Otodynamics

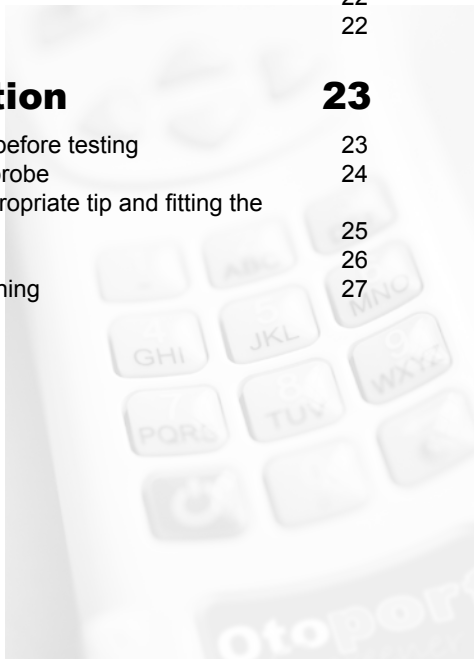
Otoport Screener

Otoport Screener User Manual

Issue 2 : November 2007

CE 0120

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

1.1.g 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.h 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.i Do not allow liquid to enter the instrument.

1.1.j If additional hygienic protection is required, clear plastic pockets designed to contain the Otoport during use are available from Otodynamics.

2 Getting started

2.1 Otoport and accessories

2.1.a Take a few moments to familiarise yourself with the equipment you have received with your Otoport case.

(Accessories not shown to scale)

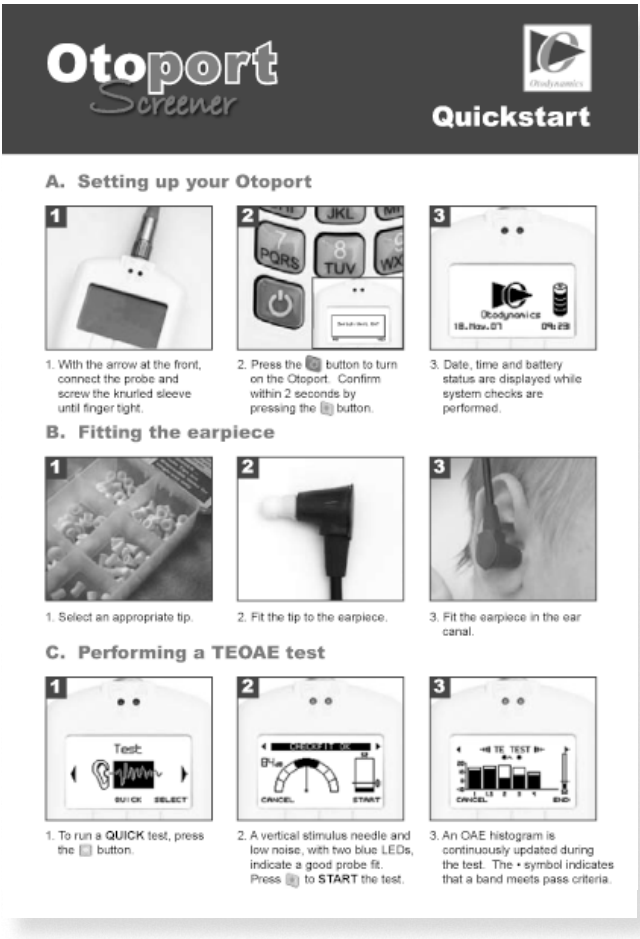
2.2

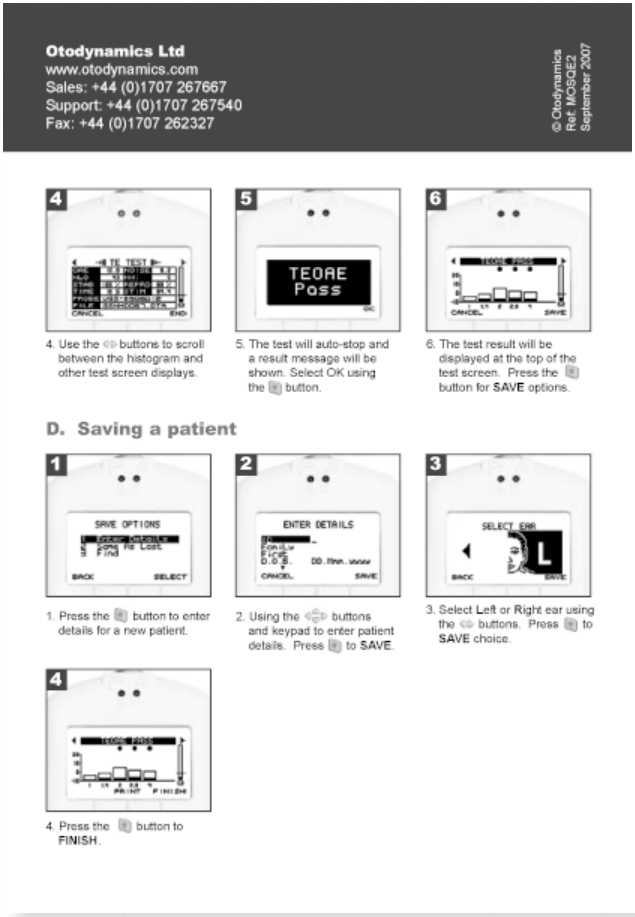
Controls, indicators and connections

2.3 Scanner and labelling

2.4 Quickstart

2.4.a The Quickstart guide is included in your document pack.



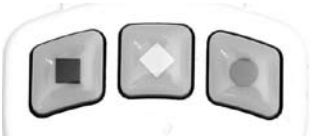


2.5 Initial charge

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

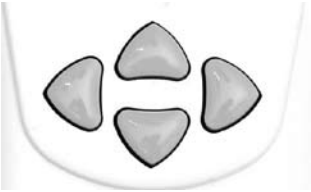
2.6 Using the buttons and keypad

2.6.1 Control buttons



2.6.1.a The buttons 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) button provides affirmative options and the left (square) button provides negative options.

2.6.2 Arrow (navigation) buttons



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

2.6.2.a The left and right arrow buttons scroll through the main menu options.

2.6.3 Entering characters

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

2.6.3.b For alphanumeric input the numbered button sequence will be lower case alpha, numeric then capitalised alpha, for example: jkl5JKL.

2.6.3.c For alphanumeric character input at the beginning of a field the numbered button sequence will be capitalised alpha, lower case alpha then numeric, for example: JKLjkl5.

2.6.3.d For patient ID input the numbered button sequence will be numeric then capitalised alpha only, for example: 5JKL.

2.6.3.e The character sequence for the 1 button is: -,'.1 which starts at 1 for patient ID entry.

2.6.3.f The character sequence for the 0 button is: (Space) 0 which switches to 0 (Space) for patient ID entry.

2.6.3.g Characters will scroll left off the screen if entering text which is greater than the visible area. A left arrow will appear at the beginning of the line to indicate that text is off screen. When the field choice changes the beginning of the text is shown with a right arrow at the end of the line to indicate that the text entered is greater than the visible area.

2.6.4 Foreign character table

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

2.6.5 Entering dates

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

2.6.5.b When the field is highlighted, press the **Right Arrow** button to access the calendar pop-up table. The day will be highlighted first and can be altered using the **Up/down Arrow** buttons. Continue to use the **Left** and **Right Arrow** buttons to jump between the Day/Month/Year and the **Up** and **Down Arrow** buttons to select the required date.

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

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

2.6.5.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.

2.6.6 Choice bars

2.6.6.a **Left** and **Right Arrow** buttons are used to move through choice bar options. For example when entering patient details in the **Gender** field, pressing the **Right Arrow** button will rotate the selected option between **Not Given**, **Male**, **Female** and **Unknown**. Choice bars options are enclosed by arrow graphics.

2.6.7 Deleting characters

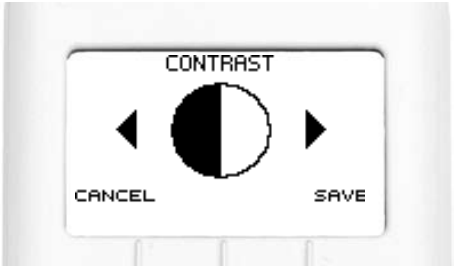
2.6.7.a The bottom right hand **Contrast/Delete** button is used as a delete key. If the cursor is at the end of a row of characters, press the **Delete** button to delete the last character.

2.6.7.b **Left** and **Right Arrow** buttons can be used to scroll back through the text. The selected blinking character can be replaced using the keypad data entry buttons or deleted with the**Delete** button. Continue to press the **Delete** button to erase characters to the right of the cursor.

2.6.8 Back light

2.6.8.a The screen is backlit to assist in testing in dimly lit environments. The back light stays on for 5 seconds (default) following any key press and remains on during testing.

2.6.9 Contrast



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

2.6.9.b Use the **Left/Right Arrow** buttons 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.

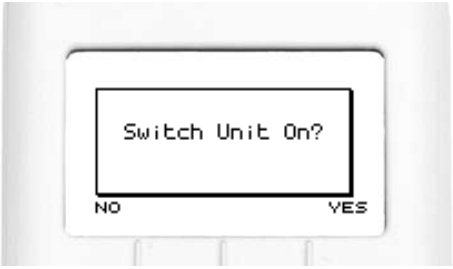
2.6.9.c The default setting should be adequate in most circumstances but adjustment may be helpful in unusual environments such as cold operating conditions.

2.6.10 Hard reset

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

3 Switching on

3.1 Switch on screen



3.1.a To switch on the Otoport press the green **On/Off power** button found at the bottom left of the keypad. The display screen will show **Switch Unit On?**. Press **Yes** to confirm Otoport switch on, or press **No** to turn the unit off again. If **Yes** or **No** are not selected within two seconds of pressing the **On/Off power** button, the device will automatically turn off. The unit will turn off if any button other than **Yes** is pressed. This is to prevent accidental switch on during transit.

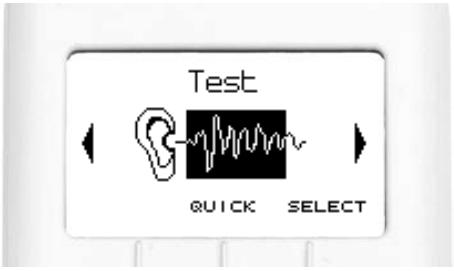
3.1.b *Note:*

Following the Otoport being switched off, it is not possible to turn it on again for 3 seconds.

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. 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. 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 Main menu



3.3.a You are then presented with the **Test** main menu screen. Other main menu screens can be accessed using the **Left/ Right Arrow** buttons. 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. The probe plug contains a ‘key’ that must be aligned with the ‘keyway’ in the probe socket on the Otoport. 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. 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. Screw up the knurled sleeve clockwise until finger tight.

4.3 Selecting an appropriate tip and fitting the probe ear piece

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 13.2 **Disposable 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 then 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

5.1 Patient menu

5.1.a New

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

5.1.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.

5.1.d Same as last

5.1.e Select **Same As Last** to begin a test using the details of the last saved patient. Patient details will be displayed in a non-editable format to allow confirmation of the patient before starting the test. Select **Test** and enter appropriate test details. Select **Test** again to begin the test. This option will not function if there is no patient information stored on the Otoport.

5.1.f

History of last

5.1.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.

5.1.h

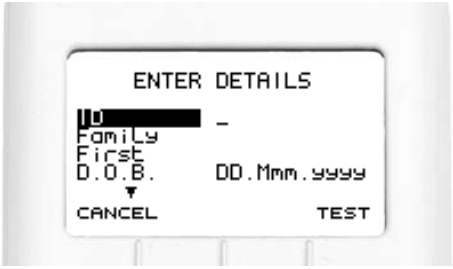
Records

5.1.i Select **Records** to test or review results of a previously saved patient.

5.1.j Select **Back** to return to the **Patient** menu.

5.2

Patient details



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

5.2.b

Patient details fields

5.2.c **Patient Details Fields** can be selected by pressing the **Up/ Down Arrow** buttons. 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.

5.2.d

Patient details description

5.2.e An explanation of the **Patient Details** fields is shown in the following table.

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	10 national and local risk factors (configure choices in **Management**) with options of Yes, No or Unknown (UKN)	n/a
Location	Either inpatient, outpatient or at home	n/a
Facility	The name of the hospital, clinic etc. where the test is being performed (configure choices in **Management**)	n/a
NICU	Is the patient in the Neonatal Intensive Care Unit, Yes or No	n/a
Consent	This option allows the consent to the test to be stored with the test details. Two levels of consent are provided, Full and Screen Only.	n/a

5.2.f

Beginning a test

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

5.2.h

Mandatory patient details

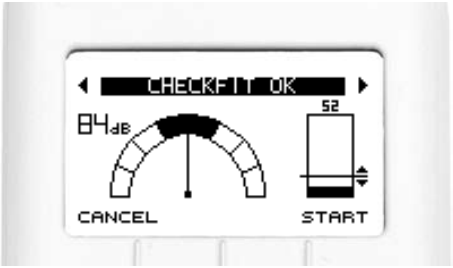
5.2.i ID and Family name entry are mandatory and must be entered before a test result can be saved.

