# Reliability Report 2022

In accordance with the European and Global Consensus on Cochlear Implant Failures and Explantations, and the ANSI/AAMI CI86 Standard

September 2022



oticon
MEDICAL

# About Oticon Medical

Oticon Medical offers cochlear implant solutions and bone anchored hearing systems for different patient groups with hearing loss. All of our solutions are specialized to meet the needs of those who face the hardest hearing challenges.

The choice to have a cochlear implant is a choice for life, which is why the reliability of the CI system you choose is of the utmost importance.

The report presents the reliability data for the Neuro Zti implant and the Neuro 2 Sound Processor; key components of the Neuro System from Oticon Medical.

The Neuro CI System is registered in 65 countries including the US, where FDA approval was obtained in 2021.

René Govaerts

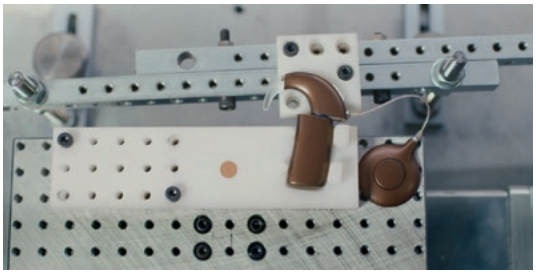
President,
Oticon Medical

## Numerous tests performed to ensure high reliability

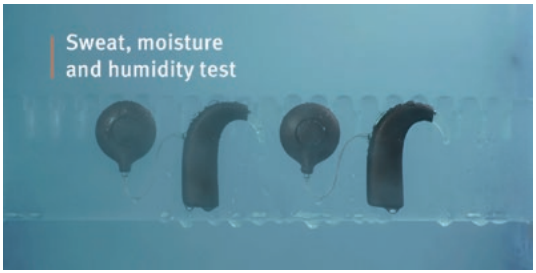
Cochlear implants help thousands of people worldwide, every day of every year. Every CI user needs to be able to rely on their device's performance, no matter what situation or environment they find themselves in products live up to the highest quality standards, in compliance with hundreds of international requirements.

To simulate patient's active lives, cochlear implants systems undergo hundreds of different tests. These tests include shock resistance, bending, stretching, exposure to extreme temperature and humidity conditions. These tests are performed thousands of times on the implant and the sound processor and also on all accessories and spare parts. For instance, one of these tests evaluates the number of times the battery compartment of the sound processor can be removed and replaced and still remain safe and usable. The requirements state the device must support it over 6,000 times.

Implant impact test



Sound processor battery compartment test – 6,000 cycles




Sound processor sweat, moisture and humidity test

## How this report has been made

All cochlear implant manufacturers are required to report any implant or sound processor failures no matter where in the world they are.

This report is written in accordance with two international standards; firstly Part 1 is presented in accordance with the principles described in the European and Global Consensus on Cochlear Implant Failures. Secondly, in Part 2 american standard /AAMI CI 86 standard – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting are presented.

# Reliability Part 1: European standards

Neuro Zti

## 97.92%

### Average CSP after 7 years

Including accident-related issues combining EVO and Classic

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Neuro 2

## 0.7% FCRR

### Average FCRR over 24 months

# Implant reliability

## Introduction

In accordance with European and Global Consensus on Cochlear Implant Failures and Explantations. The approach recommended by EU is the Cumulative Survival Percentage (CSP), which is presented in the following paragraph.

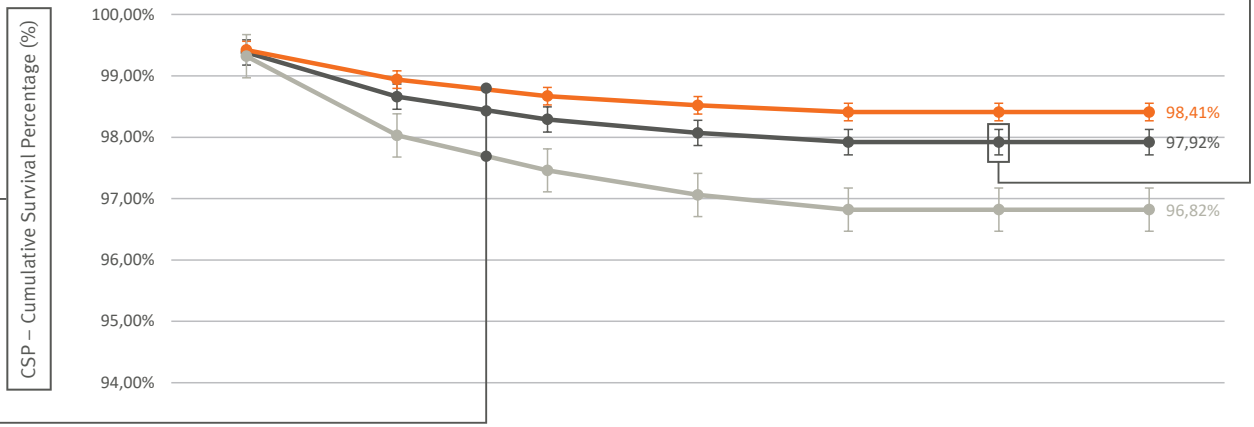
# How to read this report

## CSP – Cumulative Survival Percentage

Cumulative percentage of functioning devices over a given period of time after implantation*

## 95% confidence interval

The CSP curves report the 95% confidence interval to indicate the statistics' accuracy as required by the European and Global Consensus on Cochlear Implant Failures and Explantations




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Combined adults & children | 99.38% | 98.66% | 98.29% | 98.07% | 97.92% | 97.92% | 97.92% |
| Adults (+18y) | 99.42% | 98.94% | 98.67% | 98.52% | 98.41% | 98.41% | 98.41% |
| Children (-18y) | 99.32% | 98.03% | 97.46% | 97.06% | 96.82% | 96.82% | 96.82% |

## Curves

3 CSP curves are reported – one for adults, one for children (below 18 years old) and one combined – all including accident-related issues.

## Detailed CSP

Detailed CSP are given for each year after implantation

**Device survival time begins with closure of the wound.*

# Neuro Zti implant

It has the smallest surgical footprint[1] thanks to its unique rigid structure[1] made of zirconia and titanium. This enables it to absorb the high impacts encountered in daily life.

Neuro Zti also features a unique screw fixation system[1] that aims at making the implant stable without the need for bone bed drilling, saving precious time in the operating room.[1]

Thanks to the unique loudness coding in duration and the OM pulse shape, and the focused stimulation strategy has been developed to deliver precise stimulation and clear sound in a way that respects the natural physiology of the auditory system.

