Antenatal and Newborn Screening Programmes

NEWBORN HEARING SCREENING AND ASSESSMENT

Tympanometry in babies under 6 months

A Recommended Test Protocol

Version 2.0

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NHSP Clinical Group

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Summary

We recommend the use of 1000 Hz probe tone tympanometry to test babies under 6 months corrected age. Tympanometry using 226 Hz should not be used. A simple classification scheme is proposed in which there are only two possible clinical outcomes – normal or abnormal, indicative of middle ear effusion (MEE) absent or present respectively. This is based on a reliably recorded trace. Traces with positive peaks indicate that MEE is absent even when the positive peak is at a negative middle ear pressure (MEP); flat traces or traces with negative peaks indicate MEE present.

The sensitivity and specificity of the method is good but not perfect as a small number of traces are not easily classified. Therefore in determining the management of an individual infant, tympanometry needs to be considered in the context of other audiological test procedures as described in the NSHP protocol on early assessment.(Stevens et al 2007) .

This protocol is consistent with the recommendations of the US Joint Committee on Infant Hearing (JCIH) 2007 Position Statement for the audiological evaluation of infants birth to 6 months of age.

1. Introduction and scope

This document has been prepared as part of the advice and guidance from the Newborn Hearing Screening Programme (NHSP) in England. It is an update of that produced in 2000. Opportunity has been taken to incorporate the latest evidence-based knowledge on this procedure and provide more practical guidance on key issues, particularly around interpretation of results. Protocols for other test procedures are available on the NHSP website (http://hearing.screening.nhs.uk).

The aim of the document is to provide recommendations for accurately determining the middle ear status of young infants who have been referred for diagnostic audiological assessment following Newborn Hearing Screening. Information about the *type* of hearing loss needs to be established at the diagnostic assessment (Stevens et al 2007). The age group under 6 months is of particular importance with regard to intervention including the fitting of appropriate amplification, and the goal is to complete diagnostic audiological assessments by 3 months of age (NHSP Quality Standards 2006) to facilitate this. The accurate determination of middle ear function is required for both audiological and medical management, and oto-admittance testing (tympanometry) is important in this.

Aims of the document

1) To summarise the evidence base for high-frequency tympanometry.
2) To provide guidance as to the interpretation of test results. It assumes an understanding of conventional tympanometry (typically carried out using a probe tone of 226 Hz) and only attempts to cover those aspects that may differ for the assessment of middle ear function in young infants.

Measurement of acoustic reflexes is briefly discussed but it is not currently in the remit of this protocol to propose recommendations about this aspect of middle ear measurement.

2. Measurement

Why are adult protocols inappropriate?

There are anatomical and acoustical differences between the adult and neonatal middle ear which means that adult protocols for tympanometry are not appropriate. The mean adult middle ear resonant frequency is 900 Hz with considerable variability (650 Hz – 1400 Hz). The middle ear system is stiffness controlled below its resonant frequency and mass controlled above it. The 226 Hz probe tone

has been used successfully to measure the **stiffness-controlled component** of the admittance (known as compliance) of the adult middle ear system as it is below the resonant frequency where the effects of mass and friction are negligible. The resonant frequency of the neonatal middle ear is much lower than in adults (Weatherby & Bennett, 1980, Holte 1991) and increases to adult values at around 4 months (Meyer et al 1997). The maturational changes which occur in the first few months of life transform the middle ear from a mass-dominated to a stiffness-dominated system. Early studies predicted difficulties in using low frequency probe tones in early infancy because of the different acoustical properties of the neonatal middle ear compared to the adult (Himmelfarb 1979, Weatherby and Bennett 1980).

It has been suggested by some that there may be effects due to the greater flexibility of the neonatal ear canal walls, but this is unclear. Keefe et al (1993) commented, "…..*the frequency range from 220 to 660 Hz is the worst possible range to use for tympanograms on infants. Not only is there significant ear-canal motion, but in fact there is a resonant amplification of the wall motion in this frequency range*". Contradicting this Holte et al (1990) demonstrated that tympanogram shape was unrelated to ear canal wall movement in this age group.

For an extensive review of the literature about high frequency tympanometry in early infancy and for a more detailed explanation about the choice of a 1000 Hz probe tone see Purdy et al (2000), Petrak (2002) and Lantz et al (2004).

