

# Reliability Report December 2023

IMPLANTABLE COCHLEAR STIMULATORS AND SOUND PROCESSORS

# **POWERFUL CONNECTIONS**

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## A MESSAGE FROM THE PRESIDENT OF ADVANCED BIONICS

As Advanced Bionics celebrates 30 Years of changing lives with innovative hearing technology, we honor our commitment to delivering products of the utmost reliability and quality. We understand the significations of offering hearing solutions that stand the test of time and enabling those who use our technology to achieve physical, mental, and social well-being.

AB's dedication to reliability is embedded in our rigorous and improved quality control processes and transparent adherence to industry reporting standards. We believe that quality matters, and it is not merely a standard, but a philosophy that governs every stage of our product development. From the initial design to the engineering process, stringent measures are in place to ensure that each part of our hearing system meets, or exceeds, the expectations of those who use AB technology every day. And our dedication to comprehensive communication is why we report in full accordance with International Standard ISO 5841-2<sup>1</sup>, the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations<sup>2</sup> and ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.<sup>3</sup>

At Advanced Bionics, we recognize the vital role that product reliability plays in fostering trust and satisfaction with our hearing healthcare partners and those who utilize AB technology for hearing. Therefore, we continually invest in research and development, innovation, and technology to enhance the reliability of our cochlear implant system. According to the only standard developed specifically for cochlear implants, AB now has the lowest number of device removals among all manufactures. Rest assured, when you choose AB, you are choosing a solution built on a foundation of improved quality.

I am pleased to present our latest semi-annual report on reliability as part of our commitment to partnership and communication with the hearing healthcare community. The Report includes information on our implants and sound processors, including the Marvel CI. Marvel CI is the first sound processor which can be fully programmed remotely, which I see as the biggest change we have seen in making cochlear implant care more accessible and convenient in all of our 30 years.

AA.

Victoria E. Carr-Brendel, Ph.D. PRESIDENT, ADVANCED BIONICS

- 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

## Number of registered HiRes Ultra 3D V2 implants

As of October 13, 2023.

Date of first commercial introduction: 2019.ª

STANDARD	ADULTS	CHILDREN	COMBINED	←
ISO 5841-2:2014	17571	6016	23587 <sup>b</sup>	
ANSI/AAMI CI86	18666°	4921	23587	

Number of registered users is detailed for adults, children (defined as less than 18 years at implantation by ISO 5841, and less than 10 years at implantation by Cl86), and a combination of all ages in accordance with reporting methodologies.

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use		1.5		2.5	3	3.5
ADULTS	99.99%	99.97%	99.96%	99.96%	99.96%	99.96%
COMBINED	99.98%	99.96%	99.95%	99.93%	99.93%	99.87%
CHILDREN	99.94%	99.91%	99.91%	99.86%	99.86%	N/A*

\*Sample size is not large enough for reporting



The ANSI/AAMI CI86 Standard requires that all removed devices are classified into three categories based on the rationale for explantation: device failure, medical reason, or inconclusive.

#### COMBINED ADULT AND CHILDREN

Year	Medical CRP	Medical CRP Device CRP Inconclusive CRP		Total All Categories	Total		
fear				Iotal All Categories	CI Higher	CI Lower	
1	0.73%	0.02%	0.00%	0.76%	0.88%	0.64%	
1.5	0.89%	0.04%	0.01%	0.93%	1.07%	0.80%	
2	1.05%	0.05%	0.01%	1.10%	1.26%	0.94%	
2.5	1.18%	0.06%	0.01%	1.25%	1.43%	1.07%	
3	1.28%	0.06%	0.01%	1.35%	1.56%	1.13%	
3.5	1.28%	0.11%	0.01%	1.40%	1.64%	1.16%	

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

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>™</sup> Ultra 3D (V2) cochlear implant is an update to the previous HiRes Ultra 3D (V1) device. Based off the standard HiRes Ultra platform but featuring an innovative multi-magnet assembly, the HiRes Ultra 3D V2 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 recipient can be expected to have a hassle free and pain free experience.

The HiRes Ultra 3D (V2) device has a Cumulative Survival Rate (CSR) of 99.87%.

## Number of registered HiRes Ultra 3D V2 implants

As of October 13, 2023. Date of first commercial introduction: 2019.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	17571	6016	23587 <sup>b</sup>
ANSI/AAMI CI86	18666°	4921	23587

a. 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.

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

c. 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 RATE

Years in use	1	1.5	2	2.5	3	3.5
ADULTS	99.99%	99.97%	99.96%	99.96%	99.96%	99.96%
COMBINED	99.98%	99.96%	99.95%	99.93%	99.93%	99.87%
CHILDREN	99.94%	99.91%	99.91%	99.86%	99.86%	N/A*

\*Sample size is not large enough for reporting



5.00% - All categories - Medical - Device ---- Inconclusive 4.50% 4.00% 3.50% 3.00% CRP 2.50% 2.00% 1.50% 1.00% 0.50% 0.00% 1.5 2 2.5 3 3.5 1 Years

#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS





#### REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



#### COMBINED ADULT AND CHILDREN

Year	Medical CRP Device CRP Inconclusive CRP		Total All Categories	Total		
Tear		Device Onr		Iotal All Calegories	CI Higher	CI Lower
1	0.73%	0.02%	0.00%	0.76%	0.88%	0.64%
1.5	0.89%	0.04%	0.01%	0.93%	1.07%	0.80%
2	1.05%	0.05%	0.01%	1.10%	1.26%	0.94%
2.5	1.18%	0.06%	0.01%	1.25%	1.43%	1.07%
3	1.28%	0.06%	0.01%	1.35%	1.56%	1.13%
3.5	1.28%	0.11%	0.01%	1.40%	1.64%	1.16%

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

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.



## Number of registered HiRes Ultra V2 implants

As of October 13, 2023. Date of first commercial introduction: 2019.<sup>a</sup>

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	3048	5116	8164 <sup>b</sup>
ANSI/AAMI CI86	3545°	4619	8164

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use		1.5		2.5
ADULTS	100.00%	100.00%	100.00%	100.00%
COMBINED	99.99%	99.99%	99.99%	99.99%
CHILDREN	99.98%	99.98%	99.98%	99.98%

#### 5.00% All categories Medical - Device ---- Inconclusive 4.50% 4.00% 3.50% 3.00% CRP 2.50% 2.00% 1.50% 1.00% 0.50% 0.00% 1.5 2.5 2

#### REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



#### REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



#### COMBINED ADULTS AND CHILDREN

Year	Year Medical CRP	dical CRP Device CRP Inconclusive CRI	Inconclusive CRP	Total All Catagorian	Total		
ieai				Total All Categories	CI Higher	CI Lower	
1	0.31%	0.01%	0.00%	0.32%	0.45%	0.19%	
1.5	0.37%	0.01%	0.00%	0.38%	0.53%	0.23%	
2	0.37%	0.01%	0.00%	0.38%	0.53%	0.23%	
2.5	0.37%	0.01%	0.00%	0.38%	0.53%	0.23%	

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 3D V1

The HiRes<sup>™</sup> Ultra 3D (V1) cochlear implant is an update to the previous HiRes Ultra (V1) device. 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 October 13, 2023.

Last year of distribution: subject to voluntary field action February, 2020.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4985	1709	6694 <sup>b</sup>
ANSI/AAMI CI86	5253°	1441	6694

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use	1	1.5	2	2.5	3	3.5	4	4.5
ADULTS	99.86%	99.31%	97.53%	94.99%	91.93%	87.94%	85.07%	83.02%
COMBINED	99.79%	98.99%	96.45%	93.19%	89.41%	85.04%	81.72%	79.18%
CHILDREN	99.59%	98.04%	93.31%	87.90%	81.96%	76.48%	71.81%	N/A*

\*Sample size is not large enough for reporting

#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS







#### REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



#### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total		
ieai				Iotal All Categories	CI Higher	CI Lower	
1	0.97%	0.21%	0.01%	1.20%	1.46%	0.94%	
1.5	1.41%	1.03%	0.08%	2.50%	2.87%	2.12%	
2	1.78%	3.50%	0.17%	5.38%	5.92%	4.84%	
2.5	2.21%	6.79%	0.19%	9.01%	9.70%	8.32%	
3	2.69%	10.57%	0.20%	13.15%	13.96%	12.34%	
3.5	2.93%	14.89%	0.28%	17.61%	18.53%	16.69%	
4	3.14%	18.05%	0.32%	20.88%	21.87%	19.89%	
4.5	3.29%	20.53%	0.32%	23.39%	24.50%	22.29%	

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>™</sup> Ultra (V1) cochlear implant was subject to a Voluntary Field Action initiated by Advanced Bionics in February 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 October 13, 2023.

