



ADVANCED  
BIONICS

POWERFUL CONNECTIONS

# Reliability Report 2020

IMPLANTABLE COCHLEAR STIMULATORS  
AND SOUND PROCESSORS



# POWERFUL CONNECTIONS START HERE

<b>Our Mission</b> .....	4
<b>Reporting on Reliability</b> .....	5
<b>Implantable Cochlear Stimulators</b> .....	6
HiRes Ultra 3D (V2) cochlear implant .....	8
HiRes Ultra (V2) cochlear implant .....	10
HiRes Ultra 3D (V1) cochlear implant .....	12
HiRes Ultra (V1) cochlear implant .....	14
HiRes 90K Advantage cochlear implant .....	16
HiRes 90K cochlear implant .....	18
CII Bionic Ear cochlear implant .....	26
Clarion 1.2 cochlear implant .....	28
Clarion 1.0 cochlear implant .....	30
<b>Sound Processor Stimulators</b> .....	32
Naída CI Q90 sound processor .....	32
Neptune sound processor .....	33
Chorus sound processor .....	34
Harmony sound processor .....	35
<b>Annex</b> .....	36

# OUR MISSION

At Advanced Bionics, our goal is to offer the best hearing performance.

With this focus, we are dedicated to transparent and clear communication to our recipients and customers. We hope that the publication of our 2020 Reliability Report will support the understanding of our device performance.

On February 18, 2020 Advanced Bionics announced the voluntary withdrawal of the V1 (Version 1) of the HiRes Ultra and HiRes Ultra 3D cochlear implants due to a decrease in performance experienced by a segment of recipients. Our 2020 reliability figures will demonstrate the effect of this issue. In addition, performance for devices not affected by this issue are also clearly represented.

In response to the issue with V1, we launched V2 (Version 2) of the HiRes Ultra and HiRes Ultra 3D products. Real-world performance to date, coupled with aggressive benchtop testing demonstrate that we have effectively identified the root cause of the V1 issue and implemented the appropriate design changes in V2. As we do with all implant types, we will continue to release updated V2 reliability data as the duration of real-world experience increases.

Advanced Bionics is committed to continuous reliability improvement. We are adopting more stringent test standards than what are demanded by regulatory authorities and are making investments to increase patient experience globally.

We hold ourselves accountable for the design and manufacture of quality products that will benefit our recipients. We strive to offer our recipients the benefit of best-in-class hearing performance together with the peace of mind that comes from high product reliability.

# REPORTING ON RELIABILITY

Advanced Bionics has always been committed to providing clear and accurate information on the quality and reliability of our products.

For reporting purposes we have adhered to the global standard as defined by **ISO 5841-2:2014**<sup>1</sup> and the principles outlined in the European Consensus on Cochlear Implant Failures and Explanations.<sup>2</sup> We are also now reporting to **ANSI/AAMI CI86 Standard** – Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting.<sup>3</sup>

The ANSI/AAMI CI86 Standard classifies a child as younger than 10 years old and an “adult” as 10 years or older, rather than 17 years of age as the differentiator between the groups in traditional reporting. It also requires the result of the failure analysis to be broken out into medical related, device related, and inconclusive categories. The data for all current sound processors are also included in the report.

Throughout the report, you will see the traditional reporting presented alongside that as defined in ANSI/AAMI CI86 Standard so you can easily compare methodologies. The data will be presented for the Implantable Cochlear Stimulator (commonly referred to as the implant or device) and the Sound Processors.

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

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

3. 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 the traditional reporting methodology and with the ANSI/AAMI CI86 Standard.

### Number of registered HiRes 90K Advantage implants

As of August 27, 2020.

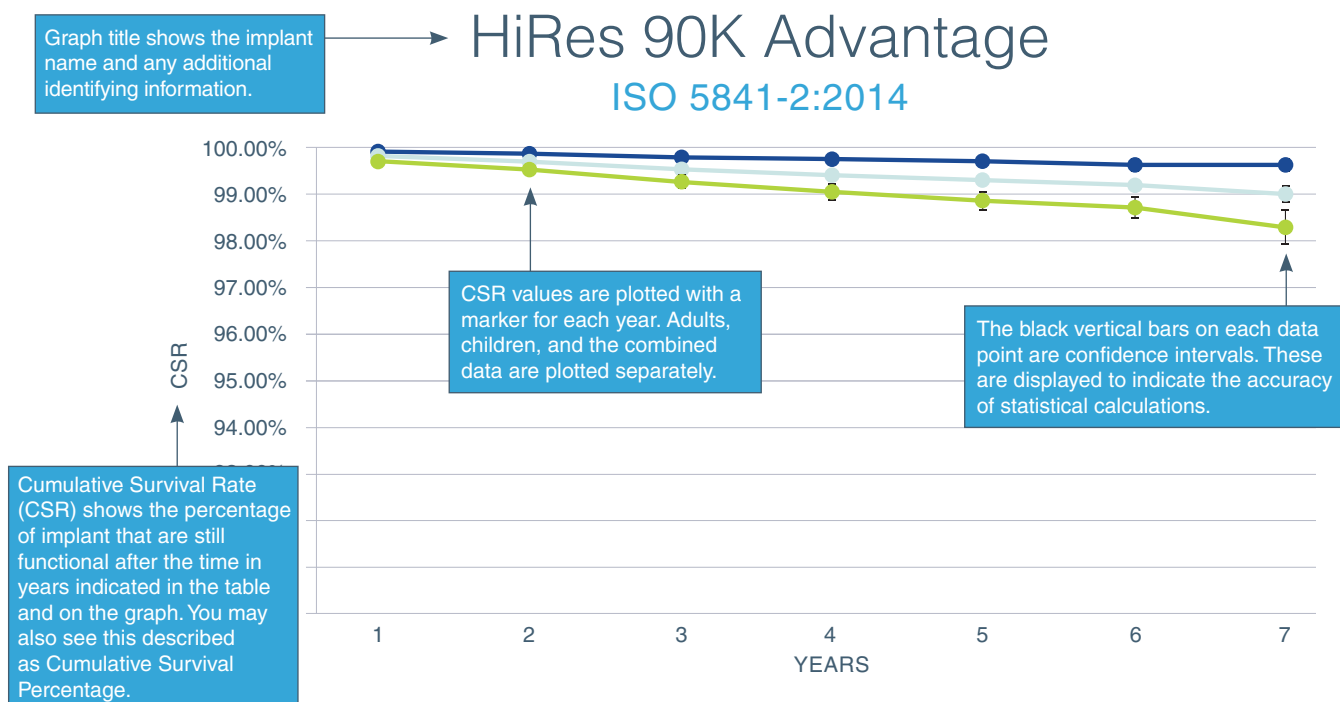
Date of first commercial introduction<sup>‡</sup>: 2012

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	15041	18934	35704 <sup>†</sup>
ANSI/AAMI CI86	18709*	16995	35704

<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.

\* 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.



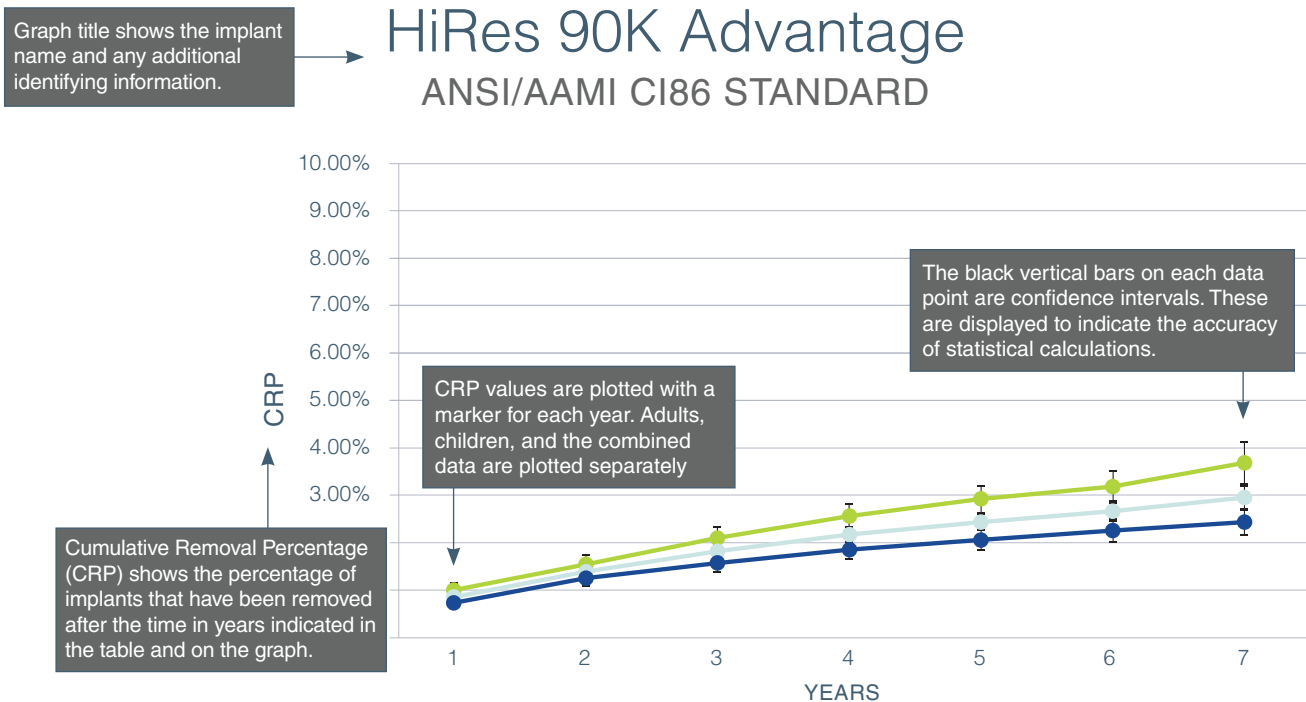
HIRES 90K ADVANTAGE CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7
ADULTS	99.93%	99.89%	99.83%	99.80%	99.76%	99.70%	99.70%
COMBINED	99.85%	99.76%	99.62%	99.52%	99.44%	99.35%	99.20%
CHILDREN	99.78%	99.62%	99.41%	99.23%	99.08%	98.96%	98.63%

Detailed CSR percentages are shown for each year in the table. Results are broken up into adults, children, and shown as a combined total.

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. These categories are reflected in the data and shown individually in the graphs, and are defined as:

- **Device Failure Explants:** applies to returned units explanted because of confirmed malfunctions, as determined either by analysis of the returned product or by in vivo testing.
- **Medical Reason for Explants:** applies to returned units explanted for medical reasons related to the implantation or functioning of the device.
- **Inconclusive Failure Analysis:** applies to those explanted units that have failed in vivo testing but are determined to be within the manufacturer’s specification, as determined by analysis of the returned product.



COMBINED ADULT AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.70%	0.14%	0.02%	0.86%	0.96%	0.77%
2	1.11%	0.24%	0.04%	1.39%	1.51%	1.26%
3	1.38%	0.37%	0.05%	1.81%	1.95%	1.67%
4	1.62%	0.47%	0.08%	2.17%	2.33%	2.01%
5	1.76%	0.56%	0.11%	2.43%	2.61%	2.26%
6	1.91%	0.63%	0.12%	2.66%	2.85%	2.46%
7	2.01%	0.78%	0.16%	2.95%	3.19%	2.71%

Detailed CRP values are shown for each year in the table. Results are broken up into adults, children, and shown as a combined total.

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.

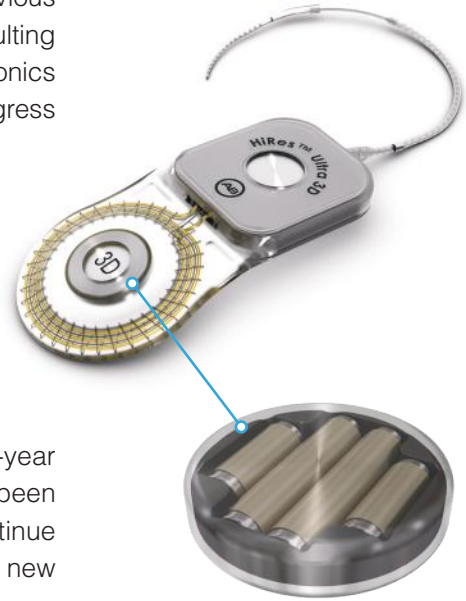
# CURRENT-GENERATION IMPLANT DATA

## HIRES ULTRA 3D V2

The HiRes™ 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.

While the HiRes Ultra 3D (V2) device does not yet have complete 1-year reliability data, the completed 6-month data shows that there have been no device related implant failures to date. 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 (V2) implants

As of August 27, 2020.

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

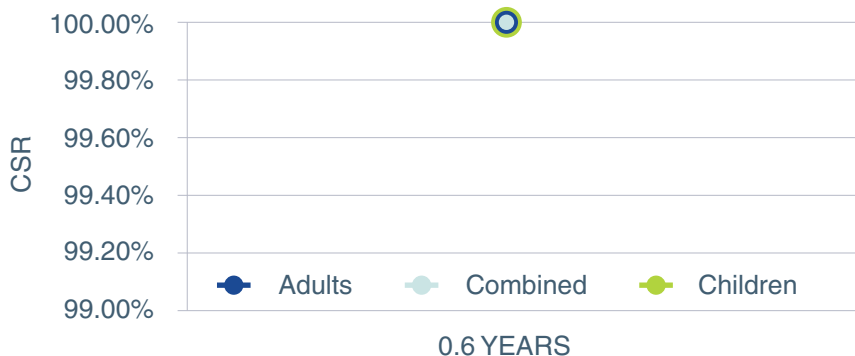
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	1019	392	1525 <sup>†</sup>
ANSI/AAMI CI86	1182*	343	1525

<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.

\* 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.

## ISO 5841-2:2014

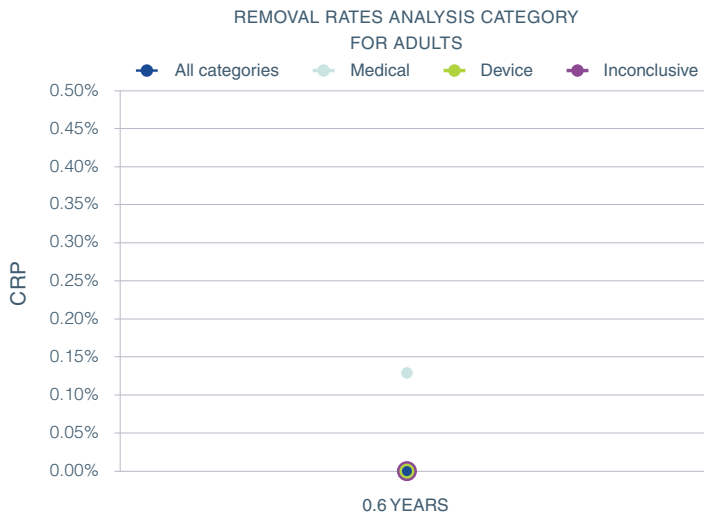
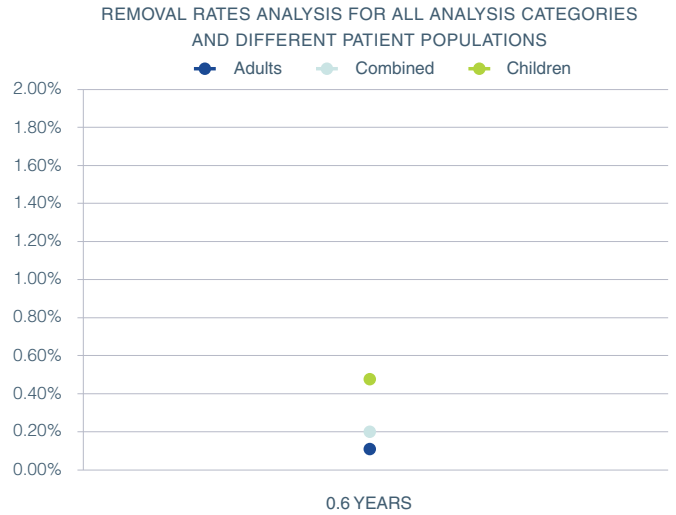
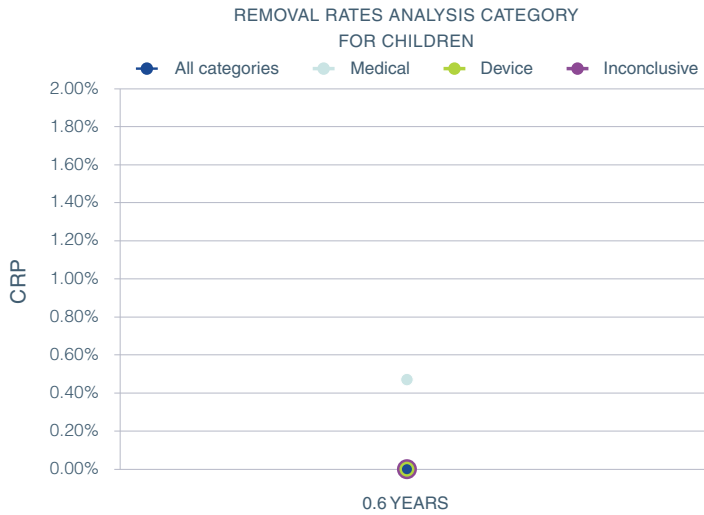


### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	0.6
ADULTS	100.00%
COMBINED	100.00%
CHILDREN	100.00%



# ANSI/AAMI CI86

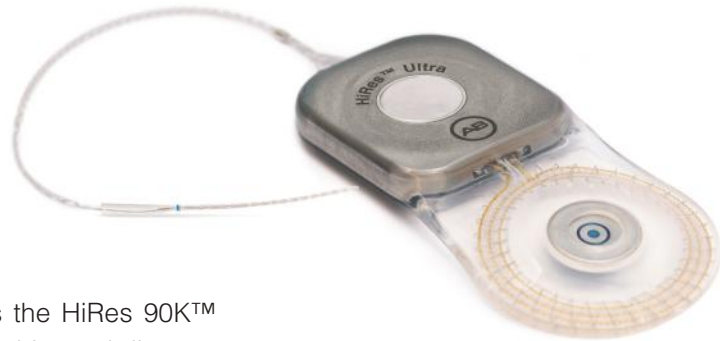


## COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
0.6	0.20%	0.00%	0.00%	0.20%

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™ Advantage, the HiRes Ultra (V2) offers a robust, thin, and discreet mechanical design that is suitable for adults and children.

