

Cochlear™ Nucleus® System

Reliability Report

Volume 20 | December 2021

Reporting to European Consensus Statement, International Classification of Reliability, ANSI/AAMI Cl86 Standard and ISO 5841-2.

A message from our CEO

We are proud to present our latest implant and sound processor reliability data in the following Reliability Report. Building on our 40-year track record, we continue to deliver the most reliable products on the market¹, opening up a world of better hearing to hundreds of thousands of people across the globe.

Innovation is at the heart of what drives us, and we are inspired by delivering products, services and care solutions that truly meet the needs of patients and the hearing health professionals who care for them.

As the global leader in implantable hearing, with more than 650,000 devices provided, our hearing solutions are built on world-class design and are tested and retested to rigorous standards.

We hold ourselves to account by publishing reliability data in full accordance with industry reporting standards. We report with full transparency on the reliability of our implants and sound processors, recognising the important role that this plays in providing reassurance for those who rely on us.

We look forward to continuing to work with the hearing health industry to deliver reliable, innovative products to those with hearing loss, bringing more people into the world of sound.

Dig Howitt
CEO & President

About this report

This report provides reliability data for the internal (cochlear implant) and external (sound processor) components of our Nucleus® Systems.

Implant reliability data

The implant data in this report is based on the reporting methodology recommended by *International Standard ISO 5841-2*^{2,3}, the reporting principles outlined in the *European Consensus Statement on Cochlear Implant Failures and Explantations*⁴ and expert recommendations from the *International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators*. This report meets the requirements for cochlear implant reliability reporting outlined in these standards.

For implant reliability data which meets the reporting standards and methodology recommended by ANSI/AAMI Cl86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting⁶, please visit www.cochlear.com/reliability.

Sound processor reliability data

The sound processor data in this report meets the reporting standards and methodology recommended by ANSI/AAMI Cl86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.⁶

For the latest sound processor reliability data, please visit www.cochlear.com/reliability.

Implant reliability

Why implant reliability matters

Longevity is an important factor when choosing an implant, especially if you are choosing for a child. High implant reliability can mean greater recipient satisfaction and less risk of additional surgery. When considering a cochlear implant, you should have access to the latest data on short and long term reliability, including success and failure rates for both adults and children.

What is Cumulative Survival Percentage (CSP)?

CSP is the metric used in this report to measure implant reliability. CSP provides information regarding the reliability of each make and model of implant over time.

CSP tells you the cumulative percentage of functioning implants over a given time period. For example, a CSP of 99% after five years means the chance of obtaining continued benefit from the cochlear implant, as described for its intended use, is 99% after five years. Put another way, the implant is 99% reliable within five years.

Calculation of CSP

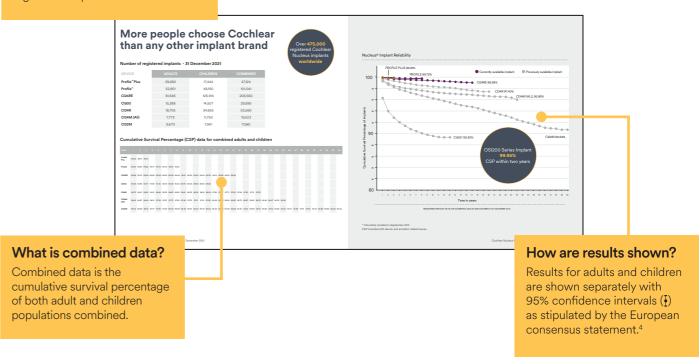
In this report, CSP includes both device and accident-related issues.

The reliability calculations used in this report are in accordance with the *International Standard ISO* 5841-2.^{2,3} They are probability calculations, which use a modified Actuarial Analysis estimator. This data estimates the probability of survival within a period of time and is represented as CSP.

How are the results shown?

What data is in this report?

The data in this report covers the entire life of implant models and registered implants* worldwide.



^{*} An implant is registered with Cochlear when the recipient/clinic/hospital submits the registration of the implanted device. Implant registrations often lag behind surgery dates.

