Otodynamics

Otocheck ABR

User Manual

Otocheck ABR
Issue 5.6

User Manual for Otocheck ABR

Firmware Revision 3.29.1.1 onwards
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1 Introduction

1.1 Intended Use

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

1.2 General guidance

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

The screening functions of this instrument are especially suitable for use with infants. The ABR screening function uses conventional Fsp methodology to detect the response supported by waveform identification (Template Correlation) which is optimised for infants from 34 weeks to 6 months gestational age. Template-free pass criteria for ABR may be selected for use with patients outside this age range (see chapter 10 **Configuration**, section 10.3.4 **Pass criteria**).

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

1.3 General use precautions

The Otocheck pass criteria are set in the **Configuration** area (see chapter 10 **Configuration**). It is the responsibility of the user to ensure that the pass criteria set meet their requirements.

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

The Otocheck includes 'stop criteria' which will automatically terminate the test when an ABR pass has been achieved or after five 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 has built in signal analysis proven to distinguish true ABRs from artefactal signals. Checks should be performed weekly and before each test session to confirm the system continues to operate effectively (see chapter 12 **Quality tests**).

In exceptional circumstances, either an equipment fault or failure to comply fully with the instructions in this manual may result in unreliable test results.

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 14.2 **Changing probe coupler tubes**).

Visually inspect the coupler tubes before use. A blocked sound delivery tube may prevent the Otocheck from achieving its target stimulation level and so prevent testing. A blocked microphone tube will prevent the Otocheck from sensing the stimulus level in the ear. As a result the Otocheck 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 contra indications to carrying out the test (see **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 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 during use are available from Otodynamics.

1.4 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.

1.5 Safety

Caution

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1.6 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.

Otocheck 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 Otocheck 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.

1.7 Auditory Brainstem Response

Auditory Brainstem Response (ABR) is an electrophysiological response that measures the auditory system's response to sound. Three voltage sensors (electrodes) are placed on the patient and a sound probe is placed in the test ear. The equipment sends a click, brief tone, or chirp sound stimuli to the test ear.

The cochlea (inner ear) converts sound into electrical signal. These signals travel in sequence to the acoustic nerve, the brainstem, and finally to the cortical areas of the brain. The electrodes pick up these electrical responses to the sound which are commonly known as auditory evoked potentials. A response which occurs within 20ms of the onset of the stimulus is referred to as an Auditory Brainstem Responses (ABR).

As the amplitude of the ABR is very small compared to the 'noise' of other brain electrical activity (EEG) the 'signal to noise ratio' is very poor. It is enhanced by a process called averaging. The amplitude of the ABR is also quite small compared to voltages generated by myogenic (muscle) activity; therefore, ideally, patients should be tested when sleeping or when very still.

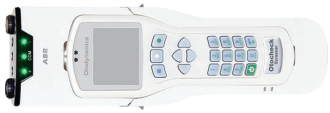
If EEG and myogenic artefacts are below a tolerable (noise reject) level, the Otocheck ABR firmware will detect the ABR and automatically give a simple Pass/Fail response to the user. Other details of the test including the ABR waveforms may also be viewed, and results interpreted, manually if so desired.

2 Equipment identification

2.1 Supplied in Otocheck ABR kit

REF OC-ABR

Otocheck ABR



REF ABR-EC1

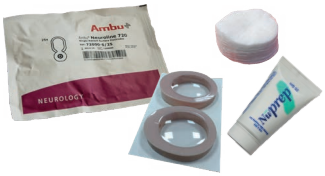
Snap electrode cables - 1m

REF ABR-EC2

Snap electrode cables - 2m

REF ABR-SK

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



REF PR-UGS

UGS probe

REF PR-POUCH

Drawstring probe pouch

Re-order quantity: 10

REF PR-CLIP

Probe cable clip

REF ABR-CAV

Probe cavity and
ABR cable tester

REF ABR-INF

Infection control sleeve for
Otocheck ABR unit only

REF ABR-CAS

Equipment case for
Otocheck ABR kit

TPC probe coupler tubes x 5

See chapter 14 for fitting instructions

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

REF BGS

BGS probe body and lid x 1

Re-order quantity: 10

REF TE-BOX

Sample probe tips

See chapter 13
Probe, tips and accessories
for re-order codes

REF OP-CHG

Charger and mains lead

Supplied with required country-specific plug adapter

REF OP-CAB

PC downoad cable

REF OTOLINK

Otolink software CD

Documentation pack

Includes instrument and software manuals, quickstart and probe use guides

REF ABR-DS

ABR Desktop stand / Crib hook

Desktop stand / crib hook insert for ABR sleeve.

2.2 Optional accessories

REF OMP-R

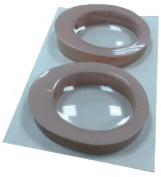
Otocheck printer

Wireless printing

REF ABR-CUP

Ear cups

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



REF OPP-CAS

Large equipment case

For use with Otocheck, with additional compartment for printer

2.2.1 Printer accessories and consumables

REF OMP-CHG

Otocheck printer charger

REF OMP-PAP

Otocheck printer paper rolls

Quantity: 10

REF OMP-SA-PAP

Otocheck printer self-adhesive paper rolls

Quantity: 6

2.3

Controls, indicators and connections

Probe sockets and electrode sockets

Impedance check indicator LEDs

Stimulus OK (S) and Noise OK (N) indicators

Display screen

Quick-release clips

Menu selection keys

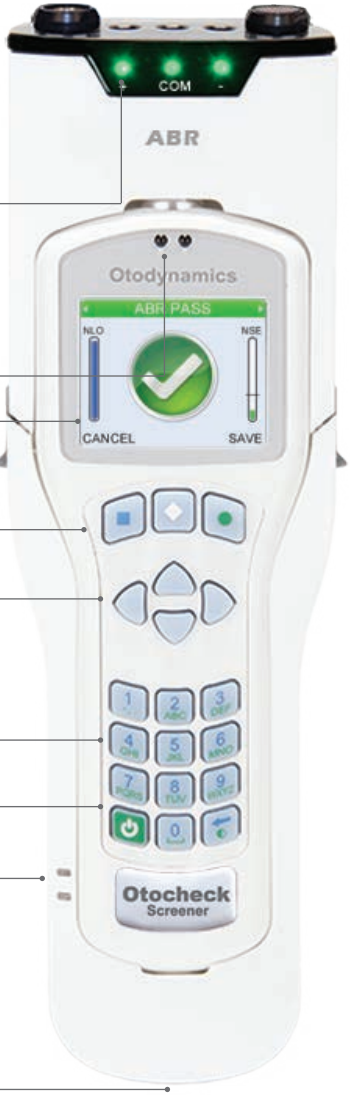
Up/down/left/right navigation keys

Otocheck controls and keypad

On/Off power key

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

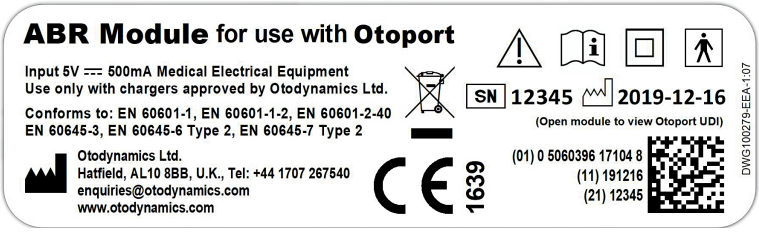
Charger / PC cable socket



2.4 ABR labelling

2.4.1 System

2.4.2 Upgrade



2.4.3 Symbols

The label and device use the following symbols:

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

continued ...

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

Note:

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

2.4.4 Serial number

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

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

(01) Company prefix: Otodynamics, Item reference: Otocheck ABR Screener
(11) Production date: 31st January 2015
(21) Serial numbers: 1234 (Otocheck) - 1234 (ABR)
(240) Additional product ID: BRT (used to identify any hardware modules fitted)
(250) Secondary serial number: AB1 (This is a proprietary electronic device identifier, called GSN)4

This information is also contained in the adjacent barcode.

2.4.5 Certification or regulatory marks

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

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

3 Getting started

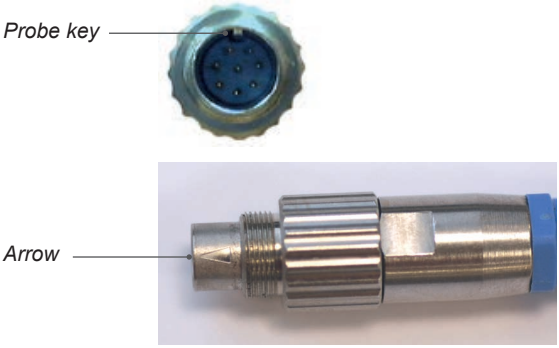
3.1 Connecting probes and electrodes

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

3.1.1 Connecting the probe

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

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 the probe in further.

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

3.1.2 Disconnecting the probe

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

Then gently pull the probe out from the probe socket.

Important Note:

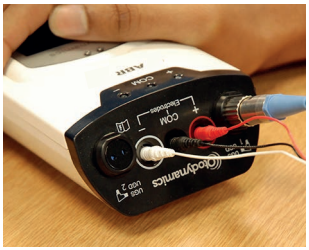
Do **NOT** attempt to screw or unscrew the probe by holding the main probe body (smooth chrome section).

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

3.1.3 Connecting the electrodes

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

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



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

Important note:

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

3.2 Initial charge

Before using the equipment for the first time, fully charge the unit. See chapter 16 **Power** for details.

3.3 Using the keys and keypad

3.3.1 Control keys

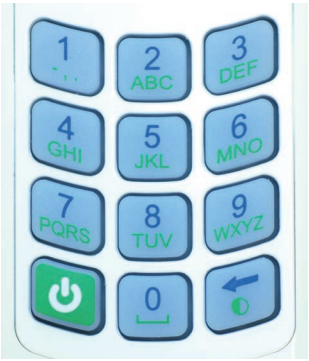
The keys directly below the screen marked with a square, a diamond or a circle enable you to execute the functions offered on the screens. Their functions vary from screen to screen, but generally the right (circle) key provides affirmative options and the left (square) key provides negative options.

