Reliability Report 2021

According to ANSI/AAMI CI86 Standard

June 2021

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.
At Oticon Medical we recognise this importance and strive for the best reliability for all our users.

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. Both exhibit the very high reliability one would expect from a company with over 100 years of research and development in hearing health.

It is Oticon Medical's aim to provide CI users with the clearest sound possible and we are well-positioned to bring the quality and technologies already widely appreciated by Oticon hearing aid users to cochlear implant development and innovation.

The Neuro CI System is available in 53 countries and has received premarket approval in the US by the FDA for use in individuals of 18 years or older, with bilateral severe-to-profound sensorineural hearing loss, who obtain limited benefit from appropriately fitted hearing aid(s). The Neuro System is the first new cochlear implant technology to earn FDA premarket approval in more than 20 years and is expected to be available to CI candidates in the USA during 2021.

Jes Olsen

President, Oticon Medical

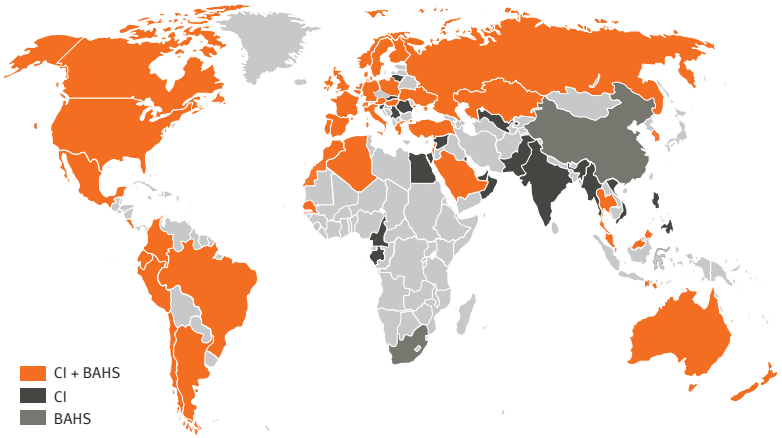
About Demant

Oticon Medical is part of the global hearing healthcare group Demant. Through multiple individual companies, the Group offers solutions and services that help people with hearing loss connect and communicate with the world around them. Our strength lies in our foundation-based ownership and the heritage of making life-changing differences. For more than a century the Demant Group has played a vital part in developing innovative technologies and know-how to help improve people's hearing and health.

In every aspect, from hearing devices, hearing implants, diagnostic equipment and services, to hearing care all over the world, Demant is active and engaged. A growing business delivering high-end audio solutions for enterprise and leisure use is also a significant part of the Group.

The Demant Group operates in a global market with own companies in more than 30 countries, employs more than 16,500 employees and generates an annual revenue of DKK 15 billion. Demant is the parent company behind a number of world-renowned brands, such as Oticon, Bernafon, Sonic, Philips HearLink, Audika, Oticon Medical, MAICO, Interacoustics, Amplivox, Grason-Stadler, MedRx, Audioscan, and EPOS. The Group's products are sold in more than 130 countries where we create life-changing differences through hearing health.

Whilst Oticon Medical is an independent company within the Demant group, we work closely together with our sister companies to combine knowledge, expertise and highly advanced technology platforms to be able to offer users both the benefit of latest technology as well as valuable insights into hearing care.



Numerous tests performed to ensure high reliability

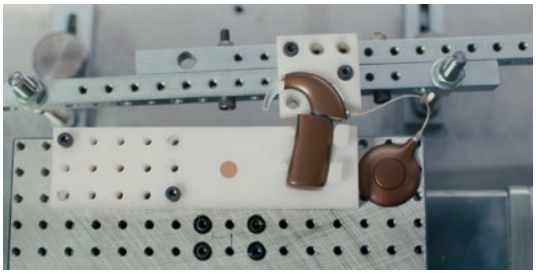
Cochlear implants help thousands of people worldwide, every day of every year.

At Oticon Medical, we understand that if patients use a cochlear implant, they need to be able to rely on its performance – for work, for play, for staying in touch – for life.