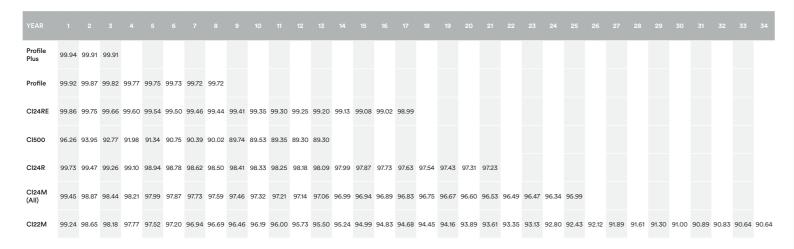
Cochlear Nucleus Reliability Report | December 2021

Over 475,000 registered Cochlear™ Nucleus® Implants worldwide

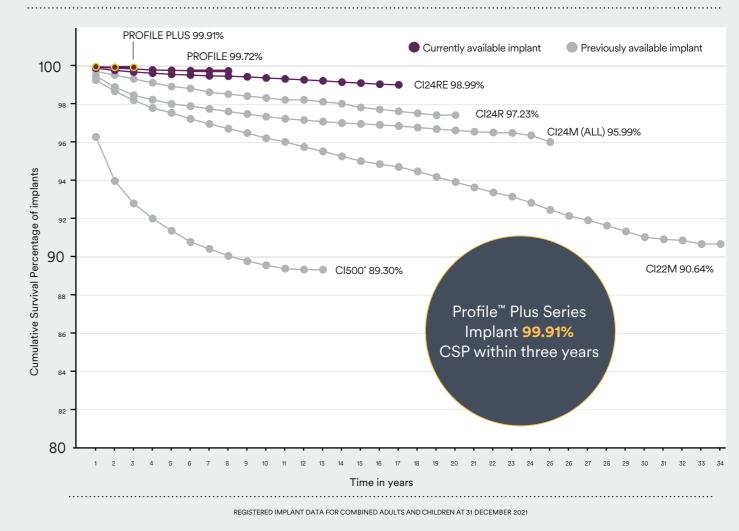
Number of registered implants - 31 December 2021

DEVICE	ADULTS	CHILDREN	COMBINED
Profile [™] Plus	29,680	17,444	47,124
Profile™	52,851	48,190	101,041
CI24RE	81,646	126,914	208,560
CI500	15,388	14,507	29,895
CI24R	18,705	34,855	53,560
CI24M (AII)	7,773	11,750	19,523
CI22M	9,670	7,991	17,661

Cumulative Survival Percentage (CSP) data for combined adults and children



Nucleus® Implant Reliability



^{*} Voluntarily recalled in September 2011. CSP includes both device and accident-related issues.

Nucleus® Profile Plus Series Implant

Number of registered Profile Plus Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
29,680	17,444	47,124



Cochlear's latest implant, the Profile Plus Series, builds on the thin design of the Profile Series Implant and provides access to MRI at 1.5 Tesla and 3.0 Tesla.

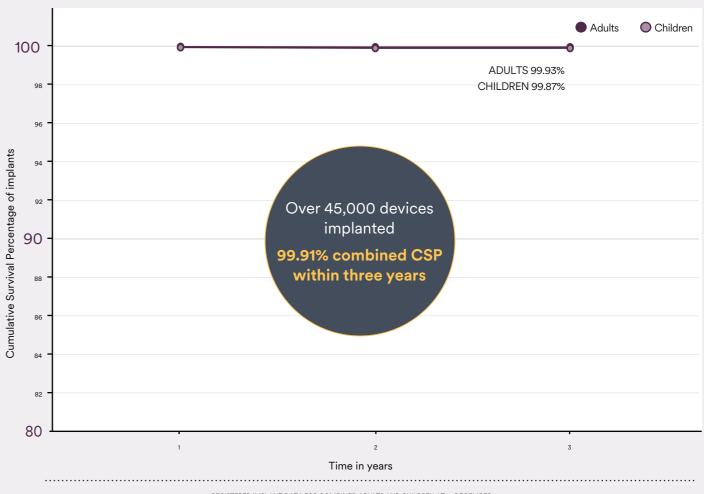
Commercially released in 2019, the Profile Plus Series Implant has delivered a combined Cumulative Survival Percentage of 99.91% within three years.

Profile Plus Series Implant Cumulative Survival Percentage

YEAR	1	2	3
Adults	99.95	99.93	99.93
Children	99.91	99.87	99.87
Combined	99.94	99.91	99.91



Profile[™] Plus Series Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2021

Nucleus Profile Series Implant

Number of registered Profile Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
52,851	48,190	101,041



At only 3.9 mm, the Profile Series Implant was commercially released in 2014 with a thin and discreet design.

