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ELECTROMAGNETIC COMPATIBILITY OF HEARING AIDS WITH DIGITAL MOBILE PHONES

by

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B.S. in Physics,
Boğaziçi University, 1994

Submitted to
the Institute of Biomedical Engineering
in partial fulfillment of the requirements for
the degree of Master of Science
in
Biomedical Science

Boğaziçi University

Istanbul

1997

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DATE OF APPROVAL : 17.6.1997

ACKNOWLEDGEMENTS

The work presented here was performed under Biomedical Engineering Institute at Boğaziçi University between September 1996 and June 1997 supervised by Associate Professor Mehmed Özkan. Electromagnetic compatibility tests were conducted at EMI/EMC Laboratory of TÜBİTAK Marmara Research Center National Electronics and Cryptology Research Institute.

I would like express my gratitude to my thesis advisor Associate Professor Mehmed Özkan for his continuous supervision throughout this study and for being more than a thesis advisor for me.

I would like to thank Dr. Temel Yalçın, my Manager at TÜBİTAK Marmara Research Center, and my colleagues, particularly Fatih Üstüner, for their valuable contribution in solving problems I have faced during laboratory testing.

I would like to thank Professor Dr. Yekta Ülgen, Professor Dr. Selim Şeker and Dr. Niyazi Arı for their precious advices and their interest in the study.

I would like to thank Professor Dr. Ferda Akdaş for providing me hearing aids I have tested and supplying me information on hearing aids. I would also like to thank Dr. Sezer Külekçi for her sincere help and her patience in co-working.

Baki Karaböce, Enver Sadıkhov and Eyüp Bilgiç from TÜBİTAK National Metrology Institute are also acknowledged for their technical support in acoustic measurements.

Finally, I would like to express my gratitude to my family and my friends who supported me morally in every phase of my life.

ABSTRACT

When the intensity of emissions from a radio transmitter varies at an audible rate, it causes interference on sensitive electronic equipment. Hearing aid user complaints caused by this kind of interference were increased by the introduction of digital mobile phones in recent years. Interference reveals itself as a disturbing "buzzing" sound in the hearing aid output.

The electromagnetic compatibility of 16 different hearing aid types was measured for high-frequency electromagnetic fields, particularly for those emitted by digital mobile phones. An automated PC-controlled test setup was developed for testing. Setup consisted of a GTEM cell where high frequency fields were generated. Draft version of IEC 118-13 standard was utilized as a basis for the test methodology. All of the hearing aids showed susceptibility to some degree. Interference levels up to 140 dB SPL was measured in 800-960 MHz range of the carrier frequency. Six of the hearing aids were found to produce levels above the level (55 dB SPL Input Related Interference Level) proposed by the standard. Increasing levels of the electric field strength resulted in a quadratic increase in sound pressure levels produced by the hearing aid. This 1:2 dB ratio proves to be a helpful tool in interpolating for any field strength level that was not tested. Test setup and methodology developed for this study together with the results can be used to evaluate the electromagnetic compatibility of hearing aids to high frequency electromagnetic fields.

ÖZET

İŞİTME CİHAZLARININ CEP TELEFONLARIYLA ELEKTROMANYETİK UYUMLULUĞU

Bir radyo vericisinden yayılan emisyonların şiddeti ses frekanslarında değiştiğinde, hassas elektonik cihazlarda girişim oluşur. Cep telefonu (sayısal mobil telefon) kullanımının yaygınlaşmasıyla, işitme cihazı kullanıcılarının bu tip girişimden kaynaklanan şikayetleri artmıştır. Girişim, işitme cihazı çıkışında rahatsız edici bir vızıltı şeklinde belirmektedir.

Onaltı değişik tip işitme cihazının elektromanyetik uyumluluğu, özellikle cep telefonlarından yayılan yüksek frekanslı elektromanyetik alanlar için test edilmiştir. Test için bilgisayar kontrollü bir düzenek geliştirilmiştir. Düzenekte, içinde yüksek frekanslı alanların üretildiği bir GTEM hücresi yer almaktadır. Testlerde IEC 118-13 taslak standardına dayanan bir usul takip edilmiştir. Bütün işitme cihazları belirli derecelerde alınganlık göstermişlerdir. 800-960 MHz taşıyıcı frekans aralığında, 140 dB SPL'ye kadar girişim seviyesi ölçülmüştür. Altı işitme cihazı, standardın öngördüğü 55 dB SPL Girişle İlişkili Girişim Seviyesi'nden yüksek seviyeler üretmiştir. Elektrik alan şiddetindeki her 1 dB artışın, işitme cihazında üretilen ses basınç seviyelerinde 2 dB artışa sebep olduğu bulunmuştur. Bu 1:2 dB oranı, test edilmeyen alan şiddeti seviyeleri için enterpolasyon yapmada kullanışlı bir araçtır. Bu çalışma için geliştirilen test düzeneği ve kullanılan test metodolojisi, ulaşılan sonuçlarla birlikte, işitme cihazlarının yüksek frekanslı elektromanyetik alanlara karşı uyumluluğunu belirlemede kullanılabilir.

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1. INTRODUCTION

Twentieth century has faced a wide application of electrical energy almost in every walk of life. We use create, transmit, transduce and dissipate electrical energy in various forms for various applications, ranging from large power requirements in factories to small household appliances. Electromagnetic interference issue is an unavoidable result of such wide spread use of electrical and electromagnetic energy. Electromagnetic interference is an undesirable response of an electrical system caused by other electrical systems or by itself. Failure of electric or electronic devices due to interference may have differing consequences depending on the function the device performed. For instance, a temporary malfunction of a TV caused by conductively interference from an electrical vacuum cleaner may not be so vital, still being a disappointing situation. On the other hand, jamming of radio receivers of an army during warfare may result in serious consequences. Medical devices is an another class of devices that needs special care when dealing with interference problems since, for instance, failure of a life-supporting device may cause injuries and even death of a patient. In addition, failure in devices that are used for diagnosis may result in false treatments.

In order to overcome the adverse effects of interference, electromagnetic compatibility concept is introduced to describe the gainful operation of an electrical equipment in its intended environment without affecting or being affected by other equipment. In order to achieve this, many aspects should be considered, of course. Control of emissions from a device, improving the immunity of a device to interference using some techniques (filtering, grounding, shielding, etc.) and suppressing coupling modes are to name a few.

There are many examples of susceptible medical devices in everyday life. Hearing aids, for instance, are used by people who have a considerable degree of hearing loss. These devices are said to be affected from interference caused by digital mobile phones which were recently introduced to public use but gained an increasing level of ubiquity. In order to have an understanding of the interaction between these devices, tests must be

performed. Underlying the physical basis of interaction, recommendations for a solution can be given in present means. Studying one interaction in detail would help us to understand the electromagnetic interference phenomena better.

In this thesis, electromagnetic compatibility of medical instruments, particularly hearing aids, are investigated in many aspects. In Chapter 2, an overview of electromagnetic compatibility is presented. Electromagnetic interference phenomenon is briefly explained starting from electromagnetic field conception and extending to coupling paths. Sources and receptors of electromagnetic interference are determined and electromagnetic compatibility design principles are introduced.

Electromagnetic compatibility of a device can be proved by performing some specific tests on it. Thus, Chapter 3 covers measurment techniques and instrumentation used in compliance testing. Measurement of emissions from a device and testing a device for immunity is the main subject of this chapter, having the emphasis on the latter.

In Chapter 4, operation principles, types, basic components and controls of hearing aids are presented. Technical standards for testing electroacoustic characteristics of hearing aids are introduced as a first level in understanding the electromagnetic compatibility testing of these devices.

In Chapter 5, interaction between the hearing aids and the digital mobile phones are studied. Previous studies about the interaction are mentioned. Necessary conditions for testing and elements of an automated setup are described.

Results of many tests performed are presented in Chapter 6 in order to have an understanding of different sides of the interaction. The results of the tests are evaluated and discussed. Further recommendations are given based on the information given preceding chapters. Chapter 7 is the conclusion of the study.

Since it is impossible to cover all electromagnetic compatibility related subjects in the scope of a thesis, some information thought to be useful are included in Appendices. Electromagnetic interference problem in medical devices, standardization efforts in electromagnetic compatibility field and square law detection of RF signals are important issues complementary to this thesis.

2. AN OVERVIEW OF ELECTROMAGNETIC COMPATIBILITY

Electromagnetic Compatibility (EMC) is defined as the gainful operation of electric, electromechanical and electronic devices, equipment and systems in a common environment such that no degradation of performance exists due to internally or externally conducted or radiated electromagnetic emissions. EMC is a general concept which needs to be understood clearly. This chapter covers a brief summary of electromagnetic compatibility and related issues.

2.1 Electromagnetic Waves and Fields

We live in an electromagnetic environment. Electromagnetic waves coming from both natural and artificial sources surround us. Light as a simple and common example is a form of electromagnetic energy and is the basis of life for most of the living things. Besides light that is visible and, thus, can be encountered and recognized easily, there are many forms of electromagnetic energy that are invisible and can not be recognized unless advanced equipment is used. Emissions from some electrical and electronic equipment while they are operating is a good example for that kind of electromagnetic energy.

In free space electromagnetic waves propagate with the velocity of light, c, which is often approximated to 3×10^{8} m/s for practical purposes. The speed of light is imposed as the ultimate speed in the universe by Albert Einstein in his special theory of relativity. This means that speed of light (and electromagnetic waves) is the maximum speed one can observe. It corresponds to a traveling distance of about 1 m only in 3 nanoseconds, i.e. in 3×10^{-9} s. Repetition rate of a wave is the frequency, f, of that wave and is expressed in Hz or 1/s. Then the period $T=1/f$ seconds and the wave travels a distance of c/f meters in this time. This distance is called the wavelength, $\lambda=c/f$. The angular frequency, $\omega=2\Pi f$ is another concept used to express a wave [1].

All electromagnetic waves, as the name suggests, consist of two essential components, an electric field and a magnetic field. The relative magnitude between the magnetic (H) field and the electric (E) field depends upon how far away the wave is from its source, and the nature of the generating source itself. The ratio of E to H is called the wave impedance, Z_w. That is,

$$Z_w = E / H \qquad (1)$$

If the source contains a large current flow compared to its potential, such as may be generated by a loop, a transformer or power lines, it is called a current, magnetic, or low impedance source. The latter definition is derived from the fact that the ratio of E to H has a small value. Conversely, if the source operates at high voltage, and only a small amount of current flows, the source impedance is said to be high, and the wave is commonly referred to as an electric field.

At very large distances from the source, the ratio of E to H is equal for either wave regardless of its orientation. When this occurs, the wave is said to be a plane wave, and the wave impedance is equal to 377 ohms, which is the intrinsic impedance of free space. Beyond this point all waves essentially lose their curvature, and the surface containing the two components becomes a plane instead of section of a sphere. In the far-field region, these two fields are perpendicular to each other when propagating and the direction of propagation is at right angles to the plane containing these two components. Propagation of electromagnetic fields in far-field is illustrated in Figure 2.1 [2].

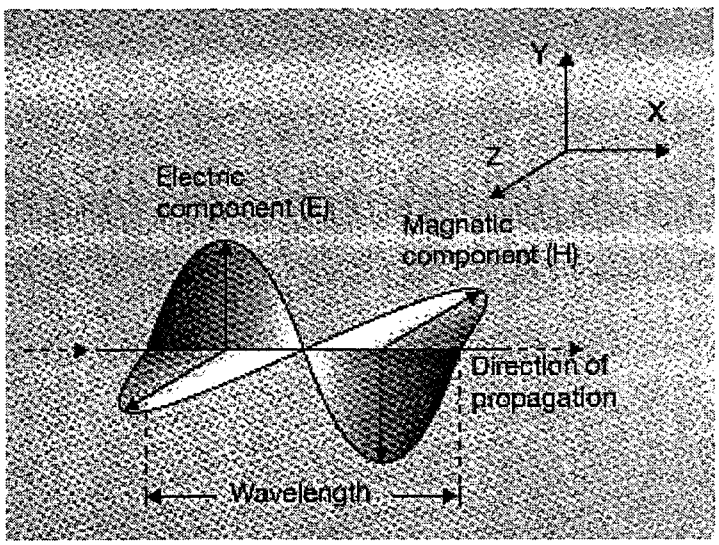


Figure 2.1 The two components of the electromagnetic field in far-field.

2.2 Units and Decibels

An electric field is produced by a charged body. On the other hand, a magnetic field arises because of electrical currents in conductors. Both field components, i.e. the electric field and the magnetic field, exert a force on the surroundings depending on their magnitude. Electric field strength is designated as E and has units of V/m (volts per meter). H is used to designate magnetic field strength, which is dependent on the flow of current through the electrical conductor. H is measured in A/m (amperes per meter). In some applications, however, magnetic flux density B is measured in T (tesla) or G (gauss) [3].

The primary quantities of interest in the EMC problem are conducted emissions (voltage in volts (V) and current in amperes (A)) and radiated emissions (electric fields in volts per meter (V/m) and magnetic field in (A/m)). Associated with these primary quantities are quantities of power in watts (W) or power density in watts per square meter (W/m^2). The numerical range of these quantities may be quite large. For instance, electric fields can range from 1 μV/m to 200 V/m. Because of this, decibel (dB) units are introduced in order to express a wide range of quantities in a compressed manner. For instance, a voltage in eight orders of magnitude (10^8) can be expressed as 160 dB [4].

Ratio of two physical quantities in decibel units is given by;

$$dB \equiv 20 \log\left(\frac{V_2}{V_1}\right) \quad \text{for voltage;} \tag{2}$$

$$dB \equiv 20 \log\left(\frac{i_2}{i_1}\right) \quad \text{for current; and} \tag{3}$$

$$dB \equiv 10 \log\left(\frac{P_2}{P_1}\right) \quad \text{for power.} \tag{4}$$

Note that decibels are the ratio of two quantities. Absolute power, voltage, or current levels are expressed in dB by giving their value above or referenced to some base quantity. For example, voltages, when referenced to 1 μV, are expressed as dBμV using:

$$dB\mu V \equiv 20 \log\left(\frac{volt}{1\ \mu V}\right) \tag{5}$$

Other common units are dBmV, dBmA and dBμA which are referenced to 1 mV, 1 mA and 1 μA respectively [5]. Since the radiating electromagnetic fields are expressed in V/m and A/m, corresponding dB units used to express them are as follows:

$$dB\mu V/m \equiv 20 \log\left(\frac{V/m}{1\ \mu V/m}\right) \tag{6}$$

$$dB\mu A/m \equiv 20 \log\left(\frac{A/m}{1\ \mu A/m}\right). \tag{7}$$

2.3 Electromagnetic Environment

Electromagnetic environment is defined as "the totality of electromagnetic phenomena existing at a given location" in International Electrotechnial Vocabulary (IEV) prepared by International Electrotechnial Commission (IEC). (A brief description of this organization is given in Chapter 4.) Note that this totality is generally time dependent and its description may need a statistical approach [6].

Sources of electromagnetic energy can be divided into natural and man-made with, in most cases, the natural sources of radiation present at a much lower level than the man-made. The majority of unintentional emissions occupy a wide range of frequencies which is called broadband. Intentional emissions such as radio and televisions transmissions are termed narrowband, which occur at a single frequency or are accompanied by a few frequencies at the sidebands.

2.4 Electromagnetic Interference

All electrical and electronic equipment operate in an electromagnetic environment and thus are subject to some form of electromagnetic energy. In some cases they are

designed to receive certain type of electromagnetic waves in the environment. For example radio receivers and radar are *intentional receivers*. On the other hand, most of the electrical and electronic equipment are not designed to receive forms of electromagnetic energy. They are *unintentional receivers* or, in a more correct sense, victims of the electromagnetic environment.

The effect of electromagnetic waves emanating from one electronic equipment on another equipment is known as "interference". More formally, this is known as electromagnetic interference (EMI). International Electrotechnical Vocabulary defines EMI as "degradation of the performance of a device, equipment or system caused by an electromagnetic disturbance". Disturbance and interference are cause and effect respectively. However, the English words "interference" and "disturbance" are often used indiscriminately. Disturbance is "any electromagnetic phenomenon which may degrade the performance of a device, equipment or system, or adversely affect living or inert matter". Note that electromagnetic disturbance may be an electromagnetic noise, an unwanted signal or a change in the propagation medium itself. Finally, electromagnetic noise is defined as "a time-varying electromagnetic phenomenon apparently not conveying information and which may be superimposed on or combined with a wanted signal" [6].

2.4.1 Examples of Electromagnetic Interference

Electromagnetic interference (EMI) is a specific kind of environmental pollution which produces associated damage. With the almost global emphasis today on the elimination or reduction of environmental pollution, the layman readily recognizes and understands water, air, noise and other forms of pollution. He probably has not heard of or doesn't know much about electromagnetic or electrical noise pollution because it cannot be directly seen, tested, smelled or felt. Therefore, he asks, ``How can it be a problem ?". However, it is just as damaging as the other forms of pollution, as explained below.

Some of the simple examples of EMI are familiar to almost everyone and are generally regarded as a nuisance or inconvenience. For example, it is readily known that certain types of electric shavers will jam a nearby radio. The resulting buzzing or crackling noise results in the inability to listen to the radio while the shaver is in use. Here the

conducted or radiated electrical noise jams the radio picking up the broadcast stations. Another example is when an unsuppressed automobile idling outside of a house or an apartment causes interference on one's TV picture by blotching, developing intermittent dash lines or bars or even causing complete flipping (loss of synchronization) of the picture.

More serious examples of electromagnetic pollution occur if a person having a heart pacemaker uses electrical appliances, shop equipment, automobiles or other RF energy emitting sources which cause his pacemaker to operate improperly or in a different mode. Here, results could manifest themselves in unconsciousness or even death.

The electromagnetic pollution problem has been and can be far more damaging than the loss of a single life. It can involve many people, industries and the like. For example, if two airplanes collide during severe weather due to either EMI navigation errors or computer memory loss because of electrical transients in a storm, the loss of life and property become substantial. If police mobile radios are jammed during a riot at rush hour due to the composite effects of many automobile ignition noises, the consequences can be enormous. Similarly, if an army in combat finds that its communications, radar and other modes of combat effectiveness are jammed by its own spectrum pollution noise sources, a battle can be lost, along with many lives and much property.

Some major electrical power blackouts can result from a pyramiding effect of fault sensing transient devices during an electrical storm. Here the impact can involve millions of lives and have enormous economic consequences [7].

And so it develops that the EMI or electrical noise problem giving rise to spectrum pollution is indeed of national concern. Some international organizations, governments, and certain industrial elements, have issued specifications with which all electrical, electro-mechanical and electronic equipment must comply. Unfortunately, policing and enforcing these specifications is another matter, and so the problems persist.

2.5 Three Elements of an EMI Problem

There are three essential elements to any EMI problem. There must be a source of an electromagnetic phenomenon, a receptor (or victim) that cannot function properly due to

the electromagnetic phenomenon, and a path between them that allows the source to interfere with the receptor (see Figure 2.2). Each of these three elements must be present although they may not be readily identified in every situation.

Electromagnetic interference problems are generally solved by identifying at least two of these elements and eliminating (or attenuating) one of them.

Potential sources of electromagnetic compatibility problems include radio transmitters, power lines, electronic circuits, lightning, lamp dimmers, electric motors, arc welders, solar flares and just about anything that utilizes or creates electromagnetic energy. Potential receptors include radio receivers, electronic circuits, sensitive medical devices, people, and just about anything that utilizes or can detect electromagnetic energy. Methods of coupling of electromagnetic energy from a source to a receptor fall into one of four categories:

(1) Conducted (electric current)

(2) Inductively coupled (magnetic field)

(3) Capacitively coupled (electric field)

(4) Radiated (electromagnetic field)

Coupling paths often utilize a complex combination of these methods making the path difficult to identify even when the source and receptor are known. There may be multiple coupling paths and steps taken to attenuate one path may enhance another.

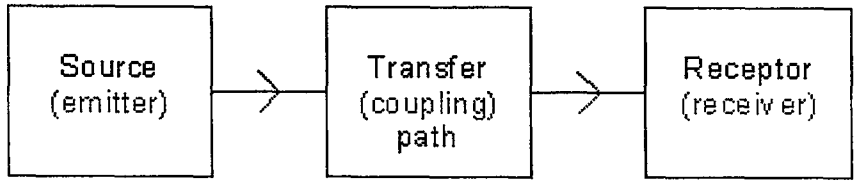


Figure 2.2 Three Elements of an EMI Problem.

2.6 Sources of Electromagnetic Noise

Interference sources can be natural or man-made. Atmospheric noise is a natural interference source produced predominantly by local thunderstorms in the summer and by tropical region thunderstorms in the winter. The electromagnetic emissions from

thunderstorms are propagated over distances of several thousand kilometers by an ionospheric skywave and thus potential EMI effects are not localized. A natural source, cosmic noise, is a composite of noise sources comprised of sky background radio noise, which is caused by ionization and synchrotron radiation which undergoes a daily variation, and solar radio noise which increases dramatically with an increase in solar activity and the generation of solar flares. Secondary cosmic noise sources are the Moon, Jupiter and Cassiopeia-A constellation. At 30 MHz the average cosmic noise is 34 dB. Because of the wide frequency span over which natural emissions occur they may cause EMI in HF/VHF/UHF/SHF transmissions.

Some of the major sources of man-made electromagnetic noise are arc welders, RF heaters, Industrial, Scientific, and Medical (ISM) equipment, AC high voltage transmission line, automotive ignition, fluorescent lamps, microwave ovens, hospital equipment, diathermy equipment, communication transmitter intentional and spurious radiation, and electric motors [8].

We can classify the sources of electromagnetic noise according to their coupling mode or their effect on sensible equipment. From this point of view, Radio Frequency Interference (RFI) sources, Electrostatic Discharge (ESD) sources and power disturbance sources are the main classes.

2.6.1 RFI Sources

Radio frequency range begins at about 10 kHz on the low end, and usually extends to 500 MHz for commercial applications, and to 40 GHz (radar frequencies) for military and aircraft applications. RFI is generally continuous (i.e. long relative to circuit response time) rather than transient. Table 2.1 shows some typical high level RF sources.

The electric field strength of an RF source drops off inversely with distance from the source. Thus, a low power walkie-talkie located a meter away poses a much greater threat than a high powered commercial broadcaster a kilometer away. Even worse, this handheld source is mobile, making it difficult to trace.

Mobile radio transmitters are also a threat, particularly near emergency vehicles. These transmitters have higher power than the handheld types and they often pose a threat

at distances of 10 meters or more. Any equipment in or near the emergency wing of a hospital will be exposed to these threats on a regular basis. Any medical devices mounted in or carried into an emergency vehicle are exposed to even higher levels of RF energy and must be protected.

Table 2.1 High Level Radio Frequency Sources of Interference.

Category	Name	Frequency Range
Medical Devices (unintentional radiators)	Diathermy	27 MHz-500 MHz
	ESU	30kHz-100 MHz
	MRI	60 MHz
	Lasers	27 MHz (varies)
Radio Transmitters (intentional radiators)	Television	54 MHz-800 MHz
	Radar	1 GHz-40 GHz
	AM Radio	550 kHz-1.6 MHz
	FM Radio	88 MHz-108 MHz
	Land Mobile *	30-50 MHz
		150-170 MHz
		450-500 MHz
	Cellular phone	900 MHz
Other	Arc welders	2-20 MHz
	RF heaters	13.5, 27, or 40 MHz typical
* Land mobile includes police, fire, ambulance, pagers and walkie-talkies.		

Many common medical devices use RF energy and can pose a threat to nearby electronic equipment. These include diathermy units, Magnetic Resonance Imaging (MRI) systems, lasers, and Electrosurgical Units (ESU). The ESU used in an operating room is particularly offensive, as it "sprays" RF all over the place, upsetting even robust electronics, not to mention sensitive monitoring equipment.

Other potential RF threats include theft detectors, RF welders and RF heat-sealing equipment. While not commonly found in the medical environment (although arc welders may be involved in hospital construction projects), they can cause problems to patients equipped with portable electronics, and biomedical engineers should be alert for these unexpected threats.

The measure for RF problems is the "electric field intensity", given in volts/meter as we discussed above. This can be measured with a field strength meter, and, in simple cases,

can also be predicted. For today's electronics failures typically occur in the 1-10 volts/meter range, although failures were observed on some sensitive equipment in the 0.1 volt/meter range. Unfortunately, nearby radio transmitters can cause levels in the 1-100 volts/meter range, depending on the power level and the distance from the transmitter. This is why most medical RF regulations now specify test levels in the 3-10 volts/meter range. But even this is not enough for equipment used in emergency vehicles carrying radio transmitters, which may experience field strengths as high as 200 volts/meter.

2.6.2 Electrostatic Discharge and Powerline Sources

Electrostatic discharge (ESD) follows a gradual charge buildup. Actual charge buildup will occur over a period of time, generally seconds or more, and usually poses no threat to electronics. When discharge occurs, it takes only a few nanoseconds, and this is what causes the ESD problem. Actual discharge can be from a human body to or near the equipment in question, or it may be accumulated by the equipment (as in the case where the equipment is portable or on rollers) and discharged from there.

The source of ESD is always due to rubbing two materials together. Even air flowing over certain materials is capable of transferring enough charge to destroy unprotected electronic components, but usually cannot build up enough charge to affect assembled equipment.

The actual buildup is not harmful to electronics- it is the discharge that does the harm. The discharge is characterized by a 1 ns rise time to peak current of about 10 A. This 1 ns rise time equates to an equivalent frequency of 300 MHz.

On the other hand, the sources of power disturbances are widely varied. These include voltage variations, frequency variations, waveform distortions, lightning surge transients and electrical fast transients (EFTs) and continuous noise.

Radio frequency interference that may be generated by nearby radio equipment, especially an AM radio, often causes continuous noise. Radio frequency interference, as described above, may enter the equipment via the power line. On an oscilloscope, RFI appears as a fuzzy sine wave, but is a actually high frequency energy imposed on the power line voltage.

Generally, electronic equipment should be able to withstand modest amounts of interference. Long-term disturbances are simply operating voltage tolerance. As the disturbance duration becomes shorter, the recommended interference amplitude tolerance increases, finally reaching several thousand volts for very brief transients [9].

2.7 EMI Coupling Paths

The modes of coupling between an emitter and a receptor can be very complicated. Coupling can also result from a combination of paths, such as conducted from an emitter to a point of radiation, then picked up by induction, and reconducted to the victim. Furthermore, these conducted paths can involve any conductor- power lines, signal lines, and ground paths as well as the fortuitous conducting paths in any facility such as building steel, conduit and plumbing.

RFI coupling mode depends on frequency and wavelength. Low frequencies travel easily along conducted paths, but do not radiate efficiently. On the other hand, high frequencies radiate efficiently, but are impeded by inductance in wires.

Then comes the question: How do we determine a frequency as low or high? A commonly applied metric is to assume that when a cable or a wire is longer than 1/10 of a wavelength, the cable or wire becomes a good antenna, so the radiated path will predominate. One-tenth factor comes from the comparison of radiation resistance of a wire with that of a quarter-wave antenna. An antenna which transmits or receives 10 per cent or less of the energy that would be transmitted or received by a quarter-wave antenna can be considered relatively inefficient. Monopoles of length $\lambda/11$ meet this criterion [10].

Below 1/10 of a wavelength conducted effects will tend to dominate. By using this metric we can see that effective radiated coupling from an AM radio transmitter needs long cables i.e. about 15 m, but above 30 MHz even a few cm may be enough to as an unwanted antenna. This criteria can be extended a bit further to cabinets and enclosures, too. Any cabinet openings or apertures greater than 1/10 of a wavelength can act as "slot antennas", and can actually couple reradiated energy from outside the box to the internal electronics. For example, at 450 MHz, a 6 cm slot can pose problems. For ESD, 1 ns rise time equates

to an equivalent frequency of 300 MHz which does not travel down a wire, due to inductance in the wire, but couples very well

Unlike ESD and RFI, which usually have multiple paths, power disturbances are always conducted through the power line. The disturbance can be line to line, or it can be line or neutral to ground.

2.8 Receptors of Electromagnetic Noise

2.8.1 Receptors of Radio Frequency Interference

Circuits are the ultimate receptors of RFI. Digital circuits have much higher noise immunity levels compared to analogue ones, but can also be upset, given a strong enough source. Most electronic devices today contain digital circuits, but many medical devices often also contain sensitive analog circuits.

Analog circuits are much more susceptible to RF than digital circuits. The most sensitive amplifiers are usually at the front end, which, unfortunately, are often connected to patients via cables (these act as unwanted antennas.) Common characteristics of such inputs are low signal levels (10 μV to 10 mV), high input impedance (1 MΩ or more), low bandwidth (under 10 kHz), and extremely low leakage currents (20 microamps). The leakage current is particularly disturbing, as it can severely limit filtering and decoupling.

Analog circuits are subject to "audio rectification". Analog amplifiers detect and demodulate RF. If these demodulated signals fall into the expected signal frequency range, they will be processed as "real" signals. Once this demodulation occurs, no amount of filtering can remove the offending signals. Incidentally, since rectification occurs due to nonlinearities, bipolar devices are more prone to these failures.

This explains why high frequency sources (such as a 150 MHz transmitter) cause problems with a low frequency receptor (such as an ECG channel). Cellular phones transmitting at high frequencies but modulated in the audio range are a common source of interference. The interaction between mobile digital phones and hearing aids is studied in this thesis in detail and the amount of audio rectification of interfering signals is determined experimentally.

2.8.2 Receptors of ESD and Powerline Disturbances

ESD will cause both momentary upset or permanent damage to electronic components. Indirect discharge is most often characterized by transient effects, from which the circuit quickly recovers. Permanent damage often arises from direct discharge, which has typically much greater amplitudes. Disturbance can be line to line, or it can be line or neutral to ground.

Permanent damage is a widely recognized problem with modern insulated gate field effect devices, as even a few hundred volts is sufficient to cause these devices to fail catastrophically. Another possibility is for the ESD to drive the circuit into latch-up, sometimes destroying the part (the chip overheats) or sometimes simply biasing the chip into a nonfunctional state.

Transient effects to active electronics are much more prevalent. Digital circuits are very vulnerable to ESD hits. Modern circuits are quite capable of responding to the narrow transient, amplifying it, and passing it on, ultimately latching it in a storage register or memory cell. In such cases external intervention is needed to restore the register or memory cell to a legitimate value. Analog circuits are fairly immune to ESD signals (but not for damage), although we have also seen upset in high impedance feedback circuits.

Power disturbances, on the other hand, may affect the power supply, or may pass through to attack the electronics within, causing temporary upset or, in severe cases, component destruction. For most power disturbances the issue is one of energy storage and regulation. If the power supply cannot be feasibly designed to handle these conditions, then external conditioning will be required.

In the case of a high voltage transient caused by lightning, the principal risk is an overstress to electronic equipment, especially the power supply. This is simply a case of too much voltage and current for the supply to handle. For severe transients it may be sufficient that the equipment is not left in an unsafe state (i.e., on fire or with dangerous voltages). For lesser transients it is desirable that the equipment survive and operate through the transient without adverse effect [9].

2.9 EMC Design: Solution to the Problem

Electromagnetic compatibility (EMC) is a necessary condition for effective electronic equipment or system performance. EMC is the ability of equipment and systems to function as designed in their intended operational environment without adversely affecting the operation of, or being affected adversely by, other equipment or systems. Thus, the manner in which modern life is conducted and its efficiency depends on the ability to achieve and maintain EMC.

Controlling the otherwise damaging effects of EMI is best accomplished in the planning stage, i.e., the conception and early design stages of devices, equipment and systems. The ability to implement this pragmatically is predicated in part on whether EMI develops within a system or equipment (intrasystem interference) or between two or more removed and discrete systems (intersystem interference).

The basic EMC requirement is to plan, specify and design systems, equipment and devices that can be installed in their operational environments without creating or being susceptible to interference. To help satisfy this requirement careful consideration must be given to a number of factors that influence EMC. In particular, it is necessary to consider major sources of EMI, modes of coupling and points or conditions of susceptibility, which are the three basic elements of any EMI problem, as we stated earlier. To effectively suppress and control EMI problems, it is necessary to develop an awareness of the role that each of these basic elements play, assess potential EMI problems (which requires quantitative information on EMI levels produced by sources, coupling from source to victim and victim susceptibility) and understand how to minimize the resulting EMI impact on potentially susceptible devices. The electronic equipment or system designer should be familiar with the basic tools (including prediction, analysis, measurement, control, suppression, specifications and standards) that are used to achieve EMC. EMI design techniques involve both hardware and methods and procedures [7].

EMI is an interdisciplinary problem that can be solved by careful consideration and attention during all phases in the life cycle of a system or equipment. To achieve EMC in an economical and effective manner, it is necessary to use a sound combination of:

1. Interference prediction and analysis techniques to identify and define the problems,

2. EMC specifications and standards to ensure comprehensiveness during equipment design and development stages,

3. EMI control devices and techniques during equipment or system design, development and production to ensure that specifications and standards are met,

4. Measurements to provide prediction inputs and ensure compliance with EMC specifications and standards,

5. Suppression techniques during installation and operation to solve specific problems that arise as a result of severe or unusual operating conditions.

During each phase of the equipment life cycle, responsible management and engineering personnel must give appropriate attention to the particular EMC considerations applicable to their areas of responsibility if EMI-free operation is to be assured.

The designer of electronic equipment or systems for use in either military or commercial applications must give careful consideration to EMI. It is particularly important for the designer to define the electromagnetic environment in which his system must operate and the system must be designed so that it can operate in that environment without experiencing operational performance degradation resulting from EMI.

3. ELECTROMAGNETIC COMPATIBILITY MEASUREMENT TECHNIQUES AND INSTRUMENTATION

One of the aspects of electromagnetic compatibility that is most difficult to understand is the raft of techniques that are involved in making measurements. EMC phenomena extend in frequency to well beyond 1 GHz and this makes conventional and well-known techniques, which are established for low frequency and digital work, quite irrelevant. Testing is of vital importance in proving the compliance with standards. Regulations and standards concerning EMC and medical devices are included in Appendix B. In this chapter, we will examine EMC test methods and instrumentation.

3.1 RF Emissions

For ease of measurement and analysis, radiated emissions are assumed to predominate above 30 MHz and conducted emissions are assumed to predominate below 30 MHz. Of course, there is no magic changeover at this frequency. Typical cable lengths of equipment under test (EUT) tend to resonate over above 30 MHz, leading to anomalous conducted measurements, while measurements of radiated fields below 30 MHz will need to be made in the near field if closer to the source than $\lambda /2\Pi$, which gives results that do not necessarily correlate with real situations. In practice, investigations of interference problems have found that reduction of noise voltages developed at the mains terminals has been successful in alleviating radio interference in the long, medium and short wave bands. At higher frequencies, mains wiring becomes less efficient as a propagation medium.

Emissions measurements requires that the equipment under test (EUT) is set up within a controlled electromagnetic environment under its normal operating conditions. If the object of the measurement is to test EUT alone, rather than as a part of the system, its associated equipment (if any) must be separately screened from the measurement. Any ambient signals should be well below the levels to which the equipment will be tested.

The operating configuration is normally specified within emissions standards to be that which maximizes emissions. This is not always easy to predict and test engineer must

perform some preliminary tests while varying the configuration. Also, one configuration may generate high emissions in one part of the spectrum and another configuration may generate a different set of high emissions.

3.1.1 Measurement Instrumentation

Basic equipment used in RF emissions tests are the measuring receiver, spectrum analyzer and transducers.

Conformance tests are normally taken with a *measuring receiver*. These are in most cases too expensive for ordinary companies' development labs and they are usually found in EMC test houses. They are optimized for the purpose of taking EMC measurements.

Early measuring receivers were manually tuned but current generation of receivers are fully automated and can be software controlled via an IEEE-488 standard bus. This allows a PC-resident program to take measurements with the correct parameters over the full frequency range of the test, in minimum time consistent with gap-free coverage. Results are stored in the PC's memory and can be processed or plotted at will.

A fairly basic *spectrum analyser* is cheaper than a measuring receiver and is widely used for "quick-look" testing and diagnostics. The instantaneous spectrum display is extremely valuable for confirming the frequencies and nature of offending emissions. Basic spectrum analysers are not an alternative to a measuring receiver because of their limited sensitivity and dynamic range, and susceptibility to overload [11].

One can find instruments which offer a performance equivalent to that of a measuring receiver, but the price then becomes roughly equivalent as well. A more satisfactory compromise is to enhance the spectrum analyser's front-end performance with a tracking preselector. The preselector is a separate unit which contains input protection, preamplification and a swept tuned filter which is locked to the spectrum analyser's local oscillator. The preamplifier improves system noise performance to that of a test receiver. Equally importantly, the input protection allows the instrument to be used safely in the presence of gross overloads, and the filter reduces the energy content of broadband signals that the mixer sees, which improves the effective dynamic range.

Including a tracking generator with the spectrum analyser greatly expands its measuring capability without greatly expanding its price. With it, the test engineer can make many frequency-sensitive measurements which are a necessary feature of a full EMC test facility.

The tracking generator is a signal generator whose output frequency is locked to the analyser's measurement frequency and is swept at the same rate. The output amplitude of the generator is maintained constant within very close limits, typically less than ±1dB over 100 kHz to 1 GHz. The tracking generator/ spectrum analyser combination can be used for the following applications: characterizing the loss of RF cables, performing open site attenuation calibration, characterizing components, filters, attenuators and amplifiers, making tests of shielding effectiveness of cabinet or enclosures, determining structural and circuit resonances and performing RF immunity testing of equipment.

Bandwidth, detector function and the measurement time are important aspects of measurement systems and they characterize the certainity or uncertainty level of the measurement.

The actual value of an interference signal that is measured at a given frequency depends on the bandwidth of the receiver and the its detector response. These parameters are defined in a separate standard that is referenced by all the commercial emissions standards that are based on the work of CISPR, notably EN 55011, 55013, 55014 and 55022. This standard is CISPR publication 16, Specifications for Radio Interference Measuring Apparatus and Measurement Methods [12].

There are three kinds of detector in common use in RF emissions measurement: peak, quasi peak and average. The characteristics are defined in CISPR 16 and are different for the different frequency bands.

CISPR 16 splits the measurement range of 9 kHz to 1000 MHz into four bands, and defines a measurement bandwidth for quasi-peak detection which is constant over these bands. Sources of emissions can be classified into narrowband and broadband. The actual distinction between narrowband and broadband is based on the bandwidth occupied by the signal compared with the bandwidth of the measuring instrument. A broadband signal is one whose occupied bandwidth exceeds that of the measuring instrument.

Interference emissions are rarely continuous at a fixed level. A carrier signal may be amplitude modulated, and both a carrier and a broadband emission may be pulsed. The measured level which is indicated for different types of modulation will depend on the type of detector in use.

Another aspect of testing to mention is the measurement time. Both the quasi-peak and average detector require a relatively long time for their output to settle on each measurement frequency. This time depends on the time constants of each detector and is measured in hundreds of miliseconds. When a range of frequencies is being measured, the conventional method is to step the receiver at a step size of around half its measurement bandwidth, in order to cover the range fully without gaps.

For any RF emissions measurement, a *transducer*, that is, a device to couple the measured variable into the input of the measuring instrumentation is needed. Measured variables take one of three forms: radiated electromagnetic field, conducted cable voltage and conducted cable current. For the measurement of these variables basic transducers and instrumentation used are antennas, absorbing clamps, current probes and artificial mains networks.

3.1.2 Radiated Emissions Measurements

Radiated field measurements can be made of either electric (E) or magnetic (H) field components. In the far field the two are equivalent, and related by the impedance of free space, as we have mentioned in Section 2.1 before:

$$\frac{E}{H} = Z_0 = 120\Pi = 377\Omega \qquad (8)$$

But in the near field they are unrelated. In either case, an antenna is needed to couple the field to the measuring receiver. Electric field strength limits are specified in terms of volts (or microvolts) per meter at a given distance from the EUT, whilst measuring receivers are calibrated in volts (or microvolts) at the 50 Ω ohm input. The antenna

therefore must be calibrated in terms of volts input to 50 Ω for a given field strength at each frequency; this calibration is known as antenna factor. (Figure 3.1)

Most standards allow the use of broadband antennas, which remove the need for returning at each frequency. The two most common broadband devices are the biconical, for the range 30-300 MHz, and the log periodic, for the range 30-1000 MHz. Some antennas have different frequency ranges, but it is always possible to combine a biconical and a log periodic to cover the range 30-1000 MHz.

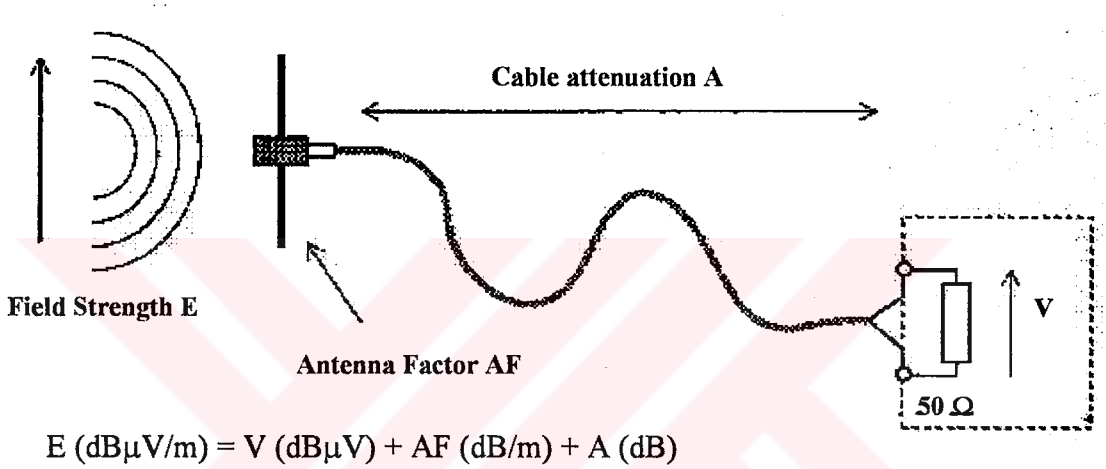


Figure 3.1 Important parameters in RF emissions measurement by an antenna.

A tuned dipole is also specified as an alternative and has the advantage that its performance can be accurately predicted. Because it can only be applied at spot frequencies it is not used for every measurement but is reserved for calibration of broadband antennas, site surveys, site attenuation measurements and other more specialized purposes.

Two aspects of antennas need to be considered are system sensitivity and polarization. System sensitivity problems are encountered when measurements are performed by an antenna to the spectrum analyser. Polarization of the antenna depends on the changing response of the antenna with its alignment according to the incident field.

