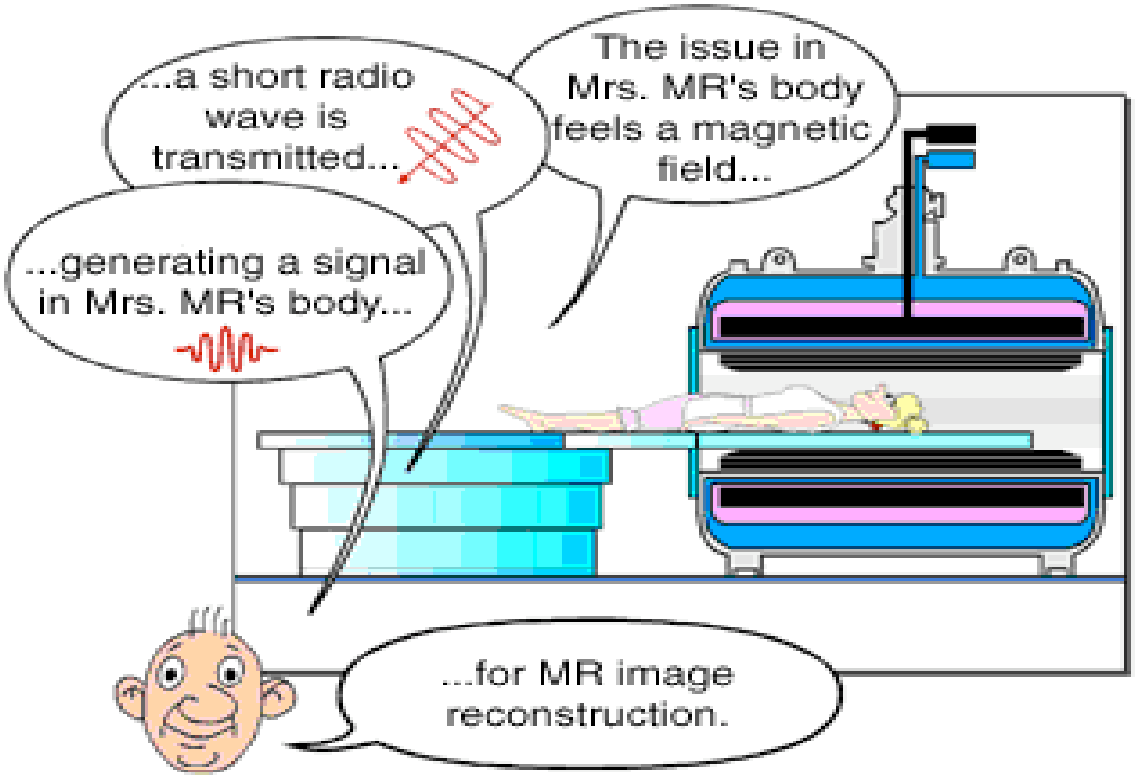
MRI Safety

EMF fields,
European guidelines etc ....

Basic principles of MRI in 30”



http://imaging.ugent.be/mr/r88_nl.html
http://www.cis.rit.edu/htbooks/nmr/

MRI Safety

- Exposure of patients, volunteers for experiments and workers to
  - static magnetic fields
  - time-varying magnetic fields
    - for workers, walking in the stray field
  - radiofrequency electromagnetic fields
  - acoustic noise
  - special environment (narrow tunnel)

MRI Safety

- Several guidelines for MRI use have been published in the past, but new reviews in recent years have prompted for a new document
  - Ordidge et al, JMRM, 2000; 12:1
  - Shellock, Shaeffer, In: *Magnetic Resonace Procedures: Health effects and safety.* New York: CRC Press 2001
  - Shellock et al: AJNR, 2003; 24:463 & Cardiovasc MR, 2003; 5:387
- Sources for information
  - Internet repository: www.mrisafety.com
  - ICNIRP: www.icnirp.de

Static Magnetic Fields

- Basic effects:
  - physical effect (translation and orientation)
    - depends on B_0 and inversely on radius of magnet: 1% of gravity @ 1.5T
  - electrodynamic forces on moving electrolytes
    - B_0 dependent Hall effect and decrease in blood flow
      - fibrillation threshold 10-20 x that for cardiac stimulation
    - @ 8T,
      - no effect on cognitive functions from PsyM testing
      - transient sensations when moved in field
      - significant slow and small rise in systolic BP
      - ECG uninterpretable, no cardiac stimulation
  - effects on electron spin states of chemical reaction intermediates

Static Magnetic Fields

- Literature does not indicate any serious adverse effects form whole body exposure of healthy subjects up to 8 Tesla
- But: to date, no epidemiological studies were performed to assess possible long term effects on health in workers, patients or normal subjects
- Importance to perform such studies, especially for workers and normal volunteers