As noted earlier, the HiRes Ultra (V2) device does not yet have complete 1-year reliability data. The completed 6-month data shows no device related implant failures to date. 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 (V2) implants

As of August 27, 2020.

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

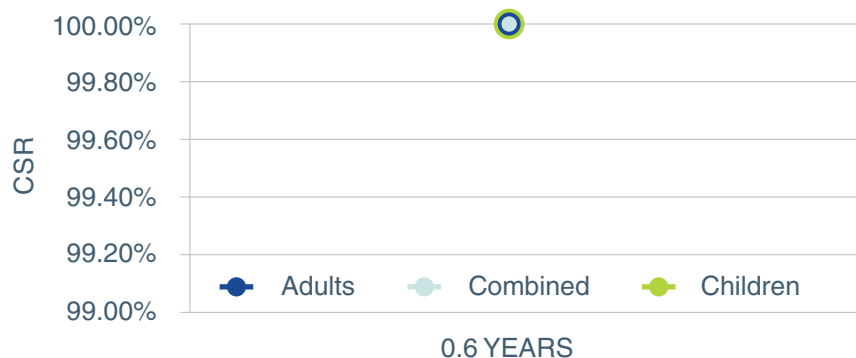
STANDARD	ADULTS	CHILDREN	COMBINED*
ISO 5841-2:2014	65	66	175 <sup>†</sup>
ANSI/AAMI CI86	114*	61	175

<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.

\* 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.

## ISO 5841-2:2014



### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	0.6
ADULTS	100.00%
COMBINED	100.00%
CHILDREN	100.00%

# ANSI/AAMI CI86

REMOVAL RATES ANALYSIS CATEGORY FOR CHILDREN



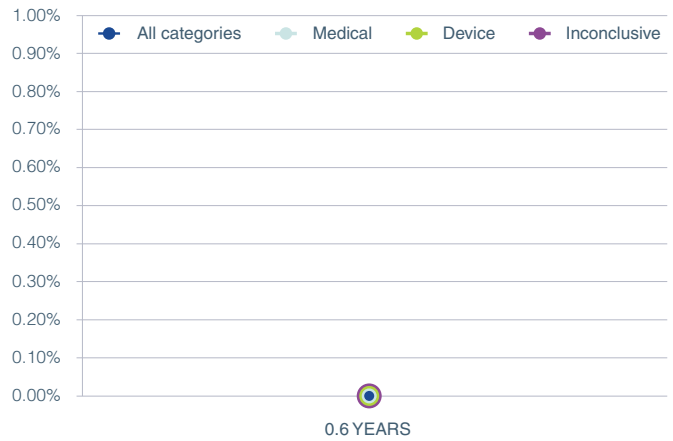
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
0.6	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™ 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 August 27, 2020.

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

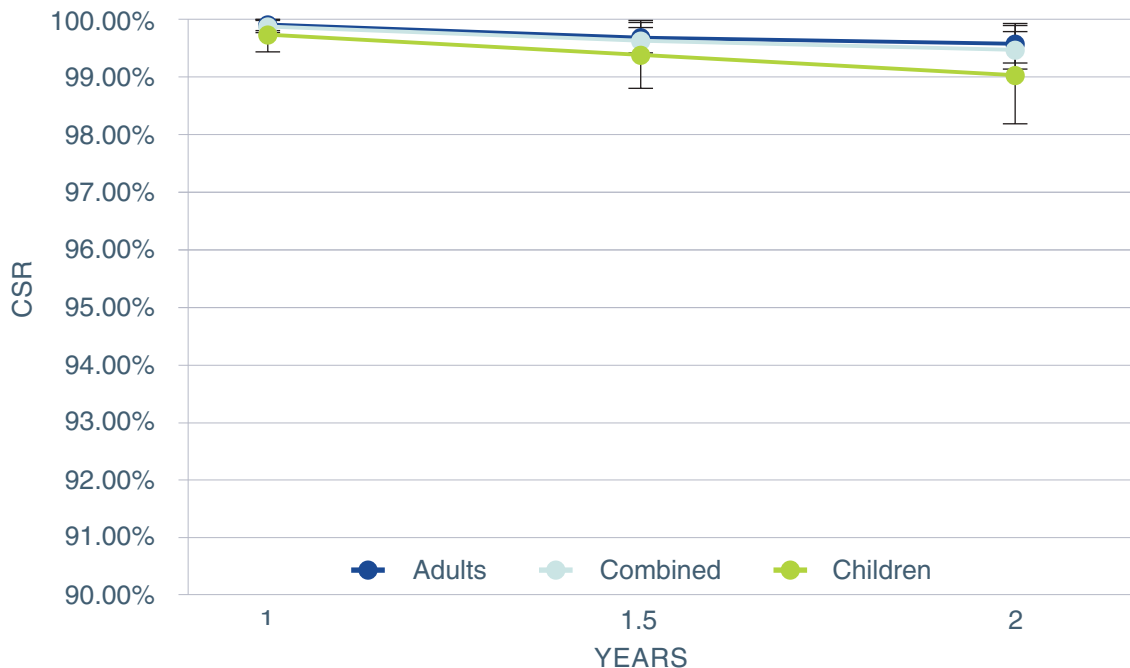
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4420	1517	6267 <sup>†</sup>
ANSI/AAMI CI86	4972*	1295	6267

<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.

\* 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.

### ISO 5841-2:2014

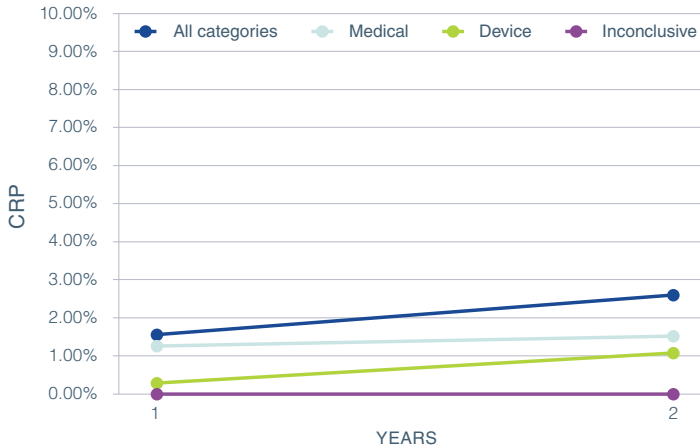


#### CUMULATIVE SURVIVAL PERCENTAGE

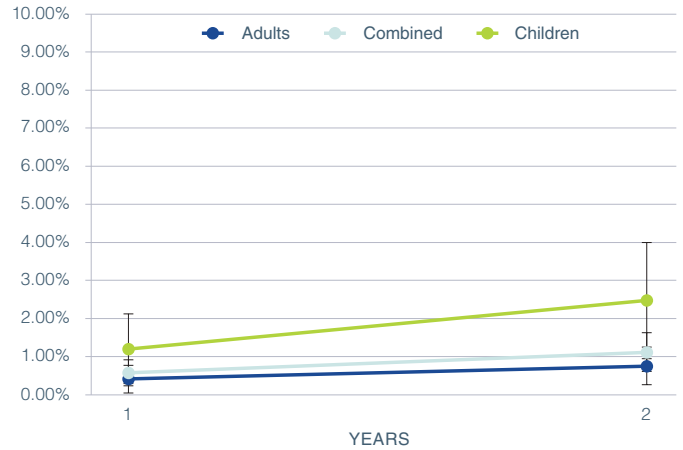
Years in use	1	1.5	2
ADULTS	99.91%	99.69%	99.60%
COMBINED	99.88%	99.64%	99.49%
CHILDREN	99.75%	99.42%	99.09%

# ANSI/AAMI CI86

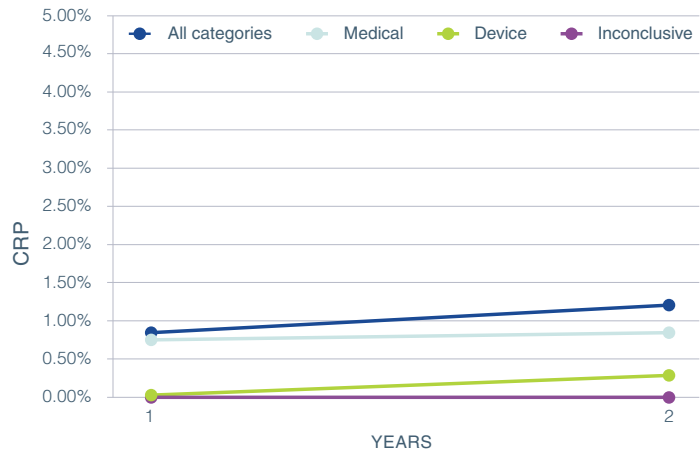
REMOVAL RATES ANALYSIS CATEGORY FOR CHILDREN



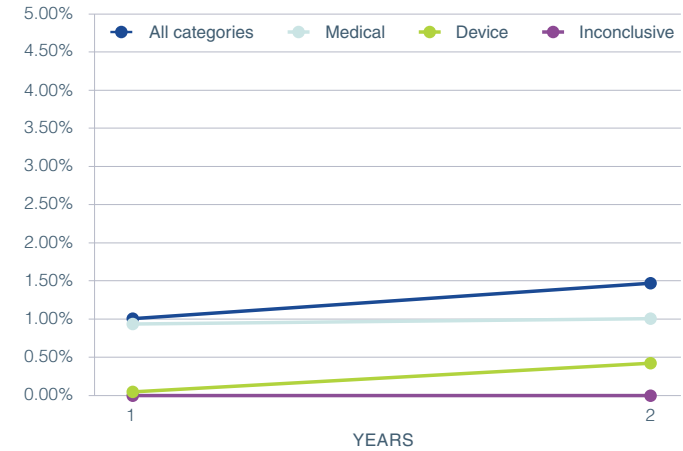
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.91%	0.12%	0.00%	1.03%	1.31%	0.75%
2	1.02%	0.45%	0.00%	1.47%	1.88%	1.06%

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™ 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 August 27, 2020.

Last year of distribution†: subject to voluntary field action February 18, 2020

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	6876	4152	11785†
ANSI/AAMI CI86	8166*	3619	11785

† 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014

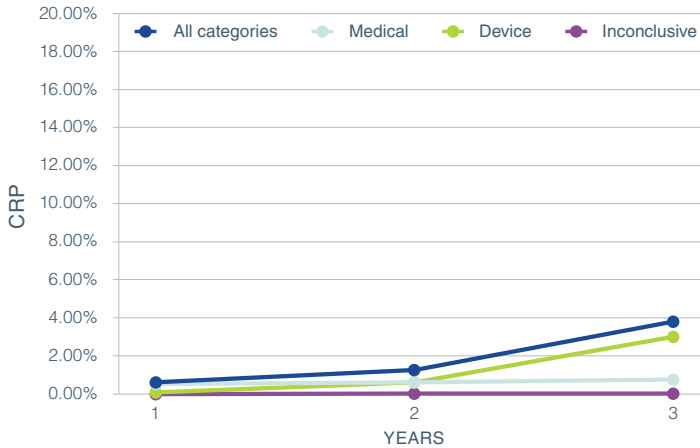


### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3
ADULTS	99.97%	99.74%	98.63%
COMBINED	99.95%	99.67%	98.31%
CHILDREN	99.92%	99.48%	97.41%

# ANSI/AAMI CI86

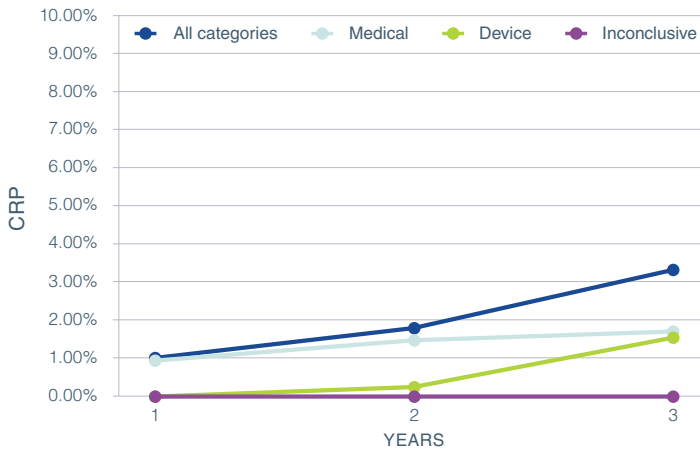
REMOVAL RATES ANALYSIS CATEGORY FOR CHILDREN



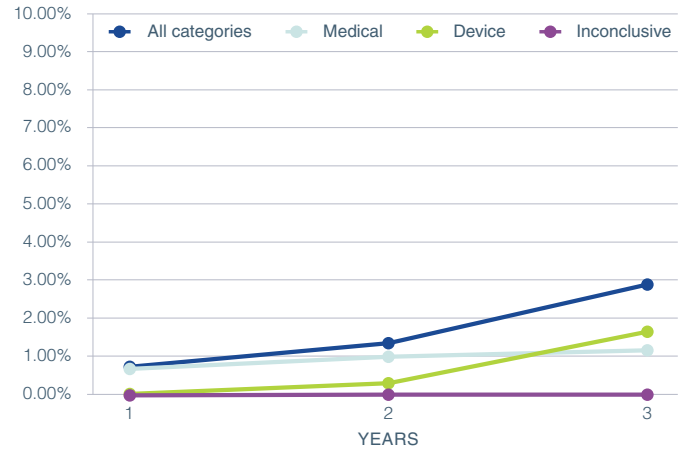
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.71%	0.05%	0.02%	0.77%	0.93%	0.61%
2	1.03%	0.33%	0.03%	1.39%	1.62%	1.16%
3	1.21%	1.69%	0.03%	2.93%	3.33%	2.53%

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 ADVANTAGE

The HiRes 90K™ 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 August 27, 2020.

Date of first commercial introduction†: 2012. Still available in selected markets.

