


⚠️ Additional warnings

BEFORE YOU START:

- **DO NOT** use the SmartCheck™ device with any application that is not the SmartCheck™ app. Also, **DO NOT** use the device without the app.
- **DO NOT** use unless the patient is on a steady surface (e.g., do not use in moving vehicle, on unstable furniture, etc.).
-  **DO NOT** use if the device gets wet. Immediately place the device on a dry surface. Allow device to dry completely before attempting to use again.

WHEN USING SmartCheck™:

- **DO NOT** use SmartCheck™ without securely attaching the single-use specula tip and battery door.
- **DO NOT** attempt to clear blockage from the patient's ear using the digital ear scope or any other mechanical tool. This may result in injury to the patient's ear.
- **DO NOT** attempt to use the device without the app.
- To avoid injury, **DO NOT** shine light from the digital ear scope in anyone's eyes.
- **STOP** use if the device becomes warm (exceeding 41°C/105°F).

AFTER YOU FINISH A RECORDING:

- If symptoms worsen after you have shared the video, contact your HCP right away, or contact a telemedicine provider for immediate access to care.

DO NOT use SmartCheck™ on any body part other than the ear.

DO NOT leave an opened device unattended. Only change battery when out of reach of infants, small children, or individuals who cannot properly use the device.

DO NOT use near flammable anesthetics, drugs, or pressurized oxygen (such as in a hyperbolic chamber, ultraviolet sterilizer, or oxygen tent).

DO NOT put fingers in positioning track when switching device positions to avoid pinching your finger.

Selecting a tip & positioning the patient

Before trying a recording on your child, you can try on an adult for practice. You will learn how to insert the SmartCheck™ into ear canal to correctly capture the eardrum.

It is important to prevent the patient from suddenly moving. If the patient has trouble staying still, it may be helpful to have a second adult hold the patient's head during the recording.

CHOOSING A SPECULA TIP:

Choose the largest specula that can comfortably be inserted into the ear canal. In general:

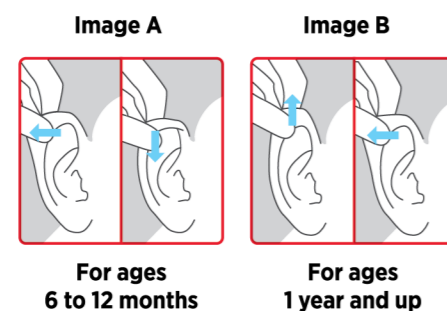
- The thinner, Pediatric tip (2.75 mm) is recommended for ages 6 months to 2.5 years. Consult with your child's HCP before using on babies 6 to 12 months old.
- The wider Child/Adult tip (4.25 mm) is recommended for patients ages 2.5 years and older.

- ⚠️ When using the Child/Adult specula tip, if the patient shows signs of discomfort, switch to the Pediatric specula tip.

POSITIONING THE PATIENT

1. Choose the largest specula that can comfortably be inserted into the ear canal.
2. Have patient sit in a comfortable place with the back of their head supported and ask the patient to stay as still as possible.
3. Distract the patient with their favorite video, book, or toy to help them stay still.
4. Most ear canals are slightly curved. Straighten the ear canal:
 - For ages 6 to 12 months: Gently pull the outer flap of the ear (the pinna) BACK and DOWN (Image A).
 - For ages 1 year and up: Gently pull the pinna UP and BACK (Image B).

Refer to "Step 2: How to conduct an ear recording" section on previous page for further instructions.



Install / change the battery

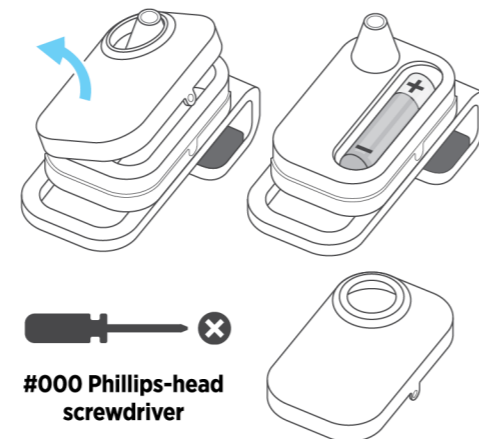
SmartCheck™ contains a battery. When the LED starts to blink, it is time to change the battery.

