see chapter 12 **Probe**).

1.1.e 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.

1.1.f 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.

1.1.g If contamination occurs the coupler tubes must be replaced (see chapter 14.2 **Changing probe coupler tubes**).

1.1.h 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.

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

1.1.j Do not allow liquid to enter the instrument.

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

2 Getting started

2.1 Otoport case contents

2.1.a Take a few moments to familiarise yourself with your Otoport kit:

Note: Otoport and accessories not shown to scale

2.1.b Otoport Screener - handheld OAE instrument

2.1.c UGS TEOAE probe

2.1.d Soft fabric drawstring probe bag

2.1.e Test cavity for probe checks

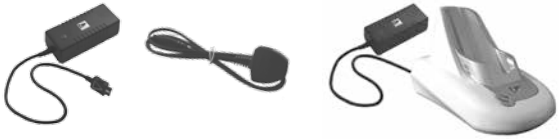
2.1.f Probe accessories (see chapter 13 for further information):

Probe cable clip

Sample probe coupler tubes

Spare probe body and lid

2.1.g Charger and mains lead or charging cradle



2.1.h PC cable for downloading patient and test data to PC

2.1.i Sample probe tips in compartmented box

2.1.j Otolink software CD

2.1.k Infection control sleeve - transparent, easy-clean cover for optional use with Otoport (shown fitted below right)

2.1.l Documentation pack - including instrument and software manuals, Quickstart and probe use guides

2.2 Optional accessories

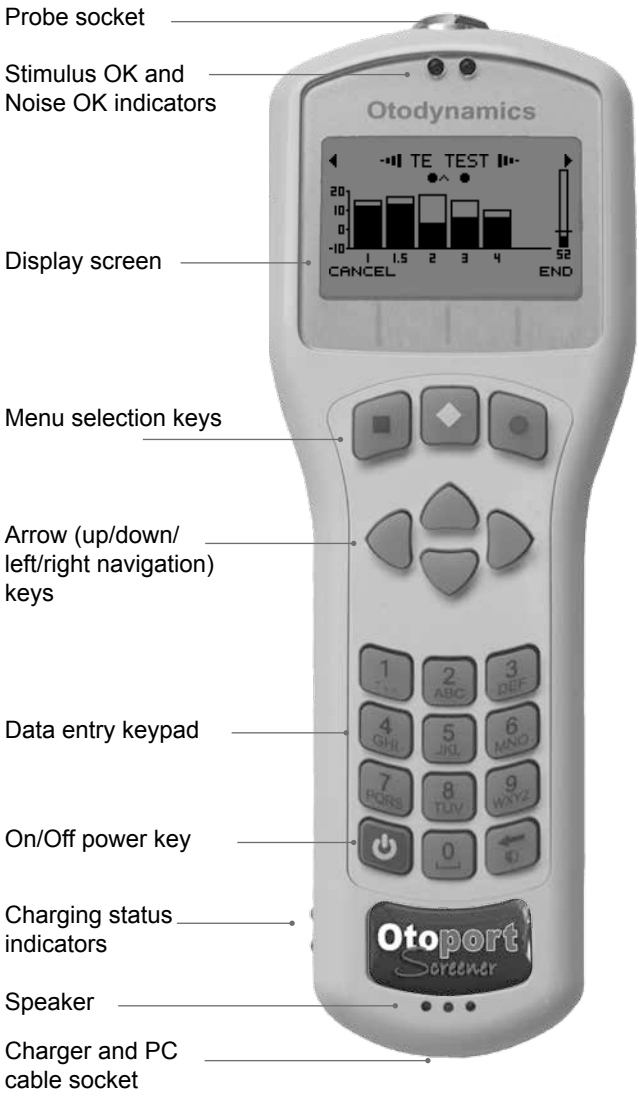
2.2.a A range of additional accessories are available from your distributor or from Otodynamics.

2.2.b Otoport docking station - a stable base to hold the Otoport, with connections for printing, charging and downloading to PC (shown with Otoport below right)

2.2.c Otoport printer - a small, portable printer for wired or optional wireless connection

2.2.d Large Otoport case, with additional compartment for printer (shown below left with Otoport kit including printer)

2.3 Controls, indicators and t



2.4 Scanner and labelling

Barcode/RFID scanner (not included as standard)

Model, serial number, certification, manufacturer details

The Otoport serial number comprises model code (OPB in this instance), year and month of manufacture (yymm) and unique manufacture ID (xxxx). The complete serial number is therefore OPB/yymmxxxx.

2.5 Initial charge

2.5.a Before using your Otoport Screener for the first time, fully charge the unit. See chapter 16 **Otoport Power** for details.

2.6 Quickstart

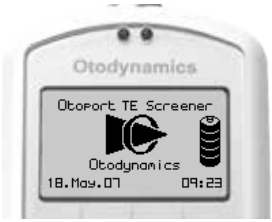
2.6.a The Quickstart guide shown on the following two pages is included in your document pack.

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.

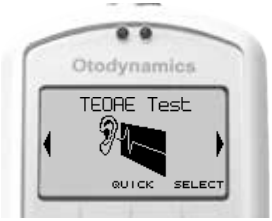
Step 2. Fitting the earpiece

1 Select an appropriate tip.

2 Fit the tip to the earpiece.

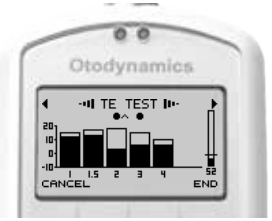
3 Fit the earpiece in the ear canal.

Step 3. Performing a TEOAE test



1 To run a **QUICK** test, press the button.

2 A vertical stimulus needle and low noise, with two blue LEDs, indicate a good probe fit. Press to **START** the test.



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

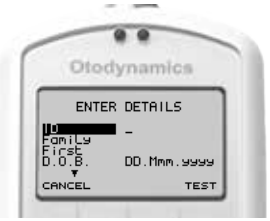
4 Use the ◀ ▶ buttons to scroll between the histogram and other test screen displays.

5 The test will auto-stop and a result graphic will be shown. Press the button to **REVIEW** the result.

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

Step 4. Saving patient details

1 Press the button to enter details for a new patient.



2 Use the buttons and keypad to enter patient details. Press to **SAVE**.

3 Select **Right** or **Left** ear using the or keys. Press to **Save** the choice.

Step 5. Disconnecting the probe

1 Unscrew the knurled sleeve.

2 Do NOT turn the main probe body.

3 Gently pull out the probe.

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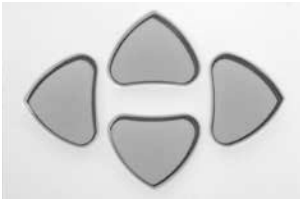
2.7 Using the keys and keypad

2.7.1 Control keys

2.7.1.a 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.

2.7.2 Arrow (navigation) keys



2.7.2.a 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.

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

2.7.3 Entering characters

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

2.7.3.b 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.

2.7.3.c 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.

2.7.4 Foreign character table

2.7.4.a 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.

2.7.5 Entering dates

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

2.7.5.b 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 and 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.

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

2.7.5.d If the date has not been edited, it will remain as dd.Mmm.yyy.

2.7.5.e 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.

2.7.6 Choice bars

2.7.6.a 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 bars options are enclosed by arrow graphics.

2.7.7 Deleting characters

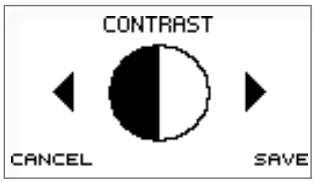
2.7.7.a The bottom right hand key is used as a **Delete** or **Contrast** key. If the cursor is at the end of a row of characters, press this key to delete the last character.

2.7.7.b 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 keys or deleted with the delete key. Continue to press the delete key to erase characters to the right of the cursor.

2.7.8 Back light

2.7.8.a 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.

2.7.9 Contrast



2.7.9.a Pressing the **Contrast/Delete** key while the logo screen is shown following switch on allows the user to adjust the screen contrast.

2.7.9.b Use the left and right arrow keys to adjust the contrast and select **Save** to store changes, or select **Cancel** to restore orginal settings. The Otoport will need to complete its start-up sequence before the next screen is displayed.

2.7.9.c The default setting should be adequate in most circumstances but adjustment may be helpful in unusual environments such as cold operating conditions.

2.7.10 Stimulus and Noise OK indicators (blue LEDs)

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

2.7.10.b The Stimulus LED is marked with an S. It is lit when the stimulus level recorded by the probe microphone is within the expected range. During testing this is the range defined in **Test setup** (see chapter 9).

2.7.10.c The Noise OK LED is marked with an N. It is lit when the noise level recorded by the probe microphone is below the noise reject level (see chapter 9).

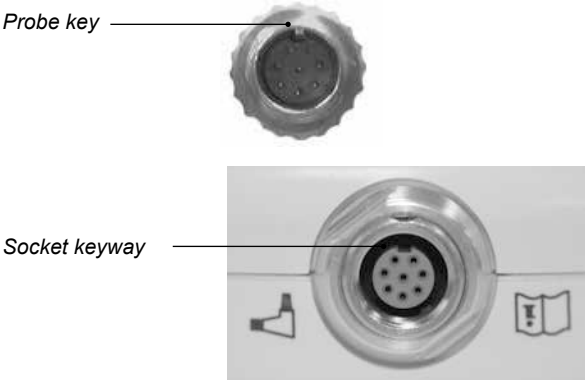
2.7.11 Hard reset

2.7.11.a 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.

2.8 Connecting the probe

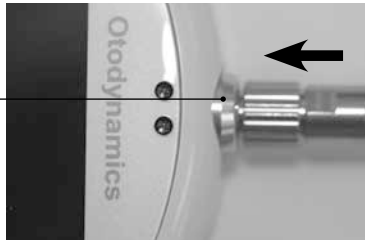
2.8.a Prior to the testing session, connect the probe to the Otoport.

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

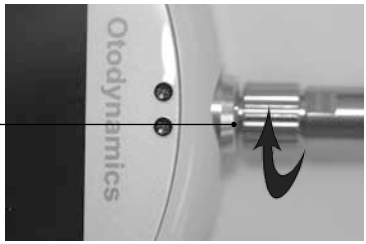


2.8.c The arrow at the front of the probe plug indicates the position of the 'key' and should be aligned with the front of the Otoport.