Choice of two component (B and G) or single admittance (Y) tympanograms

The measurement of the flow of acoustic energy through the ear canal and middle ear can be measured either in terms of acoustic impedance (the opposition to the flow of energy) or its reciprocal, acoustic admittance. Both impedance and admittance have two equivalent components. For admittance (Y) these are conductance (G) and susceptance (B) relating to frictional and stiffness/mass components respectively (such that Y = G + jB)..

For a comprehensive explanation of the theory of immittance and its application to the assessment of middle ear function in early infancy see Lantz et al (2004).

Contemporarily admittance (Y) is the measurement of choice (Sutton et al 1996, Kei et al 2003; Baldwin 2006) but susceptance tympanograms have also been usefully applied in early infancy (Marchant 1986, Williams et al 1995).

Choice of probe tone

The validity of low frequency tympanometry in early infancy was questioned when normal tympanograms were observed in babies with MEE confirmed by myringotomy (Paradise et al 1976, Shurin et al 1977). However high frequency tympanometry in early infancy has been difficult to validate with an adequate "gold standard" and traces have proven difficult to interpret and classify.

Classification of tympanograms by pattern

Low frequency tympanograms have been successfully classified by pattern in adults and the Jerger/Liden classification system is a familiar scheme (Liden 1969, Jerger 1970). However more complicated patterns are produced when the probe frequency increases towards the middle ear resonant frequency. Multi-peaked or "notched" tympanograms occur when the probe tone is close to the resonant frequency. Alternative classification schemes described by Vanhuyse et al (1975) and Beery et al (1975) have not been successfully applied to infants (Reichert et al 1978, McKinley et al 1997).

Classification of tympanograms by quantitative measures

Classifying high frequency tympanograms by a quantitative measure such as peak susceptance or peak compliance has been usefully applied to infants under 6 months of age (Marchant et al 1986, Williams et al 1995, Sutton et al 1996).

a) Marchant et al (1986) compared peak susceptance using a 660 Hz probe tone in ears with MEE confirmed by myringotomy and "normal" ears. The tympanograms were analysed by drawing a baseline between +300 daPa and –400 daPa and measuring peak susceptance above the baseline. Peak susceptance ≤ 0 mmho (i.e. no discernible peak) was highly associated with otoscopic diagnosis of MEE and evidence of MEE at myringotomy with a sensitivity of better than 0.94. Marchant et al's methodology influenced the recommendations of the earlier version of this protocol.

b) Baldwin (2006) used an adaptation of Marchant's methodology to classify admittance tympanometry using 226, 678 and 1000 Hz probe tones undertaken on 211 babies aged 2 to 21 weeks. Tympanograms recorded from babies with normal ABR thresholds or robust TEOAEs were compared with those recorded from infants who had evidence of temporary conductive hearing impairment (attributed to MEE) based on the findings of a test battery, which included air and bone conduction ABR. There were no significant differences between the two groups using the 226 Hz probe tone and the majority of tympanograms were "normal" Type A. The sensitivity of the 226 Hz probe tone in correctly identifying the presence of MEE was only 0.02. There were significant differences between the 2 groups using the higher frequency probe tones with the majority of traces from the pathological group being typically "trough-shaped" as shown in Figure 1. The sensitivity of the 678 Hz and the 1000 Hz probe tone in correctly identifying the presence of MEE was 0.95 and 0.99 respectively. The specificity was 0.83 and 0.89 respectively. This methodology forms the basis of the current protocol.

Low frequency probe tones are invalid in early infancy. The choice between 678 Hz and 1000 Hz is based on its sensitivity and ease of interpretation. McKinley et al (1997) reported that 1000 Hz results were less straightforward to interpret; however if the data are re-classified into 'flat' vs 'all other' (which seems more appropriate), then the relationship to OAE results is better for 1000 Hz tympanometry than for 678 Hz. Baldwin (2006) reported fewer difficult to classify traces when using the 1000 Hz tone compared to 678 Hz. Using the 1000 Hz tone, 5% of traces were 'difficult to classify' in the "normal" group and only 0.6% in the MEE group. The use of 1000 Hz is therefore recommended in early infancy.

