OtoSight
Middle Ear Scope

INSTRUCTIONS FOR USE

S-20485, December 2025, Revision 11

For OtoSight part numbers:

S-20464 OtoSight Model 34R with WiFi and Battery

For other OtoSight configurations, see photoni.care/otosight/ifu

PhotoniCare

PhotoniCare, Inc.
2800 Meridian Pkwy, Ste 175
Durham, NC 27713

https://photoni.care
1-866-411-3277

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 (TM). 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.

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.

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
S-20464	OtoSight Model 34R with WiFi and Battery	Includes Internal Wi-Fi and Battery

The following accessories are available for the OtoSight Middle Ear Scope. See your Sales Representative for order numbers of accessories in your market.

- OtoSight Standard S peculum Tip
- OtoSight Large Speculum Tip
- OtoSight Adaptor for Welch Allyn Speculum Tip (Factory Installed Accessory)
- Welch Allyn Tip Dispenser Accessory Pack

SECTION 1: INTRODUCTION

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.

Caution: AutoTurbidity is intended to be used under supervision of a clinician. When using the feature, ensure automatic anatomy identification is correct and the measurement zone is correctly placed.

SECTION 1: INTRODUCTION

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

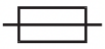

Laser Hazard Symbol — marks a device that produces visible or invisible laser radiation


Type B Applied Parts


Reading of the Instructions for Use is Required

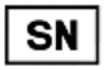

Device is not user serviceable


Do not dispose of device in trash


Fuse

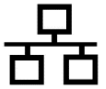

Manufacturer

Part Number



Serial Number


Date of Manufacture


Ethernet Connection

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


Indicates the device is charging


Indicates the device is running on battery power


Indicates the battery is at 20% of capacity


Indicates shutdown is imminent due to remaining battery power


Indicates battery fault. Contact service.

SECTION 1: INTRODUCTION

Cloud/Upload Status


OtoSight is connected to cloud


OtoSight is uploading to cloud

OtoSight is saving to disk


Recording is uploaded to cloud

Recording is saved to disk

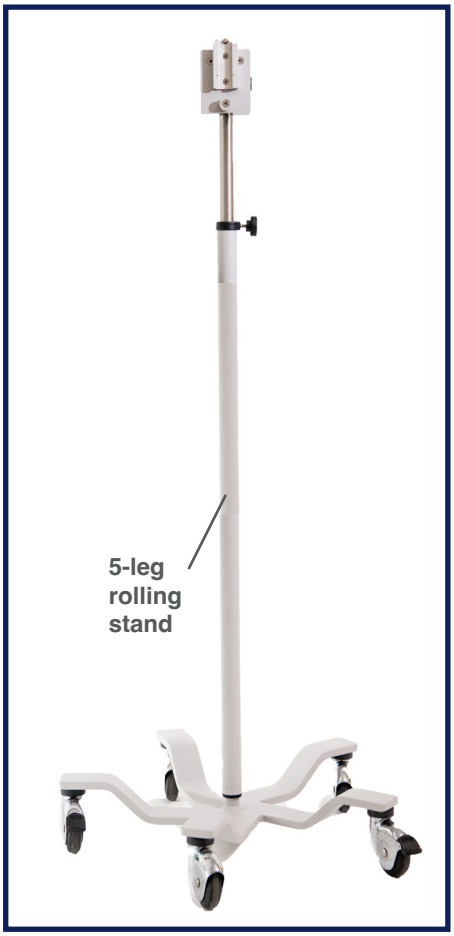

Recording failed to upload to cloud

Recording failed to save to disk

SECTION: 2. DEVICE OVERVIEW

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 to secure your Otosight unit.

Adjustment

To adjust the height of the unit, loosen the knob on the shaft of the rolling stand. Extend or contract the pole with the mounted device to the preferred height. Tighten the knob to secure.

Features

1. The stand has the ability to adjust the height of the device.
2. There are two locking wheels installed opposite each other to keep the unit from rolling around.
3. The stand may include an optional basket with a handle for ease of transport.
4. The optional basket has cord management hooks and wire loops and offers extra storage.

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 with handheld screen facing you.
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.

SECTION 2: DEVICE OVERVIEW

2.4 Accessory Installation Instructions

2.4.1 Welch Allyn Tip Dispensor Accessory Kit

1. Pry off the cap on top of the stand pole using hands or a tool.
2. Place the bracket mount into the stand pole in the desired orientation.
3. Attach the Welch Allyn Tip Dispensor to the screw heads on the bracket.

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 performancwwe.

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

2.5 Power Modes

The device can be turned on with the Power Button located on the front of the base unit.

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

The device can be turned off by pressing and holding the Power Button for 3 seconds. In the case of a system crash, a hard reset may be performed by pressing and holding the Power Button for 15 seconds.

