

# Reliability Report Spring 2021

IMPLANTABLE COCHLEAR STIMULATORS AND SOUND PROCESSORS



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# **OUR MISSION**

Advanced Bionics is proud to have been part of the Sonova Hearing Group for over 10 years, carrying on the Sonova vision of a world where everyone enjoys the delight of hearing and lives a life without limitations. Along with our sister company Phonak, we have strived to bring the latest in hearing instrument technology to our cochlear implant users and professionals.

Our goal is to offer the best hearing performance and to provide reliable and high quality products that exceed your expectations. This reliability report is an example of our commitment to an open and transparent communication to you.

# REPORTING ON RELIABILITY

Advanced Bionics remains committed to providing you with clear and accurate information on the quality and reliability of our cochlear implant system.

This report contains information presented in a format that adheres to ISO 5841-2:2014<sup>1</sup>, the principles outlined in the European Consensus on Cochlear Implant Failures and Explantations<sup>2</sup> and ANSI/AAMI CI86 Standard – Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting<sup>3</sup>. All methodologies are presented for all Cochlear Implant Stimulators (commonly referred to as the implant or device) and the current sound processors.

<sup>1.</sup> ISO 5841-2 (2014) Implants for Surgery - Cardiac Pacemakers. International Organization for Standardization (ISO), Geneva, Switzerland.

<sup>2.</sup> European Consensus Statement on Cochlear Implant Failures and Explanations. (2005) Otology and Neurology, 26(6): 1097-1099.

<sup>3.</sup> ANSI/AAMI CI86. Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting. (2017). Arlington, VA: American National Standards Institute.

# **INTERPRETING TABLES AND GRAPHS**

# IMPLANTABLE COCHLEAR STIMULATORS

For each implant type and any significant variant of that implant type, there will be a table showing the number of registered users and graphs showing cumulative survival rate. The table will include data for adults, children, and a combined number in accordance with the reporting methodologies.

There will be separate graphs presenting the data in accordance with ISO 5841-2:2014 and ANSI/AAMI CI86 Standard.

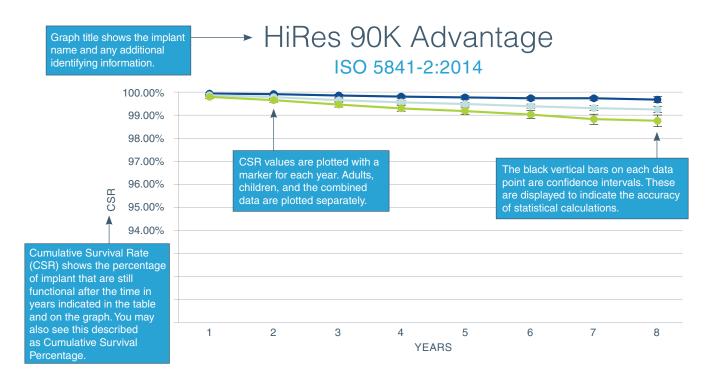
### Number of registered HiRes 90K Advantage implants

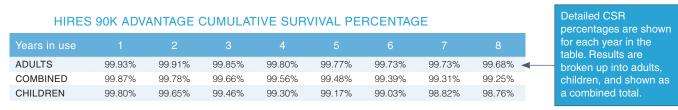
As of March 29, 2021.

Date of first commercial introduction<sup>‡</sup>: 2012

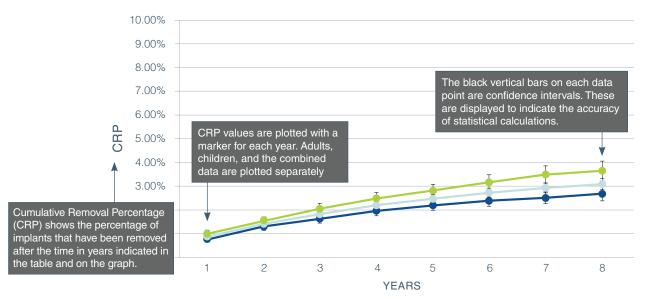
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	15283	19937	37183 <sup>†</sup>
ANSI/AAMI CI86	19292*	17891	37183

- Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.
- \* The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.
- <sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.









The ANSI/AAMI CI86 Standard requires that all removed devices are classified into three categories, namely those related to device failure, to medical reasons for explant, or those whose reason for explant cannot be determined.

### COMBINED ADULT AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
ieai	Medical Chr	Device Chr	inconclusive one	Total All Categories	CI Up	CI Down
1	0.72%	0.14%	0.02%	0.88%	0.98%	0.78%
2	1.14%	0.23%	0.04%	1.41%	1.54%	1.29%
3	1.42%	0.36%	0.05%	1.83%	1.97%	1.69%
4	1.67%	0.46%	0.07%	2.20%	2.36%	2.04%
5	1.83%	0.54%	0.10%	2.48%	2.65%	2.30% <
6	2.01%	0.62%	0.11%	2.73%	2.92%	2.55%
7	2.09%	0.71%	0.13%	2.93%	3.14%	2.72%
8	2.17%	0.79%	0.13%	3.10%	3.34%	2.85%

Throughout the report, we will present the data and graphs to represent the conditions for: all analysis categories combined; by analysis category for adults and children; removal rates by analysis category for adults; and removal rates by analysis category for children.

Not all data may be shown alongside the graphs due to space limitations. Please see the appendix at the end of the report for a complete data set.

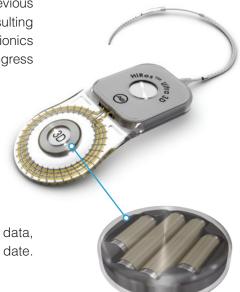
# **CURRENT-GENERATION IMPLANT DATA**

# HIRES ULTRA 3D V2

The HiRes<sup>TM</sup> Ultra 3D (V2) cochlear implant is an update to the previous HiRes Ultra 3D (V1) device. It includes reliability improvements resulting from the Corrective and Preventive Action undertaken by Advanced Bionics related to returned devices showing a common failure mode of fluid ingress into the external electrode pocket.

Based off the standard HiRes Ultra platform but featuring an innovative multi-magnet assembly, the HiRes Ultra 3D implant allows the use of clinical MRI at 1.5T and 3T without the need for magnet removal or head-bandaging. Due to the low torque, the user can be expected to have a hassle free and pain free experience.

The HiRes Ultra 3D (V2) device now has complete 1-year reliability data, and there has not been a confirmed device-related implant failure to date.



### Number of registered HiRes Ultra 3D (V2) implants

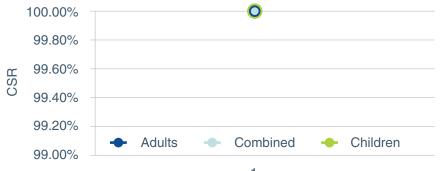
As of March 29, 2021.

Date of first commercial introduction<sup>‡</sup>: 2019

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	2843	1152	4255 <sup>†</sup>
ANSI/AAMI CI86	3282*	973	4255

- † Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.
- \* The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

# ISO 5841-2:2014

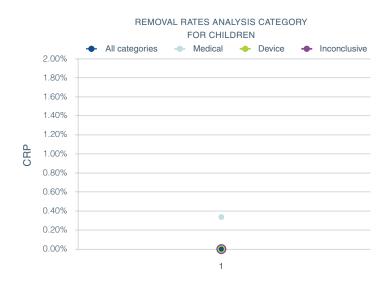


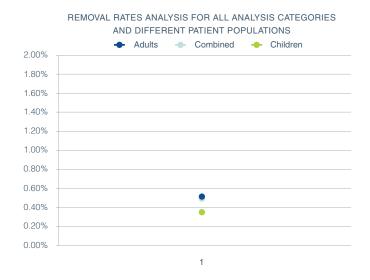
### CUMULATIVE SURVIVAL PERCENTAGE

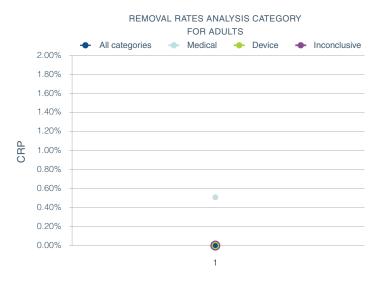
Years in use	1
ADULTS	100.00%
COMBINED	100.00%
CHILDREN	100.00%

1

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.









### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
1	0.50%	0.00%	0.00%	0.50%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES ULTRA V2

The HiRes™ Ultra (V2) cochlear implant has the same reliability improvements as the HiRes Ultra 3D (V2) device.



Featuring the proven performance platform as the HiRes 90K<sup>™</sup> Advantage, the HiRes Ultra (V2) offers a robust, thin, and discreet mechanical design that is suitable for adults and children.

The HiRes Ultra (V2) device has a limited number of devices that have completed the 1-year data point and the data presented may not reach statistical significance. There has not been a confirmed device-related failure to date.

### Number of registered HiRes Ultra (V2) implants

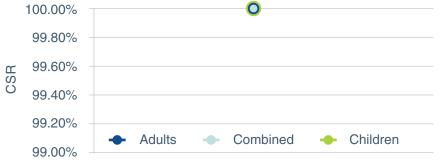
As of March 29, 2021.

Date of first commercial introduction<sup>‡</sup>: 2019

STANDARD	ADULTS	CHILDREN	COMBINED*
ISO 5841-2:2014	181	449	802 <sup>†</sup>
ANSI/AAMI CI86	375*	427	802

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

## ISO 5841-2:2014



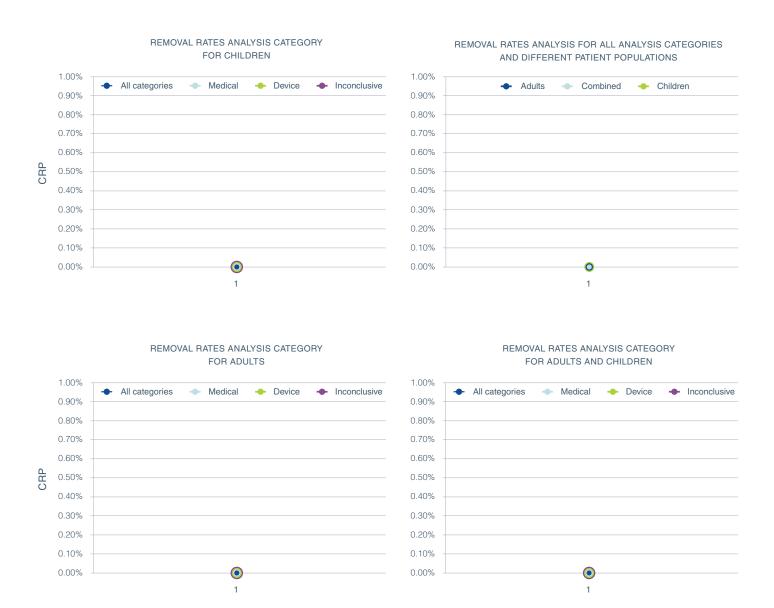
CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1
ADULTS	100.00%
COMBINED	100.00%
CHILDREN	100.00%

1

<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
1	0.00%	0.00%	0.00%	0.00%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# PREVIOUS-GENERATION IMPLANT DATA

# HIRES ULTRA 3D V1

The HiRes<sup>TM</sup> Ultra 3D (V1) cochlear implant was subject to a Voluntary Field Action initiated by Advanced Bionics on February 18, 2020, and was withdrawn from sale worldwide. This was due to recognition of a common failure mode for a small number of devices, resulting in loss of clinical benefit.