Last year of distribution: subject to voluntary field action February, 2020.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	8061	4492	12553 <sup>b</sup>
ANSI/AAMI CI86	8620°	3933	12553

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use	1	1.5	2	2.5	3	3.5	4	4.5	5	5.5	6	6.5
ADULTS	99.98%	99.90%	99.53%	98.60%	96.81%	94.21%	91.13%	88.21%	85.01%	82.07%	79.58%	77.45%
COMBINED	99.94%	99.78%	99.28%	98.07%	95.74%	92.50%	88.67%	84.95%	81.45%	78.05%	75.56%	73.56%
CHILDREN	99.89%	99.57%	98.83%	97.12%	93.84%	89.46%	84.22%	78.83%	74.57%	69.96%	67.37%	N/A*

\*Sample size is not large enough for reporting

REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS

## REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION





#### REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



#### COMBINED ADULTS AND CHILDREN

Veer		Device CDD		Total All Catagorian	Total		
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower	
1	0.71%	0.06%	0.02%	0.78%	0.94%	0.63%	
1.5	0.93%	0.22%	0.02%	1.17%	1.36%	0.98%	
2	1.15%	0.70%	0.05%	1.89%	2.13%	1.65%	
2.5	1.39%	1.91%	0.08%	3.35%	3.67%	3.04%	
3	1.54%	4.24%	0.11%	5.82%	6.23%	5.41%	
3.5	1.70%	7.47%	0.13%	9.16%	9.67%	8.65%	
4	1.84%	11.28%	0.15%	13.05%	13.65%	12.46%	
4.5	1.95%	15.01%	0.19%	16.82%	17.50%	16.14%	
5	2.04%	18.48%	0.19%	20.29%	21.04%	19.54%	
5.5	2.15%	21.87%	0.20%	23.71%	24.54%	22.87%	
6	2.21%	24.40%	0.23%	26.24%	27.18%	25.31%	
6.5	2.21%	26.36%	0.23%	28.16%	29.24%	27.08%	

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 October 13, 2023.

Last year of distribution: 2023.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	18316	24551	42867 <sup>b</sup>
ANSI/AAMI CI86	20899°	21968	42867

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use	1	2	3	4	5	6	7	8	9	10
ADULTS	99.95%	99.92%	99.87%	99.82%	99.80%	99.75%	99.74%	99.70%	99.64%	99.58%
COMBINED	99.88%	99.78%	99.66%	99.57%	99.48%	99.40%	99.34%	99.26%	99.14%	99.07%
CHILDREN	99.82%	99.68%	99.50%	99.37%	99.22%	99.12%	98.98%	98.87%	98.68%	98.61%



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS

#### REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION





#### REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



#### COMBINED ADULT AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Catagorias	То	tal
rear	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower
1	0.69%	0.13%	0.02%	0.83%	0.92%	0.75%
2	1.07%	0.22%	0.03%	1.32%	1.43%	1.22%
3	1.33%	0.35%	0.04%	1.71%	1.83%	1.58%
4	1.58%	0.44%	0.05%	2.07%	2.21%	1.93%
5	1.77%	0.53%	0.08%	2.36%	2.51%	2.22%
6	1.91%	0.60%	0.08%	2.58%	2.74%	2.42%
7	2.04%	0.66%	0.09%	2.78%	2.94%	2.61%
8	2.18%	0.73%	0.10%	2.99%	3.17%	2.82%
9	2.23%	0.82%	0.13%	3.16%	3.36%	2.97%
10	2.36%	0.85%	0.17%	3.36%	3.58%	3.14%

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<sup>™</sup> cochlear implant offers access to advanced sound coding technologies. It has undergone manufacturing modifications, 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 October 13, 2023.

Last year of distribution: 2018.<sup>a</sup>

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	34449	47221	81670 <sup>b</sup>
ANSI/AAMI CI86	40389°	41281	81670

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use	1	2	3	4	5	6	7	8	9
ADULTS	99.95%	99.93%	99.89%	99.82%	99.79%	99.73%	99.71%	99.67%	99.62%
COMBINED	99.88%	99.75%	99.60%	99.46%	99.33%	99.23%	99.16%	99.05%	98.97%
CHILDREN	99.83%	99.62%	99.39%	99.18%	98.99%	98.85%	98.74%	98.58%	98.47%
Years in use	10	11	12	13	14	15	16	17	18
Years in use ADULTS	10 99.56%	<b>11</b> 99.54%	12 99.52%	13 99.51%	14 99.49%	15 99.48%	16 99.42%	17 99.35%	18 99.35%

\*Sample size is not large enough for reporting





REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES

REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN 14 00% All categories - Medical -- Device ---- Inconclusive 12.00% 10.00% 8.00% 6.00% CRP 4.00% 2.00% 0.00% 2 3 4 5 6 8 9 10 11 12 13 14 15 16 17 7

Years





#### COMBINED ADULTS AND CHILDREN

Veer	Madiaal CDD			Total All Catagorian	To	tal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower
1	0.78%	0.13%	0.02%	0.93%	1.00%	0.86%
2	1.20%	0.28%	0.04%	1.52%	1.60%	1.43%
3	1.47%	0.45%	0.06%	1.97%	2.06%	1.87%
4	1.71%	0.60%	0.08%	2.38%	2.48%	2.27%
5	1.91%	0.73%	0.10%	2.72%	2.84%	2.61%
6	2.05%	0.85%	0.11%	2.99%	3.11%	2.87%
7	2.18%	0.92%	0.12%	3.20%	3.32%	3.07%
8	2.30%	1.02%	0.14%	3.43%	3.56%	3.30%
9	2.40%	1.09%	0.16%	3.61%	3.75%	3.48%
10	2.54%	1.18%	0.18%	3.86%	4.01%	3.72%
11	2.67%	1.21%	0.19%	4.03%	4.18%	3.88%
12	2.83%	1.25%	0.21%	4.25%	4.41%	4.09%
13	2.97%	1.28%	0.22%	4.41%	4.58%	4.25%
14	3.10%	1.31%	0.23%	4.59%	4.77%	4.41%
15	3.22%	1.35%	0.25%	4.77%	4.96%	4.58%
16	3.32%	1.42%	0.27%	4.95%	5.16%	4.75%
17	3.45%	1.50%	0.27%	5.15%	5.39%	4.91%
18	3.64%	1.50%	0.32%	5.39%	5.70%	5.07%

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 October 13, 2023. Last year of distribution: 2018.<sup>a</sup>

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	35900	48319	84219 <sup>b</sup>
ANSI/AAMI CI86	42050°	42169	84219

a. 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.