2.8.d It is possible to feel when the probe key is aligned as the probe will mate with the socket easily. Push the probe into the socket until it hits the end stop. DO NOT force in the probe.



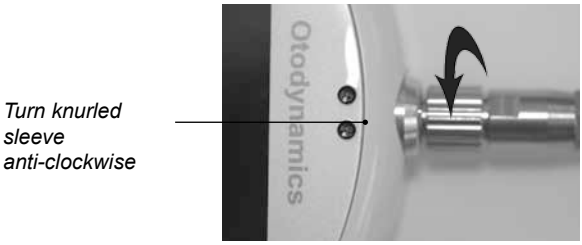
2.8.e Screw up the **knurled sleeve** in a clockwise direction until finger tight.



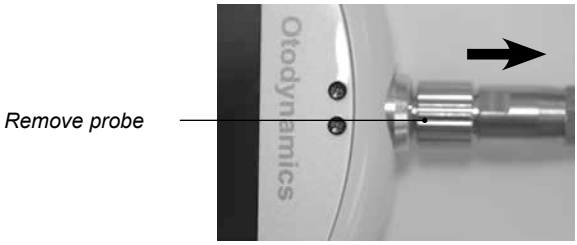
2.8.f Please see next page for instructions on disconnecting the probe.

2.9 Disconnecting the probe

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

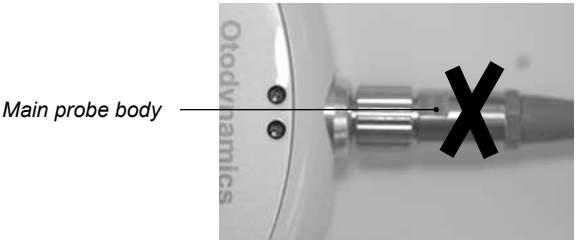


2.9.b Then gently pull the probe out of the probe socket.



2.9.c Important Note:

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

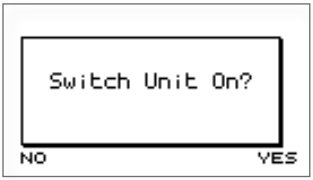


This will result in damage to the probe and will invalidate the probe warranty.

3 Switching on

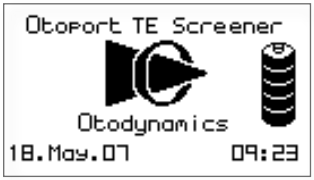
3.1 Switch on screen

3.1.a 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?**.



3.1.B 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 selected. This is to prevent accidental switch on during transit.

3.2 Logo screen

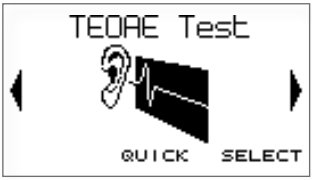


3.2.a Following switch on, an Otodynamics' logo animation is displayed whilst the device performs a series of hardware system checks. In the unlikely event of any of the system checks failing, an error message will be displayed (see chapter 17.5 **Hardware error message** for details).

3.2.b A battery graphic will appear to the right of the logo to provide an indication of the **Battery Power** remaining. Please refer to chapter 16 **Otoport Power** for battery information.

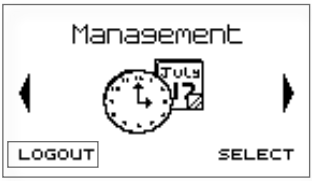
3.2.c The date and time are also shown at the bottom of the screen and can be reset by an Administrator in the device **Management** module. See chapter 8.4 **Date & Time**.

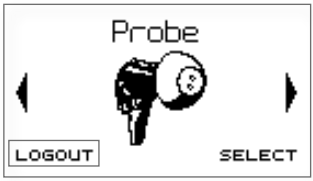
3.3 Scrolling modules



3.3.a The **Test** module screen is then displayed.

3.3.b Other module screens can be accessed using the left and right arrow keys. Choose **Select** to enter each menu.





4 Test preparation

4.1 General checks before testing

4.1.a Ensure the Otoport is charged (see chapter 16 **Otoport power** for information)

4.1.b Ensure the Otoport weekly checks are being regularly conducted (see chapter 12 **Probe** for information)

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

4.1.d Choose a quiet room, without background noises.

4.1.e Ensure the patient is comfortable and settled.

4.1.f Ensure you can clearly see the ear to be tested.

4.2 Connecting the probe

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

4.3 Tip selection and probe fitting

4.3.a 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 chapter 13.3 **TEOAE 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.

4.3.1 Fitting for newborns

4.3.1.a 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.

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

4.3.1.c Turn the probe ear piece to 12 o'clock.

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

4.3.2 Fitting for children and adults

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

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

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

4.3.2.d 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.

4.4 Helpful hints

4.4.a 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.

4.4.b 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.

4.4.c 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.

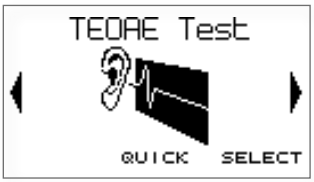
4.4.d Noises from the patient may not prevent successful recording, but will increase the test time. Constant environmental background noise, for example from air conditioning or machinery, may prevent a successful test. Testing should only be conducted in rooms where the noise level recording on the 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.

4.5 OAEs and screening

4.5.a 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.

4.5.b 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 conditions indicate the possibility of retro-cochlear/neurological disorders which the OAE test cannot detect.

5 Test



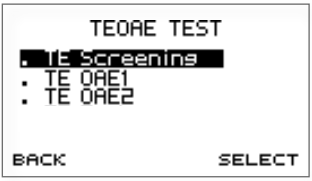
5.0.a From the main **Test** module screen, choose **Select** to enter patient details before selecting a test type and performing a test.

5.0.b Choose **Quick** to go directly to the test choice screen. Patient details may be entered after the test.

5.0.c If the Otoport detects a hardware error which may affect testing, an error screen will be displayed when you attempt to start a test. If this occurs do not continue with the test and consult chapter 17.5 **Hardware error message**.

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

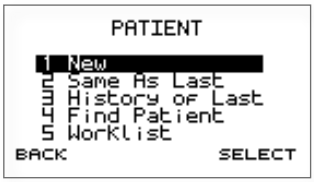
5.1 Test choice



5.1.a Choose a TEOAE test from the list using the arrow keys, then press **Select**.

5.1.b If the TE mode you wish to use is not displayed, refer to chapter 9 **Test setup**.

5.2 Patient menu



5.2.a New

5.2.b Select **New** to enter details of a new patient to test.

5.2.c 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.

5.2.d Same as last

5.2.e Select **Same As Last** to begin a test using 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.

5.2.f History of last

5.2.g 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.

5.2.h Find patient

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

5.2.j Worklist

5.2.k Select **Worklist** to test a patient stored in the worklist.

5.3 Entering patient data

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

5.3.b Patient details fields

5.3.c Fields can be selected by pressing the up and 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.

5.3.d Patient details description

5.3.e An explanation of the **Patient Details** fields is shown in the table on the next page.

5.3.f Mandatory patient details

5.3.g 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.

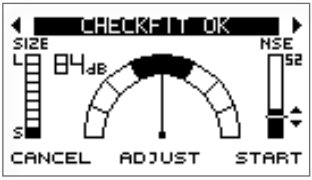
5.3.h Beginning a test

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

Field	Description	Max no. Characters
ID	The patient's ID number or local hospital number	12
Family	The patient's family name	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.	

5.4 Checkfit

5.4.1 Checkfit display



5.4.1.a It is important to perform a test in the appropriate conditions. The **Checkfit** screen allows a user to assess the testing environment before starting the test.

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

5.4.1.c Ear canal size indicator

5.4.1.d 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.

5.4.1.e 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; a 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.

5.4.1.f Noise level indicator

5.4.1.g A Noise Level Indicator is shown on the right of the **Checkfit** screen. The shaded bar moves in response to changes in noise. For good testing conditions the shaded bar should be consistently below the Noise Reject Threshold Level which is represented by the horizontal line across the Noise Level Indicator. The threshold level is displayed numerically above the indicator. Use the up and down arrow keys to change the Noise Reject Level.

5.4.1.h

Stimulus level indicator

5.4.1.i A Stimulus Level Indicator is shown on the left of the **Checkfit** screen. With the probe in an ear the device will attempt to adjust the stimulus to the set testing level. The indicator's needle and the numeric display to the left of the arc show the change in stimulus level during adjustment. The stimulus is at the set testing level when the needle is vertical.

5.4.1.j

Checkfit condition information

5.4.1.k **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.

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

5.4.1.m **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.

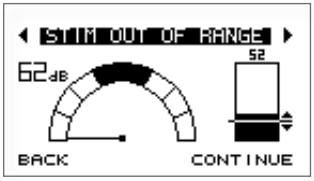
5.4.1.n **Ringing** is displayed when there is obvious oscillation within the **Stimulus Waveform** after the initial positive and negative peaks instead of a flat line response.

5.4.1.o 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

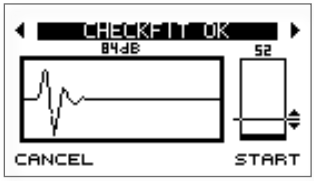
5.4.1.p When **Checkfit OK** is present on screen indicating conditions are suitable for testing, select **Start** to begin a test or **Cancel** at any point in **Checkfit** to return to **Patient Details**.

5.4.1.q **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.



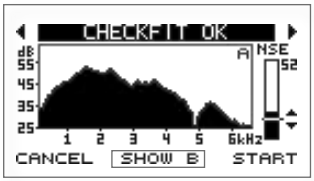
5.4.1.r Additional checks on testing conditions are the stimulus and noise LEDs above the screen. Both LEDs are lit in ideal testing conditions.

5.4.2 Stimulus waveform display



5.4.2.a Pressing left and right arrow keys during **Checkfit** switches the screen display between the Stimulus Level Indicator and the Stimulus Waveform display which 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. After stimulus adjustment the large positive peak should be just inside the **Stimulus Waveform Window** and the numerical display above the window should read **84dB** (default).