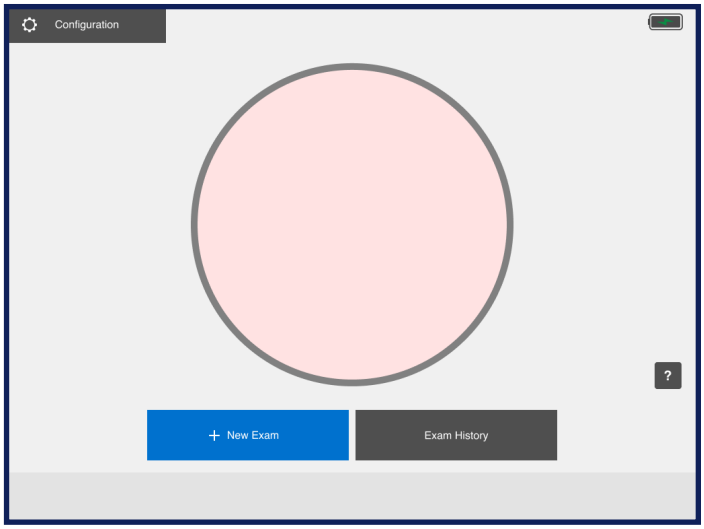
SECTION 2: DEVICE OVERVIEW

2.6 Operational Modes and Screens

Otoscopy Mode

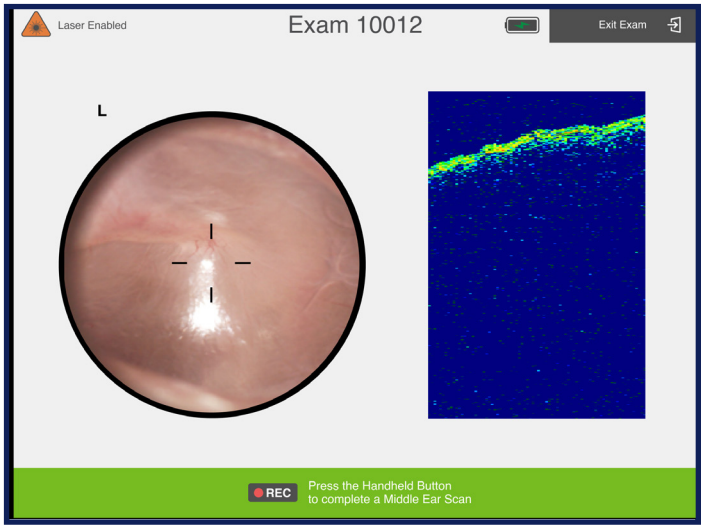
Digital otoscopy is the default mode when the device is first turned on or awakened from sleep. Exiting an exam will also bring you back to Otoscopy Mode. In this mode, the device can be used as a traditional video otoscope, providing a surface image only, on both the handheld and base unit screens.

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



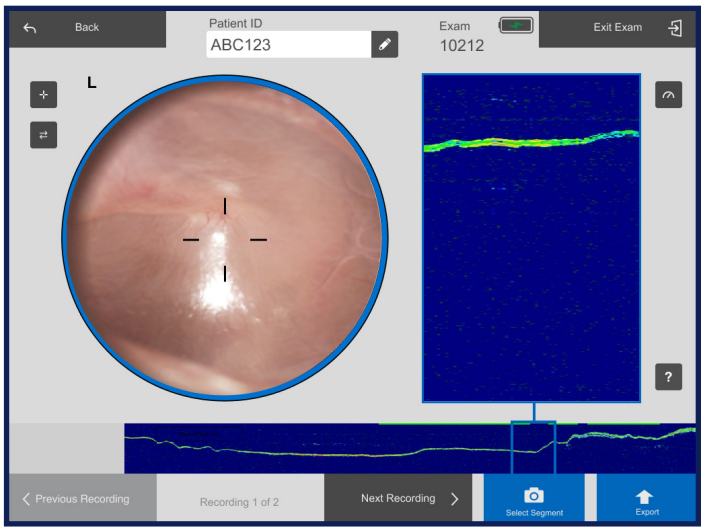
OtoSight Exam Mode

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. A Middle Ear Scan can be 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. Users have two options for finishing an exam: 1) Selecting “Exit Exam” will return the device to Otoscopy Mode. 2) If recordings have been made, selecting “Review Recordings” will enter **Review Mode**.



Review Mode

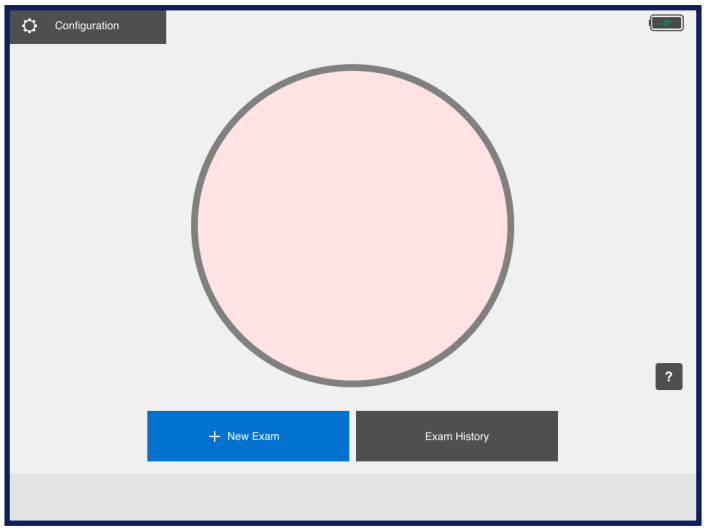
In **Review Mode**, all of the recordings from the exam can be viewed, one at a time. The entire selected recording is displayed. The bottom of the screen shows the Middle Ear Scan over time in a “film strip” style display, and the corresponding surface image is shown above. In this mode, single snapshot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

2.7 Configuration Settings

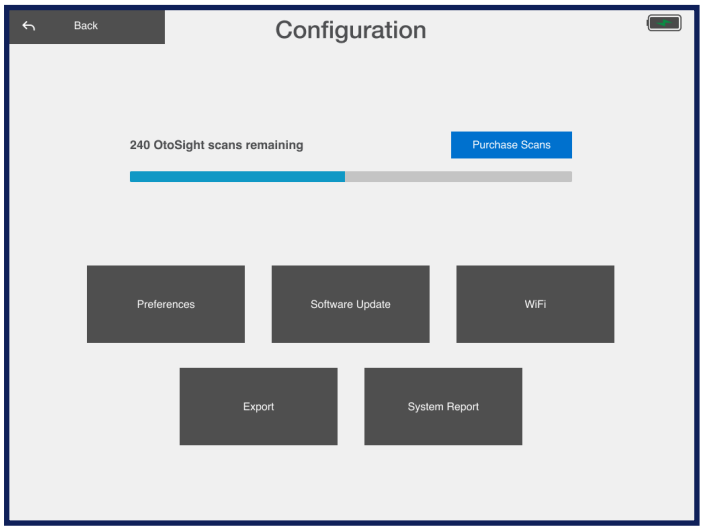


Accessing the Configuration Page
When the device is in Digital Otoscopy Mode, press the “Configuration” button on the top left of the screen. This brings up the Configuration page, which displays configuration settings for the OtoSight.

2.7.1 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.