Advanced Bionics will continue to provide regular reliability updates on the HiRes Ultra platform as new data and information becomes available.

### Number of registered HiRes Ultra 3D (V1) implants

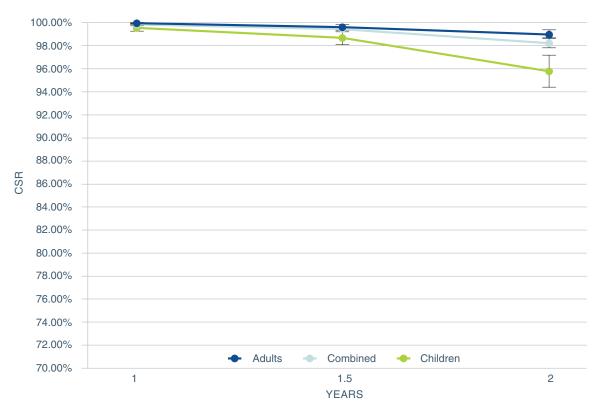
As of March 29, 2021.

Last year of distribution<sup>‡</sup>: subject to voluntary field action February 18, 2020

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4539	1575	6371 <sup>†</sup>
ANSI/AAMI CI86	5029*	1342	6371

<sup>&</sup>lt;sup>‡</sup> Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

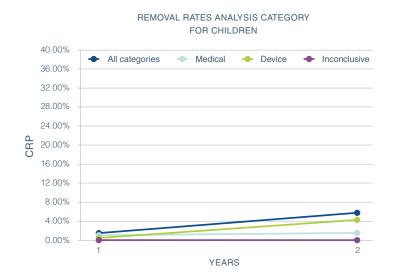
# ISO 5841-2:2014

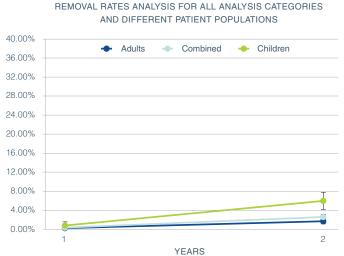


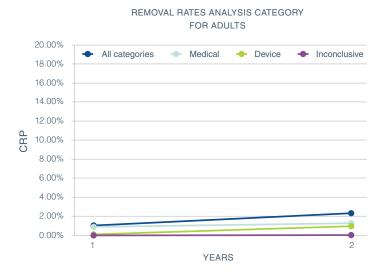
Years in use	1	1.5	2
ADULTS	99.89%	99.60%	98.99%
COMBINED	99.81%	99.39%	98.27%
CHILDREN	99.55%	98.71%	95.90%

<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.









### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Medical CRP Device CRP Ir	Incomplyaive CDD	Total All Catagories	Total	
rear	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.91%	0.19%	0.02%	1.12%	1.38%	0.86%
2	1.32%	1.65%	0.04%	3.01%	3.50%	2.52%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES ULTRA V1

The HiRes<sup>TM</sup> Ultra (V1) cochlear implant was subject to a Voluntary Field Action initiated by Advanced Bionics on February 18, 2020, and was withdrawn from sale worldwide. This was due to recognition of a common failure mode for a small number of devices, resulting in loss of clinical benefit.

Advanced Bionics will continue to provide regular reliability updates on the HiRes Ultra platform as new data and information becomes available.

### Number of registered HiRes Ultra (V1) implants

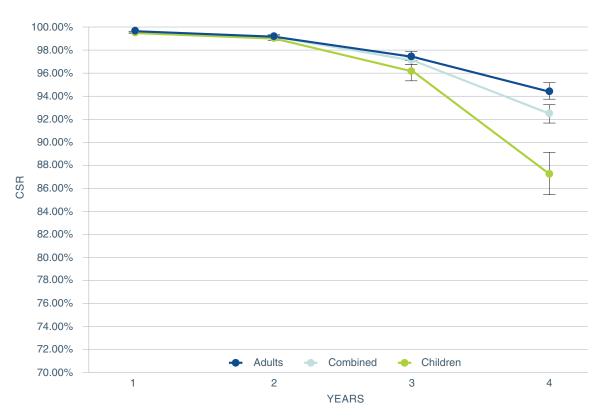
As of March 29, 2021.

Last year of distribution<sup>‡</sup>: subject to voluntary field action February 18, 2020

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	7075	4263	12131 <sup>†</sup>
ANSI/AAMI CI86	8376*	3755	12131

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

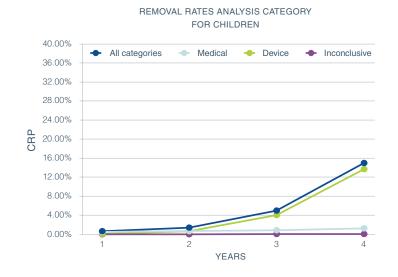
# ISO 5841-2:2014

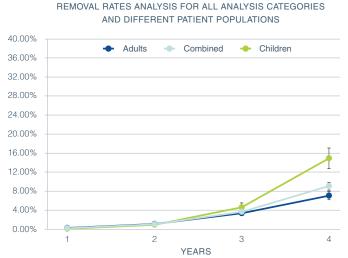


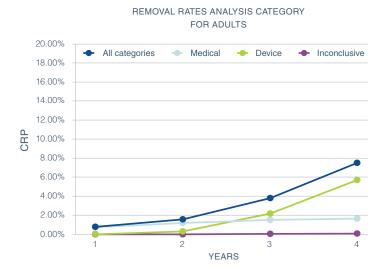
Years in use	1	2	3	4
ADULTS	99.97%	99.61%	97.79%	94.66%
COMBINED	99.95%	99.57%	97.42%	92.60%
CHILDREN	99.91%	99.44%	96.33%	87.23%

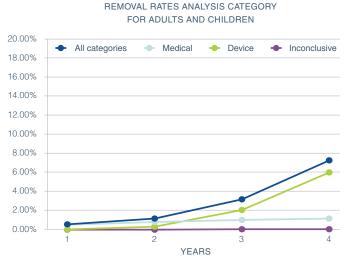
<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.









### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total		
rear	Medical Chr	Device Chr	inconclusive one	Total All Categories	CI Up	CI Down	
1	0.69%	0.05%	0.02%	0.75%	0.90%	0.60%	
2	1.06%	0.44%	0.04%	1.54%	1.76%	1.31%	
3	1.34%	2.68%	0.08%	4.10%	4.51%	3.69%	
4	1.52%	7.72%	0.11%	9.34%	10.16%	8.51%	

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K ADVANTAGE

The HiRes 90K<sup>™</sup> Advantage cochlear implant offers mechanical improvements over its predecessor, the HiRes 90K cochlear implant. It has the capability to offer advanced sound coding strategies, together with the security of a deep bone bed.

### Number of registered HiRes 90K Advantage implants

As of March 29, 2021.

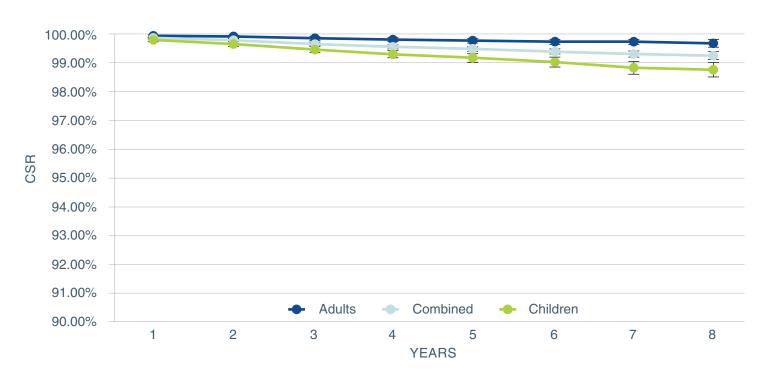
Date of first commercial introduction<sup>‡</sup>: 2012. Still available in selected markets.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	15283	19937	37183 <sup>†</sup>
ANSI/AAMI CI86	19292*	17891	37183



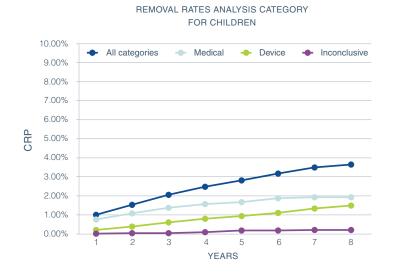
<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

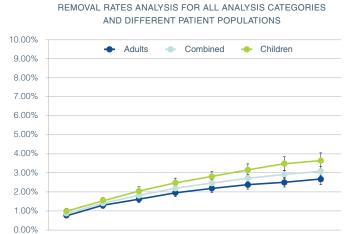
# ISO 5841-2:2014



Years in use					5	6		
ADULTS	99.93%	99.91%	99.85%	99.80%	99.77%	99.73%	99.73%	99.68%
COMBINED	99.87%	99.78%	99.66%	99.56%	99.48%	99.39%	99.31%	99.25%
CHILDREN	99.80%	99.65%	99.46%	99.30%	99.17%	99.03%	98.82%	98.76%

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



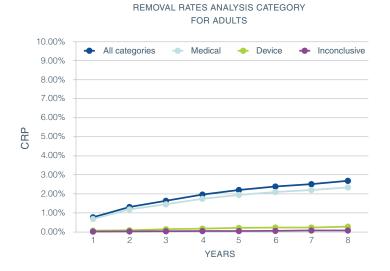


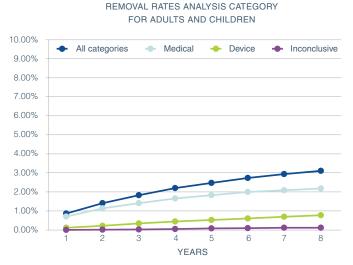
5

YEARS

6

3





### COMBINED ADULT AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To	otal
Teal	Wedical Chr	Device Onr	inconclusive one	Total All Categories	CI Up	CI Down
1	0.72%	0.14%	0.02%	0.88%	0.98%	0.78%
2	1.14%	0.23%	0.04%	1.41%	1.54%	1.29%
3	1.42%	0.36%	0.05%	1.83%	1.97%	1.69%
4	1.67%	0.46%	0.07%	2.20%	2.36%	2.04%
5	1.83%	0.54%	0.10%	2.48%	2.65%	2.30%
6	2.01%	0.62%	0.11%	2.73%	2.92%	2.55%
7	2.09%	0.71%	0.13%	2.93%	3.14%	2.72%
8	2.17%	0.79%	0.13%	3.10%	3.34%	2.85%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

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# HIRES 90K vendor A post-mod

The HiRes 90K<sup>™</sup> cochlear implant offers access to advanced sound coding technologies. It has undergone manufacturing modifications that are listed separately below, with the version currently available being designated as the HiRes 90K (vendor A post-mod) implant.

### Number of registered HiRes 90K implants (vendor A post-mod)

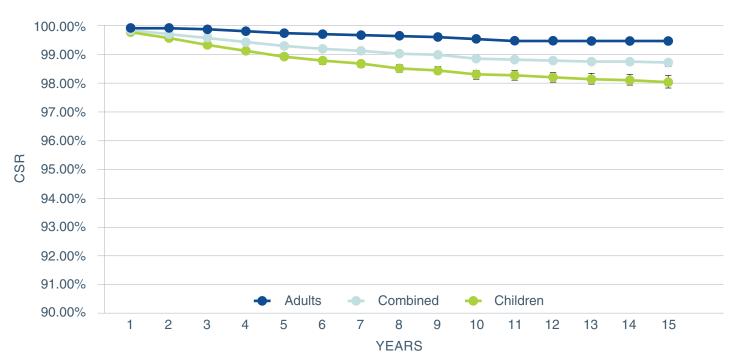
As of March 29, 2021.

