

From Children's
TYLENOL
SmartCheck™
Digital Ear Scope
Instructions for Use

PLEASE READ THESE INSTRUCTIONS CAREFULLY FOR SAFE OPERATION.



What is SmartCheck™ for?

Intended Use:

SmartCheck™ otoscope is intended to be used to visualize the external ear canal and eardrum under magnification using an integrated battery-powered LED for illumination and a smartphone camera. The SmartCheck™ mobile app will capture, store, and send records of the eardrum for healthcare provider (HCP) triage.

Smartphone System Requirements:

- Apple® iOS 13 or above
- Android™ OS 8.0 (Oreo™) or above
- At least 120MB of free space

Apple® and App Store® are registered trademarks of Apple Inc.
Android™ is a trademark of Google LLC.
Oreo™ is a trademark of Mondelez International, Inc.

What else do I need?

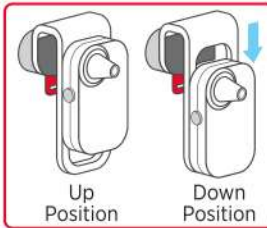
You'll need a #000 Phillips-head screwdriver (or a flathead eyeglass screwdriver) and to download the SmartCheck™ app.



Symbol glossary

- Follow Instructions for Use
- Keep out of reach of children
- Warning or Caution: Read all warnings and precautions in Instructions for Use
- On/Off
- DO NOT reuse
- Store at room temperature
- DO NOT store in humid conditions
- Keep away from moisture
- Date of Manufacture (YYYY-MM-DD)
- Model Number **LOT** Lot Number
- IP22 Enclosure protection rating against the ingress of solids and water
- Legal Manufacturer
- Part BF (A. Digital Ear Scope Body)

Step 1. Setup



Download the app and open it to create an account. Install the battery

Follow the instructions on reverse side to install the battery.

Position SmartCheck™ for your phone

Position the device to align with phone's main camera. To change between the phone clamp's 2 positions, press or pull firmly on the device body until it locks into position.

Step 2. Attach SmartCheck™ to your Phone



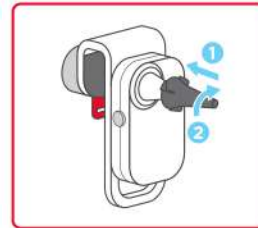
Press ATTACH & RECORD button

Follow the step-by-step instructions in the app. Please read each step carefully before performing any actions. Watch each video before doing it yourself.



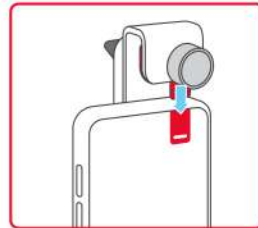
Check the patient's ear

DO NOT use SmartCheck™ and contact your HCP if you see any blockage, crusting, ear canal swelling, fluid, discharge, foreign objects, or excess ear wax.



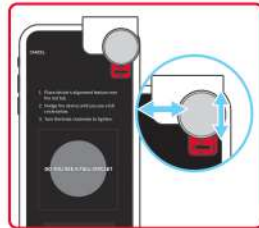
Attach new specula tip

Place a new specula tip on the end of the lens. Twist clockwise to firmly attach. Follow the instructions in the app to select correct specula size or refer to the "Selecting a tip" section on the next page.



Attach phone clamp

Remove the case from your phone. Slide the device over your phone's camera with the Attachment Knob facing you. Use the red indicator in the app to properly position the device over the camera lens.



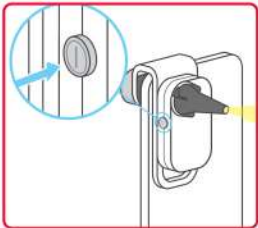
Position the device

Align the arrows on the device's Alignment Feature with the white, vertical line in the app. You'll know you have the correct alignment when you can see a full circle in the middle of the screen.



Tighten phone clamp

Turn the Attachment Knob clockwise to secure the device **FIRMLY** in place. **DO NOT** overtighten. **DO NOT** use mechanical tools to tighten; finger tighten only.



Turn on light

Push the button to turn on the light. Point the device at your hand to confirm the light is on. You should see a small circle of light on your palm. If you **do not** see a light, or the light is blinking, replace the battery. Follow instructions in the "How to change the batteries" section on reverse side.

DO NOT use the device if light does not turn on.

ALWAYS examine the device and specula tip thoroughly before every use to help ensure there is no damage (rough surfaces, sharp edges, misshapen parts, debris, or unexpected irregularities).

DO NOT use if damaged or missing parts. **DO NOT** use with any cords plugged into the phone.

