

## Cochlear™ Nucleus® System

## Reliability Report

Volume 21 | December 2022

Reporting to European Consensus Statement, International Classification of Reliability, ANSI/AAMI CI86 Standard and ISO 5841-2.

## A message from our CEO

When choosing a cochlear implant manufacturer, the reassurance of high quality products that support a lifetime of hearing is key.

And in choosing a product that is made by Cochlear, you can feel confident that it is the result of our world-class manufacturing process and meets stringent, internationally recognised standards.

As the global leader in implantable hearing, with more than 700,000 devices provided, we take our responsibility to report on the reliability of our products very seriously. This is why we report with full transparency, in accordance with International Standard ISO 5841-21, the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations<sup>2</sup> and ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.<sup>3</sup>

We are proud to present this latest report on the reliability of our implants and sound processors, including our new Nucleus 8 Sound Processor.

We look forward to continuing to work with our partners in the hearing health industry and supporting the important role that they play in delivering a lifetime of hearing outcomes to their patients.

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**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*<sup>1</sup>, the reporting principles outlined in the *European Consensus Statement on Cochlear Implant Failures and Explantations*<sup>2</sup> and expert recommendations from the *International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators*.<sup>4</sup> 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 reporting<sup>3</sup>, 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.<sup>3</sup>

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

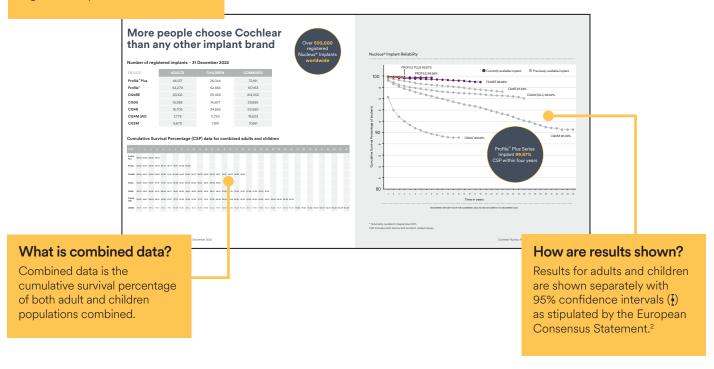
In this report, CSP includes both device and accident-related issues.

The reliability calculations used in this report are in accordance with the *International Standard ISO* 5841-2.<sup>1</sup> 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.



<sup>\*</sup> 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.

## More people choose Cochlear than any other implant brand

Over **500,000**registered
Nucleus® Implants
worldwide

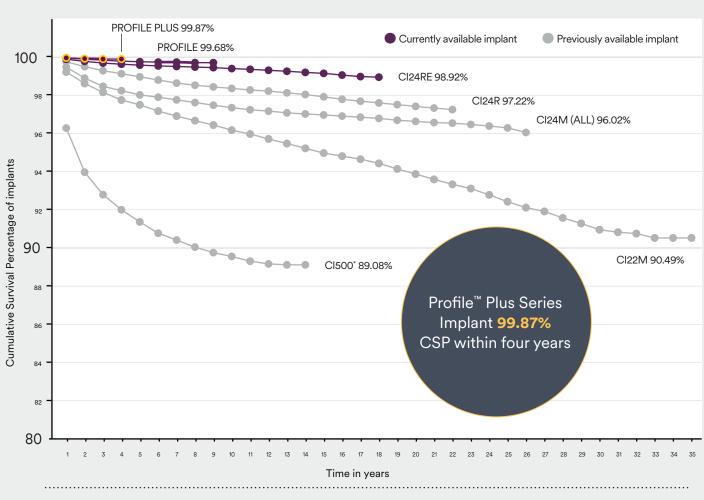
#### Number of registered implants - 31 December 2022

DEVICE	ADULTS	CHILDREN	COMBINED
Profile <sup>™</sup> Plus	46,137	26,044	72,181
Profile <sup>™</sup>	54,279	52,884	107,163
CI24RE	83,102	131,450	214,552
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

