Otodynamics

# Otocheck LE

## User Manual

**Otocheck** LE

Issue 4.7


# **Otocheck** LE

Firmware revision: v5.3.1.0 onwards

Doc Ref: MANOLE - Issue 4.7

15/08/2022



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UDI

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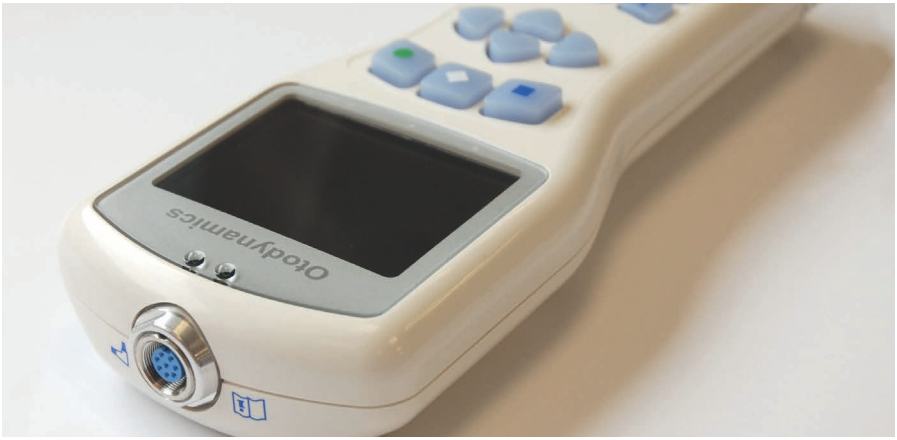


# 1 Introduction

The Otocheck LE provides high quality OAE measurement features in a compact, handheld format. Different models are available to perform either TEOAE or DPOAE tests.

The Otocheck LE 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.

The Otocheck LE's impressive list of features includes:

- TEOAE Quickscreen or DPOAE testing
- Ultra fast interactive graphic display
- Frequency band analysis
- Long battery life

## 1.1 Intended Use

This Otodynamics Otocheck LE device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user. Where the individual to be screened is healthy with no medical conditions related to the ear, as in the case of well-baby hearing screening, the user can be a trained screener. In all other cases the user should be an audiologist or medical professional.

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

These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.

Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization.

## 1.2 What do OAEs test for

- OAEs test for problems in the peripheral auditory system. It is important to remember that OAEs do not test the whole hearing system, only cochlear function.
- Absence of OAE can be due to cochlear or middle ear dysfunction. Failure to detect any OAEs can also be due to high levels of noise or a blocked or badly fitted probe.
- The presence of OAEs indicates good middle ear function and good transmission of stimulation by outer hair cells inside the cochlea, at the tested frequency.
- Good OAEs do not exclude the possibility of auditory neuropathy or higher neural dysfunctions but these higher level dysfunctions are almost unknown in the well baby population. This is why OAEs have been used as an effective primary screen in hearing screening programmes for decades in many countries.
- Higher level disorders are occasionally present in ‘at risk’ and NICU babies and for this reason both OAE and ABR screening is recommended for this group.

## 1.3 General guidance

The screening functions of this instrument are especially suitable for use with infants.  OAE screening functions include Otodynamics classic Quickscreen TEOAE technology and Rapid DPOAE technology (depending on the model).

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

The screening functions of the device are intuitive and suitable for operation by trained screeners without specialized knowledge. Testing and interpretation is automated.

# 1.4 General use precautions


The Otocheck LE pass criteria are set in the **Configuration** area (see chapter 7 **Configuration**). It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

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.

The Otocheck LE includes 'stop criteria' which will automatically terminate the test when an OAE pass has been achieved or after two minutes.

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

The Otocheck LE 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 9 **Probe checks**).

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

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

If contamination occurs the coupler tubes must be replaced (see 11.2 **Changing probe coupler tubes**).

Visually inspect the coupler tubes before use. A blocked sound delivery tube may prevent the Otocheck LE 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 Otocheck LE from sensing the stimulus level in the ear and from detecting the OAE. As a result the Otocheck LE may apply a louder than normal sound to the ear.

Before inserting the probe, the ear should be inspected to ensure that the ear canal is clean and dry and also to establish that there are no contraindications to carrying out the test (see section 1.5 **Contraindications**).

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

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

Do not allow liquid to enter the instrument.

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

## 1.5 Contraindications

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

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

1.6

# Safety

**Caution**

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

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

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

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

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

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

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

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

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

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

## 1.7 The importance of setting the appropriate stimulus levels

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

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

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

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

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

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

Note that the Otoport ABR is not intended for use in diagnostic use. In clinical testing with OAEs a wider range of stimulation levels are used, especially for DPOAEs as part of the diagnostic process.

Never over-stimulate for infant screening.

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

**TEOAEs** - never use stimulus levels above 87dBpe for screening.

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

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

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

## 1.8 Types of otoacoustic emissions

Otoacoustic emissions are sounds which can be recorded in the ear canals of functionally normal ears.

This Otocheck LE can make two types of OAE measurements: Transient Evoked OAEs (TEOAEs) and Distortion Product OAEs (DPOAEs).

The difference between the measurements is largely in the means used to generate and measure the emission, rather than in the source of the emission itself.

TEOAEs use a click to briefly stimulate the cochlea across a wide frequency range and record the response from the cochlea.

DPOAEs use a pair of pure tones of specific frequencies (f1 and f2) to stimulate the cochlea and record the distortion generated by the tones in the cochlea at a third frequency (2f1-f2). Different pairs of f1 an f2 frequencies are used in turn to acquire emissions from different areas along the length of the cochlea.

## 1.9 OAEs and screening

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

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

## 1.8 Training


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

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

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

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

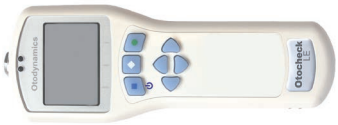
Training in operating the device is provided by Otodynamics Ltd in the UK. Training in the operation of the device elsewhere is via an approved dealer who has been trained by Otodynamics. Training on OAEs and use of the equipment may also be provided by previously trained staff and qualified audiologists.

Ensure your local policy for infection control is followed, as well as reading the recommendations in this manual (see section 12.1 **Use of the Otocheck LE and cleaning**).

If a problem occurs during the operation of your Otocheck LE or a message or warning appears that you don't understand, make note of the issue and messages provided. Refer these to your department lead, or directly to Otodynamics or your dealer for support.

# 2 Equipment identification

## 2.1 Supplied in Otocheck LE kit

| | |
|---|---|
| REF LE-ST (TEOAE model) or LE-SD (DPOAE model)<br>Otocheck LE |  |
| REF OP-CAS<br>Equipment case for Otocheck LE kit |  |
| REF UGS<br>UGS TEOAE probe<br>Supplied with TEOAE model |  |
| REF UGD<br>UGD DPOAE probe<br>Supplied with DPOAE model |  |

REF PR-POUCH

Drawstring probe pouch

REF PR-CLIP

Probe cable clip

REF TPC

TPC probe coupler tubes x 5

Supplied with TEOAE probe
Re-order quantity: 10 or 100

REF DPC

DPC probe coupler tubes x 5

Supplied with DPOAE probe
Re-order quantity: 10 or 100

REF BGS

BGS probe body and lid x 1

Supplied with TEOAE probe
Re-order quantity: 10

REF BGD

BGD probe body and lid x 1

Supplied with DPOAE probe
Re-order quantity: 10

Sample probe tips (box or pediatric screening kit)

See chapter 10
Probe, tips and accessories
for re-order codes


REF ABR-CAV

Probe test cavity

REF OP-CHG

Charger

or

REF OCC

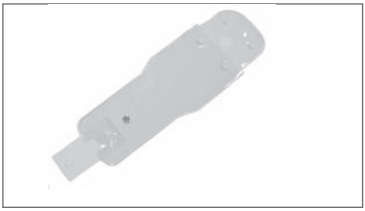
Charging cradle

REF OP-CAB

PC download cable

REF OP-INF

Infection control sleeve



Documentation pack

Includes instrument and software manuals, quickstart and probe use guides

## 2.2 Optional accessory

REF OMP

Otodynamics mini printer

Wired and wireless models available`

## 2.2.1 Otodynamics mini printer accessories and consumables

REF OMP-CAB
Mini printer cable

REF OMP-CHG
Mini printer charger

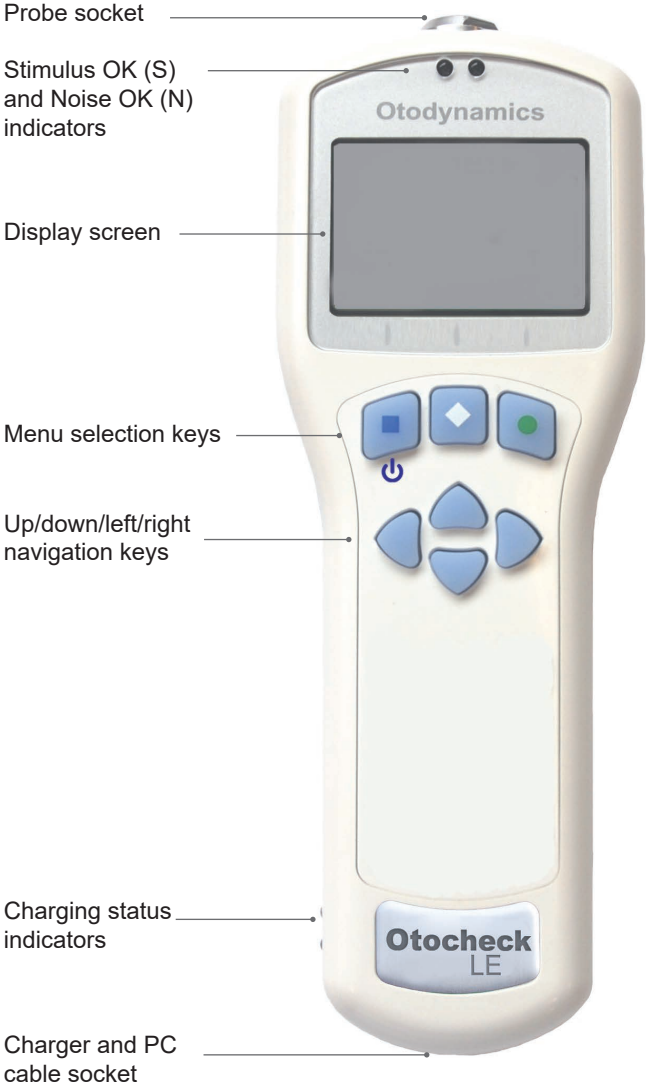
REF OMP-PAP
Mini printer paper rolls

Quantity: 10

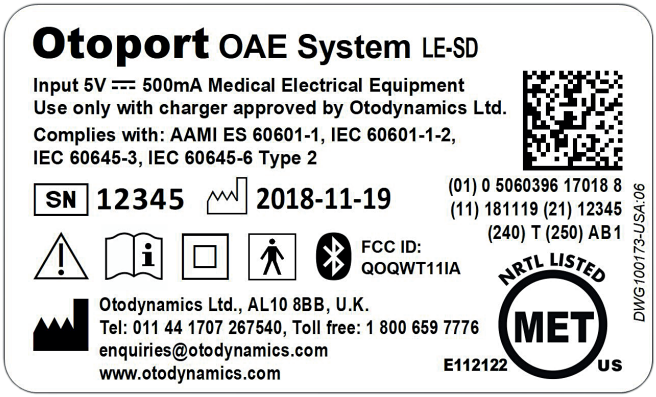
REF OMP-PAP
Mini printer self-adhesive paper rolls

Quantity: 6

## 2.3 Controls, indicators and connections



## 2.4 Labelling

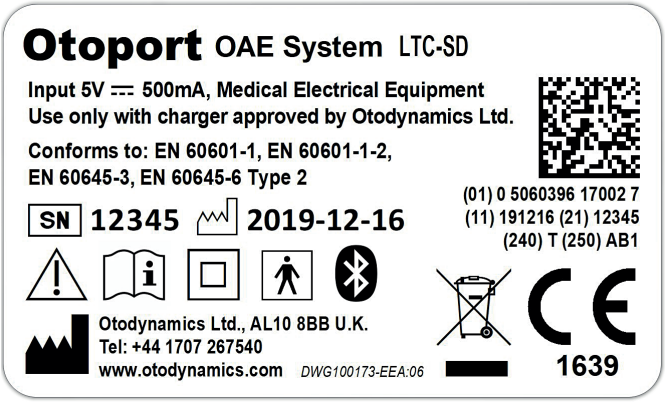



This is an example of the label fixed to the underside of your Otocheck LE. Otocheck LEs belong to the Otoport family of products. The model is indicated by the letters after 'OAE System' on the top line.

'LE-SD' indicates an Otocheck LE model with firmware for screening with DPOAEs.

'LE-ST' indicates an Otocheck LE model with firmware for screening with TEOAEs.

The number following 'SN' on your device will be the serial number of your device. The date of manufacture follows the serial number. These numbers should be quoted in all communications about your device.




