



DPOAE TEOAE DEVICE



CORTI

USER MANUAL

Title: GSI Corti™ User Manual



Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1,
5500 Middelfart
Denmark

Copyright © 2020 Grason-Stadler. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means without the prior written permission of GSI. The information in this publication is proprietary to GSI.

Compliance

The CE 0123 mark identifies compliance with the Medical Device Directive 93/42/EEC. Grason-Stadler is an ISO 13485 certified corporation.



0123

Caution: US Federal law restricts this device to sale by or on the order of a physician or licensed hearing care professional.

TABLE OF CONTENTS

| | |
|---|----|
| Table of Contents | 1 |
| Preface..... | 5 |
| Manual Conventions..... | 5 |
| Regulatory Symbols | 6 |
| Warnings and Cautions..... | 9 |
| Important Safety Instructions | 9 |
| Safety Precautions | 9 |
| Charging..... | 11 |
| Electric Shock Hazard | 11 |
| Explosion | 11 |
| Battery | 11 |
| Environmental Factors | 11 |
| Calibration | 11 |
| Introduction | 12 |
| Intended Use..... | 12 |
| Indications For Use | 12 |
| How Does the Corti Device Work?..... | 13 |
| What are DPOAEs? | 13 |
| What Are TEOAEs? | 14 |
| What Do Otoacoustic Emission Results Tell Us? | 14 |
| What Frequency Range of Hearing is Estimated? | 14 |
| How are the Results Stored and Reported?..... | 14 |
| Sensitivity and Specificity | 15 |
| Setup..... | 16 |
| Unpacking the System..... | 16 |
| Optional Accessories | 16 |
| Cradle (Optional)..... | 16 |
| Battery Charging | 17 |
| Installing the Probe..... | 18 |
| Attaching Probe Tube | 18 |
| Attaching Eartips..... | 18 |

| | |
|---|----|
| Probe Holder | 19 |
| Operating Instructions | 20 |
| Preparing the Patient for Testing | 20 |
| Turning On the Instrument | 20 |
| Control Panel | 20 |
| Main Menu | 21 |
| Selecting the Test Protocol | 21 |
| Starting a Test | 22 |
| AutoStart Probe Check | 22 |
| Test Phase | 23 |
| SNR Bar Graph View | 23 |
| Value Graph View | 24 |
| Viewing Results | 24 |
| Viewing DPOAE Results with Normative Data | 26 |
| Test Technique | 27 |
| Noise Sources | 27 |
| Turning Off the Instrument | 27 |
| Managing Results | 28 |
| Saving Results | 28 |
| Deleting Results | 29 |
| Printing to a Thermal Printer | 30 |
| Connecting to the Corti Data Manager | 31 |
| Understanding Printed Results | 31 |
| Rounding Results | 32 |
| Clock Settings | 33 |
| Accessing the Clock Menu | 33 |
| Changing the Date/Time | 33 |
| Instrument Settings | 34 |
| Wireless Device Pairing | 34 |
| Clearing Test Results | 35 |
| Auto Shutdown Time | 35 |
| Save Mode/Storing Test Results | 35 |
| Minimum Amplitude Value | 36 |

| | |
|---|----|
| Clock Mode | 37 |
| Graph Style | 37 |
| Norms | 37 |
| Reverse Frequency..... | 38 |
| Auto Stop | 38 |
| Language | 38 |
| Reset to Default..... | 38 |
| Advanced Options | 39 |
| DPOAE Diagnostic Unit..... | 39 |
| Instructions for Customizing a Test Protocol..... | 39 |
| Selecting the Level of Primary Tones..... | 40 |
| Setting the Averaging Time..... | 40 |
| Setting the PASS SNR Level..... | 40 |
| Setting the Number of Frequencies for PASS | 41 |
| Reset Protocol..... | 41 |
| Save Protocol..... | 42 |
| TEOAE Diagnostic Unit..... | 42 |
| Instructions for Customizing a Test Protocol..... | 42 |
| Selecting the Averaging Time | 43 |
| Setting the PASS SNR Level..... | 43 |
| Setting the Number of Frequencies for PASS | 44 |
| Reset Protocol..... | 44 |
| Save Protocol..... | 44 |
| Cleaning and Maintenance | 45 |
| Cleaning and Disinfection | 45 |
| Maintenance..... | 46 |
| Probe tube Replacement | 46 |
| Status/Error Messages | 47 |
| Display Messages:..... | 47 |
| Indicator LEDs (lights)..... | 48 |
| Troubleshooting | 49 |
| Appendix A: Specifications..... | 52 |
| PROBE SPECIFICATIONS | 52 |

| | |
|---|----|
| INSTRUMENT SPECIFICATIONS | 52 |
| POWER SUPPLY SPECIFICATIONS (use only approved power supply)..... | 53 |
| ENVIRONMENTAL REQUIREMENTS | 53 |
| Appendix B: Flowcharts..... | 54 |
| Measurement..... | 54 |
| Setup Menus | 55 |
| Appendix C: Test Sequence | 57 |
| DPOAE..... | 57 |
| TEOAE..... | 57 |
| Comment about Variations in the SNR Estimate | 58 |
| Appendix D: Pass/Refer Criteria | 59 |
| DPOAE..... | 59 |
| TEOAE..... | 60 |
| Appendix E: Configurations and Test Protocols..... | 62 |
| Diagnostic Configurations..... | 62 |
| DPOAE Diagnostic Default Protocols..... | 63 |
| TEOAE Diagnostic Default Protocols | 64 |
| GSI Corti Screening Configurations | 64 |
| DPOAE Screening Default Protocols..... | 65 |
| TEOAE Screening Default Protocols | 65 |
| Appendix F: Standards Compliance | 66 |
| Appendix G: Specification of Input/output Connections..... | 67 |
| OAE Probe | 67 |
| Appendix H: Warranty..... | 68 |
| Appendix I: Recycling and Disposal..... | 69 |
| Appendix J: Electromagnetic Compatibility | 70 |
| Electrical Safety, EMC and Associated Standards..... | 70 |

PREFACE

This user manual provides information about the GSI Corti OAE instrument. This manual is intended for technically qualified personnel.

Please note: This User Manual is not intended as a training manual. The reader should consult standard audiology texts for the theory and application of the tests provided by this instrument.

This operating manual contains information pertinent to the use of the GSI Corti system including safety information as well as maintenance and cleaning recommendations.



READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THE SYSTEM!

MANUAL CONVENTIONS

Throughout this manual, the following meaning of warnings, cautions and notices are used.

WARNING



The WARNING symbol identifies conditions or practices that may present danger to the patient and/or user.













CAUTION

















The CAUTION Symbol identifies conditions or practices that could result in damage to the equipment or loss of data.

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during operation.

REGULATORY SYMBOLS

| Symbol | Description |
|---|--|
|  | Serial Number |
|  | Date of Manufacture |
|  | Manufacturer |
|  | Caution, Consult Accompanying Documents |
|  | Return to Authorized Representative, Special Disposal Required |
|  | Reference Number |
|  | B Patient Applied Part According to IEC60601-1 |
|  | Consult Operating Instructions |
|  | Keep Dry |
|  | Transport and Storage Temperature range |
|  | Logo |
|  | EU Authorized Representative |

| Symbol | Description |
|---|---|
|  | Nonionizing electromagnetic radiation |
|  | Global Trade Item Number |
|  | For Use by or on the order of a licensed medical professional. |
|  | Recycle Lithium ion battery |
|  | Recycle - Taiwan |
|  | China RoHS |
|  | Direct Current (DC) |
|  | Only those products bearing the UL Classification Mark for the U.S. and Canada should be considered as being covered by UL's Classification and Follow-Up Service and meeting the appropriate U.S. and Canadian requirements. |
|  | Conforms to European Medical Device Directive 93/42/EEC |
|  | FCC 47CFR, Part 15.247 & 15.249 (Wireless) |
|  | Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative. |

| Symbol | Description |
|---|--|
|  | <p>Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com</p> <p>A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.</p> |
|  | <p>Indicates that the device is a Medical Device</p> |
|  | <p>Class II medical equipment</p> |

WARNINGS AND CAUTIONS

IMPORTANT SAFETY INSTRUCTIONS



The following safety precautions must be observed always. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The instrument must only be used by hearing health care professional qualified to perform otoacoustic tests such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the specialist. Users should use their professional skills when interpreting the results and this should be done in conjunction with other testing as deemed appropriate given their professional skills. Incorrect use could lead to wrong results. It is intended for transient use as a screening and diagnostic tool. However, no surgical or medical procedure should be undertaken solely based on results obtained from the instrument.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury. It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

SAFETY PRECAUTIONS



This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from GSI.

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with GSI published specifications.

No parts of the equipment can be serviced or maintained while in use with the patient.

Never insert the probe into a patient's ear canal without a suitable ear tip fitted to the probe. Use only the recommended disposable ear tips. These are for single use only - that is, each ear tip is intended to be used once only for a single ear for a single patient. Do not reuse ear tips as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

Latex is not used anywhere in the manufacturing process. The base material for the ear tips is made from silicone rubber.

The device is not intended to be used in environments exposed to fluid spills. No means is specified for fluid protection (not IP classed). Do not use the device in the presence of fluid that can contact any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorized service technician. Do not immerse the unit in any fluids. See the Routine Maintenance Section of this manual for the proper cleaning procedure for the instrument and its accessories and the function of single-use parts.

Do not drop or otherwise impact this instrument. If the instrument is dropped or damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

The device is not user repairable. Do not attempt to open, modify, or service the instrument. No modifications of the equipment are allowed by anyone other than a qualified GSI representative. Modification of the equipment could be hazardous. Return the instrument to the manufacturer or distributor for all repair, battery replacement and servicing requirements. Opening the instrument will void the warranty.

The Corti product has been verified by an independent laboratory to conform to international standards for EMC (electromagnetic emissions and immunity). The user is advised to avoid installation and use of this instrument in proximity with other devices or equipment that may emit or be susceptible to electromagnetic interference, including mobile phones. If the instrument is used adjacent to other devices or equipment, the user is instructed to verify that no disturbance is found in the operation of this or other equipment in proximity.



Instruments which bear the Underwriters Laboratories, Inc. label should be interconnected with accessories that have the proper electrical compatibility and are listed as meeting the requirements of the UL Medical and Dental Equipment Standard. Connection of accessories not meeting these requirements may result in electrical leakage currents in excess of those allowed by the standard and present a potential electrical shock hazard to the person being tested.



This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

CHARGING



The Corti Otoacoustic Emission Test System should be charged using only the provided power supply. Injury to personnel or damage to equipment can result when a three-prong to two-prong adaptor is connected between the Corti power supply and an AC outlet.

ELECTRIC SHOCK HAZARD



Do not open the case of the Corti Instrument. Refer servicing to qualified personnel. Do not touch the contacts on the bottom of the instrument and the patient at the same time. Do not connect the instrument to the patient and the PC at the same time. In case of emergency, disconnect the instrument from the supply mains by removing the micro-USB cable from the connector.

EXPLOSION

This system is not explosion proof.



Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device near flammable anesthetic gases. Do NOT use the system in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

BATTERY



This instrument contains a rechargeable lithium-ion battery. Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures. The battery is not user replaceable and must be returned to an authorized GSI service location for repair.

ENVIRONMENTAL FACTORS



Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30 % and 90 % (non-condensing). Transport the instrument and store the instrument in temperatures between 5 °C / 41 °F to 40 °C / 104 °F.

CALIBRATION

Annual calibration recommended. Have an authorized service technician perform electrical safety checks on the unit in order to maintain continued compliance to IEC and UL 60601-1.

INTRODUCTION

The purpose of the Corti test system is to provide rapid measurement and documentation of Distortion Product Otoacoustic Emissions (DPOAEs) or Transient Evoked Otoacoustic Emissions (TEOAEs).

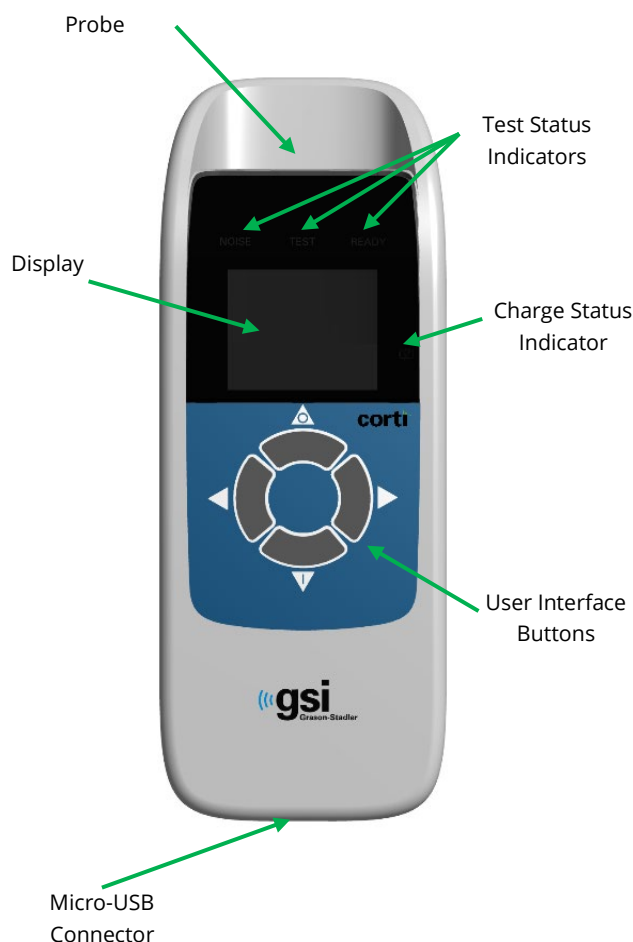
INTENDED USE

The GSI Corti is a test instrument that measures otoacoustic emissions in infants, children, and adults.

