THE OTOSCOPE. REINVENTED.

Wispr®

by WiscMed®

INSTRUCTIONS FOR USE

IFU 24701 052721 V5

INVENTED IN WISCONSIN

MADE IN THE USA

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Caution
Changes or modifications not expressly approved by WiscMed, Inc. will void the purchaser's authority to operate the equipment and its warranty.

REF wispr24701, Wispr Digital Otoscope

WiscMed, LLC
8383 Greenway Blvd., Suite 600
Middleton, WI 53562

Phone - 608.729.7234

PATENTS

For patent information, please visit, www.wiscmed.com/patents.

INTRODUCTION

Thank you for purchasing the Wispr Digital Otoscope (wispr24701).

The Wispr by WiscMed is a general-purpose digital otoscope capable of displaying real-time images of the tympanic membrane for clinical evaluation and saving individual images and videos for further review. The primary user interface is a touch screen display and a single button.

The Wispr is optimized to operate with power sources outlined below. This manual describes how to operate and maintain the Wispr Digital Otoscope.

Please read this document in full before using this product.

SUPPORTED POWER OPTIONS – REQUIRED BUT NOT SUPPLIED

The Wispr has been certified for use with the following power sources:

- Welch Allyn®, 71000-A rechargeable handle (requires WiscMed-supplied spring)
- Welch Allyn®, 71910 rechargeable handle
- Welch Allyn®, 71670 rechargeable handle
- Welch Allyn® 777 wall transformer
- Welch Allyn® 767 wall transformer
- Welch Allyn® Connex® wall transformer
- Heine, BETA 4 USB rechargeable handle (with native Welch Allyn twist-lock or Heine to Welch Allyn twist-lock adapter)
- Heine, EN 100 wall transformer

Please refer to www.wiscmed.com/support for updates to supported power sources along with WiscMed recommendations.

INDICATIONS FOR USE

The Wispr is intended to allow inspection of the external ear canal and tympanic membrane under illumination and magnification.

INTENDED USE AND ENVIRONMENT

The Wispr is intended for use in professional healthcare facilities such as examination rooms, emergency rooms, hospitals, etc. by clinicians and healthcare professionals.

WiscMed assumes no responsibility for any injury, or for any illegal or improper use of the product, which may result from failure to use this product in accordance with the instructions, cautions, warnings, or indications for use published in this manual.

SYMBOLS GLOSSARY

The following symbols may appear on the Wispr, accessories, or within these instructions for use.

Symbol	Symbol Title - Reference Number	Standard	Meaning
	Caution - 5.4.4	ANSI AAMI ISO 15223-1:2016 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements	User to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use - 5.4.3		User consult the instructions for use.
	Date of manufacture - 5.1.3 (YYYY-MM-DD)		Date when the medical device was manufactured.
	Manufacturer - 5.1.1		Medical device Manufacturer. Manufactured for: WiscMed, LLC 8383 Greenway Blvd, Suite 600 Middleton, WI 53562
REF	Catalogue Number - 5.1.6 (Model number)		Manufacturer's catalogue number so that the medical device can be identified.
LOT	Batch code - 5.1.5 (Lot number)		Manufacturer's batch code so that the batch or lot can be identified.
SN	Serial number - 5.1.7		Manufacturer's serial number so that a specific medical device can be identified.
	Do not use if package is damaged - 5.2.7		Medical device that should not be used if the package has been damaged or opened.
	Temperature Limit - 5.3.7		Temperature limits to which the medical device can be safely exposed.
	Humidity limitation - 5.3.8		The range of humidity to which the medical device can be safely exposed.
	Fragile, handle with care - 5.3.1		Medical device that can be broken or damaged if not handled carefully.
	Keep dry - 5.3.4		Medical device that needs to be protected from moisture.
	Universal Serial Bus (USB), port/plug- 3650	ISO 7000 — Graphical symbols for use on equipment — Registered symbols	USB port.
	Symbol for the marking of EEE	Directive 2012/19/EU of the European Parliament and of the Council on Waste Electrical and Electronic Equipment (WEEE) 4 July 2012	Separate collection for electrical and electronic equipment
	Type BF applied part - Table D.1 - 20	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type BF applied part
	ISO 7010-W001	ISO 7010 Third edition 2019-07 Graphical symbols - Safety colors and safety signs - Registered safety signs	Warning. Identify conditions or practices that could lead to illness, injury, or death.
	Still camera - 5885	IEC/TR 60878:2015 Graphical symbols for electrical equipment in medical practice	Camera mode. When the camera (blue) button is pressed a still image is saved.

SAFETY

The Wispr is safe for patients and clinicians when used in accordance with the instructions and safety statements presented in these instructions for use. Additional warning and caution statements may be found within the manual but not outlined below, so please read this document in its entirety.

WARNINGS

⚠ Do not modify this equipment without authorization from the manufacturer.

⚠ Check the battery charge when using battery-powered handles.

⚠ Do not use the device in the presence of flammable gases and/or liquids.

⚠ Do not immerse the device in any liquid.

⚠ Electric shock hazard. Do not open the device or attempt repairs.

⚠ Avoid shining light directly into eyes.

⚠ Never use the Wispr without a WiscMed Speculum.

⚠ USB port is only for connection of USB flash drives. USB flash drives are not to be inserted while examining a patient. When in use with a patient, the USB door shall be closed.

⚠ Use only approved accessories and handles and use them according to the manufacturer's directions for use. Unapproved handles and accessories can damage the device and void the warranty. Do not use Wispr device with a battery handle while the battery handle is charging (i.e., connected to a wall outlet).

⚠ Replace the disposable speculum between uses.

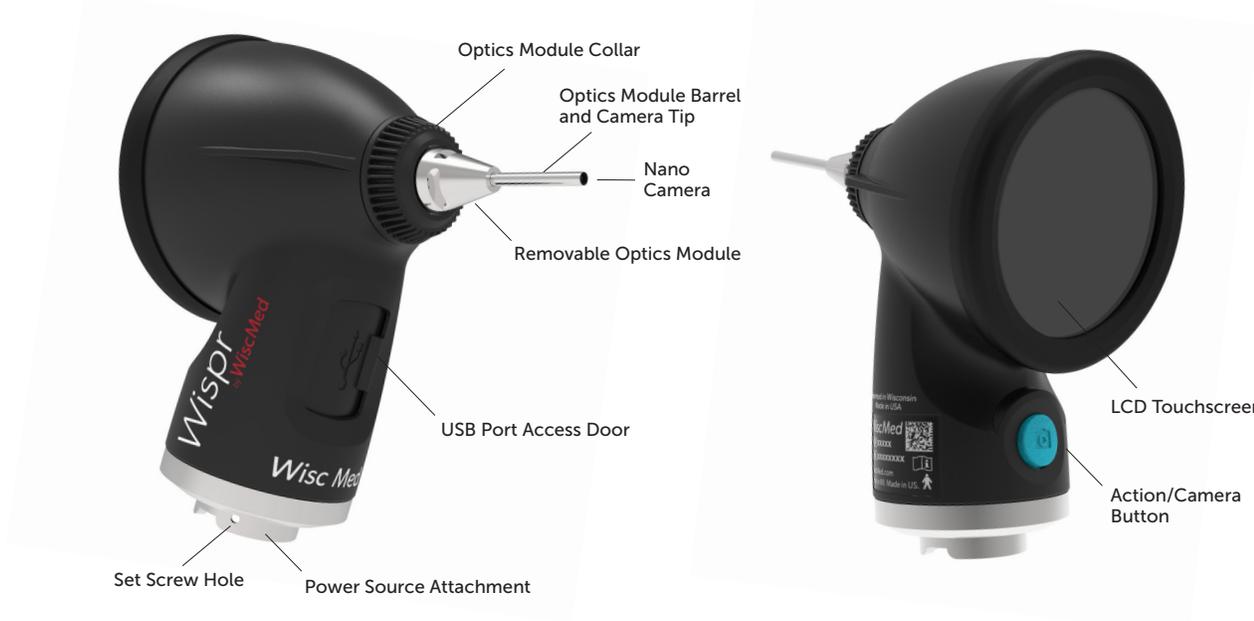⚠ Clean the optics module barrel and camera tip per cleaning instructions between use.

