STIMOLAZIONE MAGNETICA TRANSCRANICA: IMPLICAZIONI PER LA SICUREZZA DEI PAZIENTI E DEGLI OPERATORI ADDETTI

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Abstract

La Stimolazione Magnetica Transcranica (TMS) fu utilizzata per la prima volta nel 1985 e da allora è sempre più impiegata nella ricerca di base e clinica nonché per la terapia. Questa tecnica è ampiamente diffusa in tutto il mondo e la procedura di utilizzo è considerata sicura quando vengono scrupolosamente seguite le linee guida. Ciò nonostante, potrebbe produre effetti indesiderati quali male di testa, dolori al collo, convulsioni, dolori muscolari dovuti alla contrazione, perdita dell'udito, lacrimazione.

Fino ad oggi pochi studi hanno trattato gli aspetti di sicurezza correlati all'esposizione a campo magnetico. Obbiettivi di questo lavoro sono stati (i) riassumere e discutere gli effetti della radiazione indotta dal campo magnetico, (ii) studiare la forma dell'impulso magnetico e validare l'impiego di un semplice strumento a effetto Hall per la misura del campo magnetico stesso, (iii) misurare il campo magnetico prodotto da diversi tipi di stimolazione (stimolazione monofasica, bifasica, a onda smorzata).

In particolare sono state esaminate le misure di campo magnetico con diverse tipologie di stimolatori e forme d'onda in relazione ai limiti di sicurezza stabiliti dalle linee guida della Comunità Europea.

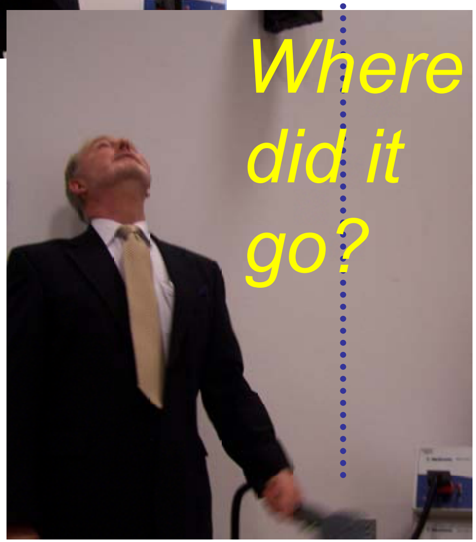
Abstract

Transcranial magnetic stimulation (TMS) was first demonstrated in 1985, and since then has been used widely for basic research, clinical investigations and therapy. Several thousands of stimulators are used world wide, and when the accepted guidelines are followed in general the procedure is considered safe. However, there may be undesired effects such as headache, neck pain, seizures, muscle pain due to contraction, hearing loss, crying. Until date few studies have dealt with safety aspects due to the exposure of the magnetic field. The aim of this work was (i) to review and discuss the effect of the radiation induced by the magnetic field, (ii) to study the magnetic pulse shape and to validate the use of a simple Hall effect instrument in order to measure the magnetic field, and (iii) to measure the magnetic field for different kind of stimulus pulses (monophasic, biphasic or damped oscillatory pulse form). We will review the European Community guidelines and the safety limits, and compare these to measurements of the magnetic field from different kind of stimulators and waveforms.

