



COCHLEAR IMPLANT SYSTEMS RELIABILITY REPORT

February 2016



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OTICON MEDICAL RELIABILITY REPORT



Cochlear implant technology helped thousands of people worldwide. Most users wear their systems throughout the entire day. At Oticon Medical, we know that any device failure impacts our patients and their families; it disrupts school or work routines, creates frustration and may precipitate a decline in personal performance. That is why we work so hard to produce the most reliable devices possible.

As a cochlear implant manufacturer, we report device failures in accordance with the **International Standard ISO 5841-2:2000** & the principles described in the **European & Global Consensus on Cochlear Implant Failures & Explantations**.

Note: Oticon Medical imposes a strict report policy as part of its quality commitment by counting all devices removed for reasons other than medical necessity as failures, including the loss of clinical benefit. All registered recipients worldwide are included.



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HOW TO READ OTICON MEDICAL RELIABILITY REPORT?



In accordance with the **International Standard ISO 5841-2:2000** & the principles described in the **European & Global Consensus on Cochlear Implant Failures & Explantations**, Oticon Medical uses the appropriate standard method to communicate device reliability, by showing:

1/ For implant:

- **The Cumulative Survival Percentage (CSP)**: percentage of devices that remain functioning over a given period of time after implantation.
- **The Cumulative Failure Percentage (CFP)**: percentage of devices that are no longer functioning over a certain period of time.

$$\text{CSP (in \%)} = \frac{[\text{Devices that are still functioning for X years}]}{[\text{All devices implanted for X years}]} \times 100$$

$$\text{CFP} = [100 - \text{CSP}]$$

HOW TO READ OTICON MEDICAL RELIABILITY REPORT?



2/ For sound processor:

- **The Monthly Service Rate (MSR)**: the qualitative characteristics and reliability of our sound processors are monitored by the MSR. It reflects the percentage of devices that are returned for service each month. Loaners and order mistakes are excluded.

$$\text{MSR (in \%)} = \frac{\text{[Number of monthly returns]}}{\text{[Cumulative number of sound processors delivered]}} \times 100$$

OTICON MEDICAL NEURO SYSTEM



The Neuro cochlear implant system has been available on the market since **November 2015**.

Due to the relatively short time on the market, the Neuro system reliability data can only be presented in the next Reliability Report update.

Oticon Medical's **first cochlear implant system combines best of hearing instrument and cochlear implant technologies**.

The Neuro system consists of an innovative new implant, and a unique approach to sound processing:

- **The Neuro Zti implant** is ultra-thin and compact to make surgery as simple and safe as possible. The implant is robust and reliable, and can be adapted for high tesla scanning, such as MRI. The Neuro Zti features an entirely new internal chip design that is flexible and powerful enough to work in combination with present and future advanced sound processors from Oticon Medical.
- **The Neuro One sound processor** uses Oticon's advanced Inium chip platform with a number of automatic features and innovative sound processing - also called Coordinated Adaptive Processing. The end goal is to empower users to achieve better understanding and take an active part in conversations wherever they go.



OTICON MEDICAL IMPLANTS PORTFOLIO



Digisonic® SP implant has been available on the market since **March 2006**.

Digisonic® SP EVO implant has been available on the market since **January 2013**.

Digisonic® SP cochlear implants are designed for **minimal invasive surgery** and **to preserve cochlear structures**:

- Compact and safe design
- Unique fixation system
- Atraumatic electrodes

	Number of registred implants 31 December 2015
Digisonic® SP	8688
Digisonic® SP EVO	1645