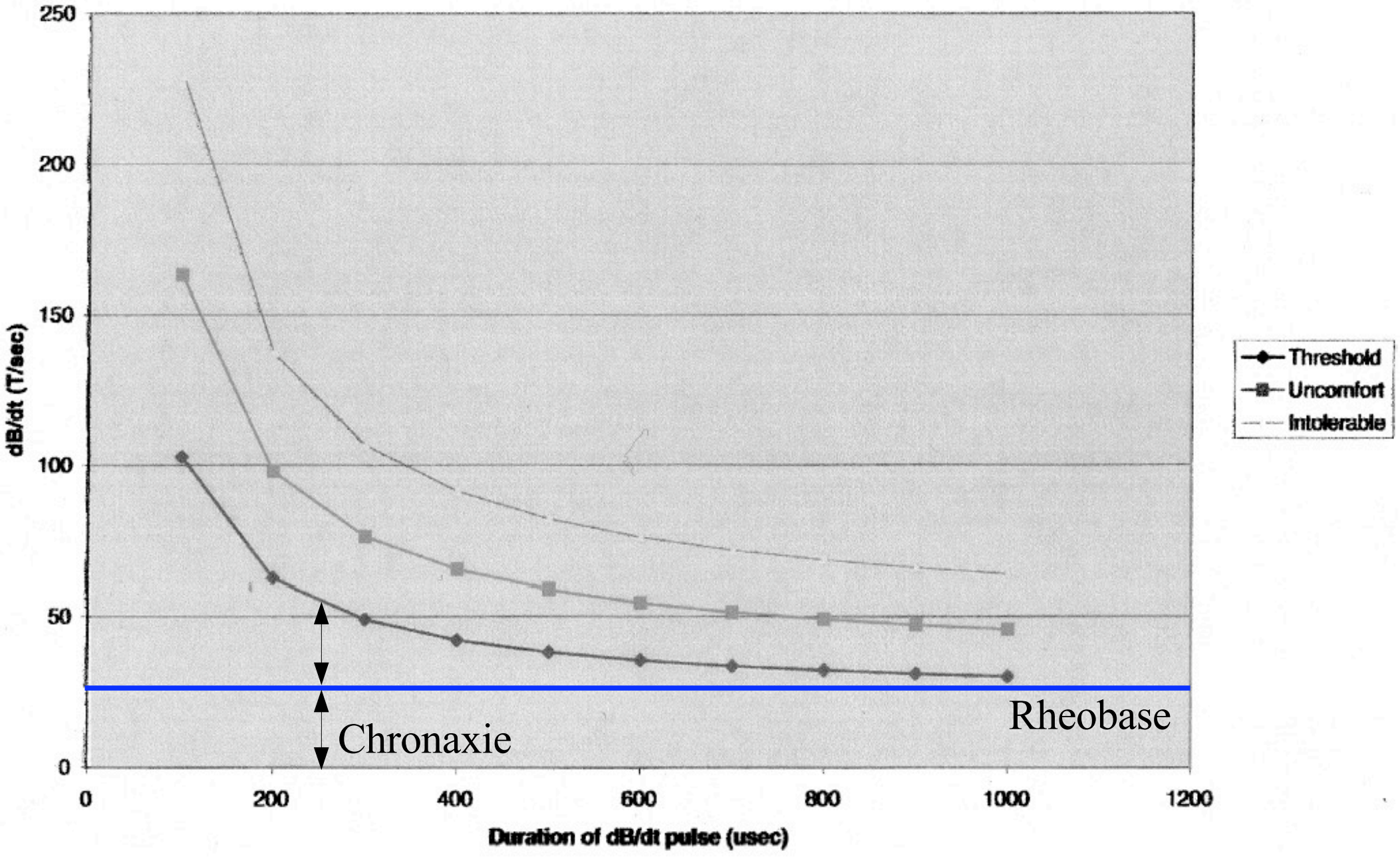
Time-varying magnetic fields: gradients

- Three orthogonal directions:
  - Z for longitudinal axis of patient, X transverse and Y antero-posterior
- Magnitude and duration (dB/dt)
- Faraday's law: induction of currents
- Safety standpoint: cardiac fibrillation
  - threshold for cardiac stimulation is lower than that for fibrillation
- Practical consideration: peripheral nerve stimulation, reached much earlier than cardiac stimulation

Gradients: peripheral nerve stimulation

- Thresholds
  - stimulation threshold for nerves: rheobase/chronaxie
    - rheobase = In the case of a nerve or single muscle cell, rheobase is the minimal electric current of infinite duration (practically, a few hundred milliseconds) that results in an action potential or the contraction of the muscle cell: 6-20 V/m for peripheral nerve, 30-40 V/m for cortex
    - chronaxie = In the mathematical description of the functioning of the nervous system, the chronaxie is the minimum time over which an electric current twice the strength of the rheobase needs to be applied, in order to stimulate a muscle fiber or nerve cell. The terms "chronaxie" and "rheobase" were coined in 1909 by the French physiologist **Louis Lapicque:** 200-350 microseconds for peripheral nerve, 350-450 microseconds for cortex
  - threshold for intolerable stimulation during exposure to ramped x- or y-gradient fields

Gradients: peripheral nerve stimulation



Gradients: cardiac stimulation data

- For long duration of induced current, threshold for cardiac stimulation = threshold for peripheral stimulation
- Present day sequences, always use very short pulsed gradients
  - cardiac threshold is much larger than for peripheral nerves (Bourland, 1999 and Reilly, 1990)
  - calculated dB/dt is 405 T/s at 0,53 ms pulse width for DTI sequence
    - = 10 x threshold for peripheral nerve stimulation
    - = 5 x threshold for intolerable peripheral nerve stim.
    - **effects are very seldom reported, never cardiac**
- → practical consideration: MRI is essentially safe, avoid uncomfortable or intolerable sensations