INDICATIONS FOR USE

The GSI Corti series is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks that are directed into the ear canal. Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing, or at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

HOW DOES THE CORTI DEVICE WORK?



The system consists of the instrument, probe, printer, single-use eartips replaceable probe tubes and other accessories. The Corti instrument contains the hardware and software for generating the test stimuli, measuring and displaying the OAEs, and storing the results until they are printed. The plastic housing contains circuit boards that provide the signal processing and display the test results. The instrument also contains a rechargeable lithium-ion battery to power the device. The instrument uses a liquid-crystal display (LCD) and three light-emitting diodes (LEDs) to provide a visual display of test status to the operator. Four push buttons located on the keypad of the device allow the user to control testing and printing, and to reset test protocols.

The Probe houses the speaker and microphone which produce test stimuli and measure the sound pressure level (SPL) present in the sealed ear canal. Interface of the instrument to the ear canal is accomplished through disposable eartips, which fit onto the probe tube. The disposable eartips are color coded to facilitate easy selection by size.

WHAT ARE DPOAEs?

Distortion Product Otoacoustic Emissions (DPOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, after stimulation of the auditory system with a pair of pure tones at frequencies f_1 and f_2 . The frequency pairs are presented at a F_2/F_1 ratio of 1.22. The resulting emission of interest is the distortion product tone at the frequency $2f_1-f_2$.

The Corti instrument generates a series of test tones, directs them into the ear canal, and then measures the level of the DPOAE tone generated by the cochlea. By using different test frequencies, the Corti device provides an estimate of outer hair cell function over a wide range of frequencies.

WHAT ARE TEOAES?

Transient Evoked Otoacoustic Emissions (TEOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, after stimulation of the auditory system with a series of wideband clicks.

The Corti instrument generates a series of clicks, directs them into the ear canal, and then analyzes the spectrum of the returning signal, separating the noise and emission. By using band pass filters, the Corti device provides an estimate of outer hair cell function over a wide range of frequencies.

WHAT DO OTOACOUSTIC EMISSION RESULTS TELL US?

The presence of otoacoustic emissions suggests normal outer hair cell function, which in turn correlates to normal hearing. However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function or the presence of pathology; however, it should be followed with full audiologic diagnostic testing and/or medical evaluation as appropriate.

WHAT FREQUENCY RANGE OF HEARING IS ESTIMATED?

DPOAEs: Approximately 1 kHz to 12 kHz (depending on the frequency range selected).

TEOAEs: Roughly 500 Hz to 4 kHz.

HOW ARE THE RESULTS STORED AND REPORTED?

When the Corti is set in its default settings, the instrument will store the results from one patient (left and right ear) in its non-volatile memory for subsequent printing. However, the Corti instrument can store up to 500 test results. The results are displayed via the LCD on the front of the device and are stored in the device's internal memory. After testing is completed, results can be printed using the printer and/or exported to a computer. Test results are stored in the non-volatile memory so the operator can delay printing until a later time if desired.

SENSITIVITY AND SPECIFICITY

Sensitivity and specificity of this type of device are based on the test characteristics defined by the user and may vary depending on environmental and operating conditions. The presence of otoacoustic emissions suggests normal outer hair cell function, which in turn correlates to normal hearing. However, a passing result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function; however, it should be followed with full audiologic diagnostic testing.

SETUP

UNPACKING THE SYSTEM

The following parts are shipped standard with each Corti system:

- Corti Unit
- Corti Probe
- GSI Corti Software and Manuals USB
- GSI Suite Software and Manuals USB
- Single Use Eartip Kit
- Communications Cable, USB A/Micro-B
- Charging Cable, PSU 5V/Micro-B
- Corti Quick Guide
- Calibration Certificate
- Sanibel Preemie Ear Tip Green
- Comply Ear Tip Sample Pack
- Probe Tube Removal Tool

If any of these parts are missing, contact your special equipment distributor or GSI. We recommend that you save the shipping box and packing materials in case you need to store or ship the system.

OPTIONAL ACCESSORIES

The Corti optional accessories include a wireless thermal printer, cradle and carry case.

Cradle (Optional)

The Corti unit can be placed in the optional cradle for charging the Corti or connected to a PC via USB or wirelessly for communication to the Corti Data Manager. Charging and connection to the PC can also be conducted directly from the Corti unit. The remainder of this manual assumes that charging and communication to the PC is direct from the Corti unit but note that either is possible.

BATTERY CHARGING



The Corti instrument is powered by an integrated rechargeable lithium-ion battery providing 20 hours of operation between full charging. The battery status is indicated by the battery icon shown in the upper right corner of the Main Menu. Full battery charge is represented by a full battery symbol on the display and reduces to an empty battery in increments corresponding to the discharge of the battery.

To charge the unit, connect the Micro-USB port on the bottom of the instrument as shown, and connect the wall charger to the mains outlet. To charge the Corti unit through the cradle, connect the Micro-USB to the back of the cradle and the wall charger to the mains outlet. Place the Corti unit firmly into the cradle.



NOTE: Misalignment of the plug and socket can cause damage. The plug and socket should be visually inspected prior to each installation of the charging cable. If damage is observed, contact GSI.

The battery charge status indicator, located to the right of the display, provides a visual indication (BLUE) of the battery recharging function and battery status during operation.

During battery charging the indicator will be lit whenever the Micro-USB connector is engaged and powered. The rate of illumination of the indicator provides a means of identifying the status of the charging function, and is defined as follows:

- Steady-state illumination indicates the battery is fully charged. This identifies that the charging cycle has been completed or was not implemented because the battery was already fully charged.
- Slow blink illumination indicates the charging function is in process.
- Fast blink illumination indicates a fault condition in which the user would be directed by the user manual to return the instrument for service.

During instrument operation, the user is warned of a low battery condition by the following illumination of the battery status indicator:

- Two fast blinks followed by a pause and then repeated until the battery is charged.

INSTALLING THE PROBE

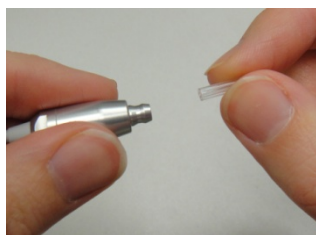


Insert the Probe's HDMI connector firmly into the socket on the top of the Corti. The plug will fit in only one direction. The GSI wave logo will align with the instrument control panel.



NOTE: Misalignment of the plug and socket can cause damage. The plug and socket should be visually inspected prior to each installation of the remote probe. If damage is observed, contact GSI.

ATTACHING PROBE TUBE



A probe tube must be applied to the probe head before an eartip is applied. Insert a new probe tube into the probe head until it is fully seated. A properly inserted probe tube will snap securely into place when it is fully seated in the probe head. It is not necessary to replace the probe tube with each ear tip; the tube is reusable as long as the probe

tube is visibly free from debris or cerumen. To remove a probe tube, grasp the tube and pull gently away from the probe head with a slight twist or use the probe tube removal tool. The Probe Tube Removal Tool may also assist in inserting and removing the probe tool. See removal tool instruction sheet.

NOTE: If the probe tube becomes dirty or clogged, it must be replaced. See the section Probe Tube Replacement for further information.

ATTACHING EARTIPS

The Corti instrument comes with a box of disposable, single use eartips that fit a variety of ear canal sizes. The Corti probe must have a probe tube applied and an eartip attached before inserting it into an ear canal. The determination of the appropriate eartip size should be made by persons with proper training and experience. The eartip must seal the ear canal. The best test results are obtained when the eartip is inserted deeply into the ear canal instead of flush with the ear canal opening. Caution must be taken, however, to ensure that the eartip does not extend too deeply into the ear canal. Use only the eartips approved for use with the instrument. The eartips are disposable and must be replaced after each patient.



After selecting an eartip, push it onto the probe tube until it is flush against the base of the probe tube. Twisting the eartip slightly while pushing it onto the probe tube is recommended. Be sure the eartip is fully seated on the probe. There should be no gaps between the eartip and the collar of the probe head.



To remove the eartip, grasp the eartip gently at the base and twist it while pulling it straight off the end of the probe tube.

NOTE: Grasping the base of the eartip will prevent the probe tube from being inadvertently pulled out of the probe head along with the eartip.

PROBE HOLDER



It is strongly recommended to place the probe into the probe holder when the Corti is not in use. This should be done while the Corti is placed on a countertop or table, or when the Corti unit is resting in the Corti cradle. Placing the probe into the holder will help to protect the probe head.



Make sure the probe holder is towards the end of the probe cable at the GSI wave logo / HDMI connector end. Gently push the probe cable into the probe holder at the point of the probe head.

PROBE TUBE REMOVAL TOOL



The probe tube removal tool may be used to remove a dirty probe tube and insert a new probe tube. See packaging instructions for description of how to use.

OPERATING INSTRUCTIONS

PREPARING THE PATIENT FOR TESTING

Otoscopic examination of the patient's ear canals should be performed prior to testing. Excessive cerumen or vernix in the ear canals may interfere with the test and give invalid or incomplete results. Patients with excessive cerumen, debris, or foreign bodies in the ear canals should be referred to an audiologist or physician for removal of the blockage prior to testing.

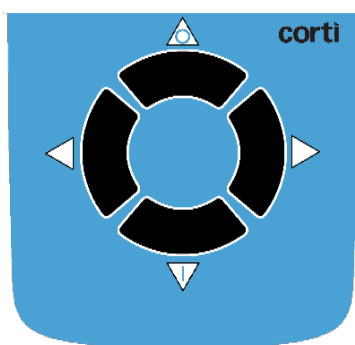
Place the patient in a position that will allow easy access to the ear canal. The patient should remain still and quiet while the test is being performed.

TURNING ON THE INSTRUMENT

To turn on the Corti instrument, press the DOWN button located below the instrument's display screen. The yellow TEST light will appear briefly just above the display. The green READY light will remain on indicating the instrument is ready for use. A Flash Screen will appear briefly, indicating the software version, serial number, next calibration date, and type of instrument:

- SCR Screener with TE or DP
- SC+ Screener with TE and DP
- STD Diagnostic TE or DP
- CMB Diagnostic TE and DP

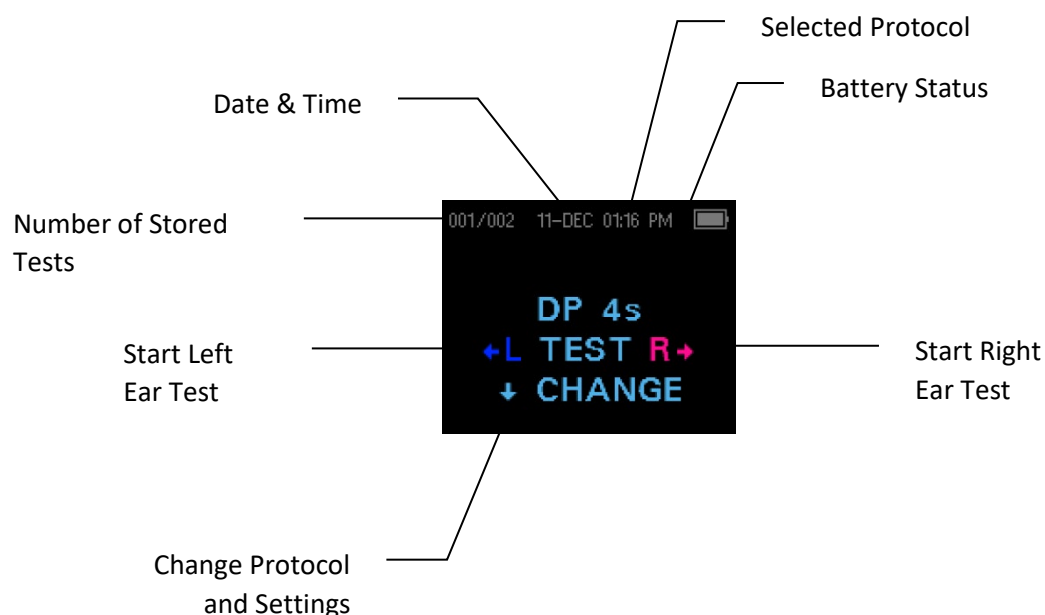
CONTROL PANEL



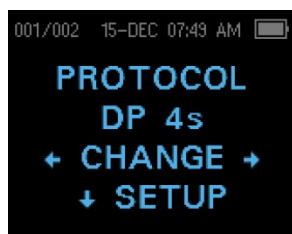
The Corti instrument uses 4 buttons to control all functions of the instrument. These buttons are arranged in a directional cursor format. The arrows on the keypad (←LEFT, →RIGHT, ↑UP, and ↓DOWN) correspond to the arrows that are used on the screen. The screen will indicate which button to push by showing the appropriate arrow.

NOTE: The UP key will always bring the instrument back to either the previous menu or the main menu. The UP key will also access the print command from the Main Menu.

MAIN MENU



SELECTING THE TEST PROTOCOL

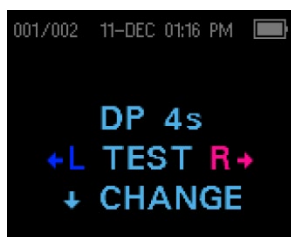


The currently selected protocol is shown on the Main Menu. To change the selected protocol press ↓CHANGE at the Main Menu. The Change Protocol display will appear. Use the ←CHANGE→ arrow buttons to change the selected protocol. Press the up arrow to return to the Main Menu to begin testing. Press the ↓SETUP to enter the setup menus.

