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## The Intra-Cochlear Impedance-Matrix (IIM) test for the Nucleus (R) cochlear implant

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# The Intra-Cochlear Impedance-Matrix (IIM) test for the Nucleus® cochlear implant

**Abstract**

**Objective:** To describe the principles and operation of a new telemetry-based function test for the Nucleus® cochlear implant, known as the CS19 Intra-Cochlear Impedance Matrix (IIM) and to present results from a multicentre clinical study to establish reproducibility (test-retest reliability) and normative ranges.
**Method:** The IIM test measures bipolar impedances between all electrode pairs and employs a normalization procedure based on common ground impedances in order to identify abnormal current paths among electrodes. Six European clinics collected IIM data from a total of 192 devices.
**Results:** Reproducibility was high between initial and repeat measurements. The normative analysis demonstrated narrow ranges among devices after normalization of impedance data. The IIM is able to identify abnormal current paths that are not evident from standard impedance telemetry and may otherwise only be found utilising average electrode voltage measurements (AEV).
**Conclusions:** The IIM test was found to be straightforward to perform clinically and demonstrated reproducible data with narrow ranges in normally-functioning devices. Because this test uses a very low stimulation level the IIM test is well suited for children or multiply handicapped CI users who cannot reliably report on their auditory percepts. The new algorithms show potential to improve implant integrity testing capabilities if implemented in future clinical software.

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## Introduction

In recent years, cochlear implants (CIs) have become a routine and effective treatment for severe or profound hearing loss. All currently available commercial CI devices use an external ear-level processor to detect and process speech and environmental sounds, which then transmits power and coded stimulation instructions to a surgically implanted "cochlear stimulator" (ICS) embedded in the temporal bone, using a transcutaneous radio-frequency link across intact skin. In turn, the ICS decodes these signals and delivers appropriate current pulses to an array of electrodes inserted into the scala tympani of the cochlea [12].

The stimuli delivered by the electrodes are typically biphasic charge-balanced square-wave pulses, which originate from constant current sources in the ICS. Several stimulation modes are employed, the most common currently in use being "monopolar" (MP), where the active intracochlear electrode is paired with one or two extracochlear reference electrodes, usually on the housing of the ICS or on a separate carrier placed under the temporalis muscle [34]. Other stimulation modes used include "bipolar" (BP), where an additional contact on the intracochlear array is used as the reference (usually adjacent or a small number of electrodes away from the active electrode), and "common ground" (CG), where all intracochlear electrodes apart from the active are temporarily electrically connected to act as the common reference. In most coding strategies, only one electrode is active at any given time, in order to avoid unpredictable cross-channel interactions, though some manufacturers also use strategies employing simultaneous stimulation [7].

Effective operation of the CI system depends on two main factors. The first is operation of the device within specification (including parameters such as charge balancing of the biphasic stimulation pulses), together with its ability to deliver an appropriate sequence of stimuli at the electrode sites. The second is the ability of the neural elements of the implanted cochlea to respond to the electrical stimuli of the ICS so that meaningful auditory information can be relayed to the higher auditory centres. The interface between these two factors is the programming or "fitting" of the CI sound processor, whereby stimulation current limits are set for each electrode, usually using behavioural estimates of threshold and maximum comfort level from the CI user, but sometimes using a variety of objective measures [6, 22].

Unfortunately, device failure occasionally occurs, resulting in either (i) total loss of function, or (ii) deterioration in some measure of the quality of the electrical stimulation delivered by the device. These situations are often termed "hard" and "soft" device failures respectively in older literature, but the International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators [2] has recommended the terms "Device Failure" or "Characteristics Decrement", which both imply a level of device malfunction but are distinct, respectively, according to whether or not there is still any clinical benefit provided by the device.

Cases of device failure are usually relatively straightforward, in that substitution of the external components and "integrity testing" of the ICS (discussed below) is usually sufficient to confirm a malfunction of the internal ICS, necessitating replacement with a new device, and device failure is the most common reason for re-implantation [13, 20]. However, in the case of characteristics decrement recipients may simply report sudden or gradual deterioration in the quality of the sound percept using the device or, in the case of young children, show a reluctance to wear the device or do not progress with language development as anticipated [1]. Sometimes, review of the processor fitting may indicate possible reasons for the deterioration (for example, individual electrodes no longer produce an auditory percept, or show large changes in the required stimulation current levels), but this is not always the case. The most common types of characteristics decrement are shorts and open circuits in individual electrodes, often caused by mechanical damage because the electrode leads are supported in a flexible carrier that is outside the housing of the ICS [34], but sometimes the result of hermeticity failure of the ICS [24]. If the short and/or open circuit electrodes are spatially isolated, stable and few in number it is usually possible to simply de-activate them

without significant reduction of the clinical benefit provided by the device [43], but sometimes many electrodes are affected, or additional electrodes develop problems over time, in which case re-implantation may eventually be indicated [9, 26]. Occasionally, the user does not report poor sound quality but a fitting review reveals individual electrode faults. This is particularly likely with young children, who are often unable to accurately report on the quality of the auditory percept. It is also important to note that changes in auditory percept may alternatively be the result of intracochlear (or even central) physiological changes, without any change in the characteristics of the electrical stimulation through device malfunction [37, 41].

