

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

**EMFnEAR**

**Directorate C - Public Health and Risk Assessment  
Health & Consumer Protection Directorate General  
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**FINAL REPORT**

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## 1. OBJECTIVES AND EXPECTED ACHIEVEMENTS

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. UMTS is already a reality in Europe and greatly differs from GSM in frequencies and patterns used (about 2 versus 0,9-1,8 GHz and code-division multiple access CDMA versus time-division multiple access TDMA).

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.

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 highly sensitive biological system to exogenous and endogenous agents and the first one to be affected by the microwaves. The EMFnEAR results represent the first international and European statement about this type of hazards for hearing. The EMFnEAR results will give a contribution to the revision of Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields in the frequency region around UMTS 2 GHz.

The specific aims of the project are:

1. Study of the potential effects on the hearing system of animals and humans of UMTS microwaves, by laboratory experimentation, including also study of the potential hearing-related cognitive effects and combined effects of UMTS fields and ototoxic agents.
2. Support informed decision-making by health and environmental authorities and public information.
3. Provide industry with adequate information for assessing and managing the potential risks of UMTS standard for hearing, defining general guidelines to producers, to improve the control and reduction of the potential health risk.
4. Contribute to the definition of the exposure limits at this modulation and frequency band, and, consequently, to the revision of Council Recommendation 1999/519/EC.

## 2. DETAILED DESCRIPTION OF ALL ACTIVITIES CONDUCTED

### 2.1 Introduction

The project proceeded as planned, on time and within budget.

The structure of the workplan and the overall methodology used to achieve the project primary objectives are:

1. Design, development and manufacturing of localized exposure and positioning systems for the exposure of animals and humans to UMTS microwaves
2. Design UMTS exposure and audiological assessment protocols for animals and humans
3. Experimental phases for animals and humans
4. Analysis and processing of data
5. Dissemination and exploitation of the results
6. Monitoring of secondary aims
7. Management activities

The duration of EMFnEAR was of 30 months, to carry out all the EMFnEAR activities and to reach all the EMFnEAR objectives.

### 2.2 Project structure, activities and results

#### 1. *Design, development and manufacturing of localized exposure and positioning systems for the exposure of animals and humans to UMTS microwaves (WP 2)*

The exposure and positioning systems for the animals and the exposure system for humans were developed (Deliverables D2.2-D2.3) and are deeply described in Deliverables D2.1 (see Annex A). These systems, although structurally and geometrically different for humans and animals, produce for both applications the field generated by UMTS mobile telephony. The systems (one type for animal exposure and two types for humans, i.e. a mobile phone exposure system and a patch antenna exposure system) allow the setting of the level of exposure in terms of total power (i.e., allowing the control of the dose at which the animals and/or subjects were exposed to) and the exposure time. Particularly, as to human experimentation, a patch antenna exposure system was designed to improve local exposure to the hearing system. As to the mechanical systems for sizing, shaping and positioning the exposure systems for humans, the Project Board agreed in using the devices already designed and manufactured in the course of project GUARD. Numerical and experimental dosimetry was performed for all the types of exposure system used in the project.

#### 2. *Design UMTS exposure and audiological assessment protocols for animals and humans (WP 3 - WP 4 - WP 5)*

The UMTS exposure and audiological assessment protocols both for animal and human experimentation were finalized and are detailed in the Deliverables D3.1-D3.2 D4.2- D4.3- D4.4- D4.6 (see Annex A). The Project Board (PB) agreed to modify the Workplan adding some additional within-subjects studies (in the following called *Additional tests*), such as exposure of subjects at a SAR (Specific Absorption Ratio) equal to 1,75 W/kg, (averaged over 10 g of tissue) close to the maximum SAR level permitted by current regulation, CAS effect on DPOAE, delayed audiological assessment. Details are in the deliverable Addendum to Deliverables D4.2- D4.3- D4.4- D4.6 (see Annex A). The PB decided also to eliminate the planned *between-subject* study, considering that currently existing UMTS systems (as a difference to what we expected when the project was designed) still do not allow the user to know what frequency and modulation (GSM 900 or GSM 1800 MHz or UMTS) are actually in use in the course of a phone call. This makes very difficult the recruitment of subjects, limiting it to the subgroup of users that are setting the phone to UMTS only.

### 3. *Experimental phases for animals and humans (WP 6, WP 7, WP 8, WP9)*

#### Animal experimentations

Animal experimentations started on the basis of the protocols developed in WP2. At the end of the project data on experiments on about 230 animals were collected.

#### Aminoglycosides ototoxicity – positive control group

Following our previous studies on the same subject (GUARD project – potential adverse effects of cellular phones on hearing, MIUR, Italian National projects 2000-2004), it was decided to include in the protocols of exposure to UMTS electromagnetic fields a number of animals as positive controls, i.e. with an evident damage on auditory function. A pilot study on this subject was carried out. Aminoglycosides antibiotics (gentamicin, GM, and kanamycin, KM) were used as ototoxic agents (daily intra-muscular injection in the hind limb).

Distortion Product Otoacoustic Emission (DPOAE) were selected as cochlear status index. Significant reduction in DPOAEs level after the treatment may be an indicator of functional or structural damage suffered by Organ of Corti's outer air cells (OHC).

A total of 48 rats were treated with different doses of antibiotics and with different times of drug consumption (GM, 150 mg/kg body weight for 7 and 14 days; KM, 250 mg/kg body weight for 22 days and 400 mg/kg body weight for 14 days).

DPOAE were measured in animals before, during and after the treatment, to evaluate the effect of the drug on the cochlear cells functionality. The procedure for the measurements and the acoustic parameters of otoemissions were the same of successive experiments with electromagnetic fields, and they will be described in the next paragraphs.

In the end, kanamycin at the dose of 250 mg/kg body weight was selected for positive control group; in particular, gentamicin was excluded because its excessive general toxicity for the rats (some animals died during treatment, and others showed major effect on general health status).

#### KM dose-effect

To obtain an optimal dose of the drug to be utilized in the successive experimental protocols, a dose-response study of kanamycin ototoxicity in rats was performed.

Animals (60 Sprague-Dawley male rats in total) are injected with 5 different doses (150, 200, 250, 300 and 350 mg/kg body weight) of KM, once a day for 2 weeks.

DPOAE were measured as follows: before treatment, at the end of week 1, three times on week 2, 3, 4, 5 and at the end of week 7. The analysis of data confirmed that the dose used in the first experiments (i.e. 250 mg/kg body weight) was optimal for our purpose.

#### UMTS Effect - experimental protocol

Four successive experiments were performed (in the following called Experiment 1 to Experiment 4). Due of the unexpected results of Experiment 1, Experiment 2 and Experiment 3 follow an identical protocol, in order to confirm or not its outcome.

The following protocol was carried out:

- Animals: Sprague-Dawley male rats, weighed 200-250 g at the beginning of the experiment were utilized;
- Exposure system: 3 sets of four loop antennas for localized exposure (right ear) at 1946 MHz UMTS signal;
- Experimental groups: 4 different groups were included, i.e. a group exposed to UMTS field, a group sham exposed to UMTS, a control group treated with KM + UMTS and a control group treated only with KM;

- Exposure conditions: 2 hours/day, 5 days/week, 4 weeks, at a SAR (Specific Absorption Rate) of 10 W/kg; exposure in blind mode. During the treatment animals were inserted in Perspex jigs to reduce movements, maintaining a minimal stress state;
- Kanamycin (KM) treatment: dose of 250 mg/kg body weight (Kanacill Fortius - kanamycin sulphate sol 20%, corresponding to kanamycin 15%), daily intra-muscular injection in the hind limb, for 22 days;
- Otoacoustic emissions: An HIS SmartOAE analyzer were used; parameters were selected as follows: stimulus frequencies 3-14 kHz, 4.5 freq/octave; 2 combinations, L1/L2 = 65/55 and 60/50 dB SPL;

Measurements were performed before exposure, during exposure (one time in the first week, three times in the second, third and fourth week) and one week after the end of exposure.

All the test sessions were carried out keeping rats under general gas anesthesia, by a mixture of isoflurane 1.5-2 % in O<sub>2</sub> flux.

Experiment 4 was differently organized: 3 groups were included, i.e. one group exposed to UMTS field + KM, one group sham exposed to UMTS + KM and a control group treated only with KM. The other experimental parameters were the same as previous experiments.

In all the experiment data analysis was performed by a two-way analysis of variance for repeated measures with day of testing as within-subject factor and exposure condition as the between-subject factor, followed by a Pairwise Multiple Comparison Test.

Two laboratories were fully involved in the animal experiments, ENEA and ISIB-CNR.

The animal experimentation activities are described in the Deliverables D6.1, D7.1 and D10.1, attached to this Final Report (Annex A).

As to in-vitro studies, considering the absence of effects even at very high level of SAR (10 W/kg), the consortium agreed to delete them (i.e., remaining with the pilot study performed at the beginning of the project), and to perform replications of the studies with KM. These replications and introduction of new experiments in the course of the project required much effort for being completed as planned in the proposal.

#### Human experimentation phases

EMFnEAR human experimentation proceeded as planned, on time and following the recording protocols for hearing assessment. The protocols were finalized and all experimentations started in all centres after the due Ethical Committee approvals, according with their expertise and availability.

The human experimentation was divided into two phases:

- “*Within-Subject study*” or “*Base experiments*”, which corresponds to the study of the potential adverse effects of UMTS cellular phones on hearing in case of exposure for 20 minutes to the maximum power level at 1947 MHz; the core tests and core procedure for the audiological assessment of the subjects are described in Deliverables D4.2, D4.3, D4.4, D4.6 (Annex A)
- “*Additional test*”, which corresponds to the studies on the effects of UMTS exposure on hearing using an exposure system based on patch antennas. The patch antenna provides more localized exposure to the ear region. The detailed description of the patch antenna is available in the deliverables D2.1 and D2.3, while the description of additional test for the audiological assessment of the human subjects and additional recording sessions are described in Addendum to Deliverables D4.2, D4.3, D4.4, D4.6 (Annex A).

Seven laboratories are fully involved in the human experiments, CNRS, ISVR, KMU, NIOM, RCA, NIRR and ISIB-CNR.

The human experimentation activities and results are described in the Deliverables D4.2, D4.3, D4.4, D4.6, Addendum, D8.1, D9.1, D10.2, D10.3 attached to this Final Report (Annex A).

#### 4. *Analysis and processing of data (WP 10)*

##### *Animals Experimentations*

The processing of the animal data obtained from the experiments (about 230 animals) to quantify the effect of UMTS exposure and the combined effect with ototoxic agents was performed by the Centralized Data Processing Unit (CDPU). The data were statistically analysed.

In summary, the analysis of the data show no effects of UMTS electromagnetic fields exposure on the inner auditory system of rats, both in normal ears as well as in ears exposed to a well recognized pathological agent (KM) (Deliverables D10.1, D10.4).

##### *Human Experimentations*

The processing of the human data obtained from the experiments (about 180 subjects) to quantify the effect of UMTS exposure on the human auditory system was performed by the Centralized Data Processing Unit (CDPU). The data were statistically analysed.

In summary, the main conclusion is that no effects was found on the main measures of the status of the human auditory system.

EMFnEAR results (both on animal and human experimentation) need at least one additional year for further additional analysis.

#### 5. *Dissemination and exploitation of the results (WP 11)*

The EMFnEAR activities were disseminated starting from the beginning towards both scientific community and general public. The EMFnEAR brochure was finalized, delivered and distributed, together with two other issues of the EMFnEAR NEWS (see Annex A, Deliverable D1.1 and D11.1). The EMFnEAR web site (<http://www.emfnear.polimi.it>) was created and maintained to give an immediate and free access to the information concerning EMFnEAR activities and results for all interested people (Deliverable D11.4).

