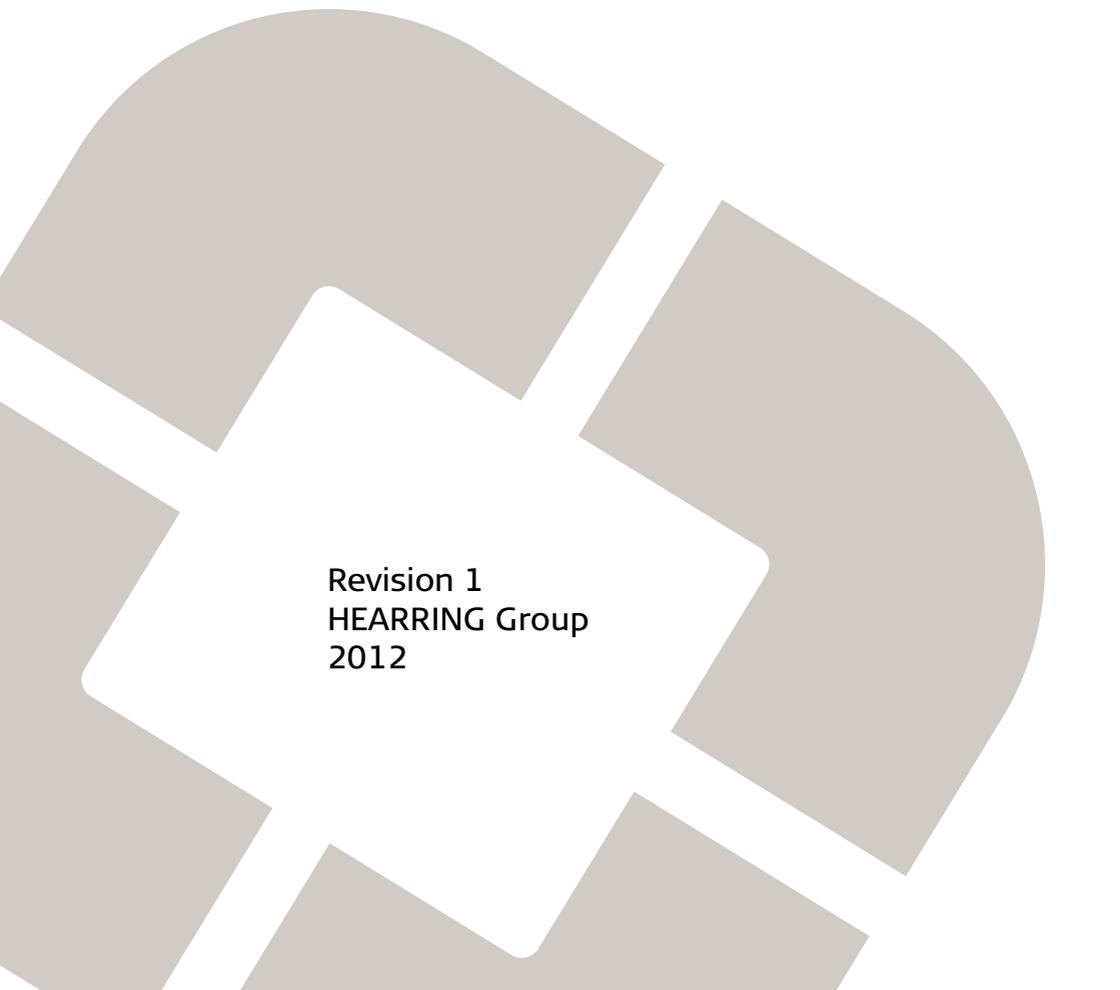


Quality Standards for Combined Electric and Acoustic Stimulation



Revision 1
HEARRING Group
2012

This clinic is a member of the HEARRING network.

HEARRING is a **learning network of collaborative experts** in the field of hearing implants. It is an association of preeminent international centers offering comprehensive hearing implant solutions for the treatment of hearing loss.

