EXPOSURE AT UMTS ELECTROMAGNETIC FIELDS: STUDY ON POTENTIAL ADVERSE EFFECTS ON HEARING

EMFnEAR

INTERIM REPORT

Annex A

December 15, 2004 – March 15, 2006

EMFnEAR

EXPOSURE AT UMTS ELECTROMAGNETIC FIELDS: STUDY ON POTENTIAL ADVERSE EFFECTS ON HEARING

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THE UMTS PHONE

In the last decade the European public concern was growing on the potential adverse health effects due to the use of mobile phones. Their use and any consequent biological effect and/or health risk cannot be reduced to an issue of personal lifestyle but involves the whole population, and should be considered as a high-priority environmental health issue.

The research on the effects of exposure to the cellular phones non-ionizing radiation is already well established in Europe, but it is well known that also very small changes in frequency and modulation strongly influence the effects of the exposure to electromagnetic fields of any type.

Europe is now facing a new era in mobile telecommunication, due to the introduction of the Universal Mobile Telecommunications System (UMTS), a key member of the "global family" of the 3G mobile technologies, the natural evolution of the GSM networks.

Research on the effects of UMTS exposure is at its very early stage, and no systematic research project is addressing this emerging health problem. Europe needs to be aware of potential problems and risks arising from this new emerging communication technology at the earliest possible time, to take appropriate steps to address them

THE PROJECT

EMFnEAR is an exploratory project with an anticipatory function which addresses the study of the potential health effects of UMTS phones on the hearing system of animals and humans.

The EMFnEAR results will represent the first international and European statement about this type of hazards for hearing

THE CONSORTIUM

EMFnEAR will involve centres with experience of investigation of EMF biological effects and development of related technology, clinically oriented centres, and one centre with expertise in biological and biomedical data processing and statistical analysis.

The EMFnEAR consortium is practically the same of EC FP5 project GUARD, with the inclusion of one additional partner. This will assure the required skills and expertise and the already established capability in network cooperation.

EMFnEAR aims at reducing key uncertainties and areas of ignorance on the exposure of the whole population to this new type of microwaves, which could lead to potential problems and risks of society concern.

Exposure at UMTS electromagnetic fields: Study on potential adverse effects on hearing

EMFNEAR Project
G.A. # 2004127

Report on the systems for UMTS exposure
Deliverable D2.1

Device for animal exposure
Deliverable D2.2

(Working Package 2)

Responsible Partner: ENEA-BIOTEC

Involved teams: ENEA.BIOTEC, CNR.ISIB, NIRR

INTRODUCTION AND PARTICIPANTS

The aim of EMF Near is to assess potential health effects of UMTS cellular phones on the hearing system of animals and humans. The project involves studies of laboratory animals and humans. This document includes the reports about the activities scheduled in the WP2, whose Lead Partner is ENEA.BIOTEC and the partner involved is CNR.ISIB, NIRR. WP2 was devoted to the *Design, development and manufacturing of localized exposure systems* both for animal (ENEA.BIOTEC) and human (CNR.ISIB.NIRR) experiments.

THE UMTS SIGNAL

Different techniques are used to manage the shared access of the users to the network (Fig.1). The 1st generation systems (TACS) used the FDMA (Frequency Division Multiple Access) where the assigned frequency band is divided in channels centred on a carrier frequency: for each user there is a frequency that is maintained during all the conversation.

The 2nd generation systems (GSM) use the TDMA/FDMA (Time Division Multiple Access/ Frequency Division Multiple Access) where each channel (frequency band 200 kHz) is divided in time slots (0.5477 ms) in order to manage up to eight users simultaneously on the same carrier.

The 3rd generation systems (UMTS) use the CDMA (Code Division Multiple Access) where every user is allocated the entire spectrum all the time, in this case codes are used to identify connections.
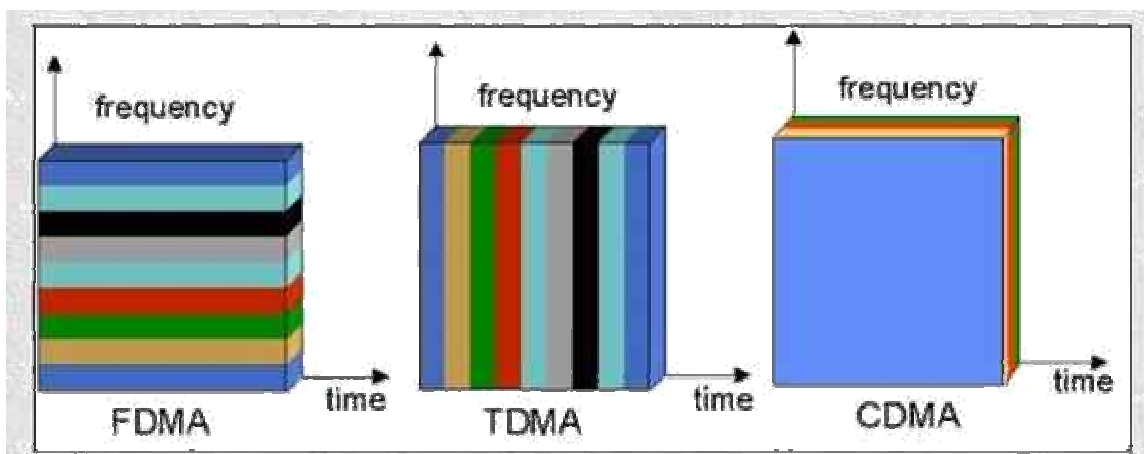

Fig.1. Techniques used in mobile phone connection

CDMA uses unique spreading codes to spread the baseband data before transmission (Fig.2). The signal is transmitted in a channel, which is below noise level. The receiver then uses a correlator to despread the wanted signal, which is passed through a narrow bandpass filter. Unwanted signals will not be despread and will not pass through the filter. Codes take the form of a carefully designed one/zero sequence produced at a much higher rate than that of the baseband data. CDMA codes are not required to provide call security, but create a uniqueness to enable call identification. Codes should not correlate to other codes or time shifted version of itself. Spreading codes are noise like pseudo-random codes, channel codes are designed for maximum separation from each other and cell identification codes are balanced not to correlate to other codes of itself

The signal that results from the spreading operation is a wide-band signal (5MHz band) (Fig.3). The up-link band is 1920-1980 MHz and the down-link band is 2010-2025 MHz.
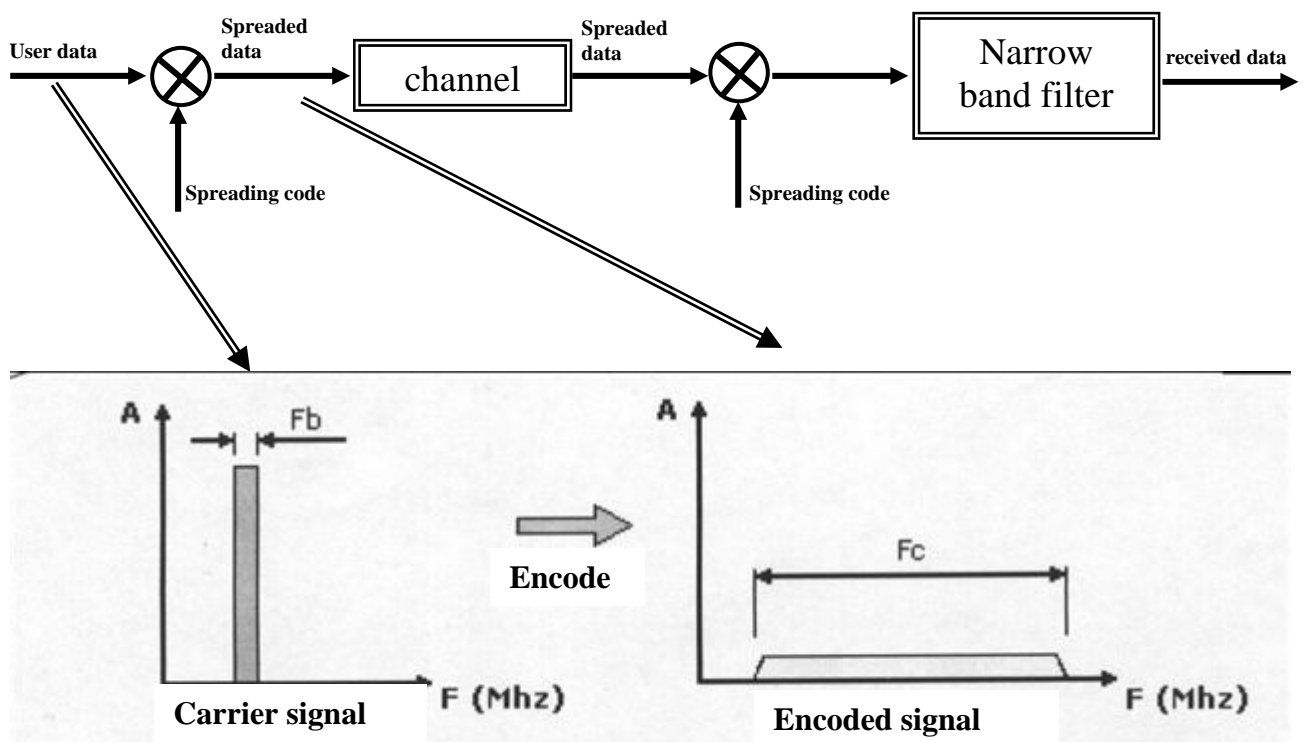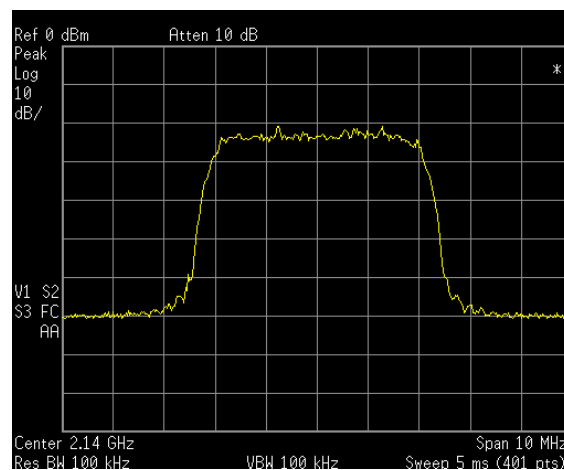
Fig.2.Scheme of the realization of CDMA

Fig.3.Spectrum of the UMTS

CDMA is interference limited multiple access system. Because all users transmit on the same frequency, internal interference generated by the system is the most significant factor in determining system capacity and call quality. The transmit power for each user must be reduced to **limit interference**, however, the power should be enough to maintain the required signal to noise ratio for a satisfactory **call quality**. For this reason a fast power control (1500 controls in a second) has been implemented on these systems in order to limit transmitted power on both the links while maintaining link quality under all conditions. Additional advantages are longer mobile battery life and longer life span of BTS power amplifiers.

In conclusion the UMTS is very different from the other signals used in mobile phone technology, not only in frequency but, overall, in its intrinsic characteristics, for this reason it represents a new issue in determining the possible effects of electromagnetic field on biological systems.

DEVICES FOR ANIMAL EXPOSURE

Exposure set-up

Loop antennas have been chosen as the source for localised exposure. This kind of antenna easily allows a local exposure of small parts of rats like brain or auditory system.