Gradients: brain stimulation data

- Brain can be stimulated: TMS
- Calculated rheobase threshold: 30-40 V/m for normal people
- Can be lower for:
  - patients with epilepsy
  - subjects with a family history of seizures
  - users of anti-depressants, neuroleptics, ...
- Cave: serious heart disease and increased intracranial pressure
- Cave: long duration experiments, long pulses
- Volunteer studies: no effects

Radiofrequency fields

- RF > 10 Mhz will deposit heat, distributed by convective heat transfer through blood flow
- Temperature is difficult to measure
- SAR = average energy dissipated in the body per unit mass and time: ESTIMATED
- whole-body SAR and partial body SAR for head, trunk and extremities
- Restrict rise in body T below occurrence of local thermal injury or systemic thermal overload (hot spots)
- Cave: hypothalamus, eyes, embryo and fetus

RF: physiological response in healthy adults

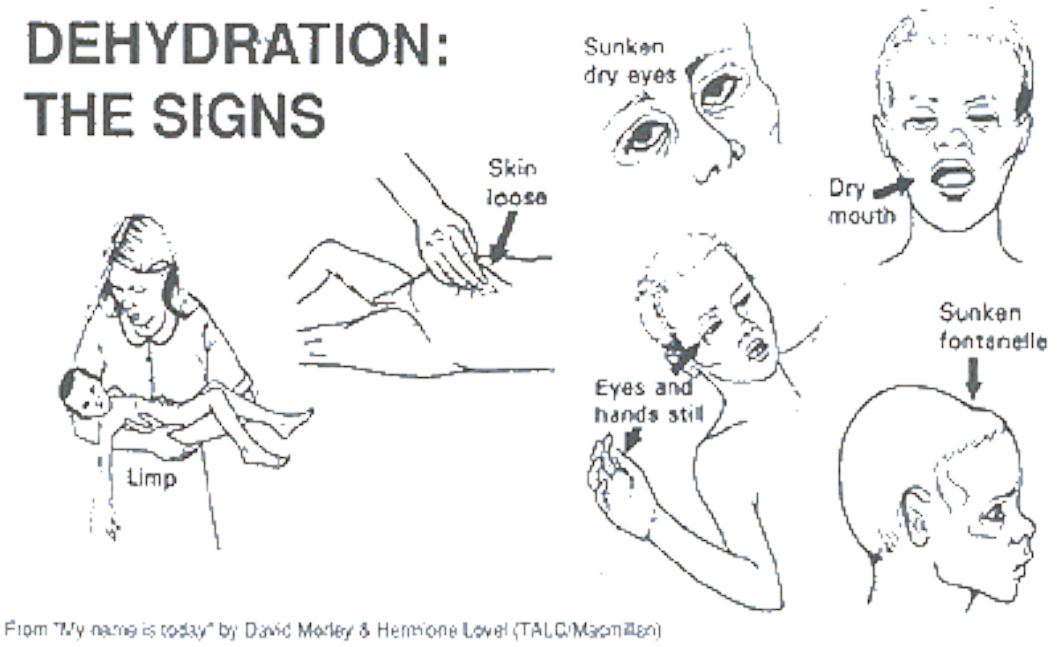
- Body core T = 37 °C (±0.5*C)
- Heat gained has to be compensated by heat loss and is often accompanied by a small increase in heat storage
  - sweat glands (total body) and cutaneous blood flow (from 0.2-0.5 ml/min to 7-8 L/min)
- Rule: prolonged heat storage restricted to body T to 38 °C
- MRI experiments with high SAR (6W/kg for 15 min):
  - produced profuse sweating and increased cutaneous blood flow, minimal changes in core T
  - Increased cardiac output: cave compromised patients

RF: complications in disease and medications

- Cardiovascular disease and/or compromized circulation
  - peripheral vascular disease due to arteriosclerosis or heart failure
  - highly prevalent in elderly
  - role of dehydratation: responsible for most of the heat-related mortality from mid-life to old age
  - decline in sweating and blood flow response in elderly
- Medication
  - barbiturates or phenothiazines depress reflex T regulation
  - anticholinergic drugs suppress sweating and vasodilatation
- DM (general autonomic hypofunction)
- Fever (problem when heat is deposited deep in body)
- **Insufficient data for effects MRI**

RF and children

- Childhood exposure
  - higher surface-area-to-mass index, rely more on increased skin blood flow
  - dehydratation can cause problems



RF: localized heating

- Local rise in T is function of local SAR and organ vascularity and blood flow
- elderly:
  - compromized blood flow (increased peripheral resistance, cardiac failure, peripheral vascular disease, medication)
- Studies of acute hyperthermia: dose-response relationship
  - lesions occur when T > 42°C for > 1h, T = 45°C for 10-30 min
  - CNS, BBB and testes most sensitive: damage from 40-41°C for 1h