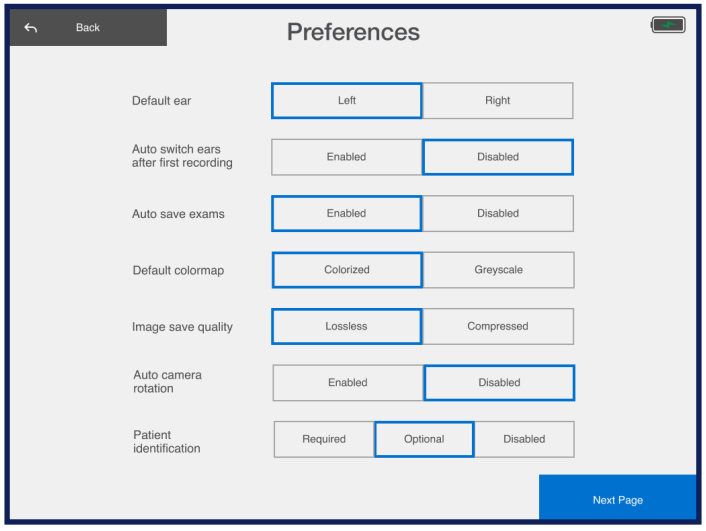
Automatically switch ears after first recording:
By default, the device will automatically switch ears after each recording. This feature can be disabled, in which case the user will have to manually switch which ear is being imaged. Users can switch ears manually by holding down the button on the handheld 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 Preferences.

The device has storage capacity for approximately 2,000 exams. When the device storage has space for less than 50 exams, a notification message will be displayed on screen.

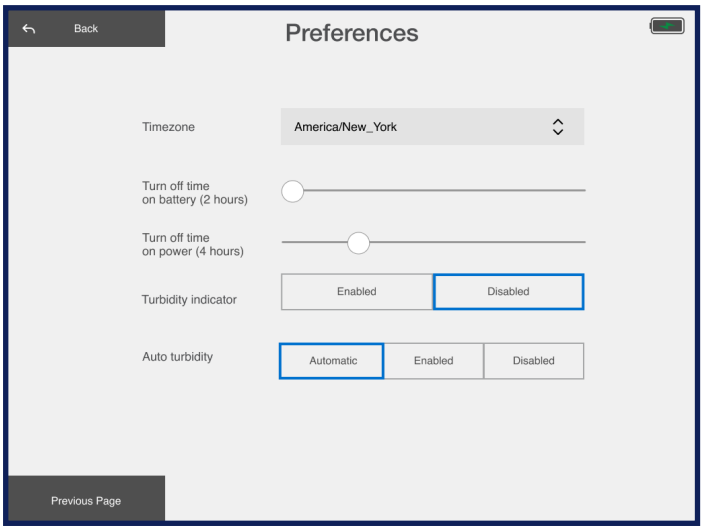
When no storage space is available, the oldest exam in storage will be deleted in order to allow space for the current exam.



Default colormap:
Select the colormap overlay used to display the Middle Ear Scan. Color is related only to the brightness of the signal and does not represent any particular anatomy.

Image save 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.



Auto camera rotation:
Rotate the surface camera displayed on the main display to match the rotation of the handheld. This mode is intended to support the use of “pencil grip” when using the handheld to image the middle ear space.

Patient identification:
Patient identification can be added during an exam. Patient identification can be ***disabled***, ***optional*** or ***required*** (default). 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 where the device is located.

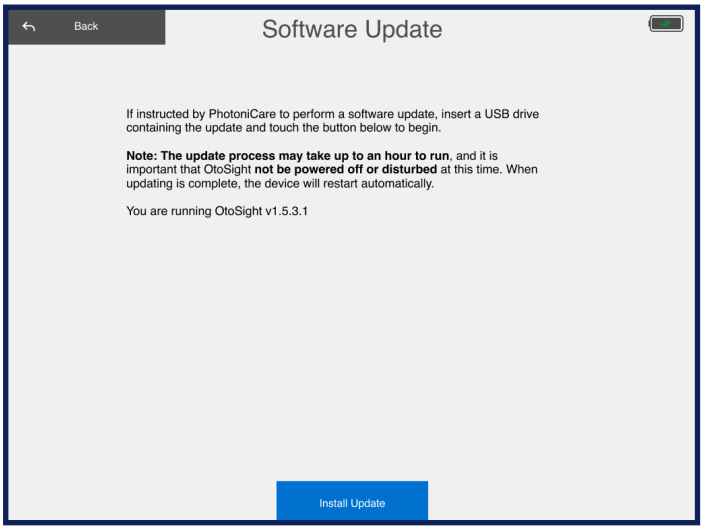
Turn off time:
The time until the device turns off after last being used. The turn off time can be adjusted for when the device is connected to mains power and when on battery power.

Turbidity Indicator:
Enables or disables the turbidity indicator feature in review mode (default enabled).

AutoTurbidity
Enables, disables or Automatically requests AutoTurbidity assessment. Using the automatic request setting increases speed of assessment by requesting a response as soon as the exam is completed. See Section 3.4 for more information on AutoTurbidity.

2.7.2 Software Update

Before initiating a software update, it is important to plug the device in. To update the OtoSight Middle Ear Scope software, navigate to the Configuration Page and press the *Software 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 25 minutes or more to complete, and the device is not usable until the update is finished.

2.7.3 Wi-Fi

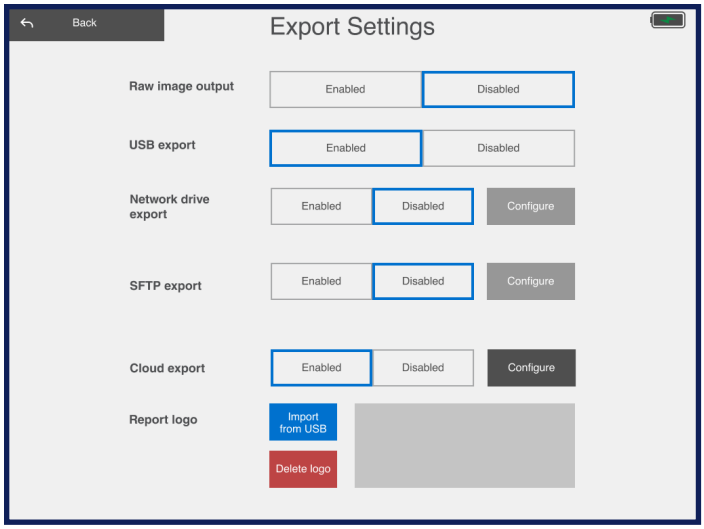
OtoSight can be connected to a Wi-Fi network in order to export exam recordings to a network drive or the OtoSight Report Viewer.