5.3

Checkfit

5.3.a

Checkfit display



5.3.b 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.

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

5.3.d

Noise level indicator

5.3.e 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/ Down Arrow** buttons to change the Noise Reject Level.

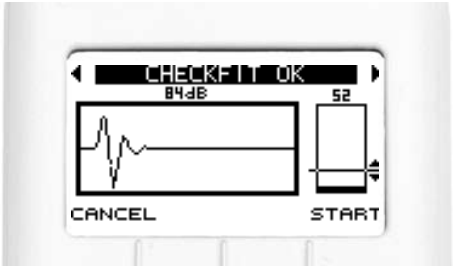
5.3.f

Stimulus level indicator

5.3.g 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.

5.3.h

Stimulus waveform window



5.3.i Pressing **Left/Right Arrow** buttons during **Checkfit** switches the screen display between the **Stimulus Level Indicator** and the **Stimulus Waveform Window** 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).

5.3.j

Test condition information

5.3.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.

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

5.3.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.

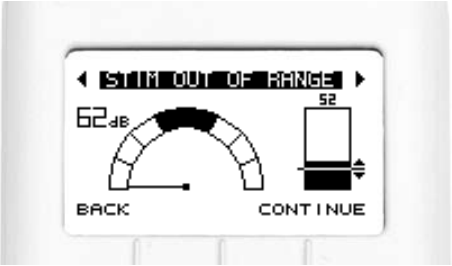
5.3.n **Ringing** is displayed when there is obvious oscillation within the **Stimulus Waveform** after the initial positive and negative peaks instead of a flat line response.

5.3.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

5.3.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**.

5.3.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.

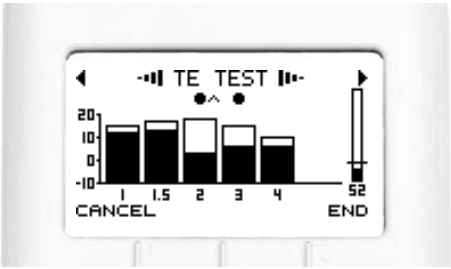


5.4 # Test

5.4.a ## Test screens

5.4.b Following **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/Right Arrow** buttons can be used to toggle between the screen choices when a test is in progress.

5.4.c ## Histogram



5.4.d 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 hand represents the OAE signal level within each band and the shaded section represents the noise level at that frequency.

5.4.e A dot will appear above a band if the band has met its pass criteria. Please refer to the **Test Setup** chapter for further information on the band pass criteria.

5.4.f If either the OAE signal or noise level in a ½ octave 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.

5.4.g 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.

5.4.h Noise level indicator

5.4.i 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/ Down Arrow** buttons to adjust the noise reject level.

5.4.j Title bar

5.4.k 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.

5.4.l Test condition information

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

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

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

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

5.4.p

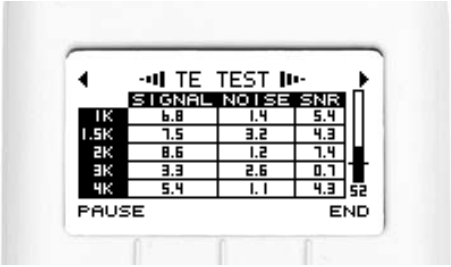
Cancel/end

5.4.q Select **End** at any time during a test to stop the test.

5.4.r 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.

5.4.s

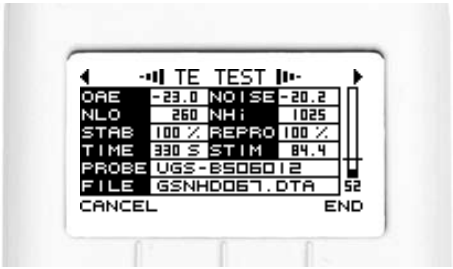
Data table 1



5.4.t **Data Table 1** numerically displays the ½ octave **OAE Signal**, **Noise** and **Signal-to-Noise** (**SNR**) levels. It can be accessed during the test by pressing the **Right Arrow** button or pressing the **Left Arrow** button twice.

5.4.u

Data table 2



5.4.v **Data Table 2** lists other statistics required for test analysis. The following table describes each field in detail:

Table Field	Description	Units
OAE	The total OAE Signal level	dB SPL
NOISE	The total Noise level	dB SPL
NLo	The amount of data accepted due to noise being below the noise reject level	n/a
NHi	The amount of data rejected due to noise being above the noise reject level	n/a
STAB	Stimulus stability shows the change in probe fit during a test	%
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 test file name (populated on Save)	

5.4.w During the test **Data Table 2** is accessed by pressing the **Left Arrow** button or pressing the **Right Arrow** button twice.

5.4.x Test stop reasons

5.4.y The test will either stop automatically or can be manually terminated by the user. A beep will sound at the end of the test. When the test stops a result is displayed as a message on the full screen (shown below). Select **OK** to accept the test stop reason. The result is then displayed at the top of the test screen.

5.4.z Pressing **End** at any time will stop the test.

5.4.aa

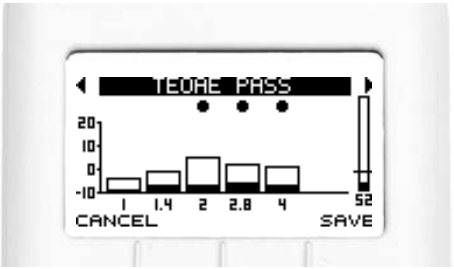
Test results

5.4.bb

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 pass 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 set pass criteria and the test conditions were acceptable
Too Few Bands	If insufficient bands meet their pass criteria
Stopped Too Soon	If a user ends the test manually before the required minimum amount of data has been collected

5.5 Save and review



5.5.a Once a test is completed, it is possible to save the result by selecting **Save**. Select **Cancel** to discard the result; a confirmation screen is provided which also gives the option to restart the test at Checkfit.

5.5.b Select left or right ear

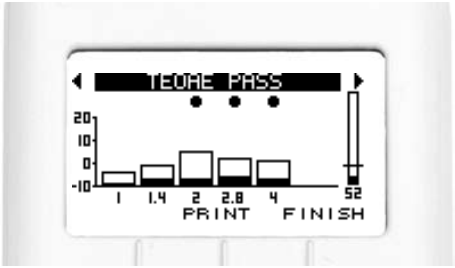
5.5.c Use the **Left** and **Right Arrow** buttons to select the ear tested. The graphic represents a patient facing you and the **L** and **R** represent the left and right ears. Press the **Left Arrow** to highlight and select the right ear, or press the **Right Arrow** to highlight and select the left ear. Once the correct test ear has been selected select **Save** to save the test record to the database.

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

5.5.e A pop-up message confirms the ear saved.

5.5.f

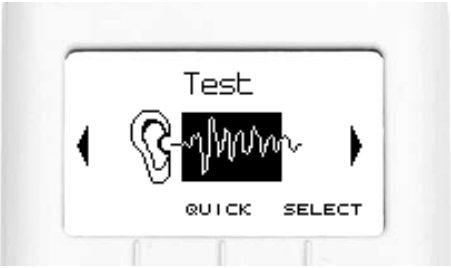
Test review screens



5.5.g When the test record has been saved to the database the **Test Screens** are displayed again to allow for further review of the data collected. The **Left/Right Arrow** buttons can be used to toggle between the three screen choices.

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

5.6 Quick test



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

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

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

5.6.1 Save options menu

5.6.1.a Enter details

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

5.6.1.c

Same as last

5.6.1.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.

5.6.1.e

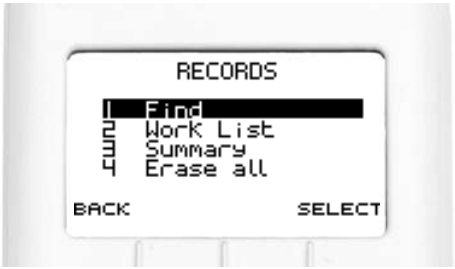
Records

5.6.1.f To append the result to a patient record in the database, select **Records**. Please refer to chapter 4 **Records** for guidance.

5.6.1.g Select **Back** to return to the **Save Options**.

6 Records

6.1 Records menu



6.1.a Find

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

6.1.c Work list

6.1.d 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.e Summary

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

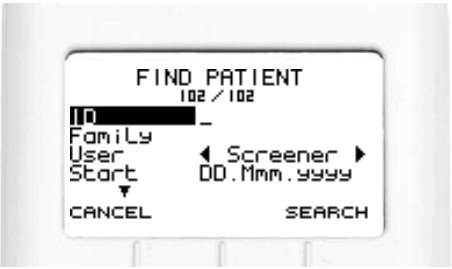
6.1.g Press **Back** to return to the main **Menu** screens.

6.1.h Erase all

6.1.i 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

ID

6.2.c The ID field provides a partial field search function. As each character is entered the database returns the number of patients meeting the criteria.

6.2.d

Family

6.2.e The family name field also provides a partial field search function.

6.2.f

User

6.2.g The Otoport can filter for patients results saved by a specific user. Choose the user with the **Left/Right Arrows**.

6.2.h

Start/end

6.2.i The start and end dates provide the option to search for patient tests within the specified date range.

6.2.j

First

6.2.k Enter characters to filter for patients with the specified first name.

6.2.l

D.O.B

6.2.m Enter a date to filter by date of birth.

6.2.n

Mother

6.2.o Enter characters to filter for patients with the specified mother's name.

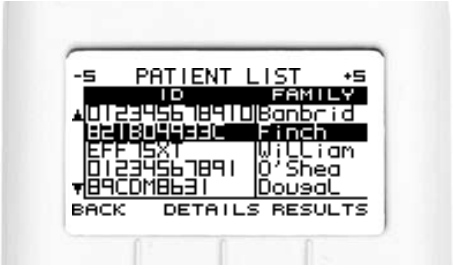
6.2.p The number on the right at the top of the screen shows the number of patients in the database; the number on the left specifies the number of patients who match the search criteria entered. This number updates as search criteria change.

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

6.2.r 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/Down Arrow** buttons 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/Right Arrow** buttons to skip through the **Patient List** ± 5 records at a time.

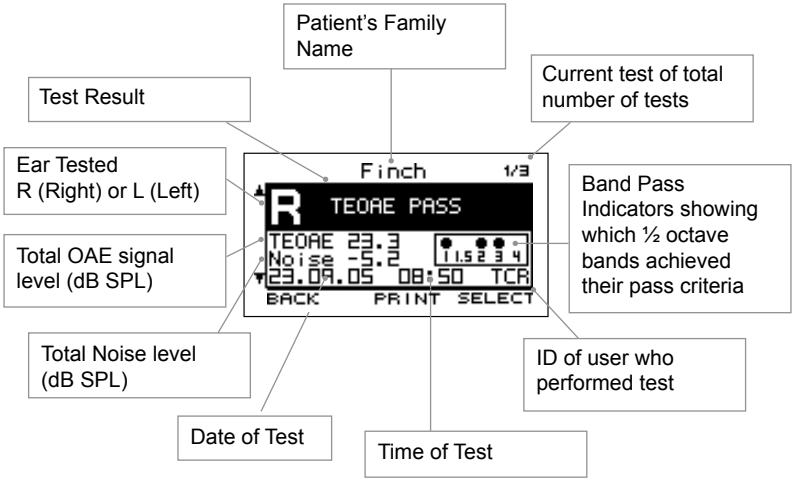
6.2.1.e Select **Details** to review the complete **Patient Details** of the highlighted patient.

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 **Cancel** 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:



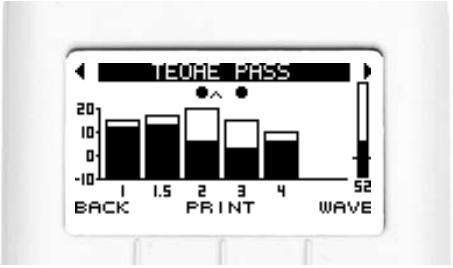
6.2.2.b The number of tests currently saved to the patient is displayed in the top right of the screen. Press the **Up/Down Arrow** buttons to scroll between tests. The test number will increment accordingly.

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 **Cancel** 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 3.4 **Test** for a full description of the screen displays.