The majority of radiated emissions are measured in the range 30 MHz to 1000 MHz. A few standards call for radiated measurements below 30 MHz. In these cases, magnetic field strength is measured, using a loop antenna. Measurements of magnetic field give better repeatability in the near field region than do measurements of the electric field,

which is easily perturbed by nearby objects. The loop is merely a coil of wire which produces a voltage at its terminals proportional to frequency.

Radiated emissions measurement must take place in environments with well-defined electromagnetic characteristics. Open Area Test Sites (OATS) and Full or Semi Anechoic Chambers are environments of this kind.

3.1.3 Conducted Emissions Measurements

To make conducted voltage emissions tests on mains port, the test engineer needs an artificial mains network or Line Impedance Stabilization Network (LISN) to provide a defined impedance at RF across the measuring point, to couple the measuring point to the test instrumentation and to isolate the test circuit from unwanted interference signals on the supply mains.

As well as measuring the emissions above 30 MHz directly as a radiated field one can also measure the interference currents on connected cables and relate these to the accepted field strengths. Standards which apply primarily to small apparatus connected only by a mains cable - notably EN 55014 - specify the measurement of interference power present on the mains lead. This has the advantage of not needing a large open area for the tests, but it should be done inside a fairly large screened room and the method is somewhat clumsy. The transducer is an absorbing device known as a ferrite clamp. The ferrite clamp consists of a current transformer using two or three ferrite rings, split to allow cable insertion, with a coupling loop.

Also useful for diagnostics is the current probe, which is essentially the same as the absorbing clamp except that it doesn't have the absorbers. It is simply a clamp-on, calibrated wideband current transformer [13].

3.1.4 Example: Emissions from a Digital Mobile Phone

Since we study the electromagnetic compatibility of hearing aids particularly against emissions from digital mobile phones in this thesis, we include here an example of measured emissions from these devices.

RF emissions were measured in a GTEM cell in EMI/EMC Laboratory of National Electronics and Cryptologic Research Institute at TUBITAK Marmara Research Center. GTEM will be studied later in this chapter.

Emissions were measured for three modes of operation: STAND-BY, CALL and TALK. In stand-by mode, digital mobile phone is ready to dial a number and to receive incoming calls. It keeps communicating with the base station. In Call mode, digital phone dials an external number. Finally, in Talk mode, a speech takes place and voice data is transferred via antenna emissions of the digital phone. In stand-by mode, emissions were at very low level. On the other hand, other two modes, particularly Talk mode, comprise high levels of emissions as it is illustrated in Figure 3.2.

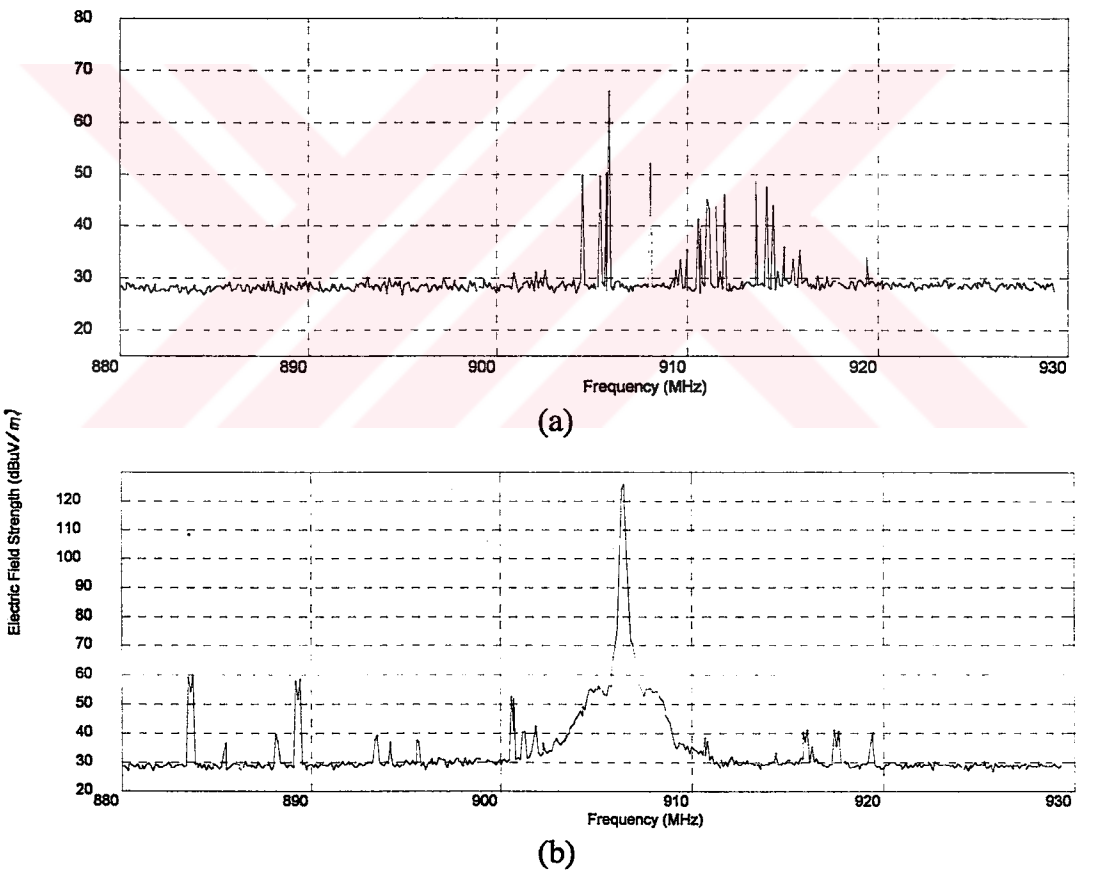


Figure 3.2 Emissions from a digital mobile phone in (a) CALL and (b) TALK modes as measured in GTEM cell.

Emissions measurements in a GTEM cell were performed for three orientations of the equipment under test in three orthogonal axes, that is, X, Y and Z. These data are then correlated for a 10 m Open Area Test Site (OATS) measurement using a software which is

provided by the manufacturer. Thus, these levels correspond to fields radiated from a digital mobile phone at 10 m distance.

However, field levels originating from a digital mobile phone is much greater in the near field. Macfarlane [14] measured field levels up to 250 V/m very close to a handheld digital mobile phone. This test was performed in an anechoic chamber using a field strength monitor for distances in the 1-10 cm range.

3.2 RF Immunity

When we refer to Appendix B we see that most commercial immunity testing was not mandatory until the European EMC Directive, but it was driven by customer requirements for reliability in the presence of interference. Military and aerospace immunity test standards have been in existence for some time and have occasionally been called up in commercial contracts in default of any other available or applicable standards. These allow for both conducted and radiated RF immunity test methods. The major established commercial standard tests were those listed until recently in IEC 801. These have now been superseded by IEC 1000-4-3 [15] and 1000-4-6, for radiated and conducted tests respectively, and their European pre-standard equivalents ENV 50140 and 50141. EN 55020 requires both conducted and radiated immunity tests, but applies only to broadcast receivers and related equipment.

Radiated field immunity testing, in common with radiated emissions testing, suffers from considerable variability of results due to the physical conditions of the test set-up. Layout of the EUT and its interconnecting cables affects the RF currents and voltages induced within the EUT to a great extent. At frequencies where the EUT is electrically small, cable coupling predominates and hence cable layout and termination must be specified in the test procedure.

Testing the electromagnetic compatibility of hearing aids is actually an immunity testing since there is no emissions from this device measured at a considerable level. Therefore immunity testing of electronic instruments will be studied in more detail.

3.2.1 Equipment

Figure 3.3 shows the components of a typical radiated immunity test set-up in a screened room. The basic requirements are an RF signal source, a broadband power amplifier and a transducer. The latter may be a set of antennas, a transmission line cell or a stripline. These will enable the test engineer to generate a field at the EUT's position, but for accurate control of the field strength there must be some means to monitor it at the EUT, together with control of the level that is fed to the transducer. A test house normally integrates these components with computer control to automate the frequency sweep and levelling functions.

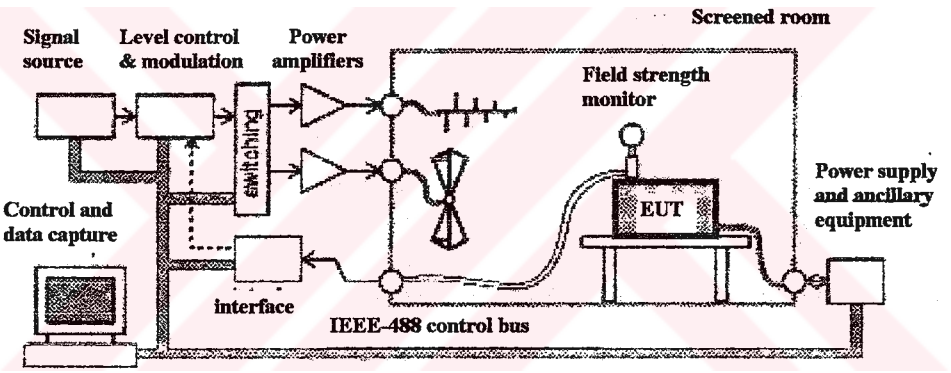


Figure 3.3 RF immunity test setup.

3.2.1.1 Signal Source

Any RF signal generator that covers the required frequency range (80-1000 MHz for IEC 1000-4-3, 150 kHz-80 MHz for IEC 1000-4-6) will be useable. Its output level must match the input requirement of the power amplifier with a margin of a few dB.

IEC 1000-4-3 calls for the RF carrier to be modulated at 1 kHz to a depth of 80 per cent, although the previous version (IEC 801-3) did not require modulation (Figure 3.4). This can be done within the signal generator or by a separate modulator. The tracking generator output of a spectrum analyser can be used for swept application, or a synthesized signal generator can be used for stepped application. Generally, if control software is used this will set the frequency in steps across the band to be covered. The required frequency

accuracy depends on whether the EUT exhibits any narrowband responses to interference. A manual frequency setting ability is necessary for when the test person wants to investigate the response around particular frequencies. No transient level changes must be caused within the signal generator by range changing or frequency stepping.

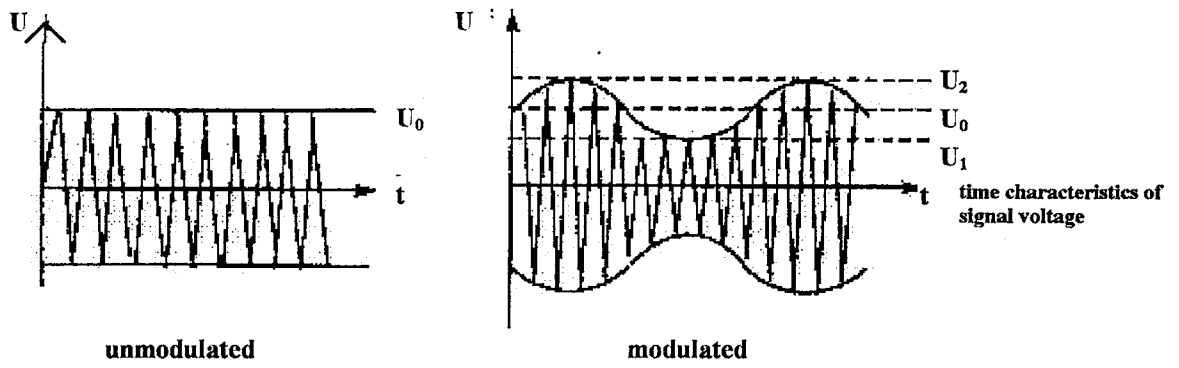


Figure 3.4 Amplitude Modulation of a carrier wave.

3.2.1.2 Power Amplifier

Most signal sources will not have sufficient output level on their own, and a set of power amplifiers are required to increase the level. The power output needed will depend on the field strength that is be generated at the EUT, and on the characteristics of the transducers used. As well as the antenna factor, an antenna will be characterized for the power needed to provide a given field strength at a set distance. This can be specified either directly or as the gain of the antenna.

The power output versus bandwidth is the most important parameter of the power amplifier and it largely determines the cost of the unit. Very broad band amplifiers (1-1000 MHz) are available with powers of a few watts, but this may not be enough to generate required field strengths from a biconical antenna in the low VHF region. A higher power amplifier with a bandwidth restricted to 30 - 300 MHz will also be needed.

Some over-rating of the power output is necessary to allow for modulation, system losses and for the ability to test at a greater distance. Modulation at 80 per cent, as required by IEC 1000-4-3, increases the instantaneous power requirement by a factor of 5.2 dB. If the system uses transducers such as a TEM cell or stripline rather than a set of antennas,

then the power output requirement for a given field strength will be significantly less. Thus there is a direct cost trade-off between the type of transducer used and the necessary power of the amplifier.

Other factors to take into account (apart from cost) when specifying a power amplifier are linearity, ruggedness, power gain, reliability and maintainability.

3.2.1.3 Field Strength Monitor and Leveling

It is essential to be able to ensure the correct field strength at the EUT. Reflections and field distortion by the EUT will cause different field strength values from those which would be expected in free space, and these values will vary as the frequency band is swept. Hearing aids are actually smaller than many other electronic equipment like TV receivers or computers. They have therefore less effect on distorting the fields in immunity testing.

RF fields can be determined by a broadband field sensor, normally in the form of a small dipole and detector replicated in three orthogonal planes so that the assembly is sensitive to fields of any polarization. The unit can be battery powered with a local meter so that the operator must continuously observe the field strength and correct the output level manually. A more sophisticated set-up uses a fiber optic data link from the sensor, so that the field is not disturbed by an extraneous cable.

3.2.1.4 Transducers

The radiated field can be generated by an antenna as already discussed. The test engineer will normally want to use the same antennas as for radiated emissions tests, i.e. biconical and log periodic, and this is perfectly acceptable.

Two other types of transducer are available for radiated RF immunity testing of small EUTs. These are the stripline and the TEM cell (or Crawford cell).

Stripline

The difficulties of testing with antennas led to developments in the 1970s of alternative forms of irradiation of the EUT. Groenveld and de Jong designed a simple transmission line construction which provides a uniform electromagnetic field between its

plates over a comparatively small volume, and this has been written into both IEC 801-3 (1984) and EN 55020 as a recommended method of performing part of the radiated immunity testing. IEC 1000-4-3/ENV 50140 allows the use of the stripline only if the field homogeneity requirements are met, and if the EUT and wires can be arranged as the standard dictates.

The stripline is essentially two parallel plates between which the field is developed, fed at one end through a tapered matching section and terminated at the other through an identical section. The dimensions of the parallel section of line are defined in the standards as 80 x 80 x 80 cm, and the EUT is placed within this volume on an insulating support over one of the plates. The field between the plates is propagated in TEM (transverse electro-magnetic) mode, which has the same characteristics as free space. The calibration of the stripline is theoretically very simple: assuming proper matching, the field is directly proportional to the voltage at the feed point divided by the distance between the plates.

The accuracy of the stripline depends to a large extent on the dimensions of the EUT. IEC 801-3 recommends that the dimensions should not exceed 25 cm, while EN 55 020 allows a height up to 0.7 m with a calibration correction factor. Either way, the stripline can only be used on fairly small test objects.

The TEM cell

An alternative to the stripline for small EUTs and low frequencies is the TEM or Crawford cell. In this device the field is totally enclosed within a transmission line structure, and the EUT is inserted within the transmission line. It is essentially a parallel plate stripline in which one of the plates has been extended to completely enclose the other. Or, we can think of it as a screened enclosure forming one half of the transmission line while an internal plate stretching between the sides forms the other half.

The advantage of the TEM cell, like the stripline, is its small size, low cost and lack of need for high power drive; it can easily be used within a company's development lab. A further advantage, not shared with the stripline, is that it needs no further screening to attenuate external radiated fields. The disadvantage is that a window is needed in the enclosure if the tester needs to view the operation of the EUT while it is being tested, if for example it is a television set or a measuring instrument. As with the stripline, it can only be used for small EUTs (dimensions up to a third of the volume within the cell) and it suffers

from a low upper frequency limit. If the overall dimensions are increased to allow larger EUTs, then the upper frequency limit is reduced in direct proportion.

3.2.1.5 The GTEM Cell

Microwave absorber-lined anechoic chambers are suitable for measurements above a few hundred MHz, and that TEM cells are useful up to a few hundred MHz. The Giga-Hertz TEM cell is a hybrid between an anechoic chamber and a TEM cell, and can be used for EMC measurements over a wide frequency range. Depending on particular needs, GTEM cells of different sizes can be built to accommodate test samples ranging from printed circuit boards to a whole equipment such as an automobile. GTEM cell used in various test in this thesis study is shown in Figure 3.5.

Figure 3.5 Gigahertz -TEM Cell.

The GTEM cell is a 50 Ω tapered rectangular coaxial transmission line with an offset center conductor (septum). The rectangular section couples at one end into a 50 Ω coaxial conductor, and the center conductor cross-section is smoothly transformed from a flat wide strip into a circular shape. The transition from asymmetric rectangular section to standard 50 Ω coaxial line is precision crafted. The far end of the taper section is terminated in a distributed matched load comprised of pyramid-shaped microwave absorbing material. The center conductor of the rectangular transmission line is also terminated in a 50 Ω load made

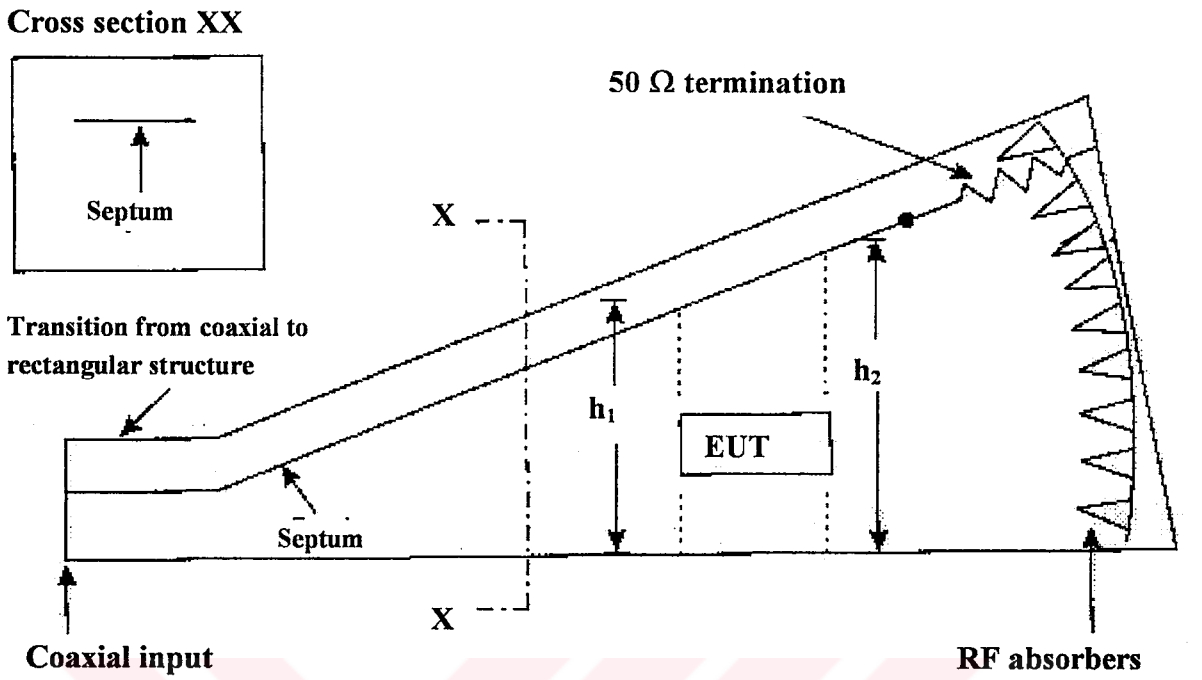


Figure 3.6 GTEM cell with location of equipment under test as shown.

up of several hundred carbon resistors (see Figure 3.6). The distribution of resistance values matches the current distribution in the center conductor. The resistive load into which the center conductor is terminated is equivalent to a current termination, whereas the distributed load into which the flared section is terminated is analogous to a matched termination for the propagating electromagnetic waves. Thus, the GTEM cell provides a broadband termination from DC to several GHz. Flare angle of the tapered section is usually kept small (say about 15^{0}) so that the field pattern set up by the propagating TEM wave has a spherical symmetry with a large radius (see Figure 3.7). The propagating wave can be approximately considered to be a plane- wave for practical measurement purposes. Length of the flared section determines the size of available test volume, and therefore size of the test samples that can be evaluated for radiated emissions or radiation susceptibility.

The tapered rectangular waveguide section of the GTEM cell, which is terminated in a coaxial connector at the apex end, acts as a waveguide below cut-off for waves that tend to propagate toward the apex. Waves propagating toward the far end of the GTEM cell, which is terminated in a matched termination, are absorbed. Thus, the geometry of a GTEM cell does not permit standing waves produced by electromagnetic fields generated

in the GTEM cell to be sustained. The field strength inside a GTEM cell is a function of the input power, as well as location along the longitudinal axis or septum height. The GTEM cell can be used for both CW (continuous wave) and pulse-mode measurements. The GTEM cell also enables EMC measurements at very high power or field strength levels in excess of 100 V/m.

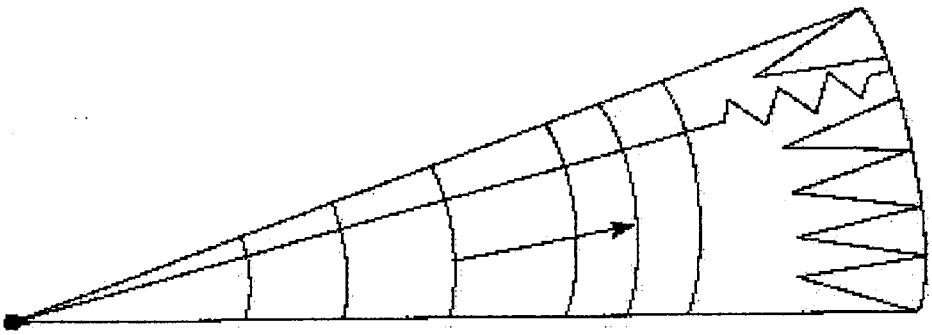


Figure 3.7 Wave propagation in a GTEM cell.

The GTEM cell holds out the promise of lower cost, well defined testing. The restriction on upper frequency limit is removed by tapering the transmission line continuously outward from feed point to termination, and combining a tapered resistive load for the lower frequencies with an anechoic absorber load for the higher frequencies. This allows even large cells, with test volume heights up to 1.75 m and potentially larger, to be made with a useable upper frequency exceeding l GHz (hence the "G" in GTEM).

The GTEM has clear advantages for immunity testing since it allows the full frequency range to be applied in one sweep, without the need for a screened enclosure or high power amplifiers

Radiation immunity (or in other point of view susceptibility) testing takes place as follows. The equipment under test whose radiation susceptibility is to be evaluated is placed inside the GTEM cell in a volume between the bottom of the GTEM cell and the septum.

An appropriate signal source, in conjunction with an amplifier when higher power levels are required, is connected to the coaxial connector. The source and the amplifier are set for the desired frequency and power levels. A power monitoring mechanism is included

between the output of the amplifier and the coaxial input of the GTEM cell so that input power level can be precisely measured. Field strength at the EUT position may be calculated based on the geometry of the GTEM cell and input power level.

Radiated emissions measurements can be also performed in a GTEM cell. Measurement of radiated emissions is similar to the situation for radiation susceptibility testing. The emissions from an EUT in this case are coupled into the GTEM cell, and propagate in TEM mode. Suitable voltage or power and frequency-measuring instrumentation is connected to the coaxial connector to measure precisely the characteristics of signals emitted by the EUT. The orientation of the EUT may be also changed, and emission characteristics measured with different orientations. As in the case of radiation susceptibility testing, response time of measuring instrumentation must be appropriately selected to ensure that the measuring instruments are able to detect and respond to emissions from the EUT.

Mathematical formulations can be used to interpret the measurements. Computer programs, which enable a translation of the measured data into radiated emissions at distances of 3 or 10 m from the EUT, are also commercially available. This compilation and translation of data allows the emission characteristics of an EUT to be checked against performance standards which are normally given for a distance of 3 or 10 m form the EUT.

3.2.2 Methods for Immunity Testing

The major concern of standardized immunity test methods is to ensure repeatability of measurements. The immunity test is complicated by not having a defined threshold which indicates pass or failure. Instead, a (hopefully) well defined level of interference is applied to the EUT and its response is noted. The test procedure concentrates on ensuring that the applied level is as consistent as possible and that the means of application is also consistent.

3.2.2.1 Preliminary Checking

Some preliminary tests must be carried out to find the most susceptible configuration and operating mode of the EUT. If it is expected to pass the compliance test with a comfortable margin, the tester may need to apply considerably greater field strengths in order to deliberately induce a malfunction. Hopefully (from the point of view of the test), with the initially defined set-up and operation there will be some frequency and level at which the operation is corrupted. This is easier to find if the EUT has some analogue functions, which are perhaps affected to a small degree, than if it is entirely digital and continues operating perfectly up to a well-defined threshold beyond which it crashes completely.

Once a sensitive point has been found, the engineer can vary the orientation, cable layout, grounding regime and antenna polarization to find the lowest level which induces a malfunction at that frequency. Similarly, the operating mode can be changed to find the most sensitive mode. It is often worthwhile incorporating special test software to continuously exercise the most sensitive mode, if this is not part of the normal continuous operation of the instrument. Note that some changes may do no more than shift the sensitive point to a different frequency, so the engineer should always repeat a complete frequency sweep after any fine tuning at a particular frequency.

3.2.2.2 Compliance Tests

Once the sensitive configuration has been established it should be carefully defined and rigorously maintained throughout the compliance test. Changes in configuration halfway through will invalidate the testing. If there are several sensitive configurations these should be fully tested one after the other. Notwithstanding this, equipment should always be tested in conditions that are as close as possible to a typical installation - that is with wiring and cabling as per normal practice, and with hatches and covers in place.

The compliance test will concentrate on making sure that the specified test level is maintained throughout the frequency sweep. This will be achieved by using the field strength monitoring or control methods. The parameters which have been chosen to

represent the operation of the EUT must be continuously monitored throughout the sweep, preferably by linking them to an automatic data capture and analysis system.

Assuming that the EUT remains correctly operational throughout the sweep, i.e. it passes, it can be useful to know how much margin there is in hand at the sensitive point(s). This can be accomplished by repeating the sweep at successively higher levels and mapping the EUT's response. This will indicate both the margin one can allow for production variability, and the possibilities for cost reduction by removing suppression components.

3.2.2.3 Sweep Rate

The sweep rate itself may be critical to the performance of the EUT. According to the standards, the signal generator should either be manually or automatically swept across the output range at $1.5 \cdot 10^{-3}$ decades per second or slower, depending on the speed of response of the EUT, or it can be automatically stepped at this rate in steps of typically 1 per cent. As an alternative, IEC 1000-4-3/ENV 50140 allows a step size of 4 per cent with a test field strength at least twice that specified. The dwell time for stepped application should be at least enough to allow time for the EUT to respond; slow responses translate directly to a longer test time. As an example, to cover the range 80 - 1000 MHz with a step size of 1per cent and a dwell time of 3 s takes 12.7 minutes.

For many systems there may be little sensitivity to sweep rate since demodulation of applied RF tends to have a fairly broad bandwidth. On the other hand, some frequency sensitive functions in the EUT may have a very narrow detection bandwidth so that responses are only noted at specific frequencies. If the sweep rate through these frequencies is too fast (or the step spacing is too great) then a response may be missed. Such narrowband susceptibility may be 25-30 dB worse than the broadband response. Therefore some knowledge of the EUT's internal functions is essential, or considerably more complex test procedures are needed.

3.2.2.4 Safety Precautions

At field strengths not much in excess of those defined in many immunity standards, there is the possibility of a biological hazard from the RF field arising to the operators if they remain in the irradiated area for an appreciable time. For this reason a prudent test facility will not allow its test personnel inside a screened chamber while a test is in progress, making it necessary for a remote monitoring device (such as a CCTV) to be installed for some types of EUT.

Health and safety legislation differs between countries. There is a European pre-standard on human exposure to EM fields, numbered ENV 50 166, which distinguishes between controlled and uncontrolled environments. Corresponding Turkish standards are TSE ENV 50166-1 and 50166-2, for low and high frequencies respectively.

3.2.3 Evaluation of Results

The variety and diversity of equipment and systems makes it difficult to lay down general criteria for evaluating the effects of interference on electronic products. Nevertheless, the test results can be classified on the basis of operating conditions and the functional specifications of the EUT according to the criteria discussed below.

It is up to the manufacturer to specify the limits which define "degradation or loss of function", and to decide which of these criteria should be applied to each test. Such specifications may be prompted by preliminary testing or by known customer requirements. In any case it is important that they are laid out in the final EMC test plan for the equipment. If the equipment is being supplied to a customer on a one-to-one contractual basis then clearly there is room for mutual agreement and negotiation on acceptance criteria, but this is not possible for products placed on the mass market, which have only to meet the essential requirements of the EMC Directive. In these cases, the engineer have to look to the immunity standards for general guidance.

3.2.3.1 Performance Criteria

The generic immunity standard, EN 50082 lays down guidelines for criteria against which to judge the EUT's performance when the various test levels are applied. These can be summarized as follows:

Performance criterion A: The apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a performance level or a permissible loss of performance specified by the manufacturer.

This criterion applies to phenomena which are normally continuously present, such as RF interference.

Performance criterion B: The apparatus shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. During the test degradation of performance is however allowed. No change of actual operating state or stored data is allowed.

This applies to transient phenomena.

Performance criterion C: Temporary loss of function is allowed provided the loss of function is self recoverable or can be restored by the operation of the controls.

This applies to mains interruption.

If the tester does not specify the minimum performance level or the permissible performance loss, then either of these may be derived from the product description and documentation (including leaflets and advertising) and what the user may reasonably expect from the apparatus if used as intended. Thus, for example, if a measuring instrument has a quoted accuracy of 1 per cent under normal conditions, it would be reasonable to expect this accuracy to be maintained when subject to RF interference at the level specified in the standard, unless manufacturer's operating manual and sales literature specifies a lower accuracy under such conditions. It may lose accuracy when transients are applied, but must recover it afterwards. A personal computer may exhibit distortion or "snow" on the image displayed on its video monitor under transient interference, but it must not crash nor suffer corruption of data.

3.2.3.2 Product Specific Criteria

Some product specific immunity standards may be able to be more precise in their definition of acceptable performance levels. For example EN 55 020, applying to broadcast receivers, specifies a wanted to unwanted audio signal ratio for sound interference, and a just perceptible picture degradation for vision interference. Even this relatively tight definition may be open to interpretation. Another possibility for telecommunications equipment is to comply with a defined criterion for bit error rate and loss of frame alignment.

The subjectivity of immunity performance criteria will present a major headache when the full legal implications of the EMC Directive come to be tested. It will undoubtedly be open to manufacturers to argue when challenged, not only that differing test procedures and layouts have been used in judging compliance of the same product, but that differing criteria for failure have also been applied. It will be in their own interest to be clear and precise in their supporting documentation as to what they believe the acceptance criteria are, and to ensure that these are in line as far as possible with the above generic guidelines. Even so, the unsatisfactorily vague nature of these guidelines will act as a spur to the development of many product specific immunity standards in the coming years.

As an example of this kind of product specific standards we can mention IEC 118-13, Electromagnetic Compatibility Product Standard for Hearing Aids, which is yet in draft phase but planned to be available by the end of 1997 [16]. This standard is included in Appendix C.

In this standard, the immunity of hearing aids is determined in dB SPL units of interference noise produced as a result of RF field coupling to the device. IRIL, the input related interference level at 1000 Hz measured in dB SPL, is used to characterize the immunity of the hearing aid. Decreasing values of IRIL indicate increasing immunity. The acceptance level corresponding to IRIL equal to or less than 55 dB SPL will probably ensure acceptable conditions for the hearing aid user in most practical situations and is recommended as performance criterion.

4. SYSTEM DESCRIPTION OF HEARING AIDS

Many examples of interference to medical equipment has been given in Appendix A. But in order to have a more profound understanding of interference phenomena, an interaction will be studied in more detail. The interference to be studied will be the hearing aid - digital mobile phone interaction, in which case the hearing aid is the victim and the digital phone is the source of interference. However, as a first step, understanding the operation principles and system components of hearing aids will help us to uncover the physical basis of the interference caused by digital mobile phones.

4.1 History and Types of Hearing Aids

4.1.1 The Need for Hearing Aid

Hearing impairment can be caused by malformation or disease at any point along the auditory pathway. The sound can be blocked before it reaches the inner ear, resulting in conductive hearing loss. The major effect of this impairment is a reduction in sound intensity; amplification from a hearing aid can effectively compensate for this type of hearing loss. If cells in the inner ear that change sound to neural energy are lost or damaged, low-intensity sounds are not heard, but high-intensity sounds are often heard at a normal loudness level. With this type of cochlear hearing impairment, the hearing loss is often greater at some frequencies than at others, so the gain of the hearing aid has to be adjusted to compensate for this. Furthermore, the maximum sound levels have to be limited to prevent sound from being too loud. If a hearing aid is appropriately fitted, it can give significant benefit to a person with cochlear hearing impairment even though there still may be distortion of speech. If nerve cells that carry the sound signal from the inner ear to the brain are lost or damaged, the sound is not transmitted or analyzed accurately and usually does not seem as loud as normal intensities. At the present time hearing aids cannot compensate for this loss of nerve cells, except to increase the intensity of the sound. In fitting a hearing aid it is important to know where in the auditory pathway there is

dysfunction and what effect this dysfunction has on the ability of the individual to recognize speech [17].

4.1.2 Hearing Aid History and Development

The function of a hearing aid is to amplify sounds to a degree so that a hearing impaired person can utilize his or her remaining hearing in an effective manner.

Hand cupped behind the ear which provides approximately 14 dB of amplification can be accepted as the first amplification system. Next came the invention of acoustic amplifiers like horns and speaking tubes. These were used from 17^{th} century till the beginning of this century. Mechanical hearing aids were followed by electric hearing aids which comprise carbon hearing aids and vacuum-tube hearing aids.

Today's hearing aids are based on the invention of the transistor. In 1950s it was introduced into hearing aids. This development made possible much smaller size, far lower battery cost, and a flexibility of design. Simple operation principle of a hearing aid is as follows: Sound is picked up by the microphone and converted to an electrical signal corresponding to the sound pressure variations. A transistor amplifier stage (field effect transistor) is usually contained within the microphone housing. The signal is then amplified by the main amplifier and delivered to a receiver (earphone) that converts the greatly amplified electrical signal back to sound.

A hearing aid will provide the greatest assistance to communication if:

1. it amplifies conversational speech in specific frequency regions between 250 and 6000 Hz to a comfortable listening level for the individual,

2. the overall level of speech can be adjusted so it is comfortable for various listening conditions,

3. the sound quality is acceptable, and

4. the maximum output does not allow the amplified sounds to surpass the individual's discomfort level.

4.1.3 Types of Hearing Aids by Manner of Replacement

In-the-Ear (ITE) Hearing Aids. The availability of very small, efficient electret microphones, correspondingly small receivers, integrated circuits (ICs), and further battery miniaturization hearing aids facilitated packaging the entire hearing aid within the concha and ear canal. ITE aids are mostly of the "custom" type with components built into a shell made from an impression of the user's ear. These are identified as full concha, low profile, and half concha instruments, depending on their physical location and dimensions within the concha.

In-the-Canal (ITC) hearing aids which are placed in the user's ear canal and have much smaller shape can be considered under in the ear category.

Behind-the-Ear (BTE) Hearing Aids. BTE aids, also referred to as over-the-ear (OTE) or postauricular hearing aids are designed to fit behind the pinna. Rugged and easily serviced, they are available in a wide selection of amplification values, for mild to profound hearing impairments. Although these aids are available in a variety of sizes, there is usually sufficient space in them for several electroacoustic adjustments such as frequency response, output, gain, etc. Some BTE hearing aids are shown in Figure 4.1. These are 6 of the 16 BTE hearing aids electromagnetic compatibility of which we have tested.

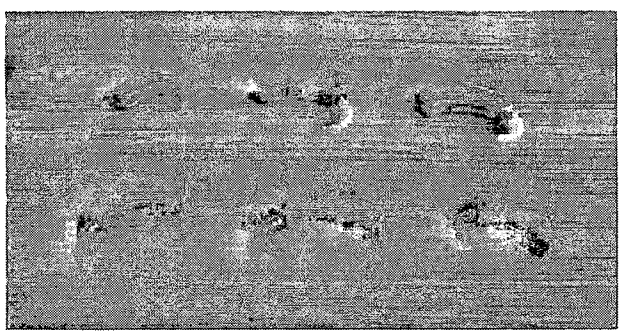


Figure 4.1 Some BTE hearing aids .

Body-Worn (BW) Hearing Aids. Primary uses of body-worn (conventional, pocket) hearing aids are for extreme hearing impairments in an effort to supply sufficient gain without feedback, or for persons who have difficulty manipulating smaller, ear-level units.

Other Types. Eyeglass hearing aids have a design such that the microphone, amplifier, and the receiver are built into the eyeglass temples (side pieces). Implantable hearing aids consist of cochlear, mastoid, and middle ear implants.

4.1.4 Hearing Aids by Mode of Operation.

Single-band vs. Multi-band Hearing Aids. Single-band hearing aids process the audio signal through a single circuit path, whose processing characteristics affect certain aspects of, or the entire, frequency range. Multi-band hearing aids have two or more circuit paths and allow for adjustments to be made separately within two or more frequency bands within the hearing aid. These are more common in programmable hearing aids.

Special Feature Hearing Aids. The original purpose of CROS (Contraleteral Routing of Offside Signals) was to pick up sound on the side of an unaidable or "dead" ear and route it to the good ear on the other side, thus overcoming the head shadow effect. The signals are then directed from the receiver into the good ear by a ~~tubing or nonoccluding~~ type earmold extending into the open ear canal.

The basic CROS concept has been utilized subsequently to overcome certain other problems relating to hearing aid use. One of its most important advantages occur in bilateral, high frequency hearing losses where hearing in the low frequencies is normal and drops off rapidly above some middle frequency such as 1000 Hz.

Nonadaptive vs. Adaptive Hearing Aids. Nonadaptive hearing aids include circuitry that does not change the basic performance of the hearing aid once its controls (functions) are set. Tone and output trimmers and fixed-function switches best identify this category.

Adaptive hearing aids include circuitry that has a processing function that alters the performance of the aid during changing input signal environments. These signal modifications are triggered mostly by frequency and/or intensity changes. Automatic Gain Control (AGC), Automatic Signal Processing (ASP), and adaptive noise filter circuits in hearing aids are the most common examples.

Analog Hearing Aids. Analog hearing aids allow for the representation of a continuously changing physical variable (i.e., sound) by another physical variable (i.e., electrical current). Almost all contemporary hearing aids are analog in nature.

Programmable Hearing Aids. Programmable hearing aids feature conventional amplifiers and filters controlled by an external digital source. These may be more accurately described as VLSI (very large scale integration) analog circuits controlled by digital means. The two primary components consist of a hearing aid that contains a CMOS (complementary metal oxide semiconductor), RAM (random access memory), and EPROM (electrically erasable programmable read only memory) memory module and an external microprocessor (computer) to access those memory locations within the chip which represent different electroacoustical performances.

Digital Hearing Aids. Digital hearing aids are distinguished from programmable (quasi-digital) hearing aids in at least three ways: (1) the input signal is digitized; (2) digital signal processing circuitry (DSP chip) is used in the hearing aid; and (3) they can be designed to "make decisions". Basic advantages of DSP relate to the potential of developing and tailoring a device, with software only, to meet the needs of the hearing impaired.

4.1.5 Hearing Aid Systems by Mode of Presentation.

Air-Conduction and Bone-Conduction Hearing Aids. Electrical hearing aids fall into two categories based upon the output transduction: air-conduction or bone-conduction. Both are similar until the last transduction stage of the amplified signal where they are converted into usable stimuli for the hearing aid user.

The air-conduction hearing aid is designed to change amplified electrical energy back to acoustical energy and direct it into the ear canal. Almost all hearing aids are of this type. The bone-conduction hearing aid is designed to change the amplified electrical energy to mechanical vibration which, when applied directly to the head, stimulates the entire skull. The use of bone-conduction hearing aids is limited to situations where a large (30-50 dB) air-bone gap exists, or where there is a chronic discharge from an ear that prevents the use of an air-conduction receiver.

Monaural vs. Binaural. A monaural hearing aid is one complete hearing aid fitted into single ear. A binaural hearing aid has two separate and complete hearing aids, one for each ear.

4.2 Hearing Aid Components and Basic Controls

The advance of hearing aid technology and subsequent sound quality has been possible primarily because of consistent improvement in hearing aid components. Following is a description of typical construction and operation of some major components. A block diagram of a hearing aid is presented in Figure 4.2.

