

Check My Ear Middle Ear Fluid Monitor PRO®

OPERATOR'S MANUAL



MODEL PEC-3

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Introduction

The Check My Ear Middle Ear Fluid Monitor PRO® is an advanced medical monitor which accurately detects the presence of middle ear fluid (i.e., otitis media with effusion) that may be associated with acute ear infection. The monitor is designed for use by doctors and other medical professionals on children from 6 months to young adults.

Important:

Save these instructions! For optimal results, please read this manual completely and thoroughly before using the Check My Ear Middle Ear Fluid Monitor PRO®.

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How the Check My Ear Middle Ear Fluid Monitor PRO® Works

The Check My Ear Middle Ear Fluid Monitor PRO® determines the condition of the middle ear by measuring the response of the eardrum to a sound stimulus. Using a built-in microphone, it registers the intensity of different frequencies of reflected sound waves to detect the absence or presence of fluid in the middle ear.

The monitor analyzes the resonance characteristic of the eardrum by measuring the Spectral Gradient angle of the eardrum's resonance curve, thereby indicating the condition of the middle ear. In a normal ear cavity, the eardrum has full freedom of motion, producing a shallow, wide-angle curve (Figure 1a). When fluid is present, the motion of the eardrum is restricted and a narrower curve results (Figure 1b).

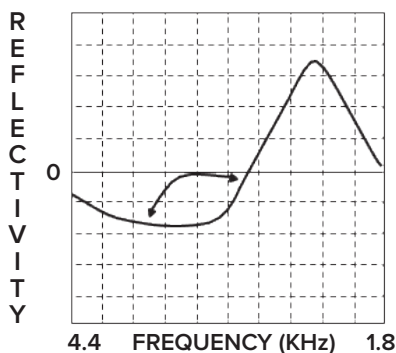


Figure 1a Normal Ear

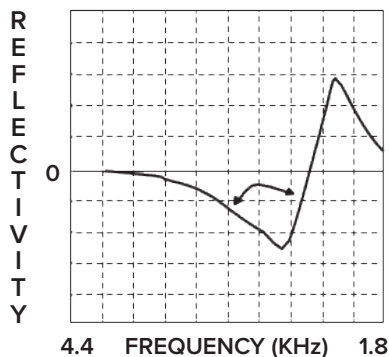


Figure 1b Effused Ear

The Check My Ear Middle Ear Fluid Monitor PRO® performs this analysis internally and displays the resulting angle. The USB cord gives you the capability of printing the information, once connected to your PC.

Spectral Gradient

The Spectral Gradient approach to the diagnosis of middle ear effusion uses information describing the shape of the null of the reflectance curve as a function of frequency. Earlier approaches used only the depth of the null. In the Spectral Gradient approach, we measure the slope of the reflectance curve at frequencies both higher and lower than the frequency of minimum reflectance (the null frequency). Mathematically, these are the derivatives of the reflectance with respect to frequency. We combine these two derivative measurements to obtain a measure of the sharpness of the null of the reflectance curve, which is in turn an indication of the likelihood of effusion. For convenience of interpretation, this measure is scaled in such a way as to correspond to angles measure on plots of reflectance.

Determining the Risk of Disease (Otitis Media)

The Spectral Gradient angle displayed by the Check My Ear Middle Ear Fluid Monitor PRO® corresponds to the presence of middle ear effusion and the risk of disease (otitis media) as shown in the table below (Figure 2). This table also appears on the monitor itself and on the data printout.

<i>Spectral Gradient</i>		<i>Risk of Disease</i>
<i>Level</i>	<i>Angle</i>	
5	< 49°	High
4	49° - 59°	Moderate-High
3	60° - 69°	Moderate
2	70° - 95°	Low-Moderate
1	> 95°	Low

Figure 2

Note: Clinical Studies conducted on more than 500 children in pediatric practices and hospitals have shown that the Check My Ear Middle Ear Fluid Monitor PRO® instrument is safe and effective in the diagnosis of otitis media.

About the Check My Ear Middle Ear Fluid Monitor PRO®

The Check My Ear Middle Ear Fluid Monitor PRO® is intended for Professional use on human ears only.