The project activities and the first results of EMFnEAR were presented in national and international scientific conferences. A Workshop on EMF interactions and hearing was organized by the EMFnEAR Consortium as the Special Session *Bioelectromagnetics and Hearing* of the International Conference *NHS 2006 Beyond Newborn Hearing Screening: Infant and Childhood Hearing in Science and Clinical Practice*, on June 3, 2006, in Cernobbio, Como, Italy. Around 100 delegates attended to the EMFnEAR event. Detailed about the Workshop can be found in the Issue #2 of the EMFnEAR NEWS, attached to this report (Deliverable D11.1).

According to the results of the projects, both in animals and in human studies, the EMFnEAR consortium produced a list of feedbacks to the UMTS mobile phones manufacturer (D11.4).

See also below for additional details (Exploitation and Dissemination Activities).

#### 6. *Monitoring of secondary aims (WP 12)*

Some secondary aims, such as the effects of handedness and gender, involving a total of about 120 subjects, were performed during the project lifetime. In summary, no effects of UMTS exposure were found in both these two studies. Additional details can be found in Deliverables D12.1(Annex A).

#### 7. *Management activities (WP 1)*

The Coordinator and the Project Board (PB) provided the necessary background, in terms of administration, management and co-ordination, to the network as a whole, and to all the demanding activities that have been planned.

As to the day-to-day management of the project, the Coordinator monitored the progress of each Development Team and related WP activities, to identify any need of immediate intervention or gap, and to monitor all project components and the respect of all the project obligations.

### **2.3 Project planning and timetable**

The project proceeded as planned, on time and within budget. Table III shows the updated Work package List (including the slight changes of WP7 and WP9 titles, according to PB decisions). Table IV shows the updated list of the deliverables.

### **2.4 Future actions**

Dissemination activities will continue also in the next two years, considering the time needed to obtain the publication of papers on scientific journals. The full processing of the huge mass of recorded data needs to be continued in 2008.

Table I: Updated Workpackages List. C: Completed.

Work-package (WP)	Work package title	Lead partner for the work package (name)	Status	Deliverable No
WP1	Central Coordination and management activities	CNR.ISIB	C	D1.1/D1.2
WP2	Design, development and manufacturing of localized exposure systems	ENEA.BIOTEC	C	D2.1/D2.2/D2.3
WP3	Design protocols for animal exposure and measuring the effects on the hearing system.	ENEA.BIOTEC	C	D3.1/D3.2/D3.3
WP4	Design of protocols for human exposure and audiological assessment. Laboratory studies (within-subject study)	ISVR	C	D4.1/D4.2/D4.3 /D4.4/D4.5/D4.6
WP5	Design of protocols for human exposure and audiological assessment. Additional test*	ISVR	C	Addendum to D4.2/D4.3/D4.4 /D4.6*
WP6	Animal exposure: effect of the SAR level (dose) and of exposure times	ENEA.BIOTEC	C	D6.1/6.2
WP7	Animal exposure: combined potentiating effect of UMTS microwaves on the ototoxicity of kanamicin (KM)*	ENEA.BIOTEC	C	D7.1/D7.2
WP8	Human exposure and audiological assessment. Laboratory studies (within-subject study)	ISVR	C	D8.1/D8.2
WP9	Human exposure and audiological assessment. (Additional test)*	ISVR	C	D9.1/D9.2
WP10	Analysis and processing of the data	CNR.ISIB	C	D10.1/D10.2/D10.3/D10.4
WP11	Dissemination and exploitation of the results	CNR.ISIB	C	D11.1/D11.2/D11.3/D11.4
WP12	Monitoring of secondary aims	CNRS	C	D12.1

\* Title modified according to the decision of the PB.

**Table II. Updated Deliverables List. R: report; DC: data corpus; DE: devices; PU: public; CO: consortium.**

<b>Deliverable No</b>	<b>Deliverable title</b>	<b>Nature</b>	<b>Dissemination level</b>
D1.1	Leaflet/ Brochure describing EMFnEAR	R	PU
D1.2	Interim Report*	R	PU
D2.1	Report on the systems for UMTS exposure	R	CO
D2.2	Device for animal exposure	DE	CO
D2.3	Device for human exposure	DE	CO
D3.1	Report on protocols for animal exposure	R	CO
D3.2	Report on protocols for measuring the effects in animals	R	CO
D3.3	Ethical Committee approvals for animal experimentation		CO
D4.1	Ethical Committee approvals for human protocols – within subject study		CO
D4.2	Report on guidelines for normal hearing subjects	R	CO
D4.3	Report on protocols for human exposure	R	CO
D4.4	Report on protocols for audiological assessment-within subject study	R	CO
D4.5	Ethical Committee approvals for CAS analysis		CO
D4.6	Report on protocols for measuring the influence on the CAS effect	R	CO
Addendum*	Ethical Committee approvals for human protocols – (Additional Test)*		
Addendum*	Reports on protocols for audiological assessment –(Additional Test )*	R	CO
D6.1	Report on various phases of animal exposure and audiological assessment (SAR, time, in-vitro)	R	CO
D6.2	Data on objective audiological effects	DC	CO
D7.1	Reports on the various phases of animal exposure and audiological assessment (KM and UMTS)	R	CO
D7.2	Data on combined effects of KM and UMTS microwaves	DC	CO
D8.1	Reports on the various phases of human exposure (within-subject study)	R	CO
D8.2	Data on within-subjects study	DC	CO
D9.1	Reports on the various phases of human exposure (Additional Test)*	R	CO
D9.2	Data on Additional Test*	DC	CO
D10.1	Report on the effects on hearing in animals	R	CO

<b>D10.2</b>	<b>Reports on the effects on hearing due to microwave exposure observed in humans (within-subject study)</b>	<b>R</b>	<b>CO</b>
<b>D10.3</b>	<b>Reports on the effects on hearing due to microwave exposure observed in humans (Additional Test)*</b>	<b>R</b>	<b>CO</b>
<b>D10.4</b>	<b>Report on data corpus</b>	<b>R</b>	<b>CO</b>
<b>D11.1</b>	<b>EMFnEAR_ News issues (#1, #2 and #3 issues)</b>		<b>PU</b>
<b>D11.2</b>	<b>Final report on the effects of UMTS phones on hearing</b>	<b>R</b>	<b>PU</b>
<b>D11.3</b>	<b>Guidelines for manufactures and providers</b>	<b>R</b>	<b>PU</b>
<b>D11.4</b>	<b>EMFnEAR website</b>		<b>PU</b>
<b>D12.1</b>	<b>Report on the preliminary analysis on the results with respect to secondary aims</b>	<b>R</b>	<b>CO</b>

\* Title changed according to the decision of the PB.

## 2.5 Description of the workpackages

<b>WP1</b>	<b>Central Coordination and management activities</b>		
<b>Start date (Month)</b>	1	<b>Completion Date (Month)</b>	30
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	CNR.ISIB	<b>Partners involved</b>	ENEA.BIOTEC, CNRS, ISVR, KMU, NIRR, RCA, NIOM

### **Objectives**

Provide the necessary background to the internal life of project EMFnEAR, and to co-ordinate and monitor all project's components.

Enhance the impact of the project outside the network itself, by disseminating project's briefs and achievements by any possible means.

Ensure liaison with the Commission Services.

The Coordinator, in agreement with the PB should also: i) present Project EMFnEAR and its briefs to international, national, regional, local political and Health Care authorities, whenever required by partners or other bodies; ii) present Project EMFnEAR and its briefs to international and national scientific conferences and symposia;

### **Progress during the project lifetime**

Five PB Meetings and 5 DT Meetings were organised in the course of the project lifetime. The Coordinator and the Project Board (PB) provided the necessary background, in terms of administration, management and co-ordination, to the network as a whole, and to all the demanding activities that have been planned.

### **Deliverables**

D1.1 – Leaflet/brochure describing EMFnEAR project (Completed)

D1.2 – Interim Report (Completed)

Input to all the other WPs

<b>WP2</b>	<b>Design, development and manufacturing of localized exposure systems</b>		
<b>Start date (Month)</b>	1	<b>Completion Date (Month)</b>	9
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ENEA.BIOTEC	<b>Partners involved</b>	CNR.ISIB, NIRR

### **Objectives**

Starting from the devices already present in the laboratories involved in this WP and on the basis of their long-standing expertise in the area, the two antenna systems (one for animals and one for humans) have been designed ad hoc, in order to optimize the UMTS field affecting the hearing systems. As a first step, the pattern of the electromagnetic fields generated have been modelled and estimated by means of finite elements methods in order to assess the field affecting the hearing system. Then, on this basis, modifications on existing devices have been defined to change field patterns in order to control the field actually affecting the hearing systems of subject involved in the study. The two systems should allow the control of exposure time and power. Measures in phantoms have been performed to optimize the devices before animal and human exposure.

### **Progress during the project lifetime**

Localized exposure and positioning systems both for animal and human experimentation were developed.

### **Deliverables**

D2.1 - Report on the systems for UMTS exposure (completed)  
D2.2 - Device for animal exposure (completed)  
D2.3 - Device for human exposure (completed)  
Input to WP 6 and to WP 7

### **Milestones**

Design, development and manufacturing of localized exposure systems. These systems, although structurally and geometrically different for humans and animals, should be able for both applications to reproduce the field generated by UMTS mobile telephony. The systems (one type for animal exposure and two for humans) should allow the setting of the level of exposure in terms of total power (i.e., allowing the control of the dose at which the animals and/or humans were exposed to). These systems have been designed and developed also taking into consideration the experience that the involved teams acquired in the course of project GUARD in the design of similar systems at different frequency and modulation (GSM). As to the mechanical systems for sizing, shaping and positioning the exposure systems for both animals and humans, the Project Board agreed in using the same devices already designed and manufactured.

<b>WP3</b>	<b>Design protocols for animal exposure and measuring the effects on the hearing system</b>		
<b>Start date (Month)</b>	1	<b>Completion Date (Month)</b>	3
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ENEA.BIOTEC	<b>Partners involved</b>	NIRR, CNR.ISIB

### **Objectives**

The work has been performed by doing a few meetings (implemented also by electronic media) between the three partners involved in this workpackage. A strong link with WP4 and WP5 (human protocols) has been established, considering that the two Workpackages share very close similarities.

### **Progress during project lifetime**

The UMTS exposure and audiological assessment protocols were finalized

### **Deliverables**

D3.1 - Report on protocols for animal exposure (completed)  
 D3.2 - Report on protocols for measuring the effects in animals (completed)  
 D3.3 - Ethical Committee approvals for animal experimentation (completed)  
 Input to WP 6 and WP 7

### **Milestones**

Design protocols for animal exposure and measuring the effects on the hearing system. The PB agreed that the protocols for animal exposure and audiological assessment share close similarities with those one generated in the lifetime of project GUARD. These protocols defined the exposure procedure of Sprague Dawley rats, including the study of the potential combined effect of UMTS EMF exposure and other ototoxic agents. Sham-exposure has been performed in all the types of experiments. Statistical analysis has been performed on the data recorded pre- and post-exposure and from the sham-exposure animals.

<b>WP4</b>	<b>Design of protocols for human exposure and audiological assessment. Laboratory studies (within-subject study)</b>		
<b>Start date (Month)</b>	3	<b>Completion Date (Month)</b>	6
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ISVR	<b>Partners involved</b>	ENEA.BIOTEC, CNR.ISIB, CNRS, KMU, NIRR, RCA, NIOM

### **Objectives**

The work has been performed by a few meetings (implemented also by electronic media) between all partners involved in this workpackage. A strong link with WP3 (Design of protocol for animals) has been established, considering that the two Workpackages share large similarities.