Problems with normative data studies

Conventional adult tympanometry uses normative values and certainly objective pass/fail criteria would also be useful in the infant population. Normative data has emerged with 5th to 95th percentile data for a variety of test parameters which the authors believe may serve as pass/fail criteria for 1000 Hz tympanometry (Kei et al 2003, Margolis et al 2003, Swanepoel et al 2007). However there are differences in the choice of criteria and also in choice of test parameters (eg. pump speed) which could influence this data (Calandruccio et al, 2006). Care would need to be taken to ensure the same parameters had been adhered to. Kei et al (2003) gathered their norms from a group of babies aged 1 to 6 days and there is doubt about the feasibility of transferring the norms from one age group to another. Margolis et al (2003) chose a pass/fail criterion of 0.6 mmho for negative tail compensated static admittance. The sensitivity of this criterion was only 0.5 when absence of TEOAE was used as a reference. Using these data, traces with small peaks (eg. static admittance <0.1 mmho calculated from peak to positive tail) may be classified incorrectly as abnormal. Marchant et al (1986) recommended peak susceptance ≤ 0 mmho to be an indication of MEE. Thus, the new NHSP protocol does not include published normative data but is based on clinical studies that have directly demonstrated the effectiveness of a simple 'normal / abnormal' classification of 1000 Hz tympanograms for babies under 6 months of age.

Up to what age is it necessary to use higher frequency probe tones?

Meyer et al (1997) predicted that valid low frequency tympanometry would only be possible when the adult middle ear resonant frequency was reached. This occurred at around 4 months in one longitudinal case study (Meyer et al 1997). However, low frequency tympanometry can remain invalid up to 5 months of age and variability is currently unknown (Baldwin 2006). Alaerts et al (2007) recommended 1000 Hz below 3 months and 226 Hz above 9 months but there was uncertainty about the appropriate choice in the intermediate period. Differences between the neonatal and adult ear in energy transmission (Keefe and Bulen 1993) and admittance phase measurements (Holte 1991) which were evident at 4 months had disappeared by the age of 6 months. Tympanometry using the 226 Hz probe tone is used clinically to differentiate pathological ears in babies over 6 months old and further

longitudinal studies would be necessary to establish the variability in the age at which it became valid. Until this is known we advise that high frequency tympanometry should be used up to the corrected age of 6 months.

Equipment

Calibration

Equipment should be calibrated regularly according to IEC 61027:1991. Before use, a simple check on functioning should be carried out by testing one's own ear or in a cavity.

Precautions against cross infection

Local procedures should be adhered to. It is recommended that local advice be sought regarding best practices for cross-infection control.

Practical considerations in testing

- Otoscopy should be carried out before tympanometry. However otoscopy in neonates has been described as "…*an onerous task even for the experienced physician*" (Zarnoch and Balkany 1978). Inter-observer agreement about the presence of MEE in neonates varied from 85% (Marchant et al 1986) to 27% (LaRossa et al 1993), and Roberts et al (1995) concluded that otoscopy could not be relied upon in this age group. It is therefore only intended, when performed by the audiologist in this context, as a general inspection of the external ear for obvious signs of disease, blockage or malformation such as atresia or stenosis. Care should be taken not to insert the otoscopic speculum deep into the ear canal of young babies.

- Conical tips, or those with a flange designed to seal against the entrance to the external auditory canal may be used for the tympanogram measurement. The pinna should be pulled gently to straighten the ear canal and position the tip.

- Movement of the infant and crying can result in a false peak in the tympanogram. The baby does not need to be asleep but should definitely be resting quietly during the test.

- Traces should usually be repeated, if possible, to check that the result is replicable and not due to artefacts such as baby movement. It is especially important to retest any ear with an abnormal or difficult-to-interpret tympanogram.

- The direction of pressure change should be from positive to negative. The range should be at least from +200 daPa to –400 daPa (and preferably –600daPa). A fast screening mode speed of up to 600 daPa/sec should be used.

- The precise value of 'Ear Canal Volume' should be disregarded when high frequency probe tones are used, although it still is useful to indicate a blockage.