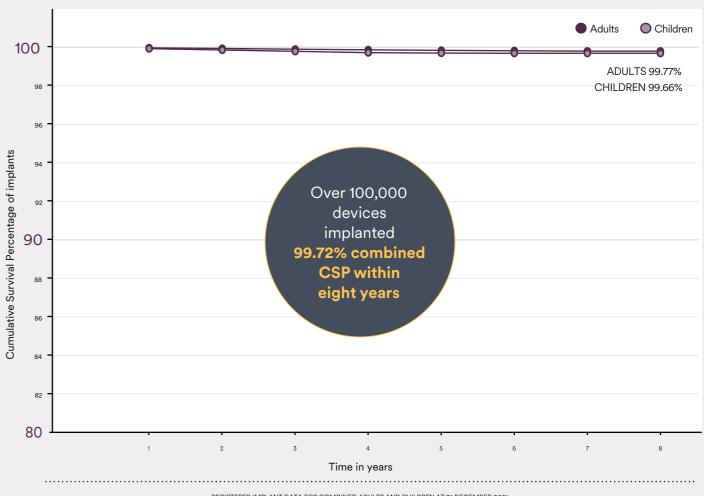
The Profile Series Implant sets the standard in implant reliability with a 99.72% combined Cumulative Survival Percentage within eight years.

Profile Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8
Adults	99.94	99.91	99.87	99.84	99.81	99.79	99.77	99.77
Children	99.90	99.83	99.76	99.69	99.67	99.66	99.66	99.66
Combined	99.92	99.87	99.82	99.77	99.75	99.73	99.72	99.72



Profile[™] Series Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2021

Nucleus Cl24RE Series Implant

Number of registered Cl24RE Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
81,646	126,914	208,560

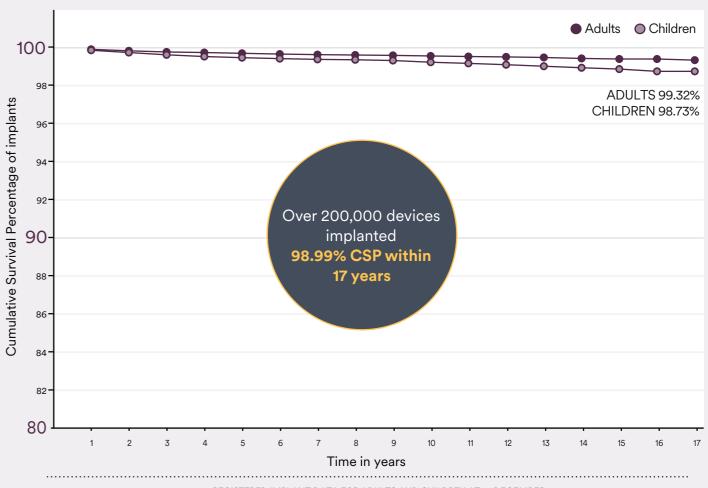


Released in 2005, it has a 98.99% combined Cumulative Survival Percentage within 17 years.

Cl24RE Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Adults	99.89	99.81	99.75	99.72	99.68	99.64	99.61	99.59	99.57	99.54	99.51	99.49	99.46	99.41	99.38	99.38	99.32
Children	99.84	99.72	99.60	99.51	99.45	99.40	99.36	99.34	99.30	99.21	99.15	99.08	99.00	98.92	98.85	98.73	98.73
Combined	99.86	99.75	99.66	99.60	99.54	99.50	99.46	99.44	99.41	99.35	99.30	99.25	99.20	99.13	99.08	99.02	98.99

CI24RE Series Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2021

Previously available implants

Nucleus® CI500 Series Implant

Number of registered CI500 Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
15,388	14,507	29,895



