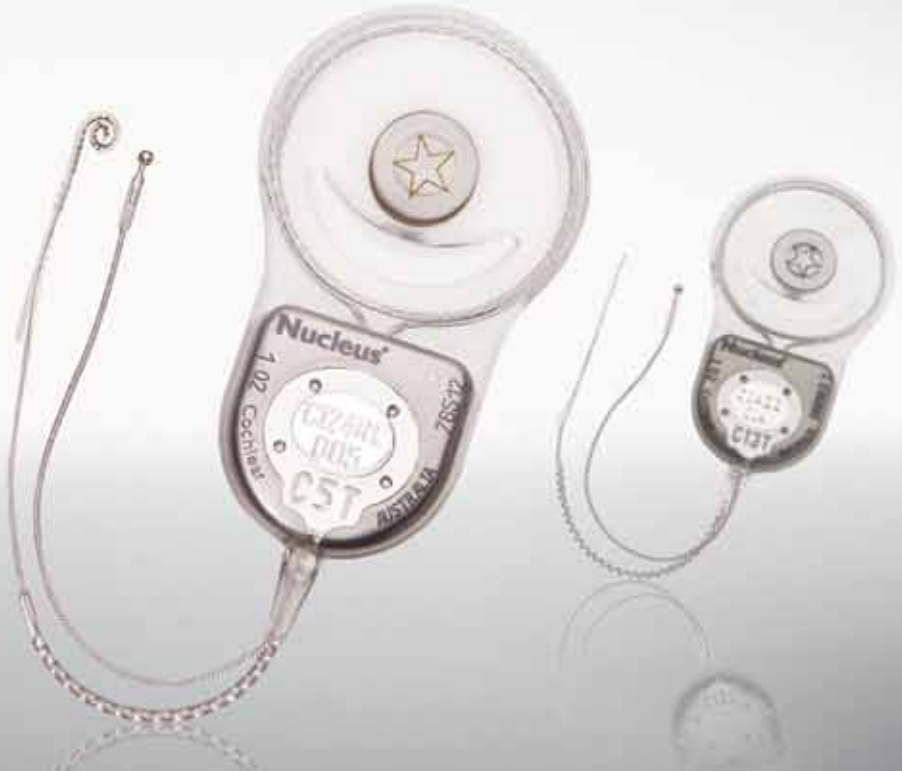
Cochlear™

Nucleus® Reliability Report



Nucleus® Reliability Report Volume 11 | February 2013

Hear now. And always

Cochlear®

About Cochlear's reliability reporting

The Nucleus® Reliability Report makes available all data relating to cochlear implant device failures in accordance with the International Standard ISO 5841-2:2000[1] and the reporting principles described in the European and Global Consensus Statement on Cochlear Implant Failures and Explantations[2,3].

In compliance with the European and Global Consensus Statements, Cochlear reports all failures in the reliability calculation, including those caused by external impact and electrode failures that lead to a loss of clinical benefit. The data in each report covers the entire life of all implant models and registered implants worldwide. Results for adults and children are shown separately with 95% confidence intervals as specifically required by the consensus statement.

In this reliability report the latest data on all Nucleus implants is provided. Data is now available for a population of over 90,000 CI24RE model implants over a period of 8 years, while the CI22M implant has now reached a reporting period of 26 years. An update on the CI500 Series Cochlear Implant is also provided with the latest data as of February 2013.

Reading this report

Cochlear's reliability data show both the percentage of devices that are still functioning and those no longer functioning over a given period of time. Respectively, these are known as the Cumulative Survival Percentage (CSP) and Cumulative Failure Percentage (CFP).

Cumulative Survival Percentage

The Cumulative Survival Percentage is the cumulative percentage of functioning implants over time and can be used to predict the reliability of the device within a given time period.

$$CSP = \frac{\text{Devices that have survived for at least "x" years X 100\%}}{\text{All devices implanted for at least "x" years}}$$

Cumulative Failure Percentage

The Cumulative Failure Percentage is the cumulative percentage of devices that are no longer functioning after a given period of time.

$$CFP = [100 - CSP]\ \%$$

Number of registered implants[##] - February 2013

DEVICE	ADULT	CHILD	COMBINED
CI22M	9,963	8,219	18,182
CI24M (All)	7,826	11,695	19,521
CI24M (Post)	5,619	8,475	14,094
CI24R	18,424	33,271	51,695
CI24RE	42,247	50,556	92,803
CI500	15,132	14,591	29,723

[##] Note: Implant registrations often lag surgery dates by up to 6 months.
'Post' refers to the addition of a structural support component to improve impact strength.