3. Tympanogram (Trace) Interpretation

The system recommended for interpretation is that of Baldwin (2006), adapted from Marchant et al (1986) which improved intra-tester agreement significantly. Admittance is used in this scheme and one should check that the equipment is set to measure this. It differs from the previous recommendation in that MEP is no longer considered. A positive peak at negative or positive MEP was more likely to occur in the "normal" group and was not a feature of the MEE group (Figure 1): the MEE group typically had no discernible peak and the tympanograms were characteristically "trough shaped".

Recommendation for middle ear measurement and trace interpretation in babies under 6 months

- Use a 1000 Hz probe tone and admittance (Y) measurement

- Draw a baseline between points on the trace at pressure extremes (+200 to –400/-600 daPa). If the trace disappears below the *x* axis the baseline should be drawn to the *x* axis as shown in Figure 1.
- Identify the main peak which can occur at any middle ear pressure
- Draw vertical line from this baseline to the peak of the trace.
- If the peak is above the baseline it is a positive peak; if it is below the baseline it is a negative peak.
- Positive peak is normal, negative peak is abnormal.
- If there is a positive and a negative peak the trace should be classified as positive.
- If the conditions are good and the outcome is clear repetition is not always necessary to draw a conclusion. However traces should usually be repeated if possible to check for reliability. Repeated traces should be classified in the same category of positive or negative. If the outcome is not clear the trace should always be repeated.

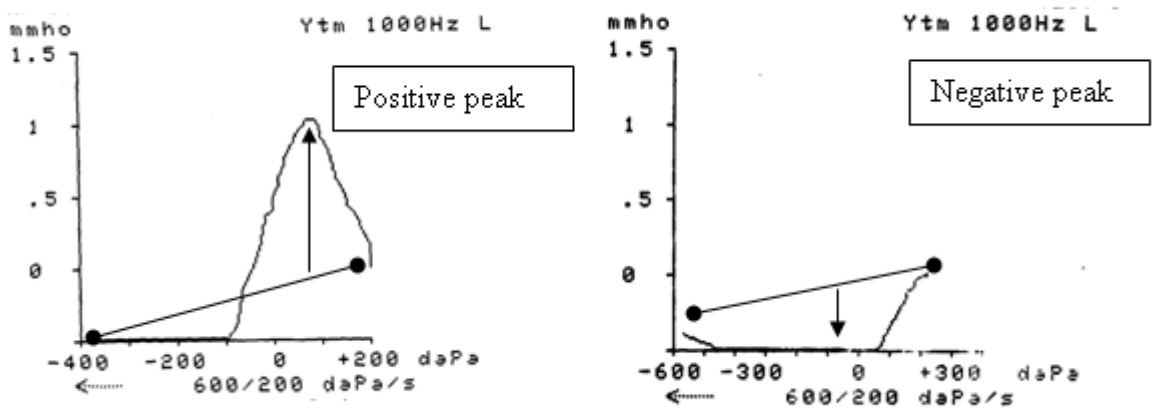

Figure 1. Examples of a positive and negative peak (adapted from a method used by Marchant et al 1986)

Further examples of normal and abnormal traces are given in the Appendix Figures 2 and 3.

4. Acoustic reflex testing

Although existing data suggest that use of a high-frequency probe stimulus is most effective in eliciting the acoustic reflex in this age group (Weatherby and Bennett 1980, Sutton et al 1996, Rhodes et al 1999) there is currently a lack of data on appropriate stimuli and the normal range of reflex thresholds in small ear canals. The mean reflex threshold measured in neonates by Weatherby and Bennett (1980) was 14 dB lower than in adults using a 1000 Hz probe tone and a broadband noise stimulus: the higher actual SPL in the infant's small ear canal would probably account for this. However Swanepoel et al (2007) reported a mean reflex threshold of 93 dBHL using a 1000 Hz stimulus with a 90% CI of 80 - 105 dBHL. Berlin et al (2005) have suggested that acoustic reflex testing may add useful information in the assessment of auditory neuropathy/auditory dys-synchrony (AN/AD). However at this stage, acoustic reflex testing it is not considered essential in the NHSP AN/AD protocol (Sutton et al 1994, Sutton 2007) and we will not attempt to cover it fully here. This will be revisited when further normative data are available.