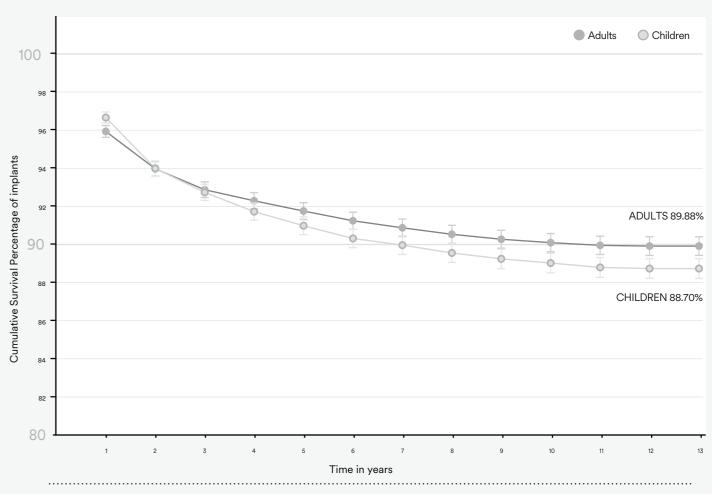
Released in 2009, the CI500 Series has a combined Cumulative Survival Percentage of 89.30% within 13 years.

The Cl500 Series was voluntarily recalled in September 2011.

CI500 Series Implant Cumulative Survival Percentage

YEAR			3				7	8		10	11	12	13
Adults	95.90	93.94	92.84	92.26	91.72	91.21	90.84	90.50	90.24	90.06	89.92	89.88	89.88
Children	96.63	93.96	92.70	91.69	90.95	90.28	89.93	89.52	89.21	88.99	88.76	88.70	88.70
Combined	96.26	93.95	92.77	91.98	91.34	90.75	90.39	90.02	89.74	89.53	89.35	89.30	89.30

CI500 Series Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2021

Nucleus Cl24R Implant

Number of registered Cl24R Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
18,705	34,855	53,560



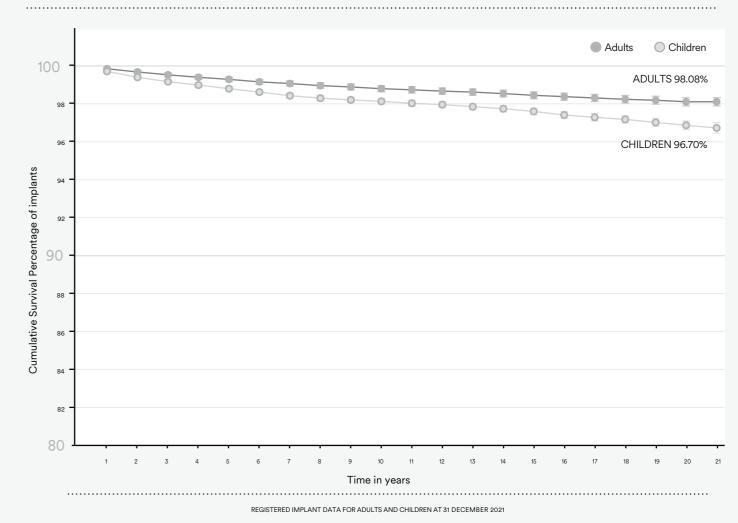
The Cl24R was released in 2000 with perimodiolar (Contour Advance®) and straight electrodes.

Within 21 years, the Cl24R Implant has a combined Cumulative Survival Percentage of 97.23%.

CI24R Implant Cumulative Survival Percentage

YEAR			3				7			10	11	12	13	14	15	16	17		19	20	21
Adults	99.82	99.65	99.50	99.37	99.26	99.13	99.04	98.93	98.86	98.77	98.71	98.64	98.59	98.51	98.42	98.35	98.28	98.21	98.16	98.08	98.08
Children	99.68	99.37	99.14	98.96	98.77	98.59	98.40	98.27	98.18	98.10	98.00	97.93	97.82	97.71	97.57	97.38	97.26	97.15	96.99	96.84	96.70
Combined	99.73	99.47	99.26	99.10	98.94	98.78	98.62	98.50	98.41	98.33	98.25	98.18	98.09	97.99	97.87	97.73	97.63	97.54	97.43	97.31	97.23

CI24R Implant Reliability



Nucleus Cl24M Implant

Number of registered Cl24M Implants - 31 December 2021

	ADULTS	CHILDREN	COMBINED
ALL	7,773	11,750	19,523
POST**	6,071	9,225	15,296



Within 25 years, the Cl24M Implant has a combined Cumulative Survival Percentage of 95.99%.