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 Entering characters



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

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

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

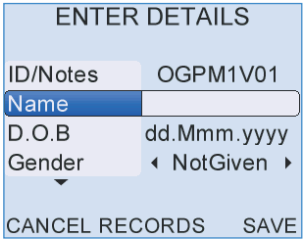
Family Name
For the first character capitals are presented first, then lower case then numbers, e.g. ABCabc2. For subsequent characters lower case is shown first, e.g. abcABC2.

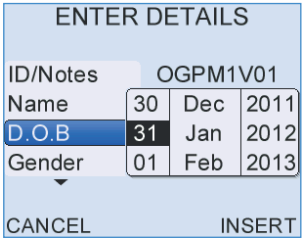
More characters can be stored than can be displayed on the screen. Arrows are displayed to indicate that the string continues to the left or the right. Pressing the appropriate **Arrow** navigation keys will display the hidden characters.

3.3.4 Foreign character table

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

3.3.5 Entering dates





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

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

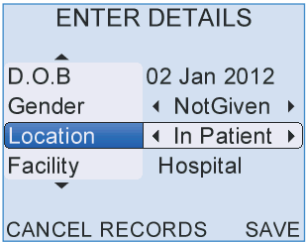
Select **Insert** to accept the date displayed or **Cancel** to ignore the changes.

If the date has not been edited, it will remain as dd.Mmm.yyyy by default.

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

3.3.6 Choice bars

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



3.3.7 Deleting characters

The bottom right hand key shown above is used as a delete key. If the cursor is at the end of a row of characters, press this key to delete the last character.

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

3.3.8 Backlight

The screen and keypad 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 10 **Configuration**).

3.3.9 Stimulus and Noise OK indicators (blue LEDs)

The two blue LEDs above the screen on the Otocheck 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 10 **Configuration**).

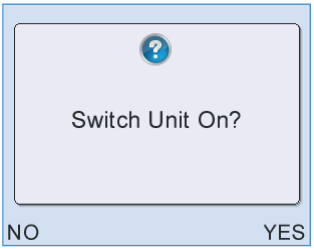
3.3.10 Hard reset

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

4 Switching On

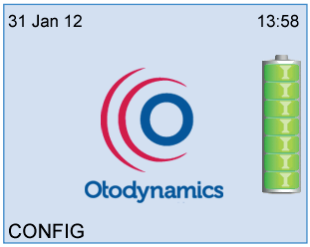
4.1 Switch on screen

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



Select **Yes** to confirm Otocheck 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 17.5 **Hardware fault messages** for details).

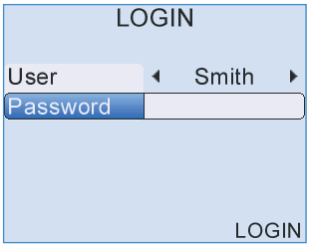
A battery graphic will appear to the right of the logo to provide an indication of the **Battery Power** remaining. Please refer to chapter 17 **Power** for battery information.

A prompt will be shown if the Otocheck is due to be calibrated (see chapter 20 **Calibration**).

The date and time are also shown at the top of the screen and can be reset if necessary via the **Configuration** menu (see chapter 10).

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 10 **Configuration**).

4.3 Login



If **Login** is **on** (see section 10.6) the login screen will be displayed and the user will be required to enter a name and password.

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

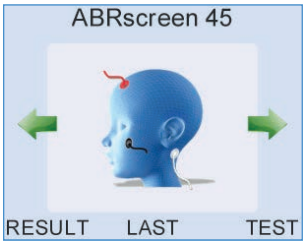
After the user is selected, use the data entry keypad to enter a corresponding **Password**, if required for that user.

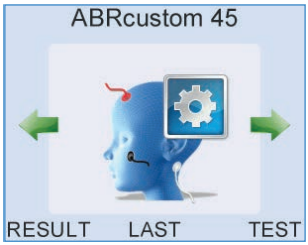
To improve security during **Login**, a * symbol will replace each character as it is entered in the **Password** field. To review charcters that have been entered, simply scroll back through the * using the left and right arrow keys.

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

4.4 Main menu

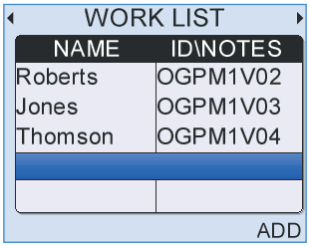
You are then presented with the main menu screen. From here you can view the **Result** of the last test, select the **Last** patient tested or perform a **Test**.





ABRcustom only available if configured (see chapter 10)

Use the left and right arrows to access **Records** and the **Work List**. See chapters 9 and 8 for further details.



5 Test preparation

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

5.1 General checks before testing

Ensure the Otocheck is charged (see chapter 16 **Power** for information).

Ensure the Otocheck weekly checks are being regularly conducted (see chapter 12 **Quality tests** for information).

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

Choose a quiet room, without background noises.

Ensure the patient is comfortable and settled.

Ensure you can clearly see the ear to be tested.

5.2 Environment checks

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

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

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

5.3 Tip selection and probe fitting

Appropriate tip selection and good probe fit are essential to ensure successful recordings. A good probe fit will help to block out external noise and enhance the signal. The Otocheck 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 newborns using ear cups

When using ear cups, there are two probe tips that you can use for the best fit of the probe to the ear cup. These are the T7M tip for TE probes and the R7M tip for DP probes; see section 13.3 for more information on probe tips.

5.3.3 Fitting for children and adults

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

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

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

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

5.4 Electrode fitting

5.4.1 Skin preparation

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

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

If using a wet prep use a gauze pad to remove any residue. Avoid touching the prepared area and, to ensure that the sensor is placed directly on the prepared area, it is preferable to prepare one site at a time and immediately apply a sensor.

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

5.4.2

Placement (montage)

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

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

High forehead (positive ⊕ red)

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

If using snap stud electrodes, now connect the electrode cables to the sensors. Connect the red cable to the high forehead, the white cable to the nape of the neck and the black cable to the back of the shoulder.

Alternative electrode placements

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

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

Note:

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

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

6 ABR test problems

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

Solutions:

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

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

6.2 High myogenic activity/artefact reject

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

Solutions:

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

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

6.3 High environment electrical noise

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

Solutions:

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

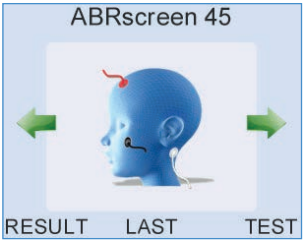
6.4 No response in ear with known normal hearing

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

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

7 ABR test

Use the left or right arrow key to choose your ABR test screen.



Note:

The ABR test can operate in different Modes. The following text refers to Screening Mode, where Autostart is ON. See section 10.3.4 in the **Configuration** chapter for Mode configuration option. The electrode colours are for the standard electrode connection cable and may differ if other cables are in use.

Connect the electrode leads and the probe to the ABR unit and prepare your patient. Connect the red (+ve) cable to the high forehead, the white (-ve) cable to the nape of the neck and the black (common) cable to the back of the shoulder (see chapter 5 **Test preparation** for full details).

Select **Test** to being testing.

Note:

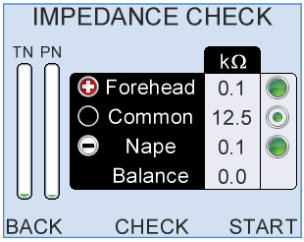
If you see the message ABR Mains is Not Set", your Otocheck has not yet been permanently configured for your region. You must select the powerline frequency in your region (see **ABR Mains** in 10.3) Test Settings).

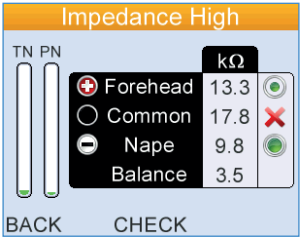
7.1

Impedance check

The Otocheck checks the quality of the connection between the skin and each of the three electrodes. This takes 2-3 seconds. A low impedance provides a good connection. Achieving optimum electrode impedance requires practice and experience.

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





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

If test conditions are good

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

If test conditions are moderately good

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

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

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

If the test still does not start automatically, observe the two noise bars TN (EEG Noise), and PN (Powerline Noise). They may be high. For advice on how to reduce the noise see chapter 6 **ABR test problems**.

The test will start automatically when conditions are good.

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

If test conditions are poor

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

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

(See chapter 6 **ABR test problems** for more detail).

Select **Back** to cancel the test.

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

Further advice on ...

Otocheck impedance measurements

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

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

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

The ranges for each symbol displayed are:

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

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

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

If the impedance values are too high refer to 6 **ABR test problems**.

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

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

Further advice on ...

Electrical noise indicators

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

Electrical noise has multiple sources:

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

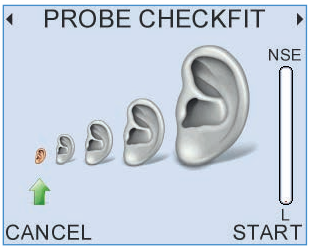
The right hand bar (labelled PN) estimates the level of noise from electrical wiring and other devices. This level is high if there is a lot of interference from electrical noise and/or one or more of the electrodes is poorly connected (has high impedance). If impedance levels are acceptable but the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

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

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

If either level remains high refer to 6 **ABR test problems**.

7.2 Checkfit



Before the ABR test starts, the probe fit will be checked.

7.2.1 Checkfit display

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

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

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 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.

Noise level indicator

A Noise Level Indicator 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.

Ear cups

The test stimulus in ABR tests can be provided either by inserting the probe into the ear, as for OAE testing, or by applying an ear cup to the ear and inserting the probe into the ear cup. Ear cups can be particularly useful in neonates with very small ear canals where a secure probe fit is not possible. They can also be useful in preventing the probe from being dislodged by movement during testing.

7.3 Ear cup Checkfit

To test with ear cups, the **Ear Cup** mode in **ABR Other Settings** must be set to **Auto** or **On**. The T7M tip (UGS probes) or the R7M tip (UGD probes) should be used to secure the probe to the ear cup. See section 10.3 for more details.

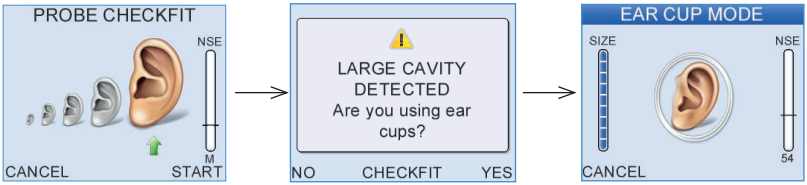
7.3.1 Ear Cup mode set to Auto

In Checkfit, the device will check whether ear cups are being used by checking if a large cavity has been detected. If this is the case, then the user will be prompted with a message to confirm. There will be three options: **Yes**, **No** and **Checkfit**. Using the probe direct in a neonate ear will always create a small cavity, but using large (adult) ears may trigger the prompt.