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	26	27	28	29	30	31	32	33	34	35
Profile Plus	99.93	99.89	99.87	99.87																															
Profile	99.92	99.87	99.81	99.76	99.73	99.71	99.71	99.68	99.68																										
CI24RE	99.86	99.75	99.66	99.60	99.55	99.51	99.48	99.45	99.42	99.37	99.33	99.28	99.23	99.17	99.12	99.03	98.95	98.92																	
CI500	96.25	93.94	92.76	91.97	91.33	90.74	90.38	90.01	89.72	89.52	89.27	89.13	89.08	89.08																					
CI24R	99.73	99.47	99.26	99.10	98.94	98.77	98.61	98.50	98.41	98.33	98.25	98.19	98.10	98.01	97.89	97.76	97.66	97.57	97.48	97.39	97.30	97.22													
CI24M (AII)	99.45	98.87	98.44	98.21	97.99	97.87	97.73	97.59	97.45	97.32	97.21	97.14	97.05	96.99	96.94	96.88	96.82	96.76	96.66	96.60	96.54	96.51	96.44	96.36	96.26	96.02									
Cl22M	99.19	98.59	98.13	97.72	97.47	97:14	96.88	96.64	96.41	96.14	95.94	95.68	95.44	95.19	94.94	94.78	94.62	94.40	94.11	93.84	93.56	93.30	93.08	92.75	92.39	92.08	91.88	91.54	91.25	90.92	90.79	90.72	90.49	90.49	90.49

#### Nucleus® Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2022

<sup>\*</sup> Voluntarily recalled in September 2011. CSP includes both device and accident-related issues.

## **Nucleus® Profile™ Plus Series Implant**

## Number of registered Profile<sup>™</sup> Plus Series Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
46,137	26,044	72,181

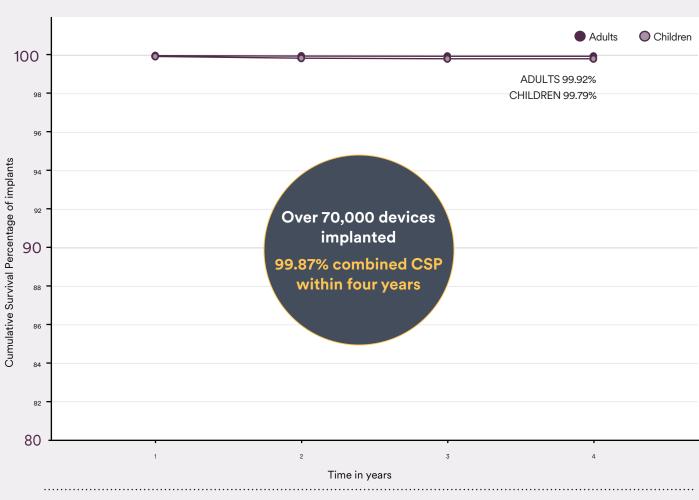


### Profile Plus Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4
Adults	99.95	99.93	99.92	99.92
Children	99.91	99.82	99.79	99.79
Combined	99.93	99.89	99.87	99.87



#### Profile™ Plus Series Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

## **Nucleus Profile Series Implant**

### Number of registered Profile Series Implants - 31 December 2022

ADULTS	CHILDREN	COMBINED
54,279	52,884	107,163

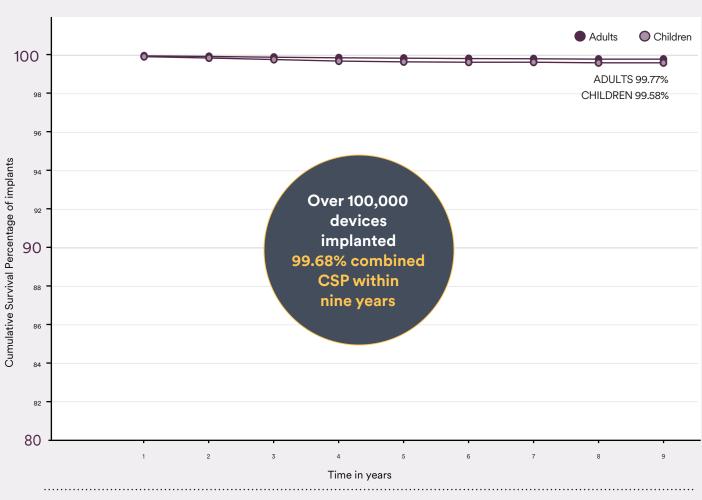


## **Profile Series Implant Cumulative Survival Percentage**

YEAR	1	2	3	4	5	6	7	8	9
Adults	99.94	99.91	99.87	99.84	99.82	99.80	99.79	99.77	99.77
Children	99.90	99.83	99.75	99.67	99.63	99.61	99.61	99.58	99.58
Combined	99.92	99.87	99.81	99.76	99.73	99.71	99.71	99.68	99.68