CAUTIONS

⚠ Do not use if the device, accessory, or packaging appears and/or is damaged. Periodically inspect the product for signs of damage, including any sharp edges, protrusions, or rough edges that could harm the user or patient.

⚠ Only use the WiscMed Wispr disposable specula.

⚠ The Wispr uses an LED fiber optic light source to minimize heating at the tip. Always use with a disposable speculum. The speculum will heat up no more than 6°C (11°F) above room temperature even with continuous use, keeping the speculum tip well below body temperature for most conditions. The Wispr is rated for use up to an ambient temperature of 40°C (104°F); at this ambient temperature, the maximum temperature of the speculum will be 46°C (115°F). Contact between the speculum and patient should be kept to less than a minute or if the patient expresses any discomfort.

⚠ Follow guidance on cleaning/routine maintenance to prevent injury and/or damage to the device.

⚠ Failure to follow recommended cleaning/maintenance may reduce the operational lifetime of the device.

⚠ LCD screen and the gold electrical contact at the base of the device can be cleaned with lint-free cloth or equivalent.

⚠ Avoid liquids entering the device which could damage internal components.

⚠ This product complies with current required standards for electromagnetic interference and should not present problems to other equipment or be affected by other devices. As a precaution, avoid using this device near other equipment.

⚠ Keep out of reach of children.

GETTING STARTED

PACKAGE CHECKLIST & PARTS LIST

Please be sure the following are included in your recent Wispr purchase. If you are missing anything please contact us at, www.wiscmed.com/support.

Wispr Digital Otoscope Head

Optics Module Collar

Optics Module Barrel and Camera Tip

Nano Camera

Removable Optics Module

USB Port Access Door

LCD Touchscreen

Action/Camera Button

Set Screw Hole

Power Source Attachment

Wispr Rheostat Locking Collar Components

Clamp Collar

Outer Collar

Rubber Inner Collar

4" Black Tape

For use during power source set-up with the wall transformer or the 3.5 V Lithium Ion rechargeable handle. See 'Set-up with Power Sources' for detailed instructions.

The Tape and Collars are placed on the wall transformer handle at set-up to ensure the Wispr always receives full power from the handle when it's removed from the wall unit.

The Outer Collar by itself can also be placed over the Welch Allyn 3.5 V Lithium Ion rechargeable handle's (71910) power button allowing the Wispr to be turned on and off by simply twisting the collar clockwise and counter-clockwise. See instructions.

4-Part Installed Collar Lock on Wall Mount Handle

Hex Wrench & Screw Set

For use during power source set-up to lock head to a rechargeable handle or wall transformer handle. See 'Set-up with Power Sources' for detailed instructions.

(Optional) For added security, the set screw can be used to lock the Wispr digital otoscope head to a rechargeable handle or wall transformer handle.
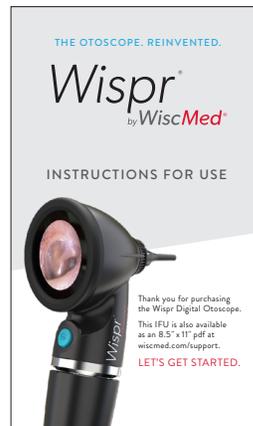
Wispr Disposable Specula

Package includes (5) one-time use disposable specula to get you started.

WiscMed Wispr disposable speculum can be placed in and dispensed from most existing wall dispensers.

Change speculum between patient exams.

Order online at www.wiscmed.com.

WiscMed Wispr Stickers

To be placed on wall-mounted speculum dispenser columns to identify Wispr disposable specula.

Wispr 3"x 5" IFU

THE OTOSCOPE. REINVENTED.

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by WiscMed®

INSTRUCTIONS FOR USE

Thank you for purchasing the Wispr Digital Otoscope.

This IFU is also available as an 8.5" x 11" pdf at wiscmed.com/support.

LET'S GET STARTED.

3" x 5" Printed version of Instructions for Use.

Wispr Removable Wall Sticker

FIRST-TIME WISPR USERS

1. Prior to first-time use, please read Instructions for Use.

2. Wispr disposable specula are 1x use only.

3. Between uses, clean Wispr per instructions. Image will be blurry if camera tip is not kept clean.

4. Need help? Please visit WiscMed.com/support or call 608.729.7234.

Stickerwallmount1 11142019 V1

Wispr® DIGITAL OTOSCOPE
by WiscMed®

Sticker should be applied near the Wispr Digital Otoscope.

WiscMed Wispr USB Drive

Use: For saving images and videos and upgrading software. Most V2.0 USB thumb drives may also be used.

SET-UP WITH POWER SOURCES

Please see 'Supported Power Options' in the Introduction for a full list of compatible power sources.
This list is updated at www.wiscmed.com/support.

Wispr & Rechargeable Battery Handles
Attaching & Removing the Wispr Digital Otoscope Head

NOTE: The Wispr Outer Collar may optionally be used with the Welch Allyn 3.5 V Lithium Ion Rechargeable Handle (71910) to smoothly integrate the Wispr with the battery handle. If you do not want this option or are using one of the other supported rechargeable handles, please skip to Step 2.

1. **(Optional)** To attach the Outer Collar onto the handle, slide the provided Outer Collar (tapered end first) over the 3.5 V Lithium Ion Rechargeable Handle. Push the Outer Collar downward until the bottom of the Outer Collar rests flush against the top of the chrome ring. It is a friction fit that when installed keeps the green locking button disengaged. This allows turning the outer collar as the method to turn the Wispr on and off. It also provides for a finished look to the handle and Wispr. Move onto Step 2.

2. Align the notch located at the base of Wispr head with the ledge on the rechargeable battery handle.

NOTE: Optional collar not shown for clarity.

3. Once aligned, press down lightly (along the axis of the handle) on the Wispr and turn the Wispr in a clockwise direction to lock in place. To remove, press down slightly (along the axis of the handle) on the Wispr and turn counter-clockwise. The device should detach easily with light pressure.

NOTE: Optional collar not shown for clarity.

4. **(Optional)** For added security, using the hex wrench and set screw provided, simply insert set screw in the hole to the right of the notch on the Wispr head and turn the set screw clockwise to lock in place.

NOTE: It is not possible to use the optional outer collar if you want to secure the Wispr with the set screw on the battery handle.

Turn set screw counter-clockwise to remove.