HEARRING members are committed to leading the exploration of new avenues of research in hearing implant science, to advancing clinical procedures and to developing and perfecting surgical techniques. Membership in the HEARRING network is founded on the belief that research, and any subsequent advancement in the field of hearing implants, is possible only through **international collaboration** and the pooling of collective experience from leading clinical centers around the world.

In order to provide each patient with the best possible hearing implant solution for the treatment of her/his individual hearing loss, the HEARRING network is committed to the **highest standards of quality**.

HEARRING surgeons are worldwide **leading experts** in restoration AND preservation of hearing.

Because the field is developing quickly and encompasses an ever-growing knowledge base which includes new scientific insights, technologies and materials, HEARRING members' **collaborative research** initiatives are extremely important to the success of each individual member clinic. To meet the challenges of the future, HEARRING will continue to not only develop and advance standards in the field but will also make these standards transparent.

... network with the experts

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1 Introduction

Electric Acoustic Stimulation (EAS) is a modification of the cochlear implantation (CI) procedure that combines electric stimulation by means of a cochlear electrode and acoustic stimulation using classical amplification of residual hearing in the same ear.

In contrast to the classical indication for CI (complete deafness, profound pancochlear hearing loss, severe progressive hearing loss), EAS is used in cases with a special type of "partial deafness", defined as a mild to moderate hearing loss in the low frequencies sloping to a profound hearing loss in the higher frequencies.

In these cases, hearing aids often provide unsatisfactory results for understanding speech in noise or for listening to music. Conventional cochlear implant systems are also not ideal because they do not allow users to benefit from their natural low frequency hearing abilities. The most effective hearing restoration should be possible by electrically stimulating the malfunctioning parts of the cochlea (in the basal turn) while using the residual (mainly low-frequency) physiological hearing of the upper parts of the cochlea.

Thus the success of EAS is based on two factors: firstly, the preservation of residual hearing of low frequency sounds following cochlear implantation, and secondly an optimised and balanced control of electric and acoustic stimulation.

The most essential part of the EAS concept is the preservation of the residual hearing in the affected ear. This means that despite the insertion of an electrode into the basal cochlear turn, the cochlear anatomy is kept intact, allowing natural acoustic stimulation of functioning parts of the cochlea (the middle turn or apex). Therefore an atraumatic surgical technique for electrode insertion is crucial.

Following electrode insertion with hearing preservation, an optimised and balanced control of electric and acoustic stimulation is necessary to obtain results superior to those of hearing aids or conventional CIs. By simultaneously processing high frequencies electrically and low frequencies naturally, input of acoustic information into the central auditory pathways can be further improved.

In several clinical studies, EAS has proven to yield superior results compared to partially deaf patients who use only hearing aids.

The system consists of two parts, an external component and an internal one.

1.1 Internal

Implant:

The implant consists of the electronics and their housing, an atraumatic electrode array, the receiving antenna, and a magnet that holds the coil in place behind the ear.

Electrode array:

In order to minimise insertion trauma and to preserve residual hearing, a special EAS-electrode has been developed, which is designed to slide smoothly along the lateral wall of the scala tympani. The electrode is extremely flexible, and its small diameter allows for a small insertion opening into the cochlea (via either the round window or cochleostomy).

1.2 External

Audio processor for combined electric and acoustic stimulation:

The EAS audio processor is worn behind the ear and combines CI technology and acoustic amplification. Thus, residual natural low-frequency hearing can be enhanced acoustically, while higher frequency sounds are conveyed electrically by the CI-function of the processor.

The HEARRING network is committed to the highest standards of quality. In order to ensure a consistently high level of service and the effectiveness of implantation, and to provide each patient with the best possible hearing implant solution for the treatment of their individual hearing loss, we have established this set of quality standards. The standards are a realistic minimum attainable by all HEARRING member clinics, and should be employed alongside current best practice guidelines.

2 Team Structure

2.1 Structure of the EAS implant team

The team structure for EAS does not differ from that for standard cochlear implantation, but additional knowledge and expertise in the field of EAS is required.