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



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.

SFTP export
The option to export exam reports and images to a SFTP server can be enabled or disabled. Press *Configure* to provide credentials for access to the SFTP server.

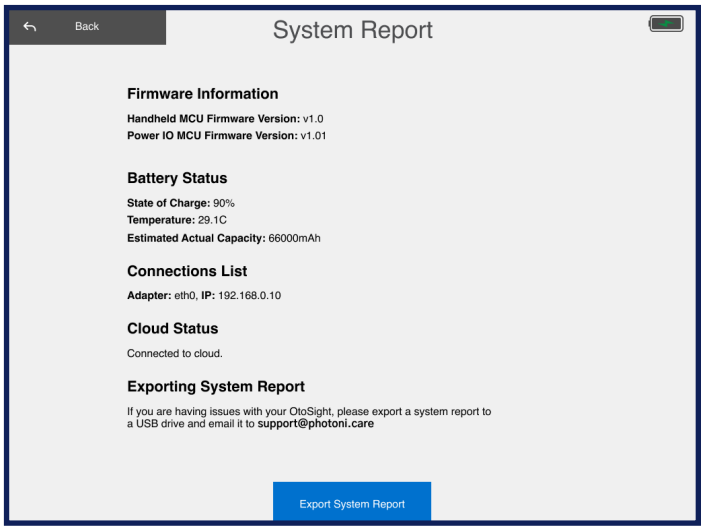
Cloud export
Export setting that integrates directly with an EMR system. Please contact PhotoniCare, Inc for support configuring this option.

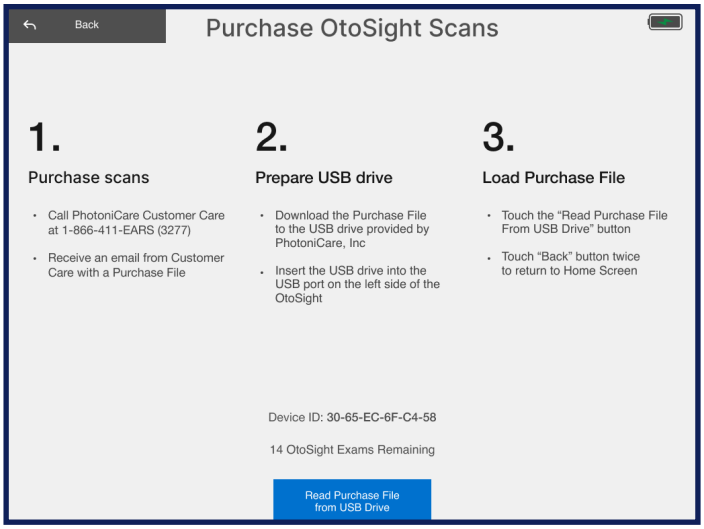
Report logo
A custom report logo can be uploaded to the device from a USB drive. To upload an logo image, place a .png file on the root folder with the file name custom_logo.png and press *Import from USB.*

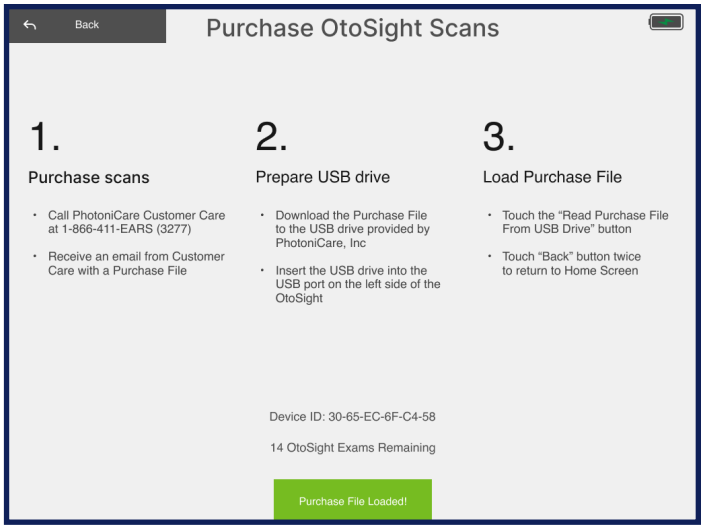
2.7.5 System Report

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.







2.7.6 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.

2.8 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 disposable 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 and turn off 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

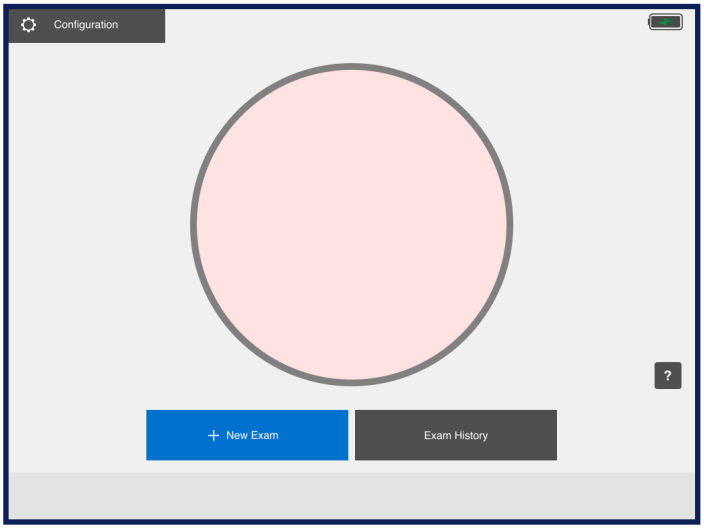
3.1 Prepare OtoSight for Use

Power on the device using the Power Button, or awakened from sleep mode by tapping the screen or pressing the Power 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.