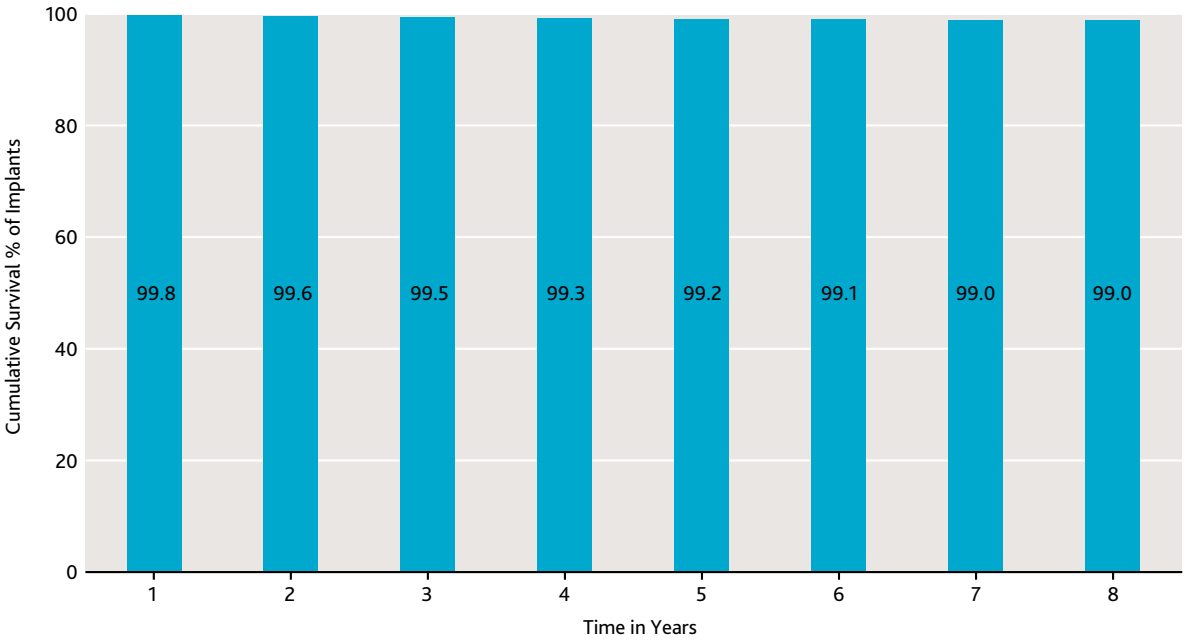
Nucleus CI24RE Implant

The Cumulative Survival Percentage for registered implants worldwide is 99.0% within 8 years.

Commercially released in 2005, the CI24RE introduced a new integrated circuit with a mechanical design and production processes based on the proven architecture of the CI24R implant. The new integrated circuit substantially increased the capability and future-readiness of the system. Features include AutoNRT™, numerous stimulation modes and native compatibility with the Nucleus CP810 Sound Processor and CR110 Remote Assistant.

The CI24RE is available with a number of electrode arrays. The reliability data reported here also includes the Cochlear Hybrid™ L24 and the Cochlear Nucleus CI422 since these implants are based on the same mechanical architecture.

CI24RE* Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 25 FEBRUARY 2013

Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8
CI24RE Adult*	99.8	99.7	99.6	99.5	99.5	99.4	99.4	99.3
CI24RE Child*	99.8	99.6	99.4	99.2	99.0	98.8	98.7	98.6
CI24RE Combined*	99.8	99.6	99.5	99.3	99.2	99.1	99.0	99.0
95% Confidence Interval*	+/- 0.0	+/- 0.0	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1

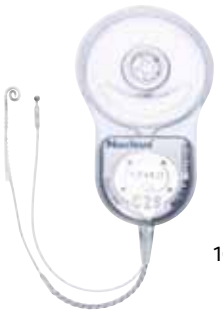
Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8
CI24RE Adult*	0.2	0.3	0.4	0.5	0.5	0.6	0.6	0.7
CI24RE Child*	0.2	0.4	0.6	0.8	1.0	1.2	1.3	1.4
CI24RE Combined*	0.2	0.4	0.5	0.7	0.8	0.9	1.0	1.0

* See page 9 for a list of implant types reported with the CI24RE receiver/stimulator

