

Cochlear Implant

A cochlear implant is a device that is able to receive processed sound signals and then stimulate the acoustic nerve so that the person is able to perceive these sounds. The first electric stimulation of the acoustic nerve in humans took place in the late 1930's. In 1957 a French group implanted microinduction coils in two patients and used these to stimulate the auditory nerve. However there were technical failures and the work was discontinued. A multiple bipolar electrode system was implanted in a deaf subject at Stanford University Medical School in 1964. This work was also abandoned due to the poor long-term benefit gained by the patient.

In the following few years many groups around the world began animal studies and showed that electrodes could be used safely and would function for long periods of time to stimulate the acoustic nerve. Two groups developed implantable systems with associated portable speech processors and techniques for screening and training patients.

In 1967 Professor G. Clark of the University of Melbourne began animal acoustic nerve stimulation studies. In 1978 and 1979 the first two implants in humans of a multichannel processor were performed and eventually, after further development, allowed the patients to understand running speech without the need for lip reading. These devices were developed commercially in Sydney and trials were begun in Melbourne in 1982.

The devices consist of a microphone, speech processor and transmitting coil worn behind the ear in the later devices, or with the speech processor in a pocket in earlier devices. Implanted in the mastoid bone behind the ear is a receiving coil. This is connected to a demultiplexor and in turn to a 22 electrode lead that is inserted into the cochlear (Figures 1 and 2).

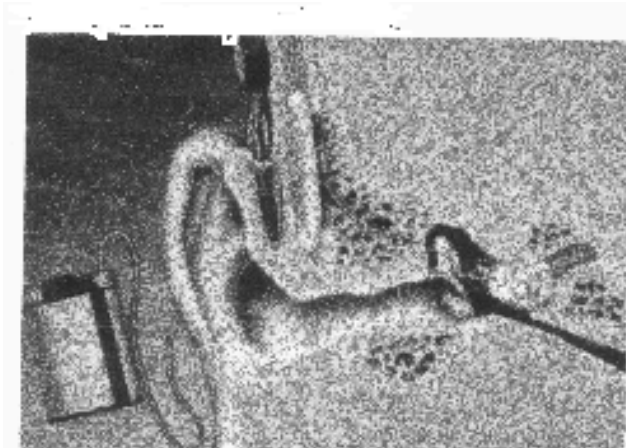


Figure 1 Earlier model bionic ear.