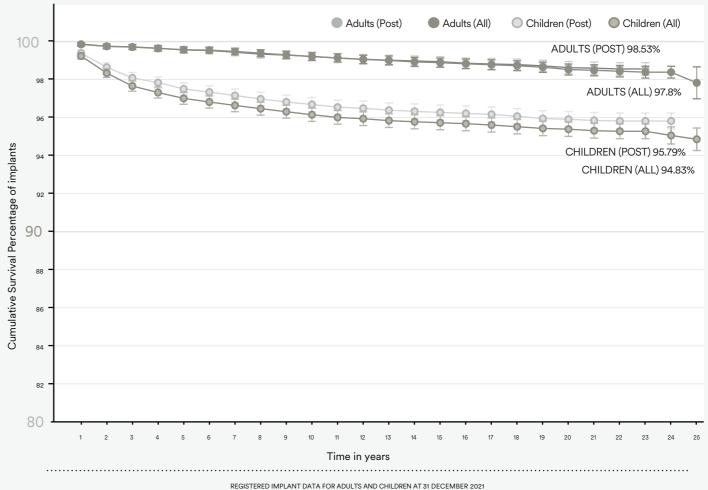
CI24M Implant Cumulative Survival Percentage

removable magnet for MRI compatibility.

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Adults (All)	99.82	99.72	99.68	99.61	99.54	99.52	99.45	99.36	99.27	99.18	99.11	99.03	98.98	98.90	98.86	98.80	98.75	98.70	98.62	98.50	98.46	98.41	98.36	98.36	97.80
Children (All)	99.21	98.31	97.63	97.29	96.98	96.79	96.61	96.44	96.28	96.12	95.98	95.91	95.81	95.75	95.70	95.65	95.58	95.49	95.40	95.36	95.28	95.25	95.25	95.03	94.83
Combined (All)	99.45	98.87	98.44	98.21	97.99	97.87	97.73	97.59	97.46	97.32	97.21	97.14	97.06	96.99	96.94	96.89	96.83	96.75	96.67	96.60	96.53	96.49	96.47	96.34	95.99
Adults (Post**)	99.84	99.72	99.69	99.62	99.53	99.50	99.41	99.31	99.26	99.19	99.10	99.04	98.99	98.95	98.91	98.83	98.79	98.76	98.69	98.60	98.57	98.53	98.53	#	#
Children (Post**)	99.36	98.62	98.06	97.81	97.48	97.31	97.13	96.95	96.79	96.66	96.52	96.46	96.36	96.30	96.24	96.19	96.14	96.04	95.92	95.88	95.82	95.79	95.79	95.79	#
Combined (Post**)	99.55	99.06	98.70	98.52	98.29	98.17	98.03	97.88	97.76	97.65	97.53	97.47	97.39	97.34	97.29	97.23	97.18	97.11	97.00	96.95	96.90	96.86	96.86	96.86	#

^{** &#}x27;Post' refers to the addition of a structural support component to improve impact strength. # Individual populations are less than the minimum required for a valid calculation.^{2,3}

CI24M Implant Reliability



Nucleus Cl22M Implant

Number of registered CI22M Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
9,670	7,991	17,661



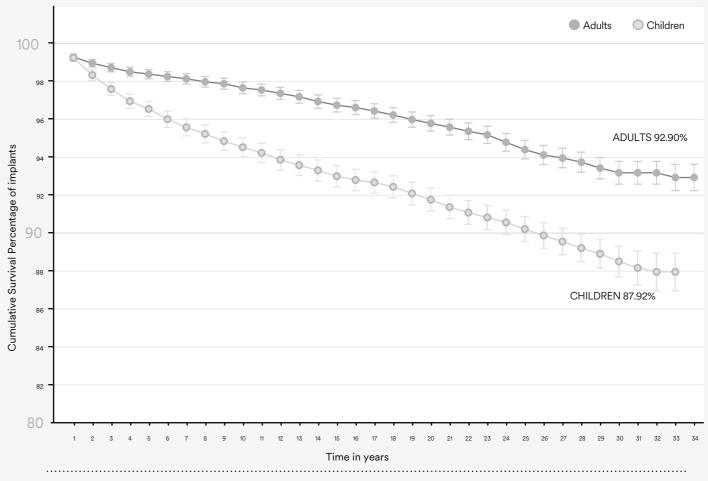
Released in 1985, the CI22M Implant was the first commercially available multi-channel cochlear implant in the world.

Within 34 years, the Cl22M Implant has a combined Cumulative Survival Percentage of 90.64%.