The antennas were built by using the coplanar line technique on dielectric substrate; the line is terminated with a rectangular loop printed on the substrate. Electromagnetic matching with the power supply and dissipative structures is done using an electric contact sliding on the substrate. The near field of such a loop simulates the localized exposure of the human head exposed to a cellular phone.

-   The loop antenna operating (see Fig.4) at UMTS uplink frequency ranges (1920-1980 MHz) were developed by the Bioelecromagnetic lab of ENEA, Rome [1].
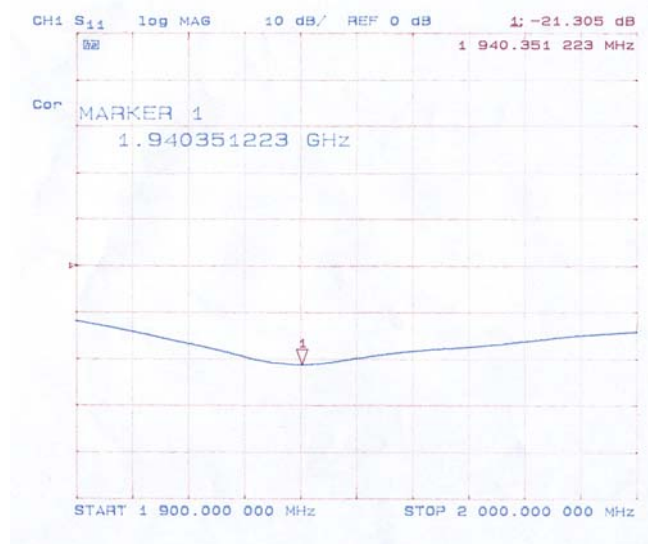

Fig.4. S11 curves of an array of four loop antennas

-   The exposure setup (Fig. 5b) consists of a wooden rack with three distinct arrays of four loop antennas (Fig. 5c) positioned at different levels. RF absorbing panels are inserted between the levels (and on three sides of the wooden rack) to avoid interference signals involving the animals. The arrays are able to work simultaneously: two are supplied for real exposure and the third one for sham exposure, so that 8 exposed and 4 sham rats can be investigated at the same time.
-   The scheme of the exposure system is showed in Fig.6. The UMTS signal is supplied by a commercial UMTS phone (MOTOROLA C975) whose frequency and emitted power can be set by means of an USB Cable and a particular software that MOTOROLA placed at disposal of our Laboratory for this project.
-   A two channel divider feeds two levels simultaneously, a black box assures the blind procedure hiding RF connections for all operators involved in rats handling procedures (exposure and DPOAE tests). Two four channel dividers feed the eight loops in the arrays.

- During the exposure periods, the rats are restrained in single plastic jigs with minimal stress. Temperature is measured by the fiberoptic sensor of an electronic thermometer (LUXTRON or FISO). Temperature and power are monitored during the exposures and data collected in a file.
- Each antenna is held perpendicular to the head surface over the left ear of rats in contact with the external side of the plastic jig, with a total distance from the cochlea system of about 8-10 mm (about 5 mm due to the plastic jig and about 5 mm due to the position of the cochlea with respect to the head surface).
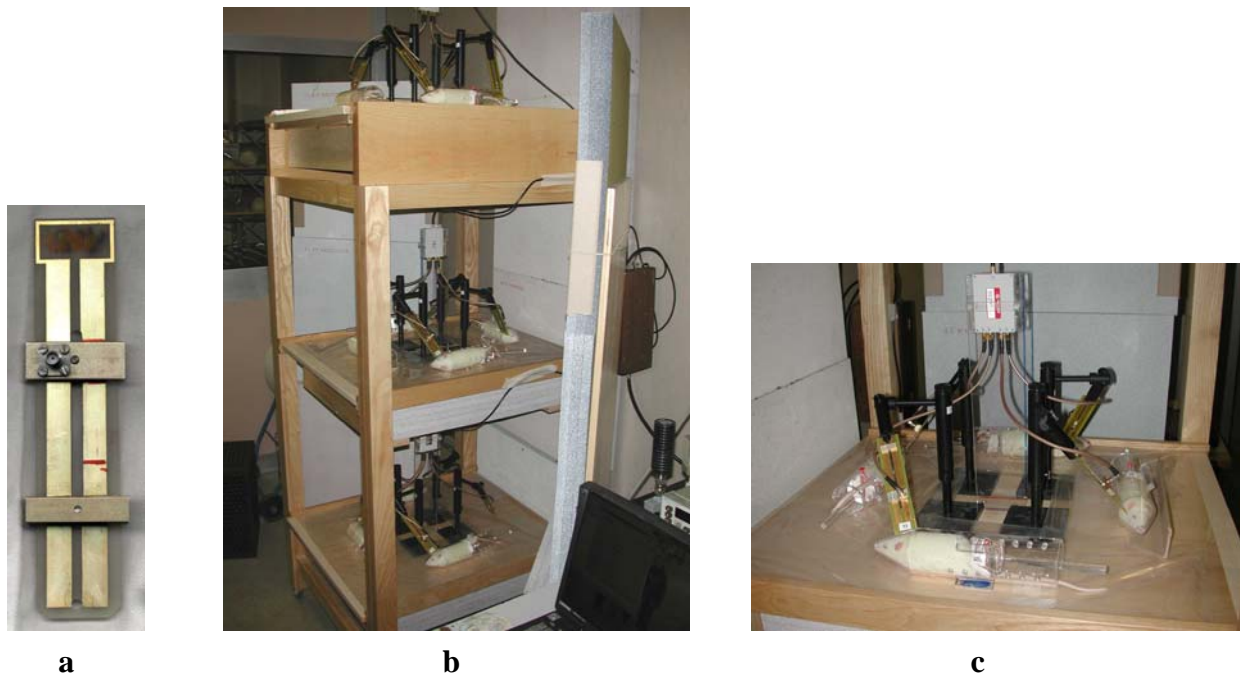

a　　　　　　　**b**　　　　　　　**c**

Fig. 5: a) the loop antenna, b) the exposure set up with the three loop arrays and the foam panels, c) one loop array:
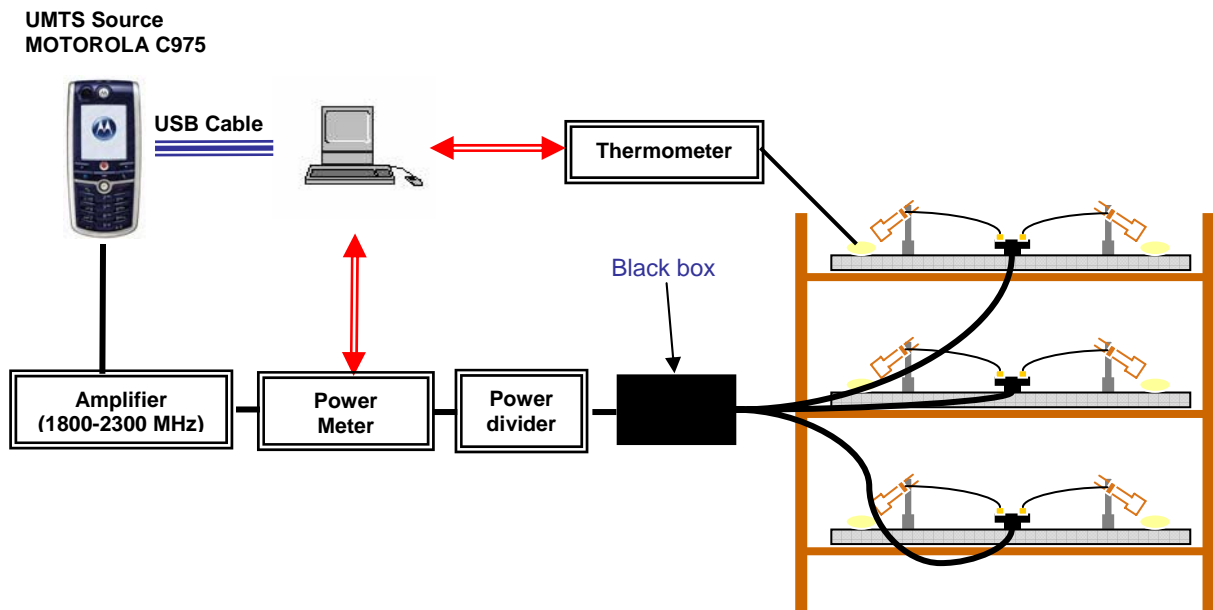

Fig. 6: scheme of the exposure system

Dosimetry

- The experimental dosimetry has been performed in a first step on tissue-equivalent phantom by power-pulse method, measuring the increase of temperature due to a 30 s RF power pulse. The Luxtron fiber optic probe (Fig.7) has been used for these measurements that has been then verified on a just sacrificed rat.
- The real efficiency of the antenna (4.5 ± 1 W/kg/W_{in}) is determined in phantom at 5 mm depth and in rat cadaver into the cochlea and compared with numerical results.
- Numerical dosimetry is performed by an XFDTD code (Fig.8) using a model of rat head with loop antenna positioned at 5 mm from the head surface [2]. The realistic model of rat head has been described with the five fundamental tissues (skin, fat, muscle, brain, bone).
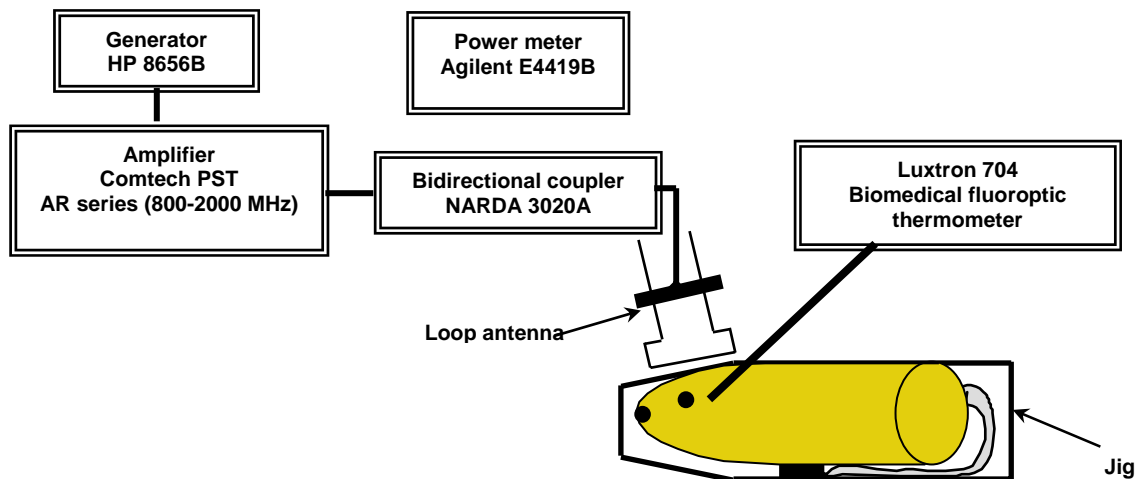

Fig. 7: Setup for experimental dosimetry
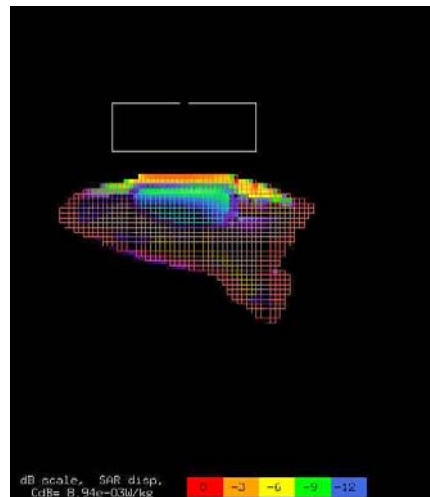
Fig.8: The rat head radiated by the loop antenna and SAR distribution.

