OtoSight
Middle Ear Scope

INSTRUCTIONS FOR USE

October 2022, Revision 9

PhotoniCare

S-20302

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TABLE OF CONTENTS

SECTION: 1. INTRODUCTION

SECTION 1: INTRODUCTION

1.1 Indications for Use and Intended Use

The OtoSight Middle Ear Scope is intended for use as an imaging tool for real-time visualization of the human tympanic membrane and fluid or air within the middle ear space. In the presence of middle ear fluid, the OtoSight Middle Ear Scope is used to visualize the fluid density. The OtoSight Middle Ear Scope is also used to provide surface images of the ear canal and tympanic membrane. It is indicated for use in children and adults.

There is no known contraindication to use of the OtoSight Middle Ear Scope.

1.2 Purpose of these Instructions

These Instructions for Use contain information essential for the safe and effective operation of the OtoSight Middle Ear Scope. Before use, review all information in these instructions.

1.3 System Overview

The PhotoniCare OtoSight Middle Ear Scope uses Low-Coherence Interferometry (LCI), a non-scanning implementation of Optical Coherence Tomography (OCT), to provide a high-resolution density profile (called a Middle Ear Scan) of the tympanic membrane and fluid or air within the middle ear space. This technology is similar to medical M-mode ultrasound, but uses near-infrared light instead of sound, which improves the resolution by more than a factor of ten and does not require the use of coupling gel.

To provide a familiar viewing experience to the clinician, and to guide image acquisition, video otoscopy is integrated into the device. The otoscopy provides the true color surface image of the ear canal and the tympanic membrane (TM).

The combination of these two images allows the clinician to make a more informed assessment of the patient's condition.

The expected users of OtoSight Middle Ear Scope are trained medical professionals.

SECTION 1: INTRODUCTION

1.4 System Components and Accessories

The OtoSight Middle Ear Scope System includes the following components:

- Base unit with touch screen
- Handheld imager with visual display
- Opto-electrical connection cable
- Power cord
- USB Flash Drive
- 5-leg rolling stand

OtoSight part numbers

Part Number	Name	Description
S-20300	OtoSight Model 34R without WiFi	Requires OtoSight Wireless Export kit for Wi-Fi
S-20460	OtoSight Model 34R with WiFi	Includes internal Wi-Fi

The following accessories are available for the OtoSight Middle Ear Scope:

- OtoSight Standard Speculum Tip
- OtoSight Large Speculum Tip
- OtoSight Adaptor for Welch Allyn Speculum Tip (Factory Installed Accessory)

Note: See your Sales Representative for order numbers of accessories in your market

1.5 Warnings and Cautions

Warning: Do not use the OtoSight Middle Ear Scope if it has been dropped or otherwise damaged.

Warning: Do not use the OtoSight Middle Ear Scope if it has been submerged in liquid, or if liquid has penetrated the housing.

Warning: Do not open the system enclosure. Opening the system may expose the user to electrical or optical hazards. This device is not user serviceable. Opening of the system will void the Product Warranty.

Warning: No unauthorized modification of the OtoSight Middle Ear Scope software or hardware is allowed. Unauthorized modification may interfere with safe operation. Activities of this nature will void the Product Warranty.

Warning: The speculum tips are intended for single use only. Do not reuse, reprocess, or re-sterilize.

Warning: Do not look into the handheld aperture and avoid direct eye exposure, as invisible laser radiation may damage your vision.

Caution: Complete In-person training before using the OtoSight Middle Ear Scope

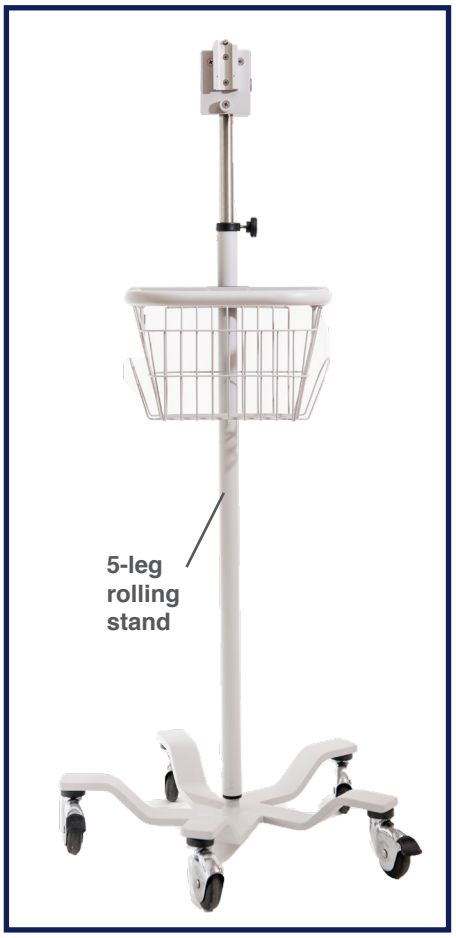
1.6 Symbols and Labels

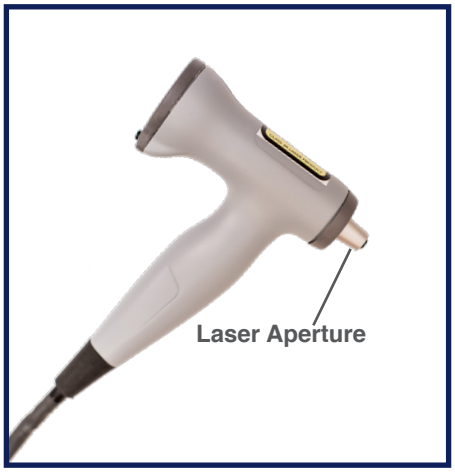
The following is a list of symbols used on the OtoSight Middle Ear Scope, along with their meanings. Review these symbols before using the device.

- Warning
- Caution
- Laser Hazard Symbol — marks a device that produces visible or invisible laser radiation
- Type BF Applied Parts
- Reading of the Instructions for Use is required
- Device is not user serviceable
- Do not dispose of device in trash
- Fuse
- Manufacturer
- REF Part Number
- SN Serial NumberDate of
- Manufacture
- Ethernet Connection
- LOT Lot Number
- Single use only
- USB Connection
- Power On/Off
- Rx Only Federal law (USA) restricts this device to sale by or on the order of a physician
- Keep Dry
- Recycle Packaging
- This End Up
- Fragile

SECTION: 2. DEVICE OVERVIEW

2.1 System Overview





Note: The speculum tip is the APPLIED PART.

Warning: When the blue laser indicator light is on, the laser is on. Avoid pointing the handheld towards the eyes of the patient or operator.

SECTION 2: DEVICE OVERVIEW

2.2 Rolling Stand Assembly and Use

Assembly

1. Use the provided diagram and tools to assemble the 5-leg rolling stand.
2. To install your Otosight unit onto the rolling stand align the grooves on the mounting insert on the back of your Otosight to the grooves in the mounting bracket on the rolling stand.
3. Pull back the plunger at the top of the mounting bracket and carefully move the Otosight down until the mounting insert slides past the plunger.
4. Release the plunger, now your Otosight unit is secure.

Adjustment

1. There are 2 adjustment points on the stand that can be utilized so that your device is mounted in a way that best fits your needs. Be sure to support your device when doing any adjustments or the unit could suddenly shift in position.
2. To adjust the height of the unit, there is a knob installed above the basket, on the shaft of the rolling stand. This knob can be loosened and the pole with the device mounted on it can be extended to the height that you prefer.
3. To adjust the tilt of your unit there are two Phillips head screws in the back of the mounting assembly that, when loosened, reduce the tension in the tilt mechanism. Upon loosening, tilt the device into the position that you desire and retighten the screws to lock into position.

