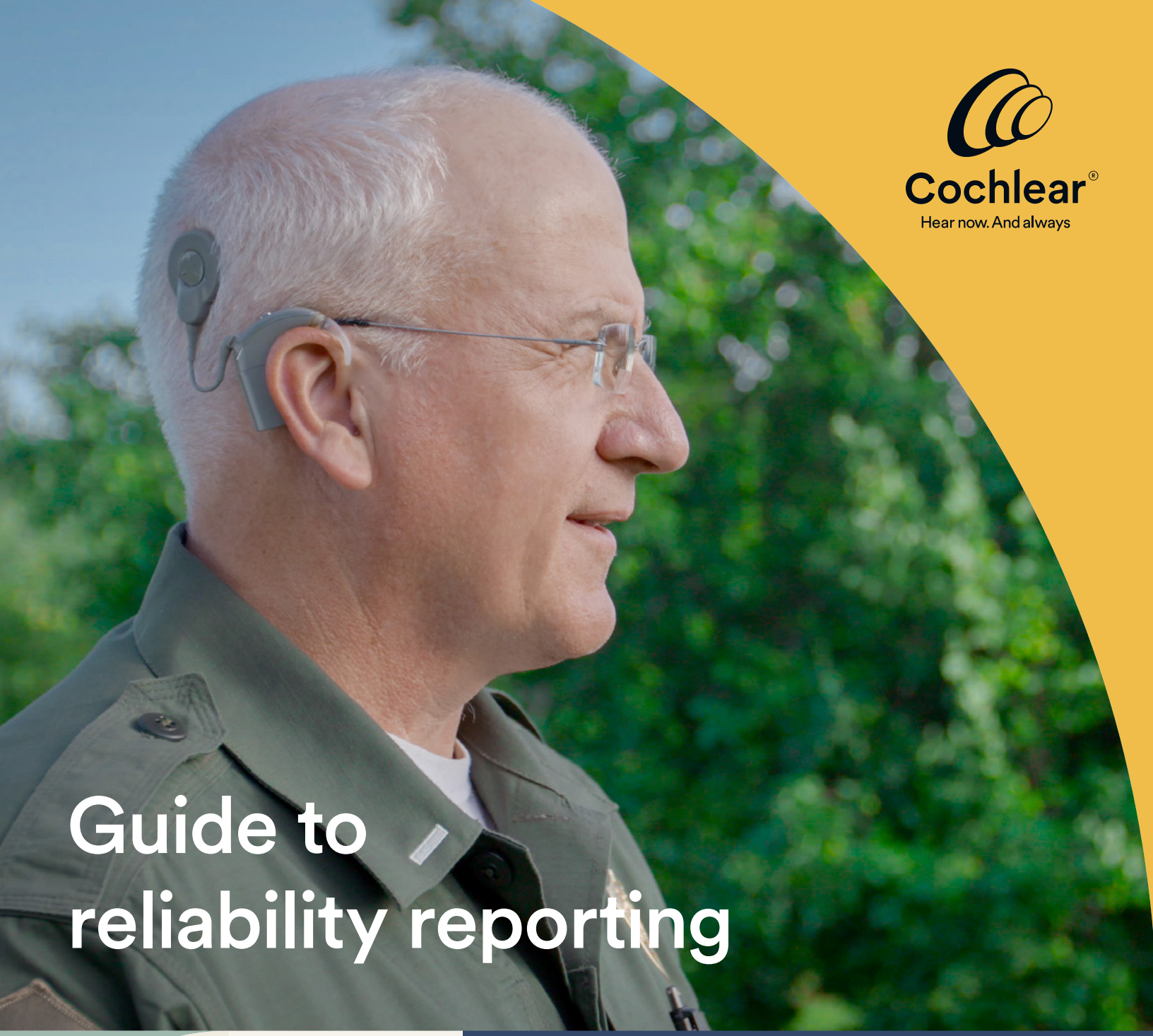

Cochlear®
Hear now. And always

Guide to reliability reporting

Understanding our implant and sound processor reliability reporting

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 5841-21, 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[1,2,3] and the ANSI/AAMI CI86 Reliability Report.[4]

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 below. 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.

Main Differences	European Consensus Statement Reliability Report[1,2,3]	ANSI/AAMI CI86 Reliability Report[7]
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).

Understanding our sound processor reliability reporting

How is sound processor reliability measured?

In 2017 a new cochlear implant industry standard 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[2] outlines requirements for the reporting of sound processor reliability.

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.

FCRR example

20 faulty sound processors are returned in the last reported month	**20**	=	**0.20%** The sound processor FCRR for June 2020 is 0.20%
10,000 sound processors have been sold between launch and same last reported month	**10,000**		

Calculating Sound Processor Reliability

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 that month. Whilst 24 months of data are reported, the cumulative sales figure may span a longer period, for example 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 centre.

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 lifecycle

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.

Additional resources

Contact your Cochlear Representative for more information.

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 600,000 implantable devices, helping people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to innovative future technologies. We collaborate with leading clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

References

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.

Cochlear Americas
10350 Park Meadows Drive
Lone Tree, CO 80124 USA
Telephone: 303 790 9010
Support: 800 483 3123

Cochlear Canada Inc.
2500-120 Adelaide Street West
Toronto, ON M5H 1T1 Canada
Support: 800 483 3123

www.cochlear.com/us

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