### **Progress during project lifetime**

The UMTS exposure and audiological assessment protocols were finalized

### **Deliverables**

D4.1 - Ethical Committee approvals for human protocols – within-subject study (completed)  
 D4.2 - Report on guidelines for normal hearing subjects (completed)  
 D4.3 - Report on protocols for human exposure (completed)  
 D4.4- Report on protocols for audiological assessment - within-subject study (completed)  
 D4.5 - Ethical Committee approvals for CAS analysis (completed)  
 D4.6 - Report on protocols for measuring the influence on the CAS effect as index of hearing-related cognitive effects (completed)  
 Input to WP 8 and WP 9

### **Milestones**

Design of protocols for human exposure and audiological assessment. Laboratory studies (within-subject study). The Project Board agreed that the protocols for human exposure and audiological assessment share close similarities with those one generated in the lifetime of project GUARD. This protocol (within-subject study) is based on the laboratory experimental exposure of the subjects. All involved subjects undertook an audiological battery of test pre- and post-exposure.

<b>WP5</b>	<b>Design of protocols for human exposure and audiological assessment. Additional test</b>		
<b>Start date (Month)</b>	3	<b>Completion Date (Month)</b>	6
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ISVR	<b>Partners involved</b>	ENEA.BIOTEC, CNR.ISIB, CNRS, KMU, NIRR, RCA, NIOM

### **Objectives**

The works focused on the definition of additional test for the audiological assessment of the human subjects, additional recording sessions and additional exposure system.

### **Progress during project lifetime**

The UMTS exposure and audiological assessment protocols for Additional test were finalized.

The Project Board (PB) agreed to modify the Workplan adding some within-subjects studies, such as CAS effect on DPOAE, delayed audiological assessment, exposure of subjects close to the maximum SAR (Specific Absorption Ratio) level permitted by current regulation (allowing to give additional answers on possible adverse effects when the worst case in exposure is taken into consideration). Therefore, the title of this WP and of the Deliverables have been slightly modified.

### **Deliverables**

Ethical Committee approvals for Additional Analysis (completed)  
Addendum to Deliverables D4.2- D4.3- D4.4- D4.6 (completed)

### **Milestones**

Design of protocols for human exposure and audiological assessment: Additional test.

<b>WP6</b>	<b>Animal exposure: effect of the SAR level (dose) and of exposure times</b>		
<b>Start date (Month)</b>	6	<b>Completion Date (Month)</b>	18
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ENEA.BIOTEC	<b>Partners involved</b>	NIRR

### **Objectives**

These activities were based on the protocols delivered in WP3. The activities of this workpackage during its lifetime were strictly influenced by the results obtained at the same time by the linked WP 10 (Central Data Processing Unit).

### **Progress during project lifetime**

Animal experimentation was performed on the basis of the protocols developed in WP3.

The performed activities are described in the Deliverables D6.1, D7.1 and D10.1 attached to this report (Annex A).

In summary, the analysis of the data show no effects of UMTS electromagnetic fields exposure on the inner auditory system of rats.

### **Deliverables**

D6.1 - Reports on the various phases of animal exposure and audiological assessment (completed)

D6.2 - Data on objective audiological effects (completed).

Input to WP 10 and RAE (Reports on Animal Effects)

### **Milestones**

Exposure of animals and measuring of the effects on the hearing system. The exposure has been performed by means of the exposure and positioning systems delivered in WP 2 and according to the protocols delivered in WP 3.

<b>WP7</b>	<b>Animal exposure: combined potentiating effect of UMTS microwaves on the ototoxicity of kanamicin (KM)</b>		
<b>Start date (Month)</b>	9	<b>Completion Date (Month)</b>	20
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ENEA.BIOTEC	<b>Partners involved</b>	ISIB.CNR

### **Objectives**

These activities were based on the protocols delivered in WP3. Also in this case, the activity of this Workpackage during its lifetime was strictly influenced by the results obtained at the same time by the linked WP 10 (Central Data Processing Unit).

### **Progress during the project lifetime**

Animal experimentation were performed on the basis of the protocols developed in WP3.

The performed activities are described in the Deliverables D6.1, D7.1 and D10.1 attached to this report (Annex A).

In summary, the analysis of the data show no effects of UMTS electromagnetic fields exposure on the inner auditory system of rats exposed to a well recognized pathological agent (KM).

### **Deliverables**

D7.1 - Reports on the various phases of animal exposure and audiological assessment (GM and UMTS) (completed)

D7.2 - Data on combined effects of GM and UMTS microwaves (completed)

Input to WP 10 and RAE (Reports on Animal Effects), Reports on the various phases of this WP;

### **Milestones**

Animal exposure: combined potentiating effect of UMTS microwaves on the ototoxicity of kanamicin (KM) in the experimental animals (Sprague-Dawley rats). These activities were based on the protocols delivered in WP3.

<b>WP8</b>	<b>Human exposure and audiological assessment. Laboratory studies (within-subject study)</b>		
<b>Start date(Month)</b>	9	<b>Completion Date (Month)</b>	22
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ISVR	<b>Partners involved</b>	NIOM, RCA, CNRS, KMU, NIRR

### **Objectives**

These activities were based on the protocols delivered in WP4. Also in this case, the activity of this Workpackage during its lifetime will strictly influenced by the results obtained at the same time by the linked WP 10 (Central Data Processing Unit)

### **Progress during the project lifetime**

Human experimentations was performed on the basis of the protocols developed in WP4. The performed activities are described in the Deliverables D8.1 and D10.2 attached to this report (Annex A). After the pooled analysis of the data, no effects were found on the main measures of the status of the auditory system.

### **Deliverables**

D8.1 - Reports on the various phases of human exposure (within-subject study) (Completed)  
 D8.2 - Data on the audiological assessment, to be processed in the next WP 10. (Completed)  
 Input to WP 10 and RHE (Reports on Human Effects) (Completed)

### **Milestones**

Human exposure and audiological assessment. Laboratory studies (within-subject study). Study of the potential effects on hearing of exposure to UMTS microwaves based on controlled laboratory exposure of human subjects.

<b>WP9</b>	<b>Human exposure and audiological assessment. Additional tests</b>		
<b>Start date (Month)</b>	9	<b>Completion Date (Month)</b>	22
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	ISVR	<b>Partners involved</b>	NIOM, RCA, CNRS, KMU, NIRR

### **Objectives**

These activities were based on the protocols delivered in WP5. Also in this case, the activity of this Workpackage during its lifetime was strictly influenced by the results obtained at the same time by the linked WP 10 (Central Data Processing Unit)

### **Progress during the project lifetime**

Human experimentations was performed on the basis of the protocols developed in WP5. The performed activities are described in the Deliverables D9.1 and D10.2, attached to this report (Annex A). After the pooled analysis of the data, no effects was found on the main measures of the status of the human auditory system.

### **Deliverables**

D9.1 – Reports on the various phases of human exposure (Additional test) (completed)  
 D9.2 - Data on the audiological assessment, to be processed in the next WP 10 (completed)  
 Input to WP 10 and RHE (Reports on Human Effects)

### **Milestones**

Human exposure and audiological assessment. Additional test. Study of the potential effects on hearing of exposure to UMTS microwaves based on controlled laboratory exposure of human subjects.

<b>WP10</b>	<b>Analysis and processing of the data</b>		
<b>Start date (Month)</b>	6	<b>Completion Date (Month)</b>	28
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	CNR.ISIB	<b>Partners involved</b>	ISVR

### **Objectives**

All data coming from the other laboratories involved in the project were collected and processed. The audiological data, in particular OAE and evoked potentials, were processed by signal processing technique. Data collected in each laboratory underwent a preliminary statistical analysis and, after that, the pooled analysis of data collected by all laboratories was performed.

### **Progress during the project lifetime**

Data have been processed and statistically analysed during the course of the project as soon as they came available.

EMFnEAR results need at least one additional year for further analysis and dissemination.

### **Deliverables**

D10.1 - Reports on the effects on hearing due to microwave exposure observed in animals (completed)

D10.2 - Reports on the effects on hearing due to microwave exposure observed in humans (within-subject study) (completed)

D10.3 - Reports on the effects on hearing due to microwave exposure observed in humans (Additional Test) (completed)

D10.4 - Report on the data corpus (completed)

Input to WP 11 and DEP (Dissemination and Exploitation Plans)

### **Milestones**

Analysis and processing of the data obtained from the experiments to quantify the effects of exposure on the hearing system with the activation of a Centralized Data Processing Unit. The procedures differed according to whether the data refer to the animal experiments (repeated measures for different exposure levels) or to the two human studies (within-subject study and additional study). Statistical analysis of all processed data.

<b>WP11</b>	<b>Dissemination and exploitation of the results</b>		
<b>Start date (Month)</b>	3	<b>Completion Date (Month)</b>	30
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	CNR.ISIB	<b>Partners involved</b>	ENEA.BIOTEC, CNRS,ISVR, KMU, NIRR, RCA, NIOM

### **Objectives**

The activities were mainly based on i) Leaflet/brochure for the presentation of EMFnEAR activities and of the newsletter EMFnEAR\_News; ii) Publications from individual laboratories; iii) On-line publication of a report on the overall activity and results of EMFnEAR; iv) Coordination with Scientific Societies and International bodies; v) Organizations of Workshop on the effects of cellular phones on hearing; vi) Preparation of general feedbacks for UMTS phone manufactures and UMTS service providers.

### **Progress during the project lifetime**

The EMFnEAR activities have been disseminated starting from the beginning towards both scientific community and general public. The EMFnEAR brochure was finalized, delivered and distributed. The EMFnEAR web site (<http://www.emfnear.polimi.it>) was created and maintained to give an immediate and free access to the information concerning EMFnEAR activities and results for all interested people.

The project activities and the results of EMFnEAR were presented in national and international scientific conferences.

A Workshop on EMF interactions and hearing has been Organized by the EMFnEAR Consortium on June 3, 2006 as the Special Session *Bioelectromagnetics and Hearing* of the International Conference *NHS 2006 Beyond Newborn Hearing Screening: Infant and Childhood Hearing in Science and Clinical Practice*, May 31-June 3, 2006, Cernobbio, Como, Italy. Around 100 delegates attended to the EMFnEAR event. Detailed about the Workshop can be found in the Issue #2 of the EMFnEAR NEWS, Deliverables D11.1 attached to this report (Annex A).

Three issues of the EMFnEAR NEWS have been published on an ad hoc basis, that is when the Consortium decided to disseminate specific information and news related to the project activities.

EMFnEAR results need at least one additional year for further analysis and dissemination and for the publication of peer review papers.

### **Deliverables**

D11.1 - EMFnEAR\_News issues (completed)

D11.2 – Report on the effects of UMTS phones on the hearing system (completed)

D11.3 – Guidelines for manufactures and providers (completed)

D11.4 - EMFnEAR Website (completed)

### **Milestones**

Dissemination and exploitation of the results. The dissemination activities of EMFnEAR were performed in close link with the activities of all other WPs.

<b>WP12</b>	<b>Monitoring of secondary aims</b>		
<b>Start date (Month)</b>	16	<b>Completion Date (Month)</b>	28
<b>Current Status</b>	COMPLETED		
<b>Partner responsible</b>	CNR.ISIB	<b>Partners involved</b>	NIOM, ISVR, KMU, RCA,

### **Objectives**

On the basis of the results achieved during the lifetime of EMFnEAR the possibility of enlarge the investigation to topics such as handedness and gender and presence of pathological conditions was monitored.

### **Progress during the project lifetime**

Some secondary aims, such as the effects of handedness and gender, involving a total of about 120 subjects, were studied during the project lifetime. In summary, no effects of UMTS exposure were found in both these two studies. Additional details can be found in Deliverable D12.1 ( Annex A).

