

EarCheck[®]
Middle Ear Monitor

Use & Care Manual



IMPORTANT: Read this manual completely before using the EarCheck[®] Middle Ear Monitor.

Save these instructions.

For answers to questions about use or service, call our Customer Care department toll free at:

1-888-EAR-CHEK
(1-888-327-2435)

or visit www.earcheck.com

Innōvia
MEDICAL



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Thank You for Purchasing EarCheck Middle Ear Monitor, one of the most thoroughly tested and independently evaluated consumer medical products available. To date, EarCheck has been used by more than 5,000 medical professionals and 70,000 parents.

Though EarCheck Middle Ear Monitor is for home use, it is based on acoustic reflectometry (sound waves), the same patented and proven technology used in doctor's offices since 1997. Acoustic reflectometry technology is included in the American Academy of Pediatrics' and American Academy of Family Physicians' Clinical Practice Guideline for the Diagnosis and Management of Acute Otitis Media (middle ear infection).¹

¹Source: American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Clinical Practice Guideline for Diagnosis and Management of Acute Otitis Media. *Pediatrics*. 2004;113(5):1451-1465. The EarCheck Pro® model used by physicians. The AAP/AAFP have not specifically recommended the EarCheck Middle Ear Monitor.

Please read this entire Use & Care Manual prior to using your EarCheck and keep it in a safe place for future reference.

For more information, please visit our website at www.earcheck.com or call our Customer Care Team at 1-888-Ear-Chek (327-2435).

Innovia Medical, LLC
Customer Care
1-888-EAR-CHEK • 1-888-327-2435

This manual includes specific information as to your rights and obligations under the guarantee offered by the Manufacturer.

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IMPORTANT SAFETY INFORMATION

IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following:

READ ALL INSTRUCTIONS BEFORE USE SAVE THESE INSTRUCTIONS

DANGER – To reduce the risk of electrocution:

- ❶ Do not use while bathing.
- ❷ Do not place or store product where it can fall or be pulled into a bathtub or sink.
- ❸ Do not place in or drop into water or other liquids.

WARNING – To reduce the risk of burns, electrocution, fire or injury to persons:

- ❶ Close supervision is necessary when this product is used by, on or near children or invalids.
- ❷ Use this product only for its intended use as described in this Use & Care Manual. Do not use attachments not recommended by the manufacturer.
- ❸ Do not use EarCheck Middle Ear Monitor as a substitute for consulting your doctor if your child needs medical attention or treatment.
- ❹ Batteries can corrode and leak toxic liquid. Do not allow contact with skin or get into eyes. Discard device appropriately.
- ❺ There are NO User Serviceable Parts. Do not attempt to take device apart or repair. Contact Customer Care at **1-888-EAR-CHEK** (1-888-327-2435).

CAUTION – The EarCheck Middle Ear Monitor should NOT be used for the following children:

- Children under 6 months of age
- Children with ear tubes (ventilation tubes)
- Children with water in the outer ear, such as those with swimmer's ear
- Children with known perforation or rupture of the eardrum
- Children with excessive cerumen (wax) blockage
- Children with facial or ear deformities
- Children with visible drainage of pus or blood in the outer ear canal

Ear Infections and Your Child

The Ear

A healthy middle ear allows sound waves to easily enter the canal, causing the eardrum to vibrate and the ear to clearly hear sounds. If the middle ear becomes filled with fluid (called effusion), the eardrum's vibrations can be restricted and may result in temporary hearing loss (called conductive hearing loss).

Ear Infections

Young children are more likely to have middle ear fluid and develop ear infections. This is because their Eustachian tubes (the tubes that connect the ear to the back of the nose and help drain and control fluids in the middle ear) are shorter, narrower and more horizontal than adults'. As a result, infected fluids from the nose and throat may reach the middle ear more easily. When the middle ear becomes inflamed and infected the condition is called a middle ear infection or acute otitis media.

