TNO Physics and Electronics Laboratory

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TNO-report

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Effects of Global Communication system radio-frequency fields on Well Being and Cognitive Functions of human subjects with and without subjective complaints.

Oude Waalsdorperweg 63 PO Box 96864 2509 JG The Hague The Netherlands

www.tno.nl

Phone +31 070 374 00 00 Fax +31 070 328 09 61 info@fel.tno.nl

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|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Author(s) | Prof. dr. ir. A.P.M. Zwamborn Dr. ir. S.H.J.A. Vossen Ir. B.J.A.M van Leersum Ing. M.A. Ouwens W.N. Mäkel, Statistician (CRF) | |
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MANAGEMENTUITTREKSEL

Effects of Global Communication system radio-frequency fields on Well Being and

Cognitive Functions of human subjects with and without subjective complaints.

Probleemstelling

Ondanks eerder wetenschappelijk onderzoek naar de relatie tussen elektromagnetische velden en klachten van mensen, is het trekken van duidelijke wetenschappelijk verantwoorde conclusies daarover moeilijk. Het in de wetenschappelijke literatuur gepubliceerde onderzoek richt zich sterk op de mogelijke effecten die gebruikers van mobiele telefoons kunnen ondervinden of toeschrijven aan radiofrequente (GSM) velden. Het Tweede-Kamerlid Wagenaar diende bij het overleg over de nota Nationaal Antennebeleid een motie in (Tweede Kamer, 2000-2001, 27 561, nr. 10) waarin de regering verzocht werd "initiatieven te nemen om tot onafhankelijk wetenschappelijk epidemiologisch onderzoek te komen naar de effecten van straling door antennes op de langere termijn en onderzoek te laten verrichten naar geuite klachten". Daarmee werd specifiek aandacht gevraagd voor klachten die mensen toeschrijven aan de aanwezigheid van GSM basisstations. Dit onderzoek kan gezien worden als een eerste antwoord op die motie en heeft dan ook de onderzoeksvraag meegekregen om de subjectieve klachten die werden toegeschreven aan GSM basisstations nader te onderzoeken.

Het onderzoek is verricht door TNO Fysisch en Elektronisch Laboratorium (TNO-FEL) in samenwerking met het onderzoeksbureau Clinical Research Facilities International (CRF-I) in Schaijk en TNO Technische Menskunde (TNO-TM) te Soesterberg. TNO heeft voor dit onderzoek opdracht gekregen van het directoraat-generaal Telecommunicatie en Post DGTP van het Ministerie van Economische Zaken (voorheen van het Ministerie van Verkeer en Waterstaat), het Ministerie van Volksgezondheid, Welzijn en Sport en het Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer. Het ministerie van Economische Zaken coördineerde namens de opdrachtgevende Ministeries. Het onderzoek is uitgevoerd op basis van een vooraf door de Medisch Ethische Toetsingscommissie (METC) goedgekeurd onderzoeksprotocol.

Beschrijving van de werkzaamheden

Dit onderzoek is uitgevoerd met twee groepen van elk 36 proefpersonen groot. Eén groep bestond uit mensen die zich in het verleden hebben aangemeld bij het Meldpuntennetwerk Gezondheid en Milieu. Zij schrijven de door hen ervaren klachten toe aan de aanwezigheid van GSM basisstations. Deze groep noemen we in dit rapport groep A. De andere groep was onze referentiegroep bestaande uit mensen zonder aangegeven hinder van deze GSM basisstations. De referentiegroep is gerekruteerd door middel van advertenties in kranten, via aankondigingen op het Internet en mond op mond reclame. De referentiegroep noemen we in dit rapport groep B.

In het onderzoek is getracht een relatie te vinden tussen blootstelling aan elektromagnetische velden afkomstig van een antenne voor mobiele telefonie en (meetbare) effecten bij mensen. De hypothese was dat er geen relatie gevonden zou worden. Tijdens het onderzoek zijn het ervaren welzijn van de mensen en de cognitieve prestaties gemeten. Het onderzoek is uitgevoerd met behulp van verschillende vragenlijsten en een, door TNO-TM vastgestelde en standaard toegepaste, set van cognitieve testen in een speciale daarvoor ingerichte onderzoeksruimte bij TNO-FEL. Deze ruimte was afgeschermd van de buitenwereld voor wat betreft de radiofrequente velden. Daardoor wisten de onderzoekers precies aan welk veld en niveau de proefpersonen werden blootgesteld.

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September 2003 Auteur(s) Prof. dr. ir. A.P.M. Zwamborn Dr. ir. S.H.J.A. Vossen Ir. B.J.A.M van Leersum Ing. M.A. Ouwens W.N. Mäkel, Statistician (CRF) Rubricering rapport Ongerubriceerd Effects of Global Communication system radio-frequency fields on Well Being and Cognitive Functions of human subjects with and without subjective complaints.

Resultaten en conclusies

Het resultaat van het onderzoek is dat er een statistisch significante relatie gevonden is tussen de aanwezigheid van radiofrequente velden die lijken op die van een UMTS basisstationsignaal en het ervaren welzijn van de proefpersonen. Deze statistisch significante relatie is voor zowel groep A als voor groep B gevonden. Met betrekking tot de cognitieve prestaties vinden we, net als in de literatuur, statistisch significante relaties die veelal een verbetering van de cognitieve prestaties inhouden. Afhankelijk van de cognitieve taak vinden we voor GSM900, GSM1800 en UMTS voor zowel groep A als groep B statistisch significante relaties tussen de uitgevoerde taak en het wel of niet aanwezig zijn van het elektromagnetische veld. Een eenduidige conclusie over de oorzaken en het biologisch mechanisme hierachter is op basis van deze resultaten niet te geven. In de internationale wetenschappelijke literatuur zijn dergelijke statistisch significante relaties in de cognitieve prestaties ook beschreven. In deze onderzoeken heeft de blootstelling echter steeds plaatsgevonden met de relatief hoge veldsterkten van mobiele telefoons bij het hoofd. Locale thermische effecten zijn in deze onderzoeken als mogelijke oorzaak gesuggereerd. Het TNO-onderzoek is uitgevoerd met lage veldsterkten, vergelijkbaar met die afkomstig van een basisstation waaraan men in de dagelijkse praktijk maximaal kan zijn blootgesteld.

Computerberekeningen tonen aan dat het onwaarschijnlijk is dat de in dit onderzoek gevonden statistisch significante effecten van thermische oorsprong zijn.

Aanbeveling

Zonder twijfel zijn de resultaten van dien aard dat nader wetenschappelijk onderzoek gerechtvaardigd en noodzakelijk is. Het door ons uitgevoerde onderzoek dient gerepliceerd te worden door een van TNO onafhankelijke onderzoeksgroep. Dit is noodzakelijk om de gevonden effecten te bevestigen. Verder zal nader wetenschappelijk onderzoek moeten worden uitgevoerd of er een relatie bestaat tussen veldsterkteniveau, gebruikte frequentie en pulsvormen maar ook of er verschillen te vinden zijn tussen mannen en vrouwen en tussen volwassenen en kinderen.

De definitie van gezondheid van de Wereldgezondheidsorganisatie luidt: "a state of complete physical, mental and social well being and not merely the absence of disease or infirmity". Binnen deze definitie van de WHO is het ervaren welzijn onderdeel van de gezondheid. Het is daarom van groot belang aandacht te schenken aan de vraagstelling of er daadwerkelijk, en zo ja in welke mate, er een (blijvend) effect op de gezondheid bestaat. Belangrijk is onderzoek te verrichten naar de mogelijke biologisch mechanismen die verantwoordelijk zijn voor de gevonden effecten.

ONGERUBRICEERD

TNO Fysisch en Elektronisch Laboratorium

Oude Waalsdorperweg 63 2597 AK 's-Gravenhage Postbus 96864 2509 JG 's-Gravenhage

www.tno.nl Info@fel.tno.nl

T 070 374 00 00 F 070 328 09 61

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Abbreviations

| AE | Adverse Event |
|---------|----------------------------------------------------------|
| ANOVA | Analysis of Variance |
| CDR | Cognitive Drug Research |
| CDROM | Compact Disc Read Only Memory |
| CRF | Case Report Form |
| CRF-I | Clinical Research Facilities International B.V. |
| DNA | Deoxyribo Nucleic Acid |
| EM | Electromagnetic |
| FDA | Food and Drug Administration |
| GCP | Good Clinical Practice |
| GSM | Global System for Mobile Communication |
| Hz | Hertz, unit of frequency |
| IARC | International Agency on Research on Cancer |
| ICH | International Conference on Harmonization |
| ICNIRP | International Commission on Non-Ionizing Radiation |
| | Protection |
| (k)g | (kilo)gram, unit of mass |
| METC | Dutch acronym, translated into Medical Ethical Review |
| | Committee |
| Neo FFI | Neo (New) Five-Factor InventoryQAQuality Assurance |
| QOL | Quality Of Life |
| SAE | Serious Adverse Event |
| SAR | Specific Absorption Rate |
| Sec | Second, unit of time |
| SAS | Statistical Analysis System |
| Std | Standard Deviation |
| SEM | Standard Error of the Mean |
| TNO | Netherlands Organisation for Applied Scientific Research |
| TNO-FEL | TNO Physics and Electronics Laboratory |
| UMTS | Universal Mobile Telecommunications System |
| V/m | Volts per meter, unit of electric field strength |
| W | Watt, unit of power |
| WHO | World Health Organization |
| | |

1. Introduction

Worldwide, the introduction of the Global System for Mobile Communication (GSM) in the 1990's has dramatically increased the use of cellular telephones. Full-wave electromagnetic and thermal numerical models give insight into the thermal effects related to exposure to electromagnetic fields. However, very little information is available on the non-thermal influence of the electromagnetic fields caused by these telephones on human tissues and more specifically on brain tissues. Regularly reports on health effects associated with the use of mobile telephone systems are published in scientific magazines and usually taken over by the lay press. In virtually all cases the reports relate to experiments that are either studies in animals or short-term studies in human subjects. The investigated items are the incidence of brain tumors [1,2,3], influence on Electroencephalogram [4,5], excretion of pituitary hormones [6], cognitive functions [7-18], thermal changes in the brain [19-21], DNA damage [22], lymphocyte and mitogen stimulation [23], visual functions [24] etc.

The existing scientific evidence does not support the hypothesis that a relation exists between the incidence of brain tumors and the use of GSM-telephones. An extensive international epidemiological study is presently ongoing under the coordination of the International Agency on Research on Cancer (IARC). In this study the relationship between the use of a GSM-telephone and the incidence of tumors in the head and neck region is being investigated. Initial results will probably not be available until 2004.

Many studies with contradictory results on the influence of cellular phones have been published. Concerning the cognitive functions we have found five publications [7,8,9,12,13] that report on short-term effects on cognitive functions. Recently, Cook *et.al.* [25] published an overview. A slightly significant increase in reaction time was found by Preece *et.al.* [7] but was not supported by results obtained by Koivisto *et.al.* [8]. Krause *et.al.* [9] reported a slight increase for some memory tasks in humans exposed to a GSM-like signal. All above mentioned studies concern the acute effect on the items studied in either healthy subjects or in animals which were exposed to GSM-like signals.

Concerning hypersensitivity symptoms we have found two papers [16,18] that report a relation between subjective symptoms and RF-fields and two papers [10,17] that report no statistically significant relations.