Features

1. The stand has both height and tilt adjustment.
2. There are two locking wheels installed opposite each other to keep the unit from rolling around.
3. The stand includes a basket with a handle for ease of transport.
4. The basket has cord management hooks and wire loops and offers extra storage to roll along with your unit.

2.3 Installation Instructions

1. After assembly of the 5-leg rolling stand, carefully wrap the handheld cord around the base unit in the groove provided and place the handheld securely in the dock on the side of the base unit.
2. Insert the included power cord firmly into the port on the back of the device and plug directly into a standard 120V outlet.

Note: The power cord is detachable and may be replaced by hospital personnel. The power cord shall be a medical grade power cord provided by PhotoniCare.

Note: The device should be set up so that disconnection of the device from the main power supply is not difficult to perform.

Note: Do not attach an ethernet cord to the device.

Power Conditioning and Uninterruptable Power Supplies

If the device is to be used with a surge protected uninterruptable power supply, the following minimum specifications are recommended.

Specification Item	Value	Measure
Peak Inrush Current	40A	Current/Amps
Nominal Voltage	120V	Voltage/Volts
Power Rating	400VA	Power/VA
Earth Connection	Protective Earth	N.A

Warning: Do not plug device into a power strip or extension cord.

Warning: Use only the power cord and accessories provided with the system. Use of other cables and accessories may negatively impact system performance.

Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2.4 Power Modes

The device can be turned on and off with the power switch located on the back of the base unit.

When the device is not in use, it can be put in sleep mode by pressing the sleep button located on the front of the device. It can be awakened from sleep mode by pressing the sleep button again. When not in use, the device should be kept in sleep mode to extend its operating life.

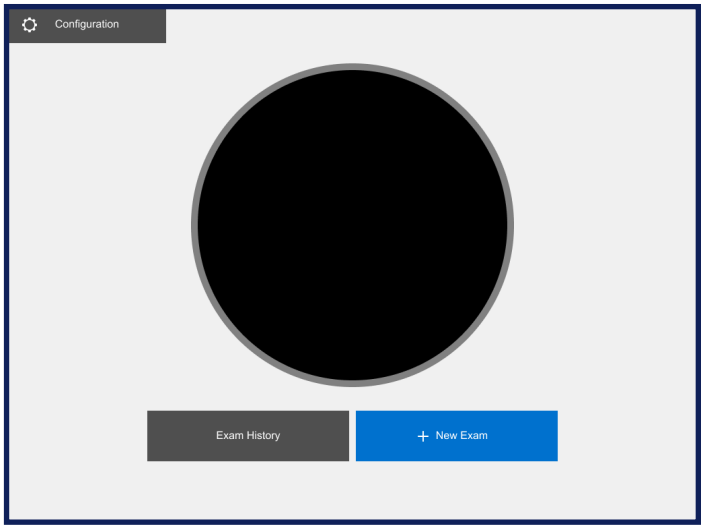
SECTION 2: DEVICE OVERVIEW

2.5 Operational Modes and Screens

Otoscopy Mode

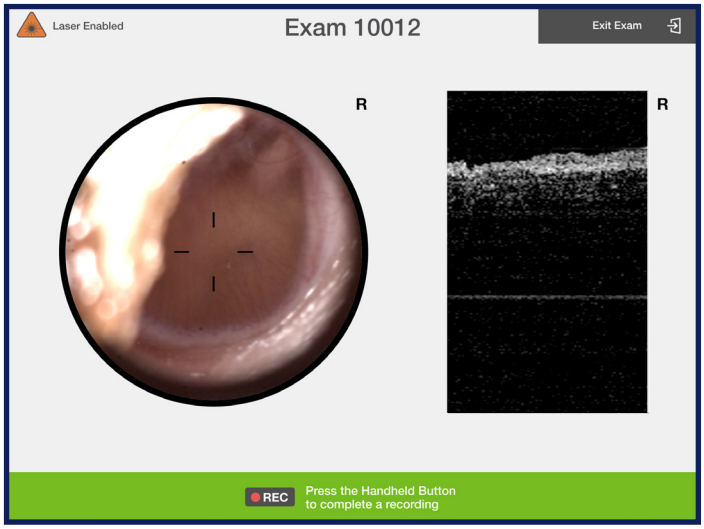
Digital otoscopy is the default mode when the device is first turned on or awakened from sleep. Exiting an exam will also bring you back to Otoscopy Mode. In this mode, the device can be used as a traditional video otoscope, providing a surface image only, on both the handheld and base unit screens.

If the device is left idle on any other screen for fifteen minutes, it will automatically return to Otoscopy Mode.



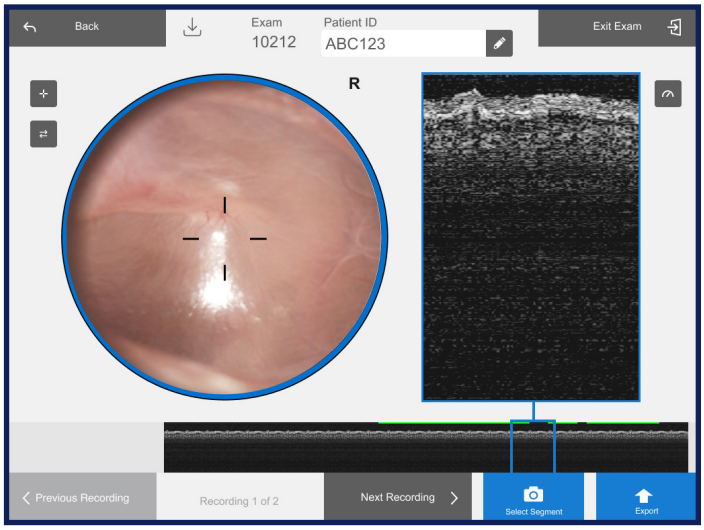
OtoSight Exam Mode

An exam can be initiated by selecting the “New Exam” button on the digital otoscopy screen or by pressing the button on the handheld. On the OtoSight Middle Ear Scope base unit screen, the digital otoscopy surface image can be seen in a window on the left side of the screen. On the right side of the screen, the Middle Ear Scan is displayed. While performing an exam, clinical users can record the data from the Middle Ear Scan as well as the corresponding surface image video for one or both ears. Recording is started and stopped by pressing the button on the handheld. Holding the handheld button down for two seconds will switch the active (labeled) ear for the recording (i.e. right or left ear). Recordings can be made in intervals of up to 90 seconds per patient exam. These recordings can be viewed in Review Mode (described below) and exported for later analysis or recordkeeping. When a user would like to finish an exam, there are two options. Selecting “Exit Exam” will return the device to Otoscopy Mode. If recordings have been made, selecting “Review Recordings” will enter Review Mode.



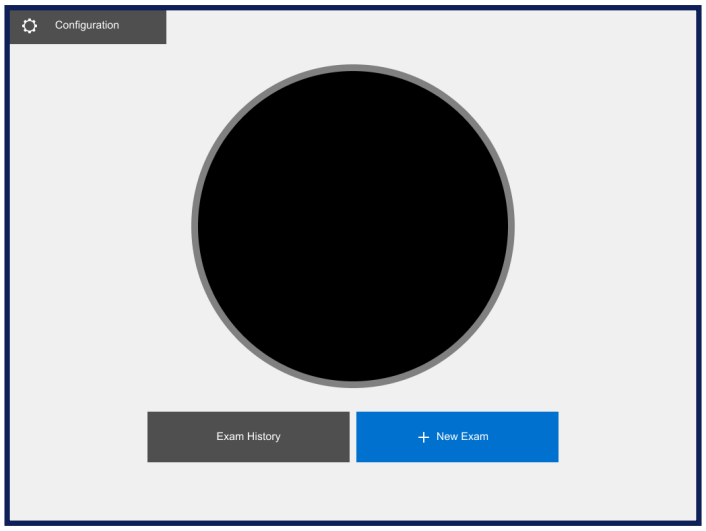
Review Mode

In Review Mode, all of the recordings from the exam can be viewed, one at a time. The entire selected recording is displayed. The bottom of the screen shows the Middle Ear Scan over time in a “film strip” style display, and the corresponding surface image is shown above. In this mode, single snapshot image pairs (surface and Middle Ear Scan) from the exam recording can be selected, saved, and exported.