Use the Check My Ear Middle Ear Fluid Monitor PRO® ONLY on a child sitting or standing in an upright position.

DO NOT USE THE CHECK MY EAR PRO® MONITOR ON:

- Children under 6 months of age
- Children with ventilation tubes
- Children with water in the outer ear canal
- Children with perforation of the eardrum
- Children with facial or ear deformities
- Children with drainage of pus or blood in the ear canal

IMPORTANT

Read the "Set-Up Procedure" section of this manual (Pages 8-9) before using the Check My Ear Middle Ear Fluid Monitor PRO®.

IMPORTANT

After reading this manual, practice using the Check My Ear Middle Ear Fluid Monitor PRO® on a cooperative child to familiarize yourself with proper technique before use.

Components and Features

Your Check My Ear Middle Ear Fluid Monitor PRO[®], Model PEC-3 includes:

Check My Ear Middle Ear Fluid Monitor PRO[®]

100 Disposable Tips

2 AA Alkaline batteries

1m USB Cable

Verification Tube

Operators Manual

Study the diagram below (Figure 3) to become familiar with the Check My Ear Middle Ear Fluid Monitor PRO[®].



Figure 3

Set-Up Procedure

Prior to using Check My Ear Middle Ear Fluid Monitor PRO[®], you must install the 2 AA Alkaline batteries and test to verify that the device is functioning properly.

1. Unpack the Check My Ear PRO[®] Middle Ear Monitor.

Ensure that each item is included (see “Components and Features” on Page 7).

2. Install Batteries (Figure 4).

Check My Ear Middle Ear Fluid Monitor PRO[®] comes with 2 AA Alkaline batteries which must be installed before use. To install the batteries, open the battery door by pressing in with thumb and forefinger at base of door and pulling out. Place batteries firmly in compartment with the battery's positive symbol (+) positioned as shown in the battery compartment. Slide the top lip of the compartment cover in place. Press the cover toward the bottom of the monitor and snap in place.



Figure 4

3. Install a Disposable Tip (Figure 5).

WARNING: Check My Ear Middle Ear Fluid Monitor PRO® WILL NOT PROVIDE ACCURATE RESULTS WITHOUT A TIP INSTALLED.

The Check My Ear Middle Ear Fluid Monitor PRO® Model PEC-3 system includes 100 disposable tips. You should always use a new disposable tip for each patient.

Remove a new tip from the package. Use the thumb and forefinger to hold the base of the tip. Match the 4 notches with those at the monitor opening, press the tip in place, and twist 1/8 turn to the right. This locks the tip in place.

Do not touch the monitor opening during installation as it may cause damage to the microphone.

To remove tip carefully place thumb and forefinger at base of tip and twist 1/8 turn to the left and gently pull out.

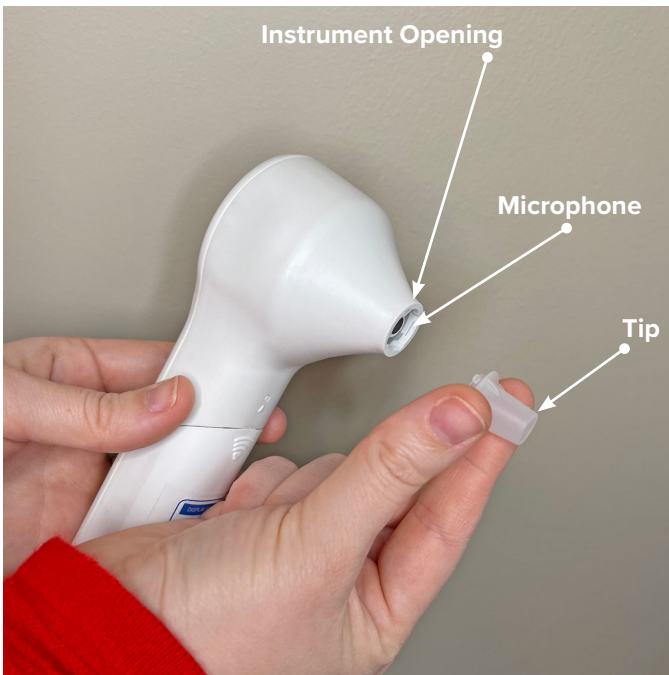


Figure 5

Verifying the Check My Ear Middle Ear Fluid Monitor PRO®

Before using the Check My Ear Middle Ear Fluid Monitor PRO®, you must test it to ensure that it is functioning properly. (Figure 6) To do so, follow these 3 steps:

1. With a tip in place, insert the monitor as far as possible into the Verification Tube.
2. Press the “R” SCAN button. The angle displayed should be 35 or less. If an angle greater than 35 or if no angle appears, take a second reading.
3. Press the “L” SCAN button. The angle displayed should be 35 or less. If an angle greater than 35 or if no angle appears, take a second reading.



Figure 6

Once both readings have displayed the appropriate angles, the Check My Ear Middle Ear Fluid Monitor PRO® is ready for use.

CAUTION: If, after multiple attempts, you still do NOT get the appropriate angle or if the ERROR symbol is displayed, do not use the instrument. Refer to the troubleshooting section on Page 19 for more information.

Using the Check My Ear Middle Ear Fluid Monitor PRO®

CAUTION: Before using the Check My Ear Middle Ear Fluid Monitor PRO®, you must attach a disposable tip. See “Set-Up Procedure” on Page 9 for more information.

IMPORTANT: THE CHECK MY EAR MIDDLE EAR FLUID MONITOR PRO® USES SOUND WAVES TO DETECT FLUID AND SHOULD BE USED IN A QUIET ENVIRONMENT.

Operating Instructions

Step 1 Place child in an upright position, sitting or standing.

Step 2 Grasp the outer edge of the child’s ear. Firmly pull the ear straight back and up. Continue “ear tug” throughout the test procedure (Figure 7).



Figure 7

You may need to try several different “ear tugs” to obtain an accurate reading. If you cannot get a reading by pulling the ear straight back and up, try pulling straight back, or straight back and down, or rotate Check My Ear Middle Ear Fluid Monitor PRO® tip in a small circular motion while in the ear.

Step 3 Gently place the Check My Ear Middle Ear Fluid Monitor PRO® tip into the child's outer ear canal behind the Tragus. completely cover the ear canal (Figure 8).

NOTE: The Check My Ear Middle Ear Fluid Monitor PRO® tip is designed to prevent it from being inserted too far into the ear canal.



Figure 8

Step 4 Press and hold the appropriate SCAN button for approximately 5 seconds. Press the “R” SCAN button for the right ear and press the “L” SCAN button for the left ear. The User should press the appropriate scan button momentarily once the device is in the ear canal and wait until either the result appears on the display or an error is indicated.

Step 5 Release the SCAN button before removing the monitor from the child's ear and read results (see “Reading Results” below).

NOTE: Spectral Gradient angle will remain displayed for 5 seconds after the SCAN button has been released.

Step 6 Repeat Steps 1 to 5 with the child's other ear.

As you learn to use the Check My Ear Middle Ear Fluid Monitor PRO® monitor you may get an ERROR symbol ⊗.

Practice using the monitor on a cooperative child. If the ERROR symbol appears on the monitor's display, repeat "Operating Instructions" Steps 1 through 6 (Page 11 and 12). If the ERROR symbol reappears, check for ear wax or excessive background noise, and refer to the "Troubleshooting" section on Page 19 of this manual.

Helpful Hints

- Use the Check My Ear Middle Ear Fluid Monitor PRO® in a quiet environment to ensure best results.
- The Check My Ear Middle Ear Fluid Monitor PRO® can only be used on children sitting or standing in an upright position.
- Calm a crying child before using an Check My Ear Middle Ear Fluid Monitor PRO®.
- Change the Check My Ear Middle Ear Fluid Monitor PRO® disposable tip after each patient.
- It is recommended that ear wax be removed before using the Check My Ear Middle Ear Fluid Monitor PRO®.

Reading Results

Compare the Spectral Gradient angle indicated on the display panel with the chart on the monitor itself or the chart below.

Spectral Gradient

<i>Level</i>	<i>Angle</i>
5	< 49°
4	49° - 59°
3	60° - 69°
4	70° - 95°
5	> 95°

Fluid Presence Probability

High
Moderate-High
Moderate
Low-Moderate
Low

The lower the Spectral Gradient angle, the more likely the presence of middle ear effusion and risk of disease (Otitis Media).