EFFETTO MECCANICI NELLA STIMOLAZIONE MAGNETICA

A

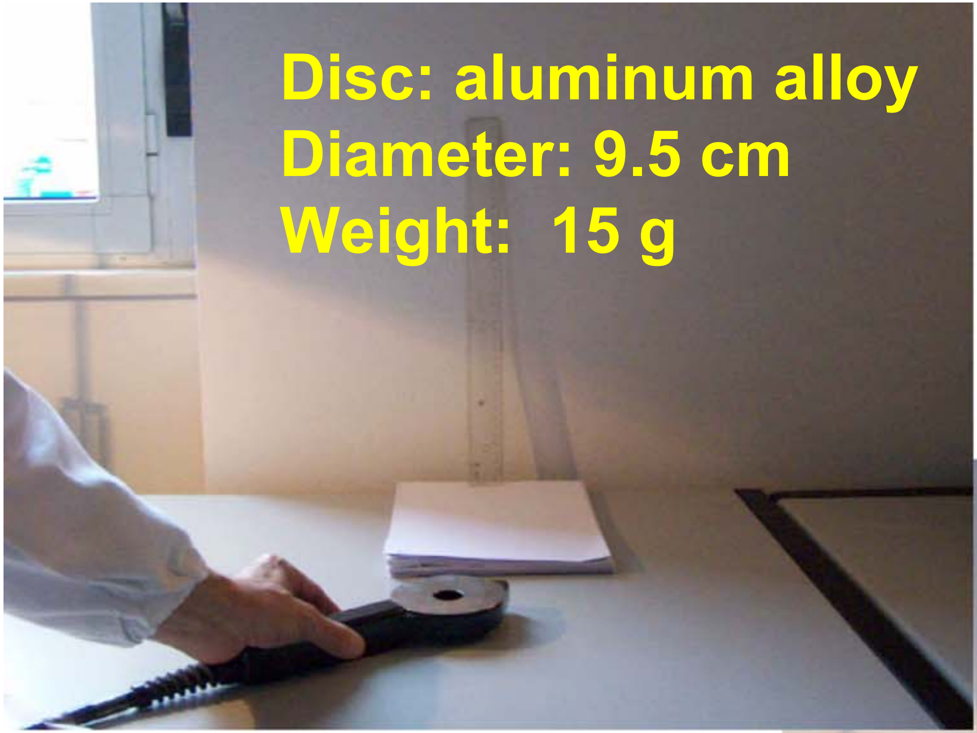
B



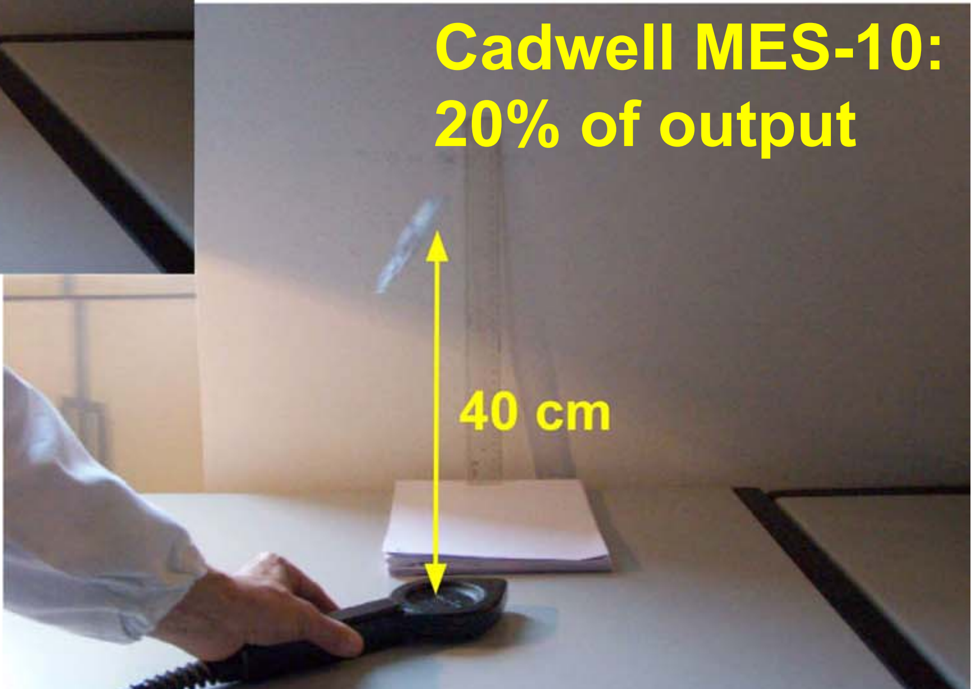
Demonstration of the force that is generated when the current from the charged capacito is discharged in the coil of the magnetic stimulator.

During a workshop in Pavia in November 2005 Professor Anthony Barker is holding the coi of the magnetic stimulator in his left hand (A), and in the right hand he is holding a metal disc from a computer hard disc. The metal disc was placed on top of the coil of the magnetic stimulator. The coil was placed horizontally, and at the moment of the stimulus there was a tremendous noise burst and the disc flew until the roof (about meters), and in (B) Anthony Barker is watching out for the flying disc.

IN CASO DI OTTIMALE ACCOPPIAMENTO → FORZE DOVUTE AL CAMPO AUTOINDOTTO (in grado di proiettare corpi contundenti)