Common Signs of Ear Infections

The signs of a middle ear infection can range from mild to severe, but often include:

- Fluid in the middle ear
- Runny/stuffy nose or cough
- Irritability
- Pulling or rubbing the ear (indicating ear pain)
- Decrease in appetite
- Fever

It is important to note that fluid may be present in the middle ear without an active infection; this is called otitis media with effusion and is often associated with an oncoming ear infection or recovery from one.

Ear Infections and Your Child - Continued

Treatments

Parents of children who have signs of an ear infection should consult their child's physician, who may prescribe antibiotics. Additionally, the option of observation or "watchful waiting" (for 48-72 hours) may be considered for a child who has mild-to-moderate signs and/or an uncertain diagnosis and is older than 2 years of age.²

²Bluestone CD, Klein JO. *Otitis Media in Infants and Children, Fourth Edition*. 2007: BC Decker, Inc. Hamilton.

Why Monitor Fluid in the Ear at Home

Home monitoring of middle ear fluid is important because common signs of an ear infection—like pain, fever or irritability—can also be signs of other ailments, especially in younger children. Knowing the likelihood of fluid in a child's middle ear can help parents and physicians determine whether or not the child might have an ear infection. Plus, it can be useful after treatment to help determine if the fluid is going away or gone.

Impact on Hearing

In some children, the fluid in the middle ear may create a sensation of ear fullness or popping. In addition, the fluid behind the eardrum can block sound, so temporary hearing loss can happen, but may not be obvious.³

³Source: *Kids Health*. Middle Ear Infections. www.kidshealth.org. Accessed August 1, 2007.

Your doctor is the best source of information about your child's health. At any time if you have a question or concern about your child's health, contact your doctor.

When to Use EarCheck Middle Ear Monitor

EarCheck is recommended for use on children 6 months to young adult. Use EarCheck Middle Ear Monitor if your child:

- Shows signs of an ear infection
- Is being treated for an ear infection
- Has a cold
- Suffers from frequent ear infections

NOTE: EarCheck Monitor should NOT be used on children under 6 months of age, or on those who have ear tubes (ventilation tubes), water in the outer ear (swimmer's ear), known perforation or rupture of the eardrum, excessive cerumen (wax) blockage, facial/ear deformities or visible drainage of pus or blood in the outer ear canal.

Monitoring Your Child's Ear Health

If your child is already being treated for an ear infection, you can continue to use your EarCheck to monitor your child's ear health. If middle ear fluid is still present after a reasonable amount of time or if other signs of illness get worse, consult your doctor.

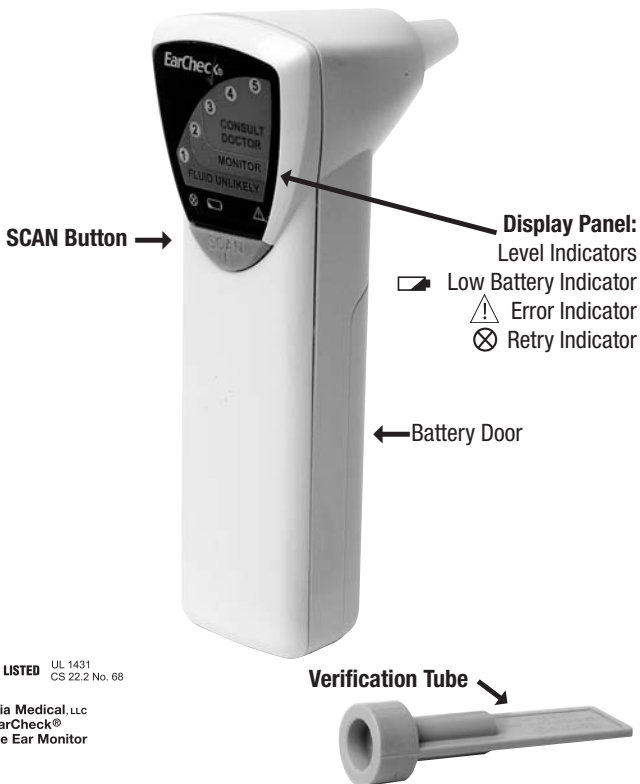
Middle ear fluid can fluctuate. A well child may have occasional high Level readings that do not last which may be due to a temporary blockage of the Eustachian tube. If a seemingly well child has occasional readings in Levels 3-5, continue to monitor daily to determine if the condition is temporary. If the child is sick, consult your doctor. If a child with known middle ear fluid has an occasional low reading, the child may have temporarily cleared the middle ear fluid by sneezing, blowing the nose, etc. Higher Level readings may return until the condition clears.