References

1) L. Ardoino, R. Pinto, S. Mancini, C. Marino, G. A. Lovisolo, F. Apollonio, G. D'Inzeo. Exposure systems and dosimetry in biological experiments. In *Proceedings of 2nd International Workshop on Biological Effects of Electromagnetic Fields*, Rodhes, 7-11 October 2002, pp 266-271, 2002.
2) P.E. Dulou, I. Faraone, V. Vignéras, J.-M. Moreau, R. Hlavac, C. Marino, G.A. Lovisolo, and B. Veyret. *Characterisation of new loop antennas operating at 900 and 1800 MHz for head-only exposure of rats and guinea pigs: experimental measurements and fdtd calculations*. Proceedings of BEMS, p. 152, 1998

DEVICES FOR *IN VITRO* EXPOSURE

Exposure set-up

The Wire Patch Cell (WPC) [3] operating at 1920-1980 MHz has been chosen as the *in vitro* radiating system. It consists of two parallel plates (18.2 x 18.2 x 1.8 cm^3), short-circuited at the edges by four posts; the outer conductor of the power supplying coaxial cable is connected to the top plate, whereas the inner conductor is connected to the bottom, the ground plane (Fig. 9). Thanks to the symmetry of the device, four Petri dishes (diameter 3.5 cm) can be simultaneously placed inside the cell, where the E field distribution is homogeneous; moreover, the size of the device is small enough to be placed into a standard incubator.
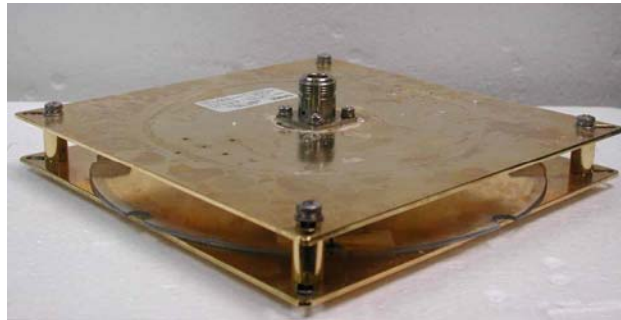

Fig.9: UMTS Wire Patch Cell

The designed exposure system consists of four WPCs, independently fed by different power levels. Two WPCs can be placed in the same incubator; therefore, a shielding of the devices is necessary, in order to avoid both electromagnetic compatibility problems with the electronic system of the incubator and interferences between WPCs. The shielding has been realized with a metal grid box (40 x 40 x 20 cm^3) and each WPC is surrounded by four blocks of foam absorbing material (15 dB attenuation) to avoid that the E fields, scattered by the grid, could change the E field distribution inside the WPC.

Another arrangement has been set up to avoid unwanted temperature increase within the exposed samples. Two water spiral coils have been positioned on the external faces of both plates of the WPC; in each coil the circulating water is maintained at 36.7 °C, in order to obtain a temperature of 36.7 ± 0.3 °C within the exposed Petri dishes. Since temperature is a critical parameter, it is always monitored during the experiments in a dummy dish placed inside each WPC with a fiber optic thermometer. The experimental blind conditions are obtained by using a black box for feeding the antennas (Fig. 10).
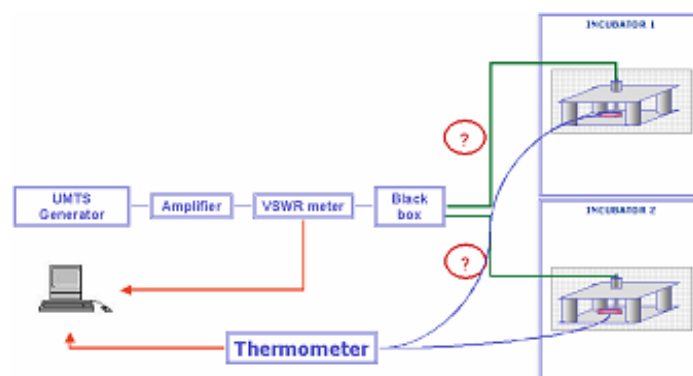

Fig.10: In vitro system set up

Dosimetry

Numerical and experimental dosimetry have been carried out in order to evaluate the SAR levels and distribution within the sample used in the experiments [4].

Numerical dosimetry (Fig. 11) has been performed by means of a commercial code CST Microwave Studio 5.0 by Computer Simulation Technology, Germany. The numerical model of the homogeneous sample allows a spatial resolution of about 0.5 mm and the calculated efficiency is 0.3 W/kg/W with a standard deviation of 2.3 dB, where the efficiency is expressed as the dose absorbed by the biological sample (W/kg) normalized to the input net power (W) to the sample.

a)   b)   c)
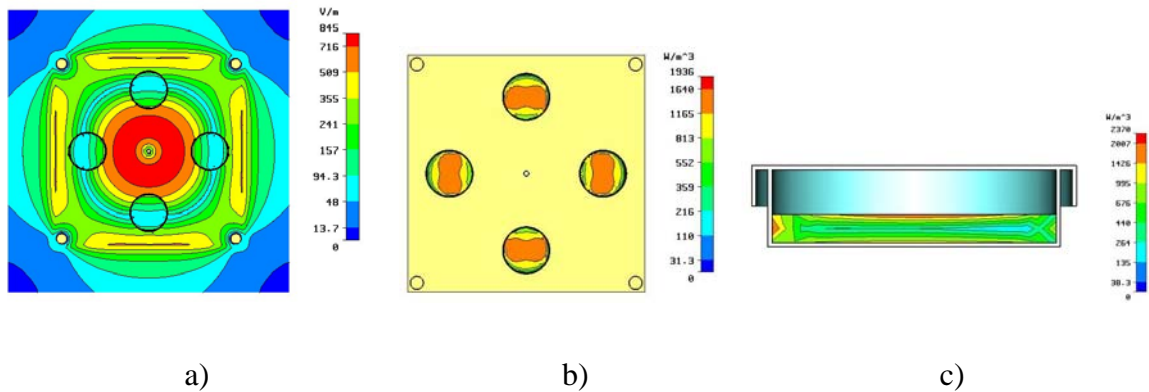
Figure 11: a) E-field distribution (rms values, calclated for 1 W input power) in the cell containing four 3.5 cm Petri dishes; b) SAR distribution in Petri dishes (top view); c) SAR distribution in a Petri dish (vertical section view)

These results present good agreement with experimental dosimetry, performed by means of thermal measurements of SAR in five different points of the sample.

In the model the Petri dishes are filled with 3 mm of culture medium ($\varepsilon' = 76$ and $\sigma = 1.9$ S/m).

The analysis of SAR distribution (Fig. 12) shows that the 80.23% of the cells are exposed to 65% or higher SAR levels with respect to the maximum SAR in the bottom layer (4 W/kg/W,.with a good homogeneity in the exposed sample. This means that 80.23% of the cells in the bottom layer of the Petri dish are exposed to at least 2.6 W/kg/W [5].
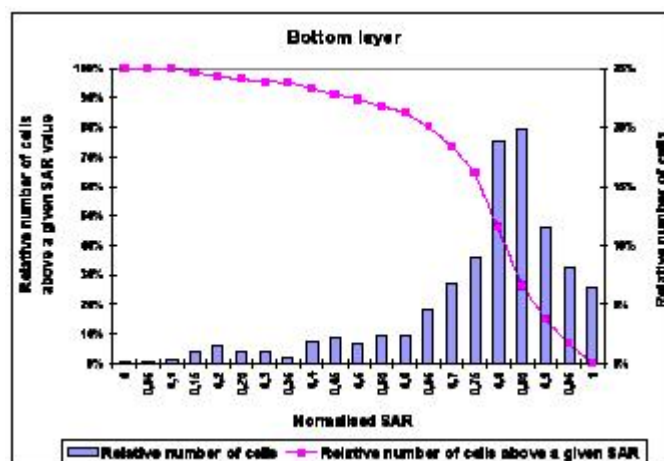
Fig.12: Dose-volume analysis

References

3) L. Laval , Leveque Ph, and Jecko B. A new *in vitro* exposure device for the mobile frequency of 900 MHz. Bioelectromagnetics 21: 255-263. 2000.

4) L. Ardoino, Lopresto V., Mancini S., Pinto R., and Lovisolo G.A. 1800 MHz in vitro exposure device for experimental studies on the effects of mobile communication systems. Radiation Protection Dosimetry 112: 419 – 428, 2004.

5) V. Lopresto, L. Ardoino, S. Mancini, R. Pinto and G. A. Lovisolo. An *in vitro* exposure device for experimental studies on the effects of UMTS mobile communication system. *Books of abstracts* BEMS-EBEA, Dublin, 2005.

Human Experimentation

Report on the systems for UMTS exposure
Device for human exposure

Deliverables D2.1 and D2.3

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Specific Aims

The aim of EMFnEAR is to assess potential changes of the hearing function of animals and humans after exposure to low-intensity electromagnetic fields produced by 3G cellular mobile phones before and after exposure to WCDMA RF fields.

The aim of this work to provide the exposure facilities for human studies within the EMFnEAR project. This report includes the report about the relevant RF dosimetry and exposure device of UMTS exposure.

According to the EMFnEAR Reports on protocols for human exposure (Deliverable D 4.2- D 4.3- D 4.4- D 4.6) the human studies will be carried out the exposure system and device described below.

Selection of the source

General aspects

Within the EMFnEAR project the specific aim is to provide relatively high absorbed power (SAR) within the ear region. There are two possibilities providing relevant source and exposure system for the human studies:

- using a commercial phone (preferred due to ethical reasons)

- developing a specific source and applicator with UMTS (WCDMA) signal

The selected exposure system must be cost effective since 5 laboratories will use the system in the same time.

The other specific requirement was to use an exposure device that acceptably from ethical point of view. Therefore using a commercial 3G phone is preferred due to the costs and easy handling as well. The exposure level must be below the EU 519/99 recommendation in any cases within the study (2W/kg)

Specific requirements

The following requirements were preferred choosing the commercial phone used in the research:

- the phone must be commercially available in the market

- the phone has to have the EC label according to the CENELEC product standard

- having 3G band

- the phone has to have maximum exposure at the ear region of the head symmetrically

- needs an external antenna connector

- relatively recent model

- relatively widely used model

- low weight

- available PC connection for external PC control

Selected device

Since the UMTS service is a relatively new system in Europe and the development of mobile technology is moving toward the high level of integration most of the commercially available 3G phones are not completely fulfil the above requirements.

In case of developing of a specific source and antenna applicator for human exposure the following requirements are preferred:

- the exposure characteristics and energy absorption must be similar to a normal 3G phone

- low weight

- easy using by researchers

- power and system control facilities

- low cost

Regarding the above requirements the new development seems to be more complicate as using commercially phone. The main difficulties getting from the development of WCDMA generic signal source. The commercially available measurement equipment is not relevant in this project since the high cost.