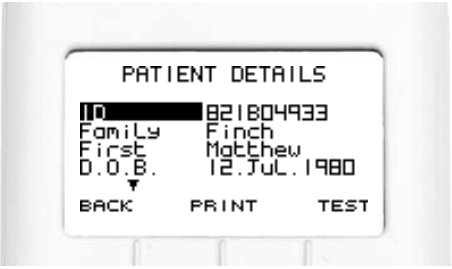
6.2.3.b Use the **Left/Right Arrow** buttons to scroll between the screen choices.

6.2.3.c Select **Wave** to show the OAE waveform. Two interleaved OAE waveforms are collected during a test, named A and B. The current waveform displayed is labelled on the OAE waveform graph. 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 (database)



6.2.4.a A non-editable version of highlighted **Patient Details** can be reviewed by selecting **Details** in the **Patient List**. Please refer to chapter 3.2 **Patient Details** for a full description of the screen format.

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 3.3 **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 Worklist menu

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 Add patient

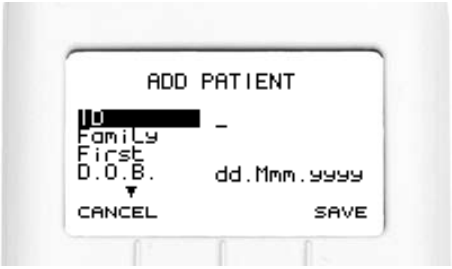
6.3.c Select **Add Patient** to add a new patient to the work list.

6.3.d View work list

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

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

6.3.1 Add patient



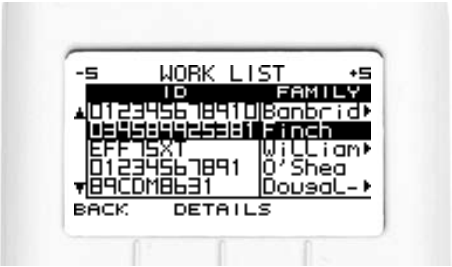
6.3.1.a A new patient can be added to the current **Work List** by entering their **Patient Details** in the **Add Patient** screen.

The screen format and data entry is identical to entering patient information when performing a test. Please refer to chapter 3.2 **Patient Details** for guidance on entering data in fields and mandatory requirements for save.

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



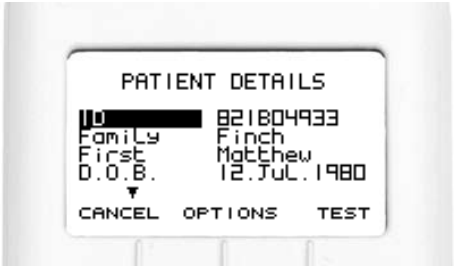
6.3.2.a The **Work List** displays the **ID** and **Family** name of each patient to be tested. The format of the **Work List** is identical to the **Patient List**. Use the **Up/Down Arrows** to scroll between patients and the **Left/Right Arrows** to jump 5 patients at a time.

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

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

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

6.3.3 Review patient details (work list)



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

6.3.3.b Select **Test** to enter test details specific to the test. Please refer to chapter 3.3 **Checkfit** for an explanation on how to setup and perform a test.

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

6.3.3.d Choose **Select** when **Edit** is highlighted to show an editable version of the **Patient Details**. Please refer to chapter 3.2 **Patient Details** for guidance on field entry and format. Select **Save** when changes to the **Patient Details** have been made. A pop-up message may appear if edits to mandatory fields (e.g. **ID** and **Family name**) prevent the **Patient Details** from meeting the requirements for saving a patient. The screen will return to **Edit Patient** to modify the changes made.

6.3.3.e 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.

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

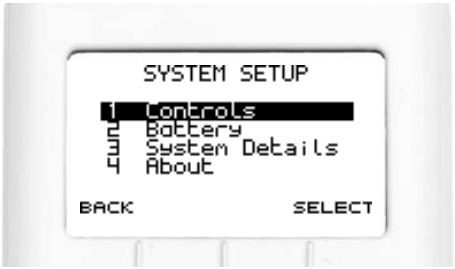
6.5 Erase all

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 Controls

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

7.1.c Battery

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

7.1.e System details

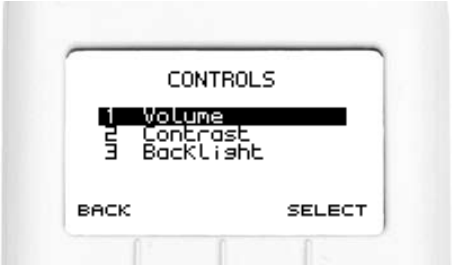
7.1.f **System Details** displays information for Otodynamics engineers.

7.1.g About

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

7.1.i Select **Back** to return to the main menu screens.

7.2 # Controls menu



7.2.a ## Volume

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

7.2.c ## Contrast

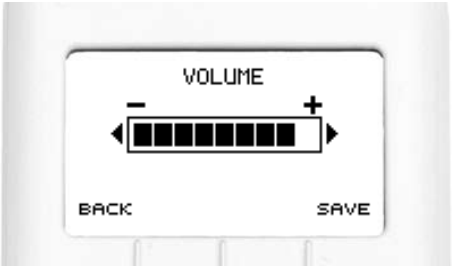
7.2.d Select **Contrast** to adjust the contrast of the screen for varying light conditions.

7.2.e ## Backlight

7.2.f Select **Backlight** to configure the status of the blue screen backlight.

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

7.2.1 Volume

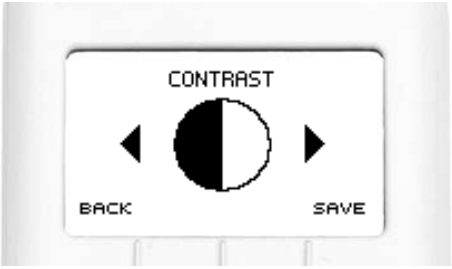


7.2.1.a The current **Volume** level is represented on the display by a number of shaded blocks. Use the **Left/Right Arrow** buttons to decrease or increase the **Volume** level. To turn the sound off press the **Left Arrow** button repeatedly until **Sound Off** appears in the centre of the display.

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 press of the **Left/ Right Arrow** buttons. 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 **Back** to ignore changes and return to the **Controls Menu**.

7.2.3 Backlight

7.2.3.a Use the **Left/Right Arrow** buttons 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 (5, 10, 20 or 30sec) after a button 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** is provided as a diagnostic tool at the bottom of the screen.

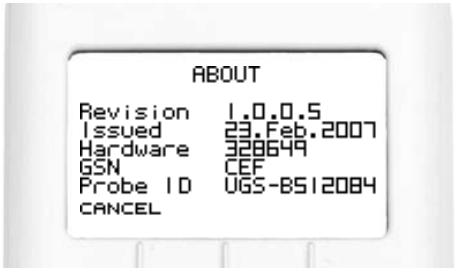
7.3.e The battery graphic is also displayed on the **Logo** screen to inform the user of the **Battery Power** every time the device is switched on.

7.3.f Select **condition** to condition the Otoport battery. See chapter 15 **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 Users

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

8.1.c Defaults

8.1.d Select **Defaults** to enter custom **Facility** or **Risk Factor** options.

8.1.e Date and time

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

8.1.g Other options

8.1.h 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.i Select **Back** to return to the main **Menu** screens.

8.2 Users menu

8.2.a Add new user

8.2.b Select **Add New User** to enter details of a new user and save to the **User List**.

8.2.c View users

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

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

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 (capitalised only)
Password	An alphanumeric password required for secure login.	8 (capitalised only)
Admin	Select **Yes** to give the new user administrator access rights. Select **No** to restrict the user to 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.

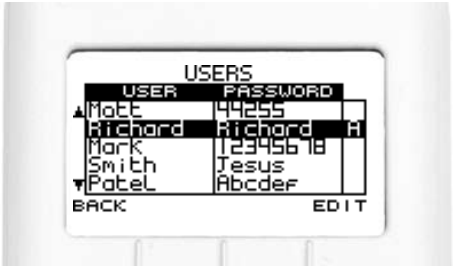
8.2.1.c A new user is given a choice of two levels of access rights. If **Yes** is selected in the administrator field then the user will have full access to all modules of the device. Select **No** to restrict the user's rights to only **Test**, **Records**, **Probe**, **Print** and **System** modules.

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 press of **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 user list

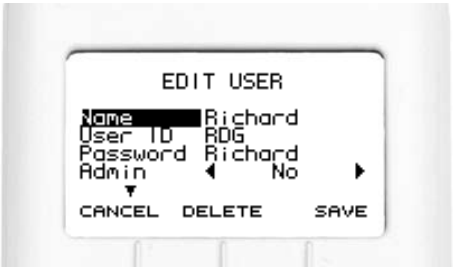


8.2.2.a The **User List** displays the **Name**, **Password** and **Status** of all users currently saved to the device.

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**.

8.2.3 Edit user



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

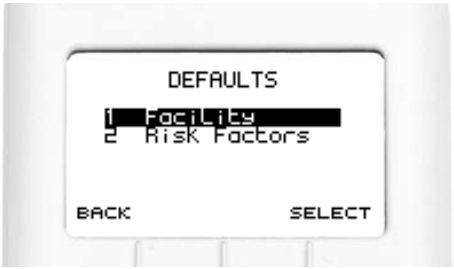
8.2.3.b Select **Save** to save changes to the user's details and return to the **User List**.

8.2.3.c 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.

8.2.3.d 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.

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

8.3 # Defaults menu



8.3.a ## Facility

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

8.3.c ## Risk factors

8.3.d Select **Risk Factors** to view or customise the list of 10 patient risk factors 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.

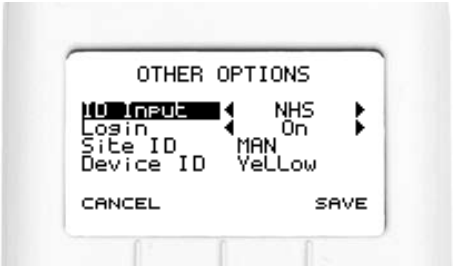
8.4.b When the **Date** field is highlighted press the **Right Arrow** button to access the calendar pop-up table. The day will be highlighted first and can be altered using the **Up/Down Arrow** buttons. Continue to use the **Left/Right Arrow** buttons to jump between the **Day/Month/Year** and the **Up/Down Arrow** buttons 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.

8.5 Other options



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

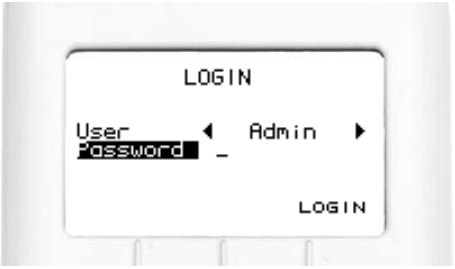
8.5.b ID Input

8.5.c 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.d

Login



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

8.5.f 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 **Navigation Arrow** buttons to select a **User** from the choice bar if necessary.

8.5.g Once a **User** is selected, use the **Navigation arrows** to return to the password entry row and the data entry keypad to enter a corresponding **Password**.

8.5.h To improve security during **Login** a ***** symbol will replace each character as it is entered in the **Password** field. To review characters that have been entered simply scroll back through the ***** using the **Left/Right Arrow** buttons.

8.5.i 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:

8.6 Site ID

8.6.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.

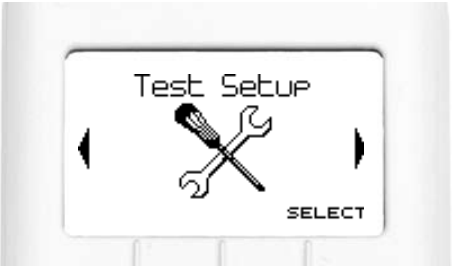
8.6.1 Device ID

8.6.1.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.

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

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

9 Test set-up

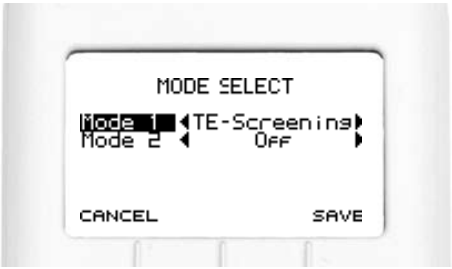


9.1 Test setup menu

9.1.a The Otoport TEOAE screener provides comprehensive test configuration settings to enable you to tailor the device to specific testing requirements. Flexible programmable pass criteria control the device's OAE detection logic, where the device will automatically end the recording when the criteria have been met. There are 4 separate test modes, 3 of which may be set by the user.

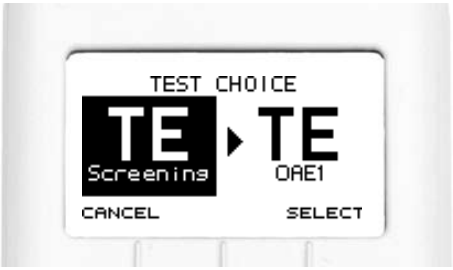
9.1.b Once you have navigated to the **Test setup** area, choose **Select**. You will be presented with the **Test setup** menu.