Exam History Mode

Exam History shows a list of saved exams for the device. Exams can be reviewed by selecting the row of the exam listed.



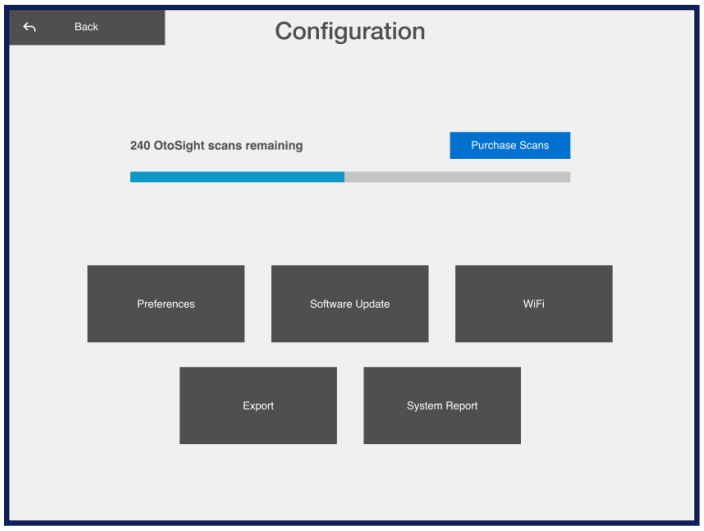
2.6 Configuration Settings

Accessing the Configuration Page

When the device is in Digital Otoscopy Mode, press the “Configuration” button on the top left of the screen. This brings up the Configuration page, which displays configuration settings for the OtoSight.

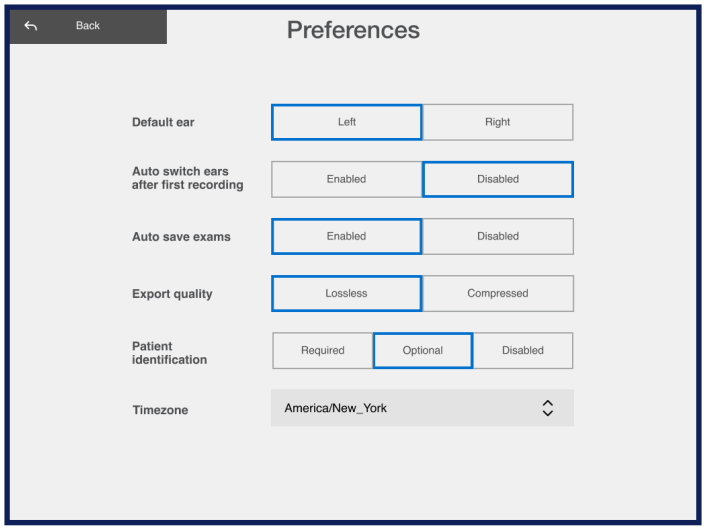
2.6.1 Preferences

Default ear:
This allows the user to select which ear will be automatically selected when the device is turned on or woken up from sleep. The default selection is the right ear.



Automatically switch ears after first recording:
By default, the device will automatically switch ears after each recording. This feature can be disabled, in which case the user will have to manually switch which ear is being imaged. Even when automatic switching is enabled, users can still switch ears manually by holding down the button on the handheld device for two seconds.

Auto save exams:
The device will save recorded exams as they are captured with entered patient information if enabled (default). This feature can be ***enabled*** or ***disabled*** in the preferences.



The device has storage capacity for approximately 2000 exams. When the device storage has space for less than 50 exams, a notification message will be displayed on screen.

When no storage space is available, the oldest exam in storage will be deleted in order to allow space for the current exam.

Export quality:
By default, surface images are saved in a compressed

format to maximize the number of exams that can be saved on a device. Lossless saving can be selected.

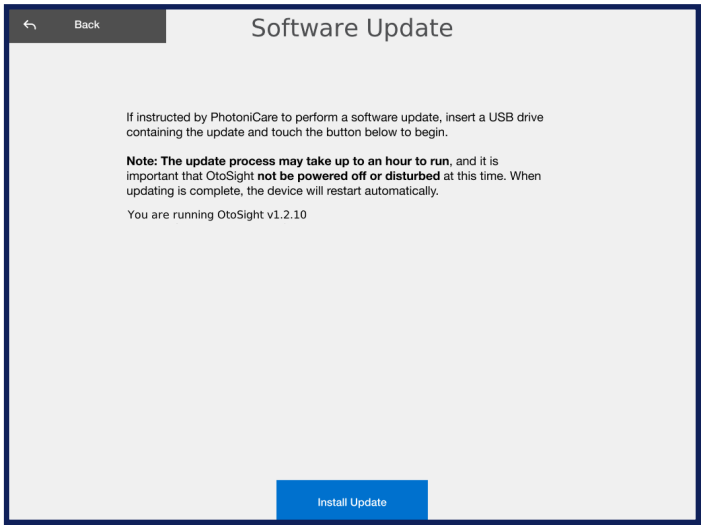
Note: Lossless saving will greatly decrease the number of exams that can be stored on the device and increase the time required to save exams.

Patient identification:
Patient identification can be added during an exam. Patient idendification can be ***disabled***, ***optional*** (default) or ***required***. If patient identification is ***required***, users cannot end an exam without entering a patient identifier.

Timezone:
Timezone can be selected to reflect the current timezone for the device.

2.6.2 Software Update

In order to update the OtoSight Middle Ear Scope Software, navigate to the Configuration Page and press the *Install Update* button. From a computer, download the update file from the email that was sent to you from PhotoniCare, onto the root folder of the supplied USB flash drive and place the USB flash drive into the USB port of the device. Press the *Install Update* button on the bottom of the Software Update page. The software will update, and the device will restart when the update is complete. After the software update is complete, verify that the version number displayed on the software update page matches the version number of the software update you installed. For questions related to the update process, please contact PhotoniCare at: support@photoni.care.



If there is no USB flash drive in the device, or the software update folder is not located in the root folder of the USB flash drive, the device will display an error message. Verify that the file is correctly located, and the USB flash drive is installed. If the problem persists, contact PhotoniCare at: support@photoni.care.

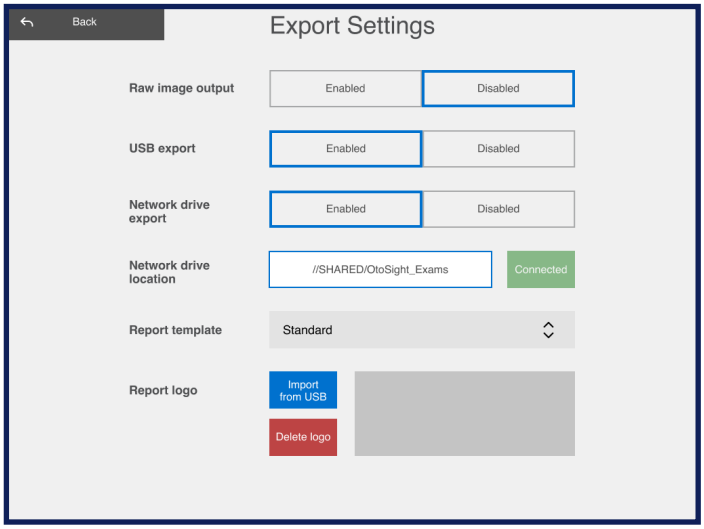
Caution: Software updates may take one hour or more to complete, and the device is not usable until the update is finished.