#### Profile™ Series Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

## **Nucleus CI24RE Series Implant**

#### Number of registered CI24RE Series Implants - 31 December 2022

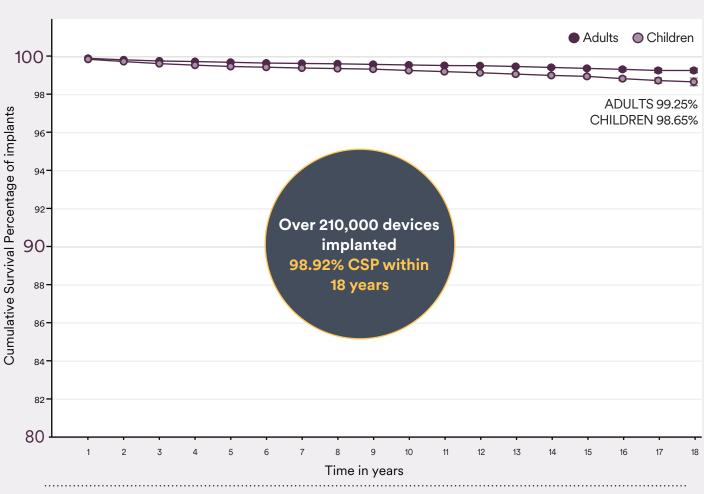
ADULTS	CHILDREN	COMBINED
83,102	131,450	214,552



#### Cl24RE Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Adults	99.89	99.81	99.75	99.72	99.68	99.64	99.62	99.60	99.57	99.54	99.51	99.50	99.46	99.41	99.36	99.31	99.25	99.25
Children	99.84	99.72	99.61	99.53	99.46	99.42	99.38	99.35	99.32	99.25	99.19	99.13	99.06	98.99	98.94	98.82	98.72	98.65
Combined	99.86	99.75	99.66	99.60	99.55	99.51	99.48	99.45	99.42	99.37	99.33	99.28	99.23	99.17	99.12	99.03	98.95	98.92

#### CI24RE Series Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

# Previously available implants

## **Nucleus® CI500 Series Implant**

## Number of registered Cl500 Series Implants - 31 December 2022

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

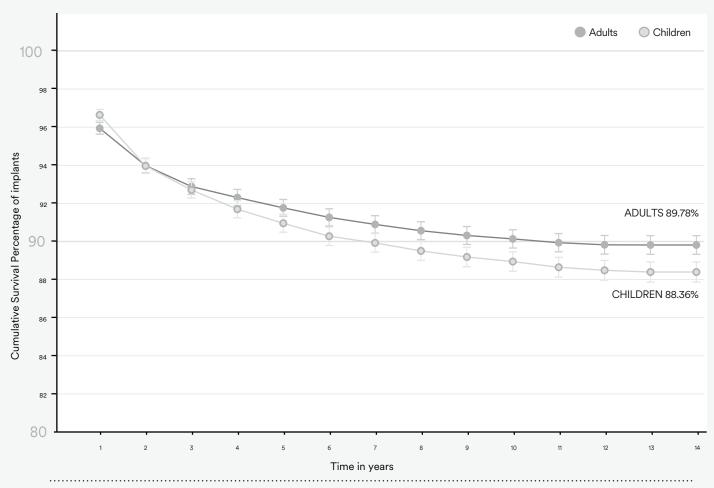


#### CI500 Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Adults	95.91	93.95	92.85	92.27	91.73	91.23	90.86	90.53	90.28	90.10	89.90	89.79	89.78	89.78
Children	96.61	93.93	92.67	91.66	90.92	90.24	89.89	89.47	89.15	88.91	88.61	88.45	88.36	88.36
Combined	96.25	93.94	92.76	91.97	91.33	90.74	90.38	90.01	89.72	89.52	89.27	89.13	89.08	89.08

