Cochlear™

Nucleus® Reliability Report

Volume 9 | August 2011

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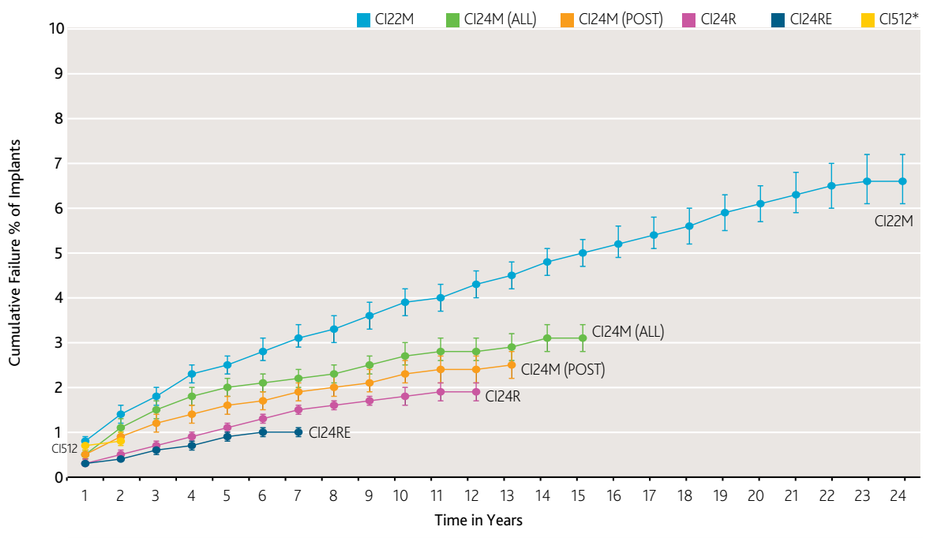
Cochlear™

Implant Reliability August 2011

Cochlear™ takes implant reliability extremely seriously. While less than 1% of the Cochlear Nucleus® CI512 Cochlear Implants have failed within the two years since launch, a recent increase in the number of failures has led to a voluntary recall of unimplanted CI500 series implants while the issue is investigated. No other Nucleus implants are affected.

Cochlear is recommending use of the functionally equivalent Cochlear Nucleus CI24RE Cochlear Implant range. The CI24RE has set an industry benchmark for its very high reliability. With over 61,000 registered implants worldwide, the CI24RE implant has achieved a Cumulative Survival Percentage of 99.0% within 7 years, an achievement unmatched by any other implant.

Nucleus Implants Reliability



REGISTERED IMPLANTS DATA COMBINED FOR ADULT AND CHILD AS OF AUGUST 31, 2011

* On 11 September 2011 Cochlear announced a voluntary recall of Nucleus CI500 Series cochlear implants.

Number of registered implants† - August 2011

DEVICE	ADULT	CHILD	COMBINED
CI22M	9,960	8,222	18,182
CI24M (All)	7760	11631	19,391
CI24M (Post)	5,612	8,456	14,068
CI24R	17,880	31,299	49,179
CI24RE	28,328	33,597	61,925
CI512	13,118	12,107	25,225

† Implant registrations often lag surgery dates by up to 6 months.
'Post' refers to addition of a structural support component to improve impact strength.

Cumulative Survival Percentage for combined adult and child data

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
CI22M	99.2	98.6	98.2	97.7	97.5	97.2	96.9	96.7	96.4	96.1	96.0	95.7	95.5	95.2	95.0	94.8	94.6	94.4	94.1	93.9	93.7	93.5	93.4	93.4
CI24M (All)	99.5	98.9	98.5	98.2	98.0	97.9	97.8	97.7	97.5	97.3	97.2	97.2	97.1	96.9	96.9	-	-	-	-	-	-	-	-	-
CI24M (Post)	99.5	99.1	98.8	98.6	98.4	98.3	98.1	98.0	97.9	97.7	97.6	97.6	97.5	-	-	-	-	-	-	-	-	-	-	-
CI24R	99.7	99.5	99.3	99.1	98.9	98.7	98.5	98.4	98.3	98.2	98.1	98.1	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	99.7	99.6	99.4	99.3	99.1	99.0	99.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI512	99.3	99.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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.

