Cochlear®
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Understanding our implant 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 5841-2[1], the reporting principles in the European Consensus Statement on Cochlear Implant Failures and Explantations[2], and the International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators.[3]

In 2017 a new cochlear implant industry standard (CI86) was published by the Association for the Advancement of Medical Instrumentation (AAMI) in conjunction with the American National Standards Institute (ANSI). The ANSI/AAMI CI86 Standard[4] outlines new requirements for the reporting of implant reliability data.

We understand that access to the latest information on implant reliability assists both candidates and professionals in making important decisions, so we provide implant reliability data based on both sets of reporting requirements.

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), which measures the percentage of functioning implants, within given time intervals, after implantation.	The reliability metric used is Cumulative Removal Percentage (CRP), which measures the percentage of implanted devices that have been removed, within 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.
REPORTING CATEGORIES	Only device failures are considered when reporting implant reliability.	The 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).

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, as shown above. As a result of these differences, primarily the inclusion of device removals for medical reasons, the implant reliability figures in the ANSI/AAMI CI86 Reliability Report will normally be slightly lower.

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.