New aspects of hearing aid documentation according IEC 60601-2-66 and updated IEC 60118-13
Hearing Aids are medical devices!

- Medical devices should be documented according IEC 60601 standards

- Generic IEC 60601 standards are very comprehensive !!!

- Therefore IEC 60601-2-66 has been developed

- IEC 60601-2-66 Ed. 1.0: Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

- Hearing aids has NO essential performance!
Hearing Aids are medical devices!

- IEC 60601-2-66 Ed. 1.0: Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

- The numbering in IEC 60601 series is complex

- TC 29 – WG 13 decided to develop a guidance report

- IEC/TR 62809: Summary of requirements and tests to products in the scope of IEC 60601-2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems
IEC/TR 62809 – some extracts

- Expected Service life of HA – shall be stated and documented
- Markings – shall be clearly legible through service life
- Protective packaging – marking for transportation procedures
- Accompanying documents – instructions for use etc.
- Electrical Hazards – leakage current measurements
- Auditory Hazards – special marking if output > 132 dB SPL (60118-7)
- Ingress of water – IP classification
- Embedded and fitting software shall conform to IEC 62304
- Electromagnetic compatibility is tested according to IEC 60118-13
- Etc....................
IEC 60118-13

- Until now only covered immunity for mobile phones
- Will be extended to cover
  - Generic immunity
  - Electrostatic discharge
  - High power low frequency fields
  - Emission
Hearing Aids are medical devices!

- Approval of medical devices according IEC 60601 is (very) complex!

- IEC 60601-2-66 is an comprehensive but also helpful guideline for Hearing Aids

- IEC/TR 62809: Give a Summary of requirements and tests

- IEC 60118-13 regarding hearing aid EMC is updated to follow IEC 60601-1-2

- New standards will ensure an comprehensive – but known – structure for documentation in future