9.2 Current modes



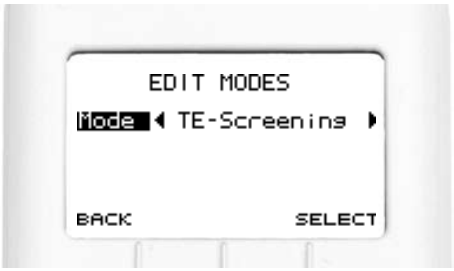
9.2.a Select **Current Modes** to view the **Mode Select** screen, which enables the selection of the test mode to be used during OAE measurement. The Otoport TEOAE screener has a choice of 4 test modes. By default the device will conduct OAE tests in accordance with test **Mode 1**, named **TE-Screening** by default (see the test mode table for details).

9.2.b It is possible to configure the device to provide a choice of two test modes at the point of test. To enable this function, turn on **Mode 2** by selecting a test mode. When **Mode 2** is **Off** (as per default) the device will run the OAE test in accordance with the **Mode 1** test set. If a test mode is selected for both modes, you are presented with the **Test Choice** screen, prior to starting a test (shown below). **Mode 1** is on the left and **Mode 2** on the right. Set **Mode 1** to your most frequently used mode, for ease of use at the time of test.



9.2.c Select the desired mode using the navigation buttons. Select **Save** to store the selection made, which is confirmed with a pop up screen, or **Cancel** to exit discarding changes. You will be returned to the **Test Setup** screen.

9.3 Edit modes

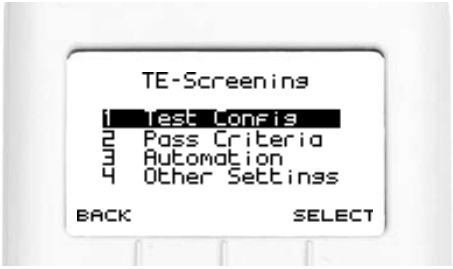


9.3.a Select **Edit modes** to modify Test Modes.

9.3.b On the **Edit Modes** screen, use the **Left/Right Arrows** to scroll the test mode choice bar and press **Select** to choose the mode to edit. **Back** will return to the **Test Setup** menu.

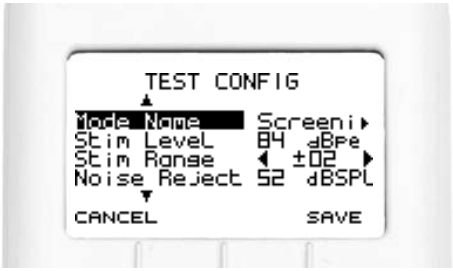
9.3.c The user defined name for the test mode selected is displayed at the top of the screen. The Factory test mode is used when performing system tests. A padlock symbol adjacent to the mode indicates the mode settings can be viewed but not edited.

9.4 Edit mode menu



9.4.a The settable parameters for each test mode are split into 4 sections, **Test Config**, **Pass Criteria**, **Automation** and **Other Settings**. Choose the section to edit then **Select**.

9.4.1 Test config



9.4.1.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/Down** navigation buttons to scroll up and down the settings and highlight a parameter to edit. The parameter variable will flash. Use the **Left/Right Arrow** buttons 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 affect 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). In most ears, the stimulus click becomes 'flat' following the click stim (see fig. 2), but in longer large ear canals the stimulus can oscillate for longer. The Ring alert displays the ratio in dB of the peak stimulus over the stimulus level recorded at 3 milliseconds.	-10 to – 30dB
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

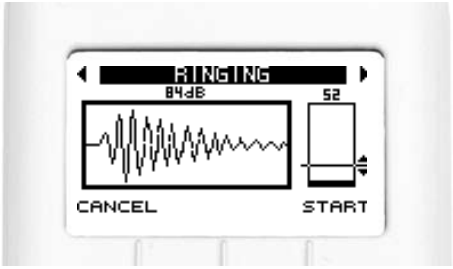


Fig 1

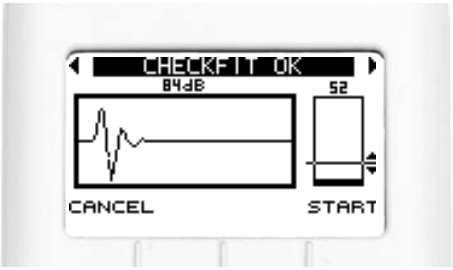


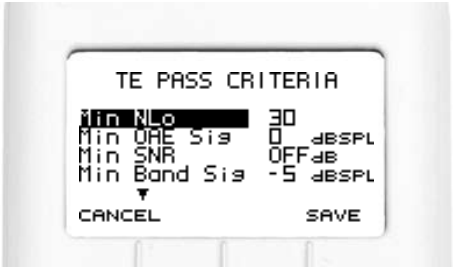
Fig 2

9.4.1.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.

9.4.2 Pass criteria



9.4.2.a The test pass 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/Down** navigation buttons to scroll up and down the settings and highlight a parameter to edit. The parameter variable will flash. Use the **Left/Right** arrows to change each setting. It is possible to turn off some settings, which means the parameter will not be included in the pass criteria logic.

9.4.2.b When **Setup Bands** is selected a pop up table enables the edit of each ½ octave band criteria. Use the **Up/Down Arrows** to select the parameter to edit and to move between the **SNR** and **RQRD** (required) columns and **Left/Right Arrows** to edit the settings. Move down at the bottom of the **SNR** column to edit the **RQRD** column.

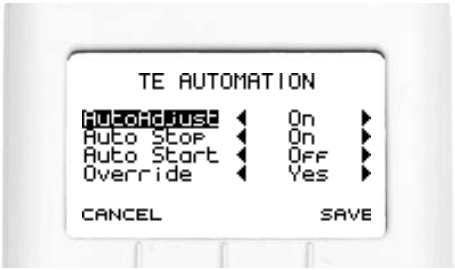
9.4.2.c See the table below for details of the settable pass criteria.

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

Note:

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

9.4.3 # Automation



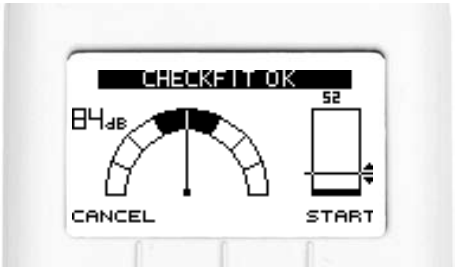
9.4.3.a The Otoport Screener has programmable automation logic to enable the user to configure the test routine to their preference. The test process can be set to be fully automated or manually operated, depending on the desired control over the test.

9.4.3.b All settings have an **On/Off** or **Yes/No** option. Use the **Up/Down Arrows** to highlight a setting and use the **Left/Right Arrows** to change the choice bar setting.

9.4.3.c ## Autoadjust

9.4.3.d 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.

9.4.3.e 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.



9.4.3.f

Auto stop

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

9.4.3.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**.

9.4.3.i

Auto start

9.4.3.j 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.

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

9.4.3.l

Override

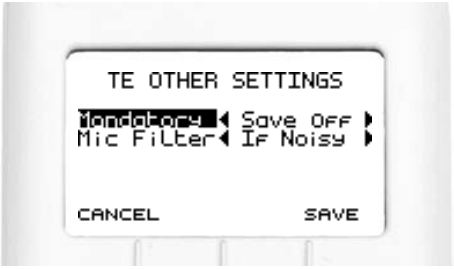
9.4.3.m When **Auto Start** is **On**, the **Override** setting controls the option for the user to manually start the test overriding the **Auto Start** function.

9.4.3.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.

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

9.4.3.p

Other settings



9.4.3.q 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.

9.4.3.r 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.

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

9.4.3.t

Mic filter

9.4.3.u It is possible to select various **Mic Input Filters** on the Otoport, which can be helpful when testing in various environmental noise conditions. The filters significantly attenuate signals outside the filter frequency range. This helps to stop noise at these frequencies having a negative affect on the result. Only data collected within the filter frequency range will be added to the OAE recording process.

9.4.3.v There are three filter settings provided. The following table shows the name of the filter and the frequency cut off points. Frequencies outside the filter range will be attenuated.

Filter name	Frequency range (Hz)
Wide band	400-6400
Normal	841-4757
If noisy	1189-4757

9.4.3.w The **Wide band** filter will collect data at the widest frequency range. The **Normal** filter allows data collection between a tighter range, eliminating more low and high frequency noise. This filter will attenuate OAE signal and noise collected at 1 and 4Khz, by a few dB. The **If noisy** filter is a tight filter that attenuates a significant range of low frequency signals which are in practice often contaminated by noise. This filter will help measurements to be taken, even in noisy conditions, but the signal and noise will be attenuated by around 6dB at 1 kHz and 3dB at 1.5 khz. Data at 4kHz is also attenuated by a few dB. The attenuation at these frequencies does not affect the signal to noise ratio obtained during recording, which is a primary pass criteria for good data quality.

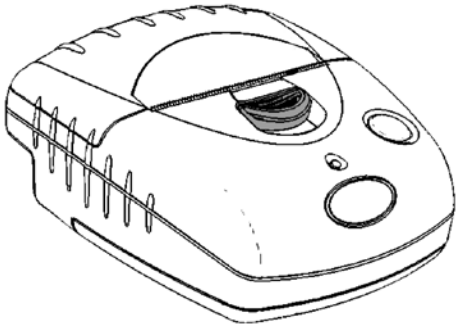
9.4.3.x

Test setup defaults

9.4.3.y The table below shows the test setup default parameters for the Otoport. OAE 2 pass criteria is configured according to the UK NHS screening program.

Test Setup Parameter	Default Mode 1			
TE Test Config				**Locked**
Mode Name	**Screening**	**OAE 1**	**OAE 2**	**Factory**
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	300sec	300sec	300sec	300sec
TE Pass Criteria				
Min NLo	30	30	40	40
Min OAE Sig	0dB SPL	0dB SPL	0dB SPL	0 dB SPL
Min SNR	Off	Off	Off	Off
Min Band Sig	-5dB	-5dB	-5dB	-5dB
Pass Bands	2	3	2	3
1K SNR	6	6	Off	6
1.5K SNR	6	6	6	6
2K SNR	6	6	6	6
3K SNR	6	6	6	6
4K SNR	6	6	6	6
1K RQRD	No	No	No	No
1.5K RQRD	No	No	No	No
2K RQRD	No	No	No	No
3K RQRD	No	No	No	No
4K RQRD	No	No	No	No
TE Automation				
AutoAdjust	On	Off	On	On
AutoStop	On	Off	On	Off
AutoStart	Off	Off	On	Off
Override	Off	Off	Yes	Off
TE Other Settings				
Mandatory	Save Off	Save Off	Save Off	Save On
Mic Filter	If noisy	Normal	If noisy	Normal

10 Printing



10.1 Printer accessory

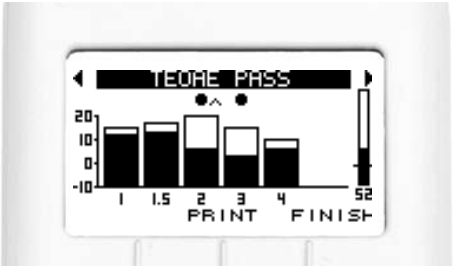
10.1.a An Otoport mini printer is available as an optional accessory. The printer is used to create a paper record of the OAE test results recorded on the Otoport. The Otoport either communicates with the printer using Bluetooth wireless technology (optional) or with a custom printer cable.

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.b Printing at the end of a test

10.2.c When the OAE recording is finished and the result has been saved, you are presented with the following screen that provides the option to print.



10.2.d If you wish to print the test select **Print**. When a print is initiated at the end of a test, the Otoport will print the patient details and test results.

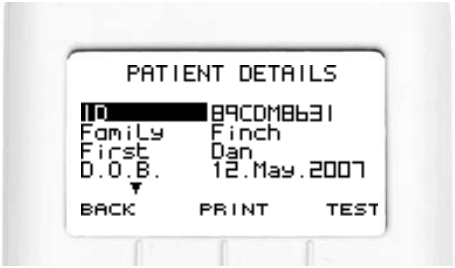
10.2.1 Printing from records

10.2.1.a Results can be printed from the **Records** area of the user interface, which enables the print of any patient tests stored within the Otoport database. 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).

10.2.1.b Once you have located the patient to print you have two options.

10.2.1.c 1: Printing the patient details and all OAE results

10.2.1.d Initiate the print from the **Patient Details** screen.