### **Deliverables**

D12.1 - Reports on the preliminary analysis with respects to secondary aims (completed)

### **Milestones**

Monitoring of the secondary aims

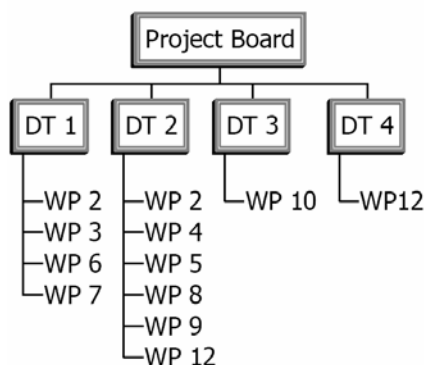
Monitoring of the influence of age and pathological conditions.

## 2.6 Project management and coordination

### Project management

#### *General structure*

Project EMFnEAR was managed by a Project Board (PB), composed by the Coordinator and by the persons in charge for each participant centre. The Project Board controlled and coordinated the activity of the four Development Teams (DT), composed by personnel of all centres. The DT directly implemented and developed the research activities described in the workpackages (WPs) of the workplan. A schematic representation of the management structure of EMFnEAR is given in Fig. 1.



*Fig. 1 - Management structure of EMFnEAR project. The activities related to WPI (Central coordination and management activities) are not included in this schematic representation*

#### *The EMFnEAR Project Board (PB)*

The EMFnEAR Project Board was led by P. Ravazzani (I, CNR.ISIB, Coordinator) and composed by L. Collet and A. Moulin (F, CNRS), M. Lutman (UK, ISVR), C. Marino (I, ENEA.BIOTEC), M. Sliwinska-Kowalska (PL, NIOM), G. Tavartkiladze (RU, RCA), G. Thuroczy (HU, NIRR) and I. Uloziene (LT, KMU).

The Project Board took all the decisions about the activities and strategies of the EMFnEAR research project. It was responsible for the activities of all DTs, monitoring the progress of the Project as a whole and the use of resources. The PB had the responsibility to recommend changes or termination of a sub-activity and/or a workpackage based on performance and feasibility of completion.

#### *The Development Teams DT*

Each Development Team, led by a DT Manager (DTMs) appointed by the PB, was responsible of the implementation of the research activities assigned to it. **DT 1**: Exposure systems and animal experimentation, WP 2, 3, 6 and 7 (CNR.ISIB, ENEA.BIOTEC, and NIRR); **DT 2**: Exposure systems and human experimentation, WP 2, 4, 5, 8, 9, 12 (all teams); **DT 3**: Centralized Data Processing Unit, WP 10 (CNR.ISIB and ISVR); **DT 4**: Dissemination and exploitation plans, WP 11 (all teams).

#### *The communication flow*

The communication flow among the different levels of the project management was performed by scheduled meetings as represented in Table V.

**Table III - Schematic representation of the scheduled meetings at the different management levels.**

<b>Participants</b>	<b>Agenda</b>	<b>Deliverables</b>
PB	Set actions and targets, monitoring progresses, identify problems, define next strategies	Executive orders, directives and instructions for DT
DT	Monitor execution of DT tasks, evaluate results, define next steps to be achieved	Report to PB on the achieved objectives, the produced deliverables and end-points

Informal communications was guaranteed by the close contacts among members of different management levels. In order to allow quick and effective responses to the need of the project and also to reduce the travel costs, the use of rapid communication media was encouraged and *ad hoc* infrastructures was developed such as electronic mail and web-pages and EMFnEAR Chat areas in the EMFnEAR website.

#### *Management of legal aspects*

As a rule, all participants shared freely between themselves the know-how necessary to the execution of the project. As to the intellectual property rights and access rights to knowledge generated under the EMFnEAR project, all participants access to them for the execution of the project and for the purpose of its use on a royalty-free base. All participants could access to the pre-existing intellectual properties (pre-existing know-how necessary for the execution of the project or to use its knowledge) at favourable conditions. All participants formerly involved in the GUARD project, agreed on the free use of the results, deliverables, knowledge and acquired know-how of that project for the execution of EMFnEAR. At present, the participants do not envisage any direct commercial benefit from the results of this project. Should any deliverables rise some commercial interest, the PB will take all the decisions regarding any marketable products, after consultation with the legal offices of the Commission Services.

As to the regulations for the dissemination of the results of EMFnEAR, all partners were requested to explicitly mention that the results were generated under and with the support of EMFnEAR Project. As to other issues (see also below), considering ethical and safety provision management, the Project Board was responsible that all the research fulfils all legal or ethical requirements of the Member States where they are carried out and that research complies with all relevant national and international laws, conventions and codes of conduct.

The PB was also responsible for the respect of all the fundamental safety issues of good laboratory practices and also monitors gender issues also considering the influence of this aspect on the scientific activities.

## Coordination during the project lifetime

In the course of the project lifetime both PB meetings and DT meetings took place as described in the following Table IV:

**Table IV – List of PB and DT Meetings**

MEETING TYPE	PARTICIPANTS
Preparatory PB Meeting Bruxelles, December 20, 2004	Alessandra Brazzale (I, ISIB), Mark Lutman (UK, ISVR), Paolo Galloni (I, ENEA), Lionel Collet (F, CNRS), Annie Moulin (F, CNRS), Marta Parazzini (I, ISIB), Rosanna Pinto (I, ENEA), Paolo Ravazzani (I, ISIB), George A. Tavartkiladze (RU, RCA), Gyorgy Thuroczy (HU, NIRR), Virgilijus Uloza (LT, KMU),
Kick-off PB meeting Milan (I) Feb 5, 2005	Alessia Bianchi (I, ISIB), Mark Lutman (UK, ISVR), Carmela Marino (I, ENEA), Annie Moulin (F, CNRS), Paolo Ravazzani (I, ISIB), Mariola Sliwinska-Kowalska (PL, NIOM), George A. Tavartkiladze (RU, RCA), Gyorgy Thuroczy (HU, NIRR), Virgilijus Uloza (LT, KMU).
PB meeting Milan (I) Jan 13, 2006	Alessia Bianchi (I, ISIB), Mark Lutman (UK, ISVR), Carmela Marino (I, ENEA), Paolo Ravazzani (I, ISIB), Mariola Sliwinska-Kowalska (PL, NIOM), George A. Tavartkiladze (RU, RCA), Gyorgy Thuroczy (HU, NIRR), Virgilijus Uloza (LT, KMU).
PB meeting Cernobbio (I) June 03, 2006	Mark Lutman (UK, ISVR), Paolo Ravazzani (I, ISIB), Gyorgy Thuroczy (HU, NIRR), George Tavartkildze (RU, RCA).
PB meeting Milan (I) Nov 29, 2006	Mark Lutman (UK, ISVR), Carmela Marino (I, ENEA), Annie Moulin (F, CNRS), Paolo Ravazzani (I, ISIB), Gyorgy Thuroczy (HU, NIRR).
PB meeting Milan (I) Feb 02, 2007	Carmela Marino (I, ENEA), Paolo Ravazzani (I, ISIB), Mariola Sliwinska-Kowalska (PL, NIOM), Gyorgy Thuroczy (HU, NIRR), Ingrida Uloziene (LT, KMU).
DT meeting (DT1, DT2, DT3) Milan (I) Feb 5, 2005	Alessandra Brazzale (I, ISIB), Mark Lutman (UK, ISVR), Carmela Marino (I, ENEA), Annie Moulin (F, CNRS), Marta Parazzini (I, ISIB), Rosanna Pinto (I, ENEA), Paolo Ravazzani (I, ISIB), Mariola Sliwinska-Kowalska (PL, NIOM), George A. Tavartkiladze (RU, RCA), Gyorgy Thuroczy (HU, NIRR), Virgilijus Uloza (LT, KMU).
DT meeting (DT2) Vilnius (LT) May 26-28, 2005	Ferdinando Grandori (I, ISIB), Ingrida Uloziene and Virgilijus Uloza (LT, KMU)
DT meeting (DT1, DT2, DT3) Milan (I) Jan 13, 2006	Claudia Franzoni (I, ISIB), Mark Lutman (UK, ISVR), Carmela Marino (I, ENEA), Alessia Paglialonga (I, ISIB) Marta Parazzini (I, ISIB), Rosanna Pinto (I, ENEA), Paolo Ravazzani (I, ISIB), Mariola Sliwinska-Kowalska (PL, NIOM), Srikanta Mishra (UK, ISVR), George A. Tavartkiladze (RU, RCA), Gyorgy Thuroczy (HU, NIRR), Gabriella Tognola (I, ISIB), Virgilijus Uloza (LT, KMU), Marek Zmyslony (PL, NIOM).
Meeting (DT1) Bologna, February 14, 2006	Carmela Marino (ENEA, I), Paolo Ravazzani (CNR.ISIB, I)
DT meeting (DT2, DT3) Cernobbio (I) June 03, 2006	Mark Lutman (UK, ISVR), Marta Parazzini (I, ISIB), Paolo Ravazzani (I, ISIB), Gyorgy Thuroczy (HU, NIRR), George Tavartkildze (RU, RCA), Claudia Franzoni (I, ISIB)
DT meeting (DT1, DT2, DT3) Milan (I) Nov 29, 2006	Cécile Barnel (F, CNRS), Istvan Hernadi (HU, NIRR), Mark Lutman (UK, ISVR), Carmela Marino (I, ENEA), Annie Moulin (F, CNRS), Alessia Paglialonga (I, ISIB), Marta Parazzini (I, ISIB), Paolo Ravazzani (I, ISIB), Federica Sibella (I, ISIB), Gyorgy Thuroczy (HU, NIRR).

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DT meeting (DT1) Milan (I) January 30,31, 2007	Paolo Galloni(I, ENEA), Marta Parazzini (I, ISIB), Paolo Ravazzani (I, ISIB)
DT meeting (DT1, DT2, DT3, DT4) Milan (I) Feb 02, 2007	Istvan Hernadi (HU, NIRRR), Giorgio A. Lovisolo (I, ENEA), Carmela Marino (I, ENEA), Marta Parazzini (I, ISIB), Paolo Ravazzani (I, ISIB), Mariola Sliwinska-Kowalska (PL, NIOM), Gyorgy Thuroczy (HU, NIRRR), Ingrida Uloziene (LT, KMU), Marek Zmyslony (PLO, NIOM).

## 2.7 Exploitation and dissemination activities

EMFnEAR activities were presented in international and national scientific conferences, as reported in Annex B to this progress report, and summarized in the following Table V.