CHANGING THE BATTERY:

1. Ensure the light button is in the OFF position.
2. Using #000 Phillips-head screwdriver (or flathead eyeglass screwdriver), loosen the side screw. Please note, screw will not unscrew all the way out for safety.
3. Grip the sides of the battery door near the bottom with thumb and index finger. Gently tilt the battery door toward the button to release the screw, then lift straight up to remove the door from the device.
4. Remove the old AAA battery and properly dispose.
5. Install a new AAA by inserting the positive end in first. Follow the markings in the battery compartment.
6. Immediately replace the battery door and tighten the securing screw.

⚠️ BATTERY WARNINGS:

- **ONLY USE ALKALINE AAA** batteries in your SmartCheck™ device. Using other battery types may lead to battery leakage and damage to your device.
- **HARMFUL IF SWALLOWED** Swallowing batteries may lead to serious injury or death. In case of swallowing, call the Poison Control Center at 1-800-222-1222. If the patient is having trouble breathing, call 911 or seek medical help right away.
- Batteries can leak or explode and cause injury if installed incorrectly, disassembled, charged, crushed, mixed with used or other battery types, or exposed to fire or high temperature. Always dispose of batteries properly and immediately.
- **Note:** Please remove battery if the device will be stored unused for an extended period of time.



Troubleshooting

If the patient becomes fussy during a recording:

- **STOP** using the device and slowly remove it from the patient's ear. Try again later when the patient is more calm. If you cannot obtain a clear recording, call your HCP.

If you notice a blockage in the patient's ear canal:

- **STOP** using the device and slowly remove it from the patient's ear. **DO NOT** try to clear the blockage. Contact your HCP right away.

If the video image looks dark:

- **STOP** using the device and slowly remove it from the patient's ear. Check to ensure the light is turned on. Confirm the light is working by shining it against your hand and looking for a small circle of light. If the light does not work, follow directions to change the battery.

If the video image is partially blocked (not a circle):

- Double check the alignment of your device with the alignment feature. Check the lens and specula tip for debris or damage.

If the Eardrum Finder arrow does not appear, or disappears during a recording:

- Try gently pointing the specula tip in slightly different directions until it reappears. If this does not work, or the arrow was never visible, remove the device from the ear and restart the app.

If the video image is blurry or generally unclear:

- **STOP** using the device and slowly remove it from the patient's ear. Check the device thoroughly for damage. If there is no obvious damage, follow the Cleaning Instructions. If the video is still blurry, your digital ear scope may have internal damage. Do not use it and contact your HCP.

If the Eardrum Finder is not finding the eardrum:

- Be sure to straighten the ear canal. This important step helps to create a clear path toward the eardrum. Also, double check the alignment of your device and that the light is turned on.

If the LED is blinking:

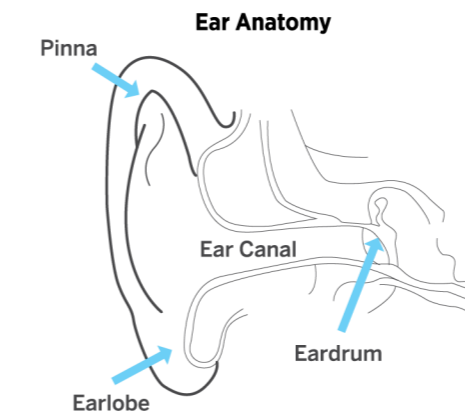
- It is time to change the battery. Follow the instructions on this page to install a new AAA battery.

How SmartCheck™ works

SmartCheck™ Digital Ear Scope, in combination with the SmartCheck™ app, will allow the user to look into an ear canal and see the eardrum.

It is important to understand some basic ear anatomy to properly use your SmartCheck™ device.

While every person's anatomy is different, most ear canals naturally curve toward the patient's nose. In the image below, key anatomical features of the ear are labeled.