Following the above requirements a Nokia 6680 phone has been tested as the first approach. During the discussion about the decision of the source selection the project team contacted to the NOKIA Research Laboratory for technical information and technical support. The Nokia 6680 mobile phone provides many of above requirements but not all of them. The phone has integrated antenna, expected widely used type in Europe, 3G band, low weight, but the phone doesn't have external antenna connector that is an important aspect in our case.

Therefore in the next step a Nokia 6650 commercial phone was tested. Taking into account the results of both the tests the Nokia 6650 was selected for the device of human exposure in the EMFnEAR project. The Nokia 6650 mobile phone provides most of the above requirements.

The following tests will form the additional methods for assessment of auditory function. The test will be performed immediately before and after exposure to electromagnetic fields.

All testing will be carried out in a sound-treated room or booth satisfying criteria in ISO 8253-1 for air conduction audiometry using earphones down to 0 dB HL.

RF power output measurements on the selected phone

RF power level measurement

The power output of the phones was measured through the external RF connector using the Nokia test software (Phoenix) and RF adapter (Fig.1).

Fig.1. Power measurements and the external RF output and cable on the Nokia 6650 phone

Start level	P [mW]	Start level	P [mW]
1	0.5	12	7.78
2	0.65	13	9.7
3	0.83	14	12
4	1.1	15	15
5	1.4	16	18.5
6	1.8	17	24.3
7	2.35	18	31.8
8	3	19	39.4
9	3.9	20	49
10	5.1	21	65.5
11	6.3	22	65.5
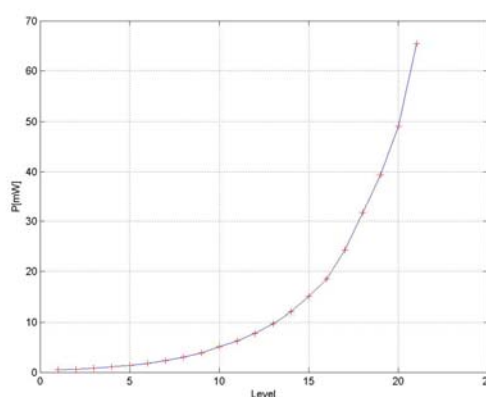
Fig.2 Power output measurements using the power level codes of Nokia 6650 phone by Phoenix software via the coupled external RF connector.

The aim of this measurement is to compare the power output of the selected phones. For interlaboratory harmonisation the phones must have the same output power within at each power level provided by the software and the UMTS system. Therefore the laboratories will use the devices with the same RF powers in the human experimental studies.

WCDMA spectral analysis

Regarding the 3G technology the RF signal characteristic definitely differs from the GSM signal. According to the WCDMA system an 5 MHz bandwidth modulation signal covers the carrier frequency (1947 MHz). The frequency spectra of the emitted RF signal was investigated in anechoic room using wide band (1-18 GHz) RF antenna and spectrum-analyser and through the RF output of Nokia 6650 phone (Fig.3).

Fig.3 Frequency spectrum of Nokia 6650 mobile phone

Within the project 12 Nokia phones will be distributed for the human studies. Each human laboratory will have got 2 phones (one sham and one radiating phone), a PC control syste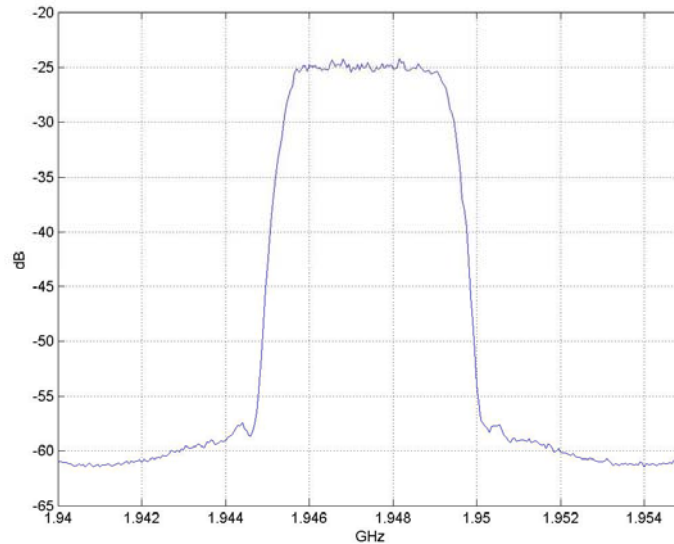m and a positioning system. The output power of the phones will be measured before and after the whole human experimental series.

RF power output stability measurement

According to the human experimental protocol the phones must emit the same RF power during the exposure period. Since the phones have battery supply, the measurement of long term RF output stability is needed before the experimental work. The long term measurement was made by PC data acquisition of the output power during the lifetime of the battery. The phones were switched on the highest output RF power level.

The sample rate of PC controlled Voltage multimeter was 20 sec. The RF power uncertainty of the phone during the first 60 minutes below 2 % using the highest power level (Fig.4).

The Nokia 6650 phone system did not allowed any decrease of the output RF power during the lifetime of the battery. Decreasing the battery below a certain level the phones were switched off. Therefore the RF power stability during the experimental exposure period will be provided by selected GSM phone.
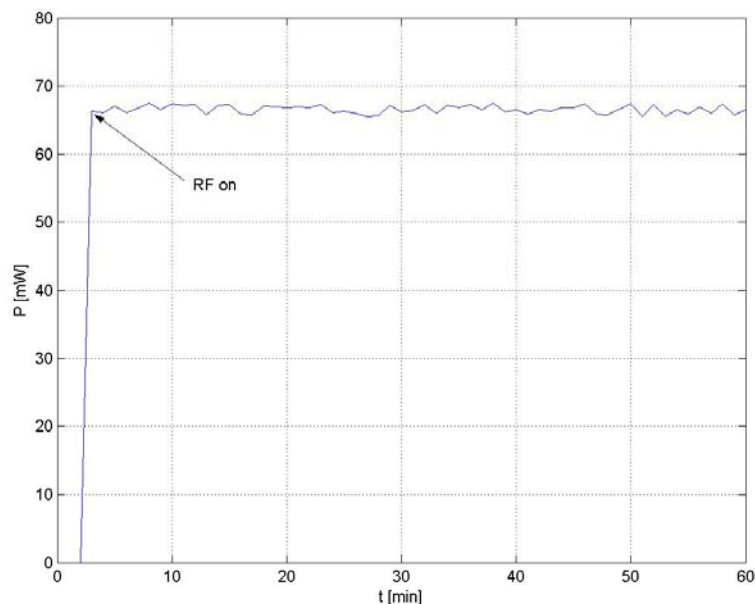
Fig 4. Level of power output in the first 60 min with maximum power level

Surface scanning of the RF emission

   For the evaluation of the exposure characteristic of the phone, the near E-field has been scanned on the surface. The scanning was performed within 6x16 cm area at 1 cm distance from the surface of the phone (Fig.5). The resolution of step was 0,5 cm. Automatic scanning driver was used for moving the near field probe (Kuster-probe)
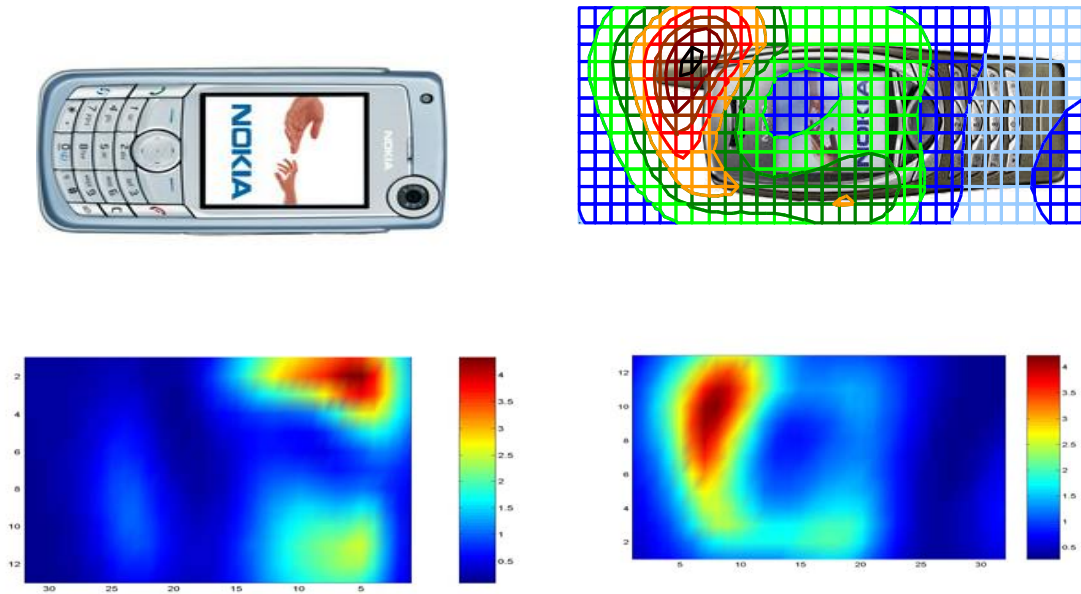
Fig.5 Near-field power density distribution above Nokia 6680 (left) and Nokia 6650 (right) phone. The 3D scale indicates the power density in W/m^2. The maximum power density was 5,17 W/m^2 at Nokia 6680, and 5,13 W/m^2 at Nokia 6650 phone respectively.

Free space radiation pattern and total emitted RF power

Free space radiation

Testing the Nokia 6650 phone free space RF radiation pattern was measured in anechoic room with human head phantom filled tissue equivalent liquid. The phone was positioned at the centre of a rotating table and the free space pattern was measured with and without the head phantom (Fig.6).
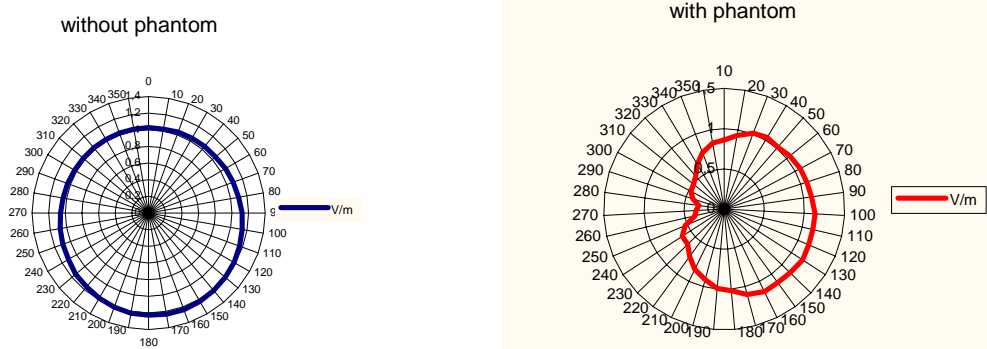
Fig.6. Radiation pattern with and without head phantom in free space without (left) and with (right) phantom.

Total emitted RF power

The total emitted power was measured on both Nokia phones in *Bluetest Reverberation Chamber (RC800)* with and without SAM phantom (touch position). The measurements were performed in the France Telecom Research and Development Laboratory (Table 1).

Table 1: Total emitted power in free space and close to the SAM head phantom

Phone	Free space without SAM phantom (dBm)	Close to SAM phantom right (touch) (dBm)	Close to SAM phantom left (touch) (dBm)
Nokia 6650	18,9	17,5	18,5
Nokia 6680	19,7	17,2	19,4

Measurement uncertainty 1 dB

SAR measurements

The SAR measurements were made in CENELEC liquid phantom using the "touch position" of the phone (Fig. 7). In the measurements 3D step motor robot system internal E-field probe (Kuster-probe) and non metallic phone positioning system was apply according to the CENELEC standard. The SAR measurements were performed with and without modelling the ear tube in the liquid phantom.