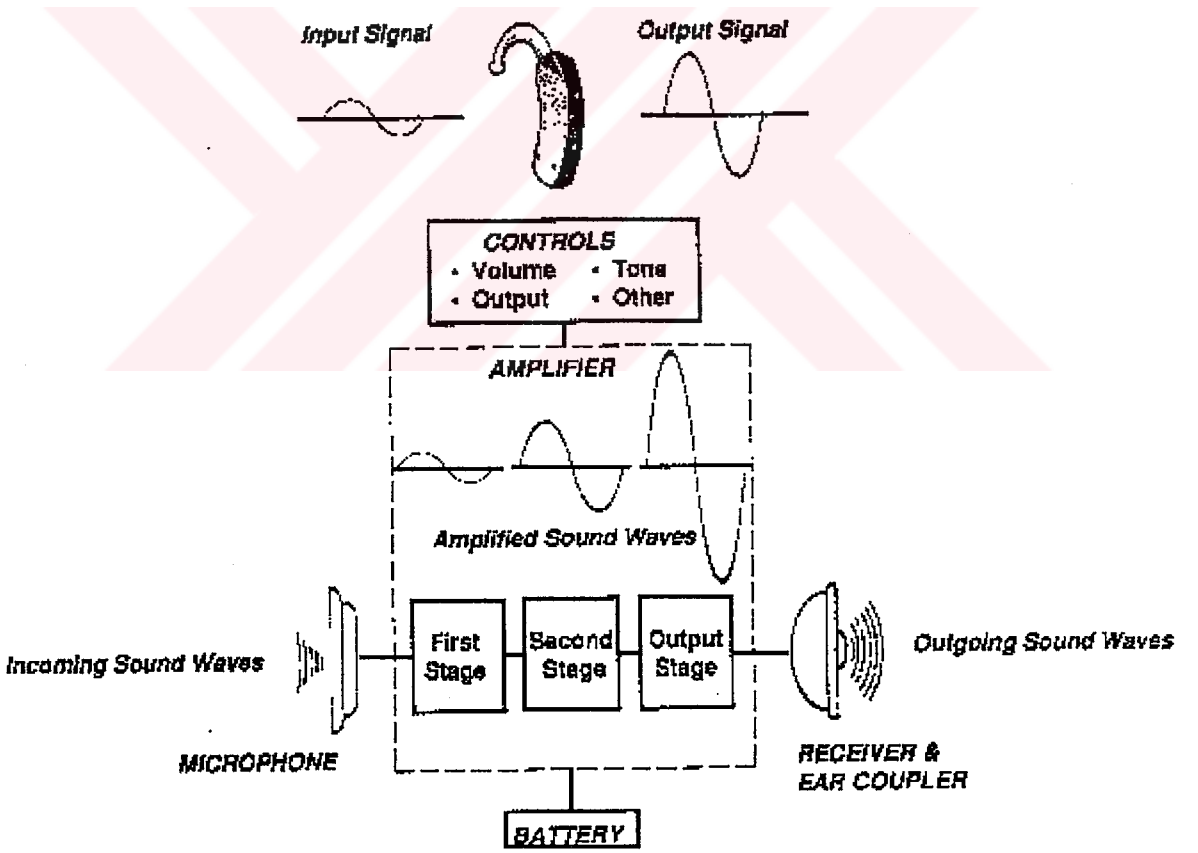


Figure 4.2 Block diagram of a hearing aid.

4.2.1 Power Supply

The amplification provided by the hearing aid derives its "power" from the hearing aid battery. Generally, the greater the gain and the output requirement of hearing aid (resulting in a higher current drain), the greater the battery's mAh (milliampere-hour) capacity must be, and the larger the physical size. Hearing aid batteries (mostly single cells) are currently of two main types; zinc-air or mercury. Zinc-air cells constitute approximately 63% of all hearing aid battery sales and mercury sales 36%. An attractive feature of zinc-air cells is their reported long shelf life, because they are not activated until a tape seal is removed from small holes in the cell through which air enters to initiate the activation. Also, a zinc-air cells of a given size will last approximately twice as long as their mercury counterpart.

Hearing aid cells have a relatively flat discharge rate; that is, the voltage does not drop much during the cell's useful life. The cell's capacity is rated in mAh for typical load currents.

4.2.2 Transducers in Hearing Aids

The microphone and receiver in a hearing aid are transducers. They are devices that are activated by power in one form and convert, or transduce, that power into another form.

Microphones. The microphone (input transducer) converts the sound pressures that impinge upon its diaphragm into small analog electric signals. A number of technologies, like carbon microphones, crystal (piezoelectric) microphones and electromagnetic microphones was used over years.

In today's hearing aids, the electret microphone has almost universally been used since 1971 for hearing aids because of its good sensitivity, excellent wide band frequency response and sound quality, tiny size, reliability, low internal noise and insensitivity to mechanical vibration. The electret itself is not a microphone but is a very thin fluorocarbon plastic with a metallic coating that holds or stores a permanent electric charge- it is an electric capacitor. As the diaphragm vibrates due to the action of sound waves entering the sound inlet, a voltage is generated between the backplate electrode (conducting plate on

which the electret is mounted) and the diaphragm, which acts as the other electrode of the capacitor. This small voltage is then amplified by a field effect transistor (FET) located inside the microphone housing and delivered to the input terminals of the main amplifier.

Hearing aid microphones can be categorized as pressure (omnidirectional) or pressure gradient (directional).

Alternate Inputs. Although not transducers, other inputs are sometimes used in hearing aids in addition to the microphone. The most frequently used is the telephone induction pick-up coil, frequently called the "telecoil". The telecoil consists of a core of high permeability metal around which is wound a coil of a large number of turns of fine enameled wire. The alternating magnetic leakage field around most telephone receivers induces a voltage in the telecoil, which is then amplified. Better telephone reception is obtained because the microphone is usually switched off and, thus, does not pick up local ambient noise. Also, the frequency response of the system is smoother than that which occurs when acoustic coupling from the telephone receiver to the microphone is used.

Still other hearing aids have provision for electrical inputs, using plugs or special contacts to make the connections to the amplifier. These inputs might be from FM radio receivers worn on the person or from tape recorders, televisions, etc.

Receivers. Also identified as earphones, speakers, or as output transducers, these convert the amplified electrical signal from the hearing aid to an acoustic or vibratory output. Receivers may be of the air-conduction or bone-conduction types.

Magnetic type air-conduction receivers are especially well suited to function with low supply voltage amplifiers found in hearing aids because they operate efficiently directly from the output stage. Windings in magnetic receivers can be made to have the desired electrical impedance for different amplifier designs.

Receivers for the ear level hearing aids (ITE, ITC, BTE and eyeglass) are generally of the balanced-armature magnetic type because of the high performance that can be achieved in an unbelievably small space.

Bone-conduction receivers operate on the "reaction" principle and are designed to vibrate their housings (cases) rather than setting up sound waves in the air. A mass, free to vibrate inside an enclosed case, is caused to do so by a magnetic driving system.

Amplifiers. The amplifier increases the amplitude of the weak AC voltages picked up by the microphone. It may have a number of stages of amplification. Today's hearing aids achieve amplification primarily through the use of transistors. In a hearing aid, for example, transistor converts the current supplied by the battery into the desired output current; the total amplification being controlled by the microphone input current.

Hearing aid amplifiers are typically of the monolithic integrated circuit (IC) or of the hybrid IC; sometimes a combination of the two. The concept of the IC is that of having all required circuit elements built into a single monolithic block or chip. In the IC amplifier, the components used to from the amplifier (transistors, diodes, capacitors, and resistors) are formed on a silicon chip to give the desired electronic performance. Advantages of ICs are those of small size, sealing against environmental conditions, uniform manufacturing, low electronic noise, fewer solder connections, and low power requirements.

Hybrid circuits consist of very tiny discrete circuit components soldered by special techniques to a circuit pattern on a ceramic substrate with deposited networks or onto a printed circuit board.

Hearing aid circuits usually have three or more stages of amplification. The output (final) amplifier interfaces with the preceding amplifier and provides the necessary drive to the receiver.

4.2.3 Controls

Amplifier controls are a very important part of a hearing aid and are used to modify its basic performance. The control receiving the most wear is the "user-operated gain or volume control (VC)", which is a variable resistor used to select the most effective listening level. As the volume control rotates, its resistance value varies and controls the amount of current flow between amplification stages.

A "master adjustment of gain" is a trimmer control adjusted by the dispenser and is not the user-operated volume control. When set to a lower level, this control can be used to keep an instrument's gain below feedback, even when the user turns the volume control full-on.

"Electronic tone controls" can alter the frequency response of the hearing aid and consist of filter networks (capacitors and resistors) [18].

4.2.4 Limiting Systems in Hearing Aids

Part of the function of every hearing aid is to amplify soft sounds strong enough to make them audible but not to over amplify them to produce an uncomfortable listening level. It is the upper level of amplification that limiting systems address. Every hearing aid has a maximum deliverable pressure (saturation, overload) determined by the receiver, battery voltage, and amplifier. In practice, it is within the amplifier that most limiting occurs, at the saturation of the amplifier. The maximum deliverable pressure the hearing aid can produce, or its limiting level, however, can be adjusted below the level of saturation.

"Hard peak clipping" (peak limiting) is the simplest form of output limiting and can be defined as the removal, by electronic means, of one (unsymmetrical) or both extremes (symmetrical) of alternating current amplitude peaks at a predetermined level.

"Peak rounding" (soft peak clipping, curvilinear compression, diode compression control, diode clipping, modified peak clipping) is a form of nonlinear amplification that is evidenced by a gradual, ever-diminishing increase in output with each successive increase in input.

"Automatic Gain Control (AGC)" systems have a built-in monitoring circuit that automatically reduces the electronic gain of the hearing aid as a function of the magnitude of the signal being amplified. Gain is reduced by means other than peak clipping. Two major purposes of these systems are (1) to reduce the gain of an aid as the input SPL increases so that the output capability of the aid is not exceeded and distortion is kept low, and (2) to reduce the dynamic range of the output signal so that it is a better match to the dynamic range of an impaired ear. A wide variety of AGC characteristics exists in hearing aids, providing for individual differences.

Automatic gain control action is fundamental to all circuits within the category of "limiting by time-dependent gain regulation", even though additional functions may be incorporated. Because the circuitry is designed to act "automatically" to changes in the

input stimulus and to process the incoming signals in some predetermined manner, it has more recently been termed "automatic signal processing (ASP)".

A differentiation of ASP circuits can be made as follows: Those circuits that reduce gain at high levels and/or increase gain at low levels but do not change the frequency response of the hearing aid in the process, include the traditional automatic signal processing circuits (i.e., the AGC or compression circuits). Well-defined terms for these fixed frequency response (FFR) automatic signal processing circuits already exist. More recently developed circuits that automatically change not only the gain but also the frequency response of the hearing aid as a function of the input signal are more accurately identified as level dependent frequency response (LDFR) circuits.

4.3 Earmolds

The earmold system includes the complete sound path from the exit port of the hearing aid receiver to the tip of the earpiece in the ear canal. It is longer can be more complex in BTE and eyeglass aids than in ITE or ITC aids, where the custom-molded shell of the aid forms the outer part of the earmold. The primary function of the earmold system is to direct sound efficiently and with the desired frequency response from the receiver to the tympanic membrane. The earmold system can have a dramatic effect on the overall performance of a hearing aid and must be given careful consideration. Some earmold types are illustrated in Figure 4.3.

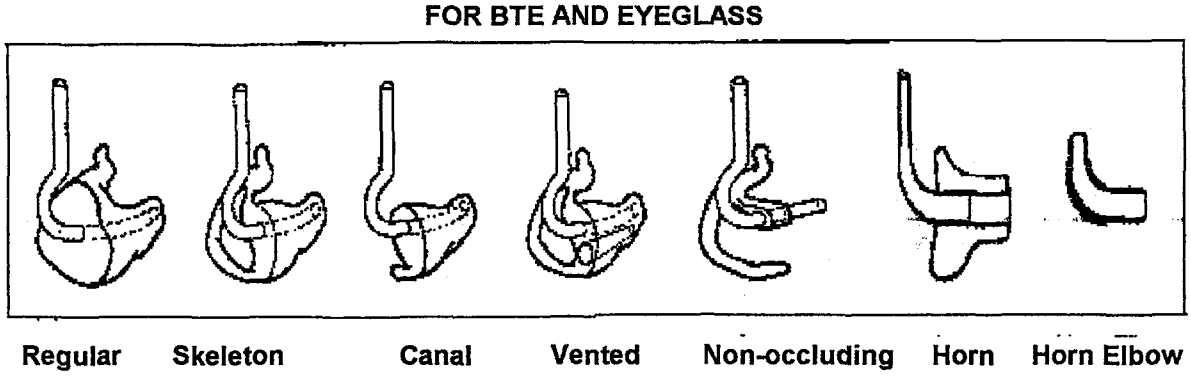


Figure 4.3 Earmolds used in BTE and eyeglass hearing aids.

The ear canal, head, and pinna have a resonance, and although differing among individuals, it measures approximately 17 dB near 2700 Hz. When an earmold is inserted into the ear, this normal resonance loses its effectiveness. A goal of some ear mold acoustic modification procedures is to increase the response in 2700 Hz region to compensate for the loss of this resonance.

Although earmold is an important element regarding the overall hearing aid performance, it is not considered in immunity tests since it is only a mechanical element containing no electronic components.

4.4 Technical Standards for Hearing Aids

The ultimate objective of obtaining acoustic measurements on hearing aids is to provide data that are of maximal usefulness in selecting or adjusting a hearing aid for a particular impaired ear. Today, this objective is easier to meet but any attempt to cross the chasm from electroacoustic performance to suitability of the hearing aid for a listener must be done with a full understanding of the difference between real-ear and coupler measurements of hearing aid characteristics.

Other important objectives include those of assuring uniformity of quality, and to permit accurate comparison and reproducibility of hearing aid measurements by different facilities. These objectives have been realized by the development of national and international hearing aid standards.

4.4.1 Acoustic Measurement Units Employed

The unit of sound pressure is the Pascal (Pa), equivalent to a force of 1 newton (N) per m^2. In this thesis, sound pressure level (SPL) will be used to express the root mean square (RMS) alternating sound pressure. SPL is expressed in dB, using a reference sound pressure of 20 μPa (0.00002 Pascal). This is identical with a reference pressure of 0.0002 dynes/cm^2. A sound pressure of 1 Pa corresponds to a SPL of 94 dB. The formula relating sound pressure (p) is Pascals and SPL in dB re 20 μPa is:

$$SPL = 20\log\frac{p}{0.00002} \qquad (9)$$

Although dB were originally intended to express power ratios, they are rarely used in this manner for acoustics. They are conveniently used to express sound pressure, voltage and current levels and ratios, and even mechanical impedance levels relative to an appropriate reference value [19].

4.4.2 General Measurement Arrangement for Hearing Aids

The basic principle of hearing aid measurement is simple: with the controls of the hearing aid appropriately adjusted, a suitable input signal is applied to its microphone, and the output of the hearing aid's receiver is measured and analyzed on a standardized device (coupler) that is similar to a median ear acoustically.

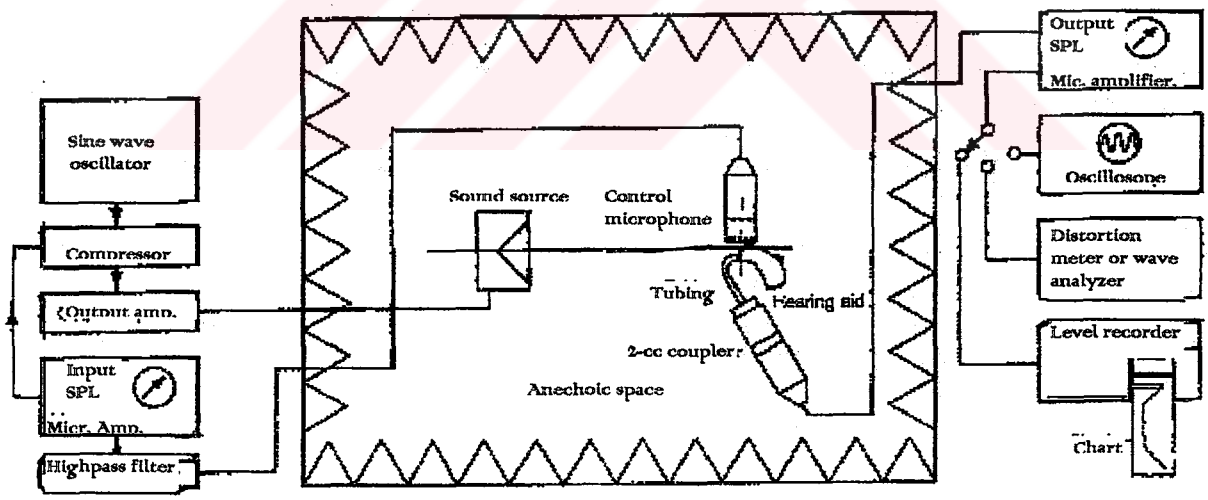


Figure 4.4 Elements of a hearing aid measurement system.

Figure 4.4 diagrams a hearing aid regulation and measurement system and illustrates the functions of important elements. A very quiet test space with sound absorbent walls is necessary. Ideally, this would be an anechoic chamber to absorb nearly all sound, but a suitable equivalent can be used. In the regulation portion of the system, the electrical test

signal is developed by a sine wave (or other wave) generator. The signal passes through a compressor amplifier whose gain is determined by the output control of a microphone. The compressor circuit compensates for irregularities of the SPL in the test enclosure across the frequency range and "flattens" it so that the sound source (loudspeaker) SPL at the hearing aid microphone is constant across the frequency range. In the measurement portion of the system, the hearing aid microphone is placed at an accurately determinable test point facing the loudspeaker. Standard laboratory pressure microphones of different sizes may be used as the control microphone. The output of the hearing aid is transmitted through a specified acoustic earmold substitute to a standardized coupler or ear simulator. The SPL in the coupler is measured by a calibrated standard microphone. The output of this microphone is recorded versus frequency, or examined for other characteristics, such as harmonic distortion.

4.4.3 Acoustic Output Considerations

The acoustic output of an air-conduction receiver is measured on a 2-cc coupler or ear simulator, depending on the nature of the measurement and on the standard test method to be followed. The purpose of the coupler or ear simulator is to simulate acoustically the average ear canal on which hearing aid is used. The vibratory output of a bone-conduction receiver is measured on an artificial mastoid, or mechanical coupler. Common air-conduction receiver couplers and ear simulators are as follows:

2-cc Coupler. The 2-cc (or 2 cm^3) coupler was first described by Romanow in 1942 and has been used successfully since because it is simple and gives accurately reproducible results when properly used. The effective volume of the coupler cavity is 2-cc. This volume was originally intended to take into account the compliance of the ear canal/middle ear system when the ear the canal is occluded by a hearing aid earmold. Thus, these couplers were once called "artificial ears". A leak of high acoustic impedance provides barometric equalization. Sound from the hearing aid receiver is directed into the 2-cc cavity at the center of the face of the cylindrical cavity opposite the standard microphone diaphragm. The microphone forms the other face of the coupler and simulates the tympanic membrane.

T.C. YÜKSEKÖĞRETİM KURULU
DOKÜMANTASYON MERKEZİ

In reality, 2-cc coupler has greater volume than median adult ears and does not incorporate any acoustic resistance. The latter fact makes it unsuitable for testing hearing aids with vented earmolds, unless the vents are closed. Many tests made on a 2-cc coupler, however, relate well to those on ear simulators or mannequins. 2-cc couplers have different types called HA-1, HA-2, HA-3, and finally HA-4 used for different applications [20].

The Ear Simulator. An alternate coupler that has been accepted and that more closely resembles the real ear was developed by Zwislocki, and made available commercially in 1972 as a device termed an "ear simulator". It has for acoustical networks allowing for simulation of the acoustic impedance of the human eardrum and takes into account the acoustic capacitance (volume), inertance (mass), and acoustic resistance of ears. It also more closely resembles the ear physically, with an ear canal portion of appropriate diameter and length. The reference plane, or entrance, to the ear simulator is considered to be where the tip of an average hearing aid earmold would terminate. The other end is terminated with a ½-inch condenser microphone.

The Zwislocki ear simulator allows for measurement of either vented or open canal earmolds. The application for use of ear simulator with adapters is specified in International Electrotechnical Commission Publication, 118-0, 1983. Ear simulator type couplers have been standardized internationally by IEC Publication 711 [21].

4.4.4 Descriptive Performance of Hearing Aids

The performance of air-conduction hearing aids suitable for specification and tolerance purposes can be evaluated using procedures specified in national and international standards. "ANSI S3.22-1987 Specification of Hearing Aid Characteristics" is an example of a national standard whereas IEC 118 series form the example for a widely accepted international standard. Since the procedure used for testing hearing aid immunity to electromagnetic fields is based on draft IEC 118-13 standard, we will concentrate on a few aspects of hearing aids which relate to their performance. In short, these are OSPL90, Reference Test Gain Control Position and Frequency Response.

The object of IEC 118-0 standard is expressed as "to describe methods of measurement for the evaluation of the electroacoustical characteristics of hearing aids"

[22]. The test results obtained by the methods specified in this standard express the performance under test conditions and may deviate substantially from the performance of the hearing aid practical conditions of use. This is because measurement conditions do not include such effects as ear canal resonance and diffraction produced by the head and torso.

Ambient and operating conditions, test equipment and measurements are all specified in the Standard. SPL measurements are performed using an Ear Simulator prepared according to IEC 711. On the other hand, IEC 118-7 stipulates the use of a 2-cc coupler. However, main procedures for the tests remain the same [23].

It is important to know at what level a hearing aid limits its output when it receives a high-level input signal. The maximal possible level should not exceed the threshold of discomfort for a user. Conversely, too little output capability will not allow a clean signal to be delivered to an individual having a more severe hearing impairment. As a practical measure of the output handling capability of a hearing aid, OSPL90 test is described. This is the sound pressure level produced in a coupler with an input sound pressure level of 90 dB at the specified frequency (or frequencies), the gain control being in the full-on position and the other controls being set for maximum. The result is presented as a frequency response curve which employs output SPL in dB in the ordinate versus frequency in Hz in the absisca.

A basic test is the one which is performed to obtain the basic frequency response curve. This is done at the reference test gain setting with an input sound pressure level of 60 dB. Reference test gain control position is the setting of the hearing aid gain control which provided an output sound pressure level in the acoustic coupler of 15 +/-1 dB less than OSPL90 for an input sound pressure of level of 60 dB at the reference test frequency. Finally, reference test frequency shall normally be 1600 Hz. But for certain hearing aids for which a higher reference test frequency is more appropriate (so called high-tone hearing aids) 2500 Hz shall be used.

Other important aspects related to hearing aid performance are harmonic distortion, intermodulation distortion, equivalent input noise level, input-output characteristics for AGC aids, etc.

5. STUDY OF THE INTERACTION BETWEEN HEARING AIDS AND DIGITAL MOBILE PHONES

Digital mobile phones, also known as cellular phones, are introduced to the public use only about ten years ago but their commercial and social benefits have quickly caused them to be accepted as an indispensible adjunct to modern life. Besides, digital mobile phones, with their portability and pulsed transmissions, has created a new class of interference issues. This interference typically presents itself as a buzz in the effected audio electronic equipment especially when the intensity of the radio wave transmitted from the digital phone varies at an audible rate. Interference to other equipment is also possible [24].

In the past incidents of this type of interference, caused by rectification of radio frequency signals by equipment susceptible to this type of interference, were the exception. They mostly occured within general proximity to high powered radio transmitters. However, the increasing use of small low power digital mobile telephones has the potential to make the interference from this class of device more prevalent. Even though their radiated power is low, digital mobile telephones used in close proximity (i.e. within metres), to other electronic equipment such as hearing aids, may produce greater interference than can much higher powered transmitters at ranges of a few hundred metres.

In the digital system known as GSM (Global System for Mobile communications) which is used widely in Turkey and many European countries the voice information is digitally encoded. The GSM standard offers improvements in call security, subscriber coverage and subscriber capacity. The GSM phones transmit to the base station in the frequency band 890 to 915 MHz. The transmission is pulsed with a repetition frequency of approximately 217 Hz and a pulse width of approximately 0.6 ms. There are a number of power ranges for the GSM system, but for the handheld mobile phones only 0.8 and 2.0 W peak power will be available. Transportable units may operate up to 8 W peak power depending on the size of the battery pack and the required time-to-discharge.

Another "advantage" of the digital phones is that the information can be compressed and transmitted about eight times more quickly than a person can speak; hence the information is compressed into approximately 217 packets per second, each with a width of

approximately 0.6 ms. This has several advantages, one of which is the instantaneous transmitted power can be greater, giving better reception, although the average power is still low enough to conserve battery life. Unfortunately, the level of EMI depends on the instantaneous power and engineers would therefore intuitively expect more interference problems from digital phones than with analogue phones. Typical emissions from a mobile phone are illustrated in Figure 3.2 in Chapter 3.

The interference problem with hearing aids is due to the essential nature of the emissions, and is not an incident by-product which might, for example, be solved by improved shielding of the digital phones.

This chapter includes tests performed in order to understand the physical basis of interaction between hearing aids and digital mobile phones. Tests are conducted in EMI/EMC Laboratory of National Electronics and Cryptology Research Institute at TUBITAK Marmara Research Center, Gebze, Kocaeli.

5.1 Background

There had been researches held in different parts of the world after experience showed that hearing aids do not work well together with digital phones. The most remarkable one is that carried out by DELTA Technical Audological Laboratory and TELECOM Denmark for European Hearing Instrument Manufacturers Association (EHIMA) from 1991 till 1995 [25]. In this project, evaluation of the annoyance from GSM interference (900 MHz) in some typical hearing aids in order to propose a quantity to characterize this interference and propose acceptance levels was the main purpose. Other main areas of interest were the development of a practical measurement procedure for assessing the interference performance of a hearing aid and development of equipment and procedures for these practical measurements including a "low-cost" arrangement for development and routine purposes.

The work of EHIMA led to an international standard, IEC 118-13, which is yet in draft phase but presents an efficient method of measurement of the interference. June 1995 version of this draft standard is included in Appendix A since the measurement procedure followed in this thesis is mainly based on it. Standardization process of the hearing aids for

electromagnetic compatibility was initiated in August 1993 by Working Group 13 of Technical Committee 29 in IEC and is expected to come to an end in October 1997.

Almost in the same period of time as the study conducted in Denmark, a similar study was carried out at National Acoustic Laboratories of Australia. They have tested 8 hearing aids for a set of parameters and as a result defined their own acceptable levels for the immunity and test procedures [26].

These two studies were followed by another research performed in PTB (Physikalisch-Technische Bundesanstalt) of Germany. PTB Mechanic and Acoustic Department tested 20 types of hearing aids based on the procedure set forth in IEC draft standard. They have also reported their study in November 1996 [27].

Last research to be mentioned is of Oklahoma University, Center for Study of Wireless Electromagnetic Compatibility [28]. They were supposed to finish the second phase of their study which covers the physical basis of the interaction between hearing aids and many cellular phone modalities in January 1997.

These studies mentioned particularly deal with objective measurement of the interaction between two technologies. However, since we can't isolate the victim of the interference i.e. the hearing aid user from the interaction picture, we have to talk about subjective measurements also. A remarkable study was performed in New Zealand on behalf Ministry of Health on 29 hearing impaired adults using real digital phones and yielded important consequences in understanding the interaction [29]. Phase I of Oklahoma study also covered this kind of subjective tests.

5.2 Hearing Aid Selection

In order to understand the interaction between hearing aids and digital mobile phones, tests are performed on 16 Behind-the-Ear (BTE) aids from 7 different brand names. There are approximately 15 brand names in hearing market of Turkey and 16 hearing aids which are selected to test include most widely used types. They cover a range electroacoustical characteristics as shown in Table 5.1. Hearing aids are supplied from Audiology Department of Marmara University Faculty of Medicine.

Table 5.1 Hearing aids tested for immunity.

No	Name / Model	Frequency Range (Hz)	Output (dB SPL)	Characteristics
1	Phonak PP-C-L-4+	110 - 4800	133	Super High Power
2	Rexton MP PP-2	270 - 5800	126	Powerful
3	Rexton Fortissimo PP-L	120 - 4500	140	Mini, high power
4	Phonak PP-C-4	320 - 4800	137	Extremely powerful, high gain
5	Danavox 145 DFS Genius II	125 - 4300	140	Extremely powerful, digital feedback supression
6	Danavox 143 V	300 - 5700	122	Adaptive voice processing
7	Siemens 604 P	150 - 5000	140	High Power, Tone Control
8	Danavox 155 PP AGCI Amplius	150 - 5000	134	High power, input AGC
9	Danavox 155 AGCI Amplius	200 - 6200	132	Power, input AGC
10	Oticon Personic 425	225 - 6000	133	Extra power (severe-profound)
11	Oticon E 35	215 - 4300	133	Powerful, input AGC (mild-severe)
12	Oticon 390 PL	75 - 4800	139	Super power, low frequency emphasis
13	Interton Suprema 47	325 - 6000	126	Output AGC
14	Hansaton OPAL/44 C-WR-H	900 - 7100	134	Variant with high tone
15	Interton Integra AD	50 - 6200	129	Mini, auto dynamic, input AGC
16	Phonak Pico Forte PP-C-L-2	110 - 4800	133	Mini, high gain, low frequency emphasis

5.3 Test Environment and Test Setup

In order to measure immunity of hearing aids, tests have to be carried out in an RF controlled environment. This means there must not been any electromagnetic fields inside the test space except for the interested field. In other words, hearing aid must be isolated from other sources interference and must be exposed to only one type of source that will be studied. Using standard digital wireless telephone as an RF source is not feasible due to reflections, telephone power switching, variation in carrier frequency, etc. In addition, it is a cumbersome process to have a digital telephone still operating inside a shielded enclosure since it will lose its connection with the base station.

Instead of using the emissions of a digital phone itself, simulating the emissions using a RF signal source and generating it inside a GTEM cell is preferred. A GTEM cell associated with proper RF signal source is a suitable means to make the tests. GTEM cells are discussed in Chapter 3. GTEM cell is a rectangular tapered transmission line with a 50

ohm input/output impedance. GTEM seems to be the most economic way to make the immunity tests.

Signal generator that generates fields of the swept frequencies at a specific field strength is controlled by a computer via a GPIB card. GPIB also reads data from the power meter and compares it with the calculated level in order to generate a field of desired strength.

Generating a specific electromagnetic field in a controlled area is one end of the immunity test set-up. At the other end lies the acquisition of data which emerges from the hearing aid as a result of electromagnetic field exposure. In this part of the setup acoustic output is measured and recorded. The first element of this end is a 500 mm plastic tubing that is connected the horn of a Behind-the-Ear (BTE) type hearing aid under test. This tubing extends till it connects to the 2 cc coupler which is a standard device used in hearing aid testing (IEC 126, IEC 118-7) for simulating the ear cavity. Since the coupler and the microphone are metallic and can distort the electromagnetic field around the hearing aid, both must be kept at a distance from the hearing aid. Keeping the microphone away from the test space is furthermore beneficial since the microphone itself can be affected from the field also. That is why we use a tubing of such length, e.g. 500 mm instead of standard 25 mm. Plastic tubing is taken outside GTEM through the honeycomb waveguides installed for ventilation purposes under GTEM. This resulted in the shift of test volume nearer to the input port and new calculation for the electric field generated since the septum height is changed. Placement of coupler-microphone-preamplifier system under GTEM is shown in Figure 5.1 below.

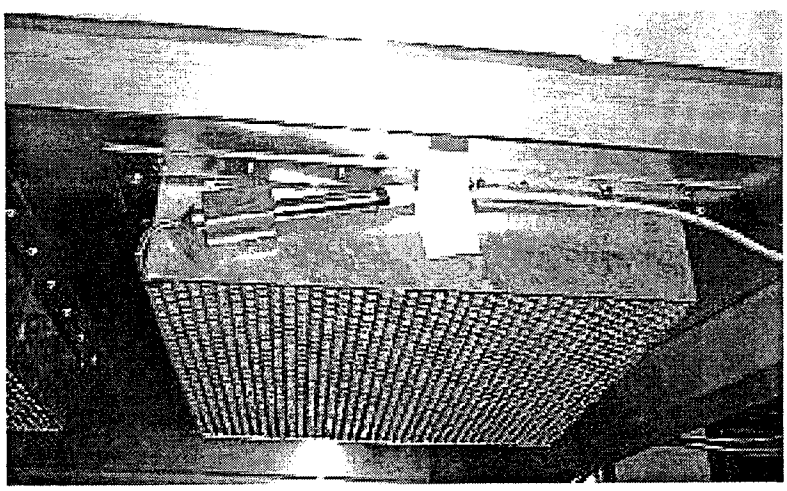


Figure 5.1 Placement of 2-cc coupler, microphone and preamplifier on honeycomb waveguides under GTEM.

Microphone needs a preamplifier and they are connected to their power supply which also acts as a signal output port of the microphone-preamplifier system. The signal output is then connected to a DSP Lock-In Amplifier in order to measure the sound pressure levels and to an oscilloscope to monitor the interference signal. Lock-In amplifiers need an internal or an external reference frequency and they measure the component of the input signal only at that specific reference frequency. This reference frequency (i.e. 1 kHz) is provided by the signal generator. Signal generator also uses this 1 kHz frequency as a modulation frequency of its carrier wave. The data obtained form the lock-in amplifier is read by the computer via GPIB and saved to analyze them later.

Generation of field with specific characteristics using signal generator and power meter and acquisition of interference data from the DSP lock-in amplifier are both are automatically controlled by means of a programme written in National Instruments LabWindows CVI software. After appropriate setting of the test parameters, the test is performed by clicking only one button in the user interface of the programme. Data storage, however, needs another button to click. User interface of the programme is shown in Figure 5.2 .

Equipment used in the experiment is listed in Table 5.2 below.

A schematic of the test setup is illustrated in Figure 5.3. Also a picture of some equipment in the setup is shown in Figure 5.4.

Table 5.2 List of the equipment used in the experiment.

Equipment	**Model / Type**	**Manufacturer**
GTEM cell	1750	Messelektronik Berlin
Signal Generator	SMY 01	Rohde & Schwarz
Power Amplifier	50W1000A	Amplifier Research
Power Meter	NRVS	Rohde & Schwarz
Directional Coupler	RK 100	Messelektronik Berlin
Acoustic 2-cc Coupler	Acc. to IEC 126	-
Microphone	4134	Brüel & Kjaer
Mic. Preamplifier	2639	Brüel & Kjaer
Mic. Power Supply	2804	Brüel & Kjaer
DSP Lock-In Amplifier	SR 850	Stanford Research Systems
Oscilloscope	54615 B	Hewlett-Packard
Computer	Pentium 100	Tulip
GPIB card	AT-TNT +	National Instruments
Software	Lab Windows CVI	National Instruments

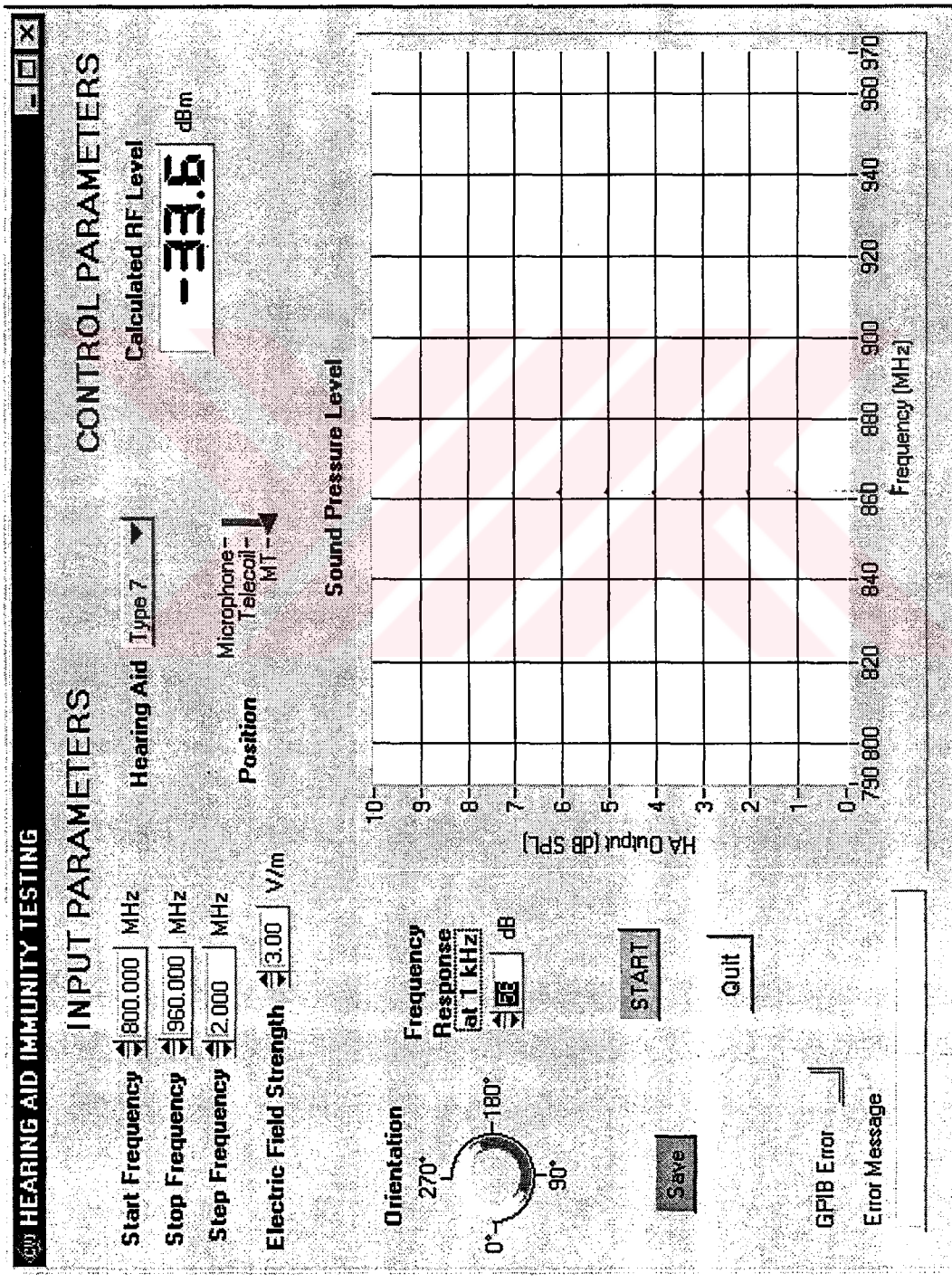


Figure 5.2 User interface of the programme used for automated immunity testing of hearing aids.

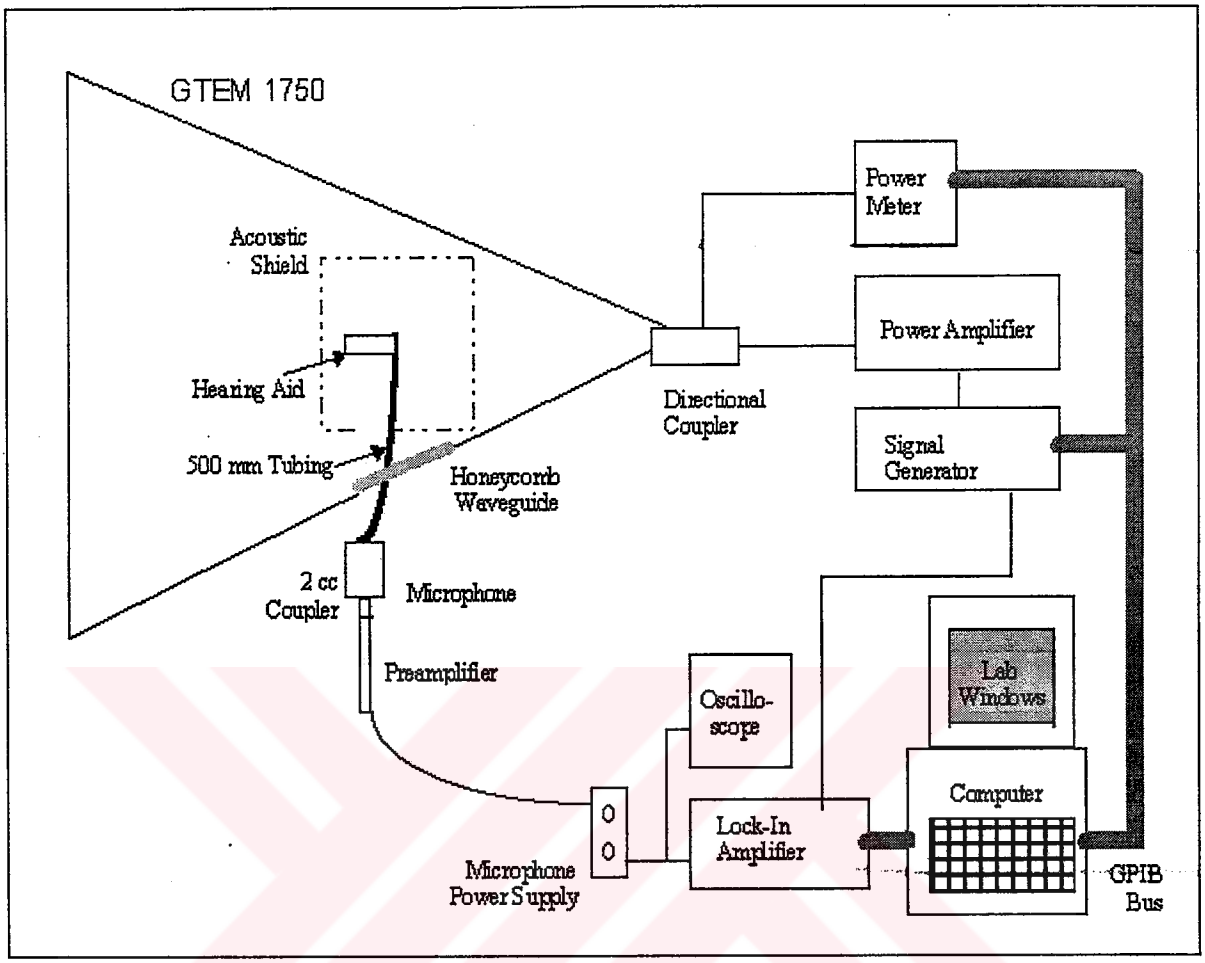


Figure 5.3 Experimental setup for immunity testing of hearing aids.

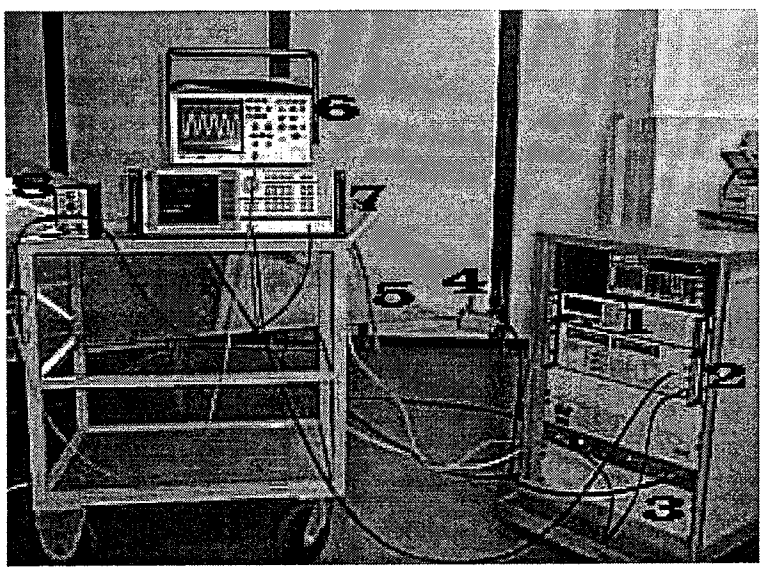


Figure 5.4 Some of the test equipment during testing.

(**1**. Power Meter, **2**. Signal Generator, **3**. Power Amplifier, **4**. Directional Coupler, **5**. Input Port of GTEM, **6**. Oscilloscope, **7**. DSP Lock-In Amplifier and **8**.Microphone Power Supply)

5.4 Test Methodology

Electromagnetic compatibility tests of hearing aids are performed based on the draft standard IEC 118-13 published by International Electrotechnical Commission as mentioned above.