⚠️ *Caution:*
If the set screw is used to secure the Wispr to the handle, it must be removed before attempting to detach the head from the handle.

Powering On & Off the Wispr on a Rechargeable Handle

The WiscMed Wispr requires full power from the handle to operate.

1. Provide full power to the Wispr by turning the power rheostat clockwise to maximum. This should be done in one fluid movement. The WiscMed logo will appear briefly on the LCD touchscreen as the device initializes.

2. When finished with the exam, turn the power off by turning the power rheostat counter-clockwise to 'off'.

Wispr & Wall Transformers
(applies to Welch Allyn 767, 777 and Connex Wall Transformers)

The WiscMed Wispr requires full power from the wall transformer to operate. Just as with your previous otoscope, the wall system only supplies power to the handle when the device is removed from the wall mount.

Attaching the Wispr Collar & Digital Otoscope Head

NOTE: The included Wispr Locking Collar system should be placed on the wall handle at set-up to ensure that the Wispr Digital Otoscope always receives full power from the handle. If this is not done, the rheostat can inadvertently be set to less-than full power and the device will not function.
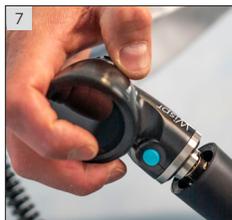
1. Turn the rheostat of the wall mount handle in a clockwise direction to the 'full on' position.

2. Slip the provided **Outer Collar** (tapered end first) over the wall mount handle so, it sits loosely at the base of the handle.

3. Using the provided **Tape,** wrap it around the rheostat such that the Tape spans both the rheostat and the portion of metal below the rheostat. Take care to make sure rheostat remains on "Full".

4. Manipulate the provided **Rubber Inner Collar** over the previously applied tape as far as it will go, only a small portion of tape should remain visible at the bottom.

5. Install the provided **Clamp Collar** with extension clips over the Rubber Inner Collar. The Clamp Collar should sit flush around the base of the Rubber Inner Collar.

NOTE: For added security, you can use the optional set locking screw. If you wish to install the set screw, please see the 'Optional Set Screw Steps' section below. If not continue onto Step 6.

6. Align the internal grooves of the previously installed Outer Collar and slide up over the Clamp Collar until it clicks in place. The Wispr Rheostat Collar Lock assembly is complete, and the rheostat is now locked in an 'on' position.
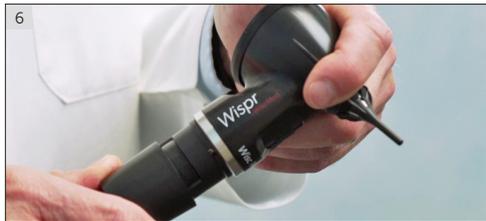
7. Align the notch located at the base of the Wispr head with the ledge on the wall unit handle.

8. Once aligned, press down lightly (along the axis of the handle) on the Wispr and turn the Wispr in a clockwise direction to lock in place.

To remove the Wispr or the locking collar reverse the steps above.

Optional Set Screw Steps:

1. Follow Steps 1 – 5 above.

2. Align the notch located at the base of the Wispr head with the ledge on the wall unit handle.

3. Once aligned, press down lightly (along the axis of the handle) on the Wispr and turn the Wispr in a clockwise direction to lock in place.

4. Rotate the Clamp Collar on the Rubber Inner Collar until the cutout in the top of the Clamp Collar is aligned with the set screw location on the installed Wispr. When rotating the clamp collar, take care not to disturb the position of the rubber collar as this may change the underlying rheostat position.

5. Using the hex wrench and set screw provided, insert the set screw into the hole on the Wispr head and turn the set screw clockwise to lock in place. Turn set screw counter-clockwise to remove.

6. Align the internal grooves of the previously installed Outer Collar and slide up over the Clamp Collar until it clicks in place. The Wispr Rheostat Collar Lock assembly is complete.

⚠️ *Caution:*
If the set screw is used to secure the Wispr to the handle,
it must be removed before attempting to detach the head from
the handle.

Powering On & Off the Wispr from a Wall Mount Unit

When the handle is removed from the wall mount, power is automatically supplied to the Wispr and the WiscMed logo will appear briefly on the LCD touchscreen as the device initializes.

Attaching & Removing Speculum

Unlike traditional otoscope specula, the Wispr disposable speculum simply slides over the tip and clips into place. A slight clockwise motion can be used to assure that the speculum is locked in place.

To remove, turn counter-clockwise on the base flutes and discard after each use.

⚠️ *Warning:*
Only use WiscMed Wispr disposable specula, as the unique
geometry of the device will not support other specula.
Inspect speculum and make sure there is no damage that
could harm the patient.

⚠️ *Warning:*
Inspect the optics module and optics module collar before
installing speculum. Confirm there are no sharp edges or
protrusions that could interfere with the speculum or harm
the patient.

OPERATING THE WISPR

To operate, complete the following steps:

1. Clean the optics module barrel and camera tip according to cleaning instructions (found in device cleaning section).

2. Place a new speculum onto the Wispr.

3. Turn on the Wispr

⚠️ *Warning:*
Before inserting the Wispr tip into a patient's ear, ensure that the view on the LCD screen is displaying the active camera video and not a static image or a previously recorded video.

Image Capture Home Screen:
When first turned on, the WiscMed screen displays for about 3 seconds. The "home" screen will then be presented. It is used to view the clinical exam and capture either photos or videos. The default mode is photo mode (indicated by the small camera icon at the bottom of the screen).
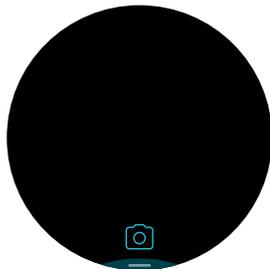
Start-up Screen   Home

To change to video mode, tap on the camera icon. The video recorder icon replaces the camera icon. To change back to photo mode, tap on the video icon.
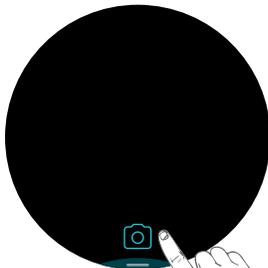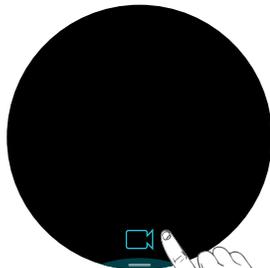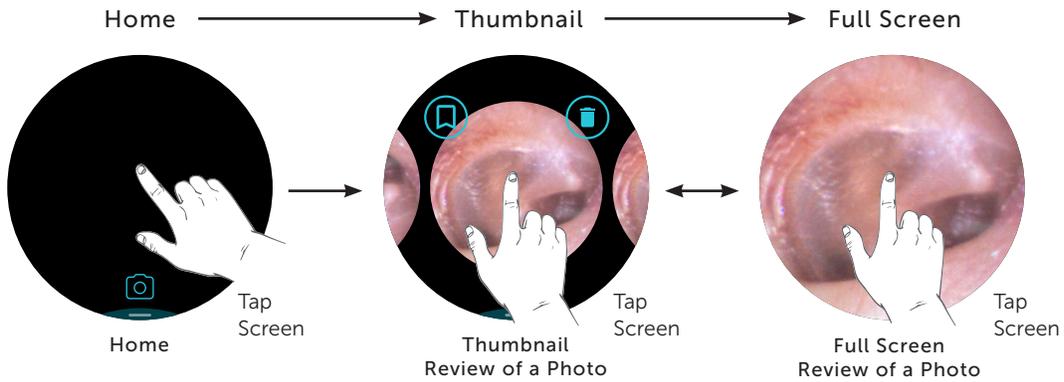

Photo Mode   Video Mode

Tap video icon to change back to photo mode,

NOTE: The Wispr defaults to the last active mode (video or picture) when it is turned off and back on.
(e.g. Wispr is in video mode when turned off, it will be in video mode when it's turned back on.)