Your doctor is the best source of information about your child's health. At any time if you have a question or concern about your child's health, contact your doctor.

Getting to Know Your EarCheck Middle Ear Monitor

Your EarCheck package contains the following:

- EarCheck Middle Ear Monitor
- Verification Tube
- 2 AA Alkaline Batteries
- Use & Care Manual
- Quick Reference Guide



 **US LISTED** UL 1431
3LPT CS 22.2 No. 68

Innovia Medical, LLC
EarCheck®
Middle Ear Monitor

Using Your EarCheck Middle Ear Monitor

Step 1 - Install Batteries

Before using the Monitor, install the two (2) AA Alkaline batteries that are included in your package. To install the batteries, use the tip of a ballpoint pen and press the battery cover lock while pressing the top of the cover with your thumb and forefinger (**see Figure A**). Once the cover releases, slide it down. Install the batteries making sure that they are positioned as indicated inside the battery compartment (**see Figure B**). Slide the top lip of the cover into place. Press the lower edge of the cover down and slide up until it snaps into place (**see Figure C**).



Figure A




Figure B



Figure C


Using Your EarCheck Middle Ear Monitor - Continued

Step 2 - Test Monitor for Use

To test to make certain the Monitor is functioning properly, insert the EarCheck Monitor tip into the Verification Tube then press the SCAN button. The Monitor will sound a short series of beeps while each Level indicator flashes in sequence. When the Red Level 5 indicator light remains on the display, the Monitor is ready for use. If Red Level 5 is not displayed, take a second reading. If Red Level 5 is still not displayed, or the ERROR symbol  appears, refer to the Troubleshooting section (pg. 19).



Step 2

CAUTION: EarCheck uses sound waves to detect middle ear fluid and should be used in a quiet area. Excessive noise may prevent the Monitor from obtaining a reading and cause the RETRY Symbol  to be displayed.


WARNING: To prevent possible choking hazard, keep the Verification Tube away from young children.

Step 3 - Stabilize the Child

Make sure the child is sitting in an upright position – sitting (on your lap if necessary) or standing.

NOTE: Do not lay the child down as this may affect accuracy.

Step 4 - Hold the Ear Up and Back

Holding the ear up and back straightens the natural curve of the ear canal and allows the Monitor to send sound waves straight down the ear canal. Continue to hold the ear in this position while the Monitor scans the ear for fluid. If the RETRY Symbol  appears, try holding the ear straight back or straight back and down.



Step 4

Using Your EarCheck Middle Ear Monitor - Continued

Step 5 - Insert the EarCheck Tip

Carefully insert the Monitor's tip into the child's ear canal until the canal is fully covered, making certain the tip points directly down the canal opening.

NOTE: The EarCheck tip is designed for safety, preventing it from being inserted too far into the ear. However, remove the EarCheck tip from the child's ear at any indication or sign of discomfort.



Step 5

Step 6 - Press the SCAN Button

Continue to hold the ear up and back with the EarCheck Monitor tip in the ear. Press the SCAN button once; EarCheck will make a soft chirping sound as the Level indicators light up in a sequence. You will hear a series of short tones followed by one long tone alerting you that the SCAN is complete. Level results will be indicated on the display panel.

NOTE: It may be helpful to slowly move the EarCheck tip in a small circular motion. If the child's ear were a clock, rotate the Monitor from 4 to 8 o'clock.



Step 6

CAUTION: Excessive noise, such as a crying child or background sounds from a TV or radio, may affect the performance of EarCheck. If this occurs, move to a quiet area and re-check.