The EAS implant team may function independently or as part of a wider service within a hearing or hearing implant centre, including paediatric and teen cochlear implant services. It is a multidisciplinary team made up of the following key personnel:

a. **Otologists**

The responsibility for EAS implantation and all completed diagnostic procedures will remain with the surgeon, who must be skilled in the special field of CI. A minimum of 20 cochlear implant operations per year is recommended to maintain the necessary level of expertise. In addition, the surgeon must be familiar with surgical techniques for hearing preservation as they apply to specialist EAS centres. In particular, surgeons should be trained in atraumatic electrode insertion in temporal bones.

The surgeon will participate in the process of auditing EAS cases and in compiling a detailed database of such cases.

b. **Audiologists, Clinical Scientists, Physiologists, Rehabilitation Therapists, Hearing Therapists, Speech & Language Therapists, Clinical Physiologists, Engineers, Coordinator**

These personnel must be qualified to a post-graduate level, and hold an accredited MSc or similar qualification according to national standards. In addition, two years of practical experience, a qualification in approved hearing therapy modalities and an adequate knowledge of EAS are mandatory.

The team must be skilled in the field of cochlear implantation, including having knowledge of the multidisciplinary areas and research responsibilities within the EAS programme. The Coordinator is responsible for the day-to-day management of the programme and will ensure that appropriate services are provided for each patient according to the EAS patient pathway. They will be a core team member with further specialist training in cochlear implantation and the special features of EAS. The Coordinator will have a high level of clinical, organisational, leadership and professional skills.

c. **Administrator/Secretary**

The administrator will hold appropriate secretarial qualifications and have a high level of organisational, communication and information technology skills. They will work closely with the Head of Service.

d. **EAS Implant Head of Service**

The Head of Service, in addition to the above, is accountable for the delivery of the multidisciplinary service. They will provide scientific and clinical leadership and will have managerial responsibility for service design, forward planning, finance, patient management and human resources. They will typically be a senior clinician of their profession and be qualified to PhD level (or have equivalent knowledge and skills), with further specialist training and experience (ideally a minimum of 10 years) within the field of cochlear implantation, together with knowledge and understanding of the multidisciplinary areas within the programme.

- e. EAS implant team personnel should be members of the relevant national and / or international cochlear implant professional groups.
- f. Clinical team members should attend regular training in developments within the field of cochlear implantation. Attendance at relevant courses, conferences and meetings at national and international levels is desirable. Regular attendance at national meetings should be available for all team members. All team members should have a plan for their continuing professional development.
- g. All team members should be trained in awareness of Deaf culture and in practical aspects of communicating with people with hearing loss, as part of their induction.
- h. Personnel requirements for EAS implantation should be in line with national standards and guidelines. One person can be in charge of several of the roles described above.
- i. Newly appointed members of the team who are less experienced must undergo an appropriate programme of training for EAS and should be supervised by adequately experienced members of a cochlear implant team.

2.2 EAS Implant Team: Additional support

For the necessary fitting and adjustment of the acoustic part of the EAS audio processor, a skilled acoustician and / or audiologist, with ample experience in providing hearing aids to severely or profoundly deaf people, should be part of the team.

If the EAS team does not include professionals from the following services or specialities, a close clinical contact with them must be guaranteed:

- a. Hearing aid acoustician services
- b. Tinnitus
- c. Balance
- d. Radiology
- e. Medical physics
- f. Genetic counselling
- g. Psychology
- h. Psychiatry
- i. Interpreter services
- j. Social services for the deaf
- k. Deaf advocacy

EAS implant teams may cooperate with local services where appropriate. Such partnership services must have appropriate training and expertise.

