

Nucleus® Reliability Report

Introduction

Cochlear's industry leading implant reliability reflects our lifetime commitment to recipients. Since the release of Cochlear's first multi-channel system in 1982, there have been many improvements in cochlear implant technology and in recipient outcomes. Cochlear has produced several generations of cochlear implants, with each successive generation of implant more reliable than the last.

Cochlear applies the lessons it learns from each generation of implant to the next generation to improve reliability and recipient outcomes. Cochlear's latest generation cochlear implant system, Nucleus® Freedom™, was released in 2005. After four years, Freedom implant reliability data continue to demonstrate implant reliability.

As at 30 June 2008, there were 31,959 recipients with Nucleus Freedom cochlear implants. After four years, the Cumulative Failure Percentage (CFP) of the Freedom implant is 0.63% for adults and children combined.

Results Summary

Nucleus® Freedom™ – CI24RE

At four years, CFP is 0.54% for adults and 0.72% for children.

Nucleus® 24 – CI24R

At eight years, CFP is 0.9% for adults and 2.0% for children.

Nucleus® 24 – CI24M (All)

At 11 years, CFP is 0.7% for adults and 4.0% for children.

Nucleus® 22 – CI22M

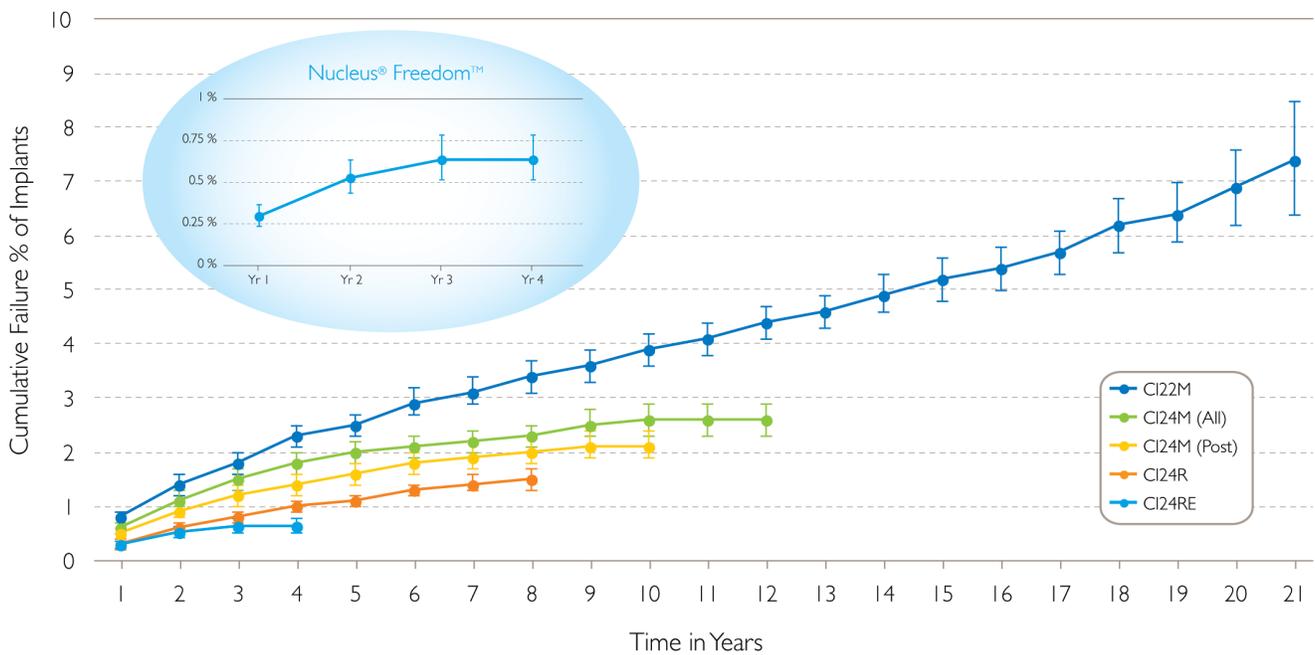
At 21 years, CFP is 5.8% for adults, and at 19 years CFP is 9.0% for children.