Last year of distribution<sup>‡</sup>. Still available in selected markets.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	31417	44578	78531 <sup>†</sup>
ANSI/AAMI CI86	39337*	39194	78531

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

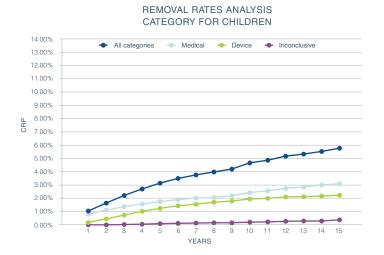
# ISO 5841-2:2014



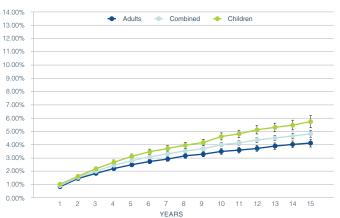
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
ADULTS	99.95%	99.93%	99.89%	99.83%	99.79%	99.72%	99.71%	99.67%	99.63%	99.56%	99.50%	99.49%	99.49%	99.49%	99.49%
COMBINED	99.88%	99.74%	99.60%	99.45%	99.32%	99.22%	99.16%	99.06%	99.01%	98.89%	98.85%	98.81%	98.78%	98.77%	98.74%
CHILDREN	99.82%	99.60%	99.37%	99.14%	98.94%	98.80%	98.70%	98.55%	98.49%	98.33%	98.30%	98.23%	98.18%	98.15%	98.08%

<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

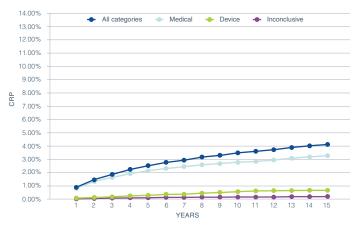
<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



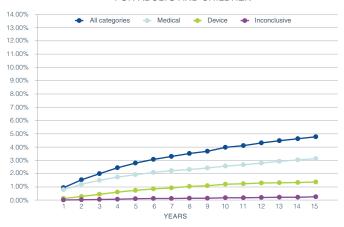








# REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS AND CHILDREN



### COMBINED ADULTS AND CHILDREN

V	Madiaal CDD	Davies CDD	la canalysis CDD	Total All Catagorica	To	otal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.81%	0.14%	0.02%	0.96%	1.03%	0.90%
2	1.23%	0.29%	0.04%	1.56%	1.65%	1.48%
3	1.52%	0.45%	0.06%	2.03%	2.14%	1.93%
4	1.76%	0.62%	0.09%	2.47%	2.58%	2.36%
5	1.96%	0.75%	0.11%	2.82%	2.94%	2.70%
6	2.11%	0.87%	0.13%	3.12%	3.24%	2.99%
7	2.24%	0.94%	0.14%	3.33%	3.46%	3.19%
8	2.35%	1.05%	0.16%	3.56%	3.70%	3.41%
9	2.45%	1.11%	0.17%	3.72%	3.87%	3.57%
10	2.61%	1.22%	0.19%	4.02%	4.18%	3.86%
11	2.69%	1.27%	0.20%	4.16%	4.33%	3.99%
12	2.83%	1.31%	0.21%	4.36%	4.54%	4.17%
13	2.96%	1.33%	0.24%	4.53%	4.72%	4.33%
14	3.08%	1.36%	0.24%	4.67%	4.88%	4.46%
15	3.17%	1.39%	0.27%	4.82%	5.07%	4.57%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K vendor A all

### Number of registered HiRes 90K implants (vendor A all)

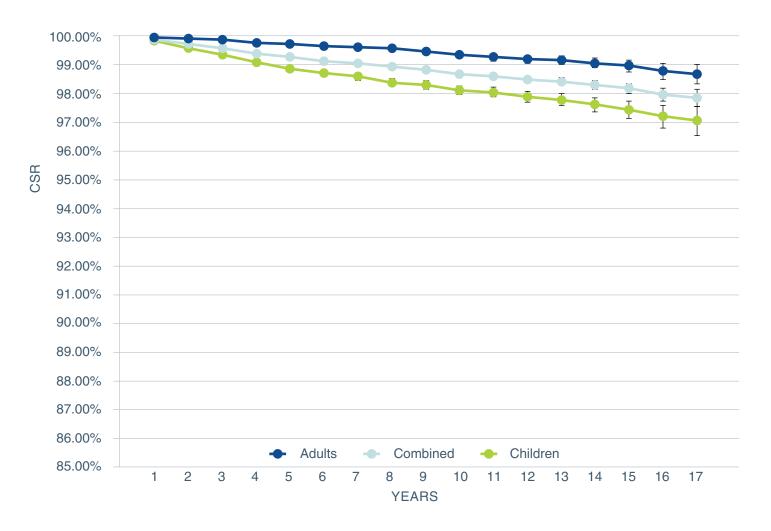
As of March 29, 2021.

Last year of distribution<sup>‡</sup>. Still available in selected markets.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	32867	45672	81086 <sup>†</sup>
ANSI/AAMI CI86	40383*	39156	79539

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

# ISO 5841-2:2014

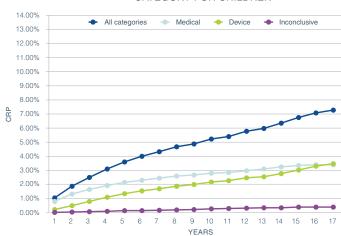


Years in use					5	6		8	9	10	-11	12	13	14	15	16	17
ADULTS	99.93%	99.90%	99.86%	99.77%	99.73%	99.64%	99.62%	99.56%	99.46%	99.37%	99.27%	99.20%	99.17%	99.08%	98.98%	98.80%	98.70%
COMBINED	99.87%	99.72%	99.58%	99.41%	99.28%	99.16%	99.08%	98.95%	98.85%	98.72%	98.63%	98.53%	98.46%	98.34%	98.21%	98.02%	97.90%
CHILDREN	99.81%	99.58%	99.35%	99.11%	98.90%	98.74%	98.62%	98.42%	98.33%	98.16%	98.10%	97.94%	97.84%	97.67%	97.51%	97.28%	97.13%

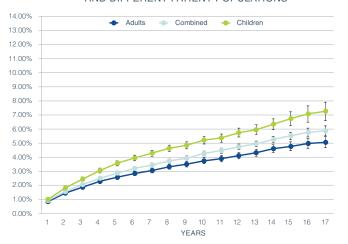
<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.

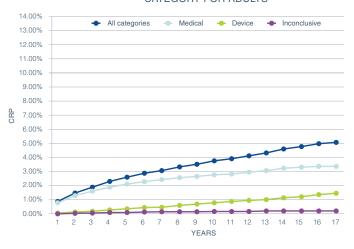




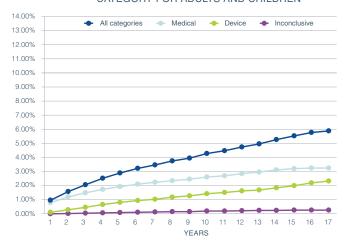
# REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS



# REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS AND CHILDREN



### COMBINED ADULTS AND CHILDREN

Voor	Madical CDD	Device CRP	Incomplyaive CDD	Total All Catagorias	To	otal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.81%	0.15%	0.02%	0.98%	1.05%	0.91%
2	1.23%	0.32%	0.05%	1.59%	1.68%	1.50%
3	1.52%	0.49%	0.07%	2.08%	2.18%	1.98%
4	1.76%	0.68%	0.10%	2.54%	2.65%	2.43%
5	1.96%	0.83%	0.13%	2.91%	3.03%	2.79%
6	2.11%	0.97%	0.15%	3.23%	3.36%	3.10%
7	2.25%	1.06%	0.17%	3.47%	3.61%	3.34%
8	2.37%	1.20%	0.18%	3.75%	3.90%	3.61%
9	2.46%	1.30%	0.19%	3.95%	4.10%	3.80%
10	2.62%	1.44%	0.22%	4.28%	4.45%	4.12%
11	2.72%	1.53%	0.23%	4.48%	4.65%	4.30%
12	2.86%	1.65%	0.24%	4.75%	4.94%	4.56%
13	2.97%	1.71%	0.27%	4.95%	5.15%	4.75%
14	3.12%	1.87%	0.27%	5.26%	5.48%	5.03%
15	3.22%	2.02%	0.29%	5.52%	5.79%	5.26%
16	3.25%	2.21%	0.29%	5.76%	6.06%	5.45%
17	3.25%	2.33%	0.29%	5.88%	6.22%	5.53%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K vendor A pre-mod

### Number of registered HiRes 90K implants (vendor A pre-mod)

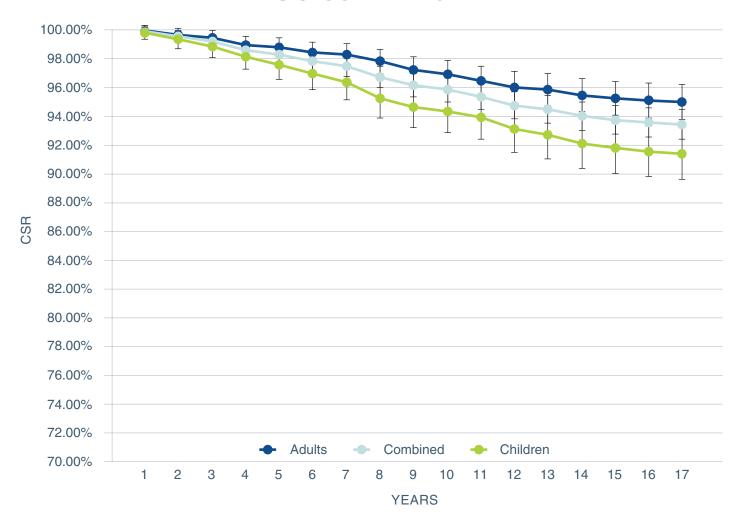
As of March 29, 2021.