**Table V – List of Dissemination Meetings**

Event	Site	Date	EMFnEAR Participants
27th Annual Meeting of the Bioelectromagnetic Society BioEM2005	Dublin	June 19-24, 2005	Carmela Marino Marta Parazzini Paolo Ravazzani Rosanna Pinto Gyorgy Thuroczy
XI National Symposium of Radio Sciences	Poznan	April 7, 2005	Paolo Ravazzani
International Conference and COST 281 Workshop on Emerging EMF-Technologies, Potential Sensitive Groups and Health	Graz	April 20-21, 2006	Paolo Ravazzani
Working Party on Health DG Sanco	Luxemburg	September 18-19, 2005	Paolo Ravazzani
Meeting at CNR Headquarters and ICEmB	Rome	February 24, 2005	Ferdinando Grandori Paolo Ravazzani
Deaf and Hearing Impaired Children Europe 2005	Londra	May 13-14, 2005	Ferdinando Grandori
ICNIRP Workshop	Berlin	March 18-22, 2006	Rosanna Pinto Paolo Ravazzani
Meeting of ENGI-HEALTH Group at French Ministry of Research	Paris	April 22, 2005	Paolo Ravazzani
8th Congress of European Bioelectromagnetics Association Congress (EBEA)	Bordeaux	April 10-13, 2007	Carmela Marino Giorgio Lovisolo Paolo Ravazzani György Thuróczy Györgyi Kubinyi Tamás Fábíán
ICEmB Meeting	Naples	May 17-19, 2007	Carmela Marino
6th International European Congress of Oto-Rhino Laryngology, Head and Neck Surgery (EUFOS)	Vienna	June 30-July 4, 2007	Annie Moulin Ingrida Uloziene Virgilijus Uloza Mariola Śliwińska-Kowalska Gabriella Tognola Ferdinando Grandori
French National Congress of Oto-Rhino Laryngology, Head and Neck Surgery	Paris	October 14-16, 2007	Annie Moulin

Meeting at the Otolaryngology Department of Medical University of Warsaw	Warsaw	September 14-17 2006	Egle Gradauskiene Ingrida Uloziene Virgilijus Uloza
Meeting at the Otolaryngology Department of J. Stradins University Hospital in Riga	Riga	March 23-24, 2007	Ingrida Uloziene Virgilijus Uloza
4th International Workshop on Biological Effects of Electromagnetic Fields	Crete	October 16-20, 2006	Ingrida Uloziene Virgilijus Uloza György Thuróczy Györgyi Kubinyi
The First European Conference on Antennas and Propagation (EuCAP 2006)	Nizza	November 6-7, 2006	György Thuróczy Paolo Ravazzani
NHS2006 Beyond Newborn Hearing Screening: Infant and Childhood Hearing in Science and Clinical Practice	Cernobbio	May 31- June 3, 2006	Paolo Ravazzani Gyorgy Thuroczy Marta Parazzini Mark Lutman George Tavartkildze Claudia Franzoni Ferdinando Grandori Gabriella Tognola Sharon Scagnetti Alessia Paglialonga Alessia Bianchi
8th European Federation of Audiology Society Congress (EFAS 2007)	Heidelberg	June 6-9, 2007	Piotr Kotyło Mariola Śliwińska-Kowalska Gabriella Tognola Ferdinando Grandori
Pediatric Growth Research Centre, Department of Pediatrics, Institute of the Health of Women and Children, Göteborg University	Goetteborg	06.2007	Mariola Śliwińska-Kowalska
International Conference on Electromagnetic Fields, Health and Environment (EHE'06)	Madeira	April 27-29, 2006	Claudia Franzoni
Working meeting at University of Ljubljana	Ljubljana	May 2-4, 2006	Paolo Ravazzani
Working Party on Health DG Sanco	Luxemburg	May 23, 2006	Paolo Ravazzani
Meeting at the Irish Society of Audiology	Dublin	October 19-22, 2006	Ferdinando Grandori
Cost 281 Seminar on Electromagnetic Fields	Ljubljana	September 12-14 2006	Paolo Ravazzani
Meeting at CNR Headquarters	Rome	March 28, 2007	Gabriella Tognola Paolo Ravazzani
Meeting at CNR Headquarters and ICEmB	Rome	March 12 2007	Paolo Ravazzani
Meeting "Salute e campi elettromagnetici", ISS	Rome	March 16 2007	Paolo Ravazzani
Meeting Univ. "La Sapienza" and "Campus Biomedico"	Rome	May 28 2007	Marta Parazzini

Seminars on numerical dosimetry in EMF and health	Darmstadt	31/01-01/02/2007	Federica Sibella
International Joint Meeting on Numerical Dosimetry	Paris	April 16, 2007	Paolo Ravazzani
Working Party on Health DG Sanco	Luxemburg	May 23-24, 2006	Paolo Ravazzani
Meeting at the Austrian Research Center on EMF and hearing	Vienna	March 19, 2007	Paolo Ravazzani
Workshop France Telecom	Paris	December 20-21, 2006	Paolo Ravazzani
Meeting SC4 ICES London	London	March 1, 2007	Paolo Ravazzani
First European Congress on Prevention, Detection and diagnostic of verbal communication disorders	Patrasso	December, 14-16, 2006	Ferdinando Grandori

A leaflet describing EMFnEAR objectives, partnership, social relevance, was prepared and largely diffuse (as the EMFnEAR NEWS #1) towards both scientific societies and international bodies and general public. Three issues of the newsletter (The EMFnEAR NEWS) were prepared and largely distributed.

As to the specific action for covering the whole European area, George Tavartkiladze from RCA was in charge for the dissemination of the results of the project beyond the borders of the European Union, and in particular to Russia, NIS and Eastern Europe.

The EMFnEAR website (<http://www.emfnear.polimi.it>) was published in the course of 2005 and it is regularly updated.

The EMFnEAR project was presented at the Italian Consortium ELETTRA 2000 (press release in Italian is available at <http://www.elettra2000.it/newsletter/n61/bioem61.htm>)

The EMFnEAR Project Board organized on June 3, 2006 a workshop on the effects of EMF on the hearing system: “*Bioelectromagnetics and hearing*”, in the framework of the NHS2006 Beyond Newborn Hearing Screening: Infant and Childhood Hearing in Science and Clinical Practice, May 31-June 3, 2006, Cernobbio, Como, Italy.

## **2.8 Ethical aspects and safety provisions**

As a rule, research must fulfil all legal, ethical or regulatory requirements of the Member States where it is carried out (authorization from national or local bodies, including animal welfare committees, existing code of practices or of international bodies) and relevant community legislation. The research complied with all relevant national and international laws, conventions and codes of conduct.

All the teams of the EMFnEAR consortium conformed to the Declaration of Helsinki and the conventions of the Council of Europe on Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, in their latest versions and obtained clearance from the competent ethical committees.

### **Animal experimentation**

Animal experimentations were performed in one centre (ENEA.BIOTEC). The project involves the use of small laboratory animals (rats Sprague-Dawley). Italian law (DL 116/92), according to the European guidelines, provides an authorization by the Ministry of Health. The law does not provide submission to an ethical committee, therefore in the ENEA laboratory all experimental activities were approved by an internal ethical committee.

### **Human experimentation**

Ethical approvals were obtained by all centers involved in human experimentations, according to all local laws, rules and codes of good conduct. A written informed consent from the subjects involved in the experiments was obtained.

### **Safety provisions**

All the participants in EMFnEAR respected fundamental safety issues of good laboratory practice and of general practices involving and handling biological agents.

No experiment of exposure of human to Specific Absorption Rate (SAR) higher than or for longer time than what is indicated in all relevant national and international laws, guidelines, conventions and codes of conduct was performed.

### 3. MANPOWER FOR THE EXECUTION OF THE ACTIVITIES

The following Table VI presents the complete list of all the persons who have participated in the execution of the project and, for each of them, the person/days of work, the professional level and the corresponding unit and total costs.

**Table VI – Manpower of the execution of the activities**

Person	Partner	Function	Person/days	Total Cost
Paolo Ravazzani	ISIB.CNR	Senior Researcher	368	99,980.84 €
Gabriella Tognola	ISIB.CNR	Senior Researcher	378	89,669.69 €
Alessandra Brazzale	ISIB.CNR	Researcher	44	8,793.76 €
Marta Parazzini	ISIB.CNR	Researcher	360	61,681.22 €
Ferdinando Grandori	ISIB.CNR	Director	88	41,304.55 €
Carlo Pirovano	ISIB.CNR	Technician	455	72,990.41 €
Sharon Scagnetti	ISIB.CNR	Technician	356	64,250.45
Carmela Marino	ENEA.BIOTEC	Researcher	192	45,706.82 €
Paolo Galloni	ENEA.BIOTEC	Researcher	406	73,389.69 €
Giorgio Lovisolo	ENEA.BIOTEC	Researcher	85	20,219.80 €
Sergio Mancini	ENEA.BIOTEC	Technician	63	14,039.17 €
Rosanna Pinto	ENEA.BIOTEC	Researcher	131	22,866.94 €
Marta Piscitelli	ENEA.BIOTEC	Veterinary	60	13,473.30 €
Annie Moulin	CNRS	Researcher	204	50,388.30 €
Hung Thai-Van	CNRS	Researcher	12	2,964.00 €
Cécile Barnel	CNRS	Research Assistant	209	36,985.29 €
Nicolas Brunel	CNRS	Research Assistant	66	11,460.74 €
Lionel Collet	CNRS	Director	31	9,207.00 €
Mark E. Lutman	ISVR	Professor	75	41,940.30 €
Srikanta Mishra	ISVR	PhD Student	229	49,982.38 €

Ingrida Uloziene	KMU	Researcher	160	787,20 €
Virgilijus Uloza	KMU	Researcher	140	688,80 €
Egle Gradauskiene	KMU	Researcher	140	688,80 €
György Thuróczy	NIRR	coordinator	255	24,990.00 €
József Bakos	NIRR	Researcher	180	14,400.00 €
Tamás Fábrián	NIRR	Researcher	180	9,720.00 €
Ferenc Molnár	NIRR	Researcher	53	2,862.00 €
Györgyi Kubinyi	NIRR	Researcher	190	12,350.00 €
Judit Szabó	NIRR	Researcher	125	8,125.00 €
Noémi Nagy	NIRR	Researcher	165	9,075.00 €
Gábor Jánossy	NIRR	Researcher	135	7,425.00 €
Istvánné Rostás	NIRR	Technician	224	7,616.00 €
Mariola Śliwińska-Kowalska	NIOM	Senior Researcher	221	25,774.31 €
Marek Zmysłony	NIOM	Senior Researcher	105	6,597.15 €
Ewa Zamysłowska-Szmytke	NIOM	Senior Researcher	26	1,296.26 €
Piotr Kotyło	NIOM	Senior Researcher	89	4,308.41 €
Ewa Kotyło	NIOM	Assistant	104	2,760.97 €
Piotr Politański	NIOM	Technical assistant	170	4,479.32 €
A.Gajda-Szadkowska	NIOM	Technical assistant	14	474.42 €
Marek Bąk	NIOM	Technical assistant	63	2,344.94 €
Ewa Kaczmarek	NIOM	Assistant	44	1,445.34 €
E.Woźnicka	NIOM	Technical assistant	328	7,968.79 €

The total costs for manpower resulted incremented of about 21.500 Euro, corresponding to a percentage of about 2.2 % with respect to the budget for staff estimated at the beginning of the project. This was mainly due to:

1. A transfer of tasks between partners, relative to the staff not pertaining to National Officials, and
2. The change in the position of one person belonging to CNRS partner, from National Official to non National Official.

*E1a. Staff costs not pertaining to national officials*

The expenditures related to this cost category raised of about 37.900 Euro, corresponding to the 4 %, approximately. This increase was mainly due to:

- Modification in the tasks related to WP10 *Analysis and processing of the data*, for which was decided in the course of the project that activities originally in charge of both CNR.ISIB and ISVR should remain in charge of CNR.ISIB only.
- Replications of experiments related to the workpackage WP7 *Animal exposure: combined potentiating effect of UMTS microwaves on the ototoxicity of kanamicin (KM)*. These replication studies have been decided after a first set of experiments showed a possible protective effects of UMTS exposure on the hair cells, during administration of kanamicin. This change concerned both ENEA directly involved in the animal experimentations and CNR.ISIB for data processing and analysis.

These transfers of tasks were approved by the Project Board in the course of the project. The above modifications resulted in the change in the amount of person/months both among participants and in total. Moreover, change in daily/rate in personnel costs for many partners occurred, resulting in corresponding increase of the total amount of the costs for staff. This change in budget was compensated by a corresponding decrease of all other categories but *E4. Consumables and supplies*.