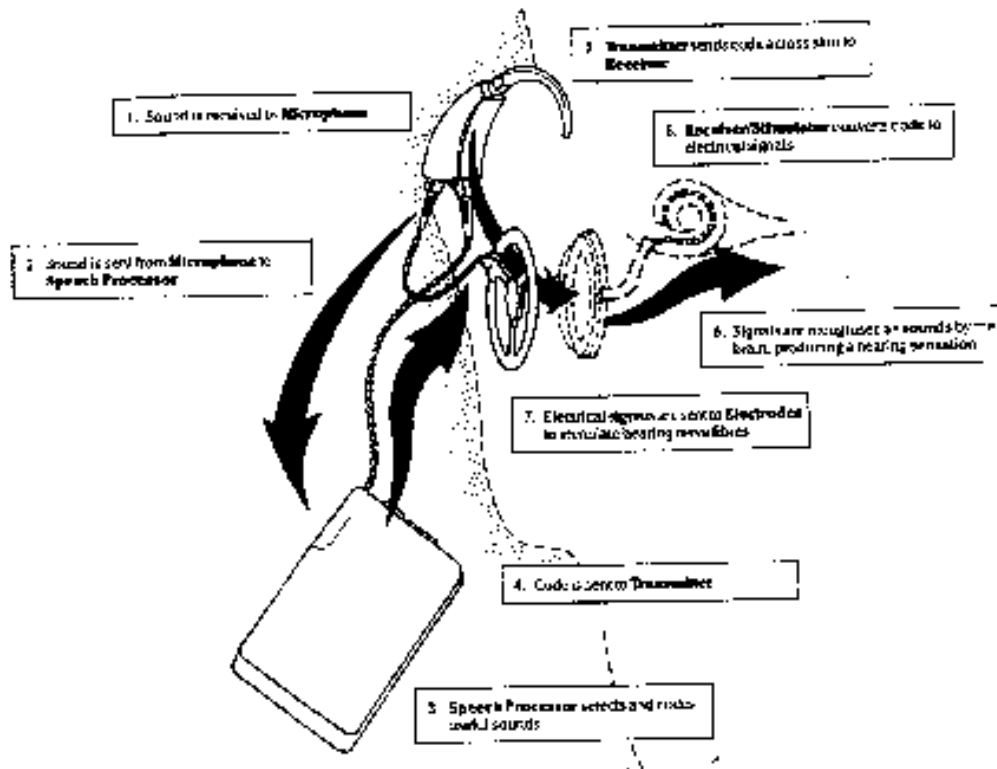


Figure 2 Mechanism of action of implanted bionic ear.

Physiology

The frequency or pitch of a sound is perceived according to the place in the cochlear where the stimulus is received and also according to the rate at which action potentials are received at the brain. Different places in the cochlear resonate at different frequencies, basically according to the distance they are from the round window; with lower frequencies (longer wavelengths) resonating the furthest from the window. In perceiving speech the frequency content can be important in “voiced” speech, which is mainly formed by the vocal chords. In this type of speech, there is a quasi-periodicity, particularly with vowels. The dominant frequencies are known as formants (Figure 3). Other components of speech are formed by the air passages, mouth, tongue and palate. These tend to be fricative or explosive in nature, are of shorter duration and contain higher frequency components. This is characteristic of many of the consonants.

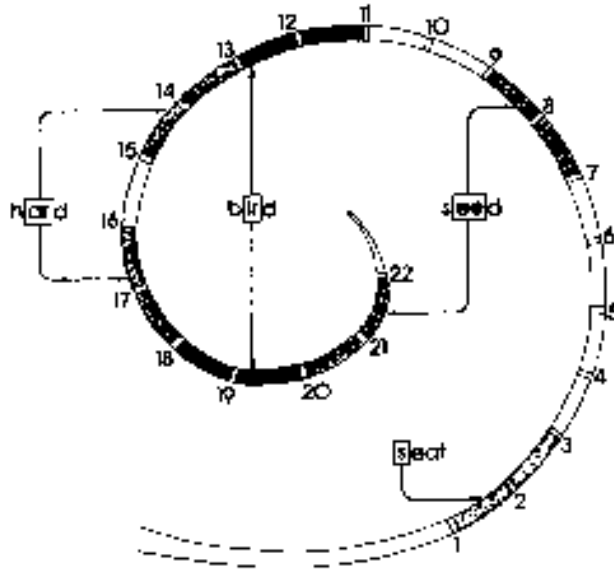


Figure 3 The electric patterns of stimulation in the cochlea for the first and second formants of some vowels and consonants.

Localised fibres of the auditory nerve can be stimulated by electrodes placed in the cochlear, thus mimicking the normal function of the cochlear. It has been found that a radial arrangement with bipolar stimulation (between two electrodes) or with a local ground in the cochlear is the most effective way of stimulation (Figure 4). Practical aspects of the implantation limit the placement of radial electrodes: surgeons need to rotate the lead as it is fed into the cochlear and there is also an unpredictable rotation as the electrode curves around the spiral of the cochlear. Thus electrodes are usually placed serially on the lead and surround the lead on its circumference. The spread of current and the practical limitations to the size of the lead and electrodes limit the number of electrodes to 22 (Figures 5, 6 and 7)