If **No** is selected, the device will go into normal Checkfit.

If **Checkfit** is selected, the device will go back into Checkfit and re-check whether ear cups are being used or not.

If **Yes** is selected, the device will go into ear cup Checkfit as shown below.



7.3.2 Ear Cup mode set to On

The device will go straight to ear cup Checkfit without checking for ear cup use.

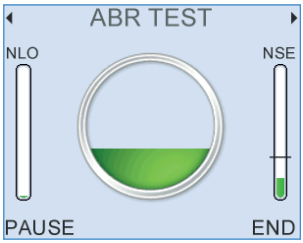
7.3.3 Ear Cup mode set to Off

The device will go straight to normal Checkfit without checking for ear cup use.

7.4 ABR test

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

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



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

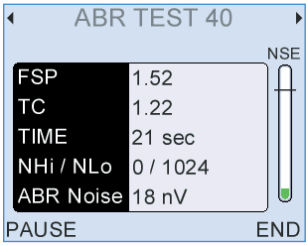
NLO is an indication of the amount of data which has been collected with the noise lower than the noise reject level.

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

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

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

7.4.1 Data summary



Fsp

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

TC

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

Time

Shows the duration of the test.

NHi/NLo

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

Accepted

Shows the number of sweeps accepted into the average.

Rejected

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

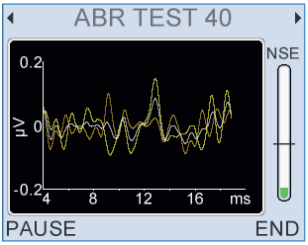
ABR Noise

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

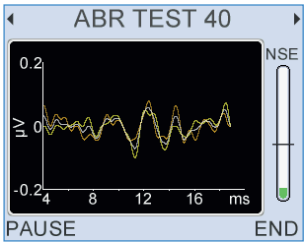
If the signal which has been recorded is very small (<15nV), and no sign of an ABR has been detected, the test will stop automatically with a 'No Valid ABR' result as continuing the test would not find an ABR present.

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

7.4.2 Waveform display



Noisy ABR



Good ABR

This screen shows the averaged ABR waveforms collected. Two waveforms are collected from interleaved averages so that the correlation between the two can be assessed. Close agreement between the waveforms indicates that a clear response is present (right), disagreement between them shows the presence of noise (left). Excess noise may obscure an ABR. The alternative waveforms are displayed in orange and yellow. The average of these two waveforms is shown in white.

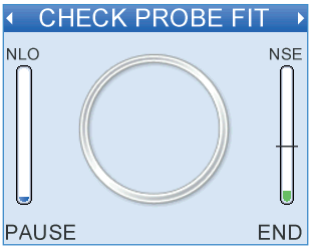
The Fsp and template correlation (TC) measures are based on the final average (the white line), not on the subaverages.

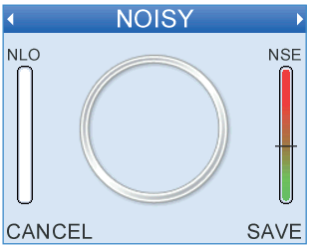
7.4.3 Impedance monitoring

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

- If impedances are low, the test will continue.
- If impedances are high, the test is paused and the ‘Impedance Check’ screen will be displayed.

7.4.4 Stimulus monitoring





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

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

7.4.5 Pausing the test

Select **Pause** to temporarily stop data collection. You may wish to do this if the test environment worsens (for example the subject becomes temporarily active, an electrode becomes detached or the probe falls out of the ear). If a test is paused an impedance check is automatically run and electrical noise is monitored (as in section 7.1).

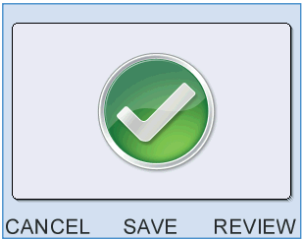
Failure to measure discernible ABR data within the defined test time, and within acceptable NLO range or before ABR noise target is reached, will return a **No Valid ABR** result.

7.4.6 Test stop reasons

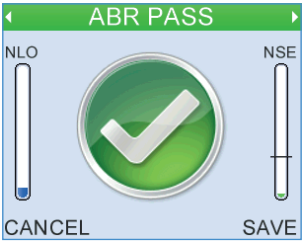
There are five possible ways in which a test can stop, described below. When the test stops the data collected is assessed. The result is given as a pop-up graphic and written highlighted at the top of the test screen. The Otocheck will beep once if a test has stopped with an ABR Pass result and will beep twice if the test has stopped with any other result.

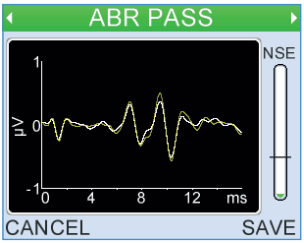
AutoStop

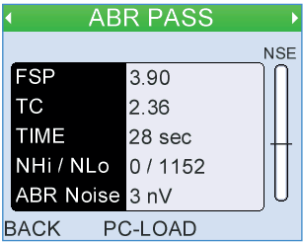
If the test data collected meets the set pass criteria then the test will AutoStop and a large checkmark will be displayed.



The test result can be saved at this point, or the results can be reviewed prior to saving. If **Review** is selected, three screens are available by using the left and right arrow keys.







Test timeout

If a test has not met the set pass criteria then the test will stop after 10240 sweeps have been collected, or after 10 minutes.

Noise target reached

If the residual noise in the averaged test (ABR Noise) becomes so low that any ABR present would already have been detected, then further testing is redundant, so the test is ended.

Probe fit lost or high acoustic noise

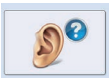
If the 'Check Probe Fit' or 'Noisy' messages (see 7.4.4) are displayed for an extended period, the test will automatically stop.

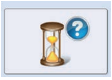
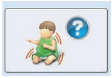
Manual end

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

7.4.7 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
ABR Pass 	The data collected has met the pass criteria. A clear ABR has been found. Note: Optimum pass criteria will depend on your application, e.g. screening or clinical measurement (see 10.3 **Test settings**).
Note: One of the following will be shown if a Pass is not obtained.	
No Valid ABR 	The data collected has not met the set pass criteria and the test conditions were acceptable. In infant screening, this result supports referral for audiological investigation.
Noisy 	There was too much acoustic noise to test. The 'Noisy' message would have been displayed during testing (see 7.4.4).
Poor Probe Fit 	The last stimulus level recorded changed from that recorded at the start of the test by >3dB, or the last acoustic noise level recorded was high.

Stopped Too Soon 	The test has been ended manually before the minimum amount of data required had been collected.
Atypical Waveform 	The template correlation (TC) is low but Fsp is high. A possible ABR has been detected but it did not match the neonate template. This might occur if an adult were tested or if electrodes were incorrectly connected or reversed. (Only obtained with pass criteria PC2 and PC3).
High Mains Noise 	Interference from electrical equipment prevented the test from passing. The Fsp pass threshold was elevated due to this interference and the Fsp did not reach this higher threshold.
High Impedance 	The electrode impedances measured at the end of the test were high and may have prevented an ABR from being recorded. This could be caused by electrodes becoming disconnected from the patient during testing.
High EEG Noise 	Electrical noise during the test prevented an ABR from being recorded. This occurs when the noise recorded is too high (above 40nV) at the end of the test. This is most likely caused by the baby being unsettled during the test (myogenic interference).

After the test end, ABR test results are saved.

7.5 Quick Save option

The options available from the test result screen depend on the **Quick Save** option (see chapter 10 **Configuration**)

7.5.1 Quick Save On

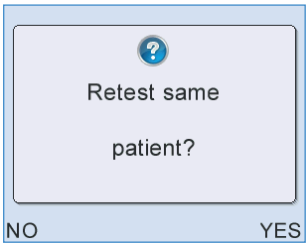
If **Quick Save** is **On,** select **Left** to save the test to the left ear, or **Right** to save to the right ear.

The test will be saved to the current patient or will be given an automatic ID and name. This name and ID may be edited by selecting **Last** from the main menu screen.

If **Automatic print** is selected (see chapter 10 **Configuration**), the print routine will be activated at this stage. After printing or immediately after saving, the unit will return to the **Main Menu**.

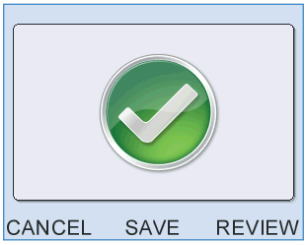
Select **Cancel** to proceed without saving the test. The user will be prompted to confirm **Cancel without save**.

After the save is confirmed, the option to retest the same patient will be displayed. Select **Yes** to run another test on the same patient or **No** to return to the main menu.



7.5.2 Quick Save Off

If **Quick Save** is **Off,** select **Save** to skip to the **Patient Details** screen ready to **Save**.



Select **Review** to view the data of the completed test, prior to saving.

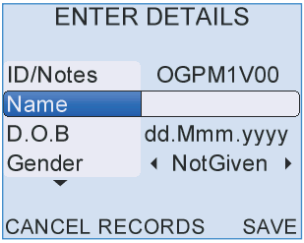
Select **Cancel** to discard the test result. A prompt requiring confirmation will be shown before the result is discarded.

7.6 Review

The review screen shows the result of the test.

The user may **Save** or **Cancel** the result from the **Review** screen (at the end of review).

7.7 Save



The **Enter details** screen is shown. The patient **ID** is filled with an automatically generated ID. The **Name** field displays **Auto**. The user may either save these details or overwrite them with alternative patient's details. If an ID is not required, this field may be used as a notes field.

A Date of Birth (**D.O.B**) and **Gender** may also be added for the patient.

A further three fields are available by scrolling down using the arrow keys. These are **NICU** (Yes or No), **Location** (Inpatient, Outpatient or At Home) and **Facility**.

Note:

Only one **Facility** can be stored on the Otocheck. It is not possible to store different facilities for different patients. If you wish to change the **Facility**, download and erase all test records from the Otocheck first.

