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Which tympanometer is optimal for an outpatient primary care setting?

Four models out of 16 made the cut for best in field

Practice recommendation

■ Four tympanometers are suitable for outpatient primary care, and each has positive and negative attributes. The Earscan was rated easiest to use and provided the most consistent data.

In a primary care setting where patient volume, time constraints, and provider turnover are on the increase, you need dependable biomedical equipment that produces quality data and is easy to use, ergonomic, and affordable. This is certainly true of the tympanometer, which is used to measure mobility and impedance of the tympanic membrane and ossicles, provide an objective measurement of the middle ear, augment visual and pneumatic otoscopy, and confirm and document otitis media with effusion (OME) and acute otitis media (AOM).¹⁻³ Our study aimed to determine which tympanometer is optimal in the outpatient primary care setting.

Based on objective and subjective analysis, the Earscan appears to be an excellent choice for outpatient primary care, though users also liked the MT 10 and GSI 37.

■ Four units made initial cut

Of 16 tympanometers we found through a review of market literature, an Internet search, and audiology recommendations, 4

met the minimum requirements (**TABLE 1**)—Earscan (www.microaud.com), GSI 37 (www.viasyshealthcare.com), MicroTymp 2 (www.welchallyn.com) and MT 10 (www.interacoustics-us.com).

■ What we looked for in our in-depth evaluation

We evaluated the tympanometers with formal objective testing, clinical use, subjective user rating, and feature comparison.

We assessed reproducibility with a volume calibration tool (in vitro), and with intra- and inter-device testing (in vivo) on volunteers. The tympanometers were also compared side by side in a clinical setting on adults and children with and without ear disease.

Eight evaluators with various clinical and technical backgrounds were our subjective raters. They used a Likert scale survey to rate the following tympanometer attributes: appearance, size, safety, durability, capabilities, ergonomics of physical design, ease of use (overall operations, specific control features), screen information layout, LCD screen/monitor, printing, maintenance, software interface, data quality and reliability, and accessories. Participants independently reviewed the tympanometers and were blinded to others' evaluations.

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We prioritized categories as high, medium, or low importance. Finally, important features of each unit were identified and verified.

I Our rankings

Earscan comes out on top

Formal testing, clinical use, and feature comparison suggest the Earscan is the tympanometer best suited for primary care (see "How the units compared," page 948).

The Earscan delivered high-quality data with excellent results in reproducibility testing for volume, pressure, and compliance. It proved reliable in the clinical setting with positive comments from participants.

Ergonomics. The Earscan was rated the easiest to use and the simplest to obtain a probe tip-ear seal. The Earscan has a small cylindrical probe affixed to a pressure/sound tube that attaches to the control unit. Anecdotally, these kinds of box-and-tube tympanometers provide the best seal and true readings. The probe is small, lightweight, and well suited for the clinician's hand and patient's ear so the tip-ear seal is easily viewed during the procedure. The tips are malleable, beveled, and tapered to provide an excellent fit in the ear canal.

The control unit is a reasonable size with finger-sized buttons and a viewable screen. It is simple to turn the unit on, press the Impedance button and perform the exam. The unit displays understandable feedback as to status.

Construction. The air pump, tone inducer, tubing, probe, and compliance pressure sensor are sturdy and yield consistent results. The unit is rugged and portable making it popular for occupational health.

Features. The Earscan is affordable and comes with additional functionality of audiometry and acoustic reflex testing. It has RS232 serial port capability to facilitate printer and limited computer integration.