Last year of distribution<sup>‡</sup>: 2005.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	1450	1094	2555†
ANSI/AAMI CI86	1661*	894	2555

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

## ISO 5841-2:2014



Years in use					5	6		8	9	10	- 11	12	13	14	15	16	17
ADULTS	99.58%	99.31%	99.09%	98.60%	98.46%	98.10%	97.95%	97.52%	96.94%	96.65%	96.22%	95.78%	95.63%	95.27%	95.04%	94.90%	94.79%
COMBINED	99.53%	99.17%	98.85%	98.29%	97.96%	97.51%	97.18%	96.48%	95.91%	95.62%	95.16%	94.58%	94.33%	93.86%	93.61%	93.44%	93.32%
CHILDREN	99.45%	98.98%	98.51%	97.85%	97.28%	96.71%	96.13%	95.06%	94.48%	94.18%	93.79%	93.01%	92.61%	92.02%	91.72%	91.51%	91.37%

<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



### COMBINED ADULTS AND CHILDREN

Voor	Madical CDD	Davisa CDD	Inconclusive CDD	Total All Catagories	To	otal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.90%	0.55%	0.00%	1.45%	1.92%	0.99%
2	1.18%	1.03%	0.20%	2.41%	3.00%	1.81%
3	1.58%	1.47%	0.40%	3.45%	4.15%	2.74%
4	1.86%	2.31%	0.44%	4.61%	5.42%	3.80%
5	1.98%	2.87%	0.52%	5.38%	6.25%	4.51%
6	2.15%	3.44%	0.61%	6.19%	7.12%	5.26%
7	2.47%	3.88%	0.73%	7.09%	8.08%	6.10%
8	2.72%	4.62%	0.73%	8.07%	9.12%	7.03%
9	2.76%	5.19%	0.73%	8.69%	9.77%	7.60%
10	2.89%	5.60%	0.82%	9.31%	10.42%	8.19%
11	3.10%	6.01%	0.86%	9.97%	11.12%	8.82%
12	3.27%	6.63%	0.86%	10.76%	11.95%	9.57%
13	3.31%	6.91%	0.91%	11.14%	12.34%	9.93%
14	3.53%	7.49%	0.91%	11.93%	13.17%	10.69%
15	3.66%	7.78%	0.91%	12.35%	13.61%	11.09%
16	3.70%	7.95%	0.91%	12.56%	13.83%	11.29%
17	3.70%	8.07%	0.91%	12.68%	13.96%	11.40%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K vendor B

### Number of registered HiRes 90K implants (vendor B)

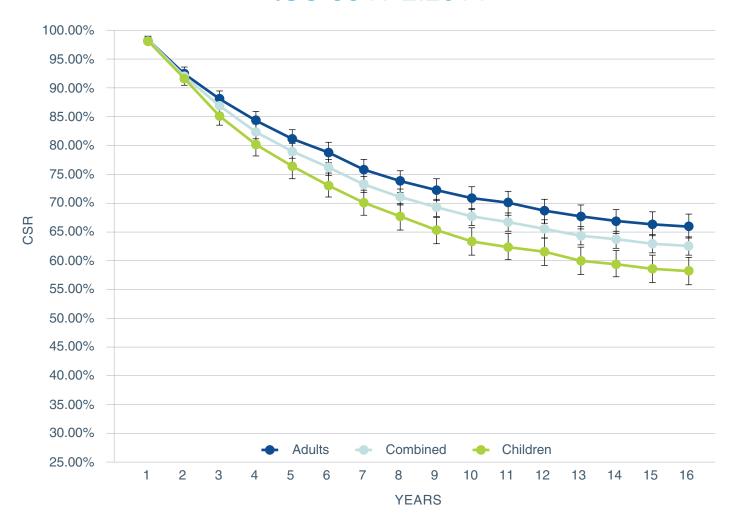
As of March 29, 2021.

Last year of distribution<sup>‡</sup>. Subject to voluntary recall in 2006.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	2204	1837	4065 <sup>†</sup>
ANSI/AAMI CI86	2561*	1504	4065

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

# ISO 5841-2:2014



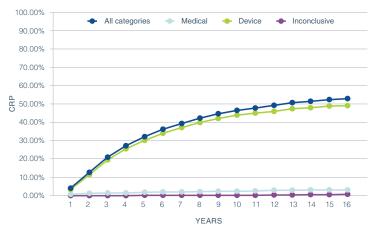
Years in use					5	6			9	10	-11	12	13	14	15	16
ADULTS	97.89%	91.83%	87.54%	83.70%	80.50%	78.17%	75.22%	73.16%	71.77%	70.36%	69.42%	68.06%	67.05%	66.26%	65.78%	65.40%
COMBINED	97.79%	91.55%	86.24%	81.86%	78.44%	75.69%	72.69%	70.49%	68.66%	67.05%	66.11%	64.97%	63.73%	63.07%	62.37%	62.00%
CHILDREN	97.64%	91.17%	84.59%	79.50%	75.77%	72.53%	69.45%	67.03%	64.67%	62.79%	61.84%	60.95%	59.42%	58.90%	57.93%	57.56%

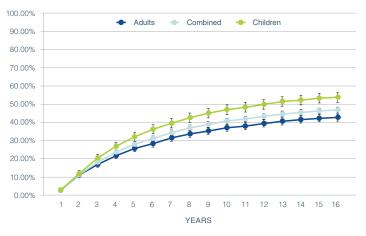
<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



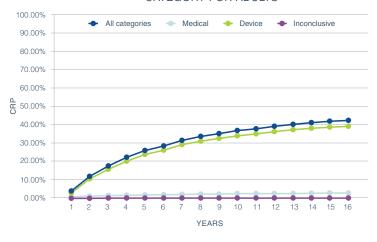
# REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS

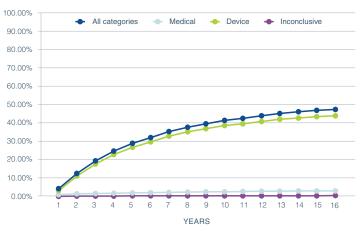




# REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS

REMOVAL RATES ANALYSIS
CATEGORY FOR ADULTS AND CHILDREN





### COMBINED ADULTS AND CHILDREN

Voor	Medical CRP	Device CRP	Inconclusive CBB	Total All Catagories	To	otal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.98%	3.14%	0.00%	4.12%	4.73%	3.51%
2	1.32%	11.11%	0.08%	12.52%	13.53%	11.50%
3	1.58%	17.53%	0.14%	19.26%	20.46%	18.05%
4	1.74%	22.69%	0.17%	24.60%	25.92%	23.28%
5	1.90%	26.67%	0.24%	28.81%	30.20%	27.42%
6	2.04%	29.65%	0.24%	31.93%	33.36%	30.50%
7	2.12%	32.76%	0.24%	35.12%	36.58%	33.65%
8	2.39%	34.95%	0.24%	37.58%	39.07%	36.09%
9	2.42%	36.79%	0.24%	39.45%	40.96%	37.95%
10	2.55%	38.43%	0.24%	41.21%	42.73%	39.69%
11	2.63%	39.44%	0.24%	42.31%	43.84%	40.79%
12	2.80%	40.60%	0.33%	43.72%	45.25%	42.19%
13	2.84%	41.83%	0.33%	45.00%	46.54%	43.46%
14	2.98%	42.52%	0.37%	45.86%	47.40%	44.32%
15	3.02%	43.26%	0.37%	46.65%	48.19%	45.11%
16	3.02%	43.67%	0.44%	47.13%	48.68%	45.58%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

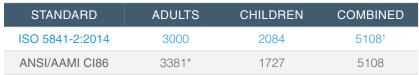
# CII BIONIC EAR

The CII Bionic Ear cochlear implant is the base for the advanced technology found in Advanced Bionics implants today. The platform can still take advantage of the latest innovations today. It benefited from the mechanical improvement made to the earlier C1.2 implants.

### Number of registered CII implants

As of March 29, 2021.

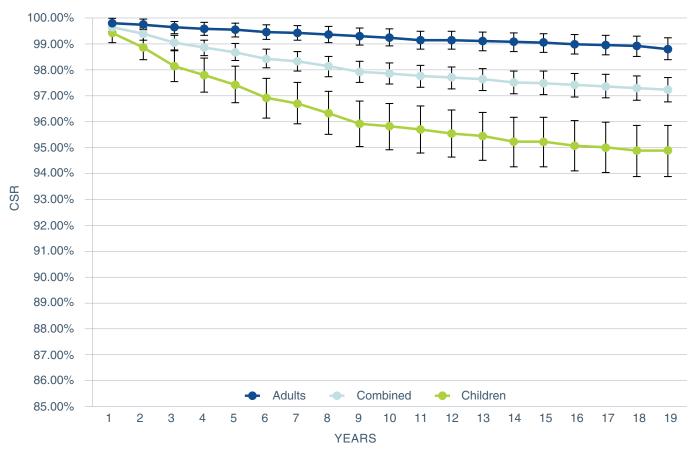
Last year of distribution<sup>‡</sup>: 2004





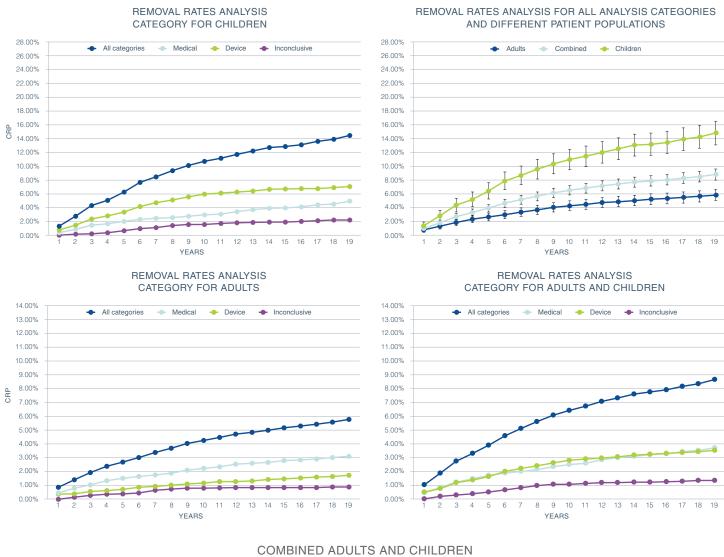
<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

# ISO 5841-2:2014



Years in use					5	6		8	9	10	11	12	13	14	15	16	17	18	19
ADULTS	99.77%	99.70%	99.60%	99.53%	99.50%	99.43%	99.39%	99.32%	99.25%	99.22%	99.12%	99.12%	99.08%	99.05%	99.01%	98.98%	98.94%	98.90%	98.80%
COMBINED	99.61%	99.35%	99.01%	98.83%	98.67%	98.43%	98.33%	98.14%	97.94%	97.88%	97.77%	97.71%	97.65%	97.54%	97.52%	97.44%	97.40%	97.33%	97.26%
CHILDREN	99.37%	98.84%	98.15%	97.81%	97.46%	96.96%	96.76%	96.40%	95.99%	95.89%	95.79%	95.63%	95.53%	95.32%	95.32%	95.17%	95.11%	94.98%	94.98%

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



V/	Madian ODD	Davis ODD	la constant of ODD	T	To	otal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.47%	0.55%	0.06%	1.08%	1.36%	0.80%
2	0.89%	0.81%	0.22%	1.91%	2.29%	1.54%
3	1.24%	1.22%	0.32%	2.79%	3.24%	2.34%
4	1.50%	1.42%	0.42%	3.35%	3.84%	2.86%
5	1.74%	1.66%	0.54%	3.95%	4.48%	3.42%
6	1.93%	2.03%	0.68%	4.64%	5.21%	4.06%
7	2.05%	2.25%	0.85%	5.15%	5.75%	4.54%
8	2.17%	2.45%	1.01%	5.63%	6.26%	5.01%
9	2.37%	2.66%	1.10%	6.13%	6.78%	5.47%
10	2.54%	2.84%	1.10%	6.47%	7.14%	5.80%
11	2.64%	2.94%	1.18%	6.76%	7.44%	6.08%
12	2.89%	3.00%	1.22%	7.11%	7.81%	6.41%
13	3.03%	3.09%	1.24%	7.36%	8.07%	6.65%
14	3.13%	3.23%	1.26%	7.63%	8.35%	6.91%
15	3.24%	3.29%	1.26%	7.79%	8.52%	7.06%
16	3.32%	3.35%	1.28%	7.96%	8.69%	7.22%
17	3.47%	3.40%	1.33%	8.19%	8.94%	7.45%
18	3.56%	3.47%	1.37%	8.40%	9.16%	7.65%
19	3.76%	3.57%	1.37%	8.70%	9.47%	7.92%

Not all data may be shown alongside the graphs due to space limitations. Please see the Appendix at the end of the report for a complete data set.