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

c. 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 RATE

Years in use	1	2	3	4	5	6	7	8	9	10
ADULTS	99.94%	99.90%	99.86%	99.77%	99.74%	99.66%	99.64%	99.58%	99,49%	99.42%
COMBINED	99.87%	99.73%	99.58%	99.42%	99.29%	99.17%	99.09%	98.97%	98.86%	98.75%
CHILDREN					98.95%					
CHILDREN	99.82%	99.60%	99.37%	99.15%	98.95%	98.80%	98.67%	98.49%	98.36%	98.21%
Years in use	11	12	13	14	1	5	16	17	18	19
ADULTS	99.35%	99.30%	99.27%	99.21%	% 99.	17%	99.11%	98.94%	98.86%	98.78%
COMBINED	98.69%	98.60%	98.56%	98.46%	% 98.	39%	98.25%	98.11%	97.99%	97.86%
CHILDREN	98.17%	98.04%	97.98%	97.85%	% 97.	73%	97.52%	97.40%	97.24%	97.04%

#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS

#### REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION











#### COMBINED ADULTS AND CHILDREN

Veer	Madiaal CDD	Device CDD		Total All Catagorian	То	tal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower
1	0.78%	0.14%	0.02%	0.94%	1.01%	0.88%
2	1.20%	0.31%	0.04%	1.54%	1.63%	1.46%
3	1.47%	0.48%	0.07%	2.01%	2.11%	1.92%
4	1.71%	0.66%	0.09%	2.45%	2.55%	2.34%
5	1.91%	0.80%	0.11%	2.80%	2.92%	2.69%
6	2.05%	0.93%	0.13%	3.09%	3.21%	2.97%
7	2.19%	1.01%	0.14%	3.32%	3.45%	3.20%
8	2.32%	1.14%	0.16%	3.59%	3.72%	3.46%
9	2.41%	1.24%	0.17%	3.78%	3.92%	3.65%
10	2.55%	1.35%	0.20%	4.06%	4.20%	3.92%
11	2.69%	1.40%	0.21%	4.26%	4.41%	4.11%
12	2.85%	1.49%	0.23%	4.52%	4.68%	4.36%
13	2.98%	1.54%	0.24%	4.71%	4.88%	4.54%
14	3.12%	1.64%	0.26%	4.95%	5.13%	4.77%
15	3.24%	1.72%	0.27%	5.16%	5.35%	4.97%
16	3.34%	1.83%	0.28%	5.38%	5.59%	5.17%
17	3.46%	1.96%	0.30%	5.63%	5.87%	5.40%
18	3.59%	2.08%	0.32%	5.90%	6.18%	5.62%
19	3.76%	2.21%	0.32%	6.19%	6.54%	5.84%

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 October 13, 2023. Last year of distribution: 2005.<sup>a</sup>

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	1451	1098	2549 <sup>b</sup>
ANSI/AAMI CI86	1661°	888	2549

a. 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.

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

c. 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 RATE

Years in use	1	2	3	4	5	6	7	8	9	10
ADULTS	99.59%	99.31%	99.10%	98.60%	98.46%	98.10%	97.96%	97.53%	96.95%	96.66%
COMBINED	99.53%	99.17%	98.85%	98.28%	97.96%	97.51%	97.18%	96.52%	95.94%	95.61%
CHILDREN	99.45%	98.99%	98.52%	97.86%	97.29%	96.72%	96.14%	95.18%	94.60%	94.21%
Years in use	11	12	13	14	1	5	16	17	18	19
ADULTS	96.16%	95.72%	95.58%	95.21	% 94.9	99% 9	94.92%	94.55%	94.40%	94.32%
COMBINED	95.19%	94.61%	94.36%	93.90	% 93.6	65% 9	93.35%	93.06%	92.89%	92.74%
CHILDREN	93.91%	93.13%	92.73%	92.14	% 91.8	35% 9	91.25%	91.05%	90.85%	90.62%

CSR

#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION









#### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Catagorian	To	tal
rear				Total All Categories	Cl Higher	CI Lower
1	0.83%	0.55%	0.00%	1.37%	1.83%	0.92%
2	1.18%	1.03%	0.20%	2.40%	2.99%	1.80%
3	1.58%	1.47%	0.40%	3.42%	4.13%	2.71%
4	1.87%	2.31%	0.44%	4.56%	5.37%	3.75%
5	1.99%	2.88%	0.52%	5.31%	6.18%	4.44%
6	2.11%	3.45%	0.61%	6.06%	6.98%	5.13%
7	2.48%	3.89%	0.73%	6.96%	7.95%	5.97%
8	2.73%	4.58%	0.73%	7.87%	8.92%	6.82%
9	2.77%	5.16%	0.73%	8.46%	9.54%	7.38%
10	2.90%	5.61%	0.82%	9.09%	10.21%	7.97%
11	3.11%	5.98%	0.86%	9.68%	10.83%	8.53%
12	3.28%	6.59%	0.86%	10.44%	11.62%	9.25%
13	3.32%	6.88%	0.91%	10.79%	12.00%	9.58%
14	3.54%	7.46%	0.91%	11.54%	12.79%	10.30%
15	3.67%	7.75%	0.91%	11.94%	13.20%	10.68%
16	3.75%	8.04%	0.91%	12.29%	13.57%	11.02%
17	3.84%	8.29%	0.95%	12.65%	13.95%	11.36%
18	3.93%	8.50%	0.95%	12.93%	14.24%	11.62%
19	4.08%	8.64%	0.95%	13.20%	14.52%	11.88%

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 October 13, 2023.

Last year of distribution: subject to voluntary recall in 2006.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	2214	1847	4061 <sup>b</sup>
ANSI/AAMI CI86	2559°	1502	4061

a. 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.

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

c. 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 RATE

Years in use	1	2	3	4	5	6	7	8	9
ADULTS	97.90%	91.91%	87.65%	83.89%	80.67%	78.42%	75.65%	73.58%	72.20%
COMBINED	97.79%	91.57%	86.25%	81.94%	78.48%	75.77%	72.82%	70.64%	68.80%
CHILDREN	97.65%	91.17%	84.58%	79.61%	75.86%	72.59%	69.43%	67.10%	64.70%
Years in use	10	11	12	13	14	15	16	17	18
Years in use ADULTS	10 70.82%	<b>11</b> 69.95%	12 68.56%	<b>13</b> 67.58%	14 66.80%	15 66.28%	16 65.81%	<b>17</b> 65.17%	18 64.86%

\*Sample size is not large enough for reporting



REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



**REMOVAL RATES ANALYSIS CATEGORIES** 

FOR CHILDREN

CRP



#### COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	То	tal
Teal				Iotal All Galegones	CI Higher	CI Lower
1	0.93%	3.12%	0.00%	4.02%	4.62%	3.41%
2	1.33%	11.09%	0.08%	12.34%	13.36%	11.33%
3	1.56%	17.53%	0.14%	18.93%	20.13%	17.72%
4	1.74%	22.61%	0.14%	24.07%	25.39%	22.75%
5	1.94%	26.63%	0.21%	28.20%	29.59%	26.81%
6	2.08%	29.56%	0.21%	31.17%	32.60%	29.74%
7	2.15%	32.62%	0.21%	34.21%	35.68%	32.75%
8	2.42%	34.77%	0.21%	36.48%	37.97%	35.00%
9	2.46%	36.65%	0.21%	38.33%	39.84%	36.83%
10	2.58%	38.17%	0.21%	39.89%	41.40%	38.37%
11	2.66%	39.15%	0.21%	40.89%	42.41%	39.37%
12	2.83%	40.28%	0.29%	42.14%	43.67%	40.62%
13	2.87%	41.50%	0.29%	43.35%	44.88%	41.82%
14	3.00%	42.20%	0.34%	44.13%	45.66%	42.59%
15	3.04%	42.96%	0.34%	44.88%	46.42%	43.34%
16	3.09%	43.35%	0.38%	45.31%	46.85%	43.77%
17	3.22%	44.02%	0.38%	46.03%	47.57%	44.49%
18	3.29%	44.60%	0.38%	46.63%	48.19%	45.08%

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 October 13, 2023.