For Diagnostic DPOAE or TEOAE units, there is one default test protocol and several user definable protocols. For Screener DPOAE or TEOAE units there are 2 fixed protocols. *Appendix E* contains a list of protocols for each device configuration. Instructions for customizing protocols on the Diagnostic units can be found in the sections *Advanced Options for DPOAE Diagnostic Unit* or *Advanced Options for TEOAE Diagnostic Unit*.

NOTE: The default protocols: DP 4s, DP 2s, TE 64s and TE 32s cannot be customized.

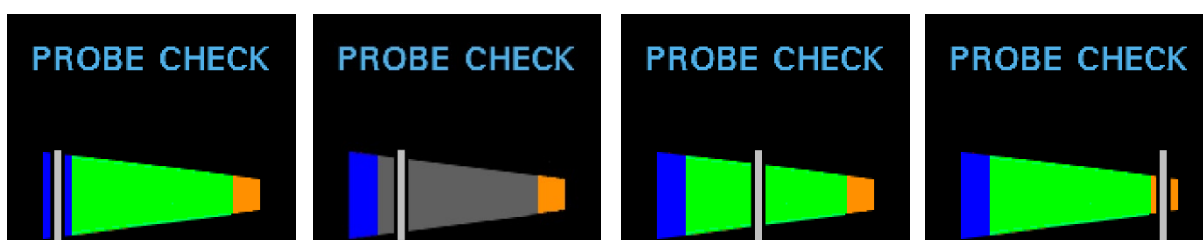
STARTING A TEST



To obtain a seal and measure emissions, gently insert the eartip into the patient's ear canal. It should fit snugly and comfortably. The best test results are obtained when an eartip is inserted deeply into the ear canal instead of flush with the ear canal. To begin a test, insert the probe into the ear and select either the ←LEFT or RIGHT→ arrow key to indicate which ear will be tested.

AUTOSTART PROBE CHECK

After the test ear is selected, the AutoStart Probe Check will begin automatically. The Probe Check display shows a cone, larger at the left and tapering toward the right, representing the ear canal volume from very large (blue area) to very small (orange



area).

The vertical white bar indicates the measured ear canal volume and probe fit stability:

- Blue = The ear canal volume is too large for the test to begin. The probe is not in the ear or there is a large leak.
- Gray = Ear seal indicator will remain gray until a seal is obtained.
- Green = The ear canal volume is in the target range for testing. The test will begin automatically if the probe fit is stable.
- Orange = The ear canal volume is too small for the test begin. The eartip may be pressed against the ear canal wall or the probe tube may be completely clogged.

Appropriate adjustments of the eartip position and size selection should be made until the white indicator falls within the green area and remains stable. If the test will not progress past the Probe Check phase, change the probe tube, check that the probe connector is fully seated in the socket, and try again.

NOTE: To test children with PE tubes, the Probe Check needs to be disabled. This is accomplished by first inserting the probe with appropriate ear tip into the ear canal and obtaining a proper seal. To disable AutoStart at the Main Menu select the ear to be tested by holding down the RIGHT or LEFT arrow keys for 3 seconds until the green “ready” light turns off. Once the key is released, the Corti will calibrate and test as before. The appropriate in-the-ear stimulus intensity levels are applied to ears with PE tubes.

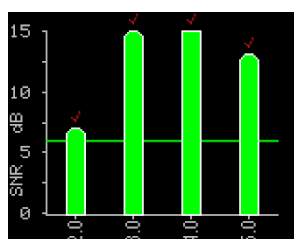
TEST PHASE

The Corti instrument will automatically perform a calibration at the start of each test. During calibration a series of tones will be presented to the ear canal to calibrate the levels of the frequencies to be tested. Following calibration of the test tones, the test phase will begin automatically.

The display on the Corti test instrument will indicate the results of the test with a graphic display. The display will be generated and shown during the test and can be reviewed after the test is complete.

The Corti allows the user to select from two options for viewing the results. The SNR graph view shows the signal-to-ratio for each DP test frequency or TE test band. The Value graph view shows the absolute emission and noise levels for each DP test frequency or TE test band.

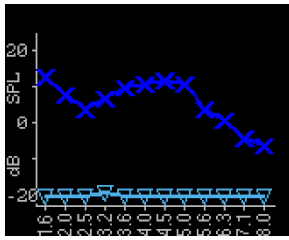
SNR BAR GRAPH VIEW



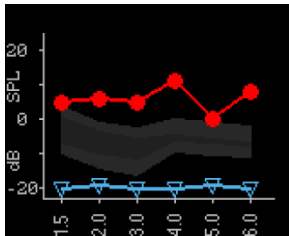
The SNR bar graph view displays the signal-to-noise ratio (SNR) test results as the emissions and noise floor are measured. Each column represents one DP test frequency or TE frequency band. The height of each column represents the SNR measured.

When a protocol with a Pass criterion has been selected, the user will see a horizontal green line at the decibel level corresponding to the SNR required for a PASS. Green bars are a Pass, yellow a non-Pass. A red check above a green bar indicates the Pass results are for the Right ear. A blue check mark indicates the Pass results are for the Left ear.

VALUE GRAPH VIEW



The Value graph view for left ear test displays dark blue “x” symbols representing the absolute emission levels at each DP test frequency or TE frequency band. Light blue upside-down triangles represent the noise floor at each DP test frequency or TE frequency band. For screening protocols, a blue check mark above the blue “x” indicates a pass for that frequency.

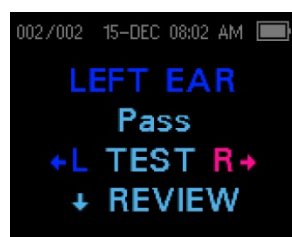
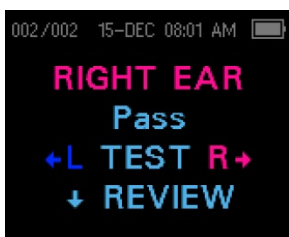


The Value graph view for a right ear test displays red circle symbols representing the absolute emission levels at each DP test frequency or TE frequency band. The shaded area is the Expanded Boys Town Norms template. For screening protocols, a red check mark above the red “circle” indicates a pass for that frequency.

See the *Viewing DPOAE Results with Normative Data* section for a description of the template. Refer to Instrument Settings section for instructions to switch the default setting of the graphs and for turning on the normative template.

NOTE: The ↑ up arrow key can be used to abort a test in progress. No record of an aborted test will be saved in memory.

VIEWING RESULTS



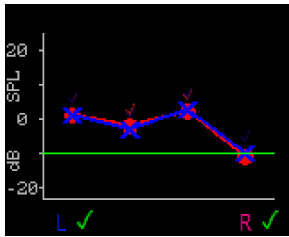
When testing is complete, the green “READY” light is illuminated, and a Results display will appear. The results of the test are automatically saved in memory as soon as the test is complete. The results will be saved even if the instrument is

turned off or the battery is temporarily depleted. This screen indicates the test ear and further gives the results of the test.

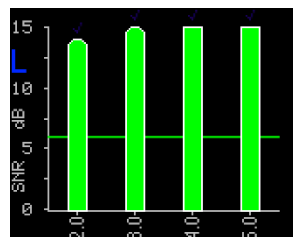
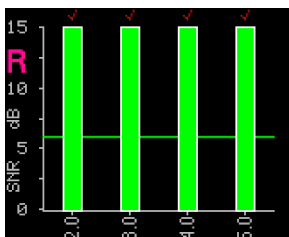
- “PASS” on the screen indicates the patient passed screening
- “REFER” indicates the patient did not pass screening
- “NOISY” indicates excessive noise was present during the test
- “NO SEAL” indicates a seal was not maintained throughout the test
- “FIT ERR” indicates inadequate probe placement in the ear canal to produce target stimulus intensities

When the test result is “NOISY,” “NO SEAL,” or “FIT ERR,” the tester should reposition the probe, selecting a different size eartip if necessary, and retest. To review the results,

push the DOWN arrow key to return to the bar graph. After reviewing the results, again push the DOWN arrow key to return to the Results display or the up arrow to return to the Main Menu.



The Corti will display the both Right and Left results at the end of the test, when in Save L/R Mode. After both ears have been tested, press the DOWN arrow key. When in Value Graph, both right and left results will display on the same graph. A green check mark below the graph indicates a pass. An orange 'X' indicates a refer and a '?' indicates Noisy, No Seal, or Fit Err. Red and blue check marks above the data points indicate a Pass for the right and left ear results respectively for that frequency or frequency band. Press the up arrow to return to the Main Menu.



In SNR Mode, when both ears have been tested, press the DOWN arrow key and the results of the last test performed will display. An R or L in the upper left side of the screen indicates the ear tested. Red and blue check marks above green bars

indicate a Pass for the right and left ear results respectively for that frequency or frequency band. Press the Right or Left arrow key to view the result of the other ear. Press the up arrow to return to the Main Menu.

NOTE: Completed tests are automatically saved. By default (Save L/R Mode), the Corti instrument will save only the last test for each ear. Starting a new test for the same ear will overwrite the existing test.

See the section *Managing Test Results* for more information on how the Corti saves results and how to print or transfer those results to the Corti Data Manager. See the section *Instrument Settings - Save Mode* for more information on the Corti save mode options.

VIEWING DPOAE RESULTS WITH NORMATIVE DATA

The Corti will display the Expanded Boys Town Norms template for eligible DPOAE test results. The norms template has no effect on the overall test results and is for display purposes only. The values used to create the template are from Gorga, M.P., Neely, S.T., Ohlrich, B., Hoover, B., Redner, J. and Peters, J. (1997). "From laboratory to clinic: a large scale study of distortion product otoacoustic emissions in ears with normal hearing and ears with hearing loss." *Ear & Hearing*, 18, 440-455.

The template may be used as a guide when evaluating DPOAE test results. The light shaded area at the top of the template represents the 90th to 95th percentile of DP amplitudes from the hearing impaired population. DP amplitudes within or above this range indicate a high probability of normal hearing. The light shaded area at the bottom of the template represents the 5th to 10th percentile of DP amplitudes from the normal hearing population. DP amplitudes within or below this range indicate a high probability of hearing loss. The dark shaded area in between represents a range of uncertainty where the normal hearing and hearing impaired populations overlap.

TEST TECHNIQUE

As with other otoacoustic emission test instruments, there is a technique to learn when using the Corti instrument, especially while testing infants. Experience with existing OAE systems suggests that it may take up to 3 months to become completely proficient at screening infants.

When testing an infant with the Corti instrument, the infant has to be relatively quiet and calm; it is usually preferred for the infant to be asleep. A pacifier may be used to calm the infant; however, sucking will add noise to the test and decrease the likelihood of a passing result. Pull gently down and back on the pinna to straighten out the ear canal. Gently place the probe tube into the infant's ear canal.

When testing children and adults, pull gently up and back on the outer ear during insertion to straighten the ear canal and ensure proper placement.

Noise Sources

When the noise level exceeds the noise rejection limit of the instrument, the red NOISE light will appear. It is common for the NOISE light to appear while testing. The light will appear infrequently if the noise level in the ear canal is low, and it will appear more often if the noise level in the ear canal is high. Otoacoustic emissions are very low-level sounds. Any noise in the ear canal at the time of testing can mask this emission. This noise can come from a variety of sources.

For TEOAE protocols, the test will pause when noise levels exceed the noise rejection limit. Pause is indicated when the Noise, Test and Ready lights turn on simultaneously. Testing will automatically resume when noise levels decrease. Total pause time will not exceed 30 seconds.

The largest source of noise can come from the patient. This is biological noise, such as movement, coughing, sucking, talking, etc. The patient must be calm and not move or talk. Ambient noise in the testing environment can also be a large source of noise during the test. A properly sealed eartip can block a large amount of this noise but performing the testing in a relatively quiet environment is recommended.

TURNING OFF THE INSTRUMENT

The Corti instrument has an automatic "shutdown" feature, designed to prolong battery life. The unit will automatically shut down after 1 minute (default) of inactivity. To turn it back on, simply press the DOWN key. This feature can be re-programmed for various periods of inactivity before shutdown. See the Changing Instrument Settings section – Auto Shutdown Time.

NOTE: The up arrow can be used to manually power off the instrument.

MANAGING RESULTS

Users have the option of printing to the optional thermal printer, transferring results to the GSI Data Manager database or utilizing Auto Print. Specific options will vary depending on the configuration of the system purchased.

GSI Corti test results may be transferred into GSI Suite. See GSI Suite user manual for more information.

NOTE: Results from screening protocols (DP 2s, DP 4s, TE 32s, TE 64s) may be stored and viewed in HearSIM™ and OtoAccess®. For more information review the HearSIM™ and OtoAccess® user manuals.

SAVING RESULTS

The Corti instrument automatically saves the results of completed tests in the non-volatile memory (meaning tests are saved even if the battery is temporarily discharged). However, the Corti is not intended for long-term storage of test results.

NOTE: Users are strongly encouraged to print/transfer all test results at the completion of testing to avoid potential loss of data.

When operating in the default "**Save L/R**" mode, the Corti instrument will save the most recent test results for each ear and print/transfer only these results. This allows the user to retest a patient after a "REFER" result and to print/transfer only the most recent test result for each ear. It is recommended that the results be printed after each patient in the default mode.