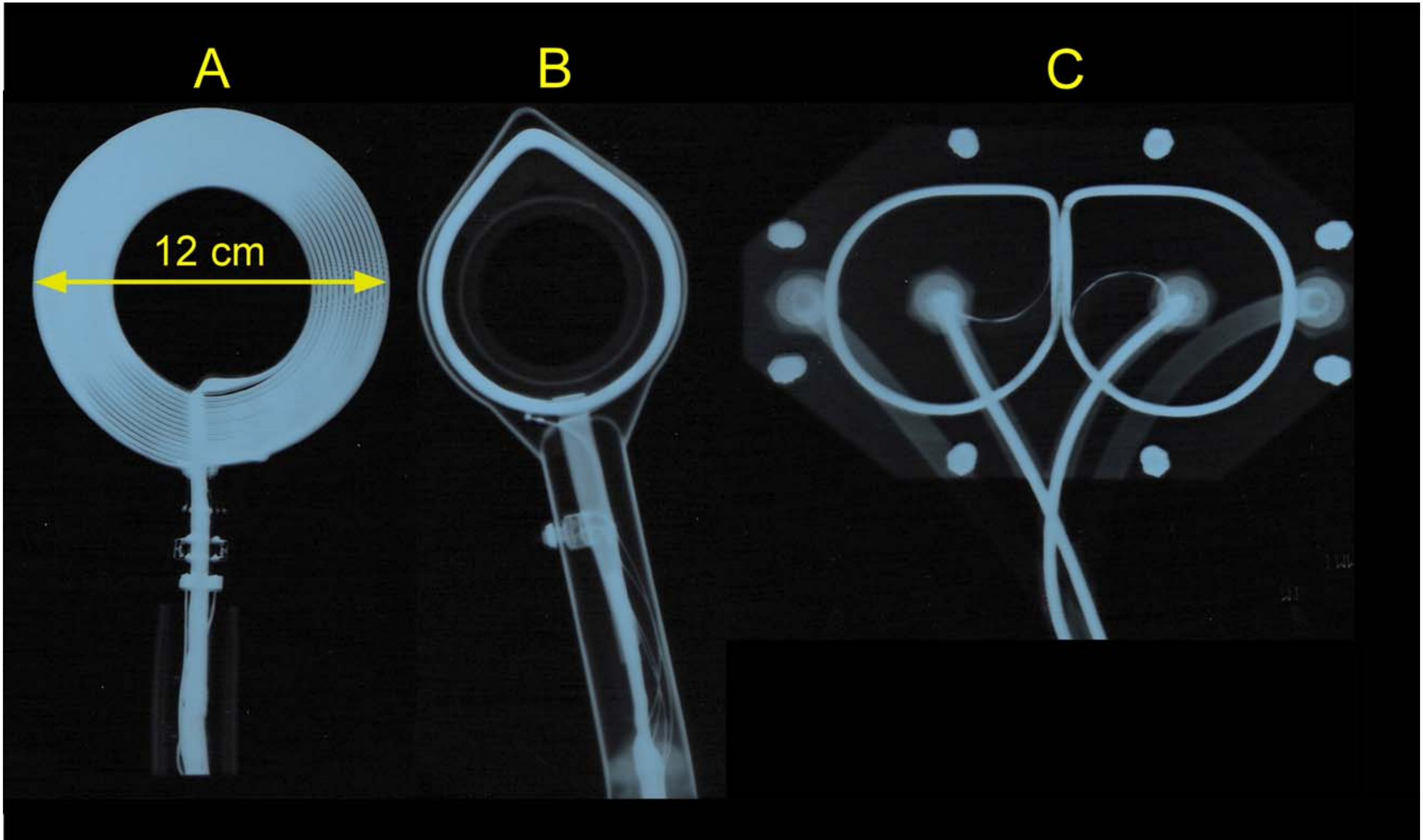


Best coupling:
Force generated by self induced fiel
In poor coupling situations:
A force is applied directly by the magnetic field on ferromagnetic objects.