Last year of distribution: 2004.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	3017	2094	5111 <sup>b</sup>
ANSI/AAMI CI86	3394°	1717	5111

a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use	1	2	3	4	5	6	7	8	9	10	11
ADULTS	99.77%	99.70%	99.60%	99.53%	99.50%	99.43%	99.40%	99.33%	99.26%	99.22%	99.12%
COMBINED	99.65%	99.41%	99.07%	98.89%	98.75%	98.51%	98.41%	98.23%	98.02%	97.96%	97.86%
CHILDREN	99.47%	98.99%	98.31%	97.97%	97.67%	97.18%	96.98%	96.63%	96.22%	96.12%	96.02%
Years in use	12	13	14	15	16	17	18	19	20	21	22
Years in use ADULTS	<b>12</b> 99.12%	<b>13</b> 99.12%	14 99.09%	15 99.05%	<b>16</b> 99.02%	<b>17</b> 98.98%	18 98.95%	<b>19</b> 98.88%	<b>20</b> 98.84%	<b>21</b> 98.80%	<b>22</b> 98.64%



#### 30.00% - All categories ---- Medical ---- Device ---- Inconclusive 27.00% 24.00% 21.00% 18.00% CRP 15.00% 12.00% 9.00% 6.00% 3.00% 0.00% 14 15 16 17 18 19 20 21 22 6 8 9 10 11 12 13 Years

REMOVAL RATES ANALYSIS CATEGORIES

FOR ADULTS

#### REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



FOR CHILDREN ---- Inconclusive All categories Medical - Device

30.00%

27.00%

24.00%

21.00%

18.00%

12 00%

9.00%

6.00%

3.00%

0.00%

3

4 5

2

6

9 10

Years

8

11 12 13 14 15 16 17 18 19 20 21

CRP 15.00% REMOVAL RATES ANALYSIS CATEGORIES





#### COMBINED ADULTS AND CHILDREN

		D : 000		<b>T</b>	To	tal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower
1	0.33%	0.51%	0.04%	0.88%	1.14%	0.62%
2	0.67%	0.75%	0.20%	1.61%	1.95%	1.26%
3	1.03%	1.16%	0.30%	2.47%	2.89%	2.04%
4	1.23%	1.36%	0.40%	2.96%	3.42%	2.49%
5	1.45%	1.58%	0.52%	3.51%	4.01%	3.00%
6	1.59%	1.94%	0.66%	4.14%	4.68%	3.59%
7	1.71%	2.16%	0.82%	4.63%	5.21%	4.05%
8	1.83%	2.37%	0.99%	5.10%	5.71%	4.50%
9	2.03%	2.57%	1.07%	5.57%	6.20%	4.94%
10	2.18%	2.73%	1.07%	5.87%	6.52%	5.22%
11	2.28%	2.83%	1.15%	6.15%	6.81%	5.49%
12	2.53%	2.88%	1.20%	6.46%	7.14%	5.79%
13	2.67%	2.92%	1.22%	6.66%	7.34%	5.97%
14	2.75%	3.06%	1.24%	6.89%	7.59%	6.20%
15	2.83%	3.12%	1.24%	7.03%	7.73%	6.33%
16	2.94%	3.18%	1.26%	7.21%	7.92%	6.50%
17	3.06%	3.25%	1.30%	7.43%	8.15%	6.71%
18	3.14%	3.31%	1.36%	7.63%	8.35%	6.90%
19	3.39%	3.41%	1.36%	7.96%	8.71%	7.22%
20	3.65%	3.41%	1.41%	8.25%	9.01%	7.49%
21	3.73%	3.44%	1.44%	8.38%	9.14%	7.61%
22	4.16%	3.63%	1.48%	9.00%	9.83%	8.18%

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 October 13, 2023.

Last year of distribution: 2004.ª

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4330	4155	8485 <sup>b</sup>
ANSI/AAMI CI86	4964°	3521	8484

a. 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.

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

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. C.



## ISO 5841-2:2014

#### CUMULATIVE SURVIVAL RATE

Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13
ADULTS	99.84%	99.63%	99.00%	98.03%	96.82%	95.94%	95.08%	94.08%	93.47%	92.72%	91.95%	91.43%	91.06%
COMBINED	99.47%	98.80%	97.61%	96.11%	94.44%	92.92%	91.76%	90.37%	89.47%	88.41%	87.57%	86.97%	86.47%
CHILDREN	99.08%	97.93%	96.15%	94.09%	91.93%	89.73%	88.25%	86.45%	85.22%	83.83%	82.92%	82.23%	81.58%
Years in use	14	15	16	17	18	19	20	21	22	23	24	25	26
Years in use ADULTS	14 90.65%	15 90.32%	16 90.03%	17 89.60%	18 89.30%	19 88.97%	<b>20</b> 88.72%	21 88.59%	<b>22</b> 88.40%	<b>23</b> 88.16%	<b>24</b> 87.97%	<b>25</b> 87.85%	26 87.85%



#### REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS





REMOVAL RATES ANALYSIS CATEGORIES

FOR CHILDREN

- Device

9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

Medical

Years

All categories

----

7

Inconclusive

100.00%

90.00%

80.00%

70.00%

60.00%

40.00%

30.00%

20.00%

10.00%

0.00%

3 4 5 6 8

СВР 50.00%



Years

REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



#### COMBINED ADULTS AND CHILDREN

Veer	Madical CDD			Total All Catagorian	To	tal
Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower
1	0.26%	0.86%	0.13%	1.25%	1.49%	1.01%
2	0.38%	1.63%	0.21%	2.21%	2.52%	1.90%
3	0.55%	2.92%	0.36%	3.80%	4.21%	3.39%
4	0.78%	4.53%	0.51%	5.75%	6.25%	5.26%
5	0.94%	6.23%	0.75%	7.81%	8.39%	7.24%
6	1.16%	7.84%	0.92%	9.75%	10.38%	9.11%
7	1.34%	9.13%	1.08%	11.32%	12.00%	10.65%
8	1.57%	10.69%	1.29%	13.24%	13.96%	12.51%
9	1.79%	11.64%	1.54%	14.57%	15.32%	13.81%
10	2.04%	12.84%	1.88%	16.22%	17.01%	15.43%
11	2.24%	13.73%	2.07%	17.41%	18.22%	16.60%
12	2.51%	14.31%	2.30%	18.38%	19.21%	17.55%
13	2.73%	14.84%	2.42%	19.16%	20.01%	18.32%
14	2.96%	15.32%	2.52%	19.90%	20.75%	19.04%
15	3.33%	16.04%	2.65%	20.98%	21.86%	20.11%
16	3.83%	16.59%	2.82%	22.05%	22.93%	21.16%
17	4.30%	17.11%	3.02%	23.06%	23.96%	22.16%
18	5.14%	17.57%	3.09%	24.23%	25.14%	23.31%
19	5.89%	17.97%	3.22%	25.28%	26.21%	24.35%
20	6.77%	18.24%	3.33%	26.31%	27.25%	25.36%
21	7.46%	18.49%	3.44%	27.17%	28.12%	26.21%
22	8.14%	18.86%	3.58%	28.14%	29.11%	27.17%
23	8.95%	19.22%	3.62%	29.11%	30.10%	28.13%
24	9.67%	19.56%	3.75%	30.06%	31.06%	29.06%
25	10.21%	19.82%	3.83%	30.76%	31.79%	29.73%
26	10.70%	19.93%	3.96%	31.33%	32.40%	30.26%

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 technologyforward 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 in the combined data.

## Number of registered C1.0 implants

As of October 13, 2023.

Last year of distribution: 1997.<sup>a</sup>

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	294°	50	344 <sup>b</sup>
ANSI/AAMI CI86	_	_	_



a. 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.

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

c. 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.



#### CUMULATIVE SURVIVAL RATE

Years in use			3	4	5	6	7	8	9	10	11	12	13	14
ADULTS	100.00%	100.00%	99.65%	98.94%	97.52%	97.16%	96.81%	96.45%	95.37%	95.37%	95.37%	95.37%	95.37%	95.00%
COMBINED	100.00%	100.00%	99.70%	99.09%	97.87%	97.56%	97.25%	96.94%	96.02%	96.02%	96.02%	96.02%	95.70%	95.38%
Years in use	15	16	17	18	19	20	2	1	22	23	24	25	26	27
Years in use ADULTS	15 95.00%	<b>16</b> 94.63%	17 94.63%									<b>25</b> 93.08%	<b>26</b> 93.08%	<b>27</b> 93.08%

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 measure of reliability 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. Processors that meet all specifications are included and they are classified as no fault found. Where available, the number of registered users is shown, categorized into adult, children, and combined.