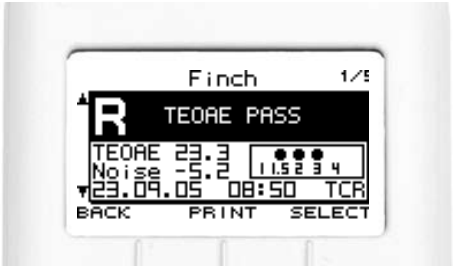


10.2.1.e

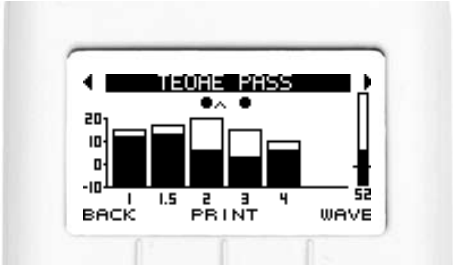
2: Printing patient details and individual OAE results

10.2.1.f

Initiate the print from the test summary screen or any of the test details screens. To select a specific test to print, scroll through the different tests for the patient (using the **Up** and **Down arrow** keys) on the test summary screen.



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.c Last test

10.3.d This prints the last test recorded including the associated patient details.

10.3.e Last patient

10.3.f This option prints all the test results for the last patient including their patient details.

10.4 Print options

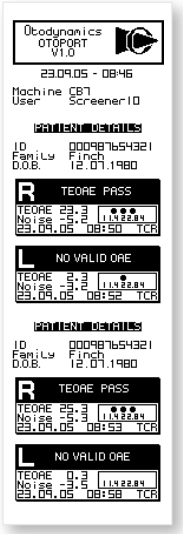
10.4.1 Manual or automatic printing

10.4.1.a 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/Down Arrow** buttons to ensure that **Print** is highlighted and then use the **Left/Right Arrow** buttons to change the choice bar setting from **Manual** to **Automatic**.

10.4.1.b **Print manual** is the default setting.

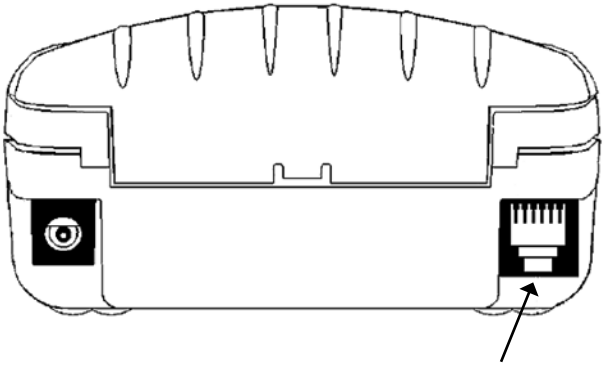
10.4.2 Print type

10.4.2.a 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 (below right) prints all the test screens and a fuller set of patient details.



10.5 The printing process

10.5.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.

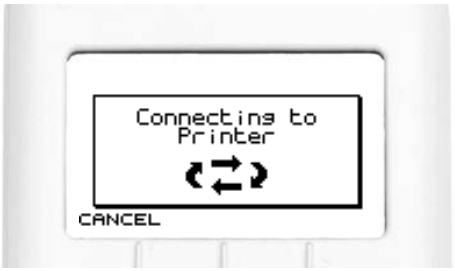


Printer cable socket

10.5.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.

10.5.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 button on the top. When the printer is powered, a green light will be displayed. To save power, the printer will automatically switch off after 4 minutes or inactivity.

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



10.5.e The printout will then commence. Each screen to be printed will briefly be displayed on the Otoport. Once the printout is completed the screen from which the print was initiated will be displayed.

10.5.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.

10.5.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.

10.5.h To **Retry** the print, ensure the printer is switched on and is within range (5m). Then select the **RETRY** button. If printing wirelessly and you have an alternative printer available, select **ALTER**. and the Otoport will connect to this printer.

10.5.i To cancel the printout, select the **CANCEL** button.

10.5.j Once 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.

10.6 Printer fault detection

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

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

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

10.6.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.

10.6.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.

10.7 Printer light summary

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

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

10.7.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)

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

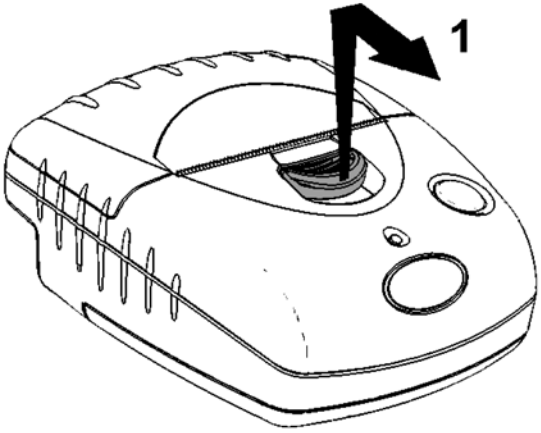
10.7.e **Red** - Low battery or other problem

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

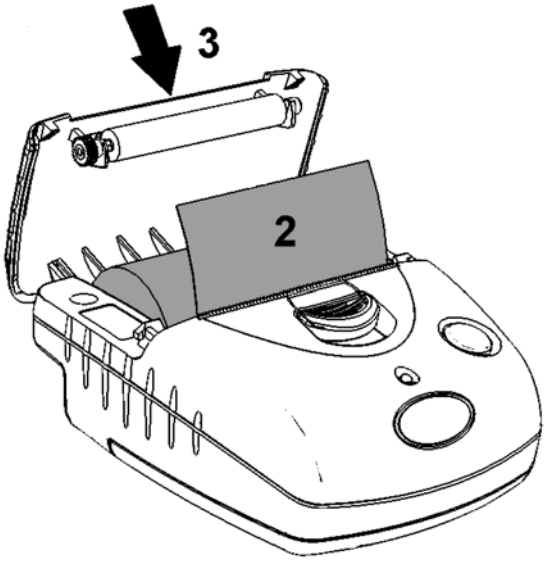
10.8 Paper

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

10.8.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.



10.8.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.

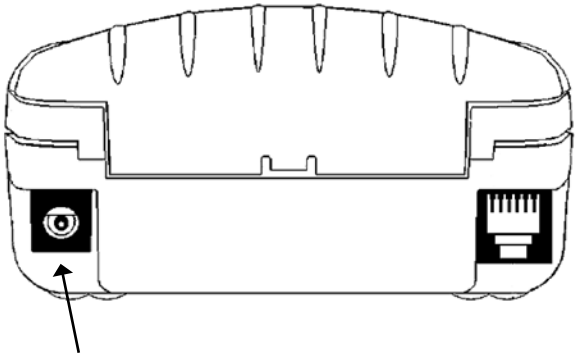


10.8.d After loading, check that the paper advances properly using the paper feed function, and tear off any excess by pulling the paper sharply towards you across the serrated tear bar. In the event of a jam or other paper loading problem, release the lid and straighten the paper before closing again.

10.8.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.

10.9 Charging the printer

10.9.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

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

10.9.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.

10.9.d Note:

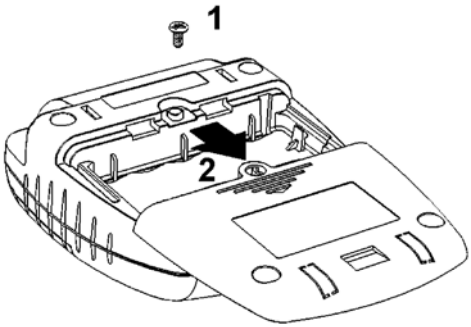
The printer charger is not medically approved. The Otoport must not be in patient contact if connected to the printer whilst the printer is charging.

10.10 Changing the battery

10.10.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.

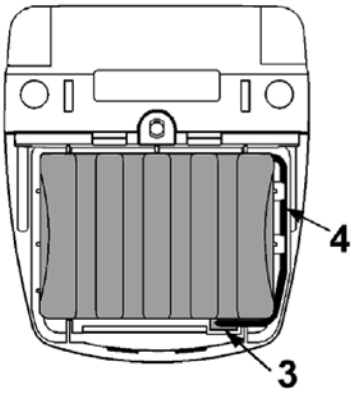
10.10.b To change the battery pack:

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



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

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



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

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

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

10.10.f

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

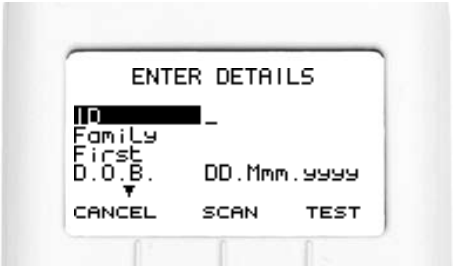
11.2.2.a This method scans radio frequency identification (RFID) chips, which can hold enough alphanumeric data for a complete patient data record on the Otoport.

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

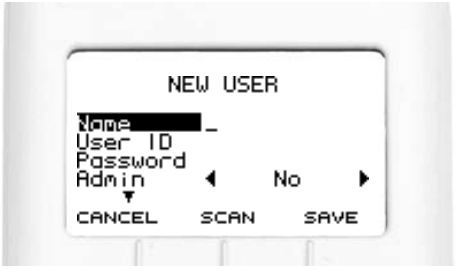


11.3.1.a Select **Scan** when on the Enter details screen to populate the patient details. Make further edits manually with the keypad.

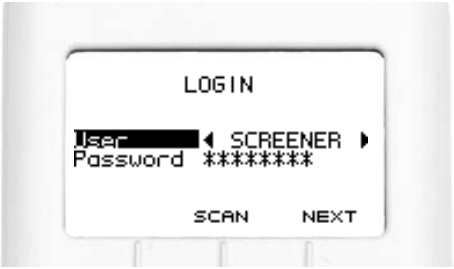
11.3.1.b Then continue to either test or save the result as normal.

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.



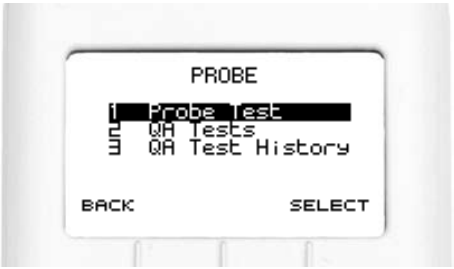
11.3.2.b To login using a scanner, select **Scan** on the login screen.



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

12 Probe

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 Probe test

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

12.1.d QA tests

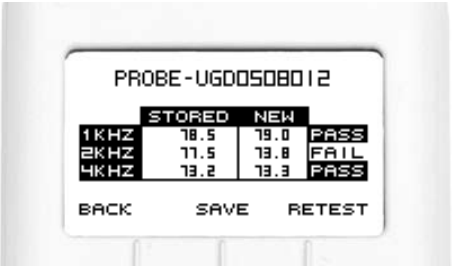
12.1.e Select **QA Tests** to conduct system checks to ensure the device is functioning correctly.

12.1.f QA test history

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

12.1.h 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. Ensure the probe ear piece (without a tip attached) has been firmly inserted into an Otodynamics test cavity and the cavity has been positioned on a flat surface. Select **OK** to begin the **Probe Test** or **Cancel** to return to the **Probe Menu** screen.

12.2.c The probe outputs sound at 1, 2 and 4kHz and the system compares the response at these frequencies against values already **Stored** on the probe. A **Pass** result is given for each frequency if the **New** and **Stored** data are within ± 3dB. If the values differ by more than ± 3dB then a **Fail** result is given.

12.2.d If all frequencies **Pass** then select **Back** to exit the probe test and return to the **Probe Menu** screen.

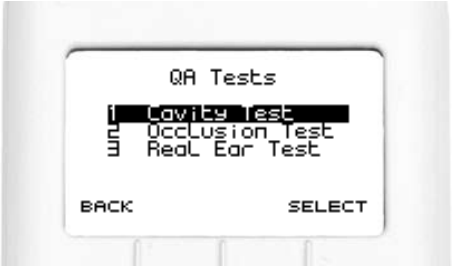
12.2.e If a **Fail** is shown on screen inspect the probe coupler tubes for debris, replace the coupler if necessary and repeat the **Probe Test**, by selecting **Retest**, ensuring the ear piece is firmly inserted in the test cavity. If the test continues to fail there may be a fault with the probe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

12.2.f 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.g 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.h Select **Back** to exit the **Probe Test** screen and return to the **Probe Menu** screen.

12.3 QA test menu



12.3.a Cavity test

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

12.3.c Occlusion test

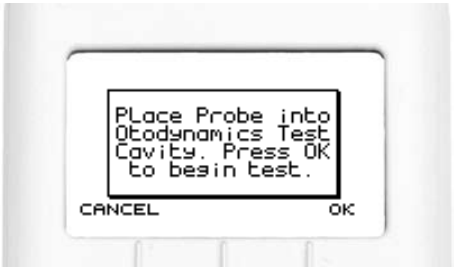
12.3.d Select **Occlusion Test** to check for sound leakage within the probe ear piece.