Navigating the Device Screens

The Wispr features an intuitive navigation functionality via a touch screen that allows for familiar touch and swipe input.

Home   ⟶   Thumbnail   ⟶   Full Screen

Home   Tap Screen   Thumbnail Review of a Photo   Tap Screen   Full Screen Review of a Photo   Tap Screen

The blue action button has two functions:

1. Captures photos or videos.
2. Returns you to the previous screen - i.e. If the viewer is in full screen, it returns to the thumbnail view. If in the thumbnail view, it returns to the capture screen. If in a menu, it exits to the prior screen.

Home

Full Screen   ⟶   Thumbnail   ⟶   Home

WiscMed®

Capturing Clinical Images

Photo Capture

To capture photos, press the blue action button on the device while in photo mode.

Photo Capture in Process

A **brief blue circle** flashes around the perimeter of the screen to indicate that a photo has been taken.

NOTE: The Wispr stays in capture mode. To review images, see below

Video Capture

To capture videos, **first tap** on the camera icon to switch to video mode. Ensure that the video camera icon is displayed at the bottom of the screen.

Press the blue action button on the device to begin recording.

Video Capture in Process

When capturing video, a **continuously flashing blue circle** around the perimeter of the screen indicates that video is being recorded.

When the exam is complete, press the blue action button on the device to stop recording.

NOTE: The Wispr stays in capture mode. To review images, see below

NOTE: The Wispr contains built-in memory that allows for storage of videos and photos. The Wispr is designed such that should storage be depleted; the oldest videos and photos are overwritten. Because of this, a storage shortage never prevents the saving of new images or videos. The Wispr can store about 30 minutes of video or thousands of images.
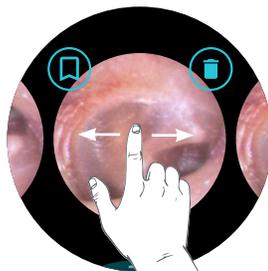
Thumbnail Screen (image/video review):

After images or videos have been captured you can pull up a thumbnail list of previously captured snapshot images or videos.
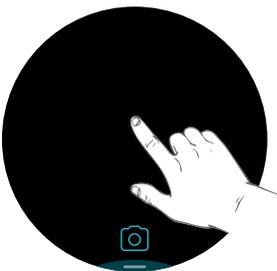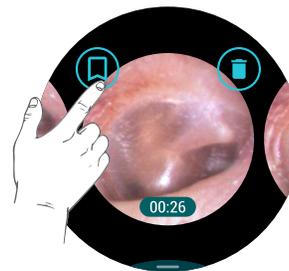
Home

Tap in the middle of the image capture screen to pull up a thumbnail list.

Thumbnail Review of a Photo

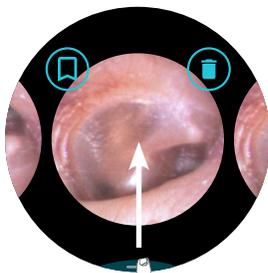**Thumbnail Review of a Video**
Note the 00:26 representing the length of the video.

You may now:

- Review saved images/videos by swiping left or right. Video clips are identified by a time-lapse notation on the thumbnail image.

- Delete or select image/video by tapping on one of the icons on the upper half of the screen.

Icon	Feature
	Select image/video. Tap to select.
	Selected image/video. Tap to unselect.
	Tap to delete image/video. Requires confirmation tap below.
	Delete image/video confirmation (Shown in pressed/"Confirm Delete" state. Tap to Delete Forever). Tap anywhere else to abort delete.
	Export frame from video.
	This image was exported from video (Shown unselected).

Taking action on images and videos (saving, deleting).
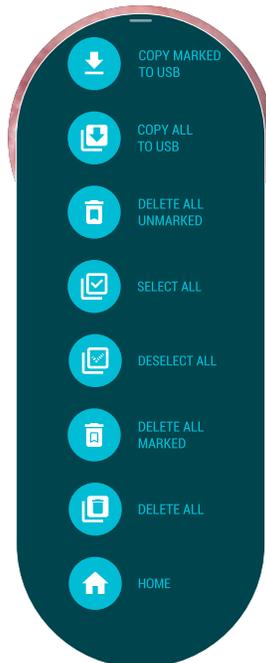

Thumbnail Review of Photo

The pull up menu is accessed from the photo/video thumbnail review by smoothly sliding a finger up from the bottom of the screen.

Thumbnail View Swipe Menu

To see all menu options, scrolling in this menu is required. Menu items are grayed out if not available. For example, if no USB is inserted, the USB options will not be available.

Thumbnail View Swipe Menu Shown Fully Expanded

COPY MARKED TO USB

COPY ALL TO USB

DELETE ALL UNMARKED

SELECT ALL

DESELECT ALL

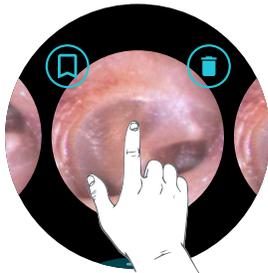DELETE ALL MARKED

DELETE ALL

HOME

Exit the menu by pressing the blue action button.

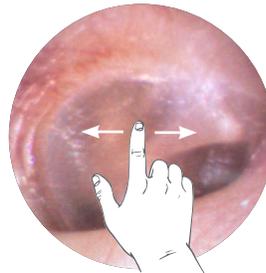Press the blue action button to exit the thumbnail review and return to the image capture screen.

Full Screen Review:

Full screen review is for reviewing previously captured photos or playing previously captured videos.

Thumbnail Review

Full screen review is accessed by tapping on the photo or video of interest from the thumbnail review.

Full Screen Review of a Photo

In full screen review, swiping left or right will bring you to the next photo or video.

Exit full screen review by tapping on the photo or video. Alternatively, pressing the blue action button will exit full screen review.

Video Review:

Full Screen Video with Play Button

Full Screen Video Playing with Video Controls

1. Press play to start the video. The video will begin playing without any icons on the screen.

2. Touch anywhere on the playing video to bring up the video controls. The video will continue to play with the controls visible.

3. The video may be paused by pressing the pause button.


Full Screen Video Paused

**Full Screen Video Paused with Current Frame Selected for Export**

4. Once paused, the "smiley face" timeline can be used to scrub through to a frame of interest. It is also possible to swipe left and right in a paused video to review adjacent frames.

5. When an image of interest is found, it may be exported from the video by selecting the export icon. Exporting an image places just that frame it in storage immediately after the video.