In addition, Neuro Zti has received the CE mark for extended MRI compatibility*. Thanks to a unique combination of an innovative magnet and a unique fixation system, the Neuro Zti MRI 3T is able to withstand MRI scans up to 3T with the magnet in place.

In October 2021 Oticon Medical voluntarily withdrew non-implanted Neuro Zti CI implants from circulation due to the identification of a number of devices exhibiting a loss of hermeticity. The issue was attributed to a small number of devices from specific batches. This is clearly reflected in the reliability data, where an irregular drop of around 2% is apparent. All potentially affected non-implanted devices were removed from the market on the day of the notification.

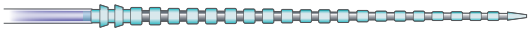
The root cause of loss of hermeticity was identified and corrective and preventive actions put into place. The Neuro Zti implant was cleared for re-entry to market by regulatory authorities in June 2022. The reliability of the new implant version will be reported in 2023.

**Subject to local availability according to local regulatory standards*

# Electrode arrays

The Neuro Zti cochlear implant features two kinds of electrode arrays – Classic and EVO – both composed of 20 platinum iridium full-band electrodes.

**The CLASSIC electrode array** has a stiff profile proving greater insertion forces to support some compromised cochlear patency insertions.



Neuro Zti CLA

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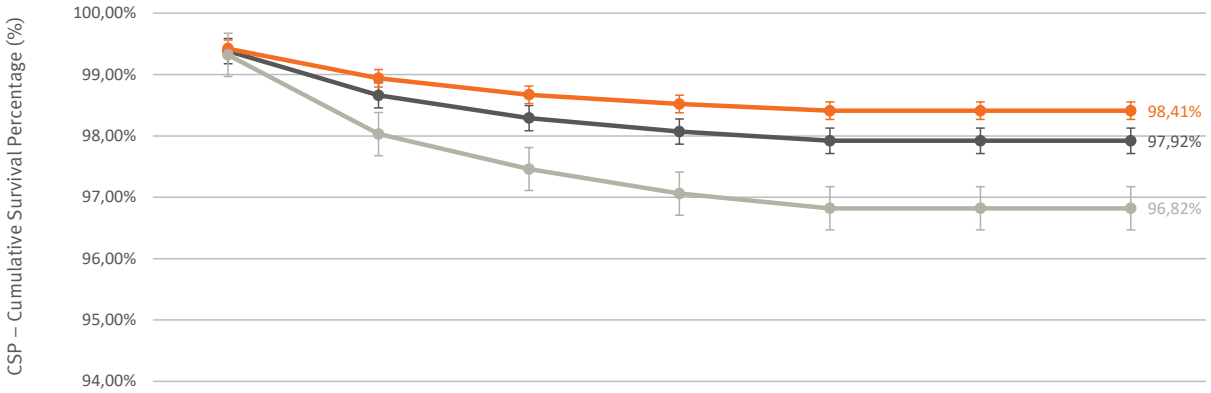
**The EVO electrode array** has been designed for soft surgery[2, 3] and is mainly used for normal cochleas insertions, also when surgeons want to preserve fragile cochlea's structure, and reduce the risk of trauma.[2, 3, 4]

Neuro Zti EVO

# Neuro Zti – Classic & EVO




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Combined adults & children | 99.38% | 98.66% | 98.29% | 98.07% | 97.92% | 97.92% | 97.92% |
| Adults (+18y) | 99.42% | 98.94% | 98.67% | 98.52% | 98.41% | 98.41% | 98.41% |
| Children (-18y) | 99.32% | 98.03% | 97.46% | 97.06% | 96.82% | 96.82% | 96.82% |

## 2015
## First implantation
# 97.92%
**Including accident-related issues**

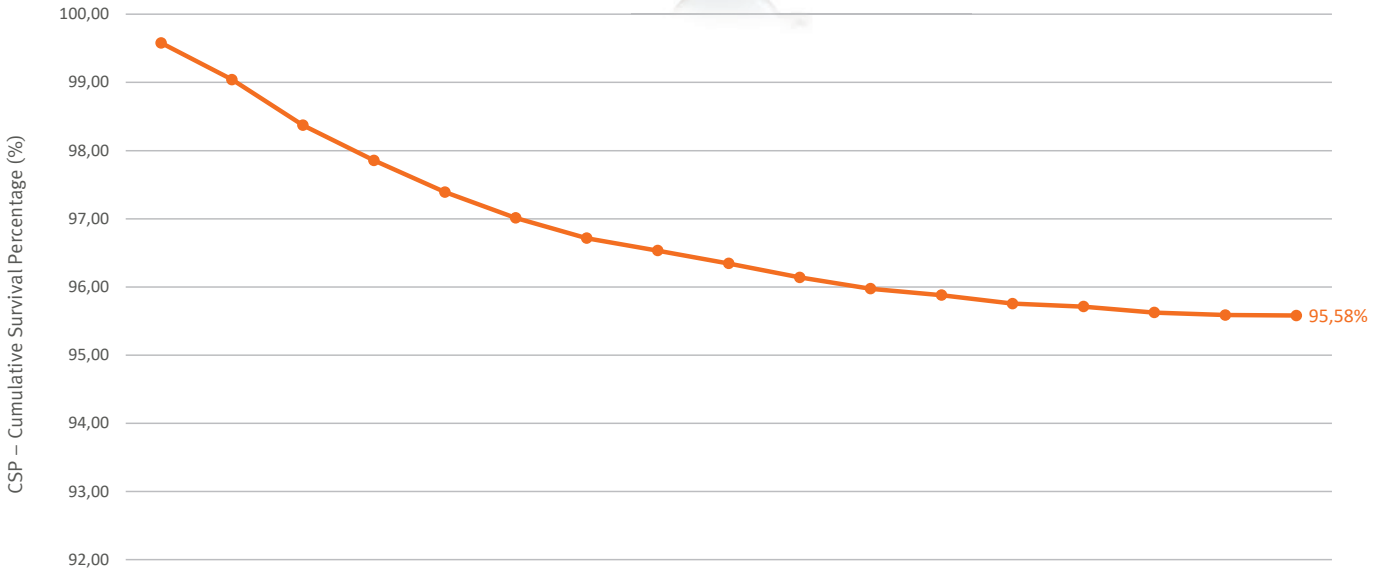
*Data as June 30th 2022*
*Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.*

## Digisonic SP implant

In 2005, the Digisonic® SP implant revolutionized the cochlear implant market thanks to its unique monobloc design with the magnet and the receiver in a single unit. The implant's structure, combined with an exclusive screw fixation system, removes the need to drill a bone bed during surgery.