Hietanen *et.al.* [10] studied the hypothesis that there are hypersensitive persons who perceive subjective complaints attributed to electromagnetic fields emitted by hand held mobile telephones. Double blind provocation experiments were used. From their research, they concluded that no causal link was found between exposure to cellular telephones and hypersensitivity complaints. The present study contributes to the research on finding a relation between electromagnetic fields and brain functions. In contrast to Hietanen *et.al.* [10]

- We focused our research on people living close to base station antennas.
- We measured the cognitive functions of the subjects during the exposure (including placebo).
- We measured the Well Being by using a questionnaire.
- We performed our measurements under controlled electromagnetic conditions inside a shielded semi-anechoic chamber.
- We <u>did not</u> measure the physical parameters Blood Pressure and Heart Rate.

In this kind of studies, assuring reproducibility in dosimetry and electromagnetic environment is a very important issue to guarantee.

1.1 Scientific goal

The goal of this research was to determine whether a relation exists between electromagnetic fields and the subjective complaints together with cognitive performance associated with an electromagnetic stimulus. Note that only effects present during and shortly after exposure to electromagnetic fields have been studied. In addition, we examined whether thermal effects can be responsible for possible effects found in this study.

This research goal was pursued by using a double blind crossover design in order to investigate the real influence of fields on the complaints reported. Comparing the complaints as reported by the subjects with and without the presence of GSM and UMTS-like fields, and without their knowledge of that exposure condition, eliminates subjectivity. At the same time cognitive functions have been evaluated.

The objectives of the study were:

- To investigate under double-blind conditions whether or not certain complaints were reported more frequently with exposure to GSM and UMTS-like fields than in periods without GSM and UMTS-like fields, without revealing to the subject the exposure conditions at that moment.
- To investigate under double blind conditions the influence on cognitive functions of exposure (including Placebo) to GSM fields.
- To investigate under double-blind conditions the influence on cognitive functions of exposure (including Placebo) to UMTS-like fields.

1.1.1 Subjects

One way to study if the reported complaints are really an effect of exposure is to bring these subjects into an experimental setting in which they randomly undergo a period with exposure and a period without exposure, without knowing which is which. If the complaints are an effect of the GSM and UMTS-like fields the subjects should more frequently report complaints during a period of exposure than during a period without exposure. By choosing this experimental set-up it is assumed that, if the relationship exists, this pertains to a short-term effect. In general the complaints arise shortly after exposure to GSM fields and go away once exposure is stopped. This typical feature of the complaints reported by the study subjects supports this assumption. However, not all subjects report the same complaints and not under all exposure conditions. This makes it difficult to select an optimal experimental set-up that covers all reported complaints.

In the Netherlands, people can address complaints that they ascribe to environmental factors to the Monitoring Network for Environmental Health, a nonprofit organization. Subsequently, they are entitled to register their complaints. These registered people form an interesting study population. Due to legal restrictions concerning privacy protection, the Monitoring Network for Environmental Health was asked to cooperate in this study and it has acquired half the subjects for this study from their database.

The subjects for this study are classified into two groups. Group A denotes the group of subjects that have previously reported to experience complaints and have attributed these complaints to GSM exposure, Group B denotes the reference group, namely a group of subjects without any complaints. It is noted that subjects who have an impaired health status have been excluded. Persons suffering from coronary disease and psychiatric illness have been excluded as well.

1.1.2 Experimental setup

The subjects within group B do not experience complaints at any given GSM exposure and at any instance that they are exposed. Therefore it is necessary to perform the study by means of comparing the occurrence of complaints between groups. As elucidated in Chapter 16 of our study protocol [26], we have calculated that with a total sample size of 72 subjects we obtain a power of 80% to find statistically significant results regarding reported complaints between the periods with exposure and without exposure. The proposed sample size of the experiment has been capable of statistically detecting a difference of 5% on the cognitive tests that have been used.

Every subject (from groups A and B) is requested to undergo a period with GSM and UMTS-like exposure and a period without exposure. In this way every subject will serve as his/her own control. Within the design of the study a washout period has been adhered to, in order to make sure that possible effects of the exposure are not carried over to the next exposed period.

Exposure arms that have been used in the study are

- 1. Placebo.
- 2. GSM900.
- 3. GSM1800.
- 4. UMTS-like signals.

1.1.3 Experimental design

With respect to the electromagnetic field strength used in this study, it is noted that due to the lack of scientific data a prediction of reasonable electromagnetic exposure during the experiments is not possible. Exposures presented in literature were generally in the near field, because mobile phones have been used as the source of exposure. Instead, we have chosen to generate electromagnetic field strengths that can be considered a maximum value that can be found occasionally in a general living environment. We focus on base-station exposure because that is to what the subjects of group A attribute their subjective complaints.

Currently, there is no scientific evidence that electromagnetic fields induce a cumulative effect that leads to any kind of saturation. Therefore, the authors assume the absence of cumulative effects and saturation.

The scientific community lacks data concerning the causal relationship between electromagnetic field strength (stimulus) and the symptoms subjectively attributed to the stimulus. The number of symptoms and the subject's perception is diverse.

Our test system, denoted as Taskomat, which has been used in this study, has proven to be effective in the evaluation of cognition as an exponent of brain functioning, the influence of pathological processes and the effect of drugs [27].

Finally, it is noted that the constant presence of the base-station antennas during the measurements might invite the subjects to malinger the results. If that is the case, the design of the proposed study will lead to the conclusion that no relationship between electromagnetic field and the subjective complaints from this electromagnetic stimulus are found.

2. Study design considerations

Experience with questionnaires related to quality of life has shown that the first time a subject fills in such a questionnaire, the answers are given in an exaggerated way. Even a randomization as scheduled in this study and thus creating the possibility to eliminate a sequence effect cannot prevent that the discriminative power of the comparison has been affected substantially. Therefore in the present study the subjects have been evaluated during all four sessions. During the first session the subjects filled out the questionnaire and performed the cognitive function test for training reasons only. It is stressed that during that first session none of the subjects have been exposed to electromagnetic fields. The subjects were informed on the absence of GSM and UMTS-like fields.

During the second, third and the fourth session the real comparison took place under double-blind randomized conditions. The subject information sheet states that during each session it is possible that there could be exposure to GSM and UMTS-like fields. However, it was unknown to the subject during which session(s) this took place.

To ensure reproducibility of the data, the field was generated in a controlled environment. The physical parameters of the exposure were monitored and stored during the experiments. A field strength has been used that can be considered as a maximum value to account for field strengths measured in public places which are generated by GSM base stations. For uniformity within the study, we used a similar field strength for the UMTS-like fields.

On the basis of numerous measurements we determined that the electromagnetic field strengths in houses and other freely accessible locations generally does not exceed 1 V/m. Therefore, the electromagnetic field value located at a height of 1.5 m was chosen to be 1 V/m at the location of the subjects. This value is within the pertaining exposure guidelines [28] and corresponds to less than 2.5% of the lowest reference value. The measurement setup is presented in more detail in Chapter 3.

2.1.1 Hypothesis

In this study, the following hypothesis are verified:

<u>Null-hypothesis:</u> There is no statistically significant difference with respect to any of the subjective complaints and the Taskomat parameters as recorded during placebo exposure, relative to standardized 900 MHz exposure, 1800 MHz GSM field exposure or 2100 UMTS-like field exposure.

<u>Alternative hypothesis:</u> The data analysis shows that there is a statistically significant difference between one or more subjective complaints and/or Taskomat parameters as recorded during placebo exposure, relative to standardized 900 MHz exposure, 1800 MHz exposure or 2100 UMTS-like field exposure (α =0.05, two-tailed).

3. Exposure set-up

Subjects have been exposed to GSM and UMTS-like fields in a special shielded chamber at the facilities of TNO Physics and Electronics Laboratory located in The Hague. This room shields electromagnetic fields between 10 kHz and 20 GHz better than 70 dB and is fully anechoic with respect to electromagnetic fields. Therefore, this anechoic chamber provides a conditioned environment in which exposure to RF-fields is limited to the in-room generated RF-fields. Before the experiments, the exposure of 900 MHz GSM-fields, 1800 MHz GSM-fields and 2100 MHz UMTS-like fields has been defined and verified, as described in Appendix A. The field strength at the location of the subjects has been determined not to exceed 1 V/m.

The exposure setup is presented scenatically in Figure 3.1.



Figure 3.1: Setup in the full anechoic room.

The output of the signal generator is applied to an amplifier configuration consisting of a separate amplifier for each frequency and a coaxial switch box, see Figure 3.2.



Figure 3.2: Amplifier configuration: The selection of the amplifier and antenna combination is performed by a coaxial switch box.



The antenna configuration consisted of two antennas placed on a tripod as shown in Figure 3.3

Figure 3.3: Antenna configuration.

In figure 3.3 the antenna on the left is used to transmit UMTS-like fields. The dual band antenna at the right hand-side is used to transmit GSM fields for GSM 900 MHz band as well as DCS 1800 MHz band.

To ensure that the prescribed exposure is actually generated, a monitor probe was used for field verification and logging during the measurements. The probe is positioned in front of the antennas.

The measuring equipment consisted of the following items:

- Signal generator, Agilent E4437B.
- Amplifiers:
 - ENI 603L serial number 894, 3 Watt, used for GSM 900.
 - Varian VZL-6941-K1 serial number 7517, used for DCS 1800.
 - Varian VZS-6951-K1 serial number 7514, used for UMTS.
- Switch box, Comtest Instrumentation model 1405.
- Antenna configuration:
 - Kathrein 741 320 (GSM 900 and DCS 1800).
 - Huber + Suhner 1320.41.0012 (UMTS).
- Monitor probes:
 - Holaday HI-4433-GRE, serial number 96651.
 - Holaday HI-4433-GRE, serial number 96653 (spare).

To control the signal generator and switch box as well as to register the applied field we have developed the program 'Cogni4.vee' dated 7 October 2002. This program is based on HP VEE, product identity E2120F, revision 5.01, serial number US50600241, dated 7 October 1998. In Appendix A, more details considering the verification and monitoring are presented. A screen dump of the 'Cogni4.vee' is shown in Figure 3.4.



Figure 3.4: Screen dump of the 'Cogni4.vee' program.

3.1 Generated electric fields

During the experiments, we needed to simulate GSM and UMTS-like fields. GSM uses Time Division Multiple Access (TDMA) modulation, while UMTS uses Code Division Multiple Access (CDMA) modulation. For more information about both multiple access techniques, the reader is referred to Chapter 15 of [29]. As point of departure, we have used the European prestandard ENV 50204 [30] for the GSM-like signal. For the definition of the UMTS-like fields we have used ETSI TS 125 102 [31] and TS 125 105 [32]. The following frequencies are used to simulate the RF-fields that are generated by base stations: GSM 900 945 MHz.

DCS 1800 1840 MHz. UMTS 2140 MHz.

3.1.1 GSM

In the GSM-protocol there are 8 timeslots available, each with a duration of approximately 546.5 μ sec. The guard time between the timeslots amounts to approximately 30.5 μ sec. For the simulation, timeslots 0, 1, 2 and 3 are on (transmitted) and timeslots 4, 5, 6 and 7 are chosen to be off. This results in a nearly pulsed modulated field with a frequency of approximately 217 Hz. The amplitude-demodulated GSM-field is given by Figure 3.5. The frequency spectrum of this GSM signal is given in Figure 3.6.



Figure 3.5: Demodulated GSM signal.



Figure 3.6: Frequency spectrum of GSM signal transmitted at 1840 MHz.