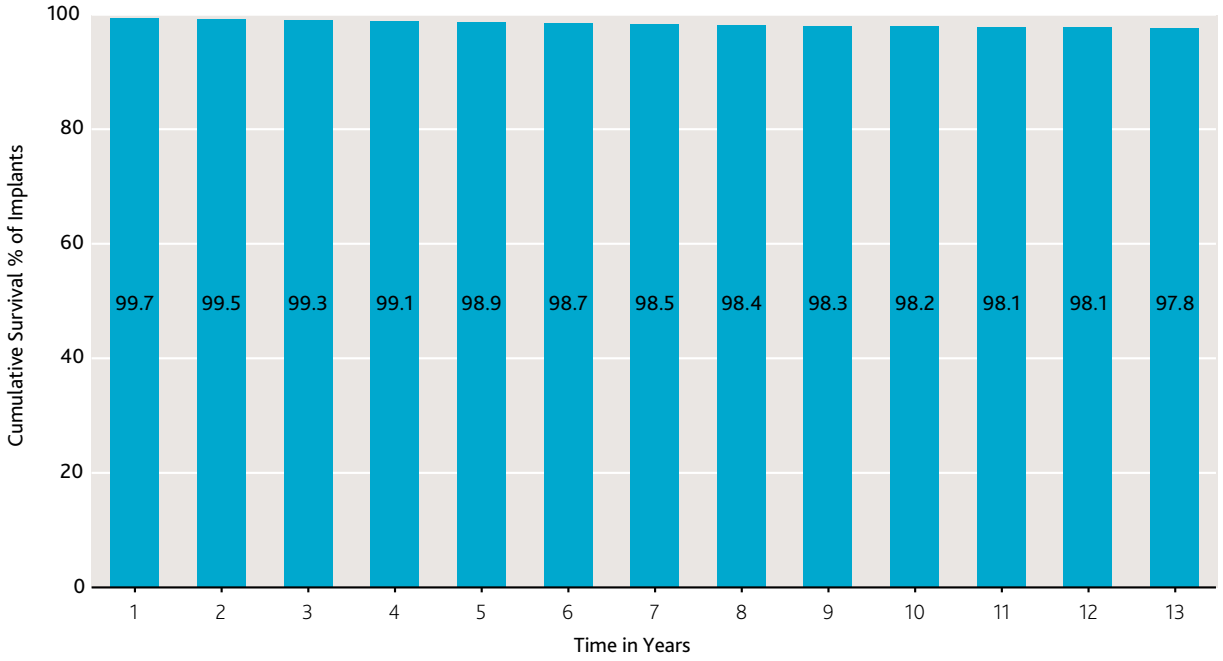
Nucleus CI24R Implant

The Cumulative Survival Percentage for registered implants worldwide is 97.8% within 13 years.



The CI24R was released in 2000 with perimodiolar (Nucleus® Contour Advance™) and straight arrays (Nucleus® 24k).

CI24R Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 25 FEBRUARY 2013

Cumulative Survival Percentage

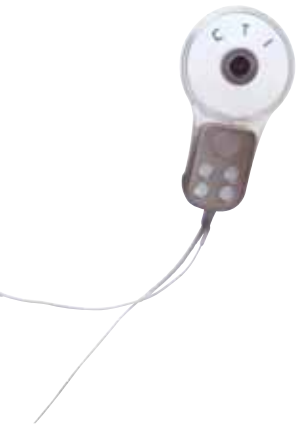
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13
CI24R Adult	99.8	99.6	99.4	99.3	99.2	99.0	98.9	98.8	98.8	98.7	98.6	98.5	98.1
CI24R Child	99.7	99.4	99.2	99.0	98.8	98.6	98.3	98.1	98.0	97.9	97.7	97.7	97.6
CI24R Combined	99.7	99.5	99.3	99.1	98.9	98.7	98.5	98.4	98.3	98.2	98.1	98.1	97.8
95% Confidence Interval	+/- 0.0	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+0.1/-0.2	+/- 0.2	+0.3/-0.4

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13
CI24R Adult	0.2	0.4	0.6	0.7	0.8	1.0	1.1	1.2	1.2	1.3	1.4	1.5	1.9
CI24R Child	0.3	0.6	0.8	1.0	1.2	1.4	1.7	1.9	2.0	2.1	2.3	2.3	2.4
CI24R Combined	0.3	0.5	0.7	0.9	1.1	1.3	1.5	1.6	1.7	1.8	1.9	1.9	2.2