When operating in the "**Save 500**" mode, the Corti will save up to 500 tests. There are two options in the Save 500 mode:

1. The Corti will automatically number each test from 1 to 500 when no patient names are on the device.
2. The Corti Data Manager is used to transfer patient names to the Corti and the Corti will display the names.

The **Save 500** mode allows the user to save all tests for each patient (tests of the same ear are NOT overwritten) and to test multiple patients before printing or transferring results. When patient names are used (patient names are uploaded from the Corti Data Manager to the Corti unit) the patient names are displayed on the Corti Unit in alphabetical order. To move to a different name than the one displayed on the Corti

screen, use the left or right arrows to cycle through the names until the desired name is on the display. A patient named "Unnamed" is always included at the beginning of the Corti list for instances when a patient is being tested but the patient name was not transferred to the Corti. See Instrument Settings - Save Mode for more information.

NOTE: When the Corti automatically numbers the tests, it is important to manually keep a record of the test numbers for each patient.

DELETING RESULTS

The Corti holds data in non-volatile memory. The data stays in the memory even after data is printed or downloaded to the Corti Data Manager. Data can be deleted through a few methods, depending on the Save mode.

Save L/R Mode

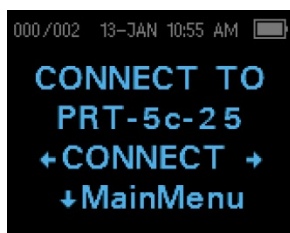
- A single test for the Left ear and a single test for the Right ear are held in memory. Data is deleted when a new test for the left or right ear is acquired.
 - Data can be deleted using the Clear function in the System Menu.
-

NOTE: Following printing or data transfer to the PC software, all tests saved in memory are marked for deletion and will be permanently deleted when a new test is started. It is not necessary to manually clear the results.

Save 500 Mode:

- Data is deleted when new Patient Names are uploaded from the Data Manager to the Corti (a warning indicates that data will be deleted).
- Data can be deleted using the Clear function in the System Menu.
- Data can be deleted in the Corti from the Data Manager when the device is connected to the Data Manager (cable from OAE Screener to PC). When Names is selected, the window allows data to be deleted via the Clear Instrument button.
- Data printed using Auto Print will be deleted when a new test is started.

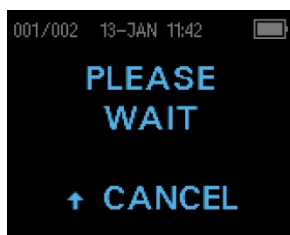
PRINTING TO A THERMAL PRINTER



Printing to an optional thermal printer is by way of wireless connection. First establish wireless pairing between the Corti instrument and the printer by following the instructions in the section Instrument Settings - Wireless Device Pairing.

NOTE: See the printer operating manual for instructions on using the printer.

Following instructions provided with your printer, be sure the printer is on and ready for communication/printing. From the Corti instrument Main Menu, press the ↑UP button to enter the device connection screen. Press the ←CONNECT→ button.



The Corti will search for the paired printer displaying 'Please Wait' while searching. When the printer is found, all test results stored in memory will print out automatically.

The Corti instrument will power off when printing is complete.

NOTE: All printed test results are marked for deletion but will continue to be stored in memory until a new test is started. When a new test is started all tests in the memory will be erased. This allows the user to reprint the tests if printing is unsuccessful (for example the paper runs out before printing is complete).

CONNECTING TO THE CORTI DATA MANAGER

For the PC to Corti connection, plug the USB-A connector into an available USB port on the computer and the Micro-USB of the cable into the port found at the base of the Corti instrument.

For the PC to Corti Cradle connection, plug the USB-A of the cable into a computer USB port and the USB-B connection to the back port of the Cradle. Note the Cradle does not need to be charging the Corti unit to transfer data.

For the PC to Corti wireless connection, make sure the Corti is paired to the PC. From the main screen press the up arrow. Press the left or right arrows at ←CONNECT→ for data transfer.

The Corti instrument will display “Waiting on PC”, detect the connection to the PC and wait for an action or communication from the Corti Data Manager. Refer to the Data Manager User manual for detailed operation.

NOTE: Corti must be in the Main Menu screen to communicate with the PC.

UNDERSTANDING PRINTED RESULTS

Results from the Corti can be transferred to Corti Data Manager or Auto Print for a full page printout or to a portable thermal printer. The following information is included on printouts for each test.

DPOAE Printout

- 1) The time and date of the test, based on the setting of the internal clock; if the clock is set correctly, the time and date will be correct.
- 2) The test number (if operating in “Save 500” mode)
- 3) The protocol selected (e.g.: DP 4s)
- 4) The averaging time used for the test (e.g.: 2 sec avg.)
- 5) Instrument and Probe serial number (SN)
- 6) The software version number (e.g.: V107.05)
- 7) The ear tested (Right or Left)
- 8) A PASS/REFER indication if there is a criterion set for the selected protocol.
- 9) The f2 frequency in kHz (e.g.: 2.0, 3.0, 4.0, 5.0)
- 10) The measured intensity level of f1 and f2 (L1, L2)

- 11) The noise floor (NF) in dB SPL
- 12) The emission level (DP) in dB SPL
- 13) The signal-to-noise ratio (SNR)- DP level minus the noise floor – in dB
- 14) A “P” to the right of the SNR if pass criteria were met for that frequency
- 15) The Value or SNR graph as selected on the Corti
- 16) “MIN*” if the Minimum Amplitude setting was enabled

TEOAE Printout

- 1) The time and date of the test, based on the setting of the internal clock; if the clock is set correctly, this time and date will be correct.
- 2) The test number (if operating in “Save 500” mode)
- 3) The protocol selected (e.g.: TE 64s)
- 4) The averaging test time for the test (e.g.: 12 sec avg.)
- 5) Instrument and Probe serial number (SN)
- 6) The software version number (e.g.: V107.05)
- 7) The ear tested (Right or Left)
- 8) A PASS/REFER indication if there is a criterion set for the selected protocol.
- 9) The frequency band center (F)
- 10) The noise floor (NF) in dB SPL
- 11) The emission level (TE) in dB SPL
- 12) The signal-to-noise ratio (SNR) - TE level minus the noise floor – in dB
- 13) A “P” to the right of the SNR if pass criteria were met for that frequency
- 14) The Value or SNR graph as selected on the Corti.
- 15) “MIN*” if the Minimum Amplitude setting was enabled.

Rounding Results

The user needs to be aware that the SNR and single PASS criterion on the Corti are calculated from the full internal precision of the instrument, and not from the values shown in the printout for the emission (DP/TE) and noise floor (NF) estimates.

This approach is used to preserve the full precision of the test results but can result in some apparent errors in the printout because of rounding. Assume the actual values at a given frequency was DP = 5.5 dB, NF = -0.4 dB, which results in SNR = 5.9 dB. The

printout values are rounded up to the nearest integer and are shown as DP = 6, NF = 0, and SNR = 6. This can result in what appears to be an error regarding the pass criterion. If the pass criterion is 6 dB while the actual SNR is 5.9, the printed value will be 6 but the frequency will not be judged as a PASS with a "P" printed.

Again, the pass/refer criterion is based on the full precision of the results, and not the rounded values that are printed. The full precision value for the SNR must be equal to or greater than the pass criterion (6 dB in this example) for the "P" to be printed. To view precise results, it is recommended that the test results be transferred to the Data Manager where numeric test results are displayed with an additional decimal place.

CLOCK SETTINGS

When the Corti test instrument is first used, the correct date and time may need to be set on its internal clock. The clock should be set prior to testing, as changing it after tests are saved will not change the date on the printout.

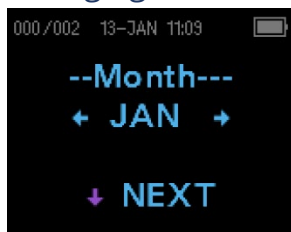
Seasonal time changes such as Daylight Saving time will also require resetting the clock. If the instrument is being powered on for the first time or if the instrument's battery is completely discharged and the battery is not charged within approximately one hour, a TIME/DATE ERROR! may appear. If this message appears, reset the time and date.

Accessing the Clock Menu

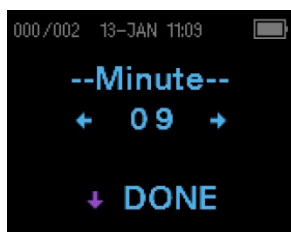


To change the time and date press ↓CHANGE at the main menu and then press ↓SETUP at the protocol selection display. The current date and time presently set in the unit will be shown. If the time and date are correct, press the UP key to escape back to the main menu.

Changing the Date/Time



If either the date or time is incorrect, press the ↓CHANGE key to make a change. The menu items appear in this order: Month, Day, Year, Hour and Minute. Press the ←LEFT or RIGHT→ keys to scroll forward or backward through each selection. When the desired selection appears on the display, press the ↓NEXT key to save this selection and to move on to the next menu item.



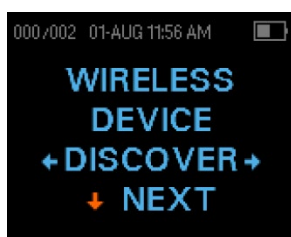
Continue through each menu item until the correct date and time are set. Press the ↓DONE arrow key will return to the Main Menu. The time and date changes are automatically saved.

INSTRUMENT SETTINGS

The Corti instrument allows the user to change many of the instrument's settings or functions. These settings include Wireless Device Pairing, Clearing Test Results, Auto Power Off Time, Save Mode, Minimum Amplitude Value, Clock Mode, Graph Mode, DPOAE Norms On/Off, DPOAE Reverse Frequency, DPOAE Auto Stop, Language, and Reset to Default Settings.

To access the menus to change these functions, press ↓CHANGE at the Main Menu and then press ↓SETUP at the Protocol Change to enter the Clock menu. At the Clock menu, **hold down** the ↓CHANGE key for 3 seconds until the READY light (green LED) turns off and release the key. Releasing the key will access the menus to change the instrument settings.

WIRELESS DEVICE PAIRING



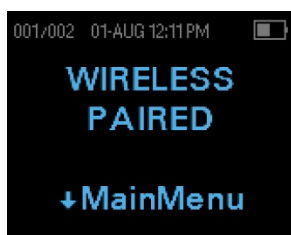
The wireless pairing menu allows the user to pair the Corti unit with a wireless device, such as a thermal printer or personal computer, for printing test results and data transfer. The Corti unit can be paired to only one device.

To establish wireless pairing, turn on the device that will be paired with the Corti unit (e.g.: thermal printer). Follow the above instructions to access the Wireless Device menu then select ←DISCOVER→ to initiate discovery of available wireless devices. The Corti will search for available wireless devices for approximately 15 seconds. The Corti will display the message "Please Wait" and the yellow LED will flash.



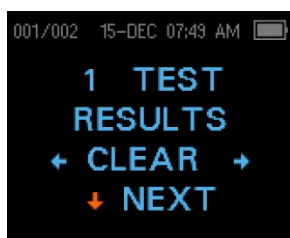
When discovery is complete, all discovered devices are shown. A compatible thermal printer will appear as "**PRT-##-##**" (example: PRT-5c-25) and other devices will be shown by their name. Use the ←CHANGE→ buttons to find the desired device and then use the ↓PAIR button to pair the Corti to the device.

For PC Pairing: On the PC, select Devices and Printers. Select **Add a Device**. From the list of identified devices, select **OAE Device**. Select and enter the pairing code **1234**. Select Next. A device driver may be loaded automatically on the PC. The first time the Corti Data Manager software is launched, select **Detect Com Port** to finalize the Corti and PC wireless connection.



Pairing will be confirmed. The pairing process is complete. Select ↓Main Menu to exit the Wireless pairing menu. See the Troubleshooting section if wireless pairing is unsuccessful or if any error messages are displayed

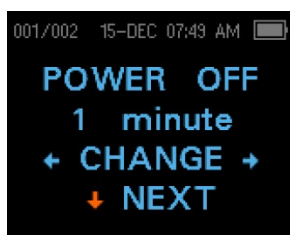
CLEARING TEST RESULTS



The Test Results Clear menu allows the user to clear the test results stored in the unit without printing them. Select the ←LEFT or RIGHT→ arrow key to clear the results and select ←Yes or No→ to verify clearing or to cancel. To advance to the next menu without clearing the results, press ↓NEXT.

NOTE: Following printing or data transfer to the PC software, all tests saved in memory are marked for deletion and will be permanently deleted when a new test is started. It is not necessary to manually clear the results using this menu.

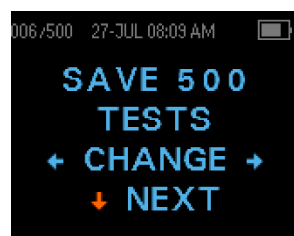
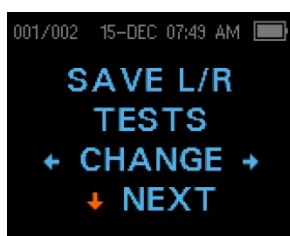
AUTO SHUTDOWN TIME



The Power Off menu refers to the Auto Shutdown time which controls how long the Corti instrument remains on before shutting off after a period of inactivity. It is not necessary to manually turn off the Corti unit. The Automatic Shutdown feature is designed to prolong the battery life of the instrument when it is not in use. By default, the instrument automatically shuts off after 1 minute of inactivity has elapsed.

The Auto Shutdown time may be increased or decreased by pressing the ←CHANGE→ keys. The times available are 0.5, 1, 2, or 4 minutes. Once you have made your selection, press ↓NEXT.