Glossary

ABR	Auditory brainstem response
Corrected age	Age adjusted for prematurity (based on 40 week term)
MEE	Middle ear effusion
MEP	Middle ear pressure
NHSP	Newborn Hearing Screening Programme (England)
PCHL	Permanent Childhood Hearing Loss - defined here as ≥40dBHL averaged over 0.5, 1, 2 & 4 kHz pure tone thresholds. It includes both sensorineural and permanent conductive impairments.
OAE	Otoacoustic emission
SNHL	Sensorineural hearing loss
TEOAE	Transient-evoked otoacoustic emission

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APPENDIX

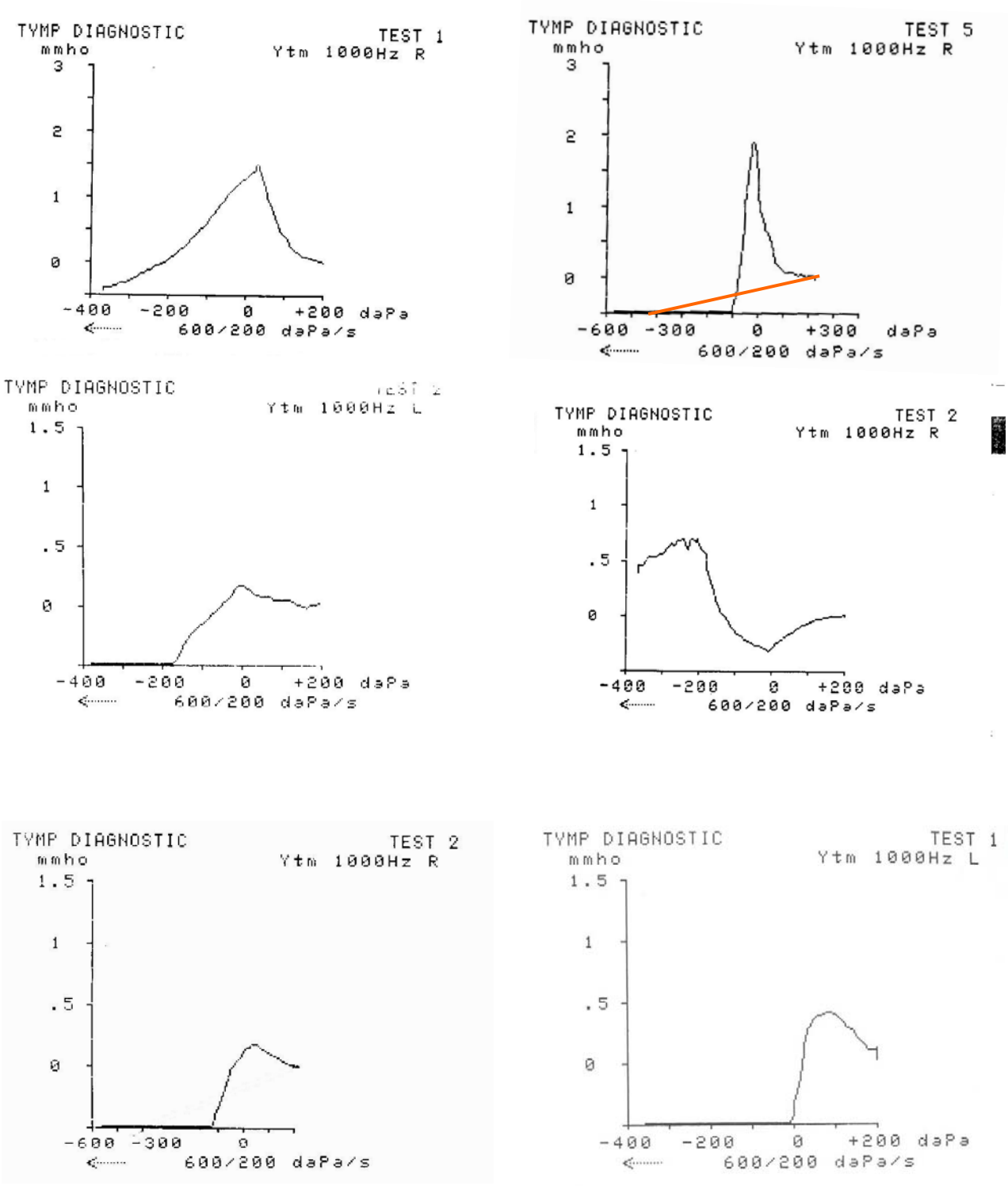

Figure 2: Examples of tympanograms with positive peaks classified as "normal".

