Characterization of medical devices electromagnetic immunity to environmental RF fields.

INTRODUCTION

The diffusion of personal communication devices and radio communication systems has strongly increased the electromagnetic field levels in environment. These levels can cause interference on sensitive electronic equipments. Personal use medical devices, like hearing aids, pace makers, infusion pumps are particularly interesting, because they may be used in non clinical environments, where EM field levels are not controlled. Electromagnetic interference produced by RF sources on hearing aids and infusion pumps was evaluated. In this work we present the immunity tests carried out on medical devices, in particular on hearing aids. We spend only some words about tests carried out on infusion pumps, since these tests put in evidence that the tested infusion pumps aren't susceptible to electromagnetic field (at least until to 20-30 V/m electromagnetic fields). All these tests were carried out in a GTEM cell *(giga-hertz transverse electromagnetic mode*), using signals of intensity and modulation comparable to those present in the environment. The purpose of this work is to characterise the interference, establishing immunity threshold for different frequencies and finding out which types of medical devices are more susceptible, and in which frequency range.

METHODS

Experimental setup

Hearing aids

Immunity tests were carried out in a GTEM cell. First working draft for revision of IEC 60118-13 (1999) [1] was utilized as reference for the experimental setup. Experimental setup is given in figure 1.

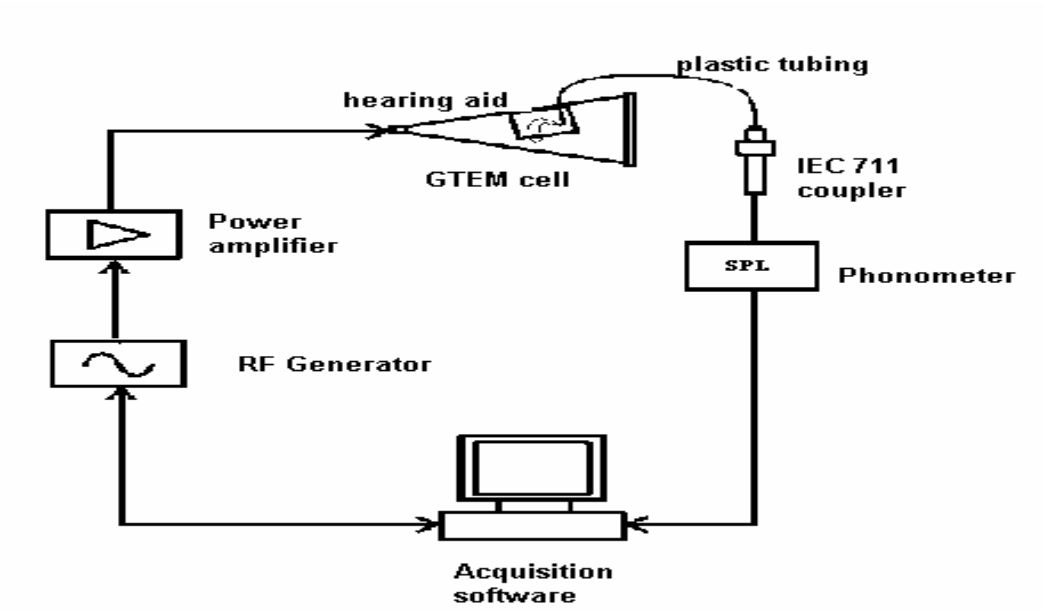

Fig.1 Experimental setup

In order to quantify the immunity level of the hearing aids, IRIL (input related interference level) was used. IRIL is the sound pressure level that, in input at the hearing aid, produces an output pressure level with the same intensity to that of measured signal, when the hearing aid is exposed to an EM field. IRIL is found by subtracting the acoustic gain of the hearing aid at 1 kHz from the interference level produced at the hearing aid output, at 1 kHz, because of EM field exposure.

The sound pressure level produced at the hearing aid output was measured by a phonometer kept out from the cell. An IEC711 2cc coupler and a 1 meter long plastic tubing of 2 mm inner diameter were used to connect the hearing aid to the microphone of phonometer. In particular the tubing was used to keep the coupler and the microphone out from the cell, because they are metallic and could distort the EM field generated inside the cell. The length of the tubing wasn't critical, because the hearing aid gain had to be measured in the test configuration. The EM field was generated by a RF generator and amplified by a power amplifier connected to the cell.