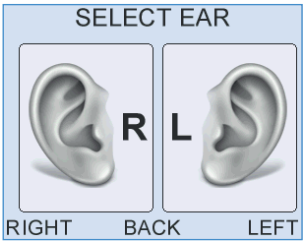
It is also not possible to set the **NICU** field to **Yes** if **Location** is set to **Outpatient** or **At home**. The fields are automatically corrected in this case.

Alternatively, the user may select **Records** and choose an existing patient record to which the current results may be appended.

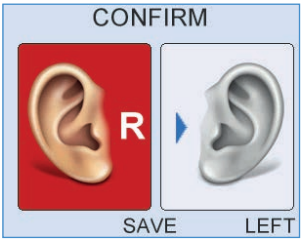
If the test was run using the **Last** option test results will be saved with the same details as the last performed test.

When the patient details are entered, select **Save** to store the result.

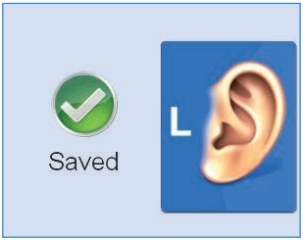
7.7.1 Select left or right ear



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



When the correct test ear has been selected press **Save** to save the test record to the database. A screen will be displayed briefly which confirms the test has been saved.



The pop up message **Last Test Saved to Left/Right Ear. Save Test to Left/Right Ear Again?** may appear on **Save** if the patient's previous test was saved to the same ear. Select **Yes** to accept the current ear choice or **No** to return to the **Select Ear** screen.

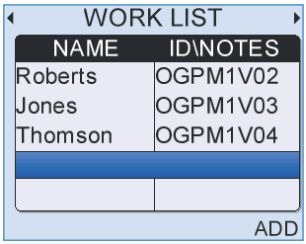
If **Auto print** is selected, the print routine will be activated at this stage.

8 Worklist

The Worklist allows details for multiple patients to be entered into the Otocheck prior to testing. This eliminates the need for data entry while with the patient, allowing for faster, more flexible testing. The Worklist is **On** by default but can be switched **Off** in the Config area (see chapter 10).

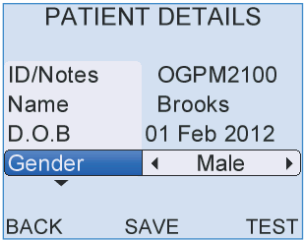
Access the Worklist by using the left or right navigation keys from the main menu.

8.1 Adding Patients



If the worklist already contains patients, scroll down to the last line, which will be empty, then select **Add**.

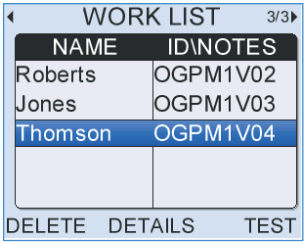
Complete the required details. The **ID/Notes** and **Name** fields are prefilled but can be over-written.



When details are complete, select **Save** to save the details to the Worklist, **Test** to run a test on this patient, or **Back** to discard these patient details.

Up to 50 patients may be added to the Worklist.

8.2 Testing from the Worklist



Scroll to the required patient. Select **Test** to begin testing this patient. When a test has been saved to a patient those details are removed from the Worklist.

8.3 Editing details

Scroll to the required patient. Select **Details** to edit. The options available are the same as when adding a patient.

8.4 Deleting patients

Scroll to the required patient. Select **Delete** to remove.

Select **Yes** to delete the selected patient from the Worklist. Select **All** to delete all of the patients from the Worklist. Select **No** to return to the Worklist without deleting any patient details.

9 Records

The **Records** section allows the user to see the **Results** of previous tests and to view the **Details** of patients previously tested.

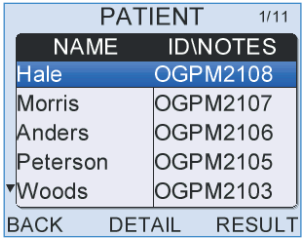
Records may be erased from the **Memory Status** screen accessed from the **Configuration** area (see chapter 10).

Records also allows the user to select a previously tested patient for a new **test**.

Selecting **Records** from the **Main Menu** takes the user to the **Patient List** screen.

If Bluetooth is set to **PC-Load** (see 10.5.4 **Setup**) then test data can be downloaded wirelessly to PC by selecting **PC-Load**.

9.1 Patient list



The **Patient** list displays the **ID/Notes** field and **Name** of each patient. The up and down arrow indicators to the left of the **Patient** list show that there are other patient records not currently visible on screen. At the top of the screen, the total number of patients in the list and the position of the current patient in the list are displayed: 12/34 indicates that the current patient is twelfth in a list of 34 patients.

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

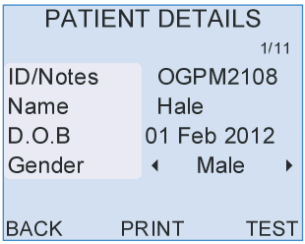
Use the left and right arrow keys to skip through the **Patient** list ± 5 records at a time.

Select **Detail** to review the complete **Patient Details** of the highlighted patient or to run a new test on this patient.

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

Select **Back** at any time to exit the **Patient** list screen and return to the main menu.

9.1.1 Details



The **Patient Details** screen allows the user to see the **ID/Notes** field, **Name**, Date of Birth (**DOB**) and **Gender** stored for a particular patient.

Selecting **Test** from this screen starts a new test, the result of which will be saved with the records of the selected patient.

Selecting the up and down arrow keys on the patient details screen displays the patients before or after the current patient in the patient list. Selecting the left and right arrow screens displays the test results for the selected patient.

Select **Back** to return to the **Patient** list.

9.1.2 Test summary

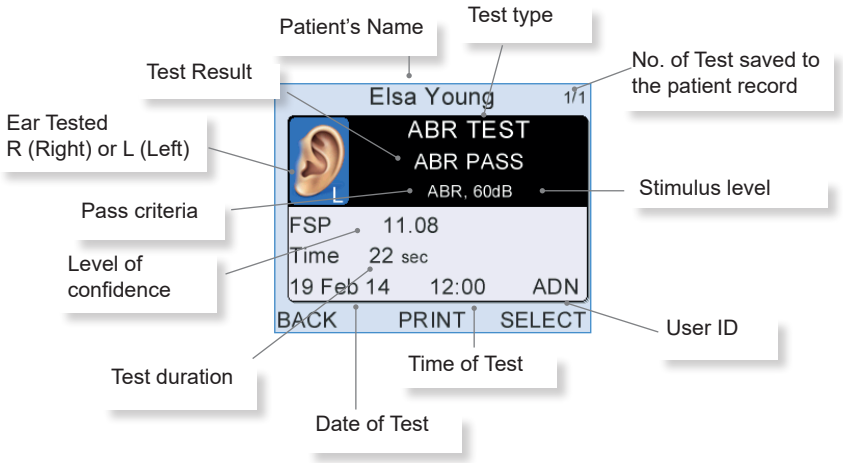
The test summary gives an overview of the test result. The diagrams below illustrate the features of a test summary screen.

The number of tests currently saved to the patient is displayed in the top right of the screen.

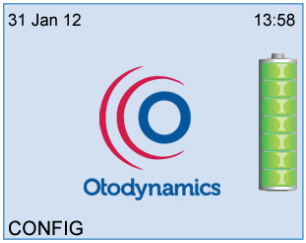
The up and down arrow indicators to the left of the screen show that there are other saved test records for this patient. The left and right arrow indicators display the **Patient Details** for this patient.

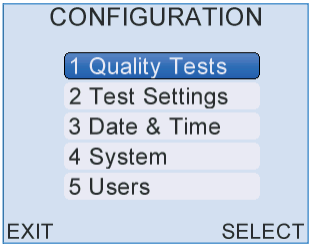
Select **Print** to print an individual test summary.

Select **Back** at any time to exit the test summary screen and return to the **Patient** list to review tests of an alternative patient.



10 Configuration





10.1 Configuration menu

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

Select **Quality Tests** to check the performance of the probe or the ABR electrode cables.

Select **Test Settings** to change test display and pass criteria.

Select **Date & Time** to set the current date and time.

Select **System** for memory, battery and system information.

Select **Users** for login options.

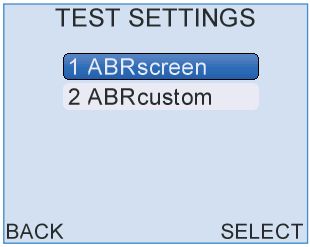
Note:

Users without Admin rights will only have access to **Quality Tests**. The other items will be hidden.

10.2 Quality tests

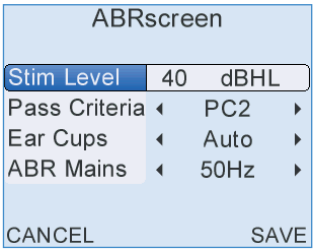
Details of how to perform the probe and elecrode cable tests are in chapter 12 **Quality tests**.

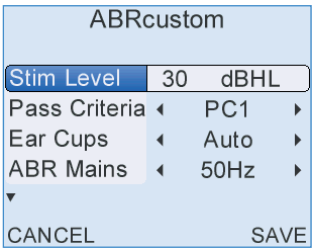
10.3 Test settings

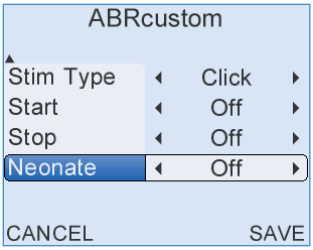


The Otocheck ABR has two different ABR test modes, **ABRscreen** and **ABRcustom**. ABRscreen is optimised for the screening of neonates and is less configurable than ABRcustom. Choose the mode you wish to edit.

10.3.1 ABRscreen and ABRcustom







Use the arrow keys to navigate and choose between the setup options.

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

Select **Cancel** to discard changes and return to the **Configuration** screen.

Stim level

Stim Level sets the stimulus level used in the ABR test in dBHL.

If Stim Level is set to OFF then the selected mode (ABRscreen or ABRcustom) is not available for testing and it will not appear in the main menu carousel.

The **ABRscreen** mode is intended for newborn hearing screening.

The stim level can be set from 30-45dBHL in 5dB steps.

