

OAE Hearing Screener

Directions for Use

REF 29400

WelchAllyn®

Advancing Frontline Care™



MERCOFRAMES OPTICAL CORP

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Chapter 1: Introduction

The Welch Allyn OAE Hearing Screener performs otoacoustic emissions tests. Using a combination of hardware and software, the Welch Allyn OAE Hearing Screener produces a controlled acoustic signal in the ear canal and measures the resulting evoked emission that is generated by outer hair cells in the cochlea. The system collects and averages data samples until specified measurement parameters are achieved. For distortion product otoacoustic emissions (DPOAEs), the DP and noise floor amplitudes appear on the LCD. A pass or refer result is assigned at the end of the test based on comparison of the test measures to the active protocol criteria. Users can view and analyze the results for further evaluation of the test outcomes.

The Welch Allyn OAE Hearing Screener is a medical device that produces information about the auditory system of a patient. This information is then available for medical diagnosis or screening. Therefore:



The Welch Allyn OAE Hearing Screener is intended for use by a health care professional or a technician who is trained and supervised by a health care professional or accredited organization.

Indications for use

The Welch Allyn OAE Hearing Screener produces controlled acoustic signals in the ear canal and measures the resulting evoked otoacoustic emissions (OAEs) that are generated by the outer hair cells of the inner ear as a result of normal peripheral hearing processes. The Welch Allyn OAE Hearing Screener performs distortion product otoacoustic emissions (DPOAE) tests that can be utilized in hearing screening and diagnostic test environments.

As an OAE based screening tool, Welch Allyn OAE Hearing Screener is indicated for use by any personnel (nurses, technicians, volunteers) who are trained to operate the device for the purpose of performing an objective, automated physiologic screening measure with pass/refer result requiring no further clinical interpretation. Additionally, as a tool that can provide diagnostic information, the device is indicated for use by trained health care professionals (audiologists, physicians) to further assess cochlear function for the purpose of diagnosis and treatment of hearing disorders, since additional information may be obtained by viewing the details of the performed otoacoustic emissions test.

The device can be used for patients of all ages, from newborn infants through adults, to include geriatric patients. The otoacoustic emissions test is especially indicated for use in testing individuals for whom behavioral results are deemed unreliable, such as infants, young children, and cognitively impaired adults.

About this manual

This manual gives step by step instructions on how to perform OAE tests and view results on the Welch Allyn OAE Hearing Screener.

Conventions The Welch Allyn OAE Hearing Screener manual uses specific font styles to identify aspects of the system operation.

References to the buttons on the front label of the Welch Allyn OAE Hearing Screener are always typed in all caps.

Labels referring to the names of the connectors that are on the front label of the Welch Allyn OAE Hearing Screener are typed in bold text.

Help For additional assistance, please contact Welch Allyn Technical Support at 1-800-535-6663.

Abbreviations **ART LVL** - artifact level; refers to the threshold at which samples of data coming into the Welch Allyn OAE Hearing Screener for processing are rejected before averaging in order to keep noise from averaging into the response. Artifact level is reported in pressure units, milliPascals (mPa).

WA OAE Load Software - loads the firmware that resides on the memory chip inside the Welch Allyn OAE Hearing Screener. This software also can be used to update the Welch Allyn OAE Hearing Screener date, time and default protocol.

COM - communications port on a computer; also known as serial port.

dB - decibel; a logarithmic measure of sound intensity.

DP Frequency - the frequency at which the distortion product (DP) emission occurs.

DPOAE - distortion product otoacoustic emission; refers to the acoustic energy generated by the outer hair cells of the cochlea in response to stimulation with two pure tone stimuli.

DP - distortion product; used interchangeably with DPOAE. The DP that has received the greatest interest and is most often measured clinically is the DP that is calculated by the formula $2F_1-F_2$.

DP-NF - the dB difference between the distortion product emission and the noise floor amplitudes. To be sure that a response is present, the DP-NF value must match or exceed a minimum. On the Welch Allyn OAE Hearing Screener, this value is 6 dB or greater.

DX - a button on the front panel of the Welch Allyn OAE Hearing Screener which is used to SELECT and implement functions described on the LCD.

F2 - the higher of the two stimulus frequencies used in a DPOAE test.

F1 - the lower of the two stimulus frequencies used in a DPOAE test.

F2/F1 ratio - the numeric relationship of the two stimulus frequencies to one another. Most research has shown that an F2/F1 ratio of approximately 1.2 produces the most robust emissions.

Hz - Hertz; a unit of measurement of frequency; also known as cycles per second.

LCD - liquid crystal display; refers to the message window on the upper portion of the Welch Allyn OAE Hearing Screener front panel.

LED - light emitting diode; a light that illuminates to indicate a hardware function. On the Welch Allyn OAE Hearing Screener, an illuminated green LED at the bottom left of the front panel indicates that the AC adapter is plugged in and AC power is flowing to the box.

L1 - level or intensity of F1; the lower of the stimulus frequencies expressed in dB SPL.

L2 - level or intensity of F2; the higher of the stimulus frequencies expressed in dB SPL.

NF - noise floor; refers to the average amplitude of the background noise measured at frequencies surrounding the DP frequency during the DPOAE test. This value is expressed in dB SPL.

RS232 - a cylindrical hardware connector with pins that must be aligned to the corresponding holes in the connector to which it attaches the Welch Allyn OAE Hearing Screener to a serial printer.

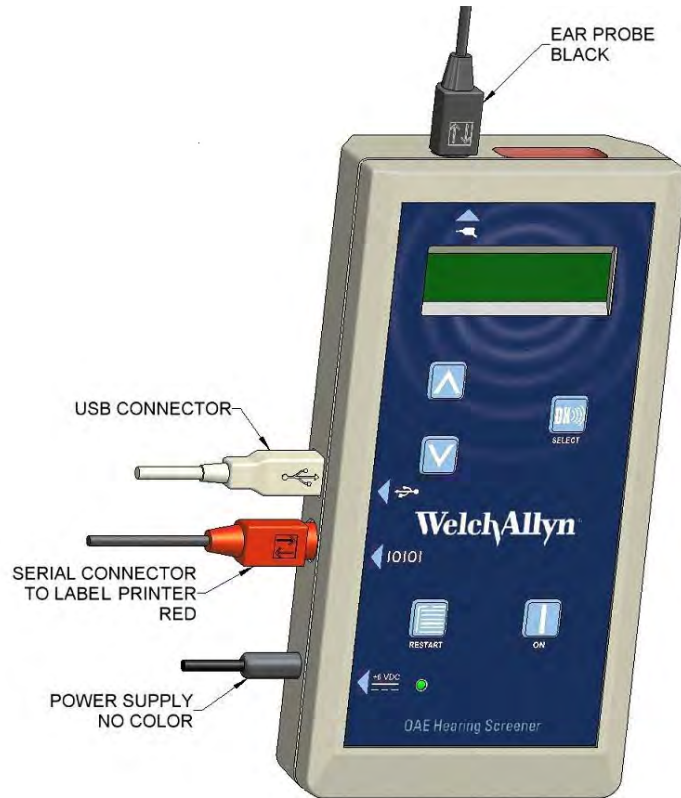
Serial connector - an external peripheral interface standard for communication to a label printer.

USB connector - An external peripheral interface standard for communication between a computer and the Welch Allyn OAE Hearing Screener box for updating the software in the Welch Allyn OAE Hearing Screener, setting the time and date or to download data to the PC.

Chapter 2: Welch Allyn OAE Hearing Screener Components and Hardware Setup

Cable Connections

The cable connections to the Welch Allyn OAE Hearing Screener box are described in the figure and the instructions below.



Welch Allyn OAE Hearing Screener Box with Cable Connections Indicated

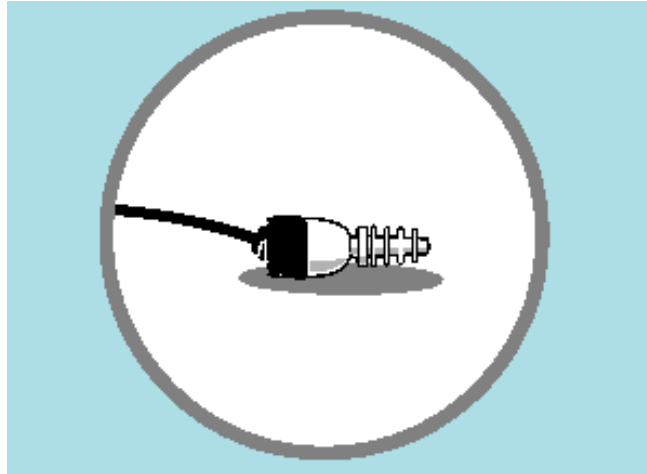
Probe Cable Assembly

1. Align the pins in the connector end of the probe cable to the holes in the jack on the top of the Welch Allyn OAE Hearing Screener box. An arrow on the connector shows the correct orientation of the probe connector to the Welch Allyn OAE Hearing Screener.
2. After verifying the connector is properly aligned, slide the probe connector end securely into its matching connector.



CAUTION

No other probes are compatible with the Welch Allyn OAE Hearing Screener (blue) hardware 29400/29401. The connectors do not match and attempting to force the connectors together may damage pins in the connector.



Probe part #29402 is compatible only with Welch Allyn OAE Hearing Screener (blue) hardware 29400/29401.

Charger Unit Assembly

The charger unit is not required for normal operation. The unit is attached to the Welch Allyn OAE Hearing Screener for the purpose of recharging the battery or to perform tests when the battery charge is low.

1. Plug the charger unit into the connector labeled +6V DC on the left side of the Welch Allyn OAE Hearing Screener box.
2. Connect the detachable power cord to the charger unit.
3. Plug the grounded power cord into an AC outlet.



WARNING!

AC ADAPTER UNITS ARE NOT INTERCHANGEABLE!

Use only the 6 volt AC adapter (520-PS6VDC) supplied for the Welch Allyn OAE Hearing Screener (blue) hardware 29400/29401. Using an AC adapter/charger supplied for other devices such as notebook computers or printers may cause damage to the Welch Allyn OAE Hearing Screener unit. Likewise, using the Welch Allyn OAE Hearing Screener adapter/charger on other devices may cause damage to that device.

Communication Cable Assembly

The communication cable is provided only for loading the Welch Allyn OAE Hearing Screener internal firmware or for downloading data to a computer. Communication takes place through a serial port or USB port and requires connection to a computer.

To connect the communication cable, align the connector on the communication cable to the connector on the left side of the Welch Allyn OAE Hearing Screener box.

1. After verifying the connectors are properly aligned, slide the communication cable connector end securely into its matching connector on the Welch Allyn OAE Hearing Screener box.
2. Insert the opposite end of the communication cable into the appropriate port (USB or Serial) on the computer.

Battery

Welch Allyn OAE Hearing Screener (29400/29401) uses either a lithium ion battery or an AC charger as a power source. When fully charged, the battery will last for approximately three hours of continuous testing. The auto OFF feature conserves battery life by turning the Welch Allyn OAE Hearing Screener off after approximately 180 seconds of dormancy. When the system turns off automatically, the user presses the ON button to turn the system on again. If the battery becomes depleted, the LCD display will briefly flash a LOW BATTERY message before the Welch Allyn OAE Hearing Screener automatically turns off.