SAVE MODE/STORING TEST RESULTS



The Corti unit automatically stores only the most recent test result for each ear (Save L/R) but has the capacity to store 500 individual tests. The number of stored tests will appear in the upper left hand corner of the display. To change the mode

to save up to 500 tests, press the ←LEFT or RIGHT→ arrow keys to change the menu to 500. The Verify Clear Menu will appear. Selecting “Yes” will clear the stored tests and change the Save Mode. Selecting “No” will not change the save Mode. Once you have made your selection, press ↓NEXT.

There are two options in the Save 500 mode:

1. The Corti will automatically number each test from 1 to 500 when no patient names are on the device.

2. If the Corti Data Manager is used to transfer patient names to the Corti, the Corti will display the names.

When numbers are used (no patient names are uploaded from the Data Manager to the Corti), each test is automatically incremented, starting with test number 1.

When patient names are used (patient names are uploaded from the Corti Data Manager to the Corti unit) the patient names are displayed on the Corti Unit in alphabetical order. To move to a different name than the one displayed on the Corti screen, use the left or right arrows to cycle through the names until the desired name is on the display. A patient named "Unnamed" is always included at the beginning of the Corti list for instances when a patient is being tested but the patient name was not transferred to the Corti.

NOTE: When using the 500 test mode for numbered tests, it is important to keep a record of the test number for each patient. When 445 tests have been saved, the user will be warned that the memory is almost full. When the Corti unit reaches 500 saved tests, it will not allow any further testing. When this occurs, the results must be printed, transferred to the PC software, or cleared from memory.

MINIMUM AMPLITUDE VALUE

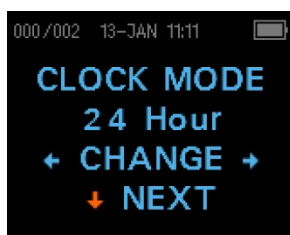


The Minimum Amplitude setting allows the user to set the unit to include minimum amplitude values in the pass/refer criterion. If the MIN VALUE is set to a specific dB SPL value, a result is not considered a Pass unless the amplitude at each frequency is equal to or greater than the minimum value programmed into the unit. This is in addition to meeting the other pass criteria including the minimum SNR and the number of passing frequencies for overall test "Pass." The Corti is set with this feature at -10 dB SPL for TEOAE and DPOAE test protocols when shipped from the factory.

To change the Minimum Amplitude, press the ←LEFT or RIGHT→ arrow keys to select OFF or the desired Minimum Amplitude level in dB. Once you have made your selection, press ↓NEXT. When Value Graph is the selected graph style, a horizontal green line will appear at the enabled minimum amplitude level.

The minimum amplitude options are -10 to +5 dB SPL in 1 dB steps.

CLOCK MODE



The Clock Mode menu allows the user to change the clock from a 24 hour mode to a 12 hour mode. To change the clock mode, press the ←CHANGE→ keys. Press the ↓NEXT to exit this menu. When 12 hour mode is selected, AM or PM will appear in the time/date screen.

GRAPH STYLE



The Graph Style menu allows the user to select from two options for viewing the results. The SNR graph view shows the signal-to-ratio for each DP test frequency or TE test band in bar graph form. The Value Graph view shows the absolute emission and noise levels for each DP test frequency or TE test band. To change the graph style, press the ←CHANGE→ keys. Press the

↓NEXT to exit this menu.

NORMS



The Norms setting allows the user to display the Expanded Boys Town Norms template on the Value Graph for eligible DPOAE protocols. The norms template has no effect on the overall test results and is for display purposes only. The Norms menu will not appear when SNR is the selected graph style. To change between ON or OFF, press the ←CHANGE→ keys. Press the

↓NEXT to exit.

NOTE: The template will display when target L1 and L2 levels are 65 and 55 dB SPL respectively.

REVERSE FREQUENCY



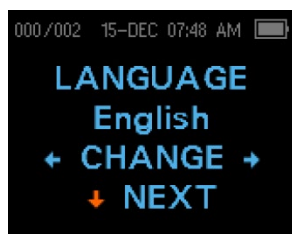
The Rev FREQ setting allows for reversing the presentation of the test frequencies from 'low frequency to high frequency' to 'high frequency to low frequency' for DPOAE protocols. For example, when Rev Freq is off, the 4s protocol frequency order is 2.0, 3.0, 4.0, and 5.0 kHz. When Rev Freq is ON, the frequency order will be 5.0, 4.0, 3.0 and 2.0 kHz. To change between ON or OFF, press the ←CHANGE→ keys. Press the ↓NEXT to exit this menu.

AUTO STOP



By default, the all DPOAE protocols with Pass/Refer criteria enabled will test every frequency in the protocol. When Auto Stop is set to ON, the DPOAE screening will stop as soon as all pass criteria are met. This means some frequencies may not be tested. For example, for the 4s protocol if pass results are obtained at 5.0, 4.0 and 3.0 kHz, the screening will stop without testing 2.0 kHz. To change between ON or OFF, press the ←CHANGE→ keys. Press the ↓NEXT to exit this menu.

LANGUAGE



The Language setting allows the user to select among several languages. To change the language, press the ←CHANGE→ keys until the desired language is shown. Press the ↓NEXT to exit this menu. Available languages are English US, English UK, Chinese, Russian, Spanish, Polish, Portuguese, Turkish, French, German, Italian, Korean, Japanese and Arabic.

RESET TO DEFAULT



The Reset to Default menu will return all instrument settings and protocol settings to their original factory defaults. Select the ←LEFT or RIGHT→ arrow key to reset and select ←Yes or No→ to verify reset. To exit the System menu without resetting the instrument, press ↓NEXT to return to the Main Menu.

NOTE: Reset to Default will unpair the wireless device, clear the test results, and reset ALL system and protocol settings.

ADVANCED OPTIONS

DPOAE DIAGNOSTIC UNIT

The Advanced Options menus permit modification of the test parameters and pass criterion for the customizable protocols on the DP Diagnostic unit. Changes to the protocol should be made only by qualified personnel, usually the administrator. If you are not familiar with the use of these variables, do not attempt to change the protocols.

The Corti instrument comes with pre-programmed protocol settings. See Appendix E for the default manufacturer settings of these protocols. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when the battery is discharged temporarily.

Instructions for Customizing a Test Protocol

To enter the DPOAE Menu:

- 1) Press ↓CHANGE at the main menu.
- 2) Using the ←CHANGE→ buttons, select the DPOAE protocol you want to customize (the "DP 4s" protocol is not customizable).
- 3) Press ↓SETUP at the Protocol menu.
- 4) At the Clock menu **hold down** the ↓CHANGE key for 3 seconds until the Ready light (green LED) turns off.
- 5) At the Wireless Device Discover menu **hold down** the ↓CHANGE key for 3 seconds until the Ready light (green LED) turns off.

The first setting in the DPOAE advanced menu is the Level L1 screen. Scroll through the available protocol parameters with the ↓NEXT button and make changes by using the ←LEFT or RIGHT→ arrow keys to CHANGE the selection.

NOTE: If you push the DOWN arrow key without holding it for 3 seconds, you will scroll through date and time, etc., rather than accessing the displays that allow you to make changes to the custom protocols.

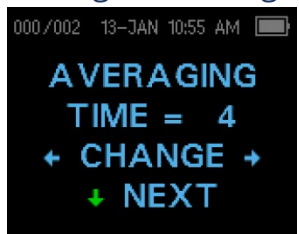
Selecting the Level of Primary Tones



The intensity of the primary tones (L1, L2) may be changed to any level between 40 dB SPL and 70 dB SPL. The level L1 will change in 1 dB increments by pushing the ←LEFT or RIGHT→ arrow keys and press ↓NEXT to move to the L2 screen.

Press the ↓NEXT key to set the level of L2 as with L1 above.

Setting the Averaging Time



The DP Averaging Time default is 4 seconds per frequency and may be changed. The Averaging Time will impact the time required to perform the test and the signal-to-noise ratio (SNR). A 2 second average for 4 frequencies would produce a test in 8 seconds. A 4 second average for 4 frequencies would produce a test in 16 seconds.

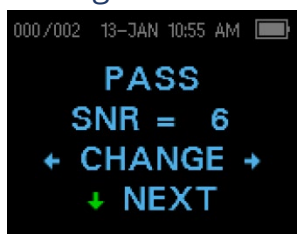
The possible settings for the Averaging Time are as follows:

- 0.5 sec.
- 1.0 sec.
- 2.0 sec.
- 4.0 sec. (default)

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit.

NOTE: Longer averaging times help to reduce the noise floor which can improve the likelihood of obtaining a passing result, particularly with a noisy patient (like a baby sucking a pacifier) or in a noisy environment. However, shorter averaging times may be preferred for young children and/or uncooperative patients.

Setting the PASS SNR Level



To provide a PASS/REFER determination for each test, the PASS SNR must be set. This number refers to the number of decibels that the DPOAE signal must be above the noise to be considered a PASS at that frequency. The limits for the PASS SNR are 3 dB to 10 dB. Pressing the ←LEFT or RIGHT→ arrow keys will increase or decrease the dB level. The SNR level requirement is used in combination with the number of frequencies (discussed below) to determine an overall PASS/REFER for each test.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit.

Setting the Number of Frequencies for PASS



The number of frequencies required for determining a PASS can be set from 0 to 12 depending on the protocol selected. **If the setting is on 0, then no indication of PASS/REFER will be made.** This setting is used in conjunction with the PASS SNR to set the criteria for the overall test PASS/REFER indication. For example, if the PASS SNR is set to 5 dB and the number of frequencies for PASS is set to 3, then the test must contain at least 3 frequencies where the emission is at least 5 dB above the noise to indicate a PASS.

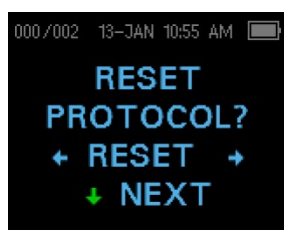
The number of frequencies for PASS should also be based on the number of frequencies being tested. Setting the number of frequencies for PASS to 5 when only 4 frequencies are being tested would result in every test being labeled as a REFER.

The 12 frequency protocols (DP 1.6-8.0, DP 1.5-12) allow for setting the number of frequencies to pass. When enabled, a "P" will appear to the right of the SNR in the numerical data if the pass criteria were met for that frequency. However, an overall Pass or Refer will not display for these protocols.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit.

NOTE: To disable the PASS/REFER indication set the number of frequencies for pass to 0.

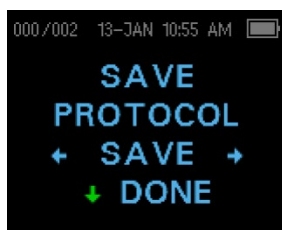
Reset Protocol



Selecting the ←RESET→ arrow key in the Reset Protocol menu will return the selected protocol settings to their original factory settings. Press the ↓NEXT key to exit.

NOTE: This does not affect the instrument settings or the settings of any other protocol.

Save Protocol



Once all the settings have been selected for the protocol, these settings can be saved by selecting the ←SAVE→ keys. Press the ↓NEXT key to exit.

NOTE: If a protocol has been modified, an * will appear in the protocol name. For example, if protocol DP 2.0-5.0 has been modified, it will appear on the Corti as DP*2.0-5.0.

TEOAE DIAGNOSTIC UNIT

The Advanced Options menu permits modification of the test stimuli and measurement values for the customizable protocols of the TE Diagnostic unit. Changes to the protocol should be made only by qualified personnel, usually the administrator. If you are not familiar with the use of these variables, do not attempt to change the protocols. Changes to any of these characteristics may yield test results that differ from those obtained in other test modes.

The Corti instrument comes with pre-programmed protocol settings. See Appendix E for the default manufacturer settings of these protocols. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when the battery is discharged temporarily.

Instructions for Customizing a Test Protocol

To enter the TEOAE Menu:

- 1) Press ↓CHANGE at the main menu.
- 2) Using the ←CHANGE→ buttons, select the TEOAE protocol you want to customize (the "TE 64s" protocol is not customizable).
- 3) Press ↓SETUP at the Protocol menu.
- 4) At the Clock menu **hold down** the ↓CHANGE key for 3 seconds until the Ready light (green LED) turns off.
- 5) At the Wireless Device Discover menu **hold down** the ↓CHANGE key for 3 seconds until the Ready light (green LED) turns off.

The Averaging Time menu should appear on the display. You are in the TEOAE menu and will be able to scroll the available protocol parameters with the ↓NEXT button and make changes by using the ←LEFT or RIGHT→ arrow keys to CHANGE the selection.

NOTE: If you push the ↓DOWN arrow key without holding it for 3 seconds, you will scroll through date and time, etc., rather than accessing the displays that allow you to make changes to the custom protocols.

Selecting the Averaging Time



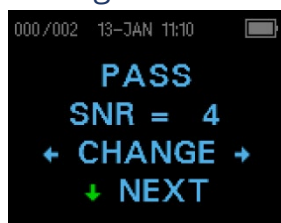
The *maximum* Averaging Time has four available settings. The Averaging Time sets the maximum test time to obtain a Pass and will affect the signal-to-noise ratio (SNR). For example, a setting of 32 seconds would stop the TE test after 32 seconds if the Pass criteria are not met.

The possible settings for the maximum Averaging Time are as follows:

- 8 seconds
- 16 seconds
- 32 seconds
- 64 seconds (default)

The instrument will automatically stop the test when the pass criterion is met prior to the averaging time. Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit.