The EM field exposure values were measured using a sensor that was placed in the same point where hearing aid was kept during the tests.

The tests were conducted with hearing aids in microphone (M) mode of operation.

Infusion pumps

Immunity tests were carried out in a GTEM cell. The experimental setup was the same used for tests on hearing aids, unless the phonometer was replaced by an oscilloscope or by a video camera (but the video camera was put inside the cell), according to the method used to evaluate the electromagnetic immunity of infusion pumps. In some case some parameters could be defined, like the alimentation tension of motor that pilots the cart that pushes the syringe or the cart advancement. The parameter choice depends on the infusion pump kind. When a parameter could not be defined, the pump was monitored with a video camera during the tests, to notice possible malfunctions (such as alarms on display).

Exposure conditions

Hearing aids

80% amplitude modulated with a 1 kHz sine wave signals were used for testing hearing aids (as specified in IEC 61000-4-3 [2]). GSM and DCS signals were also used (although these tests are not provided for by normative in force). Although testing in the frequency range below 800 MHz is not considered necessary by the IEC 60118-13, the hearing aids were also tested on the radio and TV transmission range, because of the high EM field levels that are emitted by radio and TV signals sources and that may be found in the environment. Just AM signals were used, because FM signals don't cause interference on hearing aids (as it was verified).

The exposure conditions are given in table 1. The maximum reported test level is subordinated to the performances of the used amplifiers.

Source	Frequency range	Frequency step size	Test levels (V/m)
AM Radio			
Long wave	150-285 kHz	5%	1-2-3-5-10-15-20-25-30
Medium wave	525-1605 kHz	5%	1-2-3-5-10-15-20-25-30
Short wave	2-26 MHz	10%	1-2-3-5-10-15-20-25-30
TV			
VHF	47-230 MHz	1%	1-2-3-5-10-15-20-25-30
UHF	470-862 MHz	1%	1-2-3-5-10-15-20-25-30
Frequencies in accordance to IEC 60118-13			
Wireless digital phone	800-3000MHz	1%	1-2-3-5-10-15-20-25-30-35-40-45-50-55

Table 1. Exposure conditions

For each frequency and for each test level, the hearing aid was placed in the reference orientation (hearing aid microphone in front of the RF emitting source) and then rotated in steps of 90° in the horizontal plane around the vertical axis. For each orientation and for each test level, the carrier frequency was changed using the step size given in the table. The IRIL determination was carried out at the orientation where interference was maximum.

Infusion pumps

The same exposure conditions were used, unless the maximum tested level was always 30 V/m and only some frequencies were tested for each frequency range (usually 3), because of the long times necessary to test a infusion pump.

Requirements for immunity

Hearing aids

In order to be considered immune to an EM field, a hearing aid must have an IRIL below 55 dB, when the hearing aid is exposed to the field. The EM field levels, which hearing aid should be immune to, are established in the draft version of IEC 60118-13. Those levels are established like E_{55} values. E_{55} is the unmodulated carrier field value where the hearing aid reaches an IRIL of 55 dB. Increasing values of E_{55} indicate increasing immunity.

In order to be usable with a digital wireless device, a hearing aid has to be immune to 75 V/m EM fields in the 0.8 – 0.96 MHz frequency range and to 55 V/m EM fields in the 1.4 – 2 MHz frequency range [2].

Infusion pumps

CEI EN 60601-2-24 [7] was used as reference: infusion pumps must be immune to electromagnetic field of intensity at least 10V/m.

Test procedures

Hearing aids

For each expositive condition (see table 1) the IRIL was measured and the EM field value where IRIL reached 55 dB was determined.

Figure 2 shows the interference levels produced in an analogical hearing aid in M-mode in the 0.8 – 3 GHz frequency range for different EM field test levels. The E_{55} value is 3V/m, since IRIL reaches 55 dB in a 5V/m EM field.