Using Your EarCheck Middle Ear Monitor - Continued

Step 7 - Read Results of SCAN

Remove EarCheck tip from ear and read results. Results will display for approximately 5 seconds after SCAN is complete.

NOTE: Do NOT remove the EarCheck tip from the ear without first hearing the long tone or you may get an incorrect reading.



Step 7

RETRY Symbol

Due to variances in usage, as you are familiarizing yourself with the EarCheck Monitor, you may occasionally receive the RETRY Symbol ⊗. If this occurs, repeat Steps 3 to 6 as listed above. If you continue to receive the RETRY Symbol ⊗, refer to the Troubleshooting section (pg. 19).

IMPORTANT: If, after following the above steps, the RETRY Symbol ⊗ continues to appear on the display, try taking a reading on both ears. If you obtain a reading on one ear but the RETRY Symbol ⊗ appears on the other, consult your doctor. An ear condition that EarCheck cannot measure may exist. (See list of conditions that EarCheck should not be used for on pg. 7.)

Reading Results

Compare the Level indicated on your EarCheck Monitor display panel with the chart below:

LEVEL	COLOR	PROBABILITY OF MIDDLE EAR FLUID
5	Red – Consult Doctor	High
4	Red – Consult Doctor	Moderate to high
3	Red – Consult Doctor	Moderate
2	Yellow – Monitor	Low to moderate
1	Green – Fluid Unlikely	Low

Interpreting EarCheck Levels

LEVEL	COLOR	COURSE OF ACTION
RED (LEVELS 3-5)	THIS RESULT MAY APPEAR WITH: A sick child (a child with pain, fever or other signs of illness) with an untreated ear infection.	CONSULT DOCTOR.
	OR A sick child who has been treated for an ear infection, but is not responding to antibiotics within a reasonable amount of time.	CONSULT DOCTOR.
	A sick child who appears to be getting better.	CONTINUE MONITORING DAILY. If reading Level does not continue to decrease within a reasonable amount of time, consult doctor.


Interpreting EarCheck Levels - Continued

LEVEL	COLOR	COURSE OF ACTION
YELLOW (LEVEL 2)	<p>THIS RESULT MAY APPEAR WITH:</p> <p>A sick child whose signs of illness may warrant medical attention.</p>	<p>MONITOR. CONSULT DOCTOR if Level does not decrease within a reasonable amount of time.</p>
	<p>A sick child who appears to be getting better.</p> <p>OR</p> <p>A well child. (Note: Some well children will always have Level 2 as a normal reading.)</p>	<p>CONTINUE MONITORING DAILY.</p> <p>If reading Level does not continue to decrease within a reasonable amount of time, consult doctor.</p>
GREEN (LEVEL 1)	<p>THIS RESULT MAY APPEAR WITH:</p> <p>A well child.</p> <p>A sick child who does not have middle ear fluid.</p>	<p>NO ACTION REQUIRED. CONSULT DOCTOR if signs of illness warrant a medical opinion.</p>

NOTE: Fluid may remain in the middle ear for several weeks after an ear infection has cleared. If it does, consult with your doctor.

IMPORTANT: Make sure to inform your doctor of any other signs and/or symptoms of illness the child may have, such as fever, pain, pulling or rubbing the ear, etc. Your doctor is the best source of information about your child's health. At any time if you have a question or concern about your child's health, contact your doctor.

Replacing Batteries

EarCheck Middle Ear Monitor operates using two (2) AA Alkaline batteries. Replace batteries when the LOW BATTERY symbol  appears. Low batteries or defective batteries can result in a false or inaccurate reading.

To replace batteries, use the tip of a ballpoint pen and press the battery cover lock while pressing the top of the cover with your thumb and forefinger (see Figure A). Once the cover releases, slide it down and off to remove batteries. Dispose of used batteries in the appropriate manner.

Replace with new batteries making sure that they are positioned as indicated inside the battery compartment (see Figure B). Slide the top lip of the cover into place. Press the lower edge of the cover down and slide up until it snaps into place (see Figure C).

After replacing batteries, test with verification tube to make sure EarCheck is working properly.