Setting the PASS SNR Level

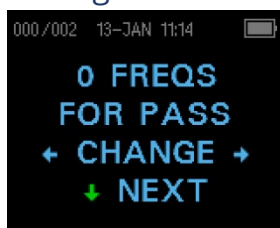


To provide a PASS/REFER determination for each test, the PASS SNR must be set. This number refers to the number of decibels that the TEOAE signal must be above the noise to be considered a PASS at that frequency. The limits for the PASS SNR are 3 dB to 10 dB. Pressing the ←LEFT or RIGHT→ arrow keys will increase or decrease the requirement. This requirement is used in

combination with the number of frequencies (discussed below) to determine an overall PASS/REFER for each test.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit.

Setting the Number of Frequencies for PASS



The number of frequencies for determining a PASS can be set from 0 to 6. **If the setting is on 0, then no indication of PASS/REFER will be made.** This setting is used in conjunction with the PASS SNR to set the criteria for the overall test PASS/REFER indication. For example, if the PASS SNR is set to 4 dB and the number of frequencies for PASS is set to 3 then the test must contain at least 3 frequencies where the emission is at least 4 dB above the noise to indicate a PASS.

Press the ←CHANGE→ keys to select an option and the ↓NEXT key to exit.

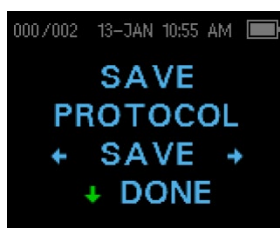
Reset Protocol



Selecting the ←RESET→ arrow key in the Reset Protocol menu will return the selected protocol settings to their original factory settings. Press the ↓NEXT key to exit.

NOTE: This does not affect the instrument settings or the settings of any other protocol.

Save Protocol



Once all the settings have been selected for the protocol, these settings can be saved by selecting the ←SAVE→ keys. Press the ↓NEXT key to exit.

NOTE: If a protocol has been modified, a * will appear in the protocol name. For example, if protocol TE 1.5-4.0 has been modified, it will appear on the Corti as TE*1.5-4.0.

CLEANING AND MAINTENANCE

CLEANING AND DISINFECTION

Use a new eartip for each patient. Eartips are for single patient use only. The probe tube, which does not make direct contact with the patient, should be replaced if there is any sign of contamination or if the test will not progress past the AutoStart phase. Disinfection of the probe tube between patients is not required.

External parts of the instrument/probe can be cleaned to remove visible particulate contamination. Do not attempt to insert any object into probe.

This instrument is not designated as a 'sterile' device. Wiping with a clean cloth or towel and a mild non-alcohol-based disinfecting solution, provides a suitable form of cleaning and low-level disinfection of the housing and probe exterior. Repeat this weekly, or as often as conditions warrant, to prevent a build-up of grime from normal handling and use.

We believe low-level disinfection is appropriate for this type of instrument. This may not conform to the infection control guidelines of the user's facility. The disinfection materials and procedures applied in the users' facility may be more appropriate for their circumstances than the methods outlined above (see cautions below). The frequency of cleaning and disinfecting is dependent on the facility's risk assessment, usage, and test environment.

Important:



- Do not immerse the instrument or probe in fluids or attempt to sterilize the instrument or any of its accessories.
- Do not allow any fluid to enter the device.
- Do not use autoclave sterilization.
- Do not use alcohol-based disinfectants.
- Take care not to put excessive pressure on the clear display window or allow any utensil to puncture the display window or control panel.

NOTE: Long-term exposure to any disinfecting agents has the potential to alter the material properties of the plastic housing and labeling of the device.

Always follow the safety and disposal guidelines given by the manufacturer of cleaning and disinfectant chemicals.

MAINTENANCE

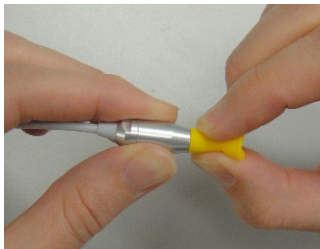
This instrument requires no regular maintenance beyond routine cleaning and annual calibration. The probe tube requires replacement only when it becomes clogged.

A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from GSI.

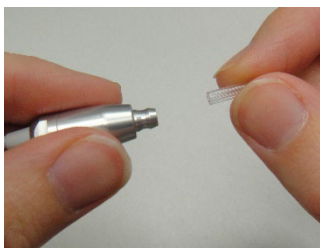
Equipment is not user repairable. Repairs and battery replacement must be performed by a qualified service representative only.

Annual calibration is recommended. A **Due for Service** screen will appear after 1 year has elapsed from the calibration date. Have an authorized service technician perform electrical safety checks on the unit in order to maintain continued compliance to IEC and UL 60601-1.

PROBE TUBE REPLACEMENT



Probe tubes are disposable and should be replaced when they become clogged. Replacement probe tubes are included with this instrument. Do not attempt to clean the probe tube.



To replace the probe tube, use the eartip to grasp the probe tube (the plastic tube) and twist slightly while pulling the probe tube straight out of the probe head. Dispose of the used probe tube immediately to avoid confusing used tubes and new tubes. Take a new probe tube from the package and insert the tube into the probe head until it is fully seated. A properly inserted probe tube will snap securely into place when it is fully seated in the probe head. The Probe Tube Removal Tool may also be utilized to remove and insert a probe tube.



Do not attempt to clean the probe tubes. This may cause damage to the probe.

STATUS/ERROR MESSAGES

DISPLAY MESSAGES:

| | |
|------------------------------|---|
| Attach Probe | No probe is detected at the start of a test. |
| Device not Responding | The printer is not responding to queries from the instrument. |
| Wireless Device Not Found | The paired wireless device cannot be detected. The device may be turned off or too far away. |
| Wireless Error #xxx | There is an error condition with the wireless device. Check the status. |
| Wireless Not Configured | The Corti instrument is not paired with any wireless device. |
| Fit Error Cannot Obtain P | For a DP test, the desired level (L1 or L2) cannot be obtained within allowable limits. User should refit the probe and retry the test. |
| Fit Error Too High | For a DP test, the level of the calibration tone is too high. User should refit the probe and retry the test. |
| Fit Error Too Low | For a DP test, the level of the calibration tone is too low. User should refit the probe and retry the test. |
| Limit Error | Overflow error during the calculation of the DFTs for a DP test. User should repeat the test. |
| Memory Almost Full | Saved tests are within 5 tests of the maximum limit. |
| Memory Full! | The maximum saved test limit is reached. The user will need to clear the memory before any additional tests can be performed. |
| Power Low! | The battery charge level is too low for operation. The user must charge the battery before additional tests can be performed. |
| Printer Error | Indicates a problem with the printer. Check the printer status. |
| Printer Paper Out! | Indicates printer paper has run out. |
| Time/Date Error! | The clock is checked during power on to ensure it has not lost time and been reset. In the case of clock reset, this message is shown. The user should set the correct date/time. |

| | |
|-----------------|--|
| Due for Service | Reminder will appear when the calibration due date has passed. |
|-----------------|--|

INDICATOR LEDs (LIGHTS)

| | |
|----------------|---|
| NOISE / Orange | <p>The indicator labeled 'NOISE' provides a visual indication (AMBER) that the noise level measured during the test exceeds a nominal threshold.</p> <p>Also used to indicate some error conditions and when the outcome of test is REFER, NOISY, or NO SEAL.</p> |
| TEST / Yellow | <p>The indicator labeled 'TEST' provides a visual indication (YELLOW) that the selected test is being performed. This indicator will remain on steady state during the test function.</p> |
| READY / Green | <p>The indicator labeled 'READY' lets the user know that the instrument is not currently performing a test function and that it is available to perform a test function.</p> |
| CHARGE / Blue | <p>The indicator labeled 'CHARGE' provides a visual indication (BLUE) of the battery recharging function and battery status. The rate of illumination of the indicator provides a means of identifying the status of the charging function.</p> |

TROUBLESHOOTING

| Problem | Solutions |
|---|--|
| Instrument does not turn on | <ul style="list-style-type: none"> The ↓DOWN arrow must be pressed for a full second (the Yellow test LED will illuminate). Connect the charger and confirm that blue "Charging" LED is illuminating in a slow blink pattern. Wait at least 10 minutes and then attempt to turn on the instrument Contact GSI for service if the problem persists. |
| The test will not start | <ul style="list-style-type: none"> Select a different sized eartip. Reposition the probe. Be sure the probe cable is secured with the shirt clip. Change the probe tube. Verify that the eartip is sealed in the ear canal via feedback from the Probe check during AUTOSTART. Check that the instrument will start in your own ear with the proper eartip for testing yourself. If the test will not start or if the AutoStart tones sound unusual, replace the probe tube. Contact GSI for service if the problem persists across several patients. |
| The results will not print | <ul style="list-style-type: none"> Check the printer status. Turn the thermal printer on (wake from sleep mode) by pressing the power button. If the printer doesn't turn on, plug in the power supply to charge the battery. Be sure the printer has paper. If paper comes out of the printer but there is no text on the paper then the paper is in backwards. Perform a self-test by pressing the power button and the paper feed button simultaneously for 3 seconds when powered off. Contact GSI for service if the problem persists. |
| Display is frozen and instrument will not respond to button presses | <ul style="list-style-type: none"> Press and hold the DOWN arrow button for 10 seconds to force the instrument to power off. Powering the instrument back on again should reset/restore normal function. Contact GSI for service if the problem persists. |

| | |
|------------------------------|---|
| TE screening test is paused | <ul style="list-style-type: none"> • Re-insert probe tip into ear canal • Reposition the probe tip • Wait for noise levels to decrease; test will resume |
| Attach Probe | <ul style="list-style-type: none"> • Probe not detected. Check that the probe connector is fully seated in the socket. • Disconnect and reconnect the probe. • Cycle instrument power. • Contact GSI for service if problem persists. |
| Wireless Device Not Found | <ul style="list-style-type: none"> • Paired to Printer: <ul style="list-style-type: none"> ◦ Check that the printer is turned on. ◦ Move closer to the printer. ◦ Try again. • Paired to PC Computer or wireless dongle: <ul style="list-style-type: none"> ◦ Check that the serial port is open. Establishing the serial port is handled by the PC and/or the software, not by the Corti instrument. |
| Wireless Error #xxx | <ul style="list-style-type: none"> • Check Wireless device (printer or PC) status. • Attempt to connect to wireless device again. • Contact GSI if problem persists. |
| Wireless Not Configured | <ul style="list-style-type: none"> • Printing has been attempted, but no wireless device is paired with the Corti Instrument. Establish wireless pairing. |
| Device Not Responding | <ul style="list-style-type: none"> • The printer is not responding to queries from the instrument. Check printer status. • Awaken printer from sleep mode. • Charge printer battery if necessary. |
| Fit Error Cannot Obtain P | <ul style="list-style-type: none"> • For a DP test, the desired level (L1 or L2) cannot be obtained within allowable limits. User should refit the probe and retry the test. • Replace the probe tube. • Contact GSI for service if problem persists across several patients. |

| | |
|-----------------------|--|
| Fit Error Too High | <ul style="list-style-type: none"> For a DP test, the level of the calibration tone is too high. User should refit the probe and retry the test. Replace the probe tube. Contact GSI for service if problem persists across several patients. |
| Fit Error Too Low | <ul style="list-style-type: none"> For a DP test, the level of the calibration tone is too low. User should refit the probe and retry the test. Replace the probe tube. Contact GSI for service if problem persists across several patients. |
| Limit Error | <ul style="list-style-type: none"> Overflow error during the calculation of the DFTs for a DP test. User should repeat the test. Cycle instrument power. Contact GSI for service if problem persists. |
| Memory almost full | <ul style="list-style-type: none"> Saved tests are within 5 tests of the maximum limit. Print or transfer test result to avoid interruption in testing. |
| Memory Full! | <ul style="list-style-type: none"> The maximum saved test limit is reached. The user will need to clear the memory before any additional tests can be performed. |
| Power Low! | <ul style="list-style-type: none"> The battery charge level is too low for operation. The user must charge the battery before additional tests can be performed. |
| Printer Error | <ul style="list-style-type: none"> Indicates a problem with the printer. Check the printer status. Reset the printer or cycle the printer power. |
| Printer Paper Out! | <ul style="list-style-type: none"> Replace the paper roll. |
| Time/Date Error! | <ul style="list-style-type: none"> The clock is checked during power on to ensure it has not lost time and been reset. In the case of clock reset, this message is shown. The user should set the correct date/time. |

APPENDIX A: SPECIFICATIONS

PROBE SPECIFICATIONS

| | |
|---------------------------|--|
| Measurement Type: | Distortion Product Otoacoustic Emissions (DPOAE) Transient Evoked Otoacoustic Emissions (TEOAE) |
| Frequency Range: | DPOAE: 1.5 to 12 kHz TEOAE: 0.7 to 4 kHz |
| Stimulus Intensity Range: | DPOAE: 40 to 70 dB SPL TEOAE: 80 dB SPL peak equivalent (± 3 dB) |
| Microphone System Noise: | -20 dB SPL @ 3 kHz (1 Hz bandwidth) / -13 dB SPL @ 1 kHz (1 Hz bandwidth) |
| Dimensions and Weight: | Length: 40 in. (1.0 meter) Weight: 1.00 oz. (28 gm) |
| Connector: | HDMI |