3 Accommodation

- 3.1 To ensure ease of communication there should be suitable telecommunication access for hearing impaired or partially deaf patients and their relatives. This should include the necessary facilities for the patient to contact the clinic through a variety of modes (e.g. speech-to-text, text-to-text, fax, or e-mail).
- 3.2 All patient areas should be appropriate to the needs of hearing impaired persons. This should include consideration of visual alerts (e.g. patient appointment information), visual alarms (e.g. fire alarms) and appropriate listening devices in the patient clinic.
- 3.3 Proper accommodation for the patient and family members should be offered, and rooms for clinical examinations and counselling interviews (by clinician,

observer, and / or interpreter) must be appropriate, and must have the necessary technical equipment.

- 3.4 Common rooms for group work including patient activities and team meetings / trainings should be available.
- 3.5 Waiting areas should be easily accessible and offer proper facilities for all patients and accompanying persons. This should include a separate area suitable for children.
- 3.6 Examination rooms should be sufficiently separated from waiting areas so that noise from the waiting areas does not disturb counselling and treatment, and privacy is guaranteed.
- 3.7 All facilities and rooms must comply with current relevant health and safety regulations and guidelines.

4 Clinical Facilities

4.1 Clinical facilities should be available for:

- a. Pure tone audiometry
- b. Speech perception testing
 - (1) In quiet
 - (2) In noise
- c. Sound field audiometry (preferably sound localisation tests)
- d. Hearing aid testing and fitting
- e. Probe-tube microphone measurements
- f. Tympanometry
- g. Otoacoustic emissions testing
- h. Objective measurements
 - (1) Evoked response audiometry
 - (2) Electrically evoked potentials
 - (3) Electrocochleography, e.g. neural response telemetry
- i. Balance function testing
- j. Imaging procedures

4.2 Audiological equipment

All audiological equipment must meet nationally recognised standards.

Audiological equipment must be calibrated to national standards as required, on an annual basis, using recommended methods, and must undergo a daily on-site system check.

All testing should be carried out according to professionally recommended protocols and procedures.

5 Referral and Selection Criteria

5.1 Guidelines for the referral of patients for assessment of their suitability for EAS, and patient selection criteria, should be available in writing on request.

5.2 The selection criteria for EAS:

a. Pure tone audiogram (PTA):

A sloping curve of pure tone thresholds with normal hearing or a mild to moderate hearing loss in the low frequencies decreasing to a profound hearing loss in the higher frequencies.

b. Speech recognition scores:

Despite intensive fitting of hearing aids, satisfactory speech understanding cannot be obtained. On language-adapted monosyllable testing the patient's individual word recognition score is $\leq 60\%$ at 65 dB SPL in the best aided condition.

c. A sufficient distance between useful amplification levels with the hearing aid and uncomfortable loudness limit is a precondition for the later use of acoustic amplification by the EAS audio processor.

d. Additional patient criteria:

(1) No progressive hearing loss within an adequate observation period

(2) No autoimmune disease

(3) No hearing loss as a result of cochlear ossification (e.g. due to meningitis or otosclerosis)

(4) No malformation or obstruction of the cochlea

(5) No air-bone gap > 15 dB

(6) No external ear contra-indications to using amplification devices.

Selection of candidates should be in line with relevant national standards and guidelines.

- 5.3 If a patient does not fulfil the selection criteria for EAS, their suitability for CI should be assessed.
- 5.4 Patient selection criteria should be reviewed regularly by the HEARING Group, to inform national authorities regarding recommendations for future developments in this area.

6 The Assessment Process

The assessment process shall be performed in the most efficient and timely way possible. The time frame for necessary diagnostics depends on individual needs, but shall not exceed 18 weeks.

- 6.1 Unless clinically contra-indicated, all patients must have a comprehensive EAS implant assessment. The assessment process follows a standardised diagnostic path that allows classification of the patient's individual hearing abilities as precisely as is necessary for a final recommendation of EAS implantation. This means that EAS is clearly expected to provide better speech perception than hearing aids or CIs alone.
- 6.2 Coordinated management of the pre-implant assessment process should be organised and reviewed by a coordinating member of the EAS team (e.g. the Head of Service).
- 6.3 Service delivery should consider the aims and objectives of the national governmental authority frameworks.
- 6.4 For each patient, the assessment track must be followed according to a written check-list and recorded in the patient's hospital file.
- 6.5 Following the pre-operative assessment, a written report detailing the outcome of the assessment will be sent to the referring agent within the appropriate reporting timescales.