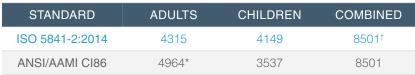
# **CLARION 1.2**

The Clarion 1.2 (C1.2) implant offers mechanical improvements over its predecessor the C1.0 implant, which first introduced independent current-sources, a key technology differentiator for Advanced Bionics implants.

### Number of registered C1.2 implants

As of March 29, 2021.

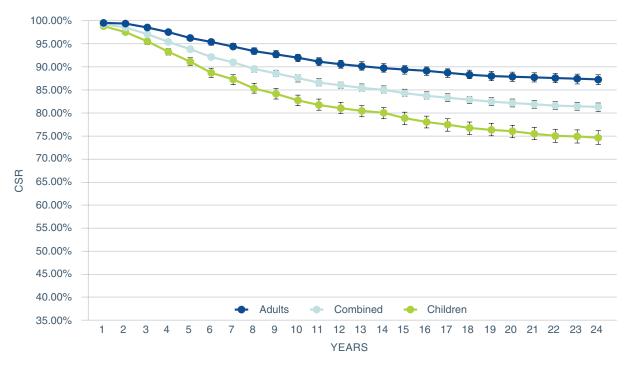
Last year of distribution<sup>‡</sup>: 2004





<sup>\*</sup> The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

# ISO 5841-2:2014



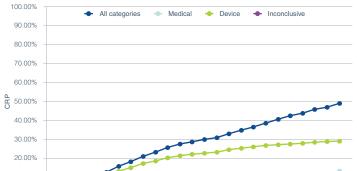
Years in use					5	6		8	9	10	11	12
ADULTS	99.81%	99.56%	98.83%	97.76%	96.57%	95.66%	94.77%	93.73%	93.08%	92.30%	91.51%	90.97%
COMBINED	99.42%	98.72%	97.36%	95.75%	94.10%	92.51%	91.34%	89.93%	89.01%	87.94%	87.09%	86.49%
CHILDREN	99.00%	97.83%	95.80%	93.61%	91.46%	89.14%	87.66%	85.83%	84.63%	83.24%	82.30%	81.63%
Years in use	13	14	15	16	17	18	19	20	21	22	23	24
Years in use ADULTS	13 90.55%	14 90.13%	15 89.80%	16 89.48%	17 89.07%	18 88.77%	19 88.45%	20 88.23%	21 88.13%	22 87.98%	23 87.82%	24 87.67%

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.



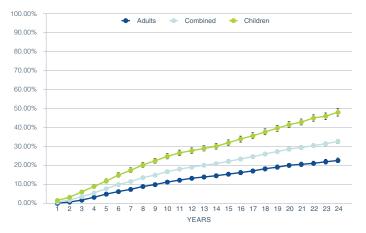






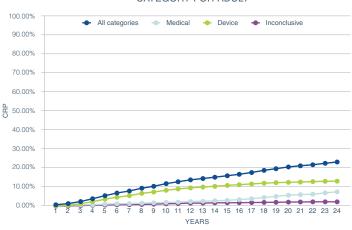
10.00%

REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS

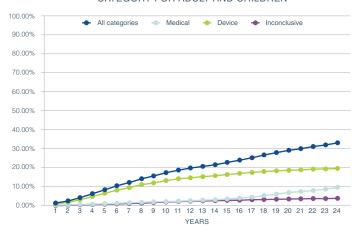


REMOVAL RATES ANALYSIS CATEGORY FOR ADULT

10 11 12 13 14 15 16 17 YEARS



### REMOVAL RATES ANALYSIS CATEGORY FOR ADULT AND CHILDREN



### COMBINED ADULTS AND CHILDREN

Year         Medical CRP         Device CRP         Inconclusive CRP         Total All Categories         Total CI Up CI Down           1         0.36%         0.97%         0.13%         1.45%         1.71%         1.20%           2         0.50%         1.80%         0.24%         2.54%         2.87%         2.20%           3         0.68%         3.26%         0.41%         4.35%         4.78%         3.92%           4         0.88%         4.98%         0.58%         6.45%         6.97%         5.93%           5         1.07%         6.67%         0.84%         8.58%         9.17%         7.99%           6         1.37%         8.34%         1.01%         10.72%         11.37%         10.07%           7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         18.20%           12         2.72%			00111	DINED ADOLIO	THE OTHER TEN		
1         0.36%         0.97%         0.13%         1.45%         1.71%         1.20%           2         0.50%         1.80%         0.24%         2.54%         2.87%         2.20%           3         0.68%         3.26%         0.41%         4.35%         4.78%         3.92%           4         0.88%         4.98%         0.58%         6.45%         6.97%         5.93%           5         1.07%         6.67%         0.84%         8.58%         9.17%         7.99%           6         1.37%         8.34%         1.01%         10.72%         11.37%         10.07%           7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%	Voor	Modical CDD	Davisa CDD	Inconclucivo CDD	Total All Catagorica		
2         0.50%         1.80%         0.24%         2.54%         2.87%         2.20%           3         0.68%         3.26%         0.41%         4.35%         4.78%         3.92%           4         0.88%         4.98%         0.58%         6.45%         6.97%         5.93%           5         1.07%         6.67%         0.84%         8.58%         9.17%         7.99%           6         1.37%         8.34%         1.01%         10.72%         11.37%         10.07%           7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%	Teal	Wedical Chr	Device Chr	Inconclusive Chr	Total All Categories	CI Up	CI Down
3         0.68%         3.26%         0.41%         4.35%         4.78%         3.92%           4         0.88%         4.98%         0.58%         6.45%         6.97%         5.93%           5         1.07%         6.67%         0.84%         8.58%         9.17%         7.99%           6         1.37%         8.34%         1.01%         10.72%         11.37%         10.07%           7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97% <td>1</td> <td>0.36%</td> <td>0.97%</td> <td>0.13%</td> <td>1.45%</td> <td>1.71%</td> <td>1.20%</td>	1	0.36%	0.97%	0.13%	1.45%	1.71%	1.20%
4         0.88%         4.98%         0.58%         6.45%         6.97%         5.93%           5         1.07%         6.67%         0.84%         8.58%         9.17%         7.99%           6         1.37%         8.34%         1.01%         10.72%         11.37%         10.07%           7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70	2	0.50%	1.80%	0.24%	2.54%	2.87%	2.20%
5         1.07%         6.67%         0.84%         8.58%         9.17%         7.99%           6         1.37%         8.34%         1.01%         10.72%         11.37%         10.07%           7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%	3	0.68%	3.26%	0.41%	4.35%	4.78%	3.92%
6       1.37%       8.34%       1.01%       10.72%       11.37%       10.07%         7       1.57%       9.65%       1.17%       12.38%       13.08%       11.69%         8       1.80%       11.24%       1.38%       14.42%       15.16%       13.68%         9       2.01%       12.22%       1.66%       15.89%       16.66%       15.12%         10       2.25%       13.46%       1.99%       17.70%       18.50%       16.90%         11       2.46%       14.36%       2.21%       19.03%       19.85%       18.20%         12       2.72%       14.93%       2.44%       20.09%       20.94%       19.25%         13       2.97%       15.49%       2.57%       21.03%       21.88%       20.17%         14       3.22%       15.97%       2.67%       21.86%       22.73%       20.99%         15       3.59%       16.70%       2.80%       23.09%       23.97%       22.20%         16       4.08%       17.28%       2.97%       24.33%       25.23%       23.43%         17       4.57%       17.83%       3.18%       25.58%       26.50%       24.67%         18 <td< td=""><td>4</td><td>0.88%</td><td>4.98%</td><td>0.58%</td><td>6.45%</td><td>6.97%</td><td>5.93%</td></td<>	4	0.88%	4.98%	0.58%	6.45%	6.97%	5.93%
7         1.57%         9.65%         1.17%         12.38%         13.08%         11.69%           8         1.80%         11.24%         1.38%         14.42%         15.16%         13.68%           9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%	5	1.07%	6.67%	0.84%	8.58%	9.17%	7.99%
8       1.80%       11.24%       1.38%       14.42%       15.16%       13.68%         9       2.01%       12.22%       1.66%       15.89%       16.66%       15.12%         10       2.25%       13.46%       1.99%       17.70%       18.50%       16.90%         11       2.46%       14.36%       2.21%       19.03%       19.85%       18.20%         12       2.72%       14.93%       2.44%       20.09%       20.94%       19.25%         13       2.97%       15.49%       2.57%       21.03%       21.88%       20.17%         14       3.22%       15.97%       2.67%       21.86%       22.73%       20.99%         15       3.59%       16.70%       2.80%       23.09%       23.97%       22.20%         16       4.08%       17.28%       2.97%       24.33%       25.23%       23.43%         17       4.57%       17.83%       3.18%       25.58%       26.50%       24.67%         18       5.45%       18.29%       3.31%       27.05%       27.98%       26.12%         20       7.10%       18.92%       3.56%       29.58%       30.54%       28.62%         21	6	1.37%	8.34%	1.01%	10.72%	11.37%	10.07%
9         2.01%         12.22%         1.66%         15.89%         16.66%         15.12%           10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%	7	1.57%	9.65%	1.17%	12.38%	13.08%	11.69%
10         2.25%         13.46%         1.99%         17.70%         18.50%         16.90%           11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%	8	1.80%	11.24%	1.38%	14.42%	15.16%	13.68%
11         2.46%         14.36%         2.21%         19.03%         19.85%         18.20%           12         2.72%         14.93%         2.44%         20.09%         20.94%         19.25%           13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%	9	2.01%	12.22%	1.66%	15.89%	16.66%	15.12%
12     2.72%     14.93%     2.44%     20.09%     20.94%     19.25%       13     2.97%     15.49%     2.57%     21.03%     21.88%     20.17%       14     3.22%     15.97%     2.67%     21.86%     22.73%     20.99%       15     3.59%     16.70%     2.80%     23.09%     23.97%     22.20%       16     4.08%     17.28%     2.97%     24.33%     25.23%     23.43%       17     4.57%     17.83%     3.18%     25.58%     26.50%     24.67%       18     5.45%     18.29%     3.31%     27.05%     27.98%     26.12%       19     6.22%     18.67%     3.42%     28.31%     29.25%     27.37%       20     7.10%     18.82%     3.56%     29.58%     30.54%     28.62%       21     7.60%     19.17%     3.69%     30.46%     31.43%     29.48%       22     8.21%     19.51%     3.82%     31.54%     32.54%     30.54%       23     8.85%     19.69%     3.87%     32.41%     33.45%     31.37%	10	2.25%	13.46%	1.99%	17.70%	18.50%	16.90%
13         2.97%         15.49%         2.57%         21.03%         21.88%         20.17%           14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%         19.51%         3.82%         31.54%         32.54%         30.54%           23         8.85%         19.69%         3.87%         32.41%         33.45%         31.37%	11	2.46%	14.36%	2.21%	19.03%	19.85%	18.20%
14         3.22%         15.97%         2.67%         21.86%         22.73%         20.99%           15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%         19.51%         3.82%         31.54%         32.54%         30.54%           23         8.85%         19.69%         3.87%         32.41%         33.45%         31.37%	12	2.72%	14.93%	2.44%	20.09%	20.94%	19.25%
15         3.59%         16.70%         2.80%         23.09%         23.97%         22.20%           16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%         19.51%         3.82%         31.54%         32.54%         30.54%           23         8.85%         19.69%         3.87%         32.41%         33.45%         31.37%	13	2.97%	15.49%	2.57%	21.03%	21.88%	20.17%
16         4.08%         17.28%         2.97%         24.33%         25.23%         23.43%           17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%         19.51%         3.82%         31.54%         32.54%         30.54%           23         8.85%         19.69%         3.87%         32.41%         33.45%         31.37%	14	3.22%	15.97%	2.67%	21.86%	22.73%	20.99%
17         4.57%         17.83%         3.18%         25.58%         26.50%         24.67%           18         5.45%         18.29%         3.31%         27.05%         27.98%         26.12%           19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%         19.51%         3.82%         31.54%         32.54%         30.54%           23         8.85%         19.69%         3.87%         32.41%         33.45%         31.37%	15	3.59%	16.70%	2.80%	23.09%	23.97%	22.20%
18     5.45%     18.29%     3.31%     27.05%     27.98%     26.12%       19     6.22%     18.67%     3.42%     28.31%     29.25%     27.37%       20     7.10%     18.92%     3.56%     29.58%     30.54%     28.62%       21     7.60%     19.17%     3.69%     30.46%     31.43%     29.48%       22     8.21%     19.51%     3.82%     31.54%     32.54%     30.54%       23     8.85%     19.69%     3.87%     32.41%     33.45%     31.37%	16	4.08%	17.28%	2.97%	24.33%	25.23%	23.43%
19         6.22%         18.67%         3.42%         28.31%         29.25%         27.37%           20         7.10%         18.92%         3.56%         29.58%         30.54%         28.62%           21         7.60%         19.17%         3.69%         30.46%         31.43%         29.48%           22         8.21%         19.51%         3.82%         31.54%         32.54%         30.54%           23         8.85%         19.69%         3.87%         32.41%         33.45%         31.37%	17	4.57%	17.83%	3.18%	25.58%	26.50%	24.67%
20     7.10%     18.92%     3.56%     29.58%     30.54%     28.62%       21     7.60%     19.17%     3.69%     30.46%     31.43%     29.48%       22     8.21%     19.51%     3.82%     31.54%     32.54%     30.54%       23     8.85%     19.69%     3.87%     32.41%     33.45%     31.37%	18	5.45%	18.29%	3.31%	27.05%	27.98%	26.12%
21     7.60%     19.17%     3.69%     30.46%     31.43%     29.48%       22     8.21%     19.51%     3.82%     31.54%     32.54%     30.54%       23     8.85%     19.69%     3.87%     32.41%     33.45%     31.37%	19	6.22%	18.67%	3.42%	28.31%	29.25%	27.37%
22     8.21%     19.51%     3.82%     31.54%     32.54%     30.54%       23     8.85%     19.69%     3.87%     32.41%     33.45%     31.37%	20	7.10%	18.92%	3.56%	29.58%	30.54%	28.62%
23 8.85% 19.69% 3.87% 32.41% 33.45% 31.37%	21	7.60%	19.17%	3.69%	30.46%	31.43%	29.48%
	22	8.21%	19.51%	3.82%	31.54%	32.54%	30.54%
24 9.77% 19.85% 3.97% 33.50% 34.73% 32.45%	23	8.85%	19.69%	3.87%	32.41%	33.45%	31.37%
24 3.77% 10.00% 0.07% 00.00% 04.70% 02.40%	24	9.77%	19.85%	3.97%	33.59%	34.73%	32.45%