To recharge the battery, plug the charger unit into the +6V DC connector on the left side of the Welch Allyn OAE Hearing Screener box and the power cord into an AC outlet. A green LED on the front of the Welch Allyn OAE Hearing Screener illuminates when the charger is plugged in. The AC charger can fully recharge the system battery in approximately three hours. The system can be used to perform tests while it is plugged into the charger. While the charger is plugged in, it will recharge the batteries between tests and the LCD will display a message continuously.

Chapter 3: Environment and Patient Preparation

There is minimal patient preparation required for an OAE test. Since the test measures a physiologic event, no behavioral response is required from the patient. Therefore, OAEs can be recorded on sleeping individuals or on patients who cannot reliably perform a pure tone audiometric test of hearing either because of illness, language barrier, developmental delays or cognitive deficits.

It is necessary, however, that the patient cooperate by allowing for insertion of the ear tip into the ear canal and by leaving the ear tip in place for the duration of the test. Depending on the test parameters used, the patient's emissions and the level of background noise, test time can vary from as little as 10 seconds to several minutes.

During the OAE test, very soft sounds are measured by the probe in the patient's ear canal. Because sound measurements are being performed it is important that the noise in the environment be controlled as much as possible. OAE tests are fastest when the background noise and patient generated noise is low. Be aware of sources of noise in the room. Take measures to control them or find a quieter room, if possible.

Patient Preparation

1. If you are trained and equipped to perform an examination of the ear canal with an otoscope, it is highly recommended that you do so prior to insertion of the ear tip into the patient's ear. Verify that the ear canal is clear of cerumen (earwax) that can interfere with the OAE test. Performing an OAE test on an ear draining fluid is not recommended.
2. Select a disposable ear tip that seems appropriate for the size of the patient's ear canal and install it on the probe. Use the largest ear tip that will fit into the patient's ear canal. An ear tip that is too small will result in low stimulus intensity and may cause a refer result. (See Chapter 4 for proper ear tip instructions.)
3. Insert the ear tip into the patient's ear canal. When using the larger size foam tips, be sure to compress the tip with your fingers until it is a small diameter cylinder. Quickly, while it is still compressed, gently pull up and back on the patient's ear to straighten the ear canal and insert the ear tip deeply and securely into the canal. Hold it in place for a few seconds while the foam expands in the canal. If the ear tip stays in place without holding it, it is in securely.
4. When using the OAE Tree Ear Tip, gently pull down and back on the patient's ear to straighten the ear canal and insert the ear tip deeply and securely into the canal. If the ear tip stays in place without holding it, it is in securely. Do not hold the probe in place as this will create noise.
5. Clip the probe cord to the patient's clothing, infant carry-all or bassinet with enough slack so that it is not pulling down on the probe. This will reduce the chance that the weight of the probe cord will pull the probe out of the ear. For young children, clipping the probe cable on the back of the shirt could help prevent the child from grabbing the cable and pulling the probe out of the ear.
6. When testing a newborn or young infant, it may be helpful to swaddle the baby in a blanket to try to keep movement at a minimum. Placing the infant on his/her stomach or side with a rolled blanket behind the back (to keep the baby from rolling onto his back) can facilitate testing. With the test ear facing up, the probe is more likely to remain in the ear canal for the duration of the test.

Patient Instructions

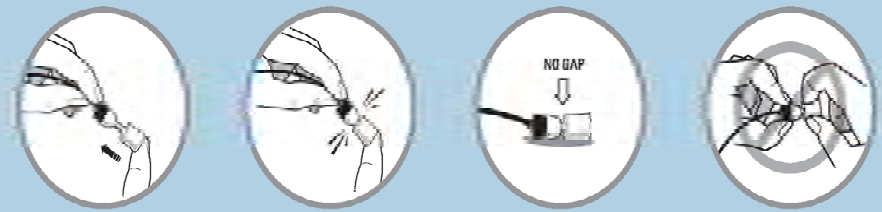
For patients who can understand instructions, the following information will help prepare them for the test. Inform them that:

1. You will insert the ear tip into the ear canal.
2. He/She will hear a series of sounds for a few seconds, up to a minute or so.
3. The test will be fastest and most accurate if the patient remains quiet throughout the entire test which will be brief, no more than a minute. That means no talking, minimal movement, and the patient should not respond to the sounds in any way.

Chapter 4: Care and Maintenance of the Probe

Welch Allyn OAE Hearing Screener Ear Probe Instructions

Attaching Foam Ear Tips




Place the clear tube slightly onto the nozzle of the probe body.

Using your fingertip, continue pushing on the top of the foam until the clear tube covers the entire nozzle.

The end of the clear tube of the ear tip should cover the nozzle completely leaving no gap at the base.

Do not pinch foam while attaching ear tip onto the nozzle.

Removal of Foam Tips

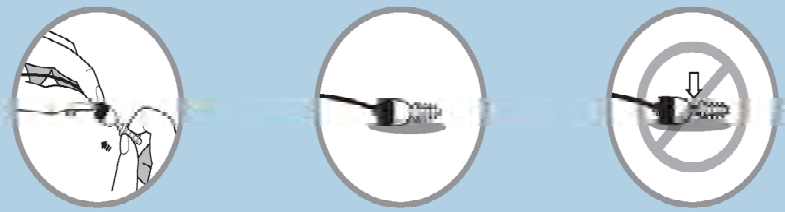


To remove foam tips, hold the probe body with your fingertips on top of the nozzle clips. Then, with the other hand, place your fingernails behind the clear tube at the base of the nozzle and slide the tube toward the end.

Do not pull on the foam. This will cause suction of the tube around grooves in the nozzle and will actually impede the removal.

You may end up pulling the foam off of the clear tube while the tube remains on the nozzle.

Attaching Silicone Ear Tips



Slide ear tip onto the probe nozzle until you meet with resistance. Then place your fingernails behind the thickened ring around the base of the tip and slide the tip on until it is all the way on the nozzle.

Correct Ear Tip Placement

Incorrect Ear Tip Placement (Base-end of the ear tip is not flush against base of nozzle.)

To remove the silicone ear tips, hold the probe body with your fingers on top of the nozzle clips. With the other hand, place your fingernails at the base of the ear tip and slide it off the nozzle.

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Cleaning of Probe Nozzle

After removing the disposable ear tip, inspect the probe nozzle for debris in any of the three grooves.

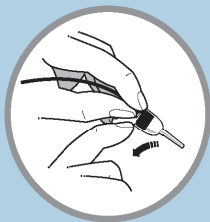
Note: At the base of two of the grooves, a short protrusion of nylon filament may be visible. This is part of the design and should not be removed.

If debris is present, clean the grooves with a tissue or gauze pad. (A hearing aid wax removal tool may be useful for this as well if one is available.) Be sure to clean the grooves from the base to the tip to avoid pushing debris back into the closed channels at the base of the grooves. You may use an alcohol pad to clean the nozzle. Do not let excess alcohol drip down the grooves into the closed channels at the base. That portion of the probe cannot be cleaned.

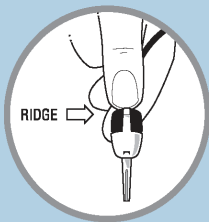
Removal of Probe Nozzle

The probe nozzle should only be removed to troubleshoot data collection problems. After a few times being removed, the clips will no longer hold the nozzle securely in place on the body and the semidisposable nozzle will have to be replaced.

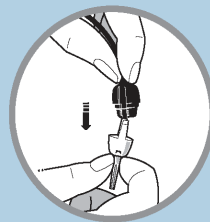
The nozzle has two clips that secure it to the probe body. The bottom clip is flat and smooth to the touch. The top clip has a ridge of additional plastic on its surface.



Locate the smooth, flat clip. Use your fingernail to lift up on the end of the clip to unlock it.

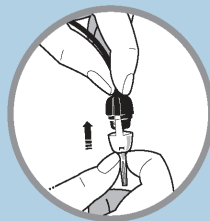


Locate the clip with the ridge and use your fingernail to lift up and unlock it.

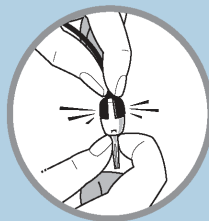


After both clips are unlocked, gently pull nozzle off of the probe body.

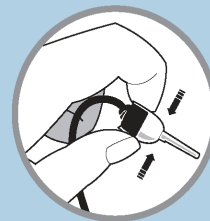
Installation of Replacement Probe Nozzle



To install a new nozzle onto the probe body, align the clips on the probe nozzle with the corresponding slots in the probe body. Be sure that the probe nozzle component is oriented so that the shape of the cavity matches the shape of the probe body.



Once the two pieces are aligned to match, slide the nozzle clips down the slots until they lock into the small indentations at the back of the probe body.



Make sure that the nozzle component is securely attached to the probe body.

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Chapter 5: Quick Guides and Instructional Videos

This section of the document presents Quick Guides, step-by step test procedures and other useful information. The Quick Guides:

- List the steps required for performing an OAE test and for reviewing OAE data.
- Present suggestions to help you use otoacoustic emissions to test infants, toddlers and preschoolers.
- Explain conditions that could cause a Refer result for a Welch Allyn OAE Hearing Screener.

One laminated copy of the Quick Guide is provided with the Welch Allyn OAE Hearing Screener.

Instructional Videos on the Welch Allyn OAE Hearing Screener Inservice Guide

The Welch Allyn OAE Hearing Screener Inservice Guide supplied with your Welch Allyn OAE Hearing Screener contains Instructional Help Videos along with the Directions for Use document.



Welch Allyn OAE Hearing Screener

System Setup

1. Connect the probe cable to the top of the OAE Hearing Screener box.
2. Align the pins in the end of the cable with the holes in the jack.
 - The arrow on the connector shows the correct orientation of the probe connector to the OAE Hearing Screener.
3. Select appropriate ear tip.
4. Slide probe tip all the way onto the probe body.
 - Verify that no hard surfaces are exposed at the end of the ear tip that will be inserted into the ear canal.
 - The tips are designed to extend beyond the plastic tip by approximately 1/16th inch.
 - Dispose of probe tip after each patient.

Data Collection

1. Press the **ON** button on the OAE Hearing Screener.
2. When the Welch Allyn DPOAE software message appears in the display area:
 - Press the **DX SELECT** button to continue.
3. When message "PERFORM DPOAE" appears in the display area:
 - Press **DX SELECT** to initiate test.
4. When message "TEST R EAR" appears in the display area:
 - Record unique test number assigned to the test, if necessary.
5. If the ear to be tested is the left ear:
 - Press the **DOWN** arrow to display the message "TEST L EAR."
6. When the correct ear is displayed:
 - Press the **DX SELECT** button to initiate the automated check fit, calibration and test.
 - Test continues until completion.
 - When the test is complete, the test number and "PASS" or "REFER" result appears on the display along with the message "SEE DETAILS"
7. To see test results for individual frequencies: Press **DX SELECT**.
8. Use the **DOWN** and **UP** arrows to move through the test frequencies.
9. To print test results, use the **UP** or **DOWN** arrow until "PRINT" appears on the display. Press **DX SELECT** to print.