## NAÍDA CI MARVEL AND SKY CI MARVEL

The Naída<sup>™</sup> CI M sound processor for adults and Sky CI<sup>™</sup> M sound processor for children are the newest Advanced Bionics products integrated with the latest advancements from Phonak, the Marvel platform. With built-in 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.

## RELIABILITY: 99.32%<sup>a</sup>



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

Cause	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 2023	Aug 2023	Sep 2023
MECHANICAL	0.19%	0.20%	0.18%	0.12%	0.12%	0.25%	0.21%	0.17%	0.19%	0.37%	0.25%	0.17%
MOISTURE	0.01%	0.02%	0.03%	0.05%	0.09%	0.02%	0.01%	0.04%	0.04%	0.10%	0.11%	0.19%
ELECTRICAL	0.51%	0.39%	0.21%	0.32%	0.36%	0.38%	0.28%	0.35%	0.40%	0.37%	0.46%	0.42%
OTHER	0.03%	0.19%	0.22%	0.03%	0.02%	0.07%	0.01%	0.06%	0.04%	0.00%	0.09%	0.00%

a. Reliability is 1 minus the return rate. The return rate is the average global monthly return rate between October 2022 and September 2023.

b. The number per month represent the unit that complete failure analysis in that month.





## NAÍDA CI Q SERIES

The Naída<sup>™</sup> CI Q sound processors feature state-of-the-art technologies exclusively available from Advanced Bionics and Phonak for the best possible hearing experience.



## RELIABILITY: 99.90%<sup>a</sup>



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

Cause	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 2023	Aug 2023	Sep 2023
MECHANICAL	0.06%	0.05%	0.04%	0.05%	0.03%	0.04%	0.04%	0.04%	0.05%	0.06%	0.04%	0.01%
MOISTURE	0.02%	0.03%	0.00%	0.04%	0.03%	0.01%	0.02%	0.01%	0.02%	0.04%	0.02%	0.02%
ELECTRICAL	0.06%	0.06%	0.02%	0.03%	0.03%	0.04%	0.03%	0.04%	0.03%	0.03%	0.05%	0.01%
OTHER	0.00%	0.01%	0.03%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

## CHORUS

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

# Other

## RELIABILITY: 99.81%<sup>a</sup>



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

Cause	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 2023	Aug 2023	Sep 2023
MECHANICAL	0.04%	0.23%	0.02%	0.00%	0.10%	0.05%	0.23%	0.08%	0.15%	0.05%	0.00%	0.07%
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%
ELECTRICAL	0.12%	0.23%	0.04%	0.00%	0.10%	0.05%	0.00%	0.08%	0.00%	0.08%	0.06%	0.12%
OTHER	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

a. Reliability is 1 minus the return rate. The return rate is the average global monthly return rate October 2022 to September 2023.

b. The number per month represent the unit that complete failure analysis in that month.

## NEPTUNE

The Neptune<sup>™</sup> sound processor is the first and only swimmable sound processor.



## RELIABILITY: 99.97%<sup>a</sup>



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

Cause	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 2023	Aug 2023	Sep 2023
MECHANICAL	0.01%	0.06%	0.00%	0.01%	0.01%	0.00%	0.01%	0.01%	0.02%	0.00%	0.00%	0.01%
MOISTURE	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
ELECTRICAL	0.02%	0.01%	0.00%	0.04%	0.02%	0.01%	0.02%	0.03%	0.02%	0.07%	0.01%	0.03%
OTHER	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%

a. Reliability is 1 minus the return rate. The return rate is the average global monthly return rate October 2022 to September 2023.

b. The number per month represent the unit that complete failure analysis in that month.

## HIRES ULTRA 3D V2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To	tal
	real				Iotal All Categories	CI Higher	CI Lower
	1	0.76%	0.01%	0.00%	0.77%	0.90%	0.63%
	1.5	0.92%	0.01%	0.01%	0.95%	1.11%	0.79%
ADULTS	2	1.12%	0.03%	0.01%	1.16%	1.35%	0.97%
ADULI 5	2.5	1.25%	0.03%	0.01%	1.28%	1.50%	1.07%
	3	1.37%	0.03%	0.01%	1.41%	1.67%	1.16%
	3.5	1.37%	0.03%	0.01%	1.41%	1.67%	1.16%
	1	0.63%	0.08%	0.00%	0.71%	0.97%	0.46%
	1.5	0.77%	0.11%	0.00%	0.88%	1.18%	0.59%
CHILDREN	2	0.77%	0.11%	0.00%	0.88%	1.18%	0.59%
CHILDREN	2.5	0.95%	0.17%	0.00%	1.12%	1.50%	0.74%
	3	0.95%	0.17%	0.00%	1.12%	1.50%	0.74%
	3.5ª	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES ULTRA V2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	То	tal
	real				Iotal All Categories	CI Higher	CI Lower
	1	0.35%	0.00%	0.00%	0.35%	0.56%	0.14%
ADULTS	1.5	0.49%	0.00%	0.00%	0.49%	0.74%	0.23%
ADULI 5	2	0.49%	0.00%	0.00%	0.49%	0.74%	0.23%
	2.5	0.49%	0.00%	0.00%	0.49%	0.74%	0.23%
	1	0.27%	0.02%	0.00%	0.29%	0.46%	0.13%
CHILDREN	1.5	0.27%	0.02%	0.00%	0.29%	0.46%	0.13%
CHILDREN	2	0.27%	0.02%	0.00%	0.29%	0.46%	0.13%
	2.5	0.27%	0.02%	0.00%	0.29%	0.46%	0.13%

## HIRES ULTRA 3D V1

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To	tal
	ieai		Device Chr		Iotal All Categories	CI Higher	CI Lower
	1	0.93%	0.13%	0.02%	1.09%	1.37%	0.81%
	1.5	1.37%	0.71%	0.10%	2.17%	2.57%	1.78%
	2	1.72%	2.41%	0.18%	4.26%	4.80%	3.71%
ADULTS	2.5	2.08%	5.07%	0.20%	7.23%	7.93%	6.52%
ADULI 5	3	2.39%	8.23%	0.22%	10.61%	11.45%	9.78%
	3.5	2.65%	12.23%	0.28%	14.80%	15.77%	13.84%
	4	2.78%	15.03%	0.34%	17.68%	18.73%	16.63%
	4.5	2.92%	17.30%	0.34%	19.99%	21.17%	18.81%
	1	1.11%	0.49%	0.00%	1.60%	2.24%	0.95%
	1.5	1.54%	2.18%	0.00%	3.68%	4.66%	2.71%
	2	1.98%	7.52%	0.15%	9.49%	11.01%	7.97%
CHILDREN	2.5	2.70%	13.10%	0.15%	15.56%	17.45%	13.68%
CHILDREN	3	3.89%	19.22%	0.15%	22.48%	24.66%	20.31%
	3.5	4.08%	24.71%	0.25%	27.96%	30.30%	25.62%
	4	4.64%	29.26%	0.25%	32.71%	35.20%	28.65%
	4.5ª	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES ULTRA V1

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Tot	al
	rear			Inconclusive Chr	Iotal All Categories	CI Higher	CI Lower
	1	0.78%	0.02%	0.02%	0.82%	1.02%	0.63%
	1.5	1.03%	0.09%	0.02%	1.15%	1.38%	0.92%
	2	1.30%	0.44%	0.05%	1.78%	2.06%	1.50%
	2.5	1.58%	1.41%	0.08%	3.05%	3.41%	2.68%
	3	1.75%	3.24%	0.11%	5.04%	5.50%	4.58%
ADULTS	3.5	1.90%	5.94%	0.14%	7.86%	8.43%	7.29%
ADULI 5	4	1.98%	9.04%	0.16%	10.98%	11.65%	10.31%
	4.5	2.07%	12.09%	0.19%	14.07%	14.82%	13.32%
	5	2.15%	15.38%	0.19%	17.36%	18.20%	16.52%
	5.5	2.25%	18.34%	0.21%	20.35%	21.28%	19.41%
	6	2.29%	20.93%	0.21%	22.90%	23.96%	21.85%
	6.5	2.29%	23.10%	0.21%	25.03%	26.26%	23.79%
	1	0.56%	0.13%	0.00%	0.69%	0.94%	0.43%
	1.5	0.71%	0.49%	0.03%	1.22%	1.56%	0.88%
	2	0.82%	1.28%	0.05%	2.14%	2.59%	1.69%
	2.5	0.97%	3.01%	0.08%	4.02%	4.64%	3.41%
	3	1.08%	6.42%	0.11%	7.53%	8.35%	6.70%
CHILDREN	3.5	1.25%	10.80%	0.11%	12.01%	13.03%	10.99%
CHILDREN	4	1.56%	16.23%	0.14%	17.66%	18.87%	16.44%
	4.5	1.69%	21.72%	0.19%	23.19%	24.59%	21.79%
	5	1.81%	25.78%	0.19%	27.26%	28.81%	25.70%
	5.5	1.99%	30.65%	0.19%	32.16%	33.95%	30.36%
	6	2.11%	33.10%	0.31%	34.71%	36.70%	32.73%
	6.5ª	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES 90K ADVANTAGE

