



# Human Studies

## 13 year overview & 2015 update

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**Strål  
säkerhets  
myndigheten**

Swedish Radiation Safety Authority

## Advantages and limitations:

Human experimental or provocation studies can investigate *acute effects* of an exposure up to given regulatory limits

- in homogeneous populations (*in- and exclusion criteria*)
- under controlled conditions (*e.g. time of day*)
- well defined exposure conditions and standardised settings

# Human studies: static magnetic fields (SMF)

All studies investigated exposure from MRI scanners

## Outcomes:

- Effects on subjective sensations occurred due to movements in the field
- Transient effects on postural control

## Note:

Exposure from MRI scanners is not restricted to magnetic fields

# Human studies: extremely low frequency (ELF) fields

## Outcomes

- Cardiovascular responses, postural control, heart rate and heart rate variability - no (consistent) effects
- Symptoms and cognition - no effects
- Electroencephalography (EEG) – inconsistent effects

# Human studies: radiofrequency (RF) fields

## Various outcomes

- Heart rate and heart rate variability: no effects
- Imaging an PET: inconsistent results
- Isolated report on effects and pain desensitization

# Human studies: radiofrequency (RF) fields

## Cognition

- Early reports: inconsistent results
- Some replication studies: negative
- Methodologically more rigorous studies: negative
- Growing evidence against acute RF-EMF effects on various aspects of perception, attention, memory and executive functions.

### Note:

Great diversity in tools used to measure cognitive functions.

# Human studies: radiofrequency (RF) fields

## Symptoms

*Comparative studies in subjects, who consider themselves as electromagnetically hypersensitive and controls*

- When the exposure condition (either sham or real fields) was neither known to the subject nor to the study staff, symptoms were not more prevalent during real exposure than during sham exposure
- Several studies have indicated a nocebo-effect, i.e. an adverse effect due to expectation that something is harmful

# Human studies: radiofrequency (RF) fields

## **Waking EEG** (includes resting state activity, slow potentials, evoked potentials, excitability)

- inconsistent results, e.g. resting state EEG-power
  - **No exposure effect**  
(Croft et al. 2010 (WCDMA), Trunk et al. 2013, Loughran et al. 2013)
  - **Increased alpha power under exposure**  
(Croft et al. 2002, Croft et al. 2010 (GSM), Roggeveen et al. 2015)
  - **Decreased alpha activity under exposure**  
(Perentos et al. 2013; Ghosn et al. 2015)
  - **Increased beta and gamma activity** (Roggeveen et al. 2015)

### **Note:**

Waking EEG studies are sensitive to numerous factors (e.g. level of vigilance, age, time of the day etc.), which need to be carefully controlled.

# Human studies: radiofrequency (RF) fields

Author(s)	Year	Effect(s)
Huber et al.	2002	yes
Huber et al.	2003	yes
Hinrichs et al.	2005	no
Loughran et al.	2005	yes
Regel et al.	2007	yes
Hung et al.	2007	yes
Fritzer et al.	2007	no
Lowden et al.	2011	yes
Loughran et al.	2012	yes
Schmid et al.	2012a	yes
Schmid et al.	2012b	yes
Lustenberger et al.	2013	yes
Nakatani-Enomoto et al.	2013	no
Lustenberger et al.	2015	no

## Sleep-EEG – effects on the sleep EEG-power

No exposure effect: 4  
Exposure effect: 10

### Note:

Sleep here is not a “symptom” or subjectively assessed, sleep here refers to a physiological measure.