*EU regional label*

### 2.4.1 Symbols

See section 18.6 for the meaning of symbols used on the label.

### 2.4.2 Unique Device Identifier (UDI)

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

The UDI is to be found on the right side of the produce label, under the 2D barcode.

The fields in the UDI are made up of the following parts:

(01) Global Trade Item Number (GTIN): *Otodynamics prefix followed by product reference number*
(11) Production date: *in the format yymmdd*
(21) Serial numbers: *five digits*
(240) Additional product ID: *'T' indicates that a Bluetooth Module is fitted*
(250) Secondary Serial Number: *proprietary device identifier called GSN*

This information is also contained in the adjacent barcode.

### 2.4.3 Certification or regulatory marks

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

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

# 3 Getting started

## 3.1 Initial charge

Before using your Otocheck LE for the first time, fully charge the unit. See chapter 13 **Power** for details.

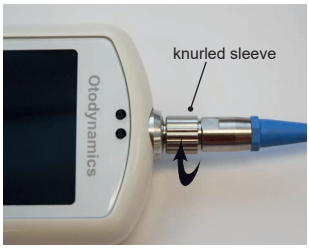
## 3.2 Quickstart

The Quickstart guide, included as a separate item in your document pack, is shown on the next two pages.

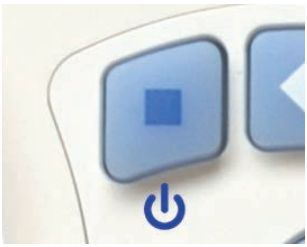
QUICKSTART

# Otocheck LE

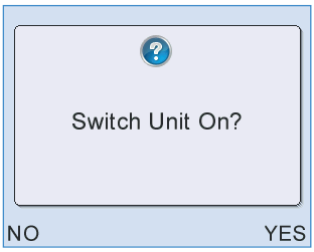
## Step 1. Setting up your Otocheck LE



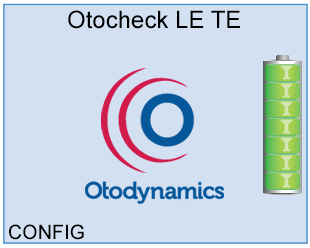

1 With the arrow at the front, connect the probe and screw the knurled sleeve until finger tight.



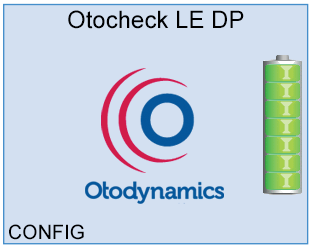
2 Press the button to turn on the Otocheck LE.




3 Confirm within 2 seconds by pressing the button.



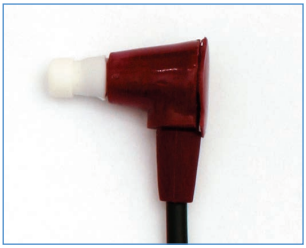

4 The logo screen shows the battery status (TEOAE model shown above).




5 DPOAE model logo screen.

## Step 2. Fitting the earpiece

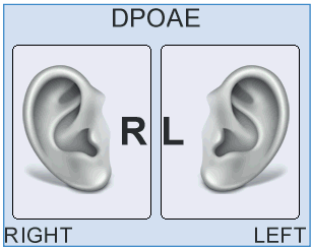
1 Select an appropriate tip (TE tips and probe shown).



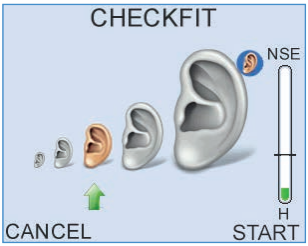
2 Fit the tip to the earpiece.

3 Fit the earpiece in the ear canal.

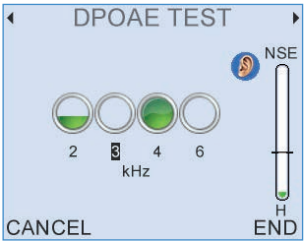
## Step 3. Performing a test



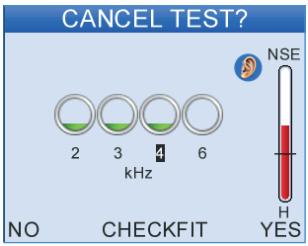

**1** Begin a test with a **new** patient by selecting **LEFT** or **RIGHT** ear. If the memory already contains results from a previous patient and you have the print option, **PRINT** will appear. Up to four results from the last patient can be printed. All results are deleted when a new test session is started.



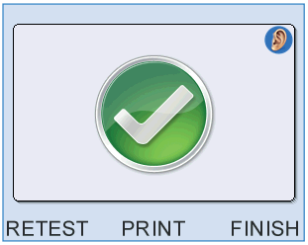

**2** The **CHECKFIT** screen shows the noise level (NSE) and the size of the ear seen by the probe as fitted. Press to **START**. There will be a short pause as in-the-ear stimulus adjustments are made.
Two blue LEDs light on the Otocheck LE when conditions are good for testing.



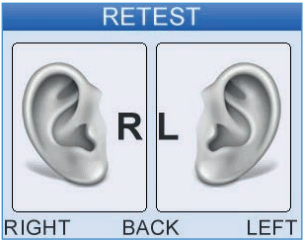

**3** During the test a circle is displayed for each frequency band tested. Each circle fills as OAEs are detected. You can pause the test at any time, e.g. during noisy periods, by pressing to **CANCEL**.




**4** When a test is paused you will see the **CANCEL TEST?** screen. **NO** will resume the test. **YES** will abort the test. **CHECKFIT** will allow restarting of the test.

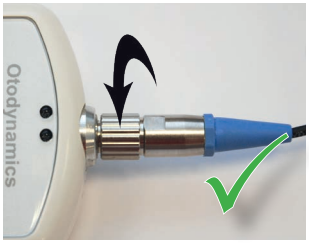



**5** The test will automatically stop and show the result. For details see manual. Use **RETEST** to start another test on this patient from screen 3.6. **PRINT** will print a report of this test if a printer is available. **FINISH** will end the testing session for this patient and will take you to the Main screen 3.1 where the results of up to four tests on the patient can be printed.




**6** The **RETEST** screen allows further tests on the same patient. Selecting **RIGHT** or **LEFT** will take you to screen 3.2 (Checkfit). Up to four results will be retained in memory for printing until a new session is started or the unit is switched off. **BACK** will return to the result screen 3.5.

## Step 4. Disconnecting the probe




**1** Unscrew the knurled sleeve.


**2** Do NOT turn the main probe body.

**3** Gently pull out the probe. To turn off press and hold the button.


Ref: MOLEQ-6 May 2019

CE 1639

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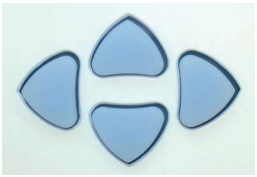
# 3.3 Using the keys

## 3.3.1 Control keys

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

## 3.3.2 Arrow (navigation) keys



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

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

## 3.3.3 Backlight

The screen and keys are backlit to assist in testing in dimly lit environments. The backlight stays on for 7 seconds following any key press and remains on during testing. The backlight can be configured (see chapter 7 **Configuration**).

### 3.3.4 Stimulus and Noise OK indicators (blue LEDs)

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

The Stimulus LED is marked with an S. It is lit when the stimulus level recorded by the probe microphone is within the expected range.

The Noise OK LED is marked with an N. It is lit when the noise level recorded by the probe microphone is below the set noise reject level (see chapter 7 **Configuration**).

### 3.3.5 Hard reset

In the unlikely event that the Otocheck LE fails to respond to any user control, you may need to RESET the device. To reset the device, while the unit is on, hold down the On/Off key AND the Down arrow key for 10 seconds. You may then switch on the device again as normal.

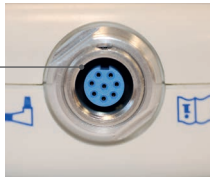
## 3.4 Connecting the probe


Prior to the testing session, connect the probe to the Otocheck LE.

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

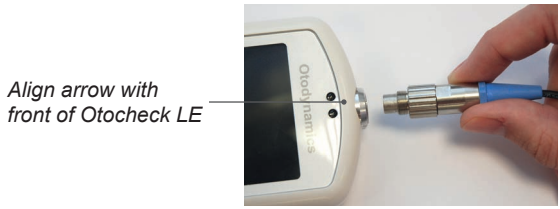
*Probe key*

*Socket keyway*

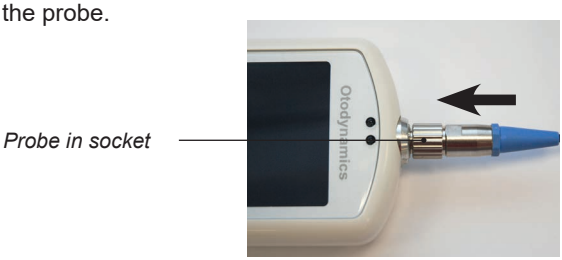


The arrow at the front of the probe plug indicates the position of the ‘key’ and should be aligned with the front of the Otocheck LE.

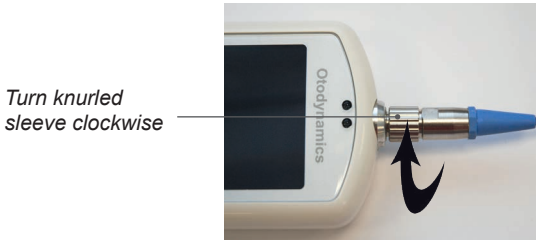

It is possible to feel when the probe key is aligned as the probe will mate with the socket easily.




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



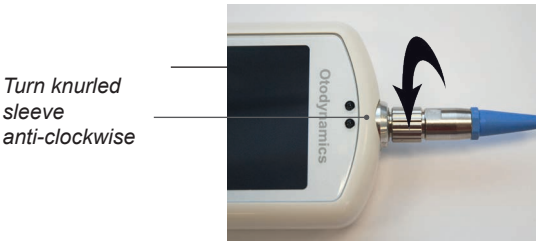

Screw up the **knurled sleeve** in a clockwise direction until finger tight.

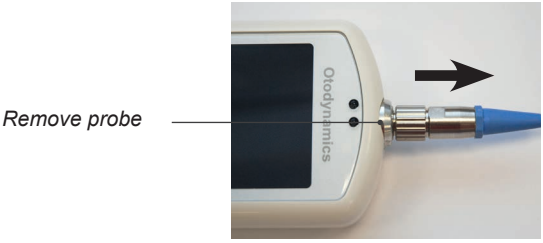


## 3.5 Disconnecting the probe

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

Then gently pull the probe out from the probe socket.

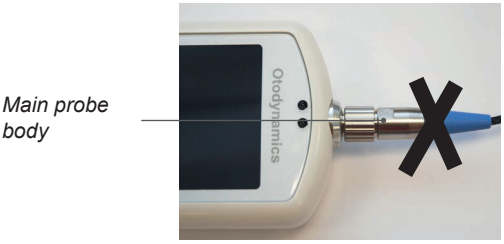



### Important Note:

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

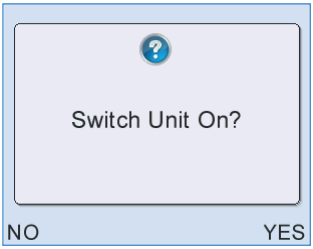
This will result in damage to the probe and will invalidate the probe warranty.



# 4 Switching On

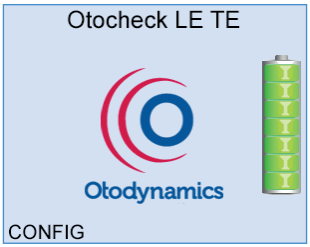
## 4.1 Switch on screen

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




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

## 4.2 Logo screen



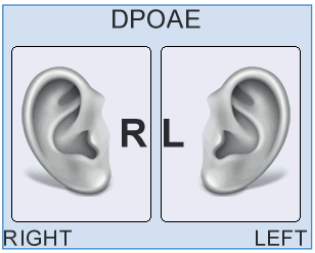

Following switch on, an Otodynamics' logo animation is displayed whilst the device performs a series of hardware system checks. In the unlikely event of any of the systems checks failing, an error message will be displayed (see section 14.5 **Hardware fault messages** for details).

A battery graphic will appear to the right of the logo to provide an indication of the **Battery Power** remaining. Please refer to section 13.4 for battery information.

Selecting **Config** during start up takes the user to the **Configuration** menu where probe test, test settings, date, time, system details and users may be viewed or edited (see chapter 7 **Configuration**).

It is important that the date and time in the Otocheck LE are correct, especially if test results are printed. Enter **Configuration** mode, as above, to check and set the date and time.

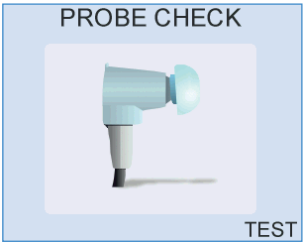
## 4.3 Main screen




After the Logo screen you will see the Main screen above. Note that Otocheck LE TEOAE models will show TEOAE at the top.