NOTE: If a child is being treated for an ear infection, the Spectral Gradient angle should increase with time.

CAUTION: If you take more than one scan of the same ear within minutes and the results differ, a borderline condition may exist. Use the lower of the two Spectral Gradient angle readings.

Printing Report

The Check My Ear Middle Ear Fluid Monitor PRO[®] allows you to keep a record of your patient's ear condition by storing a PDF or printing out results. Follow these steps.

1. Connect USB to Check My Ear Middle Ear Fluid Monitor PRO[®].
2. Connect USB to PC Computer..
3. The device will appear as a removeable drive in your computer's file explorer application.
4. The drive will contain a single text file named EarCheck.txt which you can view, save, or print using the usual methods for your computer's operating system.
5. Unhook USB Cord from PC and Monitor.



NOTE: The Check My Ear Middle Ear Fluid Monitor PRO[®] shall not be used when the USB cable is connected to the device.

EarCheck Pro Spectral Gradient Angle Report

Left Ear Spectral Gradient Angle: 048 degrees

Intensity Levels:

00348 00341 00337 00342 00344 00342 00348 00350 00343 00337 00332
00331 00317 00319 00354 00356 00353 00353 00347 00345 00342 00341
00341 00340 00337 00340 00339 00335 00325 00302 00281 00267 00258
00245 00256 00272 00286 00304 00321 00344 00370 00388 00399 00410

Right Ear Spectral Gradient Angle: 049 degrees

Intensity Levels:

00350 00341 00336 00342 00344 00344 00345 00347 00346 00337 00332
00329 00319 00317 00352 00358 00354 00351 00348 00346 00344 00342
00339 00338 00336 00340 00337 00335 00326 00302 00280 00267 00256
00241 00252 00269 00284 00301 00316 00341 00367 00385 00398 00410

Reference Information

Angle	Risk of Fluid
<49	High
49-59	Moderate High
60-69	Moderate
70-95	Low Moderate
>95	Low

Name of Patient: _____

Date of Read: _____

Maintenance

Cleaning

The Check My Ear Middle Ear Fluid Monitor PRO® should be cleaned regularly to ensure accurate operation. Use a soft dry cloth to clean the monitor display panel and exterior.

CAUTION: Do NOT get water inside the Check My Ear Middle Ear Fluid Monitor PRO®.

When cleaning the monitor, you can use:

- A 5% Solution of household bleach (approx. 2500ppm Sodium Hypochlorite)
- Sporicidin
- IPA 70/30

Care

Although ruggedly constructed, the Check My Ear Middle Ear Fluid Monitor PRO® should be handled carefully to ensure trouble-free operation.

WARNING • Do not drop, toss, or otherwise mishandle the Check My Ear Middle Ear Fluid Monitor PRO®. Damage to the monitor's electronics may result.

WARNING • Never let the Check My Ear Middle Ear Fluid Monitor PRO® get wet. It could become permanently damaged if water or other liquids get inside.

WARNING • Do not expose the Check My Ear Middle Ear Fluid Monitor PRO® to direct sunlight, temperature or humidity extremes, moisture, or dust. (See "Technical Specifications" on page 20).

WARNING • Do not take the Check My Ear Middle Ear Fluid Monitor PRO® apart. Taking it apart will invalidate the monitor's warranty.

Helpful Hints

Follow these instructions at all times:

Always replace batteries when “Low Battery” symbol appears.

WARNING

WHEN REPLACING BATTERIES - ONLY USE AA ALKALINE BATTERIES.

Storage




Always store the Check My Ear Middle Ear Fluid Monitor PRO® with a disposable tip in place for protection.

Store the Check My Ear Middle Ear Fluid Monitor PRO® in a dry environment away from dust and contamination.

WARNING

If the Check My Ear Middle Ear Fluid Monitor PRO® will not be used for several months, please remove the batteries to prevent corrosion.