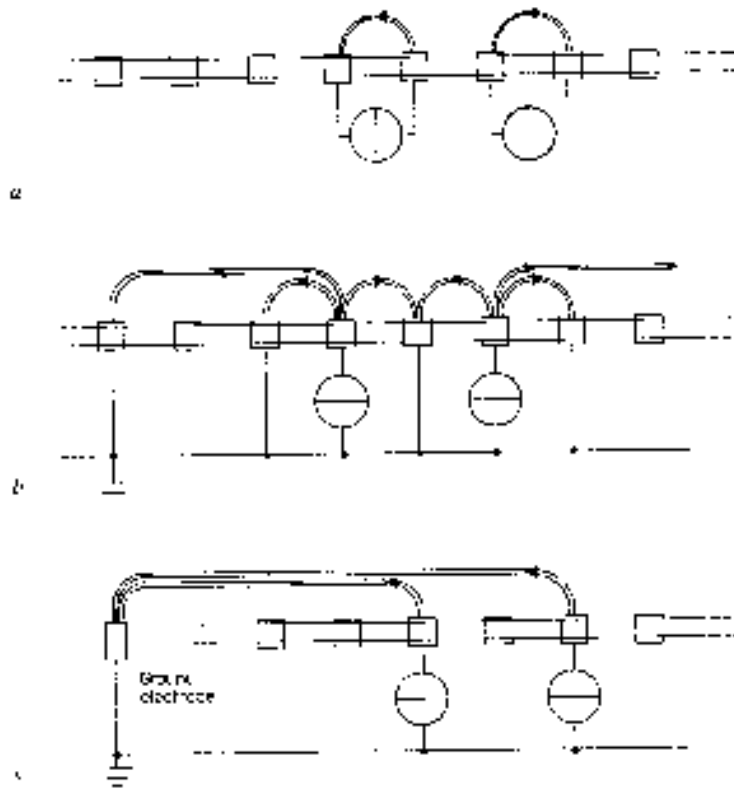


Figure 4 Cochlear lead with multiple electrodes showing current flow for (a) bipolar, (b) common intracochlear ground, (c) monopolar stimulation.

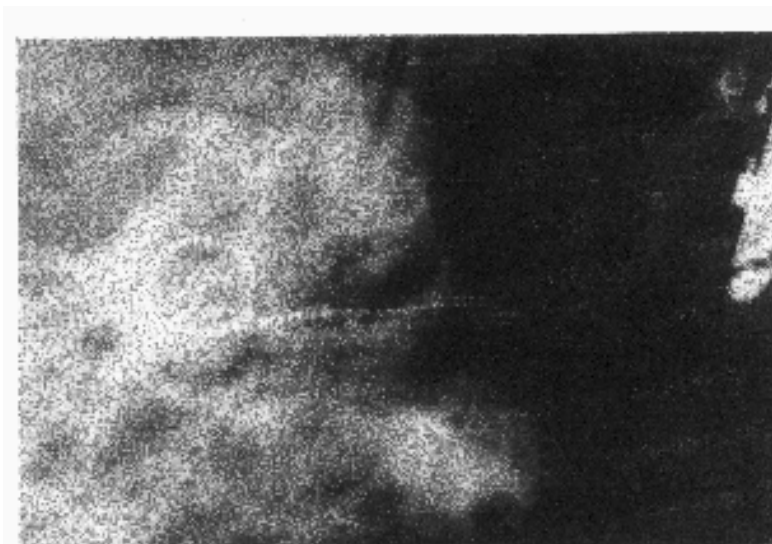


Figure 5 X-ray of the temporal bone during a cochlear implant showing the electrode in the basal spiral of the cochlea.

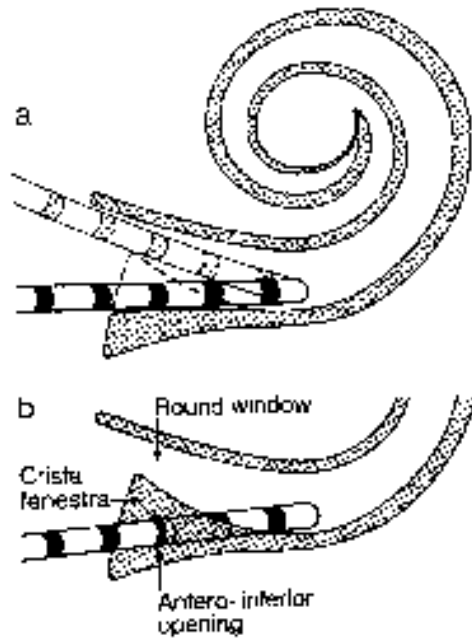


Figure 6 Alternate ways of introducing the electrode into the cochlea: (a) through the round window or (b) through an artificial opening next to the round window.