First stage of the test consists of frequency response testing of the hearing aid under test with 60 dB input. This test is performed in Audiology Department in Marmara University Faculty of Medicine according to IEC 118 standard series as explained in Chapter 4. Particularly to mention, frequency response of the hearing aid at 1 kHz is tested using 500 mm long, 2 mm diameter (500 mm /ϕ2 mm) plastic tubing. Effect of switching to that length of tubing for HA 7 (hearing aid no.7) is illustrated in Figure 5.5.

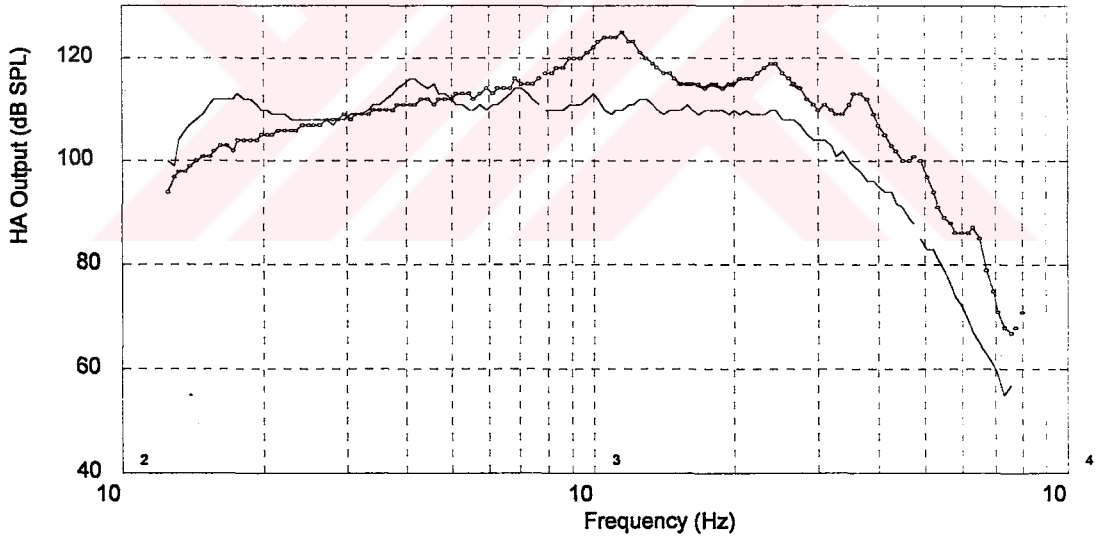


Figure 5.5 Frequency response curves of HA 7 measured with 25 mm (light line) and 500 mm (bold line) tube lengths and 60 dB input sound level.

For three other hearing aids (HA 6, HA 8 and HA 9) the same relation is shown in Appendix D. A comparison table for 16 hearing aids is given in Table 5.3. The difference between sound pressure levels obtained by two kinds of tubing range from 3 dB to 17 dB being 9 dB in average. This implies that the same tubing must be used both in determining the gain of the hearing aid at 1 kHz and in testing the hearing aid for immunity.

Table 5.3 Gain of 16 BTE hearing aids at 1 kHz tested with 25 mm and 500 mm long tubings.

HA No	Gain at 1 kHz with 25 mm tubing (dB SPL)	Gain at 1 kHz with 500 mm tubing (dB SPL)	HA No	Gain at 1 kHz with 25 mm tubing (dB SPL)	Gain at 1 kHz with 25 mm tubing (dB SPL)
1	68	57	9	55	50
2	48	38	10	51	33
3	73	56	11	47	37
4	57	50	12	55	39
5	56	51	13	33	27
6	56	41	14	45	39
7	62	53	15	49	46
8	56	50	16	57	51

The next and undeniably the main stage is carried out at EMI/EMC Laboratory of National Electronics and Cryptology Research Institute at TUBITAK Marmara Research Center, Gebze, Kocaeli.

Electromagnetic compatibility testing of a hearing aid is performed as follows: The hearing aid is placed in the working area inside GTEM. It is not necessary but in this study we preferred to put the hearing aid in an acoustically shielded box. Acoustic box was built using hard polystyrene foam and pyramidal absorbers. It helps to attenuate the external sounds which may be produced and may effect the results during testing. Attenuation characteristics (or effectiveness) of this acoustic shield is included in Appendix E. Placement of hearing aid inside the acoustic shielded box and the box inside GTEM are illustrated in Figure 5.6 and Figure 5.7 respectively.

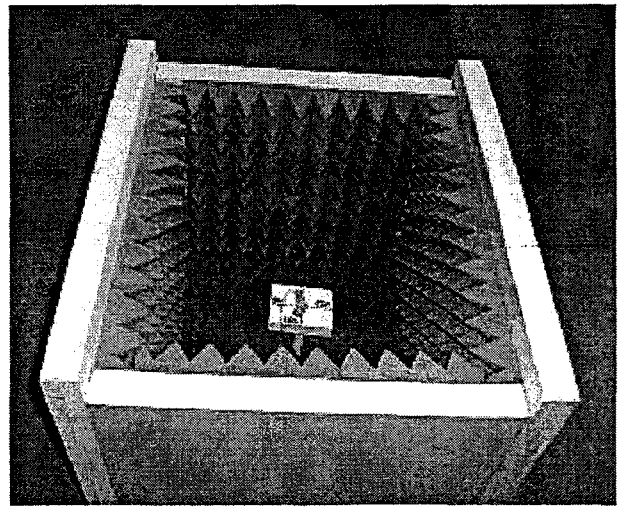


Figure 5.6 Placement of hearing aid under test inside the acoustically shielded box.

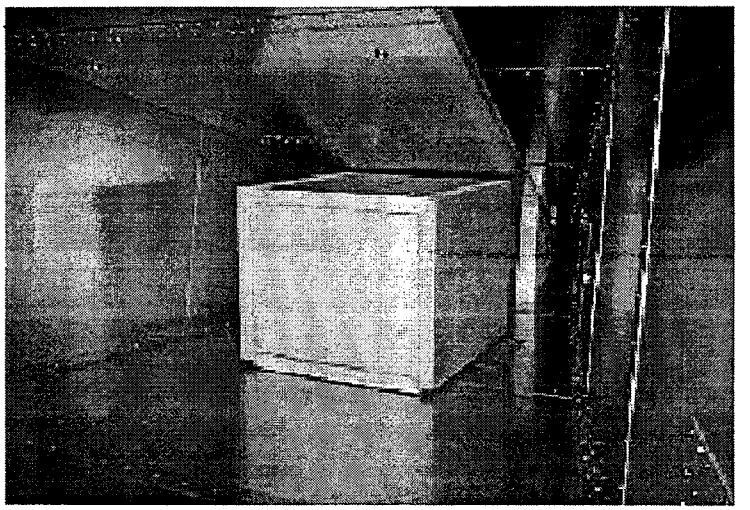


Figure 5.7 Placement of acoustically anechoic box in the test volume inside GTEM.

There are five orientations for the hearing aid to be placed. Four of them lie in the horizontal plane with 90 degrees separation between each (i.e. 0, 90,180 and 270 degrees) and the fifth is on the vertical plane. Orientation of the hearing aid is illustrated in Figure 5.8.

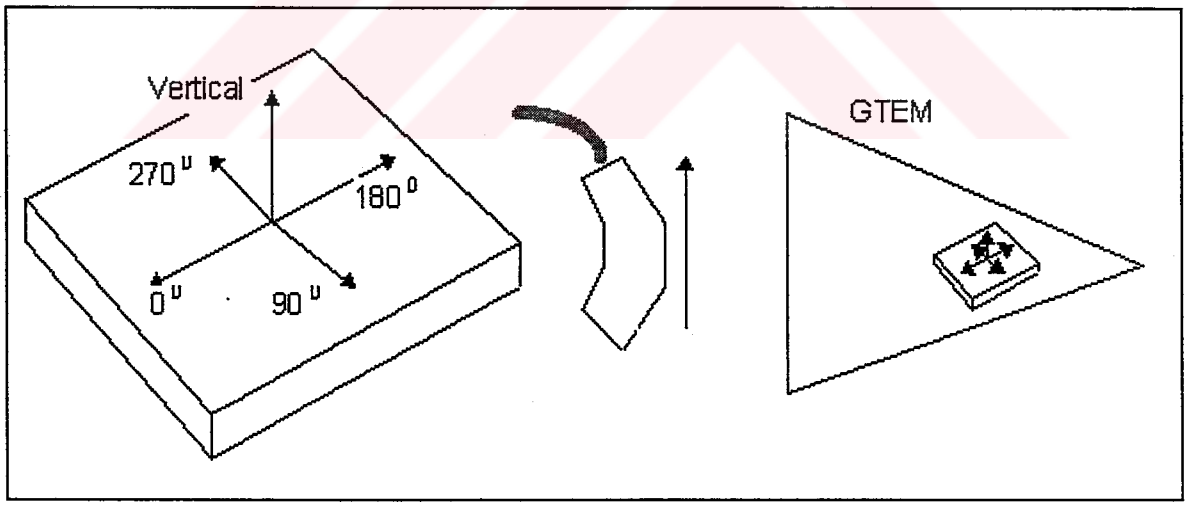


Figure 5.8 Orientation of the hearing aid in test volume.

After setting the position of the hearing aid as microphone, telecoil or MT (an input used for FM communication in education) test area is left closing the door of the GTEM cell.

The draft IEC standard requires the carrier frequency to be swept between 800 and 960 MHz range with at least 16 MHz step size. Start and step frequencies are set to 800

MHz and 960 MHz by default. However, step frequency is chosen as 2 MHz in order to have more precise graphs. Electric field level is also entered in the user interface of the automated test software. These are the parameters concerning the applied electric field. Although not related with field production inside GTEM, a few parameters specific to the hearing aid under test are also entered for data recording purposes. These parameters are the Type (1 to 16), Gain, Position (Microphone, Telecoil or MT) and Orientation (0, 90, 180, 270 degrees or Vertical) of the hearing aid under test. Then the test is performed for these specific parameters just set.

Actually, GSM system for the digital phones consists of a 100 per cent amplitude modulated radio frequency envelope with a repetition rate of 217 Hz. However, 80 per cent AM modulation of the carrier frequency at 1 kHz is accepted as a standard scheme for immunity tests in latest version of IEC 1000-4-3. This modulation scheme applies to all electronic equipment and hearing aids are no exception since no product specific standard for hearing aids exists yet. Comparison of 80 per cent AM sine modulation with GSM modulation can be investigated in detail in Appendix F.

As mentioned earlier, carrier frequency is swept from 800 MHz to 960 MHz with 2 MHz steps in order to include the GSM transmitting frequencies. For some countries where other modulation schemes like DCS 1800 and PDC are used 1400-2000 MHz range must also be swept. In this study this frequency range is not covered since it is not in use in our country.

Then consecutive tests are carried out for other orientations and hearing aid positions. For each hearing aid 10 or 15 set of data is obtained depending on the type. Each set of data consists of frequency data from 800 MHz to 960 MHz versus hearing aid output data expressed in dB SPL (sound pressure level).

An important point to be careful at is the noise level of the measuring system. This level must be well below the hearing aid output. 10 dB is an acceptable value to make sure that signal output is not distorted or masked by the system noise. Since lock-in amplifier has a very narrow bandpass around the interested frequency we don't have to worry about noise level.

5.5 Electric Field Level Correction

The IEC draft standard proposes a test level of 3 V/m for 800 - 960 MHz range. This 3 V/m is the level of the unmodulated carrier. Unfortunately, this was overlooked and a level for a modulated carrier was applied. Modulation at 80 per cent, as required by IEC 1000-4-3, increases the instantaneous power requirement by a factor of 5.2 dB. Modulated 3 V/m level was not sufficient to create measurable response in hearing aids in most of the cases so an increase in level to 10 V/m as a standard level for all the hearing aids tested was applied. This 10 V/m level was again for the modulated carrier and need to be corrected. Calculations for correction of the field level is explained below.

Electric field level inside GTEM is a function of voltage applied and the distance between plates:

$$E = k \frac{U_0}{d} \quad (V / m) \tag{10}$$

where E is the electric field strength, k (=0.975) is a correction factor calculated previously for our GTEM, U_0 is the voltage applied and d (=0.68 m) is the septum height. However, in order for a voltage level of U_0 to be applied, a power level of

$$P = \frac{U_0^2}{Z} \quad \text{Watts} \tag{11}$$

must be supplied to the input port of GTEM. Here Z (=50 Ω) is the transmission line impedance of GTEM.

When we consider Figure 3.4 in Chapter 3 Section 3.2.1.1, modulation depth is calculated from:

$$m = \frac{(U_2 - U_1)/2}{U_0} \tag{12}$$

In the case of amplitude modulation, two sideband frequencies having the amplitude

$$U = \frac{m}{2}.U_0 \qquad (13)$$

are formed above and below the carrier frequency, which corresponds to an increase in level. Thus, while unmodulated power is

$$P_{un\,mod} = \frac{U_0^2}{Z} \quad W$$

the modulated power is greater by a factor as calculated below:

$$P_{mod} = \frac{U_0^2}{Z} + 2.\frac{(U_0.m/2)^2}{Z} = P_{unmod}.(1+\frac{m^2}{2}) \quad W \qquad (14)$$

For a 80 per cent AM sine modulation, m = 0.8 ; therefore, $P_{mod} = 1.31 \cdot P_{unmod}$.

Unfortunately, for the second time, this was not the only overlooked point. There was another fault made during field generation: Power meter was set to "Pulse" reading though it should have been set to "Average" reading. For pulse power reading in power meter

$$P_{pulse} = \frac{100}{\text{Duty cycle in per cent}}.P_{average} \qquad (15)$$

Because default duty cycle setting of power meter was 50 per cent, power meter read the power levels twice as much and decreased the power level to its half. So there comes another correction factor of 2 to the power applied. Finally,

$$P_{average/unmod} = 2 \cdot 1.31 \cdot P_{pulse/mod} = 2.62 \cdot P_{pulse/mod} \qquad (16)$$

From Equation.10 and Equation 11,

$$P \alpha E^2 \qquad (17)$$

Therefore, we have to decrease the value of each applied electric field by a factor of

$$\frac{1}{\sqrt{2.62}} = 0.615$$

Then the following correction table applies:

3 V/m	→	1.85 V/m
10 V/m	→	6.15 V/m
20 V/m	→	12.3 V/m

In this study, first 3 V/m (actually 1.85 V/m unmodulated and power corrected) field level was applied. Since this level was not sufficient to create measurable output in most of the hearing aids, the electric field level was increased to 10 V/m (actually 6.15 V/m unmodulated and power corrected). So immunity testing of 16 hearing aids was performed for an unmodulated applied field level of 6.15 V/m. For 2 hearing aids 12.3 V/m, and for 1 hearing aid 1.85 V/m data was also obtained. Results of the test are given in next Chapter.

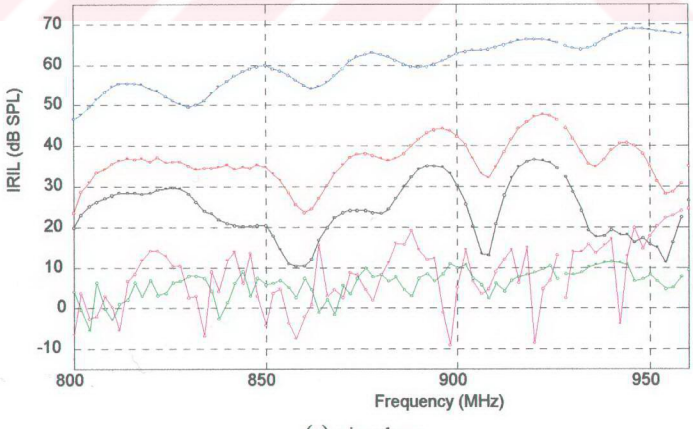
6. TEST RESULTS AND DISCUSSION

6.1 Results of Standard Test

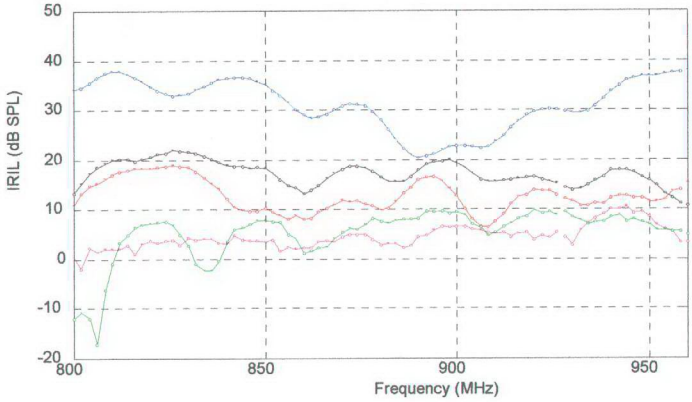
For the analysis of data of the standard tests performed, a performance criteria, which is known as "Input Related Interference Level (IRIL)", is utilized. IRIL, as defined in IEC draft standard 118-13, is the level to characterize the immunity of the hearing aid, measured in dB SPL. In brief, hearing aid gain at 1 kHz (see Table 5.3) is subtracted from the corresponding levels of interference which is determined using the Test Methodology in Section 5.4. Sixteen hearing aids were tested for an electric field level of 6.15 V/m. For the reasons outlined in the previous chapter, a test level other than 3 V/m was applied. One hearing aid was tested for 1.85 V/m level and 2 were tested for 12.3 V/m level.

6.1.1 Results of 6.15 V/m Test Level

Figure 6.1 shows interference levels produced in HA 4 at microphone and telecoil positions when an electric field of 6.15 V/m is applied.



(a) microphone



(b) telecoil

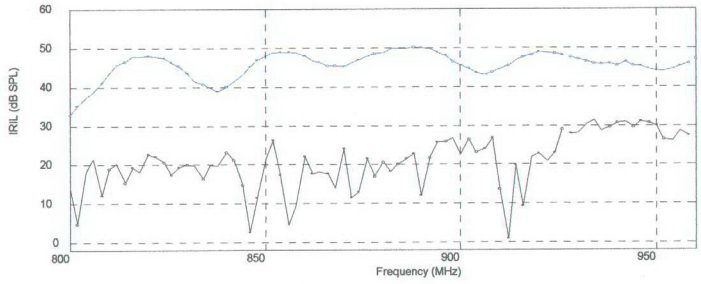
Figure 6.1 Interference levels produced in HA 4 (a) for Microphone and (b) Telecoil input for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

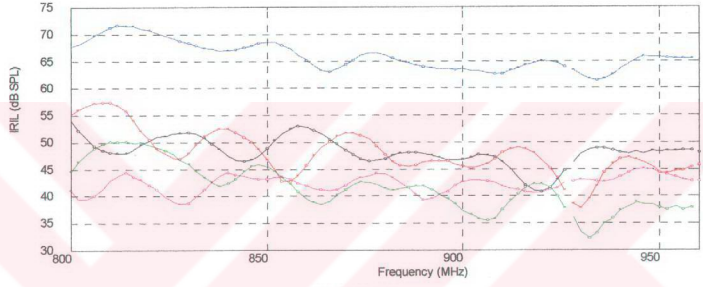
Since it will take much space to include all the graphs of this test level here, they are rather included in Appendix G.

6.1.2 Results of 1.85 V/m Test Level

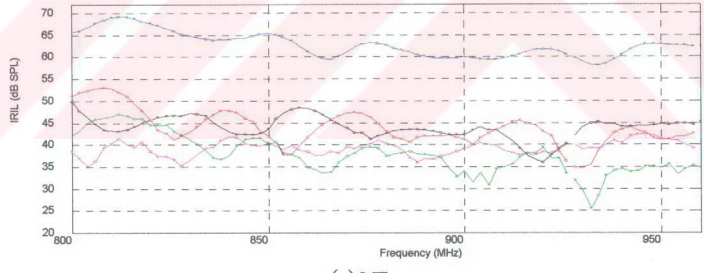
As an example for 1.85 V/m test level, graph of HA 12 is shown below in Figure 6.2. (Note that HA 12 was not tested in 90, 180 and 270 degrees orientations because low interference levels were expected.)



(a) microphone



(b) telecoil

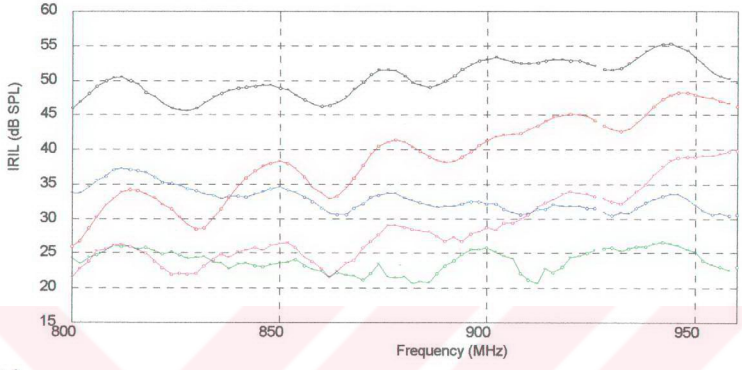


(c) MT

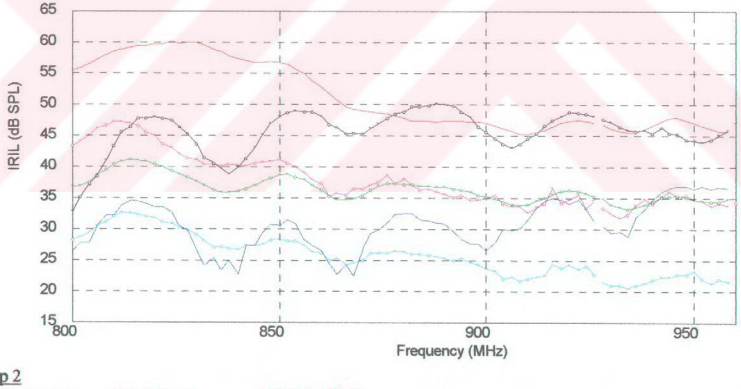
Figure 6.2 Interference levels produced in HA 12 (a) for Microphone, (b) Telecoil and (c) MT input for an electric field level of 1.85 V/m

Not all of the hearing aids were tested for 1.85 V/m test level in all their orientations. However, some of them were tested at 0 degree and Vertical orientations. Figure 6.3 shows interference levels produced for 11 hearing aids at microphone position and vertical

orientation. Graphs illustrating the interference levels of some hearing aids at 1.85 V/m test level are included in Appendix G.



Group 1
HA 1: magenta, HA 2: green, HA 3: blue, HA 4: red, HA 7: black



Group 2

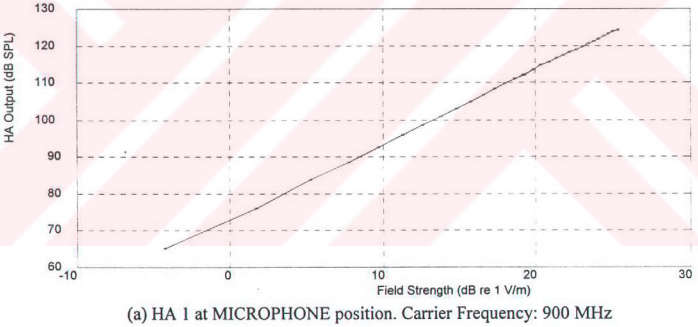
HA 10: magenta,	HA 11: red,	HA 12: black,
HA 14: green,	HA 15: blue,	HA 16: cyan

Figure 6.3 11 Hearing aids at microphone position and vertical orientation with an applied electric field strength of 1.85 V/m.
(Note: 11 hearing aids are grouped in two in order to decrease complexity in graphs)

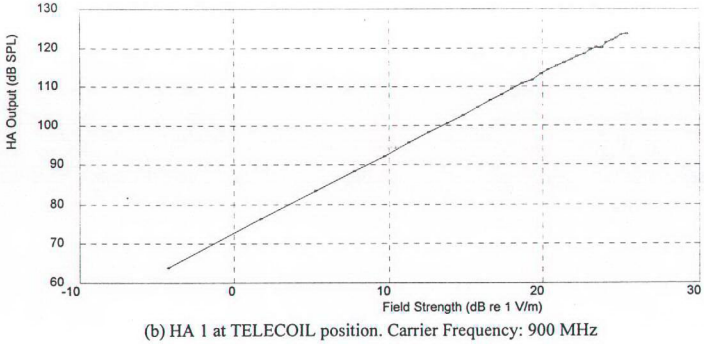
6.2 Increasing Field Strength

The standard test was performed sweeping the carrier frequency from 800 to 960 MHz at a specific test level. In order to investigate the relation between hearing aid output and the field strength, we can fix the test frequency (say 900 MHz) and apply the test level in a suitable range where hearing aid output will not saturate or masked by noise. We may propose that hearing output will increase as we increase the electric field strength. It is obvious that finding a relation between two parameters would help us a lot.

Figure 6.4 illustrates a typical linear relationship between field strength and interference level. Note that we expressed the electric field strength in dB with reference to 1 V/m. While Figure 6.4 (a) and (b) show this relationship for microphone and telecoil inputs of HA 1 at 900 MHz, Figure 6.4 (c) shows that this is not special case for 900 MHz and is valid for other carrier frequencies also.



(a) HA 1 at MICROPHONE position. Carrier Frequency: 900 MHz



(b) HA 1 at TELECOIL position. Carrier Frequency: 900 MHz

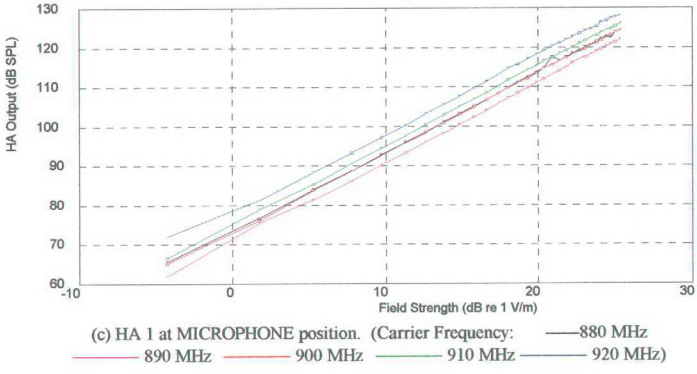


Figure 6.4 Output interference level of HA 1 (hearing aid no.1) as a function of field strength for different inputs and different carrier frequencies.

As the graphics implies there is a linear relationship between the applied field strength and hearing aid output. We can find this linear relationship by applying basic analytical geometry principles to the graphics. A line in xy-plane can be expressed as

$$y = nx, \tag{18}$$

where n is the slope of the line. The slope can be calculated if we know two points on the line:

$$n = \frac{y_2 - y_1}{x_2 - x_1} \tag{19}$$

From Figure 6.4.(a) two points, (x_1,y_1)=(5.34,83.88) and (x_2,y_2)=(16.61,106.76), are arbitrarily selected to give:

$$n_{mic} = \frac{y_2 - y_1}{x_2 - x_1} = \frac{106.76 - 83.88}{16.61 - 5.34} = \frac{22.88}{11.27} = 2.03$$

We can calculate the slope for telecoil input also. From Figure 6.4 (b) two points, (x_1,y_1)=(1.81,76.5) and (x_2,y_2)=(18.06,109.5), are arbitrarily selected to give:

$$n_{telecoil} = \frac{y_2 - y_1}{x_2 - x_1} = \frac{109.5 - 76.5}{18.06 - 1.81} = \frac{33}{16.25} = 2.03$$

Increasing field strength graph of another hearing aid (HA 12) is included in Appendix G. When we follow the same calculation procedure for HA 12 also, we find 2.06 and 2.00 slope values for microphone and telecoil inputs, respectively.

From all these calculations, we can conclude that n=2 is an acceptable and reasonable value for the slope. That means there is 1:2 dB ratio between the electric field strength and hearing aid interference level. In other words, whenever we increase field strength in 1 dB, hearing output will increase in 2 dB. However, this relationship will hold true for field strength range where the interference signal is above the noise floor of the hearing aid and does not saturate the hearing aid. We can express it briefly as:

$$\Delta y \text{ (dB SPL)} = 2 \cdot \Delta x \text{ (dB re 1 V/m)} \qquad (19)$$

Finding a linear relationship can help us in evaluating hearing aid output at other test levels which are not tested. By interpolation, we can find a way to evaluate IRIL at 3 V/m which is the desired test level of the IEC standard and was not tested for most of the hearing aids.

In order to see that this linear relationship is not a special case for HA 1 and HA 12, we can work on another hearing aid, and see that it is valid for other hearing aids also. We will start working with HA 4 since we already have shown 6.15 V/m graphs of it and we luckily have another set of data for it at another field strength. We will interpolate 12.3 V/m data from 6.15 V/m data and compare it with the measured ones.

Interpolation calculation is as follows. Electric field strength, E, can be expressed in decibel units referenced to 1 V/m (dB re 1 V/m) by applying following transformation:

$$E \text{ [dB re 1 V/m]} = 20 \cdot \log (E \text{ [V/m]}) \qquad (20)$$

Therefore we have electric field strength levels, E_1 = 6.15 V/m = 15.78 dB re 1 V/m and E_2 = 12.3 V/m = 21.8 dB re 1 V/m. Applying Equation 20:

$\Delta x = 21.80\text{-}15.78 = 6.02$ dB re 1 V/m

$\Delta y = n \,.\, \Delta x = 2 \cdot 6.02 = 12.04 \cong 12$ dB SPL.

Therefore we will add 12 dB SPL for each 6.15 V/m data in order to find interpolated 12.3 V/m data. Then will compare it with the measured 12.3 V/m data. In Figure 6.5, measured values at 12.3 V/m test level for HA 4 at microphone and telecoil positions are illustrated, whereas Figure 6.6 shows interpolated values for 12.3 V/m for the same settings.

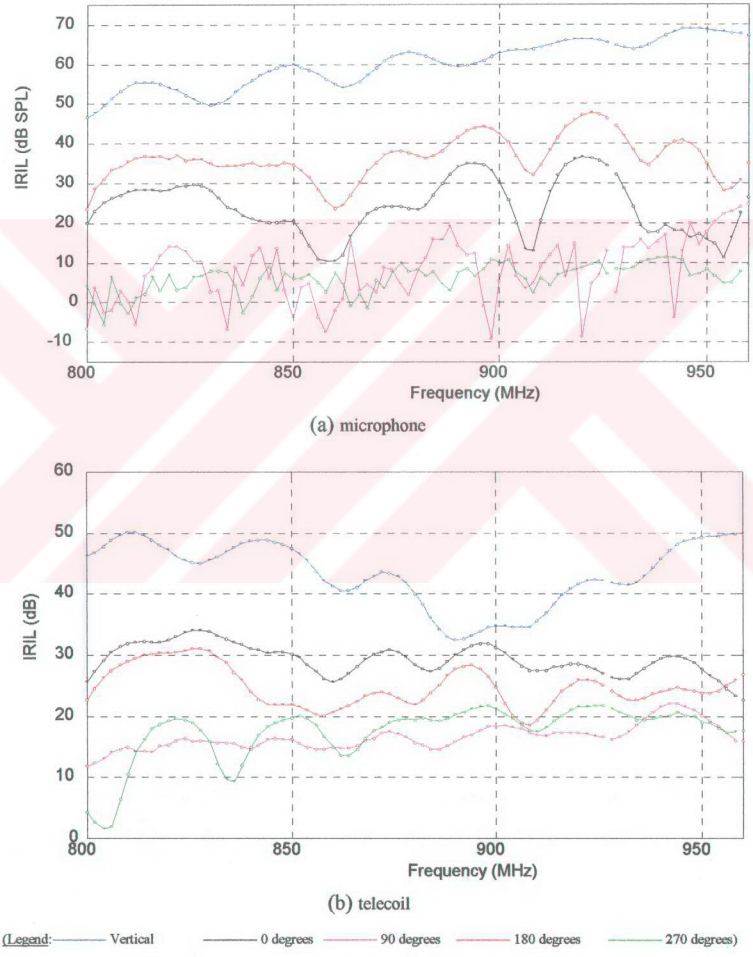
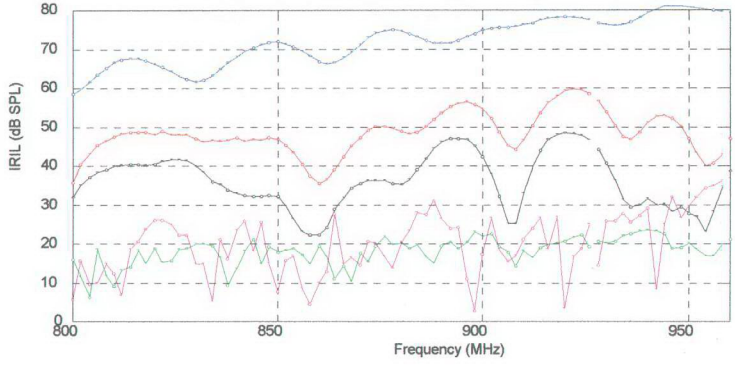
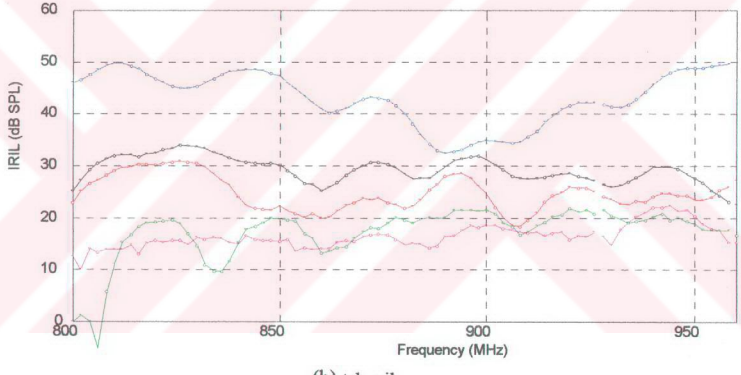


Figure 6.5 Measured 12.3 V/m data for HA 4 at 5 orientations.



(a) microphone



(b) telecoil

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

Figure 6.6 Interpolated 12.3 V/m data for HA 4 at 5 orientations.

A comparison of Figure 6.5 and Figure 6.6 yield that there is a one-to-one correspondance between the measured and interpolated data. Only exception is for the vertical orientation in the 900-960 MHz region where the hearing aid seems to be saturated and interpolated data is about 3 dB greater than the measured data. The rest of the graphics shows consistency of the interpolated data with the measured data especially for 0 deg, 180 deg and vertical orientations.

We can generalize the relationship for other hearing aids also. The physical basis for this generalization lies in the characteristics of the input elements of the amplifier system in a hearing aid. In brief, RF signals coupled to the input of a transistor are amplified resulting in a square law detection. This is explained in detail in Appendix F.

6.3 Interpolation for 3 V/m Test Level

Since we have 6.15 V/m data for all the hearing aids as a standard test level, we can interpolate 3 V/m data in order to check the hearing aids for the requirements of IEC Draft Standard 118-13. The requirement is 55 dB SPL IRIL for approving immunity. The calculation for 3 V/m will be in the same manner as we did before.

$E_1 = 6.15$ V/m = 15.78 dB re 1 V/m as we already know.

$E_2 = 3$ V/m = 9.54 dB re 1 V/m.

$\Delta x = 15.78 - 9.54 = 6.24$ dB re 1 V/m

$\Delta y = n \,.\, \Delta x = 2 \cdot 6.24 = 12.48 \cong 12.5$ dB SPL.

For shifting from 6.15 V/m test level to 3 V/m test level, we will just decrease 12.5 dB SPL from the hearing aid output interference levels. The results of the interpolation are summarised in Table 6.1 and Table 6.2. Tables show the maximum interference level for each orientation of the hearing aids without any reference to the carrier frequency it occured. Note that some IRIL values are negative since we subtract hearing aid gain at 1 kHz from output SPL levels obtained. Negative IRIL imply that interference levels less than gain of the hearing aid were measured.

Table 6.1 Maximum IRIL (dB SPL) values of 12 hearing aids for 3 V/m test level in 800-960 MHz range. These values are interpolated by subtracting 12.5 dB SPL from 6.15 V/m test level data .

Position →	*MICROPHONE*					*TELECOIL*				
Orientation → Type ↓	**0**	**90**	**180**	**270**	**Vert.**	**0**	**90**	**180**	**270**	**Vert.**
HA 1	21.5	3	30.7	10.1	48.9	14.9	-3.6	15	-5.9	38.9
HA 2	32.5	27.2	24.4	31.3	34.9	26.6	13.9	9.1	7.6	11.8
HA 3	18.3	-1	22.8	6.9	46.8	19	-10.7	11.8	-13.3	9.4
HA 4	24	12.2	35.1	-0.9	**56.5**	9.5	-2	6.4	-2.7	25.3
HA 6	19.3	11.4	11.2	13.3	25.6	2.6	-1.9	6.4	-3.4	26.3
HA 7	6.7	7.6	30.2	14.2	**61.3**	27.2	16.4	27.3	16.7	**59.2**
HA 10	41.8	12.7	41	21.5	**55.5**	35.1	9.7	35.2	18.6	**67.7**
HA 11	48.8	26.9	44.5	25.1	**65.7**	46.7	**55.1**	**58**	26.9	**67.3**
HA 13	17.3	23.6	14.6	15.7	51.5	11.3	8.6	3.8	14.3	30.3
HA 14	21.3	6.6	18.9	7.5	50.5	40.6	11.4	31.3	16.6	**60.3**
HA 15	33.8	22	37.5	26.2	40.1	-11.2	-11	-11.6	-12.2	(*)
HA 16	15.4	15.1	13.9	14.6	40.6	-4.1	-27.2	-4.7	-19.9	11.1

(*) This orientation was not tested. Human factor in experimentation.

Table 6.2 Maximum IRIL (dB SPL) values of 4 hearing aids (those with MT input also) for 3 V/m test level in 800-960 MHz range. These values are interpolated by subtracting 12.5 dB SPL from 6.15 V/m test level data .

Position →	*MICROPHONE*					*TELECOIL*				
Orientation → Type ↓	**0**	**90**	**180**	**270**	**Vert.**	**0**	**90**	**180**	**270**	**Vert.**
HA 5	21.1	8.2	18.5	7.6	35.8	29	14.5	20.4	15	31.8
HA 8	26.7	16.4	23.5	21	24.3	39.2	28.6	36.3	32.7	38.4
HA 9	24.1	0	25.7	0	23.4	33.6	10.2	33.7	7.1	34.2
HA 12	38.8	29.2	29.6	30.4	**58.8**	**62.5**	53.7	**66.1**	**58.8**	**76.3**

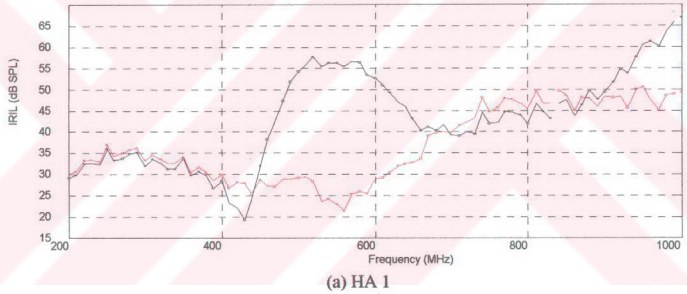
Position →	*MT*				
Orientation → Type ↓	**0**	**90**	**180**	**270**	**Vert.**
HA 5	38.4	14.2	31	17	31.2
HA 8	41	30.5	38.1	34.3	38.4
HA 9	35.7	12.3	36	8.1	35.7
HA 12	**71.3**	**63.3**	**74.2**	**67.6**	**88**

6.4 Other Important Parameters

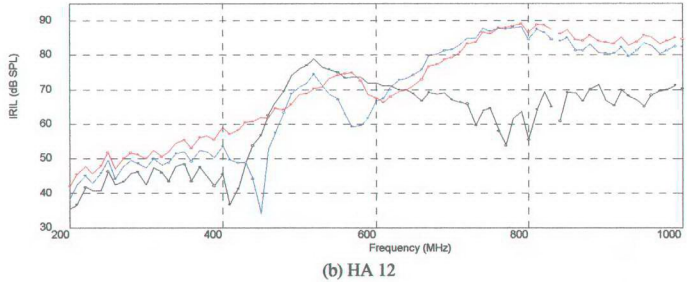
Tests were also performed changing some parameters of the standard test procedure in order to see the effect of these parameters on the results. These include enlarging the frequency range of the carrier frequency, changing of the modulation depth, changing modulation frequency and finally effect of tube size.

6.4.1 Testing in 200 MHz -1000 MHz Range

In the standard method, hearing aids are tested in 800-960 MHz range in order to evaluate them for the interference caused by GSM transmitting near 900 MHz. HA 1 and HA 12 are tested for a carrier frequency range of 200 MHz - 1000 MHz under 6.15 V/m electric field applied and at vertical orientation. Figure 6.7 shows the results of this test.



(a) HA 1

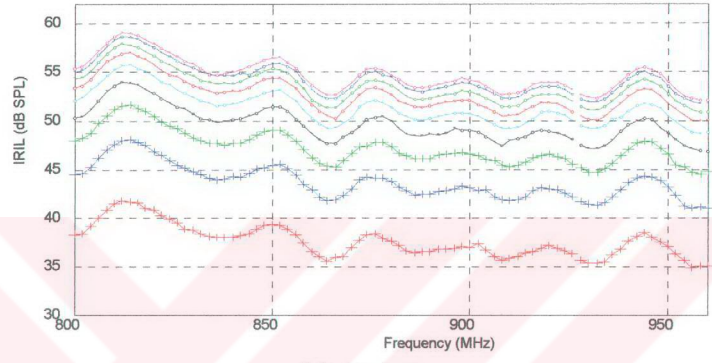


(b) HA 12

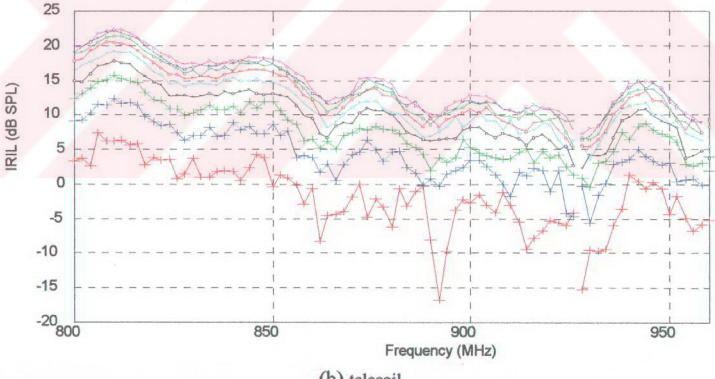
Figure 6.7 HA 1 and HA 12 tested in 200-1000 MHz range and vertical orientation keeping all other parameters fixed. *(MICROPHONE:Black, TELECOIL: Red, MT: Blue)*

6.4.2 Changing the Modulation Depth

In the standard procedure the carrier frequency is exposed to 80 per cent AM sine modulation of at 1 kHz. HA 3 is tested for modulation depth increasing from 10 per cent - 90 per cent. The results are illustrated in Figure 6.8 below.