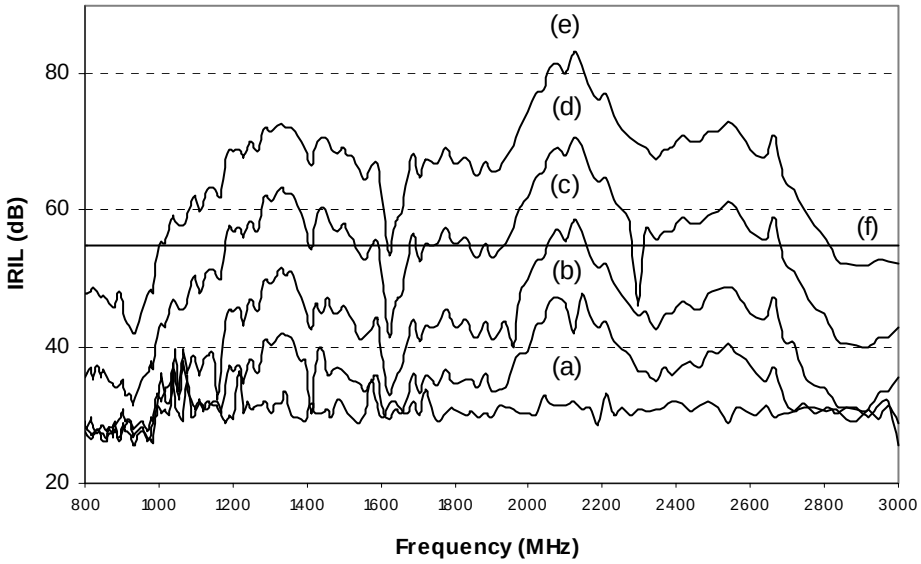

Figure 2. Sample of hearing aid electromagnetic immunity valuation: interference levels produced in an analogical hearing aid by different values of electrical field; (a) 1 V/m, (b) 3V/m, (c) 5V/m, (d) 10V/m, (e) 20 V/m, (f) limit

Infusion pumps.

For each expositive condition, one or more parameters defined for the pump under test were measured and confronted with the same measured when the pump wasn't exposed to electromagnetic fields, to notice possible differences. Alternately the pump was monitored with a video camera (to notice possible alarms on display).

RESULTS E CONCLUSIONS

Hearing aids

The immunity tests were conducted on 4 analogical and 3 digital hearing aids.

The obtained results may be summarized as follows:

- Hearing aids are generally susceptible to AM and GSM signals, while they are practically immune to unmodulated and FM signals. In fact to difference of the FM signals or the unmodulated ones, that have constant amplitude in the time, amplitude modulation causes interference because the semiconductor junctions in the circuitry of hearing aids demodulate the input signal and produce a noise with the same frequency of the modulating signal. About GSM signal, the TDMA modulation results in the transmitter carrier being switched on and off at a rate of 217 Hz. This in effect causes an AM modulation of the carrier at this frequency. In the same way, therefore, this signal is demodulated by the circuitry of hearing aid and an audible 217 Hz buzz in the signal path is produced. In figure 3 E_{55} values are shown for tested hearing aids. They were obtained in accordance with [2], using AM signals: some hearing aids are susceptible to AM signals already for field values of some V/m and just one hearing aid could be

considered usable with a digital wireless device (the hearing aid number 7 that is immune to the maximum tested EM field level).