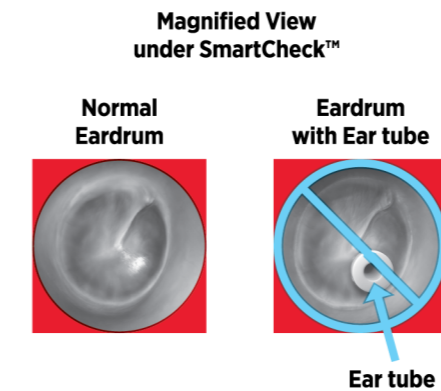


The digital ear scope lens adds magnification to your smartphone camera.

The built-in LED light is button-operated and battery-powered and provides illumination for the recording.




The app provides visual guidance to the user to help guide them to the eardrum.

Confirm that your HCP is willing and able to review an eardrum recording or consider working with a telemedicine provider.



Storage and refills

STORAGE AND HANDLING

-  **Store out of reach of children** or individuals who cannot use the device properly. Contains small parts (battery and specula tips) which could be a choking hazard.
-  Avoid using or storing in hot and humid conditions (maintain 15-75% Relative humidity, non-condensing). Moisture can damage your device.
- Pressure Condition: Transport, Store, and Operate at Atmospheric Pressure (700-1060hPa).
-  Operating Temperature: 5°C to 35°C (41°F to 95°F)
- Storage Temperature: 5°C to 35°C (41°F to 95°F)
- Transport Temperature: -20°C to 40°C (-4°F to 104°F)
- Allow device to equilibrate to ambient temperature for approximately 5 min before operation.
- Avoid contact with dust during use or storage. Always be sure the LED light is OFF before storing.

USE LIFE EXPECTANCY

- The expected use life of the device is 2 years from the date of manufacture, or until LED no longer works.

SPECULA TIP REFILLS

- ⚠️ **DO NOT** use other brands of specula tips.

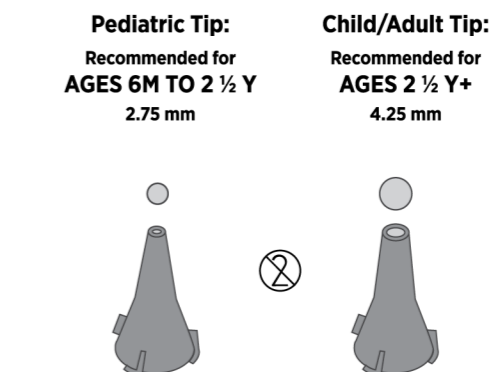
Additional tips can be purchased by searching online for:

Pediatric Tips:

Welch Allyn Universal KleenSpec® Single-Use Specula Pediatric 2.75mm Part Code: 52432-U

Child/Adult Tips:

Welch Allyn Universal KleenSpec® Single-Use Specula Adult 4.25mm Part Code: 52434-U



KleenSpec® is a registered trademark of Welch Allyn, Inc.

Cleaning

CLEANING INSTRUCTIONS

Proper care, handling, and storage is essential for satisfactory performance of SmartCheck™.

If the digital ear scope needs to be cleaned, use a dry, non-scratching, lint-free microfiber cloth, dampened with 70% isopropyl alcohol.

Use of improper cleaning solutions or methods may damage the device. Care should also be taken not to scratch the lenses of the digital ear scope.

You can also check your phone camera lens to see if it needs cleaning. Follow your phone manufacturer's instructions for camera lens care.

CAUTIONS:

- ⚠️ **DO NOT** attempt to sterilize SmartCheck™ or single-use specula tips in boiling water, microwave, or dishwasher.
- ⚠️ **DO NOT** get water or liquid inside any part of the device.
- ⚠️ **NEVER** attempt to repair or modify the device.

The digital ear scope should not be submerged in liquid.

Failure to clean SmartCheck™ may cause blurry images.

Q: Is it okay to use a bleach or antibacterial wipe to clean my SmartCheck™ digital ear scope?

A: No. Use of improper cleaning solutions or methods may damage the device. Use a dry, non-scratching, lint-free microfiber cloth, dampened with 70% isopropyl alcohol.

DISPOSAL

Dispose of used batteries and device according to local regulations.

🔍 Are you running into an app or hardware issue not covered here?

Please visit the FAQs in the SmartCheck™ app or visit our website to learn more: tylenol.com/products/smartcheck-otoscope or call 1-800-458-1635

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