Recipients as at 30 June 2008:

Device	Adult	Child	Total
CI24RE	15,765	16,194	31,959
CI24R	16,401	22,976	39,377
CI24M (All)	7,444	11,269	18,713
CI22M	9,818	8,150	17,968

Nucleus Implants Reliability

Combined Adult/Child Data
as at 30 June 2008



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20	Yr 21
CI22M	0.8	1.4	1.8	2.3	2.5	2.9	3.1	3.4	3.6	3.9	4.1	4.4	4.6	4.9	5.2	5.4	5.7	6.2	6.4	6.9	7.4
CI24M (All)	0.6	1.1	1.5	1.8	2.0	2.1	2.2	2.3	2.5	2.6	2.6	2.6	-	-	-	-	-	-	-	-	-
CI24M (Post)	0.5	0.9	1.2	1.4	1.6	1.8	1.9	2.0	2.1	2.1	-	-	-	-	-	-	-	-	-	-	-
CI24R	0.3	0.6	0.8	1.0	1.1	1.3	1.4	1.5	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	0.29	0.52	0.63	0.63	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20	Yr 21
CI22M	99.2	98.6	98.2	97.7	97.5	97.1	96.9	96.6	96.4	96.1	95.9	95.6	95.4	95.1	94.8	94.6	94.3	93.8	93.6	93.1	92.6
CI24M (All)	99.4	98.9	98.5	98.2	98.0	97.9	97.8	97.7	97.5	97.4	97.4	97.4	-	-	-	-	-	-	-	-	-
CI24M (Post)	99.5	99.1	98.8	98.6	98.4	98.2	98.1	98.0	97.9	97.9	-	-	-	-	-	-	-	-	-	-	-
CI24R	99.7	99.4	99.2	99.0	98.9	98.7	98.6	98.5	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	99.71	99.48	99.37	99.37	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Notes:

- 'All' refers to all devices manufactured.
- 'Post' (i.e. Post Modification) refers to devices with a strengthened case.

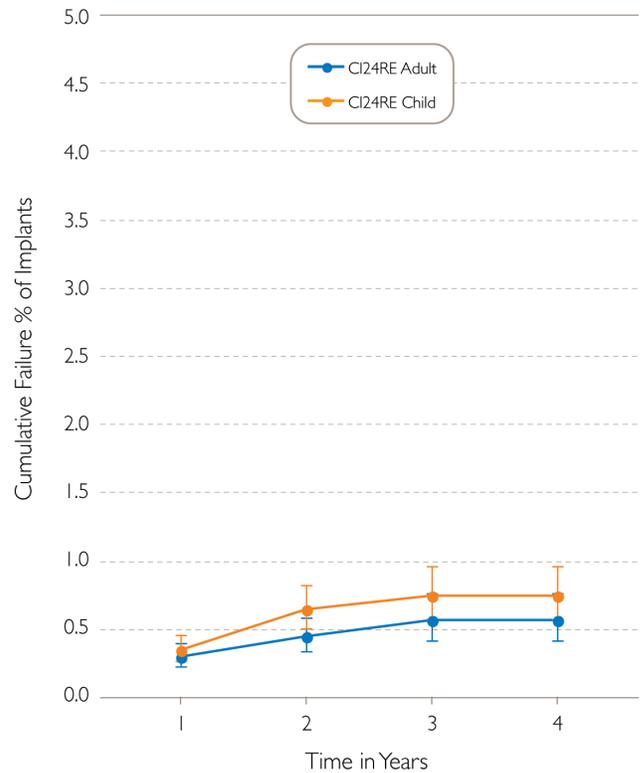
Freedom™ Implant (CI24RE)

At four years, CFP is 0.54% for adults and 0.72% for children.

The Freedom implant, commercially launched in 2005, has improved electronic capabilities compared with previous implants. Significant advantages include more efficient asynchronous stimulation and the availability of telemetry enabling new AutoNRT™ functionality. The Freedom implant has the same small physical packaging and accrues the same surgical benefits as the CI24R implant. In addition the Freedom implant was strengthened to protect the sensitive electronics against external impact.