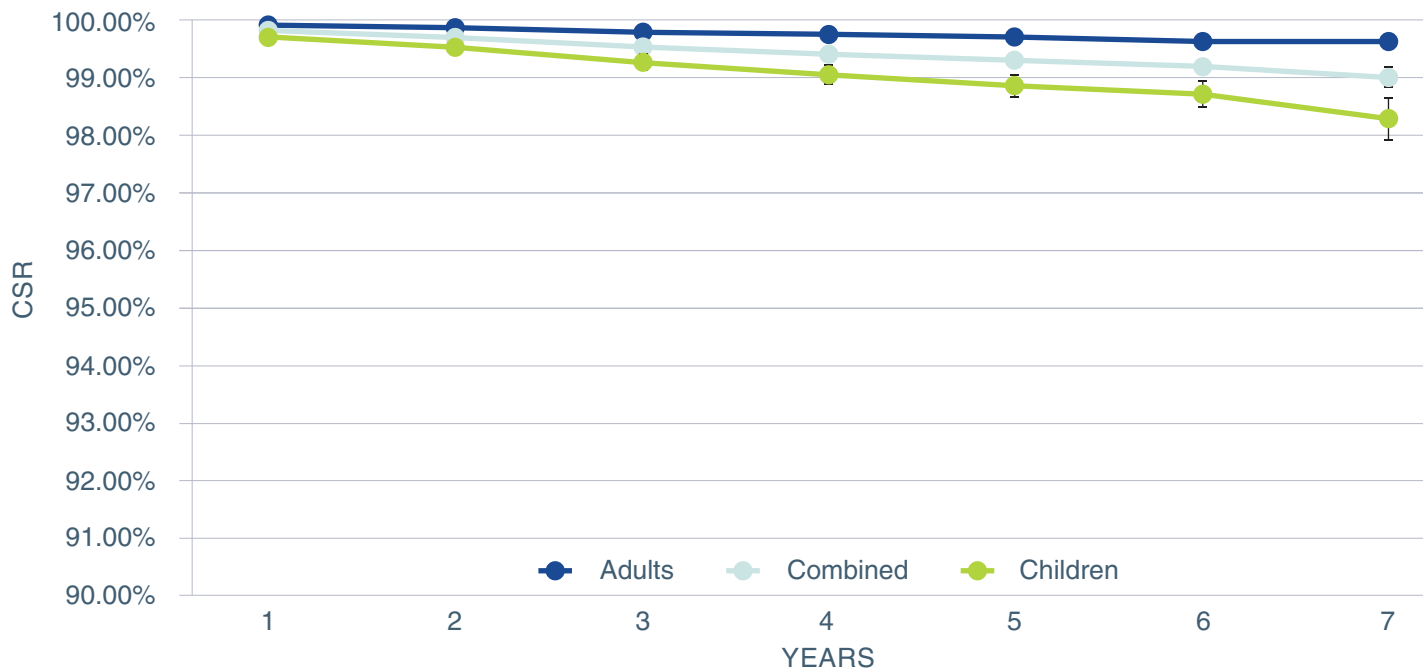
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	15041	18934	35704†
ANSI/AAMI CI86	18709*	16995	35704

† 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014



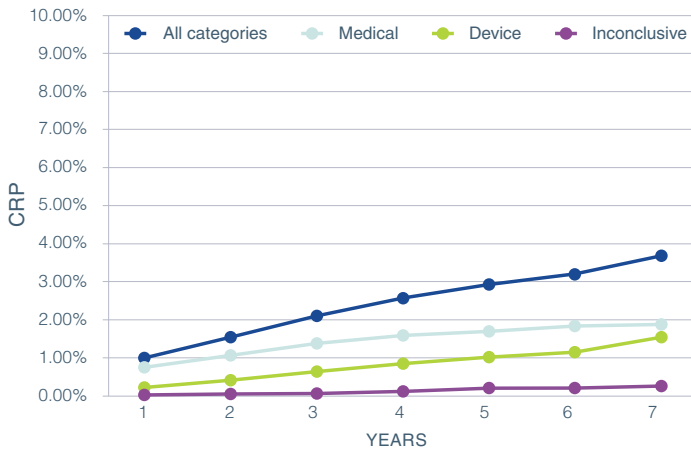
### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7
ADULTS	99.93%	99.89%	99.83%	99.80%	99.76%	99.70%	99.70%
COMBINED	99.85%	99.76%	99.62%	99.52%	99.44%	99.35%	99.20%
CHILDREN	99.78%	99.62%	99.41%	99.23%	99.08%	98.96%	98.63%

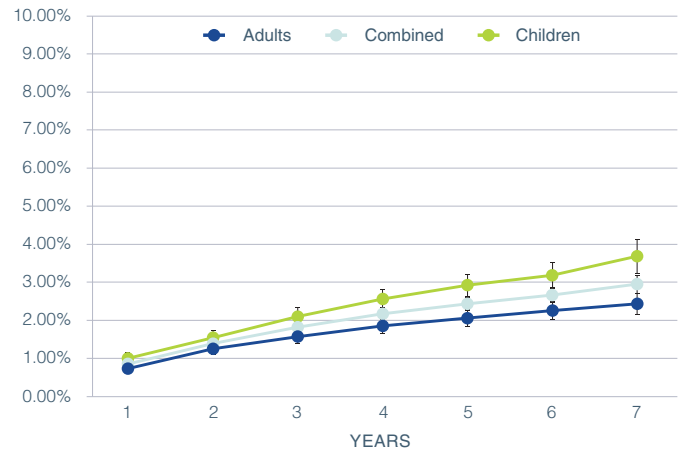


# ANSI/AAMI CI86

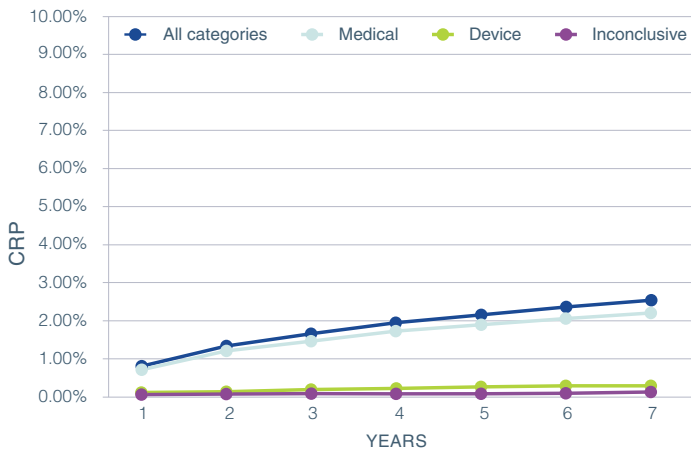
REMOVAL RATES ANALYSIS CATEGORY FOR CHILDREN



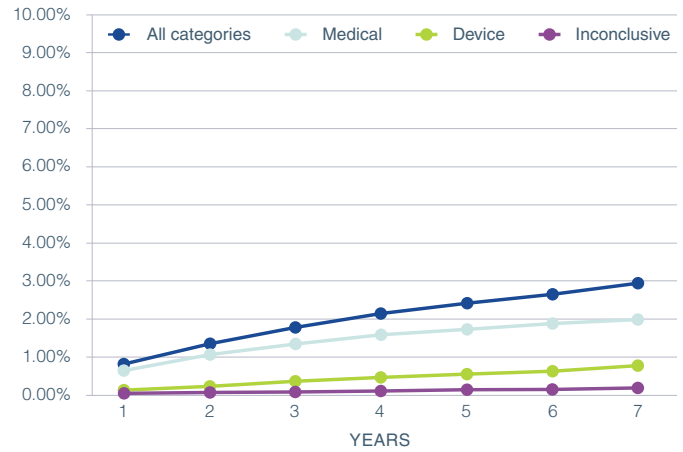
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.70%	0.14%	0.02%	0.86%	0.96%	0.77%
2	1.11%	0.24%	0.04%	1.39%	1.51%	1.26%
3	1.38%	0.37%	0.05%	1.81%	1.95%	1.67%
4	1.62%	0.47%	0.08%	2.17%	2.33%	2.01%
5	1.76%	0.56%	0.11%	2.43%	2.61%	2.26%
6	1.91%	0.63%	0.12%	2.66%	2.85%	2.46%
7	2.01%	0.78%	0.16%	2.95%	3.19%	2.71%

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 post-mod

The HiRes 90K™ 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 August 27, 2020.

Last year of distribution†. Still available in selected markets.

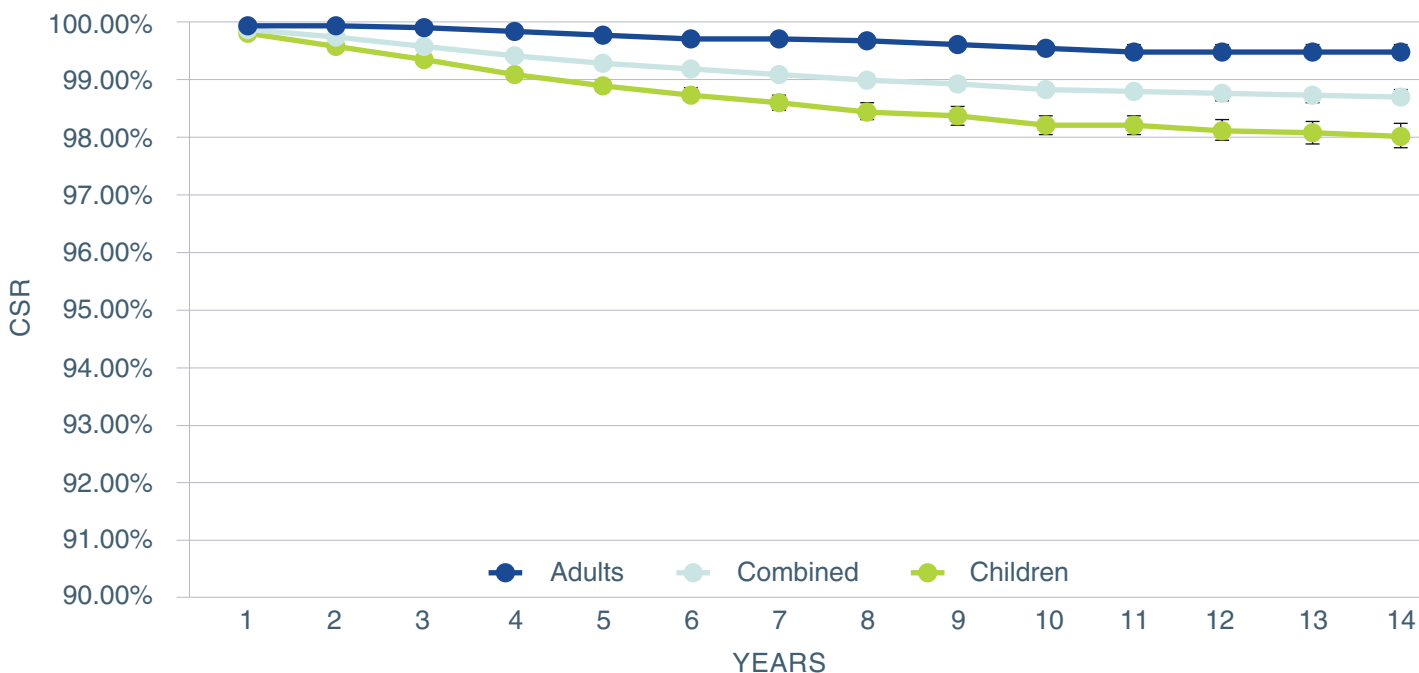
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	31163	43525	76985†
ANSI/AAMI CI86	38721*	38264	76985

† 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014

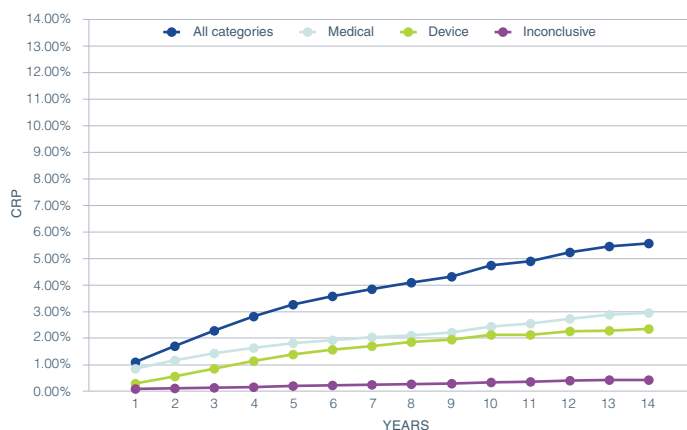


## CUMULATIVE SURVIVAL PERCENTAGE

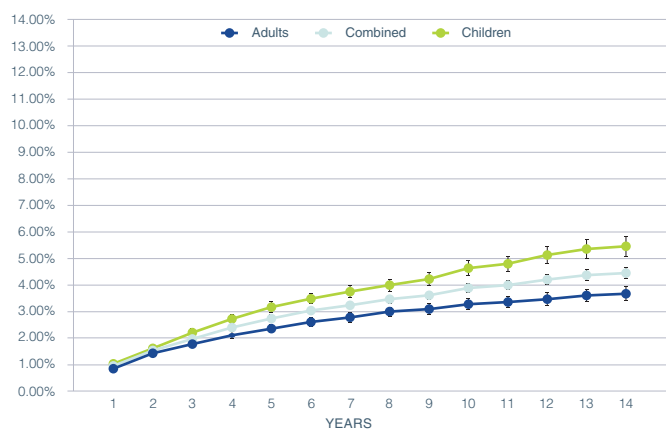
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14
ADULTS	99.94%	99.92%	99.88%	99.82%	99.78%	99.70%	99.69%	99.66%	99.61%	99.53%	99.48%	99.48%	99.48%	99.48%
COMBINED	99.87%	99.73%	99.58%	99.42%	99.29%	99.17%	99.10%	98.99%	98.93%	98.82%	98.79%	98.74%	98.72%	98.70%
CHILDREN	99.81%	99.58%	99.33%	99.09%	98.88%	98.73%	98.60%	98.44%	98.36%	98.21%	98.20%	98.11%	98.06%	98.02%

# ANSI/AAMI CI86

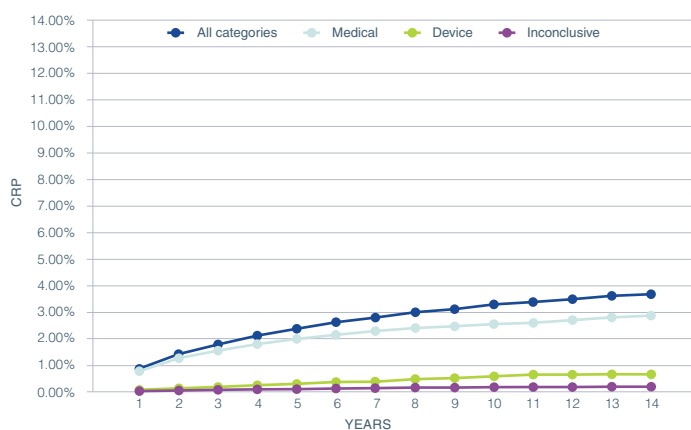
REMOVAL RATES ANALYSIS  
CATEGORY FOR CHILDREN



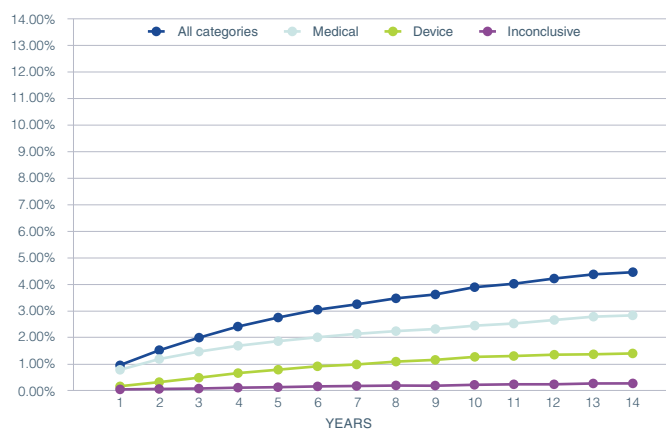
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES  
AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY  
FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.78%	0.14%	0.02%	0.94%	1.01%	0.87%
2	1.18%	0.30%	0.04%	1.52%	1.61%	1.43%
3	1.45%	0.47%	0.07%	1.98%	2.08%	1.88%
4	1.68%	0.64%	0.09%	2.41%	2.52%	2.29%
5	1.86%	0.78%	0.11%	2.75%	2.87%	2.63%
6	2.00%	0.89%	0.14%	3.03%	3.16%	2.90%
7	2.13%	0.97%	0.15%	3.25%	3.39%	3.11%
8	2.22%	1.08%	0.17%	3.47%	3.61%	3.32%
9	2.31%	1.14%	0.18%	3.62%	3.78%	3.47%
10	2.44%	1.25%	0.20%	3.90%	4.06%	3.73%
11	2.52%	1.29%	0.21%	4.02%	4.19%	3.84%
12	2.64%	1.34%	0.23%	4.21%	4.40%	4.02%
13	2.77%	1.36%	0.25%	4.38%	4.58%	4.17%
14	2.83%	1.38%	0.25%	4.46%	4.68%	4.24%

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 August 27, 2020.