2.6.3 Wi-Fi

OtoSight can be connected to a Wi-Fi network in order to export exam recordings to a network drive. This option may require the Wireless Export Accessory Pack Wi-Fi USB adapter to be connected. Consult Section 1.4 and the device label to understand Wi-Fi support.

2.6.4 Export Settings

OtoSight can be configured to export images to a network folder location or an attached USB drive.



USB export
The option to export exam reports and images to an attached USB drive can be enabled or disabled.

Network drive export
The option to export exam reports and images to an shared network drive can be enabled or disabled.

Network drive location
The location to save exported exam reports and images. The location should be given in the format: //{COMPUTER_NAME}/{FOLDER} where {COMPUTER_NAME} is the network name or IP address of the server containing the network drive.

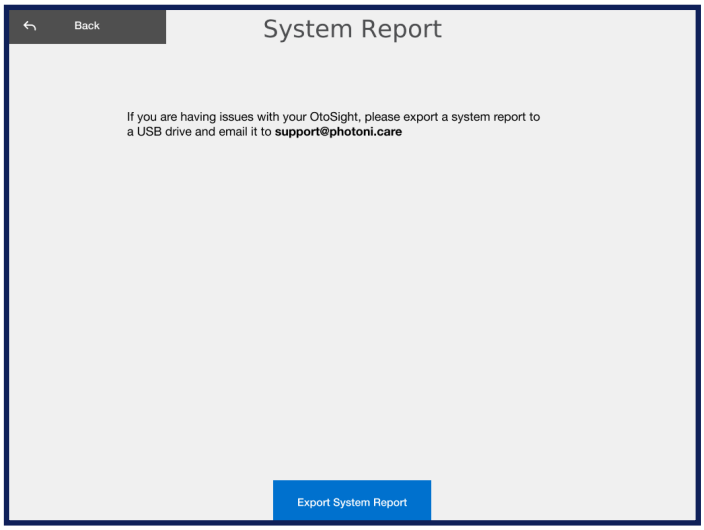
Press *Connect* to provide credentials for access to the Network drive location.

NOTE: Forward-slash notation should be used even with Windows file share locations.

Report logo
A custom report logo can be uploaded to the device from a USB drive. To upload an logo image, place a png file on the root folder with the file name custom_logo.png and press *Import from USB.*

2.6.5 System Report

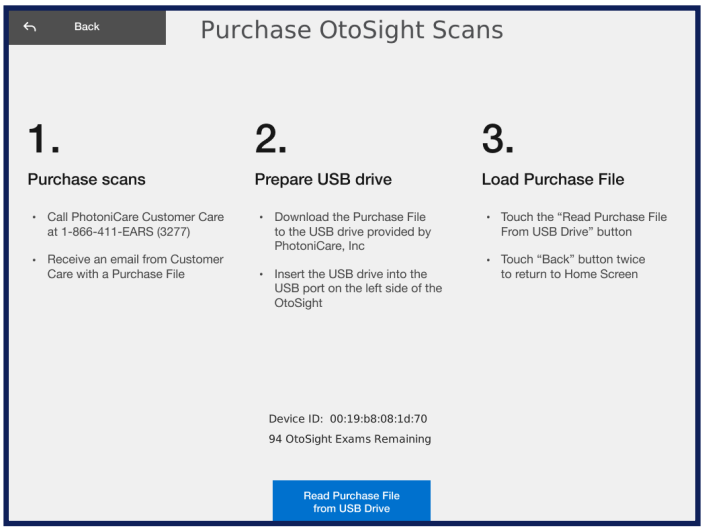
The Configuration page also allows users to export the system log files to a USB flash drive by pressing the “System Report” button. This takes the user to the System Report page. The user can insert the provided USB flash drive into the USB port on the device and press the “Export System Report” button to export the system log files. If there is no USB flash drive in the USB port, the device will prompt the user to insert one. Third party USB flash drives not provided by PhotoniCare should not be used.

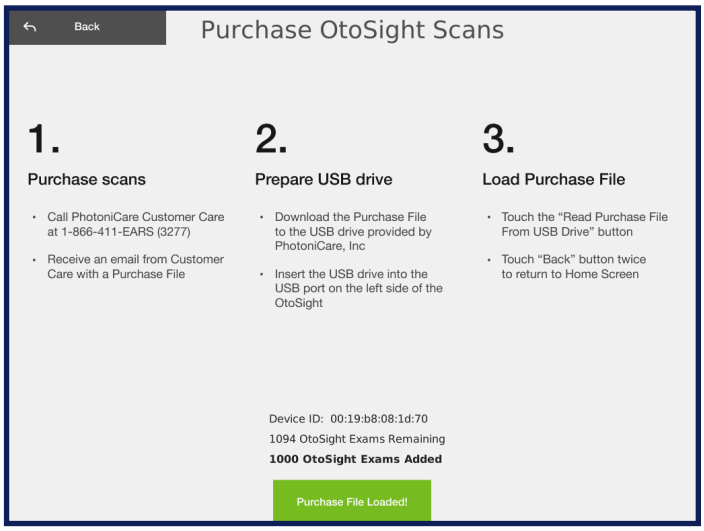


If there are issues with the device, please export the system log files and email them to: support@photoni.care.

2.6.6 Purchase Scans

In the configuration menu, press *Purchase Scans* to enter the Purchase OtoSight Scans page. Follow the instructions on the screen and press the *Read Purchase File* button.





2.7 System Cleaning, Sterilization, Maintenance and Repair

The OtoSight Middle Ear Scope base unit and handheld can be cleaned externally with standard clinical disinfectants, such as isopropyl alcohol. Refer to the disinfectant manufacturer's instructions for use. Always use a soft lint-free cloth to prevent damage to your OtoSight Middle Ear Scope base unit and handheld piece.

The device does not require preventative maintenance. The device, including the speculum tip, is not intended to be sterilized.

The device is not intended to be repaired in the field. For repair, contact PhotoniCare Customer Support at: support@photoni.care.

Caution: The OtoSight Middle Ear Scope has no special protections against liquid ingress (IPXO – ordinary equipment). Do not place containers of liquid on or near the device and do not allow liquid or aerosols to penetrate the housing.

Caution: It is recommended that you unplug the device before cleaning or disinfecting.

Warning: Do not use the device if liquid has penetrated the housing.

Warning: Each speculum tip is intended for single use only. Do not reuse, reprocess, or re-sterilize the speculum tips.

SECTION: 3. PERFORMING AN EXAM

SECTION 3: PERFORMING AN EXAM

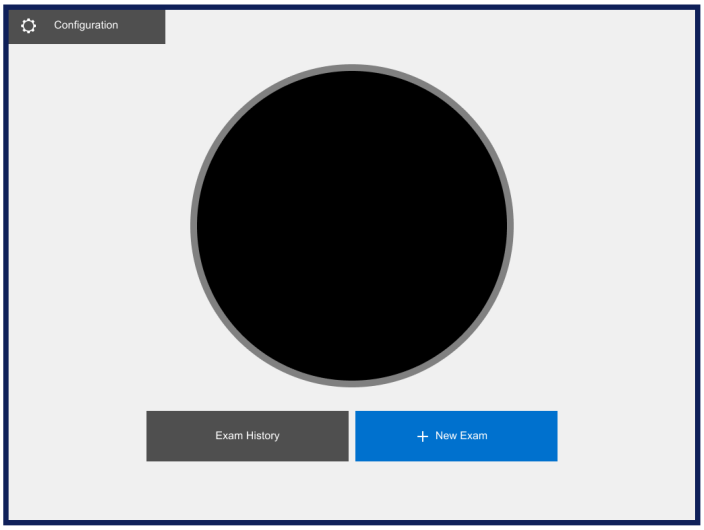
3.1 Prepare OtoSight for Use

Make sure OtoSight is plugged in, and power on the device using the power button, or awaken from sleep mode by pressing the Sleep Button. Choose an appropriately sized speculum tip for the patient and install it onto the nose cone of the handheld by screwing it, clockwise, into place.