The Main screen is where you begin testing a new patient. Begin testing by choosing your test ear by selecting **LEFT** or **RIGHT**. You will be returned to this screen when you finish testing a patient. **Review** will then appear as the centre option to indicate test results are in memory. Memory is erased when you start testing a new patient and when you switch off the device.

### 4.3.1 Probe check




From the Main screen you can also enter **Probe Check** mode to perform quality tests on the probe. You will need to check the probe if you have replaced the coupler due to contamination, or if you suspect the probe is defective.

To access the Probe Check mode from the Main screen, press either the Left or Right arrow (navigation) keys. See chapter 9 for information on Probe Check.

# 5 Test preparation


## 5.1 General checks before testing

Ensure the Otocheck LE is charged (see chapter 13 **Power** for information).

Ensure the Otocheck LE weekly checks are being regularly conducted (see chapter 9 **Probe checks** for information).

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

Choose a quiet room, without background noises.

Ensure the patient is comfortable and settled.

Ensure you can clearly see the ear to be tested.

## 5.2 Connecting the probe

Prior to the testing session, connect the probe to the Otocheck LE. See section 3.4.

# 5.3 Tip selection and probe fitting

Appropriate tip selection and good 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 Otocheck LE is supplied with a full range of tips to fit all ear canal sizes. When selecting a tip, first inspect the ear to be tested to assess its size and to check that it is clear and free from debris. If debris subsequently enters the probe sound tubes, do not attempt to clean them; the coupler tubes should be changed. The correct size tip will look slightly larger than the ear canal and should fit snugly, forming a complete seal with the ear canal wall.

## 5.3.1 Fitting for newborns

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

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

Turn the probe ear piece to 12 o'clock.

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

### 5.3.2 Fitting for children and adults

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

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

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

No discomfort should be felt by the patient. The weight of the probe cable should be supported to minimise the risk of the probe being pulled out during testing. Use the probe cable clip supplied, ensuring there is sufficient slack in the cable to allow for movement of the patient's head. If the correct tip is used, the probe should stay in place without aid. However, it is acceptable to hold the probe gently in the ear if the patient is restless.

## 5.4 Helpful hints

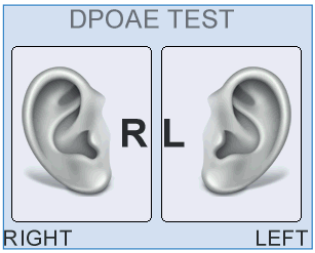
The most frequent cause of unsuccessful OAE recordings is failure to fit the probe correctly, so that it is deep enough in the ear canal. The presence of fluid and debris in the ear canal or middle ear will also inhibit recordings.

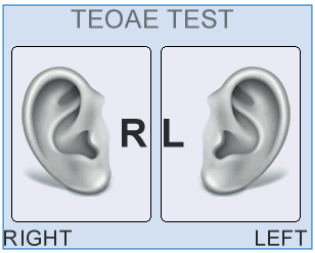
If a pass result is not obtained, remove the probe and inspect the probe tip. Discard the tip if it has collected debris or moisture. Also check that the probe coupler tubes are clear and replace these if a blockage is noticed. Then refit the probe and try again. Problems of debris and middle ear fluid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

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

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

# 6 Testing


Ensure test preparations have been completed (see chapter 5).

If you have already completed tests on another patient, **Review** will appear as the centre option, to show that results are held in memory and can be printed (see chapter 8). Previous test results are deleted when you start a new test session from the Main screen.

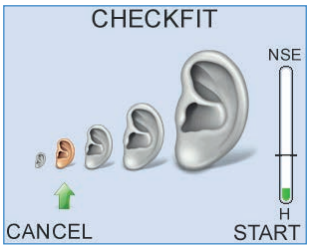
Choose your test ear by selecting **LEFT** or **RIGHT**.

After selecting the ear to be tested, the Otocheck LE will show the Checkfit display.

You will not be able to start a test if the Otocheck LE is connected to a PC or power supply.

# 6.1 Checkfit

## 6.1.1 Checkfit display




The **Checkfit** display appears after you select an ear for the next test.

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.

Excessive noise or a poor probe fit may mean that the test cannot be performed or that the quality of data collected may be too low for an accurate test result to be determined.

### 6.1.1.1 Fit Size Indicator

The **Checkfit** screen shows a Fit Size Indicator; this shows a series of ears of increasing size, indicating increasing ear canal volumes. The size of ear canal detected in Checkfit is indicated by an arrow.

During **Checkfit** the Otocheck LE repeatedly plays a click at a fixed level and records the sound level this click produces in the ear.

The sound level recorded depends on the fit of the probe and the size of the ear canal in which the probe is inserted.

Ear canal size increases from birth to adulthood. So, given a good probe fit the sound level recorded correlates with the age of the patient.

For example, if the arrow is below the smallest ear, this indicates that the sound level recorded is that which would be expected from a small ear canal. You would expect this if you were testing a baby.

Individual ear canals vary considerably in size, so the indication of canal size can only be used as an approximate guide to probe fit.

If the position of the **Fit Size Indicator** corresponds with the age of the patient and **Checkfit** is displayed on the top of the screen then the probe fit and the test conditions are adequate for testing. The Stimulus and Noise OK indicators (above the screen) should also be illuminated. Select **Start** to continue the test.

If there is a disagreement between the **Fit Size Indicator** and the ear canal size expected of your patient, then there may be a problem with the probe or the probe fit. For example: an indication of a large ear canal in a neonate may occur if the probe has fallen out of the ear or if the probe is blocked; an indication of a small ear canal in an adult may occur because of wax blocking the canal.

#### 6.1.1.2 Noise Level Indicator

A Noise Level Indicator (NSE) is shown on the right of the **Checkfit** screen. The red/green bar moves in response to changes in noise. For good testing conditions the bar should be green and remain consistently below the Noise Reject Level, which is represented by the horizontal line across the Noise Level Indicator. In poor testing conditions, when the noise level is above the Noise Reject Level, the bar will be red.

The letter below the indicator represents the noise reject threshold level. This can be altered using the up and down arrow keys.

Generally higher noise reject can give faster data collection but poorer quality data. The best noise reject setting depends on both test conditions and the strength of the emission being tested. Strong emissions may be detected in a noisy environment with a high noise reject threshold. Weak emissions may only be detected in a quiet environment with a low noise reject threshold.

#### 6.1.1.3 Checkfit condition information

When conditions are good for data collection, testing can start and **TE TEST** (or **DP TEST**) will be shown at the top of the screen. If conditions are not good then the following messages will appear:

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

**Noisy** appears if the noise level is consistently above the Noise Reject Level for a period of time.

**Ringing** is displayed when there is obvious oscillation within the **Stimulus Waveform** after the initial expected positive and negative peaks.

The following table describes what **Highlighted Message** will appear if more than one condition is met.

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

## 6.2 TE test (TEOAE model only)

During TEOAE testing the Otocheck LE plays a series of clicks into the ear and records the response. The OAE signal is very small and difficult to distinguish from the noise made by other sounds in the room and by the patient. The longer the Otocheck LE records for, the easier it is to distinguish the OAE signal from the noise. The Otocheck LE looks at the ratio of the OAE signal to the noise; this is known as the Signal to Noise Ratio or SNR. The Otocheck LE measures the SNR in a number of different frequency bands. The pass criteria is set in the **Configuration** area (see chapter 7 **Configuration**). The default pass criteria is an SNR of 6dB and a minimum signal of >-5dBSPL in at least two frequency bands.

It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

### 6.2.1 Stimulus adjustment


After selecting the ear to be tested and observing the Checkfit screen (see above), select **Start** to begin the test.

The Otocheck LE will then adjust the stimulus level in the patient's ear to the correct level (84dBpe) before beginning the test. The message **Adjusting…** is displayed while this is happening. Once the correct level has been reached, by default the Otocheck LE automatically begins the test.

The Otocheck LE may not be able to adjust the stimulus to the correct level in noisy environments, if the probe fit is poor or if the patient's ear canal is unusually large. If the correct stimulus level is not reached after 10 seconds then the message **Stim out of range** will be displayed. The user then has the option to **Continue** or **Cancel** the test.

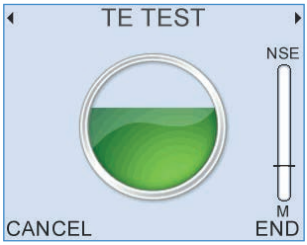
In these circumstances Otodynamics recommends that the test is cancelled. Efforts should then be made to improve the probe fit, check the probe coupler tubes are clear and improve the test environment. Probe checks should be conducted if the Otocheck LE fails to adjust correctly (see chapter 9 **Probe Checks**). If stimulus adjustment is still unsuccessful, continuing the test may provide useful results but it is likely that the stimulus level will be incorrect. This will affect the level of OAE recorded.

## 6.2.2 Test screens

During testing, **TE TEST** will be shown at the top of the screen. These words will repeatedly fade and then darken to show that the test is currently running. The test screen display depends upon the display option set from the **Configuration** menu (see chapter 7 **Configuration**).

Alternative test screens can be displayed by pressing the left or right arrow keys during testing. The test screen selection is retained for the next test; if you switch to your favoured screen in one test, that will be the default screen for the next test.

### 6.2.2.1 SNR circle




A single circle display represents progress towards meeting the pass criteria. The level of green displayed within the circle represents the strength of the OAE detected compared with the level of noise recorded (the SNR). A fuller circle indicates that the SNR and signal level are closer to the pass criteria.

### 6.2.2.2 Noise level indicator

A noise level indicator is shown on the right of screen. The shaded bar moves in response to changes in noise and is high when there is excessive ambient noise or if the probe is fitted poorly in an ear. The bar displayed on screen will be green if it is acceptable i.e. below the reject value, or red if it unacceptable i.e. higher than the reject value.

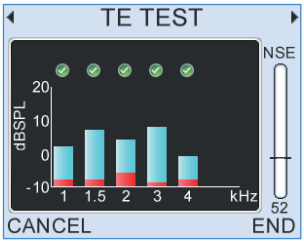
The letter below the indicator represents the noise reject threshold level. This can be altered using the up and down arrow keys between High (H), Medium (M) and Low (L). Noise rejection threshold can also be fixed at one level in the **Config** area (see chapter 7).

The noise level indicator allows continuous monitoring of the noise level during a test.

### 6.2.2.3 Test condition information

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. If test conditions are not optimum, a highlighted message will appear, indicating the problem.

### 6.2.2.4 Signal and noise histogram




The screen displays test data graphically on the screen in ½ octave bands: 1k, 1.5k, 2k, 3k and 4kHz. The blue section of each band represents the OAE signal level within each band and the red section represents the noise level at that frequency. A tick/checkmark will appear above a bar if the band has met its pass criteria. Please refer to **Configuration** (chapter 7) for further information on the band Stop criteria.

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

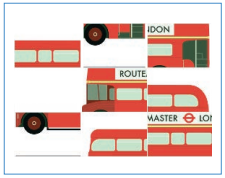
If no data has been collected, then a histogram will not be drawn and diamond symbols will be shown instead.

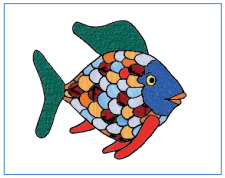
### 6.2.2.5 Infant distraction screens

Animated distraction screens are available during a test by pressing the left and right arrow keys.

Once displayed, different distraction themes can be accessed using the up and down arrow keys. See section 6.4 **Infant distraction screens** for more details.





## 6.2.3 Test stop reasons

There are four possible ways in which a test can stop: **AutoStop**, **Maximum NLo Sweeps**, **Test Timeout** and **Manual End**. When the test stops the data collected is assessed and a result given as a pop-up graphic and then written highlighted at the top of the test screen. The Otocheck LE will beep once if a test has stopped with a **TEOAE Pass** result and will beep twice if the test has stopped with any other result.

### 6.2.3.1 AutoStop

If the test data collected meets the set pass criteria then the test will AutoStop and a large checkmark will be displayed.

### 6.2.3.2 Maximum number of NLo sweeps

If a test has not met the set pass criteria it will stop when the **Maximum NLo Sweeps** (NLo sweeps are recordings made with a noise level below the rejection threshold) is reached. This is a representation of the amount of good data sweeps required before a **No valid OAE** result can be given.

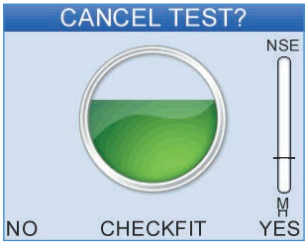
### 6.2.3.3 Test timeout

If a test has not met the set pass criteria and the noise is consistently above the **Noise Reject Threshold Level** so that the **Maximum NLo Sweeps** cannot be achieved, then the test will stop after 120 seconds, regardless of the amount of good data collected. This is to prevent overexposure of stimulus in an ear and to limit the test time to allow for reassessment of the ambient noise and of probe fit before a retest.

### 6.2.3.4 Manual end

Selecting **End** at any time will stop the test.