CI24RE Reliability

All patients worldwide
as at 30 June 2008



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4
CI24RE Adult	0.27	0.42	0.54	0.54
CI24RE Child	0.32	0.62	0.72	0.72

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4
CI24RE Adult	99.73	99.58	99.46	99.46
CI24RE Child	99.68	99.38	99.28	99.28

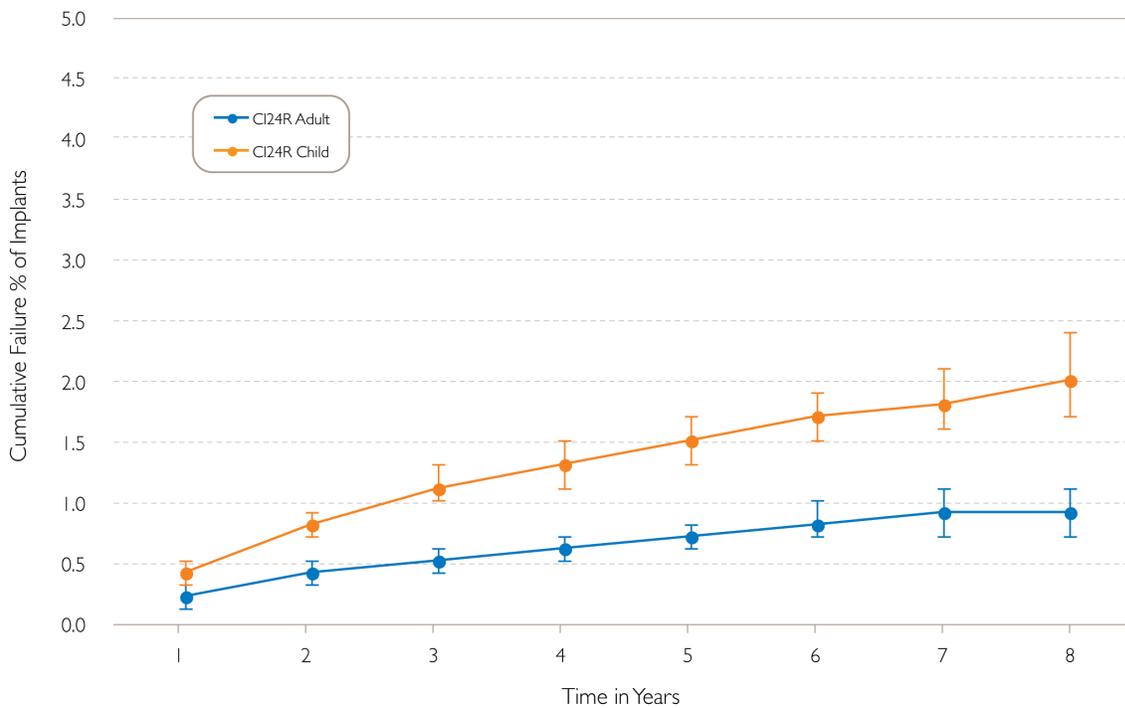
CI24R Implant

At eight years, CFP is 0.9% for adults and 2.0% for children.

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 were considerably smaller than those of the CI24M and the housing was designed with a low profile to allow very young children (older than 12 months) to be considered for implantation. The CI24R implant is well suited to minimal-access surgery. The enhanced design of the Contour Advance® electrode, introduced in 2003, was designed to minimize force on sensitive structures of the cochlea, and to provide ease of insertion of the electrode array with minimal insertion force.

CI24R Reliability

All patients worldwide
as at 30 June 2008



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
CI24R Adult	0.2	0.4	0.5	0.6	0.7	0.8	0.9	0.9
CI24R Child	0.4	0.8	1.1	1.3	1.5	1.7	1.8	2.0

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
CI24R Adult	99.8	99.6	99.5	99.4	99.3	99.2	99.1	99.1
CI24R Child	99.6	99.2	98.9	98.7	98.5	98.3	98.2	98.0