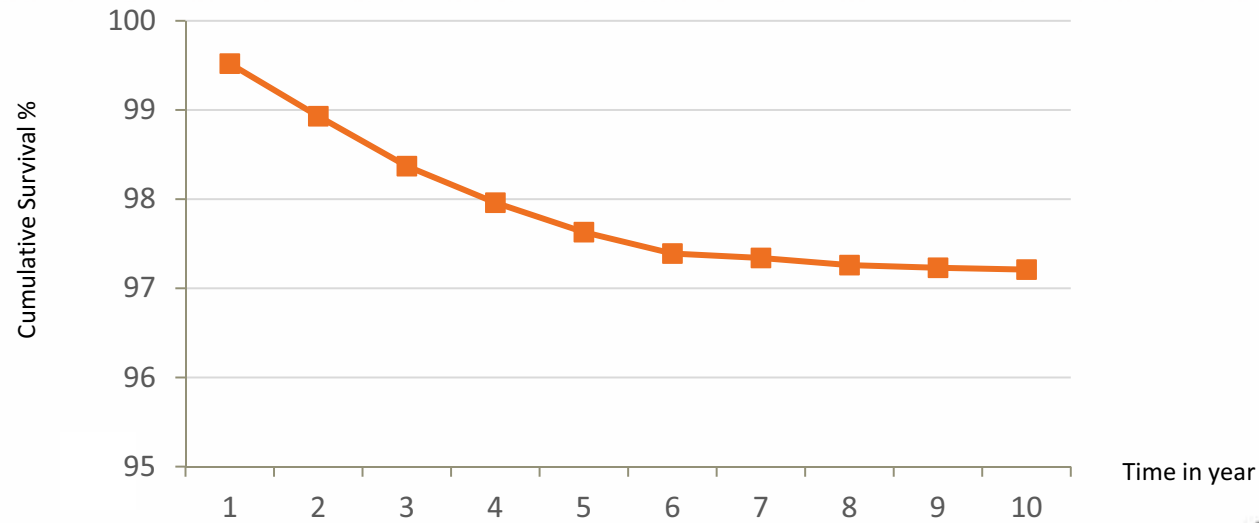
ELECTRODE ARRAY	Digisonic® SP	Digisonic® SP EVO
Number of active electrodes	20	20
Active length	25 mm	24 mm
Insertion length	26 mm	25 mm
Type of electrode array	Active area: 0,39 mm ² to 0,77 mm ² Diameter at apex: 0,5 mm Diameter at base: 1,07 mm	Active area: 0,39 mm ² to 0,52 mm ² Diameter at apex: 0,4 mm Diameter at base: 0,5 mm

DIGISONIC[®] SP COCHLEAR IMPLANT



Cumulative Survival Percentage as of end December 2015.

YEAR	1	2	3	4	5	6	7	8	9	10
DIGISONIC[®] SP CSP (%)	99.52	98,93	98.37	97,96	97.63	97.39	97.34	97.26	97.23	97.21



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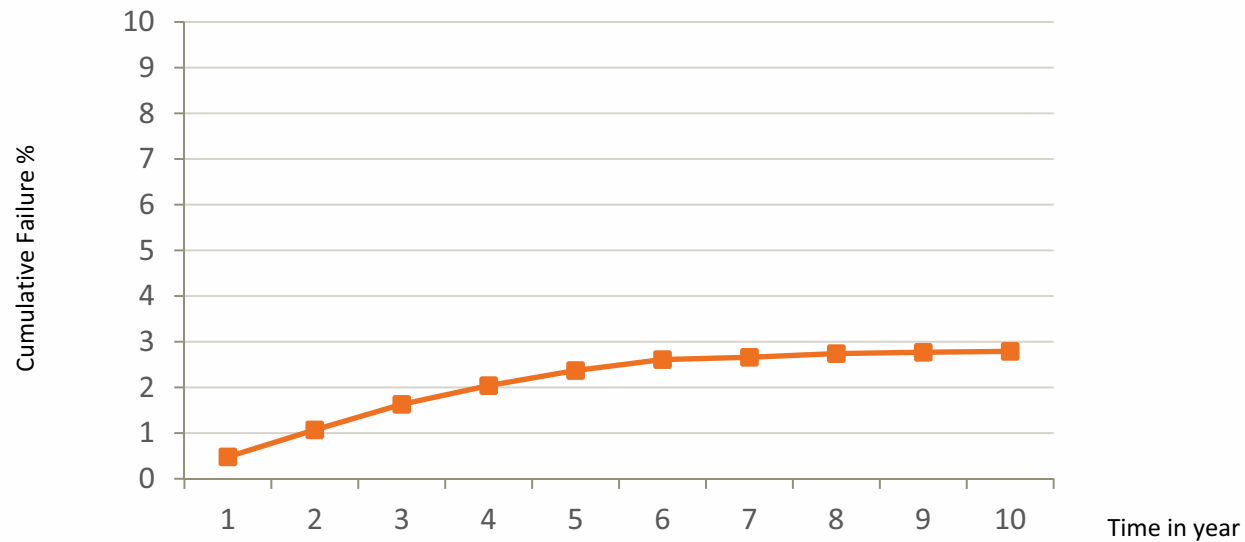


DIGISONIC[®] SP COCHLEAR IMPLANT



Cumulative Failure Percentage as of end December 2015.

