

This is the peer reviewed version of the following article: Stam R. New developments in cosmetic applications of electromagnetic fields: Client and occupational hazard assessment. Bioelectromagnetics. 2024 Sep;45(6):251-259. doi: 10.1002/bem.22503, which has been published in final form at [<http://doi.org/10.1002/bem.22503>]. This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions. This article may not be enhanced, enriched or otherwise transformed into a derivative work, without express permission from Wiley or by statutory rights under applicable legislation. Copyright notices must not be removed, obscured or modified. The article must be linked to Wiley's version of record on Wiley Online Library and any embedding, framing or otherwise making available the article or pages thereof by third parties from platforms, services and websites other than Wiley Online Library must be prohibited.

Review

New developments in cosmetic applications of electromagnetic fields: client and occupational hazard assessment

Rianne Stam¹

¹National Institute for Public Health and the Environment, Bilthoven, the Netherlands

Corresponding author:

Dr. Rianne Stam

Centre for Sustainability, Environment and Health

National Institute for Public Health and the Environment

P.O. Box 1, 3720 BA Bilthoven

The Netherlands

E-mail: rienne.stam@rivm.nl

Running title:

Cosmetic Applications of Electromagnetic Fields

Grant support information:

This study was supported by a project grant from the Ministry of Social affairs and Employment, the Netherlands (Z/110071/22).

Conflicts of interest: None.

Abstract

Energy-based devices are used to improve features of appearance for aesthetic reasons while avoiding more invasive methods. Examples of treatment targets are the reduction of wrinkles, sagging, unwanted skin lesions, body hair and excess fatty tissue and the enhancement of muscle tissue. One treatment modality is the use of electromagnetic fields (EMF, 0–300 GHz). The present work aims to give an up-to-date survey of cosmetic applications of EMF for professional use with an assessment of client and worker exposure and possible adverse effects. A systematic search was conducted for peer-reviewed articles (2007–2022), patents, premarket notifications, manufacturer data and adverse effects reports. Five categories of cosmetic EMF device with increasing frequency were identified: sinusoid low frequency magnetic fields for lipolysis; pulsed low frequency magnetic fields for skin rejuvenation; pulsed low frequency magnetic fields for muscle building; radiofrequency EMF for lipolysis or skin rejuvenation; microwaves for hair removal or hyperhidrosis. In the vicinity of the last four device categories, there is a potential for exceeding the occupational exposure limits in the European Union EMF Directive, which could lead to nerve or muscle stimulation, burns or overheating. There are also potential hazards for clients or workers wearing active or passive medical devices. The severity of reported adverse effects increases with EMF frequency.

Key words: electromagnetic fields; medical devices; cosmetic treatment; exposure; hazard assessment

INTRODUCTION

The past 15 years have seen rapid developments in the use of energy-based devices, applying heat, cold, electric current, ultrasound, optical radiation or electric, magnetic and electromagnetic fields (EMF, frequencies 0–300 GHz), for cosmetic purposes. These devices are used to improve features of appearance for aesthetic reasons while avoiding more invasive methods such as surgery. Examples of treatment targets are the reduction of wrinkles, sagging, unwanted skin lesions, body hair and excess fatty tissue (lipolysis) and the enhancement of muscle tissue ('body shaping'). The International Commission on Non-Ionizing radiation Protection (ICNIRP) published a Statement on cosmetic applications of EMF, optical radiation and ultrasound in 2020 [ICNIRP, 2020a]. Its conclusions were that there was a significant potential for harm to clients and workers associated with these devices and ICNIRP recommended complete coverage by relevant regulations and greater oversight regarding their use. For those devices employing EMF, potential risks for clients or workers depend on the frequency. Low frequency EMF that are sufficiently strong can stimulate sensory organs, nerves and muscles and cause pain or involuntary contractions. Radiofrequency EMF that are sufficiently strong can cause heat stress or burns. These health risks are a consequence of direct effects of EMF on the body or its constituents. EMF can also cause safety risks via their interaction with metallic objects and electronics in their environment (indirect effects). In its guidelines, ICNIRP has set exposure limits for the strength of EMF and their effects on the body for which potentially harmful direct effects do not occur [ICNIRP, 2010; ICNIRP, 2020b]. Lower limits are set for the general public than for occupational exposure, because the general public includes individuals of all ages and differing health status, and are not trained to be aware of the risks or subject to appropriate risk mitigation measures. However, ICNIRP has stated that only clients exposed to EMF as a result of cosmetic treatments without control by a qualified medical practitioner are subject to the general public limits in their guidelines and that any decisions concerning potential exemptions are the role of national regulatory bodies [ICNIRP, 2020b].

In the European Union (EU), the Medical Devices Regulation (2017) covers six groups of products for which the manufacturer claims only an aesthetic or other non-medical purpose, but which

are similar to medical devices in terms of functioning and risk profile [European Parliament and Council, 2017]. In addition, the European Commission issued an implementing regulation listing common specifications addressing risk management for these devices [European Commission, 2022]. With regard to energy-based devices, devices (including EMF sources) intended for reducing, removing or destroying adipose tissue, devices using optical radiation for skin resurfacing, tattoo or hair removal or other skin treatment, and devices intended for brain stimulation (including EMF sources) are included. The requirements of the Medical Devices Regulation regarding post market surveillance of device safety experience and vigilance for serious incidents and corrective action also apply to these specified categories of non-medical devices. In the United States, the Food and Drug Administration (FDA) regulates the putting on the market and surveillance for medical devices and electronic devices emitting radiation. It does not make a distinction between devices for medical or cosmetic purposes: as long as they affect the structure or any function of the body of humans or animals, they are considered to be medical devices. The FDA can take corrective action against devices that are marketed without FDA review, clearance, or approval [ICNIRP, 2020a].