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

The stimulus level should be set to the lowest value compatible with the aims and targets of the hearing screening program. For high sensitivity detection of even slight hearing impairments the Otocheck 35dBnHL

setting has been successfully used. At this stimulus level the number of unnecessary referrals (i.e., false positives) will be higher than with 40dBHL stimulation. Many major infant screening programs (e.g., UK English, and Welsh national programs) use the 40dBHL setting. They find it gives both good sensitivity to mild and clinically significant losses with an easily manageable refer rate. Typically, in the well-baby population, an OAE test fail is immediately followed up by an AABR screen using the Otocheck. Note that screening with stimulus levels significantly above 40dBnHL is likely to miss some mild hearing losses.

In **ABRcustom** mode the stimulus level can be set from 5-60dBHL in 1dB steps. The default setting is OFF (i.e. ABR custom mode test is unavailable).

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

In **Ear Cups** mode the stimulus level limits are 40 dBHL when the stimulus type is chirp and 35 dBHL when the stimulus type is click.

Notes:

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

The Otocheck ABR is capable of recording ABR responses from patients of all ages provided a non-template (Fsp only) pass criteria is selected (PC1 or PC4). However the specificity of the

device has only been established for neonates and therefore it is not intended for use as screen for hearing loss in older children or adults.

Pass criteria

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

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

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

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

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

PC1 requires:

Fsp level exceeds the dynamic Fsp with no template requirement

PC2 requires:

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

PC3 requires:

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

Or

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

PC4 requires:

Fsp level exceeds the dynamic Fsp with no template requirement

Or

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

When to use each PC:

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

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

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

Ear Cups

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

OFF – Will always go into test assuming ear cups are not being used.

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

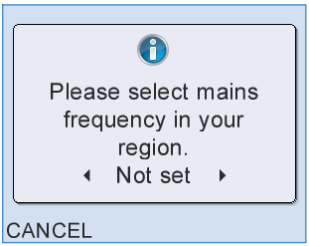
ON – Will always go into test assuming ear cups are being used.

ABR mains

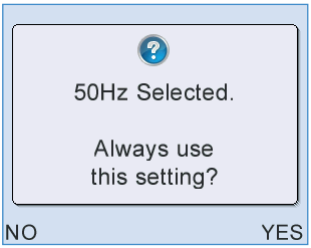
ABR mains sets the ABR test configuration for optimum test recording in mains (powerline) noise. The mains frequency varies in different countries. Set 50Hz if the mains in your region is 50Hz and 60Hz if your region is 60Hz. Select Not Set if you are unsure of the mains frequency in your region.

Setting ABR mains from the main menu

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



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



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

Stim Type

Stim type sets the stimulus type used in the ABR test. The types available are 'click' and 'chirp'. See chapter 21 **Mode of operation** for further details of these stimulus types. The chirp stimulus has been demonstrated to give a larger ABR response for the same stimulus level. Stim Type is configurable only in ABRcustom, default is chirp in both modes.

Start

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

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

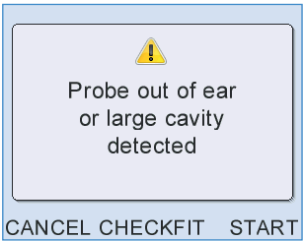
Start is configurable only in **ABRcustom**, default is ON in both modes.

Stop

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

Stop is configurable only in **ABRcustom**, default is ON in both modes.

Neonate mode



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

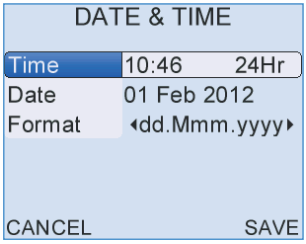
The warning message is displayed after Checkfit and before the test starts. Selecting **Start** will start the test as normal. **Checkfit** returns the user to Checkfit. **Cancel** returns the user to the main test screen.

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

With Neonate setting OFF (default). no warning message is displayed if a large ear volume is detected.

10.4

Date and time



The date and time set on the device can be altered in the **Date & Time** screen.

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

The date **Format** can be changed between dd.Mmm.yyyy and mm.dd.yyyy or dd.mm.yyyy via the choice bar.

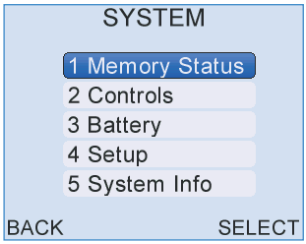
Select **Save** to set the current date and time settings and return to the **Configuration** screen.

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

Important Note:

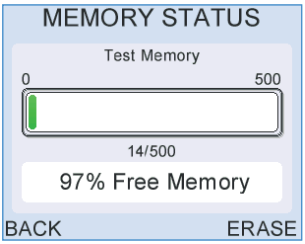
Do not set the date on the Otocheck to an earlier date, if there is data stored on the device.

10.5 System



The **System** screen allows users to view information on **Memory Status**, **Controls**, **Battery** power, **System Information** or to change the **Setup**.

10.5.1 Memory status



The Otocheck has the capacity to store up to 500 test records. The memory status screen displays the number of records currently stored and the percentage memory still available.

Selecting **Erase** deletes all test records from the Otocheck after requesting confirmation from the user. A screen confirming the **Erase** is then displayed and the user is returned to the main menu.

If there is less than 10% free memory then the **Memory Status** screen will be displayed at start up.

If there is 0% free memory then the **Memory Status** screen will be displayed automatically and no further tests may be performed until tests have been erased.

The **Memory Status** screen will be displayed immediately after the 450th result has been saved warning the user that there is limited storage capacity left.

If the **Memory Status** screen has been displayed because the Otocheck memory is full or nearly full, the user will also have the option to **Download** data to a PC using Otolink.

10.5.2 Controls

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.

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.

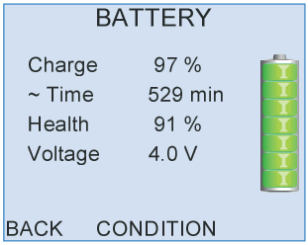
Backlight

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.

10.5.3 Battery



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

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

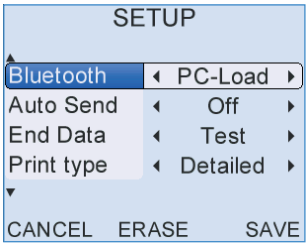
Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

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 battery. See chapter 16 **Power** for more information.

10.5.4 Setup



Quick Save

If **Quick Save** is **On** then test results can be saved from the test result screen with a single key push (see chapter 7 **ABR Test** for details).

If **Quick Save** is **Off** then options to enter patient details and review the test result are available before test is saved.

Bluetooth

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

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

If **Bluetooth** is set to **Print** then the Otocheck can use Bluetooth communication to send test results to the mini-printer (see chapter 11 **Printing**).

Wireless printing and download are only available on Bluetooth enabled Otochecks. You can tell if a Bluetooth module is fitted, as a Bluetooth symbol (shown above) is included on the product label on the back of the Otocheck. If **Bluetooth** is set to **None** then the Otocheck cannot take advantage of the Bluetooth Communication for either Print or PC-Load as it does not contain the necessary hardware.

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

Auto Send

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

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

End Data

If **End Data** is set to **Patient**, then all the test results for the current patient are printed at the end of the test.

If **End Data** is set to **Test**, then only the last test performed is printed at the end of the test.

Select **Save** to accept the setting and **Cancel** to discard any change.

Note:

To avoid printout duplication, it is not possible to set **Auto Send** to **On** and **End Data** to **Patient**.

Print

If **Print** is set to **Automatic** then the test result is automatically printed after the test is saved.

If **Print** is set to **Manual** then the user has the option to print the test after save.

End Print

If **End Print** is set to **Patient**, then all the test results for the current patient are printed at the end of the test.

If **End Print** is set to **Test**, then only the last test performed is printed at the end of the test.

Select **Save** to accept the setting and **Cancel** to discard any change.

Note:

To avoid printout duplication, it is not possible to set **Print** to **Automatic** and **End Print** to **Patient**.

Print type

Print type controls the length and detail contained in the Otocheck printout. The **Summary** format prints only core patient and test details. The **Detailed** format prints a fuller set of patient and test quality details.

On connect

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

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

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

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

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

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

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

Worklist

The **Worklist** allows details for multiple patients to be entered into the Otocheck prior to testing. If **Worklist** is set to **On**, the list is accessible from the main menu. If the **Worklist** is set to **Off**, it is not available.

Language

Select the language you require using the left and right arrowkeys.

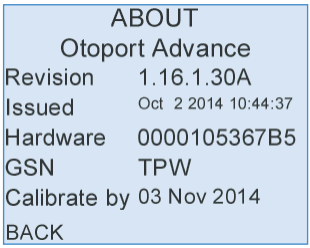
10.5.5 System info

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

System Details

System Details displays information for Otodynamics engineers. (See section 17.3 for further details).

About



The **About** screen provides information relating to the Otocheck's identification and mode of operation. The firmware revision number and issue date is stated, together with the unit's unique hardware ID. The next scheduled Calibration Due date is also shown. A dash is shown if no calibration date has been set.
Select **Back** to return to the **System** menu.

10.6 Users

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

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

Select **Settings** to turn **Login** on or off.

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

10.6.1 Add New User

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

Field	Description	Max No. Characters
Name	User's name that appears at Login	8
User ID	The user's unique identification This is attached to a test record when saved to the database	3 (capitalised only)
Password	An alphanumeric password required for secure login (optional)	8 (capitalised only)
Admin	Select **Yes** to give the new user administrator rights	N/A
	Select **No** to restrict the user to screener rights	N/A

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

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

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

A new user is given a choice of two levels of access rights. If **Yes** is selected in the administrator field, then the user will have full access to all the **Config** areas of the device. Select **No** to restrict the user's rights to only the **Probe** test area in **Config,** disabling access to higher level functions.

10.6.2 View Users

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

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

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

Edit user

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

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

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

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

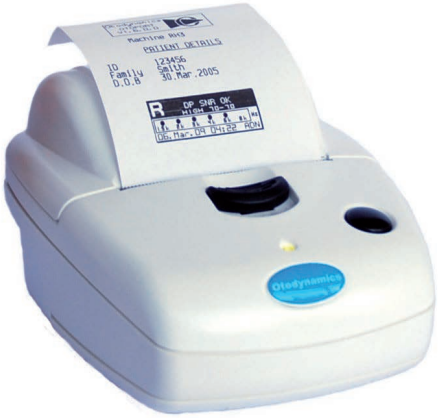
Select **Cancel** at any time to discard changes and return to the **User List**.