The Digisonic SP range has been discontinued in 2020. In accordance with the European consensus, Oticon Medical keeps on reporting its reliability over time.

# Digisonic SP




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years | 8 years | 9 years | 10 years | 11 years | 12 years | 13 years | 14 years | 15 years | 16 years | 17 years |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Combined adults & children | 99,58% | 99,04% | 98,37% | 97,86% | 97,39% | 97,01% | 96,71% | 96,53% | 96,34% | 96,14% | 95,97% | 95,88% | 95,76% | 95,71% | 95,62% | 95,59% | 95,58% |

## 2006
## First implantation
# 95.58%
**Including accident-related issues**

*Data as June 30th 2022*

# Sound processor reliability

## Introduction

As for sound processors, we calculate the Failed Component Return Rate (FCRR) to describe their reliability, in accordance with the ANSI/AAMI CI 86 standards. The manufacturer tests sound processors that have been returned to determine if they are working and, if not, why they failed.

*I started noticing some sounds straight away. At first it was the sound of drawers being closed and cars in the street, then I started being able to hear the sound of my children's voices."*

Mette, Denmark, cochlear implant user

# How to read the sound processor data

Failed Component Return Rate (FCRR): percentage of the total number of original non-implantable components sold which are returned as failed devices each month.

### Electronic failure

A functional failure of the electronics or the electronic assembly.

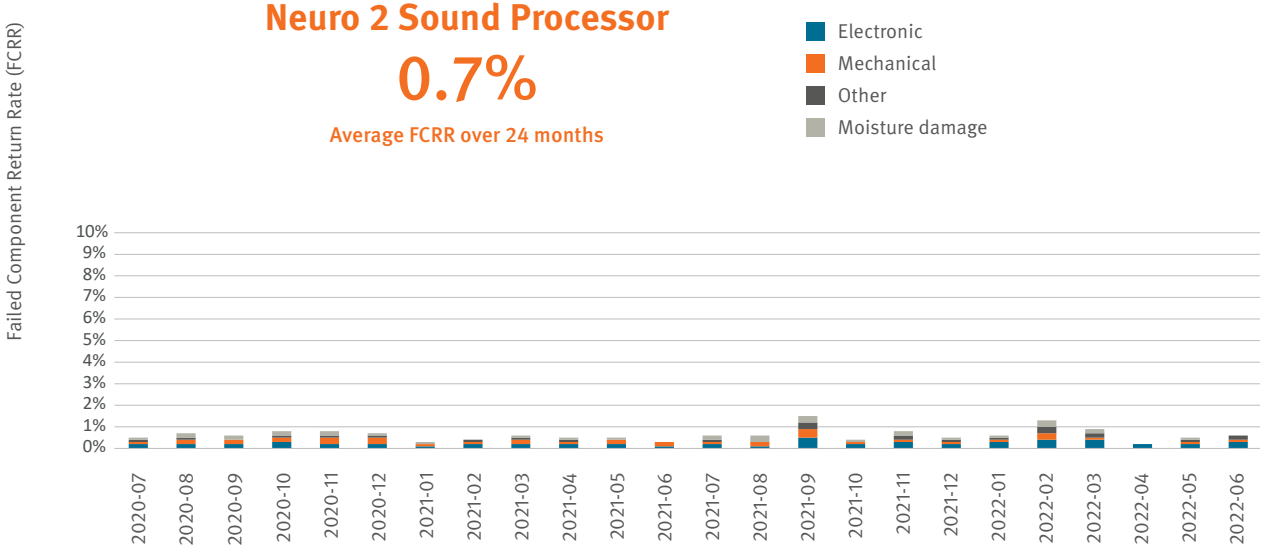
### Other/unknown failure

Failures that don't fit in the other categories (e.g. firmware failures).

## Neuro 2 Sound Processor

**0.7%**

Average FCRR over 24 months




### Mechanical failure

A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use.

### Moisture damage failure

A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.

The Neuro 2 sound processor commercialized in 2018 is the smallest sound processor on the market.[1] It is sweeping up prizes in the cochlear implant industry due to its groundbreaking design.

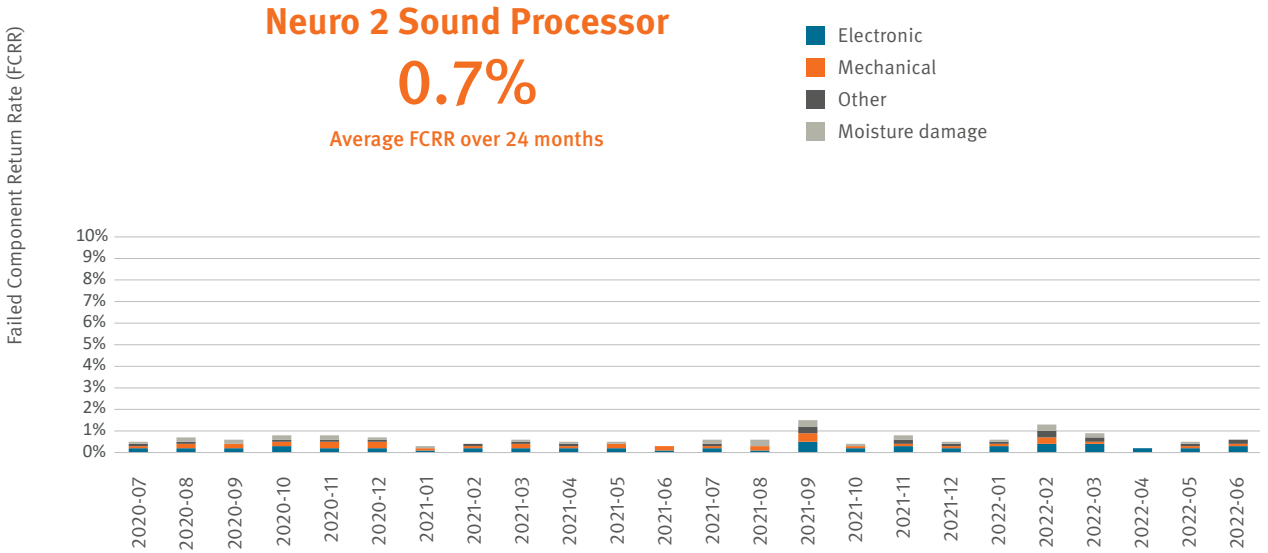
All cochlear implant systems can help users understand speech in quiet conditions. It's the noisy environments that remain the biggest challenge. Built on the advanced Inium Sense chip platform from Oticon, the Neuro 2 sound processor features key technologies that capture sound details, efficiently remove noise and are clinically proven to improve speech understanding in noisy conditions.[5, 6]