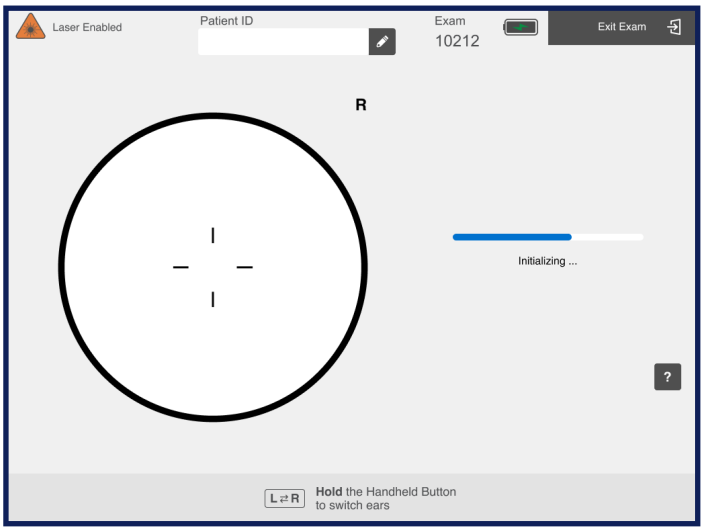
Caution: Use only PhotoniCare specula that are compatible with the OtoSight Middle Ear Scope, unless the device is equipped with a Welch Allyn Tip Adapter. If the device is equipped with a Welch Allyn Tip adaptor, the device is not compatible with PhotoniCare specula and a 4.25mm Welch Allyn Speculum 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 Begin a Middle Ear Exam

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 device will take several seconds to initialize before a Middle Ear Scan can be started.



Caution: The device should not be placed in the ear before recording is started. Doing so will reduce the quality of the Middle Ear Scan.

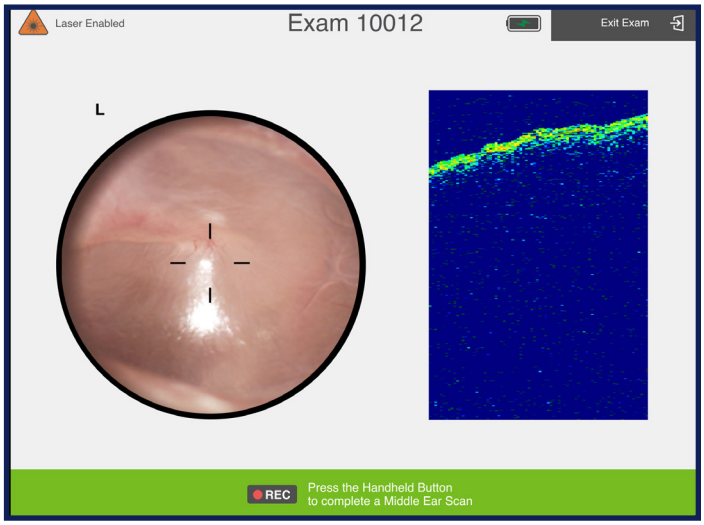
SECTION 3: PERFORMING AN EXAM

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 a Middle Ear Scan on the right. Once the handheld is placed into the patient's ear, users can view the eardrum on both displays.

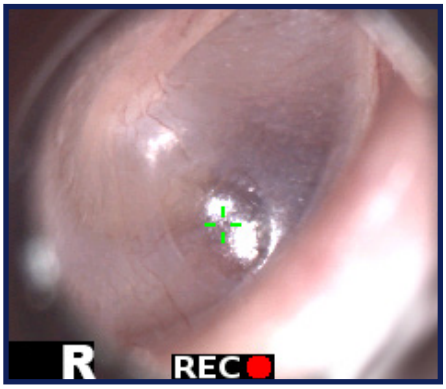
Both the handheld and the base unit screens will display either "R" or "L" to indicate ear label laterality (right vs. left ear) being applied to the images. The default setting is "R". Users can change this setting if desired. See Section 2.6.1 for details.

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 turn green.



The crosshair on the digital otoscopy surface image displayed on both the handheld and the base unit displays will 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.



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

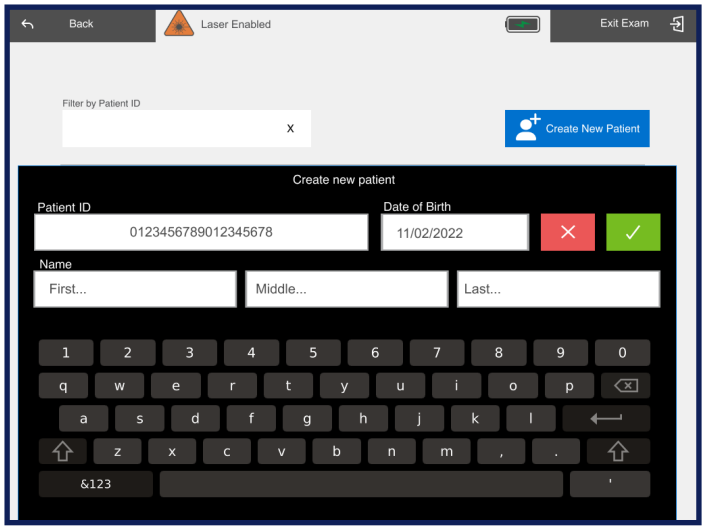
3.3 Patient Information

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.

If cloud is enabled, a patient selection view will appear allowing user to search for an existing patient or create a new patient. If cloud is not enabled, use the onscreen keyboard popup to enter a patient ID.

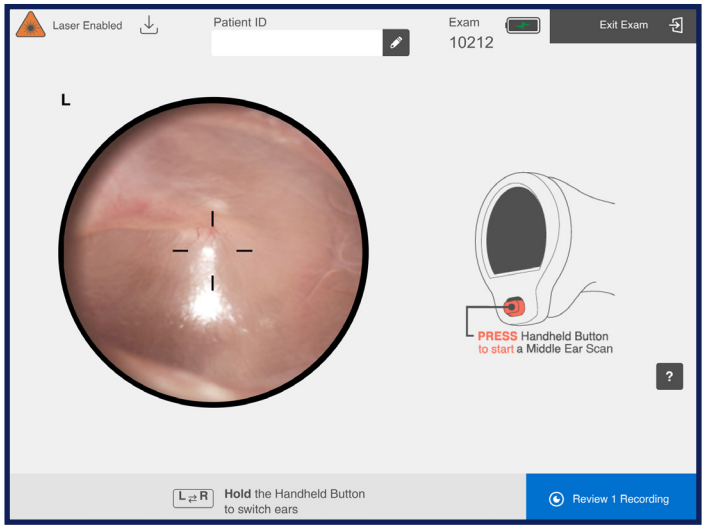
Patient Information can be configured as optional, disabled or required in the configuration menu. If required, a patient identifier must be entered before the exam can be closed.