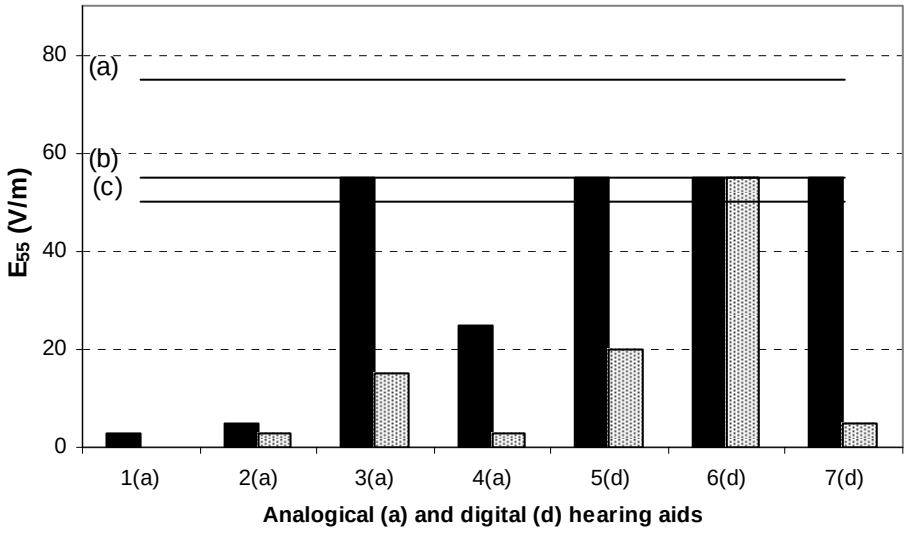

Figure 3. E_{55} values and immunity requirements in M-mode; (a) requirements for immunity - 800-960 MHz, (b) maximum tested level, (c) requirements for immunity - 1400-2000 MHz; ■ E_{55} values - 800-960 MHz; ▨ E_{55} values - 1400-2000 MHz

- E_{55} medium values are shown in figure 4 for analogical and digital hearing aids for AM and GSM signals. The interference was evaluated at 1 kHz, in accordance with [2]. Since AM signals modulating frequency is 1 kHz, hearing aids are naturally more susceptible to AM signals than to GSM signals, at 1 kHz. Really, while the interference to AM signals is essentially shown to 1 kHz, (and upper harmonics in the case of signal distortions), the interference to GSM signals expands on all the frequency spectrum, as is shown in figures 5a) and 5b).

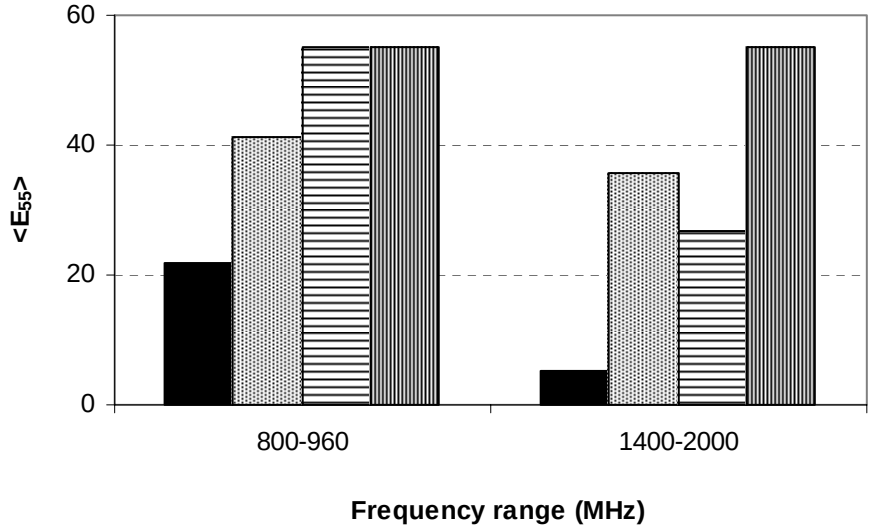

Figure 4. E_{55} medium values: ■ AM signals and analogical hearing aids, ▨ GSM signals and analogical hearing aids; ⊟ AM signals and digital hearing aids; ▥ GSM signals and digital hearing aids