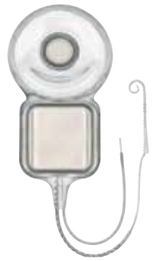
Cumulative Failure Percentage for combined adult and child data

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
CI22M	0.8	1.4	1.8	2.3	2.5	2.8	3.1	3.3	3.6	3.9	4.0	4.3	4.5	4.8	5.0	5.2	5.4	5.6	5.9	6.1	6.3	6.5	6.6	6.6
CI24M (All)	0.5	1.1	1.5	1.8	2.0	2.1	2.2	2.3	2.5	2.7	2.8	2.8	2.9	3.1	3.1	-	-	-	-	-	-	-	-	-
CI24M (Post)	0.5	0.9	1.2	1.4	1.6	1.7	1.9	2.0	2.1	2.3	2.4	2.4	2.5	-	-	-	-	-	-	-	-	-	-	-
CI24R	0.3	0.5	0.7	0.9	1.1	1.3	1.5	1.6	1.7	1.8	1.9	1.9	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	0.3	0.4	0.6	0.7	0.9	1.0	1.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI512	0.7	0.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

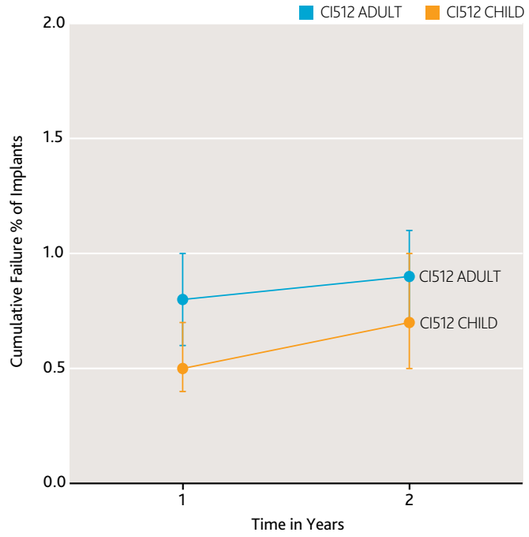
Cochlear™ Nucleus® CI512 Cochlear Implant *(Currently under voluntary recall)*

The Cumulative Survival Percentage for registered implants worldwide is **99.2%** within **2 years**.



While less than 1% of CI512 implants have failed since launch in 2009, Cochlear has identified a recent increase in the number of CI512 implant failures. In an abundance of caution Cochlear has issued a voluntary recall of the CI500 range of cochlear implants while it further investigates the cause of this issue.

CI512 Reliability



REGISTERED IMPLANTS DATA FOR ADULT AND CHILD AS OF AUGUST 31, 2011

Cumulative Survival Percentage

YEAR	1	2
CI512 Adult	99.2	99.1
CI512 Child	99.5	99.3
CI512 Combined	99.3	99.2

Cumulative Failure Percentage

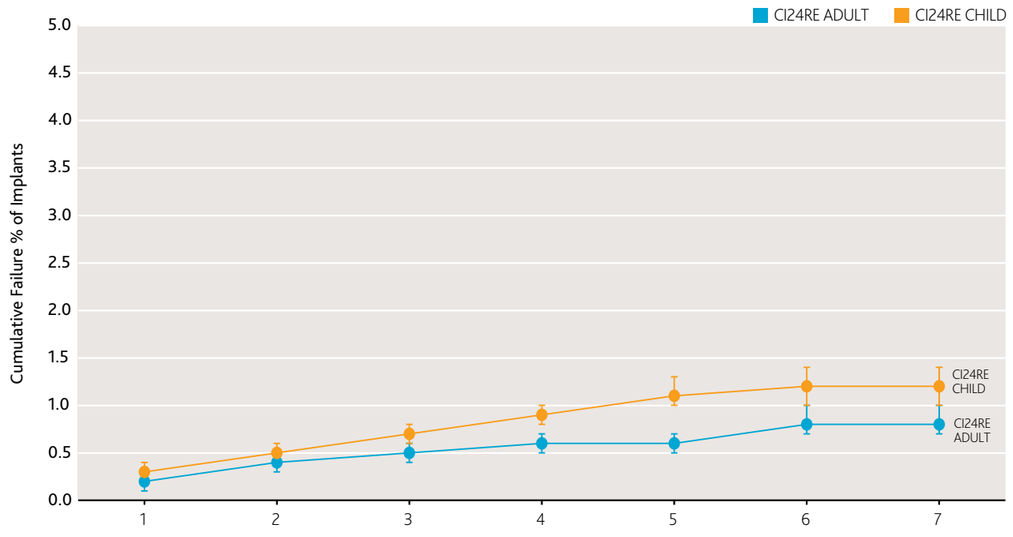
YEAR	1	2
CI512 Adult	0.8	0.9
CI512 Child	0.5	0.7
CI512 Combined	0.7	0.8