12.3.e Real ear test

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

12.3.g 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. Ensure the probe ear piece has been firmly inserted into an Otodynamics test cavity (without a tip attached) and the cavity has been positioned on a flat surface. 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.c **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.d 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 3.3 **Checkfit** and 3.4 **Test** for a detailed description of how to perform a standard TEOAE test.

12.3.1.e 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.g 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.h 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. If the result occurs a second time, contact your dealer or Otodynamics for advice.

12.3.1.i 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.j 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.

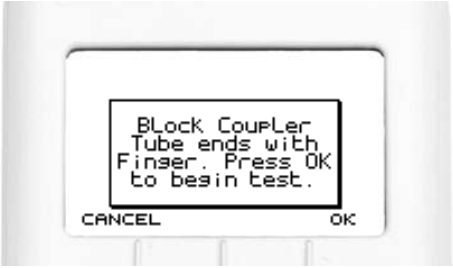
12.3.1.k

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 enter the standard **Checkfit** screen. The stimulus needle should be to the bottom left of the scale and no noise should be detected. On selection of **Start**, the **Stim Out of Range** message will appear, which is expected as the stimulus is being occluded. Select **Continue** to start the test.

12.3.2.c The **Occlusion Test** utilises the identical test sequence as a standard TEOAE ear test.

12.3.2.d Data collected during the **Occlusion Test** is analysed against set pass 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.e **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?	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 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 Fit	If the final test stimulus level is > 40dB.
Occlusion OK	The data collected is acceptable and in good environmental conditions.
Incomplete	If a user ends the test manually.

12.3.2.f 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.g 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. If the result occurs a second time, contact your dealer or Otodynamics for advice.

12.3.2.h 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.i 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 **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.e The result logic for a **Real Ear Test** is set to the locked factory mode. Please refer to chapter 5.4 **Test** for descriptions of stop results.

12.3.3.f 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.

13 Probe tips and accessories

13.1 Probe and service accessories

UGS TEOAE probe (red) with screw locking connector

TPC Coupler Tubes for UGS probe

BGS Body & Lid for UGS probe

13.2 Disposable tips

13.2.a 

T3E Twin-holed elliptical tip, fits 3mm ear canal. Suitable for small and premature newborns.

13.2.b 

T4.5C Twin-holed conical tip, fits 4.5mm ear canal. Suitable for small newborns.

13.2.c 

T5.5B Twin-holed blob shaped tip, fits 5.5mm ear canal. Suitable for most newborns.

13.2.d 

T6.5B Twin-holed blob shaped tip, fits 6.5mm ear canal. Suitable for large newborns and first year infants.

13.2.f 

T8M Twin-holed, mushroom, fits 8mm ear canal. Suitable for infants and small adult ears.

13.2.g 

T9M Twin-holed, mushroom, fits 9mm ear canal. Suitable for most adults.

13.2.h 

T11M Twin-holed, mushroom, fits 11mm ear canal. Suitable for large adult ears.

13.2.i 

T13 Twin-holed, mushroom, fits 13mm ear canal. Suitable for very large adult ears.

13.3 Use of tips

13.3.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.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.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.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.

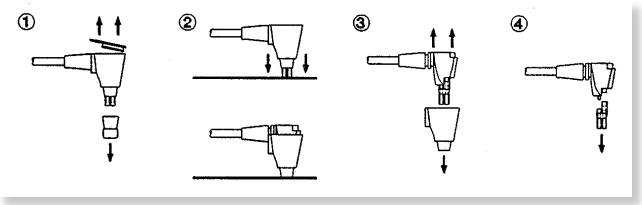
14.1.d **Coupler assembly -** Each coupler assembly has two sound tubes. These are protected from ingress of foreign materials by wax guards in the tubes and by the disposable probe tip. There is a loudspeaker at the end of one tube and a microphone at the end of the other. Cleaning solution must not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

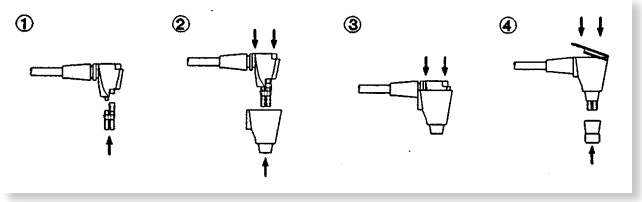
14.2.1 Disassembling the probe

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 10.3 **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 Otodynamics clear plastic pocket. This can also be cleaned with a sterile wipe or cloth with antiseptic fluid. The plastic pockets are disposable, so should be replaced weekly or after approximately every 50 tests.

16 Otoport power

16.1 Battery life

16.1.a The Otoport is powered using an internal rechargeable battery. The battery will provide enough power for over 100 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 many days intense 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 button 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

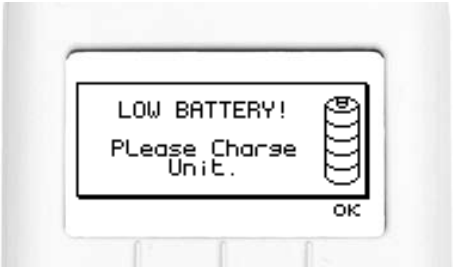
Battery charge

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.

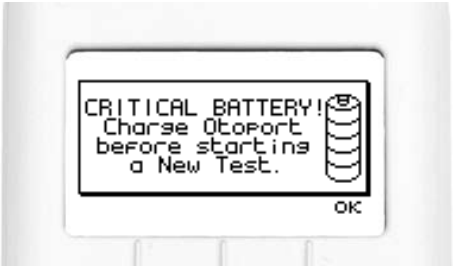
Segments Displayed	Battery Power (%)
5	≥ 95%
4	≥ 70%
3	≥ 50%
2	≥ 30%
1	≥ 10%
0	< 10%

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 level reaches 2%. 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 arrows are facing upwards.

16.5.1.d

Note:

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.

Press in the release buttons on the connector and re-insert with the arrows facing upwards.

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.

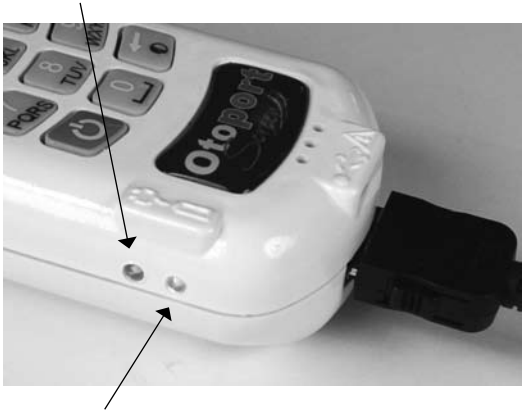
16.5.1.f A full charge will take up to 4 ½ hours.

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 To disconnect the Otoport from the charging lead, squeeze the release buttons together and pull out the cable.

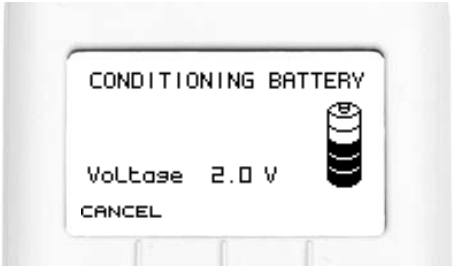
16.5.3.b The power light will extinguish on the Otoport and if the Otoport was off prior to the charging session, the screen will return to blank. If on during the charging session the current screen will remain displayed.

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 conditioning 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 Installing PC software

17.1 Introduction

17.1.a **Otolink** software is provided with the Otoport OAE system to enable download of Otoport data to PC and provide PC based system configuration. The intelligent software detects an Otoport when connected and automatically opens a user friendly options screen. The Otoport patient and test data is then seamlessly transferred to PC for review in a **Data Viewer**. If you have purchased the **EZ•Screen** software option, the downloaded information will be merged with EZ•Screen. Here the full Otoport test data including OAE waveforms can be viewed in high resolution on your PC screen.

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

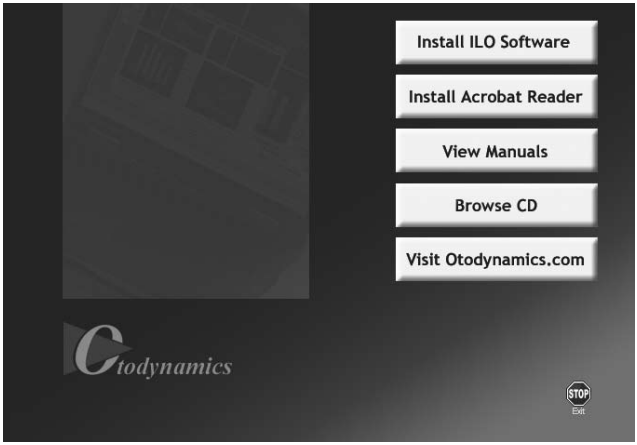
17.1.c Note:

For Windows XP and Windows 2000 you will require Windows Administrator privileges to complete this installation. Please contact your IT administrator if you do not have this level of PC access.

17.2

Installing EZ•Screen 2 software

(Available if the EZ-Screen option has been purchased)



17.2.a The first stage of the installation is to install EZ•Screen 2 software.

17.2.b Insert your EZ•Screen CD into your CD-ROM drive and a CD menu will automatically appear shortly. Select **Install ILO Software** from the CD menu.

17.2.c Follow the on-screen instructions to proceed with the installation.

17.2.d

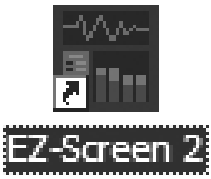
Note:

EZ•Screen must be installed as a standard Desktop or Network server version for use with the Otoport.

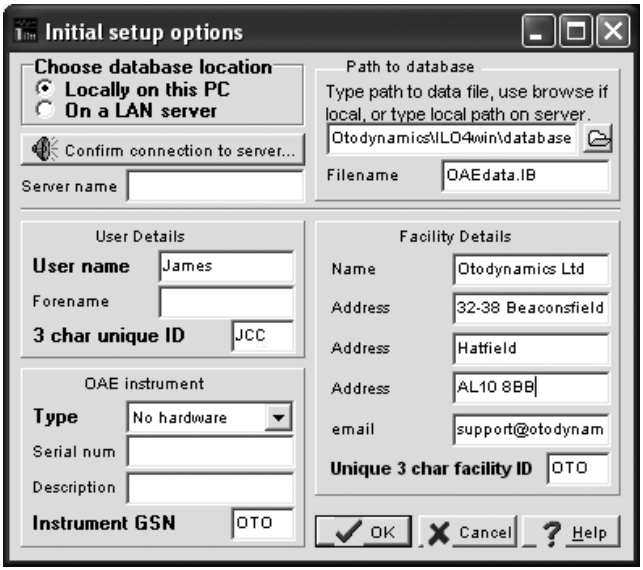
17.2.e You will be asked to enter a password - this will be found on the CD sleeve.

17.2.f Accept a PC re-start if requested.

17.2.g Following installation, an EZ•Screen 2 icon will be placed on your PC desktop.



17.2.1 EZ•Screen initial setup



17.2.1.a Open EZ•Screen from the shortcut provided. You will be required to enter a license key when running the software for the first time. The license key can be found on the CD sleeve and can be entered in upper or lower case letters.

17.2.1.b Following a brief software introduction to read, you will be presented with **Initial Setup** options. When used with an Otoport, EZ•Screen 2 will be used purely for the review of data and not for OAE recording, so the software should be configured accordingly.

17.2.1.c Enter the mandatory fields (displayed on screen in bold) as listed below.

17.2.1.d **User details**

17.2.1.e **User name** - Enter a user name.

17.2.1.f **3 character unique ID** - Enter an abbreviation for your user name.

17.2.1.g **OAE instrument**

17.2.1.h **Type** - Select **No hardware** from the drop down list.

17.2.1.i **Instrument GSN** – As provided on the CD sleeve.

17.2.1.j **Facility details**

17.2.1.k **Name and Address** - Enter your facility name and address if desired.

17.2.1.l **Unique 3 character facility ID** - Enter an abbreviation to represent your facility.

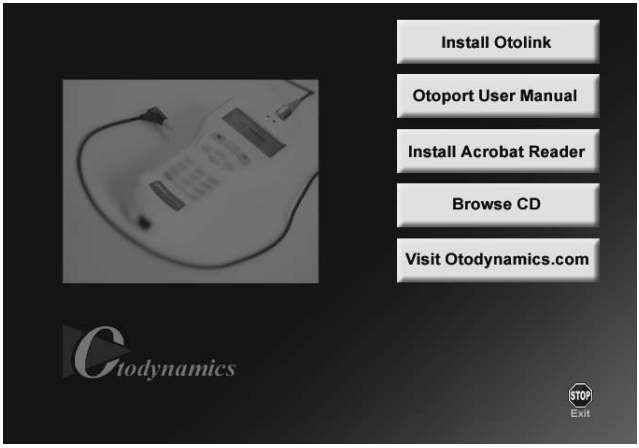
17.2.1.m Click **OK** to open EZ•Screen software. Please see the EZ•Screen manual provided for further information on reviewing data in EZ•Screen.