With regard to protection of workers against the risks of EMF in the workplace, Directive 2013/35/EU (further called 'EU Directive') contains obligations for employers regarding risk management, information and training and sets exposure limits for workers based on ICNIRP guidelines [European Parliament and Council, 2013]. These consist of exposure limit values in terms of the induced electric field strength, specific absorption rate (SAR) and (absorbed) power density, as well as action levels in terms of the environmental electric field strength, magnetic flux density and (incident) power density. When action levels are exceeded, this gives an indication that exposure limit values could be exceeded. There are also action levels for indirect effects aimed at preventing safety risks.

The present work aims to update and expand the survey of cosmetic applications conducted by ICNIRP specifically for EMF sources and to provide a more detailed assessment of client and worker exposure and possible adverse effects based on the scientific literature and relevant technical documents.

METHODS

The working definition for cosmetic EMF sources is devices that apply EMF to alter the appearance for aesthetic reasons. Thus, treatment of clinical conditions such as severe acne or varicose veins are outside the scope, because they are primarily considered medical conditions [ICNIRP, 2020a]. Treatments solely aimed at cognitive enhancement (e.g. through transcranial magnetic stimulation, TMS) were also excluded because they do not have an aesthetic purpose. TMS for medical purposes has a well-established risk profile for workers, with likely transgression of occupational exposure limits in the vicinity of the coil [Stam and Yamaguchi-Sekino, 2018]. Some cosmetic devices termed 'radiofrequency' actually apply radiofrequency alternating electric current via an electrode in direct contact with the skin (monopolar or bipolar). Since they do not employ EMF as a treatment modality and do not convey energy to the body with the same mode, localisation and damage pattern as EMF, they also fall outside the scope of this review. The focus is on devices for professional use, where the potential exposure level is expected to be higher than for home use and where occupational exposure may occur. The type of pulsed magnetic field therapy mats intended for private use [De Santis et al., 2015; Jaermann et al., 2011] were therefore excluded. Devices were not assessed with regard to efficacy for the stated cosmetic aim, but solely for potential hazards with regard to the client or the operator (worker).

A systematic search for peer-reviewed research articles in English involving human subjects was conducted for the period from January 2007 to November 2022 in Pubmed (<https://www.ncbi.nlm.nih.gov/pubmed/>) and Scopus (<https://www.scopus.com/>). Pagination of advance publications was added if available before submission of the manuscript. The first, general search used a combination of search terms for EMF [(((magnetic OR electric OR electromagnetic OR emf OR "radio frequ*" OR radiofrequ* OR rf OR "low frequ*" OR elf OR radar* OR "non ioni*" OR nonioni*) AND (field* OR radiat* OR wave*)) OR microwave* OR "millimeter wave*" OR "millimetre wave*" OR "mm wave*") NOT ("optical radiation" OR ultraviolet OR uv OR infrared OR "visible light"))] with search terms for cosmetic applications in general [cosmetic OR esthetic OR aesthetic]. A second search combined the EMF search terms with search terms or for specific cosmetic treatment targets [epilat* OR ((hair OR tattoo OR make-up OR makeup OR wrinkle* OR

scar* OR acne OR rosac* OR pigment* OR naev* OR fat OR cellulite) AND (reduc* OR remov*)) OR lipolysis OR lipectom* OR electrolysis OR "body shaping" OR "body contouring" OR "body sculpting" OR "muscle stimulat*" OR hyperhidrosis OR osmidrosis OR curing OR bleaching OR (skin AND (tighten* OR rejuvenat*)) OR laxity]. In Scopus, document types such as conference abstracts, commentaries and book chapters that were not full journal articles were excluded. For Scopus, 743 results were found with the general search terms and 2,059 with the source-specific search terms (with an unknown overlap between the two). After screening of titles and, if necessary for clarification, abstracts, 61 articles were selected as relevant. Articles were considered relevant when they contained information about devices or treatments using EMF to alter the appearance for aesthetic reasons. For Pubmed, 1,196 results were found with the general search terms and 1,680 with the source-specific search terms (with an unknown overlap between the two). After screening of titles and, if necessary for clarification, abstracts, 6 articles were selected as relevant that were not also found with the Scopus search.

Since information on the frequency or strength of EMF was often missing in the peer-reviewed articles, which usually focus on the cosmetic effects obtained, additional technical information was sought in November 2022 by keyword searches for the device or manufacturer name in the Patent Public Search tool of the United States Patent and Trademark Office (<https://ppubs.uspto.gov/pubwebapp/static/pages/landing.html>) and the 510(k) Premarket Notification medical device database of the U.S. Food and Drug Administration (FDA) (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>) and on manufacturers' websites. Additional information on adverse events in the previous 10 years was obtained by device and manufacturer name searches in the FDA MAUDE database in November 2022 (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>). This searchable database only contains the last 10 years of medical device report data on a given search date. Other stated limitations of this database include the potential submission of incomplete, inaccurate, untimely, unverified, or biased data, and the fact that the incidence or prevalence of an event cannot be determined from its record alone due to potential under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency

of device use. An EU-wide digital system (EUDAMED) for medical device traceability and proactive market surveillance, including a vigilance module for adverse effects, is under development but not yet operational [European Commission, 2023]. Websites of regulatory authorities in the EU, USA, and Australia were searched for institutional reports in English, French or German on cosmetic applications of EMF. Three relevant reports were found [ANSES, 2016; Dürrenberger et al., 2018; Strahlenschutzkommission, 2019], but these yielded no additional references or cosmetic techniques that fell within the scope of the present review. Devices were not assessed with regard to efficacy for the stated cosmetic aim, but solely for potential hazards for the client or the operator (worker).