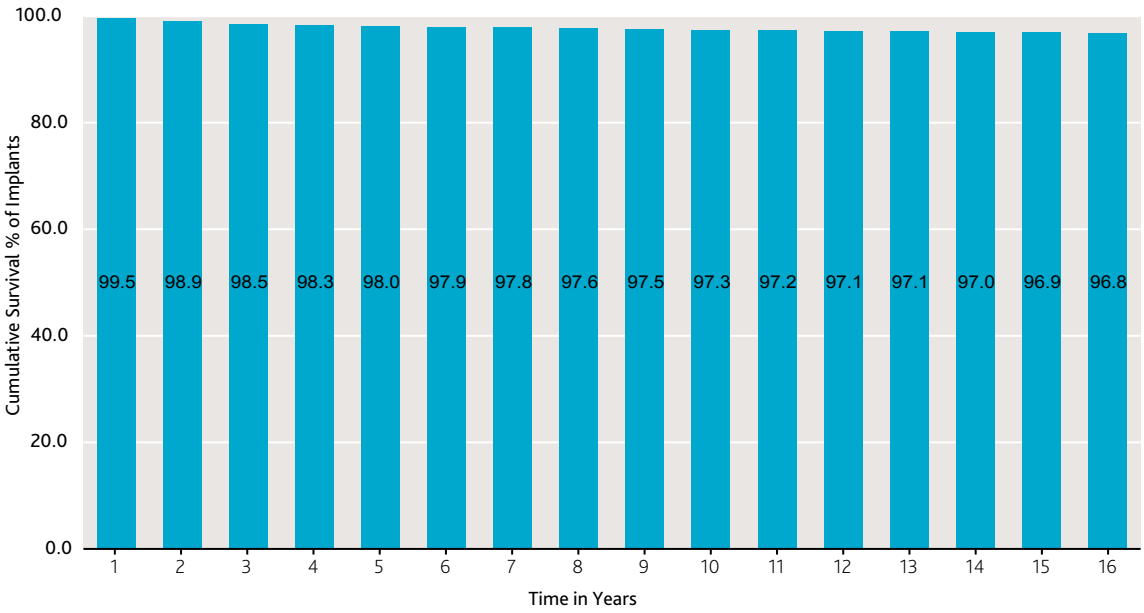
Nucleus CI24M Implant

The Cumulative Survival Percentage for registered implants worldwide is 96.8% within 16 years.



The CI24M, released in 1997, consisted of the CI24M receiver/stimulator and a 22-electrode straight array. The CI24M introduced new stimulation capability by the addition of a plate electrode on the package and a lead wire connected to a ball electrode, enabling monopolar stimulation mode. Telemetry was included to measure electrode voltage compliance and impedance and to diagnose implant and electrode function. Telemetry also supported the world's first recording of the electrically evoked compound action potential (ECAP) using the intracochlear electrodes via Neural Response Telemetry (NRT).

CI24M Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 25 FEBRUARY 2013

Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CI24M Adult (All)	99.7	99.5	99.5	99.3	99.2	99.2	99.2	99.1	99.0	98.9	98.8	98.7	98.6	98.5	98.4	98.4
CI24M Child (All)	99.3	98.5	97.8	97.6	97.2	97.0	96.9	96.7	96.5	96.3	96.2	96.1	96.1	96.0	96.0	95.6
CI24M Adult (Post†)	99.8	99.5	99.5	99.4	99.3	99.2	99.2	99.1	99.0	98.9	98.8	98.7	98.7	98.7	98.7	-#
CI24M Child (Post†)	99.4	98.8	98.3	98.1	97.8	97.6	97.5	97.3	97.1	97.0	96.8	96.8	96.7	96.7	96.7	-#
CI24M (All) Combined	99.5	98.9	98.5	98.3	98.0	97.9	97.8	97.6	97.5	97.3	97.2	97.1	97.1	97.0	96.9	96.8
95% Confidence Interval	+/- 0.1	+0.1/-0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+0.2/ -0.3	+0.2/ -0.3	+0.2/ -0.3	+0.2/ -0.3	+/- 0.3	+/- 0.4

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
CI24M Adult (All)	0.3	0.5	0.5	0.7	0.8	0.8	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.6
CI24M Child (All)	0.7	1.5	2.2	2.4	2.8	3.0	3.1	3.3	3.5	3.7	3.8	3.9	3.9	4.0	4.0	4.4
CI24M Adult (Post†)	0.2	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.1	1.2	1.3	1.3	1.3	1.3	-#
CI24M Child (Post†)	0.6	1.2	1.7	1.9	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.2	3.3	3.3	3.3	-#
CI24M (All) Combined	0.5	1.1	1.5	1.7	2.0	2.1	2.2	2.4	2.5	2.7	2.8	2.9	2.9	3.0	3.1	3.2

† 'Post' refers to the addition of a structural support component to improve impact strength.

