

COCHLEAR IMPLANT QUALITY OF LIFE (CIQOL)

User Manual

Version 1.0



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INTRODUCTION

The Cochlear Implant Quality of Life (CIQOL) suite of instruments provides a comprehensive assessment of functional abilities in adults with cochlear implants (CI). Using stringent psychometric methods, including factor analysis and item response theory (IRT), and following the Patient-Reported Outcomes Measurement Information System (PROMIS) and Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) methodology, we created the CIQOL item banks, CIQOL-35 Profile instrument, CIQOL-10 Global measure, and the CIQOL-Expectations instrument. The CIQOL Functional Staging System enhances the interpretability and clinical application of the CIQOL instruments and associated domain scores. Our research program has taken a patient-centered approach, including direct engagement with CI users, their families, and CI clinicians, to ensure that all outcomes are meaningful to CI users and to encourage realistic expectations and shared decision-making.

PURPOSE

The purpose of this manual is to serve as the singular resource for the CIQOL instruments, scoring instructions, and interpretation of scores. References to our published manuscripts will be provided throughout the manual and can be accessed for more background and details when needed. Please see the "Publications" section of the MUSC CIQOL website (https://education.musc.edu/CIQOL) to download these references and cite the primary literature, rather than this manual, when referring to the CIQOL in your publications and presentations.



CIQOL-35 PROFILE INSTRUMENT AND CIQOL-10 GLOBAL MEASURE

KEY PUBLICATIONS

1) McRackan TR, Velozo CA, Holcomb MA, Camposeo EL, Hatch JL, Meyer TA, Lambert PR, Melvin CL, Dubno JR. Use of Adult Patient Focus Groups to Develop the Initial Item Bank for a Cochlear Implant Quality-of-Life Instrument. JAMA Otolaryngol Head Neck Surg. 2017;143(10):975-82. doi: 10.1001/jamaoto.2017.1182. PMCID: PMC5710256.

2) McRackan TR, Hand BN, CIQOL Development Consortium, Velozo CA, Dubno JR. Development of the Cochlear Implant Quality of Life Item Bank. <u>Ear Hear.</u> 2019;40(4):1016-24. doi: 10.1097/AUD.00000000000684. PMCID: PMC6749825.

3) McRackan TR, Hand BN, CIQOL Development Consortium, Velozo CA, Dubno JR. Cochlear Implant Quality of Life (CIQOL): Development of a Profile Instrument (CIQOL-35 Profile) and a Global Measure (CIQOL-10 Global). <u>J Speech Lang Hear Res.</u> 2019;62(9):3554-63. doi: 10.1044/2019_JSLHR-H-19-0142. PMCID: PMC6808347.

4) McRackan TR, Hand BN, CIQOL Development Consortium, Velozo CA, Dubno JR. Validity and reliability of the Cochlear Implant Quality of Life (CIQOL)-35 Profile and CIQOL-10 Global instruments in comparison to legacy instruments. <u>Ear Hear.</u> 2021;42(4):896-908. doi: 10.1097/AUD.00000000000001022. PMCID: PMC8222065.

The Cochlear Implant Quality of Life-35 Profile (CIQOL-35 Profile) includes 35 items and assesses the functional abilities of adult CI users in 6 domains:

- **Communication:** receptive and expressive communication ability in different situations
- **Emotional:** impact of hearing ability on emotional well-being
- **Entertainment:** enjoyment and clarity of TV, radio, and music
- **Environmental:** ability to distinguish and localize environmental sound
- Listening effort: degree of effort and resulting fatigue associated with listening
- **Social:** ability to interact in groups and to attend and enjoy social functions

The CIQOL-10 Global measure is an additional patient-reported outcome measure that includes 10 of the items from all domains of the CIQOL-35 and provides an overall assessment of quality of life in CI users without domain-specific data. The CIQOL-10 Global score is calculated from responses to a subset of items from the CIQOL-35 Profile **(see pages 8-10)**.

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DEVELOPMENT OF THE CIQOL-35 PROFILE INSTRUMENT AND CIQOL-10 GLOBAL MEASURE

There were four main stages of the development of the CIQOL-35 Profile instrument and CIQOL-10 Global measure: (1) focus groups to create the CIQOL item pools; (2) psychometric analyses of the CIQOL item pools to create the CIQOL item banks; (3) selection of items for the CIQOL instruments based on the results of IRT analyses of the CIQOL item bank; and (4) validation of the CIQOL instruments.

The focus group protocol was based on the results from a systematic literature search. Focus group participants were representative of the adult CI population, based on demographics, communication abilities, and listening modalities. A 101-item pool was then developed based on thematic analysis of the responses from focus group participants. The item pool was finalized after item clarity was confirmed using cognitive interviews with 20 additional adult CI users. Next, 371 experienced adult CI users, recruited from all regions of the United States through the 31-institution CIQOL Development Consortium, completed all items in the item pool. Their responses were psychometrically analyzed (using confirmatory factor analysis and IRT analyses) to create the final 81 item CIQOL item banks with known measurement properties. These psychometric measurement parameters were then used to select items for the CIQOL-35 Profile and CIQOL-10 Global that (1) best matched item difficulty level with the ability level of the population, (2) had the greatest capacity to differentiate individuals according to ability, and (3) had the best item fit to the measurement model. See references #2 and #3 for more information.