6.6 Waiting times for diagnostic testing and treatment should be as short as possible and comply with current national and local targets. Current HEARRING targets are six weeks for diagnostics and 18 weeks for treatment.

6.7 Details on locally agreed patient pathways should be available on request.

6.8 Fast tracking of patients through the assessment process must be available when clinically indicated.

6.9 Pre-operative assessments should include the following:

6.9.1 Medical:

- a. All patients referred to the EAS / cochlear implant centre should have a medical consultation with the team Otologist or other locally agreed on appropriately trained and experienced medical practitioner. The Otologist should adhere to the current recommendations provided by the medicines and health care products agency.
- b. Possible contra-indications to CI or EAS, according to the patient's indication criteria, must be evaluated.
- c. The referral of patients for MRI, CT or X-ray is the responsibility of the Consultant Otologist or other appropriately trained and experienced medical practitioner. Final evaluation of radiological findings is the responsibility of the surgeon.
- d. A balance / vestibular examination is part of the diagnostic path.
- e. The surgeon, or a specially authorised medical practitioner of the team, must check:
 - (1) Whether medical findings allow the patient to undergo surgery
 - (2) Whether all associated risks have been sufficiently explained to the patient
 - (3) Whether the need for vaccination to minimise the risk of pneumococcal meningitis has been adequately clarified
 - (4) Whether genetic counselling is required and / or has already been performed
 - (5) Whether the patient's consent to the treatment has been confirmed in writing and has been based on the necessary information.

6.9.2 Audiological

- a. Each patient must receive a full audiological assessment performed according to professionally accepted protocols.
- b. The audiological assessment must include:
 - (1) Otoscopic examination of the ears by microscope
 - (2) Determination of hearing thresholds bilaterally using pure tone audiometry
 - (3) Determination of uncomfortable loudness limits
 - (4) Objective hearing threshold identification (BERA)
 - (5) Determination of bilateral middle ear function using tympanometric techniques
 - (6) Speech perception testing in quiet and in noise
 - (7) Hearing aid testing and evaluation
 - (8) APHAB test or appropriate quality of life test
- c. In addition to the above audiological assessments, the EAS implant programme should include electrically evoked response audiometry, promontory stimulation testing and measurement of otoacoustic emissions.

6.9.3 Hearing aid evaluation

Testing or evaluation of best hearing aid conditions is indispensable. This includes:

- a. Aided soundfield hearing thresholds
- b. Speech perception testing using standardised pre-recorded speech material, and live voice where appropriate
- c. Measurement of electroacoustic performance of hearing aids according to current standards, and programming them to optimal settings

6.9.4 Patients fitted with new hearing aids or given a change of hearing aid settings

Patients fitted with new hearing aids or given a change of hearing aid settings may require access to a structured programme of auditory rehabilitation. For some patients the period may be extended to several months for clinical reasons.

6.9.5 Communication

Pre-operative assessment may include a full assessment of the patient's communication and social strategies. These assessments may take the form of observation, subjective description, or evaluation using formal test procedures. The assessment procedure will take into account the patient's age and hearing status and will normally include a detailed case history, and an assessment of the patient's receptive and expressive skills.

The following areas may be assessed:

- a. Receptive skills - listening skills for speech
 - (1) Lip reading skills
 - (2) Comprehension of spoken language

- b. Expressive skills
 - (1) Language skills in all communication modes
 - (2) Intelligibility, voice and speech sound system

- c. Details should be collated about the environments in which each adult typically communicates and where they find the most difficulty.

6.9.6 Psychological status

Some patients will require a psychological assessment. A referral to a qualified psychologist or psychiatrist should be initiated when there are concerns regarding the candidate's mental health, learning ability, personality and motivation, adaptation to their hearing loss, or unrealistic expectations about EAS implantation that cannot be addressed through counselling by the EAS implant team.

