# Quality Standards for Auditory Brainstem Implantation (ABI) in South Africa

South African Cochlear Implant Group (SACIG)

Guidelines Established: January 2021

For review: January 2023

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#### 1. Introduction

# 1. Auditory Brainstem Implantation

1.1 Auditory Brainstem Implantation (ABI) is a process that involves the surgical implantation of an electrode array into the foramen of Luschka within the brainstem to provide direct electrical stimulation of the cochlear nucleus and subsequent central auditory pathways. A sound processor unit worn on the side of the head transmits to the internal receiver-stimulator package. The resulting electrical stimulation of the cochlear nucleus may provide auditory sensation but does not restore normal hearing. An auditory brainstem implant (ABI) may be suitable for patients who have no functional hearing secondary to damage to or congenital abnormalities of the auditory nerves or the cochlea, rendering them unable to gain adequate benefit from conventional well-fitted hearing aids or cochlear implants.

#### 1.2 Indications:

- 1.2.1. The first indication is Neurofibromatosis type 2 (NF2) which is a rare, dominantly inherited tumour predisposition syndrome predominantly affecting the nervous system, eyes and skin. The main tumours are bilateral vestibular schwannomas (formerly known as acoustic neuromas), meningiomas and ependymomas. Vestibular schwannomas usually cause deafness and balance difficulties and can cause compression of the brainstem. They may require surgical removal, which usually results in loss of the auditory nerve. Where the auditory nerves are damaged bilaterally, the only option for hearing rehabilitation is the ABI.
- 1.2.2. A second indication is where an acquired deafness develops secondary to a disease, process or injury that damages the auditory nerves bilaterally or the cochleae to such an extent that cochlear implantation is not possible or provides no benefit. Causes such as meningitis, otosclerosis or a severe head injury can occasionally lead to this outcome.
- 1.2.3. A third indication is where a child is born with no functional hearing secondary to congenital abnormalities of the cochlea or auditory nerves and a cochlear implant is not possible or provides no benefit.

#### 2. Scope

# 2.1 Aims and objectives of ABI team

- 2.1.1 The aim of an ABI service is to improve the hearing and quality of life for those with no functional hearing secondary to damage to or congenital abnormalities of the auditory nerves or the cochlea, rendering them unable to gain adequate benefit from conventional well-fitted hearing aids or cochlear implants.
- 2.1.2. The service has the following objectives:
  - ➤ To provide equitable access for all eligible children and adults meeting the referral criteria and who require an ABI.
  - > To provide a cost-effective, comprehensive service.
- 2.1.3. Additional considerations for paediatric caseload

Aims for paediatric rehabilitation

- ➤ To promote the normal developmental processes of auditory awareness and spoken language development recognising that this is unlikely to fully occur in the majority of pre-lingually deafened children
- To identify where these processes are not unfolding naturally
- ➤ To provide a remediation service in these cases —this could be through direct input or an advisory service

# 2.2 Service description/care pathway

- 2.2.1. An ABI team will function as part of a wider service including paediatric and adolescent/adult cochlear implant services. It is a multidisciplinary team made up of the following core professionals:
  - Co-ordinator / Head of Service
  - Administrator
  - Clinical Audiologist(s) with experience in advanced cochlear implant programming in adults and children
  - Clinical Audiologist (s) with experience in electrophysiological testing
  - Speech & Language Therapist(s) with extensive experience working with cochlear implant patients
  - ➤ ENT surgeon(s) who specialise(s) in both cochlear implantation and Skull Base Surgery
  - Neurosurgeon(s) who specialise in Skull Base Surgery

#### Additional Professionals:

- Psychology services
- Radiologist with a special interest and experience in neuro-imaging
- Consultant adult and paediatric neuro-anaesthetists where applicable with access to high dependency and intensive care facilities
- Geneticist