See Section 2.6.1 for details.

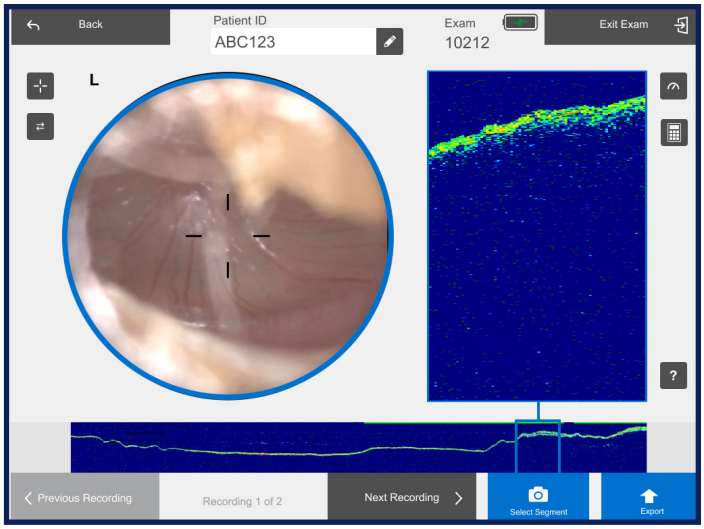


3.4 Review and Export OtoSight Exams

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.



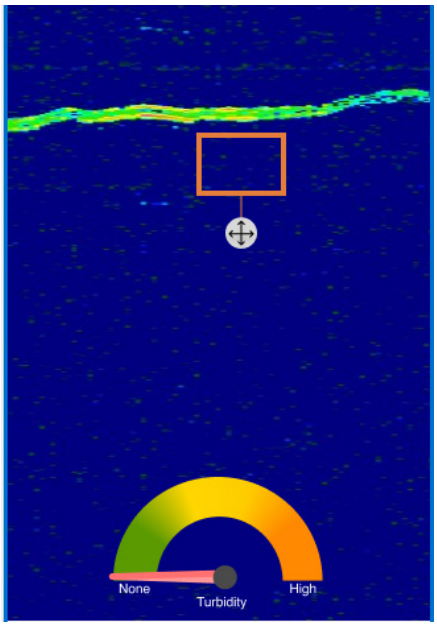
Once in **Review Mode**, all the data collected during the exam can be viewed and evaluated by medical professionals. The Middle Ear Scan is displayed along the bottom of the screen in a “film strip” style display, with the corresponding surface images above it. The Middle Ear Scan shows a continuous 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. Both the film strip and middle ear scan are interactive and can be used to scroll through the exam. Swipe left to view data further right in the exam strip. Swipe right to view data further left in the exam strip.

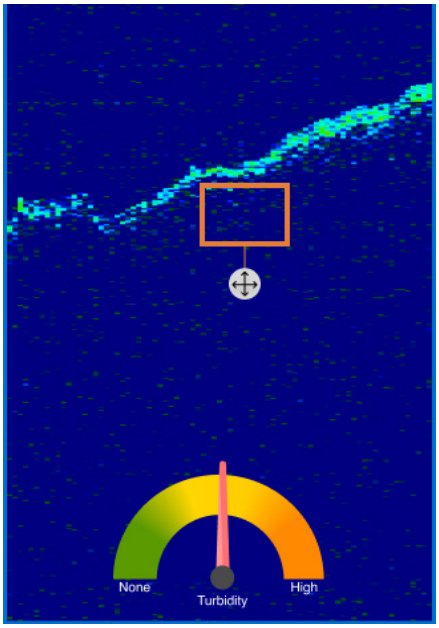


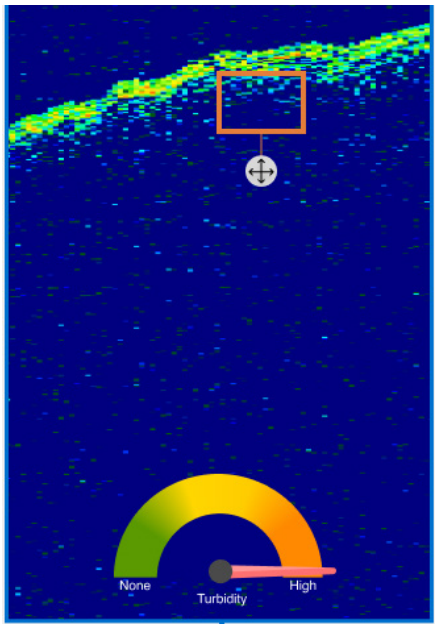
SECTION 3: PERFORMING AN EXAM

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**.

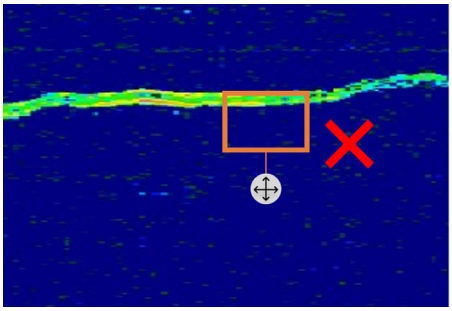




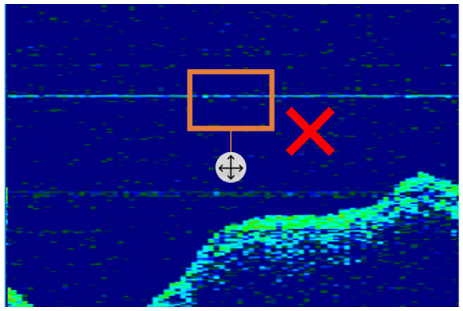


CAUTION: For an accurate reading, place the turbidity selection box just below the tympanic membrane (TM), placed over the middle ear space only. Ensure no part of the TM is within the selection box, as the turbidity indicator can be skewed by tissue not in the middle ear space.

