

Document Maintainer:

Release Date Document Change Log

November 19, 2009 Initial release

1.0 Purpose

The purpose of this document is to describe the Hearlab cautions and warnings for use of Hearlab during setup and actual measurements.

2.0 Acoustical Levels and Patient Safety

2.1 The software and hardware are designed to limit the acoustical signal to levels that are not harmful to a patient, even if a malfunction should occur. Malfunction of the device, including the software, may result in uncomfortably loud levels but is unlikely to cause even minor injury to the patient.

2.2 Acoustically evoked electro-physiological signals are picked up by passive electrodes placed on the scalp of the subject. Malfunction of the device, including the software, is unlikely to cause minor injury or discomfort to the patient.

3.0 Setup and Connections

3.1 To avoid electric shock hazard, care must be taken to connect cables and accessories in exact accordance with the user instructions. Only appropriately trained and skilled personnel should attempt to install the HEARLab System. The HEARLab System should be used in a clinical test environment with low ambient noise and electromagnetic field levels.

3.2 Safe use of the HEARLab System may be compromised if the user connects unsuitable equipment to the Stimulus Controller Unit.

3.3 Use only the electrode cables supplied with the HEARLab System. Do not attempt to substitute with any other cables.

3.4 Avoid the use of extension cables, or placing power cables where they present a tripping hazard. Keep hardware and cables out of children's reach.

3.5 Keep the HEARLab System hardware isolated in a well ventilated area. It should not be operated in a very enclosed area or stacked with other electrical equipment.

- 3.6 All electrical equipment within the patient test area should have approved medical safety status.

4.0 Electrode application and removal:

- 4.1 Electrodes must be applied by suitably qualified and experienced personnel. Universal precautions should be applied to reduce the risk of patient infection.
- 4.2 Avoid contact with broken skin, or patients with existing skin conditions.
- 4.3 Substances used to prepare electrode sites (e.g., abrasive liquids, gel, cream or paste), or to adhere electrodes to the skin (e.g., self adhesive electrodes, medical tapes), or the electrode itself, may produce allergic or other dermatologic reaction in some individuals. Check for history of allergic reactions before preparing electrode sites/applying electrodes.
- 4.4 Be aware that some patient populations may be at particular risk (e.g., burns patients, premature infants). If in any doubt, seek medical advice.
- 4.5 Substances used for electrode preparation and placement should be selected with regard to the manufacturer's recommendations for use with patients. Always read and follow the manufacturer's written instructions. Avoid contact with the patient's eyes. Alcohol preparation swabs are not recommended for use on infants.
- 4.6 Clinicians who have skin sensitivities should also avoid prolonged contact with preparation substances or consider wearing gloves during electrode preparation application and removal.
- 4.7 Dispense preparation substances in a hygienic manner using single use, disposable applicators (e.g., cotton swabs). To reduce the risk of discomfort or infection, avoid aggressive abrading of the skin when preparing electrode sites. Avoid the use of dry abrasive pads.
- 4.8 Do not use undue physical force when preparing skin or applying electrodes. Take particular care when applying electrodes to infants, particularly the vertex electrode, where the fontanel area is particularly susceptible to injury.

- 4.9 Thoroughly clean the skin immediately after electrode removal using clean water. Harsh agents (e.g., alcohol, acetone) are not recommended.