#### Social worker

- 2.2.2. All team members should be suitably qualified and registered with appropriate professional bodies, comply with HPCSA requirements and be members of the South African Cochlear Implant Group (SACIG). All will have training in deaf awareness. Clinical team members should attend regular training in developments within the field of cochlear and auditory brainstem implantation. Attendance at relevant courses, conferences and meetings at national and international levels is desirable.
- 2.2.3. Newly appointed members of the team who are less experienced must undergo an appropriate programme of training and supervision provided by relevant experienced members of an ABI team. All team personnel must maintain a programme of continued professional development to ensure ongoing competency.
- 2.2.4. All patients will undergo comprehensive assessment by a specialist multidisciplinary team to assess suitability for auditory brainstem implantation. Good, transparent communication between all team members is essential to ensure the patient is holistically evaluated and receives congruent feedback. Once the assessment has been completed the core ABI team will meet to discuss candidacy and their recommendation will be communicated to the patient following the meeting.
- 2.2.5 Given the very high level of expertise required to deliver the service, the ABI teams will be required to seek international mentorship from clinicians who are recognised leaders in this field.
- 2.2.6. The pre-operative assessment will include all or some of the following:
- 2. 2.6.1. Audiological assessment may include (as appropriate): case history, otoscopy, tympanometry, age-appropriate behavioural assessment, objective hearing assessments, hearing aid evaluation, aided speech perception testing and balance function testing (See **Appendix A**: *Guidelines for Pre- and Post-Operative Audiological Assessment for adults and children*).
- 2.2.6.2. Medical assessments: clinical history; physical examination; fitness for surgery; radiological evaluation via MRI and CT imaging; additional handicaps with associated co-morbidities and medical suitability for ABI.
- 2.2.6.3. Rehabilitative team assessments: speech and language skills; functional listening; quality of life; development and cognitive ability, level of cognitive function (including intellect, learning and memory, language development, motor abilities, concentration); psychological fitness for ABI; ability to access intervention services and participate in rehabilitation programme; availability of support & liaison with local services; family support and involvement (The Family Involvement Rating Scale (Moeller, 2000) should be completed for children to assess the family's participation in their child's re/habilitation) and future schooling options (children)/employment options (adults).
- 2.2.6.4. Socio-economic assessment of patient and family

2.2.6.5. Patient / family / carer understanding and expectations of implantation and informed consent.

The service will ensure access to further appropriate services and care for patients with complex and special needs.

- 2.2.7. As part of the assessment process, patients who may be candidates for implantation and their families / carers as appropriate, should receive information about support groups including contact with deaf patients of a similar age (and their families for paediatric patients) who are users of ABIs, either face to face or via alternative media. Patients should be offered written information to help them make informed decisions about their healthcare, at appropriate points within the assessment process.
- 2.2.8. Patients (and their families or carers) should be given appropriate time and space to consider all the information and the implications of implantation. If, following a multi-disciplinary team assessment, it is determined that patients are not suitable or would not benefit from an ABI, the ABI team will ensure that:
  - ➤ The patient and/or the family/caregivers have the opportunity to discuss the outcome of the assessment.
  - ➤ A report is sent to the referring agent which will include:
    - o Reasons why an ABI is considered unsuitable.
    - Recommendations for future management, and referral for other equipment and /or services if appropriate.
- 2.2.9. For patients who meet the suitability criteria, the service will provide appropriate surgical auditory brainstem implantation. Verbal information should be supported by a written summary to the patient or family / carers. Throughout the assessment period patients or families / carers should have a clear understanding of the benefits and limitations of implantation. They should demonstrate that they have realistic expectations of auditory brainstem implantation, e.g. by using a measurement tool such as an expectations questionnaire and be aware that outcomes with ABI are variable.
- 2.2.10. The ABI device offered will
  - Have a proven track record for safety and reliability.
  - ➤ Have FDA and/or CE approval.
  - Conform to the recommendations of the Medical and Health Care Product requirements in South Africa.
  - ➤ Have high quality clinical and technical support available from the manufacturer and distributor in South Africa.
- 2.2.11. The in-patient period will include the following:
  - The surgery completed by an experienced, specialist team comprising neurosurgeon, ENT surgeon and adult or paediatric neuroanaesthetist. Implantation must be carried out by appropriately qualified surgeons who have an adequate caseload to maintain

- surgical skills and optimise outcomes. Anaesthetics must be carried out by appropriately qualified anaesthetists carrying out an adequate caseload of neurosurgery to maintain skills and optimise outcomes.
- Intra-operative testing
- A minimum of a 1-night stay in high dependency settings postoperatively with the option for intensive care if necessary, followed by admission to a neurosurgical ward until discharge.
- Surgical facilities should afford appropriate standards of safety, accessibility, cleanliness, privacy and dignity and also take into account the communication needs of deaf patients. The service may be required to provide evidence of quality standards relating to surgical facilities.