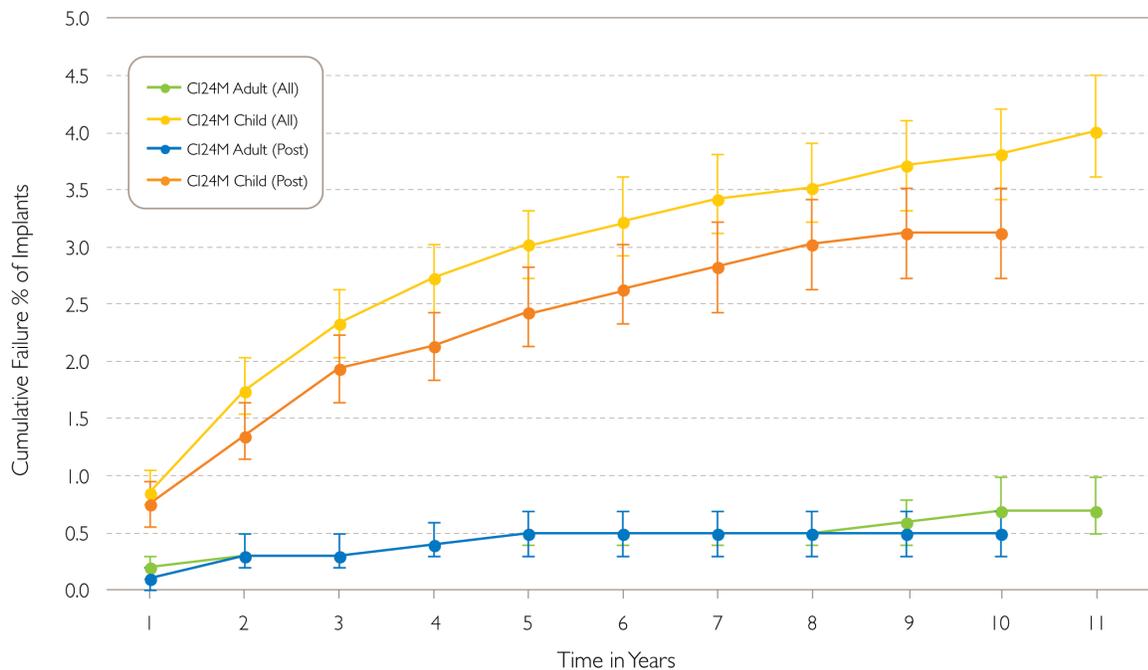
CI24M Implant

At 11 years, CFP is 0.7% for adults and 4.0% for children.

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, intended to be placed under the temporalis muscle. The CI24M allowed for an increase in available pulse rates up to 14.4 kHz. 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

All patients worldwide
as at 30 June 2008



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11
CI24M Adult (All)	0.2	0.3	0.3	0.4	0.5	0.5	0.5	0.5	0.6	0.7	0.7
CI24M Child (All)	0.8	1.7	2.3	2.7	3.0	3.2	3.4	3.5	3.7	3.8	4.0
CI24M Adult (Post)	0.1	0.3	0.3	0.4	0.5	0.5	0.5	0.5	0.5	0.5	–
CI24M Child (Post)	0.7	1.3	1.9	2.1	2.4	2.6	2.8	3.0	3.1	3.1	–

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11
CI24M Adult (All)	99.8	99.7	99.7	99.6	99.5	99.5	99.5	99.5	99.4	99.3	99.3
CI24M Child (All)	99.2	98.3	97.7	97.3	97.0	96.8	96.6	96.5	96.3	96.2	96.0
CI24M Adult (Post)	99.9	99.7	99.7	99.6	99.5	99.5	99.5	99.5	99.5	99.5	–
CI24M Child (Post)	99.3	98.7	98.1	97.9	97.6	97.4	97.2	97.0	96.9	96.9	–

Notes:

- 'All' refers to all devices manufactured.
- 'Post' (i.e. Post Modification) refers to devices with a strengthened case.