The last step in the development process was to recruit a new sample of 334 experienced adult CI users through our Consortium of CI centers to validate these instruments. The results from these CI users demonstrated that the CIQOL-35 Profile and CIQOL-10 Global were more psychometrically sound and comprehensive as compared to legacy instruments often used in the assessment of adult CI users (Nijmegen Cochlear Implant Questionnaire [NCIQ] and Health Utilities Index-3 [HUI-3]). In addition, all CIQOL domains and the global score demonstrated high test-retest reliability. See Table 1 and reference #4 for more information.

Table 1: Test-retest reliability								
Instrument	Pearson's r (95% CI)							
CIQOL-35 Profile Domains								
Communication	0.89 (0.86, 0.91)							
Emotional	0.83 (0.80, 0.86)							
Entertainment	0.90 (0.88, 0.92)							
Environment	0.84 (0.80, 0.87)							
Listening effort	0.85 (0.81, 0.88)							
Social	0.83 (0.80, 0.86)							
CIQOL-10 Global	0.90 (0.88, 0.92)							

SCORING OF THE CIQOL-35 PROFILE INSTRUMENT AND CIQOL-10 GLOBAL MEASURE

All items in the instruments use the same five response choices. Individual items are forward scored where 1=Never, 2=Rarely, 3=Sometimes, 4=Often, 5=Always or reversed scored where 5=Never, 4=Rarely, 3=Sometimes, 2=Often, 1=Always. Table 2 includes a list of each item in each domain of the CIQOL-35 Profile and whether the item should be forward or reversed scored. Note that the Communication domain includes 10 items and the other five domains include 5 items.

Table 2	Forward Items	Reversed Items		
CIQOL-35 Profile Domains				
Communication (1-10)	1,2,3,4,5,7,8,9,10	6		
Emotional (11-15)	11	12,13,14,15		
Entertainment (16-20)	17,18,19,20	16		
Environment (21-25)	21,22,23,24,25			
Listening Effort (26-30)	26,27,28	29,30		
Social (31-35)	31,32	33,34,35		
CIQOL-10 Global	1,5,9,11,17,25,26	14,30,33		

Table 3 includes a list of which CIQOL-35 Profile items are included in the stand-alone CIQOL-10 Global measure. The numbers for the CIQOL-10 Global in Table 2 have been converted to item numbers 1-10 and Table 3 shows which items should be forward or reversed scored.

Table 3								
Forward Items	Reversed Items							
1,2,3,4,6,7,8	5,9,10							

To calculate scores for each domain of the CIQOL-35 Profile and the Global measure, sum the individual item scores to obtain the raw score. Then use Tables 4-10 to convert the raw score for each domain and the Global score to the interval-scale score ("outcome measure") as derived from item-response theory. **Note, raw scores should never be used to report Cl user outcomes. Rather, the IRT-derived outcome measure scores should always be used.**

Each outcome measure score has a standard error (SE) term, which is a statistical measure of variance. The 95% confidence interval around the outcome measure can be calculated from the SE: 95%Cl=±(1.96*SE). For example, a communication raw score of 34 is converted to an outcome measure score of 52.84 with a standard error of 3.18 and 95% Cl of ±6.23.

SCORE CONVERSION TABLES

	Table 4: Communication													
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE						
10	0.0	12.08	24	38.21	3.04	38	59.48	3.37						
11	8.61	7.01	25 39.64 3.03 39 61.28		3.43									
12	14.22	5.28	26	41.07	3.02	40	63.15	3.51						
13	17.91	4.53	27 42.49 3.03 41 65.10		3.58									
14	20.78	4.09	28	43.92	3.03	42	67.15	3.68						
15	23.19	3.80	29	45.35	3.05	43	69.32	3.78						
16	25.31	3.59	30	46.81	3.06	44	71.63	3.93						
17	27.23	3.44	31	48.28	3.08	45	74.14	4.12						
18	29.01	3.33	32	49.77	3.11	46	76.95	4.40						
19	30.69	3.24	33	51.29	3.14	47	80.26	4.85						
20	32.28	3.17	34	52.84	3.18	48	84.47	5.63						
21	33.82	3.12	35	54.43	3.22	49	90.78	7.37						
22	35.31	3.08	36	56.06	3.26	50	100.00	12.32						
23	36.77	3.05	37	57.74	3.31									

	Table 5: Emotional													
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score Outcome Measure		SE						
5	0.0	14.44	12	40.88	5.24	19	66.48	5.20						
6	11.12	8.82	13	44.55	5.23	20	70.13	5.24						
7	19.08	6.88	14	48.21	5.23	21	73.90	5.39						
8	24.62	6.07	15	51.88	5.23	22	78.02	5.72						
9	29.20	5.66	16	55.56	5.23	23	82.90	6.43						
10	33.30	5.43	17	59.22	5.22	24	89.83	8.28						
11	37.16	5.31	18	62.86	5.20	25	100.00	14.07						

	Table 6: Entertainment													
Raw Score	Outcome Measure	SE	Raw Score	Raw Score Outcome Measure SE Raw Score		Outcome Measure	SE							
5	0.0	16.94	12	35.92	5.22	19	60.24	6.10						
6	11.48	9.51	13	38.92	5.30	20	64.39	6.26						
7	18.55	7.03	14	42.05	5.43	21	68.79	6.49						
8	23.13	6.05	15	45.35	5.58	22	73.65	6.91						
9	26.76	5.56	16	48.82	5.73	23	79.42	7.77						
10	29.96	5.32	17	52.47	5.86	24	87.69	10.07						
11	32.96	5.22	18	56.28	5.98	25	100.00	17.26						