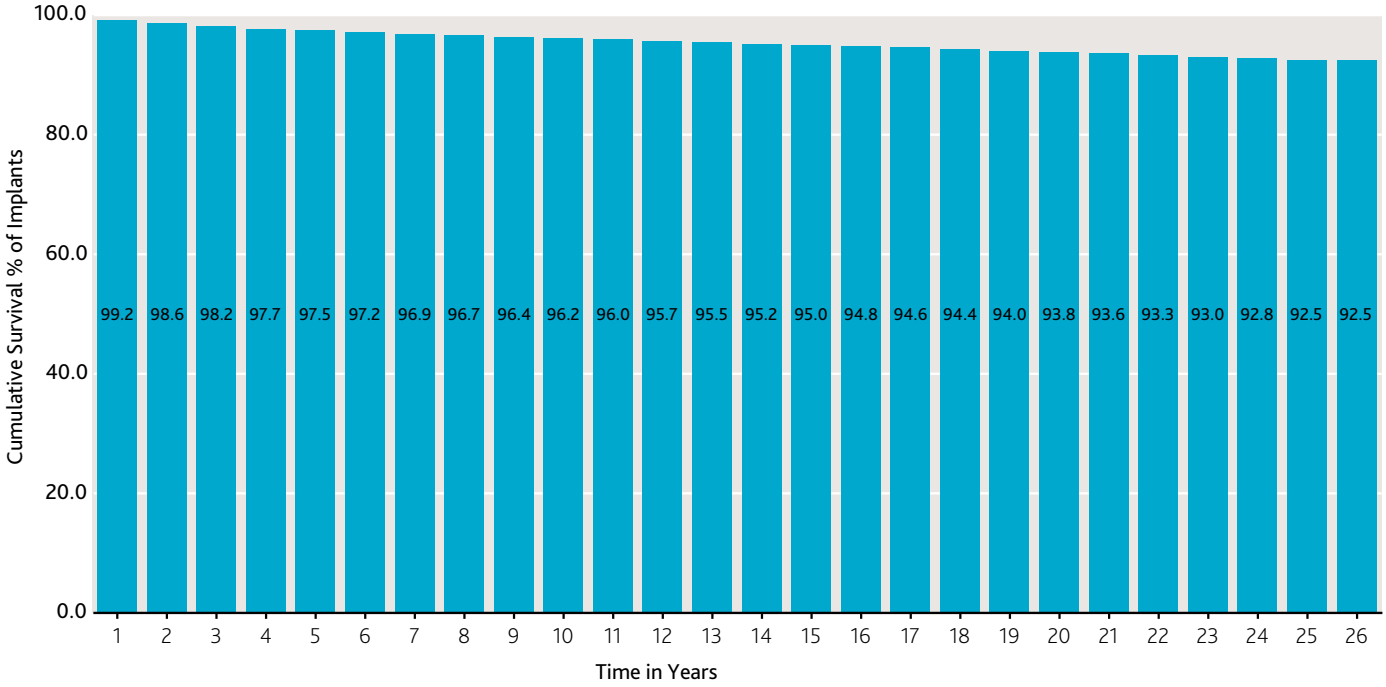
' - ' refers to individual populations less than the minimum required for a valid calculation.

Nucleus CI22M Implant

The Cumulative Survival Percentage for registered implants worldwide is 92.5% within 26 years.

The CI22M implant, released in 1985, was Cochlear's first commercial implant. In 1986, the CI22M was released with an internal magnet to hold the external transmitting coil in place.

