



PLEASE NOTE: If your device is licensed with the Vestibular Evoked Myogenic Potential (VEMP) test module, the intended use in your device manual (chapter 1.3) is adapted as follows:



Devices of the Senti and Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics and vestibular diagnostics (Sentiero Advanced only). Devices of the Senti device family provide multiple psycho-acoustic test procedures including conventional and image-based pure-tone audiometry (e.g. Audio, MAGIC) and speech tests (e.g. SUN, MATCH). Devices of the Sentiero device family additionally provide physiological test procedures including otoacoustic emissions (OAE) (e.g. transitory evoked otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE)), evoked potentials (e.g. auditory brainstem responses (ABR), auditory steady state responses (ASSR); vestibular evoked myogenic potentials (VEMP)) (Sentiero Advanced only), and auditory impedance and acoustic reflex measurements (Sentiero Desktop, Sentiero and Sentiero Advanced with tympanometry add-on).

Available psycho-acoustical methods on Senti and Sentiero are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do play/interactive audiometry. Physiological modules which require active patient participation (e.g. VEMP) are indicated for use with cooperative patients who are mentally and physically able to perform the required task. All other physiological modules are suitable to be used for all ages elder than infants from 34 weeks (gestational age) that are ready for discharge from the hospital.

All physiological test methods are especially indicated for use in defining the type and configuration of hearing loss particularly for individuals whose behavioral audiometric results are deemed unreliable or to assist in the diagnosis of otologic or vestibular disorders. Estimation of cochlear hearing thresholds (DPOAE Threshold) is possible at various frequencies without the need of cooperative interaction with the patient. Acoustic reflex and tympanometry are featured to evaluate the functional condition of the middle and outer ear. VEMP is featured to assist in the evaluation of the functional condition of the vestibular system. For each method, several protocols can be configured. The results can be used to make further recommendations regarding appropriate intervention strategies.

Devices of the Sentiero device family are intended for the following purposes:

- Diagnostics, monitoring and follow-up after newborn hearing screening
- Pre-school, school, and adult hearing screening
- ENT diagnostics based on measurement of
 - a) Otoacoustic emissions
 - b) Tympanometry and acoustic reflex (Sentiero Desktop, Sentiero and Sentiero Advanced with tympanometry add-on)
 - c) Evoked potentials (Sentiero Advanced only)



Senti and Sentiero are intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing/ENT health care professionals and personnel trained on the available test modules in a medical environment. Please consider local regulations regarding the qualification requirements for performing measurements with a specific test module.



Senti and Sentiero are not intended for operational use by the general public. All test procedures must be supervised or conducted by qualified personnel. In the United States of America, Federal law restricts this device to sale by or on the order of a licensed physician.



Senti and Sentiero are intended for indoor-use only and must be operated at defined environmental conditions. See also operating conditions in section [9: Technical Specifications](#) and information about environmental conditions regarding electromagnetic disturbances in section [10: Electromagnetic Compatibility Information](#). Senti and Sentiero are not intended for use in oxygen-rich environments.

CONTRAINDICATIONS:



Senti and Sentiero must not be used in cases of external otitis (outer ear canal infection) or in any case which yields to pain when inserting the ear probe or applying any other transducer. cVEMP on Sentiero Advanced must not be used in cases of neck, muscular and cervical injury problems and in cervical spine problems if the sternocleidomastoid muscle contraction cannot be maintained without further discomfort or pain.

SIDE EFFECTS:

There are no known undesirable side effects for devices of the Senti and Sentiero device families.