INSTRUMENT SPECIFICATIONS

| | |
|------------------------------|--|
| Power Supply: | Lithium-Ion rechargeable |
| Battery Life: | 20 hours on-time |
| Dimensions and Weight: | 7 in. x 2.75 in x 1.25 in (17.78 cm x 6.98 cm x 3.17 cm) Instrument Weight: 6.4 oz. (180 gm) |
| User Interface: | OLED Display to provide user information and progress of measurement. 4-button keypad to control instrument functions |
| Connectors / Communications: | Integrated USB communication capability for battery charging and communication with PC- |

based database programs or an optional PC printer

HDMI Connector for connection to the Probe

Integrated wireless Class 2 + EDR with SPP Protocol for communication with optional printer

POWER SUPPLY SPECIFICATIONS (USE ONLY APPROVED POWER SUPPLY)

| | |
|-----------|------------------------------|
| Model No: | UE08WCP-050160SPA |
| Output: | 5.0V DC, 1.6A |
| Input | 100-240V AC, 50-60Hz, 400 mA |

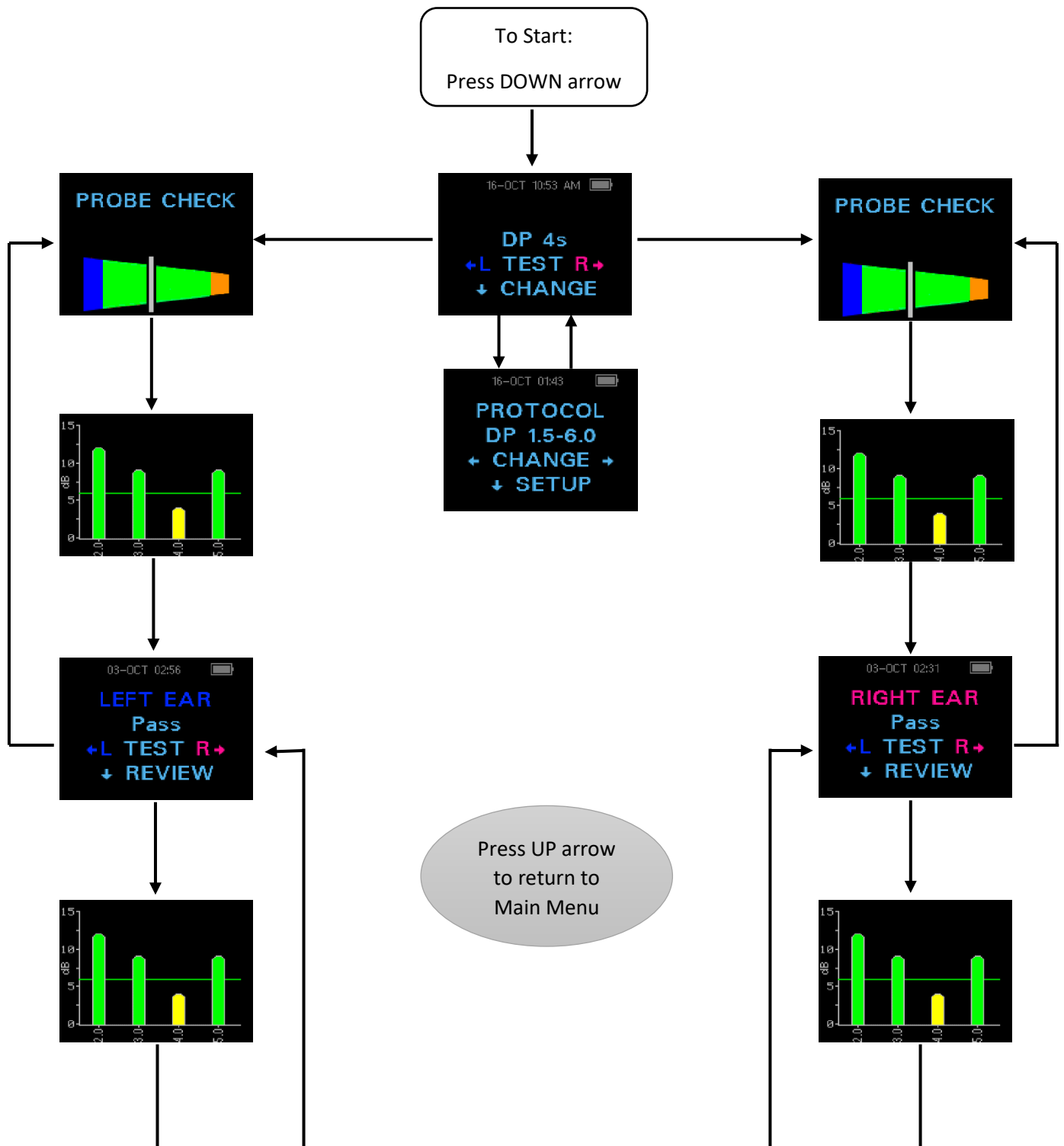
ENVIRONMENTAL REQUIREMENTS

| | |
|------------------------------------|-----------------------------|
| Operating Temperature: | 15°C to 35°C (59°F to 95°F) |
| Operating Relative Humidity: | 30% to 90% (non-condensing) |
| Maximum Operating Altitude: | 2000 meters (6000 feet) |
| Transport and Storage Temperature: | 5°C to 40°C (41°F to 104°F) |



APPENDIX B: FLOWCHARTS







MEASUREMENT



SETUP MENUS

⏻ Press and hold DOWN arrow for three seconds to enter next menu

| Clock Menu | ⏻ System Menu | ⏻ DP Settings | ⏻ TE Settings |
|---|---|--|--|
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  | |
|  |  |  | |
|  |  | | |

| | | | |
|--|--|--|--|
| |  <p>000/002 15-DEC 07:48 AM</p> <p>GRAPH SNR ← CHANGE → ↓ NEXT</p> | | |
| |  <p>000/002 15-DEC 07:48 AM</p> <p>GRAPH VALUE ← CHANGE → ↓ NEXT</p> | | |
| |  <p>002/002 30-OCT 03:07 AM</p> <p>NORMS OFF ← CHANGE → ↓ NEXT</p> | | |
| |  <p>000/500 27-JUL 08:03 AM</p> <p>REV FREQ OFF ← CHANGE → ↓ NEXT</p> | | |
| |  <p>000/500 27-JUL 08:03 AM</p> <p>AUTO STOP OFF ← CHANGE → ↓ NEXT</p> | | |
| |  <p>000/002 15-DEC 07:48 AM</p> <p>LANGUAGE English ← CHANGE → ↓ NEXT</p> | | |

APPENDIX C: TEST SEQUENCE

A complete test sequence consists of an AutoStart, calibration, and test phase. The AutoStart phase determines when the calibration phase should proceed, while the calibration phase calibrates the level of the tones that will be applied during the actual test phase. Artifact rejection is employed during the test phase to reduce the effect of transient noise bursts.

Immediately after the test button is pressed, the AutoStart phase of the test begins. AutoStart checks both the quality and stability of the seal by measuring the response obtained from a sequence of test tones. The stability of the seal is determined by comparing the responses obtained over time. When the level of the response is within an acceptable range and is stable over time, the unit proceeds to the calibration phase.

DPOAE

The calibration phase automatically measures the response obtained from a sequence of calibration tones and calculates the voltage needed to obtain the desired pressures. If the desired peak pressure cannot be obtained, the unit will use the maximum voltage. A successful calibration leads to the actual test phase.

The test phase consists of measuring the response obtained from the pairs of test frequencies (f_1 , f_2) applied to the receivers. Two receivers are used, with each receiver generating one frequency in order to reduce intermodulation distortion. Frequency domain estimates of the actual L1, L2, distortion (DP) and noise floor (NF) are obtained via the discrete Fourier Transform, with a bin resolution of approximately 31 Hz. The NF estimate is obtained by averaging the power in the 4 closest (± 2) bins to the DP bin.

TEOAE

The calibration phase automatically measures the peak pressure obtained from a sequence of clicks and calculates the voltage required to obtain the target peak pressure. If the desired peak pressure cannot be obtained, the unit will use the maximum voltage.

The test phase consists of measuring the response obtained from repeated sequences of clicks applied to the receivers. The click sequence is 3-1-1-1 repeated twice. Signal and noise floor estimates are obtained by adding/subtracting the two response sequences, respectively. The energy of the signal and noise floor estimates in various frequency bands is obtained in real time and displayed once per second. The average peak pressure of the stimulus is calculated after completion of the test.

Artifact rejection is employed during the test phase to reduce the effect of transient noise bursts by the use of an adaptive rejection threshold. The unit attempts to accept the quieter sections of the test, while rejecting the noisier portions of the test. When the noise level is approximately constant during the test, the instrument will tend to accept

most of the data in the test. However, as the level of the noise becomes more variable over time, the instrument will attempt to accept the quieter portions of the recording. Noise estimates are obtained approximately 32 times per second and a suitable threshold is estimated from the data. Data segments with a noise floor above this threshold are rejected, which tends to lower the noise floor of the test. In order to reduce the possibility of obtaining an artificially low noise floor, the minimum threshold level is limited.

COMMENT ABOUT VARIATIONS IN THE SNR ESTIMATE

The user needs to be aware that the SNR estimate has an inherent statistical variation because of random noise, especially when no emission is actually present. If a test is performed with the instrument's probe placed in a test cavity, it can be shown theoretically that the SNR will be greater than 6 dB approximately 7 times out of 100. This is not a limitation of the instrument, but a fundamental property of the method used to estimate the SNR in all emission testing. In order to reduce the occurrence of this "false" emission, the instrument limits the minimum value of NF, which has the effect of reducing the SNR for tests that have a low noise floor. As the noise level of the test increases, the user will notice that more "false" emissions will appear, which is to be expected.

APPENDIX D: PASS/REFER CRITERIA

DPOAE

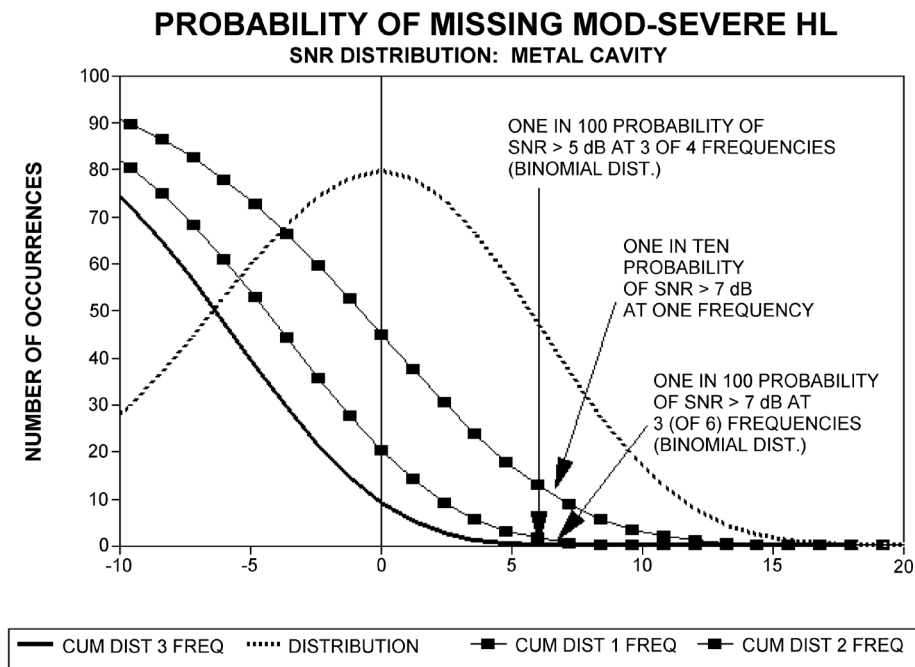
The decision that a DPOAE exists is based on detecting a signal whose level is significantly above the background noise level. This requires a statistical decision, since the random noise level in the DPOAE filter channel can be expected to exceed the average of the random noise levels in the four adjacent filter channels — used as the reference for comparison — roughly half the time.

Extended measurements of the noise distributions in both the DPOAE filter channel “DP level” and the rms average of the 4 adjacent channels “N level” indicate that the signal-to-noise ratio (the difference between DP and N) has a standard deviation of 5.5 dB. As shown in the figure below, this implies a 10% probability of seeing a 7 dB SNR simply from the variability of the noise levels in the 2 filter sets.

Requiring an SNR of 6 dB in three out of four frequencies drops the probability of passing an ear with significant hearing loss to 1% or less. Note: By the binomial distribution, two of three frequencies at >8.4 dB or three of six frequencies at >7 dB should also ensure less than 1% probability of passing a moderately-severe hearing-impaired infant.

Preliminary trials with infants indicate that the tester’s technique is the single most important variable in the pass rate on normal-hearing infants. Some testers pick up the technique (see Operating Instructions section, page 19) with only a couple of days’ practice, producing pass rates comparable to those for other DPOAE equipment they have used for months; other testers take longer.

Occasional claims of extraordinarily low probabilities of missing an ear with hearing loss appear to be based on poor statistics. As discussed by Gorga (Mayo Clinic Teleconference, 1998), since the incidence of significant hearing loss is roughly 2 per 1,000, verifying a 99.7% accuracy would require testing hundreds of thousands of babies with a given system. Thus, to demonstrate that only 3 babies out of 1,000 with hearing loss were missed would require follow-up testing on 500,00 babies. To our knowledge, no one has performed such tests to date.