	Year	Medical CRP	Device CDD	Inconclusive CRP	Total All Catagorias	To	tal
	rear	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower
	1	0.65%	0.06%	0.01%	0.73%	0.84%	0.61%
	2	1.11%	0.08%	0.02%	1.21%	1.36%	1.06%
	3	1.37%	0.13%	0.03%	1.53%	1.70%	1.36%
	4	1.64%	0.18%	0.03%	1.85%	2.04%	1.67%
ADULTS	5	1.88%	0.20%	0.04%	2.11%	2.31%	1.91%
ADULIS	6	2.00%	0.23%	0.05%	2.27%	2.48%	2.06%
	7	2.13%	0.24%	0.05%	2.42%	2.64%	2.20%
	8	2.27%	0.27%	0.06%	2.59%	2.82%	2.37%
	9	2.33%	0.34%	0.08%	2.73%	2.97%	2.49%
	10	2.48%	0.34%	0.13%	2.94%	3.22%	2.65%
	1	0.72%	0.19%	0.02%	0.93%	1.06%	0.81%
	2	1.04%	0.36%	0.04%	1.43%	1.59%	1.27%
	3	1.29%	0.55%	0.04%	1.87%	2.06%	1.69%
	4	1.52%	0.70%	0.08%	2.29%	2.49%	2.08%
CHILDREN	5	1.66%	0.87%	0.12%	2.62%	2.84%	2.40%
CHILDREN	6	1.82%	1.00%	0.12%	2.91%	3.15%	2.67%
	7	1.94%	1.13%	0.13%	3.17%	3.43%	2.92%
	8	2.09%	1.25%	0.15%	3.45%	3.74%	3.17%
	9	2.13%	1.37%	0.21%	3.67%	3.99%	3.36%
	10	2.22%	1.46%	0.21%	3.85%	4.20%	3.49%

## HIRES 90K vendor A post-mod

	Year	Medical CRP Device CRP Inconclusive CRP	Total All Categories	Total			
	- icar				e e e e e e e e e e e e e e e e e e e	CI Higher	CI Lower
	1	0.77%	0.07%	0.01%	0.86%	0.95%	0.77%
	2	1.28%	0.11%	0.04%	1.43%	1.55%	1.32%
	3	1.58%	0.17%	0.06%	1.81%	1.94%	1.68%
	4	1.86%	0.24%	0.08%	2.17%	2.31%	2.02%
	5	2.09%	0.28%	0.09%	2.45%	2.60%	2.29%
	6	2.23%	0.34%	0.10%	2.67%	2.83%	2.51%
	7	2.38%	0.36%	0.11%	2.84%	3.00%	2.67%
	8	2.52%	0.43%	0.12%	3.06%	3.23%	2.88%
ADULTS	9	2.62%	0.48%	0.13%	3.21%	3.39%	3.03%
ADULI 5	10	2.74%	0.53%	0.15%	3.39%	3.58%	3.21%
	11	2.85%	0.57%	0.15%	3.54%	3.74%	3.35%
	12	2.97%	0.58%	0.15%	3.68%	3.88%	3.48%
	13	3.09%	0.60%	0.16%	3.83%	4.04%	3.62%
	14	3.23%	0.62%	0.18%	4.00%	4.23%	3.78%
	15	3.35%	0.63%	0.18%	4.13%	4.37%	3.90%
	16	3.45%	0.68%	0.18%	4.27%	4.53%	4.02%
	17	3.56%	0.77%	0.18%	4.47%	4.77%	4.18%
	18	3.71%	0.77%	0.18%	4.62%	4.98%	4.27%
	1	0.78%	0.20%	0.03%	1.00%	1.10%	0.91%
	2	1.11%	0.46%	0.04%	1.60%	1.72%	1.48%
	3	1.36%	0.72%	0.06%	2.13%	2.27%	1.99%
	4	1.56%	0.96%	0.08%	2.59%	2.74%	2.43%
	5	1.73%	1.18%	0.11%	3.00%	3.17%	2.84%
	6	1.87%	1.35%	0.12%	3.32%	3.49%	3.14%
	7	1.99%	1.48%	0.13%	3.57%	3.75%	3.38%
	8	2.08%	1.63%	0.16%	3.82%	4.02%	3.63%
	9	2.17%	1.72%	0.19%	4.03%	4.24%	3.83%
CHILDREN	10	2.34%	1.85%	0.22%	4.36%	4.58%	4.15%
	11	2.50%	1.88%	0.24%	4.56%	4.78%	4.33%
	12	2.71%	1.96%	0.29%	4.89%	5.14%	4.64%
	13	2.88%	1.99%	0.29%	5.08%	5.35%	4.81%
	14	2.98%	2.05%	0.30%	5.26%	5.54%	4.97%
	15	3.12%	2.14%	0.34%	5.52%	5.83%	5.20%
	16	3.23%	2.25%	0.39%	5.78%	6.13%	5.43%
	17	3.38%	2.30%	0.39%	5.97%	6.37%	5.57%
	18 <sup>a</sup>	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES 90K vendor A all

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To CI Hiaher	tal CI Lower
	1	0.77%	0.08%	0.01%	0.86%	0.95%	0.77%
	2	1.27%	0.14%	0.05%	1.46%	1.57%	1.35%
	3	1.57%	0.20%	0.08%	1.85%	1.98%	1.72%
	4	1.84%	0.31%	0.10%	2.24%	2.38%	2.10%
	5	2.07%	0.36%	0.10%	2.53%	2.68%	2.38%
	6	2.22%	0.44%	0.13%	2.77%	2.93%	2.61%
	7	2.37%	0.47%	0.13%	2.96%	3.12%	2.80%
	8	2.51%	0.56%	0.14%	3.20%	3.37%	3.03%
	9	2.60%	0.65%	0.14%	3.38%	3.56%	3.20%
ADULTS	10	2.73%	0.72%	0.17%	3.60%	3.78%	3.41%
ADOLIS	11	2.84%	0.72%	0.17%	3.77%	3.97%	3.58%
	12	2.97%	0.84%	0.17%	3.96%	4.16%	3.75%
	12	3.09%	0.89%	0.19%	4.13%	4.10%	3.92%
	14	3.25%	0.96%	0.21%	4.13%	4.60%	4.14%
	14	3.36%	0.98%	0.21%	4.52%	4.76%	4.14 %
	16	3.46%	1.06%	0.21%	4.68%	4.70%	4.20 %
	17	3.58%	1.20%	0.23%	4.08%	5.25%	4.43%
	18	3.69%	1.31%	0.23%	4.96%	5.51%	4.67%
	18	3.69%	1.31%	0.23%	5.17%	5.59%	4.83%
	19	0.79%	0.21%	0.03%	1.03%	1.12%	4.87%
	2	1.12%	0.47%	0.04%	1.63%	1.75%	1.50%
		1.37% 1.58%	0.75% 1.01%	0.06%	2.17% 2.65%	2.31%	2.03%
	4	1.58%	1.24%	0.08%	2.65%	2.81% 3.25%	2.50% 2.91%
	6	1.89%	1.43%	0.13%	3.42%	3.59%	3.24%
	7	2.01%	1.58%	0.15%	3.70%	3.89%	3.51%
	8	2.12%	1.75%	0.17%	4.00%	4.19%	3.80%
		2.21%	1.85%	0.20%	4.21%	4.42%	4.01%
CHILDREN	10	2.38%	2.01%	0.24%	4.56%	4.78%	4.34%
	11	2.55%	2.05%	0.26%	4.79%	5.02%	4.56%
	12	2.74%	2.20%	0.30%	5.17%	5.43%	4.91%
	13	2.90%	2.25%	0.30%	5.37%	5.64%	5.10%
	14	2.99%	2.39%	0.32%	5.62%	5.91%	5.33%
	15	3.15%	2.54%	0.35%	5.93%	6.25%	5.61%
	16	3.24%	2.74%	0.39%	6.26%	6.61%	5.90%
	17	3.35%	2.85%	0.39%	6.47%	6.86%	6.07%
	18	3.54%	2.98%	0.46%	6.85%	7.35%	6.35%
	19	4.05%	3.23%	0.46%	7.58%	8.34%	6.82%