CI22M Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10		12		14		16	
Adults	99.26	98.93	98.70	98.48	98.36	98.23	98.11	97.95	97.85	97.63	97.52	97.34	97.16	96.91	96.72	96.59	96.41
Children	99.22	98.31	97.57	96.93	96.52	95.98	95.55	95.20	94.82	94.50	94.20	93.84	93.55	93.28	92.97	92.77	92.64
Combined	99.24	98.65	98.18	97.77	97.52	97.20	96.94	96.69	96.46	96.19	96.00	95.73	95.50	95.24	94.99	94.83	94.68
YEAR	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
YEAR Adults	18 96.20	19 95.96	20 95.76	21 95.56	22 95.34	23 95.15	24 94.76	25 94.37	26 94.09	27 93.93	28	29	30 93.15	31 93.15	32 93.15	33 92.90	34 92.90

CI22M Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2021

Sound processor reliability

Why sound processor reliability matters

The reliability of a cochlear implant system depends not only on the implant, but also on the sound processor. Sound processors are typically used for a number of years, so high reliability enables ongoing access to a consistent hearing experience.

Sound processors, as an externally worn device, are subject to a range of environmental factors, so it's important to have access to the latest data on short and long term reliability.

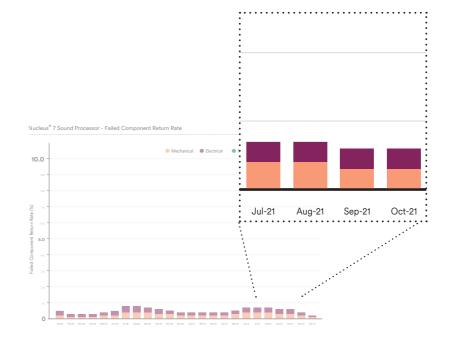
What is Failed Component Return Rate (FCRR)?

Failed Component Return Rate (FCRR) is the metric used in this report to measure sound processor reliability. FCRR provides information regarding the reliability of each make and model of sound processor.

Cochlear tests sound processors that have been returned to determine if they are working and, if not, why they failed. The FCRR is a percentage which represents the total number of failed processors received within a month compared to the total number of the same processor sold by the end of that month.

For example, if 20 faulty sound processors are returned in a month and 10,000 of the same sound processors have been sold as at the end of the month, the FCRR is 0.2%.

How are the results shown?



What is 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.

What is electrical failure?

A functional failure of the electronics or the electronic assembly.

What is moisture damage failure?

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

What is other/unknown failure?

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

What is Fault-Free data?

A returned device that is found to be fully functional is classified as faultfree. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discolouration), corrosion, and/or moisture damage that did not result in a functional failure.

Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Mechanical	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%	0.1%
Electrical	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.1%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.1%

Nucleus Kanso® 2 Sound Processor

Released in 2020, the Nucleus® Kanso® 2 Sound Processor combines our latest connectivity features and a simple and durable all-in-one design in the smallest and lightest rechargeable off-the-ear sound processor.7



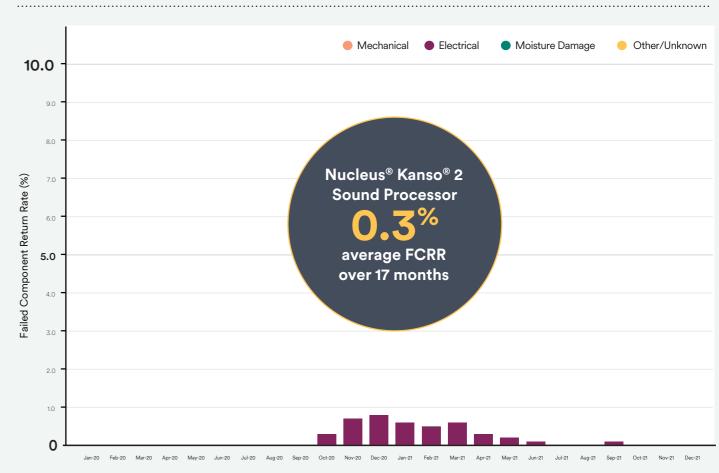
Nucleus Kanso 2 Sound Processor - Component Return Rate

Fail mode	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Mechanical	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Electrical	-	-	-	-	-	-	-	0.0%	0.0%	0.3%	0.7%	0.8%
Moisture	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Other	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	-	-	-	-	-	-	-	0.1%	0.0%	0.1%	0.3%	0.3%

Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Mechanical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Electrical	0.6%	0.5%	0.6%	0.3%	0.2%	0.1%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.3%	0.3%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%

* The Cochlear Nucleus Kanso 2 Sound Processor is compatible with Apple and Android™ devices. For compatibility information visit www.cochlear.com/compatibility.