Figure A



Figure B




Figure C

Care, Cleaning and Storage

Caring for Your EarCheck Middle Ear Monitor

Your EarCheck is simple to use and easy to maintain. However, it must be handled carefully to remain in good operating condition. Follow these instructions at all times:

- ❶ Do not drop your EarCheck Monitor. Damage to the Monitor's electronics may result.
- ❷ Never let your EarCheck get wet. It could become permanently damaged if water or other liquids get inside.
- ❸ Do not use cleaning solvents (with the exception of rubbing alcohol to sterilize the tip) as they may damage the Monitor. For EarCheck Monitor cleaning instructions, see pg. 17.
- ❹ Do not introduce foreign objects into your EarCheck tip's opening. This can damage sensitive parts.
- ❺ Do not take your EarCheck apart, as this will invalidate the Monitor's guarantee. Contact Customer Care at **1-888-EAR-CHEK** (1-888-327-2435).
- ❻ Do not expose your EarCheck to direct sunlight, temperature or humidity extremes, moisture or dust.
- ❼ Always replace batteries when LOW BATTERY symbol  appears. Low batteries or defective batteries can result in a false or inaccurate reading.

Care, Cleaning and Storage - Continued


Cleaning Your EarCheck Middle Ear Monitor

To operate properly and to help prevent cross-contamination, it is important that you keep the EarCheck tip clean. After each use, gently wipe the surface of the tip with a cotton swab or lint-free, soft cloth moistened with rubbing alcohol. Allow the alcohol to completely dry prior to using your EarCheck Monitor. Do not allow alcohol or any objects to get inside the tip as they may damage the sensitive electronics inside your EarCheck Monitor.

Storing Your EarCheck Middle Ear Monitor

Store your EarCheck Monitor in a dry place away from dust, contamination and liquids. Store it at room temperature (50°F - 95°F). Do not expose your EarCheck Monitor to extreme temperatures or humidity. For example, do not store in a car. If your EarCheck Monitor has not been stored at room temperature, keep it at room temperature at least 60 minutes before using it.

Helpful Hints


While monitoring with EarCheck Middle Ear Monitor, you may occasionally receive an ERROR symbol . If an ERROR symbol persists, refer to the Troubleshooting section (pg. 19) of the Use & Care Manual. If you continue to experience difficulty with EarCheck, please call **1-888-EAR-CHEK** (1-888-327-2435) for product usage assistance and support.

- To familiarize yourself with proper technique, practice using EarCheck on a well and cooperative child. Refer to the Using Your EarCheck Middle Ear Monitor section (pg. 9) of this Manual for further information.
- Be sure to hold the child's ear straight up and back. If you still do not receive a reading, hold the ear straight back or straight back and down.
- Use EarCheck in a quiet area, eliminating all background noise, such as TVs and radios. If the child is crying, try to calm him or her down before taking a reading.
- It is not unusual for EarCheck to display different results for the left and right ears. This may be an indication that one ear has more fluid present than the other.
- Middle ear fluid may develop or disappear rapidly or the child may have a borderline condition; therefore, it is not uncommon to get different Level readings from the same ear on the same day.
- EarCheck is designed to work properly if some earwax is present in the canal. However, if the ear canal is blocked by wax, consult your doctor to remove excess earwax.

For product assistance or more information, call **1-888-EAR-CHEK** (1-888-327-2435) or visit www.earcheck.com.



Troubleshooting

Your EarCheck Middle Ear Monitor is designed for trouble-free use. Should you encounter difficulty, consult the information below or call our Customer Care department at **1-888-EAR-CHEK** (1-888-327-2435).