Data Review

1. Press the **ON** button on the OAE Hearing Screener.
2. When the Welch Allyn DPOAE software message appears in the display area:
 - Press the **DX SELECT** button to continue.
3. When message "PERFORM DPOAE" appears in the display area:
 - Press **DOWN** arrow:
 - The message changes to "VIEW DPOAE RESULTS." Press **DX SELECT**.
 - The last test performed appears on the display.
4. Use the **UP** and **DOWN** arrow buttons to move through the tests that are stored in the OAE Hearing Screener memory.
5. When the desired test number appears on the display:
 - Press the **DX SELECT** button to review the details of this test.
6. To print the results or view another test:
7. Press the **DX SELECT** button.
8. Use the **UP** and **DOWN** arrows to move through the tests that are stored in the OAE Hearing Screener memory.

Testing Hints for Newborns

1. Do not screen patient more than three times per ear. Overscreening can result in a false negative result.
2. Swaddle baby and position on side for best access to ear.
3. Test at least 11 hours after birth, if possible, to prevent false positives due to vernix.
4. If infant fails, re-test at least one more time before discharge.
5. If one ear fails, try to have baby lay so that the failed ear is facing up for a while to clear vernix before retesting.
6. If infant is fussy or crying, offer pacifier.
7. OK to test while infant is nursing.

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Welch Allyn OAE Hearing Screener

Troubleshooting the Probe (29402 Semidisposable probe only)

Error Messages/Problem

Probe in Ear? Refit and Retry Or Occluded Probe	<ol style="list-style-type: none"> 1. Clean probe and make sure ear tip is properly placed. 2. Verify secure connections of all cables. 3. Verify that no pins are bent or broken on the probe cable connector. 4. Verify that there is no damage to probe connection on OAE Hearing Screener box. 5. Reconnect probe cable into OAE Hearing Screener box.
Empty Database	<ol style="list-style-type: none"> 1. When a new software version is uploaded from a computer to OAE Hearing Screener, the database of tests is erased from memory.
Reset Date/Time	<ol style="list-style-type: none"> 1. Use WA OAE Load program.
Memory Error Reload Software or No Loader Reload Software or Error 000##	<ol style="list-style-type: none"> 1. Detach printer cable or USB cable. 2. Allow OAE Hearing Screener to power down. Then press ON button and initiate internal software installation. 3. If the above does not work, use WA OAE Load program to reinstall software.
Turn Printer On Try Again	<ol style="list-style-type: none"> 1. Verify that printer power is on. 2. Verify secure cable connection from printer to OAE Hearing Screener. 3. Reload paper in printer, if needed.
Printer Skipping Labels	<ol style="list-style-type: none"> 1. Reload paper in printer.

Using the Test Cavity

1. Place a Tree Tip on the probe.
2. Insert the probe securely into the test cavity.
3. Perform test on OAE Hearing Screener as usual.
4. Test results should show a "REFER."
5. If error messages are obtained, follow the troubleshooting suggestions above.
6. A "PASS" result may be observed at individual test frequencies in a DPOAE test due to the resonance properties of a hard-walled cavity. But the overall test result should be a "REFER."

**Welch Allyn OAE Hearing Screener
Troubleshooting Quick Guide: Causes of Refer Results**

Noise	
Problem	Possible solutions
<ul style="list-style-type: none"> ◆ Noisy surroundings <ul style="list-style-type: none"> — Other people in or near test site. — Devices such as fans, air conditioners, intercoms, and public address systems. 	<ul style="list-style-type: none"> ◆ Eliminate or reduce noise <ul style="list-style-type: none"> — Isolate and completely sound-proof the test site (optimal). — Ask others in or near test site to refrain from talking or other activity. — Ask noisy people to move to another location; ask parents to move noisy children to another location. — Deactivate or remove any device that is a potential source of noise. — Use larger probe tip, if possible.
<ul style="list-style-type: none"> ◆ Patient noise <ul style="list-style-type: none"> — Crying or struggling against the probe — Sucking a pacifier or bottle — Excessive movement — Talking 	<ul style="list-style-type: none"> ◆ FOR NEWBORNS OR INFANTS: <ul style="list-style-type: none"> — Swaddle child in blanket and test while child is asleep. — Ask parent to hold child comfortably and to prevent child from pulling probe or cable. ◆ FOR TODDLERS: <ul style="list-style-type: none"> — Distract fussy toddlers with a quiet toy or book. — Ask parent to help by holding the toddler comfortably on lap or shoulder. ◆ FOR OLDER CHILDREN: <ul style="list-style-type: none"> — Explain that being quiet will speed up the test and reduce the possibility of retesting.
Middle Ear Involvement	
Problem	Possible solutions
<ul style="list-style-type: none"> ◆ Middle ear conditions that add mass or stiffness to the middle ear such as: <ul style="list-style-type: none"> — Otitis media — Severe Eustachian tube dysfunction — Otosclerosis 	<ul style="list-style-type: none"> ◆ Refer results caused by temporary conditions that cause middle ear involvement will improve as the middle ear returns to normal.

Obstructions	
Problem	Possible solutions
<ul style="list-style-type: none"> ◆ Cerumen, vernix, or other debris <ul style="list-style-type: none"> — In the ear — On the probe tip — On the probe 	<ul style="list-style-type: none"> ◆ IN THE EAR: <ul style="list-style-type: none"> — Make sure that a properly trained technician examines the ear canal for obstructions BEFORE inserting the probe. — Delay testing newborns until 11 hours after birth, if possible. (Note: 'Refer' results caused by vernix decrease with each hour after birth.) ◆ ON THE PROBE TIP: <ul style="list-style-type: none"> — Remove, discard, and replace the probe tip before each test (optimal). — Remove, examine, and wipe probe tip clean; make sure that both the inside and outside of the tip are clean; replace cleaned probe tip. ◆ ON THE PROBE: <ul style="list-style-type: none"> — Clean the probe carefully by following the instructions in the Directions for Use guide.
<ul style="list-style-type: none"> ◆ Temporary collapse of the ear canal <ul style="list-style-type: none"> — Occurs often with "down ear" when infant is lying on side. — Collapse is normal because bones haven't formed in ear yet. 	<ul style="list-style-type: none"> ◆ Manipulate the ear in a gentle, circular motion before inserting the ear tip. ◆ Make sure to have a good probe fit. ◆ If infant is lying on side, reposition infant so that down ear faces up; ask attending nurse or parent to keep infant in this position as much as possible; wait a few hours before testing "down" ear.
Cochlear Outer Hair Cell Loss	
<ul style="list-style-type: none"> ◆ Hearing loss <ul style="list-style-type: none"> — Problems include communication difficulties in noisy environments and speech and language development delays. 	
<ul style="list-style-type: none"> ◆ Refer on OAE and not on Pure Tone Audiometry <ul style="list-style-type: none"> — Occurs most frequently in people exposed to high levels of sound energy (noise or music) or those treated with ototoxic medications. — OAE responses are often affected before evidence of hearing threshold change appears on a behavioral hearing test. 	
False Positives	
<ul style="list-style-type: none"> ◆ 'Refer' criteria maximizes the detection of individuals with true hearing impairment. ◆ A small percentage of people with normal hearing sometimes get a 'Refer' result. <ul style="list-style-type: none"> — These are people whose OAE responses fall below the 10th percentile for the normal population. — Such low OAE responses warrant additional testing. 	

Chapter 6: Welch Allyn OAE Hearing Screener Clinical Competency Evaluation and Result Letters

The Welch Allyn OAE Hearing Screener Clinical Competency Evaluation is used for the Train the Trainer approach to learning the Welch Allyn OAE Hearing Screener. This evaluation can be used to ensure that new screeners are competent in using the Welch Allyn OAE Hearing Screener. This evaluation can also be used to document that training occurred and use of the Welch Allyn OAE Hearing Screener has been mastered.

The Result Letters can be used to give to patients or their caregivers to provide additional documentation of the screening results.

The Welch Allyn OAE Hearing Screener Clinical Competency Evaluation and Result Letters are on separate pages so that they can be copied and used multiple times.

Welch Allyn Hearing Screener Clinical Competency Evaluation

Purpose: This evaluation certifies that _____ has met Welch Allyn’s requirements for utilizing the OAE Hearing Screener. The training involved hands-on exercises. Although further training may be needed, this individual has demonstrated competency in the following areas at this time.

TASK	Performed Task	Needed Training	Did Not Observe
1) Properly plugs in equipment	_____	_____	_____
2) Properly turns on equipment	_____	_____	_____
3) Powers on label printer	_____	_____	_____
4) Demonstrates how to clean probe	_____	_____	_____
5) Follows facility infection control	_____	_____	_____
6) Launches Screener program	_____	_____	_____
7) Records patient Log Number	_____	_____	_____
8) Swaddles baby and/or prepares patient for test	_____	_____	_____
9) Selects patient's ear in software	_____	_____	_____
10) Selects proper sized probe tip	_____	_____	_____
11) Places probe into patient’s ear	_____	_____	_____
12) Troubleshoots probe fit if needed	_____	_____	_____
13) Knows how to View Details	_____	_____	_____
14) Prints results from label printer	_____	_____	_____
15) Restarts for next patient	_____	_____	_____
16) Provides appropriate counseling to patient or caregiver regarding results	_____	_____	_____
17) Documents results according to facility’s protocol	_____	_____	_____

The above evaluation was successfully completed on _____.

Name and Title of Person Supervising the Competency Evaluation

Pediatric Hearing Screening Results

Date of Exam: _____

Patient's Name: _____

Date of Birth: _____

This patient's hearing was screened using otoacoustic emissions. The patient **passed** the hearing screening in both ears, which indicates that hearing is adequate for normal speech and language development. No further testing is recommended at this time.

A delayed onset hearing loss can develop and this screening does not rule out the need for future evaluation if parental concerns regarding speech and language development arise or if future medical events place this child at risk for a hearing loss. The Joint Committee on Infant Hearing advises that follow-up hearing evaluations occur if this patient has a congenital infection, or a family history of hearing loss. If you have questions concerning the screening, do not hesitate to contact us.

Insert OAE Screener Sticker Here

Pediatric Hearing Screening Results

Date of Exam: _____

Patient's Name: _____

Date of Birth: _____

This patient's hearing was screened using otoacoustic emissions. The patient **referred** on the hearing screening in one or both ears. The purpose of this screening is to detect any hearing loss that could be detrimental to normal speech and language development.

The hearing screening result does not mean that the patient definitely has a hearing loss; however, it does mean that the patient needs further audiological evaluation to either rule out or confirm a hearing loss. Further evaluation by an audiologist experienced with pediatric assessment is recommended. Early detection of hearing loss is critical for language development and/or school success. If you have additional questions, do not hesitate to contact us.

An appointment has been made for further evaluation.

Date: _____ Time: _____

If you have any questions, do not hesitate to contact us.

Insert OAE Screener Sticker Here

Chapter 7: System Operation

The front label of the Welch Allyn OAE Hearing Screener incorporates five buttons that the user presses to turn on or reset the box and move through the possible program operations. Refer to the figure and the instructions that follow it to understand the functions of each button. Other sections of this chapter provide flow charts of the software.

Buttons and Their Function



Welch Allyn OAE Hearing Screener and Buttons

The ON button is used to power on the Welch Allyn OAE Hearing Screener when it is turned off. It also acts as a reset button if pressed when the screener is already on. If the ON button is pressed during any operation it will function as a reset, aborting the current process and returning to the beginning of the Power ON sequence flow chart.