Because of the many uncertainties around ICS and electrode malfunction, CI manufacturers have developed ways of testing the various components of their devices *in situ*, most of which currently involve retrieving data on component function from the ICS through "back-telemetry". Early devices, such as the Nucleus CI22, had no telemetry capability, however, and diagnosis of electrode problems was mainly achieved by psychophysical measures. In these devices it was also possible to monitor the output of the electrodes by recording surface potentials generated during electrode stimulation using scalp electrodes – so-called "averaged electrode voltages" (AEVs) [25], or "electrode-by-electrode" (E-E) mapping [29]. This straightforward procedure can confirm normal stimulus morphology and amplitude modulation of individual electrodes and is usually termed "integrity testing" because it objectively confirms that the CI device is delivering the appropriate electrical stimuli [3]. A semi-automated integrated system for measurement of AEVs, known as the "Crystal" device, was later developed by Cochlear Limited [30]. As well as confirming device function in a general sense (most components of the system must be functioning if normal stimulation pulses are recorded) integrity testing is very efficient at identifying shorts and open circuits on individual electrodes [23].

All current devices now have telemetry functions, which are able to monitor and test a range of ICS and electrode functions and transmit data back to a recording system, usually via the external sound processor. The main features of most telemetry systems include: (i) verification of communication between the external processor and the ICS (usually incorporating checks on the ICS circuitry); (ii) measurement of voltages developed at the electrodes in response to stimulation pulses (from which individual electrode impedances and spread of electric field can be derived) [44]; (iii) back-telemetry of the neural response of the auditory nerve due to electrical stimulation [36, 39]. In the latter case the activity detected

is generated by multiple fibres and constitutes the electrically-evoked compound action potential (eCAP) of the auditory nerve, and this procedure is known as neural response telemetry (NRT) in Cochlear's Nucleus systems [14]. In this way, verification of an auditory response is obtained as well as some level of confirmation of device function, and response characteristics can be useful in the setting of processor fitting parameters, particularly in young children who are unable to provide reliable behavioural responses [6, 16]. Because of the evolved state of this method and its automatic determination of the neural responses [18], the method has gained broad clinical application in this patient group. In addition, eCAP measures are able to identify certain electrode anomalies, although the amount of direct information is limited. For example, electrode "fold-over" has been shown to produce characteristic eCAP spread of excitation profiles [21, 31]. Lack of an NRT response, conversely, provides very little information about the reason for the problem, which may be a technical device issue, may relate to the status of the patient's neural substrate or the device placement or even to parameter settings used for the NRT measurement.

The most routinely used telemetric measure is electrode impedances as the data are useful for a variety of purposes. First, very high or low impedance values are usually associated with electrode malfunctions. Very high values indicate open circuits usually due to lead fracture, whereas low values suggest current shunting to other electrodes (shorts). Second, moderately high values may identify the risk of compliance problems in viable electrodes, as the maximum current that can be delivered by an electrode contact is dependent on the (fixed) implant supply voltage and the electrode impedance. In such cases, increase of stimulus pulse durations may be required in order to obtain sufficient loudness growth. Thus, impedance measures assist the audiologist programming the device, particularly regarding any need to de-activate individual electrodes. Third, monitoring of impedance values for new devices [15] or over time may highlight impending electrode or even device failure [9] and can also indicate physiological changes in the proximity of the electrode array [33, 38].

Thus, information on the characteristics of the stimulus actually delivered by the electrodes is very important to the audiologist, not only to confirm normal device function but also to assist in optimal processor fitting. However, no single test currently provides all the necessary information. Standard impedance measures via backtelemetry are quick and easy to perform, but do not detect all electronics problems, such as abnormal amplitude growth. In a study comparing impedance telemetry and

AEV measures in users of the Nucleus CI24 device, Hughes et al. (2004) [23] reported that 2.5% of electrodes with normal impedance telemetry results showed abnormalities on AEV testing, some of which produced abnormal auditory percepts. CI centres often use a battery of objective measures in order to verify device function as well as to gain information to assist device fitting [27, 28].

A new telemetry test software suite has recently been developed by Cochlear Limited. Known as the "CS19" software, this is currently only available as an internal tool used by Cochlear's clinical technical specialists or for research purposes. The software suite is used to analyze the functionality of the electrode array, the RF link and implant electronics, and is designed to be used alongside an AEV-based integrity test system. CS19 also introduces new ways to record and display voltage and impedance measurements, using measurements between every possible electrode combination. The actual method uses a combination of intracochlear bipolar and CG impedance measures, whereas Vanpoucke applied the EFI method for the Advanced Bionics cochlear implant by monopolar measurements [40]. Based on voltage matrix of the EFI data Choi et al. [10] proposed a finite element method to create an impedance matrix based incorporating an electrode-tissue interface. As well as identifying a range of electrode problems, early trials have shown that certain matrix patterns appear to be associated with certain pathological intracochlear conditions. A preliminary report on the voltage matrix feature was presented by Müller-Deile et al. (2010) [32].