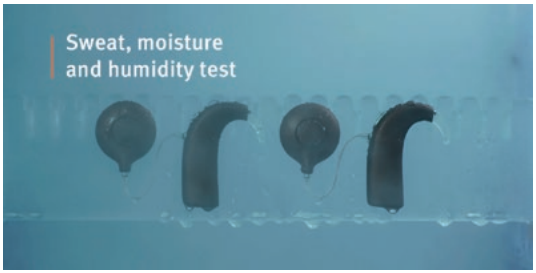
That's why our products live up to the highest quality standards, in compliance with hundreds of international requirements.

To simulate patient's active lives, our 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 states the device must pass over 6,000 cycles which represents more than 15 years of use.

Implant impact test



Sound processor battery compartment test – 6,000 cycles



Sound processor sweat, moisture and humidity test

How this report has been made

In 2017, guidelines were approved (ANSI/AAMI C186) outlining procedures that manufacturers should follow when reporting the reliability of cochlear implants. This report meets the reporting standards and methodology recommended by 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.

As for sound processors, we calculate the Failed Component Return Rate (FCRR) to describe their reliability, in accordance with the ANSI/AAMI guideline.

The manufacturer tests sound processors that have been returned to determine if they are working and, if not, why they failed.

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

Reliability at a glance

Neuro Zti

1.39%

Average CRP* after 6 years

Neuro 2

0.6%

Average FCRR over 24 months**

Data as of June 30, 2021

* *CRP = Cumulative Removal Percentage*
** *FCRR = Failed Component Return Rate*

You will note that no implant device has perfect reliability over time.
You are encouraged to discuss concerns and questions you have about device reliability with your hearing professional.

Implant reliability

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.

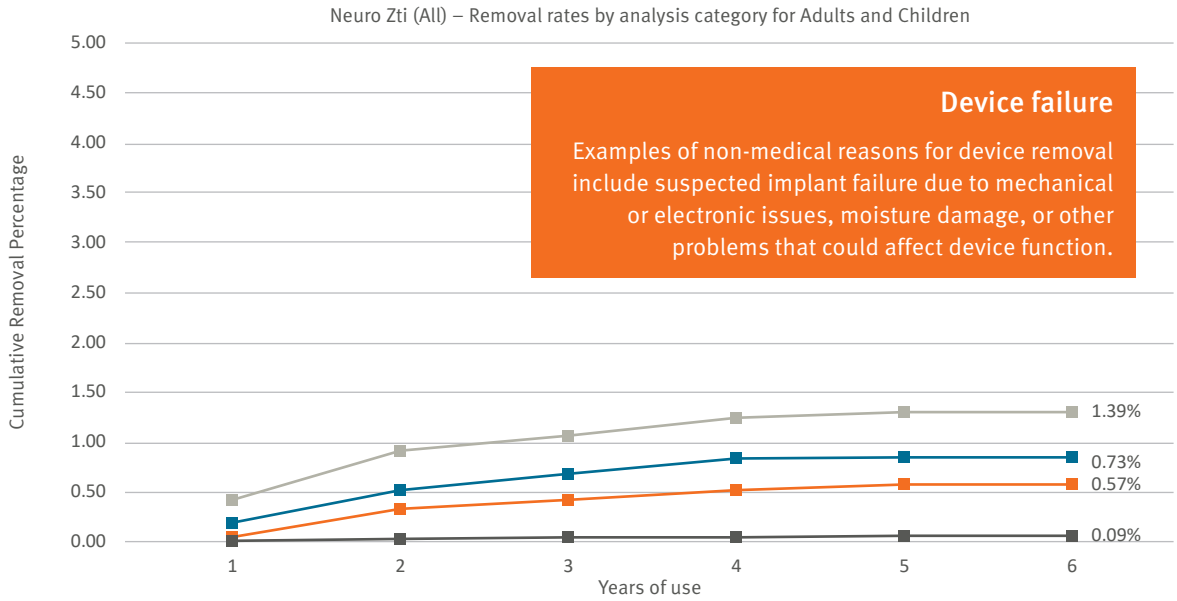
How to read the implant data

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.



