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Magnetic stimulation and the control of electromagnetic fields at work act (2016): an update

Dear Editor, the Control of Electromagnetic Fields at Work Regulations (CEMFAW) came into effect within the UK in 2016, with the purpose of implementing the European Union Physical Agents (Electromagnetic Fields [EMF]) Directive (2013/35/EU). Two Volumes of a Guide to Good Practice for implementing the EMF directive have been published, where magnetic stimulation is acknowledged as an *"important and widely used technique"* [[1], p 4]. However, in Volume 2 [2], a case study reports how being in close proximity of a discharged stimulating coil, exceeds the conservative EMF exposure limit value (ELV, internal electric field strength of 1.1 Vm^{-1}, Table ELV2; [3]). Such data, obtained via modelling, was carried out whilst a stimulator discharged a maximum, single stimulation (1 ms) with a 'body' placed two distances (30 & 15 cm) from a circular coil. The data show how the health effect ELV is exceeded by 24,100% at 30 cm and 35,700% at 15 cm from the coil. Such a breach of the ELV is concerning to read from a health and safety perspective, especially for those who are not experienced with using the technique.

The ELVs are set by the International Commission on Non-Ionizing Radiation Protection [ICNIRP; 4] and it is likely that many countries use ELVs within EMF legislation. As such, this will have significant implications to the way in which researchers around the world use magnetic stimulation. Due to the focal nature of the discharged magnetic field, it is common practice for stimulating coils to be held manually over sites in the peripheral (i.e., femoral and phrenic nerves) and central nervous systems, to elicit desired responses in patients or research volunteers. Holding the coil means that operators will very likely exceed the ELV, something which is an inevitable consequence when using the technique. For occupational settings, there are few well-established acute effects of exposure to low-frequency, sinusoidal EMFs on the nervous system: the direct stimulation of nerve and muscle tissue and the induction of retinal phosphenes, which form the basis for the ELVs. There is also indirect scientific evidence that brain functions such as visual processing and motor co-ordination, can be transiently affected by induced electrical fields. However, evidence from other neurobehavioral research is not sufficiently reliable to provide a basis for human exposure limits [4]. Guidelines for exposure to EMF and the associated acute and chronic health effects, are regularly reviewed by the ICNIRP, however, the quality of such reviews has recently been questioned. Nordhagen & Flydal [5] suggest a wider pool of experts need to be consulted to appropriately determine exposure limits for human health. Additionally, long-term epidemiological evidence recently confirmed no association between occupational exposure to EMF and lymphoma risk [6].

Engineering-based literature demonstrate how discharged currents can spread into *models* of a human body. Recently, D'Agostino et al. [7] evaluated the risk of occupational exposure from administering magnetic stimulation, however, using the word '*risk*' suggests there is an adverse effect to the operator. The paper does not state what hazard exists to a user and none have been documented. Whilst merits of the work are appreciated, as a standalone paper, it has the unfortunate effect of being prohibitive for the use of magnetic stimulation in research and clinical contexts. One method of quantifying responses evoked by an EMF in human tissue is the recording of muscle activity in the form of electromyography (EMG), along with perceptual responses. Fig. 1 shows EMG data measured in an operator's hand holding a stimulating coil, whilst eliciting stimuli in a participant; when stimuli are given, a clear dose-response relationship is visible in the participant, but no detectable activity was elicited or felt, in the operator's hand. If such an E−field was being produced in a part of the body, *"rich in peripheral nerve innervation"* [7, p 3417], operators would likely feel a twitch like contraction in their hand, but this does not occur in practice. The present data suggest that the EMF released from the stimulating coil is not sufficient to evoke a response in an operator, corroborating previous literature [8], whilst refuting the stance of D'Agostino et al. [7].

Placing coils in holders and delivering stimuli remotely can ensure that operators do not exceed ELVs, such approaches are used when subthreshold stimuli are delivered at rest. However, it is not possible to use coil holders for all sites of stimulation and many testing regimes involve stimulations above motor threshold delivered during muscle contraction. When delivering stimuli in this way, it is important to manually hold the coil in place to adjust for any participant movement and ensure the correct site is stimulated. Magnetic stimulation users should be aware that short-term exposure to EMFs is contraindicated for certain populations and individuals with metal implants. As such, these groups should not operate or be in the vicinity of stimulation, as it is not reasonably practicable to screen the EMF. Responsible users of magnetic stimulation follow risk-assessments covering the above and it seems unfair for users of the technique to be seen as 'law breakers' giving license for health and safety teams to prevent such use. Furthermore, if use of magnetic stimulation is prevented, it should also be noted that commonly used university library gates likely breach ELVs [9]. One would be exposed for a longer duration when passing through library gates, compared to magnetic stimulation, and there could be multiple gates in one vicinity where users are not risk assessed.