Troubleshooting

PROBLEM	POSSIBLE CAUSE	ACTION	
	The Check My Ear Middle Ear Fluid Monitor PRO® tip is not properly inserted in ear.	Make sure the Check My Ear Middle Ear Fluid Monitor PRO® tip is in the ear canal and aimed straight down the canal. Continue ear tug while scanning.	
	Ear tug is incorrect	Try a variety of tugs, pulling the ear straight back and up, or back and down.	
	The Check My Ear Middle Ear Fluid Monitor PRO® tip is not lined up correctly	Rotate the Check My Ear Middle Ear Fluid Monitor PRO® tip in a small circular motion while continuing ear tug.	
	The Check My Ear Middle Ear Fluid Monitor PRO® tip is dirty.	Replace the Check My Ear Middle Ear Fluid Monitor PRO® tip.	
	Too much background noise.	Try a quiet location.	
	Crying child.	Calm child.	
	Ear canal completely blocked with wax.	Remove wax.	
*IMPORTANT: If error symbol is still displayed after taking all of the above steps, scan both ears. If the Error Symbol appears for one ear, but a Spectral Gradient angle for the other, an ear condition that the Check My Ear Middle Ear Fluid Monitor PRO® cannot measure may exist.			
	Low Battery Symbol	Weak batteries	Replace batteries.
	Low Battery, no Spectral Gradient angle	Non-functional batteries	Replace batteries.

Technical Specifications/Compliance Information

Check My Ear Middle Ear Fluid Monitor PRO®

Dimensions: 7.0in H x 2.75in W x 2.5in D (169mm x 88mm x 87mm)

Weight: 6.2 oz (174 g). (With batteries)

Measuring Range: 1.8 kHz to 4.4 kHz

Sound Volume: < 115 dB SPL

Sound Duration: 0.2 second sweep

Display: LCD display

Display Hold Time: 10 sec

Power: Two AA Alkaline Batteries

Battery Symbol: Low Battery


Battery Life: 1000 readings in 4 months

High Noise Level: Error Indicator

Ambient Temperature Operating Range: +68°F to 86°F (20°C to 30°C)

Relative Humidity Operating Range: <75% 

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

Relative Humidity Storage Range: <85% 

Operating Altitude Range: Sea Level to 6000 ft elevation

Operating and Storage/Transport Atmospheric Pressure Range for 85kPa to

106kPa 

Disposable Tips - Type BF Applied Parts 

Storage Altitude Range: Sea Level to 12,500 meters

Compliance Information

The device is designed to comply with the following standards:

- EN/IEC 60601-1 4th Edition Electromagnetic Compatibility
- EN/IEC 60601-1 3rd Edition General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment and applicable collateral standards (IEC 2005+A1:2012)

Customer Service

For assistance or service, contact:

Check My Ear LLC

P.O. Box 22252

Lincoln, NE 68542-2252

Customer Service at 1-800-895-9921 or customercare@checkmyear.com

Monday-Friday: 8:00AM - 8:00PM (EST)

IMPORTANT

To ensure prompt response and service do not return any Check My Ear Middle Ear Fluid Monitor PRO® without first obtaining a return authorization number from Check My Ear LLC. Write or call explaining the exact nature of the problem. Please indicate the serial number of the monitor located in the battery compartment.

Limited One-Year Warranty

Your Check My Ear Middle Ear Fluid Monitor PRO® is warranted to be free from manufacturing defects for a period of one year from date of purchase.

Should repair be needed within the Warranty period call Customer Service 1-800-895-9921 or email us at customercare@checkmyear.com. Do not return any Check My Ear Middle Ear Fluid Monitor PRO® without first obtaining a return authorization number from Check My Ear LLC. Be sure to identify the problem and include your address and phone number on any correspondence.

During the Warranty period, Check My Ear LLC will either repair or replace (at our option) free of charge any parts necessary to correct faults in the materials or workmanship and excludes damage to the product resulting from accident or misuse.

The above Warranty is complete and exclusive. Check My Ear LLC expressly disclaims liability for incidental, special, or consequential damages of any nature. IN NO EVENT SHALL Check My Ear LLC LIABILITY EXCEED THE ORIGINAL COST OF THE PRODUCT.

Any implied warranties arising by the operation of law shall be limited in duration to the term of this warranty.

CHECK MY EAR LLC DISCLAIMS ALL STATUTORY AND IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Notes

Notes

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