The RESTART button returns the Welch Allyn OAE Hearing Screener to the PERFORM DPOAE message in preparation for performing another test or for viewing data from previous tests. By pressing the RESTART button at any point during program operation, the current operation will be aborted and the PERFORM DPOAE message will appear.

The DX SELECT button is used to initiate the procedure that is displayed on the LCD display. For example, if the PERFORM DPOAE message is displayed, pressing the DX SELECT button initiates a test sequence. Press the UP or DOWN arrow keys until the desired program function appears in the LCD display. Then press the DX SELECT button.

The UP and DOWN arrow buttons move through the list of program choices and data files. Press the UP or DOWN arrow keys until the desired program function appears in the LCD. Then press the DX SELECT button.

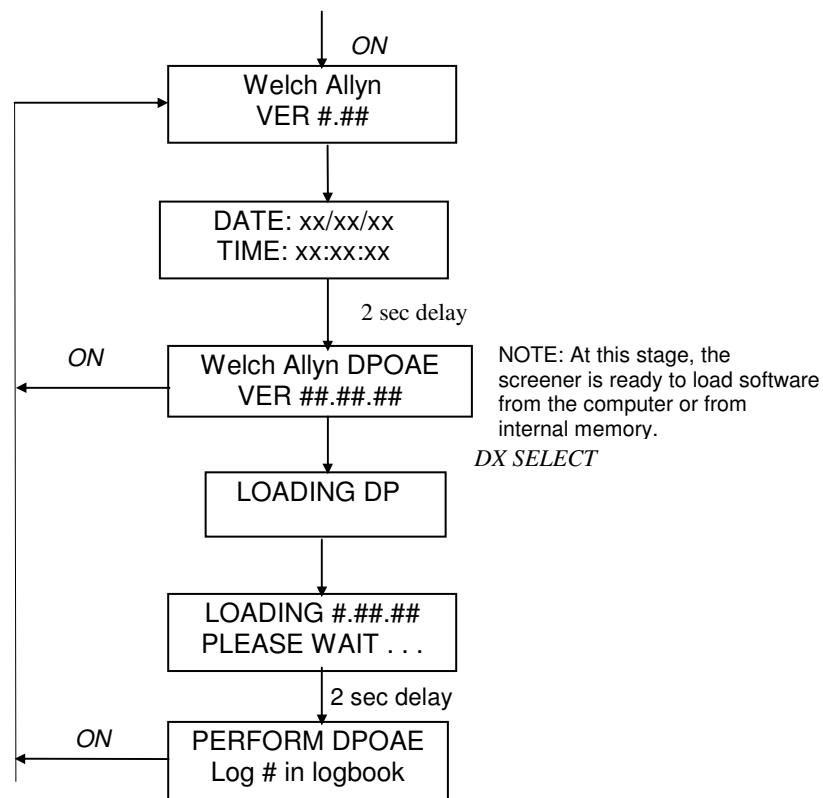
Program Flow Chart

In this section the Program Flow Chart is broken down into four sections: Power ON, Performing a Test, Viewing Test Details, and Viewing Previously Collected Data.

In the flow charts, the boxes represent the display messages seen on the LCD of the screener. The lines in between boxes show the software flow direction as indicated by the arrow. The text beside the flow arrows indicates how the step is initiated. For example, the text may describe a button press or a condition that initiates an automatic progression to the next step.

The paragraphs below the flow chart provide information that is not covered in the flow chart format.

Power ON

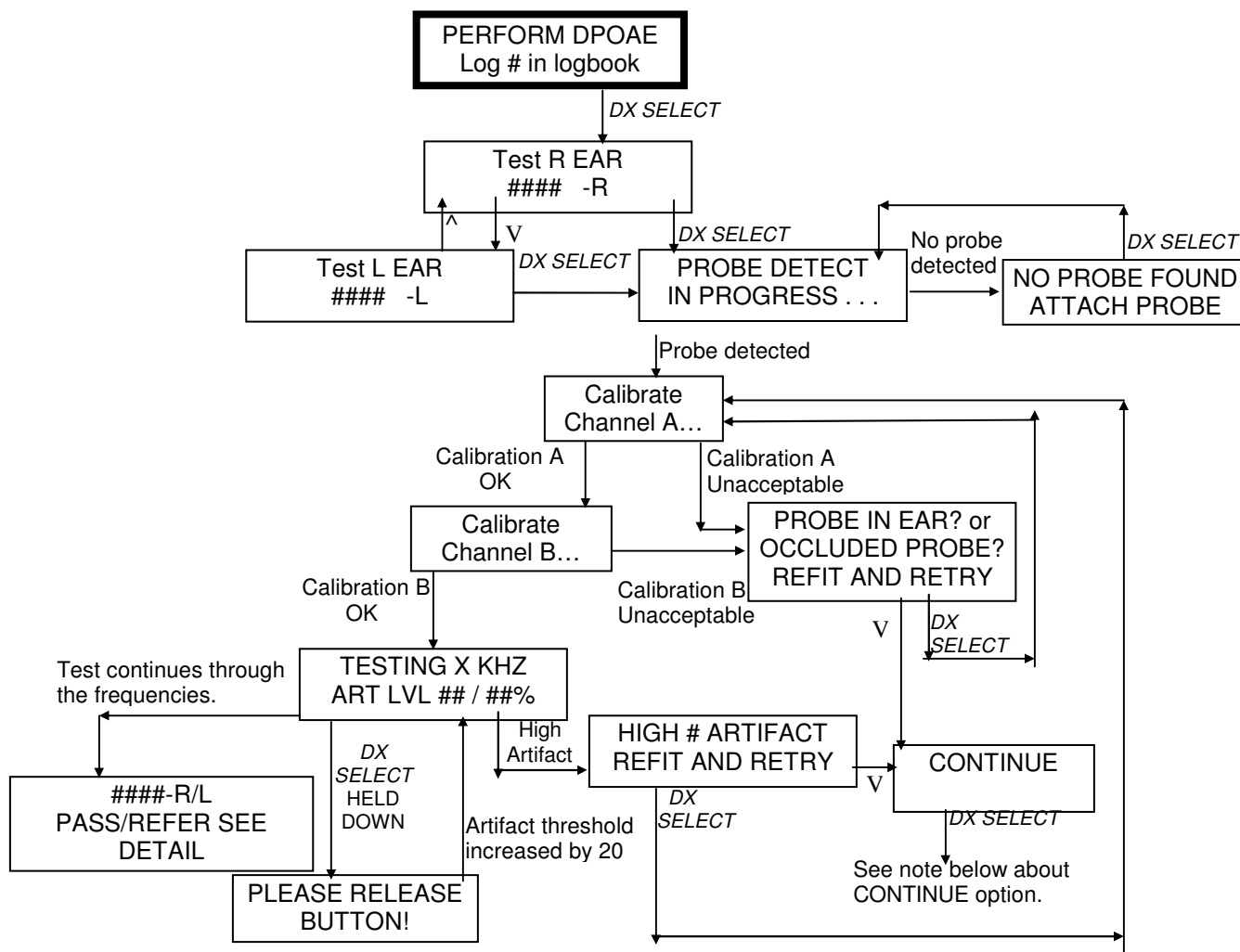


The operation of the ON button is the same for the following flow charts. That is, it will always return the user to the initial Welch Allyn message on the LCD. It will not be depicted in the following charts.

Chapter 8: Distortion Product Otoacoustic Emissions

Performing a DPOAE Test

This flow chart begins at the point where the Power ON flow chart ended. The steps shown here are specific for performing the pre-programmed DPOAE test procedure. Note: Selection of the RESTART button from any point in the program flow chart returns to the PERFORM DPOAE message so that function is not represented in the flow chart.



Re: CONTINUE option. When the *DX SELECT* button is chosen when the CONTINUE message is displayed, the program will try to proceed to the next step in the test process, but possibly with poor calibration results or test conditions, so it is not recommended on a routine basis.

Each test is assigned a unique test number that is displayed in the Test R/L EAR box. Since the Welch Allyn OAE Hearing Screener holds 10 tests in memory, this unique number can assist you in associating a test with a particular patient. To keep track of the patient test numbers, the patient's name, test numbers and details of the test (if desired) should be recorded in a logbook or patient file.

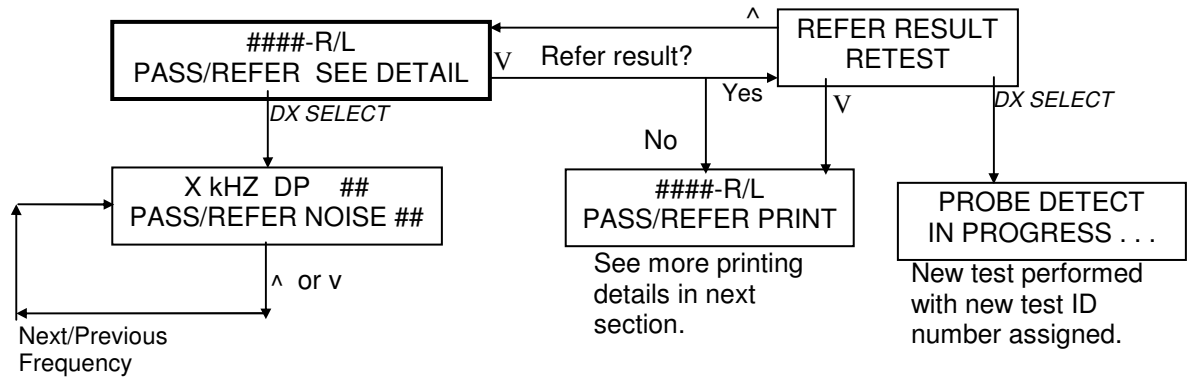
After 10 tests have been performed, the next test (test 11) will overwrite the first test. This proceeds in a continuous loop so that only the last 10 tests performed are saved and accessible in memory. Once overwritten, a test cannot be retrieved. If you wish to record or print the details of a test, it is important that you do so before it is overwritten.

Increase Artifact Reject Level

During a test you can increase the artifact rejection threshold in small increments by pressing and holding down the DX SELECT button until the message PLEASE RELEASE BUTTON! flashes on the LCD. It may take a few seconds to see the change on the LCD since the display only updates every few seconds. The default artifact rejection threshold is 30 mPa. Each press of the DX SELECT button increases the artifact rejection level by 20 mPa and this will be displayed on the LCD. This feature can be used when a high percentage of data samples are being rejected from averaging caused by a noisy environment or patient, resulting in prolonged test time. However, increasing the artifact rejection threshold allows more noise into the average and that may confound interpretation of the data. If possible, try to control the environmental or patient noise instead of increasing the artifact rejection threshold. However, newborns and infants often produce high levels of internal noise just due to breathing and the artifact rejection threshold may have to be increased in order to collect any data successfully. This procedure will have to be repeated for each test frequency in the DPOAE test.

Viewing DPOAE Test Details or Retesting an Ear with a Refer Result Immediately After a Test

This flow chart begins at the point immediately after the DPOAE test has been successfully completed and the SEE DETAILS message is displayed.