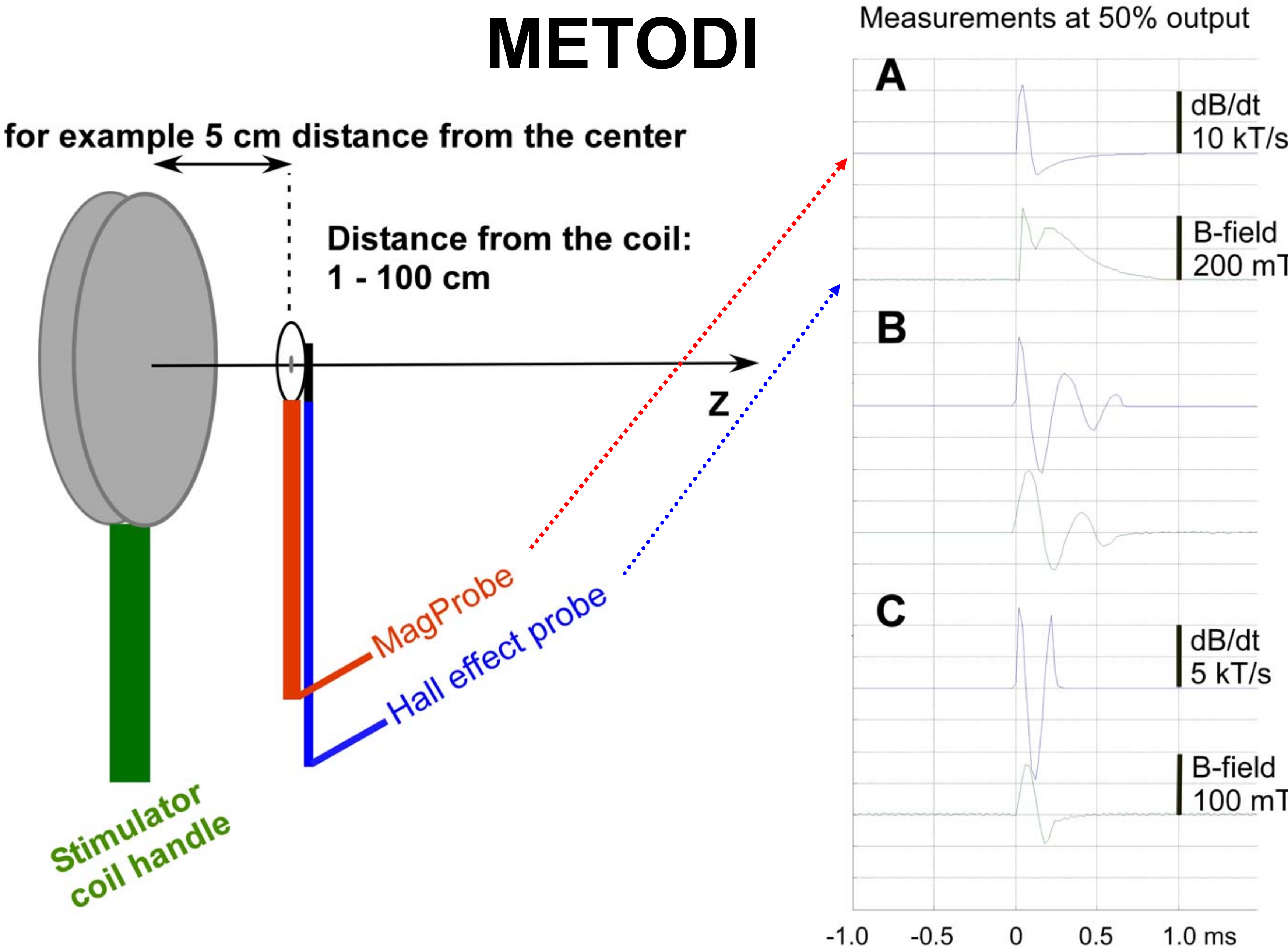


n brain stimulation for a brief moment the energy is about 500 J, which should be enough to ift 1 Kg to a height of about 50 meters (Ruohonen, 1998).

STIMOLATORI: A – MAGSTIM 200
B – CADWELL MES-10
C – CADWELL rTMS



METODI



Measurements at 50% output
for example 5 cm distance from the center
Distance from the coil:
1 - 100 cm
Z
MagProbe
Hall effect probe
Stimulator
coil handle
A
dB/dt
10 kT/s
B-field
200 mT
B
C
dB/dt
5 kT/s
B-field
100 mT
-1.0
-0.5
0
0.5
1.0 ms

METODI

The induced electric field in the tissue is proportional to the rate of change of the magnetic field dB/dt