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

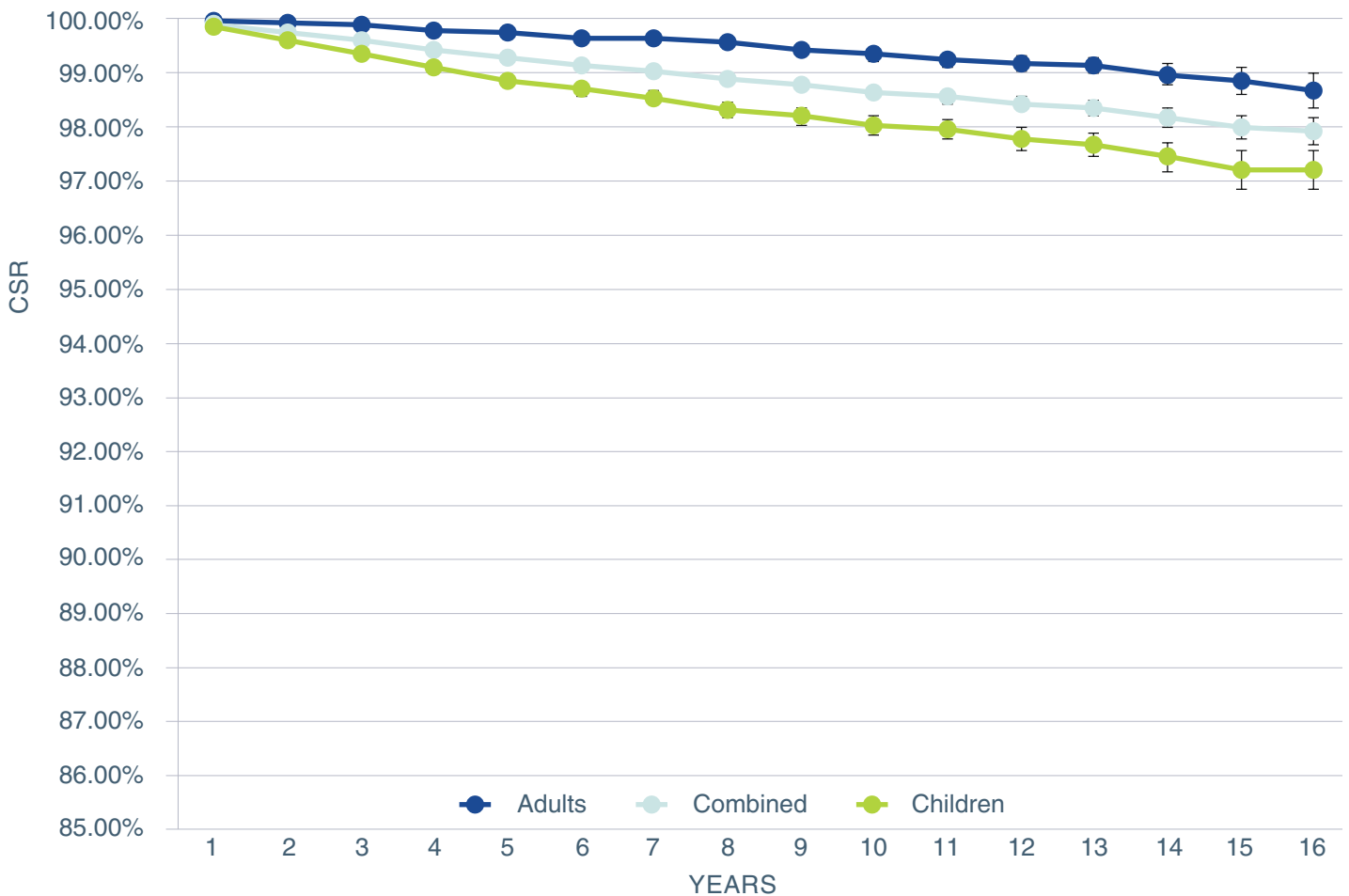
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	32613	44616	79539 <sup>†</sup>
ANSI/AAMI CI86	40383 <sup>*</sup>	39156	79539

<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.

<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> The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014

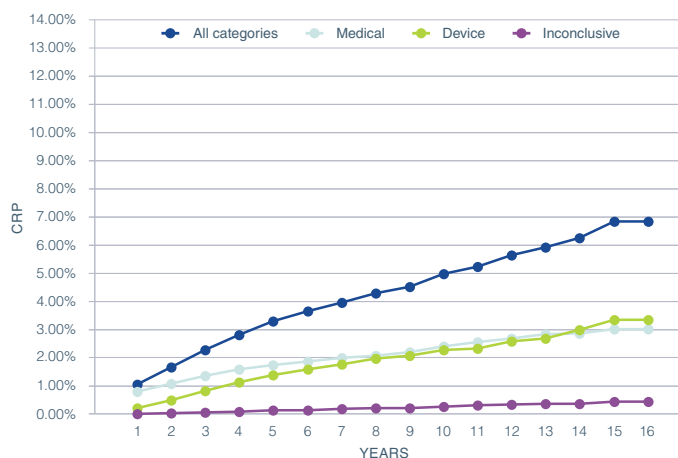


### CUMULATIVE SURVIVAL PERCENTAGE

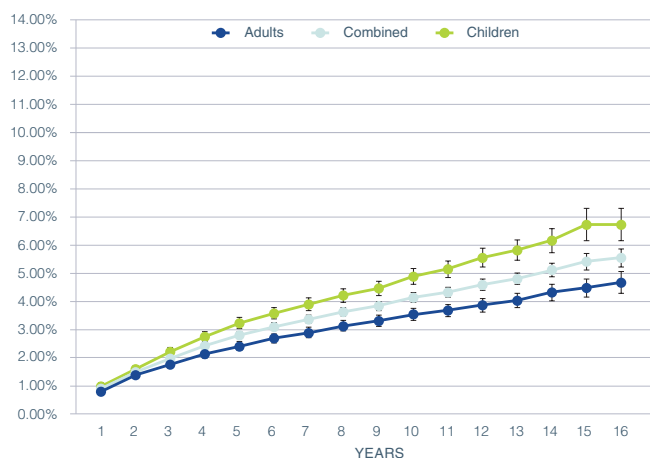
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ADULTS	99.93%	99.88%	99.84%	99.75%	99.71%	99.61%	99.59%	99.51%	99.40%	99.31%	99.20%	99.13%	99.10%	98.94%	98.81%	98.65%
COMBINED	99.86%	99.70%	99.55%	99.38%	99.23%	99.10%	99.01%	98.86%	98.74%	98.61%	98.52%	98.40%	98.33%	98.15%	97.98%	97.89%
CHILDREN	99.80%	99.56%	99.31%	99.05%	98.83%	98.67%	98.52%	98.29%	98.17%	98.01%	97.95%	97.76%	97.65%	97.43%	97.20%	97.20%

# ANSI/AAMI CI86

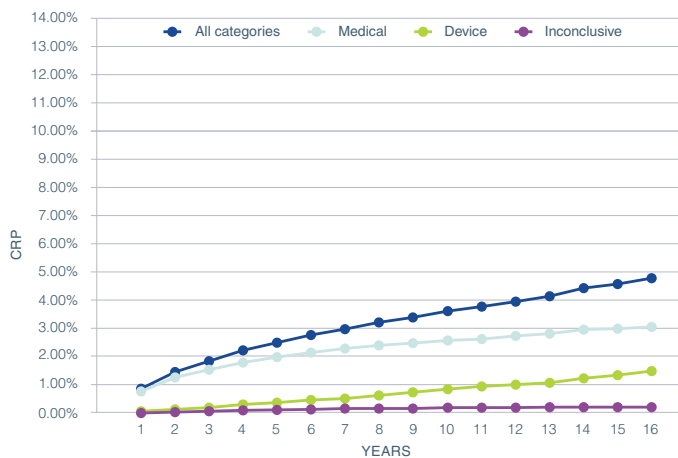
REMOVAL RATES ANALYSIS  
CATEGORY FOR CHILDREN



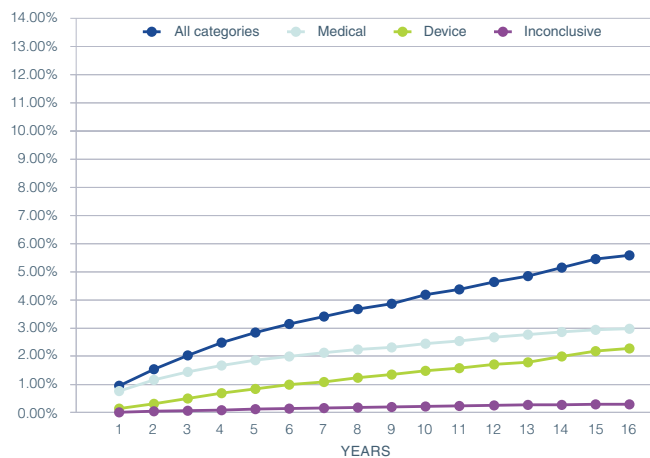
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES  
AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.78%	0.15%	0.02%	0.95%	1.02%	0.89%
2	1.17%	0.32%	0.05%	1.55%	1.63%	1.46%
3	1.45%	0.50%	0.08%	2.03%	2.13%	1.93%
4	1.68%	0.70%	0.10%	2.48%	2.59%	2.37%
5	1.86%	0.85%	0.13%	2.84%	2.96%	2.72%
6	2.00%	0.99%	0.15%	3.15%	3.28%	3.02%
7	2.14%	1.09%	0.18%	3.40%	3.54%	3.27%
8	2.24%	1.25%	0.19%	3.67%	3.82%	3.53%
9	2.32%	1.35%	0.20%	3.87%	4.03%	3.72%
10	2.45%	1.49%	0.23%	4.18%	4.35%	4.01%
11	2.54%	1.58%	0.25%	4.36%	4.54%	4.18%
12	2.67%	1.71%	0.26%	4.64%	4.83%	4.44%
13	2.77%	1.79%	0.28%	4.84%	5.05%	4.63%
14	2.87%	1.99%	0.28%	5.15%	5.39%	4.90%
15	2.94%	2.19%	0.31%	5.44%	5.74%	5.15%
16	2.99%	2.28%	0.31%	5.58%	5.90%	5.25%

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 August 27, 2020.

Last year of distribution†: 2005.

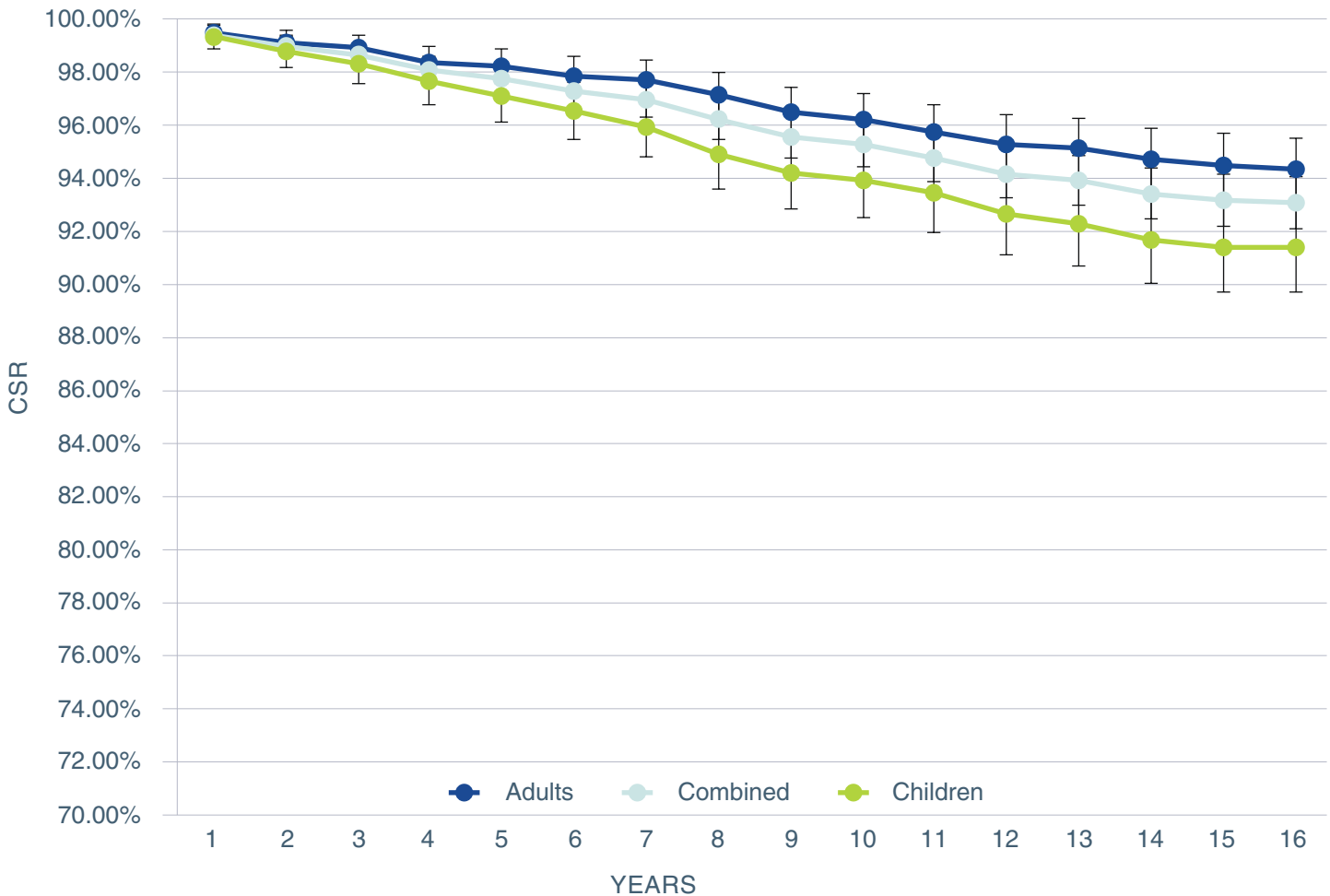
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	1450	1091	2554†
ANSI/AAMI CI86	1662*	892	2554

‡ 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014

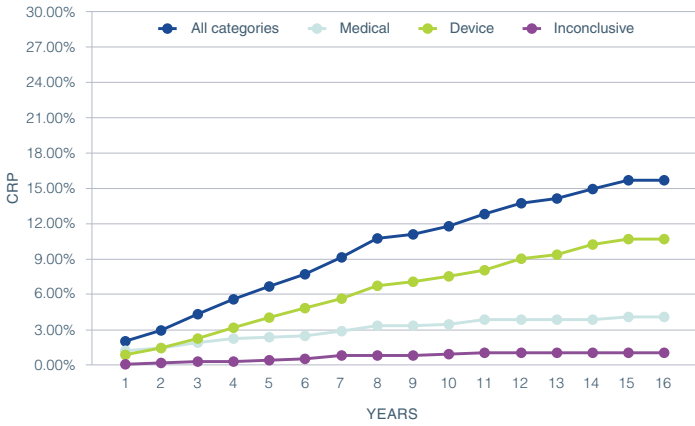


CUMULATIVE SURVIVAL PERCENTAGE

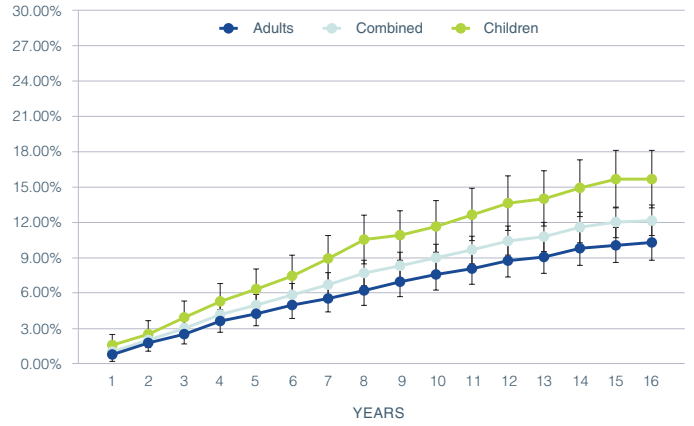
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ADULTS	99.58%	99.24%	99.03%	98.46%	98.32%	97.96%	97.81%	97.24%	96.59%	96.30%	95.80%	95.36%	95.22%	94.78%	94.56%	94.39%
COMBINED	99.53%	99.09%	98.77%	98.17%	97.84%	97.39%	97.07%	96.29%	95.63%	95.34%	94.80%	94.22%	93.97%	93.47%	93.21%	93.11%
CHILDREN	99.45%	98.89%	98.42%	97.75%	97.18%	96.61%	96.03%	94.96%	94.28%	93.98%	93.49%	92.70%	92.31%	91.72%	91.42%	91.42%