#### CI500 Series Implant Reliability





REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

## **Nucleus Cl24R Implant**

## Number of registered Cl24R Implants - 31 December 2022

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

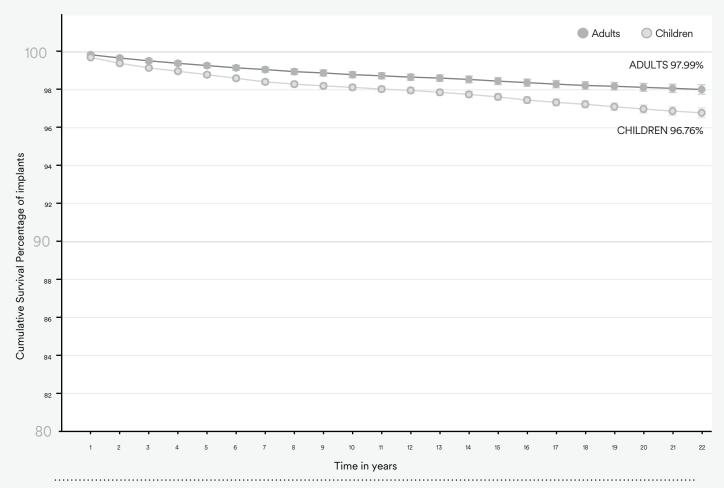


## Cl24R Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Adults	99.82	99.65	99.50	99.37	99.25	99.13	99.04	98.93	98.86	98.77	98.71	98.64	98.59	98.52	98.43	98.35	98.27	98.20	98.16	98.10	98.05	97.99
Children	99.68	99.37	99.13	98.95	98.77	98.58	98.39	98.27	98.18	98.10	98.01	97.94	97.84	97.73	97.60	97.43	97.31	97.21	97.08	96.96	96.85	96.76
Combined	99.73	99.47	99.26	99.10	98.94	98.77	98.61	98.50	98.41	98.33	98.25	98.19	98.10	98.01	97.89	97.76	97.66	97.57	97.48	97.39	97.30	97.22

#### CI24R Implant Reliability





REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

## **Nucleus Cl24M Implant**

## Number of registered Cl24M Implants - 31 December 2022

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



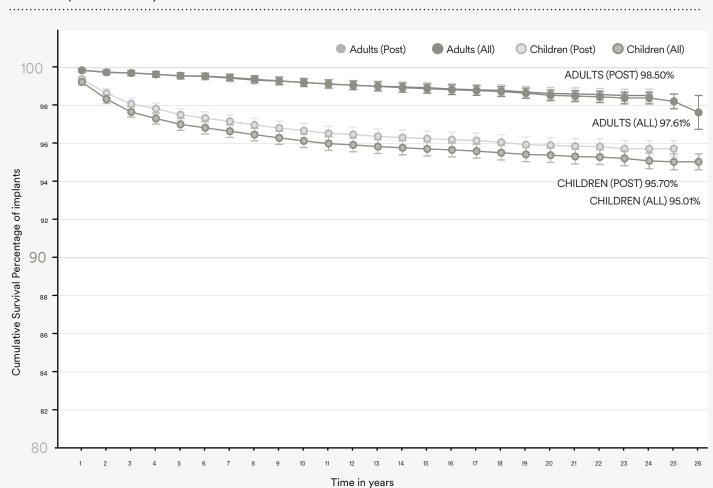
#### Cl24M Implant Cumulative Survival Percentage

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	26
Adults (All)	99.82	99.72	99.68	99.61	99.54	99.52	99.45	99.36	99.27	99.18	99.11	99.04	98.98	98.91	98.86	98.80	98.76	98.71	98.62	98.51	98.47	98.43	98.37	98.37	98.19	97.61
Children (All)	99.21	98.31	97.63	97.29	96.98	96.80	96.62	96.44	96.27	96.11	95.97	95.90	95.81	95.75	95.69	95.64	95.57	95.49	95.40	95.36	95.29	95.26	95.19	95.06	95.01	95.01
Combined (All)	99.45	98.87	98.44	98.21	97.99	97.87	97.73	97.59	97.45	97.32	97.21	97.14	97.05	96.99	96.94	96.88	96.82	96.76	96.66	96.60	96.54	96.51	96.44	96.36	96.26	96.02
Adults (Post**)	99.84	99.72	99.69	99.62	99.53	99.50	99.42	99.31	99.26	99.19	99.10	99.04	98.99	98.95	98.91	98.84	98.80	98.77	98.68	98.61	98.58	98.55	98.50	98.50	#	#
Children (Post**)	99.36	98.62	98.06	97.81	97.49	97.31	97.14	96.95	96.79	96.65	96.51	96.45	96.35	96.29	96.23	96.18	96.13	96.04	95.91	95.88	95.83	95.81	95.70	95.70	95.70	#
Combined (Post**)	99.55	99.06	98.70	98.52	98.29	98.17	98.03	97.88	97.76	97.65	97.52	97.47	97.39	97.34	97.28	97.22	97.18	97.11	97.00	96.95	96.90	96.88	96.80	96.80	96.80	#

<sup>\*\* &#</sup>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.