# Neuro 2 Sound Processor

## Neuro 2 Sound Processor – Failed Component Return Rate

| Fail Mode | July 20 | Aug 20 | Sep 20 | Oct 20 | Nov 20 | Dec 20 | Jan 21 | Feb 21 | Mar 21 | April 21 | May 21 | Jun 21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Electronic | 0.2% | 0.2% | 0.2% | 0.3% | 0.2% | 0.2% | 0.1% | 0.2% | 0.2% | 0.2% | 0.2% | 0.1% |
| Fault-free* | 0.3% | 0.5% | 0.3% | 0.3% | 0.4% | 0.2% | 0.1% | 0.2% | 0.2% | 0.2% | 0.1% | 0.2% |
| Mechanical | 0.1% | 0.2% | 0.2% | 0.2% | 0.3% | 0.3% | 0.1% | 0.1% | 0.2% | 0.1% | 0.2% | 0.2% |
| Moisture damage | 0.1% | 0.2% | 0.2% | 0.2% | 0.2% | 0.1% | 0.1% | 0.0% | 0.1% | 0.1% | 0.1% | 0.0% |
| Other | 0.1% | 0.1% | 0.0% | 0.1% | 0.1% | 0.1% | 0.0% | 0.1% | 0.1% | 0.1% | 0.0% | 0.0% |

| Fail Mode | July 21 | Aug 21 | Sep 21 | Oct 21 | Nov 21 | Dec 21 | Jan 22 | Feb 22 | Mar 22 | Apr 22 | May 22 | Jun 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Electronic | 0.2% | 0.1% | 0.5% | 0.2% | 0.3% | 0.2% | 0.3% | 0.4% | 0.4% | 0.2% | 0.2% | 0.3% |
| Fault-free* | 0.2% | 0.1% | 0.4% | 0.1% | 0.3% | 0.3% | 0.3% | 0.4% | 0.4% | 0.1% | 0.1% | 0.2% |
| Mechanical | 0.1% | 0.2% | 0.4% | 0.1% | 0.1% | 0.1% | 0.1% | 0.3% | 0.1% | 0.0% | 0.1% | 0.1% |
| Moisture damage | 0.2% | 0.3% | 0.3% | 0.1% | 0.2% | 0.1% | 0.1% | 0.3% | 0.2% | 0.0% | 0.1% | 0.0% |
| Other | 0.1% | 0.0% | 0.3% | 0.0% | 0.2% | 0.1% | 0.1% | 0.3% | 0.2% | 0.0% | 0.1% | 0.2% |




** Fault-free fail mode is a returned device that is found to be fully functional. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discoloration), corrosion, and/or moisture damage that did not result in a functional failure.*

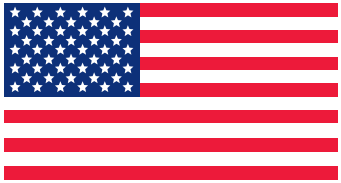
# References


1. Oticon Medical CI Unique, sept 2020, version G (DOC-00067651).
2. Sipari et al., Cochlear Implantation With a Novel Long Straight Electrode: the Insertion Results Evaluated by Imaging and Histology in Human Temporal Bones, Otology & Neurology, 2018. 7.
3. Martins et al., Evaluation of intracochlear trauma caused by insertion of cochlear implant electrode arrays through different quadrants of the round window, Biomed Res Int, 2015.
4. Wanna GB, O'Connell BP, Francis DO, Gifford RH, Hunter JB, Holder JT, Bennett ML, Rivas A, Labadie RF, Haynes DS., Predictive factors for short- and long-term hearing preservation in cochlear implantation with conventional-length electrodes. Laryngoscope. 2017 Jun 22. doi: 10.1002/lary.26714. [Epub ahead of print].
5. Segovia-Martinez M, Gnansia D & Hoen M. (2016). Coordinated Adaptive Processing in the Neuro Cochlear Implant System. Oticon Medical White Paper (M80293)
6. Langner F, Gnansia D, Hoen M, Büchner A, & Nogueira W (2017). Effect of dynamic range in different stages of signal processing in Cochlear Implant listeners on speech. ENT World Congress, IFOS 2017, June 24-28th, Paris, France.

*I'm much more relaxed now during conversations since I got my Neuro CI. I simply get much more out of it without the extra effort"*

Kim, Denmark, cochlear implant user

# Part 2 Reliability: American standard



Neuro Zti

**2.08%**

Average CRP after 7 years

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Neuro 2

**0.7% FCRR**

Average FCRR over 24 months

# Implant reliability

## Introduction

In accordance with the ANSI/AAMI CI86 – Cochlear implant systems:
Requirements for safety, functional verification, labeling and reliability reporting.

The guidelines require manufacturers to provide information to the public about the percentage of implanted devices that have been removed following implantation. This number is the cumulative removal percentage (CRP). It is important to track device reliability information over time because cochlear implants typically remain implanted for years. It is also important to track the reasons for removal when devices are replaced.