3.1.2 UMTS

The signal generator is capable of generating the downlink settings of a base station. The signal generator is used in such a way that the following frames were transmitted:

| Frame | | Description | Frame power* |
|---------|---------|----------------------------------------------|--------------|
| 1 P-SCH | | The P-SCH consists of a modulated code, | -8.30 dB |
| | | 256-chips long, transmitted once every slot. | |
| | | The primary synchronization code is the | |
| | | same for every cell in the system. | |
| 2 | S-SCH | The S-SCH consists of a repeating | -8.30 dB |
| | | synchronization code sequence transmitted | |
| | | in parallel with the P-SCH. The sequence | |
| | | has a length of 15 slots, consisting of | |
| | | modulated codes, each 256-chips long and | |
| | | indicating to which of the code groups the | |
| | | cell's downlink scrambling code belongs. | |
| 3 | P-CCPCH | The primary common control physical | -5.30 dB |
| | | channel is a fixed rate physical channel | |
| | | used to carry the broadcast transport | |
| | | channel (BCH) and the incrementing | |
| | | system frame number (SFN). | |
| 4 | CPICH | The common pilot channel is a fixed rate | -3.30 dB |
| | | physical channel that carries a pre-defined | |
| | | bit/symbol sequence. | |

* The Frame Power with respect to the total RF-power (default values).

The chiprate (clock frequency) is 3.840000 MHz.

The amplitude-demodulated time signal of the described UMTS-like signal is presented in Figure 3.7. The frequency spectrum of this UMTS-like signal is given in Figure 3.8. It is observed that this time domain signal looks more complex in comparison with the GSM signal. Furthermore, it is noted that the time scales are different.



Figure 3.7: Demodulated UMTS signal.



Figure 3.8: Frequency spectrum of UMTS signal.

3.1.3 Electric field strength

We have used two different modulation techniques, namely TDMA for GSM and CDMA for UMTS. Therefore, maximizing the electric field strength means that some choices need to be made. In our experimental setup we have decided to maximize the <u>peak</u> value to 1 V/m. This implies that the <u>effective</u> field strength amounts to 1 V_{eff}/m for UMTS. Taking into account the duty cycle of 50% that has been used for GSM, the effective field strength under GSM exposure amounts to 0.71 V_{eff}/m. Hence, by using 1 V/m we refer to the peak amplitude of the electric field.

Finally, it is verified that this field strength did not influence our measuring equipment.

4. Thermal effects of radiofrequency electromagnetic fields

A human body interacts with electromagnetic fields present in an environment. For radiofrequencies, the only scientifically established interaction are induced currents and/or thermal effects, depending on frequency. In the next two chapters, the relevant thermal effects that might occur during the exposures of group A and group B are discussed.

4.1 Radio-frequency dosimetry

The amount by which a body is influenced by electromagnetic fields is determined by the field generated within that body, the so-called internal field. The strength of that field is not the same as the field that would be present without the body, which is denoted as external field. Determination of the internal field, whether by calculation or by measurement, is often very difficult. In general the strength of the internal field is a function of the external field, the size, the shape and electrical characteristics of the body, the frequency of the field and the orientation of the body with respect to the electrical field vector. For a given external field, the internal field of two bodies can be completely different. The discipline that specifically concerns the relationship between an external field and the field generated in an absorbing body, due to exposure of the body to that external field, is called radio-frequency dosimetry.

A number of factors in daily life can increase the heat load in the human body, such as a high temperature of the environment, solar radiation or physical exercise. Electromagnetic fields can also be included in these factors. The effect of electromagnetic fields on the body proceeds via various mechanisms, depending on the frequency of the fields.

- In the frequency range to 1 MHz, electrical currents are generated in the body and these currents can influence biological systems. This can be expressed as stimulation of nerves and muscles, or in involuntary movements. The relevant dosimetric quantity is the current density, expressed in A/m² or mA/m².
- In the range between 100 kHz and 10 GHz, the absorption of electromagnetic energy results in heat generation. The quantity used for this energy transfer is the 'specific absorption rate' (SAR). The SAR is the amount of energy absorbed by a medium per unit of time per unit of volume or per unit of time per unit of mass and is expressed in W/kg. In the frequency range 100 kHz to 1 MHz, a gradual changeover takes place from current density to SAR as the important dosimetric quantity.

• In the frequency range from 10 GHz to 300 GHz, the penetration depth of the electromagnetic field is so small that only absorption at the surface of the exposed object takes place. Therefore, in this frequency range, the power density (W/m²) of the field is taken as the relevant dosimetric unit.

Currently, exposure guidelines are intended to limit both the total body temperature and the local temperature. They are expressed as 'whole body SAR' and as 'local SAR', respectively, averaged over a small mass of tissue. Using some simplifications, the SAR is given by:

$$SAR = \frac{\boldsymbol{s} \left| \vec{E}_{int} \right|^2}{\boldsymbol{r}}, \qquad [W/kg],$$

where

s = conductivity of the medium in S/m, r = density of the medium in kg/m³, $\vec{E}_{int} =$ RMS value of the electric field in the medium in V/m.

The heat generated in a medium is proportional to the absorbed power. The temperature increase of the medium is not necessarily proportional to the SAR because of processes present in a human body that leads to the discharge of heat, such as blood flow, convection, sweating, etc.

Extensive study has been done to thermal effects. According to the Radiofrequency Radiation Committee of the Health Council of the Netherlands [28] and ICNIRP, energy absorbed equivalent to a SAR of 4 W/kg, averaged over the whole body, should be taken as the maximum permissible level from a health viewpoint. This decision is based on experimental data obtained from subjects, which showed that a SAR of 4 W/kg during a period of more than 20 minutes led to an increase in body temperature of less than 1 degree Centigrade. Although the human body can cope with such a temperature increase, it is uncertain whether a long-term increase of body temperature increases the risk of adverse effects. In order to avoid this, a safety factor is applied to the SAR value of 4 W/kg. For workers, this safety factor amounts to 10. This results in a basic restriction of 0.4 W/kg averaged over the whole body. For the general population, a safety factor of 50 is generally used, resulting in a basic restriction of 0.08 W/kg. Adherence to these basic limits will avoid any adverse effects on health that result from thermal effects. For the extremities, a value of 2 W/kg is given as the maximum permissible level. The Health Council of the Netherlands and ICNIRP conclude that the data on nonthermal effects are insufficient to serve as the basis for exposure guidelines.

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Little research data is available regarding the specific thermal effects accompanying the use of mobile telephones and portable terminals. Van Leeuwen *et.al.* [20] have described a study in which the temperature distribution in a human head was calculated as a result of exposure to an electromagnetic field originating from the aerial of a mobile telephone. For this purpose, the calculated SAR values were coupled to a computer program by which the temperature distribution in a head could be determined.

Based on calculations using a dipole-aerial transmitted mean power of 0.25 W at 900 MHz, the maximum temperature increase was 0.25 degrees Centigrade in the skin and 0.12 degrees Centigrade in the brain. Wainwright [21] reached a similar conclusion. He developed a thermal model of the head to be able to calculate the increase in temperature in the brain as a result of electromagnetic fields transmitted by cellular telephones and similar equipment. The maximum temperature increase calculated using this model was about 0.1 degrees Centigrade. Wang et.al. [33] calculated the increases in temperature that would occur for a SAR as large as the limit values for the head according to the American standard ANSI/IEEE (1.6 W/kg) and according to ICNIRP (2 W/kg). The temperature increases were 0.06 and 0.11 degrees Centigrade, respectively, at both 900 MHz and 1.5 GHz. Temperature increases this small are not thought to be a threat to health because they fall within the normal variations of the body temperature. Interestingly, a study by Bernardi [34] showed that the mere presence of a nontransmitting GSM telephone made a greater contribution to the temperature increase that occurred than the electromagnetic field. The temperature increase in the presence of a non-operational GSM telephone was 0.9 degrees Centigrade in this study, which is much greater than the observed temperature increase caused by the electromagnetic field.

To the authors' knowledge, there are no published reports in which calculations of the temperature increase in the head have been performed for UMTS signals. To gain insight into the SAR due to UMTS-like signals, calculations have been performed. These results are described in Chapter 5.

5. Electromagnetic energy absorption in a human head under exposure to UMTS-like fields as used in this study

5.1 Introduction

To obtain an impression of the absorption of electromagnetic energy in the head as a result of the exposure to UMTS-like signals, the SAR is calculated for plane wave incidence. Interactions between electromagnetic fields and the human body are caused by the fact that the composition of the body differs electromagnetically from its surroundings. Air clearly has different electromagnetic properties than the human body. Being different from the surroundings is indicated by differences in the permittivity and conductivity. The conductivity of a tissue in fact determines the energy absorption, the power to convert electromagnetic energy into heat. Because, seen from a magnetic viewpoint, man is not very different from his surroundings, the permeability of the body is equal to the one of air. For the purpose of the calculation process, a MRI scan of a head was taken. This head-scan was then divided into small cubic, volume elements, so-called 'voxels'. Each voxel was assigned a tissue type with its associated electromagnetic properties.

5.2 Method used

The SAR calculations are performed by a global numerical method called the three-dimensional volume integral equation. The problem of the electromagnetic interaction problem by the human body, a strongly inhomogeneous dielectric object, is formulated in terms of an integral equation for the electric field over the object domain. Its discretized weak form is solved numerically by using an iterative conjugate gradient method to circumvent the inversion of a large matrix. For more details about this method, that is called the WCGFFT method, the reader is referred to [35,36].

This code can calculate the electric field at every place within a certain space as a result of an excitation. In this case, a homogeneous plane wave is used.

It should be mentioned again that the whole space in which the calculations are to be performed is divided into so-called voxels. The voxels used for the calculation are cubic with sides of 2 mm. In this discrete space, objects can then be placed. In this case it is a model of a human head. The model of the head, as shown in Figure 5.1, was taken from an MRI scan performed at the University Medical Centre Utrecht (UMCU) [20]. The tissue parameters for 2100 MHz are presented in Appendix F.



Figure 5.1: MRI image of the head, showing tissue types [8].

The model of the head used is divided into $106 \ge 101 \ge 80$ steps in the x, y and z directions, respectively. In total this provides approximately 0.9 million voxels. The electric field inside the head has been calculated for plane wave incidence. The incident field was a homogeneous plane wave polarised along the y-axis. Subsequently, the SAR value is calculated inside each voxel.

The incident plane wave has an amplitude of 1 V/m, which corresponds to the exposure of the subjects in the experimental setup. Because the current partial body exposure limits are given for an average SAR over 10 g of tissue, in addition an averaging of the calculated results is applied. Finally, the total absorbed power in the model of the human head is calculated.

The calculations are performed for two cases. The first case pertains to exposure of a vertically polarized incident plane wave impinging at the ear. This is the situation that has been present during the experiments. The second case pertains to exposure of a vertically polarized incident plane wave impinging at the nose. This was used to check if a significant difference would occur with respect to the first case. Both calculations have been performed for a frequency of 2100 MHz.

The calculations are performed with the WCG-FFT method [35,36]. This method is implemented in H3DEM4COFAM, version.1.4. dated August 22, 2003.

The SAR distribution in the head is shown in three cross-sections of the head at the places of maximum SAR (averaged over 10 g). In order to obtain a good picture of this division, the cross-sections were also made in the model of the head for which the different tissue types can be seen. Both the cross-sections of the head with SAR values and the head showing tissue types are shown (see Appendix F for tissue parameters).

5.3 **Results of the SAR calculations**

The first configuration that was studied is depicted in Figure 5.2. The model was irradiated with a plane with an amplitude of 1 V/m moving in the *x*-direction. This illumination will be referred to as "front illumination".



Figure 5.2: Model of the human head.

After averaging over 10 g of tissue, a maximum SAR value of 0.064 mW/kg was found. This maximum value occurs in the voxel with coordinate (5,29,37) which is around the mouth and nose region. The results show successive cross-sections in the *xz* plane, in the *xy* plane and in the *yz* plane at the location of the maximum averaged SAR, see Figure 5.4. In Figure 5.3, cross sections of the model of the human head (Figure 5.2) in the *xz*, *xy* and *yz* planes for *y*=50, *z*=40 and *x*=53, respectively, are depicted. The coordinates given above are exactly at the center of the head.