6.9.7 Candidature for unilateral / bilateral implantation

Bilateral EAS implantation is possible and should always be considered. However, due to national restrictions, opportunities for bilateral implantation may vary.

7 Cooperation of the EAS Implant Team with Other Services

- 7.1 All members of the EAS implant team should meet on a regular basis to ensure effective internal communication, thereby ensuring quality service for each patient.
- 7.2 Contact must be maintained with the referring agent, the general practitioner and local professionals.
- 7.3 The EAS implant programme should cooperate with other services, including the following:
 - a. Other hospital departments
 - b. Audiology, radiology, medical physics, wards, ambulatory care, etc.
 - c. Local / national support groups
 - d. Social services
 - e. Community services
 - f. Educational services
- 7.4 Contact with support services should only be made with the permission of the patient and at the discretion of the EAS implant team.

8 Pre-operative Information and Counselling

- 8.1 Basic information and counselling should be given to the patient according to a written check-list and recorded in the patient's hospital file.
- 8.2 Whenever possible, information should be given to patients in a language or medium that is appropriate to their preferred method of communication.
- 8.3 If necessary, interpreters should be offered, in accordance with local practice.
- 8.4 Teams should continuously monitor, review and update the quality and quantity of the information they provide, and should have a written protocol to determine what information is given at which time.
- 8.5 Verbal information should be supported by a written summary for the patient whenever required.

- 8.6** Throughout the assessment period, patients should have a clear understanding of the main benefits and limitations of implantation. Unrealistic expectations regarding hearing results and implant management must be avoided. If possible, a measurement tool such as an expectations questionnaire should be included in the general assessment protocol.
- 8.7** It is recommended that patients and family members meet with experienced EAS or CI users. Matching candidates and users in terms of age and duration of hearing loss and type of EAS or CI device may be beneficial.
- 8.8** Patients' relatives and friends should be encouraged to become involved in all aspects of pre- and post-implant management. This should be done only with the permission of the patient and at the discretion of the EAS implant team.
- 8.9** All issues regarding EAS implantation should be discussed, and the patient should have the opportunity to meet people who have decided against EAS, if they wish.
- 8.10** Waiting times for surgery and information about the hospital stay and post-operative follow-up should be outlined at the end of assessment.
- 8.11** Patients should be given information about EAS / CI organisations, national and local charities and self-help organisations, and equipment and services for people with hearing loss.
- 8.12** The patient should be offered contact between the team and the patient's employers and / or work colleagues. Contact should only be made with the permission of the patient and at the discretion of the EAS implant team.
- 8.13** A final counselling interview of the patient by the surgeon must take place at the end of the assessment procedure. The result of this interview is documented in written form.
- 8.14** If EAS or cochlear implantation is not recommended due to critical evaluation of the assessment results, the patient must be counselled on appropriate alternatives and support procedures. This should include the possibility of re-evaluation for EAS or CI in an individually adjusted period of time. These issues must be communicated in a written report to the referring clinician or agency, including the reasons why EAS or CI are considered unsuitable for the patient, recommendations for future management, and referral of the patient to other equipment and / or services.

9 The EAS Implant Device

- 9.1 There are different CI manufacturers supplying CI centres with EAS devices. Information regarding the technical specifications of these different currently approved devices should be made available.
- 9.2 The patient should be informed as to why in their individual situation a particular device is being offered for implantation. Written information on the selected equipment should also be made available.
- 9.3 HEARING centres only use and implant devices that are legally approved by national authorities.
- 9.4 The EAS implant device offered to the patient will:
 - a. Have a proven track record of safety and reliability
 - b. Have all necessary approvals (e.g. CE)
 - c. Conform to the recommendations of the national regulatory agency
 - d. Have high-quality clinical and technical support available from the manufacturer
 - e. Meet national purchasing requirements, where applicable

