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1.0 Purpose

The purpose of this document is to describe the intended use of Hearlab.

2.0 Intended Use

The HEARLab system with the NAL-ACA software is a medical device intended to present a stream of auditory stimuli to a human subject and to acquire the auditory evoked cortical responses in a clinical environment. NAL-ACA is intended for use as a diagnostic aid to clinicians. It does not provide any direct diagnosis.