Settings

Select **Settings** to turn the **Login** facility **On** or **Off**.

Select **Save** to save a change to the settings or **Cancel** to return to the **Users** menu.

11 Printing and downloading



Test results can be printed on the optional Otocheck mini-printer or downloaded to PC for printing, archive or export.

11.1 Bluetooth wireless technology enabled printing and download

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

However, the Bluetooth connection supports *either* printing *or* downloading, not both (see 10.5.4 **Setup** to select which function is available). The softkey **Print** or **PC-Load** is shown on screen whenever the function is available.

Bluetooth download requires that Otolink software is installed and that your Otocheck ABR is paired with your PC. The password for pairing is 4679. See your Otolink manual for full instructions. Refer to **Custom Settings** in Otolink manual (currently chapter 15).

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

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

Bluetooth printing is described throughout this chapter.

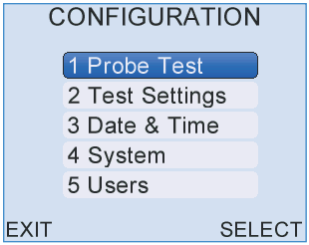
11.2 Wired downloading

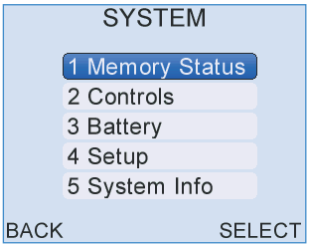
Wired download is available at any time when a test is not in progress and the Otocheck database is not open. See the Otolink manual for details.

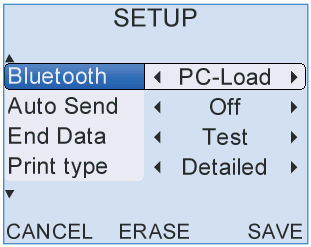
11.3 When you can print and download

The Otocheck provides flexible options, as described on the following pages.

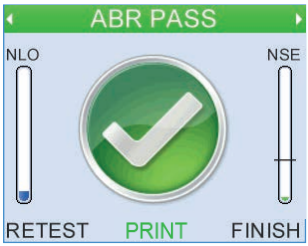
Print and PC-Load settings are located under **Configuration** in **System**, **Setup**. Bluetooth must be set to **Print** or **PC-Load** as required (see section 11.5.4 **Setup**).







11.3.1 Printing at the end of a test



When the ABR test is finished and the result has been saved, select **Print** for a printout of the patient details and test results (see section 10.5).

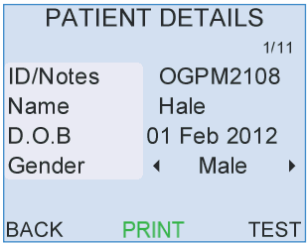
11.3.2 Automatic print/download on save

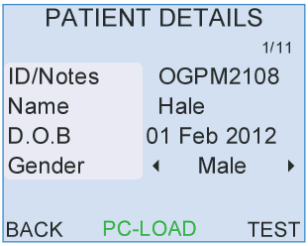
For efficiency, you can configure the Otocheck to automatically print/ download when the test is saved (see 10.5.4 **Setup** for details). The test is saved and a print/download initiated with one key push.

11.3.3 Printing or downloading from records

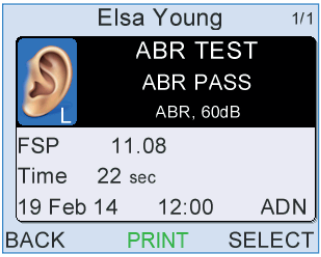
Results can be printed or downloaded from the Otocheck **Records** area. Select the patient for whom you would like to print/download results (see the **Records** section for details of how to retrieve specific records from the database).

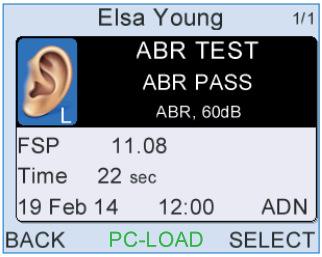
To print or download patient details and all test results for that patient, select **Print** or **PC-Load** on the **Patient Details** screen.





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





Select **PC-Load** on the **Records** menu to download all new records for all patients and tests that haven't previously been downloaded. It is useful to use this option after collecting results over a day's work for instance, when you wish to download all new records for that day.

11.4

The printing process

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

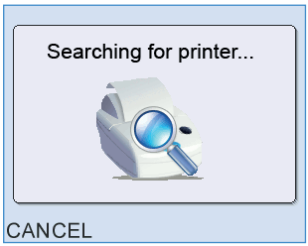
The **Print** option will be shown in green if the Otocheck is currently connected to a printer wirelessly. Otherwise, the **Print** option is shown in black.

Note:

When using multiple Otochecks with wireless connection to a single printer, the last Otocheck to print must be switched off before another Otocheck can print.

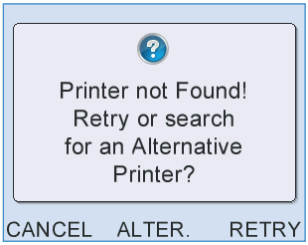
The printer is powered from batteries, or can be connected to mains power when printing. Prior to printing, switch on the printer, using the power button on the top. When the printer is powered, a green light will be displayed. To save power, the printer will automatically switch off after 30 minutes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

When a print is initiated, the Otocheck 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 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 will connect to this printer.

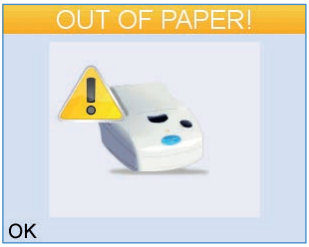
To cancel the printout, select **Cancel**.

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.

11.5 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 will report the printer is out of paper and the following message will be displayed.



Select **OK** to cancel the print job. Retry the printout when you have rectified the problem.

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

11.6 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

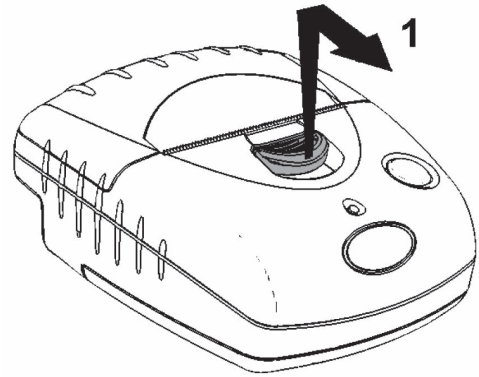
No light
Unit is in sleep mode, has a flat battery, or the battery is not connected

11.7

Paper

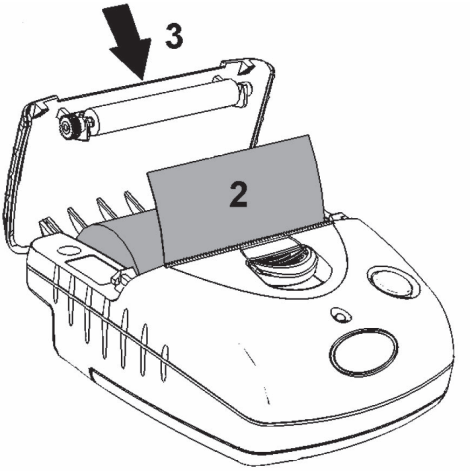
When the printer is switched on, the button provides a paper feed function. A double press of the button will initiate a test print.

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.

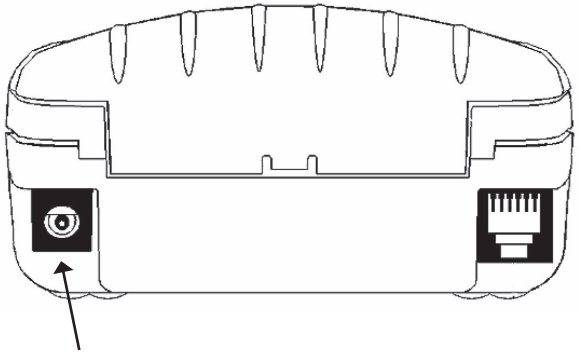


Self-adhesive paper rolls are also available and may be used in the same way as standard paper, but can be stuck to your patient records.

11.8

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.

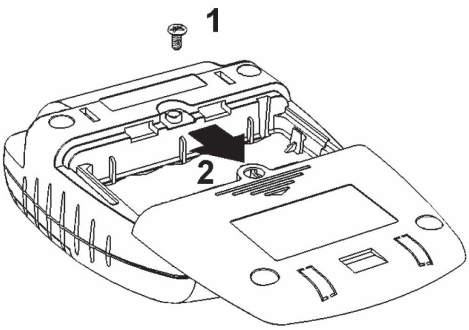
Once fully charged, the printer has enough power for around 10 hours standby use. The batteries should provide enough power to print several rolls of paper. The printer light will flash green/red when the batteries are low.

Note:

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

11.9

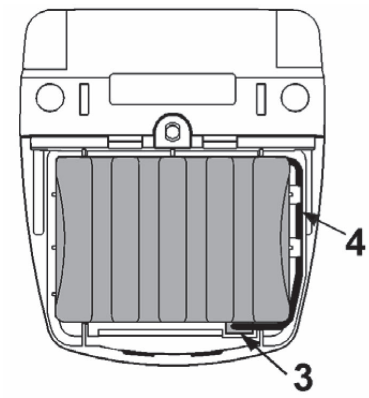
Changing the battery



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.

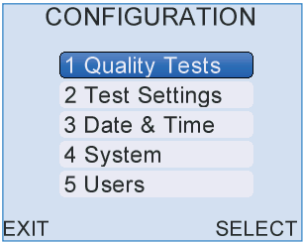
12 Quality tests

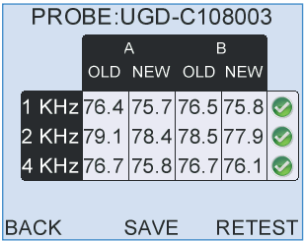
Damage or malfunction of the Otocheck, the probe or the cables can lead to errors in testing. To ensure that any faults are detected before they lead to faulty data collection, the following tests can be performed.

Quality tests should be carried out on a weekly basis.

The quality tests are described below. The Probe Test and ABR Cable Test are initiated from within the **Configuration** menu.