### 6.2.3.5 Pausing and cancelling the test




You may wish to pause a test for instance during periods of noise. When the test is paused, it is possible to cancel the test and discard the data. Select **Cancel** to pause the test. Select **Yes** to end the test and discard the data, **No** to resume the test and **Checkfit** to restart the test at the Checkfit stage.

6.2.4

## Test results

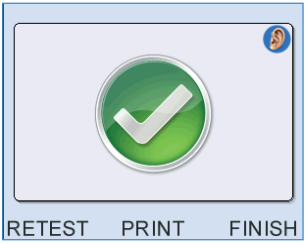
The following table lists all possible test results with the associated result graphic and gives an explanation of the circumstances under which each result would be shown.

| Test Result | Description |
|---|---|
| TEOAE Pass  | The data collected has met the set pass criteria. The optimum test setting will depend on your application (see section 7.5 **Test setup**). |
| *Note:* | *The following results will only occur if a TEOAE Pass is not obtained* |
| No Valid OAE  | The data collected has not met the set pass criteria and the test conditions were acceptable |
| Noisy  | The noisy data collected is three times greater than the low noise data collected |
| Poor Probe Fit  | Probe movement has been detected |
| Too Few Bands  | Insufficient bands meet their pass criteria |
| Stopped Too Soon  | The test was ended manually before the required minimum amount of data has been collected |

## 6.2.5 Test review

When the test has ended the **Result** screen will be shown, as described in 6.2.4.

A large checkmark in the display indicates a pass.

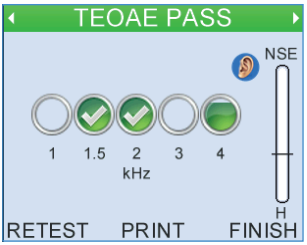


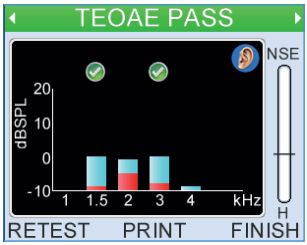

If more details of the test are required, these can be seen on the **Review** screens. Use the left or right arrow keys to access the review screens from the Result screen.

From the **Test Result** screen or any **Review** screen the user may **Retest** the current patient, **Print** the result of the test just completed, or **Finish** the current patient session and return to the Main Screen. (See chapter 8 for more information on printing).

### 6.2.5.1 TEOAE test result details

Example review screens for a Pass on the TEOAE model, configured for




**Any 2 bands**, are shown below.

Note:

The default TEOAE configuration mode is **Narrow**. In the Narrow mode individual 'frequency' circles are NOT shown. See 7.5.1 for TEOAE configuration options.

These screens are only available on the Otocheck LE immediately after a test has ended.

If your Otocheck LE has the Print option, detailed results of up to four previous tests from the same session can be printed from the Main screen.

## 6.2.6 Further tests on the same patient (Retest)

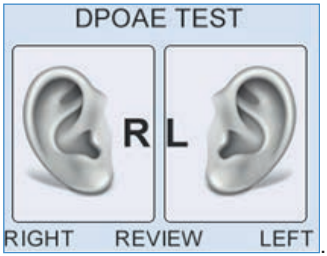
After you have completed a test you may want to repeat the test or move to the other ear.

If you want to start another test on the same patient, select **Retest** on the **Result** screen or on the **Review** screen. This will take you to the **Retest** screen.

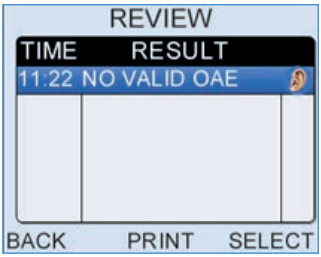

Select the ear to be tested and proceed as described above for **Test**.

If you have completed your testing on this patient, select **Finish** from the **Result** screen or the **Review** screen.

This will take you to the Main screen where you can print the last 4 tests performed by selecting the **Review** button,




and selecting PRINT on the test you want to print (see chapter 8).



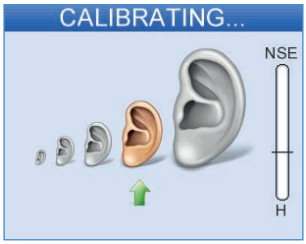

The memory of a previous patient test session is deleted when a new session is started from the Main screen or when the device is switched off

## 6.3 DP Test (DPOAE model only)

During a DPOAE test the Otocheck LE plays pairs of tones at different frequencies into the ear and records the response. The OAE signal is very small and difficult to distinguish from the noise made by other sounds in the room and by the patient. The longer the Otocheck LE records for, the easier it is to distinguish the OAE signal from the noise. The Otocheck LE looks at the ratio of the OAE signal to the noise; this is known as the Signal to Noise Ratio or SNR. The Otocheck LE measures the SNR in a number of different frequencies. The pass criteria is set in the **Configuration** area (see chapter 7 **Configuration**). The default pass criteria is an SNR of 6dB and a minimum signal of >-5dBSPL in at least three frequency bands.

It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

### 6.3.1 DP stimulus calibration




After selecting the ear to be tested and observing the Checkfit screen (see above), select **Start** to begin the test. The Otocheck LE will calibrate the levels of the stimulus tones which are to be used in the test. This is necessary to account for the acoustic properties of individual patients' ear

canals. If the required levels cannot be reached then the Otocheck LE will display the message **Unable to calibrate. Check probe fit** and return to the checkfit screen.

If calibration fails, check the probe fit and check that the probe coupler tubes are clear. Excessive noise may inhibit calibration, so ensure environmental noise levels are low. Make sure a DP (UGD - grey) probe is connected to the Otocheck LE and not a TE (UGS - red) probe.

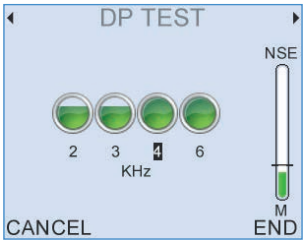
If calibration continues to fail, run **Probe Checks** (see chapter 9) to test the probe and Otocheck LE performance.

Following **Stimulus Calibration**, the OAE recording begins and data is collected.

## 6.3.2 Test screens

During testing, **DP TEST** will be shown at the top of the screen. These words will repeatedly fade and then darken to show that the test is currently running. Alternative test screens can be displayed by pressing the left or right arrow keys during testing. The test screen selection is retained for the next test; if you switch to your favoured screen in one test, that will be the default screen for the next test.

### 6.3.2.1 SNR circles




The Otocheck LE looks at the ratio of the OAE signal to the noise; this is known as the Signal to Noise Ratio or SNR. The Otocheck LE measures the SNR in a number of different frequencies.

The display shows a series of small circles, each representing the SNR recorded at a particular DP frequency. The numbers below the circles indicate the F2 frequency in kHz.

### 6.3.2.2 Noise level indicator

A noise level indicator is shown on the right of screen. The shaded bar moves in response to changes in noise and is high when there is excessive ambient noise or if the probe is fitted poorly in an ear. The bar displayed on screen will be green if it is acceptable i.e. below the reject value, or red if it unacceptable i.e. higher than the reject value.

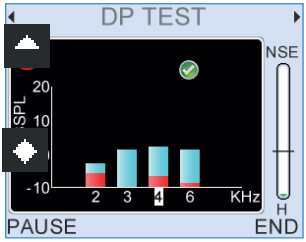
The letter below the indicator represents the noise reject threshold level. This can be altered using the up and down arrow keys between High (H), Medium (M) and Low (L). Noise rejection threshold can also be fixed at one level in the **Config** area (see chapter 7).

The noise level indicator allows continuous monitoring of the noise level during a test.

### 6.3.2.3 Test condition information

When conditions are good for data collection **DP 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.

### 6.3.2.4 Signal and noise histogram




The screen displays test data graphically on the screen in ½ octave bands: 2k, 3k, 4kHz and 6kHz. The clear section of each band represents the OAE signal level within each band and the shaded section represents the noise level at that frequency. A tick/checkmark will appear above a bar if the band has met its pass criteria. Please refer to **Configuration** (chapter 7) for further information on the band Stop criteria.

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

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

### 6.3.2.5 Infant distraction screens

Animated distraction screens are available during a test by pressing the left and right arrow keys.

Once displayed, different distraction themes can be accessed using the up and down arrow keys. See section 6.4 **Infant distraction screens** for more details.

## 6.3.3 Test stop reasons

There are three possible ways in which a test can stop: **AutoStop**, **Test Timeout** and **Manual End**. When the test stops the data collected is assessed and a result given as a pop-up graphic and then written highlighted at the top of the test screen. The Otocheck LE will beep once if a test has stopped with a **DPOAE Pass** result and will beep twice if the test has stopped with any other result.

### 6.3.3.1 AutoStop

If the test data collected meets the set pass criteria then the test will AutoStop and a large checkmark will be displayed.

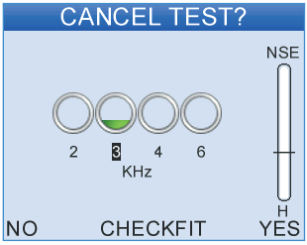
### 6.3.3.2 Test timeout

If a test has not met the set pass criteria then the test will stop after 60 seconds.

### 6.3.3.3 Manual end

Selecting **End** at any time will stop the test.

### 6.3.3.4 Pausing and cancelling the test




You may wish to pause a test for instance during periods of noise. When the test is paused, it is possible to cancel the test and discard the data. Select **Cancel** to pause the test. Select **Yes** to end the test and discard the data, **No** to resume the test and **Checkfit** to restart the test at the Checkfit stage.

6.3.4

## Test results

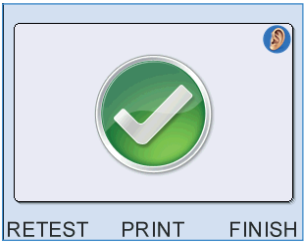
The following table lists all possible test results with the associated result graphic and gives an explanation of the circumstances under which each result would be shown.

| Test Result | Description |
|---|---|
| DPOAE Pass  | The data collected has met the set pass criteria. The optimum test setting will depend on your application (see section 7.7 **Test setup**) |
| *Note:* | *The following results will only occur if a DPOAE Pass is not obtained* |
| No Valid OAE  | The data collected has not met the set pass criteria and the test conditions were acceptable |
| Noisy  | The noisy data collected is three times greater than the low noise data collected |
| Poor Probe Fit  | Probe fit movement is detected that results in less than 85% of stimuli reaching calibration levels |
| Too Few Bands  | Insufficient bands meet their pass criteria |
| Stopped Too Soon  | The test has been ended manually before the required minimum amount of data has been collected |

### 6.3.5 Test review

When the test has ended the **Result** screen will be shown, as described in 6.2.4 and 6.3.4.

A large checkmark in the display indicates a pass.



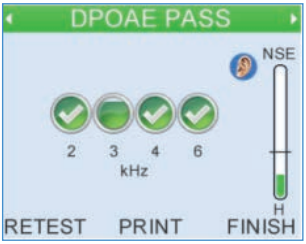

If more details of the test are required, these can be seen on the **Review** screens. Use the left or right arrow keys to access the review screens from the Result screen.

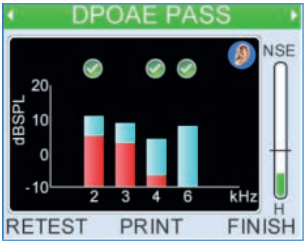
From the **Test Result** screen or any **Review** screen the user may **Retest** the current patient, **Print** the result of the test just completed, or **Finish** the current patient session and return to the Main Screen. (See chapter 8 for more information on printing).

#### 6.3.5.1 DPOAE test result details

Example review screens for a 3 band Pass on the DPOAE model are shown below. The default configuration for DPOAE is **Any 3 bands**.

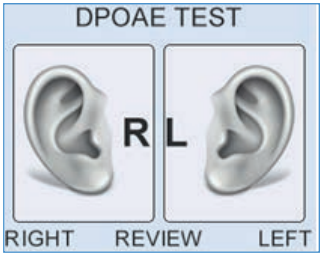
See section 7.7 for DPOAE configuration options.



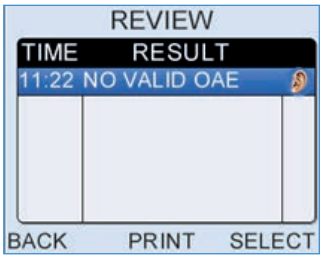




These screens are only available on the Otocheck LE immediately after a test has ended.

If your Otocheck LE has the Print option, detailed results of up to four previous tests from the same session can be printed by selecting the REVIEW button from the main menu,




and selecting PRINT on the test you wish to print (see chapter 8).



## 6.3.6 Further tests on the same patient (Retest)

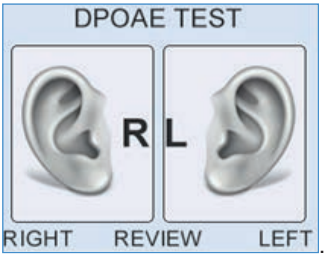
After you have completed a test you may want to repeat the test or move to the other ear.