The PASS/REFER indicator displayed in the first SEE DETAIL box is for the overall test. The PASS/REFER indicator in the second X KHZ DP ## box is for the individual frequency being displayed. The displayed PASS/REFER indicator is based on research published by Gorga, Neely, Ohlrich, Hoover, Redner and Peters (1997)¹. For more information about the criteria needed for a PASS or REFER indicator to appear, see Chapter 12 System Default Protocol.

In the X KHZ DP ## message box, the number after the DP abbreviation is the amplitude of the distortion product emission. In the second line, the number following the word NOISE is the amplitude of the noise floor. Remember that RESTART will return to the PERFORM DPOAE message at any time.

When a Refer result has occurred, selection of the DOWN arrow key from the SEE DETAILS message will display a REFER RESULT RETEST message. Selection of the DX SELECT button will then initiate another test and increment to the next test ID number so that all tests performed in this way will be present in memory, until the tests begin to be overwritten once the capacity of the memory is achieved.

1. Gorga MP, Neely ST, Ohlrich B, Hoover B, Redner J, 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: 6, 440-455.

Printing DPOAE Test Details Immediately After a Test

The Welch Allyn OAE Hearing Screener with the serial label printer prints out a 2" x 4" self-adhesive label showing the test details immediately after it is performed or to print it out later by retrieving it from memory.

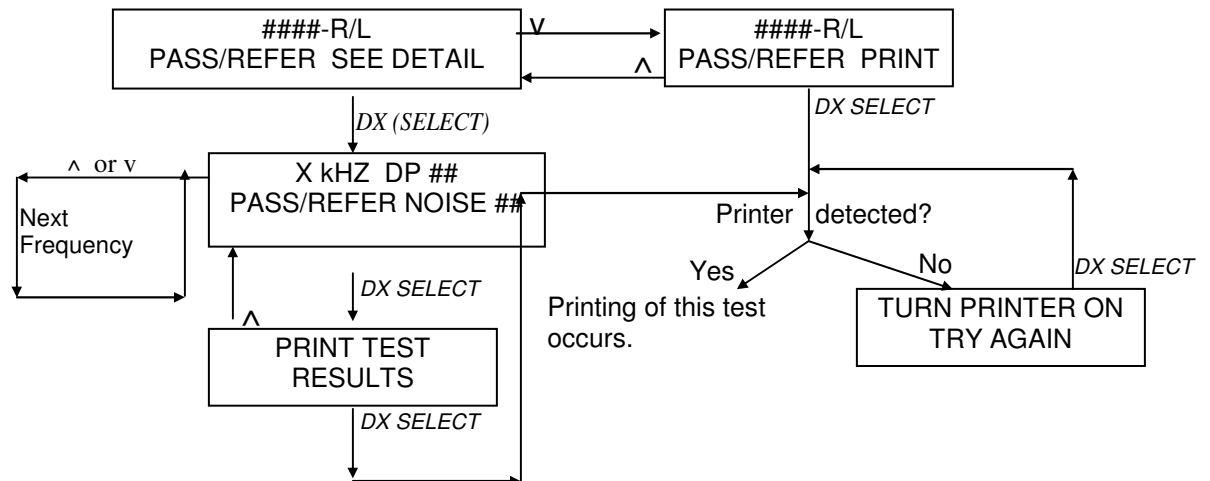
The AC power supply must be connected to the back of the printer and plugged into an outlet. The printer must be powered ON using the ON/OFF switch on the printer.

To print out the results immediately after a test is performed using the serial printer it must be connected to the screener before the test is begun using the special cable provided with the printer. The cylindrical RS232 connector end of this cable should be aligned and plugged securely into the receptacle labeled IOIOI on the left side of the screener. The other end of this cable is a RJ12 connector that is commonly seen on telephone cords. It should be connected into the bottom of the serial printer.

If the serial printer was not attached to the screener during collection of the data, see the section entitled **Printing Previously Collected Data** for the details on printing test results.

This flow chart begins at the point immediately after the DPOAE test has been successfully completed. With the serial label printer, the assumption is that the printer is already powered ON and is connected to the screener.

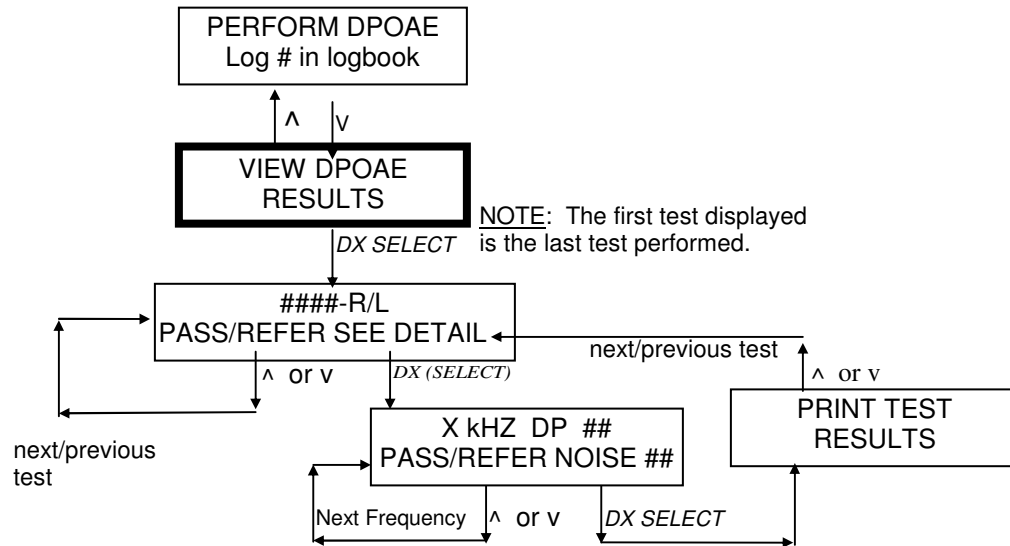
If result is a Refer, then pressing the down arrow 2 times will display the Print message; Retest LCD message displays in between.



As can be seen from the flow chart above, printing of the test just completed can be performed in two different ways. From the SEE DETAIL screen, the user can press the down arrow button to access the PRINT message and press DX SELECT. Or, from the SEE DETAIL screen, the user can elect to first see the details on the LCD by pressing the DX SELECT button and use the up/down arrow buttons to move through the test frequencies. Pressing the DX SELECT button from any one of the frequency details displays will access the PRINT TEST RESULTS screen. Pressing the DX SELECT button implements the printing of this test.

Viewing Previously Collected DPOAE Data

This flow chart begins at the point where the PERFORM DPOAE message is displayed and shows the program flow for instances in which you wish to view data that is saved in memory.



Recall that only the last 10 tests are retained in memory for retrieval and review. Tests collected prior to the last 10 are sequentially overwritten with each new test performed. There is no way to retrieve them after they have been overwritten.

The PASS/REFER indicator displayed in the first SEE DETAIL box is for the overall test. The PASS/REFER indicator in the second X KHZ DP ## box is for the individual frequency being displayed. The displayed PASS/REFER indicator is based on research published by Gorga et al (1997). For more information about the criteria needed for a PASS or REFER indicator to appear, see Chapter 12 System Default Protocol.

In the X KHZ DP ## message box, the number after the DP abbreviation is the amplitude of the distortion product emission. In the second line, the number following the word NOISE is the amplitude of the noise floor.

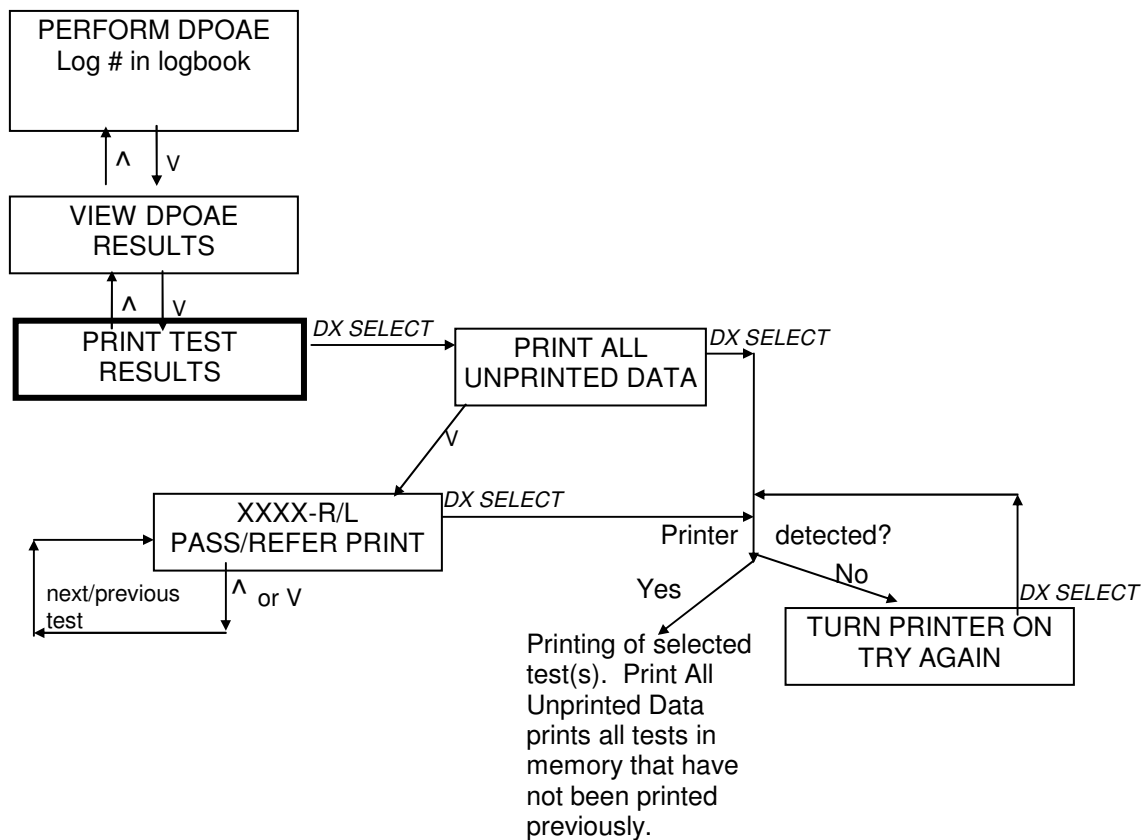
Remember that RESTART will return to the PERFORM DPOAE message at any time.

Chapter 9: Printing Previously Collected Data – Single Ear

The AC power supply must be connected to the back of the printer and plugged into an outlet. The printer must be powered ON using the ON/OFF switch. When using the serial label printer, be sure to have it plugged into the screener serial port before you print.

To print out the results on a serial printer, it must be connected to the screener using the special cable provided with the printer before you select the test for printing. The cylindrical RS232 connector end of this cable should be aligned and plugged securely into the receptacle labeled IOIOI on the left side of the screener. The other end of this cable is a RJ12 connector that is commonly seen on telephone cords. It should be connected into the corresponding receptacle of the serial printer.

This flow chart begins at the point where the PERFORM DPOAE message is displayed and shows the program flow for instances in which you wish to print data that is stored in memory.