5.4.3 Stimulus spectrum display



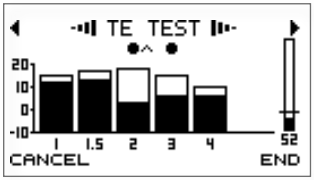
5.4.3.a Press the left and right arrow keys during **Checkfit** to access the **Stimulus Spectrum Display**. This shows how the energy in the stimulus waveform is distributed over frequencies. This distribution is dependent on the fit of the probe and the geometry of the individual ear canal.

5.4.3.b 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.

5.5 Test

5.5.a When **Start** is pressed after **Checkfit**, the OAE recording begins and data is collected and displayed on a choice of three test screens - an OAE histogram 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 and right arrow keys can be used to toggle between the screen choices when a test is in progress.

5.5.1 Histogram



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

5.5.1.b A dot will appear above a bar if the TE in the half-octave band which has met its Stop criteria. Please refer to the **Test Setup** (chapter 9) for further information on the band Stop criteria.

5.5.1.c 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 dot to show the level is off the graphical scale.

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

5.5.1.e Brackets can be displayed to indicate normative ranges (see chapter 9 **Test setup**).

5.5.1.f 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.

5.5.1.g Noise level indicator

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

5.5.1.i Test condition information

5.5.1.j When conditions are good for data collection **TE TEST** will be shown at the top of the screen and progress indicators will move either side of the title to show that a test is currently running.

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

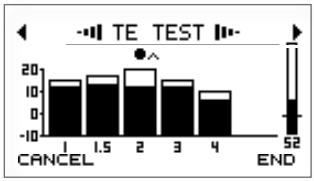
5.5.1.l **Check Probe Fit** is shown if the adjusted stimulus level falls outside the accepted range.

5.5.1.m The following table describes the test condition information which appears if more than one condition is met:

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

5.5.1.n

Cancel and End



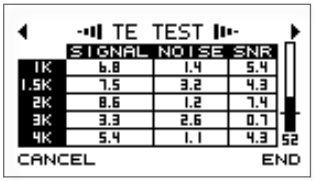
5.5.1.o Select **Cancel** at any time during a test to pause the test. This may be useful if the ambient noise increases. **Cancel Test?** is displayed at the top of the screen and three options are provided. **Yes** will terminate the test; **No** will continue the OAE recording and **Checkfit** will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

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

5.5.2 Data tables

5.5.2.a During the test the two data tables are accessed by pressing the left and right arrow keys.

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



5.5.2.c 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)

5.5.2.d The SNR value is highlighted (displayed white on black) in bands that have met the pass criteria set.

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

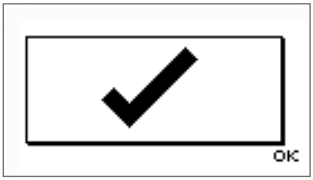
5.5.2.f The following table describes each field in detail:

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 he 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	%
REPRO	The correlation of the two OAE waveforms	%
TIME	Test time	sec
STIM	The Stimulus level at the start of the test	dB pe
PROBE	The probe identification number	n/a
FILE	The unique gtest file name (populated on Save)	

5.5.3 Test stop reasons

5.5.3.a The test will either stop automatically or can be manually terminated by the user. A single beep will sound at the end of the test when Stop criteria have been met. Two beeps are emitted for other Stop reasons.

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

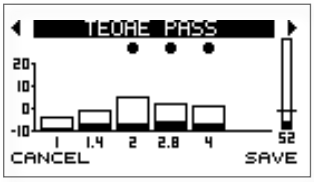


5.6 Test results

5.6.a 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
TEOAE Pass 	The data collected has met the set Stop criteria
Note: The following results will only occur if a TEOAE Pass is not obtained, providing test information feedback to the user	
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%
No Valid OAE 	The data collected has not met the setStop criteria and the test conditions were acceptable
Too Few Bands 	If insufficient bands meet their stop criteria
Stopped Too Soon 	If a user ends the test manually before the required minimum amount of data has been collected

5.7 Save and review



5.7.a When a test is completed, select **Save** to save the result. Select **Cancel** to discard the result; a confirmation screen is provided which also gives the option to restart the test at Checkfit.

5.7.1 Select left or right ear

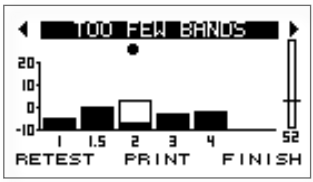
5.7.1.a The **Select Ear** screen represents the patient facing you. By defaulting to a **No Ear Choice** the **Select Ear** screen forces the user to choose an ear before the test can be saved. Press the right control key or the right arrow to select the **Left Ear** or press the left control key or the left arrow key to select the **Right Ear**. Select **Back** to return to the **Patient details** screen.

5.7.1.b Once the correct test ear has been selected press **Save** to save the test record to the database.

5.7.1.c If **Save** is not confirmed within 5 seconds, the choice will be cancelled. The **Select Ear** screen will be displayed again.

5.7.1.d Following **Save** confirmation, a screen will be displayed briefly which confirms the test has been saved.

5.7.2 Test review screens



5.7.2.a 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 and right arrow keys can be used to toggle between the three screen choices.

5.7.2.b Select **Retest** to repeat the test.

5.7.2.c Select **Print** to print the patient details and test result (see chapter 10 **Printing** for further details).

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

5.8 Quick test

5.8.a By selecting **Quick** on the **Test** module screen an OAE test can be started directly, bypassing **Patient Details** entry. This option gives the user flexibility when testing conditions are variable.

5.8.b On selecting **Quick** the device will enter the **Checkfit** screen.

5.8.c When a test has stopped, select **Save** to access the **Save Options** menu screen.

5.8.1 Save options menu

5.8.1.a Enter details

5.8.1.b Select **Enter Details** to add new **Patient Details** before saving the test.

5.8.1.c Same as last

5.8.1.d Select **Same As Last** to save the test to the last saved patient. A non-editable view of the patient's details will be shown on screen to confirm the patient before the test is saved. Enter the test details and **Save** the results.

5.8.1.e Find patient

5.8.1.f To append the result to a patient record in the database, select **Find patient**.

5.8.1.g Worklist

5.8.1.h To append the result to a patient record in the Work List, select **Worklist**.

5.8.1.i Select **Back** to return to the test data.

6 Records

6.1 Records menu

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

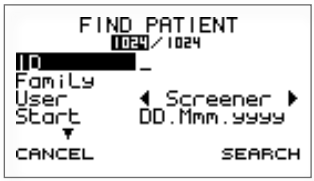
6.1.b Select **Work List** to edit or add a new patient to the **Worklist.** The **Worklist** can be reviewed and a patient selected to test.

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

6.1.d Select **Back** to return to the main **Menu** screens.

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

6.2 Find patient



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

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

6.2.c Filter by **User** with the left and right arrows.

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

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

6.2.f 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.

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

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

6.2.1 Patient list

6.2.1.a 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.

6.2.1.b 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.

6.2.1.c Use the up and 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.

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

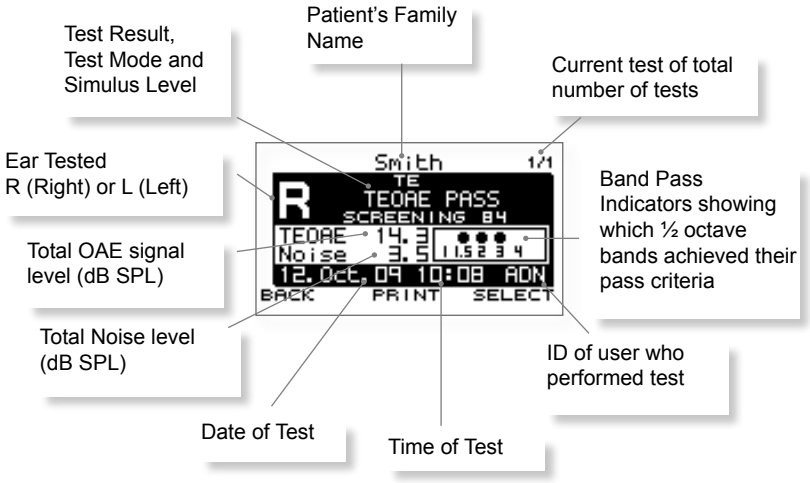
6.2.1.e Select **Details** to review the complete **Patient Details** of the highlighted patient.

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

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

6.2.2 Test summary

6.2.2.a When reviewing **Results**, a summary of each of the patient's tests is given on screen. This includes ½ octave band passes and total OAE signal level. The following diagram details all features of a **Test Summary** screen:



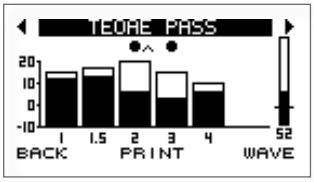
6.2.2.b The number of tests currently saved to the patient is displayed in the top right of the screen. Press the **Up/Down Arrow** keys to scroll between tests. The test number will increment accordingly.

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

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

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

6.2.3 Detailed test review



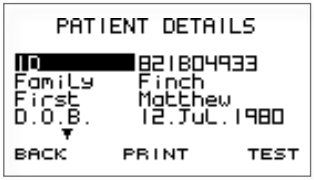
6.2.3.a **Test Results** can be reviewed in detail by choosing **Select** on the **Test Summary** screen. The OAE test data is shown on three test screens and test details are also available. Please refer to chapter 5 **Test** for a full description of the screen displays.

6.2.3.b Use the left and right arrow keys to scroll between the screen choices.

6.2.3.c Select **Wave** to show the OAE waveform. During a test, two interleaved OAE waveforms (named A and B) are collected. When **Wave** is selected, one of these two waveforms will be displayed. Select **Show A** or **Show B** to toggle between the two waveforms. Waveforms that correlate well represent good quality recordings where the noise level is low. If the waveforms are significantly different, this indicates noise was present during the measurement. Examine the waveforms to help identify artefactual signals, which typically do not have an even distribution of energy across the complete response window. If you are concerned about the performance of your Otoport, run the system **QA test** (see chapter 12 **Probe**).