Device failure

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
Medical related	0.29%	0.52%	0.68%	0.72%	0.73%	0.73%
Device failure	0.15%	0.36%	0.44%	0.52%	0.57%	0.57%
Inconclusive	0.01%	0.05%	0.08%	0.08%	0.09%	0.09%
All categories	0.44%	0.91%	1.19%	1.31%	1.39%	1.39%

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

Neuro Zti implant Cumulative Removal Rates

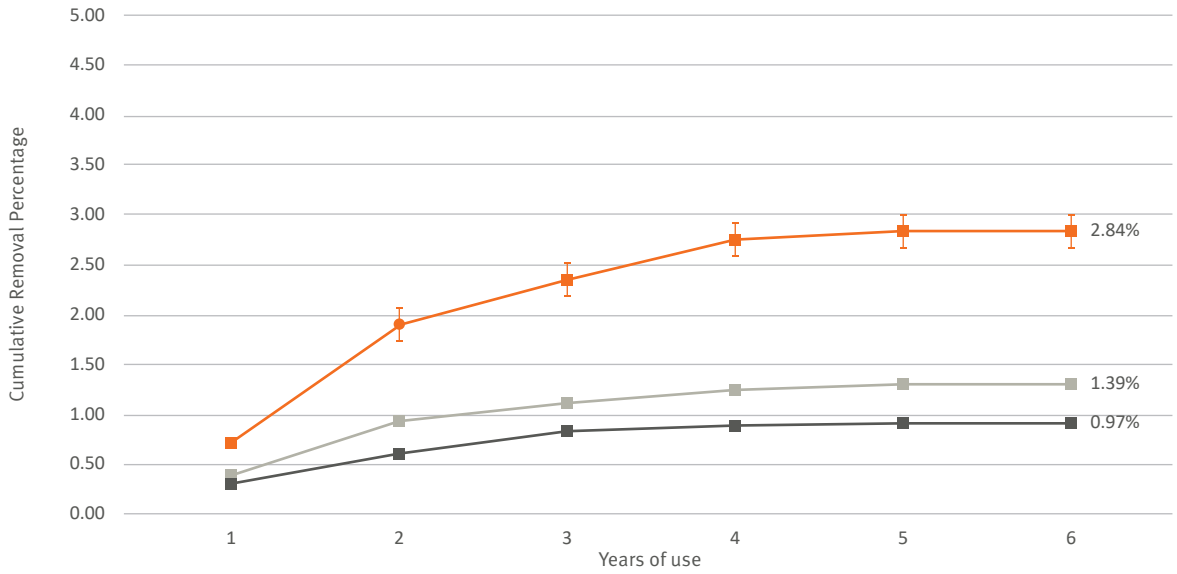
Group	Adults					
Subcategory	Medical related	Device failure	Inconclusive	Total	Total	
Years	CRP	CRP	CRP	CRP	CI_up	CI_down
Y1	0.26	0.09	0.02	0.36	0.59	0.13
Y2	0.39	0.20	0.02	0.61	0.85	0.38
Y3	0.55	0.24	0.03	0.82	1.05	0.59
Y4	0.58	0.29	0.03	0.90	1.14	0.67
Y5	0.58	0.34	0.05	0.97	1.21	0.74
Y6	0.58	0.34	0.05	0.97	1.21	0.74

Group	Children					
Subcategory	Medical related	Device failure	Inconclusive	Total	Total	
Years	CRP	CRP	CRP	CRP	CI_up	CI_down
Y1	0.41	0.30	0.00	0.71	1.50	-0.08
Y2	0.95	0.83	0.18	1.95	2.74	1.16
Y3	1.12	1.06	0.24	2.42	3.22	1.63
Y4	1.18	1.30	0.24	2.72	3.51	1.93
Y5	1.24	1.36	0.24	2.84	3.63	2.05
Y6	1.24	1.36	0.24	2.84	3.63	2.05