TABLE 1

Tympanometers had to meet these minimum requirements to be considered

1. COMPLIANCE

Pressure measurement: +200 to -300 daPa
Sound frequency: 226 Hz ± 3%
Sound amplitude: 85 dB SPL ± 3dB

2. PRESSURE PUMP

Accuracy: ±15% or 10 daPa (or better)
Positive to negative pressure sweep

3. DATA DISPLAY

Screen size: 2.5 cm x 2.5 cm
Horizontal axis (pressure): +200 to -300 daPa
Vertical axis (volume): 1.0 to 2.5 cm³ displayed

4. PRICE

<\$3000 list price per unit

5. SIZE AND ERGONOMICS

Main box or docking station: dimensions < 30 cm x 23 cm x 10 cm; weight <2.7 kg
Handheld component: dimensions < 10 cm x 25 cm x 13 cm; weight <500 g

Drawbacks. The unit is powered by a 120-volt adapter, making it less convenient than a handheld tympanometer. It may not be reasonable to carry the Earscan from one exam room to another. The Earscan has an older appearance with sealed buttons that are encased and provide little tactile feedback.

When other units may be preferable

If a handheld tympanometer with a docking station is necessary, then the MT10 or GSI 37 would be an appropriate choice.

MT10. This unit received the highest overall user ratings, slightly higher than the Earscan. The MT10 has a larger monitor and better control features than the GSI 37. It also has the capability for computer integration. However, the MT 10 gave less consistent readings for same-ear measurements when compared with the Earscan and GSI 37.

GSI 37. This unit provided more consistent pressure and compliance readings than the MT 10, and had no glare on its screen. It also has a longer track record in the field than does the newer MT10. It has an excellent operation manual.

FAST TRACK

Earscan's air pump, tone inducer, tubing, probe, and compliance pressure sensor are sturdy and yield consistent results

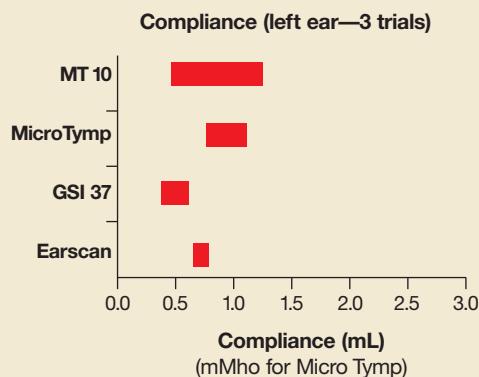
TABLE 2

For compliance and pressure readings, the Earscan showed the most consistency while the MT 10 showed the least

	EAR A	EAR B	EAR C	EAR D	EAR E
Range of readings (variance) for compliance in mL					
Earscan	0.2	0.1	0.2	0.1	0.4
MT 10	0.8	0.65	0.64	0.12	0.62
Range of readings (variance) for pressure in daPa					
Earscan	0	6	0	0	6
MT 10	30	53	31	16	82

FIGURE 1

Compliance data obtained from 4 tympanometers



FAST TRACK

If a handheld device with docking station is preferred, consider the MT10 or GSI 37

While all 4 gave normal readings, the MT10 showed the least consistency.

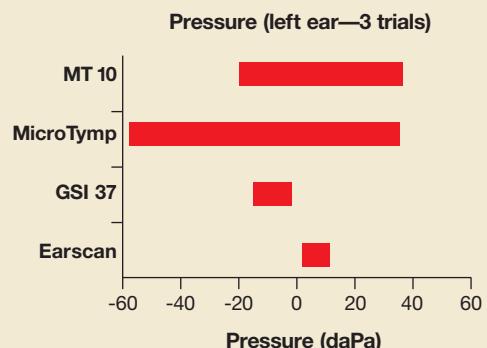
How the units compared

In vitro testing for volume using a fixed object (calibration tube) demonstrated excellent reproducibility. There was little to no variation for 10 consecutive measurements for each tympanometer. In vivo reproducibility testing was performed taking 3 consecutive readings on each of 5 different ears using the tympanometers. For Compliance and Pressure readings the Earscan showed the most consistency while the MT 10 showed the least (**TABLE 2**).