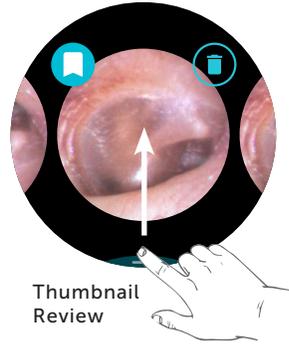**WiscMed**®

Saving or deleting a photo or a video

In thumbnail review, select the video or photo that you wish to save or delete. You may select any combination of videos or photos at one time. Swiping left or right will bring you to the next photo or video.
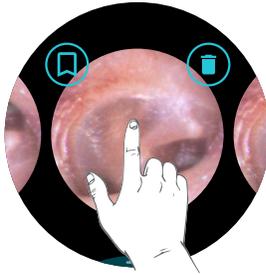
Thumbnail Review
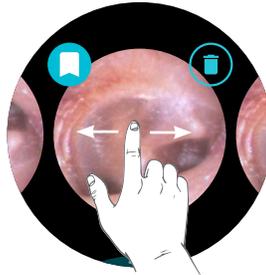
Thumbnail Review

Thumbnail Review

Access the thumbnail review menu by sliding a finger up from the bottom edge of the screen.

To see all menu options, scrolling is required.

DELETE ALL MARKED

DELETE ALL

HO

Thumbnail View
Swipe Menu

COPY MARKED TO USB

COPY ALL TO USB

DELETE ALL UNMARKED

SELECT ALL

DESELECT ALL

DELETE ALL MARKED

DELETE ALL

HOME

Thumbnail View
Swipe Menu Shown
Fully Expanded

Saving photos or videos;

To save selected images, insert a supported USB drive in the Wispr. The selected photos and videos are stored in sequentially numbered folders on the USB thumb drive. *Note: Saving videos or a large number of images can be time consuming.*

COPY MARKED TO USB

COPY ALL TO USB

SELECT ALL

IMAGES SAVED
TAP TO CONTINUE
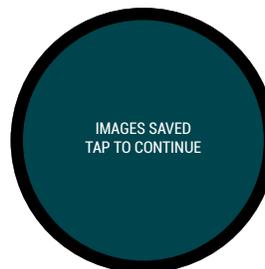
Successful completion of the save is indicated by "IMAGES SAVED TAP TO CONTINUE." After saving the images, they are automatically unselected in the thumbnail review.

The option "COPY MARKED TO USB" will become available (icon changes color from gray to blue). Alternatively, "COPY ALL TO USB" may be selected which will copy all photos and videos, regardless of whether they are selected.

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How the saved images/videos appear on the USB
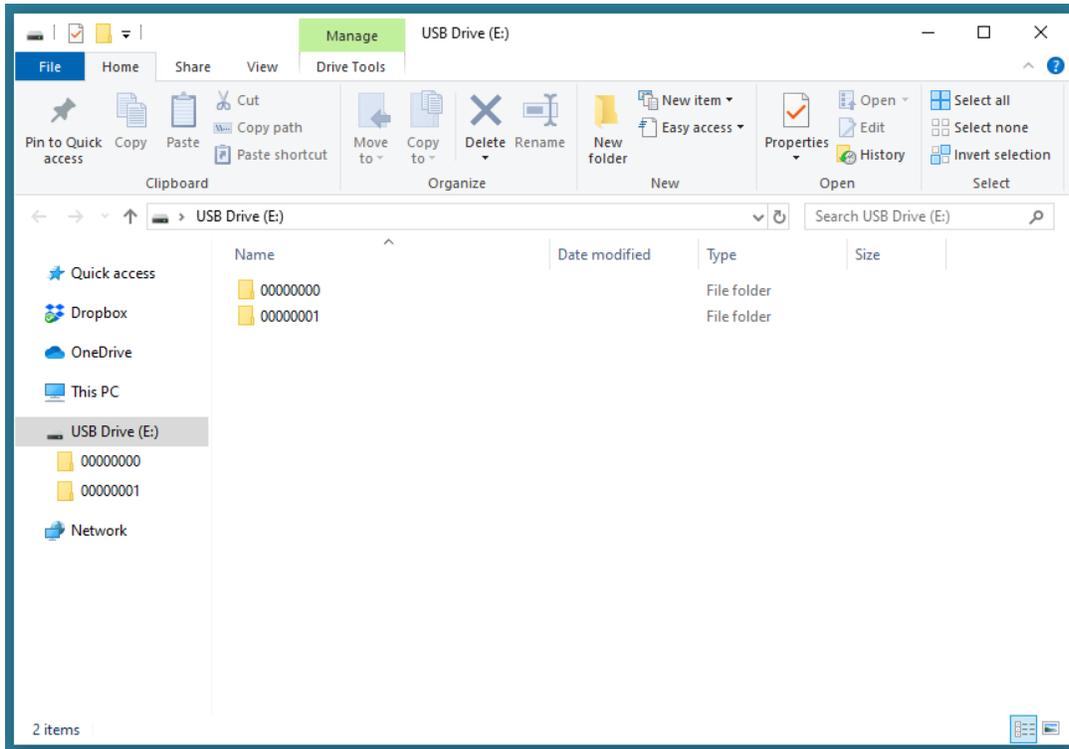
Each time you save images or videos, a new folder is created on the USB drive. The folders are incremented by "1" for each save request. The most recent save has the highest folder number.
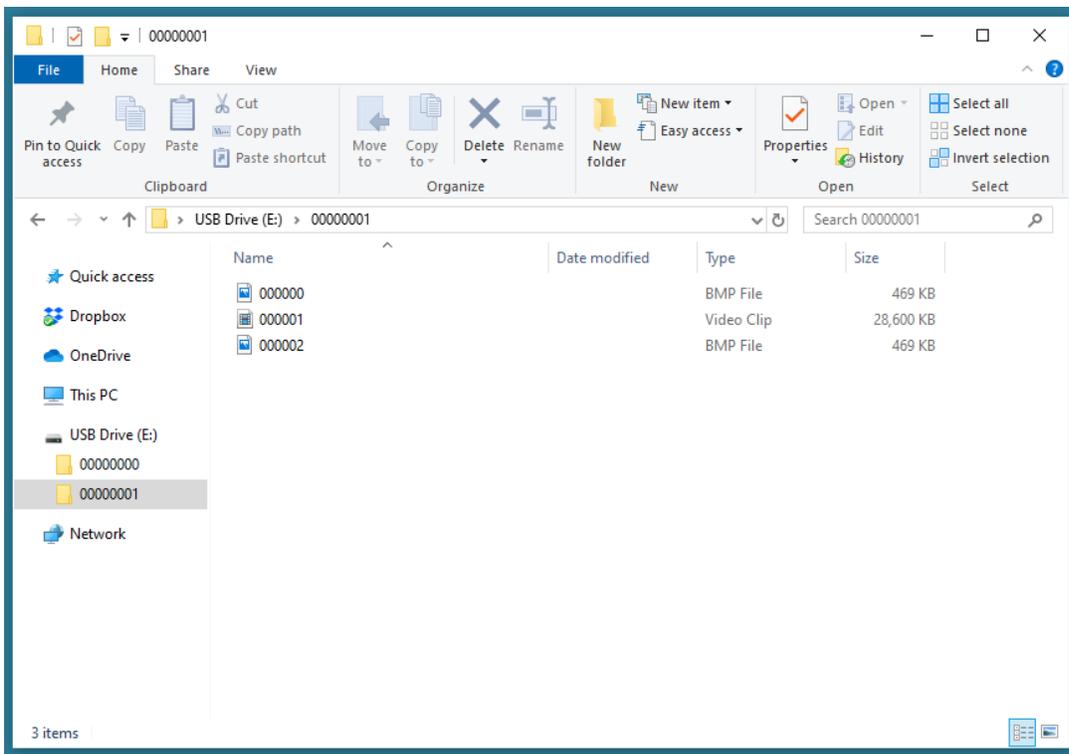
Opening the folder of interest reveals the images or videos saved during a single save request. In this example, two images and one video were saved during the save request.