RESULTS

The vast majority (92%) of relevant articles concerned case studies or case series. Only 8% of articles concerned controlled clinical trials, half of which were not randomized or blinded. Devices for professional use employing EMF for cosmetic purposes were identified in five categories with increasing frequency.

1. Low frequency, sinusoid magnetic fields for lipolysis

Low frequency, sinusoid magnetic fields with power frequency (50 Hz) are used with the stated aim to stimulate lipolysis [Beilin et al., 2012]. The magnetic induction coils are located in a pressure suit which the client wears during the treatment to stimulate lymphatic drainage. The maximum magnetic flux density for the client is 200 μT [U.S. Patent and Trademark Office, 2016], which is equal to the ICNIRP 2010 reference level for the general population and 20% of the occupational low action level in the EU Directive at 50 Hz. Adverse direct effects of EMF exposure are therefore unlikely and have not been reported. The manufacturer does list a contra-indication for clients wearing a pacemaker or women who are pregnant or breastfeeding [Bodysculptor, 2022]. Hazards from indirect effects for workers wearing active medical devices in the immediate vicinity of the client during treatment cannot be excluded. However, although interference with pacemakers can

be detected at this flux density in less than 10% of individuals in power frequency provocation tests [Stunder et al., 2017], actual reports of adverse effects due to interference with active implanted cardiac devices by household appliances of similar strength are generally lacking [Misiri et al., 2012].

2. Low frequency, pulsed magnetic fields for skin rejuvenation

Pulsed low frequency magnetic fields with an equivalent frequency [ICNIRP, 2003] of 2 kHz (pulse duration 0.5 ms, pulse frequency 15 Hz) are applied for the treatment of wrinkles and skin laxity [Few et al., 2016; Krueger et al., 2012; Oliveira et al., 2017; Wattanakrai et al., 2022]. The maximum magnetic flux density in the pulse for the client is 1.5 mT [U.S. Food and Drug Administration, 2019b; Krueger et al., 2012; Wattanakrai et al., 2022], which is 38 times the ICNIRP 2010 reference level for the general population and 10 times the occupational high action level for nerve stimulation or 3 times the action level for limb exposure in the EU Directive at the equivalent frequency. This indicates that action levels could potentially be exceeded for workers in close vicinity, but no measurement results at the worker position were available. This form of pulsed magnetic field is always combined with the application of radiofrequency (1 MHz) electric current on the client's skin, making it harder to distinguish possible adverse effects of the low frequency magnetic field. For clients there is clearly a hazard of exceeding the threshold for nerve or muscle stimulation, which has indeed been observed when EMF with a similar frequency and intensity are applied (in the absence of radiofrequency current) for muscle building (see category 3). By analogy with electrosurgical equipment using radiofrequency currents, the electrode and cable may also generate EMF that exceed the action levels in the EU Directive [Stam and Yamaguchi-Sekino, 2018]. Temporary adverse effects for clients reported by the authors are heat sensation, pain, redness and swelling and are most likely caused by the radiofrequency current [Few et al., 2016; Krueger et al., 2012; Oliveira et al., 2017; Wattanakrai et al., 2022]. The FDA MAUDE database only listed 2 medical device reports in the past 10 years, which together reported one instance of redness, swelling, itching, scarring or pigmentation change.

3. Low frequency, pulsed magnetic fields for muscle building

Pulsed low frequency magnetic fields with an equivalent frequency of 3.6 to 4 kHz (pulse duration 0.25 to 0.28 ms, pulse frequency 1 to 150 Hz) are applied to generate repeated muscle contractions and thereby build up muscle mass and tone ('body shaping') [Duncan, 2021; Giesse, 2021; Goldberg, 2021; Jacob et al., 2021; Katz, 2020; Katz and Duncan, 2021; Kent and Jacob, 2019; Kilmer et al., 2020; Kinney and Lozanova, 2019; Leone et al., 2021; Negosanti et al., 2022; Nisticò et al., 2022; Samuels et al., 2022]. The oval applicator is generally held in place adjacent to (but isolated from) the skin of the body region treated by flexible straps. The maximum magnetic flux density in the pulse for the client ranges from 1.5 to 2.5 T [U.S. Food and Drug Administration, 2019a; U.S. Food and Drug Administration, 2022; Nisticò et al., 2022], which is approximately 93,000 times the ICNIRP 2010 reference level for the general population and 25,000 times the occupational high action level for nerve stimulation or approximately 8,000 times the occupational action level for limb exposure at the equivalent frequency in the EU Directive. This not illogical, since the stated aim is to cause muscle contractions in the client. It indicates that action levels could potentially be exceeded for workers in close vicinity, but no measurement results at the worker position were available. With regard to possible adverse effects in clients, the FDA MAUDE database listed 4 medical device reports in the past 10 years (after removing duplicate reports), 25% of which reported burns or blisters, 50% ulceration, abscess, cyst, hematoma, seroma or wound infection and 50% ovarian symptoms. Low frequency pulsed muscle stimulation is sometimes combined with the application of radiofrequency EMF [Nisticò et al., 2022] (see under 4.) or radiofrequency electric current [Duncan, 2021; Goldberg, 2021; Jacob et al., 2021; Samuels et al., 2022] (see under 2.), either of which may generate radiofrequency EMF exposure of workers in the vicinity.