Not all data may be shown alongside the graphs due to space limitations. Please see the Appendix at the end of the report for a complete data set.

# **CLARION 1.0**

The Clarion 1.0 (C1.0) implant was Advanced Bionics first device, the start of a technology-forward lineage that continues today. As the number of children implanted with the C1.0 is below the level required for statistical analysis, the data is included with the adult data.

# THIS SIDE OUT LEFT EAR ANDEL MAY-1-105

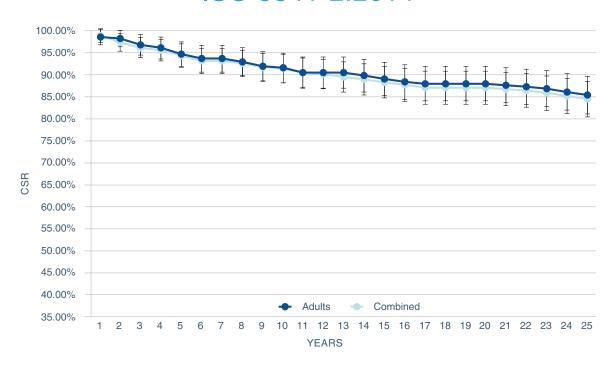
### Number of registered C1.0 implants

As of March 29, 2021. Last year of distribution<sup>‡</sup>: 2004

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	316	49	367†
ANSI/AAMI CI86	-	-	-

Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

# ISO 5841-2:2014



Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13
ADULTS	97.78%	97.47%	96.19%	95.56%	94.28%	93.32%	93.32%	92.68%	91.72%	91.39%	90.42%	90.42%	90.42%
COMBINED	98.09%	96.73%	95.63%	95.08%	93.99%	92.89%	92.89%	92.34%	91.50%	91.23%	90.39%	90.11%	89.55%
Years in use	14	15	16	17	18	19	9	20	21	22	23	24	25
ADULTS	89.77%	89.11%	88.45%	88.12%	6 88.12	% 88.1	2% 88	.12% 8	37.78%	87.44%	87.11%	86.42%	85.72%
COMBINED	88.98%	88.42%	87.85%	87.28%	6 87.28	% 87.2	8% 87	.28% 8	37.00%	86.71%	86.13%	85.54%	84.94%

<sup>&</sup>lt;sup>†</sup> The combined number also includes any registered users for whom we do not have date of birth information.

The ANSI/AAMI CI86 Standard does not require reporting for devices older than 20 years after the last implantation of that device type. Please refer to the ISO data for information.

# SOUND PROCESSOR STIMULATORS

For each currently-available sound processor, there will be a simple reliability number based on the average global yearly return rate and graphical data in compliance with ANSI/AAMI CI86 Standard that shows the monthly failure rate.

Where possible this monthly data is further categorized into failure mechanisms, if known, to include mechanical, electronic, moisture damage, and other. In specification processors, commonly referred to as no-fault-found, are also included. Where available, the number of registered users is shown, categorized into adult, children, and combined.

# NAÍDA CI M AND SKY CI M

The Naída™ CI M sound processor for adults and Sky CI™ M sound processor for children are the newest Advanced Bionics products integrated with the latest advancements from Phonak, the Marvel platform. With builtin connectivity solutions and the ability to automatically sense and adapt to every situation, the Naída CI M and Sky CI M processors are designed to give you the best hearing experience.

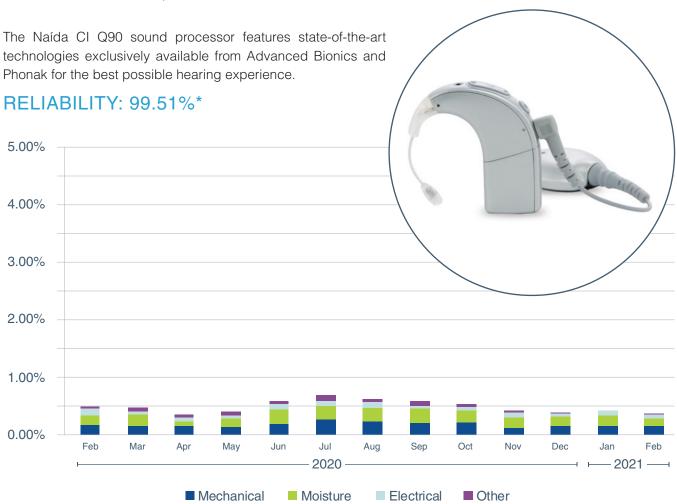
As field data becomes available we will present the reliability metrics on these processors in future reports.



NAÍDA CI M SKY CI M



# NAÍDA CI Q90



### FAILED COMPONENT RETURN RATE<sup>‡</sup>

Cause	Feb 2020	Mar 2020	Apr 20202	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021
Mechanical	0.16%	0.15%	0.14%	0.13%	0.19%	0.27%	0.23%	0.20%	0.22%	0.11%	0.15%	0.15%	0.15%
Moisture	0.18%	0.21%	0.09%	0.15%	0.26%	0.23%	0.23%	0.26%	0.20%	0.20%	0.17%	0.18%	0.13%
Electrical	0.12%	0.06%	0.08%	0.06%	0.09%	0.10%	0.10%	0.06%	0.07%	0.08%	0.04%	0.08%	0.07%
Other	0.04%	0.06%	0.05%	0.07%	0.05%	0.10%	0.07%	0.09%	0.04%	0.03%	0.02%	0.00%	0.01%

<sup>‡</sup>The number per month represents the unit that complete failure analisys in that month.

<sup>\*</sup> Reliability is 1 minus the return rate. The return rate is the average global monthly return rate over a 12-month period from February 2020 to February 2021.

### **NEPTUNE** The Neptune™ sound processor is the first and only swimmable sound processor. RELIABILITY: 99.74%\* 5.00% 4.00% 3.00% 2.00% 1.00% 0.00% Jul Feb Mar Apr May Jun Aug Sep Oct Nov Dec Jan Feb 2020 -**—** 2021 **—** ■ Mechanical Moisture Electrical Other

### FAILED COMPONENT RETURN RATE<sup>‡</sup>

Cause	Feb 2020	Mar 2020	Apr 20202	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021
Mechanical	0.12%	0.00%	0.00%	0.04%	0.00%	0.04%	0.00%	0.00%	0.00%	0.02%	0.05%	0.00%	0.04%
Moisture	0.00%	0.00%	0.06%	0.02%	0.00%	0.04%	0.05%	0.00%	0.05%	0.00%	0.00%	0.00%	0.00%
Electrical	0.12%	0.25%	0.12%	0.14%	0.35%	0.34%	0.35%	0.34%	0.15%	0.10%	0.14%	0.12%	0.12%
Other	0.00%	0.00%	0.03%	0.00%	0.00%	0.04%	0.05%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

<sup>‡</sup>The number per month represents the unit that complete failure analisys in that month.

### **CHORUS** The Chorus™ sound processor is compatible with C1.0 and C1.2 cochlear implants, and offers integrated Roger™ technology for connectivity and performance. **RELIABILITY: 99.65%\*** 5.00% 4.00% 3.00% 2.00% 1.00% 0.00% Feb Mar Apr May Jun Jul Aug Sep Nov Dec Jan Feb 2020 - 2021 **-**---

### FAILED COMPONENT RETURN RATE<sup>‡</sup>

Moisture

Electrical

Other

■ Mechanical

Cause	Feb 2020	Mar 2020	Apr 20202	May 2020	Jun 2020	Jul 2020	Aug 2020	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021
Mechanical	0.00%	0.16%	0.00%	0.00%	0.00%	0.00%	0.22%	0.41%	0.64%	0.00%	0.38%	0.00%	0.00%
Moisture	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Electrical	0.35%	0.00%	0.16%	0.15%	0.44%	0.13%	0.43%	0.62%	0.00%	0.00%	0.00%	0.00%	0.13%
Other	0.00%	0.17%	0.00%	0.00%	0.00%	0.13%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

‡The number per month represents the unit that complete failure analisys in that month.