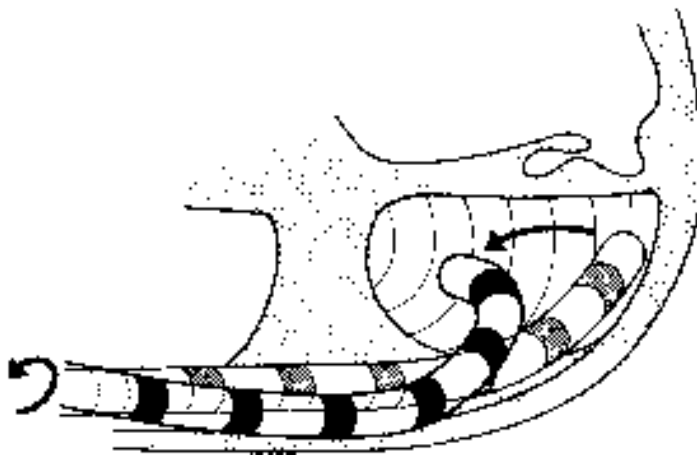


Figure 7 Introduction of the lead into the round window of the cochlea: it is necessary to rotate the lead to induce it to bend around the spiral of the cochlea.

The electrodes and the connecting wires are made from platinum, which is a biocompatible material. They are insulated with polytetrafluorethylene (Teflon), which is slippery, making insertion easy, biocompatible and flexible.

Engineering Design

It was determined, when first designing the system, that the following problems would have to be solved:

A. Receiver-stimulator

1. Transcutaneous versus percutaneous link
2. Analogue versus digital circuits
3. Data and power transfer
4. Electronic design
5. Packaging
6. Connector
7. Lead wire assembly
8. Biocompatibility
9. Reliability
10. Smaller version for children

B. Speech processor

1. Laboratory based speech processor
2. Ambulatory speech processor
3. Diagnostic programming system

Receiver Stimulator

Transcutaneous Link

There needs to be a communication between the electrodes in the cochlear and a speech processor, which, because of its size, needs to be worn outside the body. Direct linkage through a connector at the skin is prone to infection that can track along the lead to the cochlear. So magnetic induction through a coil implanted in the mastoid bone behind the ear, and an overlying coil placed on the skin was chosen as the means of communication (Figure 8). The coil in the mastoid bone was a single turn and the external coil was 8 turns. Magnets in the centre of each coil ensured that there would be correct alignment between the coils. Provided the separation was no more than 10 mm, it was determined that adequate power, as well as signals, could be transmitted.

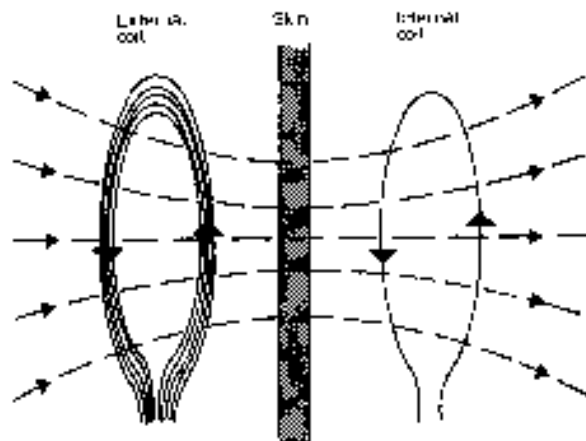


Figure 8 External transmitting coil and implanted receiver coil providing transcutaneous electromagnetic link.

Digital Processing

It was decided to use digital signals as these could be easily combined with control information and transmitted through a single pair of coils, whereas an analogue system would require multiple pairs of coils or a frequency multiplexed system with multiple channels. This would be a larger volume to implant and require more power. A digital circuit is more immune to noise and more flexible in terms of the ability to program the device to suit individual patient needs.

Data and Power Transfer

Data, including control signals, and power were transmitted by a modulated carrier wave of frequency 2.5 MHz (Figure 9).