Deleting photos or videos;

To delete selected images, select "DELETE ALL MARKED." This action requires a confirmation tap on the icon. The deletion may be aborted by tapping anywhere other than the confirmation icon. Alternatively, "DELETE ALL" may be selected. This also requires a confirmation tap on the icon.

System Information

Sliding a finger up from the bottom edge of the image capture screen presents the system information screen.

Home

System Information Screen
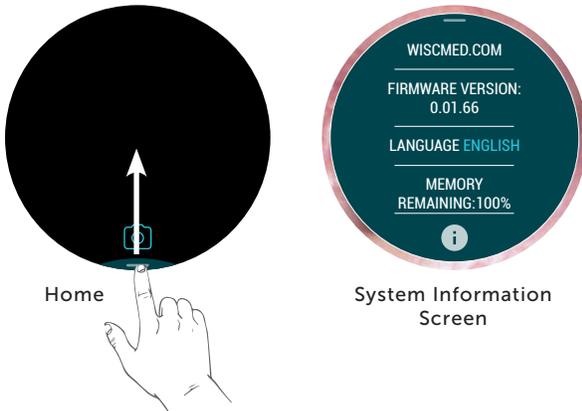
The system information screen presents company information, firmware version and remaining memory. The latest firmware version update can we found at https://wiscmed.zendesk.com/hc/en-us/articles/1500000397061-WiscMed-Wispr-Software-Comparison. Changing languages is also done from this screen. Supported languages are available at www.wiscmed.com/support.

General Screen Notes

The following may appear during operation to inform the user of specific conditions.


LOW POWER TAP TO DISMISS

Wispr has detected a low power state. Please make sure you are using a supported battery handle and that the battery is charged. If you continue to get this message, it's possible you have an old battery. In low power mode, it is possible to review photos and videos but not capture or save photos or videos to USB.

USB INCOMPATIBLE

Wispr has detected an incompatible USB drive. Please try a different USB drive.

IMAGE ERROR LIKELY LOW POWER
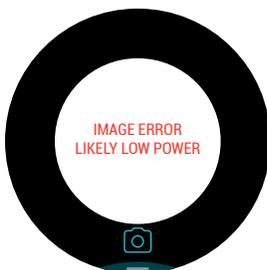
There is a problem with the image signal from the optics module. If you are using a battery power handle, make sure it is fully charged and that you are using fresh batteries. Make sure the rheostat on the handle is turned to its highest position. If the problem persists, remove the optics module collar and make sure the optics module is properly connected, see section "Replacing or reconnecting the optics module." Reinstall the optics module collar. If the problem continues, please contact WiscMed Support.

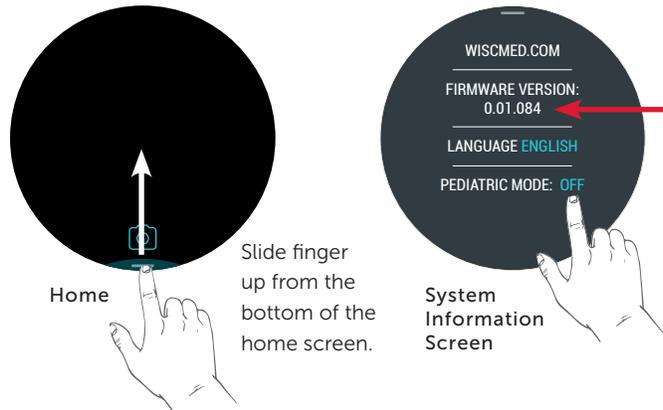FAULT 00000210

SAVE LOG TO USB

SAVE DB TO USB
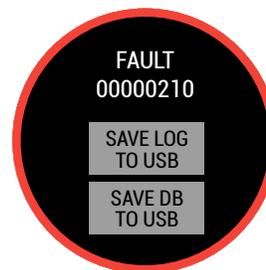
A fault has occurred with the Wispr. This can generally be resolved by turning the device off and then back on again. If the problem continues, please contact WiscMed Support.

Pediatric Mode

Pediatric mode enables the display of pre-loaded images meant to appeal to children. This feature can be used to build patient comfort prior to the otoscopy exam, "What do you think I'll see in your ear?", or to have a light moment with the patient or the family after the exam, "Look what I found in your ear!" Pediatric mode is optional and by default is turned off.
It is implemented such that it will not interfere with your normal clinical flow.

Turning On Pediatric Mode:

*NOTE: Pediatric mode is only available with **software versions 0.01.084 and higher***

Home

Slide finger up from the bottom of the home screen.

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FIRMWARE VERSION: 0.01.084

LANGUAGE ENGLISH

PEDIATRIC MODE: OFF

System Information Screen

1. Check the software version. If an upgrade is needed please follow the instructions on page 21. Once the upgrade is complete you will see a screen similar to this.

NOTE: Initial software default for pediatric mode is OFF.

2. Tap OFF to turn pediatric mode ON.
(Tap ON to turn OFF).

3. From the top edge of the screen slide a finger down to exit to the home screen

Navigating Pediatric Mode:

With pediatric mode turned on, both the home and thumbnail review screens will include a second 'tab' at the top edge of the screen. Swipe down on the 'tab' to access the first image and then swipe either left or right to view the remaining images. To stop viewing images simply slide a finger up from the bottom of the screen.

Pediatric Mode - Home

00:26

Pediatric Mode - Thumbnail Review
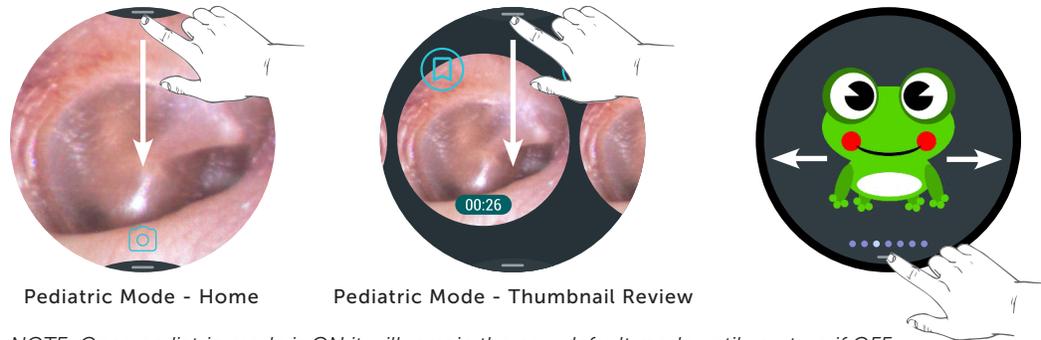
NOTE: Once pediatric mode is ON it will remain the new default mode until you turn if OFF.
To turn OFF pediatric mode see #2 under Turning On Pediatric Mode.