RF: localized heating

- Margin of safety: keep T < 38°C in the head, 39°C in the trunk and 40°C in the extremities.
- Calculation in the head: SAR of 3 W/kg increases T of the eye < 1.6°C, brain < 1°C
- Finite element calculation: max SAR of 100 gr tissue can be 10 times as high as whole body average @ 1.5T
- Modeling: local SAR depends on tissue: in extremities, more SAR in muscle than in fat
- bio-heat transfer model: maximum SAR at center of large homogeneous tissue regions

RF summary

- whole body exposures, no adverse effects if rise in core body T < 1°C
- infants and persons with cardiocirculatory impairment: rise of core body T < 0.5°C
- Avoid local T rises above
  - 38°C in the head
  - 39°C in the trunk
  - 40°C in the extremities

MR in pregnant patients

- safety of mother and unborn child
- susceptible processes:
  - highly ordered sequences of cell proliferation and differentiation
  - cellular migration
  - programmed cell death: apoptosis
- susceptible period:
  - organogenesis: first trimester of pregnancy
  - later, growth of organs = less susceptible period

MR in pregnant patients

- Static magnetic fields:
  - few studies, no consistent effects
    - in mice, various periods of exposure to fields from 1 - 9.4 T had no effects on implantation, pre- or post-natal development (Sikov 1979, Konermann 1986, Murakami 1992, Okazaki 2001)
    - one study (Mevissen, 1994) reported a slightly decreased number of fetuses for continuous exposure to a 30 mT field

MR in pregnant patients

- Low frequency magnetic fields: gradients
  - mostly at levels encountered occupationally and in the environment
  - several well designed studies noted an increase incidence in minor skeletal variants for in utero exposure (50Hz and 30 mT; 10-20 kHz and 15μT)
  - three generations of rats in 60Hz @ 1 mT had no effect on fertility and reproductive performance (Ryan 1999)

MR in pregnant patients

- RF-induced hyperthermia
  - fetal T is clamped to the T of the mother but usually 0.5°C higher due to counter-current heat exchange in the vessels of the umbilical chord
  - can be affected by heat stress
  - neural tube and facial defects were seen in children whose mothers experienced prolonged and repeated hyperthermia (> 39°C)
  - experimental: T rise > 1.5-2°C for > 1h (Graham 1998, Edwards 2003)
  - effects not fully characterized

MR in pregnant patients

- MRI exposure – animal and human studies
  - general lack of consensus considering possible MRI effects on reproduction and development
  - reported effects: diminished crown-rump length, altered craniofacial perimeter, post-natal survival, fetal weight in mice, but no standardization, what about acoustic noise, several unspecified parameters (SAR, litter size, ...)
  - human studies (Coletti 2001): 3 y follow-up after EPI for pregnancies deemed abnormal from ultrasound
    - no unexpected abnormalities that could be attributed to MRI exposure in one study, the other study reported decreased birth weight for the MRI exposed group

Delayed effects / Acoustic noise

- Delayed effects: no information
- Acoustic noise:
  - noise results from Lorentz forces in gradient coils
  - level can be as high as 140 dB
  - >100 dB(A) may result in disturbance in microcirculation in the cortical organ, short term pulse of 120-130 dB(A)produce mechanical damage
  - sufficient levels produce permanent hearing loss
  - 85 dB(A) is threshold for permanent hearing loss following long term exposure
  - 67 dB(A) is hazardous threshold for dangerously ill patients (Jansen 1991)
  - Scala of problems with noise: annoyance, difficulties for verbal communication, anxiety, temporary hearing loss, potential permanent hearing problem

Occupational exposure

- Routine MR procedures
  - positioning patients, short time near B_0 exposure, but walk through B_0 stray field
  - continuous low field exposure (0.1 – 0.5 mT)
  - RF exposure 10000 times less than patient in scanner room, outside virtually nil
  - more and more high field systems, review of safety guidelines necessary (ICNIRP)
- Open MR devices
  - up till 3T, but only limited number of centers
  - surgeons and other non-MR workers