Compliance data is graphed from 1 left ear to portray the range of values

FIGURE 2

Middle ear pressure data obtained from 4 tympanometers



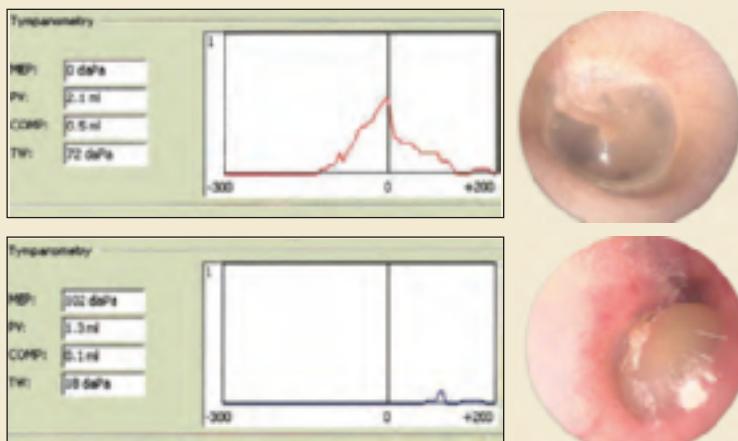
All 4 units gave values within normal range; there was a wide range from the MT10 and MicroTymp.

obtained from 4 tympanometers (**FIGURE 1**). While all tympanometers gave normal compliance readings, some units were less consistent than others. The MT10 showed the widest range of readings (least consistency). For this patient's right ear (not shown), 3 tympanometers identified an overly compliant ear drum, while the MT10 gave normal and close to normal values. The MicroTymp 2 did not provide a compliance reading for the right ear.

Middle ear pressure data is graphed from the same left ear to portray the range of values obtained from 4 tympa-

FIGURE 3

Earscan tympanograms agree with corresponding video otoscope images



Top: Earscan demonstrating a normal left tympanogram and corresponding video otoscope image. *Bottom:* Earscan demonstrating an abnormal right tympanogram with elevated middle ear pressure, reduced compliance and reduced physical volume. The video otoscope image is consistent with otitis media.

nometers (**FIGURE 2**). Overall, the units gave values that were within the clinically acceptable range of normal. However, there was a wide range of readings from the MT10 and MicroTymp 2. Assuming the participants' middle ear pressure was truly close to zero, the outlier values reported by the MT10 and MicroTymp 2 might have clinical significance.

More than 100 tympanograms were obtained on children and adults; observations were noted. The Earscan, GSI 37 and MT 10 were easier to use and to obtain a good seal. The MicroTymp 2 proved more difficult to obtain a seal with and at times presented a falsely positive flat tympanogram. Earscan and MT10 gave similar readings on several occasions. On several occasions, the MicroTymp 2 and GSI 37 values significantly disagreed with each other. At times the MicroTymp 2 provided a graphical tympanogram but did not provide the numerical data. It was also easy to inadvertently combine previous data from one ear with new data from contralateral ear

when using the MicroTymp 2.

Earscan tympanograms and corresponding video otoscope images are shown in **FIGURE 3**. The right tympanogram (bottom) is consistent with the video otoscope findings of otitis media. Observe the low compliance, elevated middle ear pressure, and low physical volume. The normal left tympanogram and otoscopy are concordant.

User ratings are shown in **TABLE 3**. Overall, participants ranked the MT10 highest (56.3) with the Earscan second (54.9), GSI 37 third (50.4), and MicroTymp 2 fourth (46.0). The MT10 rated highest in Ergonomics, Ease of Use of Control Features, Screen, Accessories, Appearance, Size and Information Layout. The Earscan rated highest in Overall Ease of Use and Perceived Durability. The MT10 and Earscan were tied for Capabilities and Interfacing. The MT10, GSI 37 and Earscan were tied for Perceived Data Quality. The GSI 37 was rated highest in Perceived Maintenance. Seven out of 8 reviewers (2 ties with the