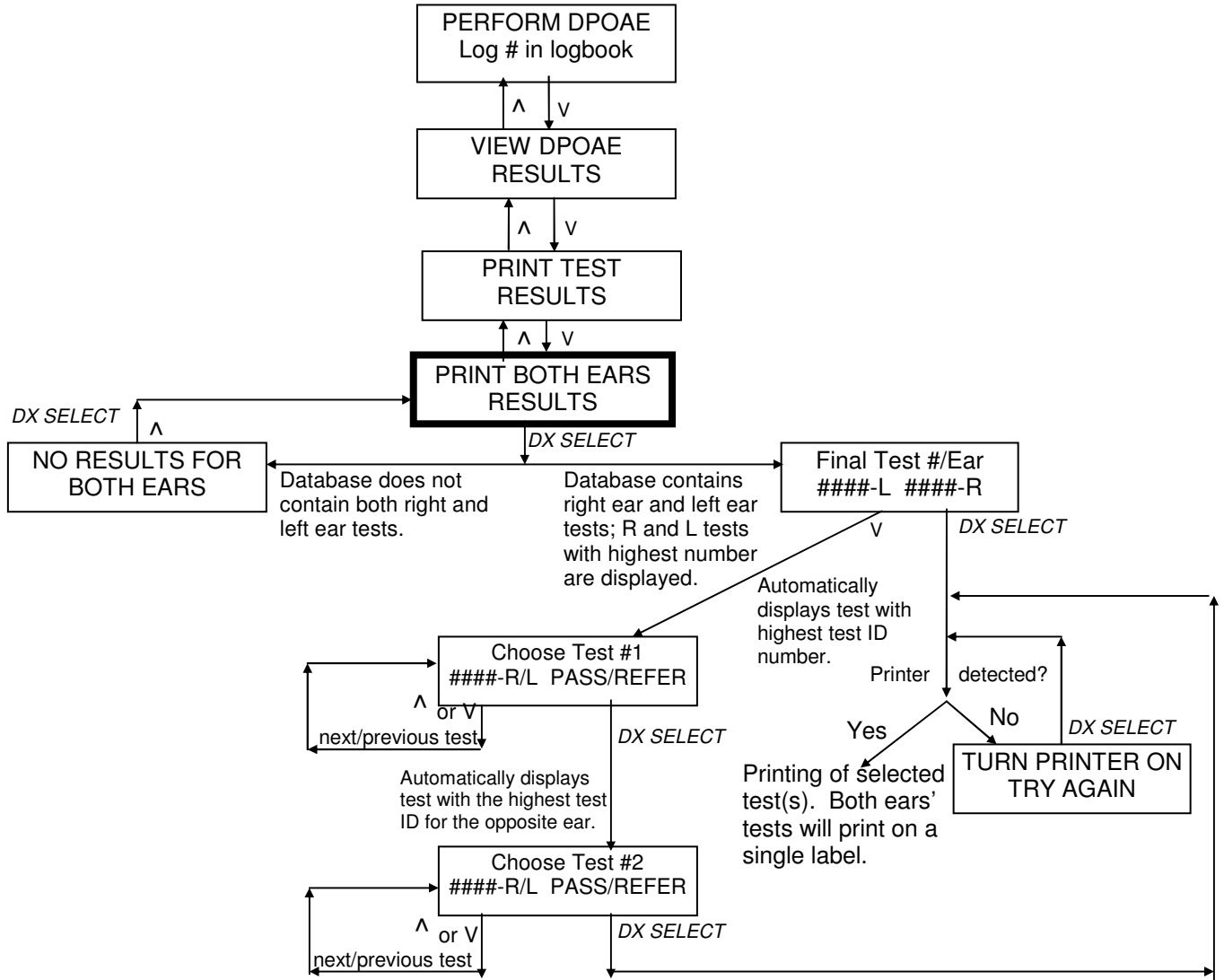
The PRINT ALL UNPRINTED TESTS feature is intended for use when multiple tests are stored in memory and the user wishes to print out all of them at one time. Every test that is stored in memory that has not been printed before will be printed if the DX SELECT button is pressed when the PRINT ALL UNPRINTED TESTS message is displayed. If the intent is only to print individual tests, bypass the PRINT ALL UNPRINTED TESTS message by pressing the DOWN arrow button until the PRINT BOTH EARS RESULTS is displayed on the LCD. The first individual test displayed will be the last test performed. When the desired test numbers have been chosen, press the DX SELECT button to print out a label for that particular patient.

If the printer is not connected to the screener or is not powered ON when an attempt is made to print, the message TURN PRINTER ON, TRY AGAIN will display on the LCD. Verify that the cable is securely attached to both the screener and the printer and that the printer power is ON. Then press the DX SELECT button again to attempt to print.

If PRINT ALL UNPRINTED TESTS is selected when no remaining unprinted tests are stored in memory, the LCD will return automatically to the PERFORM DPOAE message. This is an indication that all of the tests currently stored in memory were previously printed out. However, if the user wishes to print a test result again, this can be accomplished by printing out the desired test(s) individually.

Chapter 10: Printing Previously Collected Data – Both Ears on One Label

This flow chart begins at the point where the PERFORM DPOAE message is displayed and shows the program flow for instances in which you wish to print data that is stored in memory.



Chapter 11: Printer

See Chapters 8, 9 and 10 for instructions about how to print out tests from the Welch Allyn OAE Hearing Screener.

The Welch Allyn OAE Hearing Screener 29400/29401 (blue label) is only compatible with the Seiko label printer supplied by Welch Allyn. The screener uses serial communication to print test results using the label printer. USB printing from the screener to the label printer is not possible.

Some models of Seiko label printers are only compatible with a newer version of the firmware that is installed on the OAE Hearing Screener using the WA OAE Load Software. This means that the Seiko printer provided with a new system purchase may not print when connected to a previously purchased Welch Allyn OAE Hearing Screener system. To resolve this issue, the user can update the firmware version installed on the older OAE Hearing Screener, using the WA OAE Load Software provided with the new system or printer. Refer to Chapter 13 for instructions about how to install the firmware.

Operating Steps

1. Connect the white power supply to the back of the Seiko label printer and plug into wall outlet.
2. Turn Seiko label printer on by pressing white button (green light should display).
3. Place white cylinder thru roll of labels. Labels should be facing downward. Feed label thru into slot behind and below the label roll container. Press the white Label feed button to start the label roll.
4. Connect the serial cable to the printer (telephone jack) and to the OAE Hearing Screener (red connector).
5. See chapter 8, 9 and 10 regarding how to print data.



For additional questions, please make contact with Welch Allyn Technical Support at 1-800-535-6663.

Ordering Labels

To order labels call Welch Allyn at 1-800-535-6663.

Chapter 12: System Default Protocol

The Welch Allyn OAE Hearing Screener comes pre-programmed with a DPOAE default screening protocol. The system default protocol is:

DPOAE System Default Protocol

Collection Parameters, Stopping Parameters and Pass/Refer Criteria

The DP system default protocol is set with the following stimulus parameters, response parameters, measurement-based stopping rules, and Pass/Refer criteria.

Creation Date:	03/23/04	Power down time:	3
Number of frequencies for overall pass:	3	Number of samples per set:	60
Checkfit trials:	10	Calibration trials:	10
Number of successes to pass:	1	Number of calibration successes to pass:	1
Number of checkfit failures until refit:	7	Number of calibration failures until refit:	7
Checkfit / Calibration Artifact Rejection:	250	Checkfit is not done during test.	
Lower frequency shift:	On	Higher frequency shift:	Off

The action taken when an overall refer is achieved is to stop the test.

The action taken when an overall pass is achieved is to stop the test.

Collection Parameters				
Frequency	L1	L2	F2 / F1	Artifact Level
5000	65	55	1.22	30
4000	65	55	1.22	30
3000	65	55	1.22	30
2000	65	55	1.22	30

Stopping Rules					
Frequency	DP	And / Or	DP - NF	NF	Time-Out
5000	-5	And	8	-17	12
4000	-5	And	8	-17	12
3000	-5	And	8	-17	12
2000	-5	And	8	-17	12

Pass / Refer Criteria					
Frequency	DP	And / Or	DP - NF	Noisy Message	Include in P / R
5000	-6	And	6	-5	Yes
4000	-5	And	6	-5	Yes
3000	-8	And	6	-5	Yes
2000	-7	And	6	-5	Yes

DPOAE Measurement-Based Stopping Rules per Test

The system default DPOAE protocol stops the test when the conditions for an overall test Pass or Refer occur. For example, if the first 3 frequencies “Pass”, then the final frequency will not be tested since the overall pass criterion is that 3 out of 4 frequencies must pass. Likewise, if the first 2 frequencies “Refer” then the final two frequencies will not be tested since there is no chance for an overall Pass result even if the final two frequencies Pass. This has the advantage of shortening the test time.

If you would like the system to continue through all of the test frequencies rather than stopping when conditions for an overall Pass or Refer are achieved, refer to the section entitled **Changing the Default Protocol to Continue through All Frequencies**.

DPOAE Pass or Refer Criteria

For an overall PASS result to display on the LCD at the completion of a DPOAE test when using the DPOAE system default protocol, three of the four test F2 frequencies must meet the response conditions defined for a PASS.

The PASS/REFER criteria incorporated into the screener are based on published data by Gorga, Neely, Ohlrich, Hoover, Redner and Peters (1997)¹. In Gorga et al's study, hearing impairment was defined as a behavioral, pure tone audiometric threshold of 25 dB HL or greater at a particular frequency. The interested reader is referred to this study for more detailed information.

Screener Sensitivity and Specificity Estimations

If normal hearing at a frequency is defined as having an audiometric threshold of 20 dB HL or better, and an equivalent hardware is used to record responses and generate stimuli with the same characteristics described in the article Gorge, et al. 1997 (i.e., high frequency and low frequency stimulus tone intensities are kept at 55 dB SPL and 65 dB SPL, respectively while the frequency ratio is kept as 1.22 as is the case with Welch Allyn OAE Hearing Screener protocol), then the device's clinical performance in terms of its sensitivity and specificity can be estimated from the cumulative distribution functions published by Dr. Gorga and his colleagues (Gorga et al., 1997; Dorn et al. 1999). With the use of cumulative distribution graphs for normal and hearing impaired populations, the sensitivity and specificity for each tested frequency using the specific protocol parameters can be determined for the DPOAE amplitude and SNR criteria separately and then the statistical theory can be used to calculate the results for combined DPOAE and SNR criterion. Furthermore the overall expected test sensitivity and specificity ranges for the representative sample population (ages 1.3 years to 96 years) can be determined by using probability theory. The overall sensitivity and specificity values for the screening protocols estimated using the methods described above is provided in the Table below. Frequency specific sensitivity and specificity values are given in the next Table.

	Overall DPOAE Performance Estimates	
	Sensitivity	Specificity
Highly Correlated	0.89	0.85
Independent	0.992	0.904

Table: Overall Sensitivity and Specificity range estimates of screening protocols that provide an overall Pass/Refer recommendation. A minimum of 3 individual frequency 'Pass' results are required for an overall 'Pass'. Note that 'highly correlated' designation represents the case where individual tested frequencies are considered to be clinically correlated to each other, whereas 'independent' means they are considered individually and not correlated to each other. Since some degree of correlation is expected in real life, but the correlation amount is not known, the test sensitivity and specificity is expected to be between the boundary values represented in the table.