Group	Combined Adults and Children					
Subcategory	Medical related	Device failure	Inconclusive	Total	Total	
Years	CRP	CRP	CRP	CRP	CI_up	CI_down
Y1	0.29	0.15	0.01	0.44	0.79	0.08
Y2	0.52	0.36	0.05	0.91	1.27	0.56
Y3	0.68	0.44	0.08	1.19	1.55	0.83
Y4	0.72	0.52	0.08	1.31	1.67	0.95
Y5	0.73	0.57	0.09	1.39	1.75	1.03
Y6	0.73	0.57	0.09	1.39	1.75	1.03

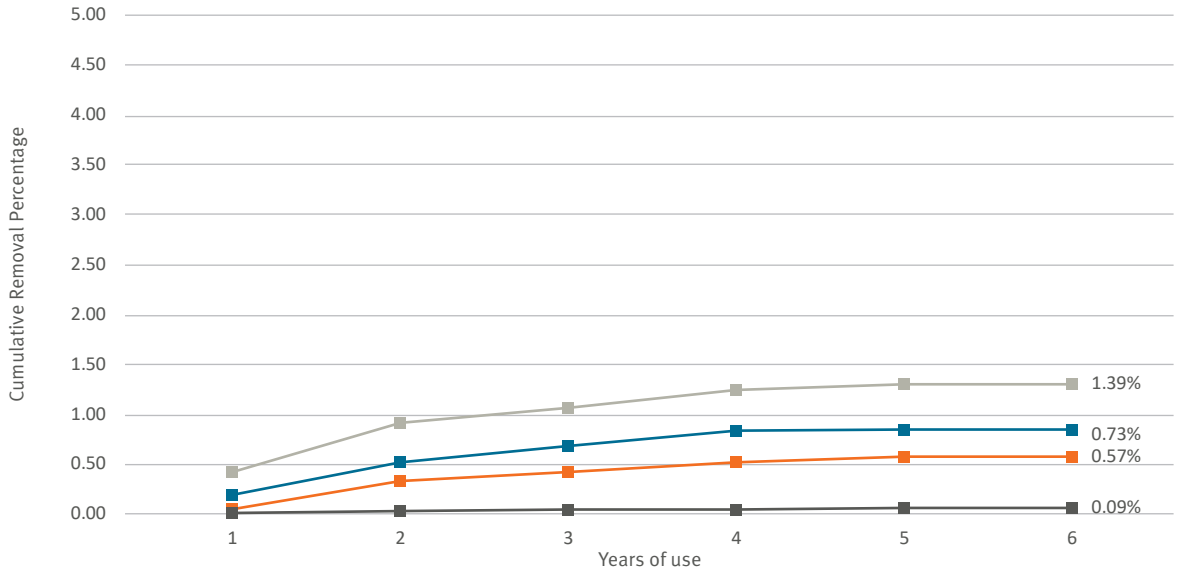
Note: CI_up and CI_down are 95% Confidence Limits.