17.3 Installing Otoport drivers

17.3.a In order for your PC to communicate correctly with the Otoport it is necessary to load driver software. The software is available on the Otolink software CD provided.

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

17.3.c Insert the Otolink CD into your CD-ROM drive. A menu will appear shortly with various options.



17.3.d The menu is not required at this stage, but leave the menu open as it will be needed later.

17.3.1 Connecting the Otoport

17.3.1.a Plug the Otoport into the PC using the PC download cable provided. Do not connect more than one Otoport to the same PC at any one time.

17.3.1.b The end with USB symbol (fig 1) should be connected to a USB socket on the PC (fig 2).

Fig 1

Fig 2

17.3.1.c The Otoport connector (fig 3) should be plugged into the bottom of the Otoport (fig 4) with the arrows facing upwards.

Fig 3

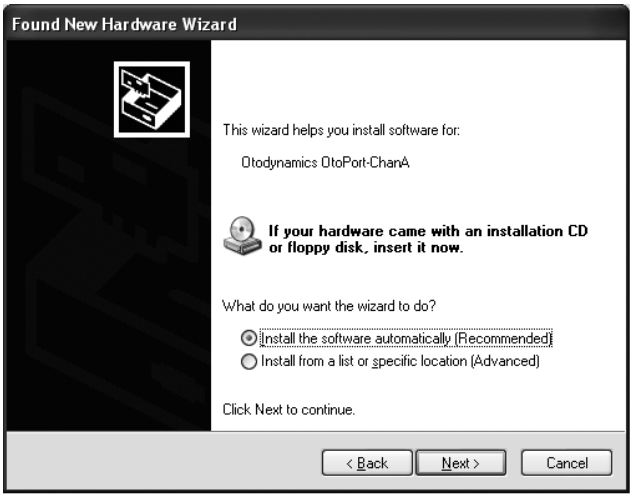
Fig 4

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

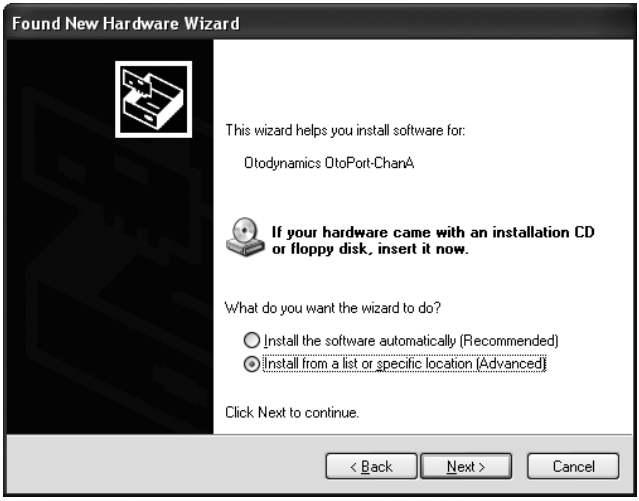
17.3.1.e When the Otoport is connected it will be detected by your PC and a message will pop up to acknowledge the detection of new hardware.

17.3.1.f The found new hardware wizard will automatically start.

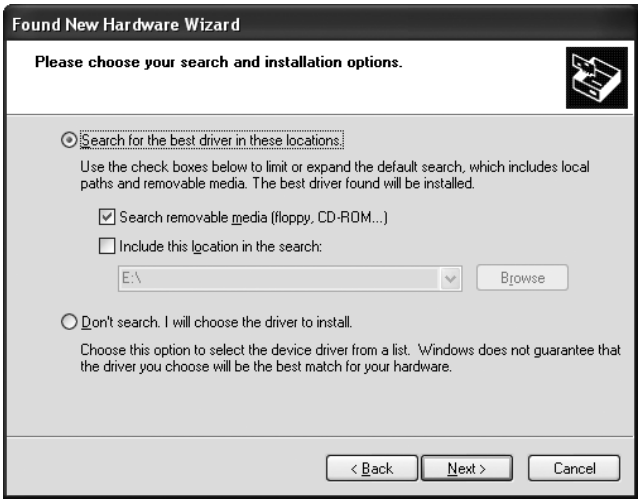
17.3.1.g Select **No, not this time** and click **Next**.



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



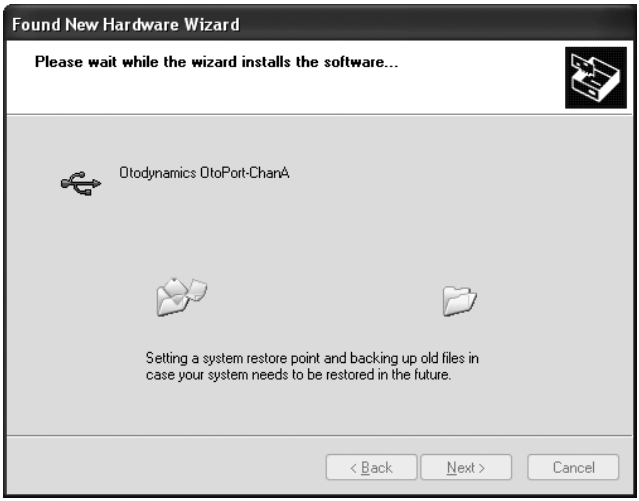
17.3.1.i If the driver is not found during the automatic search, click **Back** and select **Install from a specific location** then **Next**.



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

17.3.1.k Windows will search for the correct drivers.

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



17.3.1.m Windows will then install the drivers.

17.3.1.n Once complete click **Finish**. The driver installation for Otoport channel A is now complete and the same process is necessary for channel B.

17.3.1.o Repeat the process for the channel B installation, as described from paragraph 14.2.1.e onwards.

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

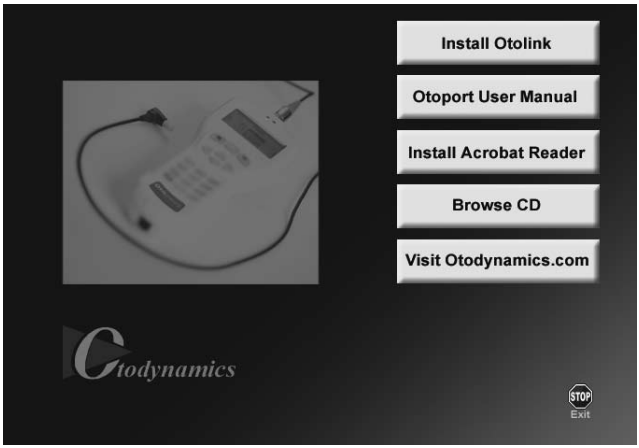
17.3.2 Disconnecting the Otoport

17.3.2.a To disconnect the Otoport gently squeeze the release buttons together as indicated by the arrows and pull out the connector.

17.3.2.b DO NOT ATTEMPT TO PULL OUT THE CABLE WITHOUT SQUEEZING THE RELEASE BUTTONS.

17.4 # Otolink CD menu

17.4.a Following Otoport driver installation, return to the CD menu screen which should be open on your PC desktop. If this has been closed simply open and then close your CD ROM drive and the menu will shortly appear.



17.4.b Select the various options using a left mouse click.

17.4.c ## Install Otolink

17.4.d This will begin the Otolink software installation.

17.4.e ## Otoport user manual

17.4.f This opens the Otoport user manual.

17.4.g ## Install Acrobat Reader

17.4.h This will install Adobe Acrobat Reader (the program used to view the product manual provided).

17.4.i ## Browse CD

17.4.j This allows the contents of the CD to be viewed.

17.4.k **Visit Otodynamics.com**

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

17.5 Installing Otolink software

17.5.a The final stage of the installation is to install Otolink software.

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

17.5.c Follow the on-screen instructions to proceed with the installation.

17.5.d Following the installation, Otolink will automatically run. A shortcut will also be placed on your PC desktop, in case it is necessary to start Otolink manually.

17.5.e Note:

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

18 Using Otolink

18.1 Opening Otolink

18.1.a Otolink will automatically start each time your PC is started. The software will run in low PC memory usage mode until an Otoport is detected.

18.1.b An Otolink tray icon will be placed in your system tray on the bottom right of your PC screen.

18.1.c Prior to connection switch off the Otoport.

18.1.d *Note:*

It is possible to connect the Otoport to the PC when the Otoport is ON, but it will not be possible to control the Otoport once the PC is connected.

18.2 Connecting the Otoport

18.2.a Plug the Otoport into the PC using the PC cable provided.

18.2.b The end with USB symbol (fig 1) should be connected to a USB socket on the PC (fig 2).

Fig 1

Fig 2

18.2.c The Otoport connector (fig 3) should be plugged into the bottom of the Otoport (fig 4) with the arrows facing upwards.

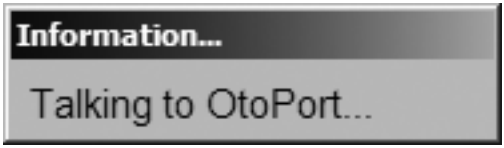
Fig 3

Fig 4

18.2.d If the Otoport is off when connected, a battery charge graphic will be displayed on the Otoport screen that indicates the current battery level. See battery charging section for more information.

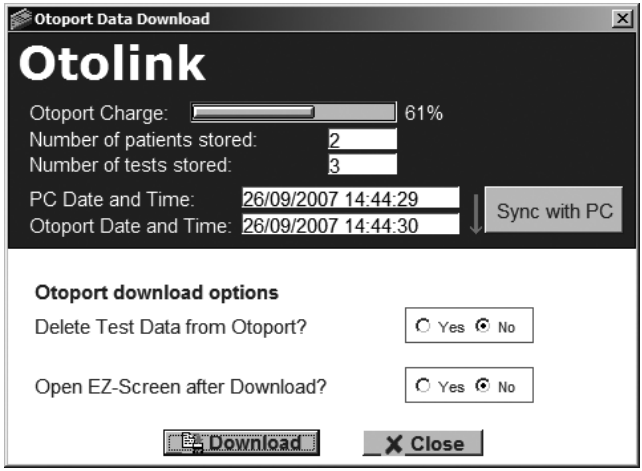
18.2.e If the Otoport is on when connected to the PC, the Otoport screen will remain on the screen displayed at the time of connection. It is not possible to control the Otoport until disconnected from the PC.

18.2.f Once connected, Otolink will automatically detect the Otoport. After a few seconds a window will appear on your PC screen stating 'Talking to Otoport'.



18.3 Download options

18.3.a The download options screen will appear.



18.3.b The Otolink download screen provides download options and Otoport information.

18.3.c An Otoport charge indicator provides information on the Otoport battery level and the charge percentage is given adjacent to the graphic.

18.3.d The number of patients and number of tests stored on the Otoport are displayed for information.

18.3.e The PC and Otoport dates and times are displayed. Select **Sync with PC** to synchronise the Otoport date and time with the PC's.

18.3.f *Note:*

Ensure the PC date and time are correct before you synchronise the date and time.

18.3.1 Otoport download options

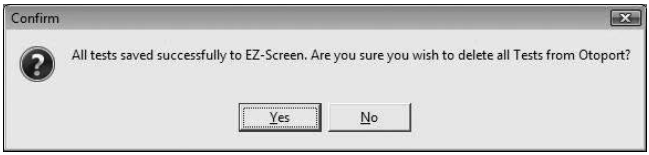
18.3.1.a Download options are provided in the bottom half of the screen.

18.3.1.b Each option is presented as a question and with **Yes** or **No** choices.

18.3.1.c Delete test data from Otoport?

18.3.1.d This option enables the deletion of Otoport data following successful download. If **Yes** is selected a confirmation message will appear after the download is complete.

18.3.1.e Select **Yes** to delete the data or **No** to leave the data stored on the Otoport.



18.3.1.f **Open EZ-Screen after download?**

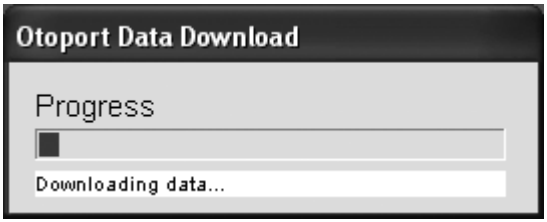
18.3.1.g This function provides the option to automatically open EZ•Screen software following download of data (if EZ•Screen is installed). This is useful if you wish to review the Otoport data at the time of download. Alternatively EZ•Screen can be opened using the shortcut provided on your PC desktop.

18.3.1.h Select **Yes** to open EZ•Screen or select **No** if you do not wish to open EZ•Screen. If you choose to open EZ•Screen, see the EZ•Screen manual for more information.