## HIRES 90K vendor A pre-mod

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To CI Higher	tal CI Lower
	1	0.60%	0.42%	0.00%	1.02%	1.51%	0.54%
	2	1.03%	0.85%	0.24%	2.11%	2.80%	1.42%
	3	1.33%	1.09%	0.49%	2.89%	3.70%	2.09%
	4	1.58%	1.89%	0.55%	3.98%	4.92%	3.04%
	5	1.70%	2.32%	0.62%	4.58%	5.59%	3.57%
	6	1.83%	2.76%	0.68%	5.18%	6.25%	4.12%
	7	2.14%	3.00%	0.74%	5.79%	6.91%	4.66%
	8	2.20%	3.56%	0.74%	6.39%	7.57%	5.21%
	9	2.27%	4.25%	0.74%	7.11%	8.35%	5.88%
ADULTS	10	2.39%	4.62%	0.81%	7.66%	8.94%	6.38%
100210	11	2.52%	5.00%	0.81%	8.14%	9.46%	6.82%
	12	2.78%	5.44%	0.81%	8.81%	10.17%	7.44%
	13	2.84%	5.69%	0.87%	9.17%	10.56%	7.78%
	14	3.17%	6.13%	0.87%	9.90%	11.33%	8.46%
	15	3.23%	6.32%	0.87%	10.14%	11.59%	8.68%
	16	3.37%	6.44%	0.87%	10.38%	11.85%	8.91%
	17	3.50%	6.70%	0.94%	10.81%	12.30%	9.31%
	18	3.56%	6.89%	0.94%	11.05%	12.56%	9.54%
	19	3.56%	6.96%	0.94%	11.12%	12.63%	9.60%
	1	1.25%	0.79%	0.00%	2.03%	2.96%	1.10%
	2	1.47%	1.37%	0.12%	2.94%	4.05%	1.82%
	3	2.05%	2.18%	0.23%	4.41%	5.76%	3.06%
	4	2.40%	3.11%	0.23%	5.66%	7.18%	4.14%
	5	2.52%	3.93%	0.35%	6.68%	8.33%	5.03%
	6	2.64%	4.75%	0.48%	7.70%	9.46%	5.94%
	7	3.12%	5.57%	0.72%	9.18%	11.08%	7.27%
	8	3.73%	6.52%	0.72%	10.65%	12.69%	8.62%
	9	3.73%	6.87%	0.72%	10.99%	13.06%	8.93%
CHILDREN	10	3.85%	7.47%	0.85%	11.79%	13.92%	9.66%
	11	4.23%	7.83%	0.98%	12.59%	14,78%	10.40%
	12	4.23%	8.79%	0.98%	13.50%	15.75%	11.24%
	13	4.23%	9.15%	0.98%	13.84%	16.12%	11.56%
	14	4.23%	9.99%	0.98%	14.64%	16.97%	12.31%
	15	4.48%	10.47%	0.98%	15.32%	17.70%	12.95%
	16	4.48%	11.08%	0.98%	15.89%	18.31%	13.48%
	17	4.48%	11.32%	0.98%	16.12%	18.55%	13.69%
	18	4.62%	11.56%	0.98%	16.47%	18.92%	14.02%
	19	5.08%	11.85%	0.98%	17.14%	19.64%	14.64%

## HIRES 90K vendor B

	Year	Medical CRP	Device CRP	Inconclusive CRP		Total		
	rear	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower	
	1	0.95%	3.03%	0.00%	3.95%	4.71%	3.20%	
	2	1.33%	10.84%	0.09%	12.10%	13.37%	10.84%	
	3	1.56%	16.18%	0.18%	17.63%	19.11%	16.16%	
	4	1.85%	20.72%	0.18%	22.32%	23.94%	20.70%	
	5	1.95%	24.35%	0.23%	25.99%	27.70%	24.29%	
	6	2.06%	26.69%	0.23%	28.37%	30.12%	26.61%	
	7	2.17%	29.65%	0.23%	31.33%	33.14%	29.53%	
	8	2.45%	31.52%	0.23%	33.35%	35.19%	31.52%	
ADULTS	9	2.45%	33.11%	0.23%	34.90%	36.75%	33.05%	
ADULI 5	10	2.64%	34.54%	0.23%	36.41%	38.28%	34.54%	
	11	2.64%	35.44%	0.23%	37.28%	39.17%	35.40%	
	12	2.70%	36.75%	0.23%	38.60%	40.49%	36.70%	
	13	2.76%	37.78%	0.23%	39.64%	41.54%	37.73%	
	14	2.89%	38.56%	0.23%	40.47%	42.39%	38.56%	
	15	2.96%	39.22%	0.23%	41.15%	43.07%	39.24%	
	16	3.02%	39.68%	0.23%	41.63%	43.55%	39.71%	
	17	3.09%	40.31%	0.23%	42.29%	44.21%	40.36%	
	18	3.09%	40.80%	0.23%	42.76%	44.70%	40.82%	
	1	0.88%	3.28%	0.00%	4.13%	5.14%	3.13%	
	2	1.31%	11.53%	0.07%	12.76%	14.45%	11.07%	
	3	1.55%	19.82%	0.07%	21.13%	23.20%	19.06%	
	4	1.55%	25.84%	0.07%	27.05%	29.30%	24.79%	
	5	1.93%	30.51%	0.17%	31.97%	34.34%	29.60%	
	6	2.13%	34.44%	0.17%	35.95%	38.39%	33.51%	
	7	2.13%	37.69%	0.17%	39.12%	41.60%	36.64%	
	8	2.35%	40.32%	0.17%	41.82%	44.33%	39.32%	
CHILDREN	9	2.47%	42.68%	0.17%	44.19%	46.72%	41.67%	
CHILDREN	10	2.47%	44.35%	0.17%	45.82%	48.35%	43.28%	
	11	2.71%	45.47%	0.17%	47.04%	49.57%	44.50%	
	12	3.09%	46.30%	0.43%	48.19%	50.73%	45.65%	
	13	3.09%	47.85%	0.43%	49.68%	52.22%	47.13%	
	14	3.22%	48.41%	0.56%	50.36%	52.90%	47.81%	
	15	3.22%	49.33%	0.56%	51.24%	53.78%	48.70%	
	16	3.22%	49.61%	0.70%	51.58%	54.12%	49.04%	
	17	3.50%	50.34%	0.70%	52.42%	54.96%	49.87%	
	18ª	N/A	N/A	N/A	N/A	N/A	N/A	