Figure 5.3: Cross sections of the model of the human head in they yz, xy en xz planes. The planes are chosen at y=50, z=40 and x=53, respectively.



Figure 5.4: Calculated SAR in the transverse cross-sections of the head in the xz, xy, and yz planes at the location of the maximum SAR of 0.064 mW/kg for front illumination.

An increase in the SAR can be seen in Figure 5.4 around the nose, mouth and forehead. In the introduction to this chapter, it was explained that interaction between electromagnetic fields in the human body is caused by the fact that the composition of the body differs electromagnetically from its surroundings. In addition, the frequency of the plane wave is such that the penetration depth is small. Therefore, effects are only expected at the surface of the model of the head, except for the nose area where many tissue/air interfaces exist. This means that the electric field here exhibits a strongly discontinuous behavior, which explains the occurrence of maximums in this region.

The second configuration concerns a plane wave with an amplitude of 1 V/m moving in the *z*-direction, see Figure 5.2. This illumination will be referred to as "side illumination".

After averaging over 10 g of tissue, a maximum SAR value of 0.078 mW/kg was found. This maximum value occurs in the voxel with coordinate (79,12,12) which is near the right ear and the back of the neck. The results show successive cross-sections in the xz plane, in the xy plane and in the yz plane at the location of the maximum averaged SAR (right ear), see Figure 5.5.

It is clearly seen that only surface effects occur. In the previous configuration, it was pointed out that this is directly related to the high frequency of the plane wave which consequently has a low penetration depth.

In addition, the total SAR in the head was calculated according to

$$TOTSAR = \Delta x \Delta y \Delta z \iiint_{V} SAR dV$$
(5.1)

where V is the total volume of the computational space and ?x, ?y and ?z are the stepsize in the x,y and z-direction, respectively. In this case, the stepsizes are all equal to the sides of a voxel, i.e. 2 mm.

The total SAR is 0.327 nW/kg and 0.316 nW/kg for front and side illumination, respectively.

Apart form 2100 MHz, we have also carried out the calculations for side illumination and frequencies of 900 MHz and 1800 MHz, respectively. For these configurations, only the maximum SAR after averaging over 10 g of tissue and the total SAR are given in Table 5.1. For the sake of completeness, the values for side and front illumination for 2100 MHz are included as well.



Figure 5.5: Calculated SAR in the transverse cross-sections of the head in the xz, xy, and yz planes at the location of the maximum SAR of 0.078 mW/kg for side illumination.

| Frequency [MHz] | Type of illumination | SAR* [mW/kg] | Total SAR [nW/kg} |
|-----------------|----------------------|--------------|-------------------|
| 900 | side | 0.045 | 0.513 |
| 1800 | Side | 0.082 | 0.383 |
| 2100 | Front | 0.064 | 0.327 |
| 2100 | Side | 0.078 | 0.316 |

Table 5.1: SAR and total SAR for plane wave illumination with an amplitude of 1 V/m.

* After averaging over 10 g of body tissue.

It is easily verified that the maximum averaged SAR and total SAR is not significantly different for all three frequencies.

5.4 Conclusions on SAR calculations

For 2100 MHz the calculated maximum SAR values of 0.064 mW/kg and 0.078 mW/kg after averaging over 10 g of tissue lies well below the basic restriction value of 2 W/kg in the exposure guidelines for the general population from the Health Council of the Netherlands and ICNIRP. The latter also applies for the other frequencies of Table 5.1. Therefore, it is unlikely that any biological effects can be addressed to thermal effects in the head region.

6. Experimental design

6.1 Schedule of exposure

Subjects have been randomly allocated according to a balanced block randomization (For group A, 18 blocks of 2 subjects and for group B, 18 blocks of 2 subjects) taking into account all sequences. An example of an exposure scheme is given in Table 6.1.

Table 6.1:Example of exposure scheme.

| Group | Block | N | Session 1 | Session 2 | Session 3 | Session 4 |
|-------|-------|---|-----------|-----------|-----------|-----------|
| | 1 | 2 | Training | Placebo | 2100 MHz | 900 MHz |
| | 2 | 2 | Training | Placebo | 2100 MHz | 1800 MHz |
| | 3 | 2 | Training | Placebo | 900 MHz | 2100 MHz |
| | 4 | 2 | Training | Placebo | 1800 MHz | 2100 MHz |
| | 5 | 2 | Training | Placebo | 900 MHz | 1800 MHz |
| | 6 | 2 | Training | Placebo | 1800 MHz | 900 MHz |
| | 7 | 2 | Training | 900 MHz | Placebo | 2100 MHz |
| A/B | 8 | 2 | Training | 1800 MHz | Placebo | 2100 MHz |
| | 9 | 2 | Training | 2100 MHz | Placebo | 900 MHz |
| | 10 | 2 | Training | 2100 MHz | Placebo | 1800 MHz |
| | 11 | 2 | Training | 900 MHz | Placebo | 1800 MHz |
| | 12 | 2 | Training | 1800 MHz | Placebo | 900 MHz |
| | 13 | 2 | Training | 900 MHz | 2100 MHz | Placebo |
| | 14 | 2 | Training | 1800 MHz | 2100 MHz | Placebo |
| | 15 | 2 | Training | 2100 MHz | 900 MHz | Placebo |
| | 16 | 2 | Training | 2100 MHz | 1800 MHz | Placebo |
| | 17 | 2 | Training | 900 MHz | 1800 MHz | Placebo |
| | 18 | 2 | Training | 1800 MHz | 900 MHz | Placebo |

7. Taskomat test and Questionnaires procedure

7.1 Taskomat test

The Taskomat procedure was conducted according to [27]. The Taskomat provides an experimental setup in which Reaction Time, Memory Comparison, Visual Selective Attention, and Dual Tasking are tested. The duration of the entire procedure was 20 minutes. The training session was conducted while the door was closed and the coordinator was present to assist and instruct the subject.

7.2 Questionnaires

During the research, two questionnaires were used. The so-called Big-Five questions give insight in psychologically related factors that may be relevant to this study while the so-called well-being questions provide insight in the general Well Being of subjects, see also Chapter 11.

For both questionnaires (Big Five and Well Being) a customized computer program was designed. The questionnaires were presented on an LCD touch screen. A LCD screen was chosen to minimize the contribution to the electromagnetic environment that a normal monitor produces. The completion of the questionnaire was checked automatically by the program, giving a message in case one or more questions were skipped.

7.2.1 Big Five (Neo-FFI)

The Big-Five questionnaire was filled out on a customized touch screen immediately before the training session. The time necessary was approximately 20 minutes.

The paper version of the Big-Five (Neo-FFI) questionnaire is validated in [37,38]. For this study an electronic version was developed where subjects could answer the questions on a LCD-touch screen. To validate the "electronic" version, the "paper" version test was performed with 10 subjects in a 2-way randomized crossover setting. The test revealed no statistically significant difference between the electronic version and the paper version [39].

7.2.2 Well-being questionnaire

The well-being questionnaire was filled out on a customized touch screen immediately after each Taskomat test, outside the testing area. The time necessary was approximately 10 minutes.

The well-being questionnaire is a subset of a quality-of-live questionnaire which is validated as a paper version [40].

For this study, not all questions in the above mentioned quality-of-live questionnaire were relevant. In agreement with the METC an appropriate subset was taken. Subsequently, an electronic version was developed where subjects could answer the questions on a LCD-touch screen. To validate the "electronic" version, the "paper" version test was performed with 10 subjects in a 2-way randomized crossover setting. The test revealed no statistically significant difference between the electronic version and the paper version [39].

7.3 Flow chart procedures and time schedule

The procedures and time schedule are given in a flow chart, see Table 7.1.

Table 7.1: Flow Chart.

| | | Training | Randomized Placebo/ 900 MHz/1,800 MHz | | |
|-----------------------------------|---------------------|-----------|------------------------------------------|-----------|-----------|
| Activity | Selection procedure | Session 1 | Session 2 | Session 3 | Session 4 |
| Timing | Week -1 | Time 0:00 | Time 0:45 | Time 1:30 | Time 2:15 |
| Informed consent | | Х | | | |
| Demography | Х | Х | | | |
| In- exclusion criteria | Х | Х | | | |
| Big Five | | Х | | | |
| Well-being questionnaire | | Х | Х | Х | Х |
| Cognitive functions Taskomat | | | | | |
| Reaction Time test | | Х | Х | Х | Х |
| Memory Comparison test | | Х | Х | Х | Х |
| Visual Slective attention test | | Х | Х | Х | Х |
| Dual tasking test | | Х | Х | Х | Х |
| Filtering irrelevant information | | Х | Х | Х | Х |
8. Subject selection

8.1 Subjects with complaints (group A)

Subjects with complaints were selected from the list of persons that reported themselves to the Monitoring Network and were invited in writing by the Monitoring Network to participate in the study. The subject information was included in the protocol together with a questionnaire for general information and the demographic data on the subject. In the questionnaire, questions were included on concomitant diseases, concomitant medication and other information relevant to the inclusion and exclusion criteria. This questionnaire was returned by mail to Clinical Research Facilities International B.V. (CRF-I). In some cases, subjects were contacted by phone in order to complete the information, especially on concomitant diseases and concomitant medication.

8.2 Reference group (group B)

The subjects necessary for group B were invited to participate in the study within TNO-FEL through an internet message. Furthermore, in an advertisement in a local newspaper subjects were invited to participate. These subjects received the subject information as included in the protocol together with a questionnaire for general information and the demographic data on the subject. In the questionnaire, questions were included on concomitant diseases, concomitant medication and other information relevant to the in and exclusion criteria. This questionnaire was returned by mail to CRF-I.

In some cases, subjects were contacted by phone in order to complete the information especially on concomitant diseases and concomitant medication.

8.3 In- and exclusion criteria

Although the exclusion criteria are similar for both groups, they are treated separately in this report.

8.3.1 Inclusion criteria for subjects of group A

- Male or female subjects that reported subjective complaints to the Monitoring Network for Environmental Health.
- Age between 18 and 75 years (inclusive).
- Willing to give consent for participation in the study.

8.3.2 Exclusion criteria for subjects of group A

- History of brain injury.
- History of epilepsy.
- History of claustrophobia.
- Subject under treatment for a mental disease within six months prior to enrollment.
- Subject treated with psycho-active drugs within two weeks prior to enrollment.
- Any other condition that may interfere with the study according to the opinion of the investigator.
- Subjects carrying pacemakers or/and hearing aids.

8.3.3 Inclusion criteria for subjects of group B

- Male or female subjects willing to give consent for participation in the study.
- Age between 18 and 75 years (inclusive).

8.3.4 Exclusion criteria for subjects of group B

- History of brain injury.
- History of epilepsy.
- History of claustrophobia.
- Subject under treatment for a mental disease within six months prior to enrollment.
- Subject treated with psycho-active drugs within two weeks prior to enrollment.
- Any other condition that may interfere with the study according to the opinion of the investigator.
- Subjects carrying pacemakers or/and hearing aids.

All subjects have been asked to refrain from consumption of any xantine– derivative containing drinks (e.g., coffee, tea) within six hours prior to the test procedure. Checking the in- and exclusion criteria before the start of the experiments has covered this issue.

8.4 Sample size justification

For the reaction time in the Taskomat test [27] similar values are applicable. Literature indicates [7,27] that the intra-subject variance is approximately 40-60% of the inter-subject variance. Therefore, we based ourselves on a between subject standard deviation of 100 msec and a within subject standard deviation of 50 msec.

In this study an increase of 5% (37.5 msec) in delayed picture recognition and reaction time is considered as an important change and is therefore set as a value of significance. The sample size in a crossover setting, with α =0.05 and β =0.20 (power 80%) results in a group sample size of 28 subjects.