Fig.7. SAR measurement system with liquid phantom and 3D motor driver system.

All measurements were performed at 1947 MHz. The mobile phone under test was controlled by PC program user interface and powered at the maximum RF level. After the measurement of the internal E-field in the liquid phantom the results were introduced in SAR (W/kg) according to the CENELEC standard requirements (Fig 8, Table 1 and 2).
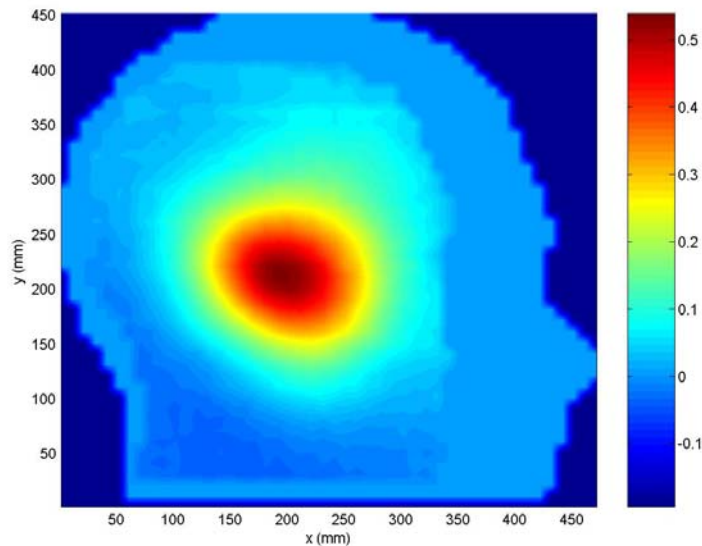
Fig.8 SAR distribution within the head phantom with Nokia 6650 phone at 1947 MHz.

Table 2. The maximum SAR values at different layers in the liquid phantom, at 1947 MHz.

Distance from the bottom surface at the ear	Measured SAR [W/kg]	Extrapolated SAR[W/kg]
0 cm	-	0.836
0.5 cm	0.531	0.546
1 cm	0.336	0.337
1.5 cm	0.198	0.195
2 cm	0.105	0.109
2.5 cm	0.069	0.068

Table 3. Local SAR maximum values at 1947 MHz

Mode	Local SAR_{max} [W/kg]	Averaged 1 g SAR_{max} [W/kg]	Averaged 10 g SAR_{max} [W/kg]
WCDMA	0.83	0.65	0.44

External load application

For the sham exposure conditions an external power load have been applied using the external antenna connector output of the phone. Small and light 50 ohm load and dummy load were developed for sham/exposed conditions with the same shape and structure. In order to control the efficiency of the load surface scanning near field measurements were performed (Fig.9).

Fig.9 External load and dummy load connected to the external RF output on the backside of Nokia 6650 phone

The external load application also may provide the double-blind conditions for the human studies. The sham or genuine exposure is performed using a "load" or a "dummy load". The "load" intercepts the RF signal to the internal antenna on the phone and dissipated the RF in the load, while the "dummy load" looks identical but does nothing, allowing the RF to reach the antenna. No radiated RF fields were measured using the RF load connected to the external antenna output.

Exposure device using patch-antenna

Construction of the patch antenna

In order to improve local exposure to the hearing system an alternative and extended exposure device was investigated. For this purpose a small patch antenna was measured connected directly to the external RF output of the Nokia 6650 phone. By this way the mobile phone provides the RF WCDMA signal to the patch antenna. The diameter of the patch antenna is 31 mm with 2 mm thickness (Fig.10).

Fig.10. Front and back side of the patch antenna.

Reflection measurements

The reflections both in free space and close (touch) to a flat liquid phantom were measured by wide band reflection meter. It was found that the reflections did not change due to the proximity to the tissue phantom (Fig.11)
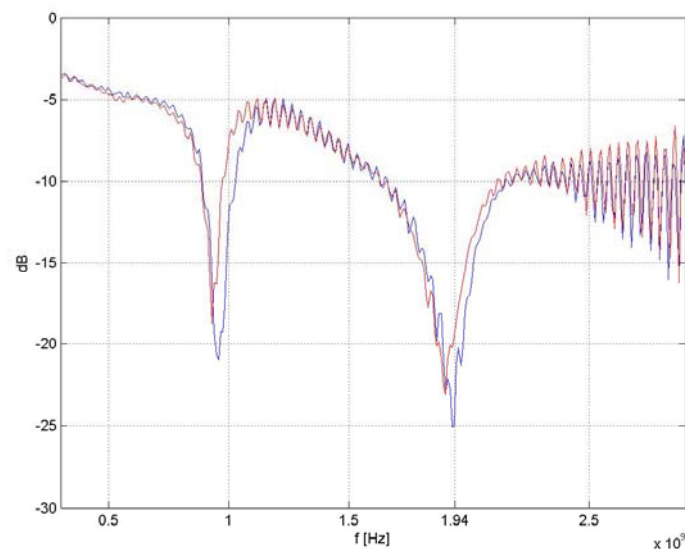
Fig. 11. Frequency spectrum of the RF reflection in free space (red) and close to the flat phantom (blue)

SAR measurements of patch antenna

The SAR distribution in a flat liquid phantom was also measured. The results show that the SAR pattern was localised closely to the area of the antenna surface where the SAR was highly concentrated (Fig.12, Table 4). This solution may provide better localisation of the SAR in the hearing sensory system.
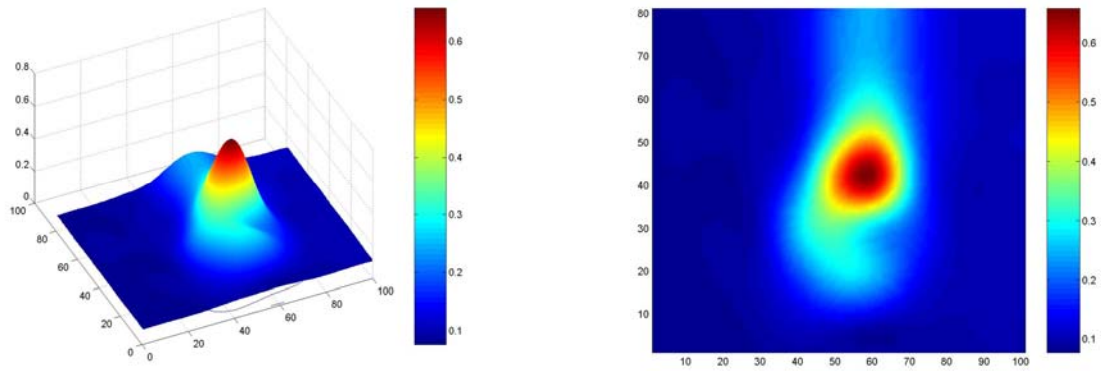
Fig.12 SAR distribution of the RF exposure from the patch antenna in flat liquid phantom.

Table 4 SAR values at different distance from the bottom of the flat phantom

Distance from bottom	SAR with *patch* antenna [W/kg]	SAR *N6650* [W/kg]
0 cm	-	-
0.5 cm	0.38	0.52
1 cm	0.16	0.31
1.5 cm	0.08	0.17
2 cm	0.05	0.1
2.5 cm	-	0.07

Since the SAR at the patch antenna is less than the SAR from the mobile phone an RF power amplifier my required. In case when the patch antenna will be used for the exposure the double blind condition may provide by a black-switch in the power amplifier system. The WCDMA 3G signal is generated from a mobile phone.

Summary

Commercially available mobile phones were tested for the human exposure system.

RF output power and long term power stability of the selected mobile phones have been measured in order to evaluate acceptance of the device for human studies.

The SAR measurements were performed according to the EU requirements.

The possible application of patch antenna as the exposure device was also tested for further investigation.

Further studies are needed for the final solution of a combination with mobile phone and RF power amplifier.

EMFnEAR

Reports on protocols for animal exposure

Reports on protocols for measuring the effects in animals

Deliverables D 3.1- D 3.2

Health and Consumer Protection Directorate-General

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Introduction

EMFNEAR is an exploratory project with an anticipatory function which addresses the study of the potential health effects of UMTS phones on the hearing system of animals and humans, actually a highly sensitive biological system to exogenous and endogenous agents.

This document includes the report about animal experiments relative to the protocols for animal exposure (EMFnEAR Deliverable D 3.1) and the protocols for measuring the effects in animals (EMFnEAR Deliverable D 3.2).

The project will involve both *in-vivo, in-vitro* and *ex-vivo* study.

In-vivo study

Animals:

Sprague-Dawley rats (SD), 250-300 g at the beginning of the experiments;

Exposure Parameters: First experimental phase

Monaural exposure

Equal number of exposed and sham animals;

Exposure timing of 2 hours/day, 5 days/week, for 4 weeks;

Frequency: 1950 MHz;

Level of local exposure (SAR) of 10 W/kg as first experimental phase;

Exposure System: see Deliverable D 2.1 Report on the systems for UMTS exposure (to be prepared)

Assessment of auditory function:

The hearing function will be evaluated by Distortion Product Otoacoustic Emissions (DPOAE), before, during (i.e. at the end of each week of exposure) and after exposure (i.e. the day after and one week after exposure).

DPOAE recordings system: Smart DPOAE Analyzer (Intelligent Hearing System HIS Ltd, Miami, USA);

DP-grams parameters: L1/L2 = 65/55 and 60/50 dB SPL, F2/F1 = 1.22, F2 frequency range from 3 to 14 kHz; resolution of the DP-gram 4.5 points per octave;

During DPOAE measurements all the animals will be anaesthetized under gas anesthesia by mixture of O2/Isoflurane 1.8 % (by IMPAC6 system, from Vetequip Inc, USA).

Statistical analysis:

Sample size calculations for detecting a given minimum effect size with an appropriate statistical power;

Data analysis by a two-way analysis of variance for repeated measures with day of testing as within-subject factor and exposure condition (i.e. sham vs. real exposure) as the between-subject factor, followed by a Pairwise Multiple Comparison Test.

Other experimental phase

Changes of the SAR level to identify the minimum exposure level capable of producing a quantitative effect on auditory function;

Study of the combined effects of ototoxic drug and microwave exposure;

In-vitro and ex-vivo study

Animals:

In-vitro experiments will be performed on the cochlea of Sprague-Dawley or Wistar newborn rats (3-4 days postnatal). One cochlea for each animal will be exposed and the other cochlea will be used as sham.

For ex-vivo experiments, newborn animals will be exposed or sham exposed and the cochlea will be explanted after exposure for examination;

Exposure Parameters:

Equal number of exposed and sham animals or cochlea;

Exposure timing of 1 hour;

Frequency: 1950 MHz;

Level of local exposure (SAR) of 10 W/kg (in vitro) or 2 W/kg (ex vivo) as first experimental phase;

Exposure System: see Deliverable D 2.1 Report on the systems for UMTS exposure (to be prepared)

Endpoints for the analysis:

Evaluation of potential morphological and metabolic alterations, as analysis of specific hair cells markers expression (by fluorescence microscopy), apoptosis and ions concentration, in Outer Hair Cells (OHCs) following UMTS-exposure.