# 2.2.12. Prior to discharge the patient should receive:

- Written information regarding care of the wound/ear and pain management post operatively.
- Written guidelines on what to do should medical /surgical problems arise.
- Advice regarding health and safety with an ABI.
- Written manufacturers safety guidelines.
- 2.2.13. Initial activation to take place approximately 6-8 weeks postoperatively or as close as practicable. Young children will be admitted for 48 hours as an in-patient; initial activation will take place under general anaesthetic allowing repeat intra-operative testing; second activation will take place the following day with access to cardiac monitoring and resuscitation equipment. Adults, older children and adolescents will have initial activation with access to cardiac monitoring and resuscitation equipment, typically in a High-Care unit.
- 2.2.14. The service will ensure that the intensive rehabilitation needs of the patient will be appropriately addressed. For most patients, this will routinely take place during the first year following implantation but flexibility should be available to target support to the needs of the patient as necessary. The service must be able to provide all elements of rehabilitation and long-term follow up but tailor what is provided according to the needs of each patient. For pre-lingually deafened children in particular it may not be possible by the end of the first year post implant to identify their developmental trajectory and hence their future support needs.

# 2.2.15. Rehabilitation requirements may include:

- Medical check following implantation of surgical site and device placement and functioning.
- Initial activation and programming of sound processor.
- On-going sound processor programming and assessment dependent on individual need – at least six appointments will be required in the first year following activation. This may reduce to a minimum of 1 review appointment annually thereafter for adults however more may be required for children initially and for long term management.

- After the first year following implant surgery, the patient should be seen annually for audiological review. Patients should also have access to additional appointments as required.
- Sound awareness training and auditory training to develop auditory skills (including detection, pattern perception and, if possible, higher levels of auditory skills).
- Auditory-visual training with sign supported communication if indicated
- Communication skills training
- Listening and language skills development training and / or support on an individual patient needs basis.
- Training provided at the centre and as outreach where appropriate. Advice to patient (and carers if appropriate) on care and use of processor and equipment.
- Advice to other organisations e.g. trouble shooting advice for local staff (for children).
- ➤ On-going support and maintenance including a comprehensive spares and repairs service.
- ➤ Medical access to an annual appointment and ad hoc as required.

# 2.2.16. Post-operative audiological assessment:

- Recognised & validated developmentally age appropriate audiological and speech perception measures should be performed on at least two occasions in the first year following surgery (at 3-6months post activation and at 1 year) then at a minimum annually after activation to monitor progress with the ABI.
- The patient's daily use of their ABI sound processor, their ability to hear sounds and speech, as well as their quality of life should be monitored (See Appendix A: Guidelines for Pre- and Post-Operative Audiological Assessment for adults and children)
- 2.2.17. Patients and or carers will be trained by the service to carry out simple trouble-shooting and maintenance such as visual inspection of external parts, including any leads and adaptors, battery replacement and subjective listening checks (where possible). For more complex maintenance needs, the ABI team will provide advice via telephone, e-mail, text etc. and make arrangements whereby external implant parts can be bought or posted to the ABI team during opening hours. The service should aim to resolve repair issues within 2 working days. Adequate spares/ replacements of external equipment must be available as required. Replacement equipment should be issued or dispatched on the same or next working day. Sound processor batteries should be available to implant users either from the ABI programme or manufacturer.
- 2.2.18. Patients should be advised they have access to urgent medical support as required 24 hours per day.
- 2.2.19. The ABI team will have appropriate policies which cover, as a minimum:
  - Device failure
  - Lost processor/s

- Assistive Listening Devices
- Upgrade of sound processor/s
- Transfer of care pathway to another service
- 2.2.20. The ABI team will provide re-implantation under the manufacturers 10-year warranty in the case of implant failure. If an implant fails after this time, funding options to cover the cost for a new device and associated surgery and programming will be explored and motivated for. The device failure should be reported to the local ABI distributor. If device failure is suspected the patient must be offered an appointment promptly (within 7 working days) to check the external and internal components of the implant device.
- 2.2.21. Essential consumables and spare parts should be available to users. They will be supplied free of charge if they are within warranty. Users will be asked to pay for items that are out of warranty, repair or replacement of parts or devices if damage, loss or failure is determined to be due to inappropriate care, with appropriate provision for appeal.
- 2.2.22. Records of consultations, programming and all tests performed must be kept on file.
- 2.2.23. All records and measurements should be available on request and provided, with patient or parent consent, to other parties who may have a legitimate reason for using them, e.g. education, health services etc.
- 2.2.24. The following are over-arching principles that are to be applied to each provider delivering an auditory brainstem implantation service:
  - Consideration should be given to the needs of a deaf population in all aspects of the design of the service.
  - ➤ There must be clearly defined clinical and managerial accountability within the service.
  - ➤ All work processes are to be protocol-led and clearly defined.
- 2.2.25. Where elements of the ABI service are referred to another provider, there should be clear and formal accountability processes and structures in place to ensure continuity of clinical care that is safe and effective. All referral agreements have to be agreed in advance. These service providers will be expected to provide services of the same level and quality of service as the core ABI team.