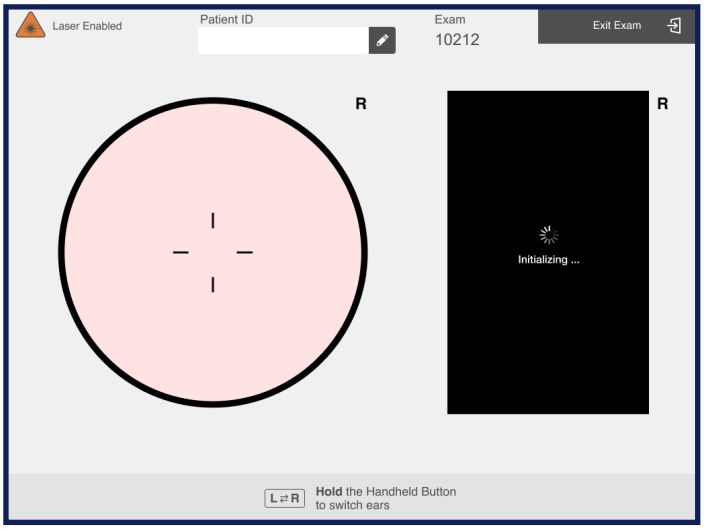
Caution: Use only PhotoniCare specula that are compatible with the OtoSight Middle Ear Scope, unless the device is equipped with a Welch Allyn Tip Adapter. If the device is equipped with a Welch Allyn Tip adaptor that device is no longer compatible with Photonicare specula and a 4.25mm Welch Allyn Speculum Tip (Hillrom PN 52434-U) or a 2.75mm Welch Allyn Speculum Tip (Hillrom PN 52432-U) must be used. Use of unapproved specula can result in damage to the device and void the Product Warranty. The device, including the speculum tip, is not intended to be sterilized.

3.2 Acquire Middle Ear Scans

Press the “New Exam” button on the base unit screen to start an exam for a new patient. This causes the device to enter OtoSight Exam Mode and begin a Middle Ear Scan. The User will have 15 minutes to complete an exam (Exam Time).

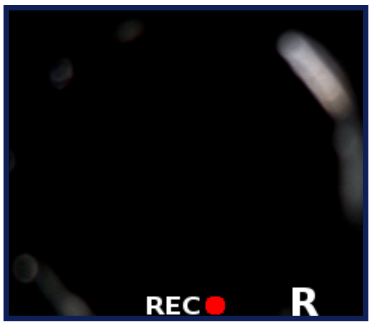


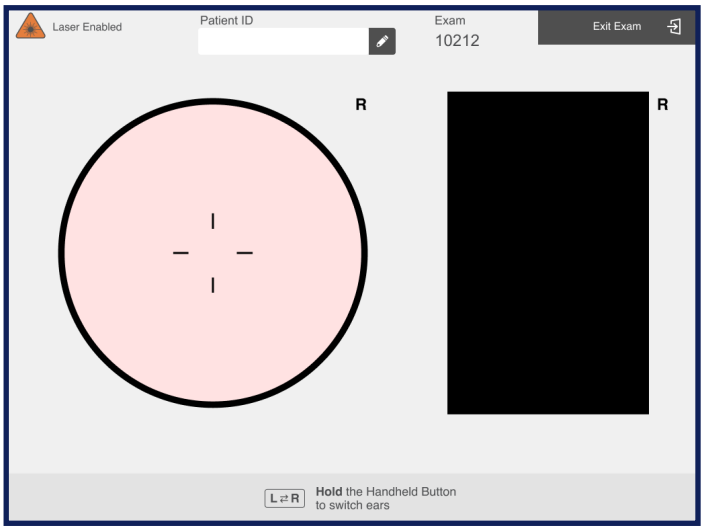
The device will take several seconds to initialize before displaying the Middle Ear Scan. During this time a message is displayed on both the base unit and handheld screens informing the user to keep the device out of the ear until initialization is complete.



Caution: The device should not be placed in the ear during the initialization period. Doing so will reduce the quality of the Middle Ear Scan.

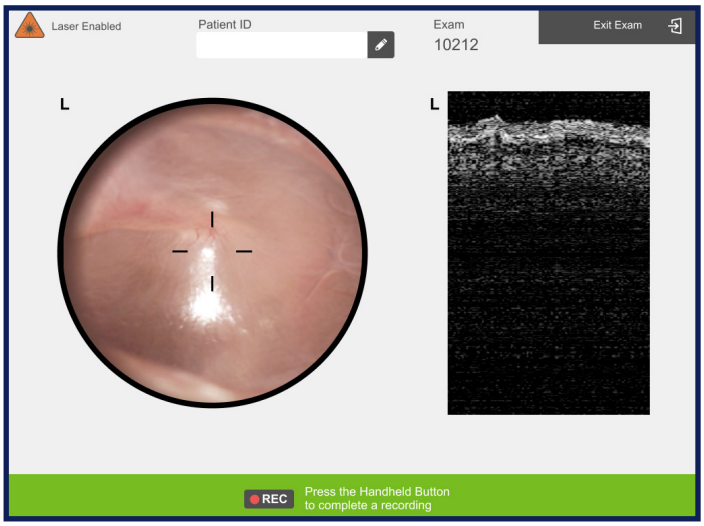
Before inserting the speculum tip into the patient's ear, press the handheld button to start a recording. The status at the bottom of the base unit screen and the handheld screen will show that recording ("REC") is taking place.





The OtoSight Exam Mode screen will display a digital otoscopy surface image on the left side and an Middle Ear Scan on the right. Once the handheld is placed into the patient's ear, users can view the eardrum on both displays.

Both the handheld and the base unit screens will display either "R" or "L" to indicate ear label laterality (right vs. left ear) being applied to the images. The default setting is "R". Users can change this setting if desired. See Section 2.6.1 for details.

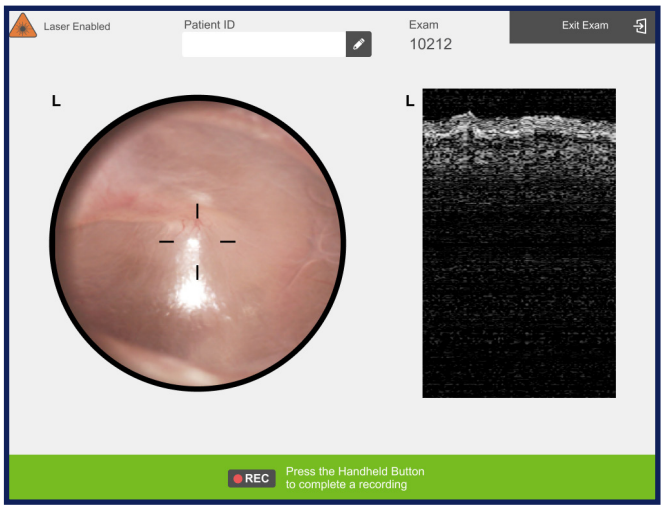


Caution: If the ear canal is completely impacted with cerumen and no eardrum is visible in the otoscopy image, consider removing cerumen by a methodology approved by your practice or institution before proceeding with the exam.

Note: Consider the effects of the patient's body position on any air-fluid interface that may be present in the middle ear.