(a) microphone



(b) telecoil

Magenta:	90 per cent	Red:	60 per cent	Green +:	30 per cent
Blue:	80 per cent	Cyan:	50 per cent	Blue +:	20 per cent
Green:	70 per cent	Black:	40 per cent	Red +:	10 per cent

Figure 6.8 HA 3 exposed to different modulation depths of the carrier frequency.

6.4.3 Changing the Modulation Frequency

Carrier frequency in standard procedure is amplitude modulated at 1 kHz. Two hearing aids, HA 3 and HA 12, were tested for different modulation frequencies. Hearing aids were tested in vertical orientation. Applied electric field strength is 6.15 V/m for the unmodulated carrier. The results for HA 3 are shown in Figure 6.9. For comparison we can mention the gain of this device measured with 25 mm tubing as 63, 55, 43, 41, 24 and 8 dB SPL for 1 kHz, 2 kHz, 3 kHz, 4 kHz, 5 kHz and 6 kHz respectively.

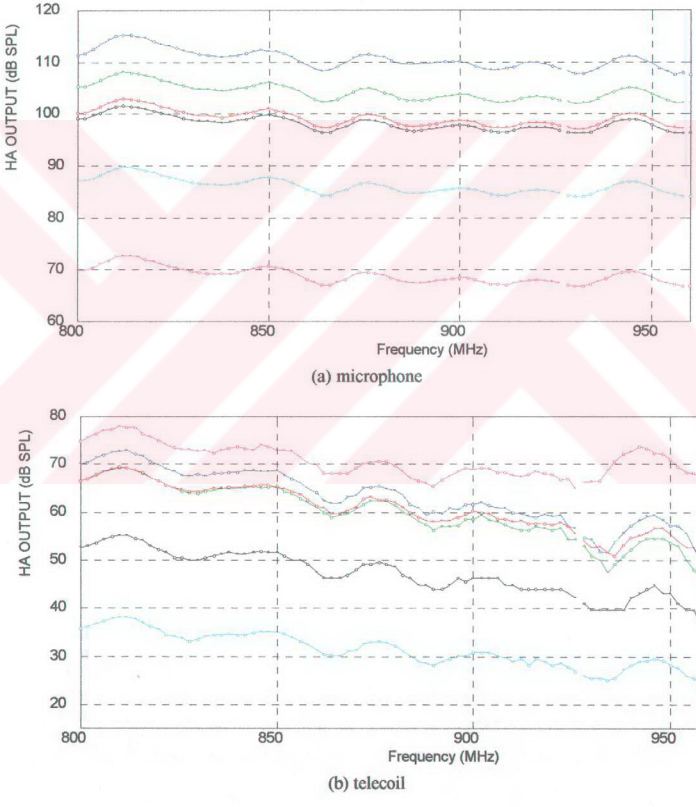
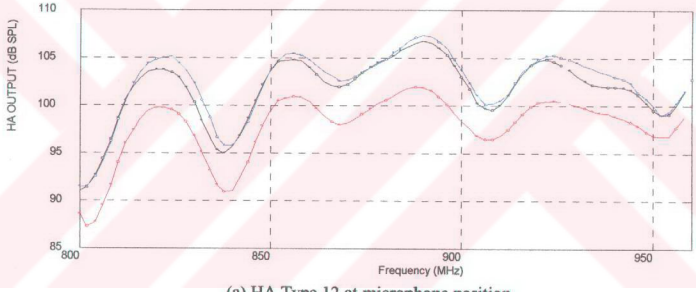


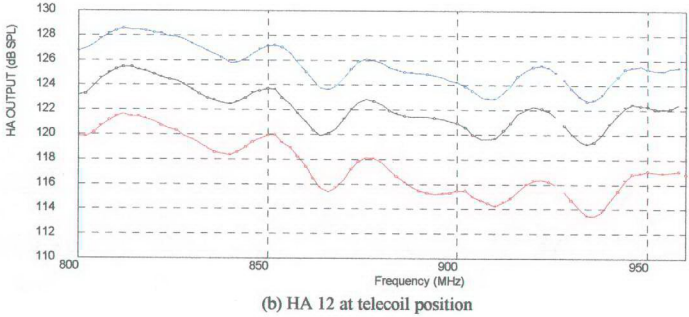
Figure 6.9 HA 3 for different modulation frequencies.

6.4.4 Effect of the Tube Size

According to IEC 118, frequency response and other sound pressure level testing of hearing aids are performed using a 25 mm long, 2 mm diameter tubing between the horn of a BTE hearing aid and the acoustic coupler. In electromagnetic compatibility testing of hearing aids a 500 mm/⌀2 (500 mm long, 2 mm diameter) tubing is used in order to keep away metallic components away from the test space. Since acoustic coupling is an important parameter in the measurement of hearing aid output, different tubing sizes, like 500 mm/⌀1 and 1000 mm/⌀2, are also tested for comparison. Though it is not a parameter directly related to the hearing aid, it is apart of the test setup. In Figure 6.10, testing of HA 12 at vertical orientation under an electric field level of 6.15 V/m for different tube sizes are illustrated.



(a) HA Type 12 at microphone position



(b) HA 12 at telecoil position

Figure 6.10 HA 12 tested for different tube sizes.

(blue: 500 mm/⌀2 ; **black**: 500 mm/⌀1 ; red:1000 mm/⌀2)

6.5 Discussion

Output of the standard test in the scope of this thesis with a test level of 6.15 V/m is a graph of the IRIL level produced (in dB) versus the RF carrier frequency along 800-960 MHz range for each hearing aid at a specific position (microphone or telecoil) and at a specific orientation (0, 90, 180, 270 degrees and vertical). For simplification and clarity, results of the standard test are presented for a specific position including all 5 orientations. Refer to Appendix G for detailed test results.

The results for 6.15 V/m test level can be summarised as follows:

- Output related interference levels up to 140 dB SPL was created by just exposing the hearing aid to electromagnetic fields and without any sound input.
- Of all the 5 orientations tested, vertical orientation resulted in highest interference levels for each hearing aid with a few exceptional cases.
- 90^{0} and 270^{0} orientations on the horizontal plane yielded lowest interference levels and were often near the noise level.
- Interference levels produced at 0^{0} and 180^{0} orientations were correlatable in many instances. The response of the hearing aid at these orientations were nearly the same only with a shift of a few dB SPLs along the 800-960 MHz range.
- Microphone input generally produced higher interference levels than the telecoil input. But for the hearing aids with MT input also, microphone input showed up lower levels than the telecoil and MT inputs.
- Mini type hearing aids showed lowest interference levels with one exception.

Hearing aid output caused by RF interference is a function of orientation of the hearing aid in the test volume. Similar interference levels produced in 0^{0} and 180^{0} orientations may be a result of nearly similar location of the effected component of the hearing aid during RF field exposure. The same holds for 90^{0} and 270^{0} orientations also. In vertical orientation hearing aid is oriented along the electric field vector and this may be the explanation of higher interference levels observed at this orientation. Hearing aid size is

also important since size of the effective antenna that picks up the RF interference is important.

A linear relationship between the applied field strength and hearing aid output was proved. Every 1 dB increase (or decrease) in electric field level resulted in 2 dB increase (or decrease) in hearing aid output provided that hearing aid was not saturated and output was not masked by the noise. Finding a relationship between the applied fild level and hearing aid output is a useful tool in predicting, or interpolating in a more scientific sense. the interference levels for the field levels that are not tested. For instance, we can easily find the response of hearing aids to 3 V/m unmodulated carrier field level which is stipulated in draft IEC standard. When we make this interpolation, we see that, among 16 hearing aids tested, 6 of them showed susceptibility to electromagnetic fields more than the acceptance level suggested (55 dB SPL) in at least one orientation.

Increasing the modulation depth of the carrier electromagnetic signal resulted in increase in interference level in a logarithmic manner. Since we make a logarithmic transformation for hearing aid output when calculating dB SPL levels, we can conclude that there is a linear relationship between the amplifier output of the hearing aid and the modulation depth of the RF signal. This is well documented in Appendix F.

Changing the modulation frequency from 1 kHz to other frequencies (2-6 kHz) results in a change in hearing aid output at microphone position proportional to respective hearing aid gain values at those frequencies. To state it clearly, HA 3 has its highest gain at 1 kHz with decreasing values as we go along other frequencies (2 to 6 kHz) and the interference levels produced also decreases as we increase the modulation frequency. However, this does not hold at telecoil position since frequency response ar this position may be different.

Necessity for using the same tube size both in the frequency response measurements and immunity tests are also illustrated.

As mentioned in Section 5.1, there were other objective tests performed in different countries. EHIMA study (Denmark) was performed in a radio anechoic chamber with a pulse modulation. TAL study (Australia) was performed in a waveguide built specially for this application using 8 hearing aids only one in common. PTB study (Germany) was conducted in a GTEM cell using 10 BTE and 10 ITE hearing aids but the types of the hearing aids tested was not mentioned in their report. Since none of these studies were conducted with all the same equipment, methodology and hearing aids as those in this

study, we can not make a one-to-one comparison. But general ideas derived can be compared. For example, quadratical increase of hearing aid output with increase in field level is documented both in EHIMA and TAL study. PTB study resulted in output related interference levels up to 121 dB for 3 V/m test level. For this level, we have observed maximum 127 dB SPL output related interference levels.

These were the results of the tests performed. But many others were could not be performed because of lack of time for testing and limited domination on hearing aids. Since the hearing aids were lent for a short period of time, only standard tests could be carried out most of the case. However, we can prepare a strategy for future studies by mentioning here the tests that we would like to perform.

First of all,.we have only tested BTE hearing aids. This was partly because we could not find a way to measure the electroacoustic characteristics of this kind of hearing aids. The 2-cc coupler used for BTE is not the same as the one used for ITE. So other types of hearing aids, ITE to Body Worn, need to be tested for immunity also.

Second additional test recommended for future studies is trying the 1.4-2.0 GHz range also. IEC draft standard stipulates tests on this range with a test level of 2 V/m. The signal generator, amplifier and directional coupler used in testing had an upper level of 1 GHz so it could not be used for this application. However, it is clear using another signal generator satisfying this range is the way to solution.

Thirdly to mention, tests were performed only with 80 per cent AM modulation of the carrier frequency since the draft standard requires this modulation and its reciprocity with the pulse modulation is well-documented (see Appendix G). However, pulse modulation testing with 1:8 duty cycle and other duty cycles would still be meaningful. For instance, testing for 1:24 duty cycle would give us an idea about the interference resulted from DECT (Digital European Cordless Telephone) System.

An important point of consideration is that the 3 V/m test level in IEC standard is for "bystander" situation or Class I. This test level corresponds to a user at about 1 m away form a digital phone user. Class II, or "user" situation, however, corresponds to the case where the hearing aid user is expected to use the digital mobile phone himself on the same ear. While bystander situation requires 3 V/m test level in 800-960 MHz range and 2 V/m in 1.4-2.0 GHz range, there is not yet a test level specified for user situation because of lack of suffiecient data on near field emissions of digital mobile phones. However, as mentioned before, field levels up to 250 V/m can be created near the antenna of the phone.

For a hearing aid to provide Class I requirements, it must be immune for 100 V/m test level at least. We can interpolate the response of hearing aids for this level from data obtained for lower test levels. For instance, 100 V/m test level corresponds to 40 dB re 1V/m and interpolating data from 3 V/m (9.54 dB re 1V/m) implies an increase in interference level about 61 dB SPL. When we look at Table 6.1 and Table 6.2, we see that only 9 orientations of 4 hearing aids satisfy this condition. No hearing aid is immune to 100 V/m level at all its orientations.

Last, but by no means least, subjective tests on hearing aids users must also be performed since the output of the interaction directly affect them and users may react to interference in different ways. While 60 dB SPL is an important nuisance level for a person with mild hearing loss, it may not be disturbing for a person with severe or profound hearing loss. However, the practicability of subjective tests must be discussed because subjective tests require a diffrent arrangement of the test equipment and the facility for this test must be specially designed to satisfy some conditions.

7. CONCLUSION

Electromagnetic interference (EMI) appears in electronic systems as an unwanted response or malfunctioning because of uncontrolled coupling between them. Electromagnetic compatibility (EMC), on the other hand, is the proper operation of a system in its intended electromagnetic environment. These two concepts, EMI and EMC, cover all electronic instruments and medical devices are no exception.

In order to solve problems associated with interference, coupling mechanisms and vulnerability of a system to interference should be understood clearly. In this thesis, a typical interference problem is investigated. Physical measurements were performed to study the interaction between hearing aids and digital mobile phones (also referred to as cellular phones).

Although digital mobile phones were introduced to public use very recenty, they gained prevalence increasingly being the latest improvement in the telecommunications technology. Hearing aids, on the other hand, are used by people with hearing impairment in order to keep them communicating with the society. Since the modulation technologies used in digital mobile phones (TDMA or CDMA) code the data in an audible rate, the radiation from these devices are detected by hearing aids nearby and amplified creating a disturbing buzzing sound in the output.

Understanding the physical basis of this interaction lies in performing physical tests on these devices. Every test, of course, needs a test methodology. For this purpose, a PC-controlled test setup was prepared. Setup consisted of devices that generate electromagnetic fields and devices that measure the acoustic output from a hearing aid. An automated test methodology was developed to carry out immunity tests on hearing aids based on international standardization efforts in this area (IEC 118-13 draft standard).

GSM modulation consists of 100 per cent amplitude modulated radio frequency envelope at a repetition rate of 217 Hz. Since this scheme could not be generated using current means, 80 per cent AM modulation of the carrier frequency at 1 kHz is preferred. This 80 per cent 1 kHz scheme is a universal modulation accepted in many standards. As a

further step to facilitate the test, response of the hearing aid only at 1 kHz was point of interest. This approach opened a way to develop a usable performance criterion, IRIL (input related interference level). IRIL is calculated by subtracting the gain of hearing aid from output interference levels. Standard test strategy required an input related interference level of 55 dB SPL for 3 V/m unmodulated test level of the carrier frequency.

16 hearing aids covering 7 different brands which are widely used in Turkey were tested for immunity at 6.15 V/m test level. All of the devices produced acoustic output to some degree when they were exposed to electromagnetic fields with modulated frequencies. Interference level depended on many parameters like the orientation of the hearing aid in the test field, input of the hearing aid and the test field level.

Particularly, a 1:2 dB ratio between the electric field strength and hearing aid interference level has been proved. In other words, whenever we increase field strength in 1 dB, hearing output increases in 2 dB. However, this relationship will hold true for a field strength range where the interference signal is above the noise floor of the hearing aid and does not saturate the hearing aid.

The information given up to this point is related to the testing of the hearing aids for interference from digital mobile phones. We must also say a few words about the avoidance of the interference problem. We are now sure that radiated energy from the antenna of a transmitting digital mobile phone couples to circuitry of hearing aids and causes disturbance as a result of its amplification. Thus, reduction of the size of the effective "antenna" in the hearing aid (by new design techniques) that responds to the 900 MHz radiation can help us. Electrostatic shielding of the hearing aid may also be a solution, but it is said to increase interference in some instances [30].

Use of shunt capacitors may be another form of solution. Ravn [31] reports improvement of hearing aid immunity to interference by only changing the microphone in the hearing aid. New microphone shows the same acoustical characteristics as the standard microphone, and has the same physical dimensions, but a small decoupling capacitor has been integrated in the microphone shell to reduce RF interference. Improvements provided can be proved by modifying hearing aid of one type and keeping the second of the same kind unchanged. A comparison of two can be a means to evaluate the modification.

Modifications to existing hearing aids are not practical. Design modification to existing hearing aids in production is likely to require extensive work comparable to designing a completely new hearing aid.

Some modifications on cellular phone technology can also be discussed. Since the interaction is an inevitabe result of the transmission characteristics of the telephones, shielding the antenna i.e. suppressing the source can not be applicable. However, interference level produced depends on the modulation scheme used. Oklahoma study on hearing aid users yielded that anolog cellular phones did not produce any interference. Among the digital cellular phone technologies, IS-95 (North American Digital Cellular Phone) which uses CDMA as multiple access method resulted in lower interference accross all measures. CDMA (code division multiple access) is a digital technology that unlike TDMA (time division multiple access) employed in GSM phones, uses a continous-wave rather than a pulsing form of radiation [32].

Manufacturers of PCS (personal communication systems) devices may be required to offer models in each price range that include a separate handset. Separating acoustic components (i.e. microphone and receiver) of the phone would allow hearing aid wearers to keep enough distance between their hearing aid and the interference-generating part of the PCS so that they could use the device without being bothered by interference [33].

Since dimensions of the interference can not be outlined clearly for all cases, some sort of interference is likely to occur although precautions listed above are taken. Therefore, users of hearing aids should be made aware of the possibility of the interference so they can recognize it. The amount of immunity should be explained and demonstrated to the user before purchase of a new hearing aid or a mobile telephone. This should be done in both a noisy and a quiet environment, with the mobile telephone or hearing aid that the user proposes to use.

Users of mobile telephones should be aware of the potential for interference to hearing aids (and other potentially susceptible equipment) currently being used in the community, and what they can do to reduce any evident annoyance, e.g. by moving away from hearing aid users.

APPENDIX A

MEDICAL DEVICES AND ELECTROMAGNETIC INTERFERENCE

Electromagnetic interference in electronic devices can cause problems in nuisance level, but when it occurs in life-supporting electronic devices it may have further fatal consequences. Most medical devices are either life-supporting or have vital diagnostic importance. Failure or false reading of these devices must be dealt with care. This chapter covers the medical devices and interference problems that may likely occur in them.

A.1 General Characteristics of Medical Devices

A.1.1 Overview

The universe of medical devices encompasses some 6000 distinct types or generic entities and an estimated 750 000 or more brands, models, and sizes. They range from simple disposable devices, such as tongue depressors and gauze pads, to complex systems, such as computed tomography scanners or surgical lasers. Approximately 700 are implanted products, over 1500 are capital equipment with a unit value exceeding 500 USD, and approximately 200 are specialized types of surgical instruments. This disparate collection of entities produces by more than 10 000 manufacturers worldwide in many thousands of manufacturing locations.

The vast majority of medical device manufacturing firms are very specialized and quite small and fewer than 50 employees. There are relatively few large national or multinational manufacturers with either highly specialized or very diverse and extensive product lines. Several huge international firms produce and distribute comprehensive lists of devices and supplies for hospitals and other health care providers. Some firms specialize in catalog sales of medical equipment directly to consumers. Others, very small ones, fabricate and fit custom-made devices to patients upon a physician's prescription. In

addition to direct sales by manufacturers and their field sales forces, there are tens of thousands of importers, distributors, and dealers that sell medical devices.

Medical devices are defined broadly as devices, apparatus, or systems used for the prevention, diagnosis, or treatment of disease in humans, that do not normally enter metabolic pathways. While the qualification appears to distinguish devices from drugs, the real world does not conform to such semantic precision.

A.1.2 Classification

Despite the lack of semantic exactness, medical devices do fall into several commonsense classes that are helpful in thinking about this highly diverse collection of entities. For example:

1. implanted devices versus non-implanted devices;
2. single-use (disposable) devices versus non-disposable devices;
3. diagnostic devices versus therapeutic devices;
4. energy-emitting devices versus non-energy-emitting devices;
5. life-support devices versus non-life-supporting devices.

Such groupings are helpful to understanding broad similarities and distinctions between entities and the general risks associated with them. Implanted devices, for example, may in turn be temporary (a surgical drain) or permanent (a hip joint). But all implants tend to share two common risks, infection and tissue reaction.

Energy-emitting devices may emit ionizing radiation (a diagnostic X-ray machine. CT scanner, or cobalt therapy unit) or may emit non-ionizing radiation or energy. Non-ionizing forms are divided into:

1. electrical energy (defibrillator, electroconvulsive therapy unit, neuromuscular stimulator);
2. high-frequency electricity (electrosurgical unit);
3. microwave radiation (diathermy machine);
4. thermal radiation (infant incubator, heating pad);
5. ultrasonic radiation (fetal monitor, blood flow detector, imaging system); and
6. visible light (phototherapy unit, laser).

Differentiating between energy- and non-energy-emitting devices and the types of energy emitted is useful because there are special risks and safe guards associated with each type of energy.

While there are obviously many ways to group or classify devices, in the ultimate analysis, medical device designs or problems generally involve a very specific brand and model of device with highly specific performance and safety characteristics

A.1.3 Use of Medical Devices

The environment in which medical devices are used and the variety of people who use them are highly varied. Use environments range from hospitals, freestanding clinics and centers, and doctors' offices to ambulances, accident sites, ships, and aircraft. They include homes, schools, and the workplace, as well as remote or mobile clinics. The use environment may affect the proper function of devices not designed specifically to operate in that environment (e.g. exhaled patient breaths may condense and freeze in resuscitator valves in cold climates).

Medical device users range from family physicians, physician specialists, pharmacists, nurses, doctors' assistants, technologists, technicians, and nurse's aids to patients and their families, police, paramedics, ski patrols, army medics, and navy corpsmen. They include adults, children, and bystanders. Some patients or family members become remarkably knowledgeable and proficient about medical devices, despite a lack of formal medical or engineering training, and take an extremely active role in their own care or that of family members. Others lack the motivation or competence to do so effectively.

Patients receive the benefits and, on occasion, experience the adverse effects associated with medical devices [33].

A.2 EMI in Medical Electronic Devices

Problems may occur when radiated or conducted electromagnetic energy interacts with the sensitive electronics incorporated into many medical devices. Over the years, many incidents of suspected electromagnetic interference with medical devices have been

documented. An electric powered wheelchair suddenly veering off course, an apnea monitor failing to alarm and a ventilator suddenly changing its breath rate because of electromagnetic interference (EMI) are a few examples. EMI can be a serious problem for any electronic device, but with medical devices it may have life-threatening consequences. The continued occurrence of disruption due to conducted and radiated EMI, power-line disturbances, and electrostatic discharge (ESD) underscores the need for increased attention to medical device electromagnetic compatibility (EMC) by users, manufacturers, and standards organizations.

As the society seeks new technology, medical devices can usually be found on the forefront. There is an ever-increasing use of electronics and microprocessors in devices of all kinds from relatively simple devices like electrical nerve stimulators to the more recent advances in imaging such as magnetic resonance imaging (MRI). In the medical industry there is a tendency toward more automation in devices to monitor patients and help perform diagnoses. Microminiaturization has revolutionized the medical device industry; smaller devices require less power and can perform more functions.

At the same time, there is a proliferation of new communications technology, personal communications systems, cellular telephones, and wireless computer links, to name a few. With these advances are coming some unforeseen problems: the interactions between the products emitting the EM energy and sensitive medical devices. Even the devices themselves can emit EM energy which can react with other devices or products.

The key to addressing EMI in medical devices is the recognition that it involves not only the device itself but also the environment in which it is used, and anything that may come into that environment. More than anything else, the concern with EMI must be viewed as a systems problem requiring a systems approach [34].

Medical EMC is difficult because it deals with all the electromagnetic interference effects on digital and analog circuits that other industries must deal with. In addition, it must consider unique radiated electromagnetic interference effects -both impulsive and continuous- caused by unshielded High Frequency, near and far field RF sources. Furthermore, it must consider unique conducted electromagnetic interference effects -both impulsive and continuous- caused by almost filtered Low to very High Frequency conductive sources. And finally, it must satisfy unique equipment and facility safety

grounding rules that mitigate against good EMC grounding practice. All of these unshielded, unfiltered, uniquely grounded devices, enclosures and facilities are found only in the medical industry.

A.2.1 Importance of Medical Device EMI Problem

The following considerations motivates the emphasis on and effort toward assuring electromagnetic compatibility of electronic medical devices:

- EMI-related performance degradation in electronic medical devices has resulted in deaths, serious injuries, and the administration of inappropriate and possibly life-threatening treatment.
- Various electronic medical devices are often used in close proximity to one another, and electromagnetic emissions from one device may cause performance degradation in another.
- The ambient electromagnetic environment continues to intensify (e.g., with cellular and portable phones, wireless modems, mobile communications, paging systems, and telemetry).
- Medical telemetry devices share communication frequencies with commercial and industrial communications equipment, and interference has been reported during potentially catastrophic physiological events.
- Performance degradation of modern microprocessor-based electronic systems as a result of transient interference is likely to result in the loss of stored data and to require operator intervention or system reset.
- More homes and hospitals are now located near transmitters (and vice versa).
- More medical devices are today being used in the home, where trained health-care providers may not be present to intervene in case of device performance degradation.
- Device users are generally not aware of the field strengths, frequency distribution, or temporal characteristics of their electromagnetic environment.
- Caution statements in a device's operator's manual, such as the admonition to "avoid electromagnetic interference," usually provide little guidance in how to

recognize and mitigate EMI. (And even if further guidance were provided, the device and the manual are in any case seldom in the same place at the same time.)

- When experiencing medical device performance degradation, users may not suspect EMI as a possible cause; EMI problems are thus likely to be underreported relative to other medical-device failures.
- Isolated incidents of interference may be difficult or even impossible to trace or reproduce.
- Users and manufacturers often disagree about who is responsible for solving EMI problems.
- While some manufacturers of medical devices test their products to EMC standards, either voluntarily or at the request of regulatory authorities, many more do not. Much of the medical equipment that is presently in use has not been tested for EMC.
- Many of the medical-device EMC problems reported so far might have been prevented had existing design techniques, standards, and test methods been employed to control emissions and ensure adequate immunity.

A.2.2 Sources and Victims of EMI in Medical Environment

In medical electronics there is a diversity of high amplitude sources of wide frequency range in proximity to sensitive receiving devices. This situation can be contrasted with most commercial or residential electronics, a personal computer for example, where there are no internal devices that pose a major self compatibility threat and external threats are usually not severe enough to cause a problem.

A.2.2.1 High Energy Sources

There are many high energy sources found in a medical environment. The most famous one is the electrosurgical unit (ESU), which generates fierce broad band noise from about 100 kHz to as high as 100 MHz. Typical ESUs generate a wave in the 500 kHz to 1 MHz range, but this wave is modulated at a low frequency for certain operating modes-

thus the broadband noise. The principle interference problems are currents conducted out the power and magnetic fields. Low frequency magnetic fields are always difficult to shield, and require permeable materials. Cathode Ray Tube (CRT) monitors are the major. but not the only, victim of these sources. Measured electric field strengths can approach 100 V/m close to the source, enough to upset most equipment [35].

Another popular hospital emission culprit, diatehermy, has frequency components in the 15 to 30 MHz range. Interference control in this frequency range is relatively easy, as it is high enough that filtering and shielding is effective and inexpensive, while being low enough that shield gasketing is probably not needed. Field strengths up to 0.5 V/m are measured for this equipment.

Magnetic resonance imaging (MRI) generates a very high magnetic field in the 50-100 MHz range. In this frequency range effective shielding is required with careful control on openings. Radiology is characterized by high voltage power supplies, often using thyristers, a copious source of power line interference.

Light is not generally a source of interference to electronic equipment, but some significant interference sources are used in the process of powering a laser. Unfortunately, medical device manufacturers usually buy lasers, and have but little control over the interference the product generates. The only way is to cope with the interference.

Magnetic field associated with a pulsed laser is the greatest threat in lasers. The sudden discharge may produce a 100 A pulse with 100 μs rise time. This gives an equivalent frequency of about 3 kHz, and current change (*di/dt*) of millions of amps per second.

Some continuous lasers use one of the Industrial, Scientific, Medical (ISM) frequencies for modulation. Governmental agencies worldwide allows unlimited radiation in the ISM frequencies. As a practical matter laser manufacturers need to limit the radiated energy, or nearby electronics would not work at all. But interference control is far from being perfect, leaving plenty to impact sensitive analog circuits.

All of the above devices draw copious amounts of power while producing significant amounts interference in the process. Adequate suppression requires high quality line filters, which are large and expensive.

Emergency generators are found in most of the hospitals. While not normally a source of interference, they do need to be tested periodically. Depending on the design of the power system, cutting in these generators can cause a significant power dislocation, of a type not commonly found elsewhere. Modern Uninterruptable Power Supplies (UPS) are capable of transitioning to and from emergency power with barely a ripple in the voltage, but standby engine generator sets commonly found in a hospital will not be on-line - they are started up when power fails, and are not expected to provide uninterrupted power.

A defibrillator generates a substantial transient, with a pulse less than 10 ms, a peak voltage of several thousand volts, and a current in the ampere range. Any equipment that may be connected to the patient at this tie must withstand this transient. Of course, any equipment operating nearby may also be affected.

A.2.2.2 Radio Frequency Sources in Medical Environment

Radio sources abound in a medical environment. The obvious ones are television and radio, some of which are inevitably close to some equipment. But these are not primary sources. Close in are land mobile units, with a base unit on top of the hospital and mobile units in the emergency wing of the hospital [36]. Handheld radios, such as used by maintanence personnel, and cellular phones are much more of a problem, as they are often in close proximity to medical equipment. [37] Patient telemetry is a lesser, but a real, threat. Awareness of this problem results in banning the use of such interfering devices in certain parts of the hospital, but this does not control the clinic, which is often in an uncontrolled facility, nor does it control the residential environment [38].

A.2.2.3 Receiving Devices

In many cases there are sensitive instruments operating along side these high energy threats. All of them can not be identified one by one but we can cite some representative cases.

ECGs, EMGs, and EEGs include low frequency, low level analog amplifiers. Typically, an ECG has a 1 mV sensitivity at a bandwidth of 50 Hz. An EMG has a 100 μV

at 3 kHz and an EEG has a 50 μV sensitivity at 100 Hz. Note that all of these have a band-pass in the power line frequency range, making filtering a difficult proposition. The ECG, while least sensitive, is often most exposed to a hostile environment - they are used everywhere in a hospital. These sensitive front ends are most sensitive to RFI [39].

Typically, ultrasound units generate high frequency (in MHz range) acoustic waves, and are looking for a very low level echo, typically in the 100 nV range. These are primarily a threat to themselves, being exposed to their own signals.

Apnea monitors are characterized by a low level signal being sensed by sensitive amplifiers. As with the ECG, they are quite sensitive to RFI, and, worst, they are usually found in an uncontrolled residential environment.

Pacemakers are obviously exposed to a completely uncontrolled environment, and, even worse, may be subjected to a defibrillator jolt. Fortunately, these devices are very compartmentalized, and are capable of being immunized from even severe threats. There can be inhibition of cardiac pacemaker function when these devices are located near digital mobile phones [40].

Increasingly found in the hospital environment, telemetry operates on either of three bands (approximately 160 MHz, 460 MHz, and 900 MHz). These are not usually threatened with radio sources, but they are threatened with loss of signal. Engineers expect to see more of these issues in the future as this technology proliferates.

Hearing aids using analogue technology are particularly susceptible to interference caused by high frequency fields that are modulated at an audible rate. These audio signals are rectified as if they are wanted signals.

A.2.3 Reported Medical Device EMI Problems

The Center for Devices and Radiological Health (CDRH) division of the Food and Drug Administration (FDA) is responsible for regulating the manufacture and sale of medical devices in the United States of America. CDRH (originally called the National Center for Devices and Radiological Health) was formed in 1982 through the merger of the Bureau of Radiological Health (BRH) and the Bureau of Medical Devices (BMD). The BMD was sufficiently concerned about medical device EMC that it developed and

circulated in 1979 a draft guideline, MDS-201-0004, specifying electromagnetic emissions and immunity limits and test methods for medical devices. Because the regulated industry was opposed to the application of a single set of limits to all medical devices, however, MDS-201-0004 was never officially adopted.

In recent years, the CDRH has renewed its efforts to control medical device EMC by enhancing its in-house testing capability, participating in the development of national and international standards, and requiring that EMC test data accompany premarket notification submissions (applications for FDA "approval") for some devices. EMC and other environmental-testing recommendations have been included in a draft guidance document for CDRH reviewers of premarket notification submissions for respiratory devices; this document has been made available to the medical-device industry, and similar documents are under development for other devices.

CDRH representatives have continued to keep EMC standards committees apprised of EMI incidents involving medical devices. While the number of EMI reports may be small relative to the number of reported problems from all causes, the steady influx of such reports and the severity of the problems they describe demonstrate that EMC design techniques, standards, and testing, as well as user awareness of EMC issues, are essential to the safety and effectiveness of electronic medical devices

Manufacturers of medical devices are required to report to the FDA any incident in which one of their marketed devices may have caused or contributed to a death or serious injury. Under recently enacted regulations, user facilities must also report such events. Problem reports submitted to the FDA affect the agency's priorities, though little significance is assigned to the absolute number of reports of any particular type, as both overreporting and underreporting are common. In addition, many reported EMC problems (including several of those listed here) are classified according to the nature of the device malfunction, rather than its cause. While it is probable that many nuisance-level EMC problems are never reported by users, increased awareness of the existence and hazards of EMI has contributed to the steady influx of problem reports from both users and manufacturers.

The medical-device EMI incidents listed below came to the attention of CDRH staff between 1979 and 1993, through FDA reporting programs, FDA regulatory activity,

professional contacts, and the public press. Included here are most of the incidents that were classified as EMI in the CDRH databases and that appeared actually to be attributable to EMI. They are categorized according to the first of the possible coupling mechanisms mentioned in the report; where no coupling mechanism is specified, the authorities have assigned a category based on an educated guess. In several instances the interference occurred despite explicit user warnings in the manufacturer's labeling.

A.2.3.1 Conducted Interference, Intra-Patient Coupling, and Power-Line Disturbances

- A blood-cell counter displayed high, fluctuating background levels for both white and red blood counts due to an AC junction box or a hospital paging system (July 1979).

- EMI interrupted functions, prevented heating, and set off alarms in blood warmers. Reset was required to restore normal operation (March 1981).

- "Pseudoarrhythmia" was caused in a cardiac monitor by an infusion controller (July 1979 and September 1982).

- Defibrillators picked up a signal resembling a QRS from an isolation transformer, particularly when the patient was dead (three occasions July 1980).

- Artifact appeared on the screens of new cardiac monitors thanks to an infusion controller (two occasions in January 1982).

- Transcutaneous oxygen monitors caused 60-Hz interference on cardiac monitors unless the former were used on battery power (November 1982).

- Severe interference was observed in the heart rate and graphs of an ICU patient monitor when a blood-pressure monitor was in use. The interference disappeared when the blood-pressure monitor was turned off (April 1983).

- ECG monitors and TV systems in surgery experienced interference traceable to a blood-pressure monitor (August 1983).

- In a survey conducted by the American Association for Medical Systems and Informatics (AAMSI), EMI was found to be the most common cause of problems in computerized medical devices, particularly with regard to poor AC power-line quality.

- During an electrical storm, a hospital's power was interrupted three times. A microprocessor-controlled ventilator returned to "Normal Operation" but was not ventilating. The problem could not be duplicated (May 1986).

- A ventilator went into "Safety Valve Open" mode and displayed an error code during a chest X ray (July 1986).

- In two instances, electrical noise prevented an ultraviolet phototherapy unit from turning off upon reaching the prescribed dose. The patients were overexposed, causing severe skin irritation (January 1987).

- Power-line transients from a radiant warmer disrupted the operation of an infant incubator, causing the display to freeze and the temperature to be uncontrolled (FDA regulatory activity, 1987-1988).

- An ECG monitor in a defibrillator was subjected to radio-frequency interference that affected the monitor readout and caused distortion of the ECG signal (April 1988).

- An infusion device on an isolated circuit (high-source impedance) behaved erratically due to conducted EMI at 33 MHz.

- In an investigation of more than 100 locations throughout the United States, General Electric Medical Systems identified sources of power-line disturbances both internal and external to the hospital. However, most problems were found to be caused by poor-quality power supplied by the power utility.

- An intra-aortic balloon pump stopped pumping when the system printer was turned on (four cases in June 1990 and one in September 1990).

- An infusion pump caused interference with patient monitors (June 1991; August 1991; and October 1991).

- An improperly grounded video recorder caused video interference in a laparoscope system, necessitating traditional gallbladder surgery instead of the scheduled laparoscopy (two cases in November 1991).

- The primary and secondary dose counters of a radiation-therapy machine frequently reset themselves to zero, apparently due to noise spikes. In one instance, the device continued treatment after the counters had reset (January 1992).

- A new physiological monitor amplified external noise signals such as static on personnel and power-line transients (June 1992).

- Capacitive coupling through the patient between a urine-output monitor and an ECG monitor produced artifact resembling abnormal cardiac morphology on 12-lead ECGs. Patient-isolation power-supply circuits at different frequencies caused beat frequencies in the ECG, one of which appeared to be a physiological signal.

A.2.3.2 Radiated Interference

- A fetal heartbeat detector picked up radio and CB broadcasts and static instead of heartbeats (July 1980).

- Erratic blood-pressure and temperature data were displayed on a patient monitor during electrosurgery (three cases in February 1981).

- Transmissions from an amateur radio station interfered with an infant monitor, but only when the remote alarm was attached (January 1982).

- EMI from the valve motor caused malfunctioning of valve-position sensors in an infusion pump, potentially resulting either in failure to deliver fluid at the prescribed rate or in flush-back of blood into the extension tubing (two cases in August 1982).

- A pacemaker ceased functioning during an ambulance radio transmission (February 1983).

- A pacemaker programmer did not provide an EKG in the presence of a fluorescent light, did not program, and displayed a "Too Much Interference" message with auto table on and, in nuclear medicine, with the scintillation camera on (July 1984).

- A radio station played through the speaker of a vascular recorder (October 1984).

- A battery pack emitted at 160-175 MHz, causing interference with telemetry cardiac monitors (December 1985).

- The monitor on a defibrillator displayed a "Severe Interference" message during a defibrillation attempt (January 1986).

- A pacemaker programmer displayed a "Too Much Interference" message 80 to 90% of the time (February 1986).

- A microprocessor-based intensive-care ventilator ceased operating and alarmed, and microprocessor-based infusion pumps stopped working, when a portable x-ray machine was turned off in the vicinity (January 1987).

- While in use during an airplane flight, a portable ventilator operating and alarmed, and microprocessor-based infusion pumps stopped working, when a portable X-ray machine was turned off in the vicinity (January 1987).

- Patient monitoring systems comprising remote units communicating with a central station picked up interference that prevented alarms from sounding and caused settings to return to factory defaults. At least two patients died when the system failed to detect arrhythmia (June 1987).

- Neonatal monitors operating in the shallow breathing mode at high gain experienced interference when placed in close proximity to similar models of neonatal or adult monitors (August 1987).

- A ventilator suffered keyboard lockup due to interference from a guard's walkie-talkie.

- A muscle stimulator caused a chiropractic table to move, subjecting the patient on the table to an electric shock (March 1988).

- A patient wearing a transcutaneous electrical nerve stimulator that was turned off received a shock when he transmitted at 144 MHz with his hand-held transceiver.

- A pulse oximeter displayed an oxygen saturation of 100% and a pulse rate of 60 for a patient who had expired earlier that day. A telemetry transceiver that was part of the system had been placed too close to the oximeter (December 1990).

- A pacemaker returned to the STAT mode after exposure to RF from a security system (January 1991).

- A microsurgical drill began to run when an electrosurgical unit was activated.

- Because they can interfere with the operation of incubators, infusion pumps and controllers, dialysis equipment, and defibrillators, cellular telephones have been banned from some hospitals in Europe.

- Disruptions in the operation of a particular model of ventilator resulted in the cessation of ventilation, the loss of monitoring functions, and the display of "Error" or other, unintelligible messages. The disruptions were caused by "extreme events" of EMI or power-line disturbances, perhaps attributable to the use of electrosurgical, laser, x-ray, or other equipment (November 1991).

- Interference from the power-line frequency interrupted the ECG waveform, which went off the screen. The patient subsequently went into tachycardia (December 1991).

- Paramedics attempting to monitor a patient could not sense the heart rhythm due to excessive artifact on the CRT of the monitor. The patient was not resuscitated (March 1992).

- The heating element of a radiant warmer was turned on and off by movement of people in the vicinity.

- The readings on all invasive blood-pressure monitors in an ICU/CCU jumped 3 to 10 mm Hg when a 150W paging transmitter was activated on the hospital roof.

- The displays of a telemetry patient monitor would "flat-line" when a paging company transmitted digital control information to its remote sites.

- A hearing aid was adversely affected by high-frequency security systems (May 1992).

- During a laparoscopic cholecystectomy, video equipment malfunctioned, resulting in a picture that was distorted and had lines. The surgeon was unable to see what he was doing well enough to complete the surgery laparoscopically, so an open cholecystectomy had to be performed. An electrosurgery unit was in use at the time (May 1992).

- RF transmission from either an internal (e.g., a hand-held two-way radio in the hospital) or an external source caused a ventilator to activate alarms. The hospital was able to duplicate the event (July 1992).

- An external pacemaker fired inappropriately when a UHF telemetry-monitor transmitter -whose power was nominally 2mW- touched the pacemaker leads. The manufacturer of the telemetry monitor agreed to add a warning label cautioning against such placement (July 1992).

- An infusion pump changed its rate when a cellular phone was placed on the instrument stand (August 1992).

- When certain types of cauteries were used in conjunction with a camera control unit, the picture became distorted (two cases in August 1992).

- An investigational implantable defibrillator transmitted inappropriate shocks when the user operated a radio-controlled model car (September 1992).

- A pacemaker programmer occasionally powered down following an external transthoracic shock (October 1992).

- The operation and readouts of ventilators were affected by the keying of two-way hand-held FM radios both in the same room and in the next room. The low-minute-volume alarm would sound, the analog display would show an exhaled minute volume of zero, and the digital display would indicate negative values of exhaled minute volume (November 1992).

- Respiratory heater/humidifiers alarmed, displayed "Service" messages, and exhibited disruption of readouts when two-way hand-held FM radios were keyed within the same room (November 1992).

- Two ventilators that were within 20 feet of each other alarmed simultaneously and continued to alarm frequently for the rest of the day. After it was discovered that the power company was using walkie-talkies in the area, the hospital staff was able to duplicate the problem with walkie-talkies in the hospital (November 1992).