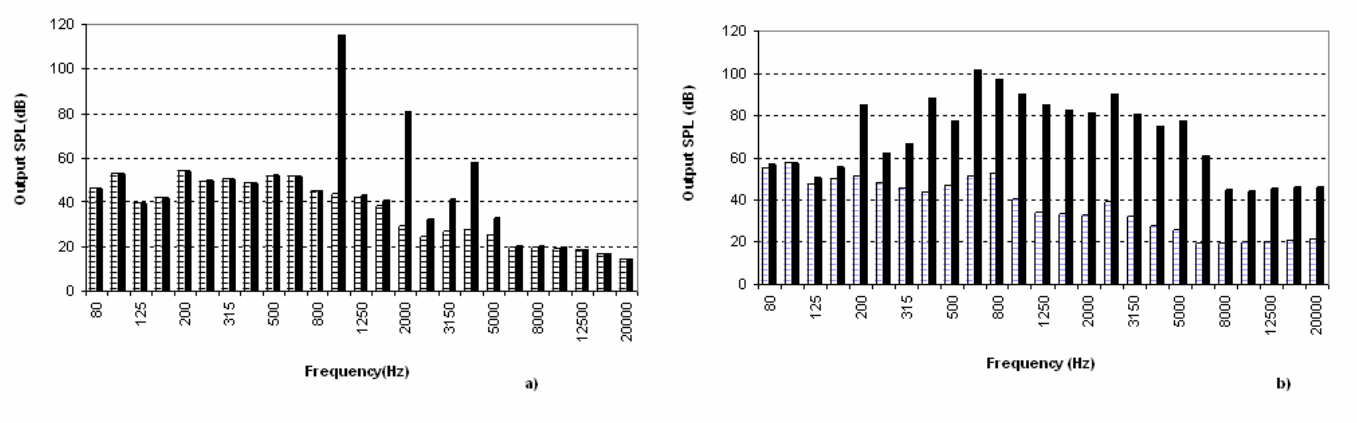

Figure 5. Sound pressure level spectrum in output from the hearing aid: ⊟ in absence of EM field■ in a 40 V/m EM field (a: AM b:GSM)

- E_{55} measured values are shown in figures 6 for the 7 tested hearing aids in the TV and radio transmission range: also EM fields in the frequency range below 0.8 GHz may cause interference on hearing aids. However hearing aids are more susceptible to electromagnetic fields in the 0.8-3 GHz range than in the TV and Radio transmission range (fig.3 and fig.7). This stronger interference could be due to the higher frequency. In fact when the frequency rises, the wave length decreases and the electrical connections in the circuitry are more electrically coupled and so more susceptible.

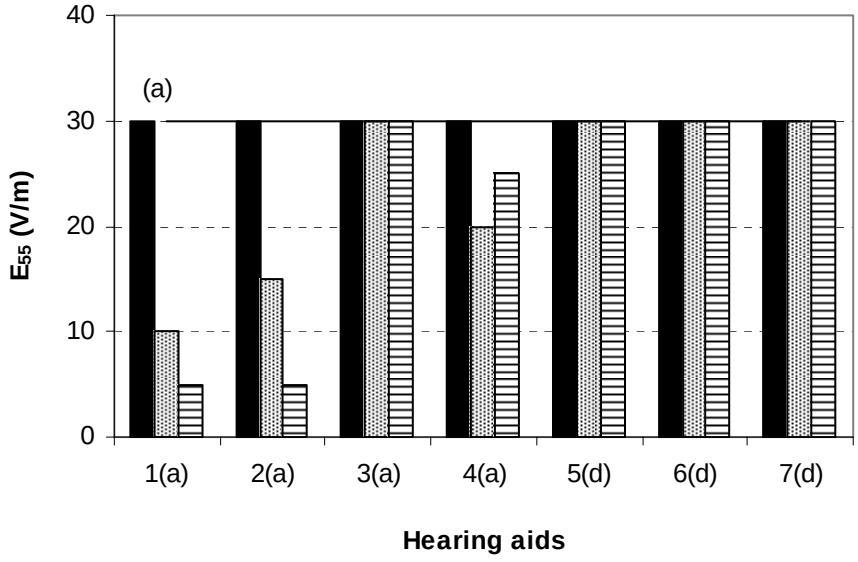

Figure 6. E_{55} values in TV and AM radio transmission range in M-mode; (a) maximum tested level, ■ AM radio, ▩ VHF, ⊟UHF

- Digital hearing aids are usually more immune to EM fields than analogical ones. In fact the analogical signal in output from the digital hearing aid microphone is converted to digital signal. So, after the conversion, the signal is naturally less susceptible to external signals.

- Although just a hearing aid could be considered usable with a digital wireless device, the most of the tested hearing aids (5 at least) can be considered sufficiently immune to signals of intensity and modulation comparable to those usually present in the environment.

Infusion pumps

6 different kind infusion pumps were tested: no pumps resulted susceptible to electromagnetic fields.

ACKNOWLEDGEMENT

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REFERENCE

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