# ANSI/AAMI CI86

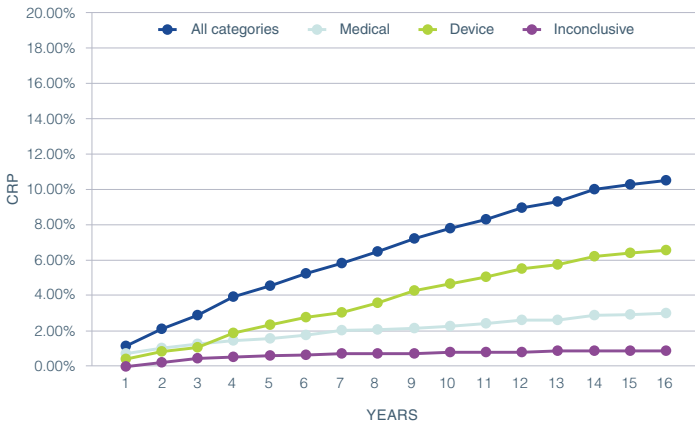
REMOVAL RATES ANALYSIS  
CATEGORY FOR CHILDREN



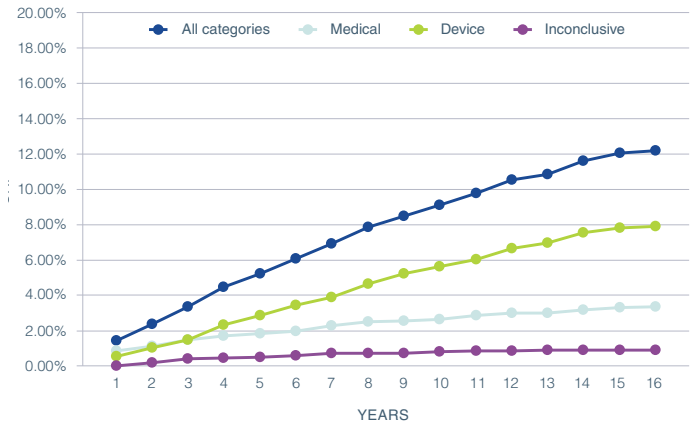
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES  
AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.86%	0.55%	0.00%	1.42%	1.87%	0.96%
2	1.14%	1.03%	0.20%	2.37%	2.96%	1.78%
3	1.46%	1.47%	0.40%	3.33%	4.02%	2.64%
4	1.70%	2.31%	0.44%	4.46%	5.25%	3.66%
5	1.82%	2.87%	0.52%	5.22%	6.08%	4.37%
6	1.99%	3.44%	0.61%	6.04%	6.95%	5.12%
7	2.28%	3.89%	0.73%	6.90%	7.87%	5.92%
8	2.48%	4.62%	0.73%	7.84%	8.87%	6.80%
9	2.53%	5.19%	0.73%	8.45%	9.52%	7.38%
10	2.65%	5.60%	0.82%	9.07%	10.18%	7.97%
11	2.86%	6.01%	0.86%	9.74%	10.88%	8.60%
12	2.99%	6.63%	0.86%	10.48%	11.66%	9.30%
13	2.99%	6.92%	0.91%	10.81%	12.01%	9.62%
14	3.17%	7.50%	0.91%	11.57%	12.80%	10.34%
15	3.30%	7.79%	0.91%	11.99%	13.24%	10.74%
16	3.35%	7.89%	0.91%	12.14%	13.40%	10.88%

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 August 27, 2020.

Last year of distribution†. Subject to voluntary recall in 2006.

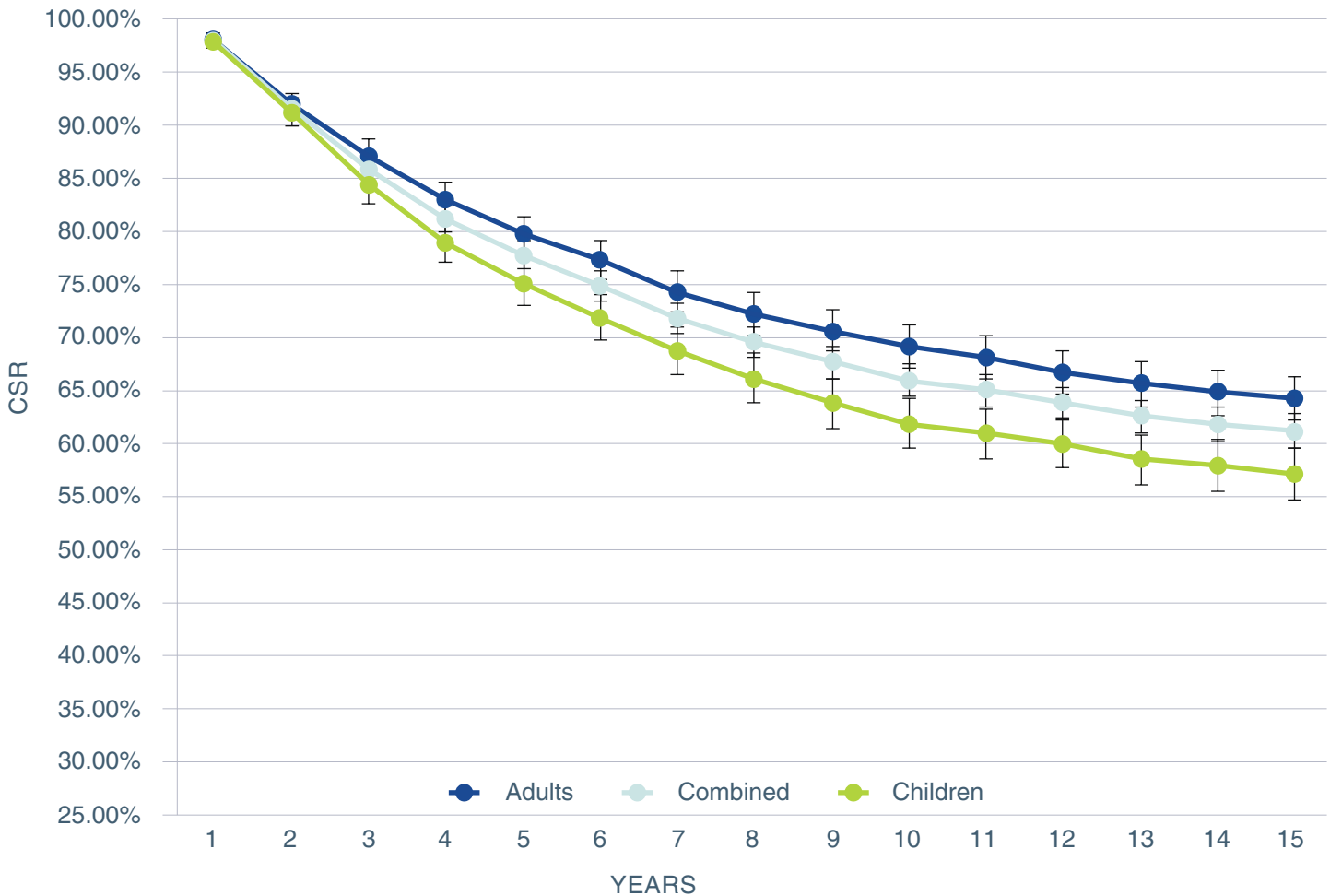
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	2204	1837	4065†
ANSI/AAMI CI86	2561*	1504	4065

† 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.

\* 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014



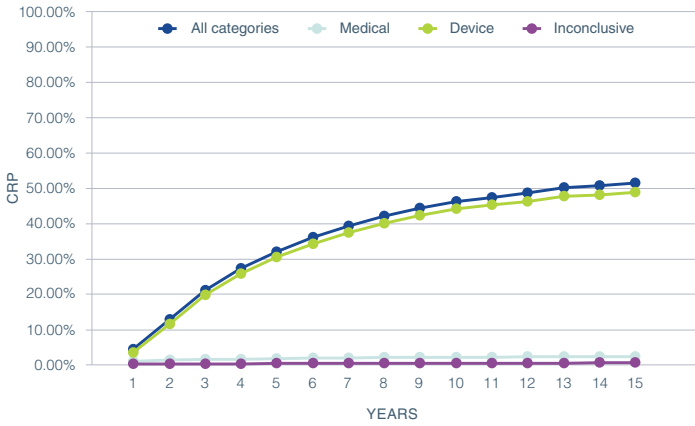
CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
ADULTS	97.84%	91.69%	87.03%	82.83%	79.66%	77.31%	74.33%	72.25%	70.72%	69.24%	68.21%	66.76%	65.72%	64.89%	64.37%
COMBINED	97.79%	91.40%	85.80%	81.11%	77.69%	74.91%	71.89%	69.63%	67.74%	66.07%	65.09%	63.91%	62.66%	61.95%	61.31%
CHILDREN	97.69%	91.00%	84.27%	78.92%	75.15%	71.88%	68.77%	66.26%	63.92%	62.00%	61.06%	60.19%	58.67%	58.10%	57.29%

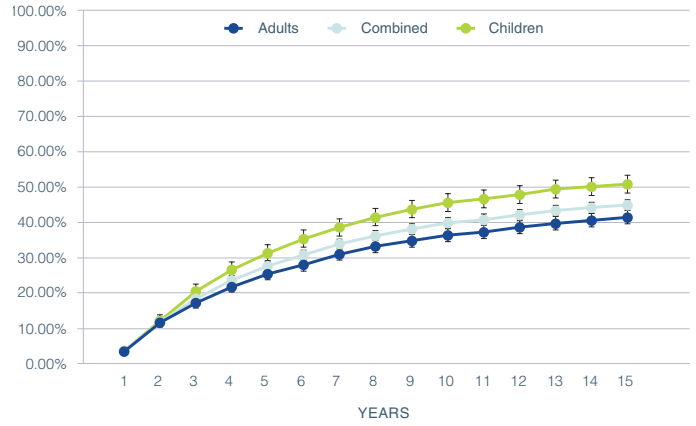


# ANSI/AAMI CI86

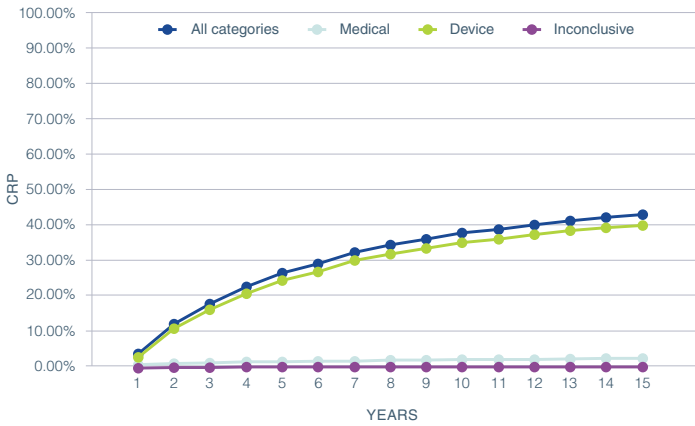
REMOVAL RATES ANALYSIS  
CATEGORY FOR CHILDREN



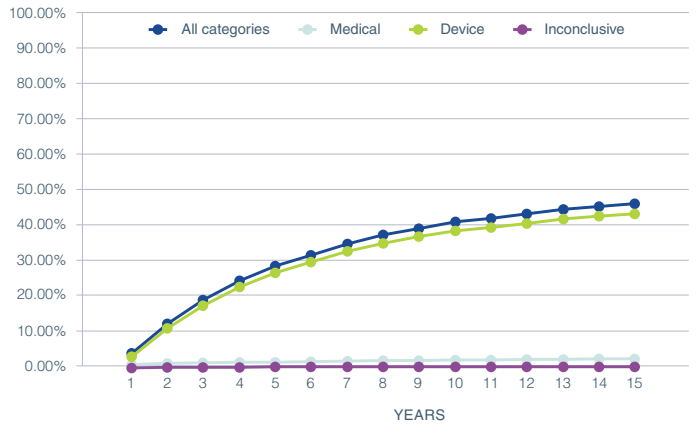
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES  
AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.93%	3.12%	0.00%	4.04%	4.65%	3.44%
2	1.22%	11.11%	0.08%	12.41%	13.42%	11.40%
3	1.42%	17.53%	0.14%	19.09%	20.30%	17.89%
4	1.58%	22.69%	0.17%	24.44%	25.75%	23.12%
5	1.64%	26.67%	0.24%	28.55%	29.94%	27.17%
6	1.79%	29.65%	0.24%	31.67%	33.10%	30.24%
7	1.86%	32.76%	0.24%	34.86%	36.33%	33.39%
8	2.13%	34.95%	0.24%	37.32%	38.81%	35.83%
9	2.13%	36.79%	0.24%	39.16%	40.66%	37.65%
10	2.25%	38.43%	0.24%	40.92%	42.43%	39.40%
11	2.25%	39.44%	0.24%	41.93%	43.46%	40.41%
12	2.33%	40.60%	0.28%	43.21%	44.74%	41.68%
13	2.38%	41.83%	0.28%	44.49%	46.03%	42.95%
14	2.47%	42.52%	0.33%	45.31%	46.85%	43.77%
15	2.52%	43.25%	0.33%	46.10%	47.65%	44.55%

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 August 27, 2020.

Last year of distribution†: 2004

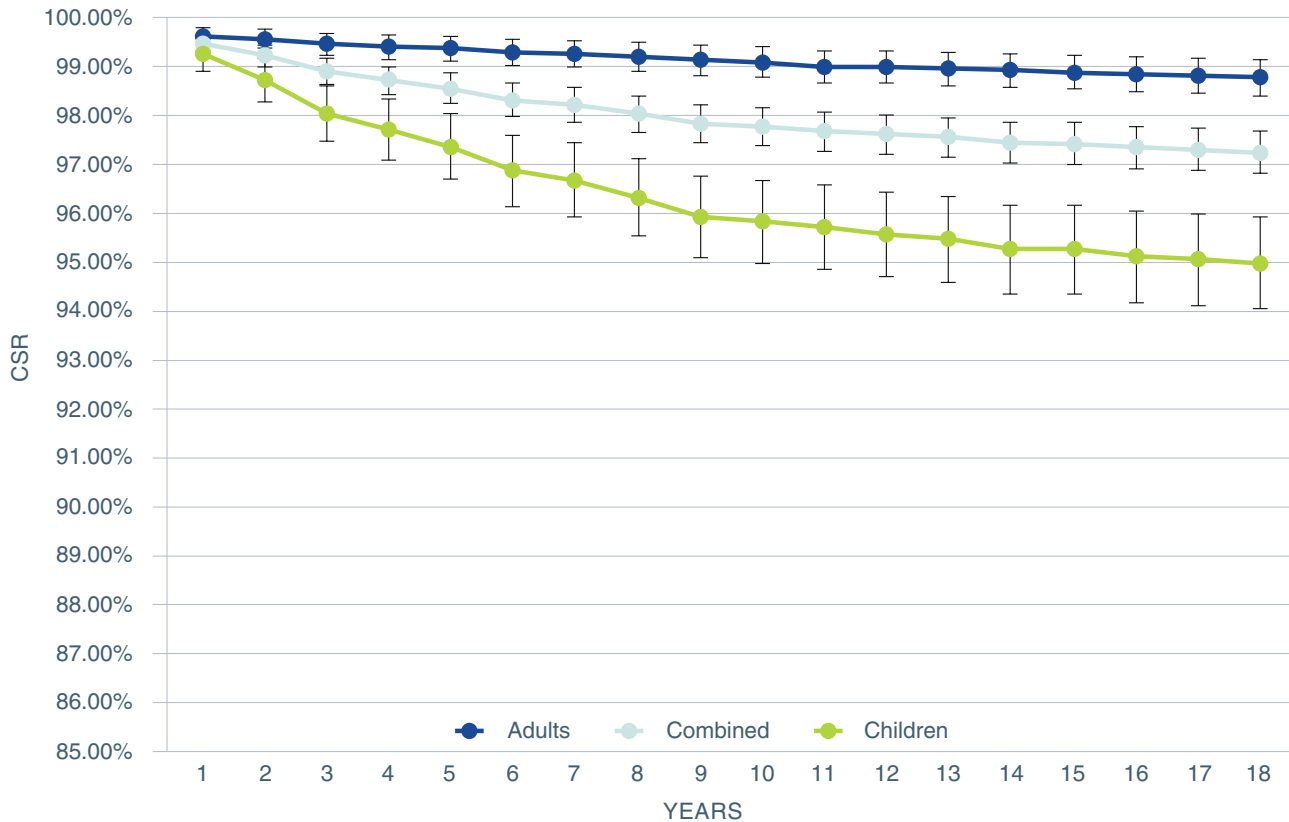
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	2998	2084	5108†
ANSI/AAMI CI86	3385*	1723	5108