4. Radiofrequency EMF for lipolysis or skin rejuvenation

Radiofrequency EMF with a frequency of 27 MHz are applied to stimulate lipolysis [Agochukwu-Nwubah and Mentz, 2020; Choi et al., 2018; Downie and Kaspar, 2016; Elnaggar, 2020; Fajkosova et al., 2014; Fritz and Salavastu, 2017; Fritz et al., 2016; Hayre et al., 2016; Key, 2014; Kim, 2017; McDaniel and Samková, 2015; Moradi and Palm, 2015; Moradi et al., 2020; Pumprla et al., 2015; Suh et al., 2017]. This EMF frequency is also applied in diathermy for medical therapeutic

purposes. The antennas are placed at some distance from the body of the client. Absorbed power density in the client can be up to 10 kW/m², which is 500 times the ICNIRP 2020 basic restriction for the general population and 200 times the occupational exposure limit value in the EU Directive, and local tissue temperature can reach 45 °C [U.S. Food and Drug Administration, 2016]. No measurement results were available at the potential position of the worker, but in view of the absorbed power density in clients it is possible that action levels for thermal effects are exceeded in the vicinity. With regard to possible adverse effects in clients in the past 10 years, the FDA MAUDE database listed 13 medical device reports in the past 10 years, 92% of which listed burns or blisters, 25% pain, 20% redness or bruising and 20% scarring.

Radiofrequency EMF with a frequency of 2.5 GHz are applied to stimulate lipolysis or for the treatment of wrinkles and skin laxity [Bennardo et al., 2022; Bonan et al., 2019; Bonan and Verdelli, 2021; Pahlavani et al., 2022; Salsi and Fusco, 2022]. No data on absorbed or incident power density was found, but since the temperature in adipose tissue can reach 47 to 50 °C they are likely to exceed both the ICNIRP 2020 basic restrictions for the general population and the occupational exposure limit values at the level of the client. Active cooling is used in combination with the device to prevent damage to more superficial tissues (skin). No measurement results were available at the potential position of the worker, but in view of the fact that the EMF are strong enough to thermal effects observed in clients it is possible that occupational action levels are also exceeded in the vicinity. The only short term adverse effects for clients reported by the authors were redness and a tingling sensation [Bennardo et al., 2022]. The FDA MAUDE database did not list any medical device report of adverse effects for this type of device.

5. Radiofrequency EMF for depilation or hyperhidrosis

Radiofrequency EMF, or microwaves, with a frequency of 5.8 GHz are applied to reduce excessive sweating or remove body hair, primarily in the axillary areas (armpits) [Abd Hamid et al., 2015; Brauer et al., 2017; Chang et al., 2015; Chen et al., 2022; Glaser et al., 2012; Hatano et al., 2021; Hong et al., 2012; Kaminaka et al., 2019; Lee et al., 2013; Lin et al., 2021; Lupin et al., 2014; Mohamoud et al., 2022; Scuderi et al., 2017; Yang et al., 2019]. The mechanism of action is

destruction of sweat glands or hair follicles by heating. The local SAR during treatment lies in the order of 100 kW/kg, which is 50,000 times the ICNIRP 2020 reference level for the general population and 10,000 times the exposure limit value in the EU Directive. However, active cooling of the client's skin is applied to limit potential damage and local anesthesia is given. No measurement results were available at the potential position of the worker, but in view of the SAR value in clients it is possible that action levels for thermal effects are exceeded in the vicinity. With regard to possible adverse effects in clients, the FDA MAUDE database listed 523 medical device reports in the past 10 years, 29% of which listed ulceration, abscess, cyst, hematoma, seroma or wound infection, 15% pain, 10% numbness, 8% redness or bruising, 7% swelling, 6% burns or blisters, 5% scarring, nodules, lumps or erosions, 5% muscle atrophy or weakness, 4% neurological symptoms, 2% a tingling or stinging sensation and 1% necrosis. Case reports have been published on some of these adverse outcomes, in particular inflammation [Aleisa and Feingold, 2020; Wen et al., 2022] and neurological symptoms [Puffer et al., 2019; Suh et al., 2014].

DISCUSSION

Five categories of cosmetic EMF sources with increasing frequency were identified: 1) low frequency sinusoid magnetic fields for lipolysis; 2) low frequency, pulsed magnetic fields for skin rejuvenation; 3) low frequency, pulsed magnetic fields for muscle building; 4) radiofrequency EMF for lipolysis or skin rejuvenation; 5) radiofrequency EMF for depilation or hyperhidrosis. Compared with the previous assessment by ICNIRP [ICNIRP, 2020a], two additional types of EMF application were identified in the present review: sinusoid low frequency EMF devices for lipolysis (category 1) and 2.5 GHz radiofrequency EMF devices for lipolysis or skin treatment (category 4). In addition, supplementary data on EMF frequency and strength were obtained from manufacturer documentation, patents or premarket notifications. Since most of these devices are designed to stimulate nervous or muscle tissue or to heat skin or adipose tissue, it is not surprising that their strength (for categories 2 to 5) exceeds occupational exposure limits at the level of the client. This is also reflected in adverse effect reports, which generally reflect effects related to nerve or muscle stimulation (redness,

soreness, skin lesions) or heating (redness, pain or soreness, bruising, swelling, skin lesions, neurological symptoms).