Occupational exposure

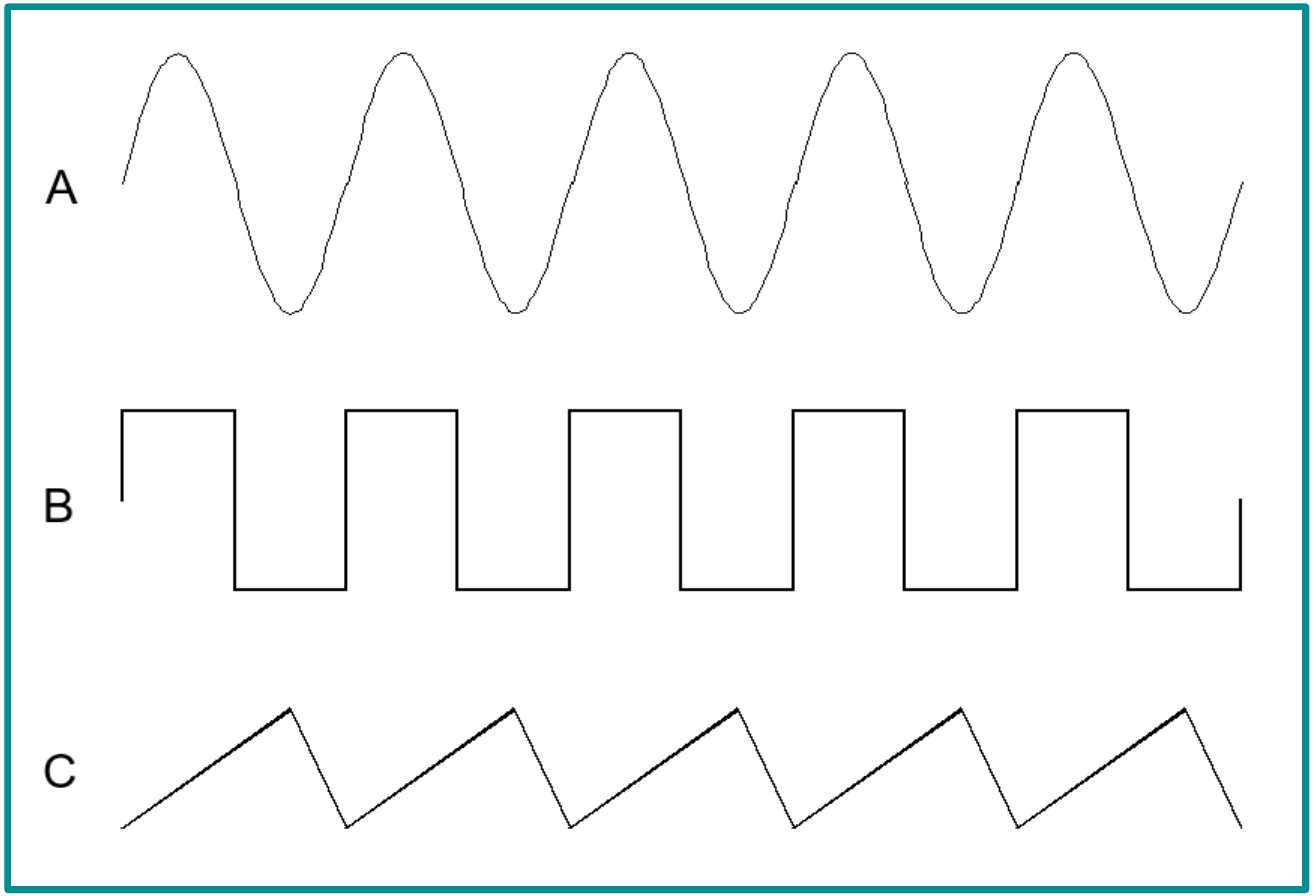
- European Guidelines to be implemented 2008 – extracted from ICNIRP guidelines
  - occupational limits for time varying EMF also apply to MR environment
  - no limits for static field B_0 (in preparation)
  - RF: no problem
  - dB/dt: serious problem, movement of MR-techs in stray field of magnet while positioning patient and other procedures
  - www.icnirp.de

Occupational exposure - ICNIRP

- Occupational hazards
  - low frequency EM fields: induction of electrical fields
  - high frequency EM fields: heating of tissue
- ICNIRP reference for limits dates from inventarisations by Bernhardt (1988) on stimulation of nerves and the prevalence of phosphenes