PROBLEM	POSSIBLE CAUSE	ACTION
RETRY Symbol 	Ear position/hold is incorrect or not held throughout the entire testing process.	Try a variety of positions/holds, holding the ear straight up and back, down and back or straight back.
	EarCheck tip is not properly placed over ear canal (not completely covering the outer ear canal).	Make sure EarCheck tip is over the ear canal and aimed straight down the canal. Continue ear hold while scanning (see pg. 9-12).
	EarCheck tip is not aimed straight down the canal.	Slowly re-aim device down ear canal, while continuing ear hold.
	EarCheck tip is dirty.	Clean EarCheck tip using proper technique (see pg. 17).
	Background noise is too loud.	Find a quiet area and retry.
	Child is crying.	Calm child before using.
	Ear canal is blocked with earwax.	Do NOT attempt to remove earwax. Consult your doctor.
	Tip is removed from ear prior to completing scan.	Take another reading.

Troubleshooting - Continued

Your EarCheck Middle Ear Monitor is designed for trouble-free use. Should you encounter difficulty, consult the information below or call our Customer Care department at **1-888-EAR-CHEK** (1-888-327-2435).

PROBLEM	POSSIBLE CAUSE	ACTION
Fails Verification Test	Verification tube is blocked.	Remove blockage.
	The EarCheck tip is not properly inserted in Verification tube.	Insert your EarCheck tip straight into the Verification tube as far as possible (see pg. 10).
	The EarCheck Monitor is not at room temperature.	Bring EarCheck Monitor to room temperature. Wait 60 minutes before using.
ERROR Symbol* 	Device malfunction.	Test with Verification tube. If test is successful, retry. If unsuccessful, call Customer Care (1-888-327-2435).
LOW BATTERY Symbol 	Weak batteries.	Replace batteries (see pg. 15).

***IMPORTANT:** If ERROR is still displayed after taking all of the above steps, SCAN both ears. If the ERROR Symbol appears for one ear, but a Level reading appears for the other, a condition that the EarCheck Monitor cannot measure may exist.

Technical Specifications

EarCheck Middle Ear Monitor

Dimensions: 5.25 in. (H) x 1.8 in. (W) x 2.75 in. (D) (133 mm x 47 mm x 70 mm)

Weight: 4.5 oz (128 g). (With Batteries)

Sound Volume: 80 dB. SPL. (± 6 dB)

Display: LED display.

Display Hold Time: 5 sec.

Power: Two AA Alkaline Batteries.

Battery Life: Approximately 1,000 readings.

Ambient Temperature Operating Range: +59°F to +95°F (15°C - 35°C).

Relative Humidity Operating Range: <75%

Storage Temperature Range: -4°F to +122°F (-20°C - +50°C).

Relative Humidity Storage Range: <85%

Operating Altitude Range: Up to 10,000' MSL

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulation.



Limited One Year Guarantee

Your EarCheck Middle Ear Monitor is guaranteed to be free from manufacturing defects for a period of one year under normal household use. This guarantee extends only to the original purchaser. The guarantee excludes the batteries. Should repair become necessary within the guarantee period, please contact customer service at:

1-888-EAR-CHEK (1-888-327-2435)
or visit **www.earcheck.com**

We will either repair or replace (at our discretion) free of charge any parts necessary to correct defects in the materials or workmanship. This guarantee is complete and exclusive. The guarantor expressly disclaims liability for incidental, special, or consequential damages of any nature. (Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above guarantee may not apply to you.) This guarantee gives you specific legal rights and you may have other rights which vary from state to state.



How the EarCheck® Middle Ear Monitor Works

The EarCheck Monitor uses gentle sound waves to accurately and painlessly detect the presence of middle ear fluid, a key sign of an ear infection. This is the same patented and proven acoustic reflectometry technology used by thousands of physicians since 1997 and a technique recommended by the American Academies of Pediatrics and Family Physicians.^{1,2}

The Monitor works by sending a pleasant chirping sound into the ear canal. Some of this sound bounces off the eardrum and travels back to the instrument's built-in microphone. The EarCheck Monitor then analyzes the reflected sound to determine if the eardrum is working normally. If there is fluid in the ear, the eardrum's vibrations may be restricted. The greater the fluid level, the greater the reflected sound. Within only seconds, you will be able to determine if your child has fluid in the middle ear.

¹Compared to EarCheck Pro model used by physicians

²The AAP/AAFP have not specifically recommended the EarCheck Monitor

Innovia
M E D I C A L

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