Statistical analysis:

In addition to descriptive analysis of the data, the two groups will be compared (sham and exposure). Statistical analysis methods will include Student's t-test for independent samples and analysis of covariance.

Other experimental phase

Changes of the SAR level to identify the minimum exposure level capable to produce a detectable qualitative/quantitative effect on cochlear epithelium cells;

Study of the combined effects of ototoxic drug and microwave exposure.

EMFnEAR

Reports on guidelines for normal hearing subjects

Reports on protocols for human exposure

Reports on protocols for audiological assessment (within-subject study)

Reports on protocols for measuring the influence on the CAS effect

Deliverables D 4.2- D 4.3- D 4.4- D 4.6

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Background and rationale

EMFNEAR is an exploratory project with an anticipatory function which addresses the study of the potential health effects of UMTS phones on the hearing system of animals and humans, actually a highly sensitive biological system to exogenous and endogenous agents.

The present protocol focuses on studies of humans.

The human experimentation will be performed in the following laboratories: ISVR, CNRS, NIOM, KMU, RCA, NIRR

The human experiment entails a longitudinal (*within subject*) design where participants are assessed before and after exposure to electromagnetic fields. This approach maximises sensitivity to change because between subject variation in the results is minimised by calculating the difference between before and after measurements. However, for human studies, practical and ethical considerations impose severe restraints on the intensity and duration of exposure that can be allowed.

The human studies will be carried out in several laboratories. Each laboratory has different interests, expertise and equipment. The protocols will define a common core of measurements to be carried out in all laboratories, using equipment that is similar in principle but may differ in some respects.

Participants and Screening

Participants will be healthy young adults without any evidence of hearing or ear disorder, corresponding to the ISO definition of *otologically normal*. Similar numbers of males and females will be included. The rationale is to test a group that is representative of the population of young otologically normal people. Absence of pre-existing hearing or ear disorder will maximise the sensitivity of the study to detect small changes that may occur. Specifically, participants will satisfy the following criteria:

- Age between 18 and 30 years.

- In a good state of general health.

- Hearing threshold levels (HTL) in both ears no worse than 20 dB at any of the standard audiometric frequencies between 0.5 and 8 kHz.

- No evidence of conductive hearing loss based on air-conduction and bone-conduction audiograms.

- Normal tympanograms and acoustic reflexes present in both ears for stimulation using a 1-kHz tone at 100 dB HL.

- Normal appearance of the tympanic membrane on otoscopy.

- No history of otological disorder.

- No history of familiar hearing disorder.

- Noise exposure infrequent (e.g. night clubs) and without persistent effects.

- No self-reported hearing difficulty or persistent tinnitus.

- No exposure to ototoxic drugs by injection or topical spray (e.g. for severe burns).

- No excess consumption of alcohol or drugs 24 hours prior to testing.

- Presence of clear recordable TEOAE (only for CAS analysis), defined as SNR greater than 6 dB in two more half octave bands centred at 1.5,2,3 and 4 kHz.

Acceptance as participants will be based on otoscopy, audiometry by air conduction (0.5, 1, 2, 3, 4, 6, 8 kHz) and bone conduction (0.5, 1, 2 kHz), tympanometry and acoustic reflex testing, and a simple screening questionnaire concerning medical and otological history (see Appendix I), to be filled in by the subject in the presence of investigator.

Methods for assessment of auditory function

The following tests will form the core methods for assessment of auditory function. The test will be performed immediately before and after exposure to electromagnetic fields (see below for exposure protocol).

All testing will be carried out in a sound-treated room or booth satisfying criteria in ISO 8253-1 for air conduction audiometry using earphones down to 0 dB HL.

- Contralateral suppression of TEOAEs (CAS effect)
- P300
- Distortion product otoacoustic emissions (DPOAE): DP-gram and I/O function.

Further details of the protocols are given below. The equipment used will vary amongst laboratories; the apparatus specified here is described as an example. As a consequence, there will be minor variations in the implementation and parameters of the test protocols amongst laboratories.

Tests description

Contralateral suppression of TEOAEs (CAS effect)

Two TEOAEs will be recorded (one with and one without contralateral acoustic stimulation), using the linear mode, at five different intensities (3 dB steps between the different intensities), with intra-meatal intensities from 57 dB pSPL to 69 dB pSPL (usually, *gain between -21 and -6*). The click intensities are presented randomly.

The order of the different click intensities is randomized.

The contralateral stimulation consists in 35 dB SL white noise, (*Menu 3, Noise generation, option 6: white-noise*), generated by the ILO88 system (or, alternatively, by a separate audiometer), by means of ILO alternating protocol (called difference on/off): 6 epoch of 80 clicks (3 with and 3 without CAS) = 480 response averaged (240 with/240 without).

If the rejection rate is higher than 15%, the recording must be repeated.

Duration: 15 – 20 minutes per ear.

P300

Cognitive event related potentials (wave P-300) recorded using the stimulus oddball paradigm . All the details of the stimulus parameters are reported in Table a.

Suggested device: Nicolet Spirit 2000 & Spirit 2000 Lite model from Nicolet Biomedical

Table a – Stimulus parameters for P300 recording

Stimulus	
Type	Tone burst
Duration	
Rise/fall	10 msc
Plateau	30 ms
Frequency	
Frequent	1000 Hz
Infrequent	1500 Hz
Repetition rate	1.1/second
Intensity	70 dBnHL
Number of averages (infrequent)	at least 300
Target/ non-target ratio	20/80% and random
Presentation ear	Binaural
Transducer	Headphones or Insert
Acquisition	
Analysis time	
Over all time window	800 ms
Pre-stimulus	0%
Sample points	512
Amplification	50,000
Sensitivity	100 micro-Volts
Filters	
Band pass	1-30 Hz
Notch	50 Hz
Artefact rejection	Depending upon the recording instrument
Electrode montage	
Two channel Channel 1 Channel 2 Ground	 Cz- Ai Cz- Ac Fpz
Impedance Intra-electrode Inter-electrode	 Max 5k Ohms Max 2k Ohms
Electrode type	Silver bowls covered with Ten20 conductive

DPOAE measurement

The Otodynamics ILO-96 or similar system will be used to record DPOAE. If this equipment is not available, other equipment may be used if it gives similar performance.

DP-gram: The frequency ratio f_2/f_1 will be constant at 1.22. Primary tone levels will be fixed at the following combination of L_1 and L_2: 60/50 dB and 50/40 dB. The tones will be swept with f_2 covering the range 2 to 6 kHz in 1/16-octave steps. For each step, measurement of the DPOAE will utilise signal averaging for 6 seconds, or until a signal-to-noise ratio of at least 15 dB is reached, whichever occurs first. [Duration 6 minutes per ear].

I/O function: With a frequency ratio f_2/f_1, an input-output (I/O) function will be measured for $f_2 = 2$ and 4 kHz and the following combinations of L_1 and L_2: 50/35, 55/40, 60/50, 65/60, 70/70. These combinations approximate the "scissor-level" paradigm of Kummer et al. (2000). For each step, measurement of the DPOAE will utilise signal averaging for 6 seconds, or until a signal-to-noise ratio of at least 15 dB is reached, whichever occurs first. [Duration 1 minute per ear.]

Variation in testing between centres

The audiological measurements will differ across laboratories (Table *b*). The following table suggests the provisional allocation of test methods to laboratories. All laboratories will carry out audiometry before and after exposure. The principle of sharing test types among laboratories aims to keep test times as short as possible.

The timing are shown in Table *c* The schedule will be somewhat different for other combinations. Note the reversal of order before and after exposure, with tests most likely to show an effect of UMTS closest to exposure period.

Table b – Audiological measurement across EMFnEAR laboratories

Laboratory	CAS	P300	DPOAE
CNRS	☑	☑	☑
ISVR	☑	☑	☑
KMU	☑	☑	
NIOM	☑	☑	☑
RCA	☑		☑
NIRR		☑	

Table c–Timing to illustrate the schedule for testing

Phase	Timing	Action
Pre-exposure	5 minutes	Audiometry (air conduction using 2-dB steps in test ear only)
	10 minutes	P300
	6 minutes	DPOAE measurement
	15-20 minutes	CAS
	5 minutes	Prepare for UMTS exposure
Exposure	20 minutes	UMTS exposure
Post-exposure	15-20 minutes	CAS
	6 minutes	DPOAE measurements
	10 minutes	P300
	5 minutes	Audiometry (air conduction using 2-dB steps in test ear only)

Methods for exposure

The within-subject study consists of baseline audiological measurements, genuine or sham UMTS exposure, followed by repeat audiological measurements. Participants attend for two sessions: genuine and sham exposures. The administration of genuine and sham exposure will be double blind and counterbalanced in order.

Objectives

The exposure will consist of speech at a typical conversational level delivered via an earphone to one ear, plus EMF exposure in either genuine (test) or sham (control) conditions. Genuine and sham exposures will be on separate days (at least 24 hours apart) with the test participant and tester both blind to the condition being used. UMTS exposure will utilise the normal output of a consumer mobile phone (see Deliverable D 2.1 (in preparation)).

Equipment requirements

1. Commercial mobile phone without SIM card, including battery charger and spare battery.

2. Ad hoc software to control mobile phone (carrier frequency, output level, transmit/receive mode). This should be installed from CD onto a suitable PC or notebook computer.

3. Headband and positioning system (provided by Gyorgy Thuroczy) with bracket attached to spare battery for phone.

4. A method of using either a "sham load" or "dummy load" will be available. The "sham load" intercepts the RF signal to the internal antenna on the phone and dissipated the RF in the load. The "dummy load" looks identical but does nothing, allowing the RF to reach the antenna.

5. Sound replay system with Etymotic ER-3A insert earphone to replay speech to the ear of the participant. For example, the replay system might consist of a CD player, audiometer and insert earphone (for all additional details, see also below Appendix II "Notes on using the ER-3 insert tube for sound presentation at the tragal notch")

6. Timer to indicate elapsed time of 20 minutes.

7. Otoscope for ear examination.

8. Tissues and alcohol for cleaning phone.

Procedure

1. Collect the phone to be used for the current test participant. This will have been fitted with either the genuine or sham dummy load by an independent researcher.

2. Ensure that there are no other mobile phones switched on in the test room.

3. Clean the phone with alcohol wipes before use.

4. Ensure that the battery on the phone is fully charged (if not, change to fully charged spare battery).

5. Select the test ear according to the audiometric and other audiological test data that have already been obtained during the screening session. The principle is to select the ear with the better results on the main outcome measure(s) for the laboratory. This approach is designed to give maximum sensitivity to detect any change.

6. Examine the test ear using the otoscope to check for excessive earwax. Ears with more than 50% occlusion will be rejected. If the test ear is occluded with earwax while the opposite ear is not, and the opposite ear is suitable in all other respects, change the selection of the test ear.

7. Ask the participant to remove spectacle frames, earrings or any other metal ornaments on the pinna or close by that might alter the electromagnetic field generated by the phone.

8. Attach the sound tube from the ER-3A so that it lies along the jaw with the end within the tragal notch of the pinna. Fix the tube on place using tape designed for attachment to the skin (e.g. Micropore).

9. Place the headband and positioning system on the head. Adjust the position of the mobile phone as follows, ensuring that it will remain comfortable for the 20-minute exposure period. The longitudinal axis of the phone should follow an imaginary line from the entrance to the ear canal to the corner of the mouth. The centre of the radiated field should be over the entrance to the ear canal. The area of the phone around the earphone grille should rest with light pressure on the pinna, causing slight deformation of the pinna in most participants. Tighten the adjustment screws on the headband and check that it is comfortable.