*E1b. Staff costs pertaining to national officials*

The expenditures related to this cost category decreased of about 16.300 Euro. Prof. Lionel Collet of CNRS has been elected president of the Lyon1 University in May 2006, so Dr Hung ThaiVan and Dr Annie Moulin have replaced him in his functions within EMFnEAR. Therefore, the total expenditure for national officials for CNRS has been lower than expected, and the expenditure for the cost item E1a. has been greater than expected.

*Resources that complemented the project expenditures*

The financial cost for “Staff” cover only the manpower relative to the partners eligible to receive EC contribution. However, one other participants (Participant No: 8 National Research Centre for Audiology and Hearing Rehabilitation RCA, Department of Experimental and Clinical Audiology Moscow, Russian not financed) committed itself to provide to the consortium an additional amount of person/months.

#### 4. PARTNERS INVOLVED

The summary of the involvement of the various EMFnEAR participants in the project activities is shown in Table VII

**Table VII – Subdivision of the main tasks among the participants in the course of the project lifetime**

	Exposure System and Animal experimentation	Exposure System and Human Experimentation	Centralised Data Processing	Dissemination
CNR.ISIB	X	X	X	X
ENEA.BIOTEC	X			X
CNRS		X		X
ISVR		X	X	X
KMU		X		X
NIRR		X		X
NIOM		X		X
RCA		X		X

**Participant No: 1****Short Name: CNR.ISIB****Consiglio Nazionale delle Ricerche****Istituto di Ingegneria Biomedica****Milan-Padua, Italy****Scientific Team***Paolo Ravazzani*, CNR Senior Researcher, Project Coordinator of EMFnEAR*Ferdinando Grandori*, CNR Director of Research and Director of CNR.ISIB.*Gabriella Tognola*, CNR Senior Researcher at CNR.ISIB.*Marta Parazzini* CNR Researcher at CNR.ISIB.*Federica Sibella* CNR Researcher at CNR.ISIB*Alessandra Brazzale* CNR researcher at CNR.ISIB*Sharon Scagnetti* technician at CNR.ISIB.*Claudia Franzoni*, fellowship researcher at CNR.ISIB*Carlo Pirovano*, technician at CNR.ISIB*Claudio Cavaggion*, technician at CNR.ISIB*Rosanna Meneghetti*, technician at CNR.ISIB.*Francesca Tonin*, technician at CNR.ISIB.**Objectives**

The CNR.ISIB warrants the coordination of project EMFnEAR. It directly takes part in the data processing (Work packages 1, 3, 4, 5, 10, 11).

**Research activities during the project lifetime**

CNR.ISIB was fully involved in the coordination activities, organisation of meeting and dissemination of the achieved results, in the data processing and in their statistical analysis. Moreover, CNR.ISIB participate directly or as observer in all project activities.

Specific activities of CNR.ISIB are detailed in some of the Deliverables attached in Annex A to this report, and in particular in Deliverable D3.1, D3.2, D4.2, D4.3, D4.4, D4.6, Addendum, D6.1, D7.1, D8.1, D9.1, D10.1, D10.2, D10.3, D10.4, D11.1, D11.2, D11.3, D12.1. The main responsibility of CNR.ISIB has been to contribute to the strategic planning of the testing of animals and human subjects, the detailed development of protocols for animal and human testing, in processing of the data and in their statistical analysis in both human and animal experimentations. During the lifetime of the project, the involvement of CNR.ISIB in some tasks of WP10 was increased due to changes in the subdivision of the tasks with ISVR and additional replication tests on animal administrated by KM (see also the description above).

**Participant No: 2****Short Name: ENEA.BIOTEC****Ente per le Nuove Tecnologie, l'Energia, l'Ambiente****Unità Biotecnologie, Protezione della Salute e degli Ecosistemi,****Sezione Tossicologia e Scienze Biomediche****Rome, Italy****Scientific Team***Carmela Marino* is the scientific project responsible for EMFnEAR*Marta Piscitelli*, medical veterinary*Giorgio A. Lovisolo*, physicist, research scientist*Paolo Galloni* research scientist*Rosanna Pinto* research scientist*Sergio Mancini*, technician**Objectives**

ENEA directly takes part in the research on the design of the exposure apparatus and in animal and human exposure.

**Research activities during the project lifetime**

ENEA.BIOTEC was fully involved in the setting of positioning and exposure systems, in the definition of the animals protocols and in animal experimentation on Sprague-Dawley rats (WP1, WP2, WP3, WP4, WP5, WP6, WP7 and WP11) and related Deliverables (additional details in Annex A).

In some more detail, ENEA.BIOTEC were involved in the experiments on exposure of Sprague-Dawley rats to 10 W/kg, the study of the combined effects of GSM and kanamicin. Moreover, they performed pilot experiments on in-vitro studies on hair-cells of Sprague-Dawley rats..

The ENEA.BIOTEC personnel was involved in the different tasks as follows:

*Carmela Marino and Paolo Galloni* planned the experimental protocols, carried out the in vivo exposure procedures on rats, performed the functional evaluation on rats' cochlea (DPOAEs test sessions), gathered all data files and send them to the ISIB –CNR group in Milan for the “blind” analysis of results.

*Marta Piscitelli*, as veterinary officer in charge at ENEA research centre, collaborated to plan the experimental protocol, and also helped to perform the exposure procedures.

*Giorgio A Lovisolo*, collaborated to the protocols planning, realized and tested the exposure set-up, performed the dosimetry procedures.

*Rosanna Pinto and Sergio Mancini*, realized and tested the exposure set-up, performed the dosimetry procedures.

During the lifetime of the project, the involvement of ENEA.BIOTEC in some tasks of WP7 was increased due to the need of additional replication tests on animal administrated by KM (see also the description above).

**Participant No: 3****Short Name: CNRS****Centre Nationale de la Recherche, Scientifique-Délégation Rhône-Alpes-UMR5200****Neuroscience et Systèmes Sensoriels****Lyon, France****Scientific Team**

*Lionel Collet* is the scientific project responsible for EMFnEAR

*Alain Moulin* is Chargée de Recherche CNRS, researcher,

*Cécile Barnel*,

*Nicolas Brunel*,

*Dr Hung ThaiVan*

**Objectives**

CNRS directly takes part in the research relative to exposure of humans (Work packages 4, 5, 8, 9, 11, 12). The experience of CNRS is useful in monitoring the secondary aims of the project (influence of gender and age on UMTS effects, UMTS effects on pathological subjects).

**Research activities during the project lifetime**

CNRS was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements, considering particularly the cognitive effect (CAS effect). Moreover CNRS was involved in human experimentation.

**Research activities during the first year**

CNRS was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements, considering particularly the cognitive effect (CAS effect).

The research activities have been centred on the reproducibility and feasibility of different auditory tests in humans, especially reproducibility of otoacoustic emissions and definition of a protocol to test auditory medial efferent system, adapted to the exposure protocols.

Otoacoustic emissions are sounds emitted by the inner ear, and that reflects outer hair cells status. Those outer hair cells are under the control of medial auditory efferent fibres, via cholinergic synapses. Some *in vitro* studies have shown an influence of GSM exposure on cholinergic system. Therefore, it seems legitimate to investigate whether mobile phone exposure could affect the inner ear, and its control by efferent auditory fibres. Those efferent fibres are connected to afferent fibres at the brainstem level, in a crossed pathway, so that an acoustic stimulation of one ear induces a decrease of outer hair cell activity (and hence a decrease of otoacoustic emissions amplitude) of the contralateral ear. Therefore, the efferent fibres feedback can be explored in humans using the effect of a contralateral acoustic stimulation on otoacoustic emissions amplitude.

The reproducibility of both TEOAE and of the efferent effect feedback has been investigated in 30 subjects, using a contralateral broad band stimulation on clicked evoked emissions. Inter-subject variability has been also defined in more than 100 subjects. The results led to the protocol defined in the deliverables.

**Research activities during the second reporting period :**

During this period, two research assistants have been recruited :

- Cécile Barnel has been recruited in May 2006 to assist with the ethical agreement file, the recruitment of human subjects for the study and all the recordings.
- Nicolas Brunel has been recruited in March 2007 to assist with the data processing.

Prof. Lionel Collet has been elected president of the Lyon1 University in May 2006, so Dr Hung ThaiVan and Dr Annie Moulin have replaced him in his functions within EMFnEAR.

Ethical agreement for the study:

The Ethical agreement was obtained from the CPP Sud-Est III the 6th November 2006, under the number 206-114B (EudraCT number 2006-A-00166-45) and the agreement from the high health authority (Direction générale de la santé) was obtained the 8th of November 2006 (DGS2006-0033).

Material and methods:

The research activities focused in performing auditory tests before and after two 20 minutes UMTS/sham exposures, according to the protocols defined in the deliverables, plus several additions detailed below. The UMTS exposure used has been a patch antennae, allowing focusing of the exposure in the inner ear region, with a maximum SAR level of 1,75W/Kg (averaged over 10g of tissue). All the exposure equipment has been provided, calibrated and tested by Dr G. Thuroczy 's team (Budapest, NIRR).

Several additions were added to the initial protocol:

- After each exposure, subjects were asked to quote the severity of the symptoms experienced (headache, fatigue, dizziness, warmth...) on 10 cm visual analogue scales, graded from 0 (no symptoms) to 10 (unbearable). The list of symptoms was defined from the most common symptoms reported in the literature (Rubin et al., 2007; Oftedal et al., 2007), and subjects could specify any symptom experienced that were not on the list.
- The recording of the medial efferent auditory system reflex has been performed according to the protocol we defined in the deliverables (i.e. the influence of a contralateral acoustic stimulation on Transiently Evoked Otoacoustic Emissions), and to a new protocol involving the influence of a contralateral stimulation on acoustic distortion products
- The P300 electrophysiology test provided data on only 21 subjects, due to failure of the equipment, yielding to poor traces on 11 subjects
- Lastly, the auditory tests have been performed, for each subject and session, before, immediately after, and 60 minutes after the sham/real UMTS exposure. The P300 recording has been performed only twice per session, before and after the exposure, as P300 traces are very sensitive to repetition of the recordings
- A total of 42 subjects have been recruited for the tests. 4 subjects were rejected in the selection process, and 6 subjects participated in the preliminary study. Finally, 32 subjects underwent the general protocol

Dissemination of results:

Results showing the lack of effect of real exposure on symptoms experienced by subjects were presented, in Poster format, at the 6th International European Congress of Oto-Rhino Laryngology, Head and Neck Surgery in Vienna (Austria) the 29th June 2007 : "A double-blind study of medical complaints reported during mobile phone use". By Annie Moulin, Gyorgy Thuroczy, Sandra Peyraud, Gwenaëlle Turlonias, Cécile Barnel, Lionel Collet.

General results about the influence of UMTS exposure on auditory system in humans will be presented at the French National Congress of Oto-Rhino Laryngology, Head and Neck Surgery in Paris, the 14th-16th of October 2007, in the form of Oral presentation : Abstract n° : 20074164-2904161938 "Audition et téléphonie mobile GSM et UMTS: Un bilan de deux recherches à échelle européenne: GUARD et EMFnEAR. By Moulin A, Barnel C, Brunel N, Nottet J, Thuroczy G, Ravazzani P, Collet L.

**Participant No: 4**  
**Short Name: ISVR**  
**University of Southampton**  
**Institute of Sound and Vibration Research**  
**Southampton, United Kingdom**

### **Scientific Team**

*Mark E Lutman* is the scientific project responsible for EMFnEAR  
*Srikanta Mishra*, Audiological Scientist

### **Objectives**

ISVR directly takes part in the research relative to exposure of humans (Work packages 4, 5, 8, 9, 11, 12).

### **Research activities during the first year**

ISVR was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements.

#### *Contribution to overall planning of the project*

This work has continued from the development of the original proposal to determine the overall shape of the project and its aims, building on knowledge obtained from the EU GUARD project.