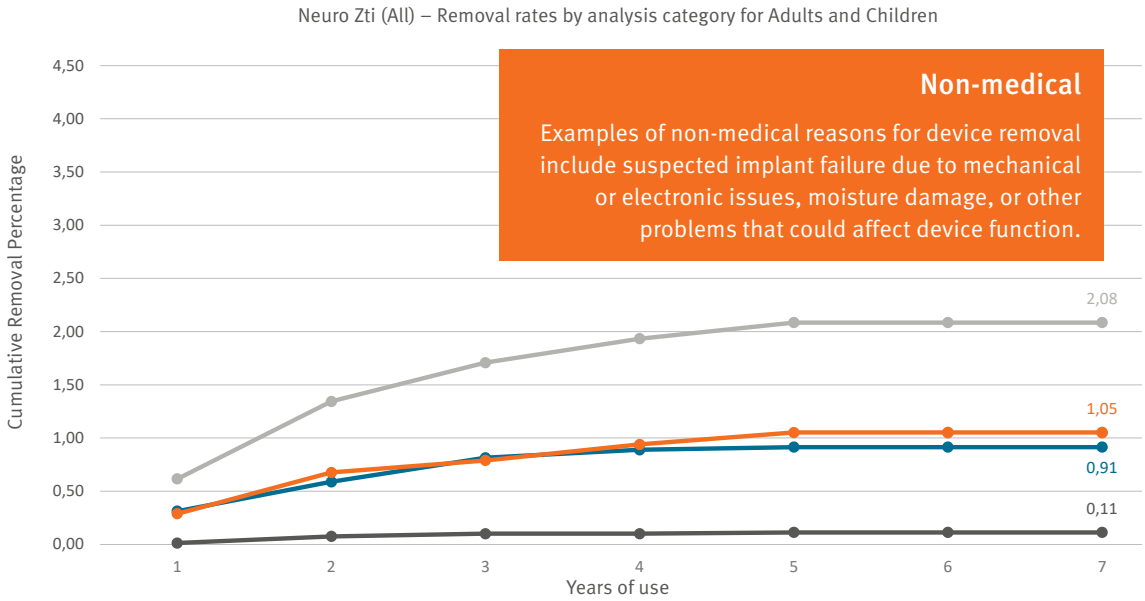
# How to read the implant data

## Medical reason

Examples of medical reasons for device removal include infection, rejection of the device due to allergy, or improper positioning of the internal device.

## Inconclusive reason

Occasionally, manufacturer testing of the device indicates no fault found with the device, despite a reason for removal.




## Non-medical

Examples of non-medical reasons for device removal include suspected implant failure due to mechanical or electronic issues, moisture damage, or other problems that could affect device function.

| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Medical related | 0.31% | 0.59% | 0.81% | 0.89% | 0.91% | 0.91% | 0.91% |
| Non-medical | 0.29% | 0.68% | 0.79% | 0.94% | 1.05% | 1.05% | 1.05% |
| Inconclusive | 0.01% | 0.08% | 0.10% | 0.10% | 0.11% | 0.11% | 0.11% |
| All categories | 0.62% | 1.34% | 1.71% | 1.93% | 2.08% | 2.08% | 2.08% |

## CRP – Cumulative Removal Percentage

Percentage of the total number of removed devices compared to the total number of implanted devices of the same model.

## Age-related CRP

3 CRP data are reported – one for adults, one for children (below 10 years old) and one combined. Age-related differences may affect the CRP. Typically, children younger than 10 years of age have a higher chance of activity-related damage to the device.

*Note: data and graphs on this page are for example only.*

## Neuro Zti implant

The Neuro Zti cochlear implant commercialized in 2015 is the result of more than 25 years' experience in cochlear implant development, manufacturing know-how and material science expertise.

In October 2021 Oticon Medical voluntarily withdrew non-implanted Neuro Zti CI implants from circulation due to the identification of a number of devices exhibiting a loss of hermeticity. The issue was attributed to a small number of devices from specific batches. This is clearly reflected in the reliability data, where an irregular drop of around 2% is apparent. All potentially affected non-implanted devices were removed from the market on the day of the notification.

The root cause of loss of hermeticity was identified and corrective and preventive actions put into place. The Neuro Zti implant was cleared for re-entry to market by regulatory authorities in June 2022.

The reliability of the new implant version will be reported in 2023.

# Neuro Zti implant

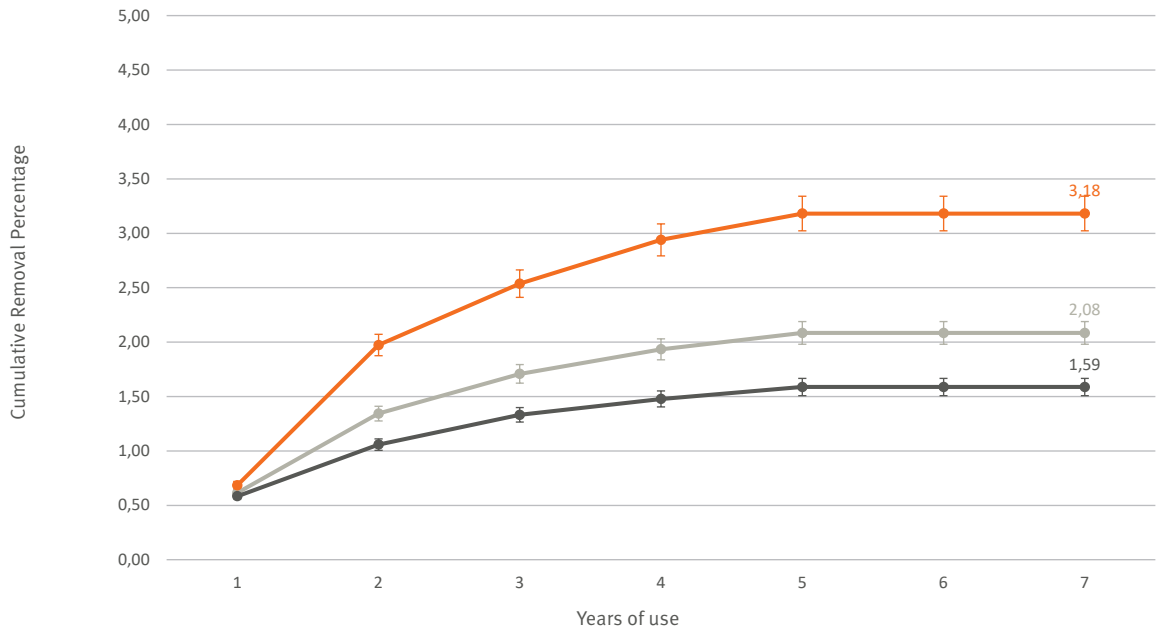
| Group | Adults | | | | | |
|---|---|---|---|---|---|---|
| Subcategory | Medical related | Device failure | Inconclusive | Total | Total | |
| Years | CRP | CRP | CRP | CRP | CI_up | CI_low |
| Y1 | 0.29 | 0.27 | 0.02 | 0.58 | 0.91 | 0.26 |
| Y2 | 0.47 | 0.55 | 0.04 | 1.06 | 1.38 | 0.74 |
| Y3 | 0.68 | 0.60 | 0.05 | 1.33 | 1.65 | 1.01 |
| Y4 | 0.75 | 0.68 | 0.05 | 1.48 | 1.80 | 1.16 |
| Y5 | 0.77 | 0.75 | 0.07 | 1.59 | 1.91 | 1.27 |
| Y6 | 0.77 | 0.75 | 0.07 | 1.59 | 1.91 | 1.27 |
| Y7 | 0.77 | 0.75 | 0.07 | 1.59 | 1.91 | 1.27 |