YEAR	1	2	3	4	5	6	7	8	9	10
DIGISONIC[®] SP CFP (%)	0.48	1.07	1.63	2.04	2.37	2.61	2.66	2.74	2.77	2.79

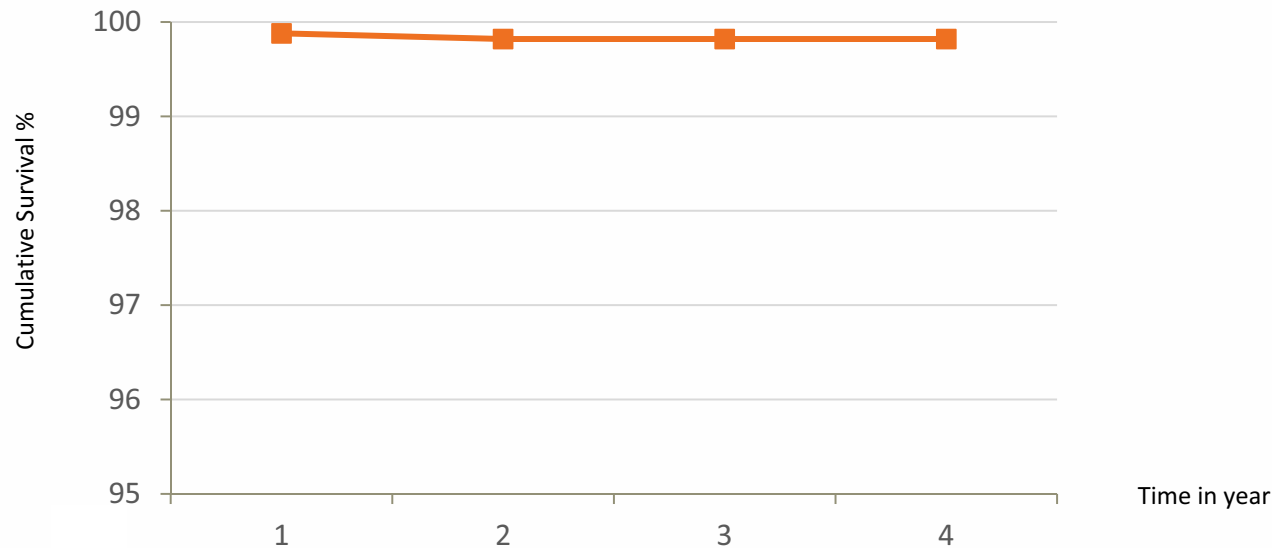
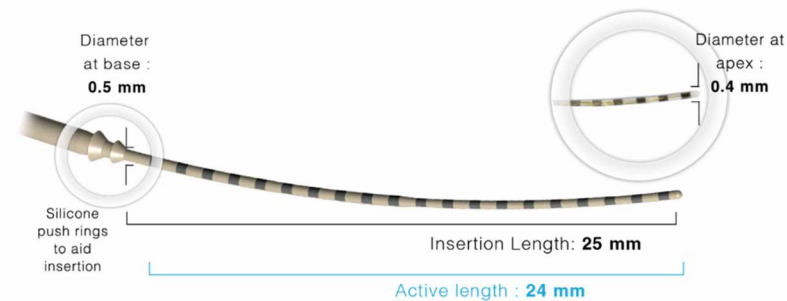


DIGISONIC[®] SP EVO COCHLEAR IMPLANT



Cumulative Survival Percentage as of end December 2015.

YEAR	1	2	3	4
DIGISONIC [®] SP EVO CSP (%)	99.88	99.82	99.82	99.82



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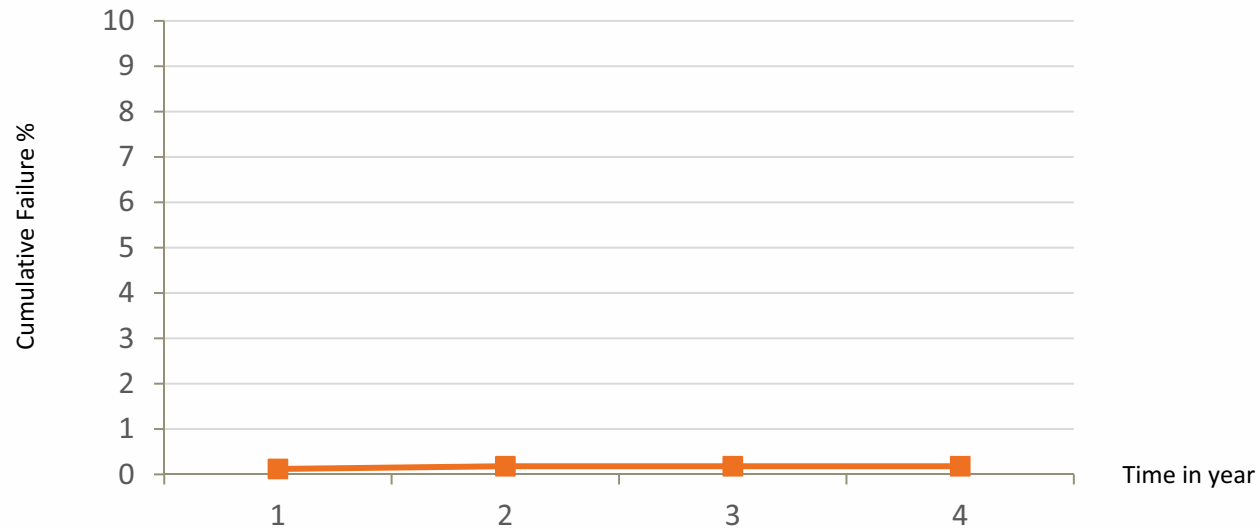