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

6.2.4 Review patient details in database

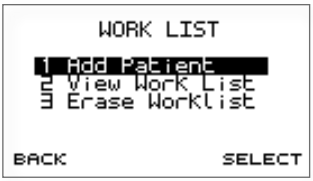


6.2.4.a A non-editable version of highlighted **Patient Details** can be reviewed by selecting **Details** in the **Patient List**.

6.2.4.b Select **Test** to enter specific test details for the current test. Select **Test** again to start the test process. Please refer to chapter 5.4 **Checkfit** for an explanation on how to setup and perform a test.

6.2.4.c Select **Back** at any time to exit **Patient Details** and return to the **Test Summary**.

6.3 Work list



6.3.a 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.

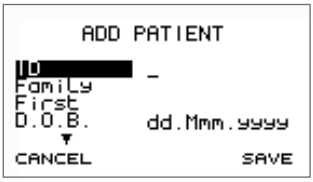
6.3.b Select **Add Patient** to add a new patient to the work list.

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

6.3.d 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.

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

6.3.1 Add patient



6.3.1.a 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 5.3 **Entering patient data** for guidance on entering data in fields and mandatory requirements before saving.

6.3.1.b 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 to discard entered data.

6.3.1.c A warning will appear if the patient added to the **Work List** is already present in the Otoport database. It is possible to append the entry to that patient record, or edit the **Work List** entry.

6.3.2 View work list

6.3.2.a 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 and down arrows to scroll between patients and the left and right arrows to jump 5 patients at a time.

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

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

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

6.3.2.e Review patient details in work list

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

6.3.2.g Select **Test** to enter test details specific to the test. Please refer to chapter 5.4 **Checkfit** for an explanation on how to setup and perform a test.

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

6.3.2.i Choose **Select** when **Edit** is highlighted to show an editable version of the **Patient Details**. Please refer to chapter 5.3 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** to modify the changes made.

6.3.2.j 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.

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

6.3.3 Erase work list

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

6.4 Database summary

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

6.4.b The Otoport can store up to 1024 patient records and over 3000 test results. An individual patient record can store up to 256 test results.

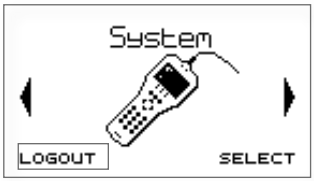
6.4.c Select **Back** to return to the **Records Menu**.

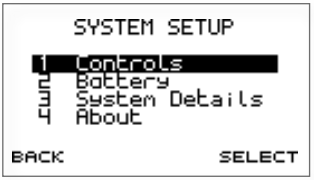
6.5 Erase all

6.5.a 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.

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

7 System





7.1 System menu

7.1.a Select **Controls** to adjust **Volume**, **Contrast** and timing of the **Backlight**.

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

7.1.c **System Details** displays information for Otodynamics engineers.

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

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

7.2 Controls

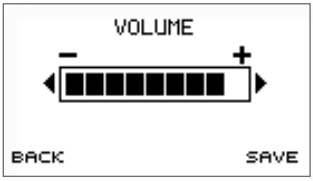
7.2.a Select **Volume** to increase or decrease the unit's volume level or to turn sound off.

7.2.b Select **Contrast** to adjust the contrast of the screen for varying light conditions.

7.2.c Select **Backlight** to change the setting of the screen backlight.

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

7.2.1 Volume

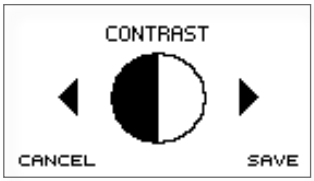


7.2.1.a Use the left and right arrow keys to decrease or increase the **Volume** level. To turn the sound off press the left arrow key repeatedly until **Sound Off** appears in the centre of the display.

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

7.2.1.c Select **Back** to ignore changes and return to the **Controls Menu**.

7.2.2 Contrast

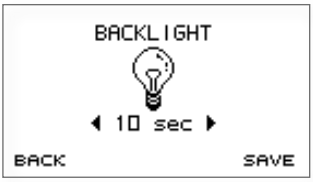


7.2.2.a The screen **Contrast** can be altered by pressing the left and right arrow keys. The shaded section of the graphic will vary according to the chosen **Contrast** level.

7.2.2.b Select **Save** to accept the adjusted **Contrast** level.

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

7.2.3 Backlight

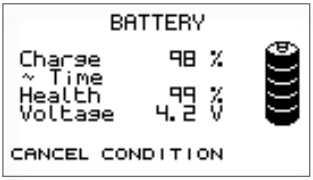


7.2.3.a Use the left and right arrow keys to toggle between the **Backlight** control choices. The backlight can be configured to be either always **on** or **off**, or **on** for a limited period of time (7, 10, 20 or 30 sec) after a key press. Reduction in the backlight time will help to preserve battery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

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

7.2.3.c Select **Back** to ignore changes and return to the **Controls Menu**.

7.3 Battery



7.3.a 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.

7.3.b 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.

7.3.c 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 (%)
5	≥ 95%
4	≥ 70%
3	≥ 50%
2	≥ 30%
1	≥ 10%
0	< 10%

7.3.d The battery **Voltage** and **Health** are provided as diagnostic tools for the Otodynamics support team.

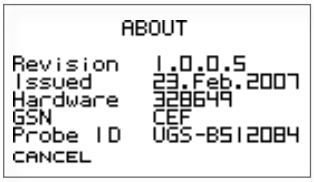
7.3.e The battery graphic is also displayed on the **Logo** screen to inform the user of the **Battery Power** every time the device is switched on.

7.3.f Select **Condition** to condition the Otoport battery. See chapter 16 **Otoport power** for more information.

7.4 System details

7.4.a **System Details** displays information for Otodynamics engineers. The device performs electrical self-checks and any errors during these tests are displayed.

7.5 About



7.5.a The **About** screen details information relating to the Otoport's identification and mode of operation. The firmware revision number and creation date is stated together with the unit's unique hardware ID. If a probe is connected the **Probe ID** will also be displayed for reference.

8 Management

8.1 Management menu

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

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

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

8.1.d Select **Other Options** to alter patient ID format and login activation preferences and to add a site and device identification which are then saved to **Test Records**.

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

8.2 Users

8.2.1 Add new user

8.2.1.a To add a **New User**, complete the field entries shown on the **New User** screen. The following table 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 (caps only)
Password	An alphanumeric password required for secure login.	8 (caps only)
Admin	Select **Yes** to give the new user administrator access rights. Select **No** to restrict the user to screener rights (described on the next page).	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 (configure choices).	n/a
NICU	Are patients tested by this user predominantly in the neonatal intensive care unit, **Yes** or **No**?	n/a

8.2.1.b 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.

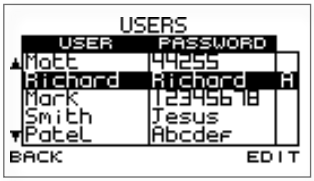
8.2.1.c A new user is given a choice of two levels of access rights. If **Yes** is selected in the administrator field then the user will have full access to all modules of the device. Select **No** to restrict the user's rights to only **Test**, **Records**, **Probe**, **Print** and **System** modules.

8.2.1.d 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**.

8.2.1.e 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, User ID and Password** may appear on selecting **Save** if any of the three fields have been left unfilled.

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

8.2.2 View users



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

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

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

8.2.2.d Edit user

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

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

8.2.2.g 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.

8.2.2.h The message **Cannot Delete! User has tests in database** will appear if the user has performed tests that are still present within the database. It is necessary to delete all **Patient Records** from the device prior to deletion of users. Note: **Patient Results** should be downloaded to PC first.

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

8.2.3 Login

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

8.2.3.b 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.

8.2.3.c 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**.

8.2.3.d 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 and right arrow keys.

8.2.3.e 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:

8.3 Facility and risk

8.3.a Select Facility to edit the name of the hospital or clinic where the device is commonly used.

8.3.b Select **Risk Factors** to view or customise the list of 10 patient risk factor choices available.

8.3.1 Facility

8.3.1.a 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.

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

8.3.1.c Select **Cancel** to return to the **Defaults Menu** screen and discard alterations made to **Facility** names.

8.3.2 Risk factors

8.3.2.a The **Risk Factors** screen allows a user with Administrator access to modify the list of 10 risk factors available. The name chosen to identify each risk factor should be no longer than 12 characters and organised from 1 to 10.

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

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

8.4 Date and time

8.4.a 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.

8.4.b When the **Date** 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 and 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.

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

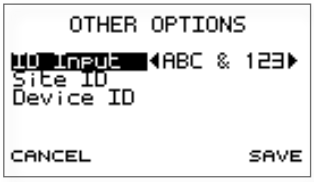
8.4.d Select **Save** to set the current date and time settings and return to the **Management Menu** screen.

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

8.4.f Important Note:

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

8.5 Other options



8.5.a **Other Options** are available to customise the use of the device within a specified screening environment.

8.5.1 ID Input

8.5.1.a 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

8.5.2 Site ID

8.5.2.a 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.

8.5.3 Device ID

8.5.3.a 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.

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

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

9 Test set-up

9.1 Test setup menu

9.1.a The Otoport Screener 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 detection logic, where the device will automatically end the recording when the criteria have been met.

9.1.b There are four separate test modes, three of which may be set by the user.

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

9.1.d Use the **Select** option to view the TE test modes.

9.1.e 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.

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

9.1.g 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.

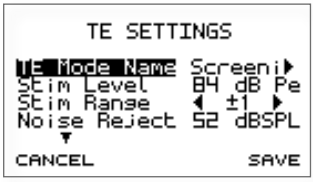
9.1.h Select **Cancel** to return to the **Test Setup** menu screen without saving changes to the available test modes.

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

9.2 Edit mode

9.2.a The name of the selected mode is shown. Test parameters are split into four sections, **Test Config**, **Stop Criteria**, **Automation** and **Other Settings**. It is not possible to edit the factory mode. Choose the section to edit then **Select**.