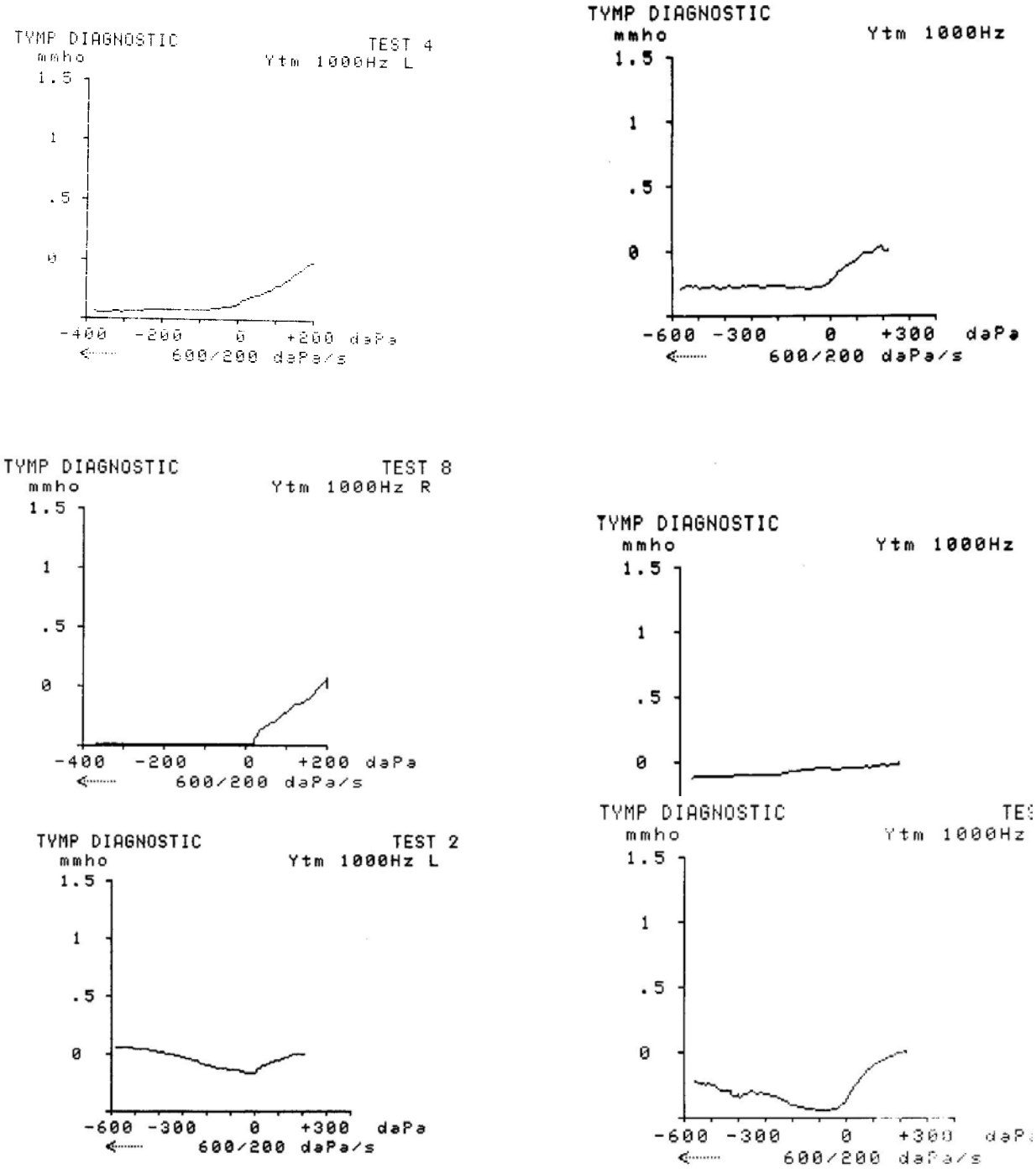

Figure 3: ***Examples of tympanograms classified as "abnormal".***