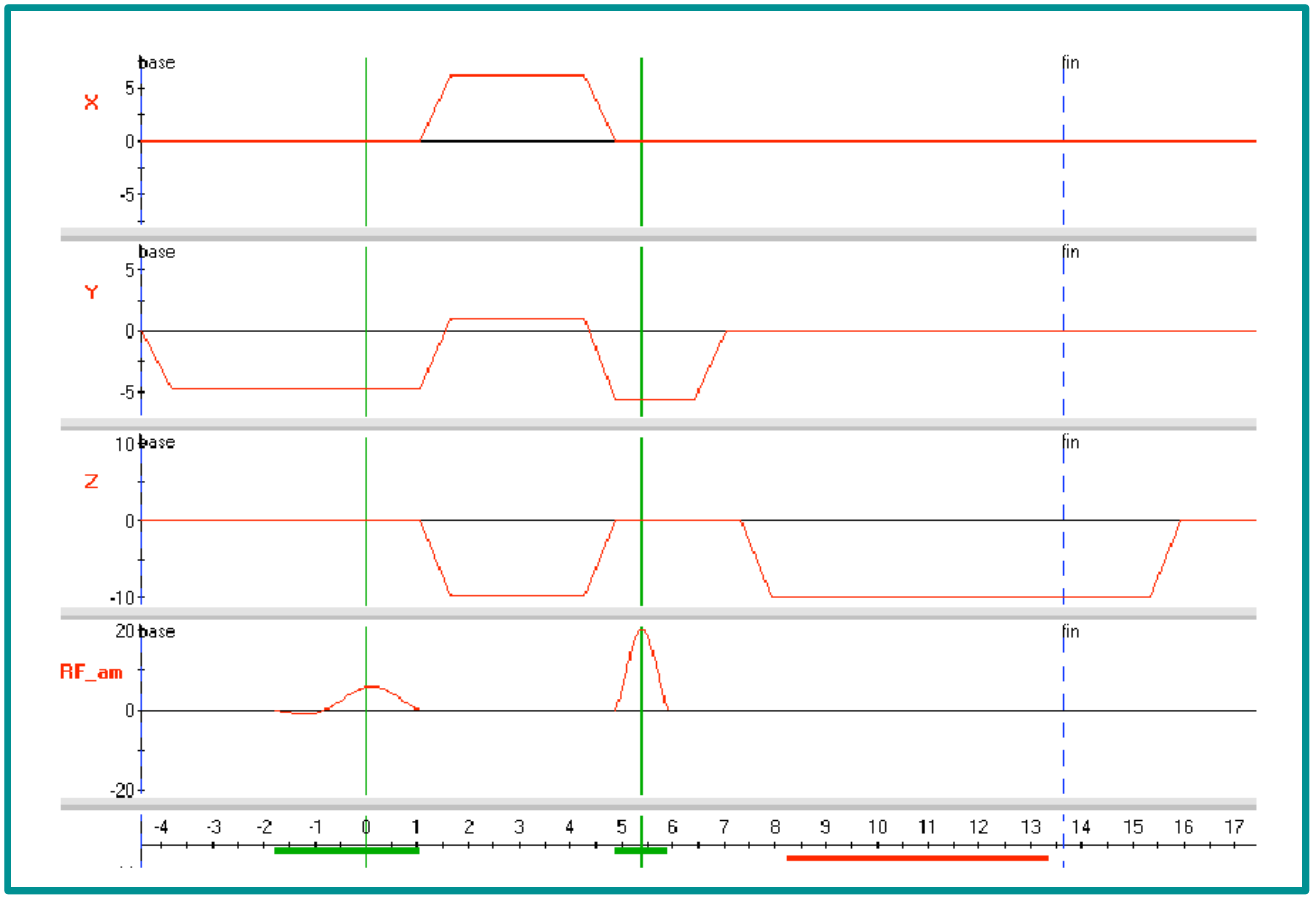
Occupational exposure - ICNIRP

- Description is for continuous waves

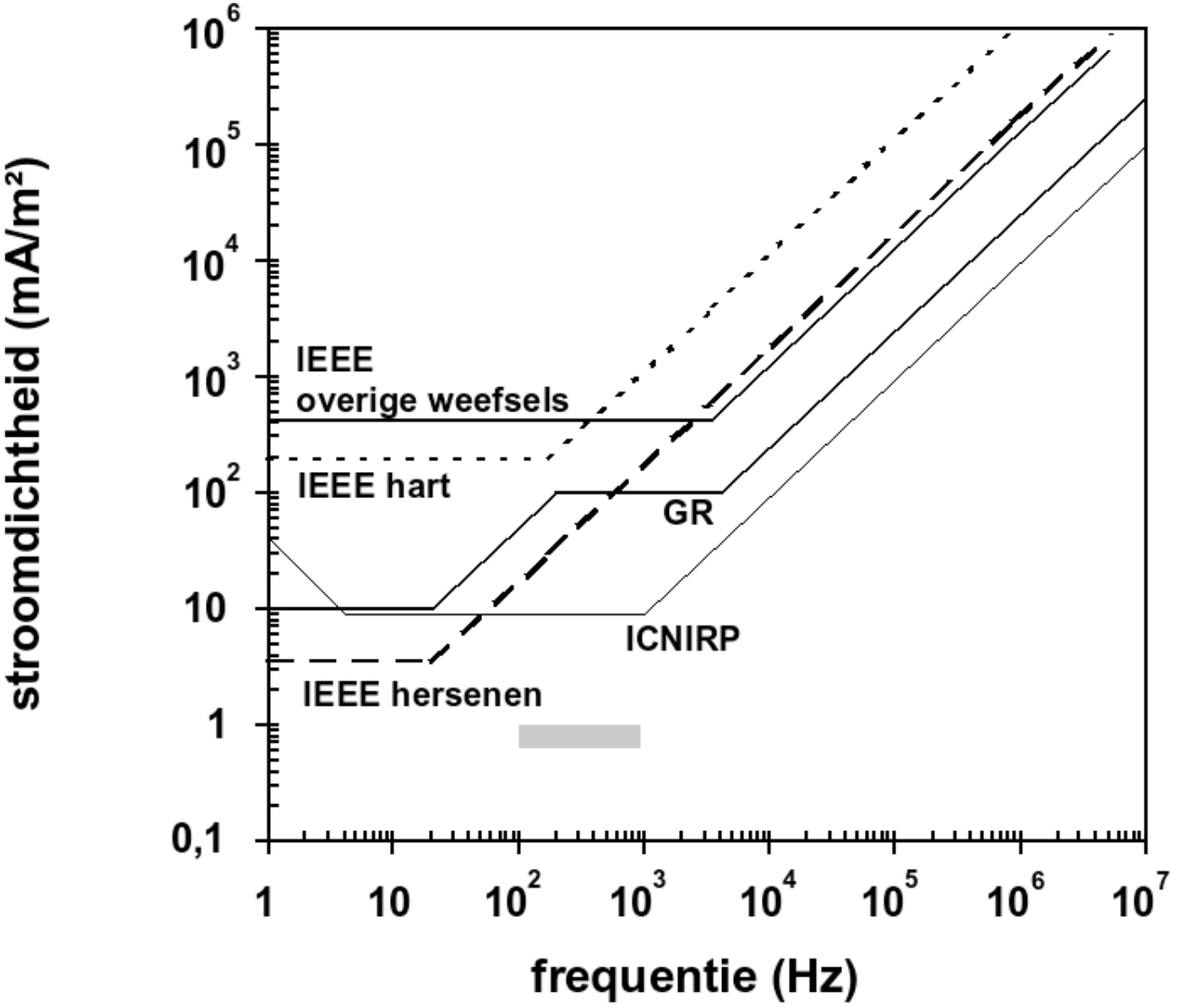


Occupational exposure - ICNIRP

- MR gradients are pulsed waves
- Equivalent frequency: $f = 1/(2t_p)$



Occupational exposure limits EMF
ICNIRP / GR NI / IEEE



Occupational exposure MRI
ICNIRP limits

- From empirical data, relation between perception of the field and the speed of change of the amplitude of the magnetic field

$$\frac{dB}{dt} = 20\left(1 + 0.36/\tau\right) Ts^{-1}$$

median perception threshold with τ the median stimulus duration in ms, the duration of the period of monotonic increase or decrease of the gradient

- ICNIRP proposes this relation for defining maximum admissible exposure for patients
- In approximation, the lower limit for the occurrence of effects

$$\frac{dB}{dt} = 10\left(1 + 0.36/\tau\right) Ts^{-1}$$

Occupational exposure MRI

- During scan procedures which require personnel to be near the magnet while scanning is performed, dB/dt limits may be exceeded
- Walking through the stray field of a highly shielded high field (1.5T or above) scanner with reasonable speed will exceed the limits
- No problem with high frequency fields unless in the center of the scanner (pediatric patients, interventional procedures)

Problematic procedures in The Netherlands

Tabel 1. Medische handelingen met MRI waarbij de blootstellingslimieten uit de Europese richtlijn mogelijk worden overschreden. (Bron: prof dr GP Krestin, hoofd afd. Radiologie. Erasmus MC, Rotterdam)

Handeling	Aantal in Nederland in 2005		Opmerkingen
	Academische ziekenhuizen	Perifere ziekenhuizen*	
Totaal aantal MRI-verrichtingen	71272	293022	Totaal in Nederland: 364294
Verrichtingen met mogelijk overschrijding van grenswaarden			
MRI met toediening van contrastmiddel	49099 (13,5%)	53131 (14,6%)	In academische centra zijn meestal contrastmiddelinjectoren aanwezig
MRI bij kinderen	10500 (2,9%)	662 (0,18%)	
MRI onder narcose	2853 (0,8%)	1314 (0,36%)	
MRI-gestuurde biopten	47 (0,01%)	1 (<0,001%)	Aantal is sterk stijgend
Intraoperatieve MRI	26 (0,007%)	0	Alleen in AZ Maastricht

* Gegevens van 66 van 77 perifere ziekenhuizen.