If you want to start another test on the same patient, select **Retest** on the **Result** screen or on the **Review** screen. This will take you to the **Retest** screen.

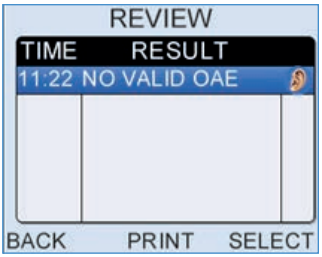

Select the ear to be tested and proceed as described above for **Test**.

If you have completed your testing on this patient, select **Finish** from the **Result** screen or the **Review** screen.

his will take you to the Main screen where you can print the last 4 tests performed by selecting the **Review** button,




and selecting PRINT on the test you want to print (see chapter 8).



The memory of a previous patient test session is deleted when a new session is started from the Main screen or when the device is switched off

## 6.4 Infant distraction screens

Animated infant distraction screens are available during the test. After the test has started, press the left or right arrow key to access the distraction screens.

These screens are designed to encourage young patients to keep still and quiet during OAE testing. They show a simple drawing that becomes more colourful if they are quiet. The quieter they are the more quickly the picture 'story' progresses. If they become noisy then the colour in the picture starts to fade. A number of alternative images are available. Choose between different images by pressing the up and down arrow keys. Different images will appeal to different ages.

The distraction screen may be locked so that the arrow keys do not function. The Otocheck LE can then be given to a child to view without the risk of them stopping the test.

Press the key to **LOCK** the screen. Unlock is child proofed. To unlock you must press the **UNLOCK** key and the up arrow simultaneously.

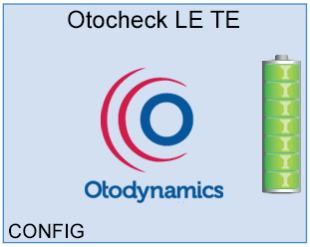
When the test is completed, the result screen will be shown as normal - but if locked, the screen will remain locked.

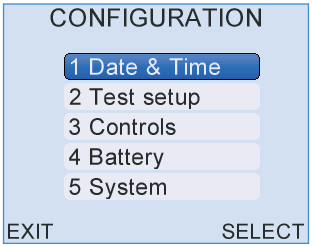
To unlock the result screen press the **UNLOCK** and up arrow key simultaneously.

The Otocheck LE will remember the last choice of distraction screen, and will present that screen first if you select a distraction screen for the next test.

# 7 Configuration


## 7.1 Configuration menu




The **Configuration** menu can be accessed by selecting **Config** on the logo screen after switching on.

Select **Date & Time** to set or check the date and time set on the Otocheck.

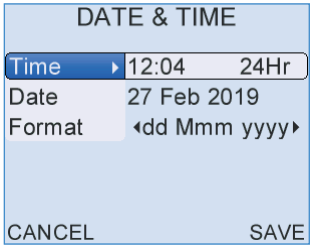
Select **Test Setup** to change test settings, including pass criteria.

Select **Controls** for display and volume settings.

Select **Battery** for battery information and conditioning.

Select **System Info** for information on your Otocheck.

## 7.2 Date & Time




Set the Date and Time stored on your Otocheck. These details will be included in the printout of test results.

When the **Date** or **Time** field is highlighted press the right arrow key to access the pop-up table. Use the left and right arrow keys to jump between the Day/Month/Year and the up and down arrow keys to select the required date. Press **Insert** to keep your changes or **Cancel** to discard them.

The date **Format** can be changed between dd.Mmm.yyyy and mm.dd.yyyy or dd.mm.yyyy using the left and right arrow keys.

Select **Save** to set the current date and time settings or **Cancel** to discard changes.

## 7.3 Selecting the appropriate stimulus level

Otodynamics instruments differ in the facility to change stimulus levels.

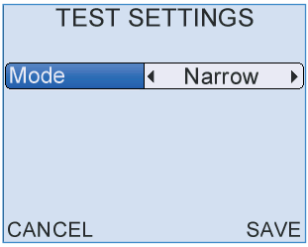
Where the stimulus is pre-set and unchangeable on a screening instrument, the stimulus level will have been chosen on the basis of independent trials reported in the literature which reliably alerts to the possibility of a mild loss.

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

# 7.4 Selecting levels for TEOAE screening

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

# 7.5 Test setup (TEOAE model)




Use the arrow keys to navigate and choose between the setup options (described below).

Select **Save** to apply the settings changes you have made and return to the **Configuration** screen.

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

## 7.5.1 Mode

Mode sets the pass criteria for screening.

The **Narrow** setting requires a signal to noise ratio (SNR) of 6dB over the 841-4757Hz frequency range in order to meet the pass criteria. However this setting uses a filter of 1.6-3.2kHz and a stimulus response window 4-10ms to reduce the impact of environmental noise on the recording. This makes this setting particularly appropriate for screening in a noisy environment.

The **Any 2 Bands**, **Any 3 Bands** and **Any 4 Bands** settings require a 6dB SNR and a minimum signal level of -5dBSPL in each of the stated number of half octave frequency bands to meet the pass criteria.

All test modes require a minimum overall (wide band) signal level of 0dBSPL and that the amount of data collected has reached a minimum level to met the pass criteria.

The fixed and configurable test parameters are summarised in the tables below:

**Configurable test parameters**

| Name | Any 2 | Any 3 | Any 4 | Narrow |
|---|---|---|---|---|
| **Min pass bands** | 2 | 3 | 4 | None |
| **Min total (wide band) SNR** | None | None | None | 6dB |
| **Min SNR per pass band** | 6dB | 6dB | 6dB | None |
| **Filter (Hz)** | 1189-4757 | 1189-4757 | 1189-4757 | 1600-3200 |
| **Response Window (ms)** | 2-5-12.5 | 2-5-12.5 | 2-5-12.5 | 4-10 |

The default setting is **Narrow**. However, it is recommended that you carefully choose pass criteria which suit your particular screening program.

**Fixed test parameters**

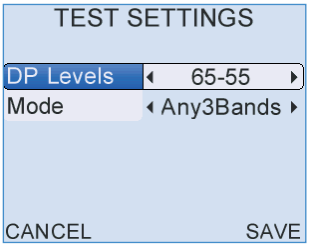
| | |
|---|---|
| **Min sweeps (NLo)** | 30 |
| **Min total (wide band) OAE signal** | 0dBSPL |
| **Min band signal** | -5dBSPL |
| **Stimulus level** | 84 +/- 1dB pe |
| **Max test time** | 120 seconds |
| **Max low noise (NLo) sweeps averaged** | 260 sweeps of 16 stimulus presentations |
| **Ring reject** | -20dB |
| Max ratio of stimulus peak to the level 3ms after stimulus presentation. Stimulus ring can hamper accurate OAE measurement | |
| **Input filter** | 1189Hz - 4757Hz or 1600-3200Hz (narrow mode only) |
| The attenuation at these frequencies is 3dB. Attenuation increases by 80dB/decade below and 40dB/decade above these frequencies | |

## 7.6 Selecting levels for DPOAE screening

- For DPOAEs L1, L2 levels of 65/55dBSPL is most commonly used for hearing screening. Many studies have confirmed the appropriateness of these levels.
- Gorga et al found that L1/L2 stimulus levels of 65/55dBSPL “resulted in the greatest separation between normal and impaired ears. (See “The use of cumulative distributions to determine critical values and levels of confidence for clinical distortion product otoacoustic emission measurements” Michael P. Gorga, Lisa Stover, and Stephen T. Neely, in The Journal of the Acoustical Society of America 100, 968 (1996).
- The appropriateness of stimulus levels 65/55 was confirmed by Stever et al who also noted that levels of stimulus f2 (L2) between 50 and 60dBSPL were “optimum for separating normal hearing from hearing impaired ears” provided that L1 was made 10dB higher than L2. That corresponds to settings of 60/50, 65/55 and 70/60dBSPL. (See “Toward optimizing the clinical utility of distortion product otoacoustic emission measurements”, The Journal of the Acoustical Society of America 100, 956 (1996); Lisa Stover, Michael P. Gorga, and Stephen T. Neely.
- Stimulus level adjustments are provided on some instruments so that locally preferred levels can be used.

DPOAE stimulus levels of 70dBSP and above (e.g. 70/70dBSPL) should NOT be used for screening as it will be insensitive to mild losses. These higher levels ARE useful for clinical investigations, demonstration and training.

## 7.7 Test setup (DPOAE model)




Use the arrow keys to navigate and choose between the setup options (described below).

Select **Save** to apply the settings changes you have made and return to the **Configuration** screen.

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

### 7.7.1 DP levels

This sets the target stimulus levels for the tones L1 and L2 that are represented during the test. The options available are:

60-50
60-55
65-50
65-55
65-60
70-70

Higher intensities give a less sensitive hearing screen but may be necessary to record a response in older patients.

### 7.7.2 Mode

**Mode** sets the pass criteria for screening.

The **Any 2 Bands**, **Any 3 Bands** and **Any 4 Bands** settings require a 6dB SNR and a minimum signal level of -5dBSPL in each of the stated number of half octave frequency bands to meet the pass criteria.

The default setting is **Any 3 Bands**. However, it is recommended that pass criteria is carefully chosen to suit the particular OAE testing programme.

**Fixed test parameters**

| | |
|---|---|
| **Min band signal** | -5dBSPL |
| **Max test time** | 60s |
| **Min data collected** | 0.64s per frequency |

## 7.8 Controls


### 7.8.1 Volume

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

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

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

### 7.8.2 Brightness

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

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

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

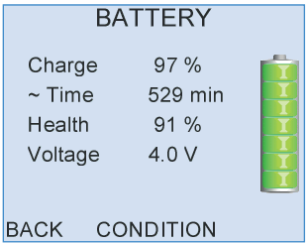
### 7.8.3 Backlight

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

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

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

# 7.9 Battery




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

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

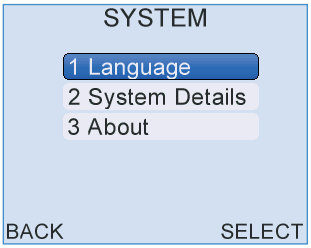
| Segments Displayed | Battery Power (%) |
|---|---|
| 7 | 95 - 100 |
| 6 | 75 - 94 |
| 5 | 55 - 74 |
| 4 | 40 - 54 |
| 3 | 30 - 39 |
| 2 | 20 - 29 |
| 1 | 10 - 19 |
| 0 | < 10 |

The **Battery Voltage** and **Health** values are provided as a diagnostic tool at the bottom of the screen.

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

Select **condition** to discharge the Otocheck LE battery. See chapter 13 **Otocheck LE power** for more information.

# 7.10 System




The **System** screen provides information on the Otocheck LE.

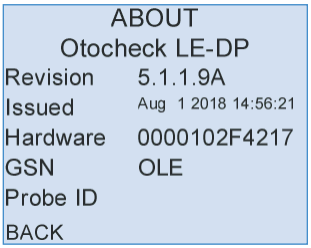
## 7.10.1 Language

Select **Language** to change the language of text messages on the Otocheck LE.

## 7.10.2 System Details

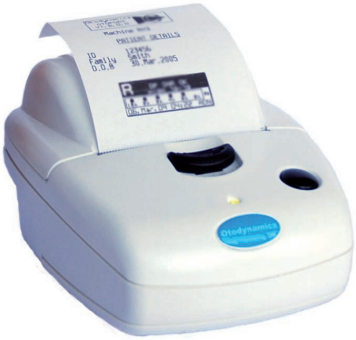
**System Details** displays information for Otodynamics engineers. (See chapter 14.3 for further details).

## 7.10.3 About




The **About** screen provides information relating to the Otocheck LE's identification and mode of operation. The firmware revision number and issue 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.

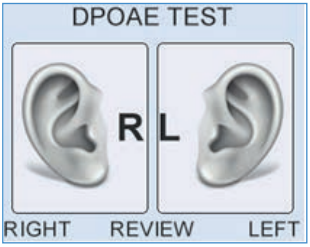
# 8 Printing



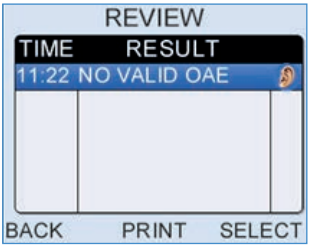
## 8.1 When can you print?

The option to print the last completed test is available from the **Results** screen shown at the end of each test.

The option to print up to four tests on the same patient is only available after the test session with the current patient is finished. From the main menu Select the **REVIEW** button,



and selecting **PRINT** on the test you wish to print (see chapter 8).




When the last test is completed on the patient, select **Finish** and go to the Main screen.

Notes:

The last four test results of the current session are held in memory. If more than four tests are made in a session, only the four most recent test results are kept.

Saved test records from the previous test session (i.e. the previous patient) are deleted when a new test session is begun from the Main screen, or if the Otocheck LE is switched off.

Only Otocheck LEs supplied with the Otodynamics mini printer and firmware with printing enabled can print test results.