DO NOT use if the camera view is not a full circle. Confirm that the device has been properly aligned and there is no debris on the lens or specula tip. Always make sure you see a live camera view before proceeding.

Is SmartCheck™ right for your family?

DEVICE OPERATORS HAVE TO BE:

- ✓ Adults 18 years and older

Contraindications:

DO NOT OPERATE SmartCheck™ IF:

- ✗ You are under 18 years old
- ✗ You have hand/arm dexterity or steadiness issues (e.g., shakiness due to Parkinson's disease, multiple sclerosis, stroke, etc.)
- ✗ You have any cognitive impairment that may prevent you from using the device properly

PATIENTS HAVE TO BE:

- ✓ Adults and children ages 1 year and up

ASK YOUR PEDIATRICIAN BEFORE USE:

- ✓ If your child is 6 to 12 months old

Contraindications:

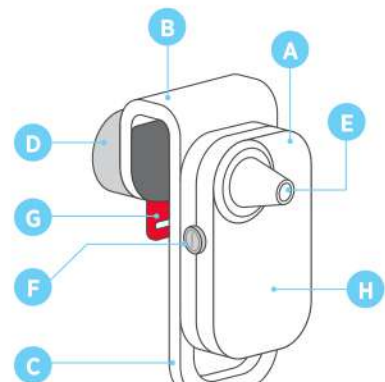
DO NOT USE SmartCheck™ ON:

- ✗ Children under 6 months old
- ✗ A patient with ear tubes
- ✗ A patient who recently underwent any ear surgery
- ✗ A sleeping patient
- ✗ Yourself
- ✗ A patient that is moving excessively (e.g., highly irritable or temper tantrum)
- ✗ A patient who has health conditions which may affect their ear anatomy, balance, and steadiness

What is in your SmartCheck™ kit?

SmartCheck™ Device:

- A. Digital Ear Scope Body
- B. Phone Clamp
- C. Positioning Track
- D. Attachment Knob
- E. Lens with Included LED
- F. Light Button
- G. Alignment Feature
- H. Battery Door Access



DBDR103-201
LOT and located behind battery door.

Welcome Card:

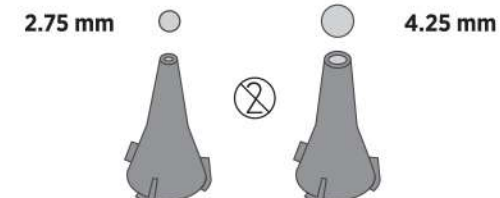


Instruction for Use (this document):



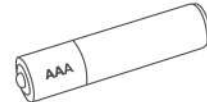
Single-Use Specula Tips:

- Six (6) 2.75 mm Pediatric Specula Tips
- Six (6) 4.25 mm Child/Adult Specula Tips



Replaceable Battery:

One AAA battery (install before using by following instructions on next page)



Step 3. How to Conduct an Ear Recording



Position the patient

Watch the app's how-to videos and see the "Selecting a tip & positioning the patient" section on reverse side.

Hold the phone in same hand as the ear you intend to record (i.e., hold phone with right hand if recording right ear).

Use your other hand to gently position the top of the ear to straighten the ear canal.

STOP USING SmartCheck™ and contact your HCP if the patient shows any signs of or experiences any discomfort.



Position hands and insert specula

Position the hand holding the phone so the back of your smaller fingers rest firmly against the patient's face. This will steady your grip in case the patient moves their head.

Press the START button. Follow the prompts to gently insert the specula tip into the patient's ear.



Record first ear

Guide the specula tip into the ear canal.

The Eardrum Finder arrow will help guide you. When you see the STOP hand icon, a 6-second countdown will begin.

Gently move the specula tip in a circular motion to record the entire eardrum.

DO NOT go deeper into the ear once you see the STOP hand icon. **DO NOT** touch eardrum with specula tip.



Record second ear

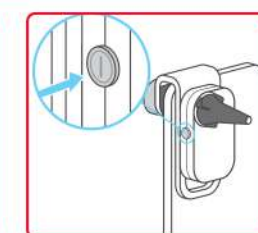
Repeat the same steps used to record the first ear. Be sure to switch the hand holding the phone when you switch ears.



Troubleshooting Eardrum Finder

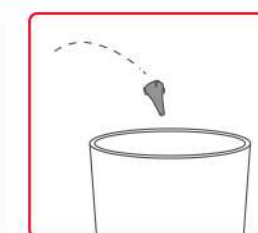
If the eardrum is not located, the SmartCheck™ Eardrum Finder will time out after 30 sec. Remove the device from the patient's ear, recheck device alignment, and confirm the light is ON before trying again.

STOP USING if Eardrum Finder arrow function is not working. Restart the app.