Measured with a MagProbe (Alpine Biomed):

One circular winding of a 2.8 mm^2 insulated wire

Outer/inner diameter: 2.5 / 2.0 cm

Calibration: 1 mV = 1 kT/s

Recording: Dantec Counterpoint Mk2

Frequency range: 0.2 Hz – 20 kHz

A/D conversion: 50 kHz

Measurement of first phase of impulse:

Hitachi Digital Oscilloscope (500 kHz)

METODI

The magnitude and time course of the induced magnetic field (B-field) was measured via a:

HALL EFFECT probe

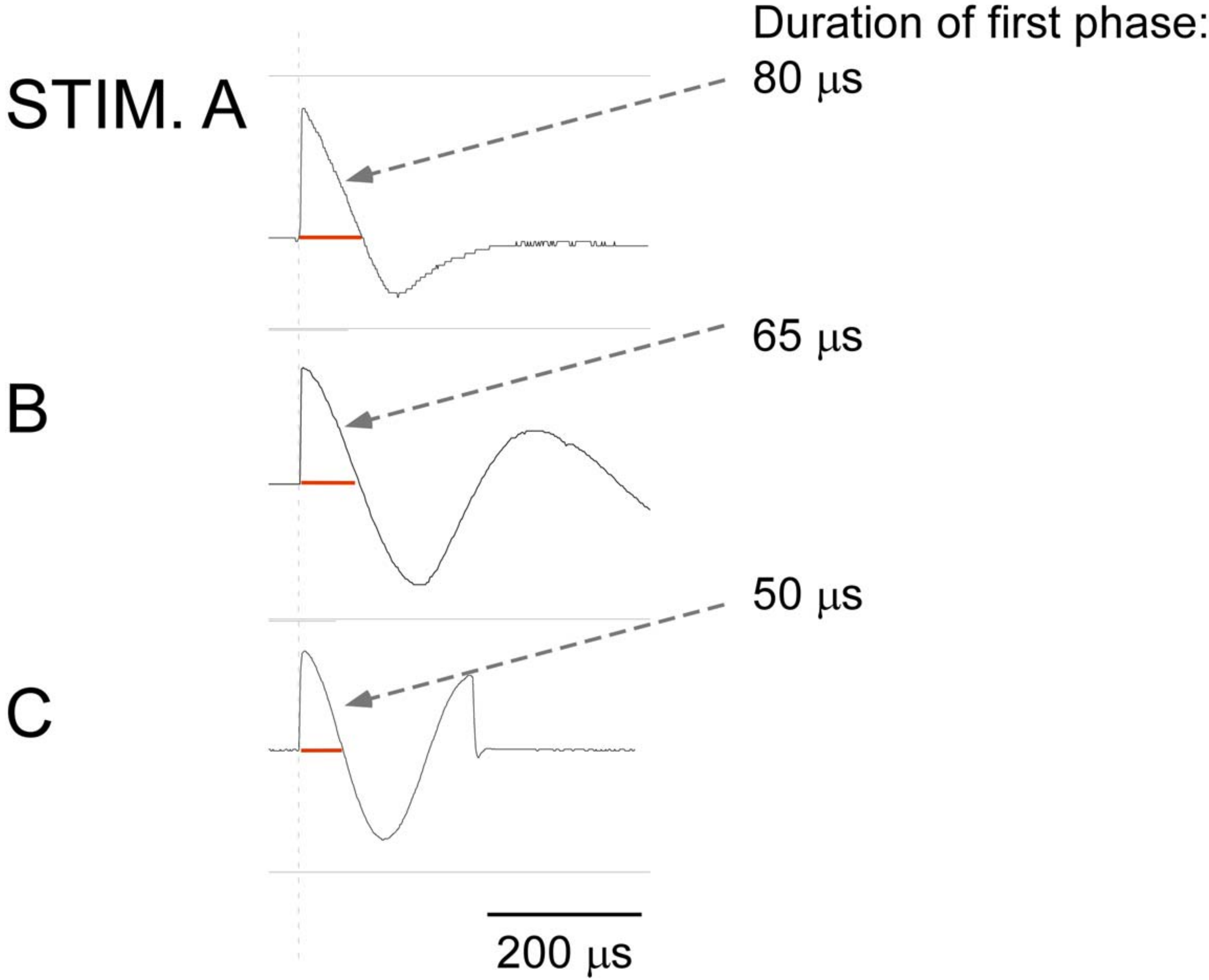
Measurement of induced magnetic field (B-field)