Cochlear™ Nucleus® CI24RE Cochlear Implant

The Cumulative Survival Percentage for registered implants worldwide is **99.0%** within **7 years**.

Commercially released in 2005, the CI24RE mechanical design and production processes were based on the proven architecture of the CI24R implant which is significantly different from the CI512 implant. The CI24RE introduced a new integrated circuit which substantially increased the capability and future-readiness of the system. Features include AutoNRT,™ numerous stimulation modes and native compatibility with the Nucleus 5 Sound Processor (CP810) and Nucleus 5 Remote Assistant (CR110). The CI24RE is functionally equivalent to the CI512 as both implants are based on the same integrated circuit.

CI24RE Reliability



REGISTERED IMPLANTS DATA FOR ADULT AND CHILD AS OF AUGUST 31, 2011

Cumulative Survival Percentage

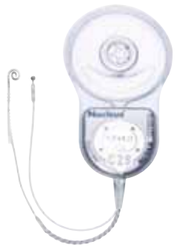
YEAR	1	2	3	4	5	6	7
CI24RE Adult	99.8	99.6	99.5	99.4	99.4	99.2	99.2
CI24RE Child	99.7	99.5	99.3	99.1	98.9	98.8	98.8
CI24RE Combined	99.7	99.6	99.4	99.3	99.1	99.0	99.0

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7
CI24RE Adult	0.2	0.4	0.5	0.6	0.6	0.8	0.8
CI24RE Child	0.3	0.5	0.7	0.9	1.1	1.2	1.2
CI24RE Combined	0.3	0.4	0.6	0.7	0.9	1.0	1.0

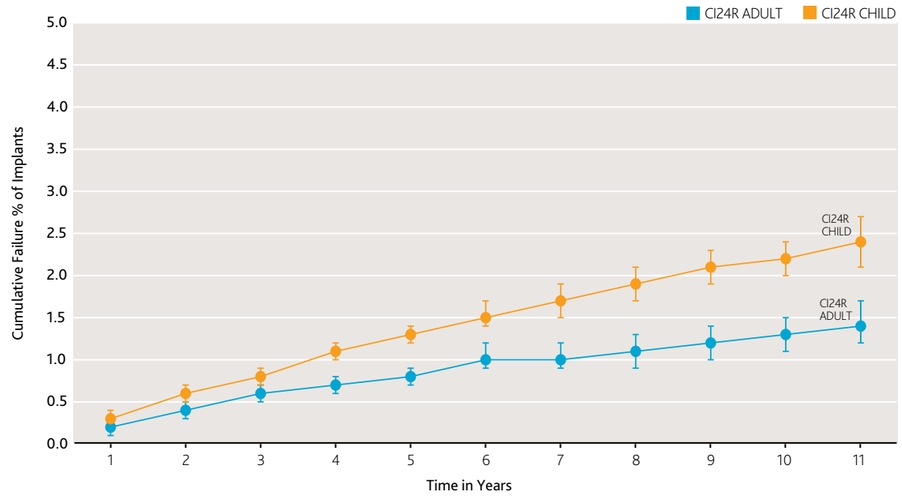
Cochlear™ Nucleus® CI24R Cochlear Implant

The Cumulative Survival Percentage for registered implants worldwide is **98.1%** within **11 years**.