#### CI24M Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

## **Nucleus Cl22M Implant**

## Number of registered Cl22M Implants - 31 December 2022

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



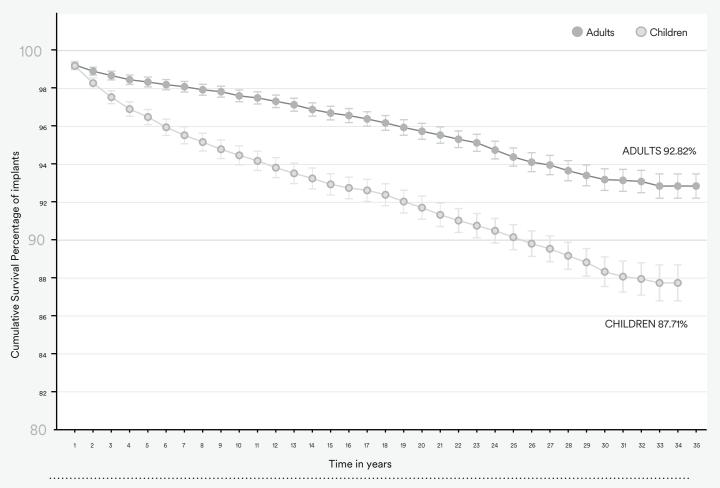
## Cl22M Implant Cumulative Survival Percentage

YEAR	1	2	3	4												16	17
Adults	99.21	98.88	98.65	98.43	98.31	98.17	98.06	97.90	97.80	97.58	97.47	97.29	97.11	96.86	96.67	96.54	96.36
Children	99.16	98.25	97.51	96.88	96.46	95.92	95.50	95.14	94.76	94.44	94.15	93.79	93.49	93.22	92.91	92.72	92.59
Combined	99.19	98.59	98.13	97.72	97.47	97.14	96.88	96.64	96.41	96.14	95.94	95.68	95.44	95.19	94.94	94.78	94.62

YEAR		19							26			29				33	34	35
Adults	96.15	95.91	95.71	95.51	95.29	95.10	94.72	94.35	94.08	93.93	93.63	93.38	93.16	93.12	93.06	92.82	92.82	92.82
Children	92.36	92.00	91.68	91.30	91.00	90.73	90.46	90.12	89.78	89.51	89.14	88.79	88.30	88.04	87.92	87.71	87.71	#
Combined	94.40	94.11	93.84	93.56	93.30	93.08	92.75	92.39	92.08	91.88	91.54	91.25	90.92	90.79	90.72	90.49	90.49	90.49

#### CI22M Implant Reliability





REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs. CSP includes both device and accident-related issues.

# 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, an externally worn device, are typically used for a number of years, so high reliability enables ongoing access to a consistent hearing experience.

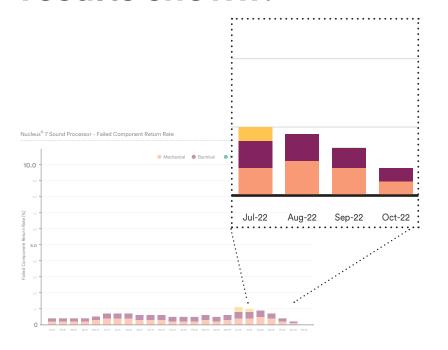
## What is Failed Component Return Rate (FCRR)?

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 and 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 fault-free. 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-22	Feb-22	Mar-22	Apr-22	May-22		Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
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® 8 Sound Processor**

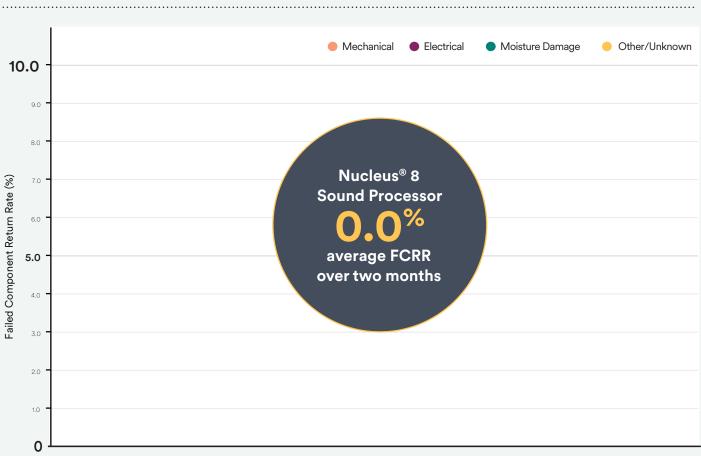


### Nucleus 8 Sound Processor – Failed Component Return Rate

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	-	-	-	-	-	-	-	-	-	-	-	-
Electrical	-	-	-	-	-	-	-	-	-	-	-	-
Moisture	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-
Fault-Free	-	-	-	-	-	-	-	-	-	-	-	-