9.2.1 Test config



9.2.1.a 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 and down arrow keys to scroll up and down the settings and highlight a parameter to edit. The parameter variable will flash. Use the left and right keys to change each setting. See the following table for details of the settable test parameters.

Field	Description	Range
TE mode name	User settable mode name	8 characters max
Stim level	Peak target stimulus level for testing	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’.	+/- 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, but this could have a negative effect on data quality as it could contain more noise and there is an increased risk of noise artefacts.	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 below). In most ears, the stimulus click becomes ‘flat’ following the click stim (see fig. 2 below), 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.	-10 to -30dB

Field	Description	Range
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.	10-990
Test time	The maximum time the test before automatic stop.	10-900 secs
Resp 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	Function not available on this device.	Off
Norms	User settable normative data ranges for each frequency band.	-10 to 20 or off

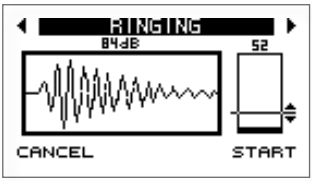


Fig 1

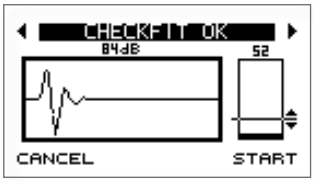


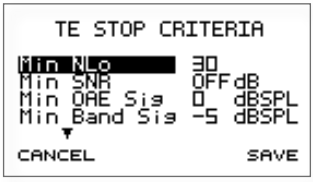
Fig 2

9.2.1.b 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.

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

9.2.2 Stop criteria



9.2.2.a The test stop logic is controlled in this section. Up and down arrows on the screen indicate other fields are available, but not currently visible. Use the up and down arrow keys to scroll up and down the settings and highlight a parameter to edit. The parameter variable will flash. Use the left and right arrows to change each setting. It is possible to turn off some settings, which means the parameter will not be included in the stop criteria logic.

9.2.2.b When **Setup Bands** is selected a pop up table enables the edit of each ½ octave band criteria. Use the up and down arrows to select the parameter to edit and to move between the **SNR** and **RQRD** (required) columns and left and right arrows to edit the settings. Move down at the bottom of the **SNR** column to edit the **RQRD** column.

9.2.2.c See the table below for details of the settable stop criteria.

Field	Description	Range
Min NLo	The minimum number of low noise data samples (when the noise present is below the reject level) that has to be been collected	10 to 222
Min OAE sig	The minimum total OAE signal level required	-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)	0 to 20 or Off
Min band sig	The minimum level of OAE signal required in each band	-10 to 20 or Off
Pass bands	The minimum number of band passes required in order to meet the overall pass criteria	1 to 5
Setup bands:		
Min SNR	The minimum signal to noise ratio required for a band pass	1 to 14 or Off
RQRD	Controls which bands are mandatory for a pass to be achieved	Yes/No

9.2.2.d Note:

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

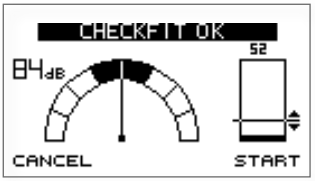
9.2.3 Automation

9.2.3.a The Otoport Screener 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.

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

9.2.3.c Auto start

9.2.3.d 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.



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

9.2.3.f Auto stop

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

9.2.3.h 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**.

9.2.3.i Autoadjust

9.2.3.j 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.

9.2.3.k 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.

9.2.3.l Override

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

9.2.3.n 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.

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

9.2.4 Other settings

9.2.4.a Mandatory

9.2.4.b 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.

9.2.4.c 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.

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

9.2.4.e Mic filter

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

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

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

9.2.4.i 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.

9.2.4.j 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.

9.2.4.k **0.4-6.4k** (400-6400Hz): Collects data at the widest frequency range possible.

9.2.4.l **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.

9.2.4.m **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.

9.2.4.n **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 9.2.2 **Stop criteria**).

9.2.4.o Test setup defaults

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

9.2.4.q **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.

9.2.4.r **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.

9.2.4.s **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.

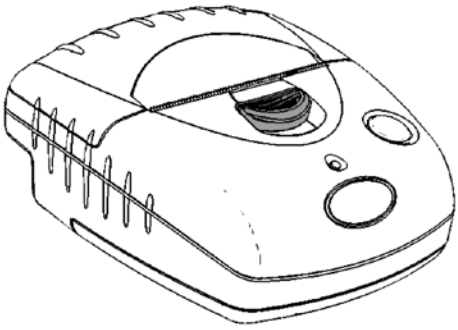
9.2.4.t **Factory** mode cannot be edited and is designed for Quality Assurance purposes.

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	
Test 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	

NB: The 6K band function is not available on the Otoport Screener. It is set to Off and cannot be changed on this device.

10 Printing



10.1 Printer accessory

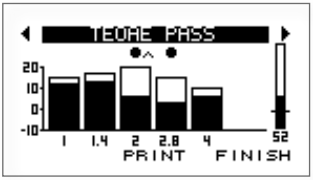
10.1.a An Otoport mini printer is available as an optional accessory. The printer is used to create a paper record of the OAE test results recorded on the Otoport. The Otoport either communicates with the printer using wireless technology (optional) or with a custom printer cable.

10.2 When you can print

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

10.2.1 Printing at the end of a test

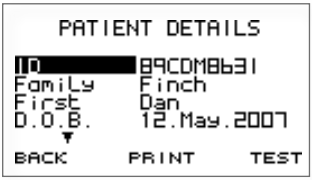
10.2.1.a When the OAE recording is finished and the result has been saved, select **Print** for a printout of the patient details and test results.



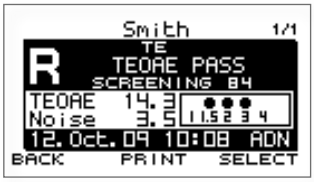
10.2.2 Printing from records

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

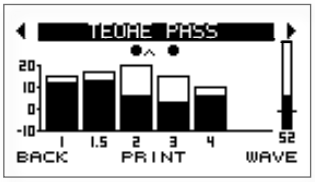
10.2.2.b To print patient details and all test results for that patient, select **Print** on the **Patient Details** screen.



10.2.2.c To print 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 view the test details and select **Print**.



Test summary screen



Test details screen

10.3 Print menu

10.3.a From the Otoport **Print** menu, it is possible to initiate prints for the last test, or last patient, as well as configuring print options.

10.3.b Choose **Select** to enter the **Print** menu.

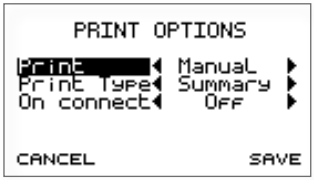
10.3.1 Last test

10.3.1.a This prints the last test recorded including the associated patient details.

10.3.2 Last patient

10.3.2.a This option prints all the test results for the last patient including their patient details.

10.3.3 Print options



10.3.3.a Manual or automatic printing

10.3.3.b If you always wish to print OAE results it is possible to set the device to automatically print the test at the point when the test is saved. This eliminates the need to initiate the print manually. To change the setting, using the up and down arrow keys to ensure that **Print** is highlighted and then use the left and right arrow keys to change the choice bar setting from **Manual** to **Automatic**.

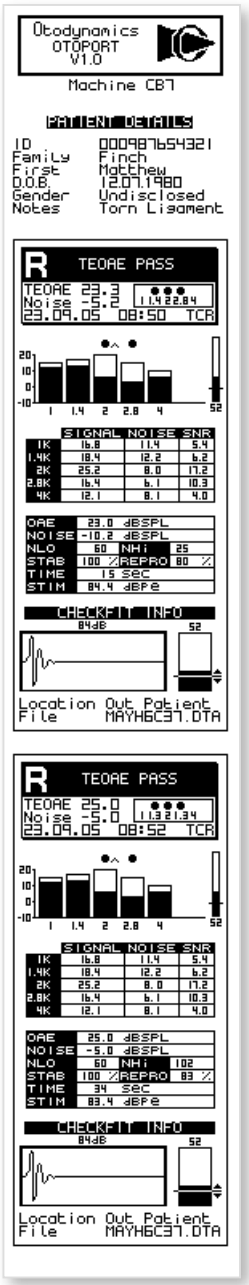
10.3.3.c **Print manual** is the default setting.

10.3.3.d

Print type

10.3.3.e

There are two printing formats provided on the Otoport - **Summary** and **Detailed**. The **Summary** format (below left) prints core patient details and the test summary screen. The **Detailed** format (right) prints all the test screens and a fuller set of patient details.



10.3.3.f On connect

10.3.3.g **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.

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

10.3.3.i Printing will only start if the Otoport is on and displaying one of the main module screens (see chapter 3.3).

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

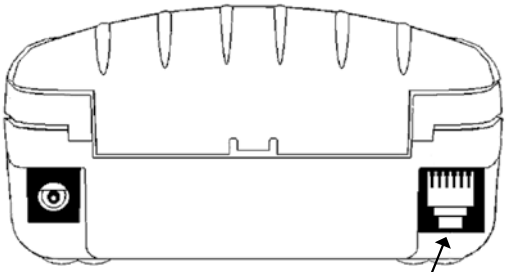
10.3.3.k If **Cancel Print** is selected, the Otoport will not attempt to automatically print the test(s) again (test may still be selected to be printed manually).

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

10.3.3.m 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.

10.4 The printing process

10.4.a 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

10.4.b 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.

10.4.c 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.

10.4.d When a print is initiated, the Otoport will establish communication with the printer. The screen **Connecting to Printer** will be displayed.

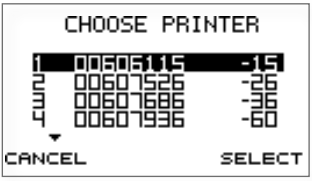
10.4.e The printout will then commence. The screen will display **Printing** during the print process. Select **Cancel** to terminate the printout. When the printout is completed, the screen from which the print was initiated will be displayed.

10.4.f If there is a problem connecting to the printer using the wired method, the message **Printer not connected!** 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.

10.4.g 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**.

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

10.4.i 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.