The purpose of this report is to describe the aims and function of the CS19 Intra-Cochlear Impedance Matrix (IIM) test and to present outcomes from a multicentre European study to collect normative data from a large number of users of the Nucleus™ CI24M, CI24R, CI24RE, CI400 and CI500 series implants. It was anticipated that such a population would inevitably include a proportion of abnormally functioning electrodes, so that study data would also provide example patterns obtained from such cases.

## Principles and function of the CS19 Intra-Cochlear Impedance Matrix (IIM) test

The CS19 software suite incorporates a range of telemetry measures to provide diagnostic information on the status of the RF link, power supply, internal ICS electronics and electrode array. It is designed to be used in conjunction with an AEV-based integrity test system and is distinct from the NRT system. This report relates to the IIM test

as a part of the CS19 software and only this component is described in detail here.

Previous impedance measurement systems, including voltage matrices used by other manufacturers, typically measure impedances using the same stimulation mode as is used by the device in everyday use – usually some form of monopolar (MP) mode. Such systems are designed primarily to identify electrode open and short circuits and to estimate compliance limits. As described below, the IIM test of the CS19 battery uses variable bipolar and CG measurement modes, together with a normalization procedure, which enables identification of a greater range of electrode faults than monopolar testing. Many electrode faults can be identified using AEV measures, including some not detected by standard impedance telemetry, but the precise relationship between the electrodes with abnormal current paths is not easily determined. The IIM can identify specific electrodes that are anomalous and so identify individual or multiple electrodes that may be involved in these atypical current paths. Furthermore, the IIM is able to highlight certain characteristics of the field distribution generated along the electrode array. These may reflect local differences in the properties of the surrounding tissues and can therefore indicate the presence or development of conditions such as ossification or scar tissue growth around the implant's electrode array.

CS19 uses the same hardware as the current clinical telemetry system, i.e., a Freedom® sound processor, Programming Pod and laptop/PC with the CS19 software. The system can be used with all Nucleus CI24M, CI24R, CI24RE, CI400 and CI500 series implants, but not the earlier CI22M devices or auditory brainstem implants. The software allows annotation of certain client demographics and test session background information, and an implant connection check is always run prior to the main tests, most of which contain optional sub-routines and basic/advanced versions. A loudness check is also carried out at the start of each session in order to verify that all stimulation levels are comfortable for the subject. CS19 will only allow stimulation at a maximum level representing 75 µA stimulation current, which is low enough that most patients are not able to perceive any auditory percept during the test. This is consistent with levels used during standard impedance telemetry testing with the Custom Sound™ software used for the clinical programming of recipients.

The principal measures carried out in order to construct the IIM are (i) CG impedance values for all individual electrodes, and (ii) variable bipolar impedance values, whereby the impedance between each electrode and all others is measured, to include all electrode combinations. This results in a 22×22 matrix of measurements with 22 CG values along the diagonal and all other values being bipolar measures between all electrode pairs.

Impedance values are recorded by delivering a biphasic square-wave pulse of known current and measuring the developed voltage for each electrode combination (impedance is then calculated using Ohm's law). Stimulation pulses of 25 µs/phase duration are delivered at a rate of 5000 pps. Averaging (four repetitions) is also used to facilitate low noise recordings. Within this paradigm, data collection takes approximately 5 min.

Figure 1A shows raw variable bipolar impedance values for a subject showing normal results, plotted by active electrode number. Impedances have a minimal value for CG measures and rapidly increase to an asymptotic value as the distance between active and reference electrode increases. The asymptotic values vary among electrodes, however, making interpretation from visual inspection difficult.

In order to simplify interpretation, normalization of the variable BP measurements is next performed using the active and reference electrode CG impedance (Z) values, according to the formula:

$$Z_{norm} = \frac{Z_{BP} - Z_{CG(reference)}}{Z_{CG(active)}}$$

The benefit of the normalization process is to produce profiles that are insensitive to the actual electrode impedance profile (within certain limits). The normalized matrix data are then displayed as in Figure 1B, which shows normalized data from the same subject as presented in 1A. It is evident that the normalized data have a value of zero when the active and reference electrodes are the same, increase to a value of around 0.8 at the neighbouring electrode, and asymptotically reach a value of around 0.9 for electrodes more distant on either side of the active electrode. This normalization process makes visual identification of electrode anomalies far more straightforward. While values are usually between 0 and 1 in normal cases, abnormal conditions can sometimes result in values considerably >1, depending on the relative dominance of the parameters in the normalization formula.