Namicon gauss-meter: Model MP-U

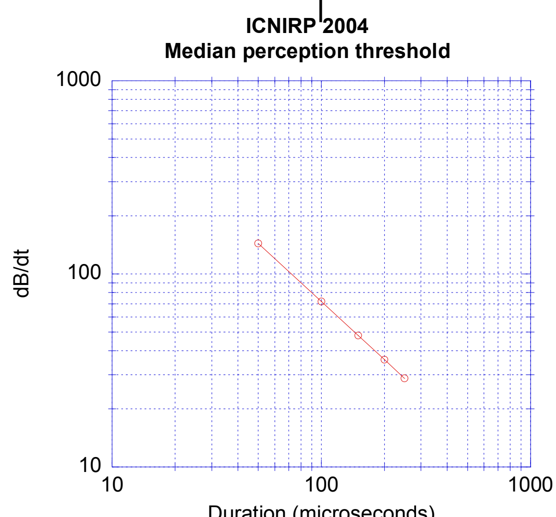
Sensitivity: 0-20 mT; 0-200 mT; 0-2 T

Calibrated output: 0-2 Volt

RISULTATI



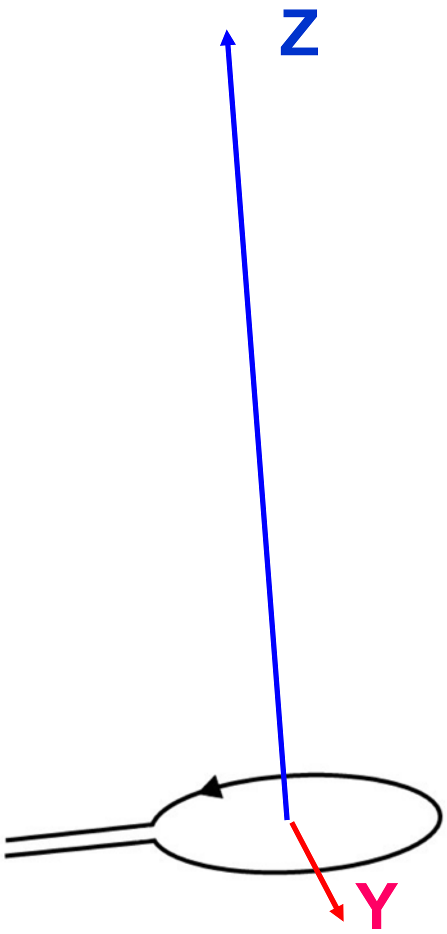
LINEE GUIDA

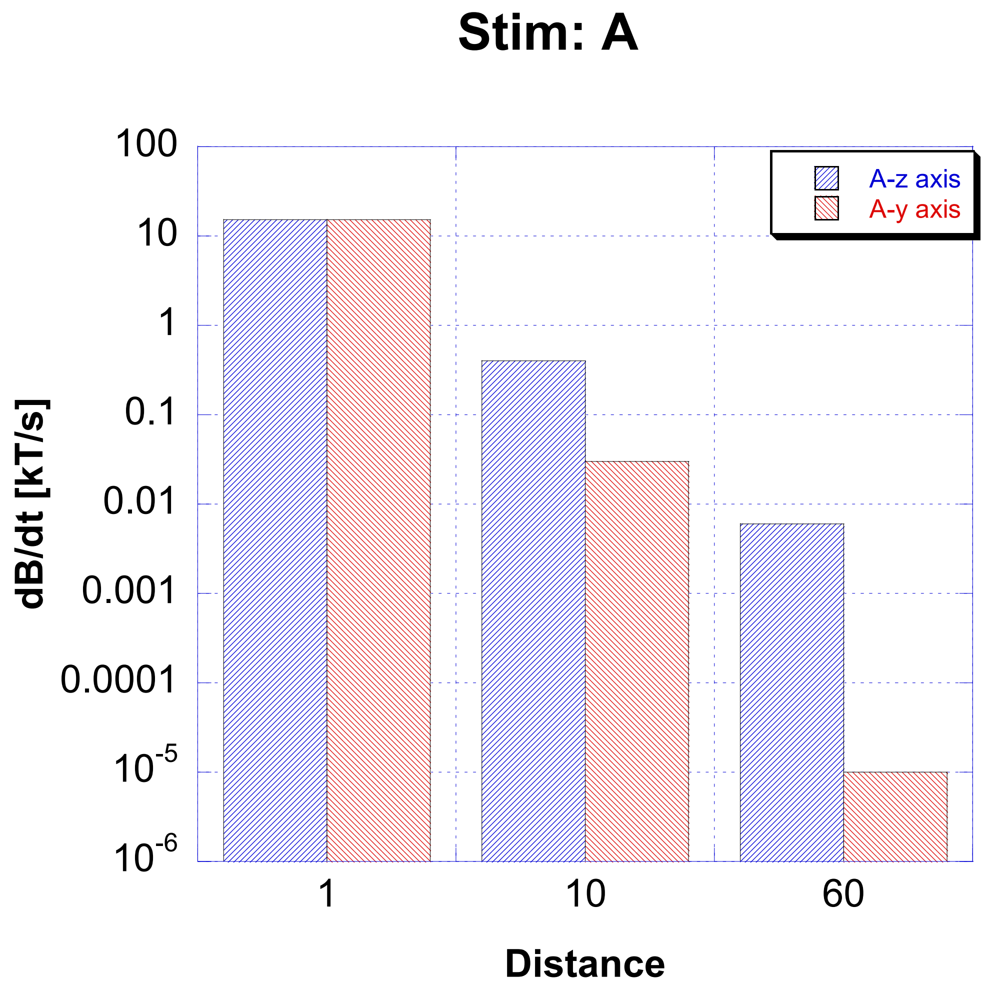
ECOMMENDATIONS	ESTIMATED MAX INDUCED CURRENT DENSITY	MAGNETIC FIELD [T rms]	TIME-VARYING MAGNETIC FIELD dB/dt [T/s]
J DIRECTIVE	**10 mA/m² (4-1000 Hz) [f/100] mA/m² (1-100 kHz)**	**30.7 μT**	**31.7 (< 1 kHz)**
ALY	**10 mA/m² (4-1000 Hz) [f/100] mA/m² (1-100 kHz)**	**30.7 μT [0.82-65 kHz)**	**2400 / Δt** [12 μs ≤ Δt < 120 μs] **20** [Δt ≥ 120 μs]
CNIRP **ased on** **okela 2000; Reilly 1998** **820 Hz: constant** **820 Hz: frequency ependent and phase lated complex eighting function**			Frequency dependent 31.2 T/s [< 820 Hz, 194 μs] 100 T/s [8 kHz]]