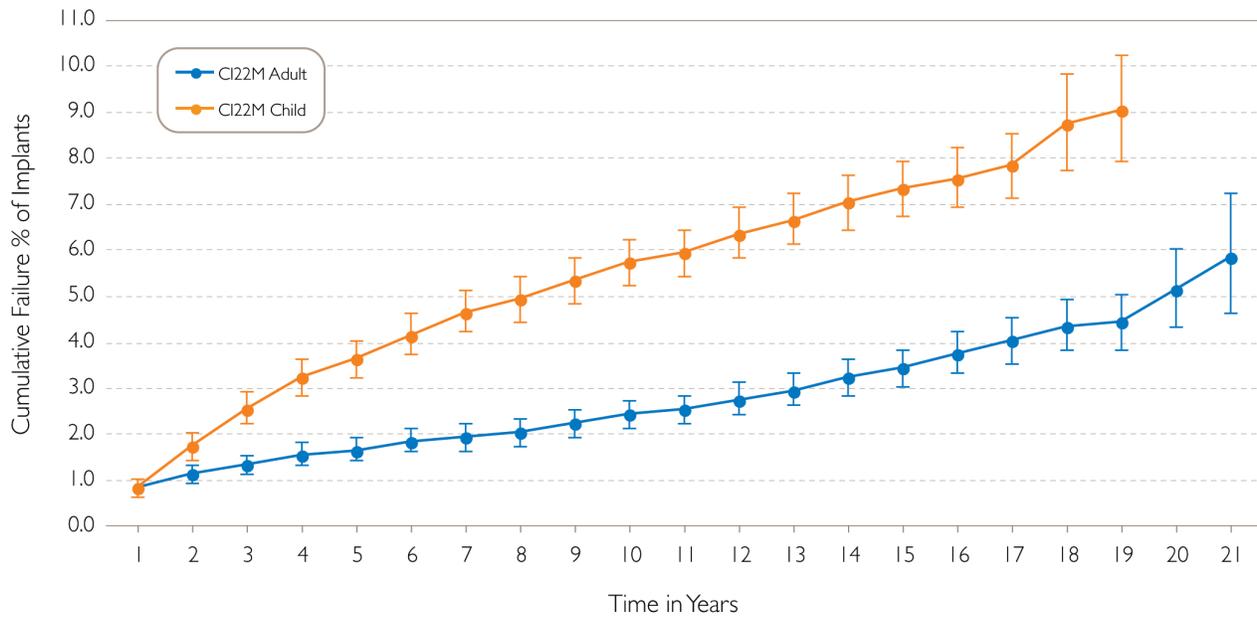
CI22M Implant

At 21 years, CFP is 5.8% for adults, and at 19 years CFP is 9.0% for children.

The CI22M implant, released in 1985, was based on Cochlear's earliest model implant - the CS22. In 1986, the CI22M was released with an internal magnet to hold the external transmitting coil in place.

CI22M Reliability

All patients worldwide
as at 30 June 2008



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20	Yr 21
CI22M Adult	0.8	1.1	1.3	1.5	1.6	1.8	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.2	3.4	3.7	4.0	4.3	4.4	5.1	5.8
CI22M Child	0.8	1.7	2.5	3.2	3.6	4.1	4.6	4.9	5.3	5.7	5.9	6.3	6.6	7.0	7.3	7.5	7.8	8.7	9.0	-	-

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20	Yr 21
CI22M Adult	99.2	98.9	98.7	98.5	98.4	98.2	98.1	98.0	97.8	97.6	97.5	97.3	97.1	96.8	96.6	96.3	96.0	95.7	95.6	94.9	94.2
CI22M Child	99.2	98.3	97.5	96.8	96.4	95.9	95.4	95.1	94.7	94.3	94.1	93.7	93.4	93.0	92.7	92.5	92.2	91.3	91.0	-	-

About the Nucleus Reliability Report

This report is prepared in accordance with International Standard ISO 5841-2000¹ and the reporting principles described in the European Consensus Statement on Cochlear Implant Failures and Explantations².

Cochlear has a long history of openly and regularly reporting device failures in accordance with these international standards and principles. This report has been produced twice a year for over 15 years to update cochlear implant professionals on the reliability of Nucleus implants in the field.

In compliance with the European Consensus Statement, Cochlear reports all failures in the reliability calculation, including those caused by external impact and electrode failures that lead to loss of clinical benefit. The data cover all implant models and results for adults and children are shown separately with 95% confidence intervals.

Cumulative Survival Percentage

The Cumulative Survival Percentage (CSP) is the cumulative number of functioning implants over time and can be used to predict the reliability of the device within a given time period. The data in this report cover the entire life of each device and all registered recipients worldwide.

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

Cumulative Failure Percentage

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

$$\text{CFP} = (100 - \text{CSP})\%$$

Graphical Representation

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

Receiver / Stimulator	Implants
CI24RE	Nucleus® Freedom™ with Contour Advance® electrode, Nucleus® Freedom™ 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

References:

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, 2nd ed. 2000.
2. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005;26:1097-1099.

Cochlear™

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