The IIM can be used to provide information on the integrity of the electrical insulation between the physical electrode contacts and can detect conductive bridges between individual electrodes. Simple open circuits (Z>30 kΩ) and electrode shorts (Z<600 Ω) can readily be identified by standard impedance telemetry, whereas the
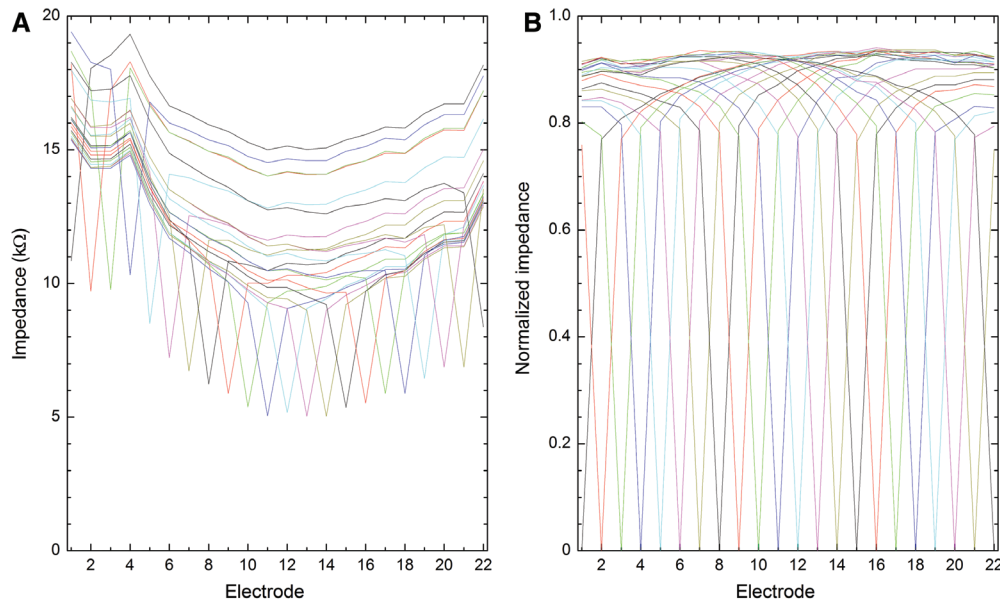
**Figure 1** (A) Display of the raw CG and variable bipolar impedance matrix from a subject showing normal values (typical measurement of one subject). (B) Display of the normalized IIM from the raw data presented in (A).

IIM is able to identify more subtle impedance shunts and current paths. Examples of such results are provided later in this report.

In addition, the IIM may identify changes in the conductive properties of the environment surrounding the electrode array in the cochlea, such as scar tissue growth or ossification, which can influence intracochlear current flow. Figure 2 illustrates a model showing that the electrode impedance profiles in the IIM will be affected by changes in the longitudinal impedance values between electrodes as well as by influences local to the electrode contacts. The model separates the intracochlear impedance into the electrode tissue impedance component ($Z_e$) and the longitudinal impedance component ($Z_l$) between each electrode along the array. The longitudinal component is usually much lower than the electrode tissue

component [42], but certain intracochlear abnormalities, such as scar tissue growth or ossification, may result in an increase in the longitudinal component.

# Methods – European CS19 validation and normative data study

## Study aims

The principal aim of this multicentre study was to collect a pool of normative CS19 data from a large number of users of suitable Nucleus devices. These data were used to establish mean and percentile values of normally-functioning devices/electrodes and the clinical significance of deviations, as it was anticipated that some subjects would inevitably have electrodes with identifiable problems. CS19 offers several different test routines. All these routines were examined by this study, but the present report focuses on the IIM test and so only these data are provided here.

The study involved two separate parts. The first was a test of reproducibility, i.e., test-retest variability, in which a subset of subjects were tested twice at the same session. The second part was to identify the normative ranges of IIM values in subjects with no known electrode anomalies, which could be used to calculate test sensitivity and specificity for the complete dataset that included a number of
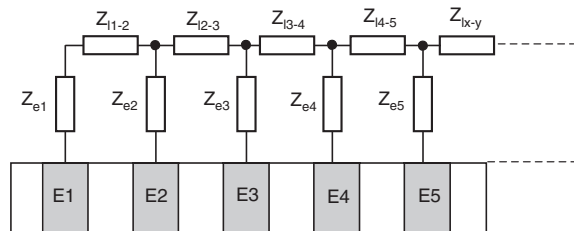


**Figure 2** A model of the principal components contributing to individual electrode impedance values in a five-electrode segment of an intracochlear array. $Z_e$ represents the electrode tissue component, while $Z_l$ represents the longitudinal impedance between electrode contacts.

known electrode problems (i.e., with standard impedance measures outside the normal range). These latter calculations will be presented in a follow-up report.