Neuro Zti removal rates for all analysis categories and patient populations



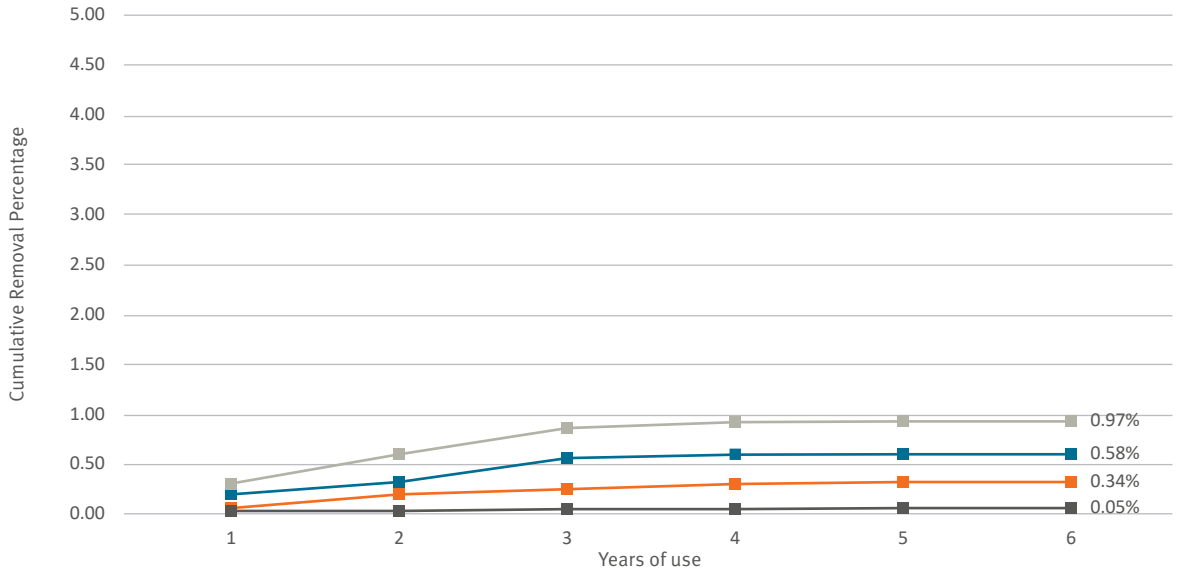
	1 year	2 years	3 years	4 years	5 years	6 years
Combined adults & children	0.44%	0.91%	1.19%	1.31%	1.39%	1.39%
Adults (≥10y)	0.36%	0.61%	0.82%	0.90%	0.97%	0.97%
Children (<10y)	0.71%	1.95%	2.42%	2.72%	2.84%	2.84%

Neuro Zti removal rates by analysis category for adults and children



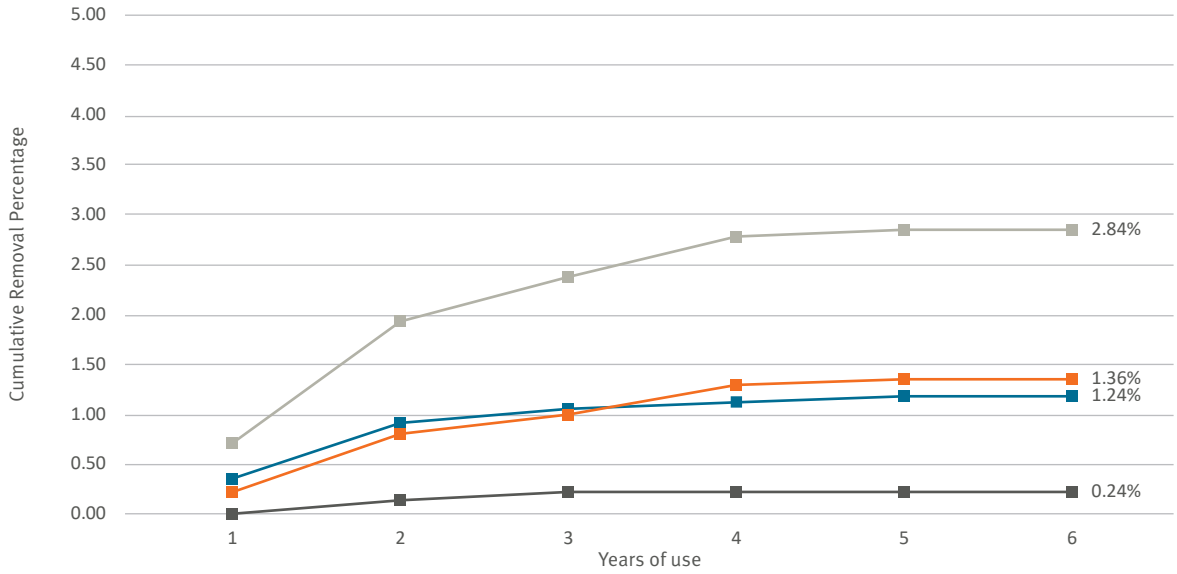
	1 year	2 years	3 years	4 years	5 years	6 years
Medical related	0.29%	0.52%	0.68%	0.72%	0.73%	0.73%
Device failure	0.15%	0.36%	0.44%	0.52%	0.57%	0.57%
Inconclusive	0.01%	0.05%	0.08%	0.08%	0.09%	0.09%
All categories	0.44%	0.91%	1.19%	1.31%	1.39%	1.39%