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New subjects exposed to the same schedule as the subject withdrawn have replaced withdrawals.

Since three different frequency exposures and a placebo exposure were employed in three sessions, a balanced nested crossover model was necessary. In this nested crossover model (see section 9.1 of the protocol [26]) a minimum number of 28 subjects per group with exposure to 900MHz and 1800 MHz was needed. This number was inflated to 36 for unexpected withdrawals and/or exclusions from the analysis. Simulations of the data in the nested model at a standard deviation of 50 msec revealed a difference of 35 msec as statistically significant for the comparison between 900 MHz, 1800 MHz, 2100 MHz and placebo. To obtain a completely balanced design, blocks of 18 subjects were taken. Note that a minimum of 28 subjects was needed for the study, therefore we have chosen a sample size of 36 subjects per group, i.e. 36 subjects in group A and 36 subjects in group B, thus compensating for the loss of power due to multiple comparisons.

With respect to the well-being questionnaire we have estimated that with a standard deviation (Std) equal to 3.0 [40] between the subjects, a mean difference in sumscore of two points is considered as statistically significant (α =0.05, β =0.20 i.e. power 80%) at a group sample size of 36 subjects per group. For subject corrected data, we assumed that the Std within the subjects would be 50% of the Std between the subjects. For such analysis, a sample size of 17 subjects was sufficient to detect a difference of two points as statistically significant (α =0.05, β =0.20 i.e. power 80%).

With respect to the reaction time as measured in the Taskomat test, a Std between the subjects of approximately 80 msec is reported at an average of 650 msec [4,24]. In order to be able to detect a difference of 65 msec (~10%) between the group with complaints and the control group as statistically significant with respect to reaction time a minimal sample size of 25 subjects per group would be required (α =0.05, β =0.20). The Std within the subjects, however, has shown to be ~ 50% of the Std between the subjects. Therefore, in order to detect a difference of 40 msec between the exposure sessions (within a group) as statistically significant, a sample size of 17 per group was required.

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9. Statistical Analysis and Results

9.1 Statistical Analysis

During the primary evaluation, data has been collected. Data after exposure to "placebo" and data after exposure to 900 MHz, 1800 MHz and 2100 MHz for subjects of group A and group B was compared. The comparison was made for the cognitive parameters and the well-being questionnaires.

The design of the study was a completely balanced 3-way crossover design where each subject participated in three experimental sessions and was exposed to three different situations.

All subjects participated in a training session (always the first session) and in a placebo session (randomized to session 2, 3 or 4). Since there were three different frequencies (900 MHz, 1800 MHz and 2100 MHz) to be exposed to and, due to the practical conduct of the study, it was only possible to have an (active) exposure during two sessions, the active exposure (900 MHz, 1800 MHz and 2100 MHz) took place for 48 subjects for each frequency, see Table 9.1.

| Session | Number of subjects of group A | Number of subjects of group B |
|----------|-------------------------------|-------------------------------|
| Training | 36 | 36 |
| Placebo | 36 | 36 |
| 900 MHz | 24 | 24 |
| 1800 MHz | 24 | 24 |
| 2100 MHz | 24 | 24 |

Table 9.1: Exposure of subjects per session.

In 50% of the cases the experiment was performed in the morning and 50% in the afternoon ("timing").

In total 18 different sequences of exposure are possible.

All elements (exposure, session, subject, timing and sequence) were randomized completely in a balanced way, having a replicated observation in each circumstance to avoid confounding elements. The randomization method distributed all confounding elements in a balanced way.

Furthermore the randomization procedure enabled us to evaluate session effects, sequence effects and timing effects separately and, in case of presence of such effects, to reduce the residual variance and consequently increase the power of the comparisons of the main effects.

The comparison was performed in SAS using a nested ANOVA model (Proc GLM option SS3) including as factors: Exposure (Placebo, 900 MHz, 1800 MHz, 2100 MHz) Group (group A, group B) Session (first, second, third exposure) Subject within sequence (36 subjects in group A, 36 subjects in group B) Sequence (18 sequences were possible) Timing of the procedure (morning, afternoon).

Where applicable, confirmation of the outcome of the comparisons was performed by using the non-parametric SAS testing procedures of Wilcoxon (Mann-Whitney U-test), Rank-sign test and Cochran Mantel Haenszel. All tests were performed at two-tailed α = 0.05 significance level.

10. Study Subjects

10.1 Disposition of subjects

Subjects that reported themselves to the Monitoring Network as having complaints that they attributed to the presence of GSM antennas (group A) were invited and selected to participate in the study as indicated in section 8.1 of this report. Furthermore, subjects of the reference group (group B) were invited and selected as indicated in section 8.2 of this report. An overview of the disposition of the subjects is given in Table 10.1.

| Group | Projected | Screened | Randomized | Withdrawals | Completed |
|-------|-----------|----------|------------|-------------|-----------|
| А | 36 | 44 | 37 | 1 | 36 |
| В | 36 | 42 | 37 | 1 | 36 |
| Total | 72 | 86 | 74 | 2 | 72 |

Table 10.1: Disposition of subjects in both groups.

10.2 Subject Data Sets

The subject dataset contains data on all subjects included in the study whom:

- completed the entire test period,
- had valid data available for the primary criteria,
- had no major deviation.

10.3 Subject Discontinuations

For two randomized subjects the procedure was discontinued. The subject numbers and reasons for discontinuation were:

Subject 2 (group A): During the third double blind session the subject did not feel well and wished to discontinue the procedure. No Taskomat data on this session was available for analysis. Although this subject completed the well-being questionnaire after the session, this subject has been replaced by a new subject with the same sequence of exposure in order to maintain the balance of the design.

Subject 71 (group B): During the double blind session 3 a technical problem occurred. The procedure had to be discontinued and therefore, the subject could not be included in the analysis.

The test with this subject was repeated one week later using the same sequence of exposure in order to maintain the balance of the design within the study. The results of the repeated test are included in the analysis.

10.4 Protocol Amendments

No amendments were made to the protocol

10.5 Deviations from the protocol

No deviations of the protocol occurred

10.6 Conduct of study

During the study some mistakes were made regarding the opening of the randomization envelopes by the operator.

To maintain the balance of the study, replacement envelopes were indicated. All changes in envelope assignments were clearly documented in notes-to-file. It is noted that this does not affect the results.

10.7 Data analysis

The design of the study is a balanced, nested 3-way crossover model in order to be able to analyze and to eliminate the carry-over effects. An additional complication was that in practice it was only possible to perform a 3-way crossover design while in fact the influence of four different exposures was to be evaluated, i.e. placebo, 900 MHz, 1800 MHz and 2100 MHz. To avoid any bias due to imbalance of the data, the design had to be completely symmetrical. The analysis of the data included:

10.7.1 Big Five (Neo-FFI)

The Big-Five questionnaire was analyzed according to the guidelines. Scoring key for obtaining raw scores for the five factors are tabulated in Table 10.2.

| Factor | Normal-Keyed Items | Reverse-Keyed Items |
|-------------------|-------------------------------|-------------------------------|
| Neuroticism | | 1, 16, 31, 46 |
| Extroversion | 2, 7, 17, 22, 32, 37, 47, 52 | 12, 27, 42, 57 |
| Openness | 13, 28, 43, 53, 58 | 3, 8, 18, 23, 33, 38, 48 |
| Agreeableness | 4, 19, 34, 49 | 9, 14, 24, 29, 39, 44, 54, 59 |
| Conscientiousness | 5, 10, 20, 25, 35, 40, 50, 60 | 15, 30, 45, 55 |

Table 10.2: Scoring key for obtaining raw scores for Big Five.

The numbers between brackets refer to the well-being questions as given by the study protocol [26].

10.7.2 Well-being scores

The well-being questionnaire is analyzed as a whole by estimation of the total sumscore defined as follows:

- Not at all = 0.
- A little, slightly = 1.
- A great deal, quite a bit = 2.
- Extremely, could not have been worse = 3.

Furthermore the scores are analyzed by grouping the answers according to the guidelines as indicated by Bulpitt, see Table 10.3.

Table 10.3: Categories with the pertaining questions.

| Category | Questions |
|---------------------|---------------------------|
| Anxiety symptoms | 3, 7, 14, 17 |
| Somatic symptoms | 1, 4, 5, 6, 8, 11, 16, 18 |
| Inadequacy symptoms | 10, 12, 13, 15, 19 |
| Depression symptoms | 2, 19 |
| Hostility symptoms | 20, 21, 22, 23 |

10.7.3 Taskomat data

• Reaction time test

For the reaction time test, the testee judges the category to which a stimulus belongs and presses a button of the response panel. It provides an indication of basic speed and indications about four specific components of the reaction time process being perceptual coding, response choice, response programming and motor activation, respectively. The parameter evaluated is basic speed in msec [27].

• Memory comparison test

For the memory comparison test, the testee judges whether or not a 2x2 matrix of letters contains an element of a predefined memorized set of letters and presses a "yes" or a "no" button accordingly. The parameter evaluated is the basic speed of memory comparison in msec [27].

• Visual selective attention test

The visual selective attention test requires the testee to focus attention on predefined areas of the display and to ignore information presented in other areas of the display. The parameter evaluated is the basic speed of focusing attention [27].

• Dual tasking test

The dual tasking test presents both a tracking and a counting task at the same time. The specific objective of dual tasking is to test the tracking skill while the testee is put under a strain imposed by a counting task.

Two parameters are derived from the test [27]:

- General reaction time in msec
- o Indicator for filtering irrelevant information

11. **Results**

11.1 Demographics and other subject characteristics before treatment

There are substantial differences between group A and group B with respect to gender distribution and age. In Table 11.1, the demographic data of the subjects included in the study are presented.

| Item | | group A | group B |
|--------|------------------------|-----------------|---------------|
| Gender | | | |
| I | Male (n) | 11 | 22 |
| I | Female (n) | 25 | 14 |
| Total | | 36 | 36 |
| Age | | | |
| I | Mean \pm Std (years) | 55.7 ± 12.0 | 46.6 ± 16.4 |
| | Range (min, max) | (31,74) | (18, 72) |

Table 11.1: Demographic data of subjects.

11.2 Pre-procedure Big-Five evaluation (Neo-FFI)

The data on the Big Five are processed as indicated in section 10.7.1. As can be noticed from Table 11.2 statistically significant differences existed between group A and group B with respect to the item Extroversion and the total sum of scores. According to literature [18] there might be substantial differences between male and female subjects. However, our data does not confirm this statement. Since differences occurred between group A and group B with regard to gender distribution data should be analyzed accordingly as presented in Table 11.3 and 11.4 indicating that the overall significant difference with respect to extroversion and total score found may be caused by female subjects. Furthermore, the introduction of the Big-Five score in the analysis did not contribute to the power of the analysis of the key items. Hence, further inclusion in the analysis is omitted.

| g | roup A | g | roup B | p-value* group A vs. group B | | |
|---------------|------------------------------------------|-------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Mean | SEM | Ν | Mean | SEM | Ν | |
| 21.06 | 0.68 | 36 | 20.22 | 0.37 | 36 | 0.053 |
| 21.41 | 0.70 | 36 | 19.86 | 0.62 | 36 | <0.001 |
| 24.94 | 0.57 | 36 | 25.22 | 0.44 | 36 | 0.132 |
| 21.78 | 0.42 | 36 | 21.64 | 0.32 | 36 | 0.210 |
| 23.33 0.42 36 | | 23.03 0.43 36 | | 0.706 | | |
| | Mean 21.06 21.41 24.94 21.78 | 21.06 0.68 21.41 0.70 24.94 0.57 21.78 0.42 23.33 0.42 | Mean SEM N 21.06 0.68 36 21.41 0.70 36 24.94 0.57 36 21.78 0.42 36 23.33 0.42 36 | Mean SEM N Mean 21.06 0.68 36 20.22 21.41 0.70 36 19.86 24.94 0.57 36 25.22 21.78 0.42 36 21.64 23.33 0.42 36 23.03 | Mean SEM N Mean SEM 21.06 0.68 36 20.22 0.37 21.41 0.70 36 19.86 0.62 24.94 0.57 36 25.22 0.44 21.78 0.42 36 21.64 0.32 23.33 0.42 36 23.03 0.43 | MeanSEMNMeanSEMN21.060.683620.220.373621.410.703619.860.623624.940.573625.220.443621.780.423621.640.323623.330.423623.030.4336 |

Table 11.2: Big-Five (Neo-FFI) all sum of scores.