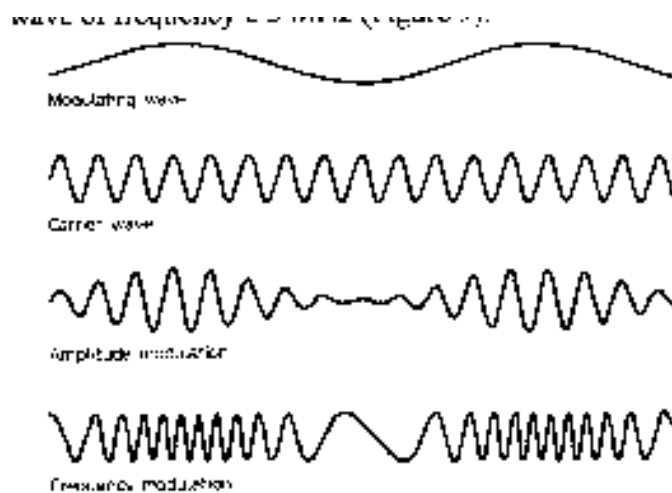


Figure 9 Frequency modulated carriers were used to provide speech, control signals and power.

Electronic Design

Animal experiments showed that it would be necessary to code pitch by rate (or timing) of stimulation, as well as by place of stimulation in the cochlear. There was a need to allow for as much flexibility as possible, as there is much still not known as to how speech is processed by the cochlear, transmitted to and interpreted by the brain.

Intensity was varied from a minimum of 25 μ A to a maximum of 1.5 mA in 3% steps. The rate of stimulation was varied in 125 μ s steps up to 1 kHz on each of 22 electrode pairs as well as using a common ground. Stimulating pulse width could be varied from 20 to 400 μ s per phase in steps of 0.4 μ s. As it was difficult to predict loudness in simultaneous stimulation of electrodes, stimulus was for one pair of electrodes at a time. There was thus no need to control the phase between different pairs of electrodes.

Packaging

The implanted electronics was packaged in a welded titanium case (Figure 10). This is a relatively inert material as far as the body is concerned. It can transmit magnetic

fields, however it was not possible to transmit sufficient power so that the receiver coil was placed around the case and was embedded in silicone rubber. At operation it is easier to drill into the mastoid bone using a milling burr. So a round shape was preferred. The size of the mastoid bone limited the dimensions to 30 mm in diameter with a depth of 8 mm. A smaller package was required for children. Ceramic feed-throughs were used to bring wires through the case.

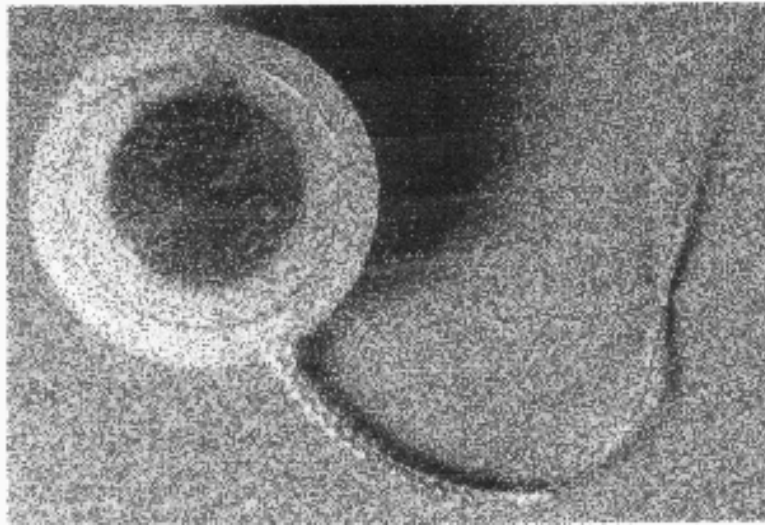


Figure 10 Adult sized case surrounded by receiving coil with lead connected to other side.

