



EarCheck[®] Middle Ear Monitor Frequently Asked Questions

What does the EarCheck Middle Ear Monitor do?

EarCheck Middle Ear Monitor is a first-of-its kind, clinically proven and physician-recommended, home-use device that accurately detects middle ear fluid, a key sign of an ear infection, to help parents identify when a child might have an ear infection, when it is necessary to seek medical attention and when the fluid is going away or gone.

How does the EarCheck Middle Ear Monitor measure middle ear fluid?

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

How does the EarCheck Middle Ear Monitor work?

The EarCheck Middle Ear Monitor uses acoustic reflectometry (sound waves) to detect the presence of middle ear fluid.

By placing the tip of this handheld device into the child's outer ear canal and pressing the Scan button, EarCheck sends 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 processor. EarCheck then analyzes the reflected sound to determine if there is fluid in the middle ear.

The presence of fluid is represented on a 1-5 color scale on an easy-to-read display, where level 1 (Green) indicates Fluid/Ear Infection Unlikely and where levels 3-5 (Red) indicate a high Likelihood of Fluid/Ear Infection and suggest you consult with your child's doctor.

Is the EarCheck Middle Ear Monitor easy to use?

Yes. The EarCheck Middle Ear Monitor is very easy to use. Users simply place the tip of the handheld device into the outer ear canal, press the Scan button, and obtain a reading in seconds.

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Is there any other home-use monitor out there that detects middle ear fluid?

No. The EarCheck Middle Ear Monitor is the only home-use monitor on the market used to detect the presence of middle ear fluid, a key sign of an ear infection.

Who is the EarCheck Middle Ear Monitor recommended for?

The EarCheck Middle Ear Monitor is recommended for children 6 months of age and older.

Is EarCheck Middle Ear Monitor Clinically Proven and Physician Recommended?

Yes. EarCheck Middle Ear Monitor is one of the most thoroughly tested and independently evaluated consumer medical products. It has been tested by over 5,000 medical professionals and numerous independent medical institutions as well as 70,000 parents.

The patented acoustic reflectometry technology, used exclusively by EarCheck, 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.²

Is the EarCheck Middle Ear Monitor approved by the FDA?

Yes. The EarCheck Middle Ear Monitor is FDA cleared and UL approved.

Does the EarCheck Middle Ear Monitor cure ear infections?

No, the EarCheck Middle Ear Monitor does not cure ear infections. This device is used to detect the presence of middle ear fluid, which is a key sign of an ear infection.

EarCheck helps parents identify when a child might have an ear infection, when it is necessary to seek medical attention, and when the fluid is going away and an infection is clearing up or gone.

Is there anyone who should NOT use the EarCheck Middle Ear Monitor?

The EarCheck Middle Ear Monitor is not indicated for children with: ear tubes (ventilation tubes); water in the outer ear as in swimmer's ear; known perforation or rupture of the ear drum; facial or ear deformities; visible drainage of pus or blood in the outer ear canal.

How much does the EarCheck Middle Ear Monitor cost?

The EarCheck Middle Ear Monitor's suggested retail price is \$49.00 - \$59.00, depending on the retailer.

Where can I purchase the EarCheck Middle Ear Monitor?

The EarCheck Middle Ear Monitor can be purchased at Wal-Mart and Babies"R"Us or through one of the many online retailers that can be located from EarCheck's website, www.earcheck.com.

Where can I learn more about the EarCheck Middle Ear Monitor?

More information about the EarCheck Middle Ear Monitor is available by calling 1-888-EAR-CHEK (327-2435) or visiting www.earcheck.com.

About Innovia Medical

Who Is Innovia Medical?

Innovia Medical, LLC is a medical device company that develops and markets pediatric medical products based on patented, proprietary, acoustic reflectometry technology under the EarCheck® brand.

Innovia Medical's patented products represent the only objective solution for parents to cost-effectively, painlessly, safely, and quickly test for signs of an ear infection in children at home.

Where is Innovia Medical located?

Innovia Medical is located in Lenexa, Kansas.

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About Ear Infections

What is a middle ear infection?

A middle ear infection, or acute otitis media, is an infection that occurs behind the eardrum.

What causes middle ear infections?

There are many causes of an ear infection including exposure to bacteria or germs, the inflammation of the nasal passage as a result of the common cold, allergies or other health problems. Consult your physician for more information.

What are the signs/symptoms of a middle ear infection?

Common signs of a middle ear infection in children include: fever, irritability, pulling or rubbing the ear, decrease in appetite, fluid in the middle ear, nausea, vomiting, and fluid discharge from the ear.

Who gets middle ear infections?

Anyone can get a middle ear infection, but it is more common among children.

- 83 percent of children under the age of three have had one or more ear infections and 46 percent have had three or more³.
- Middle ear infections occur more often in boys than girls.⁴

Why are middle ear infections a concern?

Middle ear infections are:

- The #1 reason for children's visits to the emergency room;
- The #1 reason for illness visits to the doctor's office;
- The #1 reason for antibiotic prescriptions in children, but often hard to diagnose.⁵

How do you treat an ear infection?

Parents of infants and children who have signs and symptoms of an ear infection should consult their physician. If the child is diagnosed with acute otitis media (an ear infection), he/she may be prescribed antibiotics.

The option of observation or "Watchful Waiting" (for 48- 72 hours), may be considered by the doctor for the child who has mild-to-moderate signs and symptoms and/or an uncertain diagnosis and is older than 2 years of age.⁶

Are middle ear infections contagious?

No, middle ear infections are not contagious.

Are middle ear infections curable?

Some ear infections may clear up on their own, while others need to be treated with antibiotics. However, ear infections often recur.

¹ American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Clinical Practice Guideline for the 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.

²Ibid.

³ Garbutt J, Jeffe DB, Shackelford P. Diagnosis and Treatment of Acute Otitis Media: An Assessment. Pediatrics. 2003; 112:143-149

⁴ Kids Health. Middle Ear Infections. www.kidshealth.org. Accessed August 1, 2007.

⁵ Garbutt J, Jeffe DB, Shackelford P. Diagnosis and Treatment of Acute Otitis Media: An Assessment. Pediatrics. 2003; 112:143-149.

⁶ Bluestone, Charles D; Klein Jerome O. Otitis Media in Infants and Children, Fourth Edition. 2007:BC Decker, Inc. Hamilton.