‡ 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014

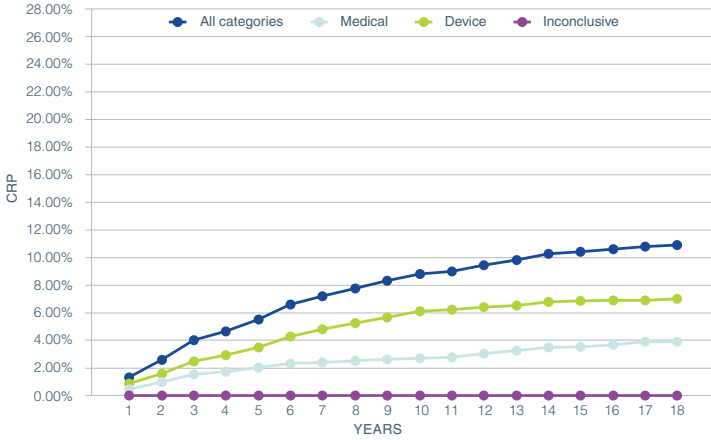


### CUMULATIVE SURVIVAL PERCENTAGE

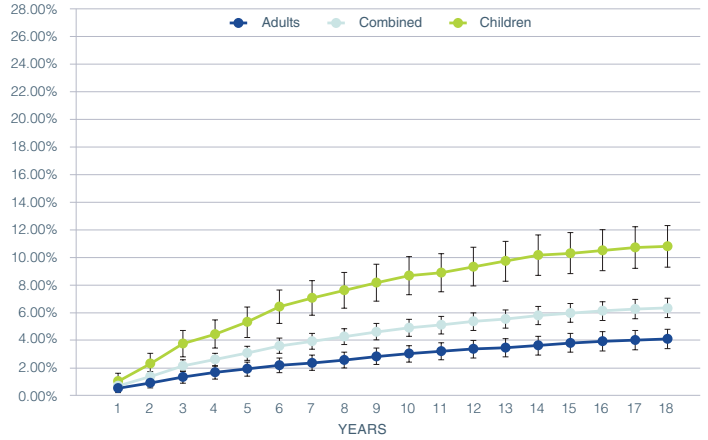
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ADULTS	99.77%	99.70%	99.60%	99.53%	99.49%	99.43%	99.39%	99.32%	99.25%	99.22%	99.11%	99.11%	99.08%	99.05%	99.01%	98.97%	98.94%	98.90%
COMBINED	99.61%	99.35%	99.01%	98.83%	98.67%	98.43%	98.33%	98.14%	97.94%	97.88%	97.77%	97.71%	97.65%	97.54%	97.52%	97.44%	97.40%	97.34%
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%	95.16%	95.11%	95.03%

# ANSI/AAMI CI86

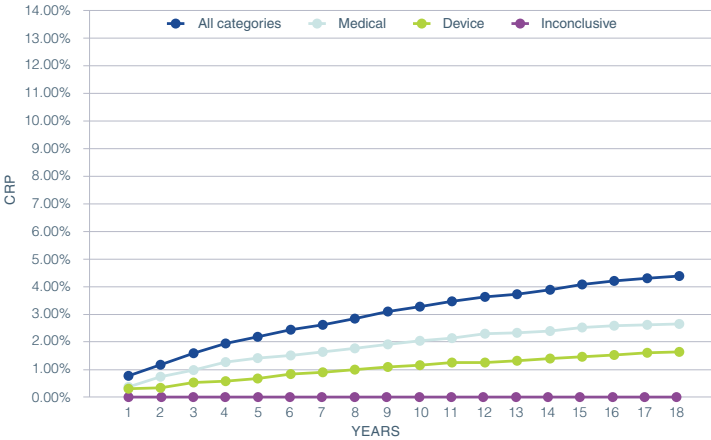
REMOVAL RATES ANALYSIS  
CATEGORY FOR CHILDREN



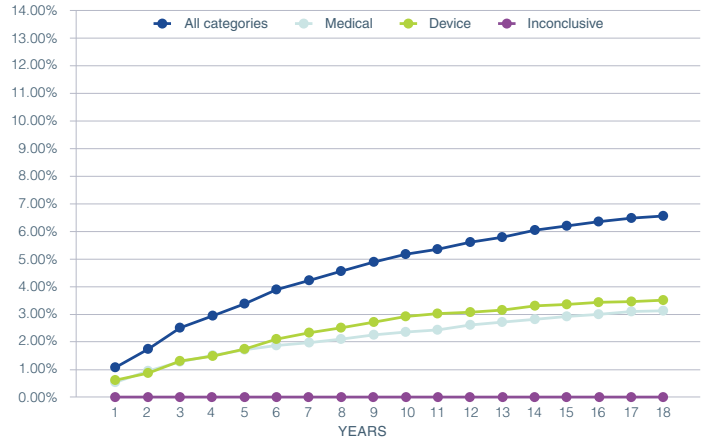
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES  
AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY  
FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.45%	0.55%	0.00%	1.00%	1.27%	0.73%
2	0.87%	0.81%	0.00%	1.67%	2.02%	1.32%
3	1.20%	1.22%	0.00%	2.43%	2.85%	2.01%
4	1.44%	1.42%	0.00%	2.87%	3.33%	2.41%
5	1.65%	1.66%	0.00%	3.31%	3.80%	2.82%
6	1.81%	2.03%	0.00%	3.83%	4.36%	3.31%
7	1.91%	2.25%	0.00%	4.16%	4.70%	3.61%
8	2.03%	2.45%	0.00%	4.48%	5.05%	3.92%
9	2.17%	2.66%	0.00%	4.83%	5.42%	4.24%
10	2.28%	2.84%	0.00%	5.12%	5.72%	4.51%
11	2.36%	2.94%	0.00%	5.30%	5.91%	4.69%
12	2.54%	3.00%	0.00%	5.55%	6.17%	4.92%
13	2.65%	3.09%	0.00%	5.73%	6.37%	5.10%
14	2.75%	3.23%	0.00%	5.98%	6.63%	5.33%
15	2.85%	3.29%	0.00%	6.15%	6.80%	5.49%
16	2.94%	3.36%	0.00%	6.29%	6.96%	5.63%
17	3.03%	3.40%	0.00%	6.42%	7.10%	5.75%
18	3.05%	3.45%	0.00%	6.51%	7.18%	5.83%

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 August 27, 2020.

Last year of distribution†: 2004

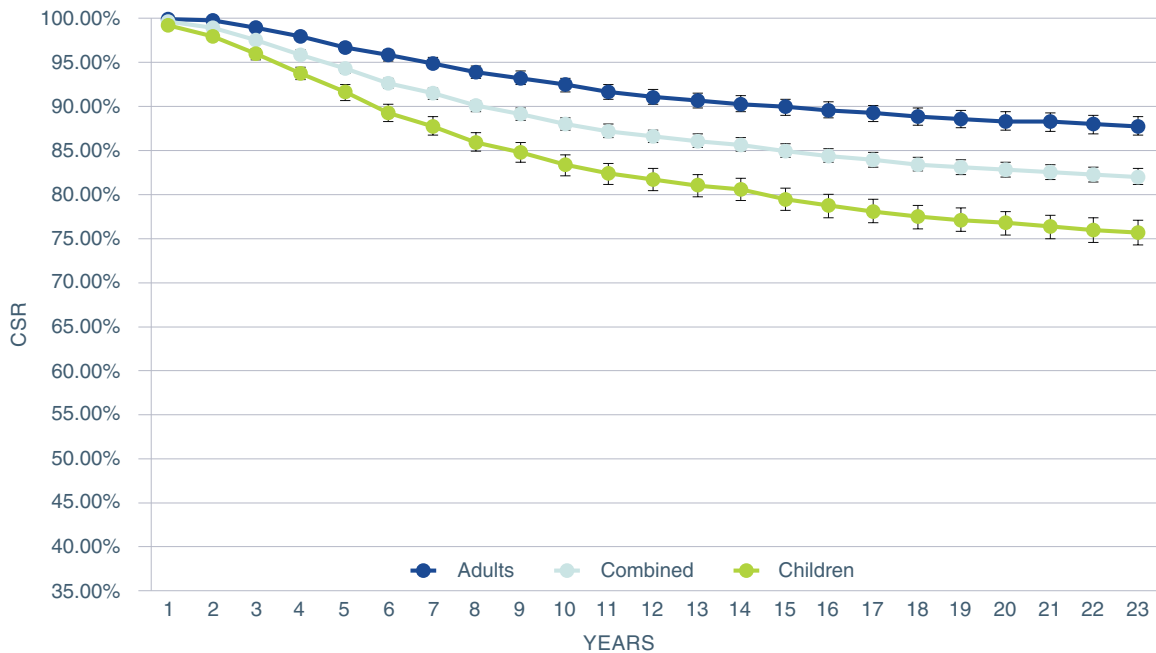
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4310	4146	8497 <sup>†</sup>
ANSI/AAMI CI86	4981*	3516	8497

‡ 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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014



## CUMULATIVE SURVIVAL PERCENTAGE

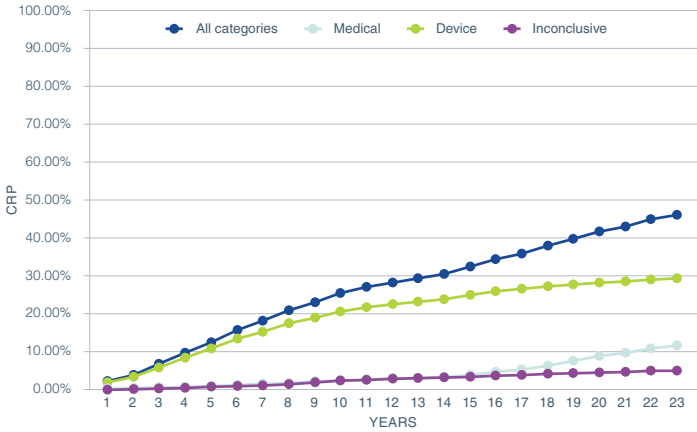
Years in use	1	2	3	4	5	6	7	8	9	10	11	12
ADULTS	99.81%	99.56%	98.82%	97.76%	96.56%	95.65%	94.76%	93.72%	93.07%	92.29%	91.50%	90.96%
COMBINED	99.42%	98.72%	97.36%	95.75%	94.10%	92.51%	91.34%	89.92%	89.00%	87.93%	87.07%	86.47%
CHILDREN	99.00%	97.82%	95.80%	93.61%	91.45%	89.13%	87.65%	85.82%	84.59%	83.20%	82.26%	81.59%

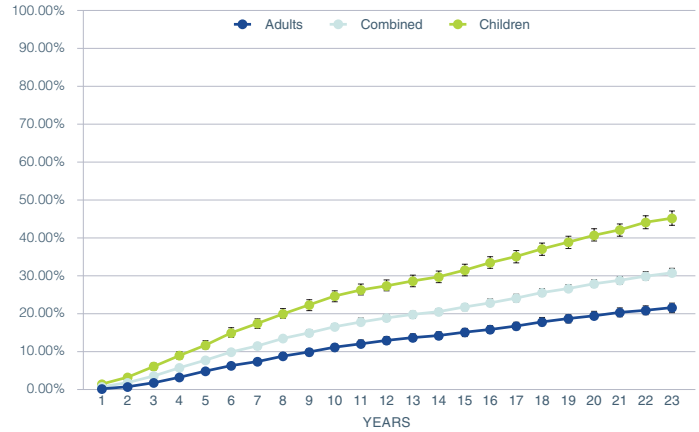
Years in use	13	14	15	16	17	18	19	20	21	22	23
ADULTS	90.54%	90.12%	89.79%	89.47%	89.06%	88.75%	88.45%	88.22%	88.09%	87.84%	87.63%
COMBINED	85.93%	85.52%	84.82%	84.28%	83.79%	83.32%	83.00%	82.71%	82.46%	82.15%	81.92%
CHILDREN	80.92%	80.51%	79.38%	78.60%	78.00%	77.35%	77.00%	76.62%	76.22%	75.83%	75.56%

# ANSI/AAMI CI86

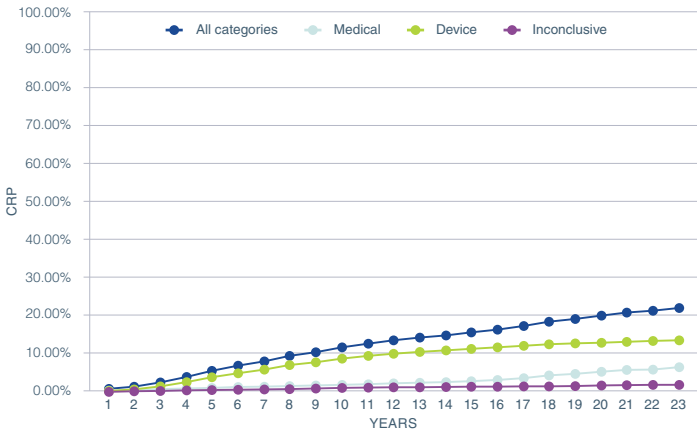
REMOVAL RATES ANALYSIS  
CATEGORY FOR CHILDREN



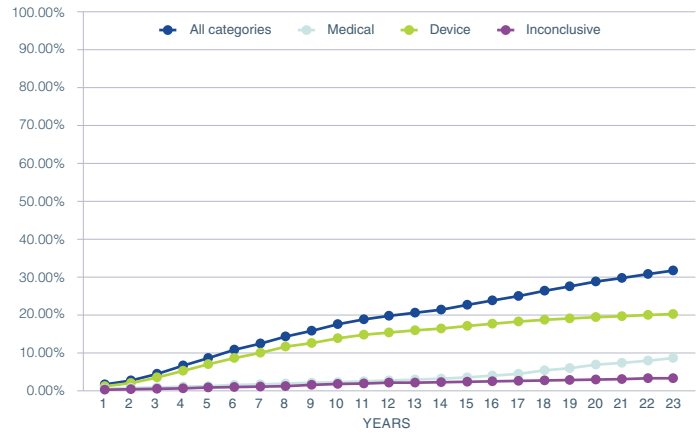
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES  
AND DIFFERENT PATIENT POPULATIONS



REMOVAL RATES ANALYSIS  
CATEGORY FOR ADULTS



REMOVAL RATES ANALYSIS CATEGORY  
FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total CI Up	Total CI Down
1	0.36%	0.97%	0.07%	1.40%	1.65%	1.15%
2	0.50%	1.80%	0.17%	2.47%	2.80%	2.14%
3	0.68%	3.26%	0.30%	4.24%	4.67%	3.81%
4	0.88%	4.99%	0.45%	6.32%	6.84%	5.80%
5	1.05%	6.68%	0.63%	8.35%	8.94%	7.76%
6	1.33%	8.35%	0.77%	10.45%	11.10%	9.81%
7	1.50%	9.65%	0.89%	12.05%	12.74%	11.36%
8	1.69%	11.25%	1.04%	13.98%	14.71%	13.25%
9	1.90%	12.23%	1.29%	15.42%	16.18%	14.66%
10	2.06%	13.48%	1.59%	17.13%	17.92%	16.33%
11	2.26%	14.38%	1.71%	18.35%	19.17%	17.54%
12	2.48%	14.95%	1.86%	19.29%	20.13%	18.46%
13	2.68%	15.51%	1.96%	20.15%	21.00%	19.31%
14	2.93%	15.99%	2.02%	20.95%	21.80%	20.09%
15	3.26%	16.72%	2.14%	22.12%	22.99%	21.24%
16	3.72%	17.30%	2.28%	23.30%	24.19%	22.41%
17	4.22%	17.84%	2.42%	24.47%	25.38%	23.57%
18	5.07%	18.31%	2.51%	25.89%	26.81%	24.96%
19	5.74%	18.65%	2.63%	27.02%	27.96%	26.08%
20	6.56%	18.92%	2.75%	28.23%	29.18%	27.28%
21	7.11%	19.18%	2.88%	29.17%	30.14%	28.20%
22	7.62%	19.55%	3.04%	30.21%	31.22%	29.19%
23	8.28%	19.73%	3.04%	31.05%	32.12%	29.98%

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.