- 4W walkie-talkies used for communication inside a hospital interfered with the operation of high-frequency ventilators within a distance of 10 feet, causing the bar-graph display of piston location and amplitude to be driven out of the display window and the pressure readout to decrease enough to trip low-pressure alarms, which in turn made the piston stop. The manufacturer found that replacing the plastic cover of the electronic control assembly with a metal one would result in only a -2 cm error in the displayed mean pressure and no error at all in the actual delivered mean pressure (December 1992).

- An amateur radio operator with an implanted pacemaker fainted several times after installing a new one-kilowatt linear amplifier. The radio operator returned to using 100 watts and had no further episodes.

- The magnetrons of some linear accelerators interfered with the electrometer of a beam-characterization device used in radiation-treatment planning, affecting electrometer operation and causing distorted readings (December 1992).

- A pacemaker patient was scanned several times with a metal detector prior to entering a courtroom. Thirty seconds later, the patient coded. Paramedics found the patient in ventricular fibrillation (March 1993).

- A blood warmer indicated an overtemperature alarm and shut down when an electrosurgical unit a few feet away was activated in the "Cut" or "Coagulate" mode (March 1993).

- After a powered wheelchair moved spontaneously, the user noticed a taxi nearby. The unintended motion was eventually attributed to the taxi's radio transmissions.

- Telemetry monitors in a hospital sounded excessive false alarms. The problem was traced to arcing on an elevator wire that ran the full height of the elevator shaft.

- Portable (cellular) phones using the new European GSM standard are expected to produce a 200-Hz tone in hearing aids up to 30 meters away. At a distance of 1.5 m, the audio output resulting from the interference could be as high as 130 dBA.

- A signal-averaging electrocardiographic analyzer that worked properly in other areas of the hospital would not work in the intensive-care unit.

- Radio-frequency interference from a CT system caused artifact in an ultrasound scan, resulting in misdiagnosis (M383011, April 1993).

- A 10-year-old external-demand pacemaker emitted pace pulses regardless of intrinsic cardiac activity when the patient was inside an ambulance during ambulance radio transmissions or within 10 feet of transmitting walkie-talkies.

- A transport incubator indicated a system failure and the heater relay clicked off when inside an ambulance during ambulance radio transmissions.

- A user of a powered wheelchair had moved to a new home and was showing his friends, also in powered wheelchairs, around the neighborhood. While moving up a hill, the user heard clicking noises and took his hand off the joystick. The wheelchair made a sudden about-face and headed downhill at high speed, refusing to respond to further movement of the joystick. After continuing down the hill for about yards, the chair veered left and went over a cliff. The user suffered a broken hip and several other injuries. His friends' wheelchairs had been made by a different manufacturer and were not affected. This incident took place several miles away from a radio station and only three blocks from a major interstate highway.

Devices for audio testing (audiometers) were found to be highly susceptible to EMI and may need to be used in a shielded room.

A.2.3.3 Magnetic Interference

- The respiration-rate controller of a respirator ceased to function when an oxygen analyzer containing a large magnet was placed on top of it (January 1981).

- A battery charger in a modular respiration monitor cycled between fast and trickle-charge modes at a 1-Hz rate because the battery was old and had a high self-discharge rate. The 1-Hz signal was magnetically coupled into the respiration-detection circuitry. The alarm did not sound when the infant being monitored died (December 1988).

- Discharging one defibrillator caused another that was directly adjacent to it (within three inches) to power on. The proximity and alignment of the defibrillators caused coupling of fields from the waveshaping inductor (December 1990).

- A pacemaker went into an asynchronous mode when the patient's "bed phone" was placed on her shoulder (April 1991).

- Subway trains and garbage trucks caused fluctuations in the DC magnetic field of an MRI machine. Magnetic shielding was installed to correct the problem.

- A combination pulse oximeter and capnograph that used a switching power supply with a frequency of 62.5 kHz interfered with the impedance measurement circuit of respiration (apnea) monitors, resulting in false readings. The oximeter's power supply frequency was close to that used to measure transthoracic impedance in respiration monitors made by three different manufacturers. The manufacturer of the pulse oximeter has issued a safety alert and will change the power-supply frequency of the oximeters to prevent a recurrence of the problem (April 1993).

A.2.3.4 Electrostatic Discharge

- Loose-lead alarms failed to sound and respiration sensitivity was reduced in apnea monitors due to component damage from ESD (February 1984).

- The respiratory or heart-rate alarms of apnea monitors failed to sound due to electrostatic discharges to the screws on the setting knobs (February 1985).

- Electrostatic interference affected the normal operation of the synchronization unit of a ventilator in a European hospital. Customers were warned not to use the synchronization unit (April 1986).

- ESD caused "System Check" alarms or failure of infusion pumps (May 1986).

- Ventilators stopped cycling while being used on patients in a hospital. The ventilators were found to be susceptible to ESD (December 1986).

- Infusion pumps shut down because of ESD, sometimes without first activating an alarm (August 1990).

- In radiation-therapy devices, ESD caused powering on of the source, blanking of the display, unintended gantry movement, and timer failures that could have resulted in patient overdose. The device had to be switched off to recover (one case in January 1990; six cases in July 1990). In one instance, a discharge from an operator to the timer of a radiation-therapy system caused the timer's display to blank just as the treatment began; the treatment was terminated by opening the door of the treatment room (October 1991).

- ESD from an operator to the membrane switch of an enteral feeding pump resulted in a continuous alarm and destructive failure of the firmware EPROM (September 1991).

- ESD affected infant radiant warmers, causing the heater to turn on or off, the alarm to fail, and the display to become blank or corrupted (four cases in January 1992).

A.2.3.5 Failure to Observe Manufacturer's Warnings

- An ECG monitor in a defibrillator was subjected to interference when an emergency crew transmitted with an antenna that was inside the same station wagon as the defibrillator and the patient. No EMI warnings were provided in the defibrillator labeling (FDA regulatory activity, April 1988).

- The pacing mode of a pacemaker changed when the patient welded or operated his farm combine (November 1990).

- An external defibrillator/pacemaker stopped pacing when an ambulance attendant used a hand-held transmitter too close to the patient. The patient could not be resuscitated (March 1991 and April 1991).

- A patient received burns from a pulse-oximetry probe used during MRI (January 1991; February 1991; and April 1991).

- Telemetry dropout from the patient's being out of range coincided with ventricular standstill (October 1991).

- Implanted defibrillators were deactivated by magnetic fields when:

  * patients came into contact with stereo speakers (February 1990, and April 1992);

  * patients played bingo with a magnetic wand (July 1990 and November 1992);

  * a patient was in a junkyard near a magnetic car carrier (August 1990);

  * a patient had a large magnet on his workbench (December 1991);

  * a patient carried a magnet in her purse (January 1992);

  * a patient was exposed to magnetic resonance imaging (February 1992);

  * a patient came into contact with a magnet (July 1992); and

  * a patient worked on a farm near high-voltage fences (October 1992).

- One patient's defibrillator was deactivated on two separate occasions. The second incident (March 1993) was classified as electromagnetic interference, though the first (December 1992) was categorized as electrical failure.

- New technicians failed to follow the proper procedure for shut-down of a portable X-ray machine, and when the power plug was pulled from the wall before the charge was bled off the x-ray machine's capacitor, the resulting EMI/RFI emissions caused a ventilator to go into "inop" mode without an audible alarm. The emissions caused the ventilator's audible-alarm module to fail (August 1992).

- An external pacemaker operated asynchronously (undersensing) when it was in physical contact with a telemetry transmitter (October 1992).

- Finally, there have been more than 100 reports of no output from pacemakers following electrosurgery. While the problem here is actually electrical overstress, the sheer number of reports makes this failure worthy of mention [41].

APPENDIX B

B. REGULATIONS AND STANDARDS CONCERNING ELECTROMAGNETIC COMPATIBILITY AND MEDICAL DEVICES

Electromagnetic Compatibility (EMC) can be summarised as the ability of electrical/electronic equipments to operate without any one piece of equipment causing malfunction in any other. In addition, those involved in EMC must ensure satisfactory operation of a diversity of equipment ranging from safety of life systems, such as aeronautical navigational aids, through to broadcast equipment and the avoidance of annoyance caused by continuous interference to television reception. This is where first standardisation efforts began.

The use of radio communications equipment has drawn attention to the problems caused by radio interference from as early as 1933, when interested international organisations held a special meeting in Paris. As a result of this meeting, and to formulate internationally agreed recommendations on radio interference, the Comite International Special des Perturbations Radioelectriques (CISPR) held its first meeting in 1934. The work of CISPR resulted in recommendations, reports, specifications and other documents mainly related to radio interference. This reflected the needs at that time.

Within the European countries, national regulations based on the work of CISPR were used to control radio interference from a wide range of equipment from industrial equipment and motor vehicles with ignition systems, to domestic appliances. Often, the regulations included the limits and methods of measurement, and some countries implemented type approval or licensing arrangements.

Over the years governments have introduced EMC regulations as the need has arisen. Besides military standards established for military purposes, commercial regulations involving specific standards in different countries have been taken into force independent of each other. Though there was a international standardization effort in this field, every country had its own regulations and standards.

In some cases, where product was under mandatory control of electrical safety, the authorities were able to carry out radio interference tests or require such tests through their national authorities, as a prerequisite to electrical safety testing.

These different approaches to the same problems caused delay and additional costs to manufacturers, who intended to market product in a number of countries. In some cases, national differences in the test method or limits led to different technical solutions to the suppression problem, and therefore market variants, depending on the country on which the product would be sold.

In this chapter, we will mainly consider European solution i.e. the European Directives to acheive this problem. And we will learn about well-known national and international standardization efforts in the field of EMC.

B.1 European Regulations

On the 1st January 1993, the European Single Market came into being. This means that European Union became a single trading entity, a customs union with no tariff barriers. Goods imported into one Member State will be on free circulation throughout the Union without further hinderance.

The objective of creating a single common market in the European Community goes back to the Treaty of Rome, 1958. This was not achieved for years but, by means of the Single European Act in 1985 the Community Heads of Government committed themselves to achieving the Single European Market progressively by the 31st December 1992.

The Single European Market is defined as "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the Treaty of Rome" [42].

In order for this to happen it has been necessary for the Member States to undertake a major programme of technical harmonisation to ensure that products and the technical standards supporting them are acceptable throughout the Union and the European wide regulations replace widely differing national regulations which have been technical barriers to trade.

This has been brought about by the introduction of a whole family of Directives which will harmonise the regulation of many products but principally electrotechnical products, in the areas of product safety and electromagnetic compatibility.

These are the "New Approach" Directives and they differ from the traditional Directives in that they do not contain technical specifications or standards nor do they make the meeting of standards mandatory. They define the essential requirements only, together with the conformity assessment procedures that must be applied and the various routes open to the manufacturer by which he must demonstrate compliance. One of these routes is invariably the use of harmonised European standards and a whole raft of standards are being put into place to support these Directives.

Among the new approach Directives emerged so far, we will mostly be interested in the Electromagnetic Compatibility Directive and Medical Devices Directive.

B.2 European EMC Directive

The first Directives of the European Council to address the need for harmonisation applied to motor vehicles with ignition systems. These were followed by Directives on household appliances and fluorescent luminaries. These product-specific Directives related to radio interference only and included a technical annex. Subsequent amendments replaced the technical annex by a harmonised standard.

A proposal was made in 1974 for a Directive on the radio interference characteristics of industrial, scientific and medical equipment, but this project was never completed.

By 1976, there were Directives which harmonised the requirements for a wide range of products which were principally domestic. Where national provisions existed concerning product not covered by the Directives, certification prior to placing product on the market was not compulsory. For most products in all countries, the manufacturer now needed only one radio interference suppression solution, and while compulsory testing and application of national marks to show conformity was permitted by the Directives, this too had ended with the amending Directive 83/447/EEC in 1983.

However, at about this time, the growth in use of electronic equipment was accelerating. In addition to natural phenomena such as solar effects, lightning and electrostatic discharge from different materials, electrical and electronic equipment itself is producing an increasingly significant contribution to the electromagnetic environment. Much of this equipment produces radiated or conducted electromagnetic interference

unintentionally, but, for some equipment, including certain medical and industrial equipment, the electromagnetic effect is necessary for the intended function.

Today, we are dependent on the proper functioning of electronic equipment in almost every walk of life and are likely to become more so. The problem this presents is that, without proper precautions and design, the more sophisticated the electronic equipment becomes, the more likely it is to cause, and be affected by, electromagnetic interference. Thus, we are now faced with two problems, the control of unwanted radiated and conducted electromagnetic interference, and the need to provide equipment with an adequate level of immunity to electromagnetic interference.

The EMC Directive published in 1989 addressed these matters through the essential requirements in Article 4, as follows:

The apparatus shall be so constructed that:

- the electromagnetic disturbance it generates does not exceed a level allowing radio and telecommunications equipment and other apparatus to operate as intended; and
- the apparatus has an adequate level of immunity to electromagnetic disturbance to enable it to operate as intended.

At the time of coming into force of 89/336/EEC, the EMC Directive on 1 January, discussion on the needs of the industry concerning a transition period was still taking place. An amending Directive 92/31/EEC published on April 1992 laid down the conditions for a transition period ending on 31 December 1995. During the transition period, numerous changes took place many of which affected the manufacturer. The most important of these were:

1. national implementation of EMC Directive;
2. implementation into the requirements of the European economic area states who are not members of EEC;
3. the development of standards;
4. the identification of competent and notified bodies;
5. the interaction with other Directives;
6. guidance form the Commission

B.2.1 Objectives and Scope of the EMC Directive

The objectives of the EMC Directive are twofold. Firstly, to support the implementation of the Single Market by removing technical barriers to trade. The other objective is to use the requirements for control of emissions and immunity to limit the pollution of electromagnetic spectrum and its affects.

The equipment within the scope of the Directive includes all electrical/electronic appliances, equipment, systems and installations which are placed on the market or brought into service within the Community. There are no exceptions. thus, included are information technology, telecommunications, radio, industrial, medical, domestic, electricity supply, motor vehicle, electric traction, maritime, scientific, aeronautical, legal metrology and military equipment, irrespective of whether the equipment is powered from the mains, from high-voltage supplies, from specialised supplies or from batteries.

All EMC phenomena are included: emissions, both radiated and conducted along cables (mains, signal or control); immunity from electromagnetic discharge; immunity from spikes, dips, outages and other distortions on the mains supply; immunity from lightning induced surges; in short, all EMC phenomena over the whole frequency range are within the scope of the Directive.

Products which fall under the scope are termed "relevant apparatus". There are exclusions and restricted applications, which are:

- all apparatus covered in some or all of its EMC aspects by other Directives like the Active Implantable Medical Devices, Medical Devices, Spark Ignition Vehicles. Telecommunications Terminal Equipment, Military Equipment, etc.
- apparatus not intended for use in the Community
- installations not intended to be placed on the market as a single unit
- components and subassemblies which do not have an intrinsic function for an end user
- spare parts
- second hand apparatus previously not taken into service in the Community.

There are, of course, some controversial points in identifying whether a product is a relevant product, i.e. it is not a component or subassembly or it will not be placed on the

market as a single unit. But Commission have agreed on some common views in order to clear away these controversies [43].

So we can see that the EMC Directive seeks to control electrical interference by setting these essential requirements and then defining the routes by which compliance the these requirements may be demonstrated. It should be clearly understood that there is no legal requirement to comply with standards. Standards are not mandatory but available as one means to demonstrate and attest compliance.

B.2.2 Attestation and Certification

Conformity of apparatus with the requirements of the Directive shall be certified by an EC declaration of conformity issued to the manufacturer or his agent established in the Community.

A statement of conformity shall accompany the apparatus. Also EC conformity mark shall be affixed to the apparatus or, where this is not possible, to the packaging instructions for use or to the guarantee certificate.

As illustrated in Figure B.1, the EC conformity mark shall consist of the letters "CE" and the figures of the year in which the mark was affixed [44].

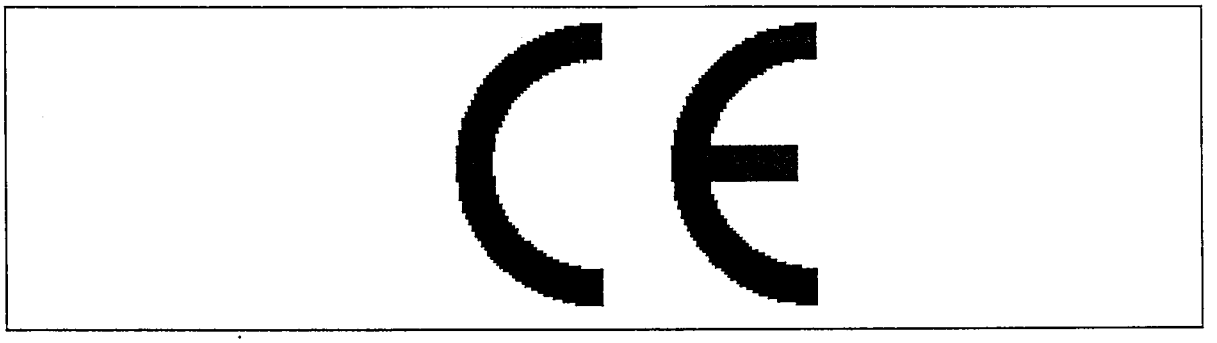


Figure B.1 CE Mark.

Where the manufacturer has not applied, or has applied only a part of the relevant standard, or where no standard exists, the holding of a "technical file" is a requirement in addition to the certification and marking requirements already mentioned.

In the case of radio communications apparatus, an "EC type examination certificate" must be obtained from an approved or so called Notified Body before the CE marking can be affixed and the declaration of conformity signed. These will be explained in detail in next section. Another thing to mention is that, manufacturers must retain the documentation for ten years.

Furthermore, it is likely that the CE mark will be relevant to more than just the EMC Directive. In this case the mark will be the manufacturer's claim that his apparatus conforms with the requirements of all the relevant Directives to which it is subject.

B.2.3 Routes to Compliance with the Directive

There are three routes to compliance allowable within the EMC Directive. The routes to compliance are shown in a flow diagram scheme in Figure B.2 and explained in detail below:

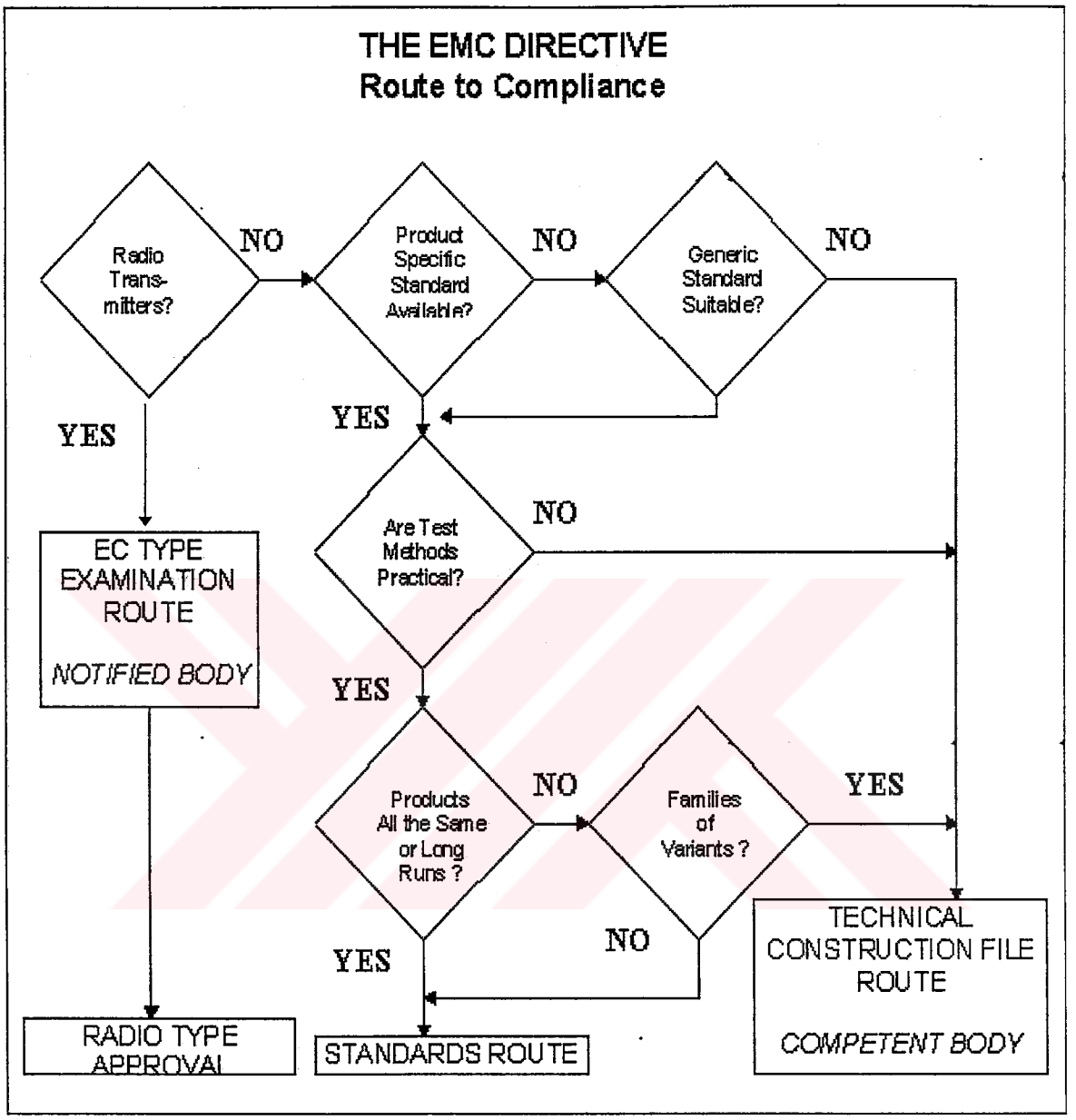


Figure B.2 Route to Compliance to EMC Directive

B.2.3.1 Standards Route

In standards route, also referred to as "self certification", apparatus is tested to the methods and limits defined in relevant harmonised European standards or norms which have been published in the Official Journal of Communities. These standards cover both emissions and immunity. Compliance with the directive is presumed if conformity to these standards can be demonstrated. As we have mentioned before, the manufacturer signs an

EU declaration of conformity. It should be emphasized that is standards have not been published in the Journal, they are not available for use and have no validity in this route.

Where it is claimed that the apparatus complies with the standards the declaration of conformity must contain:

- identification of the apparatus to which it refers
- reference to the relevant standards and, if appropriate, the class of protection under which conformity is declared, and
- identification of the signatory empowered to bind the manufacturer or his agent.

In following this route, there are a number of responsibilities of the manufacturer. Firstly the manufacturer must decide which standard and standards need to be applied to his product remembering that the standards chosen must make complete provision in respect of the product for EMC matters. This is not so difficult as it sounds because most products are covered by well-defined product specific or generic harmonised standards for both emissions and immunity. However should the manufacturer choose for whatever reason not to use an applicable standard or part of an applicable standard for any provision then this must be covered by a technical file.

B.2.3.2 Technical File Route

In the absence of transposed European standards or where the manufacturer chooses, a Technical Construction File (or TCF in short) for the product may be raised in which the apparatus is described and a rationale presented which justifies the claim of compliance with the essential requirements of the Directive. This may or may not be upon the results of testing to all or some of the existing standards or may include test results based on other specifications such as MIL-STD-461C. Whatever the case, the Technical Construction File must be assessed and approved by a Government appointed "Competent Body" before the manufacturer can claim and certify compliance. The manufacturer or importer must notify the national authority that he is using a technical file.

The technical file must contain:

- an identification of the apparatus

- a description of the procedures used to ensure conformity of the apparatus with the protection requirements, and
- a technical report or certificate obtained from a competent body, which must meet certain criteria [45].

According to Annex II of the Directive, the minimum requirements for accreditation of a Competent Body (CB) are as follows:

1. availability of personnel and of necessary means and equipment;
2. technical competence and professional integrity of personnel;
3. independence, in carrying out the tests, preparing the reports, issuing the certificates, and performing the verification function provided for in this Directive, of staff and technical personnel in relation to all circles, groups, or persons directly or indirectly concerned with the product in question;
4. maintenance of professional secrecy by personnel;
5. possession of civil liability insurance unless such liability is covered by the State under national law.

The annex further specifies that "fulfillment of the conditions under points 1 and 2 shall be verified by the competent authorities of the Member States."

In addition to the above-mentioned points, the stringent requirements of EN 45011/CENELEC/Sept. 89 - "General Criteria for Certification Bodies Operating Product Certification"- also apply to CBs. This standard covers, among other items, the CBs governing board, organizational structure, certification personnel, quality manual, confidentiality, appeals, internal audits, and periodic reviews [46].

As we can see easily these requirements are not simple to meet. This explains the relatively small number of 17 CBs in Germany, for example. Europe in total has about 70 CBs. Any CB can only operate presently presently from EC ground. Offices outside the EC are illegal. A CB is basically assigned to an EMC competent person with outstanding capabilities and experience in all areas and sectors of EMC. An essential element is the profound and proven capability of the CB to correctly perform system assessment and

analysis. Normally this type of experts has 10 to 20 years of military and commercial EMC / NEMP (Nuclear Electromagnetic Pulse) system expertise.

On the other hand, it is not necessary to be a test house to be a competent body. The main criteria is the ability to assess a product based on test data and design details and decide whether or not it meets the essential EMC requirements of the Directive.

B.2.3.3 The EC-Type Examination Route

This route applies to radio communications equipment only. For the purposes of the regulations this is described as wireless telegraphy apparatus for:

a) Transmitting or

b) Both transmitting and receiving other than

i) Radio amateur apparatus

ii) Apparatus neither designed nor intended to be used for transmitting in conjunction with other wireless telegraphy apparatus.

iii) Apparatus which is dependent for its operation on a magnetic as distinct from an electromagnetic field.

In this route compliance with the Directive is presumed for relevant apparatus if there is in force an EC-type examination certificate issued by a "Notified Body". This body is not the same as a CB which cannot issue type examination certificates.

In order to issue the type examination certificate, the Notified Body will examine the apparatus and its design and subject it to or cause it to be subjected to whatever tests it feels appropriate to determine whether or not the apparatus conforms. These could well be relevant transposed harmonised standards. As with the CB the Notified Body may do the testing itself or sub-contract it to a Competent facility.

In addition to the EC type examination certificate, radio communications equipment must be given a national radio type approval certificate which certifies that the equipment complies with those requirements in place for the correct radio operation of the equipment and use of the frequency spectrum. This type of approval can be carried out by the same Notified Body or by a different one. Unfortuantely type approval is required due to national differences in the technical requirements for various radio services for which,

unlike EMC, there is no common European requirement in the year of 1996. This means that manufacturers marketing radio communications equipment must seek national radio type approval in each and every community country in which they wish to sell.

B.2.4 Administrative Issues

The obligations on the administrations of Member States are that:

- They shall take all necessary measures to ensure that apparatus may be placed on the market and taken into service only if it complies with the requirements laid down in the Directive when it is properly installed and maintained and when it is used for purposes for which it is intended
- They shall not impede for reasons relating to electromagnetic compatibility the placing on the market and taking into service on their territory of apparatus covered by the EMC Directive which satisfies the requirements of the Directive.

Thus compliance with the Directive is a necessary and sufficient condition for apparatus to enjoy the freedom of Single European Market.

Where an administration ascertains that an apparatus does not comply with the requirements of the Directive it can take all appropriate measures to withdraw the apparatus from the market, prohibit its placing on the market or restrict its free movement. It can also take appropriate action against the author of the attestation who, as it has already been stated, must be named in the EC declaration of conformity. The administration must immediately inform the Commission of any such measure, indicating the reasons for its actions.

When the Commission has been informed of such action it shall consult with the parties concerned as soon as possible to satisfy itself that the action is justified.

B.2.5 Testing for Compliance

Whichever route to compliance is chosen, it is inevitable that some EMC testing of either emissions, immunity or both will be necessary. For the vast majority of complex electronic equipment this testing will need to be extensive. There are however some

differences in the testing approaches to standards and TCF routes which need to be pointed out.

The testing for standards route can be done in house or outside but must be carried out according to CISPR 16 (Specification for Radio Disturbance and Immunity Measuring Apparatus and Methods) methods and with the correct equipment and facilities as specified in the appropriate standards. There can only be confidence in the results if the measuring facility is competent and the equipment is properly calibrated.

Testing for Technical Files on the other hand may not necessarily use methods, limits and equipment in the harmonised standards. The test plan is by agreement between the manufacturer and the competent body. Here, however, the competent body, is being body to assess test results and make a judgement. It is therefore likely that competent body will wish to assure himself of the reliability of the results by assessing and approving the test facility himself.

A major reason for using a TCF is when the apparatus is too large or the installation is too complex or awkward to apply the standard in the prescribed fashion. In other words, it may not be possible to use the test methods, setups or equipment as defined in the standards [47].

B.2.6 Use of Standards

The Directive itself does not contain detailed technical specifications, just the statement of the essential protection requirements. Where a manufacturer demonstrates that his product complies with the relevant standards then that product is deemed to meet this essential protection requirement. It is expected that conformity with standards will be the normal means of demonstrating compliance with the requirements of the Directive.

Part of the problem which caused the need for a transitional period was the lack of sufficient harmonised standards which met the manufacturers' needs when demonstrating conformity with the Directive and the essential requirements. Product and generic standards are published in the Official Journal of the European communities (OJ).

These standards will remain the standards used by most manufacturers to demonstrate conformity. There are two reasons for this. First, if able to apply standards

listed in OJ in a complete assessment of his product, retains full control over his conformity assessment programme. Once satisfied that conformity is demonstrated, by this assessment, the manufacturer completes the declaration of conformity and applies CE marking to the product. Secondly, even if the assessment programme deviates from full harmonised standards and the manufacturer creates the technical construction file as described in Article 10(2) of the Directive, he will need to agree the deviations with a competent body. Where the programme can be based on harmonised standards, agreement will be easier to reach.

In both cases, during the transition period and later, it will be necessary to follow the progress of new standards [48].

B.2.7 Relevant Standards and Work of CENELEC

The European Committee for Electrotechnical Standards (CENELEC) produces European Standards. The preferred mode of working is to adopt the appropriate international standard.

CENELEC is made up of the National Committees of the Western European countries. Once CENELEC has produced a European EMC standard, all the CENELEC countries are required to produce identical national standards. The reference numbers of a European Standard and the equivalent national standards will then be published in the Official Journal of the European Communities. Once these references have been published then the standards are deemed "relevant standards" for the purposes of a manufacturer demonstrating that his products comply with the requirements of the Directive.

CENELEC has four main driving forces which define its *raison d'etre*:

First, CENELEC aims to provide a single set of harmonized standards for the electrotechnical marketplace in 18 countries in the European Community and European Free Trade Association (EFTA). These standards are referred to in EC and EFTA directives as the best way of conforming to European law i.e. they are "notified by law".

Secondly, CENELEC's overall aim is to provide a market for electrotechnical goods and services that is free of technical barriers to trade, where companies from any part of the

world, be they general product or niche firms or huge multinationals, can trade freely without incurring any unnecessary transaction costs.

A third point is that CENELEC's standards should be up-to-date. Product characteristics, and testing procedures, must represent the very best in state-of-the-art technology.

And last, but by no means least, standards must not be seen as a barrier to innovation. They should be flexible and leave all the space in the world for researchers and developers to launch their innovative ideas onto the market.

Another very important point is that CENELEC's standards are international standards. CENELEC has two very good agreements with the International Electrotechnical Commission (the IEC), its worldwide partner, which means that the two organizations now vote in parallel on the same draft standards and that they plan all new work together. Because of the global nature of the electrotechnical industry, and the fact that consumers want low-priced, safe, high-quality products whichever part of the world they are from, European standards must be international standards, so that the marketplace is as fair to non-European producers as it is to European ones. So, what CENELEC and IEC have done through a long, historic period of cooperation is to create a situation where 72 per cent of European standards are in fact identical to the IEC standards. Another 17 per cent of these standards are based on IEC results; that means CENELEC has modified the existing IEC standard or draft so that it can be implemented in Europe. Of the eleven per cent that originate in Europe, CENELEC has started to offer some of them to the IEC for parallel voting, so that the IEC has the opportunity to adopt the CENELEC European standard as an international standard [49].

CENELEC's EMC catalogue is formed by four kind of standards:

- *basic standards,* which are being written by the IEC and which will be adopted by CENELEC as European standards when they are ready. Basic standards define and describe detailed test and measurement methods, test instrumentation and the overall test setup. These basic publications are, by definition, independent of any specific product.
- *generic standards,* which are almost already completed by CENELEC, relate to a given environment and are applicable to all equipment installed in this environment

when there are is no EMC standard specific to the equipment. These standards refer only to basic standards and specify only a limited number of requirements and tests so as to ensure an optimum balance between technological and economic considerations. Also they consider the requirements and tests relating to both the immunity of equipment and the limitation of emission from it.

- *product family standards* relate to a group of similar products to which the same rules may be applied.
- *dedicated product standards*, specify the requirements and tests specific to the products considered. There are and will be both emission and immunity product standards. Where a product standard exists it takes precedence over a generic standard.

Product standards, together with the product family standards, apply only to the basic standards (except for fully justified exceptions). They are coordinated as far as possible with the generic standards relating to the environment in which the products are installed [50].

The programme of new work on the product standards has important implications. There will be additions to the list, changes to the standards at present on the list, and there will be more product immunity standards. For those manufacturers who issued their declaration of conformity under article 10(1), and who used generic standards, the emergence of a product standard will make reappraisal necessary because of the order of preference among standards described above.

B.3 International EMC Standardization

For the work relating to EMC many organizations take part in at the international level. Some of the main ones besides IEC, which has the most spectacular work on this field, are:

- CIGRE (International Conference on Large High Voltage Electric Systems)
- UNIPEDE (International Union of Producers and Distributors of Electrical Energy)
- ISO (International Organization for Standardization)
- ITU (International Telecommunication Union)

- OIML (International Organization for Legal Metrology)
- IRPA/ICNIRP (International Commission on Non-Ionizing Radiation Protection)

These organizations undertake work that may serve as a basis for IEC standardization documents (CIGRE, UNIPEDE) or for the development of standards specific to their fields of interest.

B.3.1 International Electrotechnology Commission

The mission of International Electrotechnology Commission (IEC) is to promote and coordinate at the international level the standardization work in the fields of electrical engineering, electronics, information technology, etc. It deals with these problems in a general way but leaves certain specific fields to specialized organizations (telecommunications, motor vehicles and others). The IEC's objectives are "to promote international cooperation on all questions of standardization... (this is) achieved by issuing publications including recommendations in the form of international standards which the National Committees are expected to use for their work on national standards" [51].

The IEC was founded in 1906 and at present is made up of the National Committees of 48 countries, including Turkey. Most of the industrialized countries are members. In particular, it includes all the EU and EFTA countries (except for Iceland).

The IEC comprises some 200 committees and subcommittees of which about half are concerned by EMC to varying degrees. These committees and subcommittees present the results of their work in the form of standards, technical reports or guides.

The first work in the EMC field can traced back to when CISPR (an organization now associated with the IEC) was set in 1936.

The organization of the EMC work is currently as follows:

- Technical Committee No. 77 is responsible -together with other committees to some extent- for basic standards having general application and for generic standards.
- CISPR is responsible primarily for the protection of radio and television broadcasting but has extended its field of activity to include information technology equipment (ITE).

• Numerous "product" committees have the task of developing standards specific to their products.

• To ensure coordination between all these special committees and with the outside world, the Advisory Committee on Electromagnetic Compatibility (ACEC) was set up to coordinate the work and provide advice to the "product" committees.

B.4 Regulations on Medical Devices

As medical devices become more and more sophisticated, international regulatory compliance issues associated with design and manufacture of electronic medical instrumentation have become increasingly important. Some countries had their own standardization programmes.

There is a flurry of activity from standards committees to formulate and adopt EMI performance standards for medical electronics. These standards are intended to limit emissions from medical equipment and to establish the minimum levels of interference that equipment must tolerate.

The IEC EMI requirements serve as the basis for all the current and pending EMI requirements. The primary requirements include emissions, radio frequency interference, electrostatic discharge, and various forms of power and signal line interference.

The actual requirements are dependent on the equipment category, whether the device is invasive, or patient connected or neither. Failure criteria has not been well established, but the direction is to define failure in immunity tests as loss of *clinical utility*, as will ultimately need to be decided by clinicians. Brief upsets may be tolerable, providing equipment self recovers without losing active parameter, i.e. reseting to default parameters would usually not be acceptable). Where analog devices are involved, an operating tolerance may need to be specified.

B.4.1 Emission and Immunity Considerations

Both emissions and immunity are of interest to the equipment designer, but for different reasons. Emissions standards limit the emanations from the equipment. Some

very sensitive equipment is very vulnerable and may well benefit by emissions controls on adjacent equipment, but the emissions limit were originally intended for protecting licensed radio communications from interference.

Some medical equipment generates high energy radio frequency (RF) as part of its function, but most electronic equipment emanates too little energy to affect digital electronics or even most analog electronics. But radio devices are very sensitive, responding even to very low levels of energy, and will receive radio energy from most modern electronics, such as a personal computer. Even so, field strengths fall of reciprocally with distance, and typical test distances range from 3 to 30 meters.

Immunity is an issue that concerns external interference that impairs the function of the equipment. Such interference can arise from a variety of sources, but there are a few characteristic signatures that have been categorized and for which standards have been formulated. These cases include radio frequency interference, electrostatic discharge and several types of power disturbances. Typical levels have been studied exhaustively, and standards have been formulated.

Sometimes the term *susceptibility* is used instead of *immunity*. These terms really refer to the same thing. Equipment will be susceptible above a certain level of EMI, and immune below that level. So the boundary is the same for both conditions, and the terms are used interchangably. The military has used the term *susceptibility* for many years. In recent years, the term *immunity* has come into common usage, mostly as a result of the European Union activity.

B.4.2 Medical Device Regulations in United States

In the United States, key organizations involved in developing and implementing regulations associated with medical products are the U.S. government's Food and Drug Administration (FDA) and the Association for Advancement of Medical Instrumentation (AAMI).

AAMI prepares standards for medical equipment, which the FDA and other agencies may use when specifying a device. The association maintains a large database of standards

and provides a forum for manufacturers to voice concerns and issues relating to their types of products.

In 1979, the FDA published MDS-201-0004, a voluntary standard addressing electromagnetic immunity that drew heavily on test methods of MIL-STD-461. Later, the FDA began to require that manufacturers provide EMC test data using that document [52].

As electromagnetic interference and electromagnetic compatibility become ever more crucial factors in performance of electronic medical devices, the FDA and other agencies will become increasingly attentive. Manufacturers of medical instrumentation or other devices that could affect performance of such instruments must be aware of issues related to regulations.

Standards in the U.S. and in international area are generally formulated by non-government agencies, typically committees formed up of industry and government representatives. Subsequently, governments enact these standards as regulations or law. This results in a potpourri of standards, some of which are identical.

Although the U.S. and the E.U. are generally the most active in EMC regulations, other countries are following closely behind. Generally, Canada (via Canadian Standards Association, or CSA) and Mexico follow U.S. standards with little modification, but the rest of the world generally follows EU requirements.

B.4.3 European Medical Devices Directive

By January 1, 1995, the Medical Devices Directives have been implemented across Europe. As with all of the EU directives, a three-year transitional period will be in effect, meaning that CE Marking for medical devices will not become mandatory until 1998.

Basically, the directives are a series of rules that member states and manufacturers must follow to prove that products are safe to use. All the medical devices manufacturers should have a copy of the Medical Devices Directives, published in the Official Journal of the European Communities, document number L169 volume 36, dated July 12, 1993.

The above-mentioned document contains everything a manufacturer will need to know in advance of the implementation. The Medical Devices Directives (93/42/EEC) are designed to effect a fundamental change in the overall safety of medical devices used in

Europe; one of their primary objectives is that "Medical devices should provide patients, users and third-parties with a high level of protection and attain the performance levels attributed to them by the manufacturer."

Three years may seem like a long time, but if it is put off for 18 months one may find it's too late to implement changes in design, quality systems, and methods of manufacture and then carry out assessment, type testing, and certification. The competitors won't wait that long, but will start to put required changes into effect before the end of the transition period and begin CE Marking as soon as possible. It is important to remember that "if one manufacturer's product is not compliant at the end of the transition period, he will not be able to market his product in the EEC until it is compliant."

In Medical Devices Directive, medical devices are grouped into 4 classes according to their "intended function". These are:

- Class I: General unpowered (non-active) devices which do not penetrate the body or non-surgically inasive devices for transient use (less than 60 minutes). Some low risk, powered (active) devices for patient support or examination.
- Class IIA: Generally nonhazardous, active therapeutic and diagnostic devices.Low-risk, surgically invasive devices for transient use or short-term use (up to 30 days).
- Class IIB: Generally potentially hazardous active therapeutic and diagnostic devices (e.g. X-ray sources). Higher risk surgically invasive devices for transient or short-term use. Surgically invasive devices for long-term (more than 30 days) or implantable (non-active) use.
- Class III: All devices which make contact with the heart, central circulatory system or central nervous system. All long term invasive or implantable devices which have a biological effect on the body or are absorbed into it [53].

The Medical Devices Directives can be described as being made up of articles and annexes. The articles may be looked upon as mandatory procedures or requirements, and the annexes as a method of auditing the systems used by manufacturers to ensure that the procedures are being implemented and used properly. A summary of the articles and annexes follows.

Article 1: Definitions, scope. Definitions of the meaning of the terms used in the directive and restatement in unambiguous language.

Article 2: Placing on the market and putting into service. Requirement that member states of the EU supervise the manufacture of medical devices and ensure that devices placed on the market are safe to use.

Article 3: Essential requirement. Requirement that devices meet the essential standards.

Article 4: Free movement, devices intended for special purposes. Requirement that member states not create any obstacles 1) to the placing on the market or the putting into service of articles carrying the CE Marking; 2) to the manufacture of devices intended for clinical evaluation or of custom-made devices.

Article 5: Reference to standards. Requirement that member states assume compliance with the essential standards referred to in Article 3 for devices that conform to the relevant harmonized national standards published in the Official Journal of the European Communities.

Article 6: Committee on standards and technical regulations. Internal EU administration requirement that does not directly affect manufacturers.

Article 7: Committee on medical devices. Another internal EU administration requirement that does not directly affect manufacturers.

Article 8: Safeguard clause. A very powerful control mechanism to be invoked in cases where the safety of patients or users is continually put at risk by a device that does not comply with the directives. Essentially, the member state is obligated to inform all other member states and can prohibit sale of the device and/or cause all other devices of the same type the same manufacturer to be withdrawn from the market.

