

Understanding our Reliability Reporting

Why does Cochlear have two reliability reports available?

For many years, an annual Cochlear™ Nucleus® Implant Reliability Report has been produced in accordance with the reporting methodology recommended by ISO 5841-2¹, the recommended reporting principles in the European Consensus Statement on Cochlear Implant Failures and Explantations², and the International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators.³

In the United States, a new cochlear implant industry standard (CI86) has now been published by the Association for the Advancement of Medical Instrumentation (AAMI) in conjunction with the Food and Drug Administration (FDA). As a result, Cochlear has produced two reliability reports to ensure we provide both the public and the regulators with fully compliant data.

We will refer to these two reports as the European Consensus Statement Reliability Report and the ANSI/AAMI CI86 Reliability Report.

What are the main differences between the two reliability reports?

	European Consensus Statement Reliability Report	ANSI/AAMI CI86 Reliability Report
 IMPLANT RELIABILITY METRIC	The reliability metric used is Cumulative Survival Percentage (CSP). CSP measures the percentage of functioning implants, at given time intervals, after implantation.	The reliability metric used is Cumulative Removal Percentage (CRP). CRP measures the percentage of implanted devices that have been removed, at given time intervals, after implantation.
 DEFINITION OF ADULT AND CHILD POPULATION	A child is defined as a recipient who was aged less than 18 at the time of implantation.	A child is defined as a recipient who was aged less than 10 at the time of implantation.
 INCLUSION OF SOUND PROCESSOR RELIABILITY	Sound processor reliability data is not included.	The standard specifies principles for the reporting of sound processor reliability. Data is reported for all sound processors which are currently marketed in the US.

Why is the implant reliability data in the two reports different?

Both reliability reports provide data in accordance with the standards they are based on, however the standards have different requirements for implant reporting. The European Consensus Statement Reliability Report only considers device failures when reporting implant reliability. The ANSI/AAMI CI86 standard requires reporting on all device removals, including those for medical reasons which may be unrelated to the device or its operations (e.g. infection).

How is sound processor reliability being measured?

The measure for sound processor reliability is the Failed Component Return Rate (FCRR). The FCRR is a percentage calculated by comparing the number of failed processors returned within a month to the cumulative sales of the same processor by the end of that month. The FCRR is reported as a monthly figure over a period of 24 months.

Failed Processors



Cochlear tests all returned sound processors to determine if they are working and, if not, why they failed. The FCRR calculation includes four types of processor failure: mechanical failure, electronic failure, moisture damage failure and unknown failure. If a returned processor is found to be fully functional it is reported as fault free and not included in the FCRR calculation.

Processor Sales



The sales figure used to calculate the monthly FCRR is total sales from the launch of the processor to the end of the month being reported. While 24 months of data are reported, the cumulative sales figure may span a longer period. (eg. if the processor was launched 36 months prior)

Global vs US data



Cochlear has used global sales and returns data to calculate the FCRR in the ANSI/AAMI CI86 Reliability Report, not US specific data. This is primarily because we operate a global returns center.

FCRR example

20 faulty sound processors are returned in the month of June 2019

20

10,000 sound processors have been sold between launch and the end of June 2019

10,000

=

0.20%

The sound processor FCRR for June 2019 is 0.20%

Things to consider when comparing sound processor reliability

Compare the FCRR over time

Monthly processor return volumes are variable and can be impacted by factors such as seasonality. By considering the full 24 months of FCRR, rather than individual months, you will gain a better view of overall processor reliability.

Evaluate product generations

Predictors of manufacturer reliability would include both a consistent record of sound processor reliability and improving FCRR data for each new generation of processor.

Consider product life-cycle

FCRR can be impacted by how long a sound processor has been available in the market as it is based on sales and returns volumes. The FCRR of a newly launched device, for example, may not be comparable with the FCRR of a device which has been available for a number of years.

1. International standard ISO 5841-2. Implants for surgery — Cardiac Pacemakers — Part 2: Reporting of clinical performance of populations of pulse generators or leads. Geneva (Switzerland): International Organization for Standardization – second edition 2000, third edition 2014. 2. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005 Nov;26(6):1097-9. 3. Battmer RD, Backous DD, Balkany TJ, Briggs RJ, Gantz BJ, van Hasselt A, et al. International classification of reliability for implanted cochlear implant receiver stimulators. Otol Neurotol. 2010 Oct;31(8):1190-3. 4. ANSI/AAMI CI86:2017 Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.

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