## Number of registered C1.0 implants

As of August 27, 2020.

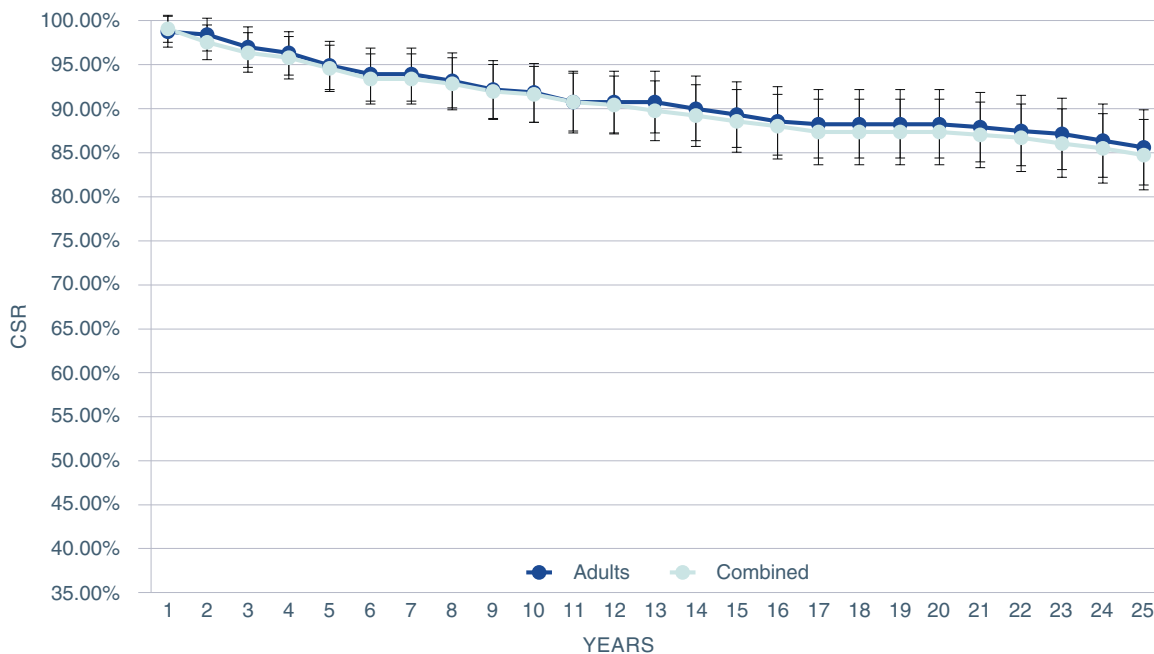
Last year of distribution†: 2004

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.

† The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014



### CUMULATIVE SURVIVAL PERCENTAGE

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%	89.54%

Years in use	14	15	16	17	18	19	20	21	22	23	24	25
ADULTS	89.76%	89.10%	88.44%	88.11%	88.11%	88.11%	88.11%	87.77%	87.43%	87.09%	86.40%	85.69%
COMBINED	88.98%	88.41%	87.84%	87.27%	87.27%	87.27%	87.27%	86.98%	86.69%	86.11%	85.52%	84.90%

# ANSI/AAMI CI86

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 table showing the number of registered users and graphs showing the reliability. The tables will include data for adults, children, and a combined number in accordance with the reporting methodologies.

The ANSI/AAMI CI86 Standard requires identified failure modes or symptoms to be documented and categorized by failure mechanism, if known. The failure categorization should, at minimum, include mechanical, electronic, moisture damage, and other. In specification processors, commonly referred to as no-fault found, are also to be included.

Advanced Bionics is adjusting our failure analysis methodology to better reflect the ANSI/AAMI CI86 Standard. In the meantime, the data shown is a combination of all known failures modes.

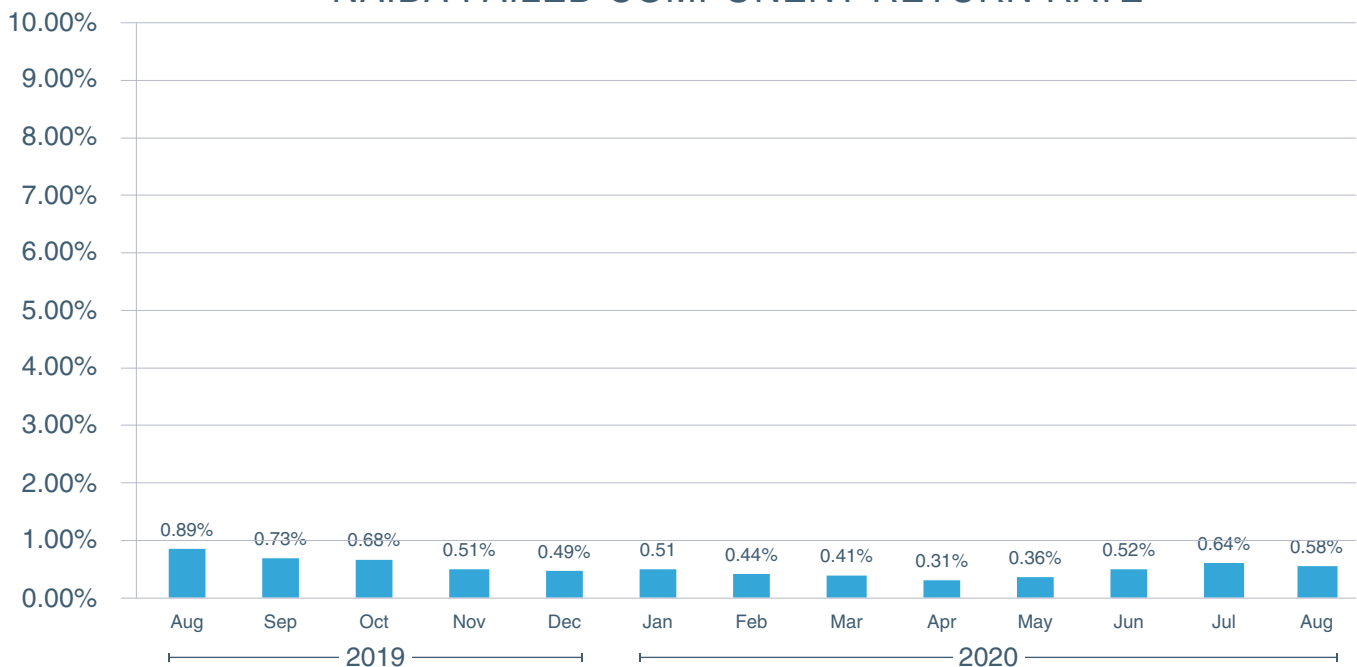
## NAÍDA CI Q90

The Naída CI Q90 sound processor features state-of-the-art technologies exclusively available from Advanced Bionics and Phonak for the best possible hearing experience.

**RELIABILITY: 98.73%\***



### NAÍDA FAILED COMPONENT RETURN RATE





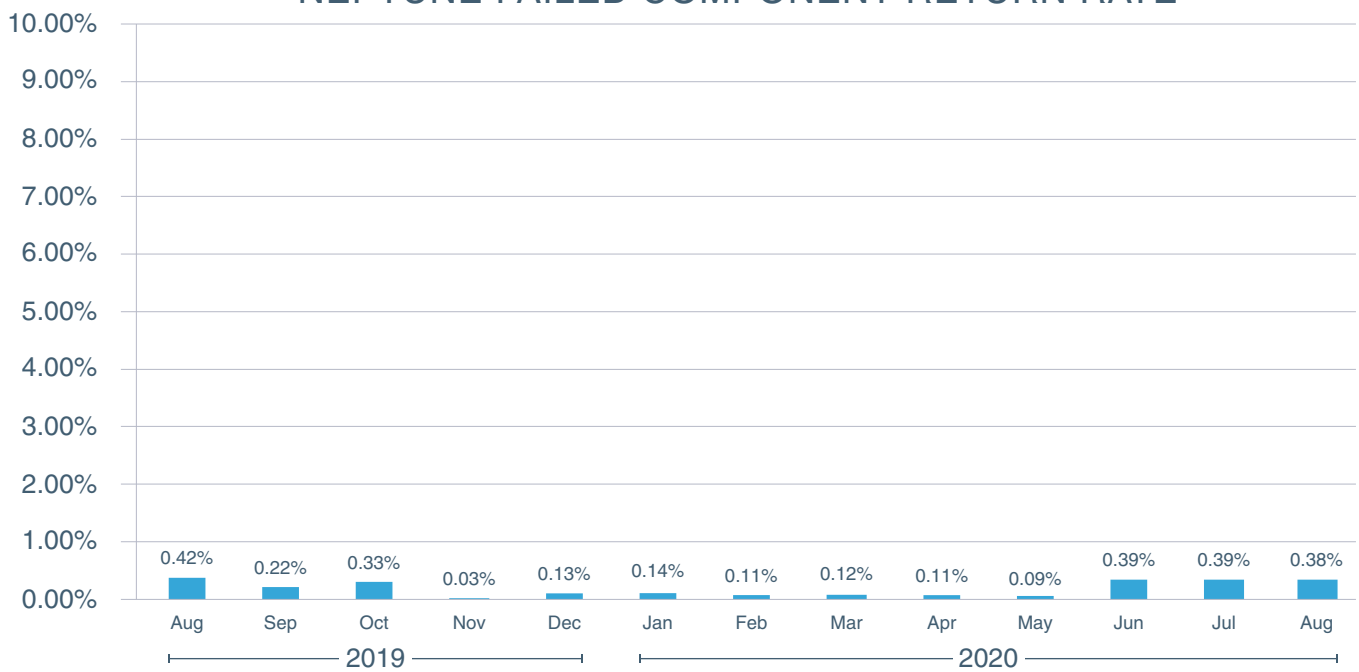
# NEPTUNE

The Neptune™ sound processor is the first and only swimmable sound processor.

**RELIABILITY: 99.15%\***



## NEPTUNE FAILED COMPONENT RETURN RATE



\* Reliability is 1 minus the return rate. The return rate is the average global monthly return rate over a 12-month period from August 2019 to August 2020.

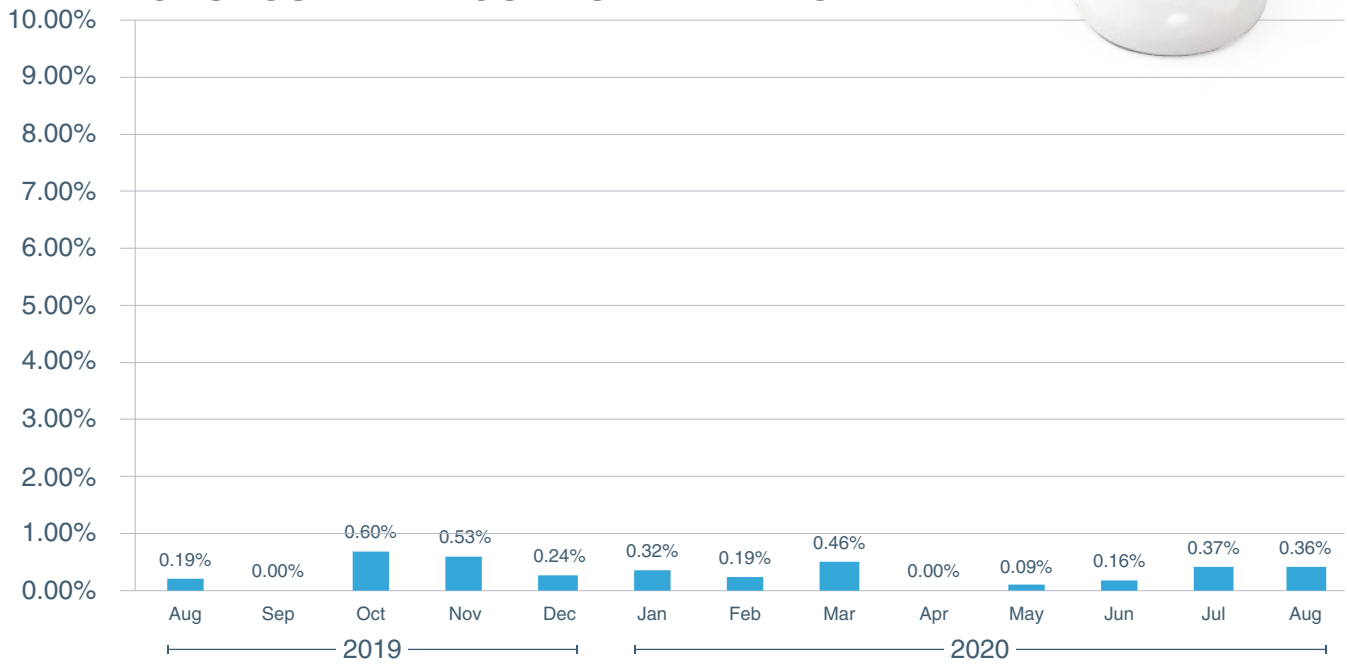
# CHORUS

The Chorus™ sound processor is compatible with C1.0 and C1.2 cochlear implants, and offers integrated Roger™ technology for connectivity and performance.

**RELIABILITY: 99.96%\***



### CHORUS FAILED COMPONENT RETURN RATE



# HARMONY

The Harmony™ sound processor is compatible with C1.0 and C1.2 cochlear implants, providing performance-driven technology.

**RELIABILITY: 99.63%\***

Harmony processor is no longer being commercially marketed in the United States. It is only being provided as an upgrade processor for C1 users, and therefore is out of the scope for the CI86 reporting.



\* Reliability is 1 minus the return rate. The return rate is the average global monthly return rate over a 12-month period from August 2019 to August 2020.

## STANDARD ANSI/AAMI CI86

## HIRES ULTRA 3D V2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
ADULTS	0.6	0.13%	0.00%	0.00%	0.13%
CHILDREN	0.6	0.48%	0.00%	0.00%	0.48%

## HIRES ULTRA V2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories
ADULTS	0.6	0.00%	0.00%	0.00%	0.00%
CHILDREN	0.6	0.00%	0.00%	0.00%	0.00%

## HIRES ULTRA 3D V1

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.82%	0.08%	0.00%	0.89%	1.19%	0.60%
	2	0.89%	0.29%	0.00%	1.17%	1.57%	0.77%
CHILDREN	1	1.25%	0.29%	0.00%	1.54%	2.29%	0.79%
	2	1.51%	1.06%	0.00%	2.57%	3.81%	1.33%

## HIRES ULTRA V1

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.78%	0.03%	0.03%	0.83%	1.03%	0.63%
	2	1.20%	0.23%	0.03%	1.45%	1.73%	1.17%
	3	1.38%	1.25%	0.03%	2.66%	3.10%	2.22%
CHILDREN	1	0.52%	0.09%	0.00%	0.61%	0.88%	0.35%
	2	0.60%	0.60%	0.04%	1.25%	1.66%	0.83%
	3	0.76%	2.95%	0.04%	3.76%	4.70%	2.81%

# HIRES 90K ADVANTAGE

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.65%	0.07%	0.02%	0.74%	0.86%	0.62%
	2	1.14%	0.09%	0.03%	1.26%	1.42%	1.10%
	3	1.39%	0.15%	0.04%	1.57%	1.76%	1.39%
	4	1.64%	0.18%	0.04%	1.86%	2.06%	1.66%
	5	1.81%	0.21%	0.04%	2.06%	2.28%	1.84%
	6	1.96%	0.24%	0.05%	2.26%	2.50%	2.02%
	7	2.11%	0.24%	0.08%	2.43%	2.71%	2.15%
CHILDREN	1	0.75%	0.23%	0.03%	1.00%	1.16%	0.85%
	2	1.07%	0.42%	0.05%	1.54%	1.73%	1.35%
	3	1.38%	0.65%	0.07%	2.10%	2.33%	1.87%
	4	1.58%	0.85%	0.13%	2.56%	2.82%	2.29%
	5	1.69%	1.01%	0.21%	2.92%	3.21%	2.62%
	6	1.82%	1.15%	0.21%	3.18%	3.51%	2.85%
	7	1.87%	1.54%	0.26%	3.67%	4.11%	3.23%