#### 2.3 Population covered

The population covered is adults and children with bilateral profound functional deafness due to severe disease processes or congenital abnormalities affecting the cochleae and/ or auditory nerves rendering them unsuitable for cochlear implantation.

Initially the ABI team will start only with adult cases until such time as they are experienced enough to take on paediatric cases.

# 2.4 Acceptance and exclusion criteria

## 2.4.1. Referral sources may include:

- General Practitioners
- State or private audiologists
- Ear, Nose and Throat (ENT) Services
- > NF2 Service providers
- Cochlear Implant Services
- Neurosurgeons
- Neurologists
- Paediatricians

#### 2.4.2. Written referrals should be made to the ABI team providing evidence of:

- ➤ A hearing aid trial of at least 6 weeks (where possible) or a reason as to why this is contraindicated or inappropriate.
- Why a cochlear implant may be contraindicated (where possible), specifically including MRI and CT scans done to date.
- 2.4.3. When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team should be mindful of the need to ensure equality of access. Tests should take into account a person's disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, and may need to be adapted. If it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment should be considered
- 2.4.4. Prelingually deaf children referred over the age of 3 years will be considered for ABI on a case-by-case basis. Considerations include previous auditory input, level of spoken language, home support and input and access to rehabilitation

#### 2.4.5. Patients will be excluded if:

- they are not medically suitable to undergo skull base neurosurgery
- there are inappropriate expectations as to the expected outcome of auditory brainstem implantation despite counselling
- a pre-lingually deafened child has significant cognitive disability

# 2.5 Interdependencies with other services

The ABI team will interact with the following other services:

- In-patient Neurosurgical services including critical care
- Primary Care
- Audiology Services

- Newborn Hearing Screening Programmes
- Appropriate rehabilitative services which may include Speech & Language Therapy, Educational Services or other specialist teaching services, Social Services including Social workers, Occupational therapy, Physiotherapy, and Psychology.
- Cochlear Implant teams

# 3. Applicable Service Standards

# 3.1 Applicable national standards

- 3.1.1. Primary ABI services will be provided through the Johannesburg Cochlear Implant Programme as well as the Tygerberg Hospital Stellenbosch University Cochlear Implant Unit. A core ABI team within the Johannesburg Cochlear Implant Programme as well as the Tygerberg Hospital Stellenbosch University Cochlear Implant Unit will take the responsibility for the primary care of ABI patients in South Africa. As the rehabilitation required to support successful use of ABIs can be intensive and long-term, these services could be provided either by the nearest ABI centre or on a shared-care basis with the local cochlear implant service.
- 3.1.2 Auditory Brainstem Implant clinical outcomes will be combined and shared by the two ABI teams in South Africa.
- 3.1.3 The two ABI teams will work collaboratively and meet at least annually (or more frequently on a virtual platform) to discuss patients under assessment, share combined clinical outcomes, adverse events, discuss relevant published literature and developments in the field to ensure the safe and effective provision of an equitable national service that meets the needs of the identified population.
- 3.1.4. ABI teams should have access to appropriately calibrated and up-to-date equipment and facilities to enable all appropriate assessments to be undertaken (See **Appendix B**: *Clinical and Audiological facilities*).
- 3.1.5. Facilities should afford appropriate standards of safety, accessibility, cleanliness, privacy and dignity and also take into account communication needs of deaf patients and requirements for specific assessments such as sound-proofing. The design and layout should take into account the needs of families and young children within their client group (See **Appendix B**: *Clinical and Audiological facilities*).