For operators who hold or are in very close proximity to a stimulating coil, the legislation is in place to protect against involuntary stimulation of nerve and muscle tissue. However, these responses do not occur in practice and the adverse effects (e.g., muscle/nerve stimulation and development of phosphenes), upon which the health effect ELV is based, are not reported, or observed in operators using magnetic stimulation. Accordingly, the technique is set to be made exempt from relevant UK legislation, like MRI [10], and using magnetic stimulation should not be considered a '*risk*' to operator(s).

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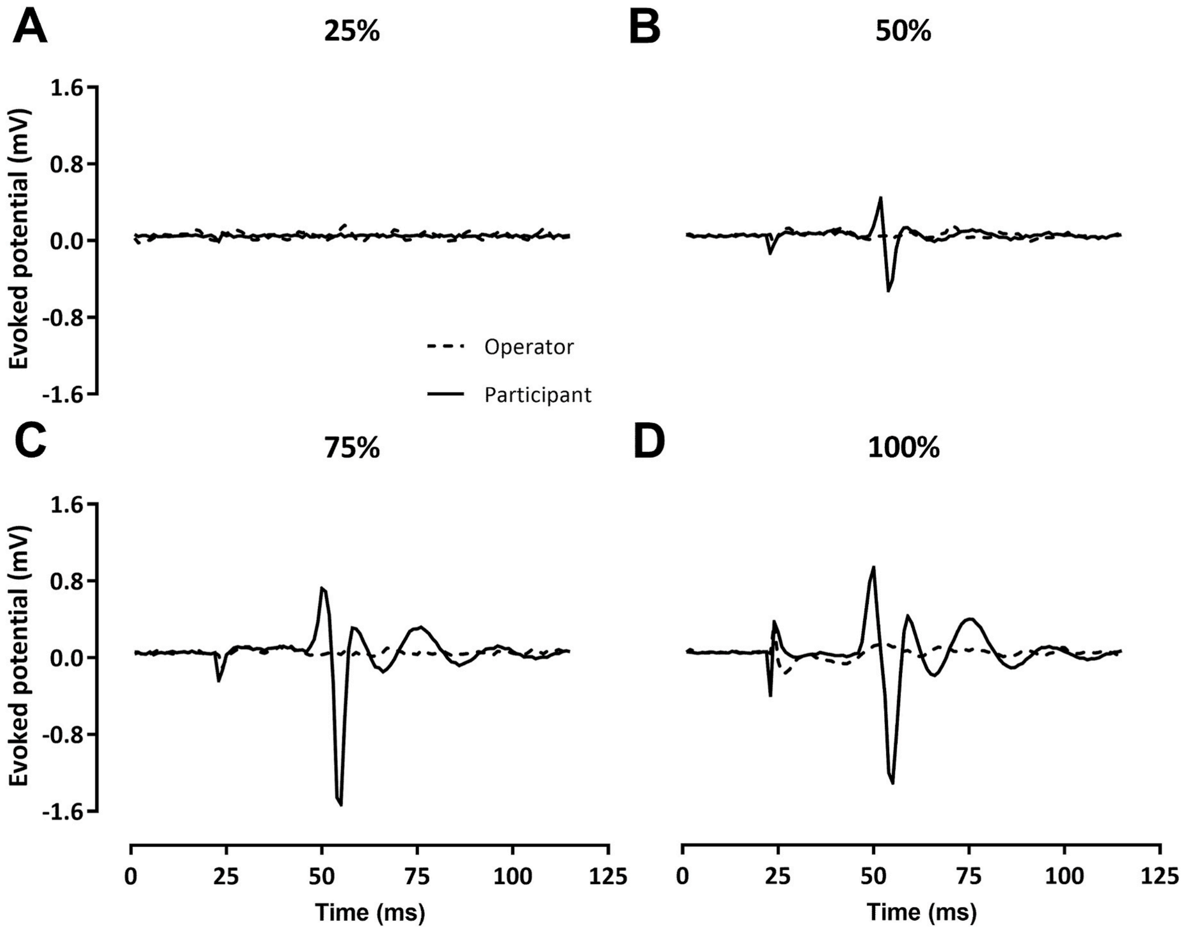

Fig. 1. Responses to magnetic stimulation in FDI at 25 (A), 50 (B), 75 (C), and 100% (D) stimulator output in the participant (solid trace) and the operator (dashed trace). Note the absence of any electromyographic response in FDI in the operator holding the flat figure of 8 coil when both hands are placed around the handle (~7 cm from the coil centre). All responses shown are the average trace of two single, monophasic stimuli, delivered over the motor cortex using a Magstim 2002 stimulator (The Magstim Company, Whitland, UK) via a double 70 mm coil (P/N: 3190-00). The intersection of the coil was held tangentially to the scalp by the operator, with the handle pointing backwards and laterally at a 45° angle away from the midline.

Declaration of competing interest

No conflicts of interest exist with any of the authors that could inappropriately influence this work.

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