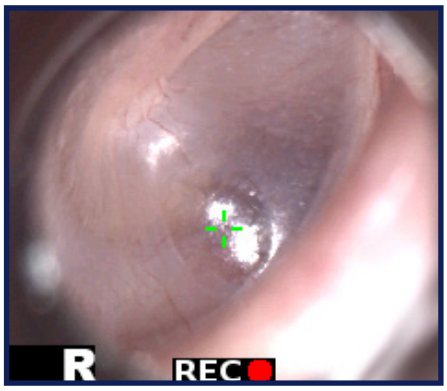
SECTION 3: PERFORMING AN EXAM

Insert the OtoSight Middle Ear Scope into the ear using standard otoscopic technique. The crosshair reticle in the center of the otoscopy screen indicates the location from which the Middle Ear Scan is being produced. Start by aligning the crosshair with the light reflex, then continue to advance the scope along the ear canal until the crosshairs on the base unit and handheld screen turns green.



When a strong signal is detected, the crosshair on the digital otoscopy surface image on both the handheld and the base unit displays turn green to indicate that the user is collecting Middle Ear Scan data of appropriate signal strength.

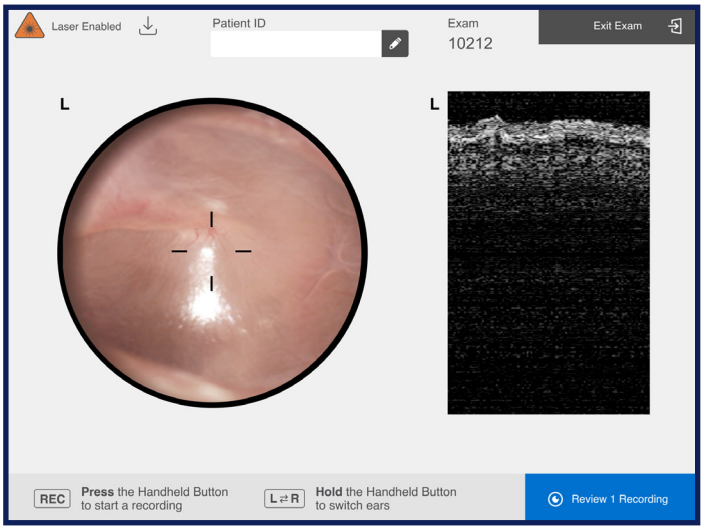
When done with the exam, remove the handheld from the patients ear and press the button to end the recording. The device will automatically switch ears, unless this setting is disabled by the user. The user can hold down the handheld button for two seconds in order to manually switch between right vs. left ears.



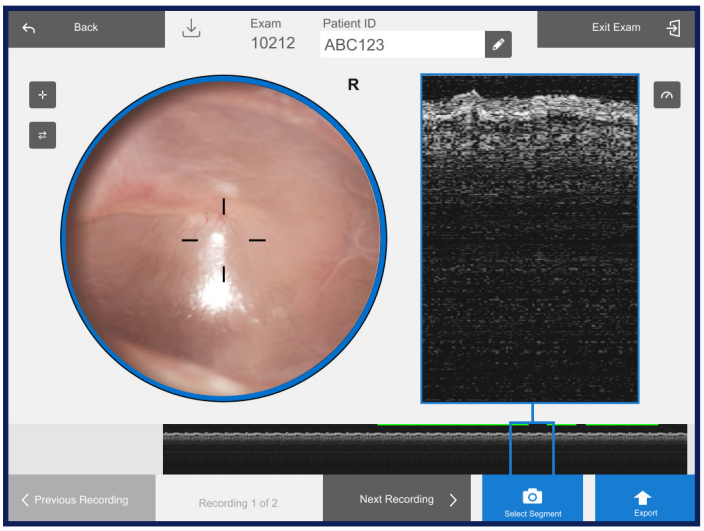
3.3 Patient Information

A 20 character patient identifier can be entered at any time during an exam, in **Exam Mode** or **Review Mode**. To enter a patient identifier, select the pencil symbol next to the patient ID text field, and use the onscreen keyboard to enter a patient ID.

Patient Information can be configured as optional, disabled or required in the configuration menu. If required, a patient identifier must be entered before the exam can be closed.



3.4 Review and Export OtoSight Exams

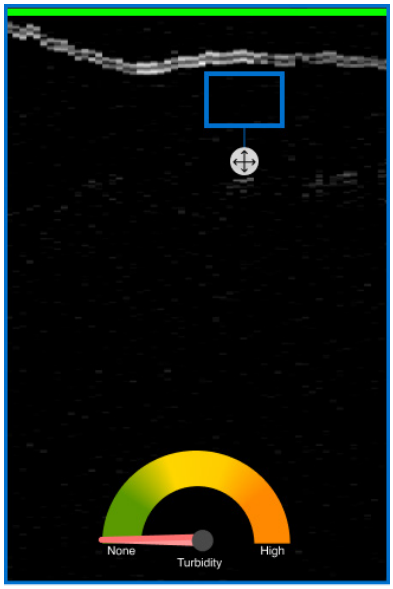


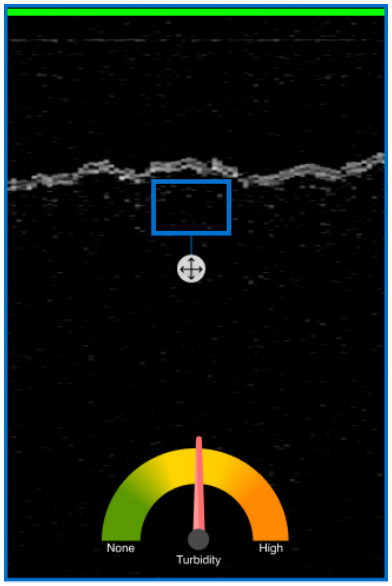
To review recorded results, the user must exit OtoSight Exam Mode by pressing the “Review (#) Recordings” button on the base unit screen. Pressing this button enters Review Mode. The number on this button will indicate the total number of recordings (right and/or left ear) that have been captured during that particular exam.

Once in Review Mode, all the data collected during the exam can be viewed and evaluated by medical professionals. The Middle Ear Scan is displayed along the bottom of the screen in a “film strip” style display, with the corresponding surface images above it. The Middle Ear Scan shows a continuous exam strip collected over time and displays the entire duration of the recording, allowing the user to scroll through the exam to identify sections of the exam to save. The exam strip starts at the beginning, or the farthest left point in the strip. Scrolling through this exam strip is done in a similar fashion to reviewing photos on a smart phone. Swipe left to view data further right in the exam strip. Swipe right to view data further left in the exam strip.

Turbidity Indicator

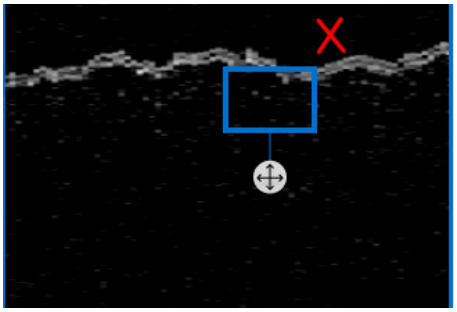
The turbidity indicator feature on the OtoSight can be used to assess the presence and turbidity of fluid in the middle ear space. The feature will calculate the brightness of the pixels within a user moveable box compared with the brightness of the overall background noise. The feature can be accessed by pressing the turbidity indicator button on the right of the display in **Review Mode**.