FAST TRACK

Earscan was most consistent for compliance and pressure readings; MT 10 was least consistent

TABLE 3

User ratings of 4 tympanometers (Likert scale 1 to 5)

CATEGORY	EARSCAN	GSI 37	MICROTYMP 2	MT10
Categories deemed highest importance				
Ease of use: overall	4.1	3.8	3.0	3.8
Data quality	4.4	4.4	4.0	4.4
Ergonomics	4.5	4.6	4.4	4.0
Durability	4.9	4.3	4.4	4.6
Maintenance	4.7	4.8	3.7	4.4
Categories deemed medium importance				
Ease of use: controls	3.8	3.7	4.2	4.5
Screen	4.3	4.5	3.1	4.7
Accessories	4.2	3.9	3.8	4.3
Categories deemed lowest importance				
Appearance	4.0	3.8	3.7	4.1
Size	4.1	3.8	4.2	4.4
Capabilities	4.0	2.0	1.0	4.0
Info layout	4.2	4.2	4.1	4.7
Interface	3.7	2.6	2.4	3.7
Total	54.9	50.4	46.0	56.3

MT10) selected the Earscan as easiest to use. Eight out of eight (2 ties with MT10) selected the Earscan as the most simple to obtain a good seal.

The features representing the main differences between the 4 tympanometers are listed on pages 951 and 952. Features are identified as positive or negative and ranked according to how they impacted the final selection from most influential to least. ■

REFERENCES

- American Academy of Family Physicians; American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Pediatrics Subcommittee on Otitis Media with Effusion. *Pediatrics* 2004; 113:1412-1429.
- American Academy of Family Physicians; American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Pediatrics Subcommittee on Acute Otitis Media. *Pediatrics* 2004; 113:1451-1465.
- Onusko E. Tympanometry. *Am Fam Physician* 2004; 7: 1713-1720.

Features of 4 primary care tympanometers

EARSCAN	
Positive features <p>Easiest to use and obtain a seal Provides excellent feedback on little screen when “Testing” or “Blocked,” etc Offers Tympanometry, Acoustic Reflex Testing and Audiometry Performs Tympanometry followed by Acoustic Reflex Testing at one time Compatible with software integration Small pencil-like probe: fits in hand nicely and noninvasive appearance to patient Easy to view the ear-tip seal when performing the exam Excellent ear tips (cuffs) in terms of shape and malleability; affordable Probe tip easily disassembled and cleaned Low rate of reported mechanical problems Three-year warranty Control unit contained/packaged and protected No issues related to battery power No hinged parts and no separate portable parts Sealed buttons</p>	Easy to turn on with toggle switch Monitor signals completion, “Remove Probe” Sound of air pump signals completion Best fit of calibration volume tube Also accepts GSI ear tips Popular in the field for occupational health Retail price \$2595 with printer
MT10	
Positive features <p>Easy to use and obtain a seal Performs Tympanometry followed by Acoustic Reflex Testing at one time Offers Tympanometry, Expanded Tympanometry, Acoustic Reflex Testing, and Audiometry Screening Second smallest footprint if obtained without the printer Easy to view the ear-tip seal when performing the exam Controls are generally navigable once user is trained Can be programmed to make certain functions available Portability in a cable-free handheld device Looks sleek and modern Compatible with software integration Very good ear tips with multiple shapes Large screen and graph size Soft background color and high screen resolution Probe tip easily disassembled and cleaned Uses nonproprietary batteries (3 AA NiMH or NiCa batteries) Changing the batteries is simple Auto shutoff to save battery life Probe head removes for inserting into infant ears Turns on with pressing any button Stores multiple tests Very good volume calibration tool Retail price \$2995 with printer</p>	Negative features <p>Large size can be difficult to manipulate, clumsy Large size can be intimidating to patient Provides subtle feedback on screen when “Open” or “Blocked,” etc; difficult to notice it because of other displayed data; busy screen Turning on the unit reveals prior saved data and performing test can replace data for one ear and leave old data in the other. Navigating options are confusing to some users Storing multiple tests (up to 20) may cause confusion or error if information is transferred by software User manual is rated as fair Glare decreases viewing angle from 160° x 160° to 90° x 90° Requires battery power</p> <p>Relies on contacts for power & data transfer Looks like a radar gun going into patient's ear Can be dropped or knocked out of docking station Battery charging issues: Before use, batteries require cycle of charge 3 hours, off for seconds, then charge 3 hours It is recommended to discharge NiCa batteries totally at intervals of 2 to 3 weeks Charging lamp is a little difficult to notice Need to unplug the charger if you put non-rechargeable AA batteries in the unit</p>