| Group | Children | | | | | |
|---|---|---|---|---|---|---|
| Subcategory | Medical related | Device failure | Inconclusive | Total | Total | |
| Years | CRP | CRP | CRP | CRP | CI_up | CI_low |
| Y1 | 0.36 | 0.32 | 0.00 | 0.68 | 1.48 | -0.11 |
| Y2 | 0.85 | 0.97 | 0.16 | 1.97 | 2.77 | 1.18 |
| Y3 | 1.13 | 1.21 | 0.20 | 2.54 | 3.33 | 1.74 |
| Y4 | 1.21 | 1.53 | 0.20 | 2.94 | 3.73 | 2.15 |
| Y5 | 1.25 | 1.73 | 0.20 | 3.18 | 3.98 | 2.39 |
| Y6 | 1.25 | 1.73 | 0.20 | 3.18 | 3.98 | 2.39 |
| Y7 | 1.25 | 1.73 | 0.20 | 3.18 | 3.98 | 2.39 |

| Group | Combined Adults and Children | | | | | |
|---|---|---|---|---|---|---|
| Subcategory | Medical related | Device failure | Inconclusive | Total | Total | |
| Years | CRP | CRP | CRP | CRP | CI_up | CI_low |
| Y1 | 0.31 | 0.29 | 0.01 | 0.62 | 1.08 | 0.15 |
| Y2 | 0.59 | 0.68 | 0.08 | 1.34 | 1.81 | 0.87 |
| Y3 | 0.81 | 0.79 | 0.10 | 1.71 | 2.18 | 1.24 |
| Y4 | 0.89 | 0.94 | 0.10 | 1.93 | 2.40 | 1.46 |
| Y5 | 0.91 | 1.05 | 0.11 | 2.08 | 2.55 | 1.62 |
| Y6 | 0.91 | 1.05 | 0.11 | 2.08 | 2.55 | 1.62 |
| Y7 | 0.91 | 1.05 | 0.11 | 2.08 | 2.55 | 1.62 |

*Note: CI_up and CI_down are 95% Confidence Limits.*

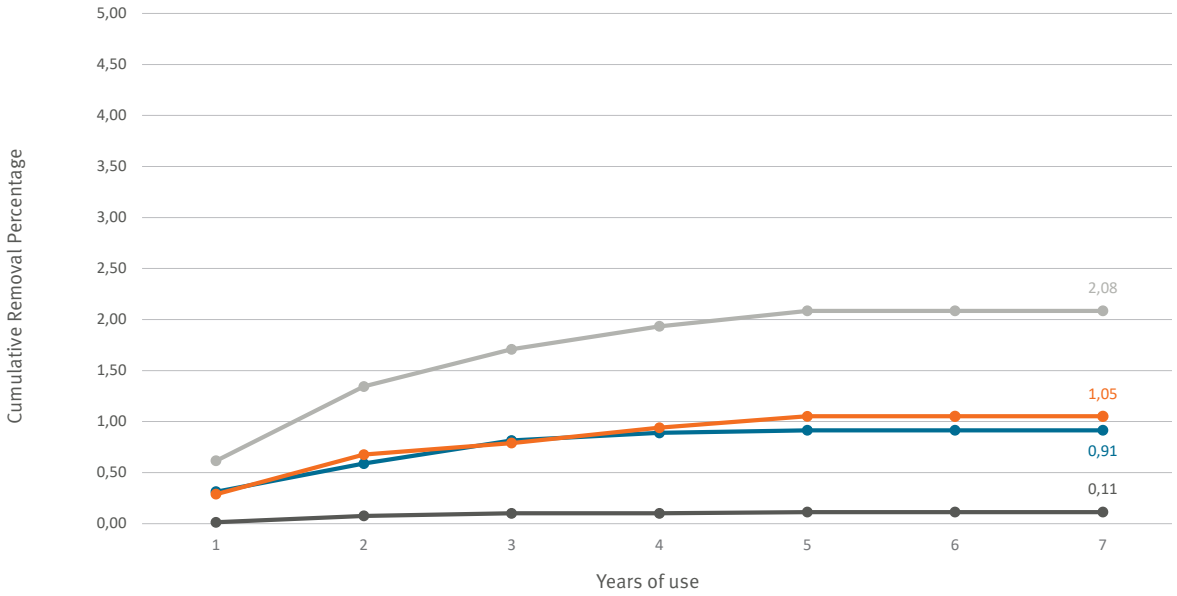
# Neuro Zti removal rates for all analysis categories and patient populations




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Combined adults & children | 0.62% | 1.34% | 1.71% | 1.93% | 2.08% | 2.08% | 2.08% |
| Adults ( ≥10y ) | 0.58% | 1.06% | 1.33% | 1.48% | 1.59% | 1.59% | 1.59% |
| Children ( <10y ) | 0.68% | 1.97% | 2.54% | 2.94% | 3.18% | 3.18% | 3.18% |

*data as june 30th 2022*

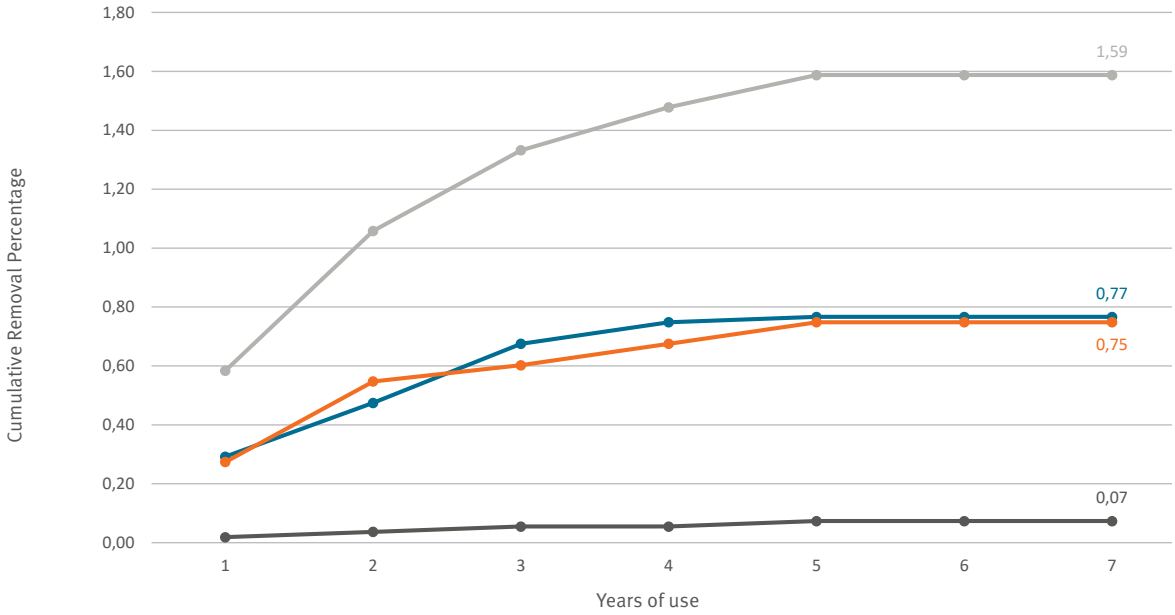
# Neuro Zti removal rates by analysis category for adults and children