Occupational exposure

- Pregnant operators
  - Kanal et al, 1993: survey with 2000 responses from MR workers and various control groups (low response rate)
  - no large statistical difference in pregnancy outcome (premature delivery, low birth weight, spontaneous abortion) in 280 MR workers compared to other workers.
  - conclusion: data did not suggest substantial increase in common adverse reproductive outcomes in women working in MR environment
  - we need larger and more detailed studies to confirm this

MRI Safety: recommendations

- General
  - many gaps in knowledge of biological effects and interaction mechanisms of MRI-related electromagnetic fields
    1. need for MRI and safety of patient is responsibility of medical practitioner
    2. MRI as part of research project: local ethics, informed consent
    3. MR equipment users must be adequately trained (contra-indications, record keeping, safety, precautions, etc..)
    4. MR manufacturers must supply complete documentation about patient and staff exposure levels for their equipment, and safety should be an important aspect in design

MRI Safety: recommendations

- Exposure levels to patients
  - clinical experience indicates that adequate diagnostic information can be obtained in exam times between 5 minutes and 1 hour
  - because of uncertainties over deleterious effects, exposure limits are divided in three tiers:
    1. routine MR for all patients (**normal operating mode**)
    2. special MR exams where discomfort and/or adverse effects for some patients may occur: a clinical decision must be taken to balance against foreseen benefits, medical supervision necessary (**controlled operating mode**)
    3. experimental procedures: special ethics approval is required in view of potential risks (**experimental operating mode**)

MRI Safety: recommendations

- Static magnetic field
  - No European guidelines, ICNIRP prepares!
  - FDA – significant risk should be considered above these limits

Main Static Magnetic Field

Population	Main static magnetic field greater than (tesla)
adults, children, and infants aged > 1 month	8
neonates i.e., infants aged 1 month or less	4