10. Connect the serial data cable from the PC to the phone. Run the software to set the exposure parameters to the required frequency and maximum power.

11. The subject will be asked to perform an attention task so that they attend to the speech stimulus, such as counting the number of times a specific work occurs in the speech material. Start the speech replay system, set the software into Transmit mode, disconnect the serial data cable and start the exposure timer. The exposure has now started.

12. When the timer indicates that the exposure is complete, stop the speech replay system, remove the phone immediately from the positioning system and ask the participant appropriate questions about the speech material. The purpose of asking questions is to ensure that the participant has been actively listening to the speech.

13. Ask the subject if they experience any subjective effect from the exposure.

14. Remove the ER-3A earphone and prepare for audiological testing.

15. After audiological testing, re-connect the phone to the PC and set the phone back to the default mode.

Experimental procedures

Ethical Committee approval will be required for all studies involving human participants. Particular emphasis will be attached to the deliberate exposure to electromagnetic fields involved in the *within-subject* study. Justification will rely on similarity with usual levels of exposure for users of mobile telephones, careful control of exposure levels and absence of effects in animal studies for similar exposures.

Pilot studies

The purpose of the pilot studies will be to ensure that the test protocols can be implemented in all laboratories successfully and timings are viable. Each laboratory will test a minimum of three participants according to the protocol. Data from all laboratories will be collected at ISVR to ensure consistency across laboratories. Translation of questionnaires will be required into the local language(s).

Recruitment of participants

Participants will be divided across the six laboratories in approximately equal numbers. The *within-subject* study will involve approximately 30 to 40 participants per laboratory. Initial recruitment will include explanation of the purpose of the study, signature by the participant indicating informed consent, and screening tests against inclusion criteria. Sufficient potential participants will be screened to allow for attrition due to exclusion and poor data acquisition. Participants will be paid reasonable travelling expenses. Some centres may pay a participation fee.

Within-subject study

Participants who have satisfied the inclusion criteria will be scheduled to attend for two test sessions lasting approximately one hour. During one test session the exposure will be real and during the other session the exposure will be sham. The participant will be unaware of the exposure condition. The order of conditions will be counter-balanced across participants. Electrodes will be attached for P300 measurement and will remain in place for the entire session. Electrode contact impedance will be lower than 5 kΩ. Suitable probe tips will be selected for TEOAE, DPOAE measurement. Pre-exposure measurements will be taken, with this order of tests: P300, DPOAE, CAS TEOAE, while post-exposure measurements will be in the reverse order as pre-exposure for each participant. The measurements will be completed in succession without unnecessary delays. Following pre-exposure measurements, the exposure system will be adjusted and electromagnetic fields applied. Immediately following exposure, the post-exposure measurements will be carried out. The time at which each measurement is recorded, relative to the end of exposure, will be logged. Finally, the electrodes will be removed and participants asked whether they noticed any effects of the exposure.

Analysis of results

Statistical analysis will be performed initially at each laboratory for the local data and finally at ISIB for the pooled data across laboratories. As there will be some variation in data format across laboratories, the pooled analysis will be limited to a common subset of data. For both local and pooled data analysis, the data sets will be encoded such that the person performing the analysis is unaware of the exposure condition (genuine or sham) for each data set.

Within-subject study

In addition to descriptive analysis of the data, differences in the measures obtained before and after exposure will be compared between the genuine and the sham exposure. Statistical analysis methods will include Student's t-test for related samples and repeated-measures analysis of variance. Hearing threshold levels and other data obtained at the screening stage will be used as covariates.

Schedule of activities planned for EMFnEAR project

According to the schedule proposed in the EMFnEAR Technical Annex, human studies are due to commence at Month 16 (April 2006). The test protocols must be full established before that date. Therefore, pilot work should commence in February 2006.

Time	Laboratories	Activities
January 2006	CNRS, ISVR, KMU, NIOM, RCA,	Establish test protocols including exposure system and translation of questionnaires. Recruit participants for pilot study.
March 2006	ISVR-ISIB	Obtain pilot study measures. Inspect pilot study data and fine-tune protocols. Preliminary analysis based on pilot data.
April 2006	CNRS, ISVR, KMU, NIOM, RCA	Commence recruitment for main studies
December 2006	CNRS, ISVR, KMU, NIOM, RCA	Completion of main studies. Interim analysis of data locally at half-way point.
January 2007	CNRS, ISVR, KMU, NIOM, RCA	Local analysis of data and transmission of data to ISVR.
April 2007	ISIB	Analysis of pooled data. First draft of report.
June 2007	CNRS, ISVR, KMU, NIOM, RCA, ISIB	Comments on draft report and production of final report.

Appendix I
SCREENING QUESTIONNAIRE CONCERNING MEDICAL AND OTOLOGICAL HISTORY
Deliverables D 4.2- D 4.3- D 4.4- D 4.6

Subject _____

Please circle the correct answer:

1)   Do you think that your hearing is normal?   Yes / No

2)   Have you ever had any persistent problems with your ears or
         hearing, for example discharging ears or earache?   Yes / No

3)   Do you suffer from troublesome tinnitus?   Yes / No

4)   Have you been exposed to loud noises, for example
         at work, gunfire or explosives?   Yes / No

5)   Do you attend loud night clubs frequently   Yes / No

6)   Are you suffering from or have you recently had a cold?   Yes / No

7)   Have you ever had attacks of dizziness or loss of balance
         related to vestibular disorder (if known)?   Yes / No

8)   Are you receiving any medical treatment or medication that
         may affect your hearing?   Yes / No

9)   Have you consumed excessive alcohol or other drugs
         in the last 24 hours?   Yes / No

10)   Is there a history of hearing loss in your family?   Yes / No

If yes, please give details :

Appendix II
NOTES ON USING THE ER-3 INSERT TUBE FOR SOUND PRESENTATION AT THE TRAGAL NOTCH
Deliverables D 4.2- D 4.3- D 4.4- D 4.6

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Introduction

For the human protocol of the ENFnEAR project, it has been decided that subjects will be exposed to both EMF and an acoustic stimulus (speech material) to simulate the normal use of a phone. However, to prevent any possible effects from using the speaker in the handset, the speech material will be delivered via an ER-3A insert phone. The insert phone will be used without the eartip inserted and the tube will be taped along the subject's jaw with the entrance of the tube placed at the tragal notch of the subject.

The following document is designed to standardise the presentation level used with the ER-3A insert phones.

The effect of tragal presentation on the frequency weighting of the speech material

A pilot investigation compared the presentation of speech material though an ER-3A insert tube placed at the tragus and though TDH-50P headphones. It was found that :

1. Material is significantly quieter when presented at the tragal notch (approximately 25 dB).

2. Low frequencies are significantly quieter than high frequencies when presented at the tragal notch.

Fig. 1 compares the PSD of speech material presented at the tragal notch and through TDH-50P headphones. The speech material was the UK Institute of Hearing Research's (IHR) running speech B (English). The reduction in low frequency energy using ER-3A presentation of speech material at the tragus can be seen.
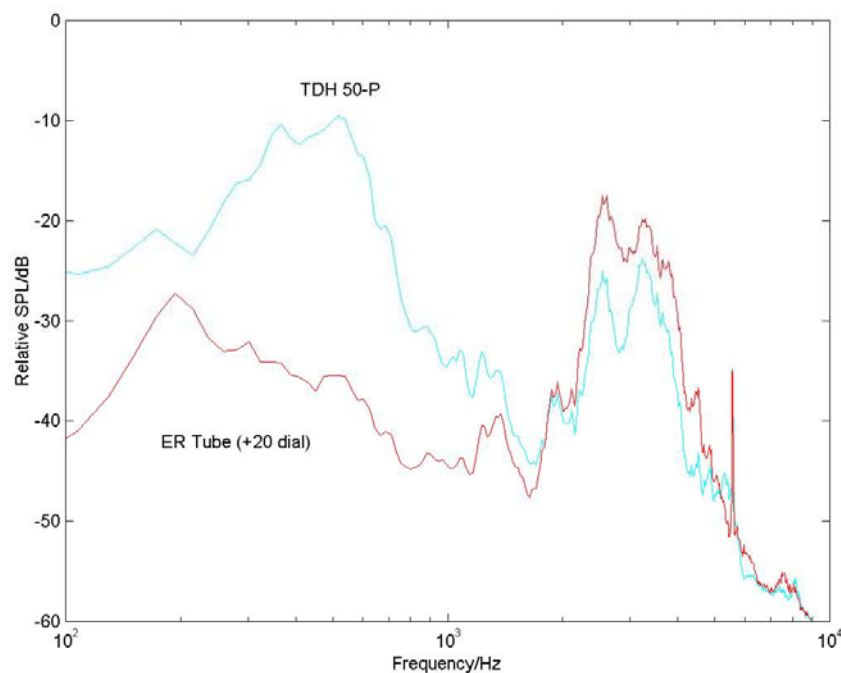

Fig. 1. Power Spectral Density Plots of the IHR 'running speech B' presented though TDH 50-P headphones and the ER Tube placed at the tragal notch. The speech was recorded using a probe tube microphone located approximately 5 mm from the tympanic membrane.

A filter to compensate for the frequency weighting introduced by the tragal presentation of material

Although the reduced amplitude of low frequencies in the speech material using tragal presentation is not of great concern, the speech sounds more 'tinny' (high-pitched) due to the reduced amplitude of low frequencies in the speech. It has been decided at ISVR to filter the speech material in order to compensate (in part) for the frequency-weighting of the speech introduced when using a tragal placement.

A filter was created using Syntrillium 'Cool Edit' to amplify the low frequencies in the speech material and compensate to some extent for the frequency weighting of the tragal presentation. The frequency weighting of the filter used is shown in Fig. 2. This weighting compensated for most of the difference between the tragal and headphone presentation of speech. Whilst it did not completely correct the difference, there was a trade-off between making the frequency weighting of the speech sound normal and not distorting the speech though excessive filtering. After filtering the speech, the subjective quality of the speech was still good when presented at the tragus and the speech not longer sounded high-pitched.
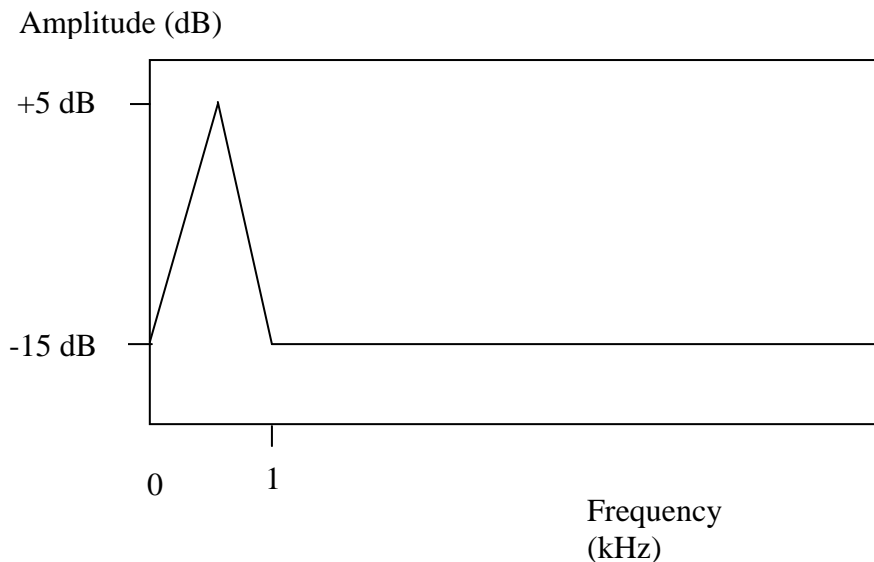

Fig. 2. The filter weighting used to boost the low frequencies in the IHR running B material (FFT filter in Syntrillium 'Cool Edit').