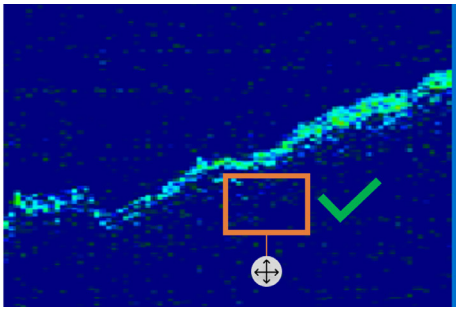
To use the turbidity indicator, drag the selection box to be directly underneath the ribbon of the tympanic membrane. The indicator will automatically update based on the location of the selection box.



Selection box corner is placed over TM.



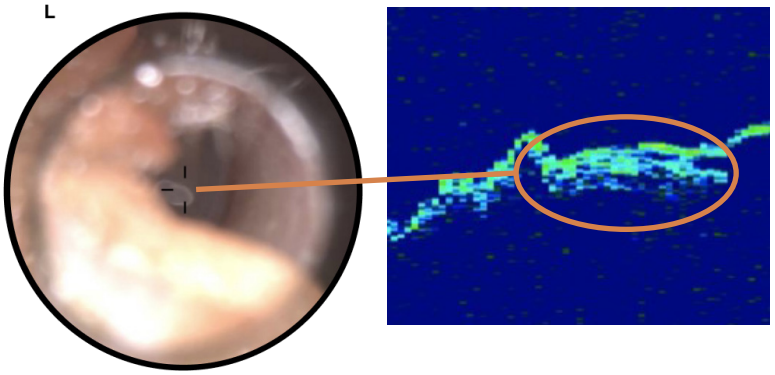
Selection box includes imaging artifact.



Selection box is correctly placed.

SECTION 3: PERFORMING AN EXAM

Note: Tympanosclerosis is characterized by scarring within the fibrous layer of the tympanic membrane and appears as a white or yellow plaque on visual inspection. If tympanosclerosis is present on the tympanic membrane, the Middle Ear Scan may reflect this. Special care should be taken when imaging in the presence of tympanosclerosis to distinguish between a thickened TM and the presence of fluid in the middle ear space and the turbidity indicator should not be placed over this region.



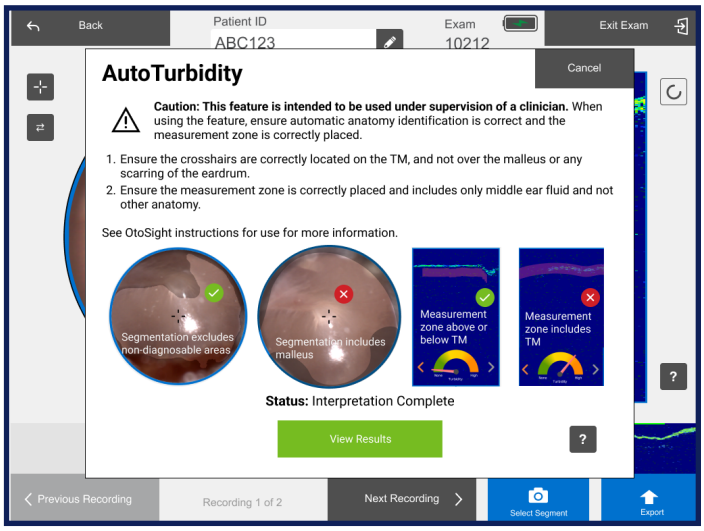
AutoTurbidity

The AutoTurbidity feature provides an assessment of the turbidity of the contents of the middle ear by identifying the middle ear in the scan and averaging the brightness of pixels in a measurement area.

Note: AutoTurbidity requires an internet connection to function.

To use AutoTurbidity, press the AutoTurbidity button during review mode.

A processing icon and information popup will be displayed while the recording is processed.



The *Status* message will update based on the processing status. When the status shows *Interpretation Complete,* press View Results to see the AutoTurbidity assessment.

AutoTurbidity will identify the anatomy in the surface image and middle ear scan and place a measurement region in the middle ear space. Care should be taken to ensure that segmentation is correct before reading the turbidity speedometer.

Note: The turbidity reading applies only to the measurement zone identified in the middle ear scan, not the entire middle ear space.

Caution: When using the feature, ensure automatic anatomy identification is correct and the measurement zone is correctly placed.

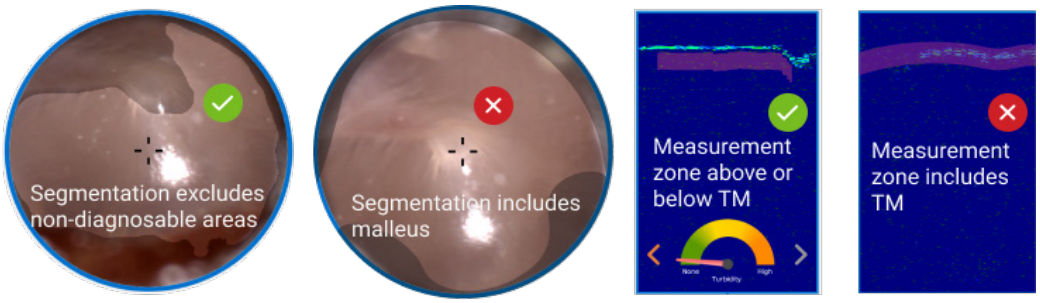
Exporting OtoSight Exams

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. The snapshot will save and export exactly what is on the screen at the time of selection.

SECTION 3: PERFORMING AN EXAM

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.

SFTP
Export a PDF report to an SFTP server on a local network or the internet.

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.

Cloud Export
If enabled and connected, export PDF report directly to OtoSight report viewer. Contact PhotoniCare representative for setup and assistance.

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.