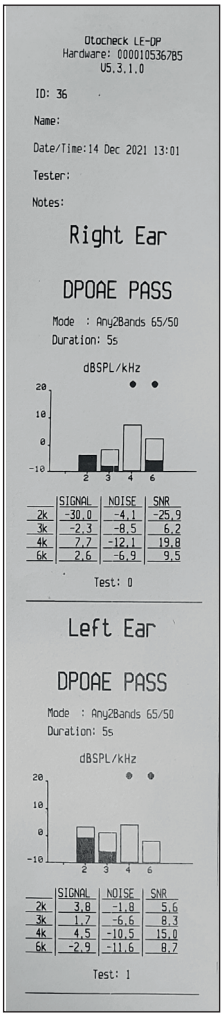
Contact your dealer to add printing to your Otocheck LE.

## 8.1.1 Sample prints

Each print begins with a form which allows the user to manually add details of the patient, tester and other information.

A test sequence number is included at the bottom of the print.

The option to print up to four tests on the same patient is only available after the test session with the current patient is finished. From the main menu Select the **REVIEW** button, and selecting **PRINT** on the test you wish to print (see chapter 8).


Otocheck LE-DP
Hardware: 0000010536785
V5.3.1.0

ID: 36

Name:

Date/Time:14 Dec 2021 13:01

Tester:

Notes:

Right Ear

DPOAE PASS

Mode : Any2Bands 65/50
Duration: 5s

dBSPL/kHz

| | SIGNAL | NOISE | SNR |
|---|---|---|---|
| 2k | -30.0 | -4.1 | -25.9 |
| 3k | -2.3 | -8.5 | 6.2 |
| 4k | 7.7 | -12.1 | 19.8 |
| 6k | 2.6 | -6.9 | 9.5 |

Test: 0

Left Ear

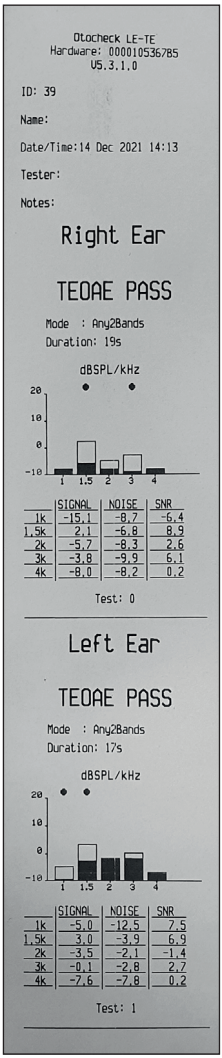
DPOAE PASS

Mode : Any2Bands 65/50
Duration: 5s

dBSPL/kHz

| | SIGNAL | NOISE | SNR |
|---|---|---|---|
| 2k | 3.8 | -1.8 | 5.6 |
| 3k | 1.7 | -6.6 | 8.3 |
| 4k | 4.5 | -10.5 | 15.0 |
| 6k | -2.9 | -11.6 | 8.7 |

Test: 1


Otocheck LE-TE
Hardware: 0000010536785
V5.3.1.0

ID: 39

Name:

Date/Time:14 Dec 2021 14:13

Tester:

Notes:

Right Ear

TEOAE PASS

Mode : Any2Bands
Duration: 19s

dBSPL/kHz

| | SIGNAL | NOISE | SNR |
|---|---|---|---|
| 1k | -15.1 | -8.7 | -6.4 |
| 1.5k | 2.1 | -6.8 | 8.9 |
| 2k | -5.7 | -8.3 | 2.6 |
| 3k | -3.8 | -9.9 | 6.1 |
| 4k | -8.0 | -8.2 | 0.2 |

Test: 0

Left Ear

TEOAE PASS

Mode : Any2Bands
Duration: 17s

dBSPL/kHz

| | SIGNAL | NOISE | SNR |
|---|---|---|---|
| 1k | -5.0 | -12.5 | 7.5 |
| 1.5k | 3.0 | -3.9 | 6.9 |
| 2k | -3.5 | -2.1 | -1.4 |
| 3k | -0.1 | -2.8 | 2.7 |
| 4k | -7.6 | -7.8 | 0.2 |

Test: 1

## 8.2 The Otodynamics mini printer

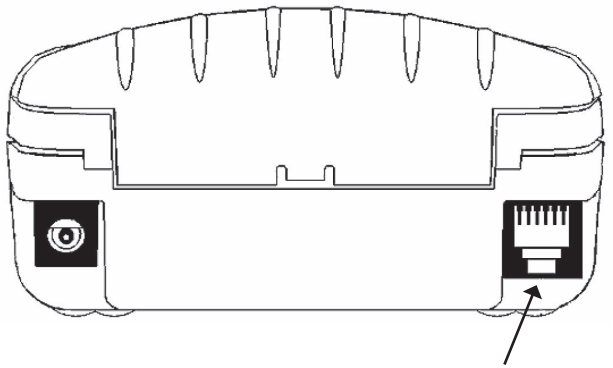
Otocheck LE is available with or without the Otodynamics mini printer. The printer is used to create a paper record of the OAE test results recorded on the Otocheck LE. The Otocheck LE either communicates with the printer using **Bluetooth**® wireless technology or with a custom printer cable.

Note:

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

## 8.3 The printing process

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



*Printer cable socket*

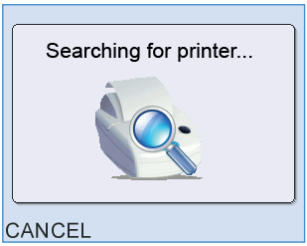
The wireless printing method has a range of up to 10m in direct line of sight. It is recommended that the printing distance is reduced to 5m to help ensure robust communication. Remain within this range for the duration of the printout. Printouts will not complete if wireless communication is lost.

Note:

When using multiple Otocheck LE units with wireless connection to a single printer, the print session on the current Otocheck LE must be closed before printing on another Otocheck LE can begin. Print sessions are closed when the Otocheck LE screen shows the main menu, or when the Otocheck LE or the printer has been switched off. If printing is attempted while a previous session is still open, the **Printer not found!** screen will be displayed.

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 30 minutes of inactivity. If it is connected to mains power, the printer will remain on indefinitely.

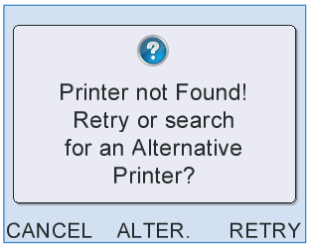
When a print is initiated, the Otocheck LE will establish communication with the printer. The screen **Searching for Printer** will be displayed.




The printout will then commence. Once the printout is completed the screen from which the print was initiated will be displayed.

If there is a problem connecting to the printer using the wired method, the message **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.

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 printer (ALTER) or retry.




To retry the print, ensure the printer is switched on and is within range (5m). Then select **Retry**. If printing wirelessly and you have an alternative printer available, select **Alter**. and the Otocheck LE will connect to this printer.

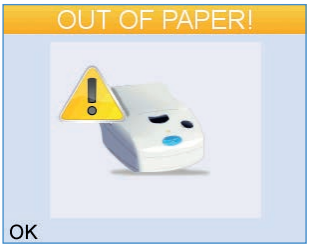
To cancel the printout, select **Cancel**.

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.

## 8.4 Printer fault detection

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

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




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

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

## 8.5 Printer light summary

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

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

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

**Flashing green/orange** - Battery is being charged

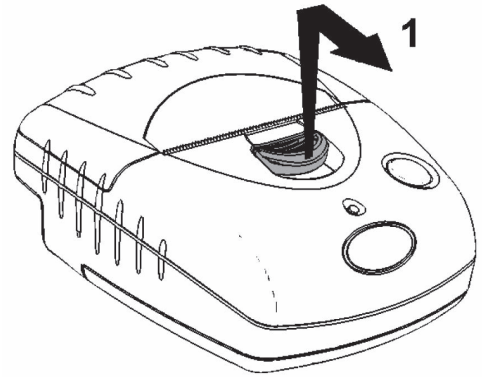
**Red** - Low battery or other problem

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

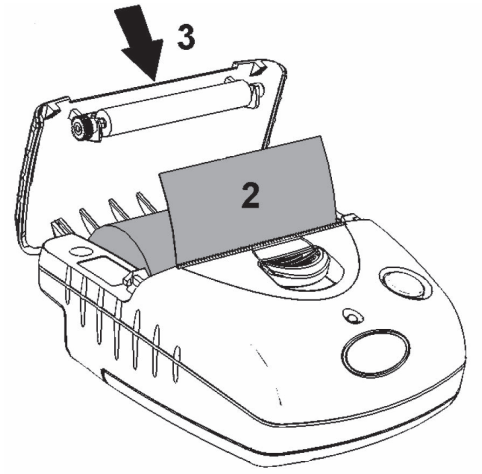
## 8.6 Paper

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

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




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

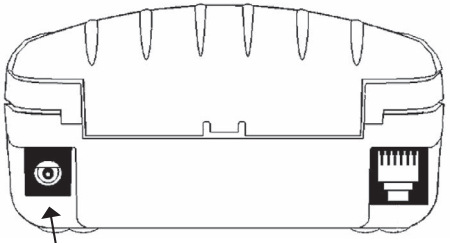


After loading, check that the paper advances properly using the paper feed function, and tear off any excess by pulling the paper sharply towards you across the serrated tear bar. In the event of a jam or other paper loading problem, release the lid and straighten the paper before closing again.

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

## 8.7 Charging the printer


To charge the printer, plug the charger into a mains outlet socket and insert the charger jack plug into the rear of the printer. The light on the printer will flash green/orange to show the printer is on charge. The red charger light will also illuminate. A full charge will take approximately 15 hours.



*Charger jack plug socket*

The printer can be used as normal whilst charging.

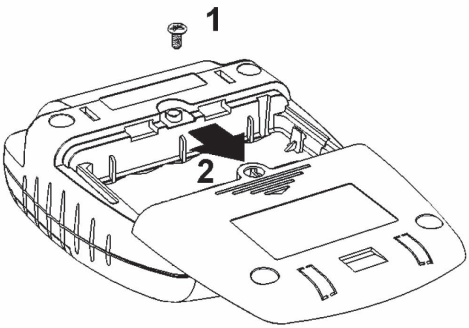
Once fully charged, the printer has enough power for around 10 hours standby use. The batteries should provide enough power to print several rolls of paper. The printer light will flash green/red when the batteries are low.

Note:

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

8.8

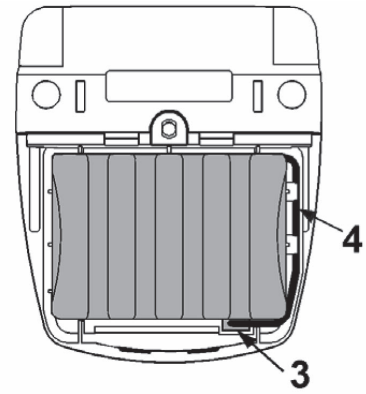
# Changing the battery


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

To change the battery pack:

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




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

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

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

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

Slide back the battery compartment cover and replace the screw.

## Important Note:

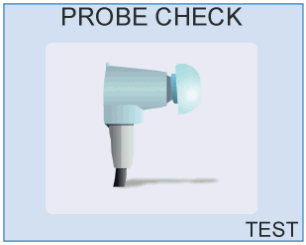
Only charge the printer if it contains an approved battery pack, supplied by your dealer or Otodynamics Ltd.

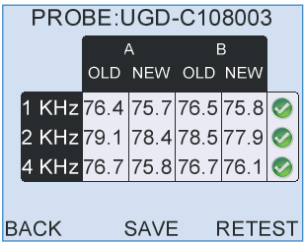
# 9 Probe checks

Damage or malfunction of the Otocheck LE or the probe can lead to errors in OAE recording. To ensure that any faults are detected before they lead to faulty data collection, the following tests can be performed.

Probe checks should be carried out on a weekly basis.

## 9.1 Probe test




**Probe Test** is accessed by pressing the left or right arrow key from the main screen (the first screen shown after the Otocheck is turned on. See section 4.3 **Main screen**).

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

Note:

---

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

On selection of **Probe Test** the message **Place Probe into Otodynamics Test Cavity. Press OK to begin test.** will be displayed.

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


Inserting the probe head over one of the screws may result in incorrect test results due to leakage. If the probe is not upright in the cavity, it may give incorrect results.

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

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

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

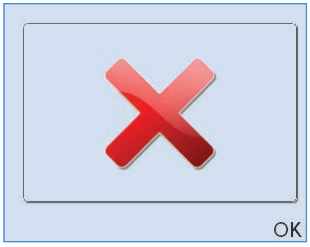
## 9.1.1 Results

The possible results of the test are:

### 9.1.1.1 Pass

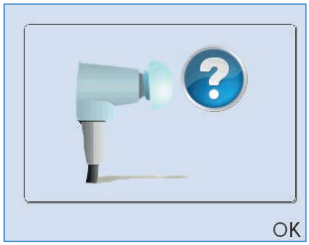

The levels recorded at all frequencies are within the absolute range and within ± 3dB of the probe specific values.