	Table 7: Environment													
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score Outcome Measure		SE						
5	0.0	13.41	12	34.60	4.92	19	61.22	5.65						
6	9.59	7.84	13	38.02	4.97	20	65.74	5.71						
7	16.06	6.06	14	41.53	5.04	21	70.36	5.80						
8	20.58	5.38	15	45.14	5.11	22	75.26	6.09						
9	24.38	5.07	16	48.85	5.20	23	81.01	6.81						
10	27.87	4.93	17	52.73	5.34	24	89.06	8.63						
11	31.23	4.89	18	56.85	5.51	25	100.00	13.92						

SCORE CONVERSION TABLES continued

	Table 8: Listening Effort													
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE						
5	0.0	12.60	12	35.05	4.66	19	59.57	5.19						
6	9.30	7.54	13	38.30	4.63	20	63.73	5.33						
7	15.88	5.95	14	41.53	4.64	21	68.21	5.58						
8	20.62	5.33	15	44.82	4.71	22	73.28	6.06						
9	24.63	5.02	16	48.24	4.82	23	79.59	6.97						
10	28.29	4.84	17	51.83	4.94	24	88.66	8.73						
11	31.73	4.73	18	55.61	5.07	25	100.00	13.29						

	Table 9: Social													
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE						
5	0.0	13.64	12	38.61	5.07	19	64.15	5.22						
6	10.28	8.25	13	42.20	5.05	20	68.05	5.33						
7	17.62	6.49	14	45.79	5.06	21	72.17	5.53						
8	22.85	5.79	15	49.40	5.07	22	76.72	5.88						
9	27.24	5.43	16	53.03	5.09	23	82.10	6.58						
10	31.21	5.23	17	56.68	5.11	24	89.60	8.32						
11	34.97	5.12	18	60.38	5.15	25	100.00	13.68						

			Ta	ble 10: Glob	bal			
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE
10	0.0	13.31	24	38.21	3.13	38	58.00	3.36
11	9.14	7.54	25	39.56	3.12	39	59.60	3.42
12	14.86	5.59	26	40.91	3.11	40	61.26	3.50
13	18.53	4.77	27 42.26 3.12 41 63.01		63.01	3.59		
14	21.36	4.30	28	43.62	3.12	42	64.86	3.71
15	23.74	3.98	29	44.98	3.14	43	66.85	3.87
16	25.82	3.76	30	46.35	3.15	44	69.04	4.07
17	27.69	3.59	31	47.74	3.17	45	71.49	4.34
18	29.42	3.46	32	49.14	3.18	46	74.34	4.73
19	31.03	3.36	33	50.56	3.20	47	77.82	5.31
20	32.57	3.28	34	51.99	3.22	48	82.42	6.27
21	34.03	3.22	35	53.45	3.25	49	89.54	8.31
22	35.45	3.18	36	54.93	3.28	50	100.00	13.84
23	36.84	3.14	37	56.45	3.32			



CIQOL-35 PROFILE AND CIQOL-10 GLOBAL NORMATIVE OUTCOMES

KEY REFERENCE

5) McRackan TR, Hand BN, Chidarala S, Velozo CA, Dubno JR. Normative Cochlear Implant Quality of Life (CIQOL)-35 Profile and CIQOL-10 Global Scores for Experienced Cochlear Implant Users from a Multi-Institutional Study. <u>Otol Neurotol.</u> 2022;43(7):797-802. doi: 10.1097/ mao.000000000003596. PMCID: PMC9335896.

CIQOL domain-specific and global outcome scores are available for 705 adult CI users from all regions of the United States who met candidacy criteria and have been using their CIs for at least 12 months. Patients receiving CIs for single-sided deafness were excluded. The results in Table 11 are mean (SD) outcome measures (not raw scores) and can serve as normative data describing the functional abilities of experienced adult CI users. Also shown are the number and percentage of the sample whose scores were at ceiling and floor. See reference #5 for more information.

Table 11	Mean (SD)	Ceiling N (%)	Floor N (%)
CIQOL-35 Profile Domains			
Communication	51.4 (±13.3)	4 (0.57)	1 (0.14)
Emotional	64.7 (±15.9)	29 (4.11)	0 (0)
Entertainment	55.8 (±23.0)	56 (7.94)	18 (2.55)
Environment	61.0 (±17.7)	28 (3.97)	1 (0.14)
Listening Effort	41.5 (±14.8)	0 (0)	3 (0.43)
Social	67.7 (±19.1)	79 (11.2)	1 (0.14)
CIQOL-10 Global	52.6 (±10.9)	0 (0)	0 (0)

Figure 1 contains reverse cumulative distributions that display the percentage of experienced Cl users who obtain each score or higher for each CIQOL domain and the global measure.