## Subjects

We recruited 180 patients using CI24R, CI24M, CI24RE or CI500 series cochlear implants. The inclusion criteria were completely open. The implants CI24M, CI24R, CI24RE(ST) use a straight electrode array, whereas the CI24RE(CA) and CI500 show a modiolus hugging array. There were no age limits or minimum duration of device use (i.e., including initial device activation). By this the collected group represents a broad variety of cochlear implant patients. The great number of investigated implants and the unrestricted inclusion criteria give evidence for a mostly representative collective.

The only specific inclusion criterion related to the ability/motivation of the subject to attend the test session (with parents in the case of children). The study was conducted according to the guidelines established by the Declaration of Helsinki (Seoul, 2008), appropriate local ethical committee approval was obtained at all participating centres and all subjects/parents completed written informed consent and were allocated an anonymous ID code.

192 implants of 168 unilaterally and 12 bilaterally implanted subjects were included in the study at six participating CI centres from Germany, Switzerland, Sweden and the UK. From these subjects, 182 (94.8%) test sessions were conducted successfully. The small number of unsuccessful tests was the result of a calibration issue with some of the older implants. A subset of 31 subjects at Kiel (unselected) were tested twice at the same session and their results were used to assess reproducibility (test-retest variability).

## Test protocol

CS19 data were recorded at a single test session in most cases, although up to three sessions were permitted if necessary according to the study protocol. The sequence of testing procedures was as follows:

1. Background information (demographics, current processor map and programming notes) was recorded and examined in order to identify deactivated electrodes and, in particular, any electrodes known to produce uncomfortable percepts. These data can be entered into the CS19 software.

2. Any electrodes known to produce uncomfortable sensations were flagged in the software (thereby excluded from testing), but electrodes with other known abnormalities (including shorts and open circuits) were not excluded.

3. The CS19 tests were run on a PC equipped with a Cochlear Programming Pod connected to a Freedom™ sound processor and transmitter coil, with the coil placed over the participant's implant site. During testing, the participant was unable to hear through the device and so full explanation of the procedures was provided before testing.

4. The CS19 Implant Connection Check first verified connection with the implanted device and the loudness check was run next in order to ensure that stimulation did not produce any discomfort. These procedures took <1 min.

5. The "Electrode Array Test" was run, which incorporates several sub-routines including standard monopolar impedances, the intracochlear and extracochlear voltage matrix, and the IIM. Data collection took 10 min for CI24M/R implants and 20 min for CI24RE/CI500 implants (5 min for the IIM in both cases). The subject was able to read or write, and even eat or drink if desired during the test as long as the transmitter coil remained in place throughout the whole test.

6. In the subset of subjects in which reproducibility was assessed, the electrode array test was repeated (as in 5 above) after an interval of 1–2 h.

7. Test data, together with the participant's ID number, were exported from the CS19 software for subsequent analysis.

## Results

### Reproducibility (test-retest variability)

It was possible to include all 22 electrodes in all of the 31 subjects who were tested twice at a single session, i.e., there were no electrodes that had to be deactivated during testing due to discomfort. Of the 682 (22×31) electrodes tested, nine (1.3%) were deactivated in their normal clinical maps for a variety of reasons (but were included in the test routine). Figure 3A and B show the relationship between retest-test difference and mean measured value of test and retest impedances, for raw and normalized values respectively [4]. Each of the 22×31 data points represents the mean of the bipolar impedances relative to the other 21 electrodes plus the CG impedance value. The two datasets of repeated measurements were very highly correlated for
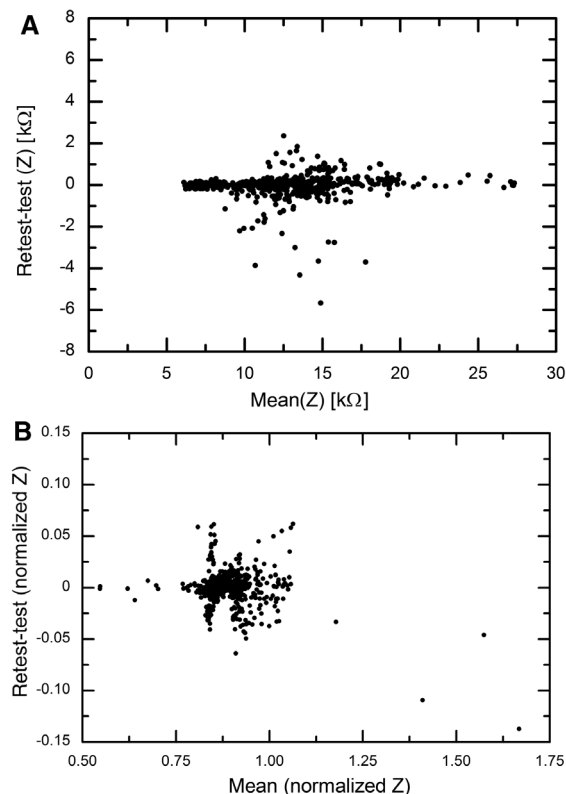
**Figure 3** Retest-test difference between initial and repeat mean raw impedance (A) and normalized IIM values (B) in 31 subjects (22 electrodes in all cases) tested twice during a single test session.

the raw and normalized values (R=0.99 in both cases). There was no significant difference between the data sets on paired t-tests (p=0.1, p=0.5 for raw and normalized values respectively). Median absolute difference between first and second measurement was calculated as 123 Ω and 0.005 for raw and normalized values respectively. It is notable that the plot of raw values (Figure 3A) shows a number of outliers with higher impedances for the initial measurement, but that these are not evident after the normalization process (Figure 3B).