No data were available for the EMF strength at the normal position of the worker, and it would be useful if such assessments were made in the future using realistic exposure scenarios. Based on the strength or induced fields at the level of the client, which greatly exceeded occupational limits for devices in categories 2 to 5, they could potentially exceed the limits for workers in the vicinity of the client. This possibility is made more plausible by analogy with medical sources with similar EMF frequency and strength, for which occupational exposure data are available. For devices in categories 2 and 3, the frequency and magnetic flux density of the pulsed fields are comparable to those applied in transcranial magnetic stimulation, where recent studies have confirmed that the exposure limit values in the EU Directive can be exceeded for workers in the vicinity of the coil [D'Agostino et al., 2022; Rutherford et al., 2020]. For the devices in categories in category 4, the frequencies (27 MHz and 2,5 GHz) and thermal levels in the patient are comparable to those used for radiofrequency diathermy or hyperthermia treatment for medical purposes, where EMF exceeding the occupational levels at the position of the worker have been observed [Stam and Yamaguchi-Sekino, 2018]. For devices in category 5, no measurement data at the position of the worker were found for medical sources at a similar frequency (5.8 GHz) and strength. Although radar applications in this frequency band are becoming available for medical diagnostic purposes, they use an EMF strength below the general public limits at the level of the patient [De Santis et al., 2012]. The possibility of exceeding occupational exposure limits at the worker position for devices in category 5 therefore remains speculative.

Devices in category 2 apply pulsed magnetic fields in combination with radiofrequency electric current (1 MHz). The electrode and cable of radiofrequency electrosurgical equipment are known to generate radiofrequency EMF which can exceed the action levels in the EU directive in their vicinity [Stam and Yamaguchi-Sekino, 2018]. For devices in category 3 and 4, standard practice is already to mount the EMF source (electrode and cable) on a stand or to strap it to the client's body. In such a setup it should be possible for workers to keep their distance to the device and prevent overexposure. For devices in categories 2 and 5, normal practice is for the worker to manually hold

the EMF source to the target area on the client. If occupational exposure can be exceeded, measures would have to be taken to reduce exposure, for example by improved shielding of the device [Zucca et al., 2017] or by using an appliance to fix the source to the treatment area and allow workers to keep their distance [Chronicle et al., 2005]. This would also require that the device can be activated remotely.

With regard to indirect effects of EMF exposure, in view of their strength at the level of the client, there is a potential hazard for clients or workers wearing active medical devices (e.g. pacemaker, insulin pump) in the vicinity of all five categories of cosmetic devices. Possible harmful effects include damage, malfunction, and inappropriate stimulation or inhibition [Beinart and Nazarian, 2013]. For clients and workers with passive metallic medical devices (e.g. artificial joint, electrode wire), there is a potential hazard of indirect effects for devices in categories 2 to 5. Possible harmful effects include burns and local reinforcement of the induced electric field [Virtanen et al., 2006]. For EMF devices aimed at lipolysis, the common specifications in the EU already require manufacturers to reduce the risks and instruct the user about the contra-indications for wearers of active medical devices or passive metallic medical devices or objects on or inside the body [European Commission, 2022]. It would be advisable to also provide such warnings for the other EMF devices reviewed here.

In conclusion, for the five categories of cosmetic EMF device identified, the severity of reported adverse effects in clients increases with EMF frequency. For four categories of devices there is a potential for exceeding the occupational exposure limits in the EU EMF Directive, which could lead to nerve or muscle stimulation, burns or overheating. There are also potential hazards for clients or workers wearing active or passive medical devices, which may occur at field strengths below the occupational exposure limits.

ACKNOWLEDGEMENTS

This study was supported by a project grant from the Ministry of Social affairs and Employment, the Netherlands (Z/110071/22). Part of the data were presented at the BioEM 2023 conference in Oxford, UK.

REFERENCES

- Abd Hamid AI, Gall C, Speck O, Antal A, Sabel BA. 2015. Effects of alternating current stimulation on the healthy and diseased brain. *Front Neurosci* 9:391.
- Agochukwu-Nwubah N, Mentz H. 2020. Paradoxical adipose hyperplasia after noninvasive radiofrequency treatment: A novel report and review. *J Cosmet Dermatol* 19:866–868.
- Aleisa A, Feingold DS. 2020. Development of inflammatory nodules and scarring mimicking hidradenitis suppurativa after treatment of axillary hyperhidrosis using a microwave-based energy device. *JAAD Case Reports* 6:999–1000.
- ANSES. 2016. Risques sanitaires liés à l'utilisation des appareils mettant en oeuvre des agents physiques destinés à la pratique des actes à visée esthétique. Maisons-Alfort: ANSES (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail).
- Beilin G, Benech P, Courie R, Benichoux F, Audran S. 2012. Electromagnetic fields applied to the reduction of abdominal obesity. *J Cosmet Laser Ther* 14:24–42.
- Beinart R, Nazarian S. 2013. Effects of external electrical and magnetic fields on pacemakers and defibrillators: from engineering principles to clinical practice. *Circulation* 128:2799–2809.
- Bennardo L, Fusco I, Cuciti C, Sicilia C, Salsi B, Cannarozzo G, Hoffmann K, Nisticò SP. 2022. Microwave therapy for cellulite: an effective non-invasive treatment. *J Clin Med* 11:515.
- Bodysculptor. 2022. Questions les plus fréquemment posées sur nos appareils minceur professionnels. https://beaute.biostimology.com/?page_id=8760. [Accessed November 13, 2023]
- Bonan P, Marini L, Lotti T. 2019. Microwaves in body sculpting: A prospective study. *Dermatol Ther* 32:e12782.