# HIRES 90K vendor A post-mod

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.77%	0.07%	0.02%	0.85%	0.94%	0.76%
	2	1.26%	0.11%	0.04%	1.42%	1.53%	1.30%
	3	1.54%	0.17%	0.06%	1.77%	1.90%	1.64%
	4	1.79%	0.24%	0.08%	2.11%	2.26%	1.97%
	5	1.98%	0.29%	0.09%	2.36%	2.52%	2.21%
	6	2.13%	0.36%	0.12%	2.61%	2.78%	2.44%
	7	2.27%	0.38%	0.13%	2.79%	2.96%	2.61%
	8	2.39%	0.46%	0.14%	2.99%	3.18%	2.80%
	9	2.46%	0.50%	0.15%	3.10%	3.30%	2.91%
	10	2.54%	0.57%	0.16%	3.28%	3.49%	3.08%
	11	2.59%	0.63%	0.16%	3.38%	3.59%	3.16%
	12	2.69%	0.63%	0.16%	3.48%	3.70%	3.26%
	13	2.79%	0.64%	0.18%	3.61%	3.86%	3.37%
	14	2.85%	0.64%	0.18%	3.68%	3.93%	3.42%
CHILDREN	1	0.79%	0.22%	0.03%	1.03%	1.13%	0.93%
	2	1.09%	0.49%	0.04%	1.62%	1.75%	1.49%
	3	1.36%	0.79%	0.07%	2.21%	2.36%	2.06%
	4	1.56%	1.07%	0.10%	2.72%	2.90%	2.55%
	5	1.72%	1.32%	0.14%	3.18%	3.37%	2.99%
	6	1.85%	1.49%	0.15%	3.49%	3.70%	3.29%
	7	1.97%	1.63%	0.17%	3.76%	3.98%	3.55%
	8	2.03%	1.77%	0.20%	4.00%	4.23%	3.77%
	9	2.14%	1.87%	0.21%	4.23%	4.47%	3.98%
	10	2.35%	2.03%	0.26%	4.64%	4.92%	4.36%
	11	2.47%	2.05%	0.29%	4.81%	5.10%	4.51%
	12	2.64%	2.18%	0.32%	5.14%	5.47%	4.81%
	13	2.81%	2.21%	0.35%	5.37%	5.73%	5.01%
	14	2.86%	2.26%	0.35%	5.48%	5.87%	5.09%

# HIRES 90K vendor A all

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.76%	0.08%	0.01%	0.86%	0.95%	0.77%
	2	1.25%	0.14%	0.05%	1.45%	1.56%	1.33%
	3	1.53%	0.21%	0.08%	1.81%	1.95%	1.68%
	4	1.78%	0.31%	0.10%	2.19%	2.34%	2.05%
	5	1.97%	0.38%	0.12%	2.46%	2.62%	2.31%
	6	2.12%	0.47%	0.15%	2.73%	2.90%	2.57%
	7	2.27%	0.51%	0.16%	2.94%	3.12%	2.76%
	8	2.38%	0.63%	0.17%	3.18%	3.36%	2.99%
	9	2.44%	0.73%	0.17%	3.35%	3.55%	3.15%
	10	2.54%	0.84%	0.19%	3.57%	3.78%	3.36%
	11	2.59%	0.93%	0.19%	3.72%	3.94%	3.50%
	12	2.70%	1.00%	0.19%	3.90%	4.13%	3.67%
	13	2.78%	1.07%	0.22%	4.08%	4.33%	3.82%
	14	2.91%	1.22%	0.22%	4.36%	4.65%	4.07%
	15	2.95%	1.34%	0.22%	4.51%	4.84%	4.19%
	16	3.02%	1.47%	0.22%	4.71%	5.11%	4.32%
CHILDREN	1	0.79%	0.23%	0.03%	1.05%	1.15%	0.95%
	2	1.09%	0.51%	0.05%	1.65%	1.78%	1.52%
	3	1.37%	0.82%	0.07%	2.26%	2.41%	2.11%
	4	1.57%	1.12%	0.10%	2.80%	2.97%	2.62%
	5	1.74%	1.39%	0.15%	3.27%	3.46%	3.08%
	6	1.87%	1.58%	0.16%	3.61%	3.82%	3.41%
	7	1.99%	1.75%	0.19%	3.93%	4.15%	3.72%
	8	2.08%	1.96%	0.22%	4.25%	4.48%	4.02%
	9	2.18%	2.07%	0.23%	4.49%	4.74%	4.24%
	10	2.38%	2.26%	0.28%	4.93%	5.21%	4.65%
	11	2.53%	2.32%	0.32%	5.17%	5.47%	4.88%
	12	2.68%	2.57%	0.35%	5.59%	5.93%	5.26%
	13	2.81%	2.66%	0.38%	5.85%	6.22%	5.48%
	14	2.85%	2.97%	0.38%	6.20%	6.62%	5.77%
	15	2.99%	3.32%	0.45%	6.76%	7.33%	6.20%
	16	2.99%	3.32%	0.45%	6.76%	7.33%	6.20%

# HIRES 90K vendor A pre-mod

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	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	1.27%	1.09%	0.49%	2.86%	3.65%	2.06%
	4	1.46%	1.89%	0.55%	3.90%	4.83%	2.98%
	5	1.58%	2.32%	0.61%	4.52%	5.51%	3.53%
	6	1.77%	2.76%	0.68%	5.20%	6.26%	4.14%
	7	2.02%	3.01%	0.74%	5.77%	6.88%	4.65%
	8	2.08%	3.57%	0.74%	6.39%	7.56%	5.22%
	9	2.14%	4.25%	0.74%	7.14%	8.37%	5.91%
	10	2.27%	4.63%	0.81%	7.71%	8.98%	6.43%
	11	2.40%	5.00%	0.81%	8.21%	9.52%	6.90%
	12	2.59%	5.44%	0.81%	8.84%	10.20%	7.49%
	13	2.59%	5.69%	0.87%	9.16%	10.54%	7.79%
	14	2.86%	6.14%	0.87%	9.87%	11.29%	8.44%
	15	2.92%	6.33%	0.87%	10.12%	11.56%	8.69%
	16	3.00%	6.48%	0.87%	10.35%	11.80%	8.89%

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
CHILDREN	1	1.13%	0.79%	0.00%	1.92%	2.82%	1.02%
	2	1.36%	1.36%	0.11%	2.83%	3.92%	1.75%
	3	1.82%	2.17%	0.23%	4.22%	5.53%	2.90%
	4	2.17%	3.09%	0.23%	5.49%	6.98%	4.00%
	5	2.28%	3.91%	0.35%	6.54%	8.16%	4.93%
	6	2.40%	4.72%	0.47%	7.60%	9.33%	5.87%
	7	2.76%	5.54%	0.72%	9.03%	10.89%	7.16%
	8	3.25%	6.60%	0.72%	10.57%	12.58%	8.57%
	9	3.25%	6.96%	0.72%	10.93%	12.96%	8.90%
	10	3.37%	7.43%	0.85%	11.65%	13.74%	9.56%
	11	3.75%	7.91%	0.97%	12.63%	14.79%	10.47%
	12	3.75%	8.86%	0.97%	13.58%	15.81%	11.36%
	13	3.75%	9.22%	0.97%	13.94%	16.20%	11.69%
	14	3.75%	10.06%	0.97%	14.78%	17.09%	12.47%
	15	4.01%	10.55%	0.97%	15.53%	17.88%	13.17%
	16	4.01%	10.55%	0.97%	15.53%	17.88%	13.17%

## HIRES 90K vendor B

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.95%	3.02%	0.00%	3.98%	4.73%	3.22%
	2	1.21%	10.88%	0.09%	12.17%	13.43%	10.91%
	3	1.48%	16.19%	0.18%	17.85%	19.33%	16.37%
	4	1.67%	20.71%	0.23%	22.61%	24.22%	20.99%
	5	1.73%	24.32%	0.28%	26.32%	28.03%	24.62%
	6	1.83%	26.76%	0.28%	28.87%	30.63%	27.12%
	7	1.94%	29.79%	0.28%	32.01%	33.82%	30.20%
	8	2.23%	31.68%	0.28%	34.19%	36.03%	32.35%
	9	2.23%	33.24%	0.28%	35.75%	37.61%	33.89%
	10	2.42%	34.73%	0.28%	37.42%	39.30%	35.55%
	11	2.42%	35.68%	0.28%	38.38%	40.27%	36.49%
	12	2.42%	37.02%	0.28%	39.71%	41.62%	37.81%
	13	2.48%	38.06%	0.28%	40.82%	42.74%	38.91%
	14	2.62%	38.86%	0.28%	41.75%	43.67%	39.83%
	15	2.70%	39.60%	0.28%	42.58%	44.51%	40.64%
CHILDREN	1	0.88%	3.28%	0.00%	4.16%	5.16%	3.15%
	2	1.24%	11.52%	0.07%	12.83%	14.52%	11.15%
	3	1.32%	19.82%	0.07%	21.21%	23.27%	19.15%
	4	1.41%	26.05%	0.07%	27.54%	29.79%	25.28%
	5	1.50%	30.67%	0.17%	32.35%	34.71%	29.98%
	6	1.71%	34.55%	0.17%	36.42%	38.86%	33.99%
	7	1.71%	37.81%	0.17%	39.69%	42.17%	37.20%
	8	1.93%	40.52%	0.17%	42.62%	45.13%	40.11%
	9	1.93%	42.83%	0.17%	44.93%	47.46%	42.40%
	10	1.93%	44.71%	0.17%	46.81%	49.35%	44.27%
	11	1.93%	45.83%	0.17%	47.93%	50.48%	45.39%
	12	2.19%	46.68%	0.30%	49.16%	51.71%	46.62%
	13	2.19%	48.23%	0.30%	50.72%	53.27%	48.17%
	14	2.19%	48.73%	0.44%	51.35%	53.91%	48.80%
	15	2.19%	49.46%	0.44%	52.08%	54.64%	49.52%

# CII BIONIC EAR

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.44%	0.39%	0.00%	0.83%	1.13%	0.52%
	2	0.80%	0.41%	0.00%	1.22%	1.58%	0.85%
	3	1.04%	0.59%	0.00%	1.63%	2.06%	1.21%
	4	1.31%	0.65%	0.00%	1.96%	2.43%	1.50%
	5	1.46%	0.75%	0.00%	2.20%	2.70%	1.71%
	6	1.55%	0.90%	0.00%	2.45%	2.97%	1.93%
	7	1.67%	0.96%	0.00%	2.63%	3.16%	2.09%
	8	1.79%	1.05%	0.00%	2.84%	3.40%	2.28%
	9	1.94%	1.14%	0.00%	3.08%	3.66%	2.50%
	10	2.06%	1.20%	0.00%	3.26%	3.86%	2.67%
	11	2.15%	1.29%	0.00%	3.45%	4.06%	2.83%
	12	2.31%	1.29%	0.00%	3.60%	4.23%	2.97%
	13	2.34%	1.36%	0.00%	3.69%	4.33%	3.06%
	14	2.40%	1.45%	0.00%	3.85%	4.49%	3.20%
	15	2.52%	1.51%	0.00%	4.03%	4.69%	3.37%
	16	2.58%	1.57%	0.00%	4.15%	4.82%	3.48%
	17	2.61%	1.64%	0.00%	4.25%	4.93%	3.57%
	18	2.65%	1.67%	0.00%	4.33%	5.01%	3.64%
CHILDREN	1	0.47%	0.87%	0.00%	1.34%	1.88%	0.80%
	2	1.00%	1.58%	0.00%	2.58%	3.32%	1.83%
	3	1.53%	2.47%	0.00%	4.00%	4.92%	3.08%
	4	1.72%	2.94%	0.00%	4.66%	5.65%	3.66%
	5	2.02%	3.48%	0.00%	5.50%	6.57%	4.43%
	6	2.33%	4.26%	0.00%	6.59%	7.76%	5.42%
	7	2.39%	4.81%	0.00%	7.20%	8.41%	5.98%
	8	2.51%	5.24%	0.00%	7.75%	9.01%	6.49%
	9	2.64%	5.66%	0.00%	8.30%	9.60%	7.00%
	10	2.70%	6.09%	0.00%	8.79%	10.13%	7.46%
	11	2.77%	6.22%	0.00%	8.98%	10.33%	7.63%
	12	3.02%	6.40%	0.00%	9.42%	10.80%	8.05%
	13	3.28%	6.52%	0.00%	9.80%	11.20%	8.40%
	14	3.47%	6.77%	0.00%	10.25%	11.67%	8.82%
	15	3.54%	6.84%	0.00%	10.37%	11.81%	8.94%
	16	3.67%	6.90%	0.00%	10.57%	12.01%	9.12%
	17	3.88%	6.90%	0.00%	10.78%	12.24%	9.32%
	18	3.88%	6.99%	0.00%	10.87%	12.34%	9.40%



# CLARION 1.2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.40%	0.34%	0.08%	0.83%	1.08%	0.57%
	2	0.54%	0.71%	0.20%	1.46%	1.79%	1.12%
	3	0.75%	1.46%	0.31%	2.52%	2.95%	2.08%
	4	0.94%	2.61%	0.45%	3.99%	4.54%	3.45%
	5	1.10%	3.90%	0.56%	5.56%	6.20%	4.93%
	6	1.34%	4.95%	0.62%	6.91%	7.62%	6.21%
	7	1.45%	5.87%	0.69%	8.00%	8.75%	7.25%
	8	1.60%	7.07%	0.77%	9.44%	10.25%	8.64%
	9	1.71%	7.78%	0.93%	10.42%	11.27%	9.58%
	10	1.87%	8.72%	1.11%	11.70%	12.59%	10.82%
	11	2.03%	9.46%	1.16%	12.65%	13.56%	11.73%
	12	2.26%	9.97%	1.25%	13.48%	14.42%	12.53%
	13	2.44%	10.46%	1.30%	14.20%	15.16%	13.24%
	14	2.63%	10.84%	1.32%	14.79%	15.77%	13.81%
	15	2.89%	11.27%	1.39%	15.55%	16.55%	14.55%
	16	3.19%	11.66%	1.44%	16.29%	17.31%	15.28%
	17	3.65%	12.07%	1.51%	17.23%	18.27%	16.19%
	18	4.36%	12.43%	1.54%	18.33%	19.39%	17.26%
	19	4.76%	12.71%	1.62%	19.09%	20.17%	18.00%
	20	5.33%	12.89%	1.73%	19.96%	21.06%	18.85%
	21	5.79%	13.10%	1.81%	20.70%	21.83%	19.57%
	22	5.90%	13.38%	1.94%	21.22%	22.38%	20.05%
	23	6.51%	13.47%	1.94%	21.92%	23.16%	20.68%
CHILDREN	1	0.29%	1.86%	0.06%	2.20%	2.69%	1.72%
	2	0.43%	3.35%	0.12%	3.90%	4.54%	3.26%
	3	0.59%	5.81%	0.30%	6.69%	7.51%	5.86%
	4	0.80%	8.36%	0.45%	9.62%	10.59%	8.64%
	5	0.96%	10.61%	0.74%	12.31%	13.40%	11.23%
	6	1.33%	13.17%	1.01%	15.50%	16.69%	14.31%
	7	1.60%	15.04%	1.21%	17.85%	19.11%	16.59%
	8	1.84%	17.19%	1.46%	20.49%	21.82%	19.17%
	9	2.20%	18.58%	1.86%	22.64%	24.02%	21.27%
	10	2.39%	20.26%	2.34%	24.98%	26.41%	23.56%
	11	2.65%	21.40%	2.60%	26.65%	28.10%	25.20%
	12	2.85%	22.08%	2.83%	27.76%	29.23%	26.29%
	13	3.08%	22.73%	3.03%	28.84%	30.33%	27.36%
	14	3.44%	23.36%	3.15%	29.95%	31.45%	28.44%
	15	3.88%	24.54%	3.35%	31.76%	33.29%	30.24%
	16	4.61%	25.40%	3.64%	33.65%	35.20%	32.10%
	17	5.20%	26.12%	3.89%	35.21%	36.78%	33.64%
	18	6.29%	26.77%	4.11%	37.17%	38.76%	35.59%
	19	7.47%	27.21%	4.31%	38.98%	40.59%	37.37%
	20	8.77%	27.64%	4.42%	40.83%	42.46%	39.19%
	21	9.49%	27.98%	4.65%	42.13%	43.79%	40.46%
	22	10.73%	28.52%	4.89%	44.13%	45.88%	42.38%
	23	11.50%	28.83%	4.89%	45.22%	47.06%	43.38%

## CONTACT US

This report is intended to provide both professionals and our users with relevant information on the reliability of our products. If you have any questions, please contact us by emailing [hear@AdvancedBionics.com](mailto:hear@AdvancedBionics.com) or visit [AdvancedBionics.com](https://www.AdvancedBionics.com) for more general information.



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