The CI24R, released in 2000, was made available with perimodiolar (Nucleus 24 Contour™) and straight (Nucleus 24k) electrode arrays with 22 intracochlear electrodes. The dimensions of the CI24R implant housing are considerably smaller than those of the CI24M, and the housing designed with a low profile to allow very young children (older than 12 months) to be considered for implantation.

CI24R Reliability



REGISTERED IMPLANTS DATA FOR ADULT AND CHILD AS OF AUGUST 31, 2011

Cumulative Survival Percentage

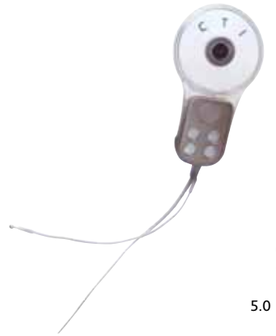
YEAR	1	2	3	4	5	6	7	8	9	10	11
CI24R Adult	99.8	99.6	99.4	99.3	99.2	99.0	99.0	98.9	98.8	98.7	98.6
CI24R Child	99.7	99.4	99.2	98.9	98.7	98.5	98.3	98.1	97.9	97.8	97.6
CI24R Combined	99.7	99.5	99.3	99.1	98.9	98.7	98.5	98.4	98.3	98.2	98.1

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11
CI24R Adult	0.2	0.4	0.6	0.7	0.8	1.0	1.0	1.1	1.2	1.3	1.4
CI24R Child	0.3	0.6	0.8	1.1	1.3	1.5	1.7	1.9	2.1	2.2	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

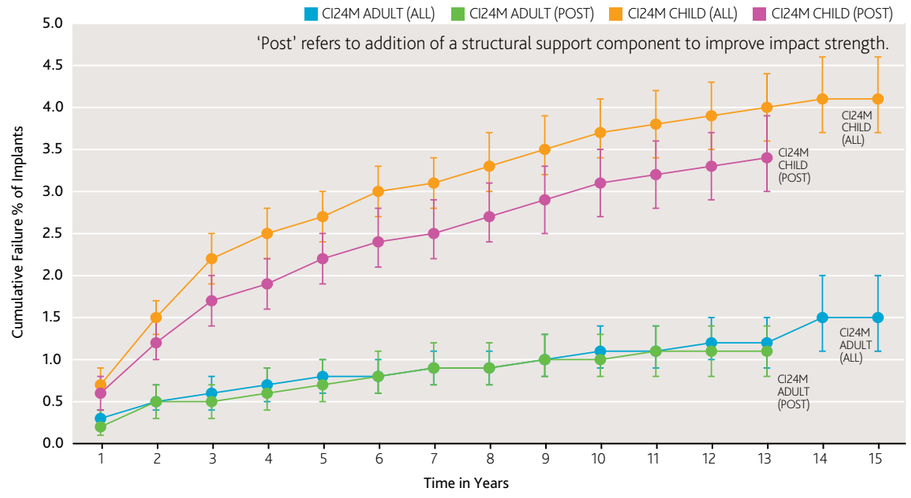
Cochlear™ Nucleus® CI24M Cochlear Implant

The Cumulative Survival Percentage for registered implants worldwide is **96.9%** within **15 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 an additional lead wire connected to a ball electrode, enabling monopolar stimulation mode. In addition, 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 ADULT AND CHILD AS OF AUGUST 31, 2011

Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
CI24M Adult (All)	99.7	99.5	99.4	99.3	99.2	99.2	99.1	99.1	99.0	98.9	98.9	98.8	98.8	98.5	98.5
CI24M Child (All)	99.3	98.5	97.8	97.5	97.3	97.0	96.9	96.7	96.5	96.3	96.2	96.1	96.0	95.9	95.9
CI24M Adult (Post)	99.8	99.5	99.5	99.4	99.3	99.2	99.1	99.1	99.0	99.0	98.9	98.9	98.9	-	-
CI24M Child (Post)	99.4	98.8	98.3	98.1	97.8	97.6	97.5	97.3	97.1	96.9	96.8	96.7	96.6	-	-
CI24M (All) Combined	99.5	98.9	98.5	98.2	98.0	97.9	97.8	97.7	97.5	97.3	97.2	97.2	97.1	96.9	96.9