Figure 1: Reverse cumulative distribution plots for normative CIQOL-35 Profile domain and global scores

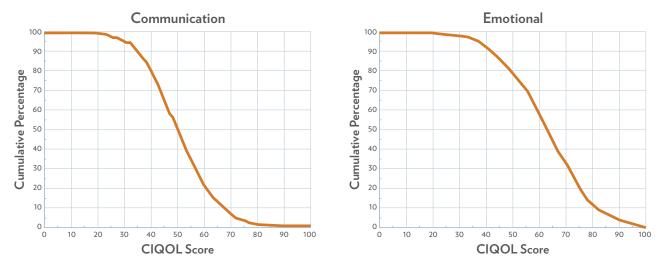
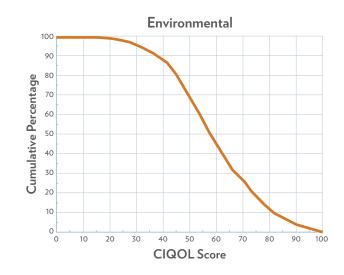
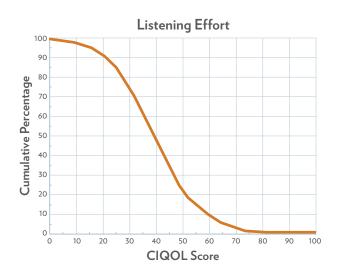
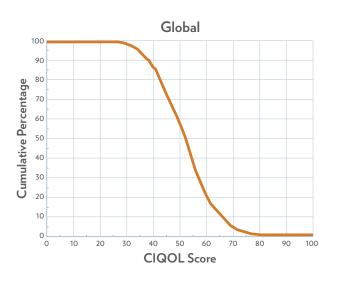


Figure 1: continued









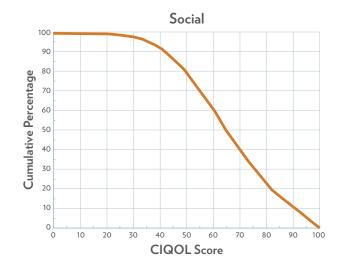
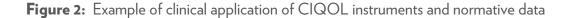
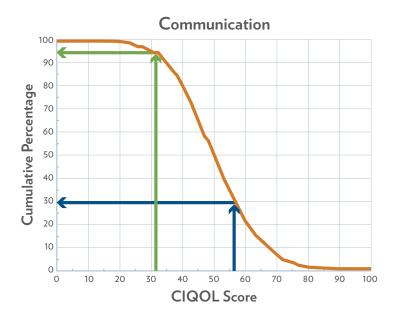


Figure 2 demonstrates how these curves can be used to help guide pre-implantation counseling. Here, a potential CI user's score for the CIQOL-35 Profile communication domain prior to implantation and their CIQOL-Expectations communication score (discussed later) can be marked on the x-axis and the corresponding point along the curve can be marked on the y-axis, representing the percentage of experienced CI users who obtained that score or higher. In the example in Figure 2, a patient's pre-CI CIQOL-35 Profile communication domain score is 32.28 (marked in green; x-axis) and the corresponding point on the y-axis demonstrates that 94% of experienced CI users achieved that score or higher (see reference #5 for details). The same patient's CIQOL-Expectation score for the communication domain is marked in blue. Here, the patient expects their score for the communication domain to increase to 56.06 (x-axis) after implantation, which was achieved by only 30% of experienced CI users (y-axis). In this way, the use of pre-CI CIQOL-35 Profile domain scores and pre-CI CIQOL-Expectation scores in combination with normative data provide the framework for conducting evidence-based CI counseling.





CLINICALLY IMPORTANT OUTCOME VALUES

Clinically important outcome values (CIOV) is the accepted term for describing clinically meaningful improvement in patient outcomes. This inclusive term addresses both the patient perspective regarding meaningful change (minimally clinically important difference; MCID) and the measurement parameters of the instrument (conditional minimal detectable change; cMDC). We are in the process of determining MCIDs for each domain and the Global measure. In the meantime, we include cMDC values for each domain and the Global score in Table 12. cMDC values are not uniform and vary with the initial score, given differences in measurement error along the score continuum; namely, lower measurement error in midrange scores and larger error at the extremes of the scale. Table 12 provides cMDC values for each domain organized by initial outcome score. Using this, clinicians can determine whether the change in an individual patient's CIQOL scores is meaningful or not. For example, if a patient has a baseline communication domain score of 30.69, their follow up score would have to be at least 10.4 points higher to be considered clinically meaningful improvement.

Tal	ble 12: Conditio	onal Mii	nimal D	etectab	le Chan	ge (cM	DC) Values fo	or CIQC)L Dom	iains an	d Globa	al Meas	ure
Com	Outcome Score	0	8.61	14.22	17.91		20.78-74.14		76.95	80.26	84.47	90.78	100
Com	cMDC value	22.5	15.5	13.1	12.0		10.4		11.9	12.5	13.6	16.0	22.8
-	Outcome Score	0	11.12	19.08		24.62-78.02					82.9	89.83	100
Emo	cMDC value	29.2	21.4	18.7		16.6					18.1	20.7	28.7
Ent	Outcome Score	0	11.48	18.55		23.13-64.39 68				73.65	79.42	87.69	100
Ent	cMDC value	33.7	23.4	20.0		18.1				19.8	21.0	24.2	34.2
Env	Outcome Score	0	9.59	16.06			20.58-75.2	26			81.01	89.06	100
Env	cMDC value	27.6	19.9	17.4			16.3				18.4	21.0	28.3
LE	Outcome Score	0	9.3	15.9			20.6-68.21			73.28	79.6	88.7	100
LC	cMDC value	26.1	19.1	16.8			15.5			17.0	18.3	20.7	27.0
Soc	Outcome Score	0	10.28	17.62			27.24-76.7	72			82.1	89.6	100
Soc cMDC value 27.9 20.4 18.0 16.2										18.1	20.5	27.9	
Global	Outcome Score	0	9.14	14.86	18.53	21.36	23.74-69.04	71.49	74.34	77.82	82.42	89.54	100
Giobal	cMDC value	24.5	16.5	13.8	12.7	12.0	10.7	12.1	12.6	13.4	14.7	17.6	25.2

CIQOL-EXPECTATIONS INSTRUMENT

KEY REFERENCE

6) McRackan TR, Hand BN, Chidarala S, Dubno JR. Understanding Patient Expectations Before Implantation Using the Cochlear Implant Quality of Life-Expectations Instrument. <u>JAMA</u> <u>Otolaryngol Head Neck Surg.</u> 2022. doi:10.1001/jamaoto.2022.2292. PMCID: PMC9372907.