#### *Recruitment and training of research assistant for project*

A research assistant has been recruited with an appropriate background in audiology. He commenced in November 2005 and has received extensive induction and training in the specific skills required for the project.

#### *Contribution to the development and presentation of the protocols for animal testing*

ISVR has contributed by offering general scientific critique and improvement of the English used in the protocol (ISVR being the English partner).

#### *Contribution to the development of the protocols for testing human subjects*

The main responsibility of ISVR has been to contribute to the strategic planning of the testing of human participants and the detailed development of protocols for human testing. The GUARD project has provided a baseline set of tests and has indicated the best ranges of parameters to use for EMFnEAR. The work has involved selection of tests from those used within GUARD and extension of those parts that appear to be the most promising. Specifically, we have extended the contralateral suppression testing so that it is available at all test laboratories for transient otoacoustic emissions. This has involved making the test generic to apparatus that is available in all laboratories. We have also extended the contralateral suppression testing to distortion product otoacoustic emissions, following a suggestion from a reviewer of the GUARD project. We have also chosen to introduce measurement of the P300 auditory evoked potential. This has involved setting up and validating new methods in our laboratory. For all the methods to be used, pilot testing has been carried out to ensure that they are working satisfactorily and with adequate sensitivity for the EMFnEAR project.

#### *Pilot testing of new methodology for testing humans*

To potentially increase the sensitivity of distortion product otoacoustic emission testing to detect effects of EMF, methodology has been implemented and evaluated for separating the two components of the emission: distortion and reflection components. In particular this approach is being applied to the contralateral suppression effects. If the contralateral suppression affects mainly one component, this separation may enable the test to be made more sensitive. Pilot work has been carried out to explore contralateral suppression effects on distortion product otoacoustic emissions, to find the best combination of parameters to show such effects. This work is continuing.

### **Research activities during the second year**

EMFnEAR description of work done March 2006 to June 2007 (ISVR)

#### **1. Contribution to overall planning of the project**

This work has continued from the first period of the project, adapting the plan according to developments within the project..

## **2. Training of research assistant for project**

A research assistant was recruited with an appropriate background in audiology and commenced towards the end of the first reporting period. He has received continuing training in the specific skills required for the project throughout the second reporting period.

## **3. Contribution to animal studies**

ISVR has contributed by offering general scientific critique.

## **4. Contribution to the development of the protocols for testing human subjects**

During the reporting period, pilot testing has refined the protocols for human studies. ISVR has also extended the protocol for contralateral suppression of distortion product otoacoustic emissions to separate out the distortion and reflection components of the emission. This work has quantified the extent that each component is suppressed, showing that suppression of the reflection component is greater than suppression of the distortion component. This implies that there is further suppression occurring at the reflection source. This work has been presented at the International Congress of Audiology in Innsbruck, September 2006. Although it was not practical to use this extension of the protocol for the main EMFnEAR study, it will be used in further similar work.

## **5. Main human studies**

ISVR has encountered particular difficulties with ethical committee approval for the human studies, leading to severe delays.

## **6. Dissemination**

ISVR has contributed to publications at the EBFA conference in Bordeaux April 2007, the special session on the EMFnEAR project at the meeting in Como May-June 2006.

**Participant No: 5****Short Name: KMU****Clinic of Neurology, Kaunas University of Medicine****Kaunas, Lithuania****Scientific Team**

*Ingrida Uloziene* is the scientific project responsible for EMFnEAR

*Virgilijus Uloza* is Professor in Otorhynolaryngology

*E. Gradauskiene*, Physician Audiologists

**Objectives**

KMU directly takes part in the research relative to exposure of humans (Work packages 4, 5, 8, 9, 11, 12).

**Research activities during the first period**

KMU was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements.

During the first period of the Project one more researcher has been included in the group- Egle Gradauskiene, MD PhD, physician audiologists of the Dept. Otorhinolaryngology, Kaunas University of Medicine.

All three participants – I. Uloziene, V. Uloza, E. Gradauskiene have been preparing necessary documents for the permission of Lithuanian Bioethical Committee (Project description, informed consent of the patient, description of the tests to be performed, translation of the questionnaire etc.). Preliminary evaluation of the documents by the evaluator was positive.

Prof. V. Uloza participated in 2 project board meetings replacing the PB member I. Uloziene who was not available for the dates of the meetings. He also met 30 people who will be tested for the project. The questionnaires were given for them and were filled in. They were collected by V. Uloza.

The group of 30 people selected for the testing was preliminary otologically and audiologicaly evaluated by the researches E. Gradauskiene and I. Uloziene. All necessary audiological tests were performed.

All three researchers were involved in the laboratory activities within the project. The special listening material for the tests were performed and recorded.

**Research activities during the second period**

During the second period of the Project three researchers – I. Uloziene, V. Uloza, E. Gradauskiene have been mainly performing laboratory activities. They have been also disseminating the results of the project in several European countries – first of all in the closest neighbour countries Latvia and Poland, where they have visited and spoke in the Otolaryngology Department of Medical University of Warsaw, Poland and Otolaryngology Department of J. Stradins University Hospital in Riga, Latvia.

I. Uloziene participated in the project board meeting in Milano in 2007/02/14-16, where she brought the rough data of the performed tests.

I. Uloziene and V. Uloza presented preliminary results of the project in the 4th International workshop "Biological Effects of Electromagnetic fields", which took place in Creta, Greece. I. Uloziene and V. Uloza will have oral presentation in the EUFOS (European Union of Otorhynolaryngological Societies) meeting in July 2, 2007 which is the largest meeting of ENT specialists in Europe.

After the necessary mobile phones were received in the second half of the project life time the group of 32 people pre-selected for the participation in the project was tested - DP-grams and I/O function tests were performed by all three researches V. Uloza, E. Gradauskiene and I. Uloziene. All tests were performed strongly following the protocol.

I. Uloziene devoted much time for the preparation of the report as well as for the preparation of the data tables for the project board and statistical analysis of our own data. For the preparation of the data tables which were necessary for the statistics, special program with Mat Lab was created and successfully applied.

At the nearest future our group has planned to present a paper in the Lithuanian- Polish ENT meeting in 2008 and send an article to the Biomed Central Journal "Public health".

**Participant No: 6****Short Name: NIRR****National Center of Public Health, Frederic Joliot-Curie****National Research Institute for Radiobiology and Radiohygiene****Department of Non-Ionising Radiation****Budapest, Hungary****Scientific team:***György Thuróczy*, researcher, scientific project responsible*József Bakos*, researcher*Györgyi Kubinyi*, researcher*Noémi Nagy*, researcher*Ferenc Molná*, researcher*Tamás Fábrián*, researcher PhD student*Gábor Jánossy*, researcher*Judit Szabó*, researcher*István Hernádi*, researcher*Istvánné Rostás*, technician**Workplan**

According to the work packages the NIRR was involved in the following items during the second reporting period.

- Developing of human exposure systems
- Human ERP measurements according to the human protocol

**Deliverables**

The NIRR team participated in contribution of the following Deliverables during the second reporting period:

- D4.3 Report on protocols for human exposure
- D4.1 Ethical Committee approvals for human protocols – within subject study
- D8.1 Reports on the various phases of human exposure (within-subject study)
- D10.2 Reports on the effects on hearing due to microwave exposure observed in humans (within-subject study)

**Research activities during the first period**

According to the work packages the NIRR was involved in the following items during the first reporting period.

- Setting of positioning and exposure systems
- Definition of the human protocol

The NIRR team participated in contribution of the following Deliverables during the first reporting period:

- D 2.1 Report on the systems for UMTS exposure
- D 2.3: Device for human exposure
- Addendum to Deliverables D 4.2- D 4.3- D 4.4- D 4.6

The NIRR team was involved in the development of protocol of human studies. The main tasks in the first period were to define the exposure of UMTS (WCDMA) device to be used in the human studies and to develop the positioning system of the human exposure protocol. The positioning system was developed. Design the position of the mobile phone, ensuring that it will remain comfortable for the exposure period. The position of the mobile phone mimics the normal use of wireless devices. Four positioning systems have been distributed within the human laboratories will be involved in the pilot studies.

The research team also designed the measurements protocol of the defined UMTS device, in order to control the output power, stability, handling and quality of the exposure device of the human studies. In the NIRR laboratory the UMTS device were measured, controlled before to send the human laboratories. All devices will be controlled again after the human studies with the same methodology. The method by which the “sham exposure device” will be carried out loading the output power of the UMTS phone has been designed.

The dosimetry of the exposure system has been also started in the first period. Automatic step motor system was used in order to determine the location of maximum level close to the ear scanned the spatial distribution of the RF radiation on the surface of the phone. The radiation of “sham exposure device” was measured and tested. No RF radiation emitted by the loaded UMTS device.

The spatial distribution of Specific Absorption Rate (SAR) within the human head phantom, according to the European standard (CENELEC) was measured. The measurement methods in order to measure the SAR levels at the most interesting anatomical area within the head has been started at the end of the first reporting period as well. All cases the absorbed exposure (SAR) will be below 2 W/kg, which is the limit of European recommendation.

### **Research activities during the second period**

The NIRR team was involved in the development of protocol of human studies. The main tasks in the second period were to design the exposure of UMTS (WCDMA) device to be used in the human studies and to develop a system with improving the local exposure of the hearing system.

The research team developed a UMTS human exposure system with RF sources using commercial 3G phone and also with UMTS RF syntheser. The RF amplifiers in order to provide sufficient SAR levels for the human studies were also developed. The system was designed to perform the exposure with double-blind approach. The exposure systems were delivered to the human laboratories of the consortium.

Special patch antenna applicator was developed and tested for focusing the SAR in the anatomical area of human hearing system

The research team also designed the measurements protocol for evaluate and measure the SAR of the UMTS exposure device including the control of the output RF power, power stability and quality of the exposure device of the human studies. In the NIRR laboratory all UMTS device were measured, controlled before to send the human laboratories. The method by which the “sham exposure device” will be carried out loading the output power of the UMTS phone has been designed.

The dosimetry of the exposure system has been finished second period. Automatic step motor system was used in order to determine the location of maximum level close to the ear scanned the spatial distribution of the RF radiation on the surface of the phone. The radiation of “sham exposure device” was also measured and tested.

The spatial distribution of Specific Absorption Rate (SAR) within the human head phantom, according to the European standard (CENELEC) was measured. All cases the absorbed exposure (SAR) will be below 2 W/kg, which is the limit of European recommendation.

Human studies were performed on 27 subjects with recording the Event Related Potential (ERP) before and after the RF UMTS and sham exposure according to the EMF-NEAR human protocol. All data were sent to the common database for further evaluation.

**Participant No: 7**  
**Short Name: NIOM**  
**Nofer Institute of Occupational Medicine**  
**Department of Physical Hazards**  
**Lodz, Poland**

### **Scientific Team**

*Mariola Sliwinska-Kowalska*, is the scientific project responsible for EMFnEAR

*Marek Zmyslony*, researcher

*Anna Gajda-Szadkowska*; researcher

*Ewa Kaczmarek*, researcher

*Ewa Kotyło*, researcher

*Ewa Zamysłowska*, researcher

*Marek Bąk*, researcher

*Piotr Kotyło*, researcher

*Piotr Politański*, researcher

*Ewelina Woźnicka*, audiological technician

### **Objectives**

NIOM directly takes part in the research relative to exposure of humans (Work packages 4, 5, 8, 9, 11, 12).