10 Surgery and In-patient Care

- 10.1 The consultant EAS / CI surgeon is responsible for the overall medical care of the patient.
- 10.2 The surgical team, which may include a suitably trained medical practitioner, is responsible for conducting a comprehensive pre-operation discussion of the surgical procedure and potential complications with the patient, and for obtaining the patient's informed consent.
- 10.3 As preservation of residual hearing is essential in the EAS-concept, a surgical procedure with the highest probability of hearing preservation should be used. This procedure currently focusses on an atraumatic insertion of the electrode, concomitant medical treatment (administration of cortisone) and intra-operative monitoring (if available).
- 10.4 The surgeon will monitor the patient's post-operative progress, and will be

responsible for correct treatment of surgical or medical problems that may arise in relation to the implant.

- 10.5 Information regarding the outcome of surgery, especially concerning residual hearing, must be documented and should be made available to the audiological and rehabilitation teams as soon as reliable data are available.
- 10.6 A radiological check of the positioning of the electrode (intra- or post-operatively) will support optimisation of results (allowing for early revision if needed).
- 10.7 Prior to discharge from hospital, the patient should receive written information on post-operative wound care and pain management as well as on what to do should any complication arise.
- 10.8 Prior to discharge from hospital, in addition to post-operative counselling on health and safety with an EAS implant, the patient should receive the manufacturer's written safety guidelines.

11 Postoperative Fitting and Tuning of the EAS Audio Processor

- 11.1 The audio processor should be fitted and programmed once the patient's wound has healed completely. For EAS fitting, an updated audiogram is necessary.
- 11.2 Fitting and programming requires specialised personnel (see 2.1.b), who have been fully trained in the relevant protocols and procedures.
- 11.3 Before the initial programming, responsible team members must:
 - a. Check the external EAS components
 - b. Explain the programming procedures
- 11.4 Each device should be fitted and programmed according to the manufacturer's recommended procedures and to maximise benefit for the patient. The appropriate number of programming sessions should be offered to each patient according to individual needs.

- 11.5 The use of the audio processor must be explained in detail. Patients should be given precise instructions as to how to contact the implant programme team if they have any queries or concerns.
- 11.6 Printed materials on the handling, operation and care of the audio processor should be issued to the patient and to relatives / caregivers, as appropriate.
- 11.7 The number of programming sessions required by patients may vary.
- 11.8 The patient must have open access to the implanting EAS / CI centre (or a designated local partner-service) for checking the entire implant system, for acoustic settings, and for reprogramming the audio processor.
- 11.9 A written report including a current audiogram should be sent to the referring agent following initial processor fitting and at the one-year treatment interval.
- 11.10 A written report should also be sent to the referring agent if any serious problems arise.

12 Postoperative Rehabilitation and Assessment

- 12.1 Following implant surgery, the patient must be examined by the implant surgical team and have open access to additional supporting measures as required. The patient should be encouraged to accept regular checks of the implant and audio processor function and the concomitant documentation.
- 12.2 Post-operative rehabilitation should begin immediately after initial fitting, according to the individual needs of the patient, to:
 - a. Facilitate acclimatisation to the new quality of sound
 - b. Aid the patient and the family / caregiver
 - c. Outline the rehabilitation programme
- 12.3 The rehabilitation programme should be tailored to each individual's needs. Patients and their families / caregivers should be intensely counselled on all aspects of the rehabilitation procedure in order to ensure maximum acceptance of all parts of the programme.

- 12.4** The rehabilitation programme may include evaluation of and training in:
- a. Detection of sound, including localisation and spatial tests
 - b. Auditory discrimination
 - c. Voice quality
 - d. Speech intelligibility
 - e. Language comprehension and expression
 - f. Lip reading
 - g. Hearing strategies
 - h. Social skills
- 12.5** Sufficient rehabilitation sessions should be offered to optimise EAS use. The patient must have open access to the implanting EAS / CI centre (or a designated local partner-service) for rehabilitation and counselling as required.
- 12.6** Appropriate standardised audiological, speech perception, and quality of life measures should be performed after initial tuning, at least twice in the first year following surgery, and at regular intervals thereafter, to allow progress to be monitored.
- 12.7** After the first year following implant surgery, the patient should be offered annual audiological re-evaluation. This structured schedule can be adapted to the patient's wishes, if necessary. Moreover, patients should have access to additional appointments for examination, as required.
- 12.8** It is recommended that the referrer and locally involved professionals receive written reports on patient progress.

