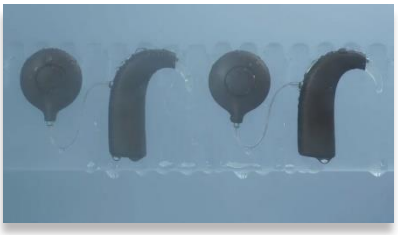
Feel fully confident about the reliability of the Neuro System

Over 99% reliability for Neuro Zti implant and Neuro 2 sound processor Cochlear implant systems from Oticon Medical are renowned for the sound quality and reliability they provide to users – and the Neuro System is no exception. The latest reliability data have confirmed that both the Neuro Zti implant and the Neuro 2 sound processor have some of the highest reliability rates in the market.

Reliability matters



Reliability has been a key part of the Neuro System design work and both the implant and the sound processor are subject to an extensive testing program with hundreds of different tests that simulate how the implant system is used in daily life. For example, the antenna cable is tested in a cable bend robustness test that simulates the patient bending the antenna cable over 3000 times.

Neuro Zti implant – 99.70% reliability

The recent annual reliability report 2019 by Oticon Medical clearly confirms that the Neuro Zti implant has the necessary resilience to withstand the impact of users' daily lives – today and for many years to come. Neuro Zti has an impressive Cumulative Survival Percentage (CSP)[1] over 99.7%[2] after four years, making it one of the most reliable implants in the CI industry[3]. As a cochlear implant manufacturer, we report device failures in accordance with the International Standard ISO 5841-2:2014[4] and the principles described in the European and Global Consensus on Cochlear Implant Failures and Explantations[5].

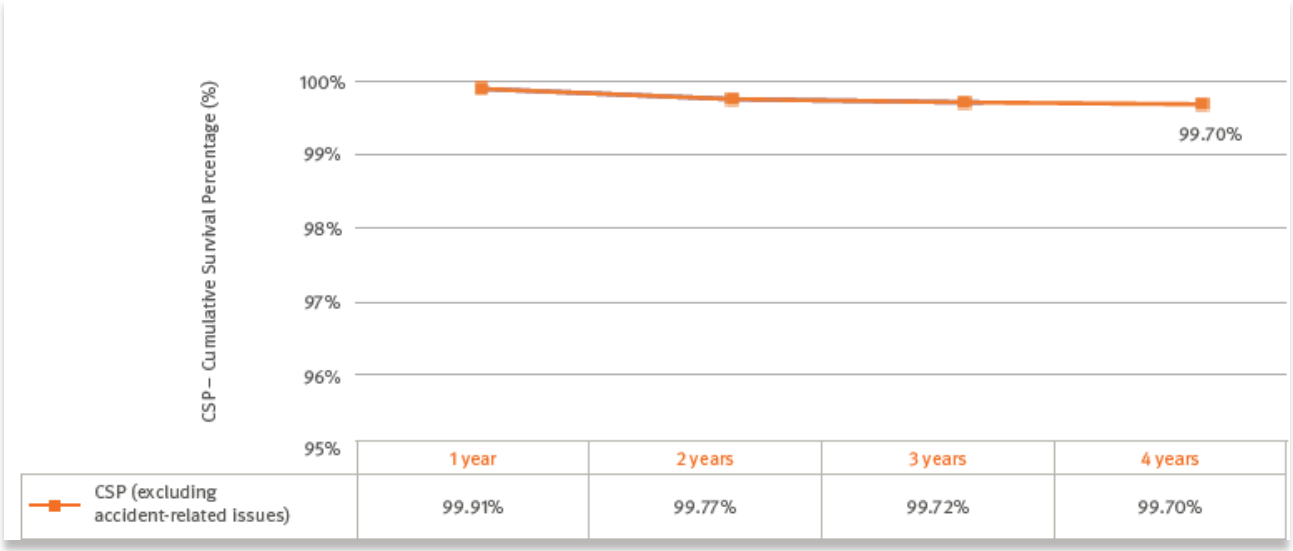
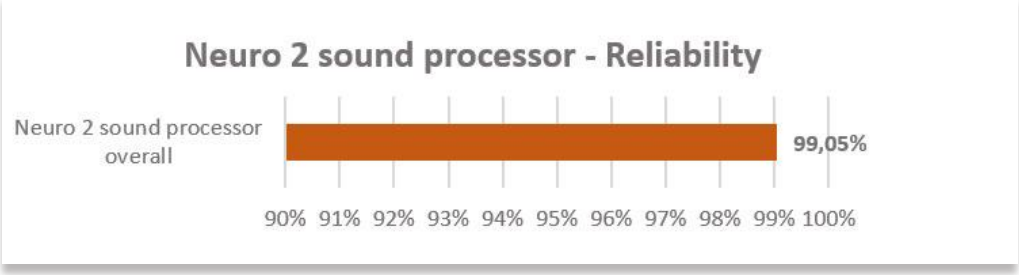


Fig.1 Neuro Zti reliability after 4 years – Cumulative Survival Percentage (data from 30th June 2019)

Neuro 2 sound processor - Over 99% reliability

The Neuro 2 sound processor is just as dependable with a reliability rate of over 99% after 18 months[6] on thousands of Neuro 2 sound processors delivered worldwide. This result is calculated based on the FCRR (Failed Component Return Rate), recommended by the latest Association for the Advancement of Medical Instrumentation (AAMI) standard[4]. The AAMI standard is considered one of the toughest and requires the inclusion and publication of the types of recorded failure, thereby setting the bar high for reliability measurement.



Based on the Failed Component Return Rate, FCRR, calculated according to the international standard ANSI/AAMI* (CI86: 2017), 30th June 2019.

The mechanical parts of Neuro 2 sound processor receive a reliability rating of 99.02%[4], largely due to the sound processor's design robustness. This is the result of numerous real-life reliability tests including guided and random free fall, wear and extreme temperatures to make sure the sound processor can stand up to the challenges of users' daily life.

Humidity in general, and particularly rain and sweat, can potentially affect a device worn outside but close to the body, and consequently cause oxidation. However, the durable, hydrophobic coating (interior and exterior), hand-sealed with white-silicone components and mechanical capillary barriers effectively protect the electronic board and its components. As a result, Neuro 2 has been designed to meet the highest Ingress Protection index and it is certified IP 68, the only CI sound processor to do so without needing any extra accessory. That's why only 3.2 out of 1000 Neuro 2 have been returned because of oxidation in the 18 months since its introduction.

This data and the reports from thousands of satisfied users around the world confirm that the Neuro System is a safe and reliable solution.

1. Calculated following international standard ISO 5841-2:2014 and the principles described in the European and Global Consensus on Cochlear Implant Failures and Explanations
2. Oticon Medical annual reliability report 2019
3. Cochlear reliability report 2018,
Advanced Bionics reliability report 2018,
MedEl website reliability data April 2018
4. 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. 2014.
5. European consensus statement on cochlear implant failures and explantations. Otol Neurotol. 2005 Nov;26(6):1097-9.
6. Data as for 30th of June 2019 - Based on the Failed Component Return Rate, FCRR, calculated according to the international standard ANSI/AAMI (CI86: 2017)*

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