Neuro Zti removal rates by analysis category for adults



	1 year	2 years	3 years	4 years	5 years	6 years
Medical related	0.26%	0.39%	0.55%	0.58%	0.58%	0.58%
Device failure	0.09%	0.20%	0.24%	0.29%	0.34%	0.34%
Inconclusive	0.02%	0.02%	0.03%	0.03%	0.05%	0.05%
All categories	0.39%	0.61%	0.82%	0.90%	0.97%	0.97%

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



	1 year	2 years	3 years	4 years	5 years	6 years
Medical related	0.41%	0.95%	1.12%	1.18%	1.24%	1.24%
Device failure	0.30%	0.83%	1.06%	1.30%	1.36%	1.36%
Inconclusive	0.00%	0.18%	0.24%	0.24%	0.24%	0.24%
All categories	0.71%	1.95%	2.42%	2.72%	2.84%	2.84%

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

Sound processor reliability

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

[1] *Data on file Oticon Medical*

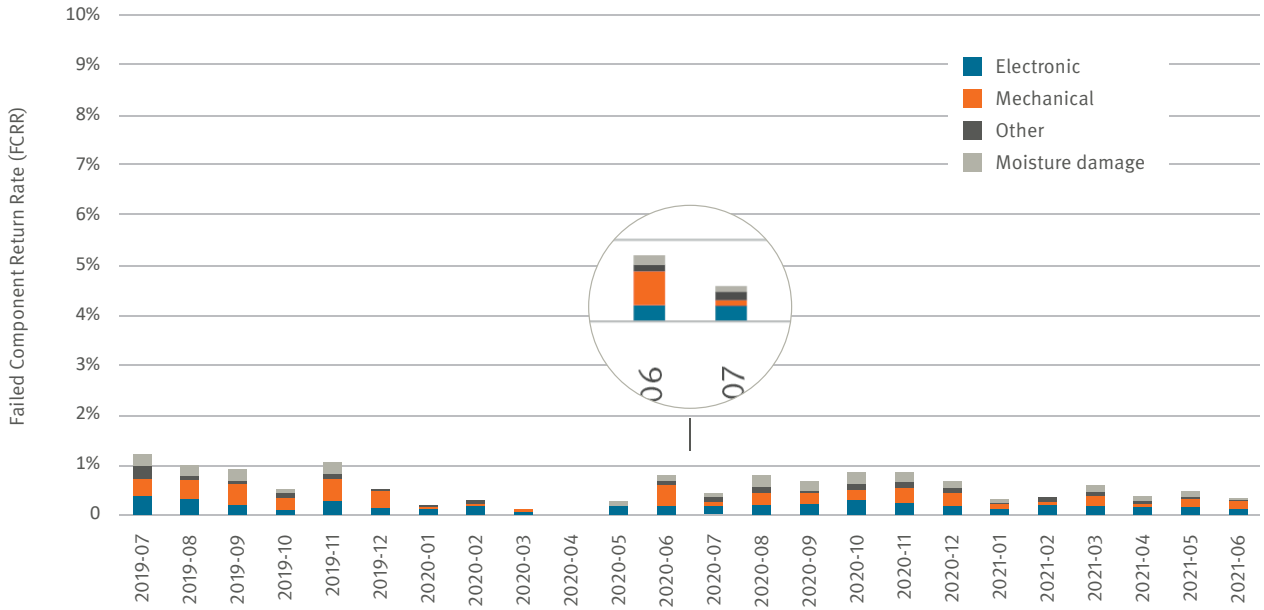
How to read the sound processor data

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).