10.4.j 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.

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

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

10.4.m 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.

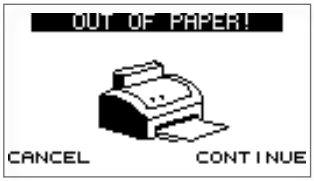
10.5 Printer fault detection

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

10.5.b For wired printing, the Otoport will report the printer is out of paper and the following message will be displayed.

10.5.c Select **Continue** to restart the printout once you have rectified the problem or **Cancel** to cancel the print job.

10.5.d For wireless printing, print jobs sent to the printer will be stored (spooled) and printed when the detected condition is rectified. The printer's green light will flash when a print job is being stored.



10.5.e 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.

10.6 Printer light summary

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

10.6.b **Constant green** - Normal operation, running on battery power.

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

10.6.d **Flashing green/orange** - Battery is being charged

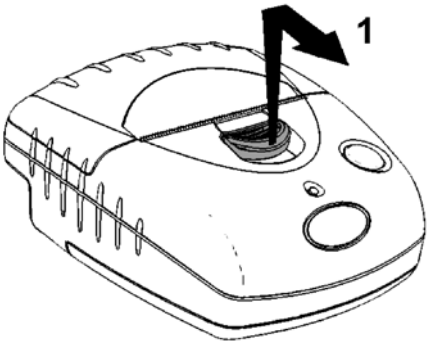
10.6.e **Red** - Low battery or other problem

10.6.f **No light** - Unit is in sleep mode, has a flat battery, or the battery is not connected

10.7 Paper

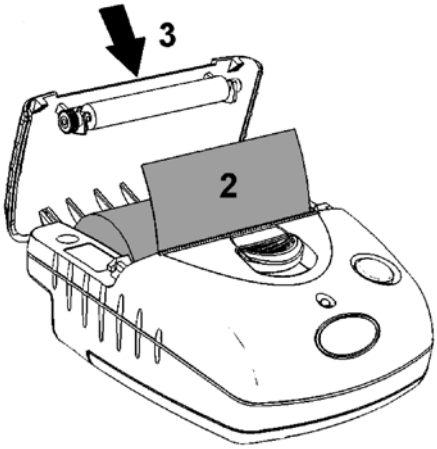
10.7.a When the printer is switched on, the key provides a paper feed function. A double press of the key will initiate a test print.

10.7.b 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.



10.7.c 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.

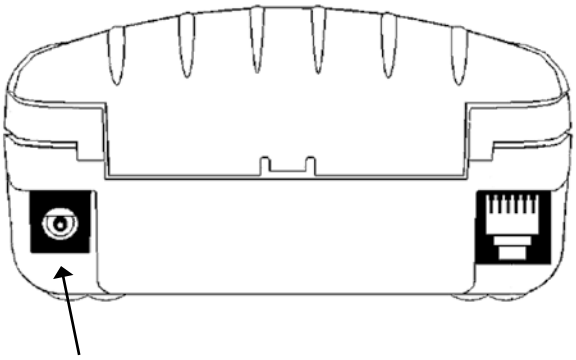
10.7.d After loading, check that the paper advances properly using the paper feed function, and tear off any excess by pulling the paper sharply towards you across the serrated tear bar. In the event of a jam or other paper loading problem, release the lid and straighten the paper before closing again.



10.7.e 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.

10.8 Charging the printer

10.8.a 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

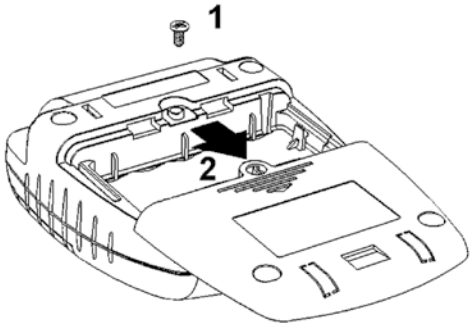
10.8.b The printer can be used as normal whilst charging.

10.8.c 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.

10.8.d 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.

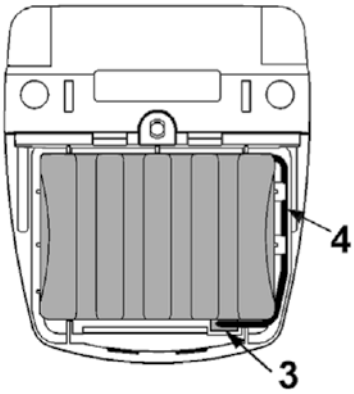
10.9 Changing the battery



10.9.a 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.

10.9.b To change the battery pack:

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



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

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

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

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

10.9.h Slide back the battery compartment cover and replace the screw.

10.9.i Important Note:

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

11 Scanning

11.1 Scanning facility

11.1.a As well as the standard data entry method using the keypad, the Otoport provides two optional methods for data entry using scanners. The scanning methods are designed to reduce testing session times by making the patient data entry method efficient.

11.1.b The scanners can also be used as part of the device security system during login. Each operator can be assigned a login card, which the Otoport will scan and verify in order to provide access to the machine.

11.2 Scanner types

11.2.a The Otoport has two scanning methods available.

11.2.1 Barcode scanning

11.2.1.a This method will scan barcodes which as standard hold numerical data. In screening programs which use barcode identification for patient ID, the Otoport can be used to scan this number quickly into the device.

11.2.1.b To scan with the barcode scanner, position the Otoport parallel with the barcode at a distance of around 10cm and select **Scan**. Line up the red light across the barcode.

11.2.1.c The Otoport will show a **Scanning** screen.

11.2.1.d When the barcode is read successfully a beep will sound and the barcode number will populate the required field. Select **Cancel** to abort the scan.

11.2.2 RFID scanning

11.2.2.a This method scans radio frequency identification (RFID) chips, which can hold enough alphanumeric data for a complete patient data record on the Otoport.

11.2.2.b To scan with the RFID scanner, hold the card up to the Otoport scanning window. Select **Scan** and swipe the Otoport across the card slowly. The Otoport will show a Scanning screen as above.

11.2.2.c When the RFID card is read successfully a beep will sound and data will populate the required fields. Select **Cancel** to abort the scan.

11.3 When to use the scanners

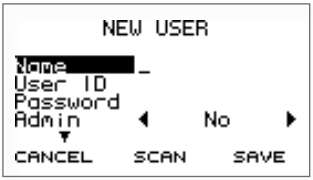
11.3.1 Entering patient details

11.3.1.a Select **Scan** when on the Enter details screen to populate the patient details. Make further edits manually with the keypad.

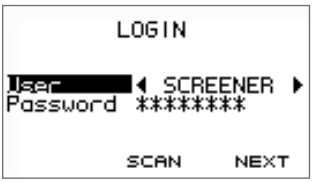
11.3.1.b Then continue to either test or save the result as normal.

11.3.2 At login

11.3.2.a In order for a user to login using the scanning method it is necessary to set-up their login account in the **Management** area (see chapter 8 **Management** for more details). On the **New user** screen, select **Scan**. The RFID method can set all user parameters. For barcode scanning, the user name, ID and password are automatically set, but the other user parameters need to be set manually.

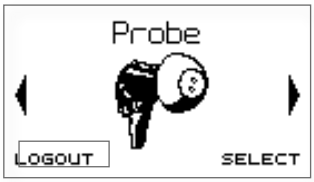


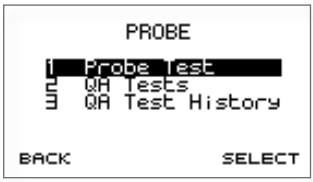
11.3.2.b To login using a scanner, select **Scan** on the login screen.



11.3.2.c The Otoport will automatically login the user with their appropriate access rights and present the **Test** main menu.

12 Probe checks





12.1 Probe menu

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

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

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

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

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

12.2 Probe test

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

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

12.2.c 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.

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

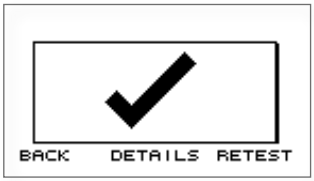
12.2.e The probe outputs sound at 1, 2 and 4kHz via its loud speaker. There is one loud speaker in the UGS (TEOAE) probe. The Otoport compares the response at each frequency against an absolute range and probe specific values stored on the probe connected.

12.2.f 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.

12.2.1 Results

12.2.1.a The possible results of the test are:

12.2.1.b Pass

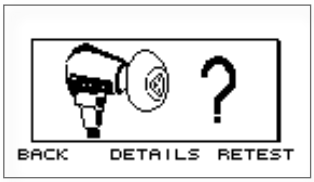


12.2.1.c The levels recorded at all frequencies are within the absolute range and within ± 3dB of the probe specific values.

12.2.1.d Fail

12.2.1.e 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.

12.2.1.f Query



12.2.1.g The levels recorded at all frequencies are with 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.

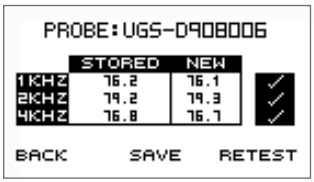
12.2.1.h Noisy

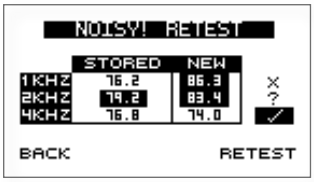
12.2.1.i There was significant noise during the calibration test. This noise may have influence the levels recorded so a **Retest** should be performed.

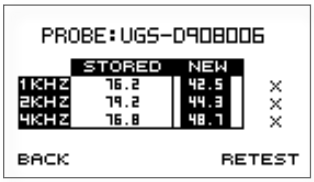
12.2.1.j Select **Back** to exit the probe test and return to the Probe Menu screen.

12.2.1.k Details

12.2.1.l The full test result can be viewed by selecting **Details**. 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.







12.2.1.m 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.

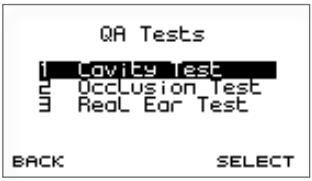
12.2.1.n The 1, 2 and 4kHz values may not be stored in the probe if a new probe is being used with the system. To save new data, run a Probe Test, record the values for each frequency and repeat by selecting **Retest.** Check that the values from two sequential tests are within ± 0.5dB before selecting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

12.2.1.o **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.