TEOAE

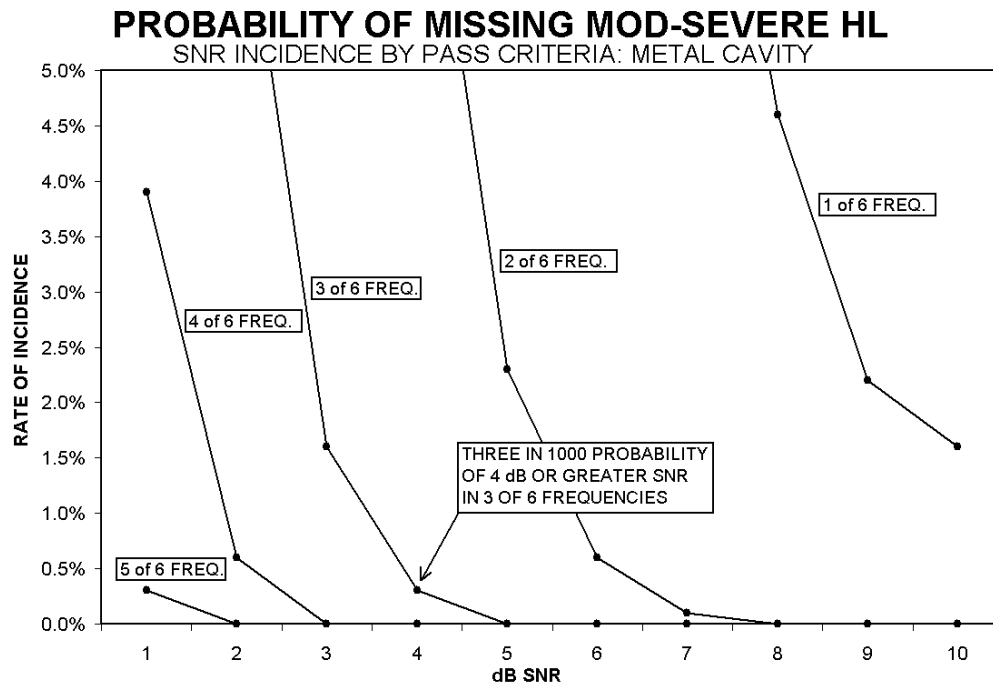
The same basic principles that underlie DPOAE Pass/Fail criteria underlie TEOAE Pass/Fail criteria. In the case of transients, requiring SNR of 4 dB at any three out of the six test frequencies drops the probability of passing an ear with a significant hearing loss to less than 1%.

NOTE: The SNR limits for transients are lower than the corresponding limits for distortion products primarily because the traditional noise calculation used in TEOAE measurements (and in the Corti instrument) gives a 3 dB lower SNR than the calculation used for DPOAEs. Without that difference, the numerical SNR value for a PASS with the two methods would be quite similar.

The Corti uses a patented noise-rejection algorithm that permits accurate DPOAE and TEOAE measurements in background noise and babble as high as 55 to 65 dB SPL (A-weighted). Briefly explained, use of available memory in the Corti processor permits a post-hoc statistical analysis that identifies those samples whose retention would improve the overall accuracy. Those samples are included in the final analysis; the noisier samples are rejected.

The improved operation in noise with the new algorithm was so substantial that a complete replica of the original validation tests in "fully impaired ear" cavities was conducted and it was verified that no increase in false negatives (false passes) was introduced. Under no test conditions was any such degradation uncovered.

The artifact rejection can only reject the noisiest samples in a measurement period. If the ambient noise level rises too high (and/or the eartip seal is poor), then all samples will be noisy and accurate measurements will be impossible, in which case the test result will indicate “noisy.”



APPENDIX E: CONFIGURATIONS AND TEST PROTOCOLS

DIAGNOSTIC CONFIGURATIONS

| <u>Configuration</u> | <u>Protocols Included</u> |
|-----------------------------------|--|
| DP Diagnostic: | DP 4s (default - not customizable) DP 2.0-5.0 DP 1.5-6.0 DP 1.6-8.0 DP 1.5-12 |
| TE Diagnostic: | TE 64s (default - not customizable) TE 1.5-4.0 TE 0.7-4.0 |
| DP and TE Diagnostic Combo: | DP 4s (default - not customizable) DP 2.0-5.0 DP 1.5-6.0 DP 1.6-8.0 DP 1.5-12 TE 64s (default - not customizable) TE 1.5-4.0 TE 0.7-4.0 |

DPOAE DIAGNOSTIC DEFAULT PROTOCOLS

| Protocol Name | # of Freqs | F2 Frequency* | L1/L2 | Averaging Time | Pass SNR | # Passing Freq. for Test Pass |
|----------------------|-------------------|--|--------------|-----------------------|-----------------|--------------------------------------|
| DP 4s | 4 | 2.0, 3.0, 4.0, 5.0 kHz | 65/55 | 4 sec | 6 dB | 3 |
| DP 2.0-5.0 | 4 | 2.0, 3.0, 4.0, 5.0 kHz | 65/55 | 4 sec | 6 dB | 3 |
| DP 1.5-6.0 | 6 | 1.5, 2.0, 3.0, 4.0, 5.0, 6.0 kHz | 65/55 | 4 sec. | - | 0 |
| DP 1.6-8.0 | 12 | 1.6, 2.0, 2.5, 3.2, 3.6, 4.0, 4.5, 5.0, 5.6, 6.3, 7.1, 8.0 kHz | 65/55 | 4 sec. | - | 0 |
| DP 1.5-12 | 12 | 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 kHz | 65/55 | 4 sec. | - | 0 |

* Frequency pairs are presented at a F2/F1 ratio of 1.22.

TEOAE DIAGNOSTIC DEFAULT PROTOCOLS

| Protocol Name | # of Frequency Bands | Frequency Center Bands | Averaging Time (max) | Pass SNR | # Passing Freq. for Test Pass |
|---------------|----------------------|----------------------------------|----------------------|----------|-------------------------------|
| TE 64s | 6 | 1.5, 2, 2.5, 3, 3.5, 4 kHz | 64 sec | 4 dB | 3 |
| TE 1.5-4.0 | 6 | 1.5, 2, 2.5, 3, 3.5, 4 kHz | 64 sec | 4 dB | 3 |
| TE 0.7-4.0 | 6 | 0.7, 1.0, 1.4, 2.0, 2.8, 4.0 kHz | 64 sec. | - | 0 |

NOTE: Those protocols for Diagnostic Units with "0" for the Pass SNR and the number of passing frequencies required for a test "PASS" do not have a factory provided pass criteria. Users may establish a custom pass criterion based on normative data collected in their own clinics or information available by literature review.

GSI CORTI SCREENING CONFIGURATIONS

Configuration **Protocols Included (not customizable)**

DP Screener: DP 2s

DP 4s

TE Screener: TE 32s

TE 64s

DP and TE

Screener

Combo:

DP 2s

DP 4s

TE 32s

TE 64s

DPOAE SCREENING DEFAULT PROTOCOLS

| Protocol Name | # of Freqs | F2 Frequency* | L1/L2 | Averaging Time | Pass SNR | # Passing Freq. for Test Pass |
|----------------------|-------------------|------------------------|--------------|-----------------------|-----------------|--------------------------------------|
| DP 2s | 4 | 2.0, 3.0, 4.0, 5.0 kHz | 65/55 | 2 sec | 6 dB | 3 |
| DP 4s | 4 | 2.0, 3.0, 4.0, 5.0 kHz | 65/55 | 4 sec | 6 dB | 3 |

* Frequency pairs are presented at a F2/F1 ratio of 1.22.

TEOAE SCREENING DEFAULT PROTOCOLS

| Protocol Name | # of Frequency Bands | Frequency Center Bands | Averaging Time (max) | Pass SNR | # Passing Freq. for Test Pass |
|----------------------|-----------------------------|-------------------------------|-----------------------------|-----------------|--------------------------------------|
| TE 32s | 6 | 1.5, 2, 2.5, 3, 3.5, 4 kHz | 32 sec | 4 dB | 3 |
| TE 64s | 6 | 1.5, 2, 2.5, 3, 3.5, 4 kHz | 64 sec | 4 dB | 3 |

APPENDIX F: STANDARDS COMPLIANCE

| Standard | Title |
|--------------|--|
| ANSI/ASA 3.6 | Specification for Audiometers |
| IEC 60601-1 | Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance, Ed. 3.1 |
| IEC 60645-1 | Electroacoustics - Audiological equipment -- Part 1: Pure-tone audiometers |
| IEC 60645-3 | Electroacoustics - Audiometric equipment -- Part 3: Test signals of short duration |
| IEC 60645-6 | Electroacoustics – Audiometric Equipment – Part 6: Instruments for the measurement of otoacoustic emissions |
| ISO 14971 | Application of Risk Management to Medical Devices |
| ISO 10993 | Biological Evaluation of Medical Devices |
| EN 60601-1-2 | Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and Tests. |
| FCC Part 15 | FCC 47CFR, Part 15.247 & 15.249 (Wireless) |
| EN ISO 15223 | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements. |

APPENDIX G: SPECIFICATION OF INPUT/OUTPUT CONNECTIONS

OAE PROBE

| Pin | Description |  <p>HDMI Type A</p> |
|-----|--------------|--|
| 1 | REC 1 + | |
| 2 | REC 1Shield | |
| 3 | REC 1 - | |
| 4 | REC 2 + | |
| 5 | REC 2 Shield | |
| 6 | REC 2 - | |
| 7 | MIC Power + | |
| 8 | MIC Shield | |
| 9 | MIC Out | |
| 10 | Mic Power - | |
| 11 | Not Used | |
| 12 | Not Used | |
| 13 | Not Used | |
| 14 | Battery | |
| 15 | SCL/UIOP | |
| 16 | SDA/SCIO | |
| 17 | I2C/UIO GND | |
| 18 | Probe +3.3 V | |
| 19 | Power GND | |

APPENDIX H: WARRANTY

We, Grason-Stadler, warrant that this product is free from defects in material and workmanship and, when properly installed and used, will perform in accordance with applicable specifications. If within one year after original shipment, it is found not to meet this standard; it will be repaired, or at our option, replaced at no charge except for transportation costs, when returned to an authorized Grason-Stadler facility. If field service is requested, there will be no charge for labor or material; however, there will be a charge for travel expense at the service center's current rate.

NOTE: Changes in the product not approved in writing by Grason-Stadler shall void this warranty. Grason-Stadler shall not be responsible for any indirect, special or consequential damages, even if notice has been given in advance of the possibility of such damages.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

APPENDIX I: RECYCLING AND DISPOSAL



Many local laws and regulations require special procedures to recycle or dispose of electrical equipment and related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all local laws and regulations for the proper disposal of batteries and any other parts of this system.

Below is the contact address for proper return or disposal of electronic wastes relating to Grason-Stadler products in Europe and other localities. The contact information for the WEEE in Europe:

Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

APPENDIX J: ELECTROMAGNETIC COMPATIBILITY

Portable and Mobile RF communications equipment can affect the GSI Corti. Install and operate the GSI Corti according to the EMC information presented.

The GSI Corti has been tested for EMC emissions and immunity as a standalone instrument. Do not use the GSI Corti adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, except for servicing parts sold by GSI as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device. Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

ELECTRICAL SAFETY, EMC AND ASSOCIATED STANDARDS

UL 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use

IEC/EN 60601-1-1: Collateral Standard, Safety Requirements for Medical Electrical Systems

IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests

Essential Requirements of the current European Union Medical Device Directive 93/42/EEC

RoHS (Restriction of the use of certain Hazardous Substance)

WEEE (Waste Electrical & Electronic Equipment) Legislation

| Guidance and Manufacturer's Declaration - Electromagnetic Emissions | | |
|---|------------------|--|
| The GSI Corti is intended for use in the electromagnetic environment specified below. The customer or the user of the GSI Corti should assure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic environment - Guidance |
| RF Emissions CISPR 11 | Group 1 | The GSI Corti uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class B Limits | The GSI Corti is suitable for use in all commercial, industrial, business, hospital, and residential environments. |
| Harmonic Emissions IEC 61000-3-2 | Class A Category | |
| Voltage Fluctuations / Flicker Emissions IEC 61000-3-3 | Complies | |

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the GSI Corti

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

| Rated Maximum Output Power of Transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|--|
| | 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.22 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.23 |
| 10 | 3.70 | 3.70 | 7.05 |
| 100 | 11.70 | 11.70 | 22.30 |

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

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

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


| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
|---|---|---|--|
| The GSI Corti is intended for use in the electromagnetic environment specified below. The customer or the user of the Corti should assure that it is used in such an environment. | | | |
| Immunity Test | IEC 60601 Test Level | Compliance | Electromagnetic Environment-Guidance |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 15 kV air | ± 8 kV contact ± 15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 30%. |
| Electrical Fast Transient/Burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial, hospital, or residential environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial, hospital, or residential environment. |
| Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines IEC 61000-4-11 | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles | <5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles | Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the GSI Corti requires continued operation during power mains interruptions, it is recommended that |

| | | | |
|--|--|--|---|
| | 5% <i>UT</i> (>95% dip in <i>UT</i>) for 5 sec | 5% <i>UT</i> (>95% dip in <i>UT</i>) for 5 sec | the Corti be powered from an uninterrupted power supply. |
| Power Frequency (50/60 Hz) IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Note: <i>UT</i> is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

| Immunity Test | IEC 60601 Test Level | Compliance | Electromagnetic Environment-Guidance |
|-------------------------------|--------------------------|------------|--|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Corti, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 1.17\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field Strengthens from fixed RF transmitters, as determined by an electromagnetic site survey (a^*), should be less than the compliance level in each frequency range (b^*).</p> <p>Interference may occur in the vicinity of equipment marked:</p> |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |

| | | | |
|--|--|--|--|
| | | |  |
| <p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |

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

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