SECTION 3: PERFORMING AN EXAM

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:

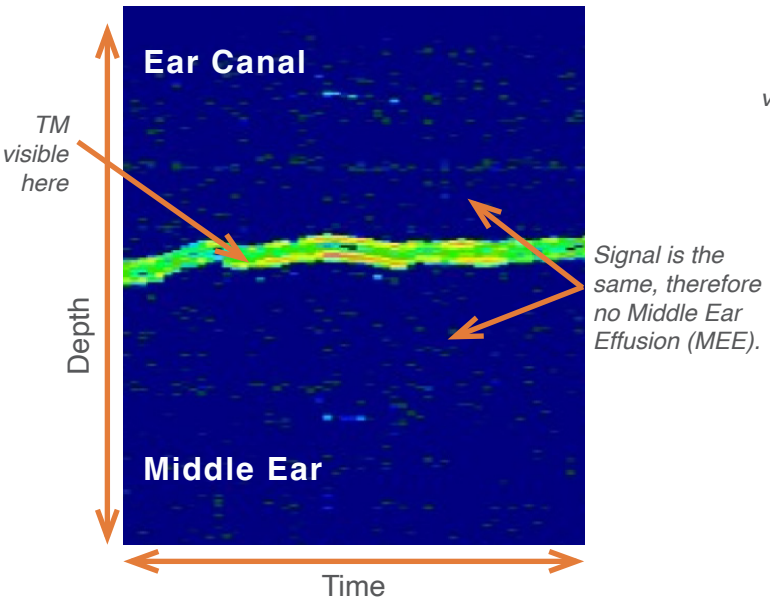


Fig A. This figure shows an example of an Middle Ear Scan obtained from a normal ear. The tympanic membrane (TM) is clearly visible as a thin, bright ribbon across the image. The signal above and below the line of the TM is similar, which suggests that there is air in the middle ear space (not fluid).

Figure B:

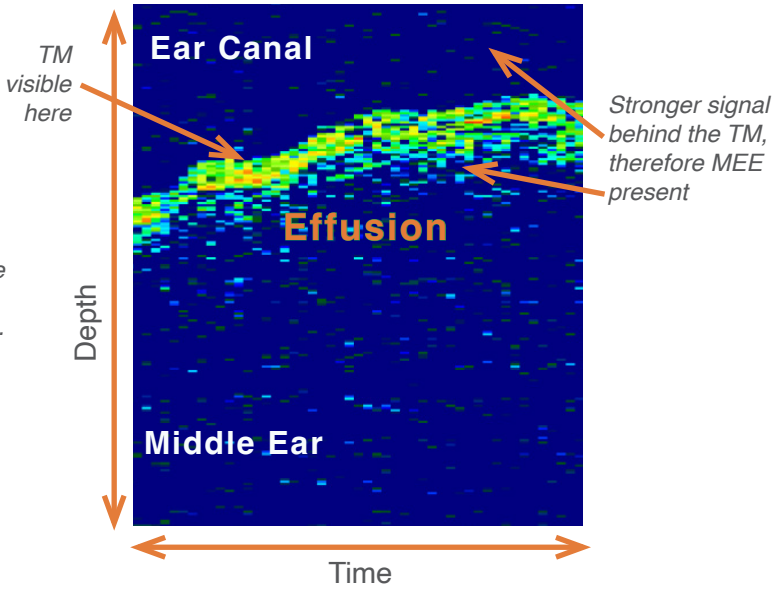
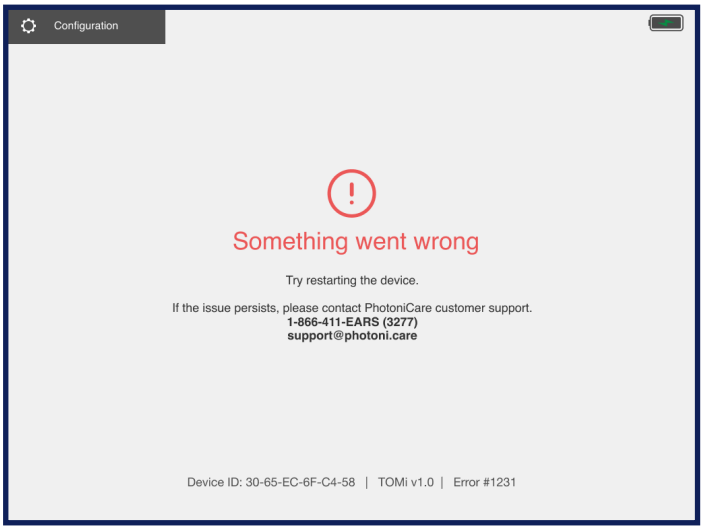


Fig B. This figure shows an example of an Middle Ear Scan obtained from an ear with fluid behind the TM. The TM is still clearly visible here, as in the normal ear image. However, the signal from below the TM is stronger and more dense (white) than the signal from above it. This suggests the presence 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 to fully power off the device, and then restart it. If the error persists, contact PhotoniCare Customer Support at: support@photoni.care.



3.7 Help Screen

While on the **Home Screen**, in **Exam Mode** or **Review Mode**, clicking the question mark icon will bring up help screen images relevant to the current mode.

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 +/- 30nm (Class 3R Laser Product per IEC 60825-1)
Beam Divergence	9.8 mrad

4.3 Battery Specifications

Voltage:	11.1 volts
Capacity:	6400 mAh
Charging:	5% - 80% 1h 30m
Expected Battery Life During Typical Use:	7 hours
Chemistry:	Lithium Ion

SECTION 4: SPECIFICATIONS

4.4 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	

SECTION 4: SPECIFICATIONS

4.5 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

4.6 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 holding the Power Button for 15 seconds 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.

SECTION 4: SPECIFICATIONS

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.

4.7 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 62133-2:2017

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.

4.8 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)

4.9 Electrical Requirements

Device is designed for use with power supplies 100V ~ 240 V, 50/60 Hz, with a maximum current rating of 2A.

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

Note: Mains voltage is isolated from the device by multiple methods. To isolate the device from mains voltage, remove the power cord from the rear 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 HTTPS://PHOTONI.CARE