* Mann-Whitney U-test

Table 11.3: Big-Five (Neo-FFI) males sum of scores.

| | G | roup A | | G | Group B | p-value* group p A vs. group B | |
|-------------------|-------|--------|----|-------|---------|-----------------------------------|-------|
| Item | Mean | SEM | N | Mean | SEM | Ν | |
| Neuroticism | 20.55 | 1.14 | 11 | 19.72 | 0.48 | 22 | 0.757 |
| Extroversion | 21.36 | 1.50 | 11 | 20.18 | 0.90 | 22 | 0.551 |
| Openness | 24.09 | 0.97 | 11 | 25.54 | 0.61 | 22 | 0.240 |
| Agreeableness | 21.18 | 0.89 | 11 | 21.41 | 0.42 | 22 | 0.969 |
| Conscientiousness | 23.00 | 0.73 | 11 | 23.36 | 0.49 | 22 | 0.383 |

* Mann-Whitney U-test

Table 11.4: Big-Five (Neo-FFI) female's sum of scores.

| | G | roup A | | G | Group B | p-value* group A vs. group B | |
|-------------------|-------|--------|----|-------|---------|---------------------------------|-------|
| Item | Mean | SEM | N | Mean | SEM | Ν | |
| Neuroticism | 21.28 | 0.86 | 25 | 21.00 | 0.54 | 14 | 0.617 |
| Extroversion | 21.44 | 0.79 | 25 | 19.36 | 0.77 | 14 | 0.054 |
| Openness | 25.32 | 0.70 | 25 | 24.17 | 0.57 | 14 | 0.929 |
| Agreeableness | 22.04 | 0.47 | 25 | 22.00 | 0.51 | 14 | 0.859 |
| Conscientiousness | 23.48 | 0.53 | 25 | 22.50 | 0.78 | 14 | 0.615 |

* Mann-Whitney U-test

11.3 Well-being questionnaire

11.3.1 Well-being sumscore

The results for Well Being are tabulated in Table 11.5. This data is visualized in Figure 11.1

The maximum sumscore for the 23 questions of the well-being questionnaire is 69. There was a clear statistically significant difference before the start of the procedure (i.e. training session) between group A (mean 5.72) and the group B (mean 1.83) with respect to the total sumscore (p=0.004), see Table 11.5. As also can be seen in Table 11.5, the standard error of the mean in group A is substantially higher when compared to group B. Therefore, a comparison of the baseline values was tested non-parametric (Wilcoxon) which also shows a statistically significant difference (p=0.0013).

The difference between placebo exposure and 2100 MHz exposure was statistically significant for subjects of both groups. No statistically significant difference could be observed between placebo exposure, 900 MHz exposure and 1800 MHz exposure.

Table 11.5: Well-being scores.

| | | Gr | oup A | N . | | | | | |
|----------|-------|------|-------|-------------------------|------|------|----|----------------------------|---------------------------------------|
| Session | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Training | 5,72 | 1,25 | 36 | | 1,83 | 0,42 | 36 | | <0.05 |
| Placebo | 7,47 | 1,38 | 36 | | 2,44 | 0,42 | 36 | | |
| 900MHz | 8,71 | 2,21 | 24 | NS | 2,25 | 0,45 | 24 | NS | |
| 1800MHz | 7,33 | 1,19 | 24 | NS | 1,96 | 0,51 | 24 | NS | |
| 2100MHz | 10,75 | 2,05 | 24 | <0.05 | 3,08 | 0,70 | 24 | <0.05 | |

* ANOVA; NS=not statistically significant



Figure 11.1: Well-being scores.

11.3.2 Well-being subscores

The results of the individual questions in the well-being questionnaire are presented in Appendix E. In this section, the well-being subscores of each category of symptoms are presented.

11.3.2.1 Anxiety symptoms

The anxiety symptoms are tabulated in Table 11.6.

Table 11.6: Well-being scores anxiety symptoms.

| | Gr | oup A | L. | Group B | | | | |
|------|------------------------------|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| 1.27 | 0.27 | 36 | | 0.50 | 0.12 | 36 | | P<0.05 |
| 1.44 | 0.28 | 36 | | 0.61 | 0.13 | 36 | | |
| 1.50 | 0.39 | 24 | NS | 0.79 | 0.17 | 24 | NS | |
| 1.58 | 0.25 | 24 | NS | 0.54 | 0.16 | 24 | NS | |
| 2.00 | 0.41 | 24 | P<0.05 | 0.83 | 0.19 | 24 | NS | |
| | 1.27 1.44 1.50 1.58 | MeanSEM1.270.271.440.281.500.391.580.25 | Mean SEM N 1.27 0.27 36 1.44 0.28 36 1.50 0.39 24 1.58 0.25 24 | MeanSEMNplacebo1.270.27361.440.28361.500.3924NS1.580.2524NS | Mean SEM N p-value* vs. placebo Mean 1.27 0.27 36 0.50 1.44 0.28 36 0.61 1.50 0.39 24 NS 0.79 1.58 0.25 24 NS 0.54 | Mean SEM N p-value* vs. placebo Mean SEM 1.27 0.27 36 0.50 0.12 1.44 0.28 36 0.61 0.13 1.50 0.39 24 NS 0.79 0.17 1.58 0.25 24 NS 0.54 0.16 | Mean SEM N p-value* vs. placebo Mean SEM N 1.27 0.27 36 0.50 0.12 36 1.44 0.28 36 0.61 0.13 36 1.50 0.39 24 NS 0.79 0.17 24 1.58 0.25 24 NS 0.54 0.16 24 | Mean SEM N p-value* vs. placebo Mean SEM N p-value* vs. placebo 1.27 0.27 36 0.50 0.12 36 - 1.44 0.28 36 0.61 0.13 36 - 1.50 0.39 24 NS 0.79 0.17 24 NS 1.58 0.25 24 NS 0.54 0.16 24 NS |

* ANOVA; NS=not statistically significant

11.3.2.2 Somatic symptoms

The somatic symptoms are tabulated in Table 11.7.

Table 11.7: Well-being scores somatic symptoms.

| | | Gr | oup A | | | Gr | | | |
|----------|------|------|-------|-------------------------|------|------|----|-------------------------|---------------------------------|
| Session | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Training | 2.27 | 0.46 | 36 | | 0.89 | 0.23 | 36 | | P<0.05 |
| Placebo | 3.44 | 0.56 | 36 | | 1.16 | 0.22 | 36 | | |
| 900MHz | 3.91 | 0.84 | 24 | NS | 1.04 | 0.23 | 24 | NS | |
| 1800MHz | 3.25 | 0.55 | 24 | NS | 0.79 | 0.22 | 24 | NS | |
| 2100MHz | 5.04 | 0.86 | 24 | P<0.05 | 1.29 | 0.30 | 24 | NS | |

11.3.2.3 Inadequacy symptoms

The inadequacy symptoms are tabulated in Table 11.8.

Table 11.8: Well-being scores inadequacy symptoms.

| | | Gr | oup A | Ą | | Gr | 3 | | |
|----------|------|------|-------|-------------------------|------|------|----|-------------------------|---------------------------------|
| Session | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Training | 1.13 | 0.28 | 36 | | 0.28 | 0.09 | 36 | | P<0.05 |
| Placebo | 1.33 | 0.31 | 36 | | 0.31 | 0.10 | 36 | | |
| 900MHz | 1.71 | 0.49 | 24 | NS | 0.25 | 0.11 | 24 | NS | |
| 1800MHz | 1.21 | 0.26 | 24 | NS | 0.33 | 0.12 | 24 | NS | |
| 2100MHz | 1.88 | 0.44 | 24 | P<0.05 | 0.54 | 0.19 | 24 | P<0.05 | |

* ANOVA; NS=not statistically significant

11.3.2.4 Depression symptoms

The depression symptoms are tabulated in Table 11.9.

Table 11.9: Well-being scores depression symptoms.

| | | Gr | oup A | Ą | | Gr | | | |
|----------|------|------|-------|-------------------------|------|------|----|-------------------------|---------------------------------|
| Session | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Training | 0.31 | 0.14 | 36 | | 0.06 | 0.04 | 36 | | NS |
| Placebo | 0.33 | 0.15 | 36 | | 0.19 | 0.08 | 36 | | |
| 900MHz | 0.46 | 0.20 | 24 | NS | 0.08 | 0.06 | 24 | NS | |
| 1800MHz | 0.25 | 0.14 | 24 | NS | 0.17 | 0.10 | 24 | NS | |
| 2100MHz | 0.42 | 0.21 | 24 | NS | 0.21 | 0.10 | 24 | NS | |

11.3.2.5 Hostility symptoms

The hostility symptoms are tabulated in Table 11.10.

Table 11.10: Well-being scores hostility symptoms.

| | | Gı | oup A | L. | | | | | |
|----------|------|------|-------|-------------------------|------|------|----|-------------------------|------------------------------------|
| Session | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Training | 0.72 | 0.22 | 36 | | 0.11 | 0.05 | 36 | | P<0.05 |
| Placebo | 0.92 | 0.23 | 36 | | 0.17 | 0.06 | 36 | | |
| 900MHz | 1.12 | 0.38 | 24 | NS | 0.08 | 0.06 | 24 | P<0.05 | |
| 1800MHz | 1.04 | 0.25 | 24 | NS | 0.12 | 0.07 | 24 | NS | |
| 2100MHz | 1.41 | 0.35 | 24 | P<0.05 | 0.21 | 0.08 | 24 | NS | |

* ANOVA; NS=not statistically significant

11.4 Cognitive Functions

The cognitive functions measured are described in Section 10.7.3. The data as collected during the training session, are not used further in the analysis. The reason for this is that the training session took place while in most of the cases guidance was given during the test. The data collected are therefore incomparable with the data as collected during session 2, 3 and 4.

The data for the parameters slope and selective attention for one subject (subject 21: placebo session) were missing due to unknown circumstances. The data could indicate that the subject must have had a period of lack of action during the test. Statistically significant difference were found between the sessions (p<0.05) and for the sequences (order of exposure; p<0.05).

11.4.1 Reaction Time test

The results for the reaction test are tabulated in Table 11.11. This data is visualized in Figure 11.2.

The difference between group A and group B is not statistically significant for placebo exposure. For an exposure of 900 MHz of group A and for an exposure of 2100 MHz for group B, a statistically significant increase of Reaction Time was observed, see Figure 11.2.

| | | | Group | A | | Gı | | | |
|----------|------|------|-------------------------|--------|------|------|----|-------------------------|---------------------------------|
| Exposure | Mean | SEM | p-value* 1 N placebo | | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Placebo | 1153 | 22,3 | 36 | | 1139 | 23,2 | 36 | | NS |
| 900MHz | 1196 | 34,6 | 24 | P<0.05 | 1161 | 32,3 | 24 | NS | |
| 1800MHz | 1161 | 25,5 | 24 | NS | 1121 | 24,7 | 24 | NS | |
| 2100MHz | 1172 | 27,2 | 24 | NS | 1179 | 38,8 | 24 | P<0.05 | |

Table 11.11: Reaction Time test (intercept; msec).