The Cochlear Implant Quality of Life-Expectations (CIQOL-Expectations) is a patient-reported outcome measure that assesses potential CI candidates' anticipated functional abilities after implantation in the same 6 domains as in the CIQOL-35 Profile and the CIQOL-10 Global measure **(see page 5)**. The CIQOL-Expectations instrument uses the established, patient-centered CIQOL framework. Given that the items and domains for CIQOL-Expectations correspond to the CIQOL-35 Profile, pre-CI expectations of individual patients can be directly compared to functional abilities from a large group of experienced CI users (see the reverse cumulative distribution plots in Figures 1 and 2). Using scores from the CIQOL-Expectations instrument and CIQOL-35 normative data for experienced CI users, the pre-CI evaluation process can be improved by providing clinicians the opportunity for evidence-based counseling with their patients.

DEVELOPMENT OF THE CIQOL-EXPECTATIONS INSTRUMENT

As a first step, we converted all items from the CIQOL-35 Profile instrument into statements reflecting expected outcomes. For example, the item from the Communication domain "I can understand a conversation in a crowded environment (restaurant, party, etc.)" was converted to "I will be able to understand a conversation in a crowded environment (restaurant, party, etc.)." We then performed cognitive interviews with 20 potential CI users to ensure that each item had its intended meaning and that the included themes were comprehensive. Next, 131 potential adult CI candidates completed the new instrument and psychometric analyses were performed to confirm its construct validity.

The highest mean expectation scores were obtained for the environment (70.2) and social (68.4) domains (scale 0-100). On average, potential CI users had substantially higher expectations as compared to the CIQOL-35 scores obtained from the large group of experienced CI users for all domains except emotional and social. Finally, 28 participants completed the CIQOL-Expectations instrument before and after their CI evaluation to determine whether their expectations changed following discussions during the CI evaluation. Indeed, after the CI evaluation, participants demonstrated large changes in scores (both higher and lower expectations) for all domains, suggesting that expectations are modifiable. See reference #6 for more details.

SCORING OF THE CIQOL-EXPECTATIONS INSTRUMENT

All items in the instrument utilize the same five response choices as in the CIQOL-35 Profile and the scoring procedure is the same. Individual items are forward scored where 1=Never, 2=Rarely, 3= Sometimes, 4=Often, 5=Always or reversed scored where 5=Never, 4=Rarely, 3=Sometimes, 2=Often, 1=Always. Table 13 lists how each item is assigned to a domain and whether the item should be forward or reversed scored.

Table 13	Forward Items	Reversed Items
CIQOL-Expectation Domains		
Communication (1-10)	1,2,3,4,5,7,8,9,10	6
Emotional (11-15)	11	12,13,14,15
Entertainment (16-20)	17,18,19,20	16
Environment (21-25)	21,22,23,24,25	
Listening Effort (26-30)	26,27,28	29,30
Social (31-35)	31,32	33,34,35
Global	1,5,9,11,17,25,26	14,30,33

To calculate the scores for each domain and the Global measure, sum the individual item scores to obtain the raw score. Then use Tables 14-20 to convert the raw score to the interval-scale score ("outcome measure") as derived from item-response theory. **Note, raw scores should never be used to report potential Cl user expectations. Rather, the IRT-derived outcome measure scores should be used.**

Each outcome measure score has a standard error (SE) term, which is a statistical measure of variance. The 95% confidence interval around the outcome measure can be calculated from the SE: 95%Cl=±(1.96*SE). For example, as was shown previously for the ClQOL-35, a communication-expectation raw score of 34 is converted to an outcome measure score of 52.84 with a standard error of 3.18 and 95% Cl of ±6.23.

	Table 14: Communication										
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE			
10	0.0	12.08	24	38.21	3.04	38	59.48	3.37			
11	8.61	7.01	25	39.64	3.03	39	61.28	3.43			
12	14.22	5.28	26	41.07	3.02	40	63.15	3.51			
13	17.91	4.53	27	42.49	3.03	41	65.10	3.58			
14	20.78	4.09	28	43.92	3.03	42	67.15	3.68			
15	23.19	3.80	29	45.35	3.05	43	69.32	3.78			
16	25.31	3.59	30	46.81	3.06	44	71.63	3.93			
17	27.23	3.44	31	48.28	3.08	45	74.14	4.12			
18	29.01	3.33	32	49.77	3.11	46	76.95	4.40			
19	30.69	3.24	33	51.29	3.14	47	80.26	4.85			
20	32.28	3.17	34	52.84	3.18	48	84.47	5.63			
21	33.82	3.12	35	54.43	3.22	49	90.78	7.37			
22	35.31	3.08	36	56.06	3.26	50	100.00	12.32			
23	36.77	3.05	37	57.74	3.31						

SCORE CONVERSION TABLES:

SCORE CONVERSION TABLES continued

	Table 15: Emotional									
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE		
5	0.0	14.44	12	40.88	5.24	19	66.48	5.20		
6	11.12	8.82	13	44.55	5.23	20	70.13	5.24		
7	19.08	6.88	14	48.21	5.23	21	73.90	5.39		
8	24.62	6.07	15	51.88	5.23	22	78.02	5.72		
9	29.20	5.66	16	55.56	5.23	23	82.90	6.43		
10	33.30	5.43	17	59.22	5.22	24	89.83	8.28		
11	37.16	5.31	18	62.86	5.20	25	100.00	14.07		

	Table 16: Entertainment									
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE		
5	0.0	16.94	12	35.92	5.22	19	60.24	6.10		
6	11.48	9.51	13	38.92	5.30	20	64.39	6.26		
7	18.55	7.03	14	42.05	5.43	21	68.79	6.49		
8	23.13	6.05	15	45.35	5.58	22	73.65	6.91		
9	26.76	5.56	16	48.82	5.73	23	79.42	7.77		
10	29.96	5.32	17	52.47	5.86	24	87.69	10.07		
11	32.96	5.22	18	56.28	5.98	25	100.00	17.26		

	Table 17: Environment									
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE		
5	0.0	13.41	12	34.60	4.92	19	61.22	5.65		
6	9.59	7.84	13	38.02	4.97	20	65.74	5.71		
7	16.06	6.06	14	41.53	5.04	21	70.36	5.80		
8	20.58	5.38	15	45.14	5.11	22	75.26	6.09		
9	24.38	5.07	16	48.85	5.20	23	81.01	6.81		
10	27.87	4.93	17	52.73	5.34	24	89.06	8.63		
11	31.23	4.89	18	56.85	5.51	25	100.00	13.92		

	Table 18: Listening Effort									
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE		
5	0.0	12.60	12	35.05	4.66	19	59.57	5.19		
6	9.30	7.54	13	38.30	4.63	20	63.73	5.33		
7	15.88	5.95	14	41.53	4.64	21	68.21	5.58		
8	20.62	5.33	15	44.82	4.71	22	73.28	6.06		
9	24.63	5.02	16	48.24	4.82	23	79.59	6.97		
10	28.29	4.84	17	51.83	4.94	24	88.66	8.73		
11	31.73	4.73	18	55.61	5.07	25	100.00	13.29		

	Table 19: Social									
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE		
5	0.0	13.64	12	38.61	5.07	19	64.15	5.22		
6	10.28	8.25	13	42.20	5.05	20	68.05	5.33		
7	17.62	6.49	14	45.79	5.06	21	72.17	5.53		
8	22.85	5.79	15	49.40	5.07	22	76.72	5.88		
9	27.24	5.43	16	53.03	5.09	23	82.10	6.58		
10	31.21	5.23	17	56.68	5.11	24	89.60	8.32		
11	34.97	5.12	18	60.38	5.15	25	100.00	13.68		

	Table 20: Global										
Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE	Raw Score	Outcome Measure	SE			
10	0.0	13.31	24	38.21	3.13	38	58.00	3.36			
11	9.14	7.54	25	39.56	3.12	39	59.60	3.42			
12	14.86	5.59	26	40.91	3.11	40	61.26	3.50			
13	18.53	4.77	27	42.26	3.12	41	63.01	3.59			
14	21.36	4.30	28	43.62	3.12	42	64.86	3.71			
15	23.74	3.98	29	44.98	3.14	43	66.85	3.87			
16	25.82	3.76	30	46.35	3.15	44	69.04	4.07			
17	27.69	3.59	31	47.74	3.17	45	71.49	4.34			
18	29.42	3.46	32	49.14	3.18	46	74.34	4.73			
19	31.03	3.36	33	50.56	3.20	47	77.82	5.31			
20	32.57	3.28	34	51.99	3.22	48	82.42	6.27			
21	34.03	3.22	35	53.45	3.25	49	89.54	8.31			
22	35.45	3.18	36	54.93	3.28	50	100.00	13.84			
23	36.84	3.14	37	56.45	3.32						

THE CIQOL FUNCTIONAL STAGING SYSTEM

KEY REFERENCE

7) McRackan TR, Hand BN, CIQOL Development Consortium, Velozo CA, Dubno JR. Development and Implementation of the Cochlear Implant Quality of Life (CIQOL) Functional Staging System. <u>Laryngoscope</u>. 2022 Nov;132 Suppl 12(Suppl 12):S1-S13. doi: 10.1002/lary.30381. PMID: 36082873; PMCID: PMC9650765.

Functional staging systems directly address a major limitation of many outcome measures, including patient-reported outcome measures and speech recognition scores, which is the inability to provide patients with real-world interpretations of numerical scores. Functional staging systems have been used in many fields to provide detailed descriptions of patient-reported abilities (in the form of clinical vignettes) without sacrificing the inherent value of the scores themselves. For the CIQOL functional staging system, each domain has multiple stages that maintain the hierarchic ability structure established during the development process.