## RF-EMF effects on the sleep-EEG seem to be the most consistent finding

However, there is increasing inconsistency in

- the affected **frequency range** (in early studies it was the spindle frequency range)
- occurrence during the **course of the night** (in early studies with exposure prior to sleep it has been at the beginning of the night)
- the **sleep stage** at which the effect is observed (NREM, stage S2 NREM sleep, meanwhile also REM sleep)

**The slight physiological effects observed in EEG studies do not translate systematically into variations in sleep stages and consequently into measures, which are associated with perceived sleep quality.**

**Effects observed in the resting state waking EEG do not translate into behavioural effects.**

# Possible reasons for inconsistencies

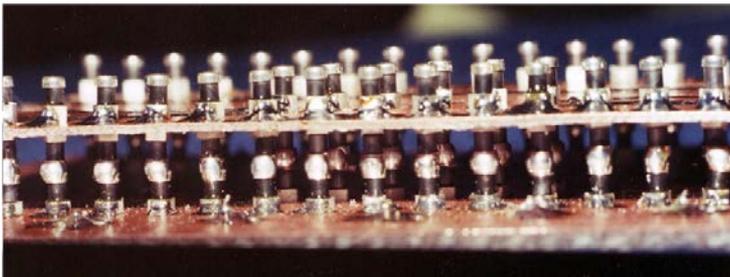
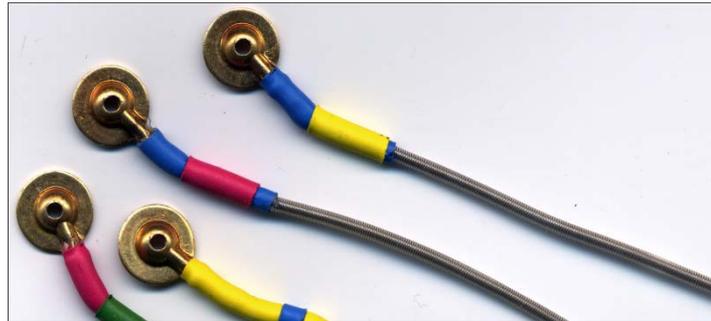
- **Study design:** double-blind vs single-blind; cross-over vs parallel group design
- **Sample:** sex, age, and size
- **Exposure:** point in time and duration, device, standard, signal, SAR values
- **Study nights per exposure condition:** one or more
- **Statistics:** with control for multiple testing, statistical procedure, approaches to ensure test assumptions when e.g. one-, two- or three-way ANOVAS as parametric tests are applied
- **EEG leads for powerspectral analysis:** just one or up to 128 channels
- **Stages for powerspectral analysis:** variable from first 30 min NREM – with and without S1 –, first 30 min S2, NREM whole night, S2, S3, S4, SWS REM whole night, or by sleep episodes/sleep cycles

# Open questions and outlook

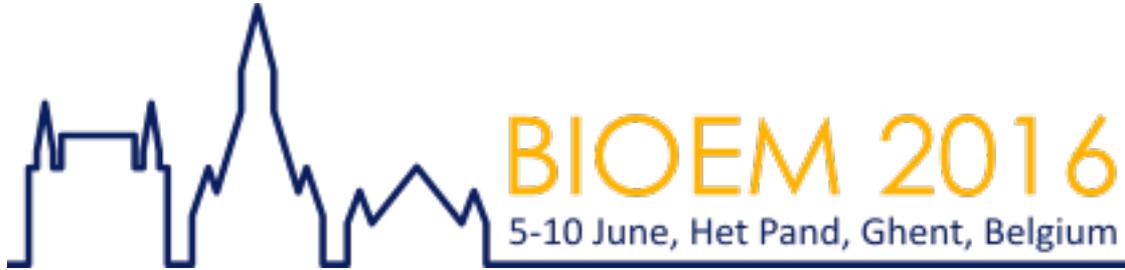
- Most studies are performed in samples of young healthy male volunteers or mixed gender and age samples
- The most affected endpoint: sleep (and wake) EEG is known to vary with age and sex
- We do not know whether effects are age and sex specific nor do we know whether effects on the sleep EEG are different in subjects with sleep disturbances
- With very few exceptions effects are analysed at the group level, we do not know whether there are individual differences, which are not seen at the group level

## Sleep and wake EEG

In all EEG studies interferences between the recording device and the electromagnetic fields have to be addressed and to be avoided by appropriate technical measures, e.g. by shielding and filters, as well as specifically designed cables, which do only minimally disturb the RF field.



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Thank you