Features of 4 primary care tympanometers (continued)

GSI 37

Positive features

Easy to use and obtain a seal
 Easy to view the ear-tip seal when performing the exam
 Portability in a cable-free handheld device
 No glare on screen
 Best viewing angle 170° x 170°
 Excellent manual
 Very good ear tips
 Probe easily disassembled and cleaned
 Turns on when removed from docking station and press L or R
 Very good volume calibration tool
 Auto shutoff to save battery life
 Can use 9-volt alkaline battery if needed
 Changing this battery is only slightly difficult, with lead wires requiring positioning to close the unit
 Also accepts Earscan tips
 Popular among audiologists for mobile screening
 Retail price \$2475 with printer

Negative Features

No software interface and no plans to develop an interface
 Displays confusing symbols as feedback when "Testing"

or "Blocked," etc

Memory function is confusing and might lead to mis-identified data
 Does not provide Acoustic Reflex Testing
 Relies on contacts for data transfer and power charging (on rare occasions, data did not transfer due to contact misalignment)
 Requires battery power and proprietary GSI battery recommended
 Storing multiple tests (up to 2 for each ear) may cause confusion or error in identifying data
 Somewhat unstable in docking station; dislodges slightly with Jolt test
 Looks like a drill going into patient's ear
 Can be dropped or knocked out of docking station
 Slow printer
 Battery charging issues:
 Longest life for battery if cycled from full charge to low charge to full charge
 Sitting in charger all of the time reduces battery capacity somewhat
 Full discharge requires 14 hours recharging to restore
 Charger should be unplugged if unused for >1 month

MICROTYMP 2

Positive Features

Familiar appearance to clinicians (resembles an otoscope)
 Provides excellent feedback on little screen when "Testing" or "Blocked," etc
 Smallest footprint if obtained without the printer
 Portability in a cable-free handheld device
 Excellent manual
 Turns on by removing from docking station and press Test
 Has a tip ejector on the probe
 Auto shutoff to save battery life
 Prints the fastest
 Various options for printing data
 Commonly found in family practice clinics
 Retail price \$2900 with printer

Negative Features

Not always easy to use and obtain a seal
 Head of unit is in the way of viewing the ear-tip seal when performing exam
 Handle hits patients shoulder
 Does not provide Acoustic Reflex Testing
 Graph resolution is poor (large blocks on small screen)
 Vertical (y-axis) data plots that exceed maximum (1.5 mmho) are plotted at the bottom (zero); this

is confusing

Will print a graph without the numerical data
 Small screen and graph size
 Glare on screen decreases viewing angle from 170° x 170° to 120° x 120°
 Poor ear tips
 Label the graph L or R after performing the exam
 Only unit that uses L or R from patient's view
 Data retained can be mixed with new data
 Probe tip cannot be removed for cleaning
 Requires battery power and proprietary WA battery
 Relies on infrared for data transfer and contacts for charging
 Can be dropped or knocked out of docking station
 Battery charging issues:
 Longest life for battery if cycled from full charge to low charge to full charge
 Full discharge requires 14 hours recharging to restore
 Battery must be removed if the unit is out of the charger and unused for >1 month
 Changing this battery is moderately difficult