13 Follow-up and Long-term Maintenance

- 13.1** The patient must have open access to the EAS / CI centre (or a designated local partner-service) for programming, rehabilitation and surgical reviews as required.
- 13.2** Necessary replacement of external equipment must be guaranteed. If necessary, the service centres should provide patients with the required support on the same or the next working day. Audio processor batteries should be available for implant users either from the EAS / CI implant programme or from a local audiology department by prior agreement.

- 13.3 Individual centres should have a policy for replacing lost or damaged processors that is equitable for all patients.
- 13.4 Upgrading of audio processors and contralateral hearing aids should be carried out in a standardised way.
- 13.5 The audio processor should be upgraded at intervals of no more than 5 years, subject to the availability of new technology for the relevant implant system.
- 13.6 Following the annual re-evaluation, a written report detailing the outcome of the examination should be sent to the referring agent.

14 Device Failure

- 14.1 If an internal EAS implant device failure is suspected, the patient should be offered an appointment as soon as possible to check the device's internal and external components.
- 14.2 The implant manufacturer should be contacted promptly regarding investigation of the device failure. If required, a clinical / engineering representative of the company should be available at the patient's appointment to provide support.
- 14.3 If internal device failure is confirmed, the implant team must decide whether revision surgery is indicated. In contrast to classic CI revision surgery, with EAS a detailed audiological reevaluation is necessary to gather sufficient information about whether there is still preservable hearing remaining. In case of an unchanged inner ear function, re-implantation of a new EAS device may be considered. At present, there is only limited information on hearing preservation following exchange of an EAS electrode.
- 14.4 The device failure must be reported to the relevant national health authorities.
- 14.5 If re-implantation of a new EAS system is agreed upon with the patient, it should be carried out using the same surgical technique for hearing preservation. In contrast to CI candidates with severe to profound hearing loss, EAS patients still receive some sound information from the part of the device providing acoustical stimulation.

- 14.6** In case of further deterioration of inner ear function with little hearing benefit from acoustic stimulation, a CI implantation must be considered.
- 14.7** Planning for revision surgery also depends on the hearing status of the second ear. If the patient has no satisfactory hearing at all following unilateral device failure (i.e. if they are deaf or nearly deaf on the second side without hearing aid / EAS / CI), re-implantation should be carried out as soon as all necessary audiological and other medical data are available, to minimise the burden of auditory deprivation.
- 14.8** Re-implantation and programming should be carried out as detailed above. Further rehabilitation needs should be assessed and provided for as appropriate.

15 Clinical Management

- 15.1** The clinical EAS implant service should provide well-defined documentation paths to facilitate internal quality management and to establish a database, which can then be used for scientific exchange with other implant centres and with device manufacturers.
- 15.2** The implant programme should include regular audits and comply with the requirements of the responsible national authorities. Audits should cover:
- a. Clinical activity
 - b. Staffing levels
 - c. Patient performance outcomes
 - d. Medical and surgical complications
 - e. Device failures
 - f. Research interests and outcomes
 - g. Patient feedback on the service

16 Patient and Other Feedback and Complaints

- 16.1 Documentation provided by the EAS implant programme should include written information on complaint management within the hospital and other related services.
- 16.2 Patient and caregiver feedback should be integrated into the general documentation of the EAS implant programme to allow for regular evaluation of the subjective estimation of the services by users.

Acknowledgement

The "Quality Standards for Combined Electric and Acoustic Stimulation" were developed by Prof. Rudolf Hagen and the HEARRING Group based on Framework of the British Cochlear Implant Group Standards.