18.3.2 Initiating the download

18.3.2.a Once you have chosen your desired download options, click **Download** to initiate the download. Select **Cancel** to close the Download options screen.

18.3.2.b During the download process a sequence of **Otoport download** screens will appear. Each screen has a progress bar, which indicates progress of each sub task. When the progress bar is full the sub task is 100% complete.



18.3.2.c As standard there are two sub tasks. First, the software builds a list of patients to download. The sub task states **Building download list**. The data is then downloaded and the sub task states **Downloading data**.

18.3.2.d If EZ•Screen is installed, the data is then imported into the EZ•Screen database and the sub task states **Importing data**.

18.3.2.e When the download is complete the **Download data** screens will close. If you have selected to delete the Otoport data, the delete confirmation screen will appear. Select **Yes** to delete the data or **No** to leave the data stored on the Otoport.

18.3.2.f All the Otoport data has been downloaded and is available for viewing in a **Data Viewer**, which will automatically open.

18.3.2.g If EZ•Screen is installed, all the data will be transferred to EZ•Screen for review. See the EZ•Screen manual for details. The data is also available via the **Data Viewer**, but this will not automatically open.

18.3.3 EZ•Screen data notes

18.3.3.a The OAE waveform response from the Otoport is reprocessed in EZ•Screen and all of the OAE data is recalculated from this waveform. You may notice up to 0.2dB difference in signal and noise values. The total noise is 3dB different. The test outcome and band passes will not be affected as these are imported directly from the Otoport.

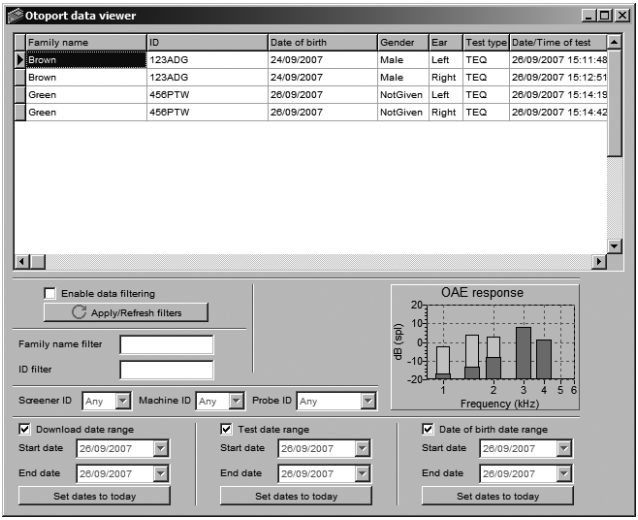
18.3.3.b The stimulus level is recalculated from the stimulus waveform and a variation of a few dB may be observed.

18.3.3.c The stimulus stability figure for all imported Otoport data will be 1, irrespective of the value on the Otoport.

18.3.3.d The level of noise reject will be reported at the level set in the Otoport in dB SPL.

18.3.3.e If there is no Gender set on the Otoport, the patient will default to Male in EZ•Screen.

18.3.4 Data viewer



18.3.4.a The **Data Viewer** provides the facility to view all the downloaded Otoport data, including patient and test details, with OAE data.

18.3.4.b All data is downloaded to the **Data Viewer** which shows a test per row. On subsequent downloads new data appends to the bottom of the table.

18.3.4.c Selecting a patient to view

18.3.4.d Use the Up/Down arrows on your PC keyboard or your mouse to select an individual test for a patient. Their half-octave OAE data will be displayed in an OAE response histogram. The blue represents the signal and the red represents the noise.

18.3.4.e To search for a specific test, various filters are provided. It is possible to search for data downloaded between specific dates, tests conducted in a specific data range, or patients with a specific date of birth. Tick the relevent boxes to filter by any of these options.

18.3.4.f The Data Viewer will also filter by Screener ID, Machine ID or Probe ID. Use the drop-down lists to select the variable.

18.3.4.g The family name and ID fields are provided to enable a partial field search. Select/deselect the required filters and click ‘Apply/Refresh filters’ to update the data displayed.

18.3.5 Tray icon control

18.3.5.a As standard, Otolink software automatically starts when the PC is started. The software runs in low PC memory usage mode until the software is opened or detects an Otoport. A tray icon is present in the system tray. Otolink software will automatically open when an Otoport is detected, but it is also possible to open the software manually using the tray icon.

18.3.5.b **Note:**

The download options and administration areas of the Otolink software will only open when an Otoport is connected. If there is no Otoport connected the software will display the message **No Otoport connected. Please check connection from PC to Otoport and retry**. Ensure the Otoport is connected correctly and re-try.

18.3.5.c The Otolink tray icon provides four options. Right click with the mouse on the tray icon to display the options.

18.3.5.d 1. Open

This option will open the Download options screen.

18.3.5.e **Note:**

A left mouse click on the Otolink tray icon will also initiate the Open function.

18.3.5.f

2. Administration area

The Otolink **Administration area** provides additional functions to control the configuration of the Otoport.

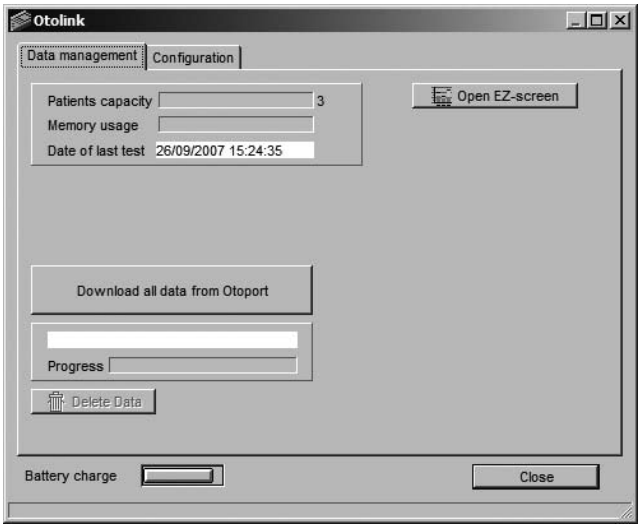
18.3.5.g

Note:

A PC operator with Windows user permissions cannot access the **Administrator area**.

18.3.5.h On each of the various tabs a green battery charge indicator shows the current Otoport battery level as a percentage. When the indicator is filled completely, the battery charge on the Otoport is 100%.

18.3.5.i **Data management**



18.3.5.j The data management tab provides duplicated data download functions but allows the user more manual control over the process.

18.3.5.k Various database information is provided.

18.3.5.l **Patient capacity:** Shows the number of patients stored on the Otoport. A bar graphic shows the amount of patients stored as a percentage of the patient storage limit. When the blue bar is full the capacity is reached. The number of patients stored is also displayed to the right of the graphic. The maximum number of patients that can be stored is 1024.

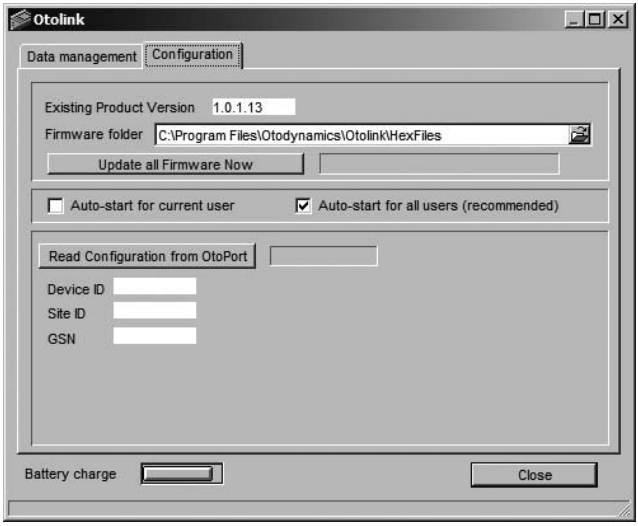
18.3.5.m **Memory usage:** The database memory on the Otoport can be filled with either patient or test data with a varying number of tests per patient. There is no limit to the number of tests that can be conducted on one patient, other than the memory capacity of the device. The device can potentially hold 1024 patients and each of these could have up to 3 tests. However, if one patient record has say 100 tests, this will reduce the memory capacity for other patients and tests. A bar graphic shows the total percentage of memory used.

18.3.5.n **Download all data from the Otoport:** This function enables download of data from the Otoport.

18.3.5.o **Delete data:** Once the download has been completed successfully the **Delete data** button will become active. The button remains inactive and greyed out until successful download has occurred. Select the **Delete data** button to erase the Otoport memory. A confirmation message will appear. Select **Yes** to delete or **No** if you wish the data to remain on the Otoport.

18.3.5.p **Open EZ-Screen:** This button will open EZ•Screen software to allow review of the data downloaded. See the EZ•Screen manual for full details.

18.3.5.q **Configuration**



18.3.5.r The **Configuration** page enables the update of the Otoport firmware. The existing product version is displayed at the top of the screen and it is possible to select the location of the firmware to upload. Either type the filepath or select the **Browse** button using your mouse.

18.3.5.s Select **Update all Firmware Now** to update the Otoport firmware. A confirmation message will appear upon successful completion of the firmware update.

18.3.5.t

Important Note:

Only select **Update all firmware now** if it is necessary to re-install or upgrade the Otoport firmware. Your dealer or Otodynamics will provide you with the necessary files in order to do this.

DO NOT disconnect the Otoport during this process. A confirmation message appears at the end, stating the process has completed.

18.3.5.u The **Configuration** area also allows various device identifiers to be read from the Otoport. Select **Read configuration from Otoport** to download various device identifiers.

18.3.5.v **Device ID:** This field is provided so that a user defined description of the device can be read if desired.

18.3.5.w **Site ID:** This field is provided so that the site of use for the Otoport can be read if desired.

18.3.5.x **GSN:** The GSN is the unique machine ID, which is programmed at the Otodynamics factory. All data file names generated on the device start with the unique 3 character machine GSN.

18.3.5.y The **Configuration** page also enables control over the automatic start of Otolink following PC boot. Click on the box to enable the setting. A tick will appear in the box when the function is selected.

18.3.5.z **Auto start for current user:** With this setting on, Otolink will automatically start for the user currently logged into Windows.

18.3.5.aa **Auto start for all users:** With this setting on, Otolink will automatically start for all the users set-up on the PC.

18.3.5.bb Note:

Only a user with Windows administrator privileges will be able to change the auto start setting for all users.

18.3.5.cc ### 3. Data viewer

Select **Data Viewer** to open a data table which shows downloaded Otoport data. See chapter 18.3.4 **Data Viewer**.

18.3.5.dd ### 4. Exit

Select **Exit** to close Otolink software. To re-start the software, either double click on the Otolink shortcut on your desktop, or re-start your PC.

18.4 Backing up data

18.4.a It is advisable to back-up all the downloaded Otoport data. Using Windows Explorer, back-up folder C:\Program files\ Otodynamics\Otolink.

18.4.b See the EZ•Screen Manual for back-up of data in EZ•Screen.

19 Troubleshooting

19.1 Otoport lock-up

19.1.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 button for 10 seconds; this will force the unit to switch off. Turn on the Otoport again.

19.2 Switch on

19.2.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 it still does not turn on, hold down the **On/off** power button for 10 seconds and then try to switch on the device. If the Otoport still fails to complete its start up sequence then contact your dealer or Otodyamics for support.

19.3 System details

19.3.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.

19.4 Instrument fault message

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

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

19.4.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. Run all three QA Tests from the **Probe** main menu, in order to check the system (see chapter 10 Probe for details). If the all three QA tests are 'OK' the device is functioning correctly and can be used for OAE testing again.

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

20 Obtaining service

20.0.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.

20.0.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.

20.0.c If you have a problem with your Otoport or probe, contact your distributor or Otodynamics for advice before returning the item for repair. You will be asked for your unit serial number, which can be found on the back on the Otoport.

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

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

www.otodynamics.com

21 Technical specifications

Physical

Handheld device:	195mm x 70mm(max) x 30mm – Weight 250g
Charger:	90mm x 38mm x 28mm – Weight 120g

Interfaces

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

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	

Keyboard

19 key alphanumeric with cursor control and soft keys

Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

Power

Intelligent multi-level power control for charging/testing/idle/sleep/shutdown:
After 3 minutes unit will enter sleep mode
After 30 minutes in sleep mode unit will shut down

Sleep time:	20 hours (with fully charged battery)
Running time:	8 hours minimum (continuous testing)
Max consumption when testing:	720mW
Max consumption when charging:	2.5W
Source:	860mAh NiMh internal rechargeable cells
Charge time:	3 hours to 80% capacity Approximately 4.5 hours to 100%

Hardware Options

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

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

Analogue performance

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

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

Classifications and standards

Device Class 2a	(Directive 93/42/EEC)
BS EN ISO 13485:2001	(REF: EN46001superseded 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 Index

Symbols

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

Otoport