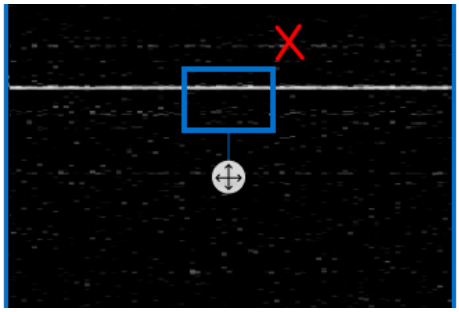


CAUTION: For an accurate reading, place the turbidity selection box just below the tympanic membrane (TM), placed over the middle ear space only. Ensure no part of the TM is within the selection box, as the turbidity indicator can be skewed by tissue not in the middle ear space.

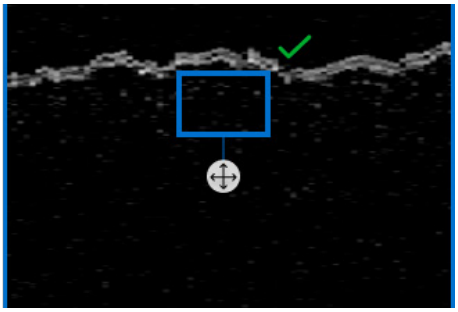
To use the turbidity indicator, drag the selection box to be directly underneath the ribbon of the tympanic membrane. The indicator will automatically update based on the location of the selection box.



Selection box corner is placed over TM.



Selection box includes imaging artifact.



Selection box is correctly placed.

Exporting OtoSight Exams
Single snapshot images of quality data can be saved by pressing the “Select Segment” button below the depth view display. Saving a snapshot will save the depth view and its corresponding surface image for export.

Once the user has selected a segment, they can continue to scroll through the exam to save more snapshots using the touch screen. All selected segments will be shaded blue to make it easy to identify which segments have been saved. Users can move from one recording to another using the “Next Recording” and “Previous Recording” buttons located at the bottom right and left side of the base unit screen.

When the user is ready to export an exam report or captured images, the “Export” button provides options for export, which can be configured in the Configuration menu. Export methods that are disabled in the configuration will be hidden from view in the Export window.

Network Drive:
Export a PDF report to a network drive on a local wireless network. This option may require the Wireless Export Accessory Pack Wi-Fi USB adapter to be connected. Consult Section 1.4 and the device label to understand Wi-Fi support. A network drive location must also be configured in the configuration menu.

USB Thumb Drive
Export a PDF report to a USB thumb drive. If there is no USB thumb drive inserted in the USB port, the device will prompt the user to insert one. buttons located at the bottom right and left side of the base unit screen.

Warning: Do not plug anything into the USB port other than USB accessories provided by PhotoniCare.

Once the desired data have been exported, pressing the “Exit Exam” button in the upper right corner of the Review Mode screen returns the user to Otoscopy Mode. The user can return to Review Mode by pressing the Previous Exam button.

Caution: Performance of procedures other than those specified herein may result in hazardous radiation exposure.

3.5 Example Middle Ear Scans

These images are intended as examples to assist users in interpreting the Middle Ear Scan results obtained with the OtoSight Middle Ear Scope.

Figure A:

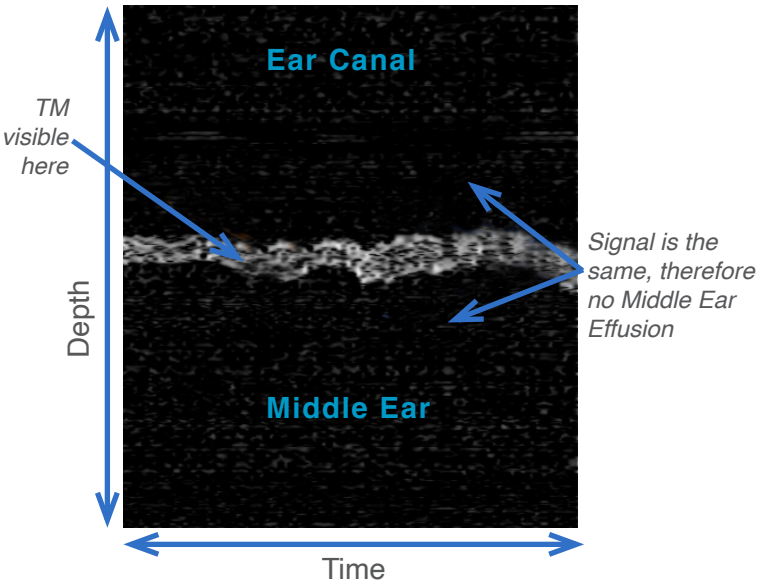


Fig A. This figure shows an example of an Middle Ear Scan obtained from a normal ear. The tympanic membrane (TM) is clearly visible as a thin, bright ribbon across the image. The signal above and below the line of the TM is similar, which suggests that there is air in the middle ear space (not fluid).

Figure B:

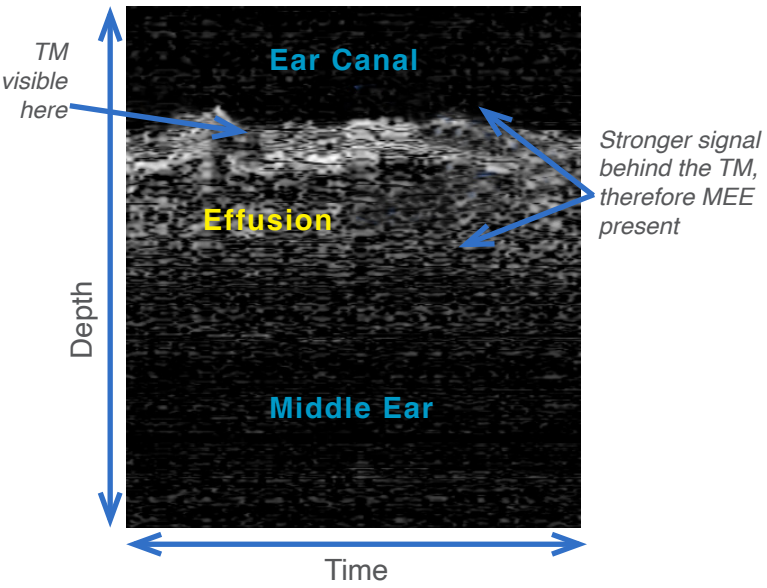
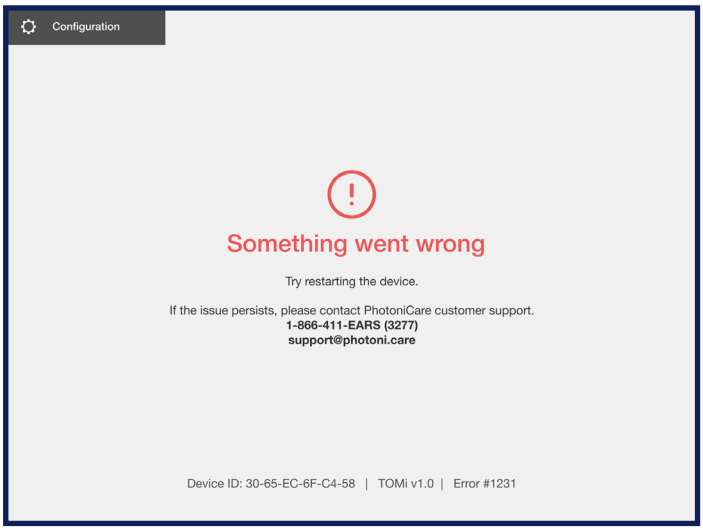


Fig B. This figure shows an example of an Middle Ear Scan obtained from an ear with fluid behind the TM. The TM is still clearly visible here, as in the normal ear image. However, the signal from below the TM is stronger and more dense (white) than the signal from above it. This suggests the presence of fluid in the middle ear space.