Connector

It was decided to use a connector between the implanted case and the lead, so that the case could be replaced if there was an electronics failure. Connectors must have pressure between contacts maintained for a lifetime, must use the same metals to avoid corrosion and must not permit the ingress of body fluids to prevent current leakage between contacts. The connector contacts were on two substrates with the conductors etched on them. Connection was made by conducting and non-conducting elastomate material which was compressed between the two substrates. An additional compressed elastic pad was placed between the package and the electrode assembly pad to maintain the contact pressure.

Lead Wire Assembly

It is possible to move the implanted case by rubbing behind the ear. For this reason stress relief was provided for the lead where it emerged from the case by tapering the bundle and spiralling the wires.

Biocompatibility

Biocompatibility was assessed by implanting the assembly in animals. Both the titanium case and the silicone (Silastic) cover of the receiving coil and lead wires were known to be biocompatible from extensive experience with heart pacemakers implanted for many years in humans.

Reliability

The device will operate normally in electric fields of up to 10 V/m in the frequency range 10 kHz to 1 GHz, except that the patient perceives a low-level background acoustic noise. With a magnetic field of 1 mT at a frequency of 60 Hz a low-level background acoustic noise could also be perceived, otherwise the device operated normally. There was greater than 100 dB noise immunity against the maximum recommended 60 Hz magnetic fields specified by the Food and Drug Authority (FDA) of the USA. It also had more than 36 dB noise immunity against maximum electromagnetic field strengths beyond 5 MHz as specified by the FDA. The device could also withstand thermal cycling, free fall, impact shock and vibration as specified by the Australian Standards Association.

Children

The connector occupied a substantial portion of the total volume of the assembly. It was thought necessary as it was thought that if the electronics had to be replaced, it was better to leave the lead in place as removing and replacing it would cause too much damage to the cochlear. It was found with several patients, in whom it was necessary to replace the leads, that no injury was caused by this replacement. So to reduce the volume for a child's device, the connector was left out (Figure 11, 12 and 13). The lead exits from one side of the case and the receiving coil is offset to the other side of the case. The receiving coil surrounds a rare earth magnetic in a sealed titanium case. This aligns with a similar magnet in the transmitting coil.

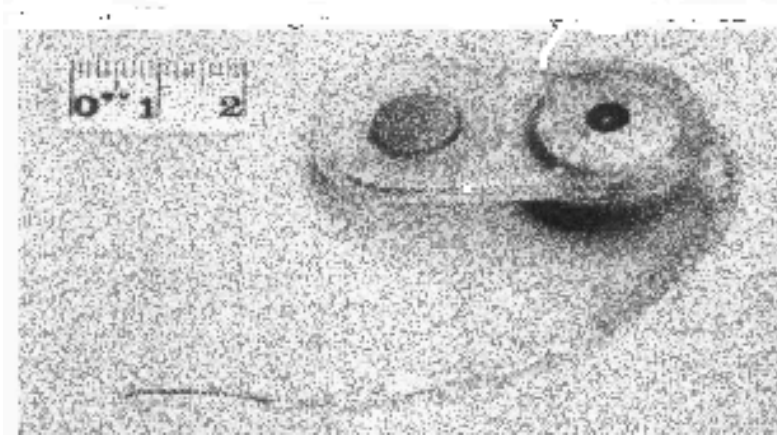


Figure 11 Child sized device with receiving coil offset and locating magnet in centre.



Figure 12 Child wearing the headset with magnet that is used with the child sized receiver-stimulator.