Note: Normal hearing is defined as pure tone audiometric threshold of 20 dB HL or better at each test frequency.

Frequency Specific Performance Estimates		
Frequency (Hz)	Sensitivity	Specificity
2000	0.8	0.85
3000	0.87	0.83
4000	0.89	0.88
5000	0.9	0.88

Table 2: Frequency specific Sensitivity and Specificity estimates for each tested frequency range

Changing the DPOAE Default Protocol to Continue through All Frequencies

If you would like the system default DPOAE protocol to test all of the frequencies even after conditions for an overall Pass or overall Refer are met, you can load a new default protocol into your Welch Allyn OAE Hearing Screener.

1. Using Windows Explorer do one of the following depending on operating system in use:
 - In Windows 7 open the directory C:\Users\Public\Documents\Welch Allyn\Welch Allyn OAE Load.
 - In Windows XP open the directory C:\Documents and Settings\All Users\Documents\Welch Allyn\Welch Allyn OAE Load.
2. Delete the file named "default.adx".
3. Locate the folder named "AA" and open it.
4. Select and copy the file named "default.adx" contained in the AA folder.
5. Return up one level to the WA OAE Load directory.
6. Paste the copied "default.adx" file into the WA OAE Load directory.
7. Exit Windows Explorer.
8. Connect the screener to the PC using the provided communication cable.
9. Launch the WA OAE Load program.
10. Select Start to load the firmware into the screener.

See Chapter 13 if you need additional instructions about how to install the WA OAE Firmware onto the screener.

1. Gorga MP, Neely ST, Ohlrich B, Hoover B, Redner J, 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: 6, 440-455.

Chapter 13: Reloading WA OAE Firmware (WA OAE Load software)

The Welch Allyn OAE Hearing Screener runs on firmware that resides on a memory chip inside the unit. Each Welch Allyn OAE Hearing Screener comes with this firmware pre-installed so that the device is fully functional upon delivery. Users can, however, reprogram this memory chip with a PC-based application called WA OAE Load. This application comes with every new system. You can use this application if the delivered firmware becomes corrupted and must be reinstalled, to update the date and time on the Welch Allyn OAE Hearing Screener, or to upgrade the system if you receive new firmware.

To install the WA OAE Load application on your computer:

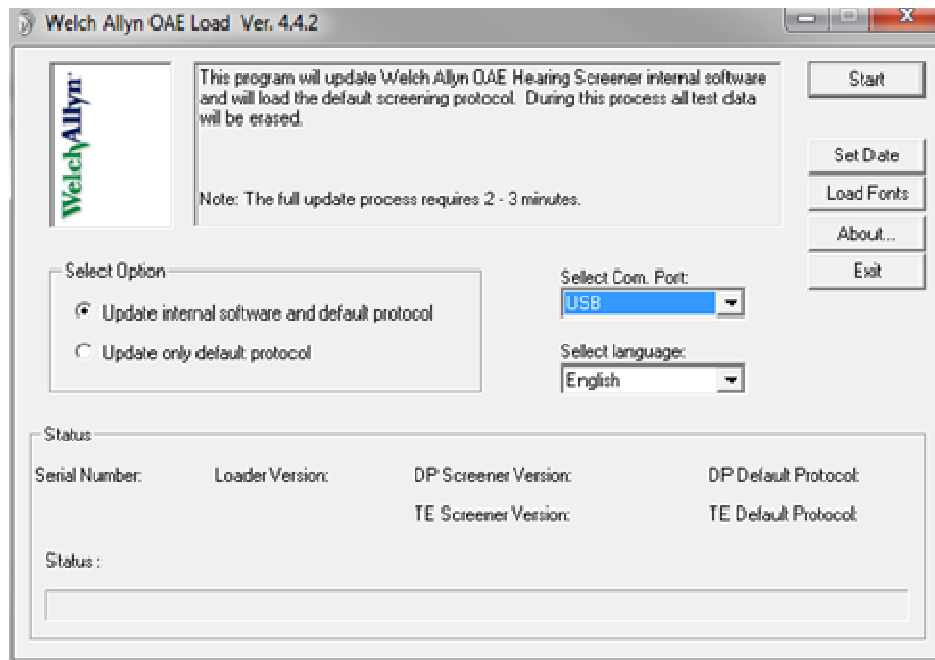
1. Turn on your computer.
2. Make sure the system date and time settings on your computer are correct. During the WA OAE Load process, the date and time set on the PC will be used to set the clock inside of the screener.
3. Locate the Welch Allyn OAE Hearing Screener Inservice Guide CD provided with your Welch Allyn OAE Hearing Screener.
4. Insert the CD into the computer's CD drive. If your PC supports automatic opening of the installation program, you will see the following screen when the CD is opened.



- If your PC does not support the automatic running of the installation software on the CD you will need to browse to the CD drive using Windows Explorer and open the file named “install.exe” to view this screen.
5. Select the “**Welch Allyn OAE Software**” button.
 6. Follow the on-screen prompts to complete the installation of WA OAE Load onto your PC. A WA OAE Load shortcut icon will be placed on the PC’s desktop.
 7. Select the Exit button on the WA OAE Load installation screen.

To install the WA OAE Firmware to your screener:

1. **Verify that the tests in the screener can be deleted safely!** The process of re-installing the firmware into the screener will delete all tests.
2. Verify that the screener is connected to the PC using the cable provided with the system.
3. It is advisable to plug the screener charger/power supply into the screener during this operation so that a low battery charge does not cause interruption of the download of firmware into the screener.
4. Launch the WA OAE Load application using the shortcut icon on your PC desktop and the following screen will appear.



5. If you are using a serial cable between the screener and the PC, verify that the setting in the Select Com. Port field is set correctly for your hardware. If you are using USB connection, then this setting is irrelevant.
6. Select the Start button in the upper right corner of the screen. (Note: If you only want to reset the Date and Time in screener, select the Set Date button.)

7. The "Status:" area toward the bottom of the screen will show the progress of the download of firmware into the screener. The complete process takes 2-3 minutes.
8. Exit the application when the WA OAE Firmware download is complete.

Note: If you need assistance installing the WA OAE Load software on your PC or downloading WA OAE Firmware, please contact Welch Allyn Technical Support at 1-800-535-6663.

The table below provides more details about the various buttons and options on the WA OAE Load application screen.

Component	Description
Information area	This area of the Main Screen displays information about the WA OAE Load program.
Start command button	Select (click on) the Start command button to begin to download the firmware. Note that the program requires 2-3 minutes to complete the installation process. Make sure the time and date on your PC are accurate.
From Disk command button	Select (click on) this command button to launch an Open dialog box. This dialog box lets you run the WA OAE Load installation program from another disk.
Set Date command button	Select (click on) this command button to update the time and date settings in screener. The date and time will be taken from your PC.
Load Fonts	Select (click on) this command button to load the fonts for the Label Printer. I will check to make sure this is still accurate.
Help command button	This command button is inactive.
Exit command button	Select (click on) the Exit command button to close the WA OAE Load Main Screen.
Select Option radio buttons	This area of the Main Screen contains a set of radio buttons next to a list of the options that apply to the WA OAE Load process. In most cases, select (click on) the radio button next to "Update internal software and default protocol." Select (click on) the radio button next to "Update only default protocol" only if you have received a new test protocol file and you only want to update that part of the WA OAE Firmware.
Select ComPort field	The setting in this field is only relevant if you are using a serial cable for communication between the PC and screener. In that case, select (click on) the arrow to display a list of the Communication ports available. Click on the communication port to which the screener is connected.
Status area	This area displays information about the progress of the WA OAE Firmware download.

Chapter 14: Exporting using ASCII Link

ASCII Link is a utility program that lets you download data from the Welch Allyn OAE Hearing Screener unit's memory to a PC and convert it to an ASCII file. This tool lets you save Welch Allyn OAE Hearing Screener data in your own spreadsheet where you can use it for research. To use the ASCII Link program:

1. Install the ASCII Link program from the Welch Allyn OAE Inservice Guide CD.
2. Attach the Welch Allyn OAE Hearing Screener unit to the computer using the USB cable provided with the system.
3. Launch the ASCII Link program.

(Be aware that this application will automatically delete all tests from the Welch Allyn OAE Hearing Screener memory after the conversion to ASCII format has been performed.)

This application automatically transfers the data from the Welch Allyn OAE Hearing Screener to the computer and converts it to an ASCII file.

4. The ASCII file "transfer.axo" can be found in one of the following folders depending on the operating system in use as follows:
 - In Windows 7, the ASCII file "transfer.axo" is found in the folder C:\ProgramData\Welch Allyn\ASCII Link.
 - In Windows XP the ASCII file "transfer.axo" is found in the folder C:\Documents and Settings\All Users\Welch Allyn\ASCII Link.
5. The AXO file is a space delimited ASCII file. Each line contains the following information:

Description	Example Data
Date and time (day-month-year-hour-minute-second) DDMMYYYYHHMMSS	10052005134513
ID Number of protocol used for test	3
ID number of patient/Orphan	Orphan (i.e. no patient ID available) AB123456789A01
Ear	Right Left
Pass/Refer/No Result	OverAll_PASS OverAll_REFER OverAll_NOT_RESULT
Printed/Not printed	Printed Not_Printed
Number of frequencies in test	3
Frequency (F2 for DP)	5000
Frequency Pass/Refer/Noisy	PASS REFER NOISY
DP Result	DP=7
DP-NF Result	DP-NF=18
Noise Result	Noise=-21

OAE Test ID (1000-9999); prefix 10= DP	102001 (<i>DP</i>)
OAE Serial Number	05369
Reproducibility %	Reproducibility=85

Chapter 15: Troubleshooting, Service and Warranty

Error messages usually appear on the LCD when the system is unable to perform a desired function. This section lists some of the more common error messages and possible solutions.

Error Messages

LOW BATTERY!!!
CONNECT CHARGER

This message appears when the battery charge is completely depleted. The message will flash for 10 seconds after which the unit will power off. Connecting the AC adapter/charger unit will allow continued data collection and will charge the unit between tests. Complete charging of the Welch Allyn OAE Hearing Screener takes about 3 hours.

NO LOADER
RELOAD SOFTWARE

This message appears when the initialization software is not found either because it was not installed on the Welch Allyn OAE Hearing Screener or because it has become corrupted. Press the *ON* button to reset the device. If the problem persists call Welch Allyn Technical Support at 1-800-535-6663 for further instruction.

CHECK SUM ERROR

This message appears when the software protocols are not found either because it was not installed on the Welch Allyn OAE Hearing Screener or because it has become corrupted. Reload the WA OAE Firmware using the WA OAE Load program. If the problem persists call Welch Allyn Technical Support at 1-800-535-6663 for further instruction.

MEMORY ERROR
RELOAD SOFTWARE

This message appears when the initialization software is not found either because it was not installed on the Welch Allyn OAE Hearing Screener or because it has become corrupted. Press the *ON* button to reset the device. If the problem persists call Welch Allyn Technical Support at 1-800-535-6663 for further instruction.

PLEASE RELEASE
BUTTON!

This message appears when one of the buttons on the Welch Allyn OAE Hearing Screener label is depressed for more than .3 sec. Releasing the button returns the system to normal operation. If depressed during data collection the artifact rejection threshold level will be increased by 20mPa.