There are many potential applications of the CIQOL functional staging system, and several are highlighted below:

- For patients and clinicians, provides evidence-based understanding of Cl users' real-world functional abilities across 6 domains following implantation
- Allows comparison of pre-Cl expectations (using the ClQOL-Expectations instrument) and pre-Cl and post-Cl functional abilities (using the ClQOL-35 Profile instrument) for individual patients to functional stage outcomes for experienced Cl users (normative outcomes)
- Monitors individual patient progress following implantation and identifies patient and domainspecific factors that inhibit or facilitate patient progress

DEVELOPMENT OF THE CIQOL FUNCTIONAL STAGING SYSTEM

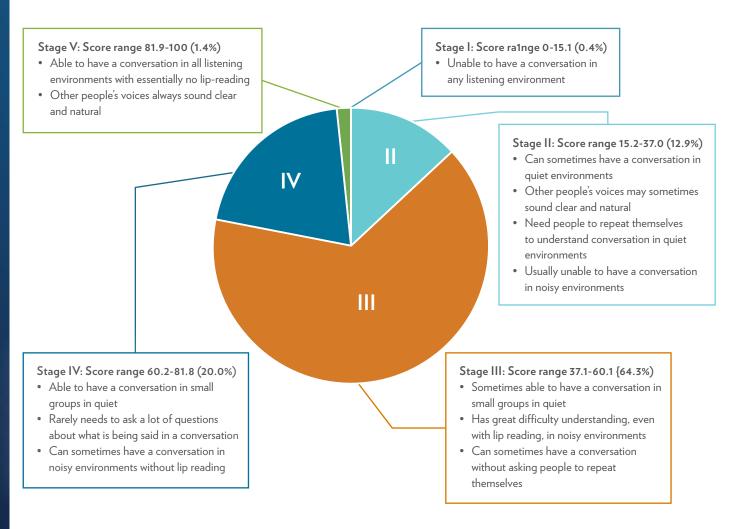
The CIQOL Functional Staging System was based on CIQOL-35 responses of the 705 experienced CI users described earlier **(see page 7)**.

The number of stages for each domain was determined by the psychometrically derived value, termed strata. This determines the number of statistically distinct groupings, based on ability levels, to which patients can be reliably assigned. This resulted in five stages for the communication domain and three stages for the other five domains. Cut scores were then defined to separate Cl users into each of these distinct functional stages. Then, based on the item responses for each stage, clinical vignettes were developed that describe the functional abilities for each stage and then validated by adult Cl users to confirm that each higher stage represents meaningful improvement in functional abilities.

SCORING AND NORMATIVE DATA

The range of scores and clinical vignettes (in boxes) associated with each stage are provided in Figure 3 for the Communication domain (followed by the remaining domains). In addition, the pie charts demonstrate the percentage of 705 experienced Cl users in each stage (based on ClQOL-35 normative data). As an example for the Communication domain, 64.3% of experienced Cl users were in Stage III (orange) and 20.0% were in Stage IV (dark blue). The bulleted lists within each box are the clinical vignettes that correspond to each stage. See reference #7 for more details.

Figure 3: Score ranges, normative data, and clinical vignettes for each stage and each domain.



