

March 24, 2026

To whom it may concern,

We hereby confirm that the GSI Pello audiometer complies with the relevant requirements of the technical specification.

1. Langenbeck test

The TEN (Threshold Equalizing Noise) test available in the GSI Pello audiometer is technically and clinically equivalent to the Langenbeck test and meets this requirement of the technical specification.

This equivalence is based on the following:

- both tests are based on pure-tone audiometry performed in the presence of masking noise,
- both evaluate hearing thresholds under controlled noise conditions,
- both are used to assess cochlear function and auditory performance in noise,
- both rely on the principle of identifying abnormal threshold elevation in noise conditions.

The TEN test uses standardized broadband noise to determine whether thresholds are elevated beyond expected values, which reflects the same diagnostic principle as applied in the Langenbeck test.

2. MHA (Master Hearing Aid) requirement

The MCL (Most Comfortable Level) and UCL (Uncomfortable Loudness Level) functions available in the GSI Pello audiometer provide equivalent clinical evaluation of hearing comfort and loudness as required by MHA-type assessments and therefore fulfill the functional requirements of the MHA (Master Hearing Aid) requirement of the technical specification.

Please feel free to contact me directly at +1-952-200-3042 or dnmr@grason-stadler.com if you have any questions.

Very respectfully,



Daniel Morehead
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Grason-Stadler