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Medical related | 0.31% | 0.59% | 0.81% | 0.89% | 0.91% | 0.91% | 0.91% |
| Device failure | 0.29% | 0.68% | 0.79% | 0.94% | 1.05% | 1.05% | 1.05% |
| Inconclusive | 0.01% | 0.08% | 1.10% | 0.10% | 0.11% | 0.11% | 0.11% |
| All categories | 0.62% | 1.34% | 1.71% | 1.93% | 2.08% | 2.08% | 2.08% |

*data as june 30th 2022*

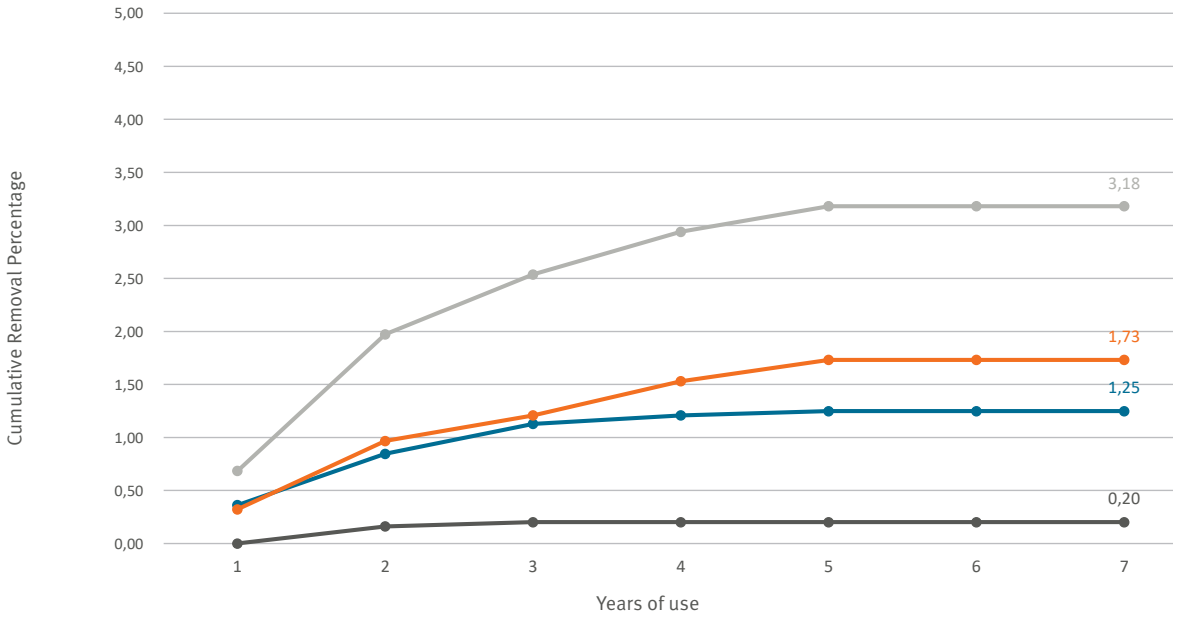
# Neuro Zti removal rates by analysis category for adults




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Medical related | 0.29% | 0.47% | 0.68% | 0.75% | 0.77% | 0.77% | 0.77% |
| Device failure | 0.27% | 0.55% | 0.60% | 0.68% | 0.75% | 0.75% | 0.75% |
| Inconclusive | 0.02% | 0.04% | 0.05% | 0.05% | 0.07% | 0.07% | 0.07% |
| All categories | 0.58% | 1.06% | 1.33% | 1.48% | 1.59% | 1.59% | 1.59% |

*data as june 30th 2022*

# Neuro Zti removal rates by analysis category for children ( <10 years old )




| | 1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years |
|---|---|---|---|---|---|---|---|
| Medical related | 0.36% | 0.85% | 1.13% | 1.21% | 1.25% | 1.25% | 1.25% |
| Device failure | 0.32% | 0.97% | 1.21% | 1.53% | 1.73% | 1.73% | 1.73% |
| Inconclusive | 0.00% | 0.16% | 0.20% | 0.20% | 0.20% | 0.20% | 0.20% |
| All categories | 0.68% | 1.97% | 2.54% | 2.94% | 3.18% | 3.18% | 3.18% |

*data as june 30th 2022*

# Sound processor reliability

As for sound processors, we calculate the Failed Component Return Rate (FCRR) to describe their reliability, in accordance with the ANSI/AAMI CI 86 standards. The manufacturer tests sound processors that have been returned to determine if they are working and, if not, why they failed.

*I started noticing some sounds straight away. At first it was the sound of drawers being closed and cars in the street, then I started being able to hear the sound of my children's voices."*

Mette, Denmark, cochlear implant user

# How to read the sound processor data

Failed Component Return Rate (FCRR): percentage of the total number of original non-implantable components sold which are returned as failed devices each month.

### Electronic failure

A functional failure of the electronics or the electronic assembly.