## Normative ranges

Establishing normative values for the IIM first required identification of a dataset of electrodes that were considered to be functioning normally. As described above in the Introduction, significant numbers of electrodes are deactivated in routine clinical practice for a wide variety of reasons, some related to electrode faults and others to recipient characteristics. It would not be appropriate to include such electrodes in calculations of normative ranges. As there is no fundamental "gold standard"

by which to verify normal electrode function a pragmatic approach was considered necessary, whereby data were included only from implants with no known anomalies according to several criteria. The individual CI teams examined the relevant surgical and programming records for each subject and flagged devices where any of the following were present: (i) ossification or abnormal cochlear morphology; (ii) arrays showing tip fold-over on post-operative imaging (because these would not exhibit normal longitudinal profiles); (iii) electrodes with impedances outside the normal range, as identified by standard impedance telemetry (this would include electrodes with shorts/shunts and open circuits); (iv) electrodes producing non-auditory stimulation or unclear auditory percepts; (v) implants from subjects who were performing less well than would be expected.

Not all the above criteria necessarily indicate defective electrodes (particularly the case for subjects who were poor performers), as some of these situations can be produced by other patient-specific factors. However, these exclusion criteria were considered likely to produce the cleanest possible dataset with which to establish a reliable estimate of normative ranges. Further, it was necessary to exclude all data from all devices with even one single suspect electrode, as measurements for individual electrodes are affected by the characteristics of all others along the array.

From the total number of 192 implants, 144 devices were judged to have no known technical, medical or anatomical anomalies and 46 of these were randomly selected and used to calculate normative ranges. Data from the remaining subjects will subsequently be used in order to assess sensitivity and specificity for identification of normal and abnormal electrodes in a second paper.

Figure 4 shows normative IIM profiles for all electrodes along the array, where each curve consists of the median values from all 46 subjects. It is evident here that the electrodes towards both ends of the array exhibit slightly different characteristics from those near the centre; specifically, the values of electrodes immediately adjacent to the active electrode are slightly but systematically lower towards either end of the array.

For this reason, it was considered necessary to calculate normative ranges (medians and percentiles) for each electrode individually, rather than combining all electrodes. Figure 5 shows an example for electrode 12 (close to the middle of the array) and electrode 22 (at the apical end of the array). Medians and 5th and 95th percentile limits are indicated for each. It is notable that these limits appear quite narrow, even for locations remote from the test electrode. As the 5th percentile is closer to the median than the
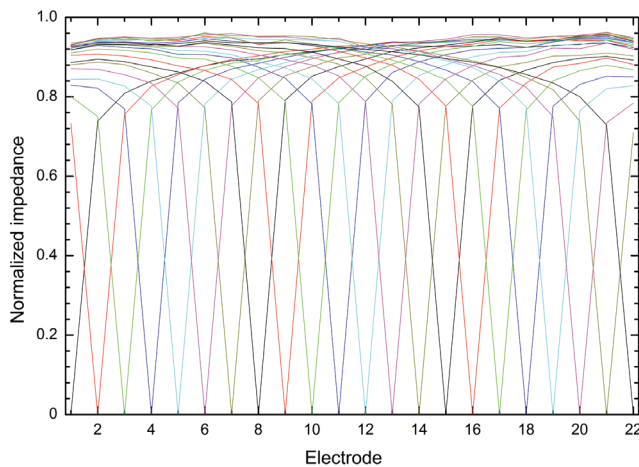
**Figure 4**  Median normalized IIM profiles for 46 electrodes judged to be functioning within specification. Each curve is based on median values from all subjects (n=46).
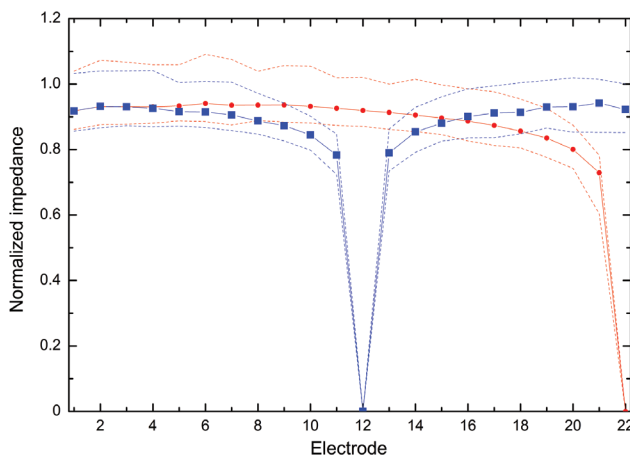


**Figure 5**  IIM limits for electrodes 12 and 22. Median (solid lines) and 5th and 95th percentile limits (dashed lines) are shown.