Cumulative Failure Percentage

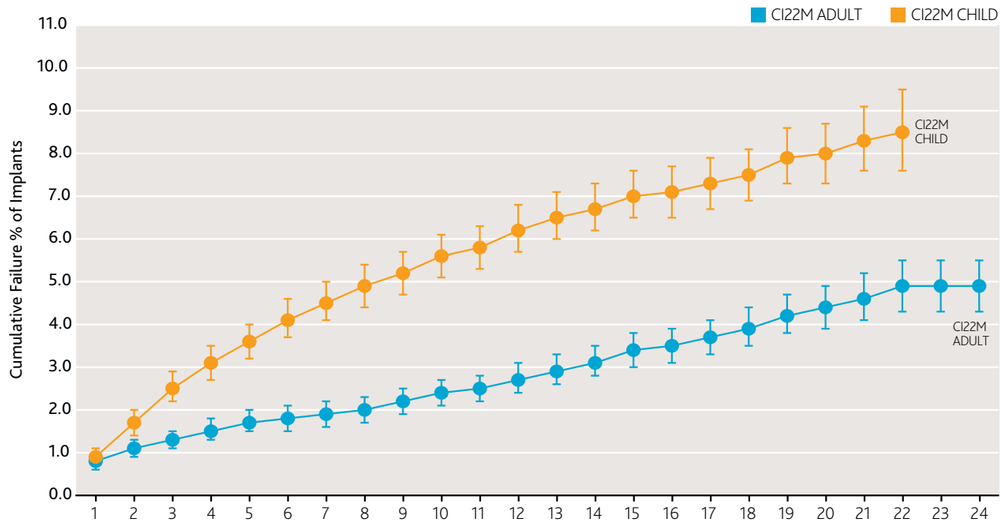
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
CI24M Adult (All)	0.3	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.0	1.1	1.1	1.2	1.2	1.5	1.5
CI24M Child (All)	0.7	1.5	2.2	2.5	2.7	3.0	3.1	3.3	3.5	3.7	3.8	3.9	4.0	4.1	4.1
CI24M Adult (Post)	0.2	0.5	0.5	0.6	0.7	0.8	0.9	0.9	1.0	1.0	1.1	1.1	1.1	-	-
CI24M Child (Post)	0.6	1.2	1.7	1.9	2.2	2.4	2.5	2.7	2.9	3.1	3.2	3.3	3.4	-	-
CI24M (All) Combined	0.5	1.1	1.5	1.8	2.0	2.1	2.2	2.3	2.5	2.7	2.8	2.8	2.9	3.1	3.1

Cochlear™ Nucleus® CI22M Cochlear Implant

The Cumulative Survival Percentage for registered implants worldwide is **93.4%** within **24 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 ADULT AND CHILD AS OF AUGUST 31, 2011

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
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	96.6	96.5	96.3	96.1	95.8	95.6	95.4	95.1	95.1	95.1
CI22M Child	99.1	98.3	97.5	96.9	96.4	95.9	95.5	95.1	94.8	94.4	94.2	93.8	93.5	93.3	93.0	92.9	92.7	92.5	92.1	92.0	91.7	91.5	-	-
CI22M Combined	99.2	98.6	98.2	97.7	97.5	97.2	96.9	96.7	96.4	96.1	96.0	95.7	95.5	95.2	95.0	94.8	94.6	94.4	94.1	93.9	93.7	93.5	93.4	93.4

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
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	3.4	3.5	3.7	3.9	4.2	4.4	4.6	4.9	4.9	4.9
CI22M Child	0.9	1.7	2.5	3.1	3.6	4.1	4.5	4.9	5.2	5.6	5.8	6.2	6.5	6.7	7.0	7.1	7.3	7.5	7.9	8.0	8.3	8.5	-	-
CI22M Combined	0.8	1.4	1.8	2.3	2.5	2.8	3.1	3.3	3.6	3.9	4.0	4.3	4.5	4.8	5.0	5.2	5.4	5.6	5.9	6.1	6.3	6.5	6.6	6.6

About Cochlear's reliability reporting

Since launching the world's first multi-channel cochlear implant system in 1982, reliability has been a focus for Cochlear. This report presents the reliability of all Nucleus cochlear implants.

