

European Consensus Statement on Cochlear Implant Failures and Explantations

Objective

Cochlear Implants are technical systems that can fail. Reliability is a central consideration for clinicians, patients and the competent authorities. So far different definitions of device failure and reliability have been used by different manufacturers and different cochlear implant centres. This situation makes any comparison between different devices impossible and does not provide physicians or patients with the necessary transparency on this essential topic. In order to achieve a common definition of device failure and how to report it, a European consensus meeting was held in Frankfurt on June 10, 2005. The following document represents this European consensus statement on cochlear implant failures and how to report them. At the meeting were present representatives of the major cochlear implant centres across Europe, representatives of the competent authorities and the device manufacturers (see added list of participants).

Definition of Device Failure (see Figure 1)

Device failure:

A device with characteristics outside the manufacturer's specification resulting in a loss of clinical benefit.

Depending on clinical circumstances, reimplantation would usually be recommended. According to ISO standard 5841-2:2000 a device having one or more characteristics outside the limits established by the manufacturer for clinical use. All such failures must be reported to the competent authority.

Exceptions:

Characteristics Decrement

A device with measured characteristics outside the manufacturer's specification, but still of benefit to the patient.

Such failures would not need reporting. The implant team would decide if or when a reimplantation should become necessary. The device would then be deemed to have incurred a device failure and should be reported as such.

Performance Decrement

Unexplained but documented decrement in performance or a device that causes non-auditory sensations necessitating explanation.

Testing of the device may not show any failure either in vivo or after explantation. If re-implantation restores function or abolishes non-auditory sensations, the implant should be considered to have had a device failure and should be reported to the competent authority. If the new device fails to do so, the episode should be considered as a medical explantation.

Loss to follow-up

Implanted patients which have been lost to clinical surveillance.

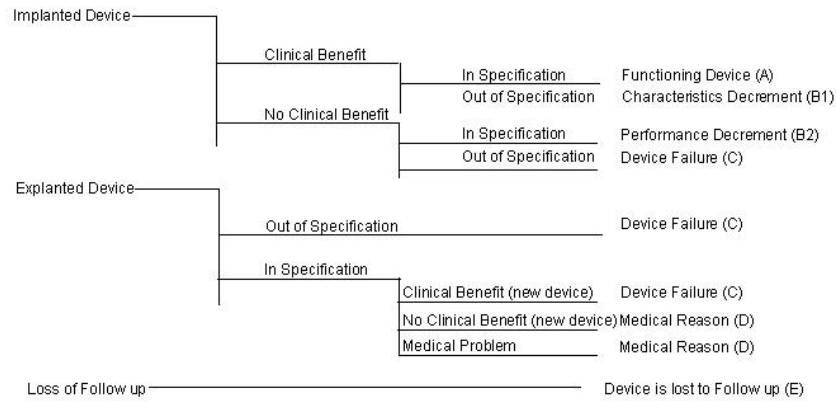
Future common databases at either a national or European level should account for all devices lost to follow-up.

Medical Reasons

Devices that are believed to be functioning normally but that need to be removed for medical reasons e.g. infection, biological failure etc.

Such explantations are not device failures but should be reported to a later European data bank as medical explantations.

Figure 1:



- A Normal functioning device
- B1 Characteristics Decrement: Replacement of device not necessary as long as clinical benefit is preserved
- B2 Performance Decrement: Explantation and reimplantation recommended
- C Device failure. Explantation and reimplantation recommended. Report to competent authority and manufacturer is mandatory. Goes into cumulative survival rate calculation.
- D Medical Reason: Explantation due to medical problems (i.e. infections, electrode misplacement etc.). Shall be reported into a future European data bank
- E Population of implantees who no longer show up for after care. Shall be reported into a future European data bank

Fig. 1: Assignment of failure categories based on manufacturer specification and clinical benefit. The different possible assignments are explained in the lower part of the figure.

Principles of Reporting on Device Failure

1. All device failures must be reported to the competent authority and must be included in the calculation of the cumulative survival rate (CSR). Reporting of the CSR should be in accordance with ISO standard 5841-2:2000.
2. Manufacturer's reports of device failure should indicate the sources of data and the sample size. There must be no exclusions. The time period over which the data was collected should be specified.
3. Reports of CSR should give complete historical data of a given device, describing any technical modifications (which can be integrated into historical data by starting at time 0).
4. The complete data set of the 'mother' product should always be supplied when presenting data on subsequent device modifications.
5. A new device can be attributed when there has been a change in either the case and/or the electrodes and/or the electronics and has been labelled by its own CE mark.
6. Cumulative survival rates should be split into data for adults and for children and 95% confidence intervals (80% or 90% if the population is below 1000 units) should be provided.
7. Device survival time starts to count with closure of the wound intraoperatively.

Common Form for Reporting Cause of Device Failure or Explantation by a Manufacturer to the Competent Authority, the Notified Body and Clinics

I. Header:

Report header:
Manufacturer:
Type of device:
Serial number:
Manufactured date:
Implant date :
Explant date :
Institution:
Initials of patient:
Hospital Number
Date of birth:
Gender:
Date of report to the Competent Authority:
Date of report to the Notified Body:
Date of report to Clinic

II. Main Body:

The report should contain the following sections:

1. Clinical summary
2. Test results : the result of each test performed on the implant should be described
3. Conclusion: the primary mode of failure according to the agreed classification* should be described.
4. Corrective actions, schedule of implementation of corrective actions, safety notice and information of customers

*Modes of Failure:

1. Impact failure,
2. Hermeticity failure,
3. Electronic Failure
4. Electrode array problem,
- 5 Other: specify
6. No cause determined

References:

1. ISO 5841-2 Implants for surgery – Cardiac pacemakers Part 2: Reporting of clinical performance of populations of pulse generators or leads
2. prEN 45502 Active Implantable Medical Devices Part 2-5: Particular requirements for cochlear implant systems

List of participants

Last name	First name	Institution
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* Did not contribute any data.