- Bonan P, Verdelli A. 2021. Combined microwaves and fractional microablative CO₂ laser treatment for postpartum abdominal laxity. *J Cosmet Dermatol* 20:124–131.
- Brauer JA, Neckman JP, Zelickson B, Vasily DB, Geronemus RG. 2017. A prospective study of axillary hair reduction in patients treated with microwave technology. *Dermatol Surg* 43:558–565.
- Chang YY, Chen CH, Hui RCY, Jung SM, Yang CH. 2015. A prospective clinical and histologic study of axillary osmidrosis treated with the microwave-based device. *Dermatol Sin* 33:134–141.
- Chen SQ, Wang TT, Zhou Y, Li W, Man XY. 2022. Comparison of long-term effectiveness and safety of microwave and surgery in the treatment of axillary osmidrosis: a single-center retrospective study. *Dermatol Surg* 48:126–130.
- Choi SY, Kim YJ, Kim SY, Lee WJ, Chang SE, Lee MW, Choi JH, Won C. 2018. Improvement in abdominal and flank contouring by a novel adipocyte-selective non-contact radiofrequency device. *Lasers Surg Med* 50:738–744.
- Chronicle EP, Pearson AJ, Matthews C. 2005. Development and positioning reliability of a TMS coil holder for headache research. *Headache* 45:37–41.
- D'Agostino S, Colella M, Liberti M, Falsaperla R, Apollonio F. 2022. Systematic numerical assessment of occupational exposure to electromagnetic fields of transcranial magnetic stimulation. *Medical physics* 49:3416–3431.
- De Santis V, Douglas M, Nadakuduti J, Benkler S, Chen XL, Kuster N. 2015. Human exposure from pulsed magnetic field therapy mats: a numerical case study with three commercial products. *Bioelectromagnetics* 36:149–161.
- De Santis V, Sill JM, Bourqui J, Fear EC. 2012. Safety assessment of ultra-wideband antennas for microwave breast imaging. *Bioelectromagnetics* 33:215–225.
- Downie J, Kaspar M. 2016. Contactless abdominal fat reduction with selective RFTM evaluated by magnetic resonance imaging (MRI): Case study. *Journal of Drugs in Dermatology* 15:491–495.

- Duncan DI. 2021. Combination treatment for buttock and abdominal remodeling and skin improvement using HIFEM procedure and simultaneous delivery of radiofrequency and targeted pressure energy. *Journal of cosmetic dermatology* 20:3893–3898.
- Dürrenberger G, Fröhlich J, Meya K, Schmid M. 2018. Kosmetik, Wellness und die Gesundheit – EMF-Quellen ausserhalb der Medizin. Systematische Erfassung und Charakterisierung von hoch- und niederfrequenten Quellen einschl. Ultraschall im gewerblichen Bereich und in der Anwendung für zuhause. Salzgitter: Bundesamt für Strahlenschutz.
- Elnaggar RK. 2020. A randomized, controlled trial on the effectiveness of photobiomodulation therapy and non-contact selective-field radiofrequency on abdominal adiposity in adolescents with obesity. *Lasers Surg Med* 52:873–881.
- European Commission. 2022. Commission Implementing Regulation of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. *Official Journal of the European Union L* 311:60–93.
- European Commission. 2023. EUDAMED – Overview. https://health.ec.europa.eu/medical-devices-eudamed/overview_en. [Accessed November 13, 2023]
- European Parliament and Council. 2013. Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) and repealing Directive 2004/40/EC. *Off J Eur Union L*179:1–21.
- European Parliament and Council. 2017. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 april 2017 on medical devices. *Off J Eur Union L* 117:1–175.
- Fajkosova K, Machovcova A, Onder M, Fritz K. 2014. Selective radiofrequency therapy as a non-invasive approach for contactless body contouring and circumferential reduction. *J Drugs Dermatol* 13:291–296.
- Few J, Gold M, Sadick N. 2016. Prospective Internally Controlled Blind Reviewed Clinical Evaluation of Cryolipolysis Combined With Multipolar Radiofrequency

- and Varipulse Technology for Enhanced Subject Results in Circumferential Fat Reduction and Skin Laxity of the Flanks. *J Drugs Dermatol* 15:1354–1358.
- Fritz K, Salavastru C. 2017. Long-term follow-up on patients treated for abdominal fat using a selective contactless radiofrequency device. *J Cosmet Dermatol* 16:471–475.
- Fritz K, Samkova P, Salavastru C, Hudec J. 2016. A novel selective RF applicator for reducing thigh circumference: a clinical evaluation. *Dermatol Ther* 29:92–95.
- Giesse S. 2021. A German prospective study of the safety and efficacy of a non-invasive, high-intensity, electromagnetic abdomen and buttock contouring device. *J Clin Aesth Dermatol* 14:30–33.
- Glaser DA, Coleman WP, Fan LK, Kaminer MS, Kilmer SL, Nossa R, Smith SR, O'Shaughnessy KF. 2012. A randomized, blinded clinical evaluation of a novel microwave device for treating axillary hyperhidrosis: The dermatologic reduction in underarm perspiration study. *Dermatol Surg* 38:185–191.
- Goldberg DJ. 2021. Deletion of adipocytes induced by a novel device simultaneously delivering synchronized radiofrequency and hifem: Human histological study. *J Cosmet Dermatol* 20:1104–1109.
- Hatano T, Fukasawa N, Miyano C, Wiederkehr I, Miyawaki T. 2021. Pathological changes in axillary hyperhidrosis and axillary osmidrosis induced by microwave treatment: comparison of single- and double-pass irradiation. *Lasers Surg Med* 53:1220–1226.
- Hayre N, Palm M, Jenkin P. 2016. A clinical evaluation of a next generation, noninvasive, selective radiofrequency, hands-free, body-shaping device. *J Drugs Dermatol* 15:1557–1561.
- Hong HCH, Lupin M, O'Shaughnessy KF. 2012. Clinical evaluation of a microwave device for treating axillary hyperhidrosis. *Dermatol Surg* 38:728–735.
- ICNIRP. 2003. Guidance on determining compliance of exposure to pulsed and complex non-sinusoidal waveforms below 100 kHz with ICNIRP guidelines. *Health Phys* 84:383–387.
- ICNIRP. 2010. Guidelines for limiting exposure to time-varying electric and magnetic fields (1 Hz to 100 kHz). *Health Phys* 99:818–836.