The PSD of speech material presented from an ER-3A insert tube before and after filtering is shown in Fig. 3. The filtering does not completely correct the difference in spectra shown in Fig. 1, but it increases the low frequency content of the speech significantly, so that the speech does not sound too unnatural.
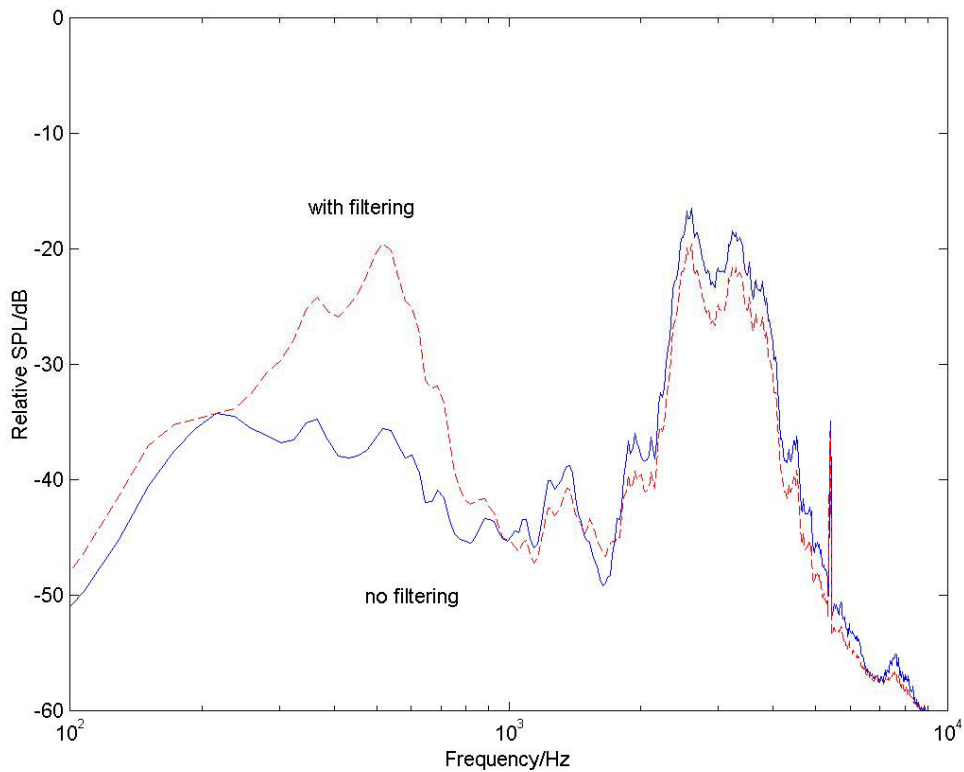
Fig. 3. Power Spectral Density Plots of the IHR 'running speech B' with and without filtering presented though an ER-3A tube placed at the tragal notch. The speech was recorded using a probe tube microphone located approximately 5 mm from the tympanic membrane.

An experiment to calculate the correction between speech presented in free-field and that presented via an ER-3A insert tube placed at the tragus

Rationale

An experiment was performed to find the level of presentation needed for speech material from the ER-3A insert tube placed at the tragus to produce equal SPL at the eardrum to speech material presented in free field at 60 dB A.

Method

A room was set up with speech material (IHR running speech B) being played from a computer, routed though an audiometer and presented via a loudspeaker. The level of the speech was adjusted so that the average level at a fixed reference point in the room was 60 dB (A).

Next a subject was positioned so that the centre of their head was at the fixed reference position. A probe tube microphone was placed in the subject's ear and an ER-3A insert tube taped along the subject's jaw with the entrance placed at the tragal notch of the ear. The speech material was again played from the loudspeaker and the level at the subject's ear canal was recorded. Next the filtered speech material (filtered IHR running speech B using the filter specified in Figure 2) was presented via the ER-3A insert tube. The level of the filtered speech was adjusted until the SPL at the ear canal was the same as that produced by the speech material presented from the loudspeaker. The SPL of the speech produced at this level by the ER-3A insert tube in a 2-cc coupler,

and in a 4157 Occluded Ear Simulator, was recorded as a reference. The method of coupling the tube of the ER-3A earphone to each coupler was as shown in ISO 389-2.

This procedure was repeated in 9 ears (5 subjects). All ears were free of wax.

Results

Table AII-1 shows the audiometer dial setting required for each subject to produce the same SPL at the ear drum as free field speech at 60 dB (A), for filtered speech material played from an ER-3A insert tube placed at the tragus.

Table AII-1. The audiometer dial setting required to produce the same SPL at the ear drum as free field speech at 60 dB (A).

Subject	Ear	Dial setting needed to give equal SPL at eardrum as FF speech at 60 dB (A)
1	R	93.3
1	L	97.1
2	R	98
2	L	100.4
3	R	100.1
3	L	99.9
4	R	102.1
4	L	98.5
5	R	102.33
Mean		99.1
s.d.		2.8

The average Sound Pressure Level for filtered speech B from the ER-3A tube at a dial setting of 99 is shown in Table AII-2.

For each centre involved in the GUARD human study, the level of speech material to be presented from the ER-3A insert tube should be set to produce the given level in one of these couplers. If the speech material is then presented with the end of the ER-3A insert tube placed at the tragal notch of the subject, the level of the sound at the eardrum will be equivalent to that produced by free field speech material at 60 dB (A).

Table AII-2. The Sound Pressure Level required in a coupler which, when presented from the ER-3A insert phone placed at the tragal notch, produces the same SPL at the eardrum as free field speech at 60 dB (A).

Level (dB SPL)	Coupler
79.5	2-cc
83.5	4157 Occluded Ear Simulator

Note that there will be some variation in speech level due to variation in the exact position of the ER-3A tube, the shape of the tragal notch and the shape of the subject's ear. A difference of ± 2 standard deviations corresponds to approximately ± 6 dB. This range of deviation is considered satisfactory for this project.

Summary

We have explored the effects of presenting speech material from an ER-3A insert tube placed at the tragus. The effect of using such a presentation compared to using headphones is that the level of sound at the eardrum is reduced and that the low frequency content of the sound is reduced, resulting in the speech sounding unnaturally high pitched.

We have designed a simple filter that when applied to speech material will boost the low frequency content and correct in part for the spectral weighting introduced when material is presented from an ER-3A tube placed at the tragal notch. This filter will make speech material presented in this way sound more natural.

We have performed an experiment to find the level at which sound should be presented from the ER-3A insert tube placed at the tragus, in order to produce a level at the ear drum equivalent to free field speech at 60 dB (A). We have also defined the sound pressure levels required to calibrate the earphone in either a 2-cc couple or ear simulator, in order to achieve this free-field equivalent level. There will be some variation in the level at the eardrum due to the placement of the tube and variations in the shape of the subject's ear.

Recommended actions

Each centre should identify suitable speech material for use in the project, with a duration of 20 minutes. The material should be filtered as shown in Figure 2 and re-recorded for experimental work. If the material is recorded digitally (e.g. waveform file), the filter can be implemented simply using Cool Edit or other appropriate software. If the material is recorded in analogue format (e.g. tape recording), the filtering can be implemented using a graphic equaliser.

Having re-recorded the filtered material, the speech should be calibrated to the required level by correcting the earphone to either the 2-cc coupler or Occluded Ear Simulator (using corrected method from ISO 389-2) and adjusting the output to the corresponding SPL from Table AII-2. This will give a free-field equivalent of approximately 60 dB (A).

Reports on protocols for audiological assessment (Additional test)

Addendum to Deliverables D 4.2- D 4.3- D 4.4- D 4.6

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Introduction

EMFnEAR is an exploratory project with an anticipatory function which addresses the study of the potential health effects of UMTS phones on the hearing system of animals and humans, which is a biological system highly sensitive to exogenous and endogenous agents.

The human experiment entails a within-subject study design where participants are assessed before and after exposure to electromagnetic fields. The core tests and core procedure for the audiological assessment of the subjects are described in Deliverables D 4.2- D 4.3- D 4.4- D 4.6.

The present protocol focuses on the description of additional test for the audiological assessment of the human subjects, additional recording sessions and additional exposure system.

Additional methods for assessment of auditory function

The following tests will form the additional methods for assessment of auditory function. The tests will be performed immediately before and after (genuine or sham) exposure to electromagnetic fields.

All testing will be carried out in a sound-treated room or booth satisfying criteria in ISO 8253-1 for air conduction audiometry using earphones down to 0 dB HL.

- CAS effect on DPOAE

Test description

The Otodynamics ILO-96 or similar system will be used to record DPOAE. If this equipment is not available, other equipment may be used if it gives similar performance. The frequency ratio f2/f1 will be constant at 1.22. Primary tone levels will be fixed at the following combination of L1 and L2: 60/50. The tones will be swept with f2 covering the range 1 to 6 kHz in 1/16-octave. For each step, measurement of the DPOAE will utilise signal averaging for 6 seconds, or until a signal-to-noise ratio of at least 15 dB is reached, whichever occurs first.

Two DPOAE sweeps will be recorded (one with and one without contralateral acoustic stimulation). The contralateral stimulation consists in 35 dB SL white noise, generated by the ILO-96 system (or, alternatively, by a separate source). The noise will be presented via insert earphone (e.g. ER-3A earphone). [Duration 3 minutes per ear].

Additional recording sessions

The core recording sessions will be performed immediately before and after exposure to electromagnetic fields (Deliverables D4.2/D4.3/D4.4/D4.6)

A further post-exposure set of test, starting 60 minutes after exposure, will be performed to look for any delayed effects of UMTS. Test measurements will be identical to those carried out immediately after the exposure interval. The only difference will be the timing of the testing.

Additional exposure system

The core exposure system, based on commercial but software controlled 3G phones will be used in all the centres involved in the project (Deliverables D4.2/D4.3/D4.4/D4.6 and D2.1)

A further exposure system based on patch antennas will be optionally used in some centres. The patch antenna will provide more localized exposure to the ear region. The detailed description of the patch antenna is available in the deliverables D 2.1/D 2.3.

The source of the patch antenna will be a commercially available mobile phone, therefore the switching "on" or "off" the phone will be made the same procedure as with mobile phone by the Phoenix software. Between the mobile phone and the patch antenna RF power amplifier will support the RF power. On the front panel of the RF amplifier a "black-switch button" will be operated in order to provide the double blind experimental conditions. In one position the black-switch provides the RF power to the antenna and on the other position not. The amplifier and the black-switch device has a battery based power supply in order to avoid any contact to the high voltage 220 V system.

The investigator does not know the meaning of the status of the black-switch. All subjects will be exposed twice using each black-switch button position. One person in the NIRR group has the "code" of the black-switch button only.

The position of the patch antenna on the subject's head is the same as in the case of using mobile phone. The radiation side of the patch antenna will be labeled.