Nucleus® Kanso® 2 Sound Processor - Failed Component Return Rate



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Nucleus® 7 Sound Processor

Released in 2017, the Cochlear[™] Nucleus[®] 7 Sound Processor is our smallest and lightest⁷ behind-the-ear sound processor offering world-first connectivity and control directly from a compatible smartphone.^{*}



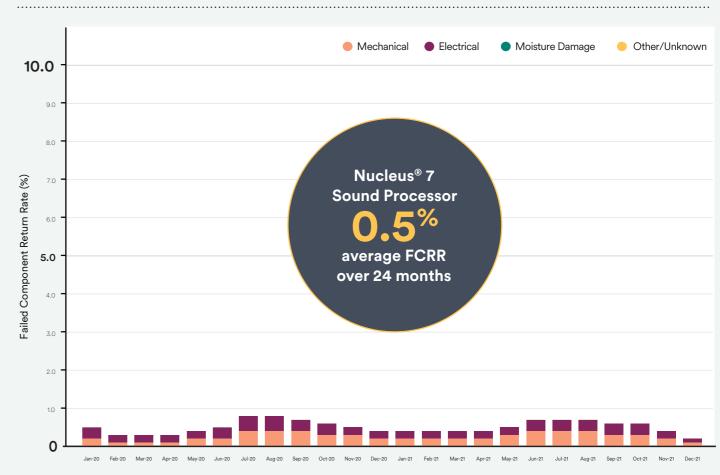
Nucleus 7 Sound Processor - Component Return Rate

Fail mode	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Mechanical	0.2%	0.1%	0.1%	0.1%	0.2%	0.2%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%
Electrical	0.3%	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.3%	0.3%	0.2%	0.2%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.2%	0.2%	0.2%	0.2%	0.1%	0.2%	0.2%	0.1%	0.1%	0.2%	0.1%	0.2%

Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Mechanical	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%	0.1%
Electrical	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.1%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.1%

* The Cochlear Nucleus 7 Sound Processor is compatible with Apple and Android™ devices. For compatibility information visit www.cochlear.com/compatibility.

Nucleus® 7 Sound Processor - Failed Component Return Rate



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Appendix

GRAPHICAL REPRESENTATION OF IMPLANT DATA

Each implant graph represents a type of device based on the receiver/stimulator portion.

RECEIVER/ STIMULATOR	IMPLANTS'
Profile [™] Plus Series	Cochlear™ Nucleus® Profile™ Plus with Contour Advance® Electrode (CI612) Cochlear Nucleus Profile Plus with Slim Straight Electrode (CI622) Cochlear Nucleus Profile Plus with Slim Modiolar Electrode (CI632) Cochlear Nucleus Profile Plus with Slim 20 Electrode (CI624)
Profile Series	Cochlear Nucleus Profile with Contour Advance Electrode (CI512) Cochlear Nucleus Profile with Slim Straight Electrode (CI522) Cochlear Nucleus Profile with Slim Modiolar Electrode (CI532) Cochlear Nucleus Profile Auditory Brainstem Implant (ABI541)
CI24RE Series	Nucleus Freedom® with Contour Advance Electrode Nucleus Freedom with Straight Electrode Cochlear Nucleus Cl422 Cochlear Implant Cochlear Hybrid™ L24 Cochlear Implant
CI500 Series	Cochlear Nucleus CI512 Cochlear Implant Cochlear Nucleus CI513 Cochlear Implant Cochlear Nucleus CI551 Double Array Cochlear Implant Cochlear Nucleus ABI541 Auditory Brainstem Implant
CI24R	Nucleus 24 with Contour Advance Electrode Nucleus 24 with Contour® Electrode Nucleus 24k with Straight Electrode
CI24M	Nucleus 24 with Straight Electrode Nucleus 24 with Double Array Nucleus 24 Auditory Brainstem Implant [ABI]
Cl22M	Nucleus 22

^{*} Implant availability varies by market.

References

- 1. Compared with competitor implants/devices that have been implanted for the same duration.
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- 3. 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. 2014.
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