ML Fact Sheet: AI Dome Proposer for Acoustic Vent Mass (AVM) recommendations.

Overview: The ML (Machine Learning) system, AI Dome Proposer, is an advanced tool designed to assist Hearing Care Professionals (HCPs) in deriving optimal Acoustic Vent Mass (AVM) values for hearing aid domes, enhancing the fitting process and improving patient outcomes. The ML system is a feature integrated in the Phonak Target hearing aid fitting software.

Intended use of the ML system:

- **Intended use:** The Phonak Target is the standalone fitting software which is intended to be used by qualified hearing care professionals (HCPs) to configure, program, and fit hearing aids to the intended person's specific requirements.
- **Integration of the ML system:** The ML system is integrated in the Phonak Target hearing aid fitting software.
- **Purpose of the ML system:** To provide recommendations for hearing aid domes based on audiological data
- **Contraindications:** There are no contraindications which are specific to the use of the ML system beyond those already specified for Phonak Target in the accompanying user guide.
- **Users:** Hearing Care Professionals (HCP).

Key features:

Output:

Generates hearing aid dome recommendations based on:

- Audiogram
- Hearing aid user experience level with hearing aids
- Fitting Formula.

User interface:

- Does not require input data other than that already required in the scope of the hearing aid fitting process via hearing aid fitting software
- No interpretation required
- Usability was evaluated as per IEC 62366-1 standard.

No additional instructions:

- General software usage instructions provided in the User Guide of Phonak Target.

How the ML system works:

Input parameters:

- Audiogram
- Hearing aid user experience level with hearing aids
- Fitting Formula.

All data is obtained through the standard fitting software workflow.

Factors influencing the output:

- Incomplete audiogram data.

Compatibility:

- Compatible with hearing aids listed in Phonak Target
- No additional hardware or software requirements beyond those specified in the User Guide of Phonak Target.

Calibration and monitoring:

- The ML system does not require calibration, local validation, or ongoing performance monitoring.

Data and training:

Training approaches:

- The ML System utilizes a Multilayer Perceptron (MLP) trained with supervised learning methods.

Training data:

- Approximately 50,000 samples covering typical (N1 – N5, S1 – S3) and atypical hearing loss profiles (N1 – N7, S1 – S3).
- Data collected from previous fitting software versions.

Determination of reference standard:

- The system has been tested using synthetic data as a reference standard. It covers all typical hearing loss profiles (N1 – N7, S1 – S3) as well as atypical hearing loss profiles.

Inclusion criteria:

- Complete audiogram data
- Data from hearing losses relevant for dome fitting, specifically covering N1 – N5 and S1 – S3 as per IEC 60118-15
- Samples from users with varying experience levels
- Data from countries with a Human Development Index (HDI) of ≥0.9, ensuring the consideration of high quality data.

Exclusion criteria:

- Corrupt or incomplete samples
- Samples associated with inexperienced HCPs
- Inconsistent audiogram measurements
- Fitting sessions shorter than 60 days
- Samples expected to provide low audiological performance due to feedback threshold-related gain limiting

Risk management:

- Risk management was applied in accordance with ISO 14971.
- The primary risk is the potential selection of an inappropriate dome, which may cause reduced intelligibility or a reduced wearing comfort. This is usually detected by the user and corrected by the Hearing Care Professional (HCP) during the standard dome selection process.
- All risks have been mitigated as far as possible without adversely affecting the benefit-risk ratio.

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