## CII BIONIC EAR

	Veer	Madiaal CDD			Total All Categories	Total		
	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Higher	CI Lower	
	1	0.38%	0.38%	0.03%	0.80%	1.09%	0.50%	
	2	0.65%	0.41%	0.18%	1.24%	1.61%	0.87%	
	3	0.89%	0.59%	0.30%	1.77%	2.21%	1.33%	
	4	1.19%	0.65%	0.39%	2.21%	2.71%	1.72%	
	5	1.37%	0.74%	0.42%	2.51%	3.03%	1.98%	
	6	1.46%	0.89%	0.48%	2.80%	3.36%	2.25%	
	7	1.58%	0.95%	0.66%	3.16%	3.75%	2.57%	
	8	1.70%	1.04%	0.75%	3.45%	4.07%	2.84%	
	9	1.91%	1.14%	0.81%	3.81%	4.45%	3.17%	
	10	2.03%	1.20%	0.81%	3.99%	4.65%	3.33%	
ADULTS	11	2.12%	1.29%	0.84%	4.20%	4.87%	3.52%	
ADULI 5	12	2.33%	1.29%	0.87%	4.43%	5.13%	3.74%	
	13	2.39%	1.29%	0.87%	4.49%	5.19%	3.79%	
	14	2.45%	1.38%	0.87%	4.64%	5.35%	3.93%	
	15	2.54%	1.44%	0.87%	4.79%	5.51%	4.07%	
	16	2.60%	1.50%	0.87%	4.91%	5.63%	4.18%	
	17	2.67%	1.56%	0.87%	5.03%	5.76%	4.29%	
	18	2.76%	1.60%	0.94%	5.20%	5.95%	4.46%	
	19	2.85%	1.66%	0.94%	5.35%	6.11%	4.59%	
	20	3.10%	1.66%	0.97%	5.63%	6.41%	4.85%	
	21	3.14%	1.70%	1.01%	5.74%	6.53%	4.95%	
	22	3.41%	1.90%	1.01%	6.20%	7.06%	5.35%	
	1	0.23%	0.76%	0.06%	1.05%	1.53%	0.57%	
	2	0.71%	1.41%	0.24%	2.33%	3.05%	1.62%	
	3	1.30%	2.29%	0.30%	3.85%	4.77%	2.94%	
	4	1.30%	2.77%	0.42%	4.44%	5.41%	3.46%	
	5	1.61%	3.25%	0.72%	5.49%	6.57%	4.41%	
	6	1.85%	4.03%	1.03%	6.78%	7.97%	5.59%	
	7	1.98%	4.57%	1.16%	7.55%	8.80%	6.29%	
	8	2.10%	5.00%	1.47%	8.37%	9.68%	7.05%	
	9	2.29%	5.43%	1.60%	9.07%	10.43%	7.71%	
	10	2.48%	5.79%	1.60%	9.60%	11.00%	8.20%	
CHILDREN	11	2.61%	5.91%	1.79%	10.01%	11.43%	8.59%	
CHILDREN	12	2.93%	6.04%	1.86%	10.48%	11.93%	9.03%	
	13	3.24%	6.16%	1.92%	10.95%	12.43%	9.47%	
	14	3.37%	6.41%	1.99%	11.36%	12.87%	9.86%	
	15	3.44%	6.47%	1.99%	11.48%	12.99%	9.97%	
	16	3.63%	6.53%	2.05%	11.77%	13.30%	10.25%	
	17	3.89%	6.60%	2.18%	12.19%	13.74%	10.63%	
	18	3.95%	6.72%	2.25%	12.42%	13.99%	10.86%	
	19	4.53%	6.91%	2.25%	13.13%	14.73%	11.53%	
	20	4.81%	6.91%	2.32%	13.45%	15.07%	11.83%	
	21	4.99%	6.91%	2.32%	13.61%	15.24%	11.98%	
	22ª	N/A	N/A	N/A	N/A	N/A	N/A	

## CLARION 1.2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	To	
	Ital					CI Higher	CI Lower
	1	0.28%	0.28%	0.14%	0.71%	0.94%	0.47%
	2	0.38%	0.59%	0.22%	1.19%	1.49%	0.89%
	3	0.57%	1.26%	0.33%	2.14%	2.55%	1.74%
	4	0.78%	2.33%	0.49%	3.56%	4.08%	3.05%
	5	0.92%	3.60%	0.64%	5.10%	5.72%	4.49%
	6	1.09%	4.62%	0.73%	6.34%	7.02%	5.66%
	7	1.16%	5.49%	0.81%	7.34%	8.07%	6.61%
	8	1.36%	6.65%	0.94%	8.78%	9.57%	7.99%
	9	1.51%	7.34%	1.08%	9.72%	10.55%	8.89%
	10	1.76%	8.26%	1.28%	11.02%	11.90%	10.15%
	11	1.91%	9.00%	1.37%	11.96%	12.87%	11.06%
	12	2.21%	9.48%	1.58%	12.88%	13.82%	11.95%
ADULTS	13	2.40%	9.93%	1.62%	13.52%	14.47%	12.56%
ADULI 5	14	2.58%	10.31%	1.72%	14.13%	15.10%	13.16%
	15	2.86%	10.74%	1.79%	14.85%	15.84%	13.85%
	16	3.21%	11.11%	1.86%	15.56%	16.58%	14.55%
	17	3.61%	11.56%	1.93%	16.40%	17.44%	15.37%
	18	4.32%	11.91%	1.93%	17.35%	18.41%	16.29%
	19	4.80%	12.24%	2.03%	18.15%	19.23%	17.07%
	20	5.38%	12.44%	2.10%	18.89%	19.99%	17.80%
	21	5.92%	12.62%	2.15%	19.57%	20.68%	18.45%
	22	6.20%	12.81%	2.26%	20.06%	21.18%	18.94%
	23	7.00%	13.07%	2.26%	20.98%	22.13%	19.84%
	24	7.44%	13.31%	2.33%	21.63%	22.80%	20.46%
	25	7.93%	13.41%	2.39%	22.19%	23.39%	20.98%
	26	8.30%	13.41%	2.49%	22.57%	23.82%	21.33%
	1	0.23%	1.68%	0.11%	2.02%	2.49%	1.56%
	2	0.38%	3.09%	0.20%	3.65%	4.27%	3.03%
	3	0.53%	5.26%	0.41%	6.15%	6.95%	5.35%
	4	0.77%	7.65%	0.54%	8.85%	9.80%	7.91%
	5	0.97%	9.96%	0.92%	11.65%	12.72%	10.59%
	6	1.26%	12.42%	1.22%	14.57%	15.75%	13.40%
	7	1.63%	14.32%	1.49%	16.98%	18.23%	15.73%
	8	1.91%	16.46%	1.84%	19.56%	20.88%	18.24%
	9	2.24%	17.79%	2.27%	21.45%	22.82%	20.09%
	10	2.49%	19.38%	2.82%	23.61%	25.03%	22.20%
	11	2.76%	20.50%	3.19%	25.16%	26.60%	23.71%
	12	2.99%	21.21%	3.46%	26.21%	27.68%	24.74%
	13	3.26%	21.87%	3.69%	27.20%	28.69%	25.72%
CHILDREN	14	3.57%	22.50%	3.81%	28.11%	29.61%	26.61%
	15	4.09%	23.64%	4.04%	29.73%	31.25%	28.20%
	16	4.85%	24.48%	4.37%	31.29%	32.83%	29.74%
	17	5.43%	25.10%	4.78%	32.55%	34.12%	30.99%
	18	6.51%	25.73%	4.99%	34.03%	35.62%	32.45%
	19	7.74%	26.23%	5.17%	35.46%	37.06%	33.86%
	20	9.16%	26.61%	5.34%	36.90%	38.51%	35.28%
	20	10.13%	26.97%	5.58%	38.03%	39.66%	36.40%
	21	11.56%	27.67%	5.78%	39.73%	41.38%	38.08%
	22	12.38%	28.21%	5.89%	40.80%	41.36%	39.14%
	23	13.65%	28.73%	6.12%	42.23%	43.93%	40.53%
	24	14.30%	29.27%	6.24%	43.17%	43.93%	40.53%
	25 26ª	N/A	29.27% N/A	0.24% N/A	43.17% N/A	44.91% N/A	41.42% N/A
	20-	IN/M	IN/A	IN/A	N/A	N/M	N/A

## CONTACT US

This report is intended to provide both professionals and our CI recipients with relevant information on the reliability of our products. If you have any questions, please contact us by emailing hear@AdvancedBionics.com or visit AdvancedBionics.com for more general information.



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