#### 4. Location of South Africa's ABI teams

The current South African ABI teams' premises are located at:

 Johannesburg Cochlear Implant Centre, Wits Donald Gordon Medical Centre, 18 Eton Rd, Lower level, Parktown, Johannesburg

+27 11 482 6141 / admin@jcic.co.za

 Tygerberg Hospital Stellenbosch University Cochlear Implant Unit Room 21, 5<sup>th</sup> Floor Gold Ave Tygerberg Hospital Francie van Zijl Drive Tygerberg, Cape Town

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#### Resources

The following resources were used in the compilation of this document and can be referred to for further information:

- Asfour, L, Friedmann, D.R., Shapiro, W.H., Roland, J.T. & Waltzman, S.B. Early experience in and health related quality of life outcomes following auditory brainstem implantation in children. International Journal of Pediatric Otorhinolaryngology 113 (2018): 140-149.
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# APPENDIX A: GUIDELINES FOR PRE- AND POST-OPERATIVE AUDIOLOGICAL TESTING OF ADULTS AND CHILDREN WITH ABI

#### A. PRE-OPERATIVE AUDIOLOGICAL ASSESSMENT

The audiological assessment should include:

#### **Audiometric assessment:**

- Detailed case history.
- Otoscopic examination.
- Determination of bilateral middle ear function using tympanometric techniques.
- Determination of ear-specific unaided hearing thresholds (air and bone conduction) at all frequencies (125 – 8000Hz) bilaterally using pure tone audiometry (5dB steps).
- In the case of children developmental age appropriate test procedures should be used.
- Objective hearing threshold assessment, including Stapedius Reflexes, Otoacoustic Emissions and Auditory Evoked Response Audiometry including click ABR, cochlear microphonic testing, tone burst ABR and ASSR as indicated.
- Unaided ear specific speech perception testing (recorded speech) if indicated.

# **Hearing Aid Evaluation:**

- Each patient should have their current hearing aid provision re-evaluated and where appropriate have new hearing aids fitted or settings revised. Verification of the suitability of amplification should be undertaken.
- In some cases a hearing aid trial may be waived at the discretion of the audiologist (e.g. adult NF2 patients who are not wearing a hearing aid due to severe distortion or because they still have enough residual hearing to cope without a hearing aid).

# Assessment of ear-specific aided benefit should include:

- Aided sound-field thresholds at all frequencies (250-6000Hz) tested with warble tones (frequency modulation) at 0° azimuth (1m from loudspeaker) (5dB steps).
- Speech perception testing:
  - i. Use recorded speech materials or, in the case of younger children, live voice.
  - ii. Presentation level of speech materials should be 60dBSPL 0° azimuth 1m from loudspeaker.
  - iii. The speech perception materials should be hierarchically organized and test the ability to discriminate words in a closed set based on temporal and stress cues as well as phonemic identification. According to the

linguistic level of the patient, open set monosyllabic word identification and sentence tests should be performed. If indicated, these tests should be performed in the auditory only, visual only and auditory-visual conditions.

- iv. Speech perception tests:
- Adults and older children:
- Closed-set words: e.g. 4-Choice Spondee Test/4-Keuse Spondee Toets.
- Open set Spondee Recognition / Spondee Herkenning.
- Open-set monosyllable words: e.g. NU6 words/FG Woorde
- Sentence Test: e.g. CID Sentences/CID Sinne
- Young children:
- Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) (Zimmerman-Phillips, Robbins & Osberger, 2001)
- Phoneme and vowel detection and identification test
- Closed-set words: e.g. Early Speech Perception Test (Low verbal/standard version) in English/Afrikaans; WIPI/ODPI
- Open-set monosyllable words: e.g. Open set Monosyllables/Oop Stel Monosillabes; Lexical Neighbourhood Test/Multisyllabic Neighbourhood Test
- Sentence Test: e.g. Listen and Do; TAPS 5B Modified open set sentences; BKB Sentences/BKB Sinne
- Determine Category of Auditory Performance (CAPII) score based on speech perception scores and observation

#### Vestibular assessment:

Any patient with vestibular / disequilibrium - related complaints to be referred for further vestibular function investigation as directed by the ENT surgeon. Subjective or behavioural as well as objective testing may be required.

Dizziness Handicap Inventory (Jacobsen, & Newman, 1990) to be administered for adults if any history of dizziness / vertigo incidents reported.

#### Tinnitus assessment:

The Tinnitus Handicap Inventory (Newman, Sandridge & Jacobsen 1998)) should be used if the patient reports a history of tinnitus.

#### Self-assessment questionnaires:

Questionnaires to determine additional hearing impairment, handicap and disability symptoms as well as functional performance are recommended as appropriate viz.