### **Research activities during the first period**

NIOM was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements

#### *I. Work undertaken:*

1. Participation in designing of protocols for human exposure and audiological assessment for laboratory human studies (within subject study). It was done through the participation in two meetings and the discussion by electronic media.
2. Performing an experiment on the effects of controlled laboratory exposure to GSM microwaves on cognitive response P-300 wave. The outcomes of this preliminary experiment contributed to the final protocol for human audiological assessment. In total 15 healthy volunteers; 7 male (mean age 36+/-9) and 8 female (mean age 33+/-5). P-300 was recorded using the Nicolet Viking IV model Spirit 2000/NT. The measurement was performed three times – two times without exposure to GSM and one time during the exposure.
3. Participation in the delivery of the report on protocols for human audiological assessment.
4. Preparing the documents for local Ethical Committee approval of the project.

#### *II. Personnel hired*

One audiological technician has been employed since March 2006 for the study

### **Research activities during the second period**

NIOM was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements; for performing human exposure and audiological assessment of the potential effects of UMTS microwaves on hearing; and for dissemination and exploitation of the results.

#### *I. Work undertaken:*

1. Participation in designing of protocols for human exposure and audiological assessment for laboratory human studies (within subject study). It was done through the participation in two meetings and the discussion by electronic media.
2. Performing an experiment on the effects of controlled laboratory exposure to GSM microwaves on cognitive response P-300 wave. The outcomes of this preliminary experiment contributed to the final protocol for human audiological assessment. In total 15 healthy volunteers; 7 male (mean age 36+/-9) and 8 female (mean age 33+/-5). P-300 was recorded using the Nicolet Viking IV model Spirit 2000/NT. The measurement was performed three times – two times without exposure to GSM and one time during the exposure.
3. Participation in the delivery of the report on protocols for human audiological assessment.

4. Preparing the documents for and receiving the approval of local Ethical Committee of the project.  
5. Performing the experiments on the effects of controlled laboratory exposure to UMTS microwaves generated by a standard mobile phone (Nokia typ NHM-1, model 6650) on: distortion product otoacoustic emission (DPOAE), medial efferent system using transient-evoked otoacoustic emissions (TEOAEs) and contralateral acoustic stimulation (CAS effect), auditory brainstem response (ABR), cognitive response P-300 wave.

In total 40 healthy volunteers age from 18 to 30 (mean  $23.4 \pm 3.25$ ), including; 20 males and 20 females were examined. The measurements were performed four times in each individual (prior and after exposure and sham-exposure). The results of those experiments contributed to the final outcome of the project, i.e. assessment of the potential effects of UMTS microwaves of standard mobile phones on human hearing.

6. Performing the experiments on the effects of controlled laboratory exposure to UMTS microwaves generated with the use of a patch antenna on: distortion product otoacoustic emission (DPOAE), medial efferent system using transient-evoked otoacoustic emissions (TEOAEs) and contralateral acoustic stimulation (CAS effect), auditory brainstem response (ABR), cognitive response P-300 wave.

In total 10 healthy volunteers age from 18 to 30 (mean  $23.4 \pm 3.25$ ), including; 5 males and 5 females were examined. The measurements were performed four times in each individual (prior and after real exposure and sham-exposure, and for P-300 wave additionally during the exposure). The results of those experiments contributed to the final outcome of the project, i.e. assessment of the potential effects of UMTS microwaves at the levels exceeding standard mobile phone (but not higher than maximal admissible values according to the EU standards) on human hearing.

7. Dissemination of the results of the study at the International Conference (European Federation of Audiological Societies Congress, 6-9 June, 2007)

## *II. Personnel hired*

One audiological technician (Ewelina Woznicka) has been employed since March 2006 till June 2007 for the study

**Participant No: 8****Short Name: RCA****National Research Centre for Audiology and Hearing Rehabilitation****Department of Experimental and Clinical Audiology****Moscow, Russia****Scientific Team***George A. Tavartkiladze* is the scientific project responsible for EMFnEAR*Teimuraz Gvelesiany*, Head of the Laboratory for Hearing Testing.*Alexander V. Kruglov* is Head of the Laboratory of Hearing Instruments Standardization*Oleg A. Belov* is Senior Researcher**Objectives**

RCA is involved in EMFnEAR for human experimentation (Work packages 4, 5, 8, 9, 11, 12). RCA, due to the current regulation related to Russian groups participation in DG SANCO projects, is not eligible to receive European Commission contribution.

**Research activities during the project lifetime**

RCA was fully involved in the preparation and finalization of the protocols for human exposure and audiological measurements. RCA performed audiological measurement in the framework of the within-subjects study.

## 5. COUNTRIES INVOLVED

EMFnEAR involved 7 different European countries (Italy, France, UK, Lithuania, Hungary, Poland from the European Union plus Russia).

The project activities were conducted in the different countries according to the specific expertise of the local research centre/audiological clinic which were involved. The different activities are described in details in Section 3 above.

The activities and results of the project were disseminated at National level on responsibility of the local EMFnEAR partner, mainly, in interviews to national press and media, meeting of national associations and so forth. The website <http://www.emfnear.polimi.it> of the project (in English) was the channel through which, at national level, the general public could acquire information about the project activities, including the possibility to contact the national center involved for acquiring further information.

## 6. ACHIEVEMENT OF THE OBJECTIVES

### Introduction

The main objective of EMFnEAR was the study of the potential effects on the hearing system of animals and humans of UMTS microwaves, by laboratory experimentation, including possible combined effects due to UMTS fields and ototoxic agents. Hearing is a highly sensitive biological system to exogenous and endogenous agents and the first one to be affected by the microwaves emitted by that type of devices. EMFnEAR is an exploratory project with an anticipatory function. Its results represent the first international and European statement about this type of hazards for hearing. In that perspective EMFnEAR is contributing to regulatory processes such as the revision of Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields in the UMTS frequency region around 2 GHz.

The main objectives of the project were achieved as summarized in the following sections.

### Animal experimentation

EMFnEAR animal experimentation proceeded as planned, on time and following the recording protocols for hearing assessment. Two different types of experiments involving a total of about 230 animals, were performed:

1. Study of the acute effects of UMTS exposure (1947 MHz, 10 W/kg) on the auditory system of Sprague-Dawley rats;
2. Study of the combined effects of ototoxic drugs (i.e. kanamycin) and microwave exposure on the auditory system of Sprague-Dawley rats;

Table VIII reports more details on the type of effects found after the statistical analysis of the data.

**Table VIII: Results of the statistical analysis**

Experiment	Audiological Endpoint	Rats	Effect
Acute effects of UMTS exposure (sham vs. real)	DPOAE	48	No effect
Combined effects of ototoxic drugs	DPOAE	84 (+98)	No effect

In summary, the analysis of the data show no effects of UMTS electromagnetic fields exposure on the inner auditory system of rats, both in normal ears as well as in ears exposed to a well recognized pathological agent (KM), even when the hearing system is exposed to a high SAR level of 10 W/Kg.

### Human experimentation

EMFnEAR Human experimentation proceeded as planned, on time, following the recording protocols for hearing assessment. During the lifetime of the project, two different types of experiments involving a total about 180 subjects, were performed:

1. Study of the acute effects of UMTS cellular phone on the auditory system of humans (*Within-subject study*);
2. Study of the acute effects of UMTS exposure (i.e. by using the patch antenna exposure system) on the auditory system of humans (*Additional test*);

Moreover, during the lifetime of the project, two different types of analysis involving a total about 120 subjects, were performed on the data from the *Within-Subject study*:

- study of the effects of UMTS cellular phone on the auditory system of men and women (*Gender effect*);
- study of the effects of UMTS cellular phone on the left and right exposed ear (*Handedness effect*);

Tables IX and Table X reports more details on the outcomes after the statistical analysis of the pooled data.

**Table IX: Within –Subject study results**

<b>Audiological Endpoint</b>	<b>EMF Effect</b>	<b>Women</b>	<b>Men</b>	<b>Left</b>	<b>Right</b>
Audiometry	No effect	No effect	No effect	No effect	No effect
Input/Output DPOAE	No effect	No effect	No effect	No effect	Sporadic
DP_gram	No effect	No effect	No effect	No effect	Sporadic
CAS TEOAE	No effect	No effect	No effect	No effect	No effect
P300	Sporadic	No effect	No effect	No effect	No effect

**Table X: Additional study results**

<b>Audiological Endpoint</b>	<b>Effect</b>
Audiometry	No effect
Input/Output DPOAE	No effect
DP_gram	No effect
CAS TEOAE	No effect
P300	Sporadic

In summary, the analysis of the data show no effects of UMTS electromagnetic fields exposure on the auditory system of humans, both in the case of cellular phone exposure and patch antenna exposure.

EMFnEAR results (both on animal and human experimentation) need at least one additional year for further additional analysis.

### **Dissemination, support to informed decision-making processes, feedback to producers and contribution to regulatory processes**

EMFnEAR activities were presented in international and national scientific conferences, as detailed above in this report. A Workshop on EMF interactions and hearing has been Organized by the EMFnEAR Consortium on June 3, 2006 as the Special Session *Bioelectromagnetics and Hearing* of the International Conference *NHS 2006 Beyond Newborn Hearing Screening: Infant and Childhood Hearing in Science and Clinical Practice*, May 31-June 3, 2006, Cernobbio, Como, Italy. Around 100 delegates attended to the EMFnEAR event. Detailed about the Workshop can be found in the Issue #2 of the EMFnEAR NEWS, (see D11.1, attached to this report in Annex A).

EMFnEAR activities and results were and are of support for informed decision making processes, made by the European Commission and other national international bodies. This was and is also assured by the opportunity represented by the EC FP6 EMF-NET Coordination action, that is running in these years, coordinated by Paolo Ravazzani. Through EMF-NET an immediate dissemination of the results of EMFnEAR through the whole concerned scientific community, the policy and health authorities and the concerned stakeholders took place. As an example, the results of EMFnEAR are taken into consideration in the EMF-NET Report “Report on laboratory studies and projects related to tissues and organs (nervous system, blood brain barrier, sensory organs and behaviour, cardiovascular system, endocrine system)”, that should be ready by next October 2007, delivered to the EC Services and published.

Same considerations hold also for the support of EMFnEAR results on regulatory processes. The contacts with EC Services allowed EMFnEAR outcomes, directly or through EMF-NET, to be available for support to policy and to the regulatory processes of the European Commission at first.

As to the direct feedback to UMTS mobile phones manufacturers, these are described in the deliverable D11.3 (attached to this report in Annex A) and summarized as follows:

- There is no need to change the UMTS signals characteristics;
- There is no need to change, in particular to reduce, the maximum power emitted by the mobile phones. However, the EMFnEAR Consortium does not suggest to increase the maximum power.
- The results of the EMFnEAR project can not be directly extrapolated to others RF and modulations.
- There is the need to include in the numerical or experimental head models used in the dosimetry that systems that can be considered, for their biological characteristics, more potentially affected by electromagnetic field exposure, such as the sensory systems and, in particular, the vestibular and hearing system.
- There is the need to move towards a “system specific” dosimetry, which has to be considered crucial both from the scientific and regulatory points of view.

### **Additional remarks**

From the data corpus obtained during the lifetime of the EMFnEAR projects, the following remarks can be inferred:

- The EMFnEAR data corpus could provide answers to public concerns about cellular phones and health;
- The EMFnEAR data corpus could generate a relevant impact on concerned stakeholders and general public;
- The EMFnEAR data corpus could influenced the scientific process, helping in focusing the research on EMF and sensory systems;
- The EMFnEAR data corpus could be an input to industries and other stakeholders to assess potential impact on health;
- The EMFnEAR data corpus could be used for the continuous request/exchange of information from consumer associations in Europe, media or European citizens.
- The EMFnEAR data corpus could contribute to the revision of Council Recommendation 1999/519/EC on the limitation of exposure of the general public to electromagnetic fields in the frequency region around UMTS 2 GHz band.

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