



Thank you for purchasing the CellScope Oto™ for use as a smartphone-enabled digital otoscope. Please read these instructions carefully to ensure safe operation.

PRODUCT DESCRIPTION

The CellScope Oto System consists of a smartphone case, optical otoscope attachment and mobile app for image/video capture. It enables users to perform and track otoscopic exams over time. The CellScope Oto device uses the following components:

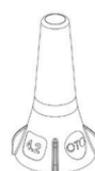
1. A specially designed iPhone® 5/5s/SE case (for everyday use) and iPhone 6/6s connector.
2. The optical otoscope (Oto) attachment compatible with the supplied phone case.
3. A storage container for the optical attachment and tips.
4. Appropriately sized tips that attach to the Oto during an exam.
5. A user-supplied Apple iPhone 5/5s or 6/6s operating with iOS 8.4 or later. *NOTE: the iPhone 6, 6s, 5, 5s, or SE must be purchased separately. CellScope Oto device is not compatible with the iPhone 6s Plus, iPhone 6 Plus, 5c, iPhone 4s, iPhone 4, iPhone 3GS or iPhone 3.*
6. A mobile application used to collect, view, save and transmit otoscopic exam data to the secure CellScope web app. There are two applications that can be used for image/video capture and transmission:
 - Seymour:** Snap photos of all your family's health concerns and record them in one place. Send ear and other photos to our on-call doctors for an evaluation in just 2 hours. Available for download at www.cellscope.com/getseymour
 - CellScope:** Clinicians may use the CellScope companion app with the Oto device in the clinic. Save magnified images of the tympanic membrane to share with patients to engage them in their treatment plan. Available for download at www.cellscope.com/download
7. A web app to enable review of ear exam information recorded on the mobile application. Access the user portal at **www.cellscope.com**. *NOTE: the CellScope web app is supported on the following web browsers: Google Chrome on OS X and Windows 7, Internet Explorer 8 on Windows 7 and Firefox on OS X.*

PACKAGE CONTENTS

- CellScope iPhone 5/5s/SE compatible case
- CellScope iPhone 6/6s compatible connector
- Optical otoscope (Oto) attachment (with insufflation bulb port, see Compatible Insufflation Accessories)
- Storage container for optical attachment and tips
- Lanyard to attach to the storage case
- 2 infant-sized reusable tips (2.5mm diameter)
- 2 standard-sized reusable tips (4.25mm diameter)
- Quick Start Guide
- Instructions for Use



Infant-sized tip



Standard-sized tip

ADDITIONAL ITEM FOR DOWNLOAD

One of two mobile apps can be used for image capture:

Seymour: Snap photos of all your family's health concerns and record them in one place. Send ear and other photos to our on-call doctors for an evaluation in just 2 hours. Available for download at www.cellscope.com/getseymour

CellScope: Clinicians may use the CellScope companion app with the Oto device in the clinic. Save magnified images of the tympanic membrane to share with patients to engage them in their treatment plan. Available for download at www.cellscope.com/download

Follow the steps within either app or visit www.cellscope.com/register to create an account. You may proceed to login to the corresponding companion app, if a username and login were previously provided. Contact CellScope support with any questions.

ACCESSORIES REQUIRED BUT NOT SUPPLIED

Compatible iPhone (5, 5s, SE, 6, or 6s) with iOS 9 or later (Available for purchase from Apple Retailers. See a list of authorized retailers at <http://www.apple.com/buy/>)

COMPATIBLE INSUFFLATION ACCESSORIES

The Oto attachment is capable of insufflation for the purpose of pneumatic otoscopy. The following products are compatible with the Oto:

- Welch Allyn® Otoscope Insufflation Bulb (21504)
- Welch Allyn MacroView Otoscope Insufflation Bulb (23804)

INTENDED USE

The CellScope Oto is intended for inspection of the external ear canal and eardrum under magnification using an external illumination source.