Figure 11.2: Reaction Time test.

11.4.2 Memory Comparison test

The results for the memory comparison test are tabulated in Table 11.12. This data is visualized in Figure 11.3.

One extraordinary value in group A was not included in the analysis (subject 21 placebo value 603).

The difference between group A and group B is not statistically significant at placebo exposure. For an exposure of 1800 MHz and 2100 MHz of group B, a statistically significant decrease of comparison speed was observed, see Figure 11.3.

| | | Gr | oup A | 4 | | Gr | | | |
|----------|------|-----|-------|----------------------------|------|-----|----|----------------------------|-------------------------------|
| Exposure | Mean | SEM | Ν | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group vs. group B |
| Placebo | 27,8 | 2,9 | 35 | | 26,4 | 2,8 | 36 | | NS |
| 900MHz | 25,8 | 3,6 | 25 | NS | 23,3 | 2,6 | 24 | NS | |
| 1800MHz | 29,4 | 4,6 | 24 | NS | 20,2 | 4,2 | 24 | P<0.05 | |
| 2100MHz | 32,6 | 4,2 | 24 | NS | 20,7 | 3,8 | 24 | P<0.05 | |

Table 11.12: Memory Comparison test.



Figure 11.3: Memory Comparison test.

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11.4.3 Visual Selective attention Test

The results for the visual selective attention test are tabulated in Table 11.13. This data is visualized in Figure 11.4.

The difference between group A and group B is statistically significant at placebo exposure. For an exposure of 2100 MHz of group A as well as group B, a statistically significant reduction of the steering time parameter was observed, see Figure 11.4.

Table 11.13: Visual selective attention test.

| | | Gr | oup A | Ą | | | p-value* | | |
|----------|------|-----|-------|-------------------------|------|-----|----------|-------------------------|---------------------------|
| Exposure | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | group A vs. group B |
| Placebo | 10,6 | 0,9 | 36 | | 7,2 | 0,3 | 36 | | P<0.05 |
| 900MHz | 11,3 | 1,6 | 24 | NS | 7,0 | 0,4 | 24 | NS | |
| 1800MHz | 11,1 | 1,1 | 24 | NS | 7,3 | 0,3 | 24 | NS | |
| 2100MHz | 9,2 | 0,8 | 24 | P<0.05 | 6,8 | 0,3 | 24 | P<0.05 | |



Figure 11.4: Visual selective attention test.

11.4.4 Dual tasking test

11.4.4.1 General Reaction time

The results for the general reaction time test are tabulated in Table 11.14. This data is visualized in Figure 11.5.

The difference between group A and group B is not statistically significant at placebo exposure. For an exposure of 1800 MHz of group B, a statistically significant reduction of the reaction parameter was observed, see Figure 11.5.

Table 11.14:General Reaction Time.

| | | Gr | oup A | | | Group B | | | | | |
|----------|--------|------|-------|-------------------------|--------|---------|----|-------------------------|---------------------------------------|--|--|
| Exposure | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B | | |
| Placebo | 1304,0 | 37,0 | 36 | | 1260,9 | 34,7 | 36 | | NS | | |
| 900MHz | 1317,1 | 43,4 | 24 | NS | 1272,9 | 46,4 | 24 | NS | | | |
| 1800MHz | 1324,0 | 42,1 | 24 | NS | 1201,7 | 28,4 | 24 | P<0.05 | | | |
| 2100MHz | 1336,5 | 40,7 | 24 | NS | 1246,7 | 35,4 | 24 | NS | | | |



Figure 11.5: General reaction time.

11.4.4.2 Indicator for filtering irrelevant information

The results for filtering irrelevant information are tabulated in Table 11.15. This data is visualized in Figure 11.6.

One extraordinary value in group A was not included in the analysis (subject 21 placebo value -2570).

The difference between group A and group B is not statistically significant at placebo exposure. For an exposure of 900 MHz of group A, a statistically significant reduction of the alertness parameter was observed, see Figure 11.6.

Table 11.15: Indicator for filtering irrelevant information.

| | | Gro | oup A | | | Gro | | | |
|----------|-------|------|-------|----------------------------|-------|------|----|----------------------------|---------------------------------------|
| Exposure | Mean | SEM | N | p-value* vs. placebo | Mean | SEM | N | p-value* vs. placebo | p-value* group A vs. group B |
| Placebo | 192.0 | 37,5 | 34 | | 124,7 | 30,5 | 36 | | NS |
| 900MHz | 150,5 | 31,6 | 24 | P<0.05 | 128,5 | 22,4 | 24 | NS | |
| 1800MHz | 220,5 | 31,6 | 24 | NS | 94,9 | 11,2 | 24 | NS | |
| 2100MHz | 168,9 | 20,9 | 24 | NS | 104,0 | 15,7 | 24 | NS | |



Figure 11.6: Indicator for filtering irrelevant information.

11.5 Discussion on hypersensitivity and Well Being

Concerning hypersensitivity symptoms, we have found two papers [16,18] that report a relation between subjective symptoms and RF-fields and two papers [10,17] that report no statistically significant relations. New in our research is that we haven't studied subjective hypersensitivity symptoms, but studied the relation between GSM and UMTS-like exposure and the well-being sumscore. From the well-being sumscores, presented in 11.3.1, it may be concluded that before entering the test procedure, a difference between both groups with respect to well-being exists.

For the UMTS-like fields we have found a statistically significant effect on the well-being sumscore for both groups. Also, it is noted that in literature research to hypersensitivity has not been conclusive [10,16,17,18]. Although hypersensitivity and Well Being are two separate parameters, we would like to discuss a recently published paper on hypersensitivity by Hietanen et.al. [10]. We are not convinced that the study by Hietanen et.al. [10] has been performed in an appropriate way. First, it is not adequately verified that the electromagnetic environment was sufficiently low. They reported that their RF-environment was lower than 2 W/m^2 , which indicates that the electric field strength is less than 27 V/m. Our conclusion is that they have used an inappropriate E-field sensor to verify their electromagnetic environment for their purpose. They should have verified their electromagnetic environment at least in the mV/m range, preferably frequency dependent, by using appropriate equipment and simultaneously during the experiments. Their findings that the subjects were not able to distinguish real RFexposure to sham exposure might be compromised because it is not clear that during sham exposure the electromagnetic environment was sufficiently low with respect to the studied exposure. If that would be the case, the RF-exposure considered as stimulus could lead to non-measurable differences in the parameters under consideration.

In our research we have a completely controlled electromagnetic environment assuring that our measurements are not influenced by unknown electromagnetic sources. Secondly, Hietanen *et.al.* [10] report that the subjects were asked to describe their experienced subjective complaints. It is our opinion that the present set up provides a better way to evaluate subjective complaints by using a questionnaire for each subject throughout the study and thus obtaining an objective measure to be analyzed statistically.

Interpretation of the results should be done very carefully. It is noted that the dimension of the changes observed in the Well Being for UMTS-like exposure, though statistically significant, is relatively small. On the other hand, factors such as carry-over between sessions and the relative short exposure that is used might limit the effects observed.

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12. Conclusions and recommendations

The research is carried out according to rigorous scientific standards and exhibits no major problems with respect to methodology, sample size and analysis. This is the result of two independent specialists who have reviewed the relevant documents.

From our research it is concluded that our hypotheses to find no causal relation between the presence of RF-fields and the measured parameters is rejected. We have found a statistically significant relation between UMTS-like fields with a field strength of 1 V/m and the Well Being. Both group A and group B show similar effects in the well-being results. It is noted that the World Health Organization (WHO) the definition of health reads as "a state of complete physical, mental and social well being and not merely the absence of disease or infirmity". Within this WHO definition the perceived Well Being is part of health.

Also, a statistically significant difference is observed between the generally experienced Well Being within group A and group B. The bias introduced by the selection procedure together with the different demographical structure between both groups makes a direct comparison between group A and group B invalid.

From the cognitive tasks, it is observed that a slightly higher number of significant effects is found in group B when compared to group A. The results are unlikely to be attributed to statistical noise. From the 30 cognitive function tests, we found that eight cognitive function tests are statistically significant. Statistical noise could allow up to four false statistically significant results. Note that each exposure frequency is associated with changes in some tasks or parameters, while other frequencies are not.

In Table 12.1, statistical significancies obtained from the study are presented.

| | | Group A | | Group B | | | |
|-------------------------------------|--------|---------|---------------|---------|---------|---------------|--|
| | GSM900 | GSM1800 | UMTS- like | GSM900 | GSM1800 | UMTS- like | |
| Well Being | | | | | | | |
| Sumscore | - | - | Х | - | - | Х | |
| Anxiety | - | - | Х | - | - | - | |
| Somatic | - | - | Х | - | - | - | |
| Inadequacy | - | - | Х | - | - | Х | |
| Cognitive Test | | | | | | | |
| Reaction time | Х | - | - | - | - | Х | |
| Memory comparison | - | - | - | - | Х | Х | |
| Visual Selective | - | - | Х | - | - | Х | |
| Dual tasking | - | - | - | - | Х | - | |
| Filtering irrelevant information | Х | - | - | - | - | - | |

Table 12.1: Overview of Statistical Significancies.

In literature, similar results on cognition are found. From our results and the available literature, it is not possible to speculate on a scientifically justified hypothesis to explain the potential effects of RF fields on cognition. However, one aspect can be tackled. In literature, it is speculated that the effects on the cognitive parameters may be explained by an unknown mechanism induced by thermal effects. In our study, it is shown that the thermal effects are negligible and therefore, an explanation based on thermal effects seems highly unlikely for effects on the cognitive parameters.

An important scientific issue is the fact that relations that are found must be reproducible. Since this research is the first one to find a statistically significant relation on Well Being by using a subset of Bulpitt's questionnaire, reproduction of our research by a research group independent of TNO is necessary.

Without any question, the results justify more scientific research into this area. Apart from the reproduction as mentioned above, research is recommended in the following area's:

- Examine a dose-response relation, decrease and increase the radio frequency field strength in order to find the effects on the dimensions found in the Well Being.
- Examine whether a difference exists between sex and adult versus children.

- Examine the biological mechanism to better understand whether the effects found can be ascribed to physical quantities and to better understand the impact to health related questions.
- Examine the biological mechanism within the brain functions to understand the potential effects on cognitive tasks.
- Examine the effect of different pulse forms and frequencies used.
- Examine why some cognitive function tests exhbit response to an RF stimulus while other cognitive function tests do not.
- Examine if the effects found for the UMTS-like signal also holds for other CDMA signals.

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13. References

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15. Signature

J.P. Dezaire, MSc Group leader Prof. dr. A.P.M. Zwamborn Principal investigator/Project leader

Las

Dr. S.H.J.A. Vossen Author

W.N. Mäkel Co-investigator Clinical Research Facilities, The Netherlands

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Appendix A Exposure verification

In this Appendix, we present the verification of the electric field strength generated at the location of the subjects during the experiments.

A.1 Verification of the field

The verification of the field is performed by using the isotropic electric field probe Holaday HI-4433-GRE, with serial number 96651. This field probe was placed on the planned position where the subjects were invited to sit during the experiments. In the full anechoic room the field is measured at a height of 1.3 m. The verification measurements were performed on the 2^{nd} and 3^{rd} of October 2002.

The relationship between the actual electric field strength and the reading of the electric field probe is given by the so called correction factor (Cf). By using this correction factor, the actual field is calculated from the reading of the probe by using:

$$E(V/m) = Reading * Cf$$

The correction factors are frequency dependent and follow from the calibration document EH-A369/01 of Siebersdorf dated 29.10.2001. The specified correction factor pertaining to the electric field probe in the frequency range of interest is presented in Table A.1.