Fail mode	Jan-22		Mar-22	Apr-22	May-22			Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Mechanical	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Electrical	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Moisture	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Other	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Fault-Free	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%

## Nucleus® 8 Sound Processor - Failed Component Return Rate



## **Nucleus Kanso® 2 Sound Processor**



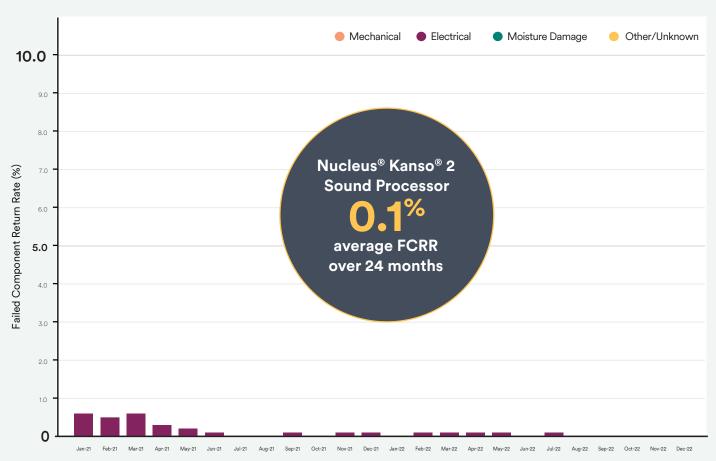
## Nucleus Kanso 2 Sound Processor - Failed Component Return Rate

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%	0.1%	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	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fail mode	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
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	0.0%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.0%	0.0%	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	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

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

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## **Nucleus® 7 Sound Processor**



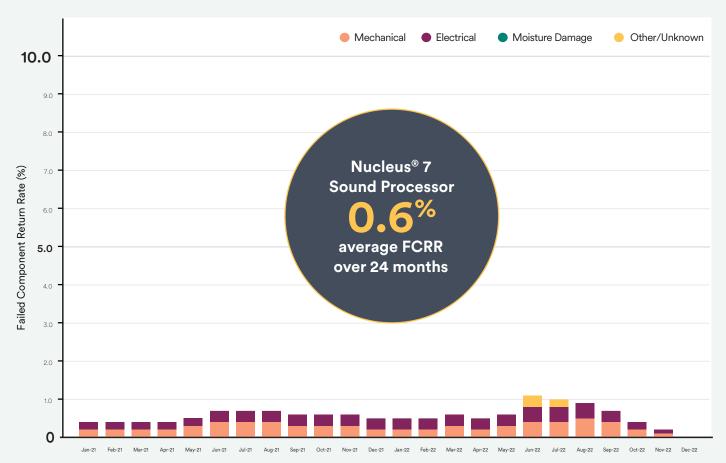
### Nucleus 7 Sound Processor – Failed Component Return Rate

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%	0.3%	0.2%
Electrical	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
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%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%

Fail mode	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Mechanical	0.2%	0.2%	0.3%	0.2%	0.3%	0.4%	0.4%	0.5%	0.4%	0.2%	0.1%	0.0%
Electrical	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%	0.3%	0.2%	0.1%	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%	0.3%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%

## Nucleus® 7 Sound Processor - Failed Component Return Rate





## **Appendix**

### **GRAPHICAL REPRESENTATION OF IMPLANT DATA**

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

RECEIVER/ STIMULATOR	IMPLANTS*
Profile <sup>™</sup> 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 CI422 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
Cl24M	Nucleus 24 with Straight Electrode Nucleus 24 with Double Array Nucleus 24 Auditory Brainstem Implant [ABI]
Cl22M	Nucleus 22

<sup>\*</sup> Implant availability varies by market.

## References

- 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.
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- 3. ANSI/AAMI CI86. Cochlear implant systems: Requirements for safety, functional verification,. (2017). Arlington, VA: American National Standards Institute.
- 4. 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.

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Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 700,000 devices and helped 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 next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

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Please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always follow the directions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

In Australia, Cochlear™ Nucleus® implant systems are intended for the treatment of moderately severe to profound hearing loss. For Cochlear™ Nucleus® systems: This product is not available for purchase by the general public. For information on funding and reimbursement please contact your healthcare professional.

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントウア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

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