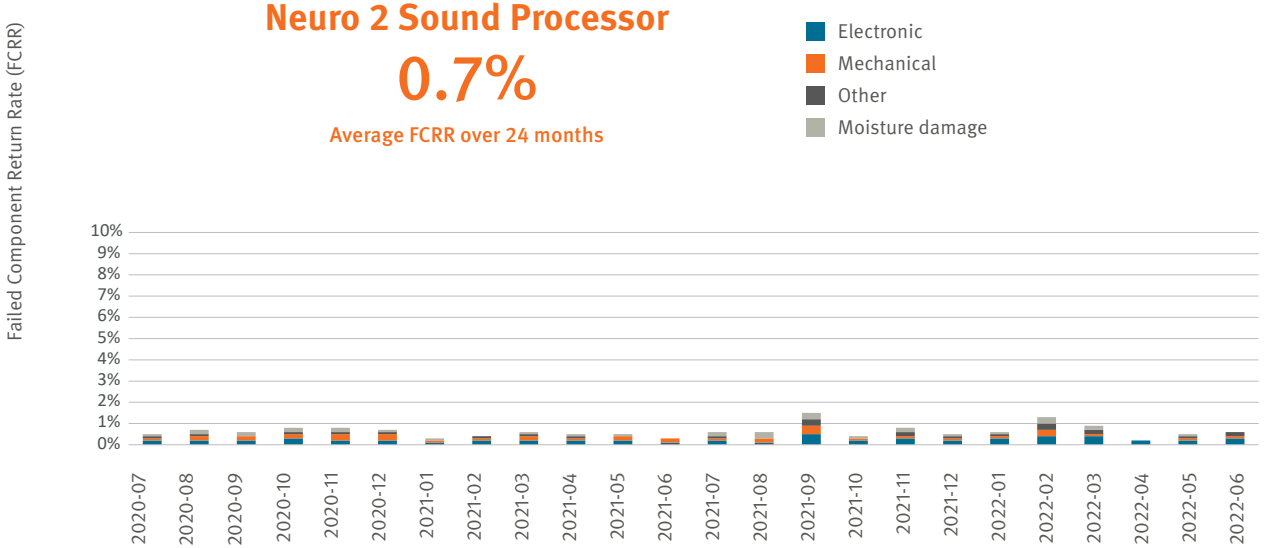
### Other/unknown failure

Failures that don't fit in the other categories (e.g. firmware failures).

## Neuro 2 Sound Processor

**0.7%**

Average FCRR over 24 months




### Mechanical failure

A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use.

### Moisture damage failure

A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.

The Neuro 2 sound processor commercialized in 2018 is the smallest sound processor on the market.[1] It is sweeping up prizes in the cochlear implant industry due to its groundbreaking design.

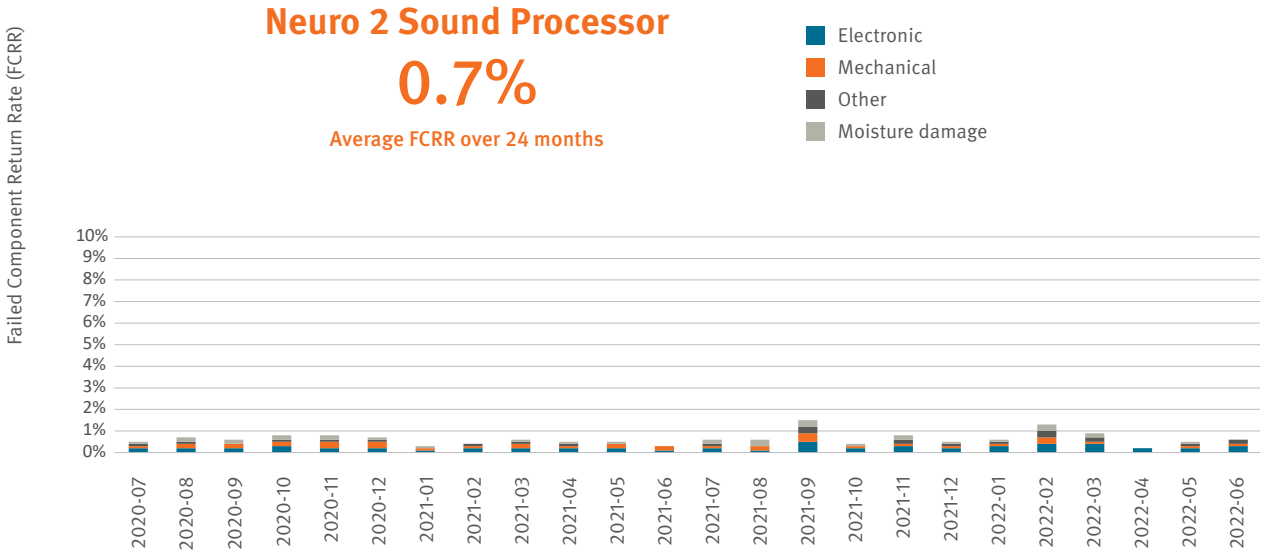
[1]*Oticon Medical CI Unique, sept 2020, version G (DOC-00067651).*

# Neuro 2 Sound Processor

## Neuro 2 Sound Processor – Failed Component Return Rate

| Fail Mode | July 20 | Aug 20 | Sep 20 | Oct 20 | Nov 20 | Dec 20 | Jan 21 | Feb 21 | Mar 21 | April 21 | May 21 | Jun 21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Electronic | 0.2% | 0.2% | 0.2% | 0.3% | 0.2% | 0.2% | 0.1% | 0.2% | 0.2% | 0.2% | 0.2% | 0.1% |
| Fault-free* | 0.3% | 0.5% | 0.3% | 0.3% | 0.4% | 0.2% | 0.1% | 0.2% | 0.2% | 0.2% | 0.1% | 0.2% |
| Mechanical | 0.1% | 0.2% | 0.2% | 0.2% | 0.3% | 0.3% | 0.1% | 0.1% | 0.2% | 0.1% | 0.2% | 0.2% |
| Moisture damage | 0.1% | 0.2% | 0.2% | 0.2% | 0.2% | 0.1% | 0.1% | 0.0% | 0.1% | 0.1% | 0.1% | 0.0% |
| Other | 0.1% | 0.1% | 0.0% | 0.1% | 0.1% | 0.1% | 0.0% | 0.1% | 0.1% | 0.1% | 0.0% | 0.0% |

| Fail Mode | July 21 | Aug 21 | Sep 21 | Oct 21 | Nov 21 | Dec 21 | Jan 22 | Feb 22 | Mar 22 | Apr 22 | May 22 | Jun 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Electronic | 0.2% | 0.1% | 0.5% | 0.2% | 0.3% | 0.2% | 0.3% | 0.4% | 0.4% | 0.2% | 0.2% | 0.3% |
| Fault-free* | 0.2% | 0.1% | 0.4% | 0.1% | 0.3% | 0.3% | 0.3% | 0.4% | 0.4% | 0.1% | 0.1% | 0.2% |
| Mechanical | 0.1% | 0.2% | 0.4% | 0.1% | 0.1% | 0.1% | 0.1% | 0.3% | 0.1% | 0.0% | 0.1% | 0.1% |
| Moisture damage | 0.2% | 0.3% | 0.3% | 0.1% | 0.2% | 0.1% | 0.1% | 0.3% | 0.2% | 0.0% | 0.1% | 0.0% |
| Other | 0.1% | 0.0% | 0.3% | 0.0% | 0.2% | 0.1% | 0.1% | 0.3% | 0.2% | 0.0% | 0.1% | 0.2% |




** Fault-free fail mode is a returned device that is found to be fully functional. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discoloration), corrosion, and/or moisture damage that did not result in a functional failure.*

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