STORAGE AND HANDLING

Store the device in the provided container at a temperature between -20° and 45° C (-4° to 113° F) and humidity between 5 and 95% (non-condensing). Avoid contact with dust during use or storage.

MAINTENANCE

No preventative maintenance is required. To prevent cross-contamination between patients, clean the reusable tips in between each exam using the cleaning instructions below. Any modification or repair of this device is strictly prohibited.

CLEANING INSTRUCTIONS

The Oto attachment can be cleaned with a dry, non-scratching, lint-free microfiber cloth. The attachment and case can be disinfected with a cloth dampened with alcohol. Only use EPA-approved disinfectant. Use of improper cleaning solutions or methods may damage the device. The attachment should not be submerged in liquid. Care should also be taken not to scratch the lens of the otoscope attachment. Failure to clean the device may cause blurry images.

The reusable tips should be disinfected after each use. Submerge the tip in rubbing alcohol (minimum 70% isopropyl alcohol) for 20 minutes. Wipe clean of any excess debris. Dry off the tip and store for future use.

SET UP INSTRUCTIONS

1. Download the appropriate mobile app for the intended use
 - Seymour for home use of the Oto can be downloaded here: www.cellscope.com/getseymour
 - CellScope for Clinician use of the Oto can be downloaded here: www.cellscope.com/download
2. Attach the case to the iPhone. To attach, slide the case onto your iPhone.
3. Connect the Oto attachment and slide into place.
4. Place a tip on the end of Oto attachment and twist lightly to firmly attach it.
5. Launch the mobile application and login using your username and password.
6. Begin an exam and follow the instructions within the app to store or share the image or video.

NOTE: A small info button on the bottom right of important screens will display a help overlay.

For answers to Frequently Asked Questions and Troubleshooting Tips, visit www.cellscope.com/support

MOBILE APP OPERATING INSTRUCTIONS

1. To start an ear exam, select Left or Right to indicate the ear that you will be recording first.
2. Start the recording.
3. Gently insert the appropriately sized tip into the patient's ear canal and find the eardrum.
4. Once you have captured a view of the eardrum on the iPhone screen, end the recording. Note: there is no required video length.
5. Repeat steps 2-4 for the other ear.
6. Follow the instructions within the app to add additional information and save the exam.
7. When the exam is complete, detach the Oto from the case and store safely. Clean the reusable tip for future use.

IMPORTANT: Always use the mobile app while connected to the internet to ensure correct operation.

CONDUCTING AN EAR EXAM

The following instructions are guidelines for conducting an ear exam on a child. If one method does not work with your child, try one of the other two methods. Before trying this on your child, try on an adult for practice. You will then get a feel for how far the device needs to be inserted into the canal in order to correctly capture a view of the eardrum.

FOR BABIES UNDER 1 YEAR OF AGE:

1. Lay the child on her back or on a blanket on the floor.
2. It may be helpful to have a second adult hold the child's legs or body to prevent sudden movement during the exam.
3. Gently press the child's head to one side.
4. Gently pull the outer flap of the ear (called the pinna) DOWNWARD and BACKWARD to straighten the ear canal.
5. Insert a infant-sized tip and look at the iPhone screen to see inside the canal. *Note: Look for the logo of a baby to identify the infant-sized tip.*
6. Aim towards the darkest area as this indicates a deeper area of the canal where the eardrum is found.

FOR CHILDREN AGES 1 TO 3:

1. Distract the child with a toy or game.
2. It may be helpful to have a second adult hold the child's head in an upright position during the exam to prevent them from moving suddenly.
3. Gently press the child's head to one side.
4. Gently pull the outer flap of the ear DOWNWARD and BACKWARD to straighten the ear canal.
5. Aim towards the darkest area as this indicates a deeper area of the canal where the eardrum is found.