95th percentile, the IIMs are not normally distributed. The median was therefore used, instead of the mean, in the subsequent analysis of normative data.

**Example records**

Presentation and discussion of all types of abnormal IIM measurements are beyond the scope of this paper, which focuses on outlining the operation of the test and the outcomes of the clinical study into reproducibility and normative ranges. However, Figure 6 shows examples in order to provide the reader with some insight into how these appear using the IIM test. We intend to present further examples and more detailed methods of an automated

analysis of the IIM data using distance measures. This should be presented in a subsequent paper.

In Figure 6, two IIM examples are shown. There is a short circuit between electrodes 4 and 6 indicated by the IIM test, which cannot be found in CG impedance measurement (left figure). On the right there is a so-called "zig-zag" impedance. In this device the CG impedances of the abnormal electrodes 2, 4, 6, 8, 10, 12 and 14 were in the range of 2–5 kΩ, whereas all other electrodes had impedances of >5 kΩ. According to the clinical evaluation, the electrodes 2, 4, 6, 8, 10, 12 and 14 were classified as conspicuous. The evaluation of the IIM measurement indicated a short circuit between electrodes 2 and 4 and a borderline short circuit between electrodes 6 and 8, the electrodes 10, 12, 14 are therefore not affected by a short circuit problem. These electrodes were turned on again. The IIM test gives a more detailed status on multiple shorts.

# Discussion

This report describes the operation of the CS19 IIM test and documents results obtained in normal cases. The current version of CS19 is essentially configured for research purposes and includes a range of test routines in addition to the IIM test. Nonetheless, none of the participating clinicians in this study had any significant practical difficulties in administering the IIM in its present form. There were no reports of uncomfortable percepts and the test produced satisfactory recordings in almost all subjects (94.8%). Due to the fact that the stimulation level used is very low (in the same range as is used in normal clinical impedance measurements) the IIM test is well suited for small children or multiply handicapped CI users who cannot reliably report on their auditory percepts. This test therefore may help to ensure safe functioning implants in such patients.

The results of the reproducibility part of the study are very encouraging as there was a very close correlation between initial and retest values (Figure 3, R=0.99). Within our protocol, the two tests were performed with an interval of 1–2 h, which is close enough to assume the same physiological conditions for the two sets of measures. These results provide general confidence in the test and have an important impact on the reliability of the normative ranges calculated.

It is interesting to note that there were apparently more outliers to the right of the diagonal in Figure 3A than to the left, indicating that initial impedance values were higher than the second (repeat) values for a small number
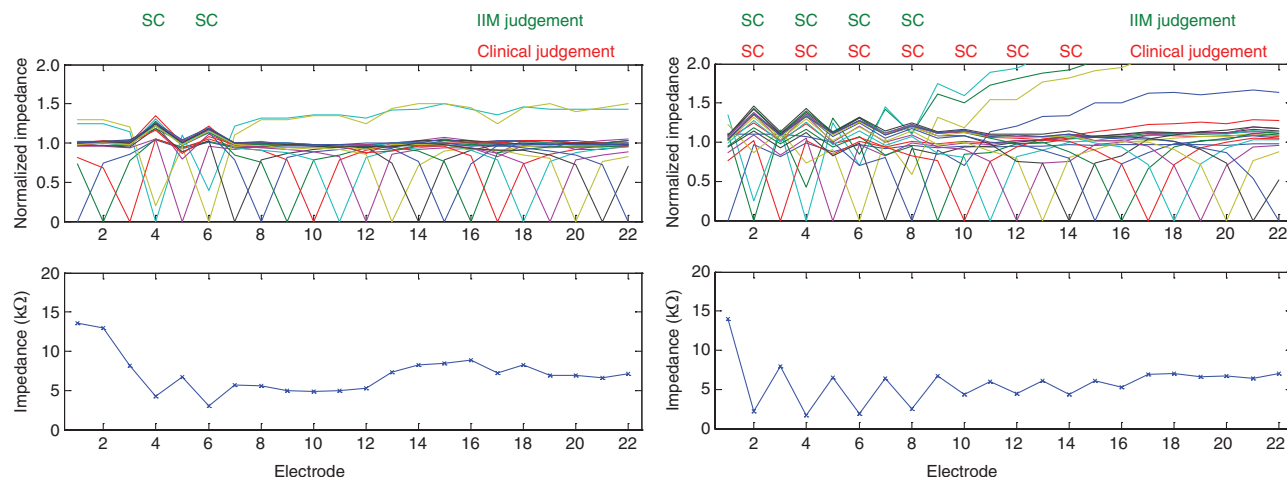
**Figure 6** Example of two IIM measurement are shown from top to bottom: (1) the IIM measurement; (2) the clinical impedance measurement in the CG – mode. (Left) short circuit between electrodes 4 and 6, which is not obvious in clinical CG measurement. (Right) following clinical diagnosis, a series of short circuits between the electrodes 2, 4, 6, 8, 10, 12 and 14 was identified. IIM test results in a short circuit between electrodes 2 and 4 and a borderline abnormal short circuit between the electrodes 6 and 8; the electrodes 10; 12; 14 are harmless.