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

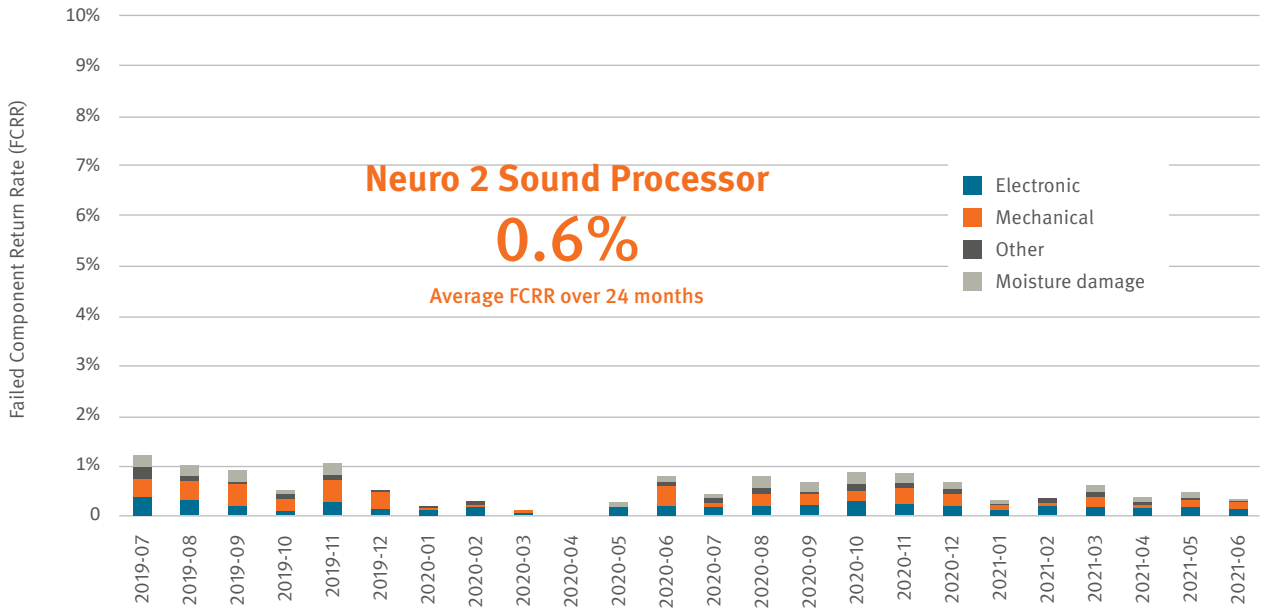
A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.

Neuro 2 Sound Processor

Neuro 2 Sound Processor – Failed Component Return Rate

Fail Mode	July 19	Aug 19	Sep 19	Oct 19	Nov 19	Dec 19	Jan 20	Feb 20	Mar 20	April 20	May 20	Jun 20
Electronic	0.4%	0.3%	0.2%	0.1%	0.3%	0.1%	0.1%	0.2%	0.0%	0.0%	0.2%	0.2%
Fault-free*	0.5%	0.5%	0.2%	0.4%	0.5%	0.3%	0.3%	0.2%	0.2%	0.0%	0.2%	0.3%
Mechanical	0.4%	0.4%	0.4%	0.2%	0.4%	0.4%	0.1%	0.0%	0.1%	0.0%	0.0%	0.4%
Moisture damage	0.2%	0.2%	0.2%	0.1%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%
Other	0.3%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	0.1%

Fail Mode	July 20	Aug 20	Sep 20	Oct 20	Nov 20	Dec 20	Jan 21	Feb 21	Mar 21	Apr 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%	0.1%
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%



** 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.*

I can now participate in dinners and can have conversations with people. That is very different compared to before and has been a great change.”

Jes, Denmark, cochlear implant user

Notes

Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the power of sound to people at every stage of life. As part of the Demant group, a global leader in hearing health care with more than 16,500 people in over 30 countries and users benefitting from our products and solutions in more than 130 countries, we have access to one of the world's strongest research and development teams and the latest technological advances and insights into hearing care.

Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology. We work collaboratively with patients, physicians and hearing care professionals to ensure that every solution we create is designed with user needs in mind. We have a strong passion to provide innovative solutions and support that enhance quality of life and help people live full lives – now and in the future.
Because we know how much sound matters.

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