### 9.1.1.2 Fail




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

### 9.1.1.3 Query




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

### 9.1.1.4 Noisy

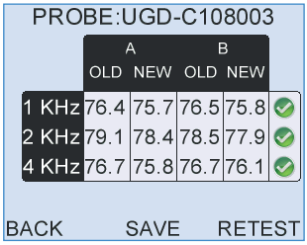

There was significant noise during the calibration test. This noise may have influence the levels recorded so a **Retest** should be performed.

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

### 9.1.1.5 Details

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

Results are given for each frequency tested:




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

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

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

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

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

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

Select **Back** to exit the **Probe Test** screen and return to the **Configuration** screen.

## 9.2 Cavity test

Due to mechanical or electrical failure or a faulty probe, the system may itself produce signals during a test that have similar characteristics to an OAE response. The test cavity will not produce any OAE signal so any signal produced in the cavity is the result of a fault.

By performing an OAE test in a cavity rather than an ear it is possible to determine whether signal responses recorded in the ear are being generated by a fault.

Follow the instructions in 9.1 for inserting the probe into the test cavity.

Start a test on the Otocheck LE as you would for an ordinary ear (see chapter 6 **Testing**).

Follow the **Checkfit** and **Test** screen sequences until the test stops. In a cavity the Checkfit screen should indicate a large cavity volume.

If the result **No Valid OAE** is displayed and the **Circles** are no more than 25 percent full when the test stops, the cavity test has passed.

If the result **Stopped Too Soon**, **Too Noisy** or **Poor Probe Fit** is achieved, 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 either **No Valid OAE** or **Pass** result is given.

If **Pass** is shown at the end of the test or if the circle for any band is more than ¼ filled, save and retest making sure the ear piece has been firmly pressed into the test cavity.

Check the top of the test cavity and ensure it is securely attached to the clear plastic part of the test cavity. If the resources are available, repeat the test with a different test cavity and then with a different probe. This will identify which component is responsible for the problem. Contact your dealer or Otodynamics for further advice.

Note:

---

If a signal is detected in the test cavity, ensure that five successful cavity tests are performed on the Otocheck LE before returning it to use. Refit the probe in the cavity between each test.

## 9.3 Occlusion test

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

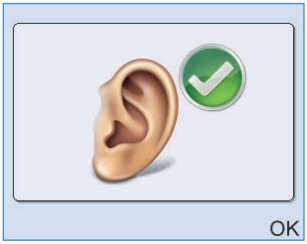
To occlude the probe place a finger firmly over the end of the coupler tubes to block sound from being omitted from the ear piece and to prevent ambient noise from being read by the microphone. Then start a test as normal.

All the cavity size indicators in **Checkfit** should be filled, indicating a very low sound level and **Check probe fit** should be displayed.

If so, the **Occlusion Test** has passed.

If not, check that the coupler is fitted to the probe correctly, making sure the coupler tube ends are fully occluded by a finger and that the environmental noise level is low. It may be necessary to change the coupler tubes. Repeat the test if necessary.

## 9.4 Real ear test




Testing with a known good ear allows for test data to be checked for reproducibility.

A test may then be performed using the standard test procedure on the known good ear. This result may then be compared with previous results from the same ear. Real ear tests should be performed in similar test environments to be comparable.

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

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

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

If you are still unable to achieve a **Real Ear OK** result then, if the resources are available try recording with a different probe or with a different Otocheck LE. If the problem persists, contact your dealer or Otodynamics.

# 10 Probe, tips and accessories

## 10.1 Probe and service accessories

Your kit will include either a TEOAE or DPOAE probe, with appropriate accessories and sample probe tips, depending on the Otocheck LE model purchased.

## 10.2 Probe cable clip

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

### 10.2.1 Using the cable clip

Push the plunger to open the cable grip.

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

Open the crocodile clothing clip.

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

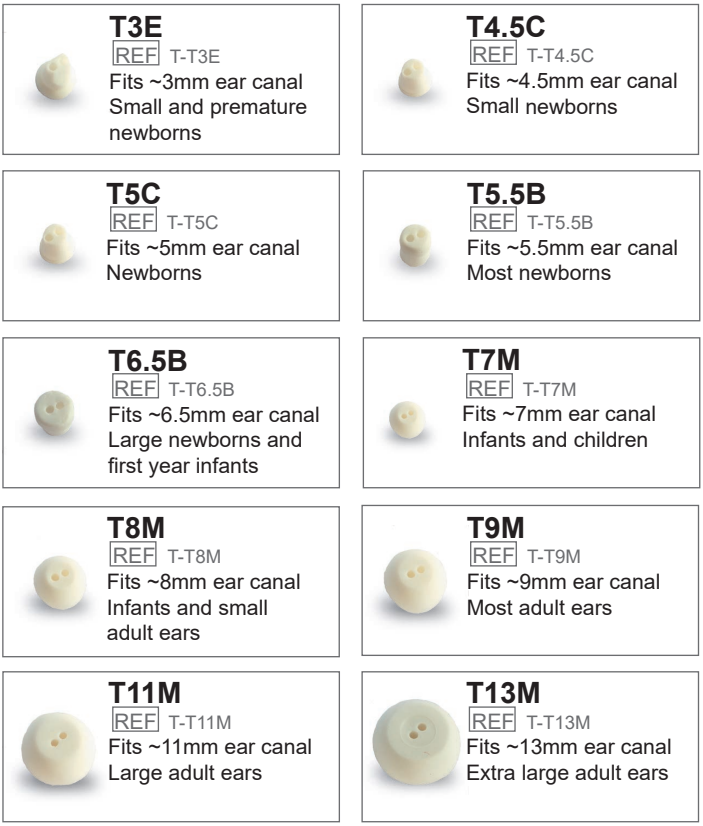
If the cable slips through the grip, turn the head to grip the cable.

Use a sterile wipe to clean the clip.

# 10.3 Probe tips

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

## 10.3.1 TEOAE probe tips



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

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

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

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

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

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

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

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

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

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

## 10.3.2 DPOAE probe tips

**R4.8S**
REF T-R4.8S
Fits ~4.8mm ear canal
Small newborns

**R5.8B**
REF T-R5.8B
Fits ~5.8mm ear canal
Most newborns

**R6.8B**
REF T-R6.8B
Fits ~6.8mm ear canal
Large newborns and first year infants

**R7M**
REF T-R7M
Fits ~7mm ear canal
Infants and children

**R8M**
REF T-R8M
Fits ~8mm ear canal
Infants and small adult ears

**R9M**
REF T-R9M
Fits ~9mm ear canal
Most adult ears

**R11M**
REF T-R11M
Fits ~11mm ear canal
Large adult ears

**R13M**
REF T-R13M
Fits ~13mm ear canal
Extra large adult ears

## 10.3.3 Use of tips


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

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

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

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

# 11 Probe care


## 11.1 Cleaning

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

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

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

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

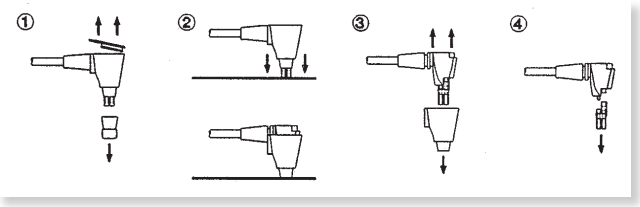
**Coupler assembly -** Each coupler assembly has two sound tubes. These are protected from ingress of foreign materials by wax guards in the tubes and by the disposable probe tip. There is a loudspeaker at the end of one tube and a microphone at the end of the other. Cleaning solution must not penetrate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

## 11.2 Changing probe coupler tubes

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

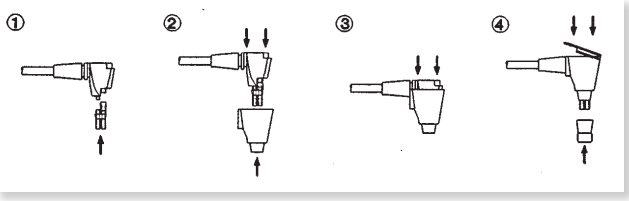
## 11.2.1 Disassembling the probe

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




## 11.2.2 Reassembling the probe

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




## 11.2.3 Notes:

- 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 9 **Probe checks**).

## 11.3 Probes safety note

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

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

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

# 12 Care of the Otocheck LE


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

- Do not drop the Otocheck LE
- 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
- Do not expose to moisture (keep it dry)

## 12.1 Use of the Otocheck LE and cleaning

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

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

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

Before fitting each tip, ensure the sound tubes are carefully examined for any sign of debris that may have entered them. Replace any part of the probe ear piece as necessary. (See chapter 11 **Probe care** for details)

Ensure your hands are cleaned thoroughly between each patient tested.

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

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

## 12.2 Care of cradle

- Place the Otocheck LE gently in the cradle
- Do not use force
- Periodically inspect the connector visible in the cradle and in the base of the Otocheck LE; if it appears damaged, do not use
- Contact your dealer or Otodynamics if the cradle is damaged

# 13 Power

Important Note:

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

## 13.1 Battery life

The Otocheck LE is powered using an internal rechargeable battery. The battery will provide enough power for over 250 OAE tests from a single charge with a battery life of up to 8 hours. Note that the battery life depends on the Otocheck LE usage pattern. With built in power save functions and by switching the device off for the periods between tests, the battery will provide enough power for over a week's intensive use.

## 13.2 Initial charge

It is recommended that an initial charge is provided to fully charge the battery before using your Otocheck LE for the first time. The battery will discharge slowly, even if the device is switched off.

## 13.3 Standby

To save power, the Otocheck LE will go into standby mode after 3 minutes of inactivity. The screen illumination will turn off.

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

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

If the Otocheck LE 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.

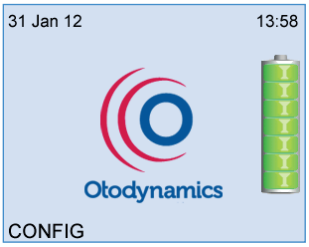
Notes:

Print or record the results of the tests soon after the testing session. Test results are deleted when the device automatically switches off.

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.

13.4

# Battery charge

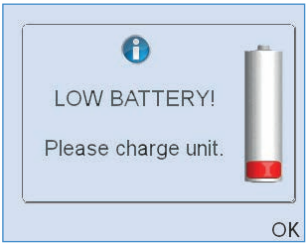



When the Otocheck LE is switched on, the opening screen shows a battery indicator which displays the remaining level of battery charge.

The indicator has 5 segments which convey the total Battery Charge remaining. The battery segments are shaded according to the following criteria.

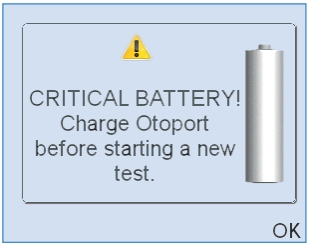
| Segments Displayed | Battery Power (%) |
|---|---|
| 7 | 95 - 100 |
| 6 | 75 - 94 |
| 5 | 55 - 74 |
| 4 | 40 - 54 |
| 3 | 30 - 39 |
| 2 | 20 - 29 |
| 1 | 10 - 19 |
| 0 | < 10 |

### 13.4.1 Low battery




When the battery power reaches less than 10% remaining a **Low Battery** warning message will be displayed. This equates to approximately 30 minutes of testing time. Select **OK** to accept the message and return to the previous screen. This screen will continue to appear every minute, as a reminder to charge the battery.

### 13.4.2 Critical battery




When the battery power reaches 7% remaining a **Critical Battery** warning message will appear on screen. This equates to approximately 10 minutes of use. Select **OK** to accept the message and return to the previous screen. It will not be possible to start a new test when the Otocheck LE has reached this level of charge. The Otocheck LE should be charged as soon as convenient.

### 13.4.3 Auto switch off

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

# 13.5 Charging the Otocheck LE


Observe the on-screen battery indicators to determine when to charge your Otocheck LE. In general it is advisable to charge the Otocheck LE 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.

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

Note:

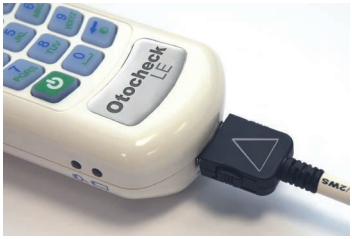
Do not charge more than one Otocheck LE on the same PC at any one time.

## 13.5.1 Connecting the Otocheck LE for charging

Switch off the Otocheck LE prior to charging.

Plug the charger into a power socket and switch on the power.

Then connect the slotted charger plug to the Otocheck LE. Ensure the arrow points to the front of the device.

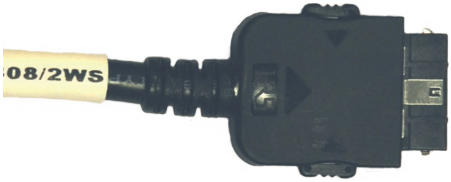


Notes:

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

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

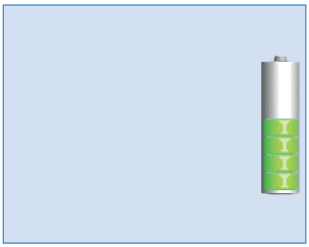
If the cables provided with your Otocheck LE have a locking connector, as shown below, squeeze the release keys at the sides of the connector when removing the plug.