It is important that manufacturers read this article and carefully and avoid falling into a situation where the safeguard clause could be put into effect (e.g., see Article 18).

Article 9: Classification. Requirement that devices be correctly classified in one of the four classes (I, IIa, IIb, and III). Rules for disputes arising between manufacturers and their chosen Notified Bodies over classification are also outlined here.

Article 10: Information on incidents occurring following the placement of devices on the market. An internal requirement to be enacted by each member state, concerning the

obtainment of information from manufacturers relating to the malfunctioning or deterioration in characteristics/performance of the device, and so on.

Article 11: Conformity assessment procedures. Procedures are the classification of medical devices and conformity requirements for each class. Manufacturers should familiarize themselves with this article, as it will involve them.

Article 12: Particular procedure for systems and procedure packs. An extension of Article 11 relating to systems and procedure packs. This article should be carefully read by any company that intends to market sterile procedure packs.

Article 13: Decisions with regard to classification, derogation clause. A set of rules for member states that does not directly affect manufacturers.

Article 14: Registration of persons responsible for placing devices on the market. Requirement whereby all manufacturers producing medical devices must be registered with the competent authority. If the seller of the equipment has products manufactured for him and the product is "own-branded," then the seller shall be legally responsible for registering the name of his company with the competent authority. If the product manufactured for him is not own-branded and the manufacturer is outside the EU, the seller is responsible for ensuring that the marketer is designated and notified by the competent authority in each member state where the product is to be sold.

Article 15: Clinical investigation. Requirements regarding devices intended for clinical investigation.

Article 16: Notified Bodies. A series of rules for member states concerning Notified Bodies. The Notified Bodies must meet the requirements of annex XI.

Article 17: CE Marking. Rules for applying the CE marking. Manufacturers should make special note of the requirements outlined in this article.

Article 18: Wrongly affixed CE Marking. Requirement that member states act immediately if a manufacturer is found to have affixed a CE Marking to his product without its having been proved to meet the essential or relevant requirements for its type and class. This could also cause Article 8 to be enforced.

Article 19: Decision with respect to refusal or restriction. Rules applying to the competent authority. If approval to place a device on the market has been refused or

restricted, the competent authority must make absolutely clear the reasons for the refusal or restriction.

Article 20: Confidentiality. A rule binding everyone involved in the application of the directive to confidentiality.

Article 21: Repeal and amendments of directives. Rules for changing the contents of the directives. These do not directly affect manufacturers.

Article 22: Implementation; transitional periods. Requirement that member states adopt and publish the laws, regulations, and administrative provisions no later than July 1, 1994. This requirement does not directly affect manufacturers.

Article 23: This article has no heading. Its intent is to specify to whom the directive is addressed [54].

There are two other directives defined by EU: the Active Implantable Device Directive and In Vitro Device Directive. There are also categories within each directive, depending on the application.

APPENDIX C

DRAFT

IEC 118-13
HEARING ~~AIDS~~

Part 13. ELECTROMAGNETIC COMPATIBILITY (EMC) PRODUCT STANDARD FOR HEARING AIDS

(June 1995)

0. Introduction

This standard only deals with hearing aid immunity, as experience has shown that hearing aids do not emit electromagnetic signals to any extent which can disturb other equipment.

Hearing aids are battery powered devices and therefore disturbances related to AC or DC power inputs are not relevant and are therefore not considered.

In some cases hearing aids are connected to other equipment, but this standard does not cover common mode transients and common mode surges on such cable connections.

Hearing aids whose output is not acoustic e.g. cochlear implants are not covered by this standard.

Other EMC phenomena, such as electrostatic discharge, are not known to be a problem in connection with hearing aids and are therefore not dealt with. Based on new knowledge, they could be considered in connection with future revisions or extensions of this standard.

Based on experience in connection with the use of hearing aids, relevant sources of disturbance for hearing aids include high frequency radiated electromagnetic fields originating from digital telephone systems and low frequency radiated magnetic fields which may interact with the telecoil input included in some hearing aids.

As the telecoil input is an intended feature of some hearing aids, and the hearing aid therefore must have a certain sensitivity to low frequency magnetic fields it is not relevant to specific immunity against disturbing low frequency magnetic fields. To avoid unintended

interference from low frequency magnetic noise fields the recommendations specified in IEC 118-4 [1]), regarding specifications for induction loop systems, should be followed.

With regard to high frequency radiated electromagnetic fields originating from digital telephone systems only sources of disturbance which are known, at present, to be a problem in connection with hearing aids are covered. Reference is made to IEC 1000-4-3 including Amendment 1, which covers the frequency range 0.08 to 3 GHz and identifies digital radio telephone systems operating in the frequency ranges 0.8 to 0.96 GHz and 1.8 to 2.0 GHz to be potential sources of interference.

1. Scope

This international standard covers all relevant EMC phenomena for hearing aids. It specifies measurements methods and acceptance levels for hearing aid immunity to high frequency electromagnetic fields originating from digital telephone systems as specified in IEC 1000-4-3.

Methods for the measurement of hearing aids with non-acoustic outputs and hearing aids connected to other equipment by cables are not given in this standard.

2. Normative References

The following normative documents contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents listed below. Members of IEC and ISO maintain registers of currently valid normative documents.

1. IEC 1000-4-3: 1995, Electromagnetic compatibility for electrical and electronic equipment - Part 4: Testing and measurement techniques - Section 3: Radiated, radio frequency, electromagnetic field immunity test.

Amendment 1 to IEC 1000-4-3: Immunity to RF emissions from digital radio telephones. [2]

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[1] At present under revision.

2. IEC 118-0:1983, Hearing Aids - Part 0: Measurement of electroacoustical characteristics.

Amendment 1 to IEC 11 8-0.

3. IEC I18-4: 1981, Methods of measurement of electroacoustical characteristics of hearing aids - Part 4: magnetic field strength in audio-frequency induction loops for hearing aid purposes. [3]

4. IEC I18-7:1983, Hearing Aids - Part 7: Measurement of the performance characteristics of hearing aids for quality inspection for delivery purposes.

Amendment 1 to IEC I 18-7.

5. IEC 126:1973, IEC Reference Coupler for measurement of hearing aids using earphones coupled to the ear by means of ear inserts.

6. IEC 711:1981, Occluded-ear simulator for the measurement of earphones coupled to the ear by ear inserts.

3. Specification of the Product

This standard relates to hearing aids, which are electroacoustical devices worn by a person to compensate for a hearing impairment by amplifying sound. They include aids placed on the body (BW), aids placed behind the ear (BTE) and aids placed in the ear (ITE).

4. Operation and Function of the Product

Hearing aids basically consist of a microphone, an amplifier and a small earphone (receiver). The sound is normally fed to the ear canal by means of an individually made ear mould (ear insert). The power source normally used is a small battery. Some adjustments of the controls of the hearing aid are performed by the user, which in some cases is by means of a remote control.

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[2] At present at the stage of draft. The latest draft can be found in Annex B for information.
[3] At present under revision.

5. Specification of EMC Environment

Hearing aids are used in all environments.

6. Definitions

For the purposes of this standard the following definitions apply in addition to those specified in IEC I18-0, IEC I18-7 and IEC 1000-4-3

6.1 *Reference orientation (of a hearing aid):* The orientation of the hearing aid, with respect to the RF emitting source, which corresponds to the orientation of the hearing aid under actual use on a person facing an RF emitting source.

6.2 *IRIL: Input related interference level.* The level used to characterise the immunity of the hearing aid, measured in dB SPL. Decreasing values of IRIL indicate increasing immunity.

7. Requirements for Immunity

7. 1 Performance Criteria

The IRIL shall not exceed **55 dB SPL**.

The background for establishing this performance criteria can be found in Annex A.

7. 2 Test Levels

Hearing aids are classified in two classes related to their use:

Class I: Hearing aids for use in environments where digital radio equipment is in operation.

Class II: Hearing aids for use together with portable or mobile digital radio equipment on the same ear.

The RF test levels to establish immunity have been chosen for Class I according to IEC 1000-4-3, Amendment I, Annex F as shown in Table 1 below.

Table 1
Levels of RF test signals to be used to establish immunity at a stated distance for Class I.

Frequency Range GHz	Test Level (unmodulated carrier) V/m	Approx. protection distance for 2 W GSM m	Approx. protection distance for 1 W DCS 1800 m
0.08-0.8	See text	n/a	n/a
0.8-0.96	3	2	n/a
1.4-2.0	2	n/a	2

As sources of disturbance in the frequency range below 0.8 GHz are not known to affect hearing aids testing in this frequency range is not considered necessary.

For Class I use a distance of 2 m has been chosen for evaluating immunity from handheld terminal equipment. This distance is based on experience with the practical use of hearing aids, the possibility of the user being at this distance from the source of interference, and a comparison between the actual test procedure and practical situations (see Annex A).

Currently test levels for Class II use have not been established due to lack of knowledge about the influence of the human head on the near field strength.

8. Immunity Test Procedures

8.1 The RF-test equipment, test configuration and test procedures specified in IEC 1000-4-3 and Amendment I shall be applied. This requires that a I kHz 80% sine modulation of the carrier wave is used.

Note: For small systems (hearing aids without external cables) suitable GTEM cells and striplines may be used as indicated in Annex D of IEC 1000-4-3.

8.2 For hearing aids with external cable connections, the cables should be stretched out vertically.

8.3 No objects other than the hearing aid, which could distort the RF-field, shall be present in the test volume.

In order to remove the metallic ear simulator or coupler as specified in IEC 126 and IEC 711 from the test volume, the normal tubing between the hearing aid and the ear simulator or coupler shall be replaced by a 2 mm inner diameter tubing with a length typically between 50 mm and 500 mm. For in-the-ear instruments the outlet from the receiver shall be coupled to the tubing by a suitable adapter. This adapter and the length of the tubing are not critical, as the hearing aid gain is determined in each individual test configuration.

The complete acoustical coupling arrangement used shall be described when presenting the results.

Note: Measurements should be made to ensure that interference in the measuring system is at least 10 dB lower than the lowest interference level to be measured.

8.4 The hearing aid volume control shall be adjusted to the "Reference Test Gain Control Position" as described in IEC I18-0 Amendment I or IEC I18-7 Amendment I. either controls shall be set to positions giving the widest frequency response and the maximum acoustic output.

8.5 With the acoustical coupling described in 8.3 the basic frequency response of the hearing aid shall be measured as described in IEC I18-0 or IEC I18-7.

8.6 The hearing aid shall be placed in the RF-field, and the sound pressure level of the interference signal at 1000 Hz shall be determined employing a band-pass filter with a maximum bandwidth of 1/3 octave.

The hearing aid shall be placed in the reference orientation and then rotated in steps of 90 degrees. in the horizontal plane. For each orientation the carrier frequency shall be

stepped within the actual frequency range being measured with a step size equal to or less than 10 per cent.

At the orientation where the interference signal reaches its maximum value, the measurement of the interference sound pressure level shall be carried out. The maximum value within each frequency range is used to characterise the interference.

Note: Measuring results from hearing aids with ASP (automatic signal processing) characteristics or other non-linear processing should be interpreted with care, as the interference signal may activate these systems in an unpredictable way.

8.7 The hearing aid gain at 1000 Hz as determined in 8.5 shall be subtracted from the corresponding levels of the interference signal as determined in 8.6. The result of this calculation is the IRIL.

8.8 The measurement shall be carried out with both the microphone and the telecoil (if provided) as an input option. The adjustment of the hearing aid should be the same as defined in 8.4, and the acoustical gain as determined in 8.5 should be used.

9. Overview of Tests and Performance Criteria

The hearing aid immunity against high frequency radiated electromagnetic fields should be established as indicated in Table 2 below:

Table 2
Requirements to establish hearing aid immunity.

Frequency Range **GHz**	**Class I** **Test Level** **(unmodulated carrier)** **V/m**	**Class II** **Test Level** **(unmodulated carrier)** **V/m**	**Performace criteria** **IRIL** **dB**
0.08-0.8	Note 1	Note 1	Note 1
0.8-0.96	3	Note 2	55
1.4-2.0	2	Note 2	55

Note 1 : Testing in this frequency range is not considered necessary (see clause 7.2).
Note 2: Test levels for Class II have not been established.

ANNEX A

(Informative)

Background for establishing test methods, performance criteria and test levels

The EHIMA GSM Project, Final report presents the results of the "Development phase" of the EHIMA GSM Project, which is a comprehensive project set up by the European Hearing Instrument Manufacturers Association (EHIMA), to establish a test environment to enable the member. Companies to deal with the GSM interference problems which may occur with their products.

It also includes results from other investigations carried out in connection with the EHIMA GSM Project.

Below the relevant parts of the project are summarized.

Test Methods

Initially, five different hearing aids types from a previous EMC-project were selected for a laboratory investigation, representing different electroacoustic characteristics, interference levels and interference spectra. The overall input related interference level (OIRIL), expressed in dB SPL, was chosen to characterize the interference performance of the hearing aids.

First, the aids were acoustically tested according to IEC standard 118-0. To be able to remove the metallic ear simulator from the RF-field the acoustical coupling between the hearing aid and ear simulator was modified by using 500 mm long tubing. Relatively large variations in the acoustical effect of this modification were seen. This therefore means that the hearing aid gain should be measured for each individual hearing aid under test for use in the determination of OIRIL.

The hearing aids were then exposed to a simulated GSM RF-field in a radio anechoic room being placed in a position corresponding to normal use. A peak field strength of 10 V/m, corresponding to an 8 W mobile telephone at a distance of 2 m or a 2 W mobile telephone at a distance of 1 m, was then employed as the test signal.

The frequency spectra of the interference signal at the orientation causing maximum interference was determined. The input related spectra was then calculated by subtracting the hearing aid gain, and finally the OIRIL was determined.

The normalized input related spectra appeared to be almost identical for all the hearing aids tested, the level of the harmonics decreasing with increasing frequency. This means that only the low frequency part of the spectrum is needed to determine OIRIL with sufficient accuracy for the purpose of measuring immunity.

It was seen that rotation of the hearing aid in the horizontal plane affected the interference performance to some degree and that maximum interference occurs at different angles for different hearing aids. Vertical polarization of the RF-field, as used in the GSM system gave rise to the highest interference levels in practically all cases .

In general the use of the telecoil as an input to the hearing aid instead of the microphone did not give rise to increased interference levels.

Relatively large differences in OIRIL between different hearing aid types were seen, and also in a small number of cases between samples of the same type.

A typical 1:2 dB relationship between field strength and interference level were seen for a field strength range where the interference signal is above the noise floor of the hearing aid and does not saturate it. .

Experiments were carried out to determine the effect of placing the hearing aid behind the ear and in the ear. It turned out that the human head significantly attenuated the GSM signal when the head is between the transmitting source and the hearing aid, whereas no significant difference was seen when the hearing aid was facing the transmitting source. Based on these findings, it was therefore decided that no "Human-factor" correction to the measuring results is required.

The investigations also showed that the use of 80%, 1000 Hz sine modulation with the same "peak RMS" level of the carrier as the simulated GSM signal produced approximately the same input related interference level in the hearing aid. This is in agreement with the conclusions and recommendations of IEC 1000-4-3 Amendment 1.

It is therefore decided to recommend sine modulation for testing of hearing aids. The measuring result is denoted IRIL (input related interference level). It is determined in the same way as OIRIL, but only the frequency component at 1 kHz is considered.

Performance Criteria

To establish a basis for proposing acceptance levels a series of listening tests was carried out. As the normalised input related spectra of the interference signal were almost identical for all the aids, only one of the signals was presented to a group of five persons with a normal sense of hearing instructing them to judge the interference as "Not annoying", "Slightly annoying", "Annoying" and "Very annoying". The interference signal was presented at different levels together with three different noise and speech signals to simulate different listening situations.

From the results of these tests acceptance levels, expressed as free field SPL's, are proposed. Based on the results of these listening tests and the laboratory investigation it is concluded that an acceptance level around 55 dB SPL will probably ensure acceptable conditions for the hearing aid user in most practical situations. This value has been chosen as the performance criterion in this standard. The choice was confirmed by an additional investigation using hearing impaired subjects.

To summarize, IRIL, the input related interference level at 1000 Hz measured in dB SPL, should be used to characterize the immunity of the hearing aid. Decreasing values of IRIL indicate increasing immunity. The acceptance level corresponding to IRIL equal to or less than 55 dB SPL will probably ensure acceptable conditions for the hearing aid user in most practical situations and is recommended as performance criterion.

Test Levels

To be able to suggest realistic field strengths for testing of hearing aids, which simulate the situations where the hearing aid user is disturbed by a nearby person using a hand-held mobile telephone, a number of points should be taken into account.

Firstly, the proposed test procedure is based on a number of worst-case considerations:

The maximum interference for four different orientations of the hearing aid relative to the disturbing field is used.

The maximum interference within a certain carrier frequency band is used. This carrier frequency will normally be different from the actual carrier frequency.

The maximum transmitting power is used, despite the fact that the mobile telephones only transmit with maximum power in certain situations.

Secondly, some practical circumstances should be noted:

Users of mobile telephones will probably tend to obtain as much privacy as possible and thereby increase the distance to nearby persons as much as possible.

Very few complaints on hearing aid disturbance from mobile telephones are reported, even in countries where the GSM system is very widespread.

A field strength of 3 V/m (80 % sine modulation) corresponds to a theoretical protection distance of approximately 2 m for a 2 W handheld mobile telephone. A distance of 2 m is judged to be realistic taking the above-mentioned considerations into account.

ANNEX B
(informative)

(Draft IEC 1000-4-3 Amendment 1)

ANNEX C
(informative)

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EHIMA GSM Project, Final Report

"Hearing Aids and GSM Mobile Telephones: Interference problems, methods of measurement and levels of immunity" (1995). EHIMA. Brussels.

APPENDIX D

FREQUENCY RESPONSE CURVES

Frequency response characteristics of hearing aids are obtained at Audiology Department of Marmara University Faculty of Medicine using methods described in Chapter 4. Frequency curves for three hearing aids are here presented to show the difference observed when different tube sizes are utilized.

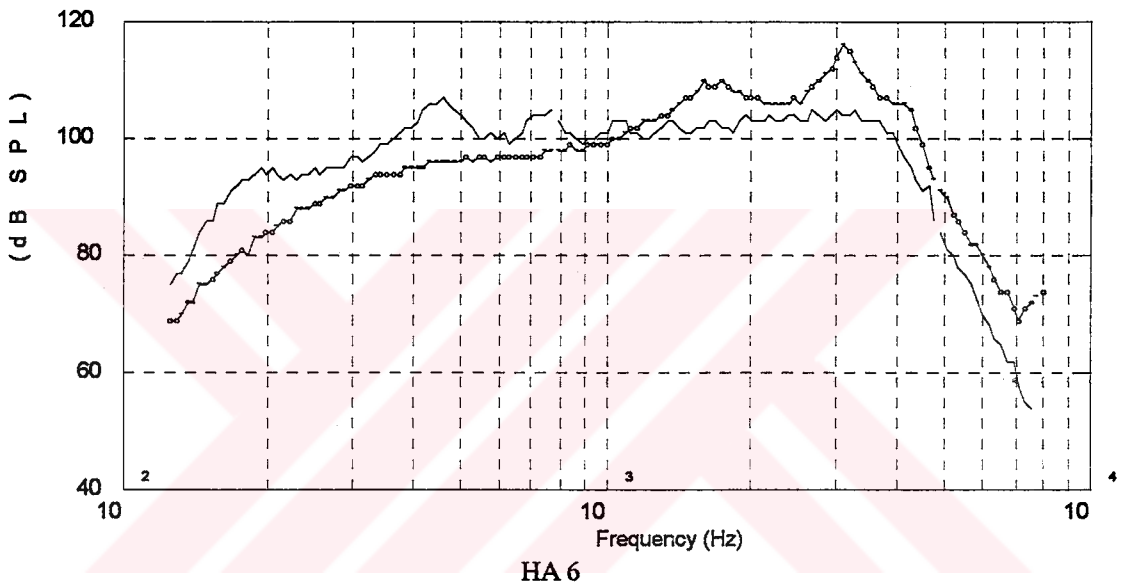
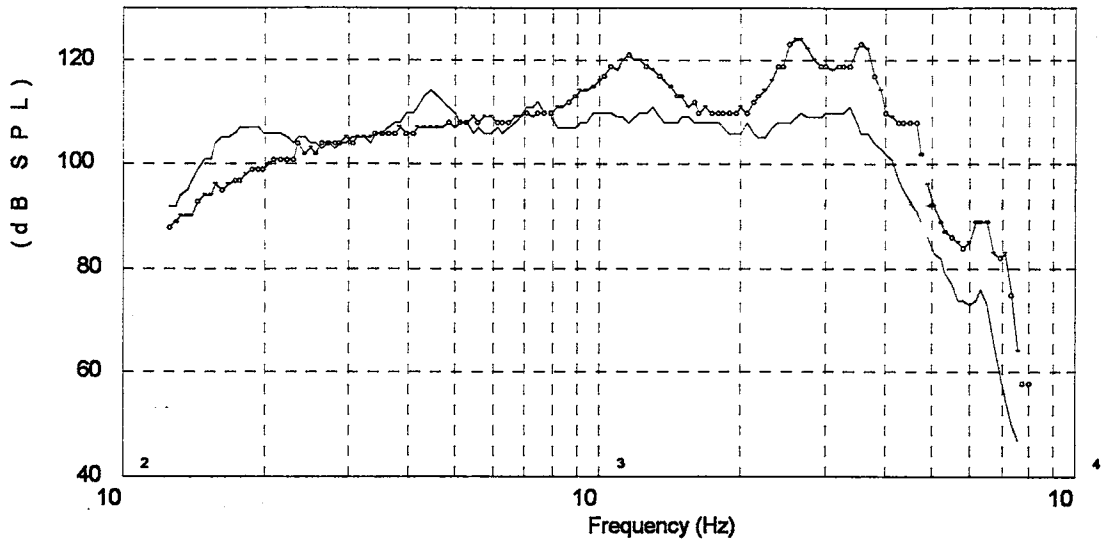


Figure D.1 Frequency response curves for HA 6 measured with 25 mm and 500 mm tubings and with 60 dB SPL Input

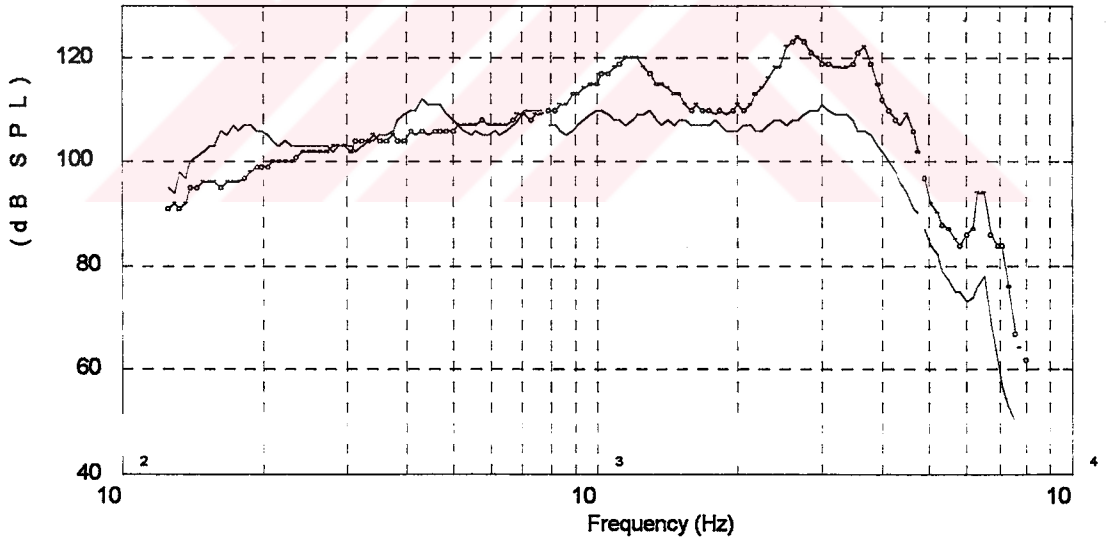
Legend: Bold: 25 mm Light: 500 mm



HA 8

Figure D.2 Frequency response curves for HA 8 Measured with 25 mm and 500 mm tubings and with 60 dB SPL Input

Legend: Bold: 25 mm Light: 500 mm



HA 9

Figure D.3 Frequency response curves for HA 9 measured with 25 mm and 500 mm tubings and with 60 dB SPL Input

Legend: Bold: 25 mm Light: 500 mm

APPENDIX E

ATTENUATION PROVIDED BY ACOUSTIC ANECHOIC BOX

In the immunity testing of hearing aids, hearing aid under test is placed in an acoustically anechoic box. Thus hearing aid does not amplify unwanted external sounds that may appear during testing. The box is made up of hard polystyrene walls inner surfaces of which are covered with pyramidal sound absorbers.

Attenuation provided by this box is measured at Acoustic and Vibration Laboratory of TÜBİTAK National Metrology Institute. Measuring equipment consisted of Brüel & Kjaer Type 2133 Dual Channel Real-Time Frequency Analyzer, Type 4134 Microphone and Type 2645 Preamplifier. The microphone had a sensitivity of 11.5 mV/Pa. The pressure at the time of measurement was 1001 milibar. In first stage of the measurement, the microphone read background noise levels. Then in the second stage it is placed in the box reading again noise levels. The box provided about 20 dB SPL attenuation along the 100-10000 Hz frequency range as illustrated in Figure E.1.

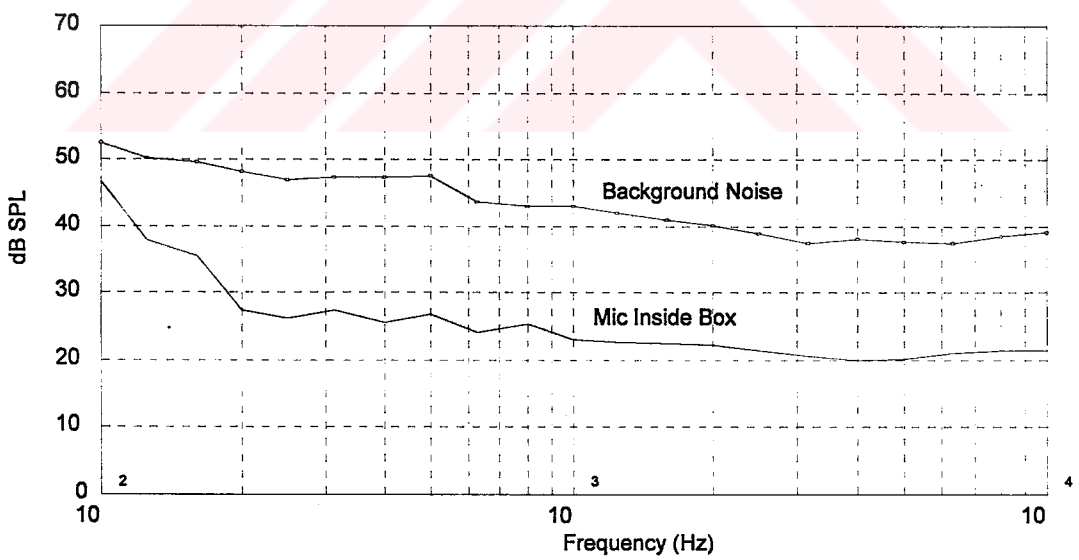


Figure E.1. Attenuation provided by anechoic box used in hearing aid immunity testing.

APPENDIX F

SQUARE LAW DETECTION OF RF SIGNALS

Response to RF signals appearing at the input of an amplifier is caused by rectification at the input transistor where amplitude variations are transformed into voltages that are amplified along with the desired signal. Formulae for the detected signals with sinusoidal and pulsed amplitude modulation are derived. It is shown that about one millivolt of RF voltage caused by a pulse modulated carrier, simulating a GSM transmission results in an equivalent input sound pressure of 30 dB SPL in a hearing aid.

TRANSISTOR CHARACTERISTICS

Transistor amplifiers designed for amplification of audio frequency signals respond to amplitude modulation of radio frequency signals applied to the input. The nonlinear characteristic of the input transistor causes square law detection of the amplitude modulation.

Bipolar Transistor

In the normal active region at low currents, the instantaneous collector current I is, with sufficient accuracy [1]:

$$I(V) = I_0 \cdot e^{\left(\frac{V}{v_T}\right)}$$

where (1)

$$v_T = \frac{kT}{q}$$

where v_T is approximately 26 mV, k is Boltzmann's Constant, T is absolute temperature, q is the charge on an electron and V is the voltage across the diode. The small

[1] It is assumed that this applies for modern transistors at 900 MHz.

signal gain is found by expanding *I(V)* in Equation (1) as a Taylor series about the quiescent bias (V_q, I_q).

The small signal collector current i_C as a function of small signal base voltage v_B is:

$$i_C = I(V_q - v_B) - I_q = I_q\left[\frac{v_B}{v_T} + \frac{1}{2}\left(\frac{v_B}{v_T}\right)^2 + \frac{1}{6}\left(\frac{v_B}{v_T}\right)^3 + \ldots.\right]$$

where (2)

$$I_q = I(V_q)$$

i_C is the sum of the desired linear term in v_B, plus the quadratic term in v_B^2 which causes the "detection" of amplitude variations of RF signal voltages, plus third and higher order terms that are normally negligible, since v_B / v_T << 1. To allow direct comparison between the desired signal being amplified (i.e. microphone or telecoil signals) and the detected interference signal, Equation (2) may be written in the form, ignoring the third and higher order terms:

$$\frac{i_c}{g_m} = v_B + \Lambda v_B^2$$

where $$g_m = \frac{I_q}{v_T}$$ (3)

and $$\Lambda = \frac{1}{2v_T}$$

g_m is the familiar small signal transconductance term (for linear amplification) and Λ is the small signal input referred square law coefficient used in the following section. The detected signals calculated in the next section using A are referred to the voltages across the input transistor.

MOSFET Transistor

The transistor may be designed to operate under conditions varying from weak to strong inversion. Low power, low voltage circuits (hearing aid amplifiers) require operation in weak inversion. In strong inversion, the transistor exhibits the familiar square law characteristic.

Weak Inversion: The current is mainly due to diffusion current between source and drain. The drain current may be expressed as:

$$I_D = I_{D0} \cdot e^{\frac{V_G}{nv_T}} \left[e^{\frac{V_S}{v_T}} - e^{\frac{V_D}{v_T}} \right] \tag{4}$$

where V_G, V_S and V_D are the gate, source and drain voltages referred to the local substrate, and n is the slope factor usually between 1.2 and 1.3.

If the source and drain voltages are constant, the response is the same as for the bipolar transistor except that in Equation (3) we have:

$$g_m = \frac{I_{Dq}}{nv_T}$$

and

$$\Lambda = \frac{1}{2nv_T} \tag{5}$$

where I_{Dq} is the quiescent drain current

Strong Inversion: The transistor operates in the saturation region. The drain current may be expressed as:

$$I_D = \frac{\beta}{2n}(V_G - V_T - nV_S)^2$$

where (6)

$$V_D \geq \frac{V_G - V_T}{n}$$

and β is the usual transfer parameter in strong inversion, and V_T is the threshold voltage. Writing the small signal gain in the same form as Equation (3), the small signal drain current i_D as a function of small signal gate voltage v_G, is:

$$\frac{i_D}{g_{mg}} = \left(v_G + \Lambda v_G^2\right)$$

where (7)

$$g_{mg} = \sqrt{\frac{2\beta I_D}{n}} = \frac{\beta}{n}\left(V_G - V_T - nV_S\right)$$

and

$$\Lambda = \sqrt{\left(\frac{\beta}{8I_D n}\right)} = \frac{1}{\left(V_G - V_T - nV_S\right)}$$

where and g_{mg} is the gate transfer conductance and Λ is the small signal square law coefficient, of the same order as before.

DETECTION OF AMPLITUDE MODULATION

Sinusoidal Amplitude Modulation

Let an amplitude modulated carrier voltage be applied to the base (or gate) of the input transistor of the amplifier. The input referred component of the input voltage causing the detection is:

$$\Lambda\left[\sqrt{2}V_C\left[1 + m\cos(\omega_m t)\right]\cos(\omega_C t)\right]^2 \quad (8)$$

where ω_m is the sinusoidal modulation frequency, ω_c is the carrier (radio) frequency, m is the modulation index (0.8), V_c is the RMS radio frequency carrier voltage and Λ is given by Equations (3), (5) or (7).

Expand Equation (8) by substituting for cosine squared terms and discard the DC and cos(2ω_c t) terms that are filtered out and not amplified. This leaves first and second harmonic terms in ω_m:

$$2\Lambda V_C^2 m\left[\cos(\omega_m t)+\frac{m}{4}\cos(2\omega_m t)\right] \tag{9}$$

which appear in the output of the hearing aid. These terms are the input referred detected amplitude modulation. The magnitude of the detected signal is proportional to the square of the magnitude of the RF carrier signal. Of interest is the RMS value of the fundamental component, $\sqrt{2}\,\Lambda\, m\, V_c^2$. The RMS value of the second harmonic component is ($\sqrt{2}\,\Lambda\, m\, V_c^2$) / 4, giving 20 per cent harmonic distortion of the detected signal,

Pulsed (Interrupted Carrier) Modulation

Let periodic pulses of RF signal voltage be applied to the input transistor. During each pulse the input referred component of the input voltage causing detection is:

$$\Lambda\left[\sqrt{2}V_C\cos(\omega_C t)\right]^2 \tag{10}$$

Expand Equation (10) by substituting for the cosine squared term and discard the cos(2ω_c t) term that is not amplified. This leaves the DC shift:

$$\Lambda V_C^2 \tag{11}$$

which is the peak to peak amplitude of the input referred detected pulse-train. If the duty cycle of the pulse is *d*, the average of the pulse is *d* times its magnitude. The RMS value of the pulse train obtained by evaluating the integrals:

$$\Lambda\frac{V_C^2}{T}\sqrt{\left[\int_0^{Td}(1-d)^2\,dt+\int_{Td}^{T}(-d)^2\,dt\right]}=\Lambda V_C^2\sqrt{d-d^2} \tag{12}$$

Comparison of Response to Sinusoidal & Pulsed Modulations

From Equations (9) and (11) the ratio of the detected fundamental output with sinusoidal modulation to the detected pulse modulation is:

$$m\sqrt{\frac{2}{(d-d^2)}} = 3.421 \tag{13}$$

i.e. the detected sine wave is 10.68 dB greater than the detected pulse. If the second harmonic is included, the ratio is 12.27 dB.

If the pulsed carrier V_c is increased to have the same peak value as the sinusoidal modulated carrier, i.e increased by:

$$20\log(1+m)^2 = 10.21 \text{ dB} \tag{14}$$

then the difference in detected output is only 0.47 dB.

Discussion

When the detected voltage is referred to the input using Equation (3), (5) or (7) it can be compared with the microphone (or telecoil) voltage and thus with the sound pressure (or magnetic field strength) being amplified by the hearing aid.

The effect of any frequency shaping of the hearing aid circuitry is assumed to take place after detection, and is amplified and filtered identically to the microphone (or telecoil) signal.

Relation between the RF Amplitude to the Input Referred Sound Pressure

Consider Equation (3). The second term gives rise to a detected voltage given by Equations (9) and (11). The first term is proportional to the voltage (microphone or telecoil) being amplified. By equating two terms, the carrier level V_c that produces the same output in the hearing aid as a signal voltage v_m (proportional to the microphone or telecoil voltage) is given by:

$$\textit{For Sinusoidal AM (fundamental only)},\quad v = v_m = \sqrt{2}\Lambda m V_C^2$$
$$\textit{and for Pulsed AM},\qquad v_m = \Lambda\sqrt{d - d^2}\,V_C^2 \tag{15}$$

If there is no signal feedback, then v_m is equal to themic voltage. Given the microphone sensitivity, the carrier voltage may be expressed in terms of an *equivalent detected input sound pressure* using:

$$\textit{For Sinusoidal AM},\qquad V_C = \sqrt{\frac{v_m}{\sqrt{2}\Lambda m}}$$
$$\textit{and for Pulsed AM},\qquad V_C = \sqrt{\frac{v_m}{\Lambda\sqrt{d - d^2}}} \tag{16}$$

A typical microphone gives 1 mV when exposed to a sound pressure of 74 dB SPL, (or 20 μV for 40 dB SPL). The relationship between the radio frequency voltage V_c and the *equivalent detected input sound pressure* is illustrated in Table D.1 under the assumed conditions that the microphone and RF voltages appear on the same transistor input.

Table D.1 Interfering Carrier - Equivalent Detected Input Referred Sound Pressure

Interfering Carrier Voltage (mV RMS)		*Equivalent Detected Input Sound Pressure (dB SPL)**
Sinusoidal Modulation (m = 0.8)	*Pulse Modulation (d = 1/8)*	
0.54	1.00	30
0.96	1.77	40
1.70	3.15	50
3.303	5.61	60
5.39	9.97	70

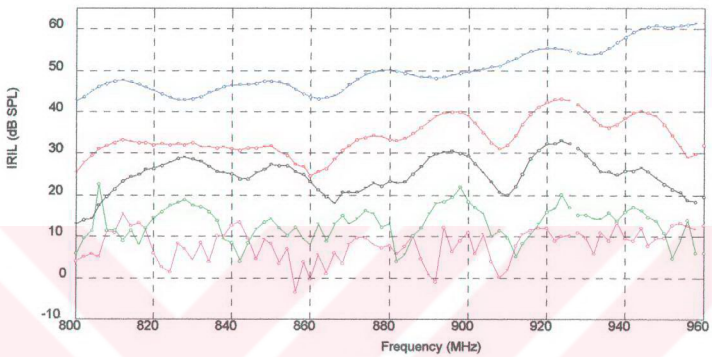
(*) Calculations are for a bipolar transistor amplifier.