#### Adults:

• The Revised Hearing Handicap Inventory /Gehoorgestremdheid Inventaris (Cassarly, 2020)

## Children (3-17years old):

 KINDL-R: Questionnaire for measuring Health Related Quality of Life in Children and Adolescents (www.kindl.org/english/questionaires). The choice of questionnaire (kiddyKINDL, kidKINDL or kiddoKINDL) and use of child/parent version is age dependent. The preliminary CI specific subscale considered appropriate for ABI recipients as well can be included where appropriate (Warner-Czyz in Asfour et. al., 2018)

#### **B. POST-OPERATIVE AUDIOLOGICAL ASSESSMENT**

#### Audiometric assessment:

- 1. Otoscopic examination and tympanometry.
- 2. Aided sound-field thresholds 125Hz 6000Hz tested with warble tones (frequency modulation) at 0° azimuth, 1m from loudspeaker, in 2dB steps.
- 3. Aided speech detection/awareness threshold.
- 4. Aided threshold testing of the implanted ear/s to be conducted at the following intervals:
  - Young children: 3-monthly for the first two years, 6-monthly for the following two years and annually thereafter.
  - Older children: 6 monthly for the first two years and annually thereafter.
  - Adults: at 3 months, 6 months, one year and annually thereafter.

#### 5. Aided speech perception testing:

- Age and linguistically appropriate speech perception materials should be conducted at the following intervals:
- Children: 6 monthly for the first two years and annually thereafter.
- Adults: 6 months, one year and annually thereafter.
- Speech test materials: phonemes, monosyllabic word and / or sentence materials (same tests and conditions as pre-implant) should be used.
  Presentation level at 60dBSPL 0° azimuth 1m from loudspeaker, ideally recorded materials), or live voice for young children.
- In cases where a patient cannot be tested auditory only and speech materials are presented with lip reading live voice should be used.
- Determine Category of Auditory Performance (CAPII) score based on speech perception scores and observation

#### **Objective measure of ABI use:**

A record of the patient's average daily use of his/her ABI sound processor should be obtained from data logging.

# Self-assessment questionnaires

The same self-assessment questionnaires used pre-operatively should be readministered annually for the first three years post-implantation.

In addition, for children, parents to complete the **Children with Cochlear Implants: Parental perspectives survey** (as adapted for ABI in Asfour et al., 2018) at the 1 year follow up.

#### References:

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# APPENDIX B: CLINICAL AND AUDIOLOGICAL FACILITES

# • CLINICAL FACILITIES:

Clinical areas should be large enough to comfortably accommodate the patient, family member(s) and clinician together with the necessary equipment. A suitable room should be available for group work including patient activities and team meetings / training. There should be a suitable waiting area near the treatment rooms, large enough and with sufficient comfortable chairs to accommodate the number of people likely to be waiting at any one time. The treatment rooms and waiting area should be sufficiently separated that noise from the waiting area does not disturb the treatment, and that privacy is maintained.

#### • AUDIOLOGICAL FACILITES:

Audiological testing should be performed in a soundproof booth according to SANS 10182:2006 standards. The size of the soundproof booth should also allow for free-field testing that is at least 2.2m in dimension. Examination rooms must meet current appropriate South Africa health and safety guidelines. All rooms should comply with health and safety regulations.

Centres who provide ABI's to children should also have the following audiometric equipment and facilities in place:

- 1. The test should be performed in a room that is of adequate size to accommodate parent(s), child and a distractor/assistant comfortably. The size of the soundproof booth should allow for free-field testing (2.2 meters in dimension).
- 2. Audiometer with sound field capability:
  - Loudspeakers shall be positioned at 90°azimuth (reference equivalent threshold sound pressure levels, RETSPLs, are only available for these angles of presentation) relative to, and at least 1 m from, the test position to each side (BSA, 2008). The speakers should be approximately level with the child's head; such positioning provides the most efficient means for conditioning the behaviour and establishing Minimum Response Level (MRL).
  - Visual re-enforcers (e.g., multiple animated toys individually housed in dark Plexiglass boxes; illuminated and/or activated remotely) or video reinforcement system located 90-degrees to both sides of the child at eye level. The reenforcers should be located approximately level with the child's head at a distance of 1-2 m. Close proximity between speaker and re-enforcer is preferred in order to aid conditioning when using sound-field stimuli; adjacent positioning of loudspeaker and re-enforcers is recommended. Re-enforcers should be positioned to both sides Earphone masking system for mid-line distracter and parent are recommended.

All audiological equipment should be calibrated annually, and a system of daily checking should be in place.