FOR ADULTS AND CHILDREN OVER AGE 3:

1. Sit your child in a comfortable place and ask your child to stay as still as possible.
2. It's helpful for the child to be in an upright position during the exam.
3. Gently pull the outer flap of the affected ear UPWARD and BACKWARD to straighten the ear canal.
4. Insert the tip and look at the iPhone screen to see inside the canal.
5. Aim towards the darkest area as this indicates a deeper area of the canal where the eardrum is found.

Video tutorials (which include sample images of the eardrum are available for viewing within the mobile app and on the web at www.cellscope.com/support/videos

CONTRAINDICATIONS

This device may only be used for inspection of the external ear canal and eardrum. Do not use for any purpose other than an otoscopic exam to avoid injury or damage to the device. If you can see something stuck in the ear canal, do not insert the otoscope.

GENERAL SAFETY PRECAUTIONS:

 CAUTION: This device is not designed or intended to provide a diagnosis of ear infections or other ailments of the ear. This device should not be used as a basis for starting or modifying treatment without independent confirmation by medical examination. Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.

 CAUTION: Proper care and handling is essential for satisfactory performance of the Oto device. Examine the device thoroughly before and after use. If any damage or irregularities are found, do not use the device.

- To avoid injury, do not place Oto attachment directly against skin or other objects. Light emitted from the Oto may be intense enough to increase surface temperature or cause damage to objects or living beings.
- Use appropriate tips for the age and anatomy of the patient to avoid possible discomfort.
- Patients should always consult their physician if they notice changes in their health, regardless of ear exam results.
- To avoid cross-contamination between patients, do not reuse the same tip without disinfecting it prior to use. See Cleaning Instructions.
- Do not use the device with any objects plugged into the iPhone Lightning® connector, the headphone jack or other non-standard areas of the iPhone.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not place other equipment adjacent to the phone and device during use.
- Store out of reach of infants, small children, or anyone incapable of using the device properly.
- Do not use the device anywhere that usage of the iPhone is not permitted. The Oto was not tested for immunity to electromagnetic disturbances and may not function correctly in an environment where electromagnetic disturbances generated by other equipment are present.
- Do not use the device in conjunction with water, or in a wet environment.

SYMBOL GLOSSARY

 Review instructions for use.

 The CellScope Oto is a type BF applied part.

 95%
5%

 LOT
Batch Code

 REF
Catalog Number

 45° C (113° F)
-20° C (-4° F)

WARRANTY

CellScope provides a limited warranty for the CellScope Oto product. Please visit www.cellscope.com/warranty for a full description of the warranty.

IMPORTANT

Report any injury or adverse event to a physician immediately. For general or product related comments, questions, concerns or experiences, please contact CellScope, Inc. directly.

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U.S. and Foreign Patent information is available online at www.cellscope.com/legal

CELLSCOPE OTO MODEL NUMBER: FG1455 TECHNICAL DESCRIPTION

Optical Oto Attachment

Dimensions: 1.4" x 0.7" x 1.0"
(34.2mm x 18.9mm x 25.5mm)
Weight: 0.25oz (7g)
Magnification Factor: 4.14x

Storage Container with Specula Attachment

Dimensions: 1.7" x 1.1" x 4.2"
(43.3mm x 27.7mm x 105.5mm)
Weight: 1.05oz (30g)

CellScope Case (iPhone 5/5s/SE)

Dimensions: 5.0" x 2.5" x 0.5"
(128mm x 63.7mm x 11.85mm)
Weight: 0.90oz (25.5g)

CellScope Infant Specula

Dimensions: 1.3" x 0.7" x 0.7"
(33.0mm x 18.0mm x 18.0mm)
Weight: 0.02oz (0.6g)

CellScope Case (iPhone 6/6s)

Dimensions: 1.1" x 2.8" x 0.7"
(28.6 mm x 70.0 mm x 17.2 mm)
Weight: 0.25 oz (7g)

CellScope Standard Specula

Dimensions: 1.3" x 0.7" x 0.7"
(33.0mm x 18.0mm x 18.0mm)
Weight: 0.02oz (0.6g)

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