- ICNIRP. 2020a. Intended Human Exposure to Non-ionizing Radiation for Cosmetic Purposes. *Health Phys* 118:562–579.
- ICNIRP. 2020b. Guidelines for Limiting Exposure to Electromagnetic Fields (100 kHz to 300 GHz). *Health Phys* 118:483–524.
- Jacob C, Kent D, Ibrahim O. 2021. Efficacy and Safety of Simultaneous Application of HIFEM and Synchronized Radiofrequency for Abdominal Fat Reduction and Muscle Toning: A Multicenter Magnetic Resonance Imaging Evaluation Study. *Dermatol Surg* 47:969–973.
- Jaermann T, Suter F, Osterwalder D, Luechinger R. 2011. Measurement and analysis of electromagnetic fields of pulsed magnetic field therapy systems for private use. *J Radiol Prot* 31:107–116.
- Kaminaka C, Mikita N, Inaba Y, Kunimoto K, Okuhira H, Jinnin M, Kao B, Tanino R, Tanioka K, Shimokawa T, Yamamoto Y. 2019. Clinical and histological evaluation of a single high energy microwave treatment for primary axillary hyperhidrosis in Asians: A prospective, randomized, controlled, split-area comparative trial. *Lasers Surg Med* 51:592–599.
- Katz B. 2020. MRI assessment of arm and calf muscle toning with high-intensity focused electromagnetic technology: Case study. *J Drugs Dermatol* 19:556–558.
- Katz B, Duncan D. 2021. Lifting and Toning of Arms and Calves Using High-Intensity Focused Electromagnetic Field (HIFEM) Procedure Documented by Ultrasound Assessment. *J Drugs Dermatol* : JDD 20:755–759.
- Kent DE, Jacob CI. 2019. Simultaneous Changes in Abdominal Adipose and Muscle Tissues Following Treatments by High-Intensity Focused Electromagnetic (HIFEM) Technology-Based Device: Computed Tomography Evaluation. *J Drugs Dermatol* : JDD 18:1098–1102.
- Key DJ. 2014. Preliminary demonstration using localized skin temperature elevation as observed with thermal imaging as an indicator of fat-specific absorption during focused-field radiofrequency therapy. *J Drugs Dermatol* 13:864–866.
- Kilmer SL, Cox SE, Zelickson BD, Bachelor EP, Gamio S, Ostrowski R, Pham LD, Stevens WG. 2020. Feasibility Study of Electromagnetic Muscle Stimulation and Cryolipolysis for Abdominal Contouring. *Dermatol Surg* 46:S14–S21.

- Kim H. 2017. The combination of extracorporeal shock wave therapy and noncontact apoptosis-inducing radiofrequency achieved significant waist circumferential reduction: A pilot study. *Laser Ther* 26:129–136.
- Kinney BM, Lozanova P. 2019. High intensity focused electromagnetic therapy evaluated by magnetic resonance imaging: Safety and efficacy study of a dual tissue effect based non-invasive abdominal body shaping. *Lasers Surg Med* 51:40–46.
- Krueger N, Levy H, Sadick NS. 2012. Safety and efficacy of a new device combining radiofrequency and low-frequency pulsed electromagnetic fields for the treatment of facial rhytides. *J Drugs Dermatol* 11:1306–1309.
- Lee SJ, Chang KY, Suh DH, Song KY, Ryu HJ. 2013. The efficacy of a microwave device for treating axillary hyperhidrosis and osmidrosis in Asians: A preliminary study. *J Cosmet Laser Ther* 15:255–259.
- Leone A, Piccolo D, Conforti C, Pieri L, Fusco I. 2021. Evaluation of safety and efficacy of a new device for muscle toning and body shaping. *J Cosmet Dermatol* 20:3863–3870.
- Lin MJ, Dubin DP, Genece J, Younessi S, Rai S, Khorasani H. 2021. A survey of long-term results with microwave energy device for treating axillary hyperhidrosis. *J Cosmet Laser Ther* 23:49–51.
- Lupin M, Hong HCH, O'Shaughnessy KF. 2014. Long-term efficacy and quality of life assessment for treatment of axillary hyperhidrosis with a microwave device. *Dermatol Surg* 40:805–807.
- McDaniel D, Samková P. 2015. Evaluation of the safety and efficacy of a non-contact radiofrequency device for the improvement in contour and circumferential reduction of the inner and outer thigh. *J Drugs Dermatol* 14:1422–1424.
- Misiri J, Kusumoto F, Goldschlager N. 2012. Electromagnetic interference and implanted cardiac devices: the nonmedical environment (part I). *Clin Cardiol* 35:276–280.
- Mohamoud AA, Zeraiq L, Vestergaard T. 2022. A case series evaluating microwave-based therapy for axillary hyperhidrosis and bromhidrosis. *J Dermatol Treat* 33:1572–1575.
- Moradi A, Palm M. 2015. Selective non-contact field radiofrequency extended treatment protocol: Evaluation of safety and efficacy. *J Drugs Dermatol* 14:982–985.