COMMUNICATION

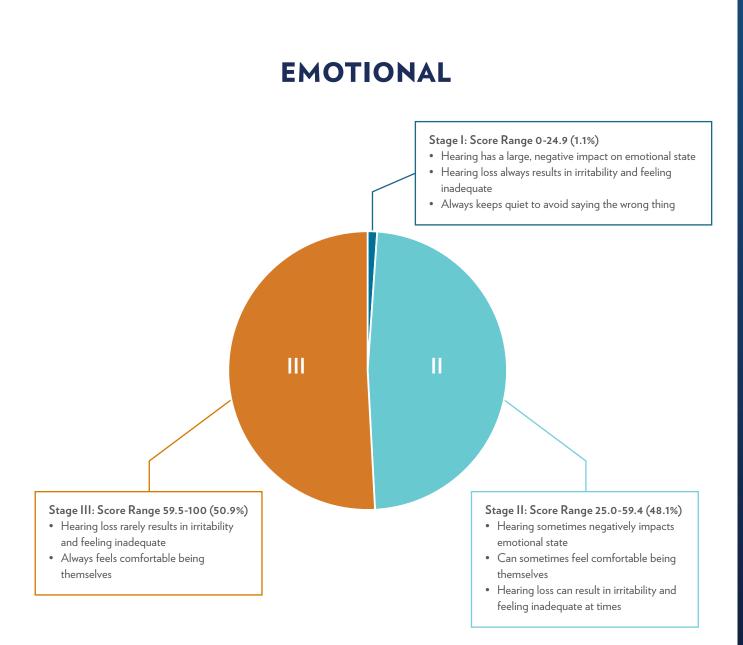


Figure 3: continued



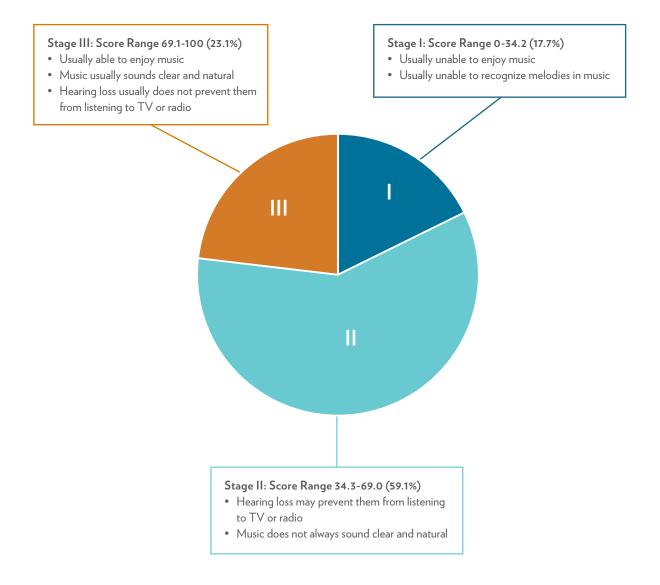
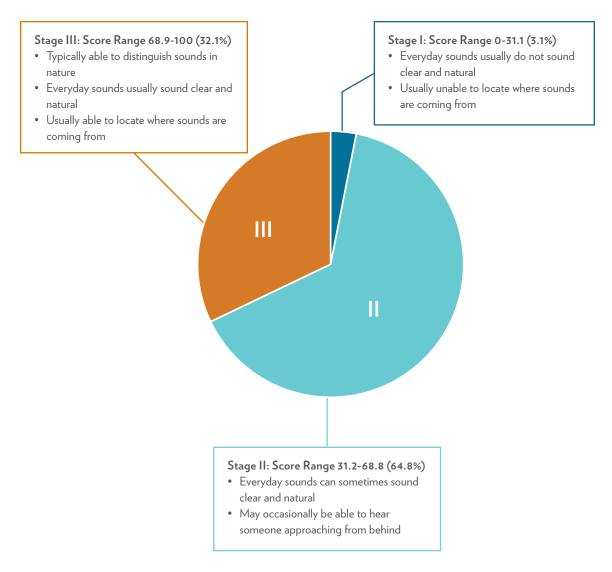
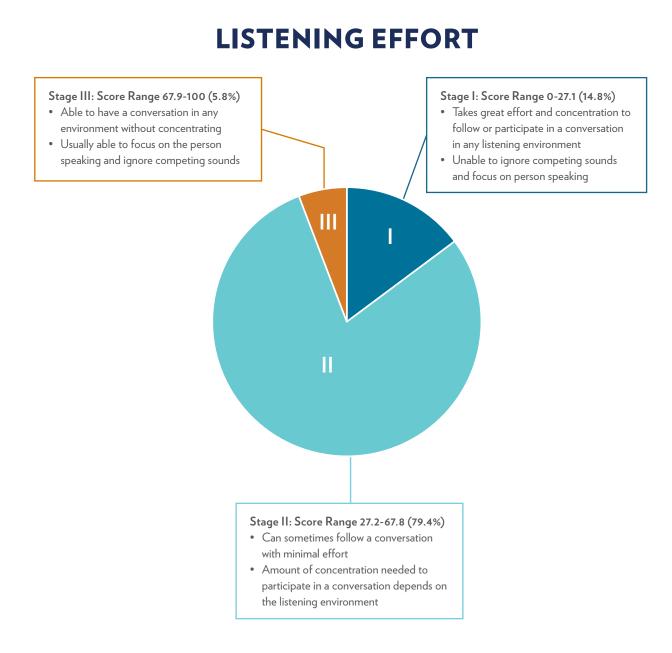
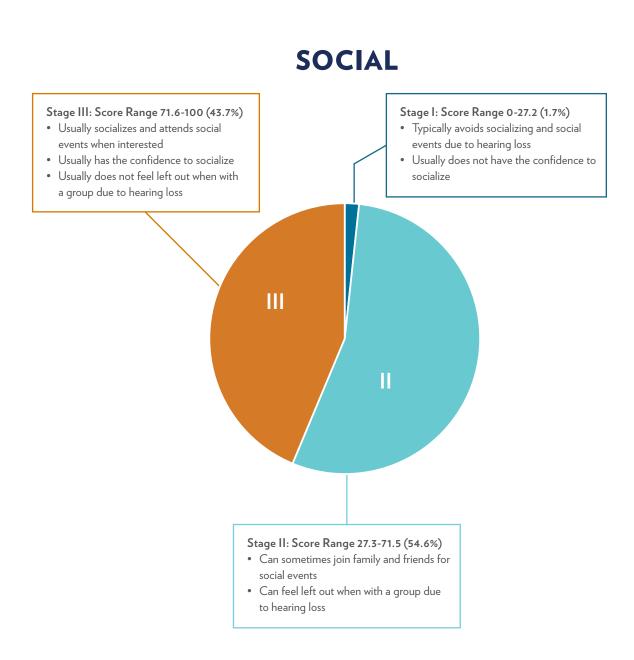


Figure 3: continued

ENVIRONMENT









ΤХ

CIQOL DEVELOPMENT CONSORTIUM

We established the CIQOL Development Consortium to recruit a large sample of adult CI users representative of the broader adult CI population. The 31-member consortium of CI Centers was instrumental in the timely recruitment of research participants and are listed below. We are extremely grateful for their involvement in this process and their continued participation.

LA

- Columbia University
- Duke University
- Eastern Virginia Medical School
- Georgetown University
- House Ear Clinic
- Johns Hopkins University
- Kaiser Health Los Angeles
- Kaiser Health San Diego
- Loyola University
- Mass Eye and Ear
- Mayo Clinic Rochester
- Medical University of South Carolina
- New York Eye and Ear Infirmary
- Ohio State University
- Oregon Health Sciences University
- Rush Medical Center

- Stanford University
- Summit Medical Group
- SUNY Downstate
- University of Arkansas
- University of Cincinnati
- University of Colorado
- University of Maryland
- University of Miami
- University of Pennsylvania
- University of Utah
- University of South Carolina
- University of Texas Southwestern
- Vanderbilt University
- Virginia Mason Seattle
- Washington University

CHANGING WHAT'S POSSIBLE