CI22M Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 25 FEBRUARY 2013

Cumulative Survival Percentage

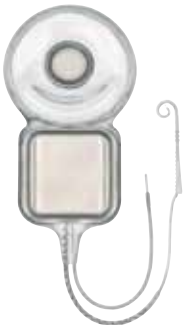
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
CI22M Adult	99.2	98.9	98.7	98.5	98.3	98.2	98.1	98.0	97.8	97.6	97.5	97.3	97.1	96.9	96.7	96.5	96.3	96.1	95.8	95.5	95.3	95.0	94.9	94.5	94.1	-#
CI22M Child	99.2	98.3	97.5	96.9	96.5	95.9	95.5	95.1	94.8	94.5	94.2	93.8	93.5	93.3	93.0	92.8	92.7	92.4	92.0	91.8	91.5	91.2	90.6	90.6	-#	-#
CI22M Combined	99.2	98.6	98.2	97.7	97.5	97.2	96.9	96.7	96.4	96.2	96.0	95.7	95.5	95.2	95.0	94.8	94.6	94.4	94.0	93.8	93.6	93.3	93.0	92.8	92.5	92.5
95% Confidence Interval	+/-0.1	+/-0.2	+/-0.2	+/-0.2	+/-0.2	+0.2/ -0.3	+0.2/ -0.3	+/-0.3	+/-0.3	+/-0.3	+/-0.3	+/-0.3	+/-0.3	+/-0.3	+/-0.3	+/-0.3	+0.3/ -0.4	+0.3/ -0.4	+/- 0.4	+/- 0.4	+/- 0.4	+0.4/ -0.5	+/-0.5	+/-0.6	+/-0.7	+/-0.7

Cumulative Failure 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
CI22M Adult	0.8	1.1	1.3	1.5	1.7	1.8	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.1	3.3	3.5	3.7	3.9	4.2	4.5	4.7	5.0	5.1	5.5	5.9	-#
CI22M Child	0.8	1.7	2.5	3.1	3.5	4.1	4.5	4.9	5.2	5.5	5.8	6.2	6.5	6.7	7.0	7.2	7.3	7.6	8.0	8.2	8.5	8.8	9.4	9.4	-#	-#
CI22M Combined	0.8	1.4	1.8	2.3	2.5	2.8	3.1	3.3	3.6	3.8	4.0	4.3	4.5	4.8	5.0	5.2	5.4	5.6	6.0	6.2	6.4	6.7	7.0	7.2	7.5	7.5

' - ' refers to individual populations less than the minimum required for a valid calculation.

Nucleus CI500 Series Implant

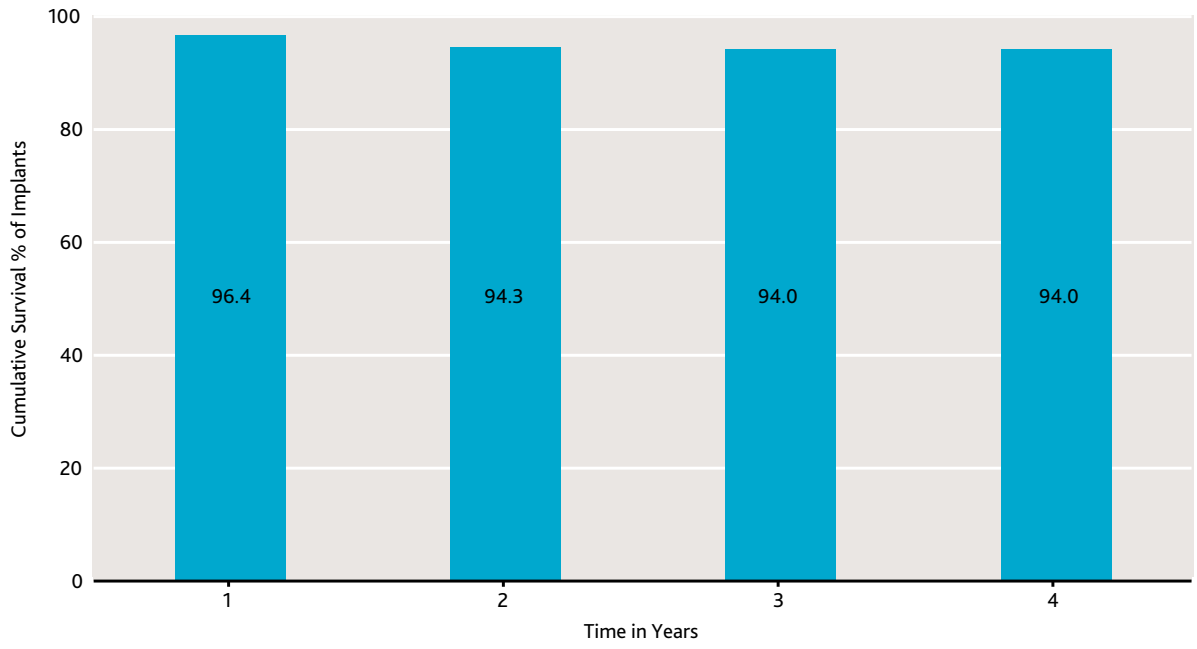


The CI500 Series Implant was withdrawn from the market in a voluntary recall in September 2011. Cochlear will continue to monitor and report on this population of devices in future reliability reports.