LINEE GUIDA

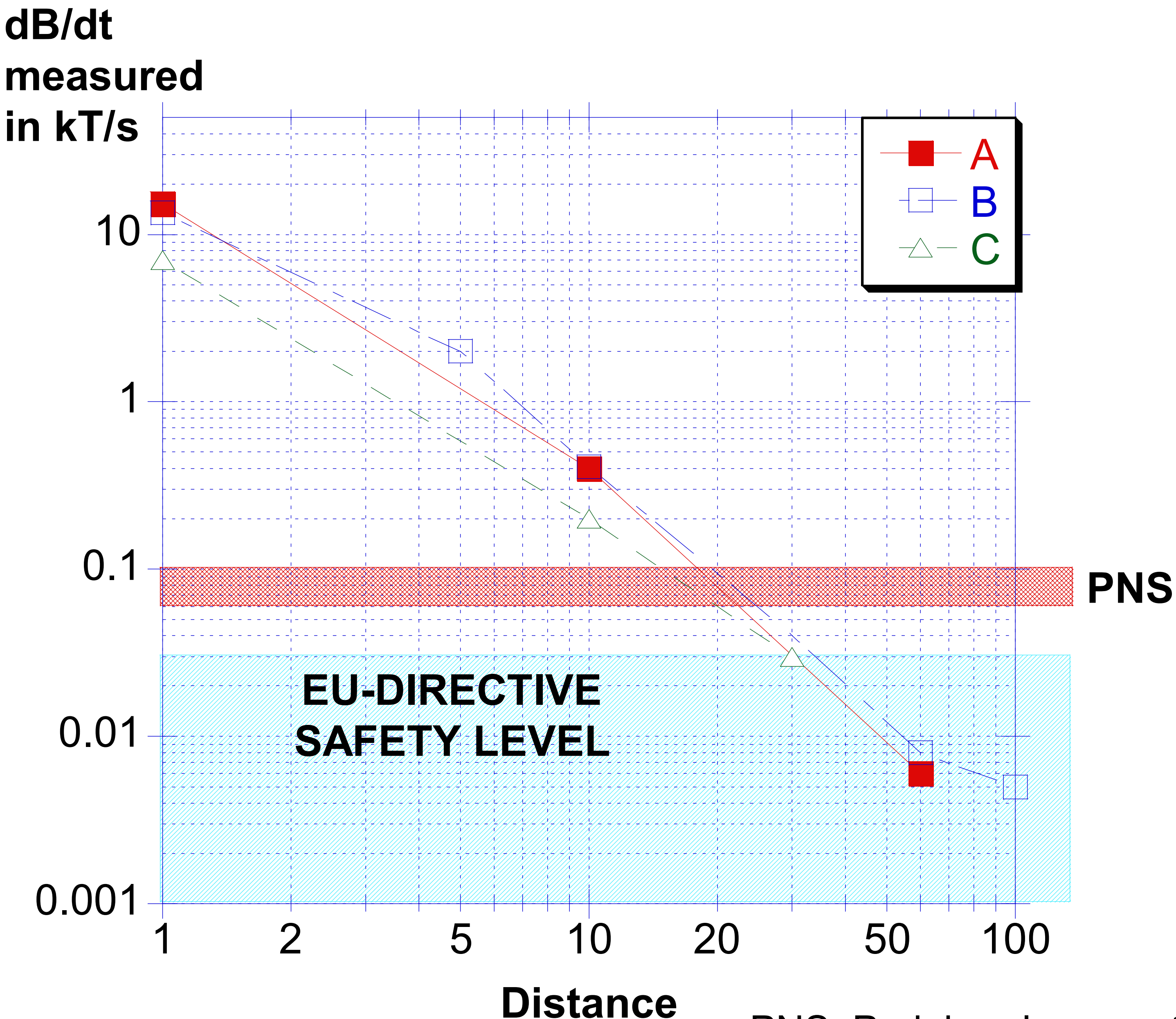
RELEVANT EXAMPLES	THRESHOLD CURRENT DENSITY
KOWALSKI ET AL. 2002 **EXCITATION OF 20 μm NERVE FIBERS - ELECTRIC** **EXCITATION OF MOTOR CORTEX (UPPER LIMB – MAGNETIC)**	1 A/m^2 (< 1 kHz) 6 and 2.5 A/m^2 (2.44 kHz and 50 Hz)
CARDIAC FIBRILATION	1 A/m^2
MAGNETOPHOSPHENES	10 mA/m^2

RISULTATI


Z
Y

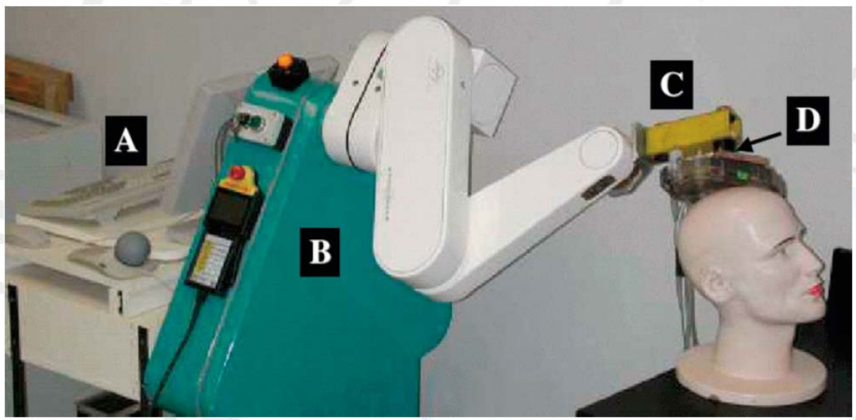

Stim: A
A-z axis
A-y axis
100
10
1
0.1
0.01
0.001
0.0001
10^{-5}
10^{-6}
dB/dt [kT/s]
1
10
60
Distance

50% OUTPUT DATA



PNS: Peripheral nerve stimulation

IL FUTURO ???



CONCLUSIONE

Alla luce di quanto sopra si può concludere che l'impiego della TMS non comporta un rischio particolarmente elevato per i pazienti e per gli operatori anche se devono essere osservate un certo numero di precauzioni. Situazioni di pericolo possono facilmente essere evitate se l'impiego della TMS avviene secondo un rigoroso protocollo clinico, fondato anche sulla conoscenza dei rischi potenziali (IFCN - International Federation of Clinical Neurophysiology).