MRI Safety: recommendations

- Gradients (time-varying magnetic fields)
  - threshold for cardiac stimulation is well above the level for intolerable stimulation (except for very long pulses)
  - ICNIRP: maximum exposure = a dB/dt of 80% of the median perception threshold for normal operation, 100% for controlled operation

$$\frac{dB}{dt} = 20\left(1 + 0.36/\tau\right) Ts^{-1}$$

median perception threshold with τ the median stimulus duration in ms, the duration of the period of monotonic increase or decrease of the gradient

  - FDA – significant risk should be considered above these limits

Gradient Fields Rate of Change

Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation

MRI Safety: recommendations

- RF fields
  - whole-body exposure should not rise the body T > 1°C
  - infants, pregnant women, persons with cardiocirculatory impairment: < 0.5°
  - consider partial-body exposure (no models exists for pregnant women)
    1. partial-body SAR's scale dynamically with the ratio *r* between the exposed/total body mass: $r \rightarrow 1$, whole-body SAR, $r \rightarrow 0$, localized SAR of 10W/kg (head and trunk)
    2. SAR restrictions do not relate to an individual MR sequence, but rather to running SAR averages computed over 6 minute periods (thermal equilibrium time of small masses of tissue)
    3. whole-body SARs are valid for ambient T below 24°C, for higher Ts, they should be reduced

MRI Safety: recommendations: RF

		Spatially localized temperature limits		
	Rise of body core temperature	Head	Trunk	Extremities
Operating Mode	(°C)	(°C)	(°C)	(°C)
Normal	0,5	38	39	40
Controlled	1	38	39	40
Experimental	>1	>38	>39	>40

MRI Safety: recommendations: RF

- FDA – significant risk should be considered above these limits

Specific Absorption Rate (SAR)

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	4
head	averaged over	10	3
head or torso	per gram of tissue	5	8
extremities	per gram of tissue	5	12

MRI Safety: recommendations: RF

	Average time: 6 min					
	Whole Body SAR (W/kg)	Partial-body SAR (W/kg)		Local SAR (averaged over 10g tissue) (W/kg)		
Body region →	Whole	Any,	head	Head	Trunk	Extremity
Operating mode ↓	Body	except head				
Normal	2	2-10	3	10	10	20
Controlled	4	4-10	3	10	10	20
Restricted	>4	>(4-10)	>3	10	>10	>20
Short term SAR	The SAR limit over any 10s period should not exceed 3 times the corresponding average SAR limit					

Partial body SARs scale dynamically with the ratio *r* between the patients mass exposed and the total patient mass:
- normal operating mode: SAR = (10 - 8 ·*r*) W/kg
- controlled operating mode: SAR = (10 - 6 ·*r*) W/kg

The exposed patient mass and the actual SAR levels are calculated by the SAR monitor implemented in the MR system for each sequence and compared to the SAR limits

In case where the eye is in the field of a small local coil used for RF transmission, care should be taken to ensure that the temperature rise is limited to 1 °C

MRI Safety: recommendations

- Acoustic noise - FDA

Sound Pressure Level

Peak unweighted sound pressure level greater than 140 dB.

A-weighted root mean square (rms) sound pressure level greater than 99 dBA with hearing protection in place.

  - recommendations: always hearing protection if noise level > 80 dB(A), best headphones allowing verbal communication
  - Best: combine earplugs with headphones!
  - earplugs may hamper verbal communication
  - also protect workers and guardians
  - “quiet” systems should be developed

MRI Safety: recommendations

- Pregnant patients
  - insufficient knowledge to establish unequivocal guidelines
  - MR only after a critical risk/benefit analysis, in particular in the first trimester
  - Informed consent always, also as compared to other diagnostic procedures
  - reduce exposure to strict minimum
  - no Gd (post-implantation fetal loss, retarded development, increased locomotive activity, skeletal and visceral abnormalities in experimental animals)
  - studies have not revealed effects in humans, but too small number of patients
  - "*MR imaging may be used in pregnant women if other non-ionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would otherwise require exposure to ionizing radiation*"

MRI Safety: recommendations

- Normal volunteers
  - MR in framework of research project, guided by rules of human ethics
  - Declaration of Helsinki, leading principles:
    1. expected scientific results justify the performance of studies on volunteers
    2. the schedule of the study contains the aim of the research, the methods of examination including technical details
    3. criteria of inclusion and exclusion of volunteers are justified
  - review by local ethics comity
  - written informed consent
  - special care for experimental procedures outside the controlled operating mode, and special ethics comity approval is necessary in view of the potential hazards
  - **special insurance: no-fault**

MRI Safety: recommendations

- Special requirements for the experimental operating mode
  - specific security measures are provided to prevent unauthorized operation in the experimental operating mode
  - the specific security measures involve a key-lock, a software password or other protective devices
  - the experimental operating mode is guaranteed to avoid possible detriments caused by the well known interaction mechanisms. In addition, a permanent supervision of the state of health of the volunteer in general must be put in safe keeping
  - a permanent optical and acoustical contact is provided between the investigator and the volunteer
  - specific emergency medical procedures are defined in order to provide medical treatment if necessary

MRI Safety: contra-indications and further considerations

- Contra-indications: www.MRIsafety.com
- Considerations related to patient's condition
- Projectile/missile effect
- Record keeping and patient follow-up
- Electromagnetic interference
- Research needs

MRI Safety Video Presentation