IMPORTANT: The reliability calculations used in this report are in accordance with the ISO 5841-2:2000 standard. They are probability calculations which use a modified Kaplan-Meier estimator. This estimates the probability of survival over a period of time and is represented as Cumulative Survival Percentage (CSP) and Cumulative Failure Percentage (CFP).

In clinical updates on the status of the Nucleus CI500 Series, what is reported is the proportion of Nucleus CI500 Series devices that have failed at a particular time. This uses the absolute number of failures divided by the total Nucleus CI500 Series registered population to give an overall percentage of devices failed. It is for this reason that you may notice differences between the numbers reported in this reliability report and the the numbers reported in the clinic updates. The probability calculations (CSP, CSP) cannot be compared to the overall proportion of devices failed at a point in time.

CI500 Series Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 25 FEBRUARY 2013

Cumulative Survival Percentage

YEAR	1	2	3	4
CI500 Adult	96.0	94.3	94.0	94.0
CI500 Child	96.7	94.4	94.0	94.0
CI500 Combined	96.4	94.3	94.0	94.0
95% Confidence Interval	+/-0.2	+/-0.3	+/-0.3	+/-0.3

Cumulative Failure Percentage

YEAR	1	2	3	4
CI500 Adult	4.0	5.7	6.0	6.0
CI500 Child	3.3	5.6	6.0	6.0
CI500 Combined	3.6	5.7	6.0	6.0

Full Compliance with International Reporting Standards

In 2005 a consensus regarding the reporting of common device failures was reached between the major European cochlear implant centers, global regulatory authorities and device manufacturers. This consensus statement was further refined by the International Consensus Group for Cochlear Implant Reliability Reporting.

The resulting European and Global Consensus Statement on Cochlear Implant Failures and Explantations[2,3] provides a definition of - and seven principles of best practice reporting on - device failure.

Cochlear's definition of device failure and principles of best-practice reporting is in agreement with the consensus statement. Cochlear defines device failure as:

- any device that is explanted and out-of-specification resulting in the loss of clinical benefit; and
- any device that remains in-situ and is out-of-specification resulting in the loss of clinical benefit.

CONSENSUS STATEMENT PRINCIPLE	COCHLEAR COMPLIANCE	COCHLEAR REPORTING PRACTICE
All device failures must be reported to the competent authority and must be included in the calculation of the cumulative survival rate (CSR††). Reporting of the CSR should be in accordance with ISO standard 5841-2:2000[1].	✓	All device failures are reported to the competent authority. Cochlear uses the applicable definitions, categorisation scheme and calculation procedures of ISO 5841-2:2000[1]. All device failure modes are included, including failures due to external impact.
Manufacturer's reports of device failure should indicate the sources of data and the sample size. There must be no exclusions. The time period over which the data was collected should be specified.	✓	The source of data is Cochlear's global complaints handling database. Sample size and time period are specified with each report.
Reports of CSR should give complete historical data of a given device, describing any technical modifications (which can be integrated into historical data by starting at time 0).	✓	All models and all versions of each model are included in reports. Descriptions of any significant technical modifications are given.
The complete data set of the 'mother' product should always be supplied when presenting data on subsequent device modifications.	✓	Reports aggregate the reliability of all devices (pre and post modification). If the post-modification is significantly different, "post mod" is reported separately from the aggregate of all devices.
A new device can be attributed when there has been a change in either the case and/or the electrodes and/or the electronics and has been labelled by its own CE mark.	✓	A new device can be attributed when there has been a change in either the case and/or the electrodes and/or the electronics and has been labelled by its own CE mark.
Cumulative survival rates should be split into data for adults and for children and 95% confidence intervals (80% or 90% if the population is below 1,000 units) should be provided.	✓	Reports show separate data for adults and children. This Nucleus Reliability Report contains reliability data with 95% confidence intervals, in compliance with the consensus statement.
Device survival time starts to count with closure of the wound intraoperatively.	✓	All failures are counted that occur any time after wound closure.

†† CSR is identical to Cumulative Survival Percentage (CSP).