3.6 Error Messages

When a hardware error is detected, the following error message will appear on the OtoSight Middle Ear Scope base unit screen. If this error occurs, use the power button on the back of the device to fully power off the device, and then restart it. If the error persists, contact PhotoniCare Customer Support at: support@photoni.care.



SECTION: 4. SPECIFICATIONS

SECTION 4: SPECIFICATIONS

4.1 Environmental Conditions

Storage Conditions

Ambient Temperature	10°C to 40°C
Relative Humidity	Minimum 10% RH, Maximum 85% RH, Non-Condensing
Atmospheric Pressure	Minimum 70kPa, Maximum 106kPa

Transport Conditions

Ambient Temperature	-20°C to 50°C
Relative Humidity	Minimum 10% RH, Maximum 95% RH, including Condensing
Atmospheric Pressure	Minimum 70kPa, Maximum 106kPa

Operating Conditions

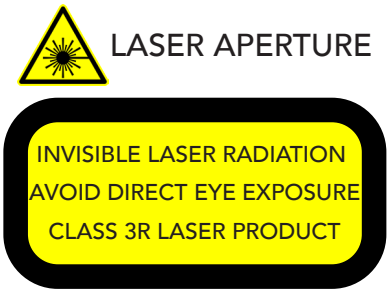
Ambient Temperature	10°C to 35°C
Relative Humidity	Minimum 10% RH, Maximum 85% RH, Non-Condensing
Atmospheric Pressure	Minimum 70kPa, Maximum 106kPa

4.2 Laser Specifications and Labels

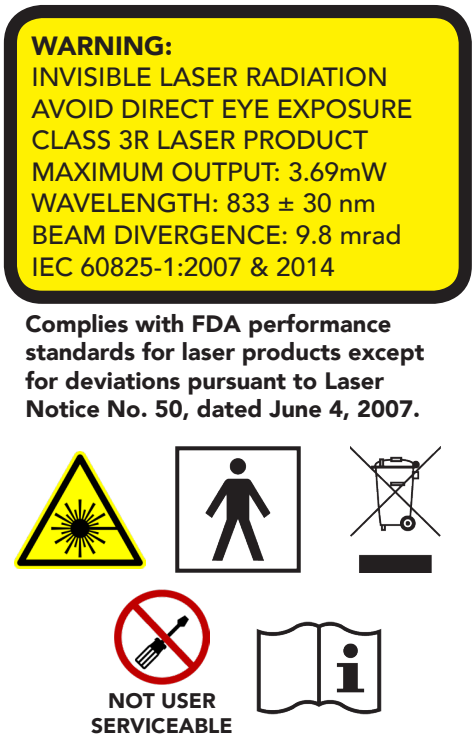
Laser Source Optical Power 3.69 mW maximum @ 833 nm +/- 10nm (Class 3R Laser Product per IEC 60825-1)

Beam Divergence 9.8 mrad

Handheld Laser Warning Label



Base Unit Laser Warning Label



SECTION 4: SPECIFICATIONS

4.3 Electromagnetic Emissions

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The device complies with IEC 60601-1-2 Electromagnetic Performance standards, and the operator should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11	Group 1	The instrument 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 A	
Harmonic Emission IEC 61000-3-2	Class A	The instrument is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations / Flicker Emissions IEC 6100-3-3	Complies	

4.4 Electromagnetic Immunity

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8kV contact ± 2kV air ± 4kV air ± 8kV air ± 15kV air	Complies	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	AC/DC power input: +/- 2kV,100 kHz prf I/O Port Cables: +/- 1kV, 100kHz prf	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC mains L/G: +/- 0.5, 1, 2 kV AC mains L/L: +/-0.5, 1 kV	Complies	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	0%UT for 0.5 Cycles @0° 0%UT for 0.5 Cycles @45° 0%UT for 0.5 Cycles @90° 0%UT for 0.5 Cycles @135° 0%UT for 0.5 Cycles @180° 0%UT for 0.5 Cycles @225° 0%UT for 0.5 Cycles @270° 0%UT for 0.5 Cycles @315° 0%UT for 1 Cycle @0° 70%UT for 25 Cycles @0° 0%UT for 250 Cycles @0°	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OtoSight Middle Ear Scope requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
Conducted RF IEC 61000-4-6	AC mains and I/O's: 3V rms 150kHz - 80 MHz, 80% amplitude modulation at 1 kHz and 6V rms for ISM frequencies between 150kHz-80MHz.	Complies	
Radiated RF IEC 61000-4-3	80-2700MHz :3 V/m, 80% AM,1 kHz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m,PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz	Complies	
Power frequency magnetic field IEC 61000-4-8	30 Amps/meter	Complies	

Note: The OtoSight Middle Ear Scope has no essential performance requirements where the absence or degradation of a function would result in unacceptable risks.

SECTION 4: SPECIFICATIONS

4.5 Electromagnetic Isolation

The OtoSight Middle Ear Scope produces Middle Ear Scan data and digital otoscopy by using digital signal processing techniques that operate in the radio frequency (RF) energy range. The device is therefore susceptible to electromagnetic interference (EMI) generated by other RF emission sources such as other medical devices or information technology products, etc. The device is compliant with IEC 60601-1-2 Electromagnetic Performance standards. However, in a complicated clinical environment, electromagnetic interference could occur. The user may need to identify symptoms of EMI, which include but are not limited to artifacts in the displays, frozen or shut-off displays, hardware error message prompted in the user interface, or other symptoms that negatively impact image quality.

A general rule of thumb to mitigate EMI is to remove RF emission equipment from proximity to the OtoSight Middle Ear Scope or move the OtoSight Middle Ear Scope to a different location. Performing a hard reset by turning the rear power switch off and then back on may also be required to return the device to normal operating conditions. Note that some of these RF emission equipment (e.g. RFID) might be concealed and the device can potentially be exposed to EMI from this RF emission equipment without the user's awareness.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the OtoSight Middle Ear Scope			
The OtoSight Middle Ear Scope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OtoSight Middle Ear Scope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OtoSight Middle Ear Scope, 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

Warning: OtoSight Middle Ear Scope has not been tested in close proximity with other medical devices, such as MRI, CT, diathermy, or other Radio Frequency Identification (RFID), and electromagnetic security systems such as metal detectors. Therefore the OtoSight Middle Ear Scope should not be used in close proximity to such devices.

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

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

4.6 Compliance

IEC 60601-1:2005 + AMD1:2012 CSV

IEC 60601-1-2:2014

IEC 60601-1-6:2010+AMD1:2013 CSV

IEC 60825-1:2007 and 2014

IEC 62304:2006+AMDI:2015

IEC 62471:2006IEC 62304:2006+AMD1:2015 CSV

ISO 10993-1:2018

Note: This device complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 4, 2007.

4.7 Physical Specifications

Weight	6.6 kg (14.5 lbs.)
Dimensions (Base Unit)	33 x 31 x 15 (cm)
Dimensions (Handheld Unit)	17 x 14 x 2 (cm)

4.8 Electrical Requirements

Device is designed for use with power supplies 100V ~ 240 V, 50/60 Hz, with a maximum current rating of 1A.

Warning: Do not operate the device outside the recommended electrical voltage.

Note: Mains voltage is isolated from the device by multiple methods. The back of the device has a power switch, which, when in the off position, prevents the mains from reaching the power supply of the device. This is the primary means for removing the device from mains voltage. Additionally, a medical grade power supply isolates the mains voltage from the device electronics, converting the AC mains voltage to DC voltages appropriate for the electronics in the device.

SECTION: 5. LEGAL NOTICES

SECTION 5: LEGAL NOTICES

5.1 Copyright

5.2 Warranty

See additional product terms, including warranty, at https://photoni.care/terms-and-conditions.

LEARN MORE AT WWW.PHOTONI.CARE