12.2.1.p 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.

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

12.3 QA test menu



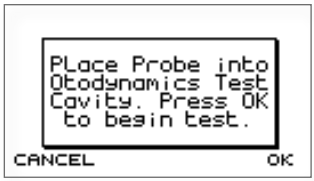
12.3.a Select **Cavity Test** to run a test in the test cavity.

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

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

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

12.3.1 Cavity test



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

12.3.1.b 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.

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

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

12.3.1.e **Patient Details** are automatically entered depending on the QA test type selected. For a **Cavity Test**:

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

12.3.1.f 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 chapter 5 **Test** for a detailed description of how to perform a standard TEOAE test.

12.3.1.g Data collected during the **Cavity Test** is analysed against set pass 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 pass 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.

12.3.1.h 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.

12.3.1.i 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.

12.3.1.j 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.

12.3.1.k 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.

12.3.1.l Contact your dealer or Otodynamics for further advice.

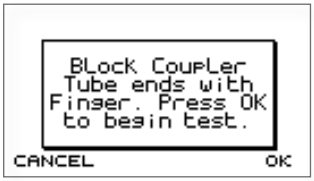
12.3.1.m If the result **Cavity OK** is displayed when the test stops, the test has passed. Save the test and perform the other QA tests if required or exit the **QA Tests Menu** screen.

12.3.1.n On selecting **Save** each test is automatically saved with a unique date/ time stamp and can be reviewed individually in the **QA Cavity Test History** area.

12.3.1.o 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.

12.3.2 Occlusion test



12.3.2.a 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.

12.3.2.b 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 omitted from the ear piece and prevent ambient noise from being detected by the microphone. Select **OK** to begin the test.

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

12.3.2.d **Patient Details** are automatically entered when the test is saved.

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

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.
Poor Probe	If the final test stimulus level is > 60dBSPL Fit in a TE test.
Occlusion OK	The data collected is acceptable and in good environmental conditions.
Incomplete	If a user ends the test manually.

12.3.2.e 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.

12.3.2.f 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.

12.3.2.g 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** chapter for details). If one is available then repeat the test with another probe.

12.3.2.h 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.

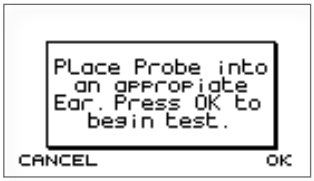
12.3.2.i If the result persists, contact your dealer or Otodynamics for further advice.

12.3.2.j On selecting **Save** each test is automatically saved with a unique date/time stamp and can be reviewed individually in the **QA Occlusion Test History** area.

12.3.2.k 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.

12.3.3 Real ear test



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

12.3.3.b 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.

12.3.3.c The **Real Ear Test** utilises the identical test sequence as a standard TEOAE ear test.

12.3.3.d The test will not autostop if an OAE is detected, but will always run until 260 NLo (low noise sweeps) have been collected.

12.3.3.e **Patient Details** are automatically entered for a **Real Ear Test**:

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

12.3.3.f The result logic for a **Real Ear Test** is set to the locked factory mode. Please refer to chapter 5 **Test** for descriptions of stop results.

12.3.3.g On selecting **Save** each test is automatically saved with a unique date/time stamp and can be reviewed individually in the **QA Real Ear Test History** area.

12.3.3.h Some adult ears with no significant hearing loss produce little or no TEOAE. If possible, the Real Ear Test should be performed on an ear which is known to have strong TEOAEs. 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.

12.3.3.i If you are unable to achieve a Real Ear OK result in an ear which is known to have OAEs, then:

12.3.3.j
- 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 is not blocked.
- Check that the probe still passes the probe calibration test (see above).
- Try recording emissions from another subject.

12.3.3.k If you are still unable to achieve a Real Ear OK result and if the resources are available, try recording with a different probe or with a different Otoport. If the problem persists, contact your dealer or Otodynamics.

13 Probe, tips and accessories

13.1 Probe and service accessories

13.1.a **UGS TEOAE probe** (red) with screw locking connector (see 4.2 **Connecting the probe**).

13.1.b **TPC Coupler Tubes** for UGS probe. See chapter 14 **Probe care** for information on changing coupler tubes.

13.1.c **BGS Body & Lid** for UGS probe

13.2 Probe cable clip

13.2.a 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.

13.2.1 Using the cable clip

13.2.1.a Push the plunger to open the cable grip.

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

13.2.1.c Open the crocodile clothing clip.

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

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

13.2.1.f Use a sterile wipe to clean the clip.

13.3 # TEOAE probe tips

T3E
A90-01-2-0
Fits ~3mm ear canal
Small and premature newborns

T4.5C
A90-02-2-0
Fits ~4.5mm ear canal
Small newborns

T5C
A90-20-2-0
Fits ~5mm ear canal
Newborns

T5.5B
A90-03-2-0
Fits ~5.5mm ear canal
Most newborns

T6.5B
A90-04-2-0
Fits ~6.5mm ear canal
Large newborns and first year infants

T7M
A90-24-2-0
Fits ~7mm ear canal
Infants and children

T8M
A90-05-2-0
Fits ~8mm ear canal
Infants and small adult ears

T9M
A90-06-2-0
Fits ~9mm ear canal
Most adult ears

T11M
A90-07-2-0
Fits ~11mm ear canal
Large adult ears

T13M
A90-18-2-0
Fits ~13mm ear canal
Extra large adult ears

13.3.a Samples of each tip size are provided with your instrument. Further supplies may be obtained from your distributor or from Otodynamics.

13.3.1 Use of tips

13.3.1.a 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.

13.3.1.b 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.

13.3.1.c 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.

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

14 Probe care

14.1 Cleaning

14.1.a 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.

14.1.b **Cable -** The cable may be cleaned with antiseptic fluid or wipes.

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

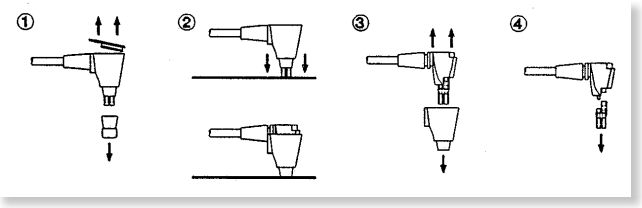
14.1.d **Coupler assembly -** Each coupler assembly has two sound tubes. These are protected from ingress of foreign materials by wax guards in the tubes and by the disposable probe tip. There is a loudspeaker at the end of one tube and a microphone at the end of the other. Cleaning solution must not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

14.2 Changing probe coupler tubes

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

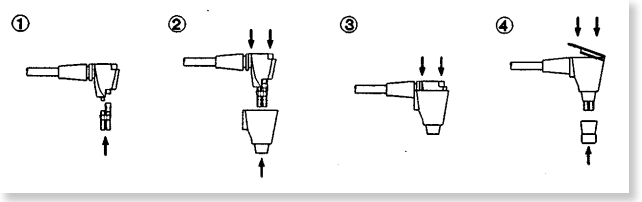
14.2.1 Disassembling the probe

14.2.1.a 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).



14.2.2 Reassembling the probe

14.2.2.a 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).



14.2.3 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 12.3 **QA Tests**).

14.3 Probes safety note

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

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

14.3.c 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.

15 Care of the Otoport

15.0.a 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.

15.0.b
- 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 or charger/PC cable/printer cable

15.1 Use of the Otoport and cleaning

15.1.a 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.

15.1.b 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.

15.1.c 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.

15.1.d 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 14 **Probe care** for details)

15.1.e Ensure your hands are cleaned thoroughly between each patient tested.

15.1.f 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.

15.1.g If additional hygienic protection is required, use the Otoport in an infection control sleeves. 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.

16 Otoport power

16.0.a Important Note:

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

16.1 Battery life

16.1.a 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's intensive use.

16.2 Initial charge

16.2.a 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.

16.3 Standby

16.3.a To save power, the Otoport will go into standby mode after 3 minutes of inactivity. The standby screen will be displayed.

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

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

16.3.d If the Otoport is left for 20 minutes in standby it will turn off. An audible beep will be emitted from the device for a period of 10 seconds to alert the user prior to the automatic shut down.

16.3.e 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.

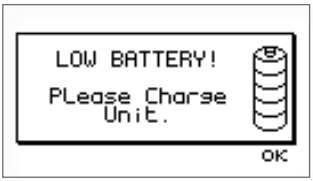
16.4 Battery charge

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

16.4.b The indicator has 5 segments which convey the total battery charge remaining. The battery segments are shaded according to the following criteria.

Segments Displayed	Battery Power (%)
5	≥ 95%
4	≥ 70%
3	≥ 50%
2	≥ 30%
1	≥ 10%
0	< 10%

16.4.1 Low battery



16.4.1.a 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.

16.4.2 Critical battery

16.4.2.a When the battery power reaches 5% 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.

16.4.3 Auto switch off

16.4.3.a 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.

16.5 Charging the Otoport

16.5.a Observe the on-screen battery indicators to determine when to charge your Otoport. In general it is advisable to charge the Otoport batteries when the indicator is empty, showing less than 10% charge. However, the batteries should be at least 30% charged if a full day's testing is planned.

16.5.b It is recommended to charge the Otoport using the charger supplied, but it is also possible to charge the device using the PC cable connected to a PC.

16.5.c Note:

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

16.5.1 Connecting the Otoport for charging

16.5.1.a Switch off the Otoport prior to charging.

16.5.1.b 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.

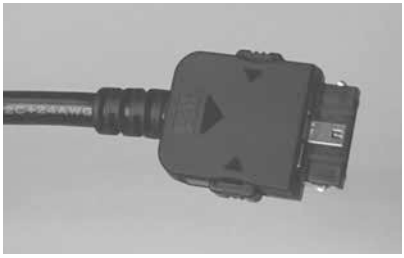
16.5.1.c Then connect the slotted charger plug to the Otoport. Ensure the arrow is facing upwards.

16.5.1.d 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.