Graphical representation

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

RECEIVER/STIMULATOR	IMPLANTS
CI500 Series	• Cochlear Nucleus CI512 cochlear implant • Cochlear Nucleus CI513 cochlear implant** • Cochlear Nucleus CI551 cochlear implant** • Cochlear Nucleus ABI541 Auditory Brainstem Implant**
CI24RE	• Nucleus Freedom™ with Contour Advance Electrode • Nucleus Freedom with Straight Electrode • Cochlear Nucleus CI422 cochlear implant** • Cochlear Hybrid L24 cochlear 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]**
CI22M	• Nucleus 22

** Implanted in some countries.

1. International Organization for Standardization, International Standard ISO 5841-2 Implants for Surgery - Cardiac Pacemakers – Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads, Oct 15, 2000.

2. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 26: 1097-1099, 2005.

3. Battmer RD, Backous DD, Balkany TJ, Briggs RJS , Gantz BJ, van Hasselt A, Kim CS, Kubo T, Lenarz T, Pillsbury HC, O'Donoghue GM. International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators, Otol Neurotol, 2010.

NOTES

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Hear now. And always

As the leading global expert in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. For thirty years, Cochlear has pioneered this technology, helping more than a quarter of a million people reconnect to their families and friends.

Along with the industry's largest investment in research and development, we continue to partner with leading international researchers and hearing professionals, ensuring that we are at the forefront of hearing science.

For our customers, that means access to our latest technologies throughout their lives, and the ongoing support they need.

That is why seven out of ten people worldwide who choose a cochlear implant choose Cochlear as their hearing partner.

Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove NSW 2066, Australia Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
Cochlear Americas 13059 E Peakview Avenue, Centennial, CO 80111, USA Tel: +1 303 790 9010 Fax: +1 303 792 9025
Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada Tel: +1 416 972 5082 Fax: +1 416 972 5083
Cochlear AG EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland Tel: +41 61 205 0404 Fax: +41 61 205 0405
EC REP **Cochlear Deutschland GmbH & Co. KG** Karl-Wiechert-Allee 76A, 30625 Hannover, Germany Tel: +49 511 542 770 Fax: +49 511 542 7770
Cochlear Europe Ltd 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey KT15 2HJ, United Kingdom Tel: +44 1932 87 1500 Fax: +44 1932 87 1021
Cochlear Benelux NV Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium Tel: +32 15 79 55 11 Fax: +32 15 79 55 70
Cochlear France S.A.S. Route de l'Orme aux Merisiers, Z.I. Les Algorithmes – Bât. Homère, 91190 Saint-Aubin, France Tel: +33 805 200 016 Fax: +33 160 196 499
Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italy Tel: +39 051 601 53 11 Fax: +39 051 39 20 62
Cochlear Nordic AB Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden Tel +46 31 335 14 61 Fax +46 31 335 14 60
Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti. Çubuklu Mah. Boğaziçi Cad., Boğaziçi Plaza No: 6/1, Kavacık, TR-34805 Beykoz-Istanbul, Turkey
Tel: +90 216 538 5900 Fax: +90 216 538 5919
Cochlear (HK) Limited Unit 1810, Hopewell Centre, 183 Queens Road East, Wan Chai, Hong Kong SAR Tel: +852 2530 5773 Fax: +852 2530 5183
Cochlear Korea Ltd 1st floor, Cheongwon building, 828-5, Yuksam dong, Kangnam gu, Seoul, Korea Tel: +82 2 533 4663 Fax: +82 2 533 8408
Cochlear Limited (Singapore Branch) 6 Sin Ming Road, #01-16 Sin Ming Plaza Tower 2, Singapore 575585 Tel: +65 6553 3814 Fax: +65 6451 4105
Cochlear Medical Device (Beijing) Co Ltd Unit 2208 Gemdale Tower B, 91 Jianguo Road, Chaoyang District, Beijing 100022, P.R. China Tel: +86 10 5909 7800
Fax: +86 10 5909 7900
Cochlear Medical Device Company India Pvt. Ltd. Ground Floor, Platina Building, Plot No C-59, G-Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India Tel: +91 22 6112 1111 Fax: +91 22 6112 1100
Nihon Cochlear Co Ltd Ochanomizu-Motomachi Bldg, 2-3-7 Hongo, Bunkyo-Ku, Tokyo 113-0033, Japan Tel: +81 3 3817 0241 Fax: +81 3 3817 0245

www.cochlear.com

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