# **HARMONY**

The Harmony<sup>™</sup> sound processor is compatible with C1.0 and C1.2 cochlear implants, providing performance-driven technology. Harmony processor is no longer commercially marketed in the United States. It is only provided as an upgrade processor for C1 users, and therefore is out of the scope for the Cl86 reporting.

RELIABILITY: 99.83%\*

<sup>\*</sup> Reliability is 1 minus the return rate. The return rate is the average global monthly return rate over a 12-month period from February 2020 to February 2021.

# STANDARD ANSI/AAMI CI86

# HIRES ULTRA 3D v2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
ADULTS	1	0.54%	0.00%	0.00%	0.54%
CHILDREN	1	0.36%	0.00%	0.00%	0.36%

# HIRES ULTRA v2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
ADULTS	1	0.00%	0.00%	0.00%	0.00%
CHILDREN	1	0.00%	0.00%	0.00%	0.00%

# HIRES ULTRA 3D V1

	Voor	Madical CDD	Device CRP	Inconclusive CDD	Total All Catagorias	To	otal
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
ADULTS	1	0.88%	0.12%	0.02%	1.02%	1.29%	0.74%
ADULIS	2	1.26%	0.95%	0.05%	2.26%	2.73%	1.79%
CHILDREN	1	1.05%	0.45%	0.00%	1.50%	2.15%	0.85%
CHILDREN	2	1.54%	4.35%	0.00%	5.89%	7.41%	4.37%

# HIRES ULTRA V1

						_	
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To	otal
	icai	Medical Offi	Device Of it	IIICOIICIUSIVE OI II	Total All Categories	CI Up	CI Down
	1	0.75%	0.02%	0.02%	0.80%	0.99%	0.61%
ADULTS	2	1.21%	0.34%	0.04%	1.58%	1.86%	1.31%
ADULIS	3	1.53%	2.17%	0.07%	3.78%	4.24%	3.31%
	4	1.65%	5.64%	0.11%	7.40%	8.23%	6.57%
	1	0.53%	0.11%	0.00%	0.64%	0.90%	0.39%
CHILDREN	2	0.72%	0.67%	0.03%	1.43%	1.83%	1.03%
CHILDREN	3	0.87%	4.05%	0.08%	5.01%	5.90%	4.12%
	4	1.24%	13.72%	0.08%	15.04%	17.14%	12.94%

# HIRES 90K ADVANTAGE

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Catagories	To	otal
	rear	Medical CRP	Device CRP	inconclusive CRP	Total All Categories	CI Up	CI Down
	1	0.68%	0.07%	0.02%	0.76%	0.89%	0.64%
	2	1.19%	0.09%	0.03%	1.30%	1.47%	1.14%
	3	1.46%	0.14%	0.04%	1.64%	1.82%	1.45%
ADULTS	4	1.74%	0.17%	0.04%	1.96%	2.16%	1.76%
ADULI 5	5	1.94%	0.21%	0.04%	2.20%	2.42%	1.98%
	6	2.10%	0.23%	0.06%	2.39%	2.62%	2.16%
	7	2.21%	0.23%	0.07%	2.51%	2.76%	2.26%
	8	2.33%	0.28%	0.07%	2.68%	2.99%	2.38%
	1	0.76%	0.21%	0.03%	1.01%	1.15%	0.86%
	2	1.09%	0.40%	0.05%	1.53%	1.72%	1.35%
	3	1.38%	0.62%	0.06%	2.06%	2.28%	1.84%
CHILDREN	4	1.57%	0.81%	0.11%	2.49%	2.74%	2.24%
CHILDREN	5	1.68%	0.95%	0.19%	2.82%	3.09%	2.54%
	6	1.88%	1.11%	0.19%	3.18%	3.49%	2.87%
	7	1.94%	1.34%	0.22%	3.50%	3.86%	3.14%
	8	1.94%	1.49%	0.22%	3.65%	4.06%	3.23%

# HIRES 90K vendor A post-mod

	V "	Madiaal CDD	Davies CDD	Incomply size CDD	Tatal All Catagorica	To	otal
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
	1	0.80%	0.06%	0.02%	0.88%	0.97%	0.78%
	2	1.32%	0.11%	0.04%	1.48%	1.59%	1.36%
	3	1.64%	0.16%	0.06%	1.86%	2.00%	1.73%
	4	1.92%	0.23%	0.08%	2.24%	2.39%	2.09%
	5	2.15%	0.28%	0.09%	2.52%	2.68%	2.36%
	6	2.30%	0.35%	0.12%	2.77%	2.94%	2.60%
	7	2.45%	0.37%	0.13%	2.95%	3.12%	2.77%
ADULTS	8	2.59%	0.45%	0.14%	3.18%	3.36%	2.99%
	9	2.68%	0.48%	0.14%	3.31%	3.50%	3.11%
	10	2.79%	0.56%	0.16%	3.51%	3.72%	3.30%
	11	2.84%	0.62%	0.16%	3.61%	3.82%	3.40%
	12	2.96%	0.63%	0.16%	3.74%	3.97%	3.52%
	13	3.09%	0.64%	0.18%	3.91%	4.15%	3.67%
	14	3.19%	0.66%	0.18%	4.03%	4.30%	3.77%
	15	3.29%	0.66%	0.18%	4.13%	4.42%	3.84%
	1	0.81%	0.21%	0.03%	1.05%	1.16%	0.95%
	2	1.13%	0.48%	0.04%	1.65%	1.78%	1.53%
	3	1.39%	0.76%	0.06%	2.21%	2.36%	2.06%
	4	1.59%	1.03%	0.09%	2.71%	2.88%	2.54%
	5	1.75%	1.26%	0.13%	3.14%	3.33%	2.96%
	6	1.90%	1.45%	0.15%	3.49%	3.69%	3.30%
	7	2.02%	1.57%	0.16%	3.74%	3.95%	3.54%
CHILDREN	8	2.08%	1.71%	0.18%	3.97%	4.19%	3.75%
	9	2.19%	1.80%	0.19%	4.18%	4.41%	3.95%
	10	2.43%	1.97%	0.24%	4.63%	4.90%	4.37%
	11	2.56%	2.00%	0.26%	4.83%	5.11%	4.55%
	12	2.73%	2.11%	0.29%	5.13%	5.44%	4.82%
	13	2.86%	2.13%	0.31%	5.30%	5.63%	4.98%
	14	3.00%	2.17%	0.31%	5.48%	5.85%	5.12%
	15	3.09%	2.25%	0.40%	5.74%	6.19%	5.28%

# HIRES 90K vendor A all

	V "	Madiaal CDD	Daviss CDD	Incomply size CDD	Total All Catagogias	To	otal
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
	1	0.79%	0.08%	0.01%	0.89%	0.98%	0.80%
	2	1.31%	0.14%	0.05%	1.50%	1.62%	1.38%
	3	1.63%	0.20%	0.08%	1.91%	2.04%	1.77%
	4	1.91%	0.31%	0.10%	2.32%	2.46%	2.17%
	5	2.13%	0.37%	0.11%	2.61%	2.77%	2.45%
	6	2.29%	0.46%	0.14%	2.88%	3.05%	2.72%
	7	2.44%	0.49%	0.16%	3.09%	3.26%	2.91%
	8	2.58%	0.61%	0.16%	3.35%	3.54%	3.16%
ADULTS	9	2.66%	0.70%	0.17%	3.53%	3.73%	3.34%
	10	2.78%	0.81%	0.19%	3.77%	3.98%	3.56%
	11	2.83%	0.90%	0.19%	3.92%	4.14%	3.70%
	12	2.97%	0.97%	0.19%	4.12%	4.36%	3.89%
	13	3.09%	1.02%	0.22%	4.33%	4.58%	4.08%
	14	3.24%	1.15%	0.22%	4.61%	4.89%	4.33%
	15	3.33%	1.23%	0.22%	4.78%	5.09%	4.47%
	16	3.38%	1.39%	0.22%	4.98%	5.34%	4.62%
	17	3.38%	1.47%	0.22%	5.07%	5.47%	4.67%
	1	0.79%	0.22%	0.03%	1.05%	1.15%	0.94%
	2	1.31%	0.50%	0.04%	1.86%	1.99%	1.73%
	3	1.63%	0.79%	0.07%	2.49%	2.64%	2.34%
	4	1.91%	1.08%	0.09%	3.08%	3.25%	2.92%
	5	2.13%	1.33%	0.14%	3.60%	3.78%	3.41%
	6	2.29%	1.54%	0.15%	3.98%	4.17%	3.78%
	7	2.44%	1.69%	0.18%	4.30%	4.51%	4.09%
	8	2.58%	1.87%	0.20%	4.65%	4.87%	4.43%
CHILDREN	9	2.66%	1.98%	0.21%	4.85%	5.09%	4.62%
	10	2.78%	2.17%	0.26%	5.21%	5.47%	4.94%
	11	2.83%	2.25%	0.29%	5.37%	5.66%	5.09%
	12	2.97%	2.45%	0.32%	5.74%	6.06%	5.43%
	13	3.09%	2.53%	0.34%	5.96%	6.29%	5.62%
	14	3.24%	2.75%	0.34%	6.34%	6.72%	5.95%
	15	3.33%	3.01%	0.39%	6.72%	7.20%	6.25%
	16	3.38%	3.29%	0.39%	7.06%	7.63%	6.49%
	17	3.38%	3.47%	0.39%	7.24%	7.90%	6.58%

# HIRES 90K vendor A pre-mod

	Voor	Medical CRP	Device CRP	Inconclusive CDD	Total All Catagorica	To	otal
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
	1	0.72%	0.42%	0.00%	1.15%	1.66%	0.64%
	2	1.03%	0.85%	0.24%	2.12%	2.81%	1.43%
	3	1.33%	1.09%	0.49%	2.92%	3.72%	2.11%
	4	1.58%	1.89%	0.55%	4.03%	4.97%	3.09%
	5	1.70%	2.33%	0.62%	4.64%	5.65%	3.64%
	6	1.89%	2.76%	0.68%	5.33%	6.40%	4.26%
	7	2.14%	3.01%	0.74%	5.89%	7.01%	4.77%
	8	2.20%	3.57%	0.74%	6.51%	7.69%	5.34%
ADULTS	9	2.27%	4.25%	0.74%	7.26%	8.50%	6.03%
	10	2.40%	4.63%	0.81%	7.83%	9.11%	6.55%
	11	2.52%	5.01%	0.81%	8.34%	9.65%	7.02%
	12	2.78%	5.45%	0.81%	9.04%	10.40%	7.67%
	13	2.85%	5.70%	0.87%	9.42%	10.81%	8.03%
	14	3.17%	6.14%	0.87%	10.19%	11.63%	8.75%
	15	3.24%	6.33%	0.87%	10.44%	11.90%	8.99%
	16	3.31%	6.46%	0.87%	10.64%	12.11%	9.17%
	17	3.31%	6.55%	0.87%	10.73%	12.20%	9.25%