- Moradi A, Poehler J, Bell M. 2020. A randomized double-blind trial evaluating the efficacy and tolerability of topical body treatment with TriHex Technology® combined with abdomen cryolipolysis or radiofrequency procedures. *J Cosmet Dermatol* 19:677–681.
- Negosanti F, Cannarozzo G, Zingoni T, Leone A, Fusco I. 2022. Is It Possible to Reshape the Body and Tone It at the Same Time? *Schwarzzy: The New Technology for Body Sculpting. Bioengineering* 9:284
- Nisticò SP, Bonan P, Coli F, Verdelli A, Fusco I, Gratteri F, Sicilia C, Cantisani C, Pellacani G, Bennardo L, Cannarozzo G. 2022. A New Protocol to Treat Abdominal Subcutaneous Fat Combining Microwaves and Flat magnetic stimulation. *Bioengineering* 9:182.
- Oliveira TCFD, Rocha SDFS, Ramos DG, Ramos CG, Carvalho MVDA, Ramos MG. 2017. Effects of Multipolar Radiofrequency and Pulsed Electromagnetic Field Treatment for Face and Neck Rejuvenation. *Dermatol Res Pract* 2017:4146391.
- Pahlavani N, Nattagh-Eshtivani E, Amanollahi A, Ranjbar G, Aghdaei HA, Navashenaq JG, Shabaninezhad Z, Sharahi NR, Maleki M, Malekahmadi M, Norouzy A. 2022. Effects of microwave technology on the subcutaneous abdominal fat and anthropometric indices of overweight adults: A clinical trial. *J Cosmet Dermatol* 21:1482–1488.
- Puffer RC, Bishop AT, Spinner RJ, Shin AY. 2019. Bilateral brachial plexus injury after MiraDry procedure for axillary hyperhidrosis. *World Neurosurg* 124:370–372.
- Pumpřla J, Howorka K, Kolackova Z, Sovova E. 2015. Non-contact radiofrequency-induced reduction of subcutaneous abdominal fat correlates with initial cardiovascular autonomic balance and fat tissue hormones: Safety analysis. *F1000Research* 4:49.
- Rutherford G, Lithgow B, Moussavi Z. 2020. Transcranial magnetic stimulation safety from operator exposure perspective. *Med Biol Eng Comput* 58:249–256.
- Salsi B, Fusco I. 2022. Non-invasive system delivering microwaves energy for unwanted fat reduction and submental skin tightening: Clinical evidence. *J Cosmetic Dermatol* 21: 5657–5664..
- Samuels JB, Katz B, Weiss RA. 2022. Radiofrequency Heating and High-Intensity Focused Electromagnetic Treatment Delivered Simultaneously: The First Sham-Controlled Randomized Trial. *Plast Reconstr Surg* 149:893E–900E.

- Scuderi S, Manoharan P, Lim D, Manoharan S. 2017. A survey of patient satisfaction with use of microwave device for axillary hyperhidrosis. *Australas J Dermatol* 58:126–129.
- Stam R, Yamaguchi-Sekino S. 2018. Occupational exposure to electromagnetic fields from medical sources. *Ind Health* 56:96–105.
- Strahlenschutzkommission. 2019. Anwendungen elektrischer, magnetischer und elektromagnetischer Felder (EMF) zu nichtmedizinischen Zwecken am Menschen. Bonn: Strahlenschutzkommission.
- Stunder D, Seckler T, Joosten S, Zink MD, Driessen S, Kraus T, Marx N, Napp A. 2017. In Vivo Study of Electromagnetic Interference With Pacemakers Caused by Everyday Electric and Magnetic Fields. *Circulation* 135:907–909.
- Suh DH, Kim CM, Lee SJ, Kim H, Yeom SK, Ryu HJ. 2017. Safety and efficacy of a non-contact radiofrequency device for body contouring in Asians. *J Cosmet Laser Ther* 19:89–92.
- Suh DH, Lee SJ, Kim K, Ryu HJ. 2014. Transient median and ulnar neuropathy associated with a microwave device for treating axillary hyperhidrosis. *Dermatol Surg* 40:482–485.
- U.S. Food and Drug Administration. 2016. 510(k) premarket notification K152731 – XP1100 RF. Silver Spring, MD: U.S. Food and Drug Administration.
- U.S. Food and Drug Administration. 2019a. 510(k) premarket notification K190456 – BTL 799-2L. Silver Spring, MD: U.S. Food and Drug Administration.
- U.S. Food and Drug Administration. 2019b. 510(k) premarket notification K191528 – Venus Legacy Pro Device. Silver Spring, MD: U.S. Food and Drug Administration.
- U.S. Food and Drug Administration. 2022. 510(k) premarket notification K191528 – CoreLevee. Silver Spring, MD: U.S. Food and Drug Administration.
- U.S. Patent and Trademark Office. 2016. United States Patent No. US9403028B2. Device for emitting a magnetic field. Alexandria, VA: U.S. Patent and Trademark Office.
- Virtanen H, Keshvari J, Lappalainen R. 2006. Interaction of radio frequency electromagnetic fields and passive metallic implants—a brief review. *Bioelectromagnetics* 27:431–439.
- Wattanakrai P, Limpjaroenviriyakul N, Thongtan D, Wattanayingcharoenchai R, Manonai J. 2022. The efficacy and safety of a combined multipolar radiofrequency with pulsed electromagnetic

field technology for the treatment of vaginal laxity: a double-blinded, randomized, sham-controlled trial. *Lasers Med Sci* 37:1829–1842.

Wen S, Unuma K, Makino Y, Mori H, Uemura K. 2022. Fatal consequence after MiraDry® treatment: Necrotizing fasciitis complicated with streptococcal toxic shock syndrome. *Leg Med (Tokyo)* 58:102095.

Yang HH, Miao Y, Chen YT, Hu ZQ. 2019. Minimally invasive approaches to axillary osmidrosis treatment: A comparison between superficial liposuction with automatic shaver curettage, subcutaneous laser treatment, and microwave-based therapy with a modified technique. *J Cosmet Dermatol* 18:594–601.

Zucca M, Bottauscio O, Chiampi M, Zilberti L. 2017. Operator Safety and Field Focality in Aluminum Shielded Transcranial Magnetic Stimulation. *IEEE T Magn* 53:7935394.