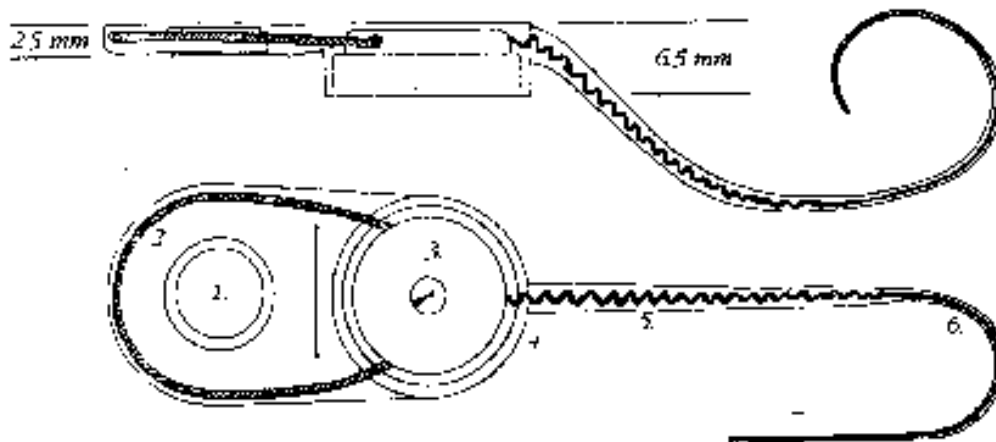


Figure 13 Child-sized implantable receiver-stimulator.

Speech Processor

Three types of speech processors were developed:

1. A laboratory version used for further psycho-acoustical research.
2. A portable processor used by the patient.
3. A diagnostic and programming system that could be coupled to the patient's processor and used for initial programming after operation, and also for trouble shooting.

Portable Speech Processor

The first speech processor was designed to be worn in a pocket and connected to a hair band containing the transmitting coil and a microphone on one side (Figure 14). Later speech processors clipped behind the ear and contained the transmitting coil and

microphone .

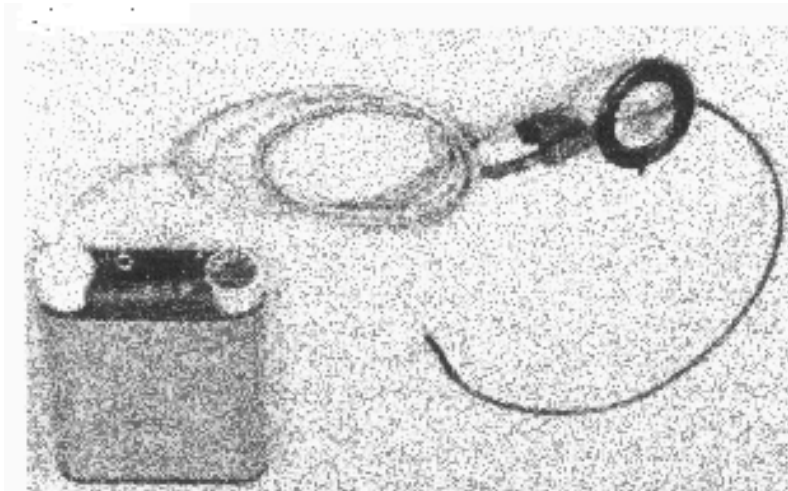


Figure 14 Wearable speech processor and headset first developed by Cochlear Pty Ltd.

The microphone is directional and designed to pick up sounds in front of the patient. The amplified speech signal is directed along three parallel paths in order to extract amplitude envelope, fundamental frequency (FO) and the frequency formants (first formant, F1, and second formant, F2) (Figure 15). The amplitude envelope detector extracts the overall envelope amplitude and also the amplitudes of F1 (A1) and F2 (A2). The fundamental frequency is converted to a pulse rate and the formant frequencies are converted to electrode positions. These parameters are digitised and then used to modulate the carrier for transmission to the receiver. An automatic gain controller compresses the dynamic range of the speech signal. Amplitudes are found by passing the signal through a filter, a full-wave rectifier then a low-pass filter.

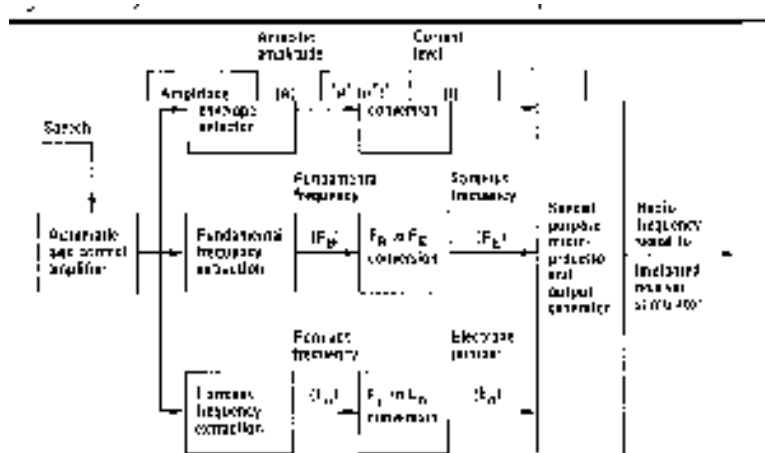


Figure 15 Block diagram of speech processor.