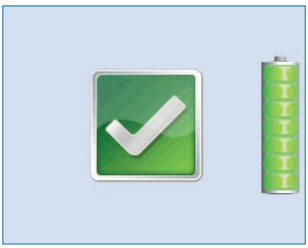



When the Otocheck LE is connected the display will show the current battery level. This screen is updated every minute to show how the charge is progressing.

A full charge will take up to 4 ½ hours.

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





## 13.5.2 Additional charge indicators

There are additional charge indicators on the side of the Otocheck LE.

- **Power light** - The green light above the plug symbol shows that the device is powered.
- **Charging light** - The orange light above the battery symbol will illuminate when the device is being charged.

Note:

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

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

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

When connected to a charger it is possible to switch on and control the Otocheck LE but it is not possible to run a test.

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

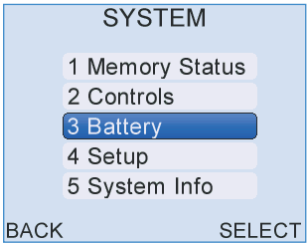
## 13.5.3 Disconnecting the Otocheck LE

When the charging cable is disconnected, the power light will extinguish on the Otocheck LE and if the Otocheck LE 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.

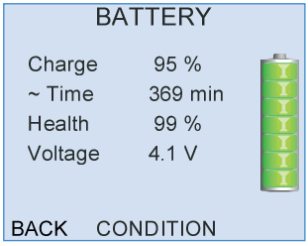
## 13.6 Conditioning the Otocheck LE battery

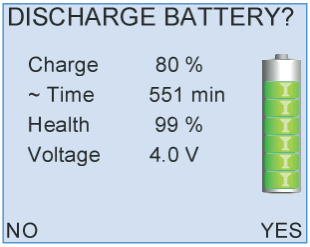
In order to maintain the Otocheck LE battery and keep it at optimal performance you should condition the battery once per year, or if the unit's battery appears to run down more quickly than expected. This process involves completely discharging the battery, using a function provided in the Otocheck LE **System** area and then fully charging the device (see chapter 7 **Configuration**).

The condition utility is available from the **Configuration** menu by selecting **System** then **Battery**. Selecting **Condition** and confirming will set the device to full power to drain the battery.




This process can take up to 6 hours. Select **Cancel** to stop the conditioning process. The Otocheck LE will automatically switch off when the battery has been fully discharged. Now fully charge the Otocheck LE 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.




## 13.7 Additional battery care

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

# 14 Troubleshooting

## 14.1 Otocheck LE lock-up

In the unlikely event of an Otocheck LE 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 left softkey and the down arrow key for three seconds; this will force the unit to switch off. Turn on the Otocheck LE again.

## 14.2 Switch on

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

## 14.3 Switch off

The Otocheck LE can be switched off, at any point outside of testing by holding down the power button, this will initiate the normal shutdown procedure for the Otoport, you will be taken to a second screen where you can either confirm or deny the shutdown. If the device becomes frozen, you can hold down the power button and down arrow together for 10 seconds to force the device to power off.

## 14.4 System details

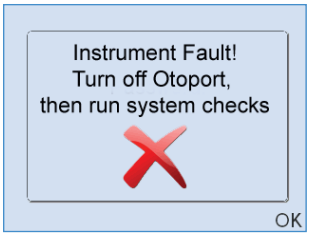
The **Configuration** area includes in the **System** menu a **System details** screen.

This screen provides information for Otodynamics engineers relating to the Otocheck LE 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.

Select **Reset** to restore the Otocheck LE to factory default settings.

## 14.5 Instrument fault message

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




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

Important Note:

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

Run the probe checks (see chapter 9). If the tests are 'OK' the device is functioning correctly and can be used for OAE testing again.

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

14.6

# Hardware fault messages

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


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

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

**Error 2**

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

If a hardware fault is detected when attempting to start an OAE test, the hardware fault error code will be displayed and it will not be possible to run a test.

# 15 Obtaining service

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

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

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

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

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

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

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# 16 Calibration

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

Users should conduct the recommended weekly checks (see chapter 9 **Probe checks**) to ensure the instrument is working correctly. In addition to this, the calibration of the instrument should be periodically checked with laboratory equipment. Otodynamics advises regular calibration checks at intervals not exceeding 3 years and ideally annually.

Contact your dealer or Otodynamics to arrange a calibration check.

# 17 Mode of operation

## 17.1 TEOAE model

| Parameter | Description |
|---|---|
| **Stimulus** | **Idle**<br>80µs positive broadband square wave pulse with an intensity of 64dB pe (peak equivalent) in a 1cc cavity.<br>**Adjusted**<br>80µs positive broadband square wave.<br>**Test**<br>300µs biphasic broadband triangular pulse. |
| **Waveform sample rate** | 20kHz |
| **Stimulus pattern** | Each sweep presents 8 stimuli for each to the two response buffers (16 stimuli in total). The stimulus presentation pattern is:<br>X X X Y -X -X -X -Y<br>Where: Y = -3X |
| **Response buffer averaging** | The responses from each stimuli in a sweep are summed and averaged.<br>Averaging this stimulus pattern removes artefacts which scale linearly leaving only the OAE signal which is non linear.<br>These sub averages are alternately added to two separate averages. These separate averages are referred to as waveforms A and B. |

**Signal and noise calculation**

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

**Stimulus repetition rate**

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

**Response window**

2.5-12.5 ms or 4-10ms after start of stimulus. Cosine filtered with rise and fall time of 2ms.

**Response frequency bands**

Half octave, centres at 1, 1.4, 2, 2.8 and 4kHz.

**Response frequency range**

841-4757Hz

**Microphone input filter**

1189-4757Hz or 1600-3200Hz for Narrow mode

The attenuation at these frequencies is 3dB. Attenuation increases by 80dB/decade below and 40dB/decade above these frequencies.

## 17.2 DPOAE model

| Parameter | Description |
|---|---|
| **Checkfit stimulus** | 80µs positive broadband square wave pulse with an intensity of 64dB pe (peak equivalent) in a 1cc cavity. |
| **Sample rate** | 25.6kHz |
| **Sample buffer** | 80ms (gives 2048 points) |
| **FFT frequency bin** | 25Hz |
| **DP Noise calculation** | DP noise from the five spectral points above and the five points below the DP frequency. The mean of these points gives the noise level. |
| **Noise rejection calculation** | The noise level for noise reject is calculated from the difference between consecutive 80ms samples. |
| **Stimulus frequencies (F2)** | Sine waves of 6, 4, 3 and 2 kHz |
| **Frequency ratio** | F2 = 1.22 F1 |

# 18 Technical specifications

## 18.1 Otocheck LE

Note:

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

### 18.1.1 Physical

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

### 18.1.2 Interfaces

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

### 18.1.3 Indicators

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

### 18.1.5 Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

## 18.1.6 Power

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

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

## 18.1.7 Options

DPOAE or TEOAE model
With or without printing with mini printer

## 18.1.8 Hardware processing and storage

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

## 18.1.9 Analogue performance

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

## 18.1.10 Accuracy

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

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

## 18.1.11 Environmental

Protect from heat and radioactive sources

Keep dry

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

Transport and storage:

Temperature range: 0 to 40 Celsius

Pressure: 23KPa to 120KPa

Humidity: 10% to 90% non-condensing

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

Operation:

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

Relative Humidity: Noncondensing: 10% to 90%

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

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

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

## 18.1.12 Classifications and standards

### Device Classification:

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

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

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

### Declared Conformity:

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

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

  PBBs (Polybrominated biphenyls) (PBB- 0.1 %); PBDEs (Polybrominated diphenyl ethers) (PBDE 0.1 %);

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

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

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

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

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

## Otocheck LE Declared Conformance relating to the following above and other standards:

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

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

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

**EMC:**

**USA:** EN 60601-1-2:2007; IEC 60601-1-2:2007

**Rest of the World:** EN 60601-1-2:2015; IEC 60601-1-2:2014, ed. 4.0; ETSI EN 301 489-17 V3.2.0; ETSI EN 301 489-1 V2.2.0

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

**Note:** The Otocheck LE product's Declaration of Conformity (DoC) can be provided on request.

## 18.2 Electromagnetic compatibility - User Guidance

In the United States of America, Otocheck LE is compliant to EN 60601-1-2:2007; IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. Support information for this EMC 3.0 compliance is given in the Issue 4.0 Otocheck LE manual, available on request.

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

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

### 18.2.1 Suitable environments for operation

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

### 18.2.2 Essential performance

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

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

(ii) remain electrically safe;

In higher levels of EM disturbance than tested for, or for different types of EM disturbance, the user can expect so see increasingly large proportions of measurement data rejected. However, for reasonably foreseeable levels of EM disturbance it is improbable that electrical safety is compromised or that damaging levels of sound are generated. In these circumstances the

increased rejection rate, and the operation of the detection algorithms, will ensure probability of falsely detecting a false OAE or ABR will not increase. However, at very high levels it will become impossible to record any data. If this occurs, you are advised to reduce or move away from the source of the EM disturbance.

**Warning**

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

### 18.2.3 Cables that may affect electromagnetic compatibility

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

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

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

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

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

**Warning**

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

**Warning**

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

# 18.3 Electromagnetic compatibility - Technical Description

## 18.3.1 Compliance levels

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

(i) Electromagnetic emissions - complies with:

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

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

(ii) Electromagnetic immunity - complies with:

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

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

## 18.3.2 Deviations from the standard

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

## 18.3.3 Maintaining essential performance for the expected service life

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

### 18.3.4 Details of radio receivers

The instrument contains the following intentional RF receivers:

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

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

### 18.3.5 Details of radio transmitters

The instrument contains the following RF transmitters:

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

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

### 18.3.6 Specific Absorption Rate SAR

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

### 18.3.7 RF Exposure

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

## 18.3.8 Regional Standards

### Europe

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

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

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

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

### US

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

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

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

### Canada

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

### Japan

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

# 18.4 EN60645-3 conformance notes

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

(a) Types of short duration stimuli:

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

(b) Transducers and headband force:

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

(c) Sound field system:

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

(d & e) Calibration cavity and measurement type:

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

(f) Signal levels:

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

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

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

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

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

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

(g) Polarity of stimulus:

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

(h) Repetition rate:

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

(i) Covered in (a) above

(j) Covered in (f) above

# 18.5 End of life management

The Otocheck LE meets the requirements of the Waste Electrical & Electronic Equipment- WEEE Directive 2012/19/EU; and of the Restriction of Hazardous Substances- RoHS Directive 2011/65/EU and of Packaging/ Packaging Waste Directive 94/62/EC.

**When the Otocheck LE product is discarded, the item must be sent to separate collection facilities for recovery and recycling.**

- No hazardous materials are included in the Otocheck LE.
- No Ozone Depleting Substances are used by the Otocheck LE.
- No Latex is included in the Otocheck LE. The Otocheck LE does not contain any phthalates.
- Local guidance for disposal of medical devices should be followed, for example in the UK follow the NHS Healthcare (clinical) Waste National guidelines.
- When sending Otocheck LE equipment that is no longer required for disposal, please ensure all items, particularly the instrument and probe(s)/cables, are clean and free from contamination (cleaned in accordance with your infection control protocols).
- Prior to battery recycling, handling precautions and prohibitions for LiIon Batteries must be read and understood. Follow VARTA Handling and Safety Precautions for LiIon & LiPolymer batteries.
- Otocheck LE shipping package is recyclable; the Otocheck LE is recyclable (Electronic Waste Recycling/Plastics recycling); Battery Recycling.
- In some territories, total waste management solutions are available and should be used for the Otocheck LE and accessories; these allow nationwide collection service and a sustainable licensed recycling solution with full traceability. Otherwise, all electrical and electronic products, batteries, and accumulators must be taken to separate collection facilities at the end of their working life. This requirement applies in the European Union.
- Do not dispose of these products as unsorted municipal waste.
- You can return your device and accessories to Otodynamics, or to any Otodynamics supplier.
- You can also contact your local authorities for advice on disposal.

## 18.6 Symbol explanations

| Symbol | Description |
|---|---|
|  | Class II |
|  | Type BF |
|  | Bluetooth® enabled |
|  | Caution |
|  | USB 1.1 |
|  | When discarded, the item must be sent to separate collection facilities for recovery and recycling |
|  | Probe socket |
|  | Battery charging indicator |
|  | Power supply connection |
| S | Stimulus OK indicator |
| N | Noise OK indicator |

| Symbol | Description |
|---|---|
|  | Refer to operating instructions |
|  | Otodynamics' factory address |
| REF | Product catalogue number |
|  | Product date of manufacture |
| SN | Product serial number |
|  | RF transmitter |
|  | Training required |

Note:

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

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# W