What gets reported?

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 Statement, Cochlear reports all failures in the reliability calculation. The data in each report covers the entire life of each device 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.

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 and Cumulative Failure Percentage.

Cumulative Survival Percentage (CSP)

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 (CFP)

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

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

100% 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.

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, categorization 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 mark with a competent authority.	✓	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 mark with a competent authority.
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. As usual, 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 anytime after wound closure.

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 with Contour Advance electrode
CI24RE	• Nucleus CI24RE with Contour Advance™ electrode • Nucleus CI24RE with straight electrode
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

1. International Organization for Standardization, International Standard ISO 5481-2 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 (in print), 2010.

Hear now. And always

This is the Cochlear™ promise to you. As the global leader in hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. With our hearing solutions, Cochlear has reconnected over 250,000 cochlear implant and Baha® recipients to their families, friends and communities in more than 100 countries.

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 in the science of hearing.

For the person with hearing loss receiving any one of the Cochlear hearing solutions, our commitment is that for the rest of your life we will be here to support you **Hear now. And always**

As your patient's partner in hearing for life, Cochlear believes it is important to convey not only the benefits, but also the potential risks associated with any cochlear implant.

Not everyone with hearing loss is a candidate for cochlear implantation. Before any cochlear implant surgery, please review the CDC recommendations regarding vaccination with your patient. Cochlear implants are contraindicated for patients with lesions of the auditory nerve, absent cochlear development, active ear infections or active disease of the middle ear.

Cochlear implantation is a surgical procedure, and carries with it the risks typical for surgery. Patients may lose residual hearing in the implanted ear. Electrical stimulation may result in some side effects, including ringing in the ear, stimulation of the facial nerve; in rare cases this may cause pain. Though rare, it is possible that additional surgery may be required at some point to resolve complications with a cochlear implant. For complete information regarding indications, warnings and adverse effects, please refer to the Nucleus Package Insert (available at www.CochlearAmericas.com/NucleusIndications).

Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove NSW 2066, Australia Tel: 61 2 9428 6555 Fax: 61 2 9428 6353
Cochlear Americas 13059 E Peakview Avenue, Centennial, CO 80111, USA Tel: 1 303 790 9010 Fax: 1 303 792 9025
Cochlear AG European Headquarters, Peter Merian-Weg 4, CH - 4052 Basel, Switzerland Tel: 41 61 205 0404 Fax: 41 61 205 0405
EC REP **Cochlear Deutschland GmbH & Co. KG** Karl-Wiechert-Allee 76A, D-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 1526
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
Cochlear (HK) Ltd Unit 1810, Hopewell Centre, 183 Queens Road East, Wan Chai, Hong Kong SAR Tel: 852 2530 5773 Fax: 852 2530 5183
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 Ltd (Singapore Branch) 6 Sin Ming Road, #01-16 Sin Ming Plaza Tower 2, Singapore 575585 Tel: 65 6553 3814 Fax: 65 6451 4105
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 Benelux NV Schaliënhoevedreef 20i, B - 2800 Mechelen, Belgium Tel: 32 1579 5511 Fax: 32 1579 5500
Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italia Tel: 39 051 601 53 11 Fax: 39 051 39 20 62
Cochlear France S.A.S. Route de l'Orme aux Merisiers, Z.I. Les Algorithmes - Bât. Homère, 91190 Saint Aubin, France Tel: 33 811 111 993 Fax: 33 160 196 499
Cochlear Nordic AB Konstruktionsvägen 14, SE - 435 33 Mölnlycke, Sweden Tel: 46 31 335 14 61 Fax: 46 31 335 14 60
Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Sti. Cubuklu Mah. Bogazici Cad., Bogazici Plaza No: 6/1, Kavacik
TR - 34805 Beykoz-Istanbul, Turkey Tel: 90 216 538 5900 Fax: 90 216 538 5919
Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1 Canada Tel: 1 416 972 5082 Fax: 1 416 972 5083
www.cochlear.com

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