The stimulating electrode current is set in proportion to the compressed signal amplitude. (Perceived loudness is also dependent on stimulating pulse width as well as current.) The relationship between perceived loudness and stimulating current is a

power function. The coefficient of the power function can be determined for an individual patient by psycho-physical experiments. The coefficient can vary between different electrodes depending on the size and location of the electrodes, and on the density of residual nerve fibres in the cochlea. A look up table is used to set the current amplitudes. Fundamental frequency is found by passing the output of the automatic gain control segmentally through a filter, a rectifier, a low-pass filter, a zero crossing counter and a frequency to voltage converter. The output analogue voltage representing frequency may be scaled before digitising. Formant frequencies are found in a similar way, using different initial filters. The electrode number is then found from a look up table. The look up table is found by psycho-physical experiments with the individual patients.

The signal parameters described above are continuously fed to the controlling logic and output transmitter in real time. A CMOS gate array encoder controls the instants at which the parameter values are sampled and modulates the carrier signal.

Diagnostic and Programming System (DPS)

This system is used to program the patient's own speech processor with the threshold, comfortable listening and maximum (discomfort) levels for individual electrodes (Figure 16). This information is obtained from psycho-physical tests and the values are then written into the EPROM of the patient's speech processor as a map.

The DPS consists of a custom microprocessor based speech processor interface (SPI) and a conventional personal computer called the diagnostic and programming unit (DPU), which controls the SPI. There is a parallel link between the DPU and SPI. The patient's own portable speech processor is plugged into the SPI, which then controls it. In this way a wide variety of stimulus parameters can be tried and psycho-physical tests performed. When a map is generated it can be tested with live speech from a microphone and if satisfactory then programmed into the EPROM of the patient's speech processor. In the earlier versions the EPROM was erased by ultra-violet light and was also housed in the SPI. The patient is also able to control stimulus levels with a knob. The audiologist controlling the tests also has headphones that broadcast an audible signal at each stimulus pulse.

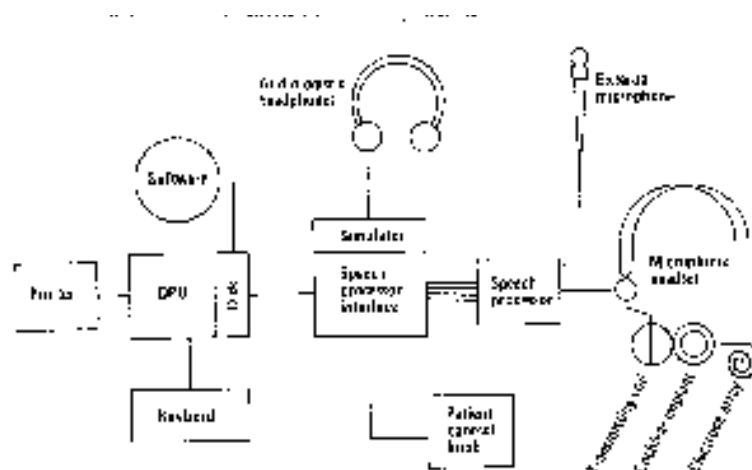


Figure 16 Block diagram of the diagnostic programming system.

Programmes and data can be stored on floppy discs of the DPU. There are five main programmes: threshold measurement, loudness scaling, place-pitch ranking, pulse rate discrimination and map generation.

Threshold measurement is used to determine minimum and maximum (comfort) levels. A burst of pulses at a rate fixed by the audiologist (usually 125 Hz) is delivered to each electrode in turn. The stimulus level may be selected by the audiologist from the keyboard of the DPU or by the patient via the control knob.