of electrodes. Although the number of such electrodes was very small (about 2% of all electrodes), we considered it possible that these might include electrodes that were not activated in normal use. Previous studies have demonstrated that impedances of electrodes that have not been used for some time tend to reduce after a period of stimulation, such that some telemetry systems deliver a preliminary "conditioning" stimulation sequence prior to recording [5]. However, further examination of the data revealed that this was not the case. In fact, almost all of these outlying electrodes were from a single device, which did not have any deactivated electrodes in the normal clinical map, and Figure 3B shows that these outliers were not evident in the normalized data.

In the current implementation of the IIM test impedances are measured at four different points in time relative to the beginning of the stimulation pulse (at the start and end of each phase), which requires about 5 min for data acquisition. However, best reliability was obtained by using a single measure at the end of first phase; the other measurement points showed considerably poorer reproducibilty compared to the data presented in Figure 3. If this single measurement was implemented into an updated version of the test then measurement time could be reduced to about 1–1.5 min, which would be beneficial in the clinical setting.

Calculation of the normative ranges was performed using a subset of test results from devices with completely normal characteristics. However, there is no absolute definition of "normal" in this context, particularly as our purposes required a normal and consistent biophysical and biochemical environment as well as normally-functioning electrodes. We tried to ensure these conditions by excluding all factors that were likely to result in differences from this ideal. Abnormal electrodes are primarily indicated by standard impedance measurements outside the normal range, while the presence of tip fold-over will result in abnormal longitudinal profiles even if all electrodes are functioning normally. Non-auditory stimulation or unclear auditory percepts can be the result of device misplacement or abnormal current flow caused by, for example, otosclerosis [35], and cochlear malformations and ossification will also inevitably result in abnormal current paths within the cochlea [11]. We also opted to exclude subjects who had not made expected progress in speech recognition performance. As mentioned above, electrode problems sometimes only become apparent when programming is reviewed because of poor performance, particularly in children [1]. Thus, it is possible that subtle electrode problems, not identifiable using standard impedance telemetry, may also affect the quality of the auditory percept. As Goehring et al. [19] stated that normal clinical impedance telemetry shows poor sensitivity for detecting shorts between electrodes when measuring impedance in monopolar mode, a complete impedance matrix based on bipolar and CG measures may provide more information on the status of the electrode array.

The normalized impedance data (Figure 4) show similar profiles for all electrodes, but with some significant differences for the more basal and apical electrodes compared to central electrodes. For this reason, normative data were calculated for each electrode rather than for all electrodes combined. Unfortunately, a general normative curve that can be used for all electrodes would not be

valid. The differences along the array might be due to the fact that the electrical field of CG stimulation shows different geometry for stimulation in the middle compared with electrodes towards either end of the array [8, 17].

The normative ranges indicated by the test population were narrow (Figure 5), which supports the likelihood that a relatively clean dataset was identified for analysis. Indeed, it may be that IIM could provide a valid and useful "gold standard" by which to define normally-functioning electrodes. The next stage in this analysis will be to take the complete dataset, including those which were excluded for the process of assessing the normative ranges, and to calculate sensitivity and specificity for identification of abnormal electrodes with respect to our defined normal range. This analysis will be presented in a subsequent paper.

The examples of IIM results obtained in this study for low impedance paths are provided in Figure 6. These were provided in order to show how some of electrode problems appear using CS19. They may not only help to identify additional conspicuous electrodes but also to provide the clinician with further information on such conspicuous electrodes for re-activating them. The profiles in these abnormal cases are distinguished from electrodes with normal profiles. The shape of these abnormal profiles depend on certain characteristics of the normalization formula, in which IIM values depend on the relative dominance of the constituent parameters (variable BP and the active and reference CG impedances) under different conditions. Open circuits can usually be clearly identified by standard impedance measurements. To identify short circuits appears to be more complicated. One of the advantages of CS19 is the detection of abnormal current paths, such as those that occur between electrode leads with defective insulation.

In a subsequent paper we intend to present sensitivity and specificity calculations based on the normative results already obtained, with typical deviations from normal behaviour, and also to present a more detailed way of analyzing the IIM data using distance measures. In addition, examples of a wider range of electrode and cochlear abnormalities will be examined in order to demonstrate the potential of the IIM test to identify a range of conditions that can affect the quality of the electrical stimulus delivered by the implant.

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