Un minimo insieme di regole da osservare per minimizzare i rischi nell’impiego della TMS può essere quello sotto riportato:

- anamnesi che escluda la presenza di pacemaker o implantable cardioverter-defibrillator;
- attenta valutazione clinica in caso di presenza di altri tipi di impianto metallico;
- impiego dello stimolatore da parte del solo personale addestrato (non azionare lo stimolatore in presenza di oggetti metallici o altri apparati elettrici);
- impiegare lo stimolatore in un ambiente che garantisca una distanza minima fra la bobina e altri oggetti metallici di almeno 1,5 m;
- mantenere la massima distanza possibile tra il corpo dell’operatore ed la bobina;
- impiegare, dove possibile sistemi di sostegno che evitino di impugnare direttamente la bobina.

Gli addetti all’impiego della TMS devono comunque essere considerato come lavoratori professionalmente esposti a campi elettromagnetici.

BIBLIOGRAFIA

Amassian VE, Cracco RQ, Maccabee PJ. Brain Res 479(2):355-360, 1989.
Amassian VE, Cracco RQ, Maccabee PJ et al. Electroencephalogr Clin Neurophysiol 74(6):458-462, 1989.
Barker AT, Garnham CW, Freeston IL. Electroenceph clin Neurophysiol Suppl   43P:227-237, 1991.
CEI EN 60601-2-33
Chen R, Gerloff C, Classen J et al. Electroenceph clin Neurophysiol. 105, 415-421, 1997.
Corthout E, Barker AT, Cowey A. Exp Brain Res 141:128-132, 2001.
Daskalakis ZJ, Chen R. Elsevier Butterworth Heinemann: 61-81, 2005.
Di Lazzaro V, Oliviero A, Profice P. et al. Electroenceph clin Neurophysiol 109:397-401, 1998.
EU Commission of the European Communities dated 26/10/2007: http://ec.europa.eu/employment_social/news/2007/oct/emf_en.pdf
Ferreri F, Curcio G, Pasqualetti P et al. Annals of Neurology 60(2):188-196, 2006.
Gowland PA, Kucharczyk W, Bongartz G et al. Jour Mangetic Resonance Imaging 26:1177-1178, 2007.
Hannula H, Ylioja S, Pertovaara A et al. Hum Brain Mapp 26(2):100-109, 2005.
Hömberg V,Netz J. Lancet. 2, 1223. 1989.
ICNIRP. Health Physics August 2004, Volume 87, Number 2.
Inomate-Terada S, Okabe S, Arai N et al. Bioelectromagnetics 28:553-561, 2007.
International Federation of Clinical Neurophysiology (IFCN): http://www.elsevier.com/homepage/sah/ifcn/doc/rtms-inf.htm
Jokola K. Health Phys 79:373-388, 2000.
Lim HB, Cook GG, Barker AT et al. Radiation Res 163:45-52, 2005.
Kammer T, Beck S, Thielscher A et al. Clin Neurophysiol 112:250-258, 2001.
Kandler R. Lancet. 335, 469-470, 1990.
Karlström EF, Lundström R, Stensson O et al. Bioelectromagnetics 27:156-158, 2006.
Kowalski T, Silny J, Buchner H. Bioelectromagnetics 23:421-428, 2002.
Lancaster JL, Narayana S, Wenzel D et al. Human Brain Mapping 22:329 –340, 2004.
Lim HB, Cook GG, Barker AT et al. Radiation Research 163:45-52, 2005.
Maccabee PJ, Amassian VE, Cracco RQ et al. Electroencephalogr Clin Neurophysiol 70(6):524-533, 1988.
Maccabee PJ, Nagarajan SS, Amassian VE et al.   J Physiol 513(2):571-585, 1998.
Panizza M, Nilsson J, Roth BJ et al. Electroenceph Clin Neurophysiol 85:22-29, 1992.
Panizza M, Nilsson J, Roth BJ et al. Electroencephalogr Clin Neurophysiol   93: 147-154, 1994.
Panizza M, Nilsson J, Roth BJ et al. Muscle Nerve 21: 48-54, 1998.
Panizza M, Nilsson J. Elsevier Butterworth Heinemann: 31-41, 2005.
Pascual-Leone A, Wassermann EM. PI-ME Press, Pavia, Italy, 2(2):105-116, 1996.
Peterchev AV, Jalinous R, Lisanby SH. IEEE Biomed Eng 55(1):257-266, 2008.
Reilly JP. IEEE Trans Biomed Eng 45(1):137-141, 1998.
Rothwell JC. Elsevier Butterworth Heinemann: 43-60, 2005.
Ruohonen J. PhD Thesis - Helsinki University of Technology (Espoo, Finland), 1998.
Scheiner A, Mortimer JT, Roessmann U. *Annals of Biomedical Engineering,* Vol. 18, pp. 407-425, 1990
Sommer M, Alfaro A, Rummel M et al. Clin Neurophysiol 117:838-844, 2006.
Unterlechner M, Sauter C, Schmid G et al. Bioelectromagnetics 29:145-153, 2008.
Wassermann EM, Cohen LG, Flitman SS et al. Lancet 347:825, 1996.
Wassermann EM et al. Electroenceph clin Neurophysiol 108: 1-16, 1998.