Sample Pediatric Images

Upgrading your Wispr software

The software on the Wispr is upgradable via the USB port. You can check the current version of the software on your Wispr by following the instructions in the System Information section. You should only upgrade software if you are instructed to do so by support, or if there are new features available that you would like to have on your Wispr.

Software versions and upgrades are available at www.wiscmed.com/support.

NOTE: It's a good idea to make sure your USB drive is compatible by saving an image from the Wispr to the USB drive. If this works, upgrading software from the USB drive should also be successful.

⚠️ ***Caution:***
Upgrading the Wispr software deletes all images and video on the device. Make sure to save the images and videos you need before upgrading the software.

To upgrade your software, download the new software version from the web site. Make sure that the version you want to use is supported by your Wispr.

1. Place the software (ends in .hex) in the root (top) directory of your supported USB drive. Make sure there is only one version of the software in the root directory.
2. Insert the USB with the correct software into the Wispr.
3. Hold down the blue action button and at the same time power up the Wispr.
4. You will get an "UPGRADE SEQUENCE STARTED" message. You may release the blue action button after getting this message.
5. You will get an "ERASING OLD FIRMWARE" message.
6. You will get an upgrade status message.
7. You will get "UPGRADE COMPLETED. RUNNING WISCMED." The upgrade should take less than a minute.
8. The device will reboot and display the running software version.

Troubleshooting

The table below lists some of the problems you may experience with your device and possible solutions to those problems. It's possible that simply power cycling the Wispr will correct the problem. Please contact WiscMed at www.wiscmed.com/support if none of the solutions work for you.

Problem	Solution
LCD screen message "CHECK OPTICS MODULE CONNECTION"	1) If you are using a battery power handle, make sure it is fully charged and that the batteries are fresh. 2) Make sure the rheostat on the handle is turned to its highest position. 3) If the problem persists, remove the optics module collar and make sure the optics module is properly connected. (see pages 22 & 23)
Device does not power on	1) Check that handle rheostat is turned to full power. 2) Remove and reinstall Wispr device onto the handle. 3) Ensure the power handle is charged, or the wall transformer is connected to power. 4) Try Wispr on a different handle, if available.
Blurry image	1) Remove speculum (if attached). 2) Clean camera tip as described in Device Cleaning and Maintenance section. 3) Reinstall speculum.
Cannot save to USB	1) Make sure USB is V2.0 and fully inserted. 2) Make sure USB has enough memory available. 3) Try a different USB 2.0.

Replacing or reconnecting the optics module

NOTE: These instructions only apply to Wisprs with serial numbers greater than 1500. If you have a lower serial number, they have a different connection. Please refer to https://wiscmed.zendesk.com/hc/en-us/articles/1500000397061-Wisc-Med-Wispr-Software-Comparison *for the IFU versions.*

The optics module on the Wispr has been designed to be replaceable by the customer. In normal operation, there is no reason to remove the optics module from the Wispr body. Indications for removal of the optics module would generally come from WiscMed support. The optics module should never be cleaned with anything but the recommended materials in the cleaning section. Never autoclave the optics module. High heat will destroy the components.
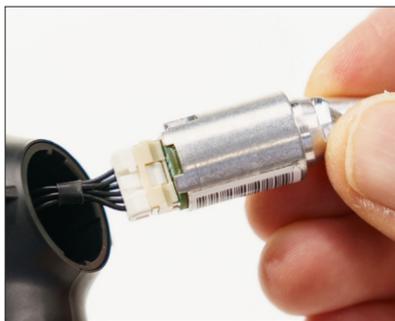
To remove the optics module;

l. Remove the speculum, if attached, with a counter-clockwise twist.


2. Turn the optics module collar counter-clockwise until is stops, about ¼ turn.

3. Gently pull on the optics module base (not the barrel) to remove it from the Wispr body until its connection is visible. A slight rocking motion of the base may help. It should come free with minimal effort. If it does not, the collar may not be completely loose.

4. Gently pull the optics module free from the body of the Wispr until the connector plug is visible.

Camera
Optics Module Camera Barrel
Base
Key
Connector
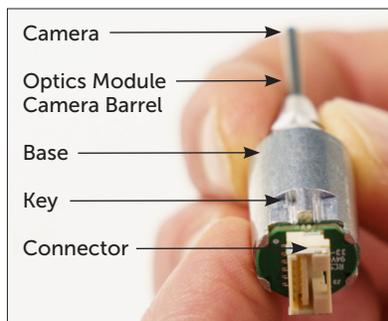
Optics Module Parts

5. Depress the small tab on the optics module connector while gently pulling the connector and attached cable away from the optics module. Make sure to keep positive control of the base of the optics module and the connector (the circuit board) so as not to damage the wire, connector or circuit board.
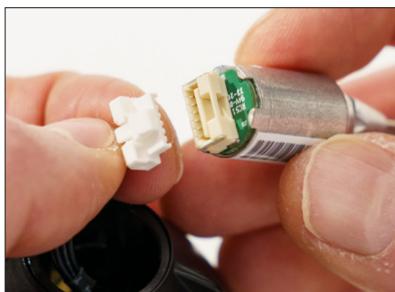
6. Leave the connector extended from the Wispr until the new optics module is attached.

To install the optics module;

7. Plug connecter into the receptacle on the optics module. The connector plug is keyed so it will only fit together in one way. Once connected the tab will snap in place and the connection will be secure.

Optics Module Key

6 o'clock Position

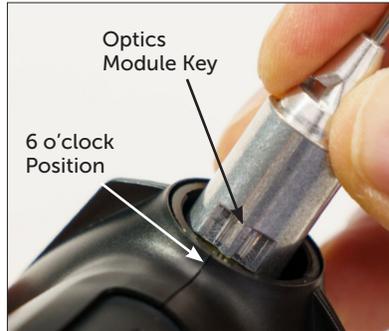8. Align the keyed notch on the optics module with the 6 o'clock receiving position on the Wispr.

Rectangular Opening
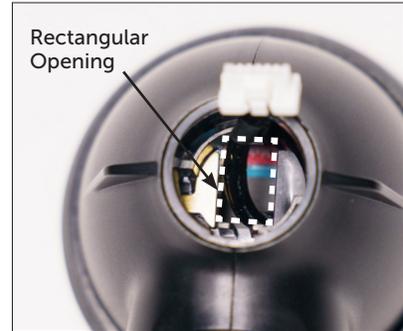
9. Cable feeds into Wispr body through rectangular opening.

10. Gently push the optics module into the receptacle. The cable needs to feed back into the Wispr through the rectangular opening as shown in step 9. This may take a bit of gentle manipulation. Do not force the cable. If it does not go in easily, examine the cable to make sure it is free to feed back into the Wispr.

11. Place the optics module collar over the optics module. The collar has teeth that align at the 12 and 6 o'clock positions.

12. While gently pressing down on the optics module collar, turn it ¼ turn clockwise until secure.

DEVICE CLEANING & MAINTENANCE

Between each patient use, clean and disinfect the Wispr optics module barrel and camera tip. Clean and disinfect the remaining exterior as needed. Wispr may be cleaned and disinfected with an appropriate health care low- or intermediate-level cleaner/ disinfecting wipe that incorporates either isopropyl alcohol or a 1:10 sodium hypochlorite (bleach) solution as the active disinfection ingredient. Follow wipe manufacturer's instructions for appropriate use, contact times and applicable warnings and precautions with the exception that disinfectant contact time should never be less than 60 seconds.