APPENDIX G

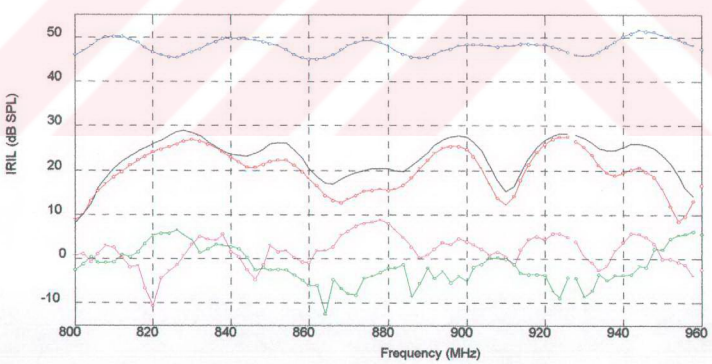
DETAILED TEST RESULTS

Gain at 1 kHz: 57 dB SPL
(with 500 mm tubing)

Noise level for microphone: 39.6 dB SPL
Noise level for telecoil: 28 dB SPL



(a) Microphone



(b) Telecoil

Figure G.1 Interference levels produced in HA 1 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

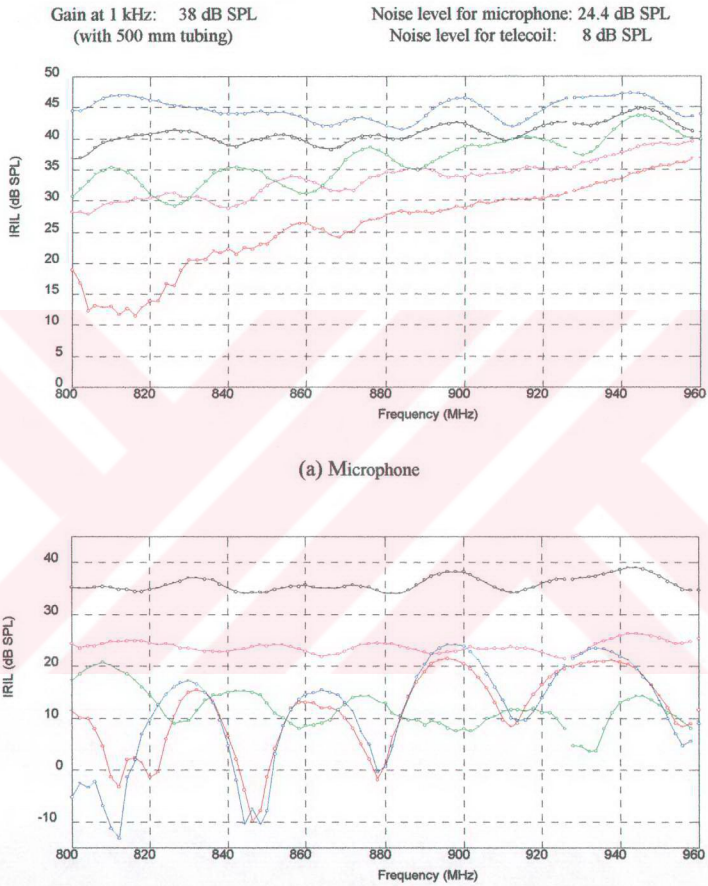


Figure G.2 Interference levels produced in HA 2 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

(Legend: Vertical, 0 degrees, 90 degrees, 180 degrees, 270 degrees)

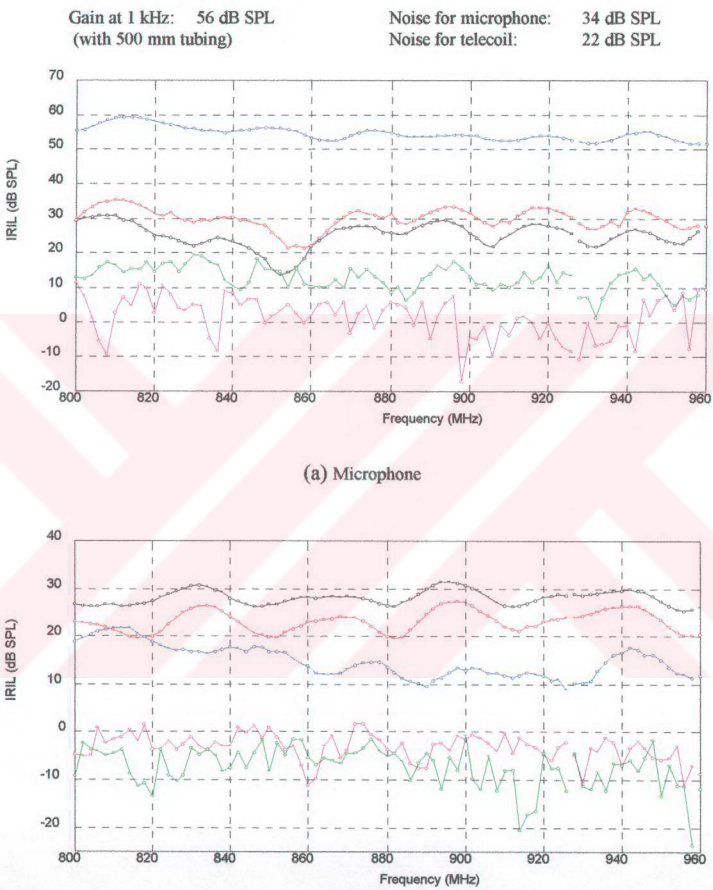
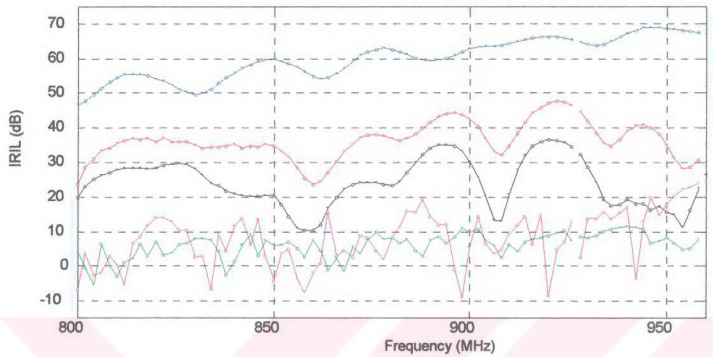


Figure G.3 Interference levels produced in HA 3 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

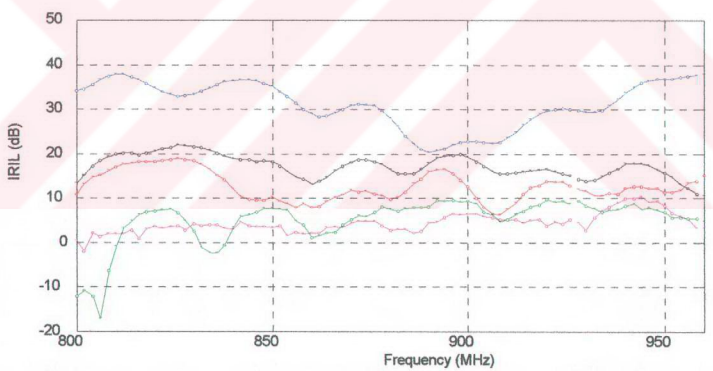
(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

Gain at 1 kHz: 50 dB SPL
(with 500 mm tubing)

Noise for microphone: 37.5 dB SPL
Noise for telecoil: 17 dB SPL



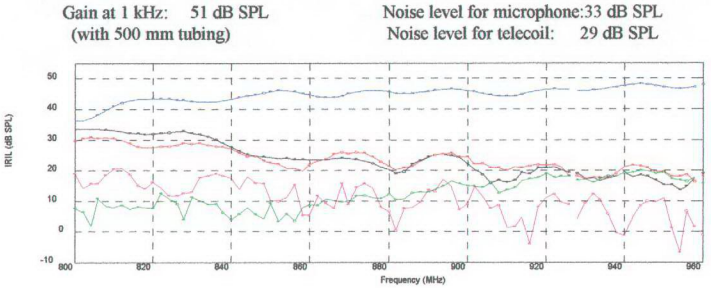
(a) Microphone



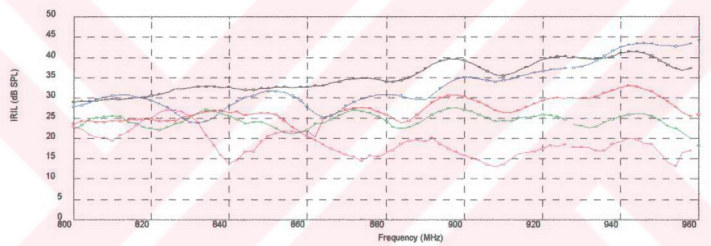
(b) Telecoil

Figure G.4 Interference levels produced in HA 4 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

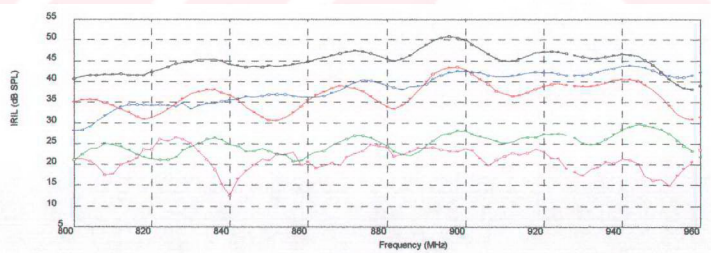
(Legend: Vertical, 0 degrees, 90 degrees, 180 degrees, 270 degrees)



(a) Microphone



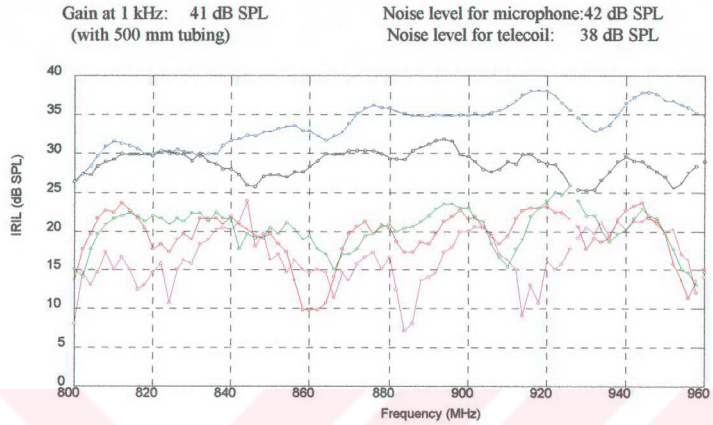
(b) Telecoil



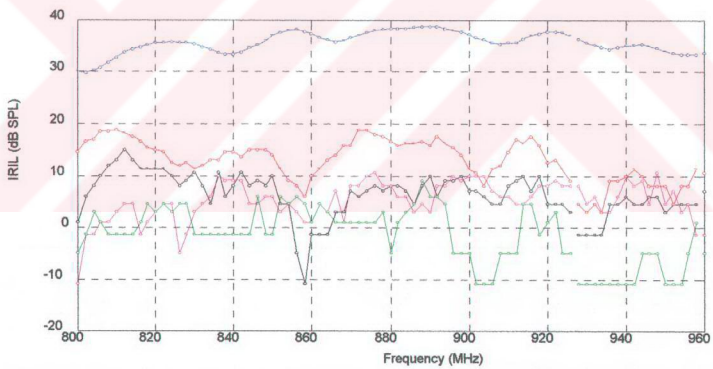
(c) MT

Figure G.5 Interference levels produced in HA 5 for (a) Microphone, (b) Telecoil and (c) MT inputs for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)



(a) Microphone



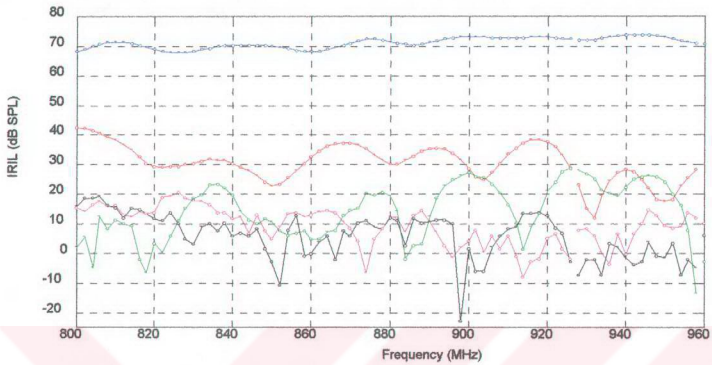
(b) Telecoil

Figure G.6 Interference levels produced in HA 6 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

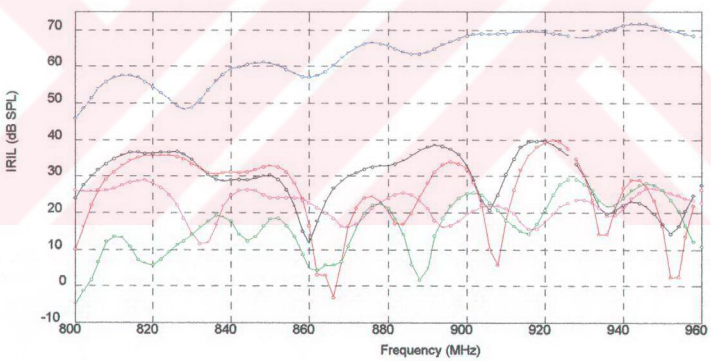
(Legend: Vertical, 0 degrees, 90 degrees, 180 degrees, 270 degrees)

Gain at 1 kHz: 53 dB SPL
(with 500 mm tubing)

Noise for microphone: 58.8 dB SPL
Noise for telecoil: 46.4 dB SPL



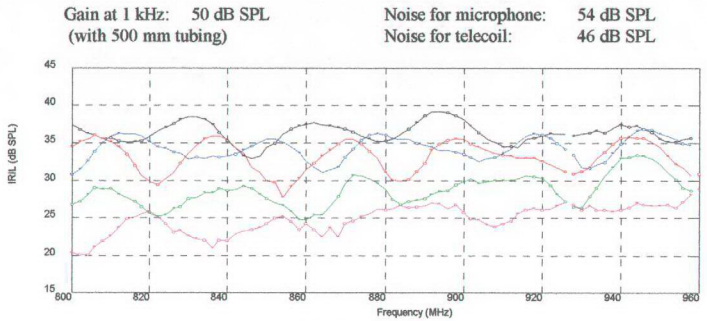
(a) Microphone



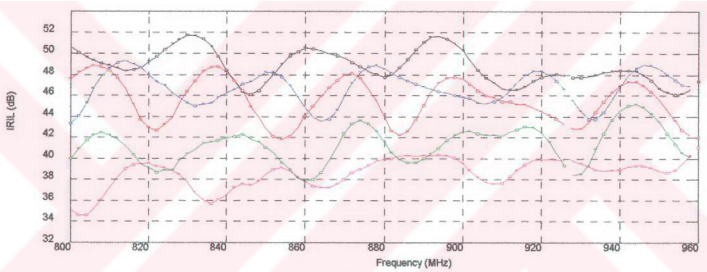
(b) Telecoil

Figure G.7 Interference levels produced in HA 7 for (a) Microphone and (b) Telecoil input for an electric field level of 6.15 V/m

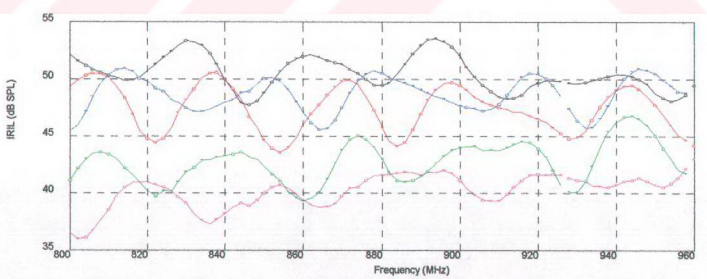
(Legend: Vertical, 0 degrees, 90 degrees, 180 degrees, 270 degrees)



(a) Microphone



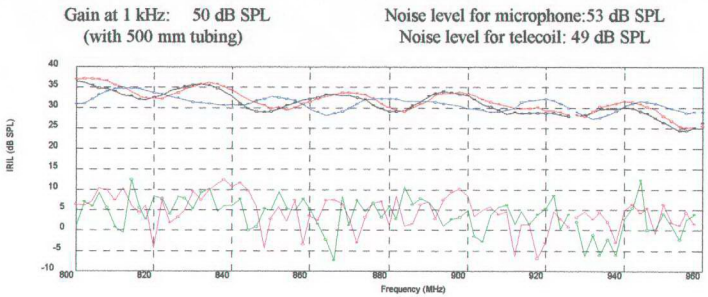
(b) Telecoil



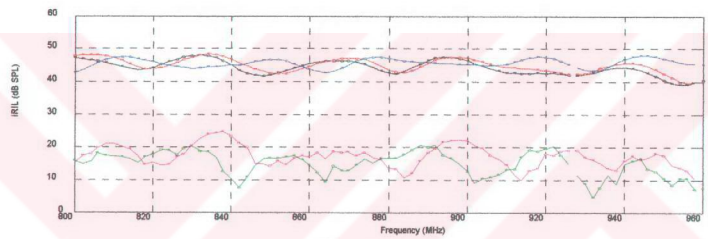
(c) MT

Figure G.8 Interference levels produced in HA 8 for (a) Microphone, (b) Telecoil and (c) MT inputs for an electric field level of 6.15 V/m

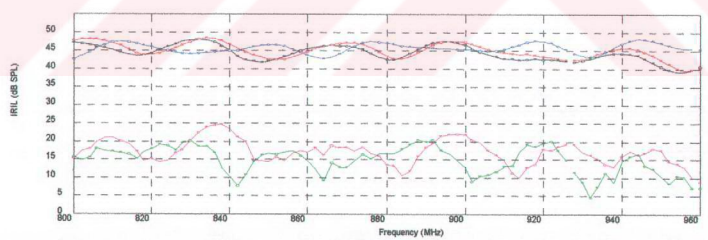
(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)



(a) Microphone



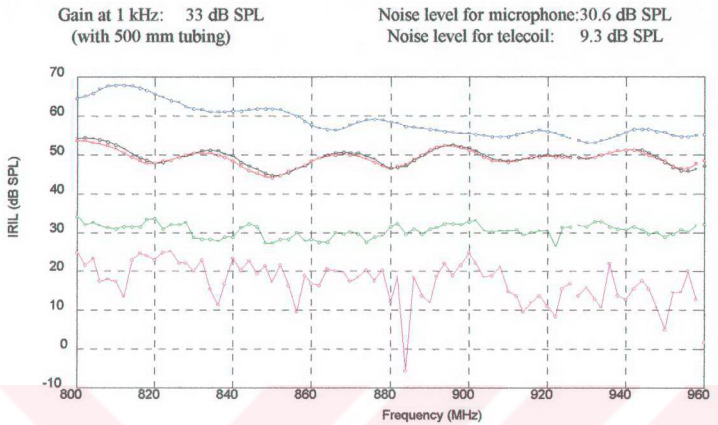
(b) Telecoil



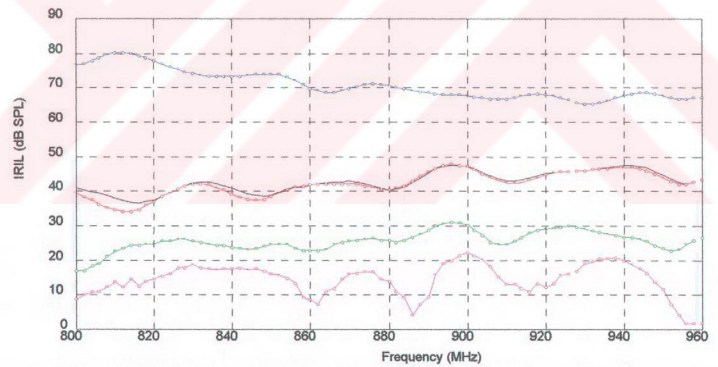
(c) MT

Figure G.9 Interference levels produced in HA 9 for (a) Microphone, (b) Telecoil and (c) MT inputs for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)



(a) Microphone



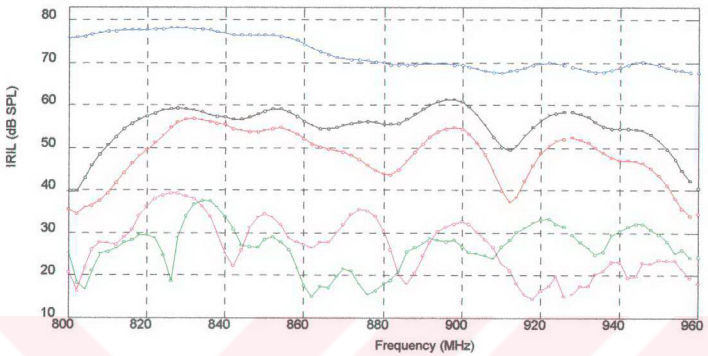
(b) Telecoil

Figure G.10 Interference levels produced in HA 10 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

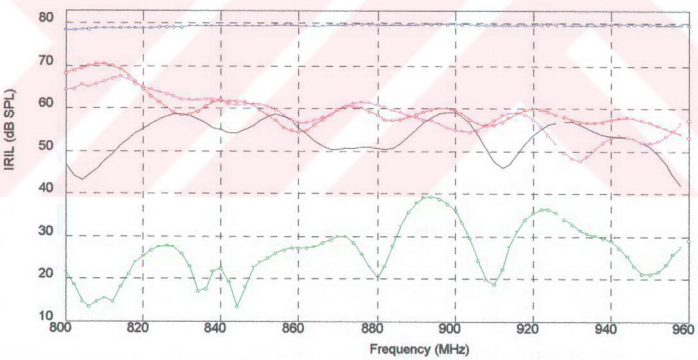
(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

Gain at 1 kHz: 37 dB SPL
(with 500 mm tubing)

Noise level for microphone:49.5 dB SPL
Noise level for telecoil: 40.4 dB SPL



(a) Microphone



(b) Telecoil

Figure G.11 Interference levels produced in HA 11 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

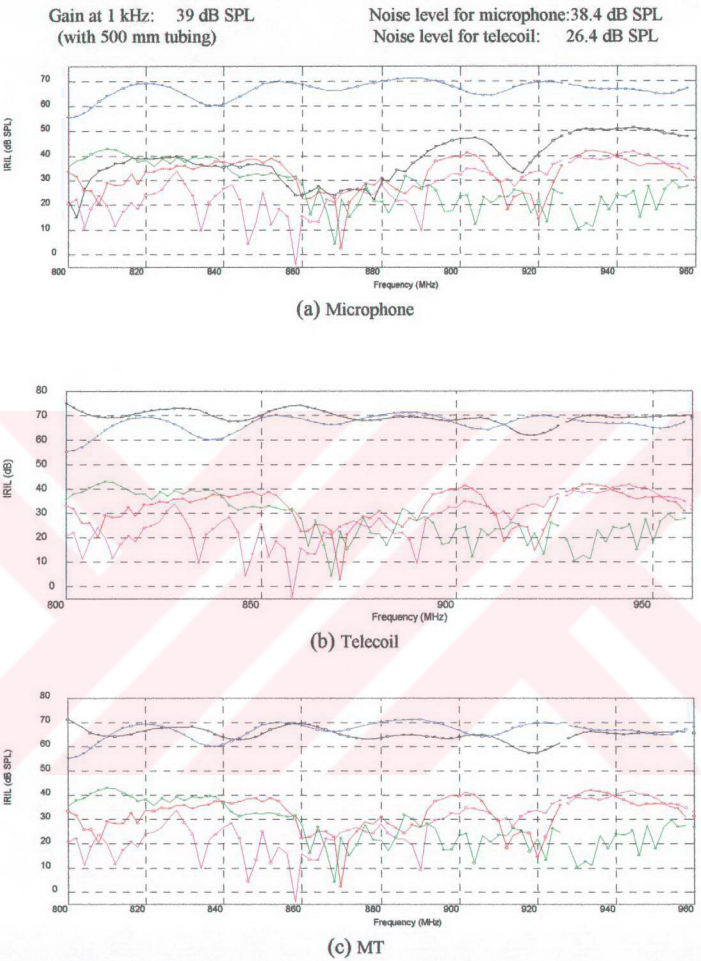


Figure G.12 Interference levels produced in HA 12 for (a) Microphone, (b) Telecoil and (c) MT inputs for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

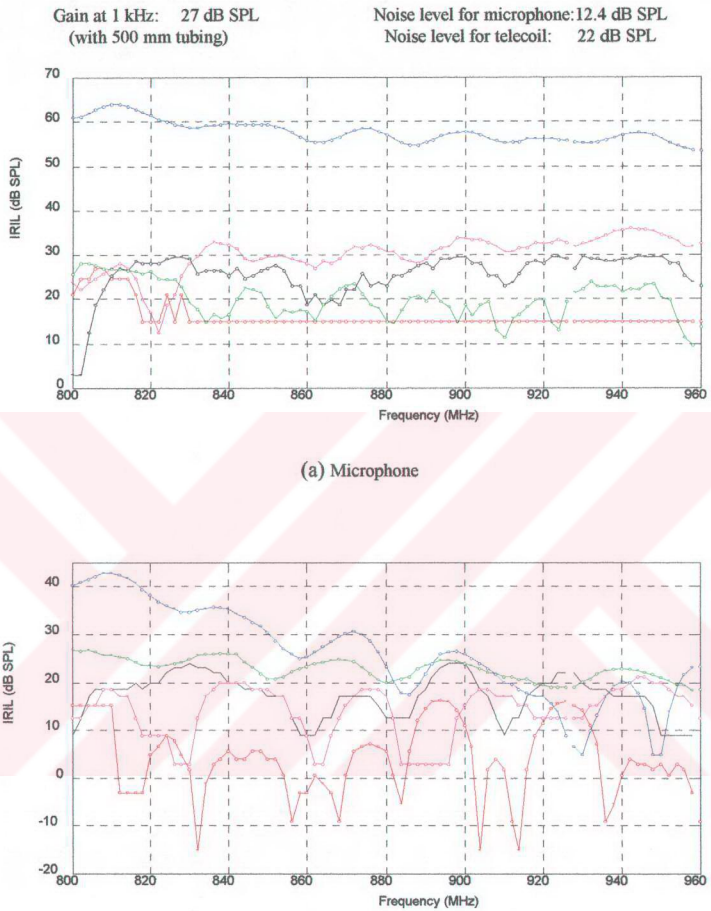
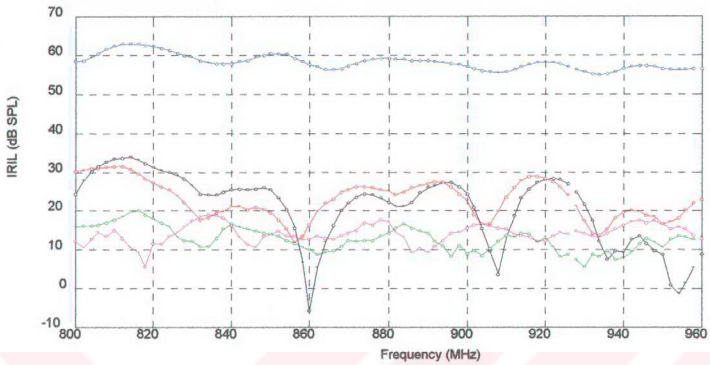


Figure G.13 Interference levels produced in HA 13 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

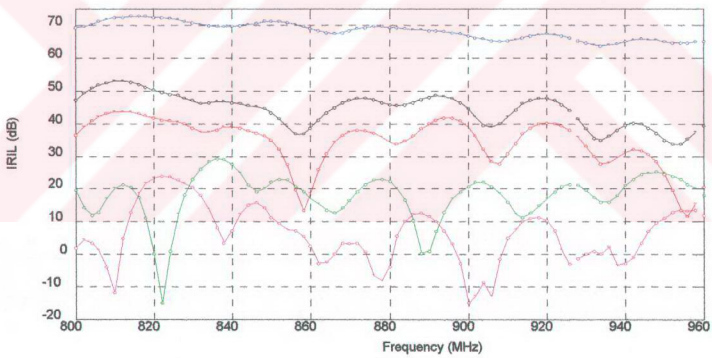
(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

Gain at 1 kHz: 39 dB SPL
(with 500 mm tubing)

Noise for microphone: 26.4 dB SPL
Noise for telecoil: 17 dB SPL



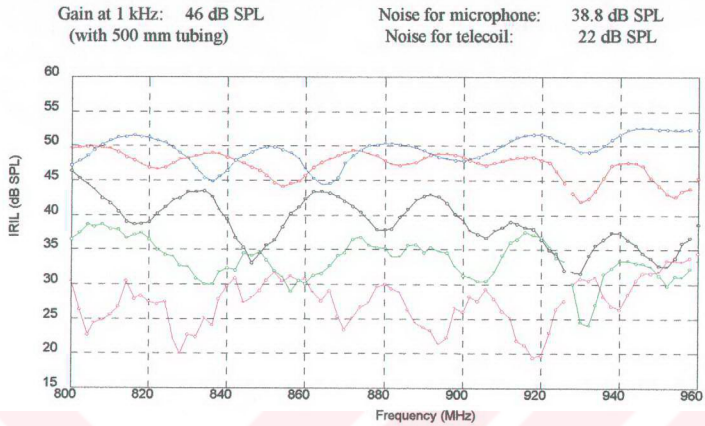
(a) Microphone



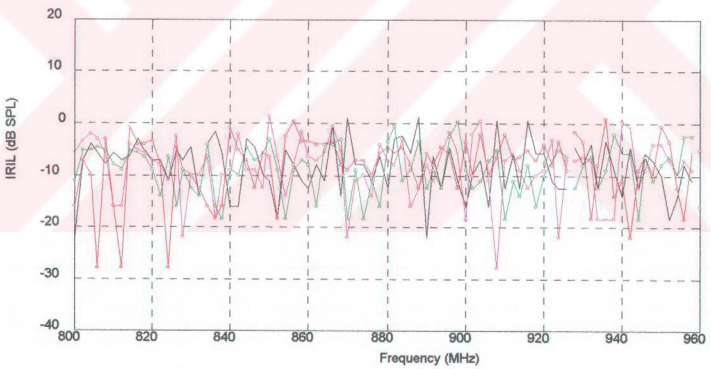
(b) Telecoil

Figure G.14 Interference levels produced in HA 14 for (a) Microphone and (b) Telecoil inputs for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)



(a) Microphone

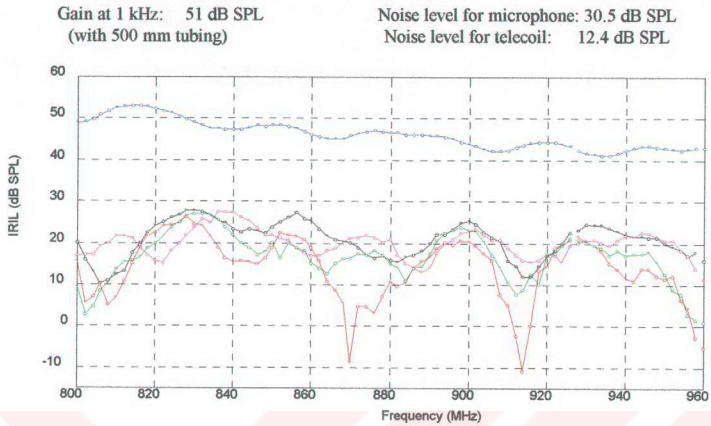


(b) Telecoil

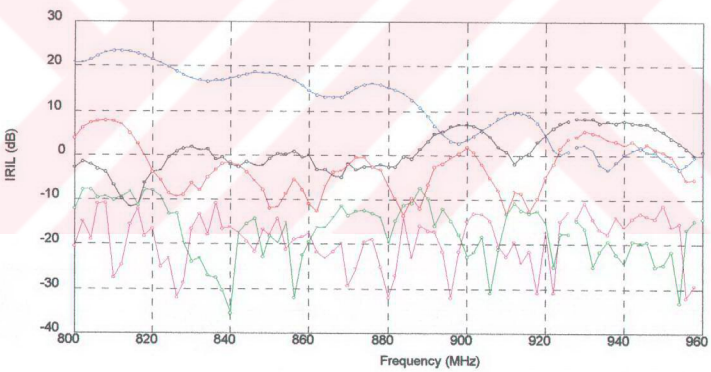
Figure G.15 Interference levels produced in HA 15 for (a) Microphone and (b) Telecoil input for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

(Vertical position for HA 15 was not tested. Human factor in experimentation)



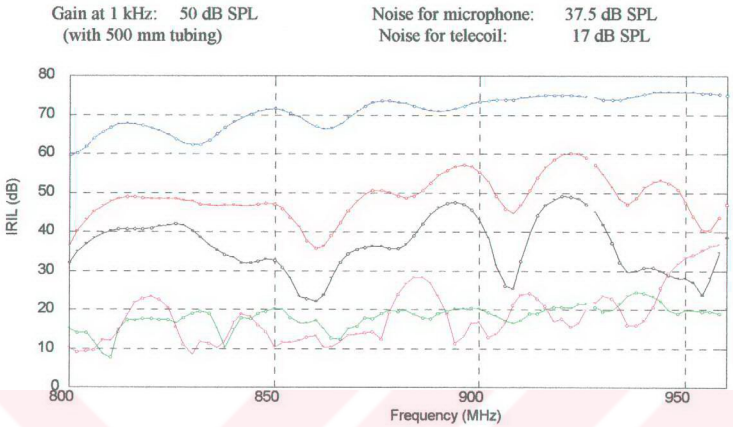
(a) Microphone



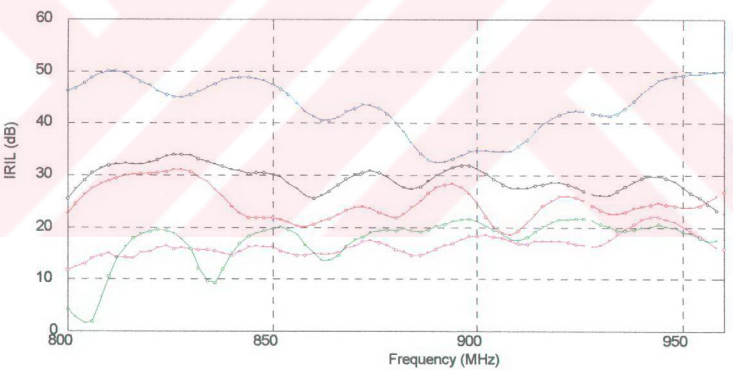
(b) Telecoil

Figure G.16 Interference levels produced in HA 16 (a) for Microphone and (b) Telecoil input for an electric field level of 6.15 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)



(a) Microphone



(b) Telecoil

Figure G.17 Interference levels produced in HA 4 for (a) Microphone and (b) Telecoil inputs for an electric field level of 12.3 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)

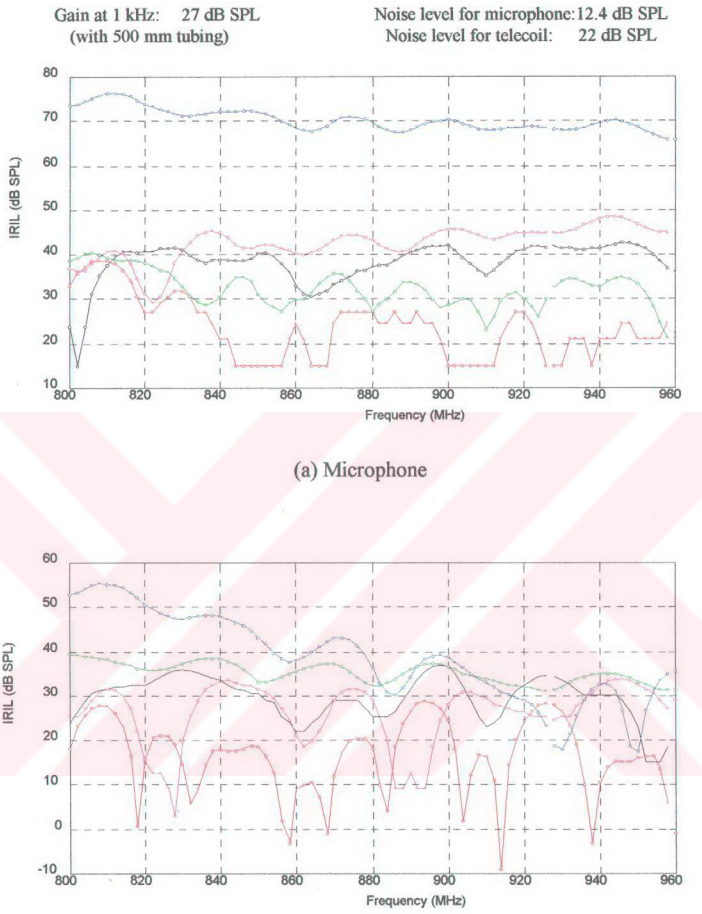
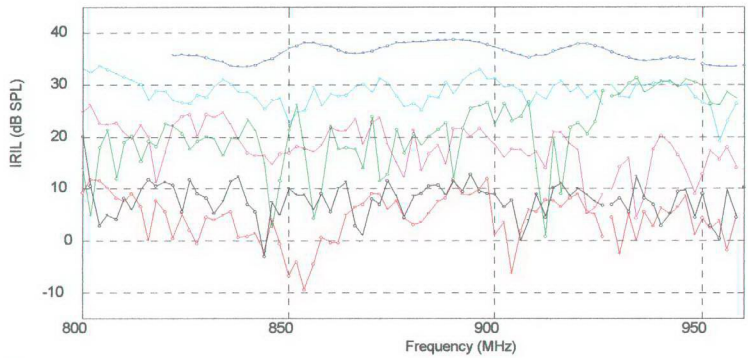


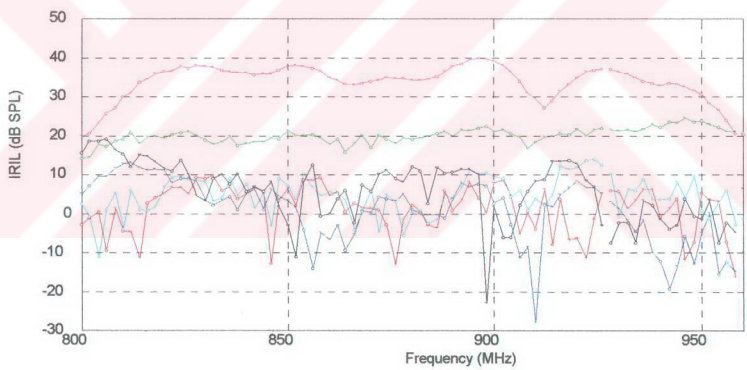
Figure G.18 Interference levels produced in HA 13 for (a) Microphone and (b) Telecoil inputs for an electric field level of 12.3 V/m

(Legend: Vertical 0 degrees 90 degrees 180 degrees 270 degrees)



Group 1

HA 3: red, HA 6: black, HA 10: cyan,
HA 12: green, HA 13: blue, HA 15: magenta

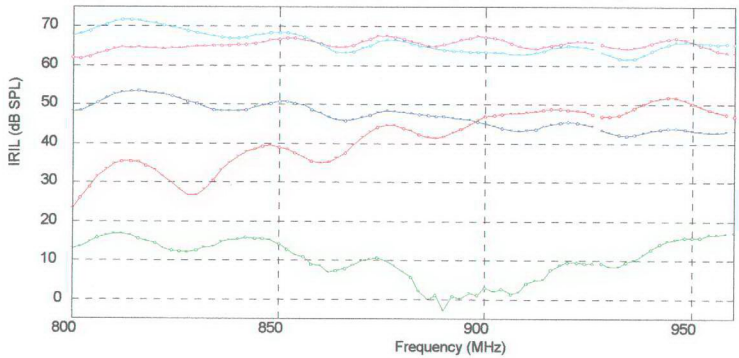


Group 2

HA1: cyan, HA 2: green, HA 7: black,
HA 11: magenta, HA 14: blue, HA 16: red.

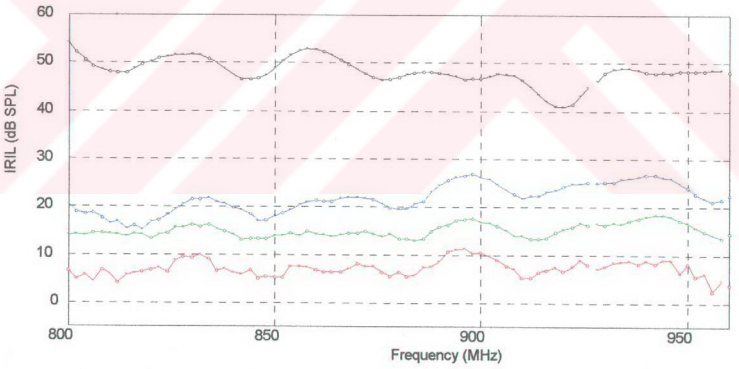
Figure G.19 12 Hearing aids at microphone position and 0 degree orientation with an applied electric field strength of 1.85 V/m.

(Note: 12 hearing aids are grouped in two in order to decrease complexity in graph)



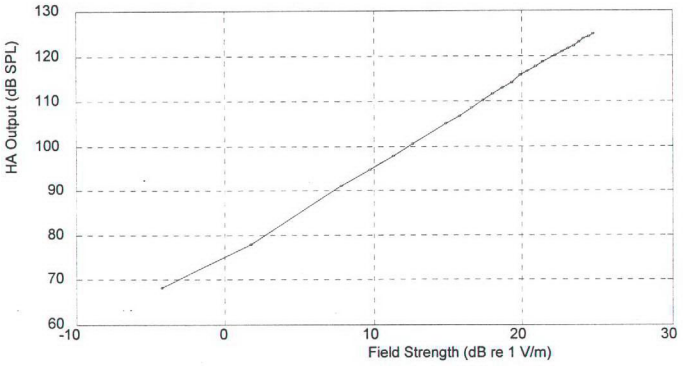
HA 4: blue HA 7: red HA 11: magenta
HA 12: cyan HA 14: blue

Figure G.20 6 Hearing aids at telecoil position and vertical orientation with an applied electric field strength of 1.85 V/m.

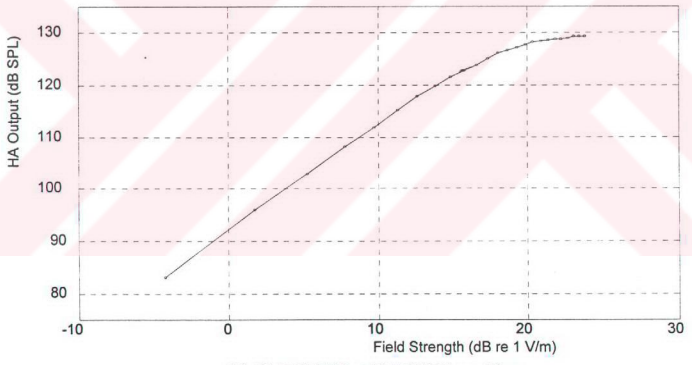


HA 2: green HA 3: red
HA 10: blue HA 12: black

Figure G.21 4 Hearing aids at telecoil position and 0 degree orientation with an applied electric field strength of 1.85 V/m.



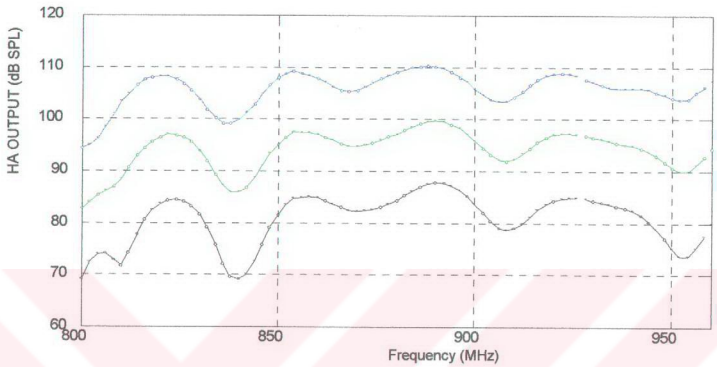
(a) HA TYPE 12 at MICROPHONE position.



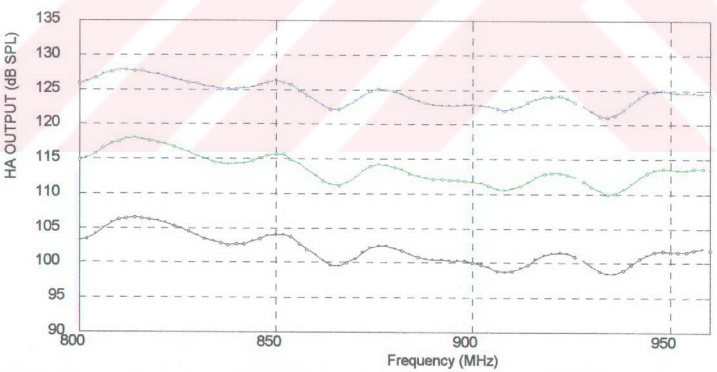
(b) HA TYPE 12 at TELECOIL position.

Figure G.22 Increasing field strength level for HA 12. Carrier Frequency: 900 MHZ

Gain of HA 12 with 25 mm tubing: 55 dB SPL at 1 kHz
51 dB SPL at 2 kHz
52 dB SPL at 4 kHz.



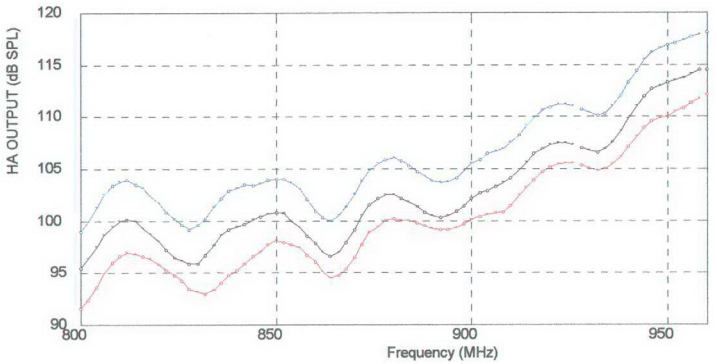
(a) HA 12 at Microphone position



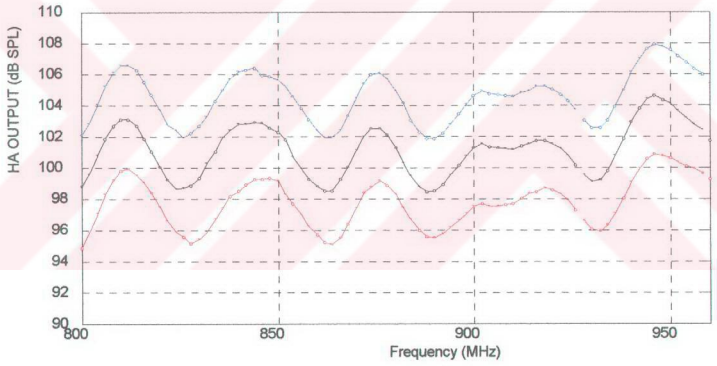
(b) HA 12 at Telecoil position

Legend: Blue: 1 kHz, Green: 2 kHz, Black: 4 kHz

Figure G.23 HA 12 for different modulation frequencies.



(a) HA 1 at Microphone position



(b) HA 1 at Telecoil position

Figure G.24 HA 1 tested for different tube sizes.

(bluc: 500 mm/⌀2 ; **black**: 500 mm/⌀1 ; red:1000 mm/⌀2)

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