12.1 Probe test





Probe Test is an option accessed from the configuration menu (see chapter 10 **Configuration**).

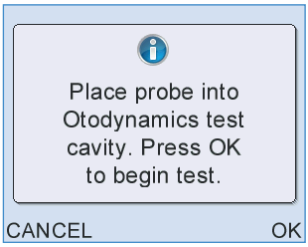
A **Probe Test** should be performed regularly to monitor the calibration of the probe's output stimulus level and microphone response.

Note:

Probes supplied with a new Otocheck 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.

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

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 at the wrong angle or with the probe head over one of the screws may result in incorrect test results.

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

The probe outputs sound at 1, 2 and 4kHz via its loud speaker. The Otocheck 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.

12.1.1

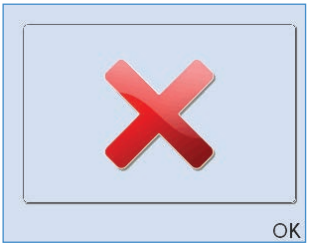
Results

The possible results of the test are:

Pass

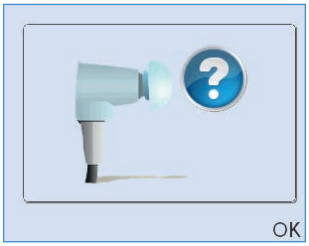
The levels recorded at all frequencies are within the absolute range and within ± 3dB of the probe specific values.

Fail



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

Query



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

Noisy

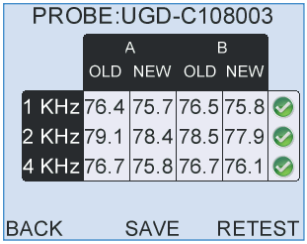
There was significant noise during the calibration test. This noise may have influenced the levels recorded so a **Retest** should be performed.

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

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

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

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

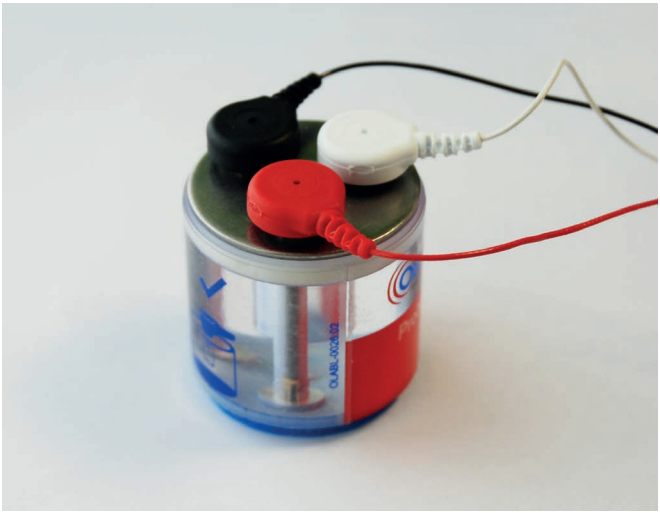
The 1, 2 and 4kHz values may not be stored in the probe if a new probe is being used with the system. To save new data, run a Probe Test, record the values for each frequency and repeat by selecting **Retest.** Check that the values from two sequential tests are within ± 0.5dB before selecting **Save**.

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.

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

12.2 ABR cable test



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

Attach the probe snaps to the top of the cable tester as illustrated.

Select **ABR Cable Test** and wait for the result to be displayed. If the electrode cables are OK then a large tick is displayed on the screen.

If any of the cables fail the test, a large cross is displayed.

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

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

12.3

ABR cavity test

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

Attach the probe snaps to the top of the cable tester as illustrated on the previous page then press **OK**.

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

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

Data collected during the cavity test is analysed against set Stop criteria.

If the result **No Valid ABR** is displayed and the circle is 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 a **No Valid ABR** or a **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 before returning it to use. Refit the probe in the cavity between each test.

13 Probe, tips and accessories

13.1 Probe and service accessories

Your kit will include a probe with appropriate sample coupler tubes and spare probe body/lid. See chapter 2 **Equipment identification** for details.

13.2 Probe cable clip

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

13.2.1 Using the cable clip

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.

13.3

Probe tips

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

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

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

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

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

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

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

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

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

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

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

Large foam tip
REF T-T200L

Small foam tip
REF T-T200S

13.3.2 Use of tips

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

The design of the tips for the UGS probe 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.

ABR tests 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 signals cannot be recorded through fluid.

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

14 Probe care

14.1 Cleaning

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 antiseptic fluid or wipes.

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

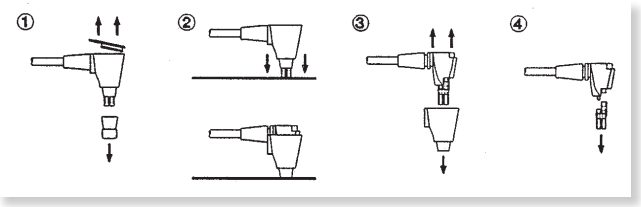
Coupler assembly - Each coupler assembly has two sound tubes. These are protected from ingress of foreign materials by wax guards in the tubes and by the disposable probe tip. There is a loudspeaker at the end of one tube and a microphone at the end of the other. Cleaning solution must not penetrate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

14.2 Changing probe coupler tubes

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

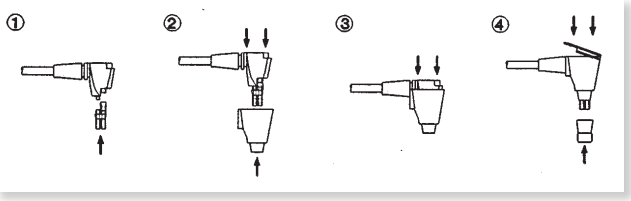
14.2.1 Disassembling the probe

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



14.2.2 Reassembling the probe

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



14.2.3 Notes:

- Fit a new tip for each test.
- Check that the coupler tubes are not contaminated before fitting the tip.
- If the coupler tubes are contaminated, **replace them**. We recommend fitting new coupler tubes at regular intervals (approx every 20-40 tests) as a preventive measure.
- Perform weekly probe QA tests (see chapter 12 **Quality tests**).

14.3 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 recording.

15 Care of the Otocheck

The Otocheck 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
- Do not leave in strong sunlight
- Do not expose to high temperatures
- Do not touch the connector socket pins by hand
- Do not force the connection of the probe or charger/PC cable/printer cable
- Do not expose to moisture (keep it dry).

15.1 Use of the Otocheck and cleaning

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

Other than the probe ear piece and cable, the Otocheck 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 14 **Probe care** for details)

Ensure your hands are cleaned thoroughly between each patient tested.

Clean the Otocheck each day before a testing session, or according to local requirements. Ensure the Otocheck is cleaned if it becomes contaminated. Clean surfaces of the Otocheck with an alcohol based sterile wipe or cloth and antiseptic fluid. Dry the Otocheck with tissue immediately afterwards. Do not allow liquid to enter the instrument and do not immerse in fluid. Do not allow liquid to come into contact with the connection sockets. Do no poke any materials into either the probe or charger/pc cable sockets.

If additional hygienic protection is required, use the Otocheck 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.

16 Power

Important Note:

Only charge your Otocheck with the charger supplied by Otodynamics.

16.1 Battery life

The instrument is powered from the Otocheck's internal rechargeable battery. The battery will provide enough power for over 100 ABR tests from a single charge with a battery life of up to 8 hours. Note that the battery life depends on the Otocheck 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.

16.2 Initial charge

However, the battery will discharge slowly, even if the device is switched off. It is therefore recommended that an initial charge is provided to fully charge the battery before using your Otocheck for the first time.
The Otocheck may be charged in situ via the **Charger and PC cable socket** at the lower end of the ABR Module.

16.3 Standby

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

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

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

If the Otocheck 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.

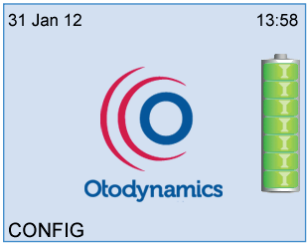
Notes:

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

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

16.4

Battery charge

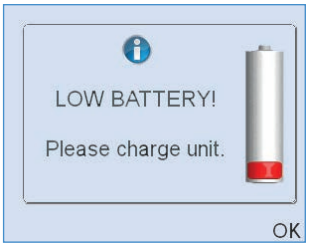


When the Otocheck is switched on, the opening screen shows a battery indicator which displays the remaining level of battery charge.

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

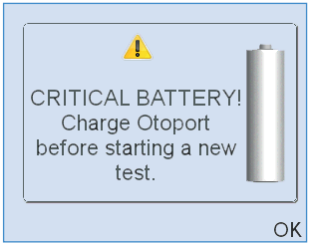
Segments Displayed	Battery Power (%)
7	95 - 100
6	75 - 94
5	55 - 74
4	40 - 54
3	30 - 39
2	20 - 29
1	10 - 19
0	< 10

16.4.1 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.

16.4.2 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 has reached this level of charge. The Otocheck should be charged as soon as convenient.

16.4.3 Auto switch off

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

16.5 Charging the Otocheck

Observe the on-screen battery indicators to determine when to charge your Otocheck. In general it is advisable to charge the Otocheck 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 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 on the same PC at any one time.

16.5.1 Connecting the Otocheck ABR to the charger cable

Switch off the instrument prior to charging.

Connect the mains lead to the charger, plug the mains lead into a power socket and switch on the power. The green light on the charger will illuminate indicating it is powered.

Then connect the slotted charger plug to the base of the instrument. Ensure the arrows are facing upwards.

Notes:

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

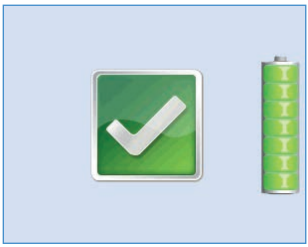
Disconnect the connector and re-insert with the arrow facing upwards.

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

When the Otocheck 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.



16.5.2 Charge indicator lights

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

- **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 for extended periods, even if the device is fully charged. This may be convenient if you wish to leave the device charging overnight.

16.5.3 Disconnecting the Otocheck

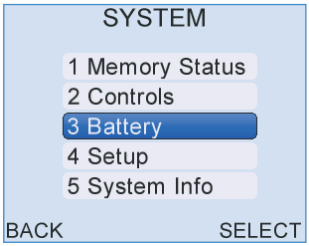
When the charging cable is disconnected, the power light will extinguish on the Otocheck and if the Otocheck was off prior to the charging session, the screen will return to blank. If on during the charging session the current screen will remain displayed.