DIGISONIC[®] SP EVO COCHLEAR IMPLANT



Cumulative Failure Percentage as of end December 2015.

YEAR	1	2	3	4
DIGISONIC [®] SP EVO CFP (%)	0.12	0.18	0.18	0.18



OTICON MEDICAL SOUND PROCESSOR



The Saphyr® neo collection sound processor has been available on the market since **September 2013**.

The Saphyr® neo collection sound processor offers advanced sound processing and is designed to improve user comfort.

- Significant⁽¹⁾ improvement of speech understanding in noise
Voice Track™ & Crystalis^{XDP}
- Comfortable and intuitive
- Wireless capabilities

⁽¹⁾ Bozorg-Grayeli A., Bébéar J.P., Guevara N., Romanet P., Gnansia D., Lavielle J.P. (2014) Clinical validation data of VoiceTrack, a noise-reduction algorithm for cochlear implants.

Montava M., Gnansia D., Saai S., Guevara N., Philippon B., Bébéar J.-P., Lavielle J.P. (2014). First clinical results Crystalis XDP coding strategy including multiband output compression function.

Bergeron, F., Hotton, M., Millette, I., Lamothe, J., Bussièrès, R., Côté, M., Philippon, D. 2014. Speech recognition with the most recent technologies from the four major cochlear implant manufacturers; an update.

13th International conference on cochlear implants and other implantable auditory technologies, June 18th-21st 2014, Munich, Germany.



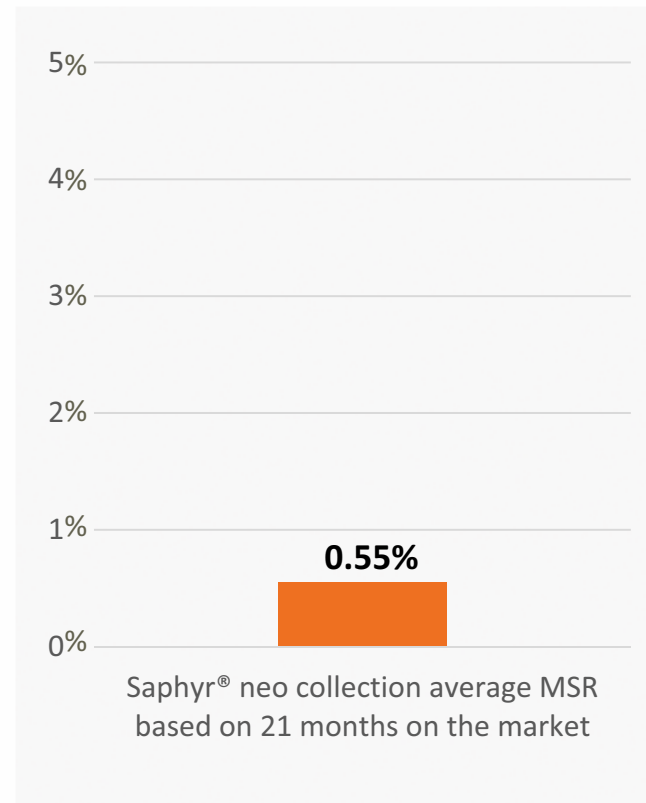
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SAPHYR® NEO COLLECTION SOUND PROCESSOR



- **Monthly Service Rate (%)**: an average percentage calculated for the period between September 2013 and end of December 2015, i.e. after **21 months on the market**.



ABOUT OTICON MEDICAL



Because Sound Matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world's largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advancements in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with user needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.

REFERENCES

International Organization for Standardization, International Standard ISO 5841-2 Implants for Surgery-Cardiac Pacemaker (2000)

European Consensus Statement on Cochlear Implant Failures and Explantations, *Otology & Neurotology*, 2005 Nov; 26:1097-1099

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