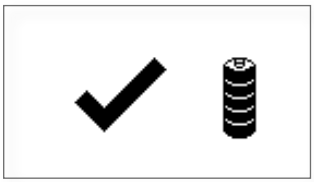
If the cables provided with your Otoport have a locking connector, as shown below, squeeze the release keys at the sides of the connector when removing the plug.



16.5.1.e 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.

16.5.1.f A full charge will take up to 4 ½ hours.

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



16.5.2 Additional charge indicators

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

16.5.2.b **Power light** - The green light below the plug symbol shows that the device is powered.

16.5.2.c **Charging light** - The orange light below the battery symbol will illuminate when the device is being charged.

16.5.2.d 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.

16.5.2.e 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.

16.5.2.f When powered by either a charger or PC, the Otoport is powered from the attached device and not its internal batteries.

16.5.2.g When connected to a charger it is possible to switch on and control the Otoport but it is not possible to run a test.

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

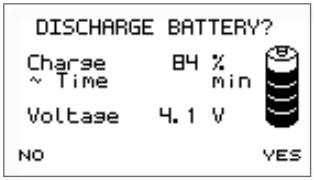
16.5.3 Disconnecting the Otoport

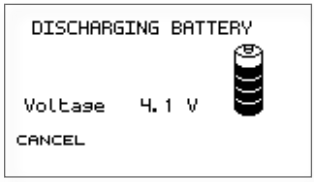
16.5.3.a When the charging cable is disconnected, the power light will extinguish on the Otoport and if the Otoport was off prior to the charging session, the screen will return to blank. If on during the charging session the current screen will remain displayed.

16.6 Conditioning the Otoport battery

16.6.a 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, using a function provided in the Otoport **System** area and then fully charging the device.

16.6.b To initiate the battery condition, enter the **System** main menu and select **Battery**. Select **Condition** and following the confirmation screen, the device will automatically be set to full power to drain the battery.





16.6.c This process can take up to 6 hours. Select **Cancel** to stop the discharge process. 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.

17 Troubleshooting

17.1 Otoport lock-up

17.1.a 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.

17.2 Switch on

17.2.a 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.

17.3 System details

17.3.a 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 check for any error number reported at the top of the screen. If zeros are reported at the top of the screen, no errors have been detected on the device. For support regarding a fault, report error numbers to your dealer or Otodynamics.

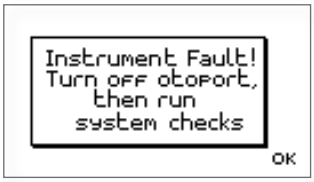
17.3.b Select **Reset** to reset the Otoport to factory default settings. Any settings made will revert to default and any users or worklist patients added to the device will be erased. No test data will be removed.

17.3.c Select **Format** to reformat the Otoport database. Any records held on the device will be permanently erased.

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

17.4 Instrument fault message

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



17.4.b **Instrument fault, turn off Otoport then run system checks**.

17.4.c 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.

17.4.d 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).

17.4.e Run the probe checks (see chapter 12). If the tests are 'OK' the device is functioning correctly and can be used for OAE testing again.

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

17.5 Hardware fault messages

17.5.a 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:

17.5.b The error code 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.

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

17.5.d If a hardware fault is detected that may affect OAE testing the message below will be displayed before a test can be started.

17.5.e If **Continue** is selected the OAE DATA RECORDED MAY NOT BE RELIABLE. DO NOT USE THE INSTRUMENT FOR OAE RECORDINGS.

17.5.f Running a test may, however, help to diagnose the hardware fault.

17.5.g The other functions of the Otoport can still be used and existing data can be safely viewed and downloaded.

18 Training

18.0.a 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.

18.0.b 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.

18.0.c Training in the UK is provided by Otodynamics Ltd. Training 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.

18.0.c Ensure your local policy for infection control is followed, as well as reading the recommendations in this manual (see section 15.1 **Use of the Otoport and cleaning**).

18.0.d 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.

19 Obtaining service

19.0.a Otodynamics or its authorised distributor will replace or service, free of charge, this Otoport for a period of 12 months from the date of purchase, where the fault is not associated with misuse. Servicing after that period will be provided at reasonable cost.

19.0.b 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.

19.0.c 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.

19.0.d 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 on the Otoport.

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20 Calibration

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

20.0.b Users should conduct the recommended weekly checks (see chapter 12) 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.

20.0.c Contact your dealer or Otodynamics to arrange a calibration check.

21 Mode of operation

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
Waveform sample rate	20kHz
Stimulus pattern	Each sweep presents 8 stimuli for each to the two response buffers (16 stimuli in total). The stimulus presentation pattern is: X X X Y -X -X -X -Y Where: Y = -3X
Response buffer 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	10 ms starting 3ms after start of stimulus presentation. Cosine filtered with rise and fall time of 2ms
Response frequency bands	Half octave, centres at 1, 1.4, 2, 2.8 and 4kHz
Response frequency range	841-4757Hz
Microphone input filer	Configurable: 400-6400, 841-4757,1189-4757 or 1600-3200Hz. The attention at these frequencies is 3dB. Attenuation increases by 80dB/decade below and 40dB/decade above these frequencies.

Memory capacity

Patients	1024
Tests per patient	256
Total tests	>3000

22 Technical specifications

22.1 General

Note:

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

22.1.1 Physical

Hand-held device:	195mm x 70mm(max) x 30mm Weight 0.55lbs (250g)
Charger:	90mm x 38mm x 28mm – Weight 120g

22.1.2 Interfaces

Data: USB 1.1/2.0
Probe connector compatible with Otodynamics UGx probes (8 pin)
Charging/Data connector - connects to Otodynamics PS (charging) or PC USB port
Serial to 115200 Baud (via Data connector)
Bluetooth wireless print/transfer (option)
RFID reader/writer (option)

22.1.3 Indicators

Data Display:	Resolution:	128 x 64 pixels
	Technology:	Graphic LCD
	Dimensions:	48mm x 30mm
Backlight:	White - intelligent control	
Probe fit:	Noise OK:	Blue LED
	Stimulus OK:	Blue LED
Power/Charge:	Power OK:	Green LED
	Fast charge:	Amber LED
Audible:	Wide range speaker provides audio feedback of status	

22.1.4 Keypad

19 key alphanumeric with cursor control and soft keys

22.1.5 Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

22.1.6 Power

Li-Polymer Battery
Intelligent multi-level power control for charging/testing/idle/sleep/shutdown:
After 3 minutes unit will enter sleep mode
After 20 minutes in sleep mode unit will shut down

Sleep time:	24 hours minimum (with fully charged battery)
Running time:	8 hours minimum (continuous data collection)
Max consumption when testing:	720mW
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%

22.1.7 Hardware Options

Bluetooth wireless printing/data transfer
Barcode scanner
RFID reader/writer

22.1.8 Hardware processing and storage

Multiple distributed processors plus dedicated hardware DSP engine

Total processor performance:	420 MIPS
Test memory:	8MB non-volatile database for patient details and test results
Program/config memory:	1.3MB

22.1.9 Analogue performance

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

22.1.10 Environmental

Transport and storage:

Temperature range:	0 to 40 Celsius
Pressure:	23KPa to 101KPa
Humidity:	10% to 90% non-condensing
Operating:	Indoor use
Temperature range:	5 to 40 Celsius
Humidity:	Max 80% up to 31C decreasing linearly to 5% RH at 40C

Otodynamics instruments and probes are calibrated at an ambient pressure of 101 kPa (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.

22.1.11 Classifications and standards

Device Class 2a	(Directive 93/42/EEC)
BS EN ISO 13485:2003	(REF: EN46001 superseded 01/03/2004)
ISO 14971:	Application of risk management
BS EN 60601-1:	Medical Electrical Equipment Part 1: General Requirements for Safety
BS EN 60601-1-1:	Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard - Safety Requirements for Medical Electrical Systems
BS EN 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
BS EN 60601-1-4:	Medical electrical equipment - Part 1 General requirements for safety. Section 4 Collateral standard, programmable electrical medical systems
UL 60601-1:	Medical Electrical Equipment, Part 1: General Requirements for Safety
CSA-C22.601:	Medical Electrical Equipment

22.2 Electromagnetic Compatibility

The Otoport should be put into service according to the EMC (Electromagnetic Compatibility) information provided here.

Portable and mobile RF (Radio Frequency) communications equipment can affect the operation of the Otoport. In particular, mobile telephones ('cellphones') should not be operated within 3.3m of the Otoport.

The use of probes, chargers and connection cables other than those supplied by Otodynamics Ltd, and specifically for use with the Otoport may result in increased emissions or decreased immunity of the Otoport.

Guidance and manufacturer's declaration – electromagnetic emissions

The Otoport is intended for use in the electromagnetic environment specified below. The user of the Otoport should ensure that it is used in such an environment.

Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Otoport uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby equipment.
RF emissions CISPR 11	Class B	The Otoport is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The Otoport should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary the Otoport should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport is intended for use in the electromagnetic environment specified below. The user of the Otoport should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/ output lines	± 2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otoport requires continued operation during power mains interruptions, it is recommended that the Otoport be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

NOTE U_T is the a.c. mains voltage prior to application of the test level.

The following functions of the Otoport are deemed ‘essential performance’ and were tested for immunity in compliance with IEC60601-1-2:

(a) The collection of Otoacoustic Emissions (OAEs)
(b) The retention of user settings and test results

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport is intended for use in the electromagnetic environment specified below. The customer or the user of the Otoport should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Otoport, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

1 At 80 MHz and 800 MHz, the higher frequency range applies.

2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Otoport is used exceeds the applicable RF compliance level above, the Otoport should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Otoport.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Otoport

The Otoport is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Otoport can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otoport as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Otoport can be optionally configured with either/both Bluetooth and RFID functions. The frequency bands for reception and transmission of RF energy for these functions are as follows:

(a) Bluetooth – 2.4GHz to 2.4835GHz
(b) RFID – 13.56MHz

The Bluetooth and RFID functions of the Otoport may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

22.3 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

22.4 Symbol explanations

Class II

Type BF

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

Refer to operating instructions

Training required

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