16.6

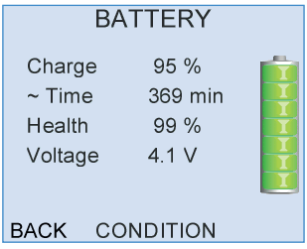
Conditioning the Otocheck battery

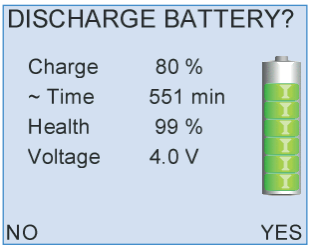
In order to maintain the Otocheck battery and keep it at optimal performance you should condition the battery once per year, or if the unit's battery appears to run down more quickly than expected. This process involves completely discharging the battery, using a function provided in the Otocheck **System** area and then fully charging the device (see chapter 10 **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 will automatically switch off when the battery has been fully discharged. Now fully charge the Otocheck 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.





16.7 Additional battery care

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

17 Equipment troubleshooting

17.1 Otocheck lock-up

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

17.2 Switch on

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

17.3 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 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.

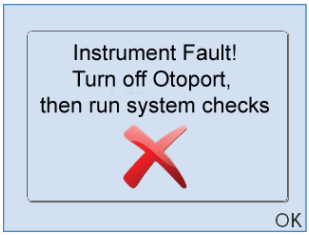
Select **Reset** to reset the Otocheck to factory default settings. Changes from the default setting and any users or worklist patients added to the device will be lost. No test data will be removed.

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

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

17.4 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 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 12). If the tests are 'OK' the device is functioning correctly and can be used for testing again.

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

17.5

Hardware fault messages

The Otocheck 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 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.

18 Training

It is important that the operator of the Otocheck 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 15.1 **Use of the Otocheck and cleaning**).

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

19 Obtaining service

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

Otodynamics highly recommends that the Otocheck is serviced every three years (this is not a device safe operation requirement). The Otocheck 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 free of charge.

The expected service life of the Otocheck 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 instrument and probe, are clean and free from contamination. Otodynamics cannot guarantee the equipment will be contamination free when returned to you and suggest that it is cleaned in accordance with your infection control protocols before being put back into use.

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

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www.otodynamics.com

20 Calibration

The Otocheck is a precision instrument designed to make accurate ABR measurements. 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 12) to ensure the instrument is working correctly. In addition to this, the calibration of the instrument should be periodically checked with laboratory equipment. Otodynamics advises regular calibration checks at intervals not exceeding 3 years and ideally annually.

The **About** screen displays the calibration due date for your Otocheck, if a date has been set (see section 10.5.5). A prompt when switching on will warn that calibration is due from 30 days before the due date.

Contact your dealer or Otodynamics to arrange a calibration check.

21 Mode of operation

21.1 ABR test

Stimulus level	5-60 dBHL
Stimulus rate	51.8-57.9Hz
Stimulus polarity	Alternating
Stimulus type	Click or Chirp (see below)
Stimulus repetition rate	51.8-57.9 Hz
Evaluation method	Fsp & Template Correlation
Sampling rate	25.6 kHz
Frame length	17.3-18.8ms
Amplifier gain	75dB
Amplifier CMRR	> 60dB at 100 Hz
Input impedance	1MΩ || 10 nF
Amplifier noise	20 nV / Hz @ 0.1-1 kHz
Input bandwidth	150-1000 Hz
Notch filter	None
Impedance sense Waveform	For the measurment of impedance, the device delivers a 400Hz square wave giving in a worst-case (in to zero ohms) RMS current of <5uA with a <5uA DC component. The complete impedance measurement takes 2-3 seconds and consists of four bursts of 400Hz square wave. The first burst is 0-700mS long and the following three are 300-700mS long. Additionally, there are transient currents produced at device switch on and shut down. These have a peak current of less than 100uA with a duration of less than 0.5 secs.

Impedance test range	0 to 99 kΩ
Display	EEG-level, ABR detection probability
Electrodes	Disposable wet gel electrodes (FDA 510(k) cleared)
Electrode Montage	
Positive electrode	Forehead
Negative electrode	Ipsilateral mastoid or nape of neck
Common electrode	Back of shoulder, cheek, or contralateral mastoid

21.1.1

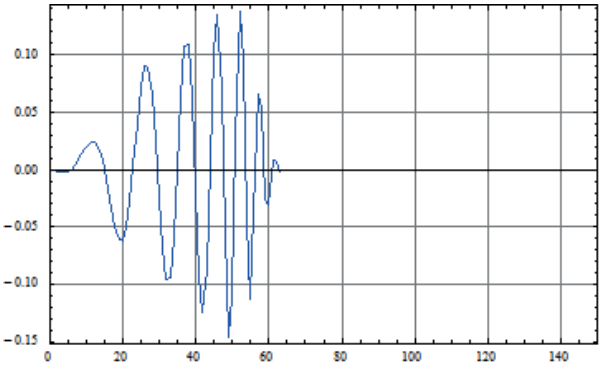
Stimuli description

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

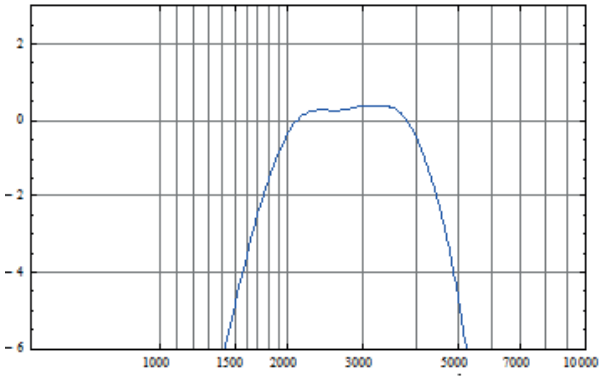
Chirp stimuli: 2.5ms duration rapidly swept tone of alternating polarity. The frequency dispersion of the chirp is defined by the delay at frequency $T(f)= k * f^{-d}$ with k=0.0920, and d=0.4356.

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

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



Short Chirp frequency domain:



21.1.2 Hearing Level determination

The hearing threshold for these stimuli was determined in a group of 20 subjects with normal hearing aged <25. The peak-to–peak levels (dBppSPL) of these stimuli were measured in a Brüel & Kjær Ear Simulator Type 4157. For short duration stimuli the dBppSPL values are always much higher than their dBHL value. For the Click dBppSPL in the ear simulator exceeds Otocheck dBHL value by 33.6dB. For the Chirp dBppSPL in the ear simulator exceeds Otocheck dBHL value by 29.5dB.

21.1.3 Screening test sensitivity

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

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

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

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

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

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

Sensitivity of the Otocheck ABR for ABR screening

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

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

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

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

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

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

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

21.1.4 ABR test specificity

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

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

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

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

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

Important Notes:

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

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

22 Technical specifications

22.1 Otocheck ABR

Note:

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

22.1.1 Physical

Hand-held module:	278mm x 84mm x 38mm
Weight:	490g
Charger:	90mm x 38mm x 28mm – Weight 120g

22.1.2 Interfaces

Probe connectors compatible with Otodynamics UGS and UGD probes (8 pin)
Electrode connectors compatible with 1.5mm 'Touchproof' DIN 42-802 connectors
Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1or 2.0) via Data Cable
Bluetooth wireless print (option)

22.1.3 Indicators

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

22.1.4 Keypad

19 key alphanumeric with cursor control and soft keys

22.1.5 Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

22.1.6 Power

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

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

22.1.7 Hardware Option

Bluetooth wireless printing

22.1.8 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

22.1.9 Analogue performance

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

22.1.10 Accuracy

The Otocheck 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.

22.1.11 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 Otocheck Product from heat and radioactive sources
Keep Otocheck 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 Otocheck Medical Device is not intended to operate in oxygen rich environments and is not to be used in conjunction with flammable agent.

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

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

Declared Conformity:

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

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

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

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

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

  Diisobutyl phthalate (DIBP – 0.1%). Otodynamics 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 (CFC's), hydrochlorofluorocarbons (HCFC's), hydrofluorocarbons (HFC's), Tributyl Tin (TBT); Triphenyl Tin (TPT) and Tributyl Tin Oxide (TBTO).
- Otodynamics products do not contain Latex and do not contain Materials Derived from Animal Sources.
- Materials used in the manufacturing processes for the Otodynamics products are not Substances of Very High Concern (SVHC) and are in line with REACH regulations.
- Otocheck and Otocheck+ABR packaging is recyclable.
- The Otocheck and Otocheck+ABR medical device / system is not supplied sterile or intended to be sterilized by the user. It is recommended that probe tips, electrodes and ear cups are for SINGLE PATIENT use only.

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

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

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

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

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

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

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

22.2 Electromagnetic compatibility - User Guidance

The Otocheck 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; and the susceptibility of the Otocheck 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.

22.2.1 Suitable environments for operation

The Otocheck 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.

22.2.2 Essential performance

Electromagnetic (EM) immunity of this Otocheck 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's specified operating environment. During these tests the Otocheck 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.

22.2.3 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 including cables specified by the manufacturer. Otherwise, degradation of the performance of this instrument could result.

22.3 Electromagnetic compatibility - Technical Description

22.3.1 Compliance levels

The Otocheck 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.

22.3.2 Deviations from the standard

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

22.3.3 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.

22.3.4 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.

22.3.5 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.

22.3.6 Specific Absorption Rate SAR

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

22.3.7 RF Exposure

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

22.3.8 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.

22.4 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 ABR test uses short duration stimuli. During test setup a ‘rectangular stimulus’ is used. During data collection either the rectangular stimuli or a ‘chirp’ is used. The rectangular is a unipolar pulse of 78uS length. The chirp stimulus is described in 21.1.1 **Stimuli description**. 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 screen and the signal level in the IEC 60711 occluded ear simulator:

rectangular stimulus: -6.1d

The following conversion factors convert between the signal level generated in the ear simulator by the Otocheck 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

Suppose, for example, that a stimulus level of 90dB is reported by the Otocheck 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 alternates between positive and negative.

22.5

End of life management

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

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

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

22.6

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

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