Turn off light and detach

Push the button again to turn off the light. Turn the Attachment Knob counter-clockwise to remove device from your phone.

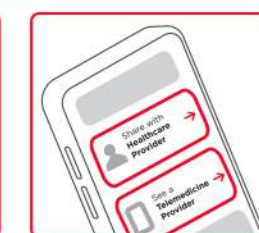


Dispose of used specula tip

Turn specula tip counter-clockwise to remove. Dispose of the used tip in your household trash right away.

Store the device safely to prevent damage.

DO NOT reuse specula tips. The single-use specula tips should be thrown away immediately after each use.



Share recording with your healthcare provider

Follow instructions in the SmartCheck™ app to add notes and share recording(s) with your HCP.

DO NOT attempt to obtain clear images of the patient's eardrum, consult your HCP.

DO NOT attempt to use the recording to determine your own diagnosis or treatment.

Have questions? Please refer to the Troubleshooting section for more details.

⚠️ 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:

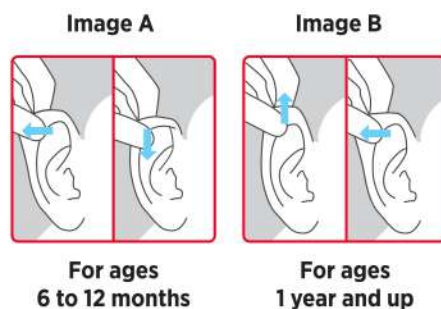
- The thinner, Pediatric tip (2.75 mm) is recommended for ages 6 months to 2.5 years. Consult with your child's HCP before using on babies 6 to 12 months old.
- The wider Child/Adult tip (4.25 mm) is recommended for patients ages 2.5 years and older.

- ▲ 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

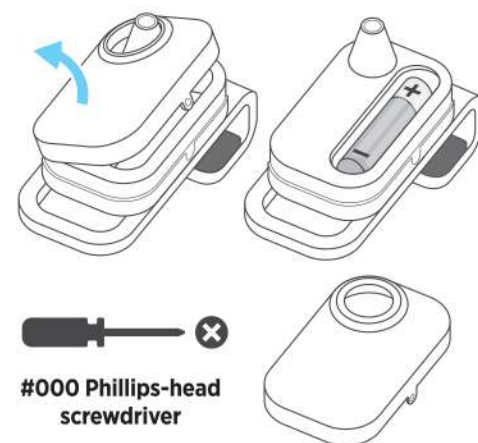
SmartCheck™ contains a battery. When the LED starts to blink, it is time to change the battery.

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:

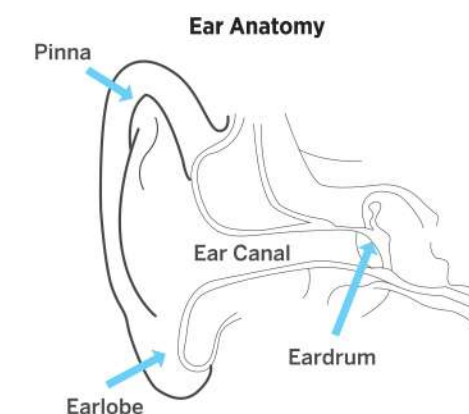
- It is time to change the battery. Follow the instructions on this page to install a new AAA battery.

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.



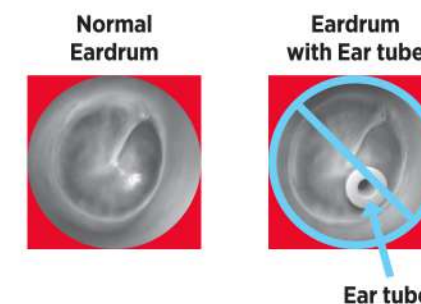
The digital ear scope lens adds magnification to your smartphone camera.

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.

Magnified View under SmartCheck™



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:

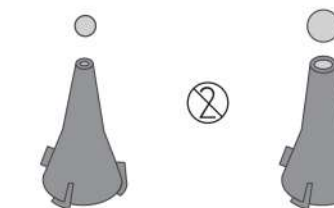
Welch Allyn Universal KleenSpec® Single-Use Specula Pediatric 2.75mm Part Code: 52432-U

Child/Adult Tips:

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

Pediatric Tip:
Recommended for
AGES 6M TO 2 ½ Y
2.75 mm

Child/Adult Tip:
Recommended for
AGES 2 ½ Y+
4.25 mm



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

Distributed by:
Johnson & Johnson Consumer Inc.
Skillman, NJ 08558
©J&JCI 2023 Made in China
Pat. www.jjcipts.com