	Voor	Medical CRP	Device CRP	Inconclusive CRP	Total All Catagorias	To	otal
	Year	Medical CRP	Device CRP	inconclusive CRP	Total All Categories	CI Up	CI Down
	1	1.24%	0.79%	0.00%	2.03%	2.95%	1.10%
	2	1.46%	1.36%	0.12%	2.94%	4.04%	1.83%
	3	2.04%	2.16%	0.23%	4.43%	5.78%	3.09%
	4	2.39%	3.09%	0.23%	5.71%	7.22%	4.19%
	5	2.50%	3.90%	0.35%	6.75%	8.39%	5.12%
	6	2.62%	4.71%	0.47%	7.81%	9.55%	6.06%
	7	3.10%	5.53%	0.72%	9.35%	11.24%	7.46%
	8	3.71%	6.59%	0.72%	11.01%	13.04%	8.98%
CHILDREN	9	3.71%	6.94%	0.72%	11.36%	13.42%	9.30%
	10	3.83%	7.42%	0.84%	12.09%	14.20%	9.97%
	11	4.20%	7.89%	0.97%	13.06%	15.24%	10.88%
	12	4.20%	8.84%	0.97%	14.01%	16.26%	11.76%
	13	4.20%	9.20%	0.97%	14.37%	16.64%	12.10%
	14	4.20%	10.04%	0.97%	15.21%	17.53%	12.88%
	15	4.45%	10.52%	0.97%	15.94%	18.31%	13.57%
	16	4.45%	10.76%	0.97%	16.19%	18.57%	13.80%
	17	4.45%	10.94%	0.97%	16.36%	18.77%	13.96%

# HIRES 90K vendor B

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
	rear	Medical CRP	Device CRP	inconclusive CRP	Total All Categories	CI Up	CI Down
	1	1.03%	3.03%	0.00%	4.06%	4.82%	3.30%
	2	1.33%	10.84%	0.09%	12.25%	13.52%	10.99%
	3	1.65%	16.16%	0.18%	17.98%	19.46%	16.50%
	4	1.84%	20.68%	0.23%	22.74%	24.36%	21.12%
	5	1.94%	24.29%	0.28%	26.51%	28.21%	24.80%
	6	2.05%	26.73%	0.28%	29.06%	30.82%	27.31%
	7	2.16%	29.76%	0.28%	32.20%	34.01%	30.39%
ADULTS	8	2.45%	31.65%	0.28%	34.38%	36.22%	32.54%
ADULI S	9	2.45%	33.21%	0.28%	35.94%	37.80%	34.08%
	10	2.63%	34.70%	0.28%	37.61%	39.49%	35.74%
	11	2.63%	35.66%	0.28%	38.57%	40.46%	36.68%
	12	2.70%	36.99%	0.28%	39.97%	41.87%	38.06%
	13	2.76%	38.04%	0.28%	41.08%	42.99%	39.16%
	14	2.90%	38.83%	0.28%	42.01%	43.93%	40.09%
	15	2.96%	39.46%	0.28%	42.71%	44.63%	40.78%
	16	2.96%	39.94%	0.28%	43.18%	45.12%	41.24%
	1	0.88%	3.34%	0.00%	4.22%	5.24%	3.21%
	2	1.31%	11.58%	0.07%	12.96%	14.65%	11.27%
	3	1.47%	19.87%	0.07%	21.42%	23.48%	19.35%
	4	1.56%	26.10%	0.07%	27.74%	30.00%	25.48%
	5	1.84%	30.72%	0.17%	32.73%	35.10%	30.36%
	6	2.04%	34.59%	0.17%	36.81%	39.25%	34.37%
	7	2.04%	37.85%	0.17%	40.07%	42.55%	37.58%
CHILDREN	8	2.27%	40.56%	0.17%	43.00%	45.51%	40.49%
CHILDREN	9	2.39%	42.86%	0.17%	45.42%	47.95%	42.89%
	10	2.39%	44.75%	0.17%	47.30%	49.84%	44.77%
	11	2.63%	45.87%	0.17%	48.67%	51.22%	46.13%
	12	3.02%	46.71%	0.43%	50.16%	52.71%	47.62%
	13	3.02%	48.27%	0.43%	51.72%	54.26%	49.17%
	14	3.15%	48.77%	0.57%	52.49%	55.03%	49.94%
	15	3.15%	49.69%	0.57%	53.41%	55.96%	50.86%
	16	3.15%	50.00%	0.77%	53.92%	56.47%	51.36%

# CII BIONIC EAR

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
	Toai	Wicalcal Of II	Device Of II	Inconcidative of the	Total All Categories	CI Up	CI Down
	1	0.47%	0.39%	0.03%	0.89%	1.21%	0.57%
	2	0.83%	0.42%	0.18%	1.43%	1.83%	1.03%
	3	1.07%	0.60%	0.30%	1.96%	2.43%	1.50%
	4	1.37%	0.66%	0.39%	2.41%	2.93%	1.90%
	5	1.55%	0.75%	0.42%	2.72%	3.26%	2.17%
	6	1.67%	0.90%	0.48%	3.05%	3.63%	2.47%
	7	1.79%	0.96%	0.66%	3.41%	4.02%	2.80%
	8	1.91%	1.05%	0.76%	3.72%	4.35%	3.08%
	9	2.12%	1.14%	0.82%	4.08%	4.75%	3.42%
ADULTS	10	2.27%	1.20%	0.82%	4.30%	4.98%	3.62%
	11	2.37%	1.30%	0.85%	4.51%	5.21%	3.81%
	12	2.58%	1.30%	0.88%	4.75%	5.47%	4.04%
	13	2.64%	1.36%	0.88%	4.88%	5.60%	4.15%
	14	2.70%	1.45%	0.88%	5.03%	5.76%	4.30%
	15	2.82%	1.51%	0.88%	5.21%	5.96%	4.47%
	16	2.88%	1.57%	0.88%	5.34%	6.09%	4.58%
	17	2.95%	1.64%	0.88%	5.46%	6.22%	4.70%
	18	3.05%	1.67%	0.91%	5.63%	6.40%	4.86%
	19	3.14%	1.76%	0.91%	5.82%	6.61%	5.03%
	1	0.47%	0.87%	0.12%	1.45%	2.02%	0.89%
	2	1.00%	1.57%	0.29%	2.86%	3.65%	2.08%
	3	1.59%	2.46%	0.35%	4.40%	5.37%	3.44%
	4	1.77%	2.94%	0.48%	5.18%	6.22%	4.14%
	5	2.13%	3.47%	0.78%	6.39%	7.53%	5.24%
	6	2.44%	4.25%	1.09%	7.79%	9.04%	6.53%
	7	2.56%	4.80%	1.22%	8.58%	9.89%	7.27%
	8	2.69%	5.22%	1.53%	9.44%	10.81%	8.08%
	9	2.87%	5.65%	1.66%	10.18%	11.60%	8.77%
CHILDREN	10	3.06%	6.08%	1.66%	10.80%	12.25%	9.36%
	11	3.19%	6.20%	1.85%	11.24%	12.72%	9.77%
	12	3.51%	6.39%	1.92%	11.81%	13.31%	10.31%
	13	3.83%	6.51%	1.98%	12.32%	13.85%	10.79%
	14	4.02%	6.76%	2.05%	12.82%	14.38%	11.27%
	15	4.08%	6.82%	2.05%	12.95%	14.51%	11.39%
	16	4.21%	6.88%	2.11%	13.21%	14.78%	11.63%
	17	4.55%	6.88%	2.25%	13.68%	15.28%	12.08%
	18	4.62%	7.03%	2.33%	13.99%	15.60%	12.37%
	19	5.06%	7.14%	2.33%	14.54%	16.20%	12.87%

# **CLARION 1.2**

	V	Maria	D		Tabal All On the state of		otal
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
	1	0.40%	0.30%	0.14%	0.85%	1.10%	0.59%
	2	0.55%	0.65%	0.26%	1.46%	1.79%	1.13%
	3	0.75%	1.39%	0.41%	2.54%	2.98%	2.11%
	4	0.94%	2.51%	0.60%	4.05%	4.60%	3.50%
	5	1.15%	3.79%	0.74%	5.69%	6.33%	5.04%
	6	1.41%	4.83%	0.83%	7.06%	7.77%	6.35%
	7	1.51%	5.72%	0.92%	8.15%	8.91%	7.40%
	8	1.71%	6.91%	1.05%	9.67%	10.49%	8.85%
	9	1.84%	7.62%	1.21%	10.67%	11.52%	9.82%
	10	2.09%	8.57%	1.41%	12.07%	12.97%	11.17%
	11	2.27%	9.31%	1.50%	13.08%	14.01%	12.15%
ADULTS	12	2.55%	9.82%	1.71%	14.08%	15.03%	13.12%
ADOLIS	13	2.76%	10.31%	1.75%	14.82%	15.80%	13.84%
	14	2.94%	10.70%	1.85%	15.49%	16.48%	14.49%
	15	3.22%	11.13%	1.92%	16.27%	17.29%	15.26%
	16	3.58%	11.52%	1.99%	17.08%	18.12%	16.05%
	17	4.03%	11.93%	2.06%	18.02%	19.08%	16.97%
	18	4.78%	12.29%	2.09%	19.15%	20.23%	18.07%
	19	5.27%	12.58%	2.17%	20.02%	21.12%	18.92%
	20	5.90%	12.78%	2.27%	20.94%	22.06%	19.83%
	21	6.27%	12.95%	2.34%	21.56%	22.69%	20.42%
	22	6.50%	13.16%	2.43%	22.10%	23.26%	20.94%
	23	7.18%	13.30%	2.43%	22.92%	24.14%	21.70%
	24	7.74%	13.44%	2.43%	23.61%	24.93%	22.29%
	1	0.29%	1.90%	0.11%	2.30%	2.80%	1.81%
	2	0.43%	3.42%	0.20%	4.05%	4.70%	3.40%
	3	0.58%	5.89%	0.41%	6.88%	7.71%	6.05%
	4	0.80%	8.45%	0.57%	9.82%	10.80%	8.84%
	5	0.96%	10.72%	0.98%	12.65%	13.75%	11.56%
	6	1.32%	13.29%	1.28%	15.89%	17.08%	14.69%
	7	1.66%	15.18%	1.55%	18.38%	19.65%	17.11%
	8	1.94%	17.35%	1.90%	21.18%	22.52%	19.85%
	9	2.29%	18.70%	2.36%	23.36%	24.74%	21.97%
	10	2.52%	20.37%	2.91%	25.79%	27.22%	24.37%
	11	2.78%	21.50%	3.33%	27.60%	29.06%	26.14%
CHILDREN	12	3.01%	22.18%	3.59%	28.78%	30.25%	27.30%
CHILDREN	13	3.32%	22.83%	3.86%	30.01%	31.50%	28.51%
	14	3.67%	23.45%	3.98%	31.10%	32.61%	29.59%
	15	4.19%	24.62%	4.22%	33.02%	34.56%	31.49%
	16	4.92%	25.48%	4.54%	34.94%	36.49%	33.39%
	17	5.50%	26.22%	5.00%	36.72%	38.29%	35.15%
	18	6.60%	26.85%	5.30%	38.76%	40.34%	37.17%
	19	7.87%	27.35%	5.48%	40.70%	42.31%	39.09%
	20	9.25%	27.70%	5.69%	42.63%	44.26%	41.01%
	21	9.97%	28.08%	5.94%	43.99%	45.64%	42.34%
	22	11.30%	28.66%	6.13%	46.08%	47.79%	44.38%
	23	11.88%	28.89%	6.28%	47.05%	48.81%	45.29%
	24	13.48%	29.11%	6.56%	49.16%	51.13%	47.18%

# **CONTACT US** This report is intended to provide both professionals and our CI wearers with relevant information on the reliability of our products. If you have any questions, please contact us by emailing <a href="mailto:hear@AdvancedBionics.com">hear@AdvancedBionics.com</a> or visit <u>AdvancedBionics.com</u> for more general information.



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