After cleaning and disinfection, inspect for visible signs of degradation. If evidence of damage or degradation is present, discontinue use and contact WiscMed.

Disposable specula are one-time use only; dispose of appropriately.

Caution:
Ensure that excess solution does not enter the device. Do not immerse the device in any solution. Do not sterilize the device.

The LCD touch screen and the gold electrical contact at the base of the device should only be cleaned with a dry, non-scratching, lint-free cloth. If necessary, dampen a cloth with water or 70 percent isopropyl alcohol.

Caution:
Use of chemical-based cleaners is not recommended for the LCD screen.

DEVICE DISPOSAL

When this device and its components reach the end of life, recycle it locally according to national, state, and local regulations. Do not dispose of this product as unsorted municipal waste.

SPECIFICATIONS

REF	Product ID	WISPR24701
	Dimensions	Height: 92 mm, Width: 83 mm, Depth: 54 mm
	Weight	104 g
	Input	5 VDC Max., 0.5 A Only specified power supply handles supported – see Supported Power Options
	Conforms with	See below—compliance with standards when used with Wispr supported battery or wall transformer handles
	Operating Temperature	+59 - 104°F (15 - 40°C)
	Relative Operating Humidity	30-90%, Non-Condensing
	Storage Temperature	-4 - 131°F (-20 - 55°C)
	Relative Storage Humidity	10-95%, Non-Condensing
	Internal Storage	64 GB, 30 minutes of video
	Screen Specifications	35 mm diameter, 400 x 400 pixels, 1.6x optical magnification
	Optics Module Barrel/Tip Dimensions	2.11 mm diameter x 18 mm length
	Speculum Tip Dimensions	3.24 mm outer diameter, 14 mm length (does not include taper)
	Camera Resolution	249 x 249 pixels, 90° field of view, Auto focus from 3.5 mm to 5 cm
	Image File Format & Size	.bmp, 496 KB/image saved
	Time to Save an Image	2 seconds
	Video Rate	15 fps
	Video File Format & Size (5 seconds)	.avi, 39 MB
	Time to Save a (5 second) Video	90 seconds
	USB Interface	USB 2.0
	Set Screw	Stainless steel flat tip set screw, m2 x 0.4 mm, 4 mm long
	Hex Allen Wrench	0.89 mm

COMPLIANCE INFORMATION

• EN/IEC 60601-1 3rd edition General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and applicable collateral standards (IEC 60601-1:2005+A1:2012).

• EN/IEC 60601-2-18 Edition 3.0 Particular requirements for the basic safety and essential performance of endoscopic equipment.

• EN/IEC 60601-1-2 Electromagnetic Compatibility

• ISO 10993-1:2018 Biological Evaluation of Medical Devices – Evaluation and Testing in the Risk Management Process.

• CAN/CSA C22.2 No. 601.1.

EMC COMPLIANCE

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

⚠️ *Warning:*
The Wispr has been designed for use in professional healthcare facilities and their typical EM environment.
EM disturbances beyond those with which the Wispr is compliant could result in a degraded or lost camera image displayed on the LCD screen.

⚠️ *Warning:*
Use only recommended handles and charging accessory. Accessories not recommended by WiscMed may affect the EMC emissions or immunity.

⚠️ *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 Wispr. Otherwise, degradation of the performance of this equipment could result.

⚠️ *Caution:*
The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMISSIONS & IMMUNITY INFORMATION

Electromagnetic Emissions

The Wispr Digital Otoscope is intended for use in the electromagnetic environment specified below. The user of the Wispr should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions (CISPR 11)	Group 1	Wispr Digital Otoscope generates RF energy only for its internal function. RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class A	Wispr Digital Otoscope is suitable for use in healthcare facilities.
Harmonic emissions (IEC 6100-3-2)	Class A	Wispr Digital Otoscope is suitable for use in healthcare facilities.
Voltage fluctuations / flicker emissions (IEC 6100-3-3)	Complies	Wispr Digital Otoscope is suitable for use in healthcare facilities.

Electromagnetic Immunity

The Wispr Digital Otoscope is intended for use in the electromagnetic environment specified below. The user of the Wispr should assure that it is used in such an environment.

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact ± 15 kV air	Wispr Digital Otoscope is suitable for use in healthcare facilities.
Electrical fast transient / burst (IEC 61000-4-4)	± 2 kV for power supply lines	Mains power supply should be that of a typical commercial healthcare facility environment.
Surge (IEC 61000-4-5)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power supply should be that of a typical commercial healthcare facility environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. (IEC 61000-4-11)	100% reduction for 0.5 cycle 100% reduction for 1 cycle 30% reduction for 0.5 sec 100% reduction for 5 seconds	Mains power supply should be that of a typical commercial healthcare facility environment. If Wispr Digital Otoscope use requires continuous operation during power mains interruptions, it is recommended that the Wispr Digital Otoscope be powered from a battery handle.
Power frequency (50-60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in commercial or healthcare facility environment.
Conducted RF (IEC 61000-4-6)	3 V, 0.15 to 80 MHz 6V in ISM Bands between 0.15 to 80 MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to the Wispr Digital Otoscope than 30 cm (12 inches).
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to the Wispr Digital Otoscope than 30 cm (12 inches).

REPLACEMENT PARTS & ACCESSORIES

The following accessories and replacement parts are available for your Wispr device:

Part ID	Description
wispr24701	Wispr Digital Otoscope
spec1-300	Speculum 300-pack for wispr24701
spec1-96	Speculum 96-pack for wispr24701
case101	Premium Carrying Case

LIMITED WARRANTY

Wispr hardware comes with a 1-year limited warranty, beginning on the date of original purchase, covering defects in materials, components, and workmanship. For repair requests and to obtain a Return Authorization (RA) number for all returns to WiscMed please contact support at www.wiscmed.com.

If the hardware is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the 1-year limited warranty period, WiscMed or its authorized representatives will, at its discretion, repair or replace the defective product or accessory with a comparable product that is new or refurbished. A repair fee will be charged if the product is outside of warranty or damage is not covered under the warranty. Refer to the Wispr repair policy as provided at the time of return authorization.

The warranty period is not extended if a warranted product or any parts are repaired or replaced. WiscMed may change the availability of limited hardware warranties, at its discretion, but any changes will not be retroactive.

The Wispr limited hardware warranty does not cover damage caused by 1) handling during shipment, 2) use or maintenance not in accordance with product labeling and instructions, 3) repair or service not authorized by WiscMed, 4) accidents, abuse, and misuse, 5) problems arising from accessories, parts or components not supplied by WiscMed, 6) normal wear and tear.

SERVICE & SUPPORT

At WiscMed, we stand by our products. Our customer service philosophy is simple and straightforward: if you have any issues whatsoever with your device, we will make it right.

The WiscMed team is here to support you and answer any questions you may have about your device. For information and support, you can:

Contact us directly at 608.729.7234 or wiscmedsupport@wiscmed.com
Or visit our Wispr Customer Support at www.wiscmed.com/support.