Table A.1Specified correction factors of the isotropic electric field probe Holaday
HI-4433-GRE, serial number 96651 in calibration document EH-A369/01.

| Frequency [MHz] | Correction factor |
|-----------------|-------------------|
| 900 | 1.40 |
| 1000 | 1.29 |
| 2000 | 1.27 |
| 3000 | 1.17 |

The verification was performed by applying full carrier frequencies of 945 MHz, 1840 MHz and 2140 MHz (no modulation). The correction factors used at these frequencies are derived from the factors of Table A.1. by means of linear interpolation and are tabulated in Table A.2.

| Table A.2 | Correction factors of the isotropic electric field probe interpolated for the |
|-----------|-------------------------------------------------------------------------------|
| | frequencies used in the experiments. |

| Frequency [MHz] | Interpolated correction factor |
|-----------------|-----------------------------------|
| 945 | 1.3505 |
| 1840 | 1.2732 |
| 2140 | 1.2560 |

The field probe is more accurate for field strength levels that exceed 50 % of its range. The minimum range amounts to 10 V/m. A compromise between accuracy of the field probe and the amplifier power was obtained by using a field strength level of 10 dB above 1 V/m, that is 3.162 V/m, for verification purposes.

Table A.3Verification table

| Frequency [MHz] | Reading for 3.162 V/m [†] | Required generator power [dBm] for 3.162 V/m | RF-generator power [dBm] to obtain 1 V/m ‡ |
|-----------------|---------------------------------------|-------------------------------------------------------|--------------------------------------------------|
| 945 | 2.34 | -1.24 | -11.24 |
| 1840 | 2.48 | +4.98 | - 5.02 |
| 2140 | 2.52 | +6.16 | - 3.84 |

[†] Using the correction factors of table 2.

[‡] The RF-power to generate 1 V/m is 10 dB lower then the required power for 3.162 V/m.

During the experiments, it was necessary to verify and monitor the electromagnetic field strength constantly . Therefore, we put an electric field probe at a fixed position in front of the antenna. The reading of the electric field probe at this monitoring position that relates to 1 V/m at the desired location is given in Table A.4. The signal generator was set manually. The output power was set to the level mentioned in the right column of Table A.3.

Table A.4Electric field probe readings by the monitoring probe. The probe reading
pertains to 1 V/m at the desired position.

| Frequency [MHz] | Modulation | Reading by HI-4433-GRE, #96651 | Reading by HI-4433-GRE, #96653 (spare) |
|-----------------|------------|--------------------------------------|----------------------------------------------|
| 945 | GSM | 2.18 | 1.68 |
| 1840 | GSM | 1.90 | 1.27 |
| 2140 | UMTS | 4.08 | 3.43 |

Appendix B Performed tests and questionnaires

B.1 Questionnaires

Three questionnaires have been used in the study

- **1. Questionnaire A:** General questionnaire recording demographic data and personality profile (Big Five).
- **2. Questionnaire B:** Questionnaire recording personality profile (Neo-FFI/Big Five).
- **3.** Questionnaire C: Well-being questionnaire which is a subset of Bulpit [28]. Evaluation questionnaire to be filled out right before and after the training session and right after each exposure session.

All questions have been derived from validated Quality-of-life questionnaires and are presented in appendix D of this report.

B.2 Cognitive Tests

TNO Human Factors located at Soesterberg, The Netherlands has developed a computer program and published [32] results of measurements that are very well applicable in this study. Due to the fact that each subject has to perform each test four times in a relative short period of time, the number of tasks should be limited. During the exposure to electromagnetic fields the subjects will perform the cognitive functions test. Exposure to electromagnetic fields has been maintained until the subject finished the session.

To evaluate cognitive functions the following tests have been performed

- Reaction Time test.
- Memory Comparison test.
- Visual Slective attention test.
- Dual tasking test.
- Filtering irrelevant information.

From these tasks reaction ability, recognition, cognitive attention, and motoric concentration are the cognitive parameters under consideration.

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Appendix C Photo gallery of the experimental facility

In this appendix a photo gallery is given to show the experimental test setup and equipment used.



C.1 Taskomat

Figure C1: The Well-being questionnaire filled in through a touch screen.

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Figure C2: The Taskomat set up inside the shielded room.



Figure C3: A Subject operating the Taskomat.

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Figure C4: The amplifiers used for the generation of the electromagnetic fields.



Figure C5: The control computer and security video link from the control room.

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Appendix D Well-being Questionnaire

D.1 In this appendix we present the well-being questionnaire derived from 'van Bortel/Bullpit'. The test is in Dutch and implemented in a computer program as defined in the study protocol [13].

Dit formulier is ontworpen om te ontdekken of u het **laatste kwartier** één van de hieronder vermelde symptomen heeft ervaren en indien dit zo is, in welke mate. Kruis a.u.b. het hokje aan dat het beste omschrijft hoe u zich heeft gevoeld.

Bijvoorbeeld: als u het symptoom helemaal niet hebt gehad, zet dan een kruisje in het hokje aan de linkerzijde, op deze manier:

| | helemaal niet | | | kon niet erger |
|-----------|---------------|-----------|-----------|-------------------|
| | | enigszins | vrij veel | |
| Hoofdpijn | X | | | |

Als u het symptoom heeft gehad, beschrijf dan hoe vervelend u het vond of hoe erg het u heeft belemmerd, op deze manier:

| | helemaal niet | enigszins | vrij veel | kon niet erger |
|-----------|---------------|-----------|-----------|-------------------|
| Hoofdpijn | | | | |

Beantwoord a.u.b. alle vragen. Denk niet lang na voordat u antwoordt.

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| | | | | | 1 |
|----|--------------------------------------------------------------------------------------------------------|------------------|-----------|-----------|-------------------|
| Nr | | helemaal niet | enigszins | vrij veel | kon niet erger |
| 1 | Duizeligheid of wee gevoel | | | | |
| 2 | Moeheid of gebrek aan energie | | | | |
| 3 | Nervositeit | | | | |
| 4 | Gevoel van druk of beklemming in hoofd of lichaam | | | | |
| 5 | Snel of hard kloppend hart zonder enige reden (bonzen of stompen) | | | | |
| 6 | Hoofdpijn | | | | |
| 7 | Rusteloos- of schrikachtigheid | | | | |
| 8 | Pijn op de borst of ademhalingsmoeilijkheden of het gevoel hebben niet genoeg lucht te hebben | | | | |
| 9 | Zich schuldig voelen | | | | |
| 10 | Zich geërgerd voelen | | | | |
| 11 | Spierpijnen | | | | |
| 12 | Boosheid | | | | |
| 13 | Moeilijkheden met helder denken | | | | |
| 14 | Zich gespannen of opgewonden voelen | | | | |
| 15 | Met gedachten afdwalen | | | | |
| 16 | Gedeelten van het lichaam voelen verdoofd of tintelen | | | | |
| 17 | Gedachten die niet weg te duwen zijn | | | | |
| 18 | Gedeelten van het lichaam voelen zwak aan | | | | |
| 19 | Zich niet kunnen concentreren | | | | |
| 20 | Gemakkelijk uw geduld verliezen | | | | |
| 21 | Gemakkelijk verstrooid | | | | |
| 22 | Zich vijandig voelen | | | | |
| 23 | Weinig aandacht hebben | | | | |

LET U ER A.U.B. OP DAT U ALLE VRAGEN HEEFT BEANTWOORD OP DEZE PAGINA

D.2

Appendix E Statistical analysis of the individual questions

The results of the individual questions in the well-being questionnaire of group A and group B are presented in Figure E.1 and Figure E.2, respectively.



Figure E.1: Mean scores of individual questions of well-being questionnaire of group A..The numbers of the questions are elucidated in Table 10.3 and appendix D.

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Figure E.2: Mean scores of individual questions of well-being questionnaire of group B.

Appendix F Tissue parameters

In Tables F.1 and F.2., the tissue parameters that are used for the model of the human head of Chapter 5 are tabulated. These parameters were obtained from the website from the Italian national research council [41]. The website provides a graphical interface for mathematical models of body tissue parameters obtained by Gabriel *et.al.*[42,43].

| Tissue | Relative permittivity e | Conductivity s [S/m] |
|-------------------------|-------------------------|----------------------|
| Air | 1 | 0 |
| Bone | 11.590 | 0.328 |
| Skin | 38.430 | 1.308 |
| Fat | 5.320 | 0.009 |
| Brain white matter | 36.600 | 1.047 |
| Brain grey matter | 49.510 | 1.574 |
| Brain liqueur | 66.760 | 3.154 |
| Maxillary sinus (blood) | 68.420 | 2.222 |
| Muscle | 53.160 | 1.514 |
| Eye humour | 68.420 | 2.222 |
| Eye lens | 52.210 | 2.050 |
| Concha (skin) | 38.430 | 1.308 |
| Fascia (skin) | 43.370 | 1.390 |

Table F.1: Tissue parameters for the 2100 MHz calculations of Chapter 5.

Table F.2:Tissue parameters for the 900 MHz and 1800 MHz calculations of
Chapter 5.

| Tissue | 900 MHz | | 1800 MHz | | |
|-------------------------|----------------|---------|----------------|---------|--|
| | e _r | s [S/m] | e _r | s [S/m] | |
| Air | 1 | 0 | 1 | 0 | |
| Bone | 12.454 | 0.143 | 11.781 | 0.275 | |
| Skin | 41.405 | 0.867 | 38.872 | 1.185 | |
| Fat | 5.462 | 0.051 | 5.349 | 0.078 | |
| Brain white matter | 38.886 | 0.591 | 37.011 | 0.915 | |
| Brain grey matter | 52.725 | 0.942 | 50.079 | 1.391 | |
| Brain liqueur | 66.638 | 2.413 | 67.200 | 2.924 | |
| Maxillary sinus (blood) | 68.902 | 1.636 | 68.573 | 2.033 | |
| Muscle | 55.032 | 0.943 | 53.549 | 1.341 | |
| Eye humour | 68.902 | 1.636 | 68.573 | 2.033 | |
| Eye lens | 55.235 | 1.394 | 52.768 | 1.858 | |
| Concha (skin) | 41.405 | 0.867 | 38.872 | 1.185 | |
| Fascia (skin) | 46.080 | 0.845 | 43.850 | 1.232 | |

FEL03-C148 Appendix F

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11. AUTHOR(S)

Prof.dr.ir. A.P.M. Zwamborn, dr.ir. S.H.J.A. Vossen, ir. B.J.A.M. van Leersum, ing. M.A. Ouwens en W.N. Mäkel (CRF-I)

12. PERFORMING ORGANISATION NAME(S) AND ADDRESS(ES)

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Effects of Global Communication system radio-frequency fields on Well Being and Cognitive Functions of human subjects with and without subjective complaints.

15. ABSTRACT (MAXIMUM 200 WORDS (1044 BYTE))

In this report a double blind randomized three-way crossover evaluation of general symptoms and cognitive functions with or without exposure to GSM and UMTS-like fields in subjects presenting with complaints subjectively attributed to GSM fields is presented. From our research it is concluded that our hypotheses to find no relation between presence of RF-fields and the measured parameters is rejected. We have found a statistically significant relation between UMTS-like fields with a field strength of 1 V/m and an effect on the Well Being. Further, from the cognitive tasks, it is observed that a number of significant effects is found. Each exposure frequency is associated with changes in some tasks or parameters, while other frequencies are not. In our study, it is shown that the thermal effects are negligible and therefore, an explanation based on thermal effects seems highly unlikely for effects on the cognitive parameters. Without any question, the results justify more scientific research into this area.

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