EMPTY
DATABASE

This message appears when an attempt is made to view data when no tests are stored in memory. When a new software version is uploaded from a computer to the Welch Allyn OAE Hearing Screener, the database of tests is erased from memory.

LOADING ###.##
PLEASE WAIT. . .

This message routinely appears when the unit is powered on and the *DX SELECT* button is pressed. It is only problematic if the message remains on the screen for a prolonged period (more than 10 seconds) and does not progress to the next message, PERFORM DPOAE. This may occur if the battery charge is marginal. If this occurs, plug in the charger unit, press the *ON* button and the *DX SELECT* button and try again. Once the battery is recharged, the unit will return to the normal Power ON sequence.

TURN PRINTER ON
TRY AGAIN

This message appears when an attempt is made to print data on the label printer but the printer is not communicating with the Welch Allyn OAE Hearing Screener. This can be due to poor connection of the printer serial cable to the printer or to the screener, or lack of power to the printer.

NO PROTOCOLS
EXIST

This message appears when an error has occurred during the installation of the WA OAE Firmware into the unit or if the firmware has been corrupted causing the protocols database in the unit to become unreadable.

NOTE: For error messages that do not appear here, or if you are unable to correct a problem, contact Welch Allyn Technical Support at 1-800-535-6663.

Service

Caution Unauthorized repairs will void the warranty.

A Welch Allyn Service Center must perform all repairs on products under warranty. Qualified electronics personnel or a Welch Allyn Service Center should repair products out of warranty.

Technical Assistance

If you have an equipment problem that you cannot resolve call the Welch Allyn Technical Support center nearest you (page ii) on normal business days.

If you are advised to return a product to Welch Allyn for repair or routine maintenance, schedule the repair with the service center nearest you. The part and serial numbers are located on the bottom of the OAE Hearing Screener.

Before returning a product for repair, you must obtain authorization from Welch Allyn. Service personnel will give you a Service Notification number. Please note this number on the outside of your shipping box. Returns without a Service Notification number will not be accepted for delivery.

Warranty

Welch Allyn warrants the OAE Hearing Screener, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of one year from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the OAE Hearing Screener to Welch Allyn or an authorized distributor, agent, or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by other than Welch Allyn or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

Remember to submit the instrument registration/warranty card for warranty validation. Complete the information and mail the pre-addressed card to Welch Allyn.

Appendix A - Precautions and Safety Instructions

IMPORTANT

This device is intended for use by qualified personnel only. Please read this section and the Welch Allyn OAE Hearing Screener Directions for Use before installing any of the hardware, then retain this section as a reference while operating, transporting, storing or re-installing equipment.

Equipment Identification Labels and Markings

Classification

The International Electrotechnical Commission classifies electro-medical equipment according to its power source (external or internal) and the degree of protection it provides against shock. The Welch Allyn OAE Hearing Screener is classified as Type B which means it qualifies as externally powered equipment capable of protecting a patient from electrical shock.

Warning Labels and Symbols

Symbols are often used on equipment in preference to words in order to simplify language differences and to provide instant comprehension of warnings and markings in a restricted space. The following symbols appear on the Welch Allyn OAE Hearing Screener equipment or in the Welch Allyn OAE Hearing Screener Directions for Use.



Follow instructions for use



Attention, consult accompanying documents



Type BF equipment



Waste electrical and electronic equipment: Product should not be disposed of in normal waste.

Electrical Installation Requirements

The following requirements are necessary only when using the Welch Allyn OAE Hearing Screener in an AC-powered configuration. Grounding is not necessary in normal battery-powered use.

Grounding Requirements

The desired installation site must have a grounding wire for electrically connecting the system equipment to a properly grounded terminal (Earth). The grounded terminal shall be connected to the steel skeleton or under the main reinforcing steel with any multiple grounding wires grounded at the same point. (One point grounding) The shield room or bed must also be grounded at the same grounding terminal as the installation site.

Power Plug Requirements

Use only the following power plug configurations.

- A 3-pin power plug requires a 3-pin wall socket with a properly installed grounding pole. Verify the wall receptacle is correctly grounded before inserting the 3-pin power plug.
- A 2-pin/3-pin adapter for connecting 3-pin power supply plugs to a 2-pin wall socket. The grounding terminal on the adapter must be fixed with the free end secured to the ground terminal.
- A 2-pin power plug with a grounding terminal for a 2-pin wall socket. The grounding terminal on the power plug must be secured to the ground terminal.

Types of Hospital Facility Groundings

Use the following information to verify the installation site has the appropriate grounding.

Grounding Resistance	The ground resistance of grounding poles connected to medical equipment must be 10 ohms or less.
Protective Grounding patient	Protective grounding must be provided for safety to let the leak current flow into the ground.
Functional Grounding	This type of grounding is not a requirement for patient safety, but will help to eliminate hums.

Hazards of Improper Electrical Installations

Improper electrical installation can cause electrical shock to either the patient or user. It can also damage system equipment under a fault condition.

Environmental Specifications

Temperature

Operating: 15 to 40 degrees C

Storage: -20 to 70 degrees C

Humidity

Operating: 15% to 95% @ 40 degrees C non-condensing

Storage: 90% @ 65 degrees C

Note: These are maximums and should not be considered 'normal' operating or storage environments.

Condensation

Recovery Time after condensation to operational specification: 24 Hours

Flammability

UL94 V-0

Electrical Standards

Safety: IEC 60601-1 Ed. 3.0 b:2005

Collateral Standard: IEC 60601-1-2 Ed 3.0 b:2007

Emissions: CISPR 11
IEC 61000-3-2:2006
IEC 61000-3-3:1995 + A1:2001 + A2:2006

Immunity: IEC 61000-4-2:2001
IEC 61000-4-3:2002
IEC 61000-4-4:2001
IEC 61000-4-5:2001
IEC 61000-4-6:2003
IEC 61000-4-8:2001
IEC 61000-4-11:2001

Performance Specifications

Signal Strength: -20 to 80 dB SPL

Frequency range: 0-10,000 Hz

Stimulus frequency range: 500-10,000 Hz

System accuracy with probe: +/- 2 dB at 1 kHz

EMC Guidance and Manufacturer's Specifications

Electromagnetic Emissions

The REF 29400 Series OAE Hearing Screener is intended for use in the electromagnetic environment specified below. The customer or user of the REF 29400 Series OAE Hearing Screener should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The REF 29400 Series OAE Hearing Screener 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	The REF 29400 Series OAE Hearing Screener is suitable for use in all establishments, other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Welch Allyn device or shielding the location.

Electromagnetic Immunity


The REF 29400 Series OAE Hearing Screener is intended for use in the electromagnetic environment specified below. The customer or user of the REF 29400 Series OAE Hearing Screener should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ± 1 kV	Mains power quality should be that of a typical commercial or hospital 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 or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	100% dip 60% dip 30% dip 100% dip	Mains power quality should be that of a typical commercial or hospital environment. If the user of the REF 29400 Series OAE Hearing Screener requires continued operation during power mains interruptions, it is recommended that the REF 29400 Series OAE Hearing Screener be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Electromagnetic Immunity

The REF 29400 Series OAE Hearing Screener is intended for use in the electromagnetic environment specified below. The customer or user of the REF 29400 Series OAE Hearing Screener should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>5 V/m from 30MHz to 1GHz, 7 V/m for 1GHz to 2.5 GHz; (1000 Hz, 80% Modulated Test Signal)</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the REF 29400 Series OAE Hearing Screener, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <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 strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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

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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the REF 29400 Series OAE Hearing Screener is used exceeds the applicable RF compliance level above, the OAE Hearing Screener should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OAE Hearing Screener.

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

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the REF 29400 Series OAE Hearing Screener

The REF 29400 Series OAE Hearing Screener is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the REF 29400 Series OAE Hearing Screener can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REF 29400 Series OAE Hearing Screener as recommended below, according to the maximum output power of the communications equipment.

Rated Max. Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0.12	0.12	0.20
0,1	0.37	0.37	0.63
1	1.17	1.17	2.0
10	3.69	3.69	6.32
100	11.67	11.67	20

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 transmitter, 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 separation distance for the higher frequency range applies.

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

Installation Precautions

Observe the following precautions when using the Welch Allyn OAE Hearing Screener and related equipment.

Environmental Conditions

- Select a room with properly grounded power sources (when using in AC-powered configuration).
- Do not use or store the Welch Allyn OAE Hearing Screener and equipment in places where chemicals are stored or where there is a potential for gas leakage.

- Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures, poorly ventilated areas and dusty, saline or sulfuric air.
- Verify the selected site maintains a relative humidity between 25% and 95% (without condensation).
- Verify all conditions meet the requirements listed in the Environmental Specifications section of this manual.

Room Topography

Place all equipment on an even, level surface. Avoid the potential for mechanical shock or possible vibrations during setup, system operation or when relocating the equipment.

System Hookups



WARNING!
Only use the Battery Charger Power Supply Models Number 520-PS6VDC with the Welch Allyn OAE Hearing Screener.

- Verify the maximum load for any multiple portable socket-outlet (if used) does not exceed 750 VA.
- Do NOT place any multiple portable socket-outlets (if used) on the floor.
- If multiple portable socket-outlets are used, DO NOT use the multiple socket-outlets to power any equipment that isn't a part of the Welch Allyn OAE Hearing Screener. (Adding other equipment may increase the current amount of leakage and exceed the safety limit.)
- Do not interconnect multiple pieces of equipment without verifying that the sum of all leakage currents does not exceed the safety limit.
- Do not connect any non-medical electrical equipment directly to a wall outlet if the Welch Allyn OAE Hearing Screener is using a multiple, portable socket-outlet with a separating iso-transformer. (The additional equipment may increase the current amount of leakage and exceed the safety limit.)
- Do not connect equipment which can potentially provide electromagnetic or other types of interference. This may cause the Welch Allyn OAE Hearing Screener equipment to function incorrectly.
- Verify the equipment is connected to a power line source with the following frequency, voltage and current capacity.

Frequency:	50 / 60 Hz
Voltage:	100 - 240 VAC
Current Capacity:	1.60 – 1.20A

Installation Verification

Use the following list to verify all equipment is correctly installed before use.

- Verify all equipment and cables are undamaged and in perfect working condition.
- Verify all equipment and cables are connected according to the instructions in this manual.
- Verify unauthorized equipment is not connected to the system.
- Verify the equipment is properly grounded.
- Verify all circuitry with a direct connection to the patient has been checked twice.
- Verify all system or equipment batteries show the correct voltage and are in perfect working condition.

Signal Output and Input

The system computer must NOT be used in a patient environment unless the following conditions are met:

1. The system computer and all other peripheral devices are plugged into an approved isolation transformer.
2. The portable computer is powered by batteries, not plugged into a wall outlet.
3. The system computer has an approved isolated power supply.

Precautions During System Operation

Follow all safety procedures, giving careful and constant attention to the patient and system equipment.

1. Verify the patient cannot become either entangled or strangled by cables connecting the patient to the system hardware.
2. Avoid direct contact between the patient and system equipment at all times.
3. Do not add other equipment which is not protected against ingress of liquids.
4. This equipment is not suitable for use in areas of flammable or anesthetic mixtures.
5. This is a Class A product. In a domestic environment this product may cause radio interference in which case the end user may be required to take adequate measures.

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